Long-term Spinal Cord Stimulation Outcomes using Fast-Acting Sub-perception Therapy Designed to Engage Surround Inhibition

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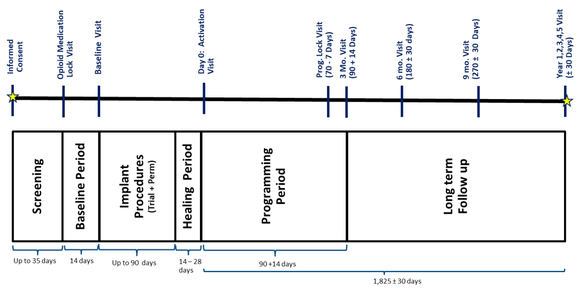
BACKGROUND

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] 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.[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.[3-5] We studied the effectiveness of FAST-SCS in a prospective, multicenter, single-arm clinical study and in this report, we present preliminary 2-year outcomes.

METHODS

Study design and Schematic

Study Design	Prospective, multicenter, single-arm study (NCT04618471)
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
Secondary endpoints	Secondary endpoints*: Pain intensity (VNRS), disability (ODI), mobility (6MWT, TUG), health-related quality of life (EQ5D-5L), emotional health (BDI, PCS), sleep quality (PSQI), and patient satisfaction (PGIC)

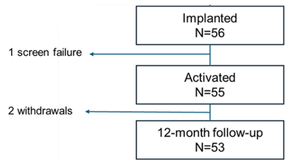


* VNRS: Verbal Numerical Rating Scale; ODI: Oswestry Disability Index; 6MWT: 6-min Walk Test, TUG: Time Up-and-Go; BDI: Beck Depression Index; PCS: Pain Catastrophizing Scale; PSQI: Pittsburgh Sleep Quality Index; PGIC: Patient Global Impression of Change

RESULTS

Baseline characteristics and FAST-SCS activation

Age (yrs.) - Mean (SD) n	59.8 (12.5) 56
Gender (Female) - % (n/N)	64.3% (36/56)
Average Overall Pain (VNRS) - Mean (SD) n	7.39 (0.13) 56
Disability (ODI) - Mean (SD) n)	51.68 (8.36) 56
Onset of Pain Relief post-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



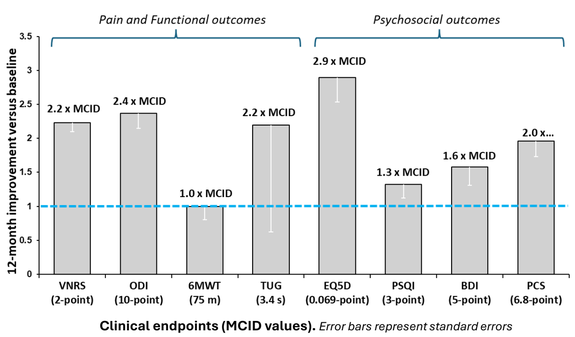
Ongoing follow-up

To date, 39 patients have completed their 2-year visit

1-YEAR OUTCOMES

Multidimensional* outcomes at 12-months

Responses to FAST-SCS were at or above the minimal clinically important differences across all dimensions



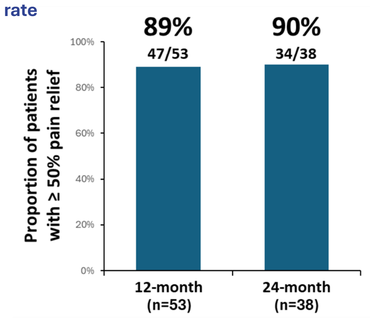
Clinical endpoints (MCID values). *Error bars represent standard errors*

Patient Survey at 12-month follow-up

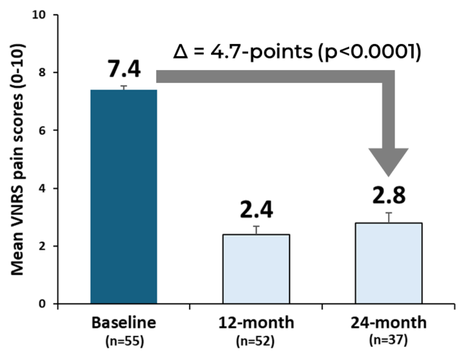
Statement	"Agree", % (n/N)
Achieving pain relief before leaving my physician's clinic gave me confidence that my SCS therapy was working	85% (29/34)
I find it easy to control my SCS therapy	97% (33/34)
I am satisfied with the frequency of charging my SCS implant	82% (28/34)

2-YEAR OUTCOMES

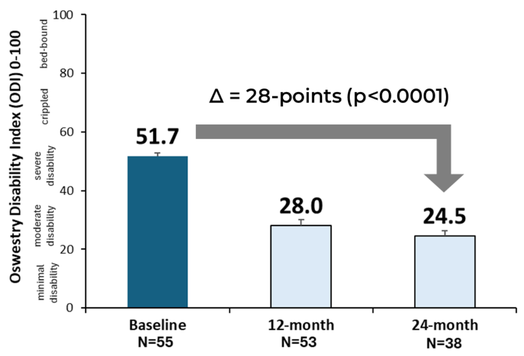
Responder rate



Low back pain



Disability



Sustained outcomes out to 2-years after FAST-SCS activation

CONCLUSION

In this ongoing prospective study, FAST-SCS therapy engaging with the Surround Inhibition MOA provided for significant outcomes out to 2 years.

1-year results showed clinically significant outcomes across multiple dimensions, including objective functional assessments and psychosocial endpoints. [6]

Preliminary 2-year results showed:

- **a 4.7-point reduction of low back pain (p<0.0001)**
- **a 28.0-point improvement in ODI (p<0.0001)**
- **≥ 90% responder rate & patient satisfaction**

Results are consistent with prior reports.[3-5]

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DISCLOSURES

Study Sponsored by Boston Scientific (NCT04618471)

Edward Goldberg is employee of Boston Scientific.

INDICATIONS FOR USE

View Boston Scientific Spinal Cord Stimulator System Indications, Safety, and Warnings at bostonscientific.com/scs-indications

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.

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

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.

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

NM-2428103-AA