




Clinical Outcomes Using New Fast-Acting Sub-Perception Therapy SCS for Chronic Pain: A European Observational Study

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BACKGROUND	METHODS	
Traditional Spinal Cord Stimulation (SCS) modalities that achieve sub-perception analgesia (e.g., ~1-10 kHz, burst SCS) require patients to wait up to 1-2 days to achieve optimal pain relief. An SCS modality called Fast-Acting-Sub-Perception Therapy (FAST) was recently developed engaging surround inhibition ^{1,2} to deliver sub-perception pain relief within minutes of activation ³ . This provides the potential benefit of allowing the healthcare provider to confirm successful pain relief before the patient leaves the clinic. Here, we report outcomes of real-world consecutive patients who preferred FAST-SCS for chronic pain in a European-based, multicenter, observational study.	Study Design	Multicenter, Consecutive, Observational, Case-Series. Data collected by site personnel
	Study Device	WaveWriter Alpha and Spectra WaveWriter Spinal Cord Stimulation System (Boston Scientific) with the following capabilities: <ul style="list-style-type: none"> • FAST (Fast-Acting Sub-Perception Therapy) • 3D neural targeting algorithm • Multiple independent current control • Tightly contact spaced leads • Active recharge waveforms at 90Hz
	Cohort	167 patients who preferred FAST-SCS
	 <p>FAST-SCS</p> <ol style="list-style-type: none"> 1. Paresthesia-guided targeting 2. Active recharge waveforms (90 Hz, 210µs) 3. 30% to 40% perception threshold 	

RESULTS

Baseline Characteristics (n = 167)

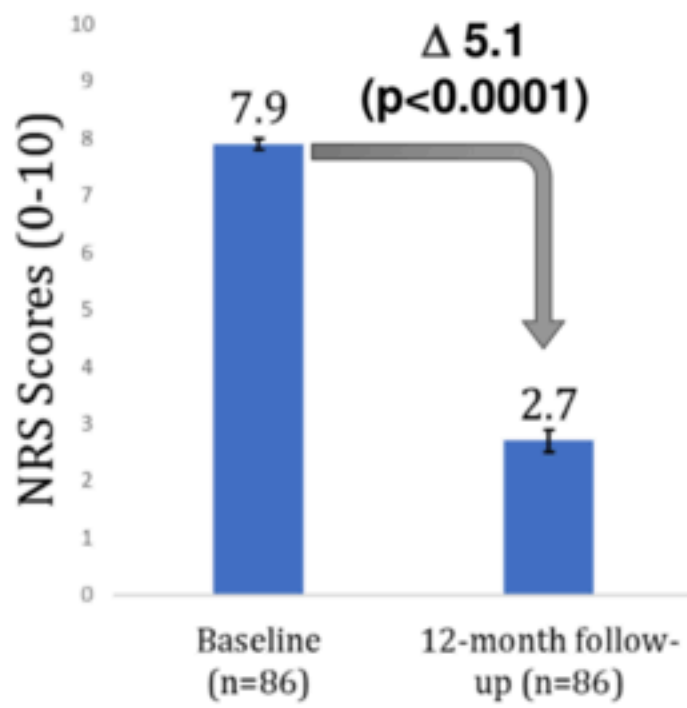
Age (yrs.) - Mean (SD) n	60.1 (12.5) 163
Gender (Female) - % (n/N)	57.5% (96/167)
Pain location (%)	Low back and legs (86%)
Diagnosis for receiving the stimulator (may have multiple diagnosis) - %	
Failed Back Surgery Syndrome	65.3%
Complex Regional Pain Syndrome	12.0%
Lumbosacral Radiculopathy	12.6%
Baseline Overall Pain (NRS)- Mean (SD) n	8.0 (1.2) 167
Follow-up Duration (days) – Mean (SD) n	586.3 (481.0) 167



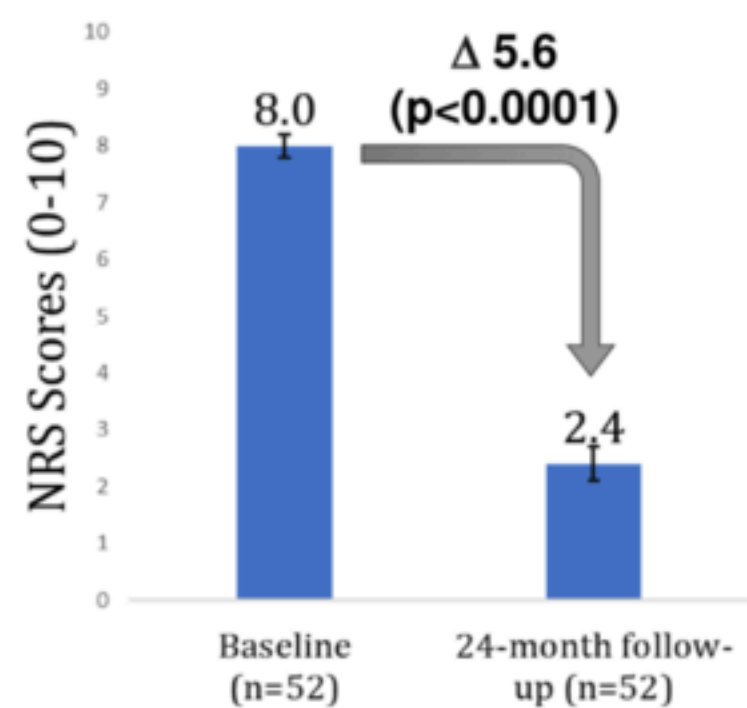
Responder rate at last follow-up (>50% reported pain relief)

At 1.6-year average follow-up after implant, 87% patients (n=87/100) had > 50% reported pain relief versus baseline.

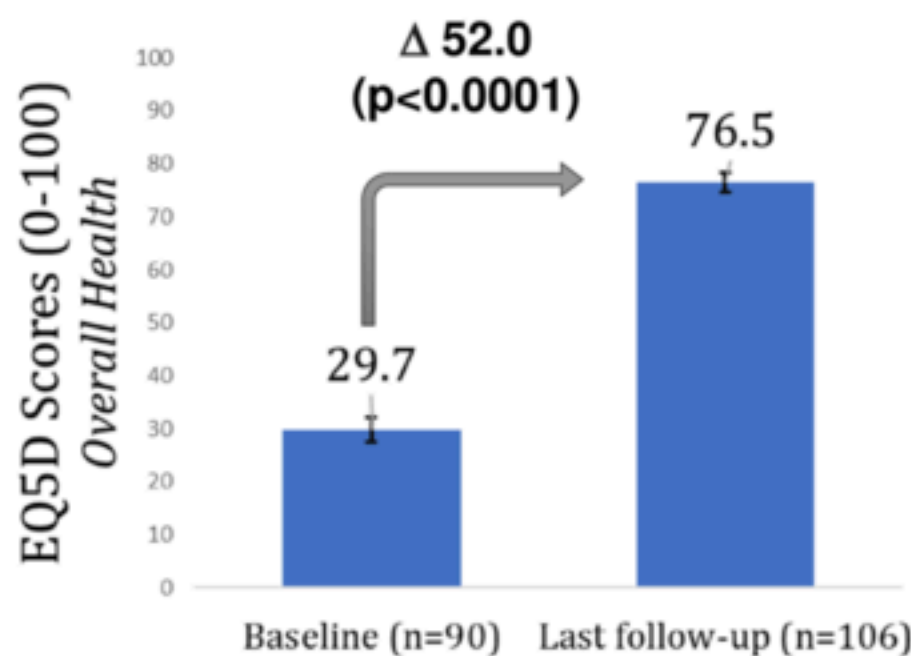
Overall Pain Scores in patients who reached 12-month (n=86) and 24-months (n=52) follow-up respectively



Overall NRS pain scores decreased by 5.1 ± 2.4 points (p<0.0001) and 5.6 ± 2.4 points (p<0.0001) for patients who reached 1-year and 2-year follow-up respectively.

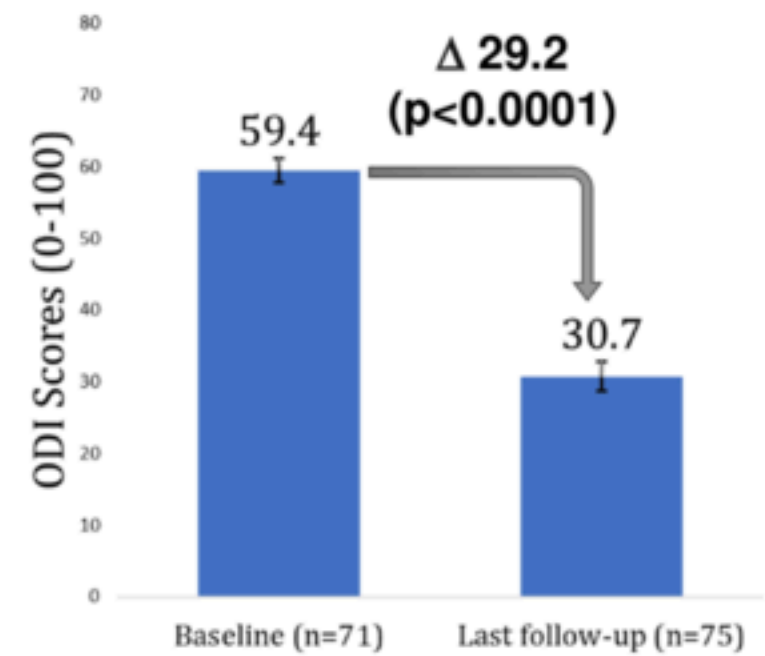


Quality of Life (EQ-5D-5L)



Significant improvements in quality of life (Δ = 52.0 ± 26.0, p<0.0001) and disability (Δ = 29.2 ± 21.5, p<0.0001, MCID = 10 points)⁴ at last follow-up (mean 1.6 years)

Disability (Oswestry Disability Index)



CONCLUSIONS

Fast-Acting Sub-perception Therapy (FAST) allows for rapid onset of pain relief, a significant benefit for both patients and clinicians. Outcomes from this multicenter, real-world, observational, case-series demonstrates significant improvement of chronic pain (>5-point improvement) in patients utilizing FAST-SCS for up to 1.6-years:

- Significant pain relief with FAST-SCS was sustained during long-term follow-up with 5.6-pt reduction in overall pain scores for patients who reached their 2-year follow-up (8.0 → 2.4, n=52).
- Significant improvements in quality of life and disability outcomes (-29.2-pt ODI reduction) were noted at last follow-up with the use of FAST-SCS.
- Responder rate (% patients with >50% reported pain relief vs baseline) at last follow-up was 87%.

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