Rapid Onset of Analgesia during Trial Period Utilizing Fast-Acting Sub-Perception Therapy SCS

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BACKGROUND

Sub-perception Spinal Cord Stimulation (SCS) offers patients an opportunity to obtain pain relief without paresthesia. Onset of maximum pain relief using traditional sub-perception techniques (e.g., 1-10 kHz) can take up to several hours and even days to occur (unlike conventional paresthesia-based SCS), thereby prolonging and potentially compromising therapy optimization.¹⁻³

Newly uncovered low frequency-based (90 Hz) Fast-Acting Sub-Perception Therapy (FAST)-SCS is now often observed to provide pain relief below threshold of perception within seconds to minutes - a characteristic more analogous to traditional paresthesia-dependent SCS.^{4, 5} Obtaining a quick response to sub-perception therapies, especially during SCS trials is crucial as it has the potential to determine expected response and provide customized therapies for effective pain relief.

Here, we assessed the effectiveness and onset time of FAST-SCS during trial period in a multicenter observational case-series.

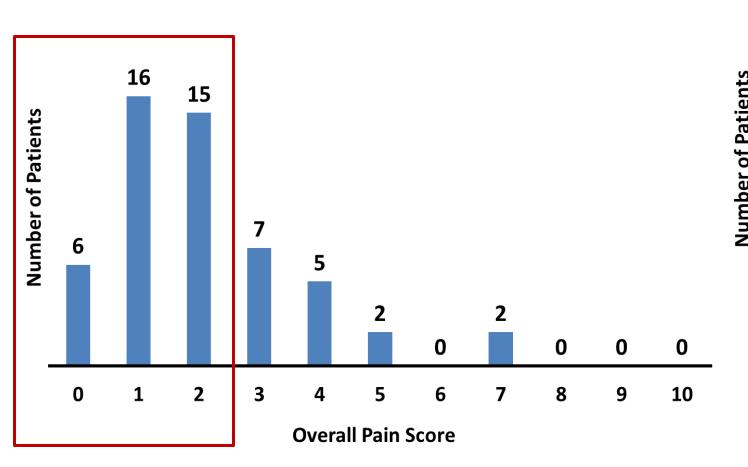
METHODS

Study Design	Multicenter, Consecutive, Observational, Case-Series Data collected by site personnel only.
Study Device	 SCS System (WaveWriter Alpha, 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	53 patients diagnosed with chronic pain who underwent a trial with FAST-SCS only

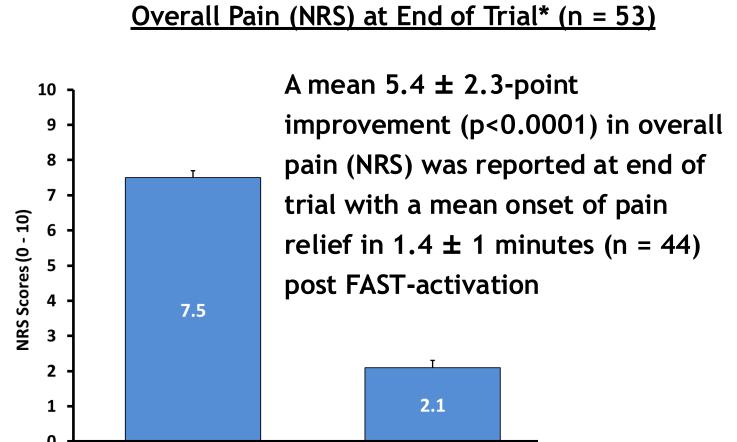
RESULTS

Baseline Characteristics (n = 53) Gender - Females (%) 64.1% (34/53) Age [Mean (SD)] 65.6 (12.1) years n = 53 Low Back and Legs (96.2%) Low Back (94.3%) Baseline NRS [Mean (SD)] 7.5 (1.7) n = 53 Trial Duration [Mean (SD)] 5.5 (1.7) days n = 53

<u>Distribution of Overall Pain Scores at End of</u> <u>Trial with FAST-SCS* (n = 53)</u>



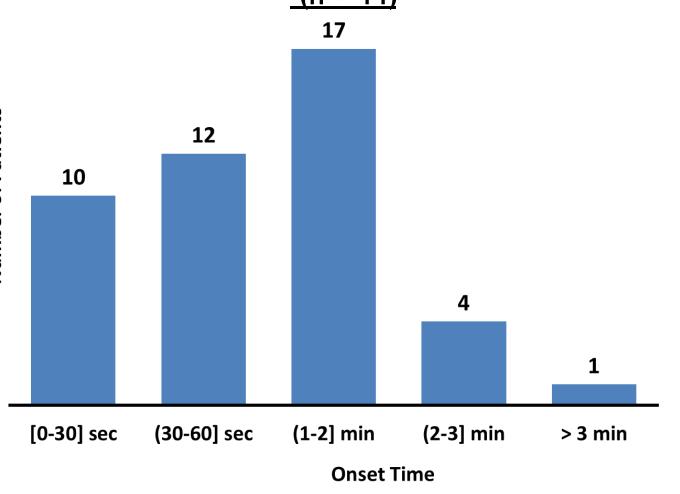
70% (37 of 53) reported a pain score ≤2 at End of Trial with the use of FAST-SCS therapy



Distribution of Onset of Pain Relief with FAST-SCS Y (n = 44)

End of Trial

Baseline



89% (39 of 44) of patients reported pain relief in ≤2 minutes following activation of FAST-SCS therapy.

*End of Trial Pain Scores: NRS or PPR converted to NRS

*Onset data not provided for 9 patients

CONCLUSIONS

- Preliminary data from this ongoing, multicenter observational case series where a cohort of 53 patients underwent a trial with FAST-SCS demonstrates:
- ➤ Significant pain relief (>5-point NRS score reduction) with a fast onset of pain relief (mean = 1.4 minutes, n = 44)
- 70% of patients reported a pain score of2 or less at end of trial with FAST-SCS
- ➤ 89% reported pain relief in ≤2-minutes following FAST-SCS activation
- Results are similar to outcomes previously presented from ongoing prospective study⁶
- The success of utilizing fast-onset therapies during trials allows physicians and patients to determine if they are responder and customize therapy in a quick and efficient manner.

REFERENCES

- 1. North JM, Hong KJ, Cho PY. Clinical Outcomes of 1 kHz Subperception Spinal Cord Stimulation in Implanted Patients With Failed Paresthesia-Based Stimulation: Results of a Prospective Randomized Controlled Trial. *Neuromodulation*. 2016;19(7):731-737
- Al-Kaisy A, Palmisani S, Smith T, Harris S, Pang D. The use of 10-kilohertz spinal cord stimulation in a cohort of patients with chronic neuropathic limb pain refractory to medical management. *Neuromodulation*. 2015;18(1):18-23.
 Lee KY, Bae C, Lee D, Kagan Z, Bradley K, Chung JM, La JH. Low-intensity, Kilohertz Frequency Spinal Cord Stimulation. Differently Affects Excitation, and Johibitory Neuroscients. 2020. Jan.
- 4. 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;18(3):299-3
- Expert Rev Med Devices. 2021 Mar;18(3):299-3

 5. Ferro R, Chen L, and Jain R. "Improved Outcomes and Pain Relief Using Novel Fast-Acting Sub-Perception SCS" [Abstract] Annual Meeting of the North American Neuromodulation Society, 2022.

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- Anitescu M, Loudermilk E, Trainor D, et al. "Prospective, Multicenter Evaluation of Novel Fast-Acting Sub-Perception-Based Spinal Cord Stimulation for Chronic Pain: FAST Study" [Abstract]. The 15th World Congress of the International Neuromodulation Society, 21 - 26 May 2022.

DISCLOSURES

Study sponsored by Boston Scientific. Yu Pei and Roshini Jain are employees of Boston Scien



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