Pain Ther (2021) 10:1255–1268
https://doi.org/10.1007/s40122-021-00287-4

ORIGINAL RESEARCH

Efficacy and Safety of 10 kHz Spinal Cord Stimulation Using Cervical and Thoracic Leads: A Single-Center Retrospective Experience

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Received: May 14, 2021 / Accepted: June 24, 2021 / Published online: July 8, 2021

ABSTRACT

Introduction: Spinal cord stimulation (SCS) with lower thoracic leads has been studied extensively. However, the evidence base for cervical SCS is less well developed, and reports of multiarea SCS lead placement are uncommon. Therefore, this single-center retrospective study evaluated outcomes from 10-kHz SCS with cervical or combined cervical and thoracic lead placement.

Method: All patients that underwent a 10-kHz SCS trial with either cervical or combined cervical and thoracic lead placement between 2015 and 2020 were included in our study. We reviewed patient's charts for demographic information, lead placement, and pain scores up to 48 months after implantation.

Results: Of the 105 patients that underwent a 10-kHz SCS trial during the review period, 92 (88%) had back/neck or extremity pain that responded to therapy (≥ 50% pain relief from baseline) and received a permanent system. Sixty-two of these patients (67%) were implanted with combined cervical and thoracic leads, while 30 (33%) received cervical-only leads. Pain relief in both regions exceeded 60% at most visits throughout the 48-month study period. Throughout follow-up, the responder rate in both pain areas was consistently ≥ 70%. No unexpected adverse events occurred.

Conclusion: The 10-kHz SCS provided effective and durable pain relief with either cervical or combined cervical and thoracic leads. The efficacy and safety profile of both applications appears to be comparable to lower thoracic SCS. Our results suggest that 10-kHz SCS is a useful paresthesia-free therapeutic option for chronic neuropathic pain originating in the cervical area, as well as more complex multiarea pain presentations.

Keywords: 10 kHz SCS; Chronic pain; Cervical SCS; Thoracic SCS; Multiarea SCS

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Key Summary Points

Chronic pain in the neck, upper extremities, and thoracic back is debilitating. While the efficacy and safety of 10-kHz spinal cord stimulation (SCS) are well documented in the upper extremities and lower back, evidence on multiarea pain is limited.

The current retrospective review aimed to analyze outcomes from patients implanted with cervical leads and combined cervical and thoracic leads.

The review identified 105 consecutive patients trialed and implanted with 10-kHz SCS devices. Pain relief, responder rate (≥ 50% relief), and safety events were analyzed, and results were reported.

The efficacy of cervical and combined leads was comparable to thoracic leads. Average pain relief was > 60% for both back and upper extremity pain. Responder rates were sustained over 4 years and exceeded 70% for both pain regions and lead placement types. Adverse events and their rates were also comparable to thoracic only lead placements.

Current findings suggest that 10-kHz SCS is a useful paresthesia-free therapeutic option for chronic neuropathic pain originating in the cervical area as well as more complex multiarea pain presentations.

INTRODUCTION

Spinal cord stimulation (SCS) is a minimally invasive, reversible, and adjustable treatment for chronic neuropathic pain that has been practiced for over 50 years. The most common indication is failed back surgery syndrome (FBSS), followed by complex regional pain syndrome (CRPS) [1]. Electrical impulses are delivered to the spinal cord by leads typically placed in the lower thoracic epidural space. Long-term favorable outcomes have been demonstrated in both FBSS and CRPS populations [2]. The therapy is generally safe but not without complications, reported in 30%–40% of patients [3]. The most frequently occurring hardware and biological complications are lead migration, lead fracture, pain at the implant site, and infection [3]. However, most complications are relatively minor and usually resolved with conservative treatment or minor revision surgery [4]. Serious adverse events such as neurological injury are infrequent [3, 5].

While SCS is well established in treating lower back and extremity pain, less evidence exists for its use in treating cervical axial spine and radicular pain [6]. Furthermore, reports of SCS to treat multiarea pain originating in both the cervical and thoracic areas are rare. Axial neck pain can be treated by stimulation at the C1–C2 vertebral level, shoulder pain at C2–C4, and hand pain at C5–C6 [7]. However, achieving adequate paresthesia coverage in the cervical area can be challenging with conventional (low-frequency) SCS [7]. Although the risk of explant has been shown to be similar for thoracic and cervical leads [8–10], the risk of complications with cervical leads is presumed to be higher than that with thoracic leads due to the highly mobile nature of the neck. For example, positional changes in the neck can alter the distance between the electrodes and the target tissue, resulting in variable stimulation intensity and distribution. For the patient, this can manifest as loss of pain relief or painful overstimulation. In addition, repeated neck flexion and extension also place considerable mechanical stress and tension on the lead, potentially leading to higher lead displacement and fracture rates than leads situated in the less mobile thoracic spine.

In contrast to conventional SCS, high-frequency stimulation at 10 kHz (10-kHz SCS) provides pain relief without any sensation of paresthesia. During conventional stimulation, activation of dorsal column fibers elicits paresthesia over the painful area, masking the sensation of pain [11]. Preclinical studies suggest that pain relief from high-frequency 10-kHz

stimulation is mediated in the dorsal horn without activation of the dorsal column fibers, which may account for the lack of paresthesia [12, 13]. Moreover, 10-kHz SCS patients demonstrate a lack of paresthesia-pain overlap when their devices are reprogrammed to conventional SCS settings [14]. The paresthesia-free aspect of 10-kHz SCS offers the opportunity to treat pain originating in the cervical region without the under- and overstimulation issues associated with conventional SCS. In addition, since the mechanisms of action of the two therapies appear to differ, 10-kHz SCS could benefit patients with more complex pain presentations previously considered inappropriate for conventional SCS, for example, widespread pain originating in both the cervical and thoracic regions. While previous retrospective study by Salmon did not report increased incidence of complications with multi-region lead placement [36], placing leads in multiple regions is commonly thought to increase the risk of complications compared with leads implanted in a single area. Therefore, studies are needed to evaluate the efficacy and safety of multiarea 10-kHz SCS.

Several studies, including a randomized controlled trial, have reported the efficacy and safety of 10-kHz SCS to treat chronic pain originating in the lower thoracic region [15–30]. However, as for SCS in general, there is currently limited clinical evidence for 10-kHz SCS with leads placed in the cervical spine or leads placed in both the cervical and thoracic areas [31–37]. This study aims to add to the existing evidence with a real-world, retrospective assessment of the efficacy and safety of 10-kHz SCS to treat chronic pain using cervical or combined cervical and thoracic leads.

METHODS

Study Design and Setting

We conducted a retrospective chart review between July 2015 and January 2021 of all chronic pain patients in our center considered for a 10-kHz SCS trial with cervical or combined cervical and thoracic lead placement. All procedures were carried out at the KH der Barmherzigen Brüder.

Ethics Statement

Ethics committee approval (reference number: 2021-15717) was obtained for this retrospective review from Ethik-Kommission Landesärztekammer Rheinland-Pfalz. The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments.

Participants and Procedure

All patients included in the review were appropriate candidates for 10-kHz SCS based on a multidisciplinary assessment and a diagnosis of neuropathic pain refractory to conventional therapies and interventions. Procedural details have been published previously [15, 32]. In brief, patients underwent a temporary trial of 10-kHz SCS (Senza® System, Nevro Corp., Redwood City, CA, USA) with percutaneous leads. In all patients, one lead was anatomically placed with its distal tip located between vertebral levels C1 and C6 to treat pain originating in the cervical area. Patients with cervical-only pain including neck pain, head pain, and shoulder pain and upper limb pain had cervical only leads. Patients with insufficient cervical space received only one cervical lead and did not receive a second lead. In patients with cervical and upper back pain, the second lead was located between vertebral levels TH1 and TH7. Patients with cervical and lower back pain had their second lead placed between vertebral levels TH8 and TH11. Stimulation was delivered at a frequency of 10 kHz, pulse width 30 μs, and an amplitude adjusted to optimize the patient's pain relief. The trial period lasted for up to 14 days. Patients who experienced at least a 50% reduction in their pain from baseline during their trial were eligible for permanent device implantation. Postimplantation clinical management and follow-up were performed according to usual clinical practice.

Table 1 Patient characteristics at baseline

Characteristic	*N* = 105
Age at 10-kHz SCS trial (mean ± SD)	56.4 ± 11.2
Gender (female)	57%
Indication	
FBSS/FNSS	47%
Virgin back	11%
Virgin neck	9%
CRPS	6%
Cervical plexus lesion	5%
Other	23%
Mean pain intensity (VAS, cm)	
Back/neck pain	8.5 ± 0.1 cm
Upper extremity pain	8.1 ± 0.1 cm

CRPS complex regional pain syndrome, *FBSS* failed back surgery syndrome, *FNSS* failed neck surgery syndrome
*Other includes brachialgia, cervical fracture, CREST, headache/migraine, phantom limb pain post-zoster neuralgia, shoulder pain after surgery, thalamic pain, thoracic fracture, thrombangitis obliterans, and trigeminal neuralgia

Variables

Patients' records were reviewed for their demographic information, lead placement, and pain scores. A 10-cm visual analog scale (VAS) was used to evaluate patients' pain intensity in the back/neck and (lower/upper) extremity areas before their 10-kHz SCS trial (baseline); at the end of their trial (EoT); and at 3, 6, 12, 24, 36, and 48 months after implantation. Adverse event data were also collected. Response to therapy was defined as at least 50% pain relief from baseline.

Statistics

Data analysis was performed using Microsoft Excel (Microsoft, Redmond, WA, USA). Continuous variables are expressed as mean ± standard error of the mean (SEM) or mean and standard deviation (SD) where indicated. Categorical variables are presented as percentages. All outcomes were analyzed as observed. The number of patients with available data is shown for each outcome.

RESULTS

Participants

Between 2015 and 2021, 105 patients were treated for chronic pain and were considered for a 10-kHz SCS trial. Table 1 shows participant characteristics. Of the 105 patients, 57% were female. The cohort's mean age was 56.4 (SD 11.2) years, with a range of 18.4 to 80.3 years. Nearly half of the patients (47%; $n = 52$) were diagnosed with either FBSS or failed neck surgery syndrome (FNSS), 20% ($n = 21$) were surgery naïve (back or neck), 6% ($n = 6$) had CRPS, and 5% ($n = 5$) had a cervical plexus lesion.

Table 2 Location of leads in patients who received only cervical leads

	Single lead	C1	Disc C2/3	C2	Disc C3/4	C6	Disc C4/5	Disc C5/6	C7	C8
Disc C2/3	1	0	0	0	0	0	0	0	1	0
C1	2	1	0	0	0	2	1	0	0	0
C2	12	0	1	3	0	4	0	1	2	0
C3	1	0	0	0	1	0	0	0	1	0
C6	0	0	0	0	0	0	0	0	0	1

*The location of the first lead is presented vertically, and the second lead is presented horizontally. Sixteen patients received only a single lead

Table 3 Location of leads in patients who received cervical and thoracic leads and/or were treated for back and upper extremity pain

	TH1	TH7	TH8	TH9	Disc TH8/9 or lower TH8/9	Disc 9/10	Disc TH10/11
Disc C2/3	0	0	2	0	6	0	0
C1	0	1	3	0	5	0	0
C2	3	3	19	8	14	2	0
C3	0	0	1	0	1	0	1
C4	0	0	1	0	0	0	0

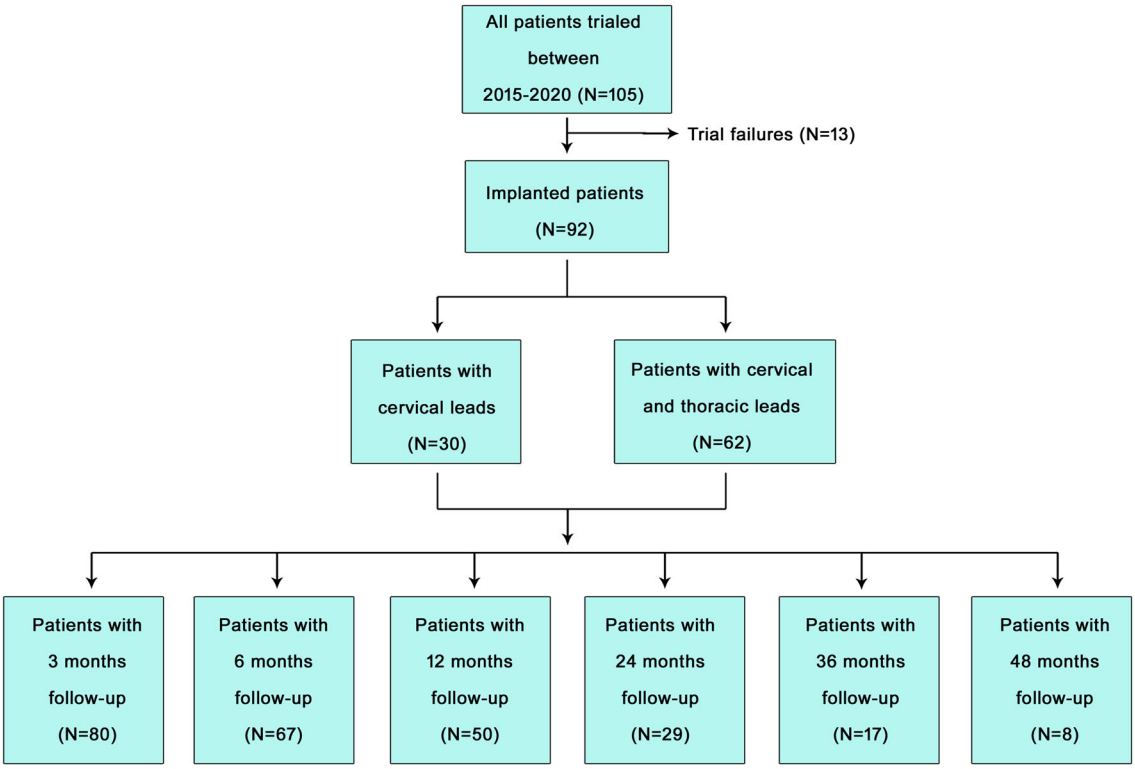

Fig. 1 Study flow chart. *There were no explants after permanent implants. Patients who were lost to follow-up were not tracked/recorded

All patients underwent a 10-kHz SCS trial with either cervical or combined cervical and thoracic lead placement for chronic treatment-refractory pain. Among the 105 patients, 70 (67%) were implanted with combined cervical and thoracic leads, and 35 (33%) had cervical-only lead placements. The locations of trial lead tips are shown in Tables 2 and 3. At the end of the trial, 92 patients (88%) had back/neck or extremity pain that responded to therapy (≥ 50% pain relief from baseline) and received a permanent system. Sixty-two of these patients (67%, 62/92) were implanted with combined cervical and thoracic leads. The remaining 30 patients (33%, 30/92) received cervical-only leads. Data were available for 80 patients at

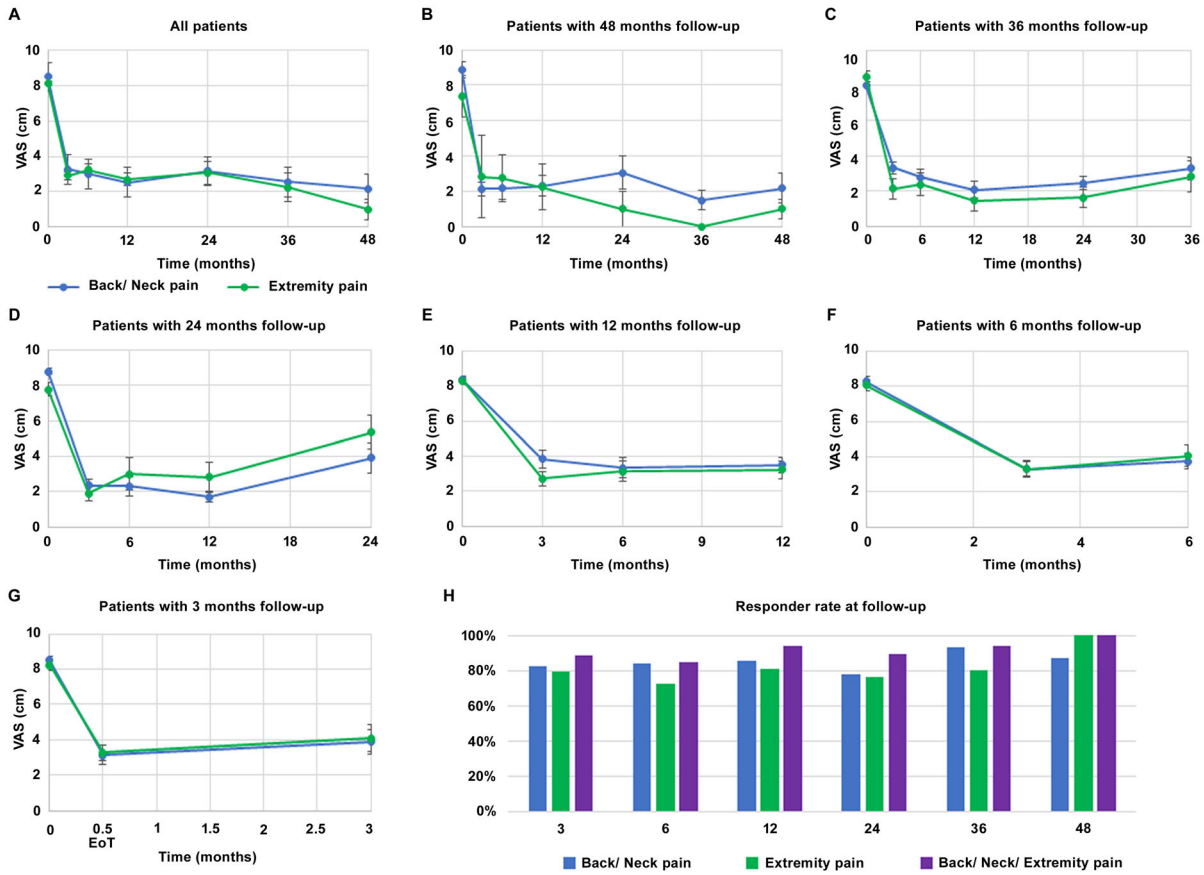

Fig. 2 Pain relief and responder rates in all patients. Longitudinal VAS scores for all patients (**A**). Longitudinal VAS scores for patients with 48 months of follow-up (**B**). Longitudinal VAS scores for patients with 36 months of follow-up (**C**). Longitudinal VAS scores for patients with 24 months of follow-up (**D**). Longitudinal VAS scores for patients with 12 months of follow-up (**E**). Longitudinal VAS scores for patients with 6 months of follow-up (**F**). Longitudinal VAS scores for patients with 3 months of follow-up (**G**) and responder rate at indicated follow-up assessment (**H**)

3 months, 67 patients at 6 months, 50 patients at 12 months, 29 patients at 24 months, 17 patients at 36 months, and 8 patients at 48 months (Fig. 1).

Pain Relief and Responder Rates (All Patients)

Pain Relief

Among the implanted patients, the average VAS score at baseline was 8.5 ± 0.1 cm (n = 89) in the back/neck area and 8.1 ± 0.1 cm in the extremity area (n = 89). Changes in pain scores are shown in Fig. 2. After 3 months of treatment, average VAS scores in the two regions decreased to 3.3 ± 0.2 cm (60% ± 3% reduction; n = 69) and 2.9 ± 0.2 cm (64% ± 3% reduction; n = 69), respectively. Sustained pain relief was noted in the patients at all follow-up assessments, and patients with longer follow-up (24 months or more) as well as patients with shorter follow-up (12 months or less) had similar low pain scores (Fig. 2B–G).

Responder Rates

Patients with ≥ 50% reduction in pain score from baseline were considered responders to therapy. At the 3-month assessment, 89% of patients (71/80) were responders in either their back/neck or extremity areas (Fig. 2H). A similar

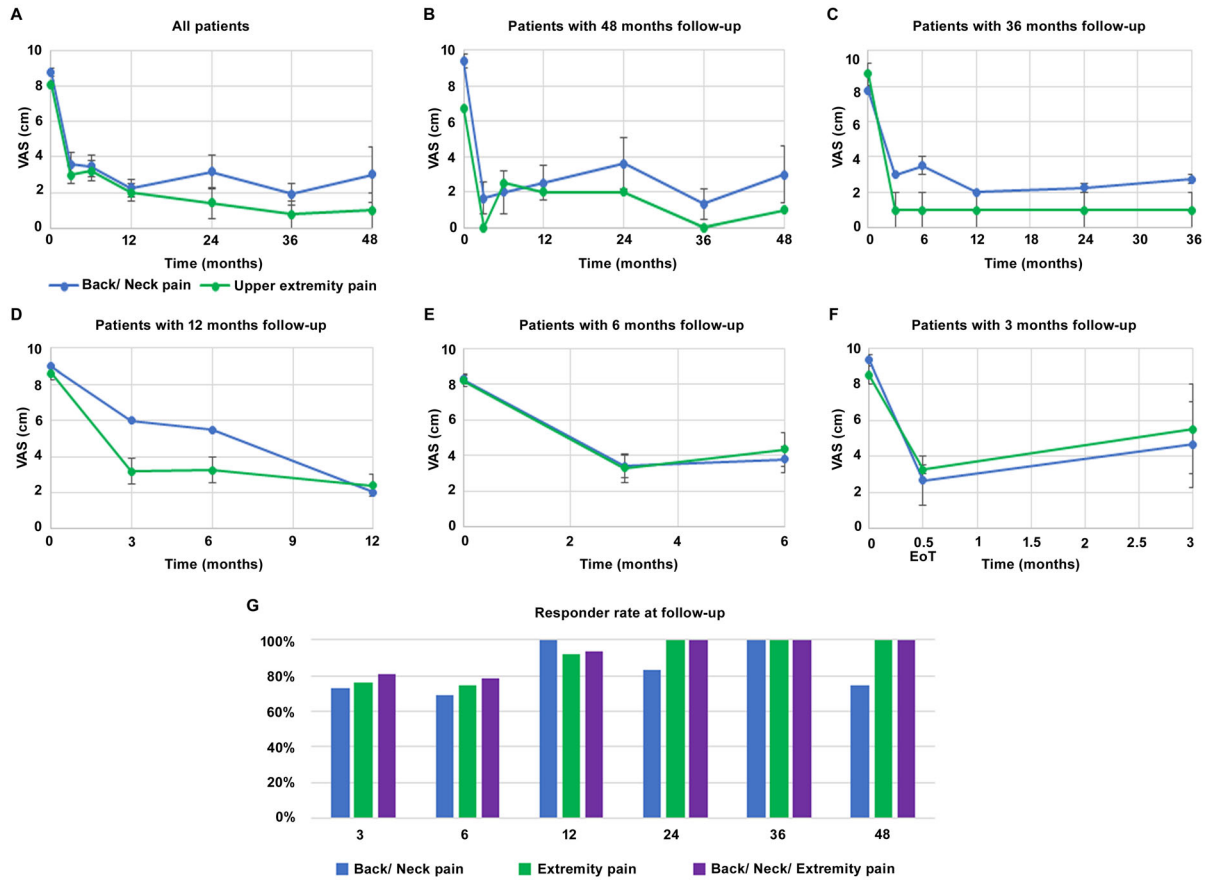

Fig. 3 Pain relief and responder rates in patients implanted with only cervical leads. Longitudinal VAS scores for all patients (**A**). Longitudinal VAS scores for patients with 48 months of follow-up (**B**). Longitudinal VAS scores for patients with 36 months of follow-up (**C**), Longitudinal VAS scores for patients with 12 months of follow-up (**D**). Longitudinal VAS scores for patients with 6 months of follow-up (**E**). Longitudinal VAS scores for patients with 3 months of follow-up (**F**) and responder rate at indicated follow-up assessment (**G**)

proportion of patients maintained response thereafter, with a rate of 90% (26/29) at 12 months and 100% (8/8) at 48 months. A high responder rate was also observed for back/neck pain (83%, 57/69) and extremity pain (78.6%, 55/69) at 3 months and sustained at subsequent follow-ups.

Pain Relief and Responder Rates in Patients with Cervical-Only Leads

Pain Relief

In patients implanted with cervical-only leads, the average VAS score at baseline was 8.8 ± 0.2 cm (n = 20) in the back/neck area and 8.1 ± 0.2 cm (n = 26) in the extremity area (Fig. 3). After 3 months of treatment, average pain intensity in the two regions decreased to 3.6 ± 0.6 cm (59% ± 7% reduction; n = 15) and 3.0 ± 0.5 cm (65% ± 6% reduction; n = 21), respectively. Pain relief sustained throughout the follow-up period and the last follow-up average pain scores seen in patients with longer follow-up (24 months or more) were comparable to scores seen in patients with shorter follow-up (12 months or less) (Fig. 3B–G).

Responder Rates

More than 80% of patients responded to therapy in either the back/neck or extremity areas at the 3-month visit (81%, 21/26). The responder rate further increased to 94% (15/16) at

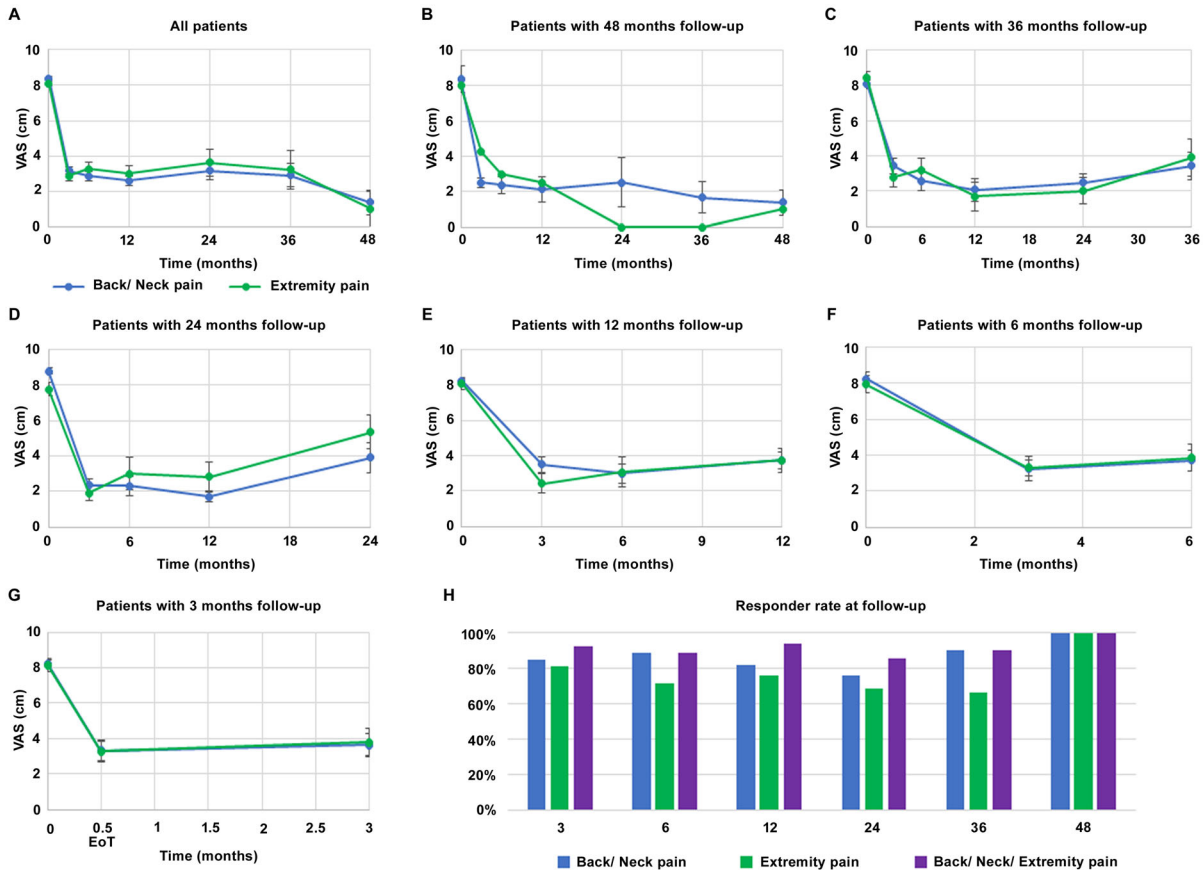

Fig. 4 Pain relief and responder rates in patients implanted with cervical and thoracic leads. Longitudinal VAS scores for all patients (**A**). Longitudinal VAS scores for patients with 48 months of follow-up (**B**). Longitudinal VAS scores for patients with 36 months of follow-up (**C**). Longitudinal VAS scores for patients with 24 months of follow-up (**D**). Longitudinal VAS scores for patients with 12 months of follow-up (**E**). Longitudinal VAS scores for patients with 6 months of follow-up (**F**). Longitudinal VAS scores for patients with 3 months of follow-up (**G**) and responder rate at indicated follow-up assessment (**H**)

12 months and was consistently high thereafter out to 48 months (100%, 4/4). For back/neck pain and extremity pain, 73% (11/15) and 76% (16/21) of patients were responders to treatment at 3 months, respectively, and this high responder rate persisted until the 48-month assessment (Fig. 3H).

Pain Relief and Responder Rates in Patients with Combined Cervical and Thoracic Leads

Pain Relief

Among the implanted patients with combined cervical and thoracic lead placement, the average VAS score at baseline was 8.4 ± 0.1 cm (n = 69) in the back/neck area and 8.1 ± 0.1 cm (n = 63) in the extremity area (Fig. 4A). At the 3-month assessment, pain intensity in the two regions fell to an average of 3.2 ± 0.2 cm (61% ± 3% reduction; n = 54) and 2.9 ± 0.3 cm (64% ± 3% reduction; n = 48), respectively. As noted with cervical only leads, pain relief with combined cervical and thoracic leads was sustained throughout the follow-up, and the average pain scores at last follow-up assessment were comparable in patients with shorter follow-up (12 months or less) to patients with longer follow-up (24 months or more; Fig. 4B–G).

Table 4 Adverse events recorded during follow-up in patients who were trialed or implanted with 10-kHz SCS (N = 105)

	Number of patients (%)	Intervention and status
Infection	5 (5%)	All infections occurred during the trial period and were resolved with standard of care treatment. Device was implanted in 1 patient
CSF leak	4 (4%)	Resolved with blood patch in all patients
Lead migration	9 (9%)	Resolved with repositioning
Pocket pain or IPG site pain	7 (7%)	Resolved with repositioning
Lead defect	4 (4%)	Resolved with replacement
Charger defect	2 (2%)	Resolved with replacement

CSF cerebrospinal fluid, *IPG* implantable pulse generator

Responder Rates

In the back/neck or extremity areas, response to therapy was noted in 93% of patients (50/54) at the 3-month assessment (Fig. 4H). Responder rates continued to be high throughout follow-up, with a rate of 94% (32/34) at 12 months and 100% (4/4) at 48 months. For back/neck pain and extremity pain, 85% (46/54) and 81% (39/48) of patients were responders after 3 months of stimulation, respectively, with high response rates in both areas persisting throughout the remaining assessments.

Safety

Treatment-related adverse events (AEs) during follow-up are detailed in Table 4. There were no unexpected AEs in the patients trialed or implanted with 10-kHz SCS devices, and all AEs were resolved. Overall, the most common AE was lead migration (9%, 9/105), followed by pocket or implantable pulse generator (IPG) site pain (7%, 7 of 105) and infection (5%, 5/105). All lead migration and pocket/IPG site pain events were resolved with surgical revision. Among the five cases of infection, all occurred during the trial period, and three required explantation of the trial leads. No other explants occurred during the available follow-up period. Other complications included four cases of a cerebrospinal fluid leak (CSF) during implantation, treated with a blood patch (4%, 4/105), and four defective leads that required replacement (4%, 4/105).

DISCUSSION

Spinal cord stimulation has been extensively studied as a treatment for chronic pain conditions, most commonly in FBSS patients with lower thoracic lead placement. To date, there are significantly fewer reports of SCS used to treat chronic pain with leads placed in the cervical spine and only rare reports of multiarea SCS. Our reported experience builds on the limited evidence base in these areas.

Due to our study's retrospective nature, granular pain scores were not available for back, neck, upper extremity, and lower extremity pain. However, we assessed back/neck and (lower/upper) extremity pain scores. Among the permanently implanted cohort, two-thirds had combined cervical and thoracic lead placement, while the remainder had cervical-only leads. Among all patients, pain relief was substantial and sustained in both regions, ranging from 60 to 90% throughout the 48-month follow-up period. Furthermore, the group responder rate exceeded 80% at most assessments.

Efficacy outcomes in patients with cervical-only leads are in line with recent observational studies of 10-kHz SCS for upper limb and/or

neck pain (ULN) [31–34]. In our study, back/-neck and extremity pain scores were reduced on an average by 74% and 77% after 12 months of treatment, respectively, with corresponding responder rates of 100% and 92%. The recent ULN studies reported 12-month neck pain relief ranging from 74 to 86% and decreases in upper limb pain between 62 and 86%. Responder rates in the two areas ranged from 63 to 89% and 77% to 95%, respectively.

Patients in our study with combined cervical and thoracic lead placement also experienced lasting improvements in pain score, with pain relief in the back/neck and extremity areas generally exceeding 60% throughout follow-up. The responder rate was also consistently high in both regions (70% to 100%) over the 48 months. These results are comparable to the recent 10-kHz SCS ULN studies and previous studies of lower thoracic 10-kHz SCS [15–27]. Over 6 to 36 months of follow-up, average pain relief across the latter studies ranged from 45 to 87% and responder rate from 52 to 90%.

Furthermore, our efficacy outcomes are in line with a retrospective study of multiarea 10-kHz SCS for chronic widespread pain by Salmon in 2019 [36]. Among Salmon's cohort, 37% of patients (13/35) had combined C2 and T9 lead placement; another 37% had leads positioned at C2, T2, and T9, while the remainder had leads located at both C2 and T2. Pain relief averaged 63% in the head/neck area, 60% in the upper back, and 59% in the lower back after a mean follow-up of 2.3 years.

Adverse events observed in our patients are similar to those commonly reported in SCS, including infection, lead migration, IPG site/pocket pain, and lead issues. No unexpected adverse events occurred in our cohort during the review period, and no systems were known to be explanted due to loss of efficacy.

Among our patients, the incidence of lead migration (9%), IPG site pain (7%), lead issues (4%), and CSF leak (4%) are within the published ranges for lower thoracic applications of SCS (migration: 0% to 23%; IPG site pain: 1% to 12%; lead fracture: 4% to 10%; CSF leak: 0.3% to 7%) [3, 38–43]. They also compare favorably to the incidence of lead migration (13.9%), IPG site pain (4.4%), and lead issues (6.7%) reported by a systematic literature review of outcomes in cervical SCS [9]. Five percent of our patients had infection during the trial, and the patients with infections had no specific underlying causes such as immunosuppression that resulted in infection. We believe that though our infection rate was slightly higher, it is within the range seen in the published literature for SCS (2.5–6.0%) [3, 38–44] and for 10-kHz SCS studies (1.7–6.0%) [17, 18, 23, 26, 27, 31, 32, 45, 46]. Notably, all of our infections were resolved with standard treatment, and the device was re-implanted in one patient. Our study suggests no additional complications with cervical leads compared with lower thoracic leads and no increase in complications with multiarea placement.

Overall, our results add to the growing evidence base that 10-kHz SCS consistently provides durable pain relief across various chronic neuropathic pain conditions, regardless of anatomical lead placement. The safety profile of cervical and combined cervical and thoracic leads appears similar to lower thoracic lead placement.

Strengths and Limitations

This study analyzed the real-world efficacy and safety of 10-kHz SCS in less common indications, providing complementary evidence to existing prospective studies in this area. Outcomes were assessed over a long period (4 years), with encouraging results regarding long-term pain relief and the absence of unexpected adverse events.

As always, our results should be considered with limitations in mind. Our study is a single-center, retrospective evaluation, reliant upon accurate documentation of pain scores during routine clinical practice. The lack of granularity in the data regarding pain location is a key limitation in our analysis. Also, patients who were lost to follow-up were not tracked, and outcomes were analyzed as observed. Furthermore, due to the retrospective nature of our study, we could not assess other patient-centered clinical measures, such as functionality and quality of life, which may provide a more

comprehensive view of the therapy's efficacy alongside pain relief variables. However, the study offers valuable efficacy and safety information in less frequently documented applications of SCS. Given the novelty in our lead placement and unmet need in the patients, this study may provide early evidence and drive further research in this area.

CONCLUSION

In this single-center, real-world experience, cervical and thoracic 10-kHz SCS was effective, durable, and relatively safe. Our results suggest that 10-kHz SCS is a useful paresthesia-free therapeutic option for complex and intractable neuropathic pain conditions originating in the cervical area as well as more complex multiarea pain presentations.

ACKNOWLEDGEMENTS

Funding. The study was not funded. The authors did not receive funding for data collection and analysis. Nevro Corp. provided funding for the journal's Rapid Service Fee.

Medical Writing/Editorial Assistance. Deborah Edgar, PhD, Commexus Ltd, Dunblane, UK, received a fee from Nevro Corp., Redwood City, CA, in her capacity as an independent medical writer.

Authorship. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Author's Contributions. GS, JP, TB, KM, and MB contributed to the procedures, data collection, conceptualization, design of the study and drafting of the manuscript, and provided scientific feedback. AR was responsible for the concept and design of the study and coordinated the drafting of the initial version of the manuscript. All authors have contributed to and read the final version of the manuscript.

Disclosures. Anand Rotte is an employee of Nevro Corp. Gernot Surges, Joachim Paulus, Theresa Blaß, Kerstin Mendryscha and Martin Bettag declare no conflicts of interest.

Compliance with Ethics Guidelines. Ethics committee approval (reference number: 2021-15717) was obtained from Ethik-Kommission Landesärztekammer Rheinland-Pfalz for the retrospective analysis and reporting of anonymized data. Study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments.

Data Availability. All data generated or analyzed during this study are included in this published article and as supplementary information files.

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