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Patient-Reported Outcomes With 10 kHz Spinal Cord Stimulation in Routine Clinical Practice: A Real-World Study With Up to Seven Years of Follow-Up

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Abstract

Context

High-frequency spinal cord stimulation at 10 kHz (10 kHz-SCS) has been validated for the treatment of various chronic pain conditions through large, multicenter, randomized controlled trials (RCTs) and real-world observational studies. However, evidence on whether pain relief is durable over the long term in routine clinical practice remains limited, as most studies report outcomes within the first one to two years of therapy.

Objectives

This study presents a retrospective, single-center analysis describing patient-reported pain relief and explant rates with 10 kHz-SCS in patients treated for chronic pain in the trunk or limbs, with individual follow-up ranging from less than one year to more than seven years.

Methods

Data from patients implanted with a 10 kHz-SCS device between February 2017 and June 2024 at Claremont Pain Clinic (Perth, Western Australia) were retrospectively extracted from a post-market surveillance database. Assessments included pain relief, responder rates (defined as achieving ≥50% reduction in pain from pre-implantation), and patient-reported improvements in sleep quality, physical function, and changes in analgesic use.

Results

This review yielded a total of 147 patients who had received a 10 kHz-SCS implant, and data analysis was performed on all patients with outcome data available (119/147). At last follow-up, 83.2% (99/119) of patients with available data reported ≥50% pain relief with 10 kHz-SCS. Mean reported pain relief among patients whose most recent assessment fell within each period was 61.8% in the early period (0-2 years), 57.9% in the intermediate period (2-5 years), and 67.0% in the late period (>5 years). Among patients with available data, 86.7% (65/75) reported improvements in function, 79.0% (60/76) reported improvement in sleep, and 40.3% (31/77) reported reduced analgesic medication intake for chronic pain.

Conclusion

This study observed clinically meaningful pain relief with 10 kHz-SCS in patients with available follow-up, including those assessed more than five years following implantation. Most patients with available data also reported improvements in physical function, sleep quality, and analgesic use. This real-world single-center analysis provides supportive data on long-term patient-reported outcomes in patients treated with 10 kHz SCS therapy, although longitudinal studies with validated measures are needed to confirm durability.

Categories: Pain Management
Keywords: chronic pain, high frequency scs, long-term outcome, real-world evidence, scs, spinal cord stimulation

Introduction

High-frequency spinal cord stimulation at 10 kHz (10 kHz-SCS) is well-established for alleviating chronic pain in the back, lower limbs, and diabetic neuropathy [1-7]. Additionally, published evidence highlights the therapy's impact on functional outcomes, quality of life, and its potential to reduce the need for analgesic medications [8,9]. However, a notable limitation in the existing research is the lack of data extending beyond two to three years, as pivotal randomized trials of 10 kHz-SCS followed patients for up to 24 months, and longer-term reports have been limited to small cohorts or conventional low-frequency SCS [10-13].

Real-world evidence (RWE) offers valuable insights by complementing randomized controlled trial (RCT) findings, particularly through more diverse patient populations and longer follow-ups. Several RWE studies on 10 kHz-SCS have already demonstrated these advantages [14-16]. However, most prospective and retrospective RWE studies have limited follow-up [14,17,18]. The objective of this study, therefore, was to conduct a real-world, single-center, retrospective review of patients with chronic pain of the trunk or lower limbs treated with 10 kHz-SCS to describe long-term patient-reported outcomes (pain relief, physical function, sleep quality, and analgesic use) and explant rates in routine clinical practice, with particular attention to patients whose most recent assessment occurred more than five years after implantation.

Materials And Methods

Study design

Data for this retrospective, single-center review were collected in conjunction with Claremont Pain Clinic under human research ethics committee approval from the Bellberry Human Research Ethics Committee (approval No. 2024-05-546) from a manufacturer-owned real-world database populated with de-identified records from patients who were permanently implanted with a Nevro SCS system (Redwood City, CA, USA) delivering 10 kHz-SCS. The 10 kHz-SCS system used in this study (Senza System, Nevro Corp., Redwood City, CA, USA) has been evaluated in prior randomized controlled trials [6], and the manufacturer-owned database from which these data were extracted has been used in previously published peer-reviewed real-world studies [15,16]. Permission to access and use these de-identified data for research and publication purposes was obtained from Nevro Corp., the database owner, and from Claremont Pain Clinic.

Participants

Database records were retrospectively extracted from all patients with chronic pain permanently implanted with 10 kHz-SCS at Claremont Pain Clinic between February 2017 and June 2024, regardless of primary pain indication. Baseline demographic characteristics are reported for this full cohort. However, outcome analyses were restricted to the subset of patients for whom at least one outcome measure was available (pain score, physical function, sleep quality, or analgesic intake). Because complete-case analysis was used, the number of patients contributing to each outcome varied according to how many patients had a recorded value for that specific measure at last follow-up, rather than reflecting a single fixed subgroup (see Statistical analysis). All consecutive patients permanently implanted during the study period were included, with no additional exclusion criteria. Of the 147 implanted patients, 126 had at least one recorded post-implant assessment date; the remaining 21 had no dated post-implant assessment in the database. Reasons for missing assessments were not systematically recorded in the database.

Interventions

The 10 kHz-SCS system (Senza System, Nevro Corp., Redwood City, CA, USA) was implanted in eligible patients following the standard practices of the participating clinical center. Patients first underwent a trial stimulation phase of 7-14 days using percutaneous leads connected to an external stimulator, and those who achieved successful pain relief (⩾50% reduction) proceeded to permanent implantation of the SCS system. Trial success was based on patient-reported pain relief relative to pre-trial pain. Leads were placed in the dorsal epidural space at vertebral levels appropriate to the pain indication. Stimulation was delivered at 10 kHz with a 30 µs pulse width and paresthesia-free amplitude titrated to effect. During follow-up, patients could be reprogrammed as part of routine care. Reprogramming episodes, lead revisions, implantable pulse generator replacements, and any changes in stimulation strategy were not systematically captured in the extracted dataset and could not be analyzed.

Patient-reported outcomes

Patient records were extracted from the database based on each patient's most recent visit. This final visit was defined as the last clinic or telephone follow-up after permanent implantation, prior to the data being consolidated for the final report. Follow-up contacts were scheduled as part of routine post-market care; however, contacts occurred at variable times in practice, and only each patient's most recent recorded assessment was available in the extracted dataset. Each patient therefore contributed a single observation to the analysis, and repeated within-patient measurements were not analyzed.

Patient-reported outcome measures included the percentage of pain relief, changes in medication use (increased, decreased, or unchanged), functional improvement (yes or no), and sleep improvement (yes or no). A successful therapy response was defined as achieving at least 50% pain reduction from baseline. For analysis of pain relief over time, follow-up duration intervals were established as early (0-2 years), intermediate (2-5 years), and late (>5 years) periods. These outcomes were captured through structured questions administered by the Nevro patient care team during scheduled clinic or telephone follow-up visits: percentage pain relief was based on the patient's self-reported estimate of overall reduction in pain intensity relative to their pre-implantation baseline; physical function and sleep quality were each assessed using a single yes/no question asking whether the patient perceived improvement relative to baseline; and analgesic use was recorded as the patient-reported change (increased, decreased, or unchanged) in pain medication intake since implantation. The reference baseline for all outcomes was the patient's status before

implantation as recalled by the patient at the time of assessment. Analgesic use referred to all medications taken for chronic pain and was not specific to opioids; the change was patient-reported only and was not quantified.

Safety outcomes

For this study, safety data were gathered from the clinical center, patients, or routine follow-ups by the Nevro patient care team, specifically focusing on any recorded device explants. Information regarding the reason for explantation, where available, was retrieved from the manufacturer's database.

Statistical analysis

Descriptive statistics were used to summarize baseline demographic and clinical characteristics: continuous variables are reported as mean ± standard deviation (SD) and range, and categorical variables as counts and percentages. The responder rate was calculated as the number of patients reporting ⩾50% pain relief at their most recent assessment divided by the number of patients with a recorded pain-relief value. Percentage pain relief was summarized as the mean value within each follow-up interval (early, intermediate, late), based on the time between permanent implantation and that assessment; each patient contributed to one interval only. To express the uncertainty of the estimates, 95% confidence intervals (CIs) were calculated. Given the descriptive, hypothesis-generating nature of this retrospective single-center review, no formal between-group statistical comparisons or hypothesis tests were performed, and a pre-specified significance threshold (alpha) was therefore not applicable. Missing data were handled using complete-case analysis: patients without a recorded value for a given outcome were excluded from the denominator for that specific outcome rather than being imputed; this is the source of the varying sample sizes reported across outcomes (e.g., n=119 for pain relief, n=75 for physical function, n=76 for sleep quality, and n=77 for analgesic use, out of N=147 implanted patients). All analyses were performed using Microsoft Excel (Microsoft Corp., Richmond, WA, USA).

Results

This retrospective review yielded a total of 147 patients who had received a 10 kHz-SCS implant. Data analysis was performed on all patients with outcome data present within the database. Baseline patient characteristics are summarized in Table *1*. The cohort was 53.7% female (n=79) and 46.3% male (n=68), with a mean therapeutic evaluation period of 3.7±2.2 years (range: 0.06 to 7.47 years). Because outcome analyses used complete-case denominators (see Methods, Statistical analysis), the number of patients contributing to each outcome (n=119 for pain relief, n=75 for physical function, n=76 for sleep quality, and n=77 for analgesic use) reflects only those with a recorded value for that specific measure at last follow-up, and therefore differs both from the full implanted cohort (N=147) and from one another. Among the 126 patients with a dated post-implant assessment, the time from implantation to the most recent assessment was zero to two years for 39 patients (31.0%), two to five years for 35 (27.8%), and more than five years for 52 (41.3%), including seven assessed more than seven years after implantation (Table *1*). Of the 52 patients assessed beyond five years, 48 had pain-relief data; the remaining four patients in this group had a dated assessment but no recorded pain-relief value. Pain-relief data were missing for 28 of 147 patients (19.0%). Physical function, sleep, and analgesic-use data were missing for 72, 71, and 70 patients, respectively.

Characteristics	N
Gender n (%)	n=147
Female	79 (53.7%)
Male	68 (46.3%)
Therapeutic Evaluation Period (Years Between Implant and Last Recorded Assessment)	n=126
Mean (±SD)	3.7±2.2
Range	0.06 to 7.47
Time Since Permanent Implant (Years Between Implant and Last Recorded Assessment)	n=126
0–1 year	16
1–2 years	23
2–3 years	17
3–4 years	13
4–5 years	5
5–6 years	20
6–7 years	25
>7 years	7

TABLE 1: Baseline patient characteristics.

SD, standard deviation; n values vary across characteristics because of missing data for that measure.

At their last follow-up, 83.2% of patients with available pain-relief data (n=99/119) reported at least 50% pain relief with 10 kHz-SCS (Figure *1*). The percentage pain relief grouped by follow-up duration is presented in Table *2*. Mean reported pain relief among patients whose most recent assessment fell within each period was 61.8% in the early period (0-2 years; n=37), 57.9% in the intermediate period (2-5 years; n=32), and 67.0% in the late period (>5 years; n=48) (Table *2*). The missing data burden was similar across periods, with 5%, 9%, and 8% of patients missing pain scores in the early, intermediate, and late groups, respectively, among patients with a dated assessment in each interval. This does not exclude attrition before the most recent assessment, such as patients with poorer outcomes discontinuing follow-up.

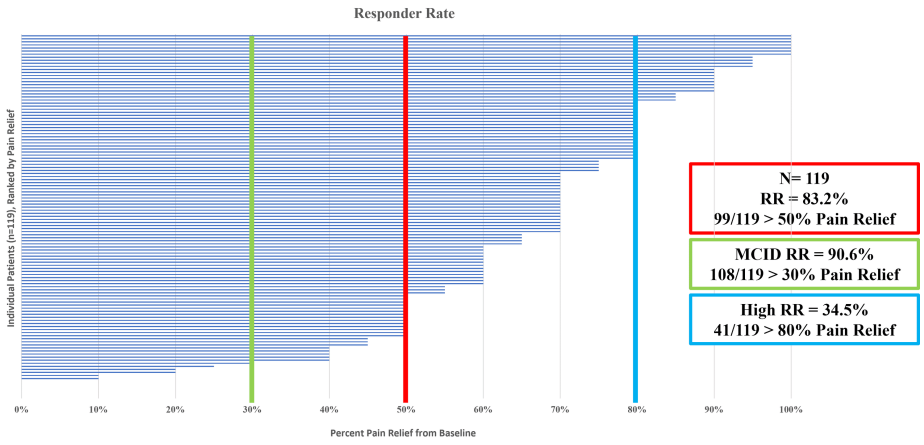


FIGURE 1: Pain relief responder rates among patients with available pain-relief data (n=119 of 147 implanted).

MCID, minimal clinically important difference; RR, responder rate; High RR, High responder rate.

Time since permanent implant	N	Mean pain relief (%)
Early (0–2 years)	37	61.8
Intermediate (2–5 years)	32	57.9
Late (>5 years)	48	67.0

TABLE 2: Mean reported percentage pain relief over time (weighted means).

Among patients with available data, the majority of patients additionally reported improvements in sleep quality (79.0%) and physical function (86.7%), while a reduction in analgesic medication intake was reported by 40.3% of patients at their most recent visit compared to pre-implantation (Figure *2*).

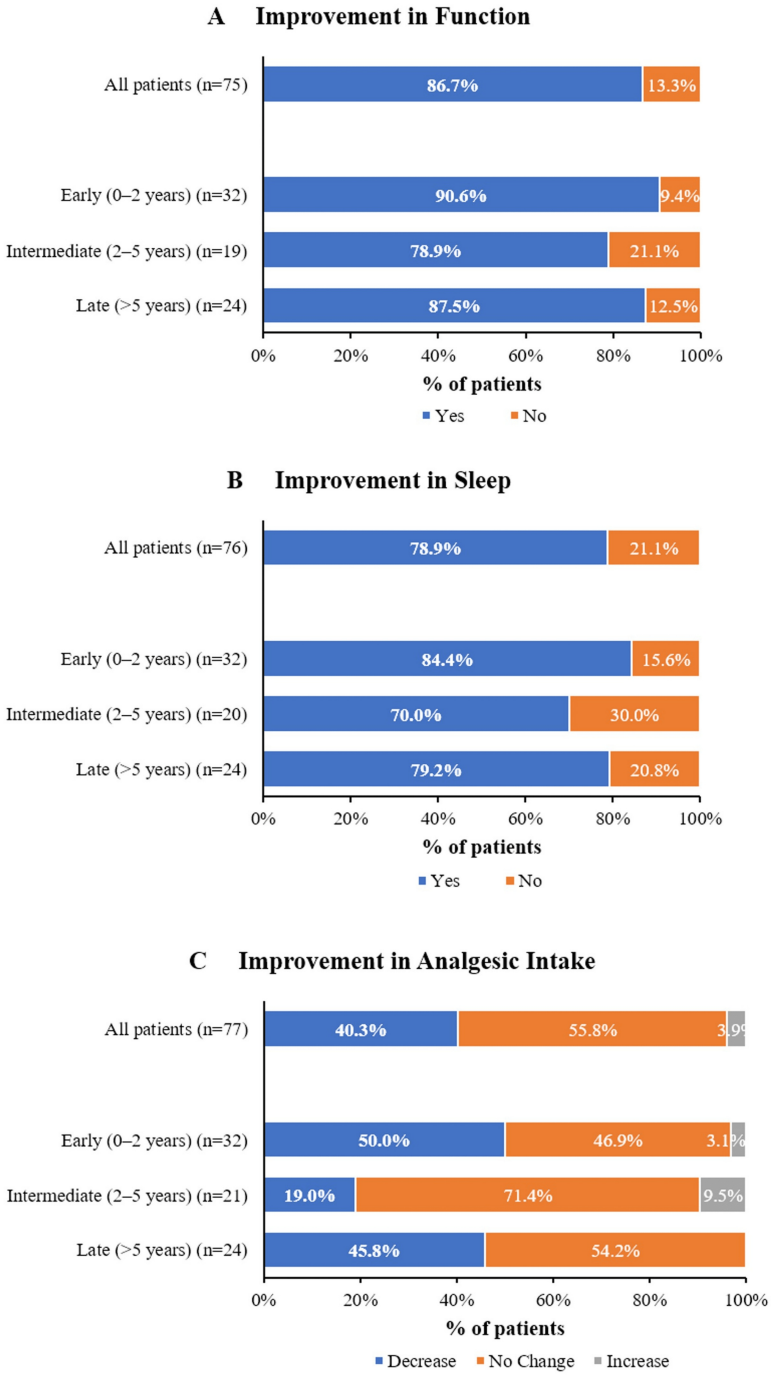


FIGURE 2: Reported improvement among patients with available data in (A) physical function (n=75), (B) sleep quality (n=76), and (C) analgesic medication use (n=77) at last follow-up assessment.

Safety outcomes

Over the study period (maximum individual follow-up 7.5 years), eight of 147 patients implanted at the clinic had their device removed, an all-cause explant rate of 5.4% (Table *3*). Of these explants, 3.4% were due to loss of efficacy and 2.0% were due to infection. No removals were performed for device malfunction or failure. The 95% CI for the all-cause explant rate was 2.8-10.4%.

Reason for explant	N	% of all patients (N=147) over 7-year follow-up (95% CI)
Loss of efficacy	5	3.4 (1.5-7.7)
Infection	3	2.0 (0.7-5.8)
Total	8	5.4 (2.8-10.4)

TABLE 3: All-cause explant summary.

Discussion

In this retrospective single-center analysis, a substantial proportion of patients with available follow-up reported clinically meaningful pain relief with 10 kHz-SCS, including patients whose most recent assessment occurred more than five years after implantation. When follow-up was grouped into early (0-2 years), intermediate (2-5 years), and late (>5 years) periods, mean reported pain relief among patients assessed in each period was 61.8%, 57.9%, and 67.0%, respectively. The magnitude of pain relief was numerically similar to previously observed outcomes at early time points of three months to two years in large prospective open-label and randomized controlled trials of 10 kHz-SCS for various pain indications [1,6,7]. The finding that 83.2% of patients with available data achieved clinically meaningful pain relief (≥50% improvement from baseline) at last follow-up adds to the real-world evidence on long-term outcomes of 10 kHz-SCS therapy [14-16]. Additionally, improvements in physical function and sleep quality in a majority of patients and reduced analgesic medication use in many at their most recent visit, although assessed with single, nonvalidated binary items and available for only approximately half of the cohort, are consistent with prior reports of multidimensional benefits of 10 kHz-SCS [8,9].

The explant rate of 5.4% over the multi-year follow-up period, with the cause of explantation attributed to loss of efficacy (3.4%) and infection (2.0%), is numerically similar to rates reported in the published literature. In an RCT evaluating 10 kHz-SCS for nonsurgical refractory back pain, the explant rate was 4.8% through two years, with causes equally divided between loss of efficacy (2.4%) and infection (2.4%) [19]. Likewise, in a randomized controlled trial evaluating 10 kHz-SCS for painful diabetic neuropathy, the explant rate was 3.2% through two years, all due to infection [20]. The high survivorship of the 10 kHz-SCS system over the extended period of the current study further suggests the durability of this therapy.

Limitations

Using retrospective real-world data introduces limitations that affect the interpretation of these findings. Natural attrition and variability in the quality and consistency of follow-ups are evident in the dataset, partly due to the extended timeframe for outcome collection. Over time, data collection from such cohorts tends to decline due to non-compliance, participant dropout, challenges in maintaining long-term follow-ups, and data fatigue. These factors contribute to a reduction in both the quantity and completeness of data over longer periods. Most importantly, outcomes were drawn from each patient's most recent available assessment, so comparisons across follow-up intervals are cross-sectional comparisons of different patients and do not establish that individual patients maintained their response over time. Pain-relief data were unavailable for 28 of 147 implanted patients (19%), and functional, sleep, and medication outcomes were unavailable for approximately half of the cohort. Missing assessments for the pain scores were notably fewer than other quality of life outcomes, so the latter should be interpreted more cautiously. In addition, patients with available long-term assessments may also differ systematically from those lost to follow-up (for example, in indication, baseline severity, or engagement with care), and the extent of this selection bias could not be fully assessed because few baseline characteristics were available for comparison.

Outcome measurement was also limited. Percentage pain relief was a single, recall-based global estimate relative to a remembered pre-implant baseline, and physical function and sleep were assessed with binary, nonvalidated questions. Validated instruments (e.g., numeric rating scale pain scores, Oswestry Disability Index, sleep or quality-of-life questionnaires) were not collected, which limits conclusions regarding functional and quality-of-life benefits.

This investigation utilized a patient database managed by the SCS manufacturer, raising the possibility of industry bias. Two features of the data-collection process may reduce, but do not eliminate, this risk. First, company protocols require that all patient interactions and associated data entries be documented, with audio recordings of patient interviews available upon request to verify outcomes and data collection methods. Second, the company's patient care team collaborates closely with the clinical center throughout both prospective and retrospective data collection, ensuring continuous monitoring, assessment, and feedback under the supervision and approval of the treating physician.

Previous studies have demonstrated the value of patient outcomes from manufacturer-managed databases

[15,21,22]. These studies show that when standardized data collection protocols are applied, the data reliably reflect real-world clinical practices and outcomes. This approach allows meaningful comparisons with clinical trials while capturing more diverse patient populations, thereby enhancing generalizability.

Conclusions

In this retrospective single-center study of patients with chronic pain of the trunk or limbs, most patients with available pain-relief data reported clinically meaningful pain relief with 10 kHz-SCS at their most recent assessment, which occurred within five years of implantation for most patients; the explant rate was low. Prospective studies with repeated, validated outcome measures and complete follow-up are needed to confirm long-term durability.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: David Holthouse, Emma J. Roberts, Ceilidh Robertson, Dom Bailey

Acquisition, analysis, or interpretation of data: David Holthouse, Emma J. Roberts, Ceilidh Robertson, Dom Bailey

Drafting of the manuscript: David Holthouse, Emma J. Roberts, Ceilidh Robertson, Dom Bailey

Critical review of the manuscript for important intellectual content: David Holthouse, Emma J. Roberts, Ceilidh Robertson, Dom Bailey

Supervision: David Holthouse, Emma J. Roberts, Ceilidh Robertson, Dom Bailey

Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. Bellberry Human Research Ethics Committee (HREC) issued approval 2024-05-546. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** D. Bailey declare(s) employment from Nevro Corp. D. Bailey was an employee of Nevro Corp. (Redwood City, CA, USA), at the time of authorship. **Other relationships:** This study used data from a database owned and maintained by Nevro Corp. (Redwood City, CA, USA), the manufacturer of the 10 kHz-SCS system evaluated. Nevro Corp.'s patient care team supported routine post-market collection of patient-reported outcome and safety data, as described in the Methods, and D. Bailey, an employee of Nevro Corp. at the time of authorship, contributed to data analysis and manuscript preparation. The remaining authors (D. Holthouse, E.J. Roberts, C. Robertson), affiliated with Claremont Pain Clinic, declare no further financial relationship with Nevro Corp. .

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