

Comparing SCS and Conventional Medical Management in Patients with No Prior Back Surgery (SOLIS RCT)

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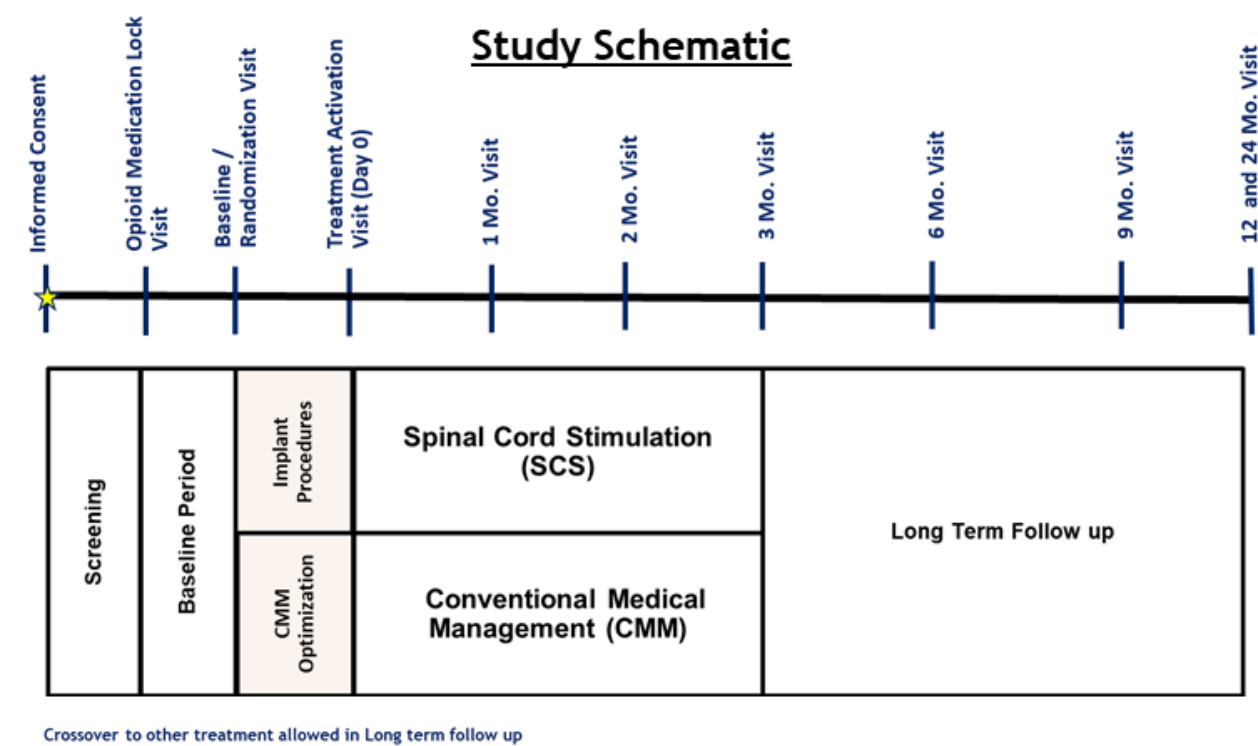
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BACKGROUND

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 device capable of customizable programming engaging multiple mechanisms of action in a prospective, multicenter, randomized controlled trial (RCT) compared with Conventional Medical Management (CMM).

METHODS

Study Design	Prospective, multicenter, parallel group design RCT (NCT04676022)
Study Device	WaveWriter SCS Systems, Boston Scientific •Fast-Acting Sub-Perception Therapy (FAST) •Customized Field Shape Programming (Contour) •Illumina3D Algorithm with Multiple Independent Current Control (MICC) •Combination therapy
Cohort	Non-Surgical Back Pain (NSBP)
Study Arms	Experimental: Spinal Cord Stimulation (SCS) 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 vs. CMM)



RESULTS

Baseline Characteristics (n = 128 treatment activated subjects)

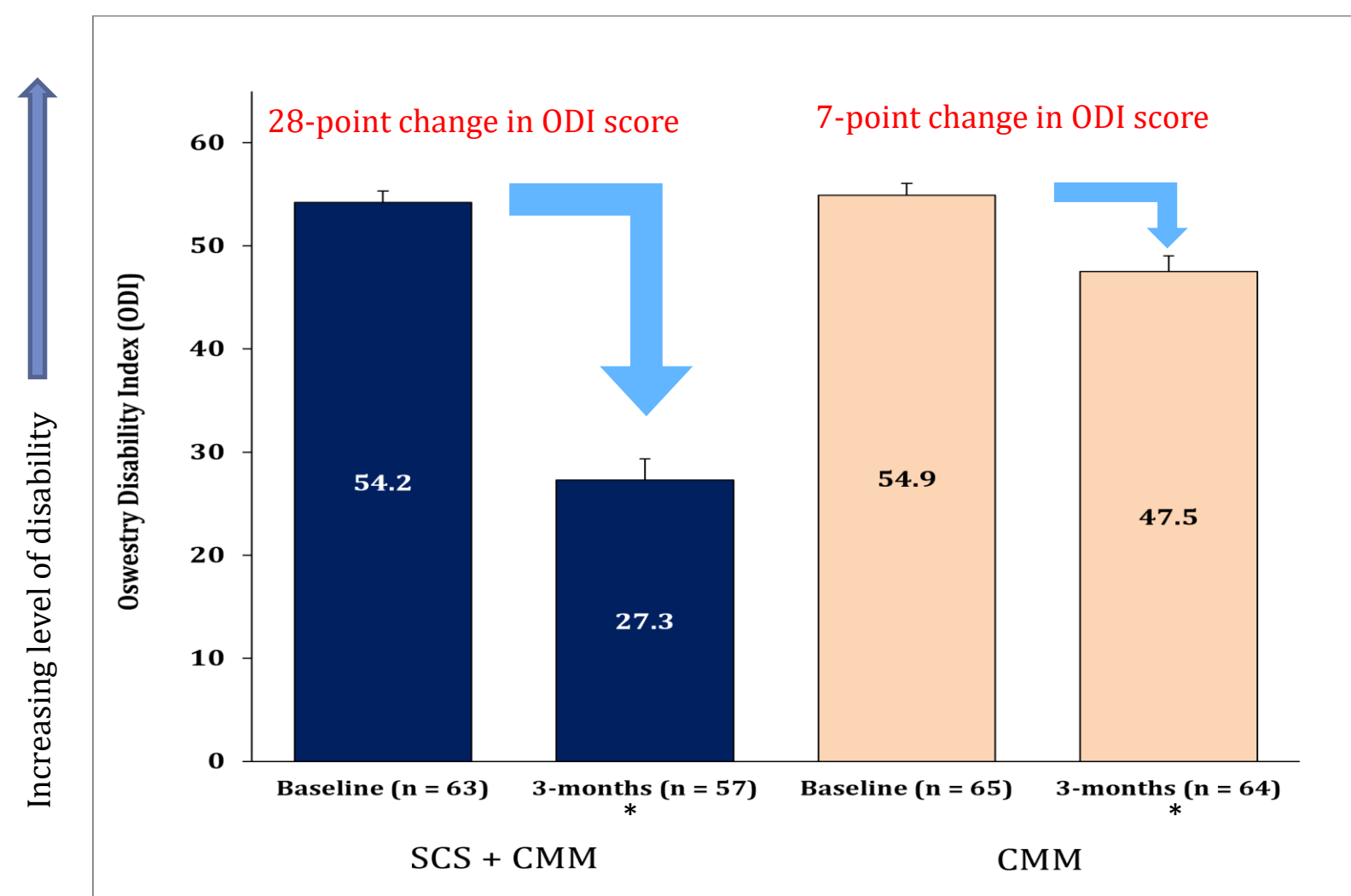
Age (yrs.) - Mean (SD) n	59.6 (11.7) 128
Gender (Female) - % (n/N)	66.4 % (85/128)
Diagnosis for receiving the stimulator (may have multiple diagnosis) - %	
Lumbosacral Radiculopathy	57%
Lumbar Spinal Stenosis	43%
Lumbar Facet Arthropathy	36%
Average Overall Pain (VRS) - Mean (SD) n	7.5 (0.9) 128
Average Low Back Pain (VRS) - Mean (SD) n	7.5 (1.0) 128
Disability (Oswestry Disability Index [ODI] - Mean (SD) n)	54.6 (8.9) 128
Duration of low back pain (yrs.) - Mean (SD) n	12.3 (11.3) 128

NOTE: 96% of subjects (123/128) were classified according to ODI as severely disabled or crippled at time of baseline measurement.

Randomization:

- Baseline number of subjects randomized to SCS + CMM arm: 63
- Baseline number of subjects randomized to CMM arm: 65

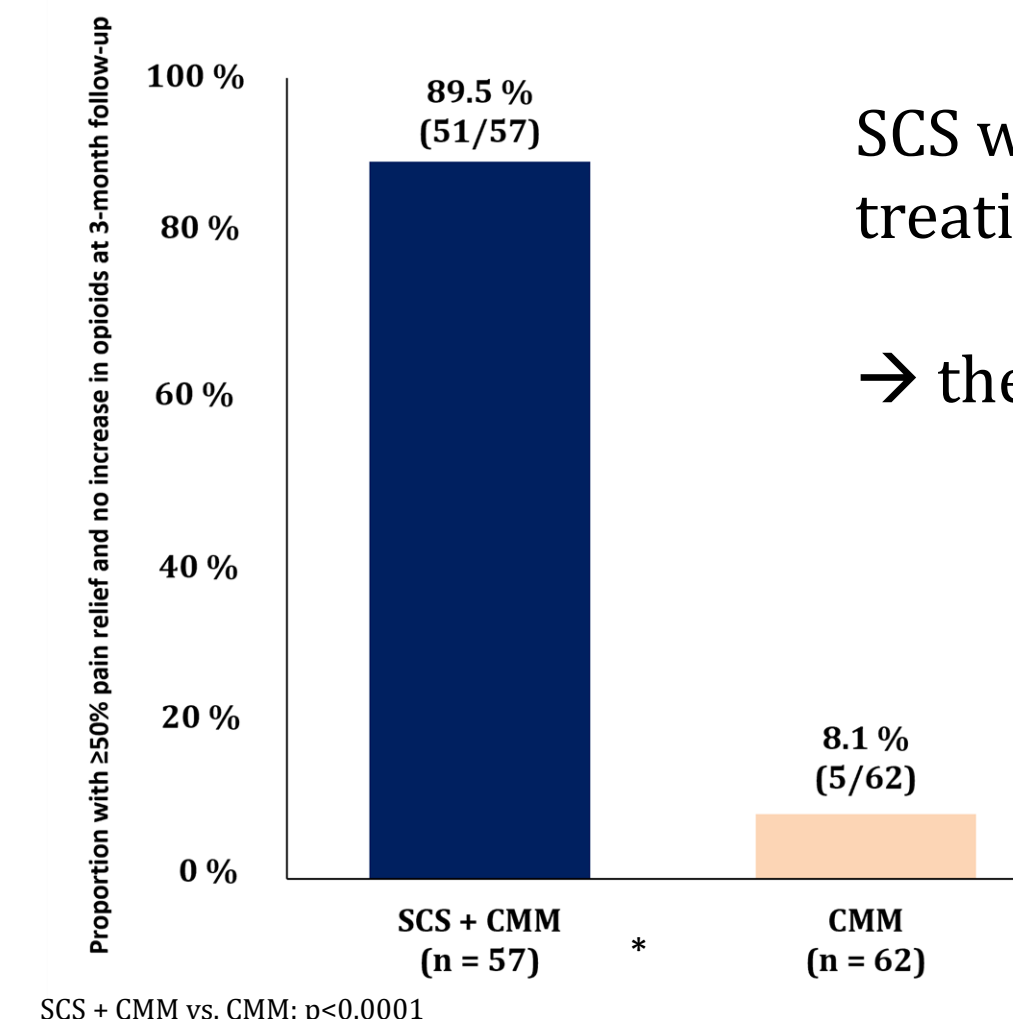
Secondary Endpoint: Mean Improvement of Disability (Oswestry Disability Index, ODI)



SCS with multiple modalities is superior to CMM in improving functional outcomes when treating NSBP patients (p<0.0001)
→ 28-point vs. 7-point ODI improvement

Primary Endpoint Analysis (3-months post-activation)

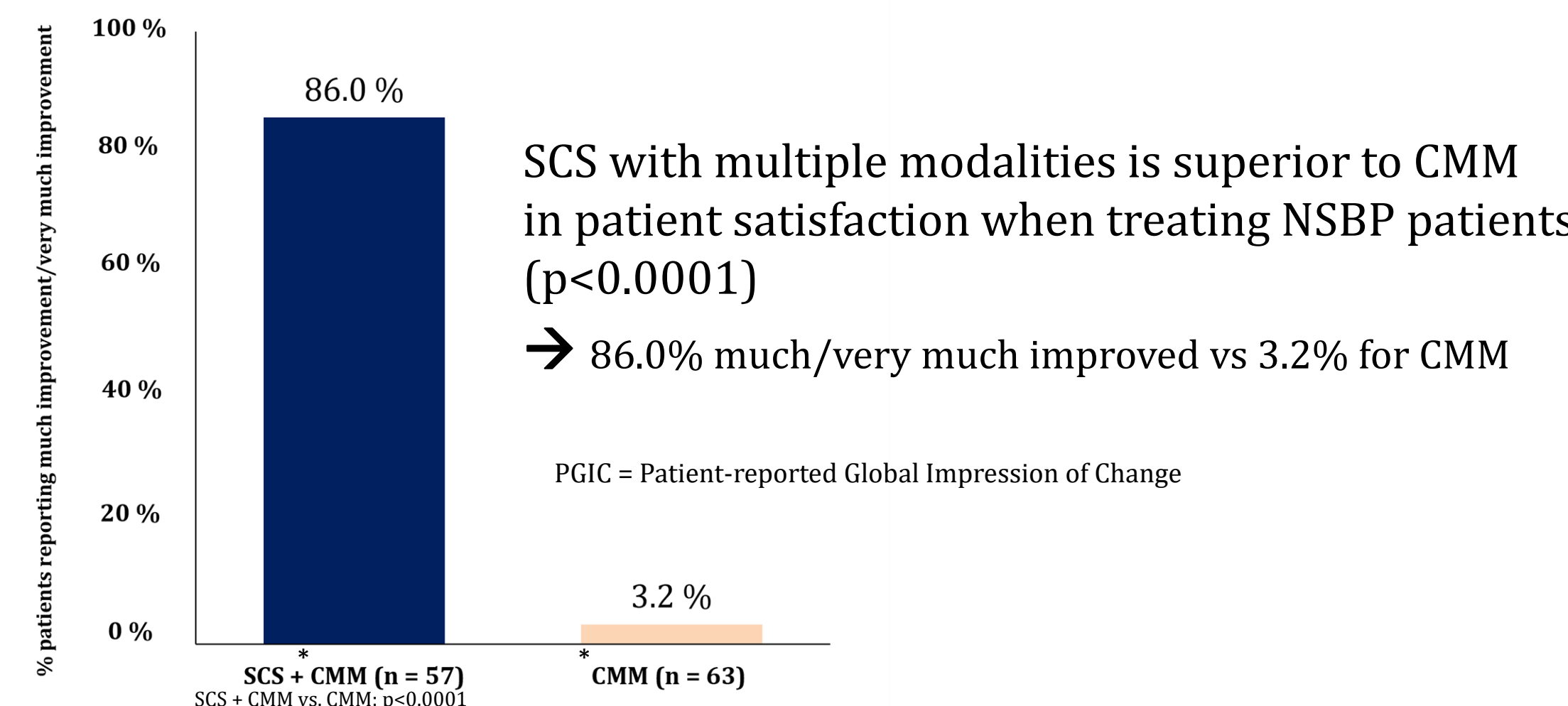
Proportion of subjects with ≥50% reduction from Baseline in average overall (low back and/or leg) pain intensity at 3-months post-activation, with no increase in baseline average daily opioid medications used to treat pain, compared between SCS and CMM.



SCS with multiple modalities was superior to CMM in treating NSBP patients at 3-months (p<0.0001)

→ the study primary endpoint was met

Secondary Endpoint: Patient Satisfaction (very much/much improved [PGIC]) at 3-months

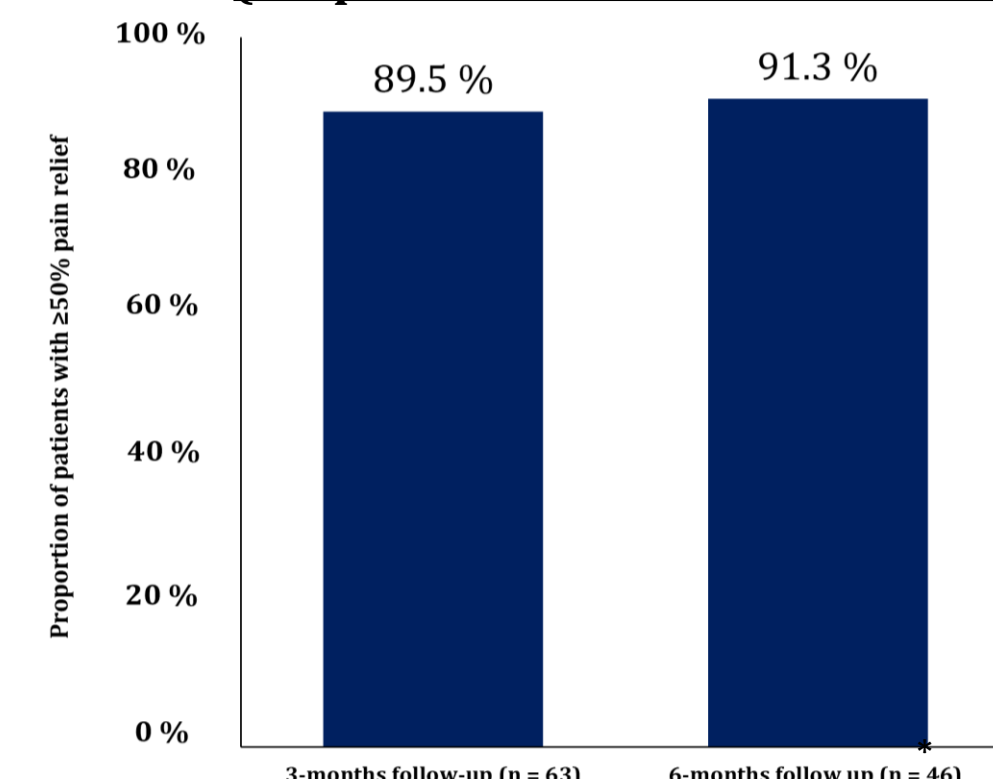


SCS with multiple modalities is superior to CMM in patient satisfaction when treating NSBP patients (p<0.0001)
→ 86.0% much/very much improved vs 3.2% for CMM

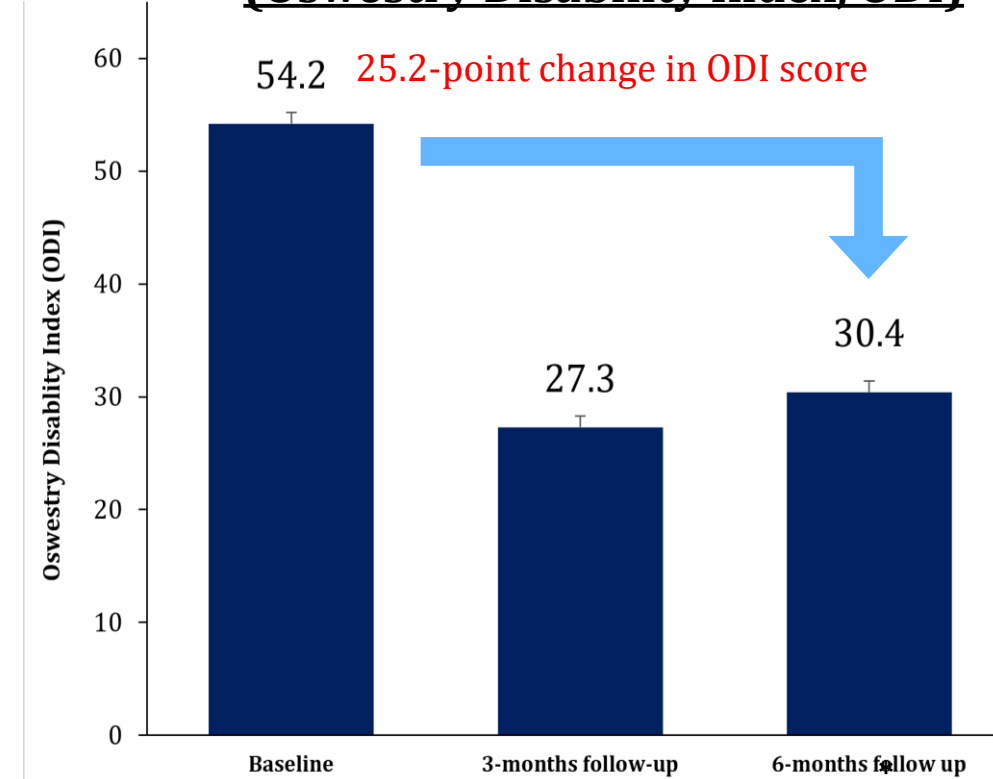
PGIC = Patient-reported Global Impression of Change

Preliminary 6-month follow-up outcomes in the SCS + CMM arm

Responder Rate (Proportion with ≥50% Pain Relief)



Mean Improvement of Disability (Oswestry Disability Index, ODI)



CMM crossover with available 6-month follow-up data:

- Responder Rate: 83.9% (n=31)
- ODI: 29.0 (n=30) → Δ 26-points vs. Baseline Measurement

*reflects subjects that have reached their 3- and/or 6-month follow-up for whom data is available

CONCLUSIONS

- The SOLIS RCT (multicenter, prospective, parallel-group design) effectively met its primary endpoint (p<0.0001) and secondary endpoints based on pre-specified cohort.
- SCS with multiple modalities is an effective treatment approach for NSBP, demonstrating superior outcomes versus CMM in patients with no prior back surgery.
- At 3-months:
 - Higher responder rate vs. CMM without increase in opioids (89.5% vs 8.1%)
 - Significant improvement in disability (i.e., 28-point improvement in SCS + CMM arm vs. 7-point improvement in CMM arm).
 - High Satisfaction (i.e., 86.0% in SCS + CMM arm vs. 3.2% in CMM arm who reported very much/much improvement)
- At 6-months:
 - SCS + CMM arm: sustained primary and secondary endpoint outcomes at longer term follow-up
 - CMM crossover cohort: consistent outcomes with the SCS + CMM arm

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DISCLOSURES

This study is sponsored by Boston Scientific.
Dr. North has a consulting agreement with Boston Scientific. Lilly Chen and Edward Goldberg are employees of Boston Scientific.

NOTE: Boston Scientific SCS Systems are not approved for sale in the US to treat non-surgical back pain (NSBP) patients

