

SOLIS RCT: 2-Year Outcomes of SCS vs Medical Management in Surgery-Naïve Back Pain Patients

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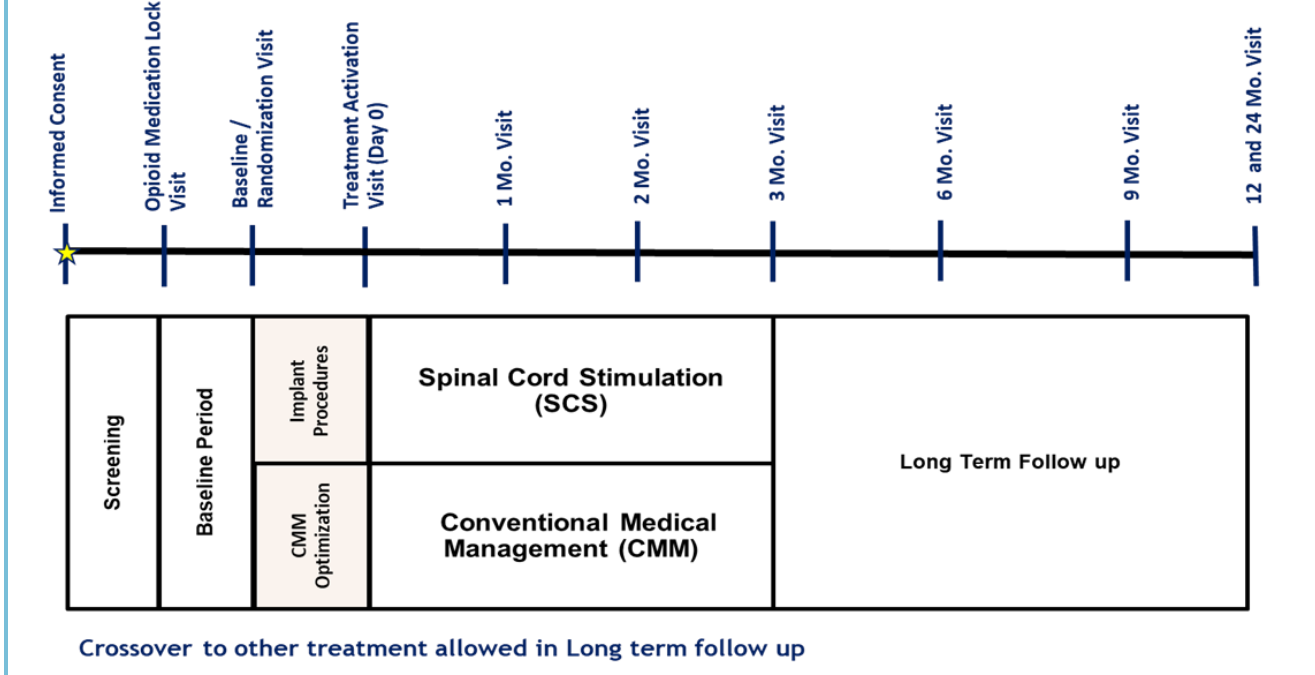
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BACKGROUND

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 neurostimulative 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 possible after 3-month follow-up visit)
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)
Secondary Endpoints	Percent Pain Relief (PPR), Oswestry Disability Index (ODI), Patient Global Impression of Change (PGIC), Euroqol 5D questionnaire (EQ-5D-5L)



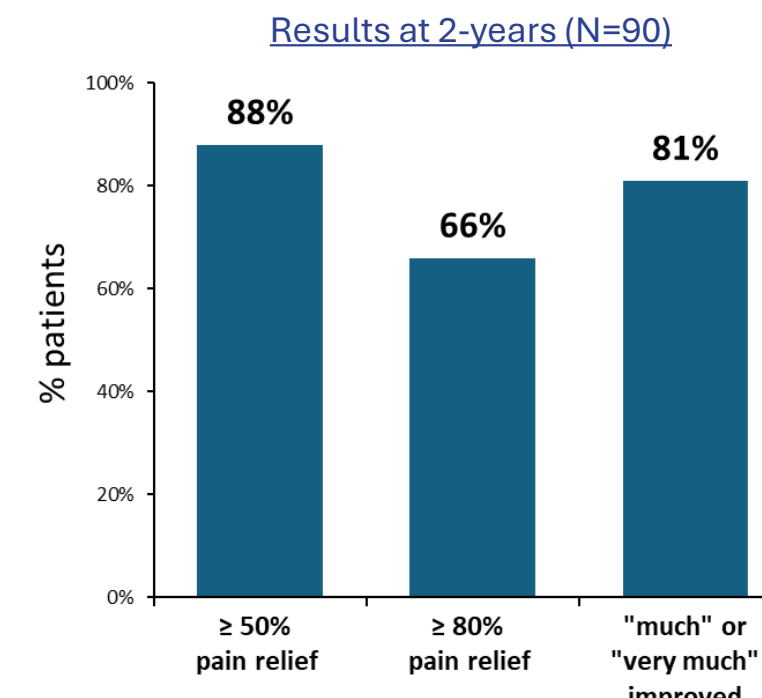
2-YEAR OUTCOMES

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.

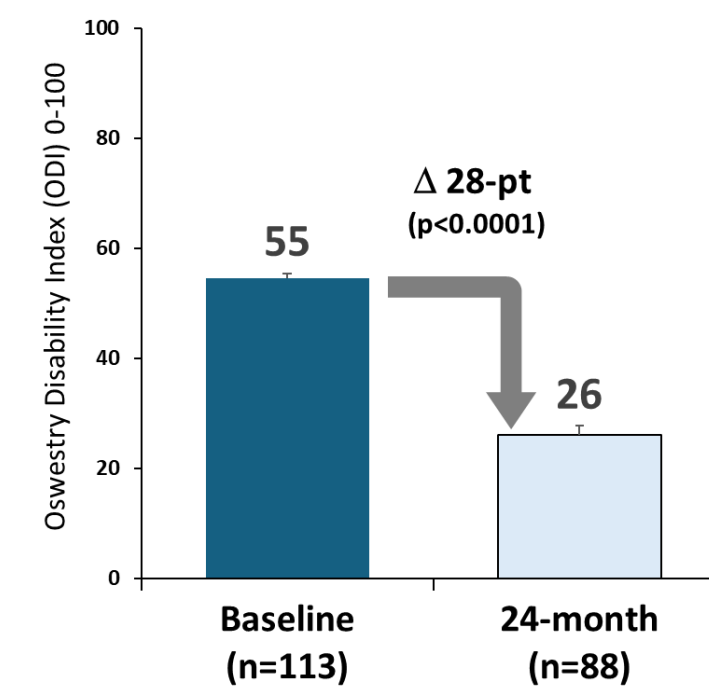
Pain Relief and Patient Satisfaction (PGIC)

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



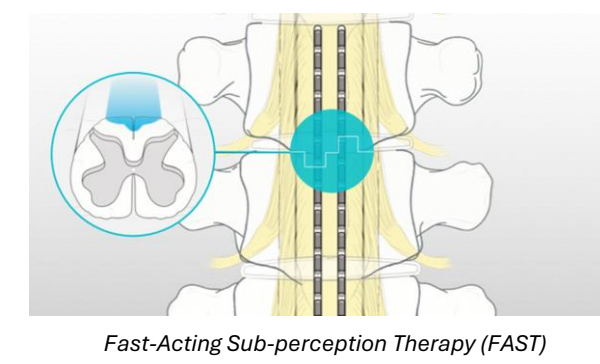
Disability (Oswestry Disability Index, ODI 0-100)

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



FAST-ACTING SUB-PERCEPTION THERAPY

Waveform usage at 2-year follow-up



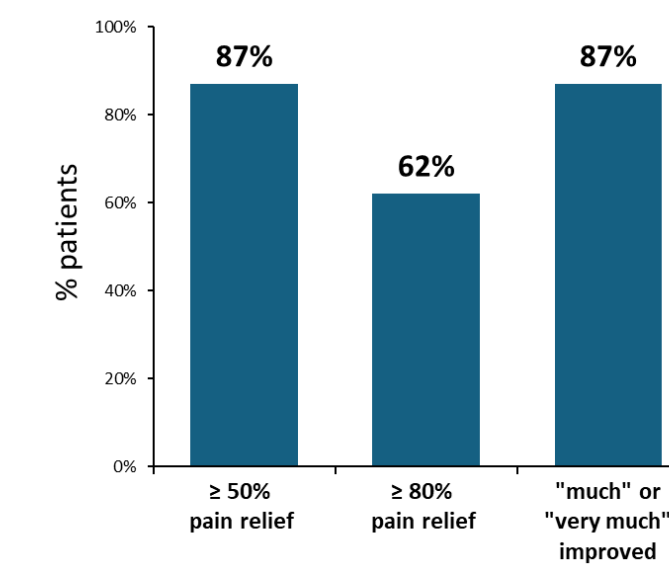
More than half of the NSRBP patients with programming usage data (39/72) reported using **FAST-SCS** therapy*.

*Note: FAST-SCS programming was not yet available when SOLIS RCT enrollment started.

FAST-SCS RESULTS AT 2-YEARS (N=39)

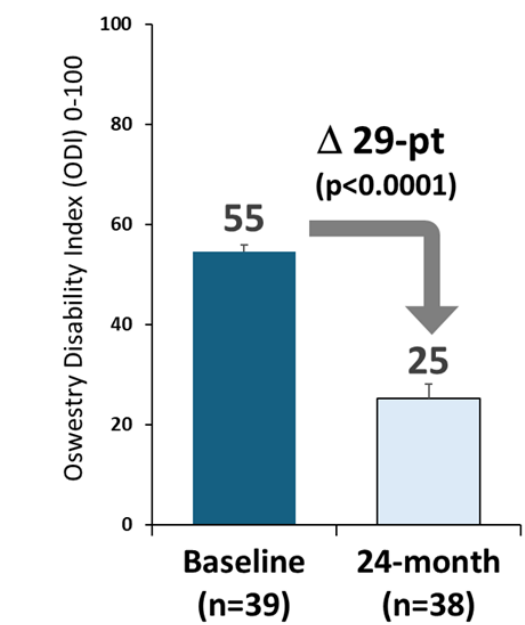
Pain Relief and Patient Satisfaction

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



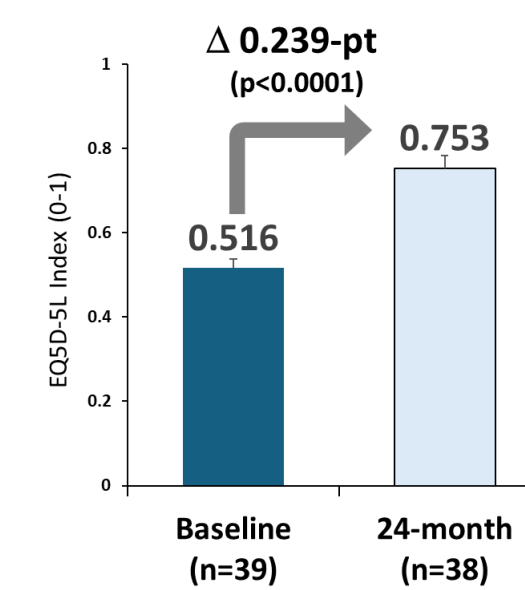
Disability

- **ODI improved by 29 points (p<0.0001)**, which is nearly 2 times the 15-point MCID⁹
- **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 MCID¹⁰** (p<0.0001)



CONCLUSION

Multimodal SCS systems had demonstrated significant clinical outcomes in PSPS Type 2 patients.⁵

The 2-year outcomes of the SOLIS RCT study show that the use of SCS for the treatment of non-surgical refractory back pain (NSRBP) patients provided significant improvements in pain, disability and quality-of-life.

Leveraging the versatility of SCS programming and the development of novel waveforms, the treatment of NSRBP patients with FAST-SCS resulted in:

- **87% responder rate**
- **29-point improvement in ODI**
- **EQ5D-5L index improved by 3X the published MCID¹⁰**

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DISCLOSURES

Study Sponsored by Boston Scientific.
Dr. North has a consulting agreement with Boston Scientific.
Edward Goldberg is employee of Boston Scientific.

INDICATIONS FOR USE



View Boston Scientific Spinal Cord Stimulator System Indications, Safety, and Warnings at [bostonscientific.com/scs-indications](https://www.bostonscientific.com/scs-indications)

OUS Indications for Use - CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Subperception stimulation has been demonstrated to be safe and effective in patients who have been treated successfully with conventional, paresthesia-inducing stimulation for at least six months. Full stimulation parameter ranges and options for both paresthesia-based and subperception therapy are available for clinician's use throughout the patient's experience and treatment with SCS.

Warning: Stimulation modes. Only paresthesia-based stimulation mode has been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population

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