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12-MONTH OUTCOMES FROM A MULTI-CENTER STUDY ON A REDUCED-ENERGY DTM™ DERIVATIVE: PATIENT ACTIVITY GOALS AND THERAPY SATISFACTION

Jeffery Peacock, David Provenzano, Michael Fishman, Kasra Amirdelfan, Todd Bromberg, Todd Schmidt, Thomas White, Prahbdeep Grewal, Rafael Justiz, Aaron Calodney, Amr El-Naggar, Binit Shah, Michael Esposito, Kliment Gatzinsky, Jan Willem Kallewaard, Kate Noel, Calysta Rice, Andrew Cleland, Maddie LaRue
Medtronic

Introduction

Differential Target Multiplexed™ spinal cord stimulation (also known as DTM™ SCS) is an established therapy that has shown superior back pain relief to traditional SCS [1]. Derivatives of the DTM™ waveform are being investigated to understand opportunities for therapy personalization. Energy-conserving approaches altering amplitude, frequency, and pulse width, have the potential to impact patient experience with rechargeable and non-rechargeable devices. This prospective, multi-center, open-label, post-market study evaluated the efficacy and energy use of a reduced-energy derivative of DTM™ SCS. Efficacy was assessed by quantification of pain relief and improvements in quality of life, as well as characterization of the percentage of subjects that achieved individually defined activity goal(s) and subject satisfaction with the therapy.

Materials and Methods

SCS candidates with an overall Visual Analog Scale (VAS) of ≥6.0cm with moderate to severe chronic, intractable back and/or leg pain were eligible. This study was IRB approved and registered on clinicaltrials.gov (NCT04601454). Eligible subjects underwent an SCS trial programmed with the reduced energy DTM™ SCS derivative (DTM™ endurance therapy) and proceeded in the study if successful. Evaluation visits occurred at 1-, 3-, 6-, and 12-months post-activation. At evaluation visits, pain relief and quality of life improvements were assessed. Additionally, subjects were asked to set specific, measurable, and realistic goals related to an activity they hoped to achieve throughout the study. Activity goals were collected at baseline, 1-, 3-, and 12-month visits. If the baseline goal was achieved, then the subject was asked to set a new goal and so on through the 12-month final study visit. Achievement status of the 12-month final goal is not known. The maximum number of goals a subject could place is 1 per visit, for a total of maximum 4 goals throughout the study.

Results/Case Report

Fifty-seven subjects enrolled at 12 US sites from November 2020 to June 2021 (Table 1). Subjects had an average

age of 63.2 years and 57.9% were female. Post-laminectomy pain/PSPS was the main etiology (91.2%). Average time since onset of chronic, intractable pain was 13.4 years. Forty-nine subjects underwent trial, 35 were implanted, and 27 completed the 12-Month visit. The primary objective analysis demonstrated a mean reduction (standard deviation) of 3.9cm (2.5) in overall pain, as measured by VAS, from baseline at the 3-month follow-up (Figure 1). Changes in overall pain were clinically sustained at 3- , 6-, and 12-months with 50.4%, 52.4%, 56.1% improvement, respectively (Figure 1). Subjects experienced sustained improvements in functional disability and quality of life through 12-months as measured by the Oswestry Disability Index (ODI) and EuroQol-5-dimension (EQ-5D) questionnaires, respectively. Therapy satisfaction was reported by 88.9% of subjects at 12-months, and 88.9% of subjects met one or more of their specified activity goals set at baseline by the 12-month visit (Figure 2). Activity goals set at baseline fell into 4 of the 5 categories set for analysis (Table 2). Most subjects set baseline goals in the basic movement and sports/higher activity categories (Figure 2).

Discussion

The use of DTM™ endurance therapy in this study resulted in clinically meaningful pain relief with reduced energy usage. In addition to assessing pain relief as the traditional core measure of SCS therapy success, this study utilized subject activity goals and therapy satisfaction as measurements of success. The results of this study demonstrate that analysis of subject-set activity goals and therapy satisfaction can be informative of clinical efficacy. Goal attainment should be more objectively measured in the future as this may enhance therapy compliance and conversations related to overall therapy satisfaction.

References

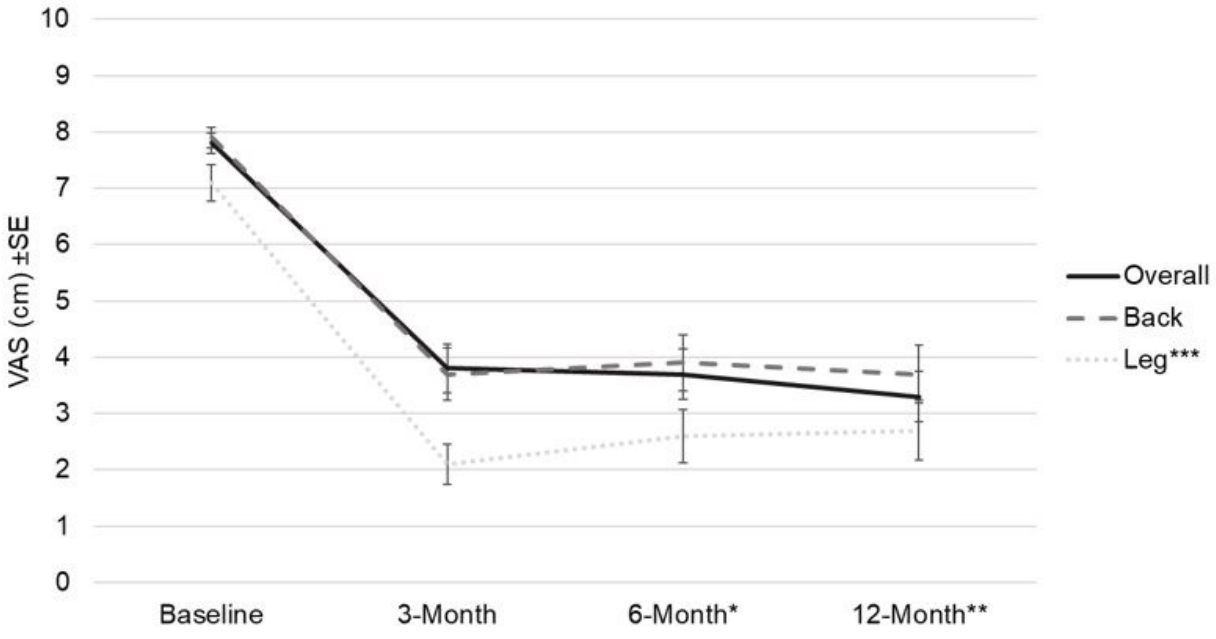
1. Fishman M, Cordner H, Justiz R, et al. 12-Month Results from Multicenter, Open-Label, Randomized Controlled Clinical Trial Comparing Differential Target Multiplexed Spinal Cord Stimulation and Traditional Spinal Cord Stimulation in Subjects with Chronic Intractable Back Pain and Leg Pain. Pain Pract. 2021; 00: 1– 12. doi: 10.1111/papr.13066. Epub ahead of print.

Disclosures

Yes

Tables / Images

Figure 1. Visual Analog Scale (VAS) scores for overall, back and leg pain. Values shown represent mean VAS scores (scale of 0.0 cm to 10.0 cm, with 10.0 cm being the most pain) from per-protocol subjects at baseline, 3-month, 6-month and 12-month follow-up. Error bars represent Standard Error (SE).



*n=29; Subjects were excluded from analysis at 6-Months due to programming changes (N=2) and due to study exit (N=1)
**n=27; Subjects were excluded from analysis at 12-Months due to programming changes (N=4) and due to study exit (N=1)
***n for leg pain is 31 at baseline and 3-Months, 28 at 6-Months, and 26 at 12-Months due to a missing value at baseline for one subject

Figure 2. Mosaic plot of activity goals set at baseline and completed by the 12-month visit (n=27). Bars represent the percentage of subjects that either achieved or did not achieve a goal set at baseline in the indicated category by the 12-month follow-up.

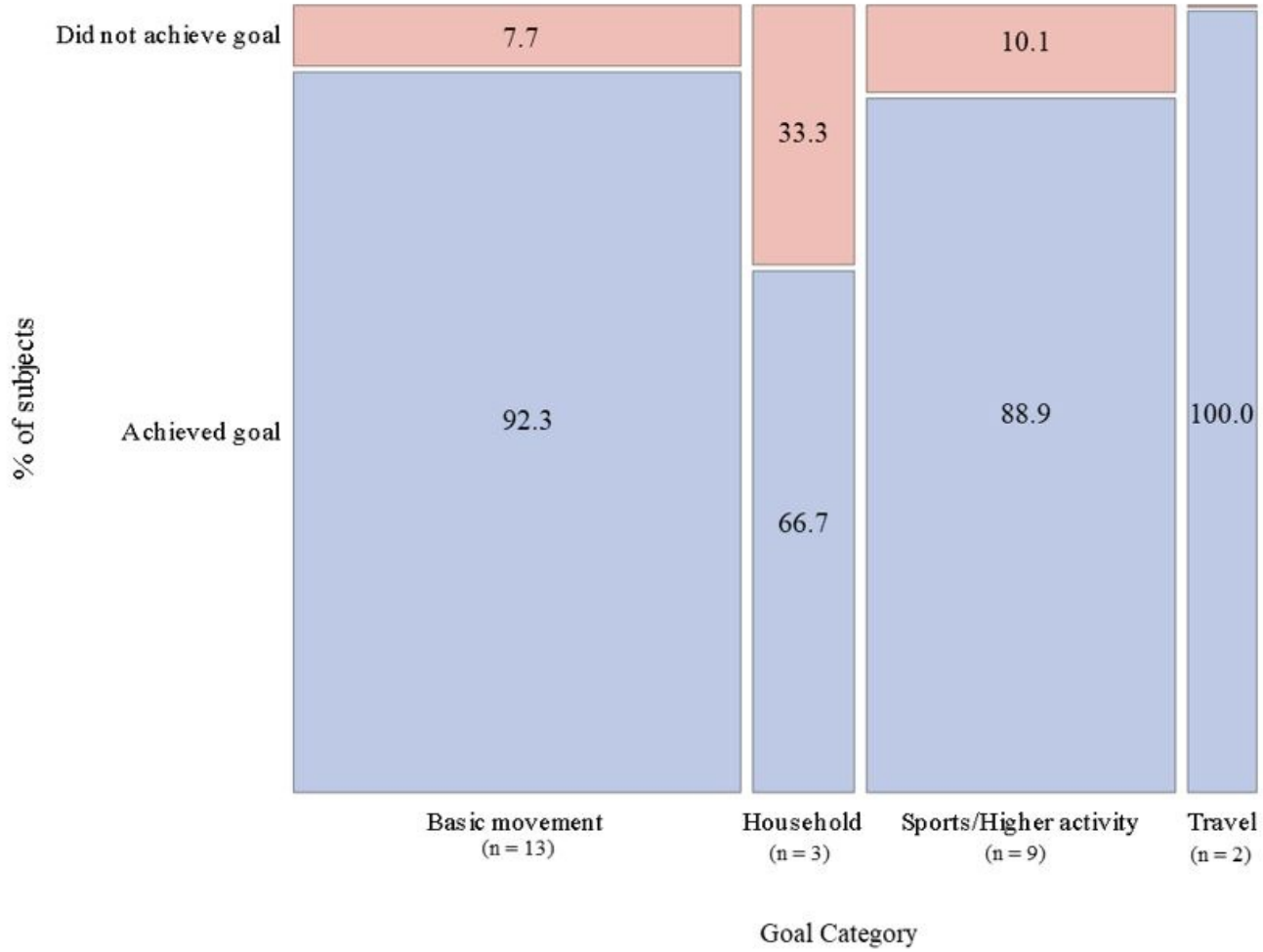


Table 1. Baseline demographics for enrolled and implanted subjects.

Subject Characteristics	Enrolled (N=57)	Implanted (N=35)
Age (years)		
Mean (SD)	63.2 (11.93)	62.4 (12.70)
Median	67	67
Minimum to Maximum	40.0 to 85.0	40.0 to 85.0
Sex (n, %)		
Female	33 (57.9%)	21 (60.0%)
Male	24 (42.1%)	14 (40.0%)
Ethnicity (n, %)		
Not Hispanic Or Latino	53 (93.0%)	33 (94.3%)
Hispanic Or Latino	3 (5.3%)	1 (2.9%)
Not Reported	1 (1.8%)	1 (2.9%)
Race (n, %)		
White	54 (94.7%)	34 (97.1%)
Asian	1 (1.8%)	0 (0.0%)
Black or African American	1 (1.8%)	1 (2.9%)
Not Reported	1 (1.8%)	0 (0.0%)
Time since pain onset (years)		
Mean (SD)	13.4 (13.27)	13.7 (13.44)
Median	7	8
Min to Max	1.0 to 60.0	1.0 to 60.0
Relevant* Surgical History (n, %)		
At Least One Relevant* Surgery	50 (87.7%)	31 (88.6%)
No Surgical History	7 (12.3%)	4 (11.4%)
Number of Surgeries		
Mean (SD)	1.7 (1.48)	1.8 (1.75)
Median	1	1
Min to Max	0.0 to 9.0	0.0 to 9.0

*related to the SCS device/pain

Table 2. Activity goals set at baseline or at 1- and 3-month follow-up that were achieved by the 12-month final study visit.

	Goals Set at Baseline			Goals Set at 1- and 3-month Follow-Up		
Category	**# subjects specifying a goal**	**# subjects achieving goal**	**% subjects achieving goal**	**# subjects specifying a goal**	**# subjects achieving goal**	**% subjects achieving goal**
Basic movement (Walk, stand, step, sit)	13	12	92.3%	18	14	77.8%
Household (Cook, clean, laundry, housework, garden)	3	2	66.7%	0	0	N/A
QOL/Self-care (Improved health, good life, continue improving, control of life, normal living, activities)	0	0	N/A	3	3	100.0%
Sports/Higher activity (Hiking, golf, yoga, swimming, hunting, fishing, basketball, bicycling, working out, throwing a ball, active life)	9	8	88.9%	4	3	75.0%
Travel (Trips, outings, driving)	2	2	100.0%	2	1	50.0%
Total	**27**	**24**	**88.9%**	**27**	**21**	**77.8%**