# Using a Novel Hybrid Decentralized Clinical Study to Evaluate Real-World Outcomes for Spinal Cord Stimulation (SCS) Therapies

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## INTRODUCTION

Over the last decade the number of randomized controlled trials (RCTs) conducted evaluating Spinal Cord Stimulation (SCS) and new SCS waveforms have rapidly expanded. RCT outcomes provide one form of evidence that have largely supported the adoption of modern SCS waveforms. While representing the gold standard of clinical evidence, RCTs can involve drawn out timelines for reporting evidence and represent highly controlled environments which rarely align completely with real-world clinical practices[1,2]. The use of digital health platforms and decentralized clinical trials (DCTs) represent a new opportunity to capture and report evidence as therapy modalities and new technology continue to evolve[3].

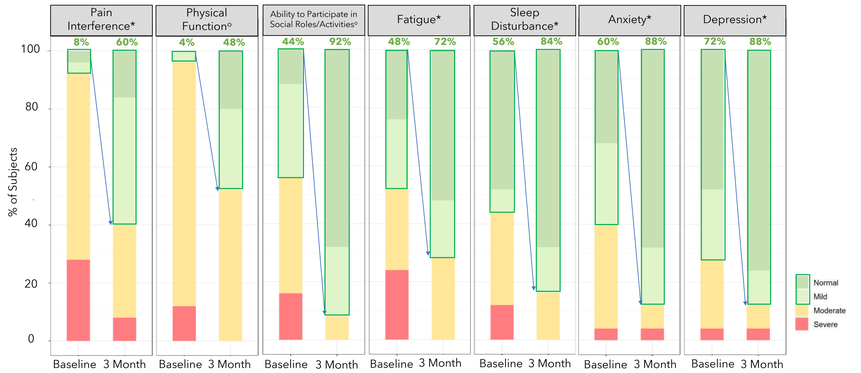
SENSE SCS is a hybrid DCT that captures patient reported outcomes (PROs) including pain relief and holistic assessments, such as PROMIS-29[4], from subjects indicated for SCS with the goal to publish and share evidence consistent with real-world clinical practice. This poster presents data from an early cohort of subjects enrolled in the pilot phase of SENSE SCS. The goal of the pilot phase of the study is to evaluate the workflow of using a mobile clinical trial application for collection of PROs and to characterize outcomes on patient experience with SCS therapy. A sub-analysis of DPN patients from this study is also being presented as a poster at this meeting[5].

## RESULTS

**Table 2. Baseline Demographics in Enrolled Subjects**

| Baseline Subject Characteristics (n = 63) | |
|---|---|
| Mean (SD) Age (Years) | 62 (11) |
| Mean (SD) Years Since Pain Onset (n = 42) | 11 (11) |
| Sex at Birth - Male | 57.1% |
| **Primary Indication for SCS** | |
| Failed Back Syndrome/Post-Laminectomy Pain | 39.7% |
| Diabetic Peripheral Neuropathy | 30.2% |
| Degenerative Disc Disease | 12.7% |
| Complex Regional Pain Syndrome | 3.2% |
| Other | 14.3% |
| **Pain Location** | |
| Lower Back | 46 (80.7%) |
| Right Leg | 28 (49.1%) |
| Lower Limb | 25 (43.9%) |
| Left Leg | 24 (42.1%) |
| Upper Limb | 14 (24.6%) |
| Other | 13 (22.8%) |

**Figure 1. Percent of Patients Reporting Normal, Mild, Moderate, and Severe PROMIS-29 Domain Scores at Baseline and 3 Months (N=25)**




◊ Defined as: Normal (≥45), Mild (40-45), Moderate (30-40) and Severe (<30)
* Defined as: Normal (≥55), Mild (55-60), Moderate (60-70) and Severe (≥70)

**Figure 2. Pain Intensity Score at Baseline, 1 Month, and 3 Months**

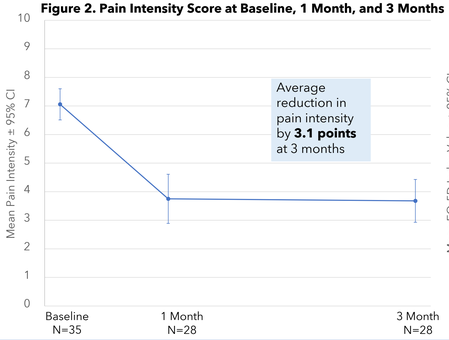



**Figure 3. EQ-5D-5L Index Scores at Baseline, 1 Month, and 3 Months**

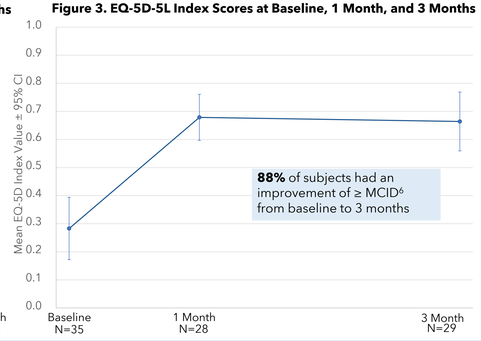
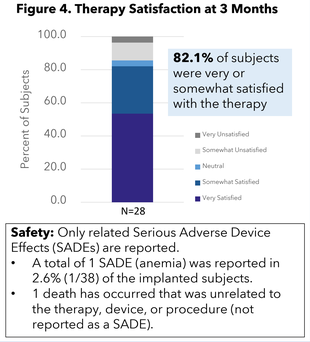



**Figure 4. Therapy Satisfaction at 3 Months**




**Safety:** Only related Serious Adverse Device Effects (SADEs) are reported.
- A total of 1 SADE (anemia) was reported in 2.6% (1/38) of the implanted subjects.
- 1 death has occurred that was unrelated to the therapy, device, or procedure (not reported as a SADE).

## MATERIALS & METHODS

**SENSE SCS – Study to Evaluate Neuromodulation Subject Experience with Contemporary Spinal Cord Stimulation Modalities for Chronic Pain**

Design: Prospective, post-market, non-randomized, observational study, enrolling in the US-only

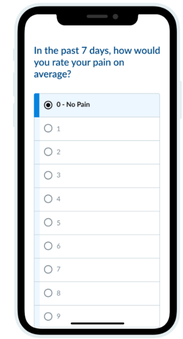
- IRB approved study, registered on clinicaltrials.gov (NCT05775510)
- Hybrid decentralized model of execution
- Subjects with an on-label indication eligible to enroll
- Ongoing enrollment and follow-up; currently in a pilot phase with 9 sites activated

Purpose: Evaluate workflow of a mobile clinical trial application for collection of PROs and to characterize outcomes on patient experience with SCS therapy

- Subjects were electronically enrolled and consented using the clinical trial application
- Subjects were trialed and implanted with commercially available SCS systems with a variety of programming types
- PROs collected electronically using a clinical trial mobile application at baseline, SCS trial, and after permanent SCS implantation through 12 months (3 month outcomes presented here)
  - EQ-5D-5L
  - Activity Goals
  - Satisfaction
  - PGIC
  - Pain Intensity Surveys
  - PROMIS-29 (Patient-Reported Outcomes Measurement Information System®)

**Table 1. Key Inclusion / Exclusion Criteria**

| Pilot Phase Key Inclusion Criteria |
|---|
| • Candidate with an on-label SCS indication for a commercially available Medtronic SCS system.<br>• Willing and able to use a personal smart phone for study surveys. |
| **Pilot Phase Key Exclusion Criteria** |
| • Any active implantable neuromodulation device |




## DISCUSSION AND CONCLUSIONS

- The PROMIS-29 profile represents a holistic assessment of outcomes beyond pain scores.
  - Mean improvements were observed across all seven health domains of PROMIS-29.
  - "Pain Interference" and "Ability to Participate in Social Roles and Activities" saw the largest increase in the number of subjects in the Normal/Mild range compared to baseline.
- An average reduction in pain intensity by 3.1 points from baseline to 3 months was observed in this initial cohort of subjects, complementing the holistic quality of life outcome measures.
- Additional outcome measures from this study will be reported as the study continues.

**CONCLUSION: SENSE SCS represents a novel approach to clinical trial design for SCS, enabling advancement of evidence for SCS via real-world outcomes, across multiple indications, as the field continues to evolve.**

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