2013 CANADIAN NEUROMODULATION SOCIETY

CONFERENCE PROGRAM

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CONFERENCE PROGRAM

Friday, September 27, 2013 | Vendredi, 27 septembre 2013

TIME		ROOM
13:00	**Welcome & Introduction | Mot de bienvenue et introduction** Michel Prud'Homme, M.D., PhD, Chris Honey, M.D., and Magdy Hassouna, M.D.	Arbutus A/B
	Session I: Chris Honey, M.D., Session Chair	
13:15	**Intrathecal Baclofen - An Overview** Michael Saulino, M.D., PhD	Arbutus A/B
13:45	**The role of SNM in Painful Bladder Syndrome/Interstitial Cystitis** Jerzy Gajewski, M.D.	Arbutus A/B
14:15	**Break with Exhibitors | Pause avec les exposants**	Arbutus A/B
14:30	**Open Papers**	Arbutus A/B
14:30	**Treatment of secondary craniofacial pain syndromes of central and peripheral origins by occipital nerve stimulation with 16 lead contacts.** Michel Prud'Homme, M.D., Sylvine Cottin, PhD, Nevair Gallani, M.D.	Arbutus A/B
14:45	**Analysis and in-vivo results of MRI radiofrequency heating due to neuromodulation systems.** Heather Orser, John Welter, Steve Manker, Jamu Alford, Jim Olsen, Bryan Stem, Wanzhan Liu, Michael Kalm	Arbutus A/B
15:00	**Intrathecal clonidine pump as a treatment for spasticity and walking: a multiple case study.** Michel Prud'Homme, M.D., Sylvine Cottin, PhD, Josée Roy, Isabelle Coté	Arbutus A/B
15:15	**Chronic nerve root stimulation for extracranial neuropathic pain.** Adrian Levine, BSc; Andrew Parrent, MD; Keith MacDougall, MD	Arbutus A/B

15:30	**Evaluation of fine motor benefits of deep brain stimulation in an essential tremor patient.** Nevair Gallani, M.D., Sylvine Cottin, PhD, Michel Prudhomme, M.D., Léo Cantin, M.D.	Arbutus A/B
15:45	**MRI safe deep brain and spinal cord stimulation systems: studies of the maximum safe lead tip temperature.** Robert J. Coffey, John Pearce, Jim Olsen, Ron Kalin, Steve Manker	Arbutus A/B
18:30	**Welcome Reception | Soirée de bienvenue**	Harbour Room

Saturday, September 28, 2013 | Samedi, 28 septembre 2013

07:30	**Poster Presentations** **Présentations par affiches**	

Session II: Bill McDonald, M.D., Session Chair

08:30	**Evolution of DBS – in search of new paradigms** Konstantin Slavin, M.D.	Arbutus A/B
09:00	**DBS troubleshooting** Konstantin Slavin, M.D., Chris Honey, M.D.[1] and Mini Sandhu, RN, Clinical Resource Nurse[1] Interactive panel discussion [1]Deep Brain Stimulation-DBS Clinic, Vancouver General Hospital, Vancouver, BC	Arbutus A/B
10:00	**Break with Exhibitors | Pause avec les exposants**	Arbutus A/B
10:15	**Dr. Tasker Lecture:** **Peripheral Nerve Stimulation for Pain-Review and Update** Konstantin Slavin, M.D.	Arbutus A/B
11:15	**Annual General Meeting of CNS** **Assemblée générale annuelle de la SCN**	Arbutus A/B
12:00	**Lunch with Exhibitors | Déjeuner avec les Exposants**	Arbutus A/B

Session III: Louise Malysh, RN, MSN, Session Chair

13:00	**Spinal Cord Stimulation: future technologies, their applications and patient selection** Michael Stanton-Hicks, M.B.; BS, Dr Med	Arbutus A/B
13:30	**Troubleshooting Spinal Cord Stimulation (SCS)** Andy Parrent[1], M.D., Michael Stanton-Hicks, M.D. and Barbara Eden[1], RN, Neuromodulation Case Manager Interactive panel discussion [1]Clinical Neuroscience Pain Program, London Health Science Center, University Hospital, London, Ontario	Arbutus A/B
14:30	**Break with Exhibitors | Pause avec les exposants**	
14:45	**Patient Selection for SCS in the FBSS population** Michel Prud'Homme, M.D., PhD and Nelson Svorkdal, M.D.	Arbutus A/B
15:45	**Evidence of the Comparative Cost-Effectiveness of SCS in Four Neuropathic Pathologies Versus Alternative Treatment** Kris Kumar, MBBS, MS, FRCS(C)	Arbutus A/B
16:30	**Meeting Adjourned for the day | Fin des conférences**	
18:30	**Dinner / Souper**	Harbour Room

Sunday, September 29, 2013 | Dimanche, 29 septembre 2013

07:00	**Breakfast with the Experts / Petit Déjeuner avec les experts**	Harbour Room

Session IV: Magdy Hassouna, M.D., Session Chair

08:15	**Neuromodulation for Angina: A Review** Nelson Svorkdal, M.D.	Arbutus A/B

09:00	**Dr. Kris Kumar Lecture:** **CRPS 1: Pathophysiology, patient selection and treatment** Michael Stanton-Hicks, M.D.	Arbutus A/B
10:00	**Break with Exhibitors / Pause avec les exposants**	
10:15	**Troubleshooting Intrathecal Pumps** Michael Saulino, M.D., PhD	Arbutus A/B
10:45	**Troubleshooting Pump Session** Michael Saulino, M.D., PhD[1], Bill McDonald[2], M.D., Louise Malysh[2], RN, MSN Interactive panel discussion [1]MossRehab, Pennsylvania, US [2]Complex Pain Program, St Paul's Hospital, Vancouver, BC	Arbutus A/B
11:45	**Best oral and poster presentations awards** **Prix pour les meilleurs présentations orales et par affiche** **Concluding Remarks / Mot de clôture** **Meeting Adjourned / Fin de la conférence**	Arbutus A/B

COURSE OBJECTIVES | OBJECTIFS

The main objective of the 7th Annual Conference of the Canadian Neuromodulation Society is the training of participants in the field of neuromodulation. / La 7e conférence annuelle de la Société Canadienne de Neuromodulation a pour objectif principal la formation des participants en ce qui a trait à la neuromodulation.

Activity Objectives | Objectifs de l'activité :

At the end of this year's conference, participants will be able to / À la fin de cette conférence annuelle, les participants seront en mesure de:

Define emerging indications in the field of neuromodulation by identifying populations and list emerging applications for 1) deep brain stimulation (DBS) in the treatment of movement disorders as well as for 2) spinal cord stimulation (SCS) in the treatment of chronic pain.

Examine the indications and practice guidelines in the treatment of spasticity with intrathecal Baclofen, peripheral nerve stimulation and spinal cord stimulation for angina. / Examiner les indications et les lignes directrices dans le traitement de la spasticité par baclofen intrathécal, la stimulation des nerfs périphériques et la stimulation médullaire pour l'angine.

List common challenges when treating patients with DBS for movement disorders, SCS and intrathecal pumps for chronic pain patients, sacral neuromodulation for painful bladder syndrome/ interstitial cystitis; troubleshoot these common difficulties and identify best practices in these patient populations. /

Énumérer les défis liés au traitement des patients par DBS pour les troubles du mouvement, la SCS ou les pompes intrathécales pour les patients douloureux chroniques, la stimulation des nerfs sacrés pour le syndrome douloureux de la vessie ou la cystite interstitielle; résoudre les difficultés les plus fréquentes et identifier les meilleures pratiques pour ces populations de patients.

Identify best practice as it relates to patient selection for spinal cord stimulation, specifically for patients with failed back surgery syndrome. / Identifier les meilleures pratiques relativement à la sélection des patients pour la stimulation médullaire, spécifiquement pour les patients atteints du syndrôme des multiopérés du rachis.

Teaching methods used | Méthodes pédagogiques utilisées :

Conference Session / Conférences magistrales: At the end of each presentation, the invited speaker will allow for a 5-10 minute question and answer period / À la fin de chaque présentation, le conférencier disposera d'une période de 10 à 15 minutes de question-réponse.

Group discussion / Groupes de discussion: There will be an opportunity for small group discussions during the "Breakfast with the Experts" session on Sunday September 29, 2013. / Des petits groupes de discussion auront l'opportunité d'échanger lors du 'déjeuner avec les experts' le dimanche 29 septembre 2013.

Panel discussions / Discussions de panel: There will be panel discussions following each invited speaker session on DBS, SCS and pumps; entitled "Troubleshooting" sessions. The panel will utilise an audience participation system to solicit feedback on each of these three topics during the Troubleshooting sessions.

Oral and poster presentations / Présentations orales et par affiches: Six oral presentations will be given on Friday September 27, 2013 at 14:30. Posters can be viewed on Saturday September 28 at 07:30 and throughout the session breaks. / Six présentations orales seront données le vendredi 27 septembre 2013. Des affiches pourront être consultées lors des pauses.

Accreditation:

This event is an Accredited Group Learning Activity eligible for up to 12.5 (CME) Section 1 credits as defined by the Maintenance of Certification program of the Royal College of Physicians and Surgeons of Canada. This program has been reviewed and approved by the Office of Continuing Education and Professional Development, Faculty of Medicine, University of Toronto./ Cet événement est accrédité par le bureau de la formation continue et du développement professionnel de la faculté de médicine de l'Université de Toronto a raison de 12,5 crédits.

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Session with industry* Session avec l'industrie*

Friday, September 27, 2013 | Vendredi, 27 septembre 2013

1600	**Platinum Sponsors' Tribune	Tribune partenaires platines** **This is a non-accredited session of the CNS conference* ** Session non-accréditée*	Arbutus A/B
1600	**1) The science behind automated programming (Illumina 3D algorithm).** Dongchul Lee, PhD, Principle Research Scientist, Boston Scientific	
1620	**2) Medtronic Innovations for Optimal Pain Management and Patient Care.** Steve Manker, PhD., Program Director for MRI Conditionally Safe Systems, Medtronic Neuromodulation	
1640	**3) Spinal Cord Stimulation Clinical Update**. Melanie Goodman Keiser PhD., St Jude Medical	

INVITED SPEAKERS

Jerzy Gajewski, M.D., FRCSC

Dr. Jerzy Gajewski, is a Professor of Urology and Pharmacology at Dalhousie University in Halifax, Nova Scotia, Canada. He is the Director of the functional Urology Program in the Department of Urology. He graduated from medical school in Poznan, Poland (1973) and pursued his urological training in Poland, Germany and Canada, before completing a fellowship in Neurology and Urodynamics at Dalhousie University. His main interests are: voiding dysfunction, incontinence, interstitial cystitis, neuromodulation and erectile dysfunction. He has published over 100 papers and book chapters and has presented over 200 times on these topics. He is a Past Chair of the Canadian Male Sexual Council and Past President of the Canadian Academy of Urological Surgeons. He is a Secretary of the Canadian Society for the Study of the Aging Male. He is an Honourary Member of the Polish Urological Society. He is a very active member of the Canadian Urological Association (CUA) and was its Treasurer for several years and then President from 2009-2010. He is now a CUA historian. He is also a Past Chair of the Publication and Communication Committee and the Past Trustee of the International Continence Society. He is now President-Elect of the Northeastern section of the American Urological Association. His hobbies include sailing. He is a member of the Royal Nova Scotian Yacht Squadron since 1993 and La Chaine des Rotisseurs since 2007.

Kris Kumar, MBBS, MS, FRCS(C)

Dr. Kris Kumar is a clinical professor of Neurosurgery at the University of Saskatchewan, College of Medicine. He graduated from Mahatma Gandhi Medical College in India in 1958 and became a Fellow of the Royal College of Surgeons of Canada (Neurosurgery) in 1961. Dr. Kumar has presented and published over 150 papers in national as well as international conferences and peer-reviewed journals. He is the recipient of numerous awards including the Queen's Diamond Jubilee medal (September 2012), the Giant in Neuromodulation (inaugural) award in 2011, the James H. Graham Award of Merit, Awarded by the Royal College of Physicians and Surgeons of Canada for "Outstanding Achievement", (2011) the Saskatchewan Order of Merit, the Queen's Golden Jubilee Medal, Honorary Life Membership from the Canadian Medical Association and the Order of Canada, Awarded by the Honourable Michaelle Jean, Governor General of Canada on July 1, 2009. This is the highest civilian honor that the Government of Canada bestows. Dr. Kumar is the founding president of the Canadian Neuromodulation Society.

Michel Prud'Homme, M.D., PhD

Dr. Michel Prud'Homme is a neurosurgeon at the Centre Hospitalier Affilié Universitaire in Quebec City and Associate Professor in the department of surgery at Laval University. He is co-chairman of neurosurgery research and co-chairman of the division of functional neurosurgery. He is a member of the program committee and admissions committee in neurosurgery at Laval University. Since 2011 he has been the secretary/treasurer of the Canadian Society for Stereotactic and Functional Neurosurgery, division of the Canadian Neurological Sciences Federation. He is the president of the Canadian Neuromodulation Society. Dr. Prud'Homme received his Certificate of Specialization in Neurosurgery, Province of Quebec (CSPQ) in 2002 and is a Fellow of the Royal College of Surgeons of Canada (FRCSC) since 2011. He received his Ph.D. in neurological sciences and M.D. in 1996 from the University of Montreal and a masters degree (MSc.) in

neurological sciences in 1989.

Dr Prud'Homme has special interest in neuromodulation for pain, movement disorders, spasticity and neuromodulation for walking. He does implantation for peripheral neurostimulation including occipital nerve stimulation, spinal cord, DBS, and intrathecal pumps. He is the principal investigator for a new close-loop peripheral neurostimulator for walking and has research projects on the use of intrathecal pump for walking. He participates in the EVIDENCE study comparing the use of neurostimulation versus reoperation for failed back surgery syndrome (FBSS).

Michael Saulino, M.D., PhD

Dr. Michael Saulino, a physiatrist at MossRehab, is board certified in Physical Medicine and Rehabilitation, Spinal Cord Injury Medicine and Pain Management. Dr. Saulino earned his PhD (Biological Chemistry) and MD degrees from the Pennsylvania State University College of Medicine in 1993. He completed a transitional internship at Mercy Catholic Medical Center in 1994 and his residency training in Physical Medicine and Rehabilitation at Thomas Jefferson University in 1997. He was chief resident in his final year of residency training.

Dr Saulino's areas of clinical and research interest include pain management, spasticity management, and intrathecal therapy. Dr. Saulino has published over 40 scientific articles in prestigious medical journals including the *PM&R, Archives of Physical Medicine and Rehabilitation, American Journal of Physical Medicine and Rehabilitation Neurorehabilitation and Neural Repair, Neurology, Spinal Cord* and *Neuromodulation.* He was recently honored with the best research paper award for 2012 by the *American Journal of Physical Medicine and Rehabilitation.*

Konstantin Slavin, M.D., FAANS

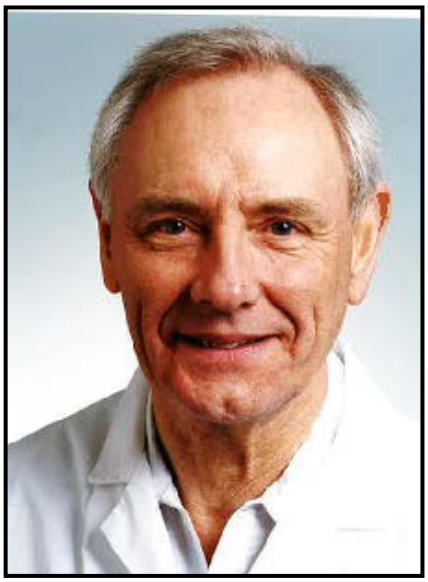
Dr. Slavin is Professor, Chief of Stereotactic and Functional Neurosurgery section, and Fellowship Director for Stereotactic and Functional Neurosurgery in the Department of Neurosurgery at the University of Illinois at Chicago (UIC).

Dr. Slavin graduated from medical school in Baku, the Soviet Union and completed his neurosurgery residency in Moscow. He completed his second neurosurgery residency at UIC and a fellowship in functional and stereotactic neurosurgery at Oregon Health Sciences University in Portland, OR.

Dr. Slavin currently serves as the President of the American Society for Stereotactic and Functional Neurosurgery and Vice-Secretary/Treasurer of the World Society for Stereotactic and Functional Neurosurgery. He is also the Secretary of the North American Neuromodulation Society (NANS) and Director-at-Large of the International Neuromodulation Society (INS). For many years, he was an Executive Committee member of the Joint Section on Pain of the American Association of Neurological Surgeons and Congress of Neurological Surgeons.

Dr. Slavin is published in many books and peer-reviewed journals and is an associate editor or editorial board member for a number of publications, including Neurosurgery, Neuromodulation, Surgical Neurology International and others. His book on Peripheral Nerve Stimulation was published in 2011; another book, co-edited with Sam Eljamel on Neurostimulation: Practice and Principles, came out earlier this year.

Michael Stanton-Hicks, M.B.; BS, Dr Med.



Michael Stanton-Hicks, MD is Vice Chairman of the Anesthesiology Institute at Cleveland Clinic in Cleveland, Ohio. His clinical interests are chronic pain, Complex Regional Pain Syndrome and regional anesthesia. Dr. Stanton-Hicks is board-certified in both pain medicine and anesthesiology.

A frequent national and international lecturer, Dr. Stanton-Hicks has authored more than 150 articles, book chapters and text books. He is an active member of numerous national and international professional societies having been president and committee chairman of many of these organizations. Dr. Stanton-Hicks has received several distinguished awards for his activities in pain medicine and continues to be principal investigator for numerous funded research projects.

Nelson Svorkdal, M.D.

A graduate from medical school in University of Saskatchewan, Dr. Svorkdal completed his anaesthesiology residency at the University of Manitoba in Winnipeg and an interventional pain fellowship at Sahlgrenska Hospital in Gothenburg, Sweden.

He is currently Assistant Professor with the University of British Columbia, Island Medical Program and works as an anaesthesiologist and interventional pain specialist at the Royal Jubilee Hospital in Victoria, BC. The applications of neuromodulation for the management of refractory cardiac disease represent some of his clinical expertise and academic interests.

Outside the hospital, he enjoys all things 'viking' and has a busy routine trying to keep pace with his wife and four children.

ABSTRACTS: ORAL PRESENTATIONS

SESSION I: Friday Sept. 27, 13:15 to 17:00

Intrathecal Baclofen – An Overview

Michael Saulino, M.D., Ph.D
MossRehab, Pennsylvania

Intrathecal administration of baclofen is a well-established technique for modulating hypertonia secondary to upper motor neuron pathology. Despite over 2 decades of widespread clinical use, this intervention presents many challenges to even experienced clinicians. The purpose of this clinical review is to describe some of the intricacies and subtleties of this treatment strategy. This narrative provides an overview of 5 topics: (1) the disease processes associated with severe spasticity; (2) the pharmacologic properties of intrathecal baclofen; (3) device optimization / troubleshooting; (4) clinician responsibilities; and (5) management

of patient expectations.

The role of SNM in Painful Bladder Syndrome / Interstitial Cystitis

Jerzy Gajewski, M.D.
Dalhousie University, Halifax, N.S.

Painful Bladder Syndrome/Interstitial Cystitis (BPS/IC) is a chronic bladder condition of unknown origin. Interstitial cystitis (IC) is a subgroup of PBS patients with inflammatory changes in the bladder. BPS/IC is characterized by debilitating bladder pain which can be associated with urgency, frequency and nocturia. These symptoms significantly impair the patient's quality of life. Its cause is not clear and it is still a disease diagnosed by exclusion.

Treatment is nonspecific and highly individual and consist of diet modification, oral medications, bladder instillations, sacral neuromodulation (SNM) or surgical interventions. Surgery is considered to be the last resort but not always with the successful outcome. This is why SNM, a minimally invasive treatment, has now a significant role in the treatment of BPS/IC.

Mechanism of action of SNM on BPS/IC symptoms remains unclear, but there are some reports indicating multilevel involvement of CNS and peripheral reflexes.

SNM consists of two phases. In the first phase - called peripheral nerve evaluation (PNE test) temporary wire like electrode is introduced to sacral foramina 3 or 4 and connected to the external stimulator. If sufficient improvement in symptoms is observed, (at least 50%) over a week or two, a permanent implant (second phase) is offered to the patient. In recent years, the "two stage approach" with initial implantation of the permanent electrodes has been favoured as it increases treatment success rates. Bilateral stimulation is utilised by some centres but there is no definite date on superiority of this approach.

There are approximately 15 publications which refer to sacral neuromodulation for BPS/IC. Long-term success rates of SNM vary significantly in the literature (50-80%) due to heterogeneous patient populations as well as different surgical approaches. With the introduction of "tined lead electrodes" (2002), tissue damage is reduced to a minimum. Our own experience showed very good long term results of 72%. However the revision rate of 50% is high but is improving with the advances in technology and surgical techniques.

SNM is an effective treatment to control symptoms of BPS/IC. It should be considered before any major invasive surgical intervention if conservative measures have failed. It is a minimally invasive, safe procedure with good long-term outcome. However, the revision rate is high and patients require lifelong follow up.

Treatment of secondary craniofacial pain syndromes of central and peripheral origins by occipital nerve stimulation with 16 lead contacts

Authors: Michel Prud'Homme, M.D., PhD, Sylvine Cottin, PhD, Nevair Gallani, M.D.

Centre de recherche du CHU de Québec, Département des sciences neurologiques, Faculté de médecine, Université Laval, Quebec City, Canada

Presented by: Michel Prud'Homme, M.D., PhD

Introduction: Secondary neuropathic craniofacial pain is a challenging clinical condition often requiring different medical and surgical approaches among which the use of neuromodulation needs to be defined. Occipital nerve stimulation (ONS) has been used to treat cluster headaches and other migraine conditions. However, it is not known if ONS can be useful in other craniofacial neuropathic pains in the trigeminal territory.

Objective: To report on two patients suffering from complex refractory craniofacial pain syndromes, one secondary to a peripheral and the other due to central lesion, both successfully treated with occipital nerve stimulation.

Material and Methods: Patients: 1) C.G. with hemifacial pain in V3 territory for three years secondary to lingual nerve avulsion during a dental procedure, and patient 2) S.R. suffering from unilateral complex craniofacial pain syndrome for five years after onset of pontine hemorrhage and subsequent surgery to remove a cavernoma. Both were treated with surgical insertion of 16-contact leads unilateral (S.R) or bilateral (C.G) for occipital nerve stimulation.

Results: Patient C.G. at a recent one month follow up shows improvement in pain control with remission of pain crisis during eating et talking; patient S.R. at one year remains with 40% reduction of pain intensity, with 50% of pain territory coverage.

Conclusions: Occipital nerve stimulation is a safe and effective treatment to control secondary neuropathic pain in the trigeminal territory. Stimulation coverage of the painful territory is not essential to be effective. Probable functional coupling is attributed to the trigeminocervical complex formed by the caudal trigeminal spinal nucleus and upper three cervical horns. Using the 16 contacts leads permit an excellent coverage of the greater and lesser occipital nerves and might improve the efficacy of the therapy.

Analysis and in-vivo results of MRI radiofrequency heating due to neuromodulation systems.

Authors: Heather Orser, John Welter, Steve Manker, Jamu Alford, Jim Olsen, Bryan Stem, Wanzhan Liu, Michael Kalm

Research and Development, Medtronic Neuromodulation, Minneapolis, MN

Presented by: Steve Manker

Introduction: A panel of international experts has developed a technical specification, ISO/TS

10974:2012, that outlines the test methodology to apply to determine active implantable medical device (AIMD) safety in an MRI environment. For neuromodulation patients, the primary hazard of concern when undergoing an MRI is heating near the electrodes due to the radiofrequency (RF) field produced by the MRI during imaging.

Objectives: 1) Characterize biological response variation due to tissue heating; 2) Confirm computational animal and lead/INS model and 3) Demonstrate the ability to accurately predict electrode heating in a complex MRI environment.

Materials/Methods: Fourteen anesthetized animals received an anatomically relevant neuromodulation system implant, comprised of an implantable neurostimulator and lead, and were scanned in an MRI while the temperature was measured at the system electrodes. The resultant temperatures were used to confirm the modeling capability of electrode heating *in vivo* and to calibrate computational models.

Results: Thermal rises at system electrodes in an MRI environment were measured in all animals. An empirical model was used to independently predict thermal rises in each animal. The resulting predicted and measured temperatures were compared to determine the accuracy of the model and expected patient variation due to thermoregulatory differences. Figure 1 shows the fit of the model to measured data for a Medtronic MRI Conditionally Safe system. The results show normally distributed errors having a standard deviation of 10.4% of max. This establishes accuracy and goodness of the model in a biological equivalent.

Discussion: The modeling techniques established and confirmed in an animal model are used to predict human temperatures in millions of situations with variations due to lead routing, patient morphology, MRI scanner coil configurations, patient placement in the bore, patient thermoregulation, and patient thermal sensitivity. RF heating safety is assessed on a therapy and system basis and should not be generalized as thermal predications are a function of MRI coil, patient positioning, lead construction, lead length, implant path, and patient morphology. Medtronic uses this level of rigor to ensure patient safety across the range of clinical scenarios.

Conclusions: The RF heating analysis performed by Medtronic demonstrates the ability to predict thermal behaviour *in vivo*. Additional analysis in accordance with ISO 10974:2012 is necessary to demonstrate patient safety. Millions of simulated MRI scans that vary the relevant variables need to be run to capture all clinically relevant exposures.

Intrathecal clonidine pump as a treatment for spasticity and walking: a multiple case study

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Authors: Michel Prud'Homme, M.D., PhD, Sylvine Cottin, PhD, Josée Roy, Isabelle Coté

Centre de recherche du CHU de Québec, Département des sciences neurologiques, Faculté de médecine, Université Laval, Quebec City, Canada

Presented by: Sylvine Cottin, PhD

Introduction: Spasticity that is refractory to oral medication is a major complication of several neurological diseases including multiple sclerosis (MS), hereditary spastic paraparesis (HSP), spinal

cord injury (SCI) and can cause problems for mobility and walking. Clonidine is a noradrenergic agonist which showed some improvement of walking in animal models of SCI and some control of spasticity by IT bolus in SCI patients. However, no studies have yet evaluated the use of clonidine in IT perfusion pumps for ambulatory spastic patients.

Objective: We present a case series of seven spastic patients refractory to oral medication evaluated for control of spasticity and ambulatory functions that were treated by IT clonidine pump.

Material and Methods: Two women and five men (mean age 44.7 yrs (17.5-59.7 yrs), mean follow up of 25.5 months (2.0- 58.1; diagnostics: 2 MS, 3 HSP, 1 CP, 1 SCI) were evaluated by a bolus test trial then implanted after positive response without major side effects.

Results: All patients but one had major improvement in their spasticity (55 to 85%) without side effects. Walking abilities were described as improved and more fluid by rehabilitation team and walking parameters improved for most patients. The 6 minutes walking test improved the most (mean 40.5%; -4.7 to 84.4%), then 10 m max speed (mean 23.9%; 8.3 – 47.6%), 10m WT normal speed (mean 13.3%; 1.4 - 40%), Time Up and Go (mean 13.1%; -15.5 – 42.9%), Berg balance (mean 13.5%; 0 – 41.1%). Quality of life improved in every aspect but mainly in the mental health domain.

Conclusions: These results indicate that intrathecal clonidine therapy can be safely used and is effective in controlling spasticity to preserve or improve walking abilities in selected patients. Most patients were able to improve their walking compared to their baseline and some improved their walking distance in 6 minutes by more than 70-80%. Theses results positively affect quality of life. More studies are needed to evaluate the comparative role of clonidine and baclofen, alone or in combination on the walking parameters, along with concomitant rehabilitation programs.

Chronic nerve root stimulation for extracranial neuropathic pain.

Authors: Adrian Levine, BSc; Andrew Parrent, MD; Keith MacDougall, MD

London Health Science Centre, University Hospital, London, ON

Presented by: Keith MacDougall, M.D.

Objectives: Spinal cord stimulation (SCS) can be useful for patients with chronic neuropathic pain. However, there are some patients who require more focused coverage with paresthesias, for whom there is insufficient somatic representation in the dorsal columns, or those where SCS is overly positional. These patients can do well with spinal nerve root stimulation (NRS). Current evidence to support its long term use is lacking. We hypothesized that NRS would allow us to treat patients that are difficult to treat with SCS, and have comparable long-term results to our SCS patients.

Materials and Methods: All 124 patients treated with spinal stimulation since July 1, 2011 were included in the study. We performed permanent implantation in 67 (55%), based on a visual analogue scale (VAS) pain score decrease of at least 50% during trial stimulation or otherwise significant increase in quality of life. Follow up visits were had at 3, 6, and 12 months following permanent implantation.

Results: Permanently implanted NRS patients had reductions in VAS of 3.6±1.1 at 3 months, 5.0±2.0 at 6 months, and 4.7±4.5 at 12 months. Improvements were seen in all components of the SF-36 at 3, 6, and 12 months. The mean equivalent daily dose of morphine was on average significantly reduced at 3, 6, and 12 months.

Conclusions: We conclude that NRS is an effective long term treatment for certain types and locations of neuropathic pain that are difficult to target with spinal cord stimulation, particular pain in the upper limbs and groin.

Evaluation of fine motor benefits of deep brain stimulation in an essential tremor patient.

Authors: Nevair Gallani, M.D., Sylvine Cottin, PhD, Michel Prud'Homme, M.D., Léo Cantin, M.D.

Centre de recherche du CHU de Québec, Département de sciences neurologiques, Faculté de médecine, Université Laval, Quebec City, Canada.

Presented by: Nevair Gallani, M.D.

Objective : Tremor represents one of the most commons neurological symptoms. The intensity of the clinical manifestation, as well as the prevalence, increase with age. Many patients can develop incapacity, and medical treatment can fail to provide good control of symptoms. For these patients, DBS may represent an additional option of treatment. Nevertheless, there is a lack of studies to evaluate fine motor achievements at outcome. The objective of this study is to evaluate possible fine motor benefits brought about by DBS surgery.

Methods : A series of eight patients who underwent thalamic DBS surgery (fifteen stimulators) were evaluated before and one year after treatment, with the Fahn-Tolosa-Marin (FTM), daily activities questionnaire (DAQ), tremor handicap questionnaire (THQ), and the 9-hole-peg-test (9-HPT).

Results : The scores obtained were as follows: FTM preoperatory 56.2 ±15.2 vs post-operatively 20.5 ±11.8 ($p<0,05$), DAQ 30.4 ±6.5 vs 5.0 ±4.2 ($p<0,05$), THQ 11.5 ±6.6 vs 0.0 ±0.0 ($p<0.05$), 9-HPT dominant hand 35.4sec ±11.2 vs 29.5 ±7.7 ($p<0.05$), 9-HPT non-dominant hand 38.7sec ±15.1 vs 37.2 ±15.3 (not significant). The results showed an improvement of all scores at one year follow up in comparison with the baseline evaluation (FTM 63.5%; DAQ 83.5%; THQ 99%, 9-HPT dominant hand 16.7%) ($p<0.05$), except for the non-dominant hand with a non-significant improvement.

Conclusion : Thalamic DBS within these patients, affected with essential tremor, refractary to any medical treatment was remarkably effective, mainly for quality of life, but also in dexterity of the dominant hand.

MRI safe deep brain and spinal cord stimulation systems: studies of the maximum safe lead tip temperature.

Authors: Robert J. Coffey[1,2], John Pearce[3], Jim Olsen[1], Ron Kalin[1], Steve Manker[1]

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Presented by: Steve Manker, PhD

Introduction: Magnetic Resonance Imaging (MRI) is the preferred imaging modality for the central nervous system (CNS) and other soft tissues, with global usage approaching 60 million studies per year. The most important MRI related hazard for neurostimulation patients is radiofrequency-induced (RF) heating at the tissue electrode interface. To develop the next generation of MRI-conditionally safe brain and spinal cord stimulation leads, we performed studies to define the maximum tolerable thermal dose (time and temperature) and the probability of symptomatic neurological injury if that dose is exceeded.

Objectives: First, to define the maximum permissible thermal dose (temperature and time) before symptomatic neural injury. Second, to develop MRI Conditionally Safe leads for Deep Brain and Spinal Cord Stimulation. Third, to predict the likelihood of symptomatic neural injury if the thermal dose is exceeded.

Materials/Methods: Methodological approaches included: 1) Animal studies where replica leads with embedded temperature-sensing probes were implanted in the brain or spinal canal of sheep and exposed to 64 MHz RF-induced temperatures of 37 to 49C for 30 minutes; and temperature-blinded histopathology examinations were performed after 7 and 21 days to allow for tissue reactions. 2) We reviewed published and unpublished (interview) data regarding the temperature threshold for therapeutic RF lesions in the brain and spinal cord; and we reviewed published data on the use of whole body hyperthermia (WBHT) for cancer treatment. 3) CEM43 (equivalent minutes of exposure at 43C) and Arrhenius analytical methods were used to extend these findings to other exposure times and temperatures.

Results: Deep brain and spinal epidural RF heating up to 43 C for 30 minutes produced effects that were indistinguishable from unheated 37 C controls. RF-induced electrode heating greater than 43 C for 30 minutes produced temperature-dependent and highly localized thermal damage. Therapeutic RF lesioning of the brain and spinal cord, with therapeutic and temporary test-lesion temperatures normalized to 43 C for 30 minutes, also supported the finding of no CNS tissue injury at that temperature and time limit. These results further agree with the practice of limiting WBHT exposure to 42.5 C for 60 minutes in cancer patients.

Discussion: MRI-related RF heating exposure above 43 C and/or for longer than 30 minutes is predicted to cause an increasing risk of clinically evident thermal damage to the brain or spinal cord regions immediately surrounding implanted neurostimulation leads.

Conclusions: The maximum safely tolerable temperature for 30 minutes exposure from 64 MHz RF heating is 43 C for 30 minutes.

SESSION II: Saturday Sept. 28, 8:30 a.m. to 12:00

Evolution of DBS – in search of new paradigms

Konstantin Slavin, M.D., FAANS
Department of Neurosurgery, University of Illinois at Chicago, US

Despite its long history in treatment of movement disorders, psychiatric conditions and chronic pain, the general paradigms of Deep Brain Stimulation (DBS) remain essentially unchanged since the inception of this modality. Current approach to DBS involves use of electrode leads with cylindrical contacts that deliver repetitive (usually high frequency) omni-directional stimulation in the area of anatomically and physiologically defined target. The results of this approach have been found to be good enough to secure regulatory approval for several common indications, such as Parkinson disease, essential tremor, dystonia and, most recently, obsessive compulsive disorder.

But in addition to overall impressive results of long-term DBS, the analysis of growing worldwide experience has identified multiple issues that lower its effectiveness. Among them are: somewhat unpredictable response of some patients to established stimulation parameters suggestive of inter-individual variability of targeted structures, gradual progressive decrease in DBS effectiveness that suggests development of tolerance, presence of stimulation-related side effects that limit its use and may be explained by a close proximity of different cerebral circuits some of which should be excluded from stimulation field. All these issues may be behind the widespread skepticism toward DBS among neurologists and other specialists who ultimately control the patient referral for DBS interventions.

Development of new paradigms in DBS may overcome some or all of the abovementioned concerns. For example, development of sophisticated pattern recognition in anatomical and, more importantly, physiological delineation of targeted structures may facilitate more precise insertion of DBS electrodes. Creation of multi-directional electrodes may introduce individually tailored sculpting of electrical field that conforms to location and shape of intended targets while sparing those that are responsible for side effects. Finally, development of closed loop feedback mechanism has a potential of optimizing the stimulation timing so it is delivered only when it's needed thereby decreasing the possibility of developing tolerance to DBS.

Progress in technology and materials, device manufacturing process, introduction of implanted and non-invasive sensors and recorders, as well as conceptual and practical DBS innovations result in slowly but surely evolving field – bringing new hope for the future DBS users, patients and physicians.

DBS troubleshooting session: interactive session

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The Dr. Tasker Lecture: Peripheral Nerve Stimulation for Pain: Review and Update

Honoured speaker: Konstantin Slavin, M.D., FAANS
University of Illinois at Chicago, Chicago, IL

By most estimates, peripheral nerve stimulation (PNS) represents the fastest growing segment of neuromodulation worldwide. And while PNS is actively used for treatment of autonomic dysfunction, motor impairment, epilepsy, depression, gastrointestinal disorders and sleep apnea, the largest clinical application of PNS remains treatment of chronic pain.

After several decades of relative obscurity, PNS is now catching up with spinal cord stimulation in terms of clinical volumes and the number of indications. In addition to the traditional PNS indications, such as complex regional pain syndromes and post-traumatic or post-surgical pain related to an injury of peripheral nerves, PNS and its close relative peripheral nerve field stimulation (PNFS) are now considered for treatment of chronic back and neck pain, chest wall and abdominal neuralgias, as well as post-amputation pain. In addition to this, a large category of craniofacial PNS indications now includes chronic migraines, cluster headaches, post-traumatic trigeminal neuropathy, and occipital neuralgia.

The less invasive nature of PNS and PNFS makes these modalities very attractive for the patients and implanters alike. But in order to gain regulatory approval, there are now multiple prospective studies being conducted all over the world – mainly to refine surgical indications for PNS and to clarify treatment expectations from this approach. Not surprisingly, large market potential attracted various device manufacturing companies to concentrate on PNS; this resulted in introduction of completely different stimulation delivery systems, most of which are dedicated to PNS.

It is fascinating to witness the progress in PNS when large-scale multi-center studies that use traditional devices take place alongside smaller investigations that try to prove new concepts and focus on specific pathological conditions. To name just few examples, there are currently a study investigating subcutaneous stimulation (PNFS) in treatment of low back pain and another study that tests occipital nerve stimulation (ONS) in treatment of migraines. At the same time, there is now a study on PNS in pain in extremities using an implanted receiver integrated with a multi-contact

electrode, another study focusing on high frequency stimulation of nerve trunks proximal to post-amputation neuroma, and a different study that tests stimulation of sphenopalatine ganglion in treatment of cluster headaches and migraines.

The preliminary results of ongoing investigations and those from earlier completed studies have paved the way for regulatory approval of PNS for treatment of migraine headaches using ONS and chronic back pain using PNFS approaches, but so far only outside of the United States. This review provides a balanced but overall optimistic outlook on current state of PNS and its perspectives in the near future.

SESSION III: Saturday Sept. 28, 12:00 p.m. to 16:30

Spinal Cord Stimulation: future technologies, their applications and patient selection

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Michael Stanton-Hicks, M.B.; BS, Dr Med
Anesthesiology Institute at Cleveland Clinic in Cleveland, Ohio

During the last 10 years, spinal cord stimulation has benefited from significant improvements in the technology and systems that are provided by the three manufacturers whose equipment are currently used. The improvements in equipment have been an improvement in battery technology which has correspondently reduced the size of the implanted programmable generator (IPG), rechargeable systems, elimination of extensions where possible, and a significant choice in electrode spacing, number of electrodes in both percutaneous and paddle type leads. While there has been no change in the standard parameters of amplitude pulse rate and frequency using the same type of square wave pulse, a wider range of frequency is available with some manufacturers.

While improvements in programming capability are incorporated in these new systems and in the case of one manufacturer, an accelerometer has been incorporated in one system that allows it to accommodate to some degree with the patient's position-lying, sitting and standing.

Future technologies have already addressed high frequency and ultra- high frequency stimulation, thus eliminating the sensory feedback. While high frequency stimulation is currently available in Europe and Australia- in North American, it can only be used as an experimental modality.

One thing is clear however, and that is the inability of some patients to obtain optimal moderation of their pain when using a stand-along SCS, even if additional electrodes are added. Analgesia (pain control), can frequently benefit from the addition of either a peripheral nerve stimulator (PNS) or peripheral nerve field stimulator (PNfS) electrodes. These enhancements can significantly improve the efficacy of spinal cord stimulation.

Another area that has been addressed is the intraspinal dorsal root ganglion (DRG) stimulation

which can provide regional analgesia at least equal to and in many cases better than can be achieved by conventional SCS. This system is currently being used clinically in the U.S. under an experimental protocol.

Much recent work emanating from Case Western Reserve University and other centers are addressing different wave form and electrical stimulation characteristics, both DC and AC. This work may change the concept of large AB-fiber stimulation having effects on the inhibitory pathways of the central nervous system to stimulation of C-fibers, having an entirely different mechanism of action.

Although SCS is primarily directed to pain of a neuropathic nature, there is increasing evidence that antinoception may also be an important attribute of this modality. The traditional areas in which many studies have now validated the use of SCS are failed back surgery syndrome and complex regional pain syndrome. However, SCS is also useful in many neuropathies-mononeuropathies, plexopathies, visceral pain myocardial and vascular conditions.

Patient selection for SCS requires a behavioural evaluation and after an invariably exhaustive attempts at addressing, stabilizing and reducing those symptoms associated with the particular chronic pain condition. While there is no specific algorithm that addresses the length of time conventional medical management (CMM) should be practiced before one can say a point has been reached for considering neuromodulation, there is a growing consensus amongst neuromodulators that spinal cord stimulation should be introduced much earlier in the treatment algorithm for certain medical diseases and syndromes. In particular, a syndrome such as (CRPS) should be considered for a trial of SCS much earlier when multidisciplinary treatment that has failed to achieve any progress. In fact, this and some other conditions may have a poor response or worse, no response to SCS there might have been the case had this modality been introduced at a much earlier stage.

A number of meta-analysis and data in the Cochran database clearly support the use of SCS for such syndromes.

SCS is not a stand-alone treatment but should always be incorporated within a multidisciplinary approach and in particular as a facilitator of exercise therapy in patients who require significant functional restoration.

Troubleshooting Spinal Cord Stimulation: interactive session

Andy Parrent[1], MD, Michael Stanton-Hicks[2], M.B.; BS, Dr Med and Barbara Eden[1], RN

[1]Clinical Neuroscience Pain Program, London Health Science Center, University Hospital, London, ON

[2] Anesthesiology Institute at Cleveland Clinic in Cleveland, Ohio

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Patient selection for SCS in the FBSS population

Michel Prud'Homme[1], M.D., PhD and Nelson Svorkdal[2], M.D.
[1] Centre de recherche du CHU de Québec, Département des sciences neurologiques, Faculté de médecine, Université Laval, Quebec City, Canada
[2] Assistant Professor, University of British Columbia, Island Medical Program and Department of Anaesthesia Royal Jubilee Hospital, Victoria, BC.

Evidence of the Comparative Cost-Effectiveness of SCS in Four Neuropathic Pathologies vs. Alternative Treatment

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Authors: Krishna Kumar, MBBS, MS, FRCS(C)[1]; Syed Rizvi, MD[2]

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Presented by: Kris Kumar, MBBS, MS, FRCS(C)

Objective: To evaluate the cost-impact of SCS compared with optimal medical management (OMM) for failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), peripheral arterial disease (PAD), and refractory angina pectoris (RAP).

Materials and Methods: Markov models were developed to evaluate the cost-effectiveness of SCS + OMM versus OMM alone from the perspective of a provincial Ministry of Health. Health effects were expressed as quality-adjusted life years (QALYs). Costs and effects were calculated over a 10-year time horizon and discounted at 3.5% annually. Cost-effectiveness was identified by deterministic and probabilistic sensitivity analysis. Outcome measures were: cost, QALY, incremental net monetary benefit (INMB), and incremental cost-effectiveness ratio (ICER). We separately compared the cost-effectiveness of rechargeable and non-rechargeable SCS.

Results: The ICER for SCS was: $7,318 (FBSS), $9,618 (CRPS), $7,294 (PAD), $8,143 (RAP) per QALY gained, respectively. The ICER for SCS fell well below the commonly accepted WTP threshold of $50,000 per QALY.

The probability of cost-effectiveness compared with OMM was 74-95% depending on pathology and willingness to pay (WTP) threshold per QALY. In all 4 pathologies, SCS provided a positive INMB over OMM at WTP thresholds ≥ $7,000 per QALY, which strongly suggests that SCS is a treatment strategy worth funding. Sensitivity analyses demonstrated that results were robust to plausible variations in model inputs. Rechargeable-SCS is more cost-effective if the lifespan of a non-rechargeable IPG ≤4.25 years.

Conclusions: SCS remains highly cost-effective compared with OMM over the next decade. These results should alert payers to the substantial economic benefits of this therapy.

SESSION IV: Sunday Sept. 29, 8:15 a.m. to 12:00

Neuromodulation for Angina: A review

Nelson Svorkdal, M.D.
Assistant Professor, University of British Columbia, Island Medical Program and Department of Anaesthesia Royal Jubilee Hospital, Victoria, BC.

Patients with persistent and chronic cardiac diseases can be refractory to conventional treatment strategies such as medical management and/or revascularization. Spinal cord stimulation is a therapeutic option for refractory angina and has been used for over 20 years. Some recent studies have reported conflicting results, however. They will be reviewed as well as alternative neuromodulation techniques such as subcutaneous electrical nerve stimulation. Independent experimental data on the effects of neuromodulation in chronic congestive heart failure and in persistent arrhythmias will also be presented.

The Dr. Kris Kumar Lecture:
CRPS 1: Pathophysiology, patient selection and treatment

Honoured speaker: Michael Stanton-Hicks, M.B.; BS, Dr Med
Anesthesiology Institute at Cleveland Clinic in Cleveland, Ohio

Complex regional pain syndrome (CRPS), a term that was used to replace the older terminology "reflex sympathetic dystrophy" (RSD) describes a variety of conditions in which abnormal inflammatory findings and excess associated pain together with neuropathic pain tend to occur in a region of the body generally an extremity. This condition may progress with time, may spread more frequently ipsilaterally to another extremity or to the opposite side of the body. Spontaneous pain, allodynia which may be superficial or deep, hyperalgesia, edema, autonomic abnormalities and in some cases progression to dystrophic or trophic features. These conditions are usually preceeded by a known injury which may be minor or extensive, most commonly a sprain or fracture (65%). CRPS I describes distal extremity pain with or without edema and no apparent nerve lesion. CRPS II includes all of the foregoing aspects but with a known nerve pathology. The autonomic abnormalities which tend to occur in most cases are responsible for the original term sympathetic, in the taxonomy. Sweating abnormalities, vasoconstriction/vasodilatation with cold or warm skin are frequent. There may be hyper or hypohydrosis. The most recent epidemiological study from the Netherlands, described an incidence of 26.2% cases per 100,000 population.

Motor abnormalities are now recognized in greater than 50% of patients with this condition and during the past 15 years, an associated immune cell-mediated inflammation with increased cytokines is well established. Furthermore, most recent studies have now focused on what appears to be an autoimmune response in patients with CRPS. Autoantibodies against rats sympathetic

neurons have been detected and in 40% of CRPS patients, immunoreactivity to campylobacter has been found in many early CRPS patients.

Sympathetically maintained pain, is a term that arose as a result of the abolition or reduction of pain that occurs after introduction of a sympathetic block that achieves a temperature of 34° C+ in the distal extremity. Treatment of this condition is primarily aimed at regaining function. This can be established by a rehabilitation pathway that emphases judicious use of physical therapeutic and occupational measures to regain the loss or reduction of function resulting from the pathologic processes in this syndrome. Techniques that are used to support rehabilitation are pharmacologic directed to the neuropathic pain, inflammation and nociceptive pain. Interventional measures may be necessary to support these patients while they are undergoing therapy.

The prognosis varies with the intensity of this condition. In all probability as many as 80% of patients will either spontaneously or ultimately remit after early treatment. The condition can always relapse and because this syndrome most likely has a genetic basis, this latter possibility remains for the patient's life.

Troubleshooting Pump Session: interactive session

Michael Saulino, M.D.[1], Bill McDonald, M.D.[2], Louise Malysh, RN, MSN[2]

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ABSTRACTS: POSTER PRESENTATIONS

Spinal Cord Stimulators for Intractable Renal Pain with Difficult Pain Mapping

Maria Eugenia Calvo Ballesteros MD.
Assistant Professor, McMaster University.

Objectives: Present a case of Spinal Cord Stimulators (SCS) as treatment for Intractable Kidney Pain with difficult pain mapping. Reinforce the fact that SCS coverage can be reported as improving over time.

Materials and Methods: To determine in patients with difficult pain mapping, if stimulation covering along the painful dermatomes with confirm paresthesia only at the level above and below, can imply adequate coverage and further improvement. Male 70 y.o. diabetic, with right flank pain, T8 to L1, due to multiple surgical interventions for kidney stones, non responsive to conservative or interventional treatment. Two SC leads (Boston Scientific) where implanted at top level T8 and T9, to cover more dermatomes. While mapping the pain, no stimulation was reported along the painful

dermatomes the paresthesia only covered the above and below levels.

Results: Six days after, the patient reported relief of all the pain along the dermatomes; T8 to L1, without changing the programming. Reduction of back spasms and referred groin pain was to 0/10.

Conclusion: SCS is a useful treatment in intractable renal pain (1). In difficult pain mapping, effort should be made into covering the distribution of the pain, but if no stimulation is reported at the moment of programming further improvement can be achieved, due to reduction of referred pain and muscle spasm. A cascade of neurotransmitters is released by SCS, complex interactions may relate to its immediate or later effect (2).

SCS- Spinal Cord Stimulators
SC – Spinal Cord.

References

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B. Linderoth, DRUG-ENHANCED SPINAL STIMULATION FOR PAIN; A NEW STRATEGY, Regional Anesthesia and Pain Medicine & Volume 35, Number 5, September-October 2010

Spinal cord stimulation lead configurations employing S-Series paddle lead(s) offer greater pain relief than dual 8-contact cylindrical leads.

Jerry Tracy, MD: Gosy & Associates Pain and Neurology Treatment Center, Buffalo, NY; Christopher Nelson, MD: Bluegrass Pain Consultants, Louisville, KY; Ioannis Skaribas, MD: Greater Houston Pain Consultants, Katy, TX; Jason Rosenberg, MD: SC Pain and Spine Specialist, Myrtle Beach, SC; Rafael Justiz, MD: Oklahoma Pain Physician, Purcell, OK; Julie Saranita, MD: Southlake Pain Institute, Clermont, FL; Camden Kneeland, MD: The Montana Center for Wellness and Pain Management, Kalispell, MT; Steven Rosen, MD: Fox Chase Pain Management Associates PC, Jenkintown, PA; George Girardi, MD: Front Range Pain Medicine, LLC, Fort Collins, CO

Objective: To compare the safety and efficacy of the percutaneously implanted single S-Series paddle leads used with a single cylindrical lead to the traditional dual 8-contact cylindrical leads.

Methods: Data was obtained from two IRB-approved, prospective studies (N=326). Based on lead configuration (dual cylindrical leads or S-Series lead combinations), measures of pain relief, satisfaction, and quality of life (QoL) were compared at 3 and 6 months post-implant. Power usage was calculated based on the patient's favourite program. Device-related adverse events were inspected. Group comparisons were performed using t-tests or Fisher's exact test.

Results: At 3 months, patients implanted with a single S-Series lead combination (n=21) reported higher patient-reported pain relief (69±31% vs. 60±25%; p=0.055) and exhibited improvement for categorical rating of pain relief (p=0.038) compared to patients implanted with dual cylindrical leads (n=298). At 6 months, patients implanted with a single S-Series lead combination (n=15) also reported higher patient-reported pain relief than patients with dual cylindrical leads (n=267), 69±32%

vs. 57±28% (p=0.058). Patients implanted with a single S-Series lead combination trended toward improved satisfaction and QoL. Power usage for patients with S-Series lead combinations was 9% less, on average, than patients with dual cylindrical leads. The proportion of device-related adverse events was similar for patients with at S-Series paddle leads and patients with dual cylindrical leads, 6.9% and 8.0%, respectively (p=1).

Conclusions: These results suggest that S-Series paddle lead configurations may result in better efficacy than traditional cylindrical leads, without any compromise in safety.

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Changes In Opioid Use Pre and Post Spinal Cord Stimulation

Monica Lawrence, Russell Munson, Traci Wiest, Krishna Kumar, MBBS, MS, FRCS(C)

Introduction: Spinal cord stimulation (SCS) has emerged as a safe, effective and economical option for the management of chronic neuropathic pain. Many patients presenting for SCS are medically managed by opiates as well as adjunctive pain medications. Post procedure, most patients return to their primary care physicians for follow up on their medication management. This has often led to patients continuing on their previous medication regimens without intervention. We propose that a personalized medication weaning process would result in decreased opioid use post SCS implant.

Materials and Methods: We gathered data on 56 SCS patients and compared opioid use pre-implant to opioid use 3, 6 and 12 months post-implant. Opioid use was converted to Morphine equivalents to provide a common frame of reference. Data was collected through direct patient interviews, the Pharmaceutical Information Program (PIP) and chart reviews. We excluded 4 patients due to repeated surgeries for new pathologies and SCS revisions.

Results: Our results showed an average opioid use reduction of 43% below baseline at the 3 month interval, 47% at 6 months, and 42% at 12 months. When comparing the patients who were given a weaning schedule, we found a 41% reduction below baseline at 3 months, 47% reduction at 6 months, and 64% reduction at 12 months.

Conclusion: Our research has shown that SCS patients who receive personalized weaning schedules post-implant, from the Neuromodulation clinic, were able to wean to a greater degree than those who weaned on their own.

Comparison of Burst and Tonic Spinal Cord Stimulation on Lumbosacral and Gracile Extracellular Recordings in an Animal Model

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Objectives: This translational study sought to explore differences between burst and tonic spinal cord stimulation (SCS): underlying mechanisms, paresthesia, and pain relief. We hypothesized that burst and tonic SCS may differentially affect nociceptive spinal networks and/or pathways involving the gracile nucleus.

Materials and Methods: Extracellular activity of neurons at L6-S2 and in the gracile nucleus of the dorsal column-medial lemniscal pathway were recorded during pinching and colorectal distension (60 mmHg) in anesthetized rats. A unipolar, ball-electrode at L2-L3 delivered burst pulses (5 pulses with 1 ms pulse width, at 500 Hz per burst, 40 Hz interburst frequency) or tonic (40 Hz) SCS at varying percentages of motor threshold.

Results: Average motor thresholds for burst SCS were significantly lower than tonic SCS at both recording locations. After high intensity (90% motor threshold) SCS, burst and tonic SCS did not differ, and all spinal neuronal responses to colorectal distension and pinch were decreased. At low intensity (60% motor threshold) SCS, only burst SCS significantly decreased the nociceptive somatic response. Interestingly, burst SCS did not increase spontaneous activity of neurons in the gracile nucleus; however, tonic SCS significantly increased activity of these cells.

Conclusions: Burst and tonic SCS suppressed lumbosacral neuronal responses to noxious stimuli; however, burst SCS had a greater inhibitory effect on the neuronal response to noxious somatic stimuli than visceral stimuli. The reason that paresthesia may be reduced or abolished in patients may be due, in part, to burst SCS not increasing activity of neurons in the gracile nucleus.

Acknowledgments: This work was supported by St. Jude Medical through a sponsored research study. Dr. Goodman Keiser is an employee of St. Jude Medical.

Low Prevalence of MRI-Related Explants in Spinal Cord Stimulation Patients

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Introduction: The need for Magnetic Resonance Imaging (MRI) among Spinal Cord Stimulation (SCS) patients is of interest to clinicians due to the potential incompatibility of SCS systems with MRI technology. A key question, however, is the magnitude of this need in the SCS patient population. In order to address this question, we performed a systematic analysis of the entire Boston Scientific Neuromodulation (BSN) US complaint reporting database over a 30-month period, to identify device

explants performed due to a need for MRI. Obtaining prevalence data on MRI-related explants in SCS patients provides both a measure of how often MRI is required in this patient population, as well as a direct measure of the average risk per patient-year of needing to undergo an explant procedure to facilitate this imaging modality.

Methods: The data analyzed comprised of all closed US complaints reported to BSN between September 2010 and February 2013. Search terms were selected to capture the intersection of SCS, MRI, and Explant. Prevalence of MRI-related SCS explants was calculated based on the frequency count of these events in relation to the total BSN SCS-implanted patient population in the US. The relative risk of needing an MRI-related explant was calculated as a hazard ratio, based on the frequency of these events relative to other explant types. Finally, the per patient-year risk (the average risk for a given patient that s/he will need to explant the device in order to undergo MRI, per year of living with an SCS implant) was calculated as the continuous probability of an MRI-related explant per 365-day period, adjusted for both the influx of newly implanted patients and the loss of newly explanted patients over time, using a two-state Markov Chain model.

Results: The prevalence estimate of MRI-related explants was found to be statistically indistinguishable published estimates of MRIs performed in the general population. Full results, hazard ratio estimates, and details of the per patient-year risk Markov Chain model will be provided in the paper. This model will incorporate not only the full per-patient risk, but also confidence bounds and error margins to account for potential under-reporting.

Conclusion: This paper will present the estimated prevalence of MRI-related explants in the SCS patient population, coupled with the patient's risk of needing an explant to undergo MRI at any given time. Our current estimates are very low, suggesting that MRI does not play a major role in SCS patients' need for device explants, and that the per-patient risk of needing an MRI while implanted with an SCS device is in-line with the general population. Further study is recommended to expand the current.

Retrograde Thoracic (T2-3,T3-4) Placement of Spinal Cord Stimulator Leads In a Patient With L1-2 Spinal Cord Injury and Neuropathic Foot Pain-A Case Report

Karl Muendel, M.D., Alan Berkman M.D., Susan Schellinck, O.T.
VIHA Pain Program, Nanaimo, BC, Canada

Objectives: 1) To introduce a novel technique for retrograde upper thoracic lead placement when other access sites are unavailable; 2) Present the possibility of spinal cord stimulator paresthesia coverage in one patient with L1 spinal cord injury with cystic cord changes status post extensive spinal surgery presenting with severe bilateral foot pain; 3) Show the difference in outcome measures at 6 mo in the same patient.

Materials and Methods: A 38 year old male suffered a L2 burst fracture after falling off a cliff while firefighting in 2000. Pt suffered incomplete paraplegia. Pt underwent extensive spinal surgery with graft and cage. He was not initially considered for SCS placement due to the area of cord damage, hardware and unlikely access. He was eventually trialed with a BS system with a retrograde approach at T4-5. The initial trial took 3 hours. The leads spanned the T10 and T11 vertebral levels. The permanent retrograde placement was quite difficult and several trials were made to access the

epidural space. Eventually we were able to access the T2-T3 as well as the T3-T4 interspaces from a lateral approach. The leads were initially guided along the anterior epidural space and directed posteriorly further down the cord. PDI, SF McGill, PCS, TSK, POQ and a subjective functional performance questionnaire were recorded pre and post procedure.

Results: The majority of his pain was covered with the above placement.
Pain Disability Index (PDI). This measures pain related disability. Improvement from 55% (moderate range of disability due to pain) to 4% (very low range).

SF McGill. Measure of pain quality and quantity: Improvement from 6/45 to 1/45. This patient no longer experiences shooting, stabbing, sharp or aching pain.

Pain Catastrophizing Scale (PCS). Measures pain and emotional distress: Improvement from 75% (moderate range of catastophizing) to 9% (very low range).

Tampa Scale of Kinesiophobia. (TSK). Measures fear of movement/re-injury: No change. Patient is in low range for fear of movement/re-injury.

Conclusion: A retrograde high thoracic lead placement from a lateral approach, although tedious and time intensive, was possible in this patient's spine where few options for coverage existed.
The pain in this patient's feet was covered almost entirely with two T10-T11 BS octad leads above the area of spinal cord surgery. All measures recorded in this case improved, except for kinesiophobia (TSK), which stayed the same.

Clinical outcomes of multiple independent current control spinal cord stimulation: a cohort study.

Sylvine Cottin, PhD, Léo Cantin, M.D., Nevair Gallani, M.D, Michel Prud'Homme, M.D., PhD

Centre de recherche du CHU de Québec, Département de sciences neurologiques, Faculté de médecine, Université Laval, Quebec city, Canada.

Objectives: To examine the outcomes in neuropathic pain patients treated by eight-contact leads with multiple independent current control technology, after two years of stimulation.

Materials and Methods – Of 37 patients who received spinal cord stimulation trial, 36 (97.3%) agreed to participate in our local neuromodulation database. All but one patient were implanted with percutaneous leads. Baseline data were extracted and compared with 2-year follow-up. Outcomes were pain relief measured by a pain numeric scale, quality of life with the SF-36v2 questionnaire and sleep quality.
Results – The rate for successful trial was 86.1% (31 patients). Mean pain decreased from 6.9 to 5 with a paresthesia coverage of 77.8%. Quality of life was significantly improved in 7 out of the 8 domains of the questionnaire and 38.95% of the patients were relieved from their sleep disorder. Sleep duration was increased and participants reported less awakenings with stimulation. Finally, 85% of the patients would receive again this therapy for the same results. Three explants were carried out, one for insufficient pain relief, one for MRI needs and one following infection. Two IPG repositionning were done because of patient discomfort and a lead breakage followed chiropractor manipulation.

Conclusions – In this cohort, multiple independent current control spinal cord stimulation was effective to improve quality of life and sleep with few adverse events.

A review of a spinal stimulation implantation program at a community hospital.

Alan Berkman, M.D., Karl Muendel, M.D., Joan MacKinnon, M.D., Susan Schellinck, O.T.
VIHA Pain Program, Nanaimo, BC, Canada

Objectives: To review a spinal stimulation implantation program at a community hospital. The review includes patient demographics and diagnosis, patient selection using an interdisciplinary team and outcome measures.

Materials and methods: Patient demographics and diagnoses were extracted from the VIHA Pain Program Neuromodulation Database. The aim is to determine best practice for these patients using SCS screening tools and an interdisciplinary assessment team. The SCS interdisciplinary assessment team includes anesthesiologists, nurses, psychology, physiotherapy, occupational therapy, social work and pharmacy. Pre/post implantation assessments include the Tampa Scale for Kinesiophobia, Pain Catastrophizing Scale, Pain Disability Index, McGill Pain Questionnaire-SF. In addition, psychological and functional assessments were used based on the patient's diagnosis/presentation.

Results: 46 SCS implantation cases were completed during this 3 year period. 40 SCS trials went to permanent implant. The average age was 50.89 years and there were 23 female and 23 male patients. The diagnostic breakdown is as follows:
FBSS 17 CRPS 10 Nep 10 PHN 2 Ischemic 1
The majority of patients found benefit with SCS implementation according to the pre/post SCS assessments and subjective reporting.

Conclusion: The above retrospective review over a 3 year period provides further information on developing best practice for the use of SCS in a community setting.

Vancouver Island Health Authority Neuromodulation Database: Design, Implementation, and Current Status

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VIHA Pain Program, Nanaimo, BC

Objectives: This study describes the design and current status of the Vancouver Island Health Authority (VIHA) neuromodulation database. The database tracks outcome and clinical data for neuromodulation patients attending VIHA's multidisciplinary Pain Program.

Materials and Methods: The study reviewed the design and implementation of the neuromodulation database. Contributors to the database, including occupational therapists, nurses, psychologists, pharmacists, physicians, and an economist, were interviewed for the study.

Results: A preliminary database with a limited number of elements was designed in 2010 to test the database concept. In 2012, a review of the preliminary database was performed. Contributors to the database met frequently to determine: the screening tools desired, especially psychological measures and therapy/education required pre-implant, and the time frame and assessments to track post-implant function, medication, and psychological coping. The data entry and collection processes were also critiqued.

The database content includes seven screening and eight follow-up questionnaires and assessments, three pharmaceutical measures, and device and procedural information.

Conclusions: The database enables the Pain Program to refine the questionnaires and measures used in patient screening, ensures sufficient patient self-management, pain education and preparation, and has opened more questions regarding patient selection, data collection and post-implant desired function and restrictions.

The data collected can be analyzed to determine patient functional change results, which provide evidence for funding. Moreover, the Pain Program is performing a cost-effectiveness analysis by combining patient data from the database with data on each patient's healthcare resource use from the BC Ministry of Health.

Determination of Patient Outcomes based on Percent Reduction on the Visual Analog Scale (VAS)

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Objectives: Percent change from baseline on the visual analog scale (VAS) varies from patient report of percentage of pain relief, making it difficult to compare patient outcomes. This study sought to determine how patients with <30%, 30-50% and >50% reduction on the VAS compare on other measures which assess function and disability in chronic pain patients.

Materials and Methods: Data analysis was performed on results obtained in an IRB-approved, prospective clinical research study that evaluated the efficacy of an SCS device. Patients, stratified by percent reduction on the VAS (<30%, 30-50%, and >50%) at 12 months post-implant, were compared on the NRS, direct patient report of percentage of pain relief, SF-36, SF-MPQ, Oswestry Disability Index (ODI), Pain and Distress (PAD) scale, Pain Disability Index (PDI), satisfaction, and quality of life (QoL). Mann-Whitney U Tests or t-tests compared groups at a significance level of 0.05.

Results: Among patients that achieved a <30%, >30-<50%, and >50% reduction on the VAS, mean direct reports of pain relief were 42.7%, 53.2%, and 75.8%, respectively. The percentage of patients

very satisfied or satisfied with SCS and the percentage with greatly improved or improved QoL were not significantly different between groups.

Conclusions: Many patients with a <50% reduction on VAS had clinically meaningful changes on other outcomes. These results should be considered when using the VAS as the primary outcome in evaluations of SCS therapy because they suggest that a many patients that achieve clinically meaningful changes would be considered "non-responders" to the therapy.

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Occipital nerve region stimulation for chronic head and facial pain

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Objectives: Occipital nerve region stimulation (ONS) is an experimental treatment for multiple headache and craniofacial pain syndromes. While Canadians are receiving ONS for multiple diagnoses, it is only with prospective study and objective outcome measures that will we learn which patients are appropriate for this therapy. Therefore our aim is to determine if ONS improves pain and quality of life in patients with specific medically refractory headache/facial pain syndromes.

Materials and Methods: Adult patients with medically refractory head/craniofacial pain diagnosis with at least moderate pain severity and significant disability are entered into our open label prospective trial. Inclusion criteria are occipital neuralgia, persistent idiopathic facial pain (atypical face pain, AFP), neuropathic-deafferentation face pain, and specific chronic headache syndromes, including hemicrania continua (HC), chronic cluster (CCH), migraine, tension-type, post-trauma, post-whiplash, new daily persistent forms. Patients must have completed multidisciplinary pain program, and be assessed independently by a headache neurologist. The primary outcome measure is change in average diary-measured pain intensity. Secondary outcomes include quality of life (SF-36), depression(CESD-R), Pain Disability Inventory (PDI), personalized function scale, and those with headache the MIDAS and HIT-6 disability scales.

Results: Seventeen patients have been referred of whom 7 are undergoing screening, and 5 have completed follow-up. Of the 3 patients with AFP, all obtained good outcomes. The patients with HC and CCH did not achieve benefit. Quantitative outcomes will be provided.

Conclusions: Initial evaluations have validated the selection process and methodology. This is an ongoing study and more patients are required before we can conclude which factors may predict success.

Impact of Wait-times on Spinal Cord Stimulation Therapy Outcomes

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Objective: Presently, the long-term success rate of spinal cord stimulation (SCS) ranges from 47-74%. SCS efficacy is inversely proportional to the passage of time between development of chronic pain syndrome and time of implantation. In order to improve outcomes, implantation should be performed early. This study identifies sources of delay and offers suggestions for improvement.

Materials and Methods: A retrospective analysis of 437 SCS patients examines delays to implantation at various points from initial diagnosis, family physician and various specialist treatments, to implantation. Analysis of variance evaluated the effect of age, sex, treating specialty and their interactions on implantation delay. A multiple linear regression model was developed to assess factors contributing to implantation delay.

Results: From time of onset of chronic pain to implantation, patients endured a delay of 65.4±2.04 months. Initial physician contact occurred at a mean of 3.4±0.12 months after development of pain syndrome. Family physicians managed cases for 11.9±0.45 months and various specialists for an additional 39.8±1.22 months. Neurosurgeons were quickest to refer to an implant physician (average wait-time 32.28±2.64 months) while orthopedic surgeons and non-implanting anesthesiologists took the longest, contributing to wait-times of 51.60±5.04 months and 58.08±5.76 months, respectively. Once the decision for implantation was made, the implanting physician required 3.31±0.09 months to organize the procedure. A gradual decline in wait-times was observed from 1980 to present.

Conclusions: To improve SCS success rates, physicians involved in the treatment of chronic pain should refer these cases early to an implant physician once failure of medical management becomes apparent.

Role of the Neurometer as adjunct to screening for Sacral Neuromodulation therapy

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Objective: To assess for the role of neurometer in improving the selection of patients with voiding dysfunction for the Sacral Neuromodulation (SNM).

Background: SNM is offered to patients to correct their voiding dysfunction. Part of the SNM therapy is a screening test (PNE) to predict the patient response to the therapy. PNE is minimally invasive screening test with the predictive value of 30%. The neurometer is a simple non invasive instrument to assess objectively the Pain Tolerance Threshold (PTT) of the patients selective dermatome.

Methodology: The current is a pilot study designed to test the feasibility of neurometer as an adjunctive to the screening test. Twenty seven patients candidates for PNE had the test with the neurometer (PTT) for the sacral 3-5 dermatome bilaterally done. Both PNE and PTT tests are done

by different investigators who were blinded for the result of the other test. The results of PNE & PTT readings were collected for all patients. The arbitrary result of PTT 90 as the cut off point for assessment of the response of the neurometer test. Study data were analyzed using SPSS database. Chi-square and Fisher exact test analysis were used to detect statistical differences. All tests were considered significant at $P < 0.05$.

Results: Total of 27 patients were included in the pilot study, median age of 45y, 24 female, 3 males. The indications for PNE were 22 patients with refractory overactive bladder (OAB), 2 patients with urinary retention and 3 patients with frequency urgency syndrome.
A total of 17 patients showed a +ve PNE.

The PTT reading did not show correlation with the type of underlying diagnosis of the voiding dysfunction, patient age nor gender. Fifteen patients who showed PTT < 90 had a positive response to the PNE screening test. PTT reading correlated with the outcome of the PNE for the patients. P=0.037

Conclusion: The neurometer is a simple and predictable test to help improving the selection of patients for SNM.

Initial Experience with the Precision Spectra Spinal Cord Stimulation (SCS) System for the Treatment of Chronic Pain

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Objectives: SCS technology has progressed over the past 25 years from 4 to 8 to 16 contacts, designed to provide more pain relief with each step. Recently, the Precision Spectra™ SCS System has been released with the capability to utilize up to 32 contacts simultaneously, each with its own dedicated power source. These 32 dedicated power sources enable independent current control delivered to simultaneously active contacts. Here we present initial experience using the Precision Spectra System from chronic pain patients implanted at our clinic.

Methods: We conducted a retrospective consecutive case-series of approximately 30 patients. Data collection included: 1) baseline characteristics: demographics, diagnosis, medical history; 2) procedural information: lead configuration, programming parameters; 3) clinical outcomes out to 3 months: pain relief, physical functioning, and satisfaction. To minimize bias, all consecutive patients implanted at our clinic with Precision Spectra were included.

Results: Our initial experience with the Precision Spectra SCS System will be presented, including baseline patient characteristics, procedural information, and the 3-month clinical outcomes of treatment. Statistical analyses were prospectively defined, with paired t-tests for improvement in clinical outcomes and multivariate models for predictive covariates of responsiveness to SCS.

Conclusions: The recently released Precision Spectra SCS System includes a 2-fold increase in its number of contacts, each with independent current control, designed to provide more targeted and more pain relief. This consecutive case-series will provide a systematic review of our real-world experience with this new system to characterize the utilization patterns and clinical benefit of

Precision Spectra at our clinic.

Back and leg pain coverage combining needle insertion of hybrid-paddle and percutaneous leads.

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Objective: Low back pain can be a common site of neuropathic pain and it may be hard to be covered with spinal cord stimulation (SCS). It can be even more challenging to treat patients having both low back and lower limb pain. We prospectively evaluated the safety and effectiveness of a configuration of one hybrid lead combined to a percutaneous lead to treat this clinical situation.

Methods: All patients suffering from both low back and leg pain and who have been implanted with one hybrid and one percutaneous lead in 2012 were enrolled in this study. Outcome measures were paresthesia coverage, pain relief, functional disability, quality of life and incidence of complications. Data were collected at baseline before surgery, and at 6 months follow-up.

Results: Eighteen (94.7%) out of the 19 patients who received trial stimulation were permanently implanted. Every patient reported paresthesia coverage over 50% with a mean of 83.3%. The overall pain relief was 46.9%, and 55.6% of the patients were relieved by at least 50%. A significant improvement of functional capacity was obtained. Three patients (16,6%) had electrode migration (6,8% of the implanted leads), which was treated with surgery. One patient had his two electrodes simultaneously displaced, traumatically, in a car accident.

Conclusion: In this case series the use of a combination of a hybrid and a percutaneous lead was effective to cover common pain areas, which resulted in daily life improvements at reasonable rate of complications.

Zero-Volt and Long Life Chemistry Enhancements to Rechargeable Batteries for Medical Devices

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Amanda Reyes
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Advanced rechargeable batteries enable significant improvements in the life and performance of

medical devices, often achieving better patient outcomes and fewer side effects than drug therapies.

Lithium ion batteries generally experience significant capacity reduction following a very deep discharge as the internal components dissolve. As a result batteries are never designed to be completely discharged. However, in cases of patient non-compliance, a battery can become completely discharged while implanted in a patient and require surgery for battery replacement. Quallion's patented Zero-Volt technology enables a lithium ion battery to be completely discharged to an inert state, stored in this condition for an extended period, and then recharged without any permanent damage to the battery or reduction in capacity or performance.

Implementing the Zero-Volt technology does not have a negative impact on cell performance; Zero – Volt achieves comparable results for capacity and cycle life with conventional lithium ion designs. Quallion has implemented this technology in thousands of lithium ion cells for medical implant and satellite applications.

Quallion's long life chemistry also represents a significant improvement over the state of the art. Quallion's technology overcomes traditional calendar fade effects and enables lithium ion cells to retain their capacity over long time periods. Quallion cells retain >93% of original capacity after 10 years of storage at body temperature. Paired with strong cycle life performance Quallion rechargeable lithium ion batteries can enable medical devices to work harder, last longer, and achieve better patient outcomes at lower cost than devices powered by non-rechargeable cells.

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