A RANDOMIZED CONTROLLED CLINICAL TRIAL COMPARING DIFFERENTIAL TARGET MULTIPLEXED SPINAL CORD STIMULATION TO TRADITIONAL SCS: POST HOC ANALYSIS OF NON-SURGICAL BACK PAIN PATIENTS

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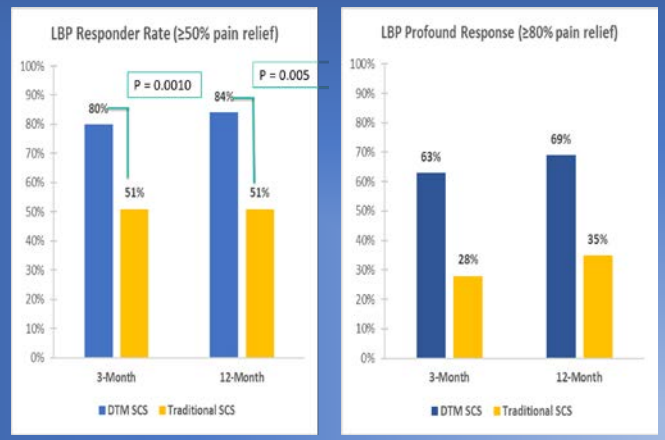
Introduction

SCS is used to treat chronic pain that develops after spinal surgery. Following a randomized controlled trial (RCT) of DTM SCS compared to traditional SCS, there was some interest on examining the demographics and low back pain (LBP) relief characteristics for the subset of patients without previous spinal surgery. Results of a post hoc analysis are presented.

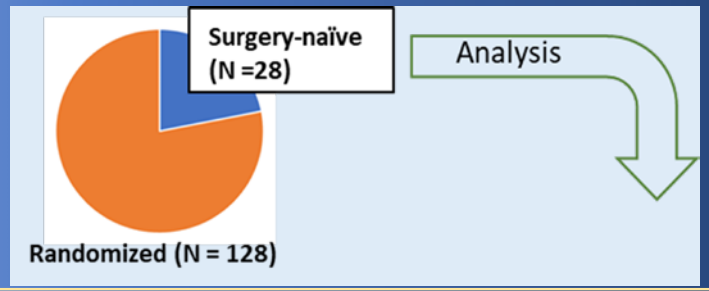


Methods

The study was a prospective, multicenter, parallel-group RCT that compared treatment using DTM SCS to traditional SCS in patients with chronic intractable low back pain (LBP) and leg pain. Consented and eligible subjects (LBP VAS ≥ 5 cm and moderate to severe leg pain) were randomized across 12 centers in the US. A post hoc analysis was performed for subjects who had not undergone previous spinal surgery.

Design:

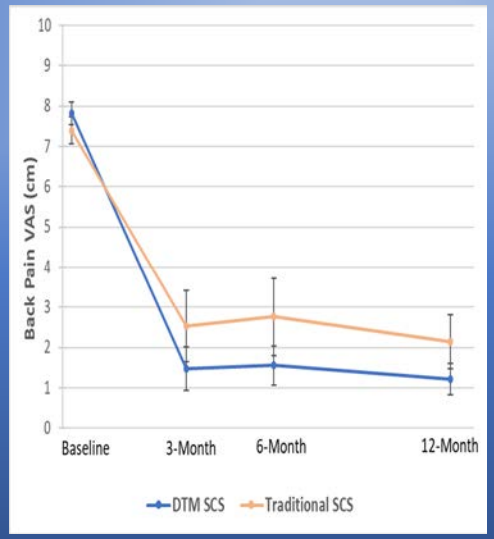
Multicenter (12 sites across the U.S.), prospective, post-market, open-label, randomized, controlled:
1:1 Randomization – Test Arm: DTM-SCS; Control Arm: Traditional SCS
3-months primary endpoint, 12-months follow up
Primary outcome: Responder rate (subjects with ≥50% back pain relief)
Device:
Same neurostimulation system in both arms (Intellis™ system)
Programming:
For Traditional SCS: Device Manufacturer representatives
For DTM SCS: Sponsor representatives

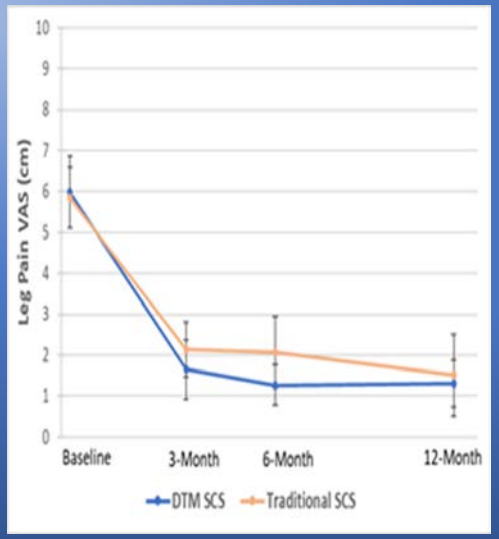


Results and Discussion

Baseline demographics of the surgery-naïve population.

	DTM SCS (N=16)	Traditional SCS (N=12)
Age (SD)	62.3 (12.9)	62.0 (11.5)
Years of pain onset (SD)	10.9 (13.4)	17.8 (13.4)
VAS (cm) Low Back Pain (SD)	7.83 (1.12)	7.39 (1.16)
VAS (cm) Leg pain (SD)	5.99 (3.48)	5.85 (2.53)





Mean VAS scores for back pain (left) and leg pain (right) for subjects with available data at the time of evaluation. Error bars are standard errors.

Low back pain responder rates (≥50% pain relief) of the surgery naïve population.

	DTM SCS	Traditional SCS
3-Months	11/12	6/8
6-Months	11/12	5/8
12-Months	11/12	5/7

Improvements in low back pain scores (~6.5 cm for DTM SCS and ~4.5 cm for traditional SCS) were substantial and sustained out to 12 months post-implant in subjects with no previous spinal surgery,

Conclusions

- Despite the limited sample size in the current analysis, the trend in responder rates and low back pain VAS scores, with DTM SCS being better than traditional SCS, is consistent with those obtained in the overall study.
- A randomized controlled trial is currently in progress to evaluate DTM SCS in a larger population of subjects.

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