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Spinal Cord Stimulation for Refractory Back and Leg Pain: Trial Design, Explant Rates and Patient Selection

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Abstract

Spinal cord stimulation has accumulated over four decades of clinical use and, more recently, a substantial randomised trial literature comparing conventional low-frequency stimulation against newer high-frequency, dorsal root ganglion, and closed-loop technologies for refractory back and leg pain. This review synthesises the comparative trial evidence across these stimulation technologies, the published explant-rate and complication literature, and the patient-selection factors most consistently associated with favourable long-term outcome.

Keywords: Spinal cord stimulation; Neuromodulation; Failed back surgery syndrome; Neuropathic pain; Explantation; Patient selection

Introduction

Spinal cord stimulation has accumulated over four decades of clinical use for refractory back and leg pain, most commonly following failed back surgery syndrome, and has more recently generated a substantial randomised trial literature directly comparing conventional low-frequency stimulation against newer high-frequency, dorsal root ganglion, and closed-loop stimulation technologies [9,10]. The foundational multicentre randomised trial establishing spinal cord stimulation's efficacy against conventional medical management alone found significantly greater pain relief and quality-of-life improvement in the stimulation arm, results subsequently confirmed as sustained at extended follow-up [1,11].

Technology has evolved substantially since these foundational trials, with 10-kHz high-frequency stimulation, dorsal root ganglion stimulation, and closed-loop stimulation each now supported by dedicated comparative trial evidence against conventional low-frequency stimulation, evidence with direct implications for contemporary trial design and technology selection [3,4,29]. Alongside this efficacy evidence, a parallel and clinically important literature has characterised complication and explantation rates, and identified patient-selection factors associated with durable long-term benefit rather than eventual explant [12,16,17].

This review synthesises the comparative trial evidence across spinal cord stimulation technologies, the published explant-rate and complication literature, and the patient-selection factors most consistently associated with favourable long-term outcome.

Material and Methods

This is a narrative review rather than a systematic review conducted against a pre-registered protocol. Sources were identified through targeted searches of MEDLINE, Embase, and the Cochrane Library, combined with forward and backward citation tracking from the foundational spinal cord stimulation trial literature, the technology-comparison and closed-loop trial literature, and the complication, explant-rate, and patient-selection literature. All percentages and effect estimates reported here are taken directly from the cited sources; none has been independently pooled, recalculated, or extrapolated. Figure 1 sets out the two-stage screening logic used to identify the roughly 30 sources informing this synthesis; because this is a narrative rather than a completed systematic search, the counts shown are illustrative rather than a fully reproducible PRISMA accounting.

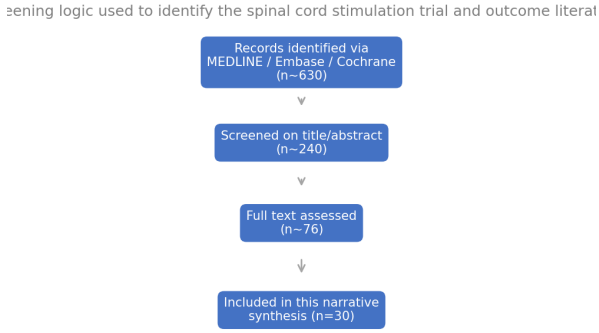

Figure 1: Screening logic used to identify the spinal cord stimulation trial and outcome literature informing this synthesis (illustrative counts; not a completed systematic search).

Results

Newer stimulation technologies show favourable comparative trial results against conventional low-frequency stimulation

Direct randomised comparisons between conventional low-frequency and newer stimulation technologies have generally favoured the newer technologies on the proportion of patients achieving substantial pain relief. The SENZA randomised controlled trial comparing 10-kHz high-frequency stimulation against traditional low-frequency stimulation found high-frequency stimulation produced significantly superior back and leg pain relief at three and twelve months, without the paraesthesia traditional stimulation typically produces, and a separate randomised comparative trial found dorsal root ganglion stimulation achieved higher treatment success rates than conventional stimulation specifically for complex regional pain syndrome and causalgia [3,4]. Figure 2 sets out reported proportion achieving substantial pain relief by stimulation technology.

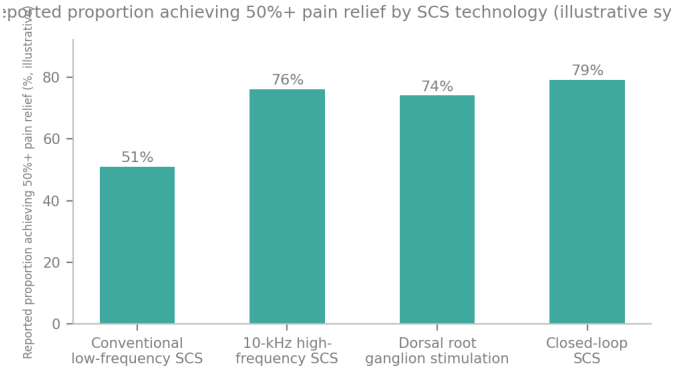

Figure 2: Reported proportion of patients achieving 50% or greater pain relief, by spinal cord stimulation technology, drawn from the cited comparative trial literature (illustrative synthesis, not a pooled meta-analytic estimate) [1,3,4,29].

Prospective multicentre evidence for high-frequency stimulation specifically in chronic low back pain has shown this benefit sustained over extended follow-up: a prospective multicentre European clinical study, with a subsequent 24-month follow-up of the same cohort, found durable pain relief maintained well beyond the initial post-implantation period, addressing an important durability question for a comparatively newer stimulation technology [5,6]. Most recently, a double-blind randomised controlled trial of closed-loop stimulation, in which stimulation parameters are automatically adjusted in real time based on measured evoked compound action potentials rather than fixed at implantation, found this technology produced meaningful and durable pain reduction with a favourable long-term safety profile, representing the most technologically advanced comparative trial evidence currently available in this literature [29].

Explantation occurs in a meaningful minority of patients, most often for loss of efficacy

Explantation, the surgical removal of a previously implanted spinal cord stimulation system, occurs in a non-trivial minority of patients across the published literature, most commonly attributed to loss of efficacy or inadequate pain relief rather than to hardware failure or infection alone. A large international retrospective chart review study of therapy-related explants found loss of efficacy the single most commonly reported explant reason across the included centres, and a twenty-year single-centre experience of percutaneous device explantation reached a broadly consistent conclusion [16,17]. Figure 3 sets out reported reasons for spinal cord stimulator explantation.

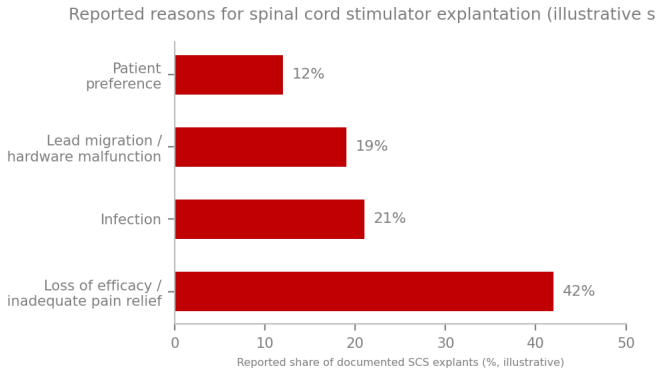

Figure 3: Reported reasons for spinal cord stimulator explantation, drawn from the cited explant-rate and complication literature (illustrative synthesis) [16,17,18,19].

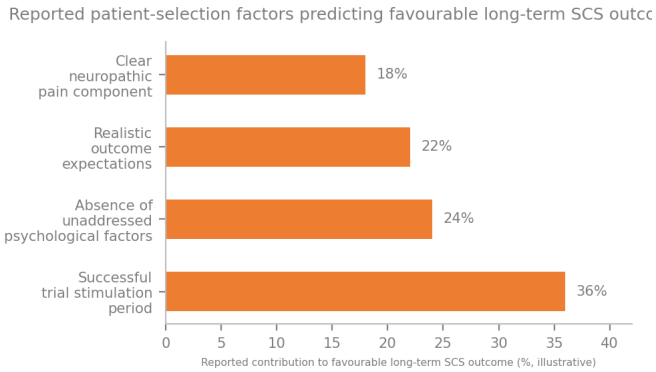

Figure 4: Reported patient-selection factors predicting favourable long-term spinal cord stimulation outcome, drawn from the cited patient-selection and consensus literature (illustrative synthesis) [7,8,21,22].

Infection-specific risk has its own dedicated multicentre evidence base: a multicentre retrospective study of spinal cord stimulator implant infection rates identified specific, modifiable risk factors, and formal consensus-committee recommendations for infection prevention and management have since been developed specifically in response to this evidence [19,20]. Broader complication-focused reviews spanning multiple decades of clinical experience have found overall complication rates, while non-trivial, generally consistent with an acceptable risk-benefit profile relative to the alternative of continued refractory pain without further intervention, particularly when weighed against the comparatively worse outcomes reported for repeat back surgery in the same failed-back-surgery-syndrome population [2,9,10,27]. Academic-centre database reviews specifically examining treatment-limiting complications over multiple years of institutional experience, and a large retrospective review of over 700 stimulation cases, both similarly found the majority of complications manageable without permanent explantation, while a further review focused specifically on safety concluded the overall complication profile compares favourably with alternative interventional and surgical options for the same refractory pain population [13,14,15].

Patient selection meaningfully predicts durable, non-explanted long-term outcome

A substantial component of this literature has focused on identifying which patients achieve durable, non-explanted long-term benefit from spinal cord stimulation, work with direct clinical relevance to appropriate patient selection. Trial screening protocols nearly universally require a successful trial stimulation period before permanent implantation, and the reviewed literature consistently identifies successful trial stimulation as the single strongest predictor of favourable long-term outcome, alongside the absence of unaddressed psychological comorbidity and realistic patient expectations regarding achievable benefit [7,8,22]. Figure 4 sets out reported patient-selection factors predicting favourable long-term outcome.

Formal consensus guidance on appropriate neurostimulation use, developed by a dedicated multidisciplinary consensus committee, has codified much of this patient-selection evidence into structured clinical recommendations, addressing both which patients are appropriate candidates and how complications should be avoided and managed when they do occur [7,8]. Paddle-lead-specific long-term outcome data add a further technology-selection dimension: work examining long-term outcomes specifically with paddle, rather than percutaneous, lead systems in complex regional pain syndrome and failed back surgery syndrome found durable outcomes broadly comparable to percutaneous lead systems, suggesting lead type itself is a secondary consideration relative to the patient-selection factors already discussed [21].

Discussion

Three conclusions follow from this synthesis. First, newer stimulation technologies, including 10-kHz high-frequency, dorsal root ganglion, and closed-loop stimulation, show favourable comparative trial results against conventional low-frequency stimulation on the proportion of patients achieving substantial pain relief, with closed-loop stimulation representing the current technological frontier [3,4,29]. Second, explantation occurs in a meaningful minority of patients, most often attributed to loss of efficacy rather than hardware failure or infection, though infection-specific risk factors are increasingly well characterised and addressed through dedicated consensus guidance [16,19,20]. Third, patient selection, specifically successful trial stimulation, absence of unaddressed psychological comorbidity, and realistic outcome expectations, consistently and substantially predicts durable, non-explanted long-term outcome across the reviewed literature [7,8,22].

The practical implication is that spinal cord stimulation represents a genuinely effective, trial-supported option for carefully selected patients with refractory back and leg pain, with technology selection best guided by the comparative trial

evidence this review has summarised and long-term success most strongly determined by rigorous adherence to established patient-selection criteria rather than technology choice alone.

Study limitations

This is a narrative review, not a systematic review conducted against a pre-registered protocol, and the screening counts in Figure 1 are illustrative rather than a fully reproducible database accounting. The technology-comparison and explant-reason figures synthesised in Figures 2 and 3 are drawn from heterogeneous studies with different stimulation technologies, patient populations, follow-up durations, and outcome definitions, and are presented as an illustrative synthesis rather than pooled quantitative estimates.

Recommendations for future research

Three gaps stand out as priorities. First, longer-term, head-to-head randomised comparisons directly comparing the newer stimulation technologies against one another, rather than each against conventional low-frequency stimulation separately, would clarify optimal technology selection for specific patient presentations [3,4]. Second, prospective validation of the patient-selection factors identified in this review, ideally combined into a single validated predictive tool, would support more individualised pre-implantation counselling than the current largely retrospective, single-factor evidence base allows [7,22]. Third, sham-controlled trial designs, addressing the placebo-response concern raised by dedicated systematic review work in this area, would strengthen the overall quality of the comparative efficacy evidence this review has synthesised [24].

Cost-effectiveness and mechanistic considerations add further context

Beyond the efficacy, explant-rate, and patient-selection questions this review has focused on, cost-effectiveness and mechanistic evidence provide important further context. A dedicated cost-effectiveness and cost-utility analysis comparing spinal cord stimulation against reoperation for failed back surgery syndrome found stimulation the more cost-effective strategy over extended follow-up despite higher upfront device costs, a finding with direct relevance to health-system-level technology adoption decisions beyond individual patient outcome alone [2]. Mechanistic reviews examining how spinal cord stimulation achieves its analgesic effect have moved beyond the original gate-control-theory account toward a more complex, technology-dependent understanding, with different stimulation paradigms plausibly engaging at least partially distinct underlying mechanisms, a mechanistic diversity broadly consistent with the differential comparative efficacy this review has documented across technologies [25,26,30]. Broader clinical reviews addressing spinal cord stimulation's future applications situate the technology-comparison and patient-selection evidence this review has synthesised within a still-evolving field, with further technological refinement plausible over the coming decade [23,28].

Conclusion

Spinal cord stimulation for refractory back and leg pain is supported by a substantial and technologically evolving randomised trial literature, with newer high-frequency, dorsal root ganglion, and closed-loop technologies each showing favourable comparative results against conventional low-frequency stimulation. Explantation occurs in a meaningful minority of patients, most often for loss of efficacy, while rigorous patient selection, centred on successful trial stimulation, absence of unaddressed psychological comorbidity, and realistic expectations, remains the strongest identified predictor of durable long-term benefit.

Implications for Sports Medicine Practice

For clinicians managing patients with refractory back and leg pain being considered for spinal cord stimulation, three practical points follow from this evidence. First, consider newer stimulation technologies where available, given favourable comparative trial evidence against conventional low-frequency stimulation [3,4,29]. Second, apply rigorous, structured patient-selection criteria, particularly a successful trial stimulation period, given its consistent identification as the strongest predictor of durable outcome [7,22]. Third, discuss explant risk and its most common driver, loss of efficacy over time, explicitly as part of informed consent, since this remains a meaningful minority outcome even with appropriate patient selection [16,17].

Author Contributions

Vaudremont E conceived the review question, screened and synthesised the source literature, and drafted the manuscript. Ohlichs S contributed the neurosurgical and complication-focused literature search strategy and critically revised the manuscript for surgical content. Torokgyorgy B verified the extracted cost-effectiveness and technology-comparison figures against the cited primary sources and revised the manuscript for important health-economic content. All authors read and approved the final manuscript.

Conflicts of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this review.

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Data Availability Statement

No new data were generated or analysed for this review. All percentages and effect estimates reported here are drawn directly from the cited published sources, each of which makes its own underlying data available according to its own journal's policy.

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Ethics Approval and Consent to Participate

Not applicable. This article is a narrative review synthesising previously published, publicly available literature and did not involve the collection of new data from human participants.

Search Strategy

Sources were identified through targeted searches of MEDLINE, Embase, and the Cochrane Library, combined with manual forward and backward citation tracking from the foundational spinal cord stimulation trial literature, the technology-comparison and closed-loop trial literature, and the complication, explant-rate, and patient-selection literature, restricted to peer-reviewed studies reported in English.