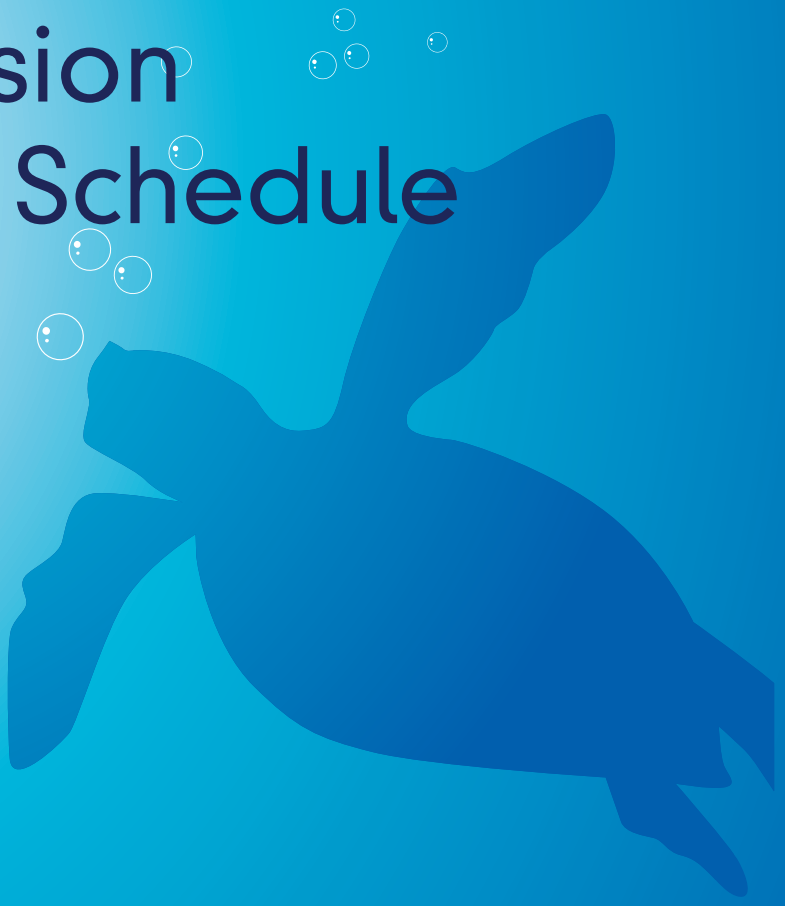
Neuromodulation: Technology at the Neural Interface

Non-CME Session Abstracts and Schedule



December 9- 12, 2007

Acapulco, Mexico

ins international neuromodulation society

8th world congress

North American Neuromodulation Society est. 1994

11th annual meeting

Non-CME Session Listing

Sunday December 9, 2007
0800 - 0840 Princessa Ballroom B-C (13)
Keynote Address
Neuromodulation: The Inter-relationship between Science and Industry (Non-CME)
Alan Levy, PhD

Sunday December 9, 2007
0920 – 1000 Princessa Ballroom B-C (13)
Surgery for obsessive-compulsive disorder
Bart Nuttin, MD, PhD

Sunday December 9, 2007
1415 – 1715 Atlantes Center (I)
Advances, Physics, and Outcome Improvements in SCS
Boston Scientific Symposium (Non-CME)

Monday December 10, 2007
1300 – 1415 Princesa Ballroom B-C (13)
Government Scrutiny of Drug and Device Marketing Practices:
What Physicians Need to Know to Keep Interactions with Manufacturers from Turning into Infractions
Advanced Neuromodulation Systems Luncheon Symposium (Non-CME)

Monday December 10, 2007
1415 – 1715 Atlantes Center (I)
Spinal Cord Stimulation – SCS
Innovative Approaches and Provocative Debate
Advanced Neuromodulation Systems Symposium (Non-CME)

Tuesday December 11, 2007
1415 – 1715 Atlantes Center (I)
PROCESS Studies in Spinal Cord and Neuro Stimulation
Medtronic Symposium (Non-CME)

Wednesday December 12, 2007
0840 - 0920 Princesa Ballroom B-C (13)
Review of Neuromodulation for Cardiac Disorder
Marc Penn, MD PhD (Non-CME)

Sunday December 9, 2007
0800 - 0840 Princessa Ballroom B-C (13)
Keynote Address (Non-CME)

Neuromodulation: The Inter-relationship between Science and Industry

Alan Levy, PhD
Northstar Neuroscience
Chairman of the Board of Directors
2401 Fourth Avenue, Suite 300
Seattle, Washington 98121, USA

Neuromodulation is an extremely exciting business opportunity. It has been described as the most exciting opportunity in medical technology. Analysts have predicted that it may rival the multi-billion dollar markets for implantable defibrillators and coronary stents.

The current applications for neuromodulation include the treatment of Parkinson's Disease, essential tremor, epilepsy, chronic pain and deafness. The clinical benefits and low rate of side effects for neuromodulation therapy, coupled with the disappointing results of pharmacological therapies for many neurological disorders have led to a dramatically heightened interest in the potential for neuromodulation. Applications currently under development include stroke motor recovery, hypertension, chronic depression, migraines and obesity.

This presentation discusses the key factors required to build a successful neuromodulation company, using Northstar Neuroscience and other early stage companies as examples. In general, building such businesses today requires a long time horizon and a large amount of capital. The benefits to patients, their families and society may be enormous and the financial rewards have the potential to be very attractive.

Sunday December 9, 2007
0920 - 1000 Princessa Ballroom B-C (13)
Surgery for obsessive-compulsive disorder
Bart Nuttin, MD, PhD
(Non-CME

Surgery for obsessive-compulsive disorder

Obsessive-compulsive disorder (OCD) is a psychiatric disorder, characterized by intrusive thoughts (obsessions) and compulsive behaviour, with a lifetime prevalence of approximately 2% worldwide. The age of onset is usually in the mid- to late 20s. Major depression or anxiety disorders are frequent comorbid conditions [1], [2], [3], [4], [5], [6]. Many patients improve under behavioural and/or pharmacological therapy. A minority (about 10% of the OCD patients) has a chronic disabling course, refractory to all available pharmacological treatment and psychotherapy[7], [8]. Some of these patients are extremely ill and severely incapacitated and meet rigorous criteria for neurosurgical treatment[9]. Nowadays neurosurgical intervention in those therapy-refractory patients aim at destroying some crucial brain tissue. The possible interventions are : anterior capsulotomy, subcaudate tractotomy, cingulotomy or limbic leucotomy. These are usually performed bilaterally. Anterior capsulotomy, one of the most intensively studied surgical procedures, improves symptoms in about 50% of these patients, with a low risk of complications and side effects[10], [11], [12], [13], [14].

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There is growing evidence for a neurobiological basis for OCD. Abnormalities in frontal lobe and basal ganglia function in OCD patients have led to hypotheses about the pathogenesis of the disorder[15], [16]. One of the important loops in OCD, the frontal-striatal-pallidal-thalamic-frontal loop, passes through the anterior limb of the internal capsule, the target in anterior capsulotomy[17].

When electrical brain stimulation is applied to the brain motor system in areas, where neurosurgical lesions used to be produced, similar clinical results were obtained by both approaches but brain stimulation induced fewer permanent adverse effects and complications[18], [19], [20].

Considering the irreversibility of lesioning procedures, and their possible side effects, a collaborative group between Leuven, Antwerp and Stockholm explored in 1999 replacing bilateral anterior capsulotomy by chronic electrical capsular stimulation in severe long-standing treatment-resistant obsessive-compulsive disorder (OCD)[21]. Thus, instead of electrically stimulating the motor system, as for patients with treatment-refractory Parkinson's disease, the limbic system in treatment-refractory OCD patients was electrically stimulated. In Parkinson's disease in general, different motor symptoms like akinesia, tremor rigidity and other symptoms seem to diminish in a clinically significant manner upon electrical stimulation of a tiny motor brain area, with induction of very few side-effects. In a similar way as for Parkinson's disease, during electrical stimulation of part of the limbic system a decrease in the different symptoms of OCD was observed (obsession and compulsion and the often associated anxiety and depression). Also in this application of electrical brain stimulation it was written that relatively few side-effects were noted[22], [23], [24], [25], [26]. Brain tissue destruction was as minimal as with electrical brain stimulation for Parkinson's disease. Stimulation parameters were adjustable over time which enabled optimisation of those parameters in order to obtain better therapeutic benefits while minimizing adverse effects.

From its inception, the research protocols had been approved by the local ethics committees and the indication for surgery was never imposed by the surgeon, but it was decided upon by a "committee for neurosurgery for psychiatric disorders" after the treating psychiatrist had proposed a surgical procedure to this committee because of the hopeless condition of the patient. This committee consists of psychiatrists, neurosurgeons, medical ethicists, scientists and lay people and its president is a psychiatrist as the different centers that are nowadays performing these kind of surgeries are convinced that the psychiatrist (and not the surgeon) needs to be the driving force when deciding for surgery.

After the first observations of beneficial effects in the treatment-refractory OCD patients, and after other centers (Dr. S. Rasmussen, Dr. B. Greenberg and Dr. G. Friehs, Brown University, Providence, U.S.; Dr. A. Rezai and Dr. D. Malone, Cleveland Clinic, U.S.) had shown similar effects in treatment-refractory OCD patients using a copy of the first research protocol, in order to be sure the effects were not induced by the Leuven-Antwerpen-Stockholm group, but were real effects induced by the electrical stimulation, those research centers decided to publish guidelines on how to proceed with this kind of research[27], [28]. Indeed, neurosurgery for psychiatric

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disorders (or "psychosurgery" as it used to be called) has sometimes been used in a poorly controlled manner in the past. The group wanted to avoid this from happening again. Therefore the group asks that centers who want to start with this kind of surgery adhere to those guidelines or publish their own new guidelines, which can then be compared with the already published guidelines.

In addition to these guidelines, the "Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé" in France have published that electrical brain stimulation in treatment-refractory OCD patients is ethically acceptable if it is performed in a research setting [29], [30], [31].

The mechanism of how electrical stimulation induces the obtained effects is largely unknown. Most of the effects obtained in electrical brain stimulation are probably a consequence of direct grey matter stimulation. However, effects may also be obtained by electrical stimulation of white matter. A good example of this mechanism is spinal cord stimulation for chronic neuropathic pain, where paraesthesiae are induced by activation of white matter. It is not clear at this moment whether the obtained effects in OCD are a consequence of activation or inhibition of either fibres or cell bodies. Further research on this topic is underway within the deep-brain-stimulation-obsessive-compulsive-disorder-collaborative-group, which constitutes a group of clinicians and basic scientists who started to come together at the occasion of the Lancet publication in 1999 in this field[21]. This group has been intensely sharing the research findings in an early stage (i.e. before publication) and had as main goals to improve electrical brain stimulation in OCD, and to understand the underlying mechanisms. Improvement of this therapeutic modality is necessary, especially with regard to the short battery life. Indeed, the major problem the Leuven-Antwerp group encountered was the high amount of energy needed to obtain a beneficial effect in those patients. This high amount of energy may dampen the feasibility of this technique. Research into this field may be directed towards construction of batteries with longer life-time, the use of implantable rechargeable batteries, optimization of the stimulation devices, especially design of new electrodes and last but not least an optimisation of the present target or a search for other targets where similar effects Following the first beneficial results of DBS in OCD, groups are also exploring other psychiatric disorders, like treatment-refractory major depression, based upon the fact that the symptom depression, often associated with severe OCD, also decreased upon electrical brain stimulation. Literature until the beginning of 2007 on the subject of electrical brain stimulation in psychiatric disorders is attached [32]. Electrical brain stimulation in severely ill, treatment-refractory psychiatric patients is attractive from an ethical standpoint for its reversible and adjustable character. Furthermore it allows randomized and blinded research, previously lacking in this field, due to the irreversibility of brain lesioning. A lesioning procedure can still be performed if stimulation is not successful. However, electrical brain stimulation for psychiatric disorders is at this stage still in an investigational phase.

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Learning Objectives
At the completion of this presentation, participants should be able to:
1. Indicate different surgical methods to relieve treatment-refractory obsessive-compulsive disorder;
2. Critically analyze the off label use of deep brain stimulation for obsessive-compulsive disorder;
3. Discuss possible complications of deep brain stimulation for obsessive-compulsive disorder.

Sunday December 9, 2007
1415 – 1715 Atlantes Center (I)
Advances, Physics, and Outcome Improvements in SCS
Boston Scientific Symposium
(Non-CME)

Advances, Physics, and Outcome Improvements in SCS

Marshall Bedder, MD
Advanced Pain Management and Spine Specialists
Ft. Myers/Cape Coral, Florida USA
mbedder@mac.com

This presentation will focus on the technological advances in spinal cord stimulation and how those advances may allow clinicians to treat a broader range of patients than those previously thought of as candidates for SCS.

Physics of Spinal Cord Stimulation

Dave Peterson, MS
Boston Scientific Corporation
Senior Director Neuro Systems and Technicians
Valencia, California USA
dpeterson@bionics.com

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This presentation will focus on the mechanisms of spinal cord stimulation.

Kerry Bradley, MS
Boston Scientific Corporation
Valencia, California USA
kbradley@bionics.com

Thomas Yearwood, MD, PhD
Comprehensive Pain and Rehabilitation
University of South Alabama
Clinical Associate Professor of Neurology
Daphne, Alabama USA
tyearwood@nopaindr.com

This presentation will focus on the effect that Pulse Width has on spinal cord stimulation and how increased Pulse Widths may change the focus and breadth of the stimulation.

Improvement of Outcomes using Multiple Independent Current Control

Brian Simpson, MA, MD
University Hospital of Whales, Consultant Neurosurgeon
Cardiff, Wales, UK
Brian.Simpson@CardiffandVale.wales.nhs.uk

Mr. Simpson's presentation will review the outcomes from his first year's experience (40 cases) with "Precision" and "Artisan" with particular emphasis on programming and on clinical outcomes.

Richard Rauck, MD
Carolinas Pain Institute, Medical Director/CEO. Wake Forest University,
Associate Professor and Director of the Pain Fellowship Program
Winston-Salem, North Carolina USA
rrauck@ccrpain.com

This presentation is a review of preliminary interim data from a single site from a controlled post market clinical trial assessing the efficacy of spinal cord stimulation in patients with Failed Back Surgery Syndrome.

James Hagen, MS
Integrative Treatment Centers
Denver, Colorado USA
jhagen@denverpain.com

Patricia Skiba, RN
Boston Scientific Corporation
Shelton, Connecticut USA
pskiba@raceagainstpain.com

This presentation with Mr. Hagen and Ms. Skiba will review a novel, patient controllable software fitting system for the Precision spinal cord stimulation system. Both presenters are pain clinicians who have extensive experience programming SCS patients. In addition, both are current SCS patients.

Monday December 10, 2007
1300 – 1415 Princesa Ballroom B-C (13)
Government Scrutiny of Drug and Device Marketing Practices
Advanced Neuromodulation Systems Luncheon Symposium (Non-CME)

Government Scrutiny of Drug and Device Marketing Practices: What Physicians Need to Know to Keep Interactions with Manufacturers from Turning into Infractions

James Dechene, Esq.
Partner
Sidley Austin, LLP
Washington, D.C. USA
wsarraille@sidley.com

The marketing practices of drug and device manufacturers have been under intense scrutiny by government prosecutors over the past several years. A number of these investigations have resulted in criminal convictions and massive fines (ranging into the hundreds of millions of dollars) and many have yet to be resolved. These investigations are having a profound impact on the manner in which companies interact with physicians as well as the content of what they say about unapproved or "off-label" uses of drugs and devices. But these investigations are not just affecting companies -- physicians too, are subject to criminal and civil investigation and sanction for working with, aiding and abetting, or conspiring with manufacturers to violate the law. This talk will describe the current enforcement environment, discuss its impact on both manufacturers and physicians, and provide practical advice on how best to avoid trouble.

Monday December 10, 2007
1415 – 1715 Atlantes Center (I)
Innovative Neurostimulation Techniques and Applications (Non-CME)
Advanced Neuromodulation Systems Symposium (Non-CME)

Innovative Neurostimulation Techniques and Applications (Non-CME)

Timothy Deer, MD
Center for Pain Relief, Inc.
400 Court Street, Suite 304
Charleston, West Virginia 25301, USA
DOCTDEER@aol.com

Abstract
SCS current treatment continuum was introduced in 1996 as a logical algorithm for treating chronic pain. It depicted a range of treatments that were progressively more expensive and invasive. Neurostimulation therapy appeared late in the continuum. Recent research, the clinical experience of key opinion leaders, and advances in technology have suggested that neurostimulation should be placed earlier in the continuum.

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Companies Manufacture Components, Implanters Create Stimulator Systems

Claudio A. Feler, MD
Semmes-Murphey Clinic
350 Sweetbriar Road
Memphis, Tennessee 38120, USA
cfeler@midsouth.rr.com

Abstract
There are several factors that should be considered when choosing a neurostimulation system for a patient, such as the patient's cognitive ability, coverage needs, and parameter requirements during the trial period. Choosing the right components to create the system is essential to obtaining and sustaining good pain relief. One size does not fit all.

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Achieving a Transverse Tripole Array with a Single Lead

Eugene Y. Mironer, MD
Carolina Center for Advanced Management of Pain
1330 Boiling Springs Road, Suite 2700
Spartanburg, South Carolina 29302, USA
y1917@aol.com

Abstract
An anatomical structure (the dorsomedian ligamentous band, or DMB) is known to exist at the midline of the epidural space. A debate is taking place as to whether this structure can be used to facilitate the placement of SCS leads. Other debates in SCS center around the sources of lead migration, whether axial pain can be covered, and how to select an optimal SCS system configuration.

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The Hot Seat With Dr. Robert Levy

Robert Levy, MD, PhD
Northwestern Medical Faculty Foundation, Inc.
Dept. of Neurological Surgery
675 N. St. Clair Street, Suite 20-250
Chicago, Illinois 60611, USA
rml199@northwestern.edu

Abstract
Through their responses to rapid-fire questions, presenters will be given a chance to quickly comment on relevant and recent topics of spinal cord stimulation. Questions will also be collected from the audience and posed to the presenter in the "Hot Seat."

References: N/A

Tuesday December 11, 2007
1415 – 1715 Atlantes Center (I)
PROCESS Studies in Spinal Cord and Neuro Stimulation
Medtronic Symposium
(Non-CME)

PROCESS Studies in Spinal Cord and Neuro Stimulation

Learning Objectives
After attending this symposium participants will be able to:
1. Compare the outcomes data for treatment of neuropathic back and leg pain in patients with FBSS treated with spinal cord stimulation (SCS) versus conventional medical management
2. Discuss the cost-effectiveness of SCS compared with medical management for patients with severe chronic pain syndromes
3. Describe the current status of neuromodulation research

Presentation Abstracts

2007 Update: Neurostimulation for the Treatment of Neuropathic Back and Leg Pain in Patients with FBSS

PROCESS Study: Spinal Cord Stimulation Improves Outcomes in FBSS Patients

Richard B North, MD
Department of Neurosurgery
Johns Hopkins University School of Medicine
Baltimore, Maryland, USA
JNorth@jhmi.edu

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Line Jacques, MD
Montreal Neurological Institute and Hospital
Department of Neurosurgery
H3A 2B4 Montreal, Quebec, Canada
ljacques2@yahoo.com

Patients with failed back surgery syndrome (FBSS) continue to experience persistent or recurrent pain, disability and reduced quality of life despite anatomically successful lumbosacral spine surgery. The PROCESS study is a randomized controlled trial (RCT) designed to evaluate the clinical effectiveness of the addition of spinal cord stimulation (SCS) to conventional medical management (CMM) of patients with FBSS. 100 patients suffering from persistent neuropathic pain predominantly in the legs were randomized to receive SCS plus CMM or CMM alone. Patients in either group received appropriate adjuvant therapy (excluding spinal surgery or intrathecal drug delivery) and were followed up to 24-months, with crossover after the 6-month visit upon patient request. Pain relief (>50% change on VAS), functional capacity (Oswestry), health related quality of life (HRQoL assessed by Short-Form 36), patient satisfaction and adverse effects were assessed at each study visit. In an intent-to-treat analysis at 6-months, patients randomized to SCS experienced the following improvements when compared to CMM alone: significantly more leg pain relief (48% vs 9%; P=0.0001), improved functionality (P=0.0002), improved HRQoL in 7 out of 8 domains (0.02 > P >0.0002) and greater satisfaction in their treatment (P<0.0004). Fourteen (29%) of the 48 patients who received SCS had a complication that required additional surgery. Intent-to-treat analysis of the primary endpoint at 12 months also showed a significant benefit to SCS compared with CMM (34% vs 7%; P=0.005) 24 month outcomes data will be presented at the symposium. Compared to CMM alone, SCS improves pain relief, HRQoL and functionality in predominantly neuropathic FBSS patients.

PROCESS Study: Cost-Effectiveness Analysis of Neurostimulation in the Management of Intractable Pain

Rod Taylor MSc PhD
Associate Professor in Health Services Research
Peninsula Medical School, University of Exeter, UK
rod.taylor@pms.ac.uk

As a part of this discussion, cost effectiveness of neurostimulation therapy will be discussed. The PROCESS study was also designed to evaluate the cost-effectiveness of the addition of spinal cord stimulation (SCS) to conventional medical management (CMM) in patients with FBSS. This was a randomized controlled trial with 52 patients in the SCS group and 48 patients in the CMM group. Corresponding healthcare resource use data relating to screening, the use of the implantable generator in SCS patients, associated hospital stay, and drug and non-drug pain-related treatment were collected. Resource use was costed at 2005-2006 prices using UK and Canadian national figures. Health-related quality of life was assessed using the EuroQol-5D (EQ-5D) questionnaire. Costs and outcomes were assessed for each patient over their first 6-months in the PROCESS trial.

After a 6-month follow-up period, the total mean patient cost was €12,820 in the SCS group (1€=1.37 $U.S.) and €3,155 in the CMM group

(cont.)

(adjusted difference: €9,519, p<0.0001). The improvement in EQ-5D over time was appreciably greater in the SCS group, with mean utility gains of 0.25 (p<0.001) and 0.21 (p<0.001) at 3 and 6 months, respectively, after adjusting for baseline EQ-5D scores and patients' characteristics. The addition of SCS to CMM in treating predominant leg pain in FBSS patients with predominant neuropathic pain results in higher costs to health systems over a 6-month period. This is, in part, due to the upfront cost of the device. However, SCS generates significant improvements in patients' health-related quality of life over the same period. A full cost-effectiveness analysis needs to be completed to understand how costs and quality of life differences develop over the long-term.

Neuropathic Pain: When and how do we diagnose?
Panel Discussion
Moderator: David Caraway, MD, PhD
Medical Director, St. Mary's Medical Center, Pain Relief Center
Senior Partner, The Center for Pain Relief Tri-State
Charleston, WV, USA
carawaymd@aol.com

Panel: Joshua Prager, MD, MS
Director
California Pain Medicine Centers
Los Angeles, California, USA
joshuaprager@gmail.com

Rod Taylor MSc PhD
Associate Professor in Health Services Research
Peninsula Medical School, University of Exeter, UK
rod.taylor@pms.ac.uk

Richard B North, MD
Department of Neurosurgery
Johns Hopkins University School of Medicine
Baltimore, Maryland, USA
JNorth@jhmi.edu

Line Jacques, MD
Montreal Neurological Institute and Hospital
Department of Neurosurgery
H3A 2B4 Montreal, Quebec, Canada
ljacques2@yahoo.com

Neuropathic pain has been defined as pain resulting from a lesion or disease of the peripheral or central nervous system. It is often chronic and persistent in nature with a large proportion of patients suffering with pain refractory to standard pharmacotherapy. A variety of pain descriptors have been used to characterize neuropathic pain but perspectives on the value of these descriptors and how to accurately recognize and diagnose neuropathic pain are widely disparate. It has been suggested that an understanding of the pathophysiologic mechanisms underlying the various neuropathic pain syndromes may be helpful in guiding therapy more effectively. Other key questions regarding neuropathic pain include how to define refractory

and when alternative therapies such as neurostimulation are reasonable considerations. This panel of expert faculty will discuss the most current views and clinical data on the identification and diagnosis of neuropathic pain and discuss the challenges faced by pain specialists in treating chronic, refractory neuropathic pain.

Future Directions in Neurostimulation (Technology update)
David Caraway, MD, PhD
Medical Director, St. Mary's Medical Center, Pain Relief Center
Senior Partner, the Center for Pain Relief Tri-State
Charleston, West Virgina USA
carawaymd@aol.com

Spinal cord stimulation provides effective pain relief for many neuropathic pain conditions including chronic radicular back and leg pain. Axial low back pain is a greater challenge and a number of different approaches to more effectively capture and stimulate the appropriate spinal nerves (L1 and L2) have been used with variable success. Triple-lead configurations have been modeled and tested. A triple-lead array using one Octad lead on the midline flanked by two quad leads permits high amplitude stimulation often used to treat axial low back pain. The use of three-lead arrays permits greater flexibility to cover and treatment complex pain. Results of computer modeling and application of this expanded technology to complex pain cases will be discussed. Finally a discussion of other future directions in neurostimulation will be presented from the clinician viewpoint. This includes topics such as MRI compatibility and miniaturization with implications for different indications.

Wednesday
December 12, 2007
0840 - 0920 Princesa
Ballroom B-C (13)

Review of Neuromodulation for Cardiac Disorder

Marc Penn, MD PhD
Department of Biomedical Engineering (ND20)
Lerner Research Institute
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195, USA
Telephone: 261. 445.1932
Fax: 261.444.9198
pennm@ccf.org