Utilizing SCS Designed to Engage Surround Inhibition Using Fast-Acting Sub-Perception Therapy (FAST): Prospective, Multicenter, Long-Term Outcomes

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BACKGROUND

Novel Fast-Acting Sub-Perception Therapy (FAST) has demonstrated robust and rapid (seconds to minutes) onset of analgesia in chronic pain patients implanted with Spinal Cord Stimulation (SCS) systems.[1] Initial published work has been supported by similar research at other centers.[2] Data derived from the long-term, real-world with use of FAST-SCS has now shown sustained improvement up to 3-year follow-up.[3]

Surround Inhibition is a well-established neural mechanism in the published literature. Recently published work suggests that FAST engages the surround inhibition mechanism of action (MOA) and computational modeling suggests that FAST activates dorsal column axons and inhibits dorsal horn projection neurons.[4] Precise stimulation location and optimal neural dose is required to generate Fast-Acting Sub-Perception Therapy.

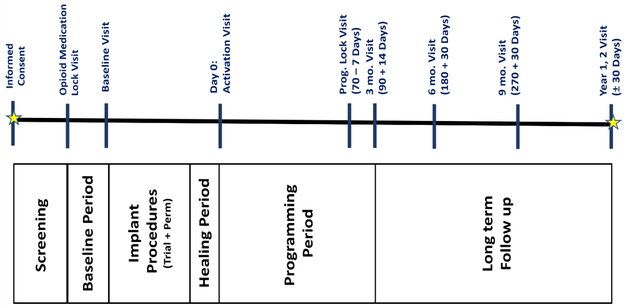
We studied the effectiveness of FAST and additional SCS therapy options for chronic pain in a prospective, multicenter, single-arm clinical study and in this report describe long-term outcomes.

METHODS

Study Design	•Prospective, multicenter, single-arm study with an adaptive design
Study Device	•Boston Scientific WaveWriter SCS Systems
Primary Endpoint	•Proportion of subjects with ≥50% reduction from Baseline Visit in average targeted pain* intensity at 3-months post-activation *Targeted pain is area of pain intended to be treated by SCS

Study Schematic

Clinicaltrials.gov ID: NCT04618471

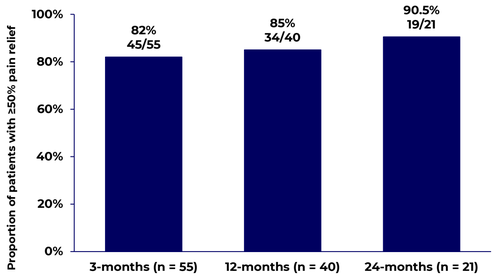


RESULTS

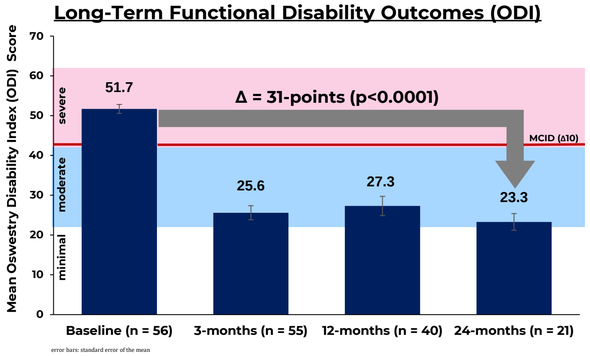
Baseline Characteristics (n = 56)

Age (yrs.) - Mean (SD) n	59.8 (11.9) 56
Gender (Female) - % (n/N)	64.3% (36/56)
Diagnosis for receiving the stimulator (may have multiple diagnosis) - %	
Failed Back Surgery Syndrome	63%
Radiculopathy	73.2%
Average Overall Pain (VRS) - Mean (SD) n	7.39 (0.13) 56
Average Low Back Pain (VRS) - Mean (SD) n	7.41 (0.13) 56
Disability (Oswestry Disability Index [ODI] - Mean (SD) n)	51.68 (8.36) 56
Duration of low back pain (yrs.) - Mean (SD) n	13.9 (10.0) 56
Onset of Pain Relief Following FAST Activation (mean time – minutes)	
50% Pain Relief (48 of 56)	2.6 minutes
75% Pain Relief (43 of 56)	4.3 minutes
100% Pain Relief (30 of 56)	4.2 minutes

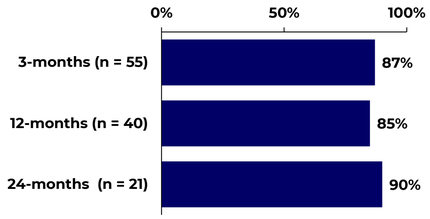
Responder Rates out to 24-months follow-up



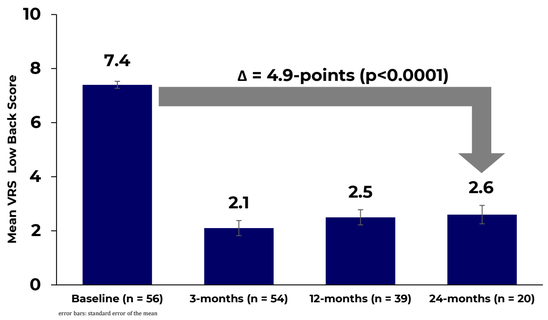
Long-Term Functional Disability Outcomes (ODI)



Patient Satisfaction
(% patients indicating "very much" or "much" improvement)



Mean Low Back Pain Score out to 24-months follow-up



Patient/Physician Survey
(n = 35 [28 patients, 7 physicians])

Category	Statement	%	Source
Ease-of-use	I find it easy to control my SCS therapy.	96%	Patient
	I am satisfied with the frequency of charging my SCS implant.	86%	Patient
	Currently, I rarely use my remote control to adjust my SCS therapy.	75%	Patient
	I rarely had to use my SCS remote control during my SCS trial.	61%	Patient
Multiple options	I would prefer to have an SCS system that gives me multiple therapy options for both paresthesia and non-tingling pain relief.	79%	Patient
Time Factors	FAST Therapy gives me confidence that SCS therapy is working before the patient leaves my clinic.	100%	Physician
	FAST helps me better evaluate SCS therapy during the trial.	100%	Physician
	I can more quickly assess the efficacy of SCS using FAST Therapy.	100%	Physician
	The ability to provide fast-acting pain relief helps me better communicate with my patients.	100%	Physician
	FAST Therapy can help shorten an SCS trial for patients when a shorter trial is desirable (e.g., patients with comorbidities or on anti-coagulants).	100%	Physician
	FAST helps me quickly resolve any issues that come up during the SCS trial.	100%	Physician
	My patients prefer to achieve fast-acting pain relief in my clinic rather than wait 1-2 days for pain relief to wash in.	100%	Physician
	Achieving pain relief before leaving my physician's clinic gave me confidence that my SCS therapy was working.	82%	Patient
	Achieving pain relief before leaving my physician's clinic helped me better evaluate whether SCS therapy was right for me.	79%	Patient
	I would rather achieve pain relief in minutes ("fast-acting pain relief") rather than wait 1-2 days for it to wash in ("slow-acting pain relief").	75%	Patient
	I would not want to wait 1-2 days to achieve pain relief during my SCS trial.	64%	Patient

Long-Term Clinical Outcomes Summary
(out to 24-months follow-up)

- Consistently high responder rates (≥82% at all study visits)
- 31-point mean improvement in ODI Scores (MCID ~Δ10 points)[5]
  - indicating significant improvement in disability
- Sustainable pain score reduction out to 24 months: Δ4.9-points
- High level of patient satisfaction observed (≥85%)
- Patients in FAST study survey patients reported that:
  - it was easy to control their SCS therapy (96%)
  - they rarely used their remote control to adjust their therapy (75%)

CONCLUSIONS

In this prospective study, engaging with the Surround Inhibition MOA via FAST-SCS out to 24-months follow-up provided for:

- rapid onset pain relief that was significant and sustainable in the long-term
  - Δ4.9-point reduction from baseline
  - 90.5% responder rate at 24-months
- clinically meaningful improvement in disability and satisfaction

Results of surveyed patients indicate that most FAST-SCS users:

- can easily control their SCS therapy
- rarely require adjustment of therapy

These results are consistent with published assessments of FAST-SCS as previously evaluated in the real-world clinical setting.[1-3, 6]

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DISCLOSURES

Study Sponsored by Boston Scientific.
Dr. Anitescu has a consulting agreement with Boston Scientific.
Lilly Chen and Edward Goldberg are employees of Boston Scientific.

NANS2025 ANNUAL MEETING

INDICATIONS FOR USE

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, Diabetic Peripheral Neuropathy of the lower extremities, intractable low back pain and leg pain, 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. The Boston Scientific Spectra WaveWriter™, WaveWriter Alpha™ and WaveWriter Alpha™ Prime SCS Systems are also indicated as an aid in the management of chronic intractable unilateral or bilateral low back and leg pain without prior back surgery.
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.

Warning: Stimulation modes. Only paresthesia-based stimulation mode has been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

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.

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