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# Evolving Spinal Cord Stimulation Technologies and Clinical Implications in Chronic Pain Management

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## Abstract

**Purpose of Review** Spinal cord stimulation (SCS), based on the gate theory of nociception, has been shown to be effective in the management of chronic pain conditions. While early-generation technology offered many patients improvement in their pain and symptoms, limitations including paresthesia, dependence on mapping, decreased chronological efficacy, and inadequate coverage left many patients with persistent pain and overt therapeutic failure.

**Recent Findings** New advances in neuromodulation technology circumvent many of these previous limitations and offer patients improved pain relief and quality of life.

**Summary** In this review, an update on recent technological developments in the field of SCS and peripheral neuromodulation is presented with discussion on differentiating characteristics which may help guide applicability to individual patient needs.

**Keywords** Spinal cord stimulation · Neuromodulation · HF-10 · Dorsal root ganglion stimulation · Burst stimulation · Wireless spinal cord stimulation

## Introduction

As opioid use in chronic pain patients has risen to staggering levels and has led to increased rates of opioid use disorder and dependence in this population, increased clinical attention has been made to explore novel interventional techniques to better manage chronic pain conditions and reduce our reliance on opioid medications. Spinal cord stimulation (SCS), as a means to modulate central nociceptive transmission, via the gate control theory, has proven to be effective in the management of various chronic pain conditions and is indicated in patients with failed back syndrome, complex regional pain syndrome (CRPS), and neuropathic and ischemic pain [1]. Despite the widespread use and observed efficacy of neuromodulation, the mechanism of action is still poorly understood, as the gate control theory inadequately explains the ability to interrupt transmission of neuropathic pain while sparing nociceptive pain [2].

Conventional SCS for the treatment of chronic pain is based on the delivery of electrical impulses at specific frequencies to the dorsal columns of the spinal cord, with the objective of inducing paresthesia overlapping with the existing distribution of pain, to effectively distort the perception of delivered pain [3]. Therefore, the success of traditional SCS is largely based on the ability of the clinician to adequately provide coverage over the patients' distribution of pain and furthermore the willingness of the patient to tolerate the induced sensations of paresthesia [4, 5]. As a result, these limitations of traditional SCS can lead to failure of SCS therapy in patients with conditions that have distributions of pain that are difficult to overlap with paresthesia, as is often seen with axial low back pain [6].

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Moreover, limitations of early-generation SCS technologies include MRI incompatibility and diminished efficacy over time [7, 8••, 9, 10]. Novel advances in SCS and the development of dorsal root ganglion (DRG) stimulation offer promising results and improved capabilities over their predecessors. In this review, novel innovations in neuromodulation technology are described, as well as how they differentiate, and their clinical applicability specific to individual patient needs.

## Medtronic: Intellis™

Medtronic recently released the Intellis™ Platform SCS. This device was designed with several improvements in mind. It is capable of delivering several modes of stimulation, either in isolation or simultaneously, and features the smallest SCS neurostimulator currently available, measuring 2.2 × 1.9 in. [11]. The implant is also flexible, MRI safe via SureScan™, and fitted with a redesigned generator that delivers high-dose therapy with an extended battery life, rapidly recharges within the limits of 1 h, and offers minimal battery fade with extended use [11]. Furthermore, the device is capable of automatically adjusting stimulation patterns in accordance with changes in body position to prevent loss of coverage. This is possible though AdaptiveStim™, an internal accelerometer technology that is also capable of sensing body position [11]. Interestingly, this technology, paired with the Intellis™ Android compatibility, allows physicians to track patient activity levels to provide objective qualitative measurement of patient improvements in mobility and quality of life.

Medtronic's SureScan™ technology has been reviewed extensively within compatible pacemakers. One multicenter prospective study, incorporating 2629 patients who underwent a total of 872 MRI scans, reported no major MRI-related complications; six patients however were observed to experience atrial fibrillation, pacing capture threshold increase, and chest symptoms [12]. Despite this, a meta-analysis of SureScan™-related studies which included the aforementioned prospective study and an additional five retrospective studies, while still remaining low, found higher rates of pacemaker dislodgement and pericardial complications among SureScan™ pacemakers [9]. Overall complication rates, however, were not significantly higher [9]. Though these studies investigate the safety of SureScan™ technology within pacemakers rather than spinal cord stimulators, the results suggest that caution and appropriate discussion of risks are warranted before employing even MRI-safe technology within an MRI scanner. Additional research pertaining to SureScan™ technology in spinal cord stimulators is needed to better elucidate the safety of combined technologies.

Several studies have also examined AdaptivStim™ technology. A 69-patient, multicenter, randomized crossover study reported that patients with automatic position-adaptive stimulation reported a statistically significant improvement in both convenience and decreased loss of coverage when compared with traditional SCS [13]. AdaptiveStim™ patients within this study reported improved comfort during position changes, improved sleep, and improved activity levels, when compared to control, and reported no additional adverse effects [13]. A separate comparison of patient's objective movement recordings and patient's self-reporting following failed back surgery syndrome, however, found that patient activity measurements had poor correlation with patient responses to the Oswestry Disability Index (ODI), the Pittsburgh Sleep Quality Index (PSQI), and a Visual Analog Scale diary [14]. This suggests that position-adaptive stimulation may benefit patients, but that both objective and subjective measures should be used to evaluate patients' treatment.

The Intellis™ SCS platform, developed by Medtronic, is indicated for the management of chronic and refractory pain that can be either unilateral or bilateral and may be related to failed back syndrome, radiculopathy, herniated disk, postlaminectomy pain, refractory degenerative disk disease, peripheral causalgia, epidural fibrosis, arachnoiditis, complex regional pain syndrome, reflex sympathetic dystrophy, or unsuccessful disk surgery. Additional research is needed to definitively determine the MRI compatibility of SureScan™ equipped devices and the clinical role for AdaptiveStim™ activity monitoring.

## High-Frequency Stimulation: Nevro HF-10™

Traditional SCS is clinically dependent upon optimizing pain-paresthesia. The relief of pain however comes at the expense of often experiencing the uncomfortable sensations of paresthesia [15••]. Nevro's HF-10™, high-frequency SCS delivers stimulation at a 10-kHz frequency designed to provide pain relief without the sensation of paresthesia [16]. The recent SENZA-RCT randomized controlled trial compares 10-kHz high-frequency stimulation to traditional SCS [17]. The study incorporated 171 patients randomized to receive either 10-kHz high-frequency stimulation or traditional stimulation. Response was defined as a 50% or greater patient-reported reduction in pain in the absence of stimulation-related neurological deficits [17]. The study reported improved pain management among patients receiving 10-kHz high-frequency stimulation for back pain (response: 84.5% vs. 43.8%, $p < 0.001$) and leg pain (response: 83.1% vs. 55.5%, $p < 0.001$) [17]. The report also indicated that patients receiving high-frequency stimulation did not report paresthesia. A similar randomized controlled trial comparing HF-10 stimulation to traditional lower frequency therapy over a 2-year period at 11 comprehensive care centers concluded that high-frequency HF10™ therapy demonstrated long-term statistically significant superiority over traditional stimulation for the treatment of both back and leg pain [15••].

In another report, De Carolis et al. considered the technical physiology behind high-frequency stimulation and examined clinical applications of HF-10™ to determine whether pain relief achieved during traditional and 10-kHz SCS is related to paresthesia [10]. They identified the ideal HF-10™ setting on 61 patients and temporarily reduced the frequency of this setting to allow patients to map zones on paresthesia on a human body diagram, which was then compared to a human body diagram in which the patients previously mapped areas of chronic and intractable pain [10]. Results suggested that there was no statistically significant correlation between the degree of anatomic mapping overlap and patient-reported excellent response to high-frequency, 10-kHz stimulation [10]. Paresthesia mapping was also used to determine the mediolateral distribution of stimulation and the group determined that non-midline stimulator positioning, as determined by asymmetric paresthesia distribution, was not statistically significantly associated with patient response to high-frequency stimulation [10]. This group concluded that HF-10™ achieved clinical response independent of both paresthesia and precise midline positioning.

These studies are limited, necessarily, by being non-blinded, patient reporting, and physician interpretation that may have been influenced to varying degrees by the Hawthorne effect. Despite these limitations, evidence suggests that clinical response to HF-10™ therapy is paresthesia-free and has the added benefit of patient response that is independent of paresthesia mapping, ultimately having important implications for operating room time and patient satisfaction. These studies suggest a pertinent clinical role for HF-10™ therapy, particularly in the management of chronic back and leg pain.

## Dorsal Root Ganglion Stimulation: Abbott Proclaim™/Axium™

Stimulation of the dorsal root ganglion (DRG) involves insertion of electrodes through the intraspinal epidural space to generate neuromodulation and pain relief [18]. Current indications for DRG stimulation include failed back surgery syndrome, chronic and intractable post-surgical pain, and complex regional pain syndromes, among others [18]. However, the mechanisms of pain relief secondary to the DRG are not yet fully understood. Kent et al. undertook a computational modeling analysis of DRG stimulation by creating computer-based models of the DRG by using validated biophysical surrogates for c-fibers, which are unmyelinated, small-diameter, and slowly conducting pain sensory neurons [19]. This model demonstrated enhanced T-junction filtering and suppressed afferent signaling with DRG stimulation as well as reduced ectopic activity of axons in close proximity and oriented towards stimulation [19]. The authors highlighted the importance not only of amplitude and location of DRG neuromodulation, but also the polarity.

A recent feasibility study assessed DRG stimulation as a means of treating chronic and intractable back pain in five patients who met criteria [20]. This study reported a 61% reduction in back pain and a 56% reduction in leg pain after 12 weeks of DRG stimulation, as well as a 100% reduction in opioid consumption [20]. A similar retrospective case series reported findings following neuromodulation of ten patients meeting criteria for chronic pain secondary to refractory diabetic neuropathy [21]. Of the ten enrolled patients, seven received dorsal root ganglion stimulators, and five proceeded to clinical follow-up. These remaining five patients reported an average pain reduction of 63.9% [21]. An additional 3-year, prospective study that enrolled 30 patients receiving permanent dorsal root ganglion stimulators for the management of chronic neuropathic groin pain reported a statistically significant reduction in Visual Analog Scale scoring, which decreased from a median of 8 to a median of 4 after a 3-year period [22]. A similar multicenter, prospective, randomized, controlled trial evaluating the use of DRG stimulation in the management of chronic, post-surgical inguinal pain is currently ongoing [23]. Finally, animal studies evaluating the in vitro and in vivo use of DRG suggest that DRG stimulation may result in pain-free outcomes [24].

Initial human studies suggest that DRG stimulation may be a safe, effective, and feasible option for the treatment of chronic pain especially pertaining to the inguinal region. However, sample sizes in each study are small and subject to biases. Additional research in the form of large prospective trials is needed to evaluate the efficacy of DRG stimulation relative to other forms of central and peripheral neuromodulation among human patients meeting criteria for chronic, intractable pain syndromes.

## Burst Stimulation: Abbott BurstDR™

Traditional SCS utilizes a low-frequency tonic stimulation to stimulate the large myelinated fibers of the dorsal columns in the spine and suppress nociceptive signals from smaller unmyelinated fibers [25]. De Ridder et al., in 2010, proposed a new paradigm—burst stimulation. He discovered that thalamic cells not only fire in a tonic fashion, but also in a burst fashion, which is considered a more powerful activator of the cortex [26]. Burst stimulation functions by delivering intermittent signals of closely spaced, high-frequency stimuli. This can be programmed, for instance, as a 40-Hz burst mode with five spikes at 500 Hz per burst, with a pulse width of 1 ms and 1-ms interspike intervals delivered in constant current mode [26]. It has been hypothesized that stimulation at different frequencies and rates can provide a distinct modality for alleviating chronic pain.

Deer et al., in the SUNBURST study, a multicenter, randomized, crossover study, assessed the safety and efficacy of a device capable of both tonic and burst modes of stimulation. One hundred patients with FBSS or radiculopathy who had a successful tonic trial with at least 50% pain relief were randomized to receive either a burst or tonic mode for 12 consecutive weeks, after which they switched to the contrary mode for an additional 12 consecutive weeks. The primary endpoint was the non-inferiority of the within-subject difference in mean VAS score in burst compared to tonic mode. Subjects were then allowed to use whichever mode they preferred and were followed for 1 year. Not only did the study demonstrate that burst stimulation was non-inferior to tonic stimulation ($p < 0.001$), superiority of burst was also observed ($p < 0.017$). Furthermore, significantly more subjects preferred burst stimulation over tonic ($p < 0.001$), with preferences sustained at 1 year [8••].

The SUNBURST trial was the first randomized controlled trial in which the study subjects experienced two modes of SCS within the same trial. In addition, it showed that burst mode had no additional safety concerns or adverse events compared to traditional SCS [8••]. Despite the merits of this study, the crossover design may confound data as having received a prior treatment could potentially influence patient perception of the subsequent treatment. Additionally, the study was unblinded which could lead to bias in reporting outcomes either from the patient or clinician. Furthermore, the study was funded by and the authors employed by Abbott who produces the BurstDR spinal cord stimulator.

A significant limitation of burst stimulation technology is the relatively increased consumption of energy and may thus only be used with rechargeable generators which can result in more frequent battery changes [27]. Safety assessment of burst stimulation technology has not shown any additional risk compared to conventional SCS technology [8••].

Burst stimulation may be beneficial to patients who have had diminishing effect with traditional SCS technology. In these patients, who have developed a tolerance to the tonic, low-frequency stimulation of a traditional SCS, burst stimulation delivering energy in a different manner and has the potential to alleviate breakthrough pain. While SCS relies on the production of adequate paresthesia coverage, burst stimulation is typically below the level of patient perception, and therefore, the perception of paresthesia by patients is reduced. As such, pain relief may be achieved while circumventing an awareness of unpleasant stimulation in those patients who previously found the sensation of paresthesia with low-frequency SCS intolerable [27].

## Wireless SCS: Stimwave Freedom Stimulator™

The Freedom stimulator, developed by Stimwave, is a proprietary technology featuring a wireless miniature stimulator allowing for faster and less invasive implantation. Unlike traditional SCS that have implanted generators, the Stimwave Freedom stimulator System uses a small implantable electrode that communicates wirelessly with a transmitter and battery worn externally by the patient called the Wearable Antenna Assembly (WAA) [28]. The device has a wide spectrum of stimulation parameters, with amplitudes ranging from 1 to 24 mA, pulse widths ranging from 10 to 1000 μs, and producible frequencies of 5–20,000 Hz [29].

Weiner et al., in a single center, prospective two-phase study assessed the efficacy and safety of Stimwave wireless technology in 11 patients who had chronic neuropathic pain of the trunk and lower limbs. Each subject had a Stimwave Freedom-4 stimulator implanted unilaterally and transforaminally at one dermatomal level within the L1–L5 interspaces. The study took place in two phases: in the first phase, stimulators were not anchored with implantation, while in the second phase, stimulators were anchored using the supplied winged anchoring device. Subjects were treated for 45 days in each phase and upon completion of a phase the device was explanted. Primary endpoints assessed were pain reduction and migration of the implant [28]. Of the 11 total participants, five subjects completed phase one of the study and six subjects completed phase two. Seven of the 11 patients reported over a 50% reduction in their VAS, while two patients reported a 25–50% improvement. Two patients reported poor improvement due to device migration in the phase one, non-anchored device group. The average overall VAS reduction was found to be 59.9% [28]. In evaluation of stimulator migration, stimulators in phase one subjects migrated an average of 8.8 mm compared to an average migration of 1.83 mm in the phase two group. Though there was no statistical significance found with regard to lead migration and inadequate pain control, it was concluded that the anchoring device should be used to mitigate the potential of stimulator migration.

The average pain relief in this study was similar to that of traditional SCS devices studied. Qualitative feedback from subjects implied that pain reduction could be improved by implanting stimulators bilaterally or by utilizing multiple stimulators at multiple levels [28]. A significant limitation of this study is the sample size used; however, the novelty of the technology and the limited number of skilled clinicians, at the time it was conducted, limited the ability to further scale in size. Furthermore, stimulator trials lasted only 45 days in each phase, which precluded assessment of long-term pain relief. Additionally, the principle investigator was employed by Stimwave Technologies, producing a source of bias. This may have been reduced however through the assessment of patient-reported outcomes rather than direct clinician observation.

In another European, single-center, prospective feasibility study, Billet et al. implanted Freedom Spinal Cord Stimulators into five subjects with chronic low back pain that was unresponsive to medical treatment. Four Freedom stimulators were

implanted over the dorsal root ganglion nerve roots bilaterally at levels T9 and L2. Subjects evaluated each level independently for 2 weeks and were then monitored for 8 weeks using the level which offered them greatest relief. Pain reduction based on VAS, Oswestry Disability Index (ODI), Patient Global Impression of Change (PGIC), and medication usage were the primary endpoints. Average pain levels 12 weeks post implantation decreased 61% for back pain and 56% for leg pain with 100% reduction in opioid medication use [20].

Previous studies have shown that approximately 50% of patients, undergoing conventional SCS, experience long-term clinical improvement. Lead migration, fracture, and positioning challenges contribute to these mediocre outcomes [20]. A significant advantage of the Freedom stimulator system is the utilization of an externally worn generator, precluding the limitations of lead hardware, battery life, and generator longevity. Moreover, an external generator avoids the requirement of pulse generator implantation via surgical approach and eliminates potential pocket site complications reducing complication rates and healthcare costs [25]. Further, while traditional stimulator technology is limited by MRI noncompatibility, the Freedom system has FDA approval for use in either 1.5- or 3-T MRI, allowing safe MRI examination of any region [29]. As the implantation procedure solely includes the electrode array, adverse events noted by Billet et al. were limited to migration of stimulators which ultimately required revision. The study did not assess long-term improvement; thus, it is difficult to determine an improvement in efficacy of the Freedom Spinal Cord Stimulator over conventional SCS.

Ultimately, given a low device profile, ease of implantation, and potential long-term cost savings, the Stimwave Freedom stimulator has the potential to benefit all patients who meet criteria for SCS therapy. Patients who have had complications at the IPG pocket site, require multiple battery changes, or have medical conditions warranting MRI surveillance are most likely to benefit from this promising technology.

## Conclusion

New advances in neuromodulation technology offer considerable improvement over early-generation devices. Limitations of SCS implantation and livability, such as paresthesia mapping and potentially uncomfortable sensation, have been overcome by HF-10 technology, developed by Nevro, which allows for function that is imperceptible to the patient and consistent anatomical implantation that requires no patient input for the process of mapping. Innovations developed by Medtronic, SureScan™ technology, and AdaptivStim™, though utilizing a conventional frequency stimulation, promise safer MRI capability and improved coverage of pain during activity. While axial low back pain has often been difficult to adequately treat, DRG stimulation has been demonstrated to be effective in this application. Burst stimulation may allow for the mitigation of decreased efficacy that has been observed with traditional SCS. Wireless stimulation technology may offer all of the benefits of conventional SCS while avoiding implantable pulse generator-related complications. Recent innovations in neuromodulation and SCS offer exciting promise to patients who suffer from chronic pain and have had little success with early-generation technology; however, despite these advances, these new technologies have varying limitations which must be weighed against promised benefit and their use should be carefully tailored to individual patient needs.

## Compliance with Ethical Standards

**Conflict of Interest** Omar Viswanath, Ivan Urits, Emily Bouley, Jacquelin M. Peck, and William Thompson declares no conflict of interest. Dr. Kaye discloses that he is on the Speakers Bureau for Depomed, Inc. and Merck.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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