

BRIDGING THE GAP

A newsletter for medical professionals

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Expanding the Horizon for Chronic Pain Patients: Advanced Spinal Cord Stimulator Technology Offers New Hope

Founded in 1993, Advanced Bionics Corporation, a Boston Scientific Company, has gained recognition as the manufacturer of the cochlear implant, which uses a sophisticated technology that delivers electrical stimulation to the auditory nerve to restore hearing. Five years ago, Advanced Bionics began exploring the feasibility of applying this technology platform to spinal cord stimulators. The company saw the possibility of creating a much more effective stimulator than conventional models, which use a less dynamic technology.

Since then, Advanced Bionics has developed the Precision™ spinal cord stimulator, for which it received FDA approval in April 2004. In the following article, physicians and patients discuss their experience with the new technology.

Physicians cite benefits of new technology

A solo practitioner, Louis Raso, MD, operates a full-service pain management clinic that provides both inpatient and outpatient invasive therapy for many acute and chronic pain syndromes. Raso believes that the Precision device provides a significant advance in stimulator technology.

Raso has implanted the unit with a wide variety of patients, from individuals who have undergone multiple back surgeries to those with Parkinson's disease. "I have seen very positive outcomes with the Precision device," he says. As an example, Raso cites the case of a 30-year-old patient with fractures and fusions in both ankles who had been confined to a wheelchair and became ambulatory after the implant. Raso also notes that many of his chronic pain patients have greatly reduced their use of medications after the implant, an outcome that not only benefits the patients' health but also helps lower care costs.

Over the past 10 years, Daniel Bennett, MD, DABPM, has witnessed the evolution of spinal cord stimulation from both a research and clinical perspective. In addition to conducting research in neuromodulation, he operates a private practice at the Integrative Treatment Center in Denver, a multidisciplinary spine/pain center.

Bennett has used the Precision technology to treat multiple forms of neuropathic pain, including complex regional pain syndrome (CRPS), diabetic neuropathy, dorsal nerve root injuries and failed back surgery syndrome.

To illustrate the benefits of the Precision system, Bennett describes its use with patients suffering from CRPS. "Typically, these patients have one or two extremities that are swollen and burning like fire," he says. "Consider the situation of a patient who can't lay his arm on the table because it hurts so much. With the previous technology, we would need to thread in the leads and install an antenna; you can imagine how painful this would be for such a patient. By contrast, the Precision mechanism does not require an antenna but instead uses a remote control

to make adjustments. In addition, we have observed that the Precision system covers the patient's pain 25 to 30 percent better. And, this technology provides coverage of both upper and lower extremities with one device. "

Bennett also notes that the simplicity of the device helps alleviate the concerns of older patients who tend to be uncomfortable with technology. "I was discussing the Precision system with a 67-year-old patient who has CRPS," Bennett explains. "She was very nervous about the fact that she would need to program the device. We arranged for her to talk with another CRPS patient who was programming her own Precision system.

As the current user described the experience step-by-step, the new patient realized, 'This is easy, it's just a matter of pushing a couple of buttons,' and her fears were put to rest."

Benchmark study focuses on relief of low back pain

With the features provided in the Precision system, Advanced Bionics has identified the opportunity to address one of the most thorny areas of pain management: lower back pain. "Historically, it has been very difficult to achieve significant relief for these patients with a stimulator," says study coordinator Jim Thacker.

In December 2004, Advanced Bionics launched a benchmark study to determine the efficacy of their device in relieving primary or secondary low back pain. "We hope to prove that the Precision unit is effective both in locating the exact 'hot spot' of the pain as well as in providing long-term relief," says Thacker.

The two-year study is being conducted at 28 sites across the continental United States. Two hundred patients will be enrolled, comprising 180 recipients of permanent implants and an observation group of 20 patients without stimulators. Participants will be assessed for 12 months after receiving the permanent implant. Proof of efficacy requires demonstrating a trial-to-implant ratio of greater than 50 percent. Currently, the study is on target to achieve a ratio of 70 percent or greater.

Both Raso and Bennett, who head up clinics engaged in the study, are hopeful about the potential of the Precision device to relieve low back pain. Raso notes the case of a 29-year-old policeman with lumbar radiculopathy and intractable lower back pain. For nine months, the patient had been unable to work, even at a desk job. He was strongly opposed to having fusion because it would result in such decreased mobility that he would not be able to return to work as an officer. "He had a young family," Raso relates. "He wanted to get back to his job, to be able to support them. After receiving the Precision implant, he received such relief that he's now back on the street force full-time."

Study uses BHI™ 2 test series to effectively measure outcomes

In selecting measurement tools for the benchmark study, Bennett strongly supported the use of the BHI 2 (Battery of Health Improvement 2) test and the shorter version of this assessment, the BBHI™ 2 (Brief Battery of Health Improvement 2) test. These instruments evaluate physical, psychological and social factors commonly associated with pain patients.

"I had become very familiar with these tools in both clinical and research settings," says Bennett. "I felt that they would be well-suited to this study because, unlike other instruments used to assess pain, these tools are normed on injury and pain patients."

"The BHI 2 test series makes the study possible," says Thacker. "Our goal is to measure the efficacy of the therapy and we can't do that without reliable measurement tools. These assessments provide well-validated, proven instruments and, most important, there are no other tests on the market that cover Biopsychosocial as thoroughly."

The study also uses a prototype of the Momentary Pain Scale, which is currently in development. Whereas the BHI 2 and BBHI 2 tests employ a 0-to-10 pain scale that evaluates the patient's pain over the course of a month, this latest addition to the BHI 2 test series includes a 0-to-10 scale that measures pain on an immediate basis.

Bennett emphasizes the value of the BHI 2 and BBHI 2 tests' brevity. "When you are conducting research with a pain population, you don't have the luxury of administering four or five hours of testing to find out everything you need to know," he says. "These patients typically have a very limited ability to concentrate and to sit for a long period of time. The BHI 2 test series enables us to gather a broad range of information quickly."

The BBHI 2 test is used initially to qualify candidates for inclusion in the study. Once the patient is admitted into the study group, the BHI 2 instrument is administered to set a baseline. Three months after the permanent implant, the patient is given the BBHI 2 test to measure progress. At six and 12 months, the patient retakes the BHI 2 test and results are compared to the baseline to measure progress over time.

Study participants take the assessments using the PAD, a hand-held electronic device. "The touch screen and large-type format of the PAD make test-taking much easier for pain patients, especially those who are unable to hold a pen," says Bennett. The PAD works particularly well for study purposes, Raso notes, because the information input by the patients feeds directly into the central research data bank.

BHI™ 2 test series useful in a variety of applications

Raso administers the BHI 2 test to many of his chronic pain patients, not only those involved with the study. He finds the test beneficial in demonstrating therapy efficacy for insurers, many of which require a psychological assessment prior to any kind of implantable pain therapy. "The BHI 2 test is an especially effective tool for demonstrating efficacy because it assesses pain in specific areas of the body," he notes.

Raso also considers the BHI 2 test's 0-to-10 pain scale to be helpful in determining appropriate candidates for therapy. "For example, if a patient reports that they are experiencing a pain level of 10 in multiple areas of the body, there is probably no therapy that is going to satisfy this individual," he says. "Or, if a patient reports that their lowest tolerable pain level is a 2, it's unlikely that any device is going to benefit them."

In addition, Raso likes the fact that the BHI 2 instrument compares patients to other individuals with similar injuries. And, he has discovered that the test's anxiety and depression scales often help uncover the root source of the problem. "Sometimes, if you simply treat the patient's anxiety or depression you have addressed the real issue, without needing to do anything anatomically."

Like Raso, Bennett uses the BHI 2 test series regularly in his clinical practice to identify underlying issues. "We physicians tend to look at

patients in the context of pathology," he says. "She's a 'ëgall bladder,' he's a 'ëfailed back.' We sometimes forget that there's a person inside there living with the pathology-and if you don't treat the whole person, you've missed the boat. The BHI 2 and BBHI™ 2 tests are very effective in helping us understand the person behind the pathology."

Technology to help restore lives

As practitioners who work daily with chronic pain patients, both Bennett and Raso are excited about the outcomes they have witnessed with the use of the Precision device. "I treat people who have lost the ability to walk, to work, to participate in family activities," says Raso. "With the availability of this technology, I am now able to say to my patients: 'I will give you your life back.'" For more information, go to www.advancedbionics.com.

What sets this technology apart?

The Precision device offers a number of unique features, including:

- **Rechargeable battery.** The patient recharges the battery using an external device that emits radio frequency waves. Patients can choose their own recharging schedule, from five minutes daily to a couple of hours monthly. Conventional systems use a primary cell battery that typically lasts an average of three to four years and then must be surgically replaced.
- **Patient control.** With the new unit, the patient uses a handheld control to navigate the current around the spinal cord with up, down, left and right buttons. Once the patient detects the exact point of pain relief, he/she pushes the "Save" button. With previous systems, the physician set up various current configurations and asked the patient for feedback as to which settings worked best.
- **Broad span for pinpointing the "hot spot."** The Precision unit has 16 electrodes, each with a separate output, allowing for greater scope in moving the current through the spinal cord to find the pain point; conventional stimulators have only two outputs that control all 16 electrodes.
- **Constant current.** The Precision unit works on constant current rather than constant voltage, enabling the voltage to adjust for any resistance in the patient's body, such as scar tissue. Previous systems operated on constant voltage, which did not accommodate for individual resistance factors.
- **No limitations on power usage.** Because the Precision battery is rechargeable, patients do not need to limit the amount of electricity they use. With past-generation systems, patients were often required to limit usage so that the primary cell battery would last at least 18 months.
- **Zero volt technology.** If the patient forgets to recharge the Precision battery, it will not be damaged and can be recharged from an empty cell. Other rechargeable batteries currently available do not offer this option.
- **Smaller size.** The Precision unit is approximately half the size of the conventional models, allowing more options for placement, such as alongside the rib cage. The old systems, which were about the size of a hockey puck, were usually implanted in the fatty tissue of the upper buttocks.

For more information on this technology, see www.ControlYourPain.com.

Finding relief from a consuming pain

In 1981, Joe was involved in a car accident that ruptured two discs, leaving him in constant pain. "I was exhausted most of the time," he says. "The pain sucks all your energy. You can't even concentrate on sedentary activities because your brain is consumed by the pain."

Over the years, Joe was prescribed various drugs and spinal cord injections to ease his suffering, but they brought minimal relief.

Due to the pressure on the nerves controlling his leg movement, he couldn't stand upright. He underwent four laminectomies to reduce the pressure so that he could walk, but continued to suffer from leg and low back pain after the operations.

Joe became dependent on his wife to help him with simple daily tasks such as dressing. He was unable to taking care of the yard, shovel the walk and perform other household duties that once had been his responsibility. "My self-esteem was virtually gone," he says. "I felt like I was nothing but a burden on my family."

Joe continued to seek medical solutions but hit a brick wall. "I can't even count the number of doctors who looked at me and said,

‘There's nothing more we can fix surgically. You'll just have to learn to live with it.’ When the doctors say there's nothing else to be done, that's when you become really hopeless," he says. "I considered suicide more than once. What was the point of going on?"

When Joe learned about the Precision system, he was excited to discover that it uses a rechargeable battery. "God willing, that meant the implant would be my last surgery," he says.

After qualifying as a suitable candidate for the procedure, Joe received the implant in late 2004. "It was nothing short of a miracle," he says. "This device really helps me control my pain." For the first time in years, he can stand upright. He is able to perform household tasks, which makes him feel like a contributing member of the family once again. "My self-esteem has improved and my bouts of depression have decreased significantly," Joe says. He also has dramatically reduced his use of prescribed narcotics, relieving his family doctor's concern about his risk for addiction.

"This area of pain management is long overdue," says Joe. "I'm glad for the chance to share my story. Whatever I can do to let others with chronic pain know that there is hope, I want to do."

A rugged individualist regains independence

For 26 years, Wally loved his work as the owner of a dry-cleaning business on the outskirts of Las Vegas, often putting in strenuous 14-hour days. In his off hours, he relished his time exploring the desert with his kids, playing with his dog, Dee Oh Gee, and socializing with friends. Then he suffered a lower disc injury in 1997 and his world caved in.

For the next year and a half, Wally was prescribed a variety of medications and injections to relieve his pain. "Nothing worked. Zero relief," he says. He then underwent surgery to install a traditional spinal cord stimulator. Wally was unhappy to discover that the battery, which he was told would last four years, gave out after only 10 months—resulting in two additional surgeries for battery replacement. But most disappointing was that the unit, which had worked well during the trial, provided him with only minimal relief once it was permanently installed.

"I can take a lot of pain, but I was a basket case," he says. "I could barely walk. I couldn't work for any length of time. I let my employees go because I couldn't manage them; I was constantly snapping at them due to the pain. I stopped going out to dinner with friends. I quit caring about life."

When Wally heard about the Precision spinal cord stimulator, he felt renewed hope. He liked the fact that the system would allow him to be in charge. "I could hold the control in my hands and make the adjustments; I could have the power over my pain."

He also was impressed that the unit offered a broad range of settings, enabling him to pinpoint the pain. And, he appreciated that the unit was much smaller and therefore more comfortable than his previous stimulator.

Since having the device implanted, Wally has been especially pleased to be able to cut his pain medications in half. "Being raised as a Christian Scientist, I was admonished against taking even an aspirin, so it was depressing to feel that a pharmacist had control over whether I could walk or not."

Wally is now back to work full-time and is doing the construction on an addition to his business. On the weekends, he goes metal-detecting along the old Spanish trail with his son, plays catch with Dee Oh Gee and has no problems driving his new Jeep across the bumpy desert roads. "I'm having a ball," he says. "I'm excited about life again. I have my independence back."

Louis Raso, MD, operates a solo practice in Tequesta, Florida, operating a full service pain clinic that provides both inpatient and outpatient invasive therapy for many acute and chronic pain syndromes. Raso is a diplomate of the American Board of Anesthesiology and a member of the American Academy of Pain Management. He received his doctoral degree from Rutgers Medical School.

Daniel S. Bennett, MD, DABPM, received his MD from the University of Miami and completed post-doctoral training in anesthesiology and interventional pain medicine. In 1996, he co-founded the Integrative Treatment Center, a multidisciplinary spine/pain center in Denver, Colorado. Bennett also established the National Pain Foundation, which is dedicated to the education and betterment of people who live with pain.

James Thacker is field clinical engineering manager at Advanced Bionics Inc. Over the past twenty years, Thacker has coordinated a variety of studies on medical technology and has directed the development of many new medical devices. He received master's degrees in electrical engineering and in veterinary physiology with a specialty in cardiology from Purdue University.

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