High-Frequency Spinal Cord Stimulation at 10 kHz for the Treatment of Combined Neck and Arm Pain: Results From a Prospective Multicenter Study

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BACKGROUND: Intractable neck and upper limb pain has historically been challenging to treat with conventional spinal cord stimulation (SCS) being limited by obtaining effective paresthesia coverage.

OBJECTIVE: To assess the safety and effectiveness of the 10-kHz SCS system, a paresthesia-independent therapy, in the treatment of neck and upper limb pain.

METHODS: Subjects with chronic, intractable neck and/or upper limb pain of ≥5 cm (on a 0-10 cm visual analog scale [VAS]) were enrolled in 6 US centers following an investigational device exemption from the Food and Drug Administration (FDA) and institutional review board approval. Each subject was implanted with 2 epidural leads spanning C2-C6 vertebral bodies. Subjects with successful trial stimulation were implanted with a Senza® system (Nevro Corp) and included in the evaluation of the primary safety and effectiveness endpoints.

RESULTS: In the per protocol population, the primary endpoint (≥50% pain relief at 3 mo) was achieved in 86.7% (n = 39/45) subjects. Compared to baseline, subjects reported a significant reduction ($P < .001$) in their mean (± standard error of the mean) VAS scores at 12-mo assessment for neck pain (7.6 ± 0.2 cm, n = 42 vs 1.5 ± 0.3 cm, n = 37) and upper limb pain (7.1 ± 0.3 cm, n = 24 vs 1.0 ± 0.2 cm, n = 20). At 12-mo assessment, 89.2% of subjects with neck pain and 95.0% with upper limb pain had ≥50% pain relief from baseline, 95.0% reported to be "satisfied/very satisfied" and 30.0% either eliminated or reduced their opioid intake.

CONCLUSION: In conclusion, 10-kHz SCS can treat intractable neck and upper limb pain with stable long-term outcomes.

KEY WORDS: 10-kHz SCS, VAS, Upper limb pain, Neck pain and opioids

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Cervical spine disorders are common conditions that are frequently disabling and costly to treat.[1,2] Some of the most common diagnoses in patients with chronic neck pain include cervical radiculopathy, discopathy, and spondylosis. Patients are typically managed with conservative care, including physiotherapy and exercise programs. Upon a lack of improvement with conservative care, interventional procedures such as epidural steroid injections, facet rhizotomies, or surgical procedures such as anterior cervical discectomy with or without fusion are employed.[3,4] Other treatment options for axial neck pain include

ABBREVIATIONS: DNRS, dorsal nerve root stimulation; **FDA,** Food and Drug Administration; **GAF,** Global Assessment of Functioning; **GIC,** global impression of change; **IDE,** investigational device exemption; **MCID,** minimum clinically important difference; **MCS,** mental health component summary score; **MME,** morphine milliequivalent; **PCS,** physical component summary score; **PDI,** Pain Disability Index; **PEA,** primary endpoint assessment; **PPP,** per protocol population; **PSQ-3,** 3 point pain and sleep questionnaire; **PSQI,** pittsburgh sleep quality index; **RCT,** randomized controlled trial; **SCS,** spinal cord stimulation; **SD,** standard deviation; **SEM,** standard error of the mean; **SF-MPQ,** Short Form McGill Pain Questionnaire; **SF-12,** Short Form Questionnaire-12; **VAS,** visual analog scale

Supplemental digital content is available for this article at www.neurosurgery-online.com.

peripheral subcutaneous field stimulation or peripheral nerve field stimulation.[5,6]

Spinal cord stimulation (SCS) is currently indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs.[7-10] Benefits of SCS for the treatment of neck and/or upper limb pain were demonstrated in a limited number of prospective studies and in multiple case-series reports.[11-17] However, the efficacy of traditional low-frequency SCS (LF-SCS) is challenged by the difficulty in obtaining sensory paresthesias in the axial neck region and the variability of the paresthesias that come with the inherent, dynamic neck and upper limb movements in the human body. This variability may result in excessive stimulation and patient discomfort or less than optimal stimulation and loss of efficacy, leading to explant of the devices in some cases.[15,16,18,19]

High-frequency SCS at 10 kHz (10-kHz SCS) does not elicit paresthesias, thereby eliminating the need to establish paresthesia mapping and coverage. Ten-kilohertz SCS also eliminates the risk of uncomfortable stimulation due to positional variation, which can compromise neck and upper limb pain relief with LF-SCS.[20] Ten-kilohertz SCS was previously shown to provide pain relief and improve quality of life in a retrospective chart review of patients with upper or lower limb pain, but the number of patients with upper limb pain included in the analysis was low and the study also did not include patients with neck pain.[17] The goal of this study is to prospectively assess the safety and effectiveness of 10-kHz SCS in the treatment of upper limb and neck pain. In addition to the safety and pain relief assessments, the study also reports data from overall quality of life assessments, patient satisfaction, and changes in opioid medication usage.

METHODS

Study Design and Population

The report includes a prospective, single-arm multicenter study designed to assess the safety and effectiveness of the 10-kHz SCS therapy in subjects with chronic, intractable pain of the upper limbs and/or neck (Figure S1, and Methods 1 and 2 in **Supplemental Digital Content**). Investigational device exemption (IDE) approval was obtained from the Food and Drug Administration (FDA) prior to the enrollment of subjects. The investigational plan, amendments, and informed consent forms were reviewed and approved prior to implementation, and the study was conducted in compliance with US Code of Federal Regulations and recommendations guiding physicians in biomedical research adopted by the 18th World Medical Assembly, Helsinki, Finland. The protocols were listed on ClinicalTrials.gov (NCT02385201). Subjects were identified from the pool of candidates for SCS therapy affiliated with, or referred to, the clinical investigation sites, who were recruited from 6 geographically diverse centers in the United States. Study sites submitted redacted medical records and flexion-extension images of the cervical spine to 2 independent medical monitors, including a neurosurgeon and an anesthesiologist, for the study and determined enrollment eligibility. Subjects who signed an informed consent were evaluated for eligibility based on the inclusion and exclusion criteria (Tables S1 and S2, respectively, in **Supplemental Digital Content**). Enrollment in this study started on June 15, 2015, and the first permanent implant was on August 4, 2015. Enrollment in the study ended on January 9, 2017, and the final subject completed the 12-mo visit on March 7, 2018. Outcomes assessed at follow-up visits are listed in Table 1.[21-29]

Procedures

Enrolled subjects who met all of the inclusion criteria and none of the exclusion criteria underwent a temporary trial stimulation with 10-kHz

TABLE 1. Outcomes Assessed

Outcome	Variables
Pain relief	
Pain assessment (VAS)	0-10 cm
Responder rates	% of subjects with ≥50% pain relief compared to baseline
Remitter rates	% of subjects with ≤2.5 cm VAS
Short Form McGill Pain Questionnaire (SF-MPQ-2)	0-10
Quality of life	
Pain Disability Index (PDI)	0-70
SF-12 (PCS & MCS subscales)	0-50
Global Assessment of Functioning (GAF)	0-100
Global impression of change (PGIC and CGIC)	No change, almost same, somewhat or a little bit better, better, moderately better, a great deal better
Sleep (PSQI and PSQ-3)	0-21 for PSQI; 0-10 cm for PSQ-3
Subject satisfaction	Dissatisfied, very dissatisfied, not sure, satisfied, very satisfied
Opioids	
Medication usage	Increased, no change, decreased, eliminated
Dosage	Morphine milliequivalents (MME)
Safety	
Neurological assessments	Deficit, maintained, improved
Adverse events	Grade I-IV

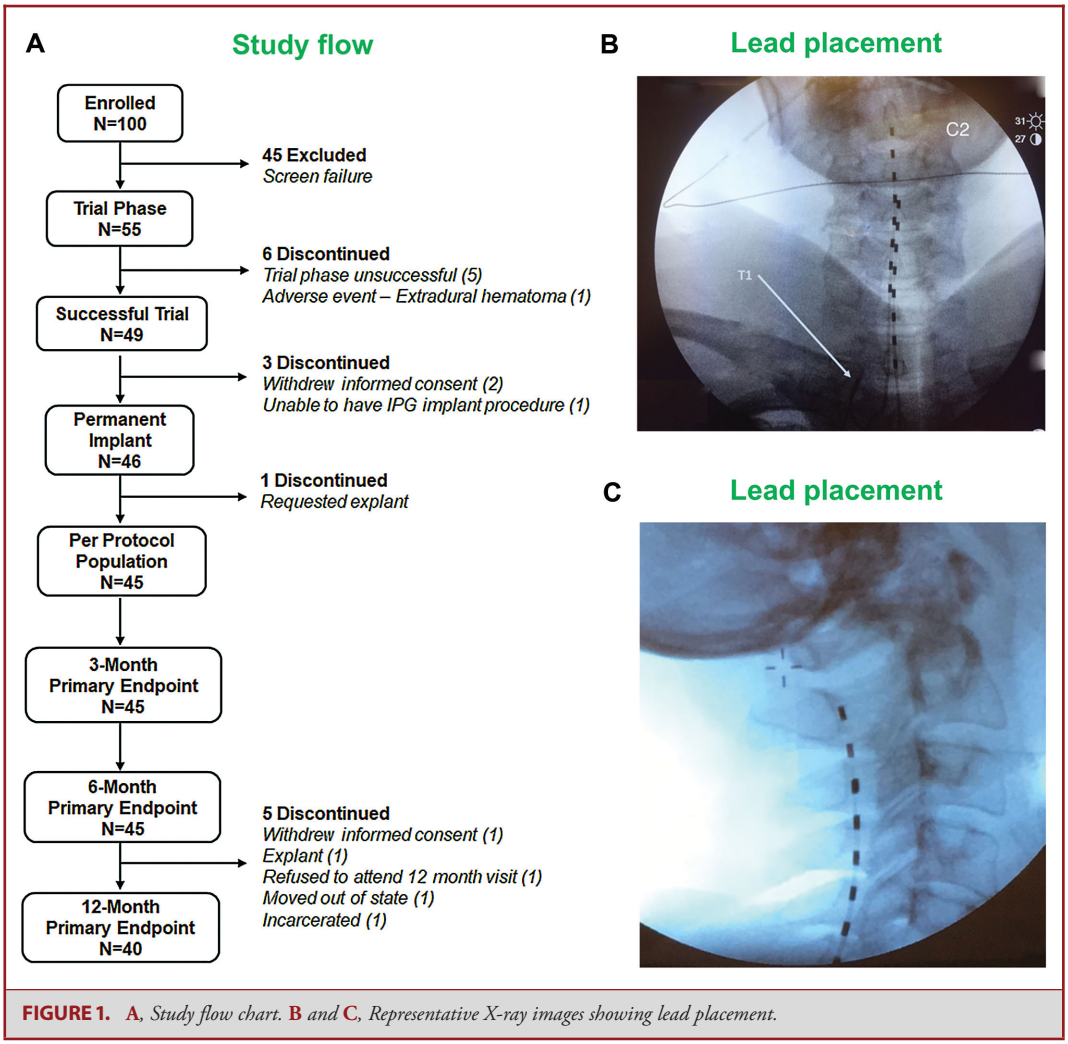

FIGURE 1. **A**, *Study flow chart.* **B** *and* **C**, *Representative X-ray images showing lead placement.*

SCS (Senza System, Nevro Corp, Redwood City, California). Leads were placed (Method 3 in **Supplemental Digital Content**) at varying vertebral levels ranging from C2 to C6 (Figure 1). The distal lead in the majority of the subjects was placed at the C2 vertebral level, and the contacts between mid-C2 and C3-C4 disc were identified as the most effective "sweet spots" in over 70% of the subjects. The sweet spots did not change through the study period. In few subjects, significant pain relief was seen with sweet spots between C4 and C7 discs. Subjects who experienced at least 40% reduction in their upper limb and/or neck pain during the trial compared to baseline (trial responders) were eligible for a permanent device implantation. Successful trial responders underwent a permanent implantation of the SCS device. Stimulation was delivered at a frequency of 10 kHz, pulse width of 30 μs, and amplitudes (mean $\pm$ standard deviation [SD], 0.9 $\pm$ 0.5 mA) adjusted to maximize the subject's pain relief. Follow-up visits were performed at 3, 6, and 12 mo after the permanent implant. If required, programming adjustments were offered throughout the follow-up period. Programming was done in a cephalad to caudad bipole search pattern starting at the tip of the most cephalad lead. This continued caudally, crossing to the second lead as needed until a positive response was obtained. Once a positive response in pain reduction was achieved, optimization was done by increasing or decreasing the amplitude, in an attempt to bring about further pain reduction. Typical wait time before moving to the next amplitude or new bipole was 8 h. During the trial phase, median time to reach at least 50% pain relief was 3 d, whereas during the permanent implant phase, it was 5 d.

As is evident from Figure S2 in **Supplemental Digital Content**, in the initial phase of the study, some subjects needed a relatively higher number of programming sessions due to the investigational nature of neck pain treatment with 10-kHz SCS. However, as the study progressed, the number of programming sessions was markedly reduced. A total of 26 subjects out of 45 needed reprogramming during the study, and the median of the number of programming sessions in the study was 2 (max, 7; min, 0).

Statistics

Descriptive analysis of continuous variables included mean and standard error of the mean (SEM), or median, as appropriate. Categorical variables were reported as counts and percentages where possible. All the outcomes (Method 4 in **Supplemental Digital Content**) were analyzed

by reporting descriptive statistics. All data were analyzed as observed. A 2-tailed paired *t*-test was used to compare the means, and a *P*-value less than .05 was considered as significant.

RESULTS

Trial Phase Results

Pain relief of ≥40% compared to baseline as measured by visual analog scale (VAS) scores was considered as success for the temporary trial phase of the study. The trial phase success rate of 89.1% was observed, with 46 subjects eligible to receive permanent implants (Figure 1).

Study Population

Of the subjects who received permanent implants and included in the intent-to-treat population (Method 5 in **Supplemental Digital Content**), 1 subject requested for a device explant 1 wk after it was implanted. The subject had a non-study-related adverse event (loss of consciousness) and requested to have the device explanted. As the device was never activated, there was no follow-up study data available for this subject and was not included in the per protocol population (PPP, Figure 1). Within the PPP, 42 of 45 subjects had a baseline neck pain score of ≥5.0 cm and were included in the neck pain subset and 24 of 45 subjects with a baseline upper limb pain score of ≥5.0 cm were included in the upper limb pain subset. Data from PPP outcome measures were used for statistical analysis and are reported in the following sections.

Demographics

Baseline demographics and clinical characteristics of the PPP enrolled in the study are shown in Table 2. Briefly, the mean age of the subjects at the time of enrollment was 55.8 yr, 66.7% were female, and the mean time since diagnosis was 11.4 yr.

Paresthesia

Uncomfortable paresthesias or uncomfortable changes in stimulation related to changes in postures were not reported in the study at the primary endpoint assessment visit (PEA, 3-mo) or 12-mo visit.

Safety

The mean duration of 10-kHz SCS utilization in the study was 51.1 wk (range: 27.4-57.1 wk). Cumulatively, there was 44.1 yr of permanent implant experience among the subject population. During the study, subjects were assessed for possible neurological deficits and other safety events, and the data were compared with baseline. Overall, there were no stimulation-related neurological deficits reported. At PEA, neurological assessments showed "no change" in neurological function in 43 subjects (95.6%) and "improvement" in neurological function in 2 subjects (4.4%). Two study-related serious adverse events were reported in 2 different subjects during the trial phase (3.6%, Table 3). Details of adverse events and the number of subjects at each follow-up assessment are described in Result 1 in **Supplemental Digital Content**.

TABLE 2. Baseline Demographics and Clinical Characteristics

Characteristics	N = 45
Gender - n (%)	
Female	30 (66.7%)
Male	15 (33.3%)
Age (years) at enrollment	
Mean ± SD	55.8 ± 9.6
Range	30.9 to 70.5
Years since diagnosis	
Mean ± SD	11.4 ± 8.2
Range	1.0 to 39.0
Diagnosis[a] - n (%)	
Chronic intractable neck pain	45 (100.0%)
Chronic intractable upper limb pain	24 (53.3%)
Upper limb pain - n (%)	
Bilateral	15 (62.5%)
Unilateral	9 (37.5%)
Pain etiology[b] - n (%)	
Radiculopathy/neuropathic pain	40 (88.9%)
Degenerative disc disease	32 (71.1%)
Failed cervical spine surgery syndrome	25 (55.6%)
Spondylosis	19 (42.2%)
Mild or moderate spinal stenosis	17 (37.8%)
Other chronic pain	14 (31.1%)
Internal disc disruption/annular tear	4 (8.9%)
Spondylolisthesis	3 (6.7%)
Previous cervical spine surgery - n (%)	30 (66.7%)
Baseline use of opioids - n (%)	35 (77.8%)
Baseline VAS in subjects with pain ≥5 cm	
Neck pain (mean ± SD)	7.6 ± 1.3
Upper limb pain (mean ± SD)	7.1 ± 1.4
Baseline Pain Disability Index (mean ± SD)	42.4 ± 11.8

[a]Subjects could have both diagnoses.
[b]Subject could have more than one etiology.

TABLE 3. Study-Related Serious Adverse Events (SAEs)

Cause	No. of SAEs	No. (%) of subjects with SAE (n = 55)
Total SAEs	2	2 (3.6%)
Extradural hematoma	1	1 (1.8%)
Medical device site infection	1	1 (1.8%)

Pain Relief

In subjects who received permanent implants, the baseline average VAS score for neck pain was 7.6 ± 0.2 cm, and for upper limb pain, it was 7.1 ± 0.3 cm, which were significantly ($P < .001$) reduced to 2.4 ± 0.4 cm and 1.8 ± 0.5 cm, respectively, at the 3-mo visit. Low pain scores were maintained at 6-mo and 12-mo endpoint assessments (Figure 2A-2D).

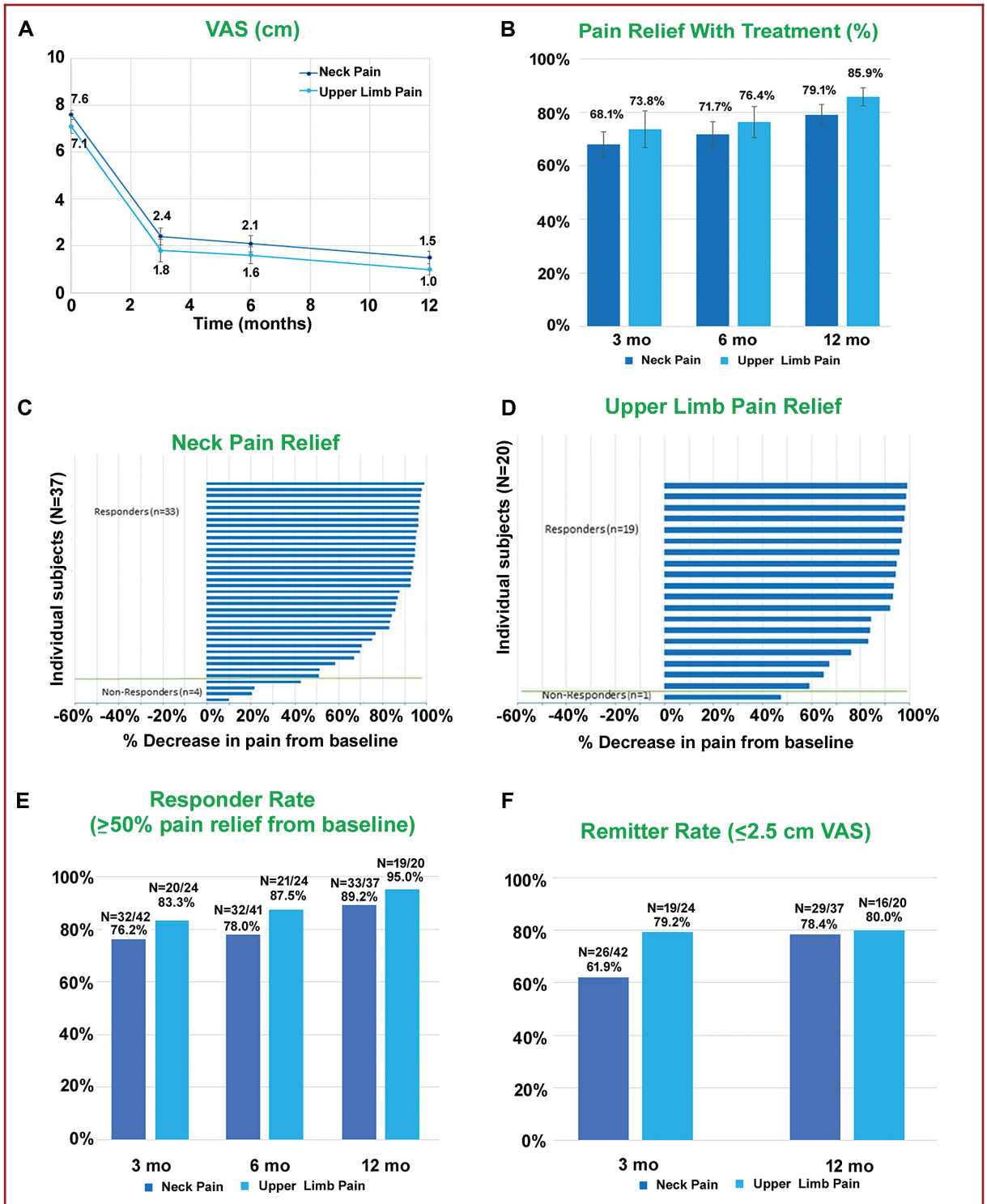

FIGURE 2. *Sustained relief from neck and upper limb pain with 10-kHz SCS.* **A**, *VAS scores (mean ± SEM).* **B**, *Pain relief (mean ± SEM).* **C**, *Tornado chart for neck pain relief in individual subjects at 12 mo.* **D**, *Tornado chart for upper limb pain relief in individual subjects at 12 mo.* **E**, *Responder rates at 3, 6, and 12 mo.* **F**, *Remitter rates at 3 and 12 mo.*

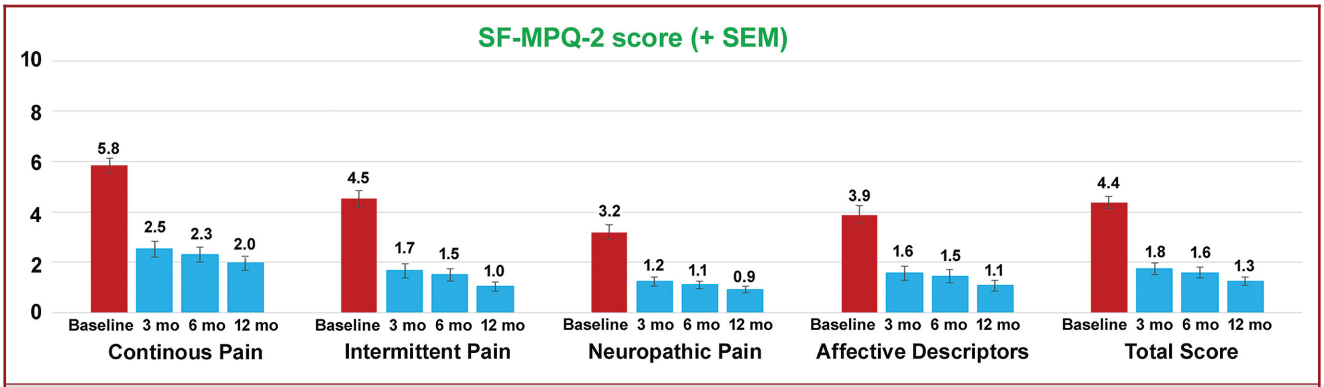

FIGURE 3. *Reduction in SF-MPQ scores after the 10-kHz SCS treatment. Data shown include mean ± SEM at indicated assessment times.*

Responder Rates

Subjects who had ≥50% pain relief as assessed by VAS were considered as responders in the study. At 3-mo assessment, >75% of subjects and at 12-mo assessment, >85% subjects responded to the 10-kHz SCS therapy (Figure 2E). For neck pain, the responder rates at 3-mo and 12-mo visits were 76.2% and 89.2%, respectively. For upper limb pain, the responder rates at 3 and 12 mo were 83.3% and 95.0%, respectively.

Remitter Rates

Subjects with VAS scores ≤2.5 cm were defined as remitters, and the remitter rate of subjects was calculated.[30,31] The remitter rates for neck pain at 3-mo and 12-mo assessments were 61.9% and 78.4%, respectively, and for upper limb pain were 79.2% and 80.0%, respectively (Figure 2F).

Short Form McGill Pain Questionnaire

As seen in Figure 3, the 10-kHz SCS therapy resulted in improved Short Form McGill Pain Questionnaire (SF-MPQ) scores at 3-mo assessment, which further improved at 6-mo and 12-mo assessments. Compared to baseline, average score for "continuous pain" decreased by 3.8 points (66.3%), "intermittent pain" decreased by 3.0 points (76.9%), "neuropathic pain" decreased by 2.3 points (71.3%), "affective descriptors" decreased by 2.8 points (72.0%), and "total score" decreased by 3.1 points (71.2%) at 12-mo assessment (Figure 3).

Improvement in Disability and Quality of Life

Improvement in disability and quality of life following the 10-kHz SCS treatment for neck and upper limb pain was assessed using multiple questionnaires including Pain Disability Index (PDI), Short Form Questionnaire-12 (SF-12), Global Assessment of Functioning (GAF), and global impression of change (GIC). Significant improvements in all the disability and quality of life related assessments were seen with the 10-kHz SCS therapy (Figure 4A-4F).

Sleep

Quality of sleep was significantly improved with the 10-kHz SCS treatment as seen by the lower pittsburgh sleep quality index (PSQI) (Figure 5A) and 3 point pain and sleep questionnaire (PSQ-3) (Figure 5B) scores. At 12-mo assessment, 20% of subjects (8/41) had PSQI <5 compared to 2% (1/45) at baseline.

Medication and Opioid Usage

At baseline, 77.8% subjects were taking at least 1 opioid medication (Table 2). At 12-mo visit, 30.0% of subjects decreased or eliminated their opioid medication (Table 4) and average morphine equivalent dose was reduced from 63.1 morphine milliequivalents (MME) at baseline to 42.1 MME at 12-mo assessment ($P = .14$).

Satisfaction

Subject satisfaction to the 10-kHz SCS therapy as assessed by the percentage of subjects responding as "satisfied" or "very satisfied" was 95.0% at 12-mo endpoint assessment (Figure 5C).

DISCUSSION

Cervical SCS with traditional paresthesia-based setting has been used to treat upper limb and/or neck pain, but the success was not satisfactory due to lack of adequate and consistent paresthesia coverage on a long-term basis.[12-17,32-39] An extensive literature review revealed that level I evidence for the use of SCS for upper limb and/or neck pain is not currently available within peer reviewed publications, but level II evidence from 3 prospective studies evaluating the benefits of traditional cervical SCS and 1 study testing the benefits of dorsal nerve root stimulation (DNRS) for upper limb and/or neck pain were available for reference and comparison.[12-14] Pain relief reported in subjects treated with 10-kHz SCS in the current study is higher than previously reported data at 12-mo endpoint assessment (79.2% for neck pain and 85.9% for upper limb pain, vs 36.8%-66.8% with cervical SCS and 52.6% with DNRS).[12-14] More importantly, the percent pain relief gradually increased from 3-mo to 12-mo endpoint

FIGURE 4. *Improvement in quality of life and functioning after the 10-kHz SCS treatment.* **A**, *PDI scores and percentage change from baseline.* **B**, *GAF scores and percentage improvement from baseline.* **C**, *SF-12 (PCS subscale) scores and mean improvement from baseline.* **D**, *SF-12 (MCS subscale) scores and mean improvement from baseline.* **E**, *Subject reported GIC.* **F**, *Clinician reported GIC. Data shown include mean ± SEM at indicated assessment times.*

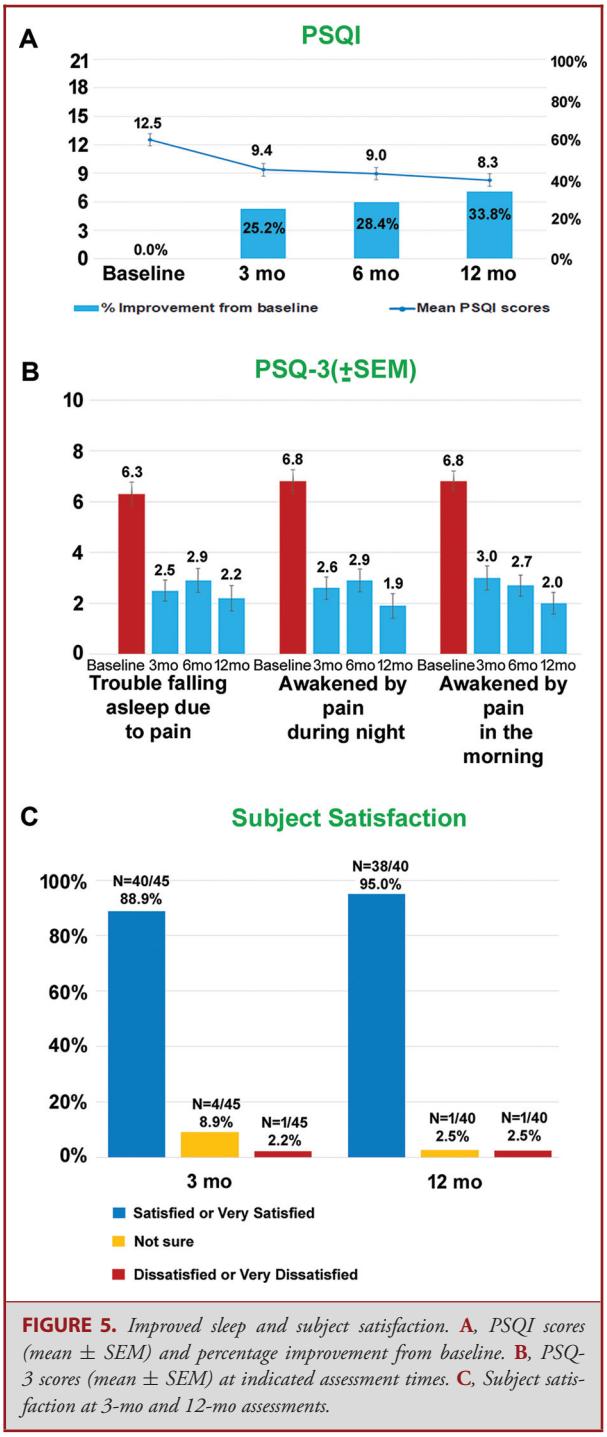

FIGURE 5. *Improved sleep and subject satisfaction.* **A**, *PSQI scores (mean ± SEM) and percentage improvement from baseline.* **B**, *PSQ-3 scores (mean ± SEM) at indicated assessment times.* **C**, *Subject satisfaction at 3-mo and 12-mo assessments.*

assessment with 10-kHz SCS, which to the best of our knowledge has never been reported with traditional SCS. Responder rate as determined by percentage of subjects with ≥50% pain relief was similarly higher (89% for neck pain and 95% for upper limb pain with 10-kHz SCS vs 67% with traditional cervical SCS as well as

TABLE 4. Medication Change Following the 10-kHz SCS Therapy

	3 mo	6 mo	12 mo
Increased	8.6% (3)	11.4% (4)	6.7% (2)
No change	80.0% (28)	65.7% (23)	63.3% (19)
Reduced or eliminated	11.4% (4)	22.8% (8)	30.0% (9)

DNRS) in subjects treated with 10-kHz SCS compared to previously reported studies.[14] Strikingly, at 12-mo assessment ~80% of subjects with upper limb and/or neck pain had achieved VAS scores of ≤2.5 cm, a cut-off defined as the point of remission in chronic pain patients.[30,31] Pain relief, responder rates, and remitter rates observed in the current study are comparable to the results reported in 10-kHz SCS-treated subjects with chronic low back and leg pain in randomized controlled trial (RCT) and to retrospective, real-world data.[30,31,40,41] The results from 12-mo SF-MPQ-2 assessments in 10-kHz SCS-treated subjects further supported the VAS, pain relief, and responder rates analysis.

Loss of efficacy and other complications leading to explant of the devices is a major concern in the field of neuromodulation as it causes excess burden to the patients and increases the treatment costs. Lead migration leading to loss of efficacy, discomfort due to positioning of the leads (positional effect), and device related complications are commonly encountered in patients with upper limb and neck pain.[15-17,34,39] In the current study, only 1 in 45 subjects required an explant (2.2%) and there were no cases of lead migration or other complications despite positioning the leads at C2 vertebral level in all enrolled subjects. More importantly, all the device-related adverse events were manageable and resolved shortly after reprogramming.

In addition to pain relief, the current study evaluated additional quality of life related outcomes such as PDI, SF-12, GIC, GAF, and patient satisfaction.[21,22,42,43] In the current study, the 10-kHz SCS treatment resulted in nearly 25-point reduction (~2.5 × minimum clinically important difference (MCID)) in PDI scores at 12-mo assessment compared to baseline, which is slightly higher than previously reported improvement with LF-SCS.[12] Similarly, 10-kHz SCS-treated subjects had 10-point reduction (~2.8 × MCID) in SF-12 physical component summary score (PCS) subscale and 5-point reduction (~1.2 × MCID) in SF-12 mental health component summary score (MCS) subscale. Although previous studies attempted to measure quality of life in upper limb and neck patients using SF-36 and euroqol 5 dimensions questionnaire questionnaires, the findings were inconclusive as the number of subjects was relatively small.[14,17] Current study included information from 40 subjects with upper limb and/or neck pain for the longitudinal analysis, and clearly showed the benefits of 10-kHz SCS in the improvement of quality of life in the enrolled subjects. Furthermore, previous studies also did not attempt to directly assess the impression of change and global functioning in upper limb and neck pain patients using GIC and

GAF questionnaires, respectively. Deer et al[12] used patient rated "greatly improved," "improved," "neither improved nor deteriorated," and "deteriorated" categories to estimate the quality of life in subjects treated with cervical SCS and reported ~63% subjects in improved or greatly improved category at 12-mo endpoint. In the current study, 95% of subjects treated with 10-kHz SCS had a positive GIC seen as "better," "moderately better," or "a significantly better" and had a 19-point improvement on GAF scores at 12-mo endpoint assessment underscoring the benefits of 10-kHz SCS for the treatment of upper limb and neck pain. The improvement in quality of life at 12-mo assessment was further reflected in patient satisfaction rate (95%), which was higher than previously reported patient satisfaction with traditional cervical SCS.[12] The findings on quality of life in chronic pain subjects in the current study are comparable to the previously reported results from randomized controlled study in chronic low back and leg pain subjects.[40]

Lack of uninterrupted and restful sleep is a common concern for patients with chronic pain. Continued reliance on opioids by chronic pain patients may partly be due to their ability to induce sleep.[44] Results from the current study indicate that subjects treated with 10-kHz SCS reported continued improvement in their sleep patterns with a 4-point improvement in both PSQI scores and PSQ-3 scores at 12-mo endpoint. Moreover, at that same time of assessment 30% of the subjects enrolled in the study reduced or eliminated their opioid medication, pointing to the overall improvement in quality of life in 10-kHz SCS-treated subjects. Current findings on PSQI scores and changes in opioid medication are similar to previously reported results from studies in chronic back and leg pain subjects and to retrospective analysis of real-world data.[30,31,40,41,45,46] The apparent disconnect between modest changes in opioid medication despite profound pain relief could be mainly because the study was not designed to test the effect of changes in opioid medication following 10-kHz SCS treatment. In order to translate the pain relief and quality of life outcomes into changes in opioid medication, reduction or elimination of opioids needs to be part of the treatment plan and the patient must understand and agree to the objectives of the treatment possibly before offering the trial. Though the current study did not include any active encouragement of changing opioid dose, 30% of the subjects either reduced their dose or eliminated opioids completely, indicating the potential of 10-kHz SCS as an alternative to opioids.

Finally, the exclusion criterion listed subjects who "are currently requiring or are likely to require" an MRI. All subjects had an MRI prior to enrollment. The subsequent medical review was intended to prevent implantation of a patient with near-term expectations of a required MRI. The safety of the Senza system for cervical MRI was not established at the time of study initiation. However, the Senza system now has full-body conditional MRI compatibility.

Additional discussion on rationale for lower (≥40%) pain relief cut-off in the trial phase and exclusion criteria can be found in Discussions 1 and 2 in **Supplemental Digital Content**. Additional references can be found in the **Supplemental Digital Content**.

Limitations

This study was not an RCT. An RCT is an important tool for clinicians to evaluate the efficacy of a new treatment or to compare treatments. However, efficacy of SCS, including10-kHz SCS, was documented in an RCT and further supported through a large real-world retrospective review.[30,31,41] In the discussion, multiple published prospective trials of cervical SCS were reviewed and the findings were compared with 10-kHz SCS to determine if similar safety and efficacy in neck pain with or without arm pain was seen in the current study.

Secondly, the study excluded subjects with "any previous history of surgery on the posterior elements (laminectomy, posterior fusion)." This criterion may be considered too restrictive since in the absence of laminectomy, laminotomy, or laminoplasty posterior surgery, such as stand-alone fusion or foraminotomy, would not have been a contraindication for safe placement of SCS leads. A new MRI and careful neurosurgical review could have been considered to include these patients. Nonetheless, this would not affect the conclusions of the study.

CONCLUSION

This study demonstrates the effectiveness of 10-kHz SCS for the treatment of neck and upper limb pain by providing durable long-lasting relief and significant improvement in quality of life. Follow-up prospective RCTs and real-world studies in clinical setting are desirable to further replicate results from this study.

Disclosures

The study was sponsored by Nevro Corp. Drs Amirdelfan, Benyamin, Yu, and Bundschu are consultants to Nevro Corp. Mr Gliner, Drs Subbaroyan, Rotte, and Caraway are employees of Nevro Corp. Dr Vallejo is an employee of Stimgenics, and a consultant for Medtronic and Avanos.

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Supplemental Digital Content. Method 1. Key inclusion and exclusion criteria; Method 2. Sample size; Method 3. Procedures; Method 4. Outcomes; Method 5. Study definitions; Result 1. Study flow; Discussion 1. Rationale for lower (≥40%) pain relief cut-off in trial phase; Discussion 2. Rationale for exclusion criteria; Table S1. Inclusion criteria; Table S2. Exclusion criteria; Figure S1. Study design flow chart; Figure S2. Number of reprogramming during the study; References.