Evaluating SCS and Medical Management for Chronic Pain Without Prior Surgery: SOLIS RCT 24-Month Outcomes

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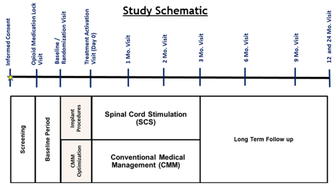
BACKGROUND

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 who have not yet undergone previous surgical intervention.[1-4] Recent SCS devices offer substantially more novel technological capabilities and neurostimulative approaches than older-generational SCS systems. Correspondingly, interventional treatment approaches capable of multimodal therapeutic strategies are now actively recommended by pain care advocates.[5, 6] Here, we describe our clinical assessment of SCS in patients with no prior history of surgery implanted with a multimodal SCS device in a prospective, multicenter, randomized controlled trial (RCT) compared with Conventional Medical Management (CMM). We present the results of the randomization period, and preliminary 24-month outcomes for the SCS group, the Crossover group, and all SCS-implanted patients.

METHODS

Study Design	Prospective, multicenter, parallel group design RCT (Clinicaltrials.gov NCT04676022)
Study Device	WaveWriter SCS Systems, Boston Scientific •Engage multiple mechanisms of action •Fast-Acting Sub-Perception Therapy (FAST) •Customized Field Shape Programming (Contour) •Combination therapy •Illumina3D Algorithm with Multiple Independent Current Control (MICC)
Cohort	Non-Surgical Back Pain (NSBP)
Study Arms	Experimental: Spinal Cord Stimulation (SCS) + Conventional Medical Management (CMM) Control: Conventional Medical Management (CMM)
Primary Endpoint	Proportion of subjects with ≥50% reduction in average overall pain with no increase in baseline opioid medications 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)

Study Schematic



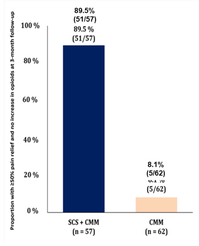
At 3-month post-activation, subjects in the SCS arm continue in the study using SCS therapy as needed, whereas CMM arm subjects can crossover to receive SCS therapy should they choose to do so.

BASELINE CHARACTERISTICS/PRIMARY ENDPOINT

Baseline characteristics (n = 128 randomized subjects)

	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)

Primary Endpoint (Responder Rate)



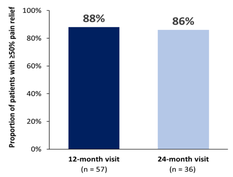
SCS with multiple modalities (+CMM) is superior to CMM alone (p<0.0001)

→ 90% vs 8% responder rate

RESPONDER RATE OUT TO 2 YEARS

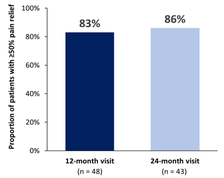
Proportion of patients with ≥ 50% Pain Relief

SCS+CMM Subjects (N=63)



Durable and high responder rates out to 24-month follow-up

CMM-Crossover Subjects (N=50)

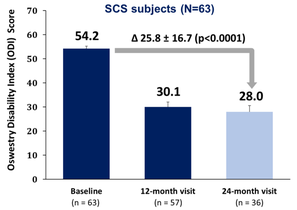


Consistent long-term responder rate between SCS+CMM and CMM-crossover subjects

FUNCTIONAL OUTCOMES OUT TO 2 YEARS

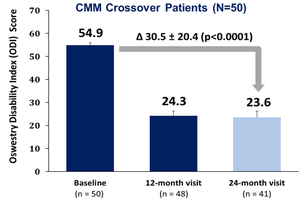
Oswestry Disability Index (ODI)

SCS subjects (N=63)



Significant 25.8-point improvement in ODI

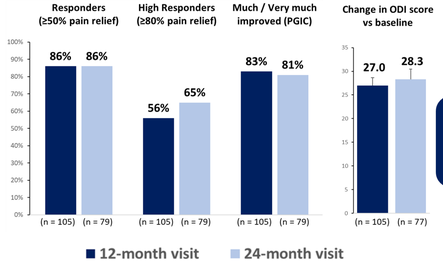
CMM Crossover Patients (N=50)



Significant 30.5-point improvement in ODI

RESULTS OUT TO 2 YEARS (ALL SCS PATIENTS)

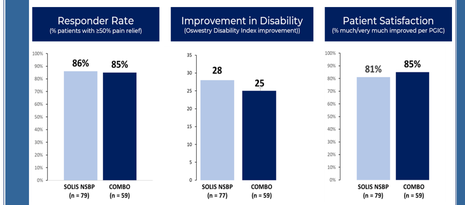
All SCS patients at 12-month (n = 105) and 24-month (n = 79)



Consistent & high level of clinical and functional success out to 2-years

CONCLUSIONS

- The SOLIS study demonstrates that multimodal SCS+CMM is superior to CMM alone and results in significant improvements in pain, function, and quality of life, sustained over 2 years.
  - **86% responder rate** (≥50% pain relief)
  - **65% high responder rate** (≥80% pain relief)
  - **ODI improved by 28-points**
- SOLIS RCT outcomes at 2-years for NSBP patients are consistent with COMBO RCT long-term results for PSPS type 2 patients (also known as FBSS)[7].



- These outcomes support incorporation of multimodal SCS in NSRBP patients

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DISCLOSURES

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Lilly Chen and Edward Goldberg are employees of Boston Scientific.