Spinal Cord Stimulation for the Treatment of Chronic Pain

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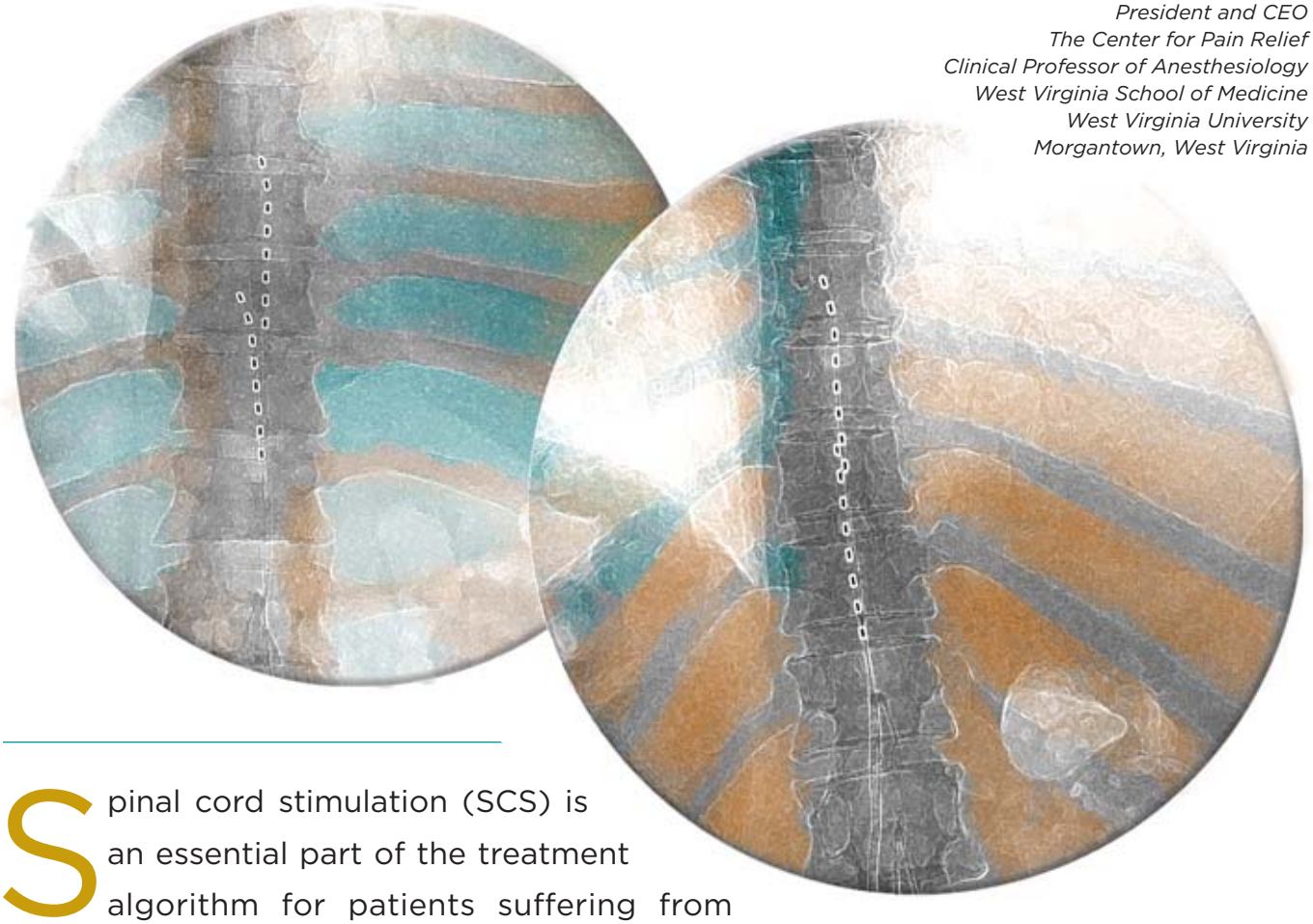

Spinal cord stimulation (SCS) is an essential part of the treatment algorithm for patients suffering from neuropathic pain. Once thought to be a treatment of last resort, it is now evident that SCS is an efficacious, cost-effective option that should be used much earlier in the treatment continuum in many disease states, including lumbar and cervical radiculopathy, failed back surgery syndrome, peripheral neuropathy, ischemic pain, and complex regional pain syndrome.

History and Background

The initial use of SCS was exciting but poorly defined. Shealy's use of an antiquated device in the intrathecal space to treat cancer pain was the first mention of this therapy in the literature.[1] Innovations during the next four decades led to new devices that resemble their predecessors in only one aspect: They have an electrical component that delivers energy to body tissue. In all other areas, the change has been transformational. The leads (Figure 1) have evolved from monopolar stimulation to multicontact lead arrays; the connectors have been eliminated in many systems in favor of direct contacts to the generator; and the generators have developed from radiofrequency devices with an external power source to miniaturized small internal generators that can be recharged. The programming has evolved from simple monopolar fields to complex arrays that can offer a cycle of different complex patterns to cover multiple pain generators. This historical development has led to more stimulation coverage and better outcomes.[2]

Spinal Cord Stimulation

The decision to implant a spinal cord stimulator into a patient is based on selection criteria.[3] The patient should have failed acceptable conservative therapy, have no untreated bleeding disorders, have no active

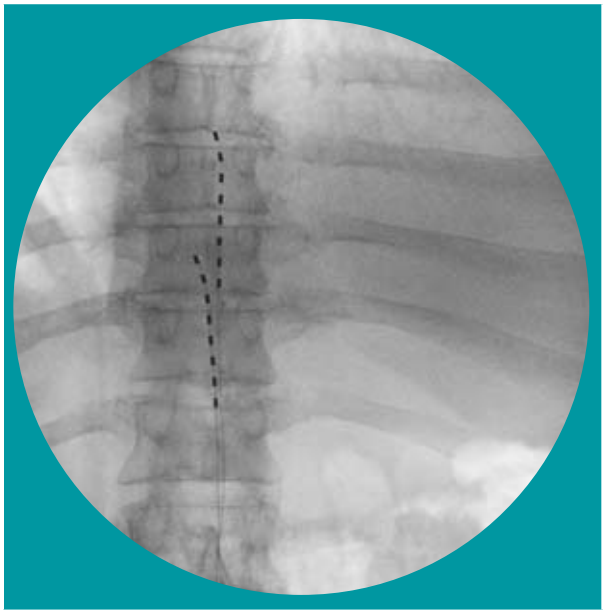

Figure 1. Percutaneous lead array with one lead crossing the midline to treat bilateral foot pain, and the other lead off midline to treat right hip and leg pain.

Table 1. Lead Placement Targets[4]

Cervical	
C2	Face, below the maxillary region
C2 to C4	Neck, and shoulder to hand
C4 to C7	Forearm to hand
C7 to T1	Anterior shoulder
Thoracic	
T1 to T2	Chest wall
T5 to T6	Abdomen
T7 to T9	Back and legs
T10 to T12	Limb
L1	Pelvis
T12, L1	Foot
L5,S1	Foot, lower limb
S2 to S4	Pelvis, rectum
Sacral hiatus	Coccyx

Table 2. Disease Processes and Probability of Success[4]

High probability of successful pain reduction
Chronic radicular pain (cervical and lumbar)
Complex regional pain syndrome, Types I and II
Painful peripheral mononeuropathies
Angina pectoris refractory to conventional drug therapy and not amenable to surgical bypass
Painful ischemic peripheral vascular disease not amenable to conventional drug therapy or surgical bypass
Low probability of successful pain reduction
Neuropathic pain following spinal cord injury
Central pain (eg, post-stroke pain)
Nerve root avulsion (eg, brachial plexus avulsion)
Unknown probability of pain reduction (case reports of successful treatment)
Postherpetic neuralgia
Axial low back pain
Phantom limb pain

systemic infection or infection at the site of implant, no untreated drug addiction issues, and be psychologically stable. The patient should have a successful trial of stimulation resulting in acceptable pain relief, good global satisfaction, and improved function. The trial can be performed with 1, 2, or 3 epidural percutaneous leads or with a surgical paddle lead. In most cases, the lead is placed in the target zone based on the patient's pain generator. Lead placement is confirmed by fluoroscopic anterior–posterior and lateral x-rays, and by handheld programming; targeting of the lead has been determined by extensive previous experience (Table 1).[4] The trial period can range from 24 hours to 14 days based on patient response and physician preference. In most cases, a 3-day trial allows for an adequate evaluation, and reduces the risk for fibrosis that can make it difficult to implant the permanent lead. Paddle leads often are used for permanent implants in more complicated pain patterns, instrumented spinal anatomy, and in those for whom the trial proved difficult in percutaneous lead delivery. Research is currently under way to develop leads that have a paddle construct, but can be delivered by a needle approach.

In addition to selecting the correct patient for implantation, the physician should focus on disease processes that may have the best chance of responding to conventional SCS therapies (Table 2).

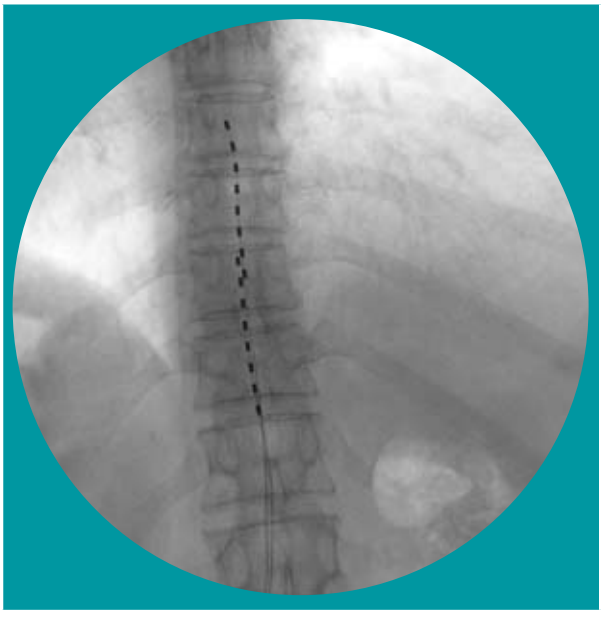

Figure 2. Percutaneous leads covering the T8 to T12 vertebral bodies to treat neuropathic pain of the back and legs.

Case Study:

A Woman With Arnold-Chiari Malformation

History of Present Illness

The patient is a 40-year-old woman who began to complain of occipital pain, ear pain, antalgic gait, arm pain with weakness, and burning arm pain. Workup was performed with magnetic resonance imaging (MRI), physical examination, and plain films. She was diagnosed with clinically significant Arnold-Chiari malformation and scheduled for surgical decompression. The surgery was successful in correcting the patient's brain compression, but she developed worsening pain of her C2 nerve distribution and of her hands. The patient presented to the clinic with failure of opioids, anticonvulsants, antidepressants, and physical medicine.

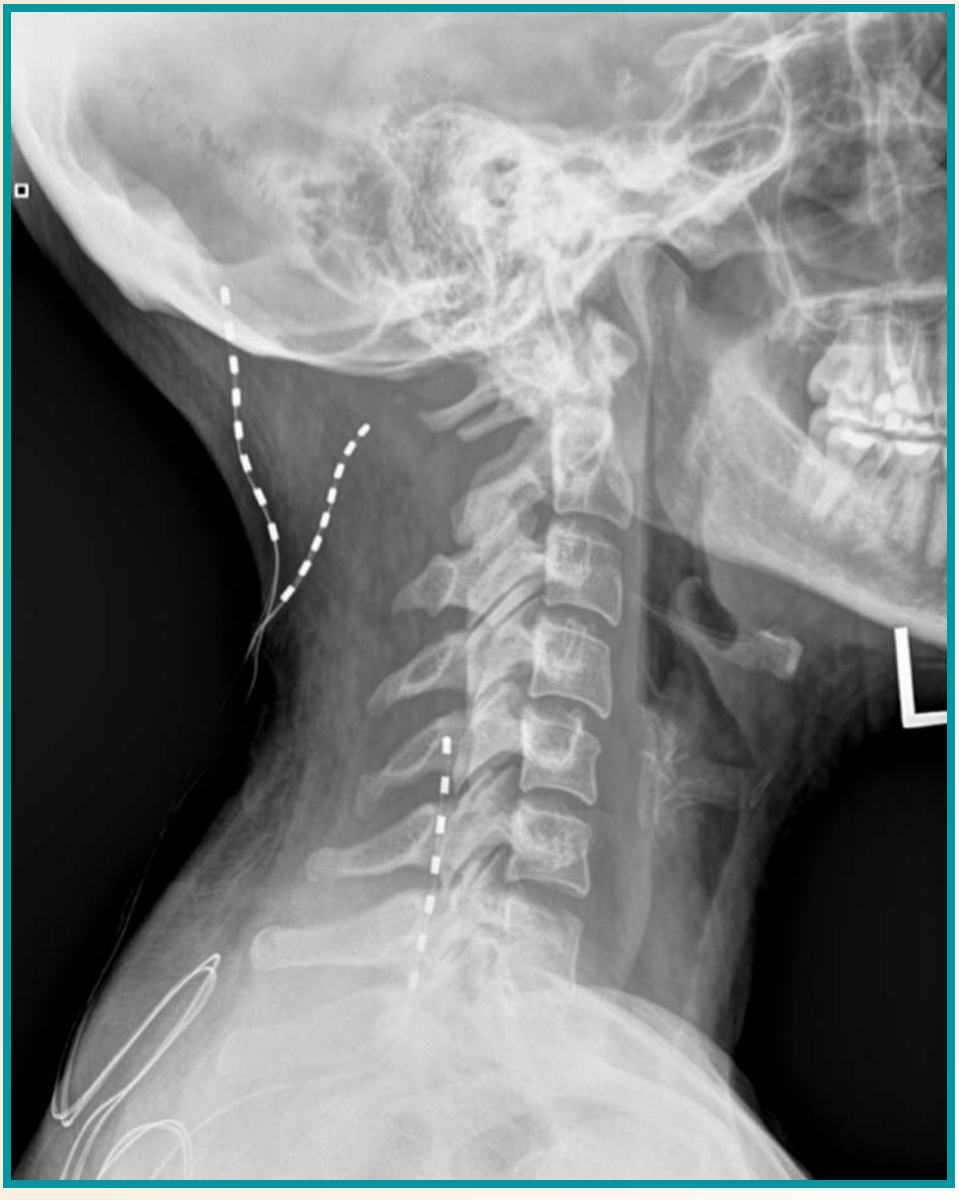

Figure 1a. Occipital leads on anterior–posterior view.[4]

Treatment Options

Interventional treatment was initiated with epidural injections, cervical facet medial branch blocks, and occipital nerve injections. The patient had only a temporary response to these interventions. She inquired about the possibility of neuromodulation for treatment.

A new MRI was obtained to rule out additional surgical needs regarding her brain compression and cervical spine. No surgery was indicated, and the patient was referred to pain management for the possibility of stimulation.

Strategy of Stimulation

A combination of epidural and peripheral nerve stimulation to alleviate pain in the arms and occipital region using a single implantable device to control both areas was planned. The leads were programmed to be used independently and in combination during the trial phase to establish the best pattern of permanent lead placement.

Stimulation Trialing

After reviewing the patient's pain pattern and anatomy, a combined trial of percutaneous and peripheral nerve stimulation was planned. The patient had no contraindications to surgery, and was felt to be an appropriate candidate based on her psychological status. The patient was given chlorhexidine soap for preoperative bathing, and was educated on risks and expectations. The patient was properly prepared for surgery with the posterior scalp shaved of hair. She was positioned in the prone position and was prepped with both povidone-iodine and chlorhexidine on 6 occasions. Laser-guided fluoroscopic vision was used to establish the targets and the points of entry for the leads.

The skin was infiltrated with 1% lidocaine with epinephrine and a 17-gauge needle was used to enter the epidural space. An 8-contact lead was placed crossing the midline at C4-6. The lead was programmed in the "double-guarded" cathode fashion preferred by the implanter. In this array, the contacts are activated with a 3+, 4–, 5–, 6+ configuration. With this plan, the patient's hands and arms achieved good coverage and the patient was very satisfied with initial patterns. Because of the posterior compression of the spine, a lead could not be driven past the C3 level, so a percutaneous lead was placed in the occipital region bilaterally (Figures 1a and 2a). The lead configuration was just below the nuchal line based on the patient's pain pattern. An array of a dominant cathode placement was used to achieve stimulation on both sides. The array was 8–, 7–, 6–, and 5+ on each lead. Only the proximal end of the lead was used to achieve a pattern that could be achieved with a widely spaced quadripolar lead at the time of permanent implant. In addition to stimulating these leads independently, a third program was configured to combine a mostly anode-driven epidural lead with a mostly cathode-driven peripheral lead combination. The patient achieved acceptable stimulation in the areas of pain in both the C2 (occipital nerve) distribution and in the cervical radicular patterns. The leads were removed after the fourth day with a successful response of more than 50% pain reduction, and improved physical and mental functioning. The patient wished to go forward with a permanent implant.

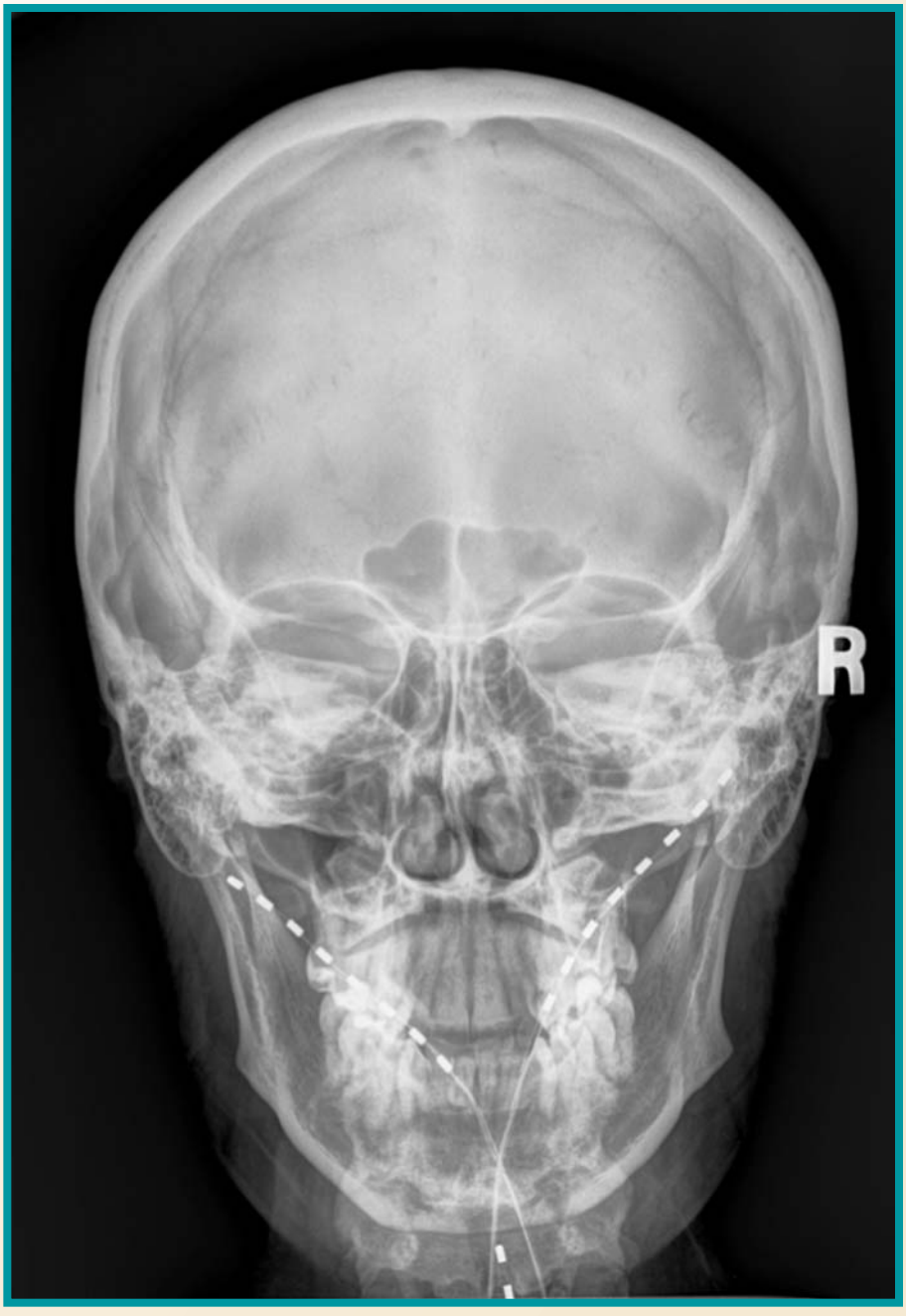

Figure 2a. Combined peripheral and percutaneous leads. Courtesy of the Deer Atlas of implantable devices.[4]

Treatment Plan

The patient was given an opportunity to ask questions and all options and risks were discussed. A permanent implant was scheduled with an 8-contact lead in the epidural space, 2 wide-spaced 4-contact leads over the nuchal ridge, and a rechargeable generator above the beltline posteriorly.

Clinical Studies

Failed Back Surgery Syndrome And Other Spinal Disorders

In many cases, the failure of a spine surgery to provide pain relief leads to additional spine surgery. When this is performed for neurologic compromise, there are few alternatives, but when it is performed for the primary purpose of pain reduction, the outcomes are often tenuous. Prospective randomized studies in patients who are candidates for a second spine surgery have shown that they do better with SCS.[5,6] This is true from multiple standpoints, including pain reduction, health care utilization, crossover to additional therapies, and long-term cost. Consequently, SCS should come before a second spine surgery when pain is the primary indication.[7,8] Considering that the cost of a primary complex spine surgery may exceed $89,000 in initial expenses, it is reasonable to consider SCS as a primary treatment option for patients whose odds of a good outcome are uncertain.[9]

Complex Regional Pain Syndrome

SCS as a treatment for complex regional pain syndrome (CRPS) has been well documented. The level of evidence for CRPS is at the highest level based on peer review criteria. In a prospective randomized trial of SCS with physical therapy versus physical therapy alone, the group receiving SCS had a significantly better outcome up to 2 years later.[10]

In this study and similar outcome evaluations, the use of SCS with other modalities such as physical medicine and anticonvulsants appears to result in the best outcome.

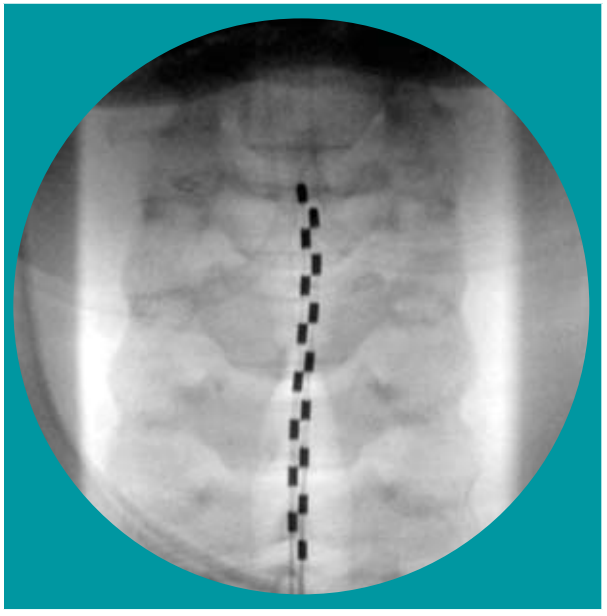

Figure 3. Cervical leads to treat radicular upper extremity pain.

Courtesy of Stanley Golovac, MD

Neuropathic Pain of the Extremities

SCS for neuropathic pain of the extremities has been shown to be effective and life-changing for many patients (Figures 2-4). Kumar et al have shown, in a prospective randomized study, that SCS is very helpful in treating patients with burning leg pain compared with conventional medical management alone.[11] In this group of patients, the primary pathology was failed back surgery syndrome. Other studies and reports have shown SCS to be efficacious in diabetic peripheral neuropathy and nerve pain of other origins. In most studies, the chance of a good outcome with SCS in neuropathic limb pain is 85% or higher.

Ischemic Pain

SCS has been shown to treat the neuropathic pain caused by ischemia, as well as improve blood flow, improve tissue oxygenation, and enhance wound healing.

SCS is used in patients who have either severe primary ischemic pain or mixed pain of both ischemic and neuropathic origin. The trial for ischemic pain involves evaluation of pain relief and blood flow. This can be assessed by visualization and examination or by complex tissue oxygenation measurements.

Large multicenter studies of SCS have shown good clinical outcomes with pain relief and improved vascular outcomes. In a review of studies of both ischemic pain of the extremities and of angina pectoris, Deer and Raso found that the current evidence for both indications is very strong.[12]

Angina

Many patients with angina are successfully treated with cardiac stenting, coronary artery bypass graft surgery, or oral medications. In a subset of patients, angina persists despite other treatments. In this group, SCS can be used to improve quality of life, decrease pain, and improve function. Angina is caused by an imbalance between the supply of and demand for oxygen. The mechanism for changing this imbalance to a more favorable status by using SCS is uncertain, but several theories exist.[13] Studies have shown that SCS improves tissue oxygenation, decreases pain, and does not mask anginal symptoms. The typical lead position is to place one lead at C7-T1 in the midline and a second lead off midline to the left side at T1-T2.

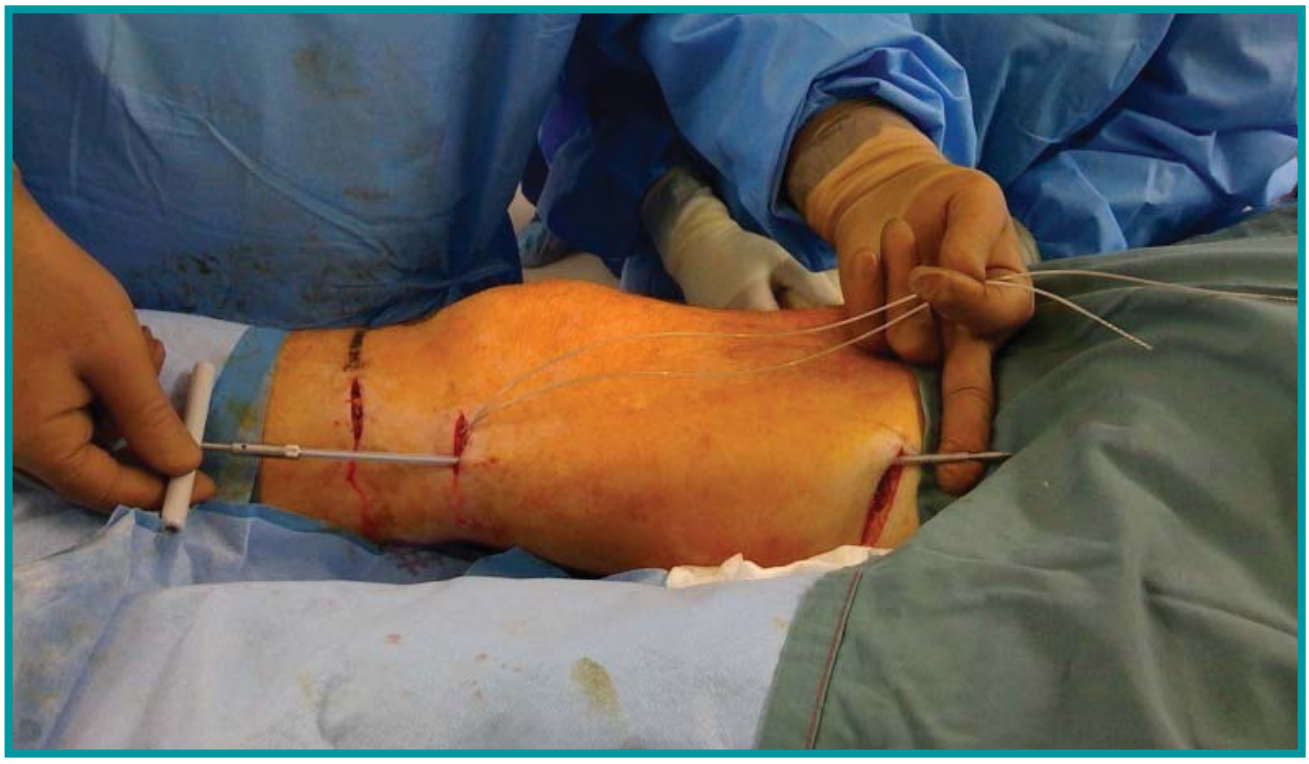

Figure 4. Peripheral nerve implant of the knee with lower extremity pocket.

Courtesy of Paul Verrils, MD

Other Disease States

SCS has been used to treat patients with many pain origins, including postherpetic neuralgia, traumatic nerve injury, postamputation syndromes, brachial plexopathy, and facial pain in the mandibular nerve distribution.[14,15] Many studies are ongoing to evaluate SCS efficacy in these patient groups.

For the future of neuromodulation, the role of implant systems in the peripheral nervous system is a growing area of research and clinical application. Peripheral targets include the occipital nerve, ilioinguinal nerve, intercostal nerve, and nerves of the face. A recent multicenter study examined occipital stimulation for the treatment of migraine. The results should be completed in the near future and may lead to a new approved indication. Recent research on SCS and peripheral nerves of the hand showed good efficacy in initial pilot evaluations.[16]

Risks, Side Effects, and Complications

SCS involves the placement of a needle into the epidural space, a lead into a targeted region about the spinal cord, and an incision to stabilize the leads and to create a pocket for an internal programmable generator. With this complex array of procedures, there are accompanying risks including epidural bleeding, epidural infection, postdural puncture headache, wound infection, and other complications.[4]

Conclusion

SCS is a reversible, minimally invasive approach to treating pain that has goals of reducing suffering, improving function, reducing health care utilization, reducing opioid use, and improving quality of life. SCS has been shown to be efficacious and cost-effective in comparative therapies, and should be considered as a viable option in the treatment continuum before a second back surgery, high-dose oral opioids, or an intrathecal pump. It is important for a patient to be educated about SCS as a treatment option before moving to more invasive and irreversible treatments.

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