

Topic: 01. Basic Science

## CARRY-OVER EFFECTS AND THE EFFECTS OF CYCLING IN AN ANIMAL MODEL OF SPINAL CORD STIMULATION

### E-POSTER VIEWING ORALS

Louis Vera-Portocarrero<sup>1</sup>, Tina Billstrom<sup>2</sup>, Melanie Goodman Keiser<sup>1</sup>, Jeffrey Kramer<sup>1</sup>

<sup>1</sup>Research & Core Technology, Medtronic, Minneapolis, United States of America, <sup>2</sup>Physiological Research Laboratory, Medtronic, Minneapolis, United States of America

**Introduction:** We have validated a large animal model of chronic sensory change to evaluate spinal cord stimulation (SCS) therapy in sheep. Understanding stimulation carry over effects may give us novel ways to deliver therapy and new methods to conserve battery. The present study investigated the carry over effect of stimulation dose and how using different cycling paradigms affected it.

**Methods/Materials:** A nerve injury was induced in four sheep. Quantitative sensory testing (QST) was performed by application of an automated von Frey filament (1000 g) to the hindlimb of the sheep and measuring the threshold for a response. Sheep were implanted with octopolar leads in lumbar segments of the spinal cord. Stimulation was applied continuously for 8 days with an amplitude of 25% motor threshold (MT) or 50% MT. Testing was performed over the 8 days while stimulation was ON and after turning stimulation OFF. Two separate cycling paradigms (stimulation ON 10% and 50% of total time) were incorporated into stimulation either at the beginning of the stimulation period or after 72 hours of continuous stimulation.

**Results:** Sheep with nerve injury presented with lower withdrawal thresholds (77% reduction) to von Frey filament application. SCS at 25% MT did not reduce the hypersensitivity. In contrast, SCS delivered at 50% MT was able to reduce hypersensitivity in a biphasic manner over the 8-day period. After stimulation was turned OFF, only the higher amplitude yielded a significant carry-over effect up to 30 minutes following the end of stimulation. A 50% stimulation ON paradigm produced a reduction of hypersensitivity like continuous stimulation, regardless if the cycling started at the beginning or later in the stimulation period. A 10% stimulation ON paradigm did not reduce hypersensitivity in a significant manner nor did it produce a carry-over effect.

**Discussion:** This study evaluated the behavioral withdrawal response to clinically relevant parameters in a large animal model. Continuous stimulation over 8 days attenuated hypersensitivity in sheep and it was still effective after stimulation was OFF only when a higher amplitude was used. Cycling yielded similar attenuation overall, but only had a carry-over effect with a higher duty cycle. This study provides evidence that continuous stimulation might not be necessary to reverse pain behaviors in our large animal model of SCS therapy. These results could have implications in extending battery life and help in reducing constant recharging by patients.

**Conclusions:** Higher amplitude and duty cycle yielded effectiveness and a carry-over effect.

### References:

**Keyword:** Spinal cord stimulation, Preclinical, Cycling, Carry-over Effects

**Topic:** 01. Basic Science

## **MECHANISM-BASED THERAPY DESIGN: ROLE OF BASIC SCIENCE IN NEUROMODULATION TECHNOLOGY DEVELOPMENT**

### **E-POSTER VIEWING ORALS**

Melanie Goodman Keiser<sup>1</sup>, Lawrence Poree<sup>2</sup>, Krishnan Chakravarthy<sup>3</sup>, Jeffrey Kramer<sup>1</sup>, Leo Litvak<sup>1,4</sup>

<sup>1</sup>Research & Core Technology, Medtronic, Minneapolis, United States of America, <sup>2</sup>Anesthesiology And Pain Medicine, University of California at San Francisco, San Francisco, United States of America, <sup>3</sup>San Diego Health System, University of California, San Diego, San Diego, United States of America, <sup>4</sup>Department Of Biomedical Engineering, University of Southern California, Los Angeles, United States of America

**Introduction:** The mechanisms of action (MoAs) of spinal cord stimulation (SCS) remain unknown for the past 50 years; however, our fundamental understanding of SCS has often followed clinical application of new technology and therapies. Current trends towards stimulation patterns that do not illicit paresthesias, often referred to as subthreshold, subsensory, or paresthesia-free stimulation. There are opportunities to utilize our understanding of underlying MoAs to help drive therapy development and outcome improvements with subthreshold stimulation.

**Methods/Materials:** A systematic literature review was performed using the PubMed and EMBASE databases. Search criteria included “spinal cord stimulation” and the following terms: subparesthesia, subthreshold, subsensory, sub-sensory, paresthesia-independent, paresthesia-free, paresthesia free, “mechanisms of action”, “mechanisms of action for burst”, and “mechanisms for 10 kHz”.

**Results:** A total of 508 individual articles was found. One hundred thirty-one articles hypothesized or reviewed proposed mechanisms of action of SCS and 20 articles presented data to support a hypothesized mechanism. Preclinical and clinical methodologies were used to explain and support MoA theories. These include extracellular recordings, behavior and immunohistochemistry experiments in preclinical models. Small clinical studies have used quantitative sensory testing, somatosensory evoked potentials and magnetic resonance imaging to support hypothesized MoAs.

**Discussion:** It is unclear if the MoA of sub-types of SCS (low dose vs. high dose) differ since most mechanistic preclinical experiments were performed upwards of 90% motor threshold, well above probable sensory thresholds for animal models. It begs to question if subthreshold SCS patterns do not activate the dorsal columns and create paresthesias, what is the target? Also, if subthreshold patterns do activate the dorsal columns then how do the dorsal column fibers track higher frequency patterns when studies have shown following-frequency limitations. Nevertheless, direct effects on dorsal horn cells, non-neuronal cells (immune, glia, etc.) and the potential for supra-spinal mechanisms are all hypothesized MOAs. Thus, animal models may continue to provide a useful model to study MoAs but attention should be paid to the parameters being delivered as an approximation of those used translationally. Moreover, disease model can play a role in response so appropriate models will be an important consideration.

**Conclusions:** Our understanding of the SCS MoAs, especially subthreshold stimulation, continues to evolve. Neuronal targets, neurotransmitters, and spinal and supraspinal pathways involved remain only partially elucidated or unknown. Nevertheless, mechanistically driven device and therapy design may be a useful pathway to study novel neuromodulation approaches.

### **References:**

**Keyword:** Spinal cord stimulation, Review, Subthreshold, Paresthesia-free, Mechanism of Action

Topic: 01. Basic Science

## MODULATORY EFFECT OF KILOHERTZ FREQUENCY ALTERNATING CURRENT NEUROMODULATION OF THE PUDENDAL NERVES ON THE ANAL CANAL AND ANAL SPHINCTER IN THE RAT

### E-POSTER VIEWING ORALS

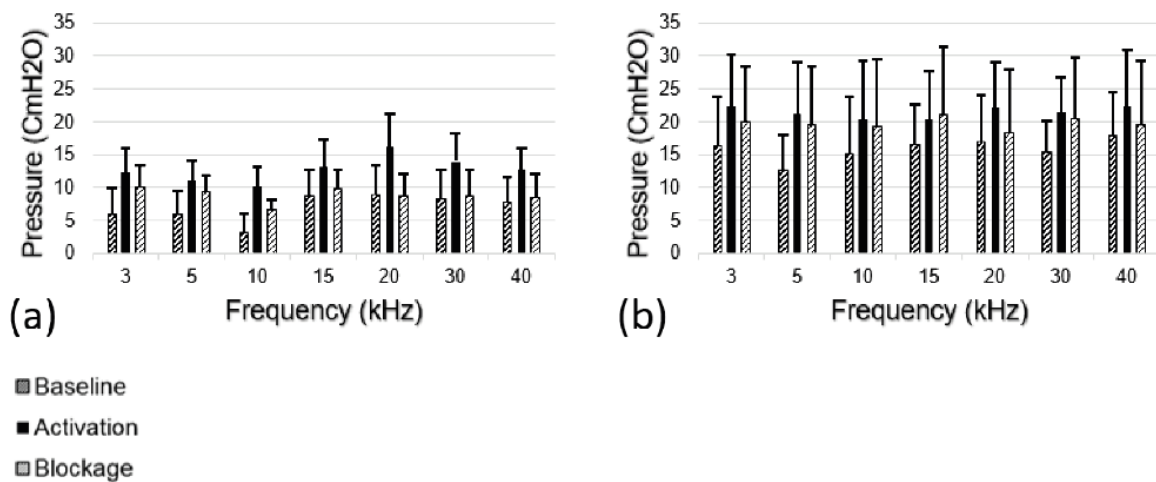
Rosa Coolen<sup>1</sup>, Koen Emmer<sup>2</sup>, Panagiota Spantidea<sup>1</sup>, Els Van Asselt<sup>1</sup>, Jeroen Scheepe<sup>1</sup>, Wouter Serdijn<sup>2</sup>, Bertil Blok<sup>1</sup>

<sup>1</sup>Urology, Erasmus Medical Center, Rotterdam, Netherlands, <sup>2</sup>Section Bioelectronics, Delft University of Technology, Delft, Netherlands

**Introduction:** Kilohertz frequency alternating current (KHFAC) neuromodulation of peripheral nerves is hypothesized to induce rapid and reversible nerve conduction block (1). Applied to the pudendal nerve, it could relax the pelvic musculature (2, 3). This might aid the emptying of the bladder and bowel providing a new therapy for urinary retention and dysfunctional defecation. The aims of the present study were: 1) to determine which stimulation parameters influence the effectiveness and safety of KHFAC neuromodulation and 2) to establish whether KHFAC neuromodulation of the pudendal nerves can relax the pelvic musculature.

**Methods/Materials:** In silico, we used the McIntyre-Richardson-Grill model to test which stimulation parameters improve the effectiveness of the nerve block (block threshold) and its safety (block threshold charge per phase). In vivo, the pudendal nerves were stimulated with 3 kHz to 40 kHz with an electrode-array in 14 urethane anesthetized male and female Sprague Dawley rats. Proximally, low frequency stimulation was applied (square wave, 20 Hz, 3 V, 20% duty cycle). Anal pressure, an indirect measure of pelvic muscle tone, was measured with a balloon catheter.

**Results:** The simulation model showed that block threshold and block threshold charge per phase are dependent on waveform (a square wave had the lowest block threshold), interphase delay, electrode-to-axon distance, interpolar distance, and electrode-array orientation. When introducing interphase delays, the required charge per phase can be reduced without increasing the amplitude. The average anal pressure during unilateral high-frequency stimulation was significantly lower than the average peak anal pressure during low-frequency stimulation ( $p < 0.001$ ,  $n = 167$  stimulations of 18 pudendal nerves at 3 - 40 kHz, Figure 1a). Similar results were obtained with bilateral high-frequency stimulation (Figure 1b). Twenty and 40 kHz (square wave, amplitude of 10 V, 50% duty cycle) induced the largest relative anal pressure decrease ( $p > 0.05$ ).



**Figure 1.** (a) Anal pressure in rats ( $n=6$  stimulations of 6 pudendal nerves) during no stimulation, during unilateral proximal activation (square wave, 20 Hz, 3 V, 20% duty cycle) and during unilateral distal blockage (square wave, 10V, 50% duty cycle). (b) Anal pressure in rats ( $n=2$  stimulations in 2 rats) during no stimulation, during bilateral proximal activation (square wave, 20 Hz, 3V, 20% duty cycle) and during bilateral distal blockage (square wave, 10 V, 50% duty cycle). Mean, error bars represent SEM.

**Discussion:** The simulations showed that a square wave has the lowest block threshold. This is an important consideration with regard to battery longevity. Furthermore, the addition of interphase delay in the electrical stimulation can improve its safety. In vivo, we showed in male and female rats that KHFAC neuromodulation of the pudendal nerve in the range of 3 – 40 kHz with a commercially available electrode-array can effectively decrease anal pressure.

**Conclusions:** Stimulation parameters and electrode design affect the efficacy and safety of KHFAC neuromodulation. In the future, KHFAC neuromodulation of the pudendal nerves might provide a new therapy for urinary retention and dysfunctional defecation that are refractory to conservative treatment options.

**References:** 1. Kilgore KL, Bhadra N. Nerve conduction block utilising high-frequency alternating current. *Med Biol Eng Comput.* May 2004;42(3):394-406. 2. Bhadra N, Bhadra N, Kilgore K, Gustafson KJ. High frequency electrical conduction block of the pudendal nerve. *J Neural Eng.* Jun 2006;3(2):180-7. 3. Cai H, Morgan T, Pace N, Shen B, Wang J, Roppolo JR, et al. Low pressure voiding induced by a novel implantable pudendal nerve stimulator. *Neurourol Urodyn.* Apr 4 2019.

**Keywords:** pudendal nerve, neuromodulation, kilohertz frequency alternating current, anal sphincter, pelvic floor, electrical stimulation

**Topic:** 04. Brain / 04a. Movement Disorders

## **DIRECTIONAL VERSUS OMNIDIRECTIONAL DEEP BRAIN STIMULATION: RESULTS OF A MULTI-CENTER PROSPECTIVE BLINDED CROSSOVER STUDY**

### **E-POSTER VIEWING ORALS**

Jan Vesper<sup>1</sup>, Pablo Mir<sup>2</sup>, Matthew Brodsky<sup>3</sup>, Leonard Verhagen<sup>4</sup>, Sergiu Groppa<sup>5</sup>, Ramiro Alvarez<sup>6</sup>, Andrew Evans<sup>7</sup>, Marta Blazquez<sup>8</sup>, Sean Nagels<sup>9</sup>, Julie Pilitsis<sup>10</sup>, Monika Pötter-Nerger<sup>11</sup>, Winona Tse<sup>12</sup>, Leonardo Almeida<sup>13</sup>, Nestor Tomycz<sup>14</sup>, Joohi Jimenez-Shahed<sup>12</sup>, Fatima Carrillo<sup>2</sup>, Christian J Hartmann<sup>15</sup>, Stefan Groiss<sup>15</sup>, Florence Defresne<sup>16</sup>, Edward Karst<sup>16</sup>, Binith Cheeran<sup>16</sup>, Alfons Schnitzler<sup>15</sup>

<sup>1</sup>Functional Neurosurgery And Stereotaxy, University Clinic Duesseldorf, Dusseldorf, Germany, <sup>2</sup>Neurology, Hospital Virgen de Rocío, Sevilla, Spain, <sup>3</sup>Neurology, Oregon Health, Portland, United States of America, <sup>4</sup>Neurology, Rush University, Chicago, United States of America, <sup>5</sup>Neurology, Johannes Gutenberg-Universität Mainz, Mainz, Germany, <sup>6</sup>Neurology, Hospital Trias I Pujol, Barcelona, Spain, <sup>7</sup>Neurology, Royal Melbourne Hospital, Melbourne, Australia, <sup>8</sup>Neurology, Hospital Universitario Central de Asturias, Oviedo, Spain, <sup>9</sup>Neurology, Cleveland Clinic Foundation, Cleveland, United States of America, <sup>10</sup>Neurology, Albany Medical Center, New York, United States of America, <sup>11</sup>Neurology, University Hospital Hamburg-Eppendorf, Hamburg, Germany, <sup>12</sup>Neurology, Mount Sinai Hospital, New York, United States of America, <sup>13</sup>Neurology, Shands, Jacksonville, United States of America, <sup>14</sup>Neurology, Allegheny General Hospital, Pittsburgh, United States of America, <sup>15</sup>Neurology, Heinrich Heine University, Düsseldorf, Germany, <sup>16</sup>Clinical Affairs, Abbott, Plano, United States of America

**Introduction:** Published reports on directional DBS have been limited to small single-center investigations. Therapeutic window (TW) has been introduced in DBS to describe the range of stimulation amplitudes achieving symptom relief without side effects. The PROGRESS study evaluated whether directional DBS provides a wider TW in a large prospective trial.

**Methods/Materials:** Participants receiving subthalamic nucleus DBS for Parkinson's disease were programmed with omnidirectional stimulation for 3 months, followed by directional stimulation for another 3 months. The subject was blinded to all details of stimulation, and a blinded evaluator assessed TW and motor symptoms. The primary endpoint was based on blinded off-medication evaluation of TW for directional vs. conventional stimulation at the 3-month follow-up. Additional endpoints at 3-, 6- and 12-month follow-ups included adverse events, subject and clinician stimulation preference, therapeutic current strength (TCS), quality of life and UPDRS part III motor score.

**Results:** A directional DBS system was implanted in 234 subjects (62±8 years, 33% female). No intracranial hemorrhages or infections occurred. At 3 months, TW was wider using directional stimulation in 90.6% of subjects, satisfying the primary endpoint for superiority ( $p < 0.001$ ). The mean increase in TW with directional stimulation was 41% ( $2.98 \pm 1.38$  mA, compared to  $2.11 \pm 1.33$  mA for omnidirectional,  $p < 0.001$ ). The TCS was 39% lower with directional stimulation ( $1.11 \pm 1.00$  mA, compared to  $1.83 \pm 1.52$  mA for omnidirectional,  $p < 0.001$ ). UPDRS part III motor score on medication was improved with either stimulation at each time point ( $p < 0.001$ ). After 6 months, 53% of subjects blinded to stimulation type (102/193) preferred the period with directional stimulation, 26% (50/193) preferred the omnidirectional period and 21% (41/193) had no preference. The directional period was preferred by 59% of clinicians (113/193) vs. 21% (41/193) who preferred the omnidirectional period.

**Discussion:** A double-blind randomized comparison of directional and omnidirectional stimulation found that 90.6% of subjects had a wider therapeutic window using directional stimulation. There were improvements in both the minimum amplitude required to achieve therapeutic benefit and the side effect threshold, leading to a 40% wider therapeutic window. Although results of the blinded motor examination did not differ significantly at 3 months after omnidirectional stimulation vs. 6 months after directional stimulation, there was improved Parkinson's disease-specific quality of life. For the first

time, we demonstrated superiority of directional programming in increasing therapeutic window compared to omnidirectional stimulation.

**Conclusions:** Directional stimulation yielded a wider TW compared to omnidirectional stimulation and was preferred by subjects blinded to stimulation type.

**References:**

**Keywords:** Movement disorders, Deep Brain Stimulation, Directional leads

**Topic:** 04. Brain / 04a. Movement Disorders

**DIRECTIONAL DBS LEADS IMPLANTED UNDER GENERAL ANESTHESIA VS. SEDATION:  
FINDINGS FROM AN INTERNATIONAL PROSPECTIVE STUDY**

**E-POSTER VIEWING ORALS**

Jan Vesper<sup>1</sup>, Kim Burchiel<sup>2</sup>, Matthew Brodsky<sup>3</sup>, Brian Kopell<sup>4</sup>, Julie Pilitsis<sup>5</sup>, Nestor Tomycz<sup>6</sup>, Leonard Verhagen<sup>7</sup>, Girish Nair<sup>8</sup>, Andrew Evans<sup>9</sup>, Wolfgang Hamel<sup>10</sup>, Pablo Mir<sup>11</sup>, Monika Pötter-Nerger<sup>12</sup>, Joohi Jimenez-Shahed<sup>13</sup>, Philipp Slotty<sup>1</sup>, Sergiu Groppa<sup>14</sup>, Sean Nagels<sup>15</sup>, Florence Defresne<sup>16</sup>, Edward Karst<sup>16</sup>, Binith Cheeran<sup>16</sup>, Alfons Schnitzler<sup>17</sup>

<sup>1</sup>Functional Neurosurgery And Stereotaxy, Univerity Clinic Duesseldorf, Dusseldorf, Germany, <sup>2</sup>Neurosurgery, Oregon Health and Science University, Portland, United States of America, <sup>3</sup>Neurology, Oregon Health, Portland, United States of America, <sup>4</sup>Neurosurgery, Mount Sinai Hospital, New York, United States of America, <sup>5</sup>Neurology, Albany Medical Center, New York, United States of America, <sup>6</sup>Neurology, Allegheny General Hospital, Pittsburgh, United States of America, <sup>7</sup>Neurology, Rush University, Chicago, United States of America, <sup>8</sup>Neurosurgery, Royal Melbourne Hospital, Melbourne, Australia, <sup>9</sup>Neurology, Royal Melbourne HOsptial, Melbourne, Australia, <sup>10</sup>Neurosurgery, UKE Hamburg, Hamburg, Germany, <sup>11</sup>Neurology, Hospital Virgen de Rocio, Sevilla, Spain, <sup>12</sup>Neurology, University Hospital Hambug-Eppendorf, Hamburg, Germany, <sup>13</sup>Neurology, Mount Sinai Hospital, New York, United States of America, <sup>14</sup>Neurology, Johannes Gutenberg-Universitat Mainz, Mainz, Germany, <sup>15</sup>Neurology, Cleveland Clinic Foundation, Cleveland, United States of America, <sup>16</sup>Clinical Affairs, Abbott, Plano, United States of America, <sup>17</sup>Neurology, Heinrich Heine University, Düsseldorf, Germany

**Introduction:** Traditionally, deep brain stimulation (DBS) leads are implanted under local anesthesia or conscious sedation to allow intraoperative testing for effects (awake procedure). Recently, asleep DBS has been investigated. Two different approaches exist to enable lead implantation under general anesthesia with intubation (asleep procedure): 1) using intraoperative image-guided targeting only and 2) reducing anesthesia to allow for microelectrode recording.

**Methods/Materials:** The PROGRESS study compared therapeutic window (TW), the difference in amplitude between side effect threshold and minimum therapeutic current, for directional vs. omnidirectional stimulation in subjects receiving STN DBS for Parkinson's disease. This post-hoc analysis compares therapeutic window and UPDRS motor scores at 3, 6 and 12 months in subjects with awake vs. asleep procedures.

**Results:** The PROGRESS study enrolled 234 subjects and met its primary endpoint of superiority with 90.6% of subjects having a wider TW using directional stimulation. A total of 160 subjects underwent an awake procedure and 69 subjects underwent an asleep procedure. Three months after initial programming, directional stimulation increased TW by 0.84 mA for the awake implants ( $2.18 \pm 1.36$  mA for omnidirectional stimulation;  $3.02 \pm 1.30$  mA for directional;  $p < 0.001$ ) and 0.88 mA for the asleep implants ( $1.92 \pm 1.22$  mA for omnidirectional stimulation;  $2.83 \pm 1.53$  mA for directional;  $p < 0.001$ ). At three months, UPDRS motor scores on medication were 42.4% lower in the awake group and 43.1% in the asleep group, compared to off stimulation scores. At 6 months, the improvement remained similar with 44.6% reduction in UPDRS motor scores in the awake group and 41.6% in the asleep group. Additional results including 12-month data will be available for presentation.

**Discussion:** In a large international study, directional stimulation was associated with a similar increase in therapeutic window, regardless if the DBS system was implanted using an asleep versus awake procedure. UPDRS motor score improved similarly in both groups. Asleep DBS was able to achieve a comparable range of symptom relief, and may offer more comfort to the patients.

**Conclusions:** Directional programming increased therapeutic window when using either an awake or asleep procedure for DBS implant.

**References:**

**Keywords:** Movement disorders, Deep Brain Stimulation, Asleep procedure, Awake procedure



**Topic:** 04. Brain / 04a. Movement Disorders

**CORTICAL MAPPING IN CONVENTIONAL AND HIGH DOSE SPINAL CORD STIMULATION: AN EXPLORATORY POWER SPECTRUM AND FUNCTIONAL CONNECTIVITY ANALYSIS WITH ELECTROENCEPHALOGRAPHY**

**E-POSTER VIEWING ORALS**

Lisa Goudman<sup>1</sup>, Bengt Linderöth<sup>2</sup>, Maarten Moens<sup>1</sup>

<sup>1</sup>Neurosurgery, UZ Brussel, Jette, Belgium, <sup>2</sup>Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

**Introduction:** Spinal cord stimulation (SCS) is considered an effective pain-relieving treatment for patients with Failed Back Surgery Syndrome (FBSS). Despite the clinical effectiveness, it is unknown whether the altered functional connectivity in such patients, as compared to healthy persons, can be influenced by SCS. Therefore, the goal of this study is to evaluate whether brain connectivity assessed by EEG differs between baseline and SCS in patients with FBSS.

**Methods/Materials:** Eight patients with FBSS underwent a resting-state EEG protocol before SCS, 1.5 months and 2.5 months after receiving SCS. At each frequency band, power spectrums were compared for no SCS, conventional (CON) SCS and High Dose (HD) SCS. Functional connectivity, with the aid of eConnectome was also calculated.

**Results:** Significant differences in the average power density spectrum over the whole scalp were observed between no SCS, CON SCS and HD SCS in delta, theta and beta frequency bands ( $p < 0.01$ ). The average power spectrum for CON SCS was significantly lower than the average power spectrum for HD SCS. Marked increases in strength of the information flow between electrode pair FC3-TP9 in the beta frequency band ( $p = 0.006$ ) were found in favor of HD SCS.

**Discussion:** This exploratory study revealed differences in the power spectrum in the delta, theta and beta frequency bands between no SCS, CON SCS, and HD SCS. Additionally, increased strength between electrode pair FC3-TP9 was found during HD SCS, as compared to CON SCS and no SCS treatment. Both types of SCS probably have other predominant bottom-up mechanisms of action whereby HD SCS seems to activate the brain, in contrast to the inhibition by CON SCS.

**Conclusions:** The differences in power spectrum and connectivity between the three conditions lead to the hypothesis that HD SCS differs from CON SCS on average power spectrum, suggesting that HD SCS may have a higher contribution on the excitatory bottom-up pathway.

**References:**

**Keywords:** EEG, high dose SCS, supraspinal mechanism

**Topic:** 05. Spine / 05a. Pain

## **INTRATHECAL DRUG DELIVERY (IDD) FOR CANCER PAIN MANAGEMENT: A SYSTEMATIC REVIEW AND META-ANALYSIS**

### **E-POSTER VIEWING ORALS**

Denis Dupouiron<sup>1</sup>, Christophe Perruchoud<sup>2</sup>, Bianca Papi<sup>3</sup>, Alessandra Calabrese<sup>4</sup>, Lisa Stearns<sup>5</sup>, Shane Brogan<sup>6</sup>

<sup>1</sup>Anesthesia And Pain Medicine, INSTITUT DE CANCEROLOGIE DE L OUEST, ANGERS, France, <sup>2</sup>Clinique De La Douleur, Hôpital de la Tour, Geneva, Switzerland, <sup>3</sup>Clinical Neuromodulation, Medtronic, Maastricht, Netherlands, <sup>4</sup>Clinical Neuromodulation, Medtronic, Tolochenaz, Switzerland, <sup>5</sup>Pain Management, Center for Pain and Support, Phoenix, United States of America, <sup>6</sup>Division Of Pain Medicine, Department Of Anesthesiology, University of Utah, Salt Lake City, United States of America

**Introduction:** Across disease states, 40 to 85% of cancer patients experience pain and more than half report moderate-to-severe pain at least monthly. Intrathecal drug delivery represents an option for patients with pain refractory to conventional medical management to improve pain treatment while reducing opioid dosages. This systematic review and pooled analyses aim to evaluate pain outcomes and systemic opioid dosage in cancer patients treated with IDD.

**Methods/Materials:** A systematic literature search was performed using Embase, PubMed, and Cochrane Central Register of Controlled Trials. Meta-analyses were performed using a random effects model to estimate the Mean Difference (MD) and 95 % Confidence Interval (CI) of pain scores compared to baseline. Systemic (non-intrathecal) opioid doses, expressed as oral morphine equivalents, were calculated as weighted mean, taking as weight the study sample size, and expressed as mean and standard error (SE).

**Results:** The review identified 29 studies (2 level 2 and 27 level 4 of the Oxford Centre for Evidence-Based Medicine) with sample size ranging from 6 to 152 patients and follow-up from 5 days to 12 months. Mean percentage of the most frequent primary cancer types was 25% lung/chest, 22% pancreatic and 21% colorectal. Of the selected studies, 13 reported pain outcome after 4-5 weeks of IDD. Compared to baseline, IDD was associated with reduced pain (MD -4.34 [95% CI, -4.93, -3.75, p<0.001] on 0-10 pain scale). Ten studies reported pain reduction after 6-12 weeks of IDD (MD -4.07 [95% CI, -4.74, -3.40, p<0.001] and 6 studies reported pain reduction after 6-12 months of treatment (MD -3.32 [95% CI, -4.60, -2.04, p<0.001]. Systemic morphine equivalents before and after IDD treatment were collected in 13 studies. Weighted mean at baseline was 572.36 (10.99) mg/day and weighted mean reduction at the last reported follow up was 357.66 (303.70) mg/day.

**Discussion:** Despite limited high-level trials due to difficulty running randomized controlled trials in a palliative setting, clinical studies included in these meta-analyses consistently showed that IDD is an effective treatment to manage cancer pain refractory to conventional medical management or when intolerable side effects limit the effectiveness of systemic medications. IDD should be considered as a therapeutic option in cancer pain management.

**Conclusions:** Meta-analyses on cancer pain management with IDD show a statistically significant and maintained (through 1 year follow-up) reduction in pain compared to baseline. Weighted means of systemic opioid dosage show in average reduction of more than 50% after IDD treatment.

### **References:**

**Keyword:** cancer pain, intrathecal, drug delivery, meta-analysis

Topic: 05. Spine / 05a. Pain

**DOES A SCREENING TRIAL FOR SPINAL CORD STIMULATION IN PATIENTS WITH CHRONIC PAIN OF NEUROPATHIC ORIGIN HAVE CLINICAL UTILITY AND COST-EFFECTIVENESS? (TRIAL-STIM STUDY)**

**E-POSTER VIEWING ORALS**

Sam Eldabe<sup>1</sup>, Ashish Gulve<sup>1</sup>, Anu Kansal<sup>1</sup>, Simon Thomson<sup>2</sup>, G. Baranidharan<sup>3</sup>, Rod Taylor<sup>4</sup>, Rui Duarte<sup>5</sup>, Raymond Chadwick<sup>6</sup>, Morag Brookes<sup>1</sup>, Jill Bell<sup>1</sup>, Jenny Earle<sup>1</sup>, Shelley Rhodes<sup>4</sup>, Susan Jowett<sup>7</sup>

<sup>1</sup>Pain Management, South Tees Hospitals NHS Foundation Trust, Middlesbrough, United Kingdom, <sup>2</sup>Pain Management And Neuromodulation, Basildon & Thurrock University Hospitals NHSFT, Basildon, United Kingdom, <sup>3</sup>Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom, <sup>4</sup>Clinical Trials Unit, University of Exeter, Exeter, United Kingdom, <sup>5</sup>Health Economics, University of Liverpool, Liverpool, United Kingdom, <sup>6</sup>Health And Social Care, University of Teesside, Middlesbrough, United Kingdom, <sup>7</sup>Health Economics, University of Birmingham, Birmingham, United Kingdom

**Introduction:** The National Institute for Health and Care Excellence (NICE) in United Kingdom recommends spinal cord stimulation (SCS) for adults with chronic neuropathic pain. NICE recommend an 'SCS trial' is used as the final step of a screening process to decide whether a patient should receive a permanent SCS implant. Whilst recommended in guidelines, little is known about the clinical utility or diagnostic accuracy of SCS screening trials. Funding from UK National Institute of Health Research (NIHR) enabled us to design a randomised controlled trial (RCT) aiming to: Determine the diagnostic performance of SCS screening trial Compare the outcomes and cost-effectiveness of an SCS trial strategy to an implantation only strategy Assess the experiences and preferences of patients.

**Methods/Materials:** Subjects with neuropathic pain and candidates for SCS according to NICE guidance i.e.  $\geq 6$  months duration and  $\geq 5$  NRS pain score were recruited in 3 UK centres, and randomised 1:1 to undergo an SCS screening trial strategy (TG) or no trial implantation only strategy (NTG). The primary outcome measure was pain on NRS. Secondary outcome measures included the proportions achieving  $\geq 50\%$   $\geq 30\%$  pain relief, health-related quality-of-life, function, patient satisfaction and complication rates. In addition to a health economic evaluation, a qualitative interview was conducted with a subset of participants.

**Results:** 105 participants were randomised to TG (n=54), or NTG (n=51). There was good balance between TG and NTG participants at baseline. Pain NRS decreased from 7.47 at baseline to 4.28 at 6-months in TG and from 7.54 to 4.49 in NTG (mean group difference: 0.2, 95% CI: -1.2-0.9, p=0.89). We found no difference in the proportions reporting  $\geq 50\%$  pain relief between TG (36.6%) and NTG (39.6%) at six-month follow-up (odds ratio: 1.2, 95% CI: 0.4-1.7, P=0.73). Screening trials had 100% (95% CI: 78-100) sensitivity, 8% (95% CI: 1-25) specificity, with positive predictive value of 38% (95% CI: 36-41%). Costs of screening trial exceeded the implantation only strategy by £1,341/per participant. Qualitative analysis (n=27) showed overwhelming preference for no trial approach.

**Discussion:** This pragmatic independently funded RCT found that while a SCS screening trial may provide diagnostic utility there was no evidence to support that a screening trial strategy provides either better patient outcomes or cost-effectiveness versus an implantation only approach.

**Conclusions:** Patients expressed a strong preference for no screening trial. NIHR funded this study. The funder had no role in study design, data collection, data analysis, interpretation of data.

**References:**

**Keywords:** neuropathic pain, Randomised Controlled Trial, Spinal cord stimulation, Spinal Cord Stimulation, screening trial, neuropathic, Screening trial

## SPINAL CORD STIMULATION IN SEVERE CASES OF COMPLEX REGIONAL PAIN SYNDROME

### E-POSTER VIEWING ORALS

Linda Eriksen<sup>1,2</sup>, Astrid Terkelsen<sup>2</sup>, Jens Christian Soerensen<sup>1</sup>, Kaare Meier<sup>1,3</sup>

<sup>1</sup>Department Of Neurosurgery, Aarhus University Hospital, Aarhus N, Denmark, <sup>2</sup>Department Of Neurology And Danish Pain Research Center, Aarhus University Hospital, Aarhus N, Denmark, <sup>3</sup>Department Of Anesthesiology, Aarhus University Hospital, Aarhus N, Denmark

**Introduction:** Complex Regional Pain Syndrome (CRPS) is a debilitating pain condition often preceded by trauma to an extremity. The acute phase is characterized by inflammation and peripheral sensitization, whereas the chronic phase is mainly due to central mechanisms.<sup>1-3</sup> Standard treatment modalities are often inadequate. Where this is the case, spinal cord stimulation (SCS) may be an option.<sup>4</sup> We aim to assess the effect of SCS for CRPS and to elucidate whether symptom duration preceding implantation is a predictor of treatment efficacy.

**Methods/Materials:** The study includes 50 CRPS patients implanted with an SCS system at the University Hospital in Aarhus or Odense, Denmark. Data for the analysis are recorded in the Neurizon Neuromodulation Database. Pain intensity determined by 7-day average pain and 7-day worst pain on a numeric rating scale (NRS 0-10) and The Patient Global Impression of Change (PGIC) is considered the primary outcomes of treatment. Change in pain intensity was assessed by means of a paired t-test. A simple linear regression was conducted to investigate whether preoperative symptom duration predicts the change in pain intensity.

**Results:** Data analysis is currently ongoing. Preliminary results indicate a significant effect of SCS treatment in patients with CRPS, with a mean reduction in 7-day average pain of 28.1% (n=39, [95% CI: 38.1-18.2],  $P < 0.001$ ) and 21.2% (n=41, [95% CI: 30.2-12.2],  $P < 0.001$ ) in 7-day worst pain. At the latest registered follow-up, 58.1% of the patients reported a clinically important effect of treatment, determined as at least much improved or better on the PGIC scale, in accordance with the IMMPACT recommendations.<sup>5</sup> A linear regression established that symptom duration prior to implantation does not statistically significantly predict the effect of treatment in terms of change in 7-day average pain [ $F(1, 37) = 0.22$ ,  $P = 0.64$ ,  $R^2 = 0.006$ ] and 7-day worst pain [ $F(1, 39) = 0.01$ ,  $P = 0.91$ ,  $R^2 = 0.0003$ ]. The final results will be ready for presentation at the e-INS 2020.

**Discussion:** SCS may be an effective treatment modality for CRPS patients. Our results are in accordance with previous published studies.<sup>4,6</sup>

**Conclusions:** From the preliminary results, we conclude that SCS significantly reduced both 7-day average pain and 7-day worst pain in CRPS patients. This effect does not appear to be predicted by preoperative symptom duration. Based on the latest registered PGIC ratings, 58.1% of the patients reported their overall change since implantation as much improved or better.

**References:** 1. Marinus J, Moseley GL, Birklein F, et al. Clinical features and pathophysiology of complex regional pain syndrome. *Lancet Neurol.* 2011;10(7):637-648. 2. Reimer M, Rempe T, Diedrichs C, Baron R, Gierthmühlen J. Sensitization of the Nociceptive System in Complex Regional Pain Syndrome. *PLoS One.* 2016;11(5):e0154553. 3. Ji RR, Woolf CJ. Neuronal plasticity and signal transduction in nociceptive neurons: implications for the initiation and maintenance of pathological pain. *Neurobiol Dis.* 2001;8(1):1-10. 4. Kemler MA, Barendse GA, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med.* 2000;343(9):618-624. 5. Dworkin RH, Turk DC, McDermott MP, et al. Interpreting the clinical importance of group differences in chronic pain clinical trials: IMMPACT recommendations. *Pain.* 2009;146(3):238-244. 6. Geurts JW, Smits H, Kemler MA, Brunner F, Kessels AG, van Kleef M. Spinal cord stimulation for complex regional pain syndrome type I: a prospective cohort study with long-term follow-up. *Neuromodulation.* 2013;16(6):523-529; discussion 529.

**Keywords:** CRPS, Spinal cord stimulation, Complex regional pain syndrome

**Topic:** 05. Spine / 05a. Pain

## **PREOPERATIVE OPIOID THERAPY DOES NOT REDUCE THE EFFICACY OF SPINAL CORD STIMULATION: A COHORT STUDY OF 366 PATIENTS**

### **E-POSTER VIEWING ORALS**

Dennis Poulsen<sup>1,2</sup>, Jens Christian Soerensen<sup>1,2</sup>, Helga Gulisano<sup>3</sup>, Morten Blichfeldt-Eckhardt<sup>4,5</sup>, Lone Nikolajsen<sup>6</sup>, Kaare Meier<sup>2,7,8</sup>

<sup>1</sup>Dept. Of Neurosurgery, Aarhus University Hospital, Aarhus N, Denmark, <sup>2</sup>Center For Experimental Neuroscience (cense), Institute of Clinical Medicine, Aarhus University, Aarhus N, Denmark, <sup>3</sup>Dept. Of Neurosurgery, Aalborg University Hospital, Aalborg, Denmark, <sup>4</sup>Eses Unit, Dept. Of Neurosurgery, Odense University Hospital, Odense, Denmark, <sup>5</sup>Dept. Of Anesthesiology And Critical Care, Odense University Hospital, Odense, Denmark, <sup>6</sup>Dept. Of Anesthesiology, Aarhus University Hospital, Aarhus N, Denmark, <sup>7</sup>Department Of Anesthesiology, Aarhus University Hospital, Aarhus N, Denmark, <sup>8</sup>Department Of Neurosurgery, Aarhus University Hospital, Aarhus N, Denmark

**Introduction:** Opioid therapy in neuropathic pain patients is prevalent<sup>1</sup>. As spinal cord stimulation (SCS) is reserved for a subset of neuropathic pain patients in which conventional medical management has failed, many patients receive opioid therapy upon referral to SCS<sup>2,3</sup>. The aim of this study was to investigate whether preoperative opioid therapy was associated with inferior SCS outcomes defined as latest rating on Patients' Global Impression of Change (PGIC) scale<sup>4</sup> and risk of explantation.

**Methods/Materials:** The Neurizon Neuromodulation Database<sup>5,6</sup> contains detailed records of patients implanted with a permanent SCS system. From the records, we identified patients with a preoperative medicine registration as well as their latest PGIC rating and current treatment status (ongoing stimulation / explantation). Patients were divided into two groups: Opioid users and non-opioid users. Associations between opioid use and latest PGIC rating as well as treatment status were assessed by Chi-squared tests. For opioid users with known dosage, OMEs (oral morphine equivalents)<sup>7</sup> were calculated in order to evaluate whether a dose-response relationship exists between preoperative opioid usage and SCS outcomes. Median OMEs of opioid users within each PGIC rating category were compared using a one-way ANOVA; for groups of treatment status an exact t-test was used.

**Results:** A total of 366 patients had a preoperative medicine registration: 62 % were opioid users, median opioid usage was 90 OMEs (n=207). Of the included patients, 265 had a PGIC rating with a median follow-up time of 3.0 years (IQR: 1.3-6.1). Preoperative opioid use was not associated with latest PGIC rating (p=0.37, figure 1) and median OME of opioid users within each PGIC rating category did not differ significantly (p=0.93). Opioid users were not more likely to undergo explantation of the SCS system (p=0.42, figure 2). Median OME of opioid users undergoing explantation did not differ from median OME of opioid users with ongoing stimulation (p=0.63).

## Association of preoperative opioid usage and latest PGIC

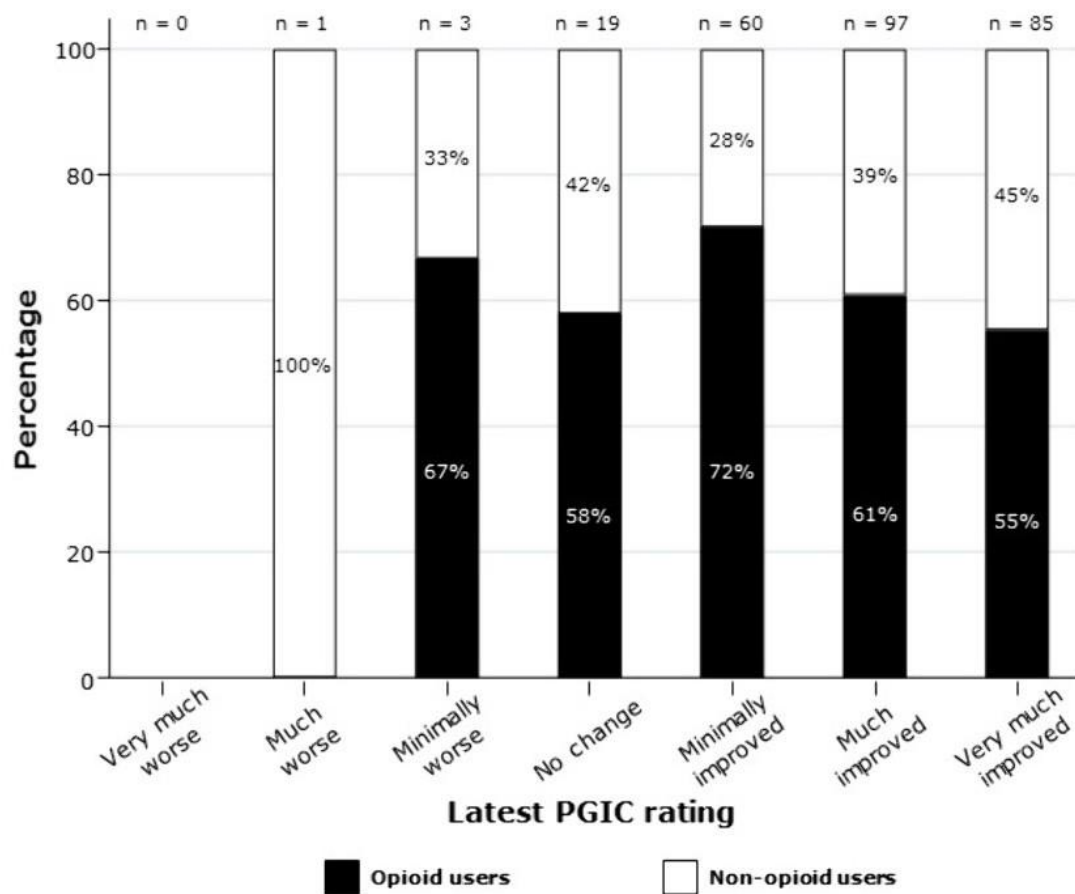


Figure 1



## Association of preoperative opioid usage and explantation

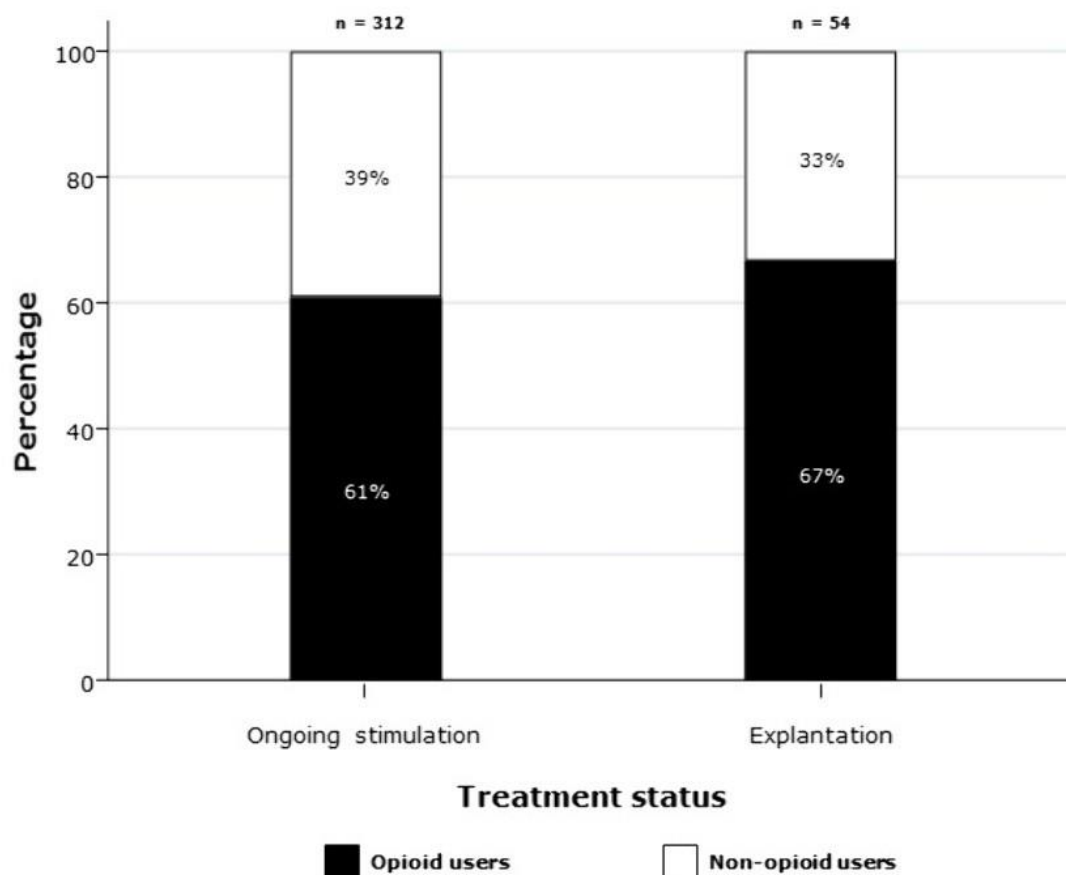


Figure 2

**Discussion:** Preoperative patient selection and incomplete follow-up are sources of potential bias and should be considered when evaluating the results. Included patients differed significantly in type of pain condition, gender and age, strengthening the generalizability of our study results.

**Conclusions:** Compared to non-opioid users, opioid users rated similarly on their latest PGIC evaluation and were not at significantly greater risk of undergoing permanent explantation of the SCS system. For opioid users, we observed no dose-response relationship between daily opioid dose in OMEs and latest PGIC rating or risk of explantation.

**References:** 1. Hoffman, E.M., J.C. Watson, J. St Sauver, N.P. Staff, and C.J. Klein, Association of Long-term Opioid Therapy With Functional Status, Adverse Outcomes, and Mortality Among Patients With Polyneuropathy. *JAMA Neurol*, 2017. 74(7): p. 773-779. 2. Kapural, L., C. Yu, M.W. Doust, B.E. Gliner, R. Vallejo, B.T. Sitzman, et al., Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial. *Neurosurgery*, 2016. 79(5): p. 667-677. 3. Sharan, A.D., J. Riley, S. Falowski, J.E. Pope, A.T. Connolly, E. Karst, et al., Association of Opioid Usage with Spinal Cord Stimulation Outcomes. *Pain Med*, 2018. 19(4): p. 699-707. 4. Guy, W., ECDEU assessment manual for psychopharmacology. 1976, US Government Printing Office: Washinton DC. 5. Meier, K., L. Nikolajsen, M. Flink, R. Simonsen, I. Milidou, T.S. Jensen, et al., The Aarhus Neuromodulation Database. *Neuromodulation*, 2013. 16(6): p. 506-13. 6. Neurizon: Official Web Page. 2019 [cited 2019 20-12]; Available from: <http://neurizon.org/>. 7. Nielsen, S., L. Degenhardt, B. Hoban, and N. Gisev, A synthesis of oral morphine equivalents (OME) for opioid utilisation studies. *Pharmacoepidemiol Drug Saf*, 2016. 25(6): p. 733-7.

**Keywords:** Spinal cord stimulation, Opioid therapy, Outcome predictors, Registries

**Topic:** 05. Spine / 05a. Pain

## **RESTORATIVE NEUROSTIMULATION FOR REFRACTORY MECHANICAL CHRONIC LOW BACK PAIN –ONE-YEAR RESULTS OF A RANDOMIZED ACTIVE SHAM-CONTROLLED TRIAL**

### **E-POSTER VIEWING ORALS**

Christopher Gilligan

Anesthesiology, Brigham and Women's Hospital/Harvard Medical School, Chestnut Hill, United States of America

**Introduction:** Refractory mechanical chronic low back pain (CLBP) is often linked to impaired neuromuscular control and reduced quality of the multifidus muscles, which provide stability to the lumbar spine. Consequently, analgesic treatments often lack long-term effectiveness. Prior studies have suggested efficacy of an implantable neurostimulator which elicits repetitive multifidus contractions aimed at restoring neuromuscular control. We evaluated this device in an international, multicenter, randomized, active sham-controlled, double-blinded trial with single-arm crossover. (clinicaltrials.gov/show/NCT02577354)

**Methods/Materials:** Eligible patients were implanted and randomly assigned to receive therapeutic or subthreshold stimulation (sham-control) for 30 minutes, twice daily. The primary endpoint compared responder rates at 120 days, with a 'Responder' having  $\geq 30\%$  average VAS reduction without any increase in pain medication. Patients in the sham-control group crossed over to therapeutic stimulation at 120 days.

**Results:** At baseline (N=204), CLBP-duration was  $14 \pm 11$  years, age  $47 \pm 9$  years, VAS  $7.3 \pm 0.7$  cm and ODI  $39 \pm 10$ . At 120 days (N=204), the primary endpoint did not reach significance (57% vs. 47%). The primary cumulative proportion of responder analysis, secondary and supporting analyses consistently favored treatment over sham ( $p < 0.05$ ). A prespecified modified intention-to-treat analysis which excluded patients who increased pain medications for reasons unrelated to low back pain, also demonstrated significance in favor of the therapy ( $p < 0.05$ ) as did the first four out of the five secondary endpoints. Blinding was assessed and considered effective. At one year, improvements in the combined treatment and crossover group (N=160) were clinically meaningful. 65% of patients had  $\geq 50\%$  VAS improvement, 53% had VAS  $\leq 2.5$  cm, 59% had  $\geq 20$  points ODI improvement and 49% (30/61) eliminated or reduced opioids. The safety profile compared favorably to published neurostimulation experiences.

**Discussion:** This was the first randomized, sham-controlled trial of a neurostimulation system for the restorative treatment of CLBP and the size of the sham response was thus far unknown. Although effects of this rehabilitative treatment accrue over time, endpoint timing was set to 120 days for ethical and pragmatic considerations. Interpretation of the composite primary endpoint is confounded by dichotomization and analgesic intake for reasons other than LBP. Indeed, both the cumulative proportion of responder analysis as well as the modified intention-to-treat analysis in this study return statistically significant results.

**Conclusions:** While the primary efficacy endpoint, a comparison of responder rates, did not reach statistical significance at 120 days, the primary, secondary, supporting and long-term outcome analyses suggest safety, effectiveness and durability of restorative neurostimulation in patients with refractory mechanical CLBP.

### **References:**

**Keyword:** Chronic low back pain, multifidus, neuromodulation

**Topic:** 05. Spine / 05a. Pain

**“HIGH RESPONDERS” TO NEUROSTIMULATION SHOW GREATER CLINICAL & OVERALL MEANINGFUL RESPONSE IN PATIENT REPORTED OUTCOMES**

**E-POSTER VIEWING ORALS**

Robert Levy<sup>1</sup>, Nagy Mekhail<sup>2</sup>, Timothy Deer<sup>3</sup>, Leonardo Kapural<sup>4</sup>, Sean Li<sup>5</sup>, Kasra Amirdelfan<sup>6</sup>, Corey Hunter<sup>7</sup>, Steven Rosen<sup>8</sup>, Shrif Costandi<sup>9</sup>, Steven Falowski<sup>10</sup>, Abram Burgher<sup>11</sup>, Jason Pope<sup>12</sup>, Christopher Gilmore<sup>13</sup>, Farooq Qureshi<sup>14</sup>, Peter Staats<sup>5</sup>, James Scowcroft<sup>15</sup>, Jonathan Carlson<sup>16</sup>, Christopher Kim<sup>17</sup>, Michael Yang<sup>18</sup>, Thomas Stauss<sup>19</sup>, Lawrence Poree<sup>2</sup>

<sup>1</sup>Director Of Neurosurgical Services, Anesthesia Pain Care Consultants, Tamarac, United States of America, <sup>2</sup>Anesthesiology And Pain Medicine, University of California at San Francisco, San Francisco, United States of America, <sup>3</sup>Pain Services, Spine & Nerve Center of the Virginias, Charleston, United States of America, <sup>4</sup>Pain Management, Carolinas Pain Institute and Wake Forest University School of Medicine, Winston-Salem, NC, United States of America, <sup>5</sup>Pain Management, Premier Pain Centers, Shrewsbury, NJ, United States of America, <sup>6</sup>Pain Medicine, IPM Medical Group, Inc., Walnut Creek, CA, United States of America, <sup>7</sup>Pain Management, Ainsworth Institute of Pain Management, New York, NY, United States of America, <sup>8</sup>Anesthesiology, Delaware Valley Pain & Spine Institute, Trevese, PA, United States of America, <sup>9</sup>Pain Management, Cleveland Clinic, Cleveland, OH, United States of America, <sup>10</sup>Neurological Surgery, Functional Neurosurgery, Neurosurgical Associates of Lancaster, Lancaster, PA, United States of America, <sup>11</sup>Pain Medicine, HOPE Research - TPC, Phoenix, AZ, United States of America, <sup>12</sup>Pain Medicine, Evolve Restorative Center, Santa Rosa, CA, United States of America, <sup>13</sup>Anesthesiology, Center for Clinical Research, Winston-Salem, NC, United States of America, <sup>14</sup>Pain Management, St Luke's Spine & Pain Associates, Easton, PA, United States of America, <sup>15</sup>Pain Management, Pain Management Associates, Independence, MO, United States of America, <sup>16</sup>Pain Management, Arizona Pain, Glendale, AZ, United States of America, <sup>17</sup>Anesthesiology, The Center for Pain Relief, Charleston, WV, United States of America, <sup>18</sup>Pain Management, Summit Pain Alliance, Santa Rosa, CA, United States of America, <sup>19</sup>Anesthesiology, Advanced Pain Management, Greenfield, WI, United States of America

**Introduction:** The Visual Analog Scale (VAS) has traditionally been the benchmark for measuring the analgesic impact of a therapy. While generally accepted, it's limited to the patient's subjective interpretation of pain and does little to gauge other important aspects of recovery. Technological advancements in spinal cord stimulation (SCS), combined with increased patient expectations and new literature on minimal clinically important differences (MCIDs) (Dworkin, 2008; Olsen, 2018), have put a larger focus on the need for defining clinically meaningful improvements. The ability to simultaneously report several outcome measures used to evaluate complex conditions like pain provides a more robust interpretation of the treatment effect for physicians to make more informed decisions.

**Methods/Materials:** Patient-reported-outcomes (PROs), including emotional/physical functioning and sleep quality, were collected in a double-blind, parallel-arm, randomized controlled trial of SCS (NCT02924129) (Levy, 2019) comparing closed-loop to open-loop SCS. The Evoke Study identified ≥80% VAS reduction in overall pain to categorize “high responders”. A post-hoc, subgroup analysis comparing PROs in subjects at 12 months (treatment groups combined) with responder rates ≥50% and <80% (N=32) versus ≥80% (N=58) was conducted to evaluate the clinical meaningfulness of the high responder rate.

**Results:** More high responders (86.2%) compared to responders (65.6%) had an ODI MCID(≥15) (p=0.031) (ODI Scoring Instructions). The proportion of high responders versus responders with a POMS TMD MCID (≥10) was 72.4% versus 50.0%, respectively (p=0.041) (Dworkin, 2008). Additionally, a higher proportion of high responders (39.7%) versus responders (12.5%) achieved remission (good sleep quality [score≤5] and an MCID[≥3]) on the PSQI (p=0.008) (Buysse, 2011).

	12 Months		
Statistically Significant Clinically Meaningful PROs	Responders VAS ≥50% and <80%	High Responders VAS ≥80%	P value
<b>Oswestry Disability Index (ODI) Score</b>			
ODI MCID (≥15 <sup>1</sup> )	21/32 (65.6%)	50/58 (86.2%)	0.031
<b>Profile of Mood States (POMS) Brief Total Mood Disturbance (TMD) Score</b>			
POMS TMD Clinically Important Change from Baseline (≥10)	16/32 (50.0%)	42/58 (72.4%)	0.041
<b>Pittsburgh Sleep Quality Index (PSQI) Score</b>			

	12 Months		
Statistically Significant Clinically Meaningful PROs	Responders VAS ≥50% and <80%	High Responders VAS ≥80%	P value
PSQI Remission (Good Sleep Quality [scores≤5] and Clinically Significant Change from Baseline [reduction≥3])	4/32 (12.5%)	23/58 (39.7%)	0.008
<sup>1</sup> Evoke Study eligibility criteria required subjects have severe to crippled disability at baseline.			

**Discussion:** High responders had statistically significantly greater proportions of subjects with clinically meaningful changes in all PROs. The concomitant improvements observed in these other PROs at this threshold support the robustness of the high responder rate and its use to evaluate SCS outcomes. Further, this analysis demonstrates the importance of assessing outcomes using a number of measures to better interpret the treatment effect and full benefit to the patient. The incidence of ≥80% reduction in VAS overall pain was statistically superior for closed-loop (55.9%) compared to open-SCS (37.3%) in the Evoke study at 12 months ( $p<0.039$ ).

**Conclusions:** The utilization of objective neurophysiological measurements to optimize outcomes through programming and closed-loop SCS may offer a greater probability of a high response.

**References:** Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the Clinical Importance of Treatment Outcomes in Chronic Pain Clinical Trials: IMMPACT Recommendations. *J Pain*. 2008 Feb;9(2):105–21. Levy R, Deer TR, Poree L, Rosen SM, Kapural L, Amirdelfan K, et al. Multicenter, Randomized, Double-Blind Study Protocol Using Human Spinal Cord Recording Comparing Safety, Efficacy, and Neurophysiological Responses Between Patients Being Treated With Evoked Compound Action Potential–Controlled Closed-Loop Spinal Cord Stimulation or Open-Loop Spinal Cord Stimulation (the Evoke Study). *Neuromodulation Technol Neural Interface*. 2019 Apr;22(3):317–26. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res*. 1989 May;28(2):193–213. Olsen MF, Bjerre E, Hansen MD, Tendal B, Hilden J, Hróbjartsson A. Minimum clinically important differences in chronic pain vary considerably by baseline pain and methodological factors: systematic review of empirical studies. *J Clin Epidemiol*. 2018 Sep;101:87–106.e2.

**Keywords:** Closed Loop, SCS, ECAP Controlled Closed Loop Spinal Cord Stimulation, ECAP, Spinal cord stimulation, Evoked Compound Action Potential

**Topic:** 05. Spine / 05a. Pain

## **OUTCOMES OF PREVIOUSLY-IMPLANTED CHRONIC PAIN PATIENTS CONVERTED TO A NEW SPINAL CORD STIMULATION SYSTEM - EUROPEAN EXPERIENCE**

### **E-POSTER VIEWING ORALS**

Philippe Rigoard<sup>1</sup>, Yu Pei<sup>2</sup>, Roshini Jain<sup>2</sup>

<sup>1</sup>Spine-neuromodulation-handicap Unit, POITIERS HOSPITAL UNIVERSITY, Poitiers, France, <sup>2</sup>Clinical Research, Boston Scientific, Valencia, United States of America

**Introduction:** Providing various waveforms and programming options can facilitate more customized delivery of analgesic neurostimulation to chronic pain patients implanted with a Spinal Cord Stimulation (SCS) device. However, technologies that offer such optimization capabilities are not accessible to long-term implanted patients using older devices, some of whom may experience loss or attenuation in therapeutic efficacy over time. These patients therefore may elect to undergo a “conversion” to a different SCS system that possesses these capabilities to gain access to these new technologies. In this study, we assessed a cohort of previously-implanted patients who converted to a new SCS device capable of combination therapy (simultaneous or sequential delivery of multiple available waveforms), enhanced algorithmic-based stimulation field targeting, and waveform automation.

**Methods/Materials:** This is a real-world, retrospective study of patients who were previously implanted with an SCS system (commercially-available device) who went on to convert to a different device (Boston Scientific) capable of multiple modality stimulation and/or combination therapy via an applicable device adaptor and new implantable pulse generator (IPG). Pain relief and other associated outcomes using both the previously-implanted SCS system and the newly connected device IPG are being collected.

**Results:** Collection and analysis of data is still on-going. Preliminary results will be presented.

**Discussion:** When experiencing problems with SCS device longevity and/or loss of efficacy, some previously-implanted patients may be able to obtain better outcomes using more advanced neuromodulation systems that offer a range of waveforms and programming options to address their chronic pain.

**Conclusions:** This European-based study will seek to evaluate previously-implanted patients who are empowered with the ability to selectively use an assortment of different waveform programming options following IPG conversion.

### **References:**

**Keyword:** spinal cord stimulation, SCS, chronic pain, conversion, real-world

**Topic:** 05. Spine / 05a. Pain

## **FUNCTIONAL MAGNETIC RESONANCE IMAGING: CEREBRAL FUNCTION ALTERATIONS IN SUBTHRESHOLD AND SUPRATHRESHOLD SPINAL CORD STIMULATION**

### **E-POSTER VIEWING ORALS**

Sander De Groote<sup>1</sup>, Mats De Jaeger<sup>2</sup>, Peter Vanschuerbeek<sup>3</sup>, Stefan Sunaert<sup>4</sup>, Ronald Peeters<sup>4</sup>, Dirk Loeckx<sup>5</sup>, Lisa Goudman<sup>6</sup>, Patrice Forget<sup>7</sup>, Ann De Smedt<sup>8</sup>, Maarten Moens<sup>9</sup>

<sup>1</sup>Neurosurgery, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>2</sup>Neurosurgery, Universitair ziekenhuis Brussel, Jette, Belgium, <sup>3</sup>Radiology, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>4</sup>Radiology, Universitair Ziekenhuis Leuven, Leuven, Belgium, <sup>5</sup>COMETRIX, Leuven, Belgium, <sup>6</sup>Neurosurgery, UZ Brussel, Jette, Belgium, <sup>7</sup>Anesthesiology, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>8</sup>Neurology, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>9</sup>Neurosurgery, UZ Brussel, Brussel, Belgium

**Introduction:** Failed back surgery syndrome (FBSS) is a common and devastating chronic neuropathic pain disorder. Conventional spinal cord stimulation (SCS) applies electrical suprathereshold pulses to the spinal cord at a frequency of 40-60 Hz and relieves pain in FBSS patients. During the last decade, two major changes have emerged in the techniques of stimulating the spinal cord: paresthesia-free or subthreshold stimulation and administration of higher frequency or higher amounts of energy to the spinal cord. Despite the positive clinical results, the mechanism of action remains unclear. A functional MRI (fMRI) study was conducted to investigate the brain alterations during subthreshold and suprathereshold stimulation at different frequencies.

**Methods/Materials:** Ten subjects with FBSS, treated with externalized SCS, received randomly four different stimulation frequencies (4 Hz, 60 Hz, 500 Hz, and 1 kHz) during four consecutive days. At every frequency, the patient underwent sub- and suprathereshold stimulation. Cerebral activity was monitored and assessed using fMRI.

**Results:** Suprathereshold stimulation is generally accompanied with more activity than sub-threshold SCS. Suprathereshold SCS resulted in increased bilateral activation of the frontal cortex, thalamus, pre- and postcentral gyri, basal ganglia, cingulate gyrus, insula, thalamus, and claustrum. We observed deactivation of the bilateral parahippocampus, amygdala, precuneus, posterior cingulate gyrus, postcentral gyrus, and unilateral superior temporal gyrus.

**Discussion:** Increasing the amplitude above the individual sensory threshold modulates more cerebral regions. At higher frequencies (500 and 1,000 Hz), suprathereshold stimulation causes activation of the insula, thalamus, nucleus caudatus and middle frontal gyrus. Those cortical regions are active in different cognitive, emotional and reward functions. A possible explanation for their increased activity is that patients reported an unpleasant sensation during stimulation. For the subthreshold stimulation at 500 and 1000 Hz, deactivation of two important structures (the precuneus and the precentral gyrus) could be related to pain processing.

**Conclusions:** Suprathereshold stimulation resulted in greater activity (both activation and deactivation) of the frontal brain regions; the sensory, limbic, and motor cortices; and the diencephalon in comparison with subthreshold stimulation. Each type of frequency at suprathereshold stimulation was characterized by an individual activation pattern.

### **References:**

**Keywords:** Supraspinal, fMRI, Spinal cord stimulation, chronic pain, Mechanism of action

**Topic:** 05. Spine / 05a. Pain

## **EXPLANT DATA ON 1177 PATIENTS IN A SINGLE CENTRE SPECIALISING IN NEUROMODULATION OVER AN 11 YEAR PERIOD**

### **E-POSTER VIEWING ORALS**

Adnan Al-Kaisy, Jonathan Royds, Omar Al-Kaisy, Samuel Wesley, Stefano Palmisani, David Pang, Stephany Harris, Thomas Yearwood, Stephen Ward  
Pain & Neuromodulation Centre, Guys and St Thomas' NHS Foundation Trust, London, United Kingdom

**Introduction:** The publication of explant rates has established risk factors and a definitive outcome of failure for Spinal Cord Stimulation (SCS) for neuropathic pain. Success of SCS is gauged subjectively and there is currently a paucity of long term efficacy data in the scientific literature. Explant rates due to a loss of perceived benefit however are a definitive objective outcome of failure. We present a UK study of explants of neuromodulatory devices for different neuropathic pain conditions over an 11-year period in a single centre specialising in Neuromodulation.

**Methods/Materials:** A retrospective analysis was performed using a departmental database between 2008-2019. Aetiology of pain, leads, device, sex, age, psychological assessment and reason for explant were recorded. Indications for implant included: Failed back or neck surgery syndrome, Back with or without radicular pain with no prior surgery, CRPS, Head pain, Neurogenic Bladder, Pelvic pain, Abdominal/Loin pain and Neuropathic pain. Reasons for explant included: loss of efficacy, infection, resolution of pain, requiring MRI, device related complications and other reasons. Explants were analysed according to condition, mode of stimulation and other demographics using logistic regression and survival curves with a Log-rank (Mantel-Cox) test.

**Results:** 1177 patients were implanted between April 2008-December 2018. Most of the explants were performed within the first 5 years (21.9% year 0-5 vs. 4.5% year 5-11). The overall explant rate was 17.8% at 5 years and 25.2% at 10 years. The most common indication for explant was due to loss of efficacy and was 13.1 % at 5 years and 17.5% at 10 years. Head pain had the highest explant rate due to loss of efficacy at 5 years (25.4%). There was a non-significant trend to greater risk of explant for non-research patients in comparison to research patients( $p=0.068$ ). There was no significant difference in the rate of explant between the different conditions( $p=0.47$ ), age( $p=0.77$ ), sex( $p=0.75$ ), waveform( $p=0.16$ ) and battery type( $p=0.53$ ).

**Discussion:** Explant rates in patients selected for neuromodulation give a long-term reliable objective outcome of failure. An acceptable explant rate has yet to be defined but the publication of further data sets will contribute to this in the future.

**Conclusions:** Research based patients likely have less risk of explant compared to non-research patients indicating selection criteria is key for SCS. Although not significant head pain may have potentially higher risk of explants; this may be related to not trialing prior to full implant. Although previously reported battery type and gender demonstrated no difference in explant rates.

**Keywords:** Explant, neuropathic pain, neuromodulation

**Topic:** 05. Spine / 05a. Pain

## HIGH FREQUENCY 10 KHZ SPINAL CORD STIMULATION FOR THE TREATMENT OF CHRONIC NEUROPATHIC PAIN RESULTING FROM SPINAL CORD INJURY

### E-POSTER VIEWING ORALS

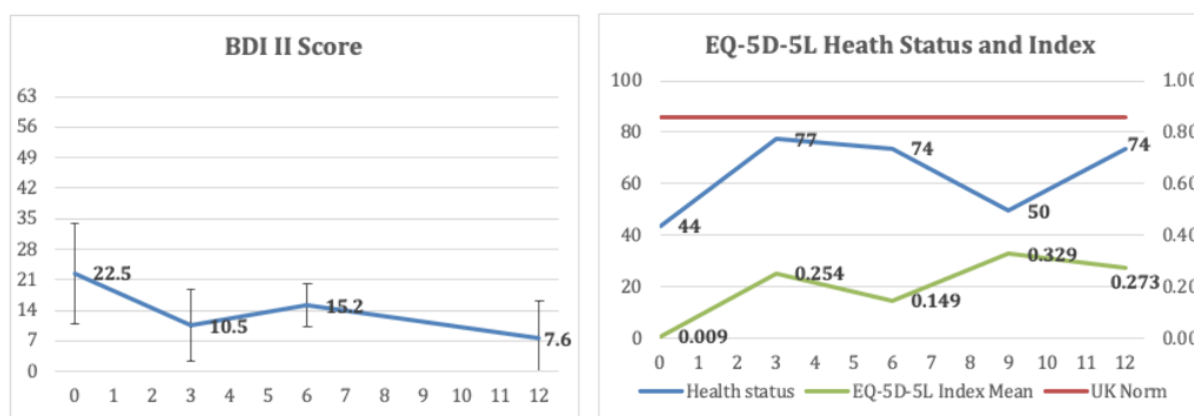
Munawar Mecci<sup>1</sup>, Wunna Aung<sup>1</sup>, Sarah Griffiths<sup>2</sup>, Anisah Tariq<sup>3</sup>, Anu Kansal<sup>3</sup>, Angela Santos<sup>4</sup>, Sam Eldabe<sup>3</sup>

<sup>1</sup>Spinal Injuries, James Cook University Hospital, Middlesbrough, United Kingdom, <sup>2</sup>Research, James Cook Hospital, Middlesbrough, United Kingdom, <sup>3</sup>Pain Medicine, James Cook Hospital, Middlesbrough, United Kingdom, <sup>4</sup>Clinical Research, Nevro, Redwood City, United States of America

**Introduction:** Prevalence of spinal cord injury (SCI) is difficult to ascertain due to its multiple causes. In the UK alone, there are over 40,000 people living with SCI.<sup>1</sup> One of the many complications of SCI is neuropathic pain. Low-frequency spinal cord stimulation (SCS) has been used to treat pain in SCI patients, however, no sufficient evidence has been found to support its use.<sup>2</sup> Case studies have shown promising results using 10 kHz SCS to treat neuropathic pain in SCI patients, including restored sensory and motor function in one patient.<sup>3,4</sup> The goal of this prospective, feasibility study is to evaluate the safety and effectiveness of 10 kHz SCS for the alleviation of chronic neuropathic pain in patients with an incomplete or complete SCI.

**Methods/Materials:** Subjects with chronic, intractable pain of  $\geq 5$  cm (visual analogue scale, VAS) in a target pain area directly related to SCI were enrolled in a prospective, single-centre study. Other eligibility criteria consisted of injury at cervical/thoracic/lumbar/sacral level, the American Spinal Injury Association Impairment Scale (ASIA) of A-D and neuropathic pain. Subjects were trialed with 10 kHz SCS, those with a successful trial ( $\geq 50\%$  pain relief) were implanted with a permanent system. Safety and effectiveness endpoints were captured up to 12 months post-implant.

**Results:** Per the latest analysis, 14 of the 21 enrolled subjects underwent a trial implant; scar tissue and fusion material precluded lead placement in 2 subjects and 7 had a successful trial (58% success rate). Data is available for 6 of the subjects with permanent implants. The baseline mean ( $\pm$ SD) pain scores (all pain areas) of  $8.1 \pm 1.5$  cm (N=6) improved to  $2.4 \pm 1.6$  cm (N=6) at the end of trial. Pain scores remained improved at  $2.7 \pm 1.8$  cm (N=6),  $3.2 \pm 3.0$  cm (N=6),  $5.4 \pm 2.7$  cm (N=5),  $2.6 \pm 2.2$  cm (N=5) and  $3.4 \pm 2.5$  cm (N=5) at 1, 3, 6, 9 and 12 month post-implant follow-up, respectively. Beck Depression Index (BDI) and EQ-5D-5L health status and EQ-5D index score also improved (Graph 1 and 2). Two subjects were reclassified from ASIA A at baseline to ASIA B at their 3, 6 and 12-month visits due to improved sensory function.



Graph 1 and 2 -BDI II score (left) and Health Status and EQ-5D-5L Index (right)



**Discussion:** Not applicable.

**Conclusions:** This study provides promising preliminary results for the use of 10 kHz SCS in SCI patients to treat their chronic pain. Additional outcomes captured suggest that there may be added benefits to this therapy including improvement in health and sensory function.

**References:** 1 -Royal College of Physicians, British Society of Rehabilitation Medicine, Multidisciplinary Association of Spinal Cord Injury Professionals, British Association of Spinal Cord Injury Specialists, Spinal Injuries Association. Chronic spinal cord injury: management of patients in acute hospital settings: national guidelines. Concise Guidance to Good Practice series, No 9. London: RCP, 2008. 2 -Lagauche et al. The chronic neuropathic pain of SCI: which efficiency of neuropathic stimulations? *Ann.Phys.Rehab.Med.* 52 (2009) 180-187. 3 -Sisson et al. Sustained pain relief and functional improvement in SCI patients treated with HF-SCS at 10 kHz: Two Case reports. Abstract & Poster, NANS congress 2017. 4 -Verdolin. Restoration of sensory and motor function after acute trial stimulation in SCI with HF-SCS at 10kHz: a case report. Abstract & Poster, NANS congress 2017.

**Keywords:** neuropathic pain, 10kHz SCS, SCI

**Topic:** 05. Spine / 05a. Pain

## **DYNAMIC BRAIN IMAGING RESPONSE TO CHANGES IN SPINAL CORD STIMULATION FREQUENCY PARAMETERS**

### **E-POSTER VIEWING ORALS**

Kavita Poply<sup>1</sup>, Alia Ahmad<sup>1</sup>, Serge Nikolic<sup>1</sup>, Habib Ellamushi<sup>1</sup>, Angie Alamgir<sup>1</sup>, Joanne Lascelles<sup>1</sup>, Richard Vangroningen<sup>1</sup>, Helena Mcmeekin<sup>2</sup>, Arman Parsai<sup>2</sup>, Maria Burniston<sup>2</sup>, Vivek Mehta<sup>1</sup>

<sup>1</sup>Pain Research Centre, Barts Health NHS Trust, London, United Kingdom, <sup>2</sup>Nuclear Medicine, Barts Health NHS Trust, London, United Kingdom

**Introduction:** Brain imaging is increasingly being used as a research tool to understand the mechanisms of pain and pain interventions. Within positron emission tomography–computed tomography (PET-CT) scans, functional changes in the brain can be identified by differential regional cerebral blood flow (rCBF); determined by changes in distribution of radioactive tracer 18F-fluorodeoxyglucose (18F-FDG) in different areas of the brain. At present, there is limited data available on functional neuroimaging following SCS. One study (n=20, 7 Complex Regional Pain Syndrome and 13 control) reports increased 18F-FDG uptake in left thalamus, anterior cingulate cortex, bilateral insula, dorsolateral prefrontal cortex and bilateral temporal gyrus in six patients where SCS is effective<sup>1</sup>. Similarly, another study reports increased blood flow following SCS in the thalamus, orbitofrontal, parietal and prefrontal cortex proportional to the pain relief (larger PET assessed increase in rCBF correlates with decrease in pain intensity)<sup>2</sup>. It has been postulated that thalamus activity may relate to whether SCS is effective or not. Since, there is limited data reporting PET-CT scan changes following the differential frequency range used in spinal cord stimulation (SCS). Our aims are to examine the changes in dynamic brain imaging following SCS against the various frequencies used (tonic or high frequency).

**Methods/Materials:** This is a single-blind, randomised, cross-over design study. Currently, ten patients with intractable lumbar neuropathic pain who were due to receive SCS as part of their standard treatment have completed the study. A 18F-FDG-PET/CT scan was conducted prior to implant. After SCS implantation, patients were provided with tonic 40Hz stimulation for 4 weeks followed by a 18F-FDG-PET/CT scan. Patients were randomised (1:1) to receive 4000Hz or 10,000Hz for four weeks followed by another PET/CT scan. Patients were then crossed over to the alternate frequency for four more weeks followed by a final PET/CT scan. Outcome questionnaires including the numerical rating scores (NRS) for back and leg pain were completed at each visit.

**Results:** The interim data supports differential metabolic activity and numerical rating score following differential frequency. We aim to present the final results of outcome data at E-INS.

**Discussion:** The interim data will demonstrate the significant reduction in pain scores in all frequency parameters- 40Hz, 10,000Hz and 4000Hz as well as the changes in F-18 FDG uptake.

**Conclusions:** This would be first study that would translate the clinical effects of differential frequency (including higher frequencies) on brain metabolism and substantiate subsequent mechanism of action pathways.

**References:** 1. Nihashi T, Shiraishi S, Kato K, Ito S, Nishino M, Ishigaki T, et al. The response of brain with chronic pain during spinal cord stimulation, using FDG-PET. International Congress Series. 2004; 1270: 315-319 2. Kishima H, Saitoh Y, Oshino S, Hosomi K, Ali M, Maruo T, Hirata M, Goto T, Yanagisawa T, Sumitani M, Osaki Y. Modulation of neuronal activity after spinal cord stimulation for neuropathic pain; H 2 15 O PET study. Neuroimage. 2010;49(3):2564-9.

**Keyword:** L2 DRG stimulation, Neurostimulation, 18F- FDG PET-CT Scans, low back pain

**Topic:** 05. Spine / 05a. Pain

## EDUCATION PREDICTS PAIN RELIEF OF SPINAL CORD STIMULATION

### E-POSTER VIEWING ORALS

Terje Kirketeig<sup>1,2</sup>, Emma Söreskog<sup>3,4</sup>, Trolle Jacobson<sup>3</sup>, Rolf Karlsten<sup>1,5</sup>, Peter Fritzell<sup>6,7</sup>, Fredrik Borgström<sup>3,4</sup>

<sup>1</sup>Inst. Surgical Sciences, Uppsala University, Uppsala, Sweden, <sup>2</sup>Multidisciplinary Pain Center, Unit For Neuromodulation, Akademiska sjukhuset, Uppsala, Sweden, <sup>3</sup>Quantify Research, Quantify Research, Stockholm, Sweden, <sup>4</sup>Lime/mmc, Karolinska Institutet, Solna, Sweden, <sup>5</sup>Akademiska Sjukhuset, Akademiska sjukhuset, Uppsala, Sweden, <sup>6</sup>Futurum Academy, Futurum Academy, Jönköping, Sweden, <sup>7</sup>Ryggkirurgiskt Centrum, Ryggkirurgiskt Centrum, Stockholm, Sweden

**Introduction:** Multiple controlled trials have proven spinal cord stimulation (SCS) to be a safe and efficacious treatment for selected pain conditions. However, comprehensive real-world outcome studies with larger population samples are lacking. The Swedish research database for spinal cord stimulation (SWECOST) is a database assembled using patient-level data from Swedish national registers, including; in- and outpatient care, drug dispensations, socioeconomic data, and SCS-specific information from the local RAY database. The objective of this study was to assess; (1) long-term predictors of the patient-reported effect of stimulation (EoS) on pain relief and (2) risk of explantation due to insufficient analgesic effect.

**Methods/Materials:** Patients registered in RAY who received SCS treatment between 2009–2018 were included. The first analysis evaluated EoS on pain, collected at the first follow-up (3–24 months) using answers categorized in six levels, from worsened pain to no pain. Ordered logistic regression was used to determine predictors for EoS. The second analysis assessed predictors for the explantation of SCS due to insufficient analgesic effect, using a time-to-event analysis with first explantation due to insufficient analgesic effect as failure event. Cox proportional hazard regression was used in this analysis.

**Results:** In total, 404 patients were included. Three percent reported pain-free, 19% considerable, 35% acceptable, 40% some, and 3% no pain relief or worsened pain compared to before the SCS. Higher education (coef.= -1.350 to -0.819 depending on category,  $p < 0.006$ ) were significantly associated with a successful outcome contrary to being unemployed (coef.= 0.648,  $p = 0.012$ ). Consuming  $\geq 200$  defined daily doses/year of opioids was associated with a less successful outcome (coef.= 0.436,  $p = 0.177$ ). For the second analysis, the survival rate for explantation at 10 years was 79% (CI: 72%–84%). Being 60 years or older (hazard ratio (HR)=3.818,  $p = 0.022$ ) was associated with a higher risk of explantation.

**Discussion:** In a patient-reported outcome in a non-selective and clinically relevant population more than half of the patients reported acceptable to complete pain-free following SCS. Risk of explantation due to loss of effect in this study largely confirms prior real-world reports.

**Conclusions:** Socioeconomic status, and opioid consumption although non-significantly, affect analgesic effectiveness and risk of explantation, implicating the need for considering these factors in future studies.

### References:

**Keywords:** Spinal cord stimulation, SCS, Real-World Evidence, pain relief

## CURRENT STATE OF SPINAL CORD STIMULATION FOR PERIPHERAL VASCULAR DISEASE

### E-POSTER VIEWING ORALS

Philipp Slotty, Jan Vesper, Sebastian Gillner, Guilherme Santos Piedade  
Functional Neurosurgery And Stereotaxy, Univerity Clinic Duesseldorf, Dusseldorf, Germany

**Introduction:** Although under investigation for several decades, spinal cord stimulation is not established in the treatment of peripheral vascular disease. The global vascular guidelines from 2019 found good scientific data on the efficacy of SCS on numerous aspects of PVD but conclude in a grade 2 (weak) recommendation based on a level 2 (moderate) level of evidence. One of the main points of criticism are the high treatment costs per case compared to other options and high complication rates.

**Methods/Materials:** We analyzed the publications and their interpretation leading to the current state of spinal cord stimulation in the treatment of peripheral vascular disease. Additionally, we looked at the neuromodulation society and experts reaction by means of new studies and concepts to increase the use of spinal cord stimulation in peripheral vascular disease.

**Results:** The available good quality studies on spinal cord stimulation for PVD all had limb salvage as a primary endpoint. The number needed to treat to save one limb was calculated as 13 with treatment costs for one saved limb exceeding \$110.000.

Smaller studies focused on the mechanism of action and found numerous well-investigated positive effects of spinal cord stimulation on peripheral perfusion. Some more recent studies have already started focusing on the problem of patient selection for SCS in PVD.

**Discussion:** There is good evidence for the use of spinal cord stimulation for peripheral vascular disease, but the high treatment costs impede a broader application. Numerous options exist to overcome this problem. Apart from reduction of implant and procedure costs, improved patient selection based on well-established, ideally objective measurements is likely the key to open this technique for the widespread use. Additionally, ways should be investigated to increase the overall responder rates e.g. by means of other stimulation paradigms.

**Conclusions:** As there is sufficient evidence on the overall efficacy, future studies on spinal cord stimulation for peripheral vascular disease should focus on improving patient selection and overall responder rates.

### References:

**Keywords:** critical limb ischemia, peripheral vascular disease, Spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

**HIGH-DOSE SPINAL CORD STIMULATION FOR PATIENTS WITH FAILED BACK SURGERY SYNDROME: A MULTICENTER EFFECTIVENESS AND PREDICTION STUDY.**

**E-POSTER VIEWING ORALS**

Lisa Goudman<sup>1</sup>, Ann De Smedt<sup>2</sup>, Sam Eldabe<sup>3</sup>, Philippe Rigoard<sup>4</sup>, Bengt Linderöth<sup>5</sup>, Mats De Jaeger<sup>1</sup>, Discover Discover<sup>6</sup>, Maarten Moens<sup>7</sup>

<sup>1</sup>Neurosurgery, Universitair ziekenhuis Brussel, Jette, Belgium, <sup>2</sup>Physical Medicine And Rehabilitation, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>3</sup>Pain Medicine, James Cook Hospital, Middlesbrough, United Kingdom, <sup>4</sup>Prismatics, Hospital University of Poitiers, Poitiers, France, <sup>5</sup>Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden, <sup>6</sup>Discover, Discover consortium, Jette, Belgium, <sup>7</sup>Neurosurgery, UZ Brussel, Brussel, Belgium

**Introduction:** Since its first use in humans in 1967, Spinal Cord Stimulation (SCS) has been established as an effective therapy to treat refractory chronic pain conditions. More recently, new waveforms and frequencies have changed the paradigm of standard SCS to address SCS long-term failures and to optimize therapy outcomes. The use of High Dose SCS (HD-SCS) has drastically increased during the last years, with positive results. However, real-world data about the effectiveness of HD-SCS are currently still lacking. Therefore, the primary aim of this study was to evaluate the effectiveness of HD-SCS in patients with Failed Back Surgery Syndrome (FBSS). The second aim was to develop a prediction model for a holistic responder.

**Methods/Materials:** One hundred ninety-four patients with FBSS were recruited in this multicenter real-world registry. Self-reporting outcome variables were evaluated at baseline (before initiating SCS) and after 1, 3 and 12 months of HD-SCS. The primary The following outcome measurements were collected over time: mean pain intensity, sleep quality, disability, health-related quality of life and medication use. Besides the effectiveness, logistic regression and decision tree analysis were performed to define a holistic responder (pain intensity reduction, medication reduction, ODI reduction and EQ5D improvement) after 12 months of HD-SCS.

**Results:** Of the 185 FBSS patients who underwent a baseline visit (before receiving SCS), 75.13% had a successful HD trial. After 12 months, 92 patients were still receiving HD-SCS. Both low back and leg pain significantly decreased at 12 months. All secondary outcome measures revealed a significant time-dependant effect. Through a logistic regression model, holistic responders at 12 months of HD-SCS could be predicted with a sensitivity and specificity of 90%.

**Discussion:** Clinically significant and sustained pain relief over a period of 12 months was achieved with HD-SCS in patients with FBSS. Additionally, HD-SCS is also able to achieve more global benefits namely an improvement in sleep quality and functionality and a decrease in pain medication in this population.

**Conclusions:** Based on real-world data, this study demonstrated the effectiveness of HD-SCS to reduce back and leg pain after 12 months, in patients with FBSS, refractory to best medical treatment.

**References:**

**Keywords:** prediction, effectiveness, holistic responder, high-dose spinal cord stimulation

## LONG-TERM QUALITY OF LIFE AND WORK STATUS AFTER HIGH DOSE SPINAL CORD STIMULATION IN PATIENTS WITH FAILED BACK SURGERY SYNDROME

### E-POSTER VIEWING ORALS

Lisa Goudman<sup>1</sup>, Ann De Smedt<sup>2</sup>, Koen Putman<sup>3</sup>, Discover Discover<sup>4</sup>, Maarten Moens<sup>5</sup>

<sup>1</sup>Neurosurgery, UZ Brussel, Jette, Belgium, <sup>2</sup>Physical Medicine And Rehabilitation, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>3</sup>Department Of Public Health, Vrije Universiteit Brussel, Jette, Belgium, <sup>4</sup>Discover, Discover consortium, Jette, Belgium, <sup>5</sup>Neurosurgery, UZ Brussel, Brussel, Belgium

**Introduction:** During the last years, the use of High Dose SCS (HD-SCS) has drastically increased as treatment strategy for patients with Failed Back Surgery Syndrome (FBSS). However, a thorough evaluation of health-related quality of life (HRQoL) and work status of this type of neuromodulation has not yet been performed. Moreover, it is not yet explored whether patients who are treated with HD-SCS can regain the same levels of HRQoL as the general population. Therefore, the aims of this study are 1) to compare HRQoL of patients who receive HD-SCS to age-and sex-adjusted population norms 2) to evaluate work status in patients who are receiving HD-SCS.

**Methods/Materials:** HRQoL was measured with the EQ5D-3L in 185 FBSS patients at baseline (i.e. before SCS) and at 1, 3 and 12 months of HD-SCS. Difference scores in utility values between patients and age-and sex adjusted population norms were calculated. One-sample Wilcoxon tests were used to assess the EQ5D-3L difference scores. Mixed models were used to evaluate the evolution over time in EQ5D-3L utility scores and EQ5D VAS scores in patients and matched controls. Quality adjusted life years (QALY) were calculated as well. Work status was evaluated at 12 months of SCS.

**Results:** An overall significant increase in EQ5D-3L utility score and EQ5D VAS score was found over time. Wilcoxon tests indicated that the difference utility scores (between patients and normal population) were significantly different from zero at all time points. The median incremental QALY after 12 months of HD-SCS was 0.228 (Q1-Q3: 0.005 – 0.487) in comparison to continued conservative treatment. At 12 months, 13.75% patients resumed work.

**Discussion:** HD-SCS is able to significantly increase HRQoL at 12 months in patients with FBSS. Despite the increase, reaching HRQoL up to the level of matched controls was not achieved. Only a limited number of patients is able to return to work, for which specialized programs to enhance return to work may possibly find their way in the field of SCS.

**Conclusions:** From an HRQOL point of view, HD-SCS seems to be an effective treatment option for patients with FBSS.

### References:

**Keywords:** high-dose spinal cord stimulation, health-economics, QALY

**Topic:** 05. Spine / 05a. Pain

## **HIGH-DOSE SPINAL CORD STIMULATION REDUCES LONG-TERM PAIN MEDICATION USE IN PATIENTS WITH FAILED BACK SURGERY SYNDROME: A REGISTRY-BASED COHORT STUDY.**

### **E-POSTER VIEWING ORALS**

Lisa Goudman<sup>1</sup>, Ann De Smedt<sup>2</sup>, Patrice Forget<sup>3</sup>, Sam Eldabe<sup>4</sup>, Discover Discover<sup>5</sup>, Maarten Moens<sup>6</sup>

<sup>1</sup>Neurosurgery, UZ Brussel, Jette, Belgium, <sup>2</sup>Physical Medicine And Rehabilitation, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>3</sup>Institute Of Applied Health Sciences, University of Aberdeen, Aberdeen, United Kingdom, <sup>4</sup>Pain Medicine, James Cook Hospital, Middlesbrough, United Kingdom, <sup>5</sup>Discover, Discover consortium, Jette, Belgium, <sup>6</sup>Neurosurgery, UZ Brussel, Brussel, Belgium

**Introduction:** High-dose Spinal Cord Stimulation (HD-SCS) revealed positive results for obtaining pain relief in patients with Failed Back Surgery Syndrome (FBSS). Several studies pointed out the beneficial effects of SCS to reduce pain medication use and more specifically opioid consumptions, compared to best medical treatment. It is, however, less clear whether HD-SCS is also able to reduce pain medication use in this population. Therefore, the aim of this registry-based cohort study is to explore the impact of HD-SCS on pain medication use in patients with FBSS.

**Methods/Materials:** Individual patient data from the Discover registry was used in which the effectiveness of HD-SCS was explored in neurostimulation-naïve FBSS patients as well as in rescue patients. Medication use was measured with the Medication Quantification Scale III (MQS) in 259 patients at baseline (i.e. before HD-SCS) and at 1, 3 and 12 months of HD-SCS. Additionally, defined daily doses (DDD) and morphine milligram equivalents (MME) were calculated as well.

**Results:** In neurostimulation-naïve patients, a statistically significant decrease in MQS ( $\chi^2=62.92, p<0.001$ ), DDD ( $\chi^2=11.47, p=0.009$ ) and MME ( $\chi^2=21.55, p<0.001$ ) was found over time. In rescue patients, no statistically significant improvement in MQS, DDD or MME scores were found. In both patient groups, a statistically significant reduction in the proportion of patients on high-risk MME doses  $\geq 90$  was found over time. At the intra-individual level, positive correlations were found between MQS scores and pain intensity scores for back pain and leg pain in neurostimulation-naïve and rescue patients.

**Discussion:** Real world data on HD-SCS in patients with FBSS revealed a statistically significant and sustained decrease in pain medication use, not only on opioids, but also on anti-neuropathic agents. Additionally, the current analysis demonstrated that HD-SCS is also beneficial for high risk patients by reducing the large amount of opioids.

**Conclusions:** In line with the results of other stimulation paradigms, HD-SCS is able to reduce pain medication use in patients with FBSS.

### **References:**

**Keywords:** Opioids, medication use, HD-SCS

Topic: 05. Spine / 05a. Pain

**DRG STIMULATION IS AN EFFECTIVE SALVAGE THERAPY FOR IMPROVING PAIN AND PSYCHOLOGICAL OUTCOMES IN PATIENTS WHO FAILED DORSAL COLUMN STIMULATION: PROLONG SUB-ANALYSIS**

**E-POSTER VIEWING ORALS**

Corey Hunter<sup>1</sup>, Julie Pilitsis<sup>2</sup>, Steven Falowski<sup>3</sup>, Jason Pope<sup>4</sup>, Misagh Mansouri<sup>5</sup>, Timothy Deer<sup>6</sup>

<sup>1</sup>Pain Management, Ainsworth Institute of Pain Management, New York, United States of America, <sup>2</sup>Neurology, Albany Medical Center, Albany, United States of America, <sup>3</sup>Neurological Surgery, Functional Neurosurgery, Neurosurgical Associates of Lancaster, Lancaster, United States of America, <sup>4</sup>Pain Medicine, Evolve Restorative Center, Santa Rosa, United States of America, <sup>5</sup>Global Neuromodulation, Abbott, Austin, United States of America, <sup>6</sup>Pain Services, Spine & Nerve Center of the Virginias, Charleston, United States of America

**Introduction:** Spinal cord stimulation (SCS) has been shown to effectively relieve chronic intractable pain. However, a portion of patients who initially succeed with SCS having waning therapeutic benefits over time. Stimulation of the dorsal root ganglion (DRG) has been found to provide more effective treatment of complex regional pain syndrome and peripheral causalgia than SCS. PROLONG (NCT039088476) is a multi-center, open-label, post-market study. The study prospectively observes subjects who switch to burst capable devices or DRG stimulation after loss of pain relief with their previous SCS system. Herein we report on subjects who received DRG stimulation. We present 6-month (6M) follow-up results for a range of patient-reported outcomes.

**Methods/Materials:** Eligible subjects had a pain score of  $\geq 6$  on the Numerical Rating Scale (NRS), had a functioning SCS system implanted, and did not report pain outside of the original treatment area. Patient-reported outcomes presented here include NRS, PROMIS-29 physical function, the Pain Catastrophizing Scale (PCS), and Pain Vigilance and Awareness Questionnaire (PVAQ). These measures can identify improvements accounting for an individual's perspective of their pain experience.

**Results:** Fifteen subjects (57% female), with waning or loss of therapeutic benefits with SCS, received DRG implants. Most subjects are of working age (median age=57, 10 subjects below 65). We present data from 13 subjects who have completed the 6M follow-up visits. The NRS score improved from  $7.5 \pm 1.6$  at baseline to  $4.1 \pm 3.0$  at 6M. 69% (9/13) of subjects showed at least a two-point reduction in NRS score at 6M. 62% (8/13) showed a reduction of 30% or higher in NRS at 6M. The average PCS score improved from  $25.8 \pm 15.6$  at baseline to  $13.7 \pm 18.2$  at 6M. Fifty percent (3/6) of subjects clinically catastrophizing at baseline ( $\geq 30$ ) reported improvement of symptoms at 6M follow-up ( $< 30$ ). 62% (8/13) of subjects with severe or moderate pain interference ( $\geq 60$ ) at baseline reduced symptoms by at least one category at 6M. Pain vigilance also improved from  $15.4 \pm 9.1$  (n=15) at baseline to  $12.5 \pm 9.0$  (n=13) at 6M.

**Discussion:** DRG stimulation can reduce pain in a patient population reporting failure of other SCS therapies. In addition, this small cohort of 6-month data supports the effectiveness of DRG stimulation in improving pain-related emotional well-being in patients with chronic intractable pain.

**Conclusions:** DRG stimulation is an effective salvage therapy for improving pain and psychological outcomes in patients who failed dorsal column stimulation.

**References:**

**Keywords:** DRG stimulation, salvage therapy, functional and psychological outcomes, chronic pain, Spinal cord stimulation



**Topic:** 05. Spine / 05a. Pain

## **BURST SPINAL CORD STIMULATION PROVIDES SUSTAINED, LONG-TERM IMPROVEMENTS IN PAIN, QUALITY OF LIFE, AND EMOTIONAL WELL-BEING: 2-YEAR RESULTS FROM THE TRIUMPH STUDY**

### **E-POSTER VIEWING ORALS**

Isaac Peña<sup>1</sup>, Edward Tavel<sup>2</sup>, Gregory Moore<sup>3</sup>, Kelby Hutcheson<sup>4</sup>, Giuliano De Carolis<sup>5</sup>, Mikael Von Und Zu Fraunberg<sup>6</sup>, Bram Blomme<sup>7</sup>, Robyn Capobianco<sup>8</sup>

<sup>1</sup>Department Of Anesthesiology And Pain Management, Hospital Universitario Virgen del Rocío, Seville, Spain, <sup>2</sup>Interventional Pain Management, Clinical Trials of South Carolina, Charleston, United States of America, <sup>3</sup>Interventional Pain Management, Pacific Sports and Spine, Eugene, United States of America, <sup>4</sup>Pain Management, Carolinas Center for Advanced Management of Pain, Columbia, United States of America, <sup>5</sup>Pain Department, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy, <sup>6</sup>Neurosurgery, Kuopio University Hospital, Kuopio, Finland, <sup>7</sup>Neuromodulation, Abbott, Zaventem, Belgium, <sup>8</sup>Neuromodulation, Abbott, Austin, United States of America

**Introduction:** We have previously presented one-year outcomes after burst spinal cord stimulation (SCS) in the prospective, multi-center, international TRIUMPH study (NCT03082261).<sup>1</sup> These data showed improvements across all evaluated psychological measures with the largest impact observed on catastrophizing and depression (the affective component of pain processing). Herein we present data for the entire follow-up period, up to 24 months after permanent implant.

**Methods/Materials:** Eligible patients with chronic, intractable pain of the trunk and/or lower limbs were enrolled. After a successful trial period using burst stimulation, subjects received a permanent SCS implant and returned for regular follow-up at 6, 12, 18, and 24 months. Pain, psychometric, and global health measures were collected at baseline and all follow-up timepoints. Responder analyses were performed based on published clinical impact scores.

**Results:** 24-month data were available for 128 subjects enrolled at 17 centers. A composite responder analysis<sup>2</sup> showed 72% (92/128) of subjects improved across quality of life, pain intensity, physical function, and emotional well-being at 24 months. Individually, quality of life (EQ-5D index) increased from 0.46 to 0.66, in line with previous timepoints. Catastrophizing on PCS (12.4) remained below the population norm (13.9). 79% who were clinically catastrophizing (PCS  $\geq 30$ ) and 61% who were clinically depressed (PHQ9  $\geq 10$ ) at baseline, were not at 24 months; within the range of previous timepoints. Patient reported pain relief was consistent across timepoints at 60-63%. The results obtained for patient satisfaction (range 80%-87%), proportion who reported at least a considerable change on PGIC (range 73%-79%), and proportion who were active (from 32% at baseline to 48%-63% at follow-up) were also maintained out to 2 years. Finally, 62% who were taking opioids at baseline decreased their intake at 24 months, including 27% who were completely off opioids; a further improvement compared with 6 and 12 months. The data collected for other pain medication followed a similar pattern with 38% (for antidepressants and muscle relaxants) and 46% (for analgesics, anticonvulsants, and NSAIDs) decreasing their intake at 24 months.

**Discussion:** 24-month data were in line with all previous timepoints; subjects improve baseline to 6 months and consecutively remained at a similar level in terms of pain, quality-of-life, and psychological profile up to 2 years post-permanent implant. After 2 years of burst SCS, subjects were satisfied with the therapy, feeling better, getting more active, while taking less pain medication.

**Conclusions:** Burst SCS provides consistent long-term effective results on pain, quality-of-life, and emotional well-being.

**References:** 1. Falowski SM, Moore GA, Cornidez EG et al. Improved Psychosocial and Functional Outcomes and Reduced Opioid Usage Following Burst Spinal Cord Stimulation. *Neuromodulation* 2021;24(3):581-590 2. Piliitsis JG, Marie Fahey M, Custozzo A et al. Composite Score Is a Better

Reflection of Patient Response to Chronic Pain Therapy Compared with Pain Intensity Alone.  
Neuromodulation 2021;24(1):68-75

**Keywords:** Spinal cord stimulation, Long-term outcomes, Burst

## PATIENT PROFILING IN PATIENTS SELECTED FOR SPINAL CORD STIMULATION

### E-POSTER VIEWING ORALS

Vincent Raymaekers<sup>1,2</sup>, Anna Sofia Keil<sup>3</sup>, Sven Bamps<sup>1,4,5</sup>, Gert Roosen<sup>4,5</sup>, Maarten Wissels<sup>4,5</sup>, Eric Put<sup>4,5</sup>, Steven Vanvolsem<sup>4,5</sup>, Wim Duyvendak<sup>4,5</sup>, Stefan Schu<sup>3,6</sup>, Mark Plazier<sup>1,4,5</sup>

<sup>1</sup>Faculty Of Medicine And Life Science, Hasselt University, Hasselt, Belgium, <sup>2</sup>Neurosurgery, Antwerp University, Edegem, Belgium, <sup>3</sup>Neurosurgery, Universitätsklinikum Düsseldorf, Düsseldorf, Germany, <sup>4</sup>Neurosurgery, Jessa Hospital, Hasselt, Belgium, <sup>5</sup>Chair, Study and education center Neurosurgery Virga Jesse, Hasselt, Belgium, <sup>6</sup>Sana Hospital Duisburg, Sana Hospital group, Duisburg, Germany

**Introduction:** A significant proportion of patients with back and leg pain end up with chronic pain for which spinal cord stimulation (SCS) has proven to be an effective treatment modality.<sup>1-2</sup> It is unclear which patient benefits most from which therapy and at what timing. Real world big data collection in the diverse population in daily practice forms an opportunity to optimize treatments.

**Methods/Materials:** A patient driven data big data collection application, the Back-App, was developed. Hundred sixteen (n=116) patients selected for SCS treatment were included in a hierarchical cluster analysis by Ward's method. The analysis was based on baseline characteristics for pain (VAS leg and back), the Pain Catastrophizing Scale, the Oswestry disability Index and quality of life (EQ-5D) before treatment. Clusters were compared for the use of pain medication and employment status.

**Results:** The multivariate analysis illustrated that three clusters can be explained by the significant effect of all five variables in the analyses ( $p < 0.001$ ).

Cluster 1 (n=77) is characterized by the highest pain scores for leg (6,92,  $p < 0,001$ ), but mostly back pain (8,26,  $p < 0,001$ ), high PCS and high disability. This results in a significantly lower QOL (0,10,  $p < 0,001$ ) compared to cluster 2 and 3. Patients in cluster 2 state lower VAS scores for back and leg pain, 4,02 and 2,82 respectively ( $p < 0,001$ ) with lower PCS and ODI. QOL is preserved in cluster 2 (0,731,  $p < 0,001$ ). The last cluster 3 includes patients with high VAS for back and leg pain (7,13 and 7,00,  $p < 0,001$ ) with high PCS and disability. In contrast to cluster 1, there is no impact on QOL in cluster 3. VAS for back pain was higher in cluster 1 than in cluster 2 and 3, whereas VAS for leg pain was comparable with cluster 3. There is no difference in employment status. Cluster 1 patients used more pain medication from the WHO II and III classification than patients in cluster 2 and 3 ( $p < 0,001$ ).

**Discussion:** It is the first study to include pain, pain catastrophizing, QOL and disability together in the cluster analysis for SCS patients. This research gives insight in the complex population selected for SCS for chronic low back and/or leg and is an added value to sparsely existing literature on big data collection in spinal cord stimulation.

**Conclusions:** Future research will focus on the outcome analysis in the different patient populations that were illustrated by this data collection.

**References:** 1. Trust, L., Oklahoma City, O. K., & Grider, J. (2016). Effectiveness of spinal cord stimulation in chronic spinal pain: a systematic review. *Pain physician*, 19, E33-E54. 2. Kumar, K., Taylor, R. S., Jacques, L., Eldabe, S., Meglio, M., Molet, J., ... & North, R. B. (2008). The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery*, 63(4), 762-770.

**Keywords:** Big Data, Real world data, Cluster analysis, Spinal cord stimulation

**Topic:** 06. Headache

## SAFETY AND EFFICACY OF 10 KHZ SPINAL CORD STIMULATION FOR THE TREATMENT OF REFRACTORY CHRONIC MIGRAINE: A PROSPECTIVE STUDY

### E-POSTER VIEWING ORALS

Adnan Al-Kaisy<sup>1</sup>, Stefano Palmisani<sup>1</sup>, Roy Carganillo<sup>1</sup>, Samuel Wesley<sup>1</sup>, David Pang<sup>1</sup>, Angela Santos<sup>2</sup>, Giorgio Lambru<sup>1</sup>

<sup>1</sup>Pain & Neuromodulation Centre, Guys and St Thomas' NHS Foundation Trust, London, United Kingdom, <sup>2</sup>Clinical Research, Nevro, Redwood City, United States of America

**Introduction:** Chronic migraine (CM) is a major public health problem affecting approximately 2% of the adult population [1]. 10 kHz spinal cord stimulation (SCS) has proven to be effective in relieving chronic back and leg pain [2] and has also shown promising efficacy in a prospective study conducted in subjects with chronic migraine and medication overuse [3]. The aim of this study was to assess safety, tolerability and efficacy of 10 kHz SCS in refractory CM subjects. This is an off-label indication for SCS.

**Methods/Materials:** Twenty-five adults diagnosed with CM as per the International Headache Society's diagnostic criteria and refractory to medical treatment (defined as a failure to respond to at least 3 prophylaxis therapies of which one is topiramate) were enrolled in this single-centre, open-label, prospective study. Medication overuse headache and severe depression were considered exclusion criteria. No stimulation trial was performed as a delayed response to neurostimulation was expected, and 20 subjects were implanted with a 10 kHz SCS system with the distal tip of leads positioned at the C2 vertebral level. Safety and effectiveness outcomes were captured up to 52 weeks.

**Results:** Summary of baseline data is presented in Table 1.

**Table 1: Baseline data (N=20; mean±SD)**

Baseline data	
Age	42.9±10.5 years
Females/Males	17/3
Chronic migraine diagnosis	10.1±9.8 years
Number of failed botulinum toxin tx	3.4±1.8
Headache days/Migraine days	24.0±5.1/22.5±6.5
Migraine-specific quality of life (MSQ)	33.4±16.4
Migraine disability assessment (MIDAS)	128.7±70.7

There was an average reduction of 3.6±2.1 and of 5.4±2.4 headache days/month at 12 weeks and 52 weeks respectively. Having 30% of subjects shown >30% reduction in headache days at 12 weeks and 50% at 52 weeks. Whereas the average reduction of migraine days was 6.7±2.4 and 9.3±2.5 at 12 and 52 weeks respectively. With 45% of subjects achieving a >30% reduction in migraine days at 12 weeks and 60% at 52 weeks. At 52 weeks, 50% of the subjects had converted from a CM pattern to an episodic migraine pattern. The average migraine-specific quality of life (MSQ) score improved 16.2 points at 24-weeks (49.6±23.2) and 24.8 points at 52-weeks (58.2±21.9). The average Migraine Disability Assessment Score (MIDAS) improved 47.1 points at 24-weeks (81.6±72.9) and 66 points at 52-weeks (62.7±63.8). At 52 weeks, 70% of the subjects were 'much satisfied' or 'very much satisfied' with the therapy and 55% reported 'much improved' or 'very much improved'. Study-related adverse events included 5 subjects with implantable pulse generator site pain.

**Discussion:** Not applicable.

**Conclusions:** The analysis supports the previous prospective study results suggesting that 10 kHz SCS may offer a potentially safe and effective therapeutic option for medically refractory CM, showing similar efficacy results to occipital nerve stimulation [4] and presenting a potentially safer profile.

**References:** 1 -Lipton R. Chronic migraine, classification, differential diagnosis, and epidemiology. *Headache*. 2011;Jul-Aug(51(2)):77-83. 2 -Kapural L, et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg PainThe SENZA-RCT Randomized Controlled Trial. *Anesthesiology*. 2015;123(4):851-860. 3 -Arcioni R, et al. Cervical 10 kHz spinal cord stimulation in the management of chronic, medically refractory migraine: A prospective, open-label, exploratory study. *Eur J Pain*. 2016 70-78. 4 -Silberstein S, et al. The safety and efficacy of occipital nerve stimulation for the management of chronic migraine. *Cephalalgia*. 2011 117.

**Keywords:** SCS, Refractory chronic migraine, 10kHz SCS

**Topic:** 12. *Neuro-regeneration*

**DEEP BRAIN STIMULATION OF THE CEREBELLAR DENTATE NUCLEUS TO ENHANCE CHRONIC, POST-STROKE MOTOR REHABILITATION: PRELIMINARY OUTCOMES AND ELECTROPHYSIOLOGICAL CORRELATES OF THERAPEUTIC PARAMETER SELECTION**

**E-POSTER VIEWING ORALS**

Kenneth Baker<sup>1</sup>, Raghavan Goplalakrishnan<sup>2</sup>, Andre Machado<sup>2</sup>

<sup>1</sup>Neurosciences, Cleveland Clinic, Cleveland, United States of America, <sup>2</sup>Neurological Institute, Cleveland Clinic, Cleveland, United States of America

**Introduction:** Cerebellar pathways are increasingly being targeted using both non-invasive and invasive neurostimulation-based approaches for the treatment of neurologic disease. Our on-going clinical trial is investigating deep brain stimulation (DBS) of the cerebello-thalamo-cortical (CTC) pathway as an approach to enhance post-injury rehabilitation by means of perilesional facilitation and promotion of cerebral cortical plasticity. In addition to the safety and efficacy of that work to date, we will present electrophysiological features of the cerebellar dentate nucleus (DN) in relation to motor behavior as well as the scalp EEG correlates of DN DBS that hold promise for guiding therapeutic programming for this novel treatment approach.

**Methods/Materials:** Patients with chronic (>1yr) post-MCA-stroke, moderate-to-severe upper extremity motor deficits underwent implantation of an 8-channel DBS lead targeting the contralesional DN. The Fugl-Meyer Assessment for upper extremity (FMA-UE) was recorded monthly over the 14–18-month trial, within which participants received up to eight months of DN DBS. Electrophysiological data were recorded at specific trial stages, including combined local field potential (LFP), scalp EEG, and electromyography (EMG) recordings made during 1) intra-operative lead placement, 2) peri-operative DBS lead externalization, and 3) DBS programming. During the latter two session types, electrophysiological data were recorded 1) at rest, 2) in relation to motor task performance, and 3) in response to low-frequency activation of the CTC pathway.

**Results:** Twelve patients have undergone device implantation. Of those, 10 have completed the treatment phase, with 7 achieving a >4.5-point improvement in FMA-UE scores (i.e., therapeutic responder). Moreover, five of seven participants with minimally-preserved hand function at study entry showed a mean FMA-UE improvement of 10.5 points. DN LFPs have revealed DBS contact-specific changes in alpha- and beta-band power during visuomotor task performance with the affected upper extremity. DBS-evoked activation of the CTC pathway, observed by time-lock averaging the EEG/EMG recordings to stimulus delivery, elicited multi-phasic responses maximal over contralateral frontal cortex, including peaks discernible as early as 8ms post-stimulation.

**Discussion:** Our preliminary, open-label results support DN DBS as a promising emerging therapy for patients with post-stroke hemiparesis, while electrophysiology-based metrics show promise for guiding lead placement and therapeutic stimulation parameters.

**Conclusions:** Novel, neuromodulation-based treatment approaches continue to hold potential to mitigate persistent post-injury deficits associated with acquired brain injuries. Our electrophysiology data support the potential development of novel biomarkers that may facilitate DBS programming in applications where acute, readily-appreciable behavioral changes are not seen.

**References:**

**Keywords:** Cerebellum, Dentate Nucleus, Acquired Brain Injury, Electrophysiology, stroke, Deep Brain Stimulation

**Topic:** 13. Late-Breaking Research

**12 MONTH OUTCOMES FROM THE EVOKED COMPOUND ACTION POTENTIAL (ECAP)-CONTROLLED CLOSED-LOOP SCS: DOUBLE-BLIND, RANDOMIZED TRIAL FOR THE TREATMENT OF CHRONIC PAIN**

**E-POSTER VIEWING ORALS**

Timothy Deer<sup>1</sup>, Nagy Mekhail<sup>2</sup>, Robert Levy<sup>3</sup>, Leonardo Kapural<sup>4</sup>, Sean Li<sup>5</sup>, Kasra Amirdelfan<sup>6</sup>, Corey Hunter<sup>7</sup>, Steven Rosen<sup>8</sup>, Shrif Costandi<sup>9</sup>, Steven Falowski<sup>10</sup>, Abram Burgher<sup>11</sup>, Jason Pope<sup>12</sup>, Christopher Gilmore<sup>13</sup>, Farooq Qureshi<sup>14</sup>, Peter Staats<sup>5</sup>, James Scowcroft<sup>15</sup>, Jonathan Carlson<sup>16</sup>, Christopher Kim<sup>17</sup>, Michael Yang<sup>18</sup>, Thomas Stauss<sup>19</sup>, Lawrence Poree<sup>20</sup>

<sup>1</sup>Pain Services, Spine & Nerve Center of the Virginias, Charleston, United States of America, <sup>2</sup>Anesthesiology, Cleveland Clinic, Cleveland, OH, United States of America, <sup>3</sup>Director Of Neurosurgical Services, Anesthesia Pain Care Consultants, Tamarac, United States of America, <sup>4</sup>Pain Management, Carolinas Pain Institute and Wake Forest University School of Medicine, Winston-Salem, NC, United States of America, <sup>5</sup>Pain Management, Premier Pain Centers, Shrewsbury, NJ, United States of America, <sup>6</sup>Pain Medicine, IPM Medical Group, Inc., Walnut Creek, CA, United States of America, <sup>7</sup>Pain Management, Ainsworth Institute of Pain Management, New York, NY, United States of America, <sup>8</sup>Anesthesiology, Delaware Valley Pain & Spine Institute, Trevese, PA, United States of America, <sup>9</sup>Pain Management, Cleveland Clinic, Cleveland, OH, United States of America, <sup>10</sup>Neurological Surgery, Functional Neurosurgery, Neurosurgical Associates of Lancaster, Lancaster, PA, United States of America, <sup>11</sup>Pain Medicine, HOPE Research - TPC, Phoenix, AZ, United States of America, <sup>12</sup>Pain Medicine, Evolve Restorative Center, Santa Rosa, CA, United States of America, <sup>13</sup>Anesthesiology, Center for Clinical Research, Winston-Salem, NC, United States of America, <sup>14</sup>Pain Management, St Luke's Spine & Pain Associates, Easton, PA, United States of America, <sup>15</sup>Pain Management, Pain Management Associates, Independence, MO, United States of America, <sup>16</sup>Pain Management, Arizona Pain, Glendale, AZ, United States of America, <sup>17</sup>Anesthesiology, The Center for Pain Relief, Charleston, WV, United States of America, <sup>18</sup>Pain Management, Summit Pain Alliance, Santa Rosa, CA, United States of America, <sup>19</sup>Anesthesiology, Advanced Pain Management, Greenfield, WI, United States of America, <sup>20</sup>Anesthesiology And Pain Medicine, University of California at San Francisco, San Francisco, United States of America

**Introduction:** Evoked compound action potential (ECAP) recording provides an objective measure of spinal cord (SC) activation during spinal cord stimulation (SCS) and can assist in the programming of the SCS system. ECAP-controlled closed-loop SCS (CL), in which the stimulation output is automatically adjusted to maintain a desired ECAP amplitude, has been shown to provide effective pain relief in an open-label study (ACTRN12615000713594) (Russo, 2017). A double-blind randomized controlled trial (RCT) was conducted under an Investigational Device Exemption (IDE) to compare the safety and efficacy of ECAP-controlled CL stimulation (investigational group) and open-loop (fixed output) stimulation (OL, control group) to treat chronic back and leg pain (NCT02924129) (Levy, 2019).

**Methods/Materials:** 134 subjects were enrolled and randomized after trial leads were implanted. The primary endpoint was  $\geq 50\%$  reduction in overall (back and leg) pain measured by the Visual Analog Scale (VAS) with no increase in baseline pain medications. Opioid usage and other patient-reported outcomes (PROs) including emotional/physical functioning, sleep quality, and quality of life were also collected. Additionally, objective neurophysiological data, including SC activation and time spent in the therapeutic range, were collected.

**Results:** Herein the Evoke Study Group reports the 12-month outcomes from this ongoing RCT being conducted. The primary endpoint demonstrated statistical superiority of CL compared to OL at 12 months (83% vs. 61% subjects, respectively;  $p=0.006$ ). 56% of CL subjects compared to 37% of OL subjects reported  $\geq 80\%$  reduction in back and leg pain ( $p=0.039$ ).

**Discussion:** CL provided greater improvement in all other PROs including POMS, ODI, PSQI, EQ-5D-5L, and SF-12, compared to OL. Additionally, opioids were reduced or eliminated in 55% and 40% of CL and OL subjects, respectively. The most frequent level of SC activation level was six times greater for CL (median ECAP Amplitude: 27.0 $\mu$ V CL vs. 4.5 $\mu$ V OL). Furthermore, SC activation was better maintained within the therapeutic range with CL (median: 95% CL vs. 48% OL). There were no differences in the safety profiles between treatment groups, and the type, nature, and severity of adverse events were similar to other SCS studies.

**Conclusions:** In this ongoing study, ECAP-controlled CL SCS provided statistically superior pain relief and greater improvement in other PROs compared with OL SCS at 12 months. CL delivered greater levels of SC activation and better maintained SC activation in the subject's therapeutic range. This suggests that the level and consistency of SC activation may be mechanistically important for outcomes with SCS.

**References:** Mekhail N, Levy RM, Deer TR et al. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomized, controlled trial. *Lancet Neurol* 2019; published online Dec 20. [https://doi.org/10.1016/S1474-4422\(19\)30414-4](https://doi.org/10.1016/S1474-4422(19)30414-4). Russo, Marc, Michael J. Cousins, Charles Brooker, Nathan Taylor, Tillman Boesel, Richard Sullivan, Lawrence Poree, Nastaran Hesam Shariati, Erin Hanson, and John Parker. "Effective Relief of Pain and Associated Symptoms With Closed-Loop Spinal Cord Stimulation System: Preliminary Results of the Avalon Study: CLOSED-LOOP FEEDBACK CONTROL SCS FOR PAIN RELIEF." *Neuromodulation: Technology at the Neural Interface*, September 18, 2017. <https://doi.org/10.1111/ner.12684>.

**Keywords:** ECAP Controlled Closed Loop Spinal Cord Stimulation, ECAP, Spinal cord stimulation, Evoked Compound Action Potentials, Closed Loop, SCS



**Topic:** 13. Late-Breaking Research

**UNILATERAL L4-DORSAL ROOT GANGLION STIMULATION EVOKES PAIN RE-LIEF IN CHRONIC NEUROPATHIC POSTSURGICAL KNEE PAIN AND CHANGES OF INFLAMMATORY AND SENSORY MARKERS: PRELIMINARY RESULTS**

**E-POSTER VIEWING ORALS**

Melanie Hamperl<sup>1</sup>, Michael Buchfelder<sup>1</sup>, Thomas Yearwood<sup>2</sup>, Thomas Kinfe<sup>3</sup>

<sup>1</sup>Neurosurgery, Friedrich-Alexander University (FAU) Erlangen-Nürnberg, Erlangen, Germany, <sup>2</sup>Pain Medicine, Guy's and St Thomas's Hospital, London, UK, London, United Kingdom, <sup>3</sup>Neurosurgery, Division Of Functional Neurosurgery And Stereotaxy, Friedrich-Alexander University (FAU), Erlangen, Germany

**Introduction:** Complex regional pain syndrome (CRPS) has been associated with a pro-inflammatory state driven by different circulating mediators. Dorsal root ganglion stimulation (DRG<sub>STIM</sub>) suppressed pain levels and improved functional capacity in intractable CRPS in observational and randomized-controlled studies. However, in-human studies evaluating the impact of selective DRG stimulation on the neuro-immune axis in CRPS patients remains under-investigated.

**Methods/Materials:** This pilot study performed molecular inflammatory phenotyping (saliva/serum), gene expression assay of neuroinflammatory genes (Panther™ pathway enrichment analysis), quantitative sensory profiling and score-based assessment of pain, mood and sleep in 24 subjects (12 CRPS patients - 12 healthy controls) before and after 3 months of selective L4-DRG<sub>STIM</sub>.

**Results:** After L4-DRG<sub>STIM</sub> CRPS pain significantly decreased with improved sleep and mood. Elevated levels were found pre- and post L4-DRG<sub>STIM</sub> for high-mobility group box 1, tumor-necrosis factor  $\alpha$ , IL-6 and leptin indicating a pro-inflammatory state in CRPS patients. IL-1 $\beta$  was elevated pre-L4 DRG<sub>STIM</sub>, but not post-treatment. IL-10 decreased after 3 months in serum, while saliva oxytocin increased after L4-DRG<sub>STIM</sub> (Fig.1). Gene expression analysis demonstrated down-regulated TLR1, FFAR2, IL1RAP, ILRN, C5, PKB and IL18 and upregulated CXCL2, CCL11, IL36G, CRP, SCGB1A1, IL-17F, TNFRSF4, PLA2G2A, CREB3L3, ADAMTS12, IL1F10, NOX1, CHIA and BDKRB1 (Fig.2). CRPS subjects showed significantly increased thresholds for warmth, tactile and vibration detection (WDT, MDT and VDT) and exaggerated pain summation (WUR). After 3 months of unilateral L4-DRG<sub>STIM</sub> all pain parameters exhibited trends towards normalization of sensitivity accumulating to a significant overall normalization for pain sensitivity (effect size: 0.91,  $p < 0.01$ ). Reduction of pain summation (WUR) correlated significantly with pain reduction after 3 months of L4-DRG<sub>STIM</sub> (Fig.3). Figure 1. Interleukin-1 $\beta$ , interleukin 6, interleukin 10, TNF- $\alpha$ , high-mobility group box 1 protein (HMGB1), Leptin, adiponectin and ghrelin serum analysis and saliva concentrations of oxytocin at baseline, after 1 week L4-DRG<sub>STIM</sub> trial and after 3 months.

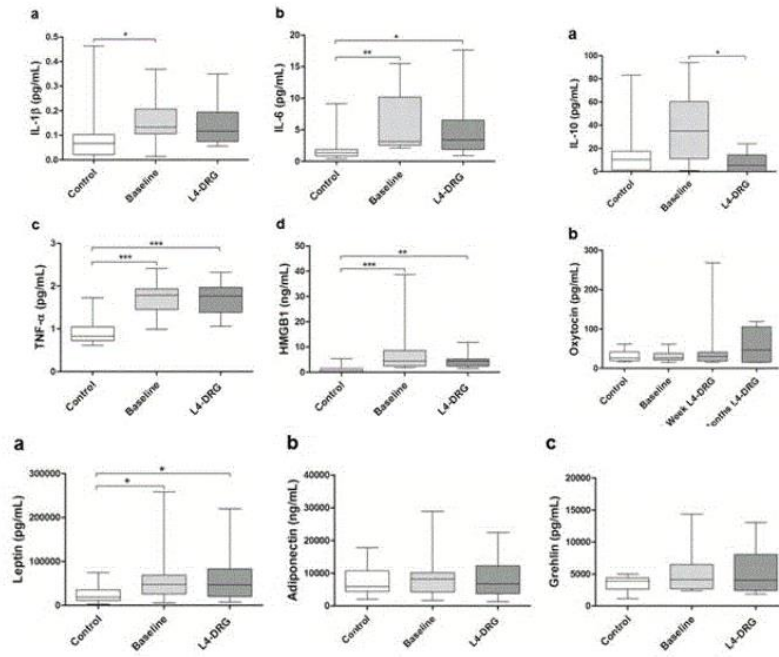


Figure 2 Baseline and post L4-DRG stimulation changes of gene expression demonstrating significant upregulation (green) for CXCL2 - CCL11 - IL36G – CRP – SCGB1A1 – IL-17F – TNFRSF4 - PLA2G2A - CREB3L3 - ADAMTS12 - IL1F10 - NOX1 - CHIA - BDKRB1 and downregulation (red) TLR1 – FFAR2 – IL1RAP – IL1RN – C5 – PKB – IL18. P value <0.05 was considered significant.

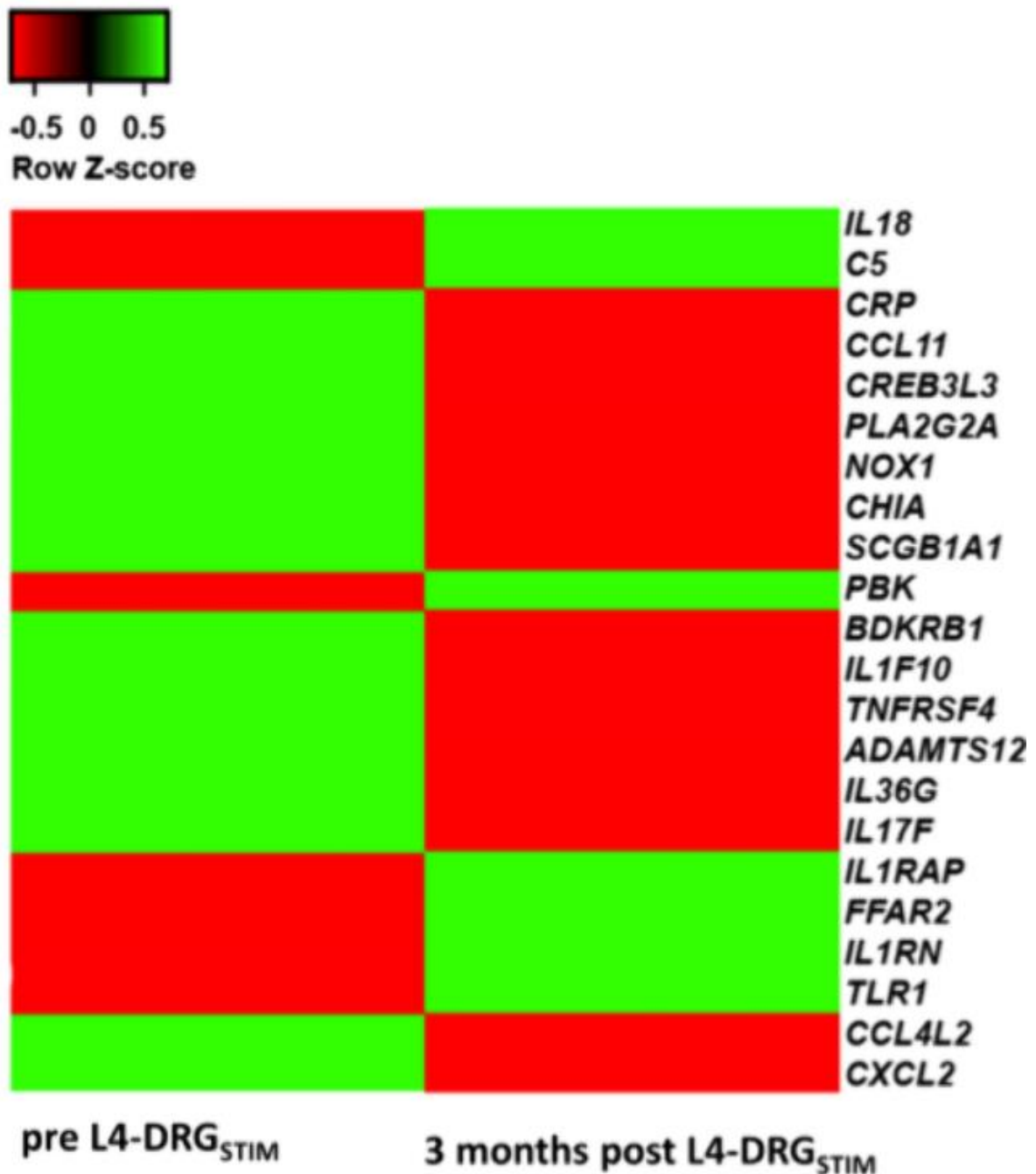
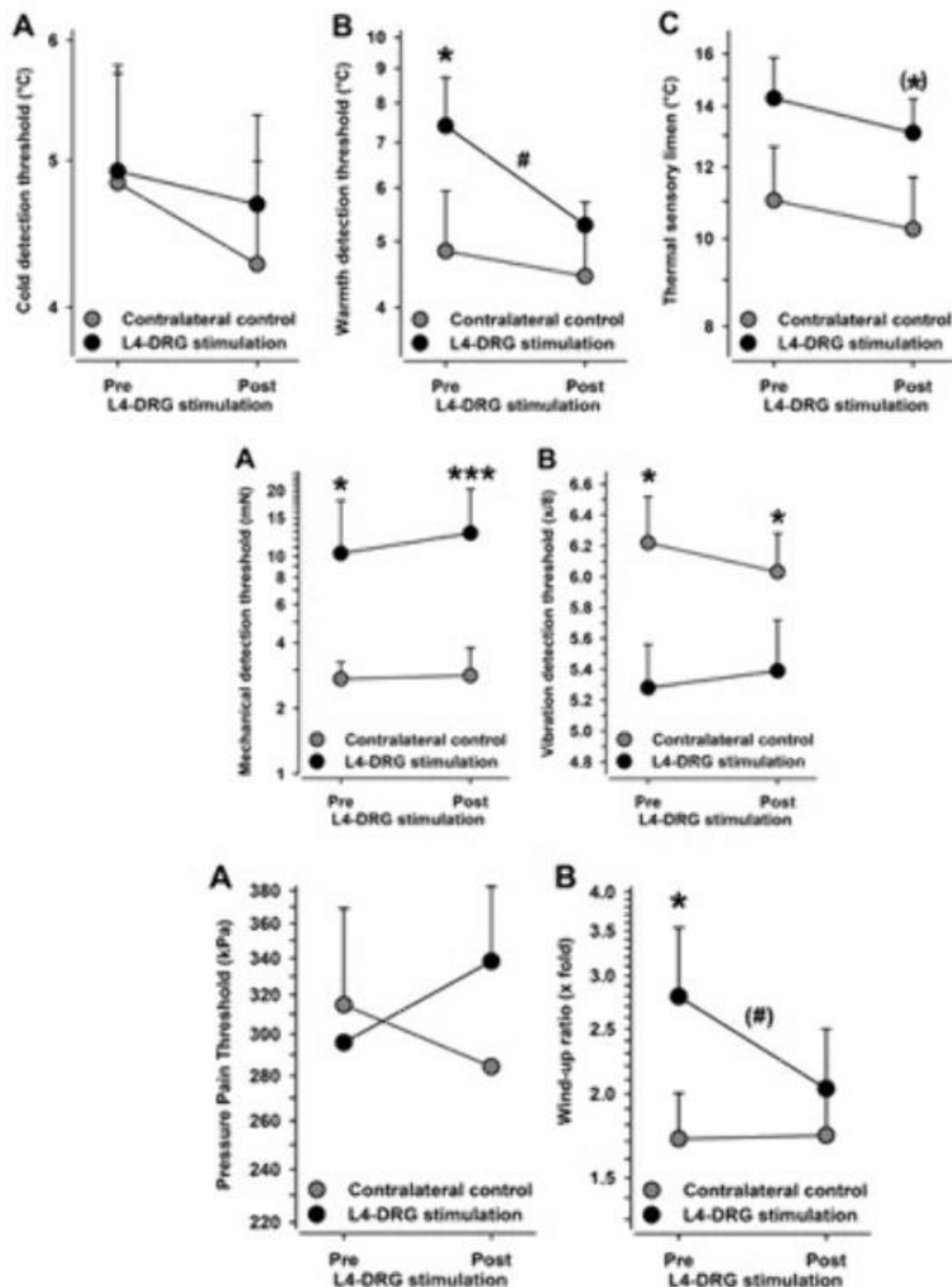


Figure 3  
 Aggregated somatosensory parameters (somatosensory principal components) in the CRPS-affected knee before ("Pre") and after L4-DRG stimulation ("Post") normalized to QST from the contralateral control knee. Sensitivity normalized for all pain components, but not for thermal and mechanical detection. Pressure pain/pain summation (PPT/WUR), thermal pain (CPT/HPT), punctate mechanical pain (MPT/MPS), thermal detection (CDT/WDT/TSL) and mechanical detection (MDT/VDT). Open circles - Non-nociceptive components ("detection"); Black circles - Nociceptive components ("pain")  
 \*  $p < 0.05$  pre vs. post L4-DRG stimulation.



**Discussion:** Although of preliminary character, L4-DRG<sub>STIM</sub> evoked pain relief and improved functional impairment in CRPS patients revealing a pro-inflammatory molecular pattern associated with an impaired sensory profile. Serum IL-10 significantly declined, while saliva oxytocin increased after L4-DRG<sub>STIM</sub>. Sub-group analysis demonstrated either upregulated or downregulated genes involved in immune host response and neural pain circuits.

**Conclusions:** Large biobank-based approaches are recommended to re-evaluate genetic phenotyping as a quantitative outcome measure for neurostimulation therapy in CRPS patients. The concept of a personalized and predictive neurostimulation therapy based on a comprehensive, preimplant mapping represents the next pivotal step in clinical neuromodulation research for pain.

**References:**

**Keywords:** complex-regional pain syndrome, dorsal root ganglion stimulation DRG, gene expression analysis, oxytocin, cytokines, neuroinflammation

**Topic:** 13. Late-Breaking Research

**DESIGN OF A RANDOMIZED ACTIVE SHAM-CONTROLLED RESTORATIVE NEUROSTIMULATION TRIAL - LEARNINGS FROM THE REACTIV8-B PIVOTAL TRIAL?**

**E-POSTER VIEWING ORALS**

Sam Eldabe

Pain Medicine, James Cook Hospital, Middlesbrough, United Kingdom

**Introduction:** Clinical trial designs in support of premarket approvals are an inherent compromise between regulatory requirements and practical, robustness and efficiency considerations. ReActiv8-B is an international, multicenter, randomized, parallel arm, active sham-controlled, double-blinded trial with a single-arm cross-over under Investigational Device Exemption, to demonstrate safety and efficacy of a novel restorative neurostimulator aimed at restoring neuromuscular control of the lumbar multifidus muscles in patients with refractory Chronic Low Back Pain (CLBP). We present protocol design features relevant to the interpretation of the detailed trial results which were submitted separately. (clinicaltrials.gov: NCT02577354)

**Methods/Materials:** We recruited 204 patients with CLBP who after implantation were randomly assigned to receive therapeutic or subthreshold stimulation (sham-control) for 30 minutes, twice daily. The primary endpoint compared responder rates at 120 days, with a 'Responder' having  $\geq 30\%$  average VAS reduction without any increase in pain medication. Secondary outcome measures included ODI, EQ-5D, Percent Pain Relief (PPR), Subject Global Impression of Change (SGIC) and Proportion of Remitters ( $VAS \leq 2.5\text{cm}$ ). Specific measures to maintain equipoise and blinding of patients, clinicians and assessors included: scripted dialogues; equal visit schedules, treatment instructions and follow-up duration; questionnaire completion before subject interactions; simulated programming; all blinded visits were attended by independent site staff to ensure dialogue neutrality. Blinding effectiveness was assessed at 120 days by direct questioning after which patients in the sham control group crossed over to therapeutic stimulation.

**Results:** Statistical Analysis The primary endpoint was tested using a two-sided binomial test for a difference in proportions using multiple imputations. Because dichotomization around a single 30% cut-off inherently leads to a loss of information and statistical power a cumulative rate of responder analysis on the same data was prespecified. Since acute pain conditions unrelated to low back pain and consequent increased analgesics consumption could confound the ITT analysis, a modified-ITT analysis was also prespecified. Secondary endpoints were tested using a completers analysis.

**Discussion:** We describe the design of the first randomized, active sham-controlled trial of a neurostimulation system for the treatment of CLBP. Treatment effects were known to accrue over time, but the sham response was unknown. Endpoint timing was set to 120 days for ethical and practical considerations. The prospective anticipation of confounding factors and the rigorous trial design, strict blinding and equipoise control measures provide a unique trial design among neuromodulation studies.

**Conclusions:** The ReActiv8-B trial design followed rigorous quality standards with many unique features.

**References:**

**Keyword:** neurostimulation, low back pain, restorative therapy, multifidus stimulation.

Topic: 01. Basic Science

## NEUROPHYSIOLOGY OF THE HUMAN SPINAL CORD IN PATIENTS WITH CHRONIC NEUROPATHIC PAIN DURING SPINAL CORD STIMULATION (SCS)

### E-POSTER VIEWING

Stefano Palmisani<sup>1</sup>, Gerrit Gmel<sup>2</sup>, Rosana Santos-Escapa<sup>3</sup>, Dave Mugan<sup>3</sup>, Adnan Al-Kaisy<sup>1</sup>, John Parker<sup>2</sup>

<sup>1</sup>Chronic Pain Management And Neuromodulation Centre, Guy's & St Thomas' NHS Trust, London, United Kingdom, <sup>2</sup>-, Saluda Medical Pty Ltd, Sydney, Australia, <sup>3</sup>-, Saluda Medical Europe Limited, Harrogate, United Kingdom

**Introduction:** The neurophysiological effects of spinal cord stimulation (SCS) in humans are still not fully characterized and understood. Here is presented preliminary findings on neurophysiology of SCS utilizing recording of evoked compound action potentials (ECAPs) in a cohort of chronic neuropathic pain patients.

**Methods/Materials:** Recruited patients (20) exhibited chronic neuropathic lower back and/or lower limb pain and underwent a trial of SCS with two leads, implanted according to standard practice. Neurophysiological recording occurred at two routine follow-up visits during trial period using a custom external stimulator capable of real-time recording of ECAPs from all non-stimulating contacts [1]. Stimulation was performed at various vertebral levels (ranging from T6 to T12) using a range of amplitudes and frequencies. Patients were asked to rate stimulation-induced sensation (paresthesia) throughout the experiments.

**Results:** Stimulus amplitude response curves led to the well-known linear relationship between ECAP amplitude and paresthesia sensation at constant frequency (30Hz). Surprisingly, frequency response curves showed an inverse relationship between perceived sensation and ECAP amplitude, with higher frequencies generating smaller ECAPs but stronger paresthesia for constant stimulation amplitude. Stimulation at the bottom of the array elicited one of 2 types of responses orthodromically. A single 3-lobe ECAP was elicited in 35.7% of patients. A linear fit applied to the normalized latencies of the recorded ECAPs resulted in a conduction velocity (CV) of 47 m/s, with a coefficient of determination ( $R^2$ ) of 0.94. Unexpectedly, in 64.3% of patients we recorded 2 separate ECAPs with distinct CVs (61 m/s,  $R^2 = 0.85$  and 85 m/s,  $R^2 = 0.83$ ), elicited within about 1ms of each other, and happening to occur more frequently at lower vertebral levels.

**Discussion:** Data from our recordings support the hypothesis that stimulation-induced paresthesia is conveyed through both frequency and population coding, fitting known psychophysics of tactile sensory information processing [2], [3]. However, the inverse relationship between ECAP amplitude and sensation at increasing frequencies challenges the common assumption of a direct relationship between neural activation and perceived sensation.

**Conclusions:** We postulate that differences in ECAP morphology and CV obtained at different vertebral levels are attributable to the activation of post-synaptic dorsal column (PSDC) fibers [4]. The PSDC pathway has been widely ignored by the field of pain management and its link to sensation and pain relief needs to be further explored.

**References:** [1] J. L. Parker, D. M. Karantonis, P. S. Single, M. Obradovic, and M. J. Cousins, "Compound action potentials recorded in the human spinal cord during neurostimulation for pain relief," *Pain*, vol. 153, no. 3, pp. 593–601, Mar. 2012, doi: 10.1016/j.pain.2011.11.023. [2] M. A. Muniak, S. Ray, S. S. Hsiao, J. F. Dammann, and S. J. Bensmaia, "The Neural Coding of Stimulus Intensity: Linking the Population Response of Mechanoreceptive Afferents with Psychophysical Behavior," *J. Neurosci.*, vol. 27, no. 43, pp. 11687–11699, Oct. 2007, doi: 10.1523/JNEUROSCI.1486-07.2007. [3] E. L. Graczyk, M. A. Schiefer, H. P. Saal, B. P. Delhaye, S. J. Bensmaia, and D. J. Tyler, "The neural basis of perceived intensity in natural and artificial touch,"

Sci. Transl. Med., vol. 8, no. 362, p. 362ra142, Oct. 2016, doi: 10.1126/scitranslmed.aaf5187. [4] V. E. Abraira et al., "The Cellular and Synaptic Architecture of the Mechanosensory Dorsal Horn," Cell, vol. 168, no. 1, pp. 295-310.e19, Jan. 2017, doi: 10.1016/j.cell.2016.12.010.

**Keywords:** Neurophysiology, Spinal cord stimulation, Pain, Evoked Compound Action Potential, SCS, ECAP



**Topic:** 01. Basic Science

## **EVOKED COMPOUND ACTION POTENTIALS (ECAPS): HELPING TO UNDERSTAND SPINAL CORD STIMULATION (SCS)**

### **E-POSTER VIEWING**

Stefano Palmisani<sup>1</sup>, Rosana Santos-Escapa<sup>2</sup>, Lucy Brister<sup>2</sup>, Milan Obradovic<sup>3</sup>, Robert Gorman<sup>3</sup>, Nastaran Shariati<sup>3</sup>, Peter Single<sup>3</sup>, James Wah<sup>3</sup>, Adnan Al-Kaisy<sup>1</sup>, John Parker<sup>3</sup>

<sup>1</sup>Chronic Pain Management And Neuromodulation Centre, Guy's & St Thomas' NHS Trust, London, United Kingdom, <sup>2</sup>-, Saluda Medical Europe Limited, Harrogate, United Kingdom, <sup>3</sup>-, Saluda Medical Pty Ltd, Sydney, Australia

**Introduction:** The mechanism of action (MoA) of Spinal Cord Stimulation (SCS) is still not well understood. Recording Evoked Compound Action Potentials (ECAPs) and ([1], [2]) on-going clinical studies employing ECAP-controlled closed-loop SCS (CL-SCS) have shown a potential application of ECAP recording that attempts to improve outcomes ([3], [4], [5]). ECAP recording has many potential applications, being an objective measure of spinal cord (SC) activation, that can provide insights into the effect of SCS and further understanding of the MoA.

**Methods/Materials:** Literature relating to ECAP recording in humans and sheep ([1], [6]) is summarized to highlight the different ways in which ECAP recording may be used to facilitate improvement and understanding of SCS.

**Results:** Estimation of chronaxie and rheobase, using ECAP activation threshold, allows for a more objective approach (instead of relying on subjective patient perception), which may be a way to track changes in neural sensitivity over time for a group of fibers. Conduction velocity (CV) of the ECAP signal confirms that A $\beta$  fibers are activated in the dorsal columns ([1], [6]). Recently published work shows conduction velocity changes as ECAPs propagate between vertebral segments [2]. ECAP amplitude is dependent on the proximity of the lead to the SC, and can vary with movement, stimulus amplitude, stimulus frequency, and the distance of the recording location to the stimulus ([7], [8], [9]). ECAP amplitude can be used to define a therapeutic range for a patient (unlike stimulus amplitude, which varies significantly with physiology and posture), and has intra-operative monitoring applications, whereby the ECAP signal and a late response (LR, corresponding to dorsal root activation) can be recorded while stimulating on different lead locations to estimate lead laterality ([10], [11]).

**Discussion:** Tracking ECAP amplitude over time can provide insights into how the device configuration interacts with both patient activity and physiology, as well as medication [12], and may be useful in improving therapy, which is currently being tested in two on-going studies using ECAP recording and closed-loop SCS.

**Conclusions:** ECAP recording has many applications, one of which is ECAP-controlled CL-SCS. However, ECAP recording provides many insights into the effects of SCS: the types of fibers stimulated, monitoring potential changes in neural sensitivity and conduction, providing an objective measure of neural activation, enabling objective lead placement, programming, and monitoring of SCS over time; these have already helped improve understanding and outcomes.

**References:** 1]J. L. Parker, D. M. Karantonis, P. S. Single, M. Obradovic, and M. J. Cousins, "Compound action potentials recorded in the human spinal cord during neurostimulation for pain relief," *Pain*, vol. 153, no. 3, pp. 593–601, Mar. 2012. [2]J. L. Parker et al., "Evoked Compound Action Potentials Reveal Spinal Cord Dorsal Column Neuroanatomy," *Neuromodulation: Technology at the Neural Interface*, Jun. 2019. [3]R. Levy et al., "Multicenter, Randomized, Double-Blind Study Protocol Using Human Spinal Cord Recording Comparing Safety, Efficacy, and Neurophysiological Responses Between Patients Being Treated With Evoked Compound Action Potential–Controlled Closed-Loop Spinal Cord Stimulation or Open-Loop Spinal Cord Stimulation (the Evoke Study)," *Neuromodulation:*

Technology at the Neural Interface, vol. 22, no. 3, pp. 317–326, Apr. 2019. [4]L. Poree, “Closed-Loop Spinal Cord Stimulation: Evoke Study Results,” presented at the INS 2019, Sydney, Australia, 2019. [5]C. Brooker, “LONG-TERM RESULTS FROM THE AVALON STUDY – FEEDBACK-CONTROLLED SCS USING EVOKED COMPOUND ACTION POTENTIALS,” presented at the INS 2019, Sydney, Australia, 2019. [6]J. L. Parker et al., “Electrically evoked compound action potentials recorded from the sheep spinal cord,” *Neuromodulation*, vol. 16, no. 4, pp. 295–303; discussion 303, Aug. 2013. [7]J. L. Parker et al., “Neural Feedback Neuromodulation [PH 446],” in 14th World Congress on Pain, IASP, Milan, Italy, 2012. [8]R. B. Gorman et al., “Stimulation Frequency and Recruitment of Dorsal Column A $\beta$  Fibers During SCS,” in 16th Annual Meeting, North American Neuromodulation Society, Las Vegas, NV, 2012. [9]M. Obradovic, T. Cameron, R. B. Gorman, N. H. Shariati, and A. D. Sharan, “Evoked Compound Action Potentials Recorded from Paddle Leads During Intraoperative Testing,” in Neuromodulation Society of Australia and New Zealand, Hobart, Australia, 2014. [10]M. Obradovic et al., “Intraoperative Recording of Evoked Compound Action Potentials as a Tool to Aid Paddle Placement for Spinal Cord Stimulation,” in 18th Annual Meeting, North American Neuromodulation Society, Las Vegas, NV, 2014. [11]S. Falowski, “EVOKED COMPOUND ACTION POTENTIALS TO GUIDE LEAD PLACEMENT: A NEUROMONITORING TECHNIQUE—CASE SERIES,” presented at the INS 2019, Sydney, Australia, 2019. [12]S. M. Rosen, “EVOKED COMPOUND ACTION POTENTIAL RECORDING TO FURTHER UNDERSTAND EFFECT OF TITRATING MEDICATION WITH SPINAL CORD STIMULATION,” presented at the INS 2019, Sydney, Australia, 2019.

**Keywords:** ECAP, Spinal cord stimulation, Pain, Evoked Compound Action Potential, SCS

## INJECTION EFFECT OF BOTULINUM TOXIN A ON HALLUX VALGUS DEFORMITY AND PAIN

### E-POSTER VIEWING

Alireza Moghtaderi Esfahani<sup>1</sup>, Negin Khakpour<sup>2</sup>

<sup>1</sup>Clinic Dr Moghtaderi, dr, esfahan, Iran, <sup>2</sup>Clinic Dr Moghtaderi, dr, Esfahan, Iran

**Introduction:** Hallux Valgus is a kind of Toes aberration where the Metatarsophalangeal joint that connects the big toe to the foot, leading to the inner side and a protrusion on the inner surface of toe arise. This study aimed to determine the effect of botulinum toxin A injection to reduce pain and deviation angle of the thumb in Hallux Valgus and to increase outcomes of treatment as an adjuvant therapy

**Methods/Materials:** Randomized clinical study was performed on 18 patients at the Clinic of Physical Medicine and Rehabilitation, Isfahan University of Medical Sciences. In this study the Halgvs valgus angle (HVA) between the metatarsals (IMA) and cartilage distal metatarsal angle (DMAA) and pain was assessed before and after injection.

**Results:** Average of Hallux Valgus angle before and after Botox injections were  $28/89 \pm 10/21$  and  $21/56 \pm 8/22$  degrees and the angle deviation in the 6 months after treatment was significantly improved ( $p < 0.001$ ).

**Discussion:** Injection of botulinum toxin A is a suitable and acceptable method to reform the skeleton deformities and also to reduce the pain in patients with Hallux valgus.

**Conclusions:** Hallux valgus is one of the most common diseases worldwide [15]. The prevalence of it is not clear. In a report, the prevalence of the disease in young adults was 1/6 of the total population and the disease in female is 4 to 9 times more frequent than male. Difference has led to considering no treatment for this disease. In this study, a new method for treatment is represented. Treatment with surgery, in addition to the high cost is also accompanied with some problems such as the duration of treatment and the risks involved as well. Of the advantages the method presented here is its low cost and the fact that it is an outpatient surgery. Hence surgery can be considered as a conservative treatment [16]. Botox type A has good prospects in the future in physical therapy to reduce chronic muscle pain and help restore normal muscle length and biomechanical balance. This study aimed to determine the effect of botulinum toxin A injection to reduce pain and deviation angle of the thumb and to increase outcomes of treatment as an adjuvant therapy [17]. The present study revealed that the Hallux Valgus angle before and after Botox injections were  $28/89 \pm 10/21$  and  $21/56 \pm 8/22$  degrees and the angle deviation in the 6 months after treatment was significantly improved ( $p < 0.001$ ).

**References:** [1] Fraissler L, Konrads C, Hoberg M, Rudert M, Walcher M .Treatment of hallux valgus deformity. EFORT Open Rev 2016;1 :295–302. [2] JAHSS, MELVIN H. M.D. The Sesamoids of the Hallux. Clinical Orthopaedics & Related Research 1981 ;157: 88-97. [3] Nakhaee Z, Rahimi A, Abaee M, Rezasoltani A, Khademi Kalantari K. The relationship between the height of the medial longitudinal arch (MLA) and the ankle and knee injuries in professional runner. Foot (Edinb) 2008; 18: 84-90. [4] Perera AM, Mason L, Stephens MM . The pathogenesis of hallux valgus. J Bone Joint Surg Am 2011;93: 1650-61. [5] Miller JW .Distal first metatarsal displacement osteotomy: its place in the schema of bunion surgery. J Bone Joint Surg Am 1974; 56 :923-31 [6] Menz HB, Munteanu SE, Landorf KB, Zammit GV, Cicuttini FM . Radiographic classification of osteoarthritis in commonly affected joints of the foot. Osteoarthritis Cartilage 2007;15 : 1333-8 [7] Easley ME, Trnka HJ .Current concepts review: hallux valgus part 1: pathomechanics, clinical assessment, and nonoperative management. Foot Ankle Int 2007;28 :654-9 [8] Sanhudo JV, Gomes JE, Rabello MC, Delucca G . Interobserver and intraobserver reproducibility of hallux valgus angular measurements and the study of a linear measurement. Foot Ankle Spec 2012; 5 :374-7 [9] Perez-Alvarez, Robertoa; Pérez-de-Lis,

Martaa; Ramos-Casals, Manuelb Biologics-induced autoimmune diseases. On behalf of the BIOGEAS study group *Current Opinion in Rheumatology*. *Curr Opin Rheumatol* 2013; 25 : 56–64 [10] Davidson A, Diamond B . Autoimmune Diseases. *Engl J Med* 2001;345 : 340-50 [11] Radovic PA, Shah E . Nonsurgical treatment for hallux abducto valgus with botulinum toxin A. *J Am Podiatr Med Assoc* 2008; 98 :61-5 [12] Wu KP, Chen CK, Lin SC, Pei YC, Lin RH, Tsai WC, Fuk-Tan Tang S Botulinum Toxin type A injections for patients with painful hallux valgus: a double-blind, randomized controlled study. *Clin Neurol Neurosurg* 2008;98 :61-5 [13] Lee JH, Han SH, Ye JF, Lee BN, An X, Kwon SO. Effective zone of botulinum toxin A injections in hallux claw toe syndrome: an anatomical study. *Muscle Nerve*. *Muscle Nerve* 2012;45 :217-21 [14] Johnson AE, Georgopoulos G, Erickson MA, Eilert R. Treatment of adolescent hallux valgus with the first metatarsal double osteotomy: the denver experience. *J Pediatr Orthop* 2004;24 : 358-62 [15] Vanore jv, christensen jc, Kravitz SR, Schuberth JM, et al..Diagnosis and treatment of first metatarsophalangeal joint disorders. Section 1: Hallux valgus.. *J Foot Ankle Surg* 2003;42 :112-23 [16] Barryj.snow mb chb.fracp.joseph k.c. et al. Treatment of spasticity with botulinum toxin: A double-blind study. *Pediatr Orthop* 2004;24 :358-62 [17] Bhidayasiri R, Truong DD . Expanding use of botulinum toxin. *Neurol Sci* 2005; 235:1-9 [18] Radovic PA, Shah E . Nonsurgical Treatment for Hallux Abducto Valgus with Botulinum Toxin A. *Journal of the American Podiatric Medical Association* (2008;98 :61-5 [19] Sherman AL, Willick SP, CardenasDD.Management of focal dystonia of extensor hallucis longus muscle with botulinum toxin injection: a case report.*Arch Phys Med Rehabil* 1998 ;79 :1303-5 [20] Aoki KR . Evidence for antinociceptive activity for botulinum toxin type A in pain management. *The Journal of Head and Face Pain* 2003;43 :9-15.

**Keywords:** Hallux valgus, botulinum toxin A, Metatarsal bone, Pain, Hallux valgus, botulinum toxin A, Pain

**Topic:** 01. Basic Science

## **EFFECTS OF SPINAL CORD STIMULATION ON HEART RATE VARIABILITY IN PATIENTS WITH FAILED BACK SURGERY SYNDROME**

### **E-POSTER VIEWING**

Lisa Goudman<sup>1</sup>, Raf Brouns<sup>2</sup>, Bengt Linderöth<sup>3</sup>, Maarten Moens<sup>1</sup>

<sup>1</sup>Neurosurgery, UZ Brussel, Jette, Belgium, <sup>2</sup>Neurology, ZorgSaam Hospital, Terneuzen, Netherlands, <sup>3</sup>Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

**Introduction:** Building on the recent finding that chronic pain patients with impaired functioning of the descending nociceptive inhibitory system (DNIS) present lower resting heart rate variability (HRV), this study aims to investigate the impact of spinal cord stimulation (SCS) on HRV in patients with Failed Back Surgery Syndrome (FBSS). More precisely, we hypothesize that SCS influences the DNIS, with increased parasympathetic tone as a consequence, as measurable by HRV analysis.

**Methods/Materials:** Twenty-two patients diagnosed with FBSS and treated with SCS participated in this study. HRV was measured with a 2-lead ECG registration tool during on and off states of SCS. HRV analysis for time, frequency, time-frequency and nonlinear domain parameters was based on a 5-minute recording segment.

**Results:** The mean heart rate and low frequency power were significantly lower when SCS was activated. HRV, absolute and normalized high frequency power significantly increased during SCS compared to without SCS. The ratio of low frequency/high frequency ratios, as parameter for global sympathetic-parasympathetic equilibrium, significantly decreased when SCS was activated.

**Discussion:** When SCS is switched off, patients with FBSS present relatively stronger sympathetic tone and weaker parasympathetic activity. Activation of the SCS, possibly via stimulation of the DNIS, restores this disbalance of autonomic activity.

**Conclusions:** Relying on the assumption that HRV measurements provide information on the sympathetic and parasympathetic system, patients with FBSS present a dominant sympathetic tone and “under-utilization” of the parasympathetic system when SCS is switched off. SCS reduces this dominance of the sympathetic system and increases the parasympathetic influence. Activation of SCS may influence HRV via activation of the DNIS.

### **References:**

**Keywords:** Heart rate variability, chronic pain, functional neurosurgery, autonomic nervous system

Topic: 01. Basic Science

## PROTEOMICS AND PHOSPHOPROTEOMICS OF DIFFERENTIAL TARGET MULTIPLEXED PROGRAMING FOR SPINAL CORD STIMULATION IN AN ANIMAL MODEL OF NEUROPATHIC PAIN

### E-POSTER VIEWING

David Cedeno<sup>1</sup>, Ricardo Vallejo<sup>2</sup>, Dana Tilley<sup>1</sup>, Courtney Kelley<sup>1</sup>, William Smith<sup>3</sup>, Alejandro Vallejo<sup>4</sup>, Samuel Thomas<sup>5</sup>

<sup>1</sup>Research, Lumbrera LLC, Bloomington, United States of America, <sup>2</sup>Interventional Pain Medicine, National Spine and Pain Centers, Bloomington, United States of America, <sup>3</sup>Geisel School Of Medicine, Dartmouth College, Hanover, United States of America, <sup>4</sup>Chicago College Of Osteopathic Medicine, Midwestern University, Downers Grove, United States of America, <sup>5</sup>Medicine, Des Moines College of Osteopathic Medicine, Des Moines, United States of America

**Introduction:** Neuropathic chronic pain is governed by over and under expression of proteins that starts at the onset of injury and continue throughout. Our group studies the molecular mechanisms involved in the electrical modulation of chronic pain using spinal cord stimulation (SCS) algorithms that differentially target neurons and glial cells. This differential target multiplexed programming (DTMP) has proven more effective than standard approaches in clinical trials and pre-clinical work. Proteomics analysis complement the understanding of the effects of DTMP already obtained in previous work by accounting its effect on protein expression in pain-related biological process. Phosphoproteomic analyses will ascertain if targets of proteins involved in the regulation and signaling within pain-related pathways were affected by DTMP.

**Methods/Materials:** Procedures were approved by the IACUC at Illinois Wesleyan University. Twenty-four male Sprague-Dawley rats were implanted with a 4-contact lead and subjected to the spared-nerve injury (SNI) model of neuropathic pain. Animals were assigned to either No-SCS or DTMP. A set of 10 rats was kept as a naïve group. Standard assessments were used to measure mechanical and thermal hypersensitivity. Rats underwent continuous stimulation for 48-h. No-SCS and naïve animals were assessed in parallel to DTMP animals. After 48-h, animals were sacrificed and the spinal cord sub-adjacent to the lead was extracted and preserved until proteomics testing.

**Results:** DTMP significantly decreased mechanical and thermal hypersensitivity relative to No-SCS. A total of 7194 proteins and 12847 phosphoproteins were identified. The SNI model significantly change the expression of 234 proteins and 2076 phosphoproteins relative to naïve. DTMP modulated the expression of about 50% of these proteins towards pre-injury. These proteins are involved in actin binding, cell adhesion in the extracellular matrix, calcium binding, cell development, enzymatic action, G-protein regulation, signaling, phosphorylation and dephosphorylation, lipid binding, transmembrane transport, and protein regulation, which are central to neuroglial interactions.

**Discussion:** DTMP modulates the activity of protein kinases, such as PKCE and GRK2, which play crucial roles in inflammation and nociception within neural tissue following the SNI. The effect on the pathways involved demonstrate their ability to modulate some regulators involved in the perception of pain. Seven phosphorylated targets of PKCE and GRK2 were also modulated by DTMP, indicating the role of DTMP on regulation of signaling cascades in pain processing.

**Conclusions:** DTMP is an effective method for pain relief. Its mode of action involves modulation of genes and proteins associated with neuroglial interactions that affect key biological processes involved in pain pathways.

**References:** 1. Ji RR, Berta T, Nedergaard M. Glia and pain: Is chronic pain a gliopathy? *Pain*. 2013; 154: S10–S28.

**Keyword:** Proteomics, Spinal Cord Stimulation, Differential Target Multiplexed Programming, Pain Model

Topic: 01. Basic Science

## SPINAL CORD STIMULATION IN RATS: TOWARDS A BETTER TRANSLATIONAL MODEL AND UNDERSTANDING OF UNDERLYING ANALGESIC MECHANISMS

### E-POSTER VIEWING

Ilona Obara<sup>1</sup>, Birte Dietz<sup>2</sup>, Amal Alsubayiel<sup>1</sup>, Milan Obradovic<sup>3</sup>, Gerrit Gmel<sup>3</sup>, Dave Mugan<sup>2</sup>

<sup>1</sup>School Of Pharmacy, Newcastle University, Newcastle upon Tyne, United Kingdom, <sup>2</sup>-, Saluda Medical Europe Limited, Harrogate, United Kingdom, <sup>3</sup>-, Saluda Medical Pty Ltd, Sydney, Australia

**Introduction:** Pre-clinical models of spinal cord stimulation (SCS) use differently designed electrodes/stimulating contacts that always result in stimulation of a relatively wider portion of the dorsal spinal cord, as compared to humans. They also rely on establishing a motor, rather than perceptual, threshold (MT) as the reference for current intensity. Evoked compound action potential (ECAP) threshold, identified during SCS in humans, has been recently observed to closely correlate with the threshold for stimulation sensation perceived as paresthesia. We adopted this new approach in rats to assess the feasibility of recording ECAPs from the spinal cord using uniquely designed equipment and to characterize the relationship between ECAP and MT.

**Methods/Materials:** Under anesthesia, rats (adult male Sprague-Dawley, 250-300g, n=6) were subjected to epidural implantation of a custom-made electrode (0.5 x 1.0mm each, Saluda Medical) inserted at T11 such that six active contacts spanned L2-T12. Positioning was confirmed by x-ray. Stimulation and recording were performed using the Saluda Medical Multi-Channel-System. One contact was used for stimulation while recordings were made from the remaining contacts. Experimental protocol was in accordance with UK Home Office regulation.

**Results:** ECAPs were recorded from all animals. Signal analysis revealed an average orthodromic conduction velocity (CV) of 52m/s and antidromic CV of 39.92m/s suggesting large myelinated fibers activation. Using monopolar 20µs pulse duration and 2Hz frequency, the average current required to generate ECAPs and MT was 0.12mA ± 0.02mA and 1.41mA ± 0.12mA, respectively. Using bipolar 20µs pulse duration and 2Hz frequency, the average current required to generate ECAPs and MT was 0.12mA ± 0.03mA and 1.25mA ± 0.11mA, respectively. Thus, MT was 17.7 ± 2.66 and 13.58 ± 0.57 times higher than ECAP threshold in the same animal. A morphometric evaluation of spinal cord slices showed that the custom-made electrode may preferentially activate dorsal column axons of myelinated fibers.

**Discussion:** In summary, this data for the first time provides evidence for the ability of ECAP recording from the rat spinal cord that is relevant to the SCS. The difference between identified ECAP threshold and MT in rats may suggest that observations from current rodents' models of SCS are resulting from excessive SCS stimulation.

**Conclusions:** ECAPs recording, combined with smaller electronics, may allow for the development of a novel model of SCS in rats with chronic pain that will enable identification of mechanisms underlying SCS analgesia that translate better between animals and human and therefore leading to the improvement of SCS in the clinic.

### References:

**Keywords:** Neurophysiology, Spinal cord stimulation, in vivo electrophysiology, Pain, rat model



Topic: 01. Basic Science

## MODULATION OF CELL-SPECIFIC TRANSCRIPTOMES IN AN ANIMAL MODEL OF NEUROPATHIC PAIN USING SPINAL CORD STIMULATION WITH DIFFERENTIAL TARGET MULTIPLEXED PROGRAMMING

### E-POSTER VIEWING

David Cedeno<sup>1</sup>, William Smith<sup>2</sup>, Ricardo Vallejo<sup>3</sup>, Dana Tilley<sup>1</sup>, Courtney Kelley<sup>1</sup>, Alejandro Vallejo<sup>4</sup>, Samuel Thomas<sup>5</sup>

<sup>1</sup>Research, Lumbrera LLC, Bloomington, United States of America, <sup>2</sup>Geisel School Of Medicine, Dartmouth College, Hanover, United States of America, <sup>3</sup>Interventional Pain Medicine, National Spine and Pain Centers, Bloomington, United States of America, <sup>4</sup>Chicago College Of Osteopathic Medicine, Midwestern University, Downers Grove, United States of America, <sup>5</sup>Medicine, Des Moines College of Osteopathic Medicine, Des Moines, United States of America

**Introduction:** Spinal cord stimulation (SCS) with differential target multiplexed programming (DTMP) utilizes multiple electrical signals in order to target neurons and glial cells in the stimulated tissue. Previous work showed that DTMP modulates biological processes related to neuroglial interactions that are perturbed in an animal model of neuropathic pain. Recently, DTMP has been shown to be more effectively than conventional SCS in a randomized controlled clinical trial. This study investigates the effect of DTMP on genes that are known to be differentially expressed in neurons and various types of glial cells.

**Methods/Materials:** Forty-eight male rats were implanted with a 4-contact lead and subjected to the spared-nerve injury (SNI) model of neuropathic pain. Animals were assigned to No-SCS, DTMP, low rate (LR) or high rate (HR) programs. Ten rats were kept naïve. SCS was applied continuously for 48-h. Spinal cords sub-adjacent to the lead were extracted and preserved. Naïve and No-SCS animals were assessed in parallel. Gene expression was quantitated via RNA-sequencing. Cell-specific transcriptomes were obtained from reported datasets for neurons, astrocytes, oligodendrocytes and microglia. Cells had been separated using cell-sorting techniques. Cell-specific gene expressions had been validated against the expression in whole tissue. These cell-specific transcriptomes were cross-referenced to the transcriptome obtained for animals in our work. Pearson correlations for each SCS vs No-SCS with the naïve vs SCS were obtained for each cell-specific transcriptome.

**Results:** SNI increased expression ( $\geq 10\%$ ), relative to naïve levels, in 55% of microglia-specific, 27% of oligodendrocyte-specific, 28% of astrocyte-specific transcriptomes, while decreasing expression ( $\leq 10\%$ ) in 57% of the neuron-specific transcriptome. DTMP and HR showed strong positive correlations ( $p < 0.0001$ ) with naïve for microglia genes, while LR showed a no correlation ( $p = 0.619$ ). DTMP showed strong positive correlations with naïve for oligodendrocytes and neurons, and a moderate significant positive correlation for astrocytes, while HR showed a moderate positive correlation ( $p < 0.001$ ) for oligodendrocytes, but a weak positive correlation ( $p < 0.01$ ) for astrocytes and neurons. LR showed weak correlations ( $p < 0.01$ ) for neurons, astrocytes, and oligodendrocytes. DTMP-SCS was the only stimulation to restore  $>70\%$  of genes towards naïve for all cell types.

**Discussion:** DTMP SCS modulates each of the different neural cell transcriptomes, while reversing the expression of such cell-specific genes toward naïve levels more effectively than HR and LR.

**Conclusions:** DTMP effectiveness in an animal model of neuropathic pain involves the differential modulation of glial cells and neurons in the stimulated spinal cord as a result of using multiple signals.

**References:** Cahoy JD, Emery B, Kaushal A, et al. A transcriptome database for astrocytes, neurons, and oligodendrocytes: a new resource for understanding brain development and function. *J Neurosci*. 2008;28(1):264–278. Hickman SE, Kingery ND, Ohsumi TK, et al. The microglial sensome revealed by direct RNA sequencing. *Nat Neurosci*. 2013;16(12):1896–1905. Artegiani B, Lyubimova A, Muraro M, van Es JH, van Oudenaarden A, Clevers H. A Single-Cell RNA Sequencing Study Reveals Cellular

and Molecular Dynamics of the Hippocampal Neurogenic Niche. 2017;21(11):3271-3284. Bennett ML, Bennett FC, Liddelow SA, et al. New tools for studying microglia in the mouse and human CNS. *Proc Natl Acad Sci USA*. 2016;113(12):E1738-46. Gokce O, Stanley GM, Treutlein B, et al. Cellular Taxonomy of the Mouse Striatum as Revealed by Single-Cell RNA-seq. *Cell Reports*. 2016;16(4):1126-1137. Hirbec H, Marmai C, Duroux-Richard I, et al. The microglial reaction signature revealed by RNAseq from individual mice. *Glia*. 2018;66(5):971-986. Friedman BA, Srinivasan K, Ayalon G, et al. Diverse Brain Myeloid Expression Profiles Reveal Distinct Microglial Activation States and Aspects of Alzheimer's Disease Not Evident in Mouse Models. *Cell Reports*. 2018;22:832-847.

**Keyword:** Transcriptomics, Spinal Cord Stimulation, Differential Target Multiplexed Programming, Pain Model

**Topic:** 01. *Basic Science*

## **WIKISTIM.ORG UPDATE: DEVELOPMENT OF A FREE ON-LINE DATABASE OF NEUROSTIMULATION STUDIES**

### **E-POSTER VIEWING**

Jane Shipley<sup>1</sup>, Richard North<sup>2</sup>

<sup>1</sup>Wikistim Development, The Neuromodulation Foundation, Inc., Baltimore, United States of America, <sup>2</sup>President, Neuromodulation Foundation, Baltimore, United States of America

**Introduction:** WIKISTIM provides searchable lists of neurostimulation papers that report primary data and study protocols. The lists are updated monthly, displayed in sections by stimulation target, and sortable by author, title, journal, etc. Each section has a customized list of data categories for uploading data from a paper (and earning free CME credits), creating tables, designing studies, creating manuscripts, and conducting peer review. Multiple (or single) datasheets are downloadable into a CSV spreadsheet that exhibits all data headings and rows to permit comparison. WIKISTIM's discussion section allows immediate correction of errors that appear in publications, and our monthly email newsletter lists new citations by stimulation target with links to PUBMED abstracts. Access to WIKISTIM is free upon registration.

**Methods/Materials:** We examined WIKISTIM's growth and development and tested the performance of our newsletter versus industry standards.

**Results:** As of February 2020, 1187 people have registered for access to WIKISTIM (Figure 1). Our growth rate was nearly 38% in the past year. The increase in the number of citations reporting primary data over the past two years is shown in Table 1. Our newsletter consistently outperforms the "Medical, Dental, and Health Care" sector mean for percent opened and percent who clicked a link (Figure 2); the newsletter archive is available without subscription at [www.wikistim.org/news/](http://www.wikistim.org/news/). This year, we launched a new section on non-invasive brain stimulation, and we have recently implemented a system to enhance our search results.

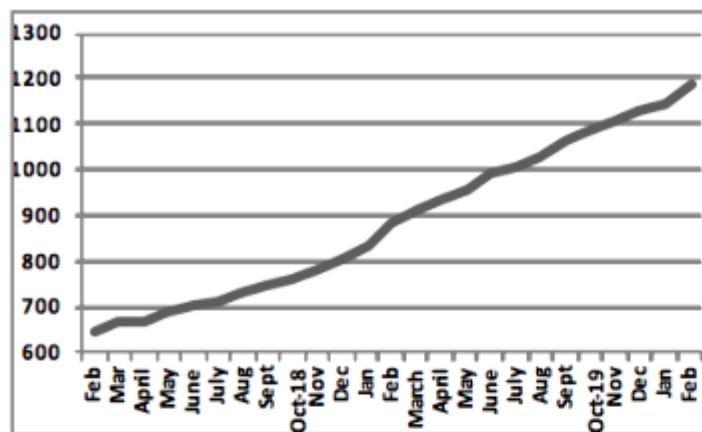


Figure 1. Subscribers 2/2018 to 2/2020.

Table 1. Increase in number of citations.

	Feb 2018	Feb 2019	Feb 2020
Deep brain stimulation	4179	4715	5280
Dorsal root ganglion stimulation	66	94	120
Gastric electrical stimulation	465	478	492
Peripheral nerve field stimulation	51	55	57
Spinal cord stimulation	2134	2283	2437
Sacral nerve stimulation	873	920	984
Total	7768	8545	9370

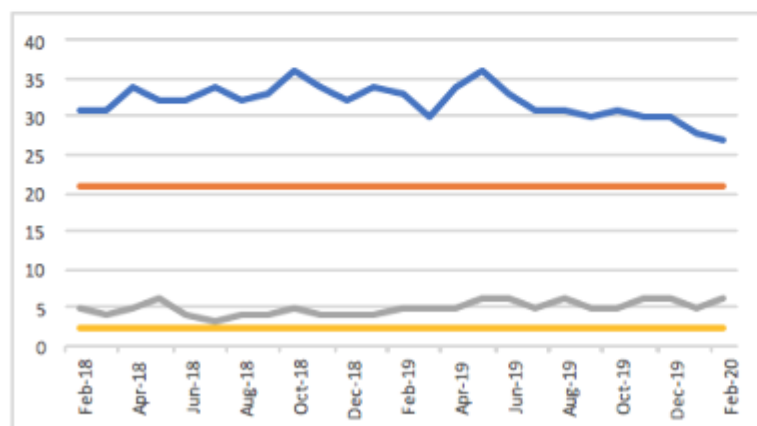


Figure 2. Newsletter statistics: % opened (top dashed line) versus industry standard (top solid line) and % clicks (bottom dashed line) versus industry standard (bottom solid line).

**Discussion:** WIKISTIM has been well received by the neurostimulation community. Enhancements to WIKISTIM's data entry scheme and search engine are underway. As resources permit, WIKISTIM will expand with additional sections (e.g., ONS, VNS) and incorporate other enhancements available to online resources.

**Conclusions:** We encourage the neurostimulation community to explore WIKISTIM and contribute to its development. Our immediate goals are for WIKISTIM to list all reports containing primary data for all neurostimulation therapies and to have all possible data extracted to support comparative analysis.

WIKISTIM, thus, points the way to a new method of publishing and evaluating primary data. The ultimate and most important goal of WIKISTIM, of course, is to improve patient care.

**References:**

**Keyword:** data management, evidence-based medicine, neuromodulation, neurostimulation, primary data

**Topic:** 01. Basic Science

## **COMPARISON OF LOW AND HIGH-DOSE PARAMETERS IN A LARGE ANIMAL MODEL OF SPINAL CORD STIMULATION**

### **E-POSTER VIEWING**

Louis Vera-Portocarrero<sup>1</sup>, Tina Billstrom<sup>2</sup>, David Cedeno<sup>3</sup>, Melanie Goodman Keiser<sup>1</sup>

<sup>1</sup>Research & Core Technology, Medtronic, Minneapolis, United States of America, <sup>2</sup>Physiological Research Laboratory, Medtronic, Minneapolis, United States of America, <sup>3</sup>Research, Lumbrera LLC, Bloomington, United States of America

**Introduction:** We have previously developed and validated a large animal model of neuropathic pain and SCS therapy in sheep. This sheep model allows us to perform experiments with fully implantable SCS systems that can provide continuous stimulation that mimics the patients' clinical experience. Parameter settings used in the clinic has been in the "low-dose" category using low frequencies (40-100 Hz) and pulse widths (300-450  $\mu$ s). The "high-dose" category involves higher frequencies/pulse widths combinations.

**Methods/Materials:** A peroneal nerve injury was induced in four sheep according to published literature. Quantitative sensory testing (QST) was used to confirm the presence of hypersensitivity after injury. QST was performed by application of an automated von Frey filament (1000 g) to the injured hindlimb of the sheep and measuring the withdrawal threshold response. Sheep were implanted with octopolar leads in lumbar segments of the spinal cord. Stimulation was tested for a period of 5 days. The conventional parameters used were 60 Hz frequency, pulse width of 250  $\mu$ s and an amplitude of 80-90% of motor threshold (MT) for a charge per second of 7.5  $\mu$ s/sec. A combination of higher frequencies (500 Hz) and pulse width (500  $\mu$ s) was tested at lower amplitudes (40-50% MT) also for a period of 5 days for a charge per second of 100  $\mu$ s/sec.

**Results:** Sheep with nerve injury presented with lower withdrawal thresholds to von Frey filament application. The testing of high dose revealed a biphasic change in hypersensitivity, with an initial rise of the withdrawal threshold in the first 15 minutes of application with a second peak observed after 24 to 72 hours of continuous stimulation. In contrast, conventional parameters yielded a sustained reversal of the hypersensitivity over the 5 days of continuous stimulation.

**Discussion:** This study evaluated the response to clinically relevant parameters in a large animal model. Conventional parameters with a lower charge per second but higher amplitudes yielded a sustained anti-nociceptive effect while stimulation was ON. A higher charge per second also had an anti-nociceptive effect but with a different temporal pattern. This study suggests that there might not be a linear relationship between charge per second and sustained reversal of hypersensitivity and that the effectiveness of stimulation relies more on the actual frequency/pulse width combinations.

**Conclusions:** Low and high-dose stimulation yielded different time course of effects suggesting the engagement of different mechanisms.

### **References:**

**Keyword:** Spinal cord stimulation, Preclinical, High Dose, Conventional SCS

**Topic:** 01. Basic Science

## **MODULATION OF THE PARASYMPATHETIC NERVOUS SYSTEM BY SPINAL CORD STIMULATION IN PATIENTS WITH FAILED BACK SURGERY SYNDROME**

### **E-POSTER VIEWING**

Lisa Goudman<sup>1</sup>, Ann De Smedt<sup>2</sup>, Frédéric Louis<sup>3</sup>, Virginie Stalmans<sup>3</sup>, Bengt Linderöth<sup>4</sup>, Philippe Rigoard<sup>5</sup>, Maarten Moens<sup>6</sup>

<sup>1</sup>Neurosurgery, UZ Brussel, Jette, Belgium, <sup>2</sup>Physical Medicine And Rehabilitation, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>3</sup>Clinique De La Douleur, Clinique Sainte-Elisabeth-CHC, Verviers, Belgium, <sup>4</sup>Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden, <sup>5</sup>Prismatics, Hospital University of Poitiers, Poitiers, France, <sup>6</sup>Neurosurgery, UZ Brussel, Brussel, Belgium

**Introduction:** Based on heart rate variability measurements, it is suggested that patients with chronic pain have a relative stronger sympathetic tone and weaker parasympathetic tone. This disbalance can be restored when patients are treated with Spinal Cord Stimulation (SCS). Based on these findings, it is hypothesised that SCS is able to influence the autonomic nervous system. The aim of this study is to further explore the influence of SCS on the autonomic nervous system by evaluating whether SCS is able to influence skin conductance, blood volume pulse, heart rate and respiration rate.

**Methods/Materials:** In this multicenter study, twenty-eight patients with Failed Back Surgery Syndrome (FBSS) took part. Skin conductance and cardiorespiratory parameters, i.e. blood volume pulse, heart rate and respiration rate, were measured with a NeXus 10 MK-II during on and off states of SCS. Paired statistics were performed on a 5-minute recording segment for all parameters.

**Results:** Both low back and leg pain intensity scores were significantly decreased when SCS was activated. Skin conductance level and blood volume pulse were not altered between on and off states of SCS. Heart rate and respiration rate significantly decreased when SCS was activated.

**Discussion:** Based on these findings, it may be suggested that SCS is able to influence the autonomic nervous system in patients with FBSS, and more specifically the parasympathetic activity.

**Conclusions:** Parameters that are regulated by the sympathetic nervous system were not significantly different between SCS on and off states, leading to the hypothesis that SCS is capable of restoring the dysregulation of the autonomic nervous system by primarily increasing the activity of the parasympathetic system instead of reducing the overweight of the sympathetic system.

### **References:**

**Keywords:** autonomic nervous system, skin conductance, Mechanism of action, neuromodulation

## ALLODYNIA, HYPERALGESIA, QUANTITATIVE SENSORY TESTING IN CRPS PATIENTS BEFORE AND AFTER SPINAL CORD STIMULATION

### E-POSTER VIEWING

Nadia Kriek, Cecile De Vos, Sara Baart, Frank Huygen  
Center For Pain Medicine, Department Of Anesthesiology, Erasmus University Medical Centre, Rotterdam, Netherlands

**Introduction:** Complex regional pain syndrome (CRPS) is a chronic and debilitating disease, with a partially unknown pathophysiology characterized by ongoing disproportionate pain and sensory abnormalities. Diagnosis and treatment can be challenging. Spinal cord stimulation (SCS) is an effective therapy to treat CRPS related neuropathic pain. Few studies investigated the effects of SCS on allodynia, hyperalgesia and sensory threshold testing <sup>1</sup>. This study investigated these characteristics in CRPS patients treated with SCS.

**Methods/Materials:** This study was part of a multicenter randomized controlled trial investigating the effects of SCS with various frequencies and waveforms in CRPS patients (ISRCTN 36655259) <sup>2,3</sup>. Patients with CRPS in one extremity and eligible for SCS were included. Pain scores (Numeric Rating Scale 0-10), allodynia (symptom and sign), hyperalgesia (symptom), QST and CPM were tested before SCS (T0) and after three month of SCS with conventional 40Hz tonic SCS (T1). Three sensory thresholds were documented with electrical QST: current perception threshold (CPT), pain perception threshold (PPT) and pain tolerance threshold (PTT). The sensory thresholds were measured on the CRPS affected extremity and the contralateral clinically unaffected extremity for comparisons. Non parametric testing was used for all statistical analysis.

**Results:** 43 patients were included of whom 31 completed the T1 assessment. Median pain scores was significantly reduced after SCS (NRS 7 versus NRS 2). Allodynia (sign), allodynia (symptom) and hyperalgesia (symptom) were all significantly reduced at T1. The QST thresholds were not statistically significantly different when comparing the "healthy" side with the contralateral CRPS side at both T0 and T1. On the healthy side, none of the QST thresholds (CPT, PPT and PTT) was significantly altered after SCS. However, on the CRPS affected side the CPT was significantly increased after SCS.

**Discussion:** Contrary to previously reported, SCS can significantly reduce allodynia in CRPS patients and therefore SCS therapy should not be withheld in these patients <sup>4</sup>. The present study however, did not manage to quantify with QST the effects of SCS on allodynia and hyperalgesia, probably due to the relatively small numbers of patients included.

**Conclusions:** SCS significantly reduces pain, allodynia (sign and symptom) and hyperalgesia (symptom) in CRPS patients. The current perception threshold on the CRPS affected side was significantly increased after SCS while all other QST parameters were not significantly altered

**References:** 1. Bordeleau M, Carrondo Cottin S, Meier K, Prud'Homme M: Effects of Tonic Spinal Cord Stimulation on Sensory Perception in Chronic Pain Patients: A Systematic Review. *Neuromodulation* 2019; 22: 149-162 2. Kriek N, Groeneweg JG, Stronks DL, de Ridder D, Huygen FJ: Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial. *Eur J Pain* 2017; 21: 507-519 3. Kriek N, Groeneweg JG, Stronks DL, Huygen FJ: Comparison of tonic spinal cord stimulation, high-frequency and burst stimulation in patients with complex regional pain syndrome: a double-blind, randomised placebo controlled trial. *BMC Musculoskelet Disord* 2015; 16: 222 4. Kemler MA, Reulen JP, Barendse GA, van Kleef M, de Vet HC, van den Wildenberg FA: Impact of spinal cord stimulation on sensory characteristics in complex regional pain syndrome type I: a randomized trial. *Anesthesiology* 2001; 95: 72-80



**Keywords:** Complex regional pain syndrome, Allodynia, quantitative sensory testing, hyperalgesia, Spinal cord stimulation, Tonic SCS

**Topic:** 02. Neuroprosthetics and Neural Engineering

## **EVOKED COMPOUND ACTION POTENTIALS (ECAPS) ARE A ROBUST MEASURE OF SPINAL CORD ACTIVATION OVER THE LONG-TERM**

### **E-POSTER VIEWING**

Lawrence Poree<sup>1</sup>, Nagy Mekhail<sup>1</sup>, Robert Levy<sup>2</sup>, Timothy Deer<sup>3</sup>, Leonardo Kapural<sup>4</sup>, Sean Li<sup>5</sup>, Kasra Amirdelfan<sup>6</sup>, Corey Hunter<sup>7</sup>, Steven Rosen<sup>8</sup>, Shrif Costandi<sup>9</sup>, Steven Falowski<sup>10</sup>, Abram Burgher<sup>11</sup>, Jason Pope<sup>12</sup>, Gilmore Gilmore<sup>13</sup>, Farooq Qureshi<sup>14</sup>, Peter Staats<sup>5</sup>, James Scowcroft<sup>15</sup>, Carlson Carlson<sup>16</sup>, Christopher Kim<sup>17</sup>, Michael Yang<sup>18</sup>, Thomas Stauss<sup>19</sup>

<sup>1</sup>Anesthesiology And Pain Medicine, University of California at San Francisco, San Francisco, United States of America, <sup>2</sup>Director Of Neurosurgical Services, Anesthesia Pain Care Consultants, Tamarac, United States of America, <sup>3</sup>Anesthesiology, The Spine and Nerve Center of The Virginias, Charleston, WV, United States of America, <sup>4</sup>Pain Management, Carolinas Pain Institute and Wake Forest University School of Medicine, Winston-Salem, NC, United States of America, <sup>5</sup>Pain Management, Premier Pain Centers, Shrewsbury, NJ, United States of America, <sup>6</sup>Pain Medicine, IPM Medical Group, Inc., Walnut Creek, CA, United States of America, <sup>7</sup>Pain Management, Ainsworth Institute of Pain Management, New York, NY, United States of America, <sup>8</sup>Anesthesiology, Delaware Valley Pain & Spine Institute, Trevese, PA, United States of America, <sup>9</sup>Pain Management, Cleveland Clinic, Cleveland, OH, United States of America, <sup>10</sup>Neurological Surgery, Functional Neurosurgery, Neurosurgical Associates of Lancaster, Lancaster, PA, United States of America, <sup>11</sup>Pain Medicine, HOPE Research - TPC, Phoenix, AZ, United States of America, <sup>12</sup>Pain Medicine, Evolve Restorative Center, Santa Rosa, CA, United States of America, <sup>13</sup>Anesthesiology, Center for Clinical Research, Winston-Salem, NC, United States of America, <sup>14</sup>Pain Management, St Luke's Spine & Pain Associates, Easton, PA, United States of America, <sup>15</sup>Pain Management, Pain Management Associates, Independence, MO, United States of America, <sup>16</sup>Pain Management, Arizona Pain, Glendale, AZ, United States of America, <sup>17</sup>Anesthesiology, The Center for Pain Relief, Charleston, WV, United States of America, <sup>18</sup>Pain Management, Summit Pain Alliance, Santa Rosa, CA, United States of America, <sup>19</sup>Anesthesiology, Advanced Pain Management, Greenfield, WI, United States of America

**Introduction:** A new system measures Evoked Compound Action Potentials (ECAPs) for closed-loop (CL) SCS. It is designed to maintain consistent ECAP amplitude by adjusting stimulation amplitude at every pulse to reduce variability in spinal cord activation [1], [2]. For any system to be useful for monitoring, and/or feedback control, the measured signal must have long-term fidelity and robustness. We present data from the Evoke Study (NCT02924129), comparing CL to open-loop (OL) SCS, demonstrating long-term utility of ECAP measurement in patients.

**Methods/Materials:** ECAPs are recorded from implanted patients at scheduled visits, over 12 months, per study protocol [3]. At these visits, an activation plot (AP, relating ECAP amplitude and stimulus current) for the patient's preferred program is measured, noting patient-reported perception threshold, comfort range and maximum (tolerable  $\leq 1$  minute) levels. Additionally, conduction velocity (CV) is estimated from ECAP N1 latencies (and known electrode separation); and chronaxie and rheobase are estimated from strength-duration curves. Stimulus amplitudes used by patients out-of-clinic were also recorded.

**Results:** of findings can be found in images attached.

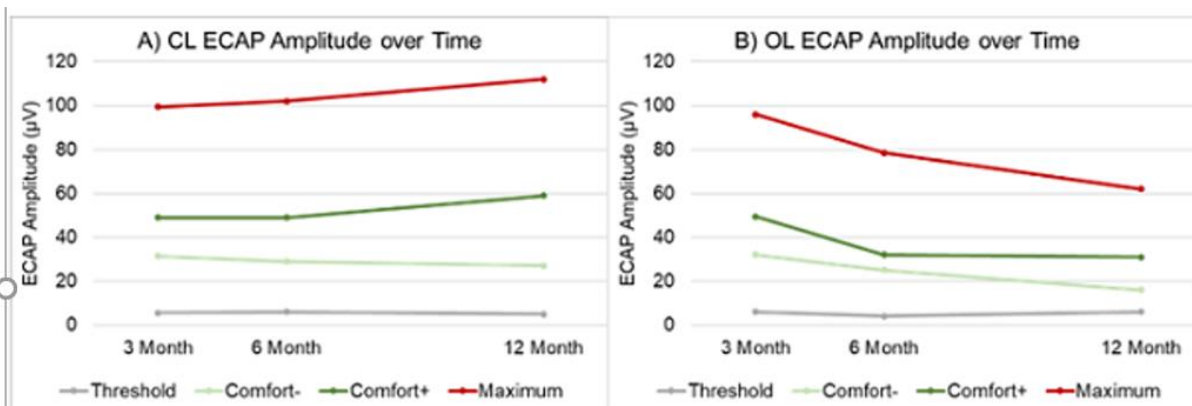


Figure 1: Median ECAP amplitude over time for each activation plot level (Perception Threshold, Comfort-, Comfort+, and Maximum). A) Median ECAP amplitude for the closed-loop group. B) Median ECAP Amplitude for the open-loop group.

Table 3: Median values for the Mode (most frequent) stimulus amplitude (μA) used across all programs since the previous visit, measured at each scheduled visit from 3 to 12-months post implant. Note that the p-values refer to statistical significance between the two groups, with  $p \leq 0.05$  at all but the 12-month visit. Note that the values remain largely consistent within each group throughout the entire time.

	Control	Investigational	Kruskal-Wallis P-value
3M	4479	7119	0.03
6M	4405	6368	0.046
9M	4304	6318	0.011
12M	4394	6675	0.058

Table 1: Conduction velocity over time. Closed-loop (CL) SCS vs. Open-loop (OL) SCS.

Parameter	3 Month		6 Month		12 Month	
	CL	OL	CL	OL	CL	OL
Number of Subjects	42	40	39	37	44	32
Conduction Velocity (CV) (m/s)						
Mean (SD)	60.1 (10.5)	61.1 (8.9)	59.5 (9.7)	58.9 (9.5)	61.1 (9.7)	60.7 (9.0)
Median	57.3	58.9	58.0	57.2	60.2	58.9
Min., Max.	45.1, 93.2	42.0, 82.9	44.1, 83.5	43.9, 80.3	43.3, 84.2	45.2, 86.2
P-value (difference between medians)	0.430				1.000	

Table 2: Chronaxie and rheobase values over time

Parameter	3 Month		6 Month		12 Month	
	CL	OL	CL	OL	CL	OL
Number of Subjects	29	27	32	25	33	26
Chronaxie (μs)						
Mean (SD)	385.9 (159.2)	344.2 (155.3)	389.0 (144.9)	376.0 (150.3)	312.9 (99.7)	291.9 (128.0)
50th Percentile (Median)	359.5	311	386.1	359.1	306.6	236.2
P-value (difference between medians)	0.181				0.259	
Rheobase (mA)						
Mean (SD)	3.0 (1.3)	3.5 (2.2)	2.7 (1.4)	3.4 (2.0)	3.2 (1.5)	3.0 (1.6)
50th Percentile (Median)	2.8	2.9	2.2	3	2.9	2.8
P-value (difference between medians)	0.676				0.725	

**Discussion:** Average CV was approximately 60 m/s for all visits (Table 1); no statistically significant differences were observed between groups at 3 or 12 months. Chronaxie and rheobase remained consistent over time and between groups (Table 2). Paired comparison, within CL and OL respectively, of CV ( $p=0.61$ ,  $0.69$ ), chronaxie ( $p=0.43$ ,  $0.63$ ), and rheobase ( $p=0.12$ ,  $0.27$ ) between 3 and 12-month visits did not show any statistical differences. ECAP amplitude (in-clinic AP levels) was consistent for CLSCS but tended to decrease over time for OL-SCS (Figure 1). Stimulation amplitude (out-of-clinic) was consistent over time for both groups, but smaller for OL-SCS compared to CL-SCS (Table 3). Pairwise comparisons of ECAP amplitude (all AP levels), within groups, showed no statistically significant differences between 3 and 12 months ( $p \geq 0.16$  for all measures), the same was true for the stimulus amplitude used.

**Conclusions:** Conduction velocity, chronaxie and rheobase, and stimulation amplitude used are stable over time. Stability in stimulus amplitude used, and rheobase, implies no physiological changes to SC activation. It is possible that the difference in AP levels between groups at 12 months could be due to OL patients developing sensitivity to paresthesia sensation over time. ECAP recording is possible long-term and may have utility in neurophysiological monitoring and for CL-SCS. Data collection is ongoing to establish ECAP stability over longer periods, showing promising results [4], [5].

**References:** [1] Holsheimer, J, J A den Boer, J J Struijk, and A R Rozeboom. "MR Assessment of the Normal Position of the Spinal Cord in the Spinal Canal." *AJNR. American Journal of Neuroradiology* 15, no. 5 (May 1994): 951–59. [2] Figley, C. R., and P. W. Stroman. "Investigation of Human Cervical and Upper Thoracic Spinal Cord Motion: Implications for Imaging Spinal Cord Structure and Function." *Magnetic Resonance in Medicine* 58, no. 1 (July 2007): 185–89. <https://doi.org/10.1002/mrm.21260>. [3] Levy, Robert, Timothy R. Deer, Lawrence Poree, Steven M. Rosen, Leonardo Kapural, Kasra Amirdelfan, Nicole Soliday, Angela Leitner, and Nagy Mekhail. "Multicenter, Randomized, Double-Blind Study Protocol Using Human Spinal Cord Recording Comparing Safety, Efficacy, and Neurophysiological Responses Between Patients Being Treated With Evoked Compound Action Potential-Controlled Closed-Loop Spinal Cord Stimulation or Open-Loop Spinal Cord Stimulation (the Evoke Study)." *Neuromodulation: Journal of the International Neuromodulation Society* 22, no. 3 (April 2019): 317–26. <https://doi.org/10.1111/ner.12932>. [4] Russo, Marc, Timothy Deer, Lawrence Poree, Michael J. Cousins, Charles Brooker, Richard Sullivan, Tillman Boesel, et al. "Long-Term Results from the Avalon Study – Feedback-Controlled SCS Using Evoked Compound Action Potentials," 2018. [5] Poree, Lawrence. "Closed-Loop Spinal Cord Stimulation: Evoke Study Results." presented at the International Neuromodulation Society 14th World Congress, Sydney, Australia, 2019.

**Keywords:** ECAP, Spinal cord stimulation, Evoked Compound Action Potential, ECAP Controlled Closed Loop SCS, Closed Loop, SCS

**Topic:** 02. Neuroprosthetics and Neural Engineering

**AIRRAY ELECTRODE TECHNOLOGY - ELECTRODE TECHNOLOGY AND DESIGN  
MODIFICATIONS FOR INDIVIDUAL ELECTRODE DESIGNS FOR SPECIFIC CUSTOMIZED  
APPLICATIONS**

**E-POSTER VIEWING**

Martin Schuettler, Joern Rickert, Colin Bierbrauer, Ronny Pfeifer, Miguel Ulloa, Christian Henle, Fabian Kohler  
Cto And Ceo, CorTec GmbH, Freiburg, Germany

**Introduction:** Research has increasingly focused on novel methods in neurology. Findings from many studies are constantly enabling new approaches to novel therapies [1]. This wide range of research findings will enable the development of novel therapies for neurological diseases. To researchers all over the world equipment tailored to their studies is essential. Here we present the °AirRay Electrode Technology which enables the development of electrodes that meet the expectations for the use in unique studies in the research of neurological diseases.

**Methods/Materials:** We developed manufacturing methods for high resolution electrode arrays made from the traditional implant materials PtIr and medical grade silicone. These materials are layered on top of each other while each new layer is micropatterned with a laser. As a result, flat arrays are produced that resembles printed circuit boards made from medical grade silicone and PtIr electrode contacts, conduction lines and weld pads. Medical grade wires are welded to the pads and the welds are sealed with silicone adhesive. The flat electrode arrays can be 3D-shaped to a peripheral nerve cuff by laminating them to the inside of a silicone tubing.

**Results:** The electrode arrays are typically between 100µm and 500µm thin, the metal thickness is between 10µm to 25µm, very much depending on the application. Flat devices (grid or strip electrode arrays) have been used acutely and chronically in animal research as well as acutely and sub-chronically in man. Cuffs have been used in acute and chronic animal studies as well as in acute human studies for fascicle-selective nerve stimulation as well as neural blocking and recording.

**Discussion:** In contrast to manual lead manufacturing, laser micromachining provides a high degree of automation combined with a very high reproducibility and processing precision. Electrode arrays can be very thin, soft and flexible and can have contacts ranging from 50µm to some mm in diameter.

**Conclusions:** Micromachining of traditional implant materials such as silicone rubber and noble metal foil allows to produce very soft and flexible, high definition neural electrode arrays as electrical interface for the peripheral and central nervous system in a semi-automated production process. The technology permits the making of human implantable devices as approved by the FDA in early 2019.

**References:** [1]: Famm, Kristoffer, et al. "Drug discovery: a jump-start for electroceuticals." *Nature* 496.7444 (2013): 159.

**Keywords:** neurotechnology, neural interface, electrode, biomedical engineering, nervous system

**Topic:** 02. Neuroprosthetics and Neural Engineering

## THE FACTOR OF TOLERANCE IN SPINAL CORD STIMULATION AMONG POST HERPETIC NEURALGIA PATIENTS

### E-POSTER VIEWING

Jaedo Lee

Pain Medicine, VHS MC, seoul, Korea, Republic of

**Introduction:** Spinal cord stimulation(SCS) may help reduce the pain in post herpetic neuralgia(PHN) patients. However, inadequate pain control may occur over time, this tolerance has been described as a progressive loss of pain control in a spinal cord stimulator system, and known as the important cause in treatment failure. We assess the tolerance of SCS among patients with PHN.

**Methods/Materials:** Multicenter retrospective observational study in PHN patients who have been treated with SCS, in the 4 pain centers between May 2015 and April 2019. Tolerance to SCS has been observed in patient where pulse amplitude needs to be increased to achieve the same analgesic effect over time or efficacy has been lost.

**Results:** A total of 58 patients, 26 men and 22 women, had SCS due to PHN and all patients who had undergone SCS were scheduled for a follow-up clinical visit. Mean follow-up time was 19 months (range 3-58 months). 18 patients (31%) developed tolerance and tolerance occurred in the range of 3 months to 26 months(mean 14.5 months). The incidence of tolerance in PHN patients who used more than 90mg of high doses of opioid(oral morphine) per day or who took oral opioid for more than six months was significantly higher than that in patients who did not. We looked for factors that could not affect the tolerance, such as age, sex, diabetes or delay of diagnosis.

**Discussion:** Most of the patients with the onset of tolerance had experience using oral opioid, although tolerance was rarely generated in low dose opioid, but the incidence of tolerance was very high in high-dose(> 90mg) morphine. In particular, the incidence of tolerance was high even after the insertion of the SCS, which appears to have a high correlation between opioid induced hyperalgesia and the occurrence of tolerance of the SCS and is thought to require further study.

**Conclusions:** High doses or long-term oral opioid use can be a factor that can increase the tolerance of the SCS in PHN patients.

### References:

**Keywords:** PHN, SCS, tolerance

**Topic:** 02. Neuroprosthetics and Neural Engineering

## **EIGHT HOURS OF ADAPTIVE VS CONVENTIONAL DEEP BRAIN STIMULATION FOR PARKINSON'S DISEASE**

### **E-POSTER VIEWING**

Sara Marceglia<sup>1</sup>, Marco Prenassi<sup>2</sup>, Mattia Arlotti<sup>3</sup>, Roberta Ferrucci<sup>4</sup>, Linda Borellini<sup>2</sup>, Tommaso Bocci<sup>4</sup>, Filippo Cogiamanian<sup>2</sup>, Marco Locatelli<sup>5</sup>, Sergio Barbieri<sup>2</sup>, Alberto Priori<sup>4</sup>

<sup>1</sup>Dipartimento Di Ingegneria E Architettura, Università degli Studi di Trieste, Trieste, Italy, <sup>2</sup>Uo Neurofisiopatologia, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, <sup>3</sup>Research And Development, Newronika SpA, Milan, Italy, <sup>4</sup>"Aldo Ravelli" Research Center For Neurotechnology And Experimental Brain Therapeutics, University of Milan, Milan, Italy, <sup>5</sup>Uo Neurochirurgia, Fondazione IRCCS Ca'Granda Ospedale Maggiore Policlinico, Milan, Italy

**Introduction:** Providing personalized and targeted therapy represents the necessary innovation in deep brain stimulation (DBS). Closed-loop adaptive DBS strategies (aDBS) able to adapt stimulation parameters to patient's clinical state are the cutting-edge technologies to achieve personalization and better efficacy. The most promising feedback variable for closed-loop aDBS is represented by the local neural activity recorded using the same lead delivering DBS, known as local field potentials (LFPs). However, long-term comparison of aDBS vs cDBS outcomes on patients is still in its infancy. In this work, we compare the clinical efficacy of LFP-based unilateral aDBS vs cDBS delivered for 8 hours in Parkinson's Disease patients.

**Methods/Materials:** We enrolled 8 PD patients who underwent surgery for subthalamic DBS electrode implant having externalized leads for a week to connect a wearable device for aDBS testing [1,2]. Two perioperative sessions lasting 8 hours were conducted on freely moving patients: in the first session cDBS was delivered while patients took their usual daily medication dose, whereas, in the second session, aDBS was delivered instead of cDBS. A blinded neurologist assessed the clinical state and fluctuations during the entire duration through the motor Unified Parkinson's Disease Rating Scale part III (UPDRS III) and the Rush scale. For the analysis, UPDRS III was normalized to the maximum and minimum values difference reported for each patient during the two days.

**Results:** During aDBS session, UPDRS III was significantly lower than during cDBS session (normalized UPDRS, cDBS vs aDBS [mean±SE]  $0.46 \pm 0.05$  vs  $0.33 \pm 0.04$ , t-test  $p=0.013$ ), thus suggesting a better control of motor symptoms by aDBS. In addition, during aDBS, dyskinesias were controlled better than during cDBS (Rush scale, cDBS vs aDBS  $2.79 \pm 0.39$  vs  $1.57 \pm 0.23$ ,  $p=0.036$ ).

**Discussion:** These results confirm previous findings of better performances of aDBS as compared to cDBS, especially in controlling stimulation side effects. These data are limited by the non-randomized administration of the two therapies (cDBS was administered always the first day, and aDBS the second day), even though this mimics the future practice with aDBS. In fact, data coming from the first days were necessary to personalize aDBS therapy in the second day, as it will happen in future practice.

**Conclusions:** Our findings support the superiority of aDBS vs cDBS in controlling motor symptoms and side effects in Parkinson's disease.

**References:** [1] Arlotti M, Marceglia S, Foffani G, Volkmann J, Lozano AM, Moro E, Cogiamanian F, Prenassi M, Bocci T, Cortese F, Rampini P, Barbieri S, Priori A. Eight-hours adaptive deep brain stimulation in patients with Parkinson disease. *Neurology*. 2018 Mar 13;90(11):e971-e976. doi: 10.1212/WNL.00000000000005121. [2] Rosa M, Arlotti M, S. Marceglia, Cogiamanian F, Ardolino G, Fonzo AD, Lopiano L, Scelzo E, Merola A, Locatelli M, Rampini PM, Priori A. Adaptive deep brain stimulation controls levodopa-induced side effects in Parkinsonian patients. *Mov Disord*. 2017 Apr;32(4):628-629. doi: 10.1002/mds.26953

**Keyword:** adaptive deep brain stimulation, neuromodulation, closed-loop, local field potentials



**Topic:** 02. Neuroprosthetics and Neural Engineering

## NEUROMODULATION FOR INTRACTABLE CHRONIC POST THORACOTOMY PAIN: A CASE REPORT

### E-POSTER VIEWING

Ricky Nagpaul<sup>1</sup>, Ashish Shetty<sup>2</sup>, Ram Dhotarkar<sup>2</sup>

<sup>1</sup>Pain Management Centre At Nhhn, University College London Hospitals NHS Trust, London, United Kingdom, <sup>2</sup>Pain Management Centre At Nhhn, University College London Hospital, London, United Kingdom

**Introduction:** Post thoracotomy pain syndrome(PTPS) is a condition that is difficult to treat and often offsets the positive results on the quality of life from the surgery. Incidence of longterm post-thoracotomy pain has been reported to be 80% at 3 months, 75% at 6 months, and 61% at one year after surgery; incidence of severe pain is 3–5%, and pain that interferes with normal life is reported by about 50% of patients(1). We hereby present a case of successful treatment of chronic intractable post thoracotomy, back and leg pain with spinal cord stimulation.

**Methods/Materials:** A 55 Year old male patient had thoracotomy and T8/T9 discectomy in 2009 following myelopathy and syringomyelia. He developed persistent neuropathic pain affecting predominantly the left thoracic region and upper quadrant of abdomen along with neuropathic pain affecting left lower back and leg. He received very little benefit from multiple anti neuropathic drugs and spinal interventions. His NRS Scores were: Thoracic -10/10 Back-10/10 Buttock-10/10 Leg 8/10 The pain had a significant impact on his sleep, work and social life.

**Results:** Following a successful trial in 2018 , he had a full implant (Boston Montage System), 2 Octad leads with tips at T9 and T5. The benefits were sustained at 3,6,12 and 18 months follow up. At 18 months, the NRS Scores were : Thoracic:5/10 Back :4/10 Leg:5/10 Patient reported reduced usage of medications, improved bladder control ,better sleep and improved daily activities and social life.

**Discussion:** PTPS is defined as pain that recurs or persists at the incision site or in the dermatomal distribution of the intercostal nerves for longer than 2 months after a thoracotomy. Thoracotomy is regarded as one of the most painful surgical procedures performed. Treatment of PTPS is multimodal and includes multiple pharmacological and interventional techniques.

**Conclusions:** PTPS can be potentially very debilitating and difficult to treat. There are no defined treatment pathways for this pain condition. Spinal cord stimulation is an effective method for managing complex neuropathic conditions. Our case report demonstrates that this modality can be used to treat persistent post thoracotomy pain not responding to conventional treatment modalities.

**References:** 1)Chronic pain after thoracic surgery: a follow-up study. Perttunen K, Tasmuth T, Kalso E Acta Anaesthesiol Scand. 1999 May; 43(5):563-7

**Keyword:** Post thoracotomy pain, SCS, neuropathic pain

**Topic:** 02. Neuroprosthetics and Neural Engineering

## **NEUROMODULATION FOR CHRONIC NEUROPATHIC PAIN FOLLOWING MULTIPLE SURGERIES IN HIP DYSPLASIA – A CASE REPORT**

### **E-POSTER VIEWING**

Ram Dhotarkar, Ashish Shetty, Ricky Nagpaul

Pain Management Centre At NHHN, University College London Hospitals NHS Trust, London, United Kingdom

**Introduction:** Hip dysplasia can cause debilitating pain . Periacetabular osteotomy is an established treatment in hip dysplasia (1) It's a debilitating condition where patient may undergoes multiple surgeries adding the risk for chronic neuropathic pain. We present a unique case of 37 year old lady with bilateral hip dysplasia and chronic neuropathic pain , whose pain improved significantly with spinal cord stimulation(SCS).

**Methods/Materials:** 37 year old businesswoman developed the left hip pain 13 years ago . Initially the pain was on bending down which gradually worsened. She had multiple surgeries on hip including acetabular osteotomy, revision osteotomy and hip replacement. Over 3 years she developed neuropathic pain. The pain had significant impact on her work and personal life. She presented to our tertiary pain management center at NHHN ( UCLH) with severe left hip and left leg pain with signs of neuropathic pain. At baseline (before SCS) following findings were reported- a)Left hip and left leg pain (NRS)– 8/10 b) Tingling along left side of leg and around left knee. c) Sleep disturbances d) Impact on relationships, feeling and life- 8 ( average score) e) Medications Oxycontin 30mg BD, Oxycodone 15mg BD PRN, Gabapentin 300mg TDS, paracetamol and Ibuprofen regularly. d) Weak hip flexion She had successful implantation of spinal cord stimulation (Boston scientific / St Jude stimulator) following a trial . Post SCS there was improvement in her pain scores.

**Results:** Follow up 9 months post SCS reported- a)70% relief of pain for left hip-NRS 4/10. b) Improved sleep c) Recently started working – changed her previous job, now working as teacher 4 days/week. d)Medications Oxycodone 15mg BD – reducing dose , off Ibuprofen and paracetamol., Pregabalin 75mgBD ( Gabapentin stopped due to side effects) e) Gradually increasing walking tolerance.

**Discussion:** Hip dysplasia can be very debilitating in younger age group because of pain and hip dislocations. Periacetabular osteotomy is an established treatment in hip dysplasia (1). Post osteotomy pain usually persists. . Spinal cord stimulation is an effective method of managing complex neuropathic pain in gluteal region and legs. Our case demonstrates effective implication of spinal cord stimulation for intractable pain in hip dysplasia. Unfortunately in this case the lady also developed pain on opposite side because of dysplasia, which is being managed with the existing SCS with change of neuromodulation settings.

**Conclusions:** Spinal cord stimulation is an effective method of managing complex neuropathic pain in gluteal region and legs due to hip dysplasia.

**References:** 1)Good pain relief in symptomatic hip dysplasia, 32 patients followed for 4 years Francesco Poggiacomi, André Stark Acta Orthopaedica Volume 76, 2005 - Issue 1 2 Predictors of Pain Relief Following Spinal Cord Stimulation in Chronic Back and Leg Pain and Failed Back Surgery Syndrome: A Systematic Review and Meta-Regression Analysis Rod S. Taylor PhD , Mehul J. Desai MD Pain Practice, Volume 14, Issue 6, 2014 489–505

**Keywords:** Periacetabular osteotomy, Spinal cord stimulation, Hip dysplasia

**Topic:** 02. Neuroprosthetics and Neural Engineering

## **SOMATOTOPY OF SENSORY THALAMUS: CONTRIBUTION OF DIRECTIONAL DEEP BRAIN STIMULATION IN A GROUP OF PATIENTS TREATED FOR CHRONIC NEUROPATHIC REFRACTORY PAIN**

### **E-POSTER VIEWING**

Aurélie Leplus<sup>1</sup>, Michel Lanteri-Minet<sup>2</sup>, Denys Fontaine<sup>1</sup>

<sup>1</sup>Neurosurgery, University Hospital of Nice, NICE, France, <sup>2</sup>Pain, University Hospital of Nice, Nice, France

**Introduction:** Deep brain stimulation (DBS) of sensory thalamus is surgical technique used to treat chronic neuropathic refractory pain. A few study who evaluated directional stimulation (in the subthalamic nucleus) showed a significant improvement of efficacy thresholds, an expansion of the therapeutic window and a reduction of adverse effects. The aim of this study was to evaluate the interest of directional DBS of the sensory thalamus in association with somatotopia.

**Methods/Materials:** Four patients (were from the EMOPAIN study which asses the feasibility and the safety of bilateral DBS of the anterior cingulum in association with sensory thalamus DBS contralateral to pain) with unilateral chronic neuropathic pain, refractory to conventional treatments were implanted in the contralateral sensory thalamus using the directional DBS electrodes. The effects of directional stimulation were compared to the omnidirectional stimulation. The therapeutic window was defined as the difference in mA between the threshold for clinical benefit of pain and the threshold of adverse effects. The coordinates for contacts of each electrode were reported on the stereotactic Atlas of Schaltenbrand and Wahren. The parasthesia location was matched with the location of each stimulating contact and compared with the already known somatotopy.

**Results:** The somatotopy found in the four patients was in accordance with the somatotopy of the previous data. All the patients showed a benefit of directional stimulation compared to omnidirectional and choosed this modality of stimulation. A best direction of stimulation was observed in all the patients. Compared to the omnidirectional stimulation, the therapeutic window in the best direction was 42,3% wider. The current of threshold producing meaningful therapeutic effect in the best direction was 35% lower than omnidirectional stimulation. No complications as a result of insertion of the dirrectional electrode was encountered. The side effects like unpleasant paresthesia or corticospinal effects were 50% reduced and permitted to improve the threshold.

**Discussion:** The small number of patients does not allow us to conclude significantly on the benefit of directional electrodes, it should also be noted that the atlas used determines a location in relation to known data and not in relation to the patient's anatomical variations.

**Conclusions:** Directional DBS in the senrory thalamus is feasible, alters adverse effects and efficacy thresholds in a highly individual manner compared to omnidirectional DBS. Directional stimulation permitted to orient the field of paraesthesia and to get a better therapeutic window. More patients in the study are needed to confirm these findings.

**References:** Anderson WS, O'Hara S, Lawson HC, Treede R-D, Lenz FA. Plasticity of pain-related neuronal activity in the human thalamus. *Prog Brain Res* 2006; 157: 353–364.  
Bittar RG, Kar-Purkayastha I, Owen SL, Bear RE, Green A, Wang S, et al. Deep brain stimulation for pain relief: a meta-analysis. *J Clin Neurosci Off J Neurosurg Soc Australas* 2005; 12: 515–519.  
Boccard SGJ, Pereira EAC, Moir L, Van Hartevelt TJ, Kringelbach ML, FitzGerald JJ, et al. Deep brain stimulation of the anterior cingulate cortex: targeting the affective component of chronic pain. *Neuroreport* 2014; 25: 83–88.  
Boccard SGJ, Prangnell SJ, Pycroft L, Cheeran B, Moir L, Pereira EAC, et al. Long-Term Results of Deep Brain Stimulation of the Anterior Cingulate Cortex for Neuropathic Pain. *World Neurosurg* 2017; 106: 625–637.

Combs HL, Folley BS, Berry DTR, Segerstrom SC, Han DY, Anderson-Mooney AJ, et al. Cognition and Depression Following Deep Brain Stimulation of the Subthalamic Nucleus and Globus Pallidus Pars Internus in Parkinson's Disease: A Meta-Analysis. *Neuropsychol Rev* 2015; 25: 439–454.

Contarino MF, Bour LJ, Verhagen R, Lourens MAJ, de Bie RMA, van den Munckhof P, et al. Directional steering: A novel approach to deep brain stimulation. *Neurology* 2014; 83: 1163–1169.

Davis KD, Kiss ZH, Tasker RR, Dostrovsky JO. Thalamic stimulation-evoked sensations in chronic pain patients and in nonpain (movement disorder) patients. *J Neurophysiol* 1996; 75: 1026–1037.

Davis KD, Lozano AM, Manduch M, Tasker RR, Kiss ZHT, Dostrovsky JO. Thalamic Relay Site for Cold Perception in Humans. *J Neurophysiol* 1999; 81: 1970–1973.

Dembek TA, Reker P, Visser-Vandewalle V, Wirths J, Treuer H, Klehr M, et al. Directional DBS increases side-effect thresholds-A prospective, double-blind trial. *Mov Disord Off J Mov Disord Soc* 2017; 32: 1380–1388.

Dostrovsky JO. Role of thalamus in pain. *Prog Brain Res* 2000; 129: 245–257.

Frankemolle AMM, Wu J, Noecker AM, Voelcker-Rehage C, Ho JC, Vitek JL, et al. Reversing cognitive-motor impairments in Parkinson's disease patients using a computational modelling approach to deep brain stimulation programming. *Brain J Neurol* 2010; 133: 746–761.

Gerhart KD, Yezierski RP, Fang ZR, Willis WD. Inhibition of primate spinothalamic tract neurons by stimulation in ventral posterior lateral (VPLc) thalamic nucleus: possible mechanisms. *J Neurophysiol* 1983; 49: 406–423.

Hamani C, Schwab JM, Rezai AR, Dostrovsky JO, Davis KD, Lozano AM. Deep brain stimulation for chronic neuropathic pain: long-term outcome and the incidence of insertional effect. *Pain* 2006; 125: 188–196.

Hassenbusch SJ, Pillay PK, Barnett GH. Radiofrequency cingulotomy for intractable cancer pain using stereotaxis guided by magnetic resonance imaging. *Neurosurgery* 1990; 27: 220–223.

Hemm S, Coste J, Gabrillargues J, Ouchchane L, Sarry L, Caire F, et al. Contact position analysis of deep brain stimulation electrodes on post-operative CT images. *Acta Neurochir (Wien)* 2009; 151: 823–829; discussion 829.

Hua SE, Garonzik IM, Lee JI, Lenz FA. Microelectrode studies of normal organization and plasticity of human somatosensory thalamus. *J Clin Neurophysiol Off Publ Am Electroencephalogr Soc* 2000; 17: 559–574.

Hua SE, Garonzik IM, Lee JI, Lenz FA. Microelectrode studies of normal organization and plasticity of human somatosensory thalamus. *J Clin Neurophysiol Off Publ Am Electroencephalogr Soc* 2000; 17: 559–574.

Lenz FA, Gracely RH, Baker FH, Richardson RT, Dougherty PM. Reorganization of sensory modalities evoked by microstimulation in region of the thalamic principal sensory nucleus in patients with pain due to nervous system injury. *J Comp Neurol* 1998; 399: 125–138.

Lenz FA, Kwan HC, Martin R, Tasker R, Richardson RT, Dostrovsky JO. Characteristics of somatotopic organization and spontaneous neuronal activity in the region of the thalamic principal sensory nucleus in patients with spinal cord transection. *J Neurophysiol* 1994; 72: 1570–1587.

Lenz FA, Seike M, Richardson RT, Lin YC, Baker FH, Khoja I, et al. Thermal and pain sensations evoked by microstimulation in the area of human ventrocaudal nucleus. *J Neurophysiol* 1993; 70: 200–212.

Levy RM, Lamb S, Adams JE. Treatment of chronic pain by deep brain stimulation: long term follow-up and review of the literature. *Neurosurgery* 1987; 21: 885–893.

Little S, Pogossyan A, Neal S, Zavala B, Zrinzo L, Hariz M, et al. Adaptive deep brain stimulation in advanced Parkinson disease. *Ann Neurol* 2013; 74: 449–457.

Mai JK, Majtanik M. Toward a Common Terminology for the Thalamus. *Front Neuroanat* 2019; 12: 114.

Maks CB, Butson CR, Walter BL, Vitek JL, McIntyre CC. Deep brain stimulation activation volumes and their association with neurophysiological mapping and therapeutic outcomes. *J Neurol Neurosurg Psychiatry* 2009; 80: 659–666.

Ohara S, Lenz FA. Medial lateral extent of thermal and pain sensations evoked by microstimulation in somatic sensory nuclei of human thalamus. *J Neurophysiol* 2003; 90: 2367–2377.

Ohara S, Weiss N, Lenz FA. Microstimulation in the region of the human thalamic principal somatic sensory nucleus evokes sensations like those of mechanical stimulation and movement. *J Neurophysiol* 2004; 91: 736–745.

Pollo C, Kaelin-Lang A, Oertel MF, Stieglitz L, Taub E, Fuhr P, et al. Directional deep brain stimulation: an intraoperative double-blind pilot study. *Brain* 2014; 137: 2015–2026.

Pollo C, Villemure JG. Rationale, mechanisms of efficacy, anatomical targets and future prospects of electrical deep brain stimulation for epilepsy. *Acta Neurochir Suppl* 2007; 97: 311–320.

Pollo C, Villemure J-G, Vingerhoets F, Ghika J, Maeder P, Meuli R. Magnetic resonance artifact induced by the electrode Activa 3389: an in vitro and in vivo study. *Acta Neurochir (Wien)* 2004; 146: 161–164.

Rainville P. Brain mechanisms of pain affect and pain modulation. *Curr Opin Neurobiol* 2002; 12: 195–204.

Reynolds DV. Surgery in the rat during electrical analgesia induced by focal brain stimulation. *Science* 1969; 164: 444–445.

Richardson DE, Akil H. Pain reduction by electrical brain stimulation in man. Part 1: Acute administration in periaqueductal and periventricular sites. *J Neurosurg* 1977; 47: 178–183.

Rodriguez-Oroz MC, Rodriguez M, Guridi J, Mewes K, Chockkman V, Vitek J, et al. The subthalamic nucleus in Parkinson's disease: somatotopic organization and physiological characteristics. *Brain J Neurol* 2001; 124: 1777–1790.

Schmid A-C, Chien J-H, Greenspan JD, Garonzik I, Weiss N, Ohara S, et al. Neuronal responses to tactile stimuli and tactile sensations evoked by microstimulation in the human thalamic principal somatic sensory nucleus (ventral caudal). *J Neurophysiol* 2016; 115: 2421–2433.

Schüpbach WMM, Chabardes S, Matthies C, Pollo C, Steigerwald F, Timmermann L, et al. Directional leads for deep brain stimulation: Opportunities and challenges: Directional Leads For DBS. *Mov Disord* 2017; 32: 1371–1375.

Stefurak T, Mikulis D, Mayberg H, Lang AE, Hevenor S, Pahapill P, et al. Deep brain stimulation for Parkinson's disease dissociates mood and motor circuits: a functional MRI case study. *Mov Disord Off J Mov Disord Soc* 2003; 18: 1508–1516.

Steigerwald F, Müller L, Johannes S, Matthies C, Volkmann J. Directional deep brain stimulation of the subthalamic nucleus: A pilot study using a novel neurostimulation device. *Mov Disord Off J Mov Disord Soc* 2016; 31: 1240–1243.

Sterio D, Rezai A, Mogilner A, Zonenshayn M, Gracies JM, Kathirithamby K, et al. Neurophysiological modulation of the subthalamic nucleus by pallidal stimulation in Parkinson's disease. *J Neurol Neurosurg Psychiatry* 2002; 72: 325–328.

Temel Y, Kessels A, Tan S, Topdag A, Boon P, Visser-Vandewalle V. Behavioural changes after bilateral subthalamic stimulation in advanced Parkinson disease: a systematic review. *Parkinsonism Relat Disord* 2006; 12: 265–272.

Tsubokawa T, Yamamoto T, Katayama Y, Moriyasu N. Clinical results and physiological basis of thalamic relay nucleus stimulation for relief of intractable pain with morphine tolerance. *Appl Neurophysiol* 1982; 45: 143–155.

Wilkinson HA, Davidson KM, Davidson RI. Bilateral anterior cingulotomy for chronic noncancer pain. *Neurosurgery* 1999; 45: 1129–1134; discussion 1134–1136.

Hassler, R. (1959). "Anatomy of the Thalamus," in *Introduction to Stereotaxic Operations With an Atlas of the Human Brain*, eds G. Schaltenbrand and P. Bailey (Stuttgart; New York, NY: Georg Thieme Verlag), 230–290.

Hassler, R. (1977). "Architectonic organization of the thalamic nuclei," in *Atlas for Stereotaxy of the Human Brain: With an Accompanying Guide*, 2nd Edn., eds G. Schaltenbrand and W. Wahren (Stuttgart: Thieme).

G.J. Mazars Intermittent stimulation of nucleus ventralis posterolateralis for intractable pain *Surg Neurol*, 4 (1975), pp. 93–95.

**Keywords:** Directional deep brain stimulation, neuropathic pain, Sensory thalamus, Directional electrode

# EFFICACY OF MOTOR IMAGERY AND ACTION OBSERVATION APPROACH THROUGH BRAIN-COMPUTER INTERFACE NEUROGAME IN VIRTUAL REALITY ON PAIN MANAGEMENT IN PARKINSON'S DISEASE PATIENTS: A STUDY PROTOCOL

## E-POSTER VIEWING

Yeray González Zamorano<sup>1</sup>, Josué Fernández Carnero<sup>2</sup>, Francisco José Sánchez Cuesta<sup>3</sup>, Aida Arroyo Ferrer<sup>3</sup>, Pedro Serrano López-Terradas<sup>4</sup>, Juan Pablo Romero Muñoz<sup>3,4</sup>

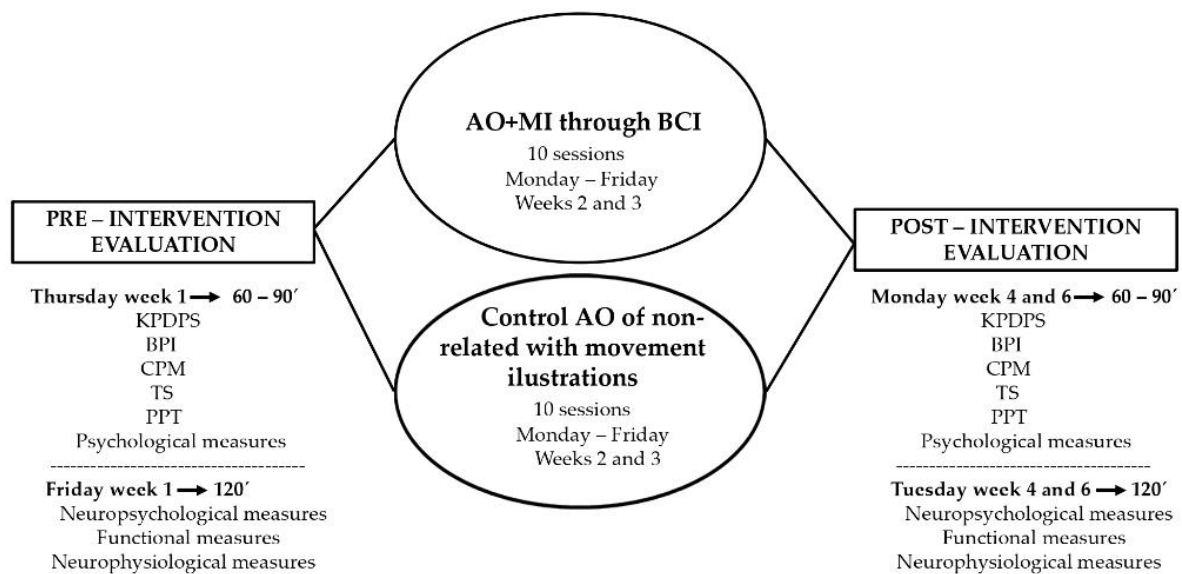
<sup>1</sup>Escuela Internacional De Doctorado En Ciencias De La Salud. Department Of Physical Therapy, Occupational Therapy, Rehabilitation And Physical Medicine, Universidad Rey Juan Carlos, Alcorcón, Spain, <sup>2</sup>Department Of Physical Therapy, Occupational Therapy, Rehabilitation And Physical Medicine, Universidad Rey Juan Carlos, Alcorcón, Spain, <sup>3</sup>Facultad De Ciencias Experimentales, Universidad Francisco de Vitoria, Pozuelo de Alarcón, Spain, <sup>4</sup>Cerebral Damage Unit, Hospital Beata María Ana, Madrid, Spain

**Introduction:** Pain currently affects 85% of Parkinson's Disease (PD) patients and is under-reported in most cases, leading to a high impact on their quality of life. The election treatment for PD patients is levodopa, but it has controversial results for the treatment of pain. "On" condition is considered when levodopa is acting while "off" condition is when not. PD patients have more hyperalgesia than healthy subjects, especially in "off" condition. Pain and off condition in PD have been related to low cortical excitability, suggesting that new therapies influencing this aspect may be effective for the management of pain in these patients. Action Observation (OA) combined with Motor Imagery (MI) increase corticospinal excitability in M1, correlating with improvements in pain processing features and clinical pain similar to physical exercise performance. The main objective of this study is to develop and validate an AO+MI based protocol for the treatment of pain in PD subjects in "on" and "off" conditions.

**Methods/Materials:** The project was designed after an extensive review of the available protocols using AO+MI. A parallel, controlled, double-blinded, randomized clinical trial will be conducted. For the analysis of the results (effectivity and correlation of identified response prediction markers), parametric tests will be used if the sample allows it. The analyses will be completed with non-parametric tests and residual, period, and sequence effect checks will be made. (Confidence level of 0.95).

**Results:** The AO+MI protocol was defined for 10 sessions of 20 minutes. Patients will play a virtual reality "neurogame" by means of a Brain-Computer Interface that allows them to row in a first-person view boat through their mental movements, with the goal of collecting flags in an established period of time.

Main Outcomes	Secondary Outcomes
Kings Parkinson's Disease Pain Scale (KPDPS)	Psychological
Brief Pain Inventory (BPI)	Functional
Pressure Pain Threshold (PPT)	Neuropsychological
Conditioned Pain Modulation (CPM)	Neurophysiological
Temporal Summation (TS)	



**Discussion:** This is the first study using an AO+MI approach to treat pain in PD patients. Mental representation combined with neurofeedback and videogames may enhance endogenous pain modulation and counteract facilitatory nociception, correlating with a reduction in clinical perceived pain in PD patients. Psychological, functional, neuropsychological, and neurophysiological aspects may be determined in our results.

**Conclusions:** Our AO+MI approach may be an effective tool for PD pain management.

**References:** 1. Chaudhuri KR, Schapira AHV. Non-motor symptoms of Parkinson's disease: dopaminergic pathophysiology and treatment. *Lancet Neurol.* mayo de 2009;8(5):464-74. 2. S S, N V, Dwc C, M F, Ah E. Pain sensitivity in Parkinson's disease: Systematic review and meta-analysis. Vol. 48, *Parkinsonism & related disorders. Parkinsonism Relat Disord*; 2018. 3. Wright DJ, Williams J, Holmes PS. Combined action observation and imagery facilitates corticospinal excitability. *Front Hum Neurosci.* 27 de noviembre de 2014;8. 4. Vourvopoulos A, Ferreira A, Bermúdez i Badia S. *NeuRow: An Immersive VR Environment for Motor-Imagery Training with the Use of Brain-Computer Interfaces and Vibrotactile Feedback.* 2016.

**Keywords:** Motor Imagery, Pain, Parkinson's Disease, Action Observation

**Topic:** 03. Socioeconomics

## **DEVELOPING AN ADVANCED PAIN NEUROMODULATION PROGRAM IN COSTA RICA'S PUBLIC HEALTH SYSTEM**

### **E-POSTER VIEWING**

Gabriel Carvajal

Interventional Pain Unit, Centro Nacional de Control del Dolor y Cuidados Paliativos, San José, Costa Rica

**Introduction:** Costa Rica is a 5 million person country located in Central America, it has upper middle income and a public universal health system assured by the Caja Costarricense de Seguro Social (CCSS) that covers more than 90% of health needs for its inhabitants. A nationwide pain and palliative care program founded in 1999 exists and currently articulates 57 pain and palliative care clinics offering 112201 consultations yearly. These pain clinics offer close follow-up to vulnerable populations focusing mainly on pharmacological and noninterventional pain management techniques and may consider referral to a National Pain Center -an ambulatory pain and palliative care center located in the capital city San José- for difficult cases. The need for higher complexity techniques was identified for these particular cases: neuromodulation implantable techniques and radiofrequency lesioning were considered the main therapeutic needs to develop when the project was first presented in 2015.

**Methods/Materials:** International cooperation allowed physician training with financing by the CCSS: a structured fellow training program was organized in two specialized centers in France (Centre Paul Papin and Hôpital Foch, France). Initial training was completed in December 2018. A specific neuromodulation team was organized in Costa Rica at the National Pain Center including 4 nurses, 2 physicians and 1 assistant. Support services were coordinated for specific cases: pharmacy, social work and psychology. Following this stage, funding destined for equipment allowed to acquire the neuromodulation devices and to equip the operating room with optimal conditions.

**Results:** On December 2018 the radiofrequency ablation program was started benefiting more than 60 patients. On January 2020 the first cases of refractory cancer pain were scheduled for intrathecal pump implantation. This advanced pain neuromodulation program will initially benefit 130 patients annually and may grow as education and personnel is assigned to the program. A thorough review of the program results is programmed for 2021.

**Discussion:** Developing a neuromodulation program is a complex endeavor requiring highly specialized personnel and high costs associated with device implantation. Main difficulties relies on personnel training and technology acquisition.

**Conclusions:** Developing a neuromodulation program is a complex endeavor requiring highly specialized personnel and high costs associated with device implantation. This study shows a successful organized development of an advanced pain neuromodulation unit in a middle income country social public security system.

**References:** 1) <https://data.worldbank.org/country/costa-rica> 2) Hoelscher C, Riley J, Wu C, Sharan A. Cost-Effectiveness Data Regarding Spinal Cord Stimulation for Low Back Pain. *Spine (Phila Pa 1976)*. 2017 Jul 15;42 Suppl 14:S72-S79. doi: 10.1097/BRS.0000000000002194. 3) Brogan SE, Winter NB, Abiodun A, Safarpour R A cost utilization analysis of intrathecal therapy for refractory cancer pain: identifying factors associated with cost benefit. *Pain Med*. 2013 Apr;14(4):478-86. doi: 10.1111/pme.12060 4) Carvajal G, Dupoirion D, Seegers V, Lebrech N, Boré F, Dubois PY, Leblanc D, Delorme T, Jubier-Hamon S Intrathecal Drug Delivery Systems for Refractory Pancreatic Cancer Pain: Observational Follow-up Study Over an 11-Year Period in a Comprehensive Cancer Center. *Anesth Analg*. 2018 Jun;126(6):2038-2046. doi: 10.1213/ANE.0000000000002903.



**Keywords:** Factors, Socioeconomic, Developing Countries, Social Security, Costa Rica

**Topic:** 03. Socioeconomics

## **CAN OPERATING TIME BE PREDICTABLE? A RETROSPECTIVE ANALYSIS OF TIME TAKEN TO IMPLANT A SPINAL CORD STIMULATOR USING PARAESTHESIA MAPPING VS ANATOMICAL PLACEMENT**

### **E-POSTER VIEWING**

Naresh Rajasekar, G. Baranidharan, Dudley Bush, Sheila Black, John Titterington  
Anaesthesia And Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom

**Introduction:** Spinal cord stimulators (SCS) implanted using paraesthesia mapping and anatomical placement are widely used in the UK. The National Institute of Clinical Excellence and Heath recommends the use of anatomically placed, non paraesthetic SCS for providing pain relief with shorter and predictable operating time. The purpose of the review was to assess this, with a view of optimising theatre efficiency. The aim of this review is to assess if anatomical placement (AP) of SCS offers shorter and more predictable operating times compared to paraesthesia mapping (PM).

**Methods/Materials:** All SCS implanted (both trial and permanent) at Leeds Teaching Hospitals between January 2018 and January 2020 were included in the review. Implants completed by operators that had done less than 10 cases in the study period were excluded. The time taken for each operator to implant a trial or full SCS using paraesthesia mapping (PM) and anatomical placement (AP) were then analysed.

**Results:** A total of 440 cases met the inclusion criteria. PM accounted for 194 cases and AP accounted for 246 cases, spread across four operators. The breakdown of the time taken from incision to closure per operator is summarised below:

Operator: mean +/- sd (mins)	AP trial: mean +/- sd(mins)	PM full: mean +/- sd (mins)
25.2	42.3 ± 21.3	96.1 ± 22.6
15.5	21.9 ± 10.5	56.6 ± 18.3
13.8	27.6 ± 13.3	70.3 ± 23.5
18.2	43.3 ± 14.8	80.3 ± 17.8

Operators performed AP SCS implants (trial and full) quicker than PM SCS (p=0.041) but there was no statistical significant difference in predictability (p=0.08).

**Discussion:** Different operators work at different speeds so the same number of patients cannot be booked on each operating list. Theatre efficiency is also affected by anaesthetic time and theatre turn over time. Although AP SCS implantation was quicker, the variability in times from incision to closure for AP SCS and PM SCS were similar. Thus, theatre sessions can be planned efficiently for both AP and PM SCS.

**Conclusions:** This single centre analysis shows that anatomical placement of SCS offers shorter procedural time as suggested by NICE MTG41 but the predictability of procedural times is similar to paraesthesia mapping.

### **References:**

**Keyword:** NICE, theatre efficiency, paraesthesia, anatomical placement

## CHRONIC PAIN AFTER SPINAL SURGERY (CPASS), A SOCIAL PAIN ? INFLUENCE AND MECHANISMS OF THE SOCIAL GRADIENT IN PATIENTS WITH CPASS

### E-POSTER VIEWING

Nicolas Naiditch, Amine Ounajim, Maxime Billot, Philippe Rigoard  
Prismatics, Hospital University of Poitiers, Poitiers, France

**Introduction:** The social gradient, or position in the social hierarchy, is one of the major determinants of health (1). It influences development and evolution of many chronic diseases such as diabetes or cancer (2). Among them, chronic pain is one of the most important, in terms of prevalence and social, individual and economic impact. The goal of this study is to highlight the importance of the social gradient in patients with Chronic Pain After Spinal Surgery (CPASS) and to examine its influence on clinical, psychological and social dimension.

**Methods/Materials:** Data from 200 CPASS patients were analyzed from the observational, prospective, multicentric PREDIBACK study. The social gradient was assessed using the Profession and Socio-professional Category (PSC) of patients. Multivariate analyses were conducted to compare patients at the bottom and those at the top of the social hierarchy on (i) the Oswestry Disability Index (ODI), (ii) the Fear-Avoidance Beliefs Questionnaire-Work (FABQ-W), (iii) the perception of psychological therapy, (iv) the consultation with a mental health professional, (v) the Pain Catastrophizing Scale (PCS), and (vi) lifestyles (tobacco consumption and sport practice before the onset of pain).

**Results:** Our results indicated that the prevalence of CPASS was higher in patients at the bottom of the social hierarchy. In fact, 82.2% of the population in the PREDIBACK study belonged to PCS employees and workers. Patients at the bottom of the social hierarchy had a significant poorer perception of psychologist's usefulness, a higher score of FABQ-W and PCS than patients at the top of the social hierarchy ( $p<0.05$ ). Patients at the bottom of the social hierarchy also had significantly fewer psychological consultations and less healthy lifestyle than patients at the top of social hierarchy ( $p<0.05$ ). Patients at the top of the social hierarchy tended to have higher ODI scores than patients at the bottom of the social hierarchy ( $p<0.10$ ).

**Discussion:** The 82.2% of employees or workers observed in the CPASS PREDIBACK population represent an overrepresentation of 32.1 points compared to the French demographic structure. Patients suffering from CPASS and implanted with a neurostimulation device are thus likely to belong overwhelmingly to popular social categories. This could imply special care in order to reduce the consequences of social inequalities in health and optimize outcomes.

**Conclusions:** Our results suggest (i) that CPASS tends to affect more patients at the bottom of the social hierarchy, (ii) the lesser acceptance of the psychological dimension of pain in patients at the bottom of the social hierarchy.

**References:** (1) Marmot M. Social Determinants of Health Inequalities. The Lancet. Volume 365, Issue 9464, 19–25 March 2005, Pages 1099-1104. (2) Cockerham W, Hamby B, Oates G. The Social Determinants of Chronic Disease. The Lancet. Volume 52, Issue 1, Supplement 1, January 2017, Pages S5-S12.

**Keywords:** Spinal cord stimulation, Social gradient, Failed Back Surgery Syndrome, Chronic Pain After Spinal Surgery, Social determinants of health

**Topic:** 03. Socioeconomics

**BIG DATA: WHAT CAN WE LEARN FROM A RETROSPECTIVE STUDY ON 959 SPINE SURGERIES WITH A FOLLOW-UP OF 15 YEARS ON THE PATHWAY TO NEUROMODULATION?**

**E-POSTER VIEWING**

Mark Plazier<sup>1,2,3</sup>, Vincent Raymaekers<sup>3</sup>, Wim Duyvendak<sup>1,3</sup>, Peter Donkersloot<sup>1,3</sup>, Maarten Wissels<sup>1,3</sup>, Eric Put<sup>1,3</sup>, Gert Roosen<sup>1,3</sup>, Sven Bamps<sup>1,3</sup>, Steven Vanvolsem<sup>1,3</sup>

<sup>1</sup>Chair, Study and education center Neurosurgery Virga Jesse, Hasselt, Belgium, <sup>2</sup>Medicine, University of Hasselt, Hasselt, Belgium, <sup>3</sup>Neurosurgery, Jessa Hospital, Hasselt, Belgium

**Introduction:** Low back pain (LBP) has a lifetime prevalence of 84% and imposes a high economical burden. Treatment is focused on preventing chronic pain. Research has shown the efficacy of treatment options. However, less is known about who benefits the most from which therapy and when they should be positioned in the treatment algorithm. This is highly important for the treatment efficacy for neuromodulation. The aim of this study was to investigate the patients flow and need for additional surgery after first low back surgery. Next we analysed the patients who developed chronic LBP and were treated with SCS.

**Methods/Materials:** In this retrospective study, data of all patients who underwent first time surgery from 2000 to 2004 were included. After 10-15 year patients were contacted about their quality of life (EuroQol-5D) and life and health perception (EQ-VAS).

**Results:** 959 patients underwent surgery at the lower back area. Follow-up time ranged from 13 to 17 years. 225 patients (23.5%) underwent a second surgery. In total 20 patients (2.1%) developed chronic neuropathic back pain and received SCS therapy. Ten years post-surgery, 438 (45.7%) patients completed the QoL and low back pain questionnaires. The health-related quality of life and health situation were significantly lower in patients with multiple surgeries ( $p < 0.001$ ).

**Discussion:** The study results indicate that large data sets, with multiple outcome measurements and long-term follow-up are necessary to improve our knowledge and to optimize the therapeutic pathway. In that way we might learn how to select a patient for the right treatment or treatments at the right moment and shorten the circulation in our health-care system. This might optimize treatment results and learn us where to ideally position neuromodulation

**Conclusions:** Big Data is the future to guide is to answer the question: Which treatment should be provided to Which patient at Which time. A prospective collection and registry is mandatory to provide the answers to this question

**References:**

**Keywords:** Big Data, Real world data, profiling, pathway to neuromodulation

**Topic:** 03. *Socioeconomics*

**PSYCHOLOGISTS IN PAIN NEUROMODULATION (PIPIN): GOOD PRACTICE GUIDELINES FOR THE PSYCHOLOGICAL ASSESSMENT OF PATIENTS FOR NEUROMODULATION.**

**E-POSTER VIEWING**

Simon Prangnell<sup>1</sup>, Anna Graham<sup>2</sup>, John O'Sullivan<sup>3</sup>, Shoma Khan<sup>4</sup>, Hazel O'Dowd<sup>5</sup>

<sup>1</sup>Psychological Medicine, Oxford University Hospitals NHS Trust, Oxford, United Kingdom, <sup>2</sup>Pain Management, NHS Glasgow and Greater Clyde, Glasgow, United Kingdom, <sup>3</sup>Pain Management, Chelsea and Westminster NHS Trust, London, United Kingdom, <sup>4</sup>Clinical Psychology, University College London Hospital NHS Trust, London, United Kingdom, <sup>5</sup>Clinical Psychology, North Bristol NHS Trust, Bristol, United Kingdom

**Introduction:** The Psychologists In Pain Neuromodulation (PIPIN) was convened by clinical psychologists working in UK neuromodulation centres as a forum to share, discuss and debate good practice in the psychological management of neuromodulation patients. Psychological distress is highly prevalent in neuromodulation patients (up to 50%) and several good practice guidelines (e.g. the British Pain Society Guidelines on Spinal Cord Stimulation) highlight the importance of an MDT approach to preoperative assessment, including a psychological assessment. Furthermore, the recently developed e-health online patient selection tool makes specific recommendations for patients requiring psychological evaluation prior to surgery. Despite the prevalence of distress and acceptance of the need for psychological assessment, there are no guidelines as to what constitutes good or best practice in the field of psychological assessment within neuromodulation services.

**Methods/Materials:** Given the lack of guidance for clinicians, the PIPIN panel undertook a mapping exercise to establish current practice in UK neuromodulation centres with a view to using this to develop recommendations for practice. The intention is to share these guidelines with colleagues working across European neuromodulation centres.

**Results:** Thirty seven registered practitioner psychologists comprise the panel. Information regarding patient pathways, assessment tools, approaches to assessment and treatment programmes was collated by the panel to produce a map of current practice in the UK.

**Discussion:** The panel will meet in April 2020 to review the material gained from the mapping exercise and then make a consensus judgement on what would be regarded as minimum safe practice, good practice and best practice. We intend to disseminate this widely to colleagues working across neuromodulation centres in Europe and further afield and hope to present the results from this process at the European Congress in Paris.

**Conclusions:** The PIPIN panel guidelines will provide clear recommendations for the psychological assessment and management of neuromodulation patients.

**References:**

**Keywords:** multidisciplinary assessment, psychological comorbidity, mental health, psychological distress, neuromodulation, psychological assessment

**Topic:** 03. Socioeconomics

**FACILITATING ACCESS TO INTRATHECAL ANALGESIA FOR CANCER PATIENTS SUFFERING INTRACTABLE PAIN AND LIVING FAR FROM EXPERT CENTERS**

**E-POSTER VIEWING**

Yves Marie Pluchon<sup>1</sup>, Denis Dupoirion<sup>2</sup>

<sup>1</sup>Loire Atlantique, CHD VENDEE, LA ROCHE SUR YON, France, <sup>2</sup>Anesthesiology And Pain Medicine, Institut de Cancérologie de l'Ouest, ANGERS, France

**Introduction:** Intrathécal drug delivery systems (IDDS) are efficient to manage refractory cancer pain but implantation of intrathécal pumps are offered only in expert centres and pumps refills requires regular travels while these cancer patients are increasingly fragile and tired. In our hospital, in a rural area, we wished to facilitate access to IDDS for all patients who require, even those leave far from cancer centers. Therefore, we tried to find solutions to offer IDDS to these patients.

**Methods/Materials:** After validation delivered during a regional multidisciplinary meeting by video conference, patients are implanted in the expert cancer center 140 kms away from our hospital. Few days after, once pain relief is obtained, patients are discharged and pumps and refills are then managed in our hospital close to their home. We perform computerized prescriptions ( Anathec° Alma ) Mixtures are prepared and controlled by the compounding pharmacy of the expert center and transported in sterile bags, in our hospital. Then we proceed to refills with quality level ( controlled syringes ) and reinforced safety ( surgical asepsis protocol ).

**Results:** Since February 2015, we have performed more than 1400 pump refills for 110 patients. This local management has also performed more 500 000 euros in sanitary travels.

**Discussion:** The kind of organization offer accessibility of such an invasive technique easier to all patients suffering refractory pain. This protocol is completed with the same quality and safety as in an expert center.

**Conclusions:** We also offer an improved quality of life compared to oral analgésic treatments for more patients.

**References:**

**Keyword:** cancer, IDDS, pump refill, intrathécal, intractable pain

## LONG-TERM OUTCOME OF SUBTHALAMIC NUCLEUS DEEP BRAIN STIMULATION FOR PARKINSON'S DISEASE: 10 YEARS AND BEYOND

### E-POSTER VIEWING

Hye Ran Park, Sun Ha Paek

Neurosurgery, Soonchunhyang University Seoul Hospital, Seoul, Korea, Republic of

**Introduction:** Deep brain stimulation (DBS) of the subthalamic nucleus (STN) has been accepted as an effective treatment for severe Parkinson's disease (PD). Although there have been some reports of long-term efficacy and safety after deep brain stimulation (DBS) surgery for PD, little is known about the fate of all patients. We performed a follow-up of all patients who undergone bilateral STN DBS surgery for PD before more than 10 years, and assessed the survival rate and long-term outcome of DBS.

**Methods/Materials:** We included all 81 patients including 37 males and 44 females who underwent bilateral STN DBS from March 2005 to Mar 2008 at single institution. Whether or not the patients were alive or dead was investigated, and pre- and postoperative follow-up assessments including UPDRS score were analyzed.

**Results:** The mean age at the time of surgery was 72 years (range, 27-82), and the median clinical follow-up duration was 145 months. Thirty-five patients (43%) died during the follow-up period. The mean duration from the DBS surgery to death was  $110.46 \pm 40.8$  months (range, 0-155). Thirteen patients (37.1%) died because of disease progression, followed by 11 patients (31.4%) died due to pneumonia. The cumulative survival rate was as follows:  $98.8 \pm 1.2\%$  (1 yr),  $97.5 \pm 1.7\%$  (3 yr),  $95.1 \pm 2.4\%$  (5 yr), and  $79.0 \pm 4.5\%$  (10 yr). Of the 46 surviving patients (57%), 36 continued to receive follow-up assessment including the UPDRS scale, but 10 survivors denied follow-up at hospitals due to economic cause or inability to move. Twelve patients (14.8%) underwent revision surgery to correct the electrode location, and the mean interval period between DBS and revision surgery was 14.5 months.

**Discussion:** STN is the most common target of advanced PD for motor fluctuation and dyskinesia. It allows a significant reduction of anti-PD medications. However its long-term efficacy are still in debate. This study is one of the largest and longest follow-up studies of advanced PD patients without follow-up loss of each individual after bilateral STN DBS. Compared with other previous studies, this study shows that follow-up scales including UPDRS III, LEDD, and daily off-time remains fairly improved over long time after bilateral STN DBS.

**Conclusions:** STN DBS is a safe and effective treatment in selective patients with PD. This study was based on the long-term follow-up of large-scale patients, and would contribute to elucidate the long-term fate of patients who underwent bilateral STN DBS for PD.

**References:** 1. Benabid AL, Chabardes S, Mitrofanis J, Pollak P. Deep brain stimulation of the subthalamic nucleus for the treatment of Parkinson's disease. *The Lancet Neurology* 2009;8:67-81. 2. Deuschl G, Schade-Brittinger C, Krack P, et al. A randomized trial of deep-brain stimulation for Parkinson's disease. *N Engl J Med* 2006;355:896-908. 3. Weaver FM, Follett K, Stern M, et al. Bilateral deep brain stimulation vs best medical therapy for patients with advanced Parkinson disease: a randomized controlled trial. *JAMA* 2009;301:63-73. 4. Lee JY, Han JH, Kim HJ, Jeon BS, Kim DG, Paek SH. STN DBS of advanced Parkinson's disease experienced in a specialized monitoring unit with a prospective protocol. *Journal of Korean Neurosurgical Society* 2008;44:26. 5. Kim HJ, Paek SH, Kim JY, et al. Two-year follow-up on the effect of unilateral subthalamic deep brain stimulation in highly asymmetric Parkinson's disease. *Mov Disord* 2009;24:329-35. 6. Kim HJ, Jeon BS, Paek SH, et al. Bilateral subthalamic deep brain stimulation in Parkinson disease patients with severe tremor. *Neurosurgery* 2010;67:626-32; discussion 32. 7. Kim H-J, Paek SH, Kim J-Y, et al. Chronic

subthalamic deep brain stimulation improves pain in Parkinson disease. Journal of neurology 2008;255:1889.

**Keyword:** Deep Brain Stimulation, Parkinson's Disease, Outcome



**Topic:** 04. Brain / 04a. Movement Disorders

**TRACTOGRAPHY AIDED DEEP BRAIN STIMULATION SURGERY FOR ALLEVIATING FREEZING OF GAIT IN INTRACTABLE PARKINSON'S DISEASE PATIENTS- A SINGLE-INSTITUTION CASE-SERIES AND REVIEW OF LITERATURE**

**E-POSTER VIEWING**

Anirban Deep Banerjee

Department Of Neurosurgery, Institute of Neurosciences, Medanta- The Medicity, Gurugram, India

**Introduction:** Tractography of the brain provides detailed information about specific neural-circuits and their connections. Given that the efficacy of deep brain stimulation (DBS) surgery probably depends on precise and accurate targeting of these circuits, better surgical planning using information obtained from fibre-tracking has been shown to improve surgical outcomes in intractable Parkinson's disease (PD), pertaining to certain tenacious symptoms such as freezing of gait. However, there is a distinct paucity of literature in this regard.

**Methods/Materials:** We prospectively analysed diffusion tensor imaging (DTI) based connectivity patterns that characterized clinically beneficial electrodes: fifty electrodes in twenty-five intractable Parkinson's disease patients, with medically refractory freezing of gait in ON-time, who underwent deep brain stimulation of the subthalamic nucleus (STN), using deterministic tractography with diffusion-tensor data. The Unified Parkinson's Disease Rating Scale (UPDRS)(III) score, axial and tremor sub-scores were analysed. Freezing of gait (FOG) was assessed by a questionnaire and stand-walk-sit test. The minimum study follow-up period was 6 months.

**Results:** At six-months follow-up, substantial improvements were also noted in the 'with-DTI' cohort of patients in terms of UPDRS(III)scores (14.29 $\pm$ 6.81 vs. 27.62 $\pm$ 9.47), axial sub-scores (2.03 $\pm$ 1.96 vs. 7.24 $\pm$ 3.01), FOG questionnaire scores (3.98 $\pm$ 5.03 vs. 8.73 $\pm$ 5.77) and stand-walk-sit test scores; although not statistically significant.

**Discussion:** The electrode-contacts modulating white-matter tracts directed to the supplementary motor area objectively enhanced the surgical efficacy, especially towards alleviating freezing of gait, in comparison to our prior conventional surgical cohort of Parkinson's disease patients of similar specifications.

**Conclusions:** Our experience corroborates that DBS can be used to modulate the neural-circuit involved in coordination, so as to enhance its efficacy in intractable Parkinson's disease, especially with regard to freezing of gait.

**References:** 1. N Vanegas-Arroyave, Lauro PM, Huang L, Hallett M, Horovitz SG, Zaghloul KA, Lungu C. Tractography Patterns of Subthalamic Nucleus Deep Brain Stimulation. *Brain* 139 (Pt 4), 1200-10. Apr 2016. 2. Chen Y, Ge S, Li Y, Li N, Wang J, Wang X, et al. Role of the Cortico-Subthalamic Hyperdirect Pathway in Deep Brain Stimulation for the Treatment of Parkinson's Disease: A diffusion Tensor Imaging Study. *World Neurosurg* 114, e1079-e1085. Jun 2018. 3. Accolla EA, Ruiz MH, Horn A, Schneider G-H, Schmitz-Hubsch T, Draganski B, Kuhn AA. Brain Networks Modulated by Subthalamic Nucleus Deep Brain Stimulation. *Brain* 139 (Pt9), 2503-15. Sept 2016.

**Keyword:** Fibre-Tracking Deep Brain Stimulation Parkinson's Disease

## ACCURACY AND PRECISION OF FRAMELESS DBS TECHNIQUE CT CONE BEAM ASSISTED WITHOUT BONE FIDUCIALS

### E-POSTER VIEWING

Alessandro Izzo, Manuela D'Ercole, Beatrice Cioni, Alessandro Olivi, Tommaso Tufo  
Neurochirurgia, Policlinico A. Gemelli, Roma, Italy

**Introduction:** Frameless stereotactic surgery with fiducial-based registration is a technique with accuracy and clinical effectiveness compared with standard frame-based surgery. The intraoperative imaging system with a cone-beam CT scan could be useful to detect the location of the microelectrodes as well as to provide the registration scan for stereotaxy. The aim of our retrospective study is to analyze the accuracy and the limits of the fiducial-less technique in frameless DBS surgery CT cone-beam assisted

**Methods/Materials:** From January 2018 to December 2019, 32 consecutive patients with PD and Dystonia (63 leads implanted) underwent DBS surgery using the NexFrame® and the O-arm® registration system. In 10 cases, the patients underwent fiducial-based registration. The fiducial-less registration was performed in 22 patients. Our final lead position has been guided by pre-operative trajectory and intraoperative microelectrode recording and macrostimulation. The primary analysis was targeting accuracy, assessed comparing the location of the implant on the Oarm images with the planned target and calculating the radial error and the vector error. Secondly, we compared the errors of the two procedures.

**Results:** The mean vector error for the two procedures was between 2 and 3 mm, according with the literature. The radial errors and the vector errors of the fiducial based and fiducial-less registration were not significantly different. No differences have been found between additional passes needed to reach the targets in the two techniques

**Discussion:** Although there was a significant difference between the planned target and the final position of the lead, the overall accuracy of the procedures was acceptable, with a vector error between 2 and 3 mm, as reported in several studies

**Conclusions:** The DBS surgery based on fiducial-less registration with intraoperative O-arm scan and intra-operative neurophysiological mapping has been accurate and reliable, compared with the standard frameless procedure with fiducials

**References:** A. Roth et al, «Accuracy of frame-based and frameless systems for deep brain stimulation: A meta-analysis,» *Journal of Clinical Neuroscience*, pp. 70-75, 2018. M. Sharma et al, «Accuracy and safety of targeting using intraoperative “O-arm” during placement of deep brain stimulation electrodes without electrophysiological recordings,» *Journal of Clinical Neuroscience*, 2015. J. Toms, S. Martin et al, «A Comparative Study of Fiducial-Based and Fiducial-Less Registration Utilizing the O-Arm,» *Stereotact Funct Neurosurg.*, pp. 97(2):83-93, 2019.

**Keywords:** frameless, fiducials, accuracy, stereotaxy, dbs

## LONG-TERM EFFICACY OF PALLIDAL STIMULATION IN 20 PATIENTS WITH HUNTINGTON DISEASE

### E-POSTER VIEWING

Witold Libionka<sup>1</sup>, Monika Stomal-Słowińska<sup>2</sup>, Krzysztof Dzięgiel<sup>1</sup>, Beata Daniluk<sup>3</sup>, Wojciech Kloc<sup>1</sup>

<sup>1</sup>Neurosurgery, Copernicus Hospital, Gdańsk, Poland, <sup>2</sup>Neurosurgery, Specialist Hospital in Wałbrzych, Wałbrzych, Poland, <sup>3</sup>Institute Of Psychology, Maria Curie-Skłodowska University, Lublin, Poland

**Introduction:** Deep brain stimulation (DBS) is a well established treatment for hyperkinetic movement disorders. However, its role in Huntington disease (HD) requires further studies to ascertain optimal anatomical target and timing of the procedure. The aim of this prospective study is to assess effectiveness and safety of DBS in HD and to show how target selection and stimulation parameters affect motor and non-motor symptoms of HD.

**Methods/Materials:** 20 patients with genetically confirmed HD, with motor symptoms resistant to medications (15 women, 5 men, aged 27-50 years), who underwent DBS with octapolar electrodes implanted in the globus pallidus interna, externa and putamen (GPi-GPe-Pu), were followed up for 12-60 months. Four patients were diagnosed with juvenile HD. Symptoms were present 3-8 years before surgery and included choreatic movements (16 cases), muscle rigidity (4), dysarthria (16), dysphagia (11), gait disturbance (11), mild dementia (16). Patients with psychiatric symptoms were excluded. Surgical procedures were performed under local anesthesia, with microrecording and macrostimulation, using frame-based stereotaxy. Assessments with UHDRS and neuropsychologic tests were performed before and 1, 3, 12, 24, 36, 48 and 60 months after surgery. The study was approved by ethics committee.

**Results:** In all patients significant motor improvement was observed during the stimulation at the consecutive follow-up examinations (motor score improved on average of 35-45%; chorea of 51-62%). We also noted reduction of dysarthria (12 patients), dysphagia (6), imbalance (6) and subcortical dementia (2). There were no hemorrhagic or infectious complications. GPi-GPe stimulation at 30-130 Hz, 65-110  $\mu$ s and 1,5-3,5 mA was optimal.

**Discussion:** Majority of studies investigated GPi-DBS in HD. Chorea reduction was most consistent; the effects on other symptoms varied depending on disease severity and active contact location. In recent trial comparing GPi/GPe-DBS, the latter was more effective. Similarly, in GPi-DBS dorsal contacts were optimal. Such stimulation reestablishes the dorsolateral prefrontal and lateral orbitofrontal circuits responsible for cognitive symptoms in HD. The authors proposed combined GPi-GPe-Pu stimulation with single octapolar electrode. This gives better opportunities for optimal programming without increasing the surgical risk. Importantly, the observed improvement included not only motor, but also cognitive symptoms. This is in line with studies on GPe-DBS in HD, and in contrast with reported GPi-DBS cases.

**Conclusions:** This abstract adds to the evidence for the long-term efficacy and safety of DBS in Huntington disease. It shows effectiveness of stimulation in patients at an early disease state. The data should improve patient selection and treatment outcomes.

**References:** 1. Zittel S et al. Prospective evaluation of Globus pallidus internus deep brain stimulation in Huntington's disease. *Parkinsonism Relat Disord.* 2018;51:96-100. 2. Wojtecki L et al. Deep Brain Stimulation in Huntington's Disease-Preliminary Evidence on Pathophysiology, Efficacy and Safety. *Brain Sci.* 2016;6:E38. 3. Delorme C et al. Deep brain stimulation of the internal pallidum in Huntington's disease patients: clinical outcome and neuronal firing patterns. *J Neurol.* 2016;263:290-298. 4. Gonzalez V et al. Deep brain stimulation for Huntington's disease: long-term results of a prospective open-label study. *J Neurosurg.* 2014;121:114-22. 5. Velez-Lago FM et al.

Differential and better response to deep brain stimulation of chorea compared to dystonia in Huntington's disease. *Stereotact Funct Neurosurg.* 2013;91:129-33. 6. Moro E et al. Bilateral globus pallidus stimulation for Huntington's disease. *Ann Neurol.* 2004;56:290-4.

**Keywords:** Deep Brain Stimulation, Huntington disease

**Topic:** 04. Brain / 04b. Psychiatric Disorders

## **DIRECTIONAL DEEP BRAIN STIMULATION OF THE HYPOTHALAMUS: A PILOT STUDY USING A NOVEL NEUROSTIMULATION DEVICE**

### **E-POSTER VIEWING**

William Contreras Lopez<sup>1</sup>, Raquel C. Martinez<sup>2</sup>, Paula Navarro<sup>1</sup>, Eduardo Lopes Alho<sup>3</sup>, Erich Talamoni Fonoff<sup>4</sup>

<sup>1</sup>Funcional Neurosurgery, Universidad Autonoma de Bucaramanga, Bucaramanga, Colombia, <sup>2</sup>A. Laboratorio De Neurociencias, Hospital Sirio-Libanes, Sao paulo, Brazil, <sup>3</sup>Functional Neurosurgery, Universidad de Sao Paulo, Facultad de Medicina, Sao Paulo, Brasil, Sao paulo, Brazil, <sup>4</sup>Functional Neurosurgery, Universidad de Sao Paulo, Facultad de Medicina, Sao paulo, Brazil

**Introduction:** Aggressive behavior is a severe symptom of diseases with varying etiologies. Deep brain stimulation(DBS) in the posteromedial nucleus of the hypothalamus(pHyp) has been an alternative therapy for extreme cases with promising results. The aim of this article is evaluate the effect and safety of deep brain stimulation (DBS) in the postero-medial hypothalamus (PMHy) using eight-contact directional leads in patients with severe aggressiveness refractory to medical treatment.

**Methods/Materials:** A prospective cohort study was carried out in which patients with a diagnosis of severe aggressiveness and profound mental retardation with deterioration in quality of life and significant social impact. Patients were evaluated and selected by board including neurosurgeons, 2 psychiatrists, neurologists and social workers and approved by the institutional ethics committee of the FOSCAL International Clinic in Bucaramanga. Bilateral PMHy-DBS was performed with eight-contact directional electrodes. The primary outcome of the study was changes in aggressive behavior, which was measured by comparing the Overt Aggression Scale (OAS) and the Agitated Behavior Scale (ABC) before and after the DBS. Secondary outcomes were: side effects, change in quality of life, measured with the SF-36 questionnaire, body weight and the average of inappropriate sexual behaviors during the day. The follow-up included all scales at 1,3 and 6 months.

**Results:** Three patients (2 men and 1 woman, with ages between 22 and 26 years) were included. Two with a history of congenital rubella and one with neonatal meningitis. The average improvement in OAS at 6 months was 28.1%, on the ABC scale of 16.5%, also documenting an important improvement of the SF36 in the domains: physical role, body pain, general health, social functioning, emotional role and mental health. In one patient there was reduction of inappropriate sexual behaviors by 50%. No adverse events were reported associated with the ECP or the stimulation parameters and there were no changes in body weight.

**Discussion:** In this case series, all patients with pathological aggressiveness had a reduction of their outbursts of violence after pHyp DBS, without significant adverse effects. Similar with other studies previous published, however, several experimental data are available on this target, further studies are necessary to confirm the long-term efficacy and safety of this procedure.

**Conclusions:** In patients who meet the criteria for PMHy/DBS and are selected appropriately, ECP-HPM with directional leads is a safe alternative, with substantial improvement in quality of life.

**References:** (1) Hernando V, Pastor J, Pedrosa M, Peña E, Sola RG. Low-frequency bilateral hypothalamic stimulation for treatment of drug-resistant aggressiveness in a young man with mental retardation. *Stereotact Funct Neurosurg* 2008;86(4):219-223. (2) Torres CV, Sola RG, Pastor J, Pedrosa M, Navas M, García-Navarrete E, et al. Long-term results of posteromedial hypothalamic deep brain stimulation for patients with resistant aggressiveness. *J Neurosurg* 2013 Aug;119(2):277-287. (3) Benedetti-Isaac JC, Torres-Zambrano M, Vargas-Toscano A, Perea-Castro E, Alcalá-Cerra G, Furlanetti LL, et al. Seizure frequency reduction after posteromedial hypothalamus deep brain stimulation in drug-resistant epilepsy associated with intractable aggressive behavior. *Epilepsia* 2015 Jul;56(7):1152-1161. (4) Franzini A, Broggi G, Cordella R, Dones I, Messina G. Deep-brain

stimulation for aggressive and disruptive behavior. World Neurosurg 2013 Sep-Oct;80(3-4):S29.e11-14.

**Keywords:** Deep Brain Stimulation, aggressive Behavior, posteromedial hypothalamus, Aggression

**Topic:** 04. Brain / 04b. Psychiatric Disorders

**A DEEP LEARNING APPROACH TO EVALUATE SEX DIFFERENCES IN ANTIDEPRESSANT RESPONSE TO NEUROMODULATION USING EEG IN MAJOR DEPRESSIVE DISORDER**

**E-POSTER VIEWING**

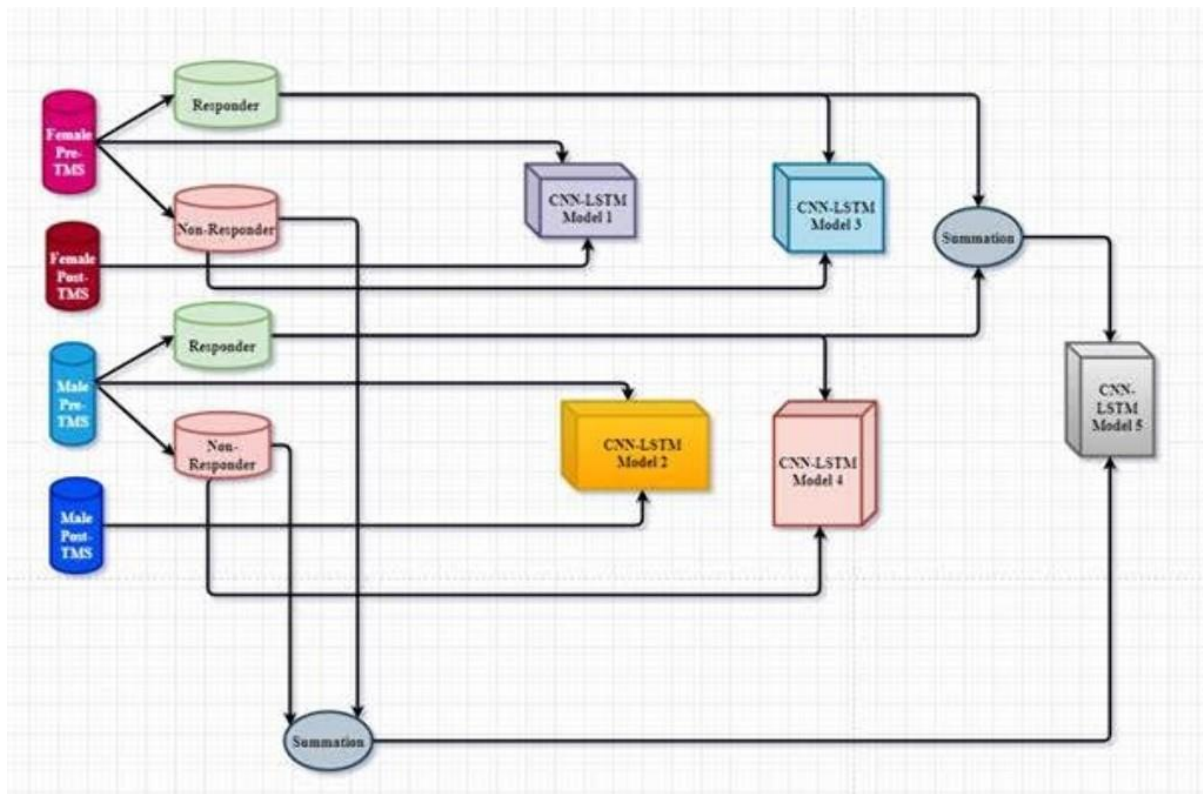
Maheen Adamson<sup>1</sup>, Abed Hadipour<sup>2</sup>, Turker Turkin<sup>3</sup>, Caglar Uyulan<sup>4</sup>, Reza Kazemi<sup>2</sup>, Angela Phillips<sup>5</sup>, Srijja Seenivasan<sup>6</sup>, Nevzat Tarhan<sup>7</sup>

<sup>1</sup>Rehabilitation/neurosurgery, VA Palo Alto/Stanford Medical School, Palo Alto, United States of America, <sup>2</sup>Psychology, University of Tehran, Tehran, Iran, <sup>3</sup>Department Ofcomputer Science And Engineering, Üsküdar University, Istanbul, Turkey, <sup>4</sup>Mechatronics Engineering, Bülent Ecevit University, Zonguldak, Turkey, <sup>5</sup>Psychiatry, VA Palo Alto/Stanford School of Medicine, Palo Alto, United States of America, <sup>6</sup>Rehabilitation Medicine, VA Palo Alto, Palo Alto, United States of America, <sup>7</sup>Faculty Of Humanities And Social Sciences, Uskudar University, Istanbul, Turkey

**Introduction:** Major depressive disorder (MDD) affects women more severely than men<sup>1</sup>, particularly in Iran where prevalence is two-fold.<sup>2</sup> There is no current research available for such sex differences in repetitive transcranial magnetic stimulation (rTMS), an efficacious MDD treatment.<sup>3</sup> Electroencephalography (EEG) serves as biomarker for rTMS treatment given its high temporal resolution, non-invasiveness, and relative affordability. <sup>4,5</sup> Deep learning (DL) algorithms can further classify these EEG signals to predict treatment responses.<sup>6,7,8</sup> In this study, five different EEG-based deep learning (DL) models were created to classify male and female subjects using their pre- and post-TMS raw EEG data.

**Methods/Materials:** Fifty MDD patients (25 men (Mean age= 35.5±13.2) and 25 women (Mean age=33.2±8.8) were enrolled in an open label rTMS study in Tehran. Repetitive TMS (1 Hz) was applied on the Right Dorsolateral Prefrontal Cortex (DLPFC) for 10 sessions. EEG data was recorded for 10 minutes with eyes open directly before and after treatment. EEG data was evaluated at pre- and post-TMS and compared to 50 healthy controls.

**Results:** 28 (57.1%) patients responded to the treatment. Significant decreases were observed in the Beck Depression Index (BDI) total score from pre- to post-treatment in males [ $P < .01$ ] and females [ $P < .01$ ]. This decrease was not significantly different between male and female ( $P \sim .058$ ). There was no significant difference between male and female for remission ( $P \sim .059$ ; remission rate = 36.7%). Using pre- and post TMS data, the first and second models classified females with 94.52% and males with 92.52% accuracy suggesting strong changes in EEG response. Using pre-TMS responder and non-responder EEG data, the third and fourth models classified females (91.54%) and males (98.15%) accuracy. The fifth model classified all participants at pre-TMS with 94.13% accuracy to predict TMS response.



Responder females = 11, NR females = 14. Males = 7 responders, 18 non responders.

**Discussion:** This is the first attempt to apply DL to study sex differences in EEG response to rTMS. The five models performed >91% accuracy in classifying pre- and post- TMS responses, model four classified responses in pre-TMS data significantly better in males than in females. Males respond better to TMS treatment but the fourth model does outperform males over females. Overall, the baseline pre-TMS EEG data achieved a 94% prediction accuracy.

**Conclusions:** Preliminary results of the models have wide implications in providing precise targets for future treatment planning in vulnerable populations, such as females with MDD, in various countries.

**References:** 1. Seney ML, Huo Z, Cahill K, et al. Opposite molecular signatures of depression in men and women. *Biol Psychiatry*. 2018;84(1):18-27. doi:10.1016/j.biopsych.2018.01.017 2. Garraee B, Zahedi Tajrishi K, Sheybani F, et al. Prevalence of major depressive disorder in the general population of Iran: A systematic review and meta-analysis. *Med J Islam Repub Iran*. 2019;33:151. doi:10.34171/mjiri.33.151 3. Phillips A, Sami S, Adamson M. Sex Differences in Neuromodulation Treatment Approaches for Traumatic Brain Injury: A Scoping Review. *J Head Trauma Rehabil*. 2020;35(6):412-429. doi:10.1097/HTR.0000000000000631 4. de la Salle S, Jaworska N, Blier P, Smith D, Knott V. Using prefrontal and midline right frontal EEG-derived theta cordance and depressive symptoms to predict the differential response or remission to antidepressant treatment in major depressive disorder. *Psychiatry Res Neuroimaging*. 2020;302:111109. doi:10.1016/j.pscychresns.2020.111109 5. de Aguiar Neto FS, Rosa JLG. Depression biomarkers using non-invasive EEG: A review. *Neurosci Biobehav Rev*. 2019;105:83-93. doi:10.1016/j.neubiorev.2019.07.021 6. Ay B, Yildirim O, Talo M, et al. Automated Depression Detection Using Deep Representation and Sequence Learning with EEG Signals. *J Med Syst*. 2019;43(7):205. doi:10.1007/s10916-019-1345-y 7. Craik A, He Y, Contreras-Vidal JL. Deep learning for electroencephalogram (EEG) classification tasks: a review. *J Neural Eng*. 2019;16(3):031001. doi:10.1088/1741-2552/ab0ab5 8. Abbasi B, Goldenholz DM. Machine learning applications in epilepsy. *Epilepsia*. 2019;60(10):2037-2047. doi:https://doi.org/10.1111/epi.16333

**Keywords:** sex, EEG, Females, rTMS, MDD, Deep learning



**Topic:** 04. Brain / 04c. Cognitive Disorders

## **SEX DIFFERENCES IN NEUROMODULATION TREATMENT APPROACHES FOR TRAUMATIC BRAIN INJURY: A SCOPING REVIEW**

### **E-POSTER VIEWING**

Angela Phillips<sup>1</sup>, Maheen Adamson<sup>2</sup>, Sohrab Sami<sup>2</sup>

<sup>1</sup>Psychiatry, VA Palo Alto/Stanford School of Medicine, Palo Alto, United States of America, <sup>2</sup>Neurosurgery, VA Palo Alto/Stanford School of Medicine, Union City, United States of America

**Introduction:** Research on mild traumatic brain injury (TBI) historically has focused on psychological, neurological and functional outcomes of mTBI, in a primarily male (~95%) cohort<sup>1</sup>. Recent studies point to this misrepresentation of female symptoms that in turn influence treatment strategies and outcomes<sup>1</sup>. Neuromodulatory interventions are now frequently used to treat TBI-related health problems, including treatments for mood, cognition and pain disorders. Due to the historical male bias in the recruitment and epidemiological reporting of TBI related research, there is limited understanding of the pathophysiology of TBI, management and treatment outcomes in females. As sex related variances in pharmacotherapy treatment outcomes are widely documented, there is an emerging need to provide guidelines on targeted treatment approaches for the female TBI population. To our knowledge, this is the first attempt to summarize and discuss the potential gaps in the literature as the field of neuromodulation moves toward the personalization of treatments across sexes in TBI populations.

**Methods/Materials:** This scoping review aims to outline the current reported sex differences in three neuromodulation interventions for TBI outcomes: repetitive transcranial magnetic stimulation (rTMS), deep brain stimulation (DBS), and transcranial electric stimulation (tES). Four research databases (PubMed, EMBASE, CINAHL, and PsycINFO) were electronically searched in February of 2020. Keywords included but were not limited to neuromodulation, brain stimulation, repetitive transcranial magnetic stimulation, deep brain stimulation, transcranial electric current stimulation, transcranial direct current stimulation, and traumatic brain injury, concussion, brain contusion, etc. Peer-reviewed, human adult subject clinical or rehabilitation studies were included, which excludes animal, pediatric and diagnostic studies.

**Results:** 22 empirical studies were identified for the final review including 4 controlled trials, 8 single or case series reports. 79% of studies included only male subjects, and a small percentage reported sex differences as a part of their methodological approach, analysis or discussion. Additionally, there is no research assessing medication dosage, menstrual cycle or menopausal changes that may influence outcomes from such treatments.

**Discussion:** This scoping review highlights the need for targeted studies of neuromodulation in female brain injury patients for better treatment outcomes.

**Conclusions:** Our review and recommendations of gender differences in TBI related neuromodulation research are hoped to contribute toward improved knowledge and development in personalized treatment for individuals with TBI, while ultimately striving to improve overall TBI rehabilitation outcomes.

### **References:**

**Keywords:** traumatic brain injury, neuromodulation, concussion, brain stimulation, neurorehabilitation

**Topic:** 04. Brain / 04c. Cognitive Disorders

**TRANSCUTANEOUS ELECTRICAL STIMULATION ON PC6, ST36, AND SP06 PREVENTS POSTOPERATIVE DELIRIUM AND IMPROVES COGNITIVE FUNCTION IN ELDERLY PATIENTS AFTER LUMBAR SURGERY**

**E-POSTER VIEWING**

Pegnfei Liu, Yutian Yu, Teng Gao, Yanting Hu, Jing Zhang, Yifan An, Wenzheng Yang, Binjiang Zhao, Tianzuo Li  
Anesthesiology, Beijing Shijitan Hospital, Capital Medical University, Beijing, China

**Introduction:** Delirium and cognition impairment are common complications in elderly patients after anesthesia and surgery. However, it remains unclear how to prevent these complications. Based on acupuncture theory, transcutaneous electrical stimulation (TES) improves brain function, which may be a preventive strategy. Therefore, we aimed to find whether TES could prevent surgery-induced delirium and cognitive dysfunction in elderly patients after surgery.

**Methods/Materials:** The elderly patients undergoing lumbar surgery with general anesthesia in Beijing Shijitan Hospital from Nov. 2016 to Nov. 2020 were selected. One hundred and sixty elderly patients were randomly divided into the control group and TES group. All patients were given general anesthesia with propofol, sevoflurane, remifentanyl, and rocuronium. TES was performed 30 min before anesthesia and lasted until the end of surgery, with stimulus frequency of 2/100 Hz on the PC6, ST36, and SP06. The stimulus intensity "short of discomfort" was used. Short-CAM was used to assess patients' delirium (POD) at 1, 3, and 7 days after surgery. The mini-mental state examination (MMSE) was used to assess cognitive function before surgery; 7 days, and 30 days after surgery.

**Results:** The incidence of POD at the time of 1, 3, and 7 days after surgery in the TES group were 11.25% (9), 5% (4), and 1.25% (1), while that of the control group were 23.75% (19), 16.25% (13) and 6.25% (5). The incidence of POD in the TES group was significantly lower than that of the control group at the time of 1 ( $P<0.05$ ) and 3 days ( $P<0.05$ ) after surgery, rather than 7 days after surgery ( $P>0.05$ ). The MMSE score of patients in the TES group was significantly higher than that of the control group at the time of 7 days after surgery ( $25.63\pm 2.17$  vs.  $24.87\pm 1.88$ ,  $P<0.05$ ), while no significant difference observed at the time of 30 days after surgery between the two groups ( $26.56\pm 1.64$  vs.  $26.18\pm 1.88$ ,  $P>0.05$ ). Fig.1 Comparison of the incidence of POD

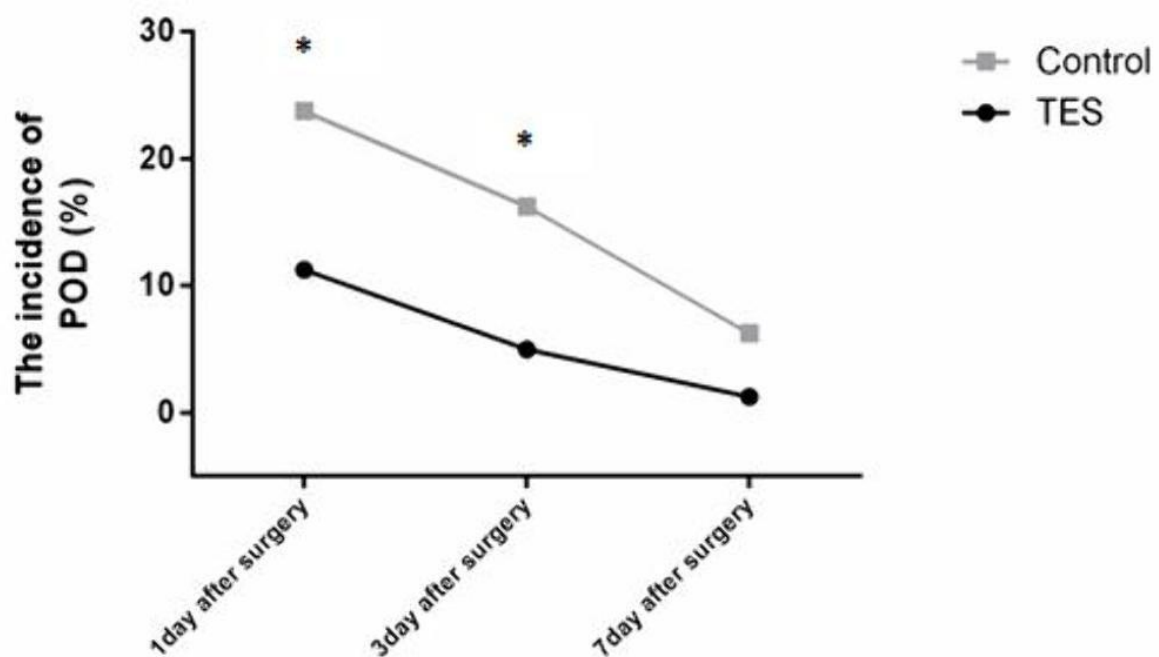
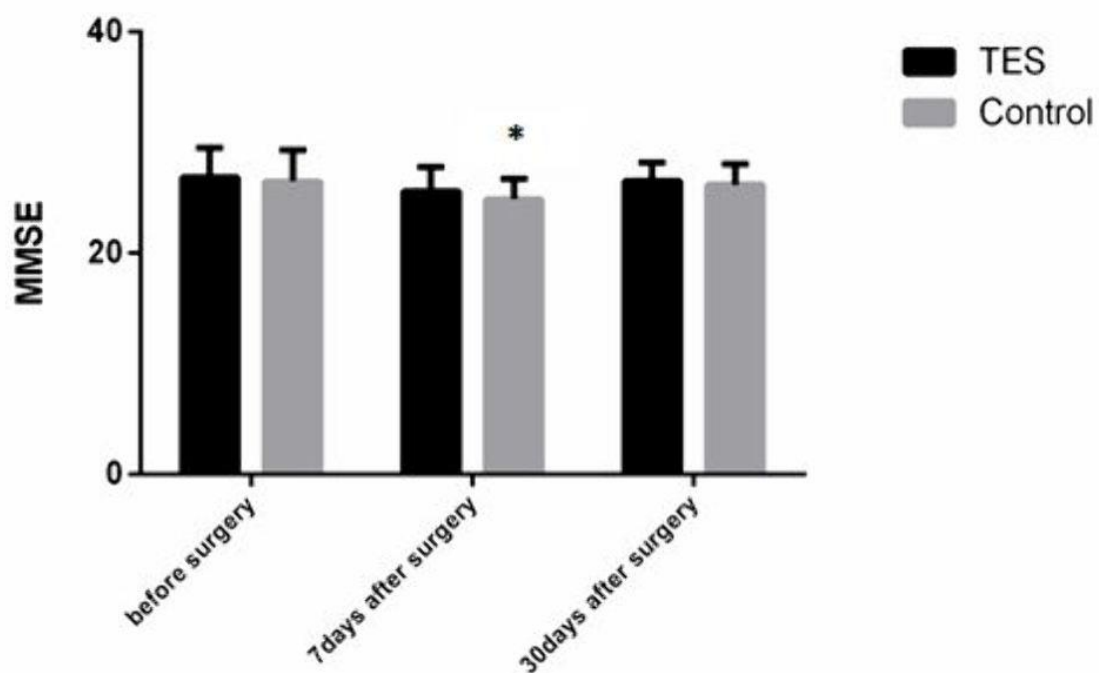


Fig.2 Comparison of the MMSE score



\* :  $P < 0.05$ , TES group vs. control group. TES: Transcutaneous electrical stimulation.

**Discussion:** Delirium and cognitive dysfunction are common in the elderly patients after lumbar surgery with no effective methods for prevention and treatment. Thus, we discussed TES's effects on neurobehavior performance in elderly patients. The data showed that TES on PC6, ST36, and SP06 effectively ameliorated surgery-induced delirium and cognition impairment in the early stage.

**Conclusions:** This study provides evidence that TES could attenuate elderly patients from surgery-induced early postoperative delirium and cognitive dysfunction.

**References:** 1 Wang Y, Qin WG, Yu CD. Clinical observation on effect of cranial suture acupuncture combined with donepezil hydrochloride tablets for Alzheimer's disease. WJAM. 2014;24:19–24. 2 Zhang Q, Li YN, Guo YY, et al. Effects of preconditioning of electro-acupuncture on postoperative cognitive dysfunction in elderly: A prospective, randomized, controlled trial. Medicine (Baltimore) 2017;96:e7375. 3 Mashour GA, Woodrum DT. Neurological complications of surgery and anaesthesia. Br J Anaesth 2015;114:194-203. 4 Acar, Volkan H . Acupuncture and related techniques during perioperative period: A literature review[J]. Complementary Therapies in Medicine, 2016,29:48-55. 5 Bishop FL, Yardley L, Prescott P, Cooper C, Little P, Lewith GT. Psychological covariates of longitudinal changes in back-related disability in patients undergoing acupuncture. Clin J Pain. 2015;31:254–64.

**Keywords:** lumbar surgery, elderly, delirium, Transcutaneous electrical stimulation, Cognition disorders

**Topic:** 04. Brain / 04c. Cognitive Disorders

## **VAGUS NERVE STIMULATION AND SLEEP APNEA MANAGEMENT IN DRUG-RESISTANT SEIZURE PATIENTS: A PROSPECTIVE STUDY**

### **E-POSTER VIEWING**

Belia Garcia<sup>1</sup>, Mercè Falip<sup>2</sup>, Neus Salord<sup>3</sup>, Jacint Sala-Padró<sup>4</sup>, Aleix Rosello<sup>5</sup>, Alejandro Fernandez-Coello<sup>5</sup>, Tim Vancamp<sup>6</sup>, Carme Monasterio<sup>3</sup>

<sup>1</sup>Neurophysiology, Hospital Universitari de Bellvitge, HOSPITALET DE LLOBRE, Spain, <sup>2</sup>Neurology, Hospital Universitari de Bellvitge, HOSPITALET DE LLOBRE, Spain, <sup>3</sup>Sleep Unit,, Hospital Universitari de Bellvitge, HOSPITALET DE LLOBRE, Spain, <sup>4</sup>Neurology,epilepsy Unit, Hospital Universitari de Bellvitge, HOSPITALET DE LLOBRE, Spain, <sup>5</sup>Neurosurgery, Hospital Universitari de Bellvitge, HOSPITALET DE LLOBRE, Spain, <sup>6</sup>Neuromodulation, LivaNova España SL, a subsidiary of Livanova PLC, Barcelona, Spain

**Introduction:** Vagus nerve stimulation therapy (VNS) is a treatment option for patients with drug-resistant seizures (DRS). Sleep apnea (SA) is a frequent side effect observed in patients with DRS treated only with antiseizure drugs, and patients with VNS. Objective: Determine frequency and evolution of SA in patients with DRS eligible for VNS. Furthermore, we evaluate the efficacy of the possible treatment solutions: positive air pressure (PAP) devices and adaptations of VNS stimulation parameters

**Methods/Materials:** Prospective single center study including patients diagnosed with DRS and eligible for VNS Therapy. IRB (Institutional Review Committee) approval and written consent from each patient or his/her guardian was obtained. A basal polysomnography (PSG) was realized and in patients with clinical SA a PAP was started prior to VNS implantation. After VNS ramp up period (4 months), PSG was repeated in all patients treated or not with PAP. PAP was adjusted and if not sufficient, VNS parameters were adapted, followed by a PSG to control changes

**Results:** 12 patients (9 male: 75%), with an average age of 43.6 years were included in the study. We found following baseline averages: Epworth: 5.5, sleep efficiency: 83.5%, PSG: normal in 6 patients, moderate-severe SA in 5 (38%) (PAP 4/5: 80%) and severe SA in 1 (8.3%, PAP treatment).After VNS implantation the patients previously treated with PAP treatment 6/12 (50%) maintained sleep efficiency (Average: 79.6%) and Epworth (Average: 8.8) not needing changes in the air pressure. In the 6 patients with a normal PSG pre-implantation, we observed 2 (33%) cases of VNS induced mild SA (average sleep efficiency: 74.9%, average Epworth: 9.1). In both patients the hypopneas were related to VNS "ON" periods. The hypopnea index was reduced by managing the electrophysiological parameters.

**Discussion:** Up to 33% of patients with DRS have been shown to have an apnea-hypopnea index (AHI) of 5 or higher. VNS stimulation can induce peripheral and central apnea, but frequency and severity among patients with DRS, as well as possible mitigation strategies are less known

**Conclusions:** Intermediate results show that 50% of our studied patient population suffers from moderate to severe SA before VNS implantation, requiring PAP treatment in 75% of them. PAP treatment and VNS therapy can coexist. PAP parameters and potentially VNS Therapy parameters may need to be adapted post implantation.

**References:** Malow BA, Levy K, Maturen K, Bowes R. Obstructive sleep apnea is common in medically refractory epilepsy patients. *Neurology* 2000;55:1002–1007. Marzec M, Edwards J, Sagher O, Fromes G, Malow BA. Effects of vagus nerve stimulation on sleep-related breathing in epilepsy patients. *Epilepsia* 2003;44:930-5. Salvadé A, Ryvlin P, Rossetti AO. Impact of vagus nerve stimulation on sleep-related breathing disorders in adults with epilepsy. *Epilepsy Behav.* 2018;79:126-129

**Keywords:** epilepsy, seizures, pharmacoresistance, sleep apnea, vagus nerve stimulation, positive air pressure treatment

**Topic:** 05. Spine / 05a. Pain

## **DIFFERENTIAL DIAGNOSIS AND TREATMENT OF MYOTONIC AND MYOFASCIAL SYNDROMES OF NECK PAIN**

### **E-POSTER VIEWING**

Aleksander Filipovich

Neurologic, Research Center Of Medical Assessment And Rehabilitation, Yukhnovka, Belarus

**Introduction:** The dynamic monitoring of 195 patients with myotonic and myofascial syndromes of neck pain was done against the control group of 45 people.

**Methods/Materials:** MRI of cervical and vertebrocranial areas of spinal column, electromyography of 7 to 9 relevant muscles, finding of the “key” muscle and the overall computer aided assessment of osteomuscular, cardiorespiratory and oxygen transport system disorders.

**Results:** Clinical and electromyographic criteria for diagnosis of myotonic and myofascial syndromes of neck pain were identified based on the occurrence rates. The role of major system disorders in pathogenesis of neurological manifests of neck pain was studied. New therapeutic approaches to stopping pain and myotonic syndromes were developed; the effectiveness of early rehabilitation measures was demonstrated. The prevailing myotonic syndromes were identified which were the musculus obliquus capitis inferior syndrome (in 68, or 39.4% patients); superscapular area syndrome (33% of patients); musculus scalenus anterior and musculus scalenus medius syndromes (18.9%); musculus pectoralis minor syndrome (9.7%). Hypodynamia caused system disorders were noted in 78.3% patients including excessive body mass and fat content; reduced blood circulation rate and heartbeat volume and the pronounced decrease of PWC<sub>170</sub>.

**Discussion:** The most informative spondylographic findings were reduced thickness of posterior areas of intervertebral disks from C1 to CVII (52.3 to 77.9% of patients), cervical lordosis impression (76.4%) and uncovertebral arthroses (58.2%).

**Conclusions:** The most seriously affected (“key”) muscles in neck pain patients were found. Diagnosis and treatment strategies for neck pain patients were developed.

### **References:**

**Keyword:** myofascial syndromes

**Topic:** 05. Spine / 05a. Pain

## **AUTOLOGOUS FAT GRAFTING, A SOLUTION FOR SPINAL CORD STIMULATION PAINFUL DEVICES**

### **E-POSTER VIEWING**

Claudia Silva, Thomas Bayti, Valentine De Larminat, Mastafa Idelcadi  
Service Anti Douleur, Hopital Nord Franche Comté, Trévenans, France

**Introduction:** Spinal cord stimulation (SCS) is a useful analgesia technique for refractory chronic pain such as complex regional pain syndrome and failed back surgery syndrome refractory to conventional medical management<sup>1</sup>. Generally SCS is considered a safe treatment option. However, incidences of complications vary from 30% to 40%<sup>2</sup> and hardware-related problems are the most common<sup>3</sup>. Pain associated with SCS hardware is often related to a conflict between derma and the Implantable Pulse Generator (IPG) as well as the anchor for electrode's fixation. The rate of pain related to the device components among patients implanted with SCS ranges from 0,9% to 12%<sup>2</sup>.

**Methods/Materials:** In order to minimize this phenomenon, we have proposed to our patients the technique of autologous fat grafting (AFG) at the level of the implanted material as a therapeutic option for pain related to the IPG site.

**Results:** We proposed this strategy to ten patients who had pain related to IPG devices, with excellent results.

**Discussion:** AFG can be used in breast and facial reconstructive procedures<sup>4,5</sup> and a range of scar-related problems<sup>6,7</sup>. This procedure offers multiple advantages: it is readily available, biocompatible, stable, long-lasting, inexpensive and natural-appearing and it does not cause rejection<sup>8</sup>. Although AFG has become accessible in the 1980s and since increasingly used for a variety of applications, there are no publications concerning the use of this procedure for the treatment of SCS-related complications. Our practice supports the findings of fat grafting as a useful technique for the management of scar tissue-related problems. Indeed AFG provides a beneficial mechanical effect. Acting as a soft tissue filler in the interface between the IPG and the skin, the adipose tissue restores missing volume and contour, and provides increased cushioning.

**Conclusions:** In this context of paucity of protocols for the treatment of scars, especially those related to foreign body devices, AFG seems to be a valuable therapeutic option. Furthermore, as the use of SCS continues to grow, it is important to prevent, recognize, and minimize complications. Although most of SCS complications are minor, they have a negative impact on patient satisfaction, safety, and healthcare expenditures<sup>9</sup>. AFG may be a helpful tool for the management of SCS-related complications with minor morbidity and cost. Further research is needed to better clarify the safety, effectiveness and efficiency of this technique, and to determine if some implanted sites are more likely to become painful than others, i.e. buttock vs abdomen.

**References:** 1-Deer TR, et al. The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: the Neuromodulation Appropriateness Consensus Committee. *Neuromodulation : journal of the International Neuromodulation Society* 2014;17(6):515-50; discussion 550. 2- Eldabe S, Buchser E, Duarte RV. Complications of Spinal Cord Stimulation and Peripheral Nerve Stimulation Techniques: A Review of the Literature. *Pain medicine (Malden, Mass.)* 2016;17(2):325-36. 3- Mekhail NA, Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. *Pain practice : the official journal of World Institute of Pain* 2011;11(2):148-53 4- Wetterau M, Szpalski C, Hazen A, Warren SM. Autologous fat grafting and facial reconstruction. *The Journal of craniofacial surgery* 2012;23(1):315-8. 5- Darrach H, Kraenzlin F, Khavanin N, Chopra K, Sacks JM. The role of fat grafting in prepectoral breast reconstruction. *Gland surgery* 2019;8(1):61-6. 6- Negenborn VL, Groen JW, Smit JM, Niessen FB, Mullender MG. The Use



of Autologous Fat Grafting for Treatment of Scar Tissue and Scar-Related Conditions: A Systematic Review. Plastic surgical nursing : official journal of the American Society of Plastic and Reconstructive Surgical Nurses 2016;36(3):131-43. 7- Riyat H, Touil LL, Briggs M, Shokrollahi K. Autologous fat grafting for scars, healing and pain: a review. Scars, burns & healing 2017;3:2059513117728200. 8- Coleman SR. Structural fat grafts: the ideal filler. Clinics in plastic surgery 2001;28(1):111-9. 9- Kumar K, Wilson JR, Taylor RS, Gupta S. Complications of spinal cord stimulation, suggestions to improve outcome, and financial impact. Journal of neurosurgery. Spine 2006;5(3):191-203.

**Keywords:** autologous fat grafting, lipofilling, Spinal cord stimulation complications, pain related to foreign devices, Spinal cord stimulation, chronic pain

**Topic:** 05. Spine / 05a. Pain

## **REAL WORLD EXPERIENCE USING A SCS-DEVICE WHICH PROVIDES INDIVIDUALIZED TREATMENT CUSTOMIZATION**

### **E-POSTER VIEWING**

Georgios Matis, Veerle Visser-Vandewalle

Department Of Stereotactic And Functional Neurosurgery, University Hospital Cologne, Cologne, Germany

**Introduction:** The spinal cord stimulation (SCS) therapy is an evolving field. Nowadays we can customize simultaneously stimulation waveforms and field shapes. The scope of this work is to provide real world experience using a new system in treating chronic pain patients.

**Methods/Materials:** Forty five consecutive patients were treated with SCS and implanted with a new neurostimulator (IPG) (Precision Spectra WaveWriter™, Boston Scientific Neuromodulation, Valencia, CA, USA). We collected baseline characteristics and reviewed the procedure information. The pain intensity was evaluated with the visual analogue scale (VAS).

**Results:** The mean age of the patients (21 males, 24 females) was 55 years. Thirty five patients had failed back surgery syndrome (FBSS), three complex regional pain syndrome (CRPS), three lumbar stenosis, and four other etiologies. Thirty two patients reported back and leg pain, seven only leg pain, and six other types of pain. The baseline VAS was 7.9, at the end of the trial 2.8 and after three months 2.9. Thirty eight patients had a SCS-system and 4 had a hybrid-system (SCS and PNFS). Twenty nine patients received a lead with 16 contacts. The tip of the lead was at T8 (48.6%), T9 (26.2%), and T10 (9%). The mean duration of the trial was 55.9 minutes. Thirty two patients preferred a polytherapy (tonic and 1kHz or tonic and Burst) and thirteen a monotherapy (Burst or 1kHz). We had one lead migration.

**Discussion:** It was possible to achieve a considerable pain relief even in patients where the coverage was not optimal. These results could be attributed to the combination therapy (layering more than one therapy at the same time), the subperception algorithms over multiple vertebral levels, and the waveform automation (automatic rotation through waveforms). Of note, the patients could enter real-time therapy ratings into their remote control which helped us identify which therapy provides the most relief with the lowest energy usage.

**Conclusions:** The goal of any advances in SCS-field should be to simplify personalization, achieve better outcomes and deliver the most effective therapy with the lowest energy usage.

**References:** Metzger et al.. Outcomes using a SCS device capable of simultaneous customization of stimulation waveform and field shape. *Neuromodulation* 2018;21:e41.

**Keyword:** SCS, combination therapy, subperception algorithms, chronic pain, waveform automation

**Topic:** 05. Spine / 05a. Pain

## **SPINAL CORD STIMULATION TRIAL OF A PATIENT WITH MULTIPLE THORACIC CARVERNOUS ANGIOMA**

### **E-POSTER VIEWING**

Pyung Bok Lee<sup>1</sup>, Yong-Chul Kim<sup>2</sup>, Ho Jin Lee<sup>2</sup>

<sup>1</sup>Pain Center, Seoul National University Bundang Hospital, Seongnam, Korea, Republic of, <sup>2</sup>Pain Center, Seoul National Universtiy Hospital, Seoul, Korea, Republic of

**Introduction:** Carvenous aniomias(CA) of the spinal cord are rare vascular malformations. CA. 5~12% of all spinal vascular pathologies exist.

The risk of hemorrhage reached to 2.5% annually.

We report the case of a 63-year-old woman who tried spinal cord stimulation(SCS) for chronic pain due to spinal cord injury after hemorrhage of multiple thoracic carvenous angioma. there are a few case in SCS trial to patients with carvenous angioma

**Methods/Materials:** The patient had multiple CA at brain and spinal cord. Suddenly she felt severe pain at low back and right lower extremity and weakness. The whole spinal cord MRI found multiple spinal cord hemorrhage at pre-existing thoracic CA. Despite of various pain intervention including epidural block, lumbar plexus block, lumbar sympathetic ganglion block, pain persisted. After spinal cord stimulation trial, pain subsided. but she had difficult on walk and it disappeared when SCS powered off. Because of walking problem, SCS trial was terminated.

**Results:** Because of walking problem, SCS trial was terminated.

**Discussion:** Spinal cord injuries due to hemorrhagic CA may cause motor weakness and pain. The pain caused by damaged central nervous system is difficult to treat with conventional pain intervention. Normal strucure of spinal cord was destroyed by hemorrhage of CA which made the spinal cord vulnerable to external stimulation. SCS might have interrupted the proprioceptive portion of the spinal cord (spino-olivary & spinocerebellar tract). SCS can propose a proper solution.

**Conclusions:** SCS may be a solution for intractable chronic pain. SCS must be performed carefully, because of unexpected complications

Further studies needed for difficult cases as such. Pulsed radiofrequency ablation therapy can be an option in treating chronic buttock and posterior thigh pain.

**References:** 1. Isumi K, Yoshinobu I, Tohoyiko I,etc: Spinal Cord Evoked Potential Monitoring after Spinal Cord Stimulation during Surgery of Spinal Cord Tumors. Neurosurgery 1993;33:451-60. 2. Dennis DanielDeyOrlandoLandrumAnne LouiseOaklander: Central neuropathic itch from spinal-cord cavernous hemangioma: a human case, a possible animal model, and hypotheses about pathogenesis. Pain 2005;113: 233-7.

**Keyword:** carvenous angioma, motor weakness, spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

**TREATMENT OF CHRONIC INTRACTABLE BILATERAL FOOT PAIN WITH 10KHZ SPINAL CORD STIMULATION (10KHZ SCS) FOLLOWING UNSUCCESSFUL LOW FREQUENCY STIMULATION (LF SCS): A CASE REPORT**

**E-POSTER VIEWING**

Juan Graterol

Pain Clinic, Royal Cornwall Hospitals, Truro, United Kingdom

**Introduction:** This case study aims to demonstrate a safe and effective treatment option using 10kHz SCS to salvage a previous LF SCS system and the sustained long-term pain relief utilizing 10kHz SCS for bilateral neuropathic foot pain. Pain reduction, functional and psychological improvements will be outlined.

**Methods/Materials:** The subject was trialed using a temporary percutaneous electrode spanning T9-T10 for 7 days using 10kHz SCS using standard programming. The previous LF SCS system remained in situ for this period. Following a successful trial with 10kHz SCS the subject proceeded to full implantation and the previous SCS system was removed.

**Results:** Subject reported sustained long term effective pain relief at 36 months with 10kHz SCS with an overall pain reduction of 80%. Numerical Rating Scale (NRS) reduced from 8 to 1.5. Functional ability improved, with a reduction on the Oswestry Disability Index (ODI) of 10% at 12 months. Brief Pain Inventory (BPI) pain interference scores also reduced from 7.14 to 3.85. Subject reports at 3 years Global impression of change to be 'Better, definite improvement'. Psychological improvements: Baseline Hospital Anxiety Depression Score (HADS) A- 9, D-7 and at 2 years HADS: A-4, D-4.

**Discussion:** Bilateral foot pain is a challenging pain indication to treat with SCS; significant pain reduction, functional advances and psychological improvements have all been reported at 24 months.

**Conclusions:** 10kHz SCS can provide long term sustained clinical outcomes when treating bilateral neuropathic foot pain and it may be effective in patients with failed LF SCS systems.

**References:** 1.Ross, E & Abejon, D. Improving Patient Experience with Spinal Cord Stimulation: Implications of Position-Related Changes in Neurostimulation. 2011 2.Russo, M; Verrills, P; Mitchell, et al. High Frequency Spinal Cord Stimulation at 10kHz for the Treatment of Chronic Pain: 6 Month Australian Clinical Experience. Pain Physician 2016. 3.Kapur, L et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial. 2016.

**Keyword:** SCS, efficacy, rescue treatment

**Topic:** 05. Spine / 05a. Pain

**VECTORS STUDY RESULTS: ASSESSING PAIN RELIEF AND FUNCTIONAL OUTCOMES USING SPINAL CORD STIMULATION (SCS) WITH HIGH DOSE (HD) STIMULATION PARAMETERS – 12-MONTH RESULTS**

**E-POSTER VIEWING**

John Hatheway<sup>1</sup>, Michael Fishman<sup>2</sup>, Vipul Mangal<sup>2</sup>, Binit Shah<sup>3</sup>, Katherine Stromberg<sup>4</sup>, Kelly Hendrickson<sup>4</sup>, Matthew Kelly<sup>4</sup>, Lachlan Davies<sup>4</sup>

<sup>1</sup>Pain Management, Northwest Pain Care, Spokane, United States of America, <sup>2</sup>Interventional Pain Medicine, Center for Interventional Pain and Spine, Wilmington, United States of America, <sup>3</sup>Pain Management, Carolinas Pain Institute, Winston-Salem, United States of America, <sup>4</sup>Pain/stimulation Clinical Research, Medtronic, Minneapolis, United States of America

**Introduction:** Many variables can play a role in spinal cord stimulation (SCS), such as location of pain, lead location, and stimulation parameters, and when not controlled, they can result in mixed outcomes. This is exacerbated by a growing number of new waveforms available to physicians. A standardized approach to therapy delivery may provide more consistent outcomes for more patients. The Vectors Study evaluated whether there is significant sustained improvement in pain when therapy is delivered using a standardized approach.

**Methods/Materials:** Vectors, a post-market, single-arm study evaluated the safety and efficacy of SCS starting with 1 kHz stimulation, targeting the T9-T10 disc space following paresthesia mapping. Subjects with chronic intractable low-back and leg pain (VAS $\geq$  50mm) were enrolled. The primary endpoint was change in overall pain (VAS) at the 3-Month Visit compared to baseline. Additional measure included change in pain (overall, low-back, leg), disability, quality of life, individual subject goals, impression of change and subject satisfaction. Subjects were followed through 12 months.

**Results:** The study met its primary objective: subjects experienced a significant reduction in overall pain at 3 months from a mean (SE) VAS of 77.2 (1.2) at baseline to 31.8 (2.5) at 3 months (Intention-to-Treat Analysis Set,  $p<0.0001$ ); this reduction was sustained through 12 months (44.5mm reduction, completers). At 12 months, 79% of subjects had  $\geq$  50% improvement in at least one pain domain (overall, low-back or leg). There was a decrease in disability (ODI; Baseline score: 54 and 12-Month score: 32) and an improved quality of life (EQ-5D; 77% subjects reported a better health state compared to baseline) through 12 months, with 70% of subjects achieving a personal activity goal by 3 months, the final time point when goals were collected. Additionally, at 12 months, 85% of subjects were satisfied with their therapy and 56% reported a meaningful positive impression of change.

**Discussion:** Subjects enrolled in the Vectors study had a significant decrease in overall pain at 3 months, which was sustained through 12 months. Through 12 months, subjects also had a decrease in disability, an increase in quality of life and were satisfied with their therapy. These findings suggest that using a standardized workflow with HD stimulation parameters for the treatment of chronic pain may provide long-term improvements.

**Conclusions:** The Vectors study provides long-term evidence for the effectiveness of SCS when using a standardized workflow starting with HD stimulation.

**References:**

**Keywords:** Pain Reduction, Spinal cord stimulation, chronic pain, Functional Outcomes

**Topic:** 05. Spine / 05a. Pain

## INTRATHECAL THERAPY MANAGEMENT AND SUPPORT ON THE SPECIALISED FRENCH PAIN CENTERS

### E-POSTER VIEWING

Claudia Silva, Valentine De Larminat, Sylvie Klopfenstein, Jean-Pierre Schoch, Mastafa Idelcadi  
Service Anti Douleur, Hopital Nord Franche Comté, Trévenans, France

**Introduction:** Pain is common in cancer patients<sup>1</sup>. Pain control is one of the four priorities in a World Health Organisation (WHO) cancer program<sup>2</sup>. Nevertheless, undertreatment is frequent<sup>3,4</sup>. Since pain relief following WHO guidelines may be inadequate or limited by side effects<sup>5</sup>, interventional pain strategies such as intrathecal therapy (ITT) have been proposed<sup>6</sup>. In France, ITT is reserved to some specialised pain management centres (PMC). There are few publications concerning its use or gathering the PMC in France<sup>7,8</sup>.

**Methods/Materials:** This is a transversal, retrospective study composed of a questionnaire with 26 questions. It has been sent by email to the french PMC that use ITT, 44 in all, in which 22 have responded. The questionnaire has been answered through an online survey tool, surveymonkey. The data were collected between November 2018 and March 2019. The questions address the daily practice of ITT on the PMC.

**Results:** The table below summarizes the main results :

- PMC structure and ITT
31.82% of PMC offer ITT for more than 2 years, 27.27% since less than 5 years
Location: 57,14% in an university hospital
50% do not have a specific schedule at the operating room dedicated to ITT

- ITT Indications
54.55% cancer rebel pain (which 80% of cases is already in a late phase)
- Drugs used for ITT
Morphine 100%, naropaine 76.19% and prialt 71.43% of cases
Association between 2 or more medications: 85%
Most common association: morphine and a local anesthetic (70%)
- ITT pompe filling
Logistic: 65% of PMC have a specific schedule dedicated to this activity
Medication preparation: 55% on the patient's bedside
Living away patients: 65% of cases do not have a nearby place to do the filling

Number of ITT implanted pompes/year	Number of PMC (year 2017)	Number of PMC (year 2018)
< 5	9	5
5-10	2	6
11-20	5	6

21-30	2	1
> 30	3	3

**Discussion:** There is a discrepancy between the PMC that offer ITT in France. Cancer pain is the main indication of ITT, although in most of cases this indication is made late on the course of the disease. The combination of drugs is a common practice in France. Patients living away from PMC represent a logistic challenge<sup>9</sup>.

**Conclusions:** A better understanding of ITT particularities in France may help to identify the challenges and difficulties faced in the ITT daily practice. Moreover, it is an essential step to improve the chronic pain management.

**References:** 1. Van den Beuken-van Everdingen MH, Hochstenbach LM, Joosten EA, Tjan-Heijnen VC, Janssen DJ. Update on Prevalence of Pain in Patients With Cancer: Systematic Review and Meta-Analysis. *J Pain Symptom Manage*. 2016 Jun;51(6):1070-1090.e9. doi: 10.1016/j.jpainsymman.2015.12.340. Epub 2016 Apr 23. 2. Organisation mondiale de la Santé . Traitement de la douleur cancéreuse. Genève, Suisse: Organisation mondiale de la Santé; 1987. 3. Shen WC et al. Impact of Undertreatment of Cancer Pain With Analgesic Drugs on Patient Outcomes: A Nationwide Survey of Outpatient Cancer Patient Care in Taiwan. *J Pain Symptom Manag* 2017 Jul;54(1):55-65.e1. doi: 10.1016/j.jpainsymman.2017.02.018. Epub 2017 May 4 4. Greco MT, Roberto A, Corli O, Deandrea S, Bandieri E, Cavuto S, Apolone G. Quality of cancer pain management: an update of a systematic review of undertreatment of patients with cancer. *J Clin Oncol*. 2014 Dec 20;32(36):4149-54. doi: 10.1200/JCO.2014.56.0383. Epub 2014 Nov 17. 5. Meuser T, Pietruck C, Radbruch L, Stute P, Lehmann K A, Grond S. Symptoms during cancer pain treatment following WHO-guidelines: a longitudinal follow-up study of symptom prevalence, severity and etiology. *Pain*. 2001;93:247–257. 6. Miguel R. Interventional treatment of cancer pain: the fourth step in the World Health Organization analgesic ladder? *Cancer Control* 2000 Mar-Apr;7(2):149-56. 7. Virginie Guastellaa, Isabelle Genauda, Bruno Pereira. Virginie Guastella *Medecine Palliative Soins de Support - Accompagnement - Ethique*, Corrected proof. doi:10.1016/j.medpal.2017.02.004 État des lieux de l'utilisation de l'analgésie intrathécale en situation palliative en France en 2016. *Médecine Palliative : Soins de Support - Accompagnement – Éthique*. Volume 16, Issue 4, September 2017, Pages 191-197 8. D, Lefebvre-Kuntz D, et al., Douleur chronique cancéreuse et analgésie intrathécale : expérience de trois centres de lutte contre le cancer. *Douleurs Evaluation Diagnostic Traitement*. 2011 ; 12, 140-146. 9. Deer TR, Prager J, Levy R, Rathmell J, Buchser E, Burton A, Caraway D, Cousins M, De Andrés J, Diwan S, Erdek M, Grigsby E, Huntoon M, Jacobs MS, Kim P, Kumar K, Leong M, Liem L, McDowell GC, Panchal S, Rauck R, Saulino M, Sitzman BT, Staats P, Stanton-Hicks M, Stearns L, Wallace M, Willis KD, Witt W, Yaksh T, Mekhail N. Polyanalgesic Consensus Conference 2012: recommendations for the management of pain by intrathecal (intraspinous) drug delivery: report of an interdisciplinary expert panel. *Neuromodulation : journal of the International Neuromodulation Society* 2012;15(5):436-64; discussion 464-6

**Keywords:** intrathecal therapy, pain management logistic, Cancer Pain, pain management center, intrathecal pump, chronic pain

**Topic:** 05. Spine / 05a. Pain

**NPOWER™- A PROSPECTIVE, MULTI-CENTER TRIAL WITH A BATTERY-FREE MICROSTIMULATOR DELIVERING A NOVEL, PULSED-STIMULATION-PATTERN TO THE SPINAL CORD TO TREAT PAIN**

**E-POSTER VIEWING**

John Salmon

Pain Medicine, PainCare Perth, Perth, Australia

**Introduction:** A new, battery-free, micro-sized spinal cord stimulation (SCS) system has been created for the treatment of chronic pain. The system utilizes an external power source that bi-directionally communicates with a small, implantable pulse generator (<1.5 cc volume) connected to multiple leads. Preliminary testing on usability, patient comfort and the use of a proprietary Pulsed-Stimulation Pattern (PSP) has led to this first-in-human clinical study.

**Methods/Materials:** A prospective, multi-center, open-label clinical trial was recently initiated to demonstrate the safety and performance of a new microstimulator in the treatment of trunk and limb pain. Subjects diagnosed with failed back surgery syndrome (FBSS) who were unresponsive to conservative treatment options, displayed adequate psychological stability and reported leg and/or back pain greater than 6/10 were recruited. Subjects meeting all of the other inclusion and exclusion criteria were consented for study inclusion. Subjects underwent an SCS trial with the new system with the Nalu PSP stimulation paradigm. Positive trial subjects continued onto the long-term implant phase with follow-ups at multiple, pre-defined time points for up to 1 year following implantation. Clinical and usability outcomes will be obtained at baseline, out to the end of study.

**Results:** Nineteen (19) chronic back and/or leg pain subjects completed the 2 week trial stimulation with no trial failures and proceeded to the follow up phase of the study which was subject to interim analysis. At the most recent follow-up visit for the 19 subjects, at which time more than half the cohort were more than 6 months post implant, the overall average NRS pain reduction in the low back was 5.7 (83%), and the overall average NRS pain reduction in the leg was 5.5 (81%). In addition, all subjects are wearing the external power source nearly continuously and rating its average comfort <1 on a 10-point scale (0 is Very Comfortable and 10 is Very Uncomfortable). The usability and efficacy data clearly illustrate robust connectivity.

**Discussion:** These early results demonstrate the favorable efficacy and usability of a battery-free, externally powered IPG utilizing dynamic feedback and a novel stimulation pattern. Study subjects are finding the external power source to be comfortable when worn continuously, and the system, as a whole, to deliver significant pain relief. These preliminary findings need confirmation in large population of chronic pain patients.

**Conclusions:** This new minimally invasive micro stimulator has demonstrated significant efficacy, safety and patient acceptability in this first in human study.

**References:**

**Keywords:** failed back surgery pain, minimally invasive micro stimulator, novel waveform



**Topic:** 05. Spine / 05a. Pain

## **SPINAL CORD STIMULATION FOR THE TREATMENT OF PREDOMINANT AXIAL LOW BACK PAIN: A PROSPECTIVE SINGLE CENTER STUDY IN 28 PATIENTS**

### **E-POSTER VIEWING**

Sophie Lamprecht, Matthias Winkelmüller  
Neurosurgery, Friederikenstift Hannover, Hannover, Germany

**Introduction:** Spinal cord stimulation (SCS) is an effective therapy for the sustained relief of neuropathic pain. However, with traditional SCS-technologies, axial pain in the lower back was poorly addressed in the past. Using more recent stimulation parameters and improving the programming platform, patients with predominantly low back pain can now be satisfactorily treated with SCS.

**Methods/Materials:** In this prospective single center study, 28 patients with predominant and therapy-resistant low back pain were examined. After implantation of two parallel epidural stab electrodes, an intraoperative test phase was performed in the awake patient. After successful programming (Illumina™ 3D software, MultiWave™ technology, Boston Scientific), a pulse generator was implanted. All patients started with intermittent tonic stimulation, a subthreshold stimulation form was added when needed. The study looked at pain reduction (PR), pain-associated factors, work status, analgesic drug use, paresthesia coverage and individually preferred stimulation form.

**Results:** The pain measured by the NRS was reduced by 50% on average, 5 patients reported an unsatisfied pain relief <30%. The pain-associated factors of sleep, activity and mood were reduced by 49%, 43% and 55%. 7/13 patients resumed or continued work, 15 were previously retired. The use of analgesics was reduced (n=18) or even eliminated (n=10). 12/24 patients with a previous opioid-intake eliminated opioids consistently. An average of 82% of the pain area was covered with paresthesia, 15 patients reported a 100% coverage. A better paresthesia coverage resulted in a significant higher PR (coverage ≥70% (n=20): 57% PR, coverage < 70% (n=8): 30% PR). Patients with tonic (n=18, 54% PR) or combined (n=6, 50% PR) and intermittent (n=17, 57% PR) stimulation forms reported a higher PR than patients with subthreshold (n=4, 28% PR) and continuous stimulation forms (n=11, 39% PR).

**Discussion:** This study shows a significant PR, an improvement of pain-associated factors, a chance to regain work ability and a reduction of analgesic drugs, opioids in particular. Full paresthesia coverage is essential for a good outcome and better results were associated with the use of an intermittent and tonic form of stimulation.

**Conclusions:** With innovative SCS-technologies patients with axial low back pain can nowadays be satisfactorily treated with SCS. Good quality SCS can reduce or even stop the need for opioids in patients with chronic low back pain and is a viable answer to the opioid crisis. The stimulation form and the electrode placement seems to have a substantial impact on the outcome what should be investigated in future studies.

### **References:**

**Keywords:** Spinal cord stimulation, Spine, neuromodulation, Axial low back pain, chronic pain, Boston Scientific

**Topic:** 05. Spine / 05a. Pain

## **10 KHZ SPINAL CORD STIMULATION FOR INTRACTABLE LEG PAIN: A PROSPECTIVE MULTICENTER DUTCH STUDY**

### **E-POSTER VIEWING**

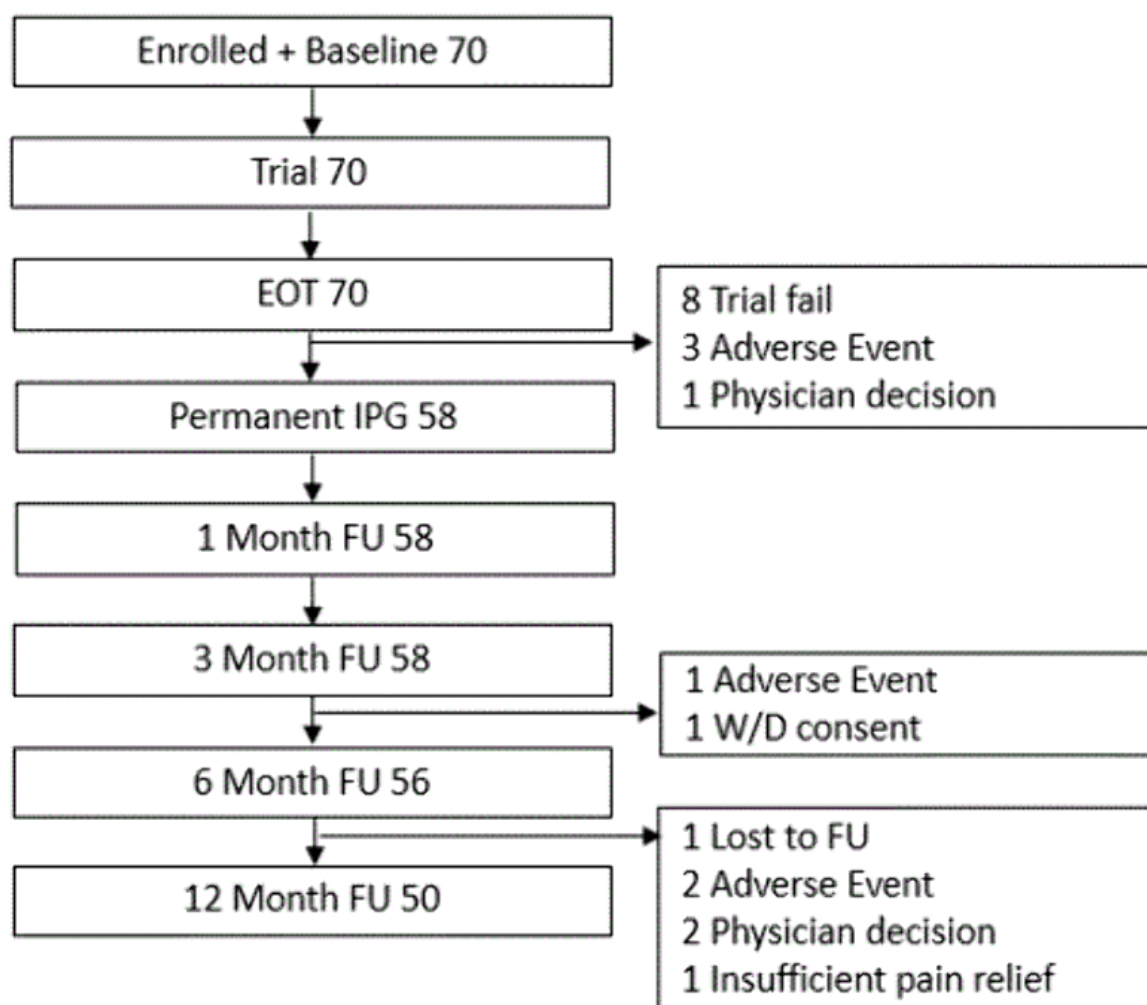
Jan Willem Kallewaard<sup>1</sup>, Ismail Gültuna<sup>2</sup>, Vincent Hoffmann<sup>3</sup>, Lars Elzinga<sup>4</sup>, Munnikes Renate<sup>5</sup>, Lisette Verbrugge<sup>5</sup>, Veerle Minne<sup>6</sup>, Pascal Reijters<sup>6</sup>

<sup>1</sup>Anesthesiology And Pain Management, Rijnstate Hospital, Arnhem, Netherlands, <sup>2</sup>Pijn Management, Albert Schweitzer Hospital, Sliedrecht, Netherlands, <sup>3</sup>Pain Management, Amphia Hospital, Breda, Netherlands, <sup>4</sup>Pain Management, Bravis Hospital, Roosendaal, Netherlands, <sup>5</sup>Pain Management, Maasstad Hospital, Rotterdam, Netherlands, <sup>6</sup>Clinical Research, Nevro Corp., Redwood City, United States of America

**Introduction:** Paresthesia-independent high frequency 10 kHz spinal cord stimulation (SCS) has been shown to provide superior outcomes compared to traditional low frequency SCS when treating patients with both chronic, intractable back and leg pain<sup>1</sup>. We report complete 12-month results from a prospective multicenter Dutch study using 10 kHz SCS for the treatment of chronic intractable leg pain.

**Methods/Materials:** After ethics committee approval and signing of informed consent, subjects reporting predominant leg pain ( $\geq 5.0$  cm) in visual analog scale (VAS) and candidates for SCS as per the Dutch guidelines were enrolled across five centers. Subjects who completed a successful trial ( $\geq 50\%$  pain reduction) received a permanent system and were followed-up at regular intervals for 12 months. Data on pain intensity and quality, functionality, quality of life, psychological assessments, opioid usage and return to work were collected.

**Results:** At final analysis, a total of 70 subjects were enrolled in the study, 62 subjects had a successful trial (89% trial success rate), 58 subjects received a permanent implant and 50 subjects completed the study (Fig.1).



**Figure 1. Study flow chart**

Baseline leg pain scores of  $7.7 \pm 1.0$  cm improved to  $1.9 \pm 1.8$  cm,  $2.4 \pm 2.4$  cm,  $3.2 \pm 3.1$  cm,  $2.0 \pm 2.1$  cm at 1-, 3-, 6- and 12-month follow-ups, respectively. The responder rate (proportion of subjects reporting  $\geq 50\%$  reduction in VAS) and remitter rates (proportion of subjects reporting  $VAS \leq 3.0$  cm) were 79.6% and 73.5% at 12-month follow-up. Improvements were reported also in functionality as measured by Oswestry Disability Index (Table 1) and change in opioid use vs. Baseline (Table 2).

ODI Categorization	Baseline	1-month	6-month	12-month
Minimal disability	0.0	28.1	29.1	34.7
Moderate disability	12.3	33.3	38.2	42.9
Severe disability	64.9	31.6	23.6	18.4
Crippling back pain	22.8	7.0	9.1	4.1
N	57	57	55	49

**Table 1: Categorization (in %) of Oswestry Disability Index through 12 month follow-up in per-protocol population**

Change in opioid use	1-month	3-month	6-month	12-month
Eliminated/Decreased	26.7	40.0	53.6	46.2
No change/Increased	73.3	60.0	46.4	53.8
N	57	57	55	49

**Table 2: Categorization (in %) of change in opioid use vs. Baseline through 12 month follow-up in per-protocol population**

**Discussion:** Not applicable.

**Conclusions:** Consistent with previous studies, this multicenter Dutch study also demonstrated that 10 kHz SCS is effective and produces durable pain relief in intractable leg pain patients.

**References:** <sup>1</sup>Kapur L et al. Comparison of 10-kHz High-Frequency and Traditional Low Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results from a Multicenter, Randomized, Controlled Pivotal Trial Neurosurgery. 2016.

**Keywords:** leg pain, paresthesia-independent, SCS, high frequency, Back Pain, 10 kHz

**Topic:** 05. Spine / 05a. Pain

## **OUTCOMES OF A SPINAL CORD STIMULATION SYSTEM CAPABLE OF MULTIPLE NEUROSTIMULATION MODALITIES: A RANDOMIZED CONTROLLED TRIAL (COMBO)**

### **E-POSTER VIEWING**

Mark Wallace<sup>1</sup>, Robert Bolash<sup>2</sup>, Farshad Ahadian<sup>1</sup>, James North<sup>3</sup>, Duane Griffith<sup>4</sup>, Lisa Stearns<sup>5</sup>, Gregory Phillips<sup>6</sup>, John Noles<sup>7</sup>, Joseph Atallah<sup>8</sup>, Edward Washabaugh<sup>9</sup>, Julio Paez<sup>10</sup>, Daniel Mankoff<sup>11</sup>, James Scowcroft<sup>12</sup>, Binit Shah<sup>3</sup>, Jennifer Lee<sup>13</sup>, Drew Trainor<sup>14</sup>, Roshini Jain<sup>15</sup>

<sup>1</sup>Pain Medicine, University of California, San Diego, La Jolla, United States of America, <sup>2</sup>Pain Management, Cleveland Clinic, Cleveland, United States of America, <sup>3</sup>Pain Management, Carolinas Pain Institute, Winston-Salem, United States of America, <sup>4</sup>Pain Management, Precision Spine Care, Tyler, United States of America, <sup>5</sup>Pain Management, Center for Pain and Support, Phoenix, United States of America, <sup>6</sup>Pain Management, Pacific Sport and Spine, Eugene, United States of America, <sup>7</sup>Pain Management, River Cities Interventional Pain, Shreveport, United States of America, <sup>8</sup>Pain Management, Toledo Clinic, Toledo, United States of America, <sup>9</sup>Pain Management, Forest Health Medical Center, Ypsilanti, United States of America, <sup>10</sup>Pain Management, South Lake Pain Institute, Clermont, United States of America, <sup>11</sup>Pain Management, Michigan Pain Consultants, Grand Rapids, United States of America, <sup>12</sup>Pain Management, Pain Management Associates, Independence, MO, United States of America, <sup>13</sup>Pain Management, Evergreen Health Pain, Kirkland, United States of America, <sup>14</sup>Pain Management, Denver Back Pain Specialists, Denver, United States of America, <sup>15</sup>Clinical Research, Boston Scientific, Valencia, United States of America

**Introduction:** Spinal Cord Stimulation (SCS) devices that enable personalized fine-tuning of stimulation parameters or waveforms offer the potential to address the variability among chronic pain patients. We endeavored to clinically investigate outcomes associated with use of multiple neurostimulation modalities as compared with conventional SCS settings alone in a prospective, randomized controlled trial.

**Methods/Materials:** COMBO is a prospective, multicenter, randomized controlled trial with an adaptive design (Clinicaltrials.gov identifier: NCT03689920). The primary endpoint was proportion of subjects permanently implanted with an SCS system capable of multiple neurostimulation modalities (Spectra WaveWriter, Boston Scientific), demonstrating 50% or greater reduction in average overall pain intensity at 3 months post-randomization (versus Baseline), with no increase in baseline average daily opioid medications used to treat pain. Additional endpoints will include assessment of quality of life and disability. Adverse events will also be collected.

**Results:** The study met its primary endpoint based on a pre-specified cohort of 89 randomized subjects ( $p < 0.001$ ). An interim analysis of 41 subjects using Combination Therapy (paresthesia-based SCS with a customized field shape algorithm) were able to achieve better clinical outcomes than those randomized to using paresthesia alone (monotherapy, 48 subjects) at 3-months post-randomization compared with Baseline as demonstrated by the following: a higher responder rate with no increase in opioid medications (88%), significant improvement in disability ( $\Delta$  25.6 points in ODI score versus subjects using monotherapy), and a very high level of patient satisfaction (90% subjects report very/much improved as measured by Patient Global Impression of Change, PGIC).

**Discussion:** Recently communicated RCTs suggest different modalities affect patients in different ways, and may potentially have different mechanism of actions (MOA).<sup>1,2</sup> In addition, these studies and others indicate that providing multiple therapeutic options elicit superior long-term outcomes when one can choose the most effective therapy.<sup>3</sup> The results of this RCT described here are in alignment with these previous reports and provide further support for the advantages of using neuromodulation systems capable of patient-specific stimulation options that enable highly customized therapy for treatment of chronic pain.

**Conclusions:** Outcomes of this prospective RCT provide Level 1 evidence regarding the use of an SCS system capable of multiple neurostimulation modalities in the treatment of chronic pain. The interim analysis described here demonstrates the effectiveness of multiple neurostimulation modalities of SCS (versus conventional SCS settings) used in treatment of chronic pain.

**References:** 1. Thomson SJ, Tavakkolizadeh M, Love-Jones S, et al. "Effects of Rate on Analgesia in Kilohertz Frequency Spinal Cord Stimulation Results of the PROCO Randomized Controlled Trial Neuromodulation 2018 Jan 21(1):67-76. 2. North J, Loudermilk E, Lee A, et al. "Outcomes of a Multicenter, Prospective, Crossover, Randomized Controlled Trial Evaluating Subperception Spinal Cord Stimulation at 1.2 kHz in Previously Implanted Subjects" Neuromodulation 2020 Jan;23(1):102-108. 3. Metzger C, Hammond MB, Pyles ST, et al. "Outcomes Using an SCS Device Capable of Delivering Combination Therapy and Advanced Waveforms/Field Shapes" [Abstract]. The Annual Meeting of the North American Neuromodulation Society (NANS), 2020.

**Keyword:** spinal cord stimulation, SCS, chronic pain, randomized controlled trial, RCT

**Topic:** 05. Spine / 05a. Pain

**PRECISE PHYSIOLOGICAL MAPPING FACILITATES RAPID ONSET OF ANALGESIA AND CLINICALLY SIGNIFICANT PAIN RELIEF AT SUB-PERCEPTION AMPLITUDE IN CHRONIC PAIN PATIENTS USING SPINAL CORD STIMULATION**

**E-POSTER VIEWING**

Georgios Matis, Veerle Visser-Vandewalle

Department Of Stereotactic And Functional Neurosurgery, University Hospital Cologne, Cologne, Germany

**Introduction:** Spinal Cord Stimulation (SCS) is regularly utilized at amplitudes below perception threshold enabling patients to achieve paresthesia-free pain relief. Despite success of this approach, to date, patients utilizing this method do not report onset of pain relief for up to 24-48 hours. The drawback to this latent interval between stimulation and clinical effect are the constraints imposed on identification of the optimal parameters that allow for maximum pain relief within each patient. We conducted an observational case-series using a new, paresthesia-free SCS technique that was reported to elicit pain relief within seconds to minutes after initial stimulation.

**Methods/Materials:** This is a single-center, observational case-series of de novo patients permanently-implanted for up to 6-months post-implant. A neurostimulator (Spectra WaveWriter) was used that provides high-resolution neural targeting capabilities and a proprietary algorithm designed to facilitate therapeutic paresthesia-free stimulation in combination with a tightly-spaced contact lead(s). Data was collected per standard of care which included reporting of pain scores (NRS).

**Results:** So far, 6 patients with chronic pain (diagnoses: FBSS, CRPS) were assessed in this evaluation. At baseline, mean NRS pain score was found to be 8.17 ( $\pm 0.21$ , S.E). The mean NRS following initial programming of patient-specific stimulation parameters [paresthesia-free stimulation ON] was 0.58 ( $\pm 0.24$ , S.E). All patients were observed to achieve paresthesia-free pain relief within seconds of turning on stimulation. Additionally, mean NRS at 3-month follow-up was 1.17 ( $\pm 0.54$ , S.E).

**Discussion:** Intriguingly, the results obtained in this initial real-world observational study are consistent with those reported by Metzger. This would suggest that achieving pain relief using sub-perception SCS is possible and that a putative mechanism of action is potentially mediating rapid onset of analgesia. Furthermore, we observed that precise targeting of neural stimulation seemed to be required to obtain these clinical outcomes. The implications of this study suggest that this approach may be a more beneficial way of employing paresthesia-free SCS as it enables much faster identification of a patient's unique "sweet spot(s)" and provides pain relief almost instantaneously.

**Conclusions:** In conclusion, we observed patients who used this new method of paresthesia-free SCS achieve very substantial pain relief within seconds that was sustained out to 3-months post-implant. In our experience, this is an unprecedented observation using paresthesia-free SCS. Therefore, these results strongly argue in favor for additional studies and a randomized controlled trial.

**References:** Tiede J, Brown L, Gekht G, Vallejo R, Yearwood T, Morgan D. Novel spinal cord stimulation parameters in patients with predominant back pain. *Neuromodulation*. 2013 Jul-Aug;16(4):370-5. Al-Kaisy A, Van Buyten JP, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med*. 2014 Mar;15(3):347-54. Metzger, Clark. "A Novel Sub-Perception SCS Therapy Enabling Clinically Significant Pain Relief and Fast Onset" [Abstract]. Biennial Meeting of the International Neuromodulation Society (INS), 2019.

**Keywords:** Spinal cord stimulation, chronic pain, subperception, physiological mapping, pain relief

**Topic:** 05. Spine / 05a. Pain

## **FOUR-YEAR FOLLOW-UP OF A CUSTOMIZED FIELD SHAPE USING SUB PERCEPTION SPINAL CORD STIMULATION IN A REAL WORLD, OBSERVATIONAL COHORT OF CHRONIC PAIN PATIENTS**

### **E-POSTER VIEWING**

Jose Paz-Solis<sup>1</sup>, Jing Wang<sup>2</sup>, Roshini Jain<sup>2</sup>, Ismael Huertas<sup>3</sup>, Que Doan<sup>4</sup>

<sup>1</sup>Neurosurgery, University Hospital La Paz, Madrid, Spain, <sup>2</sup>Clinical Research, Boston Scientific, Valencia, United States of America, <sup>3</sup>Research And Development, Boston Scientific, Madrid, Spain, <sup>4</sup>Research And Development, Boston Scientific, Valencia, United States of America

**Introduction:** Recently published data suggests that substantial pain relief can be achieved using sub-perception Spinal Cord Stimulation (SCS) within a wide range of frequencies and pulse-widths.<sup>1</sup> Contrary to traditional SCS which requires paresthesia mapping, sub-perception SCS can rely on an anatomically-guided bipolar search along the lead until the best patient-specific outcome is determined. Here, we present 4-year, real-world outcomes utilizing a novel sub-perception based SCS algorithm for customizing field shape based on delivery of precise amounts of current through multiple independently controlled contacts calibrated to each patient's anatomy and lead placement.

**Methods/Materials:** Patients were assessed at a single center as part of an on-going retrospective chart review of SCS outcomes for chronic pain. Patients were implanted with an SCS System (Precision Spectra, Precision Plus, Novi, and Precision [Boston Scientific]) using 16-contact percutaneous leads (Infinion, Boston Scientific). A customized field shape (CFS) algorithm was designed to engage anti-nociceptive terminals over a broader coverage area versus an 8mm bipole to produce a stronger dorsal horn effect. A "sweet-spot search" was performed spanning vertebral levels T8-T10 and pulse-width and amplitude were customized to each patient to provide adequate neural dosing (frequency: <1 kHz). At follow-up, patients were asked to score their pain (NRS) using a set of pre-defined CFS programs. Duration of time in which patients could sit, stand and walk without unbearable pain was determined. Additionally, duration of time between charging sessions was calculated for each patient's preferred program.

**Results:** To date, twenty-two patients with mean baseline NRS score of 8.6 and a mean follow-up duration of 4 years have been assessed. Forty-five percent of patients (10 of 22) report a pain score of 2 or less and 82% of patients (18 of 22) report a pain score of 3 or less at last follow-up. A statistically significant improvement in overall pain (68.6% reduction in mean NRS score, 8.6 to 2.7) was observed ( $p < 0.0001$ ). Additional results will be reported.

**Discussion:** Precise customization of stimulation field shape and neural dosage within each patient can provide for an effective strategy for sub-perception SCS based pain relief that is sustained long term.

**Conclusions:** So far, in this on-going, single-center case-series of 22 patients who were programmed with a patient-specific customized field shape (CFS) for 4 years, we observed the following: 68.6% improvement in overall pain ( $8.6 \Rightarrow 2.7$ ,  $p < 0.0001$ ); 82% percent (18 of 22) reported an overall pain score of 3 or less; results were sustained out to 4-years follow-up.

**References:** 1. Thomson S., Tavakkolizadeh M., Love Jones S., Patel, N.K., et al. Neuromodulation 2018 Jan;21(1):67-76.

**Keyword:** spinal cord stimulation, SCS, chronic pain, neural dosing, sub-perception



**Topic:** 05. Spine / 05a. Pain

## **OUTCOMES USING AN SCS DEVICE CAPABLE OF DELIVERING COMBINATION THERAPY AND ADVANCED WAVEFORMS/FIELD SHAPES**

### **E-POSTER VIEWING**

Clark Metzger<sup>1</sup>, M. Blake Hammond<sup>1</sup>, Stephen Pyles<sup>2</sup>, Edward Washabaugh<sup>3</sup>, Romanth Waghmarae<sup>4</sup>, Anthony Berg<sup>5</sup>, James North<sup>6</sup>, Yu Pei<sup>7</sup>, Roshini Jain<sup>7</sup>

<sup>1</sup>Ortho-spinal Surgery, NeuroMicroSpine, Pensacola, United States of America, <sup>2</sup>Pain Management, Pain Treatment Centers, Ocala, United States of America, <sup>3</sup>Pain Management, Forest Health Medical Center, Ypsilanti, United States of America, <sup>4</sup>Pain Management, Advanced Pain and Wellness Institute, Williamsville, United States of America, <sup>5</sup>Pain Management, Spine Team Texas, Rockwall, United States of America, <sup>6</sup>Pain Management, Carolinas Pain Institute, Winston-Salem, United States of America, <sup>7</sup>Clinical Research, Boston Scientific, Valencia, United States of America

**Introduction:** Developing “all-in-one” spinal cord stimulation (SCS) systems with capability for multiple types of neurostimulation paradigms likely will empower patients to identify the best treatment approach suitable for their needs. Here, we provide real-world outcomes in patients who used an SCS system designed to combine the availability of multiple waveforms, delivered either sequentially and simultaneously, with an algorithm designed to enable highly manipulatable control of field shape.

**Methods/Materials:** This is a consecutive, multi-center case-series based on retrospective chart review as part of an ongoing real-world evaluation of SCS outcomes for chronic pain (Clinicaltrials.gov identifier: NCT01550575). Patients were implanted with an SCS system (Precision Spectra WaveWriter, Boston Scientific) capable of combination therapy (sequential or simultaneous), multiple waveforms and advanced field shapes for low back and/or leg pain. Data collection included: 1) Baseline characteristics: demographics, pain diagnosis 2) procedural information: lead configuration, programming parameters; and 3) pre- and post- implant numerical rating scale pain intensities (0-10 NRS).

**Results:** Evaluation of 420 implanted patients has been conducted. A statistically significant improvement in overall targeted pain scores at last follow-up was reported (Baseline NRS: 7.2; mean last follow-up [208±200 days] NRS: 2.4;  $p<0.0001$ ). Twenty-three percent of patients (95 of 420) indicated being free of pain at last follow-up. In those patients reaching the 3-month post-implant timepoint ( $n=256$ ), a mean  $5.1\pm2.4$  point improvement ( $p<0.0001$ ) in overall pain was reported. This reduction in pain relief was similarly reported in patients who have, to date, reached the 12-month ( $n=122$ ) and 24-month timepoints ( $n=26$ ).

**Discussion:** These results support the notion that SCS patients do benefit when provided with a single device that can deliver multiple waveform types, in a sequential or simultaneous manner, and in combination with capability for highly specific targeting of the neurostimulation field. The results of this study align with previous studies suggesting that the use of various stimulation paradigms among different patients may be necessary for achieving the most effective pain relief outcomes.<sup>1-6</sup>

**Conclusions:** These results provide support for the postulate that an SCS system designed to provide combination therapy, multiple waveform options, and enhanced targeting capabilities, allows for highly effective pain relief outcomes in a patient-specific manner within the real world clinical setting.

**References:** 1. Kriek N, Groeneweg JG, Stronks DL, de Ridder D, Huygen FJ. Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial. *Eur J Pain*. 2017 Mar;21(3):507-519. 2. Berg AP, Mekel-Bobrov N, Goldberg E, Huynh D, Jain R. Utilization of multiple spinal cord stimulation (SCS) waveforms in chronic pain patients. *Expert Rev Med Devices*. 2017 Aug;14(8):663-668. 3. Provenzano DA, Rebman J, Kuhel C, Trenz H, Kilgore J. The Efficacy of High-

Density Spinal Cord Stimulation Among Trial, Implant, and Conversion Patients: A Retrospective Case Series. *Neuromodulation*. 2017 Oct;20(7):654-660. 4. Kumar V, Prusik J, Lin Y, Hwang R, Feustel P, Pilitsis JG. Efficacy of Alternating Conventional Stimulation and High Frequency Stimulation in Improving Spinal Cord Stimulation Outcomes: A Pilot Study. *Neuromodulation*. 2018 Jul;21(5):466-471. 5. Duse G, Reverberi C, Dario A. Effects of Multiple Waveforms on Patient Preferences and Clinical Outcomes in Patients Treated with Spinal Cord Stimulation for Leg and/or Back Pain. *Neuromodulation*. 2019 Feb;22(2):200-207. 6. North J, Loudermilk E, Lee A, et al. Outcomes of a Multicenter, Prospective, Crossover, Randomized Controlled Trial Evaluating Subperception Spinal Cord Stimulation at  $\leq 1.2$  kHz in Previously Implanted Subjects. *Neuromodulation* 2019 Jul 2. doi: 10.1111/ner.13015. [Epub ahead of print].

**Keyword:** spinal cord stimulation, SCS, chronic pain, multiple waveforms

**Topic:** 05. Spine / 05a. Pain

## **CLINICAL OUTCOMES IN PATIENTS USING A SPINAL CORD STIMULATION SYSTEM WITH MULTIPLE NEUROSTIMULATIVE MODALITIES FOR CHRONIC PAIN: INITIAL REAL WORLD EXPERIENCE FROM EUROPE**

### **E-POSTER VIEWING**

Jan Willem Kallewaard<sup>1</sup>, Pasquale De Negri<sup>2</sup>, Jose Paz-Solis<sup>3</sup>, Simon Thomson<sup>4</sup>, M. Angeles Canos-Verdecho<sup>5</sup>, Isaac Peña<sup>6</sup>, Christophe Perruchoud<sup>7</sup>, Yu Pei<sup>8</sup>, Roshini Jain<sup>8</sup>

<sup>1</sup>Anesthesiology And Pain Management, Rijnstate Hospital, Arnhem, Netherlands, <sup>2</sup>Pain Management, San Guiliano Hospital, Naples, Italy, <sup>3</sup>Neurosurgery, University Hospital La Paz, Madrid, Spain, <sup>4</sup>Pain Management And Neuromodulation, Basildon & Thurrock University Hospitals NHSFT, Basildon, United Kingdom, <sup>5</sup>Anesthesiology And Pain Management, University Hospital La Fe, Valencia, Spain, <sup>6</sup>Department Of Anesthesiology And Pain Management, Hospital Universitario Virgen del Rocío, Seville, Spain, <sup>7</sup>Clinique De La Douleur, Hôpital de la Tour, Geneva, Switzerland, <sup>8</sup>Clinical Research, Boston Scientific, Valencia, United States of America

**Introduction:** Spinal Cord Stimulation (SCS) systems equipped with several available modalities of neurostimulation such as multiple waveforms, customized field shape programming, and simultaneous or sequential pulse trains are designed to provide for robust customization of treatment for chronic pain. Here, we report outcomes in European patients implanted with such an SCS system.

**Methods/Materials:** This is an observational case-series conducted in Europe as part of an ongoing retrospective chart review evaluation of SCS outcomes for chronic pain (Clinicaltrials.gov identifier: NCT01550575). Patients were implanted with an SCS system (Precision Spectra WaveWriter, Boston Scientific) capable of combination therapy, multiple waveforms and advanced field shapes, and waveform automation. Assessments collected include (but not limited to) baseline characteristics (demographics, medical history, pain diagnosis), pre- and post-implant pain intensity (NRS), and quality-of-life (EQ-5D-5L) scores.

**Results:** To date, 91 patients have been analyzed demonstrating a mean overall baseline NRS pain score of  $7.9 \pm 1.8$ , and a mean follow-up duration of 118 days. At 3-months follow-up, a mean 5.2-point reduction in NRS score from baseline was observed (mean NRS: 2.6,  $p < 0.0001$ ) in a sub-set of patients reporting low back pain ( $n=51$ ). Fifty-one percent of these patients who reached their 3-month follow-up reported a pain score of 2 or less. Patients evaluated for Quality of Life (EQ-5D-5L) demonstrated significant improvement at their last follow-up ( $n=19$ ) compared to baseline assessment. On-going data collection is occurring and additional results will be presented.

**Discussion:** The capability of Spinal Cord Stimulation systems equipped with several available modalities of neurostimulation such as multiple waveforms, advanced/customizable field shape programming, and combination therapy is particularly clinically relevant given the established dynamic nature of chronic pain. A previous USA-based study describing real-world observational data reported a mean 5.1 point NRS pain score reduction in a cohort of 420 subjects at last follow up (mean 3 months) when utilizing the same SCS system evaluated in this current European-based assessment.<sup>1</sup>

**Conclusions:** In this multicenter, real-world European cohort of 91 patients implanted with a recently launched SCS System capable of delivering multiple waveforms and advanced stimulation modalities, a statistically significant improvement in low back pain ( $p < 0.0001$ ) reported at 3 months was observed ( $8.0 \Rightarrow 2.6$ ,  $\Delta = 5.2$ ). A significant improvement in quality-of-life was also noted as reported by EQ-5D-5L scores.

**References:** 1. Metzger C, Hammond MB, Pyles ST, et al. "Outcomes Using an SCS Device Capable of Delivering Combination Therapy and Advanced Waveforms/Field Shapes" [Abstract]. Annual Meeting of the North American Neuromodulation Society (NANS), 2020.

**Keyword:** spinal cord stimulation, SCS, chronic pain, multiple waveforms, neurostimulation

**Topic:** 05. Spine / 05a. Pain

## THE EFFECT OF INTERSPINOUS PROCESS DEVICE ON PAIN AND OPIOID CONSUMPTION IN PATIENTS WITH LUMBAR SPINAL STENOSIS

### E-POSTER VIEWING

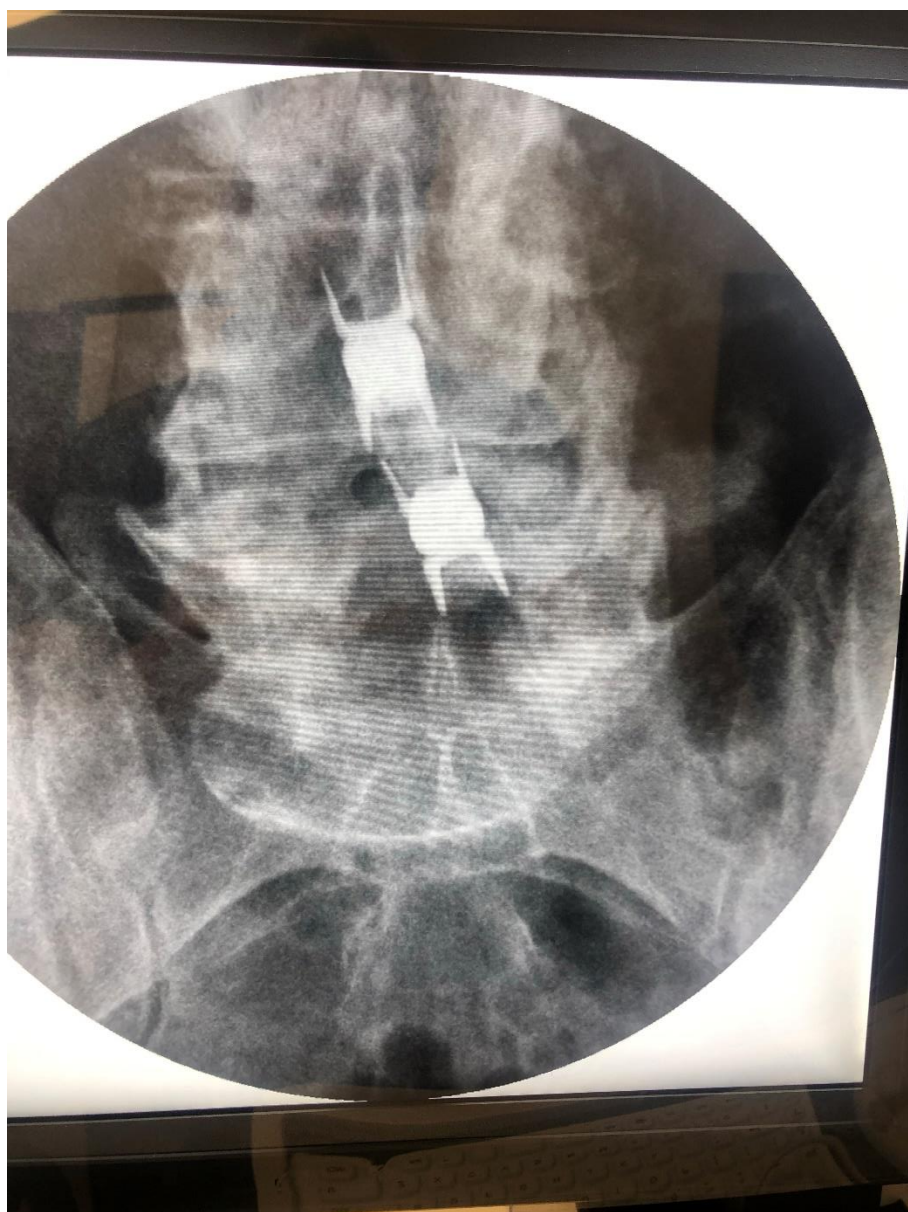
Ellen Lin<sup>1</sup>, Kaitlyn Egan<sup>2</sup>, Shravani Durbhakula<sup>3</sup>, Mitchell Engle<sup>4</sup>, Brian Rich<sup>5</sup>

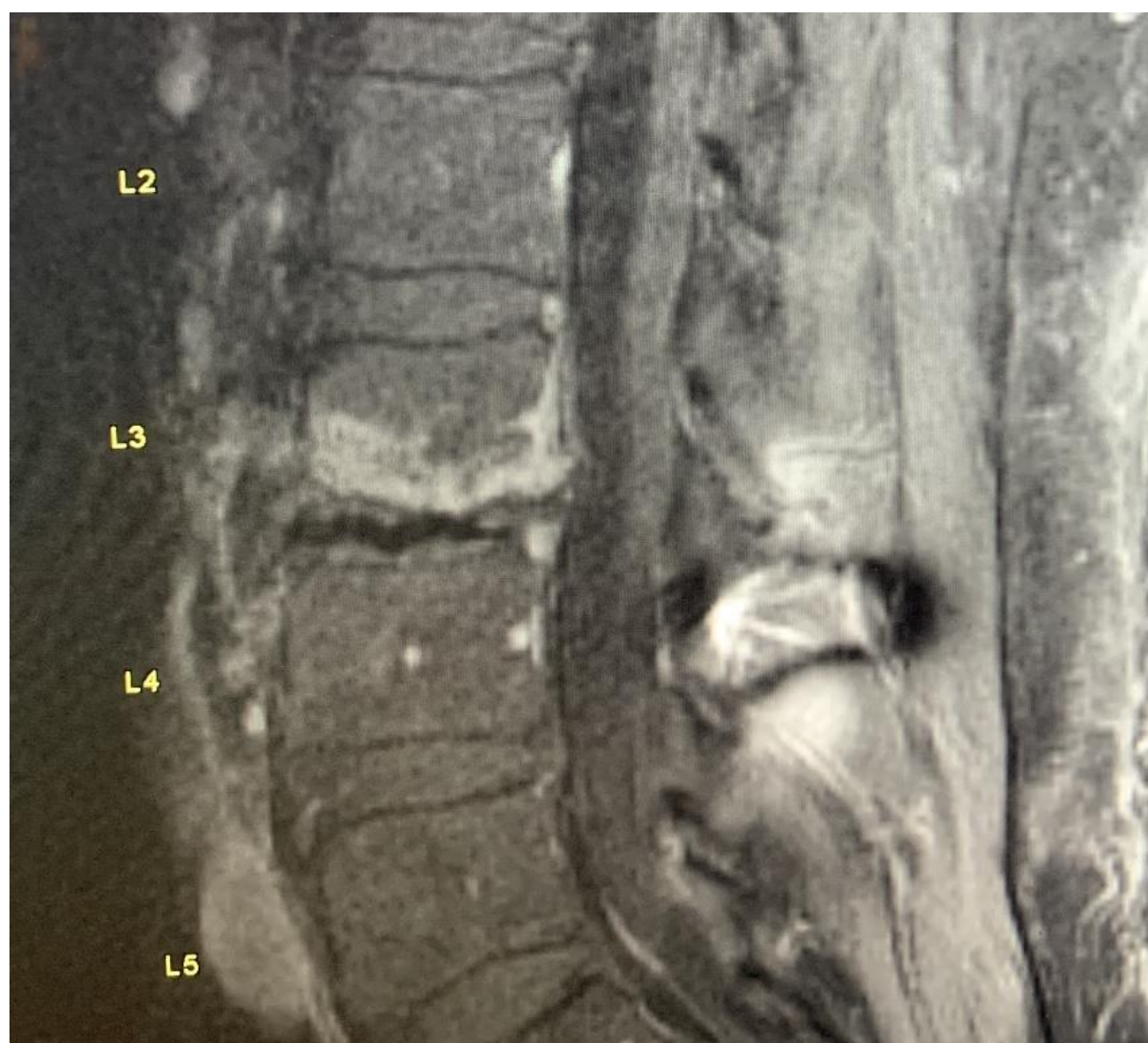
<sup>1</sup>Main Office, Advanced Spine & Pain Center, San Antonio, United States of America, <sup>2</sup>Pm&r, UT Health San Antonio, SAN ANTONIO, United States of America, <sup>3</sup>Anesthesiology & Critical Care Medicine, Johns Hopkins Medicine, Baltimore, United States of America, <sup>4</sup>Pain Medicine, Institute of Precision Pain Medicine, Corpus Christi, United States of America, <sup>5</sup>Pain Medicine, aCellerated Interventional Orthopedics, Lawton, United States of America

**Introduction:** Open decompression and fusion for lumbar degenerative stenosis has certain complication rate of 7.0%, death rate of 0.1%, and new neurological deficits of 0.6%. A novel interspinous process device (IPD) Vertiflex® has emerged offering an alternative to open decompression. The purpose of this retrospective study is to evaluate the efficacy and safety of this IPD.

**Methods/Materials:** All IPD [Vertiflex®] cases performed in a time span of two years were reviewed. This includes 69 cases, 66 patients, and 100 implants. Pain scores at clinic visits and Milligram Morphine Equivalent (MME) from the Texas Prescription Monitoring Program (PMP) were utilized to determine effect of indirect decompression via score difference between pre-implant date and furthest post-op review time-point of 1-2 months post-implant (12 cases), 2-6 months post-implant (25 cases), and 1+ year post-implant (32 cases). Device malfunction, intraoperative events, post-operative adverse events, pain scores, and concurrent interventions after implantation were also reviewed. The Wilcoxon Signed-Ranks Test was utilized to evaluate the statistical significance of decrease in MME and pain scores after indirect decompression implant.

**Results:** Overall, 65.2% (45/69) had decreased or zero MME, 18.8% (13/69) had unchanged MME use, and 15.9% (11/69) had increased MME. Overall, 63.8% (44/69) had decreased pain score, 13.0% (9/69) had no change in pain score, and 23.1% (16/69) had increased pain score. The Wilcoxon Signed-Ranks Test showed statistical significance for decrease in MME with  $p=0.026$  and showed statistical significance for decrease in pain score with  $p=0.0001$ . There was one device malfunction where the driver fractured (1.4%, 1/69). The procedure was abandoned in 1 case due to spinous process space that could not accommodate implant size (1.4%, 1/69). There was 3 patient with post-op spinous process fracture (4.3%, 3/69). There is also hardware failure in 1 case (1.4%). There were concurrent interventions such as lumbar ESI, radiofrequency ablation and surgical laminectomy in 42% (29/69) cases.









**Discussion:** IPD decreased patients' MME and pain scores with statistical significance. This study shows a low adverse events in comparison to traditional open surgeries. A confounding aspect of the study is the moderate amount of concurrent interventions such as radiofrequency ablation, and lumbar epidural steroid injections. Limitations of this study include pain score subjectivity, pain score relating to condition other than spinal stenosis, opioid use relating to condition other than spinal stenosis, and concurrent interventions post IPD implantation. Bone Density scans should be used prior to inserting IPD and better driver design so not to fracture the driver inside of the patient is crucial.

**Conclusions:** IPD can be an alternative option to open lumbar surgical options for lumbar spinal stenosis.

**References:** 1) Kalichman L, Cole R, Kim DH, et al. Spinal stenosis prevalence and association with symptoms: the Framingham Study. *Spine J.* 2009;9(7):545-550. doi: 10.1016/j.spinee.2009.03.005 2) FU, Kai-Ming et al. Morbidity and mortality in the surgical treatment of 10,329 adults with degenerative lumbar stenosis: Clinical article. *Journal of neurosurgery.* 2010;12:443-446. doi: 10.3171/2009.11.SPINE09531 3) Hicks GE, Morone N, Weiner DK. Degenerative lumbar disc and facet disease in older adults: prevalence and clinical correlates. *Spine (Phila Pa 1976)* 2009;34:1301-6. 10.1097/BRS.0b013e3181a18263 4) Urban JP, Roberts S. Degeneration of the intervertebral disc.



Arthritis Res Ther 2003;5:120-30. 10.1186/ar629 5) Cinotti G, De Santis P, Nofroni I, et al. Stenosis of lumbar intervertebral foramen: anatomic study on predisposing factors. Spine (Phila Pa 1976) 2002;27:223-9. 10.1097/00007632-200202010-00002 6) Kandel R, Roberts S, Urban JP. Tissue engineering and the intervertebral disc: the challenges. Eur Spine J 2008;17:480-91. 10.1007/s00586-008-0746-2 7) Phan K, Mobbs RJ. Minimally Invasive Versus Open Laminectomy for Lumbar Stenosis: A Systematic Review and Meta-Analysis. Spine (Phila Pa 1976) 2016;41:E91-E100. 10.1097/BRS.0000000000001161 8) Gazzeri R, Galarza M, Alfieri A. Controversies about interspinous process devices in the treatment of degenerative lumbar spine diseases: past, present, and future. Biomed Res Int 2014;2014:975052. 9) Alfieri A, Gazzeri R, Prell J, et al. Role of lumbar interspinous distraction on the neural elements. Neurosurg Rev 2012;35:477-84; discussion 484. 10.1007/s10143-012-0394-1 10) Sobottke R, Schlüter-Brust K, Kaulhausen T, et al. Interspinous implants (X Stop, Wallis, Diam) for the treatment of LSS: is there a correlation between radiological parameters and clinical outcome? Eur Spine J 2009;18:1494-503. 10.1007/s00586-009-1081-y 11) Richards JC, Majumdar S, Lindsey DP, et al. The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication. Spine (Phila Pa 1976) 2005;30:744-9. 10.1097/01.brs.0000157483.28505.e3 e Scho 12) Moojen WA, Arts MP, Jacobs WC, et al. IPD without bony decompression versus conventional surgical decompression for lumbar spinal stenosis: 2-year results of a double-blind randomized controlled trial. Eur Spine J 2015;24:2295-305. 10.1007/s00586-014-3748- 13) Kim KA, McDonald M, Pik JH, et al. Dynamic intraspinal spacer technology for posterior stabilization: case-control study on the safety, sagittal angulation, and pain outcome at 1-year follow-up evaluation. Neurosurg Focus 2007;22:E7. 10.3171/foc.2007.22.1.7 14) Guehring T, Omlor GW, Lorenz H, et al. Disc distraction shows evidence of regenerative potential in degenerated intervertebral discs as evaluated by protein expression, magnetic resonance imaging, and messenger ribonucleic acid expression analysis. Spine (Phila Pa 1976) 2006;31:1658-65. 10.1097/01.brs.0000224558.81765.56 15). Villarejo F, Carceller F, de la Riva AG, et al. Experience with coflex interspinous implant. Acta Neurochir Suppl 2011;108:171-5. 10.1007/978-3-211-99370-5\_25 16) Parker SL, Anderson LH, Nelson T, et al. Cost-effectiveness of three treatment strategies for lumbar spinal stenosis: Conservative care, laminectomy, and the Superion interspinous spacer. Int J Spine Surg 2015;9:28. 10.14444/2028 [PMC free article]

**Keywords:** interspinous spacers, opioid reduction, lumbar spinal stenosis, Interspinous device, lumbar decompression, Vertiflex

**Topic:** 05. Spine / 05a. Pain

## **INTRATHECAL TRITHERAPY WITH MORPHINE, ROPIVACAINE AND ZICONOTIDE FOR PELVIC PAIN TREATMENT IN PATIENTS WITH GYNECOLOGICAL CANCER**

### **E-POSTER VIEWING**

Marie Pechard<sup>1</sup>, Mary Saad<sup>1</sup>, Christian Jayr<sup>1</sup>, Ester Molina<sup>1</sup>, Roman Rouzier<sup>2</sup>, Denis Dupoirion<sup>3</sup>, Didier Bouhassira<sup>4</sup>, Serge Perrot<sup>5</sup>

<sup>1</sup>Anesthesia And Pain Medicine, INSTITUT CURIE, SAINT CLOUD, France, <sup>2</sup>Surgery, INSTITUT CURIE, SAINT CLOUD, France, <sup>3</sup>Anesthesia And Pain Medicine, INSTITUT DE CANCEROLOGIE DE L OUEST, ANGERS, France, <sup>4</sup>Pain Medicine, INSERM U987, BOULOGNE BILLANCOURT, France, <sup>5</sup>Pain Medicine, COCHIN, APHP, PARIS, France

**Introduction:** The most recent review reported a prevalence of pain in 66.4% of patients with advanced, metastatic or terminal cancer, with 38% of patients having moderate to severe pain regardless of cancer stage [1]. In patients with advanced cervical cancer, pelvic pain is the most common symptom [2]. A randomized clinical trial has demonstrated the efficiency of intrathecal analgesia in oncology [3].

**Methods/Materials:** This retrospective study was conducted in France. The objective was to evaluate the efficacy of intrathecal tritherapy with morphine, ropivacaine and ziconotide for pain relief after the first week of treatment, then monthly until death, in patients with pelvic gynecological cancers. Secondary objectives were the evaluation of the proportion of 30% pain-relief-responders, 50% pain-relief-responders (after the first week of treatment then monthly, until death). The local ethics committee validated this study.

**Results:** We report a series of twelve patients, with uterine and vulvar cancer. Eleven patients had metastatic disease. Mean age was 57.5 years. Before intrathecal tritherapy initiation, mean daily morphine consumption was 620mg of oral morphine equivalent and mean pain intensity was 7.08/10 on a numerical pain scale. Mean pain intensity was 1.6/10, 1.5/10, 1.5/10, 1.7/10 and 2/10 after 7 days (11 patients), one month (9 patients), two months (8 patients), three months (3 patients) and four months (3 patients) respectively. One patient was alive after 5 months of treatment and had a mean pain intensity score of 2/10 throughout the subsequent 3 months (M5, M6, M7). All twelve patients had a pain intensity reduction of at least 30% from day 7 to the fourth month after treatment initiation. After 7 days of treatment, 72.7% of patients reported a decrease in pain intensity of at least 50%. One month after initiation of the treatment, all patients had pain intensity reduction of at least 50% and this was maintained up to the fourth month, Mean intrathecal treatment duration was 101.7 days.

**Discussion:** Intrathecal tritherapy with morphine, ropivacaine and ziconotide seems to be highly efficient in the treatment of pelvic pain in patients with advanced gynecological cancer. It allows, in most cases, a reduction of at least 50% of pain intensity as early as 7 days after the initiation of the treatment and for as long as the time of death, despite cancer progression.

**Conclusions:** A prospective study is ongoing to evaluate the quality of life of patient with cancer pain treated by intrathecal analgesia.

**References:** [1] Van den Beuken-van Everdingen MH, Hochstenbach LM, Joosten EA, Tjan-Heijnen VC, Janssen DJ Update on Prevalence of Pain in Patients With Cancer: Systematic Review and Meta-Analysis. *J Pain Symptom Manage* 2016;51(6): 1070-90. [2] Kim YJ, Munsell MF, Park JC, Meyer LA, Sun CC, Brown AJ, Bodurka DC, Williams JL, Chase DM, Bruera E, Ramondetta LM. Retrospective review of symptoms and palliative care interventions in women with advanced cervical cancer. *Gynecol Oncol*. 2015 Dec;139(3):553-8 [3] Smith TJ, Staats PS, Deer T et al. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. *J Clin Oncol*, 2002;20:4040-9

**Keyword:** pelvic pain, cancer, intrathecal analgesia, morphine, ropivacaine, ziconotide

**Topic:** 05. Spine / 05a. Pain

## **FUNCTIONAL & PAIN OUTCOME MEASURES IN A LARGE TERTIARY CARE UK NEUROMODULATION CENTRE- 5 YEAR FOLLOW UP DATA .**

### **E-POSTER VIEWING**

Alia Ahmad<sup>1</sup>, Deepika Arora<sup>2</sup>, Joanne Lascelles<sup>3</sup>, Serge Nikolic<sup>3</sup>, Habib Ellamushi<sup>3</sup>, Richard Vangroningen<sup>3</sup>, Kavita Poply<sup>3</sup>, Angie Alamgir<sup>3</sup>, Vivek Mehta<sup>3</sup>

<sup>1</sup>Pain Research, Barts Health NHS Trust, London, United Kingdom, <sup>2</sup>Anaesthesia And Pain Medicine, Royal London Hospital, London, United Kingdom, <sup>3</sup>Pain Research Centre, Barts Health NHS Trust, London, United Kingdom

**Introduction:** Spinal Cord Stimulation (SCS) has emerged as a very helpful modality in treating refractory neuropathic pain secondary to various conditions like degenerative disc disease, failed back surgery syndrome, CRPS (Complex regional pain syndrome).<sup>1-3</sup> We report follow up data of patients receiving SCS at our centre from their pre-implantation assessment to up to 2 years. We assessed various parameters including pain reduction, emotional distress and functional assessment and improvement in quality of life. It is an attempt to determine long term efficacy of this technique.

**Methods/Materials:** Pain severity was assessed via NRS (Numerical rating score). Brief Pain Index (BPI) was used to assess physical functioning. Emotional distress and functioning were assessed by Hospital Anxiety Depression Scale (HADS) and Pain Self Efficacy Questionnaire (PSEQ). EQ-5D index was used to assess the quality of life. These questionnaires were given to patients in their by pre-implant assessment and subsequently in post implantation appointments at 1, 3, 6, 12 months and 2 years.

**Results:** 135 patients were assessed in the pre-implantation appointment, 75 patients at 1 month, 58 patients at 3 months, 49 patients at 6 months, 44 patients at 12 months and 23 patients at 2 years follow up. Mean age of the patients was 53 years and 61.5% of them were females. There was reduction by 38% in mean pain severity score from baseline at 3 months, 44% at 1 year and 32% at 2 years. Mean Anxiety and Depression scores which were comparable at baseline (10.9 and 10.7 respectively, abnormal) also reduced significantly in early follow ups (by 30-50%) and were under 10 at 2 years follow up. The mean PSEQ score increased to more than 30 in the all the post SCS follow ups from the baseline of value of 17.7. The quality of life improved as well as depicted from the baseline mean EQ5D index value of 0.3 rising to more than 0.6 in all the follow ups up to 2 years.

**Discussion:** This is a prospective real world follow up and highlights the need for qualitative assessment of the response to Neuromodulation in this difficult population. Besides pain scores, assessment of other outcome measures including mood, anxiety, depression, functional status and quality of life are important parameters that determine success of this therapy.

**Conclusions:** Outcome measures assessment showed an improvement in terms of pain severity, emotional distress, functional status and quality of life even at long term follow ups up to 2 years.

**References:** 1. Kapural, Leonardo, Peterson, Erika, Provenzano, David A, Staats, Peter. Clinical Evidence for Spinal Cord Stimulation for Failed Back Surgery Syndrome (FBSS)- Systematic Review. Spine: July 15, 2017 - Volume 42 - Issue - p S53-S60 2. Taylor RS, Van Buyten JP, Buchser E. Spinal cord stimulation for chronic back and leg pain and failed back surgery syndrome: a systematic review and analysis of prognostic factors. Spine (Phila Pa 1976) 2005; 30:152–160. 3. Turner JA, Loeser JD, Deyo RA, et al. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. Pain 2004; 108:137–147.

**Keyword:** neuromodulation, spinal cord stimulation, pain severity

**Topic:** 05. Spine / 05a. Pain

## **SEQUENTIAL MODE FOR TREATMENT OF REFRACTORY CANCER PAIN AFTER CONTINUOUS MODE FAILURE, RETROSPECTIVE FOLLOW-UP STUDY**

### **E-POSTER VIEWING**

Sabrina Jubier-Hamon<sup>1</sup>, Gabriel Carvajal<sup>2</sup>, Denis Dupoirion<sup>3</sup>, Florent Bienfait<sup>3</sup>

<sup>1</sup>Anesthésie/douleur, Institut de Cancérologie de l'Ouest, site Paul Papin, Angers Cedex, France, <sup>2</sup>Interventional Pain Unit, Centro Nacional de Control del Dolor y Cuidados Paliativos, San José, Costa Rica, <sup>3</sup>Anesthesia And Pain Medicine, INSTITUT DE CANCEROLOGIE DE L OUEST, ANGERS, France

**Introduction:** Despite comprehensive medical management, 10-15 % of cancer patients still suffer from pain [1] . In these situations, Intrathecal Drug Delivery System (IDDS) is a way to control pain [2]. However, in the evolution of the disease, daily drug dosage escalation appears insufficient to relieve their pain. Recent publications suggest that using boluses in addition to conventional continuous infusion may help intrathecal drug spread and thus improve analgesia [3]. Different factors may affect drug diffusion in the cerebrospinal fluid, including pump flow rate. The primary goal of this study is to ascertain whether using a low basal rate with large boluses (sequential mode) provides better pain relief than continuous infusion does.

**Methods/Materials:** A retrospective follow-up study was conducted at the Institut de Cancerologie de l'Ouest, Paul Papin. We reviewed electronic medical records of patients with IDDS who received sequential mode intrathecal treatment from January 2016 to June 2019 and who were in severe pain despite continuous infusion of a mixture of morphine, ropivacaine and ziconotide. Institutional approval was obtained before data analysis. We analyzed the percentage of patients with higher pain relief ( $\geq 30\%$  reduction in pain score) after a change in the mode of administration (sequential vs continuous). The NRS score was used to assess pain.

**Results:** 32 patients were included, with a mean age of  $63,5 \pm 21$  (20-84), and the most common primary tumor location being pancreatic (21,9%). 25 of the 31 patients (80,6%) declared their experience with sequential mode successful (1 missing answer). 21 patients (65.6%) showed a  $\geq 30\%$  reduction in their pain score with sequential mode. We observed a significant difference in pain reduction between responders and non-responders, Delta NRS (-4 (-7, -3) responders / 0 (-2, 0) non responders  $p < 0.00001$ ).

**Discussion:** A 2016 multicentric study [4] comparing the flow rate mode and the intermittent mode (sequential mode) found no significant difference between the two groups. However, unlike in our study, the population included in the 2016 study did not suffer from refractory cancer pain. Additionally, the rates for each group in the 2016 study were considerably different from the rates used in our study. It follows that the results of these two studies, though ostensibly similar, should be considered separately.

**Conclusions:** Sequential intrathecal diffusion mode appears to have a positive impact on pain relief. Sequential mode may be considered for intrathecal analgesia failure to improve diffusion and pain control.

**References:** 1. Meuser, T.; Pietruck, C.; Radbruch, L.; Stute, P.; Lehmann, K.A.; Grond, S. Symptoms during cancer pain treatment following WHO-guidelines: a longitudinal follow-up study of symptom prevalence, severity and etiology. *Pain* 2001, 93, 247-257. 2. Smith, T.J.; Staats, P.S.; Deer, T.; Stearns, L.J.; Rauck, R.L.; Boortz-Marx, R.L.; Buchser, E.; Catala, E.; Bryce, D.A.; Coyne, P.J., et al. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. *J Clin Oncol* 2002, 20, 4040-4049. 3. Reck, T.; Chang, E.C.; Bechir, M.; Kallenbach, U. Applying a Part of the Daily Dose as Boli May Improve Intrathecal Opioid Therapy in Patients With

Chronic Pain. *Neuromodulation* 2016, 19, 533-540, doi:10.1111/ner.12391. 4. Eldabe S. and al  
Comparison of the Effects of Intermittent Boluses to Simple Continuous Infusion on Patients' Global  
Perceived Effect in Intrathecal Therapy for Pain: A Randomized Double-Blind Crossover Study. *Pain  
Medicine* 2016; 0: 1–8

**Keywords:** Pain treatment (invasive), Intrathecal Drug Delivery, Cancer Pain

Topic: 05. Spine / 05a. Pain

## INTRATHECAL ZICONOTIDE AND MORPHINE USING CERVICAL CATHETERS FOR CANCER ANALGESIA IN A COMPREHENSIVE CANCER CENTER.

### E-POSTER VIEWING

Gabriel Carvajal<sup>1</sup>, Denis Dupoirion<sup>2</sup>, Sabrina Jubier-Hamon<sup>2</sup>, Nathalie Lebrech<sup>2</sup>

<sup>1</sup>Interventional Pain Unit, Centro Nacional de Control del Dolor y Cuidados Paliativos, San José, Costa Rica, <sup>2</sup>Anesthésie/douleur, Institut de Cancérologie de l'Ouest, site Paul Papin, Angers Cedex, France

**Introduction:** Cancer is the 1<sup>st</sup> leading cause of death in Western Europe and patients with cancer have a high prevalence of pain. Intrathecal analgesia is an important technique for complex cases refractory to comprehensive medical management. Analgesia using intrathecal drug delivery systems (IDDS) through cervical catheters has been poorly described on medical literature. CERVical Intrathecal Catheters for Cancer AnaLgesia (CERV-ICCAL) was a prospective follow up study designed to evaluate results of cervical IDDS for Cancer pain at the Institut de Cancérologie de l'Ouest, Paul Papin, a comprehensive Cancer Center in France.

**Methods/Materials:** Institutional ethics committee approval was granted. Patients were treated from January 2010 to November 2019. Patients were selected for IDDS based on multidisciplinary meeting discussion. All IDDS-treated patients were prescribed a combined intrathecal analgesics regimen (combining morphine and ziconotide) through a catheter placed in the cervical vertebral canal according to painful metameric level. Post-implant assessment of pain was determined using a numeric rating scale (NRS). Patients were followed via day-hospital visits and telephone calls at least monthly. Pain scores were compared using the Wilcoxon's signed rank test. Overall survival (OS) was estimated using the Kaplan-Meier method.

**Results:** 68 patients were included in this study, all received high cervical IDDS and total therapy duration accounts for 6734 IDDS-days. Median age at surgery was 61.5 years. Implanted patients suffered from severe pain (mean presurgical NRS 8±1) despite a mean 575.4 mg oral morphine equivalent daily dose. Most common primary cancer were lung (33.8%), head and neck cancer (22.1%) and breast cancer (19.1%). Median survival time after intrathecal treatment start was 3.3 ± 6 months. IDDS provided pain relief compared to initial pain score with a significant statistical difference after 1 month and 2 months ( $p < 0.01$ ). Complications did not exceed previous series.

**Discussion:** This is the largest study of Cervical IDDS published thus far. Our results are consistent with those from intrathecal catheters at other locations, this technique is a credible alternative to ablative treatments and has the advantage of adaptability over time.

**Conclusions:** Results suggest that long-term IDDS using a multidrug regimen for cancer related pain through cervical intrathecal catheters reduced pain intensity scores and was safe in our study population. We have demonstrated a clinically and statistically significant pain reduction in patients receiving IDDS through catheters placed in cervical intrathecal space using mainly a percutaneous lumbar approach.

**References:** 1. Townsend N, Wilson L, Bhatnagar P, Wickramasinghe K, Rayner M, Nichols M. Cardiovascular disease in Europe: epidemiological update 2016. *Eur Heart J*. 2016;37(42):3232-3245. doi:10.1093/eurheartj/ehw334 2. van den Beuken-van Everdingen MHJ, Hochstenbach LMJ, Joosten EAJ, Tjan-Heijnen VCG, Janssen DJA. Update on Prevalence of Pain in Patients With Cancer: Systematic Review and Meta-Analysis. *J Pain Symptom Manage*. 2016;51(6):1070-1090.e9. doi:10.1016/j.jpainsymman.2015.12.340 3. Breivik H, Cherny N, Collett B, et al. Cancer-related pain: a pan-European survey of prevalence, treatment, and patient attitudes. *Ann Oncol Off J Eur Soc Med Oncol*. 2009;20(8):1420-1433. doi:10.1093/annonc/mdp001 4. Smith TJ, Staats PS, Deer T, et al. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. *J*

Clin Oncol Off J Am Soc Clin Oncol. 2002;20(19):4040-4049. doi:10.1200/JCO.2002.02.118 5. Smith TJ, Coyne PJ. Implantable drug delivery systems (IDDS) after failure of comprehensive medical management (CMM) can palliate symptoms in the most refractory cancer pain patients. *J Palliat Med*. 2005;8(4):736-742. doi:10.1089/jpm.2005.8.736 6. Dupouiron D. L'infusion intrathécale dans les douleurs réfractaires. *Douleur Analgésie*. 2015;28(3):123-130. doi:10.1007/s11724-015-0435-y 7. Bernards CM. Cerebrospinal fluid and spinal cord distribution of baclofen and bupivacaine during slow intrathecal infusion in pigs. *Anesthesiology*. 2006;105(1):169-178. 8. Flack SH, Anderson CM, Bernards C. Morphine Distribution in the Spinal Cord After Chronic Infusion in Pigs: *Anesth Analg*. 2011;112(2):460-464. doi:10.1213/ANE.0b013e318203b7c0 9. Heetla HW, Proost JH, Molmans BH, Staal MJ, van Laar T. A pharmacokinetic-pharmacodynamic model for intrathecal baclofen in patients with severe spasticity. *Br J Clin Pharmacol*. 2016;81(1):101-112. doi:10.1111/bcp.12781 10. Deer TR, Pope JE, Hayek S, et al. The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practices and Guidelines. *Neuromodulation J Int Neuromodulation Soc*. January 2017. doi:10.1111/ner.12538 11. Hopkins Opioid Program (HOP): Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. [http://www.hopkinsmedicine.org/kimmel\\_cancer\\_center/centers/pain\\_hop/](http://www.hopkinsmedicine.org/kimmel_cancer_center/centers/pain_hop/). Accessed April 24, 2017. 12. Dupouiron D, Devys C, Bazin C, et al. Rationale for Prospective Assays of Intrathecal Mixtures Including Morphine, Ropivacaine and Ziconotide: Prevention of Adverse Events and Feasibility in Clinical Practice. *Pain Physician*. 2015;18(4):349-357. 13. Onofrio BM, Yaksh TL, Arnold PG. Continuous low-dose intrathecal morphine administration in the treatment of chronic pain of malignant origin. *Mayo Clin Proc*. 1981;56(8):516-520. 14. Jose DA, Luciano P, Vicente V, Juan Marcos AS, Gustavo F-C. Role of Catheter's Position for Final Results in Intrathecal Drug Delivery. Analysis Based on CSF Dynamics and Specific Drugs Profiles. *Korean J Pain*. 2013;26(4):336-346. doi:10.3344/kjp.2013.26.4.336 15. Hocking G, Wildsmith J a. W. Intrathecal drug spread. *Br J Anaesth*. 2004;93(4):568-578. doi:10.1093/bja/ae204 16. Haga PT, Pizzichelli G, Mortensen M, et al. A numerical investigation of intrathecal isobaric drug dispersion within the cervical subarachnoid space. *PLoS One*. 2017;12(3):e0173680. doi:10.1371/journal.pone.0173680 17. Tangen KM, Leval R, Mehta AI, Linninger AA. Computational and In Vitro Experimental Investigation of Intrathecal Drug Distribution: Parametric Study of the Effect of Injection Volume, Cerebrospinal Fluid Pulsatility, and Drug Uptake. *Anesth Analg*. 2017;124(5):1686-1696. doi:10.1213/ANE.0000000000002011 18. Kershner DE, Binhammer RT. Lumbar intrathecal ligaments. *Clin Anat N Y N*. 2002;15(2):82-87. doi:10.1002/ca.1100 19. Parkinson D. Human spinal arachnoid septa, trabeculae, and "rogue strands." *Am J Anat*. 1991;192(4):498-509. doi:10.1002/aja.1001920414 20. Parkinson D, Del Bigio MR. Posterior "septum" of human spinal cord: normal developmental variations, composition, and terminology. *Anat Rec*. 1996;244(4):572-578. doi:10.1002/(SICI)1097-0185(199604)244:4<572::AID-AR15>3.0.CO;2-M 21. Ceylan D, Tatarlı N, Abdullaev T, et al. The denticulate ligament: anatomical properties, functional and clinical significance. *Acta Neurochir (Wien)*. 2012;154(7):1229-1234. doi:10.1007/s00701-012-1361-x 22. Schulder M. Intrathecal bupivacaine for head and neck pain. *Local Reg Anesth*. October 2010;125. doi:10.2147/LRA.S7841 23. Staquet H, Dupouiron D, Nader E, Menei P. Intracerebroventricular Pain Treatment with Analgesic Mixtures including Ziconotide for Intractable Pain. *Pain Physician*. 2016;19(6):E905-915. 24. Crul BJ, van Dongen RT, Snijdelaar DG, Rutten EH. Long-term continuous intrathecal administration of morphine and bupivacaine at the upper cervical level: access by a lateral C1-C2 approach. *Anesth Analg*. 1994;79(3):594-597. 25. Appelgren L, Janson M, Nitescu P, Curelaru I. Continuous intracisternal and high cervical intrathecal bupivacaine analgesia in refractory head and neck pain. *Anesthesiology*. 1996;84(2):256-272. 26. Baker L, Balls J, Regnard C, Pridie A. Cervical intrathecal analgesia for head and neck/upper limb cancer pain: six case reports. *Palliat Med*. 2007;21(6):543-545. doi:10.1177/0269216307081130 27. Lundborg C, Dahm P, Nitescu P, Biber B. High intrathecal bupivacaine for severe pain in the head and neck. *Acta Anaesthesiol Scand*. 2009;53(7):908-913. doi:10.1111/j.1399-6576.2009.01989.x 28. Wallace MS, Rauck RL, Deer T. Ziconotide combination intrathecal therapy: rationale and evidence. *Clin J Pain*. 2010;26(7):635-644. doi:10.1097/AJP.0b013e3181e017df 29. Wallace MS, Kosek PS, Staats P, Fisher R, Schultz DM, Leong M. Phase II, open-label, multicenter study of combined intrathecal morphine and ziconotide: addition of ziconotide in patients receiving intrathecal morphine for severe chronic pain. *Pain Med Malden Mass*. 2008;9(3):271-281. doi:10.1111/j.1526-4637.2007.00355.x 30. Webster LR, Fakata KL, Charapata S, Fisher R, Minehart M. Open-label, multicenter study of combined intrathecal morphine and ziconotide: addition of morphine in patients receiving ziconotide for severe chronic pain. *Pain Med Malden Mass*. 2008;9(3):282-290. doi:10.1111/j.1526-4637.2007.00356.x 31. Dupouiron D, Richard H, Chabert-Desnot V, Devys C, Leynia P, Boisdron-Celle M. In vitro stability of low-concentration ziconotide alone or in admixtures in intrathecal pumps. *Neuromodulation J Int Neuromodulation Soc*. 2014;17(5):472-482; discussion 482.



doi:10.1111/ner.12142 32. Shields D, Montenegro R, Ragusa M. Chemical Stability of Admixtures Combining Ziconotide with Morphine or Hydromorphone During Simulated Intrathecal Administration. *Neuromodulation J Int Neuromodulation Soc.* 2005;8(4):257-263. doi:10.1111/j.1525-1403.2005.00034.x 33. Bazin C, Poirier A-L, Dupoirion D. Influence of pH and temperature on ziconotide stability in intrathecal analgesic admixtures in implantable pumps and syringes. *Int J Pharm.* 2015;487(1-2):285-291. doi:10.1016/j.ijpharm.2015.04.041 34. Robert J, Sorrieul J, Rossignol E, et al. Chemical Stability of Morphine, Ropivacaine, and Ziconotide in Combination for Intrathecal Analgesia. *Int J Pharm Compd.* 2017;21(4):347-351.

**Keywords:** Pain Management, Pain, Intrathecal Implantable Drug Delivery System, Cancer Pain

**Topic:** 05. Spine / 05a. Pain

## **PARESTHESIA MAPPED VS. ANATOMICALLY TARGETED LEAD PLACEMENT OF SPINAL CORD STIMULATION**

### **E-POSTER VIEWING**

Naoki Higashiyama, Takuro Endo, Toshiyuki Tsuji, Taku Sugawara  
Spinal Surgery, Akita Cerebrospinal and Cardiovascular Center, Akita, Japan

**Introduction:** Many studies have demonstrated the efficacy of spinal cord stimulation (SCS) for the treatment of failed back surgery syndrome (FBSS), and randomized controlled trials have shown SCS to be a clinically effective adjunct to medical management. Several studies have demonstrated the potential interest of high frequency stimulation to treat FBSS patients compared to conventional SCS. The purpose of this study is to compare the efficacy of conventional paresthesia-mapped lead placement (PM) and anatomically targeted lead placement (AT) techniques for SCS.

**Methods/Materials:** We retrospectively reviewed the outcomes of patients for FBSS who underwent implantation by PM technique or AT technique between Sep 2016 and Nov 2019. In the AT approach, the activated bipolar was overlapping the T9/10 interspace. In the PM approach, we confirmed coverage of the patient's primary pain location. We compared PM group and AT group with operative time and >50% pain relief rates at 3 months.

**Results:** A total of 41 patients (PM : n = 14, AT: n = 27) underwent SCS implantation. Operative time was shorter for AT group (47.8±9.7min) compared to PM group (82.9±20.3 min) (P<0.0001). >50% pain relief was not significantly different between the two groups.

**Discussion:** To confirm paresthesia during the procedure in the elderly may be complicated by hearing and language difficulties or by sedative-related confusion. Compared to PM group, AT group allows for lower operative times and more efficient and accurate positioning of the electrodes.

**Conclusions:** This study suggests that AT technique may provide an effective treatment for patient with FBSS.

### **References:**

**Keywords:** anatomical lead placement, paresthesia mapping, SCS, FBSS

**Topic:** 05. Spine / 05a. Pain

**GOAL IDENTIFICATION BEFORE SPINAL CORD STIMULATION: A QUALITATIVE EXPLORATION IN POTENTIAL CANDIDATES.**

**E-POSTER VIEWING**

Lisa Goudman, Maarten Moens  
Neurosurgery, UZ Brussel, Jette, Belgium

**Introduction:** Due to the difficulties encountered in the treatment process of patients with chronic pain, it is of utmost importance to involve patients themselves in their rehabilitation trajectory. Patient engagement can be obtained by motivating patients to select their own treatment goals. We hypothesize that applying goal setting, as a form of patient empowerment, in potential candidates for spinal cord stimulation (SCS) may further improve the outcome of SCS. As a first step in creating patient empowerment, patients' goals that they aim to achieve with SCS will be explored.

**Methods/Materials:** Fifteen patients suffering from failed back/neck surgery syndrome and scheduled for SCS were interviewed in depth. All interviews were audio recorded and analyzed using in vivo coding. Afterwards, the International Classification of Functioning, Disability and Health framework was used to structure the responses of patients.

**Results:** In the domain of bodily functions, all patients mentioned pain reduction, and 1 patient wanted to regain his previous sleep pattern. In the domain of activities, walking, sitting, driving a car, bending down, and picking up were the highest ranked goals. Regaining a social life was the highest ranked goal for participation. Eleven patients wanted to regain a feeling of happiness, and 5 patients wanted to focus on avoiding depression.

**Discussion:** The interviews revealed a broad spectrum of individual patients' goals, highlighting the need of individually targeted rehabilitation trajectories in the field of neuromodulation.

**Conclusions:** Goal identification could entail the first step towards individualized medicine in the SCS trajectory.

**References:**

**Keywords:** goalsetting, rehabilitation, individualized medicine

**Topic:** 05. Spine / 05a. Pain

## THE ASSOCIATION BETWEEN PAIN INTENSITY AND DISABILITY IN PATIENTS WITH FAILED BACK SURGERY SYNDROME, TREATED WITH SPINAL CORD STIMULATION

### E-POSTER VIEWING

Mats De Jaeger<sup>1</sup>, Lisa Goudman<sup>1</sup>, Sam Eldabe<sup>2</sup>, Robert Van Dongen<sup>3</sup>, Ann De Smedt<sup>4</sup>, Maarten Moens<sup>5</sup>

<sup>1</sup>Neurosurgery, Universitair ziekenhuis Brussel, Jette, Belgium, <sup>2</sup>Pain Medicine, James Cook Hospital, Middlesbrough, United Kingdom, <sup>3</sup>Anesthesiology, Pain And Palliative Care, Radboud University Medical Center, Nijmegen, Netherlands, <sup>4</sup>Physical Medicine And Rehabilitation, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>5</sup>Neurosurgery, UZ Brussel, Brussel, Belgium

**Introduction:** Pain researchers demonstrated that pain intensity is not the most reliable measure of the success of chronic-pain treatment. Several research groups have proposed “core outcome domains”, such as measurements of disability, to assess the effect of an intervention. Nevertheless, studies investigating the relation between pain intensity and disability in patients treated with spinal cord stimulation (SCS) are lacking. Therefore, the goal is to examine which pain-reporting strategy, routinely used in pain research, associates best with the degree of disability in these patients.

**Methods/Materials:** Eighty-one failed back surgery syndrome patients (37 males and 44 females, mean age 54.6 years), treated with high-dose spinal cord stimulation (HD-SCS) are recruited. Pain intensity was scored on an 11-point numerical rating scale (NRS) for leg and back pain, while disability was assessed with the Oswestry disability index (ODI). The association between both variables was investigated with Spearman's correlation and Cramer's V.

**Results:** Significant correlations ( $p < 0.001$ ) are found between the absolute and relative differences of the ODI and NRS. Significant associations were found between reported cut-offs in literature and the degree of disability. Finally, a significant association ( $p < 0.001$ ) was found between the minimal clinical important difference.

**Discussion:** This study investigated which pain reporting strategy corresponds best with the degree of disability, by exploring the association between frequently used pain-reporting strategies and the ODI, in FBSS patients. Studies defining recovery or remission often focus on an arbitrarily defined cut-off value on a pain scale in combination with a “time-component cut-off” (e.g., one month pain free), but are rarely linked to a secondary scale (e.g., quality of life, disability). Therefore, little is known about the relationship between pain intensity and disability in chronic pain conditions. The moderate to strong positive correlation between the NRS and ODI, as found in this study, might indicate that one should consider obtaining a better insight in the clinical profile of the patient by measuring the disability profile instead of a pain intensity score. This leads to the suggestion that the ODI could serve as a valid tool to measure the effect of SCS on pain, in patients with FBSS.

**Conclusions:** The degree of disability was strongly associated with the pain intensity as measured using different methods. The standard method for reporting pain intensity reduction (50%) seems to associate the strongest with the degree of disability. However, a low degree of disability does not always reflect a low pain intensity.

### References:

**Keywords:** Pain, Spinal cord stimulation, Disability, Failed Back Surgery Syndrome

Topic: 05. Spine / 05a. Pain

## HIGH DOSE SPINAL CORD STIMULATION IN PATIENTS WITH FAILED BACK SURGERY SYNDROME AFTER CONVERSION FROM STANDARD SPINAL CORD STIMULATION: AN EFFECTIVENESS AND PREDICTION STUDY.

### E-POSTER VIEWING

Mats De Jaeger<sup>1</sup>, Lisa Goudman<sup>1</sup>, Raf Brouns<sup>2</sup>, Ann De Smedt<sup>3</sup>, Bengt Linderöth<sup>4</sup>, Sam Eldabe<sup>5,6</sup>, [Maarten Moens](#)<sup>7</sup>

<sup>1</sup>Neurosurgery, Universitair ziekenhuis Brussel, Jette, Belgium, <sup>2</sup>Neurology, ZorgSaam Hospital, Terneuzen, Netherlands, <sup>3</sup>Physical Medicine And Rehabilitation, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>4</sup>Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden, <sup>5</sup>Pain Medicine, James Cook Hospital, Middlesbrough, United Kingdom, <sup>6</sup>Pain Management, South Tees Hospitals NHS Foundation Trust, Middlesbrough, United Kingdom, <sup>7</sup>Neurosurgery, UZ Brussel, Jette, Belgium

**Introduction:** Spinal Cord Stimulation (SCS) is nowadays available with several stimulation paradigms. New paradigms, such as High Dose (HD-)SCS, have shown the possibility to salvage patients who lost initial pain relief. The first aim is to evaluate the effectiveness of HD-SCS after conversion from standard SCS. The second aim is to develop a model for prediction of long-term response of HD-SCS after unsatisfactory standard SCS.

**Methods/Materials:** Seventy-eight patients with Failed Back Surgery Syndrome (FBSS) who are treated with standard SCS were enrolled in this registry. Self-reporting questionnaires and outcomes were assessed before conversion and at 1, 3 and 12 months of HDSCS. Longitudinal mixed models were used to determine the effectiveness of HD-SCS. Logistic regression and classification and decision tree analyses were performed to predict responders (NRS decrease  $\geq 2/10$ ) after 12 months of HD-SCS.

**Results:** Significant time effects were found for both low back and leg pain responders, suggesting the effectiveness of HD-SCS after conversion. Logistic regression models revealed the importance of pain intensity scores, medication use, paresthesia coverage (for back pain) and EQ5D (for leg pain) as predictors for being a responder after 12 months of HD-SCS.

**Discussion:** We present the first multicenter study evaluating the effectiveness of HD-SCS after 12 months of stimulation as a rescue from ineffective standard SCS, with an analysis of predictive factors of the outcome after the conversion. When interpreting these results, it needs to be considered that these analyses are performed in a specific population of patients with FBSS who were already treated with standard SCS. Future studies are required to evaluate the effectiveness of HD-SCS in patients who are SCS-naïve. Another limitation of this study is the amount of missing data, which has been tackled with the last observation carried forward method. This approach is rather conservative and no clear consensus on the best strategy is available yet.

**Conclusions:** Converting patients with unsatisfactory responses from standard SCS to HD-SCS may be an effective strategy to obtain and maintain pain relief in a challenging subgroup of patients with FBSS refractory to standard SCS. The prediction models may guide clinicians in their decision making when considering conversion to HD-SCS in patients with FBSS experiencing inadequate response to standard SCS

### References:

**Keywords:** Failed Back Surgery Syndrome, Spinal cord stimulation, High dose spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

**EFFECTS OF SPINAL CORD STIMULATION ON HEART RATE VARIABILITY IN PATIENTS WITH FAILED BACK SURGERY SYNDROME: COMPARISON BETWEEN A 2-LEAD ECG AND A WEARABLE DEVICE.**

**E-POSTER VIEWING**

Maarten Moens<sup>1</sup>, Lisa Goudman<sup>2</sup>, Bengt Linderöth<sup>3</sup>

<sup>1</sup>Neurosurgery, UZ Brussel, Brussel, Belgium, <sup>2</sup>Neurosurgery, Universitair ziekenhuis Brussel, Jette, Belgium, <sup>3</sup>Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

**Introduction:** Heart rate variability recordings have the potential to examine the role of the autonomic nervous system. Several wearable devices are nowadays readily available. Up until now, no studies explored whether a wearable device is able to reliably measure a treatment response in chronic pain patients. Therefore, the aim of this study is to evaluate the reliability of a Polar V800 (Polar Electro Oy, Finland) wearable device to accurately measure RR intervals in patients with failed back surgery syndrome (FBSS) during spinal cord stimulation (SCS), as compared with an eMotion 2-lead ECG recording.

**Methods/Materials:** Twenty-two patients diagnosed with FBSS and treated with SCS participated in this study. HRV was measured with a 2-lead ECG registration tool and a Polar V800 during on and off state of SCS. Intraclass correlation coefficients, correlations, limits of agreement, Cronbach's  $\alpha$ , and effect sizes were calculated.

**Results:** Analysis based on the recordings from the ECG and wearable device revealed the same HRV parameters (except for the time-frequency domain) to capture the treatment response of SCS. Parameters that are relevant for measuring the SCS treatment response have strong correlations ( $r \geq .82$ ), good ICC values ( $ICC \geq 0.82$ ), acceptable consistency ( $\alpha \geq .9$ ), and limited bias.

**Discussion:** Similar pre- to posttreatment changes were revealed between a wearable device and 2-lead ECG with reliable HRV estimates for parameters that are able to capture the treatment changes.

**Conclusions:** This suggests that a wearable heart rate monitor might be a reliable wearable tool for the detection of pre- to post treatment changes of SCS, in patients with FBSS.

**References:**

**Keywords:** SCS, Heart rate variability, functional neurosurgery, wearable device, FBSS, autonomic nervous system

**Topic:** 05. Spine / 05a. Pain

## ALTERNATIVE APPROACHES TO THE DRG

### E-POSTER VIEWING

Björn Carsten Schultheis<sup>1</sup>, Christian Wille<sup>2</sup>, Patrick Weidle<sup>3</sup>, Tim Vancamp<sup>4</sup>

<sup>1</sup>Interventionelle Schmerztherapie Msz, Krankenhaus Neuwerk, Niederkrüchten, Germany, <sup>2</sup>Department Of Neurosurgery, NCN Neurochirurgische Praxis Neus, Neuss, Germany, <sup>3</sup>Interventionelle Schmerztherapie, Krankenhaus Neuwerk "Maria von den Aposteln", Muskulo-Skeletales Zentrum, Mönchengladbach, Germany, <sup>4</sup>, e4Sci, Sabadell, Spain

**Introduction:** Anatomical structures (e.g. the intraforaminal ligaments), pathophysiological processes (e.g. spinal canal stenosis), and prior spinal surgery (e.g. decompression surgery which may lead to excessive scar tissue formation in the epidural space), may eventually prevent proper lead placement over the DRG and require modifications.<sup>1</sup> We describe three such modifications.

**Methods/Materials:** Three alternative implantation techniques were used: 1. open surgical placement of DRG leads, 2. two lead insertion via a lateral to medial transforaminal approach (level L3) and 3. percutaneous approach with two leads close to the spinal nerves L4 (PNS). We collected following pre- and post-intervention clinical data: NRS (Numeric Rating Scale), PDQ (Pain Detect Questionnaire), MPSS (Mainz Pain Staging System), MOS Sleep Scale (Sleep Scale from the Medical Outcome Study) and the PDI (Pain Disability Index).

**Results:** The 3 patients (all female, average age: 69 years) presented with following diagnosis: 1. Mononeuropathy L3 and L4 right, 2. Low back pain and bilateral mononeuropathy L3 and L4, 3. Low back pain and mononeuropathy L4 and L5 right. Average pain scores dropped in two patients from 8 to 4. The third patient did not respond to the therapy, even though paresthesia covered the entire pain area. Pain suppression and paresthesia coverage remained stable after an average follow up of 24 months. The PDI reduced from 33 to 18 in one patient and from 57 to 22.4 in the other. All patients had an MMPS of III and a significant amount of neuropathic pain, which improved after implantation. Sleep quality improved by 20%. Both responders would opt in again for the treatment. No adverse events occurred during the placement of the leads, nor during the follow-up period. More details will be revealed in the poster as the study is ongoing.

**Discussion:** The alternative approaches described herein suggest that the above techniques may be feasible to apply in those cases where the standard implantation techniques are deemed contraindicated.

**Conclusions:** In patients in whom the DRG cannot be approached by the standard percutaneous approach at least 3 alternatives may be used resulting in similar stable pain suppression.

**References:** 1. Vancamp T, Levy RM, Peña I, Pajuelo A. Relevant Anatomy, Morphology, and Implantation Techniques of the Dorsal Root Ganglia at the Lumbar Levels. *Neuromodulation*. 2017;20(7):690-702.

**Keywords:** Open Surgical Placement, Transforaminal, PNS, Chronic Neuropathic Pain, DRG

**Topic:** 05. Spine / 05a. Pain

## NEUROMODULATION FOR NEUROPATHIC POSTSURGICAL PAIN OF THE FOOT

### E-POSTER VIEWING

Björn Carsten Schultheis<sup>1</sup>, Christian Wille<sup>2</sup>, Patrick Weidle<sup>3</sup>, Tim Vancamp<sup>4</sup>

<sup>1</sup>Interventionelle Schmerztherapie Msz, Krankenhaus Neuwerk, Niederkrüchten, Germany, <sup>2</sup>Department Of Neurosurgery, NCN Neurochirurgische Praxis Neus, Neuss, Germany, <sup>3</sup>Interventionelle Schmerztherapie, Krankenhaus Neuwerk "Maria von den Aposteln", Muskulo-Skeletales Zentrum, Mönchengladbach, Germany, <sup>4</sup>, e4Sci, Sabadell, Spain

**Introduction:** Dorsal root ganglion (DRG) therapy may work where other therapies may provide no or only partial relief.<sup>1,2</sup> Whereas the sensory innervation of the foot originates in a complex manner from the L3-S2 branches, the major part of it is covered by L5 and S1. We describe peripheral nerve (PNS) - and DRG stimulation techniques used to treat chronic neuropathic postsurgical pain (NPP) of the foot in two cases.

**Methods/Materials:** 2 Male patients (average age: 68 years-old) were treated using following (alternative) implantation techniques: 1. S1 transforaminal DRG leads and L5 DRG or PNS. We collected following pre- and post-intervention clinical data: NRS (Numeric Rating Scale), PDQ (Pain Detect Questionnaire), MPSS (Mainz Pain Staging System), MOS Sleep Scale (sleep scale from the Medical Outcome Study), PDI (Pain Disability Index) and opioid usage changes.

**Results:** Both patients presented with following diagnosis: NPP of the foot (1: unilateral, 2: bilateral). Average pain scores dropped from: 8-9 to 4. Paresthesia covered the entire pain area and the suppression remained stable after an average follow up of 12 months. The negative sensory deficits in one patient, hypoesthesia and dysesthesia, completely disappeared. PDQ for neuropathic pain reduced from 38 to 15 and PDI from 47 to 25. MOS Sleep scale improved by 40% and PHQ-D improved from severe depression with suicidal tendencies to a moderate depression. One patients was on daily Oxycodon dosis 60 mg/day, while the other one was on Hydromorphon 24 mg/day. The patient on Oxycodon could totally taper off his medication, while the patient taking Hydromorphon could reduce his intake to an occasional use of Hydromorphon 2,6 mg once or twice per week No adverse events occurred during the placement of the leads, nor during the follow-up period. More details will be revealed in the poster as the study is ongoing.

**Discussion:** Feet have been notoriously hard to reach but given the availability of newer tools one can now also expand the applicability of these in order to ensure best outcomes for the individual patient.<sup>1-3</sup> Proper use of options can be explored and applied where formerly traditional techniques failed to produce satisfying outcomes for the patient.

**Conclusions:** Combined alternative techniques at different levels have proven to result in better outcomes for the reported patients when compared to traditional techniques for foot pain suppression.<sup>1,2</sup>

**References:** 1. IM Skaribas, C Peccora, E Skaribas. Single S1 Dorsal Root Ganglion Stimulation for Intractable Complex Regional Pain Syndrome Foot Pain After Lumbar Spine Surgery: A Case Series. *Neuromodulation* 2019;22(1):101-107. 2. AB Antony, BC Schultheis, SM Jolly, D Bates, CW Hunter, RM Levy. Neuromodulation of the Dorsal Root Ganglion for Chronic Postsurgical Pain. *Pain Medicine* 2019;20(Suppl. 1):S41-S46. 3. Vancamp T, Levy RM, Peña I, Pajuelo A. Relevant Anatomy, Morphology, and Implantation Techniques of the Dorsal Root Ganglia at the Lumbar Levels. *Neuromodulation*. 2017;20(7):690-702.

**Keywords:** Neuropathic Postsurgical Foot Pain, Lumbar, Transforaminal, sacral, PNS, DRG



## THE INFLUENCE OF HIGH DOSE SPINAL CORD STIMULATION ON THE DESCENDING PAIN MODULATORY SYSTEM IN PATIENTS WITH FAILED BACK SURGERY SYNDROME

### E-POSTER VIEWING

Sander De Groote<sup>1</sup>, Lisa Goudman<sup>2</sup>, Ronald Peeters<sup>3</sup>, Bengt Linderöth<sup>4</sup>, Peter Vanschuerbeek<sup>5</sup>, Stefan Sunaert<sup>3</sup>, Mats De Jaeger<sup>6</sup>, Ann De Smedt<sup>7</sup>, José De Andrés<sup>8</sup>, Maarten Moens<sup>9</sup>

<sup>1</sup>Neurosurgery, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>2</sup>Neurosurgery, UZ Brussel, Jette, Belgium, <sup>3</sup>Radiology, Universitair Ziekenhuis Leuven, Leuven, Belgium, <sup>4</sup>Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden, <sup>5</sup>Radiology, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>6</sup>Neurosurgery, Universitair ziekenhuis Brussel, Jette, Belgium, <sup>7</sup>Neurology, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>8</sup>Anesthesiology Critical Care And Pain Management, University Medical School, Valencia, Spain, <sup>9</sup>Neurosurgery, UZ Brussel, Brussel, Belgium

**Introduction:** The descending pain modulatory system (DPMS) comprises an anatomical network of cortical, subcortical and brainstem regions that regulates nociceptive processing. Human studies provided evidence of the impact of spinal cord stimulation (SCS) on the DPMS, resulting in inhibitory supraspinal effects. We hypothesized that high-dose (HD) SCS may alter the DPMS and thereby result in an inhibitory supraspinal effect of HD-SCS. In order to investigate the influence of HD-SCS on the DPMS, a hypothesis driven pilot study with resting state fMRI was performed in patients with chronic back and/or leg pain, treated with HD-SCS.

**Methods/Materials:** Resting state fMRI was obtained from eleven patients with failed back surgery syndrome who were eligible for HD-SCS. The functional connectivity strengths of specifically chosen regions of interest of the DPMS have been investigated over time. Baseline measurements were compared with measurements after three months of HD-SCS. Additionally, clinical parameters on pain intensity, pain catastrophizing and sleep quality were correlated with functional connectivity strengths.

**Results:** The study results demonstrated an increased connectivity over time between the middle frontal gyri and the insula/rostroventral medulla. An increased interhemispheric connectivity between both middle frontal gyri was revealed. A decreased connectivity was found between the anterior cingulate cortex and the insula. No statistically significant correlations were found between clinical outcomes and functional connectivity strengths.

**Discussion:** The current study is the first report exploring the functional changes in the DPMS during HD-SCS. The decrease in connection between the anterior cingulate cortex and the insula suggests that patients have a lower receptivity to nociception during HD-SCS. The increased bilateral connection of the middle frontal gyri could be related with greater pain tolerance. Based on the absence of correlations between clinical outcomes and functional connectivities, this study cannot confirm that fMRI connectivity strengths might serve as a biomarker of treatment effects based on clinical variables.

**Conclusions:** These findings support the hypothesis that HD-SCS might influence the DPMS, by an alteration of the strengths in functional connectivity in DPMS related regions during stimulation.

### References:

**Keywords:** Descending pain modulatory system, chronic pain, Mechanism of action, High dose spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

## **MAGNETIC RESONANCE IMAGING EXPLORATION OF THE HUMAN BRAIN DURING 10 KHZ SPINAL CORD STIMULATION FOR FAILED BACK SURGERY SYNDROME**

### **E-POSTER VIEWING**

Sander De Groote<sup>1</sup>, Lisa Goudman<sup>2</sup>, Ronald Peeters<sup>3</sup>, Bengt Linderöth<sup>4</sup>, Peter Vanschuerbeek<sup>5</sup>, Stefan Sunaert<sup>3</sup>, Mats De Jaeger<sup>6</sup>, David Caraway<sup>7</sup>, Kerry Bradley<sup>7</sup>, Maarten Moens<sup>8</sup>

<sup>1</sup>Neurosurgery, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>2</sup>Neurosurgery, UZ Brussel, Jette, Belgium, <sup>3</sup>Radiology, Universitair Ziekenhuis Leuven, Leuven, Belgium, <sup>4</sup>Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden, <sup>5</sup>Radiology, Universitair Ziekenhuis Brussel, Jette, Belgium, <sup>6</sup>Neurosurgery, Universitair ziekenhuis Brussel, Jette, Belgium, <sup>7</sup>, Nevro Corp, Redwood City, United States of America, <sup>8</sup>Neurosurgery, UZ Brussel, Brussel, Belgium

**Introduction:** Apart from the clinical efficacy of high frequency spinal cord stimulation at 10kHz, the underlying mechanism of action remains unclear. In parallel with spinal or segmental theories, supraspinal hypotheses have been recently proposed. In order to unveil hidden altered brain connectome patterns, a resting state functional magnetic resonance imaging (rsfMRI) protocol was performed in subjects routinely treated for back and/or leg pain with high-frequency spinal cord stimulation (HF-SCS) HF-SCS at 10 kHz.

To identify the alterations in functional connectivity (FC) in resting-state networks in patients with failed back surgery syndrome (FBSS), treated with HF-SCS at 10 kHz. The second aim is to observe whether there is an association between clinical data and functional brain changes in patients with FBSS, treated with HF-SCS at 10 kHz.

**Methods/Materials:** RsfMRI imaging was obtained from ten patients with FBSS who were eligible for HF-SCS at 10 kHz. Specifically-chosen regions of interest with different connectivity networks have been investigated over time. Baseline measurements were compared with measurements after 1 month and 3 months of HF-SCS at 10 kHz. Additionally, clinical parameters on pain intensity, central sensitization, pain catastrophizing and sleep quality were correlated with the functional connectivity strengths.

**Results:** The study results demonstrate an increased connectivity over time between the anterior insula (affective salience network) and regions of the frontoparietal network and the central executive network. After three months of HF-SCS, the increased strength in functional connectivity between the left dorsolateral prefrontal cortex (LDLPFC) and the right anterior insula (RAI) was significantly correlated with the minimum clinically important difference (MCID) value of the Pittsburgh Sleep Quality Index.

**Discussion:** From the results of the functional connectivity analysis during HF-SCS at 10 kHz, it appears that the affective salience network has a crucial role to play. In this study an important role was reserved for the anterior insula, involved in emotional awareness, who has an increased connectivity over time between regions of the frontoparietal and the central executive network. The ROI-pair LDLPFC-RAI might be a possible biomarker to monitor improvements in sleep quality, due to the significant correlation with the minimum clinically important difference value of the Pittsburgh Sleep Quality Index.

**Conclusions:** These findings support the hypothesis that HF-SCS at 10 kHz might influence the salience network and therefore also the emotional awareness of pain.

### **References:**

**Keywords:** Supraspinal, fMRI, 10 kHz Spinal Cord Stimulation, chronic pain, Mechanism of action

**Topic:** 05. Spine / 05a. Pain

## REAL-WORLD OUTCOMES OF PATIENTS USING NEW SCS PARADIGMS OFFERING DORSAL HORN MODULATION AND COMBINED WAVEFORMS FOR PERSONALIZED TREATMENT OF CHRONIC PAIN

### E-POSTER VIEWING

Maria Angeles Canos-Verdecho<sup>1</sup>, Lilly Chen<sup>2</sup>, Roshini Jain<sup>2</sup>

<sup>1</sup>Chronic Pain Unit, University Hospital La Fe, Valencia, Spain, <sup>2</sup>Clinical Research, Boston Scientific, Valencia, United States of America

**Introduction:** Recent studies now suggest that Spinal Cord Stimulation (SCS) programming settings can be finely tuned to facilitate improved neural targeting and device energy efficiency in order to give patients the best possible outcomes and experience when using SCS (using paresthesia or sub-perception) to treat their chronic pain.<sup>1,2</sup> One aspect of SCS waveform programming that can be uniquely tailored to the individual is the careful shaping of the applied stimulation field in order to maximize the targeting of neurostimulative therapy according to each patient's own particular needs.<sup>3</sup> Furthermore, utilizing a customized field shape at low frequencies allows for greatly improved device energy efficiency. We sought to extend these previously reported observations by evaluating the real-world clinical use of one such sub-perception based programming algorithm.

**Methods/Materials:** This study was conducted as part of an ongoing retrospective chart review of SCS outcomes for chronic pain (Clinicaltrials.gov identifier: NCT01550575). Patients were implanted with an SCS system (Boston Scientific, Valencia, CA USA) equipped with a customized field shape (CFS) programming algorithm (Contour, Boston Scientific, Valencia, CA USA) designed to engage anti-nociceptive terminals over a broader coverage area (versus an 8mm bipole) to produce a stronger dorsal horn effect. Baseline and treatment follow-up pain scores and programming data was documented.

**Results:** To date, study results are still being collected and analyzed, and the reporting of our results of this evaluation is planned.

**Discussion:** This study seeks to incorporate knowledge obtained from previous studies concerning the use of customized field shape programming with the aim to improve the SCS patient experience by simplifying stimulation parameter optimization and lowering device energy demand, and in turn reducing the burden on patient to carry out frequent device recharging.

**Conclusions:** Reducing burden on patients with regard to device utilization and charging as well as simplifying stimulation parameter optimization is thought to be key toward fostering improved outcomes when using SCS as therapeutic modality for treatment of chronic neuropathic pain. This study will provide further understanding concerning the implementation of customized field shape programming with the aim to improve the overall SCS patient experience.

**References:** 1. Thomson S., et al. "Effects of Rate on Analgesia in Kilohertz Frequency Spinal Cord Stimulation: Results of the PROCO Randomized Controlled Trial." *Neuromodulation* 2018 Jan;21(1):67-76. 2. Paz-Solis JF, et al. "Exploration of High and Low Frequency Options for Sub-Perception Pain Relief: The HALO Study" [Abstract]. Annual Meeting of the North American Neuromodulation Society, 2020. 3. Paz-Solis JF, et al. "Four Year Follow Up of a Customized Field Shape Using Sub Perception Spinal Cord Stimulation in a Real World, Observational Cohort of Chronic Pain Patients" [Abstract]. Annual Meeting of the North American Neuromodulation Society, 2020.

**Keyword:** spinal cord stimulation, SCS, chronic pain, neural dosing, sub-perception

**Topic:** 05. Spine / 05a. Pain

**OUTCOMES OF PERIPHERAL NERVE FIELD STIMULATION AS “ADD-ON” TREATMENT TO SPINAL CORD STIMULATION USING A DEVICE CAPABLE OF PRECISE CUSTOMIZATION OF THERAPY FOR CHRONIC PAIN**

**E-POSTER VIEWING**

Paolo Maino<sup>1</sup>, Yu Pei<sup>2</sup>, Roshini Jain<sup>2</sup>

<sup>1</sup>Anesthesiology And Pain Therapy, Regional Hospital of Lugano, Lugano, Switzerland, <sup>2</sup>Clinical Research, Boston Scientific, Valencia, United States of America

**Introduction:** Peripheral nerve field stimulation (PNFS) is a neuromodulatory modality that is applied to the patient using a stimulus to non-specific nerve fibers within a specific focal area of pain. Previous studies have demonstrated positive outcomes using PNFS as an “add-on” therapy to Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) as well as a “stand-alone” therapy for a variety of other pain conditions.<sup>1,2</sup> In this study, we will report real-world outcomes associated with use of PNFS together with SCS in patients implanted with a device that allows for precise customization of therapeutic stimulation settings for use in the treatment of chronic neuropathic pain.

**Methods/Materials:** This is an observational case-series of patients implanted with a neuromodulation system (Precision or Precision Spectra, Boston Scientific) conducted as part of an on-going retrospective chart review evaluation of real-world outcomes for chronic pain (Clinicaltrials.gov identifier: NCT01550575). Patients were diagnosed with chronic neuropathic pain and treated with PNFS as an “add-on” therapy to SCS. Assessments collected include baseline characteristics (demographics, medical history, pain diagnosis) and pre- and post-implant outcomes (NRS pain score, quality of life).

**Results:** To date, study results are still being collected. Initial results of this on-going evaluation will be presented.

**Discussion:** Neuromodulation systems capable of providing various stimulation waveforms, parameters, and programming settings are increasingly being made available to chronic pain patients. While several studies have now reported outcomes using these systems in the context of SCS as a “stand-alone” therapy, very few (if any) studies have published data following the use of these types of devices in the context of PNFS as an “add-on” therapy to SCS.

**Conclusions:** This study will seek to report real-world outcomes in patients with chronic neuropathic pain treated using PNFS alongside SCS using a neuromodulation system designed to provide for highly individualized (i.e. patient-specific) therapeutic stimulation approaches.

**References:** 1. Van Gorp EJAA, et al. Neuromodulation. 2019 Dec;22(8):970-977. 2. Verrills P, et al. Pain Med. 2011 Sep;12(9):1395-405.

**Keyword:** spinal cord stimulation, SCS, peripheral nerve field stimulation, PNFS, chronic pain

**Topic:** 05. Spine / 05a. Pain

**VECTORS STUDY RESULTS: POST-IMPLANTATION SPINAL CORD STIMULATION (SCS) PROGRAMMING IN A LARGE PROSPECTIVE MULTI-CENTER CLINICAL STUDY**

**E-POSTER VIEWING**

David Provenzano<sup>1</sup>, Michael Fishman<sup>2</sup>, Lisa Johaneck<sup>3</sup>, Katherine Stromberg<sup>3</sup>, Kelly Hendrickson<sup>3</sup>, Matthew Kelly<sup>3</sup>, Lachlan Davies<sup>3</sup>

<sup>1</sup>Interventional Pain Medicine, Pain Diagnostics and Interventional Care, Sewickley, United States of America, <sup>2</sup>Interventional Pain Medicine, Center for Interventional Pain and Spine, Wilmington, United States of America, <sup>3</sup>Pain/stimulation Clinical Research, Medtronic, Minneapolis, United States of America

**Introduction:** Many variables can play a role in spinal cord stimulation (SCS), such as location of pain, lead location, and stimulation parameters, and when not controlled, they can result in mixed outcomes. This is exacerbated by a growing number of new waveforms available to physicians. A standardized approach to therapy delivery may provide more consistent outcomes for more patients. The Vectors Study evaluated whether there is significant sustained improvement in pain when therapy is delivered using a standardized approach.

**Methods/Materials:** All available programming data from the Vectors Study was collected at visits through the 12-Month Visit. Programming at device activation was based on each subject's response during the trial. Programming changes, which, if necessary, could occur at any visit, were defined as changes to the number of available groups, electrode configuration, rate, or pulse width or a combination of these changes. Amplitude adjustments were not considered programming changes as subjects were able to adjust these settings as needed within set limits without physician reprogramming.

**Results:** Following device activation, 83% (81/98) of subjects who reached the 3-month visit had achieved  $\geq 50\%$  improvement in the overall pain at some point between week 2 follow-up through the 3-month visit, with 65% (64/98) achieving  $\geq 50\%$  pain relief by the week 4 follow-up visit. Data demonstrates pain relief was sustained through 12 months with 79% (71/90) of subjects having achieved  $\geq 50\%$  improvement in at least one pain domain (overall, low-back, or leg). From device activation through the 12-Month Visit, 72.5% (66/91) of subjects had 6 or fewer reprogramming changes. The distribution and type of programming changes were quantified. The most common change was electrodes only (38.4%), followed by adjustments to pulse width and electrodes (21.4%).

**Discussion:** Following a standardized approach to delivery of SCS therapy, which includes starting with 1 kHz stimulation, resulted in significant overall pain relief at 3 months that was sustained through 12 months. This pain relief was achieved with relatively little reprogramming with nearly 73% of subjects requiring 6 or fewer reprogram sessions.

**Conclusions:** The Vectors study provides long-term evidence for pain relief using SCS with a minimum of reprogramming when following a standardized workflow.

**References:**

**Keywords:** chronic pain, Programming, Spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

**VECTORS POST MARKET STUDY: SUBJECT ACTIVITY GOALS AND THERAPY SATISFACTION WITH SPINAL CORD STIMULATION (SCS) OVER 12 MONTHS OF FOLLOW UP**

**E-POSTER VIEWING**

Tristan Weaver<sup>1</sup>, Steven Severyn<sup>1</sup>, John Hatheway<sup>2</sup>, Michael Fishman<sup>3</sup>, Vipul Mangal<sup>4</sup>, Binit Shah<sup>5</sup>, Lisa Johaneck<sup>6</sup>, Katherine Stromberg<sup>6</sup>, Kelly Hendrickson<sup>6</sup>, Matthew Kelly<sup>6</sup>, [Lachlan Davies](#)<sup>6</sup>  
<sup>1</sup>Pain Management, The Ohio State University Wexner Medical Center, Columbus, United States of America, <sup>2</sup>Pain Management, Northwest Pain Care, Spokane, United States of America, <sup>3</sup>Interventional Pain Medicine, Center for Interventional Pain and Spine, Wilmington, United States of America, <sup>4</sup>Interventional Pain Medicine, Physical Medicine Associates, Rockville, United States of America, <sup>5</sup>Interventional Pain Medicine, Carolinas Research Institute, Huntersville, United States of America, <sup>6</sup>Pain/stimulation Clinical Research, Medtronic, Minneapolis, United States of America

**Introduction:** The Vectors Study investigated pain relief after a standardized approach to SCS therapy was used for patients with chronic back and leg pain. While pain relief is the foundational goal for SCS, additional measures in the study included characterizing the percentage of subjects that achieved individually defined objective activity goal(s) from baseline to the 3-Month Visit, subject satisfaction with SCS, and the subject's impression of change.

**Methods/Materials:** Subjects were assessed through their 3-Month Visit (n=98) on achievement of their defined therapy goal(s). If a goal was achieved, a new goal could be set. Subjects could set and achieve multiple goals. Subject-defined goals were grouped into high level categories. A sub-analysis was completed on subjects from a single center to compare goal attainment with subject-reported pain scores at each visit through the 12-Month Visit, as well as therapy satisfaction and Patient Global Impression of Change (PGIC).

**Results:** For this analysis patient goals were categorized into 7 categories. Most subjects specified a goal in the Exercise/Walking/Standing category. By the 3-Month Visit, 70% of subjects met at least one goal. Of the 91 patients that completed a 12-Month Visit, 84.6% reported satisfaction with Intellis SCS and 56.0% had a better or great deal better impression of change. The sub-analysis of five subjects from The Ohio State University Wexner Medical Center represent distinct subject response profiles to SCS. At 3-Months (primary endpoint), 4 of the 5 patients had achieved at least one of their activity goals and were also pain responders ( $\geq 50\%$  reduction in pain). These four subjects also reported being very satisfied with SCS therapy. The subject who did not achieve their defined therapy goal or achieve a 50% reduction in their pain, reported being very satisfied with therapy and Better on the PGIC at 12-Months.

**Discussion:** Pain relief is the core objective of SCS therapy; however, patients suffering from pain can have goals specific to quality of life and functional improvement that can also impact therapy success. These data suggest endpoints beyond pain are as important to the subject as pain relief. Every patient can present a unique clinical profile extending beyond the management of their chronic pain symptoms. Divergence can also exist between pain relief, patient goals and therapy satisfaction, which suggests outcome metrics in addition to pain relief could be beneficial for patients.

**Conclusions:** The Vectors study provides long-term evidence for the effectiveness of SCS when using a standardized workflow starting with HD stimulation.

**References:**

**Keywords:** Functional Outcomes, chronic pain, Activity Goal, Spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

## **COMPARISON OF CONVENTIONNAL, BURST AND HIGH FREQUENCY SPINAL CORD STIMULATION ON PAIN RELIEF IN REFRACTORY FAILED BACK SURGERY SYNDROME PATIENTS**

### **E-POSTER VIEWING**

Maxime Billot<sup>1</sup>, Nicolas Naiditch<sup>1</sup>, Claire Brandet<sup>1</sup>, Bertille Lorgeoux<sup>1</sup>, Sandrine Baron<sup>1</sup>, Amine Ounajim<sup>1</sup>, Manuel Roulaud<sup>1</sup>, Aline Roy-Moreau<sup>2</sup>, Géraldine De Montgazon<sup>3</sup>, Charrier Elodie<sup>4</sup>, Lorraine Misbert<sup>4</sup>, Benjamin Maillard<sup>1</sup>, Tanguy Vendevre<sup>1</sup>, Philippe Rigoard<sup>1</sup>

<sup>1</sup>Prismatics, Hospital University of Poitiers, Poitiers, France, <sup>2</sup>Pain Department, Hospital of Nord Deux Sèvres, Faye l'Abesse, France, <sup>3</sup>Pain Department, Hospital of La Rochelle, La Rochelle, France, <sup>4</sup>General Practice, University Hospital of Poitiers, Poitiers, France

**Introduction:** Studies have clearly demonstrated the efficacy of Spinal Cord Stimulation (SCS) to manage pain in Failed Back Surgery Syndrome (FBSS) patients (1,2). Tonic Conventional Stimulation (TCS) is the most used technique. However, studies showed that TCS does not appear to relieve pain for more than 30-55% of FBSS patients and provokes paresthesia that can be perceived as an uncomfortable sensation for the patients (3). To address these difficulties, new sub-paresthesia stimulation modalities were investigated such as BURST and High Frequency (HF) stimulation waveforms (4). Recent clinical trials reported evidence of their efficacy (5-12). Our study is the first randomized controlled trial to assess the efficacy of TCS, BURST and HF stimulation waveforms on pain relief.

**Methods/Materials:** This study is a prospective, controlled, randomized, cross-over, double-blinded study. 28 FBSS patients were recruited between February 2017 and January 2020. After implantation surgery, all patients received TCS treatment for a 2-month period and were thereafter randomized in one of the 6 arms with a 1:1:1:1:1:1 ratio. Patients then received a three-month specific set of 3 combinations of the 3 different waveforms delivering each treatment modality during a 1-month period. At the end of this 3-month period, each patient selected his/her preferred stimulation modality with a follow-up period of 12 months. Efficacy of the different waveforms was assessed using a visual analog scale of pain.

**Results:** An intermediate analysis will be conducted after the 3-month follow-up to compare pain relief depending on used waveforms.

**Discussion:** According to the literature, our study will provide new insight to support FBSS patients in regards with three possible waveform modalities.

**Conclusions:** Accessibility to the three waveforms could represent an opportunity to manage pain in FBSS patients.

**References:** (1) North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal Cord Stimulation versus Repeated Lumbosacral Spine Surgery for Chronic Pain: A Randomized, Controlled Trial: Neurosurgery. 2005;56:98–107. (2) Kumar K, North R, Taylor R, Sculpher M, den Abeele C, Gehring M, et al. Spinal Cord Stimulation vs. Conventional Medical Management: A Prospective, Randomized, Controlled, Multicenter Study of Patients with Failed Back Surgery Syndrome (PROCESS Study): SCS for Failed Back Surgery Syndrome. Neuromodulation: Technology at the Neural Interface. 2005;8:213–8. (3) Verrills P, Sinclair C, Barnard A. A review of spinal cord stimulation systems for chronic pain. J Pain Res. 2016;9:481–92. (4) Viswanath O, Urits I, Bouley E, Peck JM, Thompson W, Kaye AD. Evolving Spinal Cord Stimulation Technologies and Clinical Implications in Chronic Pain Management. Curr Pain Headache Rep. 2019;23:39. (5) Vos CC de, Bom MJ, Vanneste S, Lenders MWPM, Ridder D de. Burst Spinal Cord Stimulation Evaluated in Patients With Failed Back Surgery Syndrome and Painful Diabetic Neuropathy. Neuromodulation: Technology at the Neural Interface. 2014;17:152–9. (6) De Ridder D, Vanneste S, Plazier M, van der Loo E, Menovsky T. Burst Spinal

Cord Stimulation Toward Paresthesia-Free Pain Suppression. *Neurosurgery*. 2010;66:986–90. (7) De Ridder D, Plazier M, Kamerling N, Menovsky T, Vanneste S. Burst Spinal Cord Stimulation for Limb and Back Pain. *World Neurosurgery*. 2013;80:642-649.e1. (8) Courtney P, Espinet A, Mitchell B, Russo M, Muir A, Verrills P, et al. Improved Pain Relief With Burst Spinal Cord Stimulation for Two Weeks in Patients Using Tonic Stimulation: Results From a Small Clinical Study. *Neuromodulation: Technology at the Neural Interface*. 2015;18:361–6. (9) Russo M, Van Buyten J-P. 10-kHz High-Frequency SCS Therapy: A Clinical Summary. *Pain Med*. 2015;16:934–42. (10) Al-Kaisy A, Van Buyten J-P, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med*. 2014;15:347–54. (11) Chakravarthy K, Richter H, Christo PJ, Williams K, Guan Y. Spinal Cord Stimulation for Treating Chronic Pain: Reviewing Preclinical and Clinical Data on Paresthesia-Free High-Frequency Therapy. *Neuromodulation*. 2018;21:10–8. (12) Kiefe TM, Pintea B, Link C, Roeske S, Güresir E, Güresir Á, et al. High Frequency (10 kHz) or Burst Spinal Cord Stimulation in Failed Back Surgery Syndrome Patients With Predominant Back Pain: Preliminary Data From a Prospective Observational Study. *Neuromodulation*. 2016;19:268–75.

**Keywords:** Spinal cord stimulation, Failed Back Surgery Syndrome, Stimulation waveforms, Back Pain



**Topic:** 05. Spine / 05a. Pain

**IMPROVEMENT OF HEALTH-RELATED QUALITY OF LIFE AND FUNCTIONAL DISABILITY IN PATIENTS WITH CHRONIC PAIN AND IMPLANTED WITH A RECHARGEABLE SPINAL CORD STIMULATION SYSTEM.**

**E-POSTER VIEWING**

Rik Buschman<sup>1</sup>, Aaron Calodney<sup>2</sup>, John Hatheway<sup>2</sup>, Sam Eldabe<sup>2</sup>, Léo Cantin<sup>3</sup>, Eric Buchser<sup>4</sup>, Nathan Grunow<sup>5</sup>, Rachel Slangen<sup>6</sup>

<sup>1</sup>Neuromodulation, Medtronic Trading NL B.V., Eindhoven, Netherlands, <sup>2</sup>Interventional Pain Medicine, Precision Spine Care, Tyler, United States of America, <sup>3</sup>Surgery, Hôpital Enfant-Jésus, Québec, Canada, <sup>4</sup>Anesthesiology, Hôpital de Morges, Morges, Switzerland, <sup>5</sup>Clinical Biostatistics, Medtronic, plc, Fridley, United States of America, <sup>6</sup>Post Approval Clinical Surveillance, Medtronic, Maastricht, Netherlands

**Introduction:** We present an exploration of the effect of Spinal Cord Stimulation (SCS) with 2 rechargeable systems in patients with Back Pain of Failed Back Surgery Syndrome (BP-FBSS) on Health-Related Quality of Life (HR-QoL), and functional disability (Oswestry Disability Index, ODI).

**Methods/Materials:** Data were collected from the Product Surveillance Registry (PSR, Medtronic), a prospective, long-term, multicentre registry to monitor the performance and safety of Medtronic Spinal Cord Stimulation (SCS) systems. The devices selected were the RestoreSensor™ (Medtronic, MN, USA) and Intellis™ (Medtronic, MN, USA). Patients with a diagnosis of BP-FBSS, a general pain score  $\geq 5$ , and an initial implant were included. EQ-5D and ODI scores were summarized at baseline, 6-months, and for the change from baseline to 6-months (paired t-tests evaluated within-group change).

**Results:** EQ-5D UK scores showed statistically significant and clinically relevant improvements for both systems from baseline to 6 months;  $0.47 \pm 0.21$  to  $0.57 \pm 0.28$  ( $n=78$ ;  $P=0.001$ ), and  $0.45 \pm 0.25$  to  $0.60 \pm 0.26$  ( $n=82$ ;  $P<0.0001$ ). ODI scores reduced from  $51.1 \pm 13.3$  to  $45.1 \pm 16.4$  ( $n=76$ ;  $P=0.001$ ) and  $50.9 \pm 12.6$  to  $39.3 \pm 16.6$  ( $n=85$ ;  $P<0.0001$ ).

**Discussion:** To assess clinical relevance, research suggest a minimum clinically important difference (MCID) of 0.081 in EQ-5D in a subgroup of patients with back pain and 9.2 in ODI in patients with FBSS.

**Conclusions:** Our analysis shows statistically significant and clinically relevant improvements in health-related quality of life, and functional disability from baseline to 6-months in patients diagnosed with BP-FBSS and implanted with a rechargeable SCS-system.

**References:**

**Keyword:** Spinal cord stimulation, chronic back and leg pain, quality of life, functional disability, recharge

**Topic:** 05. Spine / 05a. Pain

**PREFERENCE BETWEEN CONVENTIONNAL, BURST AND HIGH FREQUENCY SPINAL CORD STIMULATION IN REFRACTORY FAILED BACK SURGERY SYNDROME PATIENTS : A RANDOMIZED CONTROLLED TRIAL**

**E-POSTER VIEWING**

Maxime Billot<sup>1</sup>, Nicolas Naiditch<sup>1</sup>, Claire Brandet<sup>1</sup>, Bertille Lorgeoux<sup>1</sup>, Sandrine Baron<sup>1</sup>, Amine Ounajim<sup>1</sup>, Manuel Roulaud<sup>1</sup>, Aline Roy-Moreau<sup>2</sup>, Géraldine De Montgazon<sup>3</sup>, Charrier Elodie<sup>4</sup>, Lorraine Misbert<sup>4</sup>, Benjamin Maillard<sup>1</sup>, Tanguy Venduvre<sup>1</sup>, Philippe Rigoard<sup>1</sup>

<sup>1</sup>Prismatics, Hospital University of Poitiers, Poitiers, France, <sup>2</sup>Pain Department, Hospital of Nord Deux Sèvres, Faye l'Abesse, France, <sup>3</sup>Pain Department, Hospital of La Rochelle, La Rochelle, France, <sup>4</sup>General Practice, University Hospital of Poitiers, Poitiers, France

**Introduction:** While Tonic Conventional Stimulation (TCS) constitutes the basis of Spinal Cord Stimulation (SCS), studies have shown that TCS does not appear to relieve pain for more than 30-55% of Failed Back Surgery Syndrome (FBSS) patients and provokes paresthesia that can be perceived as an uncomfortable sensation for patients (1). For these reasons, new sub-paresthesia stimulation modalities were investigated such as BURST and High Frequency (HF) stimulation waveforms relegating TCS as an has-been modality (2). However, there is no evidence of the preferred patient's modality choice between TCS, BURST and HF.

**Methods/Materials:** This study is a prospective, controlled, randomized, cross-over, double-blinded study. 28 FBSS patients were recruited between February 2017 and January 2020. After implantation surgery, all patients received TCS treatment for a 2-month period and were thereafter randomized in one of the 6 arms with a 1:1:1:1:1:1 ratio. Patients then received a three-month specific set of 3 combinations of the 3 different waveforms delivering each treatment modality during a 1-month period. At the end of this 3-month period, each patient selected his/her preferred stimulation modality with a follow-up period of 12 months.

**Results:** An intermediate analysis will be conducted after the 3-month follow-up to observe the number of waveforms used by the patients and their waveform preferences.

**Discussion:** Patients will choose their preferred modalities depending on daily activities.

**Conclusions:** The possibility offered to the patient to modify waveform modality throughout a day could be a good opportunity to manage pain with SCS.

**References:** (1) Verrills P, Sinclair C, Barnard A. A review of spinal cord stimulation systems for chronic pain. J Pain Res. 2016;9:481–92. (2) Viswanath O, Urits I, Bouley E, Peck JM, Thompson W, Kaye AD. Evolving Spinal Cord Stimulation Technologies and Clinical Implications in Chronic Pain Management. Curr Pain Headache Rep. 2019;23:39.

**Keywords:** Spinal cord stimulation, Failed Back Surgery Syndrome, Stimulation waveforms, Back Pain

**Topic:** 05. Spine / 05a. Pain

**EFFECTIVENESS OF “TRANSGRADE” EPIDURAL TECHNIQUE FOR DORSAL ROOT GANGLION STIMULATION. A RETROSPECTIVE, SINGLE-CENTER, CASE SERIES FOR CHRONIC FOCAL NEUROPATHIC PAIN**

**E-POSTER VIEWING**

Adnan Al-Kaisy, Jonathan Royds, Matteo Costanzi, David Pang, Stefano Palmisani, Samuel Wesley, Gabor Racz, Thomas Yearwood  
Pain & Neuromodulation Centre, Guys and St Thomas' NHS Foundation Trust, London, United Kingdom

**Introduction:** The recent interest in targeting the dorsal root ganglion (DRG) has led to the development of new techniques of electrode placement. We describe a new “Transgrade” approach to the DRG, accessing the contralateral interlaminar space and steering the lead out the opposite foramen. There is also much interest in applying different waveforms in neuromodulation, applying burst stimulation to the DRG may lead to advantages including paraesthesia free stimulation. Monopolar stimulation to the DRG may also create a more precise focal area of stimulation. The purpose of this study was to evaluate “Transgrade” technique to the DRG in the management of focal neuropathic pain, predominately Complex Regional Pain Syndrome (CRPS).

**Methods/Materials:** This was a retrospective, observational review of all patients selected for DRG stimulation using the Transgrade technique to the DRG. Patients with CRPS or focal neuropathic pain were trialled with 1 or 2 DRG leads. A 50% reduction in pain was required for full implant. Data was taken from a hospital password protected database, patients were assessed as standard, 6 weeks after full implant. All patients were contacted by telephone for up to date Numerical Rating pain score (NRS), Patient Global Impression of change (PGIC) score and potential complications. A patient responder was defined as having a PGIC score of 6 or 7 and a two-point reduction from baseline NRS.

**Results:** 39 patients (46% Female), with a mean age of 46 years (+/- 2) underwent a trial of DRG stimulation that resulted in an implantation rate of 82% (32/39). The responder rates, according to NRS and PGIC results, were 87% (28/32) at 6 weeks and 66% (21/32) at a mean of 18 months (+/- 1.8) follow up. Pocket pain was the most common complication, occurring in 7/32 (22%) patients, and the lead migration rate was 3 out of 57 leads placed (5.2%). A burst protocol was the favoured method of stimulation in the majority of patients, 25/32 (78%).

**Discussion:** There is a learning curve with any new procedure and would only recommend practitioners utilise this method after a period of training. The comparative efficacy of monopolar contact electrodes for DRG-stimulation remains undetermined.

**Conclusions:** The Transgrade technique of placing DRG leads offers an alternative method that is safe and effective. The majority of patients preferred a burst protocol of stimulation compared to tonic. New methods of technique and stimulation to the DRG offer more choice and potentially better efficacy for patients with chronic neuropathic pain.

**Keywords:** Dorsal Root Ganglion Stimulation, Transgrade, Focal Neuropathic Pain, neuromodulation, DRG

**Topic:** 05. Spine / 05a. Pain

## **CASCADE PROGRAMME FOR 10KHZ SPINAL CORD STIMULATION IN PATIENTS WITH NEUROPATHIC BACK WITH OR WITHOUT LEG PAIN**

### **E-POSTER VIEWING**

Adnan Al-Kaisy, Jonathan Royds, Omar Al-Kaisy, Stefano Palmisani, David Pang, Thomas Smith, Nicholas Padfield, Stephany Harris, Katie Markham, Samuel Wesley, Thomas Yearwood  
Pain & Neuromodulation Centre, Guys and St Thomas' NHS Foundation Trust, London, United Kingdom

**Introduction:** 10kHz Spinal Cord Stimulation (SCS) is usually applied in a bipolar configuration over the T9/T10 disc space for neuropathic back and leg pain. There is however a lack of programming information beyond using this supposed 'sweet spot' of T9/10. Radiological evidence suggest neuroinflammation covers a broader area of the spinal cord beyond a single disc space for chronic neuropathic back pain. Cascade is a sequential bipolar configuration across an entire 8-contact electrode lead. Potential advantages include a broader range of SCS coverage, mitigation against minor lead migration, and a reduction in the need for re-programming. It can also be utilised during the trial period to identify all potential responders to the therapy.

**Methods/Materials:** Patients with neuropathic back pain (with or without leg pain) were implanted with an SCS lead covering T9/10. Patients were put on 10kHz SCS using cascade during the trial period and continued unless reporting inadequate pain relief. Over a 2-year period, patients were followed up by telephone or outpatients at 6 months and 1 year to obtain average weekly Numerical Rating pain (NRS) and Patient Global Impression of Change (PGIC) scores. Up-to-date pain scores were obtained for patients over a year following implantation. Morbidity and deviations from cascade were also reported.

**Results:** There was a significant reduction in back NRS [8.3 vs 3.9(SEM 0.285, $p < 0.0001$ ), N=97] and leg pain [7.53 vs 3.83(SEM 0.364, $p < 0.001$ ),N=77] at 6 months and latest follow up (mean 15.1 months): Back [8.3 vs 3.95 (SEM 0.3181, $p < 0.0001$ ),N=72], Leg [7.53 vs 3.534(SEM 0.368, $p < 0.001$ ),N=58]. 70/97(72%) of patients had a PGIC score of 6 or 7 at 6 months and 49/72(68%) at latest follow-up. At 6 months 87/97(90.6%) of patients were using cascade and 58/72(81%) at latest follow-up beyond a year. Out of the patients who came off cascade, only 2/23(8.7%) reported superior pain scores when converted to multiple programming options and a single bipole program.

**Discussion:** The supposed phenomena of tolerance, habituation or tachyphylaxis to SCS has remained scientifically unanswered. The quest to find optimal dosing and target zones with novel waveforms in SCS remains a challenge while we rely predominantly on patient-reported outcomes and empiric observations.

**Conclusions:** Cascade is an effective programming methodology that may have benefits over a single bipole configuration for 10kHz SCS. This is the first-ever programmability research on 10kHz SCS using a sequential pattern. More research is required into finding the most appropriate anatomical site of the spinal cord for delivering novel waveforms including 10kHz SCS.

### **References:**

**Keywords:** Programming, cascade, 10kHz, neuromodulation

**Topic:** 05. Spine / 05a. Pain

**FINAL RESULTS OF ITALIAN MULTICENTER STUDY ON PATIENTS WITH LOW BACK AND LEGS PAIN IMPLANTED WITH SCS AND TRIALED WITH DIFFERENT WAVEFORMS**

**E-POSTER VIEWING**

Alessandro Dario, Genni Duse, Giovanni Frigerio, Claudio Reverberi  
Neurosurgery, ASST Settelaghi, Varese, Italy

**Introduction:** At present several waveforms are they are used to improve the results of Spinal Cord Stimulation; however many of the neurostimulators in use are characterized by having only one type of waveform. The objective of this abstract is to present the final results of a multicenter Italian study in patients implanted with SCS system and trialed with multimodal waveforms in random order.

**Methods/Materials:** 26 patients implanted with spinal cord stimulator system characterized by multiple energy sources and the possibility of different waveforms, did a trial of at least 3 weeks and experienced different waveforms (7 days each with a washout period): tonic, burst and 1KHz; in random order with daily diary to fill about pain, medication and sleep. Program configuration was based on paresthesia mapping and all the waveforms were customized according to the patient. All the patients had low back and legs pain with FBSS indication.

**Results:** Here we will report the first preliminary clinical outcomes (we are in the process to collect the final data): 9 patients preferred only tonic 8 patients preferred only burst 9 patients preferred two programs (tonic included in 8 cases) Reason of preference: higher pain relief (22), no paresthesia feeling (2), less charging cycle (2)

**Discussion:** Respect to a previous study performed and published by the authors on patients already with SCS and reprogrammed with different waveforms, we have seen that tonic continues to be well appreciated (35%) and we have a discrete percentage of patients using two programs (35%) . It is a good and interesting starting point to better manage patients even during trial. With new systems with combo programs we will elaborate a new approach based on these observations.

**Conclusions:** This study focuses on the importance of having multiple wave combinations

**References:** Haider N, Ligham D, Quave B, et al. Spinal Cord Stimulation (SCS) Trial Outcomes After Conversion to a Multiple Waveform SCS System.Neuromodulation. 2018 Jul;21(5):504-507. doi: 10.1111/ner.12783 Duse G, Reverberi C, Dario A. Effects of Multiple Waveforms on Patient Preferences and Clinical Outcomes in Patients Treated With Spinal Cord Stimulation for Leg and/or Back Pain.Neuromodulation. 2019 Feb;22(2):200-207. doi: 10.1111/ner.12899.

**Keyword:** Spinal Cord Stimulation - Pain - Multiple Waveform

**Topic:** 05. Spine / 05a. Pain

## **DRG FOR PAIN RELIEF: RELATION BETWEEN SENSORY THRESHOLDS AND POWERED CONTACT**

### **E-POSTER VIEWING**

Philippe Rigoard<sup>1</sup>, Maxime Billot<sup>1</sup>, Tanguy Vendeuvre<sup>1</sup>, Manuel Roulaud<sup>1</sup>, Kevin Nivole<sup>1</sup>, Marie-Christine Brunet<sup>1</sup>, Sandrine Baron<sup>1</sup>, Amine Ounajim<sup>1</sup>, Samuel Wesley<sup>2,3</sup>, Matteo Costanzi<sup>2,3</sup>, Thomas Yearwood<sup>2,4</sup>, Jonathan Royds<sup>3,5</sup>, Adnan Al-Kaisy<sup>6</sup>

<sup>1</sup>Prismatics, Hospital University of Poitiers, Poitiers, France, <sup>2</sup>Chronic Pain Dept, Guys and St Thomas's NHS Trust, LONDON, United Kingdom, <sup>3</sup>Pain & Neuromodulation Centre, Guys and St Thomas' NHS Foundation Trust, London, United Kingdom, <sup>4</sup>Pain Medicine, Guy's and St Thomas's Hospital, London, UK, London, United Kingdom, <sup>5</sup>Chronic Pain Dept, Guys and St Thomas's, London, United Kingdom, <sup>6</sup>Chronic Pain Management And Neuromodulation Centre, Guy's & St Thomas' NHS Trust, London, United Kingdom

**Introduction:** Many studies have shown the efficacy of Spinal Cord Stimulation (SCS) to manage pain (1-5) and improve quality of life (6) in patients with chronic intractable pain. However, literature has shown that 40% of SCS implanted patients are not satisfied with pain relief (7). Dorsal Root Ganglion (DRG) stimulation appears to be a promising technology (8) by being more selective on the nervous system (9,10) and having less positional sensitivity compared to SCS (11). Localization of powered contact on the DRG could have critical incidence on the capability to generate an optimal response. The aim of this study is to assess the relationship between sensory thresholds and powered contact.

**Methods/Materials:** 6 patients with refractory chronic foot, leg and/or groin pain were implanted with a DRG stimulation system including 8-contact lead(s) between 2016 and 2019 and included in this study. Each powered contact of each lead was stimulated in the same conditions for each patient to determine 3 sensory paresthesia thresholds: (i) the perception threshold corresponding to the first intensity when the patient feels the paresthesia, (ii) the optimal threshold corresponding to the intensity when the patient feels an optimal and comfortable paresthesia perception, and (iii) the uncomfortable threshold corresponding to the intensity when the patient feels uncomfortable sensations.

**Results:** Our statistical analysis revealed that the perception, optimal and uncomfortable sensory thresholds were significantly different between powered contacts ( $p < 0.0001$ ). Analysis showed that amplitude of stimulation intensity to reach the sensory threshold increased from powered contact 1 to 8.

**Discussion:** Our results indicated that sensory threshold significantly depends on the powered contact. Therefore, the level of electrical signal transmitted to the DRG could be optimally delivered to avoid energy expenditure and to increase DRG stimulation efficacy.

**Conclusions:** This study provides new insight to optimize DRG stimulation programming.

**References:** (1) Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *J Neurosurg (Spine 3)* 100:254-267,2004. (2) Taylor RJ, Taylor RS. Spinal cord stimulation for failed back surgery syndrome: a decision-analytic model and cost-effectiveness analysis. *International Journal Of Technology Assessment in Health Care*. August 2005. (3) Van Buyten JP, Buchser E. Spinal Cord Stimulation for Chronic Back and Leg Pain and Failed Back Surgery Syndrome: A Systematic Review and Analysis of Pronostic Factors. *Spine*. 2005. (4) Taylor RS. Spinal Cord Stimulation in Complex Regional Pain Syndrome and Refractory Neuropathic Back and Leg Pain/Failed Back Surgery Syndrome: Results of a Systematic Review and Meta-Analysis. *Journal Of Pain and Symptom Management*. April 2006. (5) North R, Kidd D, Farrokhi F, Piantadosi S. Spinal Cord Stimulation versus Repeated Lumbosacral Spine Surgery for Chronic Pain:

A Randomized, Controlled Trial. *Neurosurgery*. 2005. (6) Hofmeister M, Memedovich A, Brown S, Saini M, Dowsett L, Lorenzetti D, McCarron T, MacKean G, Clement F. Effectiveness of Neurostimulation Technologies for the Management of Chronic Pain: A Systematic Review. *Neuromodulation: Technology at the neural Interface*. 2019 (7) Frey M, Manchikanti L, Benyamin R, Schult D, Smith H, Cohen S. Spinal Cord Stimulation for Patients with Failed Back Surgery Syndrome: A Systematic Review. *Pain Physician*. 2009. (8) Deer T, Grigsby E, Weiner R, Wilcosky B, Kramer J. A Prospective Study of Dorsal Root Ganglion Stimulation for the Relief of Chronic Pain. *Neuromodulation: Technology at the Neural Interface*. 2012. (9) Deer T and al. Comparison of Paresthesia Coverage of Patient's Pain: Dorsal Root Ganglion vs. Spinal Cord Stimulation. An ACCURATE Study Sub-Analysis. *Neuromodulation: Technology at the Neural Interface*. 2018 (10) Mekhail N and al. Paresthesia-Free Dorsal Root Ganglion Stimulation: An ACCURATE Study Sub-Analysis. *Neuromodulation: Technology at the Neural Interface*. 2018 (11) Deer T and al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain*. 2017

**Keywords:** Back Pain, Dorsal Root Ganglion, Sensory threshold, Powered contact

Topic: 05. Spine / 05a. Pain

## DRG FOR PAIN RELIEF: RELATION BETWEEN THE AMPLITUDE OF STIMULATION INTENSITY AND THE IMPLANTATION LEVEL

### E-POSTER VIEWING

Adnan Al-Kaisy<sup>1</sup>, Jonathan Royds<sup>2,3</sup>, Thomas Yearwood<sup>3,4,5</sup>, Matteo Costanzi<sup>3,5</sup>, Samuel Wesley<sup>3,5</sup>, Amine Ounajim<sup>6</sup>, Sandrine Baron<sup>6</sup>, Marie-Christine Brunet<sup>6</sup>, Kevin Nivole<sup>6</sup>, Manuel Roulaud<sup>6</sup>, Tanguy Vendeuvre<sup>6</sup>, Maxime Billot<sup>6</sup>, Philippe Rigoard<sup>6</sup>

<sup>1</sup>Chronic Pain Management And Neuromodulation Centre, Guy's & St Thomas' NHS Trust, London, United Kingdom, <sup>2</sup>Chronic Pain Dept, Guys and St Thomas's, London, United Kingdom, <sup>3</sup>Pain & Neuromodulation Centre, Guys and St Thomas' NHS Foundation Trust, London, United Kingdom, <sup>4</sup>Pain Medicine, Guy's and St Thomas's Hospital, London, UK, London, United Kingdom, <sup>5</sup>Chronic Pain Dept, Guys and St Thomas's NHS Trust, LONDON, United Kingdom, <sup>6</sup>Prismatics, Hospital University of Poitiers, Poitiers, France

**Introduction:** Many studies have shown the efficacy of Spinal Cord Stimulation (SCS) to manage pain (1-5) and improve quality of life (6) in patients with chronic intractable pain. However, literature has shown that 40% of SCS implanted patients are not satisfied with pain relief (7). Dorsal Root Ganglion (DRG) stimulation appears to be a promising technology (8) by being more selective on the nervous system (9,10) and having less positional sensitivity compared to SCS (11). Lead implantation level could have a crucial impact on amplitude of stimulation needed to optimally stimulate the DRG. The aim of this study is to assess the relationship between the amplitude of stimulation intensity and the implantation level.

**Methods/Materials:** 6 patients with refractory chronic foot, leg and/or groin pain were implanted with a DRG stimulation system including 8-contact lead(s) between 2016 and 2019 and included in this study. One patient was implanted with one DRG lead and five patients were implanted with two DRG leads. Four leads were implanted in L1 (36.4%), one lead in L3 (9.1%), three leads in L5 (27.3%) and three leads in S1 (27.3%). Each powered contact of each lead was stimulated in the same conditions for each patient to determine 3 sensory paresthesia thresholds: (i) the perception threshold, (ii) the optimal threshold, and (iii) the uncomfortable threshold corresponding to the intensity when the patient feels uncomfortable sensations. Amplitudes of stimulation needed to reach the sensory thresholds were reported and the mean amplitude for each implantation level was calculated. Mean amplitudes were compared between the different implantation levels.

**Results:** Both the implantation level and the powered contact had a significant impact on the mean amplitude of stimulation intensity needed to reach the different paresthesia sensory thresholds ( $p=0.03$  and  $p<0.0001$ , respectively). Leads implanted at the L3 level needed significantly greater amplitude of stimulation intensity area than L5 ( $p<0.0001$ ), S1 ( $p<0.0001$ ), and L1 ( $p<0.0001$ ). In the same way, implanting the lead at the L5 level needed significantly greater amplitude of stimulation intensity than L1 ( $p=0.016$ ) and S1 ( $p=0.044$ ). No difference in the amplitude of stimulation intensity was observed between L1 and S1.

**Discussion:** While localization is crucial to deliver optimal stimulation to relieve pain, our study suggests that amplitude intensity to obtain paresthesia depends on lead implantation level.

**Conclusions:** This study provides new insight to use DRG stimulation to relieve pain.

**References:** (1) Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *J Neurosurg (Spine)* 3) 100:254-267,2004. (2) Taylor RJ, Taylor RS. Spinal cord stimulation for failed back surgery syndrome: a decision-analytic model and cost-effectiveness analysis. *International Journal Of Technology Assessment in Health Care*. August 2005. (3) Van Buyten JP, Buchser E. Spinal Cord Stimulation for Chronic Back and Leg Pain and Failed Back Surgery Syndrome: A Systematic Review and Analysis of Pronostic Factors. *Spine*. 2005. (4)



Taylor RS. Spinal Cord Stimulation in Complex Regional Pain Syndrome and Refractory Neuropathic Back and Leg Pain/Failed Back Surgery Syndrome: Results of a Systematic Review and Meta-Analysis. *Journal Of Pain and Symptom Management*. April 2006. (5) North R, Kidd D, Farrokhi F, Piantadosi S. Spinal Cord Stimulation versus Repeated Lumbosacral Spine Surgery for Chronic Pain: A Randomized, Controlled Trial. *Neurosurgery*. 2005. (6) Hofmeister M, Memedovich A, Brown S, Saini M, Dowsett L, Lorenzetti D, McCarron T, MacKean G, Clement F. Effectiveness of Neurostimulation Technologies for the Management of Chronic Pain: A Systematic Review. *Neuromodulation: Technology at the neural Interface*. 2019 (7) Frey M, Manchikanti L, Benyamin R, Schult D, Smith H, Cohen S. Spinal Cord Stimulation for Patients with Failed Back Surgery Syndrome: A Systematic Review. *Pain Physician*. 2009. (8) Deer T, Grigsby E, Weiner R, Wilcosky B, Kramer J. A Prospective Study of Dorsal Root Ganglion Stimulation for the Relief of Chronic Pain. *Neuromodulation: Technology at the Neural Interface*. 2012. (9) Deer T and al. Comparison of Paresthesia Coverage of Patient's Pain: Dorsal Root Ganglion vs. Spinal Cord Stimulation. An ACCURATE Study Sub-Analysis. *Neuromodulation: Technology at the Neural Interface*. 2018 (10) Mekhail N and al. Paresthesia-Free Dorsal Root Ganglion Stimulation: An ACCURATE Study Sub-Analysis. *Neuromodulation: Technology at the Neural Interface*. 2018 (11) Deer T and al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain*. 2017

**Keywords:** Back Pain, Dorsal Root Ganglion, Failed Back Surgery Syndrome

## SINGLE CENTER EXPERIENCE OF FOCAL, CHRONIC, POST-SURGICAL NEUROPATHIC PAIN USING 10 KHZ SPINAL CORD STIMULATION

### E-POSTER VIEWING

Bart Billet<sup>1</sup>, Karel Hanssens<sup>1</sup>, Olivier De Coster<sup>1</sup>, Werner Nagels<sup>1</sup>, Veerle Minne<sup>2</sup>, Pascale Reiters<sup>2</sup>, Jeyakumar Subbaroyan<sup>2</sup>

<sup>1</sup>Pain Clinic, AZ Delta, Roeselare, Belgium, <sup>2</sup>Clinical Research, Nevro Corp., Redwood City, United States of America

**Introduction:** Chronic post-surgical pain (CPSP) is one of the most common and serious complications after surgery. A recent multicenter observational study reported a 12-month incidence of 11.8% moderate CPSP and 2.2% severe CPSP[1]. In this study, we tested the hypothesis that a standard midline lead placement using HF-SCS at 10 kHz may provide effective pain relief in CPSP conditions without the need for a focal stimulation target.

**Methods/Materials:** Subjects with focal chronic neuropathic pain of  $\geq 5$  cm visual analog scale (VAS) score of the trunk or limb from CPSP were enrolled in this single center prospective study, after approval from ethics committee and completion of written informed consent. Two epidural leads were implanted spanning the appropriate vertebrae based on location of pain. Subjects with successful trial ( $\geq 50\%$  pain reduction) received permanent implant and were followed-up for 12 months to collect safety and effectiveness data. Results are presented as mean  $\pm$  SD in the permanent implant population.

**Results:** At final analysis, a total of 22 subjects were enrolled in the study, 16 with lower extremity pain, 3 with upper extremity pain, 2 with trunk pain and 1 with flank pain. Eighteen subjects had a successful trial (82% trial success rate) and received a permanent implant. Baseline pain scores of  $7.9 \pm 1.0$  cm improved to  $1.5 \pm 1.3$  cm,  $1.4 \pm 1.1$  cm,  $1.2 \pm 0.9$  cm,  $1.2 \pm 1.1$  cm at 1-, 3-, 6- and 12-month follow-ups, respectively. The responder rate was  $\geq 94\%$  at all time points. Mean DN4 (Douleur Neuropathique 4) questionnaire score improved from  $6.4 \pm 2.4$  to  $2.1 \pm 2.2$  and  $3.7 \pm 2.6$  at 3-month and 12-month follow-ups, respectively. Significant improvements were reported in all domains of McGill Pain Questionnaire including affective descriptors (Table 1) and 3-item pain and sleep questionnaire (Table 2).

	Total Score	Continuous Pain	Intermittent Pain	Neuropathic Pain	Affective Descriptors
Baseline (n=18)	$5.0 \pm 1.6$	$5.3 \pm 1.8$	$5.5 \pm 2.2$	$5.1 \pm 2.7$	$4.2 \pm 1.8$
3-month (n=17)	$1.4 \pm 1.0$	$1.8 \pm 1.6$	$1.4 \pm 1.4$	$1.5 \pm 1.4$	$1.0 \pm 1.0$
12-month (n=17)	$1.6 \pm 1.3$	$1.7 \pm 1.8$	$1.4 \pm 1.4$	$2.1 \pm 1.9$	$0.8 \pm 1.1$

Table 1: Domain Scores for Short Form McGill Pain Questionnaire (SF-MPQ-2)

	Trouble falling asleep due to pain	Awakened from sleep (night)	Awakened from sleep (morning)
Baseline (n=18)	$6.8 \pm 3.0$	$6.0 \pm 3.2$	$6.3 \pm 3.3$
3-month (n=17)	$1.5 \pm 1.7$	$1.6 \pm 1.9$	$1.9 \pm 2.0$
6-month (n=17)	$1.7 \pm 2.3$	$0.9 \pm 1.5$	$1.1 \pm 1.5$
12-month (n=17)	$1.1 \pm 1.8$	$1.6 \pm 2.7$	$0.9 \pm 1.5$

Table 2: Three-item pain and sleep questionnaire

**Discussion:** Results from this study demonstrate that a midline epidural, anatomically guided lead placement may offer an effective treatment to focal pain in subjects with chronic post-surgical pain.

**Conclusions:** These findings are consistent with that of a multicenter, prospective study from the United States[2].

**References:** [1] Fletcher D, Stamer UM, Pogatzki-Zahn E, et al. Chronic postsurgical pain in Europe: an observational study. *Eur J Anaesthesiology* 2015; 32(10): 725–734 [2] Gupta M et al., Spinal Cord Stimulation at 10 kHz for the Treatment of Chronic Focal Neuropathic Post-Surgical Pain, 23<sup>rd</sup> Annual Meeting of the North American Neuromodulation Society (NANS), Las Vegas, Jan 23-26, 2020

**Keywords:** 10 kHz, focal pain, paresthesia-independent, SCS, high frequency

**Topic:** 05. Spine / 05a. Pain

## **SINGLE CENTER EXPERIENCE OF 10 KHZ SPINAL CORD STIMULATION USING SURGICAL LEADS**

### **E-POSTER VIEWING**

Dimitri Vanhauwaert<sup>1</sup>, Tim Couvreur<sup>1</sup>, Olivier Van Damme<sup>1</sup>, Karel Hanssens<sup>2</sup>, Jeyakumar Subbarayan<sup>3</sup>

<sup>1</sup>Neurosurgery, AZ Delta, Roeselare, Belgium, <sup>2</sup>Pain Clinic, AZ Delta, Roeselare, Belgium, <sup>3</sup>Clinical Research, Nevro Corp., Redwood City, United States of America

**Introduction:** High frequency 10 kHz spinal cord stimulation (SCS) has shown to provide superior outcomes compared to traditional low frequency SCS when treating patients with chronic, intractable back and/or leg pain[1]. As part of a large prospective study, this single center experience reports on the clinical performance of 10 kHz SCS delivered through surgical leads in the treatment of chronic, intractable, back and/or leg pain of neuropathic origin.

**Methods/Materials:** Subjects diagnosed with chronic, intractable, neuropathic back and/or leg pain, including unilateral or bilateral pain, are being enrolled in this study. In this center the primary indication is Failed Back Surgery Syndrome (FBSS). All subjects considered for enrollment were already scheduled for either a commercial trial or a permanent implant of a 10 kHz SCS system with a 16-contact surgical lead only. This is a standard of care data collection study where the 10 kHz SCS system is used in accordance with its labeling, Institutional Review Board (IRB) or Ethics Committee (EC) approval and requires informed consent from study subjects. The primary outcome is the proportion of subjects achieving therapy success at 3 months post-implant. Subject success and the level of success will be determined based on the degree of pain relief (measured by Numeric Rating Scale - NRS) and patient global impression of change at 3-month follow-up. Secondary outcomes include other pain assessments, the Oswestry Disability Index, EQ-5D-5L, opioid usage and health and work status. Outcomes will be assessed via standardized questionnaires and data will be collected at baseline, trial and end of trial (if performed), device implant, and at 3, 6, and 12-month follow-up post-implant.

**Results:** The site has currently enrolled 26 subjects, and 14 out of 14 subjects had a successful trial and received a permanent implant. Four subjects have thus far completed their 3-month follow-up and are deemed responders per subject success criteria.

**Discussion:** Enrollment and follow-up in this study are still ongoing.

**Conclusions:** Complete data from the study subjects from this site will be reported at the time of the meeting.

**References:** [1] Kapural L et al. Comparison of 10-kHz High-Frequency and Traditional Low Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain:24-Month Results from a Multicenter, Randomized, Controlled Pivotal Trial Neurosurgery. 2016.

**Keywords:** 10 kHz, surgical lead, back and/or leg pain, paresthesia-independent, SCS, high frequency

EPV108 / #248

Topic: 05. Spine / 05a. Pain

**POST STERNOTOMY PAIN TREATED WITH 10KHZ SPINAL CORD STIMULATION (10KHZ SCS):  
A CASE STUDY**

**E-POSTER VIEWING**

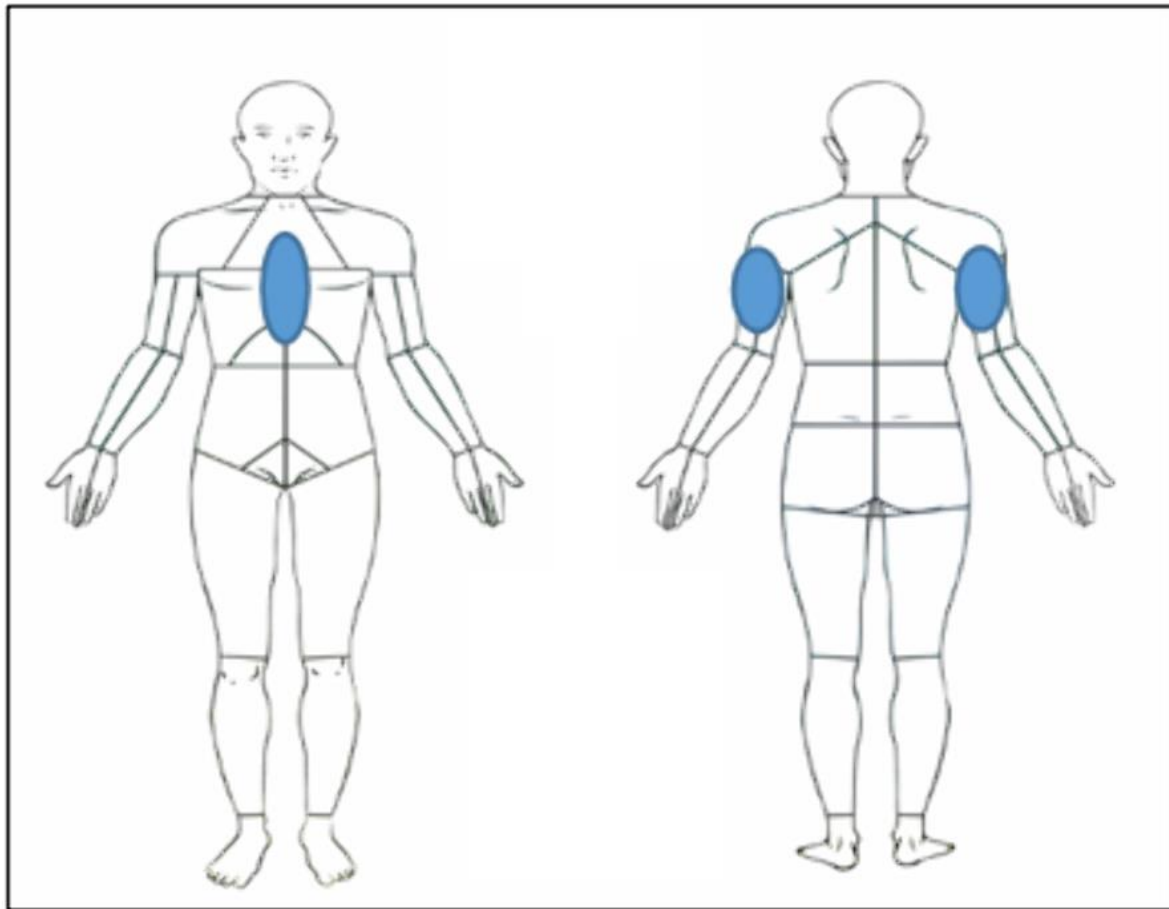
Terry Muldoon

Pain Medicine, Belfast Health and Care Trust, Belfast, United Kingdom

**Introduction:** Chronic post-sternotomy pain is common, persisting in about 30% of cases, despite the improvements in surgical techniques over the years. Its aetiology is not known but intercostal nerve damage may lead to the development of neuropathic pain<sup>1</sup>. This case study details the management of a patient with post-sternotomy pain treated successfully with 10kHz SCS.

**Methods/Materials:** A 39-year-old female with myasthenia gravis underwent a thymectomy in 2002. Post-operatively she developed chronic pain in the midline sternotomy wound. In 2007, the patient was referred to a pain clinic. Neuropathic trigger points were identified at 5 locations along the wound. The patient experienced short term relief with 6 monthly pulsed radio frequency (PRF). After several years the patient requested a more sustainable option. Spinal cord stimulation (SCS) was offered. 10kHz SCS was trialled for one week in September 2019, using 2 percutaneous leads covering C3 to T3. After successful trial, the patient was implanted with a permanent system.

## Results:



*Figure 1 – Pain map*

The pain was described as a 'jolt' phenomenon, occurring hourly, with an intensity of 10/10 in the numerical rating scale (NRS). In addition the patient experienced a burning pain (NRS of 10/10) with allodynia to the back of both arms (Figure 1). At the end of trial, the patient reported a reduction in 'jolts' to a maximum of 3 times per day and the burning pain reduced to an NRS of 1/10. These results have improved post-permanent implant, the patient reports a maximum of 3 days without any painful 'jolt' while the burning pain remains at an NRS of 1/10. The patient's mood, sleep and function have improved which has contributed to an improvement in the quality of life.

**Discussion:** The treatment of chronic post-sternotomy pain is often inadequate, relying on opioids and other medications that provide minimal benefit to the patient and have significant adverse effects<sup>2</sup>. 10kHz SCS successfully managed this case of post-sternotomy pain. The patient reports reduced frequency of jolt like sternotomy pain and significant improvement in burning pain to the arms. They indicate the pain reduction has improved quality of life, mood, sleep and function. The sustainable nature of 10kHz SCS offers long term efficacy without the need for repeated interventions.

**Conclusions:** 10kHz SCS may be considered in patients experiencing chronic neuropathic poststernotomy pain.

**References:** 1. Nicoline J. Van Leersum, Rutger L. Van Leersum, Harriette F. Verwey, Robert J. M. Klautz, Pain Symptoms Accompanying Chronic Poststernotomy Pain: A Pilot Study, Pain Medicine, Volume 11, Issue 11, November 2010, Pages 1628–1634, <https://doi.org/10.1111/j.1526-4637.2010.00975.x> 2. Kleiman AM, Sanders DT, Nemergut EC, Huffmyer JL, Chronic Poststernotomy Pain: Incidence, Risk Factors, Treatment, Prevention, and the Anesthesiologist's Role, Reg Anesth Pain Med 2017 Nov/Dec;42(6):698-708. doi: 10.1097/AAP.0000000000000663.

**Keyword:** Neuropathic pain, postoperative, sternotomy, 10kHz SCS

**Topic:** 05. Spine / 05a. Pain

## **TREATMENT OF UPPER LIMB NEUROPATHIC PAIN WITH 10KHZ SPINAL CORD STIMULATION: A CASE SERIES**

### **E-POSTER VIEWING**

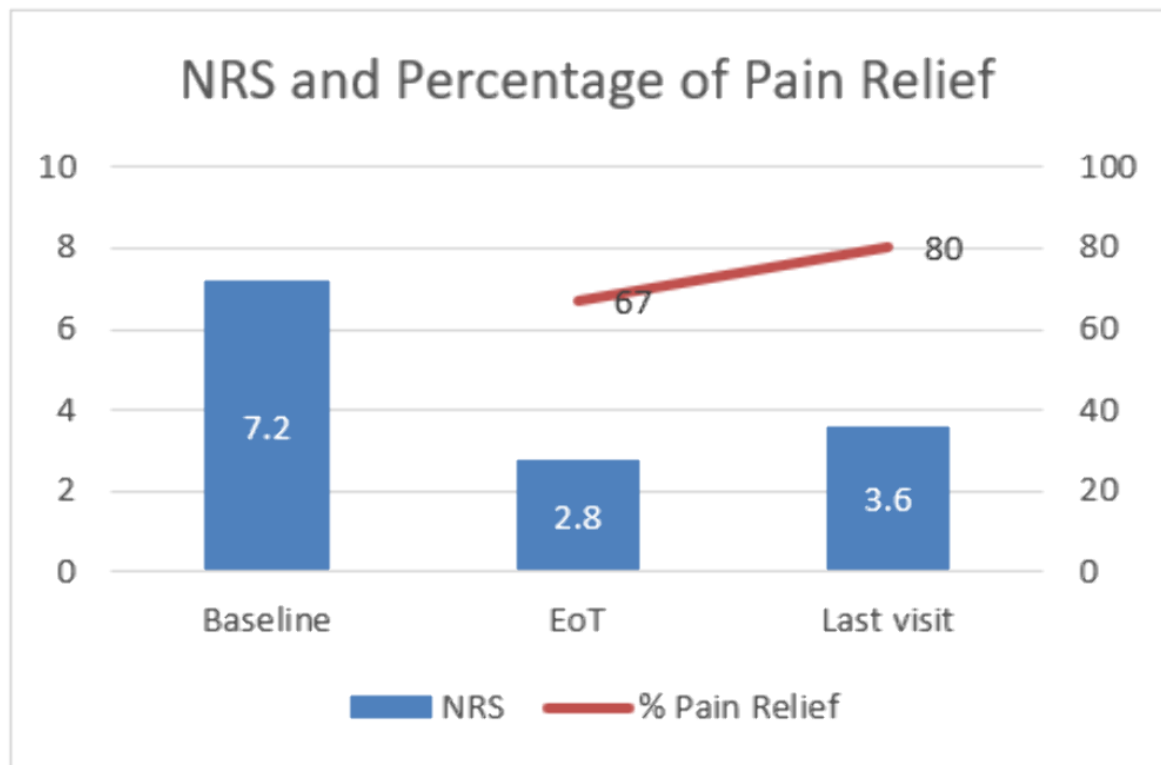
Mayowa Owolabi, Bret Claxton, Sanjeeva Gupta, Rishi Khanna, Kyriacos Kyriakides, Anthony Swanepoel, Claire Kelly, David Chaloner  
Anaesthetic Department, Bradford Teaching Hospital Foundation Trust, Bradford, United Kingdom

**Introduction:** Spinal Cord Stimulation (SCS) has shown to reduce pain scores, improve function and quality of life in patients with chronic neuropathic pain. Historically upper limb pain has been a difficult pain indication to manage. One of the main limitations with low frequency SCS is that it can cause variability in the paraesthesia, uncomfortable sensations and inadequate coverage. In contrast, 10kHz SCS is a paraesthesia-independent therapy which has been proven to be a long term safe and efficacious treatment for chronic neuropathic pain. This abstract will showcase outcomes of 10kHz SCS in a retrospective case series of 6 patients with upper limb neuropathic pain.

**Methods/Materials:** All patients over the age of 18 who have a 10kHz SCS implanted for the treatment of upper limb neuropathic pain (bilateral arms, unilateral arm and posterior thorax) were included in the analysis. Outcomes were measured at baseline, end of trial (EoT), and at the last visit (range 1 to 12 months). These included numerical rating scale (NRS) score, percentage pain relief, functional improvement and pain medication. All patients underwent a trial of 10kHz SCS with the leads spanning from C2 to C6 and then received a permanent implant.

**Results:** The average NRS and percentage of pain relief at baseline, EoT and last visit is shown on graph 1. One patient did not report NRS or percentage of pain relief but has reported improvement in hand movement and function (including writing) at EoT and at last visit. In addition, swelling has reduced and there was an improvement in grip. All patients have reported additional benefits to the pain relief such as reduction in swelling, improvement in movement and/or function and in sleep quality. Out of the 6 patients, 4 have either reduced or stopped their pain medication.





*Graph 1 – NRS and Percentage of Pain Relief*

**Discussion:** In this case series of 6 patients, 10kHz SCS has demonstrated effective treatment for upper limb neuropathic pain.

**Conclusions:** Subjects reported long-term pain relief and an improvement in functional ability along with other quality of life metrics.

**References:**

**Keyword:** Upper Limb HF10 SCS Neuropathic Pain

Topic: 05. Spine / 05a. Pain

## A SUB-ANALYSIS OF 10 KHZ SPINAL CORD STIMULATION (10 KHZ SCS) IN PATIENTS WITH NON-SURGICAL REFRACTORY BACK PAIN

### E-POSTER VIEWING

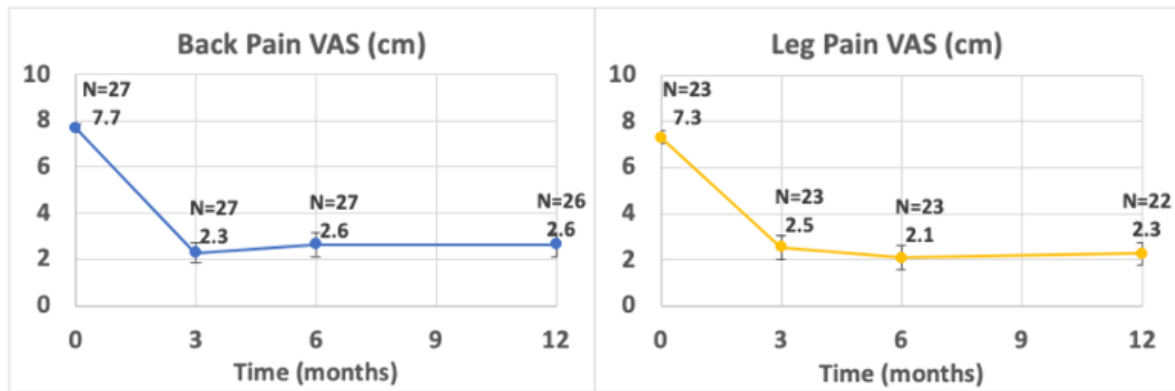
Adnan Al-Kaisy<sup>1</sup>, Jean-Pierre Van Buyten<sup>2</sup>, Kasra Amirdelfan<sup>3</sup>, Leonardo Kapural<sup>4</sup>

<sup>1</sup>Chronic Pain Management And Neuromodulation Centre, Guy's & St Thomas' NHS Trust, London, United Kingdom, <sup>2</sup>Multidisciplinary Pain Center, AZ Nikolaas, Sint-Niklaas, Belgium, <sup>3</sup>Pain Medicine, IPM Medical Group, Inc., Walnut Creek, CA, United States of America, <sup>4</sup>Pain Management, Carolinas Pain Institute and Wake Forest University School of Medicine, Winston-Salem, NC, United States of America

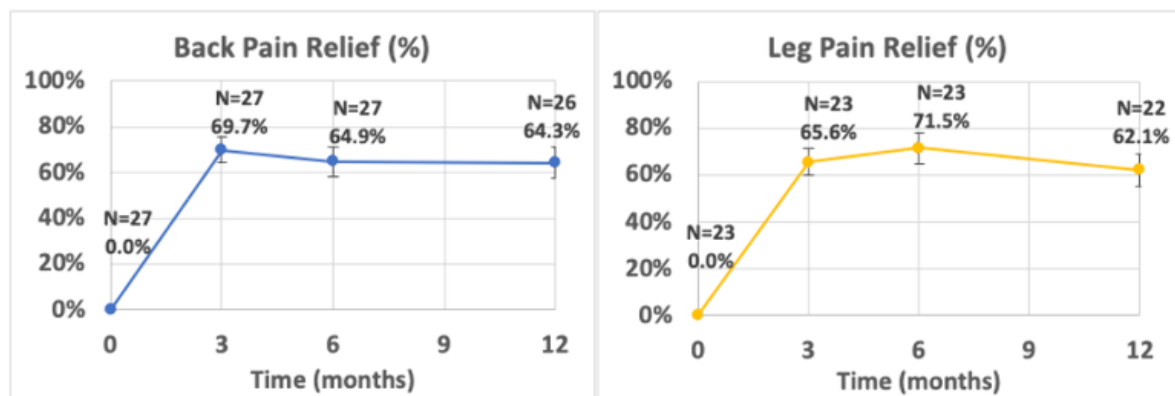
**Introduction:** High frequency 10 kHz spinal cord stimulation (10 kHz SCS) has demonstrated superiority over traditional SCS in the treatment of back and leg pain and is currently being investigated for the treatment of chronic upper limb and neck pain, abdominal pain, and other indications.<sup>1,2,3</sup> The efficacy over time of 10 kHz SCS for non-surgical refractory back pain (NSRBP) was also demonstrated in a prospective, single centre study.<sup>4</sup> The objective of this sub-analysis was to further report the benefits of 10 kHz SCS in patients with NSRBP from other prospective studies.

**Methods/Materials:** This analysis included the surgery-naïve subjects with chronic, intractable pain of the trunk and/or limbs, refractory to conservative therapy, and average back and leg pain intensities of  $\geq 5$  cm on the visual analogue scale (VAS) enrolled in the SENZA-RCT<sup>1</sup> or SENZA-EU<sup>5</sup> studies and implanted with a 10 kHz SCS system. Outcomes such as VAS scores, responder rates (those reporting  $\geq 50\%$  pain relief from baseline), remitter rates ( $VAS \leq 3.0$  cm)<sup>6</sup> and disability (using the Oswestry Disability Index - ODI) were analyzed in the combined data set.

**Results:** A total of 27 subjects (12 from SENZA-RCT and 15 from SENZA-EU) enrolled in the study were surgically-naïve and included in the analysis. Mean back and leg pain VAS scores decreased from  $7.7 \pm 0.2$  cm and  $7.3 \pm 0.3$  cm at baseline to  $2.6 \pm 0.5$  cm and  $2.3 \pm 0.5$  cm, respectively at 12 months (Figure 1). Average pain relief at 12-months was  $64.3 \pm 6.8\%$  and  $62.1 \pm 6.8\%$  for back and leg pain, respectively (Figure 2). More than 70% of the subjects were back and leg pain responders and  $>60\%$  of the subjects achieved remission at 12 months (Table 1). Twenty-six subjects had complete ODI data available at baseline and 12 months. Overall disability improved by an average of 15.7% (baseline:  $52.3 \pm 1.7\%$ ; 12 months:  $36.6 \pm 2.7\%$ ). Consequently, 21 of 26 subjects (81%) moved into a comparatively lower disability category.



**Figure 1a (Left) and 1b (Right).** VAS scores over 12 months for back and leg pain.



**Figure 2a (Left) and 2b (Right).** Percent pain relief over 12 months for back and leg pain.

	RESPONDER RATE	REMITTER RATE
BACK PAIN	73.1% (N=19/26)	61.5% (N=16/26)
LEG PAIN	72.7% (N=16/22)	68.2% (N=15/22)

**Table 1.** Responder and remitter rates for back and leg at 12 months.

**Discussion:** Not applicable.

**Conclusions:** These results from two prospective, multicenter studies confirm the significant and sustained back and leg pain relief in NSRBP patients with those reported by Al-Kaisy et al. The results also act as a precursor to the two ongoing randomized controlled trials of 10 kHz SCS aiming to investigate the safety, effectiveness and healthcare utilization in NSRBP subjects.

**References:** 1 -Kapural L et al. Anesthesiology, 123 (2015) 851-860. 2 -Amirdelfan K et al. NANS 22<sup>st</sup> AM. Las Vegas, NV. Jan 17-19, 2019. 3 -Kapural L et al. NANS 22<sup>st</sup> AM. Las Vegas, NV. Jan 17-19, 2019. 4 -Al-Kaisy A et al Pain Med. 2018 Jun 1;19(6):1219-1226 5 -Al-Kaisy A et al Pain Med. 2014 Mar;15(3):347-54. 6 -Amirdelfan K et al Postgrad Med. 2019 May;131(4):278-286.

**Keywords:** Non-surgical back pain, Back Pain, 10kHz SCS

**Topic:** 05. Spine / 05a. Pain

## FOLLOW-UP OF SPINAL CORD STIMULATION PATIENTS. METHOD AND RESULTS

### E-POSTER VIEWING

Inmaculada Herrador Montiel

Pain Unit, Hospital Universitario Reina Sofía, Córdoba, Spain

**Introduction:** The aim of this poster is to show a long-term follow-up method of our Spinal Cord Stimulation patients and to evaluate the outcomes of the therapy in our hospital so far.

**Methods/Materials:** Since October 2017, neurostimulation patients are recorded in a dedicated SCS Follow-up application. Recorded variables are Pain Intensity (NRS 0-10), Patient Satisfaction (Likert Scale 1-5), Disability (Oswestry Disability Index - ODI), General Health (SF-12), Quality of Life (EQ-5D) as well as surgical history, stimulation parameters and therapy complications, taking in account patient's sex, age, diagnosis, pain areas and pain evolution time.

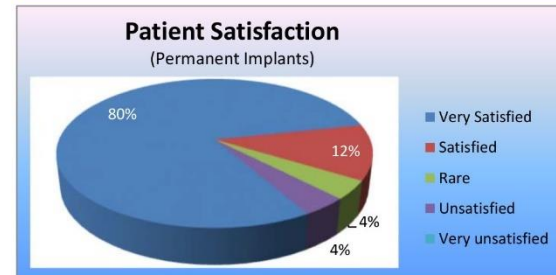
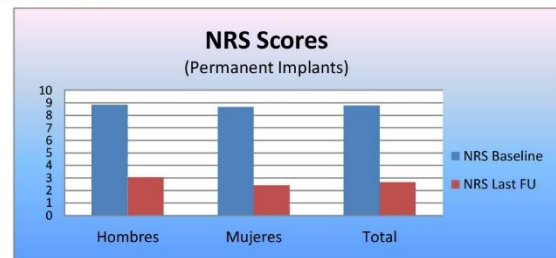
**Results:** 25 of 26 patients (13 female, 13 male, age  $51 \pm 26$ ) received the permanent implant after a stimulation trial. After a mean Follow-up time of 7 (0-22) months, 23 patients (92%) were satisfied or very satisfied and gained significant relief ( $\geq 50\%$ ) with the therapy. Conventional tonic dorsal column Stimulation lost efficacy in 4 patients between 8 and 17 months after the initial implantation, recovering the initial relief after changing to Burst (n=3) or Dorsal Root Ganglion (n=1) stimulation. Baseline, 6 month and 1 year scores were: ODI 66% , 38% , 52%. SF-12 (physical/mental) 14/32, 20/40, 17/37. EQ5 (impact/health) 54/34, 42/60, 48/49. Stimulation parameters can be seen in Table 1. 2 patients (8%) required lead repositioning after migration 3 and 11 months after implant respectively. 1 patient received a second lead 16 months after initial implantation to cover a new painful area. No explants derived from infection or other adverse events were recorded. Since the beginning of 2019 the choice therapies are Burst for back/limb pain and DRG for focal pain, and since then the number of therapy complications leading to surgical revision has been reduced to 0. All patients will be re-evaluated and data updated for the final poster to be presented during the congress.

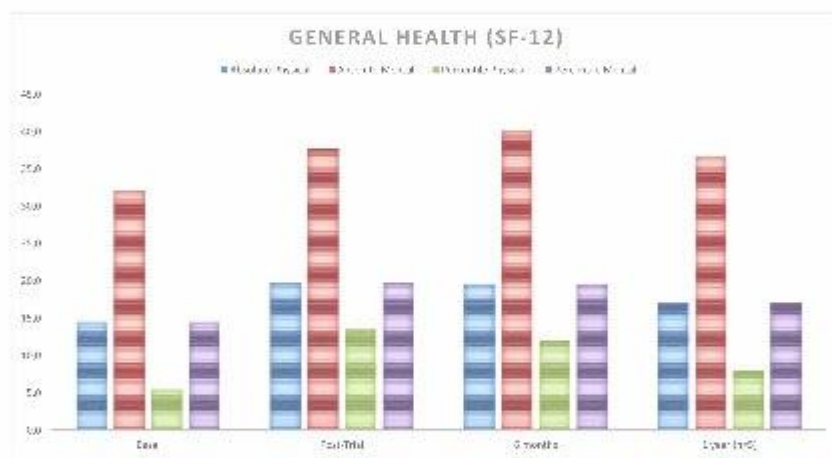
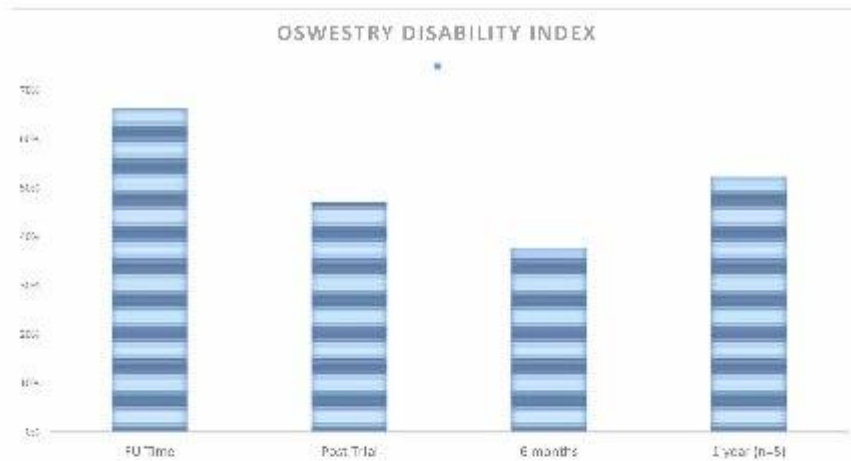
## Summary of Results

	n	%
# of patients	26	
Male:	13	50%
Female:	13	50%
Negative Trials:	1	3,8%
Explants:	0	0,0%

ESTADÍSTICAS SOBRE IMPLANTES PERMANENTES					
	n	MEAN	MIN	MAX	MEDIAN
Age at implant (Years)	25	52,8	37	70	52,0
Pain duration pre-therapy	25	72	24	180	54
NRS Baseline (0-10)	25	8,76	8,0	9,0	9,00
Follow-up (months)	25	7,0	0	22	4,5
Paresthesia coverage	25	96,0	0	100	100,0
Satisfaction (Likert 1-5)	25	1,3	0,0	4,0	1,0
NRS Last Follow-Up	25	2,8	0,0	7,0	2,5
Relief	25	69%	22%	89%	67%

Patients with relief > 50%	(25)	<b>23</b>	92% of permanent implants
	(26)		88% of total patients
Satisfied or very satisfied	(25)	<b>23</b>	92% of permanent implants





Patient/Baseline						System	Outcomes				Stimulation program					
ID	Pathology	Sex	Age	NRS	Pain Location	Lead config	Months FU	Sat	NRS	Relief	Mode	F (Hz)	Z (Ω)	PW (μs)	Amin (mA)	Amax (mA)
1	FBSS	M	54	9	LB/LEGS	8-8	16	1	3	67%	TONIC	40	391	500	2.00	5.00
2	FBSS	M	44	9	LB/LEGS	8-8	1	2	4	56%	TONICA	60	651	300	3.00	5.00
3	FBSS	M	59	9	LB/LEGS	8-8	22	2	4	56%	BURSTDR	40	491	1000	0.50	1.00
4	FBSS	F	55	9	LB/LEGS	8-8	7	1	2	78%	TONIC	60	398	300	2.00	6.00
5	FBSS	M	57	9	LB/LEGS	8-8	1	1	1	89%	TONICA	60	655	300	2.75	6.00
6	FBSS	F	58	9	LB/LEGS	8-8	5	1	2	78%	TONIC	60	721	500	3.00	6.00
7	FBSS	M	56	8	LB/LEGS	8-8	15	1	4	50%	TONIC	60	549	500	5.00	10.50
8	FBSS	F	40	9	LB/LEGS	2-4-4-4-2	20	1	3	67%	TONIC	60	930	300	12.00	24.50
9	CRPS I	M	47	9	ARM	4-8	19	3	6	33%	DRG	45	661	250	1.21	2.65
10	FBSS	F	50	9	LB/LEGS	8-8	0	1	2	78%	TONIC	60	376	300	3.00	6.00
11	FBSS	M	48	9	LB/LEGS	8-8	13	2	3	67%	TONIC	60	670	500	6.50	10.00
12	FBSS	F	40	9	LB/LEGS	8-8	17	4	7	22%	BURSTDR	40	540	1000	0.60	1.00
13	FBSS	M	69	9	LB/LEGS	8-8	1	1	3	67%	TONIC	60	301	300	3.00	6.00
14	FBSS	F	51	9	LB/LEGS	8-8	3	1	3	67%	TONIC	60	725	300	4.20	8.00
15	FBSS	F	45	9	LB/LEGS	8-8	4	1	2	78%	TONIC	60	631	300	4.50	8.50
16	CRPS I	M	52	9	MI/SHOULDERS	8-8	9	1	2	78%	BURSTDR	40	312	1000	0.20	0.60
17	CRPS I	M	50	9	ANKLE	4	7	1	3	67%	DRG	24	1003	500	0.40	2.00
18	FBSS	M	37	9	LB/LEG	8	5	1	3	67%	BURSTDR	40	380	1000	0.50	1.00
19	FBSS	F	51	9	LB/LEGS	8-8	0	1	2	78%	TONIC	60	299	300	2.00	4.00
20	FBSS	F	52	9	LB/LEGS	8-8	Negative Trial									
21	POST-SURGICAL	M	53	9	ARM	4	5	1	1	89%	DRG	24	974	300	1.00	2.00
22	POST-TRAUMA	F	60	8	FOOT	4	1	1	2	75%	DRG	26	703	300	0.30	1.00
23	FBSS	M	57	8	LB/LEGS	8-8	1	1	3	63%	BURSTDR	40	581	1000	0.50	1.00
24	FBSS	F	67	8	LB/LEGS	8-8	2	1	2	75%	BURSTDR	40	299	1000	0.50	1.00
25	FBSS	F	51	8	ARMS	8	0	1	1	88%	BURSTDR	40	299	1000	0.50	1.00
26	FBSS	F	70	8	ARMS	8-8	1	1	1	88%	BURSTDR	40	637	1000	0.50	1.00

**Discussion:** While therapy success rate is relatively high in our series, 4 patients (16%) lost initial relief, which is in line with other published results [1], but all of them could be rescued by means of other alternative SCS treatments. The use of neurostimulation systems capable of delivering alternative stimulation patterns can effectively reduce the incidence of complications that lead to surgical revisions.

**Conclusions:** Methodological Follow-up of neuromodulation patients by means of validated questionnaires and dedicated database software is a helpful tool for interventional pain management specialists.

**References:** [1] Hayek SM, Veizi, Hanes M. Treatment-Limiting Complications of Percutaneous Spinal Cord Stimulator Implants: A Review of Eight Years of Experience From an Academic Center Database. Neuromodulation. 2015 Oct;18(7):603-8; discussion 608-9.

**Keywords:** Follow-up, Spinal cord stimulation

EPV112 / #253

Topic: 05. Spine / 05a. Pain

## DE NOVO CASE REPORT ON SPINAL CORD STIMULATION FOR COMPLEX REGIONAL PAIN SYNDROME WITH BOSTON SCIENTIFIC WAVEWRITER

### E-POSTER VIEWING

Deepika Arora, Joanne Lascelles, Kavita Poply, Vivek Mehta  
Pain Research Centre, Barts Health NHS Trust, London, United Kingdom

**Introduction:** Spinal cord stimulation has proved to be an effective modality in managing refractory neuropathic pain secondary to various conditions including Complex Regional Pain Syndrome (CRPS).<sup>1,2</sup> In our centre, Boston Scientific WaveWriter spinal cord stimulators are commonly used to treat chronic neuropathic back pain secondary to degenerative disc disease or failed back surgery syndrome. It has not been used to manage chronic pain secondary to CRPS. We present a de novo case report of a 43 years old female suffering from CRPS who received Boston Scientific WaveWriter spinal cord stimulator.

### Methods/Materials:







The patient is a 43 years old female who suffered a fracture in 2013 following which she underwent fusion surgery. She eventually developed intractable neuropathic pain secondary to CRPS. None of the modalities- medications including opioids and spinal interventions helped in managing the pain. She subsequently underwent neuromodulation and received Boston Scientific WaveWriter spinal cord stimulator in February 2020. Two inflexion leads were positioned at T11 vertebrae and coverage of the painful area was confirmed with patient intraoperatively. Two programs - tonic and microburst (paraesthesia free) programs were used. The settings of the tonic program was - Continuous cycle with Amplitude-4.7mA, Pulse width 210µs, Rate 60Hz. Microburst program settings were -12.50ms ON and OFF cycle of amplitude 2.2mA, Pulse width 210µs, Rate 450Hz. Patient used the tonic program in the daytime and used the microburst program during sleep.

**Results:** There was significant improvement in the pain scores of patient from baseline pre-implantation score of 9/10 to 4/10 at day 7 post-implantation . Patient reported overall reduction in pain by 70% and also reported improvement in functional status.

**Discussion:** The novel program settings used in this patient with inflexion leads of Boston WaveWriter and the significant improvement in symptoms achieved in this case report is encouraging to continue doing similar cases of refractory neuropathic pain, considering the very fact that CRPS is one of the most difficult chronic neuropathic conditions to manage. The follow up is on-going and the case report will be further updated as the events warrant.

**Conclusions:** Spinal cord stimulation is a useful modality to treat CRPS and this is one of the early case report of using Boston WaveWriter with the novel program settings which has proved to be effective in managing pain secondary to CRPS.

**References:** 1. Visnjevac O, Costandi S, Patel BA, Azer G, Agarwal P, Bolash R, Mekhail NA. A Comprehensive Outcome-Specific Review of the Use of Spinal Cord Stimulation for Complex Regional Pain Syndrome. *Pain Pract.* 2017 Apr;17(4):533-545. doi: 10.1111/papr.12513. Epub 2016 Oct 14. 2. Grabow TS, Tella PK, Raja SN. Spinal cord stimulation for complex regional pain syndrome: an evidence-based medicine review of the literature. *Clin J Pain.* 2003 Nov-Dec;19(6):371-83.

**Keyword:** Boston WaveWriter spinal cord stimulator with novel program settings is effective in managing CRPS.

Topic: 05. Spine / 05a. Pain

## 10 KHZ SPINAL CORD STIMULATION FOR TREATMENT OF PAINFUL DIABETIC NEUROPATHY - A MULTICENTER RANDOMIZED CONTROLLED TRIAL

### E-POSTER VIEWING

Erika Petersen<sup>1</sup>, Thomas Stauss<sup>2</sup>, James Scowcroft<sup>3</sup>, Judith White<sup>4</sup>, Shawn Sills<sup>5</sup>, Kasra Amirdelfan<sup>6</sup>, Maged Guirguis<sup>7</sup>, Jijun Xu<sup>8</sup>, Cong Yu<sup>9</sup>, Ali Nairizi<sup>10</sup>, Denis Patterson<sup>11</sup>, Vincent Galan<sup>12</sup>, Richard Bundschu<sup>13</sup>, Neel Mehta<sup>14</sup>, Dawood Sayed<sup>15</sup>, Shivanand Lad<sup>16</sup>, David Dibenedetto<sup>17</sup>, Khalid Sethi<sup>18</sup>, Paul Wu<sup>19</sup>, Charles Argoff<sup>20</sup>, Christian Nasr<sup>21</sup>, Rod Taylor<sup>22</sup>, Elizabeth Brooks<sup>23</sup>, Jeyakumar Subbaroyan<sup>23</sup>, Bradford Gliner<sup>23</sup>, David Caraway<sup>24</sup>, Nagy Mekhail<sup>25</sup>

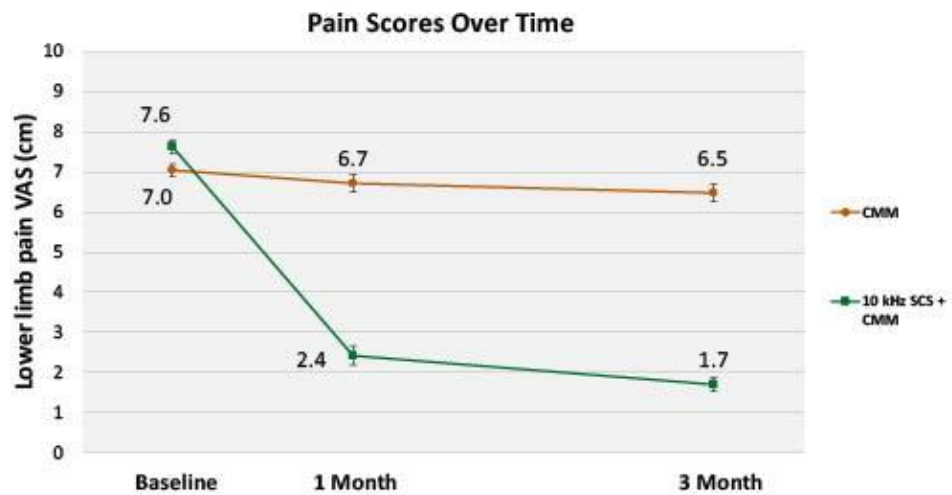
<sup>1</sup>Neurosurgery, University of Arkansas for Medical Sciences, Little Rock, United States of America, <sup>2</sup>Anesthesiology, Advanced Pain Management, Greenfield, WI, United States of America, <sup>3</sup>Pain Management, Pain Management Associates, Independence, MO, United States of America, <sup>4</sup>Clinical Research, Accelerated Enrollment Solutions, Orlando, United States of America, <sup>5</sup>Pain Medicine, Touchstone Interventional Pain Center, Medford, United States of America, <sup>6</sup>Pain Medicine, IPM Medical Group, Inc., Walnut Creek, CA, United States of America, <sup>7</sup>Pain Medicine, Ochsner Clinic Foundation, New Orleans, United States of America, <sup>8</sup>Pain Medicine, Cleveland Clinic, Cleveland, United States of America, <sup>9</sup>Pain Medicine, Swedish Pain & Headache Center, Seattle, United States of America, <sup>10</sup>Pain Medicine, Reno Tahoe Pain Associates, Reno, United States of America, <sup>11</sup>Pain Medicine, Nevada Advanced Pain Specialists, Reno, United States of America, <sup>12</sup>Pain Medicine, Pain Care, Stockbridge, United States of America, <sup>13</sup>Interventional Pain Medicine, Coastal Orthopedics Sports Medicine and Pain Management, Bradenton, United States of America, <sup>14</sup>Pain Medicine, Weill Cornell Medicine, New York, United States of America, <sup>15</sup>Pain Medicine, University of Kansas Medical Center, Kansas City, United States of America, <sup>16</sup>Neurosurgery, Duke University, Durham, United States of America, <sup>17</sup>Pain Medicine, Boston Pain Care, Waltham, United States of America, <sup>18</sup>Neurosurgery, United Health Services, Johnson City, United States of America, <sup>19</sup>Pain Medicine, Holy Cross Hospital, Fort Lauderdale, United States of America, <sup>20</sup>Neurology, Albany Medical Center, Albany, United States of America, <sup>21</sup>Endocrinology, Cleveland Clinic, Cleveland, United States of America, <sup>22</sup>Clinical Trials Unit, University of Exeter, Exeter, United Kingdom, <sup>23</sup>Clinical Research, Nevro Corp., Redwood City, United States of America, <sup>24</sup>Nevro Corp, Redwood City, United States of America, <sup>25</sup>Anesthesiology, Cleveland Clinic, Cleveland, OH, United States of America

**Introduction:** Globally, 422 million people are living with diabetes<sup>1</sup> and 20% will develop painful diabetic neuropathy (PDN),<sup>2</sup> a chronic pain condition that significantly impacts health-related quality of life (HRQoL). Neither pharmacological treatments nor low-frequency spinal cord stimulation (SCS) has provided long-term relief for PDN;<sup>3-6</sup> however, preliminary data suggest 10 kHz SCS may relieve pain and reverse sensory deficits from peripheral polyneuropathy.<sup>7</sup>

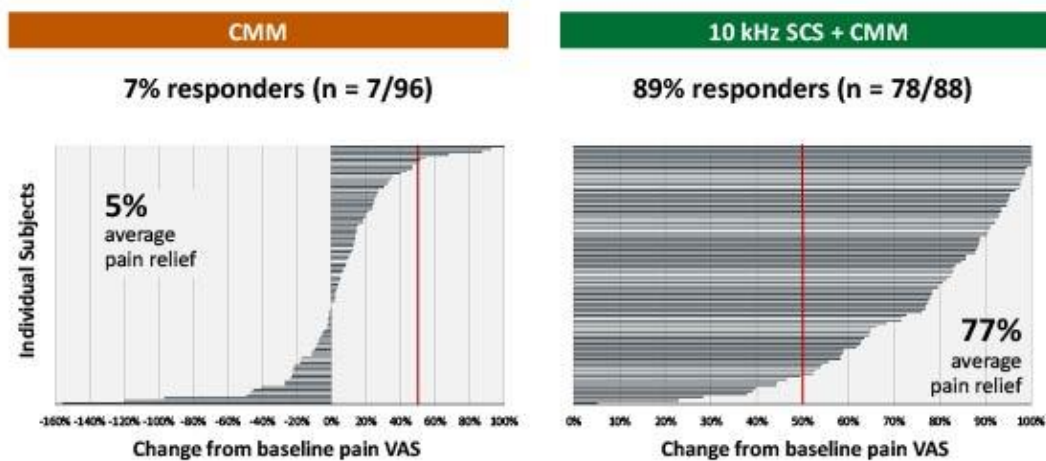
**Methods/Materials:** Prospective, multicenter, randomized controlled trial (SENZA-PDN) with 216 subjects assigned 1:1 to 10 kHz SCS (Nevro Corp.) combined with conventional medical management (CMM) or CMM alone. Key inclusion criteria: diagnosis of PDN with symptoms ≥12 months, lower limb pain intensity ≥5cm (on a 0-10cm visual analog scale [VAS]), and appropriate candidate for SCS. Key exclusion criteria: hemoglobin A1c >10%, daily opioid dosage >120mg morphine equivalents, and upper limb pain intensity ≥3cm. Primary endpoint compares responder and safety rates (≥50% pain relief without worsening baseline neurological deficit) between treatment groups at 3 months. Secondary endpoints include neurological function, HRQoL, sleep quality, patient satisfaction, and cost-effectiveness. Follow-up will last 24 months.

**Results:** Enrollment completed 2017-2019 with 430 candidates screened to randomize 113 subjects to 10 kHz SCS+CMM and 103 to CMM alone. Treatment arms well matched for baseline characteristics. There were no reported study-related adverse events (AEs) for CMM group and 19 study-related AEs reported in 10 kHz SCS+CMM group up to 3 months. Two were categorized as serious: an infection resolved with conservative care and a wound dehiscence resulting in explant prior to 3 months. There were 2 procedure-related infections in the 10 kHz SCS+CMM group (1.8%).

Fig 1 A

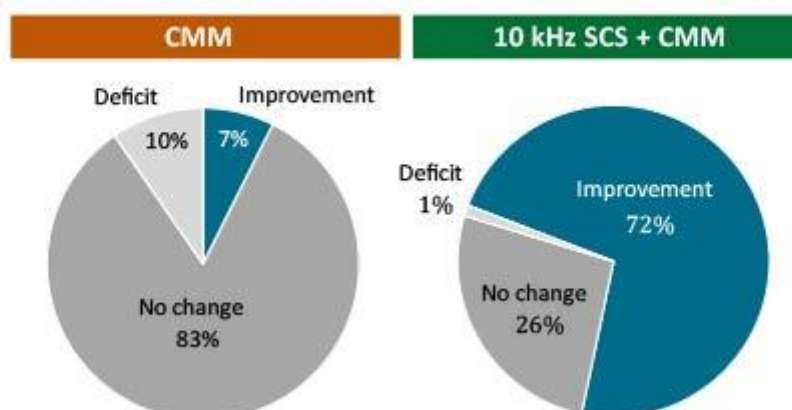


B



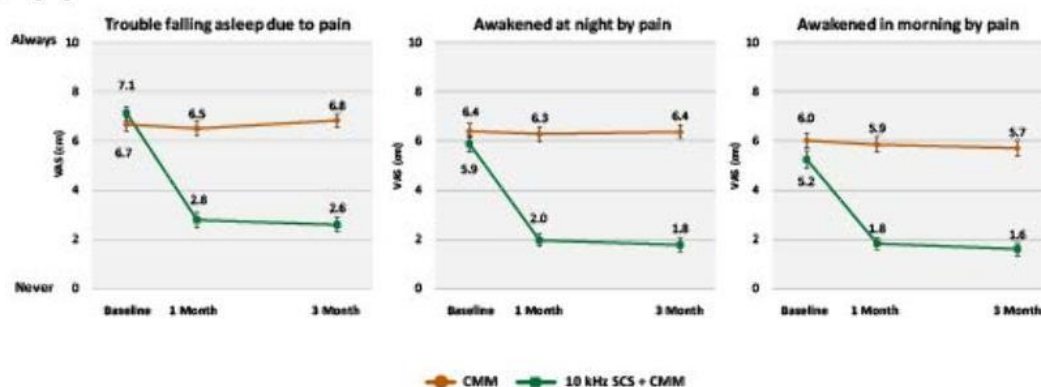
Per-protocol analysis revealed 5% of CMM and 86% of 10 kHz SCS+CMM subjects met the primary endpoint ( $p < 0.001$ ). At 3-month follow-up, there were differences in lower limb pain scores (Fig 1A), responder rates (Fig 1B), and Investigator-assessed sensory improvements (Fig 2). In addition, differences between treatment groups were observed across several HRQoL measures, such as sleep (Fig 3A) and global impression of change as rated by patient (Fig 3B) and clinician (Fig

**Fig 2** Investigator assessed sensory changes compared to baseline

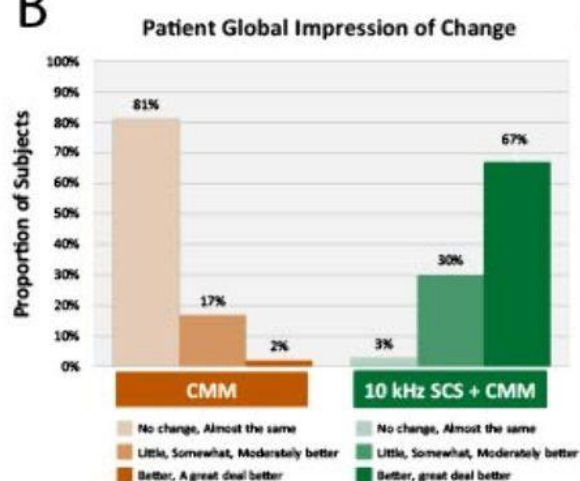


3C).

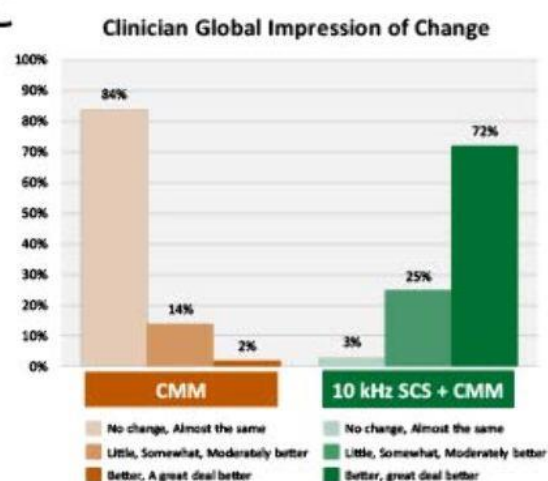
**Fig 3 A**



**B**



**C**



**Discussion:** Primary endpoint met with significant proportion of subjects responding to 10 kHz SCS. These early results are encouraging for PDN patients refractory to conventional care. Data collection continues with planned analyses for healthcare-related costs and long-term clinical utility.

**Conclusions:** SENZA-PDN is the largest RCT to-date of SCS management of PDN patients and will inform the place of 10 kHz SCS in the PDN treatment continuum.

**References:** 1. WHO Global Report on Diabetes 2016. 2. Schmader KE. Clin J Pain 2002 Nov-Dec;18(6):350-4. 3. ADA Position Statement of Diabetic Neuropathy. Diabetes Care 2017; 40:136-54. 4. van Beek M et al. Diabetes Care 2018; 41:32-38. 5. van Beek M et al. Diabetes Care 2015; 38:e132-134. 6. de Vos CC et al. Pain 2014; 155:2426-31. 7. Galan V et al. NANS 2020.

**Keywords:** 10 kHz SCS, painful diabetic neuropathy, PDN, Randomized Controlled Trial, RCT, Spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

**RESULTS FROM THE EVOKE DATA COLLECTION, SPINAL CORD STIMULATION USING EVOKE COMPOUND ACTION POTENTIALS AND CLOSED LOOP. PAIN CENTRE RIJNSTATE HOSPITAL, THE NETHERLANDS**

**E-POSTER VIEWING**

Caro Edelbroek, Jan Willem Kallewaard, Chris Terwiel, Rimke Snel  
Pain Centre, Rijnstate Hospital, Velp, Netherlands

**Introduction:** Spinal cord stimulation (SCS) has proven to be an effective therapy for chronic pain [1], [2]. Current SCS systems are fixed-output and do not account for changes in distance from the electrodes to the spinal cord caused by different postures and normal physiological processes in the body (e.g. breathing and heartbeat). Closed-loop (CL) SCS accounts for these changes by measuring the responses of the nerves elicited by electrical stimulation in the dorsal column[3]. These measured responses are called ECAPs (evoked compound action potentials). ECAPs are used to adjust and to maintain a constant recruitment of A $\beta$ -nerve fibres by constantly adjusting the stimulation output. With this a constant individualized preferred level of sensation and spinal cord activation is maintained. CL-SCS has proven to have superior pain relief over fixed-output SCS[4].

**Methods/Materials:** In this prospective data collection data is evaluated in a real world setting under normal clinical use.

The results from the first patients, will be presented. Data from baseline, 1 month, 3 months, 6 months and 12 months follow up. So far, 15 patients have reached their 1 month data point, 12 patients their 3 month data point, 5 their 6 month data point and 3 their 12 month data point.

All data is automatically stored in the implanted device and downloaded to a central database. The data and results are gathered between August 2019 and June 2021.

**Results:** The 15 patients started out with an average baseline pain score of 7.6 (6-9.6). At 1 month 80% of patients had a clinically relevant reduction in pain ( $\geq 50\%$  Pain Relief), at 3 months 75% of patients, at 6 months 100% of patients and at 12 months 66.7% of patients.

1 patient did experience no pain relief at all at the 1 month follow-up and was later explanted. At 1 month follow-up 13 out of 15 patients were programmed in CL. The patient who did not experience any pain relief was also programmed in CL. At the 1 month data point, 12 patients reported to be either satisfied or very satisfied and 3 patients reported to be quite satisfied. At the 3 month data point, 8 patients reported to be either satisfied or very satisfied, 3 patients reported to be quite satisfied and from 1 patient the data was not collected. At the 6 month data point, 4 patients reported to be either satisfied or very satisfied and from 1 patient the data was not collected. At the 12 month data point, 2 patients reported to be very satisfied and 1 patient reported to be quite unsatisfied.

**Discussion:** This summary of results is based on short term data and a small patient group. It can give a first impression and insight into this technique using CL and ECAP's to maintain a constant stimulation to improve patient satisfaction and optimize therapy outcome.

**Conclusions:** Early results for this small patient group shows that similar pain reduction levels are reached in a real world setting when compared to clinical studies with CL-SCS.

**References:** [1] P. Verrills, C. Sinclair, and A. Barnard, "A review of spinal cord stimulation systems for chronic pain," J. Pain Res., pp. 481–492, Jul. 2016.

[2] J. S. Grider et al., "Effectiveness of Spinal Cord Stimulation in Chronic Spinal Pain: A Systematic Review," Pain Physician, vol. 19, no. 1, pp. E33-54, Jan. 2016.

[3] M. Russo et al., "Effective Relief of Pain and Associated Symptoms With Closed-Loop Spinal Cord Stimulation System: Preliminary Results of the Avalon Study," Neuromodulation Technol. Neural Interface, vol. 21, no. 1, pp. 38–47, Jan. 2018, doi: 10.1111/ner.12684.

[4] N. Mekhail et al., "Long-term safety and efficacy of closed-loop spinal cord stimulation to treat

chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial," *Lancet Neurol.*, p. S1474442219304144, Dec. 2019, doi: 10.1016/S1474-4422(19)30414-4.

**Keyword:** chronic pain, spinal cord stimulation, Evoke compound action potentials, closed loop



**Topic:** 05. Spine / 05a. Pain

**AVALON STUDY: LONG-TERM IMPACT OF EVOKED COMPOUND ACTION POTENTIAL (ECAP)-CONTROLLED CLOSED-LOOP SPINAL CORD STIMULATION (CL-SCS) ON PAIN, PATIENT WELLBEING AND CLINICAL PRACTICE**

**E-POSTER VIEWING**

Marc Russo<sup>1</sup>, Charles Brooker<sup>2</sup>, Richard Sullivan<sup>3</sup>, Nathan Taylor<sup>2</sup>, Lewis Holford<sup>4</sup>, Tillman Boesel<sup>5</sup>, Gerrit Gmel<sup>6</sup>, Nastaran Shariati<sup>6</sup>, Lawrence Poree<sup>7</sup>, John Parker<sup>6</sup>

<sup>1</sup>Medical Director, Hunter Pain Specialists, Broadmeadow, Australia, <sup>2</sup>Pain Medicine, MJC Pain Management and Research Centre, Sydney, Australia, <sup>3</sup>Pain Medicine, Precision Brain, Spine and Pain Centre, Melbourne, Australia, <sup>4</sup>Pain Medicine, Northern Private Pain Centre, Sydney, Australia, <sup>5</sup>Pain Medicine, Inner West Pain Centre, Sydney, Australia, <sup>6</sup>-, Saluda Medical Pty Ltd, Sydney, Australia, <sup>7</sup>Anesthesiology And Pain Medicine, University of California at San Francisco, San Francisco, United States of America

**Introduction:** Closed-loop spinal cord stimulation (CL-SCS) has been shown to deliver high levels of pain relief in the first year of treatment. Here, we show how the maintenance of pain reduction with Evoked Compound Action Potential (ECAP)-controlled CL-SCS at the 24-month visit affects the patients' overall wellbeing as well as clinical practice through the reduction of the programming burden.

**Methods/Materials:** Fifty chronic pain patients were implanted with a CL-SCS system after a successful trial (ACTRN12615000713594). Patient ratings of pain (visual analogue scale [VAS] and Brief Pain Inventory [BPI]), function (Oswestry Disability Index [ODI]), sleep (Pittsburgh Sleep Quality Index [PSQI]), and quality of life (EuroQol instrument [EQ-5D-5L]) were collected at baseline and follow-up visits. Pain medications were monitored and adjusted per best clinical practice. In addition to study visits, patients were able to return to the clinic as needed (e.g. reprogramming).

**Results:** At 24 months, 34 of 38 (89.5%) patients experienced  $\geq 50\%$  reduction in overall VAS pain, and 68.4% had  $\geq 80\%$  reduction (Table). This represents a 15% increase in patients with  $\geq 80\%$  pain relief from 12 to 24 months. The sustained high-levels of pain relief led to clinically important improvements in QoL and BPI in  $\geq 80\%$  of patients. The number of patients with minimal or moderate disability increased from 18% (baseline) to 74.4% at 12 months and remained almost unchanged (75%) at 24 months. The improvements in sleep quality were maintained from 12 to 24 months. For patients that used opioids at baseline, an increasing number reduced or eliminated opioid intake over time (81.4% of patients at 24 months compared to 68.7% at 12 months). In these patients, Morphine Milligram Equivalents (MME/day) reduced from 62.9 MME/day at baseline to 32.1 at 12-months and 29.1 at 24 months. The clinical support required to maintain these outcomes steadily decreased over time, with projected annual visits decreasing from 6.24 to 0.72 3-months to 24-months, respectively.

**Discussion:** The outcome measures demonstrate large, clinically important improvements that are sustained or improved further out to 24 months. Opioid reduction continues over time while programming demand decreases steadily, resulting in patients requesting visits less than once a year.

**Conclusions:** Maintaining high levels of pain relief over an extended period provides profound and lasting improvements in patient wellbeing, with reduced need for supplementing pharmacotherapy. Coupled with a low programming burden in the long-term, CL-SCS is poised to become an important tool in treating chronic neuropathic pain.

**References:**

**Keywords:** Closed-Loop Spinal Cord Stimulation, neuropathic pain

**Topic:** 05. Spine / 05a. Pain

# **NEUROPATHIC PAIN MEDICATION USE IN 211 PATIENTS WITH FAILED BACK SURGERY SYNDROME TRIALED OR TREATED WITH SPINAL CORD STIMULATOR**

## **E-POSTER VIEWING**

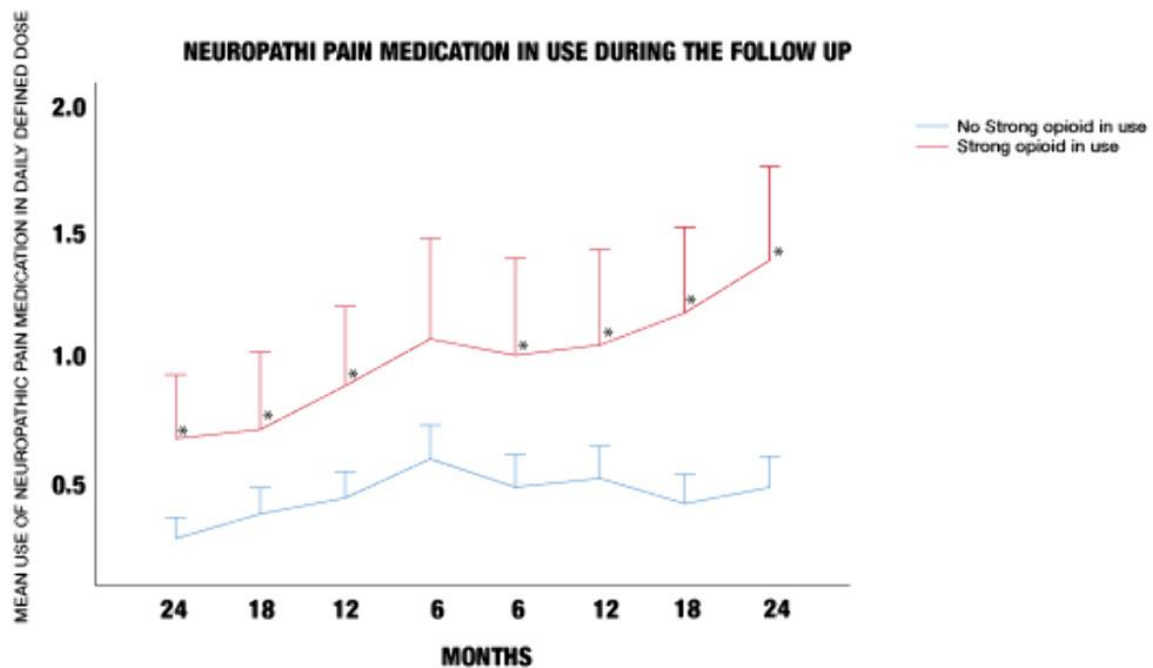
Mette Nissen, Mikael Von Und Zu Fraunberg, Jukka Huttunen  
Neurosurgery, Kuopio university hospital, Kuopio, Finland

**Introduction:** Failed back surgery syndrome (FBSS) is a challenging condition lacking curative treatment. Neuropathic pain medication is recommended as a first line treatment. Spinal cord stimulation (SCS)[1] has proven to be effective in selected patients refractory to medication [2].

**Methods/Materials:** Study group consists of all 211 patients who underwent SCS trial with a surgical lead between January 1, 1997 and March 31, 2014 in a single tertiary center. For each patient, 3 matched controls were selected. All purchases of prescribed neuropathic pain medication and opioids between January 1, 1995, and March 31, 2016, and their daily defined doses (DDD) were retrieved from nationwide registries. Continuous use was defined as two or more purchases during six months before SCS implantation. Patients were divided into three groups: 1) SCS trial only, 2) successful SCS, and 3) unsuccessful SCS, defined as explantation or revision due to inadequate pain relief. We analyzed neuropathic pain medication and opioid use during a period starting two years before SCS and ending two years after SCS implantation.

**Results:** After the one-week trial, permanent SCS was implanted in 164 (78%) patients. Of them 72 (43%) used neuropathic pain medication compared to 18 (38%) in trial group. Of 135 patients with successful SCS, 62 (46%) used neuropathic pain medication as compared to 10 of 29 patients (34%) with unsuccessful SCS. Mean DDD increased in all groups until implantation, but then it levelled off. Patients used neuropathic medication significantly more than controls (Table 1). Strong opioid use increased neuropathic medication dose significantly (Figure 1). Table 1. Neuropathic pain medication in DDD (mean±SD) ( \*p<0.001).

	2 years before
Trial only	0.2 (0.4)
Successful SCS (reference)	0.3 (0.7)
Unsuccessful SCS	0.4 (0.6)
Control	0.0 (0.0)*



**Discussion:** This is a retrospective study with all consecutive patients treated with SCS during the study period in our hospital. Neuropathic pain medication is likely to increase until interventional pain procedures. With successful SCS patients seem to be more able to reduce neuropathic pain medication. With all treatment groups, a strong opioid indicates an increase in neuropathic pain medication.

**Conclusions:** SCS patients with FBSS use more neuropathic pain medication than controls. Neuropathic pain medication can be stabilized or reduced with successful SCS. Neuropathic pain medication is almost doubled with combined strong opioid.

**References:** [1] Maher DP, Martins YC. Neuropathic Pain Medication Use Does Not Alter Outcomes of Spinal Cord Stimulation for Lower Extremity Pain. 2018;21:106–113. [2] North RB, Kidd DH. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. 2005;56:98–106.

**Keywords:** FBSS, neuropathic pain medication, opioid, SCS

**Topic:** 05. Spine / 05a. Pain

## **HIGH DENSITY SPINAL CORD STIMULATION FOR INTRACTABLE LUMBAR RADICULOPATHY ON VIRGIN-BACKS – UK SINGLE CENTRE INTERIM DATA .**

### **E-POSTER VIEWING**

Alia Ahmad, Kavita Poply, Serge Nikolic, Joanne Lascelles, Angie Alamgir, Richard Vangroningen, Habib Ellamushi, Vivek Mehta  
Pain Research Centre, Barts Health NHS Trust, London, United Kingdom

**Introduction:** Spinal cord stimulation (SCS) has been traditionally used for patients with failed back surgery syndrome (FBSS). Although National Institute for Health and Care Excellence (NICE) also recommends SCS for chronic neuropathic pain without previous back surgery<sup>1-2</sup>. Patients receiving SCS are often provided with tonic stimulation 40Hz, however newer methods include high-density stimulation (HD) that provides higher energy allowing the voltage to be reduced to subthreshold parameters, which minimizes tingling and paraesthesia sensation. HD stimulation is widely offered to patients with SCS as part of routine clinical practice, although there remains limited data on HD settings in patients with neuropathic pain without previous spinal surgery. We aim to investigate the clinical response and the effect on quality of life following SCS implant and High density programming in the virgin back population with chronic neuropathic pain.

**Methods/Materials:** This study is an open label, single-centre pilot study (Ethics 17/LO/0044, Registry NCT03716973). Patients with intractable neuropathic pain (n=20) due to undergo SCS with Medtronic RestoreSensor™ as part of their standard treatment are being recruited. Pain scores (Numerical Rating Score) and data from quality of life questionnaires will be collected pre-implant and at 4 weeks, 12 weeks and 12 months post-implant.

**Results:** Eighteen patients (17 Female, 1 Male) have been implanted with on-going follow-ups. At baseline, the average NRS for back and leg pain were  $7.64 \pm 1.29$  and  $6.15 \pm 2.10$  respectively. At 4 weeks post-implant, the average reduction in lower back pain is  $5.30 \pm 3.02$  (-30.63% vs. baseline) and  $3.04 \pm 2.54$  (-50.5% vs. baseline) for leg pain. At 3 months post implant average back pain reduction is  $2.8 \pm 3.39$  (-63.35% vs. baseline) and  $2.07 \pm 3.40$  (-66.34% vs. baseline). Whereas at 12-months post implant (n=12) the average back pain reduction was  $4.08 \pm 3.50$  (-46.6% vs. baseline) and  $3.36 \pm 2.99$  (-45.37% vs. baseline). Similarly, an improvement in ODI scores of an average  $31.76 \pm 18.69$  (41.89% vs. baseline) was seen at 4 weeks follow-up,  $31.99 \pm 20.87$  (57.09% vs. baseline) at 3 months and  $33.00 \pm 22.78$  (55.96% vs. baseline) at 12 months.

**Discussion:** Currently, the interim data of this study demonstrates High Density SCS may be an effective therapy to reduce back and leg pain in virgin back patients.

**Conclusions:** Interim data have shown promising results in terms of clinical efficacy and improvement in the quality of life. We envisage that High Density SCS may be an effective therapy to reduce back and leg pain in virgin back patients

**References:** 1. Cruccu G, Aziz TZ, Garcia-Larrea L, Hansson P, Jensen TS, Lefaucheur JP, Simpson BA, Taylor RS. EFNS guidelines on neurostimulation therapy for neuropathic pain. *Eur J Neurol* 2007;14:952–970. 2. NICE. (2008) Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. Available at: <https://www.nice.org.uk/Guidance/TA159>

**Keyword:** High density stimulation, neuropathic pain, spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

**10KHZ SPINAL CORD STIMULATION (10 KHZ SCS) FOR COMPLEX REGIONAL PAIN SYNDROME (CRPS): PRESENTATION OF CASE STUDIES**

**E-POSTER VIEWING**

Mayowa Owolabi, Bret Claxton, Sanjeeva Gupta, Rishi Khanna, Kyriacos Kyriakides, Anthony Swanepoel, Claire Kelly, David Chaloner  
Anaesthetic Department, Bradford Teaching Hospital Foundation Trust, Bradford, United Kingdom

**Introduction:** Complex regional pain syndrome (CRPS) is a debilitating, painful condition, associated with sensory, motor, autonomic, skin and bone abnormalities. This condition is often difficult to treat, and pain is typically the leading symptom. The Budapest Criteria also sets 4 categories of clinical signs and/or symptoms that are important for diagnosis of CRPS: sensory, vasomotor, sudomotor and motor. Specialist units treat patients with CRPS-specific rehabilitation techniques, advanced drug and interventional techniques, and SCS<sup>1</sup>. In this report, we present 3 retrospective cases of patients with CRPS symptoms treated with 10kHz SCS.

**Methods/Materials:** All 3 patients presented with previous CRPS diagnosis were considered for a 10kHz SCS trial. After successful trials, they were implanted with a permanent system.

**Results:** Case 1: After several meniscus surgeries, the patient developed burning knee pain and painful tingling which was graded an 8 in Numerical Rating Score (NRS, 0-10). These symptoms were accompanied by discoloration, allodynia, hyperalgesia and swelling of the knee. After trialling 10kHz SCS, pain reduced to an NRS of 3, and patient reported improvement in movement and sleep. In August 2018, the patient received a permanent implant and at the last visit reported 95% pain relief. Case 2: Patient was diagnosed with CPRS in 2001, complaining of right-hand pain, stiffness, swelling and discoloration. Amitriptyline and stellate ganglion block helped with the discoloration and swelling but increased the stiffness. A one-week trial of 10kHz SCS increased the grip strength from 11.8lbs to 29lbs and the Active Range of Movement (AROM) from an average of 40 degrees to 70 degrees during flexion. After permanent implant, these measurements continued to improve to 74lbs grip strength and 80 degrees flexion (AROM). Pictures 1 and 2 show the changes in discoloration and swelling pre and post 10kHz SCS.



Pre (left) and post (right) Case 3: Patient was diagnosed with CRPS of the knee in 2004, experienced

50% pain relief with low-frequency SCS but continued to report numbness and sharp pains. In 2018, she had a battery replacement to 10kHz SCS. Since then, she has reported a 65% improvement in pain, improvement in function and the numbness and the sharp pain have resolved.

**Discussion:** In this case series of 3 patients, 10kHz SCS has demonstrated effective treatment for Chronic Regional Pain Syndrome.

**Conclusions:** 10kHz SCS has demonstrated consistent pain relief and also alleviation of the common symptoms often associated with CRPS. This has led to motor and functional improvements in all 3 cases.

**References:** 1. Complex regional pain syndrome in adults, UK guidelines for diagnosis, referral and management in primary and secondary care, 2018, Royal College of Physicians

**Keyword:** Chronic Regional Pain Syndrome HF10 Neuropathic

## THE LEEDS TEACHING HOSPITALS TRUST EXPERIENCE OF HIGH FREQUENCY SPINAL CORD STIMULATION IN TREATING INDIVIDUALS WITH CHRONIC PAIN: A RETROSPECTIVE EVALUATION

### E-POSTER VIEWING

G. Baranidharan<sup>1</sup>, Beatrice Bretherton<sup>2</sup>, Tracey Crowther<sup>2</sup>, Nathan Marsh<sup>2</sup>, Thomas Kay<sup>2</sup>, Charlotte Romanis<sup>2</sup>, Bethan Roberts<sup>2</sup>

<sup>1</sup>Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom, <sup>2</sup>Pain Management, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom

**Introduction:** Since 1967, spinal cord stimulation (SCS) has been increasingly used in the treatment of chronic pain. In the UK, around 34,000 patients per year are implanted with a SCS, with approximately 180 of these being in the Leeds Teaching Hospitals NHS Trust (LTHT). Advancements in the technology of SCS have witnessed the development of different forms of stimulation, such as high frequency SCS. Unlike traditional SCS, this approach delivers stimulation at a high frequency (10 kHz), low pulse width (30  $\mu$ s) and reduced current amplitude (1-5 mA), relying on anatomical lead placement. This eliminates paraesthesia, therefore reducing the need for intraoperative paraesthesia mapping<sup>1</sup>. Most studies, typically prospective trials, have demonstrated that high frequency SCS is effective and safe<sup>2</sup>. In a novel study using real-world data, this study investigated the efficacy and complications associated with high frequency SCS in a teaching hospital.

**Methods/Materials:** This was a retrospective evaluation, with data collected from patients who received a high frequency SCS implant between 2013-present in LTHT. The following data were ascertained from hospital paper files and electronic records: gender, diagnosis, site of implant, implant date, age at implant, and the occurrence of revisions and explants. Baseline scores for neuropathic pain (via the SLANSS questionnaire) were recorded. Also, usual and worst pain (ascertained via visual analogue scales) and health-related quality of life (assessed by the EQ-5D questionnaire) were noted from initial and follow-up visits.

**Results:** The data are still being collected, with anticipation of a considerable dataset of around n = 400 patients by June 2020. Collated in a Microsoft Excel spreadsheet, the data will then be statistically analysed in SPSS (version 25). Descriptive statistics will explore initial characteristics and rate of revisions and explants. Repeated measure ANOVAs with Bonferroni pairwise comparisons (or Friedman tests for non-normally distributed data) will examine changes in pain and health-related quality of life scores. Finally, to examine the extent to which initial characteristics predict change following high frequency SCS therapy, linear regression modelling will be undertaken.

**Discussion:** An assessment of the initial characteristics will provide an indication of the possibility of identifying individuals from the outset who are likely to encounter benefits with this type of SCS.

**Conclusions:** It is hoped that by using real-world data, findings from this retrospective study will broaden insight into the clinical practice and effects of high frequency SCS in individuals with chronic pain.

**References:** Russo, M. and Van Buyten, J.P., 2015. 10-kHz high-frequency SCS therapy: a clinical summary. *Pain Medicine*, 16(5), pp.934-942. Verrills, P., Sinclair, C. and Barnard, A., 2016. A review of spinal cord stimulation systems for chronic pain. *Journal of Pain Research*, 9, pp.481-492.

**Keyword:** spinal cord stimulation, real world data, HF10



**Topic:** 05. Spine / 05a. Pain

## THE EFFECTS OF 10 KHZ SPINAL CORD STIMULATION IN PERSISTENT LOW BACK PAIN OF NEUROPATHIC ORIGIN: THE MAIDEN BACK STUDY

### E-POSTER VIEWING

G. Baranidharan<sup>1</sup>, Beatrice Bretherton<sup>2</sup>, Richard Feltbower<sup>2</sup>, Tracey Crowther<sup>2</sup>

<sup>1</sup>Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom, <sup>2</sup>Pain Management, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom

**Introduction:** Chronic back pain has negative effects on quality of life (QoL) and healthcare system spending. Spinal cord stimulation (SCS) appears to be an effective method for relieving chronic back pain in failed back surgery syndrome (FBSS). In this prospective, open label, pilot study, we explored the use of 10 kHz SCS in patients with allodynia and hyperalgesia.

**Methods/Materials:** Twenty-one non-surgical back pain subjects with hyperalgesia or allodynia underwent an SCS trial followed by full implantation. SCS comprised of administering electrical impulses epidurally at a frequency of 10 kHz and pulse width of 30  $\mu$ s. Subjects attended follow-up visits after 6 and 12 months of SCS. Repeated measure analysis of variance (ANOVA) and Friedman tests explored change after 6 and 12 months of 10 kHz SCS. Independent sample t-tests and Mann-Whitney U tests examined differences in response after 12 months of 10 kHz SCS.

**Results:** Back and leg pain, QoL and pain-related disability significantly improved following 6 and 12 months of 10 kHz SCS (see Table 1). Medication consumption stopped in 37% of cases with no increases reported. Over three-quarters (76%) of subjects encountered >30% improvement in their back pain between baseline and 12 months. Subjects in this group had significantly lower pain-related disability and significantly higher neuropathic pain scores at baseline compared to those who encountered <30% improvement in their back pain (see Table 2).

Table 1: Back and leg pain, QoL and pain-related disability at baseline and, 6 and 12 month follow-ups. VAS = visual analogue scale; ODI = Oswestry Disability Index. The alpha level was set to 0.05. \* = indicates a statistically significantly difference compared to baseline. Data are presented as the mean  $\pm$  1 SEM and 95% confidence interval.

	<b>Baseline</b>	<b>6 months</b>	<b>12 months</b>
Back pain (VAS in cm)	8.00 $\pm$ 0.25 (7.48, 8.52)	* 3.76 $\pm$ 0.67 (2.35, 5.16)	* 3.43 $\pm$ 0.63 (2.12, 4.73)
Leg pain (VAS in cm)	5.32 $\pm$ 0.70 (3.86, 6.79)	* 2.31 $\pm$ 0.62 (1.01, 3.62)	* 2.67 $\pm$ 0.68 (1.25, 4.09)
QoL (EQ-5D-5L)	0.32 $\pm$ 0.06 (0.20, 0.44)	* 0.60 $\pm$ 0.06 (0.48, 0.72)	* 0.58 $\pm$ 0.05 (0.48, 0.68)
Pain-related disability (ODI)	67.29 $\pm$ 2.76 (61.54, 73.04)	* 38.67 $\pm$ 4.67 (28.93, 48.40)	* 45.14 $\pm$ 4.65 (35.44, 54.84)

Table 2: Baseline neuropathic pain and pain-related disability significantly differed between the two groups. ODI = Oswestry Disability Index. The alpha level was set to 0.05. \* = indicates a statistically significantly difference compared to the <30% back pain improvement group. Data are presented as the mean  $\pm$  1 SEM and 95% confidence interval.

	<b>&lt;30% back pain improvement (n = 5)</b>	<b><math>\geq</math>30% back pain improvement (n = 16)</b>
Neuropathic pain (PainDETECT)	12.00 $\pm$ 3.21 (3.09, 20.91)	* 20.63 $\pm$ 1.76 (16.88, 24.37)
Pain-related disability (ODI)	77.60 $\pm$ 3.43 (68.08, 87.12)	* 64.06 $\pm$ 3.07 (57.53, 70.60)

**Discussion:** This is the first case series looking at using SCS for managing non operated back pain with neuropathic features.

**Conclusions:** 10 kHz SCS was an effective therapy for improving pain, QoL, pain-related disability and medication consumption in patients with non-surgical neuropathic back pain.

## References:

**Keyword:** Spinal Cord Stimulation, 10 kHz, Hyperalgesia, Allodynia, Non-surgical, Back pain

Topic: 05. Spine / 05a. Pain

## SINGLE CENTER EXPERIENCE WITH 10 KHZ SPINAL CORD STIMULATION (10 KHZ SCS)

### E-POSTER VIEWING

Mark Jackson

Pain Management, Royal Devon and Exeter hospital, Exeter, United Kingdom

**Introduction:** 10 kHz spinal cord stimulation (SCS) delivers paresthesia-independent, high frequency stimulation to the spinal cord by a system of leads and an implantable pulse generator (IPG). The aim of this analysis is to report the collective outcomes of all patients treated with 10 kHz SCS at Royal Devon and Exeter NHS Foundation Trust

**Methods/Materials:** We present retrospective data from 48 subjects with chronic neuropathic pain from a single center experience. Responder rates, functional outcomes, medication changes and sleep improvements are collected as per standard practice and were analyzed. Each subject was trialed with 10 kHz SCS, delivered through anatomically placed epidural percutaneous leads. Subjects with successful trial stimulation ( $\geq 50\%$  pain relief) received or are awaiting permanent implantation of a 10 kHz SCS system. Of this cohort, 38 subjects proceeded to implantation of 10 kHz SCS and 5 subjects are awaiting implantation following successful trial. Of those implanted, 2 were lost to follow-up and 4 subjects have been explanted with only 1 due to loss of efficacy.

**Results:** The average numerical rating scale (NRS) reduction for all trialed subjects was of 5.1 points (Figure 1). At last follow-up (mean: 14.2 months, range: 1.0-39.9), the responder rate was 93% (Figure 2). In addition, 31% of subjects reported reducing their pain medications. There has also been significant improvement in disability, 88% of subjects reported an improvement in functional ability and 81% of subjects reported sleep quality improvements.

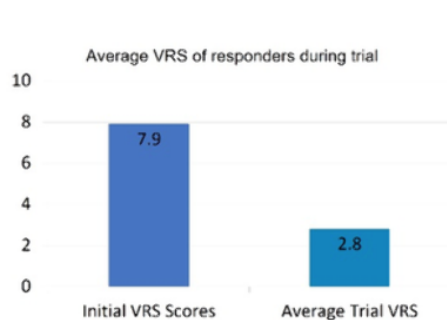


Figure 1- Baseline and end of trial NRS scores

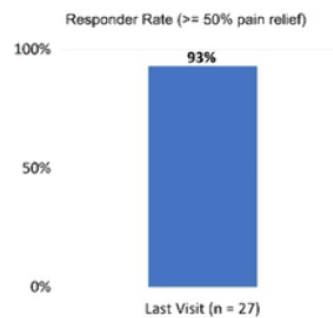


Figure 2- Responder rate at last follow-up visit

**Discussion:** In our centre, 10 kHz SCS is a safe and effective treatment, consistent and comparable with the published clinical trial results<sup>1</sup>. Subjects reported sustained long-term pain relief and an improvement in functional ability and sleep enhancement. Similar results were reported by other NHS trusts across UK

**Conclusions:** In our centre, 10 kHz SCS is a safe and effective treatment, consistent and comparable with the published clinical trial results<sup>1</sup>.

**References:** 1.Kapural, L et al. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial. Neurosurgery, (2016)

**Keyword:** Pain relief, 10kHz SCS, paresthesia-independent, high frequency

## DAYS OF SICK LEAVE AND DISABILITY PENSION ARE REDUCED FOLLOWING SPINAL CORD STIMULATION TREATMENT: A REAL-WORLD EVIDENCE STUDY CONDUCTED IN SWEDEN

### E-POSTER VIEWING

Emma Söreskog<sup>1,2</sup>, Terje Kirketeig<sup>3,4</sup>, Trolle Jacobson<sup>1</sup>, Rolf Karlsten<sup>3,5</sup>, Peter Fritzell<sup>6,7</sup>, Fredrik Borgström<sup>1,2</sup>

<sup>1</sup>Quantify Research, Quantify Research, Stockholm, Sweden, <sup>2</sup>Lime/mmc, Karolinska Institutet, Solna, Sweden, <sup>3</sup>Inst. Surgical Sciences, Uppsala University, Uppsala, Sweden, <sup>4</sup>Multidisciplinary Pain Center, Unit For Neuromodulation, Akademiska sjukhuset, Uppsala, Sweden, <sup>5</sup>Akademiska Sjukhuset, Akademiska sjukhuset, Uppsala, Sweden, <sup>6</sup>Futurum Academy, Futurum Academy, Jönköping, Sweden, <sup>7</sup>Ryggkirurgiskt Centrum, Ryggkirurgiskt Centrum, Stockholm, Sweden

**Introduction:** Current research indicates that spinal cord stimulation (SCS) has a positive short-term impact on outcomes such as quality of life, pain, and productivity. However, there is a need for studies on larger population samples. SWECOST is a database assembled using patient-level data from Swedish national registers, including; in- and outpatient care, drug dispensations, and socioeconomic data. The objective of this study was to analyze change and predictors of sick leave and disability pension two years pre- to post-SCS treatment.

**Methods/Materials:** Patients with permanent SCS were included, identified by procedure codes for SCS defining index date as the first implantation date. A control group from the general population was matched 5:1 to the cohort based on age, sex, and region of residence. Net sick insurance days (i.e. days on sick leave and disability pension) were calculated both two years pre- and post-treatment start. A difference-in-difference approach was used to compare the average change over time in net sick insurance days for the cohort, compared to the average change over time for the control group. Ordinary least-squares regression, including dummies for the time (pre- vs. post index), group (treatment vs. control), and a range of covariates, were used for the model.

**Results:** In total, 1080 SCS treated patients were included. The estimated mean number of net sick insurance days two years pre- and post-treatment in the SCS group was 136.4 days and 123.5 days, respectively. Corresponding estimates for the control group were 35.7 days and 36.3 days. The predicted mean difference in net days of sick leave and early retirement for SCS patients compared to controls was -14.5 days. Higher age (coef.=2.0, p<0.001) was associated with more sick insurance days as well as unemployment (coef.=81.0, p<0.001), high non-opioid (coef.= 23.2 to 44.2 depending on category, p<0.001) and opioid (coef.=12.5-31.6, p<0.05) usage. Higher education (coef.=-36.0 to -17.2 depending on the category, p<0.001) was associated with fewer days on sick insurance.

**Discussion:** The results imply that SCS reduces patients' need for sick leave up to two years after the procedure. This economic benefit needs to be considered, as well as the clinical, when evaluating the full societal value of SCS.

**Conclusions:** SCS leads to fewer days on sick insurance and socioeconomic factors seem to be relevant for the magnitude of the reduction.

### References:

**Keywords:** SCS, Spinal cord stimulation, Real-World Evidence, Sick leave and disability pension

**Topic:** 05. Spine / 05a. Pain

## **LONG TERM OUTCOME OF SPINAL CORD STIMULATION (SCS) AND PREGNANCY: A CASE SERIES**

### **E-POSTER VIEWING**

Giuliano Lo Bianco, Katie Netting, Simon Thomson

Pain Management And Neuromodulation, Basildon and Thurrock University Hospitals NHSFT, Orsett Hospital, Orsett, Grays, United Kingdom

**Introduction:** SCS is proven to be an effective remedy to control neuropathic pain in adults. However, SCS is not confirmed as safe and efficient in pregnancy, unborn fetus or delivery. SCS use among pregnant women has been limited.

**Methods/Materials:** We present a case series of 3 women diagnosed with complex regional pain syndrome (CRPS) and failed back surgery syndrome (FBSS) and referred to our Neuromodulation Centre. As combination treatment with physiotherapy, psychology, interventional procedures, and anti-neuropathic medication did not provide adequate analgesia, they were selected for SCS. Patient 1: developed CRPS of her right arm, scored as 8/10 on the Numeric Rating Scale Pain Intensity (NRSPI). Patient 2: diagnosed with (FBSS) in 2015 with back and legs pain NRSPI 9/10, after two spine surgeries in 2009. Patient 3: Diagnosed with post-surgical CRPS type 2 in her lower left limb, NRSPI 9/10.

**Results:** Patient 1: She was implanted in 2017, reporting NRSPI 2-3/10. She became pregnant in 2018 and used her SCS throughout her pregnancy with a continuous sub-perception program (SP-SCS). During labour she noted that the contractions felt less intense than her previous two labour experiences prior to SCS. She had a spontaneous vertex delivery of a healthy baby. She chose to breastfeed. Patient 2: She was implanted in 2015, reporting NRSPI 4/10. She was reviewed in 2020 reporting NRSPI 4/10. She carried two pregnancies in 2017 and 2019. She chose to continue to use the stimulator continuous SP-SCS throughout her pregnancies. She had no complications during pregnancy but had elective c-sections under general anaesthetic. She has two healthy children who were breastfed. Patient 3: She was implanted in 2013, reporting NRSPI 0/10. She was reviewed on February 2020 reporting NRS 0/10. She became pregnant in Sept 2015 and had a normal intrauterine pregnancy. She uses continuous PB\_SCS, even during labour. Her labour was to be induced but due to lack of progress, she had a caesarean section under general anaesthetic. She chose to breastfeed. The SCS did not reduce the pain of the contractions.

**Discussion:** All patients were counseled about the use of SCS and pregnancy but elected to use it. 2/3 patients needed re-programming after pregnancy with maintained good outcomes.

**Conclusions:** Safety of SCS has not been established in pregnancy, unborn fetus or delivery. We report 3 cases without complication.

**References:** Meagan J. Jozwiak MD\*; Hong Wu, MD, MS; Complex Regional Pain Syndrome Management: An Evaluation of the Risks and Benefits of Spinal Cord Stimulator Use in Pregnancy; World Institute of Pain, 1530-7085/18/\$15.00 Pain Practice, 2019 Ingrid C. Fedoroff, PhD\*, Ekin Blackwell, PhD\*, Louise Malysh, MSN\*, William N. McDonald, MD\*, Michael Boyd, MD; Spinal Cord Stimulation in Pregnancy: A Literature Review; Neuromodulation, DOI: 10.1111/j.1525-1403.2012.00448.x Caro Edelbroek, MANP; Michel Terheggen, MD; High-Frequency Spinal Cord Stimulation and Pregnancy: A Case Report; Neuromodulation ) DOI: 10.1111/ner.12314 Hyung Seok Yoo, MD, Francis Sahngun Nahm, MD, Kyoung Hoon Yim, MD†, Jee Youn Moon, MD\*, and Yung Suk Kim, MD\*, and Pyung Bok Lee, MD; Pregnancy in Woman with Spinal Cord Stimulator for Complex Regional Pain Syndrome: A Case Report and Review of the Literature; Korean J Pain 2010 December; Vol. 23, No. 4: 266-269 pISSN 2005-9159 eISSN 2093-0569 DOI : 10.3344/kjp.2010.23.4.266

**Keywords:** Spinal cord stimulation, pregnancy, Spinal cord stimulation in pregnancy, neuropathic pain, pregnant patient, SPINAL CORD STIMULATION AND PREGNANCY

**Topic:** 05. Spine / 05a. Pain

## THE ADDED VALUE OF INTRAOPERATIVE HYPNOSIS DURING SPINAL CORD STIMULATION UNDER AWAKE ANESTHESIA

### E-POSTER VIEWING

Chantal Wood<sup>1</sup>, Gaëlle Martiné<sup>1</sup>, Gaëlle Espagne Dubreuilh<sup>2</sup>, Karine Le Goff<sup>3</sup>, Pascaline Langlois<sup>4</sup>, Sandrine Baron<sup>4</sup>, Maxime Billot<sup>4</sup>, Philippe Rigoard<sup>1</sup>

<sup>1</sup>Spine & Neuromodulation Functional Unit, Poitiers University Hospital, Poitiers, France, <sup>2</sup>Pain Center, Limoges University Hospital, Limoges, France, <sup>3</sup>87, CHU Dupuytren - Chronic Pain Center, Limoges, France, <sup>4</sup>Prismatics, Hospital University of Poitiers, Poitiers, France

**Introduction:** Aiming to improve pain relief for refractory pain condition, SCS needs to target the dedicated neuronal fibers within the dorsal columns. Intraoperative feedback from the patient can optimize lead placement but requires an “awake surgery”, allowing interaction between patient and surgeon. This can produce negative effects like anxiety and stress. To better manage these aspects, we proposed to combine intraoperative hypnosis with awake anesthesia. The goal of this study was to assess the impact of intraoperative hypnosis during spinal cord stimulation (SCS) under awake anesthesia.

**Methods/Materials:** Seventy four patients (35 females, 39 males, aged between 32 and 78 years) presenting with chronic refractory pain, were offered intraoperative hypnosis during awake SCS lead implantation between 2016 and 2020. A Minimally Invasive Access Spine Technology (MAST) approach was used for 34 cases implanted with a surgical lead. Percutaneous lead(s) was (were) implanted in 40 cases. All patients were seen by the hypnotherapist (H) before the procedure. Hypnosis was described as a moment of focalized attention. Explanations were given about the surgical procedure and the importance of patient cooperation during the lead intraoperative programming. An experiential method using a graphite pencil was used to highlight the importance of the interaction with H. Patients were also trained with the “glove analgesia” technique. Interactive conversational hypnosis was used as well as interactive touch, which was enhanced during painful moments. All patients were congratulated at the end of the surgery to reinforce the positive memory of the surgical procedure and make them realize that they were full of resources.

**Results:** All patients participated actively during the intra-operative testing which helped to optimize the lead positioning. They kept an extremely positive memory of the surgery and of the hypnotic experience, despite some painful moments.

**Discussion:** Pain could be reduced in these patients by using interactions and touch, which works on Gate Control modulation. Positive memory was reinforced by congratulations, not only to create self-confidence but also to induce positive expectations, which could reinforce the Diffuse Noxious Inhibitory Controls at the spinal level. Cooperation was improved because the patient was actively participating and thus, much more alert when feedback was required.

**Conclusions:** Combining intra-operative hypnosis with awake anesthesia appears helpful for SCS lead implantation. It enhances patient cooperation, allows optimization of lead positioning, leads to better pain control, positive and resourceful memory.

### References:

**Keywords:** hypnosis, awake anesthesia, intraoperative, Spinal cord stimulation



**Topic:** 05. Spine / 05a. Pain

**A PROSPECTIVE AUDIT LOOKING AT PATIENTS IMPLANTED WITH SPINAL CORD STIMULATOR (SCS) EITHER USING IMPLANTED PULSE GENERATOR (IPG) AT SUPRAGLUTTEAL OR PARAVERTEBRAL SITE**

**E-POSTER VIEWING**

Angela Harris, Kathryn Wilford, Alison Cox, Joanne Dunwoodie, Jennifer Preston, Mark Draper, Rajiv Chawla, Manohar Sharma  
Pain And Neuromodulation, The Walton Centre, Liverpool, United Kingdom

**Introduction:** SCS are indicated for chronic pain conditions. To evaluate the efficacy and complications of IPG placement a prospective audit of 40 patients was conducted. Patients with history of chronic neuropathic pain that had failed conservative medical management. It is local practice to implant IPGs in the supra-gluteal region when undergoing permanent implantation of SCS. This approach requires additional tissue handling involved in tunnelling the leads to IPG. The aim was to evaluate overall incidence and extent of post-surgical pain related to implantation in patients with IPG implanted paravertebral compared to supragluteal using one incision instead of two.

**Methods/Materials:** Patients implanted with SCS during a 12 month period were audited. Subgroups were Failed back surgery syndrome (FBSS), Complex regional pain syndrome (CRPS), Lower Back and Limb pain. Data was collected from patients' casenotes, appointments and telephone discussion. A standardised data collection form was used. Primary outcome measures was obtained using the numerical rating score (NRS 0-10). Follow up was at 1, 6 and 12 months. Complications relating to IPG were collected. A total of 40 (n=40) patients; female 60% (N=24) male 40% (N=16) were implanted paravertebral 57.5% (N=23) and supragluteal 42.5% (N=17).

**Results:** 35.2% (n=6) of supragluteal patients' data is yet to be completed due to not finishing 12 months FU. At one month 30.4% (N=7) of paravertebral patients and 29.4% (N=5) of supragluteal patients reported pain that was equal to or more than their original pain. At 6 months, 30.4% (N=7) paravertebral and 11.7% (N=2) supragluteal reported pain. At 12 months, 4.3% (N=1) paravertebral and 0% (N=0) supragluteal reported pain. Average pain scores ranged from 4-10. One IPG repositioned from paravertebral to supragluteal at 3 months post, one paravertebral patient had lead revision at 12 months post and one paravertebral patient was explanted at 6 months due to IPG site pain.

**Discussion:** Pain at IPG site according to position is not commonly recorded and is not possible to determine if implant sites are associated with more pain than others; however, IPG site selection may influence patient satisfaction due to IPG pain, factors for consideration would be weight, age, medication usage.

**Conclusions:** There is no difference between the groups for pain at one year and accepting limitations of audit; patients should be offered option of implanting IPG either at supragluteal or paravertebral if appropriate. We believe paravertebral IPG implantation to be better since it is less invasive and thus may have advantages for patients who have lower back pain.

**References:**

**Keywords:** Spinal Cord Stimulator, Internal pulse generator

**Topic:** 05. Spine / 05a. Pain

## **DRG AND NON-LINEAR BURST THERAPY SUCCESSFULLY IMPROVE PSYCHOSOCIAL FUNCTION AND RESTORE PAIN RELIEF: PROLONG STUDY**

### **E-POSTER VIEWING**

Marie Fahey<sup>1</sup>, Corey Hunter<sup>2</sup>, Krishnan Chakravarthy<sup>3</sup>, Timothy Deer<sup>4</sup>, Steven Falowski<sup>5</sup>, Jason Pope<sup>6</sup>

<sup>1</sup>Clinical Science, Abbott, Austin, United States of America, <sup>2</sup>Pain Management, Ainsworth Institute of Pain Management, New York, NY, United States of America, <sup>3</sup>San Diego Health System, University of California, San Diego, San Diego, United States of America, <sup>4</sup>Pain Services, Spine & Nerve Center of the Virginias, Charleston, United States of America, <sup>5</sup>Neurological Surgery, Functional Neurosurgery, Neurosurgical Associates of Lancaster, Lancaster, PA, United States of America, <sup>6</sup>Pain Medicine, Evolve Restorative Center, Santa Rosa, United States of America

**Introduction:** Spinal cord stimulation (SCS) has been shown to effectively relieve intractable chronic pain. However, a portion of patients who initially succeed with SCS will eventually lose their therapeutic benefit. The non-linear burst waveform offers a unique mechanism of action that can potentially restore efficacy where other stimulation therapies have failed. While all forms of SCS activate the lateral pain pathway, which is responsible for the sensory aspects of pain, only burst has been shown to activate the medial pain pathway which is responsible for the affective components. It is this medial activation that may allow burst to succeed and show improvement across psychological factors such as catastrophizing and depression. Targeting the dorsal root ganglion (DRG) is highly effective when treating focal pain areas and is an additional replacement therapy for failed SCS patients. The PROLONG study (NCT039088476) prospectively observes subjects who utilize neurostimulation devices that deliver non-linear burst or stimulate the DRG after failing to sustain pain relief with their previous SCS system. We present data on the methods implemented to provide non-linear burst therapy along with 3-month follow-up data for a range of patient reported outcomes.

**Methods/Materials:** This is a multi-center, open-label, post-market study. Subjects enrolled have a SCS system failing to provide pain relief. It has been determined that the subject is still a candidate for neurostimulation, not suffering from a new pain complaint outside of the original treatment area and the current system is not malfunctioning or damaged. Data for NRS, PROMIS-29, PCS and PVAQ are collected at each follow-up visit to address improvements in both lateral and medial pain pathways.

**Results:** Enrollment for this study has completed. Full system replacements (leads and IPG) account for 50% of the current enrollments. A further 50% represent IPG changes using available adaptors or accessories for other commercial devices. Follow-up data at 3-months has been collected for 50 subjects; 20 have 6-month outcomes. We present outcomes for the medial pain pathway (PCS and PVAQ), pain scores, and PROMIS-29.

**Discussion:** Interim data shows improvements in pain intensity and interference in daily life, physical function and social participation. Catastrophizing (PCS) is reduced in subjects undergoing burst therapy.

**Conclusions:** Burst SCS and DRG therapies can restore sustained pain relief to a patient population reporting eventual failure of other SCS therapies. In addition, burst therapy is associated with improved measures of the medial pain pathway.

### **References:**

**Keywords:** DRG, non-linear burst therapy, functional and psychosocial outcomes, chronic pain, salvage

**Topic:** 05. Spine / 05a. Pain

## **L5 DRG POCKET AND MIDDLE POCKET PLANNING.**

### **E-POSTER VIEWING**

Isaac Peña Vergara, Lucia Ángel, Yolanda Camacho, Gloria Casado  
Anestesiología Y Reanimación, HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO, SEVILLA, Spain

**Introduction:** DRG implantation lead technique has specific considerations in designing pocket and middle pocket for trial period.

**Methods/Materials:** More than 20 patients has been implanted with a DRG Lead (Abbott Medical) in L5 root. An 'on table' pre-implantation design is recommended in order to clarify an appropriate approach, anchoring, extension pocket or middle pocket and extension lead exit point. L5 lead implantation has a specific consideration due to a small anatomical area to perform every single step. In our practice, more than 150 cases, we avoid any kind of anchoring for breakage reasons. A double subcutaneous loop seems to be enough for avoiding lead migration. Lead should be linked to a extension lead for trial period and that's why a middle small pocket must be perform. This middle pocket or extension pocket is a tricky point in L5 lead cases. After several designs our final decision was to perform the middle pocket where the IPG pocket will be perform after 2 to 4 weeks later. Far from what it may seem, no pocket or IPG infection has taken place.

**Results:** After more than 20 cases this design could be an optimal option to plan L5 DRG Lead implantation. A middle pocket properly performed should be considered for an IPG pocket. None infection, explantation nor other postsurgical events has been registered. Every patient has followed a standart surgical wound healig protocol by nursery. No other specific consideration has been taken. Self-care and wash-up recommendation have been standart for SCS nursery care.

**Discussion:** DRG L5 lead implantation has a difficult pocket design in trial period.

**Conclusions:** Following a appropriate wound healing protocol and postsurgical care, there's no incidences by using middle pocket as a IPG pocket after 2 to 4 weeks trial period.

### **References:**

**Keywords:** Pain, Pocket, DRG, L5, neuropathic pain

## THE IMPORTANCE OF PATIENT SELECTION BEFORE SCS IMPLANTATION

### E-POSTER VIEWING

Cristina Abad, Alberto Rios, Eva Monzon, Alba Vivas, Miriam Perez, Natalia Valencia, David Abejon, Sonia Sosa  
Pain Unit, Hospital Quiron Salud, Madrid, Spain

**Introduction:** In our practice, we always refer all candidates to SCS therapy to the pain unit's psychologist prior to making the final decision on the therapeutic option. But this practice is not universal, mostly because lack of resources and unawareness of the great importance of the psychology assessment when deciding to attempt SCS therapy. Psychologic evaluation includes several test such as Beck Depression Index (BDI), the State-Trait Anxiety Inventory (STAI), Pain Catastrophizing Scale (PCS), The 10-item Connor-Davidson Resilience Scale (CD-RISC), the Structured Inventory of Malingered Symptomatology (SIMS), and the Duke-UNC Functional Social Support Questionnaire. After an exhaustive evaluation a decision is made weather or not to proceed with SCS implantation.

**Methods/Materials:** We collected our patient data in order to ratify the literature evidence applied to the specific environment of our hospital. We reduced the number of variables only including patients implanted with the same device (Boston's Spectra Wave writer) in the last 3 years. It is an observational retrospective study. The reasons of using SCS therapy in this patients were Failed Back Syndrome, Complex Regional Pain and Dorsal Pain (the majority were FBSS).

**Results:** In our sample the success rate of the SCS therapy was 92,3%. Only in 1 case the therapy was unsuccessful. This results are consistent with previous findings in the literature and indicate that our patient selection is adequate.

**Discussion:** It is well known that 50 to 80% of patients with chronic pain have signs of psychopathology, highlighting the psychological evaluation as vital to those patients under consideration for SCS therapy. Patients with psychiatric comorbidities, more often depression, anxiety and catastrophic thinking in these patients, have poor response to treatment. It is common practice to have psychological evaluations of the patients before implantation. Patients who have drug-related problems, abnormal illness behavior and have unresolved secondary gain issues are denied the treatment. Other psychological factors, such as anxiety and depression, have been related to poor outcome of the SCS, but are not usually included in the algorithm to assess which candidates should proceed to the implantation of the SCS and which not.

**Conclusions:** In conclusion psychology evaluation prior to attempting SCS therapy is a must in order to achieve the best success rates, taking into account the high cost of SCS therapy devices. We hope that our excellent results obtained when using psychologic evaluation help to raise awareness of the great importance of having best patient selection to avoid unnecessary costs of failed therapies.

**References:** E. Gallach-Solano, M. A. Canós-Verdecho et M. Morales Suárez-Varela. Protocolo psicológico para la evaluación de candidatos a implante de neuroestimulador. Rev Soc Esp Dolor 2016; 23(6): 307-315

**Keyword:** psychologic, patient selection, SCS, depression

**Topic:** 05. Spine / 05a. Pain

## DRG LEAD SURGICAL IMPLANTATION. TECHNICAL NOTE

### E-POSTER VIEWING

Paloma Cancela<sup>1</sup>, Isaac Peña Vergara<sup>2</sup>, Gloria Casado<sup>2</sup>

<sup>1</sup>Neurosurgery, HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO, SEVILLA, Spain, <sup>2</sup>Anestesiología Y Reanimación, HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO, SEVILLA, Spain

**Introduction:** DRG lead migration is one of the most important complication in this therapy. Most cases are resolved with a percutaneous reimplantation using classic technique and a sheath managing. However some cases are extremely difficult to perform a new percutaneous reimplantation by a classic approach. Those cases are candidates for an open surgical approach.

**Methods/Materials:** 5 lumbar cases have been performed by a classic laminectomy microscopy supported, DRG lead are implanted through the neuroforamina above the dorsal aspect of the root. L1 epidural catheter local anesthetics technique have been performed in every case, under a midazolam standard sedation for an awake surgery. Many kinds of anchoring have been performed. But fascial anchoring has shown as the best option. L5 - Foot - 3 cases L3 - Knee - 1 case L1 - Groin - 1 case

**Results:** 4 out of 5 cases have been successfully implanted with a really right paresthesia coverage. L5 - Foot - 3 cases - 1 case failed L3 - Knee - 1 case L1 - Groin - 1 case After 6 months postsurgical, DRG stimulation remains as good as after surgery and before lead migration. No postsurgical complications have been recorded.

**Discussion:** Surgical technique should be an alternative in referral center for difficult cases due to migration, fibrosis, or other reason which avoid a classic approach.

**Conclusions:** Surgical technique should be an alternative in referral center for difficult cases due to migration, fibrosis, or other reason which avoid a classic approach. Neurosurgery department is a mandatory partner for Pain Unit to manage those cases. Collaboration in technique development should be basic.

### References:

**Keywords:** laminectomy, microsurgery, DRG, Surgical, Fibrosis, reimplantation

EPV131 / #325

Topic: 05. Spine / 05a. Pain

## EPIDURAL RETROGRADED IMPLANT FOR THE REPLACEMENT OF A FRACTURED DRG LEAD

### E-POSTER VIEWING

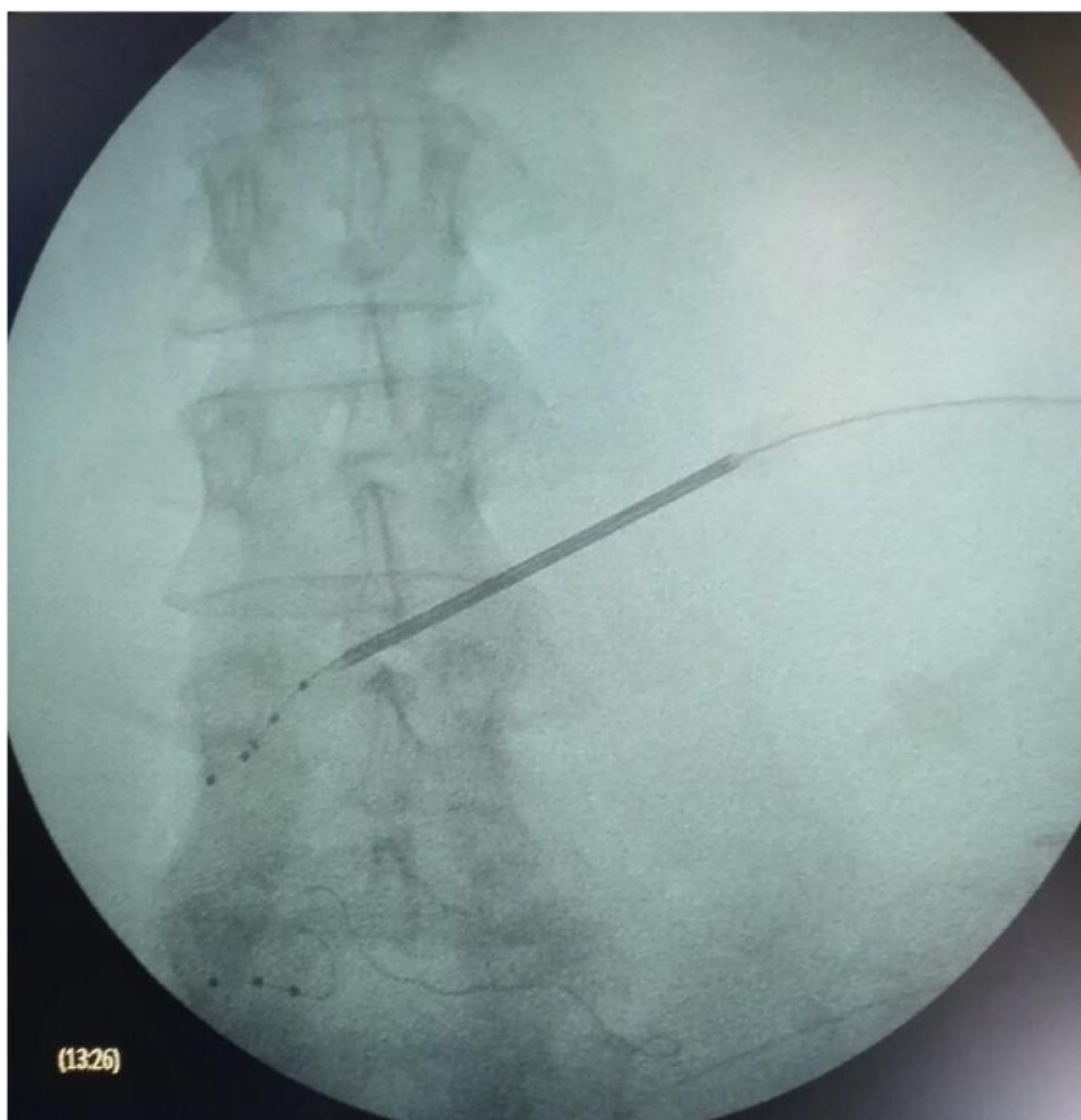
Antonio Pajuelo, Maria Auxiliadora Cormane  
Anesthesia, HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO, SEVILLE, Spain

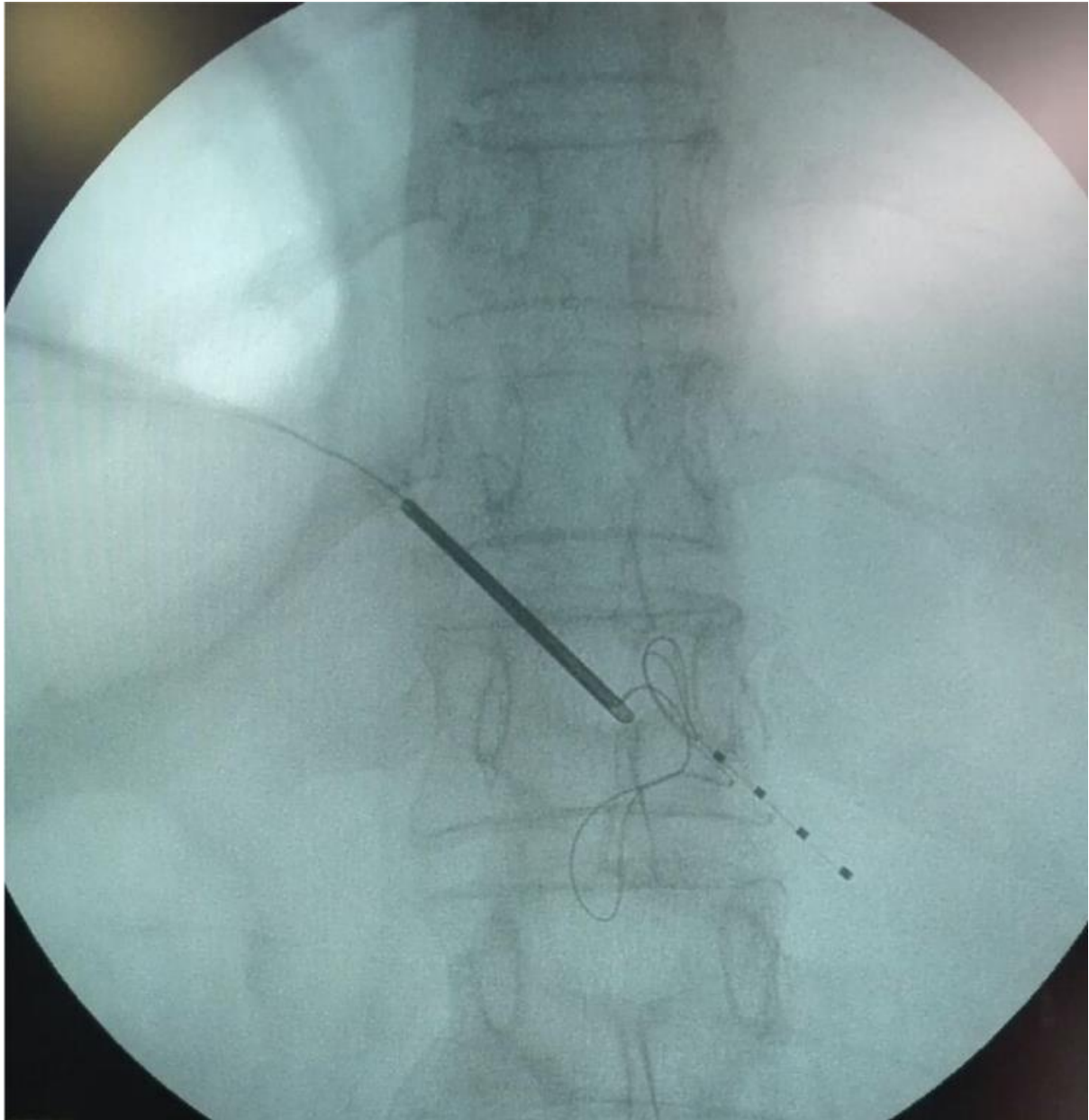
**Introduction:** The invaluable contribution of the stimulation of the dorsal root ganglion to the treatment of neuropathic pain and to the pictures of Complex Pain Syndrome based on its initial efficacy and subsequently sustained over time<sup>1</sup>, forces us to propose the obligatory replacement of it after a break or malfunction

**Methods/Materials:** We present two cases of retrograde replacement of a dorsal root ganglion stimulation electrode that were initially introduced with the standard technique (tip on tip) 2 in two patients with severe refractory neuropathic pain. One patient with right inguinodynia after repair surgery for inguinal hernia with electrode at the left L1 level and another patient with pain from the post-surgical abdominal wall (abdominal caesarean section) with DRG electrode at the left T12 level. The effective stimulation time to breakage was respectively 23 and 30 months respectively.

**Results:** After a “classic” implant attempt (with tip on tip technique) 2, the electrode was retrogradely introduced from a higher level in a contralateral way (see images) that led to a correct position of the new DRG electrode and restored to successful therapy.

**Discussion:** After a “classic” implant attempt (with tip on tip technique) 2, the electrode was retrogradely introduced from a higher level in a contralateral way (see images) that led to a correct position of the new DRG electrode and restored to successful therapy..





**Conclusions:** In conclusion, and according to other recent retrograde introduction publications<sup>3,4</sup>, this implant technique could be considered in the future not only as a form of replacement of a malfunctioning electrode but also to be considered as a first choice in certain circumstances of difficulty in the traditional approach.

**References:** 1.- Levy R. et al: Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Type I and II. J Pain. 2019 Sep 5 2.- Vancamp T., Levy R.M., Pena I., Pajuelo A. Relevant Anatomy, Morphology, and Implantation Techniques of the Dorsal Root Ganglia at the Lumbar Levels. Neuromodulation 2017; E-pub ahead of print. DOI:10.1111/ner.12651 3.- Kenneth B. Chapman; Ryan R. Ramsook; Pauline S. Groenen; Kris C. Vissers; Noud van Helmond: Lumbar Transgrade Dorsal Root Ganglion Stimulation Lead Placement in Patients with Post-Surgical Anatomical Changes: A Technical Note. Pain Practice 2019

**Keyword:** dorsal root ganglion, retrograde



**Topic:** 05. Spine / 05a. Pain

## **LONG TRIAL PERIOD WITH FOUR PARADIGMS OF SPINAL CORD STIMULATION FOR CHRONIC PAIN: PRELIMINARY EXPERIENCE**

### **E-POSTER VIEWING**

Manuela D'Ercole, Alessandro Izzo, Filomena Fuggetta, Beatrice Cioni, Tommaso Tufo  
Neurochirurgia, Policlinico A. Gemelli, Roma, Italy

**Introduction:** Spinal cord stimulation (SCS) paradigms, with tonic 80Hz frequency, Burst, high density (HD) and high frequency (HF), have indication for treatment of chronic pain. These new modalities are usually free of paresthesia in the target pain area, unlike conventional tonic stimulation, and, at least HF and burst stimulation, seem to provide a better coverage of axial lower back pain. Trial is essential to provide a proof of efficacy of this therapy. There are no studies with long trial period comparing all these paradigms

**Methods/Materials:** 27 patients (M: 9; F: 18, median age 62 years) affected by chronic neuropathic pain underwent percutaneous placement of epidural octopolar electrode in cervical or thoracic spine for a trial period of 4 to 7 weeks. 21 patients were affected by failed back surgery syndrome (FBSS), 3 by postsurgical pelvic pain, 2 following deafferentation of brachial plexus and 1 after ponto-mesencephalic stroke. Each patient underwent preliminary selection according to clinical features and specific questionnaires: PCS, ODI, SF-36, Hamilton, EQ-5D. During trial period each patient was submitted to all different paradigms of stimulation (tonic, burst, HD and HF), in random order, over a span of 3-7 days. Each patient underwent subjective evaluation of pain according to visual analogic scale (VAS) before implant and after each period of stimulation

**Results:** Following the trial period 21 patients (75%) with a significant clinical effect (63% of reduction in VAS score on average) underwent permanent stimulator implantation. The pattern of stimulation was chosen according to clinical response in trial phase: tonic in 9 patients (43%), burst in 5 (24%), HF in 5 (24%) e HD in 2 (9%)

**Discussion:** Introduction of different paradigms of spinal cord stimulation can extend the spectrum of responsive patients; in our preliminary experience, in fact, 12 patients not responsive to classic tonic stimulation, experienced satisfactory pain relief by other patterns of stimulation and underwent permanent stimulator implantation, being the 57% of the group of patient implanted.

**Conclusions:** Based on this evidence we believe that each patient should be tested according to various patterns of stimulation in the trial period in order to assess the modality of stimulation that better fits with the pain. Further investigations are necessary in order to predict the better pattern of stimulation for each kind of patient.

### **References:**

**Keywords:** tonic stimulation, Pain, FBSS, scs trial, HF stimulation, burst stimulation

EPV133 / #328

**Topic:** 05. Spine / 05a. Pain

## EXTERNAL PERCUTANEOUS IMPLANT OF A DRG ELECTRODE AT L5 LEVEL

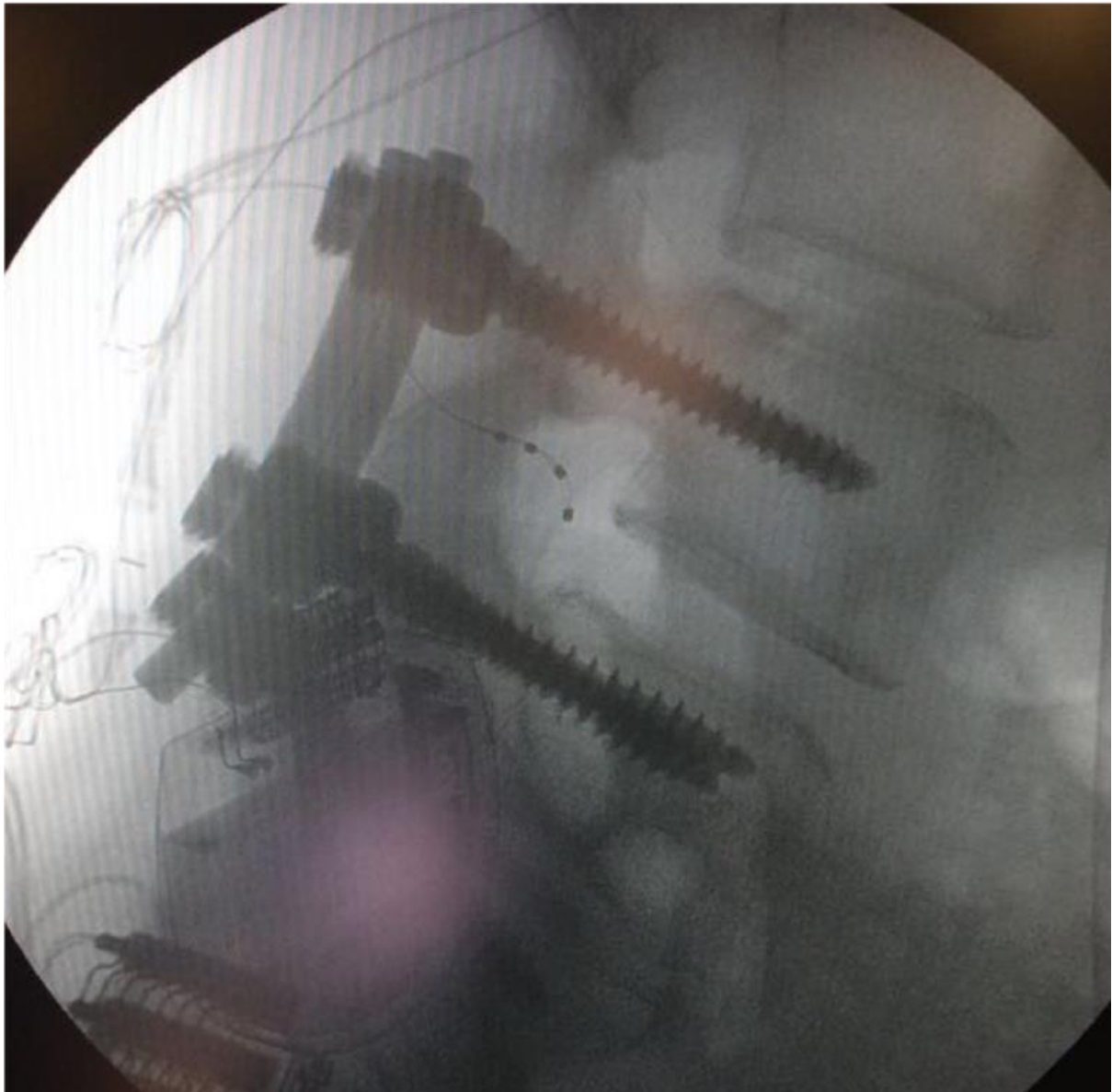
### E-POSTER VIEWING

Antonio Pajuelo, Maria Auxiliadora Cormane  
Anesthesia, HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO, SEVILLE, Spain

**Introduction:** The invaluable contribution of the stimulation of the dorsal root ganglion due to its initial efficacy and its support over time<sup>1</sup>, makes it necessary to propose alternative access routes to the dorsal root ganglion as an alternative to an inaccessible epidural pathway.

**Methods/Materials:** Percutaneous lateral access to the left L5 foramen is presented in a patient with repeated postlaminectomy neuropathy that presented a left L5 neuropathy that had been refractory to standard spinal stimulation and that after external percutaneous access (see images) adequate stimulation both in coverage and analgesic efficacy.





**Results:** This exceptional route can be contemplated in the future not only as an alternative route for difficult access by epidural route according to the classical technique (tip on tip)<sup>2</sup> but also as a novel way to study from the point of view of additional efficacy in certain cases of focused neuropathic pain. It could also be considered as an alternative route to a microsurgical access<sup>3</sup> that could be placed in an intermediate route of surgical aggressiveness.

**Discussion:** This exceptional route can be contemplated in the future not only as an alternative route for difficult access by epidural route according to the classical technique (tip on tip)<sup>2</sup> but also as a novel way to study from the point of view of additional efficacy in certain cases of focused neuropathic pain.

**Conclusions:** It could also be considered as an alternative route to a microsurgical access<sup>3</sup> that could be placed in an intermediate route of surgical aggressiveness.

**References:** 1.- Levy R. et al: Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Type I and II. J Pain. 2019 Sep 5 2.- Vancamp T., Levy R.M., Pena I., Pajuelo A. Relevant Anatomy, Morphology, and Implantation Techniques of the Dorsal Root Ganglia at the Lumbar Levels. Neuromodulation 2017; E-pub ahead of print. DOI:10.1111/ner.12651 3.- Piedade G.S., Cornelius J.F., Chatzikalfas A., Vesper

J., Slotty P.J. 2019. Open Microsurgical Dorsal Root Ganglion Lead Placement. *Neuromodulation* 2019; 22: 956–959

**Keyword:** dorsal root ganglion, external approach

EPV134 / #329

**Topic:** 05. Spine / 05a. Pain

## STIMULATION OF THE DORSAL ROOT GANGLY AT SACRAL LEVEL.

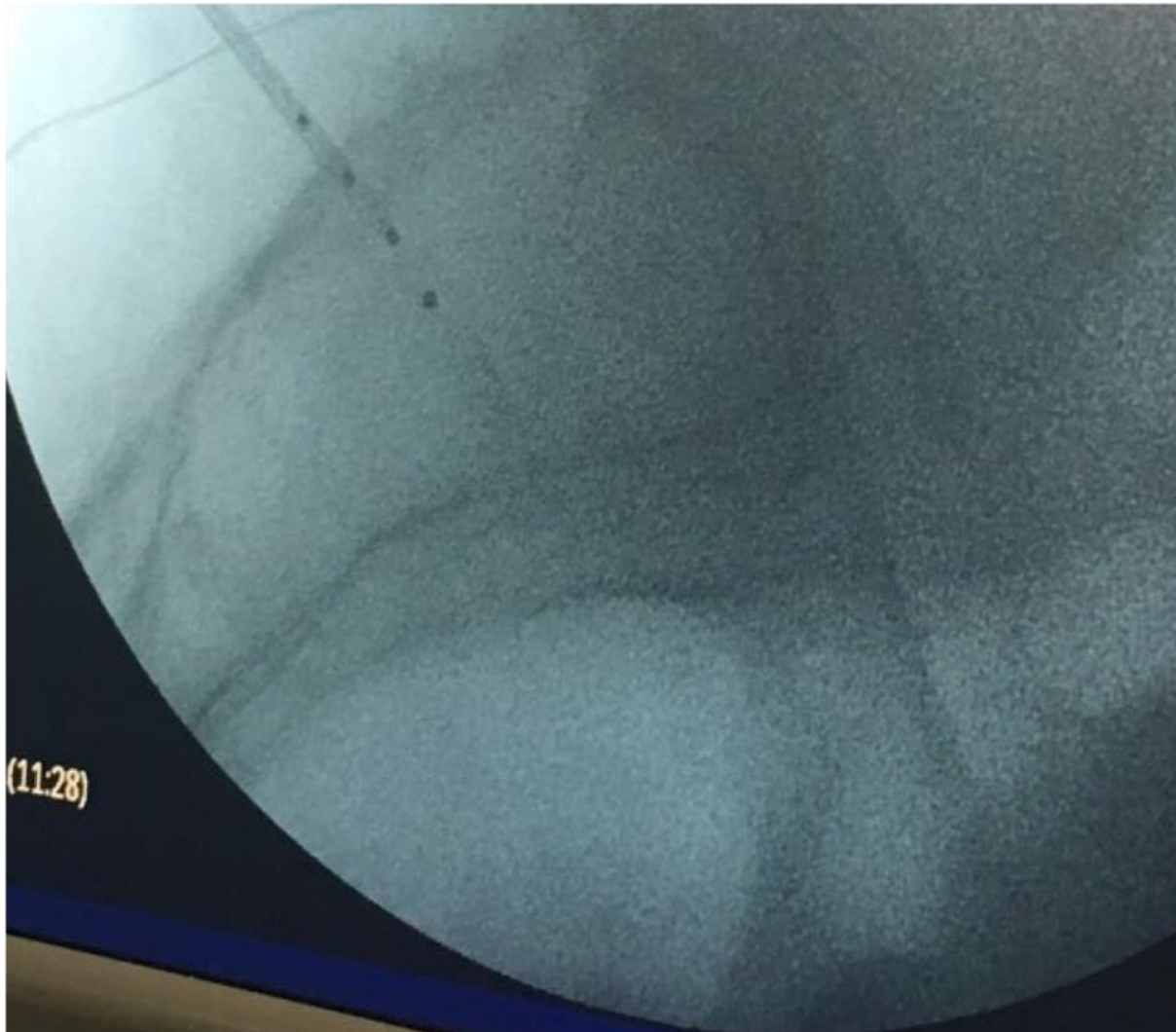
### E-POSTER VIEWING

Antonio Pajuelo, Maria Auxiliadora Cormane  
Anesthesia, HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO, SEVILLE, Spain

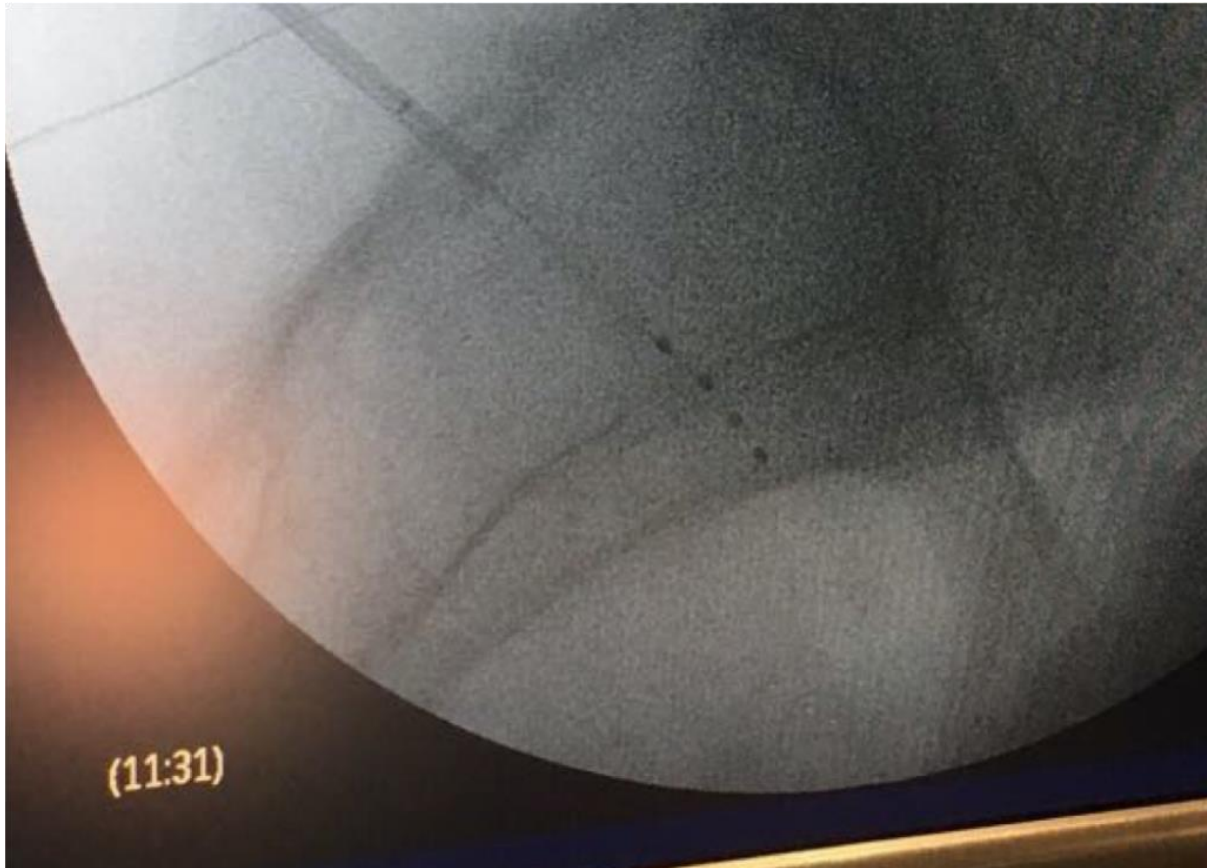
**Introduction:** The invaluable contribution of the stimulation of the dorsal root ganglion by its initial efficacy and its support over time, forces us to consider the therapeutic possibilities of stimulation of the dorsal root ganglion at levels other than the classical lumbar epidural, thoracic or cervical route<sup>1,2</sup>.

**Methods/Materials:** The implantation of DRG electrodes at the sacral level has already been described both for the treatment of neuropathic pain in the lower limb, especially at the level of the foot<sup>3</sup> and also for the treatment of pelvic neuropathic pain<sup>4</sup>.

### Results:







We present a case of neuropathic pain in the left foot after a lumbar spine instrumentation surgery and that after several attempts of therapy by means of standard spinal stimulation, not successful, the stimulation of the dorsal root ganglion was tested at the level of L5 and S1 (see images) that proved effective.

**Discussion:** Stimulation of the dorsal root ganglion at the sacral level has been proposed for the treatment of pelvic and lower limb pain and also for pelvic pain.

**Conclusions:** From the technical point of view, its implant is simple although the most effective final housing is yet to be defined.

**References:** 1.- Levy R. et al: Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Type I and II. *J Pain*. 2019 Sep 5 2.- Piedade G.S., Vesper J., Chatzikalfas A., Slotty P.J. 2019. Cervical and High-Thoracic Dorsal Root Ganglion Stimulation in Chronic Neuropathic Pain. *Neuromodulation* 2019; 22: 951–955 3.- Skaribas I.M., Peccora C., Skaribas E. 2019. Single S1 Dorsal Root Ganglia Stimulation for Intractable Complex Regional Pain Syndrome Foot Pain After Lumbar Spine Surgery: A Case Series. *Neuromodulation* 2019; 22: 101–107 4.- Hunter C.W., Yang A. 2018. Dorsal Root Ganglion Stimulation for Chronic Pelvic Pain: A Case Series and Technical Report on a Novel Lead Configuration. *Neuromodulation* 2018; E-pub ahead of print. DOI:10.1111/ner.12801

**Keyword:** DORSAL ROOT GANGLION, SACRAL

**Topic:** 05. Spine / 05a. Pain

## **SINGLE CENTRE REAL LIFE OUTCOMES WITH 10KHZ SPINAL CORD STIMULATION FOR THE TREATMENT OF CHRONIC PAIN**

### **E-POSTER VIEWING**

Ann-Katrin Fritz<sup>1</sup>, Michael Sidery<sup>2</sup>, Katherine Dyer<sup>2</sup>, Benjamin Morrison<sup>2</sup>, Bethany Roughsedge<sup>2</sup>, Grainne Daniels<sup>2</sup>, Laura Butler<sup>2</sup>

<sup>1</sup>Pain Management, Norfolk & Norwich University Hospitals NHS Foundation Trust, Norwich, United Kingdom, <sup>2</sup>Pain Management, Norfolk & Norwich University Hospitals NHS Trust, Norwich, United Kingdom

**Introduction:** The SENZA-RCT Randomized Controlled Trial<sup>1, 2</sup> has demonstrated superiority in the treatment of chronic back and leg pain with 10kHz high frequency SCS in comparison to paraesthesia based low frequency SCS systems, that had been traditionally used in the treatment of chronic neuropathic trunk and limb pain. We have reviewed our internal patient data to assess outcomes in real life patients in comparison to a carefully selected randomised controlled trial cohort.

**Methods/Materials:** We have reviewed our data to include all 87 implanted patients with 10kHz high frequency SCS at the Norfolk & Norwich University Hospital NHS Foundation Trust from 2014-2020. Data was collected prospectively at routine end of trial visits, 3, 6, 12 and 24 months post implant and sourced via the patient's notes, letters and database.

**Results:** 75% of patients had either both back and leg pain (64%), predominant back pain (14%), predominant leg pain (8%) or other pain 15%.

The trial response rate is currently 92% with average VRS scores dropping from 8.2 to 2.3. The responder rate identified as >50% pain reduction was 75% at 3 months, 86% at 6 months and 79% at 12 months.

**Discussion:** Our results confirm previously demonstrated efficacy and excellent overall outcomes treated with 10kHz high frequency SCS in carefully selected patients that have undergone a multi-disciplinary assessment pathway. Limitations include very few patients missing their routine annual appointment and therefore lack of data and some patients having been lost to follow up likely due to relocation.

**Conclusions:** 10kHz high frequency SCS can be safely used in a normal patient cohort with results mirroring the previous large multicentre randomised controlled trials.

**References:** 1. Kapural, Leonardo et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial. *Anesthesiology* 2015;123(4):851-860. doi: <https://doi.org/10.1097/ALN.0000000000000774>. 2. Kapural, Leonardo et al. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial. *Neurosurgery* vol. 79,5 (2016): 667-677. doi:10.1227/NEU.0000000000001418

**Keywords:** FBSS, SCS, HF10, Spinal cord stimulation



**Topic:** 05. Spine / 05a. Pain

## **THE DORSAL ROOT GANGLION CYST. WAS THAT AN INCIDENTAL FINDING OR COMPLICATION FOLLOWING LEAD PLACEMENT?**

### **E-POSTER VIEWING**

Martyna Berwertz, Debbie Poole, Nick Plunkett  
Sheffield Teaching Hospital, Chronic Pain Service, Sheffield, United Kingdom

**Introduction:** Neuromodulation therapy can significantly reduce neuropathic pain and therefore improve patient quality of life. Complications sometimes can significantly inhibit the efficiency of the therapy and change the outcomes.

**Methods/Materials:** A 53-year-old female developed sudden onset back pain with radicular symptoms while dancing. She was diagnosed with acute sciatica. She had no other medical problems and was planning to move abroad for retirement. She failed conservative treatment and a year later, in 2009, she underwent the L4/5 microdiscectomy with no postprocedural pain improvement. Additional conservative therapies (acupuncture, TENS machine, physiotherapy, neuropathic medications) were also nonbeneficial. In 2012, she underwent unsuccessful L4/5 revision surgery. In 2013 she was referred to the tertiary neuromodulation center. On presentation VAS score was 10, she was complaining of shooting, burning pain in L4 dermatome. She had unsuccessful two transforaminal injections. Following that she was offered neuromodulation therapy. She received positive approval from the MDT and had L4 dorsal root ganglion trial in 2014. Due to personal circumstances, the permanent trial was terminated on day four with 90% symptom relief. The second stage was planned for a later date due to her unavailability. The patient presented sooner with the hardware infection. The system was explanted.

**Results:** In June 2015 she underwent the 2<sup>nd</sup> L4 DRG trial. The surgery was technically difficult, uncomfortable and poorly tolerated by the patient. The L4 DRG lead was placed successfully, however, the patient did not report any benefits. Pain in the index area was as bad, despite different settings. With normal inflammatory markers, she was diagnosed with isolated neuropraxia. The patient was struggling with pain and discomfort which led to the explantation of the system. The subsequent MRI reported the presence of the cyst in the L4 exit foramen which was compressing the exiting left L4 nerve root.

**Discussion:** It remains within the theoretical discussion whether the cyst of the dorsal root developed after the initial lead placement, was that secondary complication of infection or caused by the difficult 2<sup>nd</sup> lead placement?

**Conclusions:** Good communication and patient engagement are essential. The need for MRI imaging was controversial. The therapy would have been planned differently should the team have known about patient relocation plans. That cases prompted a more frequent evaluation of the treatment and patient's feedback. Acknowledgments: We are thankful, to our neurosurgical consultant colleague Mr. John Yianni for his expertise and involvement, and clinical nurse specialist Mrs. Donna Hales for her help in patient's care.

### **References:**

**Keywords:** dorsal root ganglion cyst complication, cyst

**Topic:** 05. Spine / 05a. Pain

## REVISION SURGERY OF SPINAL CORD STIMULATION ELECTRODE: RETROSPECTIVE SINGLE-CENTER COHORT OF 43 CASES OVER 10 YEARS.

### E-POSTER VIEWING

Jimmy Voirin<sup>1</sup>, Mariette Delaitre<sup>1</sup>, Erwan Treillet<sup>2</sup>, Véronique Dix-Neuf<sup>3</sup>, Patrick Ledee<sup>4</sup>, Jacques Frey<sup>4</sup>, Marie-Madeleine Fehr<sup>2</sup>

<sup>1</sup>Neurosurgery, Hôpitaux Civils de Colmar, COLMAR, France, <sup>2</sup>Cetd, Hôpitaux Civils de Colmar, COLMAR, France, <sup>3</sup>Pain Medicine, Hôpital Schweitzer, COLMAR, France, <sup>4</sup>Pain Medicine, GHRMSA, MULHOUSE, France

**Introduction:** While second spinal surgery is less likely to relieve than the first one, few data exist in the literature about reoperation in spinal cord stimulation (SCS), especially for epidural electrode.

**Methods/Materials:** Between 2010 and 2020, 43 patients were operated twice for SCS electrode in our department. 76.7% of the implantations were indicated for failed back surgery syndrom (FBSS) and 55.8% were implanted with percutaneous leads. The mean visual analogue pain scale at the spinal level (sVAS) was 5/10 and 7.7 / 10 at the radicular level (rVAS).

**Results:** Mean time between both surgeries was 58 months [39.2-76.8]. Reasons for reoperation were: reimplantation after infection (18.6%), technical problem (16.3%), therapeutic failure (16.2%), migration (13.9%), and insufficient coverage (13.9%). Mean operating time was 129.6 min [109.8-149.3]. Postoperative sVASc was 3.13 / 10 [2.19-4.07] ( $p = 0.01$ ) and rVAS of 2.72 / 10 [2.18-3.27] ( $p < 10e-6$ ), while mean operation site VAS (oVAS) significantly increased by 3.98 / 10 [3.09-4.86] ( $p < 10e-6$ ). Morbidity was based on two epidural hematomas with complete neurological recovery (4.6%) and three infections (7%). Whatever second implantation technique was used, rVAS improved postoperatively ( $p < 0.01$  for percutaneous leads and  $p < 10e-6$  for surgical leads), although oVAS significantly increased by 4.6 / 10 ( $p < 10e-6$ ) exclusively after surgical technique. Six patients were operated on a third time: sVAS and rVAS improved (respectively  $p < 0.05$  and  $p < 0.01$ ) but oVAS significantly increased from 2.3 / 10 to 6.2 / 10 ( $p < 0.05$ ).

**Discussion:** Despite small size of this cohort, we described the largest cohort in the literature, to our knowledge. The revision rate varies from 9.2% to 43.5%. Some studies recognize a benefit of SCS electrode revision on VAS scores, patient satisfaction and quality of life (especially in the case of technical dysfunction) and estimate that reoperating SCS more than twice would increase the risk of result in explant.

**Conclusions:** A second surgical approach of SCS electrode significantly increases operating morbidity such as local postoperative pain and complications. Highest precautions should be required before proposing revision surgery of SCS electrode, especially when indication is not related to device technical dysfunction. Our results may favor less invasive techniques and we may wonder if paresthesia-free stimulation could also be considered as an alternative therapeutic option, and included in further prospective studies.

**References:** Babu, R., Hazzard, M. A., Huang, K. T., Ugiliweneza, B., Patil, C. G., Boakye, M., & Lad, S. P. (2013). Outcomes of percutaneous and paddle lead implantation for spinal cord stimulation: a comparative analysis of complications, reoperation rates, and health-care costs. *Neuromodulation: Technology at the Neural Interface*, 16(5), 418-427. Matias, C. M., Amit, A., Lempka, S. F., Ozinga IV, J. G., Nagel, S. J., Lobel, D. A., & Machado, A. G. (2014). Long-term outcomes after replacement of percutaneous leads with paddle leads in a retrospective cohort of patients with spinal cord stimulation systems. *Neurosurgery*, 75(4), 430-436. Mehta, S. H., Hoelscher, C. M., Sharan, A. D., Thalheimer, S., & Wu, C. (2019). Implantable Pulse Generator Site May Be Associated With Spinal Cord Stimulation Revision Surgeries. *Neuromodulation: Technology at the Neural Interface*. <https://doi.org/10.1111/ner.12976> North, R. B., Kidd, D. H., Farrokhi, F., & Piantadosi, S. A. (2005).

Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. *Neurosurgery*, 56(1), 98-107. Rosenow, J. M., Stanton-Hicks, M., Rezai, A. R., & Henderson, J. M. (2006). Failure modes of spinal cord stimulation hardware. *Journal of Neurosurgery: Spine*, 5(3), 183-190. Van Buyten, J. P., Wille, F., Smet, I., Wensing, C., Breel, J., Karst, E., ... & Vesper, J. (2017). Therapy-related explants after spinal cord stimulation: results of an international retrospective chart review study. *Neuromodulation: Technology at the Neural Interface*, 20(7), 642-649.

**Keywords:** neuropathic pain, revision surgery, Spinal cord stimulation, complication

**Topic:** 05. Spine / 05a. Pain

## **MOVING BEYOND VAS INTO DEEP PERSONALIZATION: ADVANCED ANALYTICS AND DATA METRICS UNLOCK INNOVATIVE METHOD FOR ASSESSING CHRONIC PAIN IN SCS PATIENTS**

### **E-POSTER VIEWING**

Richard Rauck<sup>1</sup>, Eric Loudermilk<sup>2</sup>, Julio Paez<sup>3</sup>, Louis Bojrab<sup>4</sup>, Mohab Ibrahim<sup>5</sup>, John Noles<sup>6</sup>, Todd Turley<sup>7</sup>, Amol Patwardhan<sup>5</sup>, James Scowcroft<sup>8</sup>, Nathan Miller<sup>9</sup>, Rene Przkora<sup>10</sup>, Sara Berger<sup>11</sup>, Mohamed Ghalwash<sup>11</sup>, Pritish Parida<sup>11</sup>, Tigran Tchrakian<sup>11</sup>, Carla Agurto<sup>11</sup>, Jenna Reinen<sup>11</sup>, Andrea Simonetto<sup>11</sup>, Zijun Yao<sup>11</sup>, Daby Sow<sup>11</sup>, Guillermo Cecchi<sup>11</sup>, Jeffrey Rodgers<sup>11</sup>, Roshini Jain<sup>12</sup>, Brad Hershey<sup>13</sup>, Dat Huynh<sup>13</sup>, Kristen Lechleiter<sup>12</sup>, Matt McDonald<sup>13</sup>

<sup>1</sup>Pain Management, Carolinas Pain Institute, Winston-Salem, United States of America, <sup>2</sup>Pain Management, PCPMG Clinical Research Unit, Anderson, United States of America, <sup>3</sup>Pain Management, South Lake Pain Institute, Clermont, United States of America, <sup>4</sup>Pain Management, Forest Health Medical Center, Ypsilanti, United States of America, <sup>5</sup>Anesthesiology And Pain Management, University of Arizona Medical Center, Tucson, United States of America, <sup>6</sup>Pain Management, River Cities Interventional Pain, Shreveport, United States of America, <sup>7</sup>Pain Management, Hope Research Institute, Phoenix, United States of America, <sup>8</sup>Pain Management, Pain Management Associates, Independence, MO, United States of America, <sup>9</sup>Pain Management, Coastal Pain and Spinal Diagnostics, Carlsbad, United States of America, <sup>10</sup>Pain Management, University of Florida, Gainesville, United States of America, <sup>11</sup>Healthcare And Life Sciences, IBM Thomas J. Watson Research Center, Yorktown Heights, United States of America, <sup>12</sup>Clinical Research, Boston Scientific, Valencia, United States of America, <sup>13</sup>Research And Development, Boston Scientific, Valencia, United States of America

**Introduction:** Advances in availability of sensors, connected systems, and data analytics present an opportunity to achieve a new level of deep personalization of therapy in patients implanted with Spinal Cord Stimulation (SCS) systems for chronic pain via identification of metric relationships that may not be obvious. Boston Scientific and IBM Research present results from an on-going partnership focused on addressing the needs of patients experiencing chronic pain by harnessing state-of-the-art technologies.

**Methods/Materials:** Two ongoing, multi-center, prospective Boston Scientific-sponsored SCS studies (NAVITAS and ENVISION, n = up to 1700 at up to 30 U.S. sites) are collecting diverse objective and subjective data streams (including pain, depression, mood/emotion, voice recordings, sleep quality/quantity, cardiac function, torso and/or wrist worn actigraphy, medication, genomics, imaging, SCS parameters/usage, fitness, satisfaction, quality-of-life) via both in-clinic visits and at-home connected mobile solutions for up to 36 months. Data are used as inputs to advanced analytics, including novel artificial intelligence (AI) and machine learning (ML) techniques.

**Results:** Initial outcomes beyond pain intensity will be presented from these ongoing studies (~250 enrolled subjects), including at least 160 enrolled subjects with a mean of 17.2±14.2 years since onset of low back (95.0%) with or without bilateral lower extremity (59.4%) or unilateral lower extremity (31.9%) pain who were followed for a mean 398.6±192.8 days post-enrollment providing >42,000 unique patient data days of data with >6750 voice recordings. Improvements in Percent Pain Relief were observed as well as several functional measures (including Sleep Quality, 6 Minute Walk Test, Function Reach Test) for de novo subjects with SCS implanted at 6 months post-trial compared to baseline (n≈50).

**Discussion:** Patient reported pain intensity alone provides an incomplete understanding of a patient's chronic pain and quality of life. A patient may achieve clinically-meaningful improvement that is not reflected in their pain score. Patients can engage with new technologies to more fully capture their experience with chronic pain. Novel advanced analytic techniques such as machine learning and artificial intelligence (AI) can help unravel dense, multi-dimensional data to derive multifactorial

outcome metrics that provide a comprehensive understanding of each patient's unique experience with chronic pain.

**Conclusions:** This advanced data analytic study conducted as part of a partnership between Boston Scientific and IBM Research aims to support increased understanding of the chronic pain experience, anticipate the needs of patients, and provide solutions that adapt and personalize chronic pain therapies.

**References:**

**Keyword:** data analytics, big data, digital health, chronic pain, spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

## **IMPROVING APPROPRIATE REFERRAL AND SELECTION FOR SPINAL CORD STIMULATION IN CHRONIC PAIN: AN INTEGRATED APPROACH**

### **E-POSTER VIEWING**

Simon Thomson<sup>1</sup>, Frank Huygen<sup>2</sup>, Simon Prangnell<sup>3</sup>, Herman Stoevelaar<sup>4</sup>

<sup>1</sup>Pain Management And Neuromodulation, Basildon and Thurrock University Hospitals NHSFT, Orsett Hospital, Orsett, Grays, United Kingdom, <sup>2</sup>Anesthesiology Center Of Pain Medicine, Erasmusmc, Rotterdam, Netherlands, <sup>3</sup>Psychological Medicine, Oxford University Hospitals NHS Trust, Oxford, United Kingdom, <sup>4</sup>Centre For Decision Analysis & Support, Ismar Healthcare, Lier, Netherlands

**Introduction:** Spinal cord stimulation (SCS) has been used for the treatment of chronic pain for over 50 years. Determining the eligibility of patients for this procedure requires careful balancing of both clinical and psychosocial factors. We aimed at developing an integrated approach that could support appropriate referral and selection for SCS in daily practice.

**Methods/Materials:** We composed an 18-member European expert panel representing the disciplines that are commonly involved in the evaluation of patients for SCS (anaesthesiology, neurosurgery, psychology, physiotherapy, and nursing). The RAND/UCLA Appropriateness Method (RUAM)<sup>1</sup> was used to combine evidence from clinical studies and clinical expertise into patient-specific recommendations on (referral for) SCS. In an iterative process of individual rating rounds and plenary discussions, the experts assessed the appropriateness of (referral for) SCS for 386 clinical scenarios, using a 9-point scale (1=inappropriate, 9=appropriate). These scenarios were combinations of clinical variables considered relevant for the decision of (referral for) SCS: treatment history, type/nature and location of pain, anatomic abnormalities, response to previous procedures, and spread of pain. Appropriateness statements (usually appropriate, maybe appropriate, rarely appropriate) were based on the median panel score and extent of agreement. In addition, a literature search and roundtable discussion were conducted to identify psychosocial factors that may reduce the effectiveness of SCS and should therefore be included in the consideration of SCS. An algorithm was developed to combine clinical and psychosocial aspects into patient-specific recommendations.

**Results:** The panel results on the clinical scenarios showed consisted patterns for the appropriateness of SCS. Strong determinants were the neuropathic or neuropathic-like pain component, location and spread of pain, anatomic abnormalities, and response to therapies targeting pain processing. Psychosocial factors considered most relevant for SCS selection were: lack of engagement, dysfunctional coping, unrealistic expectations, inadequate daily activity level, problematic social support, secondary gain, psychological distress, and unwillingness to reduce high-dose opioids. The results were embedded in an educational e-health tool that shows the combined clinical/psychosocial recommendation for a selected patient profile (Figure).

# Patient summary

## Clinical factors

- Previous spine surgery
- Main location of pain
- Dominant type of pain
- Anatomic abnormality
- Response to root block, TENS, epiduroscopy, RF and/or NP medication

Yes

Leg

Neuropathic-like

Iatrogenic nerve lesion

At least partial/temporary effect

## Psychosocial factors

- Dysfunctional coping
- Inadequate daily activity level
- Psychological distress / mental health problems

## Panel recommendation

NOT RECOMMENDED

RECOMMENDED

STRONGLY RECOMMENDED

Based on the clinical aspects, this patient may be a good candidate for SCS. However, the psychosocial evaluation raised some concerns. Consultation with a clinical psychologist and/or multidisciplinary team is therefore mandatory.

See details on **clinical aspects**

See details on **psychosocial aspects**

New profile

Save profile

Print profile

**Discussion:** Although SCS is an established treatment for chronic pain, identification of appropriate candidates is often challenging. This is partly due to the heterogeneity of the patient population, but also to the complex interaction between chronic pain and psychosocial factors. An integrated approach is therefore mandatory.

**Conclusions:** The RUAM was useful to establish patient-specific criteria for SCS in chronic pain, combining both clinical and psychosocial factors. The e-health tool may support appropriate referral and selection.

**References:** 1. Brook RH, Chassin MR, Fink A, Solomon DH, Kosecoff J, Park RE. A method for the detailed assessment of the appropriateness of medical technologies. *Int J Technol Assess Health Care* 1986;2:53-63.

**Keyword:** Spinal Cord Stimulation, Chronic pain, Appropriateness, Education, Guidelines

**Topic:** 05. Spine / 05a. Pain

## **APPLICABILITY OF AN EDUCATIONAL E-HEALTH TOOL ON THE APPROPRIATE SELECTION FOR SPINAL CORD STIMULATION IN PATIENTS WITH CHRONIC PAIN: AN INTERNATIONAL MULTICENTRE STUDY**

### **E-POSTER VIEWING**

Simon Thomson<sup>1</sup>, Frank Huygen<sup>2</sup>, Simon Prangnell<sup>3</sup>, G. Baranidharan<sup>4</sup>, Hayad Belaïd<sup>5</sup>, Bart Billet<sup>6</sup>, Laura Demartini<sup>7</sup>, Kliment Gatzinsky<sup>8</sup>, Jan Willem Kallewaard<sup>9</sup>, Matthias Winkelmüller<sup>10</sup>, Herman Stoevelaar<sup>11</sup>

<sup>1</sup>Pain Management And Neuromodulation, Basildon & Thurrock University Hospitals NHSFT, Basildon, United Kingdom, <sup>2</sup>Anesthesiology Center Of Pain Medicine, Erasmusmc, Rotterdam, Netherlands, <sup>3</sup>Psychological Medicine, Oxford University Hospitals NHS Trust, Oxford, United Kingdom, <sup>4</sup>Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom, <sup>5</sup>Neurosurgery, Fondation Ophtalmologique Adolphe de Rothschild, Paris, France, <sup>6</sup>Pain Clinic, AZ Delta, Roeselare, Belgium, <sup>7</sup>Pain Unit, Clinical Scientific Institutes Maugeri, Pavia, Italy, <sup>8</sup>Neurosurgery, Sahlgrenska University Hospital, Gothenburg, Sweden, <sup>9</sup>Pain Centre, Rijnstate Hospital, Velp, Netherlands, <sup>10</sup>Neurosurgery, Friederikenstift Hannover, Hannover, Germany, <sup>11</sup>Centre For Decision Analysis & Support, Ismar Healthcare, Lier, Belgium

**Introduction:** In 2019, a European expert panel established detailed recommendations on the appropriate referral and selection of patients with chronic pain for the consideration of spinal cord stimulation (SCS).<sup>1</sup> The panel recommendations were embedded in an educational e-health tool, considering both clinical and psychosocial factors. The applicability of this e-health tool on real-life patient data is currently being evaluated in a retrospective study.

**Methods/Materials:** Thirteen implant centres in seven European countries were asked to collect data from 25-50 patients for whom SCS was considered, aiming to include 500 patients. For each patient, data was captured on the clinical and psychosocial variables included in the e-health tool, centre decisions on SCS and patient outcomes. The initial outcomes of this ongoing study focussed on the level of improvement at 6 months follow-up as observed by the treating physician.

**Results:** By now, 334 patients from 10 centres have been included. Of these, 86 received a direct implant, 180 had an implant after a positive trial, and 68 had no implant (negative or no trial). Patients aged on average 54 years and 60% were female. Most patients were treated for chronic low back/leg pain (74%), followed by complex regional syndrome (12%), neuropathic pain syndromes (13%) and ischaemic pain syndromes (.3%). Of the patients receiving an implant, improvement correlated with the outcomes of the e-health tool, showing improvement in 15%, 67% and 79% of patients when SCS was not recommended, recommended or strongly recommended, respectively. These patterns were fairly similar in patients with a direct implant and those with an implant after a positive trial. When evaluating appropriateness in relation to trial outcomes, there was less than 10% of trial failure when SCS was (strongly) recommended, while there was 65% of trial failure when SCS was not recommended by the e-health tool.

**Discussion:** The applicability of an e-health tool was evaluated by retrospectively comparing centre decisions and patient outcomes with the panel recommendations. The preliminary results demonstrated good translatability of the eligibility criteria and a strong relationship between the panel recommendations with both the SCS trial and treatment outcomes.

**Conclusions:** Retrospective application of the e-health tool on patient data suggests predictive value of the e-health tool for SCS trial and treatment outcomes in patients with chronic pain. This will be further evaluated in a prospective validation study.



**References:** 1. Thomson S, Huygen F, Prangnell S, De Andrés J, Baranidharan G, Belaïd H, Berry N, et al. Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. *Eur J Pain*. 2020;24(6):1169-81.

**Keywords:** SCS, Spinal cord stimulation, chronic pain, Appropriateness, Education, e-health tool

## SPINAL CORD STIMULATION IN PATIENTS WITH DEGENERATIVE LUMBAR STENOSIS

### E-POSTER VIEWING

Andrey Nikitin<sup>1</sup>, Emil Isagulyan<sup>2</sup>

<sup>1</sup>Neurosurgery, Moscow State University of Medicine and Dentistry, Moscow, Russian Federation, <sup>2</sup>Neurosurgery, National Medical Research Center of Neurosurgery named after acad. N.N. Burdenko, Moscow, Russian Federation

**Introduction:** Some patients with degenerative lumbar stenosis have severe concomitant pathology and open surgery is too risky for them. In such cases spinal cord stimulation can be performed as a palliative alternative method [1, 2, 3].

**Methods/Materials:** A prospective study was conducted among 20 patients with degenerative lumbar stenosis. All patients had radicular symptoms or neurogenic claudication. Most patients (n = 18) were rejected from open decompression because of severe concomitant somatic pathology. Two patients refused from open intervention, they were offered stimulation. All patients (n=20) were implanted of the test epidural electrode for spinal cord stimulation. The exclusion criterion was the presence of mechanical axial pain in the lumbar region. Outcomes were assessed by using a visual analogue scale (VAS) and increasing of the distance of non-stop walking in 8 days after surgery. Among patients with chronic spinal cord stimulation, outcomes were assessed in 6 months after implantation. A satisfactory result was considered as a decreasing of pain more than 50% (according to VAS)

**Results:** A satisfactory result of test stimulation was noted in 18 patients, all of them were implanted of system of the chronic spinal cord stimulation. The average value of lumbar pain changed from 4.2 to 3.1 points, and the average value of leg-pain changed from 7.2 to 2.2 points. The average value of the non-stop walking distance changed from 58 to 245 meters. At the same time, the motor component of neurogenic claudication decreased in only single patient. In some patients, after regression of radicular pain, heart complaints became the main factor limiting walking. Before stimulation only three patients had no walking restriction. After stimulation seven patients had no walking restriction. We have some complications, one foot drop after 6 months of implantation. After one year of implantation one patient had period of increasing acute pain for one month with no analgetic effect from stimulation. There were three reoperations after several months of implantation: explantation because of infection, electrode replacement because of breakage, second electrode implantation because of pain occurrence in opposite leg.

**Discussion:** This technology in patients with symptomatic lumbar stenosis is a purely palliative option, because the mechanical cause of compression is not removed. Nevertheless, all patients in this observation are satisfied with the stimulation during the observation period.

**Conclusions:** Spinal cord stimulation is an effective palliative option in patients with degenerative lumbar stenosis.

**References:** 1. Kamihara M, Nakano S, Fukunaga T, Ikeda K, Tsunetoh T, Tanada D, Murakawa K. Spinal cord stimulation for treatment of leg pain associated with lumbar spinal stenosis. *Neuromodulation*. 2014 Jun;17(4):340-4. DOI: 10.1111/ner.12092. 2. Costantini, A., Buchser, E., & Van Buyten, J. P. (2010). Spinal cord stimulation for the treatment of chronic pain in patients with lumbar spinal stenosis. *Neuromodulation: Technology at the Neural Interface*, 13(4), 275–280. DOI:10.1111/j.1525-1403.2010.00289.x 3. Chandler G., Nixon B., Stewart L., Love J. Dorsal column stimulation for lumbar spinal stenosis. *Pain Physician*. 2003; 6(1):113-8. PMID: 16878166

**Keywords:** Spinal cord stimulation, spinal cord stimulation lumbar stenosis, lumbar stenosis, degenerative lumbar stenosis, lumbar pain, neurogenic claudication

## EARLY RESULTS OF THE FIRST PATIENTS, TREATED WITH ECAP-CONTROLLED CLOSED-LOOP SPINAL CORD STIMULATION IN THE NETHERLANDS

### E-POSTER VIEWING

Harold Nijhuis<sup>1</sup>, Willem-Jan Hofsté<sup>1</sup>, Jan Willem Kallewaard<sup>2</sup>

<sup>1</sup>Anesthesiology, Ziekenhuis Nieuwegein, Nieuwegein, Netherlands, <sup>2</sup>Pain Centre, Rijnstate Hospital, Velp, Netherlands

**Introduction:** Spinal cord stimulation (SCS) has proven to be an effective therapy for chronic pain[1], [2]. The first ECAP-controlled closed-loop (CL) SCS system has been developed that can record the responses of the nerves activated by electrical stimulation in the dorsal column[3]. These measured responses are called evoke compound action potentials (ECAPs). The responses are used to adjust stimulation levels real-time in order to maintain constant activation of the spinal cord. Since regulatory approval in 2019, 14 failed back surgery syndrome (FBSS) patients (9f, 5m) were implanted with the CL-SCS system to treat chronic neuropathic back and/or leg pain in two centres in the Netherlands. Currently, 14 patients have been implanted and 12 passed the 3-months. These results will be presented here.

**Methods/Materials:** All patients were implanted with two 12-contacts leads (Saluda Medical, Evoke™) placed in the epidural space at the thoracic level, with lead tips positioned between T8 and T10. The leads were connected to a rechargeable CL-SCS battery (Saluda Medical, Evoke™) which was implanted in the buttock area. Postoperatively, the system was activated and programmed. Post-implantation patients were followed as per standard of care and pain relief was assessed using a verbal numeric rating scale (VNRS). Patient satisfaction was also assessed using a 6-point Likert Scale. Data recorded from a standard follow visit 3-months post-implantation is presented here.

**Results:** To date, 12 out of 14 patients have passed the 3-month data collection point. At 3-months post-implantation all 12 patients reported a pain reduction of  $\geq 50\%$  with an average of  $81\%$  (SD =  $17\%$ ), 8 had a pain reduction  $\geq 75\%$  and 3 had a pain reduction of  $100\%$ .

**Discussion:** Patient satisfaction scores were taken from 9 of the 12 patients; 6 patients reported to be very satisfied, 2 patients reported to be satisfied and 1 patient reported to be quite satisfied. 11 out of 12 patients were programmed in Closed-loop mode at 3-months post-implantation.

**Conclusions:** CL-SCS showed high levels of pain reduction in FBSS patients in the first 3-months of therapy. These results are measured in an early stage and are looking promising for the future. The expectation is that these results will be maintained in the future and possibly improve further as seen in the Avalon and Evoke studies.

**References:** [1] P. Verrills, C. Sinclair, and A. Barnard, "A review of spinal cord stimulation systems for chronic pain," J. Pain Res., pp. 481–492, Jul. 2016. [2] J. S. Grider et al., "Effectiveness of Spinal Cord Stimulation in Chronic Spinal Pain: A Systematic Review," Pain Physician, vol. 19, no. 1, pp. E33-54, Jan. 2016. [3] N. Mekhail et al., "Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial," Lancet Neurol., p. S1474442219304144, Dec. 2019.

**Keywords:** ECAP Controlled CL-SCS, Closed Loop, Spinal cord stimulation, ECAP Controlled Closed Loop Spinal Cord Stimulation, SCS, Evoked Compound Action Potential

**Topic:** 05. Spine / 05a. Pain

## **PULSED RADIOFREQUENCY OF THE DORSAL ROOT GANGLION IN LUMBAR RADICULOPATHY: A MECHANISTIC AND EFFICACY LITERATURE REVIEW**

### **E-POSTER VIEWING**

Melanie Goodman Keiser<sup>1</sup>, Michael Verdolin<sup>2</sup>

<sup>1</sup>Research & Core Technology, Medtronic, Minneapolis, United States of America, <sup>2</sup>Private Practice, Pain Consultants of San Diego, La Mesa, United States of America

**Introduction:** Pulsed Radiofrequency (Pulsed RF) stimulation of the dorsal root ganglia (DRG) has also been used as an early treatment for lumbar radiculopathy. The mechanism of action of Pulsed RF is hypothesized to involve the inhibition of intracellular neuronal transport mechanisms. This literature review assesses the mechanistic and clinical efficacy for pulsed RF of the DRG for the treatment of lumbar radiculopathy.

**Methods/Materials:** A systematic literature review was performed in January 2020 in the MEDLINE (PubMed) and EMBASE databases. In the first search, the criteria were “pulsed radiofrequency” AND “mechanism of action” and selected English. Since only five articles were found, manual searches of the bibliographies, including review articles, were also performed for completeness. The second search criteria included “pulsed radiofrequency” AND “dorsal root ganglion” AND “lumbar” AND “pain” in English. Thirty-five articles were found through the PubMed search and the EMBASE search produced 22 articles. Exclusion criterion included all articles reporting results of a clinical study. This left 12 articles which met all criteria. Each article was assessed for pain scores, functional measures, quality of life measures, and reported adverse events. These measures are reported as a meta-analysis when appropriate and separately.

**Results:** For the mechanism of action, the articles differed methodologically, with some experiments stimulating the peripheral paw, others stimulating the DRG, and others stimulating cell cultures. Together, a high-level mechanism of action may be determined. Of the twelve articles, there were three randomized, controlled trials (RCT), five prospective studies or case series, and four retrospective chart review studies. In most studies, pulsed RF decreased pain scores ( $\Delta$ VAS score= 0.9-5.0 points;  $\Delta$ NRS score= 2.65-3.9 points) at the earliest timepoint (post-operative to 30 days). Subjects in these studies reported a slow increase in pain scores over time. ODI scores also were initially decreased and then slowly increased back toward baseline over time. Minor adverse effects included headache and transient aggravation of pain post treatment.

**Discussion:** Preclinical microscopic methodologies studies suggest pulsed RF causes mitochondrial membrane, microfilaments, and microtubules changes. Subjects reported a decrease in pain scores, functional measures, and quality of life secondary measures at initial time points that slowly increased over time. Studies reported only minor adverse events.

**Conclusions:** Pulsed RF stimulation of the DRG has been shown in multiple studies as an effective treatment for lumbar radiculopathy. As new stimulation paradigms and pulsed RF technologies emerge, new studies will be needed to determine efficacy.

### **References:**

**Keyword:** Pulsed Radiofrequency, Dorsal Root Ganglion, Lumbar Radiculopathy

**Topic:** 05. Spine / 05a. Pain

## THE EFFECT OF MULTIWAVE PLATFORMS IN THE MODERN SPINAL CORD STIMULATION ERA.

### E-POSTER VIEWING

Apostolos Chatzikalfas<sup>1</sup>, Philipp Slotty<sup>2</sup>, Jan Vesper<sup>2</sup>

<sup>1</sup>Department For Neuromodulation, University clinic of Duesseldorf, Duesseldorf, Germany, <sup>2</sup>Functional Neurosurgery And Stereotaxy, Univerity Clinic Duesseldorf, Dusseldorf, Germany

**Introduction:** For decades the success and efficiency of SCS was dependent in the coverage of the pain area from the stimulating paraesthesia. Since 2008 multiple waveforms enabled us to help considerably more patients than ever before. Different companies provide different waveforms. The fact that most companies could only offer one alternative waveform, created a dilemma of which waveform should be used to best treat the patients. The option of testing more than one waveforms in a luxury that only a few clinics have. The first multiwave IPG was introduced in 2015 and gave us considerable more options.

**Methods/Materials:** In 2019 we implanted 35 multiwave SCS Systems. All patients were filtered during trials and later controlled in the follow ups with the use of the official questionnaire of the german pain society. X Rays were used to control the placenment of the electrodes. All patients were trialed successfully before the permanent systems were implanted. All patients were trialed and later permanently implanted with a 16-contact SCS Electrode. According to our trial protocol all patients with a good intra operative coverage of the pain area through the paraesthesia, had tonic as the initial waveform and as a monotherapy. Patients with not a 100% coverage but still more than 70% got an alternativ waveform as an add-on programming. Patients with no satisfactory coverage of the pain areas had an alternativ waveform as the initial one. Patients were trialed for at least 10 days before a decision was made. Only patients with more than 50% pain relief were implanted. The follow ups were up to 12 months.

**Results:** Out of the 35 patients, 15 had initially tonic stimulation as monotherapy, 16 had a combination of tonic and Burst stimulation, 2 had a Burst stimulation, one had a micro Burst and one had a Whisper stimulation. During the last follow ups (6 to 12 months later) 10 patients retained there tonic stimulation as a monotherapy, 20 used a combination of tonic and Burst stimulation, two patients had Burst, two had Whisper and one stayed at micro Burst.

**Discussion:** The results demonstrate that Burst is an adequate alternative waveform to use. What is clearly stated is that tonic stimulation is still a very useful waveform and could still help a great deal of patients. A surprising result is the role that availability of multiple stimulation contacts in the stability the therapy.

**Conclusions:** Mutliwave platforms ensure a successful therapy. Nevertheless multiple stimulating contacts ensure the stability of the treatment.

### References:

**Keyword:** multiwave platforms, scs, pain

**Topic:** 05. Spine / 05a. Pain

## THERAPY DOSING IN SPINAL CORD STIMULATION: AN UPDATED REVIEW

### E-POSTER VIEWING

Louis Vera-Portocarrero<sup>1</sup>, Krishnan Chakravarthy<sup>2</sup>, Lawrence Poree<sup>3</sup>, Melanie Goodman Keiser<sup>1</sup>, Jeffrey Kramer<sup>1</sup>

<sup>1</sup>Research & Core Technology, Medtronic, Minneapolis, United States of America, <sup>2</sup>San Diego Health System, University of California, San Diego, San Diego, United States of America, <sup>3</sup>Anesthesiology And Pain Medicine, University of California at San Francisco, San Francisco, United States of America

**Introduction:** Therapeutic dosing of spinal cord stimulation (SCS) has historically been a process by which pulse amplitude and width were adjusted to anatomically match the area of pain with paresthesias, allowing the intensity of stimulation to be titrated to patient comfort. In sub-sensory stimulation, titrating dose becomes more difficult as patients are no longer a reliable estimate of dose apart from reporting pain relief. Acute dosing either remains related to paresthesias or programs must be set to a specific dose until the onset of pain relief occurs after 48 to 72 hours. Other aspects of chronic dosing (overall energy delivery, timing of delivery, etc.) should also be considered.

**Methods/Materials:** A literature review was completed in Pubmed and EMBASE using search terms "spinal cord stimulation" or SCS and each of the following terms: amplitude, dose, subparesthesia/ sub-paresthesia, subthreshold/ sub-threshold, subsensory/sub-sensory, paresthesia-independent/ paresthesia independent, paresthesia-free/ paresthesia free, paresthesia, threshold, accelerometry/accelerometer, neural sensing and evoked compound action potentials (ECAPs).

**Results:** A PubMed search yielded over 600 articles. Of these, the majority focused on acute dosing considerations (suprathreshold, subthreshold stimulation) and the minority focused on dosing (duty-cycling, ECAPs, etc.). Different acute control methods for dosing were implemented including patient, accelerometry or neural sensing. Various pulse amplitude studies report the impact of stimulation intensity, including lower and high frequencies. Studies also controlled total dose being delivered via cycling methods to regulate total dose over longer periods of time and ECAPs to maintain in a therapy window.

**Discussion:** Identified studies controlled SCS therapy dosing via a variety of mechanisms, including changing charge delivered (pulse amplitude, width or frequency), controlling device output via closed-loop paradigms (inertial accelerometry and neural sensing) and duty-cycling. Each dose control method can have specific applications and address individual needs, although the long-term implications are relatively unknown. Presumably, optimal dosing will provide better outcomes including enhanced pain relief, while reducing side effects. Which dosing paradigm may be optimal is not understood since there is a range of different stimulation parameters and patterns.

**Conclusions:** SCS dosing may be controlled via a variety of mechanisms and technologies that can impact dosing stability and may in turn have an impact on long-term efficacy.

### References:

**Keyword:** Spinal cord stimulation, Review, Subthreshold, Paresthesia-free, Sub-paresthesia

**Topic:** 05. Spine / 05a. Pain

## CLINICAL STUDY DESIGN METHODOLOGY FOR DOSING TITRATION OF SPINAL CORD STIMULATION

### E-POSTER VIEWING

Melanie Goodman Keiser<sup>1</sup>, Lachlan Davies<sup>2</sup>

<sup>1</sup>Research & Core Technology, Medtronic, Minneapolis, United States of America, <sup>2</sup>Clinical Pain Stim, Medtronic, Minneapolis, United States of America

**Introduction:** Spinal Cord Stimulation (SCS) is rapidly evolving with the use of new electrical parameter sets beyond what is considered conventional stimulation. This is accompanied by an increased interest in understanding the appropriate amount of energy or “dose” of SCS for patients. The amount of electrical energy delivered with SCS impacts clinical outcomes and the technology used for energy delivery, specifically battery size and recharge burden. This abstract reviews the design of recent feasibility studies that use a variety of methodologies to control and evaluate “dose” of SCS that could be incorporated into clinical practice in the future, including changing the amount of charge delivered (amplitude, pulse width, or frequency), controlling device output via closed-loop paradigms (inertial accelerometry and neural sensing), and duty-cycling.

**Methods/Materials:** Two clinical feasibility studies for dose titration were reviewed. The study designs are assessed, including limitations.

**Results:** Multiple studies have now employed dose titration methodologies in their assessments of related clinical outcomes. Three specific study designs change one experimental parameter while keeping others constant. The first increases the experimental parameter incrementally, the second decreases the experimental parameter, and the third randomizes the experimental parameters.

**Discussion:** One limitation of the “increasing” and “decreasing” study designs is that the subject might discern the resulting change to the next experimental parameter sets. This is most relevant for dosing with supra-perception SCS parameters. An example of the “decreasing” experimental design, the SCS Dosing study recorded each subject’s paresthesia threshold then reduced the amplitude at each follow-up visit. Subjects were blinded to these dose changes. The hypothesis of this study was that the subject pain relief would slowly increase with each incremental change. The parameters of interest in this study were high dose (1000Hz, 90µs). The baseline perception threshold of each subject was measured in two distinct postures. To date, no studies have been conducted with a randomized study design. A randomized study design would help to validate early feasibility study findings and remove potential bias in outcomes including the potentially confounding impact from the effects of previous therapy parameters.

**Conclusions:** Dosing titration study designs can be categorized into three types: increasing, decreasing, and randomized experimental parameters. Some studies can overcome the limitations inherent in the increasing and decreasing study design. The randomized study design would intrinsically produce the most reliable data, removing any potential bias when the outcome measure is subjective.

### References:

**Keyword:** Spinal cord stimulation, Clinical methodology, Study design, Dosing titration

**ADVERSE VASOVAGAL SYMPTOMS IN PATIENT WITH ACCIDENTAL T1 HIGH-FREQUENCY STIMULATION (120 HZ). A CASE REPORT**

**E-POSTER VIEWING**

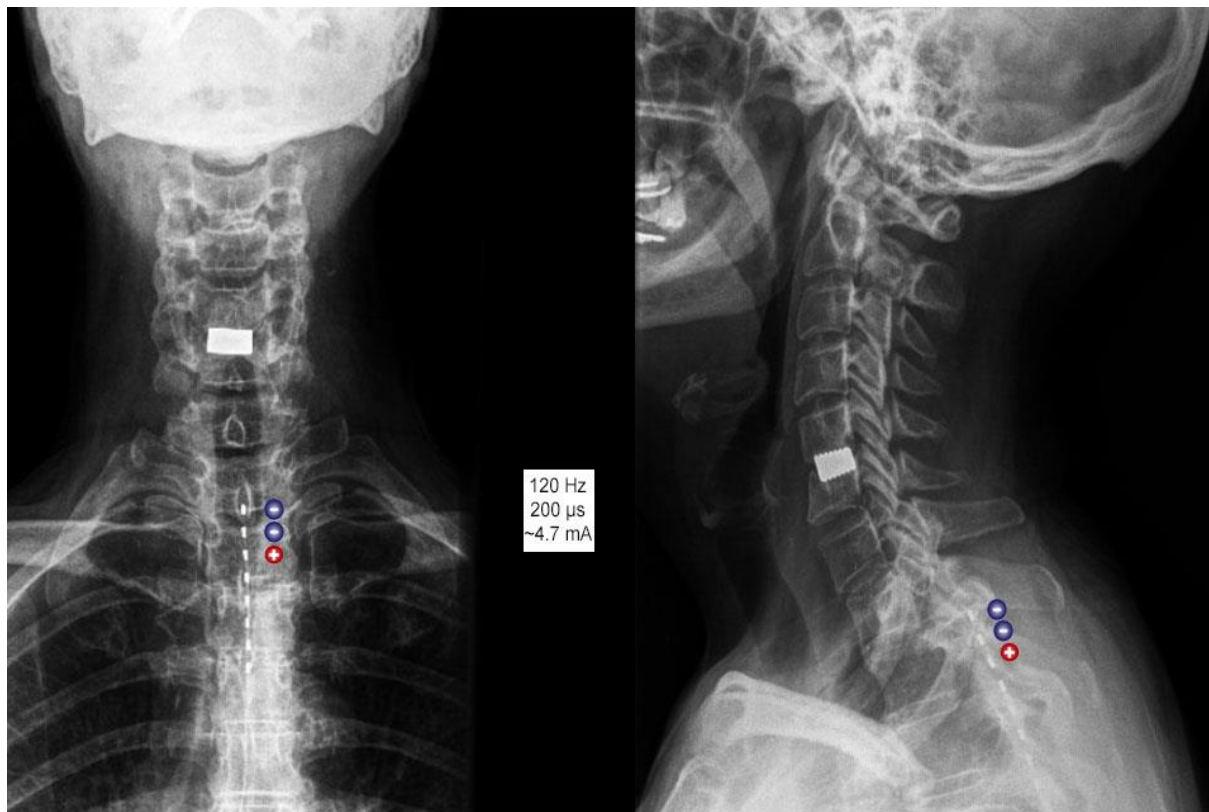
Aitziber Ereñozaga, Maria Luisa Franco, Deiene Lasuen  
Pain Unit, Hospital Universitario Cruces, Barakaldo, Spain

**Introduction:** Beneficial effects of high-thoracic spinal cord stimulation (SCS) in certain aspects of cardiac function such as contractility [1], sympathetic activity inhibition [2, 3, 4] and parasympathetic modulation [5] have been described. However, we have not been able to find any mention to potential adverse effects of T1-T2 SCS as the ones presented here.

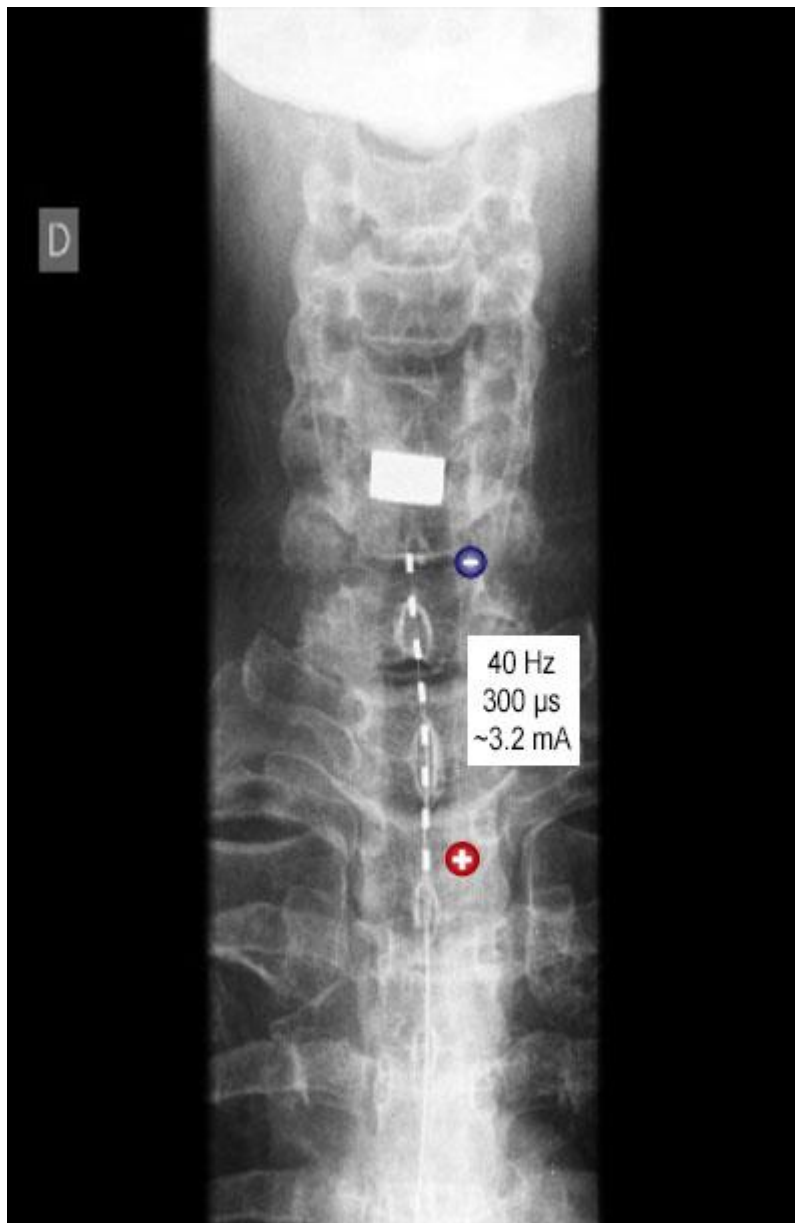
**Methods/Materials:** 58-year old female with cervical FBSS failed-neck Surgery syndrome implanted in September 2017 with a single octapolar lead at C6-C7 level for the management of chronic pain in shoulder and upper extremities. During the the 2-week trial phase the patient showed preference for a relatively high frequency settings (120 Hz), which was programmed in the permanent system with 200  $\mu$ s pulse-width and amplitudes ranging from 3.6 to 7.0 mA, obtaining high levels of pain reduction (78%) and patient satisfaction which remained constant, with no need of parameter modifications in the following 2 years.

**Results:** In September 2019 the patient came to the Clinic with loss of stimulation in the painful area and after having suffered several episodes of dizziness and fainting, compatible with the existence of vasovagal syncope. All attempts to recover the paresthesia in upper limbs were unsuccessful and stimulation was deactivated. X-Ray revealed that the lead had descended several vertebral levels and that the SCS system had been stimulating on T1-T2 (Fig 1). On the other hand, vasovagal symptoms disappeared after SCS deactivation. No pathologic issues were found in cardiologic (Holter, echocardiography, tilting table) or neurologic studies.





In November 2019 we proceeded to re-position the SCS lead at cervical levels (Fig 2), recovering both stimulation and relief in the patient's painful areas, although this time we used standard parametric settings (40 Hz, 300  $\mu$ s, 2.5-4.5 mA).



At the date of this report (Feb 2020), no dizziness or fainting episodes have recurred.

**Discussion:** Despite several studies describe beneficial modulatory effects of SCS on the autonomous nerve system related to chronotropic, dromotropic and inotropic heart functions, all these patients perused “conventional” stimulation frequencies of 50 Hz. In our patient, data seem to indicate that accidental T1 stimulation at relatively high frequencies may have produced adverse modulatory effects leading to severe dizziness and fainting episodes.

**Conclusions:** In the absence of deeper knowledge on the modulatory effects of high-thoracic stimulation with non conventional parametric ranges, especially those related to high frequencies, we recommend extreme precaution when selecting such settings when stimulating in (or around) T1-T2 spinal cord levels.

**References:** [1] Tse HF et al. Thoracic Spinal Cord Stimulation for Heart Failure as a Restorative Treatment (SCS HEART study): first-in-man experience. *Heart Rhythm*. 2015 Mar;12(3):588-595. [2] Liao SY et al. Remodelling of cardiac sympathetic re-innervation with thoracic spinal cord stimulation improves left ventricular function in a porcine model of heart failure. *Europace*. 2015 Dec;17(12):1875-83. [3] Foreman RD et al. Modulation of intrinsic cardiac neurons by spinal cord stimulation: implications for its therapeutic use in angina pectoris. *Cardiovasc Res*. 2000

Aug;47(2):367-75. [4] Armour JA et al. Long-term modulation of the intrinsic cardiac nervous system by spinal cord neurons in normal and ischaemic hearts. *Auton Neurosci*. 2002 Jan 10;95(1-2):71-9. [5] Jacques F et al. Spinal cord stimulation causes potentiation of right vagus nerve effects on atrial chronotropic function and repolarization in canines. Spinal cord stimulation causes potentiation of right vagus nerve effects on atrial chronotropic function and repolarization in canines.

**Keyword:** Spinal Cord Stimulation, High-Thoracic SCS, Autonomic Modulation, Syncope

**Topic:** 05. Spine / 05a. Pain

**SPINAL CORD STIMULATION FOR CONGENITAL TETHERED CORD SYNDROME – A CASE REPORT.**

**E-POSTER VIEWING**

Tadhg Lynch, Katie O'Neill, Satu Pelser, Catherine Butler, Jennifer Dillon  
Pain Medicine, Pain Clinic, Kilkenny, Ireland

**Introduction:** Tethered cord syndrome is a congenital condition where the spinal cord is tethered and subjected to increased tension, presenting with an array of musculoskeletal, neurological, gastrointestinal, or urological abnormalities<sup>1</sup>. Neuromodulation is potentially more difficult in patients with anatomical changes caused by a tethered spinal cord. Spinal cord stimulation is a minimally invasive approach to treating chronic pain due to a tethered spinal cord, reducing the need for strong opioid pain relief when other treatments have failed.

**Methods/Materials:** We report a 23-year-old caucasian woman with a history of persistent and severe lumbar back pain who was diagnosed with a tethered spinal cord and received significant benefit from spinal cord stimulation. MRI shows congenital fusion of vertebrae bodies L1/2/3/4 with a tethered low-lying cord unsuitable for spinal surgery. There was no nerve root encroachment or motor sensory neuropathy but radiating pain was reported. Prior to treatment patient described her pain was 7 to 9 on a numerical rating scale (NRS). Several pharmacological therapies were tried to alleviate symptoms including Diazepam, Diclofenac, Tramadol, and Fentanyl patch, combined with regular physiotherapy. Following pain specialist consultation, Tapentadol and Pregabalin medication was trialled. Following further evaluation steroid facet joint injection, denervation and epidural injection was performed, however our patient reported no relief.



**Results:** A spinal cord stimulator trial was performed and followed with a permanent implant. Following the implant, the patient reported a significant reduction in her pain levels, describing resting pain levels of 2/10 and moving pain of 4/10 on the VAS. She stopped taking painkillers most days, only occasional paracetamol. The implant was a Abbot/SJM primary cell IPG using Burst Stimulation.

**Discussion:** This is a successful example of spinal cord stimulation for tethered cord syndrome.

**Conclusions:** Spinal Cord Stimulation is an option for treating persistent spinal pain due to congenital tethered cord syndrome.

**References:** Hertzler DA, DePowell JJ, Stevenson CB, Mangano FT. Tethered cord syndrome: A review of the literature from embryology to adult presentation. *Neurosurg Focus*. 2010;29(1):1–9.

**Keywords:** burst stimulation, Tethered Cord, Congenital, Spinal cord stimulation, neuromodulation

Topic: 05. Spine / 05a. Pain

## NEXT-GENERATION CLOSED-LOOP, SPINAL CORD STIMULATION WITH DIFFERENTIAL TARGET MULTIPLEXED THERAPY

### E-POSTER VIEWING

Ricardo Vallejo<sup>1</sup>, Krishnan Chakravarthy<sup>2</sup>, Andrew Will<sup>3</sup>, Abigail Skerker<sup>4</sup>, David Dinsmoor<sup>4</sup>, David Cedeno<sup>5</sup>

<sup>1</sup>Interventional Pain Medicine, Millennium Pain Center, Bloomington, United States of America, <sup>2</sup>San Diego Health System, University of California, San Diego, San Diego, United States of America, <sup>3</sup>Pain Management, Twin Cities Pain Clinic, Edina, United States of America, <sup>4</sup>Restorative Therapies Group, Medtronic, Minneapolis, United States of America, <sup>5</sup>Research, SGX Medical, Bloomington, United States of America

**Introduction:** Recent advances in spinal cord stimulation (SCS) have focused on two highly novel areas; (1) differential target, multiplexed (DTM) SCS, which has demonstrated superior pain relief, and (2) the spinal Evoked Compound Action Potential (ECAP), a bioelectrical signal used as a measure of neural activation with closed-loop (CL) SCS systems to compensate for physiologic variability.<sup>1</sup> Simultaneous application of both approaches may allow for a new generation of neural responsive SCS that blends a science-based methodology for pain management with real-time, CL control for biophysical variation. In this study, CL DTM-SCS was explored to determine control characteristics of the system in the clinical setting.

**Methods/Materials:** Included here are a sample of ten subjects who underwent a DTM SCS trial using dual percutaneous 1x8 leads placed near T9. Following the trials and within the 10 days allowed per labeling, the leads were connected to an investigational neurostimulation system capable of recording ECAPs and delivering a novel CL DTM-SCS pattern.<sup>2</sup> The stimulating electrodes and frequencies were selected for consistency with typical DTM programming paradigms. The control policy parameters and nominal charge/phase (Q/ph) of DTM<sub>BASE</sub>—one component of the DTM waveform, also used to elicit the ECAP—was selected to optimize comfort and mitigate variability in neural activation over a range of aggressor activities, such as a back arch. The Q/ph of the priming component of DTM, DTM<sub>PRIME</sub>, was programmed relative to DTM<sub>BASE</sub>. The subjects were then asked to re-perform the aggressor activities while the system was operated for a minute in both the open-loop (OL) and CL configurations. ECAP variability in both configurations was calculated to assess the capability of CL DTM-SCS to control neural activation versus OL DTM-SCS.

**Results:** Across the subjects, average ECAP variability—and presumably variability in neural activation with the DTM SCS—was reduced by 51% ( $p < 0.001$ ) in the CL arm (3.5  $\mu$ V) versus the OL arm (7.1  $\mu$ V). On average, the CL DTM-SCS system modulated the stimulation Q/ph (DTM<sub>BASE</sub> and DTM<sub>PRIME</sub>) by  $13\% \pm 10\%$ .

**Discussion:** These results demonstrate the technical feasibility of CL DTM-SCS on conventional 1x8 leads, with the CL policy limiting ECAP amplitude variability by about a half versus the conventional OL configuration.

**Conclusions:** Potential benefits of this approach may include a more durable therapy and consistent outcomes, as well as broader SCS programming options customized for the patient. Further study is needed to characterize the chronic utility and associated clinical benefits of these methods.

**References:** 1. Russo M, Cousins MJ, Brooker C, et al. Effective Relief of Pain and Associated Symptoms With Closed-Loop Spinal Cord Stimulation System: Preliminary Results of the Avalon Study. *Neuromodulation*. 2018;21(1):38-47. doi:10.1111/ner.12684

2. Chakravarthy K, Bink H, Dinsmoor D. Sensing evoked compound action potentials from the spinal

cord: Novel preclinical and clinical considerations for the pain management researcher and clinician. J Pain Res. 2020;13:3269-3279. doi:10.2147/JPR.S289098

**Keyword:** ECAP, closed-loop, SCS

## THE IMPACT OF DRG STIMULATION ON PAIN LEVELS AND FUNCTIONALITY IN PATIENTS WITH CHRONIC POST SURGICAL KNEE PAIN.

### E-POSTER VIEWING

Björn Carsten Schultheis

Interventionelle Schmerztherapie, Krankenhaus Neuwerk, Mönchengladbach, Germany

**Introduction:** Dorsal Root Ganglion Stimulation showed its longterm efficacy to treat chronic pain after knee surgery <sup>1, 2, 3</sup>. Up to date functional outcome parameters were not measured. We studied the outcome of DRG-Stimulation over 12 months to evaluate its impact on pain levels and functional parameters.

**Methods/Materials:** This prospective, longitudinal multi-center study was performed in academic medical centers in Germany. 11 Patients (age >18 years) with chronic persistent pain after knee surgery were prospectively examined. All patients had to complete an interdisciplinary multimodal pain therapy were a treatable cause for the pain was ruled out. After 2 diagnostic testblocks with a pain reduction of more than 50%, patients were scheduled for DRG-Implantation on the corresponding levels. After a successful trial (9-13 days, pain decrease >50%) the patients were scheduled for the IPG Implantation. Patients were re-examined after 1, 3, 6 and 12 months. We used the IKDC including functional parameters (questionnaire of the international knee documentation comitee), GGZ (Gegenwärtiger Gesundheitszustand-current Health-Status), VAS, Becks Depression Index (BDI), Pain Detect Questionnaire (PD-Q), van Korff, the Pain Disability Index (PDI) and changes in Medication. Walking distance, Range of motion of the knee, walk and perform changes in direction and speed. Changes in medication at Baseline (BL), End of Trial (EOT) and at the end of the study (EOS).

**Results:** We included 11 patients (3 male, 8 female, age 64 (24-79)), Implantation levels in 9 patients (L3, L4), 1 patient (L2, L3, L4) and 1 Patient (L3, L4, L5). 8 patients were diagnosed with a mononeuropathy and 3 with a CRPS. After 1 year, the median VAS dropped from VAS 8,7 to 3,3 at EOS. Functionality improved in the IKDC (Avg.) from 27,73 at BL to 41,83 at EOT and 50,80 at EOS. The GGZ (Avg.) improved 69,27 to 88,18, BDI decreased from 13,45 (Avg.) to 11,64 after 12 months. Functionality improved in average from 2,64 to 4,73. The PDI improved from 41,36 (Avg.) to 25,10 and the PD-Q showed a decrease in neuropathic pain from 19,39 (Avg.) to 13,00 at EOT. All patients decided after 1 year to take the same decision again to be implanted.

**Discussion:** DRG stimulation does not only improve pain scores and reduces medication usage but also improves functionality of the effected limb. This study is limited by the small number of patients.

**Conclusions:** DRG Stimulation is an effective method to improve persistent neuropathic pain and functionality in this group of patients.

**References:** 1. Kretzschmar M.; Reining M. : Opioid withdrawal during DRGS treatment of chronic neuropathic Pain after peripheral nerve injury NANS congress L.V. 2020 2. Morgalla MH, Bolat A, Fortunato M, et al. Dorsal Root Ganglion Stimulation Used for the Treatment of Chronic Neuropathic Pain in the Groin: A Single-Center Study With Long-Term Prospective Results in 34 Cases. Neuromodulation. December 2017;20(8):753-760. doi:10.1111/ner.12713 3. Morgalla et al. Dorsal Root Ganglion Stimulation (DRGS) for the Treatment of Chronic Neuropathic Pain: A Single-Center Study with Long-Term Prospective Results in 62 Cases. Pain Physician. 2018;21:E377-E387.

**Keyword:** Knee pain, functional outcome parameters, chronic neuropathic pain, neuromodulation, dorsal root gan



**Topic:** 05. Spine / 05a. Pain

## CLINICAL UTILIZATION OF FAST-ACTING SUB-PERCEPTION THERAPY (FAST) IN SCS-IMPLANTED PATIENTS FOR TREATMENT OF MIXED NOCICEPTIVE AND NEUROPATHIC PAIN

### E-POSTER VIEWING

Georgios Matis<sup>1</sup>, Roshini Jain<sup>2</sup>, Lilly Chen<sup>2</sup>, Que Doan<sup>3</sup>

<sup>1</sup>Department Of Stereotactic And Functional Neurosurgery, University Hospital Cologne, Cologne, Germany, <sup>2</sup>Clinical Research, Boston Scientific, Valencia, United States of America, <sup>3</sup>Research And Development, Boston Scientific, Valencia, United States of America

**Introduction:** Mixed pain is increasingly recognized as a clinical description applied to patients that do not display discrete symptoms associated with either nociceptive (i.e. pain derived from non-neuronal tissue and nociceptor activation) or neuropathic (i.e. pain derived from lesion or disease that satisfies established neurological diagnostic criteria) pain syndromes.<sup>1,2</sup> Patients implanted with Spinal Cord Stimulation (SCS) devices can be frequently observed to exhibit mixed pain, but may present as challenging cases given the potentially heterogenous manifestation of their symptoms of chronic pain.<sup>3</sup> A recent study now reports the discovery and use of a novel SCS methodology (FAST) capable of delivering therapeutic neurostimulation using a biphasic-symmetric waveform based on active recharge, sub-perception SCS that is capable of inducing analgesia within minutes.<sup>4</sup> We surmised that this new neurostimulative approach may help to possibly improve outcomes in a population of SCS-implanted patients with mixed pain and report real-world preliminary experience in an observational, case-series.

**Methods/Materials:** This is a single-center, retrospective, observational case-series of patients demonstrating symptoms of mixed pain who were implanted with a (Boston Scientific Neuromodulation, Valencia, CA, USA) manufactured SCS device (or are converted to a new SCS system) capable of multiple independent current control (MICC) and fast-acting sub-perception therapy (FAST), as described previously.<sup>4</sup> Clinical assessments as collected per standard of care included painDETECT score, pain intensity scores (VAS), Oswestry Disability Index (ODI), opioid drug medication intake, and Quality-of-Life (EQ-5D-5L) prior to implant and follow up to 6 months post-implant.

**Results:** Analysis of collected study data is currently on-going. Determined clinical outcomes will be presented.

**Discussion:** Newly uncovered SCS techniques offer the potential to re-address longstanding challenges associated with treating patients with chronic pain. In particular, novel neurostimulative methods may mediate analgesic responses via mechanisms that differ from traditional approaches, thus presenting the potential for expanding the array of indications for which SCS may be successfully used (e.g. nociceptive pain syndromes).

**Conclusions:** This initial, single-center evaluation will seek to determine if SCS-based FAST can effectively treat or improve outcomes in patients reporting complex symptom complaint, characteristic of mixed pain.

**References:** 1. Treede RD, Jensen TS, Campbell JN, et al. Neuropathic pain: redefinition and a grading system for clinical and research purposes. *Neurology*. 2008;70:1630–1635. 2. IASP Terminology [Internet]. Washington DC, USA: International Association for the Study of Pain; [updated 2017 Dec 14]. Accessed April 6<sup>th</sup>, 2021; <https://www.iasp-pain.org/terminology?navItemNumber=576>. 3. Maheshwari A, Pope JE, Deer TR, Falowski S. Advanced methods of spinal stimulation in the treatment of chronic pain: pulse trains, waveforms, frequencies, targets, and feedback loops. *Expert Rev Med Devices*. 2019 Feb;16(2):95-106. 4. Metzger CS, Hammond MB, Paz-Solis JF, Newton WJ, Thomson SJ, Pei Y, Jain R, Moffitt M,

Annecchino L, Doan Q. A novel fast-acting sub-perception spinal cord stimulation therapy enables rapid onset of analgesia in patients with chronic pain. *Expert Rev Med Devices*. 2021 Mar 3:1-8.

**Keyword:** spinal cord stimulation, chronic pain, FAST, sub perception, nociceptive, neuropathic

**Topic:** 05. Spine / 05a. Pain

## DETOXIFICATION OF NEUROMODULATION ELIGIBLE PATIENTS BY A STANDARDISED PROTOCOL

### E-POSTER VIEWING

Ali Jerjir<sup>1</sup>, Lisa Goudman<sup>2</sup>, Jean-Pierre Van Buyten<sup>1</sup>, Ann De Smedt<sup>3</sup>, Iris Smet<sup>1</sup>, Marieke Devos<sup>1</sup>, Maarten Moens<sup>2</sup>

<sup>1</sup>Multidisciplinary Pain Center, AZ Nikolaas, Sint-Niklaas, Belgium, <sup>2</sup>Neurosurgery, UZ Brussel, Jette, Belgium, <sup>3</sup>Physical Medicine And Rehabilitation, Universitair Ziekenhuis Brussel, Jette, Belgium

**Introduction:** Patients eligible for Spinal Cord Stimulation (SCS) generally require a higher opioid consumption, due to experiencing a lot of pain, which is usually an indication for SCS implantation. After final implantation, SCS has the ability to stabilize or decrease opioid usage in around 50% of the patients. We here propose a strategy to actively eliminate opioids, prior to implantation of any neuromodulation device with a standardized detoxification protocol. This study aims to explore the feasibility, effectiveness and safety of this opioid detoxification protocol prior to neuromodulation techniques.

**Methods/Materials:** In this single-center study, 70 patients who were taking opioids and who were eligible for neuromodulation techniques, underwent the detoxification program. A combined in- and out-patient clinic protocol was applied, whereby clonidine was the main component of both parts of the program. A multidisciplinary team with pain physicians and psychologists was responsible for performing this detoxification program whereby safety and feasibility were systematically recorded during the hospitalization.

**Results:** No serious safety issues were reported. At the start of the program, patients reported a mild sedative effect of clonidine. Additionally, most patients presented mild symptoms of opioid withdrawal, which were partially countered by the sedative effect of clonidine. Concerning the effectiveness, a statistically significant decrease in median morphine milligram equivalents (MME) was found with a MME of 175 (Q1-Q3: 118.1 – 240) at baseline and at the last available follow-up visit the MME was 0 (Q1-Q3: 0 – 16.88). Both patients and the medical staff found this protocol feasible in clinical practice.

**Discussion:** Detoxification of opioids prior to neuromodulation can be achieved with a protocol combining an in-hospital and out-clinic part. Detoxification with this standardized protocol has proven to be safe in patients eligible to neuromodulation techniques.

**Conclusions:** This standardised detoxification program has proven its effectiveness, safety and feasibility in this single-center experience study in patients eligible for neuromodulation techniques.

### References:

**Keywords:** detoxification, Opioids, withdrawal, neuromodulation, Pain Medicine

**Topic:** 05. Spine / 05a. Pain

## **TREATMENT OF UPPER LIMB AND NECK PAIN USING AN SCS SYSTEM WITH PATIENT-SPECIFIC PROGRAMMING AND NEURAL TARGETING CAPABILITIES**

### **E-POSTER VIEWING**

Sylvie Raoul<sup>1</sup>, Jing Wang<sup>2</sup>, Holly Kaufman<sup>2</sup>, Roshini Jain<sup>2</sup>

<sup>1</sup>Neurosurgery, University Hospital Nantes, Nantes, France, <sup>2</sup>Clinical, Boston Scientific Neuromodulation, Valencia, United States of America

**Introduction:** Although several published studies have previously shown that positive clinical outcomes are attainable in patients using paresthesia-based cervical Spinal Cord Stimulation (SCS) for treatment of chronic upper limb or neck pain, this particular sub-population can potentially be difficult to treat and some may experience loss of pain relief over time.<sup>1-3</sup> Modern technological advances however now offer SCS using techniques that are increasingly more customized to the individual including the ability to conduct precise parameter optimization and positional targeting of therapeutic neurostimulation. We therefore chose to investigate whether cervical SCS patients with chronic upper limb and neck pain would be observed to obtain highly effective outcomes when implanted with a system equipped with these device capabilities.

**Methods/Materials:** This is a single-center, retrospective, observational case-series of patients demonstrating symptoms of upper limb and neck pain who underwent a cervical SCS implantation procedure. All included patients were implanted with a Boston Scientific-manufactured SCS device (or converted to a new system) capable of the selective use of multiple neurostimulative modalities including (but not limited to) conventional tonic stimulation, sub-perception-based programming and stimulation field targeting, and combination therapy. Clinical assessments were collected prior to implant and at follow-up timepoints up to 6-months post-implant (per standard of care) and include pain intensity scores (VAS) and other quality of life assessments.

**Results:** Analysis of collected study data is currently on-going and clinical outcomes to be presented.

**Discussion:** Previously published studies indicate that patients provided with a system capable of patient-specific customization of SCS can obtain highly effective clinical outcomes.<sup>4-6</sup> As such, outcomes may be improved in those suffering with chronic upper limb and neck pain who are implanted with such a device relative to the results reported in earlier studies using older generation SCS systems as assessed in this specific patient sub-population.

**Conclusions:** This initial, single-center evaluation seeks to determine if chronic upper limb and neck pain can be effectively treated using an SCS device with patient-specific programming and neural targeting capabilities.

**References:** 1. Deer TR, Skaribas IM, Haider N et al. Effectiveness of cervical spinal cord stimulation for the management of chronic pain. *Neuromodulation*. 2014;17(3):265-27 2. Haider S, Owusu-Sarpong S, Peris Celda M et al. A single center prospective observational study of outcomes with tonic cervical spinal cord stimulation. *Neuromodulation*. 2017;20(3):263-268. 3. Levine AB, Parrent AG, MacDougall KW. Cervical spinal cord and dorsal nerve root stimulation for neuropathic upper limb pain. *Can J Neurol Sci*. 2017;44(1):83-89. 4. Veizi E, Hayek SM, North J, Brent Chafin T, Yearwood TL, Raso L, Frey R, Cairns K, Berg A, Brendel J, Haider N, McCarty M, Vucetic H, Sherman A, Chen L, Mekel-Bobrov N. Spinal Cord Stimulation (SCS) with Anatomically Guided (3D) Neural Targeting Shows Superior Chronic Axial Low Back Pain Relief Compared to Traditional SCS-LUMINA Study. *Pain Med*. 2017 Aug 1;18(8):1534-1548. 5. Metzger CS, Hammond MB, Pyles ST, Washabaugh EP 3rd, Waghmarae R, Berg AP, North JM, Pei Y, Jain R. Pain relief outcomes using an SCS device capable of delivering combination therapy with advanced waveforms and field shapes. *Expert Rev Med Devices*. 2020 Sep;17(9):951-957. 6. Duse G, Reverberi C, Dario A. Effects of

Multiple Waveforms on Patient Preferences and Clinical Outcomes in Patients Treated with Spinal Cord Stimulation for Leg and/or Back Pain. *Neuromodulation*. 2019 Feb;22(2):200-207.

**Keywords:** neck pain, upper limb pain, Spinal cord stimulation, cervical, SCS, chronic pain

Topic: 05. Spine / 05a. Pain

## CHARACTERIZATION OF DIFFERENT ENERGY PROFILES OF DIFFERENTIAL TARGET MULTIPLEXED SPINAL CORD STIMULATION

### E-POSTER VIEWING

Michael Fishman<sup>1</sup>, John Hatheway<sup>2</sup>, Andrew Will<sup>3</sup>, Binit Shah<sup>4</sup>, Gobi Paramanandam<sup>5</sup>, David Provenzano<sup>6</sup>, Kasra Amirdelfan<sup>7</sup>, Michael Esposito<sup>8</sup>, Kliment Gatzinsky<sup>9</sup>, Prabhdeep Grewal<sup>10</sup>, Jan Willem Kallewaard<sup>11</sup>, Lawrence Poree<sup>12</sup>, Jason Brown<sup>13</sup>, Andrew Cleland<sup>13</sup>, Erin Theis<sup>13</sup>

<sup>1</sup>Pain Medicine, Center for Interventional Pain and Spine, Lancaster, United States of America, <sup>2</sup>Pain Management, Northwest Pain Care, Spokane, United States of America, <sup>3</sup>Pain Management, Twin Cities Pain Clinic, Edina, United States of America, <sup>4</sup>Pain Management, Carolinas Pain Institute, Winston-Salem, United States of America, <sup>5</sup>Pain Medicine, Center for Pain and Supportive Care, Phoenix, United States of America, <sup>6</sup>Interventional Pain Medicine, Pain Diagnostics and Interventional Care, Sewickley, United States of America, <sup>7</sup>Pain Medicine, IPM Medical Group, Inc., Walnut Creek, United States of America, <sup>8</sup>Pain Medicine, Florida Pain Institute, Melbourne, United States of America, <sup>9</sup>Neurosurgery, Sahlgrenska University Hospital, Gothenburg, Sweden, <sup>10</sup>Pain Medicine, TSAOG Orthopaedics, San Antonio, United States of America, <sup>11</sup>Anesthesiology And Pain Management, Rijnstate Hospital, Arnhem, Netherlands, <sup>12</sup>Anesthesiology And Pain Medicine, University of California at San Francisco, San Francisco, United States of America, <sup>13</sup>Neuromodulation, Medtronic, Minneapolis, United States of America

**Introduction:** Differential Target Multiplexed (DTM™) spinal cord stimulation (SCS) has shown superior back pain relief to traditional SCS<sup>1,2</sup> and has expanded the understanding of mechanism of action through preclinical studies demonstrating glial cell modulation.<sup>3,4,5,6</sup> Along with the development of advanced stimulation patterns, energy dosing and waveform optimization for different environments are being explored. This study characterizes the efficacy and energy use of a stimulation pattern designed using the principles of DTM SCS with modifications to better understand energy requirements.

**Methods/Materials:** This prospective, multicenter, post-market feasibility study enrolled a cohort of patients implanted with a rechargeable neurostimulation system to treat chronic intractable back and leg pain. Eligible cohort subjects that were implanted for at least 3 months and satisfied with SCS therapy went through a therapy washout period before being programmed to a series of DTM SCS settings with different energy profiles. After initial programming adjustments based on patient satisfaction, including intensity titration and therapy cycling settings, patients were followed for 3 months. Outcomes including Numeric Pain Rating Scale (NPRS) scores were recorded in a pain diary and patient satisfaction was recorded at the follow-up visits.

**Results:** Twenty-two patients from six US sites were enrolled in the study, with an average age of 62.4 years, 60% female. The main etiologies included post laminectomy pain/failed back surgery syndrome (72.7%), radicular pain syndrome (18.2%), and degenerative disc disease (9.1%). Average time since SCS implant was 1.6 years, with a range from 4 months to 3.3 years. Subjects were enrolled from October 30, 2020 through March 24, 2021 and are currently in follow-up. Characterization of pain scores and satisfaction throughout the follow-up periods and program energy delivery calculations will be presented. This abstract will present full results from the study including all subjects with three-month follow-up data.

**Discussion:** Advanced SCS patterns can employ energy conserving programming approaches through therapy cycling as well as manipulations of amplitude, frequency, and pulse width. These approaches have the potential to impact patient experience with rechargeable devices and to benefit those patients best suited for recharge-free devices.

**Conclusions:** This study will provide data characterizing the energy use of new DTM SCS programming methodologies.

**References:** Fishman M, Cordner H, Justiz R, et al. Randomized Controlled Clinical Trial to Study the Effects of Differential Target Multiplexed™ SCS (DTM™ SCS) in Treating Intractable Chronic Low Back Pain: Long-term Follow-Up Results. Presented at: North American Neuromodulation Society 24<sup>th</sup> Annual Meeting. Jan 15-16, 2021. Virtual. Vallejo R, Fishman M, Cordner H, et al. Differential Target Multiplexed™ SCS (DTM™ SCS) for Treating Intractable Chronic Low Back and Leg Pain: Profound Response and Long-Term Benefits in Quality of Life. Presented at: North American Neuromodulation Society 24<sup>th</sup> Annual Meeting. Jan 15-16, 2021. Virtual. Vallejo R, Kelley CA, Gupta A, Smith WJ, Vallejo A, Cedeño DL. Modulation of neuroglial interactions using differential target multiplexed spinal cord stimulation in an animal model of neuropathic pain. *Mol Pain*. 2020 Jan-Dec;16:1744806920918057. Vallejo R, Smith W, Kelley C, et al. Neuron-glia inflammasome enhanced reversal by DTM-SCS relative to high rate and low rate SCS in a neuropathic pain model. American Society for Regional Anesthesiology and Pain Medicine (ASRA); November 14-17, 2019; New Orleans, LA. Abstract #480. Vallejo R, Kelley C, Smith W, et al. Cell-specific targeting in neural tissue using Differential Target Multiplexed (DTM) SCS. American Society for Regional Anesthesiology and Pain Medicine (ASRA); November 14-17, 2019; New Orleans, LA. Abstract #513. Vallejo R, Tilley D, Kelley C, et al. Proteomics of Differential Target Multiplexed-SCS applied to an animal model of neuropathic pain. American Society for Regional Anesthesiology and Pain Medicine (ASRA); November 14-17, 2019; New Orleans, LA. Abstract #509.

**Keywords:** Pain, Differential Target Multiplexed Spinal Cord Stimulation, Spinal Cord Stimulation (SCS), Reduced Energy

Topic: 05. Spine / 05a. Pain

## A NEW SPINAL CORD STIMULATION PARADIGM TO ACTIVATE THE DORSAL HORN – 14 WEEK CLINICAL TRIAL RESULTS

### E-POSTER VIEWING

Marc Russo<sup>1,2</sup>, Willem Volschenk<sup>1,2</sup>, Michael Holt<sup>1</sup>, Danielle Santarelli<sup>1</sup>

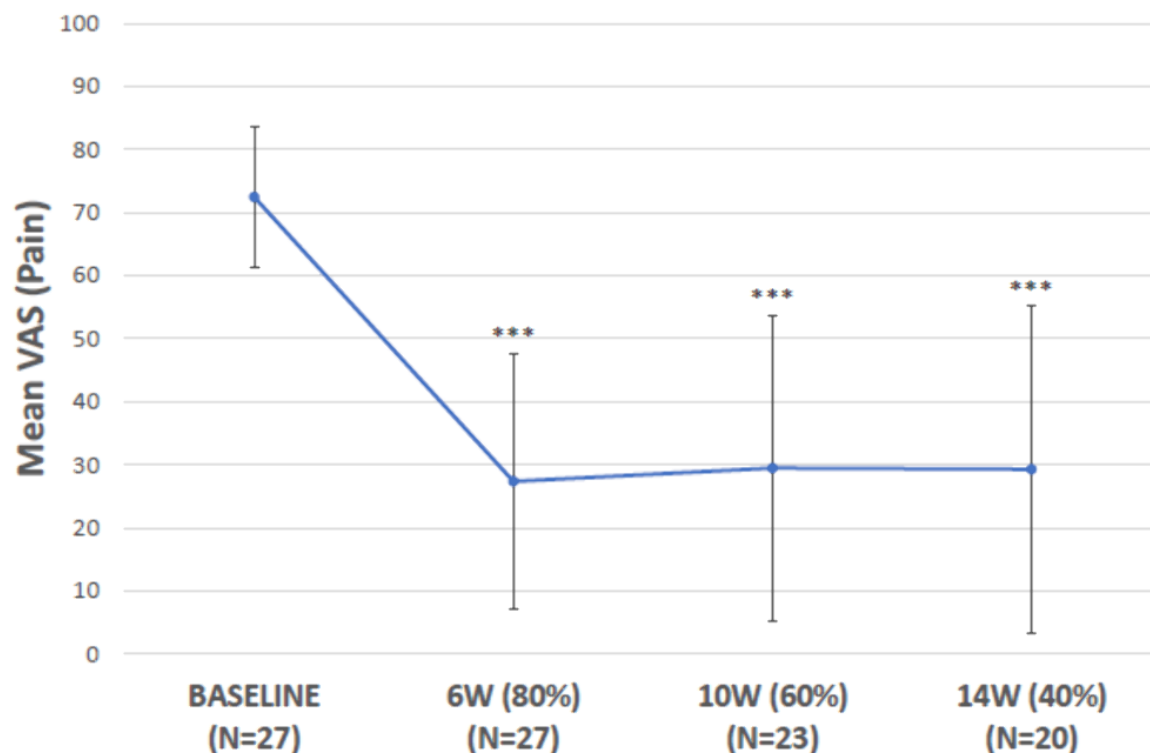
<sup>1</sup>Research, Genesis Research Services, Broadmeadow, Australia, <sup>2</sup>Pain Physician, Hunter Pain Specialists, Broadmeadow, Australia

**Introduction:** Subwave is a paresthesia-free spinal cord stimulation (SCS) waveform designed to treat chronic neuropathic low back pain by activating the dorsal horn to directly inhibit incoming nociceptive traffic. The therapy consists of a T9/10 disc bipole, 100Hz stimulation frequency, an extra wide pulse-width of 1000µs, and amplitude set to 80% perception threshold or lower. This achieves sufficient net activation charge per pulse that spreads far laterally to capture dorsal horn action potentials at the point of major traffic synapsing whilst remaining paresthesia-free.

**Methods/Materials:** Patients with chronic neuropathic low back pain were implanted with an SCS system (Intellis™, Medtronic) after a successful trial of Evolve (HD)<sup>SM</sup> (Medtronic) and Subwave 80%. Implanted patients are initially programmed to 80% stimulation perception, then 60%, then 40%, with follow-up at 6-, 10-, and 14-weeks, respectively. Patients are blinded to program settings. Program step-up is allowed (dose rescue). Patient reports of pain intensity and interference (visual analogue scale: VAS; Brief Pain Inventory: BPI), quality of life (EQ-5D-5L) and health status (SF-36) are collected at baseline and follow-up visits. Treatment satisfaction and clinician global impression of change are reported at follow-up visits. Patients report their preferred program at 14-weeks.

**Results:** 27 patients were implanted and have completed the first follow-up visit. Mean baseline VAS was  $72.5 \pm 11.2$ , reduced to  $27.4 \pm 20.3$  at 6-weeks post-activation on the 80% program ( $p < 0.001$ , mean change 61.2%). Mean VAS at 10-weeks (60% program) was  $29.5 \pm 24.3$  ( $n=23$ ,  $p < 0.001$ , mean change 59.4%), and at 14-weeks (40% program)  $29.3 \pm 25.9$  ( $n=20$ ,  $p < 0.001$ , mean change 59.3%). Significant improvements to BPI and EQ-5D-5L (index and VAS) were also seen at all 3 visits / programs. The most preferred programs were 80% (47.8% of patients) and 40% (39.1% of patients). All patients reported that they were “satisfied” or “very satisfied” with the 80% program (87% with the 60% program and 90% with the 40% program). There were no serious therapy-related adverse events.





**Discussion:** The complete 14-week data will be presented at the meeting. Current results support the effectiveness of all Subwave programs and high patient satisfaction. Only 4 patients requested program step-up within the 14-week scheduled programming phase.

**Conclusions:** Subwave appears to be an effective and safe SCS programming paradigm for patients with chronic neuropathic low back pain. Data collection will continue to 1-year post-activation for all patients on their preferred program.

#### References:

**Keywords:** chronic low back pain, low back pain, dorsal horn, neuropathic pain, paresthesia-free, Spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

## POSTOPERATIVE INFECTIONS ASSOCIATED WITH PROLONGED SCS TRIAL DURATION (PROMISE RCT)

### E-POSTER VIEWING

Richard North<sup>1</sup>, Mehul Desai<sup>2</sup>, Johan Vangeneugden<sup>3</sup>, Christian Raftopoulos<sup>4</sup>, Tony Van Havenbergh<sup>5</sup>, Marc Deruytter<sup>6</sup>, Jean-Michel Remacle<sup>7</sup>, Jane Shipley<sup>1</sup>, Ye Tan<sup>8</sup>, Mary Jo Johnson<sup>8</sup>, Carine Van Den Abeele<sup>9</sup>, Philippe Rigoard<sup>10</sup>

<sup>1</sup>N/a, The Neuromodulation Foundation, Inc., Baltimore, United States of America, <sup>2</sup>Pain Medicine, International Spine, Pain & Performance Center, Washington, United States of America, <sup>3</sup>Department Of Neurosurgery, Sint Maarten General Hospital, Duffel, Belgium, <sup>4</sup>Department Of Neurosurgery, University Hospital St-Luc (UCL), Brussels, Belgium, <sup>5</sup>Department Of Neurosurgery, GZA - Sint Augustinus Hospital, Wilrijk, Belgium, <sup>6</sup>Department Of Neurosurgery, AZ Delta Hospital, Roeselare, Belgium, <sup>7</sup>Department Of Neurosurgery, La Citadelle Regional Hospital, Liège, Belgium, <sup>8</sup>Department Of Clinical Research, Medtronic, Minneapolis, United States of America, <sup>9</sup>Department Of Clinical Research, Medtronic, Tolochenaz, Switzerland, <sup>10</sup>Department Of Neurosurgery, Poitiers University Hospital, Poitiers, France

**Introduction:** Infection, with reported rates of 2.45 to 5% in large SCS studies and up to 14% in small series, (1-6) is the most common complication leading to costly replacement of SCS systems.(7) In the multinational PROMISE RCT of SCS with multicolumn surgical leads for low back pain, clinicians followed their usual practice.(8) An early, unplanned safety analysis revealed an infection rate in Belgium (5/23), where trials lasted a median 21.5 days, versus 1/64 in the other study countries (median 5.8 days,  $p < 0.01$ ).

**Methods/Materials:** We reviewed PROMISE study infections and used descriptive statistics and tests of independent variables, to analyze potentially contributing factors (age, sex, coexisting medical conditions, tobacco use, lead type, and trial duration). We compared Kaplan-Meier cumulative incidence curves between those with infections and those infection-free using a log-rank test.

**Results:** Among 9 (5.2%) infections in 174 subjects trialed, the only significant contributing factor was trial duration: median 21 days (range 3 to 56) for infection versus 6 days (1 to 41) for none ( $p = 0.001$ , Wilcoxon Rank Sum test). The cumulative incidence of infection for trials  $> 10$  days was 24.1% versus 1.4% for trials  $\leq 10$  days ( $p < 0.001$ ). After protocol amendment limited trials to 10 days, 14 infection-free trials occurred in Belgium.

**Discussion:** This is the first examination of the duration of screening trials as an infection risk in a prospective study (in a large retrospective case series trials of  $> 5$  days resulted in an average infection rate of 3.70% compared with 1.58% for trials  $< 5$  days [3]). One previous study from Belgium reported a rate of 8.8% (9) and a larger series 4.8%.(10) In 2018, product labeling for these surgical leads clarified that they are not indicated for screening trials beyond the OR. Even when patients are not clinically infected, explanted SCS trial leads are frequently colonized with bacteria.(11,12) Thus, implanting a new system for chronic use might mitigate the risk of infection (a retrospective study involving 286 patients reported an infection rate of 1.35% after discarding the trial lead versus 6.52% after retaining it,  $p=0.02$  [13]). Our 1.8% rate with temporary percutaneous leads versus 6.8% with retained surgical leads was not statistically significant in our smaller sample.

**Conclusions:** Although not in the pre-planned analysis, our observation supports the hypothesis of a cause-effect relationship between trial duration and the risk of infection and the conclusion that prolonged SCS trials should be avoided.

**References:** 1. Bendersky D, Yampolsky C. Is spinal cord stimulation safe? A review of its complications. *World Neurosurg* 2014;82:1359-1368 2. Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *J Neurosurg* 2004;100:254-

67. 3. Hoelzer BC, Bendel MA, Deer TR, Eldridge JS, Walega DR, et al. Spinal cord stimulator infection rates and risk factors: a multicenter retrospective study. *Neuromodulation* 2017;20:558-562. 4. Kumar K, Wilson J, Taylor R, Gupta S. Complications of spinal cord stimulation, suggestions to improve outcome, and financial impact. *J Neurosurg Spine* 2006;5:191-203. 5. Mekhail N, Mathews M, Nageeb F, Guirguis M, Mekhail M, et al. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. *Pain Pract* 2011;11:148–153. 6. Turner JA, Loeser JD, Deyo RA, Sander SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systemic review of effectiveness and complications. *Pain* 2004;108:137-47. 7. Patel SK, Gozal YM, Saleh MS, Gibson JL, Karsy M, Mandybur GT. Spinal cord stimulation failure: evaluation of factors underlying hardware explantation. *J Neurosurg Spine* 2019;doi: 10.3171/2019.6.SPINE181099. 8. Rigoard P, Basu S, Desai M, Taylor R, Annemans L, et al. Multicolumn spinal cord stimulation for predominant back pain in failed back surgery syndrome patients: a multicenter randomized controlled trial. *Pain* 2019;160:1410-1420. 9. Logé D, De Coster O, Washburn S. Technological innovation in spinal cord stimulation: use of a newly developed delivery device for introduction of spinal cord stimulation leads. *Neuromodulation* 2012;15:392-401. 10. Van Buyten J-P, Al-Kaisy A, Smet I, Palmisani S, Smith T. High-frequency spinal cord stimulation for the treatment of chronic back pain patients: results of a prospective multicenter European clinical study. *Neuromodulation* 2013;16:59-65. 11. Hong B, Winkel A, Stumpp N, Abdallata M, Saryyevaa A, et al. Detection of bacterial DNA on neurostimulation systems in patients without overt infection. *Clin Neurol Neurosurg* 2019;184:105399. 12. Lalkhen AG, Mahindra C, Patel J. Microbiological evaluation of the extension wire and percutaneous epidural lead anchor site following a “2-stage cut-down” spinal cord stimulator procedure. *Pain Pract* 2017;17:7:886-891. 13. Simopoulos T, Sharma S, Aher M, Gill JS. A temporary vs. permanent anchored percutaneous lead trial of spinal cord stimulation: a comparison of patient outcomes and adverse events. *Neuromodulation* 2018;21:508-512.

**Keyword:** SCS, infection, adverse events, screening trial duration

**Topic:** 05. Spine / 05a. Pain

**EFFECTIVENESS OF HIGH DOSE SPINAL CORD STIMULATION FOR NON-SURGICAL INTRACTABLE LUMBAR RADICULOPATHY- 1-YEAR PROSPECTIVE HIDENS STUDY**

**E-POSTER VIEWING**

Vivek Mehta<sup>1</sup>, Kavita Poply<sup>1</sup>, Alia Ahmad<sup>1</sup>, Joanne Lascelles<sup>1</sup>, Amin Elyas<sup>1</sup>, Sanskriti Sharma<sup>1</sup>, Balaji Ganeshan<sup>2</sup>, Habib Ellamushi<sup>1</sup>, Serge Nikolic<sup>1</sup>

<sup>1</sup>Pain Research Centre, Barts Health NHS Trust, London, United Kingdom, <sup>2</sup>Nuclear Medicine, University College of London, London, United Kingdom

**Introduction:** Persistent spinal pain syndrome may involve a significant population who are not candidates for spinal surgery and have diverse symptoms of paresthesia, numbness and radicular pain. This investigator-initiated study was designed to evaluate the efficacy of High Dose SCS (utilizing subthreshold stimulation with higher frequency and pulse width) in non-surgical predominant low-back pain population at 12 months.

**Methods/Materials:** 20 patients were recruited (March 2017-July 2018) to undergo SCS (Medtronic 8 contact standard leads and Restore® IPG), T8 -T9 midline anatomical parallel placement at Barts Neuromodulation Centre, St Bartholomew's and Royal London Hospital, London, UK NRES 17/LO/0044, clinicaltrials.gov NCT03716973. 17 patients completed 12 months follow-up (500 Hz frequency, 500 µseconds pulse width, 25% pulse density). Differences in patients' clinical outcome Numerical Rating Scale (NRS) back, NRS leg, ODI, PGIC, and PSQ at one month, three months, and twelve months from the baseline were assessed using non-parametric Wilcoxon paired test.

**Results:** The mean NRS scores for back pain (baseline 7.53) improved significantly at one month, three months, and 12 months; 2.78 ( $p<0.001$ ), 4.45 ( $p=0.002$ ), and 3.85 ( $p=0.002$ ) respectively. The mean NRS score for leg pain (baseline 6.09) improved significantly at one month and three months; 1.86 ( $p<0.001$ ) and 3.13 ( $p=0.010$ ) respectively. Though the mean NRS for leg pain at 12 months was low 3.85, the difference was not statistically significant from the baseline ( $p=0.057$ ). The mean baseline ODI score 53.13 improved significantly at one month, three months and 12 months; 35.33 ( $p=0.003$ ), 33.64 ( $p=0.004$ ) and 37.40 ( $p=0.011$ ) respectively. In comparison to the baseline (240.5) the mean PSQ at one month, three months, and 12 months were significantly lower; 100.6 ( $p=0.001$ ), 127.2 ( $p=0.001$ ), and 118.7 ( $p=0.004$ ) respectively.

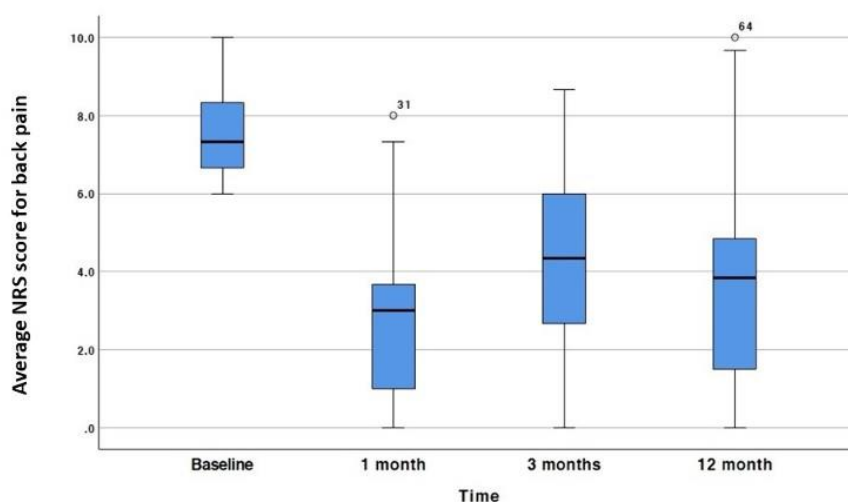


Figure 1: Box-plot highlights the back pain NRS score at one (2.78  $p<0.001$ ), three (4.45  $p=0.002$ ), and 12 months (3.85  $p=0.002$ ) in comparison to baseline.

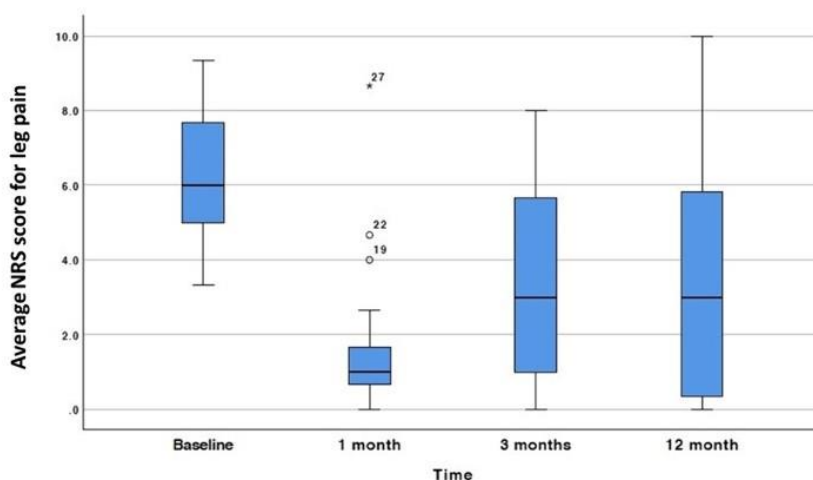


Figure 2: Box-plot highlights the leg pain NRS score at one (1.86  $p<0.001$ ), three (3.13  $p=0.010$ ), and 12 months (3.85  $p=0.057$ ) in comparison to baseline.

**Discussion:** This study reports significant improvement in pain scores for lower back that persisted at 12 months in patients who were deemed unsuitable for spinal surgery. There was a significant improvement in disability and sleep at 12 months. This suggests use of SCS as an early intervention in the management paradigm of this group.

**Conclusions:** This is the first long-term evaluation to demonstrate that anatomical placement of leads with sub-perception HD stimulation could provide effective pain relief in patients who are unsuitable for spinal surgery.

**References:**

**Keywords:** Non-surgical low back pain, High dose, Sub-threshold stimulation, neuropathic pain, Spinal cord stimulation

**Topic:** 05. Spine / 05a. Pain

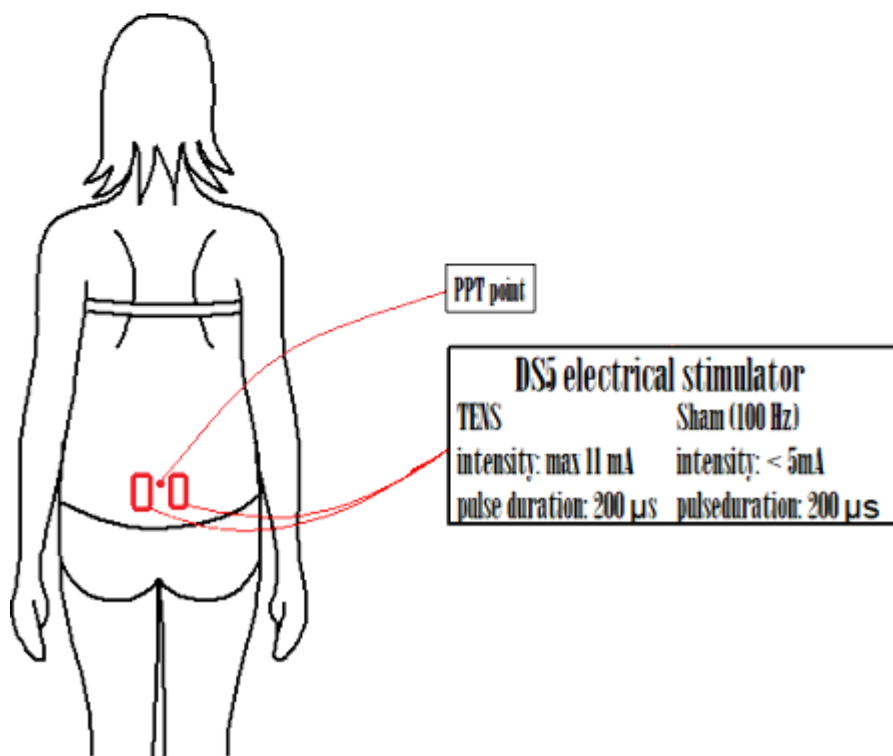
**TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION AS A PAIN RELIEVING APPROACH IN THE FIRST STAGE LABOURING PARTURIENTS – A RANDOMISED DOUBLE-BLINDED CONTROLLED PILOT STUDY**

**E-POSTER VIEWING**

Kenoja Thuvarakan<sup>1,2</sup>, Henrik Zimmermann<sup>1</sup>, Iben Lorentzen<sup>3</sup>, Anne Hammer<sup>3,4</sup>, Parisa Gazerani<sup>2</sup>  
<sup>1</sup>Medical Device Development, CentaFlow, Søborg, Denmark, <sup>2</sup>Department Of Health Science And Technology, Aalborg University, Aalborg, Denmark, <sup>3</sup>Department Of Gynecology And Obstetrics, Region Hospital Gødstrup, Herning, Denmark, <sup>4</sup>Department Of Clinical Medicine, Aarhus University, Aarhus N, Denmark

**Introduction:** •Transcutaneous electrical nerve stimulation (TENS) is a non-invasive modality involving cutaneous application of electrical current to reduce pain in several pain conditions including labour pain.<sup>1,2</sup> •The efficacy of TENS for reducing labour pain is yet not determined neither the optimal frequency nor the placement of electrodes.<sup>3,4</sup> •As a result, TENS is not routinely used yet at the labour ward for intrapartum care.

**Methods/Materials:** • Objective: To investigate if low (4/100 Hz) or high (80/100 Hz) alternating frequencies lead to a better pain relief compared to sham-TENS measured in lower visual analogue scale (VAS) and higher mean pressure pain threshold (PPT) in labouring parturients. •Healthy non-smoking and low-risk singleton pregnant women, between ages of 18 and 39 years, admitted for delivery at Region Hospital Gødstrup were recruited. •Data were presented as median with interquartile range (IQR). •IBM SPSS (v. 27.0) was used for statistical analysis, and  $p < 0.05$  was considered statistically significant.



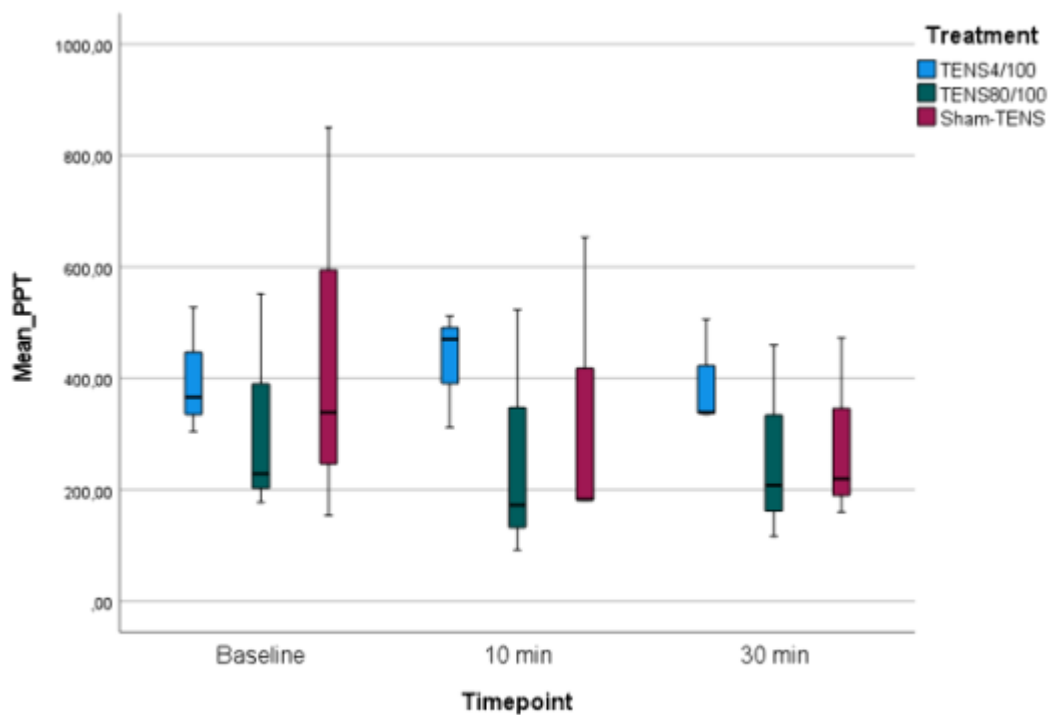
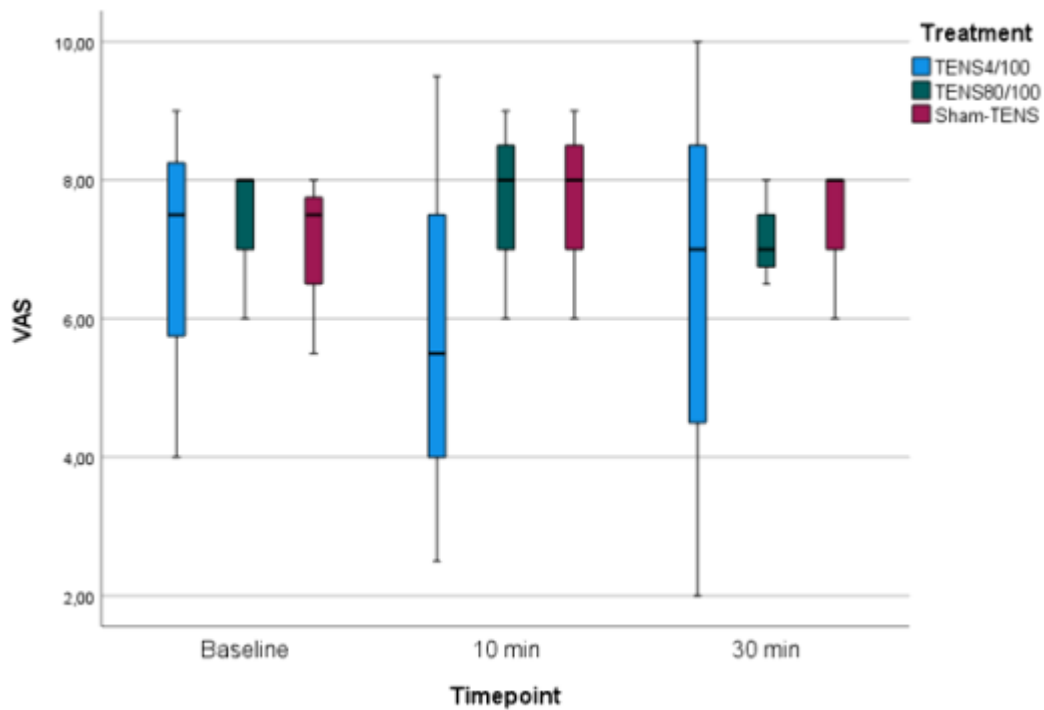
	Study overview
Beginning	Screening questionnaire
Baseline	VAS & PPT
Right before	Sensory intensity threshold
Test	4/100Hz, 80/100Hz, or sham
10 min post intervention	VAS & PPT
30 min post intervention	VAS & PPT



Completion	Satisfaction questionnaire
Postpartum	Evaluation of delivery

**Results:** •9 subjects were included following the screening and recruitment process of 157 labouring parturients at the labour ward. •No significant differences were found in PPT and VAS for each treatment group using Kruskal-Wallis test ( $p>0.05$ ). •Neither TENS with 4/100Hz nor TENS with 80/100Hz showed better pain relief compared to the sham-TENS. •However, a tendency was found for the TENS with 4/100 Hz to lower the VAS and increase the PPT from baseline to 10 min.

Subject n = 9	Median ( $\pm$ IQR)
Age (years)	32.00 $\pm$ 5.00
Body mass index (BMI) ( $\text{kg}/\text{m}^2$ )	24.28 $\pm$ 1.08
Gestational Age (weeks)	40.30 $\pm$ 1.80
Parity	1.00 $\pm$ 1.00
Cervical dilation (cm)	4.00 $\pm$ 0.50



The diagrams show both VAS (to left) and PPT (to right) in comparison to the specific time points. For TENS4/100 Hz (blue bars) showed a small tendency of lowering in VAS, while it was increased in PPT for baseline to 10 min.

**Discussion:** •A tendency was seen towards TENS with 4/100 Hz, which could suggest a short-term efficacy of TENS.

**Conclusions:** •The present study showed no efficacy of TENS compared to sham-TENS. •A larger pilot study considering the trend of TENS with 4/100 Hz can reveal if this can be an effective frequency for the main study with TENS in labouring women.

**References:** 1.Moran, F. et al. Hypoalgesia in response to transcutaneous electrical nerve stimulation (TENS) depends on stimulation intensity. *J. Pain* 12, 929–935 (2011). 2.Walsh, D. M. The evolution of TENS. *Hong Kong Physiother. J.* 21, 1–4 (2003). 3.Dowswell, T., Bedwell, C., Lavender, T. & Jp, N. Transcutaneous electrical nerve stimulation (TENS) for pain relief in labour. *Cochrane Database Syst. Rev.* 15, 67–69 (2009). 4.Carroll, D. et al. Transcutaneous electrical nerve stimulation in labour pain: A systematic review. *Br. J. Obstet. Gynaecol.* 104, 169–175 (1997).

**Keywords:** Transcutaneous electrical nerve stimulation, Pilot study, Labour pain, Double-blinded RCT

**Topic:** 05. Spine / 05a. Pain

**A RANDOMIZED CONTROLLED CLINICAL TRIAL COMPARING DIFFERENTIAL TARGET MULTIPLEXED SPINAL CORD STIMULATION TO TRADITIONAL SCS: LOW BACK PAIN OUTCOMES THROUGH 12-MONTHS FOLLOW UP**

**E-POSTER VIEWING**

Michael Fishman<sup>1</sup>, Harold Cordner<sup>2</sup>, Rafael Justiz<sup>3</sup>, David Provenzano<sup>4</sup>, Binit Shah<sup>5</sup>, Christopher Merrell<sup>6</sup>, Julian Naranjo<sup>7</sup>, Philip Kim<sup>1</sup>, Aaron Calodney<sup>8</sup>, Jonathan Carlson<sup>9</sup>, Richard Bundschu<sup>10</sup>, Mahendra Sanapati<sup>11</sup>, Vipul Mangal<sup>12</sup>, David Cedeno<sup>13</sup>, Ricardo Vallejo<sup>14</sup>

<sup>1</sup>Pain Medicine, Center for Interventional Pain and Spine, Exton, United States of America, <sup>2</sup>Interventional Pain Medicine, Florida Pain Management Associates, Sebastian, United States of America, <sup>3</sup>Pain Medicine, Oklahoma Pain Physicians, Oklahoma City, United States of America, <sup>4</sup>Interventional Pain Medicine, Pain Diagnostics and Interventional Care, Sewickley, United States of America, <sup>5</sup>Interventional Pain Medicine, Carolinas Research Institute, Huntersville, United States of America, <sup>6</sup>Pain Medicine, Low Country Orthopaedics, Charleston, United States of America, <sup>7</sup>Interventional Pain Medicine, South Florida Clinical Research, South Miami, United States of America, <sup>8</sup>Interventional Pain Medicine, Precision Spine Care, Tyler, United States of America, <sup>9</sup>Pain Medicine, Hawai'i Pain and Spine, Kailua, United States of America, <sup>10</sup>Interventional Pain Medicine, Coastal Orthopedics Sports Medicine and Pain Management, Bradenton, United States of America, <sup>11</sup>Interventional Pain Medicine, Global Scientific Innovations, Evansville, United States of America, <sup>12</sup>Pain Medicine, National Spine and Pain Centers, Oxon Hill, United States of America, <sup>13</sup>Research, Lumbrera LLC, Bloomington, United States of America, <sup>14</sup>Research, SGX Medical, Bloomington, United States of America

**Introduction:** Differential Target Multiplexed Spinal Cord Stimulation (DTM SCS) utilizes various pulsed signals that are multiplexed spatially and temporally. The approach was inspired from basic science research that demonstrated the modulation of neuron-glial interactions by SCS.<sup>1,2</sup> This abstract presents pain relief outcomes from a Randomized Controlled Trial (RCT) of DTM SCS compared to traditional SCS in patients with intractable low back and leg pain.

**Methods/Materials:** This prospective, post-market, multicenter, parallel-group RCT compared DTM SCS to traditional SCS in patients with chronic intractable low back pain (LBP) and leg pain. Key inclusion criteria: adult subjects,  $\geq 5$  cm VAS in LBP, moderate to severe leg pain, and candidate for SCS under a stable pain medication regime. Key exclusion criteria: other active implants, contraindications for SCS, and mechanical spine instability. Consented and eligible subjects were randomized 1:1 to treatment groups. Subjects underwent a standard of care SCS trial. All subjects progressing to implant received the same neurostimulator system. Primary endpoint assessed the non-inferiority of LBP responder rate (subjects with  $\geq 50\%$  relief) between the treatment groups at 3 months post-implant in an intent-to-treat (ITT) analysis. Pain-related outcomes were assessed at 3, 6 and 12-months post-implant.

**Results:** The study randomized 128 subjects at 12 centers across the US. At the primary endpoint (3 months) LBP responder rate with DTM SCS (80%) was non-inferior ( $p < 0.0001$ , ITT) and superior ( $p=0.0010$ , ITT) relative to traditional SCS (51%). LBP Responder rate was sustained through 12 months with DTM SCS (84%) and traditional SCS (51%). At 12 months LBP mean VAS reduced to 1.74cm (75.2% reduction) and 3.71cm (49.9% reduction) for DTM SCS and traditional SCS respectively. At 12-months DTM SCS had a profound ( $\geq 80\%$  relief) LBP responder rate of 69%. Both therapies provided improved and sustained leg pain relief. At 12-month follow up mean reduction in leg pain relative to baseline was 75.7% with DTM SCS, slightly higher than 67.9% with traditional SCS. The nature and severity of study-related adverse events were similar between treatments and consistent with other SCS studies.<sup>3-4</sup>

**Discussion:** This RCT provides evidence of superior LBP relief with DTM SCS compared to traditional SCS. Outcomes from this study including quality of life, impact on disability, and subject

satisfaction have been submitted as a separate abstract. Peer-reviewed publication of the RCT is expected early summer 2021.

**Conclusions:** In a large RCT, DTM SCS provided superior LBP relief relative to traditional SCS with pain relief sustained through 12 months.

**References:** 1. Cedeño DL, Smith WJ, Kelley CA, Vallejo R. Spinal cord stimulation using differential target multiplexed programming modulates neural cell-specific transcriptomes in an animal model of neuropathic pain. *Mol Pain*. 2020;16:1744806920964360. 2. Vallejo R, Kelley CA, Gupta A, Smith WJ, Vallejo A, Cedeño DL. Modulation of neuroglial interactions using differential target multiplexed spinal cord stimulation in an animal model of neuropathic pain. *Mol Pain*. 2020 Jan-Dec;16:1744806920918057. 3. Rosenow JM, Stanton-Hicks M, Rezai AR, Henderson JM. Failure modes of spinal cord stimulation hardware. *J Neurosurg Spine*. 2006;5(3):183-190. 4. Mekhail NA, Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. *Pain Pract*. 2011;11(2):148-153.

**Keywords:** Spinal cord stimulation, Randomized Control Trial, Differential Target Multiplexed, Intractable Chronic Low Back and Leg Pain

**Topic:** 05. Spine / 05a. Pain

**RANDOMIZED CONTROLLED CLINICAL TRIAL COMPARING DIFFERENTIAL TARGET MULTIPLEXED SPINAL CORD STIMULATION TO TRADITIONAL SCS: PROFOUND RESPONDERS AND LONG-TERM BENEFITS IN QUALITY OF LIFE**

**E-POSTER VIEWING**

Michael Fishman<sup>1</sup>, Harold Cordner<sup>2</sup>, Rafael Justiz<sup>3</sup>, David Provenzano<sup>4</sup>, Binit Shah<sup>5</sup>, Christopher Merrell<sup>6</sup>, Julian Naranjo<sup>7</sup>, Philip Kim<sup>1</sup>, Aaron Calodney<sup>8</sup>, Jonathan Carlson<sup>9</sup>, Richard Bundschu<sup>10</sup>, Mahendra Sanapati<sup>11</sup>, Vipul Mangal<sup>12</sup>, David Cedeno<sup>13</sup>, Ricardo Vallejo<sup>14</sup>

<sup>1</sup>Pain Medicine, Center for Interventional Pain and Spine, Extion, United States of America, <sup>2</sup>Interventional Pain Medicine, Florida Pain Management Associates, Sebastian, United States of America, <sup>3</sup>Pain Medicine, Oklahoma Pain Physicians, Oklahoma City, United States of America, <sup>4</sup>Interventional Pain Medicine, Pain Diagnostics and Interventional Care, Sewickley, United States of America, <sup>5</sup>Interventional Pain Medicine, Carolinas Research Institute, Huntersville, United States of America, <sup>6</sup>Pain Medicine, Low Country Orthopaedics, Charleston, United States of America, <sup>7</sup>Interventional Pain Medicine, South Florida Clinical Research, South Miami, United States of America, <sup>8</sup>Interventional Pain Medicine, Precision Spine Care, Tyler, United States of America, <sup>9</sup>Pain Medicine, Hawai'i Pain and Spine, Kailua, United States of America, <sup>10</sup>Interventional Pain Medicine, Coastal Orthopedics Sports Medicine and Pain Management, Bradenton, United States of America, <sup>11</sup>Interventional Pain Medicine, Global Scientific Innovations, Evansville, United States of America, <sup>12</sup>Pain Medicine, National Spine and Pain Centers, Oxon Hill, United States of America, <sup>13</sup>Research, Lumbrera LLC, Bloomington, United States of America, <sup>14</sup>Research, SGX Medical, Bloomington, United States of America

**Introduction:** Differential Target Multiplexed Spinal Cord Stimulation (DTM SCS) utilizes various pulsed signals that are multiplexed spatially and temporally. We previously reported superior low back pain (LBP) relief outcomes from a Randomized Controlled Trial (RCT) of DTM SCS compared to traditional SCS. This abstract reports on secondary outcomes from the RCT including profound responders ( $\geq 80\%$  pain relief), quality of life, extent of disability, patient global impression of change (PGIC) and subject satisfaction.

**Methods/Materials:** This prospective, post-market, multicenter, parallel-group RCT compared DTM SCS to traditional SCS in patients with chronic intractable low back pain (LBP) and leg pain. Key inclusion criteria: adult subjects,  $\geq 5$  cm VAS in LBP, moderate to severe leg pain, and candidate for SCS under a stable pain medication regime. Key exclusion criteria: other active implants, contraindications for SCS, and mechanical spine instability. Consented and eligible subjects were randomized 1:1 to treatment groups. Subjects underwent a standard of care SCS trial. All subjects progressing to implant received the same neurostimulator system and were followed for 12-Months. Secondary outcomes included long-term pain relief, quality of life (PROMIS Global Health), functional disability (ODI), subject satisfaction and impression of change (PGIC).

**Results:** The study randomized 128 subjects at 12 centers. At the primary endpoint (3-months), LBP responder rate with DTM SCS (80%) was superior ( $p=0.0010$ , ITT) relative to traditional SCS (51%). Percentage of profound LBP responders ( $\geq 80\%$  relief) was 63% with DTM SCS and 28% with traditional SCS. At 12-months profound LBP responder rates were 69% and 35% respectively. Both therapies improved functional disability with 76% of subjects with DTM SCS and 62% of subjects with traditional SCS reporting minimal/moderate disability at 12-months in contrast to a combined mean of 26% at baseline. Also, 88% of subjects with DTM-SCS and 76% with traditional SCS reported the effect of treatment on physical health was fair to excellent. At 12-months, 83% of subjects were satisfied or very satisfied with DTM SCS and 84% reported feeling somewhat to a great deal better.

**Discussion:** This RCT provides evidence of profound pain relief, Quality of Life, reduced disability, subject satisfaction, and impression of change for DTM SCS and conventional SCS. These are important measures in evaluating the clinical impact of a therapy beyond basic pain measures.

**Conclusions:** This study demonstrated sustained benefits of DTM SCS on LBP through 12-months. Additional benefits were observed in quality of life, extent of disability, perceived improvement of change, and satisfaction of patients.

**References:**

**Keywords:** Differential Target Multiplexed, Randomized Controlled Trial, Spinal cord stimulation, Intractable Chronic Low Back and Leg Pain

Topic: 05. Spine / 05a. Pain

## A RANDOMIZED CONTROLLED CLINICAL TRIAL COMPARING DIFFERENTIAL TARGET MULTIPLEXED SPINAL CORD STIMULATION TO TRADITIONAL SCS: POST HOC ANALYSIS OF NON-SURGICAL BACK PAIN PATIENTS

### E-POSTER VIEWING

Harold Cordner<sup>1</sup>, Michael Fishman<sup>2</sup>, Rafael Justiz<sup>3</sup>, Philip Kim<sup>2</sup>, Binit Shah<sup>4</sup>, Aaron Calodney<sup>5</sup>, Ye Tan<sup>6</sup>, David Cedeno<sup>7</sup>, Ricardo Vallejo<sup>7</sup>

<sup>1</sup>Interventional Pain Medicine, Florida Pain Management Associates, Sebastian, United States of America, <sup>2</sup>Pain Medicine, Center for Interventional Pain and Spine, Exton, United States of America, <sup>3</sup>Pain Medicine, Oklahoma Pain Physicians, Oklahoma City, United States of America, <sup>4</sup>Interventional Pain Medicine, Carolinas Research Institute, Huntersville, United States of America, <sup>5</sup>Interventional Pain Medicine, Precision Spine Care, Tyler, United States of America, <sup>6</sup>Department Of Clinical Research, Medtronic, Minneapolis, United States of America, <sup>7</sup>Research, SGX Medical, Bloomington, United States of America

**Introduction:** Spinal cord stimulation is used to treat chronic pain that develops after spinal surgery. Clinical studies may enroll patients with a variety of pain etiologies, and typically collect the number and types of previous surgeries performed related to patients' back pain. Following a randomized controlled trial (RCT) of DTM SCS compared to traditional SCS, there was some interest on examining the demographics and low back pain (LBP) relief characteristics for the subset of patients without previous spinal surgery. Results of a post hoc analysis are presented.

**Methods/Materials:** The study was a prospective, multicenter, parallel-group RCT that compared treatment using DTM SCS to traditional SCS in patients with chronic intractable low back pain (LBP) and leg pain. Consented and eligible subjects (LBP VAS  $\geq 5$  cm and moderate to severe leg pain) were randomized across 12 centers in the US. A post hoc analysis was performed for subjects who had not undergone previous spinal surgery.

**Results:** Among the 128 randomized subjects, there were 28 (21.9%) randomized subjects without prior spinal surgery, 16 (23.9%) in the DTM-SCS arm and 12 (19.7%) in the traditional SCS arm. Baseline demographics and characteristics were similar between these subsets. For instance, mean baseline LBP VAS scores were 7.83 and 7.39 cm, mean age was 62.3 and 62.0 years, and mean number of years since onset of symptoms was 10.9 and 17.8 years for DTM SCS and traditional SCS, respectively. Mean LBP scores for DTM-SCS patients (n = 12) at 1-, 3-, 6, and 12-months were 1.17, 1.47, 1.55, and 1.22 cm. Mean LBP scores for traditional SCS patients (n = 8) at 1-, 3-, 6, months and 7 patients at 12 months were 3.46, 2.53, 2.76, and 2.14 cm. Eleven out of 12 patients in the DTM-SCS group were identified as responders ( $\geq 50\%$  LBP relief) at 3-, 6-, and 12- months. Responders in the traditional SCS group were 6 out of 8, 5 out of 8, and 5 out of 7 at 3-, 6-, and 12- months.

**Discussion:** For subjects with no previous spinal surgery, improvements in low back pain scores ( $\sim 6.5$  cm for DTM SCS and  $\sim 4.5$  cm for traditional SCS) were substantial and sustained out to 12 months post-implant.

**Conclusions:** Despite the limited sample size in the current analysis, the trend in responder rates and low back pain VAS scores, with DTM SCS being better than traditional SCS, is consistent with those obtained in the overall study.

### References:

**Keywords:** Spinal cord stimulation, Intractable Chronic Low Back and Leg Pain, Non-surgical back pain, Differential Target Multiplexed, Randomized Controlled Trial



**Topic:** 05. Spine / 05a. Pain

**REAL-WORLD OBSERVATIONAL OUTCOMES OF PATIENTS USING PULSED AND/OR THERMAL RADIOFREQUENCY ABLATION FOR TREATMENT OF CHRONIC PAIN IN EUROPE**

**E-POSTER VIEWING**

Felice Occhigrossi<sup>1</sup>, Isaac Peña<sup>2</sup>, Jing Wang<sup>3</sup>, Kristen Lechleiter<sup>3</sup>, Roshini Jain<sup>3</sup>

<sup>1</sup>U.o.s.d. Terapia Del Dolore (pain Therapy), Ospedaliera San Giovanni-Addolorata, Rome, Italy, <sup>2</sup>Department Of Anesthesiology And Pain Management, Hospital Universitario Virgen del Rocío, Seville, Spain, <sup>3</sup>Clinical Research, Boston Scientific, Valencia, United States of America

**Introduction:** Treating several chronic intractable pain syndromes with a diverse set of etiologies has been consistently shown to be successfully carried out using radiofrequency ablation (RFA). Though assessment of real-world patient data can contribute to the overall compendium of existing evidence, it may also help to spur the initiation of important new clinical studies as well. In that regard, here, we report our outcomes from a European case-series of patients who underwent an RFA procedure for the treatment of chronic pain.

**Methods/Materials:** This is a real-world, retrospective, observational, case-series study of patients in Europe who used a device capable of pulsed and/or thermal radiofrequency ablation (Boston Scientific, Marlborough, MA, USA) for treatment of chronic pain. Key data and clinical assessments include demographic characteristics, pain diagnosis, baseline and post-treatment pain scores, and percent pain relief.

**Results:** Analysis of collected study data is currently on-going. Determined clinical outcomes will be presented.

**Discussion:** RFA as a therapeutic modality for treatment of chronic pain may be particularly helpful in patients who have not achieved a sought after level of pain relief using conventional drug medications or other traditional pain management approaches. Additionally, conducting a real-world patient assessment, such as that carried out in this study, represents a key data source from which to conceive and design future RFA-based clinical studies.

**Conclusions:** This European-based, observational case-series will seek to track and assess the clinical outcomes of patients who used Radiofrequency Ablation to help manage their chronic intractable pain.

**References:**

**Keywords:** chronic pain, radiofrequency ablation, pulsed radiofrequency, thermal radiofrequency

**Topic:** 05. Spine / 05a. Pain

## REAL-WORLD OUTCOMES IN A CHRONIC PAIN PATIENT COHORT UNDERGOING A SINGLE-STAGE SCS-IMPLANTATION PROCEDURE

### E-POSTER VIEWING

Pasquale De Negri<sup>1</sup>, Jing Wang<sup>2</sup>, Kristen Lechleiter<sup>2</sup>, Roshini Jain<sup>2</sup>

<sup>1</sup>Pain Medicine, Pain Medicine - AORN S. Anna & S. Sebastiano, Caserta, Italy, <sup>2</sup>Clinical Research, Boston Scientific, Valencia, United States of America

**Introduction:** The implementation of a screening trial prior to permanent implant has been a routine experiential feature for most patients utilizing Spinal Cord Stimulation (SCS) for treatment of chronic pain. However, increased scrutiny over the necessity of a trial procedure on the basis of a recently reported randomized controlled trial has again re-ignited a long-running debate as voiced in the published literature.<sup>1,2</sup> So as to add to the compendium of real-world data in this regard, we have initiated an observational, case-series evaluation of patients who have all undergone a single-stage procedure in which an “on the table” trial was conducted as part of a permanent SCS device implantation.

**Methods/Materials:** This is a consecutive, observational, case-series based on an on-going, real-world evaluation of SCS outcomes for chronic pain (Clinicaltrials.gov identifier: NCT01550575). All evaluated patients were implanted with an SCS device (Boston Scientific, Valencia, CA, US) and underwent a single-stage, permanent-implant procedure with an on-table screening trial. Retrospective chart reviews are used to assess overall pain (numerical rating scale pain intensities [0-10 NRS]) at baseline, post-implant, 3-, and 12-months follow-up was carried out. Data collection also includes the following: baseline demographics, pain diagnosis, and procedural information (e.g. lead configuration, programming parameters).

**Results:** To date, this study is currently on-going, and outcomes derived from the analysis of collected data will be presented.

**Discussion:** Several downsides of screening trials do exist such as procedural duplication, higher infection risk, and possible increased healthcare costs. A large accrual of real-world evidence derived from patients who underwent a single-stage implantation procedure may therefore represent a potential source of evidence for inclusion in any future examination of established clinical practice guidelines pertaining to the routine implementation of a screening trial.

**Conclusions:** Results from this on-going, observational study will seek to report real-world clinical outcomes in patients who undergo a single-stage, permanent-implant procedure with an on-table screening trial.

**References:** 1. Eldabe S, Duarte RV, Gulve A, Thomson S, Baranidharan G, Houten R, Jowett S, Sandhu H, Chadwick R, Brookes M, Kansal A, Earle J, Bell J, Robinson J, Walker S, Rhodes S, Taylor RS. Does a screening trial for spinal cord stimulation in patients with chronic pain of neuropathic origin have clinical utility and cost-effectiveness (TRIAL-STIM)? A randomised controlled trial. *Pain*. 2020 Dec;161(12):2820-2829 2. Weinand ME, Madhusudan H, Davis B, Melgar M. Acute vs. Prolonged Screening for Spinal Cord Stimulation in Chronic Pain. *Neuromodulation*. 2003 Jan;6(1):15-9.

**Keywords:** Screening trial, chronic pain, Spinal cord stimulation, SCS

**Topic:** 05. Spine / 05a. Pain

**RETROSPECTIVE ANALYSIS OF SPINAL CORD STIMULATION (SCS) THERAPY  
EFFECTIVENESS AND EFFECT ON ANALGESIC MEDICATION USE AT CAMBRIDGE  
UNIVERSITY HOSPITAL**

**E-POSTER VIEWING**

Rokas Tamosauskas<sup>1</sup>, Dylan Whitaker<sup>2</sup>

<sup>1</sup>Department Of Anaesthesia, Cambridge University Hospitals NHS Foundation Trust, Addenbrooke's Hospital, Cambridge, United Kingdom, <sup>2</sup>School Of Medicine, Cambridge University, Cambridge, United Kingdom

**Introduction:** The Cambridge University Hospitals Chronic Pain Service has been offering a Spinal Cord Stimulation (SCS) for chronic neuropathic pain management for 7 years. Whilst the safety and efficacy profile of SCS therapy in the short to medium term are known well, less research has been published on long term outcomes, particularly with regards to change in analgesic medication usage. We aimed to investigate the Patient Reported Outcome Measures (PROM) and pharmacological impact, including change in opioid usage and the pharmacoeconomic impact of SCS implantation.

**Methods/Materials:** Retrospective analysis using electronic health records for rate of complication, patient reported outcomes on level of pain experienced with the British Pain Inventory (BPI) , level of disability with the Roland Morris and Euroqol 5D assessment of quality of life. The patient reported outcomes were investigated for the change after implantation. Additionally, prescription habits were extracted from GP Connect via Hospital Electronic Health Record system (EPIC) to assess changes in analgesic medication use.

**Results:** There was a significant difference in the level of pain experienced (BPI), level of disability (Roland Morris) and quality of life (Euroqol 5D) reported by patients 1 year after SCS implantation. There was a large magnitude of change in quality of life and pain experienced with a moderate change in the level of disability experienced. After SCS implantation, patients showed a 30% reduction in opioid use by the end of year 2. This in turn led to a reduction in 22% saving spending on analgesic medications at the end of year 2 post implantation. A cohort of patients with no SCS related complications showed 37% reduction in morphine equivalent consumption at the end of year 2 with the total analgesic medications cost saving of 25%.

**Discussion:** We found that SCS therapy for chronic neuropathic pain has been effective in our patient cohort. It produced a significant improvement accross all measured PROM domains. This is consistent with the published literature. Interestingly, we were able to convincingly show that the patients were able to reduce their reliance on opioids which, in turn, resulted in a long-term cost saving accross all analgesic medications by 25%.

**Conclusions:** Spinal cord simulation offers not only a significant change in patient reported outcomes of pain, disability and quality of life but it is also associated with a reduction in opioid consumption and healthcare spending.

**References:** 1. Retrospective analysis on the effect of spinal cord stimulation on opioid consumption - <https://pubmed.ncbi.nlm.nih.gov/33350351/> 2. Spinal cord stimulation as a method of reducing opioids in severe chronic pain: a case report and review of the literature - <https://pubmed.ncbi.nlm.nih.gov/21932754/> 3. Impact of Spinal Cord Stimulation on Opioid Dose Reduction: A Nationwide Analysis - <https://pubmed.ncbi.nlm.nih.gov/32866229/>

**Keyword:** Spinal Cord Stimulation (SCS); quality of life (QoL); opioids; cost-effectiveness;

Topic: 05. Spine / 05a. Pain

## ULTRA-LOW ENERGY CYCLED BURST SPINAL CORD STIMULATION YIELDS ROBUST OUTCOMES IN PAIN, FUNCTION, AND AFFECTIVE DOMAINS: A SUB-ANALYSIS FROM TWO PROSPECTIVE, MULTI-CENTER, INTERNATIONAL CLINICAL TRIALS

### E-POSTER VIEWING

Marie Fahey<sup>1</sup>, Timothy Deer<sup>2</sup>, Derron Wilson<sup>3</sup>, David Schultz<sup>4</sup>, Steven Falowski<sup>5</sup>, Edward Tavel<sup>6</sup>, Gregory Moore<sup>7</sup>, Robert Heros<sup>8</sup>, Denis Patterson<sup>9</sup>, Robyn Capobianco<sup>10</sup>, Magdalena Anitescu<sup>11</sup>

<sup>1</sup>Clinical Science, Abbott, Austin, United States of America, <sup>2</sup>Pain Services, Spine & Nerve Center of the Virginias, Charleston, United States of America, <sup>3</sup>Interventional Pain Management, Goodman Campbell Brain & Spine, Carmel, United States of America, <sup>4</sup>Interventional Pain Management, Nura Pain Clinic, Edina, United States of America, <sup>5</sup>Neurological Surgery, Functional Neurosurgery, Neurosurgical Associates of Lancaster, Lancaster, United States of America, <sup>6</sup>Interventional Pain Management, Clinical Trials of South Carolina, Charleston, United States of America, <sup>7</sup>Interventional Pain Management, Pacific Sports and Spine, Eugene, United States of America, <sup>8</sup>Interventional Pain Management, Spinal Diagnostics, Tualatin, United States of America, <sup>9</sup>Pain Medicine, Nevada Advanced Pain Specialists, Reno, United States of America, <sup>10</sup>Global Neuromodulation, Abbott, Austin, United States of America, <sup>11</sup>Anesthesiology, University of Chicago Medical Center, Chicago, United States of America

**Introduction:** DeRidder's burst stimulation design has become a key spinal cord stimulation (SCS) waveform and it uniquely reduces the intensity of pain as well as its associated emotional distress. The brain pathways underlying these outcomes may also allow for the effects of stimulation to carry-over after stimulation is turned off, making it amenable to intermittent application. Previous studies of intermittent burst stimulation were small pilot feasibility trials, with short-term testing. A six-month continuation of therapy with patients' preferred program parameters indicated that there was clinical utility; nearly of 50% of subjects chose to use the least-intense intermittent cycle. Here, the utility of intermittently-cycled burst was evaluated using data from two large real-world prospective studies.

**Methods/Materials:** Data were extracted from two prospective studies; TRIUMPH (NCT03082261) and REALITY (NCT03876054). All subjects were implanted with a burst capable SCS system and used intermittent dosing in a 1:3 ratio (30-sec on, 90-sec off; N=100) in TRIUMPH and 1:12 ratio in REALITY (30-sec on, 360-sec off; N=95) for six months. Pain intensity (0-10 numeric rating scale), pain-related emotions on the Pain Catastrophizing Scale (PCS), and physical function on PROMIS questionnaires were compared with pre-implant baseline ratings and by group.

**Results:** Mean (SD) baseline pain intensity was 7.5 (1.2) in 1:3 and 7.7 (1.2) in 1:12 with no difference between groups. At 6 months, mean scores were 4.3 (2.4) and 3.9 (2.4), respectively, with no difference between groups. Responder rates at 30% decrease in pain intensity were 66% and 67% (1:3, 1:12, respectively). PCS scores showed no statistical difference between groups at baseline. After six months scores were 12.3 (12.0) and 13.5 (12.1) for the 1:3 and 1:12 groups, with no statistical difference between groups. Of those clinically catastrophizing at baseline (PCS score  $\geq 30$ ), 69% and 68% improved at follow up. Physical function increased similarly with no statistical difference between groups. 80% and 77% of the 1:3 and 1:12 groups, were considered responders on multiple measures. No adverse events were associated with intermittent stimulation.

**Discussion:** There were no statistically significant differences between the on-off ratio groups for any patient-reported outcome measures or safety events reported.

**Conclusions:** Intermittent cycling of burst SCS lowers the overall electric charge delivered to the spinal cord and preserves battery consumption, without compromising pain relief or relief from emotional distress. Although further research is required, it may be possible that intermittent cycling

could result in less tolerance to stimulation, thus maintaining clinical outcomes or salvaging SCS treatment.

**References:**

**Keywords:** Spinal cord stimulation, BurstDR, Burst, Intermittent stimulation, Duty Cycling, Micro-dosing

**Topic:** 05. Spine / 05a. Pain

## **DERIDDER BURST STIMULATION THERAPY IMPROVES PAIN AND PSYCHOLOGICAL OUTCOMES AFTER WANING SCS THERAPY: RESULTS FROM THE PROLONG STUDY**

### **E-POSTER VIEWING**

Corey Hunter<sup>1</sup>, Davis Schultz<sup>2</sup>, Nestor Tomycz<sup>3</sup>, Jacqueline Weisbein<sup>4</sup>, Nathan Miller<sup>5</sup>, Steven Falowski<sup>6</sup>, Jason Pope<sup>7</sup>, Misagh Mansouri<sup>8</sup>, Timothy Deer<sup>9</sup>

<sup>1</sup>Pain Management, Ainsworth Institute of Pain Management, New York, United States of America, <sup>2</sup>Pain Management, Nura Pain Clinics, Minneapolis, United States of America, <sup>3</sup>Neurology, Allegheny General Hospital, Pittsburgh, United States of America, <sup>4</sup>Pain Management, Napa Valley Orthopaedic Medical Group, Napa, United States of America, <sup>5</sup>Pain Management, Coastal Pain and Spinal Diagnostics, Carlsbad, United States of America, <sup>6</sup>Neurological Surgery, Functional Neurosurgery, Neurosurgical Associates of Lancaster, Lancaster, United States of America, <sup>7</sup>Pain Medicine, Evolve Restorative Center, Santa Rosa, United States of America, <sup>8</sup>Global Neuromodulation, Abbott, Austin, United States of America, <sup>9</sup>Pain Services, Spine & Nerve Center of the Virginias, Charleston, United States of America

**Introduction:** Spinal cord stimulation (SCS) has been shown to effectively relieve chronic intractable pain. However, a portion of patients who initially receive therapeutic benefit with SCS will eventually develop stimulation tolerance. DeRidder Burst stimulation offers a unique mechanism of action that can potentially restore effectiveness where other stimulation therapies have failed. While tonic SCS modulates the lateral pain pathway, responsible for the sensory aspects of pain, only burst as developed by DeRidder has been shown to influence the medial pain pathway which is responsible for affective components of pain, such as catastrophizing and depression. PROLONG (NCT039088476) is a multi-center, open-label, post-market study. The study prospectively observes subjects who switch to burst capable devices or dorsal root ganglion (DRG) stimulation after loss of pain relief with their previous SCS system. We present 6-month (6M) follow-up results for a range of patient-reported outcomes.

**Methods/Materials:** Eligible subjects had a pain score of  $\geq 6$  on the Numerical Rating Scale (NRS), had a functioning SCS system implanted, and did not report pain outside of the original treatment area. Available salvage methods consisted of a full SCS system replacement, IPG replacement, or DRG system implant. Results for the DRG cohort are presented elsewhere. Patient-reported outcomes collected at all time points include: NRS for pain, PROMIS-29, and the Pain Catastrophizing Scale (PCS).

**Results:** Of 100 enrolled subjects, 85 received a burst capable IPG and 15 received a DRG system implant. To date, 55 subjects have completed their 6M follow-up visits. The NRS score improved from  $7.4 \pm 1.2$  at baseline to  $4.7 \pm 2.7$  at 6M. 62% (34/55) of subjects had at least a 2-point reduction in pain score at 6M compared to baseline. The PCS score also improved from  $25.1 \pm 14.8$  at baseline to  $16.52 \pm 13.1$  at 6M. 67% (14/21) of subjects clinically catastrophizing at baseline ( $\geq 30$ ) reported improvement of symptoms at 6M follow-up ( $< 30$ ). 70% (12/17) of subjects with severe pain interference ( $\geq 70$ ) at baseline reduced symptoms by at least one category at 6M. In addition, 62% (5/8) of subjects with severe physical function at baseline improved function by at least one category.

**Discussion:** The 6M follow-up results support BurstDr SCS therapy is successful in alleviating pain, improving physical function, reducing pain interference, and pain catastrophizing in patients with chronic intractable pain.

**Conclusions:** BurstDr stimulation improves pain and psychological outcomes and is an effective salvage therapy in a patient population reporting failure of other SCS therapies.

**References:**

**Keywords:** BurstDr stimulation, chronic pain, Spinal cord stimulation, functional and psychosocial outcomes, salvage

## **SURGICAL PADDLE ELECTRODE IMPLANTATION TO TREAT FAILED BACK SURGERY SYNDROME: SAFE AND EFFECTIVE**

### **E-POSTER VIEWING**

Richard Witkam<sup>1</sup>, Marije Buijse<sup>1</sup>, Inge Arnts<sup>1</sup>, Dylan Henssen<sup>2</sup>, Kris Vissers<sup>1</sup>, Robert Van Dongen<sup>1</sup>, Erkan Kurt<sup>3</sup>

<sup>1</sup>Anaesthesiology, Pain And Palliative Medicine, Radboud University Medical Center, Nijmegen, Netherlands, <sup>2</sup>Medical Imaging, Radboud University Medical Center, Nijmegen, Netherlands, <sup>3</sup>Neurosurgery, Radboud University Medical Center, Nijmegen, Netherlands

**Introduction:** Spinal cord stimulation (SCS) to treat Failed Back Surgery Syndrome (FBSS) can routinely be applied in two ways as implantation of the electrodes can be accomplished percutaneously or surgically [1]. Currently, SCS treatment is mostly accomplished by percutaneously implanted electrodes. Though, surgical paddle electrodes can be used if a percutaneous implantation is technically infeasible or if a percutaneous electrode is unable to retain sufficient pain relief [2]. Next to the fact that direct comparison of the two types of electrodes is challenging, the evidence on surgical paddle electrodes mostly relies on pain intensity scores. Therefore, the aim of the current study was to evaluate the clinical effectiveness multidimensionally, including daily medication intake and, complication rates of SCS using surgical paddle electrodes to treat FBSS.

**Methods/Materials:** Pain intensity scores, daily medication intake and psychosocial-related questionnaires were compared pre- and post-implantation. Additionally, the Quality of Life Index was derived from the questionnaire data. A clinically relevant effect was considered to be obtained if the minimal clinically important difference (MCID) regarding pain intensity (i.e., at least 1.5 points reduction on the VAS scale) was reached [3].

**Results:** Thirty-four patients were included. In 25 of these patients this was indicated due to failure of a previously implanted percutaneous electrode. In both the total study population as this subcohort, pain intensity scores were statistically significant (all p-values were < 0.001) and clinically relevant reduced with regard to short-term (0-6 months), mid-term (1-3 years) and long-term follow-up (≥ 4 years). Both the daily medication intake as the structural morphine usage were significantly decreased at short-term but not at mid- and long-term follow-up. Ten complications occurred in nine patients, of which six concerned hardware-related problems and four were of biological origin.

**Discussion:** Even if multiple percutaneous implantations have been performed, paddle electrodes diminish pain in clinically relevant fashion. Less electrode migrations and the possibility to reprogram the SCS system more extensively, are possible contributors to promising long-term results by surgical paddle electrodes. Lastly, the amount of medication intake should be considered a preoperative patient characteristic or may even be incorporated into multi-folded outcome parameters.

**Conclusions:** When indicated, SCS therapy through surgically implanted paddle electrodes can be a safe, effective and clinically relevant treatment in patients suffering from FBSS regarding short-, mid- and long-term

**References:** [1] Barolat, G., Experience with 509 plate electrodes implanted epidurally from C1 to L1. *Stereotact Funct Neurosurg*, 1993. 61(2): p. 60-79. [2] Matias, C.M., et al., Long-term Outcomes After Replacement of Percutaneous Leads With Paddle Leads in a Retrospective Cohort of Patients With Spinal Cord Stimulation Systems. *Neurosurgery*, 2014. 75(4): p. 430-436. [3] Ostelo, R.W., et al., Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine (Phila Pa 1976)*, 2008. 33(1): p. 90-4.

**Keywords:** Quality of life, Surgical Paddle Electrode, Pain intensity, Medication intake, Long-term follow-up, Failed Back Surgery Syndrome



Topic: 05. Spine / 05a. Pain

## EVALUATION OF DIFFERENTIAL TARGET MULTIPLEXED SPINAL CORD STIMULATION USING A REDUCED ENERGY PARAMETER SET IN AN ANIMAL MODEL OF NEUROPATHIC PAIN

### E-POSTER VIEWING

David Cedeno<sup>1,2,3</sup>, Ricardo Vallejo<sup>1,2,3,4</sup>, David Platt<sup>2,3</sup>, Courtney Kelley<sup>2,3</sup>, Joseph Williams<sup>3</sup>, Juan Hincapié<sup>5</sup>, Andrew Cleland<sup>5</sup>

<sup>1</sup>Research, SGX Medical, Bloomington, United States of America, <sup>2</sup>Psychology, Illinois Wesleyan University, Bloomington, United States of America, <sup>3</sup>Research, Lumbrera LLC, Bloomington, United States of America, <sup>4</sup>Pain Medicine, National Spine and Pain Center, Bloomington, United States of America, <sup>5</sup>Neuromodulation, Medtronic, Minneapolis, United States of America

**Introduction:** In an animal model of chronic neuropathic pain, spinal cord stimulation (SCS) utilizing a differential target multiplexed programming (DTMP) demonstrated significant improvements in pain-like behavior (i.e. mechanical and thermal hypersensitivity) and modulated gene expression within pain-related biological processes toward the levels of naïve animals.<sup>1,2,3,4</sup> This work has been translated successfully to the clinic (DTM™ SCS) in patients with chronic pain.<sup>5</sup> This study presents the results of a reduced energy derivative of DTMP using the same animal model.

**Methods/Materials:** Procedures were approved by the IACUC at Illinois Wesleyan University. Adult male Sprague-Dawley rats were randomly assigned to one of five groups: Naïve, No-SCS, DTRE1-SCS, DTRE2-SCS, and Low-Rate (LR)-SCS. Animals in SCS groups were subjected to the spared nerve injury (SNI) neuropathic pain model for 5 days, were implanted with a four-contact cylindrical mini-lead at L1 level and received continuous stimulation for 48 hours. Animals in the No-SCS group were given sham stimulation. Mechanical hypersensitivity was assessed by blinded evaluators using an electronic anesthesiometer before SNI, before SCS and during SCS. Statistical analyses (SPSS) were performed to evaluate the effect of treatment ( $P < 0.05$  was considered significant). Sections of the spinal cord ipsilateral to injury and adjacent to the stimulation lead were collected for RNA extraction. RNA sequencing is currently undergoing.

**Results:** Table 1 summarizes mean normalized paw withdrawal thresholds (PWT) as a percentage of pre-SNI for each group and the p-values for within group comparisons. Animals subjected to the SNI model experienced a significant reduction ( $P < 0.0001$ ) in PWT relative to naïve animals. All SCS treatments provided significant improvements of mechanical hypersensitivity. Furthermore, improvement with either reduced energy derivative of DTMP was significantly better than that obtained with LR SCS (Table 2). Transcriptomics analysis from RNA sequencing of spinal cord tissues will be presented.

**Table 1.** Mechanical hypersensitivity (normalized to PWT measure pre-intervention) for experimental groups.

Group	Pre-SCS $\pm$ SD (N)	Post-SCS $\pm$ SD (N)	P value (Pre vs. Post) <sup>‡</sup>
Naïve*	97.5 $\pm$ 7.9 (9)	98.7 $\pm$ 8.0 (9)	0.739
No-SCS*	28.1 $\pm$ 6.0 (13)	28.4 $\pm$ 5.7 (13)	0.920
LR-SCS	35.0 $\pm$ 7.8 (10)	54.5 $\pm$ 7.3 (10)	<0.0001
DTRE1-SCS	31.0 $\pm$ 5.7 (9)	66.8 $\pm$ 12.7 (9)	<0.0001
DTRE2-SCS	35.5 $\pm$ 8.2 (12)	70.9 $\pm$ 12.3 (12)	<0.0001

\* Animals in these groups did not receive SCS but were tested in parallel to the SCS groups. Animals in the No-SCS were handled as if they were stimulated by a researcher blinded to interventions. ‡ Two-tailed paired t-test.

**Table 2.** Matrix of corrected P values for the post-SCS multiple comparisons between the experimental groups with interventions.

Group*	No-SCS	LR-SCS	DTRE1-SCS	DTRE2-SCS
No-SCS	1.000	<0.0001	<0.0001	<0.0001
LR-SCS		1.000	0.0203	0.0002
DTRE1-SCS			1.000	0.463
DTRE2-SCS				1.000

\* Animals in the No-SCS group were handled as if they were stimulated by a researcher blinded to the intervention (No-SCS or SCS).

**Discussion:** A reduced energy derivative of DTMP significantly reduced mechanical hypersensitivity in an animal model of neuropathic pain. Given the congruency of this result with previously reported preclinical DTMP results<sup>1,2,3,4</sup>, a shared mechanism of action is hypothesized.

**Conclusions:** The DTMP patterns evaluated maintain the key elements of therapy based on differential stimulation of neurons and glial cells with multiple electrical signals. This research has potential benefits if translated effectively into a clinical setting to offer multiple effective therapy options that can meet the unique needs of a patient.

**References:** Vallejo R, Kelley CA, Gupta A, Smith WJ, Vallejo A, Cedeño DL. Modulation of neuroglial interactions using differential target multiplexed spinal cord stimulation in an animal model of neuropathic pain. *Mol Pain*. 2020 Jan-Dec;16:1744806920918057. Vallejo R, Smith W, Kelley C, et al. Neuron-glial inflammasome enhanced reversal by DTM-SCS relative to high rate and low rate SCS in a neuropathic pain model. *American Society for Regional Anesthesiology and Pain Medicine*

(ASRA); November 14-17, 2019; New Orleans, LA. Abstract #480 Vallejo R, Kelley C, Smith W, et al. Cell-specific targeting in neural tissue using Differential Target Multiplexed (DTM) SCS. American Society for Regional Anesthesiology and Pain Medicine (ASRA); November 14-17, 2019; New Orleans, LA. Abstract #513 Vallejo R, Tilley D, Kelley C, et al. Proteomics of Differential Target Multiplexed-SCS applied to an animal model of neuropathic pain. American Society for Regional Anesthesiology and Pain Medicine (ASRA); November 14-17, 2019; New Orleans, LA. Abstract #509 Fishman M., Codner H., et al. DTM™ SCS RCT 12-month data results. Presented at a Medtronic webinar, jointly supported by the North American Neuromodulation Society, World Institute of Pain, and the American Society for Pain and Neuroscience. October 19, 2020. Webinar available on society websites

**Keywords:** Differential Target Multiplexed Stimulation, Reduced Energy, Pain, Spinal Cord Stimulation (SCS)

## NEUROSTIMULATION IS AN EFFECTIVE TREATMENT OPTION FOR WELL-SELECTED CHRONIC BACK PAIN PATIENTS WITH OR WITHOUT PRIOR LUMBAR SURGERY

### E-POSTER VIEWING

Jan Vesper<sup>1</sup>, Davis Schultz<sup>2</sup>, Steven Falowski<sup>3</sup>, Michael Fishell<sup>4</sup>, Alfonso Papa<sup>5</sup>, Bram Blomme<sup>6</sup>, Robyn Capobianco<sup>7</sup>

<sup>1</sup>Functional Neurosurgery And Stereotaxy, University Clinic Duesseldorf, Dusseldorf, Germany, <sup>2</sup>Pain Management, Nura Pain Clinics, Minneapolis, United States of America, <sup>3</sup>Functional Neurosurgery, Neurosurgical Associates of Lancaster, Lancaster, United States of America, <sup>4</sup>Pain Management, Advanced Pain Care, Henderson, United States of America, <sup>5</sup>Pain Department, Monaldi Hospital, AO Ospedali dei Colli, Napoli, Italy, <sup>6</sup>Neuromodulation, Abbott, Zaventem, Belgium, <sup>7</sup>Neuromodulation, Abbott, Austin, United States of America

**Introduction:** Chronic low back pain (CLBP) is a highly prevalent and costly condition.<sup>1</sup> Individuals with a clear anatomic pain generator may be offered surgery. Despite successful surgery, a percentage of these patients will suffer from persistent pain. Many subjects cannot or do not need to undergo spine surgery. This could be the case for patients in which imaging does not reveal any significant abnormality or patients with comorbidities preventing surgery. Spinal cord stimulation (SCS) is considered a therapy of last resort for CLBP and may not be reimbursed in the absence of prior spinal surgery. Herein we present data on the effectiveness of burst SCS in surgical naïve and non-naïve CLBP patients from the prospective, multi-center, international REALITY study (NCT03876054).

**Methods/Materials:** Three groups of subjects with CLBP were identified: non-surgical back pain (NS-BP), subjects with persistent spinal pain syndrome (PSPS)<sup>2</sup> after lumbar spinal fusion operation (PSPS-F), and PSPS subjects who did not undergo an instrumented procedure (PSPS-NF). Responder analyses at 6 months for Numerical Rating Scale (NRS) and Oswestry Disability Index (ODI) were performed based on minimal clinically important differences (MCID).

**Results:** 6-month data were available for 187 subjects; 68, 69, and 50 in PSPS-F, PSPS-NF, and NS-BP groups, respectively. 49% in the PSPS-F group had undergone multiple back surgeries vs 16% in the PSPS-NF group. Subjects in the NS-BP and PSPS-NF groups responded similarly on pain intensity; 74% and 72% met MCID on NRS, in contrast with 59% in the PSPS-F group. MCID on ODI was achieved by 54% and 55% in the PSPS-NF and NS-BP groups, versus only 39% of PSPS-F subjects. PROMIS-29 domains confirmed the trend outlined above; PSPS-NF and PSPS-F subjects reported the highest and lowest relative changes. 80% of subjects in the NS-BP group were satisfied or very satisfied with the therapy, compared with 69% and 60% in the PSPS-NF and PSPS-F group.

**Discussion:** At 6 months of burst SCS therapy, subjects without prior back surgery or who had non-instrumented surgery reported greater improvements in pain and function compared to those who had undergone spinal fusion. Our preliminary results of burst SCS therapy hold promise for patients who are either not candidates for or cannot undergo surgery to address their CLBP. Further studies (DISTINCT NCT04479787) are underway.

**Conclusions:** Burst SCS is an effective treatment option for CLBP patients after or in the absence of prior spine surgery.

**References:** 1. Vos T, Abajobir AA, Abate KH, Abbafati C, Abbas KM, Abd-Allah F, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. *The Lancet*. 2017;390(10100):1211-59 2. Christelis N, Simpson B, Russo M, et al. Persistent Spinal Pain Syndrome: A Proposal for Failed Back Surgery Syndrome and ICD-11. *Pain Med*. 2021;pnab015

**Keywords:** Neurostimulation, chronic low back pain, Burst

Topic: 05. Spine / 05a. Pain

## BURST SPINAL CORD STIMULATION CAN ATTENUATE PAIN AND ITS AFFECTIVE COMPONENTS IN CHRONIC PAIN PATIENTS WITH HIGH PSYCHOLOGICAL DISTRESS

### E-POSTER VIEWING

Isaac Peña<sup>1</sup>, Edward Tavel<sup>2</sup>, Gregory Moore<sup>3</sup>, Kelby Hutcheson<sup>4</sup>, Bram Blomme<sup>5</sup>, Robyn Capobianco<sup>6</sup>

<sup>1</sup>Department Of Anesthesiology And Pain Management, Hospital Universitario Virgen del Rocío, Seville, Spain, <sup>2</sup>Interventional Pain Management, Clinical Trials of South Carolina, Charleston, United States of America, <sup>3</sup>Interventional Pain Management, Pacific Sports and Spine, Eugene, United States of America, <sup>4</sup>Pain Management, Carolinas Center for Advanced Management of Pain, Columbia, United States of America, <sup>5</sup>Neuromodulation, Abbott, Zaventem, Belgium, <sup>6</sup>Neuromodulation, Abbott, Austin, United States of America

**Introduction:** Psychological factors such as depression, anxiety, and poor coping strategies have been shown to predict negative outcomes after lumbar spine surgery and spinal cord stimulation (SCS).<sup>1-3</sup> Uniquely, burst SCS attenuates the emotional aspects of chronic pain, likely through preferential recruitment of the medial pain pathway in the brain that project to the dorsal anterior cingulate cortex and anterior insula.<sup>4,5</sup> Herein we present outcomes in patients with and without psychological distress undergoing burst SCS in a prospective, multi-center, single-arm, international study (TRIUMPH-NCT03082261).

**Methods/Materials:** Eligible patients with chronic, intractable pain of the trunk and/or lower limbs were enrolled. After a successful trial period, subjects received a permanent SCS implant and returned for regular follow-up. Two-year outcomes were evaluated in subjects with psychological distress (PD) and with no distress (ND). PD was defined as scores of  $\geq 30$  on the Pain Catastrophizing Scale (PCS) and  $\geq 10$  on the Patient Health Questionnaire Depression scale (PHQ-9). ND subjects were below clinical impact scores on both scales. Responder analyses were performed for several outcome measures, based on published standards and minimal clinically important differences (MCID).

**Results:** 24-month data were available for 128 subjects enrolled at 17 centers. At baseline, 31 (24%) and 54 (42%) subjects met the definition of PD and ND, respectively. Baseline measures indicated a more severe chronic pain profile with poor quality-of-life in PD subjects. Two years after implant, 71% were no longer clinically catastrophizing (on PCS) and 58% were no longer clinically depressed (on PHQ9). The proportion of subjects with a clinically meaningful reduction on PCS (55% vs 59%) and patient reported pain relief (58% vs 61%) were similar in the two groups. 74% of subjects in the PD group met the MCID for quality-of-life on EQ-5D vs 52% in the ND group. 71% had minimal or moderate impact of pain in the PD group (up from 10% at baseline) vs 78% in the ND group (up from 30% at baseline). 81% in each group were satisfied or very satisfied with the pain relief provided.

**Discussion:** After two years of burst SCS, chronic pain patients with psychological distress reported higher relative improvements and had similar levels of satisfaction and impact of pain on daily life than subjects without distress.

**Conclusions:** Burst SCS is an effective therapy for patients with chronic pain who are suffering from psychological distress, a difficult patient population when first-line treatments are unsuccessful.

**References:** 1. Amaral V, Marchi L, and Martim H et al. Influence of psychosocial distress in the results of elective lumbar spine surgery. *J Spine Surg.* 2017; 3(3):371–378 2. Jackson KL, Rumley J, Griffith M, Agochukwu U, DeVine J. Correlating Psychological Comorbidities and Outcomes After Spine Surgery. *Global Spine J.* 2020;10(7):929-939 3. Block AR, Marek RJ, Ben-Porath YS, Kukal D. Associations Between Pre-Implant Psychosocial Factors and Spinal Cord Stimulation Outcome: Evaluation Using the MMPI-2-RF. *Assessment.* 2017;24(1):60-70 4. Yearwood T, De Ridder D, Yoo

HB et al. Comparison of Neural Activity in Chronic Pain Patients During Tonic and Burst Spinal Cord Stimulation Using Fluorodeoxyglucose Positron Emission Tomography. *Neuromodulation*. 2020;23(1):56-63 5. De Ridder D, Vanneste S. Burst and Tonic Spinal Cord Stimulation: Different and Common Brain Mechanisms. *Neuromodulation*. 2016;19:47-59

**Keywords:** Burst, depression, Spinal cord stimulation, chronic pain, Catastrophizing

**Topic:** 05. Spine / 05a. Pain

**DYNAMIC BRAIN IMAGING RESPONSE TO SCS DIFFERENTIAL FREQUENCIES: DOUBLE-BLIND RANDOMISED CONTROLLED TRIAL (DIFY SCS-PET RCT)**

**E-POSTER VIEWING**

Kavita Poply<sup>1</sup>, Athar Haroon<sup>2</sup>, Serge Nikolic<sup>1</sup>, Alia Ahmad<sup>1</sup>, Habib Ellamushi<sup>1</sup>, Balaji Ganeshan<sup>3</sup>, Arman Parsai<sup>2</sup>, Vivek Mehta<sup>1</sup>

<sup>1</sup>Pain Research Centre, Barts Health NHS Trust, London, United Kingdom, <sup>2</sup>Nuclear Medicine, Barts Health NHS Trust, London, United Kingdom, <sup>3</sup>Nuclear Medicine, University College of London, London, United Kingdom

**Introduction:** This single-centre, double-blind, randomised, cross-over trial (national research ethical approval:17/LO/0655, Clinical Trial Gov: NCT03716557) with sequential 18F-FDG PET-CT scanning was designed to investigate any objective measurable effect of differential frequency stimulation (40Hz, 4000Hz and 10,000Hz frequency) on the response of specific pain matrix areas and identify changes in brain metabolic activity.

**Methods/Materials:** 22 patients were recruited to undergo SCS. Brain 18F-FDG-PET scan was performed at baseline before implant and after 40 Hz, 4000Hz and 10000Hz frequency stimulation; 1:1 randomisation and 4-week crossover. 18F-FDG-PET CT Brain scans (250 MBq dose) acquired on GE-Discovery 710 PET system with 128 slice CT PMOD software (PMOD Technologies Ltd, Sumatrastrasse 25, 8006 Zurich, Switzerland) were analyzed. 18 brain areas representing pain: right and left prefrontal cortex (PFC), insula, anterior cingulate cortex, hippocampus, amygdala, primary somatosensory cortices (SSCI), secondary somatosensory cortices (SSCII), thalami and parabrachial and periaqueductal grey (PAG) were analyzed. Absolute value, change, and % change in PET uptake (SUVmax) at each frequency (40Hz, 4000Hz, and 10,000Hz) from baseline were quantified.

**Results:** 18 patients underwent baseline PET scan (Aug 2017-Feb 2020; 15 implanted, 3 trial failures). 57 PET-CT scans (15 baselines; 14 each for 40 Hz, 4000 Hz, and 10,000 Hz) were analyzed. There was a statistically significant difference in SUVmax between 40 Hz and baseline ( $p=0.002$ ), 4000Hz and baseline ( $p=0.001$ ) when pooled across 18 pain matrices with no statistical difference in SUV max between 10,000 Hz and baseline. In the pooled data across all frequencies, proportionately higher thalamic regions (59.5%) demonstrated reduction in metabolic activity in comparison to other pain matrices PFC (52%), insula (50%), ACC (52%) SSCII (49%), and PAG (52%).



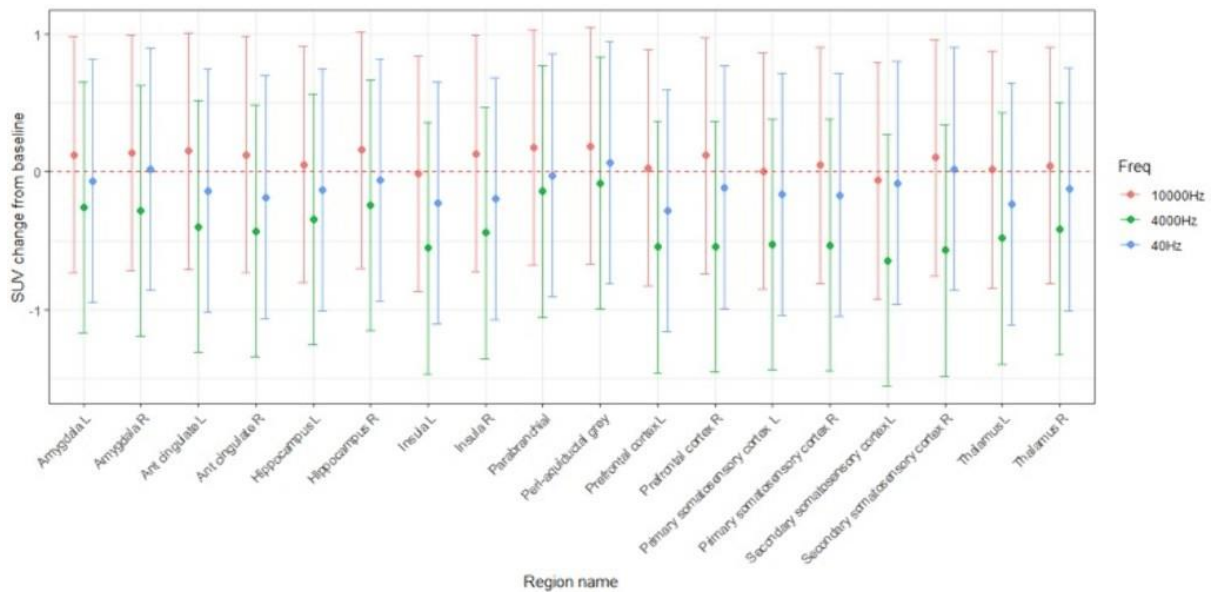


Figure 1: Least squares means plot demonstrates change in PET uptake for 18 pain matrix regions.

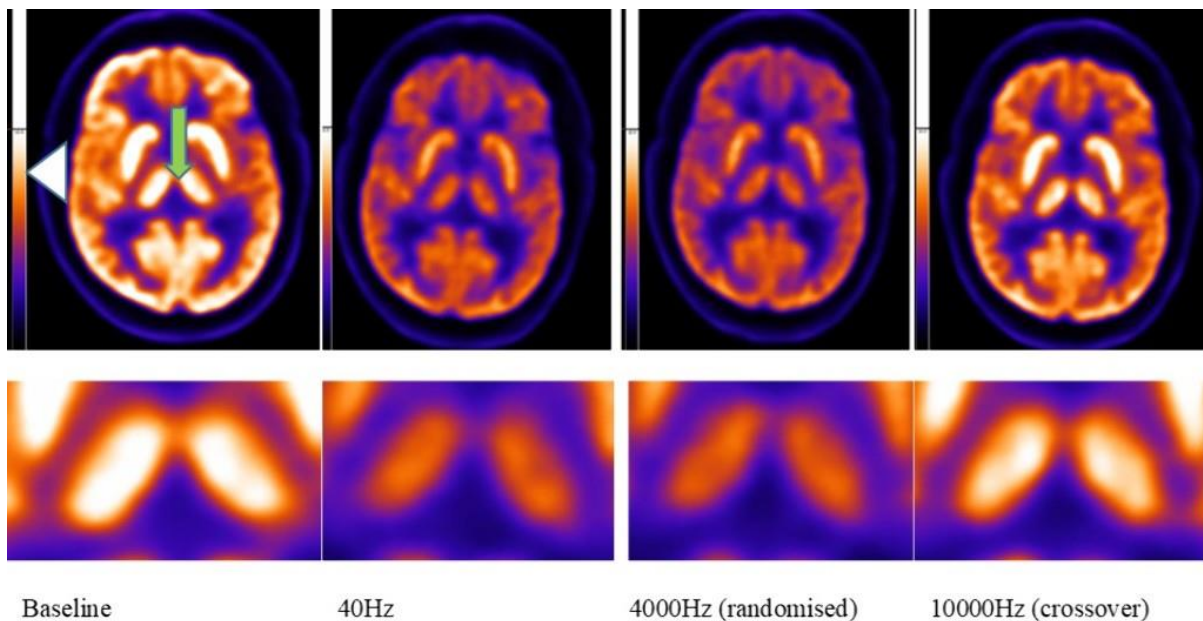


Figure 2: 18F-FDG PET brain images (Top) and corresponding axial thalamus images (bottom). Green arrow- Thalamus, White arrow- Image intensity bar

**Discussion:** This is the largest cohort of brain PET scans ( $n=57$ , scans; 15 scans at baseline and 14 scans at each 40Hz, 4000Hz and 10,000Hz) reported in patients undergoing SCS that demonstrates statistically significant differences in brain metabolic activity at 40 Hz and 4000Hz from baseline, with effect on both nociceptive and affect-cognitive pathways (proportionately higher reduction in thalamus).

**Conclusions:** This study reports statistically significant differences in brain metabolic activity at 40 Hz and 4000Hz from baseline, with effect on both nociceptive and affect-cognitive pathways, highlighting possible mechanism of SCS.

**References:**

**Keywords:** Spinal cord stimulation, brain imaging, positron emission tomography, neuropathic pain, Randomised Controlled Trial

**Topic:** 05. Spine / 05a. Pain

## **EFFECTS OF SPINAL CORD STIMULATION ON SPECTRAL FEATURES IN RESTING STATE MAGNETO- AND ELECTROENCEPHALOGRAPHY: A LITERATURE REVIEW**

### **E-POSTER VIEWING**

Lucas Ottenheim<sup>1</sup>, Bart Witjes<sup>2</sup>, Frank Huygen<sup>3</sup>, Cecile De Vos<sup>3</sup>

<sup>1</sup>Educational Program Technical Medicine, Leiden University Medical Center, Delft University of Technology & Erasmus University Medical Center Rotterdam, Delft, Netherlands, <sup>2</sup>Center For Pain Medicine, Department Of Anesthesiology, Erasmus MC, Rotterdam, Netherlands, <sup>3</sup>Center For Pain Medicine, Department Of Anesthesiology, Erasmus University Medical Centre, Rotterdam, Netherlands

**Introduction:** Spinal cord stimulation (SCS) has shown to be an effective treatment for many patients suffering from chronic pain. However despite its effectiveness there are still patients for whom SCS does not result in sufficient pain relief after implantation. Effectiveness of SCS is hard to predict, as its precise working mechanisms are yet not fully unraveled. Besides the dorsal horn pain processing circuit, also supraspinal mechanisms of action could be involved [1,2]. Neurophysiological brain activity recorded with functional neuroimaging techniques such as magnetoencephalography (MEG) or electroencephalography (EEG) could provide insights in these supraspinal mechanisms of action. In our literature review, we aimed to provide an overview of studies on the effect of SCS on neuronal activity.

**Methods/Materials:** Online databases were searched to identify studies that reported on SCS, chronic pain, and magnetoencephalography (MEG) or electroencephalography (EEG). The primary outcome measures were changes in spectral features, combined with the brain regions in which these changes occurred.

**Results:** In total 9 studies were included. These studies reported on various types of SCS, including tonic, burst, high dose and high frequency stimulation, and showed great heterogeneity in outcome parameters. Changes in alpha (7-12 Hz) and theta (4-7 Hz) band activity were most often studied, followed by beta (13-30 Hz) and gamma (30-44 Hz). The somatosensory cortex showed modulation of spectral features under tonic, burst and high-frequency stimulation in multiple studies. Furthermore, changes in connectivity were found in the dorsal anterior cingulate cortex, dorsolateral prefrontal cortex and the parahippocampus.

**Discussion:** The large heterogeneity in reported outcome measures is probably due to large variety in study design, stimulation type and spectral features studied. The variation in findings in the studies suggest that different types of stimulation affect different pain processing pathways. This would indicate that more insight in the cortical spectral modulations caused by specific SCS settings or in specific pain conditions will help to further optimize SCS treatment.

**Conclusions:** We present an overview of spectral features and cortical regions that were found to be affected by Spinal Cord Stimulation.

**References:** 1. Zhang, T.C., J.J. Janik, and W.M. Grill, Mechanisms and models of spinal cord stimulation for the treatment of neuropathic pain. *Brain Res*, 2014. 1569: p. 19-31. 2. Bentley, L.D., et al., Brain activity modifications following spinal cord stimulation for chronic neuropathic pain: A systematic review. *Eur J Pain*, 2016. 20(4): p. 499-511.

**Keywords:** Spinal cord stimulation, EEG, MEG, chronic pain

**Topic:** 05. Spine / 05a. Pain

## RETROSPECTIVE ANALYSIS OF SAFETY AND EFFICACY OF SPINAL CORD STIMULATION (SCS) THERAPY FOR CHRONIC NEUROPATHIC PAIN AT CAMBRIDGE UNIVERSITY HOSPITAL

### E-POSTER VIEWING

Rokas Tamosauskas<sup>1</sup>, [Dylan Whitaker](#)<sup>2</sup>

<sup>1</sup>Department Of Anaesthesia, Cambridge University Hospitals NHS Foundation Trust, Addenbrooke's Hospital, Cambridge, United Kingdom, <sup>2</sup>School Of Medicine, Cambridge University, Cambridge, United Kingdom

**Introduction:** At CUH we have been offering a Spinal Cord Stimulation (SCS) for chronic neuropathic pain management for 7 years. Whilst the safety and efficacy profiles are well established in both observational studies and RCTs, we looked at how well these translated into our real-world public health service. We aimed to look a safety, complication rate, patient outcomes and how these compared to a published data. In 2019 our centre started a single stage SCS implantation pilot, where selected patients have been offered a single-stage SCS implantation instead of two-stage procedure. The latter was thought to be related to a higher infection rate, as during a trial SCS implantation part of SCS system was externalised and may have become susceptible to infection.

**Methods/Materials:** Retrospective analysis using electronic health records for rate of complication, patient reported outcomes on level of pain experienced with the British Pain Inventory (BPI) , level of disability with the Roland Morris and Euroqol 5D assessment of quality of life. The patient reported outcomes were investigated for the change after implantation. Complication rates analysed before and after change of implantation pathway in February 2019 and compared to a published literature.

**Results:** There was a significant decrease in the level of pain experienced, level of disability and a significant increase in the quality of life reported by patients after SCS implantation. There was a large magnitude of change in quality of life and pain experienced with a moderate change in the level of disability experienced. The total rate of complications, including the rate of infection was less than what is considered standard in the literature after the pathway has changed to a single stage SCS implantation.

**Discussion:** We showed that the attained PROMs for SCS compared favourably with the published literature. Total complication rate compared favourably with the published literature. Although SCS infection rate seemed higher than average published infection rate, after SCS pathway change to a single-stage implantation, infection rate dropped from 12.2% to a 1.7% without any noticeable reduction in attained PROMs in the first 12 months.

**Conclusions:** The Cambridge University Hospital Chronic Pain Service is providing the gold standard of care for their patients receiving spinal cord stimulation therapy. Spinal Cord Stimulation offers not only a reduction in the patient's experience of pain and disability but also a significant increase in their quality of life. A single stage implantation has improved safety of this procedure, reduced complication rate without compromising outcomes.

**References:** 1. Bendel MA, O'Brien T, Hoelzer BC, Deer TR, Pittelkow TP, Costandi S, Walega DR, Azer G, Hayek SM, Wang Z, Eldrige JS, Qu W, Rosenow JM, Falowski SM, Neuman SA, Moeschler SM, Wassef C, Kim C, Niazi T, Saifullah T, Yee B, Kim C, Oryhan CL, Warren DT, Lerman I, Mora R, Hanes M, Simopoulos T, Sharma S, Gilligan C, Grace W, Ade T, Mekhail NA, Hunter JP, Choi D, Choi DY. Spinal Cord Stimulator Related Infections: Findings From a Multicenter Retrospective Analysis of 2737 Implants. *Neuromodulation*. 2017 Aug;20(6):553-557. doi: 10.1111/ner.12636. Epub 2017 Jul 20. PMID: 28726312. 2. North R, Desai MJ, Vangeneugden J, et al. Postoperative Infections Associated With Prolonged Spinal Cord Stimulation Trial Duration (PROMISE RCT). *Neuromodulation*. 2020;23(5):620-625. doi:10.1111/ner.13141 3. Hoelzer BC, Bendel MA, Deer TR, Eldrige JS, Walega DR, Wang Z, Costandi S, Azer G, Qu W, Falowski SM, Neuman SA, Moeschler

SM, Wassef C, Kim C, Niazi T, Saifullah T, Yee B, Kim C, Oryhan CL, Rosenow JM, Warren DT, Lerman I, Mora R, Hayek SM, Hanes M, Simopoulos T, Sharma S, Gilligan C, Grace W, Ade T, Mekhail NA, Hunter JP, Choi D, Choi DY. Spinal Cord Stimulator Implant Infection Rates and Risk Factors: A Multicenter Retrospective Study. *Neuromodulation*. 2017 Aug;20(6):558-562. doi: 10.1111/ner.12609. Epub 2017 May 11. PMID: 28493599.

**Keywords:** patient reported outcome measures (PROMs), Spinal Cord Stimulation (SCS); quality of life (QoL); complications; infection;

**Topic:** 05. Spine / 05b. Spasticity and Movement Disorders

## INTRATHECAL BACLOFEN TREATMENT IN TBI AND SPINAL CORD INJURIES

### E-POSTER VIEWING

Tanju Uçar

Neurosurgery Dept, akdeniz university medical faculty, antalya, Turkey

**Introduction:** Spasticity is associated with a various neurological condition such as cerebral palsy (CP), Traumatic brain injury (TBI), spinal cord injury (SCI), and other neurologic disorders . Intrathecal baclofen is one of the popular treatment for severe spasticity.

**Methods/Materials:** In this paper we present our experiences in treating 123 patients with spinal cord and severe head injuries with chronic infusion of Baclofen The medical records of 123 patients who underwent baclofen pump placement from 2000 to 2018 were reviewed 42 of the patients were spinal cord injury and 51 of them were severe head injuries and 30 are other etiologies. All patients evaluated by means of ashworth score, spasm frequency, barthel index, rankin scales and VAS.

**Results:** •Spasticity and spasm frequency were clinically and statistically decreased in all patients.  
•The mean Ashworth score of upper extremity decreased from  $1.91 \pm 1.75$  to  $1.0 \pm 0.89$ , and the lower extremity score decreased from  $3.64 \pm 0.50$  to  $1.36 \pm 0.80$  (  $p=0.010$  and  $p= 0.002$  respectively).  
Spasticity score and spasm frequency decreased with in the initial first year, then tend to stabilize.

**Discussion:** ITB therapy increases the quality of lifestyle and functional independence by reducing not only cerebral but also spinal related spasticity in appropriately selected cases. It is necessary to have much more controlled studies to achieve more accurate and precise outcomes of ITB therapy.

**Conclusions:** ITB therapy increases the quality of lifestyle and functional independence by reducing not only cerebral but also spinal related spasticity in appropriately selected cases. It is necessary to have much more controlled studies to achieve more accurate and precise outcomes of ITB therapy.

### References:

**Keyword:** spasticity, baclofen

**Topic:** 05. Spine / 05b. Spasticity and Movement Disorders

**SPINAL CORD INJURIES IN UAE: RETROSPECTIVE, DEMOGRAPHIC & OVERVIEW STUDY OF PATIENTS ADMITTED & MANAGED IN NEURO-SPINAL HOSPITAL /DUBAI**

**E-POSTER VIEWING**

Kaydar Al-Chalabi

Pm,r &r, Al-Moosa Medical Center/Dubai.Prime Hospital /Dubai, Dubai, United Arab Emirates

**Introduction:** Study Design: Retrospective Demographic Statistical Analysis & Overview of the Concept of Comprehensive Management & Rehabilitation in UAE. Settings: Neuro -Spinal Hospital /Dubai UAE. Objectives: 1. Demographic Statistical Analysis of 232 patients (age, gender, nationality, etiology /nationality: UAE locals, Expats: Arabs & Non Arabs, levels & types of injuries, surgical & conservative managements). 2. Overview of quality, concepts, status of comprehensive care, management & rehabilitation In

**Methods/Materials:** Patients: Spinal cord injured patients admitted in Neuro-Spinal Hospital during the period February 2003 till December 2019 were 232 patients.UAE locals were 114(49%),expats 118(51%).Males 176(76%),females 56(24%).Tetraplegia 66(28%), paraplegia 166(71.5%).Age :153 (66%) are below 40 years. Etiology :RTA 135(58%),fall from heights 44 (19%),sport injuries 23 (10%),diseases 20 (8.5%).Surgical procedures ( fixation, decompression laminectomy , excision, baclofen pumps ,spinal cord stimulation ,sacral roots stimulations ,etc.) were done on 140 patients (60%) while the rest were admitted for conservative treatment .

**Results:** Concept & status of SCI management & Rehabilitation in UAE differs from other countries where there are holistic SCI centers, such are not available & for that reason it is very difficult to obtain national data or registry of such cases or incidence,

**Discussion:** UAE is multinationalities country and according to population census 88.5% are expats while locals constitute only 11.5%.On the other hand, in UAE there is huge construction works, all kinds of sport activities, high speed modern vehicles. In each kind of work, the domain is from certain countries and each of them has different interests, hobbies as per their culture, habits, religion, traditions etc.

**Conclusions:** In spite of all modern life facilities, services &high standard health care whether governmental or private which are afforded by local emirates or federal governments for all people, locals or residents , concept of SCI comprehensive care ,management & rehabilitation is still not coping with the international standards. No national data about incidence, impact & awareness of such issue can be obtained or retrieved & no SCI center per se neither in the capital/Abu Dhabi nor in the other emirates.

**References:**

**Keyword:** SPINAL CORD INJURIES MANAGEMENT UAE

**Topic:** 05. Spine / 05b. Spasticity and Movement Disorders

## RESULTS OF SPINAL CORD STIMULATION IN PATIENTS WITH MULTIPLE SCLEROSIS

### E-POSTER VIEWING

Alessandro Rapisarda, Nicola Montano  
Neurosurgery, IRCSS Fondazione Agostino Gemelli, Rome, Italy

**Introduction:** Movement disorders, neuropathic pain and urinary dysfunction are the main symptoms in patients with multiple sclerosis (MS). These symptoms can lead to a severe disability which can be very difficult to treat with medications. In the past decades, immune-modulating therapy has been the main focus of MS research with little attention to neuromodulation approaches. Moreover the results of spinal cord stimulation (SCS) in MS patients have been reported only marginally due to the fact that MS patients usually comprise a subset of the subjects of any SCS study. Thus few studies specifically focused on SCS in MS patients. The aim of our study was to systematically review the literature on SCS in MS patients analysing the results of this technique on motor, pain and urinary symptoms recovery.

**Methods/Materials:** A Pubmed search was performed since 1973 to nowadays using the following terms: "multiple sclerosis", "spinal cord stimulation". We found 22 pertinent articles. Case series with more than 5 patients were considered for our literature analysis. We included only articles in which the data and follow-up were clearly reported. Only 9 articles were available for an analytic assessment.

**Results:** There were 229 MS patients who were submitted to a SCS trial and 269 MS patients who underwent de novo implantation. The mean age at implantation was  $44,25 \pm 0,75$  years and the mean FU was  $44,4 \pm 25$  months. Of the patients submitted to the trial 140/229 (61.13%) decided to go on with a permanent stimulation. Long-lasting improvement was documented in 94 out of 180 (52.22%) patients with movement disorders and in 90 out of 134 (67.13%) patients with bladder dysfunction. A long lasting pain relief was obtained in 43 out of 56 (76.78%) patients.

**Discussion:** Effectiveness of SCS in MS has been thoroughly debated in literature without a definitive conclusion. The main problems are the different scores used among the different papers in evaluating functional results and the selection of patients submitted to SCS. Nonetheless from our analysis bladder dysfunction and pain symptoms seem to be the most responsive to SCS.

**Conclusions:** SCS is effective in improving the quality of life of MS patients. Further studies are needed to improve the patient's selection and clarify the best timing to perform SCS in these patients.

### References:

**Keyword:** SCS, Multiple Sclerosis



## ULTRASOUND DETECTING LOCAL TWITCH RESPONSE AND `NEEDLE GRASP` PHENOMENA DURING DRY NEEDLING

### E-POSTER VIEWING

Rostyslav Bubnov<sup>1,2</sup>, Lev Kalika<sup>3</sup>

<sup>1</sup>Ultrasound, Clinical hospital `Pheophania`, Kyiv, Ukraine, <sup>2</sup>Interferon, Zabolotny Institute of Microbiology and Virology, National Academy of Sciences o, Kyiv, Ukraine, <sup>3</sup>Rehab, New York Dynamic Neuromuscular Rehabilitation & Physical Therapy <https://nydnrehab.com>, New York, Ukraine

**Introduction:** Ultrasound revolutionized myofascial pain treatment, precise muscle dry needling (DN) under ultrasound (US) guidance can multiply clinical effect [1]. Local muscle response (a.k.a. local twitch response, LTR) associated with inactivation myofascial trigger points (MTrP), however, controversies remain in the issue [2]. The aim was to test hypothesis that local muscle response is associated with clinical effect of precise DN.

**Methods/Materials:** We included 50 patients (28 females, 38±8.3 years old) with chronic low back pain. The protocol by R. Bubnov [1] was applied: MTrP were identified according to clinical examination, referred pain pattern, US identification; single fine (28G) steel needle DN under US guidance was applied to elicit LTR and/or `needle grasp`. We evaluated both phenomena, did shear wave sonoelastography (SWE), M-mode to detect fasciculations during DN. Visual analogue scale data (VAS0-10) were measured before and after procedures.

**Results:** The multifidus, shoulder rotators (subscapular, supraspinatus, etc.) muscles were the dominant localizations of MTrPs. During procedure we did re-evaluation motion and TrPs at 20-40 min after session beginning using supportive SWE and B-flow for mapping of affected muscles on medial / lateral; upper / lower portions. MTrPs were visualized as small 2-5 mm hypoechoic structures, stiff on SWE. During needling we detected LTR and locally increased stiffness in the tissue of `needle grasp`. To confirm effectiveness after DN we detected decreasing muscle stiffness, increasing echogenicity in the homogenous hypoechoic pattern appeared muscle striae, relaxation and increased motility. Crucial is comparison with contralateral side. Active MTrPs were seen as extremely stiffer areas (SWE up to 27 kPa), latent MTrPs had moderate stiffness at 6-10 kPa; stiffness decreased after treatment to 5-7 kPa. Most effective pain decrease was measured after ultraprecise needling to hypoechoic stiff area evoking strong `needle grasp` and LTR.

**Discussion:** Local muscle response (`needle grasp` and LTR) associated with precision of dry needling and predicts clinical outcomes in treatment myofascial pain. Considering ultraprecise multiparameter ultrasound mapping for multistep procedures helps to gain dramatically higher clinical effects.

**Conclusions:** Multimodality ultrasound is effective to monitor and predict dry needling outcome. Obtaining muscle response to DN is crucial for effective treatment myofascial pain.

**References:** 1. Bubnov RV: Evidence-based pain management: is the concept of integrative medicine applicable? EPMA J 2012, 3(1):13. <https://doi.org/10.1186/1878-5085-3-13> 2. Bubnov, R., Kalika, L. and Golubnitschaja, O. (2019) "IMPLICATION OF LOCAL MUSCLE RESPONSE TO PRECISE DRY NEEDLING IN CLINICAL OUTCOMES OF TREATMENT MYOFASCIAL PAIN." Morressier. doi: 10.26226/MORRESSIER.5D4434D506F5C40FC4487338.

**Keywords:** myofascial trigger points, local twitch response, ultrasound

**Topic:** 06. Headache

**ANTICEPHALGIC PHOTOPROTECTIVE PREMEDICATED MASK: A REPORT OF A SUCCESSFUL STUDY OF A TREATMENT FOR MIGRAINE AND/OR TENSION HEADACHES .**

**E-POSTER VIEWING**

Morton Hyson

Neurology, University of Nevada School of Medicine, Las Vegas, United States of America

**Introduction:** This study was performed to determine the efficacy of an anticephalgic photoprotective mask in conjunction with a topical medication containing bryonia and rhus toxicodendron in the treatment of migraine and/or tension headache.

**Methods/Materials:**

Thirty-three patients were given masks and tubes of topical medication containing the bryonia and rhus toxicodendron. They were instructed to apply the medication to their frontalis and/or temporalis regions in the event they should suffer a headache and apply a photoprotective mask. Furthermore, they were instructed to take their usual oral or parenteral medications if required for the relief of the headache. They subsequently filled out forms rating the degree of relief which they attributed to the topical medication and the mask using a 0-10 scale. At the interview following the completion of their participation in the study, the patients were also simply asked if this form of treatment helped or not.

**Results:** Thirty out of 33 patients stated the medication and the mask were effective over and above the normal degree of relief they were receiving from their oral and/or parenteral medications. This study demonstrated a significant efficacy rate (91%) in the treatment of migraine and/or tension headache with the anticephalgic mask in conjunction with a topical cream containing bryonia and rhus toxicodendron.

**Discussion:** Many clinicians are seeking headache treatment modalities with improved safety profiles. A premedicated mask would serve not only as a delivery system for benign topical medication, but simultaneously provide photorelief and exert external pressure which may alleviate vascular headaches by collapsing painfully distended extracranial arteries and reducing peripheral sensitization. There is an OPIOID EPIDEMIC. This treatment works quickly, is safe and effective.

**Conclusions:** This treatment is safe and effective. It treats frontal- temporal myalgia, cephalgia and photosensitivity. It helps migraine and/ or tension headaches. It reduces the need for analgesic/ opioid medication.

**References:** 1. Gorgl A. Pharmacological Treatment of Headache Using Traditional Persian Medicine. Trends in Pharmacological Sciences. 2003. 24(7): 331-334.  
2. Entemadifar M, Abedi, The Preventive Role of Topical Timolol in Treatment of Migraine Headaches. Journal of Research in Medical Sciences. 2005. 10(5).  
3. Cutrer M, Olesen J, Burstein R, Hand Werker H, Dickesen A, and Fielas H. Research Teaching Course (Parallel Session): Mechanisms of Prolonged Headache. Abstract. Cephalgia. 2000.  
4. Blau JN and Solomon F. Smell and others sensory disturbances in migraine. J Neurol. 1985. 232: 275-276.  
5. Woodhouse A and Drummond PH. Mechanisms of increased sensitivity to noise and light in migraine headache. Cephalgia. 1993. pp 417-421.  
6. Drummond PH. A quantitative assessment of photophobia in migraine and tension headaches. Headache. 1986. 26:465-469.  
7. Hyson M. Anticephalgic Photoprotective Premedicated Mask. A Report of a Successful Double-Blind Placebo-Controlled Study of a New Treatment for Headaches with Associated Frontalis Pain and Photophobia. Headache. 1998.

38(6): 475-477.

8. Edmeads J. Unconventional techniques. In: Olesen J, Tfelt-Hansen P, Welch KM, eds. *The Headaches*. Raven Press. New York. 1993. pp 295-297.

9. Blau JN and Dexter SL. The site of pain origin during migraines attacks. *Cephalalgia*. 1981. 1:143-147.

10. Drummond PH and Lance JW. Extracranial vascular changes and the source of pain in migraine headache. *Ann Neurol*. 1983. 13: 32-37.

11. Lance JW. The controlled application of cold and heat by a new device (Migralief apparatus) in the treatment of headaches. *Headache*. 1988. 28: 458-461

**Keyword:** Migraines

**Topic:** 06. Headache

# **FEASIBILITY STUDY TO ASSESS THE EFFICACY OF PSILOCYBIN AS A TREATMENT FOR CHRONIC CLUSTER HEADACHES (PSILOCLEAD STUDY)**

## **E-POSTER VIEWING**

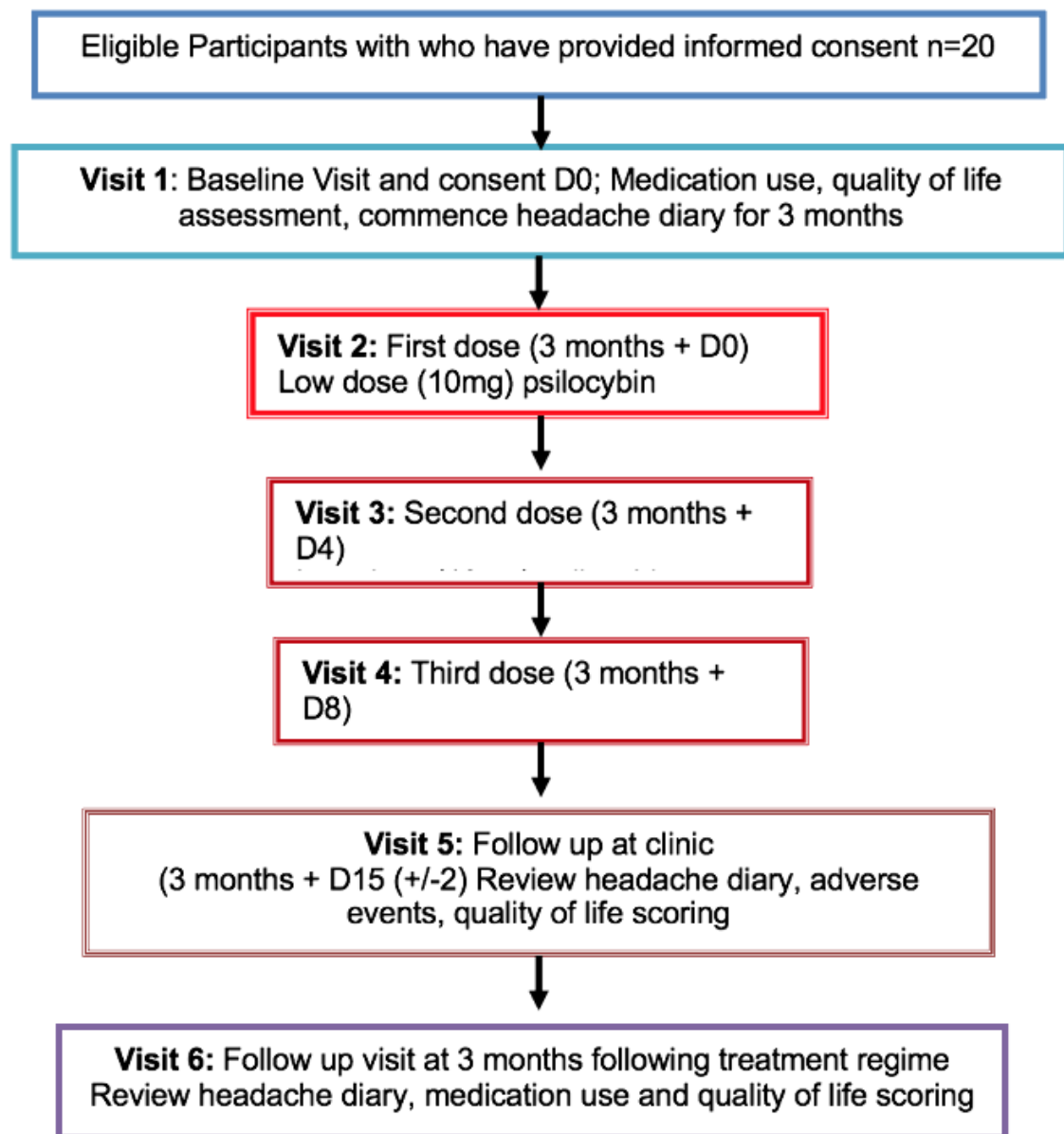
Andy Whelan, G. Baranidharan  
Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom

**Introduction:** The Psiloclead study aims to assess efficacy of a low dose pulsed Psilocybin regime as a treatment for chronic cluster headaches.

**Methods/Materials:** Psiloclead is a prospective single centre feasibility study taking place at Leeds Teaching Hospitals Trust. It is anticipated a total of 20 patients will be consented to take part in the study. Participants will be eligible to enter the study if meeting inclusion/exclusion criteria in table 1.

<b>Inclusion Criteria</b> Participants will be recruited to the study if he/she meets the following Inclusion criteria:	<b>Exclusion Criteria</b> Participants will not be recruited to the study if he/she meets any of the following exclusion criteria:
Patient is 18 years of age or older and given written informed consent.	Current or previously diagnosed psychotic disorder
In the investigator's opinion has chronic cluster headache with at least one attack every other day and no more than eight attacks each day	Immediate blood related family member diagnosed with a psychotic disorder
Attacks are managed by means involving no more than twice weekly triptan use (e.g., high-flow oxygen, heat/cold pack)	Pregnant, Breast feeding, Positive pregnancy test at screening or during the study, Lack of adequate birth control
In the Investigators opinion the patient is a suitable candidate for the trial.	Medically significant condition rendering unsuitability for the study in the opinion of the investigator (e.g. diabetes, epilepsy, severe cardiovascular disease, hepatic or renal failure etc.)
	History of suicide attempts
	Urine toxicology positive to drugs of abuse
	Use of antidepressants, (SSRIs, SNRIs and TCAs) in the last 6 weeks
	Currently using fentanyl, tramadol and MAOIs
	Use of serotonergic antiemetics (i.e. Ondansetron) in the past 2 weeks
	Patient is incapable of understanding or responding to the study questionnaires.
	Current drug or alcohol dependence within the last 2 years
	Use of vasoconstrictive medications (i.e. sumatriptan, pseudoephedrine, midodrine) within five half-lives of test days
	History of intolerance to psilocybin, lysergic acid diethylamide (LSD), or related compounds
	Patient is simultaneously participating in drug or device study within the last 30 days

If suitable for the study the participant will follow the treatment flow chart below



**Results:** The primary study endpoint for this study is as follows: Overall mean change from baseline in weekly cluster headache attack frequency at 3 months. Baseline is defined as the mean weekly headache frequency in the 3 months pre-treatment. The secondary study endpoints are Time to first attack after completion of pulse regimen; measured in days. Change in frequency of attacks; measured as average number of attacks (number per week). Use of abortive/rescue medication; number of times per week. Change in intensity of attacks; average intensity of attacks (1-10 on visual analog scale). Change in duration of attacks; average duration of attacks (minutes). Attack-free time; number of 24-hour days (may be nonconsecutive). Health-Related Quality of life, using EuroQol- 5D instrument. [Time Frame for these: Three months following the completion of pulse regimen using a headache diary (after completion of experimental sessions 1, 2, and 3)]. Adverse events (type, severity and trends) throughout the investigation including anxiety and/or paranoia, psychotic responses, and persistent perceptual changes. Patients Global impression of change [Time Frame: Measured at one week after treatment and 3 months after treatment]. Discontinuation rates

**Discussion:** The effect of treatment will be assessed by calculating the difference in the change of weekly cluster headache attack frequency mean at 3 months from baseline using the paired samples

t-test. If these differences are not normally distributed, the Wilcoxon matched-pairs test will be used. A similar approach will be used to evaluate differences in change of the secondary outcomes. The interrupted time series approach will allow an assessment of efficacy of the psilocybin after 3 months in the same pre and post treated population.

**Conclusions:** Long term it is hoped that findings from this feasibility study will generate the preliminary evidence needed to conduct larger studies, including RCT's.

**References:**

**Keyword:** Cluster Headaches, Psilocybin, Psychedelics

## INTER-ICTAL MOLECULAR PHENOTYPING OF THE NEURO-IMMUNE AXIS IN MIGRAINE PATIENTS UNDER NON-INVASIVE CERVICAL VAGUS NERVE STIMULATION

### E-POSTER VIEWING

Ilana Lendvai<sup>1</sup>, Melanie Hamperl<sup>2</sup>, Michael Buchfelder<sup>2</sup>, Thomas Kinfe<sup>3</sup>

<sup>1</sup>Neurology, Klinikum Nordwest, Frankfurt, Germany, <sup>2</sup>Neurosurgery, Friedrich-Alexander University (FAU) Erlangen-Nürnberg, Erlangen, Germany, <sup>3</sup>Neurosurgery, Division Of Functional Neurosurgery And Stereotaxy, Friedrich-Alexander University (FAU), Erlangen, Germany

**Introduction:** To evaluate a possible correlation between peripheral inter-ictal cytokine serum levels and non-invasive vagus nerve stimulation (nVNS) responsiveness in migraineurs.

**Methods/Materials:** This double-blinded, sham-controlled study enrolled 48 subjects and measured headache severity, frequency [headache days/month, number of total and mild/moderate/severe classified attacks/month], functional state [sleep, mood, body weight] and serum levels of inflammatory markers [inter-ictal] using enzyme-linked immunoassays at baseline and after 2 months of nVNS compared to suitably matched controls.

**Results:** No differences were observed at baseline and after 2 months for headache severity, total attacks/month, headache days/month and functional outcome [sleep, mood, disability] between verum and sham nVNS. The number of severe attacks/month decreased in the verum nVNS (Figure 1). Pro-inflammatory IL-1 $\beta$  was elevated significantly in the sham group compared to nVNS, while anti-inflammatory IL-10 were significantly higher at baseline in both groups compared to healthy controls, but not at 2 months follow-up [ $p < 0.05$ ]. High-mobility group box - 1, IL-6, tumor-necrosis factor- $\alpha$ , leptin, adiponectin, ghrelin remained unchanged. No correlation was found between IL-1 $\beta$  and IL-10 and the numbers of severe attacks/month (Figure 2). Figure 1. Comparison of (A) number of headache days and (B) the number of total attacks per month between sham and verum groups at baseline and follow-up after 2 months [x-axis]. (C) the number of severe rated attacks per month were assessed. A significant difference was found for the number of severe attacks/month between sham and verum group at baseline and follow-up [ $F(3,48) = 2.81$ ,  $p = 0.049$ ].

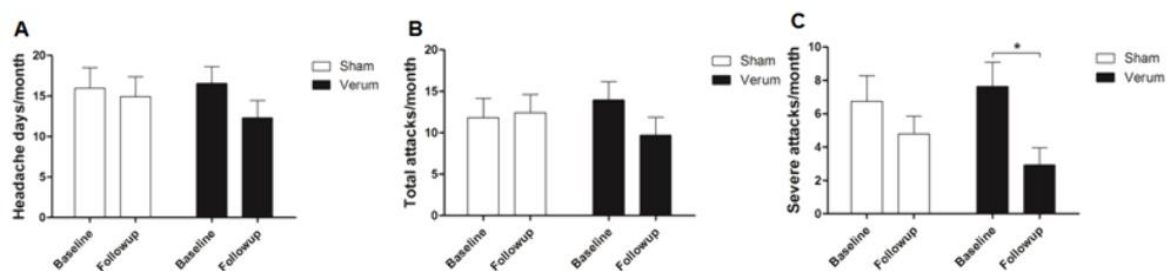


Figure 2. Peripheral levels of IL-1 $\beta$ , IL-6, TNF- $\alpha$  and IL-10 between healthy controls, sham and verum nVNS treated subjects at baseline and after 2 months. IL-10 was significantly lower in healthy controls compared to migraineurs [sham and verum nVNS] at baseline and follow-up [ $F(5,82) = 7.41$ ,  $p = 0.0001$ ] and IL-1 $\beta$  significantly increased in the sham nVNS group at follow-up compared to verum nVNS. No correlation was found between IL-1 and IL-10 levels and number of severe attacks per month.

**Discussion:** Cervical nVNS significantly declined the number of severe attacks/month. Pro-inflammatory IL-1 $\beta$  plasma levels [inter-ictal] were higher in sham-treated migraine patients compared to verum nVNS. Pro- [IL-6, HMGB-1, TNF- $\alpha$ , leptin] and anti-inflammatory [IL-10, adiponectin, ghrelin] mediators did not differ statistically. To date, it is not known whether such measures reflect disease severity marker or are involved in the observed nVNS effects.

**Conclusions:** Profiling of neuroinflammatory pathways in migraine patients remains experimental confounded by intra-/inter-individual variables deserving systematic biobank-based research.

**References:**

**Keywords:** randomized-controlled trial, abortive and preventive migraine treatment, migraine, neuroinflammation, cervical noninvasive vagus nerv stimulation



Topic: 06. Headache

## PREVENTING POST DURAL PUNCTURE HEADACHE AFTER INTRATHECAL DRUG DELIVERY SYSTEM IMPLANTATION THROUGH PREVENTIVE FIBRIN GLUE APPLICATION: A RETROSPECTIVE STUDY

### E-POSTER VIEWING

Thomas Douillard<sup>1</sup>, Denis Dupoirion<sup>2</sup>, Sabrina Jubier-Hamon<sup>3</sup>, Nathalie Lebrec<sup>3</sup>

<sup>1</sup>Réanimation Médicale, CHU d'Angers, Angers, France, <sup>2</sup>Anesthesia And Pain Medicine, INSTITUT DE CANCEROLOGIE DE L'OUEST, ANGERS, France, <sup>3</sup>Anesthésie/douleur, Institut de Cancérologie de l'Ouest, site Paul Papin, Angers Cedex, France

**Introduction:** Cerebrospinal Fluid (CSF) leakage is one of the most frequent postoperative Adverse Effect(AEs) observed after Intrathecal drug delivery implantation. These symptoms negatively affect patient quality of life and can result in additional complications. We have developed a procedure for a preventive use of Fibrin Glue during the surgery.

**Methods/Materials:** We designed a mono-centric observational retrospective cohort study, in order to compare the incidence of CSF leakage syndrome after lumbar puncture in patients implanted with an intrathecal pump, with or without preventive Fibrin Glue application during the procedure. Tisseel Bioglue was injected onto the puncture pathway, after placement of the catheter in the desired position and after needle withdrawal. The procedure was performed just before anchoring the catheter with the help of the anchorage device. The application cannula of the Fibrin glue was inserted through the puncture pathway and is pushed along the pathway to the other end. 3ml of Fibrin glue was injected. The study compared two patient cohorts over two successive periods. Institutional approval was obtained.

**Results:** The No-Glue group numbered 107, while the Glue group numbered 92. 2 failures were observed (2.04%). Fibrin Glue application results in a significant decrease in incidence, from 32.7% to 10.92 % ( $p < 0.001$ ). In the No-Glue group, 37.1% of Post Dural Puncture Headache (PDPH) Syndromes were Light, 34.3% were Moderate, and 28.6% were Severe. In the Fibrin Glue group, 80% of Post Dural Puncture Headache PDPH Syndromes were Light, and 20% were Moderate. No Severe intensity PDPH syndrome were reported after Bio Glue application. Duration of symptoms was also statistically shorter in the Fibrin Glue group (maximum of 3 days, versus 15 days). In a univariate analysis preventive Bio glue application and age are significant. In multivariate analysis only Fibrin Glue application is significant ( $OR = 0.26$   $p = 0.0008$ ). No adverse effects linked to Fibrin Glue were observed.

**Discussion:** The results of this study clearly show a significant decrease in the incidence, duration, and intensity of PDPH with the preventive use of Fibrin Glue during the implantation procedure to treat PDPH. Furthermore, this technique appears safe. No Adverse effects were observed.

**Conclusions:** This first evaluation is promising in terms of efficacy and safety. Its moderate cost and reproducibility make it an affordable and promising technique.

**References:** 1. Deer TR, Pope JE, Hayek SM et al. The polyanalgesic consensus conference (pacc): Recommendations on intrathecal drug infusion systems best practices and guidelines. *Neuromodulation* 2017;20:96-132. 2. Crul BJ, Delhaas EM. Technical complications during long-term subarachnoid or epidural administration of morphine in terminally ill cancer patients: A review of 140 cases. *Reg Anesth* 1991;16:209-13. 3. Naumann C, Erdine S, Koulousakis A, Van Buyten JP, Schuchard M. Drug adverse events and system complications of intrathecal opioid delivery for pain: Origins, detection, manifestations, and management. *Neuromodulation* 1999;2:92-107. 4. Lad SP, Li G, Lin SC, Henderson JM. Intracranial hypotension from intrathecal baclofen pump insertion. A case report and review of the literature. *Stereotact Funct Neurosurg* 2008;86:75-9. 5. Choi A, Laurito CE, Cunningham FE. Pharmacologic management of postdural puncture headache. *Ann*

Pharmacother 1996;30:831-9. 6. Turnbull DK, Shepherd DB. Post-dural puncture headache: Pathogenesis, prevention and treatment. Br J Anaesth 2003;91:718-29. 7. Arevalo-Rodriguez I, Munoz L, Godoy-Casasbuenas N et al. Needle gauge and tip designs for preventing post-dural puncture headache (pdph). Cochrane Database Syst Rev 2017;4:CD010807. 8. Miscusi M. Bioglue and spine surgery. Spine J 2011;11:983; author reply 983-4. 9. Freeman ED, Hoelzer BC, Eldrige JS, Moeschler SM. Fibrin glue to treat spinal fluid leaks associated with intrathecal drug systems. Pain Pract 2014;14:570-6. 10. Haase J. Use of tisseel in neurosurgery. J Neurosurg 1984;61:801. 11. Kassam A, Horowitz M, Carrau R et al. Use of tisseel fibrin sealant in neurosurgical procedures: Incidence of cerebrospinal fluid leaks and cost-benefit analysis in a retrospective study. Neurosurgery 2003;52:1102-5; discussion 1105. 12. Epstein NE. Dural repair with four spinal sealants: Focused review of the manufacturers' inserts and the current literature. Spine J 2010;10:1065-8. 13. Lybecker H, Djernes M, Schmidt JF. Postdural puncture headache (pdph): Onset, duration, severity, and associated symptoms. An analysis of 75 consecutive patients with pdph. Acta Anaesthesiol Scand 1995;39:605-12. 14. Neuman SA, Eldrige JS, Qu W, Freeman ED, Hoelzer BC. Post dural puncture headache following intrathecal drug delivery system placement. Pain Physician 2013;16:101-7. 15. Carvajal G, Dupoirion D, Seegers V et al. Intrathecal drug delivery systems for refractory pancreatic cancer pain: Observational follow-up study over an 11-year period in a comprehensive cancer center. Anesth Analg 2018;126:2038-2046. 16. Costigan SN, Sprigge JS. Dural puncture: The patients' perspective. A patient survey of cases at a dgh maternity unit 1983-1993. Acta Anaesthesiol Scand 1996;40:710-4. 17. Katz D, Beilin Y. Review of the alternatives to epidural blood patch for treatment of postdural puncture headache in the parturient. Anesth Analg 2017;124:1219-1228.

**Keyword:** Intrathecal system, headache prevention, fibrin glue

**Topic:** 06. Headache

**COMPINED BILATERAL OCCIPITAL AND SUPRAORBITAL STIMULATION IN MANAGEMENT OF DRUG – RESISTANT HYDROCEPHALUS RELATED HEADACHE.**

**E-POSTER VIEWING**

Stefanos Korfias, Athanasia Alexoudi, Efstathios Vlachakis, Argyro Chondrozoumaki, Stamatis Banos, Alexandros Tsimogiannis, Alexandros Kossivas, Dimitrios Skarmoutsos, Christina Zournatzidou, Panayiotis Patrikelis, Stergios Gatzonis, Damianos Sakas  
Neurosurgery, National & Kapodistrian University of Athens, CHALANDRI, Greece

**Introduction:** We present a successful treatment of a patient with a chronic migraine treated with combined subcutaneous Occipital Nerve Stimulation (ONS) and Supraorbital Nerve Stimulation (SNS).

**Methods/Materials:** A 33-year-old woman presented with a drug-resistant diffuse daily headache associated with gait impairment and visual symptoms. Brain MRI revealed ventricular enlargement and possible aqueduct stenosis. Intracranial Pressure (ICP) telemetry proved high ICP values (>30mmHg). A ventriculo-peritoneal (VP) shunt was placed and post-operatively the ICP gradually measured within the normal range (<15mmHg). However, patient's symptoms did not resolve and a brain CT scan revealed no intracranial pathology, stably decompressed ventricles, and appropriate VP shunt placement.

**Results:** The diagnosis of chronic post-intracranial disorder headache was set. Subsequently, a subcutaneous ONS was performed and considering that patient had not a total response an additional SNS was applied. Three months after the bilateral combined ONS–SNS the headache promptly and completely resolved, the quality of life was improved and she remained completely free off medications.

**Discussion:** Patient with ventricular enlargement and possible aqueduct stenosis presented with a diffuse headache that was initially treated unsuccessfully with a VP shunt insertion. This headache had the characteristics of chronic migraine mediated through the trigeminovascular system. Combined ONS–SNS proved successful in dealing with this situation.

**Conclusions:** Our report confirms the historical data that combined ONS–SNS ease refractory headaches much more than ONS does alone.

**References:**

**Keywords:** Headache, Occipital Nerve Stimulation, Supraorbital Nerve Stimulation, migraine

Topic: 06. Headache

## TRANSCRANIAL MAGNETIC STIMULATION FOR PERSISTENT POST-TRAUMATIC HEADACHE- AN INS/NANS EXPERT CONSENSUS PANEL REVIEW AND RECOMMENDATION

### E-POSTER VIEWING

Maheen Adamson<sup>1</sup>, Mark Ettenhofer<sup>2</sup>, Liu Jie<sup>3</sup>, Paul Sargent<sup>4</sup>, Albert Leung<sup>5</sup>

<sup>1</sup>Neurosurgery, Stanford School of Medicine/VA Palo Alto, Union City, United States of America, <sup>2</sup>Psychology, VA San Diego/DVBIC Naval Medical Center, San Diego/UC San Diego, San Diego, United States of America, <sup>3</sup>Tbi Clinic, Camp Pendleton, Camp Pendleton, san diego, United States of America, <sup>4</sup>Pain Medicine, US Navy/DVBIC, San Diego, United States of America, <sup>5</sup>Pain Medicine, UCSD School of Medicine/VASDHS Center for Pain and Headache Research, San Diego, United States of America

**Introduction:** The US Center for Disease Control and Prevention (CDC) estimated the prevalence of new traumatic brain injury (TBI) cases in the United States at over 1.7 million every year<sup>1</sup>. Persistent Post-Traumatic Brain Injury (PTBI) Related Headache (PTBI-HA) is one of the most common debilitating chronic pain conditions in patients after a mild/moderate traumatic brain injury. This high prevalence (>60%) of persistent chronic headache is often associated with neuropsychological dysfunction in mood, attention, and memory. Unfortunately, conventional pharmacological treatments for PTBI-HA have not been shown to be effective<sup>2-4</sup>.

**Methods/Materials:** Under the guidance of a steering committee composed of leadership from both the International Neuromodulation Society(INS) and the North American Neuromodulation Society(NANS), this multi-disciplinary expert panel aims to:1) assess and rate the existing outcome evidence of repetitive Transcranial Magnetic Stimulation (rTMS) in managing PPTH; and 2) provide TMS treatment recommendation/guideline for the PTBI-HA. A five-member expert task group was established under the guidance of a five-member INS/NANS steering committee to assess the utilization of rTMS in the treatment of PTBI-HA. Individual studies were first rated by the guideline established by American Academy of Neurology Classification of Evidence for Therapeutic Studies. The overall clinical evidence was rated based on Type of Study Design and Level of Certainty, and recommendation was provided based on the US Preventive Service Task Force (USPSTF) and CDC criteria.

**Results:** Based on the existing clinical outcome evidence for the short-term efficacy (1-2 month) in alleviating PTBI-HA symptoms, the majority of the task group members rated the Study Design as I (Randomized Controlled Trials) for TMS at M1 or left LDLPFC, Level of Certainty in Evidence as High for PTBI-HA. The task group also rated USPSTF recommendation as A (Extremely Recommendable) and CDC recommendation as IA (Strongly Recommended) for the clinical implementation of the rTMS at either M1 or left LDLPFC for mild PTBI-HA with the latter being considered as alternate treatment location for patients with PTBI-HA and co-morbid severe depression.

**Discussion:** The panel rated the overall level of evidence and recommendability for clinical implementation of TMS as; 1) High and Extremely/Strongly for both PTBI-HA ; 2) Moderate for post-operative pain and migraine prevention, and Recommendable for migraine prevention.

**Conclusions:** While the use of TMS for treating both pain and depression in one setting is clinically and financially sounded, more studies are required to fully assess the long-term benefit of the treatment for the two highly co-morbid conditions, especially with neuronavigation.

**References:** 1. Faul M, Coronado V. Epidemiology of traumatic brain injury. *Handb Clin Neurol*. 2015;127:3-13. 2. Patil VK, St Andre JR, Crisan E, et al. Prevalence and treatment of headaches in veterans with mild traumatic brain injury. *Headache*. Jul-Aug 2011;51(7):1112-1121. 3. DiTommaso C, Hoffman JM, Lucas S, Dikmen S, Temkin N, Bell KR. Medication usage patterns for headache treatment after mild traumatic brain injury. *Headache*. Mar 2014;54(3):511-519. 4. Lucas S, Hoffman

JM, Bell KR, Dikmen S. A prospective study of prevalence and characterization of headache following mild traumatic brain injury. *Cephalalgia*. Feb 2014;34(2):93-102.

**Keyword:** Pain rTMS Headaches MRI depression neuromodulation

**Topic:** 06. Headache

## TEMOROMANDIBULAR JOINT DISORDER RELATED TO VERTEBRAL COLUMN DISORDER AND HEADACHES DURING A 9-YEAR-FOLLOW-UP AFTER TREATMENT

### E-POSTER VIEWING

Tomislav Badel<sup>1</sup>, Ivana Savić Pavićin<sup>2</sup>, Vanja Bašić Kes<sup>1</sup>, Sandra Kocijan Lovko<sup>3</sup>, Sandra Anić Milošević<sup>4</sup>, Nenad Lukić<sup>5</sup>, Ladislav Krapac<sup>6</sup>, Dijana Zadravec<sup>7</sup>

<sup>1</sup>Department Of Neurology, Sestre milosrdnice University Hospital Center, University of Zagreb, Zagreb, Croatia, <sup>2</sup>Department Of Dental Anthropology, School of Dental Medicine, Zagreb, Croatia, <sup>3</sup>Outpatient Department, Psychiatry Hospital "Sv Ivan", Zagreb, Croatia, <sup>4</sup>Department Of Orthodontics, School of Dental Medicine, Zagreb, Croatia, <sup>5</sup>Clinic Of Masticatory Disorders, Center of Dental Medicine, University of Zürich, Zürich, Switzerland, <sup>6</sup>Department Of Public Health, Academy of Medical Sciences of Croatia, Zagreb, Croatia, <sup>7</sup>Department Of Radiology, Sestre milosrdnice University Hospital Center, University of Zagreb, Zagreb, Croatia

**Introduction:** The aim of this study was to compare the relationship between clinical characteristics of the patients from the subgroup with osteoarthritis (OA) and disc displacement (DD) of temporomandibular joint (TMJ) related to types of headaches and vertebral column disorders (VCD) with a 9-year-follow-up after treatment.

**Methods/Materials:** The patients were divided into two subgroups according to different diagnoses of TMJ disorders; the G1 subgroup consisted of 47 patients with DD of TMJ (mean age± standard deviation (SD) 29.53±14.16, 76.6% women). These patients were compared to the G2 subgroup of 36 patients who only had OA of TMJ (mean age±SD 50.58±16.11, 88.9% women). The patients from both subgroups were treated in the same way using the occlusal splint and physical therapy. Clinical variables were compared between the two groups (G1 and G2) as well as within the total number of patients (G1+G2) for particular clinical features in the period of the first examination (T0) and on recalls after 9 years (T1). Pain on VAS (visual analogue scale) in TMJs, occurrence of headache, and the existence of VCD were recorded. The psychological assessment was carried out by Spielberger's State-Trait Anxiety Inventory (STAI).

**Results:** There was a significant age difference ( $p<0.001$ ) between the two subgroups of TMJ diagnoses. There was no difference ( $p=0.4674$ ) for pain intensity on VAS measured at T0 and T1 for G-1 and G-2 subgroups. Measuring anxiety showed a significant difference for both score values at T0 (first appointment): for STAI 1  $p=0.029$  and for STAI 2  $p=0.006$ . VCD were found in 17% patients of G-1 and in 66,7% patients of G-2 group. For patients without VCD alone, a statistically significant difference was found between patients' age ( $p=0.0008$ ) and STAI 2 ( $p=0.004$ ): G-2 patients were older and with higher scores of anxiety than G-1 patients. Headaches were found in 34% of G-1 and 44% of G-2 patients, and there was no difference for any variables.

**Discussion:** Reversible treatments are the primary choice for the treatment of TMJ disorders, with the occlusal splint and TMJ physical therapy both equally successful.

**Conclusions:** Patients with OA (G-2) were older and with higher anxiety scores. Patients without VCD with OA (G-2) had higher pain intensity at 9-year-recall.

**References:** Di Paolo C, D'Urso A, Papi P, Di Sabato F, Rosella D, Pompa G, Polimeni A. Temporomandibular Disorders and Headache: A Retrospective Analysis of 1198 Patients. *Pain Res Manag.* 2017;2017:3203027.

**Keyword:** temporomandibular joint, osteoarthritis, headache, treatment

Topic: 06. Headache

## LONG -TERM EFFECTIVENESS OF COMBINED UNILATERAL SPHENOPALATINE AND OCCIPITAL NERVE STIMULATION IN SIX PATIENTS WITH REFRACTORY CLUSTER HEADACHE

### E-POSTER VIEWING

Juan Carlos M. Andreani<sup>1</sup>, Fabián C Piedimonte<sup>2</sup>, Osvaldo Bruera<sup>3</sup>, Diego Bashkansky<sup>4</sup>

<sup>1</sup>Director's Office, Provincial Program of Neuromodulation, CABA, Argentina, <sup>2</sup>Presidency, Cenit Foundation, CABA, Argentina, <sup>3</sup>Neurología, Fundación Favaloro, Buenos Aires, Argentina, <sup>4</sup>Pain Medicine, Cenit Foundation, CABA, Argentina

**Introduction:** Cluster Headache (CH) is a unilateral headache with episodes of excruciating pain and neurovegetative symptoms. Refractory cases were approached by many therapeutical means, but results were unclusive(1). Occipital nerve stimulation (ON) is effective, but benefits are obtained in the long term (2,3,4). Sphenopalatine (SP) stimulation is short term effective(5,6) and abortive(7) for CH attacks. Both techniques were published(8,9), and only have achieved Level B of evidence(10). We perform combined stimulation to get the advantages of both methods. This paper is the continuation of our previous works(11,12), employing combined ON- SPG stimulations.

**Methods/Materials:** Six patients with refractory CH, 3 females,3 males, underwent combined implantation. Patients were preoperatively assessed by visual analogue (VAS) and Hit -6 scales(13) and at 3,6,9,12 months postoperatively, with subsequent evaluations every 6 months. One patient, a 48 y.o woman died by a car accident on March 2019, but her data still are into the statistics One new patient ,30y.o. man operated on May2018 is now included Follow up is 5,88 + - 2,8 years.

**Results:** 5 of 6 patients experienced good to excellent pain relief, achieving total crisis disappearance with time. One of them 15 months post - operatively did not required stimulation during 23 months, when stimulation might be restarted. Pain reduction was 71,4 % +- 19,1 % and 69,03 % +- 19,71 according to VAS and Hit – 6 scales, respectively. The crisis decreased from 43,7 +- 24,6 to 16,2 +- 7,4, per year. 2 patients presented electrode migration manifested by loss of stimulation of the facial area 12 days and 3 months after surgery, respectively. After their relocation, one case regained benefit.

**Discussion:** Multiple percutaneous techniques have been proposed to control CH symptoms, including ablative techniques as radiofrequency on the Gasser ganglion (14), SPG (15) and GON(16), among other structures. With the advent of neuromodulation, Peripheral Nerve Stimulation has been tried on SPG (17) or GON (18), both isolately,Vagal Stimulation (19) and High cervical Stimulation (20), with good results reported in reduced sample of patients. Deep Brain Stimulation on the Hypothalamus has been tried with acceptable evolution with low but significant morbi-mortality (1, 21).

**Conclusions:** Synergic SPG and GON stimulation showed effectiveness in the control of frequency and magnitude of pain crisis for long term follow up, in this sample of patients. This combined method is a less invasive and safer approach compared with hypothalamic DBS with long outstanding efficacy.

**References:** 1) Fontaine D, Vandersteen C, Magis D, et al. Neuromodulation in cluster headache. *Adv Tech Stand Neurosurg.* 2015;42:3-2 2) Mueller OM, Gaul C, Katsarava Z, Diener HC, Sure U, Gasser T. Occipital nerve stimulation for the treatment of chronic cluster headache - lessons learned from 18 months experience. *Cent Eur Neurosurg.* 2011 May;72(2):84-9. Mar 2011. 3) Belvis R, Rodríguez R, Guasch M, et al. Efficacy and safety of surgical treatment of cluster headache. *Med Clin (Barc).* 2020 Feb 14;154(3):75-79. doi: 10.1016/j.medcli.2019.03.023. 4) Schoenen J, Jensen R, Lantéri-Minet M et al. Stimulation of the sphenopalatine ganglion in intractable cluster headache: expert consensus on patient selection and standards of care. *Cephalalgia.* 2014 Nov;34(13):1100-10. Apr 2014. 5) Ho KWD, Przkora R, Kumar S. Sphenopalatine ganglion: block, radiofrequency ablation

and neurostimulation - a systematic review. *J Headache Pain*. 2017 Dec 28;18(1):118. doi: 10.1186/s10194-017-0826-y. 6) Goadsby PJ, Sahai-Srivastava S, Kezirian EJ, et al. Safety and efficacy of sphenopalatine ganglion stimulation for chronic cluster headache: a double-blind, randomised controlled trial. *Lancet Neurol*. 2019 Dec;18(12):1081-1090. doi: 10.1016/S1474-4422(19)30322-9. 7) Stimulation of the sphenopalatine ganglion (SPG) for cluster headache treatment. Pathway CH-1: a randomized, sham-controlled study. 8) Magis D. Emerging treatments for cluster headache: hopes and disappointments. *Curr Opin Neurol*. 2019 Jun;32(3):432-437. doi: 10.1097/WCO.0000000000000693. 9) Cvetkovic VV, Jensen RH. Neurostimulation for the treatment of chronic migraine and cluster headache. *Acta Neurol Scand*. 2019 Jan;139(1):4-17. doi: 10.1111/ane.13034. Epub 2018 Oct 29. 10) Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache*. 2016 Jul;56(7):1093-106. doi: 10.1111/head.12866. 11) Piedimonte FC, Andreani JCM, Piedimonte L, et al. Refractory cluster headache treatment by synergic chronic stimulation of the sphenopalatine ganglion and greater occipital nerve: five years follow-up (Poster). INS 11 th World Congress, June 8 – 11, 2013 - Berlin – Germany. 12) Piedimonte FC, Andreani JCM, Bashkansky D, Barboza N. Neuromodulation for Cluster Headache (Poster - Presentation). INS 12th World Congress, June 7 – 10, 2015 – Montreal - Canada. 13) Kosinski M, Bayliss MS, Bjorner JB, et al. A six-item short-form survey for measuring headache impact: the HIT-6. *Qual Life Res*. 2003 Dec;12(8):963-74. doi: 10.1023/a:1026119331193. Jürgens TP, 14) Narouze S1, Kapural L, Casanova J, et al. N. Sphenopalatine ganglion radiofrequency ablation for the management of chronic cluster headache. *Headache*. 2009 Apr;49(4):571-7. Sep 2008. 15) Young WB. Blocking the greater occipital nerve: utility in headache management. *Curr Pain Headache Rep*. Oct 2010;14(5):404-8 16) Mueller OM, Gaul C, Katsarava Z, Diener HC, Sure U, Gasser T. Occipital nerve stimulation for the treatment of chronic cluster headache - lessons learned from 18 months experience. *Cent Eur Neurosurg*. 2011 May;72(2):84-9. Mar 2011. 17) Jürgens TP, Schoenen J, Rostgaard J, et al. Stimulation of the sphenopalatine ganglion in intractable cluster headache: expert consensus on patient selection and standards of care. *Cephalalgia*. 2014 Nov; 34(13):1100-10. Apr 2014. 18) Jürgens TP, Leone M. Pearls and pitfalls: neurostimulation in headache. *Cephalalgia*. 2013 Jun;33(8):512-25. 19) Antony AB, Mazzola AJ, Dhaliwal GS, Hunter CW. Neurostimulation for the Treatment of Chronic Head and Facial Pain: A Literature Review. *Pain Physician*. 2019 Sep;22(5):447-477 20) De Agostino R, Federspiel B, Cesnulis E, Sandor PS. High-Cervical Spinal Cord Stimulation for Medically Intractable Chronic Migraine. *Neuromodulation*. 2014 Sep 23. 21) Leone M1, Franzini A, Cecchini AP, et al. Hypothalamic deep brain stimulation in the treatment of chronic cluster headache. *Ther Adv Neurol Disord*. 2010 May;3(3):187-95

**Keyword:** Cluster Headache - Neuromodulation - Occipital Nerve - Sphenopalatine ganglion



Topic: 06. Headache

## TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION OF SHOULDERS FOR MIGRAINE PREVENTION IN MIGRAINEURS WITH SHOULDER STIFFNESS

### E-POSTER VIEWING

Noboru Imai<sup>1</sup>, Asami Moriya<sup>1</sup>, Eiji Kitamura<sup>2</sup>

<sup>1</sup>Department Of Neurology, Japanese Red Cross Shizuoka Hospital, Shizuoka, Japan, <sup>2</sup>Department Of Neurology, Kitasato University, Sagamihara, Japan

**Introduction:** Transcutaneous electrical nerve stimulation (TENS) devices reduce and relieve muscle and joint pain and stiffness and numbness in the back, arms, legs, shoulders, and feet by applying electrical nerve stimulation to the surface of the skin near the site of pain. Migraineurs often complain of shoulder stiffness. Nociceptive input from the shoulder region is transmitted to the trigemino-cervical complex. This input may cause migraine attacks. We hypothesised that relieving shoulder stiffness may decrease migraine attacks in migraineurs. The aim of this study was to evaluate whether relief of shoulder stiffness using commercially available TENS devices decreased migraine attacks in migraineurs with shoulder stiffness.

**Methods/Materials:** This was a preliminary open trial conducted at a single headache clinic. OMRON HV-F127 TENS units (OMRON Corporation, Kyoto, Japan) were used. This device consists of the main unit, electrode cord, and pads (Figure 1).

# Figure 1

1. Main unit

2. Electrode cord

3. Pads

The patients attached both pads to the shoulder with stiffness. The patients selected the mode for the shoulder and chose an intensity level from 1 to 10 that produced a gentle pulsing sensation. The device continued automatically for 15 minutes before shutting off. Patients received 15 minutes of treatment twice a day. This study included a 4-week run-in period and 12-week treatment period. The primary outcome measures were change in 4-week migraine headache days (MHDs) and percentage of patients with  $\geq 50\%$  reduction in 4-week MHDs relative to the baseline period (50% responder rate).

**Results:** Thirteen migraineurs with shoulder stiffness were prospectively enrolled, including six with chronic migraine (CM), two with high-frequency episodic migraine (HFEM), and four with low-frequency episodic migraine (LFEM). TENS relieved muscle stiffness in all patients. Between the run-in period and last 4 weeks of treatment, there was no decrease in the mean number of migraine days (11.1 vs 11.2). Among all patients, the 50% responder rate was 15%, but the 50% responder rate was 50% among patients with LFEM. There were no adverse events in any patients.

**Discussion:** Applying TENS to shoulders did not reduce MHDs in migraineurs. However, half of the patients with LFEM were 50% responders. This result suggests that applying TENS to the shoulders decreases MHDs among patients with LFEM.

**Conclusions:** Applying TENS to the shoulders did not reduce the number of MHDs in migraineurs but may be an effective therapy in patients with LFEM. Further study is needed in this regard on patients with LFEM.

## References:

**Keyword:** migraine, transcutaneous electrical nerve stimulation, shoulder stiffness

**Topic:** 06. Headache

## **TREATMENT OF CHRONIC CLUSTER HEADACHE WITH OCCIPITAL NERVE STIMULATION - A RETROSPECTIVE CASE SERIES**

### **E-POSTER VIEWING**

Ida Stisen Fogh-Andersen<sup>1</sup>, Jens Christian Soerensen<sup>1</sup>, Anne Lene Knudsen<sup>2</sup>, Kaare Meier<sup>1,3</sup>

<sup>1</sup>Dept. Of Neurosurgery, Aarhus University Hospital, Aarhus N, Denmark, <sup>2</sup>Department Of Neurosurgery, Aarhus University Hospital, Aarhus N, Denmark, <sup>3</sup>Dept. Of Anesthesiology, Aarhus University Hospital, Aarhus N, Denmark

**Introduction:** Cluster headache (CH) is a rare but extremely severe and debilitating primary headache disorder with a prevalence of approximately 1:1000 people (1). It is characterized by attacks of one-sided severe pain located periorbitally, often accompanied by ipsilateral autonomous facial symptoms (2). The attacks usually occur in clusters that are separated by periods of remission lasting months or years. However, in approximately 10% of patients, CH is chronic without any attack-free periods lasting longer than three months (2), hence severely affecting the patients' quality of life. Chronic CH often leads to a high utilization of preventive and abortive treatments, although the condition often is medically refractory, leaving the patients with no sufficient treatment. Since the 1990's, neuromodulation therapies have been examined for various headache conditions. Intriguingly, during the past decade, studies have indicated that occipital nerve stimulation (ONS) could be a possible treatment for patients suffering from chronic CH where all conventional treatment options seem exhausted (3-5).

**Methods/Materials:** This retrospective database study includes data from 18 patients with chronic CH, treated with ONS at Aarhus University Hospital, Denmark, in the period from 2017 to 2020. Baseline characteristics for duration and frequency of CH attacks and self-reported pain score prior to implantation of the ONS system were registered in the Neurizon Neuromodulation Database. Postoperative data on the same parameters was collected at clinical follow-up visits and registered in the neuromodulation database. An assessment of the clinical outcome will be obtained by comparison of the preoperative baseline data to the postoperative data in order to evaluate whether the ONS treatment is associated with a clinically meaningful reduction in attack duration and frequency as well as pain score, and furthermore to examine whether this reduction is statistically significant.

**Results:** Treatment outcome of ONS therapy on chronic CH in the case series of 18 patients will be evaluated as changes in headache attacks as defined by a reduction in duration, frequency and patient-reported pain score.

**Discussion:** ONS is a promising treatment regimen for cluster headache. We present data from a cohort of 18 patients. The results contribute to the accumulating evidence for the use of ONS in cluster headache treatment.

**Conclusions:** This study aims to assess the treatment effect of ONS in a case series of 18 patients suffering from chronic CH, defined by a reduction in frequency and duration of headache attacks as well as a reduction in attack severity.

**References:** (1) "Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition.," Cephalalgia, vol. 38, no. 1, pp. 1–211, Jan. 2018 (2) M. Fischera, M. Marziniak, I. Gralow, and S. Evers, "The incidence and prevalence of cluster headache: a meta-analysis of population-based studies.," Cephalalgia, vol. 28, no. 6, pp. 614–618, Jun. 2008 (3) B. Burns, L. Watkins, and P. J. Goadsby, "Treatment of medically intractable cluster headache by occipital nerve stimulation: long-term follow-up of eight patients.," Lancet (London, England), vol. 369, no. 9567, pp. 1099–1106, Mar. 2007 (4) B. Burns, L. Watkins, and P. J. Goadsby, "Treatment of intractable chronic cluster headache by occipital nerve stimulation in 14 patients.," Neurology, vol. 72, no. 4, pp. 341–345, Jan. 2009 (5) S. Miller, L. Watkins, and M.

Matharu, "Treatment of intractable chronic cluster headache by occipital nerve stimulation: a cohort of 51 patients.," *Eur. J. Neurol.*, vol. 24, no. 2, pp. 381–390, Feb. 2017

**Keywords:** Cluster headache, Hortons headache, Occipital Nerve Stimulation

## SUBCUTANEOUS PERIPHERAL NERVE STIMULATION AS "HYBRID STIMULATION" AFTER FAILURE OF SCS TO CONTROL THE BACK PAIN COMPONENT IN FBSS PATIENTS

### E-POSTER VIEWING

Philippe Rigoard, Bertille Lorgeoux, Amine Ounajim, Iona Maitre, Maxime Billot, Manuel Roulaud  
Prismatics, Hospital University of Poitiers, Poitiers, France

**Introduction:** It has been well documented that Spinal Cord Stimulation (SCS) can be effective to treat pain in Failed Back Surgery Syndrome (FBSS) patients (1-4). However, some patients implanted with SCS do not experience significant improvement in pain, functional outcomes and quality of life (5). Peripheral Nerve Stimulation (PNS) is now commonly used as an alternative to SCS to target pain (6,7). Combining PNS and SCS as "hybrid stimulation" could be an opportunity to treat refractory FBSS patients. In a pilot study, Hamm-Faber and al. (2015) showed that hybrid stimulation can provide persistent pain relief in FBSS patients (8). The aim of our randomized controlled study is to compare the ability of hybrid stimulation (SCS+PNS) versus SCS alone to improve pain, functional outcome, anxiety/depression and quality of life after three months.

**Methods/Materials:** This is a monocentric non-blinded randomized controlled study. 13 refractory FBSS patients implanted with SCS were recruited between February 2013 and October 2018, randomized in 2 groups with a 1:1 ratio and followed for 3 months. The 7 patients in the SCS group continued to be treated with SCS only. The 6 patients in the Hybrid group were treated with SCS plus PNS hybrid stimulation straight after the randomization visit. Pain was assessed with the Visual Analog Scale (VAS) and a specific software to quantify the percentage of low back pain covered by paresthesia (9). Functional outcome was assessed with the Oswald Disability Index (ODI), anxiety/depression with the Hospital Anxiety and Depression Scale (HADS) and quality of life with the EuroQol 5 Dimensions (EQ-5D). All data were collected before and 3-months after the randomization.

**Results:** After 3 months, statistical analysis revealed that the decrease in low back pain VAS was greater for the hybrid group (-69%) than the SCS group (-4%) ( $p < 0.0001$ ). Our results showed a significant greater increase at 3-month follow-up in coverage of pain in the hybrid group (+16%) compared to the SCS group (-1%) ( $p = 0.048$ ). However, ODI, HADS and EQ-5D scores were not significantly different between groups between before and after the 3-month period ( $p = 0.4$ ,  $p = 0.5$  and  $p = 0.6$  respectively).

**Discussion:** "Hybrid stimulation" can potentiate SCS effects and significantly increase coverage and analgesic effect in FBSS patients. This significant improvement provides a new alternative to treat FBSS.

**Conclusions:** PNS coupled with SCS is a promising therapy to improve back pain relief in FBSS patients that must be assessed in long term duration.

**References:** (1) Delmotte A, Jacques L, Kumar K, Poon K, Monlezun O, Roulaud M, et al. The Franco-Canadian multicolumn spinal cord stimulation prospective study: A subgroup analysis focusing on the decisive role of lead positioning. *Neurochirurgie*. 19 sept 2014; (2) Sator-Katzenschlager S, Fiala K, Kress HG, Kofler A, Neuhold J, Kloimstein H, et al. Subcutaneous target stimulation (STS) in chronic noncancer pain: a nationwide retrospective study. *Pain Pract Off J World Inst Pain*. août 2010;10(4):279-86. (3) Eldabe S, Kern M, Peul W, Green C, Winterfeldt K, Taylor RS. Assessing the effectiveness and cost effectiveness of subcutaneous nerve stimulation in patients with predominant back pain due to failed back surgery syndrome (SubQStim study): study protocol for a multicenter randomized controlled trial. *Trials*. 2013;14(1):189. (4) Mathew L, Winfree C, Miller-Saultz D, Sonty N. Transcutaneous electrical nerve stimulator trial may be used as a screening tool prior to spinal cord stimulator implantation. *Pain*. août 2010;150(2):327-31. (5) Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, et al. The effects of spinal cord stimulation in neuropathic pain are

sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery* 2008;63(4):762 (6) Sator-Katzenschlager S, Fiala K, Kress HG, Kofler A, Neuhold J, Kloimstein H, et al. Subcutaneous target stimulation (STS) in chronic noncancer pain: a nationwide retrospective study. *Pain Pract Off J World Inst Pain*. août 2010;10(4):279-86. (7) Eldabe S, Kern M, Peul W, Green C, Winterfeldt K, Taylor RS. Assessing the effectiveness and cost effectiveness of subcutaneous nerve stimulation in patients with predominant back pain due to failed back surgery syndrome (SubQStim study): study protocol for a multicenter randomized controlled trial. *Trials*. 2013;14(1):189. (8) Hamm-Faber TE, Aukes H, van Gorp E-J, Gültuna I. Subcutaneous Stimulation as an Additional Therapy to Spinal Cord Stimulation for the Treatment of Low Back Pain and Leg Pain in Failed Back Surgery Syndrome: Four-Year Follow-Up. *Neuromodulation J Int Neuromodulation Soc*. oct 2015;18(7):618-622; discussion 622. (9) Roulaud M, Guetarni F, Nivole K, Monluzun O, Lorgeoux B, Rigoard P. A Novel, Objective, Quantitative Method of Evaluation of the Pain Component and Paresthesia Coverage using Comparative Computerized Multiparametric Tactile Mapping and Database Analysis : The "Neuro-Mapping-Tools" Software (N3MT). *Global Spine Journal*. 2017

**Keywords:** Subcutaneous Stimulation (Sub-Q Stim), Failed Back Surgery Syndrome, Peripheral Nerve Stimulation, Randomized Controlled Trial, Back Pain

**Topic:** 07. *Peripheral Nerve*

## **EFFECTIVENESS OF WIRELESS PERIPHERAL NERVE STIMULATION IN THE TREATMENT OF NONSURGICAL INTRACTABLE JOINT PAIN**

### **E-POSTER VIEWING**

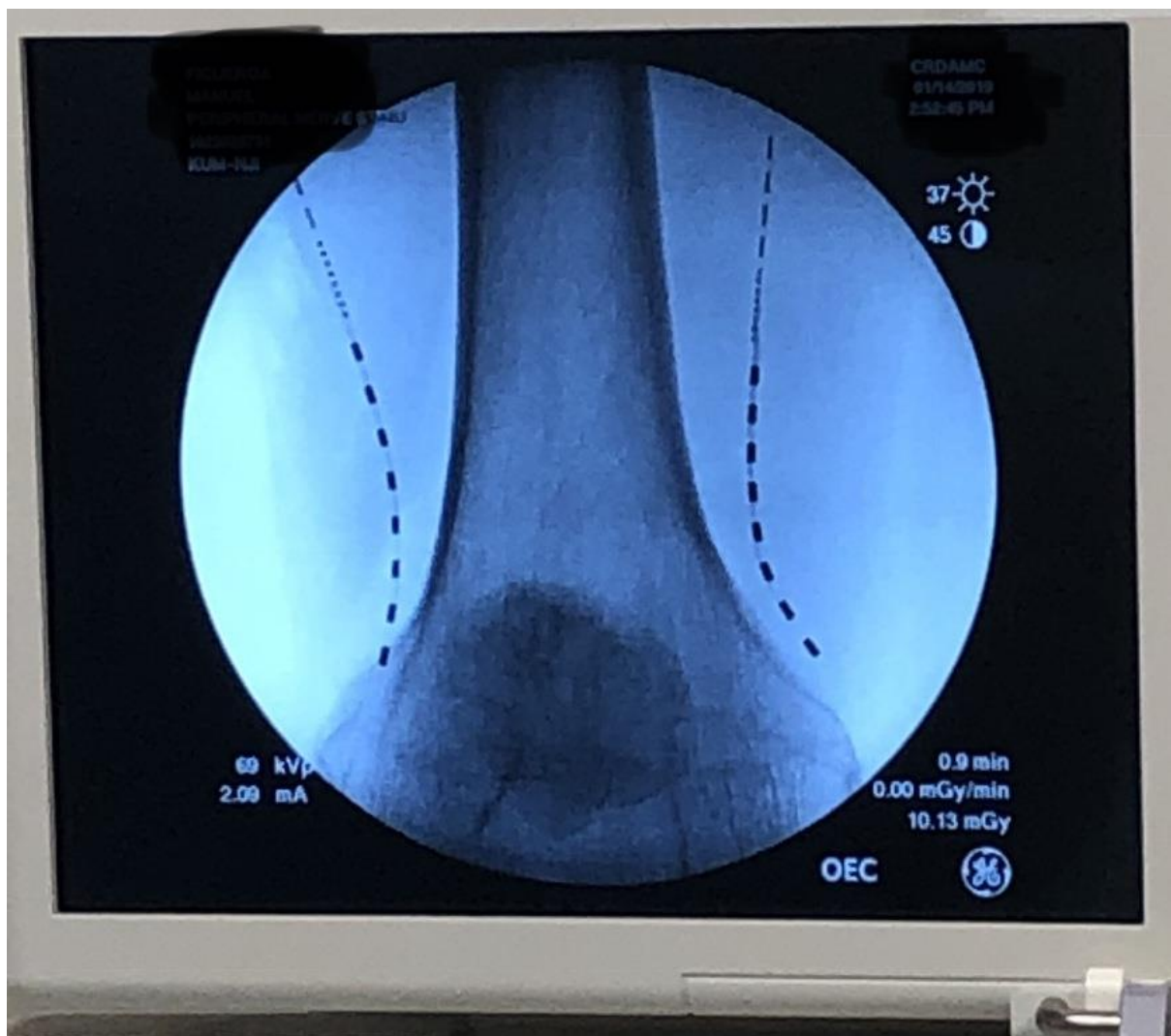
Ellen Lin<sup>1</sup>, Alexander Matthews<sup>2</sup>

<sup>1</sup>Main Office, Advanced Spine & Pain Center, San Antonio, United States of America, <sup>2</sup>Sports Medicine, Orthopedic Performance Institute, SAN ANTONIO, United States of America

**Introduction:** Peripheral nerve stimulation has long been considered a treatment option for chronic pain conditions. As the population ages, more patients will experience excruciating joint pain who may not be surgical candidates secondary to age, cardiopulmonary conditions, or nonorthopedic neuropathic post operative pain. With the new development of wireless peripheral nerve stimulation devices Stimwave®, clinicians are able to offer a less invasive, more user-friendly method of delivering pain relieving impulses to the corresponding peripheral nerves. In this retrospective review, we address outcomes of peripheral nerve stimulation to treat nonsurgical joint pain conditions.

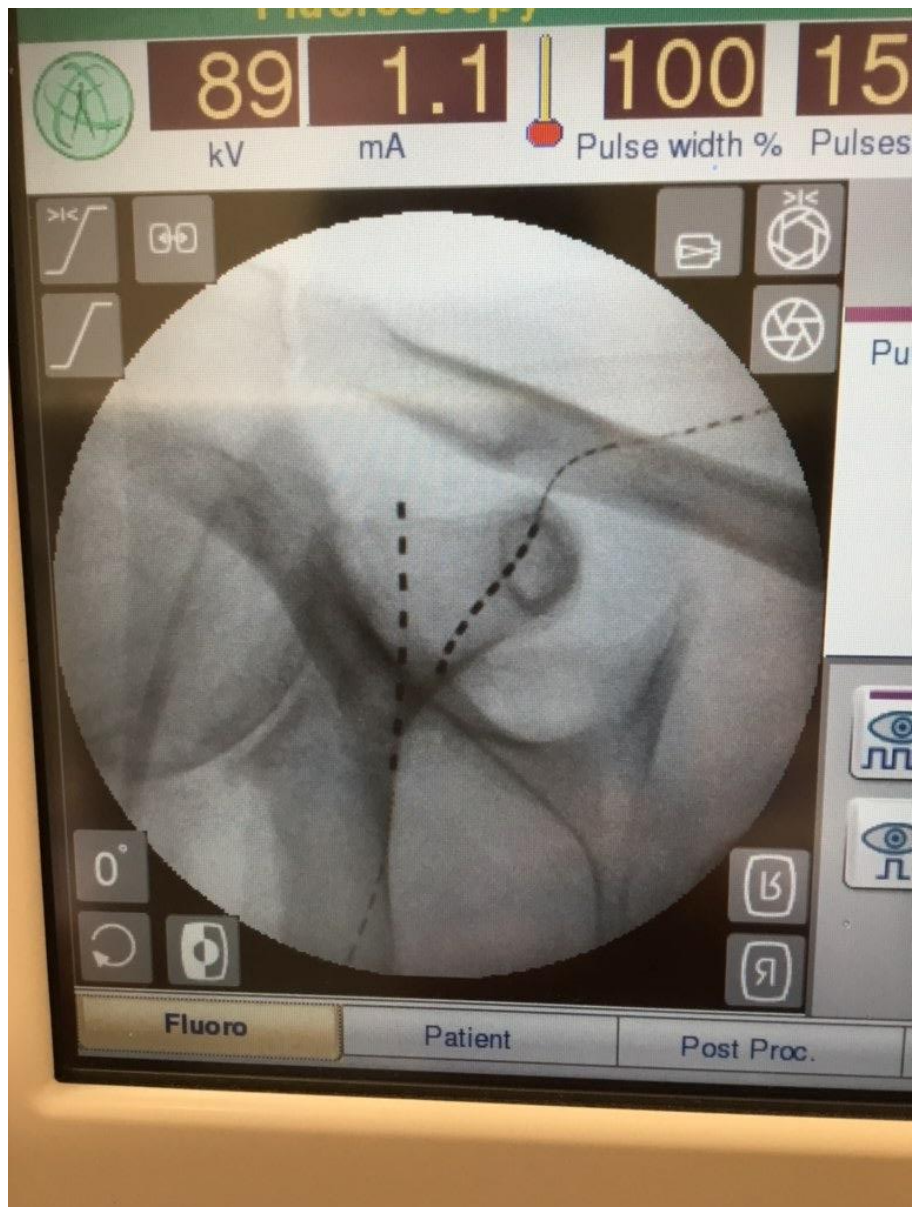
**Methods/Materials:** This retrospective study evaluated all patients over one year period of time who were implanted with wireless stimulators. A total of 31 consecutive Stimwave® patients were included in this study. Of these 31 patients, 14 had peripheral nerve stimulators implanted for various joint pain conditions, including knees, shoulders, ankles and hips. Of the 14 patients who received wireless peripheral nerve stimulator trials, 12 patients had over 50% pain relief. Of the 12 patients who had successful trials, 8 patients had a reduction of opiates intake (66.6%). The opiates dosages in milligram equivalence of morphine (MME) were collected using the Texas Prescription Monitoring Program evaluating before and 6 months or longer post peripheral nerve stimulation implantation.

GENICULAR NERVE PNS



SUPRASCAPULAR NERVE





PNS  
NERVES

HIP ARTICULAR

PNS



**Results:** Of the 14 patients who received wireless peripheral nerve stimulator trials, 12/14 (85.7%) patients had over 50% pain relief. Of the 12 patients who had successful trials, 8/12 (66.6%) patients had a reduction of opiates intake. The average opiates reduction in morphine milligram equivalence (MME) before and after implantation is 66.4% in these 8 patients. All 12 patients reported increased in physical activities, including walking longer distances, returning to playing tennis, or better use of upper extremities for ADL(activities of daily living).

**Discussion:** In a small series of patients with intractable nonsurgical joint pain, implantation of wireless peripheral nerve stimulator devices Stimwave proved their efficacy in pain reduction, opiates intake reduction and functional improvement. For future intractable joint pain patients, wireless peripheral nerve stimulation should be considered if other conservative treatments failed.

**Conclusions:** Peripheral nerve stimulation provides an alternative to patients with joint pain due to arthritis, persistent joint pain post joint replacement and other nonsurgical joint pain syndromes.

**References:** 1) EA Petersen, KV Slavin - Neurosurgery Clinics, Peripheral nerve/field stimulation for chronic pain, 2014 - neurosurgery. 2) Eisenberg, Elon; Waisbrod, Hannan; Gerbershagen, "Long-Term Peripheral Nerve Stimulation for Painful Nerve Injuries", The Clinical Journal of Pain: May-June 2004 - Volume 20 - Issue 3 - p 143-146. 3) Mobbs RJ, Nair S, Blum P: Peripheral nerve stimulation for the treatment of chronic pain. J Clin Neurosci 2007;14:216-221 4) Slavin KV: Peripheral nerve stimulation for neuropathic pain. Neurotherapeutics 2008;5:100-106 5) Stanton- Hicks M, Salamon J: Stimulation of the central and peripheral nervous system for the control of pain. J Clin Neurophysiol 1997;14:46-62 6) Thimineur M, De Ridder D: C2 area neurostimulation: a surgical treatment for fibromyalgia. Pain Med 2007;8:639-646 7) Slavin KV: Peripheral neurostimulation in fibromyalgia: a new frontier?. Pain Med 2007;8:621-622 8) Lipov EG, Joshi JR, Sanders S, Slavin KV: Use of peripheral subcutaneous field stimulation for the treatment of axial neck pain: a case report. Neuromodulation 2009;12:292-295 9) McRoberts WP, Roche M: Novel approach for peripheral subcutaneous field stimulation for the treatment of severe, chronic knee joint pain after total knee arthroplasty. Neuromodulation 2010;13:131-136

**Keywords:** Knee pain, shoulder pain, Peripheral Nerve Stimulation, hip pain, osteoarthritis pain, post operative pain

**Topic:** 07. *Peripheral Nerve*

## **CHRONIC PAIN OUTCOMES USING A NEUROMODULATION SYSTEM WITH MULTIPLE WAVEFORM AND PROGRAMMING MODALITIES IN AUSTRALIA**

### **E-POSTER VIEWING**

Peter Georgius<sup>1</sup>, Bruce Mitchell<sup>2</sup>, David Holthouse<sup>3</sup>, Thierry Vancaillie<sup>4</sup>, John Monagle<sup>5</sup>, Marc Russo<sup>6</sup>, Jing Wang<sup>7</sup>, Roshini Jain<sup>7</sup>

<sup>1</sup>Pain Management, Sunshine Coast Clinical Research, Noosa Heads, Australia, <sup>2</sup>Pain Management, Metro Pain Group, Melbourne, Australia, <sup>3</sup>Pain Management, Green Lizard Science, Claremont, Australia, <sup>4</sup>Obstetrics And Gynaecology / Pain Medicine, University of New South Wales, Sydney, Australia, <sup>5</sup>Pain Management, Frankston Pain Management, Frankston, Australia, <sup>6</sup>Medical Director, Hunter Pain Specialists, Broadmeadow, Australia, <sup>7</sup>Clinical Research, Boston Scientific, Valencia, United States of America

**Introduction:** Treatment of chronic pain is inherently challenging given the subjective nature of pain that uniquely manifests within each patient. The availability of different neuromodulatory approaches such as spinal cord stimulation (SCS), peripheral nerve stimulation (PNS), peripheral nerve field stimulation (PNFS) and occipital nerve stimulation (ONS) may help address this variability. In addition, device implanted chronic pain patients can also increasingly customize their own specific neurostimulative therapy using a growing array of available stimulation waveforms as well as ever more effective targeting and programming capabilities. Here, we present SCS and PNS outcomes in an on going, real-world study of chronic pain patients implanted with a neuromodulation system capable of multiple waveform and programming modalities in Australia.

**Methods/Materials:** This is a multicentre, observational case series of patients implanted with a multiple waveform neuromodulation system (Precision or Precision Spectra, Boston Scientific) conducted at six sites in Australia as part of an ongoing retrospective chart review evaluation of outcomes for chronic pain (Clinicaltrials.gov identifier: NCT01550575). Assessments collected include baseline characteristics (demographics, medical history, pain diagnosis) and pre- and post-implant outcomes.

**Results:** To date, data from 119 patients (23% PNS, 5% Dorsal Column Stimulation, 72% not reported), at a mean last follow-up of 670 days has been collected. In patients using PNS, a 5.0-NRS score improvement (Baseline: 7.7; Follow-Up: 2.8) in low back pain at mean last follow up was observed ( $p < 0.0001$ ). Among all patients, a 5.1-point reduction in overall pain was reported (7.6 [baseline] to 2.6 [mean last follow-up],  $p < 0.0001$ ) at the 3-months post-implant timepoint. A similar trend of pain relief was sustained out to 12-months post-implant. This study is on-going and additional data is being collected and will be presented.

**Discussion:** Systems capable of providing multiple waveforms and/or field shapes are thought capable of enabling the attainment of substantial, long-term pain relief. Studies are needed however to further understand the impact of personalized therapy on the outcomes of chronic pain patients. This real-world, case-series examination reports pain reduction outcomes within a diverse group of patients using a neuromodulation system capable of providing multiple waveform and other stimulation programming options. Future studies are needed to evaluate personalized therapy utilizing new SCS systems capable of providing combination therapy, multiple waveforms and/or advanced field shapes.

**Conclusions:** Results from this on going, multicentre, real world clinical study in Australia demonstrate significant improvement in overall pain using a neuromodulation system capable of providing multiple waveform and programming modalities.

### **References:**

**Keyword:** spinal cord stimulation, SCS, chronic pain, multiple waveforms, neurostimulation

**Topic:** 07. *Peripheral Nerve*

## TWO CASES OF VAGAL NERVE DUPLICATION DURING VNS INTERVENTION

### E-POSTER VIEWING

Javier Márquez-Rivas<sup>1</sup>, Roser Garcia-Armengol<sup>2</sup>, Manel Tardáguila Serrano<sup>2</sup>, Bárbara Blanco-Martínez<sup>3</sup>, Juan Luis Becerra Cuñat<sup>4</sup>, Raquel Garcia Mendez<sup>5</sup>, Tim Vancamp<sup>5,6</sup>

<sup>1</sup>Department Of Neurosurgery, University hospital Virgen del Rocío, Sevilla, Spain, <sup>2</sup>Department Of Neurosurgery, University hospital Germans Trias i Pujol, Badalona, Spain, <sup>3</sup>Department Of Neurology & Epilepsy Unit, University hospital Virgen del Rocío, Sevilla, Spain, <sup>4</sup>Department Of Neurology & Epilepsy Unit, University hospital Germans Trias i Pujol, Badalona, Spain, <sup>5</sup>Neuromodulation, LivaNova España SL, a subsidiary of Livanova PLC, Barcelona, Spain, <sup>6</sup>, e4Sci, Sabadell, Spain

**Introduction:** The cervical vagus nerve (CVN) should be viewed not only as anatomical entity, but also as a morphological entity of the peripheral autonomic nervous system, a composite of different fibers and (anastomosing and hitchhiking) branches of different origin with different neurotransmitters, which can act both parasympathetic and sympathetic.<sup>1</sup> Anatomical variation exists and we report on two cases where an anomaly of the anatomy of the CVN was found during VNS (Vagal Nerve Stimulation) implantation.

**Methods/Materials:** The vagus nerve stimulator must be implanted with blunt technique on the left side to avoid cardiac side effects through the classic approach for anterior cervical discectomy. The vagal nerves in 2 patients were encountered in their traditional place, nestled between the carotid artery and internal jugular vein. The CVN is then bluntly dissected for a length of 3–4 cm, avoiding damage to its vasa nervorum and preserving the perineurium sheath.

**Results:** Both patients showed duplication of the CVN during the intervention. Both surgeries happened at different hospitals in Spain and were performed by neurosurgeons very experienced with VNS implantations. Pictures will be included in the poster. It was chosen to wrap the electrode cuffs around the thicker bundle of the two parts. 1 paediatric patient (male, 8 years old) underwent VNS surgery for refractory epilepsy secondary to perinatal hypoxia. Patient has complex partial crisis, initially 5 to 6 weekly which reduced to 1 crisis per month at 3 months after implantation, and this has remained stable since. The parents are enchanted with the therapy and are extremely satisfied with the outcome. 1 Adult patient (male, 51 years old) received a VNS implant for refractory epilepsy, multiregional secondary to vascular lesions as a result of ischemic ictus. Patient has complex partial crisis and also tonic-clonic seizures with secondary generalization. Initially the patient had 1 up to 2 crises daily, which reduced post-implantation to 2 per month at last follow-up. No complications were encountered during and after the surgery resulting from the intervention. More details will be presented in the poster.

**Discussion:** Anatomical variations may lead to morphological differences, especially with respect to effects due to stimulation of the vagal nerve (both parasympathetic and sympathetic).<sup>1,2</sup> Duplication of the CVN can be a less than expected surprise when encountered and can raise some doubts when first confronted with this variation.

**Conclusions:** We haven't found any other publication so far explaining duplication of the vagal nerve encountered during VNS implantation procedures and share here our experiences and outcomes.

**References:** 1. T.J. Verlinden, K. Rijkers, G. Hoogland, A. Herrler. Morphology of the human cervical vagus nerve: implications for vagus nerve stimulation treatment. *Acta Neurol Scand.* 2016;133(3):173-82. 2. F. Giordano, A. Zicca, C. Barba, R. Guerrini, L. Genitori. Vagus nerve stimulation: Surgical technique of implantation and revision and related morbidity. *Epilepsia.* 2017;58(Suppl. 1):85-90.

**Keywords:** Cervical Vagus Nerve, VNS, Implantation, epilepsy, Anatomical Variations, Duplication

**Topic:** 07. *Peripheral Nerve*

## **FIRST USE OF STIMROUTER PERIPHERAL NERVE STIMULATION FOR THE TREATMENT OF BRACHIAL PLEXUS RELATED NEUROPATHIC ARM PAIN IN THE UNITED KINGDOM**

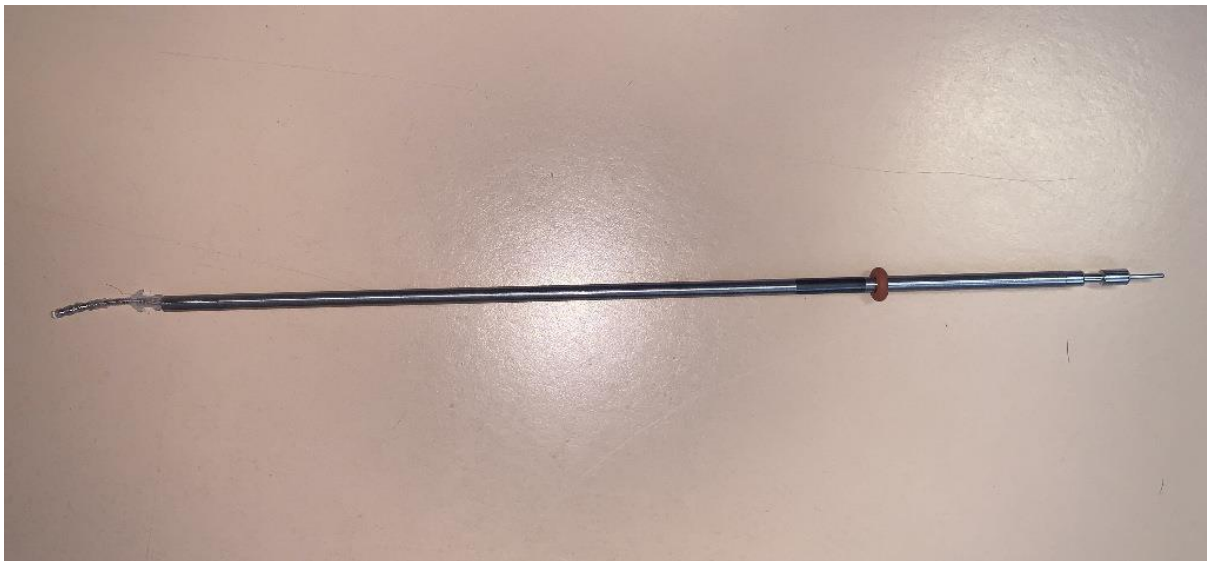
### **E-POSTER VIEWING**

Andy Whelan<sup>1</sup>, Sheila Black<sup>2</sup>

<sup>1</sup>Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom, <sup>2</sup>Anaesthesia And Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom

**Introduction:** This case report is the first use of the StimRouter peripheral nerve stimulation for the treatment of brachial plexus related neuropathic pain in the UK performed at Leeds Teaching Hospital.

**Methods/Materials:** The patient had a left sided modified radical neck dissection with adjuvant chemotherapy for a left submandibular squamous cell carcinoma. Following this he suffered neuropathic left sided neck, shoulder and arm pain which disturbed his sleep. Analgesic therapy included Pregabalin, transdermal opioid patch, Duloxetine and prn opioids. Pain was not controlled with medication and the patient was referred for consideration of an interventional option. A diagnostic left sided interscalene brachial plexus block performed under ultrasound was effective at temporarily providing complete relief of his pain and isolated his source to the left brachial plexus. Treatment with a Bioness StimRouter was therefore considered.



**Results:** Following a neuromodulation information session, the procedure was performed in theatre using local anaesthesia under ultrasound guidance, no sedation was required. The StimRouter was sited in the brachial plexus sheath using a posterior interscalene approach. On the table sensory testing demonstrated paraesthesia present throughout the left arm and utilised a pulse width of 200 milliseconds, a frequency of 100 hertz, and a current of 1.7milliamps.





**Discussion:** The patient went home uneventfully and is due to return for programming and stimulator optimisation.



**Conclusions:** Using peripheral nerve stimulation when a diagnostic block has identified a specific nerve/plexus as the source of pain should be considered as a minimally invasive technique in the treatment of neuropathic pain where standard therapies have failed. Peripheral nerve stimulators represent a long-term treatment option that avoids implanting a battery. We hope through utilising the StimRouter peripheral nerve stimulator in the use of brachial plexus related neuropathic pain this may increase use of peripheral nerve stimulation for neuropathic arm pain.

**References:**



**Keywords:** StimRouter, Peripheral Nerve Stimulation, Brachial plexus Pain, neuropathic pain

**Topic:** 07. *Peripheral Nerve*

## **REAL-WORLD INCIDENCE OF DEVICE INFECTION FOR INTRACTABLE PAIN: OBSERVATIONS FROM THE PRODUCT SURVEILLANCE REGISTRY**

### **E-POSTER VIEWING**

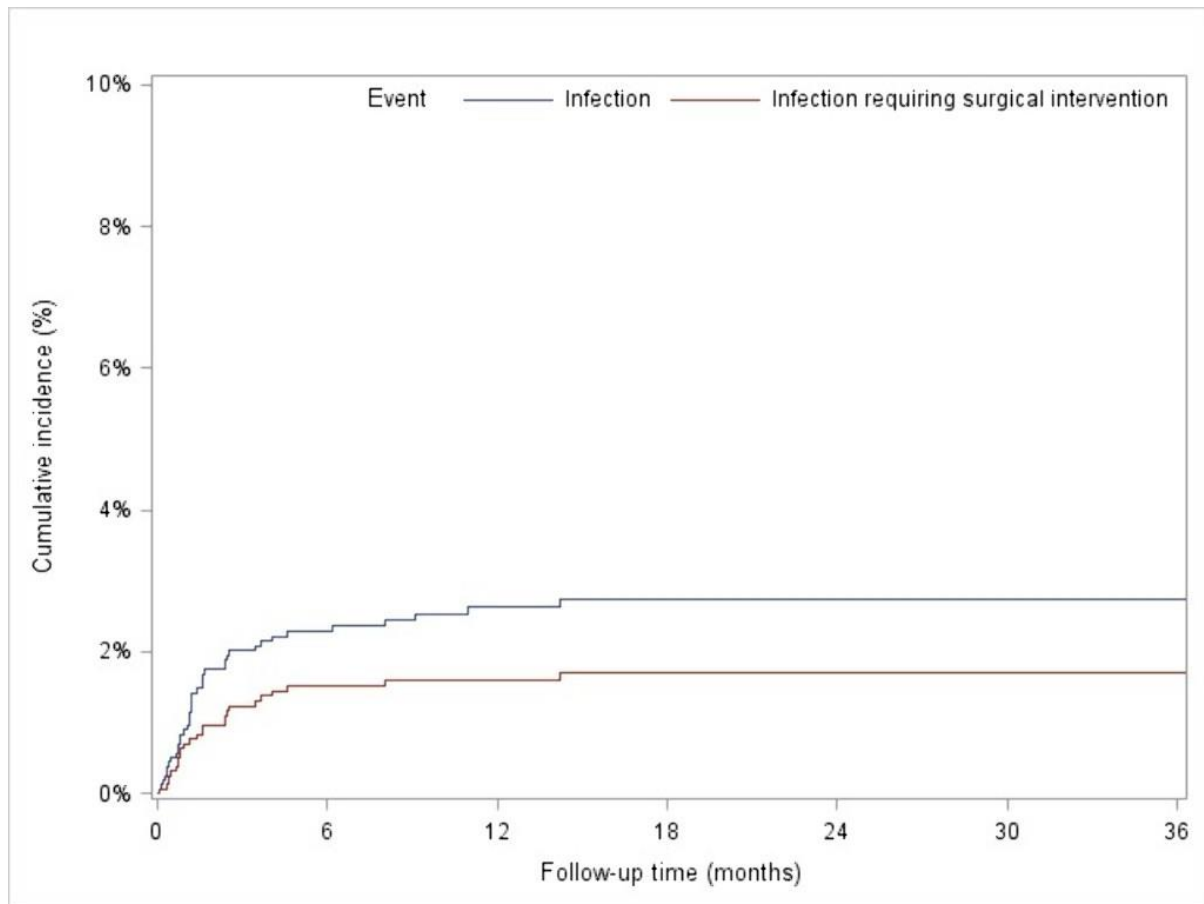
Rachel Slangen<sup>1</sup>, Aaron Calodney<sup>2</sup>, David Schultz<sup>2</sup>, Eric Buchser<sup>3</sup>, Gayle Johnson<sup>4</sup>, Todd Weaver<sup>5</sup>

<sup>1</sup>Post Approval Clinical Surveillance, Medtronic, Maastricht, Netherlands, <sup>2</sup>Interventional Pain Medicine, Precision Spine Care, Tyler, United States of America, <sup>3</sup>Anesthesiology, Hôpital de Morges, Morges, Switzerland, <sup>4</sup>Clinical Biostatistics, Medtronic, Minneapolis, United States of America, <sup>5</sup>Post Approval Clinical Surveillance, Medtronic, Minneapolis, United States of America

**Introduction:** Infections from implantation of pain stimulation systems (SCSs) are serious complications, leading to system removal and substantial morbidity. The real-world incidence and risk factors for infection are not well-understood, and the effectiveness of an absorbable antibacterial envelope (TYRX) designed to reduce SCS infection is unclear.

**Methods/Materials:** The Product Surveillance Registry (PSR) for Pain Stimulation therapies is a prospective, long-term, global multi-center registry designed to monitor the safety and effectiveness of Medtronic Pain Stimulation systems. For the purpose of this analysis, patients enrolled after August 31, 2015 were included. Incidence of infection from IPG implant through 12 months was calculated by Kaplan-Meier methods. Risk factors were assessed using Cox regression.

**Results:** A total of 1826 patients underwent 1961 SCS procedures at 45 centers in 10 countries. Device follow-up was an average of  $14 \pm 12$  months. Patients were of median age  $59 \pm 14$  years and 57% female, were implanted to treat failed back pain (49%), CRPS (10%), and other/unknown reasons (41%); 81% of SCSs were initial procedures. Within 12 months, 39 patients had an infection (2.6%; 95% CI 1.9% to 3.6%), and 2 additional patients had an infection >12 months. Infection requiring surgical revision occurred in 24 patients (12-month rate 1.6%; 95% CI 0.1.1% to 2.4%) (Figure 1). Age was a significant predictor of infection risk (HR 0.97; p-value 0.005). There was no significance difference between initial vs replacement procedures, and BMI, device indication, and implant location were also not significant predictors for SCS infection; although, we have a limited ability to detect differences due to few events. Ninety-nine patients received a TYRX envelope, with 1 having an infection (12-month rate 1.0%).



**Discussion:** Infection is a serious complication related to SCS implantation, preventing patients from receiving adequate therapy. We found that 2.6% of SCS procedures resulted in an infection within a year, which is consistent with recent estimates of 2.4% to 3.1%.<sup>1</sup> From an expert review, the TYRX envelope was provided with a Level II recommendation for prevention of SCS infection due to positive findings from an RCT for cardiac devices, but cited lack of data for SCS. To our knowledge, these are the first data on the envelope for SCS therapy.

**Conclusions:** As observed in this large global registry, SCS infection continues to remain a problem and with younger patients being at increased risk. Further research is warranted to assess interventions such as the TYRX envelope to reduce the risk of infection.

**References:** 1 Zerelda Esquer Garrigos MD, Saira Farid MD, Markus A. Bendel MD, M. Rizwan Sohail MD, Spinal Cord Stimulator Infection: Approach to Diagnosis, Management, and Prevention, Clin Infect Dis. 2019 Oct 9 [Epub ahead of print]

**Keywords:** Infection, Infection Control, Spinal cord stimulation

**Topic:** 07. *Peripheral Nerve*

## ARE THERE INTER- & INTRA-INDIVIDUAL DIFFERENCES IN IMPEDANCES WHEN APPLYING VNS?

### E-POSTER VIEWING

Tim Vancamp<sup>1,2</sup>, Javier Márquez-Rivas<sup>3</sup>, Cristina Ardisana<sup>2</sup>, Raquel Garcia Mendez<sup>2</sup>

<sup>1</sup>, e4Sci, Sabadell, Spain, <sup>2</sup>Neuromodulation, LivaNova España SL, a subsidiary of Livanova PLC, Barcelona, Spain, <sup>3</sup>Department Of Neurosurgery, University hospital Virgen del Rocío, Sevilla, Spain

**Introduction:** The cervical vagus nerve (CVN) changed to a target of nerve stimulation to treat a variety of disorders. It is well known that anatomical variation exists, thus we investigated whether impedance of the vagal nerve had any correlation related to different determinants.

**Introduction/Objective:** The cervical vagus nerve (CVN) changed to a target of nerve stimulation to treat a variety of disorders. It is well known that anatomical variation exists, thus we investigated whether impedance of the vagal nerve had any correlation related to different determinants.

**Methods/Materials:** We included 228 data points from patients implanted and treated with VNS for drug resistant epilepsy (DRE) during a period from 2016-2019. Three different implantable pulse generators were entered in the analysis: model 103, 106 & 1000 (LivaNova PLC, London, GB). Excel 16.32 was used for statistical evaluation (Microsoft, Redmond, WA, USA). P-values of 0.05 or less were considered as statistically significant.

**Results:** 228 patients (male: 133 (58.3%) and female 95 (41.7%)), were included in the analysis, of which 153 (67.1%) were adults and 75 (32.9%) children. Average age of the subjects was 30.3 years old (range: 1-74 years old). Average impedance was found to be 2058,0  $\Omega$  (Range:1006-4963  $\Omega$ ). We didn't find a statistically significant difference between impedance and gender ( $p = 0.27$ ) nor between the groups of adult and children. We did find a statistically significant difference between new implants and replacements ( $p < 0.05$ ), with a median of 1919,3  $\Omega$  for new implants versus 2295,8  $\Omega$  when the IPG is replaced. Further sub-analyses will be performed when all data have been collected as this is an ongoing study.

**Discussion:** In recent studies left and right CVN values of the diameter and cross-sectional areas were found not to vary significantly, neither did they when comparing them with gender. CVN with branching though was found to relate with significantly larger diameters and cross-sectional areas.<sup>1,2</sup>

**Conclusions:** Impedance may change over time, especially when comparing de novo implantations with device replacements (IPG). This highlights the fact that scarring occurs around the electrode after implantation, which stabilizes over time.

**References:** 1. T.J. Verlinden, K. Rijkers, G. Hoogland, A. Herrler. Morphology of the human cervical vagus nerve: implications for vagus nerve stimulation treatment. *Acta Neurol Scand.* 2016;133(3):173-82. 2. N. Hammer, J. Glätzner, C. Feja, C. Kühne, J. Meixensberger, U. Planitzer, S. Schleifenbaum, B. N. Tillmann, D. Winkler. Human Vagus Nerve Branching in the Cervical Region. *PLoS ONE.* 2015;10(2):e0118006.

**Keywords:** age, Cervical Vagus Nerve, replacement, VNS, impedance, gender

**Topic:** 07. *Peripheral Nerve*

**WIRELESS PERIPHERAL NERVE FIELD STIMULATION FOR TREATMENT OF NEUROPATHIC PAIN FOLLOWING LEFT SUPERFICIAL PAROTIDECTOMY**

**E-POSTER VIEWING**

Jane Shaw, Samantha West, Fay Garner, Ashish Gulve, Katrina Boulton  
The Pain Clinic, THE JAMES COOK UNIVERSITY HOSPITAL, Middlesbrough, United Kingdom

**Introduction:** Treating craniofacial neuropathic pain with traditional neurostimulation system is challenging. We report a case of Peripheral Nerve Field Stimulation using Freedom Wireless Neurostimulator.

**Methods/Materials:** Mr. M, a 64-year-old gentleman had left superficial parotidectomy in 2014. The neuropathic pain started few months after surgery. The pain involved left side of neck, face and radiated towards occipital area. He had some numbness anterior to scar, hyperesthesia extending to temporomandibular joint, ear and occipital area. The pain was moderate to severe and 7/10 on a numerical rating scale. He had tried all the antineuropathic medications, weak and strong opioids, simple analgesics, topical menthol and Lidocaine 5% plaster either without sustained pain relief or side effects. He had repeated injections of the scar, trigger point injections and PENS (Peripheral Electrical Nerve Stimulation) with short-term pain relief. He had two Quadripolar leads with tines (StimQ Neurostimulator Receiver & a spare lead) implanted subcutaneously on either side of the painful area in December 2019. The leads were tunneled to the anterior chest wall. The Radiofrequency connectors of both the leads were in one wound and could be activated using one stimulator pad. 2 Weeks after the implant, the system was activated using all electrodes in a -++ configuration delivering 15,000 Hertz. Three programs were configured at 2.5mA 3.0mA and 3.5mA. The patient was encouraged to work through the programs.

**Results:** At one month follow up from activation the patient reported 50% pain relief with paraesthesia coverage over 100% of his painful area on program 3 (3.5mA). The patient was satisfied with therapy.

**Discussion:** Treating craniofacial neuropathic pain with traditional neurostimulation system is challenging. We report successful treatment of post surgical cranio-facial pain with Peripheral Nerve Field Stimulation using Freedom Wireless Neurostimulator.

**Conclusions:** Using wireless Peripheral Nerve Field Stimulation is effective in treating post-surgical neuropathic pain. We aim to present six month follow up data at the conference.

**References:**

**Keyword:** Peripheral Nerve Stimulation neuropathic pain

**Topic:** 07. *Peripheral Nerve*

## **FIRST RESULTS OF STIMULATION OF THE TIBIAL NERVE FOR NEUROPATHIC PERINEAL PAIN**

### **E-POSTER VIEWING**

Alessandro Dario, Claudio Reverberi  
Neurosurgery, ASST Settelaghi, Varese, Italy

**Introduction:** To evaluate the stimulation of the posterior tibial nerve for neuropathic perineal pain by a peripheral nerve stimulator

**Methods/Materials:** Two patients suffering from perineal resistant to pharmacology due to previous surgical intervention on pelvic area were implanted on posterior tibial nerve with a system characterized by implanted lead and external pulse generator. In the first patient the lead was implanted by surgical open technique while the other patient was approached by percutaneous approach ultrasound-guided. The NRS scale was reported preoperative and at follow-up at six and two months

**Results:** All patients showed a NRS scale from preoperative value of 7 to postoperative value of 2 and 3 at follow-up. No surgical complications were recorded.

**Discussion:** The stimulation of the posterior tibial nerve has been effective in these patients with pelvic pain; the ultrasound-guided percutaneous approach appears to be less invasive with only two incisions of 1 cm each.

**Conclusions:** This technique appears to be effective in this small series and requires further studies for its validation.

**References:** Nizard J, Raoul S, Nguyen JP, Lefaucheur JP. Invasive stimulation therapies for the treatment of refractory pain. *Discov Med*. 2012 Oct;14(77):237-46. Roy H, Offiah I, Dua A. Neuromodulation for Pelvic and Urogenital Pain. *Brain Sci*. 2018 Sep 29;8(10).

**Keyword:** peripheral nerve stimulation - perineal pain - tibial nerve

**Topic:** 07. *Peripheral Nerve*

## **WIRELESS PERIPHERAL NERVE STIMULATION FOR THE TREATMENT OF CHRONIC LEG PAIN DUE TO PARTIAL PARAPLEGIA AFTER PARACHUTING ACCIDENT**

### **E-POSTER VIEWING**

Daniel Herschkowitz

Pain, Facharzt Anästhesie FMH/Notarzt SGNOR, Bern, Switzerland

**Introduction:** A 53-year old male had a parachute accident in 2015 which resulted in paraplegia. After a slow recovery the patient was able to stand alone for a short time but was wheel-chair dependent to ambulate. The patient complained of intermittent jolting pain episodes (more than 20 per day) in the left leg starting laterally under the knee and extending to the malleolus. The patient had been treated with Gabapentin but experienced side effects: at dose of 300 mg/day the patient was very sleepy and drowsy and had no pain reduction. A nerve block of the cutaneous femoral nerve with 5ml Naropin 0.75%, was done under fluoroscopy and yielded excellent short time results. The nerve area causing the pain was identified by applying StimPod stimulation (10mAmp, 10 Hz) laterally above the knee.

**Methods/Materials:** The permanent implant procedure was done under light sedation, with local anesthesia and in supine position. The entry point for the leads was laterally above the knee, and the electrodes were placed at the condylus lateralis femoris of the left knee and approached from lateral to the popliteus nerve as performed in a distal ischial block. The leads were then fixed with a conventional anchor on the muscle fascia. There were no complications during the procedure.

**Results:** Pain scores at trial stimulation were 2-4/10 compared to 8/10 without stimulation. All parameters indicated an immediate improvement after implant and a further gradual improvement through the following 6 months. The patient reported neither adverse events nor side effects.

**Discussion:** Peripheral nerve pathology has been a difficult condition to treat with conventional wired stimulation systems, because of the size of the implantable power generator (IPG), and the difficulty in finding a suitable implantation site for this bulky power source. The use of wireless stimulation has expanded the horizon of possible peripheral nerve treatment.

**Conclusions:** Wireless peripheral nerve stimulation was a successful option for this patient suffering of debilitating jolting neuropathic pain due to partial paraplegia.

### **References:**

**Keyword:** wireless stimulation, peripheral nerve stimulation, limb pain

**Topic:** 07. *Peripheral Nerve*

## **ULTRASOUND-GUIDED INSERTION OF PERIPHERAL NERVE STIMULATION FOR BRACHIAL PLEXOPATHY**

### **E-POSTER VIEWING**

Lee Jaemoon, Jeon Hyunji, Jae Hun Kim

Anesthesiology And Pain Medicine, Konkuk University Medical Center, Seoul, Korea, Republic of

**Introduction:** Brachial plexus injury (BPI) often causes severe neuropathic pain and the conservative managements such as medication, nerve block, ketamine infusion therapy and physical therapy are not effective for pain and symptoms. Despite insertion of spinal cord stimulation, some patient with BPI has no effect for decreasing pain. There are some cases for peripheral nerve stimulation (PNS) for peripheral nerve injury.

**Methods/Materials:** It is difficult to place the lead at injured peripheral nerve. For insertion the lead at peripheral nerve, ultrasound guidance can be used to place it at the correct peripheral nerve without open surgery. Here, we describe a case of successful treatment of BPI with PNS. 23 years old man had experienced severe neuropathic pain of right upper extremity (brachioplexopathy) for 3 years. Conservative managements such as medication and nerve blocks had no or short term effect for pain. Even though we had performed trial of spinal cord stimulation, it was not effective. Therefore, we decided to treat this patient's intractable pain using PNS. We used the infraclavicular approach with ultrasound, and inserted an 8-pole percutaneous electrical lead on the medial and lateral cord.

**Results:** After this procedure, the patient's pain was improved from an NRS score of 8/10 to 3/10.

**Discussion:** In this patient, peripheral nerve stimulation was effective for his pain

**Conclusions:** For intractable neuropathic pain, ultrasound guided insertion of peripheral nerve stimulation may be one of the treatment options.

### **References:**

**Keywords:** stimulation, peripheral nerve, ultrasound



## WIRELESS ILIOINGUINAL NERVE STIMULATION TO TREAT GROIN PAIN AFTER SPINAL CORD INJURY

### E-POSTER VIEWING

Bartolomäus Muskala

Zentrum Für Wirbelsäulenchirurgie Und Neurotraumatologie, DRK Klinik Westend, Berlin, Germany

**Introduction:** Patients with spinal cord injuries often have persistent neuropathic pain in the region of the injury. Because of the spinal cord pathology, spinal cord stimulation (SCS) is usually not an option. We describe a spinal cord injury patient with groin pain from ilioinguinal neuralgia, with concomitant loss of urinary and fecal continence and impaired motor function of the legs after recovering from paraplegia from Anterior spinal artery syndrome, treated with ilioinguinal wireless peripheral nerve stimulation (PNS).

**Methods/Materials:** Patient is a 61y old Caucasian (height 189 cm, weight 94kg) who was recovering from a postsurgical paraparesis caused by an anterior spinal artery syndrome after a laminectomy in 2008 at T9-T11 to coagulate and resect an AV fistula at T10. Patient had residual gait disturbance, though he was now able to walk without assistance. However, he complained of intractable left groin pain. He had a persistent weakness of the right extensor hallucis longus muscle (strength 1-2 out of 5), with reduced temperature distinction and proprioception of the left foot, and hypoalgesia of the left lower extremity. Patient complained of burning and itching every 3 minutes (attacks last about 30 seconds) above the ilioinguinal ligament, especially in the morning and evening hour. Hyperesthesia and allodynia were noted above the left ilioinguinal ligament (ilioinguinal neuralgia). Patient failed pregabalin, paracetamol, tapentadol, capsaicin, acupuncture, osteopathic manipulations, and physical therapy. VAS 7/10.

**Results:** Entry point for the PNS was 2cm ventral medial and cranial of the anterior superior iliac spine (ASIS). Freedom 4A PNS electrode with tines (Stimwave Pompano Beach, FL USA) stimulator was placed in between the internal oblique and transversus muscles, parallel to and 3 cm above the inguinal ligament. A knot was placed at the end of the stimulator and the tail was buried subcutaneously. There were no complications. Post procedure, pain decreased to 2/10.

**Discussion:** Anterior spinal artery syndrome is a dreaded complication of surgery and injections around the spine. The radikulomedullary artery of Adamkiewicz, which supplies the lower two thirds of the spinal cord arises from T9 to T11 in 75% of patients, but may be found as high as T5 or as low as L5. Because of the scar tissue after the performed operation and the high risk of paralysis DRG-Stimulation and SCS did not seem to be a good therapeutic option.

**Conclusions:** Patient who was not a good candidate for SCS noted significant relief from PNS.

**References:** Rosendal F, Moir L, de Pennington N, Green AL, Aziz TZ. Successful treatment of testicular pain with peripheral nerve stimulation of the cutaneous branch of the ilioinguinal and genital branch of the genitofemoral nerves. *Neuromodulation*. 2013;16(2):121–4. Banh DP, Moujan PM, Haque Q, Han TH. Permanent implantation of peripheral nerve stimulator for combat injury-related ilioinguinal neuralgia. *Pain Physician*. 2013;16(6):E789–91. Rauchwerger JJ, Giordano J, Rozen D, Kent JL, Greenspan J, Closson CW. On the therapeutic viability of peripheral nerve stimulation for ilioinguinal neuralgia: putative mechanisms and possible utility. *Pain Pract*. 2008;8(2):138–43.

**Keywords:** Ileoinguinal, Spinal Cord Injury SCI, PNS, Groin Pain

**Topic:** 07. *Peripheral Nerve*

## **WIRELESS PERIPHERAL NERVE STIMULATION FOR THE TREATMENT OF CHRONIC KNEE PAIN**

### **E-POSTER VIEWING**

Niek Vanquathem<sup>1</sup>, Thomas Pfandlsteiner<sup>2</sup>

<sup>1</sup>Pain, OKM Markgröningen, Markgröningen, Germany, <sup>2</sup>Neuroorthopedic Spine Center, Scoliosis Center, Paraplegic Center, Interventional Pain Department, OKM Markgröningen, Markgröningen, Germany

**Introduction:** A 76-year old male presented with chronic pain in both knees as a result of multiple surgeries (knee replacements). The patient was severely disabled since 2010 and was treated with pain medication such as oxycodone and fentanyl. He received a DRG system from another company to treat the right leg. When one of the leads broke, the system was replaced with a wireless spinal cord stimulator over the L3/L4 exiting nerve roots on the right side and two additional stimulators over the L3/L4 exiting nerve roots on the left side to treat left knee pain.

**Methods/Materials:** The stimulators targeting the right knee were placed targeting the L3 and L4 exiting nerve roots. The entry point was 8 to 10 cm lateral to the midline at the inferior edge of the disc space immediately below the targeted foramen. Electrode placement was aimed at the superior, posterior open side of the foramen. The needles were retracted and followed by intraoperative testing to verify functionality and optimal placement. The stimulators were permanently anchored in place with anchor stitches to the fascia. This procedure was repeated for the stimulators targeting the left knee. Two additional incisions were made distal to both insertion sites to house the receiver stylets. The distal portion of the receivers were tunneled towards the receiver pockets, coiled and then fixated by running anchor stitches deep into the fascia.

**Results:** The patient wears two external transmitters on his back at all times, one for each side. He grades his knee pain under movement at 0/10 compared to baseline. The patient stated that he feels a considerable improvement on QoL. The patient also stated that he was more independent since he was able to ambulate without pain.

**Discussion:** Conventional IPG-based systems are associated with several types of complications related to the implanted components. Such complications include lead migration/fracture, infections, failed stimulation and IPG related issues such as pocket pain (5). There have been recent advances with nanotechnology and wireless approaches to SCS. A wireless device reduces the complexity of the system and surgery.

**Conclusions:** Wireless spinal cord stimulation of the DRG was a successful option for an elderly patient suffering of debilitating knee pain. Wireless neurostimulation allows for various placement techniques (SCS, PNS, DRG) and patterns, which can be used to treat difficult to access sites. The procedure is more straightforward for the physician, and less cumbersome for patients as compared to conventional wired systems.

### **References:**

**Keyword:** peripheral nerve stimulation chronic knee pain

**Topic:** 07. *Peripheral Nerve*

## **WIRELESS ILIOINGUINAL NERVE STIMULATION TO TREAT GROIN PAIN AFTER SPINAL CORD INJURY**

### **E-POSTER VIEWING**

Bartolomäus Muskala

Zentrum Für Wirbelsäulenchirurgie Und Neurotraumatologie, DRK Klinik Westend, Berlin, Germany

**Introduction:** Patients with spinal cord injuries often have persistent neuropathic pain in the region of the injury. Because of the spinal cord pathology, spinal cord stimulation (SCS) is usually not an option. We describe a spinal cord injury patient with groin pain from ilioinguinal neuralgia, with concomitant loss of urinary and fecal continence and impaired motor function of the legs after recovering from paraplegia from Anterior spinal artery syndrome.

**Methods/Materials:** Patient is a 61y old Caucasian who was recovering from a postsurgical paraparesis caused by an anterior spinal artery syndrome after a laminectomy in 2008 at T9-11 to coagulate and resect an AV fistula at T10. Patient had residual gait disturbance, though he was able to walk without assistance. However, he complained of intractable left groin pain. He had a persistent weakness of the right extensor hallucis longus muscle, with reduced temperature distinction and proprioception of the left foot, and hypoalgesia of the left lower extremity. Patient complained of burning and itching every 3 minutes (attacks last about 30 seconds) above the ilioinguinal ligament. Hyperesthesia and allodynia were noted above the left ilioinguinal ligament (ilioinguinal neuralgia). Patient failed pregabalin, paracetamol, tapentadol, capsaicin, acupuncture, osteopathic manipulations, and physical therapy. VAS 7/10.

**Results:** Entry point for the PNS was 2cm ventral medial and cranial of the anterior superior iliac spine (ASIS). Freedom 4A PNS electrode with tines (Stimwave Pompano Beach, FL USA) stimulator was placed in between the internal oblique and transversus muscles, parallel to and 3 cm above the inguinal ligament. A knot was placed at the end of the stimulator and the tail was buried subcutaneously. There were no complications. Post procedure, pain decreased to 2/10.

**Discussion:** Anterior spinal artery syndrome is a dreaded complication of surgery and injections around the spine. Vessels known as the anterior radiculomedullary arteries travel with each nerve root, supplying blood flow to the anterior spinal artery, which in turn supplies the anterior spinal cord. Although there are radiculomedullary vessels at each spinal level, the anterior spinal arteries combine in utero to form one or a few major vessels, known as the artery of Adamkiewicz, which supplies the lower two thirds of the spinal cord. This vessel arises from T9 to T11 in 75% of patients but may be found as high as T5 or as low as L5. Damage to these vessels leads to paralysis.

**Conclusions:** Patient who was not a good candidate for SCS noted significant relief from PNS.

### **References:**

**Keyword:** Wireless Ilioinguinal nerve stimulation groin pain

**Topic:** 07. *Peripheral Nerve*

## **TREATMENT OF POSTHERPETIC NEURALGIA WITH VARIOUS METHODS OF SPINAL CORD AND DORSAL ROOT GANGLION STIMULATION.**

### **E-POSTER VIEWING**

Vasilii Tkachenko<sup>1</sup>, Emil Isagulyan<sup>2</sup>, Elisaveta Mackaschova<sup>2</sup>, Alexey Tomsky<sup>2</sup>, Evgeniy Dorokhov<sup>2</sup>

<sup>1</sup>Neurology, Central State Medical Academy of Department of Presidential Affairs, moscow, Russian Federation, <sup>2</sup>Neurosurgery, National Medical Research Center of Neurosurgery named after acad. N.N. Burdenko, moscow, Russian Federation

**Introduction:** Postherpetic neuralgia is pain that lasts more than 3 months after the disappearance of the rash with herpes zoster. For the treatment of postherpetic neuralgia, a wide arsenal of medications and non-medicinal techniques is used, including spinal cord stimulation.

**Methods/Materials:** The study included 14 patients with postherpetic neuralgia (the duration of pain was  $38.07 \pm 35.4$  months) after positive effect of test stimulation. The assessment was carried out on a visual analogue scale (VAS), hospital anxiety and depression scale (HADS), pain catastrophie scale (PCS). Medications was also evaluated before and after implantation of an electrical stimulator. The level of stimulator installation was determined by the affected area (occipital nerves, chest nerves). 11 patients underwent tonic spinal cord stimulation, 2 patients received reprogrammable stimulant high frequency and burst, and 1 patient with dorsal root ganglion stimulation.

**Results:** As a result of implantation of a constant stimulant, significant improvements were noted in patients: a decrease in the severity of pain according to VAS from  $8.1 \pm 0.86$  to  $3.7 \pm 1.8$ , a decrease in the score on the catastrophie scale of pain  $12.85 \pm 3.4$  after  $10.4 \pm 3.9$  and reduced manifestations of anxiety ( $14.2 \pm 3.2$  to  $11.07 \pm 4.4$ ) and depression  $13.9 \pm 3.7$  to  $11.3 \pm 4.5$ . Positive dynamics can also be monitored by taking pain medication. Pregabalin was taken by 10 patients, 7 of them completely stopped taking the drug, gabapentin was canceled 5 out of 10. The doses of duloxetine (from 60 mg to 30 mg) and amitriptyline ( $95.4 \pm 26.9$  mg to  $50 \pm 37.08$  mg) were reduced. Tramadol was canceled 5 out of 7 (Median 9000 mg / month, before the procedure, then two 6000 and 3000 mg / month were used)

**Discussion:** Various studies on the stimulation of the spinal cord and dorsal roots in postherpetic neuralgia also show a positive trend in the treatment of pain. Small groups are considered using one type of stimulation. This study examined a group of patients with three types of spinal cord and root stimulation. They show comparable results. Large groups are needed to more accurately determine the effectiveness of each type of stimulation.

**Conclusions:** Stimulation of the spinal cord can significantly reduce the severity of pain, reduce medication and improve the quality of life of patients. This is especially true for elderly patients with concomitant diseases. It is also worth noting the importance of test stimulation before implantation of a permanent stimulator.

### **References:**

**Keywords:** Spinal cord stimulation, Dorsal Root Ganglion Stimulation, neuromodulation, Postherpetic neuralgia

Topic: 07. Peripheral Nerve

## HEART RATE VARIABILITY MONITORING OF CLINICAL TRANSCUTANEOUS AURICULAR VAGAL NERVE STIMULATION

### E-POSTER VIEWING

Kristen Sparrow

Alternative Medicine, Private Practice, San Francisco, United States of America

**Introduction:** Improved autonomic balance leads to reduction in inflammation as well as other health benefits. Inflammation is implicated in medical conditions from cardiovascular disease to depression, to cancer, to aging. Efforts to “hack” the autonomic nervous system with implanted vagal nerve stimulators have had some success. Transcutaneous Auricular Vagal Nerve Stimulation (TAVNS) has the promise of being a safe alternative since it relies on noninvasive afferent input to a peripheral branch of the vagus. Recent research has helped to define best parameters for TAVNS treatment, including frequency, intensity, electrode placement and timing. As with any treatment modality, however, individual patient variation can affect the efficacy of implanted vagal nerve stimulators and TAVNS. There are some exploratory investigations using heart rate variability (HRV) as feedback for implanted vagal nerve stimulation and for TAVNS also. Acupuncture has been shown to improve autonomic balance, so the hypothesis was that TAVNS added to acupuncture treatment would further improve HRV and autonomic balance.

**Methods/Materials:** Patients monitored (HRV) in supine position for 5 minute baseline and then for entire treatment including TAVNS application, needling and resting with needles in for additional 20 minutes. TAVNS applied using clip electrode on the cymba concha bilaterally, and in some instances unilaterally. Frequency of TAVNS varied between, 1 hz, 25Hz, or 100 hz. HRV analysis of 3 minute segments during treatment using several HRV parameters including time, frequency and nonlinear analysis. 1 minute segments for DFA $\alpha$ 1 (a nonlinear parameter) were also charted.

**Results:** There was individual patient variation in HRV response with added TAVNS. HRV analysis is characterized by a significant noise/signal ratio. DFA $\alpha$ 1 mitigated that problem. Patients who showed the most improvement were those who had low HRV to start, though other variables such as clinical condition and gender might play a role.

**Discussion:** The hypothesis that TAVNS would improve HRV did not hold up in all patients. Of the HRV parameters measured and recorded, DFA $\alpha$ 1 over one minute segments had the strongest signal/noise ratio so was the most promising as a measure. Furthermore, HRV analysis might have the potential to determine best TAVNS parameters for treatment such as intensity, frequency, duration etc... Individual patients' HRV data will be presented and discussed.

**Conclusions:** TAVNS did not improve HRV in all patients so HRV may help to better define which patients would benefit most from TAVNS. DFA $\alpha$ 1 was found to be the most reliable HRV measure.

**References:** 1 Eugenijus Kaniusas<sup>1\*</sup>, Stefan Kampusch<sup>1,2</sup> et al, Marc Tittgemeyer<sup>3,4</sup> Current Directions in the Auricular Vagus Nerve Stimulation II – An Engineering Perspective Front Neurosci 13.772 July 24 2019 2 Romero-Ugalde HM<sup>1,2</sup>, Le Rolle V<sup>1,2</sup>, Bonnet JL<sup>3</sup>, et al A novel controller based on state-transition models for closed-loop vagus nerve stimulation: Application to heart rate regulation. PLoS One. 2017 Oct 27;12(10):17. 3 Liu HY<sup>1,2</sup>, Yang Z<sup>1</sup>, Meng FG<sup>3,4</sup>, et al Preoperative Heart Rate Variability as Predictors of Vagus Nerve Stimulation Outcome in Patients with Drug-resistant Epilepsy. Sci Rep. 2018 Mar 1;8(1):3856. 4 Sclocco R<sup>1</sup>, Garcia RG<sup>2</sup>, Kettner NW<sup>3</sup>, et al The influence of respiration on brainstem and cardiovascular response to auricular vagus nerve stimulation: A multimodal ultrahigh-field (7T) fMRI study. Brain Stimul. 2019 Feb 10. 5 Ulloa L<sup>1</sup>, Quiroz-Gonzalez S<sup>2</sup>, Torres-Rosas R<sup>3</sup>. Nerve Stimulation: Immunomodulation and Control of Inflammation. Trends Mol Med. 2017 Dec;23(12):1103-1120.

**Keyword:** Transcutaneous Auricular Vagal Nerve Stimulation, TAVNS, Heart Rate Variability, HRV, Acupuncture

**Topic:** 07. *Peripheral Nerve*

**WIRELESSLY POWERED, BATTERY-FREE, PERIPHERAL NERVE STIMULATION (PNS) OF THE DISTAL SUPERFICIAL RADIAL NERVE FOR THE TREATMENT OF RADIAL NERVE PALSY AS A RESULT OF SURGERY**

**E-POSTER VIEWING**

Bartolomäus Muskala<sup>1</sup>, Niek Vanquathem<sup>2</sup>

<sup>1</sup>Neurochirurgische Gemeinschaftspraxis, Inter-Neuro, Berlin, Germany, <sup>2</sup>Pain, OKM Markgröningen, Markgröningen, Germany

**Introduction:** Symptoms of nerve injury of the superficial branch of the radial nerve may include a sharp or burning pain, as well as unusual sensations in the thumb and fingers. It's common to experience numbness, tingling and trouble straightening the arm. A common term for this is radial nerve palsy. The patient is a 52-year old female who presented with severe neuropathy and allodynia in the left thumb after splitting of the ring ligament. She experiences excruciating pain upon touch. A 3-fold revision-surgery including a neurolysis of the left radial nerve with fascial flap-plasty proved unsuccessful. Subject has an intolerance to opioids and despite the administration of Gabapentin there is no improvement.

**Methods/Materials:** The patient was implanted with a 4-contact-electrode neurostimulator at the distal superficial radial nerve. The nerve was identified by ultrasound. A small stab wound was made proximally, and the introducer advanced subcutaneously along the planned route, directed toward the hand ultrasound guided and then advanced to the radial nerve near the source of pain. The electrode array was inserted and positioned across the superficial radial nerve. After confirming location, the steering stylet was removed, and the receiver was inserted into the inner lumen of the electrode array. A receiver pocket was created, and the neurostimulator was tunneled to the pocket. A knot was tied to permanently mate the receiver and electrode array. The neurostimulator was secured with 2-0 silk sutures at the entry site, and the tail was coiled and secured in the pocket with 2-0 silk sutures. The patient wears the transmitter around her forearm. The RF transmitters were programmed with a frequency of 1499 Hz, pulse width of 32 µs, and 1 mA.

**Results:** After a successful trial with 90% pain relief, pain scores remained consistent 6 months after the procedure (90% pain reduction). The patient rates her satisfaction as 7/7, with increased quality of life with index profile increasing from 0,522 to 1,000 and overall health score from 39 to 98. Functionality improved drastically from 48% to 2%, which is a change from severely disabled to minimally disabled. She no longer takes any pain medication.

**Discussion:** This battery-free system is able to offer advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator.

**Conclusions:** Wirelessly powered peripheral nerve stimulation bilaterally at the radial nerve was a successful option for this patient suffering of chronic pain in her left thumb.

**References:**

**Keywords:** PNS, wireless, radial nerve

**Topic:** 07. *Peripheral Nerve*

## **ELECTRICAL NEUROSTIMULATION FOR THE TREATMENT OF CHRONIC PRURITUS: A SYSTEMATIC REVIEW**

### **E-POSTER VIEWING**

Moustafa Badwy<sup>1</sup>, Sara Baart<sup>1</sup>, Hok Thio<sup>2</sup>, Frank Huygen<sup>1</sup>, Cecile De Vos<sup>1</sup>

<sup>1</sup>Center For Pain Medicine, Department Of Anesthesiology, Erasmus University Medical Centre, Rotterdam, Netherlands, <sup>2</sup>Department Of Dermatology, Erasmus University Medical Centre, Rotterdam, Netherlands

**Introduction:** Approximately one fifth of the world population experiences continuous itch for six weeks or more during their life, i.e. chronic itch. It is diverse in its aetiologies and it is notoriously hard to treat. Because itch and pain have largely overlapping pathophysiology and the demonstrated efficacy of neurostimulation for treatment of selected chronic pain conditions, we conducted a systematic review to investigate whether neurostimulation could be an effective treatment option for chronic itch.

**Methods/Materials:** We identified two randomized controlled trials and 17 open label studies or case-reports investigating various neurostimulation modalities for the treatment of refractory itch of various aetiologies.

**Results:** Transcutaneous Electrical Nerve Stimulation (TENS) was the most investigated modality (n=17), and in the largest number of conditions, including atopic dermatitis, burn pruritus and notalgia paresthetica. Other modalities were Cutaneous Field Stimulation (CFS) (n=2), Painscrambler (n=1), transcranial Direct Current Stimulation (tDCS) (n=1) and Peripheral Nerve Field Stimulation (PNFS) (n=1). Atopic dermatitis was the most studied condition (n=5).

**Discussion:** Despite the large heterogeneity in used stimulation modalities, stimulation paradigms and outcome parameters, all studies reported a positive effect of at least one neurostimulation modality for the treatment of chronic itch.

**Conclusions:** Our review indicates that electrical neurostimulation could be considered for the treatment of refractory chronic itch of selected aetiologies, such as atopic dermatitis or burn pruritus. However, better understanding of the mechanisms of action of the neurostimulation modalities and regimens in various pruritic conditions is necessary.

### **References:**

**Keywords:** pruritus, review, TENS, Neurostimulation, chronic itch



**Topic:** 07. *Peripheral Nerve*

**OBJECTIVE ASSESSMENT OF THERMOGRAMS TO ASSES THE EFFECTS OF SPINAL CORD STIMULATION IN PATIENTS WITH COMPLEX REGIONAL PAIN SYNDROME.**

**E-POSTER VIEWING**

Else Bijl<sup>1</sup>, Martijn Starmans<sup>2</sup>, Nadia Kriek<sup>1</sup>, Frank Huygen<sup>1</sup>, Cecile De Vos<sup>1</sup>

<sup>1</sup>Center For Pain Medicine, Department Of Anesthesiology, Erasmus University Medical Centre, Rotterdam, Netherlands, <sup>2</sup>Department Of Radiology And Nuclear Medicine, Erasmus University Medical Centre, Rotterdam, Netherlands

**Introduction:** Complex Regional Pain Syndrome (CRPS) is a complication after trauma or surgery. CRPS is characterized by chronic pain, usually combined with sudomotor, vasomotor, sensory, motor- and trophic changes. The pain in CRPS is disproportional in relation to the initial trauma. CRPS usually affects distal extremities. Temperature asymmetry between the affected and contralateral extremity is a characteristic of vasomotor disturbances (1). To assess the effect of treatment on vasomotor disturbances there is demand for an objective method to measure temperature asymmetry. One way to measure skin temperature is through thermography. CRPS can effectively be treated with spinal cord stimulation (SCS). In this study we investigate whether quantitative image features extracted from thermography can be used to objectively assess the effect of SCS on vasomotor disturbances in CRPS.

**Methods/Materials:** This analysis is part of a larger multicenter study that examined the effects of SCS in patients with CRPS (ISRCTN 36655259) (2). Before implantation (baseline) and at three months after implantation questionnaires about pain scores and patient satisfaction were filled in. Additionally, artificial skin blisters test, to determine local inflammation, and thermal imaging were done. For the analysis of thermograms various quantitative image features were extracted for both the affected and the contralateral extremity. The difference between the features of the affected and contralateral extremity will be compared between thermograms at baseline and three months.

**Results:** In total 43 patients participated in the study. Results of SCS on pain reduction, patient satisfaction (3) and immunomodulatory effects (4) have already been published. The analysis of the effects of SCS on vasomotor disturbances is ongoing. Patients whose baseline or three months thermogram is missing were excluded resulting in the analysis of thermograms of 34 patients. Currently, we are evaluating which image features may be best used to quantify the effects of SCS on vasomotor disturbances in CRPS.

**Discussion:** This is an exploratory analysis to obtain insight in which image features can assess treatment effects on vasomotor disturbances in CRPS. The ultimate goal is a machine learning model based on image features that objectively assesses the effects of SCS treatment on vasomotor disturbances while programming SCS settings, so that stimulation parameters can be optimized for every individual CRPS patient.

**Conclusions:** In this ongoing study, we investigate whether quantitative image features from thermography can be used to objectively quantify the effect of SCS on vasomotor disturbances in CRPS.

**References:** 1. Wasner G. Vasomotor disturbances in complex regional pain syndrome--a review. *Pain Med.* 2010;11(8):1267-73. 2. Kriek N, Groeneweg JG, Stronks DL, Huygen FJ. Comparison of tonic spinal cord stimulation, high-frequency and burst stimulation in patients with complex regional pain syndrome: a double-blind, randomised placebo controlled trial. *BMC Musculoskelet Disord.* 2015;16:222. 3. Kriek N, Groeneweg JG, Stronks DL, de Ridder D, Huygen FJ. Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial. *Eur J Pain.* 2017;21(3):507-19. 4. Kriek N, Schreurs MWJ, Groeneweg JG, Dik WA, Tjiang GCH, Gültuna I, et al.

Spinal Cord Stimulation in Patients With Complex Regional Pain Syndrome: A Possible Target for Immunomodulation? *Neuromodulation*. 2018;21(1):77-86.

**Keywords:** Vasomotor disturbances, Image features, Complex regional pain syndrome, Spinal cord stimulation, Thermography

Topic: 07. Peripheral Nerve

## COMPARING INFRARED NEURAL STIMULATION AND ELECTRICAL STIMULATION FOR INTRAOPERATIVE NERVE MONITORING

### E-POSTER VIEWING

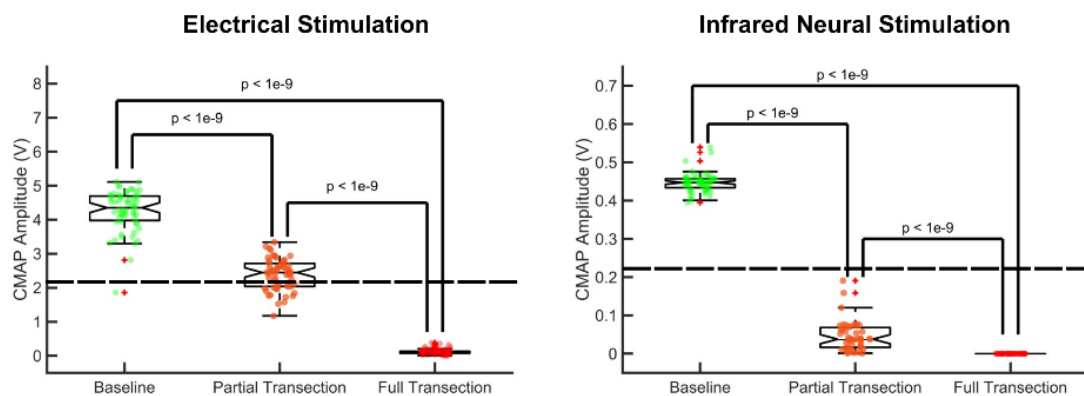
Graham Throckmorton<sup>1,2</sup>, Peter Konrad<sup>3</sup>, E. Jansen<sup>1,2,4</sup>, Anita Mahadevan-Jansen<sup>1,2,4</sup>

<sup>1</sup>Biomedical Engineering, Vanderbilt University, NASHVILLE, United States of America, <sup>2</sup>Biomedical Engineering, Vanderbilt Biophotonics Center, Nashville, United States of America, <sup>3</sup>Neurosurgery, West Virginia University, Morgantown, United States of America, <sup>4</sup>Neurosurgery, Vanderbilt University Medical Center, Nashville, United States of America

**Introduction:** During intraoperative nerve monitoring (IONM), electrical stimulation (ES) is used to assess a nerve's functional integrity and recognize the onset of nerve damage. ES, however, is subject to current spread in which the electrical stimulus extends beyond the area proximal to the electrode and into the surrounding tissue. This can result in the stimulation of multiple nerves or fascicles beyond the target introducing ambiguity as to the functionality of the specific target under consideration.<sup>1-3</sup> Infrared neural stimulation (INS), an optical and label-free means of exciting neural tissue, is capable of safely stimulating nerves with a higher degree of spatial specificity than traditional ES methods.<sup>4-5</sup> The enhanced spatial precision of INS could improve the detection of neural damage during surgical procedures.

**Methods/Materials:** Using an in vivo rat model, the trifurcations of the sciatic nerve were partially and later fully damaged either with transecting or crush injuries while using clinical ES and INS for IONM. As the current clinical standard, a  $\geq 50\%$  loss in baseline amplitude and a  $\geq 10\%$  increase in the baseline latency between the stimulus and evoked response served as the thresholds for neural damage detection.<sup>6,7</sup>

### Results:



**Figure 1. Compound muscle action potentials (CMAPs) amplitude before and after transection evoked using ES and INS.** Dashed line indicates damage threshold.

For both transection and crush injuries, INS more consistently and accurately detects partial injuries (Sensitivity = 96%) as compared to ES (Sensitivity = 32%) (Figure 1). Both INS and ES successfully classify the nerve as damaged when either fully transected or crushed. The efficacy of INS for IONM was greatly influenced by the hydration of the nerve and the degree of spatial selectivity.

**Discussion:** The superior accuracy of INS for detecting partial injuries is likely due to its inherent spatial precision. By monitoring a subset of the axons comprising the nerve, INS is more sensitive to the onset of less severe forms of damage that may otherwise be obscured when stimulating the whole nerve. For future clinical applications, multiplexed INS systems can be designed to monitor multiple axon populations simultaneously. Since water is the primary chromophore enabling INS, maintaining

proper nerve hydration is crucial to the effectiveness of this technique and requires routine bathing of the nerve with saline.

**Conclusions:** Here, we provide a direct comparison of INS to current clinical ES methods for IONM and leverage the spatial selectivity of INS to successfully identify partial injuries. Based on the results of this study, INS has the potential to improve the outcomes and standard of care in surgeries utilizing IONM.

**References:** 1. Popovic, D., Gordon, T., Rafuse, V. F. & Prochazka, A. Properties of implanted electrodes for functional electrical stimulation. *Ann. Biomed. Eng.* 19, 303–316 (1991). 2. Liang, D. H. & Lusted, H. S. The nerve-electrode interface of the cochlear implant: Current spread. *IEEE Trans. Biomed. Eng.* 46, 35–43 (1999). 3. Testerman, R. L. Comments on 'Accuracy limitations of chronaxie values'. *IEEE Transactions on Biomedical Engineering* 52, 750 (2005). 4. Wells, J., Konrad, P., Kao, C., Jansen, E. D. & Mahadevan-Jansen, A. Pulsed laser versus electrical energy for peripheral nerve stimulation. *J. Neurosci. Methods* 163, 326–337 (2007). 5. Cayce, J. M. et al. Infrared neural stimulation of human spinal nerve roots in vivo. *Neurophotonics* 2, 015007 (2015). 6. Toleikis, J. R. & Abnm, D. Intraoperative monitoring using somatosensoryevoked potentials: a position statement by the American Society of Neurophysiological Monitoring. *J. Clin. Monit. Comput.* 19, 241–258 (2005). 7. Schneider, R. et al. Continuous intraoperative neural monitoring of the recurrent nerves in thyroidsurgery: a quantum leap in technology. *Gland Surg.* 5, 607–616 (2016).

**Keywords:** nerve monitoring, infrared neural stimulation, in vivo, optical stimulation, label-free

## SPINAL CORD STIMULATION IN THE TREATMENT OF ISCHEMIC PAIN: MICROCIRCULATION AND TISSUE PERFUSION IMPROVEMENT

### E-POSTER VIEWING

Vladimir Murtazin, Roman Kiselev, Martin Kilchukov, Kirill Orlov  
Neurosurgery, National Medical Research Center n.a. acad. E.N.Meshalkin, Novosibirsk, Russian Federation

**Introduction:** Refractory angina pectoris (RAP) and peripheral vascular disease (PVD) is a chronic pain condition that affects a certain group of patients with systemic atherosclerosis. These diseases have bad control of neither by a combination of medical therapy nor by vascular surgery treatment (angioplasty or bypass surgery). Spinal cord stimulation (SCS) is an effective and safe treatment for these patients that has an excellent effect on pain relief and microcirculatory function's improvement.

**Methods/Materials:** Two groups of patients with non-reconstructable RAP (n=22) and PVD (n=75) underwent SCS procedure in our facility. Preoperative and follow-up myocardium perfusion scintigraphy (MPS), transcutaneous oximetry (TCO) and laser-doppler flowmetry (LDF) were performed on admission and in 1 year after the procedure. Pain relief was assessed by a visual analog scale (VAS) in all patients.

**Results:** The patients showed  $8,56 \pm 0,13$  marks according to VAS before the procedure and pain relief to  $2,09 \pm 0,09$  marks ( $p < 0,01$ ) in the 1-year follow-up. All the patients in the RAP group demonstrated the rise of tolerance to physical activity. MPS detected the decrement of perfusion's defect from  $13,36 \pm 4,16$  to  $10,14 \pm 3,35$  units (increase in coronary reserve up to 24%). TCO detected the microcirculatory improvement (n=75): tissue oxygenation increased from 10,5 to 39,5 mm Hg ( $p = 0,045$ ).

**Discussion:** The present study has some limitations: the follow-up period was relatively short, leading to a limited evaluation of the outcome of SCS. Measurements were not used to select patients for SCS since we intended to include this indicator as a factor that could potentially influence the clinical dynamics after this procedure.

**Conclusions:** The duration of clinical manifestations of RAP and PVD is associated with the long-term results of SCS. Hence, the approaches to the treatment of these diseases need to be optimized to timely use of surgical and nonsurgical therapy, including SCS, in order to improve the clinical and cost-effectiveness of non-reconstructable vascular disease treatment. Our experience confirms that SCS can reduce the pain and improve quality of life with vascular reserve enhancement in patients with ischemic pain syndrome.

**References:** Deer T.R. et al. The Appropriate Use of Neurostimulation of the Spinal Cord and Peripheral Nervous System for the Treatment of Chronic Pain and Ischemic Diseases: The Neuromodulation Appropriateness Consensus Committee // *Neuromodulation: Technology at the Neural Interface*. 2014; 17: 515–550.  
Eldabe S., Buchser E., Duarte R.V. Complications of Spinal Cord Stimulation and Peripheral Nerve Stimulation Techniques: A Review of the Literature // *Pain Medicine*. 2015; 17 (2): 325–336.  
Tsigaridas N. et al. Spinal cord stimulation in refractory angina. A systematic review of randomized controlled trials // *Acta Cardiologica*. 2015; 70 (2): 233–243.

**Keywords:** refractory angina pectoris, chronic pain, peripheral vascular disease, chronic limb ischemia

**Topic:** 08. Cardiovascular Disorders

## NEUROMODULATION IN END-STAGE PAD PATIENTS AND DIABETES

### E-POSTER VIEWING

Beatrix Cucuruz<sup>1</sup>, Thomas Schmitz-Rixen<sup>1</sup>, Octavian Andercou<sup>2</sup>, Karin Pfister<sup>3</sup>, Florian Zeman<sup>4</sup>, Michael Koller<sup>4</sup>, Thomas Noppeney<sup>3</sup>

<sup>1</sup>Vascular And Endovascular Surgery, University Hospital Frankfurt, Frankfurt, Germany, <sup>2</sup>Surgery, University hospital Cluj, cluj, Romania, <sup>3</sup>Vascular Surgery, University Hospital Regensburg, Regensburg, Germany, <sup>4</sup>Center For Clinical Studies Regensburg, University Hospital Regensburg, Regensburg, Germany

**Introduction:** Neuromodulation is used for chronic pain treatment and, with modest results, for end stage peripheral arterial disease (PAD). The aim of this study was to show our results in patients with end stage PAD and diabetes, treated with neuromodulation in the context of an optimized treatment protocol.

**Methods/Materials:** Between 05/2017 and 01/2020 25 patients with end-stage PAD and diabetes were treated with spinal cord stimulation (SCS). All patient's treatment possibilities were discussed in an interdisciplinary conference. If revascularization was not possible, there was no septicaemia and their major symptom was pain, they received SCS. The implantation was performed in local anesthesia under radiologic control. Tonic stimulation was used in all patients. Our new protocol consisted in intraoperative testing to avoid electrode malfunction, no trial phase, postoperative wound management and supervised walking exercise in all patients, regular adjusting the stimulation according to patient's preference.

**Results:** Follow up ranged between 2 and 28 months, mean 9.0 months. Pain (measured by VAS) was reduced from mean 7.8 to mean 4.4,  $p=0.01$ . In 4 out of 25 (16%) patients major amputations were unavoidable. Due to supervised training walking distance could be increased in 63% of the patients.

**Discussion:** SCS implantation is a therapeutic option for end-stage PAD patients and diabetes to save their limb and reduce pain. Supervised walking training and regular adjusting the stimulation led to an acceptable outcome after SCS implantation when compared to earlier case series.

**Conclusions:** SCS implantation is a therapeutic option for end-stage PAD patients and diabetes to save their limb and reduce pain. Supervised walking training and regular adjusting the stimulation led to an acceptable outcome after SCS implantation when compared to earlier case series.

**References:** none

**Keyword:** end stage PAD, diabetes, Neuromodulation

**Topic:** 08. Cardiovascular Disorders

## **EVALUATION OF SPINAL CORD STIMULATION WITH PERFUSION INDEX IN PATIENTS WITH LOWER EXTREMITY PAIN AND CIRCULATORY DISORDER**

### **E-POSTER VIEWING**

Serbülent Beyaz<sup>1</sup>, Fatih Şahin<sup>2</sup>, Alper Erkin<sup>3</sup>, Zeynep Issi<sup>4</sup>

<sup>1</sup>Anesthesiology And Pain Medicine, Sakarya University Faculty of Medicine, Sakarya, Turkey, <sup>2</sup>Anesthesiology And Pain Medicine, Sakarya Yenikent State Hospital, Sakarya, Turkey, <sup>3</sup>Cardiovascular Surgery, Sakarya University Faculty of Medicine, Sakarya, Turkey, <sup>4</sup>Pain Medicine, Sakarya University Training and Research Hospital, Sakarya, Turkey

**Introduction:** Peripheral vascular disease is often the disease in which the limb arteries are affected, and is usually caused by the gradual narrowing of the lower limb arteries due to atherosclerosis (1). Treatment of chronic critical limb ischemia is a serious problem due to comorbidity and its mortality is high due to the presence of systemic atherosclerosis (2). This study was performed to compare the effectiveness of spinal cord stimulation (SCS) in patients with rest pain in the lower extremity due to ischemic disease and skin lesions such as necrosis and gangrene.

**Methods/Materials:** Patients with persistent resting pain for at least 2 weeks, skin lesions (ulcer, gangrene) of 3 cm<sup>2</sup> and below in the lower extremity, arteria tibialis posterior / anterior artery pulsation not palpable, perfusion index (PI) below 0.5, ankle arm index below 1 patients are included. Patients in the 3-4 groups according to the Fontaine classification were evaluated. Preoperative (preop), postoperative (postop) Day 1, Day 3, Week 1, Month 1 and year 1 VAS, ODI, DN-4, right and left perfusion index (PI) values were evaluated.

**Results:** A total of 6 patients were evaluated. While all of these patients were male, there were 5 patients with right lower extremity ischemia and 1 patient with left lower extremity ischemia. It was found that VAS, ODI first month and first year values decreased significantly compared to preop values ( $p < 0.05$ ). In DN-4 evaluation, while 4 and above are considered significant, falling below at least 4 is considered significant. There was a significant decrease compared to preop values ( $p < 0.05$ ). According to the preop values in the right PI, a significant increase was observed in the 1st year data ( $p < 0.05$ ), while there was no significant difference in the left PI values.

**Discussion:** Cook et al. are the first to use SCS in patients with peripheral vascular disease (3). Many studies have investigated the effectiveness of SCS. Pathophysiology and mechanisms of action were examined and tissue oxygenation and changes in blood flow were accepted as responses. In addition, multiple healing effects in the form of exercise tolerance, limb salvage and reduction in pain level have been shown in patients presenting with critical leg ischemia of SCS (4).

**Conclusions:** Ischemic pain is an inevitable end in patients with peripheral vascular disease. While SCS contributes to the reduction of pain, we conclude that it increases the perfusion in the limbs that are lesions and accelerates the healing.

**References:** Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999-2000. *Circulation* 2004;110: 738-43. TASC Working Group. Management of peripheral arterial disease. *TransAtlantic inter-Society Consensus. International Angiology* 2000;19 Suppl 1:23-6. Cook AW, Oygur A, Baggenstos P, Pacheco S, Kleriga E. Vascular disease of extremities. Electrical stimulation of spinal cord and posterior roots. *New York State Journal of Medicine* 1976;76(3):366-8. Amann W, Berg P, Gersbach P, et al. Spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia: results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS). *Eur J Vasc Endovasc Surg* 2003;26: 280-6.

**Keyword:** Ischemic limb pain; perfusion index; peripheral vascular disease; Spinal cord stimulation; leg pain;



**Topic:** 08. Cardiovascular Disorders

## MYOFASCIAL PAIN AND TARGETED PHYSIOTHERAPY IN PATIENTS WITH COPD AND ASTHMA

### E-POSTER VIEWING

Rostyslav Bubnov<sup>1</sup>, Liudmyla Petrenko<sup>2</sup>, Lev Kalika<sup>3</sup>

<sup>1</sup>Ultrasound, Clinical hospital 'Pheophania', Kyiv, Ukraine, <sup>2</sup>Pulmonology, Clinical hospital 'Pheophania', Kyiv, Ukraine, <sup>3</sup>Rehab, York Dynamic Neuromuscular Rehabilitation & Physical Therapy <https://nydnrehab.com>, New York, Ukraine

**Introduction:** Posture, motion and muscle pain has deep reciprocal interaction with respiratory function. Dry needling under ultrasound guidance (DN-US) is proved method for treatment myofascial pain [1], restore posture, can provide beneficial effects for respiratory function and QOL. The Aim was to study the efficacy of targeted physiotherapy including DN-US in patients with chronic obstructive pulmonary disease (COPD) and asthma.

**Methods/Materials:** We included 25 patients with COPD and asthma (age 32-56 years), with muscle pain experience. Patients were considered for functional ultrasound, posture evaluation, treatment option via targeted physiotherapy including DN-US and 12 patients remained as controls. The protocol by R.Bubnov [1] was applied: MTrP were identified according to clinical examination, referred pain pattern, US identification; single fine (28G) steel needle. All patients underwent general clinical, lab tests; diagnostic tests: spirogram; and responded to QOL (36 questions), evaluated exacerbations, using bronchodilators. We determined on dynamic US markers of postural stability (ribs, spine, abdominal wall, diaphragm and pelvic floor motion). Visual analogue scale data (VAS0-10) were measured before and after procedures.

**Results:** In all patients we diagnosed postural imbalance, shoulder, dysfunction, diaphragm hypomotility / asymmetry. In patients with severe cough excessive pelvic floor dysfunction was detected. DN improved postural parameters and decreased pain and improved postural parameters in all patients: restoring shoulders motion, diaphragm motility and pelvic floor hypomotility decreased. We did needling on spine which evoked "opening" ventral parts, ribs, shoulders. After treatment we registered improved spirometry (increasing vital capacity, forced expiratory volume), increasing QOL and decreasing exacerbations and bronchodilators dosage and in the group vs controls ( $p < 0.05$ ).

**Discussion:** Respiratory dysfunction that occurs in COPD and asthma involves postural input from epaxial (spine), hypaxial (abdomen), and appendicular (extremities) myofascial systems [3]. This can be examined evaluating ribs, spine, abdominal wall, diaphragm and pelvic floor motion. At the epaxial thoracic level the two possible scenarios as follows: (1) committed dysfunction (restricted movement in functional unit in mid-thorax; and (2) uncommitted dysfunction ( hypermobility within this unit). Restoring motion at epaxial (spine) system lead to beneficial modification at hypaxial, and appendicular systems. This holistic approach addresses: movement control, pain generators, fascias and trigger points in association with visceral, respiratory function, pulmonary biomechanics at the same time.

**Conclusions:** Personalised rehab is a challenging treatment option for respiratory diseases associated with postural imbalance, various patterns of muscle trigger points. DN-US can be considered as major effective treatment option.

**References:** 1. Bubnov RV. Evidence-based pain management: is the concept of integrative medicine applicable? EPMA J 2012, 3(1):13. 2. Bubnov R, Kalika L, Babenko L. Dynamic ultrasound for multilevel evaluation of motion and posture in lower extremity and spine. Annals of the Rheumatic Diseases 2018;77:1699. <http://dx.doi.org/10.1136/annrheumdis-2018-eular.3949> 3. Fullerton BD. Prolotherapy for the Thoracolumbar Myofascial System. Phys Med Rehabil Clin N Am. 2018 Feb;29(1):125-138.

**Keywords:** dry needling, asthma, posture, myofascial pain, ultrasound

**Topic:** 09. *Gastrointestinal and Colorectal Disorders*

**PANCREATIC CANCER RELATED PAIN: PATHOPHYSIOLOGY AND THE ROLE OF INTRATHECAL DRUG DELIVERY SYSTEMS FOR PAIN MANAGEMENT.**

**E-POSTER VIEWING**

Gabriel Carvajal

Interventional Pain Unit, Centro Nacional de Control del Dolor y Cuidados Paliativos, San José, Costa Rica

**Introduction:** Pancreatic cancer (PC), is the 11<sup>th</sup> most common cancer worldwide, this disease is characterized by an often fatal evolution and a high burden of symptoms, particularly pain. Several studies have demonstrated that pancreatic cancer patients have a high prevalence of pain with up to 82% of patients reporting pain, and often requiring systemic strong opioids as mainstay treatment. This common debilitating symptom negatively impacts patients' quality of life and correlates with negative survival outcomes. This study focuses in recent developments in pathophysiology and intrathecal drug delivery systems as a pain management strategy.

**Methods/Materials:** The literature research was developed in English, French and Spanish from March 2017 to January 2020, using PubMed, Dynamed, EMBASE, Uptodate and Google Scholar. Different search strings based on MESH terms were combined.

**Results:** Pancreatic Cancer Related Pain (PCRP) published pain prevalence data show varying rates from 47%-63% at diagnosis<sup>1,2</sup> and this progresses to 82% of advanced cancer patients referred to a palliative care service in a tertiary care pain facility.<sup>3</sup> Current published experience for PCRP accumulates 192 cases.

**Discussion:** PCRP is a complex condition, and several pathophysiological mechanisms have been proposed, including pancreatic neuropathy, altered cortical processing, perineural invasion, intraductal pressure, bowel obstruction and distant progression. (Figure 1) The first intrathecal use of bolus morphine for pancreatic cancer related pain was published in 1980.<sup>4,5</sup> And IDDS are considered currently a standard pain therapy for severe pain despite noninvasive management. Main cancer pain treatment guidelines now include IDDS as an alternative for complex cases.<sup>6-8</sup> Several strategies such as multidrug regimen including morphine, ropivacaine and ziconotide<sup>9,10</sup> and a standard catheter placement for precise drug delivery close to the posterior spine at T6 allows best pain results in PCRP.<sup>11</sup> Different retrospective, prospective, observational, and randomized controlled studies despite a limited number of PCRP patients have shown its efficacy in treating cancer related pain syndromes. (Table 1)

**Conclusions:** PCRP treatment is a highly complex endeavor as patients are affected by severe pain, poor prognosis, and few disease modifying strategies. We have reviewed anatomical, biological, factors that determine PRC evolution and discussed the role of IDDS in achieving optimal pain relief. This technique should be considered early on disease as progression and functional decline and short life expectancy may limit access to the technique.

**References:** 1. Grahm AL, Andrén-Sandberg A. Prospective evaluation of pain in exocrine pancreatic cancer. *Digestion*. 1997;58(6):542-549. doi:10.1159/000201499 2. Lakatos G, Balázs A, Kui B, et al. Pancreatic Cancer: Multicenter Prospective Data Collection and Analysis by the Hungarian Pancreatic Study Group. *J Gastrointest Liver Dis*. 2016;25(2):219-225. doi:10.15403/jgld.2014.1121.252.pcr 3. Krech RL, Walsh D. Symptoms of pancreatic cancer. *J Pain Symptom Manage*. 1991;6(6):360-367. 4. Wang JK, Nauss LA, Thomas JE. Pain relief by intrathecally applied morphine in man. *Anesthesiology*. 1979;50(2):149-151. 5. Tung A, Maliniak K, Tenicela R, Winter P. Intrathecal morphine for intraoperative and postoperative analgesia. *JAMA*. 1980;244(23):2637-2638. 6. Fallon M, Giusti R, Aielli F, et al. Management of cancer pain in adult patients: ESMO Clinical Practice Guidelines. *Ann Oncol*. 2018;29(Supplement\_4):iv166-iv191. doi:10.1093/annonc/mdy152 7. Beloeil

H, Viel E, Navez M-L, Fletcher D, Peronnet D, Recommandation formalisée d'experts. [Guidelines for regional anesthetic and analgesic techniques in the treatment of chronic pain syndromes]. *Ann Fr Anesth Reanim.* 2013;32(4):275-284. doi:10.1016/j.annfar.2013.02.021

8. Swarm RA, Abernethy AP, Anghelescu DL, et al. Adult cancer pain. *J Natl Compr Canc Netw.* 2013;11(8):992-1022.

9. Dupouiron D, Bore F, Lefebvre-Kuntz D, et al. Ziconotide adverse events in patients with cancer pain: a multicenter observational study of a slow titration, multidrug protocol. *Pain Physician.* 2012;15(5):395-403.

10. Huang Y. Efficacy and Safety of Ropivacaine Addition to Intrathecal Morphine for Pain Management in Intractable Cancer. *Mediators of Inflammation.* 2015;2015:6. doi:https://doi.org/10.1155/2015/439014

11. Carvajal G, Dupouiron D, Seegers V, et al. Intrathecal Drug Delivery Systems for Refractory Pancreatic Cancer Pain: Observational Follow-up Study Over an 11-Year Period in a Comprehensive Cancer Center. *Anesth Analg.* 2018;126(6):2038-2046. doi:10.1213/ANE.0000000000002903

12. Onofrio BM, Yaksh TL. Long-term pain relief produced by intrathecal morphine infusion in 53 patients. *J Neurosurg.* 1990;72(2):200-209. doi:10.3171/jns.1990.72.2.0200

13. Gilmer-Hill HS, Boggan JE, Smith KA, Frey CF, Wagner FC, Hein LJ. Intrathecal morphine delivered via subcutaneous pump for intractable pain in pancreatic cancer. *Surg Neurol.* 1999;51(1):6-11.

14. Smith TJ, Staats PS, Deer T, et al. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. *J Clin Oncol.* 2002;20(19):4040-4049. doi:10.1200/JCO.2002.02.118

15. Rauck RL, Cherry D, Boyer MF, Kosek P, Dunn J, Alo K. Long-term intrathecal opioid therapy with a patient-activated, implanted delivery system for the treatment of refractory cancer pain. *J Pain.* 2003;4(8):441-447.

16. Smith TJ, Coyne PJ. Implantable drug delivery systems (IDDS) after failure of comprehensive medical management (CMM) can palliate symptoms in the most refractory cancer pain patients. *J Palliat Med.* 2005;8(4):736-742. doi:10.1089/jpm.2005.8.736

17. Mercadante S, Intravaia G, Villari P, et al. Intrathecal treatment in cancer patients unresponsive to multiple trials of systemic opioids. *Clin J Pain.* 2007;23(9):793-798. doi:10.1097/AJP.0b013e3181565d17

18. Dupouiron D, Lefebvre-kuntz D, Brenet O, et al. Douleur chronique cancéreuse et analgésie intrathécale : expérience de trois centres de lutte contre le cancer. *Douleurs.* 2011;12(3):140-146.

19. Brogan SE, Winter NB. Patient-controlled intrathecal analgesia for the management of breakthrough cancer pain: a retrospective review and commentary. *Pain Med.* 2011;12(12):1758-1768. doi:10.1111/j.1526-4637.2011.01262.x

20. Brogan SE, Winter NB, Okifuji A. Prospective Observational Study of Patient-Controlled Intrathecal Analgesia: Impact on Cancer-Associated Symptoms, Breakthrough Pain Control, and Patient Satisfaction. *Reg Anesth Pain Med.* 2015;40(4):369-375. doi:10.1097/AAP.0000000000000251

21. Mitchell A, McGhie J, Owen M, McGinn G. Audit of intrathecal drug delivery for patients with difficult-to-control cancer pain shows a sustained reduction in pain severity scores over a 6-month period. *Palliat Med.* 2015;29(6):554-563. doi:10.1177/0269216315570514

22. Liu H-J, Li W-Y, Chen H-F, Cheng Z-Q, Jin Y. Long-Term Intrathecal Analgesia With a Wireless Analgesia Pump System in the Home Care of Patients With Advanced Cancer. *Am J Hosp Palliat Care.* 2017;34(2):148-153. doi:10.1177/1049909115615110

23. Zheng S, He L, Yang X, Li X, Yang Z. Evaluation of intrathecal drug delivery system for intractable pain in advanced malignancies: A prospective cohort study. *Medicine (Baltimore).* 2017;96(11):e6354. doi:10.1097/MD.0000000000006354

24. Sayed D, Monroe F, Orr WN, et al. Retrospective Analysis of Intrathecal Drug Delivery: Outcomes, Efficacy, and Risk for Cancer-Related Pain at a High Volume Academic Medical Center. *Neuromodulation.* 2018;21(7):660-664. doi:10.1111/ner.12759

25. Yi S-Q, Miwa K, Ohta T, et al. Innervation of the pancreas from the perspective of perineural invasion of pancreatic cancer. *Pancreas.* 2003;27(3):225-229.

26. Dang C, Zhang Y, Ma Q, Shimahara Y. Expression of nerve growth factor receptors is correlated with progression and prognosis of human pancreatic cancer. *J Gastroenterol Hepatol.* 2006;21(5):850-858. doi:10.1111/j.1440-1746.2006.04074.x

27. Wang K, Demir IE, D'Haese JG, et al. The neurotrophic factor neurturin contributes toward an aggressive cancer cell phenotype, neuropathic pain and neuronal plasticity in pancreatic cancer. *Carcinogenesis.* 2014;35(1):103-113. doi:10.1093/carcin/bgt312

28. Yao J, Li W-Y, Li S-G, Feng X-S, Gao S-G. Midkine promotes perineural invasion in human pancreatic cancer. *World J Gastroenterol.* 2014;20(11):3018-3024. doi:10.3748/wjg.v20.i11.3018

29. Yao J, Li W-Y, Gao S-G. The advances of Midkine with peripheral invasion in pancreatic cancer. *Am J Cancer Res.* 2015;5(9):2912-2917.

30. Zhang Y, Dang C, Ma Q, Shimahara Y. Expression of nerve growth factor receptors and their prognostic value in human pancreatic cancer. *Oncol Rep.* 2005;14(1):161-171.

31. Ohhashi S, Ohuchida K, Mizumoto K, et al. Midkine mRNA is overexpressed in pancreatic cancer. *Dig Dis Sci.* 2009;54(4):811-815. doi:10.1007/s10620-008-0434-4

32. Shah A, Fehmi A, Savides TJ. Increased rates of duodenal obstruction in pancreatic cancer patients receiving modern medical management. *Dig Dis Sci.* 2014;59(9):2294-2298. doi:10.1007/s10620-014-3170-y

33. Mekaroonkamol P, Willingham FF, Chawla S. Endoscopic management of pain in pancreatic cancer.

JOP. 2015;16(1):33-40. doi:10.6092/1590-8577/2890 34. Gao F, Ma S, Zhang N, Zhang Y, Ai M, Wang B. Clinical efficacy of endoscopic pancreatic drainage for pain relief with malignant pancreatic duct obstruction. *Asian Pac J Cancer Prev*. 2014;15(16):6823-6827. 35. Maire F, Sauvanet A. Palliation of biliary and duodenal obstruction in patients with unresectable pancreatic cancer: endoscopy or surgery? *J Visc Surg*. 2013;150(3 Suppl):S27-31. doi:10.1016/j.jviscsurg.2013.03.005 36. Botwinick IC, Pursell L, Yu G, Cooper T, Mann JJ, Chabot JA. A biological basis for depression in pancreatic cancer. *HPB (Oxford)*. 2014;16(8):740-743. doi:10.1111/hpb.12201 37. Barnes AF, Yeo TP, Leiby B, Kay A, Winter JM. Pancreatic Cancer-Associated Depression: A Case Report and Review of the Literature. *Pancreas*. 2018;47(9):1065-1077. doi:10.1097/MPA.0000000000001148 38. Pop V-V, Seicean A, Lupan I, Samasca G, Burz C-C. IL-6 roles - Molecular pathway and clinical implication in pancreatic cancer - A systemic review. *Immunol Lett*. 2017;181:45-50. doi:10.1016/j.imlet.2016.11.010 39. Akizuki N, Shimizu K, Asai M, et al. Prevalence and predictive factors of depression and anxiety in patients with pancreatic cancer: a longitudinal study. *Jpn J Clin Oncol*. 2016;46(1):71-77. doi:10.1093/jjco/hyv169 40. Peixoto RD, Speers C, McGahan CE, Renouf DJ, Schaeffer DF, Kennecke HF. Prognostic factors and sites of metastasis in unresectable locally advanced pancreatic cancer. *Cancer Med*. 2015;4(8):1171-1177. doi:10.1002/cam4.459 41. Shi H, Li J, Fu D. Process of hepatic metastasis from pancreatic cancer: biology with clinical significance. *J Cancer Res Clin Oncol*. 2016;142(6):1137-1161. doi:10.1007/s00432-015-2024-0

**Keywords:** Pain Management, Prevalence, Intrathecal Implantable Drug Delivery System, Cancer Pain, Pancreatic Neoplasm, Pain

**Topic:** 09. Gastrointestinal and Colorectal Disorders

## TREATMENT OF CHRONIC PANCREATITIS WITH 10 KHZ SPINAL CORD STIMULATION

### E-POSTER VIEWING

Mark Jackson

Pain Management, Royal Devon and Exeter hospital, Exeter, United Kingdom

**Introduction:** Chronic abdominal pain (CAP) has a significant clinical impact and represents one of the most frequent and debilitating disorders in the general population. Despite the availability of therapeutic treatment options, the management of patients with CAP is often inadequate<sup>1,2</sup>. It represents a major challenge for health care professionals and usually necessitates the patient encountering a range of medical and surgical specialists, resulting in a variety of interventions<sup>3</sup>. This case study demonstrates a safe and effective treatment option for chronic pancreatitis utilizing 10 kHz spinal cord stimulation (SCS).

**Methods/Materials:** The patient presented with a diagnosis of chronic pancreatitis (CP) and CAP since 2005 with past medical history of left middle cerebral artery stroke and atrial flutter. Several interventions including partial pancreatectomy/splenectomy, conventional medical management, celiac plexus and splanchnic blocks and lidocaine infusions were made but no sustained pain relief was achieved. The patient was then considered for an SCS trial. The trial was performed using 2 percutaneous electrodes spanning T4-T8 with 10 kHz SCS for 10 days. After a successful trial period the patient was implanted using 2 percutaneous electrodes spanning T4-T8 connected to a 10 kHz implantable pulse generator (IPG). Post-IPG implant outcome reviews have been completed at 3 and 6 months. Twelve month follow-up will be completed when subject reaches that timepoint.

**Results:** During the trial period, an overall pain reduction of 95% with a decrease on the Numerical Rating Scale (NRS) from 10 to 0 was achieved. This level of pain relief was sustained at 3 and 6 months, where an overall pain reduction of 100% and an NRS of 0 were reported. Brief Pain Inventory (BPI) pain intensity and pain interference scores, Oswestry Disability Index (ODI), EQ-5D-5L and Hospital Depression Anxiety Scale (HADS) were also recorded (Table 1)

*Table 1 - Pain, disability, QoL and anxiety and depression scores at 3- and 6-months post IPG implant.*

	Baseline	3 months	6 months
<b>NRS</b>	10	0	0
<b>% Pain Relief</b>	-	100%	100%
<b>ODI</b>	42%	4%	6%
<b>EQ-5D-5L</b>	0.012	1.000	0.837
<b>BPI - Pain intensity</b>	6	0	0
<b>BPI - Pain interference</b>	9.71	0	0
<b>HADS-A</b>	11	0	0
<b>HADS-D</b>	10	0	0

**Discussion:** Chronic Pancreatitis is a challenging pain aetiology to treat. However, 10 kHz SCS has demonstrated significant pain reduction, improved quality of life and psychological improvements in a recently published study<sup>4</sup>.

**Conclusions:** Results suggest that 10 kHz SCS may be an effective treatment option for Chronic Pancreatitis.

**References:** 1.Patrizi F et al. Novel Therapeutic Approaches to the Treatment of Chronic Abdominal Visceral Pain. 2006. 2.Bornman PC, Beckingham IJ. ABC of diseases of liver, pancreas and biliary system. Chronic pancreatitis. 2001. 3.Goulden, M. The pain of chronic pancreatitis: a persistent clinical challenge. BJP. 2013. 4.Kapur L et al. Treatment of Chronic Abdominal Pain With 10-kHz Spinal Cord Stimulation: Safety and Efficacy Results From a 12-Month Prospective, Multicenter, Feasibility Study. Clinical and Translational Gastroenterology. 2020

**Keyword:** Chronic abdominal pain, chronic pancreatitis, 10 kHz SCS, pain reduction

**Topic:** 09. *Gastrointestinal and Colorectal Disorders*

## **WIRELESS SPINAL CORD STIMULATION FOR THE TREATMENT OF CHRONIC ABDOMINAL PAIN AS A RESULT OF ARTERIA MESENTERICA SYNDROME**

### **E-POSTER VIEWING**

Daniel Herschkowitz

Pain, Facharzt Anästhesie FMH/Notarzt SGNOR, Bern, Switzerland

**Introduction:** A 48-year old male presented with mesenterica syndrome and consecutive abdominal surgeries. These included laparoscopy and laparotomy. The patient reported constant pain in the upper abdomen with pain scores of 8. As a result he was taking high opioid dosages (Palexia Thapentalol 400-600 mg per day) and was not able to go to work. Other therapies tried were physiotherapy and thoracic peridural infiltration under fluoroscopy with the catheter at T8/9. Good results were noted with Naropin 0.75% (Ropivacain, 10 ml).

**Methods/Materials:** The permanent implant procedure was done under light sedation, with local anesthesia and in supine position. A stab incision was made for needle incision paramedian at T10/11. A Tuohy needle was advanced into the dorsal epidural space with a shallow angle to direct the needle cranially. Placement of the needle was confirmed using fluoroscopy. An octrode electrode arrays was inserted and directed towards T4/5 anatomical midline. After functional verification of the system, the needles were removed while holding the stimulator in place. Stimulators were secured using an injectable anchor.

**Results:** One hour after activation of the system, the patient was able to report a significant difference. Pain scores at 6 months with stimulation were 3 compared to 8 without stimulation. Due to his pain relief subject noticed an improvement in quality of life and felt less depressed. As a result he was able to go to work again. Self-reported improvement was a 7 out of 7 with the patient global impression of change scale. Medication was reduced with more than 50% and quality of sleep improved drastically. The patient reported neither adverse events nor side effects.

**Discussion:** Chronic abdominal pain has been difficult to treat. The use of a wireless SCS to treat ischemic abdominal pain significantly improved this patient's quality of life.

**Conclusions:** Wireless spinal cord simulation was a successful option for this patient suffering of debilitating abdominal pain due to arteria mesenterica syndrom. This experience hints at advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator and flexibility as related to device placement and programming protocols.

### **References:**

**Keyword:** wireless stimulation, abdominal pain



**Topic:** 09. *Gastrointestinal and Colorectal Disorders*

## **CAN RESPONDERS TO HOSPITAL PTNS TRANSITION TO HOME TTNS ?**

### **E-POSTER VIEWING**

Dave Chatoor<sup>1</sup>, Ainhoa Echeverria<sup>2</sup>, Humayra Abdul-Razak<sup>3</sup>, Kalp Patel<sup>3</sup>, Ashish Shetty<sup>4</sup>, Anton Emmanuel<sup>2</sup>, Sohier Elneil<sup>5</sup>, Mike Cummings<sup>6</sup>

<sup>1</sup>Colorectal Surgery, University College London, London, United Kingdom, <sup>2</sup>Gastroenterology, University College London Hospital, London, United Kingdom, <sup>3</sup>Neurogastroenterology, University College London Hospital, London, United Kingdom, <sup>4</sup>Pain Management Centre At Nhhn, University College London Hospital, London, United Kingdom, <sup>5</sup>Urogynaecology, University College London Hospital, London, United Kingdom, <sup>6</sup>Integrated Medicine, Royal London Hospital for Integrated Medicine, LONDON,, United Kingdom

**Introduction:** Posterior Tibial Nerve Stimulation (PTNS) was introduced in UCLH 10 years ago, since then we had approximately 1000 patients referred, with a success rate (RR50) of 70% for Faecal Incontinence (FI). Since its introduction we have had less reliance on invasive sacral neuromodulation. With a growing cohort requiring maintenance PTNS in hospital, we offered patients an alternative home therapy called Transcutaneous Tibial Nerve Stimulation (TTNS). Advantages include fewer trips to hospital, less reliance on hospital therapy and encouraging self-management. The success rate of PTNS is 63 - 82% and TTNS is 59 -77%. We report our two year experience of TTNS for FI.

**Methods/Materials:** Between February 2018 and February 2020 we had 137 patients referred for TTNS treatment of faecal incontinence (FI). Some were responding to PTNS already and wanted to have a home based therapy. Some were new to neuromodulation. Both PTNS (Urgent PC device) and TTNS (NeuroTrac device) elicited the same physical responses : tingling along the lateral border of the foot, flexing of the first toe and splaying of the toes. Success was measured by the RR50 as a composite improvement measure utilising a reduction in 50% incontinent episodes (Wexner Score) and subjective improvement (VAS + Rockwood QoL Scores).

**Results:** 137 patients were referred for TTNS, 50 patients completed the 12 week induction and were suitable for analysis. Altogether 35 patients (70%) were responders to PTNS, 30 of these (60% : 18female,12male) transitioned successfully to TTNS. The RR50 of both therapies were similar. The remaining 5 patients (10% : 4female,1male) did not respond to TTNS and reverted to PTNS. 6 patients (12%) responded to first time neuromodulation with TTNS and are on maintenance therapy at home. The last 9 patients (18%) had no benefit from TTNS, and went onto PTNS but this failed too, this parallels the 20% failure rate of SacralNeuromodulation.

**Discussion:**

Suitability , Cost, Exclusions	SNS	PTNS	TTNS
Faecal Incontinence (Urge more than passive and any severity)	✓	✓	✓
<b>Practical reasons</b> Need for MRI	<b>X</b> (Current device – Brain only, Newer devices - MRI conditional )	✓	✓
Needle Phobia	✓	x	✓
Living Far	✓	x	✓
Need for regular Maintenance	✓	x	✓
<b>Works less well</b> Uncontrolled Diarrhoea	x	x	x
Rectal Prolapse	x	x	x
Constipation	x	x	x
Evacuation difficulty	x	x	x
<b>Does not work</b> Cord Transection	x	x	x
<b>Cost of Equipment</b>	£ 11,000	£ 1363	£ 80
<b>Efficacy</b>	61 % -100 %	63 % - 82 %	59 % - 77 %

Our results support the theory that both modes of neuromodulation may have a similar end effect and efficacy . This is a non-randomized study with small numbers but translates into real life practice. Patients should be given the choice of home or hospital therapy with the merits and drawbacks of both, in the context of increasing burden on NHS services.

**Conclusions:** 72% (36/50) were RR50 responders to TTNS 86% (30/35) who responded to PTNS successfully transitioned to home TTNS TTNS is more cost effective (PTNS £1363 vs TTNS £80)  
Non-responders to TTNS also failed to respond to PTNS

**References:**

**Keyword:** TTNS, PTNS, Faecal Incontinence

**Topic:** 09. *Gastrointestinal and Colorectal Disorders*

## **MONITORING PERFORMANCE OF GASTRIC ELECTRICAL SYSTEMS IN A REAL-WORLD POPULATION: THE PRODUCT SURVEILLANCE REGISTRY**

### **E-POSTER VIEWING**

Paul Glen<sup>1</sup>, Sri Kadirkamanathan<sup>2</sup>, Jutta Keller<sup>3</sup>, Debra Edmond<sup>4</sup>

<sup>1</sup>General Surgery, Queen Elizabeth University Hospital, Glasgow, United Kingdom, <sup>2</sup>General Surgery, Mid Essex Hospital Trust, Maldon, United Kingdom, <sup>3</sup>Internal Medicine, Israelitisches Krankenhaus, Hamburg, Germany, <sup>4</sup>Corporate Clinical Affairs, Medtronic, Minneapolis, United States of America

**Introduction:** Gastric Electrical Stimulation (GES) through Enterra device therapy has been shown to be a safe and effective treatment for chronic, intractable nausea and vomiting associated with gastroparesis of diabetic or idiopathic etiology. To continually monitor safety and performance of this therapy, a registry was developed to prospectively track performance and outcomes data in real-world settings.

**Methods/Materials:** The Product Surveillance Registry (PSR) is a prospective, non-randomized, multi-center global registry originated for GES therapy in April 2018. The PSR enrolls therapy naïve patients that are followed prospectively for at least five years for safety events related to the device, procedure, or therapy. The PSR also includes a performance objective to collect patient-reported Global Clinical Response (GCR) regarding overall relief of symptoms through the duration of therapy. Analysis of GCR data will occur after a sample size of 50 patients have been followed for a minimum of six months.

**Results:** As of January 31, 2021, two centers in the United Kingdom and one center in Germany have enrolled 37 GES patients in the registry, of which 40.5% were male and 59.5% were female. The treatment indications were diabetic gastroparesis (59.5%), idiopathic gastroparesis (35.1%) and other (5.4%). The prospective aggregate follow-up time for enrolled patients was 35.7 years (428.4 months). There have been a total of two adverse events and one device deficiency reported. Over this time period, there have been no reported patient deaths.

**Discussion:** The PSR prospectively captures valuable real-world information. This information is used to monitor safety and guide future product development efforts aimed at improving product reliability and quality. In addition, data from the registry provide information about the treatment practices of physicians using therapies. As clinical practice evolves over time, the registry is continually adapted to provide meaningful data and insights into clinical outcomes and product performance related to GES therapy. Additional results will be shared in future meetings once the defined samples size and follow-up period are met.

**Conclusions:** Previous publication of outcomes for patients treated by GES have been single centre cohorts with shorter follow up. We wish to declare an intent to publish outcomes from a multicentre, prospective registry that will inform on real-world practice and outcomes.

### **References:**

**Keywords:** Enterra, product surveillance registry, gastroparesis

**Topic:** 09. *Gastrointestinal and Colorectal Disorders*

## **SPINAL CORD STIMULATION (SCS) AS POTENTIAL TREATMENT OF CROHN'S DISEASE.**

### **E-POSTER VIEWING**

Efstathios Vlachakis, Athanasia Alexoudi, Stefanos Korfias, Stamatis Banos, Christina Zournatzidou, Damianos Sakas  
Neurosurgery, 1st Department of Neurosurgery, National and Kapodistrian University of Athens, "Evangelismos" General Hospital, Athens, Greece

**Introduction:** We present the remission of symptoms of Crohn's disease, exploiting the therapeutic potential of spinal cord stimulation (SCS) implantation, which was primary used for the relief of low back pain in a young patient.

**Methods/Materials:** Three years after L5-S1 level laminectomy performed in 2008, a 31years-old man with a history of Crohn's disease from 2014, gradually developed refractory low back pain and lower limbs pain with L5-S1 nerve root distribution. As a result of abnormal posture, the pain was reflected to the neck. The pain was rated as 9/10 in VAS without medication and 6/10 with analgesic medication, respectively. The patient who was treated with adalimumab for Crohn's disease, also suffered from chronic abdominal pain, cramping of the right lower quadrant and diarrhea. He was scored 75 in the IBDQ<sup>1</sup> (inflammatory bowel disease questionnaire).

**Results:** Following a percutaneous stimulation trial, the patient underwent in a permanent implantation of two leads at TH6-TH10 level, achieving 100% regional coverage of the affected area (VAS 0/10). After 6-months of follow-up, with persistent stimulation, the patient is pain-free without episodes of pain exacerbation and total remission of the symptoms of the inflammatory bowel disease, rating 211 in IBDQ. There is absence of analgesic medication, and his abdominal symptoms do not affect his daily life. He is very satisfied and feels that SCS has led to a spectacular quality improvement of his life.

**Discussion:** Anti-inflammatory effects of SCS have been suggested. Therefore, SCS seems to have therapeutic potential for inflammatory bowel disease (IBD). The sacral nerve directly innervates the colon providing a promising option in the treatment of IBD, besides conventional treatments.

**Conclusions:** SCS is a minimally invasive method and appears as a new programming modality in the treatment of inflammatory bowel disease, which could make conventional medical therapy more effective. Future studies of SCS with long-term follow-up, using global patient registries are needed to determine its efficacy and durability.

**References:** 1. Irvine EJ. Development and subsequent refinement of the inflammatory bowel disease questionnaire: a quality-of-life instrument for adult patients with inflammatory bowel disease. *J Pediatr Gastroenterol Nutr.* 1999;28:S23-7. CrossRef

**Keyword:** Spinal cord stimulation (SCS), Crohn's disease, Inflammatory bowel disease (IBD).

**Topic:** 10. Genitourinary Disorders

**FACTORS AFFECTING PATIENTS' DECISION ON SACRAL NEUROMODULATION IN KUWAIT LEADING TO ESTABLISHMENT OF A MULTI-STEP APPROACH FOR COUNSELING THESE PATIENTS**

**E-POSTER VIEWING**

Tariq Al-Shaiji, Majd Alkabbani, Ahmed El-Nahas, Meshari Almutairi, Talal Alenezi, Abdullatif Al-Terki  
Urology Unit, Al-Amiri Hospital, Kuwait City, Kuwait

**Introduction:** Sacral neuromodulation (SNM) has been proven to be a safe and reversible procedure with good long-term outcomes. However, counseling patients can be challenging, as it is a new, unique procedure. This survey was conducted to study factors that affect patients' decision toward SNM and their worries before they undergo the procedure. The results were used to design a multi-step approach to counsel patients planned to undergo this procedure.

**Methods/Materials:** All patients who underwent SNM in Kuwait from 2012 until April 2020 have been contacted to participate in the study. A survey was produced to study the socioeconomic characters of the patients, factors that affect their decision on SNM, their worries and perceptions about SNM, the adherence to our multi-step approach in counseling them prior to the procedure, and finally their subjective improvement post implantation.

**Results:** The study included 30 patients out of 34 who underwent SNM with mean age  $41.4 \pm 16.8$  years. The indications for SNM were wet overactive bladder (OAB) (36.7%), idiopathic urinary retention (33.3%), Fowler's syndrome, dry OAB, and neurogenic urinary retention (10%). After the first counseling meeting, 46.7% of the patients agreed immediately to undergo the procedure. Eighty percent of the patients who searched for SNM in the internet, did not find adequate information in Arabic language. The most convincing factor was the counseling meeting with the surgeon, followed by the manufacturing company brochure. The most reported worries regarding SNM were limitation of the physical activity (53.3%) and worries about security check points with metal detectors (40%). The mean percentage of improvement described by the patients was  $72.5 \pm 24.7\%$ . Most of the patients were satisfied with the results as 90% will recommend SNM to others and 86.7% will do the same procedure again for treatment.

**Discussion:** According to the data analyzed, the multi-step approach was designed to start with an initial meeting with the surgeon followed by handing the company brochure, then asking the patient to contact one of our patients who underwent SNM. The 4<sup>th</sup> step is a meeting with the programmer to explain the process of the follow up visits. The approach is concluded by a final meeting with the surgeon to review all the previous steps and answer any other enquiries.

**Conclusions:** A multi-step approach in counseling patients before SNM, improves the quality of their decision and addresses many worries and false perceptions that were commonly found in majority of the patients.

**References:** 1- Tanagho EA, Schmidt RA, Orvis BR. Neural stimulation for control of voiding dysfunction: a preliminary report in 22 patients with serious neuropathic voiding disorders. *J Urol*. 1989 Aug;142(2 Pt 1):340-5. doi: 10.1016/s0022-5347(17)38751-7. PMID: 2787411. 2- Tahseen S. Role of sacral neuromodulation in modern urogynaecology practice: a review of recent literature. *Int Urogynecol J*. 2018 Aug;29(8):1081-1091. doi: 10.1007/s00192-017-3546-6. Epub 2018 Jan 4. PMID: 29302716. 3- Noblett K, Siegel S, Mangel J, Griebing TL, Sutherland SE, Bird ET, Comiter C, Culkin D, Bennett J, Zylstra S, Kan F, Berg KC. Results of a prospective, multicenter study evaluating quality of life, safety, and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder. *Neurourol Urodyn*. 2016 Feb;35(2):246-51. doi: 10.1002/nau.22707. Epub 2014 Dec 24. PMID: 25546568. 4- Al-Shaiji TF, Malallah MA, Yaiesh SM, Al-Terki AE, Hassouna MM. Does Psychological Disturbance Predict Explantation in Successful Pelvic Neuromodulation Treatment for

Bladder Dysfunction? A Short Series. *Neuromodulation*. 2018 Dec;21(8):805-808. doi: 10.1111/ner.12745. Epub 2017 Dec 19. PMID: 29265565. 5- van Ophoven A, Engelberg S, Lilley H, Sievert KD. Systematic Literature Review and Meta-Analysis of Sacral Neuromodulation (SNM) in Patients with Neurogenic Lower Urinary Tract Dysfunction (nLUTD): Over 20 Years' Experience and Future Directions. *Adv Ther*. 2021 Apr;38(4):1987-2006. doi: 10.1007/s12325-021-01650-9. Epub 2021 Mar 13. PMID: 33713279; PMCID: PMC8004509.

**Keyword:** Sacral neuromodulation, pelvic floor disorders, Neurology, Counseling

**Topic:** 10. Genitourinary Disorders

**EPIDURAL ELECTRICAL STIMULATION IN A COMPLETE SPINAL CORD INJURY PATIENT: STUDY ON AUTONOMIC FUNCTIONS**

**E-POSTER VIEWING**

Alessandro Dario<sup>1</sup>, Franco Molteni<sup>2</sup>, Elena Guanzioli<sup>2</sup>, Maurizio Cazzaniga<sup>3</sup>

<sup>1</sup>Insubria University Neurosurgery Clinic, ASST Settelaghi, Varese, Italy, <sup>2</sup>Rehabilitation Center, Valduce Hospital "Villa Beretta", Costa Masnaga, Italy, <sup>3</sup>Rehabilitation Center, Valduce Hospital "Villa Beretta", Varese, Italy

**Introduction:** Epidural electrical stimulation (EES) is a technique described since 1967 used to treat chronic pain in spinal cord lesion (1). The EES also represents one possible strategy to stimulate the pathways disrupted by the injury (2). A proper setting of epidural electrical stimulation can improve voiding efficiency, influence detrusor contraction strength and external urethral sphincter relaxation (3).

**Methods/Materials:** Due to pain syndrome and dysesthesia at lower limbs in a patient with a paraplegia from vertebro medullary trauma at D5-D6, a 16-electrode array was implanted 4 years after the acute event. The array was placed on the dorsal epidural surface of the dorso-lumbar spinal cord (vertebrae T11–L1) as suggested by Literature (4) ; the electrode lead was tunneled subcutaneously and connected to the pulse generator placed in left dorsal part at abdominal level. After to start to use the EES system for pain control, the patient underwent 36 locomotor over-ground training sessions using a powered wearable robotic exoskeleton (3 times per week for 12 weeks). Videourodynamic evaluations was performed according to recommendations from the International Continence Society (5).

**Results:** Bladder evaluation was performed with the EES off and bladder pressure during the filling with H<sub>2</sub>O is The maximun pressure value is 12.22 cmH<sub>2</sub>O reached with a volume of 400ml of H<sub>2</sub>O in the bladder. The effect of different current amplitude, with F=40 Hz and Pulse width= 210 µs on bladder filled with 400 ml of water was reported. A current of 5 mA is able to produce an intravesical pressure of 10.61 cmH<sub>2</sub>O, while a current of 10 mA produce on increase in intravesical pressure until 25.65 cmH<sub>2</sub>O.

**Discussion:** In our study, we investigated the effect of EES on bladder control and we performed videourodynamic evaluation with EES off and with EES on with two different current intensities, 5 mA and 10 mA; we tested also the EES effect on bladder pressure with a volume of 400 ml of H<sub>2</sub>O. No high intravesical pressure was recorded in all conditions considered indicating that EES excites the spinal cord circuitry without increasing bladder pressure.

**Conclusions:** EES configuration identified to improve motor pattern was able to modulate autonomic nervous system. Further study are necessary to investigate the long term effect of EES to understand if a long training of EES can improve voiding efficiency

**References:** 1.Shealy, C.N., Mortimer, J.T., and Reswick, J.B. Electrical inhibition of pain by stimulation of the dorsal columns: preliminary clinical report. *Anesth Analg* 1967;46:489–491. 2.Martin, J. H. Harnessing neural activity to promote repair of the damaged corticospinal system after spinal cord injury. *Neural Regen Res* 2016;11:1389–13913. 3.Herrity AN, Williams CS, Angeli CA, Harkema SJ, Hubscher CH. Lumbosacral spinal cord epidural stimulation improves voiding function after human spinal cord injury. *Sci Rep* 2018 6;8(1):8688.doi: 10.1038/s41598-018-26602-2. 4.Wagner FB, Mignardot JB, Le Goff-Mignardot CG, et al.Targeted neurotechnology restores walking in humans with spinal cord injury. *Nature* 2018 ;563:65-71. 5.Winters, J. C. et al. Urodynamic studies in adults: AUA/SUFU guideline. *J Urology* 2012 ; 188, 2464–2472, <https://doi.org/10.1016/j.juro.2012.09.081>

**Keyword:** paraplegia - epidural electrical stimulation - voiding symptoms - pain - exoskeleton - electrode



**Topic:** 11. *Non- and Less-Invasive Brain Stimulation*

## **EFFECTS OF BIFRONTAL TRANSCRANIAL DIRECT CURRENT STIMULATION ON FATIGUE IN MULTIPLE SCLEROSIS**

### **E-POSTER VIEWING**

Moussa Antoine Chalah<sup>1</sup>, Christina Grigorescu<sup>2</sup>, Ulrich Palm<sup>2</sup>, Samar S. Ayache<sup>1</sup>

<sup>1</sup>Service De Physiologie - Explorations Fonctionnelles, Hôpital Henri Mondor, Assistance Publique - Hôpitaux De Paris, EA 4391, Excitabilité Nerveuse et Thérapeutique, Université Paris-Est-Créteil, Créteil, France, Créteil, France, <sup>2</sup>Dept. Of Psychiatry And Psychotherapy, Klinikum der Universität München, Munich, Germany

**Introduction:** In the context of multiple sclerosis (MS), 75-90% suffer from fatigue at some point during their lifetime. Available anti-fatigue treatments are limited to a few pharmacological interventions that are partially effective and usually responsible for annoying side effects. In addition, fatigue, depression and anxiety tend to coexist in MS patients and further increase the burden of the disease (Ayache & Chalah, 2019). Transcranial direct current stimulation (tDCS) has been recently investigated in the management of these symptoms (Ayache & Chalah, 2018), and thus assessing the effects of this intervention constitutes the main aim of this work.

**Methods/Materials:** Eleven MS patients suffering from fatigue for at least 6 months were recruited. They randomly received in a crossover manner two blocks of tDCS, active and sham, separated by a three-week wash out interval. Each block was constituted of 5 daily sessions (2mA, 20min, anode over the left dorsolateral prefrontal cortex, cathode contralaterally). Assessment of fatigue, depression and anxiety took place at day 1 and day 5 of each block, and one week later.

**Results:** Following active condition, significant improvement of fatigue was observed at day 5 and these anti-fatigue effects lasted at least one week after the last session. Significant amelioration of anxiety symptoms was also shown but seemed to be delayed, appearing one week after the end of the active block. Concerning depression rating, no significant effect was found.

**Discussion:** Bifrontal tDCS led to a significant amelioration of fatigue and anxiety in patients with MS. Absence of depression improvement might be attributed to the small sample size, or to the short duration of the stimulation protocol as depression studies mostly report an effect after two weeks of stimulation. This needs to be addressed in future large-scale studies.

**Conclusions:** Bifrontal tDCS seems to have a place in the treatment of MS related fatigue and could also have an impact on anxiety.

**References:** Ayache SS, Chalah MA. Transcranial direct current stimulation: A glimmer of hope for multiple sclerosis fatigue?. J Clin Neurosci. 2018;55:10–12. Ayache SS, Chalah MA. Fatigue and Affective Manifestations in Multiple Sclerosis-A Cluster Approach. Brain Sci. 2019; 10:E10.

**Keyword:** Multiple sclerosis; tDCS; transcranial direct current stimulation; fatigue; anxiety; depression

**Topic:** 11. *Non- and Less-Invasive Brain Stimulation*

## **TRANSCRANIAL MAGNETIC STIMULATION FOR MANAGEMENT OF CHRONIC PAIN AND RELATED SYMPTOMS IN FIBROMYALGIA SYNDROME**

### **E-POSTER VIEWING**

Suman Tanwar<sup>1,2</sup>, Bhawna Mattoo<sup>3</sup>, Uma Kumar<sup>4</sup>, Renu Bhatia<sup>3</sup>

<sup>1</sup>Department Of Zoology, Govt. College for Girls, Gurugram-Haryana, India, <sup>2</sup>Physiology, All India Institute of Medical Sciences, New Delhi, India, <sup>3</sup>Physiology, All India Institute of Medical Sciences New Delhi, Delhi, India, <sup>4</sup>Rheumatology, All India Institute of Medical Sciences New Delhi, Delhi, India

**Introduction:** The fibromyalgia syndrome (FMS) is characterized by widespread, chronic musculoskeletal pain, fatigue, depression, unrefreshed sleep and psychological distress. The pathophysiology of FMS is not completely understood. The available methods for managing these kinds of disorders are of limited success. Repetitive transcranial magnetic stimulation (rTMS) has been shown to effectively treat depression, and its potential role in pain management is also highlighted by many studies. Therefore, the aim was to study the effects of repetitive transcranial magnetic stimulation (rTMS), applied over the right dorsolateral prefrontal cortex (DLPFC), on pain and pain related symptoms in fibromyalgia patients.

**Methods/Materials:** Participants were recruited from Department of Rheumatology AIIMS; after obtaining ethical approval (Ref No: IESC/T-251/15.06.2013) from the Institute Ethics Committee, All India Institute of Medical Sciences (AIIMS), New Delhi, India. The study was also registered in ICMR-CTRI; India (Ref No: CTRI/2013/12/004228). Ninety with FMS received allocated intervention (Real rTMS; n=45 and Sham rTMS; n=45). Real rTMS group received 1 Hz rTMS, for 20 sessions i.e. 5 consecutive days/week for 4 weeks. Second group was treated with sham rTMS (coil similar in shape, size and producing same sound as created by magnetic stimulation coil but without real stimulation). Pain and related symptoms were assessed with Numerical Pain Rating Scale (NPRS), McGill Pain Questionnaire (MPQ), Hamilton depression rating scale (HDRS) and Hamilton anxiety rating scale (HARS) respectively. Objective assessment of pain was done by recording nociceptive flexion reflex (NFR). To record NFR, sural nerve was stimulated at its retro-malleolar path and the surface EMG activity was recorded at the short head of biceps femoris muscle. All parameters were assessed before and after 4 weeks of Real-rTMS and Sham-rTMS. Patients were followed up after 15-days and 3 months post-rTMS.

**Results:** After completion of four weeks of rTMS, the average ratings for NPRS (0.001), MPQ (p=0.001), HDRS (p=0.001) as well as HARS (p=0.001) decreased significantly from baseline in Real-rTMS group as compared to Sham-rTMS group. The NFR responses were elicited at significantly higher thresholds in Real-rTMS patients at post-rTMS as compared to their baseline values (p=0.001). The improvement in pain and associated symptoms was sustained in follow-up period also i.e. after 15-days and 3 months post-rTMS.

**Discussion:** Our findings are consistent with previous studies which reported reduced pain after rTMS and showed that rTMS better than placebo in treating FMS (1, 2, 3).

**Conclusions:** Low frequency right DLPFC rTMS can significantly reduce both chronic pain and pain related symptoms in patients with FMS.

**References:** 1. Short EB, Borckardt JJ, Anderson BS, Frohman H, Beam W, Reeves ST & George MS. Ten sessions of adjunctive left prefrontal rTMS significantly reduces fibromyalgia pain: a randomized controlled pilot study. *Pain* 2011;152(11) 2477-2484. 2. Lee SJ, Kim DY, Chun MH, Kim YG. The effect of repetitive transcranial magnetic stimulation on fibromyalgia: a randomized sham-controlled trial with 1-mo follow-up. *American journal of physical medicine & rehabilitation* 2012; 91(12) 1077-1085. 3. Tzabazis A, Aparici CM, Rowbotham MC, Schneider MB, Etkin A, Yeomans DC. Shaped magnetic field pulses by multi-coil repetitive transcranial magnetic stimulation (rTMS)

differentially modulate anterior cingulate cortex responses and pain in volunteers and fibromyalgia patients. *Molecular pain* 2013 ;9(1) 33.

**Keyword:** Fibromyalgia, Transcranial Magnetic Stimulation , Nociceptive flexion reflex

**Topic:** 11. Non- and Less-Invasive Brain Stimulation

## **EVALUATION OF THE EFFECT OF STATIONARY BICYCLE IN CONCOMITANT WITH TRANS CRANIAL DIRECT CURRENT STIMULATION (TDCS) ON GAIT IMPROVEMENT IN MULTIPLE SCLEROSIS PATIENTS**

### **E-POSTER VIEWING**

Sarvenaz Rahimibarghani

Physical Medicine & Rehabilitation, Tehran university of medical science, Tehran, Iran

**Introduction:** Multiple sclerosis (MS) is an autoimmune disease in which the myelins of the central nervous system are attacked and destroyed by the immune cells and eventually leads to the motor disability in the patient. There are numerous studies showing that aerobic activity and physical training can improve aerobic capacity, control symptoms, and rehabilitate these patients. It has also been shown that neural stimulation of the brain through tDCS is effective in rehabilitation of the upper and lower extremities. we investigated the simultaneous effects of aerobic exercise via stationary bike and tDCS on the gait improvement in multiple sclerosis patients.

**Methods/Materials:** In this randomized clinical trial, 50 MS patients referred to Imam Khomeini Hospital Rehabilitation Clinic were randomly divided into two groups of 25 experimental and 25 control groups. In the control group, the patients used stationary bicycle with a power of 30 W / min for one and a half months and two sessions per week for 30 minutes , each session with 10 min activity and 5 min interval rest. In the experimental group, in addition to the use of stationary bike with the conditions mentioned in the control group, patients were received tDCS of 1.5 mA for 20 minutes in the C3 area. Patients with definitive diagnosis were referred by a neurologist and other examinations and measures were performed by a physical medicine and rehabilitation specialist and resident.

**Results:** In this study, the response variables of 2MWT, 5mWT, TUG, FSS and MSQOL-54 were evaluated. Before intervention, no significant differences were observed between the two groups but immediately after the intervention and one month after the intervention ,The time of 5mWT and TUG was decreased in both groups ( $P < 0.05$ ). The 2MWT increased in both groups immediately and one month after intervention , which was more in the case group than in the control group ( $P < 0.05$ ). There was no significant difference between the experimental and control groups according to quality of life and fatigue severity after the intervention.

**Discussion:** that concurrent use of Trans Cranial Direct Current Stimulation with stationary bicycles can have a synergistic effect on walking speed improvement of multiple sclerosis patients compared to stationary bicycles alone.

**Conclusions:** Based on the results of this study, it can be concluded that concurrent use of Trans Cranial Direct Current Stimulation with stationary bicycles can have a synergistic effect on walking speed improvement of multiple sclerosis patients compared to stationary bicycles alone.

**References:** 1.Koen Cuypers, Daphnie J.F. Leenus, Bart Van Wijmeersch, Herbert Thijs,Oron Levinc, Stephan P. Swinnenc, Raf L.J. Meesen. Anodal tDCS increases corticospinal output and projection strength in multiple sclerosis:Neuroscience Letters 554 (2013) 151-155 . CL Barrett, GE Mann, PN Taylor and P Strike. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis: Multiple Sclerosis 2009; 15:493-504 3.LaRocca NG. Impact of walking impairment in multiple sclerosis: perspectives of patients and care partners2011;4:189–201 .4.Massimiliano Paua , Federica Coronaa , Giancarlo Cogheb , Elisabetta Marongiuc , Andrea Loic Antonio Crisafullic , Alberto Concuc , Manuela Gallid,e , Maria Giovanna Marrosub and Eleonora Coccob Quantitative assessment of the effects of 6 months of adapted physical activity on gait in people with multiple sclerosis: a randomized controlled trial DISABILITY AND REHABILITATION, 2018 VOL. 40, NO. 2, 144–151 5. Ana Sánchez-

Kuhn, Cristian Pérez-Fernández, Rosa Cánovas, Pilar Flores and Fernando Sánchez-Santed.  
Transcranial direct current stimulation as a motor neurorehabilitation tool:an empirical review  
:BioMedical Engineering OnLine201716(Suppl 1):76

**Keyword:** Multiple Sclerosis, Trans Cranial Direct Current Stimulation (tDCS) , stationary bike

**Topic:** 11. *Non- and Less-Invasive Brain Stimulation*

**DANISH EVALUATION OF MAGNETIC RESONANCE GUIDED FOCUSED ULTRASOUND TOWARDS ESSENTIAL TREMOR.**

**E-POSTER VIEWING**

Andreas Glud<sup>1,2</sup>, Rasmus Jørgensen<sup>2</sup>, Bo Bergholt<sup>2</sup>, Erik Danielsen<sup>3</sup>, Mette Møller<sup>3</sup>, Erik Johnsen<sup>3</sup>, Torben Lund<sup>4</sup>, Niels Sunde<sup>2</sup>, Jens Christian Soerensen<sup>2</sup>

<sup>1</sup>Neurosurgery, CENSE Group, Aarhus N, Denmark, <sup>2</sup>Department Of Neurosurgery, Aarhus University Hospital, Aarhus N, Denmark, <sup>3</sup>Department Of Neurology, Aarhus University Hospital, Aarhus N, Denmark, <sup>4</sup>Center Of Functionally Integrative Neuroscience (cfni), Clinical Institute - Aarhus University Hospital, Aarhus N, Denmark

**Introduction:** MR-guided focused ultrasound (MRgFUS) used to treat selected patients with essential tremor, adds to the established essential tremor treatment, with a non-invasive supplement to already known treatment modalities.

**Methods/Materials:** In this abstract, we evaluate the history of the method and treatment, and the first Danish patient experiences. Furthermore we describe essential tremor and its possible treatment modalities.

**Results:** The first Danish patient with refractory essential tremor was treated with MRgFUS in Madrid in May 2019. The patient was prior to this, assessed by the multi disciplinary movement disorder team consisting of neurosurgeons and neurologists at Aarhus University Hospital. The patient had an severe essential tremor and was due to a previous disease not suited for DBS surgery. The patient was instead referred to MRgFUS at HM Hospitales (CINAC) in Madrid, where the treatment was conducted out-house, with a good result.

**Discussion:** MRgFUS is an innovative, gentle, and precise non-invasive treatment of essential tremor, to induce a focal one-sided lesion of the VIM-nucleus in the thalamus. The treatment should be seen as a supplement to the existing and well-documented effective deep brain stimulation treatment for essential tremor.

**Conclusions:** The treatment should be at a center, where the expertise for deep brain stimulation, neuromodulation and the necessary expertise in neurology and neurosurgery exists, as well as in a clinic that has the necessary research track record and setup for undertaking this highly specialized treatment for advanced movement disorders by MRgFUS and neuromodulation. The multidisciplinary team from Department of Neuroradiology, Center of Functionally Integrative Neuroscience, Department of Neurology and Department of Neurosurgery, have after the patient case evaluated, that a MRgFUS treatment option in Denmark will optimize the already established treatment modalities.

**References:** <https://dagensmedicin.dk/mr-guidet-fokuseret-ultralysbehandling-en-ny-behandling-i-danmark/> Dagens Medicin: 27th of Nov 2019

**Keywords:** Movement disorder, MRgFUS, Non-invasive, Essential Tremor, Neurosurgery, MRI

**Topic:** 11. *Non- and Less-Invasive Brain Stimulation*

## **RIGHT DORSOLATERAL PRE FRONTAL CORTEX: AN ADEQUATE TARGET FOR PERIPHERAL COMPONENTS OF PAIN MODULATION?**

### **E-POSTER VIEWING**

Bhawna Mattoo<sup>1</sup>, Suman Tanwar<sup>1</sup>, Rohit Bhatia<sup>2</sup>, Manjari Tripathi<sup>2</sup>, Renu Bhatia<sup>1</sup>

<sup>1</sup>Physiology, All India Institute of Medical Sciences New Delhi, Delhi, India, <sup>2</sup>Neurology, All India Institute of Medical Sciences, New Delhi, India

**Introduction:** The right dorsolateral prefrontal cortex may serve as a doorway to target the pain matrix. There are many studies exploring repetitive transcranial magnetic stimulation (rTMS) over the prefrontal cortex as a substrate for pain relief. Tension-type headache is a dichotomous disease where both central and peripheral components of pain play a role. In this study, we aim to explore the effectiveness of low-frequency rTMS over the right dorsolateral prefrontal cortex in alleviating the peripheral components of pain like muscle overactivity and sterile neuroinflammatory factors like Substance P and Interleukin 1 beta in Chronic Tension-type headache.

**Methods/Materials:** Patients (n=30) diagnosed with chronic tension-type headache were recruited and randomized into real (n=15) and sham (n=15) rTMS groups. Patient pain thresholds were recorded. Surface electromyography of the trapezius and the temporalis muscles were recorded at rest and during maximum voluntary contraction. Plasma peripheral inflammatory marker levels (substance P and Interleukin 1B) were estimated using ELISA kits. All the tests were repeated after completion of the intervention. Intervention: 1Hz 1200 pulses in 8 trains consisting of 150 pulses at 110% of the resting motor threshold were given on the right dorsolateral prefrontal cortex for 20 days (5 days/week) in the real TMS group. Placebo TMS was administered in the sham group by changing the orientation of the TMS coil.

**Results:** The pain tolerance was more in the real group after therapy compared with the sham group (P=0.024). There was no significant change observed in the levels of Plasma substance P and interleukin 1 beta in both the groups after intervention. The area under the curve for surface electromyography of the temporalis and trapezius did not show any significant change in rest or during MVC.

**Discussion:** Our patients reported improvement in the real rTMS group on the pain tolerance threshold, this suggests that the right dorsolateral prefrontal cortex may be a potential target area for pain relief in CTTH. The targeted DLPFC area may have a “top-down” mode of inhibition of neuronal connections along with the ascending midbrain–thalamic–cingulate pathway through descending fibers from the prefrontal cortex. Substance P related neurogenic inflammation and nociceptor sensitization could be important in CTTH. And elevated peripheral pro-inflammatory cytokines like IL1 $\beta$  and neuropeptides may have a role in maintaining the increased peripheral inputs due to muscle overactivity causing sensitization. Although, low-frequency rTMS over the right dorsolateral prefrontal cortex does not effectively modulate this component of pain.

**Conclusions:** The right dorsolateral prefrontal cortex may not effectively modulate factors responsible for peripheral sensitization in CTTH.

### **References:**

**Keywords:** Tension-type headache, neuromodulation, Chronic headache, dorsolateral prefrontal cortex, peripheral inflammation

**Topic:** 11. *Non- and Less-Invasive Brain Stimulation*

**STANFORD ACCELERATED INTELLIGENT NEUROMODULATION THERAPY FOR TREATMENT RESISTANT DEPRESSION (SAINT-TRD): RESULTS FROM A DOUBLE-BLINDED, RANDOMIZED, AND CONTROLLED TRIAL**

**E-POSTER VIEWING**

Angela Phillips, Eleanor Cole, Brandon Bentzley, Katy Stimpson, Romina Nejad, Claudia Tischler, Alan Schatzberg, Keith Sudheimer, Nolan Williams  
Psychiatry, Stanford Medicine, Palo Alto, United States of America

**Introduction:** Data have suggested that the left dorsolateral prefrontal cortex (LDLPFC) to subgenual anterior cingulate cortex (sg-ACC) circuit may provide a more direct repetitive transcranial magnetic stimulation (rTMS) target for acute relief of depression symptoms in individuals with treatment resistant depression (TRD). In our recent study using an accelerated, high-dose, resting-state functional connectivity MRI (fcMRI)-guided iTBS protocol for treatment-resistant depression - termed 'Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT-TRD)', 19 of 21 participants (90.48%) met remission criteria (<11 on the Montgomery Asberg Depression Rating Scale (MADRS). Here, we tested whether active SAINT-TRD targeting the LDLPFC-sgACC circuit with rTMS in patients with TRD, would yield significantly greater antidepressant response compared to sham.

**Methods/Materials:** Adults 22 to 80 years of age with treatment resistant and severe major depressive disorder (MDD) were randomized using a 1:1 ratio in a parallel design to 50 active or sham SAINT treatments. The LDLPFC-sgACC circuit was targeted to the area of LDLPFC most functionally anticorrelated with sgACC via fc-MRI and neuronavigation equipment. A total of 90,000 intermittent theta-burst (iTBS) pulses (90% MT) were delivered in hourly 10-min sessions, for 10 sessions per day, across 5 days. Blinded raters evaluated depression at baseline, immediately after SAINT, and at post-SAINT treatment weeks 1, 2, 3 and 4 (week 5). The 10-item clinician-rated MADRS was the primary depression outcome measure.

**Results:** Of the 528 individuals screened for the study, 29 participants received randomized treatment and were included in the intent-to-treat analysis. Remission at any time-point occurred in 78.57% of the active SAINT group (n=14) and 13.33% of the sham group (n=15). The percent change in MADRS from baseline to 1-month post treatment was statistically superior in the active vs sham groups ( $p < 0.002$ ;  $d = 1.53$ ). There was no significant difference between active vs sham groups on guesses as to which treatment group they were in.

**Discussion:** Our active SAINT protocol induced significant antidepressant responses in individuals with MDD after just 5 days, compared to those who received sham stimulation. The speed of the induced antidepressant responses is particularly important for inpatient, and more severely depressed populations. Targeting the LDLPFC-sgACC circuit may allow for individualized rTMS treatment for TRD.

**Conclusions:** Our active fc-MRI guided, high-dose, iTBS protocol (SAINT) targeting the LDLPFC-sgACC circuit had superior antidepressant response when compared to sham, in individuals with TRD. The high remission rate in this trial may support the LDLPFC-sgACC circuit as a neural basis of depressive symptoms. Larger, randomized, sham-controlled trials are needed.

**References:**

**Keywords:** neuromodulation, intermittent theta burst stimulation, transcranial magnetic stimulation, depression



**Topic:** 11. *Non- and Less-Invasive Brain Stimulation*

## **MOTOR CORTEX STIMULATION FOR INTRACTABLE FACIAL PAIN: A LITERATURE REVIEW**

### **E-POSTER VIEWING**

Alessandro Rapisarda, Nicola Montano  
Neurosurgery, IRCSS Fondazione Agostino Gemelli, Rome, Italy

**Introduction:** Facial pain (FP) can be very difficult to manage with medical treatment and admits different causes classified among Central or Peripheral diseases. Cerebrovascular accidents are the most reported Central cause while Peripheral disease consists primarily of Trigeminal Pain (TP) of different types (trigeminal neuralgia, trigeminal neuropathic pain, trigeminal deafferentation pain, post-herpetic neuralgia). Motor Cortex stimulation (MCS) was firstly supposed to produce analgesia by Penfield in the 1930s and was firstly reported as a treatment for central deafferentation pain by Tsubokawa et al. in 1990 (1). Since then case reports and case series were reported on this topic. However, the correct indications for MCS have not been fully established. Here we reviewed the pertinent literature and carried out a pooled analysis of available data.

**Methods/Materials:** A Pubmed search was performed using the following terms: “facial pain”, “trigeminal neuropathy”, “motor cortex stimulation” in any possible combination. We found 29 pertinent articles. We excluded papers on transcranial stimulation and headaches/cephalalgia and included case series with more than 5 patients. We included only articles in which the data and follow-up (FU) were clearly reported. Only 13 articles fulfilled the criteria for a pooled analysis.

**Results:** Out of the 159 patients tested for MCS, 137 were submitted to permanent implantation of the device (86,1 %). The mean age at MCS testing was  $55.6 \pm 6.33$  years and the mean FU was  $25.06 \pm 16.5$  months. Satisfactory pain relief was achieved in 92 patients at latest FU (57.8%). TP showed a better response to MCS compared to facial pain of Central origin (satisfactory pain reduction of 59,85% vs 48.15% at latest FU, respectively). Complications have been reported in 15,48% of the tested patients.

**Discussion:** FP is a condition which strongly reduces patient's quality of life. MCS has been proposed to treat this disorder. Our pooled analysis showed that MCS is effective in treating IFP. Moreover a Meta-analysis evidenced MCS effectiveness over placebo or transcranial stimulation (2). Complications after MCS consists mostly of transient intraoperative seizures and clinically important issues such as epidural hematoma or stroke are scarcely reported.

**Conclusions:** MCS should be considered as a valid therapeutic option for IFP mainly for patients with intractable TP. Studies with longer FU are needed to confirm the long term effectiveness of this treatment.

**References:** Tsubokawa T, Katayama Y, Yamamoto T, Hirayama T, Koyama S. Chronic motor cortex stimulation for the treatment of central pain. *Acta Neurochir Suppl (Wien)* 1991; 52: 137–9. Moises C. Lima, Felipe Fregni. Motor cortex stimulation for chronic pain. *Neurology* Jun 2008, 70 (24) 2329-2337; DOI: 10.1212/01.wnl.0000314649.38527.9

**Keyword:** Motor Cortex Stimulation, MCS, Facial Pain, Trigeminal neuralgia, Trigeminal Neuropathy

**Topic:** 11. Non- and Less-Invasive Brain Stimulation

## **EFFECTS OF FUNCTIONAL ELECTRICAL STIMULATION CYCLING EXERCISE AND CENTRAL NEUROMODULATION ON MOTOR CONTROL IN STROKE**

### **E-POSTER VIEWING**

Shih-Ching Chen<sup>1</sup>, Chien-Hung Lai<sup>1</sup>, Chih-Wei Peng<sup>2</sup>

<sup>1</sup>Physical Medicine And Rehabilitation, Taipei Medical University Hospital, Taipei Medical University, Taipei, Taiwan, <sup>2</sup>Biomedical Engineering, Taipei Medical University, Taipei, Taiwan

**Introduction:** How to enhance the effectiveness of rehabilitation for subjects with stroke is always an important issue. The effects of functional restoration by neuromodulations through peripheral and/or central intervention are assessed in this research. Functional electrical stimulation cycling exercise (FESCE) and transcranial direct current stimulation (tDCS) are applied for peripheral and central intervention individually or simultaneously. The study regarding the combined therapeutic effects of FESCE & tDCS for the hemiplegic lower extremities is still rare.

**Methods/Materials:** Subjects post-stroke more than 6 months with hemiplegic lower limbs at Brunnstrom stage III-V are recruited and are divided into 4 groups, including A group: traditional rehabilitation (TR), B group: TR combined with FESCE, C group: TR combined with tDCS, D group: TR combined with FESCE and tDCS. The kinesiological and kinematical data, balance, gait, spasticity, and quality of life were measured before and after a 4-week therapeutic protocol.

**Results:** We found that t-DCS combined with FESCE improve walking speed, spasticity, and balance control significantly. Improvement of balance is also demonstrated in the B and C groups. The results can provide clinicians or rehabilitation professionals a reference for arranging rehabilitation therapy.

**Discussion:** The functional status of most subjects with stroke usually reaches a plateau at post-stroke 6th month. Base on the concept, we recruited subjects post-stroke for more than 6 months. Physical impairments deeply affect the activities of daily living. Weakness and spasticity interfere with proper functional movement and lead to gait disorder, impaired balance control.

**Conclusions:** The results demonstrate that traditional rehabilitation (TR) combined with FESCE or/and tDCS can perform a better therapeutic effect than traditional rehabilitation alone. We expect that the results will provide important evidence-based information for clinical professionals to further promote stroke patients' functions.

**References:** [1] Reis J, Fritsch B. "Modulation of motor performance and motor learning by transcranial direct current stimulation", *Curr Opin Neurol.* 24(6):590-6, 2011. [2] DA Brown, AG Debacher. Bicycle ergometer and electromyographic feedback for treatment of muscle imbalance in patients with spastic hemiparesis. *Phys. Ther.*, 67:1715-1719, 1987. [3] Nitsche MA, Paulus W "Excitability changes induced in the human motor cortex by weak transcranial direct current stimulation", *J Physiol*, 527:633–639, 2000. [4] Lefaucheur JP. Methods of therapeutic cortical stimulation", *Clinical Neurophysiology*, 39(1):1-14, 2009.

**Keywords:** stroke, functional electrical stimulation cycling exercise, neuromodulation, transcranial direct current stimulation, gait, balance

**Topic:** 11. *Non- and Less-Invasive Brain Stimulation*

## **EFFECTS OF MEDIAN NERVE STOCHASTIC RESONANCE ELECTRICAL STIMULATION ON MOTOR LEARNING AND CORTICOMUSCULAR CONNECTIVITY**

### **E-POSTER VIEWING**

Li-Wei Chou<sup>1</sup>, Zhe-Ming Lin<sup>1</sup>, Chung-Lan Kao<sup>2</sup>, Shun-Hwa Wei<sup>1</sup>

<sup>1</sup>Physical Therapy And Assistive Technology, National Yang-Ming University, Taipei, Taiwan, <sup>2</sup>Medicine, National Yang-Ming University, Taipei, Taiwan

**Introduction:** Our previous works demonstrated that stochastic resonance electrical stimulation can be used to improve force control and joint angle proprioception. Here we investigated the effects of SRES on motor learning.

**Methods/Materials:** Subjects performed force trace task in which they generated grip force to match a sinusoidal target line displayed on a screen in front of the subject. The sinusoidal target line consisted of 0.5Hz sine waves with amplitudes equal to 10, 20 and 30% subjects' maximal grip force and last for 200 seconds. This force trace task was conducted in 2 conditions (with and without stimulation) on 2 different days. For the with stimulation condition, stochastic resonance electrical stimulation ((neuroConn DC stimulator, neuroCare Group Inc.) applied on median nerve at the elbow of the dominant arm; for the without stimulation condition, electrodes were placed on the same location with no current output. EMG of finger flexor of the dominant hand was collected (Biopac wireless EMG system) with 2 adhesive electrodes (inter-electrode distance = 1.5 cm) attached to the skin surface above the muscle belly. 16-channel EEG signals were collected and processed first (Quick Amp, Brain Product), and then eye blink artifact was removed and Principle Component Analysis were conducted (MATLAB and EEG toolbox). We then performed power spectrum analysis for the first Component and calculated relative power of alpha, beta, and gamma band of the entire spectrum. For corticomuscular connectivity, we calculated EEG-EMG coherence. Root mean square error (RMSE) between the sinusoidal target line and the actual force were calculated.

**Results:** Our preliminary results suggested that RMSE decreased in both with and without stimulation conditions, and RMSE decreased to a larger degree in the with stimulation condition. Regardless of with or without stimulation conditions, the power of alpha band in EEG increased with motor learning. Moreover, in with stimulation condition, gamma band in corticomuscular coherence increased with motor learning, but not in the without stimulation condition.

**Discussion:** The improvement in grip force tracing task indicated that subjects achieved better motor learning when SRES is applied during motor learning. Gamma band corticomuscular coherence was related to sensorimotor processing, suggesting SRES could help improve motor learning by enhancing sensorimotor processing.

**Conclusions:** SRES has immediate effect and can be used to enhance motor learning.

### **References:**

**Keywords:** corticomuscular coherence, stochastic resonance electrical stimulation, motor learning

**Topic:** 11. *Non- and Less-Invasive Brain Stimulation*

**ANTIDEPRESSANT EFFECT OF VAGAL NERVE STIMULATION IN EPILEPSY PATIENTS: A SYSTEMATIC REVIEW.**

**E-POSTER VIEWING**

Giovanni Assenza<sup>1</sup>, Tommaso Tufo<sup>2</sup>

<sup>1</sup>Neurology, Neurophysiology And Neurobiology Unit, Department Of Medicine, Università Campus Bio-Medico di Roma, Rome, Italy, <sup>2</sup>Department Of Neurosurgery, Policlinico Gemelli University Hospital Foundation IRCCS, Rome, Italy

**Introduction:** Vagal nerve stimulation (VNS) is an efficacious palliative therapy in drug resistant epileptic patients and is also approved as a therapy for treatment resistant depression. Depression is a frequent comorbidity in epilepsy and it affects the quality of life of patients more than the seizure frequency itself. The aim of this systematic review is to analyze the available literature about the VNS effect on depressive symptoms in epileptic patients.

**Methods/Materials:** A comprehensive search of PubMed, Medline, Scopus, Google Scholar was performed, and results were included up to January 2020. All studies concerning depressive symptoms assessment in epileptic patients treated with VNS were included.

**Results:** Nine studies were included because they fulfilled inclusion criteria. Six out of nine papers reported a positive effect of VNS on depressive symptoms. Eight out of nine studies did not find any correlation between seizure reduction and depressive symptoms amelioration, as induced by VNS. Clinical scales for depression, drug regimens and age of patients were broadly different among the examined studies.

**Discussion:** Reviewed studies strongly suggest that VNS ameliorates depressive symptoms in drug resistant epileptic patients and that the VNS effect on depression is uncorrelated to seizure response.

**Conclusions:** However, more rigorous studies addressing this issue are encouraged.

**References:**

**Keywords:** depression, vagal nerve stimulation, epilepsy, systematic review

**Topic:** 11. *Non- and Less-Invasive Brain Stimulation*

**LONG-TERM EFFICACY AND TOLERABILITY OF VAGAL STIMULATION IN DRUG-RESISTANT EPILEPSY: STUDY WITH FOLLOW-UP > 10 YEARS.**

**E-POSTER VIEWING**

Giovanni Assenza<sup>1</sup>, Filomena Fuggetta<sup>2</sup>, Alessandro Izzo<sup>2</sup>, Manuela D'Ercole<sup>2</sup>, Gabriella Colicchio<sup>2</sup>, Tommaso Tufo<sup>2</sup>

<sup>1</sup>Neurology, Neurophysiology And Neurobiology Unit, Department Of Medicine, Università Campus Bio-Medico di Roma, rome, Italy, <sup>2</sup>Department Of Neurosurgery, Policlinico Gemelli University Hospital Foundation IRCCS, Rome, Italy

**Introduction:** Vagus nerve stimulation (VNS) improves seizure control in patients with drug-resistant epilepsy. The aim of the study is to analyze the long-term tolerability and effectiveness of the VNS.

**Methods/Materials:** 60 consecutive adult epileptic patients implanted in our center were retrospectively studied (36 males, 42.6 ± 13.2 years of age; disease onset 8.3±9.1; implant age 29.5±13.1 years, pre-implantation disease 21.8±10.1 years) with a minimum 10-year follow-up (range 10-21 years).

**Results:** 28 patients (46.7%) use the stimulator after 1-6 battery changes (2.2±1.3) with 12.6±4.6 years of stimulation. A rapid work cycle (25%) was in 4/28 (15%) patients, intermediate (16%) in 12/28 (42.5%), slow in 12/28 (42.5%). 10/28 patients (35%) have a responder rate > 50% and, among these 5 (17.5%) are seizure-free. They maintained the VNS for seizure intensity reduction 13 pts (46%), for improvement in vigilance/cognition 5 (17.5%). 1 patient reported generator infection and 1 electrode rupture with subsequent replacement. 32 patients stopped stimulation, including 5 per death (15%).

**Discussion:** VNS is well tolerated by patients in the long term.

**Conclusions:** In our series, about half of the patients use stimulation with good control of the intensity and number of seizures.

**References:**

**Keywords:** long-term efficacy, tolerability, vagal nerve stimulation, epilepsy

**Topic:** 11. Non- and Less-Invasive Brain Stimulation

## EFFICACY OF TRANSCRANIAL DIRECT CURRENT STIMULATION ON PAIN MANAGEMENT IN PARKINSON'S DISEASE PATIENTS: A STUDY PROTOCOL

### E-POSTER VIEWING

Yeray González Zamorano<sup>1</sup>, Josué Fernández Carnero<sup>2</sup>, Francisco José Sánchez Cuesta<sup>3</sup>, Aida Arroyo Ferrer<sup>3</sup>, Juan Pablo Romero Muñoz<sup>3,4</sup>

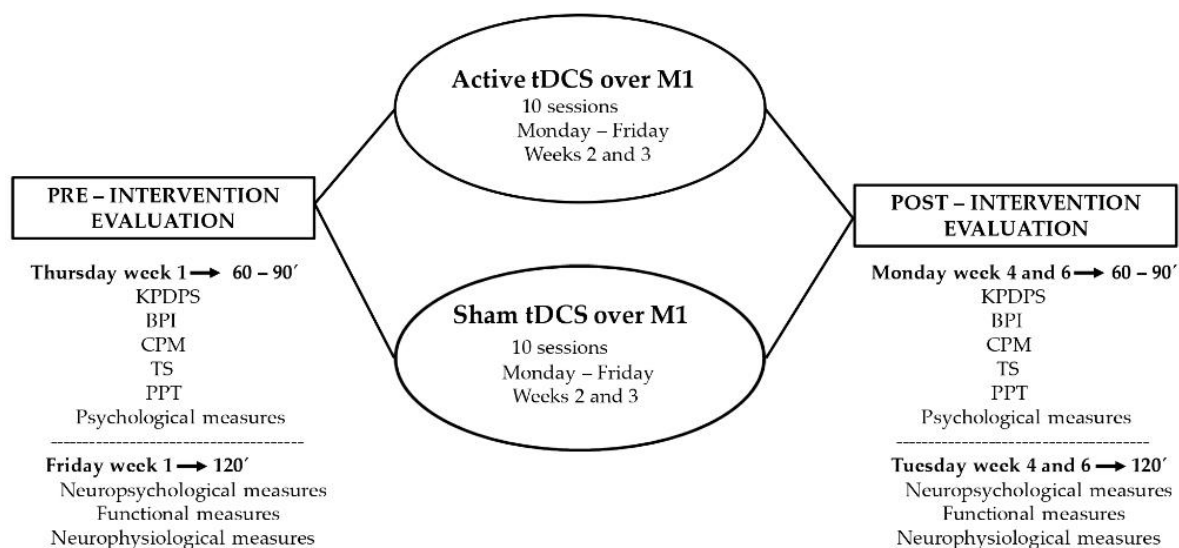
<sup>1</sup>Escuela Internacional De Doctorado En Ciencias De La Salud. Department Of Physical Therapy, Occupational Therapy, Rehabilitation And Physical Medicine, Universidad Rey Juan Carlos, Alcorcón, Spain, <sup>2</sup>Department Of Physical Therapy, Occupational Therapy, Rehabilitation And Physical Medicine, Universidad Rey Juan Carlos, Alcorcón, Spain, <sup>3</sup>Facultad De Ciencias Experimentales, Universidad Francisco de Vitoria, Pozuelo de Alarcón, Spain, <sup>4</sup>Cerebral Damage Unit, Hospital Beata María Ana, Madrid, Spain

**Introduction:** Pain currently affects 85% of Parkinson's Disease (PD) patients and is under-reported in most cases, leading to a high impact on their quality of life. The election treatment for PD patients is levodopa, but it has controversial results for the treatment of pain. "On" condition is considered when levodopa is acting while "off" condition is when not. PD patients have more hyperalgesia than healthy subjects, especially in "off" condition. Pain and off condition in PD have been related to low cortical excitability, suggesting that new therapies influencing this aspect may be effective for the management of pain in these patients. Transcranial Direct Current Stimulation (tDCS) over M1 increases corticospinal excitability in M1 and in other pain-related areas, correlating with effective pain relief in fibromyalgia, osteoarthritis, migraine, and spinal cord injury, but it has never been applied in PD patients. The main objective of this study is to develop and validate a tDCS based protocol for the treatment of pain in PD subjects in "on" and "off" conditions.

**Methods/Materials:** The project was designed after an extensive review of the available pain-related protocols using tDCS. A parallel, controlled, triple-blinded, randomized clinical trial will be conducted. For the analysis of the results (effectivity and correlation of identified response prediction markers), parametric tests will be used if the sample allows it. The analyses will be completed with non-parametric tests and residual, period, and sequence effect checks will be made. (Confidence level of 0.95).

**Results:** The tDCS stimulation protocol was defined for 10 sessions of 20 minutes at 2mA of anodic stimulation over M1 as described by Fregni et al. The stimulated hemisphere will be contralateral to pain in asymmetric pain and the dominant in bilateral pain.

Main Outcomes	Secondary Outcomes
Kings Parkinson's Disease Pain Scale (KPDPS)	Psychological
Brief Pain Inventory (BPI)	Functional
Pressure Pain Threshold (PPT)	Neuropsychological
Conditioned Pain Modulation (CPM)	Neurophysiological
Temporal Summation (TS)	



**Discussion:** This is the first study using tDCS over M1 as a therapeutic tool in pain treatment in PD patients. Neuromodulation may enhance endogenous pain modulation and counteract facilitatory nociception, correlating with a reduction in clinical perceived pain in PD patients. Psychological, functional, neuropsychological, and neurophysiological aspects may be determined in our results.

**Conclusions:** tDCS over M1 may be an effective tool for PD pain management.

**References:** 1. Chaudhuri KR, Schapira AHV. Non-motor symptoms of Parkinson's disease: dopaminergic pathophysiology and treatment. *Lancet Neurol.* mayo de 2009;8(5):464-74. 2. S S, N V, Dwc C, M F, Ah E. Pain sensitivity in Parkinson's disease: Systematic review and meta-analysis. Vol. 48, *Parkinsonism & related disorders. Parkinsonism Relat Disord*; 2018. 3. Nitsche MA, Paulus W. Excitability changes induced in the human motor cortex by weak transcranial direct current stimulation. *J Physiol.* 15 de septiembre de 2000;527(Pt 3):633-9. 4. Fregni F, Boggio PS, Lima MC, Ferreira MJL, Wagner T, Rigonatti SP, et al. A sham-controlled, phase II trial of transcranial direct current stimulation for the treatment of central pain in traumatic spinal cord injury. *Pain.* mayo de 2006;122(1-2):197-209.

**Keywords:** Pain, tDCS, Parkinson's Disease

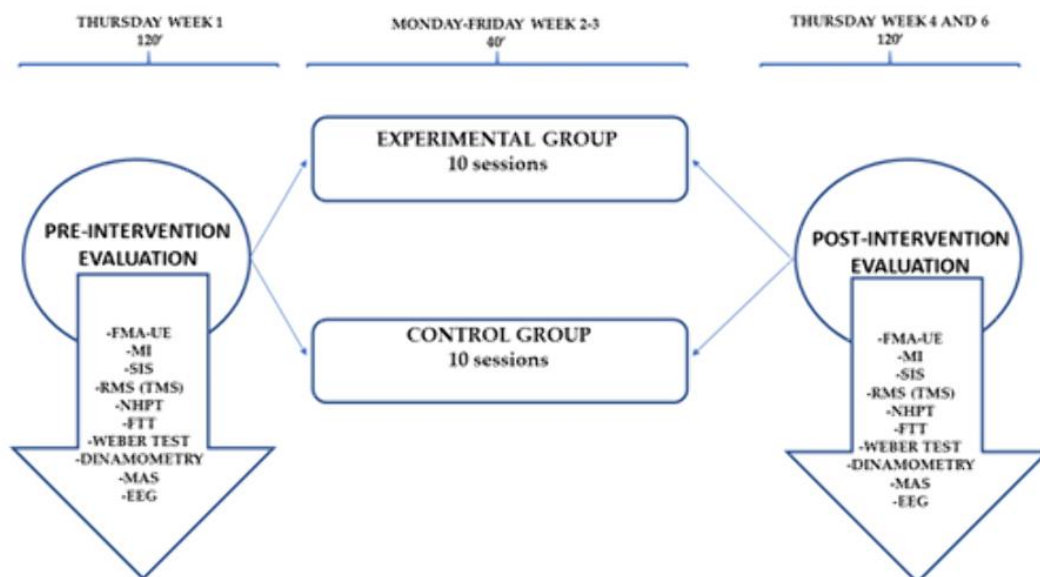
**Topic:** 11. Non- and Less-Invasive Brain Stimulation**PROTOCOL TO VALIDATE THE EFFECTS OF IMMERSIVE MULTIMODAL BCI-VR TRAINING AFTER BILATERAL STIMULATION WITH RTMS ON UPPER LIMB MOTOR RECOVERY AFTER STROKE****E-POSTER VIEWING**

Francisco José Sánchez Cuesta<sup>1</sup>, Aida Arroyo Ferrer<sup>1</sup>, Yeray Zamorano<sup>2</sup>, María Dolores Del Castillo<sup>3</sup>, Ignacio Serrano<sup>3</sup>, Juan Pablo Romero Muñoz<sup>1,4</sup>

<sup>1</sup>Facultad De Ciencias Experimentales, Universidad Francisco de Vitoria, Pozuelo de Alarcón, Spain, <sup>2</sup>Fisioterapia, Universidad Rey Juan Carlos, Madrid, Spain, <sup>3</sup>Gnec Group, CSIC, Madrid, Spain, <sup>4</sup>Cerebral Damage Unit, Hospital Beata María Ana, Madrid, Spain

**Introduction:** Stroke is a leading cause of long-term disability, it reduces mobility in more than half of stroke survivors age 65 and over(1). There are indicative studies that reflect that, six months after a stroke, more than 60% of subjects will have a non-functional hand for Basic Activities of Daily Living (BADL), and 20-25% will not be able to walk without assistance (2). One of the reasons for this is the reduction of neuroplasticity(3). An immersive multimodal BCI-VR training and bilateral rTMS protocols are likely to complement their effects achieving a stronger neuroplasticity enhancement in stroke patients. Both have been used separately for the treatment of motor sequelae in the upper limbs after stroke (4,5). The main objective of this study is to carry out a double-blind, randomized, controlled trial aiming to study the clinical effect of Neuroow system (NeuroRehabLab, Lisbon, Portugal) over bilateral rTMS plus conventional rehabilitation in upper limb motor sequelae after subacute stroke (3 to 12 months).

**Methods/Materials:** The study design corresponds to a randomized, double-blind, placebo-controlled clinical trial in which patients are randomly assigned to two groups: 1. Conventional rehabilitation + bilateral rTMS + Immersive multimodal BCI-VR training system Neuroow, and 2. Conventional rehabilitation + bilateral rTMS and sham BCI-VR training. Three evaluations will be carried out for each patient (Figure 1).



**Results:** For the analysis of the results, parametric tests will be used, if normality, equality of variance and sample size allow it. Due to the nature of the data, the analyzes will be completed with non-



parametric tests and residual effect, period effect and sequence effect checks will be made.  
(Confidence level of 0.95)

**Discussion:** Several previous studies combining two different noninvasive neuromodulation approaches have been successfully tested in stroke patient's rehabilitation (6). This is the first time that multimodal immersive BCI-VR training is evaluated as an enhancer of the proven efficacy of rTMS bilateral protocols focused on interhemispheric inhibition compensation.

**Conclusions:** This therapy could potentially reduce the time required for hand rehabilitation or improve functional outcomes reducing long term disability.

**References:** 1. Virani SS et al. *Circulation*. 2020; 3;141(9):e139–596. 2. Dobkin BH. *Lancet Neurol*. 2004;3(9):528–36. 3. Alia C et al. *Front Cell Neurosci* [Internet]. 2017; 11: 76. 4. Takeuchi N et al. *J Rehabil Med*. 2009;41(13):1049–54. 5. Vourvopoulos A et al. *Front Hum Neurosci*. 2019;13:244. 6. Yang Y-W et al. *Neural Regen Res*. 2020 May 11;15(11):1986–94.

**Keywords:** Repetitive Transcranial Magnetic Stimulation, BCI-VR Training, Motor Skills, Upper Limb, stroke

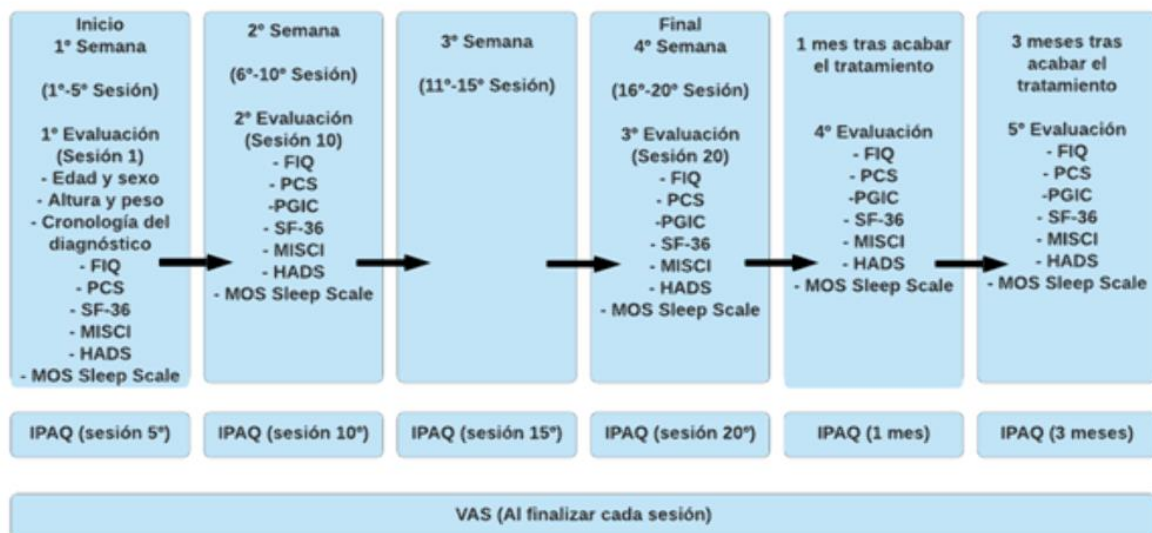
**Topic:** 11. Non- and Less-Invasive Brain Stimulation**EFFECT OF TRANSCRANIAL STATIC MAGNETIC FIELD STIMULATION OVER THE PRIMARY MOTOR CORTEX IN FIBROMYALGIA SYNDROME: A RANDOMIZED CONTROLLED PILOT STUDY****E-POSTER VIEWING**

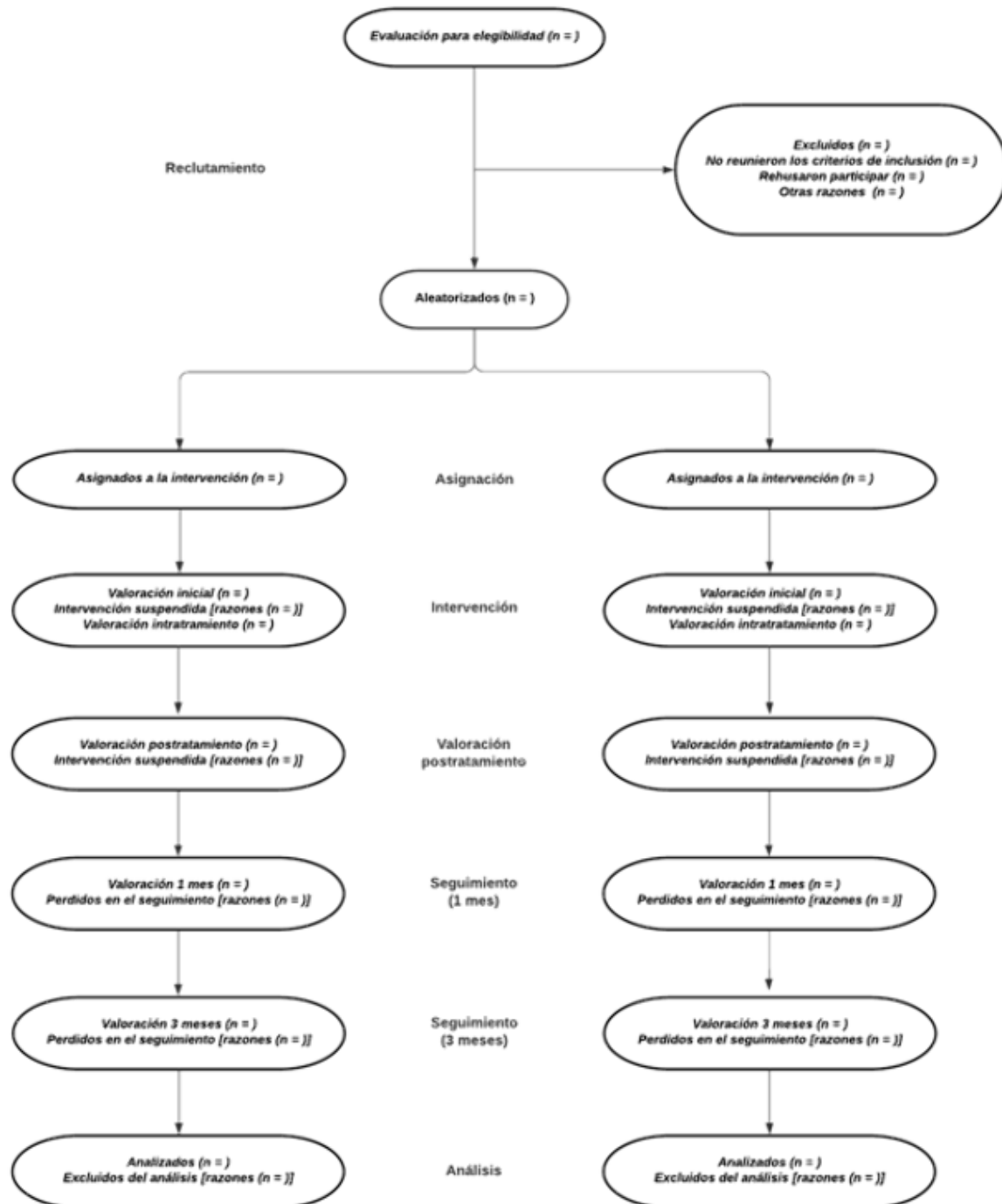
Manuel Del Valle Gratacós<sup>1</sup>, Víctor Navarro López<sup>1</sup>, José Jesús Jiménez Rejano<sup>2</sup>, Antonio Oliviero<sup>3</sup>, Samuel Jiménez Jiménez<sup>1</sup>

<sup>1</sup>Fisioterapia, Centro Téxum, Madrid, Spain, <sup>2</sup>Fisioterapia, Universidad de Sevilla, Sevilla, Spain, <sup>3</sup>Neurología, Hospital Nacional de Paraplégicos de Toledo, Toledo, Spain

**Introduction:** Various non-invasive brain stimulation techniques have been successfully tested in fibromyalgia syndrome (FMS). Transcranial static magnetic field stimulation (tSMS) is a new, portable and inexpensive non invasive brain stimulation (NIBS) technique that has shown security, biological effects, and therapeutical effects in some pathologies. Some studies have studied its effect in pain central processing, our aim is to study its effect on FMS. The safety that tSMS has demonstrated in several clinical trials opens doors to future clinical trials that will extend its clinical utility. Objectives: To investigate the effect of tSMS on pain in patients with FMS, using subjective and objective assessment measures. Identify dose response to the treatment to limit the parameters required to achieve effectiveness with the technique.

**Methods/Materials:** A design with two groups (intervention and sham), randomized and double-blinded, with a sample of 8 participants in each group with FMS, is established. The intervention group will receive a treatment of tSMS in the primary motor cortex, while the placebo group will receive a dummy treatment. Both interventions will have a duration of 30 minutes, 5 times a week, during 4 weeks, for a total of 20 sessions. Throughout the study, 5 complete evaluations will be made using validated and contrasted variables, as well as other variables that will be measured on a daily or weekly.







**Results:** To Be Completed

**Discussion:** To Be Completed

**Conclusions:** To Be Completed

**References:** (1) Eich W, Bär K, Bernateck M, Burgmer M, Dextl C, Petzke F, et al. Definition, classification, clinical diagnosis and prognosis of fibromyalgia syndrome: Updated guidelines 2017 and overview of systematic review articles. *Schmerz* (Berlin, Germany) 2017;31(3):231-8. (2) Wolfe F, Walitt B. Culture, science and the changing nature of fibromyalgia. *Nature reviews. Rheumatology* 2013;9(12):751-5. (3) Ayán Pérez CL. *Fibromialgia*. 1ª. ed. Madrid: Editorial Médica Panamericana; 2011. (4) Sociedad Española de Reumatología, SER. *Tratado de Enfermedades Reumáticas de la SER*. 1ª ed. Madrid: Editorial Médica Panamericana; 2018. (5) Wolfe F, Clauw DJ, Fitzcharles M, Goldenberg DL, Katz RS, Mease P, et al. The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity. *Arthritis Care & Research* 2010;62(5):600-10. (6) Wolfe F, Clauw DJ, Fitzcharles M, Goldenberg DL, Häuser W, Katz RS, et al. Fibromyalgia Criteria and Severity Scales for Clinical and Epidemiological Studies: A Modification of the ACR Preliminary Diagnostic Criteria for Fibromyalgia. *The Journal of rheumatology* 2011;38(6):1113-22. (7) Serra J, Collado A, Solà R, Antonelli F, Torres X, Salgueiro M, et al. Hyperexcitable C nociceptors in fibromyalgia. *Annals of Neurology* 2014;75(2):196-208. (8) Gentile E, Ricci K, Delussi M, Brighina F, de Tommaso M. Motor Cortex Function in Fibromyalgia: A Study by Functional Near-Infrared Spectroscopy. *Pain Research and Treatment* 2019; 2019:2623161-7. (9) Di Lazzaro V, Oliviero A, Pilato F, Saturno E, Dileone M, Mazzone P, et al. The physiological basis of transcranial motor cortex stimulation in conscious humans. *Clinical Neurophysiology* 2004;115(2):255-66. (10) Groppa S, Oliviero A, Eisen A, Quartarone A, Cohen LG, Mall V, et al. A practical guide to diagnostic transcranial magnetic stimulation: Report of an IFCN committee. *Clinical Neurophysiology* 2012;123(5):858-82. (11) Lefaucheur J, Antal A, Ayache SS, Benninger DH, Brunelin J, Cogiamanian F, et al. Evidence-based guidelines on the therapeutic use of transcranial direct current stimulation (tDCS). *Clinical Neurophysiology* 2016;128(1):56-92. (12) Capone F, Dileone M, Profice P, Pilato F, Musumeci G, Minicuci G, et al. Does exposure to extremely low frequency magnetic fields produce functional changes in human brain? *J Neural Transm* 2009;116(3):257-65. (13) Capone F, Pellegrino G, Motolese F, Rossi M, Musumeci G, Di Lazzaro V.

Extremely Low Frequency Magnetic Fields Do Not Affect LTP-Like Plasticity in Healthy Humans. *Frontiers in human neuroscience* 2020;14:14. (14) Oliviero A, Mordillo-Mateos L, Arias P, Panyavin I, Foffani G, Aguilar J. Transcranial static magnetic field stimulation of the human motor cortex. *The Journal of Physiology* 2011;589(20):4949-58. (15) Shibata S, Watanabe T, Yukawa Y, Minakuchi M, Shimomura R, Mima T. Effect of transcranial static magnetic stimulation on intracortical excitability in the contralateral primary motor cortex. *Neuroscience Letters* 2020;723:134871. (16) Oliviero A, Carrasco-López MC, Campolo M, Perez-Borrego YA, Soto-León V, Gonzalez-Rosa JJ, et al. Safety Study of Transcranial Static Magnetic Field Stimulation (tSMS) of the Human Cortex. *Brain Stimulation* 2015;8(3):481-5. (17) Dileone M, Mordillo-Mateos L, Oliviero A, Foffani G. Long-lasting effects of transcranial static magnetic field stimulation on motor cortex excitability. *Brain Stimulation* 2018;11(4):676-88. (18) Kirimoto H, Tamaki H, Otsuru N, Yamashiro K, Onishi H, Nojima I, et al. Transcranial Static Magnetic Field Stimulation over the Primary Motor Cortex Induces Plastic Changes in Cortical Nociceptive Processing. *Frontiers in human neuroscience* 2018;12:63. (19) Knijnik LM, Dussán-Sarria JA, Rozisky JR, Torres ILS, Brunoni AR, Fregni F, et al. Repetitive Transcranial Magnetic Stimulation for Fibromyalgia: Systematic Review and Meta-Analysis. *Pain Practice* 2016;16(3):294-304. (20) Lloyd DM, Wittkopf PG, Arendsen LJ, Jones AKP. Is transcranial direct current stimulation (tDCS) effective for the treatment of pain in fibromyalgia? A systematic review and meta-analysis. *The Journal of Pain* 2020;S1526-5900(20)30004-3. (21) Paolucci T, Piccinini G, Iosa M, Piermattei C, de Angelis S, Grasso MR, et al. Efficacy of extremely low-frequency magnetic field in fibromyalgia pain: A pilot study. *Journal of rehabilitation research and development*. 2016;53(6):1023-34. (22) Kirimoto H, Tamaki H, Matsumoto T, Sugawara K, Suzuki M, Oyama M, et al. Effect of Transcranial Static Magnetic Field Stimulation Over the Sensorimotor Cortex on Somatosensory Evoked Potentials in Humans. *Brain Stimulation* 2014;7(6):836-40. (23) Kirimoto H, Asao A, Tamaki H, Onishi H. Non-invasive modulation of somatosensory evoked potentials by the application of static magnetic fields over the primary and supplementary motor cortices. *Scientific reports* 2016;6(1):34509.

**Keyword:** transcranial static magnetic field stimulation (tSMS), fibromyalgia, pain

**Topic:** 12. *Neuro-regeneration*

**CORTICAL POTENTIALS EVOKED BY SUBTHALAMIC NUCLEUS DEEP BRAIN STIMULATION IN THE MPTP PRIMATE MODEL OF PARKINSONISM: MODULATORY EFFECTS OF STIMULATION PARAMETERS AND DOPAMINERGIC REPLACEMENT THERAPY.**

**E-POSTER VIEWING**

Brett Campbell<sup>1</sup>, Hanbin Cho<sup>2</sup>, Riley Faulhammer<sup>2</sup>, Andre Machado<sup>3</sup>, Kenneth Baker<sup>2</sup>

<sup>1</sup>Biomedical Engineering, Case Western Reserve University, Cleveland, United States of America, <sup>2</sup>Neurosciences, Cleveland Clinic, Cleveland, United States of America, <sup>3</sup>Neurological Institute, Cleveland Clinic, Cleveland, United States of America

**Introduction:** Deep brain stimulation (DBS) of the subthalamic nucleus (STN) is known to induce widespread changes in neural activity across the basal ganglia thalamocortical network. A better understanding of how STN DBS modulates cortical activity holds potential to inform its mechanistic underpinnings and to identify control signals for next-generation, adaptive DBS paradigms.

**Methods/Materials:** We characterized the effects of STN stimulation on cortical local field potential (LFP) activity in a rhesus macaque instrumented with a scaled, six contact directional STN DBS lead as well as bilateral, twelve-channel subdural, ECoG paddle electrodes spanning anterior parietal to prefrontal cortical regions. STN DBS evoked cortical potentials were collected across the naïve, mild and moderate parkinsonian states, with responses in the latter states further compared across the dopamine-treated and untreated states.

**Results:** Annular DBS below the threshold for motor activation (~ lateral capsule spread) associated with a significant improvement in motor function. Stimulation further elicited multi-phasic cortical potentials, including high-frequency components as early as 0.5ms post-stimulation followed by sequentially broader peaks that were maximal across motor and premotor cortices. Marked differences in the cortical potentials were observed based on disease state, with a larger evoked response in the naïve state that progressively dampened with disease progression. In the PD state, dopamine replacement resulted in further shifts in peak amplitude and latency that did not replicate the naïve state data despite a corresponding improvement in motor function.

**Discussion:** The observed response shows evidence of both antidromic effects, possibly involving activation of the 'hyper-direct' cortico-subthalamic pathway, as well as synaptic effects that may be mediated within cortical networks or involve polysynaptic activation across the basal ganglia and thalamus.

**Conclusions:** These data are the first to characterize the effects of STN DBS parameters on cortical LFP activity with disease progression and with restoration of dopaminergic activity. Further development of this model and its implications for delineating the BGTC network response characteristics for adaptive DBS paradigms in PD and other disease states will be discussed.

**References:**

**Keywords:** Dopamine, Deep Brain Stimulation, Evoked Potentials, Parkinson's disease

**Topic:** 12. *Neuro-regeneration*

## A NOVEL TARGET DBS FOR CENTRAL POST STROKE PAIN: A CASE REPORT

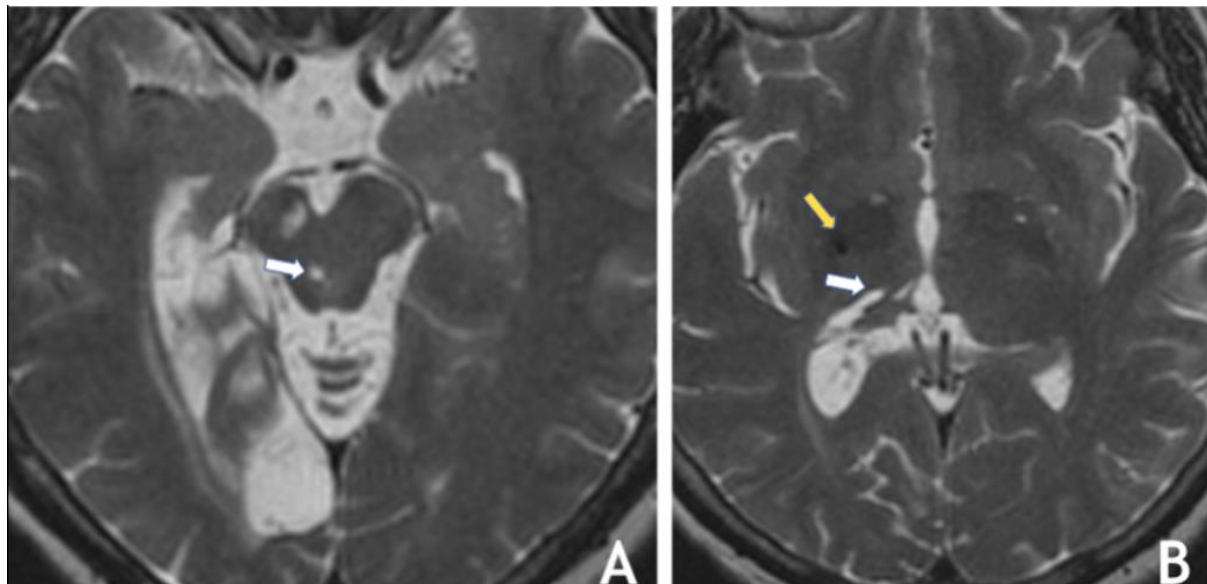
### E-POSTER VIEWING

William Contreras Lopez<sup>1</sup>, Eduardo Lopes Alho<sup>2</sup>, Paula Navarro<sup>1</sup>, Erich Talamoni Fonoff<sup>3</sup>

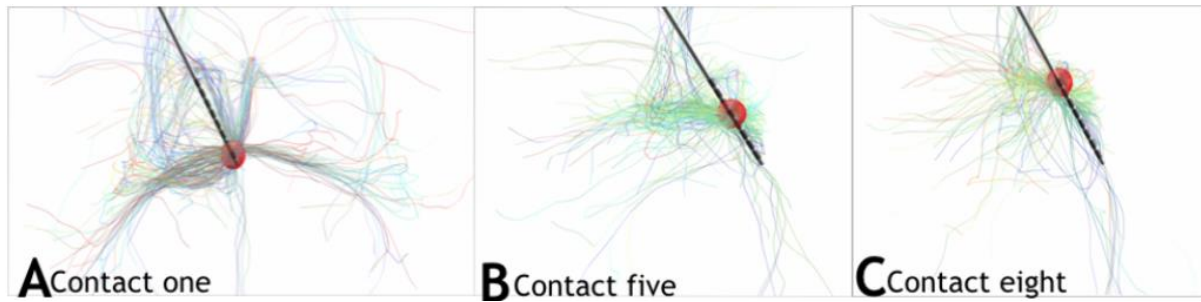
<sup>1</sup>Funcional Neurosurgery, Universidad Autonoma de Bucaramanga, Bucaramanga, Colombia, <sup>2</sup>Functional Neurosurgery, Universidad de Sao Paulo, Facultad de Medicina, Sao Paulo, Brasil, Sao paulo, Brazil, <sup>3</sup>Functional Neurosurgery, Universidad de Sao Paulo, Facultad de Medicina, Sao paulo, Brazil

**Introduction:** Deep brain stimulation (DBS) has been considered for patients with intractable pain syndromes. Modulation of the affective sphere of pain has emerged as a plausible alternative. The objective of this study is to describe the previously unknown changes in pain perception of anterior limb of the internal capsule and nucleus accumbens DBS on Central post-stroke Pain (CPSP) using an 8-contact unilateral lead.

**Methods/Materials:** A 59 years-old woman experienced a double episode of unilateral thalamic and mesencephalon infarction. She developed Holmes tremor and CPSP in the left dimidium. Tremor was totally controlled after unilateral GPi DBS. CPSP however worsened in time associating important depression. The anatomy of Classical targets for chronic central pain was grossly altered due to infarction. There is evidence of a paramount role of NAc and limbic connections (anterior limb of the internal capsule-ALIC) in the physiopathology of central pain, with no definitive conclusions about electrical stimulations of this region. In the lack of anatomical possibility of targeting classical structures, allied to important emotional impairment of the patient, the ALIC/NAc target was chosen. A 15.5mm span with tight 8 contact spacing lead was implanted following the trajectory of the ALIC, with the most ventral contact below the anterior commissure. Patient was evaluated at 1, 3 and 6 months and scores of SF36, visual analog scale (VAS) and McGill pain questionnaire were compared to baseline.



**Results:** The postoperative period was uneventful. Pain relief was noted intraoperatively and was sustained up to the last follow-up (FU) visit (6mo). The patient's pain level dropped from an intractable 10/10 VAS score to a more acceptable 3/10 with periods of complete relief; scores in McGill questionnaire decreased by 68.5% and concomitant improvement in all domains of SF-36 scale were also observed and sustained.



**Discussion:** CPSP remains intractable. DBS is a promising technique to modulate activity of implicated structures. We targeted structures representing emotion and affective behavior (ALIC/NAc) instead of traditional failed sensori-motor targets, achieving excellent results. We report novel effects of multiple independent current control for electrical stimulation of this region with emphasis on pain relief, adverse effects and mood changes.

**Conclusions:** An 8-contact ALIC/NAc DBS provided excellent pain control on a refractory CPSP case, improving quality of life up to last FU. Although this is not a definite conclusion, it is in line with previous studies that are in search of limbic system targets to treat chronic pain. Our results encourage ALIC/NAc DBS to be considered for the treatment of CPSP.

**References:** 1. Boccard SG, Pereira EA, Aziz TZ. Deep brain stimulation for chronic pain. *J Clin Neurosci.* 2015;22(10):1537-1543. 2. Owen SL, Green AL, Stein JF, Aziz TZ. Deep brain stimulation for the alleviation of post-stroke neuropathic pain. *Pain.* 2006;120(1-2):202-206. 3. Lempka SF, Malone DA, Jr, Hu B, et al. Randomized clinical trial of deep brain stimulation for poststroke pain. *Ann Neurol.* 2017;81(5):653-663.

**Keywords:** central post Stroke pain, Deep Brain Stimulation



**Topic:** 13. Late-Breaking Research

**THE PARASTIM STUDY: SAFETY AND EFFICACY OF SPINAL CORD STIMULATION FOR THE TREATMENT OF MOTOR, BLADDER AND SEXUAL DYSFUNCTIONS FOLLOWING INCOMPLETE SPINAL CORD INJURY**

**E-POSTER VIEWING**

Bechir Jarraya<sup>1,2</sup>, Caroline Hugeron<sup>3</sup>, Virginie Guitard<sup>1</sup>, Pierre Denys<sup>2,3</sup>, François Giuliano<sup>2,3</sup>, Djamel Bensmail<sup>2,3</sup>, Nicolas Roche<sup>2,3</sup>, Laura Terrier<sup>1</sup>

<sup>1</sup>Pôle Neurosciences, Hôpital Foch, Suresnes, France, <sup>2</sup>Medical School, Université de Versailles Paris Saclay, Versailles, France, <sup>3</sup>Rehabilitation, Hôpital Raymond Poincaré AP-HP, Garches, France

**Introduction:** Spinal cord injury (SCI) causes sensory-motor disability, bladder and sexual dysfunctions. There is no validated treatment to restore spinal cord function following SCI. Preclinical studies in adult rats of SCI could demonstrate the restoration of locomotor activity with a combination of locomotor training, pharmacological intervention and epidural electrical stimulation of the lumbosacral spinal cord (spinal cord stimulation, SCS). Recently, few international teams demonstrated that SCS combined with motor training induced neurological improvement in some paraplegic patients, with electromyographic patterns of muscle activation close to those observed during gait, and sometimes some improvement of bladder and sexual dysfunctions.

**Methods/Materials:** The ParaStim study is an open, randomized, controlled, cross-over, interventional study assessing the safety and efficacy of SCS (in association with a rehabilitation program) to treat motor, bladder and sexual dysfunctions in SCI patients. The study is designed to include 14 patients with incomplete SCI (ASIA B and non walking ASIA C), in whom the spinal cord lesion level is located above T10 (with no significant motor impairment of upper limbs). SCI should occur at least 2 years before the inclusion and should be considered stable. All patients will be implanted with the Specify 5-6-5 SCS lead (Medtronic) at the T12 level, and the Intellis neurostimulator (Medtronic, MN, USA). The primary analysis will be carried out using a conditional logistic regression model.

**Results:** The clinical trial had obtained a government funding (French PHRC funding program). The company agreed to offer the implantable devices for all the patients. The study involves two institutions in Paris greater area: Hôpital Foch (neurosurgery) and Hôpital Raymond-Poincaré (rehabilitation, evaluation). The study received the approval of the Ethical Committee and the French regulation agency. The study will start in the first 6 months of 2020 with a total duration of research of 36 months.

**Discussion:** So far, SCS has been evaluated for SCI treatment with either case series report or open trials with positive results. Based on a conceptual, preclinical rationale and a clinical proof of concept demonstrated in a few reported cases, we propose a clinical study with an original cross-over design, in order to validate the hypothesis that SCS combined with training may allow, with a good safety profile, to restore motor, bladder and sexual functions in incomplete SCI patients.

**Conclusions:** The Parastim study aims at testing the potential of SCS in SCI patients using a cross over design to allow for a higher clinical evidence than previously reported.

**References:**

**Keywords:** paraplegia, spinal cord injury, bladder dysfunction, Spinal cord stimulation, sexual dysfunction

**Topic:** 13. Late-Breaking Research

## **THE LEEDS TEACHING HOSPITALS TRUST EXPERIENCE OF BURST SPINAL CORD STIMULATION IN TREATING INDIVIDUALS WITH CHRONIC PAIN: A RETROSPECTIVE EVALUATION**

### **E-POSTER VIEWING**

G. Baranidharan, Beatrice Bretherton, Tracey Crowther, Thomas Kay, Nathan Marsh, Bethan Roberts, Charlotte Romanis  
Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom

**Introduction:** Since 1967, spinal cord stimulation (SCS) has been increasingly used in the treatment of chronic pain. Currently, around 34,000 patients annually are implanted with a SCS in the UK, with approximately 180 of these being within the Leeds Teaching Hospitals NHS Trust (LTHT). Technological advancements in SCS have seen the development of different forms of stimulation, such as burst SCS. This is a paraesthesia free approach, delivering groups of pulses separated by short pulse-free periods to dorsal columns in the spinal cord. Stimulation parameters are typically characterised by five 1 ms pulses with an internal frequency of 500 Hz, delivered at 40 Hz<sup>1</sup>. Most studies, typically prospective trials, have demonstrated efficacy of burst SCS<sup>2</sup>. Using real-world data, this study investigated the efficacy and complications associated with burst SCS in a teaching hospital.

**Methods/Materials:** This was a retrospective evaluation, with data collected from patients with failed back surgery syndrome (FBSS) or chronic visceral pain who received fully implanted burst SCS between March 2012 and March 2020 in LTHT. The following data were ascertained from paper files and hospital electronic records: gender, age, chronic pain diagnosis, implant date, SCS system, baseline and follow-up scores for average pain (visual analogue scale, VAS), worst pain (VAS) and health-related quality of life (QoL, EQ-5D), and the occurrence of revisions and explants. Data were statistically analysed by paired t-tests (or Wilcoxon signed-rank tests for non-normally distributed data). Descriptive statistics, counts and percentages were also generated.

**Results:** One hundred and twelve patients with FBSS or chronic visceral pain received fully implanted burst SCS. Two patients were waiting for their first follow-up and 11 patients had an explantation, resulting in a final sample of 99 patients. Average pain ( $p < 0.001$ ), worst pain ( $p < 0.001$ ) and QoL ( $p = 0.001$ ) were significantly improved at follow-up compared to baseline. The mean (SD) change in average pain, worst pain and QoL were -2.22 (2.65 cm), -2.47 (2.71 cm) and 0.20 (0.43) respectively. Remission (0-3cm average pain VAS, (3)) occurred in 23% (24 of 106) of patients and 27% (25 of 93) of patients reported reductions  $\geq 50\%$  in average pain at follow-up. Seventeen patients (of 99, 17%) underwent a revision, with battery maintenance ( $n = 6$ ) and lead migration ( $n = 6$ ) being the most common reasons for revision. In total, 11 (of 112, 10%) patients underwent a full system explantation. Insufficient pain relief was the most common reason for explant ( $n = 8$ ), followed by infection ( $n = 3$ ) and requiring an MRI ( $n = 1$ ). IPG site pain was cited as a secondary influential factor for explantation in two cases.

**Discussion:** Findings demonstrated that burst SCS in FBSS and chronic visceral pain was associated with significant improvements in pain and QoL. The low rate of revisions and explants suggests this modality is a safe and effective treatment in these chronic pain conditions.

**Conclusions:** By using real-world data, it is hoped that findings from this retrospective study will broaden insight into the clinical practice and effects of burst SCS in individuals with chronic pain.

**References:** 1. De Ridder D, Vanneste S, Plazier M, van der Loo E, Menovsky T. Burst Spinal Cord Stimulation. *Neurosurgery* [Internet]. 2010 May 1;66(5):986–90. Available from: <https://academic.oup.com/neurosurgery/article/66/5/986/2556656>

2. Kirketeig T, Schultheis C, Zuidema X, Hunter CW, Deer T. Burst Spinal Cord Stimulation: A Clinical Review. *Pain Med* [Internet]. 2019 Jun 1;20(Supplement\_1):S31–40. Available from: [https://academic.oup.com/painmedicine/article/20/Supplement\\_1/S31/5509415](https://academic.oup.com/painmedicine/article/20/Supplement_1/S31/5509415)

3. De Jaeger M, Goudman L, Eldabe S, Van Dongen R, De Smedt A, Moens M. The association between pain intensity and disability in patients with failed back surgery syndrome, treated with spinal cord stimulation. *Disabil Rehabil* [Internet]. 2019 Nov 24;1–7. Available from: <https://www.tandfonline.com/doi/full/10.1080/09638288.2019.1694084>

**Keywords:** Spinal cord stimulation, chronic pain, Burst, Retrospective

**Topic:** 13. Late-Breaking Research

## THE LEEDS TEACHING HOSPITALS TRUST EXPERIENCE OF SPINAL CORD STIMULATION: A RETROSPECTIVE EVALUATION IN CHRONIC PAIN CONDITIONS

### E-POSTER VIEWING

G. Baranidharan, Beatrice Bretherton, Tracey Crowther, Thomas Kay, Nathan Marsh, Bethan Roberts, Charlotte Romanis  
Pain Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom

**Introduction:** Since 1967, spinal cord stimulation (SCS) has been increasingly used in the treatment of chronic pain. Large numbers of patients are implanted with a SCS in the UK: around 34,000 patients per year. Approximately 180 of these are carried out in the Leeds Teaching Hospitals NHS Trust (LTHT). Most studies, typically prospective trials, have demonstrated that SCS is effective and safe in a number of diagnoses, including failed back surgery syndrome (1), failed neck surgery syndrome (2), complex regional pain syndrome (3), painful diabetic neuropathy (4), fibromyalgia (5) along with many others. Using real-world data, this study investigated the efficacy and complications associated with SCS in failed back surgery syndrome (FBSS) and chronic visceral pain in a teaching hospital.

**Methods/Materials:** This was a retrospective evaluation, with data collected from patients with failed back surgery syndrome or chronic visceral pain who received 10 kHz or BurstDR SCS from March 2012-March 2020 in LTHT. The following data were ascertained from paper files and hospital electronic records: gender, age, chronic pain diagnosis, SCS system, implant date, baseline and follow-up scores for average pain (visual analogue scale, VAS), worst pain (VAS) and health-related quality of life (EQ-5D), and the occurrence of revisions and explants. Data were statistically analysed by paired t-tests (or Wilcoxon signed-rank tests for non-normally distributed data). Descriptive statistics, counts and percentages were also generated.

**Results:** Four hundred and forty-five patients with FBSS or chronic visceral pain received fully implanted 10 kHz or burst SCS. Eleven patients were waiting for their first follow-up and three patients were lost to follow-up. Fifty-one patients had an explantation and six were waiting for explantation of their system. This resulted in a final sample of 374 patients. Average pain ( $p < 0.001$ ), worst pain ( $p < 0.001$ ) and QoL ( $p < 0.001$ ) were significantly improved at follow-up compared to baseline. The mean (SD) change in average pain, worst pain and QoL were -2.35 (2.36 cm), -2.04 (2.33 cm) and 0.30 (0.44) respectively. Remission (0-3cm average pain VAS, (6)) occurred in 23% (98 of 421) of patients and 27% (108 of 398) reported reductions  $\geq 50\%$  in average pain at follow-up. Fifty-three patients (of 374, 14%) underwent a revision with IPG or anchor site pain being the most common reason for revision ( $n = 27$ ). In total, 51 (of 445, 11%) patients underwent a full system explantation. Insufficient pain relief was the most common reason for explant ( $n = 42$ ), followed by infection ( $n = 8$ ) and requiring an MRI ( $n = 2$ ). IPG site pain was cited as a secondary influential factor for explantation in seven cases.

**Discussion:** Findings demonstrated that SCS in FBSS and chronic visceral pain were effective at reducing pain and improving QoL. Importantly, an assessment of surgical revisions and explants showed this treatment is safe in these conditions.

**Conclusions:** By using real-world data, it is hoped that findings from this retrospective study will broaden insight into the clinical practice of SCS in FBSS and chronic visceral pain.

**References:** 1. Al-Kaisy A, Van Buyten J-P, Smet I, Palmisani S, Pang D, Smith T. Sustained Effectiveness of 10 kHz High-Frequency Spinal Cord Stimulation for Patients with Chronic, Low Back Pain: 24-Month Results of a Prospective Multicenter Study. *Pain Med* [Internet]. 2014 Mar 1;15(3):347–54. Available from: <https://academic.oup.com/painmedicine/article-lookup/doi/10.1111/pme.12294>

2. De Ridder D, Plazier M, Kamerling N, Menovsky T, Vanneste S. Burst Spinal Cord Stimulation for Limb and Back Pain. *World Neurosurg* [Internet]. 2013 Nov;80(5):642-649.e1. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S1878875013001010>
3. Kriek N, Groeneweg JG, Stronks DL, de Ridder D, Huygen FJPM. Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial. *Eur J Pain* [Internet]. 2017 Mar;21(3):507–19. Available from: <http://doi.wiley.com/10.1002/ejp.944>
4. de Vos CC, Bom MJ, Vanneste S, Lenders MWPM, de Ridder D. Burst Spinal Cord Stimulation Evaluated in Patients With Failed Back Surgery Syndrome and Painful Diabetic Neuropathy. *Neuromodulation Technol Neural Interface*. 2014 Feb;17(2):152–9.
5. Salmon J. High-frequency spinal cord stimulation at 10 kHz for widespread pain: a retrospective survey of outcomes from combined cervical and thoracic electrode placements. *Postgrad Med* [Internet]. 2019 Apr 3;131(3):230–8. Available from: <https://www.tandfonline.com/doi/full/10.1080/00325481.2019.1587564>
6. De Jaeger M, Goudman L, Eldabe S, Van Dongen R, De Smedt A, Moens M. The association between pain intensity and disability in patients with failed back surgery syndrome, treated with spinal cord stimulation. *Disabil Rehabil* [Internet]. 2019 Nov 24;1–7. Available from: <https://www.tandfonline.com/doi/full/10.1080/09638288.2019.1694084>

**Keywords:** Retrospective, chronic pain, Spinal cord stimulation

## CREATING A DIGITAL MODEL OF PARKINSON'S DISEASE BASED ON THE UPDRS TEST

### E-POSTER VIEWING

Artur Biktimirov<sup>1</sup>, Kirill Fadeev<sup>2</sup>, Alexey Smirnov<sup>2</sup>, Alexey Tumialis<sup>2</sup>

<sup>1</sup>Neurosurgery, Far Eastern Federal University Medical Center, Vladivostok, Russian Federation, <sup>2</sup>Laboratory Of Educational Psychophysiology, Far Eastern Federal University, Vladivostok, Russian Federation

**Introduction:** Modern methods for diagnosing motor disorders of Parkinson's disease are based mainly on the UPDRS test. The test itself is a subjective method of diagnosis and takes a long time. The aim of our work was to objectify the assessment of the patient's condition using the UPDRS test, by digitizing the data obtained using a motion capture suit and deep machine analysis.

**Methods/Materials:** We created a video Protocol for the patient's motor state assessment test based on the UPDRS (III) test. And record the dynamics of changes in motor activity of patients with Parkinson's disease in the motion capture suit Perception Neuron 32 in 14 patients in the Off and On periods.

**Results:** It was found that the rotation amplitude, expressed in degrees, had significant effects of taking levodopa ( $F(1.13) = 8.25$ ,  $p = 0.013$ ,  $\eta^2 = 0.39$ ) and time ( $F(1.13) = 19.18$ ,  $p < 0.001$ ,  $\eta^2 = 0.60$ ). The effect of levodopa indicates that before taking the drug, the angle of pronation-supination was  $88 \pm 14$  degrees and after taking the drug increased to  $120 \pm 12$  degrees. The time effect indicates that in the first period, the angle of rotation of the hand was maximum and then significantly decreased ( $118 \pm 11$ ,  $105 \pm 12$ ,  $98 \pm 12$ ,  $97 \pm 12$  for Periods 1, 2, 3 and 4 respectively; the amplitude in Period 1 is significantly greater than in other periods ( $ps < 0.001$ ). The speed of the hand rotation repeats the results of the amplitude analysis. Significant effects of taking levodopa ( $F(1.13) = 5.85$ ,  $p = 0.031$ ,  $\eta^2 = 0.31$ ) and time ( $F(1.13) = 15.63$ ,  $p < 0.001$ ,  $\eta^2 = 0.55$ ) were found. The levodopa effect indicates that before taking the drug, the hand rotation speed was  $551 \pm 76$  degrees per second and after taking the drug, it increased to  $730 \pm 67$  degrees per second. The time effect indicates that in the first period the speed of hand rotation was maximum and then significantly decreased ( $750 \pm 55$ ,  $647 \pm 66$ ,  $591 \pm 65$ ,  $573 \pm 67$  for Periods 1, 2, 3 and 4 respectively; the speed in Period 1 is significantly higher than in other periods ( $ps < 0.01$ ).

**Discussion:** Thus the obtained digital data fully corresponds to the change in the state of patients during the UPDRS test.

**Conclusions:** The results obtained allow us to draw preliminary conclusions about the possibility of creating an automated system for assessing the patient's motor condition and subsequently introducing this technology to the clinic.

### References:

**Keywords:** digital model, Parkinson's disease, UPDRS

**Topic:** 13. Late-Breaking Research

## THE FIRST SIMULTANEOUS SCS DTM STIMULATION OF THE CERVICAL AND THORACIC SPINAL CORD

### E-POSTER VIEWING

Apostolos Chatzikalfas

Department For Surgical Pain Therapies And Neuromodulation, Pain Clinic Basel, Basel, Switzerland

**Introduction:** Clinical effectiveness of SCS has long been established through numerous publications. SCS of the cervical region hasn't been researched enough mainly because of the fact that cervical SCS is more challenging. Since 2008 multiple stimulation waveforms have given us the opportunity to treat a broader spectrum of patients with different chronic pain syndroms. In 2020 an new waveform called Differential Target Multiplexed™ was developed focusing more on the glial cells and less on the neurons.

**Methods/Materials:** In Oct. 2020 we implanted the first SCS DTM in Switzerland in a 42-year old patient. Predominantly the patient suffered from a pain in the lower back because of multisegmental degeneration of the lumbar spine and on the right foot after multiple ORs because of a Halux fracture which caused an improper stature balance of the lower back. VAS 9/10 The patient also suffered from a chronic pain in the left carpal and hand area after multiple ORs because of a fracture on the Radial bone. VAS 8-9/10. The patient had to wear a prosthetic on a regular base to minimize movement. Multiple allergies in pain medication made pain treatment that much harder. We implanted two 8-contact SCS Electrodes stimulating the T9 vertebra according to the DTM protocol. The SCS DTM stimulation resulted in a >50% pain reduction with a VAS of 4-5/10. At the same time the neuropathic pain in the left hand increased. The pain medication was adjusted multiple times unsuccessfully. After reprogramming the thoracic SCS DTM stimulation we were able to successfully stimulate the patient with just one electrode. Taking into consideration the case report of Larson et al. which was reported in the last 2021 NANS we decided to replace one of the SCS electrodes and place a new in the cervical region. On the 12th of April 2021 we successfully placed a second electrode in the cervical region. A DTM SCS stimulation protocol was selected for both the cervical and the thoracic regions.

**Results:** We had a significant pain reduction with a VAS of 4-5/10 but also the patient stopped using the prosthetic after the second post-OR day. Pain medication was also reduced significantly.

**Discussion:** Although not yet researched enough DTM SCS stimulation provides promising results and gives us another valuable solution in successfully treating chronic pain patients with SCS.

**Conclusions:** The latest advances in SCS stimulating waveforms have solidified SCS as the flagship in the greater Neuromodulation portfolio.

**References:** - Fishman et al (2020) - Vallejo et al (2020) - Larson et al.(2021) - Deer TR, Skaribas IM, Haider N, Salmon J, Kim C, Nelson C, Tracy J, Espinet A, Lininger TE, Tiso R, Archacki MA, Washburn SN. Neuromodulation. 2014 Apr - Ariel Morales 1, R Jason Yong 1, Alan D Kaye 2, Richard D Urman 3, Curr Pain Headache Rep., 2019 Mar 14

**Keyword:** SCS DTM

**Topic:** *No Topic Needed*

## CEREBELLAR ATAXIA RESPONSE TO SUBCUTANEOUS STIMULATION

### E-POSTER VIEWING

Athanasia Alexoudi, Efstathios Vlachakis, Stamatis Banos, Panayiotis Patrikelis, Anastasia Verentzioti, Stergios Gatzonis, Stefanos Korfias, Damianos Sakas  
Neurosurgery, 1st Department of Neurosurgery, National and Kapodistrian University of Athens, "Evangelismos" General Hospital, Athens, Greece

**Introduction:** We present the remission of symptoms of moderate ataxia, due to cerebellar degeneration after the application of subcutaneous stimulation of parietal and occipital areas.

**Methods/Materials:** A 37-year-old right-handed man progressively developed moderate ataxia since the age of 18. Brain magnetic resonance imaging revealed cerebellar atrophy. Ataxia significantly impaired his daily activities. He was treated with physical therapy, and conventional medication, without satisfactory improvement. Considering the refractoriness of his symptoms, we conducted a trial of transcranial direct current stimulation (tDCS) motor and pre-motor cortices. Cathode was positioned over the right mastoid. The active stimulation resulted in significant improvement in ataxia that persisted for days. Based on the good response to tDCS, the patient underwent a trial of subcutaneous stimulation. Four leads with 8 contacts, were placed: two over the parietal lobes and two over occipital lobes, under the superior nuchal line. Direction was from midline under the external occipital protuberance to the apex of the mastoid process. We observed an improvement in tremor (Fahn, Tolosa, Marin Tremor Rating Scale from 31/144 to 25/144) and cerebellar ataxia (Scale for the Assessment and Rating of Ataxia [SARA] from 14/40 to 11/40). Therefore, permanent electrodes were placed at the same positions 6 months later.

**Results:** The clinical assessment and videorecording were performed in on and off conditions, 10 days after the permanent electrode placement. The Fahn, Tolosa, Marin Tremor Rating Scale improved from 35/144 to 21/144 (10% reduction) and the SARA from 15/40 to 10/40 (12,5% reduction). There were no side effects.

**Discussion:** The cerebrocerebellum is involved in planning movement. It receives input from the cerebral cortex and projects to the motor and premotor cortices and the ventrolateral nucleus of the thalamus via the dentate nucleus (DN). Dentothalamocortical projections modulate the activity of the contralateral primary motor (M1). Degeneration of the cerebellar nuclei leads to ataxia and a loss of physiologic excitatory inputs from the DN to the contralateral M1 cortex. We decided to stimulate the area over DN and M1 in order to facilitate the normal function of the circuit.

**Conclusions:** The application of subcutaneous stimulation seems a safe and well-tolerated method for the amelioration of symptoms of refractory, neurodegenerative diseases. The use of tDCS can be a valuable tool for predicting the final response. Future larger studies and longer follow up will reveal its efficacy and durability in this patient population.

**References:** 1. Holdefer RN, Miller LE, Chen LL, Houk JC. Functional connectivity between cerebellum and primary motor cortex in the awake monkey. *J Neurophysiol* 2000;84:585–590. 2. Teixeira MJ, Cury RG, Galhardoni R, Barboza VR, Brunoni AR, Alho E, Lepski G, Ciampi de Andrade D. Deep brain stimulation of the dentate nucleus improves cerebellar ataxia after cerebellar stroke. *Neurology*. 2015;85:2075-6. 3. Alexoudi A, Patrikelis P, Fasilis T, Deftereos S, Sakas D, Gatzonis S. Effects of anodal tDCS on motor and cognitive function in a patient with multiple system atrophy. *Disabil Rehabil*. 2020;42:887-891.

**Keyword:** Ataxia, subcutaneous stimulation, transcranial direct current stimulation



