



## Spinal cord stimulation: patient selection, technique, and outcomes

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Descriptions of the biologic effects of electric stimulation date far into antiquity, most likely first described by fishermen dealing with such creatures as the electric fish, *Torpedo marmorata*, *Malopterurus electricus*, and *Gymnotus electricus*. These species are known to have been abundant near the sites of ancient civilizations, and fishermen noted their presence in nets when experiencing a painful electric shock, often leaving them with a numb sensation. The first application of this effect was possibly reported by Scribonius Largus in 46 AD in his *Compositiones Medicae* for the treatment of acute gouty attacks and headache [1]. He writes, “headache even if it is chronic and unbearable is taken away and remedied forever by a live torpedo placed on the spot which is in pain, until the pain ceases.”

With the publication of the “gate control theory” of pain by Melzack and Wall in the 1960s came the modern era of spinal cord stimulation (SCS) [2]. Based on the argument that electric stimulation of large-diameter afferent fibers would close the gate to input from the smaller diameter and unmyelinated A $\delta$  and C-fibers mediating pain, Shealy and co-workers [3] reported pain relief in a patient with cancer-related pain by the epidural application of spinal cord electric stimulation. With encouraging early results, albeit in an application for malignant origin pain no longer thought to be indicated, SCS began as a treatment modality for pain. Unfortunately, the initial belief was that

SCS would be applicable to all pain types. Its broad application in the early 1970s almost resulted in its demise as a treatment modality because of poor outcomes. Careful observers began to note that SCS was most beneficial in patients with chronic pain of peripheral neurogenic origin, although some groups still claimed relief could be obtained in musculoskeletal pain. The primary indications for the use of SCS became neuropathic pain caused by peripheral nerve or nerve root injury and almost exclusively in the United States for the treatment of the so-called failed back surgery syndrome. Syndromes with a predominantly neuropathic component were demonstrated to be relatively refractory to the usual medications, including opioid medications in the customary dose ranges [4,5]. In the currently accepted treatment algorithms, SCS often falls as a treatment of almost last resort when the pain has been designated as drug resistant. Unfortunately, even well-selected patients may not experience significant pain relief. In general, for failed back surgery syndromes, which offer the most literature data, the efficacy of SCS is about 60% to 70% [6–8]. Currently, the application of SCS encompasses not only neuropathic pain caused by peripheral nerve or nerve root injury but selected primarily sympathetically mediated pain syndromes, such as ischemic pain caused by peripheral vascular disease, angina pectoris, and type I and II complex regional pain syndrome (CRPS) [9–11]. SCS has become an important adjunct in the treatment of specific disease-related syndromes, such as interstitial cystitis and pelvic pain [12,13]. Other applications of SCS have been tried, especially when other therapies have proven ineffective [6,7].

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SCS, as with neuromodulation procedures in general, is a nondestructive, screenable, and reversible treatment option. Because there are no long-term side effects that have been reported, SCS generally is preferable as a first step when other less invasive treatments have failed to produce acceptable control of the pain. The current enthusiasm for SCS is reflected in an increasing market for implantable neurostimulation products. As of 2000, the implantable neurostimulation market was \$313 million and had shown growth of 25% to 30% per year in the previous 2 years [14]. About 61% of this market is for chronic pain management and 8% is for urinary incontinence, with approximately 60,000 spinal cord stimulators implanted. It is tempting to assume that favorable outcomes must be apparent in most clinics for at least the common applications.

### **Terminology**

As SCS has become more standardized over the last three decades, certain basic terms have developed common use and definition. Through the work of the American Neuromodulation Society, a glossary of terms has been developed to assist persons just getting involved in this work. The following are terms pertinent to a discussion of SCS.

#### *Array*

An array refers to a two-dimensional arrangement of stimulating contacts either (1) prefabricated on insulated backing as a paddle or plate or (2) created by insertion of percutaneous electrodes in parallel. Most commonly, and of necessity if placed percutaneously, the contacts are arranged longitudinally in columns; an array may have any number of columns. A prefabricated paddle or plate may have contacts in a diamond pattern or in rows.

#### *Channel*

A channel refers to a pulse generator or radiofrequency receiver output that is independent of other outputs, in particular, to amplitude (voltage or current). A true multichannel stimulator allows simultaneous delivery of different amplitudes to different contacts. (A programmable multicontact stimulator that allows rapid sequential delivery of pulses to different contacts approaches this but is not, strictly speaking, a multichannel device.)

#### *Contact*

A contact is an electrically conductive point or surface from which current passes into tissue. Contemporary electrode arrays have multiple contacts.

#### *Electrode*

An electrode refers to an assembly of electrically conductive contacts and wires, along with insulating spacers, catheters, and backing material. The word is most often used to refer to the “business end” of the assembly, where contacts deliver stimulation current to tissue. (The word is sometimes used to refer simply to a stimulating contact, but electrodes include insulation and other materials.)

#### *Implantable pulse generator*

An implantable pulse generator (IPG) is a battery-driven power source for electrically activating a contact array(s). It is designed to be implanted in a subcutaneous location and not to require an external apparatus to activate, but it may have an external control for off-on, amplitude, and rate control.

#### *Lead*

A lead refers to a linear arrangement of conductors and insulators (wires and their circumferential insulation) between stimulating contacts and connectors. (The word is sometimes used to refer to the entire electrode, particularly if it is a percutaneous catheter design.)

#### *Paddle*

A paddle is a flat and essentially two-dimensional insulated electrode or array. Because it cannot be inserted percutaneously (through a needle), it is implanted in the spinal canal by laminotomy or laminectomy (also called a plate electrode).

#### *Receiver*

With regard to SCS, a receiver is a device that is implanted in a subcutaneous location and designed to receive amplitude modulation (AM) radio-frequency transmissions from an external source. These transmissions are converted to an electric signal, which activates an implanted contact array(s).

### **Specific applications of spinal cord stimulation**

SSC or applications of stimulation equipment have been applied in a number of specific

pain-associated syndromes. The most common applications include, in order of pain relief efficacy, the following: ischemic pain caused by coronary artery disease and peripheral vascular disease, type I and II CRPS, persisting leg pain with or without back pain after spinal surgery (failed back or laminectomy syndrome), and chronic low back pain.

Disease-specific applications of stimulation include the following: interstitial cystitis and pelvic pain, occipital neuritis and occipital headache, atypical facial pain, and peripheral nerve stimulation for type II CRPS.

### Patient selection and outcomes of spinal cord stimulation

The selection of patients for treatment with SCS is the fundamental key to successful outcomes. The selection process cannot be separated from the outcomes that have been documented for the various applications of the therapy. The decision to proceed with a trial of SCS should be based on the reasonable expectation of successful relief of at least 50% of the patient's chronic pain and associated with a demonstration of improved function. The specific outcome measures for each clinic may vary but should generally be in step with reported outcome measures. A number of these measures are discussed below.

Special selection criteria apply to specific pain syndromes, such as angina, peripheral vascular disease, CRPS, interstitial cystitis, and peripheral neuropathic pain. These criteria are generally the diagnostic criteria to establish the presence of the disease or syndrome and a failure to improve with more conservative or standard treatment measures [10,12,13,15,16].

General inclusion and exclusion criteria have been developed and may be found in Table 1. For most neurological surgeons, the primary indication for SCS is a persisting radicular pain syndrome after primarily lumbar but also cervical spine surgery. When optimum medical management has failed to restore function adequately and relieve pain, it may be necessary to consider SCS to move the patient toward improved quality of life and functional ability.

A neurosurgeon who wishes to become involved in the application of SCS in his or her clinic must be well versed in the selection criteria and the technical aspects of implantation. An extensive list of criteria to be met by the physician implanter is found in Box 1.

Outcomes have become an important part of justifying the application of newer and more expensive technologies. SCS is no exception. The specific outcome measures that are applied are as varied as the groups reporting results. Frequently,

Table 1  
General inclusion and exclusion criteria for spinal cord stimulation intervention

General inclusion criteria	General exclusion criteria
Appendicular pain after at least one previous spine surgery	Surgical procedure within the 6 months before screening trial
Pain of at least 6 months in duration	Evidence of an active disruptive psychiatric disorder, including dissociative disorder, major affective disorder with psychotic features, active drug or alcohol abuse, personality disorders significant enough to influence the perception of pain, compliance to intervention, and/or ability to evaluate treatment outcome as determined by a qualified psychological or psychiatric consult
No chronic or recurring pain complaint above the level of the T <sub>10</sub> dermatome	Patients younger than 18 years of age
Leg pain that radiates below the knee greater than back pain	Patients who have not received an adequate course of optimum nonsurgical care
Informed consent	Patients who have failed a previous spinal cord stimulation trial or system
Clearance after psychologic evaluation by a clinical psychologist, the evaluation should include at least one objective normalized psychological test believed to be helpful in making this determination (eg, Minnesota Multiphasic Personality Inventory II, evaluation of motivation for return to work)	

## **Box 1. Physician implanter criteria for experience and training**

### **I. Scientific Basis**

- A. Understand scientific theories behind neurostimulation
- B. Understand the role of neurostimulation in the hierarchy of pain treatment; this includes understanding alternative methods of pain control and the place of neurostimulation in the management of specific conditions;
- C. Be familiar with the literature on neurostimulation.

### **II. Patient Selection**

- A. Understand the broad principles and importance of proper patient selection for interventional pain procedures; develop an in-depth understanding of specific patient selection criteria for neurostimulation including pathophysiologic diagnosis, psychological factors, and other factors important in chronic pain;
- B. Know the specific pain classifications, pain patterns and diagnoses which tend to respond to different interventional pain modalities; understand the relative indications for neurostimulation;
- C. Ensure that psychological evaluation is performed to rule out psychological factors which might impede a desirable outcome if not addressed;
- D. Be aware of medical, pharmacological, and technical contraindications for the use of neurostimulation;
- E. Be aware of other failed therapeutic modalities, which have led to the decision to implant a neurostimulation device.

### **III. Patient Management**

- A. Prior to becoming active in neurostimulation, the physician must be aware of patient management issues, be prepared to accept the responsibility of ensuring proper patient followup and support services, and have personnel and facilities to provide such services;
- B. Be able to provide thorough pre and post operative patient education, ensuring that the patient and family understand the device, its applications and possible complications, as well as its impact on their daily lives;
- C. Be able to recognize and treat immediate and delayed complications and/or designate consultants who will be available to assist in treating any complication;
- D. Understand the importance of the informed consent; which must include the operative procedure, alternatives, and risks and benefits to enable the patient to make an informed choice to proceed with implant.

### **IV. Implant Technique**

- A. Understand the generally accepted surgical protocols most successfully used in implant procedures including trial screening and permanent implant;
- B. Be familiar with appropriate fluoroscopic techniques and safety precautions as well as applicable licensing requirements;
- C. Be able to recognize and treat possible complications or problems;
- D. Know how to evaluate system efficacy and patient response to implanted systems;
- E. Know how to program stimulation for optimal effect.

### **V. Practice Considerations**

- A. Establish the necessary consultative relationships to provide multidisciplinary care pre and post implant;
- B. Be aware of appropriate protocols for prior authorization for neurostimulation and understand the economic impact of these procedures to the payor, community, the practice, and the patient;
- C. Know the importance of providing after-care support services and the importance of the trained implant coordinator;
- D. Understand the limitations and applications of neurostimulation systems; be able to troubleshoot system problems and otherwise manage patient and device interaction to achieve optimal patient benefit.

success is determined by patient self-reports of pain reduction. Other criteria, such as decreased use of health care resources, improved function, return to work, or closure of industrial insurance claims, are reported as outcomes. Patient satisfaction is important, especially so to the treating physician, but it may not be a major concern for a third-party insurance carrier.

Beginning in the early 1970s, numerous reports, predominantly case review studies, appeared in the literature. Significant changes in equipment were made throughout the 1970s, especially as the introduction of multichannel devices and complication rates occurring as a result of mechanical failure of the equipment changed for the better [17]. There have appeared numerous reviews of these reports [6,7,18]. To summarize what has become an extensive literature, the analysis of Turner et al [18] is helpful in analyzing published outcomes. Attempting to apply an evidence-based literature review technique, they discovered that the predominantly case review nature of the literature did not lend itself to this type of scrutiny. It was believed that certain conclusions could be drawn, however, although further more rigorous randomized outcome approaches should be undertaken to verify these conclusions. A total of 39 studies met the review criteria. At the average follow-up of 16 months, 59% of the patients had 50% or greater pain relief. Complications occurred in 42% of patients but were considered to be minor. The lack of randomized trials prevented any conclusion as to the effectiveness of SCS relative to other forms of treatment, placebo, or no treatment.

With developing pressure to produce randomized and prospective studies, preliminary results of a randomized study comparing SCS with repeat surgery for persisting leg pain after an initial spinal surgery were published after the Turner et al [18] article was compiled in 1995 by North et al [19]. Using the crossover from one treatment modality to the other after 6 months as the primary outcome measure, results for 27 patients showed a statistically significant advantage for SCS over repeat operation.

In a prospective multicenter study comprising 70 patients with at least 1 year of follow-up, a variety of outcome measures, including the average pain visual analogue scale (VAS), the McGill Pain Questionnaire, the Oswestry Disability Questionnaire, the Sickness Impact Profile, and the Beck Depression Inventory, were analyzed [20]. Success of stimulation was considered achieved if

50% pain relief and patient satisfaction were reported. SCS was successful in managing the pain in 55% of the patients in whom 1 year of follow-up was available. Statistically significant improvement was reported in all the outcome measures, confirming that SCS can be an effective treatment modality for the management of chronic lower extremity pain.

Ohmeiss et al [21] reported a prospective study evaluating SCS in patients with intractable leg pain. An isometric lift task measured lower extremity function in an attempt to identify a measurable outcome parameter. This function was statistically significantly improved 6 weeks after the initiation of SCS. Other outcome measures, such as the Sickness Impact Profile, also significantly improved, confirming the results of other studies. In a recent corollary to their earlier study, Ohmeiss and Rashbaum [22] have reported a retrospective study of patient satisfaction for predominant complaints of low back pain after using SCS for up to 19 months. Sixty percent of their patients considered themselves improved from their preoperative condition, and 75% would have the procedure performed again if they had known the outcome before the implant was performed. Barolat et al [23] have reported a retrospective analysis of 102 patients evaluated by extensive questionnaire and telephone interview techniques from a disinterested third party. The average follow-up was 3.8 years. Twenty-one percent never experienced any pain relief. Of the remaining 80 patients, 75% were still using their stimulator. In patients experiencing a reported 75% pain relief, there was no reduction in relief over time. Patients experiencing only 50% reduction in their pain relief showed a dramatic reduction in their relief over the follow-up period. These authors believed that psychologic screening contributed to a successful outcome.

Another method of analyzing the results of SCS is to evaluate results by specific syndrome. SCS has been applied in a number of pain syndromes. In the world literature, the most successful application of SCS is in the relief of intractable angina pectoris [24–29]. These patients have been selected as having refractory angina pectoris and not being candidates for revascularization. Stimulation seems to improve cardiac function in these patients coincident with relieving pain. Success rates between 80% and 90% have been consistently reported. Electrodes are generally placed at the C<sub>8</sub> to T<sub>2</sub> level to the left of the midline, with average stimulation parameters. Most notably in the

European literature, peripheral vascular disease is the next most successful indication for SCS, with relief of ischemic pain in the extremity reaching 70% to 80%, and limb salvage rates for extremities deemed appropriate for amputation are in the range of 60% to 70% [10]. In 2000, Spincemille et al [30] from the Netherlands reported an assessment of pain and quality of life in patients with critical limb ischemia during the follow-up of a multicenter randomized controlled trial of SCS. Primary outcome measures were limb salvage, pain relief, and quality of life. Limb survival at 2 years of follow-up was 52% for SCS and 46% for standard treatment. Pain relief showed no difference between the examined treatment strategies and was substantial in both. Patients in the SCS group used significantly fewer opioids. In contrast to much of the existing literature, this randomized trial revealed no major difference in overall pain and quality of life between treatment groups [30]. Type I and II CRPS is successfully treated at an 80% to 90% rate, especially if the pain is sympathetically maintained. It is interesting that neuropathic pain in the extremity, such as that found in the patient with persisting radicular pain after spinal surgery, responds at a 60% to 70% rate. Although representing the most common indication for SCS in the United States, it is the least successful in the long term. This may largely be a result of the psychosocial problems associated with any pain management for the failed back surgery syndrome.

The most frequent use of SCS in the United States comes as a result of the prevalence of lumbar spinal surgery. There has grown a definable population of patients, estimated at 20% to 40% of those operated on, who experience persistent or recurrent pain after intervention. SCS is indicated in patients who have failed to improve with optimum medical management. Optimum medical management of this problem includes such interventions as active physical rehabilitation. Generally, a physical therapy-directed program prescribed by a physical medicine and rehabilitation physician and performed by a licensed physical therapist, which may consist of strengthening and flexibility exercises, aerobic conditioning, and patient education to address lifting, posture, and strengthening, for example, neuromuscular and modality therapy may be included in this program but is not considered to constitute adequate therapy alone. Behavioral and psychologic rehabilitation may also be a part of optimum management and consists of the application of

pain control and stress management procedures, including but not limited to relaxation therapy, guided imagery, cognitive restructuring, biofeedback, behavioral modification, and group or individual education. Pharmacologic management is probably the mainstay of optimum medical management and consists of the prescription of medication as required to control pain. This therapy may include narcotics, nonsteroidal anti-inflammatory drugs, antidepressants, muscle relaxants, or anticonvulsants as required by the patient's condition and deemed appropriate by the attending physician. In addition to standard pain management treatments, patients may seek, within various insurance systems, relief from acupuncturists, chiropractors, and homeopaths.

It is generally after these treatments have failed that the neurosurgeon is asked to intervene with interventional pain treatments like SCS. The surgeon should be an integral part of a total pain management team, providing the necessary resources, experience, and follow-up to ensure excellent patient management.

### **Technique**

Certain requirements are necessary for SCS to be effective in relieving pain. The stimulation-produced paresthesias must cover as large a percentage of the area of pain as possible, and this effect must be maintained over time to obtain the best possible relief [6]. With SCS, the active electrode, cathode, or negative electrode must be located near the level of the spinal cord dorsal columns that anatomically represent the level to be stimulated. If the pain is bilateral, a single electrode must be located on the physiologic midline of the spinal cord, or multiple electrode arrays may be used to allow the ability to access bilateral structures. If unilateral pain is present, the electrode is positioned to the side of the patient's pain [31]. With axial as well as appendicular pain, multiple electrode arrays are useful to cover the axial portion of the pain with paresthesias as well as the painful extremity. The application of stimulation to produce the desired paresthesia pattern is nicely reviewed by Alo and Holsheimer [32]. Unfortunately, even the most elegant production of a paresthesia pattern does not guarantee relief of pain. The paresthesia may be nothing more than an epiphenomenon that is necessary for targeting the stimulation but is not alone sufficient for relief.

### Screening trial

Although there is no literature-proven method of screening for the efficacy of SCS, it is generally believed that a trial of 1 week or longer of externalized lead wires using a temporary external transmitter can be effective in excluding from permanent implantation up to 30% of patients screened. These patients are generally excluded because of lack of pain relief with the stimulation or because of uncomfortable stimulation effects. The criteria that must apply during a screening trial of 1 week or more for the patient to be eligible to go on to permanent receiver implantation may be summarized as follows:

1. There is a minimum of 50% (optimum is at least 70%) pain reduction based on difference in VAS scores before implantation and after lead implantation (anchors for the VAS are no pain and worst possible pain).
2. The area of paresthesia must be concordant with the area of pain.
3. The patient does not find the paresthesia to be undesirable.
4. Functional improvement is assessed by functional outcome evaluation as determined by each clinic, although some form of evaluation of physical capacities is desirable.

### Equipment

The ability of SCS to modulate the nervous system is based on the delivery of electric impulses to the spinal cord. This can be achieved by placing the active part of the SCS lead, the electrode, on the spinal cord. This was historically the earliest approach using a laminectomy and durotomy. Within a short period, however, about 6 weeks to 6 months, the electrodes became ineffective because of fibrosis and, occasionally, spinal cord injury. Placing the lead wire in the epidural space solved this problem. In doing so, long-term stimulation was possible without complications caused by lead location. This also made the dorsal cerebrospinal fluid (CSF) space an important parameter in establishing stimulation amplitude and introduced stimulation variability with movement as a side effect.

SCS electrodes are contained within lead wires. These are manufactured in numerous configurations and are available for implantation either percutaneously or via laminotomy. The simplest form of lead contains two electrodes and allows

bipolar stimulation. Lead wires progress in the number of electrodes from 4 to 8 to 16 contacts (available in laminotomy paddle or plate leads only) (Fig. 1). Currently available leads are generally linear arrays of either one or two columns. A newer lead configuration deals with a transverse tripolar arrangement allowing programming across the spinal cord, but it must be used with a special transmitter for true tripolar stimulation versatility.

Two types of power sources for producing stimulation at the electrode sites are currently manufactured (Fig. 2). The total IPGs have a finite average battery lifetime of 2 to 5 years, depending on stimulation parameters, before they must be replaced by a surgical procedure (see Fig. 2B). An IPG is programmed transcutaneously. The patient may control on, off, amplitude, and rate parameters with a handheld controller. The newest version of the IPG allows independent control of two four-contact leads. Historically, a radiofrequency transmitter, which is worn externally, powered the first device available; currently, it still powers all devices except pulse generators and broadcasts a signal to a subcutaneously implanted receiver connected to the lead wire (see Fig. 2A). Radiofrequency devices are programmed externally at the transmitter. Some devices allow the storage of multiple “programs” of positive and negative electrode combinations, which the patient may select at will (patient-controlled stimulation) or which may be run in sequence independent of the patient (multiple stimulation mode) [33].

Electric stimulation of the nervous system may excite or inhibit neuronal action. With SCS, the

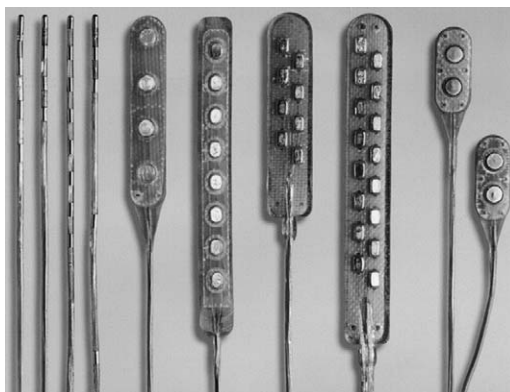


Fig. 1. An example of available spinal cord stimulation leads. (Courtesy of Advanced Neuromodulation Systems, Plano, TX.)

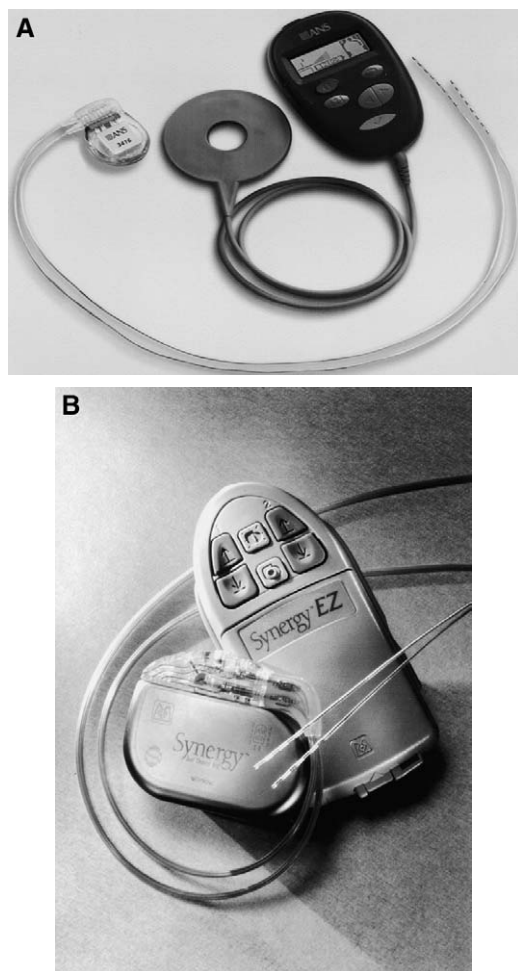


Fig. 2. Available sources of power for spinal cord stimulation. (A) Radiofrequency receiver and external generator with antenna. (B) Totally implantable pulse generators. (Courtesy of Medtronic, Minneapolis, MN and Advanced Neuromodulation Systems, Plano, TX.)

active electrode that excites the desired paresthesia response is the negative electrode or cathode. The cathode depolarizes neurons within its field, and the neuron becomes more active. The positive electrode or anode inhibits the neurons in its field by hyperpolarization. Hence, combinations of positive and negative electrodes are used to achieve the desired paresthesia coverage. This forms the basis for programming the stimulation device. There are numerous ways to approach programming and to optimize paresthesia coverage of the painful area [34]. The success of SCS at relieving pain correlates with the percentage of the painful area covered by stimulation-induced

paresthesias, making these techniques important for any implant.

### Lead implant techniques

Once a patient has been selected as a candidate for a trial of SCS, the implanting physician should be certain that the patient and the patient's support system (spouse, family member, close relative, or caregiver) have been thoroughly educated concerning the intended procedure, its potential risks, and expected outcomes. It should not be beyond the ability of the patient to understand the use of the intended system.

### General technical concerns

Handling of lead wires requires special care so as not to break the lead insulation. The lead wires should not be kinked, bent, or handled with sharp instruments. Rubber-shod forceps or clamps or vascular type instruments, such as DeBakey style forceps, should be used. Sutures should not be placed directly around the lead wires, silastic, or hard plastic anchors, and 2-0 braided suture or larger should be used to avoid cutting the insulation. Care should be taken to plan the length of lead necessary should the system be implanted. For example, a cervical lead wire with a proposed abdominal or buttock position of the receiver or transmitter requires a longer lead wire or extension wire than normal to avoid the lead being dislodged with flexion and extension movement. If an obstruction is encountered when moving the lead in the epidural space, do not force the lead. A guidewire technique may be tried, but it may be necessary to terminate the procedure and carefully evaluate the status of the spinal canal with regard to previously undetected stenosis or lesions.

### Percutaneous leads

A general rule is to select a target for the active electrode, the negative electrode, or cathode based on the distribution of the patient's pain. If the predominant rhizopathy is in the S<sub>1</sub> root, the cathode usually gives appropriate paresthesias at the T<sub>11</sub> or T<sub>12</sub> vertebral level. Always bear in mind that the anatomic midline of the spinal anatomy may not correlate with the physiologic midline for the purpose of producing paresthesias and that some movement of the electrode position mediolaterally may be necessary to find the physiologic midline.

For percutaneous lead implantation, the operating room contains an operating table enabling



fluoroscopic imaging. A C-arm image intensifier is used throughout the procedure to guide lead placement. If the implanter is right-handed, the room is configured to allow the C-arm and video screen to be located on the patient's right side when the patient is prone (Fig. 3). The scrub table is placed to the operator's right side. These procedures are generally performed with monitored anesthesia care under local anesthesia. The anesthesiologist is placed at the head of the table, allowing enough room for the nurse or technician performing the screening trial.

Each manufacturer provides the necessary accessories with each lead to allow either complete system implantation or placement of a tunneled electrode for screening purposes. These accessories include a modified Tuohy needle, a guidewire or lead blank, tunneling instrumentation, anchors, insulation boots, and hexagonal wrenches. For trial screening, disposable percutaneous extension wires are provided as well as the necessary external screening cable to allow testing.

The patient is placed prone on the operating table, prepared, and draped from table to table. A chest-breast drape has a large fenestration that works particularly well for lead implantation. The vertebral interspace where the Tuohy needle will be placed in the epidural space is localized fluoroscopically. A 1- to 2-inch incision is made caudal from this point. Some clinics prefer to perform the needle placement first and confirm access to the epidural space and lead placement before making the incision. The percutaneous lead implant technique is illustrated in Fig. 4. The Tuohy needle is inserted from a paraspinous approach at an angle of 45° and directed toward the midline at the

target level. This configuration allows insertion of the electrode more parallel to the epidural space. A loss of resistance technique or "hanging drop" technique may be used to localize the epidural space. A positive-contrast epidurogram may be performed if there is any question as to localization but generally is not needed.

The electrode is then introduced through the Tuohy needle into the epidural space. The electrode is "steered" to the desired starting location using fluoroscopic guidance. The electrode is then connected to the screening cable. One end of the cable is passed over the ether screen to the implant assistant, who connects it to the screening stimulator. Stimulation is then trialed. If a long eight-contact electrode is used, one method of intraoperative screening starts by stimulating the distal two electrodes, the proximal two electrodes, and the two in the middle as anode-cathode bipoles. This establishes the upper, middle, and lower extent of the paresthesias. Adjustments of electrode positions to locate the "sweet spot" may then be made. Starting with the distal electrode negative and the proximal electrode positive and then reversing this sequence to determine the highest and lowest level of stimulation may screen four-contact electrodes. The mediolateral orientation determines the mediolateral position of the paresthesias in the extremity. Too far lateral results in intercostal root stimulation and uncomfortable paresthesias. Perfectly midline stimulation may result in bilateral paresthesias and some interesting effects in the low back or reaching the legs if stimulating the cervical spinal cord. Occasionally, a process called "trolling" may ascertain the ideal location for the electrode. The electrode is placed higher than the expected stimulation level. The stimulator is adjusted to the perception threshold for paresthesias and slowly pulled caudally, with the patient reporting the pattern of paresthesia perception as the electrode is moved. The desired position is reached when the paresthesias "paint over" the painful areas.

When the desired electrode location has been determined, the needle is removed and the lead is anchored to the fascia by using the anchors provided with the lead (see Fig. 4). If using a silastic anchor, one method of anchoring is to place a loop through the fascia and tie the suture. The stitch is then looped around the anchor and tied again. A single loop around the anchor and fascia may loosen. Anchoring should be done only to tissue not likely to necrose or absorb. Examples of tissue not to use would be muscle or fat. The lead is then

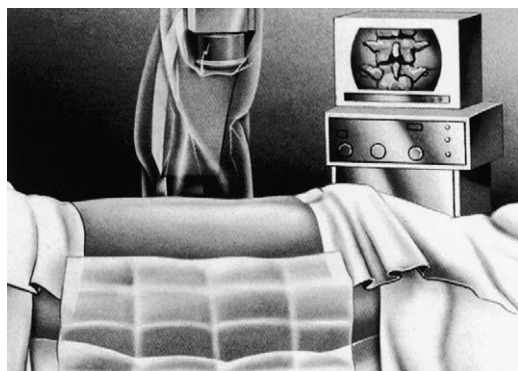


Fig. 3. Operating room configuration for implantation using fluoroscopic control. (Courtesy of Medtronic, Minneapolis, Minnesota.)

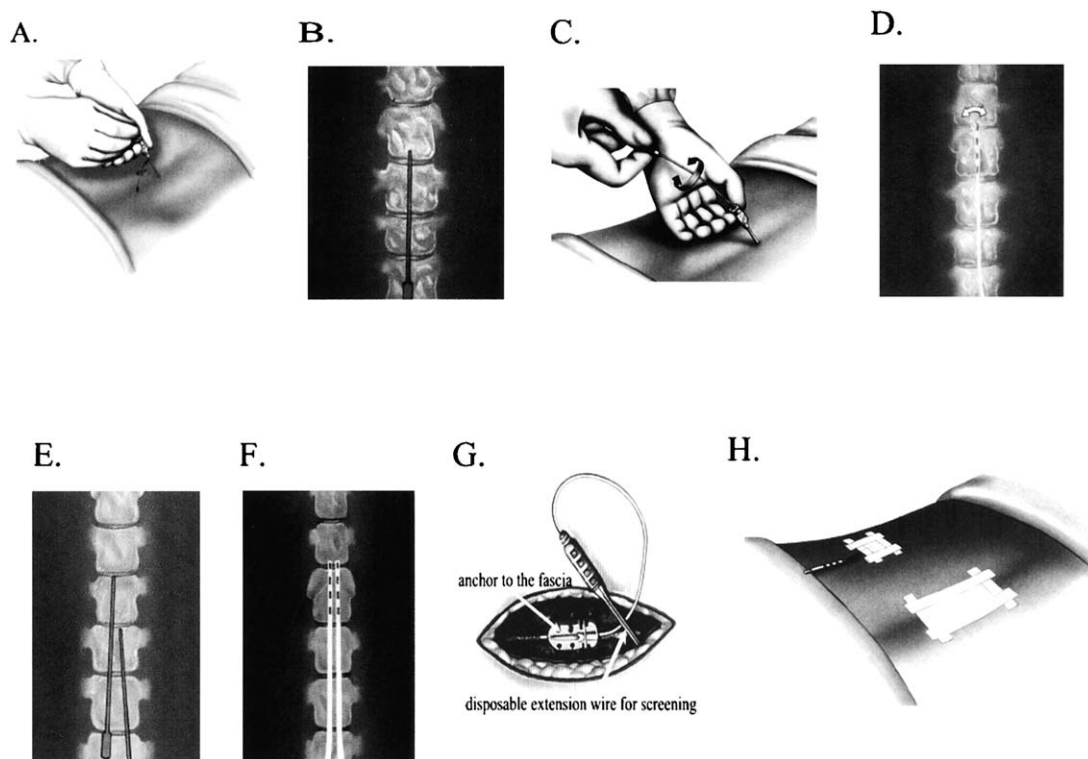


Fig. 4. Percutaneous lead implantation technique. (A) Needle placement at an angle of 45°. (B) Fluoroscopic guidance of needle placement. (C) "Steering" the needle by rotation of the tip. (D) Steering as viewed under fluoroscopy. (E) Dual needle placement for two percutaneous electrodes. (F) Fluoroscopic image of dual leads. (G) Anchoring the electrode to the lumbar fascia and the attached disposable extension wire for screening. (H) The final appearance before initiating screening. (Courtesy of Medtronic, Minneapolis, MN.)

attached to a disposable percutaneous extension and sealed with a silastic boot. A subcutaneous tunnel is fashioned to the flank using tunneling devices provided with the lead, and the disposable lead is then brought through the tunnel and externalized. The back incision is then closed. The externalization stab wound is dressed by placing an antiseptic patch (eg, a BioPatch, antimicrobial dressing, Johnson and Johnson Wound Management, Cornelia, GA) or antibiotic ointment around the lead and a suitable overlying dressing. The patient is now ready to undergo a screening trial.

With the conclusion of a successful screening trial, the patient is returned to the operating room to implant the pulse generator or radiofrequency receiver. The intended implant site determines the patient's position. Common sites are abdominal or upper outer buttocks for the pulse generator and the supracostal or upper outer quadrant of the buttocks for the radiofrequency receiver to allow a more solid position for placing the external

antenna. For abdominal or costal positions, the patient is positioned in the lateral decubitus position. For buttocks placement, the patient is prone. The prior implant site is prepared, extending the preparation to the proposed pocket site for the receiver or generator. After draping, the lead implant incision is opened and the disposable extension is cut and pulled out from under the drape by the circulator. The back incision and electrode are then packed with an antibiotic solution-soaked sponge. Attention is turned to the pocket site. An 8- to 10-cm incision is made. Subcutaneous dissection is then used to fashion the pocket, paying attention to hemostasis, usually with monopolar cautery. The lead wire or extension wire is then tunneled subcutaneously, connecting to the pocket. The lead or extension is connected to the receiver or pulse generator, which is placed into the pocket, being careful to coil any excess wire behind the unit. The wounds are closed with an interrupted inverted absorbable stitch and dressed.

Before discharge from the clinic, the patient and a significant other are instructed in the use of the device, and if an implantable pulse generator has been used, the device is programmed. The importance of this follow-up after the procedure cannot be overemphasized. Some clinics delay programming or activating the unit until the first postoperative visit, when the patient may be more alert, immediate postoperative effects have decreased, and the surgical incision has healed. This initial session of education and initiation of stimulation should not be missed to begin a successful treatment plan using stimulation.

### *Laminotomy electrode implant*

The general approach to the patient is similar to that used with the percutaneous lead implant. One significant difference is the level of implantation. The level of lead placement may have been determined by a percutaneous screening trial, and the implanting neurosurgeon is asked to reproduce the paresthesias of the screening trial with a potentially more stable laminotomy lead. A percutaneous lead may have migrated twice, necessitating the placement of a more stable electrode. Another candidate for the laminotomy implant is a patient whose predicted target is in the area of a prior surgery that has obliterated the epidural space.

The operating room is set up identically to that for a percutaneously implanted lead. C-arm fluoroscopy is used to guide lead orientation (see Fig. 3). The patient is placed prone on the radiolucent operating table. It is often helpful to position a pillow or bolster under the patient's abdomen and to have the patient lay prone rather than on the arms or elbows. The patient is then prepared over the intended implant site, most commonly, T<sub>10</sub> or T<sub>11</sub> for the lower extremities, and if the lead is to be used as a screening lead, the preparation is extended laterally to the table.

A midline incision is extended caudally from the implant level for 5 to 10 cm after anesthetizing with a long-acting local anesthetic, such as bupivacaine. The muscle fascia and paraspinal muscles are blocked with the local anesthetic. When the block is established, a subperiosteal dissection is performed using the electrocautery and a Cobb elevator or similar tool. The laminotomy lead implant is illustrated in Fig. 5. After placing a self-retaining retractor in the wound, the inferior portion of the superior spinous process is resected, exposing the ligamentum flavum. A

window is made in the ligamentum flavum and enlarged using a 2-mm or 3-mm angled Kerrison rongeur. The dura is exposed, and the opening is widened by removing bone as necessary to allow placement of the lead. The lead is then introduced into the epidural space under fluoroscopic guidance to control for side-to-side orientation. The electrode may be sutured to the dura with a 4-0 braided stitch if there is excessive movement. The electrode is then screened during surgery for appropriate paresthesia coverage as with the percutaneous lead. The position is adjusted as necessary. The ability to move the lead in a cephalic direction is limited, however, emphasizing the need for choosing the appropriate entry point or for using a large array electrode to allow electronic selection of the sweet spot. With appropriate positioning, the wound is closed with an absorbable stitch through the muscle and a second layer opposing the muscle fascia. The lead or leads are then anchored to the fascia as described for percutaneous leads. The leads may then be tunneled for a screening trial or connected to a pulse generator or radiofrequency receiver. The position of the generator or receiver pocket and its creation may be chosen as with the percutaneous leads. Before proceeding to a laminotomy style implant, a study such as MRI or myelography/CT should be performed to assess the diameter of the central canal and whether there exists a risk of spinal cord or cauda equina injury by placing a lead into the canal.

### **Complications**

Complications are events whose incidence may be known but whose occurrence is unanticipated. These events imply an adverse outcome but do not suggest, in and of themselves, negligence. Complications occur, but every effort should be taken to eliminate preventable errors.

Complications during the placement and management of spinal cord stimulators fall in three categories: surgical complications, device-related complications, and stimulation-related complications.

Overall, complications occurred about 42% (20%–75%) of the time in 13 case studies reviewed by Turner et al [18]. Most of these complications were considered to be minor and were dealt with easily.

### *Surgical complications*

The primary surgical-related complication has been perioperative infection. This occurred in the

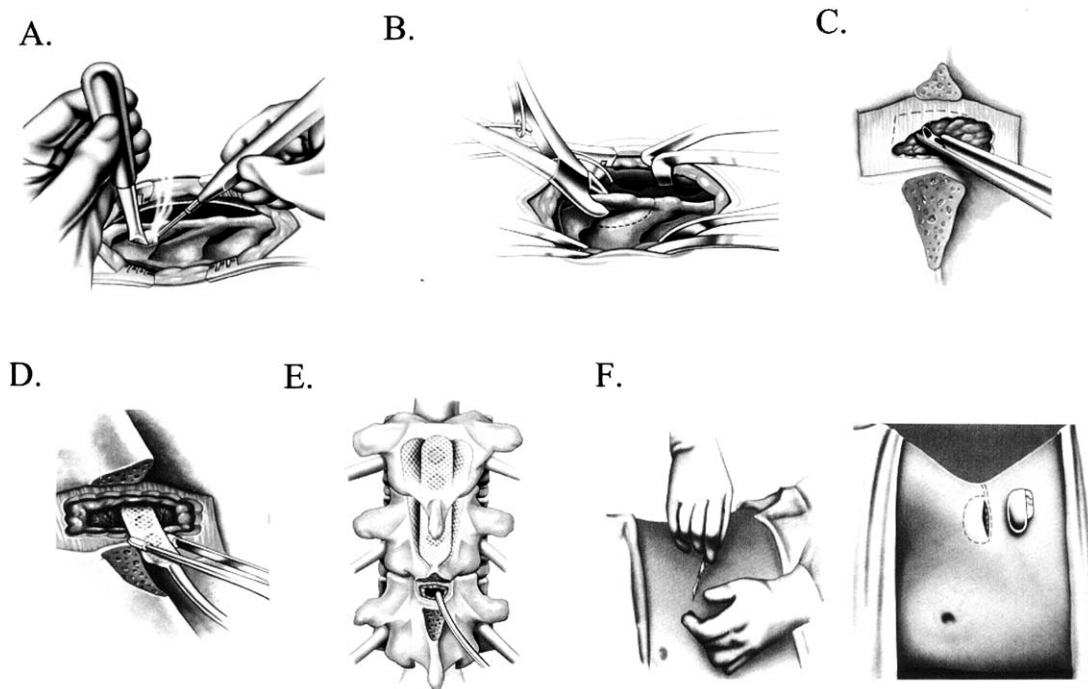


Fig. 5. Laminotomy lead implantation technique. (A) Subperiosteal dissection. (B) Removal of inferior portion of the superior spinous process. (C) Opening of the ligamentum flavum. (D) Insertion of the lead under direct vision into the epidural space. (E) Orientation of the lead under fluoroscopic guidance. (F) Incision in the abdominal skin to create the pulse generator or radiofrequency receiver pocket. (Courtesy of Medtronic, Minneapolis, MN.)

review by Turner et al [18], who surveyed 31 studies in which complications were reported 5% of the time (range: 0%–12%). Many clinics use antibiotic prophylaxis to avoid this complication. One method is to administer a cephalosporin intravenously 1 hour before the procedure. Continuation of antibiotic coverage during the externalized screening trial is variable, and there are no specific data to suggest a “best” management technique. Biologic complications other than infection occur about 9% (range: 0%–42%) of the time. These complications include spinal fluid leakage, hemorrhage, and neurologic injury. In the large prospective study of Burchiel et al [20], there were no infections either at lead implantation or internalization. In 219 cases in this study, there was 1 case each of CSF and reported muscle spasm. In their review of two decades of SCS experience, North et al [35] reported no major morbidity, defined as spinal cord injury, meningitis, or life-threatening infection. The overall incidence of infection in this study was 5%.

#### *Device-related complications*

In the analysis by Turner et al [18], stimulator complications occurred 30% of the time in 13 studies in which this could be determined. The electrodes were a problem 24% of the time. Most commonly, this represented migration of the electrode(s) or movement, especially side to side, with a subsequent loss of paresthesia coverage. The generator or receiver was a problem 2% of the time. In the Burchiel et al study [20], 12 of 219 patients required surgical procedures for revision or replacement of at least one component of the system (5%). In their survey of 20 years of experience at the Johns Hopkins Hospital, North et al [35] defined electrode failure as a loss of stimulation paresthesias overlapping a patient’s usual distribution of pain. A Kaplan-Meier survival curve was then generated demonstrating that multichannel devices were significantly more reliable than single-channel laminectomy or percutaneous leads. A similar analysis for discontinuation of use for all reasons again

demonstrated the superiority of newer multichannel devices.

#### *Stimulation-induced complications*

Rarely, patients report that the stimulation paresthesias are uncomfortable or increase the underlying pain. The exact incidence is difficult to ascertain from the literature. In the Burchiel et al study [20], the incidence of these patient-related complications was 3% (5 of 219 patients). One source of discomfort or lack of satisfaction with stimulation is posture-induced changes in paresthesia intensity. Cameron and Alo [36] investigated stimulation thresholds as a function of posture and found that in 20 patients, the threshold for paresthesia was lowest when they were lying down, although in 3 patients, the thresholds were lowest when they were sitting for thoracic electrodes.

Efficacy reports for SCS in the management of chronic pain syndromes have consistently demonstrated that 50% to 60% of patients initially receiving less than 50% relief of pain are still using their stimulators at greater than 1 year. It has been suggested that even after the 1-year period, there remains a portion of the successfully treated population who return reporting a failure of stimulation to control their pain. In a review of 126 patients (74 female) followed for longer than 2 years in the author's clinic (range: 24–168 months, average = 37.8 months) reporting initially greater than 50% pain relief, 26 (20%) were documented to have discontinued the use of stimulation or requested removal of the system. A retrospective analysis was conducted to determine the reasons why such patients with long-term relief ultimately fail therapy. Diagnoses at system implantation included myelographically proven arachnoiditis (61 patients [48%]), radicular extremity pain (30 patients [24%]), both types of CRPS (8 patients [6%]), spinal stenosis (7 patients [5%]), peripheral neuropathy (6 patients [5%]), peripheral vascular disease (5 patients [4%]), and other neuropathic pain (9 patients [7%]). All patients were implanted with four-contact percutaneous or paddle electrodes (Medtronic quadripolar or Resume style electrodes, Medtronic, Minneapolis, MN). Three reasons for failure were determined:

1. Progression of disease was determined in 12 patients (55% of failures): 7 patients were discovered to have new spine disease (32% of failures), and 5 patients presented with increased symptoms of peripheral neuropathy (23% of failures).
2. Tolerance, defined as continued appropriate paresthesias with loss of relief; this was found in 9 patients (41% of failures): 5 with arachnoiditis and 4 others, including 2 with postherpetic neuralgia (PHN).
3. Painful hardware at the pulse generator implant site was seen in 1 patient (4% of failures).

Four patients, or 3% of the total, enjoyed enough resolution of their pain that they no longer required stimulation (at 57, 58, 60, and 142 months of stimulation): two with arachnoiditis and two with radicular leg pain.

#### **Applications of stimulator equipment outside the spinal cord**

Electric stimulation of the peripheral nervous system has long been used to treat specific peripheral nerve injuries [37–39]. A recent variation on this approach at the level of the nerve root was described by Alo et al [40]. The most common application of this “retrograde” technique is in the treatment of interstitial cystitis as reported by Feler et al [12]. The technique involves percutaneously or openly placing electrodes transforaminally or inferiorly in the lateral recess of the spinal canal to allow direct stimulation of individual nerve roots (Fig. 6). In an extremity that is significantly denervated, the thresholds for paresthesia perception may be quite high, and spinal cord stimulation is limited in its ability to produce the desired pattern of paresthesias without invoking uncomfortable stimulation effects in the surrounding normal tissue. This technique allows the focal production of stimulation effects in an affected nerve root distribution without undesirable side effects. For specific syndromes mediated through known root innervation, such as interstitial cystitis mediated through the S<sub>2–4</sub> roots, successful relief may be obtained without extraneous stimulation effects. Long-term outcomes of this technique are yet to be published, but in the lumbar region, these techniques offer an alternative approach to stimulation-induced pain relief.

Weiner and Reed [41] have also described the use of stimulation systems in the treatment of occipital neuralgia and occipital head pain. The electrode is placed in the subcutaneous space inferior to a suboccipital trigger point, which produces the occipital headache, through a slightly bent needle. The headache, if present on the

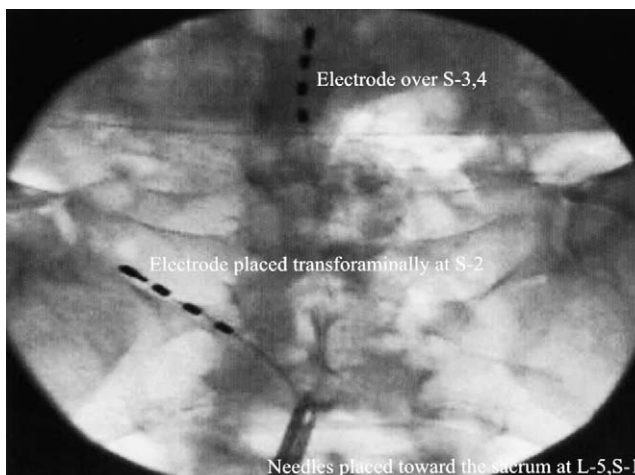


Fig. 6. An example of “retrograde” placement of spinal cord stimulation leads over the sacrum for interstitial cystitis.

operating table, is often relieved with the onset of stimulation.

#### Specific neuropathic pain syndromes and spinal cord stimulation

SCS has been applied in a number of specific neuropathic pain syndromes. The major specific applications include coccydynia, sacral and pelvic pain, occipital neuralgia, and type I and II CRPS. There are other infrequent reports of application in painful diabetic neuropathy, peripheral neuropathy of other origin, and PHN.

PHN represents an application of SCS that has had a mixed history. In 1989, however, Meglio and co-workers [42] demonstrated that in 10 patients with chronic PHN, 6 experienced 52.5% mean analgesia and underwent successful long-term implantation. A study using more contemporary stimulation techniques was reported by Harke et al [43], in which 28 patients with long-term (more than 2 years) PHN were prospectively evaluated; long-term pain relief was achieved in 82% (23 patients). Eight patients became completely pain-free during the follow-up period. Four patients with acute PHN had improved pain relief immediately with SCS, but it is difficult to know if this was better than the natural history of the disease.

Diabetic peripheral neuropathy has always represented an enticing diagnostic entity for using SCS to relieve symptoms. Results of intervention have generally been disappointing. The literature contains predominantly sporadic cases reported as a part of more general case review studies of SCS [44]. The results of individual cases have been no

better than an estimated 40% to 50% relief of pain. One promising study published by Tesfaye et al [45] from the Walton Diabetes Centre, Liverpool, United Kingdom, describes 10 patients unresponsive to conventional treatment, 6 with type II diabetes with a mean duration of neuropathy of 5 years. A standard thoracic epidural SCS target covering the pain distribution was used. A placebo external stimulator was used as well as the real external stimulator. Statistically significant relief of pain was seen in 8 patients. Both background and peak neuropathic pain was statistically significantly relieved at 3, 6, and 14 months compared with placebo. In addition, exercise tolerance was measured and improved in this group of patients. Further studies of this type are needed to validate SCS as a consideration in patients with pain caused by diabetic peripheral neuropathy.

In cases of general peripheral neuropathy of multiple origins, there exist even fewer reported cases. There has been an emerging interest in re-exploring the application of SCS in the treatment of painful peripheral neuropathy [46–48]. Although touted as a useful adjunct to the treatment of painful peripheral neuropathies, the actual data are lacking in support. This is not to say that it does not work but merely to suggest that further investigation is needed as in all areas of SCS.

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