

September 14, 2009

#1

**Abstract Title: Does greater occipital nerve stimulation influence the brain: LORETA imaging in fibromyalgia patients.**

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### **Introduction**

Stimulation of the greater occipital nerve (C2) might have a beneficial effect in occipital neuralgia, primary headache syndromes and fibromyalgia [1-3]. Possible explanations can be found in the connection with neurons of the trigeminal nerve in the Trigemino-Cervical complex[4]. However, PET data have shown differences in brain activation during stimulation [5], as did unpublished fMRI results by the authors.

LORETA imaging results during occipital nerve stimulation are presented, showing differences in cortical activation in a group of fibromyalgia patients.

### **Materials and Methods**

9 patients, suffering from fibromyalgia were implanted with a greater occipital nerve stimulator in order to treat their pain.

EEG recordings were acquired in the following situations: a) stimulation off b) stimulation at effective treatment settings c) stimulation at non-effective treatment settings. The EEGs were recorded with a 19-channel EEG according to the 19/20 system, 500 Hz sampling rate, eyes closed situation. After artifact removal, including removal of the stimulation artifact by independent component analysis (ICA) Current Source Densities were calculated using sLORETA and t-within tests were performed.

## Results

Significant results were found in the comparison between the measurements during stimulation and without stimulation. The following cortical regions were involved: cingulate gyrus, somatosensory cortex, hippocampal area and insula.

## Conclusion

These results show differences in cortical current source density during stimulation. This might suggest that subcutaneous stimulation of the greater occipital nerve, not only influences the peripheral nervous system, but the central nervous system as well. Further research including functional MR imaging and PET-scan data combined with EEG data might be useful to verify these and extend these results to subcortical structures.

## References

1. Thimineur, M. and D. De Ridder, *C2 area neurostimulation: a surgical treatment for fibromyalgia*. Pain Med, 2007. 8(8): p. 639-46.
2. Plazier, M., et al., *Occipital Nerve stimulation in Fibromyalgia: a double-blind placebo controlled pilot study.(in preparation)*
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4. Bartsch, T. and P.J. Goadsby, *Increased responses in trigeminocervical nociceptive neurons to cervical input after stimulation of the dura mater*. Brain, 2003. 126(Pt 8): p. 1801-13.
5. Matharu, M.S., et al., *Central neuromodulation in chronic migraine patients with suboccipital stimulators: a PET study*. Brain, 2004. 127(Pt 1): p. 220-30.

## Acknowledgements

St Jude Medical for providing an educational grant

## Figure and Table Legend

Figure 1: decreased current source density in the gamma band during occipital nerve stimulation.

## Learning Objectives:

1. Occipital nerve stimulation can be effective in pain treatment
2. The mechanism might involve central neuromodulation, besides peripheral neuromodulation

September 14, 2009

#2

**Abstract Title: Greater Occipital Nerve (C2) Stimulation in Fibromyalgia: Follow up results after a placebo controlled trial**

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**Introduction**

The fibromyalgia syndrome (FMS) is characterized by widespread pain, sleeping disorders and fatigue. Prevalence is up to 4% in civilized countries, mainly affecting women in a 9/1 ratio. The socio economic burden is extensive and treatment outcomes are poor [1, 2].

The authors performed a randomized controlled trial of occipital nerve stimulation in FMS. Initial results were satisfying: decrease of pain on visual analogue scale of 39.74% ( $p < 0.05$ ) [3]. and follow up results are presented.

**Materials and Methods**

All trial study patients were offered a permanent IPG implanted, and 9 patients (all female, mean age 44.44) underwent permanent implantation. An octrode lead was implanted subcutaneously in the C2 dermatoma, with an internal pulse generator (St Jude Medical, Plano, TX).

Pain was measured by Visual Analogue Scale (VAS, mean  $7.68 \pm 1.64$  SD), Pain Catastrophizing Scale (PCS, mean  $17.00 \pm 7.98$  SD) and Pain Vigilance and Awareness Questionnaire (PVAQ, mean  $28.78 \pm 12.06$  SD). Modified Fatigue Impact Scale (mFIS, mean  $51.89 \pm 15.98$  SD) and the Beck Depression Inventory (BDI-II, mean  $22.67 \pm 14.74$  SD) were analyzed as well.

**Results**

Significant results were found for the VAS at 2 months and 3 months post surgery ( $t = 3.333$ ,  $p = 0.016$ ;  $t = 3.367$ ,  $p = 0.012$ ), PCS at 2 months ( $t = 2.624$ ,  $p = 0.039$ ). A trend to significance was found for fatigue scored on the mFIS at 2 months and 3 months ( $t = 2.210$ ,  $p = 0.069$ ;  $t = 2.197$ ,  $p = 0.064$ ).

**Conclusion**

The results of this follow up data suggest that treatment of FMS with occipital nerve stimulation might be beneficial. However the long-term results are still unknown and further follow up is necessary to evaluate the evolution of these results in time.

**References**

1. Berger, A., et al., *Characteristics and healthcare costs of patients with fibromyalgia syndrome*. Int J Clin Pract, 2007. 61(9): p. 1498-508.
2. Bennett, R.M., et al., *An internet survey of 2,596 people with fibromyalgia*. BMC Musculoskelet Disord, 2007. 8: p. 27.
3. Plazier, M., et al., *Occipital Nerve stimulation in Fibromyalgia: a double-blind placebo controlled pilot study. (in preparation)*

**Acknowledgements**

Thanks to St Jude Medical for providing an educational grant.

**Learning Objectives:**

1. Occipital nerve stimulation can be effective in the treatment of fibromyalgia
2. Follow up results suggest that a long term effects can be achieved with this treatment

**September 14, 2009**

**#3**

**Abstract Title:** Peripheral Nerve Field Stimulation for Chronic Thoracic Pain and Thoracic Referred Pain – A Prospective Study

**Primary Presenter:**

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Abstract Title Peripheral Nerve Field Stimulation for Chronic Thoracic Pain and Thoracic Referred Pain – A Prospectiv

**Introduction**

Thoracic pain and thoracic referred pain to the chest and upper abdomen is historically difficult to treat, with facet joint blocks, pharmacological therapies and surgical options often failing at pain relief. Peripheral nerve field stimulation (PNFS) may prove to be an effective treatment option with previous studies demonstrating lasting pain relief for chronic low back pain (1, 2). This study evaluates thoracic PNFS as a potential treatment for patients with chronic thoracic and thoracic referred pain Study

**Materials and Methods** Over a 3.5 year period we assessed 8 consecutive patients who had a successful trial and were subsequently implanted with octrode percutaneous leads within the major area of pain in their thorax. Most of the patients selected for the PNFS trial had already undergone radiofrequency neurotomy, facet joint injections, accupunture and discograms, all of which had failed to provide significant pain relief. Questionnaires, along with patients' histories were used to assess outcomes such as pain (VAS), analgesic use, anxiety and depression (Zung depression index). A follow up rate of 100% was achieved with an average follow up of  $8.6 \pm 5.1$  months (range 3 – 20 months).

**Results**

Of the 8 patients studied, 7 patients reported over 50% pain relief, with 4 of these patients experiencing pain relief greater than 70%. Only one patient had a poor result to the implant, with negligible pain relief. Overall, a significant reduction in pain was observed with an average reduction of  $5.0 \pm 2.8$  VAS ( $p < 0.05$ ). There was no significant decrease in the anxiety and depression levels experienced by the patients post operatively. However, four of the patients reported moderate to extreme reductions in their analgesic use.

**Conclusion**

Thoracic pain and thoracic referred pain is historically difficult to treat. Here, we have demonstrated that PNS is an effective treatment option resulting in significant pain relief in chronic pain sufferers.

## References

1. Paicius RM, Bernstein CA, Lempert-Cohen C. Peripheral nerve field stimulation for the treatment of chronic low back pain: preliminary results of long-term follow-up: a case series. *Neuromodulation* 2007;10:279-290.
2. Verrills P, Mitchell B, Vivian D, Sinclair C. Peripheral Nerve Stimulation: A Treatment for Chronic Low Back Pain and Failed Back Surgery Syndrome? *Neuromodulation* 2009;12: 68-75

## Figure Legend:

Fluoroscopic images of peripheral nerve field stimulation leads implanted bilaterally over T12 and over right T6 and T7

## Learning Objectives:

1. Peripheral Nerve Field Stimulation is a potential option for patients with chronic thoracic pain who have had negative responses to previous facet joint injections, radiofrequency neurotomy and other interventions.
2. Placement of leads for thoracic pain management

**September 14, 2009**

**#4**

**Abstract Title:** The Therapeutic Validity of Peripheral Nerve Field Stimulation for Chronic Abdominal and Pelvic Pain

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## Introduction

Peripheral nerve field stimulation (PNFS) has been used in the treatment of pain since 1965, most commonly for chronic neck and back pain (1,2). However, advancements in the field of PNFS have led to its wider application. We demonstrate that PNFS is an effective treatment for abdominal and pelvic pain, and should be considered as an alternative to traditional pharmacological pain management strategies where suitable.

## Materials and Methods

Over a 2.5 year period we assessed 9 consecutive patients who had a successful trial and were subsequently implanted with octrode percutaneous leads within the major area of pain in their abdomen and pelvis. Questionnaires, along with patients' histories were used to assess outcomes such as pain (VAS), analgesic use, depression (Zung depression index) and disability (Oswestry index). A follow up rate of 100% was achieved with a follow up range of 6-18 months (average  $11.75 \pm 4.9$  months).

## Results

Of the 9 patients, only 1 reported a poor outcome to the implant. Overall, a statistically significant reduction in pain levels with an overall average reduction of  $5.7 \pm 1.8$  ( $p \leq 0.05$ ) VAS was observed. This equated to a 76.9% improvement in VAS pain, with one third of the patients also reporting an extreme reduction in their analgesic use. Where data was available, post-operatively, anxiety was seen to decrease by 44%, depression by an average of  $14.5 \pm 5.5\%$ , and disability by 8 index points on the Oswestry scale.

## Conclusion

PNFS can produce effective pain relief in the majority of carefully selected patients suffering from chronic abdominal and pelvic pain.

## References

1. Raj P. Pain Medicine: A Comprehensive Review. St. Louis, MO: Mosby-Year Book, 1996.
2. Paicius RM, Bernstein CA, Lempert-Cohen C. Peripheral nerve field stimulation for the treatment of chronic low back pain: preliminary results of long-term follow-up: a case series. *Neuromodulation* 2007;10:279–290

### Figure Legend:

Fluoroscopic images of peripheral nerve field stimulation leads placed in the groin and left abdomen.

## Learning Objectives:

1. Wider application for Peripheral Nerve Field Stimulation
2. Treating chronic pelvic and abdominal pain with groin and abdominal lead placement

**September 14, 2009**

**#5**

### Title:

Use of the SAFE Principles to evaluate pain treatments

### Presenter:

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Since the previous attempts that had been made to create algorithms of pain care including neuromodulation therapies for patients with chronic pain, much has been learned regarding assessing outcomes of therapies. These initial attempts at creating algorithms only took into account efficacy and levels of invasiveness when placing therapies in some rational hierarchy. After reviewing updated literature on efficacy and cost outcomes of care for patients with chronic pain that include spinal cord stimulation (SCS), a form of neuromodulation therapy, we offer a new way of thinking when formulating algorithms of care, the S.A.F.E principles. These S.A.F.E. principles include “safety,” “appropriateness,” “fiscal neutrality,” and “efficacy.”

**September 14, 2009**

**#6**

**Abstract Title:** Does neuromodulation method improve quality of life in patients with failed back surgery syndrome?

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**Introduction:** A significant number of patients with FBSS are so much debilitated that they are unable to return to work, suffer from of unsolvable psychological and social illness and often require a lot of analgesics with inadequate results. According to this concept a multidisciplinary treatment approach including mainly psychological and social approach is necessary. In this study we stressed on psychological and social assessment of patients with FBSS before and after neuromodulation treatment. We also studied medication of strong opioids during neuromodulation treatment.

**Materials and Methods:** Thirty six patients with FBSS who failed conventional medical analgesic management underwent neuromodulation treatment. Psychological adjustment with various questionnaire has used for the best selection and preparing patient for neuromodulation treatment. In detail, we used short version of SF-36 (Quality of \_ife) and Oswestry disability Index (ODI) before and after neuromodulation treatment. We followed changes of medication of strong opioids. For statistical evaluation were used a paired-samples test and other statistical instruments.

**Results:** All our patients were off such drugs within ten months FBSS patients improved significantly in most items of SF-36 and ODI questionnaire during neuromodulation treatment. The best results were detected in the item of pain. All of our patients were off strong opioid drugs within ten months during neuromodulation treatment.

**Conclusion:** The FBSS is the most common indication for neuromodulation treatment. Our study confirmed that neuromodulation treatment in patients with FBSS significantly improve pain profile and quality of life and reduce using of strong opioids during neuromodulation treatment. Psychological and social assessments play an important role in preparation and selection of FBSS patients for neuromodulation treatment.

**Acknowledgements:** Supported by Grants of VZ 0021620816/2005-2011

## References

Vrba I., Ko\_án M., Knotek P., Kozák J. \_t\_tká\_ová I. Bio-psycho-social assessment of neuromodulation analgetic treatment in patients with failed back surgery syndrome. *Bolest* 2009,12:40-48.

## Learning Objectives:

- 1.Spinal Cord Stimulation and Peripheral Nerve Stimulation
- 2.Intrathecal Therapies

**September 14, 2009**

**#7**

**Abstract Title:** Burst stimulation: towards paresthesia-free spinal cord stimulation

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## Introduction:

Spinal cord stimulation is commonly used for neuropathic pain modulation. The major side effect is the onset of paresthesias. The authors describe a new stimulation design which suppress the pain as well, or even better, but without creating paresthesias.

## Methods:

Twelve patients were implanted with a spinal cord stimulator for neuropathic pain. All underwent implantation of a lamitrode 44 (ANSMedical, Plano, TX) via laminectomy: 4 at the level of C2 and 8 at D9 for cervicobrachialgia and lumboischialgia respectively. During the period of external stimulation the patients received the classical tonic stimulation (40 or 50 Hz) and the new burst stimulation (40 Hz burst with 5 spikes at 500 Hz/burst).

## Results:

Pain scores were measured using a visual analogue scale (VAS) and a McGill Shortform during pre-operative, tonic and burst stimulation. Paresthesias were scored as present or not present. Burst stimulation is significantly better for pain suppression, both on VAS ( $Z=2.37$   $p=0,018$ ) as well as on the McGill Short form ( $Z=1.96$ ,  $p= 0,049$ ). Paresthesias were present in 92% of patients during tonic stimulation, during burst stimulation they were present in only 17%. The average amplitude for tonic stimulation is significantly higher than for burst stimulation: 3.1 mA (0.5-3.9 mA) versus 0.6 mA (0.05-1.6 mA),  $t(11) = 3.32$ ,  $p = .007$ . The average electrical charge per pulse for tonic stimulation is 1030 (mA\* $\mu$ s), for burst it is 654, a non-significant difference  $t(11) = 1.07$ ,  $p = .31$

The average electrical current delivery per second for tonic stimulation is 47.7 mA versus 130.8 mA, significantly lower  $t(11) = -2.627$ ,  $p=0,024$

**Conclusion:**

The authors present a new way of spinal cord stimulation using bursts in stead of tonic stimuli which suppresses neuropathic pain equally well or potentially better without inducing paresthesias. This permits future placebo controlled double blinded studies.

**Acknowledgements**

The authors thank SJM for their support

**Learning Objectives:**

1. burst stimulation can suppress pain without paresthesias
  2. burst uses lower amplitudes, but higher current delivery per second
- double blind placebo controlled studies become possible

**September 14, 2009**

**#8**

**Abstract Title:** Infrapatellar Peripheral Nerve Field Stimulation: An effective treatment option for anterior knee pain – A Case Study

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**Introduction**

Anterior knee pain is common but often difficult to treat. Here we demonstrate that peripheral nerve field stimulation (PNFS), a well accepted treatment for chronic low back pain (1, 2), can effectively treat knee pain when used to stimulate the infrapatellar branch of the saphenous nerve.

**Materials and Methods**

A 67-year-old patient with a complex history of 5 spinal surgeries, presented with neuropathic infrapatellar pain, stemming from a previous workplace accident in 1979. A previously implanted 4-electrode spinal cord stimulator system (SCS) placed centrally over T8/9 gave some relief, however high dose analgesics were being taken for referred pain in the upper tibial plate. Treatment options consisted of trialing a new SCS in lower T10, caudal to the current system or a PNFS trial with 2-leads placed along the upper anterior of the tibial pain band. Under fluoroscopy, dual octrode linear leads were trialed in the infrapatellar region for 15 days. This provided outstanding pain relief. The patient proceeded to implantation of leads, tunneling superiorly to the IPG in the supero-medial thigh caudad to scrotum.

## Results

At three months post implantation, the average stimulation parameters were  $3.9 \pm 0.6$  mA, 300-500pw and 60 Hz. Pain levels of 1 VAS (8 pre implant) was demonstrated, with 87.5% improvement in pain and a reduction of 13 points on the Oswestry disability index. Whilst a score of 42 prior and 41 post implantation was recorded on the Zung self-assessed depression index, the patient reported diminished feelings of depression 3 months on. Furthermore, pre-operative analgesic use of Oxycontin 320mg/day was weaned to nil over 6 weeks post implantation. Lastly, the patient claimed that this was the first time since 1979 that they been without pain.

## Conclusion

Infrapatellar peripheral nerve stimulation resulted in reduced pain, analgesic use and disability, and proved to be an effective treatment for chronic anterior knee pain.

## Acknowledgements

We would like to acknowledge Robert Gorman and Philippa Marks from Boston Scientific for providing technical information

## References

1. Paicius RM, Bernstein CA, Lempert-Cohen C. Peripheral nerve field stimulation for the treatment of chronic low back pain: preliminary results of long-term follow-up: a case series. *Neuromodulation* 2007;10:279–290.
2. Verrills P, Mitchell B, Vivian D, Sinclair C. Peripheral Nerve Stimulation: A Treatment for Chronic Low Back Pain and Failed Back Surgery Syndrome? *Neuromodulation* 2009; 12: 68-75

**Figure Legend:** Fluoroscopic images of dual octrode leads horizontally placed bilaterally over the infrapatellar region and the IPG placed in the supero-medial thigh caudad to scrotum.

## Learning Objectives:

1. Wider application for Peripheral Nerve Field Stimulation
2. Treating chronic anterior knee pain with infrapatellar lead placement

**September 14, 2009**

**#7**

**Abstract Title:** A Prospective, Multi-Centered Clinical Evaluation of A Newly Released 16-Channel Implantable Pulse Generator (IPG) for the Management of Chronic Pain of the Trunk and/or Limbs: Final Results.

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## **Introduction**

Spinal Cord Stimulation (SCS) is a proven treatment for chronic pain, but there is still a need of additional high-quality prospective clinical study data. The study being presented is a prospective, multi-centered, 45 day follow-up study using the Eon<sup>®</sup> Mini implantable pulse generator (IPG; St. Jude Medical Neuromodulation; Plano, TX).

## **Methods**

This IRB-approved study was a prospective, multi-centered, 45 days post implantation study. After informed consent was obtained, patients were screened according to the inclusion criteria. Following system implantation, patients were seen at initial programming, 21 days and 45 days post-implantation. The primary objective was to demonstrate that the Eon Mini is equivalent to the Eon in recharging intervals. Data collected included: device programming and stimulation coverage, pain evaluation, battery recharging information and patient satisfaction.

## **Results**

Preliminary data analysis from 36 patients at the 45 day time-point showed that 75% of patients reported 50% pain relief or better and the mean overall patient reported pain relief was 61.0% in these patients. Most patients (83.3%) were either very satisfied or satisfied with their SCS device and most (80.6%) patients say their quality of life has either greatly improved or improved since SCS implantation. The majority of patients (44.4%) recharged on a weekly basis and it took less than 1 hr to recharge in most patients (80.6%). Over the course of the study, 40.3% of patients utilized the portability of the system. No patients reported any lack of adequate pain relief while recharging. Final data will be presented.

## **Conclusion**

To date, patients have experienced good battery recharging intervals with the Eon Mini when compared with the Eon IPG in the management of chronic pain of the trunk and or limbs.

## **Acknowledgements**

This work was supported by St. Jude Medical Neuromodulation Division through a sponsored clinical research study. Dr. Deer is a paid consultant of St. Jude Medical Neuromodulation.

## **Learning Objectives:**

1. Describe results of spinal cord stimulation using percutaneous and paddle leads in conjunction with a smaller IPG for the treatment of chronic pain.
2. Discuss how the results from this study compare to those obtained using a larger IPG.
3. Understand the differences in battery recharging between the larger and smaller IPG.

**September 14, 2009**

**#8**

**Abstract Title:** An evaluation of the effect of stimulation parameters on efficacy measures in spinal cord stimulation for chronic pain

**Primary Presenter:** Jon Ruais

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### **Introduction**

There has been little examination of the impact of stimulation parameters including, frequency, pulse width, and amplitude settings in relation to spinal cord stimulation (SCS) efficacy for chronic pain. Previous work on the strength duration curve and calculation of the chronaxie has been published, but this has not been related to SCS efficacy measures. The following analysis was undertaken to examine whether specific stimulation parameters were correlated with better SCS efficacy.

### **Material and Methods**

Data is presented an ongoing, IRB-approved, clinical research study conducted with patients implanted with a rechargeable implantable pulse generator (IPG; Eon® St. Jude Medical Neuromodulation Division, Plano, TX). Mean pulse width for each patient at each visit was calculated using the patients 1 or 2 favorite programs. For each patient visit, measures of pain relief, patient satisfaction, and quality of life were available. Analysis of variance was used to determine if there was any difference in average pulse width between patients with varying levels of pain relief, satisfaction, and quality of life. Also, the relationship between frequency, pulse width, amplitude and patient reported percent pain relief was explored using a Pearson correlation.

### **Results**

The mean frequency, pulse width and amplitude for patients were 66.2 Hz, 319.6  $\mu$ s, and 7.5 mA, respectively. Analysis of variance found no significant difference in frequency, pulse width, or amplitude among patients who reported varying levels of satisfaction, pain relief, and improvements in quality of life (all  $ps > 0.05$ ). There was no trend observed of increasing pulse width in increasing satisfaction, quality of life, or pain relief. In addition, Pearson correlations for each of the stimulation parameters were not significant.

### **Conclusion**

Frequency, pulse width, and amplitude settings do not appear to have any effect or relationship to efficacy measures among patients with rechargeable IPGs.

### **Acknowledgements**

This work was supported by St. Jude Medical Neuromodulation Division through sponsored clinical research studies.

### **Learning Objectives:**

1. Review and understand the three main stimulation parameters.

2. Discuss how these parameters can be used to optimize stimulation and pain coverage.
3. Understand how stimulation parameters impact patient outcomes.

**September 14, 2009**

**#9**

**Abstract Title:**

Peripheral Nerve Field Stimulation for Chronic Craniofacial Pain A Prospective Study

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**Abstract Title**

Peripheral Nerve Field Stimulation for Chronic Craniofacial Pain □ A Prospective Study

**Introduction**

Treatment of chronic neuropathic pain in the region of the head, neck and face presents a challenge for pain specialists. Peripheral nerve field stimulation (PNFS) has been used to treat neuropathic pain for many decades, but only recently has it been applied systematically to the craniofacial region (1, 2). Here we present a study of PNFS in the treatment of craniofacial pain, demonstrating that it is an effective alternative to current pharmacological pain management strategies.

**Materials and Methods**

Over a 3.5 year period we assessed 40 consecutive patients who had a successful trial and were subsequently implanted with octrode percutaneous leads within the major area of craniofacial pain. Questionnaires, along with patients □ histories were used to assess outcomes such as pain (VAS), analgesic use, anxiety, depression (Zung depression index) and disability (neck disability index). A follow up rate of 100% was achieved with an average follow up of 8.1 ± 4.6 months (range 1-18 months).

**Results**

Overall, there was a statistically significant reduction in pain levels following PNFS, with an average reduction of 4.7± 2.4 VAS (p "d 0.05), resulting in an average pain relief of 61.2 ± 27.2%. PNFS was successful (pain relief >25) in 87% of patients and reduced pain by 5.2± 2.1 VAS (p "d 0.05) in this group. Forty-one percent of the patients received pain relief of between 75-100%. Where data was available, post-operative anxiety dropped by 53.0 ± 35.9%, whilst

disability improved by  $9.7\% \pm 12.7\%$ . Of the Zung depression scores obtained, half of the patients reported reductions in their depression index following implantation. Fifty-two percent of patients reported a moderate to extreme reduction in their analgesic use.

### **Conclusion**

PNFS for craniofacial pain is an evolving and increasingly performed treatment for craniofacial pain. This study demonstrates that this reversible and effective treatment is a promising pain relief strategy for otherwise intractable conditions.

### **References**

- 1) Goadsby PJ, Bartsch T, & Dodick DW. Occipital nerve stimulation for headache: mechanisms and efficacy. *Headache* 2008. 48:313-8
- 2) Slavin KV, Colpan ME, Munawar N, Wess C, & Nersesyan H. Trigeminal and occipital peripheral nerve stimulation for craniofacial pain: a single-institution experience and review of the literature. *Neurosurg Focus* 2006. 21:E5

Figure Legend: (Please submit original artwork in separate file.)

Fluoroscopic images of peripheral nerve field stimulator leads implanted bilaterally over the fronto-temporal area and left supra-orbital and right occipital regions. An IPG placed in a pocket created in the right infraclavicular chest wall

### **Learning Objectives:**

1. Peripheral Nerve Field Stimulation is an effective treatment option for patients with chronic craniofacial pain.
2. Placement of leads for head, neck and face pain management

**September 14, 2009**

**#10**

**Abstract Title:** Management of Loin Pain Haematuria Syndrome with the use of Spinal Nerve Root Stimulation

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### **Introduction**

Loin Pain Haematuria Syndrome (LPHS) is an uncommon condition. This condition may be associated with severe loin pain which can be difficult to treat. We are presenting two cases

where conventional medical treatment as well as interventional pain procedures failed to provide consistent long term pain relief.

### **Materials and Methods**

The first case was a 37 year old lady who was suffered from severe pain in the right loin for many years. Her condition started as (LPHS) which was then complicated by an abscess which was surgically drained. Unfortunately this left her with continuous severe neuropathic pain in her right loin radiating to the right groin area. She was on multiple medications including high dose opioids. She also underwent T10/11/12 nerve root blocks but this did not provide sustained pain relief. The urologists and the nephrologists contemplated nephrectomy despite the fact that the kidney was fully functional. A trial of spinal nerve root stimulation (SNRS) at T10/11/12 was performed in Sept 2004 with excellent pain relief. All her analgesics were stopped. She then underwent full implantation. To date she is still experiences excellent pain relief no any further analgesia.

The second case was a 45 year old lady with longstanding LPHS. She had a complex medical history including lupus erythromatosis and its associated complications. Moreover she also suffered from Fowler Syndrome (urinary retention)and had a permanent pacemaker for cardiac arrhythmia. The patient was implanted with a dual lead. The first lead was on the left at the level of T10/11/12 spinal nerve roots and the other was a quad lead inserted retrograde fashion to the right S2-S4. The implant successfully controlled her loin pain and eliminated the need for suprapubic catheterisation.

### **Conclusion**

In conclusion, spinal nerve root stimulation can be a vital tool to control complex pain including LPHS. To the best of our knowledge, this is the first report of the use of SNRS for this condition.

### **Learning Objectives:**

- 1.Spinal cord stimulation is an emerging technique for loin pain haematuria syndrome
- 2.Knowledge of its success should prompt physicians to refer appropriate patients

**September 14, 2009**

**#11**

**Abstract Title:** Peripheral Subcutaneous Field Stimulation vs Sacral Nerve Root Stimulation in the management of refractory Coccygodynia. (Preliminary report)

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### **Introduction**

Peripheral Subcutaneous Field Stimulation (PSFS) is an evolving technique in the management of a variety of neuropathic pain conditions including Coccygodynia (1). However, this technique

may be associated with lead migration and inconsistent stimulation. Sacral Nerve Root Stimulation (SNS) had been successful in the management of pelvic pain (2). This is an ongoing study comparing the two techniques in the management of refractory Coccygodynia.

## **Materials and Methods**

Two quad leads were implanted simultaneously in patients suffering from severe coccygodynia, refractory to different modalities of treatments, including radiofrequency denervation of the coccygodynia nerves. One quad plus lead was positioned to cover the painful area (PSFS) and the second sander quad lead was inserted via a retrograde approach to stimulate the S4 & S5 Sacral Nerve Roots (SNS). The patient had a one week trial of each lead independently. The patient was blinded to the knowledge of which lead was activated. The measurements consisted of pain VAS score, paresthesia coverage of desired painful area, change of the stimulation with movements and amplitude of stimulator.

## **Results**

In all parameters measured the patient preferred the SNS to the PSFS

## **Conclusion**

This preliminary report demonstrates that both Peripheral Subcutaneous Field Stimulation and Sacral Nerve Root Stimulation are effective neuromodulation techniques in the management of refractory Coccygodynia. However, our preliminary data demonstrates that SNS provides better and consistent paresthesia coverage with high patient's satisfaction.

## **References**

1. Theodosiadis P, Goroszeniuk T. short term neuromodulation trial via stimulating catheter in Coccygodynia treatment Regional Anaesthesia and pain Medicine. Sept/Oct. 2004;29,5. Supplement 2.
2. Alo K et al. Neuromodulation Volume 2, Number1, 1999 23-31

## **Learning Objectives:**

1. A choice of peripheral vs central neuromodulation for coccydynia needs careful consideration

**September 14, 2009**

**#12**

**Abstract Title:** A Prospective, Randomized, Multi-Centered Crossover Study to Evaluate Constant Current Versus Constant Voltage Trial Stimulation Systems: Patient Perceived Differences

**Primary Presenter: Roni Diaz**

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## **Introduction**

Electrical stimulation can be supplied to the spinal cord using either a constant current or a constant voltage power source. Both systems produce paresthesia and both have been shown to treat chronic pain. However, it has been suggested that patients prefer constant current over constant voltage. This study compares patient preference for the stimulation sensation elicited by constant current and constant voltage systems.

## **Materials and Methods**

This study was an IRB-approved, prospective, randomized, double-blinded, multi-centered, crossover study during a 6-day trial period. Thirty patients were randomized into 2 groups; Group A received constant voltage stimulation and Group B received constant current stimulation. Patients completed a baseline evaluation prior to implantation and returned 1 day post-operatively for randomization and stimulation programs. Three days later, patients were evaluated and crossed over into the alternate treatment group. The same trial programs were used throughout the study. At 6 days post-operatively, patients returned for the final evaluation. Patient well being, pain, satisfaction/QOL, preference and stimulation sensation were evaluated.

## **Results**

Significantly more patients preferred constant current over constant voltage stimulation, with 70% preferring constant current and only 30% preferring constant voltage (one sample z-test,  $p = 0.04$ ). In addition, constant current stimulation produced a significantly larger decrease in pain scores than constant voltage stimulation. During constant voltage stimulation, 17 patients (56.7%) were satisfied or very satisfied and 13 patients (43.3%) were unsatisfied or very unsatisfied. During constant current stimulation, 22 patients (73.3%) were satisfied or very satisfied and only 8 patients (26.7%) were unsatisfied. Interestingly, patients initially exposed to constant current stimulation were less likely to be satisfied with constant voltage stimulation. Analysis of stimulation sensation revealed that the term "soothing" was used more often to describe constant current stimulation.

## **Conclusion**

Patients preferred and experienced greater satisfaction, and pain relief with the constant current system.

## **Acknowledgements**

This work was supported by St. Jude Medical Neuromodulation through a sponsored clinical research study. Dr. Catlin and Dr. Canlas are paid consultants of St. Jude Medical Neuromodulation.

## **Learning Objectives:**

1. Understand the difference between constant current and constant voltage systems.
2. Review the evidence for patient preference for constant current systems.
3. Discuss potential mechanisms for this preference.

**September 14, 2009**

**#13**

**Abstract Title:** Final Result from a Cost-Utility Analysis of Spinal Cord Stimulation Using a Rechargeable Implantable Pulse Generator (IPG) for the Relief of Chronic Back and Leg Pain

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**Introduction**

Spinal cord stimulation (SCS) systems can be expensive, making it imperative to analyze the costs and benefits associated with SCS treatment. There are two general types of cost-benefit analysis: cost-effectiveness and cost-utility analysis. In the latter, the costs are compared against the health effects of the treatment, but health effects are measured in terms of quality-adjusted life-years (QALYs) gained. QALYs are widely used because they are a useful outcome measure that combines patient-perceived health-related quality of life (QOL), patient preference (utility), and survival. The use of QALYs is especially important for economic assessment of SCS treatment, in which increases in quality rather than quantity of life are expected. Therefore, a cost-utility analysis was chosen for this study.

**Materials and Methods**

Patient demographics, healthcare utilization data and prescription information were retrospectively collected from the medical records of patient currently enrolled in 2 ongoing studies investigating the effectiveness of a rechargeable IPG in combination with 2 or 3 leads for the treatment of chronic back and leg pain. The total cost of office visits and procedures related to patient pain, including the price of the SCS system, were totaled for the year prior to

and after implantation using 2007 Medicare reimbursement rates. Average wholesale price was used to calculate medication costs and patient-perceived health-related QOL was measured using the SF-36.

### **Results**

Preliminary data from 21 patients shows that the mean cost per QALY gained was \$27,274.64 over the 10 year life of the IPG. Subgroup analysis revealed that patients diagnosed with Failed Back Surgery Syndrome (FBSS) showed more improvement in utility scores than patients diagnosed with radiculopathy. Also, patients who received a 3 lead system showed more improvement in utility scores than those who received a 2 lead system. However, neither of these differences was statistically significant. Final results will be presented.

### **Acknowledgements**

This work was supported by St. Jude Medical Neuromodulation Division through a sponsored clinical research study.

### **Learning Objectives:**

1. Identify the different types of cost-benefit studies.
2. Understand why a cost-utility analysis was chosen for this study.
3. Describe the costs and benefits associated with spinal cord stimulation.

**September 14, 2009**

**#14**

**Abstract Title:** The Use of Patient Pain Descriptors for Better Patient Selection in Spinal Cord Stimulation Treatment

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### **Introduction**

Appropriate patient selection will undoubtedly contribute to improved spinal cord stimulation (SCS) success. It is generally assumed that spinal cord stimulation is better suited for the treatment of patients with neuropathic versus nociceptive or mixed pain syndromes. However, appropriate patient selection for SCS remains elusive. The use of pain descriptors in patient pain evaluation can help to suggest the etiology and underlying mechanisms of pain. Descriptors such as burning or shooting are often associated with neuropathic pain whereas descriptors such as cramping and squeezing suggest visceral pain. It has not been systematically evaluated whether patient pain descriptors can be used to predict SCS success and improve patient selection. The purpose of this study was to investigate this issue.

## **Materials and Methods**

This data analysis is from a prospective, IRB-approved study in which patients were implanted with either percutaneous or paddle leads and a rechargeable implantable pulse generator (St. Jude Medical Neuromodulation Division, Plano, TX). Data was collected at baseline, 1-month, 3-months, 6-months, 1-year, 18-months, and 2-years post-implant. Patient pain descriptors were obtained from the SF-McGill Pain Questionnaire (SF-MPQ) at the baseline study visit and each descriptor was correlated with overall patient reported pain relief at the 1-year study visit using Pearson correlations. This analysis was further extended to examine the relationship between groups of pain descriptors and pain relief as well as pain intensity reported for each descriptor and pain relief.

## **Results**

A significant negative correlation between cramping and patient reported pain relief ( $r = -0.27$ ,  $p < 0.01$ ), suggesting that patients who reported higher intensity cramping pain at the baseline visit experienced less pain relief at the 1-yr visit than patients who did not. No other significant correlations were observed.

## **Conclusion**

These results suggest that evaluation of patient pain descriptors may help to identify those better suited for SCS treatment.

## **Acknowledgements**

This work was supported by St. Jude Medical Neuromodulation through sponsored clinical research studies.

## **Learning Objectives:**

1. Describe the difference between neuropathic and nociceptive pain.
2. Identify which pain descriptors are typically used to describe which pain type.
3. Understand how patient pain descriptors can be used to identify those better suited for SCS treatment.

**September 14, 2009**

**#15**

**Abstract Title:** A Prospective, Multi-Centered Clinical Evaluation of a Rechargeable 16-Channel Implantable Pulse Generator (IPG) in Combination with Percutaneous or Surgical Leads for the Management of Chronic Back Pain with or without Leg Pain: Further Evidence for the Use of SCS

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## **Introduction**

We have previously shown that spinal cord stimulation (SCS) treatment results in adequate pain relief, patient satisfaction, and improved quality of life as measured by a global impression item, SF-36 and Oswestry Disability Questionnaire at 1-year post-implant (Ghodis et al., 2008). Additional data supporting the use of SCS for the management of chronic pain is presented here.

## **Materials and Methods**

This study was designed as a prospective, multi-centered, 2-year study. All study sites and the protocol were IRB approved. After informed consent was obtained, patients were screened according to the inclusion/exclusion criteria and baseline measures were obtained. Patients were implanted with a rechargeable 16-Channel IPG and percutaneous or surgical leads (all St. Jude Medical Neuromodulation Division, Plano, TX). Following system implantation, patients were seen at 1-month, 3-months, 6-months, 1-year, 18-months, and 2-years. Data presented here is from the 1-year timepoint and includes results from the following measures: Patient quality of life as measured by a global impression item, Pain Disability Index, Pain and Distress Scale, and SF-McGill Pain Questionnaire.

## **Results**

On the patient quality of life global impression item, 80.5% of patients reported being improved or greatly improved. The mean Pain Disability Index score was significantly reduced from 50.2 at baseline to 35.8 at 1-year (paired sample t-test,  $p < 0.001$ ). A significant reduction in mean Pain and Distress scale scores was also observed ((paired sample t-test,  $p < 0.001$ ). Mean scores on both the sensory and affective component of the SF-McGill were significantly reduced from baseline (paired sample t-tests,  $p < 0.001$ ). Present pain intensity and visual analog scores were also significantly reduced ((paired sample t-test,  $p < 0.001$ ).

## **Conclusion**

The results presented here provide further evidence to support the use of SCS in patients with chronic back pain with or without leg pain.

## **Acknowledgements**

This work was supported by St. Jude Medical Neuromodulation Division through a sponsored clinical research study.

## **Learning Objectives:**

- 1 Describe results of spinal cord stimulation using percutaneous and paddle leads in treatment of chronic pain.
2. Discuss low rate of surgical and treatment-related complications of spinal cord stimulation.

3. Discuss ability to maintain patient satisfaction and quality of life with spinal cord stimulation over time.

**September 14, 2009**

**#16**

**Abstract Title:** Theoretically 'best' electrode configurations in SCS for chronic back pain and clinical experience: do they match ? Preliminary results of a prospective study.

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**Introduction**

In SCS it is known to be a challenge to treat pain in the lower back effectively, in contrast to pain in the lower extremities. For a durable good result a complete coverage of the pain area is required.

Theoretical models, mainly emerging from publications by e.g. Holsheimer *et al.*, predict that certain electrode configurations produce broader stimulation of the dorsal columns, and should result in better coverage of the back: longitudinal bipole, longitudinal tripole and transverse tripole.

**Materials and Methods**

In a prospective trial we study the results of SCS on chronic back pain in two groups of each 10 patients, randomly assigned: one group receiving a single longitudinal octapolar lead (Medtronic), the other group a surgical 5-6-5 lead (Medtronic) with three rows of electrode contacts in parallel. In case the single octapolar lead is not successful in producing paresthesia in the lower back, two quadripolar leads are to be inserted additionally, permitting a transverse tripolar stimulation pattern.

The octapolar and quadripolar leads are implanted in percutaneous technique, the surgical leads in general anesthesia.

**Results**

The active electrode configurations of all patients are critically assessed, with special focus upon the configurations which produce efficient paresthesia in the lower back. These data are correlated with theoretically optimal electrode configurations.

We will discuss the preliminary results of our first 10 patients, and focus on the number of 'theoretically typical configurations'.

Furthermore we will offer possible explanations for 'out of line' electrode configurations which produce back paresthesia, and for the occurrences of being unable to reach the lower back.

**Conclusion**

The described therapeutic models seem to be promising in treating chronic back pain, supporting the theoretical models.

**Learning Objectives:**

1. summarizing the theoretically most promising electrode configurations for treating back pain in SCS
2. discussing the significance of the theoretical models in clinical practice

**September 14, 2009**  
**#17**

**Abstract Title: Permanent implantation of Brachial Plexus Stimulator- A Case Series**

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**Introduction**

Neuromodulation as a management in intractable pain is a modality being increasing used. The indications for neuromodulation are increasing as it is being recognised to be useful in various chronic pain states. Increasingly various approaches to neuromodulation are being described. The neuromodulation modalities used are spinal cord stimulation, nerve root stimulation, peripheral nerve stimulation and subcutaneous peripheral stimulation. Spinal cord stimulation is not always possible in some patients. Cervical spinal cord stimulation is further associated with higher incidence of lead migration and loss of stimulation This is a case series of Brachial plexus neuromodulation in the management of chronic pain states of arm.

**Materials and Methods**

Seven patients with CRPS, Neuropathic pain, and phantom pain were implanted with a brachial plexus stimulation. All patients were assessed in a multidisciplinary setting and underwent monopolar stimulation trial. Fifteen patients underwent stimulation trial and after a successful trial, seven patients had a permanent neurostimulation system implanted. Patients were implanted with leads stimulating the brachial plexus in the supra clavicular fossa with the IPG implanted in the pectoral area or the abdomen as was felt comfortable for the patients. Initially leads were placed with a posterior approach and later a modified anterior approach.

**Results**

All the patients had reduction in pain scores and decreased need for medication. One patient with decreased sensation and motor function had improved sensation and function of his arm following the implantation

**Conclusion**

Brachial plexus stimulation should be considered an option in management of chronic pain states. Although a small numbers of patients the results are promising with reduction in pain scores. Long term follow-up to monitor the continued response and detect problem is necessary.

**References**

**T. Goroszeniuk, S. Kothari, W.C Hamann**

Percutaneous Implantation of a Brachial Plexus Electrode for Management of Pain Syndrome Caused by a Traction Injury  
Neuromodulation Volume 10, Issue 2, Pages148 - 155

**September 14, 2009**  
**#18**

**Abstract Title:**

Infection rate of spinal cord stimulators after a screening trial period.  
A 53 month third party follow-up.

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**Background/aims:**

The aim of this audit project is to compare the incidence of SCS infections at Basildon Hospital (UK) after a screening trial period during the period 2004 to May 2008 with the infection in the literature (3.4 to 12 %) and to a previous report at Basildon Hospital (UK) (May et al. 2002)

**Methods:**

81 patients were retrospectively and sequentially reviewed during 53 successive months (2004 to May 2008). All patients had SCS implanted for the first time with a screening trial period lasting 10 days on average. This includes patients with a) 1<sup>st</sup> and 2<sup>nd</sup> stage implantation, b) 1<sup>st</sup> stage implantation + trial period + removal. Two operators with different experience levels implanted the SCS.

On the day of the 2<sup>nd</sup> stage implantation a wound swab was taken for microbiological analysis. An infection was present when a patient showed local or systemic clinical signs of an infection or in combination with a positive microbiology result when the SCS had to be removed or the patient had to be treated with a course of antibiotics.

**Results:**

43 patients were male and 38 female with a mean age of 52 years. All patients had a temporary 1<sup>st</sup> stage implant and 65 patients proceeded to a permanent implant (2<sup>nd</sup> stage). In 15 patients the SCS was removed because of inadequate pain relief and in 1 patient because of an infection of the SCS.

Peri-operatively the patients received 1-3 doses of prophylactic antibiotics (either Coamoxiclav, Cephadrine, Cefuroxime, Vancomycin or Erythromycin). In 95 % of all 2<sup>nd</sup> stage implantations wound swabs were taken for microbiological analysis.

4 patients (5 %) developed a wound infection: 1 infection during the trial period with Staph. Aureus and the SCS electrode had to be removed. 3 infections after the 2<sup>nd</sup> stage implantation (2 with MRSA and 1 with skin type flora) were successfully treated with antibiotics and did not have to be removed. Another 4 wound swabs showed skin (3) or faecal (1) type flora without clinical signs of infection.

**Conclusions:**

The infection rate following 1<sup>st</sup> stage SCS trial at Basildon Hospital was 1.2 %. The infection rate following the 2<sup>nd</sup> stage full implant was 3.8 %. This compares favourably to the previous audit period published by May et al (2002) from the same institution where the infection rate following second stage implantation had reached 7.5%. The more experienced operator (16 years experience) had an infection rate of 1.8 % whereas the less experienced operator (7 years experience) had an infection rate of 13 %.

Improved dressing (colloid dressing sandwich-like technique), enhanced prophylactic antibiotics therapy and improved operator skills may have contributed to the decreased infection rate. Most of the literature only publishes infection rates of the full implant. In this series the second stage implant rate of infection of 3.8 % is within the internationally reported range (3.4 to 12%). According to these findings a SCS screening trial does not seem to increase the incidence of SCS infections above expected levels.

The risk of infection should not be used as a reason to avoid trials of spinal cord stimulation by experienced operators providing adequate dressing, theatre and antibiotic policies are followed.

### **Learning Objectives:**

1.Brachial Plexus is an useful technique to be considered in management of neuropathic pain

**September 14, 2009**

**#19**

**Abstract Title:** The tripolar paddle lead : a tool for axial pain

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**Introduction:** Spinal cord stimulation has been used in the treatment of many chronic pain disorders since 1967 and the application list is increasing ever since. Spinal cord stimulation (SCS) is an adjustable, nondestructive, neuromodulatory procedure that delivers therapeutic doses of electrical current to the spinal cord for the management of neuropathic pain. The most common indications include Failed back surgery syndrome (FBSS), complex regional pain syndrome, ischemic limb pain, and angina.

Great advances in technology have occurred in the field. The electrodes were initially all unipolar; the bipolar arrays developed subsequently. Most of the advances following that were involving the pulse generators, batteries and programming modules.

**Materials and Methods:**The goal of this review is to report on the use of the recently released tripolar lead at the Montreal neurological Institute/Hospital

**Methods:**The review extended between July 2007 till present and included 23 patients with FBSS. These patients were submitted to surgical implantation of the 5-6-5 configuration tripolar paddle-type lead.

### **Results**

Sixty five percent of the patients in this group contributed more than 50% of the overall pain to the back as compared to the leg pain. Fifteen patients representing 65% of the cohort reported more than 50% reduction of the pain with 10 patients experiencing more than 70% reduction of the pain. The trial failure was seen in 10% of the cohort.

**Conclusion:**This is an excellent outcome in this group of patients. The tripolar lead for spinal cord stimulation broadens the degree at which the neuromodulation could be delivered, allowing

for multiple simultaneous programs to take effect targeting different body regions at various intensities tailored to the clinical response. It represents a major step into refining the neuromodulation capacity of this highly promising technology.

### **Learning Objectives**

- 1-After this presentation the audience will be able to consider other options for the treatment of failed back surgery syndrome with axial pain
- 2-Will review the anatomy concept behind the neuromodulation for axial pain

**September 14, 2009**

**#20**

**Abstract Title:** Spinal cord stimulation for the patient who had painful legs and moving toes syndrome (PLMT): A case report

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### **Introduction**

A case of 30-year-old male with painful legs and moving toes syndrome (PLMT) was successfully treated with spinal cord stimulation.

### **Materials and Methods**

A 30-year-old male has pain and involuntary movement on bilateral leg and foot. Previously, he had lumbar spinal arachnoiditis that was occurred by two times of lumbar spine surgeries. He was treated with several medications, epidural block, and transcutaneous nerve stimulation. But, those results were very poor. And so we performed spinal cord stimulation.

### **Results**

Pain and involuntary movement were near completely relieved during the stimulation and the effect was still persisting 10 months later. Postoperatively, pain score was down from 8 to 2 in visual analogue score (VAS), involuntary movement was disappeared after stimulation. But involuntary movement was recurred at off status. This patient fully satisfied to the result of operation.

### **Conclusion**

Until now, this is a third case of PLMT that was successfully treated by spinal cord stimulation. This method should be considered an alternative therapeutic tool in the treatment of cases which are refractory to pharmacological therapies.

### **References**

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2. H. Takahashi, C. Saitoh, O. Iwata, T. Nanbu, S. Takada, S. Morita. Epidural spinal cord

stimulation for the treatment of painful legs and moving toes syndrome. Pain. 2002. 96 : 343–345

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**Learning Objectives:**

1. The effect of Spinal cord stimulation of painful legs and moving toes syndrome.
2. After stimulation, what's the inhibition mechanism of involuntary movements in patient of painful legs and moving toes syndrome

**September 14, 2009**

**#21**

**Abstract Title:** Spinal cord Stimulation for the management of post-traumatic cervical syrinx associated with neuropathic pain.

**Primary Presenter:** Dr. Daniel Kirubakaran, FFARCSI

**Primary Presenter Institution:** St. Vincent's University Hospital Dublin, ROI

**Co-presenter(s):** Dr.Tolu Alugo, Dr.Femi Odejayi, Dr.Rosemary Walsh\*  
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**Introduction** Post traumatic syringomyelia may be associated with segmental neuropathic pain affecting both trunk and limb.We report the case of a 28 year old female who suffered cervical pain following MVA.She subsequently underwent cervical spine manipulation under general anaesthesia and awoke with severe neuropathic pain affecting her left upper limb and chest wall.

Subsequent MRI revealed the presence of syrinx located at C2-4 and C6-T2.The patient underwent multiple pain management procedures including,stellate ganglion blocks,cervical median branch block,cervical epidural and rhizotomy all of which were ineffective.She utilized all conventional anti-neuropathic medication and required substantial opioid doses.

Pain score were rated as 8-9/10 on VASPI. Psychometric evaluation revealed significant fear-avoidant behaviour and marked kinesiophobia. She was unable to work as a result of her ongoing pain.

The patient underwent percutaneous trial of Spinal Cord Stimulation. A single octode electrode (Medtronic Inc) was placed covering C2-C6.Stimulation was obtained over all affected areas and the patient was discharged home for a trial period. She reported 90% pain relief and subsequently underwent full implantation.

Six months post implantation, the patient continues to report analgesia in excess of 90% and is no longer utilizing analgesic medications. She has returned to full time employment and all psycho-metric parameters have normalized.

**Materials and Methods:** patient

A single octode electrode(Medtronic Inc.)

**Results:** Effective analgesia with a scs in neuropathic pain secondary to MVA associated with syringomyelia

**Conclusion**

This paper reports the use of SCS in the management of post-traumatic cervical syringomyelia associated neuropathic pain. This is the first case reporting effective use of this modality in the management of this complex pain condition.

**References**

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**September 14, 2009**

**#22**

**Abstract Title:** Spinal cord stimulation for neuropathic pain modulates rCBF pain and emotional association areas

**Primary Presenter:** Haruhiko Kishima M.D., Ph.D.

**Primary Presenter Institution:**

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**Introduction**

Spinal cord stimulation (SCS) is an effective therapy for chronic neuropathic pain. However, the detailed mechanisms underlying its effects are not well understood.

**Materials and Methods**

Nine patients with intractable neuropathic pain in the lower limbs were included in the study. All patients underwent SCS therapy for intractable pain, which was due to failed back surgery syndrome in three patients, complex regional pain syndrome in two, cerebral hemorrhage in two, spinal infarction in one, and spinal cord injury in one. Regional cerebral blood flow (rCBF)

was measured by H<sub>2</sub><sup>15</sup>O PET before and after SCS. The images were analyzed with statistical parametric mapping software (SPM2).

### **Results**

SCS reduced pain; visual analog scale (VAS) values for pain decreased from 76.1 ± 25.2 before SCS to 40.6 ± 4.5 after SCS (mean ± SE). Significant rCBF increases were identified after SCS in the thalamus and parietal association area contralateral to the painful limb, and in the ipsilateral posterior thalamus (pulvinar). The anterior cingulate cortex (ACC) and prefrontal regions were also activated after SCS.

### **Conclusion**

These results suggest that SCS modulates supraspinal neuronal activities. The contralateral thalamus, ipsilateral pulvinar, and parietal association area would regulate the pain threshold. The ACC and prefrontal region would control the emotional aspects of intractable pain, resulting in the reduction of neuropathic pain after SCS.

**September 14, 2009**

**#23**

**Abstract Title:** Indepth Analysis of the Improvement in Pain, Function and Quality of Life in Patients with Failed Back Surgery Syndrome (FBSS) Following Spinal Cord Stimulation (SCS) and Conventional Medical Management (CMM).

**Primary Presenter:** K. Kumar. M.B.B.S., M.S., F.R.C.S.C.

**Primary Presenter Institution:** Department of Neurosurgery, Regina General Hospital, Regina, Canada

**Co-presenter(s):** , Eldabe S (M.D.)<sup>1</sup>, Buchser E (M.D.)<sup>2</sup>, Taylor RS (MSc, PhD)<sup>3</sup>

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### **Introduction:**

Patients with FBSS experience pain, disability and reduced health-related quality of life (HRQoL) despite successful spine surgery. This analysis evaluates changes in dimensions of HRQoL, function and pain for patients receiving SCS plus CMM or CMM alone.

### **Materials and Methods:**

RCT of 100 patients with persistent neuropathic pain, predominantly in the legs. Back and leg pain relief, change in dimensions of HRQoL (Short-Form 36 [SF-36], EuroQoL-5D [EQ-5D]) and function (Oswestry Disability Index [ODI]) from baseline to 6 months and 24 months was evaluated.

### **Results:**

48% of the SCS-group experienced ≥50% leg pain relief at 6 months (vs 9% in CMM-group). 38% of SCS-group achieved ≥30% back pain relief at 6-months (vs 14% in CMM-group). In the SCS-group, 34% (vs 59% in the CMM-group) experienced worsening of back pain, though no pattern in daily pain over the 4 day assessment period could be identified. The proportion of patients experiencing extreme pain reduced by 40% (from 70% to 36%).

At 6-months, all dimensions of the EQ-5D, SF-36 and ODI improved with SCS compared with CMM. Main SCS effects were seen in the pain (EQ-5D, SF-36 and ODI), social life (ODI) and anxiety (EQ-5D) dimensions. On the EQ-5D, compared with baseline, the proportion of patients with no self-care problems increased from 41% to 67% and those with no anxiety increased from 24% to 48% at 24 months. On the ODI, the main areas where pain prevented activity were sex life (12%) and lifting (7%).

### **Conclusions:**

FBSS patients receiving SCS experienced clinically meaningful improvement in leg pain relief, short- and long-term function and HRQoL compared with CMM alone. While SCS provided greater back pain relief for many patients than CMM alone, some patients in both groups experienced worsening back pain.

### **References:**

Kumar, K., Taylor, R. 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 randomised controlled multicentre trial of the effectiveness of spinal cord stimulation. *Neurosurgery* (2008), 63: 762-770.

### **Acknowledgements**

**The research was supported by Medtronic Inc.**

### **Learning Objectives:**

1. Management of neuropathic pain
2. Outcomes of spinal cord stimulation for failed back surgery syndrome
3. What domains are specifically improved using spinal cord stimulation and what needs to be improved.

**September 14, 2009**

**#24**

**Abstract Title:** Transverse Tripolar Stimulation: Recapture of Stimulation Target after Lead Migration or Impedance Changes by using Multiple Independent Current Control - A Computational Modeling Study

**Primary Presenter:** Dongchul C. Lee, PhD

**Primary Presenter Institution:** Boston Scientific Neuromodulation, Valencia, CA, USA

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### **Introduction**

In spinal cord stimulation (SCS), Transverse Tripolar Stimulation (TTS) is believed to stimulate dorsal column fibers exclusively by increasing the threshold of dorsal root fibers in the spinal cord. The threshold of root fibers is elevated by hyperpolarized membrane potentials from

transversally placed flanking anodes. For deeper penetration of stimulation in the dorsal column, anodes should be properly aligned with the central cathode, both transversally and dorsoventrally. Although radiographic-guided intraoperative lead placement may be carefully done, the physiological midline may be different from the anatomical midline. Also, inhomogeneity in the epidural space can create varying impedances at each contact along the lead at time of implant, and as the lead scars in over time. To overcome these uncontrollable factors in SCS, a computational model<sup>1</sup> predicts that a programming strategy using Multiple Independent Current Control (MICC) assists in maximizing the dorsal column target in TTS. We studied, (1) the effect of lead migration on targeting nerve fibers in the spinal cord, and (2) optimal programming strategies for TTS to adjust the stimulation field for differences in impedance along the lead at time of implant, and changes in impedance over time.

### **Materials and Methods**

A volume conductor model of a low-thoracic spinal cord with three epidurally-positioned cylindrical percutaneous leads was created, and the electric field was calculated using ANSYS, a finite element model tool. The activating function<sup>2</sup> for 10 um fibers was computed as the second difference of the extracellular potential along the nodes of Ranvier on the nerve fibers in the dorsal column. The Volume of Activation (VOA) and the central point of the VOA were computed using the predetermined threshold of the activating function.

### **Results**

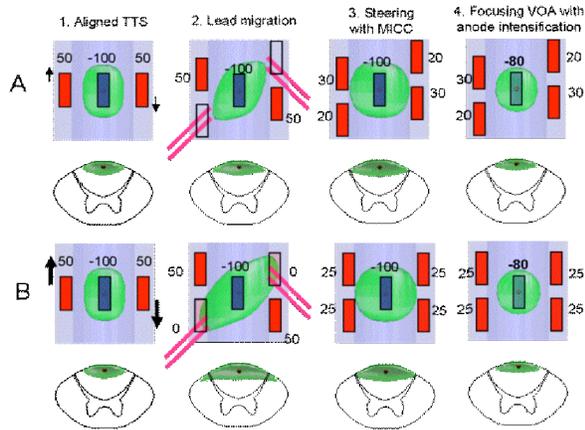
The computational model predicts that a system with MICC can recapture the original VOA which is lost when micro-migration occurs.

### **Conclusion**

To precisely correct the electric field, proper fractionalization of current to simultaneously active anodes and cathode(s) using MICC is required. When directly adjacent flanking anodes are not available (right most column in Fig 1), the model predicts that MICC can be used to focus the VOA using anode intensification.

### **References**

1. Struijk JJ, Holsheimer J, Spincemaille GH, Gielen FL, Hoekema R. Theoretical performance and clinical evaluation of transverse tripolar spinal cord stimulation. *IEEE Trans Rehabil Eng* 1998. 6(3):277-85
2. Rattay F. Analysis of the electrical excitation of CNS neurons. *IEEE Trans Biomed Eng* 1998 45(6):766-72



**Figure 1.** Programming strategy for TTS with lead migration. Volume of Activation for aligned TTS gave focused dorsal column recruitment (1). Lead migration (2) of lateral lead in rostrocaudal direction of 1mm (Row A) and 2 mm (Row B) changes the activated region (second column) and may cause root stimulation (red line). Precise programming with MICC shifted VOA back to medial dorsal column (3). Focused stimulation on medial column fibers can be achieved by local anode intensification (4), which is achieved by removing a specified portion of the local cathode to distal non-therapeutic contacts.

### Learning Objectives:

1. To study the effect of lead migration on targeting nerve fibers in the spinal cord
2. To study optimal programming strategies for TTS to adjust the stimulation field for differences in impedance

**September 14, 2009**

**#25**

**Abstract Title:** Transverse Tripolar Stimulation: Dorsal Column Steerability with Multiple Independent Current Control in a Computational Model

**Primary Presenter:** Dongchul C. Lee, PhD

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### Introduction

Transverse Tripolar Stimulation (TTS) is believed to stimulate dorsal column fibers exclusively by increasing the threshold of dorsal root fibers in the spinal cord. The threshold of root fibers is elevated by hyperpolarized membrane potentials from transversally placed flanking anodes. Previous clinical investigations using TTS have not shown that optimal programming is 'classically' transverse or tripolar in nature, possibly because device and lead design are without

certain programmable capabilities, such as field steering and positioning. Recently, a stimulator with Multiple Independent Current Control (MICC) (Precision Plus™ Spinal Cord Stimulator, Boston Scientific) and leads with tightly-spaced contacts has become available. Using a computational model based on work by Struijk and Holsheimer<sup>1</sup>, we explored the potential technical outcomes of this device when coupled to a transverse tripolar arrangement of contacts. We also compared the model results using field steering to model results of devices with a single voltage source or a single current source.

## Materials and Methods

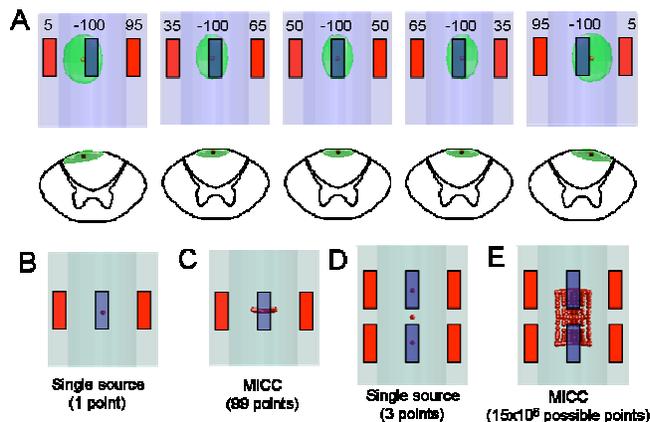
A volume conductor model of a low-thoracic spinal cord with three epidurally-positioned cylindrical percutaneous leads was created, and the electric field was calculated using ANSYS, a finite element modeling tool. The activating function<sup>2</sup> for 10 μm fibers was computed as the second difference of the extracellular potential along the nodes of Ranvier on the nerve fibers in the dorsal column. The Volume of Activation (VOA) and the central point of the VOA were computed using the predetermined threshold of the activating function.

## Results and Conclusion

The computational model makes the following predictions regarding field steerable Transverse Tripolar Stimulation (FS-TTS): (1) Using MICC, the VOA and its central point are steerable both mediolaterally and rostrocaudally by fractionalizing current to simultaneously active flanking anodes. (2) A device with MICC can target 99 times more central points mediolaterally and over 5 million times more central points in the coronal plane of the dorsal column than a conventional single source device. (3) A device with MICC can target nerve fibers more selectively than conventional single source systems.

## References

1. Struijk JJ, Holsheimer J, Spincemaille GH, Gielen FL, Hoekema R. Theoretical performance and clinical evaluation of transverse tripolar spinal cord stimulation. *IEEE Trans Rehabil Eng* 1998. 6(3):277-85
2. Rattay F. Analysis of the electrical excitation of CNS neurons. *IEEE Trans Biomed Eng* 1998 45(6):766-72



**Figure 1.** Steering volume of activation with Multiple Independent Current Control during Transverse Tripolar Stimulation (cathode: blue and anode: red). **A:** Volume of Activation and its central point during medio-lateral steering with coronal and axial view. **B:** A device with a single source can only target one central point when configured as a transverse tripole. **C:** A device

with MICC can target 98 central points medio-laterally when configured as a transverse tripole, providing left-right steering capability. (Graph shows 5% step size). **D:** A single source device configured as a TTS targets 3 central points with two rows of contacts in the coronal plane. **E:** A device with MICC configured as a TTS targets 15 million possible central points with two rows of contacts in the coronal plane.

### **Learning Objectives:**

1. To estimate the potential technical outcomes of this device when coupled to a transverse tripolar arrangement of contacts.
2. To compare the model results using field steering to model results of devices with a single voltage source or a single current source.

**September 14, 2009**

**#26**

**Abstract Title: Replacing a non-rechargeable for a novel rechargeable SCS device: a case report**

**Primary Presenter:** Maria Luisa Franco, MD

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### **Introduction**

A conventional, non-rechargeable SCS device has traditionally been replaced by yet another non-rechargeable device upon depletion of its battery. With arrival of rechargeable devices it has become possible to use them as replacement and therefore offer patient a longer-lasting device and, consequentially, less frequency of replacements. Here we report our experience with one such replacement.

### **Materials and Methods**

An FBSS patient with Synergy IPG and 2 Pisces Quad (Medtronic) leads originally implanted in parallel at Th9 came for replacement due to a depleted battery after 15 months of usage. Her therapy was fully functional before this event. During revision, the leads were left in situ and connected to a rechargeable IPG (Precision, Boston Scientific). Extension cables were used to convert 4-contact leads to 8-contact IPG ports. The existing IPG pocket in the abdomen was reused. The relative lead position was confirmed postoperatively using Electronically Generated Lead (EGL) scan feature, available on Precision system. Patient was surveyed at 1-month follow-up about the satisfaction with this replacement.

### **Results**

The result of EGL scan was verified on x-Ray and revealed a relative stagger between leads of ~5mm. Generally, such information should be used to optimize stimulation programs. Following the programming of the device, the SCS therapy was fully restored achieving equal paresthesia coverage and pain relief. At 1 month follow-up, patient reports a maintained result, thus indicating a viability of this solution. The patient is fully comfortable with the recharging process.

## **Conclusion**

Replacing a depleted non-rechargeable SCS device with a modern, rechargeable one has recently become possible. By doing so, patients may benefit not only from an expected less number of surgeries for battery replacements but also from the sophisticated technologies and solutions that some rechargeable systems offer. We reported here a single patient who has experienced such a benefit. Further evaluations are required.

## **Learning Objectives:**

- 1) Replacing a non-rechargeable SCS device by a rechargeable is feasible
- 2) Rechargeable systems may bring patients therapeutic benefits thanks to novel technologies

**September 14, 2009**

**#27**

**Abstract Title:** Failed Back Surgery Syndrome(FBSS) in patients with/without instrumented spinal fusion treated with Spinal Cord Stimulation(SCS) from 1998 to 2008.

**Primary Presenter:** Massimo Mearini, MD

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## **Introduction**

We evaluated data of patients with FBSS with or without instrumented spinal fusion and treated with SCS in 1998-2008 related to our experience since 1984 to 2008.

## **Materials and Methods**

We treated in 1984-2008 152 patients affected by FBSS. Follow-up: 114(75%).

Patients affected by FBSS treated with SCS in 1998-2008: 126. Follow-up: 97(76,9%).

Age=54-84: mean=66,8.

Epidural stimulation trial: 21 days standard. Mean=19,4hs/day.

Medtronic-USA single and dual percutaneous quadripolar and laminectomy-style leads were used.

IPG were 62(63,9% of epidural trial).

26/62(41,9%) patients had an instrumented spinal fusion.

Pain Evaluation:

- Intensity(1-10)
- Daily duration(1-5)
- Disability(1-5)
- Drug daily demand(1-4)

Outcome:

- EXCELLENT: pain suppression >75%, activity/work resumption, subtotal drugs eradication
- GOOD: pain improvement 50-75%, disability and drug levels reduction
- POOR: other

## **Results**

*Total results in 62 patients with follow-up in 1998-2008.*

Mean follow-up:4,4 years

SCS interruption:8 dead and 6 poor results.

Outcome:

- Excellent: 14 (22.5%)
- Good: 32 (51.6%)
- Poor: 16 (25.8%)

Positive outcome (Excellent+Good) in 46(74.1%) versus 58,2% in 1984-1997.

Improvement of the last ten years results should be due to

- Stricter selection (IPG= 70,5%→63,9% of epidural trial)
- No patients with lumbar pain only
- Better technology and surgical versatility.

*Results in 26 patients with spinal fusion and SCS in 1998-2008:*

- Excellent: 11 (42,3%)
- Good: 7 (26,9%)
- Poor: 8 (30,8%)

Positive outcome (Excellent+Good) in 18(72,2%).

### **Conclusion**

These series show similar results of SCS for FBSS in patients with versus without spinal fusion and confirm that FBSS in patients with vertebral stabilization system is a good indication for SCS.

### **Learning Objectives:**

1. We proved better results of SCS in FBSS in the latter period (1998-2008) respect to the former one (1984-1997)
2. We proved the same SCS good results in patients with and without a vertebral stabilization system before SCS

**September 14, 2009**

**#28**

**Abstract Title:** An Analysis of Paresthesia Areas Evoked by Spinal Cord Stimulation in Relation to the Position of Electrode Tip

**Primary Presenter:** Francis Nahm, MD

**Primary Presenter Institution:** Seoul National University Hospital, Seoul, Korea

**Co-presenter(s):** Mi Geum Lee, MD., Soo Young Park, MD., Sang Chul Lee, MD., Young Chul Kim, MD.

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### **Introduction**

Spinal cord stimulation (SCS) is a well-established method for the management of several types of chronic and intractable pain. This form of stimulation elicits a tingling sensation (paresthesia) in the corresponding dermatomes resulting in relief of pain. The goal of this study was to establish a correlation between the vertebral levels of the implanted epidural electrodes and the paresthesia elicited due to stimulation of the neural structure.

## Materials and Methods

Thirty-five patients, who received trial of SCS, were evaluated. After the insertion of the electrode to the selected position the area of paresthesia evoked by stimulation were evaluated.

## Results

Seventy-one percent of cases showed paresthesia in the shoulder area when the tip of the electrode was located between the C2-C4 levels. At the upper extremities, paresthesia was evoked in 86-93% of cases, regardless of the location of the electrode tip within the cervical spinal segments. The most common tip placement of the electrode eliciting hand stimulation was at the C5 level. The most common level of electrode tip placement eliciting paresthesia of the anterior and posterior thigh and the foot were at the T7-T12, T10-L1 and T11-L1 vertebral segments, respectively.

## Conclusion

Detailed knowledge of the patterns of stimulation induced paresthesia in relation to the spinal level of the implanted electrodes has allowed the more consistent and successful placement of epidural electrodes at the desired spinal level.

## References

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- Barolat G, Massaro F, He J, Zeme S, Ketcik B. Mapping of sensory responses to epidural stimulation of the intraspinal neural structures in man. *J Neurosurg* 1993. 78: 233-9.
- Holsheimer J, Wesselink WA. Optimum electrode geometry for spinal cord stimulation: the narrow bipole and tripole. *Med Biol Eng Comput* 1997. 35: 494-7

## Figure and Table Legend

Table 1. Level of the electrode tip at the cervical vertebrae and stimulated body area

Case	Lead position	Shoulder	External arm	External forearm	Hand (dorsum)	Hand (palm)	Internal forearm	Internal arm	Anterior chest
1	C2U	*					*	*	
2	C2L	*	*	*			*	*	
3	C2L		*	*			*	*	
4	C3U	*	*	*	*	*	*	*	
5	C4U	*	*	*	*				
6	C4L		*					*	
7	C4L	*	*	*	*	*	*	*	
8	C5U		*	*	*	*	*	*	
9	C5U	*	*	*	*	*	*	*	
10	C5L		*	*	*	*	*	*	
11	C5L		*	*	*	*	*	*	
12	C6L	*	*	*			*	*	†
13	C7U	*	*	*	*	*	*	*	
14	C7/T1 IVD	*	*	*			*	*	

\*When the patient felt paresthesia by the SCS stimulation. †When the patient felt the most prominent paresthesia by the SCS stimulation. IVD: Intervertebral space disc level

Table 2. Level of the electrode tip at the thoracic vertebrae and stimulated body area

Case	Lead position	Upper back	Flank	Low back	Abdomen	Anterior thigh	Anterior leg	Knee	Ankle	Foot (dorsum)	Foot (sole)	Posterior leg	Posterior thigh	Buttock	Inguinal	Perineum
1	T3U	*	*		*											
2	T7M					*	*	*	*	*	*	*	*			
3	T7M		*			*						*	*			
4	T7L						*	*			*	*	*	*		
5	T7/T8 IVD				*		*	*	*	*	*	*	*	*		
6	T8U					*										
7	T8U					*		†								
8	T8M		†			*	*	*	*	*	*	*	*	*		
9	T8L			*		*	*	*	*	*	*	*	*	*		
10	T9U					*	*	*	*	*	*	*	*			
11	T9U					*	*	*	*	*	*	*	*			
12	T9U			*											*	
13	T9U			*											*	
14	T9U					*										
15	T9L					*										
16	T10U					*										
17	T10M					*										
18	T10L			*			*	*	*	*	*	*	*			
19	T10L				*	*	*	*	*	*	*	*	*		*	*
20	T10L			*	*	*	*	*	*	*	*	*	*			
21	T10L						*	*	*	*	*	*	*			
22	T10L						*	*	*	*	*	*	*			
23	T10L					*	*	*	*	*	*	*	*	*		
24	T11U										*	*	*			
25	T11U											*	*			
26	T11U		*	*	*	*	*	*	*	*	*	*	*			
27	T11M							*					*	*		
28	T11M					*	*	*	*	*	*	*	*	*		
29	T11M					*	*	*	*	*	*	*	*	*		
30	T11L		*			†	*	*	*	*	*	*	*	*		
31	T11/T12 IVD						*	*	*	*	*	*	*	*		
32	T11/T12 IVD						*	*	*	*	*	*	*	*		*
33	T12U					*	*	*	*	*	*	*	*		*	
34	T12U					*	*	*	*	*	*	*	*			
35	T12M									*	*	*	*			
36	T12M					*	*	*	*	*	*	*	*		*	
37	L1M											*	*	*	*	*

\*When the patient felt paresthesia by the SCS stimulation. †When the patient felt the most prominent paresthesia by the SCS stimulation. IVD: Intervertebral space disc level

### Learning Objectives:

1. The pain physician can develop a strategic plan for determining the position of SCS electrode.

September 14, 2009

#29

**Abstract Title: Replacing Spinal Cord Stimulation (SCS) therapy delivered using conventional generators with newer technologically advanced devices**

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**Introduction:**

The battery lifetime of conventional primary cell devices is limited, determined by the stimulation parameters required, and typically would last between 3 and 7 years. At the end of its life, the device requires replacement for stimulation therapy resumption. Newer generation devices offer advanced technological features including extended range of stimulation parameters, advanced programming schemes and rechargeability. We report a method that allows patients access to these technological features, by replacing conventional generators with new devices, in anticipation of potentially improving therapy outcome.

**Materials and Methods:**

Two patients successfully treated with SCS using Medtronic systems, had for unknown reasons developed worsening of therapy following conventional generator replacement (Table 1).

In order to avoid replacement of the entire system, whilst maintaining the implanted lead in situ, we elected to first test the integrity of this lead with on table stimulation and then connect it to a novel rechargeable device (Precision, Boston Scientific) using an extension allowing conversion from a 4-contact lead to an 8-contact device port (M1 connector, Boston Scientific).

At 1 month follow-up, patients' satisfaction with this upgrade was assessed using a questionnaire

	<b>Pain indication</b>	<b>Pain location</b>	<b>Lead</b>	<b>Battery, year of implant</b>	<b>Therapy Status</b>
<b>Patient1</b>	FBSS	Lowback + right rear leg	Resume @ T11	Itrel, 1999 Versitrel 2007	Unreliable stimulation coverage
<b>Patient2</b>	polymyelitis	Left buttock + left upperleg	PiscesQuad @ T11	Itrel, 2003 Versitrel 2007	Device malfunction

**Table 1.** Two patients' SCS history

**Results:**

As a result of this upgrade to latest technology, both patients had their therapy restored to an improved level. At 1 month follow-up both patients rated perception of stimulation as "smoother" than their previous recollections. In both, a better coverage of the pain area with paresthesia was achieved, with both patients reporting a high satisfaction score.

**Conclusion:**

Patients who require frequent SCS device replacements due to battery depletion or who have developed suboptimal therapy may benefit from receiving a latest generation device equipped with advanced technology features. The method presented here demonstrates feasibility of such upgrade and resulted in therapeutic benefit for these patients. Further evaluations of this method are underway and results will be presented.

## **Learning objectives:**

- 1) It is possible to upgrade SCS therapy from non-rechargeable to rechargeable
- 2) Thanks to sophisticated features that some novel rechargeable devices offer, this upgrade may, in some cases, result in improved therapy outcome, even after therapy has been delivered for several years at suboptimal level

**September 14, 2009**

**#30**

**Abstract Title:** Posterior Spinal Cord Stimulation in a Case of Painful Legs and Moving Toes

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## **Introduction**

Painful legs and moving toes (PLMT) syndrome is an uncommon disorder featuring sharp excruciating pain in the legs and characteristic involuntary movements of the toes.

Although its etiology remains unknown, it has been associated with neuropathics (1) and diverse injuries of soft tissues, bone, peripheral nerves, lumbar roots and the spinal cord (2,3)

It was first described by Spillane (4) in 1971, who reported 6 patients who had sharp, excruciating, pressing and constant pain in their lower limbs.

The pain was on occasions accompanied by a burning sensation and associated with flexion, extension, abduction and adduction of the toes, generally in a continuous fashion.

The disorder may commence in one leg and then involve both legs or in rare cases remain unilateral. (5) Most of the times pain precedes movements and some patients even present involuntary movements in the absence of pain. (6) A similar syndrome has been described involving hands and fingers. (4, 7-9)

The therapeutic management of this disorder has been disappointing ever since it was first described. A large number of drugs as well as lumbar sympathetic block (10), sympathectomy, transcutaneous electrical stimulation with limited pain relief or a short duration of the therapeutic benefit have been used to treat this condition. (2-4, 7-9, 11)

We here present a patient with a diagnosis of painful legs and moving toes with intractable pain that had a marked response to epidural stimulation of the spinal cord dorsal tracts. (12)

Materials and Methods

## **Materials and Methods**

A 59-year-old woman with a 5-year history of right lower limb pain is reported.

Symptoms developed initially when walking and progressively became bilateral, presented at rest and involuntary movements of the toes became evident. A diagnosis of painful legs and moving toes was made.

Neurological examination was unremarkable with the exception of an absent right Achilles reflex.

A brain MRI showed a small meningioma of the falx cerebri lateralized to the right parasagittal region at the frontoparietal level. (Fig. 1)

A lumbar MRI scan showed marginal osteophytosis at L2-L3, discopathy at the level of T11-T12 with a slight right posterior lateral soft tissue hernia partially blocking the anterior spinal subarachnoid space.

Electromyography showed right L5 radicular involvement, with preserved reinnervation and normal nerve conduction velocity. Thermal perception thresholds were measured; both turned out to be normal. (Fig. 2)

As several drug therapies proved unsuccessful, a therapeutic test with a tetrapolar epidural electrode to stimulate the spinal cord dorsal tracts was performed. (Fig. 3)

## Results

Due to the marked improvement, the device and generator were implanted and she has responded satisfactorily to this therapy. (13)

The perianal pain disappeared, and she experienced an 80% improvement in her left and 50% in her right leg pain. Stimulation parameters were 100 Hz and pulse width of 182 ms, and the patient was allowed to increase or decrease the amplitude from 5.6 to 10 mA. The stimulation cycles used were 15 sec on and 5 sec off.

## Conclusion

We can speculate on two possible causes, the posterior root involvement and the falx meningioma. However, symptoms were bilateral and the typical features of pain secondary to a posterior root lesion were absent. On the other hand, both lesions were small and lacked anatomical correlation with the side where symptoms are located.

The management of this condition is frequently difficult due to the poor response to medication, sympathetic block and sympathectomy. Our case suggests that spinal cord stimulation should be considered an alternative therapeutic tool in the treatment of cases which are refractory to other treatment modalities. (14-16)

Further cases are needed to validate our findings.

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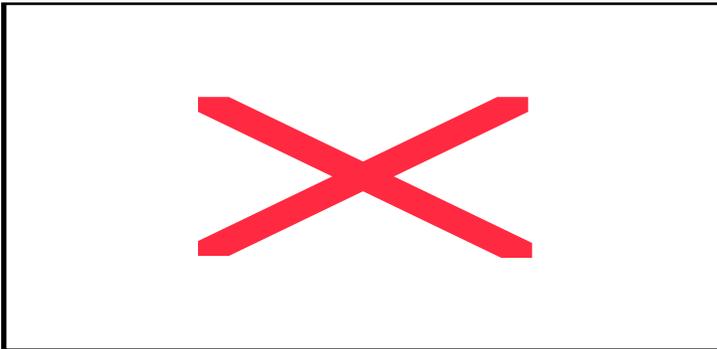


Fig.1 Brain MRI showing a normal shaped mass consistent with small meningioma of the falx cerebri lateralized to the right region at the frontoparietal level. Frontal view.

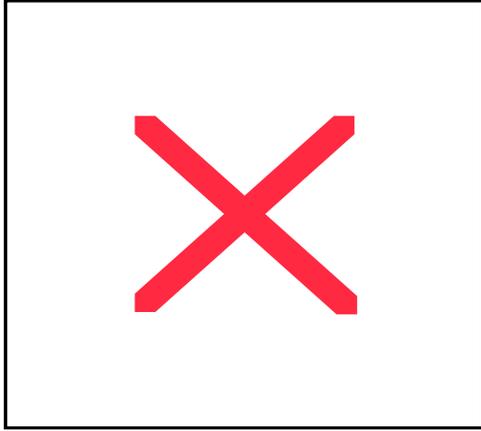


Fig. 2 Nerve conduction velocities showing normal results (retouched by hand).

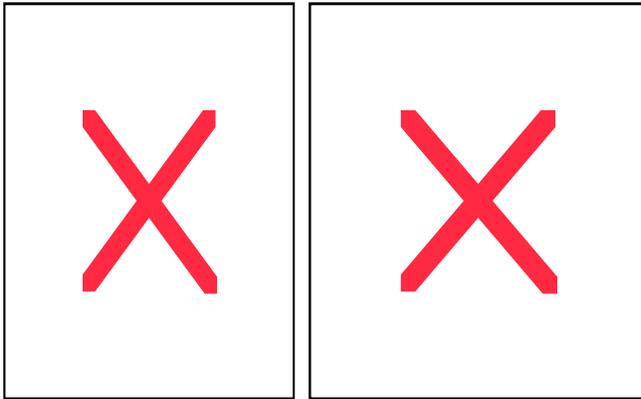


Fig. 3 Epidural tetrapolar lead, percutaneously implanted to reach T10, with connection to a compatible pulse generator. Sagittal and frontal view.

**September 14, 2009**

**#32**

**Abstract Title:** THE TREATMENT OF CAUDAL SYNDROME IN MULTI OPERATED PATIENTS FOR "SACRAL TARLOV CYSTS", WITH MULTIPLE AND INDIPENDENT POWER SOURCE SCS SYSTEM : A ONE CASE REPORT.

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**Introduction**

Tarlov cysts are sacs filled with cerebrospinal fluid that most often affect nerve roots in the sacrum.

Over-operated patients often develop a Caudal Syndrome, characterized by a radicular pain in the legs, low back pain and dysuria.

In this work we present a one case report of a multi operated patient treated for Caudal Syndrome post surgery with a multiple sources of power SCS system.

### **Materials and Methods**

The patient is a 46 old caucasian woman, multi-operated for Sacral Tarlov Cysts removal and the creation of a sacral dural bag, with the result of a caudal syndrome due to the adhesive arachnoidites. Beck Depression Inventory (BDI) baseline score was 35, Mc Gill Pain Questionnaire , Short Form (MPG- sf) score was 25 and OSWESTRY Scale score was 45.

Urge incontinence alternated with urinary retention were detected.

Two eight-polar leads were placed percutaneously in epidural space at D7-D8 level, bilateral, 5 mm apart from the midline and connected to a 16 sources of power current controlled ETS (Precision Plus System by BSC) for the trial phase.

### **Results**

At the 45 days follow-up, BDI score was 10, MGPQ-sf was 5, OSWESTRY score was 15. Diuresis has normalized and has been implanted a SCS Precision Plus System (by Boston Scientific).

### **Conclusion**

We believe that the fractionalization provided from multi sources of power system could be a significant therapeutic alternative in patient affected with Caudal Syndrome due to multi surgeries for Tarlov Cysts removal.

### **Acknowledgements**

Boston Scientific, Boston , USA, for technological contributions

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Dorsal Column Selectivity in Pulse Width (PW) Programming of Spinal Cord Stimulators (SCS) : the "Sacral Shift"

Thomas L. Yearwood MD, PhD et. Al. – 8th INS Congress, Acapulco, 2007

### **Learning Objectives:**

- 1.Evidence for original treatment with SCS for Tarlov's Cysts Syndrome
- 2.Ulterior evidence of efficacy to multiple independent sources of stimulation system and different kind of programs for different problem (in this case radicular pain in the legs, Low back Pain and Dysuria).

**September 14, 2009**

**#33**

**Abstract Title:** The improvement of ischemic pain was associated with an increase in TcpO2 after the initiation of spinal cord stimulation in a patient with Buerger's disease.

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### **Introduction**

Buerger's disease usually occurs in smoking men younger than 40 years old. The cause of this disease is an inflammatory vasculitis within peripheral arteries of arms and legs. The treatments for Buerger's disease are cessation of smoking, medication such as anti-platelet drugs and sympathectomy. However, surgical revascularization is rarely useful. If these treatments failed to improve ischemic symptoms, spinal cord stimulation is indicated. Although no randomized controlled study exists regarding Buerger's disease, spinal cord stimulation has been shown to improve the microcirculation as suggested by an increase in transcutaneous oxygen pressure (T<sub>cp</sub>O<sub>2</sub>) and limb salvage. We report here that spinal cord stimulation is useful to improve ischemic pain and a finger ulcer associated with an increase in T<sub>cp</sub>O<sub>2</sub> in a patient with Buerger's disease.

### **Materials and Methods**

A 38 years old man with Buerger's disease who had suffered from ischemic pain and ulcer on right 4th finger has been given medication and continuous epidural block. However, those treatments failed to improve ischemic symptoms. CT angiography revealed stenosis of small arm arteries, so surgical revascularization was not indicated. Therefore we started cervical spinal cord stimulation for the treatment by using of a quadripolar electrode and a generator (Medtronic). Also, we measured T<sub>cp</sub>O<sub>2</sub> by the use of measuring device (Radiometer) several hours after switching off of the stimulation at the beginning and 6 months later of the treatment.

### **Results**

Trial stimulation was effective to relieve ischemic pain and the generator was internalized after one week trial period. Ischemic pain and ulcer disappeared within 6 months of the treatment. T<sub>cp</sub>O<sub>2</sub> was 10mmHg at the beginning and 30mmHg 6 months later.

### **Conclusion**

Spinal cord stimulation is effective for pain relief and ulcer healing in a patient with Buerger's disease. T<sub>cp</sub>O<sub>2</sub> is an objectively useful outcome measure during the treatment period.

### **References**

Donas KP, Schulte S, Ktenidis K, Horsch S. The role of epidural spinal cord stimulation in the treatment of Buerger's disease. *Journal of Vascular Surgery* 2005. 41:830-836.  
Author 1 , Author 2, Author 3, Author 4, Author 5, Author 6, et al. Title. *Journal* Year. Volume: start page-end page.

### **Learning Objectives:**

1. Buerger's disease
2. spinal cord stimulation
3. transcutaneous oxygen pressure (T<sub>cp</sub>O<sub>2</sub>)

**September 14, 2009**  
**#34**

**Abstract Title:**

**Modern SCS technology maintains clinical effects of therapy long term:  
Results from a Spanish case series**

**Primary Presenter:**

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**Introduction**

Spinal Cord Stimulation (SCS) is widely accepted for the treatment of the leg pain component in patients diagnosed with Failed Back Surgery Syndrome (FBSS). Due to anatomical challenges posed by location, diameter and number of nerve fibers representing the low back dermatomes in the dorsal columns, it has historically been difficult to stimulate and to maintain stimulation in this region [1, 2], thereby hampering the success of SCS for low back pain. We report here our experience with SCS for the treatment of FBSS on a group of 19 patients over 1 year, which is an extension of our previous report [3].

**Methods**

Two narrowly-spaced 8-contact leads and a rechargeable SCS stimulator featuring 16 independent current-controlled sources (Precision™, Boston Scientific) were implanted in 19 patients diagnosed with FBSS. At 1, 3, 6 and 12 months following the implant procedure, patients' assessments on coverage of pain areas (legs and/or back) with paresthesia as well as those of therapy efficacy were collected.

**Results**

The majority of the leads were placed at vertebral level Th8-9. Of 19 patients, two lost therapeutic pain relief: one patient despite excellent coverage, whilst the other, after 6 months suddenly lost coverage which couldn't be regained with revisions. The remaining 17 patients (89%) continuing SCS therapy, achieved a median paresthesia coverage surpassing 80% in both, targeted leg(s) and back. The targeting was stable over time with the coverage of the legs rated somewhat higher (Table 1). The median VAS score decreased from baseline 8.5 to 4 and was maintained for the duration of follow-up. Similarly, at 12 months, 14 of the 17 patients

(74%) continued to report pain reduction greater than 50%, and 16 patients (84%) were very satisfied with their therapy.

**Table 1:** Assessment of leg and back coverage at 12 month follow-up: number of patients in each category shown.

	0-20%	21-40%	41-60%	61-80%	81-100%
Leg coverage	0	0	1	3	12
Back coverage	1	0	3	0	11

### Conclusions

This observational case series suggests that management of leg and back pain is feasible and is maintained for at least 1 year with the use of advanced SCS technology. It is expected that the effects in this group of patients will remain stable.

### References:

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- [3] Abejon D and Manola Lj. Chronic lowback and leg pain treatment using modern SCS technology: a Spanish case series. Abstract in: 8<sup>th</sup> INS World Congress, Acapulco, Mexico, 2007.

### Learning objectives:

- 1) Targeting of the legs and back with stimulation was achieved in majority of patients using modern SCS technology
- 2) Patients' assessment of the therapy was in general accordance with their assessment on paresthesia coverage
- 3) Stimulation effects were preserved in majority of patients for the duration of follow-up (1 year)

**September 14, 2009**

**#35**

**Abstract Title:** Some problems lie in cervical epidural spinal cord stimulation: Comparison with thoracic-lumbar epidural spinal cord stimulation focusing on the success rate and effectiveness

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2. Name: Yuugo Ohba Credentials: M.D.

3. Name: Yukiko Noda Credentials: M.D.,Ph.D.
4. Name: Sumio Hoka Credentials: M.D.,Ph.D.

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2. Place of Employment: Pain Clinic, Kyushu University Hospital, Fukuoka, Japan
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#### **Introduction**

Compared with thoracic-lumbar epidural spinal cord stimulation (t-SCS), we think that some problems lie in cervical epidural spinal cord stimulation (cSCS). Problems about the electrode in cSCS were difficult insertion and dislocation<sup>1-2</sup>. Reasons of those problems were considered with narrow cervical epidural space and mobility of cervical spine<sup>3</sup>. The purpose of this study is to compare the cSCS versus t-SCS focusing on the success rate and effectiveness<sup>3-5</sup>. And we considered some problems in cSCS<sup>3,6</sup>.

#### **Materials and Methods**

Sixteen patients received SCS for the intractable pain, consisting of 7 patients with cSCS and 9 with t-SCS in our hospital from 2005 to 2009. PISCES Quad<sup>®</sup> leads were inserted by epidural puncture with the loss of resistance method. The effectiveness after implantation was evaluated and ranked to four categories as Excellent, Good, Poor and Bad (Table1). Excellent and Good were considered as effective and Poor and Bad were considered as non-effective for simplicity.  $P < 0.05$  was considered statistically significant.

#### **Results**

Two patients out of 7 in cSCS dropped out before implantation because of troubles about insertion of the electrode. And thus 5 patients (71%) received the devices. All the nine patients of t-SCS (100%) received the devices and there is no trouble about insertion of the electrode. Table 2 shows the effect of SCS in both groups. Effectiveness was 40% in cSCS and 67% in t-SCS. These differences in success rate and effectiveness between the two groups were not statistically significant.

#### **Conclusion**

Although the statistics could not show the significant difference due to the few number of patients, our results may suggest that cSCS has a tendency of less success rate and less effectiveness than t-SCS. This tendency of cSCS seems to be due to a narrow epidural space and large mobility of cervical spines.

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5. Taylor RS, Buyte JP, Buchser E. Spinal cord stimulation for complex regional pain syndrome: a systematic review of the clinical and cost-effectiveness literature and assessment of prognostic factors. Eur J Pain 2006. 10 : 91-101.
6. Hayek SM, Veizi IE, Stanton M. Four-limb neurostimulation with neuroelectrodes placed in the lower cervical epidural space. Anesthesiology 2009. 110: 681-684.

**Table Legend:**

Table 1 Evaluation of effectiveness by SCS

Evaluation	Condition after implantation
Excellent	The patient can return to his society and completely recover from medicine
Good	The patient can return to his society and needs little medicine than before
Poor	The patient cannot return to his society and needs enough medicine
Bad	The patient drops out from SCS

**September 14, 2009**

**#36**

**Abstract Title:** Pulsed Radiofrequency As a Neuromodulation Treatment for Various Intractable Pain Syndromes

**Primary Presenter:** Jung Yul Park, M.D.

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**Co-presenter(s):** Sang-Kook Lee, M.D., Sung-Kon Ha, M.D.,Ph.D.,Sang-Dae Kim,M.D.,Se-Hoon Kim,M.D., Dong-Jun Lim,M.D.

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**Introduction**

The exact mechanism for pulsed radiofrequency(PRF) has not been documented, but several recent research works have demonstrated totally different action mechanisms that attribute to its effect on pain reduction and neuromodulating action compared to conventional RF treatment. Here, experience on PRF in patients with refractory pain in last 3 years is presented with literature review.

**Materials and Methods**

Retrospective review was conducted to verify the effectiveness of PRF treatment for 12 patients with refractory trigeminal neuralgia, 300 patients with chronic low back and radicular pain, and 50 patients with postherpetic neuralgia. All patients had refractory pain for more than 6 months with average VAS 7.2 and all patients were followed for more than 12 months.

**Results**

PRF gasserian ganglion rhizotomy for refractory trigeminal neuralgia demonstrated that pain relief of excellent or good quality was observed in 75% of patients at 12 months. However, this

effect was observed only in 56.3% at 24 month. There were 3 cases of recurrent pain (18.8%) during 2-year follow up period (average 14.3 mos). PRF lesioning on DRG for radicular pain revealed satisfactory results (> 50% reduction of pain) in 76% at 1 month, 64% at 6 months, 60% at 1 year, and 56% at 2 year period. PRF on dorsal root ganglion in management of refractory postherpetic neuralgia indicate that it provides successful pain relief in 70.0% of patients for 1 year and 67% for 2 year period. There were no complications.

### **Conclusion**

The initial clinical data on PRF demonstrate response rates similar to conventional RF lesions for various chronic pain disorders. However, delayed maximal response, less satisfactory long term response and higher recurrence rate are considered as disadvantages and should be weighted with other potential merits and advantages of this type of treatment, namely less discomforts, side effects and complications with additional indications for patients with neuropathic pain.

### **References**

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### **Learning Objectives:**

1. To know there are new types of neuromodulation treatment option available including pulsed radiofrequency treatment.
2. To understand the mechanisms of action for pulsed radiofrequency for the treatment of refractory painful states.
3. To acknowledge the differences between conventional RF, pulsed RF and more recently introduced "pulsed dose" RF technique in the management of chronic, disabling pain syndromes.

**September 14, 2009**

**#37**

**Abstract Title:** Spinal cord stimulation (SCS) makes a great effect for the visceral pain caused by chronic pancreatitis: A case report

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### **Introduction**

Recently, there are several reports which Spinal cord stimulation (SCS) is useful for the treatment of visceral pain.

### **Materials and Methods**

60 years old man suffered pancreatitis 23years ago.

When he came our hospital last year, we made a celiac ganglion block.

But it's duration was limited, so we tried SCS by puncture trial.

It made a great effect, so implant was performed.

At that time, we got a good paresthesia at different lead level, compared with former trial.

### **Results**

We obtained a remarkable effect for the visceral pain caused by chronic pancreatitis who suffered over 20years ago.

The different level of stimulation, we get an excellent effect for the visceral pain.

### **Conclusion**

SCS can make a good treatment for visceral pain caused by chronic pancreatitis.

And different level stimulation can obtain a good paresthesia; it may show a possibility to get paresthesia when paresthesia reduced in the future.

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Neuromodulation, Volume 8, Number 1, 2005 14–27

### **Learning Objectives:**

1. Visceral pain
2. Chronic pancreatitis
3. Spinal cord stimulation

**September 14, 2009**  
**#38**

**Abstract Title:** An Algorithm for Programming Spinal Cord Stimulator/Peripheral Subcutaneous Field Stimulator Systems for Axial Back Pain

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### **Introduction**

The objective is to develop an algorithm to program a spinal cord stimulator(SCS) and a peripheral subcutaneous field stimulator (PSFS) system for leg and axial back pain.

### **Materials and Methods:**

Spinal cord stimulation has been well established in covering lower extremity radicular pain, but the low back cannot reliably and consistently be covered with parasthesia in isolation of leg stimulation. Peripheral subcutaneous field stimulation is a preferred Moniker over peripheral nerve field stimulation. Peripheral subcutaneous field stimulation has recently been utilized in the treatment of otherwise refractory low back pain when spinal cord stimulation has produced unsatisfactory coverage or has produced undesired radicular parasthesia. Spinal cord stimulation can be used in conjunction with peripheral subcutaneous field stimulation to create adjunct to traditional epidural spinal cord stimulation approaches in treating axial back pain.

Once leads have been appropriately placed for coverage of both axial low back pain and radicular pain, the peripheral subcutaneous field stimulation leads and the spinal cord stimulation leads can be programmed either independently or in combination to treat each independent pain topography. The peripheral leads are programmed to treat axial back pain.

To this point, little is known about programming multi-lead systems involving peripheral subcutaneous field stimulation leads alone or in combination with spinal cord stimulation leads. This poster will demonstrate a successful algorithm of the programming of the combined system. The program methodology accounts for undesired intercostal stimulation, uneven stimulation with regards to laterality, uncomfortable "stinging" stimulation.

### **Results:**

Definitions of triangular stimulation, flow stimulation, field stimulation, and split field stimulation will be given, along with the algorithm demonstrated in two case studies.

### **Conclusion:**

In conclusion, the peripheral subcutaneous field stimulator leads are programmed to treat axial back pain, while the epidural spinal cord stimulator lead is used to treat the radicular leg pain. The intrinsic communication between the superficial peripheral lead and the deep stimulator lead, in some circumstances, produce superior coverage of the axial back pain. The

combination has increased the success in treatment of axial low back pain. An increased trial to implant ratio, as well as correlation with patient satisfaction is noted.

Thus, it is important to develop a multi-centered comparison between single-array spinal cord stimulation (SCS) versus a combination of spinal cord stimulation plus subcutaneous peripheral field stimulation (SCS + PSFS) for axial back pain: a randomized double blinded controlled trial.

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#### **Learning Objectives:**

- 1.What is field stimulation? How is it different in this SCS/PSFS combo?
- 2.What is different and new with this SCS/PSFS programming?
- 3.Why is the anatomical position of the PSFS lead in relation to the SCS lead important?

**September 14, 2009**

**#39**

#### **Abstract Title:**

Reversing Pathological Neural Plasticity to Treat Tinnitus

#### **Primary Presenter:**

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#### **Introduction**

Noise-induced peripheral damage results in plasticity characterized by a reorganization of the tonotopic map in auditory cortex and increased neural synchrony. This pathological plasticity may be responsible for the subjective experience of tinnitus. To document neural correlates of tinnitus and the

potential to restore normal organization, we combined high density microelectrode mapping with a gap detection task to assess tinnitus. Four weeks after noise trauma, rats were unable to detect a gap at frequencies bordering the edge of hearing loss. Consistent with previous reports, we observed considerable reorganization of the tonotopic map and broad receptive fields in rats that demonstrated the tinnitus correlate.

We are currently testing a novel approach using vagus nerve stimulation (VNS) paired with multiple tones to reverse the pathological plasticity hypothesized to be responsible for tinnitus.

After noise trauma, we paired brief episodes of VNS with tones surrounding the tinnitus frequency (VNS group). A sham group was passively exposed to the same tones (without pairing). Our results show that while the sham group continued to remain impaired, gap performance for the VNS group improved significantly at the tinnitus frequency. These results suggest that pairing multiple tones with VNS can reverse the gap impairment in rats with the presumed tinnitus percept. We have also quantified neurophysiology data (from the same rats) that confirm our hypothesis that VNS therapy also reverses the pathological plasticity that results from noise trauma.

Such targeted and precise neural plasticity provides a clear opportunity to restore normal operation to dysfunctional neural circuits in the auditory cortex and eliminate or attenuate the tinnitus sensation.

#### **Conclusions**

- Biphasic square pulses at 0.8 mA, 30 Hz, 100  $\mu$ s pulse width for 0.5 seconds effectively desynchronizes the cortical EEG
- An intensity of 0.4 mA is effective at desynchronizing the cortical EEG at a higher rate and pulse width
- Consistent with earlier reports, noise trauma increases excitability of A1 neurons
- Pairing VNS with tones surrounding the tinnitus

frequency restores frequency selectivity, spontaneous rate and synchrony of A1 neurons  
N.D. Engineer<sup>1</sup>, J.R. Riley<sup>2</sup>, J.D. Seale<sup>2</sup>, J.A. Shetake<sup>2</sup>, S. Sudanagunta<sup>2</sup>, M. Fink<sup>2</sup>, W. Rosellini<sup>1</sup>, M.P. Kilgard<sup>2</sup>

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**September 14, 2009**

**#40**

#### **Abstract Title:**

A MEMS-based fully-integrated wireless neurostimulator

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## Introduction

We report design, fabrication and *in-vivo* animal testing of a MEMS-based fully-integrated fully-biocompatible minimally-invasive wireless battery-free neurostimulator (3.1 x 1.5 x 0.3 mm) for chronic pain relief application. The device consists of spiral coil for inductive power coupling, rectification diodes, an ASIC neurostimulator circuit chip, biphasic platinum-iridium (PtIr) stimulation electrodes, interconnection between parts, and biocompatible SU-8 [1] packaging. The wireless neurostimulator was implanted subcutaneously in a rat and cortical responses evoked by wireless stimulation were repeatedly recorded.

Electrical stimulation has widely used to elicit or modify certain behaviors, to restore sensory perception, or to treat neurological disorders. Predominant methods of electrical stimulation involve delicate surgical procedure to implant relatively large electrodes with long electrical lead wires to connect with bulky electronic controllers. Such methods can cause the risk of infection and reduction of the functional reliability related to problems with wiring or physical motion of the implanted device. Inductively coupled wireless power transmission is a promising solution to address such issues. However, sizes of reported wireless inductive power devices [2, 3] are relatively large.

A schematic view of the wireless neurostimulator is shown in Figure 1. It consists of a round spiral inductor as a coupling element, diodes responsible for rectifying induced AC voltage, an ASIC chip to control stimulus current, and bipolar stimulating electrodes as neural interfaces. SU-8 was used as packaging material due to its biocompatibility. For the purpose of compact integration of those components, a SU-8 based socket platform was devised to tightly fit in rectifying diodes and the ASIC chip. A 1 mm diameter spiral inductor was embedded in the platform. The socket dimensions were decided by the dimensions of commercially available Schottky diodes (830 \_ 300 \_ 95  $\mu\text{m}$ ) and the ASIC chip (1 \_ 1 \_ 0.15 mm). The contact pads at the bottom floor of each socket are to make interconnection between each component. Tiny amount of conductive epoxy was applied on each contact pad, and the ASIC and diodes were slid into the fabricated sockets. After integration process was completed, the whole device was completely sealed by another layer of SU-8. Finally, 1 mm diameter PtIr stimulating electrodes were attached on both sides of the device. Figure 2 illustrates fabrication sequence and Figure 3 shows the successfully fabricated SU-8 based wireless neurostimulator (3.1 \_ 1.5 x 0.3 mm).

Prior to the animal study, wireless stimuli were recorded during open-air tests for calibration across RF power levels at different separation distances between the wireless simulator and RF power coil as shown in Figure 4. The stimulus discharge time constant was consistently about 1  $\mu\text{s}$ , decaying from a peak stimulus voltage which depended upon the applied RF power level and separation distance up to a maximum of about 6.5 V at 1 Watt power and 1 mm separation down to stimulus failure at distances over 5 mm. After open-air tests, the fabricated device was placed subcutaneously upon the peroneal nerve of a rat and recorded the cortical responses to wireless stimulation powered by an external RF coil applied to the skin over the implant. Figure 5 illustrates the subcutaneous placement of a wireless stimulator and the external RF coil on the skin overlying the implant, which was prepared to mimic the configuration planned for human trials. As can be seen in Figure 6, increasing wireless stimulation intensity by increasing external RF power resulted in an increase in the

amplitude of the evoked cortical responses. Fairly substantial cortical response was detected with wireless RF power as low as 21 dBm (125 mW) at 394 MHz.

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