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

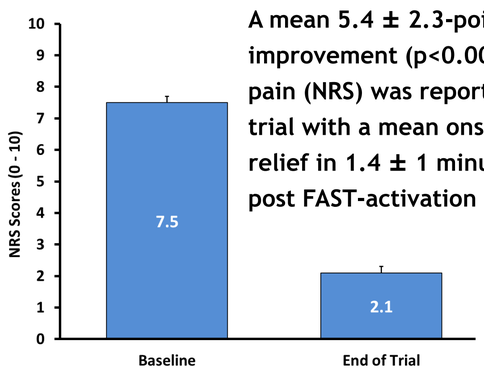
Study Design	Multicenter, Consecutive, Observational, Case-Series Data collected by site personnel only.
Study Device	SCS System (WaveWriter Alpha, Boston Scientific): • Engage multiple mechanisms of action • Paresthesia-Guided Stimulation Field Targeting, Fast-Acting Sub-Perception Therapy (FAST) • 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)

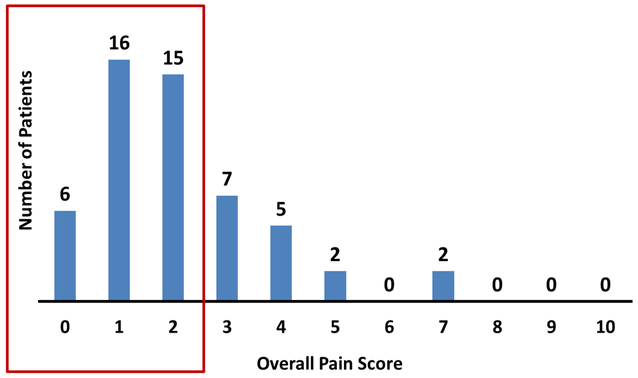
Gender - Females (%)	64.1% (34/53)
Age [Mean (SD)]	65.6 (12.1) years n = 53
Pain Location (%)	Low Back and Legs (96.2%)
	Low Back (94.3%)
Baseline NRS [Mean (SD)]	7.5 (1.7) n = 53
Trial Duration [Mean (SD)]	5.5 (1.7) days n = 53

Overall Pain (NRS) at End of Trial* (n = 53)



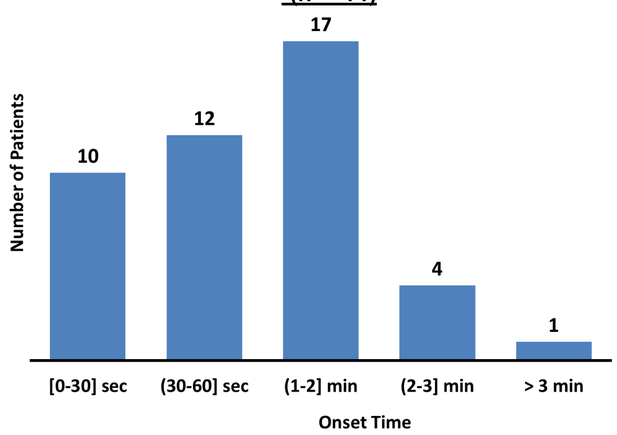
A mean 5.4 ± 2.3-point improvement (p<0.0001) in overall pain (NRS) was reported at end of trial with a mean onset of pain relief in 1.4 ± 1 minutes (n = 44) post FAST-activation

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



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[¥] (n = 44)



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 of 2 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 study[6]
- 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

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DISCLOSURES

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

INDICATIONS

US Indications for Use: The Boston Scientific Spinal Cord Stimulator Systems are indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, Complex Regional Pain Syndrome (CRPS) Types I and II, intractable low back pain and leg pain. Associated conditions and etiologies may be: radicular pain syndrome, radiculopathies resulting in pain secondary to failed back syndrome or herniated disc, epidural fibrosis, degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions), arachnoiditis, multiple back surgeries. Contraindications, warnings, precautions, side effects. The SCS Systems are contraindicated for patients who: are unable to operate the SCS System, have failed trial stimulation by failing to receive effective pain relief, are poor surgical candidates, or are pregnant. Refer to the Instructions for Use provided with the SCS System or Pain.com for potential adverse effects, warnings, and precautions prior to using this product. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

OUS Indications for USE: CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

Subperception stimulation has been demonstrated to be safe and effective in patients who have been treated successfully with conventional, paresthesia-inducing stimulation for at least six months. Full stimulation parameter ranges and options for both paresthesia-based and subperception therapy are available for clinician's use throughout the patient's experience and treatment with SCS.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

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