

Significant Pain Relief Using an SCS System Delivering Novel, Fast-Acting Sub-Perception Therapy

Richard Ferro¹, Yu Pei², Edward Goldberg²

1. Multidisciplinary Pain Management, Okemos, MI USA 2. Boston Scientific Neuromodulation, Valencia, CA USA

BACKGROUND

Treating chronic pain using Spinal Cord Stimulation (SCS) now commonly incorporates use of various sub-perception neurostimulative modalities.¹⁻³ Recent work has shown that sub-perception SCS for use in treating chronic pain can be successfully applied using a range of stimulation parameters that require substantially reduced energy demands as well as optimization of neural dose (adjustment of amplitude and pulse-width) in order to achieve effective and equivalent pain relief across frequencies.^{4,5}

Fast-Acting Sub-Perception Therapy (FAST) is a new SCS method developed in part from the knowledge gleaned in these earlier studies that also exploits the perception of paresthesia as a marker for precise targeting of sub-perception stimulation.⁶

Here, we report our experience using FAST-SCS with or without the use of a custom field shape programming algorithm during the trial period and after permanent implantation in a single-center, observational case-series.

METHODS

Study Design	Single-center, observational case-series Data collected by site personnel only
Study Device	Spinal Cord Stimulation (SCS) System (WaveWriter Alpha, WaveWriter, Precision Spectra, Boston Scientific): Engage multiple mechanisms of action • Paresthesia-Guided Stimulation Field Targeting • Fast-Acting Sub-Perception Therapy (FAST) • Customized Field Shape Programming (Contour) • Illumina3D Algorithm with Multiple Independent Current Control (MICC)
Cohort	•128 chronic pain patients considered for SCS

RESULTS

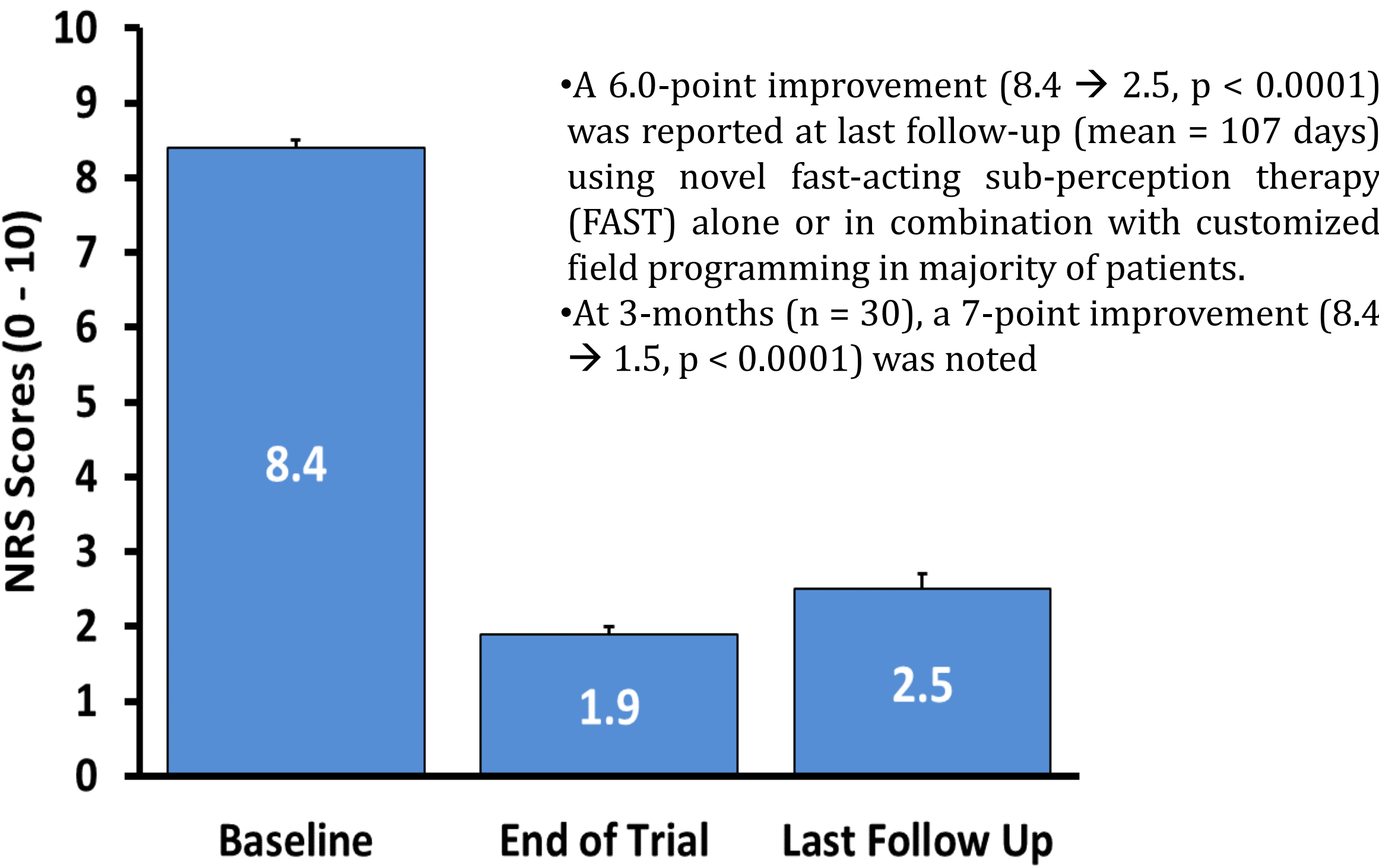
Baseline Characteristics (n = 128)

Gender - Females (%)	64.1% (82/128)
Age [Mean (SD)]	66.5 (12.4) years
Pain Location (%) (may have multiple pain locations)	Low Back and Legs (88.3%)
	Foot (2.3%)
	Legs (43%)
Baseline NRS [Mean (SD)]	8.5 (1.2) n = 128

128 patients underwent a temporary trial at a single center from July 2020 – September 2022:

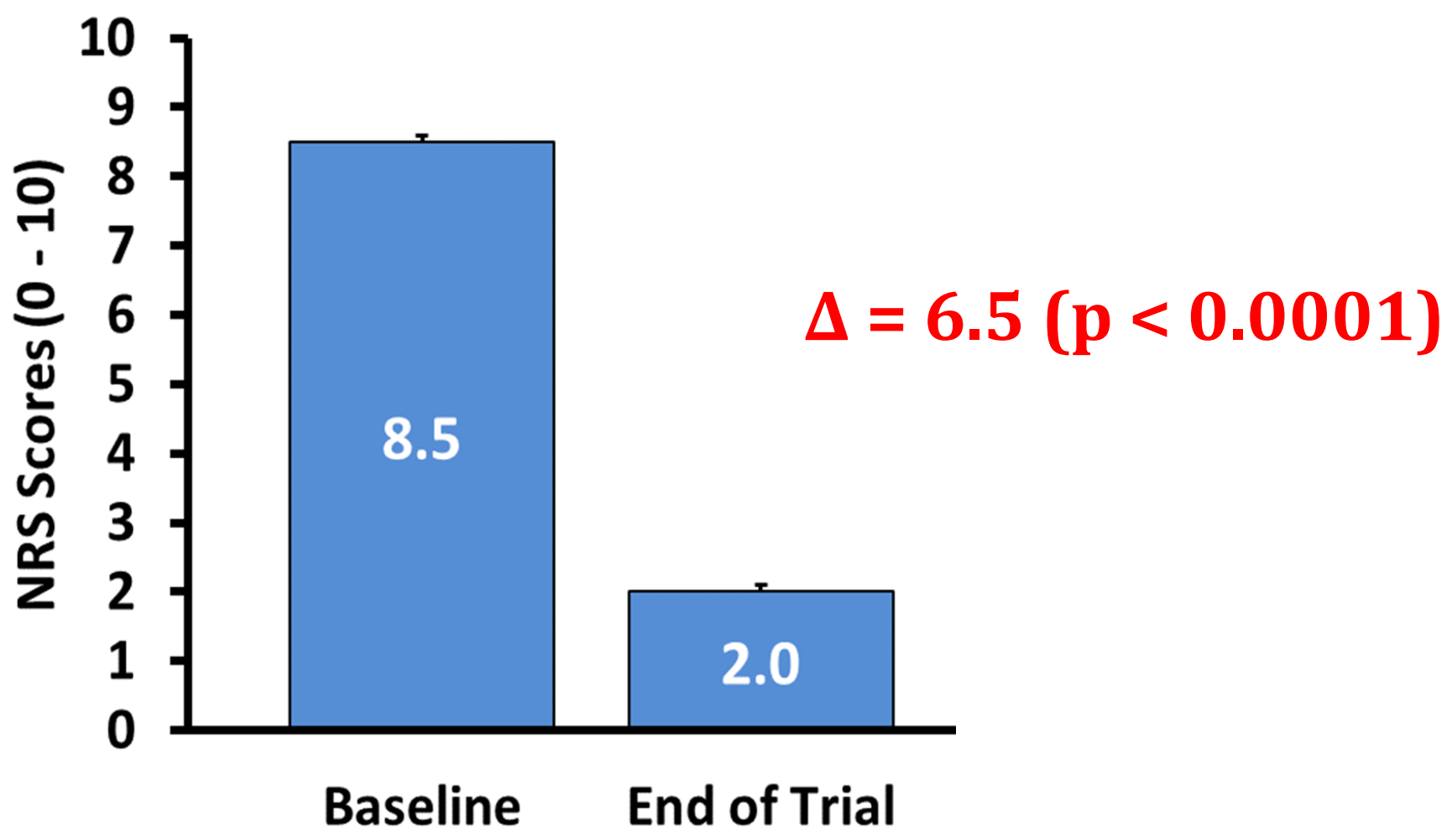
- All patients received fast-acting sub-perception during the trial (alone or in combination with customized field shape programming).
- Of these 128 patients, 116 (91%) were FAST-SCS responders (≥50% pain relief) at end of trial*

Overall Pain Scores at Last Follow-Up (n = 108†)



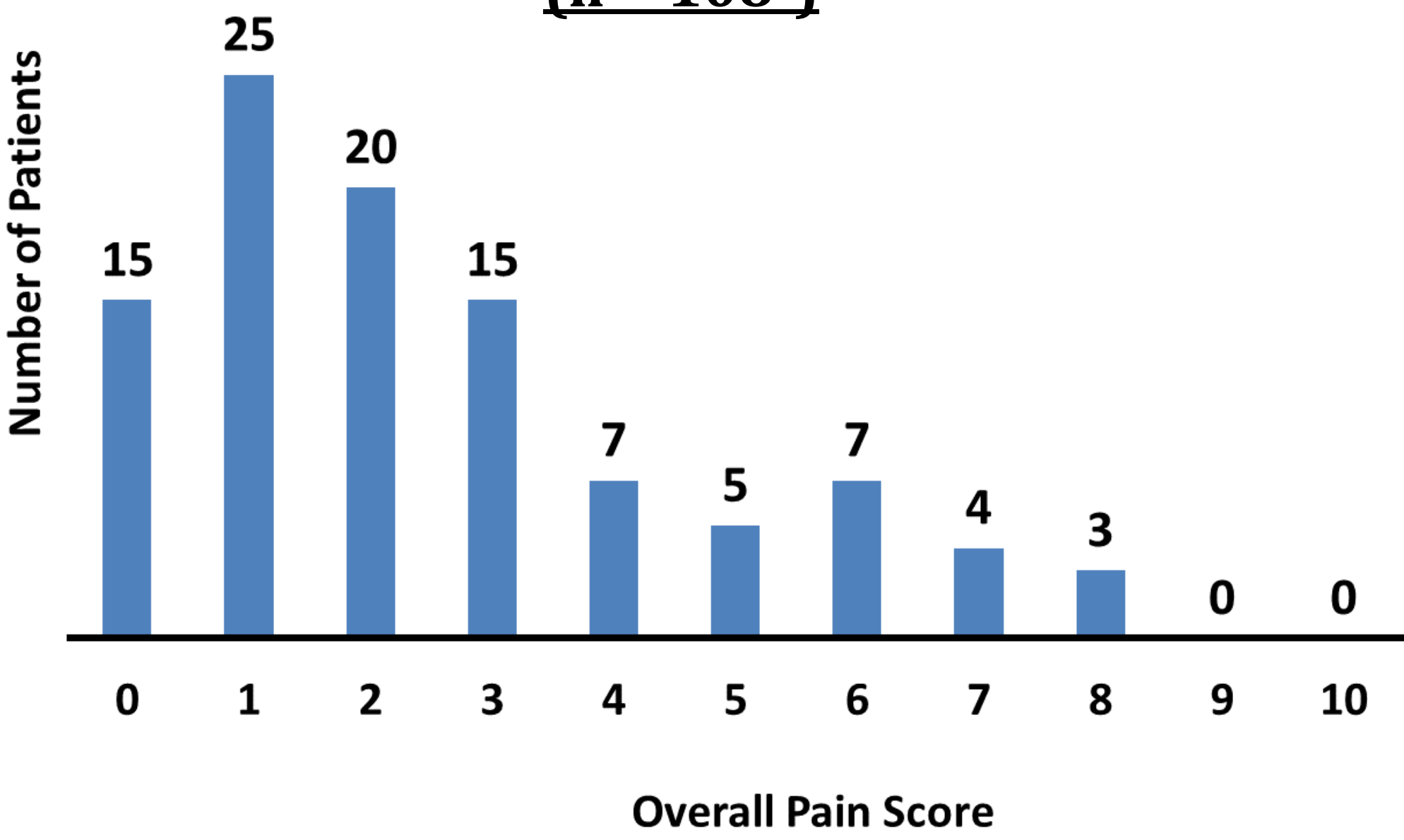
*Pain relief calculated using Percent Pain Relief (PPR) or change in pain scores as available.
†108 patients who have undergone a permanent IPG implant as time of data collection.
Seven patients did not provide pain score.

Overall Pain Scores at End of Trial (n = 116, FAST Responders)



A mean 6.5-point improvement (8.5 → 2.0, p<0.0001) was reported at End of Trial compared with Baseline in FAST-SCS responders (n = 116)

Distribution of Overall Pain Scores at Last Follow-Up (n = 108†)



At last follow-up:

- 59% (60 of 101) patients reported pain score of 2 or less
- 14% (15 of 101) were pain free (pain score = 0)

CONCLUSIONS

- Computational modeling from the Grill lab suggests that FAST-SCS activates dorsal column axons and inhibits dorsal horn projection neurons.⁷
- Published data demonstrates that Fast-Acting Sub-Perception Therapy (FAST) can provide significant pain relief within minutes of activation.⁶
- Results from this single-center, real-world, observational case series demonstrates that significant chronic pain relief (6-NRS points) may be achieved using fast-acting sub-perception therapy (FAST) alone or in combination with customized field programming following permanent implant.
- The use of FAST either alone or in combination with customized field shape programming has potential to provide significant improvement in overall pain.

REFERENCES

1. Manchikanti L, Pampati V, Vangala BP, Soin A, Sanapati MR, Thota S, Hirsch JA. Spinal Cord Stimulation Trends of Utilization and Expenditures in Fee-For-Service (FFS) Medicare Population from 2009 to 2018. Pain Physician. 2021 Aug;24(5):293-308.
2. Smith CA, Roman J, Mammis A. The Role of Spinal Cord Stimulation in Reducing Opioid Use in the Setting of Chronic Neuropathic Pain: A Systematic Review. Clin J Pain. 2022 Feb 7;38(4):285-291.
3. Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids. 87 FR 7838. (Proposed by the Centers for Disease Control and Prevention on February 10, 2022). <https://www.federalregister.gov/documents/2022/02/10/2022-02802/proposed-2022-cdc-clinical-practice-guideline-for-prescribing-opioids> Accessed October 25, 2022.
4. Thomson SJ, Tavakkolizadeh M, Love-Jones S, Patel NK, Gu JW, Bains A, Doan Q, Moffitt M. Effects of Rate on Analgesia in Kilohertz Frequency Spinal Cord Stimulation: Results of the PROCO Randomized Controlled Trial. Neuromodulation. 2018 Jan;21(1):67-76.
5. Paz-Solis J, Thomson S, Jain R, Chen L, Huertas I, Doan Q. Exploration of High- and Low-Frequency Options for Subperception Spinal Cord Stimulation Using Neural Dosing Parameter Relationships: The HALO Study. Neuromodulation. 2022 Jan;25(1):94-102.
6. Metzger CS, Hammond MB, Paz-Solis JF, Newton WJ, Thomson SJ, Pei Y, Jain R, Moffitt M, Annecchino L, Doan Q. A novel fast-acting sub-perception spinal cord stimulation therapy enables rapid onset of analgesia in patients with chronic pain. Expert Rev Med Devices. 2021 Mar 3:1-8.
7. Gilbert JE, Titus N, Zhang T, Esteller R, Grill WM. Surround Inhibition Mediates Pain Relief by Low Amplitude Spinal Cord Stimulation: Modeling and Measurement. eNeuro. 2022 Oct 5;9(5):ENEURO.0058-22.2022. doi: 10.1523/ENEURO.0058-22.2022. PMID: 36150892; PMCID: PMC9536854

DISCLOSURES

Study sponsored by Boston Scientific. Dr. Ferro has a consulting agreement with Boston Scientific. Yu Pei and Roshini Jain are employees of Boston Scientific.

