DIFFERENTIAL TARGET MULTIPLEXED SPINAL CORD STIMULATION FOR INDICATED CHRONIC BACK PAIN PATIENTS INELIGIBLE FOR SPINE SURGERY: US RCT OUTCOMES

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INTRODUCTION

- DTM SCS has been shown to be superior for the treatment of neuropathic chronic low back pain (CLBP) in patients with persistent spinal pain syndrome type 2 (PSPS-T2).[1]
- In contrast, options for the treatment of CLBP in PSPS-T1 not eligible for spine surgery, with degenerative disc disease, herniated disc, or radiculopathy are limited.
- A European RCT (ISRCTN10663814) studying the effect of DTM SCS vs conventional medical management (CMM) in the treatment of CLBP in these patients reported primary endpoint results that were consistent with those reported in the RCT for PSPS-T2 patients.[2]
- **OBJECTIVE: The current work presents a RCT that evaluated, for the first time, the efficacy of DTM SCS versus Conventional SCS on PSPS-T1 patients with CLBP who are not candidates for spine surgery across the USA.**

RESULTS

Table 2. Baseline Demographics (mITT)

	DTM SCS (N=51)	Conv-SCS (N=54)
Age (SD)	62.9 (13.5)	59.6 (12.1)
Sex	56.9% F	61.1% F
Years w/ pain (SD)	9.5 (8.0)	9.4 (8.4)
Baseline CLBP (SD)	7.9 (1.0)	8.0 (1.1)
Baseline leg pain (SD)	6.7 (2.4)	7.8 (1.6)

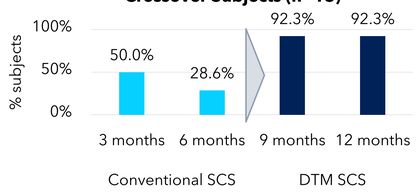
Table 3. Enrolled Subject Pain Etiologies (mITT)

Pain Etiology n (%)	DTM SCS (N=51)	Conv-SCS (N=54)
Radiculopathy	45 (88.2%)	46 (85.2%)
Degenerative Disc Disease	38 (74.5%)	42 (77.8%)
Spondylosis	35 (68.6%)	40 (74.1%)
Mild/Moderate Spinal Stenosis	27 (52.9%)	19 (35.2%)
Lumbar facet-mediated pain	15 (29.4%)	13 (24.1%)
Sacroiliac dysfunction	9 (17.6%)	6 (11.1%)
Internal disc disruption / Annular tear	8 (15.7%)	7 (13.0%)
Spondylolisthesis	5 (9.8%)	5 (9.3%)
Other chronic pain	22 (43.1%)	29 (53.7%)

Crossover Option:

- No subjects crossed over from DTM SCS to Conv-SCS. 14 out of 30 Conv-SCS subjects crossed over to DTM SCS.
- **12 out of 13 were responders at the 9- and 12-month visits.**

Figure 5. CLBP Responder Rate in Crossover Subjects (n=13)



Statistically superior CLBP responder rate with DTM SCS compared to Conventional SCS at all timepoints (p < 0.0001). Reductions in CLBP and leg pain VAS with DTM SCS.

Figure 1. CLBP Responder Rates (mITT)*

Responder Rate: ≥50% relief

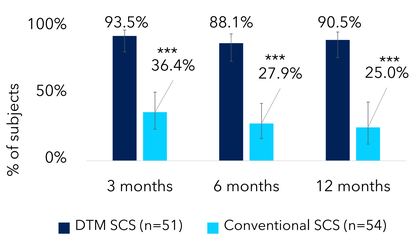


Figure 2. CLBP VAS Scores (mITT)**

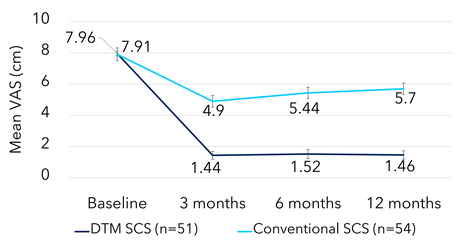


Figure 3. CLBP Profound Responder Rate by subject at 12-months (mITT)

Responder Rate: ≥80% relief

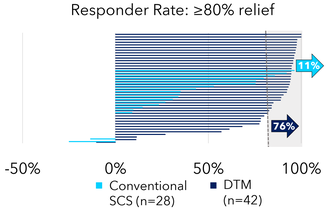
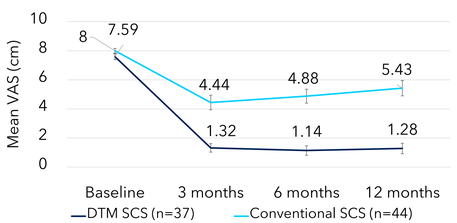
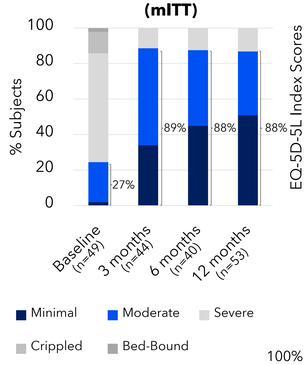


Figure 4. Leg Pain VAS Scores (mITT)**



Improvements in disability and quality of life through 12-months with DTM SCS. ODI reduction of ~24 points (>2X the MCID) from baseline.

Figure 6. ODI Scores (mITT)



93% subjects reported being satisfied or very satisfied with DTM SCS at 12 months

Figure 7. EQ5D-Index (mITT)**

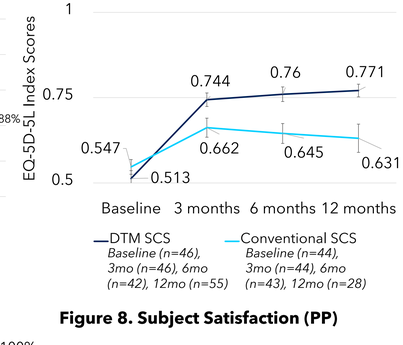
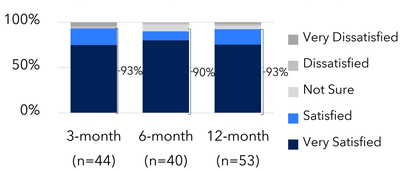


Figure 8. Subject Satisfaction (PP)



MATERIALS & METHODS

Design

Prospective Post-Market, Multi Center, Randomized Controlled

- On-label subjects indicated for SCS*: CLBP and Leg Pain
- Randomized (1:1) across 20 US Sites
- DTM™ SCS vs Conventional SCS
- Option to crossover at 6-months (2-way crossover)

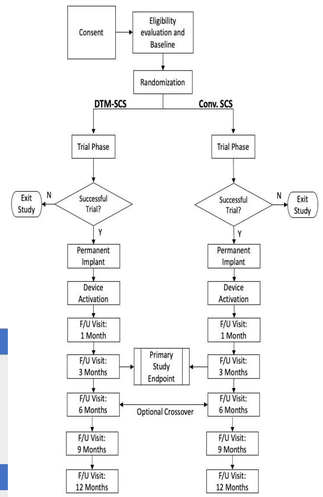
Primary endpoint: Responder rate (≥ 50% CLBP relief) at 3-months

Analysis population

- mITT: subjects completing Trial Phase
- PP: subjects implanted completing visits

Table 1. Key Inclusion & Exclusion Criteria

Inclusion
Adult subjects Non-eligible for spine surgery ≥ 6 cm BP VAS with or without leg pain SCS candidate per approved labeling* Stable pain medication regime.
Exclusion
Previous lumbar spine surgery Contraindications for SCS Mechanical spine instability



* Indications including degenerative disc disease or herniated discs refractory to conservative and surgical interventions or patients with radicular pain syndrome.

DISCUSSION AND CONCLUSIONS

- This RCT demonstrated the long-term superior efficacy of DTM SCS relative to Conv-SCS for treating neuropathic CLBP in PSPS-T1 patients who were not eligible for spine surgery.
- Significant clinical improvements in functional disability and quality of life provided by DTM SCS were sustained over the study period.
- The results of this RCT indicate that DTM SCS provides significant benefits on the management of PSPS-T1 patients who are not eligible for spine surgery, including those who were not treated satisfactorily by Conventional SCS.
- **CONCLUSION: DTM SCS is efficacious for treatment of CLBP and leg pain in PSPS-T1 patients not eligible for spine surgery.**

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*error bars represent 95% confidence intervals
**error bars represent standard error
***p < 0.0001

1. Fishman M, Cordner H, Justiz R, Provenzano D, Merrell C, Shah B, et al. Pain Pract. 2021 Nov;21(8):912-923.
2. Kallewaard JM, Billet B, Van Paesschen R, Smet I, Mendiola A., Peña I, et al. NANS Annual Meeting. 18-21 Jan 2024. Las Vegas, NV, USA.