DIFFERENTIAL TARGET MULTIPLEXED SCS FOR INTRACTABLE UPPER LIMB PAIN: RESULTS FROM 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.
- **OBJECTIVE: This study evaluated, during a 12-month follow up period, the safety and efficacy of DTM SCS in subjects with chronic ULP.**

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%)

86% ULP responder rate (≥50% ULP relief) and ~80% reduction in ULP and neck pain VAS at 12 months.

Figure 1. ULP Responder Rates (TPC)††

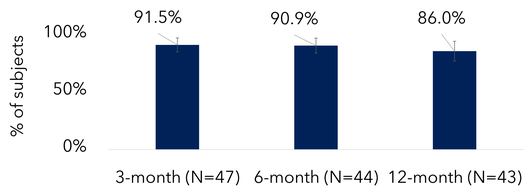
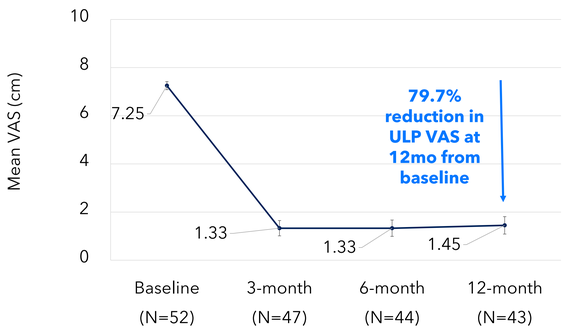
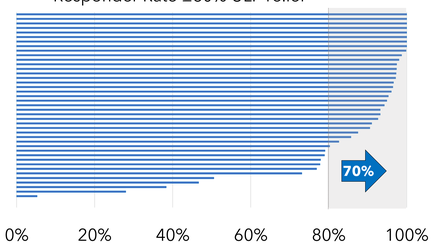


Figure 2. ULP VAS Scores (TPC)†††



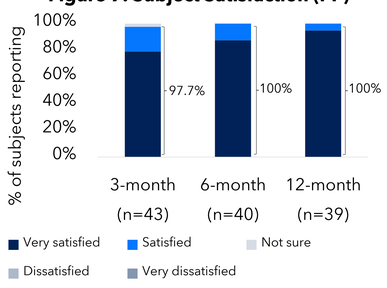
7 out of 10 patients were profound responders with DTM SCS at 12 months

Figure 5. Profound ULP Responder Rate by Subject at 12-Months (TPC, n=43)



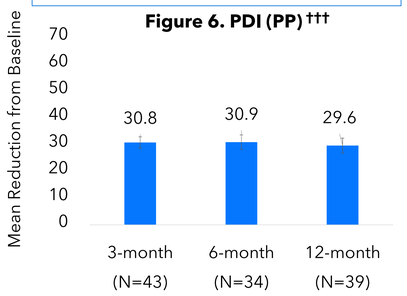
100% of subjects reported being satisfied or very satisfied with DTM SCS at 12 months.

Figure 7. Subject Satisfaction (PP)



29.6-point reduction in Pain Disability Index (PDI) scores from a baseline value of 43.3 at 12-months with DTM SCS.

Figure 6. PDI (PP)†††



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

Figure 8. PGIC (PP)

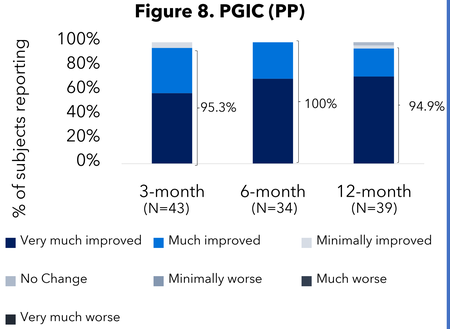


Table 4. Summary of Study-Related Adverse Events

	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††††	1 (1.7%)

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 and reason for SCS therapy
- Previous posterior laminectomy

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

DISCUSSION AND CONCLUSIONS

- 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.
- **CONCLUSION: Results imply that DTM SCS is a safe, feasible and sustainable treatment for chronic intractable ULP.**

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†pain etiologies in medical history; not necessarily primary indication for SCS
††error bars represent 95% confidence intervals
†††error bars represent standard error
††††spinal cord bruising.

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