

Clinical Outcomes of a Novel, Fast-Acting Sub-Perception SCS Therapy Engaging Surround Inhibition (FAST 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

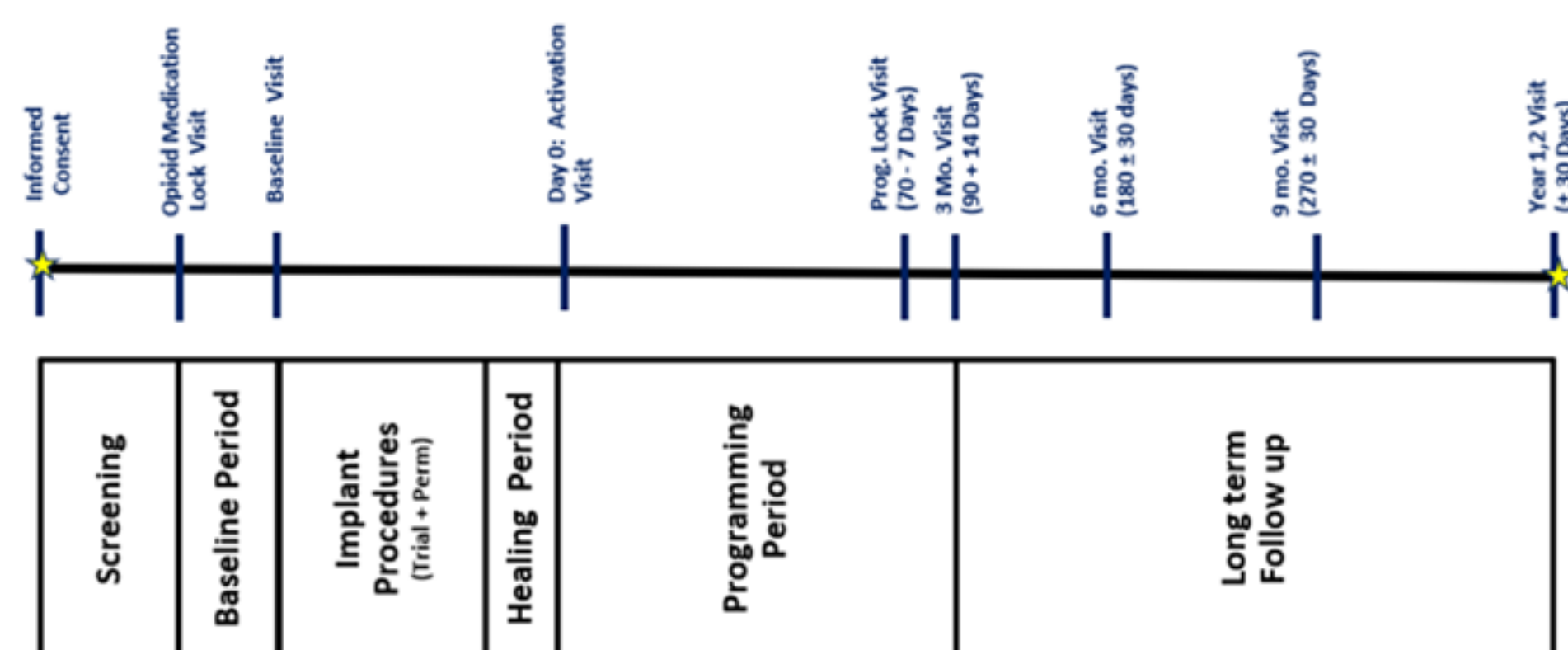
Surround Inhibition is a well-established mechanism in the published literature. Recently published work suggests that FAST engages the surround inhibition mechanism of action and computational modeling suggests that FAST activates dorsal column axons and inhibits dorsal horn projection neurons.⁴ Precise 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



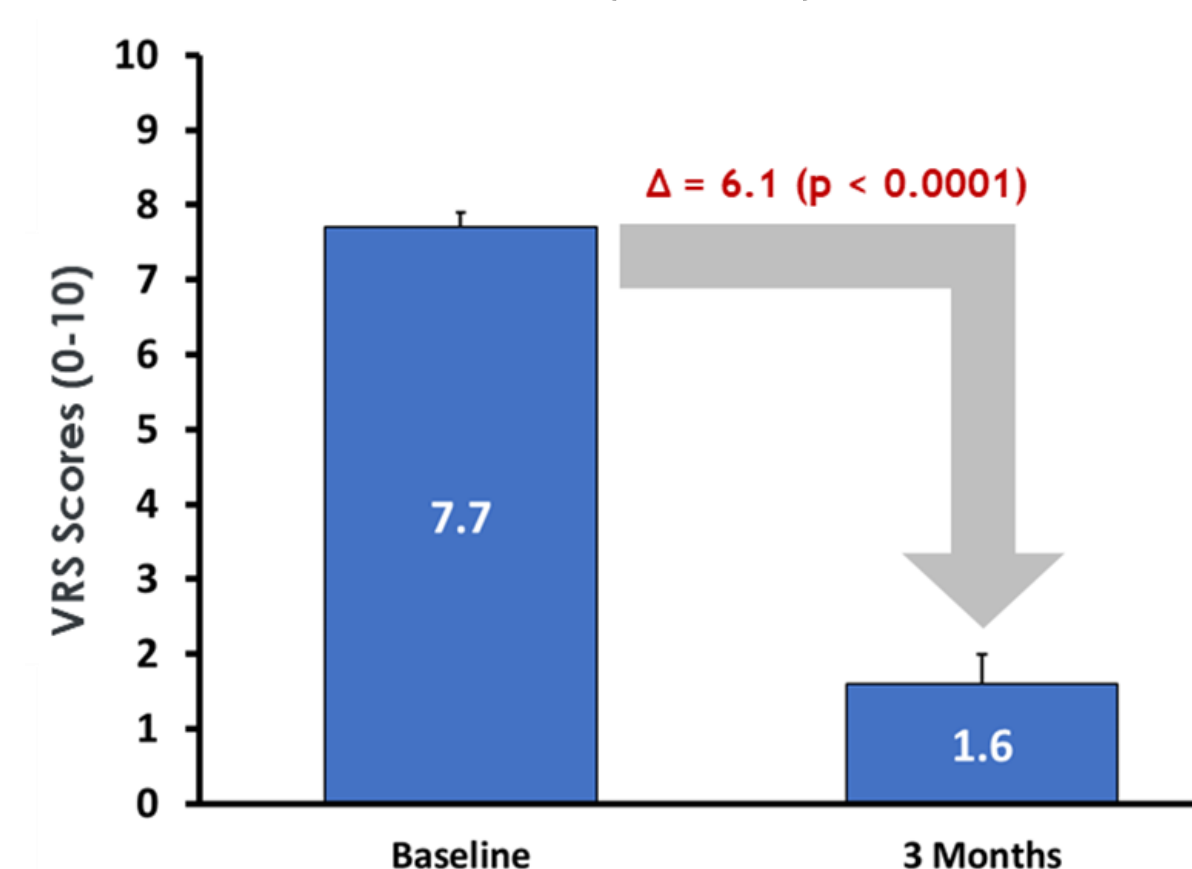
RESULTS

Baseline Characteristics (n = 20)

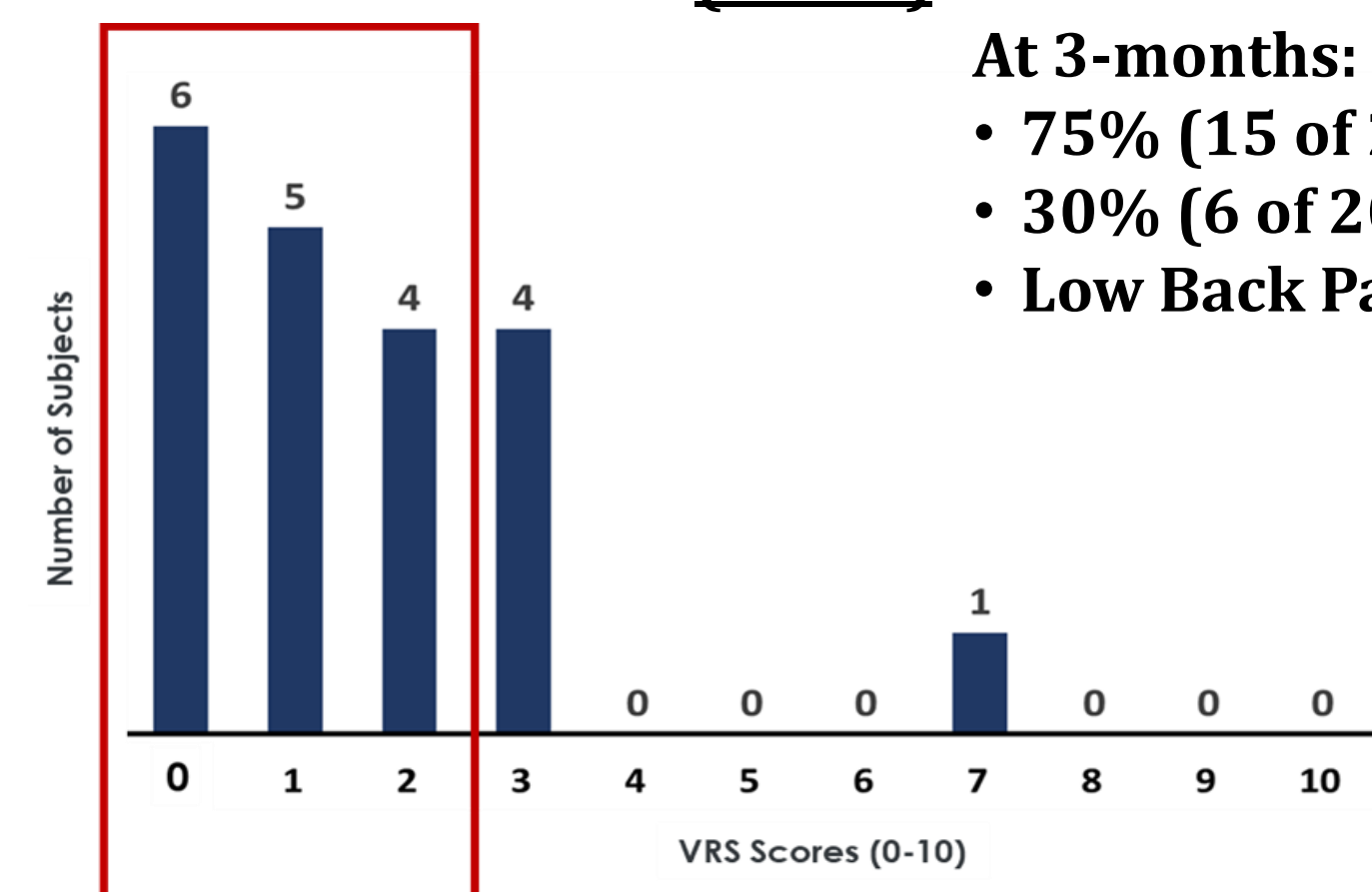
Age (yrs.) - Mean (SD) n	59.1 (15.4) 20
Gender (Female) - % (n/N)	60% (12/20)
Diagnosis for receiving the stimulator (may have multiple diagnosis) - %	
Failed Back Surgery Syndrome	65%
Radiculopathy	70%
Average Overall Pain (VRS) - Mean (SD) n	7.6 (1.1) 20
Average Low Back Pain (VRS) - Mean (SD) n	7.7 (1.1) 20
Disability (Oswestry Disability Index [ODI]) - Mean (SD) n	55.2 (9.8) 20
Duration of low back pain (yrs.) - Mean (SD) n	14.7 (12.4) 20

The study successfully met its primary endpoint (p<0.0001) based on a prespecified cohort of 20-subjects
80% (16/20) met success criteria (targeted pain responder rate with no increase in opioid medications)

Low Back Pain Scores at 3-months (n = 20)

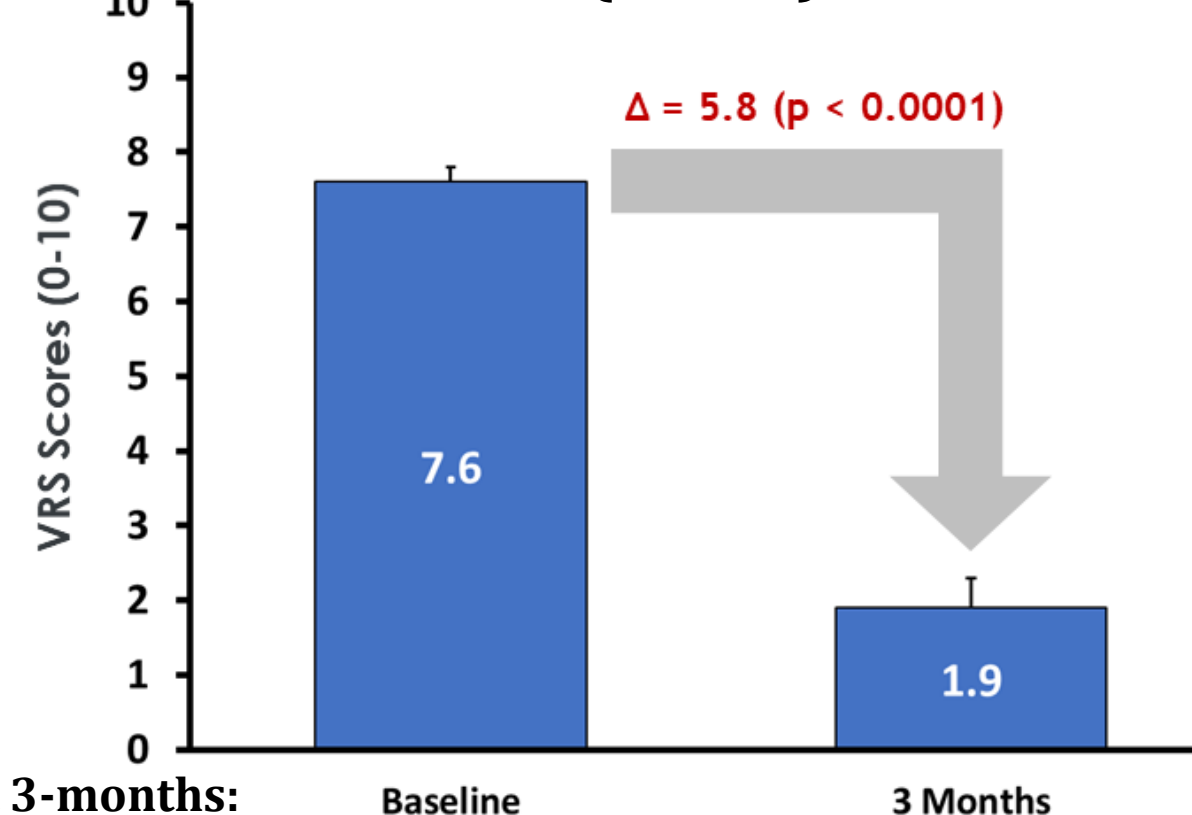


Distribution of Low Back Pain Scores at 3-months (n = 20)



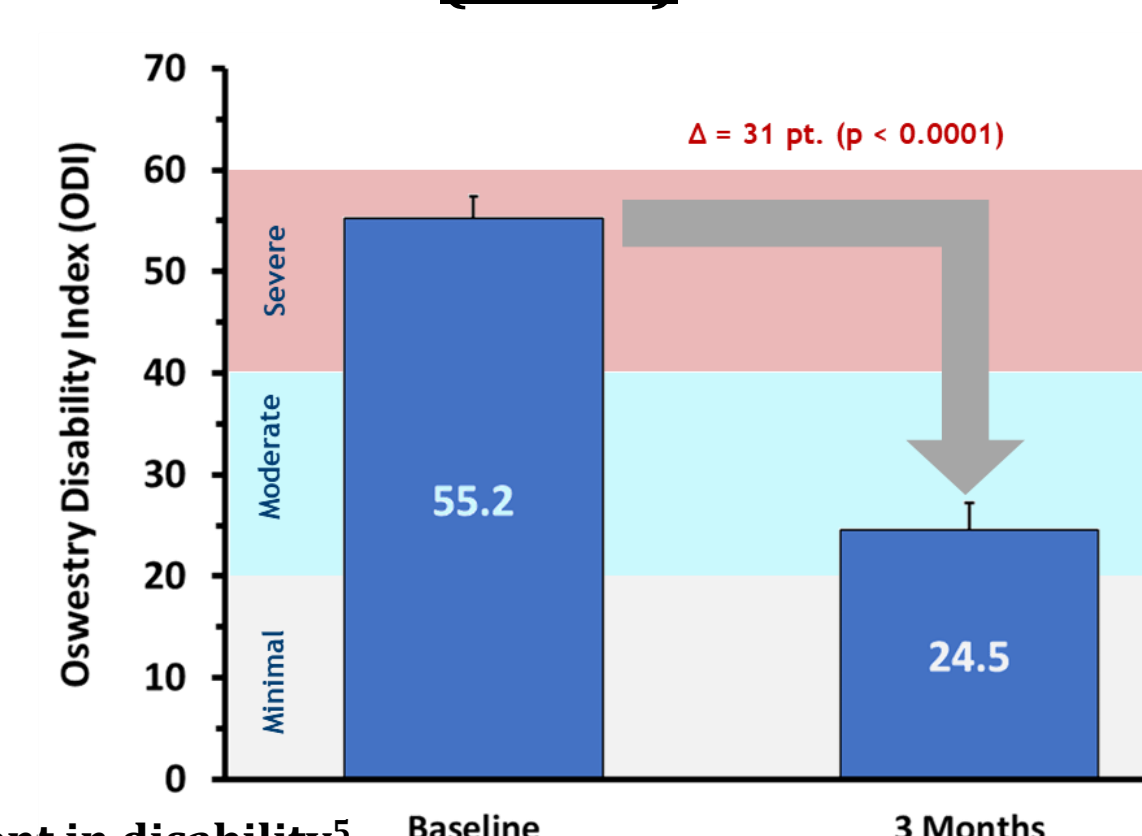
At 3-months:
• 75% (15 of 20) reported a pain score ≤2
• 30% (6 of 20) reported being pain-free
• Low Back Pain Responder Rate of 95% (19 of 20)

Targeted Pain Scores at 3-months (n = 20)

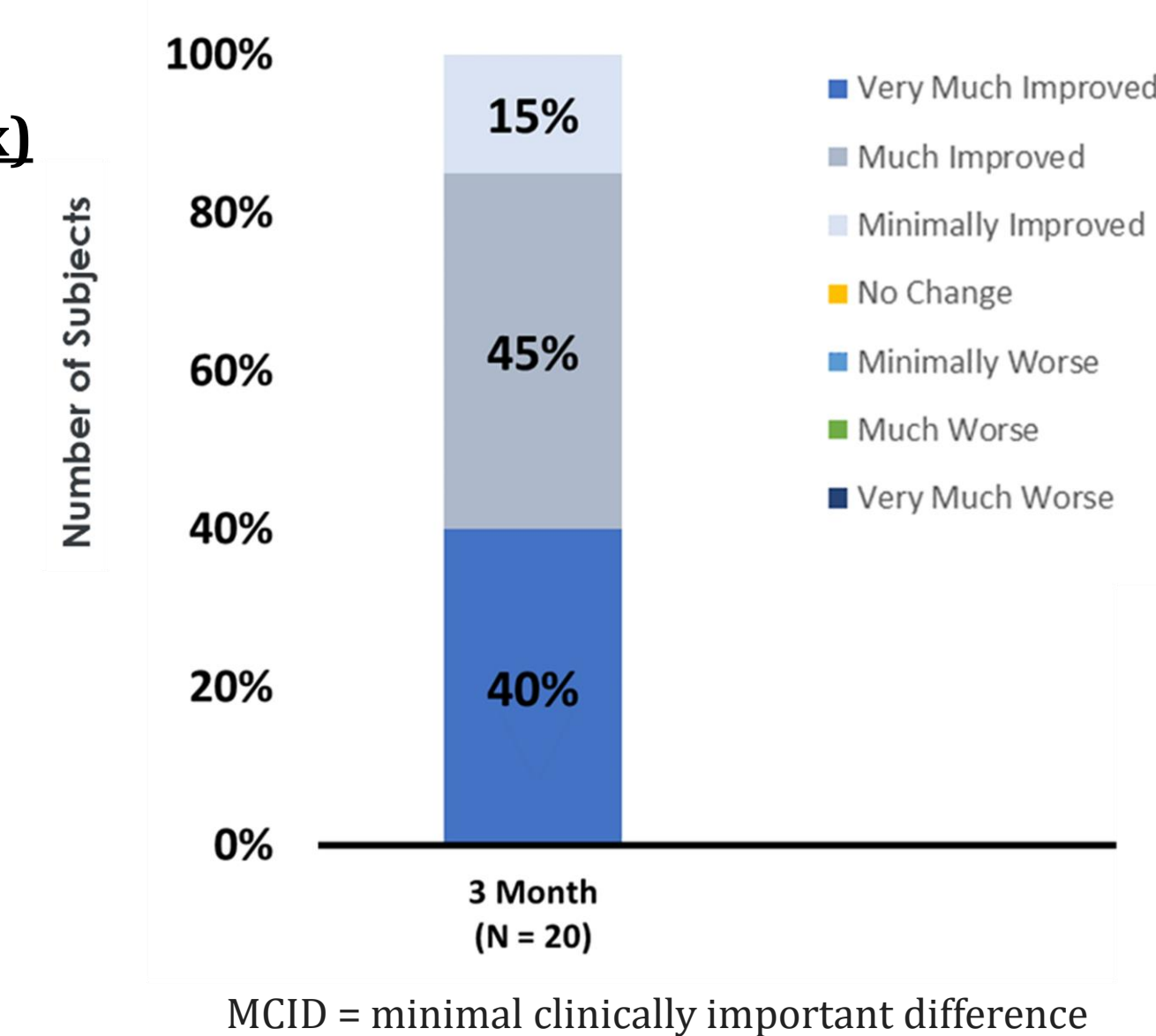


At 3-months:
• 31-point improvement in ODI Scores (MCID ~10 points) indicating significant improvement in disability⁵
• All study participants improved: 85% reported very much/much improved

Improvement in Disability (Oswestry Disability Index) (n = 20)



Patient Satisfaction [PGIC] (n = 20)



CONCLUSIONS

- The FAST Prospective, Multicenter, Single-Arm Clinical Study met its primary endpoint (p<0.0001) based on a prespecified cohort of 20-subjects.
- At 3-months (n = 20):
 - 6.1-point VRS score reduction in mean low back pain (p<0.0001)
 - Low Back Pain Response Rate: 95% (19 of 20 subjects)
 - Significant disability improvement (Δ ODI = 31-points)
 - High Satisfaction per 85% reporting very much/much improved [PGIC]) (All study participants improved)
- At the Activation Visit, FAST responders achieved maximum paresthesia-free pain relief within a mean of 5.4-minutes.
- These results are consistent with a published real-world assessment of over 200-patients.⁶

REFERENCES

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DISCLOSURES

Study Sponsored by Boston Scientific. Dr. Anitescu has a consulting agreement with Boston Scientific. Lilly Chen is an employee of Boston Scientific.

