Prospective Study

Results From a Prospective, Clinical Study (US-nPower) Evaluating a Miniature Spinal Cord Stimulator for the Management of Chronic, Intractable Pain

Mehul J. Desai, MD[1,2], Tejal Raju, MD[3], Chheany Ung, MD[4], Sailesh Arulkumar, MD[5], Leo Kapural, MD, PhD[6], Mayank Gupta, MD[7], Kasra Amirdelfan, MD[8], David Rosenfeld, MD[9], Aaron Calodney, MD[10], Dawood Sayed, MD[11], Ajay Antony, MD[12], Sean Li, MD[13], Ramana Naidu, MD[14], Joel Ackerman, MD[15], Robert Ball, DO[16], Michael Fishman, MD[17], Peter Staats, MD[18], Gary Heit, MD, PhD[19], Shilpa Kottalgi, BDS, MAS[20], and James Makous, PhD[21]

From: [1]International Spine, Pain & Performance Center, Washington, DC; [2]George Washington University, School of Medicine & Health Sciences, Washington, DC; [3]Virginia Interventional Pain & Spine Center, Christiansburg, VA; [4]Virginia Interventional Pain & Spine Center, Roanoke, VA; [5]SSM Health, Oklahoma City, OK; [6]Carolinas Pain Institute, Winston Salem, NC; [7]Neuroscience Research Center LLC, Overland Park, KS; [8]IPM Medical Group, Walnut Creek, CA; [9]Alliance Spine and Pain Centers, Atlanta, GA; [10]Precision Spine Care, Tyler, TX; [11]University of Kansas Medical Center Research Institute, Kansas City, KS; [12]The Orthopaedic Institute, Gainesville, FL; [13]Premier Pain Centers, Shrewsbury, NJ; [14]California Orthopedics & Spine, Larkspur, CA; [15]KC Pain Centers, Lee's Summit, MO; [16]Southwest Florida Pain Center, Port Charlotte, FL; [17]Center for Interventional Pain and Spine, LLC, Lancaster, PA; [18]National Spine and Pain Centers, MD; [19]Hue University of Medicine and Pharmacy, Hue, Vietnam; [20]Nalu Medical, Inc., Carlsbad, CA; [21]Makous Research, LLC, Carlsbad, CA

Address Correspondence:
Shilpa Kottalgi, BDS, MAS
Nalu Medical, Inc.
2320 Faraday Ave, Suite 100
Carlsbad, CA 92008
E-mail: skottalgi@nalumed.com

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Background: Chronic, intractable, neuropathic pain is readily treatable with spinal cord stimulation (SCS). Technological advancements, including device miniaturization, are advancing the field of neuromodulation.

Objectives: We report here the results of an SCS clinical trial to treat chronic, low back and leg pain, with a micro-implantable pulse generator (micro-IPG).

Study Design: This was a single-arm, prospective, multicenter, postmarket, observational study.

Setting: Patients were recruited from 15 US-based comprehensive pain centers.

Methods: This open-label clinical trial was designed to evaluate the performance of the Nalu™ Neurostimulation System (Nalu Medical, Inc., Carlsbad, CA) in the treatment of low back and leg pain. Patients, who provided informed consent and were successfully screened for study entry, were implanted with temporary trial leads. Patients went on to receive a permanent implant of the leads and micro-IPG if they demonstrated a ≥ 50% reduction in pain during the temporary trial period. Patient-reported outcomes (PROs), such as pain scores, functional disability, mood, patient impression of change, comfort, therapy use profile, and device ease of use, were captured.

Results: At baseline, the average pain Visual Analog Scale (VAS) score was 72.1 ± 17.9 in the leg and 78.0 ± 15.4 in the low back. At 90 days following permanent implant (end of study), pain scores improved by 76% (VAS 18.5 ± 18.8) in the leg and 75% (VAS 19.7 ± 20.8) in the low back. Eighty-six percent of both leg pain and low back pain patients demonstrated a ≥ 50% reduction in pain at 90 days following implant. The comfort of the external wearable (Therapy Disc and Adhesive Clip) was rated 1.16 ± 1.53, on average, at 90 days on an 11-point rating scale (0 = very comfortable, 10 = very uncomfortable). All PROs demonstrated statistically significant symptomatic improvement at 90 days following implant of the micro-IPG.

Limitations: Limitations of this study include the lack of long-term results (beyond 90 days) and a relatively small sample size of 35 patients who were part of the analysis; additionally, there was no control arm or randomization as this was a single-arm study, without a comparator, designed to document the efficacy and safety of the device. Therefore, no direct comparisons to other SCS systems were possible.

Conclusions: This clinical study demonstrated profound leg and low back pain relief in terms of overall pain reduction, as well as the proportion of therapy responders. The study patients reported the wearable aspects of the system to be very comfortable.

Key words: Spinal cord stimulation, chronic pain, radiculopathy, micro-IPG, battery-free, persistent spinal pain syndrome, failed back surgery syndrome, low back pain, leg pain

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Spinal cord stimulation (SCS) has been used to treat chronic intractable pain of the trunk and limbs for over 50 years (1). This approach came on the heels of the seminal work of Melzak et al (2), where they elucidated the "gate-control theory" of pain. In recent years, a number of new waveforms, beyond traditional tonic stimulation (T-SCS) have emerged. These include 10 kHz, burst, differential target multiplexed stimulation, and pulsed stimulation pattern (PSP). These modern waveforms may operate under different mechanisms of action (MOA) than T-SCS (3).

Conservative therapies are the first line of treatment for chronic pain syndromes. These include exercise, physical, occupational, and massage therapy. Biofeedback, behavioral, and cognitive therapy may also be employed. Over-the-counter pain medications round out the first-line treatments. The second line of treatment includes nerve blocks through the injection of steroids or local anesthetics. Prescription medications, such as opioids and/or membrane stabilizers, may also be indicated at this stage. The last line, and more invasive of treatments, includes neurostimulation, intrathecal drug infusion, and neuroablation. Neurostimulation may include SCS, deep brain stimulation, or peripheral nerve stimulation (PNS).

While the therapeutic assessment of novel waveforms has significantly improved SCS efficacy, other advances in technology have been incremental. Among them are smaller, rechargeable implantable pulse generators (IPGs)/batteries and improved lead anchoring techniques. Even with the newest rechargeable devices, the IPG volume remains relatively large with volumes of ~14 cm^3 or more. The removal of the battery components from the implant has allowed for a dramatic drop in the size of the IPG to < 1.5 cm^3. Recent concerns regarding the long-term comfort of a wearable battery are not well founded. For example, Salmon et al (4) found that SCS patients rated the level of comfort of the external wearable power source (Therapy Disc [TD]) to be 0.41 ± 0.73 at 90 days, on an 11-point Likert scale (0 = very comfortable, 10 = very uncomfortable). What is more, smaller implant sizes may result in a decrease in the incidence of IPG pocket pain (5). As of the date of writing this publication, there are no reported cases of pocket pain from this micro-IPG in either the Manufacturer and User Facility Device Experience (MAUDE) database (6) or within peer-reviewed journals (4,7).

The US Food and Drug Administration (FDA) has currently cleared this system for 2 indications: 1) SCS as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain; and 2) PNS for pain management in adults who have severe, intractable chronic pain of peripheral nerve origin, as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The device is not cleared to treat pain in the craniofacial region. This micro-IPG supports a large menu of therapy options, delivered via one or 2 8-contact or 4-contact leads, with the option of tines in the 4-contact configuration, to mitigate lead migration in the case of PNS. In addition, the system software is seamlessly upgraded without micro-IPG replacement, which allows for the expansion of features and therapy options.

This prospective, open-label, postmarket, multicenter, 90-day study was designed to evaluate the safety, efficacy, usability, and comfort of this SCS system, to treat severe, chronic low back and leg pain.

Methods

Patients were screened, based upon inclusion and exclusion criteria (Table 1), and signed an informed

Table 1. *Key inclusion and exclusion criteria for study eligibility.*

Key Inclusion Criteria	Key Exclusion Criteria
• Patient is between 21 and 80 years of age at enrollment. • Patient has chronic (defined as at least 6-months duration), intractable neuropathic pain of the back and/or leg(s); any nociceptive pain must be less prominent than the neuropathic pain. • Patient's pain is nonresponsive to conservative treatment options for a minimum of 3 months. • Patient has a VAS score of at least 6 in the back and/or leg at screening. • Patient has demonstrated the ability to appropriately place the adhesive clip on the low back.	• Patient has previously failed SCS therapy (either trial system evaluation or permanent implant). • Patient has had an ablative procedure directed at the spinal cord, including the DREZ or DRG. • Patient has mechanical spine instability. • Patient is on > 90 mg morphine equivalents per 24 hours. • Patient is sensitive to skin adhesives used in the system or does not tolerate the wearable aspect of the device.

Abbreviations: VAS, Visual Analog Scale; SCS, spinal cord stimulation; DREZ, dorsal root entry zone; DRG, dorsal root ganglion.

consent. Enrollment took place, from July 2020 through June 2022, at 15 US-based comprehensive pain centers. The follow-ups were conducted from July 2020 through September 2022. Data collection was carried out from July 2020 to January 2023, with the database locked on March 7, 2023. The study was approved by an independent institutional review board (IRB) (WCG IRB) and conducted in compliance regulations and with ISO-14155:2020. The study was registered on Clinicaltrials.gov (NCT04503109).

Baseline assessments were completed prior to study intervention with the following outcome measures collected in the office: Visual Analog Scale (VAS) for leg and low back pain, Beck Depression Inventory (BDI) for mood, Oswestry Disability Index (ODI) for functional disability, European Quality of Life-5 Dimensions-5 Level Version (EQ-5D-5L) for quality-of-life assessment, and the Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance short form. Following an implantation and device activation, the assessments captured at the baseline were repeated in the office. Additionally, the following patient-reported outcomes (PROs) were captured at the end of the study (90-day time point): Patient Global Impression of Change (PGIC), stimulator usability, stimulator comfort, and stimulator use profile were also captured in the office.

Prior to the SCS temporary lead placement (referred to as a "temporary trial"), patients were asked to undergo a wearability assessment for a minimum of 7 days. During this assessment, an inactive TD and adhesive clip were worn on the torso to determine their preferred location, as well as the location of the micro-IPG, which was documented in collaboration with the implanting physician.

Temporary trials were used to screen for SCS responders ("responders" were defined as patients who reported $\geq$ 50% pain relief based upon the in-office recall of the preceding 24 hours [24-hr VAS]). At the start of the temporary trial, each lead was percutaneously placed, externalized, and connected directly to the Trial TD to deliver stimulation therapy. At the end of the trial, the leads were removed, and trial success was evaluated. If the temporary trial was successful, new leads were permanently implanted with the micro-IPG at a later date. In all patients, two 8-contact leads were implanted and the contact arrays were positioned to span the T9 vertebral body, both during the temporary trial and the permanent implant phase.

Patients were offered several stimulation programs to try out at home during the temporary trial, with the goal of achieving optimal pain relief. SCS therapies offered included: Traditional (Tonic; T-SCS), PSP (see Desai et al (8) for a detailed description), T-SCS/PSP combination, and scheduled PSP. The T-SCS/PSP combination entails interleaving the 2 therapies in a single program. The PSP family of waveforms are composite, multidimensional signals. These hierarchical waveforms are created by layering up to 3 temporal patterns (i.e., pulse patterns, trains, and dosages; see Desai et al [8]) that are theorized to address up to 6 MOAs. Scheduled PSP, on the other hand, refers to delivering one specific set of PSP parameters (e.g., electrode configuration, amplitude, pulse pattern, train, and dosage) for a brief period of time (i.e., several seconds to minutes) before automatically moving on to the next PSP parameter set, including active electrode contact.

Patients were instructed to try various preprogrammed therapy settings until they identified the therapy that delivered the greatest pain relief. Patients were brought back into the clinic for up to 4 reprogramming visits, as needed, during the temporary trial period. Patients who responded to therapy, were scheduled for a permanent implant. Nonresponders during the temporary trial were screened from the study. Each micro-IPG implant was carried out using standard operative and anesthetic techniques (9).

Patients returned to the clinic following 90 days of treatment with the permanent micro-IPG device. At such time, they completed the PROs, including the validated questionnaires and questionnaires related to the wearable aspects of the device.

Study data were collected, stored, and monitored per Good Clinical Practice guidelines (10). Adverse events (AEs) were captured and summarized for all enrolled patients. This study was not statistically powered, as it was a postmarket, observational study, and no formal sample size estimation was done prior to the study start. A study sample size of 40 implanted patients was chosen to be similar to the number of patients targeted in Salmon et al (4) study, which unfortunately was halted early due to COVID-19 restrictions. Both the current study and the Salmon et al (4) study evaluated the same device. Basic statistical analyses were completed on all endpoints, including computation of average, variance, SDs, SEM, and trend analysis. Parametric and nonparametric statistics were employed, as appropriate, to test for statistical significance or for trends in the data. All means were reported with ± 1 SD unless otherwise specified. This study was not a randomized

controlled trial (RCT) but rather had a within-patient control (baseline compared to treatment). A potential bias may arise from the expectation of pain relief in any pain study. However, this study was a small, prospective, non-RCT, and therefore there was no opportunity to mitigate bias with a control arm.

Results

A total of 110 patients were screened for the study, of which 53 were enrolled and underwent the temporary trial lead placement. Forty-seven out of 53 patients (89%) passed the prespecified trial-pass criterion of ≥ 50% reduction in the VAS pain score. Trials lasted an average of 6.5 days (range 3 to 13 days). Five patients withdrew prior to implant (Fig. 1), leaving a total of 42 patients who were implanted with the permanent device. An additional 7 patients were excluded for reasons listed in Fig. 1, leaving an evaluable population of 35 patients at the end of the study. Patients were 21.5 to 76.2 years old - 54.2% were women. Patients typically had long-term chronic pain lasting 10.46 years (range 0.75 to 36.75) on average. Thirty-three patients (94%) reported both leg and low back pain - one reported leg pain only and one reported low back pain only (Table 2).

At baseline, prior to trial lead placement, the average 24-hr VAS for the leg was 72.1 ± 17.9; whereas, the average 24-hr VAS for the low back was 78.0 ± 15.4. At the end of the temporary trial, among the responders, the average pain score in the leg was 10.4 ± 9.7 (84% improvement), and in the low back was 16.5 ± 13.4 (78% improvement). The pain scores at 90 days were as follows (Fig. 2): 18.5 ± 18.8 (76% improvement) for leg pain and 19.7 ± 20.8 (75% improvement) for back pain. Responder rates at 90 days were 86% for both leg pain (Fig. 3) and low back pain (Fig. 4).

Responder rates were computed based upon the ≥ 50% pain reduction typically seen in pain studies. In addition, 3 alternate "high responder" criteria at 90 days were explored, as follows (Fig. 5): ≥ 80% VAS pain reduction relative to baseline, VAS pain score of ≤ 25, and VAS pain score of ≤ 10. The percentage of high responders, with ≥ 80% pain relief, was 49% in the leg and 54% in the back. Of patients reporting a VAS of ≤ 25 at 90 days, 69% met this criterion in the leg and 80% in the back. In the case of patients reporting VAS of ≤ 10, 46% of patients in both the leg and the back met this criterion.

Functional assessments improved as well. PGIC scores at 90 days improved in 100% of patients, with 53% (18/34) reporting they were very much improved, 35% (12/34) reporting much improved, and 12% (4/34) reporting minimally improved (Fig. 6). Improvements in functional disability were captured with ODI scores and were found to improve by more than half from a baseline of 57.03 ± 13.2 to 24.03 ± 14.37 (a 57.6% reduction in disability; $P < 0.001$). Crippled or severely disabled patients represented 86% (30/35) of the patients at baseline; this showed a big improvement with just 12% (4/34) in this category, at 90 days (Fig. 7).

BDI, EQ-5D-5L, and PROMIS sleep instruments also showed improvements. BDI scores improved by 58% at 90 days, when comparing overall BDI scores of 17.7

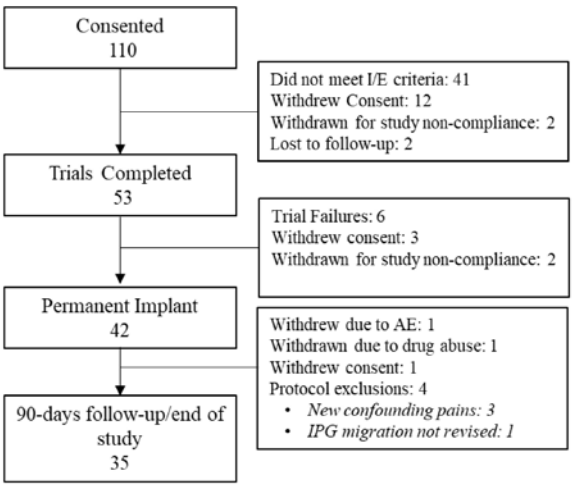


Fig. 1. Study flow chart from consent to 90 days (end of study). I/E, inclusion/exclusion; AE, adverse event; IPG, implantable pulse generator.

Table 2. *Patient demographics and baseline characteristics of evaluable population.*

Demographic Summaries	
Characteristic	**Mean ± SD (n) [Min, Max] or % (n)**
Age	55.9 ± 11.8 (35) [21.5, 76.2]
Women	19, 54.2%
Men	16, 45.7%
BMI	31.38 ± 5.08 (35) [18.0, 40.80]
Years since diagnosis	10.46 ± 9.46 (35) [0.75, 36.75]
Back and leg pain	33, 94%
Leg pain only	1, 3%
Back pain only	1, 3%
Number of back surgeries	1.17 ± 1.34 (35) [0,7]

Abbreviation: BMI, body mass index.

± 11.6 at baseline to 7.7 ± 9.6 at 90 days ($P < 0.001$). The proportion of patients who reported mild, moderate, or severe depression at baseline was 62% (21/34); whereas, only 18% (6/33) reported mild, moderate, or severe depression following 90 days of therapy (Fig. 8). The EQ-5D-5L questionnaire measures the quality of life in individuals with chronic pain. As a part of administering the questionnaire, a VAS (0 to 100) was used to evaluate overall health ranging from "best imaginable health = 100" to the "worst imaginable health = 0." The average health score was 64.7 ± 17.8 at baseline, which improved to 78.6 ± 16.6 ($P < 0.001$) at 90 days. This represented a quality-of-life improvement of 30%. A health status index (0 to 1) was then computed based upon individual EQ-5D-5L dimension scores ranging from "worst possible health = 0" to "best possible health = 1." The index reflects the health state according to the preferences of the general population in a country or region. Here, the index scores were calculated based on the US's general population valuation surveys. A score of 0.53 ± 0.17 at baseline improved significantly to 0.76 ± 0.15 at 90 days ($P < 0.001$). This represented a 59% improvement in quality of life. The PROMIS Sleep Disturbance questionnaire results showed a 14% improvement. The sleep disturbance score showed a reduction from 56.3 ± 8.4 at baseline to 47.6 ± 7.5 at 90 days; this was statistically significant at

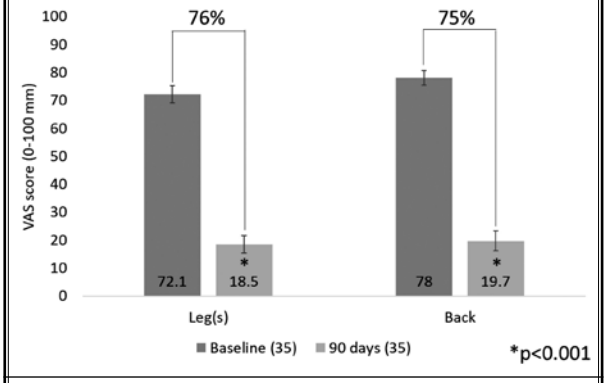


Fig. 2. *Leg and low back VAS (24 hours) pain ratings captured in-office. Results shown are at baseline and 90-days postactivation. Each data point represents mean ± SEM. Sample size shown in parentheses. Note: percent reduction is calculated within each patient and then averaged across patients. VAS, Visual Analog Scale.*

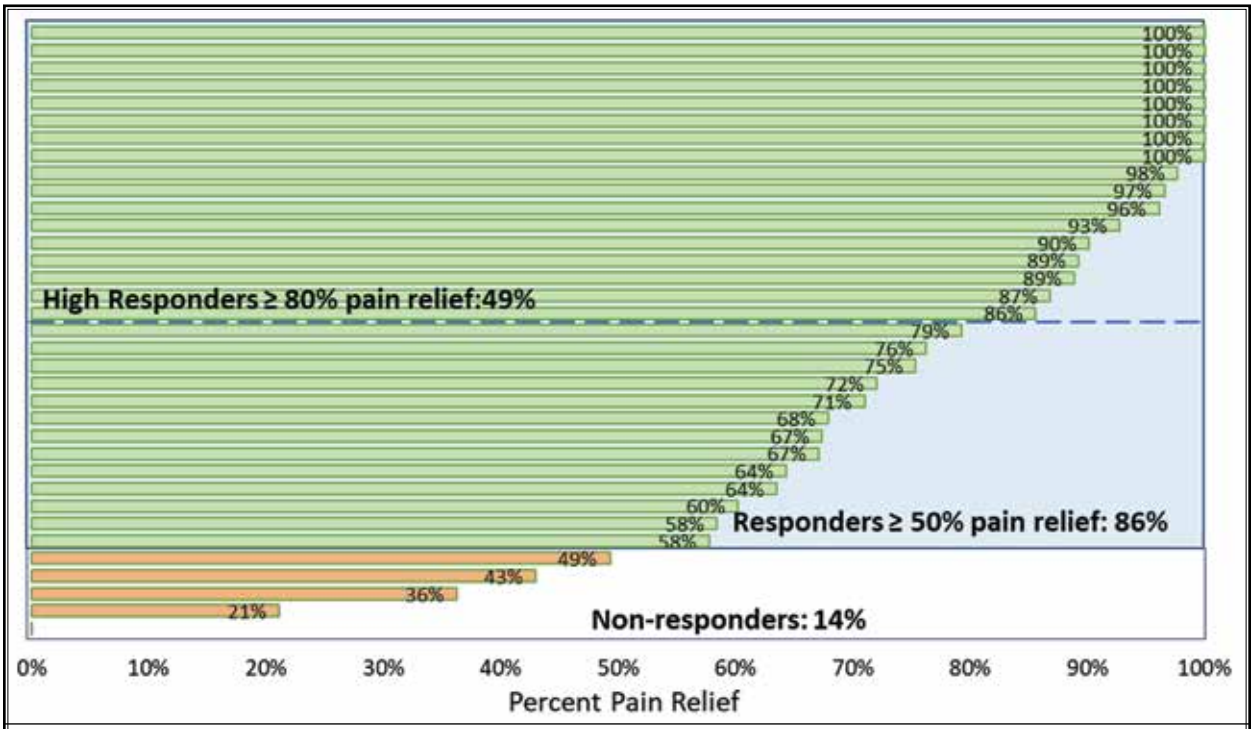


Fig. 3. *Tornado plot shows pain relief in the leg(s) of each study patient at 90 days. Responders were patients with ≥ 50% pain reduction compared to their baseline pain scores (24-hr VAS). High responders were patients with ≥ 80% pain reduction compared to their baseline pain scores. VAS, Visual Analog Scale.*

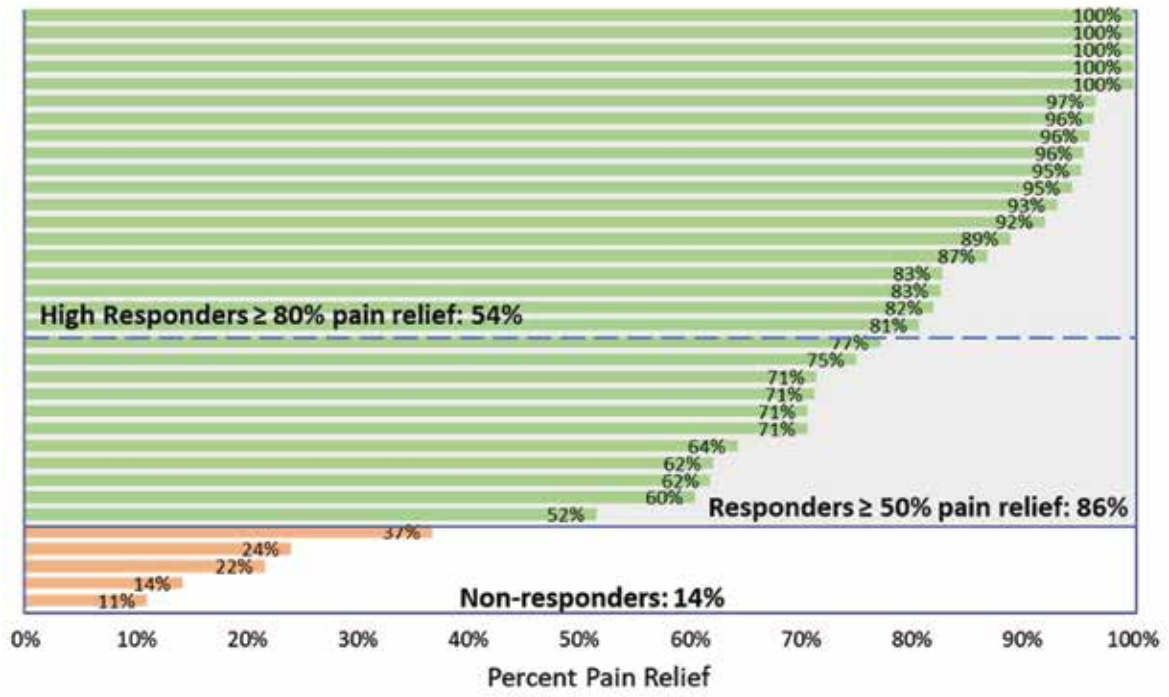
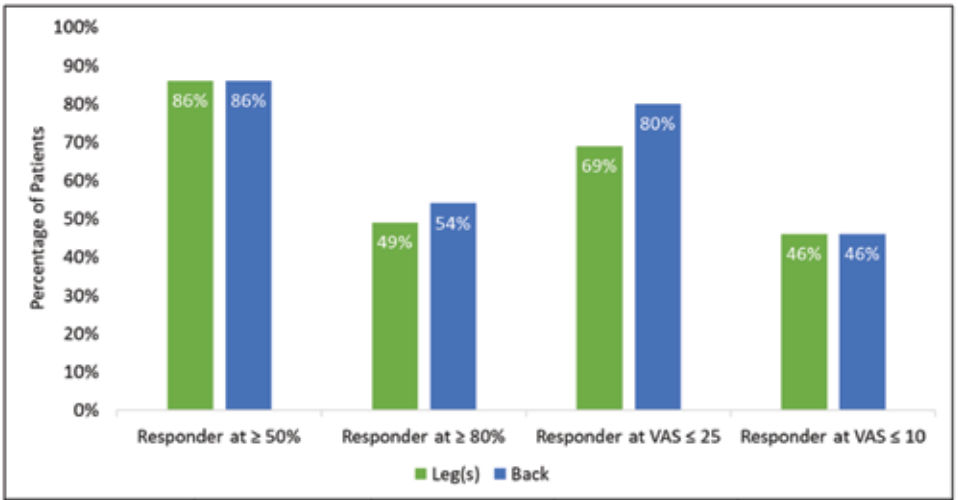


Fig. 4. *Tornado plot shows pain relief in the low back of each study patient at 90 days. Responders were patients with ≥ 50% pain reduction compared to their baseline pain scores (24-hr VAS). High responders were patients with ≥ 80% pain reduction compared to their baseline pain scores. VAS, Visual Analog Scale*



Mean Percent Pain Relief	Responder at ≥ 50%	Responder at ≥ 80%	Responder at VAS ≤ 25	Responder at VAS ≤ 10
Leg(s)	82%	96%	89%	96%
Back	83%	93%	85%	94%

Fig. 5. *Four different responder calculations at 90 days, based upon 24-hr VAS. 1) Percentage of patients showing ≥ 50% pain relief; 2) Percentage of patients showing ≥ 80% pain relief; 3) Percentage of patients reporting VAS ≤ 25; 4) Percentage of patients reporting VAS ≤ 10. The average percent pain relief in each responder group is shown in the table. VAS, Visual Analog Scale.*

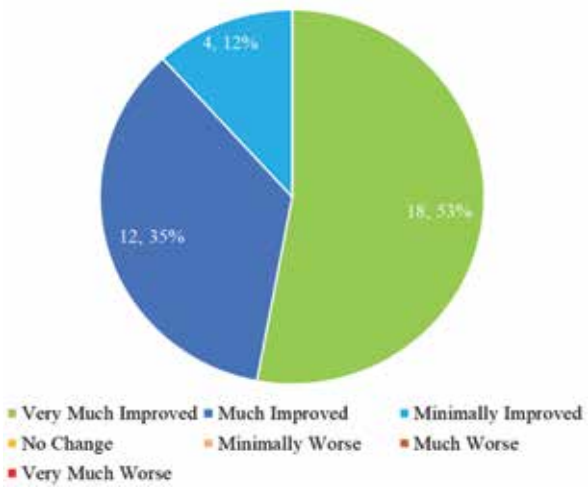
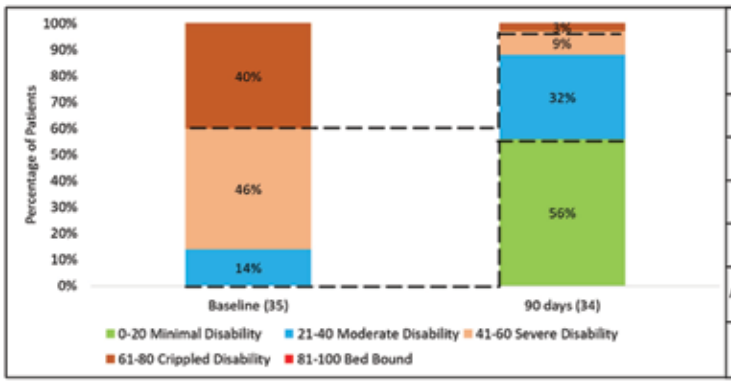
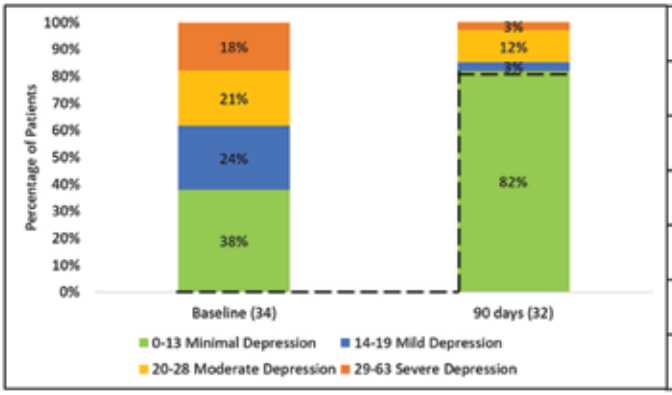


Fig. 6. *PGIC, shown as percentage of patients at 90 days following device activation who were very much improved, much improved, or minimally improved. No patients responded as no change, minimally worse, much worse, or very much worse at 90 days. PGIC, patient global impression of change.*



	Baseline (35)	90 days (34)
0-20 Minimal Disability	0% (0)	56% (19)
21-40 Moderate Disability	14% (5)	32% (11)
41-60 Severe Disability	46% (16)	9% (3)
61-80 Crippled Disability	40% (14)	3% (1)
81-100 Bed Bound	0% (0)	0% (0)
Absolute Change from baseline to 90 days	32.79± 15.33 (34); p<0.001	
Percent Change from Baseline to 90 days	58%	

Fig. 7. *Percentage of patients at 90 days reporting ODI scores ranging from 0 to 80: minimal (0-20), moderate (21-40), severe (41-60), and crippled (61-80) disability. ODI, Oswestry Disability Index.*



	Baseline (34)	90 days (32)
0-13 Minimal Depression	38% (13)	82% (27)
14-19 Mild Depression	24% (8)	3% (1)
20-28 Moderate Depression	21% (7)	12% (4)
29-63 Severe Depression	18% (6)	3% (1)
Absolute Change from baseline to 90 days	10.97 ± 10.68 (32); p<0.001	
Percent Change from Baseline to 90 days	58.46%	

Fig. 8. *Percentage of patients at 90 days reporting BDI scores ranging from 0 to 63; minimal (0-13), mild (14-19), moderate (20-28), and severe (29-63) depression. BDI, Beck Depression Inventory.*

$P < 0.001$. At baseline, 43% (15/35) of patients reported "none to slight" sleep disturbances; this proportion increased to 85% (28/33) at 90 days, demonstrating considerable improvements in sleep.

Device comfort, therapy use profile, and device ease of use were captured at the 90-day study visit. An 11-point Likert scale was employed to assess comfort and ease of use (very comfortable/easy to use = 0, very uncomfortable/very difficult to use = 10). The average comfort score was 1.2 ± 1.5 ease-of-use score average was 0.8 ± 1.4. In terms of the therapy use profile, 97% of patients reported wearing the TD and adhesive clip for > 23 hours per day. The one patient who reported wearing the TD 12-15 hours per day managed to titrate their own therapy to achieve pain relief with a VAS of 29/100 (71% relief) in the leg(s) and 19/100 (60% relief) in the low back.

There were no reports of serious adverse device effects or unanticipated adverse device effects. Two serious AEs were reported in the study, which were neither related to the device nor the procedure; both events were resolved. All device and/or procedure-related AEs were typical and had unremarkable resolution. There were no reports of pocket pain or infections. Two patients underwent micro-IPG revisions for device rotation.

Discussion

This was a single-arm, prospective, multicenter, postmarket, observational study that followed patients for 90 days after the SCS lead and micro-IPG implantation and activation. A menu of stimulator therapy options was available to the patients, including T-SCS, PSP, T-SCS/PSP combination, and scheduled PSP. Each patient chose their preferred therapy and was able to change programs at any time via the remote control application loaded on their smartphone (i.e., iOS™ or Android™). The responder rate (≥ 50% reduction in pain) was 86% for both the legs and the low back. In addition, the rate of high responders (≥ 80% reduction in pain) was 49% for leg pain and 54% for low back pain. Secondary endpoints regarding sleep, mood, functional disability, and quality of life all demonstrated statistically significant outcomes at 90 days compared to baseline.

Interestingly, Salmon et al (4) observed nearly identical responder rates when evaluating the efficacy of the current SCS system, while delivering the PSP waveform in a single-arm, prospective, Australian study. Salmon et al (4) reported responder rates of 86% in the leg and 81% in the low back; whereas, high-responder rates were 64% in the leg and 52% in the low back. Two large RCTs, evaluating different SCS systems, had similar results. For example, responder rates of 83% in the leg and 85% in the back were reported at 3 months, with 10 kHz stimulation (11,13). Mekhail et al (12) also found comparable responder rates of 82% in the overall back and the leg, with an overall high-responder rate of 58%, with closed-loop SCS. Thus, it appears that SCS findings, among studies with more advanced technologies (beyond T-SCS), such as PSP, 10 kHz, and closed-loop SCS, share roughly common responder rates all falling in the range of 81% to 86%.

Secondary outcome measures also demonstrated statistically significant improvements. When baseline PROs (i.e., ODI, EQ-5D-5L, BDI, and PROMIS) were compared to PROs collected at 90 days, there were clinically meaningful and statistically significant improvements in all of them. Comfort of the TD and adhesive clip and ease-of-device use were both clustered around 1 on an 11-point Likert scale, where a score of 0 is very comfortable and very easy to use. Regarding patient use profile with the therapy, 97% of the patients reported wearing the TD > 23 hours per day.

Device-related AEs were rare during this study. Instances in which they occurred were mild and the types of AEs were consistent with earlier published reports of SCS therapy (14). Rechargeable and primary cell batteries add considerably to the implant volume. By moving the battery to the outside of the body there is the potential to minimize IPG-related AEs, such as pocket pain and infection. Indeed, the infection rate for the current study with the micro-IPG is 0.0% (out of a total 42 implants) and the rate of IPG-pocket pain was also 0.0%.

Another advantage of moving the battery to outside of the body is a significantly decreased risk of surgery to address battery-related issues. Implanted batteries require replacement an average of 3.7 years for primary cells and 7.2 years for rechargeable cells based upon the findings of Costandi et al (15). In comparison, the micro-IPG has an expected lifespan of 18 years (16). FDA's MAUDE database shows that 22% of reportable events for SCS devices are due to battery issues (17). Additionally, with a well-designed micro-IPG and TD, software upgrades are seamless without the need for replacement surgeries, thereby allowing the system to maintain a full complement of ever-evolving stimulation waveforms or patterns.

Limitations of this study include the lack of long-term results (beyond 90 days) and a relatively small

sample size of 35 patients who were part of the analysis. This study was not an RCT and had no control arm; as such, the study was designed as a single-arm study, without a comparator, to document the efficacy and safety of the device. Therefore, no direct comparisons to other SCS systems were possible.

Conclusions

This is the second in a series of studies evaluating the efficacy, safety, comfort, and usability of a small (< 1.5 cm^3), micro-IPG in the treatment of chronic leg and back pain (see Salmon et al [4]). Responder rates in this study were 86% for both the leg and the low back with high responders at 49% and 54% in the legs and low back, respectively. Given the strong usability and comfort scores collected, along with the externalization of battery components, this system carries potential advantages in the area of pocket pain and infection risk when compared to conventional battery-containing IPGs. These outcomes warrant further investigation.

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Conflicts of Interests

Mehul J. Desai: Avanos, Nalu Medical, SPR Therapeutics, Abbott, Averitas, Mainstay, Nature Cell, Saol, Vivex, SynerFuse, Virdio. Leo Kapural: Nalu Medical, Biotronik, Saluda Medical, Nevro, Medtronic, Biotronik, Medtronic, Neuros, Gimer Medical, NeuraLace. James Makous: Nalu Medical, BackStop Medical, ABVF, Sella Therapies. Shilpa Kottalgi: Nalu Medical. Peter Staats: Nalu Medical, SPR Therapeutics, AIS Healthcare, Medtronic, Saluda, National Spine and Pain Centers, electroCore. Gary Heit: Nalu Medical, Agitated Solutions, Nesos. Kasra Amirdelfan: Nevro, Biotronik, Nalu Medical. Chheany Ung: Nalu Medical, Nevro. Dawood Sayed: Nalu Medical. Joel Ackerman: Nalu Medical, Nevro, Boston Scientific. Michael Fishman: Nalu Medical, Biotronik, Brixton Biosciences, Camber Spine, Medtronic, Nevro, NANS, Thermaquil, Celeri Health, Aurora Spine. Robert Ball: Nalu Medical, Vivex, Boston Scientific, Relievant. Ramana Naidu: Biotronik, SPR Therapeutics, Medtronic, Abbott, Boston Scientific, Nalu Medical, Bioventus, SPR Therapeutics. Sailesh Arulkumar: Nalu Medical. Sean Li: Nalu Medical, Avanos, Averitas Pharma, Biotronik, Boston Scientific, Ethos Laboratories, Neuralace, Nevro, SPR Therapeutics, Abbott, NeuroOne, PainTeq, Pria Health, Saluda, Vertos, NJSIPP, ASPN. David Rosenfeld: Abbott, Acel Rx. Tejal Raju: Nalu Medical. Aaron Calodney: PainTeq, TissueTech, Medtronic, Stryker, Nevro, Boston Scientific. Mayank Gupta: Averitas, Nevro, Grunenthal, Scilex, Stratus, Boston Scientific, Nalu Medical, SGX-Nova, Sollis. Ajay Antony: Nalu Medical, Abbott, Saluda, Boston Scientific, PainTeq, SPR Therapeutics, Biotronik, Vertos.

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