

Engaging Surround Inhibition Using SCS-Based Fast-Acting Sub-Perception Therapy: 24-Month Outcomes from a Prospective Study

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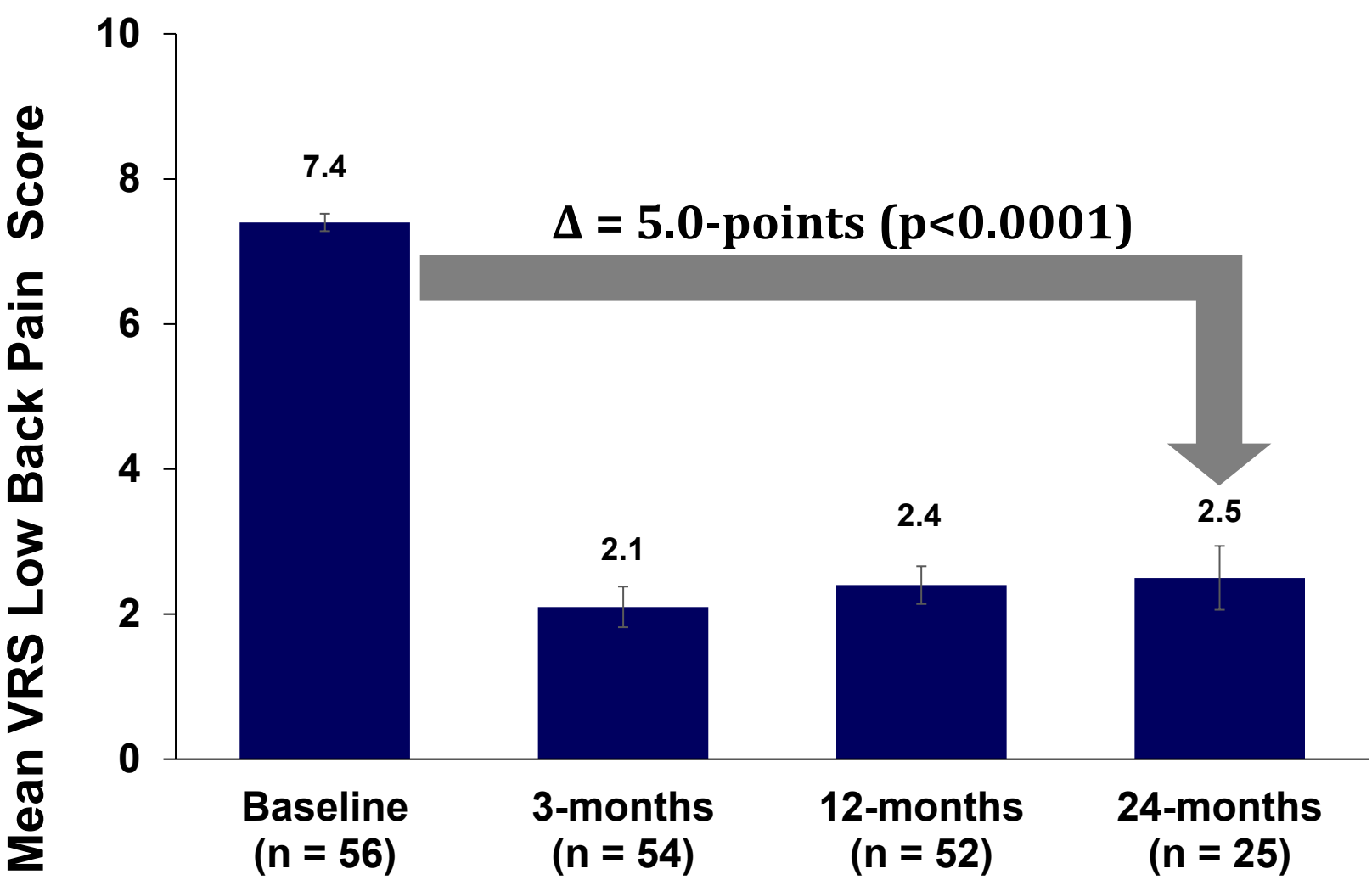
BACKGROUND

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.

BASELINE CHARACTERISTICS

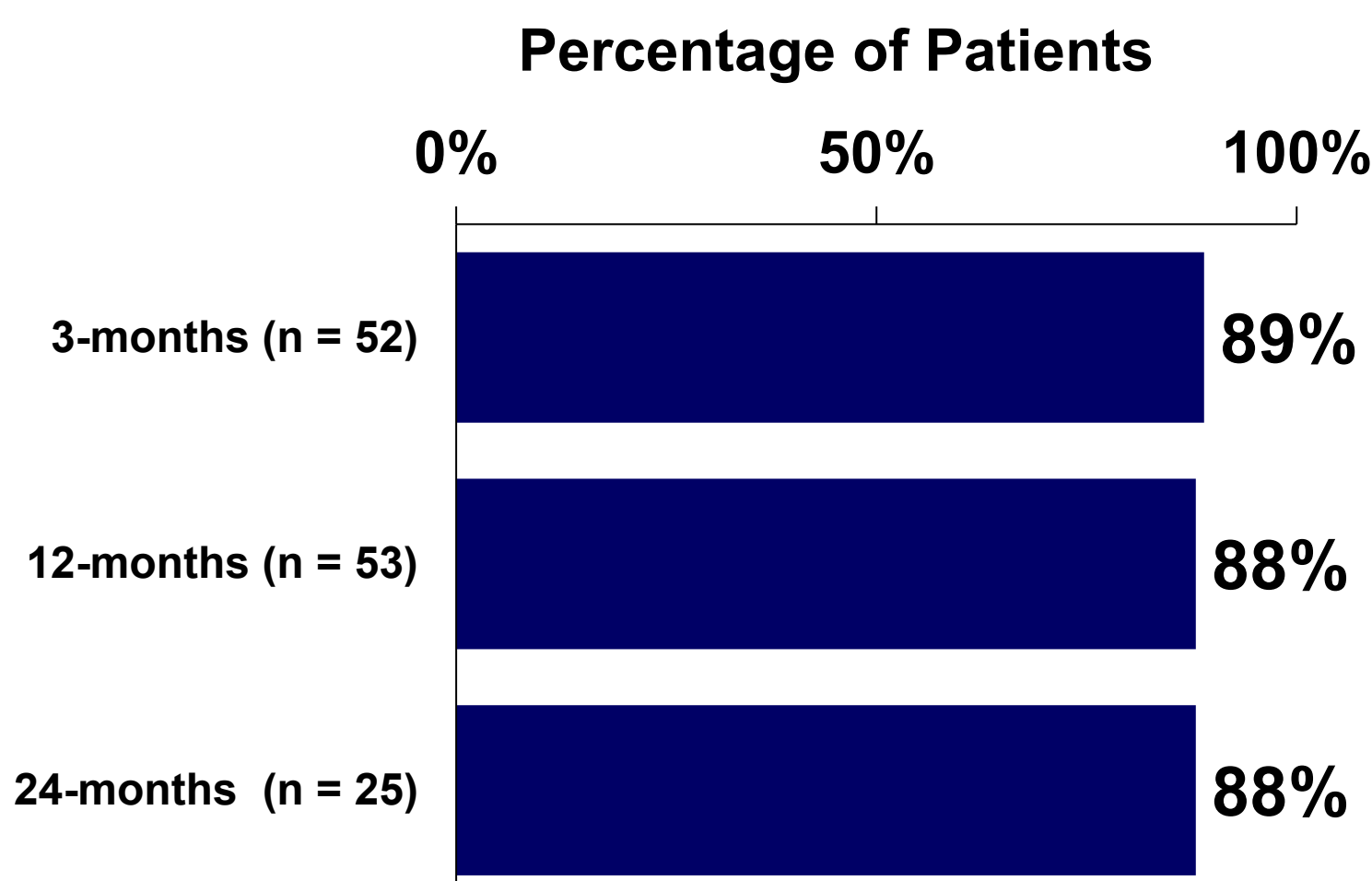
Age (yrs.) - Mean (SD) n	59.8 (12.5) 56
Gender (Female) - % (n/N)	64.3% (36/56)
Diagnosis for receiving the stimulator (may have multiple diagnosis) - %	
Failed Back Surgery Syndrome	63%
Radiculopathy	73.2%
Average Overall Pain (VRS) - Mean (SD) n	7.39 (0.13) 56
Average Low Back Pain (VRS) - Mean (SD) 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

LOW BACK PAIN OUT TO 2 YEARS



Significant 5.0-point pain score improvement

PATIENT SATISFACTION



≥88% patients indicate “very much” or “much” improvement across study visits

CONCLUSIONS

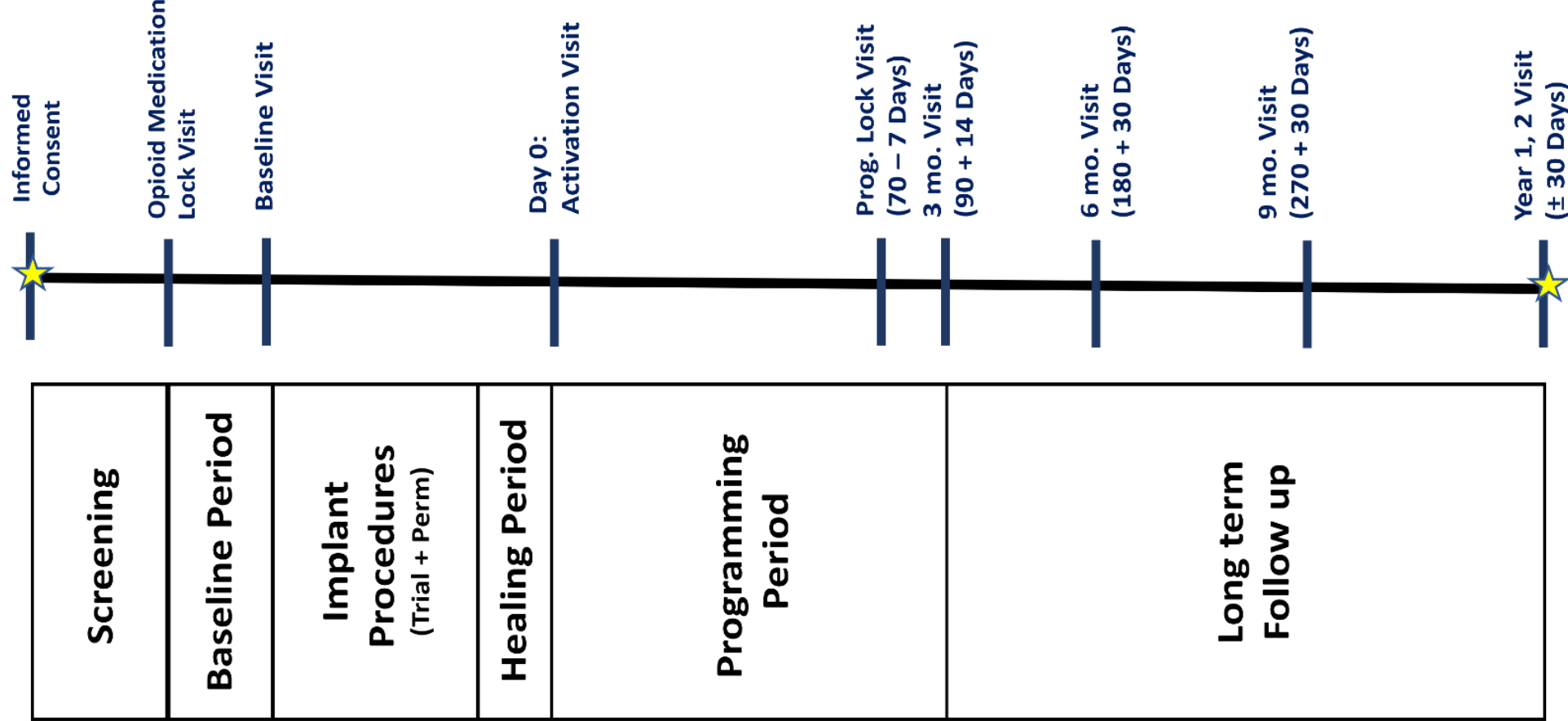
- In this prospective study, engaging with the Surround Inhibition MOA via FAST-SCS as assessed out to 24-months follow-up provided for:
 - Rapid onset chronic pain relief that was significant and sustainable in long-term
 - Δ5.0-point reduction from baseline
 - 92% responder rate at 24-months
 - Clinically 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}

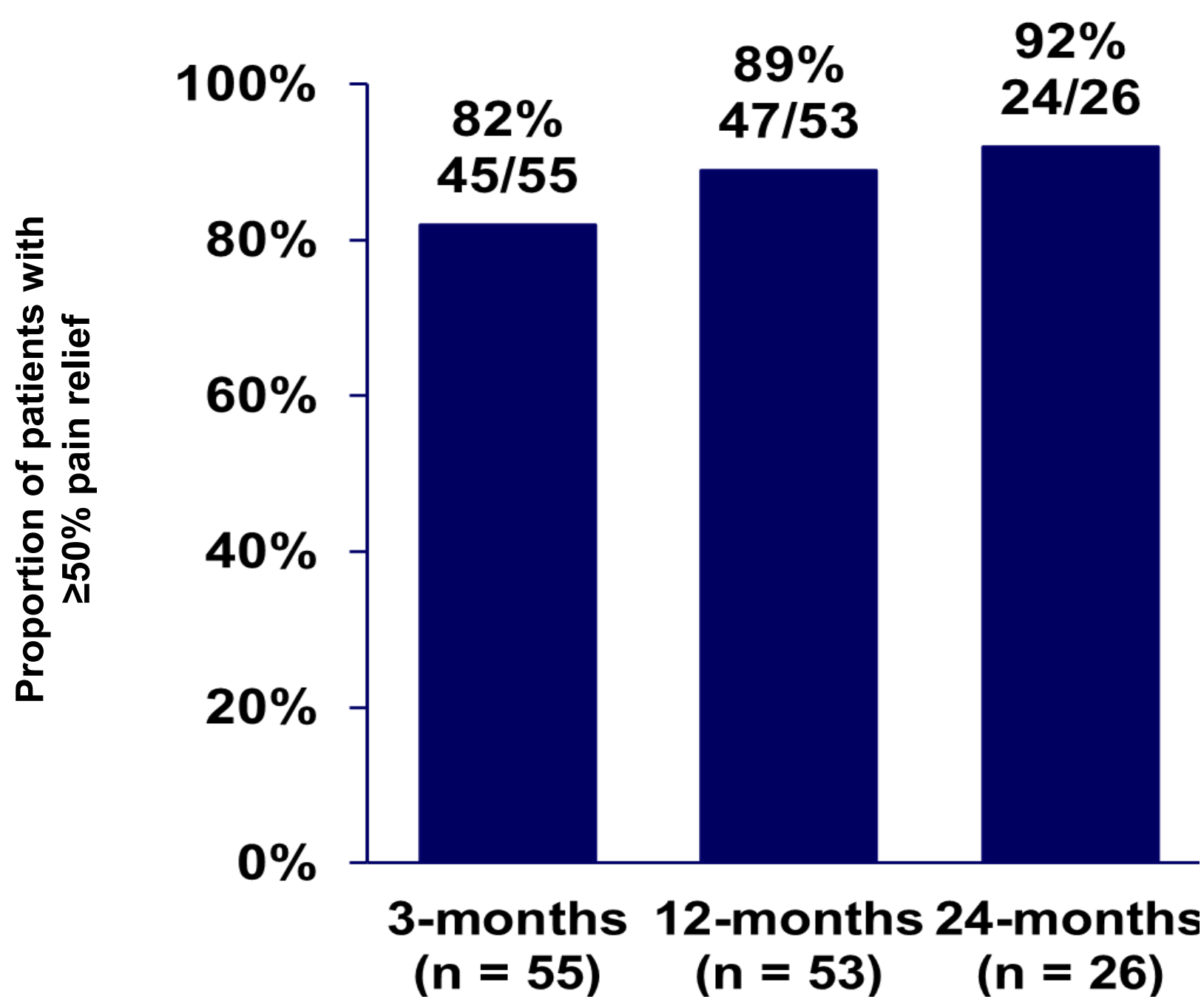
METHODS

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

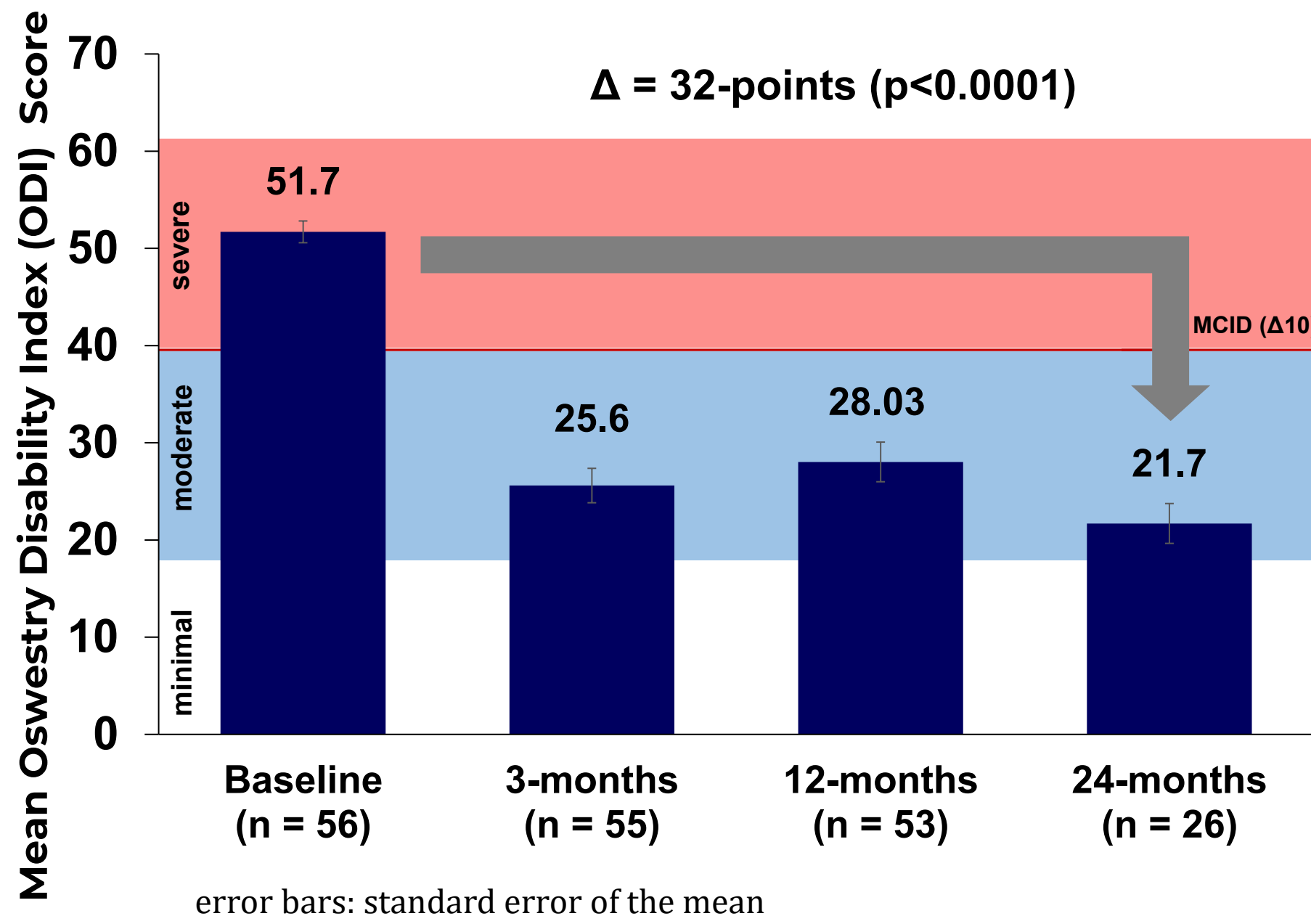


PRIMARY ENDPOINT OUTCOMES



92% responder rate out to 24-months follow-up

FUNCTIONAL DISABILITY OUTCOMES



Significant 32-point improvement in disability

(MCID ~Δ10 points)⁵

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
	FAST Therapy gives me confidence that SCS therapy is working before the patient leaves my clinic.	100%	Physician
Time Factors	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

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DISCLOSURES

Study Sponsored by Boston Scientific.
Lilly Chen and Edward Goldberg are employees of Boston Scientific.



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