Two-Year FAST-SCS Outcomes For Non-Surgical Refractory Back Pain: A SOLIS Sub-Analysis

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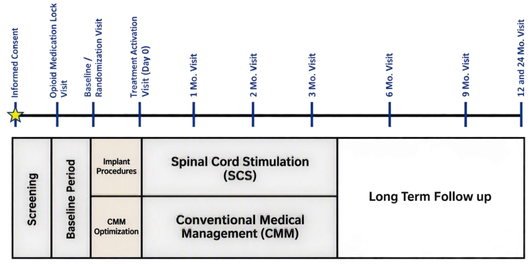
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BACKGROUND

The use of Spinal Cord Stimulation (SCS) as a treatment for chronic pain has been historically designated for patients who have had at least one prior spinal surgery. Considering the opioid drug crisis and the often-mixed clinical success of conservative treatment approaches and invasive back surgery procedures, there is growing interest in utilizing SCS in chronic pain patients with no prior history of spine surgery.[1–4] Recent SCS devices offer substantially more novel technological capabilities and neuromodulation approaches than older-generational SCS systems.[5] Correspondingly, interventional treatment approaches capable of multimodal therapeutic strategies are now actively recommended by pain care advocates.[6,7] The SOLIS study assessed non-surgical refractory back pain (NSRBP) patients implanted with a multimodal SCS device in a prospective, multicenter, randomized controlled trial (RCT) compared with Conventional Medical Management (CMM). Results of the randomization period and 12-month follow-up have been recently published.[8] Here we present 24-month outcomes as well as a sub-analysis of outcomes with the most preferred SCS waveform.

METHODS

Study Design	Prospective, multicenter, parallel group design RCT (Clinicaltrials.gov NCT04676022)
Study Device	WaveWriter SCS Systems, Boston Scientific
Cohort	Non-Surgical Back Pain (NSBP)
Study Arms	Treatment: SCS+CMM Control: CMM (crossover after 3-month follow-up)
Primary Endpoint	Proportion of subjects with ≥50% reduction in average overall pain with no increase in baseline daily opioids at 3-months (SCS+CMM vs. CMM)
Secondar Endpoints	Percent Pain Relief (PPR), Oswestry Disability Index (ODI), Patient Global Impression of Change (PGIC), Euroqol 5D questionnaire (EQ-5D-5L)



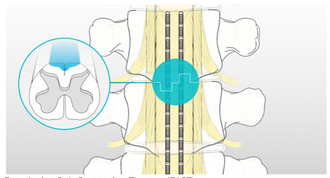
RESULTS

Baseline characteristics (N=128)

	SCS	CMM
Sample size, n	63	65
Age (years)	58.3 (11.9)	60.8 (11.5)
Female, n (%)	44 (69.8)	41 (63.1)
Overall pain intensity (NRS)	7.6 (0.9)	7.5 (1.0)
ODI score	54.2 (8.8)	54.9 (9.2)
EQ-5D-5L: index value	0.525 (0.137)	0.576 (0.140)
Low back pain duration (years)	11.5 (10.9)	13.0 (11.6)
Opioid user at baseline, n (%)	31 (49.2)	35 (53.8)
Main lumbo-sacral diagnoses, n (%)		
Lumbar degenerative disc disease	63 (100.0)	65 (100.0)
Lumbar facet arthropathy	23 (36.5)	23 (35.4)
Lumbosacral radiculopathy	33 (52.4)	40 (61.5)
Lumbar spinal stenosis	26 (41.3)	29 (44.6)

At the time of study closure, a total of 92 patients had been treated with SCS (including 46 Crossover) and had completed their 2-year follow-up visit.

Waveform usage at 2-year follow-up



Fast-Acting Sub-Perception Therapy (FAST)

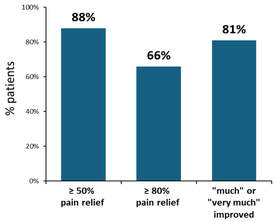
More than half (54%) of the NSRBP patients with programming usage data (39/72) reported using Fast-Acting Sub-perception Therapy at 2-years.

Note: FAST-SCS was not yet available at start of SOLIS RCT subject enrollment

2-year outcomes (n=90, SCS + Crossover Cohort)

Pain Relief and Patient Satisfaction (PGIC)

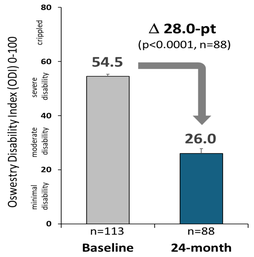
- 88% responders (≥50% pain relief)
- 66% high responders (≥80% pain relief)
- 81% "much" or "very much" improved (PGIC*).



Disability (Oswestry Disability Index – ODI)

At the 2-year visit (n=88):

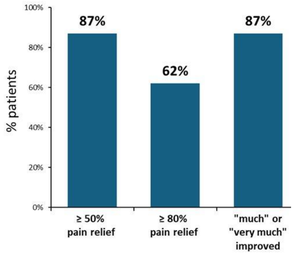
- Highly significant 28-point improvement in ODI score at 2-years (p<0.0001)



FAST-SCS sub-analysis results at 2-years (n=39)

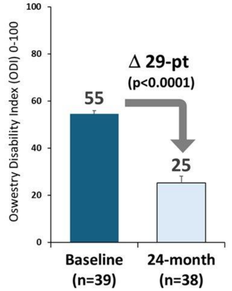
Pain Relief and Patient Satisfaction

- 87% responders (≥50% pain relief)
- 62% high responders (≥80% pain relief)
- 87% "much" or " very much" improved (PGIC)

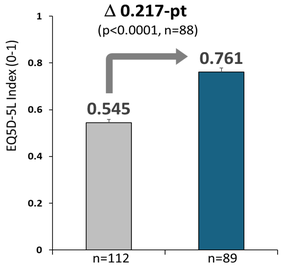


Disability

- ODI improved by **29points** (p<0.0001),which is nearly 2 times the 15-point MCID[9]
- **82%** of FAST-SCS patients had « minimal » (N=15) or « moderate » (N=16) disability



Health-Related Quality of Life



- The EQ5D-5L index improved by more than 3 times the MCID[10] (p<0.0001)

CONCLUSIONS

Multimodal SCS systems have shown significant clinical outcomes in PSPS Type 2 patients. The SOLIS RCT study further confirmed this benefit in NSRBP (PSPS Type 1) patients, who achieved superior outcomes with SCS+CMM compared to CMM alone.

At 2-years, more than half of the NSRBP patients with reported programming data were using FAST, a novel fast-acting sub-perception therapy that delivers pain relief in minutes with durable outcomes:

- 87% Responder Rate
- 29-point improvement in ODI
- EQ5D-5L index improved by 3X MCID[10]

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DISCLOSURES

Study Sponsored by Boston Scientific.
Drs. North, Trainor, and Engle have a consulting agreement with Boston Scientific
Edward Goldberg is an employee of Boston Scientific

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