ANESTHETIC TECHNIQUES IN PAIN MANAGEMENT (GJ BRENNER, SECTION EDITOR)

# **Spinal Cord Stimulation: A Review**

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**Abstract** Spinal cord stimulation (SCS) is a safe and effective treatment of a variety of chronic pain conditions. As our understanding of the mechanisms of action and potential uses of SCS has evolved, clinical and technological advancements have followed. This review provides an overview of potential mechanisms of action of SCS, evidence for its effectiveness, potential complications, and highlights of developing areas of interest.

**Keywords** Neuromodulation · Spinal cord stimulation · SCS · Failed back surgery syndrome · FBSS · Complex regional pain syndrome · CRPS · Neuropathic pain · Pain · Anesthesia · Pain management · Review

# Introduction

For over 4,500 years, electrical stimulation has been used for the treatment of pain [1]. In the first century AD, Greek physicians used the torpedo fish to treat the pain of headaches and arthritis. Although transcutaneous electrical nerve stimulation (TENS) may come to the mind of many clinicians and patients when the concept of "electricity to treat pain" is discussed, spinal cord stimulation (SCS) is the most effective and well-researched electrical stimulation

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modality. In 1967, Dr. C. Norman Shealy and coworkers at Case Western Reserve University [2] were the first to use SCS for the treatment of chronic pain; this was well before the first patented, wearable TENS unit was developed in 1974. Since this first case demonstrating the safety and utility of SCS, there has been an exponential growth in documenting its efficacy and continual refinement in device technology. This review summarizes the current concepts and potential directions of this safe, efficacious, and costeffective modality.

## **Mechanism of Action**

# Neuromodulation

There have been multiple theories promulgated to explain the mechanisms through which SCS provides analgesia. One of the earliest theories to explain the mechanism through which SCS modulates pain perception was detailed in 1965 by Ron Melzack and Patrick Wall [3] in their gate control theory of pain. While their theory has subsequently been shown to be incomplete, it nevertheless provided groundwork to expand understanding of nociceptive modulation at the level of the spinal cord. Recent investigation has focused on SCS-induced modulation of the hyperexcitability of wide dynamic range cells in the dorsal horn of the spinal cord. SCS appears to correlate with enhanced  $\gamma$ -aminobutyric acid (GABA) levels and reduced glutamate levels [4]. Acetylcholine levels also have been shown to rise in the dorsal horn of SCS-responsive rats and appear to be mediated by muscarinic 4 (M4) receptor activation [5]. Another area of focus is the interaction of SCS with descending pain modulatory systems. While serotonergic pathways have been studied more, norepinephrine pathways also are likely involved [6, 7]. Evidence for analgesia via antidromic activation during SCS has been demonstrated [8]. Mechanisms of action of SCS in ischemic pain are postulated to be different than in neuropathic pain. In ischemic pain, SCS appears to induce vasodilation by a reduction in sympathetic activity in addition to antidromic vasodilation via calcitonin gene–related peptide [9]. While our knowledge of the mechanisms of SCS has expanded dramatically since the introduction of the modality, understanding is still rather incomplete.

## Current Penetration

Optimal analgesia with SCS is achieved by placing the leads in the dorsal epidural space, near the physiologic midline of the cord. The spinal canal includes a number of structures that would be subject to the stimulation when the device is activated. The various structures in and around the spinal canal conduct current differently. Vertebral bone and epidural fat are very poor conductors of current, thereby confining current mostly to intraspinal structures and shielding vital organs such as the heart from electrical interference. Cerebrospinal fluid (CSF) has a very low resistivity, and hence, it is estimated that 90% of the induced current is dispersed in the CSF between active electrode contacts and less than 10% reaches the dorsal columns. This 10% reaches the superficial 0.2 to 0.25 mm of the dorsal column where it may preferentially activate larger fibers traveling in a longitudinal direction [10]. Therefore, the thickness of the dorsal CSF layer is the single most important determinant of stimulation efficacy [11]. Thinner dorsal CSF results in efficient dorsal column stimulation whereas larger dorsal CSF results in greater current dispersion and preferential stimulation of dorsal root fibers at dorsal root entry zones. Stimulation of the dorsal roots, many of which are proprioceptive and involved in segmental motor reflexes, is thought to be responsible for uncomfortable stimulation experienced at the discomfort threshold [10].

# **Clinical Considerations**

# Evidence of Efficacy

SCS is currently approved by the U.S. Food and Drug Administration (FDA) for chronic pain of the trunk and limbs, pain from failed back surgery syndrome (FBSS), and intractable low back pain. SCS has been used "off label" for a variety of painful neuropathic conditions, as well as vascular and visceral pain states, with diverse applications ranging from vulvodynia to cervicalgia. The nature of implantable technology makes the design of placebo-based and randomized controlled trials inherently difficult to complete. Regardless, there is strong evidence to support the use of SCS in its most common applications in the United States, FBSS and complex regional pain syndrome (CRPS).

In 2000, Kemler and colleagues [12] completed the only randomized controlled trial to date on CRPS patients. They randomly assigned 54 patients with chronic, refractory CRPS (having failed surgical sympathectomy) into two groups: SCS and physical therapy (PT) or PT alone. A 2:1 randomization ratio was chosen, ultimately resulting in 36 patients in the SCS group (active treatment) and 18 in the PT group (active control). Of the 36 patients assigned to the intent-to-treat SCS group, 24 had a successful trial and underwent subsequent system implantation. All patients were assessed at 1, 3, and 6 months and evaluated on a variety of measures including pain (visual analogue scale [VAS], McGill Pain Questionnaire), global perceived effect (7-point scale), and quality of life (Sickness Impact Profile and Nottingham Health Profile). At 6-month follow-up, the 36 patients in the active treatment group (including those who did not have a successful trial or implant, as this was an intent-to-treat analysis study) had a statistically significant (P<0.001) mean decrease in VAS of 2.4 cm compared to an increase of 0.2 cm in the active control group. When only the data of the subgroup that had an implant were analyzed, an even more robust mean decrease in VAS of 3.6 cm was noted. The SCS group also had significantly higher ratings of "much improved" on the global perceived effect measure. These patients were followed up at yearly intervals up to 5 years. At 2 years, the SCS group continued to have a statistically significant (P < 0.001) mean decrease in VAS of 2.1 cm compared to 0.0 cm for the PT-alone group [13]. Further, 43% of those in the SCS group continued to rate themselves as "much improved" compared with only 6% in the PT-alone group (P < 0.001). At 5-year follow-up there was no statistical difference in any of the measures [14]. However, an as-treated analysis of the data revealed a mean decrease in VAS scores of 2.5 cm for the SCS group compared to 1 cm for the PT group (P= 0.06). The "much improved" subscale of the global perceived effect remained significantly improved in the SCS group (P=0.02) and "18 (90%) of 20 patients with an implant indicated that they had positively responded to the treatment, and 19 patients (95%) reported that they would undergo the treatment again for the same result" [14]. A 2004 prospective study by Forouzanfar and associates [15] evaluated 36 type I CRPS patients with implanted cervical or lumbar SCS systems over a 24-month period. In the cervical SCS group, over 50% had a 50% or greater decrease in VAS and 42% had a "much improved" rating in global perceived effect. In the lumbar SCS group, over 40% had a 50% or greater decrease in VAS and 42% had a

"much improved" rating in global perceived effect. In 2005, Harke et al. [16] completed a prospective study on 29 patients with type I CRPS, unrelieved by pain medication and PT and with only temporary positive response to sympathetic block (indicating sympathetically maintained pain). All patients had implantation with an SCS system, and at 12-month follow-up, deep pain had decreased from a mean of 10 cm to 1.7 cm and allodynia had essentially resolved (P<0.01). At follow-up of roughly 3 years, deep pain remained at a mean of 2 cm and overall 70% of patients had returned to work.

For FBSS, North et al. [17] performed the first prospective, randomized, controlled study in 2005, with 50 patients randomly assigned to receive SCS or reoperation. At a mean follow-up of about 3 years, 90% (45/50) of patients were available for evaluation. SCS was significantly more successful in terms of pain control than reoperation in that 47% of SCS patients versus 12% of reoperation patients reported 50% or greater pain relief (P < 0.01). Although changes in work status and activities of daily living did not differ between groups, those randomly assigned for SCS used significantly less narcotic analgesics. The following year, Kumar et al. [18] conducted a retrospective study on 220 FBSS patients seen over the course of 22 years in a multidisciplinary pain clinic. Of the 220 patients, 184 (84%) had implantation with an SCS system, with 132 (60%) of these patients having 50% or greater pain relief at a mean follow-up period of 97.6 months. The second prospective, randomized, controlled trial was released in 2007, the PROCESS (Prospective Randomized Controlled Multicenter Trial of the Effectiveness of Spinal Cord Stimulation) study [19]. This was a multicenter study of 100 patients randomly assigned to either conservative medical management (CMM) alone or CMM and SCS. They were followed for 12 months with a primary outcome measure of 50% or greater relief of leg pain. At 6 months, 48% of the CMM and SCS group met this goal while only 9% of patients in the CMM-alone group did (P < 0.001). At 12 months, 48% of the CMM and SCS group continued to meet this goal while 18% of the CMM-alone group did (P=0.03). As it has been shown to be efficacious, the next step is assessing cost-effectiveness.

#### Cost-Effectiveness

There is now substantial literature demonstrating the costeffectiveness of SCS, in carefully selected patients, for its two most common diagnoses, CRPS and FBSS. This has been shown not only in retrospective data analysis, but also upon follow-up at an individual level. North and colleagues [20] showed the latter in 2007 when they conducted a costutility evaluation and follow-up on 42 patients about 3 years after their initial enrollment in a randomized controlled crossover trial evaluating SCS versus reoperation for FBSS. When looking at treated-as-intended patients, the cost was \$48,357 for SCS versus \$105,928 for reoperation.

Simpson and colleagues [21] conducted a systematic review and economic evaluation of SCS in a variety of conditions in 2009. Their findings showed support for the cost-effectiveness of SCS in a variety of neuropathic and ischemic conditions, with the strongest economic profile when SCS was used instead of coronary artery bypass grafting or percutaneous coronary intervention in patients with refractory angina. In 2010, Kemler and colleagues [22...] used a decision analytic model to evaluate the costeffectiveness of SCS over a 15-year timeframe comparing CMM alone to CMM and SCS in patients with CRPS using data from the United Kingdom (UK) National Health Services. They showed that "the incremental costeffectiveness of SCS compared with CMM was £3562 per QALY (quality-adjusted life-year)" and that "despite their initial increased expense.... SCS is cost-effective as an adjunct" [22...]. Also in 2010, Taylor and colleagues [23...] used a decision analytic model to evaluate the costeffectiveness of SCS compared to CMM (SCS vs CMM) and SCS compared to reoperation in patients with FBSS. They studied a UK population as well, using details from the 2008 National Institute of Health and Clinical Excellence analysis on treatments in FBSS. They found "incremental cost-effectiveness of SCS compared with CMM was £5624 per QALY" and "compared with reoperation, the incremental cost-effectiveness of SCS was £6392 per quality-adjusted life year." They concluded, "SCS is cost effective both as an adjunct to CMM and as an alternative to reoperation." Indeed, the National Institute for Health and Clinical Excellence in the UK published new guidance in October 2008 approving the use of SCS for the treatment of chronic neuropathic pain [24]. None of the previously mentioned studies included patients on workers' compensation. SCS in this population was the subject of a recent 2011 study by Hollingworth et al. [25]. Unlike in all other patient groups studied, SCS was not found to be costeffective in patients on workers' compensation.

# **Clinical Overview**

# Patient Selection

After it has been determined the patient has a condition amenable to SCS based on history, physical examination, and radiographic review, a formal psychiatric/ psychological evaluation should follow to provide guidance of the appropriateness of the patient for SCS. A full review of psychological dimensions to consider is beyond the scope of this text. However, several areas are essential to mention. The patient's understanding of the procedure, realistic expectation of pain relief, and ability to follow directions are likely to be evident from interactions with the pain practitioner. Equally important is documentation of the absence of active substance abuse, psychosis, pervasive axis II (antisocial personality disorder, borderline personality disorder) traits, malingering, somatoform disorders, or severe uncontrolled mood/anxiety disorders. Although this evaluation can certainly provide further insight into the patient's mental state, it should be considered another tool in evaluating appropriateness rather than a dictum. Often times, the psychiatrist/psychologist will have only one encounter with the patient, compared to the longitudinal relationship developed between the patient and pain practitioner. Indeed, a 40-year literature review by North and Shipley assessing "psychological predictors" concluded, "We lack sufficient information to predict SCS outcome from the result of a pretreatment psychological evaluation, but SCS, as is the case for every interventional pain treatment, is reserved for patients with no evident unresolved major psychiatric co-morbidity" [26].

# **Risks and Complications**

Although SCS provides a relatively safe, reversible, and nondestructive option to treat pain, it is not without risks. Clinicians who utilize SCS must be properly trained, and prepared to handle the potential complications. Potential problems range from minor to lifethreatening, and may occur intraoperatively, in the early postoperative period, or several months later. Potential intraoperative risks include direct damage to the neuraxial structures (including dural puncture), unpleasant stimulation, bleeding, and those risks inherent to the stress of surgery and anesthesia. In the early postoperative period, additional risks include infection, wound dehiscence, fluid collection (eg, seroma, hematoma, and hygroma), increased pain, and poor wound healing. Over time, the patient may experience diminished effective coverage, unpleasant sensations, and hardware failure. It is reassuring to realize that most of these complications are typically easily managed and without long-term sequelae. Nevertheless, these complications must be recognized and addressed promptly.

# Frequency of Complications

Our understanding of the frequency of SCS-associated complications is derived from studies of vastly varying strength. Prospective studies assessing adverse outcomes are limited; therefore, the data for complication rates are generally extrapolated. Overall complication rates are reported at about 32% to 38% [13, 19, 27, 28]. However, most of these complications are relatively minor. Most evidence is derived from studies in which SCS is used for FBSS or CRPS. A systematic review by Turner and colleagues [27] revealed an average overall adverse occurrence rate of 34.3%. Complications included infection (4.6%), surgical site pain (5.8%), biological (eg, dural puncture; 2.5%), equipment failure (10.2%), system revision (23.1%), and system removal (11%). System revision, the most common adverse event, was most often secondary to lead migration, which is often cited as the most common mechanical complication of SCS. A literature review by Cameron [28] summarized the reported complications from a data set of 2,972 patients. An overall complication rate of 36.2% was found. Issues stemming from lead migration or breakage were, again, the most frequent (22.3%). Other complication rates were generally similar, or less frequent than those in the Turner review.

In 2004, Kemler et al. [13] published data from a 24month follow-up of a randomized controlled trial looking at the efficacy of SCS for CRPS. Overall complications were noted in 38% (9/24) of patients. Side effects, consisting primarily of painful stimulation and surgical site pain, were noted in all patients to some degree. The authors concluded that because SCS is a lifelong therapy, it must be recognized that the complication rate drops significantly 1 year after implantation.

A more recent randomized control trial by Kumar et al. [19] that assessed the efficacy of SCS versus CMM for FBSS at 12 months looked secondarily at adverse events. Of the 87 patients who underwent a trial and/ or lead implant, 27 (32%) experienced an adverse event. Hardware and technical events (including poor coverage and dysesthesia) accounted for 25%. Interestingly, while lead migration remained the most common complication (occurring in 10% of patients), the rate of lead fracture was noted to be 2%, a dramatically lower incidence than older data. This may relate to improvements in lead manufacturing technology. Biological events (infection, fluid collection, and pain at site) totaled 19% of all complications, with infections occurring in 8% of patients.

Finally, a retrospective review by the Cleveland Clinic Foundation of 289 patients who had undergone SCS implantation found 43.5% of patients required system revision or removal. The most common reason for reoperation was inadequate pain relief. In line with the aforementioned evidence, lead complications were the most common (31.1%). Surprisingly, surgically implanted paddle leads had higher incidences of lead migration, lead fracture, and infection [29].

#### Infection

The risk of infection exists for any surgical procedure, including SCS. While the risk of life-threatening infection from SCS is rare [30], certain populations have been identified to be at an increased risk for surgical site infections. These include diabetics, smokers, the obese, the immunocompromised, and patients with rheumatoid arthritis [31-34]. In addition to standard, meticulous surgical technique, special planning should include the consideration of methicillin-resistant Staphylococcus aureus (MRSA) screening, antibiotic selection, and possible consultation with a specialist in infectious diseases. Studies directly investigating a benefit of preoperative antibiotics for SCS are lacking. However, their use is strongly supported for implantable cardioverter-defibrillator (ICD) implants [35, 36]. Because ICD implants share a similar degree of invasiveness, these data provide some guidance for SCS. In line with previous recommendations, the authors routinely administer intravenous antibiotics 30 to 60 min before incision [19, 37]. Though outcome data are lacking, it is the authors' preference to prescribe a 2- to 3-day postoperative course of prophylactic oral antibiotics. Also, the use of chlorhexidine for skin preparation before surgical incision has been shown to decrease bacterial counts and risk of infection [38]. Finally, it is also prudent to minimize tissue trauma by using careful, nonstrangulating approximation during wound closure and limited use of electrocautery [39•].

#### Lead Migration

As noted, lead migration is the most common complication encountered with SCS systems. Strategies have been identified to reduce the occurrence of lead migration for SCS implantation [40, 41]. In general, it should be appreciated that the propensity of a lead to migrate is influenced by its position in the body. Given that significantly more movement occurs in the cervical spine versus the thoracic or lumbar spine, a lead placed in the cervical spine is more likely to migrate [42]. The use of at least one strain relief lead coil to minimize the strain placed during spine flexion has been recommended by two panels of experts [40, 41]. A computerized model by Henderson et al. [41] revealed a 9-cm increase in distance between the implantable pulse generator (IPG) and anchor during spine flexion. This also reinforces the importance of appropriate lead length selection. Finally, the IPG location also weighs on the overall strain of the lead. Controversial computerized biomechanical models demonstrated that an abdominal site (for thoracolumbar leads) and a midaxillary site (for cervical leads) were optimal for strain relief [41, 42]. However, factors such as appropriate anchoring, strain relief, and patient education may be more important than IPG location. More recently, an abstract described using a single paraspinal incision for both lead and IPG in 26 patients, none of whom experienced lead migration [43].

## Fluid Collection

A fluid collection, including a hematoma, seroma, or abscess, can develop after any surgical procedure. The presence of an infected fluid collection in the spinal space can lead to rapid morbidity and mortality. Procedures near the spinal cord additionally confer the risk of a hygroma. The management strategies for these adverse events are beyond the scope of this discussion. However, it should be reiterated that a respect for their possibility and a solid grasp of the recognition and appropriate management for each must be understood. One can reduce risks by identifying patients at increased risk of infection and bleeding, appropriately timing perioperative medications, and using careful surgical techniques, including making the generator pocket size as small as possible to accommodate the generator. An advanced appreciation of fluoroscopy decreases unnecessary surgical maneuvers, and ultimately decreases poor outcomes in this area.

#### Neurological Events

Risk of direct trauma to neuraxial structures exists with any SCS procedure, and can range from a transient paresthesia to quadriplegia [44]. The individual patient serves as our best monitor, and minimal sedation should be utilized at any stage where leads are placed or manipulated. It is mandatory to utilize every tool (including patient feedback, fluoroscopy, and tactile feedback) during these procedures to minimize adverse events. The most common neurological event is a dural puncture. Estimates vary widely from 0.5% to 6% [45, 46]. Risk factors for a dural puncture include patient movement, previous surgery at the site of needle placement, obesity, a calcified ligamentum flavum, and spinal stenosis [39•]. A dural puncture carries the risk of a hygroma, post-dural puncture headache (PDPH), cranial nerve VI palsy, and interrupted stimulation. If a dural puncture occurs, a careful decision must be made regarding the appropriate next step. Management varies depending on patient and physician preferences, proximity of patient to medical care, whether the dural puncture occurred during a trial or during lead implant, and physician experience. It is not uncommon for a PDPH to be refractory to all conservative treatments. The placement of a blood patch after implant may involve the risk of component damage, hypothetically increased infection risk, and potential stimulation disruption.

#### The Future of Spinal Cord Stimulation

## Technological Improvements

Neurostimulation is a rapidly evolving field. Fueled by market projections of demand, coupled with multiple competitive industry players and active research programs, technological innovations in SCS have resulted in improved products. Improvements have included better, less fractureprone leads and smaller, more powerful rechargeable IPGs. Recently, mechanical anchors have been developed not only to provide better holding force, but also to bypass the step of tying the anchor to the lead and to potentially limit the leading cause of SCS complications, lead migration. Two of the three current device manufacturers have developed new mechanical anchors over the past 2 years. Previously, a mechanical anchor developed in 1998 by the third manufacturer was the only one available. They have recently filed with the FDA to improve upon their original design because it has been associated with lead damage [47]. Along the same lines, leads that stretch may be under development by St. Jude Medical (Plano, TX) to mitigate the risk of lead migration with changes of body posture. Changes in body posture also negatively influence patients' experiences with SCS because too little or too much current is perceived as a result of varying dorsal CSF depth with changes in body position. Based on experience with triaxial accelerometers in measuring free-living physical activity [48], Medtronic (Minneapolis, MN) is conducting clinical trials on a position-adaptive SCS system. FDA approval is being sought. Medtronic also has the only leads approved with magnetic resonance imaging (MRI) of the head at 1.5 T as long as they are implanted in the neuraxis. There is much interest in expanding MRI compatibility of SCS as well as compatibility with ICDs and pacemakers. Plans are underway by Boston Scientific (Valencia, CA) to have more electrode contacts per lead (a 16-contact lead has just been approved by the FDA) with potential corresponding increases in generator contact sites. Additionally, there is heightened interest in high-frequency stimulation with the possibility of obtaining paresthesia-free analgesia [49•]. A newcomer to the field (Nevro Corp, Menlo Park, CA) has gained CE (Conformité Européenne) marking and is currently marketed in Europe, where preliminary experience suggests improved back pain coverage without paresthesia while using ultra high-frequency stimulation (around 10,000 Hz).

## **Evolving Clinical Applications**

As SCS use expands, there are accumulating suggestions that there may be efficacy outside of pain control. Krames and Mousad [50] described a case in which a patient

initially implanted for the pain of irritable bowel syndrome also had a reduction in diarrheal episodes. In Europe, SCS has greater cardiovascular uses, and one long-term outcome study in those with severe peripheral vascular disease resulting in critical limb ischemia showed that those implanted with SCS had statistically significant improved limb survival at 1 year [51]. Eddicks et al. [52] reported functional and symptom improvement using SCS for refractory angina in a placebo-controlled randomized study. Interestingly, statistically significant improvements were demonstrated in the subthreshold arm. However, a more recent study showed no significant difference with subthreshold stimulation for angina [53]. Nevertheless, the possibility of effective SCS without paresthesia will significantly shift our understanding and approach to utilizing SCS [49•, 52]. Kapural and associates [54] implanted a patient with CRPS type 1 and type 2 diabetes mellitus. Successful implantation led to not only a significant decrease in pain, but also a 50% decrease in insulin requirements [54]; however, no other such reports have appeared in the literature despite common use of SCS in diabetic patients. Although pain certainly exacerbates a myriad of medical conditions, the potential positive benefits of SCS do not occur only in those with pain relief. Buonocore et al. [55] reported on a case of FBSS where the patient had minimal pain relief, but significant improvement in leg muscle strength and gait after implantation. With innovation of stimulation parameters, SCS has also been shown to "retrain" the spinal cord, allowing for remarkable neurological recovery. A recent case in The Lancet showed that a 23-year-old man with complete paraplegia regained movement in his lower extremities and was able to stand after 170 250-minute sessions of stimulation over the course of 26 months [56•]. Finally, the evidence in support of SCS for chronic visceral pain appears to be growing [57, 58].

# Potential for Modality Overuse

The field of SCS is relatively new and continually evolving. The indications and potential applicability of SCS continue to expand; however, clinicians have to weigh the evidence carefully and refrain from aggressive applications in the absence of clear literature support. Marginal indications for SCS should be best approached as part of a clinical study setting. SCS has shown tremendous expanse in clinical use due to its safety, efficacy, and robust remuneration for trials in the office setting. However, these same positives make it susceptible to overuse. Clinician zeal to help patients in dire pain conditions has occasionally resulted in questionable applications of the technology. A very low implant-to-trials ratio may prompt some to question other motives for applying the technology. Currently, the North American Neuromodulation Society (NANS) recommends no more than 16 contacts used during any in-office SCS trial.

## Conclusions

SCS has evolved into a safe and effective tool for the treatment of several chronic pain conditions. While relatively safe, reversible, and nondestructive, the use of SCS is not risk-free and should be utilized only by those with appropriate training. From our expanding appreciation of its mechanisms of action, clinical applications, and system technology, SCS will likely continue to evolve in terms of indication and efficacy.

## Disclosures

A. K. Compton: none; B. Shah: none. Dr. Salim M. Hayek has disclosed the following information about his relationship with Boston Scientific: board membership, consultancy, received grants/has grants pending, received honoraria, received payment for development of educational presentations, and received travel expense compensation.

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