

Validation and Durability of Chronic Pain Phenotypes to Measure Outcomes for Spinal Cord Stimulation Therapy

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OBJECTIVE

Spinal Cord Stimulation (SCS) is an effective non-opioid therapy for patients experiencing a variety of chronic pain syndromes¹. Chronic pain affects numerous facets of life, including psychosocial well-being, physical activity, and the capacity to work. Collection of data utilizing multi-dimensional outcomes, such as PROMIS-29, provide a broader view of outcomes than reporting from pain scores alone and allow a more complete view of a patient’s overall response to therapy.

This poster presents real-world patient-reported outcomes collected via a digital health platform, CareGuidePro™ (CGP), including PROMIS-29 outcomes. PROMIS-29 scores were analyzed using a novel methodology that clustered patients into one of 5 distinct clusters or “Pain Phenotypes”. Here we present Pain Phenotype data using PROMIS-29 scores at Baseline and End of Trail with SCS and evaluate the stability of these Phenotypes over time.

DESIGN

Design:

- This is a retrospective, observational cohort study from 2416 chronic pain patients between August 2021 and May 2023.

Methods:

- Chronic pain patients underwent SCS Screening Trial (SCS Trial) and completed PROMIS-29 (Patient-Reported Outcomes Measurement Information System®) health profile surveys pre- and post SCS screening Trial.
- Subjects received SCS implants in the US while using a mobile digital health platform for education, feedback, and patient-reported outcome collection.
- PROMIS-29 surveys were sent at start and end of SCS Trial, before implant (baseline) and then at 4 weeks, 6 weeks, 8 weeks, 3months and 6 months post-implant.
- This survey assesses seven domains (pain interference, ability to participate in social roles and activities, sleep disturbance, fatigue, depression, anxiety and physical function) through 28 questions, as well as pain intensity.
- Five pain phenotypes were derived by k-means clustering using PROMIS-29 28 questions, excluding the one about pain intensity, collected at start and end of SCS Trial .
- IRB approved study, registered on clinicaltrials.gov (NCT05775510)

Outcomes:

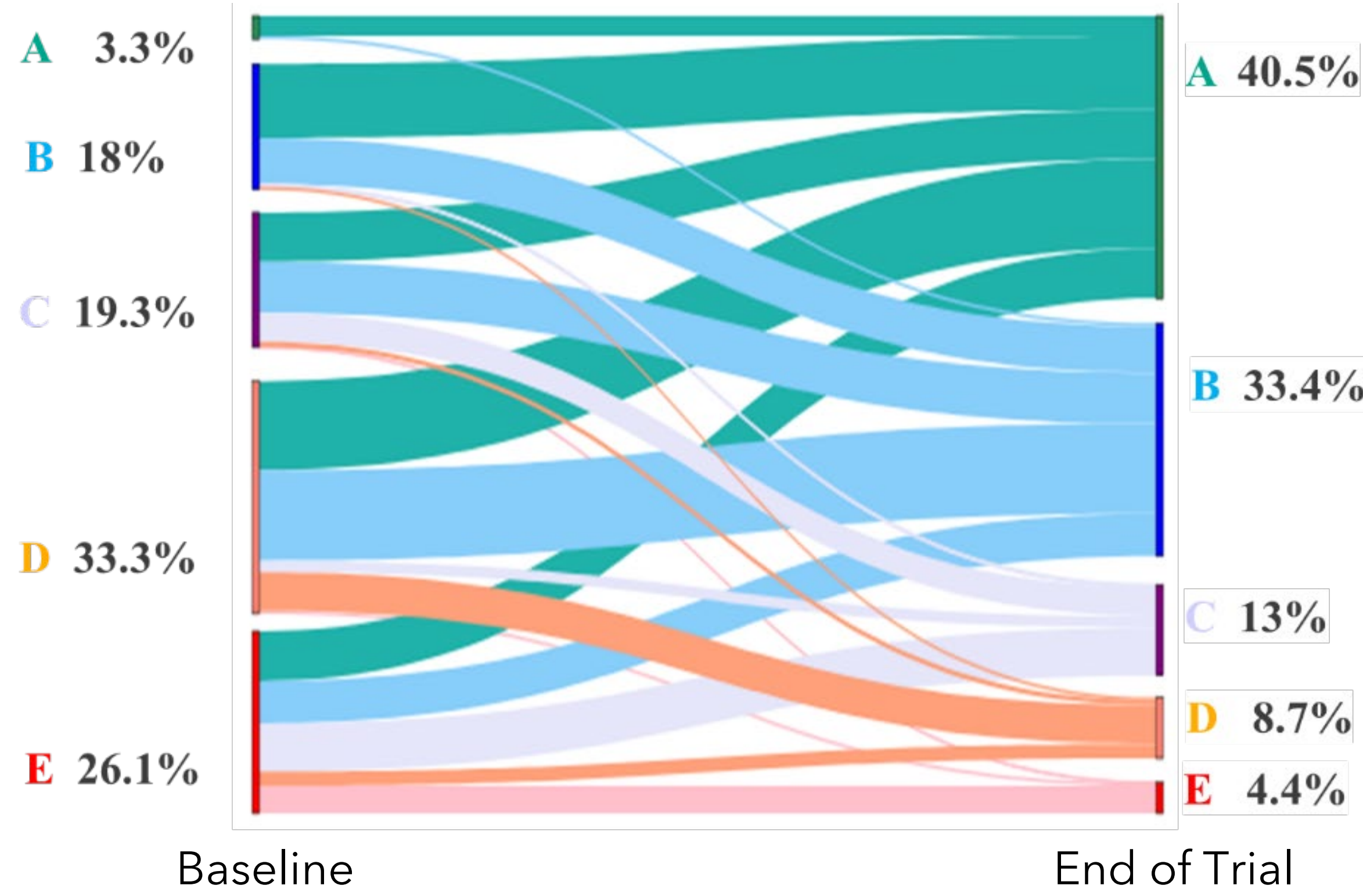
- Durability of PROMIS-29 health domains and pain phenotypes over time were assessed with data collected between August 2021 and April 2024 using Kruskal-Wallis analysis of variance and proportions at each time-point, respectively.
- Distribution of chronic pain states severity over the follow-up period was also assessed.

References
1. Rock, A.; Truong, H.; Park, YL.; Pilitsis, J. Spinal Cord Stimulation. *Neurosurg Clin N Am*. 2019 April 30 (2): 169-194.
2. PROMIS®-29 v2.0 profile physical and mental health summary scores. *Qual Life Res*. 2018 Jul.
3. Longitudinal Associations of PROMIS-29 Anxiety and Depression Symptoms with Low Back Pain Impact in a Sample of U.S. Military Service Members
4. PROMIS®-29 Adult Health Profiles: Efficient Short-Form Measures of Seven Health Domains.

RESULTS

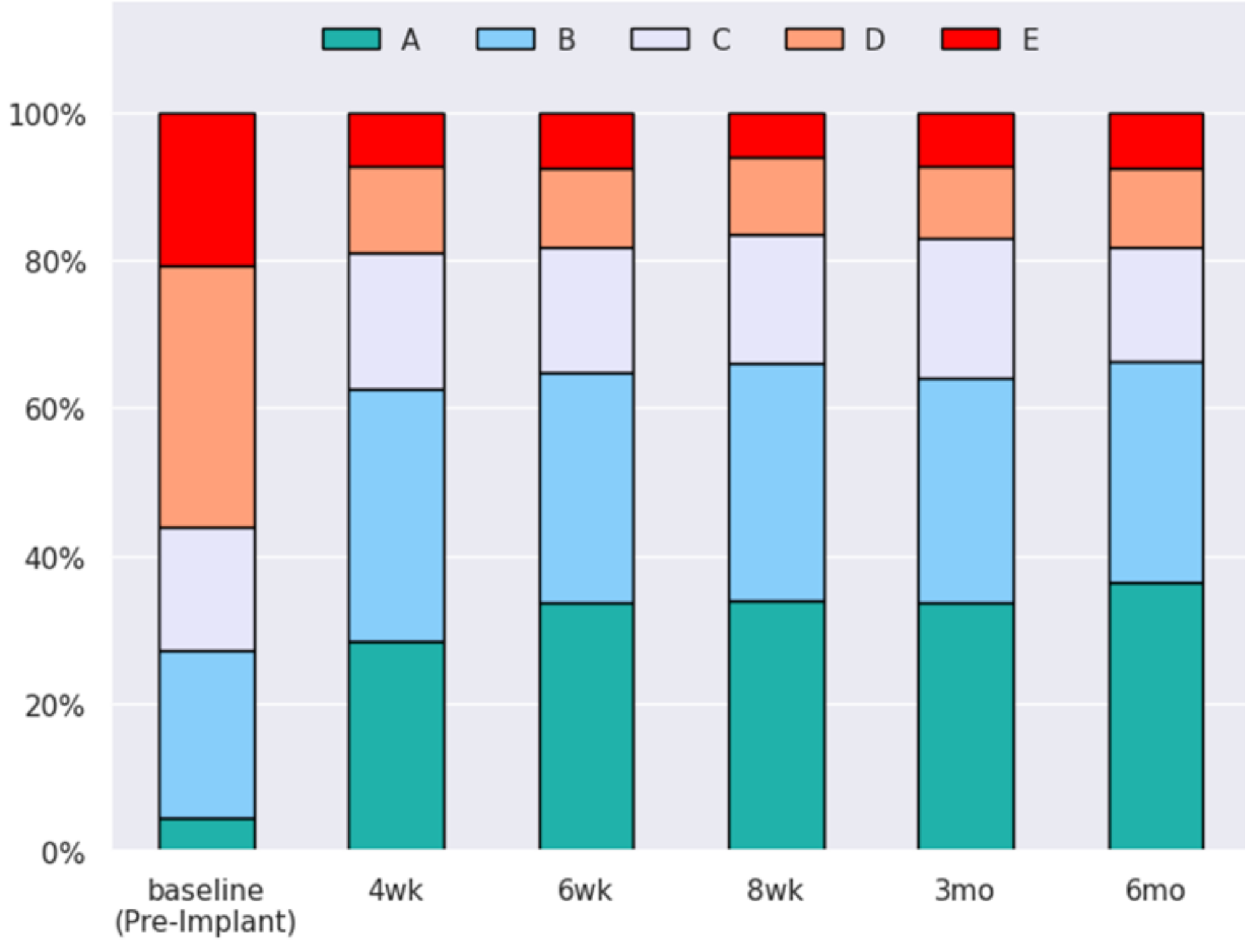
- Five pain phenotypes were able to separate patients based on increasing severity of the patient physical and mental status (from A through E).
- The pain phenotypes correlated with increased pain intensity and a decreased chance of a decision for permanent SCS implant (A: 99.5%, E: 83.5%).
- Moreover, the temporal trends did not deteriorate in the domains of anxiety, depression, fatigue, and sleep disturbance for the population (p> 0.05) for each PRO over the 4wk, 6wk, 8wk, 3mo, and 6mo timepoints relative to end of SCS Trial.

Figure 1. Chronic Pain States Transition from Baseline to End of Trial



- Patients transitioned into better chronic pain phenotypes after the SCS Trial period, with the proportion of patients categorized as “A” increasing from 3.3% to 40.5% and “E” decreasing from 26% to 4.4% (Figure 1).
- Chronic-pain phenotypes derived from PROMIS-29 measurements highlighted an improvement in states from baseline and showed stability during the follow-up period (Figure 2).

Figure 2. State distribution over follow-up period



CONCLUSIONS

- This analysis details the use and validation of a multi-dimensional model of chronic pain phenotypes in patients who underwent SCS Trial.
- This reproducible model clusters chronic pain patients into one of five unique chronic pain phenotypes that represent overall patient status across physical and mental health domains collected via the PROMIS-29 assessment.
- Using 5 distinct pain state clusters allows quantification of improvement in chronic-pain across 7 domains including Ability to Participate in Social Roles and Activities, Anxiety, Depression, Fatigue, Pain Interference, Physical Function, and Sleep Disturbance.
- Applying a Pain Phenotype categorization to a real-world dataset demonstrated both improvements in pain related outcomes as well as stability and durability of SCS therapy through 6 months follow up post SCS implant.

CONCLUSION: The findings from this analysis highlight the stability and durability of SCS therapy after SCS implant and illustrates the potential to use a novel analysis approach for categorizing patient response to SCS therapy using five pain phenotypes; this approach may be used to evaluate and improve therapy outcomes.

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