Medtronic

Clinical Summary

PROCURA Study: DTM™ Spinal Cord Stimulation (SCS) Clinical Study

A 12-month post-market, observational clinical study to evaluate the effects of DTM™ SCS programming in treating intractable chronic upper limb pain (ULP)

Overview

On-label, multicenter, observational clinical study using DTM™ Spinal Cord Stimulation (SCS). Evaluating patients with intractable chronic upper limb pain† (VAS ≥ 5 cm) at 11 sites across the United States.
Sample size:

- 58 subjects enrolled
- 46 subjects implanted
- 43 subjects with 3-month follow-up
- 39 subjects with 12-month follow-up

Primary endpoint

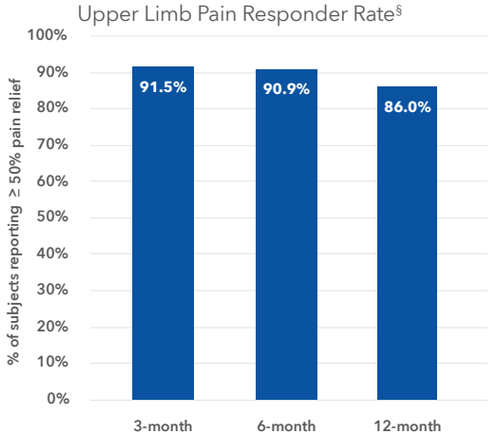
The percentage of implanted subjects who respond to DTM™ SCS therapy at 3 months post-implant (≥ 50% ULP relief)

Secondary objectives

- To further characterize the effectiveness of DTM™ SCS programming for the treatment of chronic ULP
- To report outcomes on Pain Disability Index (PDI), Patient Global Impression of Change (PGIC), and therapy satisfaction
- To characterize adverse events at all follow-up periods

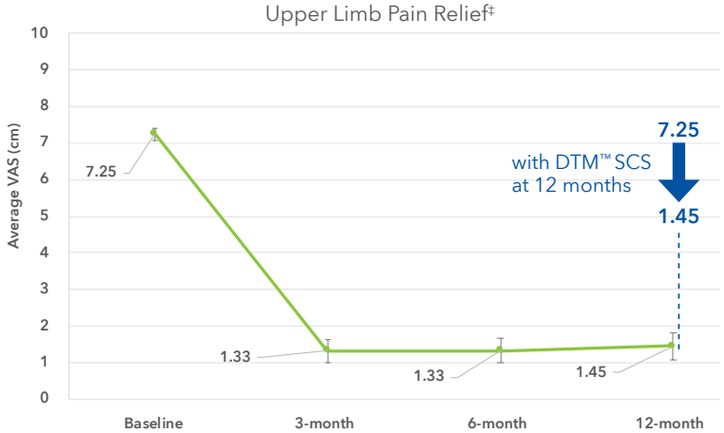
DTM™ SCS therapy outcomes

Upper Limb Pain Responder Rate§



86.0% - ULP responder rate with DTM™ SCS at 12 months (≥ 50% improvement). (n = 43)

Upper Limb Pain Relief‡



Sustained upper limb pain relief with a mean VAS score of 1.45 cm at 12 months with DTM™ SCS (n = 43)

Key takeaways for pain relief outcomes

- DTM™ SCS provides effective upper limb pain relief through 12-months
- Upper Limb Pain responder rate was 86.0% at 12 months
- Upper limb pain VAS was reduced by 79.8%, from 7.25 cm at baseline to 1.45 cm at 12 months

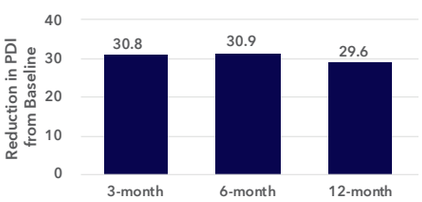
Safety outcomes

- The incidence of device-related adverse events and serious adverse events were consistent with other SCS studies

†Subjects were candidates for SCS as per indication. For example: Radicular pain syndrome or radiculopathies resulting in pain secondary to surgery or herniated disc, complex regional pain syndrome (CRPS)
‡ULP (n): Baseline (52), 3-month (47), 6-month (44), 12-month (43)
§Trial phase completer's analysis = Includes all subjects that completed the trial Phase. Subjects that fail trial or discontinue due to lack of pain relief are included.

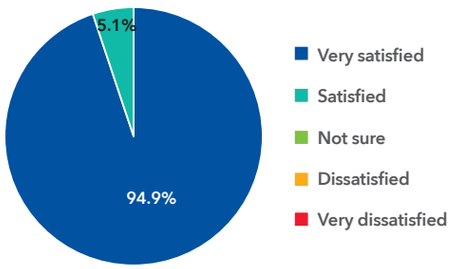
Secondary outcomes

Effect on Pain Disability (PDI)†



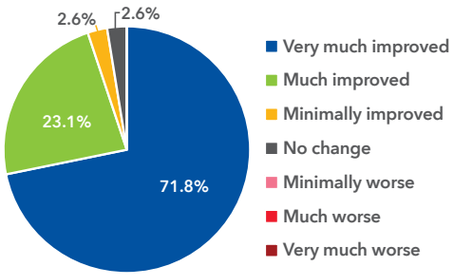
Subjects saw a 29.6 point reduction in PDI with DTM™ SCS at 12 months. (n = 39)

DTM™ SCS Subject Satisfaction†



100% of subjects were satisfied or very satisfied with DTM™ SCS at 12-month follow-up visit. (n = 39)

DTM™ SCS Patient Global Impression of Change†



94.9% of patients reported feeling much improved or very much improved with DTM™ SCS at 12 months. (n = 39)

Key takeaways for quality of life outcomes

- DTM™ SCS provided sustained improvements in degree of disability at 12-month follow-up.
- SCS therapy improved subject PDI scores: Patients with DTM™ SCS experienced a 29.6 point reduction in their reported PDI scores.
- 94.9% of subjects were very satisfied with DTM™ SCS therapy at 12 months. 100% of subjects were satisfied or very satisfied with DTM™ SCS at 12 months.

† Per protocol analysis

White T, et al. Effect of Differential Target Multiplexed SCS on Intractable Upper Limb Pain: A 12-Month Prospective Study. Presented at American Society for Regional Anesthesiology and Pain Medicine (ASRA) Annual Meeting; November 10-11, 2023; New Orleans, LA.

Spinal Cord Stimulation Brief Summary
INDICATIONS Spinal cord stimulation (SCS) is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain. **CONTRAINDICATIONS** Diathermy - Energy from diathermy can be transferred through the implanted system and cause tissue damage resulting in severe injury or death. WARNINGS Sources of electromagnetic interference (e.g., defibrillation, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the system, resulting in unexpected changes in stimulation, serious patient injury or death. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and electrical pulses from the neurostimulator may cause inappropriate response of the cardiac device. Patients with diabetes may have more frequent and severe complications with surgery. A preoperative assessment is advised for some patients with diabetes to confirm they are appropriate candidates for surgery. **PRECAUTIONS** Safety and effectiveness has not been established for pediatric use, pregnancy, unborn fetus, or delivery. Avoid activities that put stress on the implanted neurostimulation system components. Recharging a rechargeable neurostimulator may result in skin irritation or redness near the implant site. **ADVERSE EVENTS** May include: undesirable change in stimulation (uncomfortable, jolting or shocking); hematoma, epidural hemorrhage, paralysis, seroma, infection, erosion, device malfunction or migration, pain at implant site, loss of pain relief, and other surgical risks. Adverse events may result in fluctuations in blood glucose in patients with diabetes. Refer to www.medtronic.com for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events. Rx only. Rev 0422

Scan to see the Medtronic SCS publications webpage and PROCURA Study poster

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