

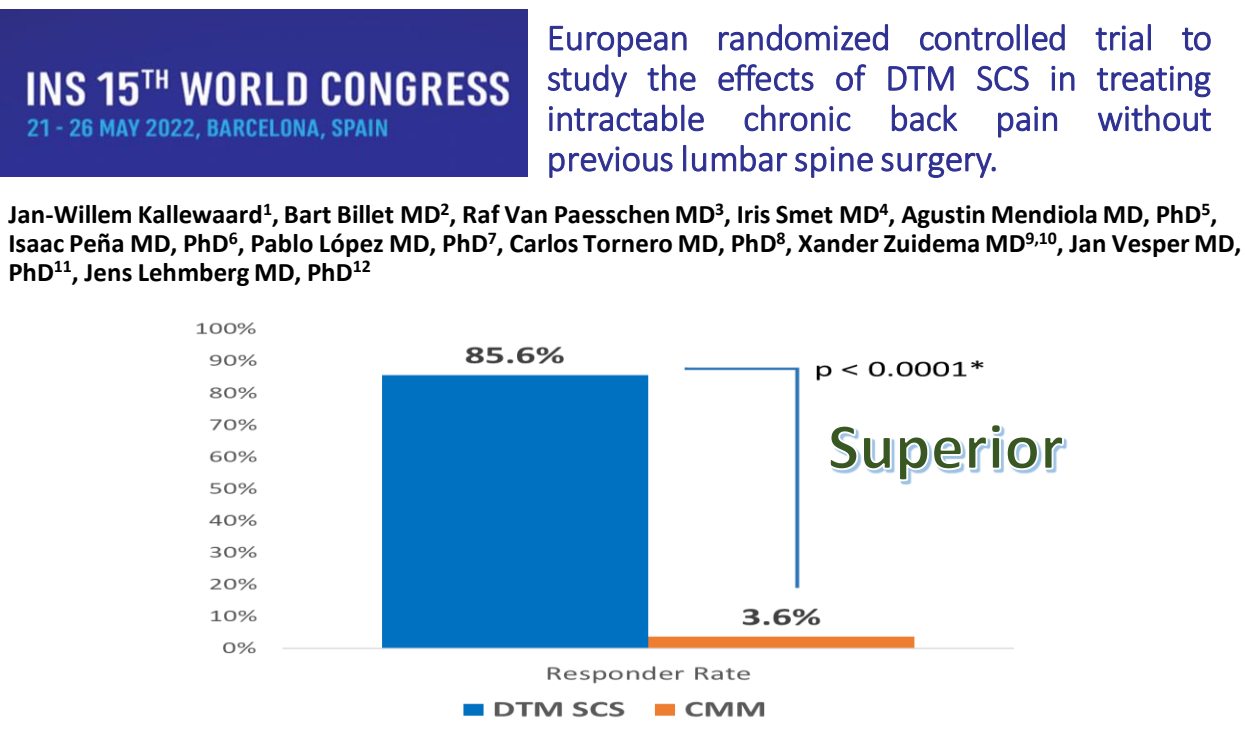
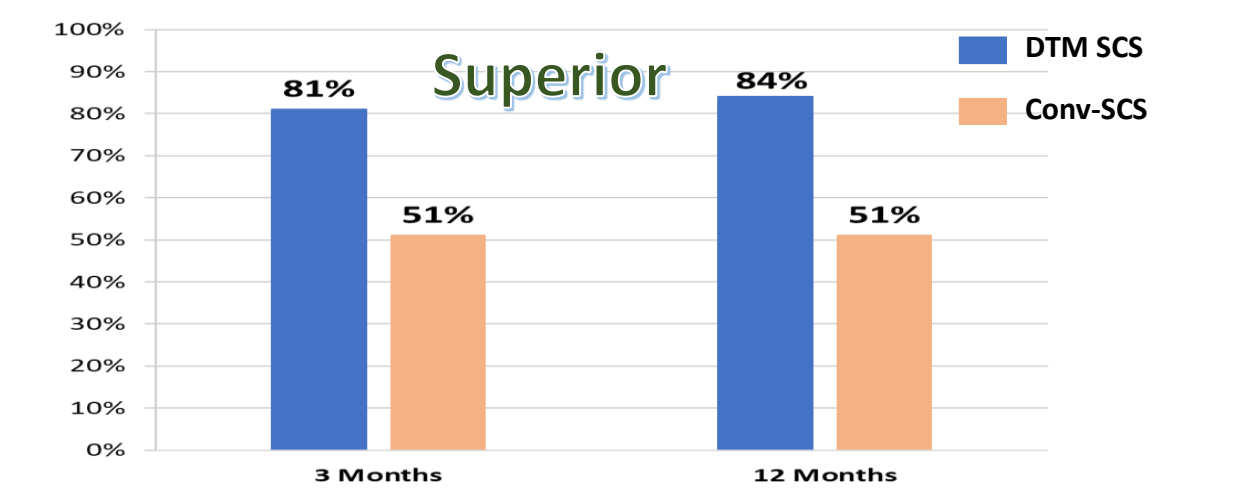
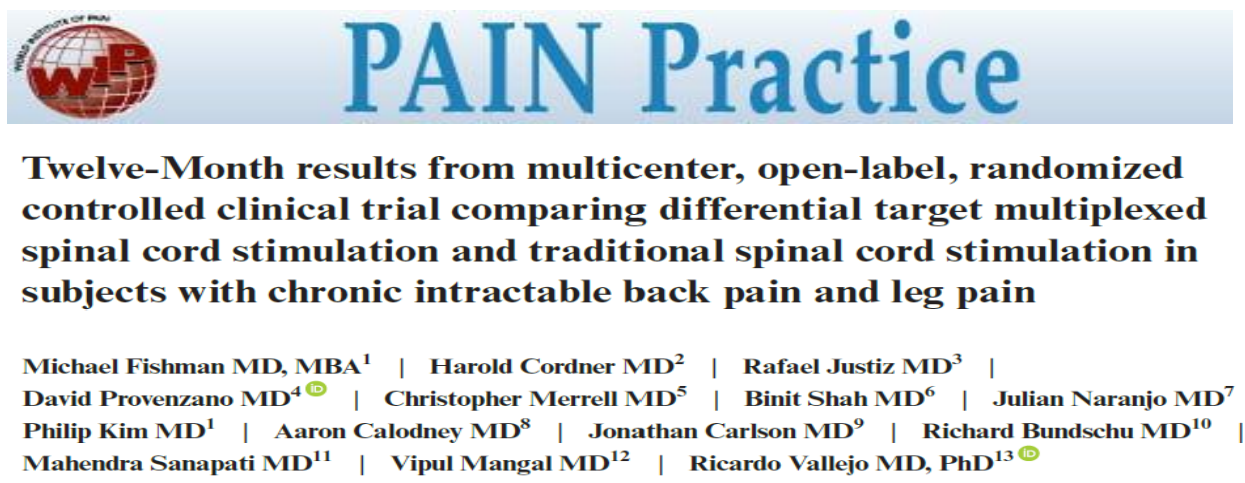
DTM™ SCS for Indicated Chronic Back Pain Patients Non-Eligible for Spine Surgery: US RCT Outcomes

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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). 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. The current work presents a RCT that evaluated, for the first time, the efficacy of DTM SCS versus Conventional SCS (Conv-SCS) on PSPS-T1 patients with chronic LBP who are not candidates for spine surgery across the USA.



MATERIALS AND METHODS

Design

Prospective Post-Market, Multi Center, Randomized Controlled

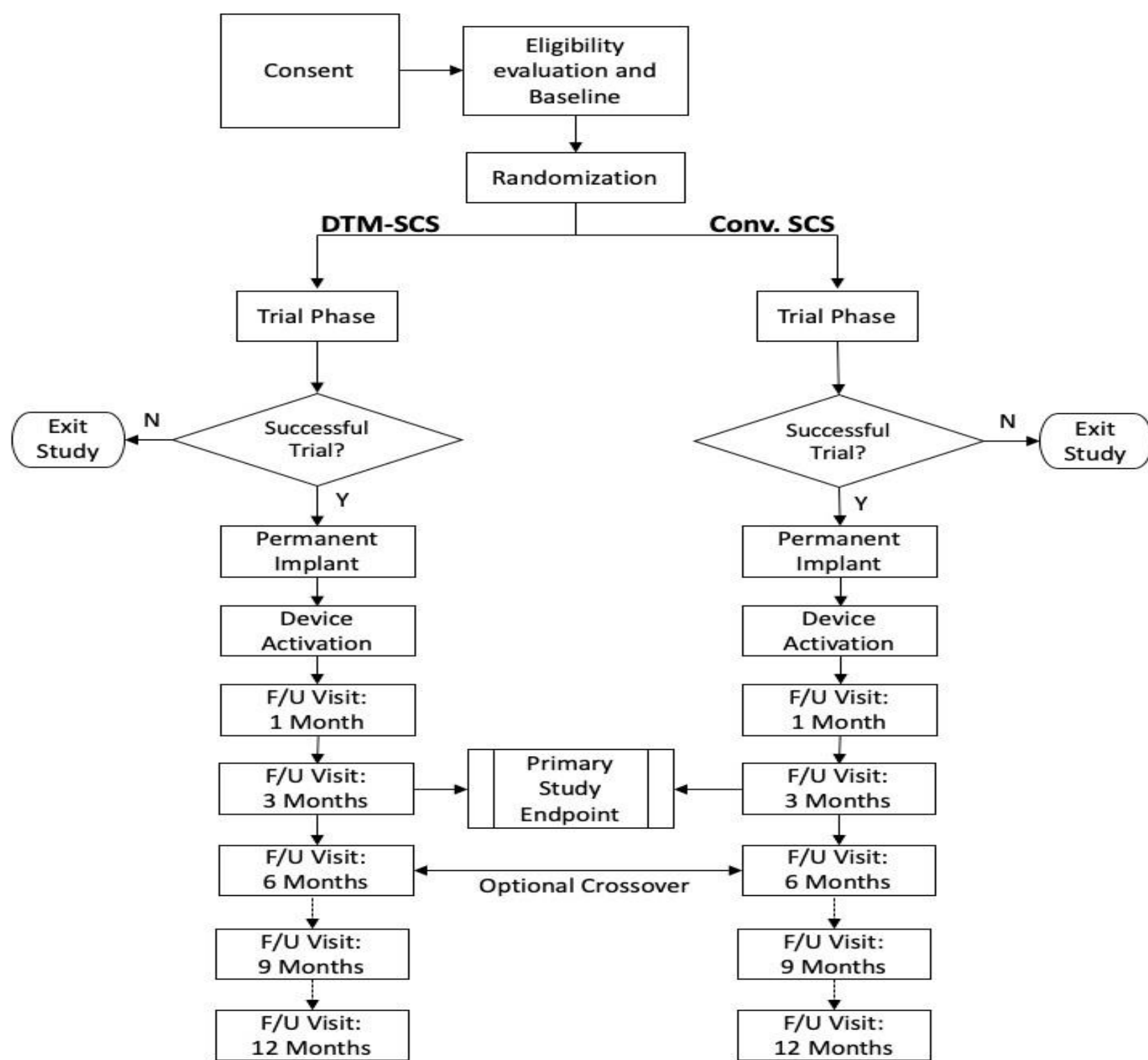
- On-label subjects indicated for SCS: CLBP and Leg Pain
- Randomized (1:1) across 20 US Sites
- DTM™ SCS vs Conv-SCS
- Option to crossover at 6-month

Primary endpoint

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

Analysis population

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



MATERIALS AND METHODS

Table 1. Key Eligibility Criteria.

Inclusion	Exclusion
Adult subjects Non-eligible for spine surgery ≥ 6 cm CLBP VAS with or without leg pain SCS candidate per approved labeling* Stable pain medication regime.	Previous lumbar spine surgery Contraindications for SCS Mechanical spine instability
* Indications included degenerative disc disease or herniated discs refractory to conservative and surgical interventions or patients with radicular pain syndrome.	

RESULTS

Table 2. Baseline Demographics and Pain Etiology for the mITT population.

	DTM SCS (N=51)	Conv-SCS (N=54)	Pain Etiology n (%)	DTM SCS N=51	Conv-SCS (N=54)
Age (SD)	62.9 (13.5)	59.6 (12.1)	Radiculopathy	45 (88.2%)	46 (85.2%)
Sex	56.9% F	61.1% F	Degenerative Disc Disease	38 (74.5%)	42 (77.8%)
Years w/ pain (SD)	9.5 (8.0)	9.4 (8.4)	Spondylosis	35 (68.6%)	40 (74.1%)
Baseline CLBP (SD)	7.9 (1.0)	8.0 (1.1)	Mild/Moderate Spinal Stenosis	27 (52.9%)	19 (35.2%)
Baseline leg pain (SD)	6.7 (2.4)	7.8 (1.6)	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%)

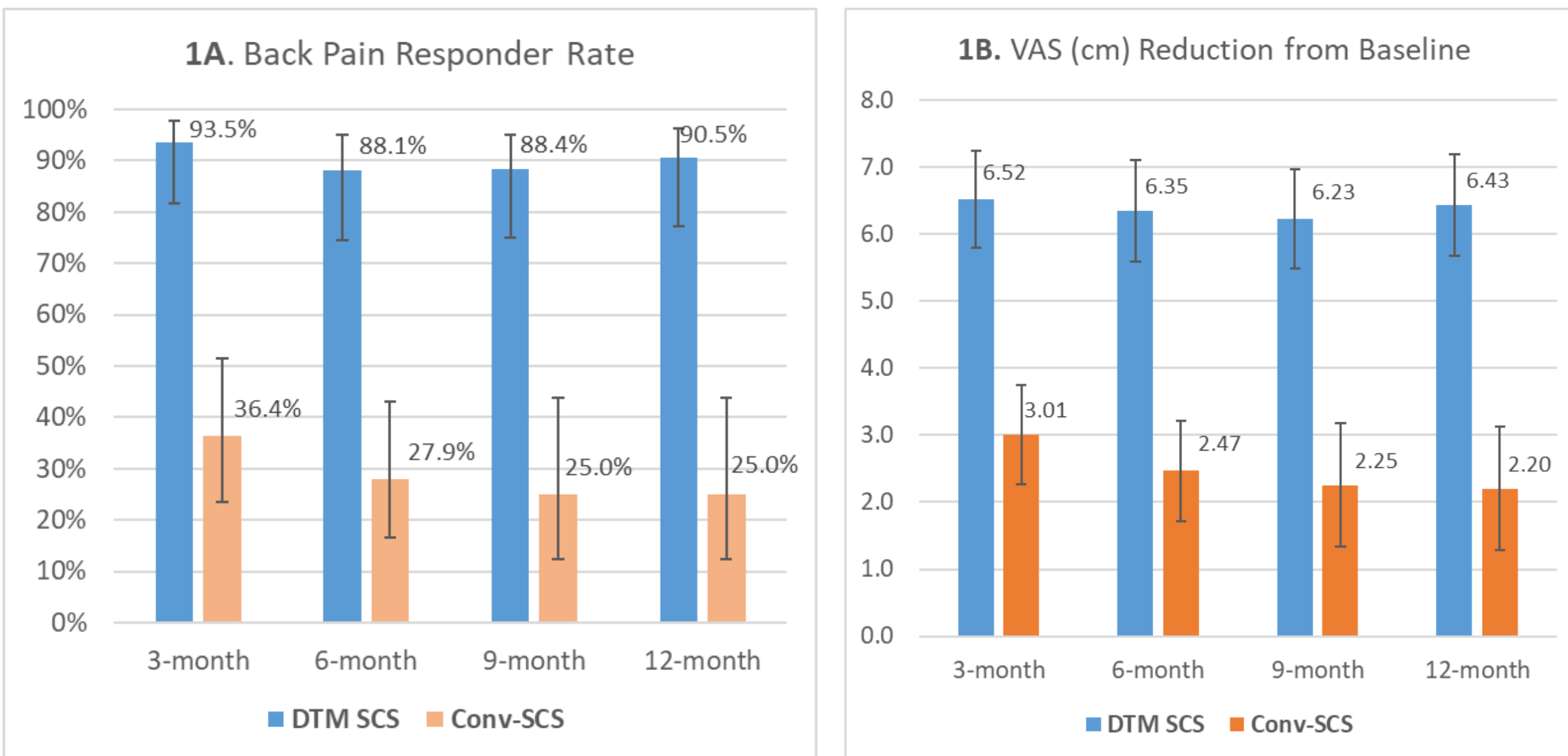


Figure 1. A. CLBP responder rate (≥50% pain relief). **B.** CLBP VAS reduction from baseline. Results from mITT population. Error bars are 95%CI. DTM SCS was superior to Conv-SCS at all timepoints (P < 0.0001).

RESULTS

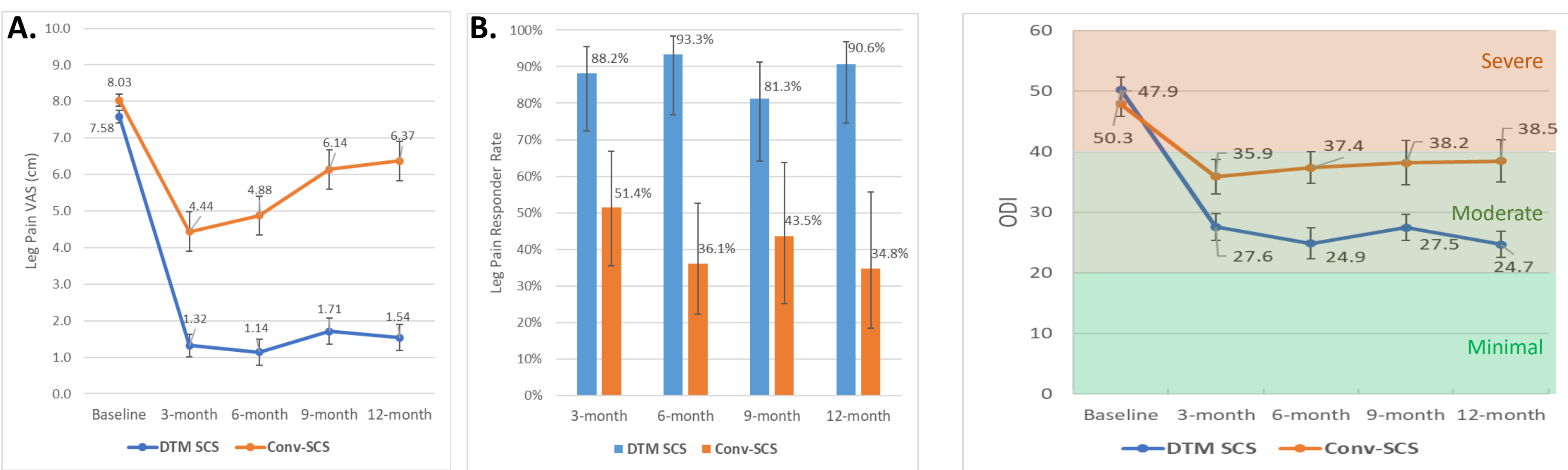


Figure 2. A. Leg pain VAS. **B.** Leg pain responder rate (≥50% pain relief). From mITT populations with basal leg pain ≥5 cm. Error bars are SE for VAS and 95%CI for responder rate.

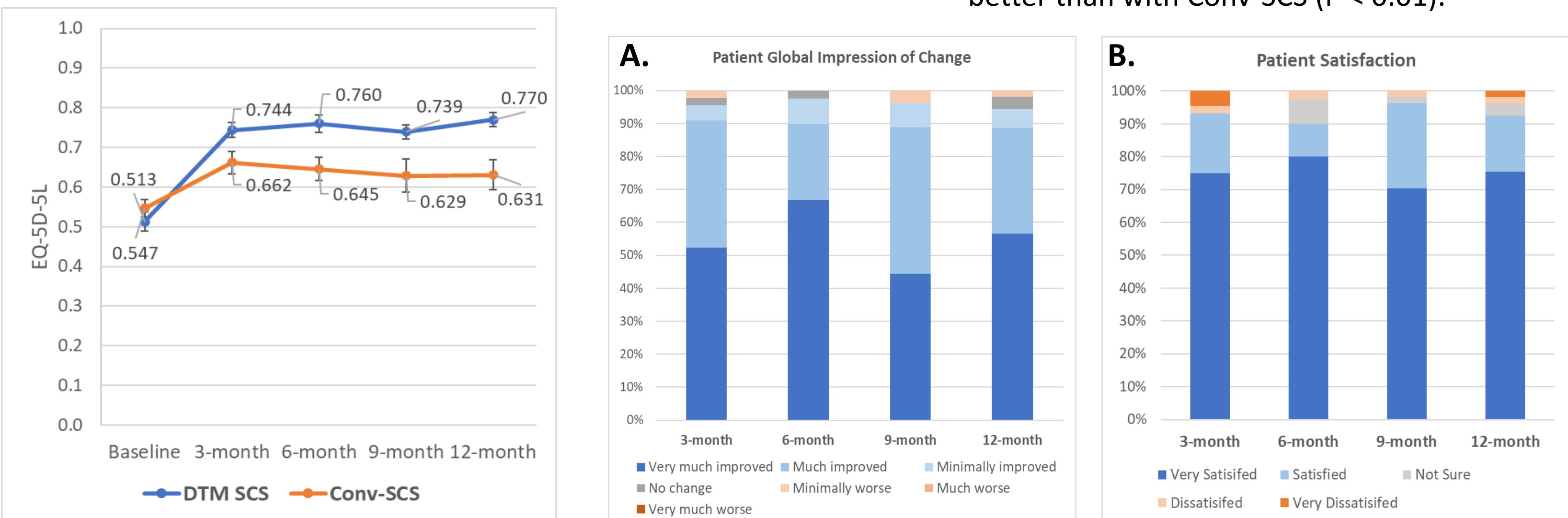


Figure 4. EQ-5D-5L index from PP populations. Error bars are SE.

Figure 5. A. PGIC and **B.** Patient satisfaction. From PP populations.

Safety. There were 28 study-related AEs in 20 (16.5%) subjects. 15 were procedure related and 7 were device related. There were 4 SAEs reported in 3 (2.5%) subjects. None were deaths. No AE was unanticipated.

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.

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