



NANS News

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President's Message



Dear NANS member:

Neuromodulation is in a dynamic period. In the last 2 years, we have witnessed the acquisition of two manufacturers of the implantable devices by major

medical equipment companies. Thus, there are now three major manufacturers competing in the field of neuromodulation, whereas just 18 months ago there was only one. Analysts from major Wall Street investment firms have been attending our annual meetings.

Why is there all this attention? The reason is simple. Neuromodulation is coming of age, and the capabilities are becoming more apparent. Major companies see the potential benefit of neuromodulation and want to participate. At the last annual scientific meeting, we heard lecturers demonstrating the effect of neuromodulation not only on pain and movement disorders, but also on depression, obsessive-compulsive disorder, and other conditions. Functional magnetic resonance imaging allows us to more effectively understand our targets. Results that were barely imaginable a decade ago are now becoming a reality.

Ali Rezai, MD, is organizing our 10th annual meeting to be held next December titled "Neuromodulation: Coming of Age." We want to make the 10th annual meeting special, both in terms of the scientific program and the venue. The meeting will be held at the new Wynn Hotel in Las Vegas. The program not only will provide better understanding of what we do, but also will take a hard look at the future.

Part of the dynamic period in which we live is represented by the challenges of reimbursement for our modalities. Challenges are occurring on a regular basis throughout North America. We have formed a coalition

of physician organizations, with members who implant neuromodulation devices with participation from the three major manufacturers. Marshall Bedder, MD, is coordinating our efforts with other organizations to develop a grassroots network around the country that can be mobilized regionally to address coverage issues efficiently. We are collaborating with other organizations to develop guidelines for neuromodulation treatment. Richard North, MD, our immediate past president is doing a yeoman's job preparing the guidelines of *Neurostimulation for Neuropathic Pain*. The first draft is completed and is scholarly, evidence based, and practical. These guidelines are a critical element necessary to communicate with payers about coverage. With the expertise of our leaders, we must leverage the existing evidence-based medicine to develop guidelines that will not only provide a framework for treatment but also positively affect the way our specialty is practiced.

We are actively participating in several efforts in Washington, DC, to improve reimbursement for procedures. We recently collaborated with the American Society of Interventional Pain Physicians to present work value information about neuraxial drug administration systems. We have received financial commitment to pursue grassroots efforts to ensure coverage of neuromodulatory procedures.

Jaimie Henderson, MD, has taken on the role of newsletter editor. The newsletter will provide us with improved communication in the coming year.

This year presents many challenges and opportunities as our field is coming of age.

Contributions Wanted!

Have you recently published a book or paper?
Do you face particular challenges in your practice or research environment?
Are you passionate about a topic in neuromodulation?
Submit an article to the newsletter editor today!

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Classified and display rates are available; please contact NANS Senior Manager Sheila Lee at 847/375-4760, fax 877/594-6704.

NANS and Its Relationship to INS

Elliot Krames, MD



In the Beginning

NANS began as the American Neuromodulation Society (ANS) in 1994 when a group of pain physicians and neurosurgeons who implant pumps and spinal cord stimulators for pain met in Atlanta, GA. The pro-

fessionals believed that the birth of this interdisciplinary society, dedicated to the dissemination of relevant information regarding implantable technologies for pain and ensuring that these devices be accessible to the patients that needed them, was important for all involved in the United States. The name was subsequently changed by the ANS board to NANS to be more inclusive—recognizing those practicing neuromodulation in Canada and Mexico.

What this group of experts did not know was that several years before, an interdisciplinary group of physicians from Europe and the United States, mostly functional neurosurgeons and others, including neurologists, neurophysiologists, a vascular surgeon, and anesthesiologists, had started a similar society, the International Neuromodulation Society (INS), dedicated to the principal of creating an interdisciplinary society that would be inclusive of all persons involved in implanting devices, no matter what their primary specialty was.

The two societies moved closer together because of their common interests, and by 1996, because several ANS board members also served on the board of the INS, the ANS (now NANS) became the first national and regional chapter of the INS.

INS: Past and Present

As I have already stated, the INS was formed by a group of neurosurgeons and others for the purpose of uniting at an international meeting once every other year to discuss new techniques, new science, and new technologies relevant to implantable technologies. The first board members were Drs. Augustinsson, Galley, Illis, Kranick, Meglio, Sier, and Staal. Their first board meeting was held in Groningen, the Netherlands, in 1989. Since the first international congress of the INS in Rome, Italy in 1992, subsequent congresses have been held once every 2–3 years.

Members of all of our chapter societies automatically become members in the INS. Membership in chapter societies and the INS are inclusive of all who have a primary interest in neuromodulation and may include physicians of all disciplines—nurses, psychologists, scientists, engineers, and members of industry. For a fuller discussion of the society's workings, rules, and regulations please visit

www.neuromodulation.com/TheSociety.htm to view the bylaws of the society. Our bylaws state the fiduciary position of the INS, where the society is incorporated, who may become society members, how our board members and members of the executive board are elected, terms of office, what constitutes a chapter society, the relationship of the chapter society (and NANS) to the INS, and more.

Although NANS started out as a society with a primary focus on implantable technologies for pain control and the INS had a broader scope to include implantable technologies for pain and other disorders, our societies and our journal, *Neuromodulation*, continue to expand the vision of the society to include most all implantables that improve life for humanity. It should be noted here that the term *neuromodulation* was proposed by Mario Meglio and accepted by the preliminary board of the society to include all neurodevices implanted to help and improve function in humankind.

Broadly speaking, the goals of our society are to

- expand the community by bringing together, on a national level, practitioners and other interested stakeholders of neuromodulation into national chapters of the INS
- protect the community by partnering with industry to expand present technologies, by advocating for government acknowledgment of the technologies used by the field, and for advocating for reasonable remuneration to practitioners of the clinical science of neuromodulation and reasonable reimbursement to industry for the research and development of the devices used by the field
- disseminate the knowledge base of the field of neuromodulation through national and international scientific meetings and the INS journal, *Neuromodulation*
- expand the knowledge base through fostering education, encouraging scientific discourse, and fostering of research germane to the field of neuromodulation.

Broadening the Scope

Neuromodulation is the fastest growing field of medicine today and encompasses bioengineering, basic science, issues at the neural interface, and care of people with a wide array of clinical disorders. For the most part, the early years of the INS and its journal, *Neuromodulation*, were dedicated to implantable devices to relieve intractable pain, which was reflective of the practices of our early members and board members in those years. In recent years, as a byproduct of changes within the field, the INS has broadened its scope and its definition of the term *neuromodulation* to include implantable devices that help to improve both sensory and

motor functions of the body. Within this expanded context, neuromodulation, as therapy, is used to treat diverse disorders such as

- abdominal disorders (irritable bowel disorder)
- angina pectoris
- epilepsy
- neurological disorders (Parkinson's disease)
- pain (ischemic, visceral, and neurogenic)
- peripheral vascular disease
- psychiatric disorders such as depression, obsessive-compulsive disorder, and Tourette's syndrome
- spasticity from spinal cord injury, cerebral palsy, multiple sclerosis, or diabetes
- urinary disorders.

As we can see, the field of neuromodulation and *Neuromodulation*, encompass and speak for many interdisciplinary fields of medicine.

Devices included in the neuromodulation arena, to name a few, include

- cochlear implants for hearing loss
- implantable pumps that deliver intraspinal and intraventricular analgesics drugs, for Parkinson's and Alzheimer's diseases, and antispasticity agents
- motor cortex stimulators for pain, epilepsy, and depression
- pacemakers for cardiac rhythm disorders
- peripheral nerve stimulators for pain and restitution of bladder functioning, deep brain stimulators for pain, headache, psychiatric disorders, and movement disorders
- retinal implants for blindness
- spinal cord stimulators for pain, spasticity, and restitution of normal gastrointestinal or genitourinary functioning
- vagal nerve stimulators for epilepsy, obesity, depression, and other mood disorders.

Neuromodulation is a field that encompasses many differing specialties and has a major impact on the lives of people with diverse disorders and diseases.

Neuromodulation addresses the broadened scope of the field of neuromodulation. Published issues have included articles about electrical stimulation for treating irritable bowel syndrome, angina pectoris,

bladder dysfunction, neuralgia, migraine, critical limb ischemia, and chronic cluster headaches. The journal publishes articles that are expanding the field of neuromodulation and are seminal to the development of new therapies for intractable disorders.

Today, neuromodulation techniques are most frequently used to treat pain. Because nearly 80 million people suffer from chronic pain in the United States, commercial interest is growing in the field of neuromodulation. In the past 5 years, the number of companies manufacturing devices for the treatment of pain has increased from one major company to five major companies, with many others, too numerous to list, all vying for a place in our world.

The Food and Drug Administration (FDA) has already approved spinal cord stimulation for painful disorders, vagal nerve stimulation for epilepsy, and implantable pumps for analgesia and spasticity and has recently approved the first implant for psychiatric disorders, a vagal nerve stimulator manufactured by Cyberonics, Inc., of Texas. All of this commercial and scientific interest bodes well for patients in need of newer neuromodulatory technologies to relieve them of their disabilities, pain, and suffering.

The number of devices available for the treatment of pain and other disorders is increasing. For example, Frost and Sullivan, an international growth consulting company, estimates that the complete neurostimulation market for spinal cord stimulation, deep brain stimulation, vagal nerve stimulation, sacral nerve stimulation, and gastroesophageal stimulation was \$337.1 million in 2001 and \$674.1 million in 2004. The market is forecasted to exceed \$1 billion by 2008. The neuro-pump market is at \$294 million and includes programmable and constant flow pumps.

During its third volume in 2000, *Neuromodulation* became the official journal of the International Functional Electrical Stimulation Society (IFESS; www.ifess.org). IFESS is dedicated to the development of electrical stimulation devices to restore normal sensory and motor function of the body. The journal now publishes articles on functional electrical stimulation in every issue and has a separate editor and editorial

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review board for functional electrical stimulation. Because INS and IFESS share a similar mission, there is a natural synergy between the two societies. Both societies are dedicated to expanding the field of external control of sensory and motor function. Their collaboration on *Neuromodulation* strengthens the journal's ability to present information on clinical applications and biomedical research engineering.

All of us who are involved in this exciting and growing field of neuromodulation, either as implanters, scientists, engineers, and manufacturers should be personally thankful and gratified that we are all in the "right place at the right time." You can be assured that your chapter society, NANS, and our parent organization, INS, will work tirelessly to improve our field on many different levels including improving the science of our field, improving reimbursement for the devices that we use, and improving the technologies for our patients. 🌐

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Select Abstracts from the NANS Annual Meeting

The 9th Annual NANS Meeting was held November 10–12, 2005, in Washington, DC. Following opening comments by President Richard North and Program Chair Elliot Krames, Dr. Michael Merzenich set the tone for the meeting with his keynote address, focusing on his groundbreaking research in plasticity of the nervous system and its implications for neuromodulation therapies. The program featured a wide range of topics including spinal cord stimulation, brain stimulation, intrathecal therapies, novel stimulation uses, and functional electrical stimulation.

Fourteen papers and nine posters were presented at the meeting. A sampling of the many outstanding abstracts follows.

Clinical Trials for Emerging Neurostimulation Therapies: Better than Level-1 Evidence Is Possible

Robert J. Coffey, MD

Neurostimulation to treat chronic pain includes both approved and investigational methods. Targets involve peripheral nerves, the spinal cord, motor cortex, and deep brain structures. Persistent pain after spinal surgery, and work or neural injuries are common indications. Medical and economic factors, and the expectations associated with pain therapies warrant a reexamination of the methods used to gather evidence for long-term efficacy. In a structured fashion, we analyzed English-language publications to investigate the nature of the evidence that supports the efficacy of neurostimulation to treat chronic pain. To formulate recommendations for future study designs, we compared the results of this analysis to established guidelines for the evaluation medical evidence. The evidence predominantly consists of retrospective series, or prospective studies that are subject to limited interpretation. To date, no successful clinical studies of neurostimulation for pain—with sufficient subjects to establish efficacy—have employed matched control groups, sham stimulation, randomization, prospective endpoints, and methods to control experimental bias. Current data provide little support for psychological or pharmacological screening, or trial stimulation to predict or improve the long-term results. These findings do not diminish the value of previous investigations or positive patient experiences and do not mean that the treatments are ineffective. Rather, they reveal that new data are required to answer the questions raised by previous studies. Investigators have advocated Level-1 studies for more than a decade. Future studies of emerging neurostimulation modalities should—whenever feasible—require unambiguous diagnoses as entry criteria and should employ randomization, parallel (sham stimulation) controls, and blinding of the patients, investigators, and device programmers. Given the chronicity of patients' symptoms and the expected long-term benefits of the therapies, efficacy

should be studied for 1 year or longer. Meticulous study methods are especially important to evaluate new and emerging therapies.

Use of Continuous Intrathecal Infusion of Octreotide in Patients with Chronic Pain of Noncancer Origin: An Evaluation of Efficacy in a Prospective Double-Blind Fashion

Tim Deer, MD; Chris Kim, MD; Richard Bowman, MD; Mathew Norris, RN; C. Douglas Stewart, PA-C; Tina Garten, RN; Yusef Khan, MD

We studied the ability of intrathecal octreotide by continuous infusion to treat chronic pain of noncancer origin.

Materials and Methods

We performed a prospective randomized double-blind study using a phase of treatment with preservative free saline and a phase of treatment with preservative free octreotide to assess pain relief and functional improvement. Twenty patients were given informed consent and then randomized to receive either saline or octreotide. Prior to starting either drug the patients underwent a 2-week wash-out phase with saline and then a 6-week treatment phase with the randomized intrathecal agent. At several points during the analysis, data were collected. Data collection included visual analog scales, quality of life assessment, functional analysis, oral opioid use, healthcare use, and global satisfaction. Intrathecal octreotide dosing was based on previous clinical studies, and animal toxicity data. Doses were initiated at 2 mcg per day and maximized at 20 mcg per day. At the conclusion of the study, patients were allowed to receive the drug in an open-label fashion if they had shown acceptable results of visual analog scale (VAS) > 3.0.

Results

Of the 20 patients randomized in the study, 19 completed all data collection points. The patient who withdrew early was unable to complete the saline arm of the study because of uncontrollable pain. Statistical analysis showed no difference in any of the endpoints between the saline and intrathecal

drug group ($p > .05$). No side effects were seen in the treatment group, even at maximum doses. In four patients good relief was obtained with octreotide and they continued treatment in the open label phase. Each of these diagnoses was classified by the treating physician as neuropathic in character. In several patients, significant improvement was seen in pain scores (3.0 VAS), functional improvement (improvement of one level on the Oswestry functional analysis scale) global satisfaction. Despite reporting good response, this subset of patients did not have any reports of complications, side effects, or significant adverse effects. This suggests that in this group of patients, we did achieve reasonable therapeutic levels. We continue to have three patients who are still in the open-label phase of evaluation.

Conclusions

Intrathecal octreotide is not helpful in chronic pain when given by continuous infusion in patients with neuropathic pain. Although the overall data did not show clinical efficacy, the group of patients classified as having neuropathic pain complaints did do significantly better. Four of these patients received the drug in an open label fashion for periods of 6 months past the conclusion of the study. The lack of side effects suggests that the dose selected for the study should be increased for future analysis of this agent.

Cost Efficacy of Spinal Cord Stimulation Versus Reoperation for Failed Back Surgery Syndrome: A Randomized, Controlled Trial

Richard B. North, MD; David Kidd, MA

We analyzed the cost-efficacy of treating failed back surgery syndrome (FBSS) with spinal cord stimulation (SCS) versus reoperation.

Materials and Methods

We conducted an intent-to-treat analysis of healthcare cost data from randomization through follow-up for FBSS patients in a randomized, controlled, crossover trial and compared treatment with SCS versus reoperation.



News Conference participants enjoy one of the outstanding seminars at the 9th Annual NANS Meeting in Washington, DC.

Results

Of 42 eligible patients, one refused consent and one died over a mean follow-up of 3.1 years (range 1.6–4.67). As randomized, 13/21 (62%) reoperation patients crossed versus 5/19 (26%) SCS patients, an SCS advantage ($p < .025$). Intent-to-treat cost per patient was \$31,532 for SCS versus \$37,681 for reoperation (\$6,149 SCS advantage). The cost per patient of each long-term success was \$48,357 ($n = 7/14$) for SCS only, \$105,691 ($n = 2/8$) for reoperation only, and \$115,986 ($n = 5/13$) for reoperation plus crossover to SCS. No SCS patient who crossed over to reoperation ($n = 0/5$) achieved success despite a \$260,611 per patient expenditure.

Conclusions

SCS is more cost effective than reoperation in selected FBSS patients and should be the initial therapy of choice. SCS is most cost-effective when patients forego repeat operation.

Bilateral Current Fractionalization in Spinal Cord Stimulation

John C. Oakley, MD; Elliot Krames, MD; Richard Weiner, MD; Vani Grandhe, MS; Michael Moffit, PhD; Kerry Bradley, MS

Programming in spinal cord stimulation (SCS) involves selection of anode-cathode combinations to create stimulation fields. The shape of the stimulation field determines which nerves are activated. Activating the appropriate nerves determines the paresthesia coverage, which is significantly correlated to clinical outcome. In conventional SCS systems with “discrete” programming, contacts can be programmed only as “cathode, anode, or off.” SCS systems, with independent current-controlled contacts, allow the patient to shape the stimulation field using current fractionalization, independent of the impedance of the contacts. We

investigated the degree to which patients choose fractionalized current distributions on dual, bilateral-lead implants.

Methods

We performed a retrospective analysis of stimulation channel settings from patients enrolled in a controlled observational study. In the Precision™ Investigational Device Exemption clinical study, after a successful stimulation trial, implanted patients were followed up at post-IPG implant, 2 weeks, 3 months, and 6 months. Using the 3-month data of FBSS patients with dual parallel eight-contact leads, we analyzed the percentage split of cathodic current on channels programmed by the patients.

Results

We found that 81% of the channels programmed by the patients had percentage split current values between 55%–95%. The median percentage split between the cathodes on parallel leads for all programmed channels was 71/29%.

Discussion and Conclusions

Discrete programming systems can only achieve fractional current splits of 0/100%, 50/50%, or 100/0% between any two cathodes. We found that, given the option, the majority of patients choose fractionalized current settings not achievable by discrete programs for their implanted dual parallel leads.

BrainGate™: First Experience with an Implantable Human Neuro-Motor Prosthesis

Michael C. Park, MD PhD; Vasilios Zerris, MD MPH MMSc; Leigh Hochberg, MD PhD; John Donoghue, PhD; Jon A. Mukand, MD PhD; Gerhard Friehs, MD PhD

The idea of connecting the brain to a machine is not new. However, advances in computer technology over the past 50 years

have made it a reality. We present our first experience with an implantable human brain-machine interface that allows identification and interpretation of motor signals that can be used to control a neuro-motor prosthesis.

Material and Methods

The ongoing study calls for up to five patients with quadriplegia from high-cervical injury, stroke, or degenerative disorder that resulted in limited movement of their arms or legs. Patients may range in age from 18 to 70 years and must be able to communicate verbally or with assistive devices. The injury must precede the participation in the study by at least 1 year. Patients undergo a standard neurosurgical craniotomy where the BrainGate™ array of 100 microelectrodes is implanted into the cortical surface of the primary motor cortex and is externalized through a percutaneous connector. The array allows for continuous extracellular recording during the scheduled recording sessions.

Results

Our preliminary results indicate that long-term recording of multiple primary motor cortex neurons is possible in humans who have been quadriplegic for an extended period of time, thus confirming indications from functional magnetic resonance imaging studies that the primary motor cortex is active and functional. Furthermore, we were able to show that participants with the implanted BrainGate™ devices are able to modulate the activity of their primary motor cortex by thought alone. We were able to decode the cell-firing pattern and extract the intent-to-move signal which in turn was successfully used as a control signal for a computer cursor, robotic arm, and limb prosthesis.

Conclusions

Our first experience is encouraging but the study is still ongoing. Future challenges will include full subcutaneous implantation of the device, miniaturization of the hardware, and further trials in other patient populations, such as amyotrophic lateral sclerosis (Lou Gehrig's disease) or epilepsy.

Acknowledgment

The support of Cyberkinetics Neurotechnology Systems, Inc., for this research project is gratefully acknowledged. 

Ethics of Neuromodulation

Paul J. Ford, PhD; Jaimie M. Henderson, MD

The field of neuromodulation is growing at a tremendous pace. One could imagine almost limitless applications of new technologies for modulating nervous system function. However, the advancement and further development of contemporary neuromodulation could face social and political challenges because of public perceptions of past missteps in neurosurgical research and interventions. The memories of “mass lobotomies” are never far from the public consciousness. Although intending to benefit a particular patient or an entire class of patients may be noble, these best intentions are not sufficient to guarantee proper action.

Even though many of the social aspects of research and practice may appear to be a distraction to the core goal of treating people’s ailments, paying attention to these elements may in fact allow practitioners to continue innovative and conscientious work and enhance the ability to provide help to patients. In this vein, there are several ethically charged issues related to neuromodulation that are important to keep in mind. For the sake of brevity, we will use the standard four ethical principles to highlight some of these challenges. These selected topics are intended just to provide examples of the types of considerations of which we should be continually cognizant.

Do No Harm

In surgical ethics, the principle “do no harm” should be understood as something like, “only attempt a procedure if you believe that there is a reasonable chance of the patient being at least as healthy after the surgical recovery period as before it.” Furthermore, it is morally significant that neuromodulation interventions are elective and generally non-life saving in themselves. In elective non-life-saving therapies there is a stronger emphasis on the avoidance of making individuals worse off than they started. The risk aversion should be more than in a life-saving intervention.

When considering “do no harm” in neuromodulation research, it is often difficult to justify a true placebo controlled trial for a procedure such as stimulator placement, because risks and effect of implantation are well known a priori. Given this principle, most current protocols call for the patient to be his or her own control by a cross-over design where a stimulator is left off or turned off for periods of time.

Benefit

Implanters are professionals and not simply employees of a patient. In this respect, neuromodulation technology needs to be judged as having a significant chance of benefiting the patient. Although this often hinges on the patient defining what a benefit would entail, there are some benefits that a surgeon may not be willing to pursue if the potential harms are too great (see previous section). Informed consent does not remove the responsibility of the treating physician to perform only interventions which will likely benefit a patient.

In clinical research this principle becomes a little more challenging. Even if an individual patient may not benefit, there must be potential for benefit from the generalized knowledge gained through the patient’s participation as a research subject.

Justice

In research, it is important to select subjects from those who are most likely to give proper consent in initial phases. Furthermore, enrollment should be independent of power or wealth (i.e., the disempowered should be neither kept out of studies that show good therapeutic potential, nor should they be exclusively the subjects in high-risk research). The risks and benefits should be distributed as equally as possible.

In clinical studies, the exclusion criteria must be well founded in evidence. In the absence of good evidence, then best scientific reasoning should apply. The criteria need to be applied evenly to similar patients

independent of such factors as social, financial, or cultural status.

Respect for Autonomy

Respecting a patient’s judgment of values can present challenges. It is important to take into account not only what the patient says, but also the actions of the patient and the judgments of the social network in which the patient finds himself or herself.

Also, neuromodulatory technologies in themselves may alter a patient’s thinking or mood. This may confound the determination after surgery as to what degree the intervention is now subverting the patient’s ability to judge his or her best interests. This is particularly difficult when a stimulator might induce a mood in which patients may not appreciate the harm they are doing to themselves. There are limited times when a therapeutic privilege can be invoked in order to modify settings without consent. (This should be done rarely and with a great deal of forethought.)

Conflict of Interest

Finally, none of the above considerations in the four ethical elements should be unduly influenced by potential secondary gains of individuals or institutions. Given this, the necessary and important collaborations between for-profit device and instrumentation companies and healthcare providers need to be both transparent and structured in a way to reduce temptation to subvert the scientific endeavor. Surgeons and other researchers rely on the trust of patients and society in order to continue their good work. One way of doing this is to be up-front about collaborations and to include a multidisciplinary set of voices in patient or subject selection and to create a collaborative relationship with your hospital ethics committee or review board. 

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	Name of Institution	Degree	Dates
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Residency			
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Other			

Dates	Name of Your Institution/Practice	Your Title/Position
From to		

Neuromodulation Coming of Age

2006

10th Annual North American Neuromodulation Society Meeting



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