

DTM™ SCS for Indicated Chronic Back Pain Patients Refractory to 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
- 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.

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

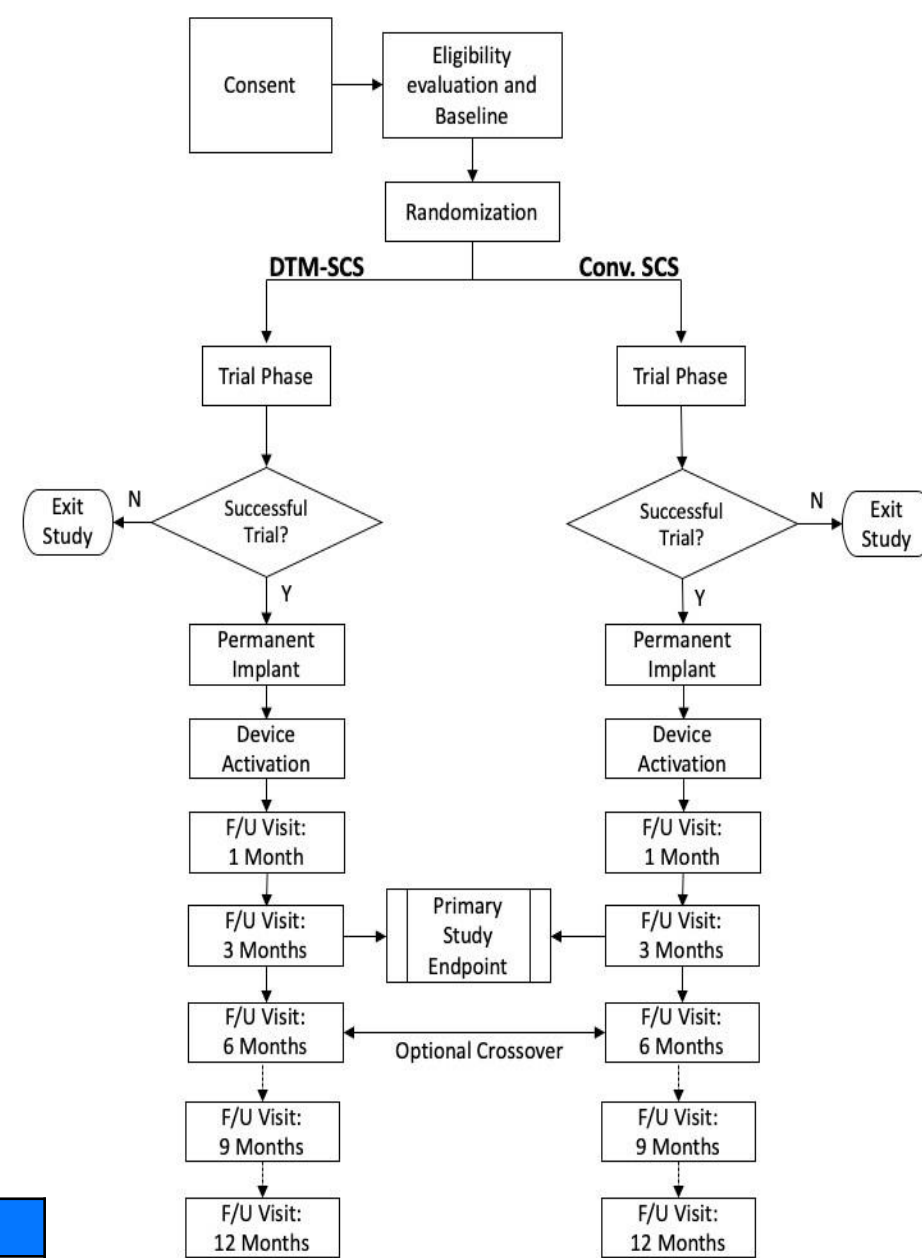
- Responder rate (≥ 50% CLBP relief) at 3-months

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.

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%)

Statistically superior CLBP and leg pain relief with DTM SCS compared to Conventional SCS at all timepoints (p < 0.0001).

Figure 1. CLBP Responder Rates (mITT)*

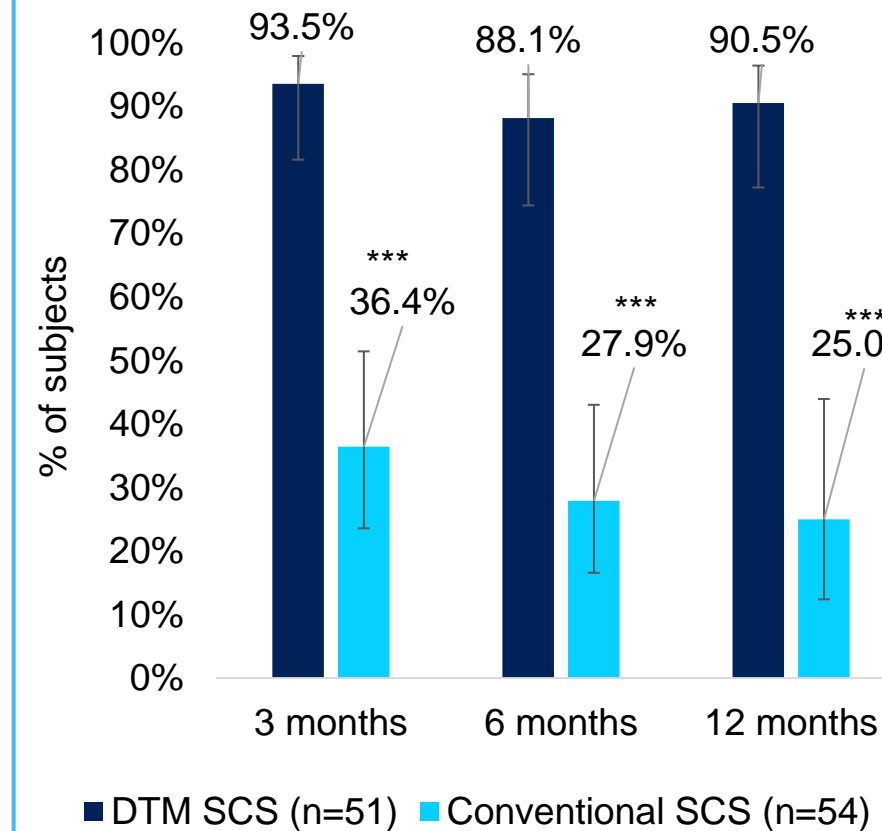


Figure 2. CLBP VAS Scores (mITT)**

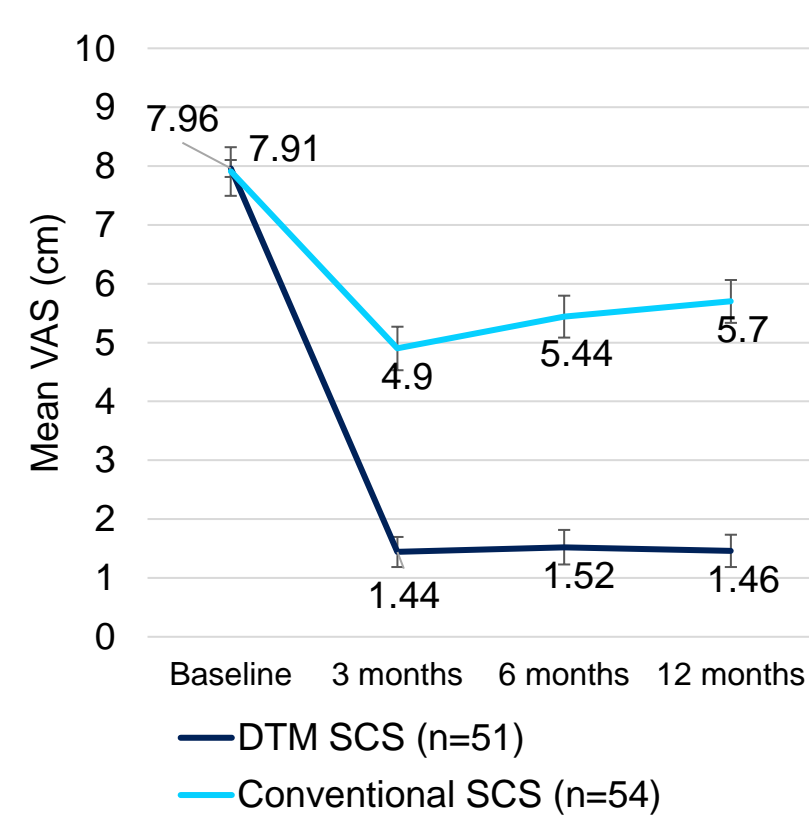


Figure 3. Leg Pain Responder Rates (mITT)*

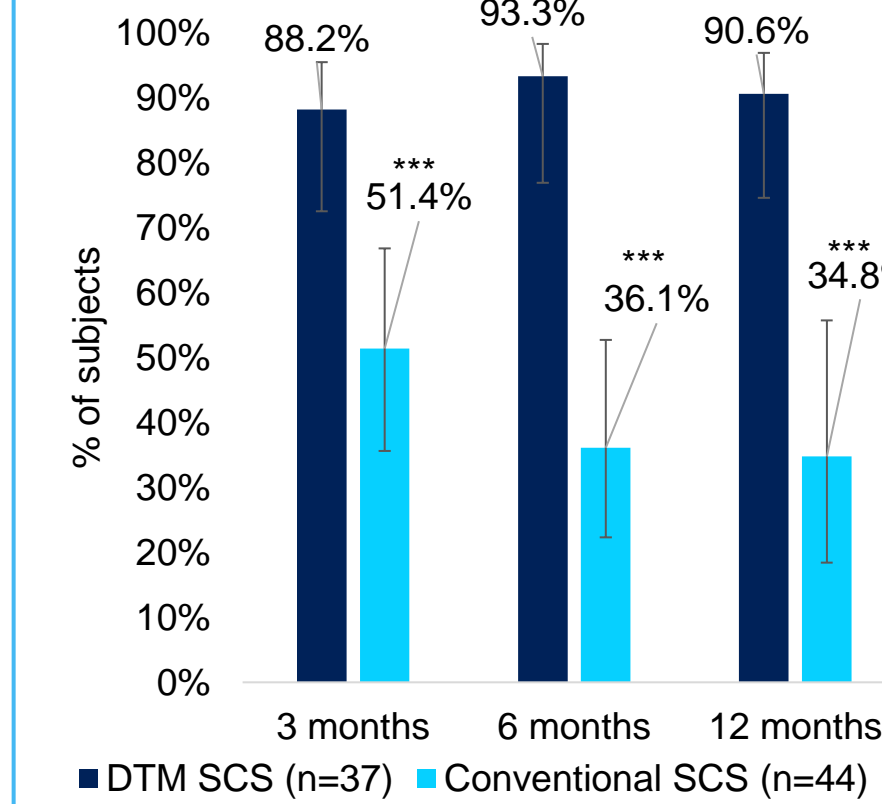
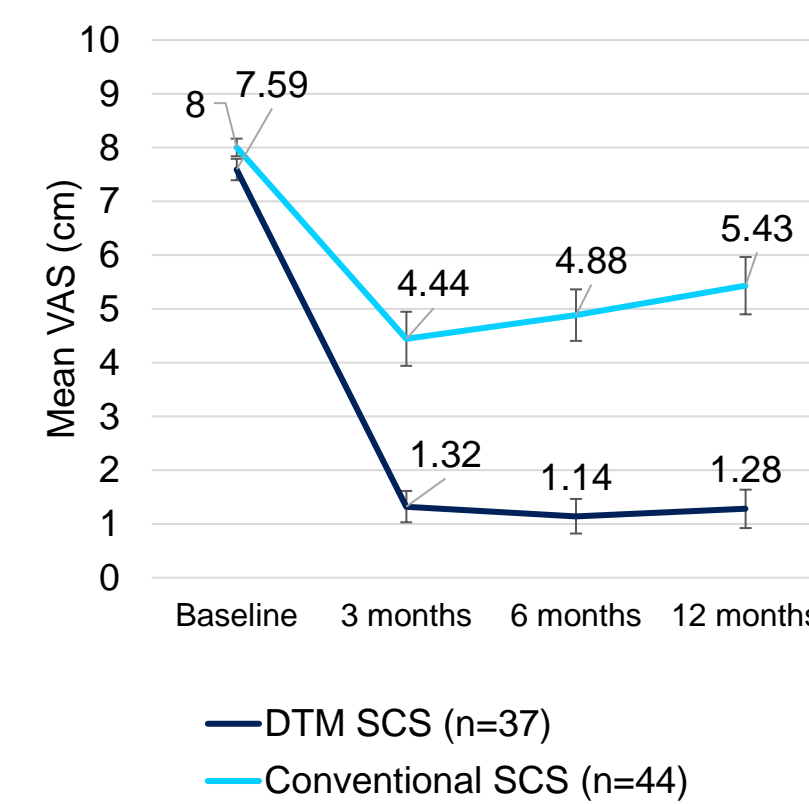


Figure 4. Leg Pain VAS Scores (mITT)**



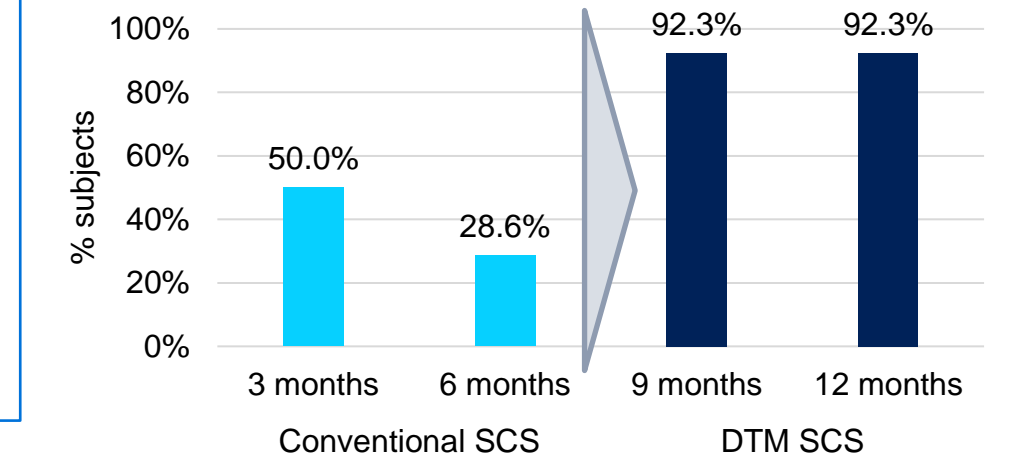
Responder Rate: ≥50% relief

RESULTS

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)*



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

Figure 6. ODI Scores (mITT)

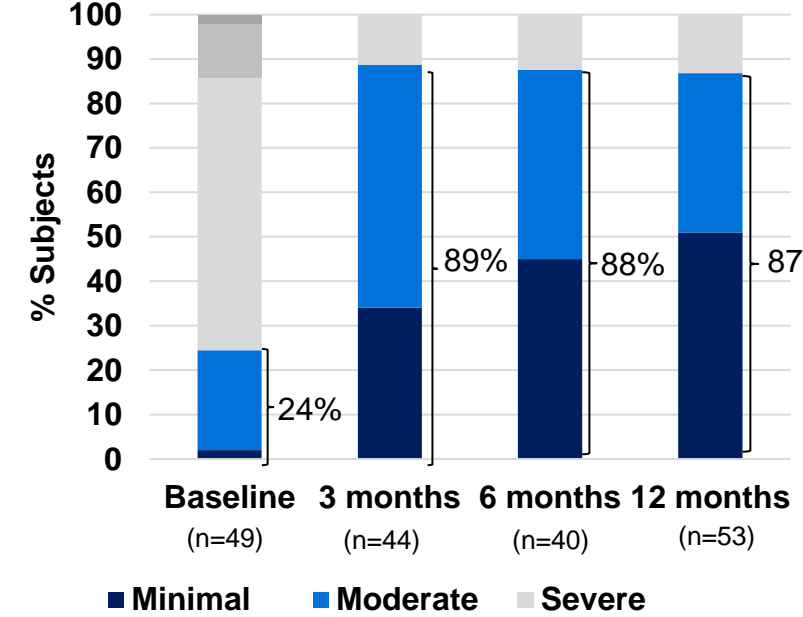


Figure 7. EQ5D-Index (PP)**

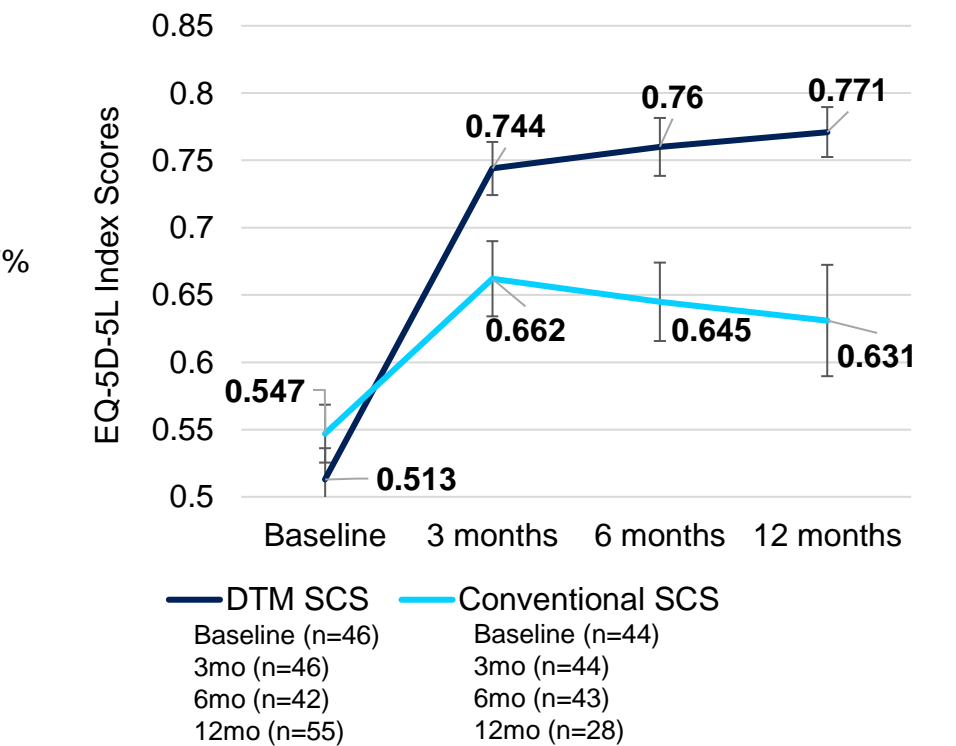
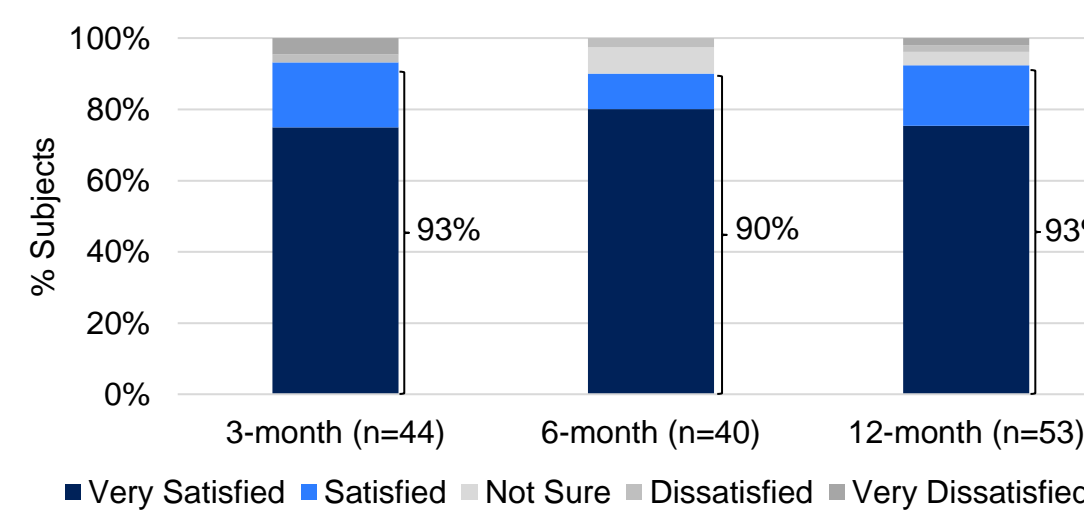


Figure 8. Subject Satisfaction (PP)



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

DISCUSSION

- 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 Conv-SCS.

*error bars represent 95% confidence intervals

**error bars represent standard error

***p < 0.0001

2024 NANS ANNUAL MEETING

