

Beyond Pain Scores: How Real-World Outcomes Tell the Story of Quality of Life Improvements for Patients Treated with SCS

Melissa Murphy¹, Andrew Will², Thomas White³, Velimir Micovic⁴, Jugal Dalal⁵, David Provenzano⁶, Xiaoxi Sun⁷, Grace Santa Cruz Chavez⁷, Cory Goracke⁷



¹North Texas Orthopedics & Spine Center, Dallas-Fort Worth, TX, United States, ²Twin Cities Pain Clinic, Minneapolis, MN, United States, ³Procura Pain and Spine PLLC, Houston, TX, United States, ⁴Pain Management Consultants of Southwest Florida, Fort Myers, FL, United States, ⁵Novant Health Spine Specialists, Winston-Salem, NC, United States, ⁶Pain Diagnostics and Interventional Care, Sewickley, PA, ⁷Medtronic Neuromodulation, Minneapolis, MN, United States.

OBJECTIVE

- While pain intensity has been the cornerstone of demonstrating the efficacy of spinal cord stimulation (SCS) as a primary outcome measure for most SCS trials, it is also recognized that a broader view of multidimensional outcomes can provide value in understanding a patient's overall response to therapy.
- Establishing a holistic view of patients in a real world setting and understanding how improvements in pain affect multiple facets of the patient's life provides a broader picture of the benefits of SCS therapy for patients^{1,2}.
- PROMIS-29 is one way of looking at this holistic view of outcomes across seven health domains.
 - Outcomes from PROMIS-29 were previously presented from the pilot phase of the SENSE SCS study^{3,4}.
- Here, we present real-world data collected from SENSE SCS study subjects, at baseline and three months post-device activation, describing functional and quality of life improvements in a variety of assessments, including across the seven health domains of PROMIS-29.**

RESULTS

Table 2. Baseline Demographics in Enrolled Subjects (N=83, Unless Otherwise Indicated)

Subject Characteristics	Enrolled Mean (SD) or N (%)
Age (Years)	63 (11)
Male	44 (53.0%)
White	75 (90.4%)
Primary Indication:Failed Back Surgery Syndrome	39 (47%)
Year Since Onset of Chronic, Intractable Pain (N=62)	12 (11)
Pain Intensity, 0-10 (N=73)	7.2 (1.5)

Figure 1. Patient Global Impression of Change (PGIC) at 3 Months (N=38, patient counts within column)

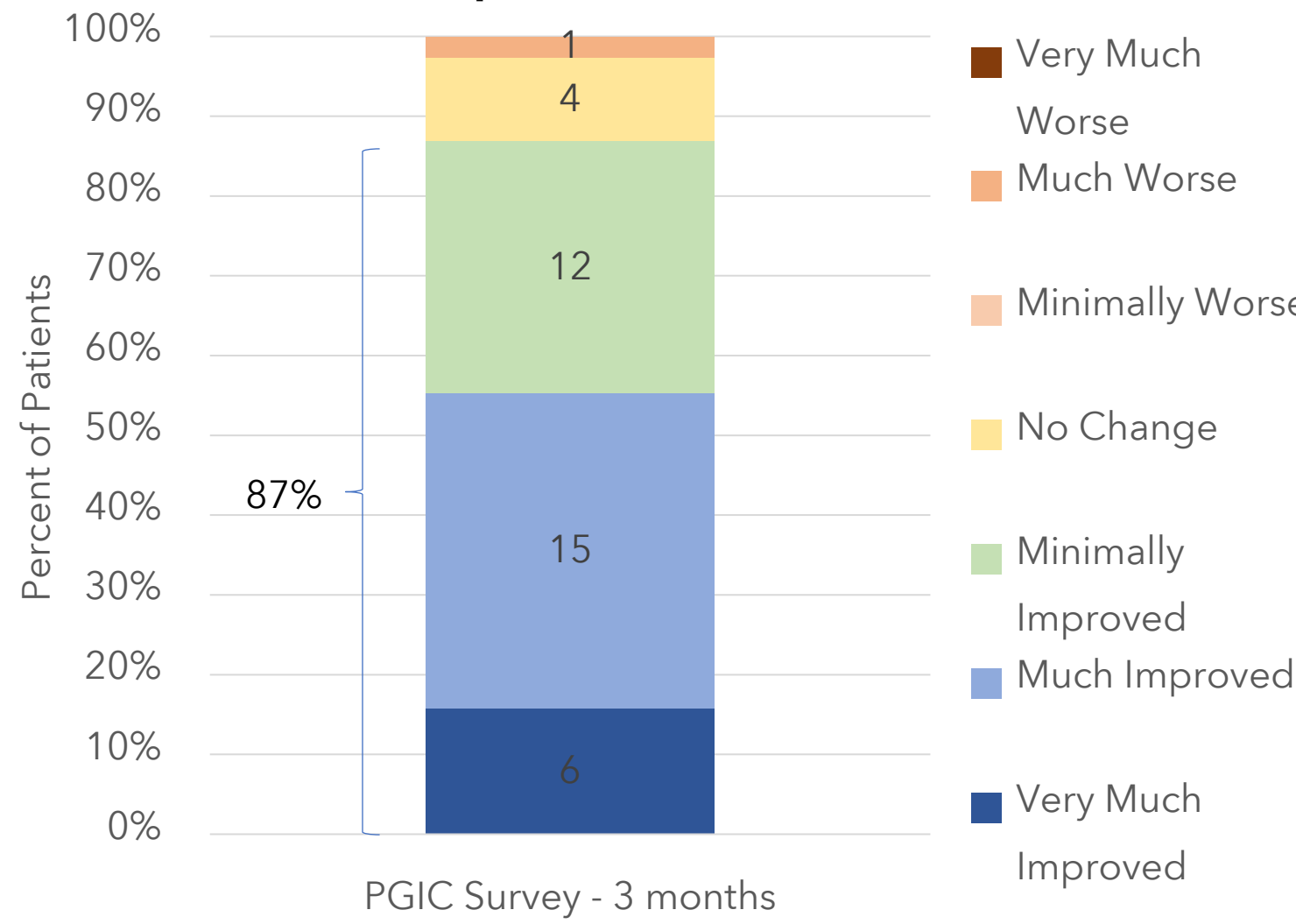


Figure 2. EQ-5D-5L Index Scores at Baseline and 3-Months (N=35)

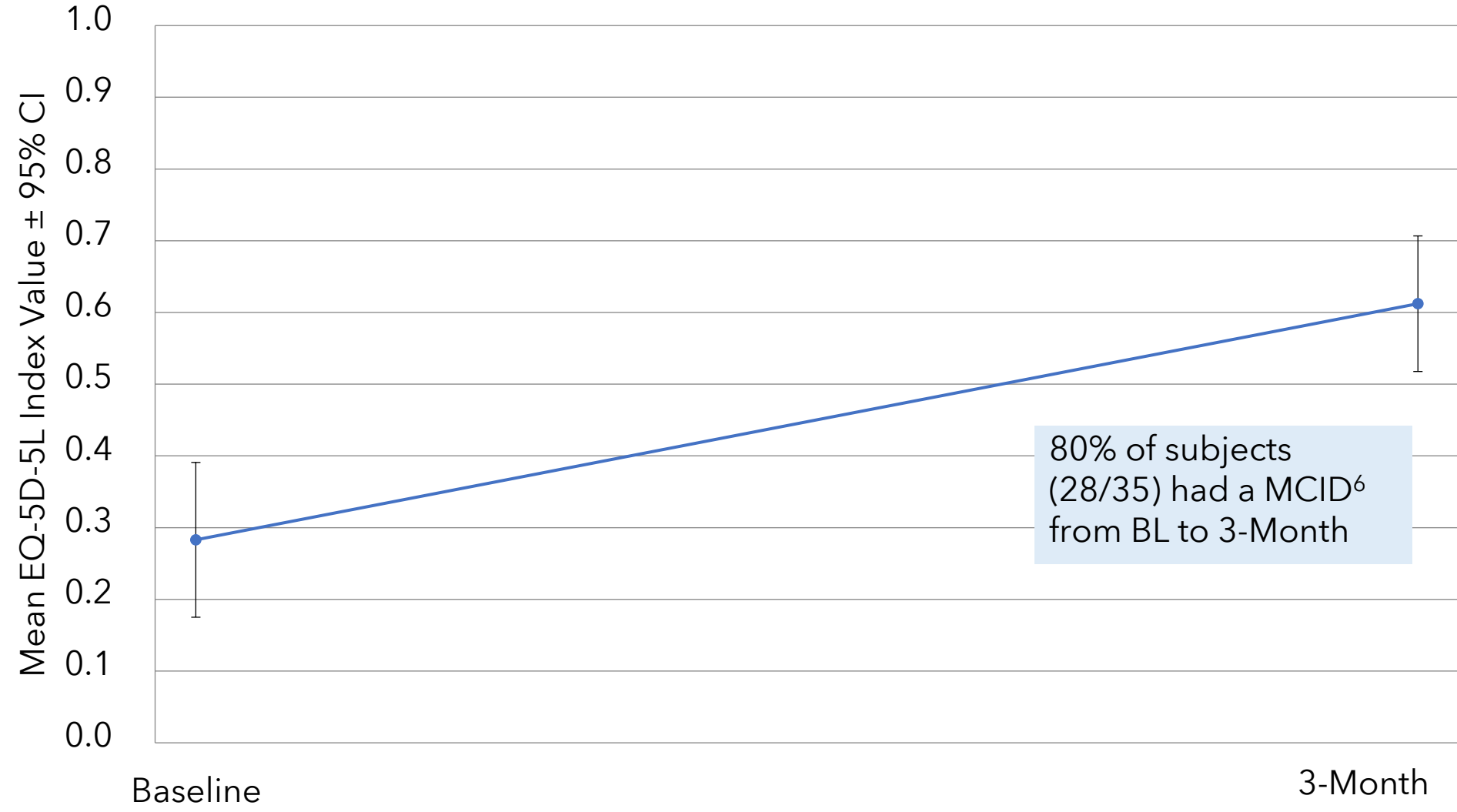


Figure 3. Percent of Patients with Normal or Mildly Impaired PROMIS-29 Domain Scores at Baseline and 3 Months (N=35)

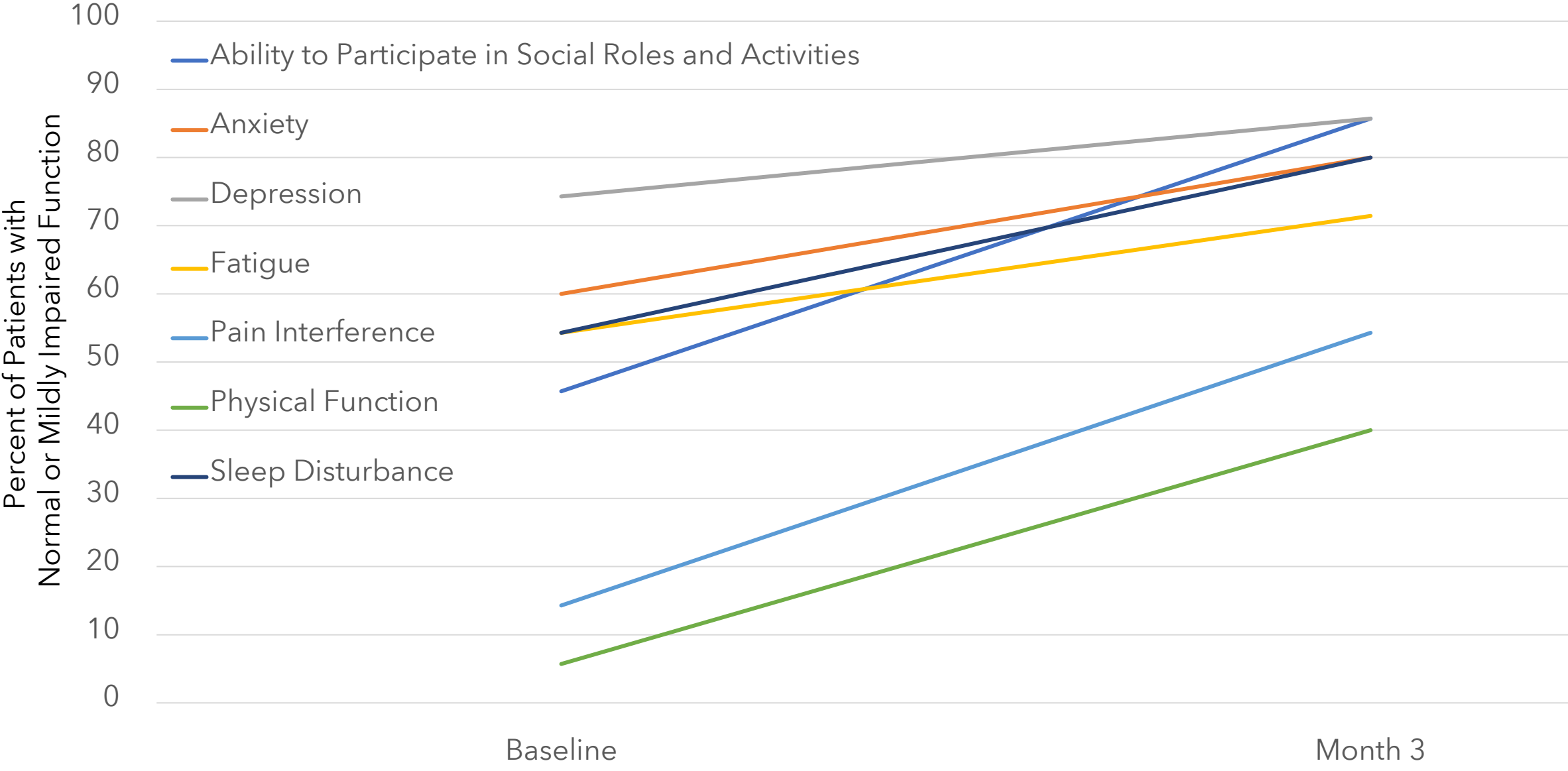


Figure 4. Therapy Satisfaction at 3 Months (N=38, patient counts within column)

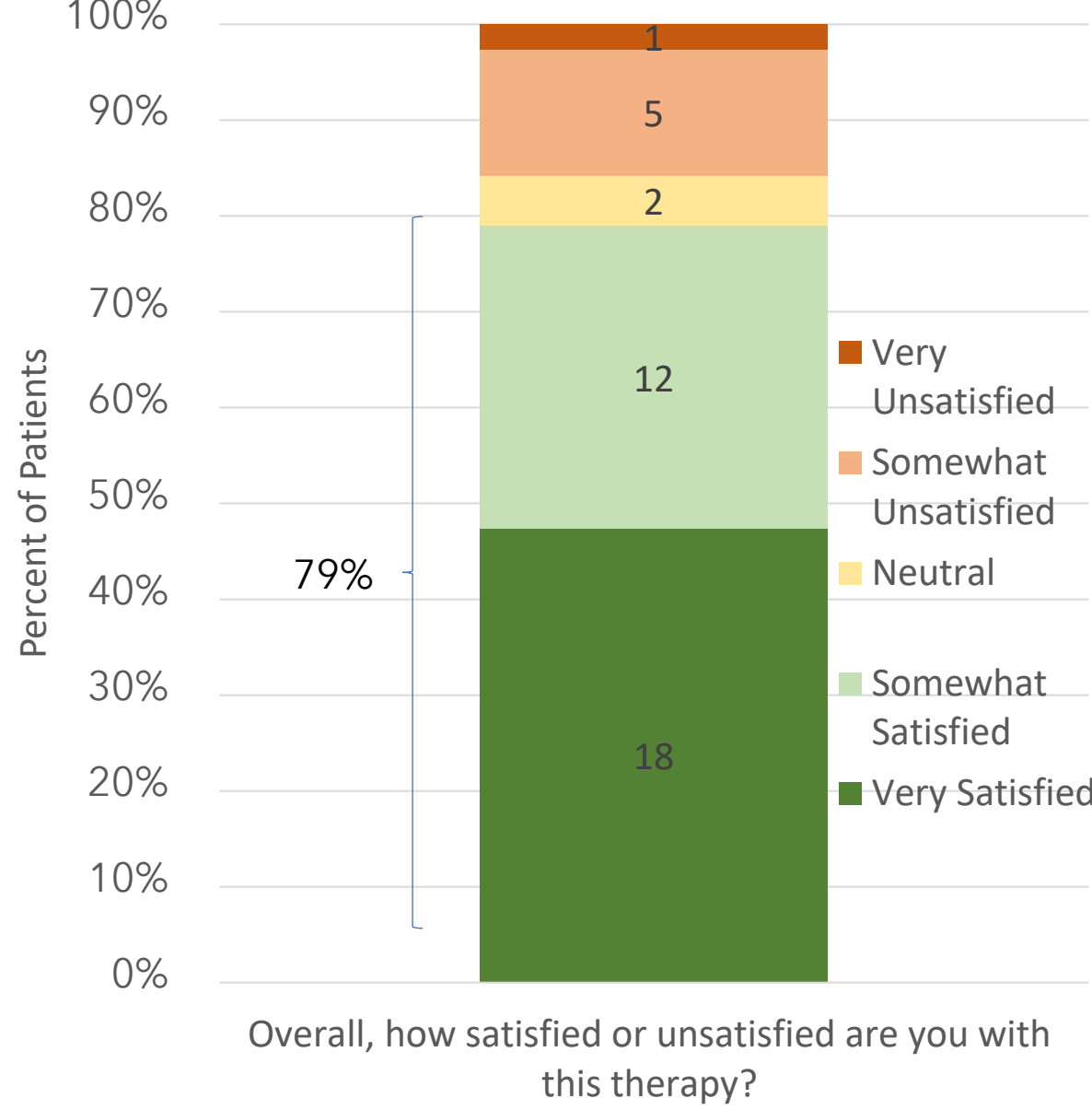
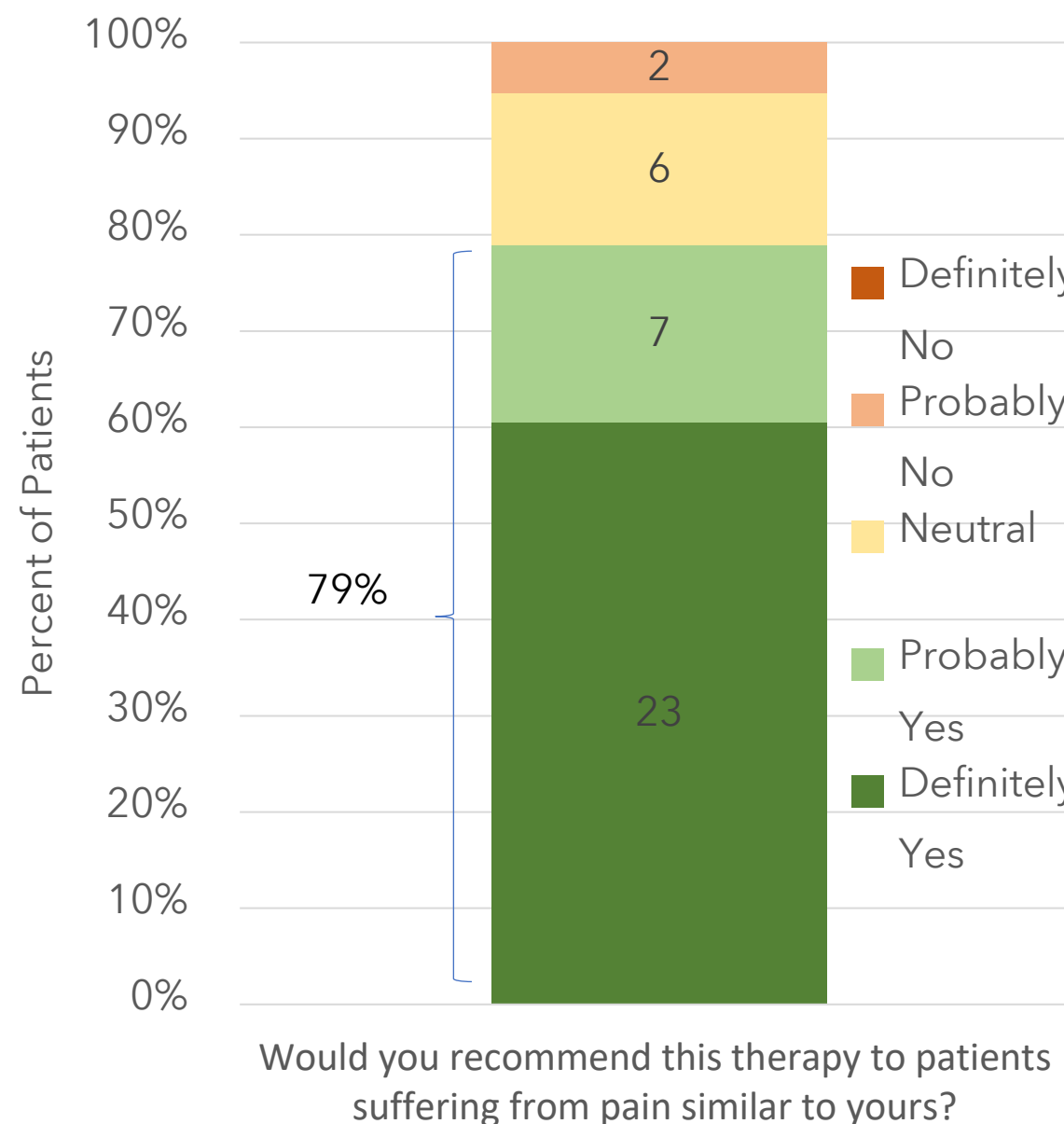


Figure 5. Therapy Recommendation at 3 Months (N=38, patient counts within column)



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 SCS indication eligible to enroll
- Ongoing enrollment and follow-up; currently in a pilot phase with 9 active sites

Purpose: Evaluate workflow of a mobile clinical trial application for collection of PROs and to characterize outcomes on patient experience with commercially available Medtronic SCS devices.

- Subjects electronically consented using a custom-made mobile application, InsightPro™ clinical trial app
- Subjects were trialed and implanted with commercially available Medtronic SCS systems with a variety of programming types, including eCAP sensing-capable neurostimulators.
- PROs collected electronically using InsightPro™ at baseline, SCS trial, and after permanent SCS implantation through 12 months (3-month outcomes presented here)

- EQ-5D-5L
- PGIC
- Satisfaction & Therapy Recommendation
- PROMIS-29 (Patient-Reported Outcomes Measurement Information System®)⁵

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. - Willing and able to use a personal smart phone for study surveys.
Pilot Phase Key Exclusion Criteria
Any active implantable neuromodulation device



RESULTS AND CONCLUSIONS

- SENSE SCS represents a novel approach to clinical trial design for SCS, enabling real-world data collection via a mobile application, including patient-reported outcome measures to assess the impact of SCS therapy on the overall quality of life and function of subjects.
- Increased percent of patients with normal function or mild impairment across all seven health domains of PROMIS-29 was observed.
- 80% of subjects experienced quality of life improvement representative of a minimal clinically important difference.
- 87% of subjects reported improvement in their condition at 3 months, with the majority of subjects reporting feeling “much improved” or “very much improved” (55%).
- Additionally, the majority of subjects were satisfied with the therapy and would recommend it (79%).
- Outcome measures from this study will continue to be reported.

CONCLUSION: These data demonstrate that improvements in functional outcomes across multiple health domains and assessments, underscoring the importance of assessing multidimensional patient-reported outcomes beyond just pain intensity.

References

- Blonde L, Khunti K, Harris SB, Meizinger C, Skolnik NS. Interpretation and Impact of Real-World Clinical Data for the Practicing Clinician. Adv Ther. 2018;35(11):1763-1774. doi:10.1007/s12325-018-0805-y
- Tan YY, Papez V, Chang WH, Mueller SH, Denaxas S, Lai AG. Comparing clinical trial population representativeness to real-world populations: an external validity analysis encompassing 43 895 trials and 5 685 738 individuals across 989 unique drugs and 286 conditions in England. Lancet Healthy Longev. 2022;3(10):e674-e689. doi:10.1016/S2666-7568(22)00186-6
- Murphy, M.; Will, A.; White, T.; Micovic, V.; Dalal, J.; Sun, X.; Santa Cruz Chavez, G.; Archila, L.; Chakravarthy, K. Using a Novel Hybrid Decentralized Clinical Study to Evaluate Real-World Outcomes for Spinal Cord Stimulation (SCS) Therapies. 2024. INS Poster.
- Murphy, M.; Will, A.; White, T.; Micovic, V.; Dalal, J.; Stromberg, K.; Santa Cruz Chavez, G.; Goracke, C. Real-World Holistic Outcomes for Spinal Cord Stimulation (SCS) Therapies Utilizing a Hybrid Decentralized Clinical Study Design. 2024. ASPN Poster.
- Hays RD, Spritzer KL, Schalet BD, Cella D: PROMIS(™)-29 v2.0 profile physical and mental health summary scores. Quality of Life Research 27 (7): 1885-1891, 2018.
- Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. Qual Life Res. 2005;14(6):1523-1532. doi:10.1007/s11136-004-7713-0 (MCID value is 0.074)

This study is sponsored by Medtronic.