Spinal Cord Stimulation: Fundamentals

Interventional pain specialists offer an overview of spinal cord stimulation (dorsal column neuromodulation) fundamentals that referring physicians can use in clinical practice.

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Spinal cord stimulation (SCS) has been used in pain management since C. Norman Shealy, MD, PhD, implanted the first neuroaugmentive device in a cancer patient in 1967. Since then, several studies have examined the long-term effects of SCS in pain management, with variable outcomes and success rates. As with many novel procedures, initial problems with SCS included poorly designed hardware, inadequate patient selection criteria, and suboptimal surgical techniques.

Significant advances in SCS, however, have been made in recent years. Postoperative outcomes of the procedures have shifted to more positive outcomes in the field of neuroaugmentation, especially with respect to such practical factors as return to work, reduction in medication use, reduction in visual analog pain scores, and improvement in activities of daily living. The hardware is more durable, more effective, more maneuverable, and provides a greater range of coverage for the affected area. The devices can be implanted percutaneously under fluoroscopic guidance (especially for the trial leads placement), which allows operator–patient verbal interaction and more accurate positioning of spinal cord stimulator leads for trial and eventual permanent placement. In addition, more than three decades of experience have provided improved patient selection criteria, which is paramount in effecting a positive eventual outcome. The net result is an improved capability to control various chronic pain conditions, especially those that are peripherally referred as opposed to centrally referred.

This article will discuss the pathophysiology, mechanism of action, and clinical applications of SCS; as well as...
current clinical results, and potential future trends in SCS, also known as dorsal column neuromodulation.

**SCS Mechanism of Action**

Although the exact mechanism for pain control from SCS is not entirely understood, it is believed to result from direct or facilitated inhibition of pain transmission. Table 1 lists the five mechanistic theories for why SCS works.

The gate control theory motivated Shealy et al to apply SCS as a means to antidromically activate the tactile myelinated A-ß fibers through dorsal column stimulation. Shealy reasoned that sustained stimulation of the dorsal columns would keep the gate closed and provide continuous pain relief. While the theoretical “gate control” model put forth by Melzack and Wall has been shown not to be precisely correct, pain gating or pain control has been shown to exist.

Others believe that pain relief from SCS results from direct inhibition of pain pathways in the spinothalamic tracts and not secondary to selective large fiber stimulation. This theory has been supported by Hoppenstein, who showed that the posterolateral stimulation of the spinal cord provided effective contralateral pain relief with substantially less current than posterior stimulation.

Some investigators think that the changes in blood flow and skin temperature from SCS may affect nociception at the peripheral level. This postulation is further supported in part by data from Marchand et al, who investigated the effects of SCS on chronic pain using noxious thermal stimuli. Since it was discovered that SCS causes vasodilation in animal studies, clinicians have used this modality for the treatment of chronic pain due to peripheral vascular disease and is the leading indication for SCS in Europe today. The precise action of pain modulation by SCS is still in debate. A better understanding of the pain system may lead to more effective stimulators and allow for even greater success.

Today, the most common indication for SCS is for the treatment of chronic low back and lower extremity pain due to chronic radiculopathy or postaminectomy lumbar pain syndrome despite adequate surgical intervention. This population represents the primary indication for SCS in our practice and has provided us with an effective treatment option. Table 2 contains a list of commonly accepted and potential indications, in addition to commonly accepted contraindications.

**Selection Criteria**

As noted, proper patient selection is essential to the long-term success of a spinal cord stimulator system. Technical advances leading to improved hardware, coupled with improved patient selection, have improved the rate of long-term efficacy of SCS to approximately 70% today, up from approximately 40% since the 1970s and 1980s.

A spinal cord stimulator neurostimulation system should be considered for patients who have failed all reasonable conservative care including appropriate diagnostic, therapeutic, and rehabilitative techniques, and have been given a reasonable period of time to recover from the condition. A reasonable time period is at least 6 to 12 months of conservative, pain-relieving, minimally invasive treatments, and/or failure of surgical treatments, with persistent extremity pain greater than axial spine pain.

An ideal patient should be motivated, compliant, and free of drug dependence. Psychological screening is recommended but not mandatory to exclude conditions that predispose to failure of the procedure (see article on psychological evaluation in SCS patients on page 35). Diagnoses that are typical indications for this procedure include chronic radiculopathy, perineural fibrosis, neuropathic pain, and complex regional pain syndrome. In the United States, peripheral vascular disease is not an FDA-approved indication.

When considering pain topography, extremity pain responds better than axial pain, and the more distal the extremity pain the greater the clinical response. Middle and upper lumbar pain as well as thoracic, cervical, and chest wall pain are difficult to adequately control and maintain long term. Pain due to severe nerve damage superimposed on cutaneous numbness (ie, anesthesia dolorosa) is also difficult to treat with SCS. Central pain syndromes do not

### Table 1. Mechanistic Theories for SCS

<table>
<thead>
<tr>
<th>Mechanistic Theory</th>
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<tr>
<td>Gate control theory</td>
<td>Segmental, antidromic activation of A-ß efferents</td>
</tr>
<tr>
<td>SCS blocks transmission</td>
<td>in the spinothalamic tract</td>
</tr>
<tr>
<td>SCS produces supraspinal pain inhibition</td>
<td></td>
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<tr>
<td>SCS produces activation of central inhibitory mechanisms</td>
<td>influencing sympathetic efferent neurons</td>
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<tr>
<td>SCS activates putative neurotransmitters or neuromodulators</td>
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SCS, spinal cord stimulation
respond to SCS and are best treated by other modalities.

**Percutaneous Trial**

The use of an outpatient percutaneous trial of between 3 to 7 days with an SCS system has been proven helpful in determining which patients will respond well enough to warrant a permanent spinal cord stimulator implantation and determine the future permanent implantation levels. Absolute criteria that must be present for a patient to have a positive trial include tolerance of paresthesia, >50% to 75% pain relief, and overall patient satisfaction. Relative requirements for a positive trial include improved functional level, reduced usage of pain medication, and reduced reliance on the healthcare system.

The process of the trial percutaneous spinal cord stimulator approach should involve an alert and communicative patient who can provide the practitioner with correct lead positioning. The patient should be made comfortable with local anesthesia infiltration at the insertion sites. The interventional pain specialist can use the trial screening lead(s) during the screening trial. Once the screening lead is positioned at the exact locations (determined from communication between the patient and the interventional spine specialist), then the temporary external power source (screener) is connected. When both the patient and physician are satisfied that the stimulation coverage is satisfactory, then the spinal cord stimulator leads are sutured tightly with anchors to the skin. Subsequently, the completed circuits are taped securely to the skin and covered to prevent them from accidently being pulled out but still allow them to be attached to the programmer. Then, to verify the final electrode position, anteroposterior and lateral radiographs should be obtained with the fluoroscopy films.

**Postprocedure Care**

The patient routinely recovers after 30 to 60 minutes in a postoperative recovery setting. Absolute criteria that must be present for a patient to have a positive trial include tolerance of paresthesia, >50% to 75% pain relief, and overall patient satisfaction. Relative requirements for a positive trial include improved functional level, reduced usage of pain medication, and reduced reliance on the healthcare system.

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**Commonly accepted indications**

- Postherpetic neuralgia
- Intercostal neuralgia
- Post-laminectomy (thoracic region) syndrome (ie, FBSS)
- Post-laminectomy (lumbar region) syndrome (ie, FBSS)
- Cauda equina (chronic) injury syndrome
- Chronic arachnoiditis
- CRPS of the upper limb
- CRPS of the lower limb
- CRPS of other specified site
- Phantom limb pain syndrome
- Cardiovascular angina/ischemic pain
- Atherosclerosis of the extremities with resting pain (ie, peripheral vascular disease)
- Brachial neuritis or chronic cervical radiculopathy
- Thoracic or lumbosacral neuritis or chronic radiculopathy
- Cervical nerve root injury
- Thoracic nerve root injury
- Lumbar nerve root injury

**Commonly accepted contraindications (Absolute)**

- Sepsis
- Coagulopathy
- Previous surgery or trauma that obliterates the spinal canal
- Localized infection at the implantation site
- Spina bifida

**Commonly accepted contraindications (Relative)**

- Physical and/or cognitive/psychological disability that interferes with proper usage of and understanding of the device
- Significant somatization/somatoform disorders
- Unmanaged substance abuse or cognitive disorders
- Lack of social support

**Other potential indications**

- Chronic occipital neuralgia/cervicalgia
- Fatigue
- Fatigue

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**Table 2. SCS Indications and Contraindications**

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CRPS, complex regional pain syndrome; FBSS, failed back surgery syndrome; SCS, spinal cord stimulation
(stimulus duration), and amplitude (volts). A typical frequency is 50 to 80 Hz, although a higher frequency may be used as a stronger counter-stimulus. Increasing the pulse width increases the density of the stimulus, which provides for deeper penetration into the spinal cord. Clinically, this usually means a broader disbursement of paresthesia. This may be beneficial when, for example, the stimulation pattern needs to cover the back but is only covering the hip. The pulse width can be increased and the paresthesia pattern may then incorporate the lower back. The amplitude represents the electrical force of the stimulus. Clinically, this usually means that the patient experiences a more dense stimulation pattern, thus, making it harder for the pain to “break through” the stimulation pattern. When the amplitude is adjusted too high, the patient may have a noxious experience.

As long as the recovery period is uneventful, the patient can be discharged home with postoperative instructions. During the recovery period, the spinal cord stimulator programming is fine-tuned, the patient and/or patient’s family is educated on how to use the device, and any questions are answered. The patient is told to keep the spinal cord stimulator area clean and dry and specifically told not to bathe or shower but to take sponge baths during the trial period. Prophylactic oral antibiotics are provided and the patient is instructed to avoid excessive bending or twisting as this may dislodge the spinal cord stimulator lead. In addition, they are told not to alter medication consumption and to maintain their routine activity level. The patient also is instructed to alert the physician in case of any alteration in stimulation pattern, signs of infection, or any other unusual occurrences.

Follow up is usually within 3 to 7 days following implantation, at which point the lead is removed, the efficacy of the SCS is assessed, and the physician should then determine whether to proceed with placement of a permanent spinal cord stimulator.

Permanent Surgical Implantation
The patient undergoing a permanent spinal cord stimulator implantation is brought into the ambulatory surgical center or hospital the morning of the procedure. A urinalysis, complete blood count with differential and sedimentation rate, should be obtained within 72 hours prior to the implantation. A chest x-ray and electrocardiogram should be obtained in all patients who are more than 45 years old, have a history of cardiac or pulmonary disease, or show ongoing signs or symptoms of cardiac or pulmonary difficulty.

Permanent spinal cord stimulator systems can be placed with percutaneously inserted round wire leads, or via open placement of flat plate or paddle leads (Figure 1). In either case, the sublaminar epidural leads are connected by wires to a subcutaneously installed generator at a separate operative site.

Percutaneous placement of wire leads is minimally invasive and is typically done without general anesthesia. The same general technique used in trial lead placement is used for permanent lead placement. After lead placement is complete, lead wires are tunneled with a trochar to a subcutaneously placed generator and the generator incision is closed. The minimally invasive nature of percutaneous lead placement may be preferable in patients who are unwilling to undergo or unsuitable for general anesthesia (Figure 2).

Although more invasive, open-paddle lead placement offers several advantages over percutaneous placement of wire leads. Placement of paddle leads is done under direct visualization, potentially mitigating the risk of dural breach. Paddle leads are less subject to migration and can provide broader stimulation coverage, with better overall clinical outcomes.

A versatile technique for placement of sublaminar paddle leads for low back pathology is via approximately T8-T10 laminectomy, with the precise level being adapted to results of previous trial stimulation. This can be done either under general anesthesia.
or conscious sedation. In either case, this is easily accomplished in an outpatient setting. The patient is placed in the prone position on a surgical saddle frame. Using fluoroscopic guidance, a midline incision is made over the spinous process and is taken through the dorsal fascia. Paraspinal muscles are elevated off of the lamina, and a complete facet-sparing laminectomy is performed. The epidural space is developed using a dural dissector. If lower extremity peripheral nerve stimulation is desired, a lead may be placed caudally to cover the posterior spinal cord, conus medullaris, and anterior cauda equina. Otherwise, the lead is placed anteriorly over the appropriate thoracic level.

Appropriate lead position is confirmed with anteroposterior and lateral fluoroscopy. If the procedure is done in an awake patient, test stimulation can be performed. Neurophysiological mapping may be used if desired for confirmation of localization with general anesthesia. Once a satisfactory position is confirmed, the wire leading into the lead is anchored to the remnant of the interspinous ligament or directly to the adjacent spinous process utilizing a sleeve and a non-absorbable suture. Wires are then passed through a trochar to the generator, which is implanted in a subcutaneous pouch commonly just below the iliac crest. Incisions are closed in a layered fashion and the patient is transported to the post-anesthesia recovery unit, where appropriate stimulation coverage is confirmed once the patient is fully awake.

An example of a patient in which the paddle lead is advantageous is one who has undergone previous instrumented fusion for spondylolisthesis. Although there is radiographic evidence of adequate fusion and no evidence of neural compression, the patient has persistent radicular lower extremity pain and disabling axial low back pain.

After a successful percutaneous lead trial, spinal cord stimulator placement using a single paddle lead centered at T9-T10 is performed. The lead consists of two or
To the patient to try, noninvasively, a wide range of programming options postoperatively until optimal stimulation coverage of low back and lower extremities is achieved without uncomfortable paresthesias.

Preoperative and postoperative intravenous antibiotics are administered and following recovery, the patient is discharged with 7 to 10 days of oral antibiotics, or kept for a 23-hour hospital observation (physician/surgical preference).

**Potential Complications of SCS**

There are rarely any serious complications from the temporary percutaneous trial or permanent procedure for spinal cord stimulator implantation. In one study, one nonfatal pulmonary embolism and one case of paraplegia lasting 3 months were reported. The latter resulted from a laminectomy that was used to place the stimulating lead. Other rare reported complications include sphincter disturbance and gait abnormality.

Most complications from the temporary or permanent devices include formation of scar tissue, poor localization of paresthesias, lead migration, lead fracture, pain at the pocket site or connection site, infection, nerve injury, and epidural hematoma. A comprehensive summary of different publications, lead migration or displacement varied from 3.7% to 69%, although most studies reported migration between 16% and 25%. Rates of lead fractures were reported in various series from <1% to >20% and superficial infections occurred in 2% to 12% of cases. Serious surgical infections were rare, as were clinically apparent epidural hematomas. In one study, cerebrospinal fluid leakage was found in 2% of patients. Avoiding complications in spinal cord stimulation should follow an analytical step-wise approach.

In our clinical experience that has involved >600 lead implants, the clinical practice has experienced only 3 in situ infections with permanent devices. One infection resulted from an occult bone stimulator infection due to a previous fusion and presented >6 months following implantation; the second infection occurred 2 1/2 months after implantation from an unknown source; and the third infection occurred 18 months following implantation. The latter infection was apparently due to hematogenous seeding when the patient broke an abscessed tooth after he bit down on an apple the week before. In the first two cases of infection, the spinal cord stimulators were removed and the patients were placed on intravenous antibiotics without further sequelae. In the third case, the spinal cord stimulator was not removed and the patient was adequately treated with oral antibiotics and dental care. We have had no complications with any of the trial lead placements.

**Clinical Results**

The largest study of SCS includes 320 consecutive patients who underwent either temporary or permanent implantation at the Johns Hopkins Hospital between 1971 and 1990. This series includes follow up on 205 patients, the majority of whom had the diagnosis of failed back surgery syndrome (FBSS). Permanent spinal cord stimulator implants were placed in 171 of these patients. At follow up (mean interval 7.1 years, SD 4.5), 52% of patients had >50% continued pain relief, and 58% had reduced or eliminated the use of medication. About 54% of patients younger than 65 were working at the time of follow up; 41% had been working preoperatively.

The percentage of patients having long-term pain relief is similar in the majority of large published studies of spinal cord stimulator implants for FBSS. The success rate in most of these studies, which is generally reported as ≥50% pain relief, is approximately 50% to 60%.

Some studies report success rates as high as 88% and others as low as 37%. Although these latter studies differ in implantation technique and
screening protocols, the success rate for pain reduction generally remains the same.

More recent published reviews specifically have looked at the reduction in pain, reduction in opioid medication consumption, improvements in activities of daily living function, and return to work status.²⁴,⁶⁰-⁶³ According to these studies, long-term pain reduction (at least 2 years after implantation) can be expected to range from 50% to 70% in approximately 60% of SCS patients. In 50% to 90% of individuals, there will be an elimination or reduction in the use of opioids. The return to full employment rate after SCS reported by two studies is 25% to 59%, which is very significant when comparing it to the usual return-to-work rate in this population of 1% to 5%.²⁴,⁶¹

Reasons for the disparity between pain reduction and return-to-work rates appear to reflect the high percentage of unskilled laborers among this population, the prolonged periods of disability, and the attendant sociobehavioral changes that take place. Despite this disparity, there is a general increase in function and activities of daily living.

The Future

The future of SCS/neuromodulation looks promising with the planned technological advances in these devices.³⁷,⁵⁹,⁶⁴-⁶⁶ Both St. Jude Medical and Medtronic have implanted pulse generators and lead devices that allow an adequate power supply for dual lead systems, which extends the life of the pulse generator. In addition, St. Jude Medical has developed a pulse generator that employs a capacitor instead of a battery that is rechargeable by an external radiofrequency-controlled device. With a coordinated program of multitreatment treatment protocols, as outlined in this spine-centered orthopedic clinic setting model, further coordinated improvements may facilitate successful long-term outcomes. Further neuromodulation devices and technology should assist in providing further options to be available for this select, but growing, population of chronic pain patients.⁷,⁹-¹¹

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Dr. Pinzon and Dr. Killeffer have no financial information to disclose.

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