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## CHARACTERIZATION OF NON-SURGICAL BACK PAIN WITHIN THE DIFFERENTIAL TARGET MULTIPLEXED SCS RANDOMIZED CONTROLLED STUDY

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### Introduction

Differential Target Multiplexed Spinal Cord Stimulation (DTM SCS) uses an approach in which electrical signals are multiplexed spatially and temporally. This was inspired from preclinical research demonstrating that multiplexed signals can differentially modulate neurons and glial cells to balance interactions that have been perturbed by neuropathic pain [1,2]. A multicenter, prospective, randomized controlled trial evaluated the effectiveness of differential target multiplexed SCS (DTM SCS) compared to traditional SCS for the treatment of chronic pain of the trunk and/or limbs. Back pain responder rate ( $\geq 50\%$  relief) of 80% with DTM SCS at the primary endpoint (3-month) was superior to the back-pain responder rate of traditional SCS (51%) [3]. Following the RCT, there has been interest to examine the demographics and low back pain (LBP) relief characteristics for the subset of patients without previous spinal surgery.

### Materials and Methods

The study was a prospective, multicenter, post-market, randomized, controlled trial (RCT) comparing DTM SCS to traditional SCS in patients with chronic intractable LBP and leg pain. Key inclusion criteria: Adult subjects,  $\geq 5$  cm VAS in LBP with moderate to severe leg pain, candidate for SCS under a stable pain medication regime. Key exclusion criteria: Other active implants, contraindications for SCS, mechanical spine instability. Consented and eligible subjects (LBP  $\geq 5$  and moderate to severe leg pain) were randomized across 12 centers in the US. The study was approved by the Western Institutional Review Board and registered in ClinicalTrials.gov. A post hoc analysis was performed for subjects who had not undergone previous spinal surgery.

### Results/Case Report

Of the 128 randomized subjects to the study there were no statistically significant differences between the treatment groups with respect to gender, age, baseline LBP and leg pain VAS, number of years since the onset of symptoms, or the number of spine surgeries. Among the 128 randomized subjects there were 28 (21.9%) without prior spinal surgery, 16 (23.9%) in the DTM-SCS arm and 12 (19.7%) in the traditional SCS arm. Baseline demographics and characteristics were also similar between the patient subsets. For example, mean age was 62.3 and 62.0 years, number of years since onset of symptoms

was 10.9 and 17.8 years, and mean baseline LBP VAS scores were 7.83 and 7.39 cm, for DTM SCS and traditional SCS, respectively. Mean LBP scores for DTM-SCS patients (n = 12) at 1-, 3-, 6, and 12-months were 1.17, 1.47, 1.55, and 1.22 cm. Mean LBP scores for traditional SCS patients (n = 8) at 1-, 3-, 6, months and 7 patients at 12 months were 3.46, 2.53, 2.76, and 2.14 cm. Eleven out of 12 patients in the DTM-SCS group were identified as responders ( $\geq 50\%$  LBP relief) at 3-, 6-, and 12-months. Responders in the traditional SCS group were 6 out of 8, 5 out of 8, and 5 out of 7 at 3-, 6-, and 12- months.

## Discussion

An RCT demonstrated that DTM SCS provided a superior back pain responder rate to traditional SCS for the treatment of chronic pain of the trunk and/or limbs. For a subset of subjects with no previous surgery, improvements in pain scores ( $\sim 6.5$  cm for DTM SCS and  $\sim 4.5$  cm for traditional SCS) were substantial and sustained out to 12 months post-implant. Despite the limited sample size in the current analysis, the trend in responder rates, with DTM SCS being better than traditional SCS, is consistent with those obtained in the overall study.

## References

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## Disclosures

Yes

## Tables / Images