Surgical Lead for the Thoracic Spine

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Introduction

Chronic pain impacts more than 100 million people. The direct costs of medical care and the indirect costs of lost productivity have been estimated at $560–635 billion, clearly making this a health crisis. Technology in the field of neuromodulation has been rapidly evolving leading to changes in operative technique for the placement of thoracic spinal cord stimulators.

Background

Historical Perspective

The first use of spinal cord stimulation (SCS) for the treatment of pain was in 1967 when Shealy and colleagues produced stimulation through a Vitallium electrode placed along the dorsal columns of a patient's spine, yielding resolution of his malignancy-induced chest and abdominal pain. The theoretical basis of the results seen in 1967 is rooted in the gate control mechanism of Melzack and Wall which states that activity in large-diameter type Aβ fibers inhibits transmission of noxious information to the brain by small C and Ad fibers. Exogenous stimulation of the larger fibers is believed to inhibit transmission of painful sensation by the smaller fibers. Combining this principle with Barolat's somatotopic mapping, symptom relief can be achieved by generating paresthesias concordant with the distribution of pain. However, newer technology is also able to provide pain relief without generating paresthesias.

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Stimulation Options

Conventional SCS

Conventional SCS relies on the generation of paresthesias in somatotopic distributions overlapping a patient's pain. Leads are placed in the extradural space over the posterior columns and are connected to an implanted pulse generator which delivers tonic stimulation at a frequency between 40 and 100 Hz. Randomized, controlled studies have demonstrated significant improvement in neuropathic radicular pain and health-related quality of life (HRQOL) metrics when comparing conventional SCS with best medical therapy and even repeat lumbar spine surgery. Where early SCS systems delivered the same current across all the electrodes, recent advances have enabled current adjustment at the level of each contact within an electrode. Fractionalization of current across individual contacts allows the electric field to be directed toward a specific region based on patient feedback, thereby improving paresthesia coverage.

High-Frequency SCS

Modification of conventional SCS hardware and software permitted investigation of a new form of tonic stimulation: high-frequency stimulation at 10,000 Hz (HF10 ® Nevro, Redwood City, CA). High-frequency stimulation provides paresthesia-free pain relief and therefore does not rely on the generation of paresthesias in a distribution overlapping with a patient's pain which allows leads to be placed anatomically without direct patient feedback. Randomized, controlled data has demonstrated significant benefits in pain control when compared with conventional SCS.

Burst SCS

The most recent waveform to receive FDA approval is BurstDR stimulation (Abbott). With the discovery that sensory information may be transmitted by parallel systems where one employs a tonic pattern of neuron firing and the other employs a burst pattern, translational work in an animal model demonstrated that burst firing is a more potent

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activator of the cerebral cortex than tonic firing. Two early studies investigated the effect of exogenously applied burst stimulation in patients with chronic low back and leg pain utilizing 40 Hz bursts with five spikes at 500 Hz per burst: results demonstrated a significant improvement in pain control versus placebo. Burst stimulation was found to be superior to conventional SCS with patient preference for this waveform.

High-Density (HD) Simulation

As conventional SCS pulse generators improved through successive iterations, their programming now permits stimulation frequencies up to 1200 Hz, even though standard programming paradigms remained in the 40–60 Hz range. Recognizing the benefit of a higher rate of energy delivery in burst and high-frequency stimulation for the treatment of chronic pain, the question arose whether maximizing energy utilization from a conventional SCS generator would yield similar results. Standardized programming has led to utilization of PW90 and a rate of 1000 Hz. Data is limited but suggests there may be some clinical benefit.

Technique

SCS therapy begins with placement of trial stimulator leads. The goals of a stimulation trial include identification of patients who may derive a clinically significant benefit from spinal cord stimulation, minimizing patient risk by reducing permanent implantation in those who do not derive significant relief, and minimizing medical waste by reducing the number of unsuccessful permanent implants. While there is no consensus, it is reasonable to obtain an MRI prior to implantation of any spinal cord stimulator lead. The rate of spinal cord injury (SCI) following SCS placement is cited at 0.6–2.35%, and it has been suggested that preoperative MRI can reduce the incidence of SCS-associated SCI.

Paresthesias-Generating SCS

For trial stimulator implantation, patients are often positioned prone on chest roles and sedated with monitored anesthesia care (MAC); alternatively, it may also be performed with the patient awake using only local anesthesia. Most trials utilize percutaneous implantation of cylindrical electrodes into the epidural space. A Tuohy needle is inserted into the skin at the level of the L3 pedicle for entrance into the epidural space at the L1-L2 interspace or the L4 pedicle level on the skin for entrance at the L2-L3 interspace. Entry and target points are localized using a C-arm or a biplanar fluoroscopy suite. A loss of resistance syringe is used to demonstrate entry into the epidural space; once accomplished, an electrode is guided through the needle, navigated to the desired spinal level, and connected to an external pulse generator. When performed under MAC, anesthesia is decreased, and the electrode positioning is adjusted until the patient confirms generation of paresthesias in a distribution overlapping with their pain; this step is unnecessary for procedures conducted with only local anesthesia. If desired, a second Tuohy needle can be inserted for placement of an additional trial lead. Once lead positioning is completed, a final radiograph is taken to document the final location. Trial duration can be variable, usually lasting 7–14 days; however, longer trials are not necessarily associated with an increased likelihood of a positive result.

Typically, a patient is eligible for a permanent implant if they experienced at least a 50% reduction in pain during the trial period. Permanent implants can be a cylindrical lead, similar to those used for the trial, or a paddle lead. While the surgical procedure for paddle implantation can have a slightly higher morbidity since it requires a laminotomy, research has shown that paddle implants offer better clinical results and improved efficiency in terms of battery life when compared to cylindrical percutaneous leads. However, recent advancements in battery technology may have mitigated some of these differences.

Permanent paddle lead implantation can be done with MAC or general anesthesia. Historically, MAC was used so patients could participate in awake testing, but the practice has shifted toward general anesthesia as data have suggested improved outcomes compared with MAC when utilizing neuromonitoring for both cord protection and confirmation of lead placement. When using general anesthesia, patients are sedated with total intravenous anesthesia (TIVA), and neuromuscular blockade is limited to preintubation. Following induction of anesthesia, the patient is positioned prone on the operating room table; if the generator is to be implanted in the abdomen, the patient may need to be in the lateral decubitus position. The implant level is determined from the trial and localized on the patient using fluoroscopy; it is important to keep the spinous processes centered between the pedicles and the endplates aligned in order to accurately localize the appropriate level. Laminotomy should be performed as close to the desired level of stimulation as possible to facilitate lead placement; accordingly, the incision is planned one or two levels below the targeted level depending on the paddle length and amount of dead space (Fig. 69.1). Once localized, the patient is prepped and draped in standard fashion with antibiotics administered prior to making incision. Subperiosteal

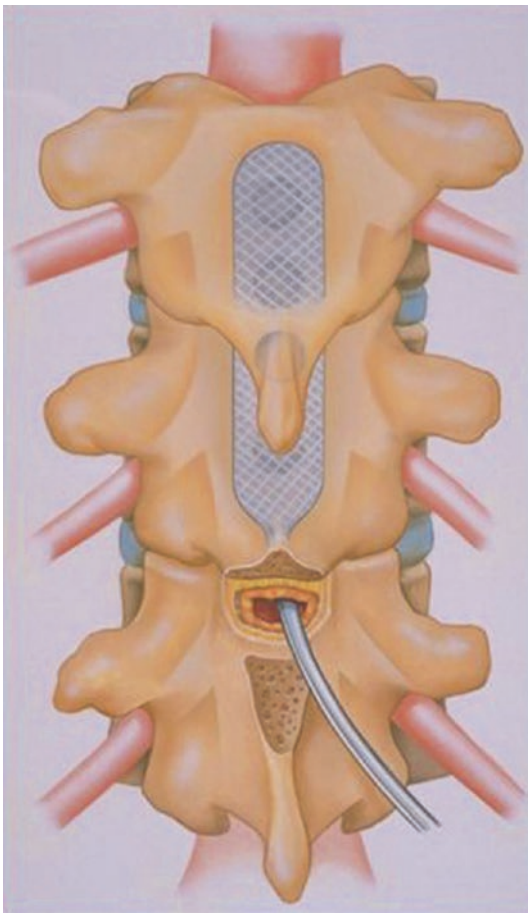

Fig. 69.1 Schematic of dorsal epidural spinal cord stimulator paddle with entry to epidural space planned below the level targeted for stimulation

dissection is performed down to the level of the lamina at which point fluoroscopy can be brought into the field to confirm the appropriate levels. Laminotomy is performed according to surgeon preference and may include the use of a high-speed drill and Leksell and/or Kerrison rongeurs; the ligamentum flavum is removed to expose the thecal sac. There have been reports of paddle placement via a unilateral laminotomy or tubular retractor and decreased length of hospital stay; however, the best procedure for placement is the one a surgeon can do most safely. The epidural space beneath the lamina can be probed with a Woodson tool or Penfield #3 to identify and break up any adhesions. The laminotomy should be wide enough to accommodate the paddle and large enough to allow the paddle to be advanced into the epidural space using a force vector directed parallel to the spinal cord. Dorsal adhesions, ligamentum infolding, or bony spurs may prevent smooth passage of the lead or cause the lead to not lay flat on the dural. If this occurs, additional bony removal may be required at the level of entry or higher levels; however, it is desirable to leave some lamina spanning the thecal sac at each level exposed to prevent the lead from floating away from the cord which could reduce its efficacy. It is generally recommended to place the base of the paddle just superior or at the lamina entry site which can aid in exposure if a revision procedure is ever necessary. This makes the level of entry very important in your preoperative planning.

Once safely in the epidural space, an x-ray is obtained to confirm placement of the lead in anatomic midline at the correct level (Fig. 69.2). At this point the lead can be connected to an external generator to guide any redirection to the physiologic midline and propagation of signal to targeted distributions. Since electrode positioning cannot be guided by patient feedback in the asleep patient, initial positioning is based on lead location from the trial, but intraoperative neuromonitoring (ION) is used to guide final lead placement. Monitoring modalities include somatosensory-evoked potentials (SSEPs), electromyography (EMG), and transcranial motor-evoked potentials. Retrospective and prospective data has shown that compound motor action potentials (CMAPs) generated from spinal cord stimulation can be used to effectively determine paddle position in relation to physiologic midline with paresthesia coverage overlapping painful dermatomes in greater than 90% of patients. ION can also be helpful in determining if a lead is lying flat on the dura by comparing the amplitudes at which a response is generated across

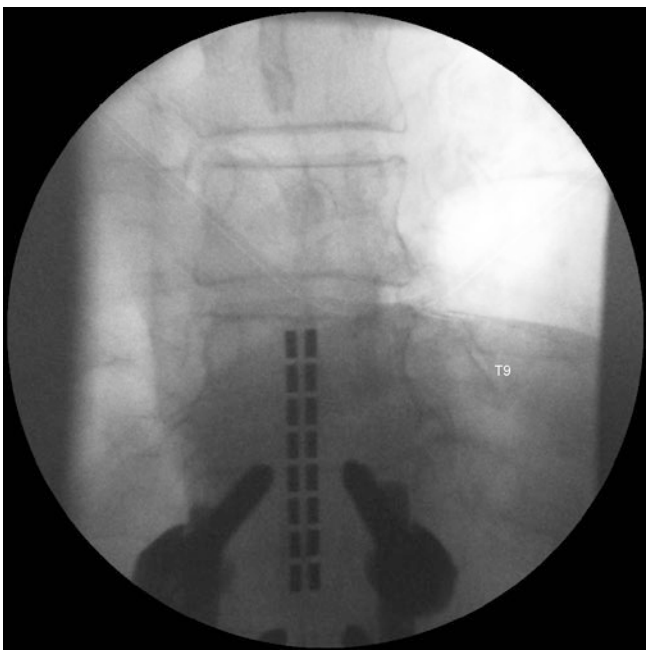

Fig. 69.2 Radiograph confirming midline placement of spinal cord stimulator paddle

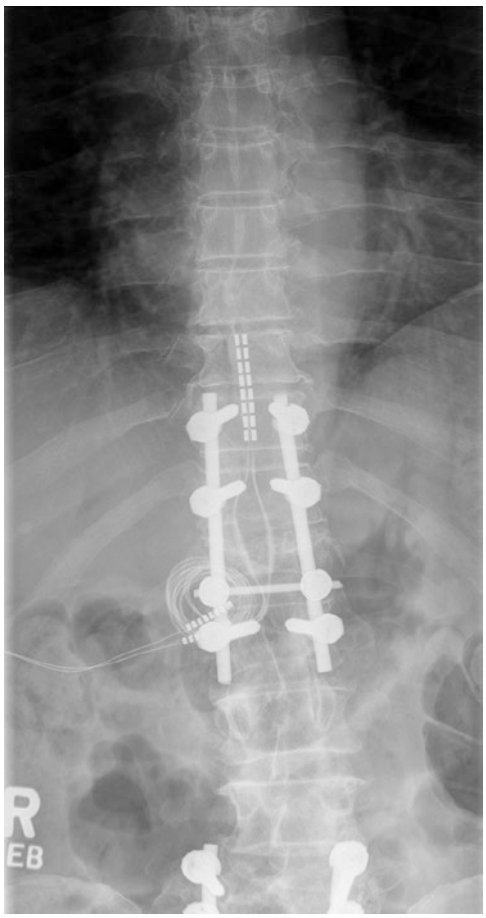

Fig. 69.3 AP radiograph showing paddle placement and strain relief loop with connectors

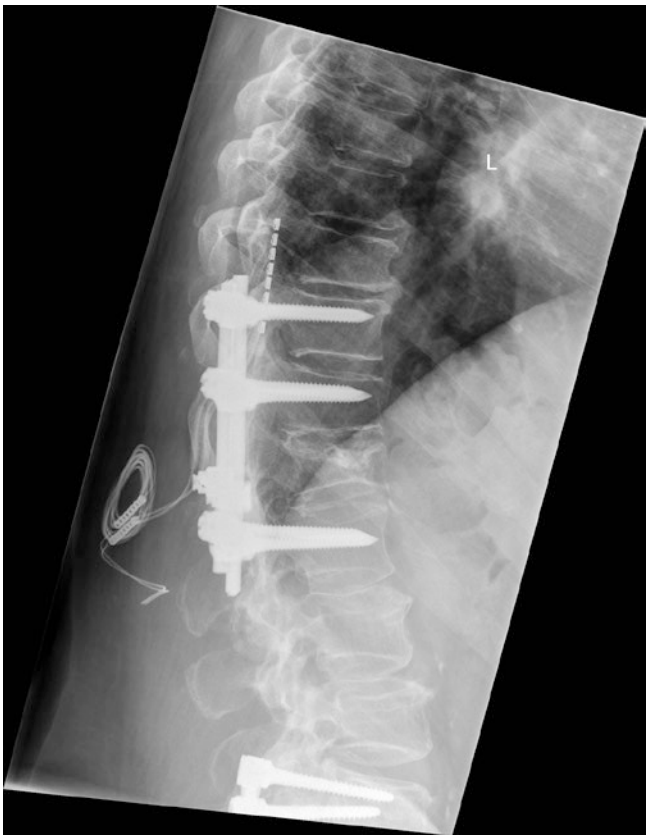

Fig. 69.4 Lateral radiograph showing paddle placement with strain relief loop with connectors

contacts. Prospectively collected data confirmed the therapeutic benefit observed with ION-assisted placement as patients were shown to have significant improvement in pain scores at 12 months, more accurate paresthesia coverage, less adverse events, and decreased operative times. EMG appears to be more effective in lead lateralization than SSEPs, 89% vs. 69%, an important point as anatomic midline does not always correlate with physiologic midline. Despite the success that is possible with ION-guided SCS placement, adequate paresthesia coverage does not guarantee pain relief; long-term data for SCS efficacy is discussed below. After satisfactory positioning is obtained, a strain relief loop is created and anchored to the paraspinal muscles (Figs. 69.3 and 69.4), and then the connectors are tunneled to the subcutaneous pocket where the generator will be implanted. For percutaneously placed leads, the leads are anchored to the fascia utilizing a strain relief loop and then tunneled to the generator pocket. Anchors are supplied with each manufacturer's kit. It is imperative that if an anchor is used, it should traverse the fascia but should not be overtightened to the point that it creates a fracture in the lead.

Non-paresthesia-Generating SCS

Similar to conventional SCS, trial implantation is an important part of patient evaluation. However, unlike conventional SCS, the therapeutic foundation of non-paresthesia-generating SCS does not rely on the generation of overlapping paresthesias. Trial and permanent implantation can be conducted based on individual patient need and clinician preference. Lead placement is solely anatomic and can be determined intraoperatively utilizing fluoroscopy. Buried trials can be inserted with tunneled connectors according to clinician preference and patient need. At the time of writing, paddle leads have recently been introduced for high-frequency stimulation, although in addition to the established cylinder percutaneous leads for this therapy.

Implantation for Non-pain Etiologies

The procedure when implanting a patient for other indications such as angina or ischemic limb pain is similar to above with electrode placement for ischemic limb pain typically between localized T9-L1 and placement for angina usually in upper thoracic spine.

Open Trial Implantation

Open trial implants can be done for patients with a history of prior thoracic and/or lumbar spine surgery where successful percutaneous lead placement would otherwise not be possible due to scar tissue formation and can also be performed with MAC or general anesthesia. Open trial implantation involves creating a laminotomy or laminectomy for placement of paddle stimulators. The benefit is that in a patient with a successful trial, only the generator needs to be implanted; however, for the negative trial, the patient must return to the operating room for removal of leads as opposed to cylindrical leads which can be removed in the office.

Uses and Indications

In the United States, spinal cord stimulation is FDA approved for the treatment of chronic pain. The chronic pain symptom complex encompasses many conditions, including persistent and/or recurrent lower extremity radicular pain following lumbar spine decompression (otherwise known as postlaminectomy syndrome or failed back surgery syndrome); persistent or recurrent axial low back pain; diabetic neuropathy; chronic regional pain syndrome (CRPS); postherpetic neuralgia; pain from severe peripheral vascular disease; pain from intractable angina; and abdominal and pelvic visceral pain.

Evidence for Efficacy

Chronic Pain

Conventional SCS

Kumar et al. observed that nearly 50% of patients derived at least a 50% improvement in lower extremity neuropathic pain after SCS implantation compared with only 9% of patients undergoing medical management at 6 months. This treatment effect was found to be durable at 12 months and even out to 24 months; however, other research has shown that there is a subset of SCS patients who experience decreasing efficacy of stimulation over time. Similar benefits were observed in a randomized, controlled study comparing SCS with reoperation in patients with signs of recurrent neural compression: nearly 50% of subjects had a minimum of 50% pain relief at 6 months with SCS compared with only 12% in the reoperation group. Conventional SCS has also been shown to be an effective treatment for diabetic neuropathy with patients deriving significant reduction in pain compared with medical therapy. Trial data suggested good response to steerable current with 75% of patients undergoing permanent implant after having received at least 50% pain relief. Unfortunately, long-term data from that study is limited owing to receipt of FDA premarket approval; however, 38 of the 49 implanted patients demonstrated an average of 60% pain relief at 3 months, decreasing slightly to an average of 53% pain relief in 34 patients followed out to 6 months.

High-Frequency Stimulation

An early prospective cohort study focusing on chronic low back pain in 25 patients observed greater improvement in VAS scores with high-frequency stimulation as compared with conventional SCS while also demonstrating the ability to achieve paresthesia-free pain relief, thereby challenging the previous paradigm of paresthesia-dependent pain control. Larger prospective trials demonstrated significant improvement of pain scores in 74% of patients with chronic, predominantly low back pain at 6 months and in 60% of patients at 24 months; significant improvements in leg pain were also noted. The observed efficacy of high-frequency stimulation led to a prospective, randomized controlled trial (SENZA-RCT) comparing it with conventional SCS. Results of the SENZA-RCT showed significantly more patients treated with 10,000 Hz stimulation derived a significant improvement in both back and leg pain at 3 and 12 months compared with traditional SCS. These findings were found to be durable with significant differences remaining for both back and leg pain with patients followed to 24 months. Recently released data at a large national meeting demonstrated efficacy of high-frequency stimulation for treatment of chronic neck and upper extremity pain as well. The stimulation frequency of 10,000 Hz may hold particular significance as another study found no difference when comparing sham to high-frequency stimulation at 5000 Hz in a patient population stabilized on conventional SCS.

Burst Stimulation

Early burst studies: Results were found to be equivocal in terms of pain control compared with conventional tonic SCS but did demonstrate a significant improvement versus placebo and an overwhelming patient preference for burst compared with SCS, possibly related to its limited incidence of paresthesias. The initial burst studies looked at differences in pain relief during a 28-day trial period, but subsequent studies have evaluated the impact of burst stimulation in patients who already had a conventional SCS implanted and had received treatment for at least 6 months. In follow-up, burst was shown to significantly reduce foot pain in patients with diabetic neuropathy, back and leg pain in patients with failed back surgery syndrome, and even further decrease leg and back pain in patients who had reduced efficacy of their conventional SCS. Given the positive results, a prospective, randomized controlled trial was undertaken to further evaluate burst versus tonic stimulation: SUNBurst IDE. Specifically designed as a crossover study, patients with medically refrac-

tory, chronic back and/or limb pain underwent a trial with conventional SCS and then were randomized to either a burst or conventional SCS treatment arm. Following 12 weeks of treatment, each patient would then be switched to the other therapy form so that each patient would serve as their own control. Final data has not yet been published, but preliminary results and presentations at large society meetings indicate a significant improvement in back, leg, and overall pain scores when comparing burst with conventional SCS. Similar to previous studies, a significant proportion of patients preferred burst stimulation to conventional tonic stimulation. These findings have led to an FDA approval with superiority labeling.

High-Density Stimulation

One study did show a significant improvement in back and leg pain following transition to HD stimulation from SCS; however, their sample size was small and only followed prospectively for 8 weeks. This has subsequently been followed up with a multicenter pivotal trial in which the results have not been published but are promising. This further demonstrates that patients may need to have options and a single waveform may not be universal for patients.

CRPS

Data also supports the efficacy of SCS for the treatment of CRPS. The degree of relief observed has been variable; early studies suggested pain relief in 43–100% of patients with durability of benefit out to 41 months. Follow-up data, however, has been mixed. One randomized, controlled study comparing SCS and physical therapy (PT) with PT alone demonstrated a significant benefit of SCS at 2 years, while this difference disappeared by 5 years. Another retrospective study showed significant improvement in VAS scores at an average of 88 months of follow-up, while a prospective cohort study observed at least a 30% improvement in VAS scores in 41% of patients at 11 years.

Angina

In Europe, SCS has approval for the treatment of refractory angina, in addition to chronic pain. Multiple studies have demonstrated significant improvement in angina pain and health-related quality of life metrics. SCS has also been shown to decrease the incidence of angina attacks and ischemic episodes, as determined by EKG. Efficacy in certain patients with coronary stenosis has even been shown to be comparable to coronary artery bypass grafting (CABG) in terms of mortality, percentage of cardiac deaths, reduction of angina attacks, and consumption of nitrates, while patients undergoing CABG had significantly more cerebrovascular events. Although a recent randomized controlled trial (RCT) was unable to meet recruitment goals for a comparison of SCS with standard of care for the treatment of refractory angina in patients otherwise ineligible for coronary revascularization procedures, a meta-analysis of seven RCTs looking at refractory angina found similar outcomes when comparing SCS with both open and percutaneous cardiac revascularization procedures.

Limb Ischemia

SCS has also been approved for ischemic pain resulting from peripheral vascular disease in Europe. Data from unmatched cohorts consistently demonstrate significant pain relief, increased skin temperature, improved blood flow, and improved healing of ulcers less than 3 cm^2. Evidence from randomized, controlled studies comparing SCS with medical therapy is mixed, with studies showing both a significant difference and no difference in pain relief. A Cochrane review drawing from six studies comparing SCS with conservative treatment found no significant difference in pain relief between groups but did see a significantly higher rate of limb salvage at 12 months in the SCS-treated group.

Abdominal and Visceral Pain

Several case series have demonstrated a benefit of SCS in the treatment of abdominal visceral pain attributed to various pathologies including mesenteric ischemia, irritable bowel syndrome, nonalcoholic pancreatitis, and postoperative abdominal wall neuroma formation. SCS has also been shown to provide improvement in VAS scores in women with a history of endometriosis and chronic visceral pelvic pain.

Pearls and Pitfalls (Table 69.1)

Fortunately, SCS implantation tends to be a well-tolerated procedure. The most common complication is lead migration and can occur in approximately 13% of patients followed by lead breakage in 9%. The risk of infection is slightly higher than 3%; at many institutions, patients with trial implants remain on oral antibiotics throughout the duration of their trial.

Traditional spinal cord stimulation relies on the generation of paresthesias overlapping the area of pain. Successful stimulation with a traditional waveform will deliver paresthesias to the full area of a patient's pain. However, it is also important to avoid paresthesia generation in any non-painful dermatome as it can be uncomfortable for patients and

Table 69.1 Pearls and Pitfalls

Pearls	Pitfalls
Successful opiate alternative	Some patients will have declining efficacy
Consider changing stimulation modalities for patients who have decreasing efficacy	A positive trial does not guarantee effective relief with stimulator implant
Limiting laminotomy size will preserve bone which can help keep the paddle in contact with the dorsal dura	An overtightened anchor can fracture the wires connecting the lead to the generator
Plan surgical incision and laminotomy close to the desired level of stimulation in order to limit the size of the exposure and the amount of epidural dissection	Rechargeable batteries may be an inconvenience for some patients
Preoperative MRI may reduce the risk of placement-induced adverse events	Poor fluoroscopy technique can hamper effective localization and placement
Utilize multiple strain relief loops when anchoring leads to limit the risk of lead migration and fracture	Laminotomies or laminectomies may need to be performed at multiple levels for patients with extensive epidural scarring who are undergoing paddle implantation

potentially negate the otherwise beneficial effects of spinal cord stimulation; this is not a concern in high-frequency stimulation as it is paresthesia-free. Prior to surgery, it is also important to review with patients the different types of pulse generators available for implantation: rechargeable and non-rechargeable. The rechargeable systems have a longer lifetime but require regular charging which can be an inconvenience for some. The high-frequency system only uses a rechargeable battery given its high energy requirement and must be charged daily. Stimulator coverage from both paresthesia- and non-paresthesia-generating SCS can change over time but often can be mitigated with changes in programming. The research behind each form of stimulation has shown they can all provide significant clinical improvement, but there are some patients that do not obtain relief or experience decreasing relief over time. Despite this, it is also clear that different stimulation modalities may provide a benefit where others have failed. While the phenomenon of pain is still poorly understood, it is clear that a single form of spinal cord stimulation will not treat everyone's pain; different forms of pain require different therapeutic modalities.