Effect of Differential Target Multiplexed™ SCS on Intractable Upper Limb Pain: A 12-month Prospective Study

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INTRODUCTION

- Radicular upper limb pain (ULP) is a common chronic condition.
- Although conventional paresthesia-based spinal cord stimulation (SCS) could be a suitable treatment when conventional medical management of ULP fails, its clinical implementation has been limited due to the possible occurrence of uncomfortable paresthesia triggered by neck motion.
- Differential target multiplexed™ SCS (DTM™ SCS) has proven successful for the treatment of low back and lower limb pain.
- This study evaluated, during a 12-month follow up period, the safety and efficacy of DTM SCS in subjects with chronic ULP.

MATERIALS & METHODS

Design

Post-market, prospective, cohort, multicenter study. On-label subjects indicated for SCS*: Upper Limb Pain (ULP)

- Single arm at 11 US Sites
- Follow up to 12-month

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

Other Outcomes: ULP VAS, pain disability index (PDI), PGIC, satisfaction, frequency of study-related AEs

Analysis populations

- TPC: Trial Phase completers
- PP: subjects implanted who completed visits

Table 1. Key Inclusion & Exclusion Criteria

Inclusion
Adult (≥18 y/o) ULP level ≥5 cm VAS-10 Candidate for SCS as per indication* Stable pain medication
Exclusion
Contraindications for SCS system Conditions that could interfere with evaluation of treatment Active implanted device Cervical stenosis, Facet spondylosis, Mechanical instability as primary indication Previous posterior laminectomy

*For example: Radicular pain syndrome or radiculopathies resulting in pain secondary to surgery or herniated disk.

RESULTS

Table 2. Baseline Demographics (TPC)

	TPC (N=52)
Age (SD)	55.9 (11.3)
Sex	71.2% F
Years w/ ULP (SD)	9.7 (8.1)
ULP Uni or Bilateral (U/B)	16 (30.8%) / 36 (69.2%)
Baseline ULP VAS (SD)	7.3 (1.2)

Table 3. Enrolled Subject Pain Etiologies (TPC)

Pain Etiology N (%)	TPC (N=52)
Radiculopathy	45 (86.5%)
Degenerative Disc Disease	32 (61.5%)
Spondylosis	32 (61.5%)
Cervicalgia	27 (51.9%)
Mild/Moderate Spinal Stenosis	22 (42.3%)
Spondylolisthesis	6 (11.5%)
Internal disc disruption / Annular tear	1 (1.9%)
Other neuropathic pain	6 (11.5%)
Radiculopathy	45 (86.5%)

86% ULP responder rate (≥50% ULP relief) and 79.7% reduction in baseline VAS at 12-months with DTM SCS

Figure 1. ULP Responder Rates (TPC)*

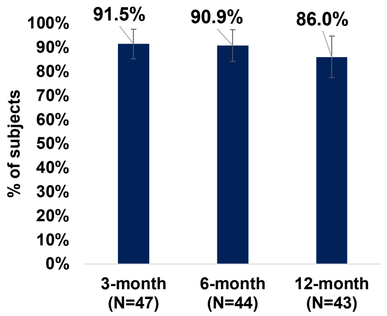


Figure 2. ULP VAS Scores (TPC)**

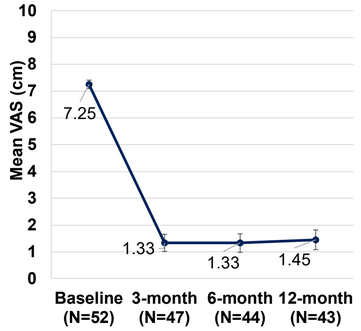
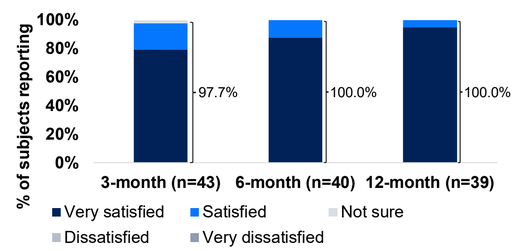


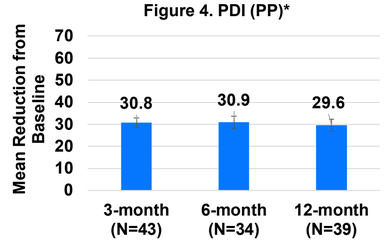
Figure 3. Subject Satisfaction (PP)



100% of subjects reported being satisfied or very satisfied with DTM SCS at 12 months.

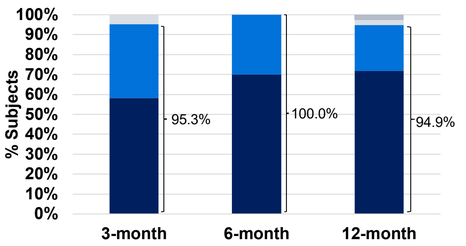
RESULTS

Figure 4. PDI (PP)*



29.6-point reduction in Pain Disability Index (PDI) scores from a baseline value of 44.1 at 12-months with DTM SCS.

Figure 5. PGIC (PP)



94.9% of subjects reported feeling much improved or very much improved with DTM SCS at 12-months

Table 4. Summary of Study-Related Adverse Events (AEs)

	Number of AEs	Number (%) of Subjects with AE (out of 58)
All study-related AEs	16	15 (25.9%)
Procedure-related	11	10 (17.2%)
Device-related	2	2 (3.4%)
Other study-related	3	3 (5.2%)
SAEs	1[a]	1 (1.7%)

a. Spinal cord bruising.

DISCUSSION

- DTM SCS provided sustained ULP responder rates ≥ 86%.
- DTM SCS also provided pain relief above 78%.
- Pain outcomes corresponded to improvement in disability of ~ 30 points (PDI), as well as >90% of patients feeling improved and satisfied with DTM SCS.
- Results imply that DTM SCS is a safe, feasible and sustainable treatment for chronic intractable ULP.

*error bars represent 95% confidence intervals
**error bars represent standard error

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