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A Case Report

Peripheral Nerve Field Stimulation in Chronic Abdominal Pain

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Introduction: Spinal Cord Stimulation (SCS) has become an accepted therapeutic modality for the treatment of intractable pain syndromes, primarily used today in the settings of failed back surgery syndrome, neuropathic back and limb pain. The use of spinal cord stimulators for peripheral nerve field electrostimulation is becoming increasingly recognized as a safe, effective alternative for chronic pain conditions that are refractory to medical management and do not respond to traditional dorsal column stimulation. Advances in technology have allowed for minimally invasive percutaneous placement of multipolar leads with complex programmable systems to provide patient- controlled relief of pain in precisely targeted regions. With these improvements in hardware, the use of Peripheral Nerve Field Stimulation (PNFS) appears to have an untapped potential for providing patients with pain relief for a wider range of underlying conditions than was previously believed possible.

We present three cases, each with a different etiology of chronic abdominal pain: one with inguinal neuralgia, one with chronic pancreatitis, and one with pain following liver transplant. Each patient was refractory to conventional medical approaches. For all three patients, PNFS provided significant relief from pain, enabling patients to decrease or discontinue their opioid medications and to enjoy significant improvement in their quality of life.

We conclude that PNFS is a safe, effective and minimally invasive treatment that may be used successfully for a wide variety of indications including chronic abdominal pain.

Key words: spinal cord stimulation, percutaneous neurostimulation, peripheral nerve field stimulation, neuromodulation, abdominal pain, pancreatitis, incisional neuroma, inguinal neuralgia

Neuromodulation for the management of chronic pain has been evolving continuously since the first applications of Spinal Cord Stimulation (SCS). New approaches have been developed to more selectively target areas of pain and provide more efficient paresthesia coverage, and the list of indications for neurostimulation has continued to grow. Direct stimulation of peripheral nerves, requiring open surgical dissection and placement of electrodes proximal to the painful segment of the exposed peripheral nerve, has had mixed results. (1) The development of cylindrical electrodes that can be placed percutaneously and advanced just under the skin has allowed for regional field stimulation without the need for the invasive surgical placement required for direct peripheral nerve stimulation.

In Peripheral Nerve Field Stimulation (PNFS), spinal cord stimulator leads are placed subcutaneously in the area of pain to stimulate the region of the affected nerves or the dermatomal distribution of these nerves, which then converge back on the spinal cord. Recently, success using percutaneous peripheral stimulation has been reported in a growing list of clinical settings, primarily in the head and cervical regions, (3, 4, 5, 6, 7), but also limb (8) and inguinal nerve (9) as well. PNFS is being applied in individual cases where conventional treatments have failed to control pain, however, there is no consensus yet as to what indications are candidates for this novel form of neuromodulation. We applied the same approach to three cases of chronic abdominal pain, demonstrating the potential use of PNFS as an additional method of pain control for patients with chronic abdominal pain.

Abdominal pain may have a wide range of underlying etiologies, and may be characterized as neuropathic, in which there is damage to peripheral nerves, or nociceptive, in which nerves are irritated or there is tissue damage. Nociceptive pain may be somatic or visceral, depending upon the origin of the pain. In settings of abdominal visceral pain, there is often secondary hyperalgesia in the dermatomes supplied by the same spinal segments that supply the involved viscera. (10) Similarly, visceral pain may also be referred to the skin in a dermatomal pattern. It is difficult to differentiate between neuropathic and nociceptive etiologies of abdominal pain. The nerves mediating nociceptive impulses from abdominal viscera synapse in the same spinal cord segments as the somatic spinal nerves, following the viscerotomal innervation pattern. Based on this principle, spinal cord stimulation has been applied to abdominal visceral pain syndromes, with the selection of lead placement based upon the viscerotomal distribution pattern of innervation. (10) In other words, the leads are placed at the spinal level selected to achieve paresthesia coverage in the relative dermatomal distribution of the viscerotome including the area of abdominal pain. Conversely, for the patients reported here, we placed leads

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subcutaneously, applying stimulation in the peripheral field based on the understanding that the dermatomal innervation and visceral innervation converge at the same spinal cord segments.

The three patients reported here had intractable abdominal pain and had failed nerve blocks, neurolysis, scar lysis and medications. We selected PNFS over SCS because we did not feel that we would be able to get adequate coverage in the affected region using SCS. We hoped to offer a therapeutic modality that would enable our patients to minimize their need for repeated office visits and allow them to return to their usual activities with a minimum of external apparatus and interruptions, and therefore offered PNFS over transcutaneous or percutaneous electrical nerve stimulation (TENS or PENS).

Successful subcutaneous PNFS for post-operative inguinal pain has been reported previously. (9) We present another case demonstrating a dramatic response to PNFS for this difficulat to treat, and relatively common indication. In addition, conventional SCS has been used for the treatment of a variety of abdominal visceral pain conditions, including chronic pancreatitis. (10) We present a patient with chronic pancreatitis and a patient with pain following liver transplant, both of whom were treated successfully with percutaneous PNFS, in what we believe to be the first use of this treatment for these conditions.

Case Reports

Case 1

Patient #1 was a 19-year-old female with a history of right lower quadrant and inguinal pain following right inguinal hernia repair four years prior to presenting to our office. The patient had no relief following two surgical procedures to release the entrapped right iloinguinal nerve and removal of scar tissue. She had persistent pain following local injections, pulsed radiofrequency thermocoagulation of the right ilioinguinal nerve, nerve blocks, and neurolysis. She developed thinning of the skin over the right inguinal region requiring a skin flap. Despite these interventions pain was described as 10 on a scale of 0 (no pain) to 10 (maximum possible pain), continuously with intermittent shooting pains into the right leg. She reported difficulty with sleep and complete inability to function due to pain, and required opiate analgesics, but was not able to take therapeutic doses because of sedation and visual changes. She was unable to work for more than two hours a day, and was not able to enroll in college because of debilitating pain. In addition, she complained of inability to socialize with friends, and was severely depressed. Medications at that time included propoxyphene, gabapentin, antidepressants and sleep aids.

A 4 day trial of PNFS stimulation was performed with excellent results. At the trial, a 14 g Tuohy needle was introduced at the superior aspect of the previous right inguinal surgical scar and advanced subcutaneously. An 8 contact electrode (Advanced Neuromodulation Systems (ANS) Plano, Texas, Octrode 3186) was then introduced through the needle and the needle was withdrawn. The patient reported comfortable stimulation in the region of the inguinal pain. The lead was secured, and complex programming was done using the Multiprogram Trial Stimulator (MTS trial system, ANS). The patient reported significant relief of pain during the trial period, with average pain reported as 4/10, and the decision was made to proceed with a permanent implant.

A permanent single octipolar lead was later placed in a similar fashion to the trial, with an Implantable Pulse Generator (Genesis IPG, ANS, Plano, Texas) placed in an abdominal pocket. During the two weeks following the implant, the patient complained of incomplete area coverage, with stimulation in the mid-pelvic area rather than over the surgical site. A revision was performed one month after the implant, and the lead was withdrawn approximately 2 inches, providing stimulation in the desired areas. VAS scores ranged from 2 - 4 in the months following revision. Programming that provided the best coverage included a Frequency of 30 Hz, Pulse Width of 507 mSec, and an electrode array 1-8: positive, positive, negative, negative, positive, positive, negative, negative; also effective was a Frequency of 30 Hz, Pulse Width of 351 mSec with array 1-8: neutral, neutral, positive, neutral, negative, negative, neutral, neutral. Final lead position is demonstrated in Figure 1. Eleven months since this revision, the patient has reported excellent stimulator coverage and has been able to completely discontinue all medications. Telephone follow-up one year post implant revealed that she is working full time and has very little pain. VAS averages range from 0-1. She uses the stimu-

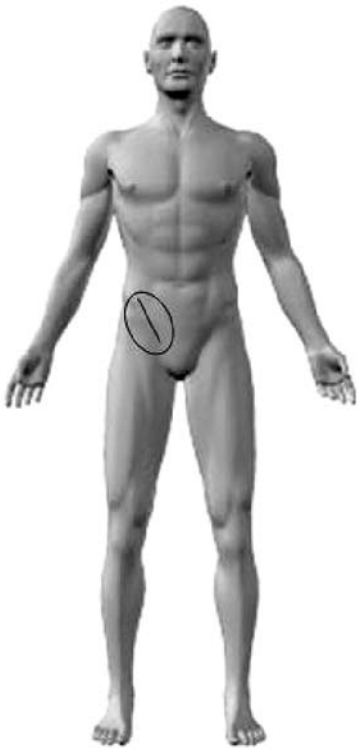


Fig 1: *Inguinal Neuralgia – Note placement of single lead and area of stimulation coverage.*

lator as needed (currently approximately once a week) turning it on for approximately 10 minutes when she experiences pain, and is able to get complete and long lasting relief. She has stopped all pain medications as well as antidepressants, has been dating and enjoying socializing with family and friends, is planning a family vacation and plans to enroll in college in the fall.

Case 2

Patient #2 was a 54-year-old male with a history of liver transplant four years prior to presenting for management of severe abdominal and incisional pain with neuroma. He reported right upper and lower abdominal pain beginning just after the transplant, followed by significantly worse pain from the time of an incisional hernia repair six months post transplant. Pain was described as severe, continual pain with intensity 9/10 in the right upper and lower quadrants, further described as dull, throbbing, burning, and hot and radiating into the right groin and testicle. He was unable to walk or get up from a seated position due to pain, and was unable to breathe comfortably. He was noted to sit stiffly taking shallow breaths, secondary to pain with even slight movement. He also complained of difficulty sleeping. At presentation to our office his Oswestry Score was 76. Initial medications included controlled release morphine and gabapentin. Intercostal nerve blocks to the right T10, T11 and T12 nerves and neuroma injections along the right abdominal incision were performed without significant benefit. Intercostal nerve blocks to the right T9, T10 and T11 nerves along with right ilioinguinal blocks provided temporary relief lasting approximately 6 months.

A trial stimulation was done with two Quattrode leads (ANS, Plano, Texas) placed subcutaneously over the right intercostal margin over the site of greatest pain. A third Octrode lead was placed over the liver transplant surgical scar. The patient reported a 90% reduction in overall pain during the trial. A permanent system was implanted with the three leads placed subcutaneously over the same sites used during the trial. (Wide Spaced Dual Quattrode, 6 mm spacing, and one Octrode, ANS) Wide spacing leads (6 mm between contacts compared to 4 mm regular spacing) were chosen to maximize the area of coverage. A rechargeable generator (EON, ANS) was placed in a pocket over the right hip. Lead position is demonstrated in Figure 2.

Maximum relief was achieved with programming cycles of 5 minutes of stimulation followed by 5-10 minutes off, using the following settings: Frequency 82 Hz, Pulse Width 387/500 mSec, lead array contacts 1-4 for each lead: positive, positive, neutral, negative. Six months post implant, the patient describes the difference in pain as "night and day", compared to the pain pre-implant. He reports a pain level of 0/10 in the right upper abdomen, has no difficulty breathing, is able to walk and accomplish his usual daily activities, and has no further difficulty sleeping. The Oswestry score at 6 months post-stimulation was 28. He continued oral morphine but discontinued gabapentin.

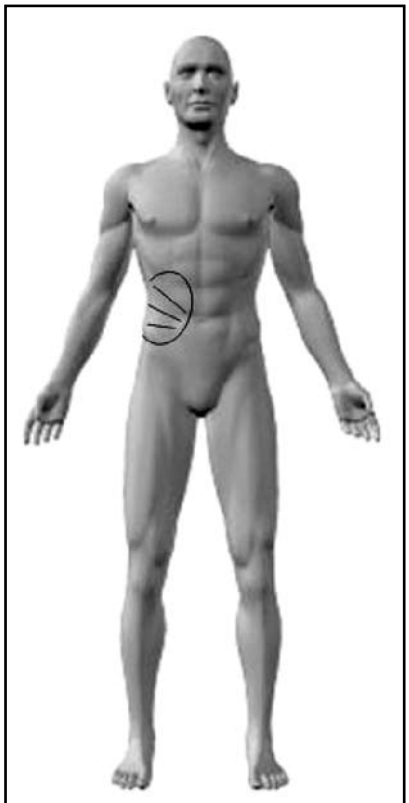


Fig 2: *Patient status post liver transplant with right abdominal and incisional pain. Note placement of three leads and region of stimulation coverage.*

Case 3

Patient #3 was a 39 year old male with a three year history of chronic pancreatitis due to pancreatic divisum. By the time of presentation to our office he had undergone cholecystectomy, sphincterotomy, and a modified Whipple procedure and placement of multiple stents. He had a history of hospitalizations one to two times a month for management of pancreatitis symptoms. Pain was localized to a well-defined 6 x 4 cm area in the right upper quadrant. He characterized pain as constant, dull, and throbbing with an intensity of 3/10 daily, with occasional increases to 9/10. These more severe episodes lasted hours to days. approximately one to two times per week. He reported incapacitating pain one to two times per month described as shooting through his body with a grabbing sensation causing him to buckle over. He reported difficulties sleeping and inability to perform daily activities, and was significantly depressed. At the time of initial presentation, medications included oral opioids and gabapentin.

Due to the refractory nature of his pain and desire to be off opioids, a trial of PNFS was offered. While SCS was a valid option, we selected PNFS to achieve the same end result with a potential for greater reliability and safety. At the time of trial, the area of maximum pain in the right upper quadrant was identified with the patient awake and responsive. The patient was then sedated and a 15 g Tuohy needle was advanced under the skin about 2 cm lateral to the field of intended coverage. With the bevel pointing down, an octipolar lead (ANS Octrode) was ad-

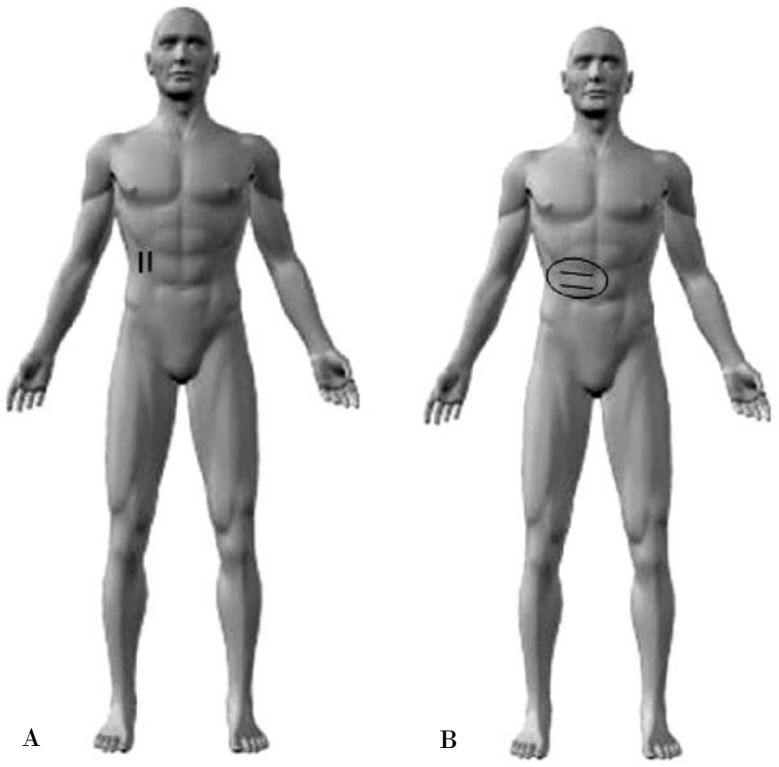


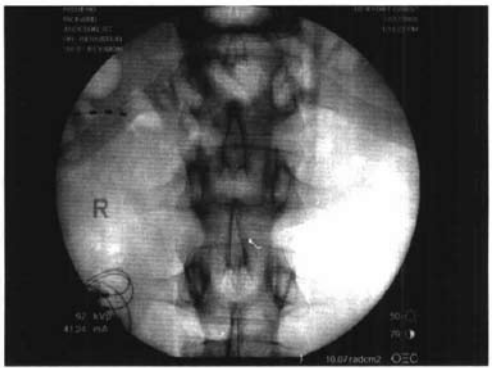
Fig 3: *Patient with chronic pancreatitis. A) Initial placement of leads with first implant. This positioning failed to provide adequate coverage. B) Note optimal lead placement and area of stimulation coverage, with orientation in parallel to dermatome.*

vanced in a subcutaneous fashion parallel to direction of the field previously outlined. The same technique was then used for a second Octrode lead approximately 2 cm inferior and parallel to the first electrode. Complex programming was done using an MTS trial system (ANS; Plano, Texas).

During the 7-day trial stimulation period the patient reported 70 - 80% reduction in pain. Using his favorite program with Frequency of 60 Hz and Pulse Width of 350 mSec he reported an 80% reduction in pain. (Both lead electrodes had a programmed array 1-8: neutral, neutral, negative, negative, neutral, positive, neutral, neutral). He was able to decrease his pain medications significantly and demonstrated improvements in activities of daily living.

Based on the success of the trial, he later underwent placement of a permanent system. Two Octrode leads were placed in the appropriate location, although this time in a vertical fashion parallel to the spine and slightly more cepahlad than before. An EON Rechargeable IPG (ANS) was connected to the leads and then placed into a pocket in the abdominal wall inferior to the leads. However, several days following implantation, the patient complained of poor paresthesia coverage as compared to the trial. This was attributed to the fact that the leads were placed vertically rather than horizontally, as they had been during the trial. A revision was performed, in which the leads were replaced in the medial to lateral orientation as they had been during the trial. Following this revision the patient has had exellent pain control, with VAS scores of 2, with further taper of analgesics. Oswestry score has decreased from 28 pre implant to 0.

Two months later the patient reported problems with his system, with stimulation turning on, and then stopping after 5 – 10 seconds. Despite these complaints the patient had had no hospitalizations since the implant and was able to continue tapering his medications. The entire unit was removed and replaced with a new identical system with two leads again placed very superficially under the dermis in the region of the epicenter of the maximum



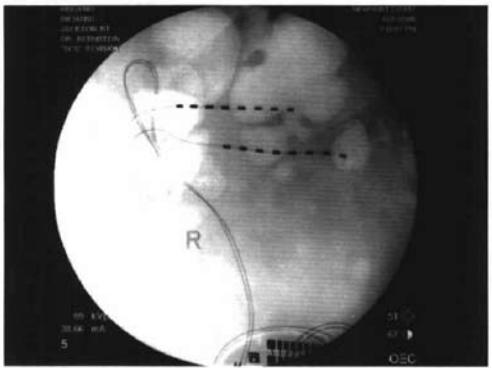


Fig 4: *Fluoroscopy pictures indicating lead placement for patient 3.*

pain. Six months since this revision the patient has had excellent pain control, with VAS scores of 2 and with further taper of analgesics. Initial and final lead positions are shown in Figures 3 and 4.

Discussion

For each of our patients, there were options for pain control. TENS or PENS may have been effective in controlling pain, however we selected PNFS to provide a long term but reversible solution that would require a minimum of office visits and interruption of activities for our patients. We hoped to provide a patient-controlled and fully implanted modality that would allow these individuals to return to an active lifestyle. In addition, for Patient 1 with skin irritation and thinning of the skin over the inguinal area we did not feel that PENS or TENS would be appropriate. For Cases 2 and 3, while SCS may have resulted in good coverage in the same dermatomal distribution, we chose the more peripheral approach to minimize the risk of complications, avoiding the potential neurologic sequelae associated with stimulation of the spinal cord. Patient 1 had failed thermocoagulation and neurolysis previously. In the other patients, we opted to proceed with PNFS rather than neurolysis because of the irreversibility and unreliability of neurolysis or thermocoagulation.

PNFS has potential advantages as a treatment for chronic pain. (11) Advantages include: reversibility, low morbidity with fewer side effects, minimally invasive implantation, percutaneous lead placement, lead insertion with the patient awake to confirm proper lead placement, and programmable stimulator systems to improve coverage and effectiveness of stimulation.

For select patients who have failed other methods of pain management, PNFS may be a viable option. Patients with entrapment neuralgias following inguinal hernia repair may represent a large group of patients who can be considered for PNFS (6,800 – 13,600 new patients per year in the United States, if an estimated incidence of 1-2% of entrapment neuralgia following herniorrhaphy is accurate). (9) Placement of one or two percutaneous leads in the inguinal area may provide appropriate paresthesia coverage in areas innervated by the ilioinguinal nerve, genital branch of the genitofemoral nerve, iliohypogastric nerve, the femoral branch of the genitofemoral nerve, lateral femoral cutaneous nerve, or femoral nerve, all of which have been implicated in postoperative neuralgias. In addition, patients with non-operative causes of ilioinguinal neuralgia may be candidates for PNFS.

Chronic pancreatitis is a major cause of morbidity in the United States. Prevalence rates vary from 12 – 45 cases per 100,000 individuals. Intractable pain is the dominant characteristic of this condition, causing frequent, prolonged hospitalizations. Pain caused by pancreatitis is one of the most difficult clinical syndromes to treat, as it is resistant to most medical therapies and surgical interventions. Conventional pain management strategies have been disappointing for pancreatitis as well as for other visceral pain syndromes (10, 12). While SCS has been reported to relieve abdominal visceral pain (10), we applied PNFS leads directly over the area of pain in our patients with pancreatitis and incisional neuroma pain following liver transplant, and achieved significant pain control. The selection of the number of leads implanted and location of the leads was tailored to the specific needs of the patient to precisely target the region of pain. Only one lead was implanted in the patient with inguinal pain, and this was adequate to completely cover the area of pain. The liver transplant patient experienced pain in a more widespread area, and two leads were placed over the upper abdomen and a third lead in the region of the incision to provide optimal coverage. Maximum capacity of currently available rechargeable IPG's utilizes a total of 16 contacts, therefore one Octrode and two widespaced Quattrodes were utilitized to cover the wider area of pain.

The patient with pancreatitis presented a more complicated but instructive scenario. Two leads placed in parallel to the area of pain provided excellent coverage during the trial period. During implant of the permanent system, because we selected his right umbilical area for implantation of the generator, the leads were placed in a vertical orientation over the same region as the trial leads. This positioning did not provide as effective coverage. However, after revision, with leads placed again in parallel orientation to the dermatome, the patient had significant relief. We opine that for optimal coverage, leads should be placed in parallel to the dermatomal distribution of the affected nerves to take advantage of presumed viscerotomal/dermatomal convergence. Similarly, during the course of revising his system it became clear that having the leads placed extremely superficially was important to the effectiveness of the system.

For each patient with PNFS, we placed the leads just under the dermis, superficially enough to be easily palpated through the skin. Location of lead placement was selected with the assistance of patients during the procedure, who were able to identify their areas of maximum pain, and to confirm paresthesia coverage before leads were secured in final position. The use of an eight contact array enabled a greater area of coverage and provided greater options for programming, as well as flexibility for changes in coverage over time. One physician selected only octipolar leads, in order to maximize the area of coverage, while another physician chose widely spaced (6 mm) quattrode leads plus one octipolar lead to maximize coverage area. In contrast to SCS, where there is conduction between leads through spinal fluid, in PNFS we assumed the leads function independently, with no "cross-talk" or conduction through tissue, and the goal of programming was to capture the broadest zone of coverage. Given a maximum of 16 total contacts available with current programmers, we selected the num-

ber, type, and programming of leads to maximize coverage for each particular patient's situation. Programming parameters were selected based on patient comfort, using our experience with peripheral stimulation to provide settings with optimal coverage.

For our patients, the most effective programming involved continuous cycling of stimulation, with five minutes of stimulation alternating with five minutes off. This appeared to minimize desensitization to the stimulation.

The question remains how and why stimulation of the peripheral field provides pain relief. Similar to the postulated mechanism for Percutaneous Electrical Nerve Stimulation (PENS), (13) neurostimulation in subcutaneous tissues with PNFS may alter local blood flow, block cell membrane depolarization and axonal conduction, affect neurotransmitters, and thereby similarly block or jam nociceptive input back at the spinal neurons. As postulated for PENS and TENS (13), PNFS may cause an increase in endogenous endorphins and other opiate-like substances, normalize nerve conduction velocity, and decrease conduction latency and the mechanical pain threshold. As described previously, we suspect that PNFS relieves abdominal visceral pain by modulating cutaneous nerves in the dermatomal distribution of the viscerotome involved in pain. (10) Further study is needed to clarify the pathophysiology and mechanism of action of peripheral nerve field stimulation.

Similarly, the nomenclature needs to be more carefully defined and specific Common Procedural Terminology (CPT) codes need to be assigned so that this therapy can be offered to appropriate candidates. PNFS is a unique form of neuromodulation, neither synonymous with direct peripheral nerve stimulation nor SCS. There is considerable controversy surrounding the naming and coding of this procedure, with the term "Peripheral Nerve Field Stimulation" agreed upon at a meeting in May 2005 of European interventionalists in Frankfurt, Germany (Personal communication with Giancarlo Barolat and Raymond Greaser, March 2006). It will remain a challenge to obtain insurance approval until there is general agreement on terminology and CPT coding for PNFS.

Conclusion

PNFS was effective in relieving pain refractory to conventional management. PNFS has advantages, including reversibility, being minimally invasive and with apparent low morbidity. Our experience suggests that PNFS has potential as a treatment option for chronic abdominal pain, including post inguinal herniorrhaphy pain, abdominal incisional pain, and pain associated with chronic pancreatitis. The technique merits further study.

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