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REVIEW

An Evidence-Based Consensus for the Use of Neurostimulation for the Treatment of Non-Surgical Low Back Pain: The NEURON Group

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Introduction: The use of electrical neuromodulation has often been limited to those with previous back surgery, peripheral neuropathy, and complex regional pain syndrome. Many patients with severe intractable low back pain were thought to be candidates for spinal cord stimulation (SCS), dorsal root ganglion stimulation, or peripheral nerve stimulation but did not meet the criteria. Recently, additional high-level data has supported the use of SCS in non-surgical low back pain (NSLBP), and United States Food and Drug Administration approval has been granted. The American Society of Pain and Neuroscience (ASPN) executive committee realized an unmet need to develop criteria for patient selection for this specific patient population. This is a NEURON project (neuroscience, education, utilization, risk mitigation, optimal outcomes, and neuromodulation), a living guideline for evolving therapies and indications, and is focused on the use of neuraxial stimulation for the treatment of refractory pain.

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Methods: After board approval, the society accepted nominees for the project, with an emphasis on experience, publication, research, and diversity. The team created an outline for discussion, chose a grading system based on published guidelines, and created consensus points.

Results: The evidence led to several consensus points to best guide patient selection based on the level of evidence and expert opinion. The results will lead to improved safety and efficacy in implanted patients, and to a new standard for best practices.

Conclusion: The selection of patients for implantation in those who have NSLBP should be based on published literature, best practice, and expert opinion. This NEURON project will allow for regular updates to create a living guideline that will allow for better assimilation of information to improve safety and efficacy going forward.

Keywords: spinal cord stimulation, SCS, low back pain, lumbar degenerative disc disease, non-surgical back, non-surgical low back pain, NSLBP, failed back surgery syndrome, dorsal root ganglion stimulation, DRG, DRG-S, peripheral nerve stimulation, PNS

Introduction and Objectives

Non-Surgical Low Back Pain: Defining the Problem

Chronic low back pain (CLBP) affects approximately 13.1% of the US population and is linked with a higher level of medical comorbidities, health care costs and lost productivity.[1,2] Although acute low back pain (LBP) typically resolves within 3 months, approximately 2% to 48% of patients progress to developing CLBP,[3,4] with one-third of this population experiencing moderate-to-severe pain intensity.[3] The management of CLBP can be multimodal and has a wide range of options. The important role of "collaboration in decision-making among different disciplines" is critical to determining when the patient with CLBP is accurately defined as a patient with also non-surgical low back pain (NSLBP). While the definition of NSLBP will undoubtedly evolve with the accessibility of innovative surgical approaches, it is important to define what NSLBP is today, currently with the writing of this guidance.

Despite considerable amounts of research completed on CLBP, there are inconsistent definitions and assessments. For this guideline, NSLBP refers to patients who have failed to respond to conventional medical management (CMM), have no history of spine surgery, and are not appropriate candidates for surgical intervention.[1] CMM refers to physical or occupational therapy, analgesic medications, nerve blocks, steroid injections, radiofrequency ablation and other validated treatments for lumbar pain.[1] The second qualifier, "not appropriate candidate for surgical intervention", in this definition, means the absence of a symptomatic surgically correctable lesion or pathology. Patients with correctable surgical lesions who are not candidates due to comorbidities are not included in the study designs included in this guidance and will be considered in future guidance.

The etiology of NSLBP is multifaceted, often due to a combination of factors including but not limited to degenerative disc disease, facet joint disease, herniated discs, fractures, and spinal stenosis.[5] Acute exacerbations can be triggered in these individuals from muscle and ligament strains, commonly precipitated by poor posture, lifting or abrupt movements. There is also an increased risk and severity of back pain in individuals with psychosocial factors such as anxiety and depression.[3,5,6] Less advanced levels of education serve as strong predictors of prolonged episode duration and poorer outcomes.[5]

Taking this into consideration, NSLBP is a prevalent condition that is not limited to any specific demographic. It is associated with age, with the highest incidence in the third decade of life and increasing prevalence with age up to 60 to 85 years old.[5,7] LBP is expected to rise in prevalence and incidence due to increasing sedentary behaviors and an aging population.[7,8]

Despite many therapeutic advances for this common and life altering condition, there are still controversies that exist, and many questions arise in the field that merit being addressed in guidelines.

- Is the use of neuromodulation an appropriate therapy for both mechanical/nociceptive and neuropathic pain, or is it more specific to pain of neuropathic origin?
- Is the degree of spinal stenosis well defined in NSLBP? Should we implant those with severe spinal stenosis that is not correctable?

- Do we need thoracic magnetic resonance imaging (MRI) as surgical staging in all patients or only those scheduled for paddles in pre-surgical work-up?
- What level of non-surgical scoliosis is appropriate for spinal cord stimulation (SCS) in NSLBP or is this a medical judgement decision?

The objective of the American Society of Pain and Neuroscience (ASPN) NEURON (neuroscience, education, utilization, risk mitigation, optimal outcomes, and neuromodulation) project for the treatment of NSLBP with neuromodulation is to provide evidence-based recommendations to address the appropriate utilization of this therapy in a group of patients who previously were treated on a case-by-case basis with no guidance. This guidance comes at a time of new peer-reviewed literature analyzed in this publication.

This guideline is intended to represent a comprehensive review of the neuromodulation options for those suffering from CLBP with NSLBP and offer recommendation based on the level of evidence and consensus. As this is a living document, this ASPN NEURON project is intended to be updated periodically to maintain relevance with the current treatment landscape and literature. The ASPN NEURON guidance does not necessarily represent a standard of care, but an expert driven assimilation of evidence to help develop patient centric treatment approaches and does not replace treatment based on an individual patient's need and the physician's professional judgement and experience. Further, this guideline is not intended to be used as the sole reason for denial or approval of treatment or services. See Table 1.

Methods for Literature Search, Evidence Ranking and Consensus Development

Working Group

The ASPN clinical guideline committee is comprised of a diverse group of physicians representing the specialties representative of the membership of ASPN and engaging in the care of patients suffering from NSLBP, including anesthesiology, neurosurgery, orthopedic surgery, physical medicine and rehabilitation, and radiology, as well as a pain psychologist/medical ethicist with many years of experience in consulting with implantable devices. Committee members were selected based on clinical experience, research, and previous publication history.

Disclosures of Potential Conflicts of Interests

All participants involved in the guideline development have been required to disclose all potential conflicts of interest, financial or otherwise. Although guidance exists regarding grading potential degree of conflict of interest and assessing the potential of bias, the organizing committee elected to have unbiased committee members finalize and approve consensus statements. All evidence grading was reviewed and validated by committee members with no perceived conflict of interest in any specific therapy. Authors with conflicts of interest on subjects with grading criteria were recused from those sections as appropriate.

Literature Review

The world literature in English from 2000 to May 2024 was searched using Medline, EMBASE, Cochrane CENTRAL, BioMed Central, Web of Science, Google Scholar, PubMed, Current Contents Connect, Meeting Abstracts, and Scopus to identify and compile the evidence for lower back interventional therapies for the treatment of pain. During the peer

Table 1 Consensus Statement on Candidacy for Surgery Vs Neuromodulation

Consensus Statement	Grade	Level of Certainty Regarding Net Benefit	Consensus
Collaborative decision making among surgical and interventional spine specialists should be used to better understand the optimal candidates for operative intervention, and the patients who should be considered for neuromodulation.	A	Moderate	High

review process additional articles were identified, and the search was expanded to include articles through December 2024. Search words were created specific to the topics for each major section pertaining to SCS, dorsal root ganglion stimulation therapy, and peripheral nerve stimulation. The search terms included low back pain, neuromodulation, neurostimulation, non-surgically correctable back pain, spinal cord stimulation, dorsal root ganglion stimulation, and lumbar disc disease. Identified peer-reviewed literature was critiqued using the United States Preventive Services Task Force (USPSTF) criteria for quality of evidence,[9] with modifications for neuromodulation therapies (Table 2). The hierarchy of evidence for the project considered randomized controlled trials (RCT) as the preeminent classification, followed by prospective observational studies, case series and finally expert opinion. Per the methodology, the process identified RCT and prospective observational studies of Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) criteria quality in the creation of guidelines. Interventions with more than one RCT were considered to have sufficient evidence to create conclusions, and observational studies were not considered. Interventions with no RCTs or only one RCT then also utilized prospective observational studies in the creation of guideline recommendations. Should an intervention be found to have no RCTs or observational studies, case series were used. These are clearly denoted by the taxonomy of the recommendation that the predominant quality of evidence is of a classification less than RCT. For interventions where RCT and prospective observational studies of requisite quality (STROBE) are not available, case series and/or expert opinion may be used in the creation of guidelines to fill in the current literature gap to assist the clinician in selecting care pathways. These designations follow a modified USPSTF process used previously by ASPN in the creation of guidelines. The details are listed in Table 2. After USPSTF letter grading was assigned, the working subgroup then assigned the "level of certainty regarding benefit" as described in Table 3. Definitions for the level of consensus are in Table 4.

The ASPN neuromodulation group for NSLBP formulated consensus points based on graded evidence in the literature and the consensus of the authors.

Scope and Purpose: Why is Non-Surgical Low Back Pain Consensus Needed?

Previously, SCS has been proven to reduce costs and healthcare resource utilization vs CMM in conditions such as failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), and painful diabetic neuropathy.[11–13] The

Table 2 Quality of Evidence Ranking Using United States Preventative Services Task Force Criteria Modified for Therapy

Grade	Definition	Suggestions for Practice
A	ASPN recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	ASPN recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	ASPN recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	ASPN recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	ASPN concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Notes: Modified from USPTF; adapted with permission from Dove Medical Press. Deer TR, Grider JS, Pope JE, et al. Best Practices for Minimally Invasive Lumbar Spinal Stenosis Treatment 2.0 (MIST): consensus Guidance from the American Society of Pain and Neuroscience (ASPN). *J Pain Res*. 2022;15:1325–1354.[10]
Abbreviations: ASPN, American Society of Pain and Neuroscience; USPSTF, United States Preventative Services Task Force.

Table 3 Levels of Certainty Regarding Net Benefit

Level of Certainty	Description
High	The available evidence includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. **Evidence Level: I-A** - At least one controlled and randomized clinical trial, properly designed.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. **Evidence Level I-B**- Well-designed, controlled, non-randomized clinical trials (prospective observational studies conforming to STROBE criteria) or **Evidence Level I-C** – Retrospective cohort or large case studies (>20 subjects).
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies. • Important flaws in study design or methods. • Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcome **Evidence Level II**- Expert opinion based of risk:benefit or based upon case reports.

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Abbreviation: STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.

Table 4 Level of Consensus Definitions

Consensus Definitions	Percentage of Agreement
High	80–100%
Moderate	60–79%
Low (no consensus)	50–59%

CMM for refractory NSLBP has historically consisted of medications, physical therapy, and interventional procedures (epidural steroid injections, nerve blocks, nerve ablations, etc.). There is a substantial economic burden associated with CMM for NSLBP, and opioids remain the most commonly prescribed medication.[14] Surgery for chronic CLBP, such as spinal fusion, has not been shown to offer significant improvement in disability compared to CMM.[15,16] Recent studies have demonstrated the superiority of SCS vs CMM in terms of pain scores, disability, pain catastrophizing, quality of life, and daily opioid use.[1,17]

Along with improvements in pain and patient-related outcomes, there is an economic benefit from the use of SCS for NSLBP. A 2023 prospective, randomized controlled trial comparing SCS to CMM for NSLBP over 12 months found a 33% average reduction in healthcare utilization cost in the SCS arm as compared to CMM.[18] The cost-effectiveness of SCS was estimated to be achieved within 2.1 years. The study also reported a superior incremental cost-effectiveness ratio in the SCS arm, such that a significant quality of life improvement was achieved at a lower cost. A 2019 retrospective study evaluating cost before and after implantation of SCS for LBP found that the average total cost

reduction at 6 months post-implantation was approximately $5840.[19] The study estimated the time to offset total device costs to be approximately 2.3 years. Other studies evaluating SCS for this condition have found parallel reductions in opioid use, healthcare utilization, and pain-related procedures, suggesting similar economic benefits.[20,21] Overall, there is increasing clarity and evidence for the favorable long-term economic impact of SCS in this population.

A myriad of studies also support the enhancement of quality of life (QOL) with SCS. This brief review summarizes the data from methodologically robust studies supporting SCS to improve QOL since the advent of new SCS waveforms more recently. Reviews, which tend to mix older and newer technologies, were excluded.

The 2017 study of 10kHz SCS (Nevro, Menlo Park, CA, USA)[22] by Al-Kaisy and colleagues included QOL as a secondary outcome, determining a significant improvement at 1-year post-implant as measured by the EuroQOL 5-Dimensional Questionnaire (EQ-5D). In the 3-year follow-up study,[20] significant improvement in QOL scores were once again identified, with even greater improvement than the 1-year data. Subsequent studies involving new waveform technologies[1,18,23–29] have yielded similar results.

The results of a 2018 study by Amirdelfan et al in which QOL was a primary outcome measure, compared 10,000 Hz stimulation therapy to traditional low-frequency SCS. The authors determined that based on multiple measures (perceived disability, functionality, sleep, pain interference, and subject satisfaction), significantly greater gains occurred on all five measures in the 10,000 Hz stimulation therapy group as compared to the traditional SCS group.[30]

In all methodologically sound studies of novel waveform SCS strategies for LBP in which QOL was measured, significant improvements in life quality were identified. These findings were strongly supported in a recent systematic review/meta-analysis.[31] However, a recent Cochrane Review[32] did not support the use of SCS for the treatment of LBP, but this has been widely criticized by many because it excluded many level one studies approved and monitored by the United States (US) Food and Drug Administration (FDA). It has been stated that this Cochrane Review attempt to reduce bias led to an opposite effect of creating a negative bias against SCS.[33,34]

It is important to note that not all NSLBP patients are candidates for neuromodulation. For the purposes of this article, patients who have not responded to conservative strategies for treatment were not candidates. Of note, the efficacy of these interventional non-implantable approaches was more comprehensively described in the ASPN Back Guideline.[9]

Current Evidence for Neuromodulation with Spinal Cord Stimulation

Spinal Cord Stimulation Food and Drug Administration Labeling

FDA labeling for SCS therapy is manufacturer-specific and updated on a regular basis. The FDA approval process involves rigorous scientific and regulatory evaluation, aiming to ensure that the product's benefits outweigh its potential risks, keenly evaluating safety and efficacy.[35] Sponsors must submit comprehensive data from preclinical and clinical studies to demonstrate the product's safety and efficacy. Once approved, the product can be legally marketed and distributed commercially in the United States, instilling confidence among healthcare providers, patients, and consumers in its safety and effectiveness. FDA approval serves as a critical milestone, opening doors to broader commercialization and accessibility of therapies for patients in need.

The FDA first approved SCS therapy for the treatment of chronic moderate or severe refractory pain in the trunk and limbs in 1989.[36] Since then, in response to numerous clinical studies,[1,17,37–47] the FDA has expanded indications for SCS therapies to specifically include treatment of failed back surgery syndrome, intractable LBP, intractable leg pain, diabetic peripheral neuropathy of the lower extremities, angina, and chronic limb ischemia.[48–50] In February 2022, the FDA approved SCS therapy for the treatment of refractory NSLBP.[49,50]

Evidence of Efficacy for Spinal Cord Stimulation in the Treatment of Non-Surgical Low Back Pain

SCS is the most studied and established form of neuromodulation and its use for chronic pain related to FBSS, CRPS, and diabetic neuropathy has been supported via multiple RCTs.[51] Despite a dearth of knowledge as to the therapeutic mechanisms behind not only conventional tonic SCS but also behind novel SCS waveforms, the clinical efficacy of SCS has been buttressed by more RCTs than any other form of neuromodulation, and some of these RCTs have met the

criteria of high-quality.[52] Moreover, the advent of paresthesia-free waveforms in SCS has heralded in a new era of SCS trials which involve a placebo or sham arm.[53] Despite challenges in placebo/sham control and blinding in SCS trials, these studies have overall helped to improve the level of efficacy evidenced in SCS and have helped to strengthen the therapeutic benefit of SCS. There are numerous prospective studies of SCS that show it may reduce opioid consumption, improve quality of life, enhance return to work, and reduce the cost of health care.[30,54,55]

Historically, neurostimulation has been viewed as a therapy of last resort, when all other treatments – including surgery – have failed, and more so has been viewed as a treatment primarily for neuropathic lower extremity pain. For example, a 2014 review of SCS indications and patient selection highlighted sixteen indications; NSLBP was not one of them.[56] To date, five (5) RCT studies have been conducted specifically investigating SCS for NSLBP.

Kapural et al 2022 randomized 159 patients with nonsurgical refractory back pain to either CMM or 10,000 Hz stimulation therapy, with an optional 6-month crossover for the CMM group.[1] The primary endpoint was the percentage of patients with >50% reduction in numeric rating scale (NRS) at 3 months; 80.9% of the treatment group reached this endpoint as compared to only 1.3% of CMM patients. These numbers were stable at 6 months (80% vs 2.7%). Other 6-month secondary endpoints included ≥10-point reduction in Oswestry Disability Index (ODI) ratings (78.5% SCS vs 4% CMM), Patient Global Impression of Change (PGIC) (70.8% "Better" or "A great deal better" for SCS and 1.3% in CMM), and change in opioid use (−45.8% SCS and +12.1% CMM). Finally, when the CMM group was allowed to crossover to SCS treatment, their results were equivalent to that of the original SCS treatment group. More recently, 24-month results were published from the implanted cohort, in which 98 patients completed the 24-month follow-up. At 24 months after implantation, the mean back pain visual analog scale (VAS) score was reduced by 73%, and the responder rate was 82%. ODI and EQ-5D-5L both improved by twice the minimum clinically important difference (MCID) difference for each measure. The rates of serious adverse events (3.4%) and surgical device explants (4.8%) were low.[57]

Patel et al, 2024 conducted a multicenter RCT evaluating 10,000 Hz stimulation therapy plus CMM versus CMM alone for NSLBP.[57] One hundred and fifty-nine patients were randomized, and a 6-month crossover option was provided for the CMM group. The primary endpoint, ≥50% pain relief on the VAS at 3 months, was achieved by 80.9% of SCS patients versus 1.3% of CMM patients, with stable results at 6 months (80% vs 2.7%). Secondary endpoints included ≥10-point ODI improvement (79% SCS vs 4% CMM), PGIC (71% "better" or "greatly better" for SCS vs 1.3% CMM) and reduced opioid use (−17.7 morphine milligram equivalents [MME] for SCS, unchanged in CMM). After crossover, SCS outcomes mirrored those of the original SCS group. At 24 months, in the implanted cohort (n=125), 98 patients completed follow-up. VAS back pain scores improved by 74%, with 82% achieving ≥50% pain relief and 58% achieving ≥80% relief. ODI and EQ-5D-5L scores improved by over twice the minimum clinically important difference. Serious adverse events (3.4%) and device explants (4.8%) were infrequent. Results confirm the long-term efficacy and safety of 10,000 Hz stimulation therapy for NSLBP.

Deer et al (2023) published the initial results from DISTINCT, an ongoing multicenter prospective randomized controlled trial comparing the use of passive recharge burst SCS (BurstDR, Abbott Neuromodulation, Austin, TX, USA) and conventional medical management in the treatment of refractory NSLBP.[58] The primary endpoint was ≥50% reduction in NRS at 6 months for the first 200 patients enrolled. This was achieved by 72.6% of SCS patients vs 7.1% of CMM patients. An analysis of the overall cohort (N=269) revealed almost identical results. Secondary outcomes included a composite responder rate combining NRS and ODI outcomes (91% for SCS vs 16% for CMM), ODI improvement (30.6 points SCS, 0.7 points CMM) and meaningful change in the Pain Catastrophizing Scale (PCS) (88.2% SCS vs 23.5% CMM). DISTINCT will follow patients for 24 months and is a Level I Investigational Device Exemption study audited and monitored by the FDA.

In a study by Kallewaard et al (2024), differential targeted multiplexed (DTM) SCS (Medtronic Neurological, Minneapolis, MN, USA) was compared to conventional medical management in a group of 112 patients with persistent back pain who were ineligible for spine surgery. The primary endpoint of the study was the responder rate of patients achieving at least 50% benefit from the associated treatment as assessed using VAS scoring. These patients were followed to 24 months post implantation. The secondary endpoints included a comparison of changes in responder rates at 1, 3, 9, 12, 18, and 24 months, as well as changes in the ODI, EQ-5D-5L, PGIC, and opioid consumption. Patients in the DTM SCS group demonstrated a high responder rate exceeding 80%, with a mean reduction in symptoms of at least 70%

reduction in symptoms, when compared to conventional medical management. Importantly, these results were sustained through the 24-month period.[59]

These studies show extremely promising results and demonstrate that SCS is superior to CMM for the NSLBP patient population. These results are early, however, and long-term outcomes are still needed before this patient population is more widely adopted as good SCS candidates. See Tables 5 and 6.

Diagnostic Testing for the Non-Surgical Low Back Pain Population

Patient selection is critical in the assignment of candidacy for NSLBP. The identification of a surgically correctable lesion precludes the diagnosis. Flexion and extension films to assess dynamic instability may be considered. Assessment of any sagittal and/or coronal deformity should be performed. Assessment of fractures (traumatic, osteoporotic and/or

Table 5 Literature Summary for Efficacy of SCS in NSLBP

Source, Year	Design	Sample Size	Level of Evidence	Results
White et al, 2024[60]	RCT	121	I-A	At 3 months, patients with chronic low back pain treated with DTM demonstrated superiority to conventional SCS of VAS scores at primary end point of 3 months (P<0.0001) and remained superior at 6, 9 and 12 months (95% CI); Leg pain VAS scores in DTM group were superior to those of conventional SCS at primary end point of 3 months and subsequent intervals at 6, 9 and 12 months (95% CI).
Kallewaard et al, 2024[59]	RCT	112	I-A	At the primary endpoint of responder rate of % of patients reporting at least 50% or more in pain reduction at 6 months when compared to CMM, DTM demonstrated superiority as well as a responder rate of > 70%. These results were sustained through 24 months.
Kapural et al, 2022[1]	RCT	159	1-A	At 6 months, patients treated with SCS had a responder rate of 80%, compared with 2.7% in the control group.
Deer et al, 2023[58]	RCT	269	1-A	At 6 months, patients treated with SCS had a responder rate of 72.6%, compared with 7.1% in the control group.
Al-Kaisy et al, 2020[61]	Retrospective	26	I-C	At 12 months, the combined cohort demonstrated a responder rate of 73% (>50% reduction in pain), average decrease in ODI of 15.7% points, opioid use more than halved.
Kapural et al, 2022[20]	Retrospective	90	II	At 12 months, the pain intensity reduced 56.3% and opioid consumption decreased 40.8%.
Mehta et al, 2022[62]	RCT	20	I-B	At 12 months, 16 patients had back pain scores from 7.53 to 3.85 (48%) reduction.
SOLIS study[63]	RCT	20	N/A	Study is currently enrolling.

Abbreviations: CI, confidence interval; DTM, differential target multiplexed; NRS, numeric rating scale; NSLBP, non-surgical low back pain; ODI, Oswestry Disability Index; RCT, randomized controlled trial; SCS, spinal cord stimulation; VAS, visual analog scale.

Table 6 Consensus Statement for SCS in NSLBP

Consensus Statement	Grade	Level of Certainty Regarding Net Benefit	Consensus
SCS is recommended for patients with NSLBP.	A	High	High
NSLBP can be treated successfully with SCS.	A	High	High

Abbreviations: NSLBP, non-surgical low back pain; SCS, spinal cord stimulation.

pathologic) and other imaging should be ascertained as needed. Plain x-ray analysis is followed by lumbar MRI evaluation. Patients with surgical pathology with concomitant complementary subjective and objective findings should undergo surgical evaluation. If there is no indication of surgery, the patient may undergo a thoracic MRI scan to assess spinal canal patency prior to undergoing SCS trialing. Thoracic preoperative MRI findings had an impact on surgical planning for 22% of patients, and in 3% of cases, additional surgical decompression was necessary to ensure safe paddle lead placement, according to one study.[64]

The presence of intrinsic spinal cord pathology may also be a relative contra-indication for SCS technology. Thoracic plain x-ray analysis can be obtained if there is concern for scoliosis. If there is a potential for the comorbidity of peripheral neuropathy, electromyography (EMG) can be performed. EMG assessment can be useful in planning trial electrode placement to optimize coverage of lower extremity symptomatology. This will not impact lead placement for NSLBP, however.

If MRI evaluation is contra-indicated, computed tomography (CT) imaging with the consideration of a myelogram of the thoracic and lumbar spine should be performed pre-operatively. The same assessment as above is then made following CT/myelogram testing.

It is essential to exercise prudence when interpreting imaging results and attributing causality of symptoms to any abnormal structural findings observed in the images. For example, emerging evidence indicates that traditional MRI evaluation may overestimate lateral recess dimensions in patients with lumbar spinal stenosis. A study demonstrated a reduction in foraminal area during upright and hyperlordotic positioning, which are positions associated with maximal symptoms.[65] Additionally, the application of artificial intelligence (AI) and machine learning in imaging analysis shows promise in comprehensive evaluation, with a recent study showing comparable detection rates for central canal and lateral recess stenosis compared to sub-specialist radiology evaluation.[66]

Although not always applicable to NSLBP pain patients, in those with coexisting limb pain, electro-diagnostic testing may be helpful where radiculopathy and plexopathy may be indistinguishable, especially in ambiguous clinical presentations or those situations where diagnostic injections are unclear. In some cases, it may be used in conjunction with the patient's clinical presentation to help determine the etiology of pain generation. For example, a study that enrolled 108 patients opined that certain electrophysiological parameters are helpful in diagnosing lumbosacral radiculopathy.[67] In addition, EMG abnormalities were found in less than 50% of cases and could be predicted by specific clinical findings. This discrepancy between test results and symptoms is also observed in asymptomatic control subjects. While EMG and nerve conduction velocity (NCV) testing can be helpful additional diagnostic tools in differentiating peripheral neuropathy from lumbar spinal stenosis, they may lack the necessary specificity to provide definitive diagnostic aid.[68–70]

Therefore, a comprehensive diagnostic approach to identify and treat the root cause of pain can enhance the overall effectiveness of SCS therapy in such situations (see Table 7).

Table 7 Consensus Statement on Diagnostic Testing in NSLBP

Consensus Statement	Grade	Level of Certainty Regarding Net Benefit	Consensus
Imaging and electro-diagnostic testing can be valuable in excluding conditions that may be better treated with therapies other than SCS. Specifically, the use of thoracic MRI imaging is recommended to evaluate for central canal thoracic stenosis and to aid in procedural planning for percutaneous implantation.	C	Moderate	Moderate
Imaging and electro-diagnostic testing can be valuable in excluding conditions that may be better treated with therapies other than SCS. Specifically, the use of thoracic MRI imaging is recommended to evaluate for central canal thoracic stenosis and to aid in procedural planning for paddle lead devices.	C	High	High

Abbreviations: MRI, magnetic resonance imaging; NSLBP, non-surgical low back pain; SCS, spinal cord stimulation.

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Demographic Considerations for Spinal Cord Stimulation in the Non-Surgical Low Back Pain Population

Age/gender: Clinical studies on SCS implantation showed age-related differences in outcomes. In successful SCS cases (those with ≥ 50% pain relief), the median age was 54 years (interquartile range [IQR] 42–60 years) compared to 66 years (IQR 50–76 years) in unsuccessful cases. SCS effectively manages pain in patients both under 75 and over 75 years old, with similar complication rates, making it a suitable option for older adults.[71–73] A survey study included patients of years 2000–2009 and significant variation in conversion rate by geographic area (patients in the North Central region vs Northeast region: odds ratio 1.48, 95% confidence interval (CI) [1.31, 1.66]; $p < 0.0001$).[74] Younger patients had higher success rates with full implantation, while older patients faced a greater risk of explantation.[74] However, a recently published study showed that from 2009 to 2018, SCS implantation rates in the Medicare group increased substantially, with notable rises in all age groups.[75] Although women demonstrated more of a preponderance for device explant due to discomfort, SCS pain relief did not differ by sex,[76] indicating that analgesic success is gender-neutral despite variances in device comfort.

Race/ethnicity: In the Medicare population, significant racial disparities were evident in the rates of SCS trials and placements. Caucasians led with the highest rates, with SCS trials increasing from 32 per 100,000 in 2009 to 72 in 2018, and placements from 19 per 100,000 to 47 in the same period. African Americans showed more moderate increases, with trials going from 21 to 35 per 100,000 and placements from 13 to 20 per 100,000. Other racial groups experienced the most substantial relative increase in placements, from 3 per 100,000 in 2009 to 10 in 2018, a 211% rise, compared to a 143% increase for Caucasians and 54% for African Americans.[75,77]

Body mass index (BMI): As obesity rates rise, more obese patients are receiving SCS implants without a corresponding increase in hospitalization costs compared to their non-obese counterparts. Obesity is associated with a higher risk of 30-day readmission and mechanical complications following SCS implantation.[78] For each increment in BMI, SCS effectiveness decreases by 2% vs 20% for underweight and/or normal patients (≤24.9), though pain scores improved at 6–12 months in both groups, respectively.[78] Individuals having a BMI ≥36.5 kg/m^2 experienced less improvement at 6–12 months.[79] Nevertheless, patients with a BMI of 40 or higher exhibit a mere 5.48% complication rate and a significant trial success rate of 93.3%, which is considerably higher than the 74.4% observed in those with a lower BMI.[80]

Pregnancy: The published literature surrounding spinal cord stimulation and pregnancy is primarily presented in case reports and small retrospective case series.[81–90] The majority of the patients did not experience any complications, however complications of intrauterine growth retardation, hypertension, and abortion were reported in singular case reports.[85,87,88] Causality is not noted and may be unrelated, but additional study is indicated.

History of chronic bleeding disorders: As spinal cord stimulation has expanded in use, the management of complex medical comorbidities has become more common as well. This includes chronic bleeding disorders. These disorders differ extensively from the management of anticoagulation medications, as the risk for these patients extends beyond the perioperative time frame when anticoagulation medications have specific discontinuation and restart time periods. In patients with chronic bleeding disorders, the risk of bleeding is ever-present, and given the permanent implantation of spinal cord stimulation hardware, the pain physician must be ready to identify and co-manage bleeding complications.

History of metallurgic allergy: Allergic contact dermatitis is a delayed-type hypersensitivity reaction caused by allergen-specific T-cells and subsequent T-cell-mediated response.[91] Allergic contact dermatitis occurs in approximately one in five people, but the incidence in spinal cord stimulators is very low, estimated around 0.1%.[92] These patients will present with chronic progressive cutaneous symptoms and discomfort without signs or symptoms of infection.

Increased risk of infection: Surgical site infection is one of the most serious complications of SCS trial and implantation. The overall incidence of surgical site infection following SCS implantation has been reported between 2.45% and 3.11%.[93,94] Unfortunately, when this occurs treatment involves explantation of the implanted device, loss of therapy, and treatment with systemic antibiotics. Patient-related factors that increase the risk of post-operative surgical site infection include uncontrolled diabetes, advanced age, intravenous drug use, human immunodeficiency virus infection, immunosuppression, history of cancer, renal failure, infection at a distant source, liver cirrhosis, history of cigarette smoking, and history of prior surgical site infections.[94]

For the NSLBP patient population, there are no special techniques for SCS that need to be considered. In patients without existing disease states, the physician should follow standard of care when placing the trial leads and permanent

leads and pulse generator. This should involve an awake, communicative patient. If general anesthesia is performed, the use of intraoperative neuromonitoring is recommended. For SCS devices utilizing a paresthesia-based programming, the leads should be placed in an area to allow paresthesia coverage over the painful areas. For SCS devices that are paresthesia-independent, the leads can be placed anatomically. In general, the SCS trial will last for approximately three to fourteen days depending on factors such as time off blood thinners, travel time and complexity. A successful trial involves pain relief and/or functional improvement of at least 50%. Currently, there are no measures that define success after implantation, but 50% improvement in pain is the most commonly reported metric. A summary of these findings is given in Table 8, and ASPN consensus statements are in Table 9.

Table 8 Literature Summary of Demographic Considerations for SCS

Source, Year	Design	Sample Size	Level of Evidence	Results
Higashiyama et al 2023[72]	Single-center retrospective study	73	II	Improvement of VAS scores for low back pain, leg pain, and overall pain in both <75-year-old and ≥75-year-old groups after one year of surgery respective preoperative scores ($p < 0.001$). SCS reduced pain effectively in both groups with no differences in complications ($p = 0.05$).
Odonkor et al 2020[71]	Single-center retrospective study	174	II	Findings highlight key factors that may be optimal for a successful SCS trial. Within this cohort of patients, young age, paresthesia based tonic stimulation, and a history of spine surgery with pain localized to the lower extremity appear to the best prognostic factors for trial outcomes.
Huang et al 2015[74]	Retrospective analysis	21,672	II	Factors associated with increased likelihood of successful conversion includes younger age (43% for those aged 35–44 vs 39% for those aged 65 and older, $p < 0.0001$) and geographical variation (patients in the North Central region vs Northeast region: odds ratio 1.48, 95% CI [1.31, 1.66]; $p < 0.0001$).
Chow & Rosenquist 2023[75]	Literature review	-	II	Notable rises of SCS implantation rates increased substantially in all age groups from 2009 and 2018. Caucasians led with the highest rates, with SCS trials increasing from 32 per 100,000 in 2009 to 72 in 2018, and placements from 19 per 100,000 to 47 in the same period. African Americans showed more moderate increases, with trials going from 21 to 35 per 100,000 and placements from 13 to 20 per 100,000.
Mekhail et al 2022[76]	Retrospective cohort study	418	II	No biological sex-based differences in the analgesic response to SCS therapy was detected at 6- and 12-months post-SCS implant between groups with similar demographics, biomedical, and psychological values.
Manchikanti et al 2021[77]	Literature review	-	II	Racial statistics showed the rate per 100,000 Medicare population of 32 in 2009 compared to 72 in 2018 in those described as Caucasian, with an increase of 128% or 9.6% annually. Comparing this to the African American population, the rate was 21 per 100,000 Medicare population in 2009, which increased to 35 in 2018, an overall increase of 66% and annual increase of 5.8%. However, the most increase was in all others, which was 6 per 100,000 Medicare population in 2009 and increased to 20 in 2018, a 222% increase, with an annual increase of 13.9%.

(*Continued*)

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Table 8 (Continued).

Source, Year	Design	Sample Size	Level of Evidence	Results
Elsamadicy et al 2018[78]	Query of National Readmission Database	1521	II	Obesity is associated with a higher risk of 30-day readmission and mechanical complications following SCS implantation.
Mekhail et al 2019[79]	Retrospective cohort study	181	II	For each increment in BMI, SCS effectiveness decreases by 2% vs 20% of underweight and/or normal patients (≤24.9), though pain scores improved at 6–12 months in both groups respectively.
Sommer et al 2023[80]	Retrospectively analyzed from a prospective database	73	II	Patients with a BMI of 40 or higher exhibit a mere 5.48% complication rate and a significant trial success rate of 93.3%, which is considerably higher than the 74.4% observed in those with a lower BMI.

Abbreviations: BMI, body mass index; CI, confidence interval; SCS, spinal cord stimulation; VAS, visual analog scale.

Table 9 Consensus Statement on Patient Selection Criteria for SCS in NSLBP

Consensus Statement	Grade	Level of Certainty Regarding Net Benefit	Consensus
There are no specific studies defining demographic patient selection criteria for NSLBP. Selection criteria for traditional indications for SCS can be used as a template.	C	Moderate	Moderate
Patient selection should be modeled after the selection criteria for the NSLBP population in the RCT trials.	C	High	Moderate
While the published literature has not shown any evidence for increased adverse events or teratogenic risks associated with spinal cord stimulation use in pregnancy, the use of spinal cord stimulation is not recommended in pregnancy because the effects on the developing fetus are unknown.	C	Low	High
Pregnancy is an absolute contraindication to SCS trialing and implantation because of the use of fluoroscopy during the procedure.	A	High	High
The pain physician should seek multidisciplinary input, including hematology, cardiology, neurology, hepatology, and others, as appropriate based on chronic bleeding disorder pathology to plan the safest and most appropriate treatment course to minimize risk to the patient and optimize outcomes.	C	Low	High
The pain physician should educate the patient, family members, and the patient's primary care physician on signs and symptoms of bleeding, particularly epidural hematoma and pulse generator pocket hematoma.	C	Low	High
All patients undergoing a spinal cord stimulation trial and implantation should be screened for a personal history of contact dermatitis.	C	Low	Moderate
In patients with a personal history of contact dermatitis to metal, referral to a specialist for patch testing is recommended.	C	Low	Moderate
In patients with elevated risk of surgical site infection, the pain physician should collaborate with the patient's entire healthcare team to optimize the surgical risk status.	A	High	High

Abbreviations: NSLBP, non-surgical low back pain; RCT, randomized controlled trial; SCS, spinal cord stimulation.

Lead Type, Waveform, and Frequency for Spinal Cord Stimulation in Non-Surgical Low Back Pain

There are several SCS paradigms that have demonstrated efficacy for NSLBP.[1,17,47] The DISTINCT study compared SCS to CMM in patients with NSLBP. The study found a significant reduction in pain and pain-related disability with the use of passive recharge burst stimulation sustained at 12 months post-implant.[17,47] The passive recharge burst stimulation paradigm consists of a five-pulse train stimulus at an internal frequency of 500 Hz delivered at 40 Hz intervals and was delivered via a paddle or percutaneous implanted electrodes.[95,96] SCS implants in this study consisted of both percutaneous and paddle leads, primarily placed between T7 and T9.

The 2022 prospective RCT by Kapural et al examining 10,000 Hz stimulation therapy also demonstrated superiority versus CMM.[1] The study reported significant improvement in pain, pain-related disability, quality of life, and daily opioid dose at 12 months post-implant in the SCS arm. This stimulation paradigm delivers electrical pulses at high frequency up to 10,000 Hz, with a 30 microsecond waveform.[97,98] This combination allows paresthesia-free delivery of stimulation. SCS implants in this study consisted of percutaneous leads only, primarily placed between T8 and T11.

The EVOKE randomized controlled trial compared a novel, physiologic real-time closed-loop controlled evoked compound action potential (ECAP)-controlled, closed-loop SCS system (Evoke, Saluda Medical, Sydney, Australia) with a fixed output open-loop SCS system for back and leg pain of all types, finding significantly higher responder rates at 24 months within the closed-loop SCS arm.[99,100] This stimulation paradigm measures ECAPs up to 4 million times per day to automatically adjust the strength of stimulation in order to deliver a maintain a consistent activation of the spinal cord. While the study only had a sub-population of a NSLBP population, the inclusion of this population in this RCT suggests that closed-loop stimulation paradigm may yield similar outcomes for the NSLBP population, although no conclusions can be made due to study design. Future studies will be needed to further establish its use for NSLBP. Fishman and colleagues performed a multicenter randomized controlled study to establish the impact of DTM SCS on low back pain, including a small population with non-surgical back pain. In this study, they compared the effectiveness of the novel therapy to traditional tonic SCS. This was done post-market and was not subject to FDA oversight since it was not an IDE. In addition, the endpoint was at 3 months. One hundred and twenty-eight subjects were treated in 12 centers, 67 multiplexed SCS and 61 traditional SCS. Only 46 patients reached the 3-month endpoint. In that implanted analysis, 80.1% of those treated with the novel waveform responded compared to 51.2% of conventional SCS ($p = 0.0010$). In that group, this response was maintained to 12 months. The small implant group and the post-market design make it difficult to make conclusions about the NSLBP group.[101]

White and colleagues demonstrated the efficacy of DTM when compared to conventional spinal cord stimulation in patients with chronic refractory axial low back pain who were not candidates for spine surgery.[60] Study subjects totaled 121 patients randomized into two groups. The primary endpoint was the responder rate, defined as the proportion of patients achieving at least a 50% reduction in chronic low back pain at three months, assessed in a modified intention-to-treat population using both noninferiority and superiority hypotheses. Secondary endpoints included an analysis of mean changes from baseline VAS scores of chronic low back pain at 3, 6, 9 and 12 months, as well as the comparison of responder rates of the studied subjects at 6, 9 and 12 months. Additional outcome measures included analysis of leg pain VAS scores, Oswestry Disability Index changes, EQ5D-5L indices, as well as patient satisfaction and PGIC. At three months, the primary end point demonstrated statistical superiority of DTM spinal cord stimulation when compared to conventional spinal cord stimulation with a responder rate of 80.1% in the DTM SCS group compared to 51.2% in the conventional SCS group. These responder rates were maintained through 12 months with statistical superiority. Patients also demonstrated significantly better leg pain relief, less measured disability and perceived improvements in both satisfaction as well as quality of life. This study demonstrated that DTM spinal cord stimulation is clinically superior to traditional spinal cord stimulation in the treatment of chronic non-surgical low back pain up to 12 months.[60]

Ultimately, multiple SCS waveform, frequency, and lead types have demonstrated superior efficacy for NSLBP compared to CMM. Clinicians should ensure a thorough understanding of the differences in these stimulation paradigms and parameters and select the appropriate stimulation type based on patient criteria for each unique NSLBP patient, although no true guidance exists due to a paucity of data for a direct comparison. ASPN consensus statements are in Table 10.

Table 10 Consensus Statement on Lead Type, Waveform, and Frequency for SCS in NSLBP

Consensus Statement	Grade	Level of Certainty Regarding Net Benefit	Consensus
Paddle leads are better than percutaneous leads in the treatment of NSLBP.	C	High	Low
Percutaneous leads are better than paddle leads in the treatment of NSLBP.	C	High	Low
Passive recharge burst SCS should be used as a neuromodulation technique for the treatment of NSLBP.	A	High	High
10,000 Hz stimulation therapy should be considered for the treatment of NSLBP.	A	High	Moderate
DTM SCS should be used in the treatment of NSLBP.	A	High	High
Closed-loop SCS should be used in the treatment of NSLBP.*	B	Moderate	Moderate

Notes: *Although two commercial closed loop systems were available only one system had available data in the review for the treatment of NSLBP. The system (Evoke, Sydney, Australia) is included in the review.
Abbreviations: NSLBP, non-surgical low back pain; SCS, spinal cord stimulation.

Current Evidence for Neuromodulation with Dorsal Root Ganglion Stimulation for Non-Surgical Low Back Pain

Dorsal Root Ganglion Stimulation Food and Drug Administration Labeling

Dorsal root ganglion stimulation (DRG-S) received its FDA approval for the treatment of CRPS type I and type II and peripheral causalgia from the levels of T10 to S2 in February of 2016. This followed the CE Mark approval for use in the European Union in November 2011. Therefore, to note, the use of DRG-S for the treatment of NSLBP is off-label.

Dorsal Root Ganglion Stimulation for the Management of Non-Surgical Low Back Pain

In a 2020 study, seventeen consecutive patients suffering mainly from chronic axial LBP, with or without additional lower extremity pain, were examined.[102] All participants underwent trials and subsequently received DRG-S implants with leads placed at T12 to target the low back. Notably, the stimulation levels were set at a very low intensity which was below the threshold for inducing paresthesias. The average follow-up period was 8.3 months. The results were encouraging, with over half of the patients experiencing significant pain relief of at least 80%, and an average relief of 78% for LBP at the last follow-up. Moreover, the study reported marked improvements in physical and mental functioning, reduced disability, and enhanced overall quality of life. In conclusion, T12 DRG-S proves to be an effective approach in treating chronic axial LBP. The stimulation leads to reduced pain and disability, leading to an improved quality of life for patients, all achieved without causing paresthesias.

Anatomically, the facet joints and posterior spinal structures are innervated by branches of individual spinal nerve roots, while the discs and anterior vertebrae receive innervation via L2. These nerve signals converge in the dorsal horn of the spinal cord around T8-T9. The T12 nerve root carries cutaneous afferents from the low back and reaches the dorsal horn of the spinal cord at T10.[103] From there, Aδ and C-fibers from the low back ascend through Lissauer's tract to T8-T9, where they join with other low back afferents. When DRG-S is applied at T12, it leads to the inhibition of the converged low back fibers through mechanisms involving endorphin and gamma-aminobutyric acid (GABA)ergic frequency-dependent processes. Consequently, T12 lead placement appears to be the most favorable location for DRG-S in treating LBP.[104] In making this mechanistic revelation, clinical studies validate the theory. Chapman's research showed significant pain reduction (76% VAS decrease), improved disability (78% ODI enhancement), better psychological well-being (93% improvement in mental functioning on the Short Form 36 health questionnaire [SF-36]), and enhanced physical health (108% boost in physical functioning on the SF-36). Notably, 70% of patients reduced opioid use, with two discontinuing entirely.[104] In an additional study by Chapman and colleagues on 11 patients with FBSS and NSLBP showed positive outcomes: 77% VAS pain reduction, 62% ODI improvement, 80% EQ-5D enhancement, 24% improvement in mental functioning on the SF-36, and 104% improvement in physical functioning on the SF-36.[105]

Although not a specific study dedicated to NSLBP, a 2023 study conducted a retrospective analysis of patients with joint pain who underwent successful DRG-S trials and implants at the institute from September 2017 to September 2021.[106] The case series included patients with intractable joint pain and without clear evidence of neuropathic pain. They used specific criteria and surveys to assess the presence of neuropathic pain. Baseline assessments for pain, function, quality of life, and joint surveys were taken before the trial and at follow-up appointments. The study identified five patients with refractory joint pain in the hip, knee, or ankle. The results showed a significant improvement in pain, function, and quality of life after DRG-S implantation. NRS pain scores improved by 74% from baseline to last follow-up, ODI scores improved by 65%, and EQ-5D scores more than doubled.

The findings suggest that DRG-S may be a valuable treatment option for predominantly refractory mechanical joint pain regardless of the location of the joint pain without a significant neuropathic component. The observed benefits could be due to DRG-S's direct influence on nociceptive signaling at the DRG and within the spinal cord.[104] This means it could be important in discogenic or facetogenic pain.

Lumbar intervertebral disc disruptions can result in severe discogenic LBP, negatively affecting both physical function and quality of life. A prospective study aimed to assess the impact of DRG-S in carefully selected patients with discogenic LBP who had no prior history of back surgeries was initiated. It was designed as a single-arm case series where DRG-S was studied as a treatment attributed to discogenic causes. The DRG-S was applied at the bilateral L2 level,[107] with the rationale being the sympathetic convergence at this specific level, supported by the findings of Huygen et al.[108] Twenty participants with confirmed discogenic LBP underwent DRG-S trials, and those with at least 50% pain reduction during the trial received permanent implants. Results showed a significant reduction in NRS scores (average 63.4% reduction at 6 months, 68.3% at 12 months), notable mood improvements (141% EQ-5D increase), enhanced functional status (58% ODI improvement), and remarkable mood state improvements (101% Profile of Mood States [POMS] improvement) over 12 months.[107]

In another study, the effects of frequency on outcomes were assessed in 20 patients who were titrated to 4 Hz.[109] The patient cohort consisted of eight individuals with a history of prior lumbar fusion, two who underwent laminectomy/discectomy, and ten treated for NSLBP. All patients received bilateral T12 leads to address LBP, and a combination of unilateral or bilateral S1 or other lumbar leads was used to address lower extremity pain. The frequency was titrated from an average of 16 Hz to 4 Hz over an average period of 80 days, and outcomes were measured at pre-DRG-S, pre-titration, and post-titration stages. The efficacy of 4 Hz frequency was sustained, as indicated by the maintained improvements from baseline, which included a 77% reduction in VAS score (from 8.8 to 2.0), a 72% improvement in disability, and a remarkable 145% improvement in QOL (EQ-5D 0.33 to 0.81) at 366 days post-implant. Additionally, the cohort showed a continued reduction in opioid consumption from 87 to 43 MME, and a decrease in the number of interventional procedures performed from 0.5 to 0.04 per month during the equivalent pre-DRG-S period. The findings were published alongside a related review of literature article exploring the mechanisms underlying stimulation at 4 Hz.[110]

In another investigation focusing on the impact of frequency, 20 patients were systematically titrated to 4 Hz. The study found that the effectiveness of DRG-S was sustained at this frequency, with substantial improvements in pain (77% reduction in VAS), disability (72% improvement), mood (145% improvement in EQ-5D), and continued opioid reduction (from 87 to 43 MME) even after 366 days post-implant.[109,110] A prospective, double-blinded trial included 20 DRG-S responders who were randomized to three consecutive two-week stimulation programs: continuous stimulation; 1 minute on: 1 minute off; or 1 minute on: 2 minutes off. Mean scores at the end of each program were similar for NRS pain (continuous = 2.9 ± 0.8, 1:1 on-off = 2.6 ± 0.7, and 1:2 on-off = 2.7 ± 0.7 cm, $p = 0.39$), disability ($p = 0.72$), and general health ($p = 0.95$). This suggests that intermittent cycled patterns can achieve comparable effects on pain relief, disability, and functional improvement as standard continuous stimulation.[111]

Ongoing research and technological advancements are anticipated to further refine this technique and broaden its application in addressing the burden of chronic back pain.[1,22,38,40,112–115] Please refer to data in Table 11 and consensus statements in Table 12. Additional evidence is needed to define the role of DRG-S in treating NSLBP in wider clinical settings.

Table 11 Literature Summary for the Efficacy of DRG-S for NSLBP

Source, Year	Design	Sample Size	Level of Evidence	Results
Kallewaard et al 2020[107]	Observational study	20	Level II	Treatment with DRG-S reduced LBP ratings (68.3% reduction), from mean 7.20 ± 1.3 at baseline to 2.29 ± 2.1 after 12 months (p = < 0.001). ODI scores significantly decreased (p = < 0.001) from 42.09 ± 12.9 at baseline to 21.54 ± 16.4 after six months of treatment and to 20.1 ± 16.6 after 12 months.
Huygen et al 2018[108]	Observational study	12	Level II	More than half of subjects reported 50% or better pain relief in the low back, and the average low back pain relief was 45.5% at 12 months.
Chapman et al 2021[104]	Literature review	n/a	Level II	Optimal lead placement is at T12 due to convergence of low back Aδ and C-fibers with other afferents. Results showed significant pain reduction (76% VAS decrease), improved disability (78% ODI enhancement), better psychological well-being (93% mental SF-36 improvement), and enhanced physical health (108% physical SF-36 boost).
Chapman et al 2021[105]	Observational study	11	Level II	77% VAS pain reduction, 62% ODI improvement.
Chapman et al 2021[110]	Literature review	n/a	Level II	Utilizing lower stimulation frequency decreases the total energy delivery used for DRG-S, extends battery life, and facilitates the development of devices with smaller generators.
Chapman et al 2021[109]	Observational study	20	Level II	After device activation DRG-S frequency tapered from 16 to 4 Hz over a 4- to 17-week period, reducing charge-per-second by nearly two-thirds. Even so, pain relief was maintained at more than 75%, with consistent findings in the other measures.
Chapman et al 2022[111]	RCT	20	Level I	Mean scores at the end of each program were similar for NRS pain (continuous = 2.9 ± 0.8, 1:1 on-off = 2.6 ± 0.7, and 1:2 on-off = 2.7 ± 0.7 cm, p = 0.39), disability (p = 0.72), and general health (p = 0.95).

Abbreviations: DRG-S, dorsal root ganglion stimulation; LBP, low back pain; NSLBP, non-surgical low back pain; ODI, Oswestry Disability Index; SF-36, Short Form health questionnaire (36-item); VAS, visual analog scale.

Table 12 Consensus Statements on DRG-S in the Treatment of NSLBP

Consensus Statement	Grade	Level of Certainty Regarding Net Benefit	Consensus
DRG-S should be considered in the treatment of NSLBP.	C	Low	Moderate
Target levels of DRG-S are T12, L2, and S1.	C	Low	High

Abbreviations: DRG-S, dorsal root ganglion stimulation; NSLBP, non-surgical low back pain.

Diagnostic Work-up for the Implementation of Dorsal Root Ganglion Stimulation for the Treatment of Non-Surgical Low Back Pain

Imaging studies should be reviewed when considering treating a patient with NSLBP with DRG-S. Review spinal imaging such as x-rays, CT scans, and MRIs and treat or refer surgical indications appropriately and assure the absence of severe spinal stenosis.

Foraminal diameter is a concern given the 0.9-mm specifically designed DRG-S lead, although still significantly narrower than the typical 1.3-mm SCS lead,[116] still poses the risk of mass effect and foraminal compromise. As such, avoid placing a DRG-S lead at a level with identified severe foraminal stenosis and consider placement at adjacent levels for potential 'cross coverage'.

Current Evidence for Neuromodulation with Peripheral Nerve Stimulation in Non-Surgical Low Back Pain

Peripheral Nerve Stimulation for Low Back Pain Food and Drug Administration Labeling

There is currently no FDA labeling for peripheral nerve stimulation (PNS) specific to NSLBP. However, with recent advancements in technology and a proven safety profile, PNS is becoming a popular focal point for treatment advancements targeting painful neuralgias.[117] For example, a recent systematic literature review by Deer et al on PNS for pain was conducted reviewing 14 RCTs studying PNS for various painful conditions such as headache, shoulder, pelvic, back, extremity, and trunk pain.[118] The results demonstrated moderate to strong evidence supporting the use of PNS as an effective treatment for pain. The conclusion suggests that additional prospective trials could help further identify appropriate NSLBP populations and pain diagnoses for PNS treatment.

There are three focal areas specific to LBP which have garnered much attention based on recent evidence pertaining to the effectiveness and sustainability of PNS. These include the superior cluneal nerve,[119] middle cluneal nerve,[120] and medial branch stimulation for multifidus dysfunction.

For example, a 2023 article by Abd-Elsayed and Moghim reviewed 57 patients retrospectively with chronic pain who underwent PNS targeting various nerves.[121] The mean baseline pain scores significantly reduced at different follow-up durations. In the one-month follow-up group, the mean pain score dropped from 7.44 ± 1.48 pre-procedure to 1.6 ± 1.49, and similar reductions were observed at 3, 6, 9, 12, 15, and 24 months ($p \leq 0.001$). Additionally, patients reported a significant reduction in MME at 6, 12, and 24 months compared to pre-procedure levels ($p \leq 0.003$). Complications occurred in a small number of cases, with 2 patients requiring explant and 1 patient with a lead migration.

Another study aimed to explore the use of percutaneous PNS as an alternative to repeat lumbar radiofrequency ablation and more invasive surgical procedures for chronic back pain.[122] In a prospective, multicenter trial, patients who experienced a return of chronic axial pain after radiofrequency ablation received percutaneous PNS leads targeting the medial branch nerves. Stimulation was delivered for up to 60 days, and positive outcomes were observed. The results demonstrated that a majority of participants experienced highly clinically significant reductions in pain intensity (67%) and significant improvements in functional outcomes, such as disability (87%) and pain interference (80%), after two months with PNS. Five months after PNS, 93% of participants reported clinically meaningful improvements in one or more outcome measures, with many experiencing meaningful improvements in all three outcomes (pain intensity, disability, and pain interference). The findings suggest that percutaneous PNS could be an effective, nondestructive, and motor-sparing neuromodulation treatment option for chronic back pain, offering a promising shift in pain management approaches.[122]

CLBP has traditionally been treated with SCS when other treatments have been tried or when medical indications suggest neuromodulation is the next best approach in the patient treatment algorithm.[123,124] However, more recently, there has been special attention to targeting the dorsal ramus at L2 bilaterally to treat CLBP. Both persistent and acute back pain have been evaluated using a 60-day implantation of percutaneous neuromodulation leads at L2.[124] In addition, special attention has been paid to the possibility of the treatment, or reversal, of dynamic instability due to multifidus muscle deterioration. The restoration of dynamic stability of the lower back is efficacious by utilizing restorative neuromodulation.[125–127]

FDA approval has been gained for implantable and temporary PNS systems.[128–130]

Evidence of Efficacy in Peripheral Nerve Stimulation in Non-Surgical Low Back Pain

As chronic pain continues to increase in global prevalence, the need for evidence-based, efficacious solutions is critical. PNS, a pain treatment that dates back to the first century and the use of electrical discharges from torpedo fish,[131,132] has in recent years become an increasingly utilized treatment option due to the minimally invasive nature and limited side effects and complications. The published literature regarding the overall efficacy of PNS depends on the indication for utilization.

In a study of NSLBP patients, Gilmore et al, in a prospective case series involving nine patients, showed a >50% reduction in pain intensity in 67% of patients which after 12 months was reported at a 63% reduction in pain intensity.[133]

Several studies have analyzed the efficacy and safety of PNS for LBP. D'Souza et al recently performed a systematic review that included twenty-nine articles (828 total participants) focusing on PNS as a primary therapy for LBP.[134] All the included articles revealed improvement in LBP after PNS, which was rated between "modest to moderate" improvement as revealed by comparison of baseline pain scores to the individual follow-up periods. There is also emerging evidence of potential effectiveness of PNS in cancer-related pain etiologies presenting as NSLBP.[135]

Gilligan et al followed 204 patients in a randomized prospective controlled trial that utilized neuromuscular electrical stimulation of the L2 medial branch of spinal nerve dorsal rami and found an average VAS decrease of 3.3 points (7.3 to 4.0).[136] In addition, the 3-year and 5-year data has been recently published showing persistent statistically significant making this therapy the most supported treatment for PNS therapy in the field. The 3-year data showed an 83% responder rate. The 5-year data showed 126 patients low back pain VAS had improved from 7.3 to 2.4 cm (−4.9; 95% CI, −5.3 to −4.5 cm; $p < 0.0001$), with a responder rate of 71.8% defined as a pain reduction greater than 50%. The ODI improved from 39.1 to 16.5 (−22.7; 95% CI, −25.4 to −20.8; $p < 0.0001$), with 61.1% being reduced ≥20 points. The EQ-5D-5L index significantly improved from 0.585 to 0.807 (0.231; 95% CI, 0.195–0.267; $p < 0.0001$).[137,138]

Eldabe et al looked at 116 patients in a separate study that showed peripheral nerve field stimulation (PNFS) in the area of back pain improved pain scores by an average of 47% after 9 months.[139] Deer et al and Gilmore et al both lead prospective observational studies evaluating the use of 60-day PNS of the medial branch nerve and found 30% or greater pain relief in most subjects.[122,140] Guentchev et al published a prospective observational study that showed average VAS scores improved from 8.8 to 1.6 in 16 patients with permanent PNS placement.[141]

Current Evidence for Neuromodulation with Peripheral Nerve Stimulation for Pain

Recent advancements in PNS have improved pain relief accessibility. Gilmore et al reported sustained ≥30% pain improvement in 72.97% (54/74) patients at 14 months.[140] Deer et al showed ≥30% pain improvement in 86.66% (13/15) of patients at 2 months, with some reduction in efficacy at 5 months.[122] Studies on 30-day PNS systems revealed significant pain reduction.[124] In neuromuscular stimulation, Gilligan et al conducted an RCT comparing it to sham stimulation, showing no statistical significance in the primary outcome of ≥30% improvement in VAS scores at 120 days.[136] However, the therapeutic stimulation group reported an average VAS reduction of 3.3 points, while the sham group also showed a significant average reduction of 2.4 points. For PNS as salvage or adjunctive therapy for LBP intensity, Rigoard et al conducted an RCT that demonstrated a 68.8% decrease in VAS scores at 3 months in the PNFS salvage cohort compared to a 4.0% increase in the SCS-only group.[142] Van Gorp et al found a 30.7 point decrease in average VAS scores with PNFS plus SCS at the 3-month follow-up, compared to a 5.6 point average decrease in the SCS-only group.[143] When the failed SCS group received PNFS after 3 months, the average VAS scores decreased by another 30.1 points at the 1-year follow-up.

A summary of these finding is presented in Table 13, and an ASPN consensus statement is in Table 14.

Diagnostic Work-up for the Implementation of Peripheral Nerve Stimulation for the Treatment of Non-Surgical Low Back Pain

Numerous PNS techniques have been described for the treatment of CLBP.[134] At present, two emerging techniques are at the forefront of PNS for NSLBP.[144,145] One is the permanent implantation of a neurostimulator device to target the multifidus muscles. This technique is considered restorative neurostimulation targeting the multifidus muscle by placement of leads at the lumbar medial branches of L2.[136,145] The other is a 60-day temporary PNS system targeting the lumbar medial branch nerves. This technique is considered palliative neuromodulation targeting the medial branch nerves corresponding to primary area(s) of pain anywhere from L1-5.[122,133] Physician knowledge of diagnostic criteria and use of appropriate imaging/diagnostic modalities is imperative for the use of PNS.

Table 13 Literature Summary of Advanced Interventions: PNS

Source, Year	Design	Sample Size	Level of Evidence	Results
Gilmore et al 2021[140]	Prospective, multicenter case series study	74	Level I-B	Sustained ≥30% axial back pain improvement in 72.97% (54/74) patients at 14 months.
Deer et al 2021[122]	Prospective, multicenter study	15	Level I-B	≥30% pain improvement with peripheral nerve medial branch stimulation in 86.66% (13/15) patients at 2 months, with some reduction in efficacy at 5 months.
Kapural et al 2018[124]	Descriptive study	2	Level II	At 1 month, PNS produced clinically significant improvements in pain (62% average reduction in BPI), and functional outcomes (73% reduction in ODI; 83% reduction in pain interference, BPI).
Gilligan et al 2021[136]	RCT	204	Level I-A	Compared to sham stimulation, there was no statistical significance in the primary outcome of ≥30% improvement in VAS scores at 120 days. However, the therapeutic stimulation group reported an average VAS reduction of 3.3 points, while the sham group also showed a significant average reduction of 2.4 points.
Rigoard et al 2021[142]	RCT	19	Level I-A	68.8% decrease in VAS scores at 3 months in the PNFS salvage cohort compared to a 4.0% increase in the SCS-only group.
Van Gorp et al 2019[143]	RCT	50	Level I-A	30.7-point decrease in average VAS scores with PNFS plus SCS at the 3-month follow-up, compared to a 5.6-point average decrease in the SCS-only group. When the failed SCS group received PNFS after 3 months, the average VAS scores decreased by another 30.1 points at the 1-year follow-up.

Abbreviations: BPI, Brief Pain Instrument; ODI, Oswestry Disability Index; PNFS, peripheral nerve field stimulation; PNS, peripheral nerve stimulation; RCT, randomized controlled trial; VAS, visual analog scale.

Table 14 Consensus Statement for PNS in NSLBP Treatment

Consensus Statement	Grade	Level of Certainty Regarding Net Benefit	Consensus
PNS is helpful in the reduction of pain for in NSLBP.	B	Moderate	Moderate

Abbreviations: NSLBP, non-surgical low back pain; PNS, peripheral nerve stimulation.

While CLBP is often nonspecific and multifactorial, multifidus muscle dysfunction and inhibition is believed to play a role in its development.[136,144,146] Proper diagnosis of multifidus dysfunction prior to utilization of the restorative neurostimulation device is critical. The prone instability test (PIT) is considered the preferred test for evaluation of multifidus dysfunction as a source of CLBP.[136,146] The multifidus lift test also serves to identify multifidus dysfunction as a source of CLBP, although it is considered less specific and to have less interrater reliability compared to the PIT.[146] Lumbar MRI for the identification of multifidus atrophy and grading (grade 0–2) is also a useful adjunct; however, such findings must always be correlated to patient history and examination, including the aforementioned tests.[146]

The use of the 60-day temporary PNS system targeting the lumbar medial branch nerve has a broader diagnostic criterion for its use in NSLBP.[122,133] In the prospective study by Deer et al, enrolled patients had MRI findings of facet arthrosis, degenerative disc disease, disc protrusion, and/or foraminal narrowing.[122]

Imaging and Scoliosis in NSLB Pain

For both techniques, lumbar imaging with MRI or CT scan is critical to ensure proper patient selection. Physicians must review this imaging to rule out pathology that may warrant surgical intervention. This imaging should also be utilized to identify any

serious underlying cause of LBP (cancer, infection, metabolic bone disorder) or previous lumbar surgery.[122,136,144] In cases of spondylolisthesis, lumbar flexion/extension x-rays should be utilized to assess for instability, in which case the patient may benefit from surgery.[147] Lumbar x-rays or CT scans should also be utilized to identify conditions such as ankylosing spondylitis and spinal scoliosis. Patients with moderate-to-severe scoliosis (>25 degrees Cobb angle) warrant a surgical consultation.[122,136] The use of EMG/NCV prior to PNS for NSLBP is limited, and not considered an integral component of patient selection of PNS.[146] Lastly, physicians must always conduct a thorough patient history to rule out significant radicular complaints, as well as assess for timing of previous radiofrequency ablations and injections.[122,133,136] Such information is a critical component of patient selection for PNS. Thus, as the role of PNS for NSLBP continues to grow, physician knowledge of device systems, their diagnostic criterion, and the use of appropriate imaging/diagnostic modalities is imperative.

Future Directions and Research

While current evidence has helped establish the use of neuromodulation for NSLBP pain, it is important that our field continues to grow this body of knowledge.[1,17,47,99,100,102,107,137] Ongoing research efforts in a myriad of avenues will be critical to this.

First, as interdisciplinary collaboration becomes increasingly more important in our field, an ongoing collaborative effort to refine the definition of the NSLBP is important. As known, a myriad of pathologies can co-exist and culminate in CLBP.[19,148–150] Being able to identify pain generators and which types of NSLBP respond to neuromodulation will help guide implementation of the optimal therapy for a given patient with NSLBP.

Level 1 studies are critical to further establish the use of these therapies versus conventional medical management or emerging minimally invasive procedures for NSLBP. This evidence will ultimately help guide clinician decision-making regarding the appropriate type of neuromodulation to utilize for their patients with NSLBP.

Finally, as technology advances, researchers must explore innovative directions to enhance the efficacy, personalization, and overall patient outcomes with neuromodulation. One such technological advancement to consider is the use of AI. AI presents several potential avenues to optimize neuromodulation. Some key applications would be using AI to aid in patient selection and to refine the targeting and programming of neuromodulation. While current systems generally require manual adjustments by clinicians and clinical specialists, AI-assisted algorithms that continuously adjust stimulation parameters based on real-time biofeedback, physiologic data, and patient feedback may help optimize therapy for each unique patient.

Another element to consider would be the use of AI to target neuromodulation based on neural data. While ECAP measurement for closed-loop stimulation is a step in this direction, further capture and utilization of the complex neural activity occurring in the spinal cord and DRG presents a potential leap forward. Future research to develop AI-assisted algorithms to adjust stimulation parameters based on this neural data presents potential means of increasing long-term patient outcomes and satisfaction as well as a reduction in loss of efficacy rates.

In conclusion, the treatment of NSLBP is poised to be transformed with the use of neuromodulation. Further research regarding current techniques will be critical to continue this transformation as will a concerted focus on the potential uses of emerging technology such as AI and closed-loop stimulation.

Psychological Considerations for Neuromodulation in Non-Surgical Low Back Pain

Despite being considered a "standard" aspect of presurgical evaluation prior to SCS and other forms of neuromodulation for back pain, a review of the literature on psychological evaluation yields a complete lack of consensus regarding what elements constitute a sound evaluation, by whom it should be provided, and even its efficacy for improving outcomes.

Results of a literature search published by Fama and colleagues[151] demonstrate a complete lack of uniformity of the assessment tools utilized in published studies, with the authors concluding that, "no individual psychological factor in the literature has significantly correlated with outcomes" (p. 431). Although depression has been associated with diminished SCS efficacy in certain studies, these investigations were largely conducted prior to the advent of more sophisticated and effective waveforms,[152–155] thus limiting their validity for outcome prediction at present.

Table 15 Consensus Statements for Psychological Screen for Neuromodulation in NSLBP Treatment

Consensus Statement	Grade	Level of Certainty Regarding Net Benefit	Consensus
Research on long-term outcomes between patients receiving psychological evaluation prior to undergoing pre-trial neuromodulation trials and implantations needs to be conducted.	I	Low	Moderate
Until such time that such research is conducted, consideration should be given to discontinuing psychological pre-trial evaluations.	D	Low	Low

Abbreviation: NSLBP, non-surgical low back pain.

A serious concern regarding psychological evaluations as prerequisites for neuromodulation trials and implantations relates to the severe shortage of trained pain psychologists in the US.[156–158] Although there are no data on such, given the paucity of qualified pain psychologists in clinical practice, it is evident that only a small percentage of pre-trial or implantation psychological evaluations are being performed by pain psychologists. In an article written over two decades ago, the authors acknowledged that generalist psychologists do not understand the full scope of pain practice.[159] There is no evidence that generalist psychologists currently have a better understanding of the scope and nuances of pain management than was the case two decades ago. As a result, we have witnessed these unqualified mental health care providers routinely "over-pathologize" reactively depressed chronic pain patients, thereby disqualifying them from neuromodulation treatments that have the potential to provide them not just with analgesia, but with emotional relief as well.

A review of the extant literature indicates that European studies and guidelines are more likely to identify and recommend psychosocial factors that should be considered relevant for SCS patient selection than is the case in the American literature. In a recent consensus guideline developed in Europe, these factors included lack of engagement, dysfunctional coping, unrealistic expectations, inadequate daily activity level, problematic social support, secondary gain, psychological distress and unwillingness to reduce high-dose opioids.[160] Perhaps, the greater availability of pain psychologists to perform pre-trial evaluations in Europe as compared to the US represents a parsimonious explanation for this difference. Although there are no data on the availability of pain psychologists in European nations, a 2016 study by Darnall and colleagues[156] indicated that only 11.5% of US psychologists and therapist considered themselves "very competent" in treating patients with chronic pain.

Finally, the possibility that insurance carriers consider delaying coverage for neuromodulation by requiring pre-trial psychological evaluations cannot be ruled out. Anecdotally, this is something of which pain physicians are aware. Given the literature identifying the strong inverse relationship between delayed neuromodulation and favorable long-term outcomes,[161] the relationship between insurance insistence on still unproven psychological evaluations prior to neuromodulation trials, the delays in treatment that result from such, and the impact on outcomes certainly merits empirical investigation. ASPN consensus statements are in Table 15.

Conclusions

The NEURON project is intended to be living guidance with regular updates on the evidence and best practices for topics in spine and nerve. As seen in this publication, the use of neuromodulation for NSLBP is building, and evidence has now led to FDA labeling for forms of SCS. The additional reproduction of these studies and real-world data will lead to more patient access, improved outcomes and safety. It appears that at this time the overall data is developing, and we will see additional modifications in recommended usage and patient selection over time.

Abbreviation

AI, Artificial intelligence; ASPN, American Society of Pain and Neuroscience; BMI, Body mass index; BPI, Brief Pain Inventory; CI, Confidence interval; CLBP, Chronic low back pain; CMM, Conventional medical management; CRPS, Complex regional pain syndrome; CT, Computed tomography; DRG, Dorsal root ganglion; DRG-S, Dorsal root ganglion

stimulation; ECAP, Evoked compound action potential; EMG, Electromyography; EQ-5D, EuroQol 5-dimension questionnaire; FBSS, Failed back surgery syndrome; FDA, Food and Drug Administration; GABA, Gamma-aminobutyric acid; IQR, Interquartile range; LBP, Low back pain; MCID, Minimum clinically important difference; MME, Morphine milligram equivalents; MRI, Magnetic resonance imaging; NCV, Nerve conduction velocity; NEURON, Neuroscience, education, utilization, risk mitigation, optimal outcomes, and neuromodulation; NRS, Numeric rating scale; NSAID, Non-steroidal anti-inflammatory drug; NSLBP, Non-surgical low back pain; ODI, Oswestry Disability Index; PCS, Pain Catastrophizing Scale; PGIC, Patient Global Impression of Change; PIT, Prone instability test; PNFS, Peripheral nerve field stimulation; PNS, Peripheral nerve stimulation; POMS, Profile of Mood States; QOL, Quality of life; RCT, Randomized controlled trial; SCS, Spinal cord stimulation; SD, Standard deviation; SF-36, Short Form health questionnaire (36-item); STROBE, Strengthening the Reporting of Observational Studies in Epidemiology; US, United States; USPSTF, United States Preventative Services Task Force; VAS, Visual analog scale.

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