A RANDOMIZED CONTROLLED CLINICAL TRIAL COMPARING THE EFFECTS OF DIFFERENTIAL TARGET MULTIPLEXED™ SCS AND TRADITIONAL SCS IN TREATING INTRACTABLE CHRONIC LOW BACK AND LEG PAIN

M. Fishman[1], H. Cordner[2], R. Justiz[3], D. Provenzano[4], B. Shah[5], C. Merrell[6], J. Naranjo[7], F. Riillo[8], R. Vallejo[9], D.L. Cedeño[10]

[1]Center for Interventional Pain and Spine, Exton, PA, United States, [2]Florida Pain Management Specialists, Sebastian, FL, United States, [3]Oklahoma Pain Physicians, Oklahoma City, OK, United States, [4]Pain Diagnostics and Interventional Care, Sewickley, PA, United States, [5]Carolinas Pain Center, Huntersville, NC., United States, [6]Low Country Orthopaedics, Charleston, SC, United States, [7]South Florida Clinical Research, South Florida, FL, United States, [8]Medtronic, Rome, Italy, [9]National Spine and Pain Centers, Bloomington, IL, United States, [10]SGX Medical, Bloomington, IL, United States

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INTRODUCTION

Spinal cord stimulation (SCS) is a treatment for chronic low back pain (LBP) relief. DTM™ SCS is a SCS programming approach inspired from science where electrical signals are multiplexed spatially and temporally. In preclinical studies DTM™ SCS showed the ability of differentially modulating neurons and glial cells to balance interactions perturbed by neuropathic pain.[1] A feasibility study of DTM™ SCS demonstrated a responder rate of 80% for back pain with 85% of subjects preferring DTM™ SCS to conventional SCS therapy[2]. This large randomized controlled trial (RCT) evaluated the efficacy and safety of DTM™ SCS compared to conventional SCS over a 12-month follow-up period.

MATERIALS & METHODS

This was a prospective, multicenter, randomized, open-label, post-market study comparing DTM™ SCS programming to conventional SCS in patients suffering from chronic, intractable pain in the low back and legs. The study was IRB approved and registered on clinicaltrials.gov. Subjects that reported Visual Analog Scores (VAS) of ≥5 in low back pain (LBP) with moderate to severe leg pain at Baseline were enrolled.

Informed and consented subjects meeting eligibility criteria were randomized 1:1 to either of the two treatment groups in a parallel assignment. Subjects underwent a SCS trial, per labeling. Subjects that reported ≥50% improvement in LBP relative to baseline during the trial phase were implanted with a rechargeable neurostimulator (Intellis™, Medtronic). Evaluation visits occurred at 1-, 3-, 6-, and 12-months post device activation.

The primary outcome was percentage of responders (subjects with ≥50% LBP relief) to therapy at 3 months after activation of the implanted SCS system. Additional outcomes included changes in leg pain, satisfaction, extent of disability, quality of life, and safety data.

RESULTS

Demographics

A total of 116 subjects completed the trial phase (58 in each arm), 94 subjects were implanted (47 in each arm), 92 subjects completed 3-month visits (46 in each arm), and 79 subjects completed 12-month visits (42 in DTM arm and 37 in control arm). Demographics for all randomized subjects (N=128) are detailed in Table 1.

Table 1. Baseline Demographics (N=128)

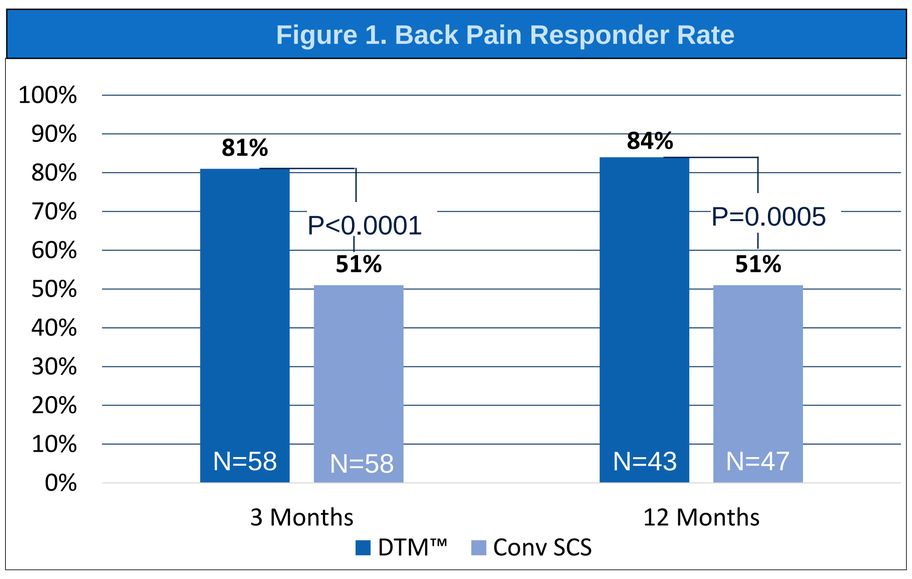
	DTM™ SCS Arm (N=67)	Conventional SCS Arm (N=61)	P-value
Mean Age (SD)	61.28 (12.16)	60.66 (11.77)	0.7675
Sex	50.7% F / 49.3% M	55.7% F / 44.3% M	0.5988
Year of pain onset (SD)	12.64 (13.05)	12.89 (11.25)	0.9106
Mean number of prior surgeries (SD)	1.49 (1.33)	1.41 (1.13)	0.7067
Baseline back pain (SD)	7.25 (1.49)	7.35 (1.26)	0.6707
Baseline leg pain (SD)	6.20 (2.58)	6.58 (2.06)	0.3576

There were no statistically significant differences between the two treatment groups with respect to gender, age, baseline back pain VAS, baseline leg pain VAS, approximate number of years since the onset of symptoms, or the number of previous spine surgeries.

Back Pain Responder Rate

Responder Rate is defined as proportion of subjects who had ≥ 50% pain relief from baseline. The study met the primary endpoint as DTM™ SCS therapy demonstrated non-inferiority to conventional SCS at 3-month (81% and 51%, respectively). Furthermore, DTM™ SCS superiority to conventional SCS was established both at 3- and 12-months (Figure 1).

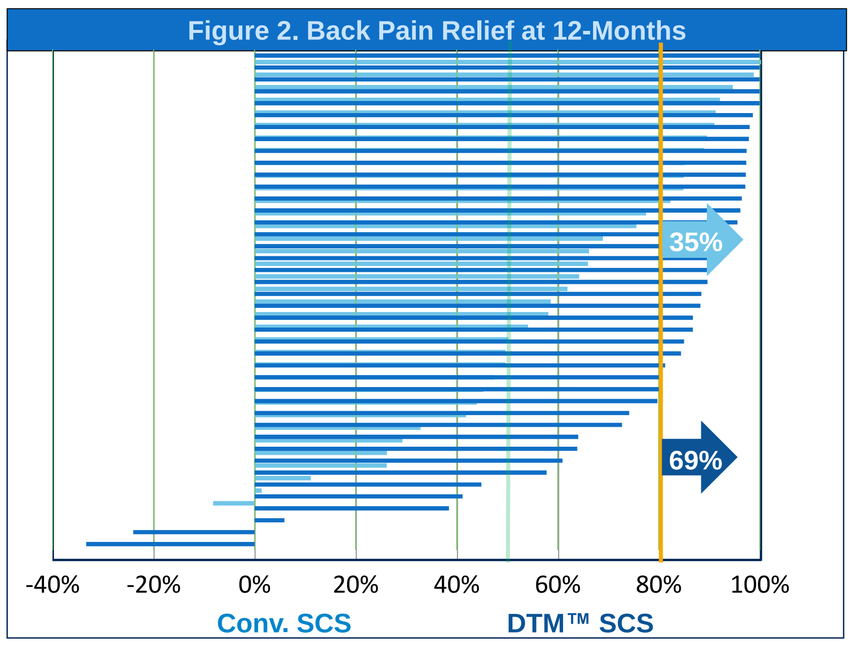
Figure 1. Back Pain Responder Rate



Profound Back Pain Responder Rate

Profound Responder Rate is defined as ≥ 80% pain relief from baseline. Profound back pain responder rate at 12-month was 69% with DTM™ SCS and 35% with conventional SCS.

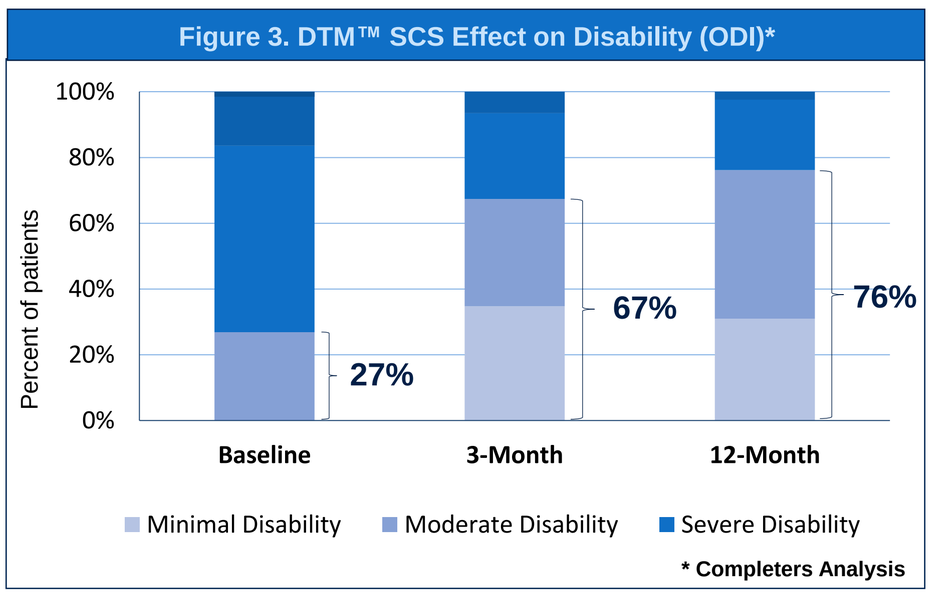
Figure 2. Back Pain Relief at 12-Months



Change in Oswestry Disability Index (ODI)

76% of subjects had minimal to moderate disability with DTM™ SCS at 12-month visit (Figure 3).

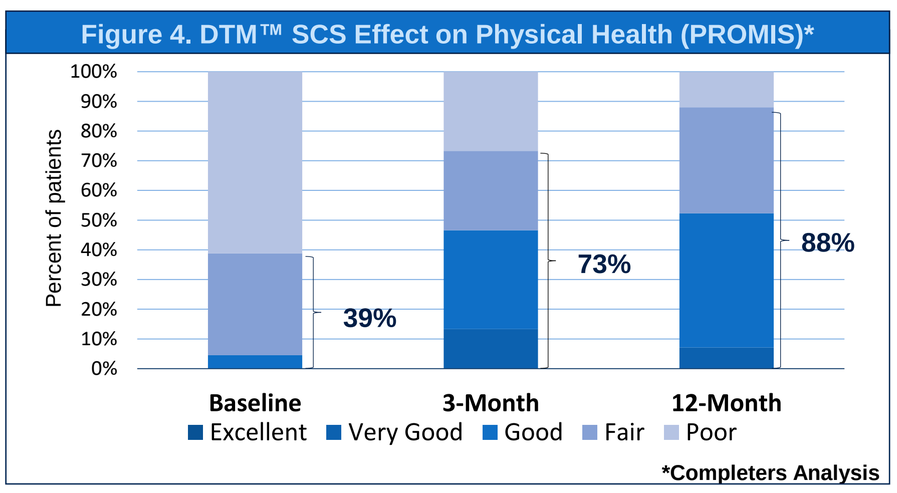
Figure 3. DTM™ SCS Effect on Disability (ODI)*



Change in Physical Health (PROMIS)

88% of subjects communicated their quality of life as being excellent, very good, good, or fair with DTM™ SCS at the 12-month follow-up visit (Figure 4).

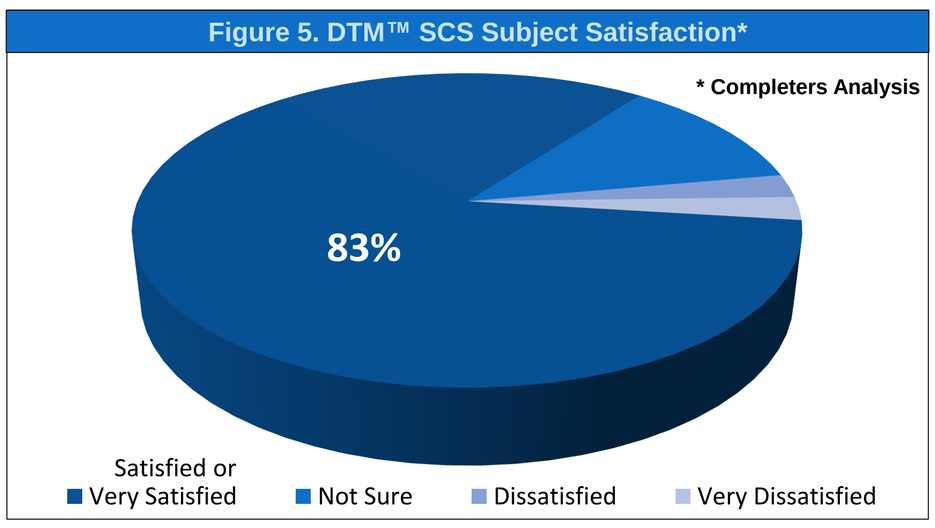
Figure 4. DTM™ SCS Effect on Physical Health (PROMIS)*



Subject Satisfaction

83% of subjects were “Satisfied” or “Very Satisfied” with DTM™ SCS at 12-month follow-up visit (Figure 5).

Figure 5. DTM™ SCS Subject Satisfaction*



CONCLUSIONS

This study demonstrated that DTM™ SCS and conventional SCS can offer LBP relief, however DTM™ SCS provided superior LBP responder rate and benefits in other clinically meaningful outcomes.

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DISCLOSURE

This study was sponsored by Stimgenics, which was acquired by Medtronic.