Spinal Stimulation for Pain: Future Applications

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Abstract With continuous progress and rapid technological advancement of neuromodulation it is conceivable that within next decade or so, our approach to the electrical stimulation of the spinal cord used in treatment of chronic pain will change radically. The currently used spinal cord stimulation (SCS), with its procedural invasiveness, bulky devices, simplistic stimulation paradigms, and frustrating decline in effectiveness over time will be replaced by much more refined and individually tailored modality. Better understanding of underlying mechanism of action will allow us to use SCS in a more rational way, selecting patient-specific targets and techniques that properly fit each patient with chronic pain based on pain characteristics, distribution, and cause. Based on the information available today, this article will summarize emerging applications of SCS in the treatment of pain and theorize on further developments that may be introduced in the foreseeable future. An overview of clinical and technological innovations will serve as a basis for better understanding of SCS landscape for the next several years.

Keywords High-frequency stimulation · Dorsal root ganglion · Subcutaneous stimulation · Feedback loop · Nanotechnology

It is exceedingly difficult to make predictions,
particularly about the future.
Niels Bohr (1885–1962)

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Introduction

Epidural electrical stimulation of the dorsal columns of spinal cord [usually referred to as spinal cord stimulation (SCS)] is, today, an arguably most commonly performed surgical intervention for the treatment of chronic pain. Since its inception in 1967 by Shealy et al. [1–3], SCS evolved in both conceptual and practical dimensions. The systems became more complex, and the choice of individual components gave clinicians many options with different degrees of invasiveness, selectivity, longevity, and adjustability.

The number of clinical indications for SCS remained relatively stable over the years—the dominant categories remain chronic radiculopathy (such as in failed back surgery syndrome), complex regional pain syndromes (type 1 and 2), and pain due to ischemia (coronary or in extremities) [2–5]. Some indications have faded away (cancer pain, pain associated with spasticity, postherpetic neuralgia, brachial plexus avulsion, phantom pain after amputations) [3, 6], while others seem to be growing (low back pain, headaches) [7, 8]. Radiofrequency-coupled systems became replaced by implantable pulse generators, and simple electrode combinations became supplemented by complex multicontact configurations. Within the last decade, there has been the introduction of rechargeable generators, multicolumn electrode leads, independent current delivery, percutaneously insertable paddle leads, long-range telemetry, self-adjustable stimulation, and magnetic resonance imaging (MRI) compatibility—and this is only a partial list of major innovations.

If such an exponential pace of innovative trend continues, one may expect even more revolutionary developments within a short period of time. But as (in the absence of crystal ball) any futuristic predictions have little validity, this article will be dedicated to those recent developments that are likely to enjoy widespread acceptance once the neuromodulation community-at-large becomes convinced in their benefits and

reliability. The main emphasis will be placed on new stimulation paradigms, new targets, and new devices.

New Stimulation Paradigms

There are several aspects of SCS that have remained essentially unchanged since the modality was introduced almost 50 years ago. Electrical stimulation that is used today is associated with the production of paresthesias and is delivered on continuous basis in a regular (rhythmic/isochronous) fashion within a relatively narrow frequency range. All of these elements (paresthesia production, continuous stimulation, regular pattern, low frequency) have been challenged as requisites of pain relieving stimulation.

One suggestion, for example, was to replace conventional synchronous stimulation with a stochastic pattern in the hope that such irregular stimuli will be more effective in suppressing signal transmission in the central nervous system and perhaps prevent development of tolerance to stimulation [9]. It appears that the use of stochastic stimulation pattern so far has not been tested in laboratory or clinical settings.

What was tested—and quite successfully—is paresthesia-free stimulation. In the absence of paresthesias, SCS within the clinically accepted frequency range (1–200 Hz) does not produce any pain relief. This known phenomenon necessitates intraoperative paresthesia mapping and requires interaction with patients during the electrode implantation procedure. However, once the stimulation frequency is increased, paresthesias disappear, whereas pain relief remains or even improves [10]. This phenomenon was observed when the stimulation frequency was increased to 10,000 Hz with 30- μ s stimulation pulses and the current ranging from 0.5 to 5.0 mA [10]. Using this concept, 10-kHz stimulation was introduced into clinical practice several years ago, and is currently used outside of the USA (mainly in Europe and Australia). It appears that 10-kHz stimulation results in significant pain reduction both in lower back area and in the extremities [11], and that this beneficial effect continues during long-term follow-up. The results of a prospective, open-label, multicenter, European study indicated that 70 % of treated patients achieved significant and sustained low back pain and leg pain relief during a 6-month follow-up [11]. To date, a 2-year follow-up on this cohort of patients treated with high-frequency SCS has been published [12], and the results were consistent: 60 % of patients reported >50 % reduction from baseline back pain and 71 % reported >50 % reduction in leg pain [12]. In addition to this, a smaller-scale cohort study (24 patients), in a short-term trial, investigated differences with conventional and high-frequency (10 kHz) SCS using an external stimulator connected to epidural SCS electrode leads [10]. Here, once again, high-frequency stimulation did not elicit paresthesias, but resulted in a significant reduction of

both back pain and overall pain; this reduction was much more pronounced in the high-frequency trial stage than in a conventional trial.

Interestingly, laboratory evidence suggests that both conventional- and high-frequency SCS suppress peripheral nociception. In a rat sciatic nerve ligation model both frequencies (1 kHz and 10 kHz) were effective, but the higher frequency was more effective in terms of onset of effect and its magnitude [9]. Clinical experience, however, showed that 5-kHz stimulation did not result in desired effects [13], whereas 10-kHz stimulation does relieve pain, but only at a very specific position of electrode contacts [11, 12]. The next steps in 10-kHz SCS will be to obtain regulatory approval in the USA based on an ongoing noninferiority study (NCT01609972) [14] and then test it in a variety of clinical conditions, perhaps defining those indications and those specific patient characteristics that are either unresponsive to conventional, lower-frequency SCS, or where a partial response makes more complete pain relief desirable. Recent experimental finding of hyperalgesia suppression [9] may translate into use of high-frequency SCS in allodynia and other neuropathic pain conditions.

An expected step in high-frequency SCS technological development will be the creation of longer-lasting batteries, as current devices require daily or even twice-daily recharging owing to the high consumption of power.

Another example of an “unconventional” stimulation paradigm is the use of a burst stimulation pattern. This type of stimulation delivers a short train of closely spaced high-frequency stimuli to the spinal cord. Each train of impulses includes five 1 ms-wide spikes with a 1-ms spike interval at a rate of 500/s (500-Hz spike mode). These trains are delivered 40 times per second, resulting in a 40-Hz burst mode. The rationale for the burst mode was the dual-firing property of the human thalamic cells that can fire in tonic and burst modes, and the earlier discovery of burst-firing being a more powerful activator of brain cortex [15].

The initial cohort of 9 patients reported in 2009 included 3 patients with paddle electrodes implanted at the upper cervical level and 6 patients with a low thoracic level of implantation [16]. Subsequently, a prospective comparative study of tonic and burst stimulation was done on 12 patients (4 cervical and 8 thoracic) [15], showing that although paresthesias during burst stimulation were present in only 17 % of patients (as opposed to 92 % of patients during tonic stimulation), the pain suppression was significantly better during burst stimulation. The most recent study of 15 patients (1 cervical, 14 thoracic) [17] investigated the effects of burst stimulation in a double-blind, placebo-controlled way and confirmed the ability of burst SCS to suppress pain in a statistically significant and clinically relevant way for limb pain, back pain, and pain in general. This entire concept of double-blind, placebo-controlled study in SCS was not feasible in the past as

paresthesias allow study participants to immediately differentiate placebo *versus* stimulation, but with the tested burst mode settings, the incidence of paresthesias did not differ between placebo and burst stimulation. Moreover, the burst SCS was able to suppress back pain in stimulated patients in the same order of magnitude as pain in extremities, similar to what is seen in high-frequency (10 kHz) SCS, which is also paresthesia free.

Currently, burst SCS is a subject of a prospective, multicenter, randomized, controlled trial (NCT2011983) [18]. Its results will determine the prospects of wide utilization of the burst stimulation paradigms, as well as the need in updating SCS hardware to allow for burst SCS mode.

The mechanism of action of burst stimulation was investigated with source-localized electroencephalogram in 5 patients who were imaged under 4 different conditions (baseline, tonic SCS, burst SCS, and placebo) [17]. Burst stimulation was found to have “a dramatically different effect on the attention to pain and pain changes”—resembling what is seen in cingulotomy—but this effect was not observed in conventional (tonic) stimulation [17], allowing investigators to postulate possible difference in mechanisms of pain suppression. They hypothesized that tonic SCS is likely to modulate primarily lateral pain system that projects to primary sensorimotor, posterior insular, and secondary somatosensory cortical fields, whereas burst SCS, in addition to the lateral pain system, also activates a medial (affective/attention) pain system that is mediated via anterior cingulate cortex [17].

So, both these approaches—high-frequency SCS at 10 kHz and burst SCS—are likely to change the way we use SCS today. Elimination of paresthesias by itself is very attractive; there is an ongoing trial testing the parameters of subthreshold stimulation and the time course of pain relief (NCT1976598) [19]. The absence of paresthesias and better success in the treatment of axial pain (e.g., low back pain, interscapular/upper back pain, neck pain) may change the current patient selection (which favors patients with pain in extremities), the process of patient preparation (readying them for paresthesias), the intraoperative trial procedure (looking for pain relief, rather than paresthesia coverage), and postimplantation programming (which relies on the patient’s ability to feel stimulation in correct body areas as a sign of device proper functioning). Adding stochastic patterns to the stimulation programming may further improve clinical results and eliminate some of the long-term tolerance issues.

Closed-Loop Stimulation

The stimulation settings of today SCS systems are set by a clinician during initial and subsequent programming sessions. In the past, more primitive pulse generators could accommodate only one program, and the patient adjustments of

stimulation were limited to an increase or decrease of the stimulation amplitude. Currently marketed devices give patients more freedom, and most devices today have an option of changing not only the amplitude, but also the rest of stimulation parameters through a choice of pre-set programs and within pre-set ranges. Digital displays of current patient controllers provide feedback about the settings that are being used. Whenever the stimulation requirements change, either because pain pattern changes as a result of activity, time of day, medication wear-off, or because of the change in stimulation perception as frequently observed with changes in body position, the patients have to use their remote controls to make proper adjustments.

This issue was partially solved with the introduction of so-called adaptive stimulation that employs a built-in accelerometer capable of detecting the body position [20]. In a randomized, prospective, multicenter study this feature allowed the patients to significantly reduce the number of manual adjustments of the stimulation amplitude when position-adaptive stimulation was turned on compared with when it was not available [20]. In addition to this, there were several other functional improvements with position-adaptive stimulation; these included improved comfort during position changes, improved activity, and improved sleep [20]. Another study testing adaptive stimulation with surgical paddle leads is currently underway (NCT1874899) [21].

But the feedback of the patient’s position compensates only the position-dependent changes in quality and intensity of stimulation; it has nothing to do with the level or location of pain. For this, there is a possibility that real-time recording from the spinal cord may not only indicate presence of nociceptive signals, but also objectively define somatotopy of SCS. The presence and details of compound action potentials may be revealed by recording from the implanted epidural stimulation electrodes. This has already been done in animals [22] and in a small group of SCS patients [23]. One of the findings suggested a correlation between depression in evoked compound action potentials (ECAP) and thresholds for stimulation [22], which may help in finding the best position for SCS electrodes, but—most remarkably—the *in vivo* recordings in patients undergoing stimulation revealed a correlation between A β ECAP amplitude and the degree of coverage of the painful area [23]. This amplitude of A β ECAP is a measure of the level of neuronal recruitment, which may become a feedback parameter for continuous optimization of neuromodulation parameters [23].

The concept seems to be far-fetched, but current technological advancements make it feasible. As the matter of fact, a miniaturized digital wireless system for closed loop inhibition of nociceptive signals has already been developed; in a rat model, such a system was used to record information from wide dynamic-range neurons of the dorsal horn of the spinal cord in response to graded mechanical stimuli administered to

the animal's lower extremity [24]. The signals, identified as a sign of nociception, were then used to trigger automatically a deep brain stimulation electrode implanted into the descending inhibitory centers of the midbrain (the periaqueductal gray matter). Such real-time data acquisition, processing, and transmission created a closed-loop mechanism for pain-relieving stimulation [24].

So, it is indeed conceivable that within the next decade we will have much smarter SCS devices capable not only of sensing pain, but also of determining the effectiveness of stimulation and adjusting the stimulation parameters as needed, in a real-time regimen.

New Stimulation Targets

Classic spinal cord stimulation is targeted at the dorsal columns with electrodes positioned in the posterior epidural space. This location was chosen based on a trial-and-error type of approach. The first SCS device was placed in the subarachnoid space [1, 2]; later there were attempts to stimulate not only the dorsal, but also the lateral and ventral, surface of the cord [25, 26], but the predictability and safety of the dorsal epidural space prevailed and this location became generally accepted. In addition to this, the dorsal columns exhibited a sufficiently wide therapeutic window (the range between onset of paresthesia and onset of discomfort) to keep SCS clinically feasible.

Today, most electrode leads are implanted at a lower thoracic level (to cover the lower extremities and lower back area), at the upper thoracic level (to cover the chest wall), and at the cervical level (to cover the neck and upper extremities). New electrode lead options (see below) have opened the door for new combinations of electrode polarities, and so on, but despite these innovations, the long-term effectiveness of SCS and the number of failed SCS trials remain problematic. To overcome this issue—and to expand to new indications—multiple new stimulation targets have been introduced.

One of them is the dorsal root ganglion (DRG)—another intraspinal structure that may be reached via a trans-spinal approach. Although technically DRG represents a component of the peripheral nervous system, its anatomical proximity to the spinal canal is likely to keep DRG stimulation grouped together with SCS in a “spinal stimulation” approach. A cluster of bodies of the primary sensory neurons, the DRG is encased by the dura and located inside each intervertebral foramen. In the past, the DRG was the target of destructive surgical intervention, so-called ganglionectomy, which was completely abandoned, partially because of the success of SCS, which became the procedure of choice for patients with failed back surgery syndrome and persistent radiculopathy. However, there are many advantages in targeting DRG with electrical stimulation, not only because it has been implicated

in the development and maintenance of chronic pain, but also because it is relatively immobile owing to its anatomic location and is surrounded by a much thinner (compared with the spinal cord) layer of cerebrospinal fluid.

DRG stimulation was the subject of a recent multicenter, prospective study [27]; of 51 patients screened, 39 obtained >50 % improvement in pain levels during the trial, 32 of whom proceeded with permanent implantation and were followed up for 6 months. Of these, >50 % reduction in pain in the back, leg, and foot 6 months after implantation was observed in 57 %, 70 %, and 89 % of patients, respectively. The ability to capture discrete painful areas (such as feet) and stable paresthesia intensities across the body positions were additional benefits encountered in the study [27].

A prospective, randomized, controlled study of DRG stimulation is currently underway in multiple centers in the USA (NCT1923985) [28]. It evaluates the safety and effectiveness of the dedicated DRG stimulation system for the treatment of chronic lower limb pain in persons diagnosed with complex regional pain syndrome or peripheral causalgia compared with conventional SCS in terms of ≥ 50 % pain relief and incidence of stimulation-related neurological deficits [28].

Another potential target for the treatment of pain is the uppermost part of the spinal cord—the part that has more to do with facial and occipital representation, rather than the trunk and extremities, the classic locations for pain syndromes for which SCS is approved and recommended. High cervical SCS has been used for the treatment of cluster headaches [8], a condition that has recently been treated with deep brain stimulation, peripheral nerve stimulation targeting occipital nerves and trigeminal nerve branches, and sphenopalatine ganglion stimulation. In 7 patients, a standard percutaneous SCS electrode was inserted up to the top of cervical spine slightly off midline, ipsilateral to the side of pain; all patients showed significant improvement in terms of the frequency, duration, and intensity of the attacks, as well as other scores of functional and mental impairment [8]. The mechanism of SCS action in the treatment of cluster headaches is not completely understood; possible explanations include attenuation of hyperexcitable multimodal wide dynamic-range neurons, increased release of gamma-aminobutyric acid (GABA) and acetylcholine, and activation of supraspinal pain-modulating centers [8]. Different from other neuromodulation modalities that may take up to several months to produce improvement, high cervical SCS resulted in immediate improvement in symptoms. This immediacy of effect, along with familiarity with the procedure and robustness of the improvement similar to other modalities, may make cervical SCS a preferred approach for this medically intractable group of patients.

However, a much more common SCS indication is pain in the lower back, and this condition has traditionally been considered less responsive to SCS than pain in the extremities. Here, the research is moving in several directions simultaneously—

and there is a hope that within the next few years our success in relieving lower back pain will be markedly better.

One direction is in use of multicolumn stimulation. With rigorous and thoughtful programming it is possible to cover the lower back with paresthesias [7]. To prove this, an international, multicenter, prospective, randomized study is now investigating the usefulness of multicolumn implantable leads for predominant low back pain (NCT01697358) [29, 30]. The main study objective is to compare proportion of patients with ≥ 50 % reduction in low back pain intensity 6 months after randomization (at a 1:1 ratio) to either optimal medical management or SCS with a surgical multicolumn lead plus the same optimal medical management.

Another approach is similar to that mentioned earlier—different stimulation frequencies. In addition to studies of the high-frequency [10 kHz] approach, which appears to be more effective for back pain relief, there is another study (NCT1750229) [31] that focuses on 4 different frequencies (3 active and 1 sham) in a randomized, controlled, double-blind, crossover fashion, with the enrollment goal of 60 patients diagnosed with failed back surgery syndrome.

Finally, the alternative to conventional SCS is a combination of SCS and peripheral (subcutaneous) neurostimulation. The idea of combining these 2 approaches was conceived a long time ago, and I and others published our experience with what we called the “hybrid” neuromodulation approach [32, 33]. Subsequently, this concept was thoroughly investigated with a prospective study of the interaction between SCS and peripheral nerve field stimulation (PNFS) [34]. Twenty patients were asked to choose between SCS, PNFS, or a combination of both; in the second part of this study, another 20 patients were given a choice between separate SCS and PNFS, or a combination of both, with either electrode serving as the cathode and the other as the anode. The majority of patients in both parts of the study chose combined stimulation, with an overall success rate of 85–90 % in terms of axial pain relief. Interestingly, the most popular configuration among implanted patients was a combination of SCS with simultaneous SCS/PNFS use where PNFS served as the cathode [34].

Another interesting concept was recently presented through a retrospective study that evaluated the benefits of combined spinal cord and PNFS in a group of 40 patients followed up for 6 months after the implantation [35]. The study showed that so-called “triangular” stimulation, with the SCS lead set as an anode and the PNFS leads set as cathodes, was a preferred program type in >50 % of the patients [35].

To investigate this further, a multicenter, prospective, randomized study (NCT1990287) [36] is currently underway. It aims to compare the responder rate in SCS–PNFS *versus* SCS alone. In this study, a “responder” is defined as a patient who achieves a reduction of at least 30 % in pain in the back and legs from baseline, and does not increase pain-related medications.

Addition of novel targets will make SCS more robust: it will allow us to explore new indications and improve clinical outcomes in situations where current SCS is insufficient or ineffective. Having an open-minded approach and expanding SCS applications will strengthen SCS’s dominant role in the management of many categories of otherwise intractable pain.

Addition of Neurochemicals

The concept of using pure electrical neuromodulation for pain suppression is perhaps too mechanistic. The central nervous system is more than electrical impulses and connections, and a neurochemical component of pain generation and transmission should not be ignored. A recent review listed neurotransmitters involved in potential segmental mechanisms of SCS action [37]; these include serotonin and epinephrine (representing descending inhibition), GABA and acetylcholine (representing intrinsic inhibition). In addition to GABAergic, adrenergic, serotonergic, and cholinergic mechanisms, there is also an adenosine-dependent mechanism, and all these mechanisms present an opportunity for potentiation of SCS clinical effects.

Multiple medications delivered intrathecally have been tried—with varying degrees of success—in laboratory animals [37], but it appears that only 2 were used in clinical setting [38]. Intrathecal adenosine turned out to be “technically problematic” [38], but intrathecal baclofen, the GABA-B receptor agonist that is commonly used both orally and intrathecally for the treatment of spasticity, has been evaluated in a prospective fashion [38, 39]. Out of 48 patients who received an intrathecal baclofen bolus during SCS trial, 20 obtained a pain relief reduction of >50 %; of these, 7 were implanted with an intrathecal baclofen pump and SCS system [39]. After an average follow-up of 6 years, they continued to enjoy >50 % improvement in pain scores. Although the dose of baclofen had to be gradually increased over the years, the range of daily doses was 140–270 μg at the last follow-up [39].

Most neuromodulation practices already have patients who have both SCS and intrathecal drug delivery systems in place. Despite this, it appears that there are no studies that investigate interaction between intrathecal medications and electrical stimulation of the spinal cord. However, it is conceivable that in the future intrathecal drug infusions will be used not as a salvage-type alternative, but rather as an augmenting tool for those who either failed a SCS trial, lost SCS benefit, or achieved only partial improvement.

Hardware Improvement and Miniaturization

There is no doubt that the future of SCS will be enhanced by multiple technological advancements. Just recently, this field

witnessed several important developments, most of which were eloquently overviewed in an editorial summary “Spinal cord stimulation in 2020” [40]. These include the introduction of rechargeable pulse generators, tools for minimally invasive implantation of paddle-type electrodes, development of multicolumn stimulation with 3, 4, and 5 column paddle leads, and the ability to connect multiple electrodes (with up to 32 active contacts) to a single generator, to name just a few. Prior to these, there were technological innovations that gave us multicontact electrode arrays with 4, 8, and, most recently, 16 contacts on percutaneous leads and a variety of configurations for all kinds of surgical paddles, implantable generators with constant voltage and constant current output, independent power sources for each stimulating contact, and multi-programming options, and so on [40].

Not everything turned out to be meeting everyone’s expectations. A rechargeability feature, for example, resulted in a significant reduction in size of the implanted generators and concomitant increase in lifespan of the device (from 2–3 years to 8–10 years). But in a sizeable minority of patients, particularly the older ones, the burden of recharging was too high, and preference was given to nonrechargeable devices [41].

Similarly surprising was the finding that the much-touted (and more recently introduced) constant current mode of SCS was no better than the older constant voltage paradigm [42]. The next generation of SCS generators may have a switch that changes the stimulation mode from a constant current to a constant voltage (as is already possible for deep brain stimulation generators) in case the patient prefers one of them over the other.

Inevitably, the MRI compatibility of SCS devices will change over the next few years. It will allow SCS patients to undergo MRI and make SCS an option for those chronic pain sufferers who are expected to require multiple MRI studies and who were excluded from SCS studies in the past. New technologies have already resulted in the approval of MRI conditional status for the latest generation of generators and leads from one SCS manufacturer; the others are expected to follow suit over the next few years.

Finally, miniaturization of SCS devices will go beyond making narrower paddles and smaller generators. The latest iteration of an SCS system is embodied in a wirelessly powered microsize, multicontact neurostimulation device that contains the telemetry unit and energy receiver inside the lead itself [43]. This miniaturized device is inserted directly into the epidural space and does not require any extension cables; the power source is located in an external device that utilizes a high-frequency transmitter and may be worn on a belt around the patient’s waist. In preparation for future clinical applications, this miniaturized, wirelessly powered SCS lead was formally tested on several MRI devices and found to be ready for conditional MRI approval [43].

Previous Predictions

This is not the first paper to discuss future SCS applications. Over the last 50 years, the tone of the predictions has changed, and one can see a trend of such predictions over time. In the 1970s and 1980s, when SCS was struggling to gain legitimacy, the future appeared to be full of conclusive research projects, and large-scale clinical studies aimed to define the mechanism of action of SCS and come up with best SCS indications [44]. At the same time, there was the idea of using the closed-loop stimulation principle in the treatment of pain—a visionary idea that involved getting signals from the brain for administering electrical stimulation when pain arises [44].

In the early 2000s, the future of SCS was seen in moving SCS up in the treatment ladder of chronic pain management and in the discovery of new applications [4]—the future appeared bright and the role of SCS was seen as rapidly growing. The technological advances in multicontact arrays and multilead generators were expected to positively impact the clinical applications of SCS [5]. And at the end of the last decade, the future of SCS was seen in the combination of SCS with drug delivery and, once again, in closed-loop systems and biofeedback [3]. Some of these sentiments, including changes in stimulation paradigms and the development of a combined SCS/PNFS approach, were mentioned in a recent look at the future of PNS [45].

And then, most recently, there was, perhaps, the most sobering, albeit quite dystopic, prediction of an SCS future that took into consideration the economic crisis, a lower per person allocation of healthcare financing, a reduction in governmental research funding, and new taxes on device manufacturing [40]. With all these political, economic, and social forces, a concern about limited innovation and potential contraction of SCS was justifiably raised [40].

These issues cannot be ignored—and one may only hope that the tide will pass, the problems will be resolved, and optimism will prevail. The recent experience shows persistent enthusiasm among the neuromodulation community, SCS developers, and SCS users. And if SCS progress brings improvement in clinical outcome, better quality of life for our patients, and cost saving or at least cost stabilization, the future of SCS will remain bright.

Knowing what we know now, it appears that we still do not have enough evidence to bring SCS to the forefront of chronic pain management and to move it to a lower rung of the “pain treatment ladder”. Multiple technological advancements, including rechargeability, multitude of leads and configurations, miniaturization, MRI compatibility, and so forth, have expanded SCS applications, but did not result in dramatic improvements in treatment outcomes. And even though the cost-effectiveness of SCS has long been documented [46], the issue of high cost remains very concerning. It has been a long-time

project of mine to promote the development of a cheaper and simpler SCS device that would become “an entry option” that may be later upgraded to a more sophisticated device—not everyone needs a super-device packed with all possible features in the beginning of treatment. As the saying goes, in an ideal world, everyone would be driving a luxury car, but common sense dictates that before getting such a car, one should spend some time in a more straightforward and less valuable vehicle.

Conclusion

SCS is a dominant neuromodulation modality in the treatment of pain; it has a long history and plenty of documentation to support clinical effectiveness and safety. New technological and conceptual developments—new frequencies and stimulation paradigms, new devices and accessories, new targets, and new approaches—are expected to translate into better outcomes and improved quality of life. Wider choices available to neurosurgeons, anesthesiologists, and other neuromodulation practitioners, as well as an ability to tailor individually the treatment to each patient’s unique needs, are expected to maintain positive momentum in the growth and advancement of SCS.

Required Author Forms Disclosure forms provided by the author are available with the online version of this article.

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