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Beyond pain scores: functional outcomes from 2 RCTs on DTM SCS for chronic back pain patients ineligible for spine surgery

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Introduction

Treatment options for chronic back pain in patients ineligible for spine surgery are limited. Differential Target Multiplexed Spinal Cord Stimulation (DTM SCS) has been shown to be an effective treatment for this patient population in 3 randomized controlled trials (RCTs) [1-3] which have consistently shown responder rates greater than 80%, along with significant and durable reductions in both back and leg pain scores [1-3]. Although pain score reduction is a gold standard for assessing chronic pain clinical efficacy, functional outcomes are equally important assessments that can potentially provide a more holistic outlook on patient improvement. We assessed functional outcomes collected as part of 2 RCTs [2,3] on DTM SCS for chronic back pain in patients ineligible for spine surgery, to evaluate the validity of these outcomes for assessment of clinical improvement.

Materials and Methods

Outcomes presented were collected from 2 post-market, multicenter RCTs comparing DTM SCS for patients with chronic back pain who are ineligible for spine surgery. One RCT conducted in the United States (US) compared DTM SCS versus conventional SCS through 12-months [2], and the other conducted in Europe (EU) compared DTM SCS versus conventional medical management through 24-months [3]. Both studies were IRB approved. The primary endpoint was back pain responder rate (RR, ≥50% relief) at either 3-2 or 6-months [3]. Secondary endpoints included back and leg pain VAS, RRs, disability, health-related quality of life, therapy satisfaction, and Patient Global Impression of Change (PGIC).

Results/Case Report

112 subjects were randomized 1:1 at 12 EU sites and 121 subjects were randomized 1:1 at 20 US sites. DTM SCS demonstrated superior back pain relief to control in each study at all timepoints. Improvements in functional outcomes were also sustained with DTM SCS. A mean (standard deviation, SD) reduction of 23.3 (14.1) Oswestry Disability Index (ODI) points relative to a 47.6 (13.5) at baseline was observed at 12-months in the US RCT, and a reduction of

25.7 (18.9) ODI points relative to a 48.0 (15.4) at baseline was observed at 24-months in the EU RCT. Mean (SD) EQ-5D-5L index scores improved to 0.79 (0.11) at 12-months from 0.54 (0.14) at baseline in the US RCT, and 0.73 (0.21) at 24-months from 0.41 (0.21) at baseline in the EU RCT. Additionally, in the EU RCT mean SF-12 MCS and PCS scores improved >9 points from baseline to 24-months. More than 92% subjects reported being satisfied or very satisfied and >82% of subjects reported feeling much improved or very much improved with DTM SCS in both studies at study end. Additional outcomes including categorized ODI and EQ-5D-5L outcomes, medication usage, and correlative analyses for pain relief and functional outcomes measures will be presented at time of meeting.

Discussion

Findings from these RCTs comparing DTM SCS for the treatment of chronic back pain in patients ineligible for spine surgery demonstrate consistent improvements in both back pain VAS as well as functional outcomes including disability and quality of life. These results suggest that functional outcomes may be a good indicator of therapy success in this patient population.

References

1. Fishman M, Cordner H, Justiz R, et al. 2021. 12-Month Results from a multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain. Pain Practice, 21(8):912-923, doi:10.1111/papr.13066.
2. White T, Justiz R, Almonte W, et al. 2024. 12-Month Results from a Randomized Controlled Trial Comparing Differential Target Multiplexed Spinal Cord Stimulation and Conventional Spinal Cord Stimulation in Subjects with Chronic Refractory Axial Low Back Pain not Eligible for Spine Surgery. North American Spine Society Journal, doi:10.1016/j.xnsj.2024.100528.
3. Kallewaard JW, Billet B, Van Paesschen R, Smet I, et al. 2024. European randomized controlled trial evaluating differential target multiplexed spinal cord stimulation and conventional medical management in subjects with persistent back pain ineligible for spine surgery: 24-month results. European Journal of Pain, doi:10.1002/ejp.2306.

Disclosures

Yes

Tables / Images

Figure 1. Mean Oswestry Disability Index (ODI) Scores collected for the DTM SCS arm in the EU RCT and US RCT throughout study duration for the per-protocol analysis set. In both studies, per-protocol is defined as all implanted subjects that contributed data to the respective endpoint. Crossover subjects are included in the US RCT analysis at 9- and 12-month follow-ups. Error bars represent Standard Error. Sample sizes are as follows for the EU RCT at each timepoint: Baseline n=45, 3-months n=45, 6-months n=45, 9-months n=42, 12-months n=43, 18-months n=42, 24-months n=40. Sample sizes are as follows for the US RCT at each timepoint: Baseline n= 44, 3-months n= 44, 6-months n= 40, 9-months n= 54, 12-months n= 53.

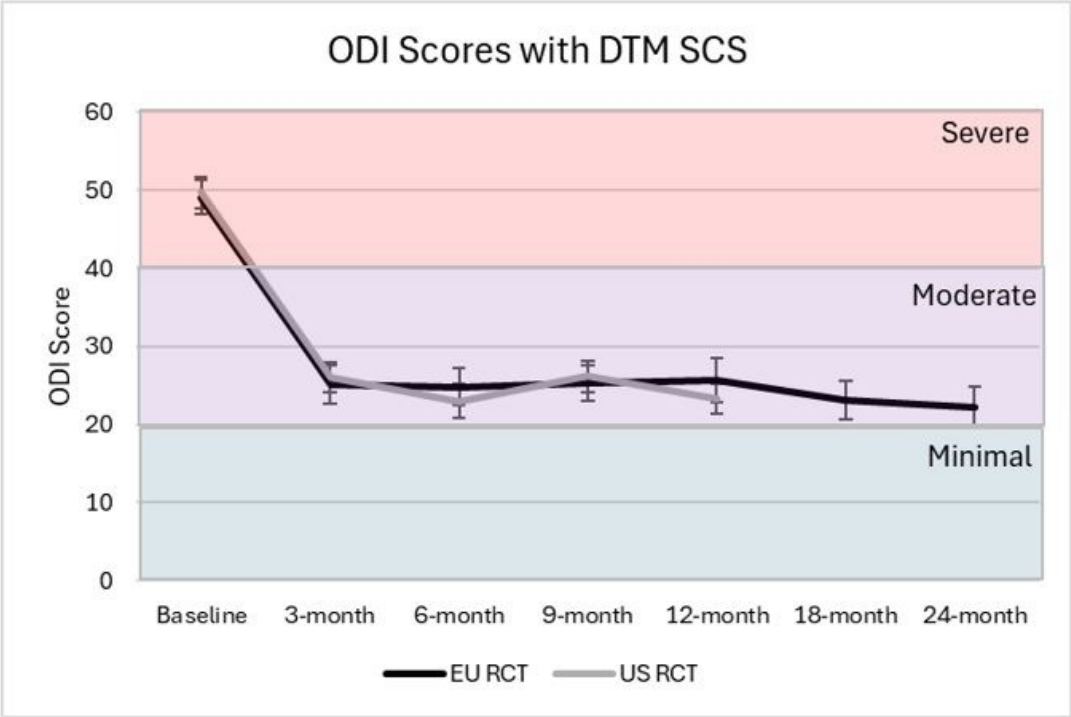

Figure 2. Mean EQ-5D-5L Index Scores collected in the EU and US RCTs throughout study duration for the per-protocol analysis set. In both studies, per-protocol is defined as all implanted subjects that contributed data to the respective endpoint. Crossover subjects are included in the US RCT analysis at 9- and 12-month follow-ups. Error bars represent Standard Error. Sample sizes are as follows for the EU RCT at each timepoint: Baseline n=45, 3-months n=45, 6-months n=45, 9-months n=42, 12-months n=43, 18-months n=42, 24-months n=40. Sample sizes are as follows for the US RCT at each timepoint: Baseline n=44, 3-months n=44, 6-months n=40, 9-months n=54, 12-months n=53.