

Prospective, Multicenter Study Utilizing an SCS-System Designed to Engage Surround Inhibition Using FAST: 1-Year 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 mechanism in the published literature. Recently published work suggests that FAST engages the surround inhibition mechanism of action 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.

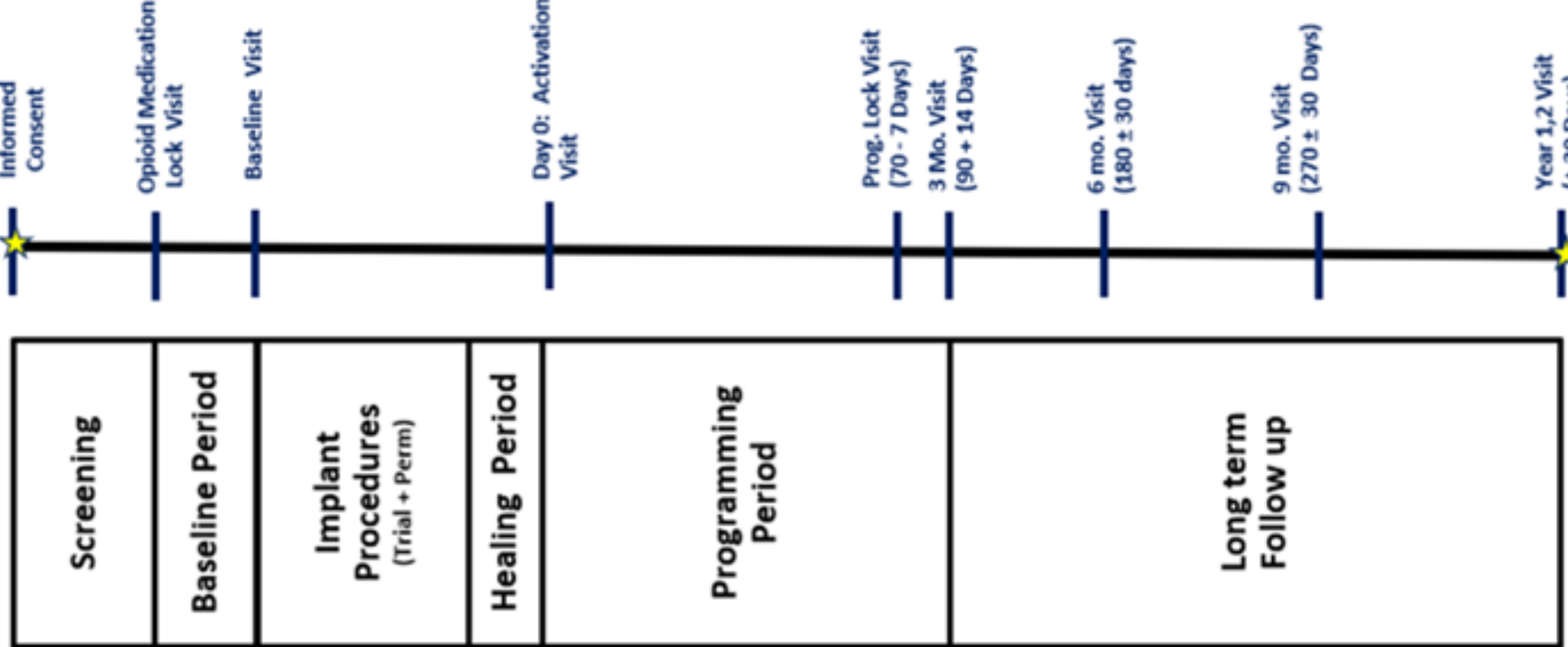
We studied the effectiveness of FAST and additional SCS therapy options for chronic pain in a prospective, multicenter, single-arm clinical study and report our preliminary findings.

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

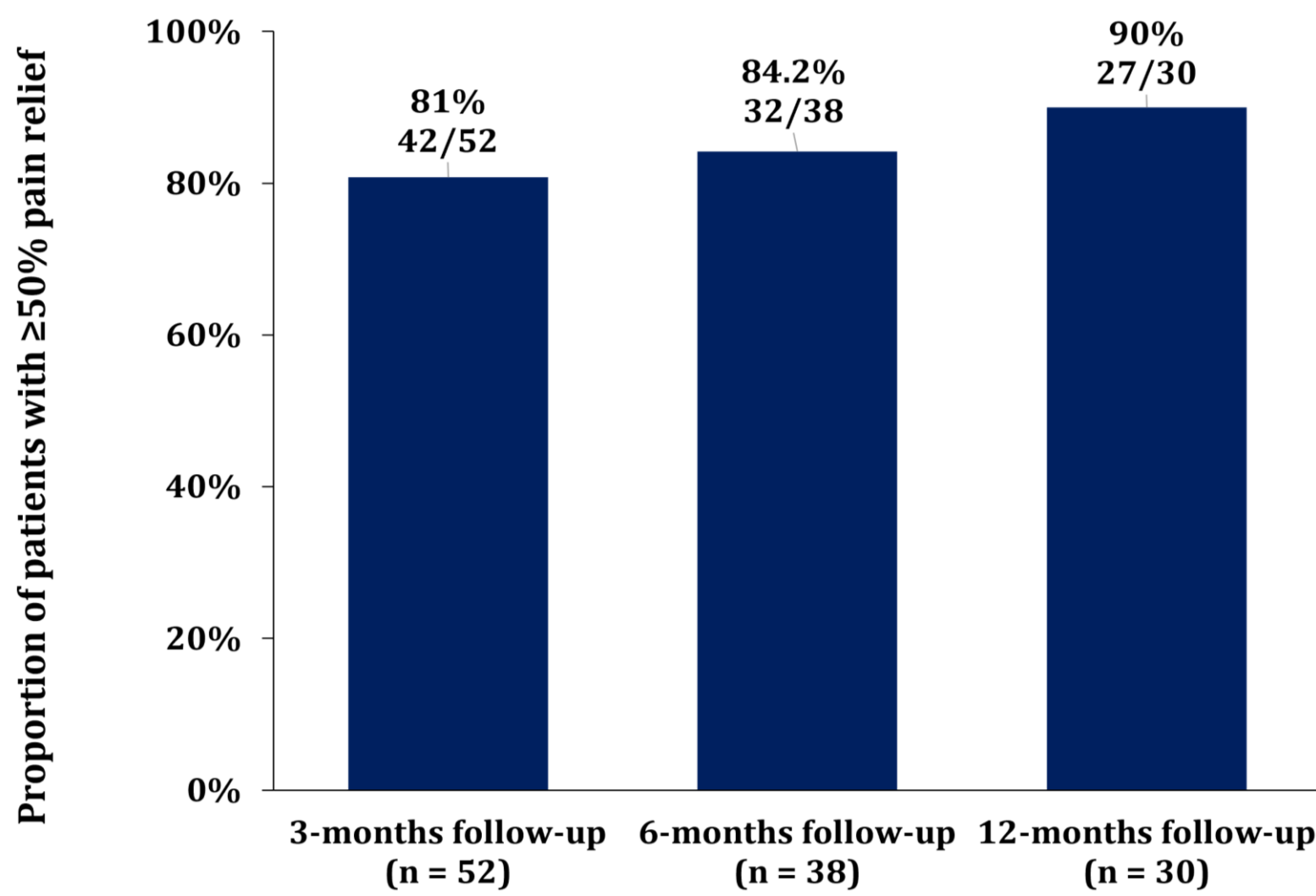


RESULTS

Baseline Characteristics (n = 56)

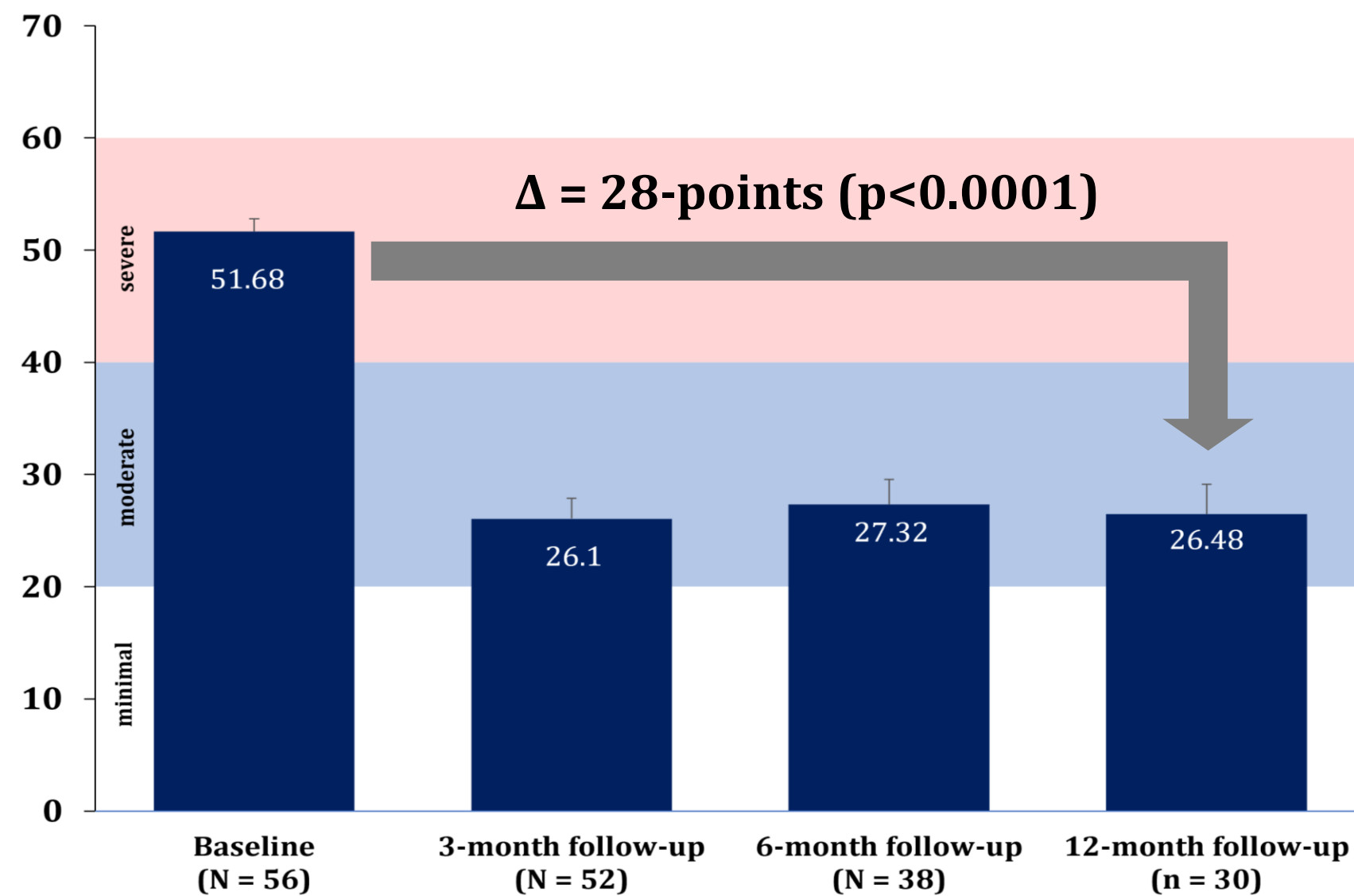
Age (yrs.) - Mean (SD) n	59.8 (12.5) 56
Gender (Female) - % (n/N)	64.3% (36/56)
Diagnosis for receiving the stimulator (may have multiple diagnosis) - %	
Failed Back Surgery Syndrome	63%
Radiculopathy	73.2%
Average Overall Pain (VRS) - Mean (SD) n	7.39 (0.13) 56
Average Low Back Pain (VRS) - Mean (SD)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

Responder Rates out to 12-months follow-up



- Consistently high responder rates out to 12-months follow-up
- 28-point mean improvement in ODI Scores (MCID ~10 points) indicating significant improvement in disability⁵

Disability (ODI) out to 12-months follow-up

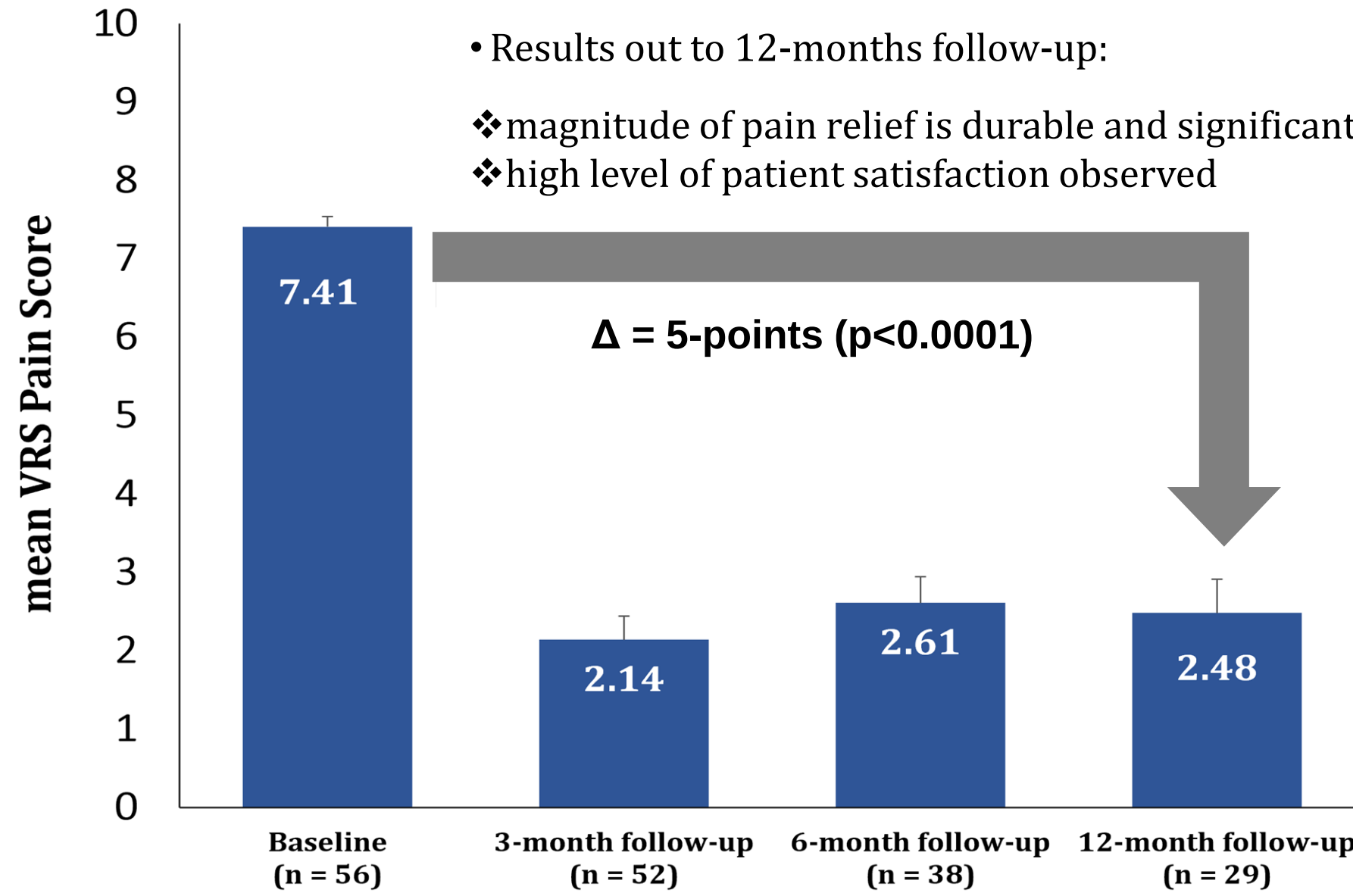


error bars: standard error of the mean

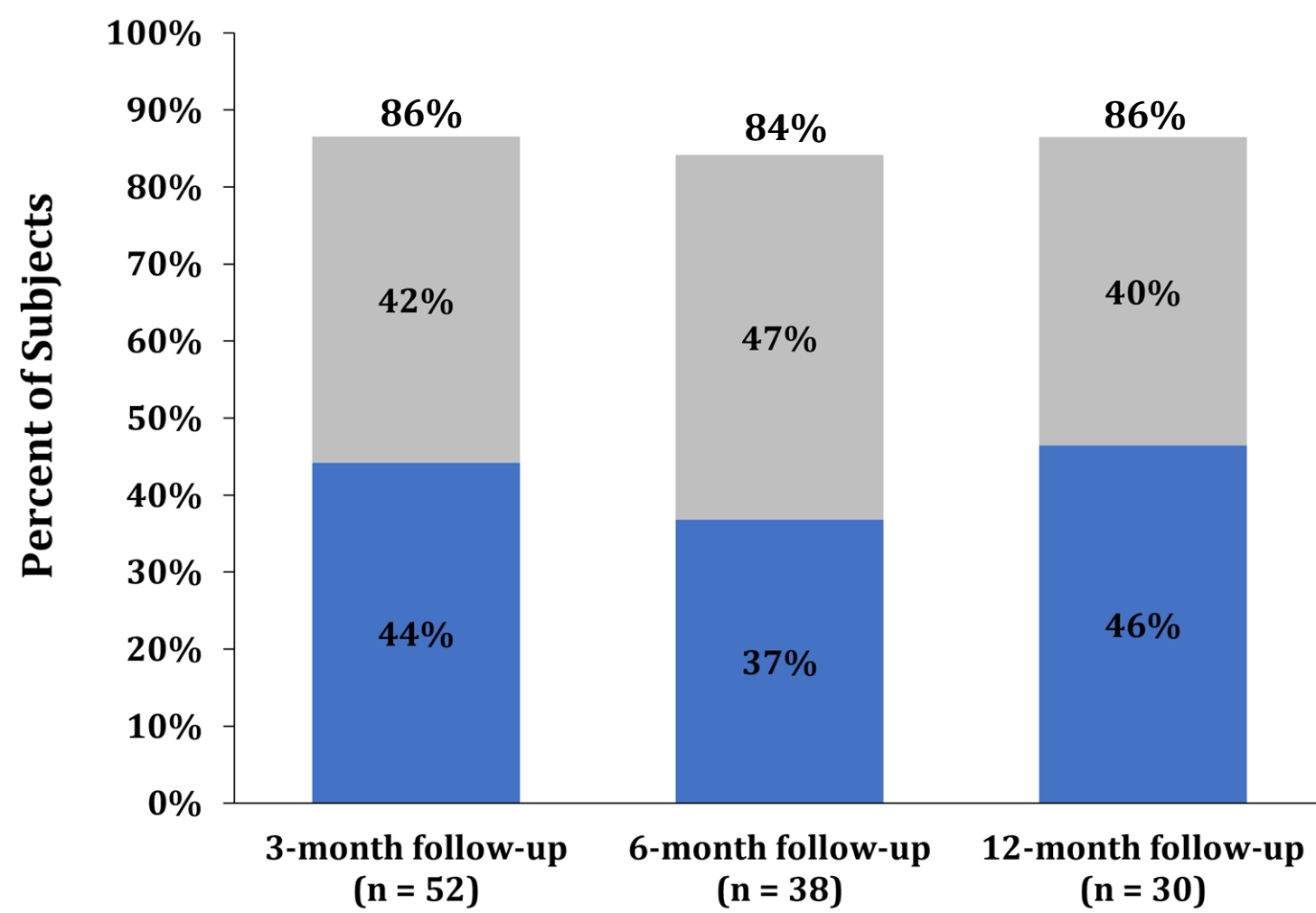
Onset of Pain Relief Following FAST Activation (n = 56)

Percent Pain Relief	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 12-months follow-up



Patient Satisfaction (Impression of Change, PGIC) out to 12-months follow-up



MCID = minimal clinically important difference

CONCLUSIONS

- In this prospective, multicenter clinical study, chronic pain patients treated with FAST-SCS achieved significant and durable sub-perception pain relief with associated improvement in disability and satisfaction out to 12-months follow-up.
- Sub-perception pain relief was achieved within minutes of FAST-SCS activation.
- Outcomes out to 12-months follow-up:
 - Up to 90% of patients reported ≥50% pain relief
 - Patients reported a mean low back pain score of 2.48
 - Patients achieved a mean improvement in disability (ODI) of up to 28-points
 - Patients achieved a high rate of satisfaction with up to 86% reporting being much or very much improved
- These outcomes are consistent with real-world observational studies in USA and Europe^{3, 6}:
 - Responder Rates ≥87% at ~1 year
 - Evaluation of enrolled patients is ongoing

REFERENCES

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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.