

12-Month Outcomes from a Multi-Center Study on a Reduced-Energy DTM™ Derivative: Patient Activity Goals and Therapy Satisfaction

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Introduction

- Differential Target Multiplexed™ spinal cord stimulation (also known as DTM™ SCS) is an established therapy, shown to provide superior back pain relief to traditional SCS¹.
- Derivatives of the DTM™ waveform are being investigated to understand opportunities for therapy personalization including energy-conserving approaches that alter amplitude, frequency, and pulse width.
- This prospective, multi-center, open-label, post-market study evaluated the efficacy of a reduced-energy derivative of DTM™ SCS (DTM™ endurance therapy).

Materials & 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.
- Eligible subjects underwent an SCS trial programmed with 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 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.

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.

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Results

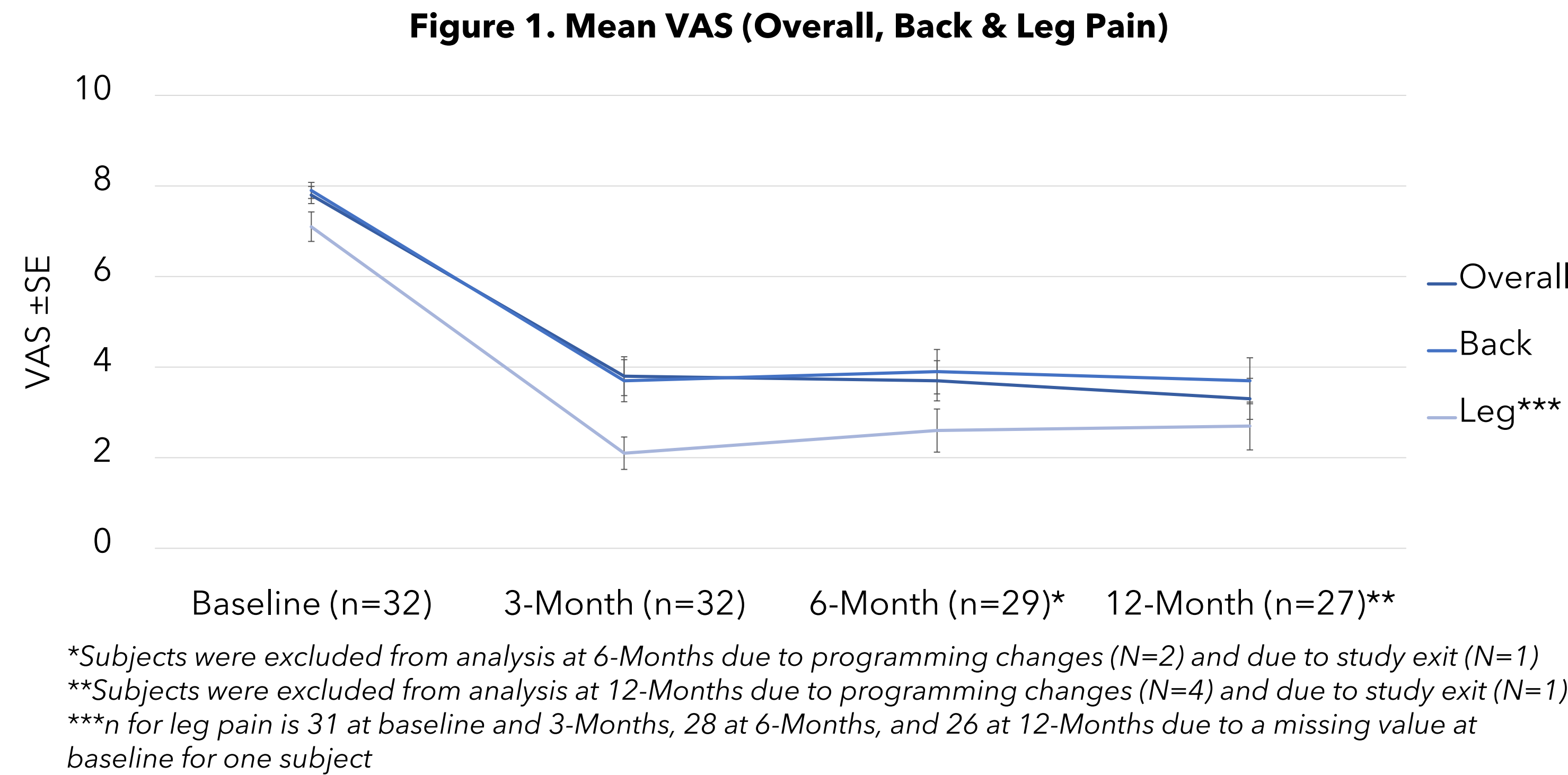
Demographics

57 subjects enrolled at 12 US sites from November 2020 to June 2021. Patient demographics are shown in Table 1. Post-laminectomy pain/PSPS-T2 was the main etiology (91.2%). 49 subjects underwent trial, 35 were implanted, and 27 completed the 12-Month visit.

Table 1. Baseline Demographics (n=57)	
Mean (SD) Age (Years)	63.2 (11.9)
Female	57.9%
Mean (SD) Years Since Pain Onset	13.4 (13.3)
Mean (SD) Number of Surgeries	1.7 (1.5)
No Surgical History	12.3%

Overall, Back, and Leg Pain Scores

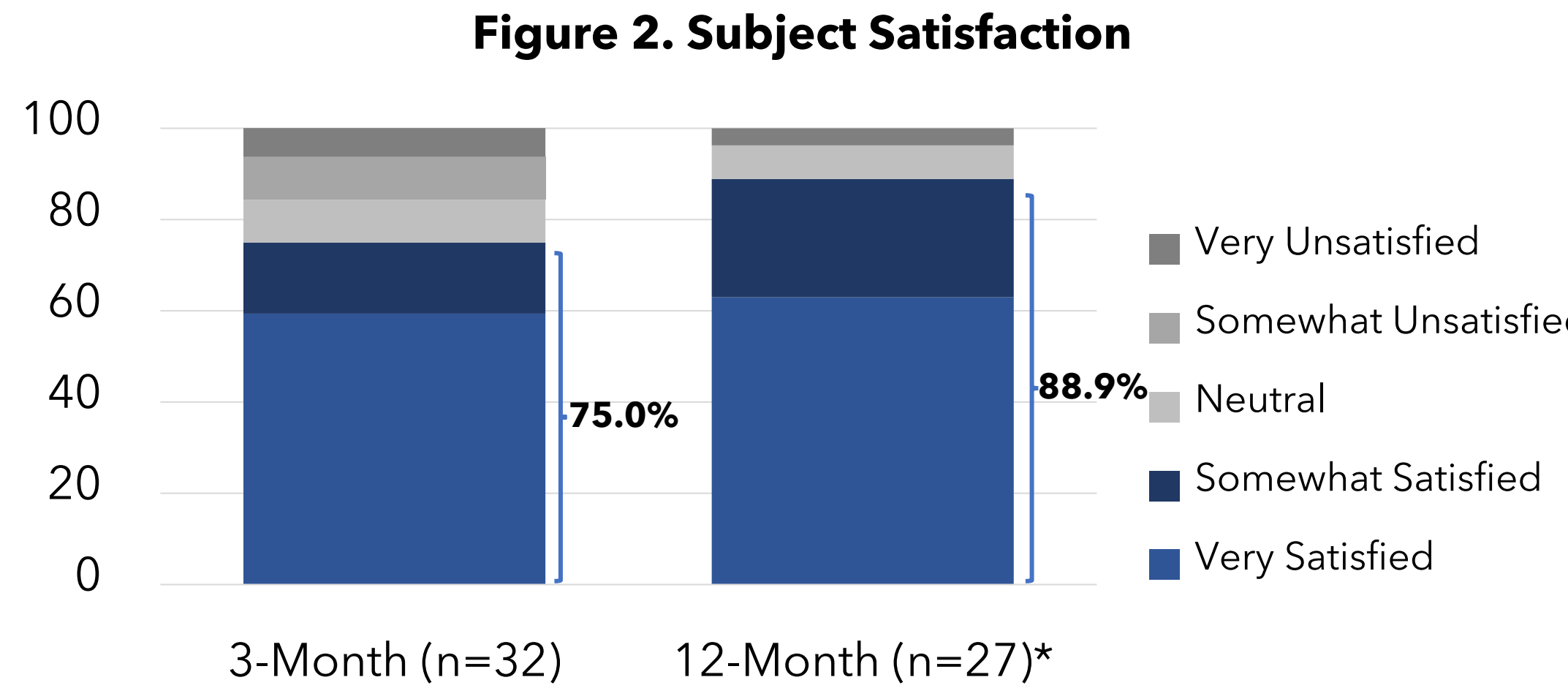
The primary objective analysis demonstrated a mean reduction (standard deviation) of 3.9cm (2.5) in overall pain, as measured by Visual Analog Scale (VAS), from baseline at the 3-month follow-up (Figure 1). Changes in overall pain were clinically sustained at 3-, 6-, and 12-months with 50.4%, 52.4%, 56.1% improvement, respectively (Figure 1).



Therapy Satisfaction

At 12-months, 88.9% of subjects reported therapy satisfaction (Figure 2).

*Subjects were excluded from analysis at 12-Months due to programming changes (N=2) and due to study exit (N=1)



Activity Goals

88.9% of subjects met one or more of their specified activity goals set at baseline by the 12-month visit (Figure 3, Table 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 3). We observed that 94% of responder subjects (≥50% pain relief) at 12-months achieved a goal set at baseline. Interestingly, we observed that 82% of non-responder subjects (did not achieve ≥50% pain relief) at 12-months were still able to achieve a goal set at baseline.

Figure 3. 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.

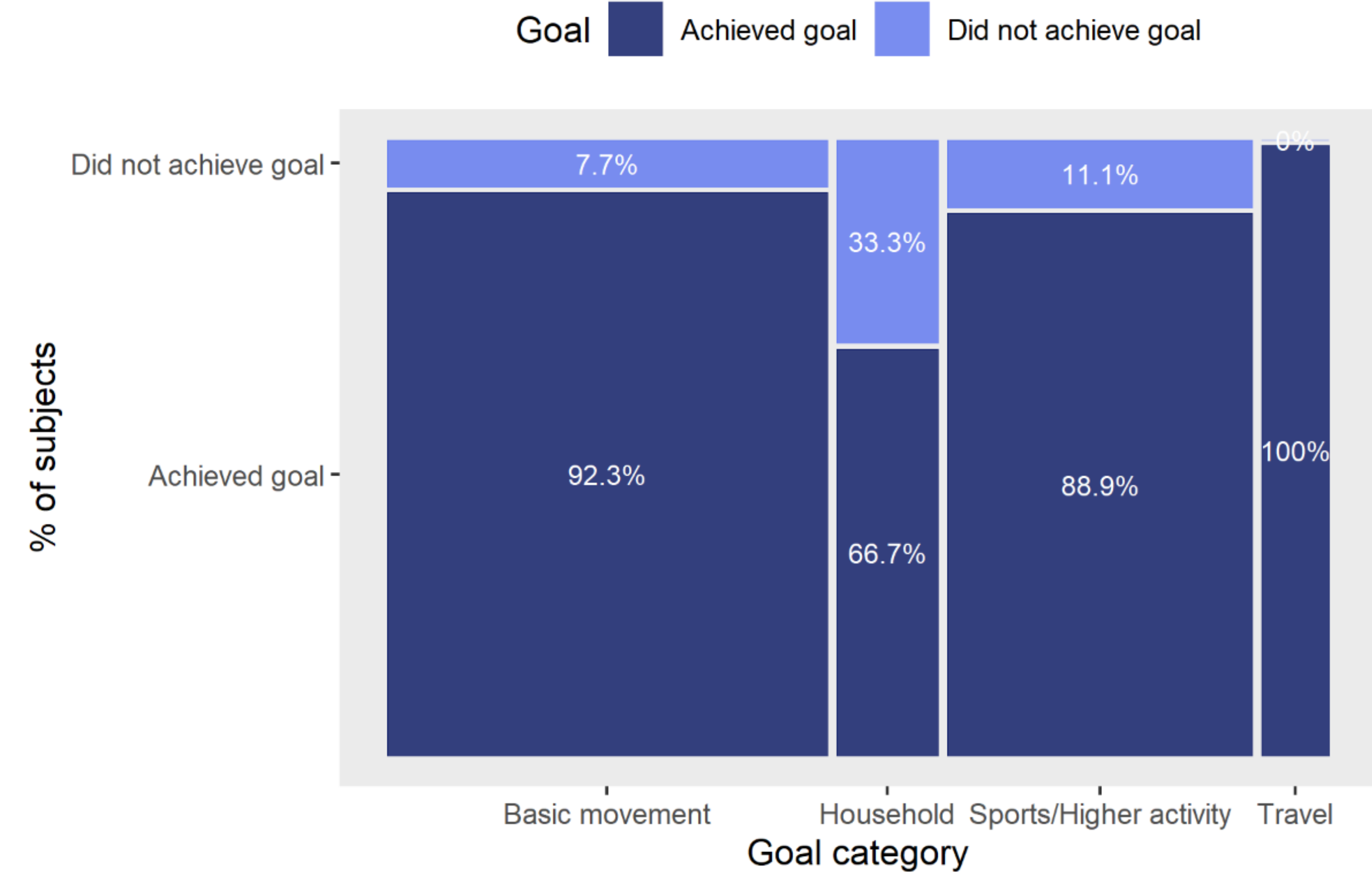


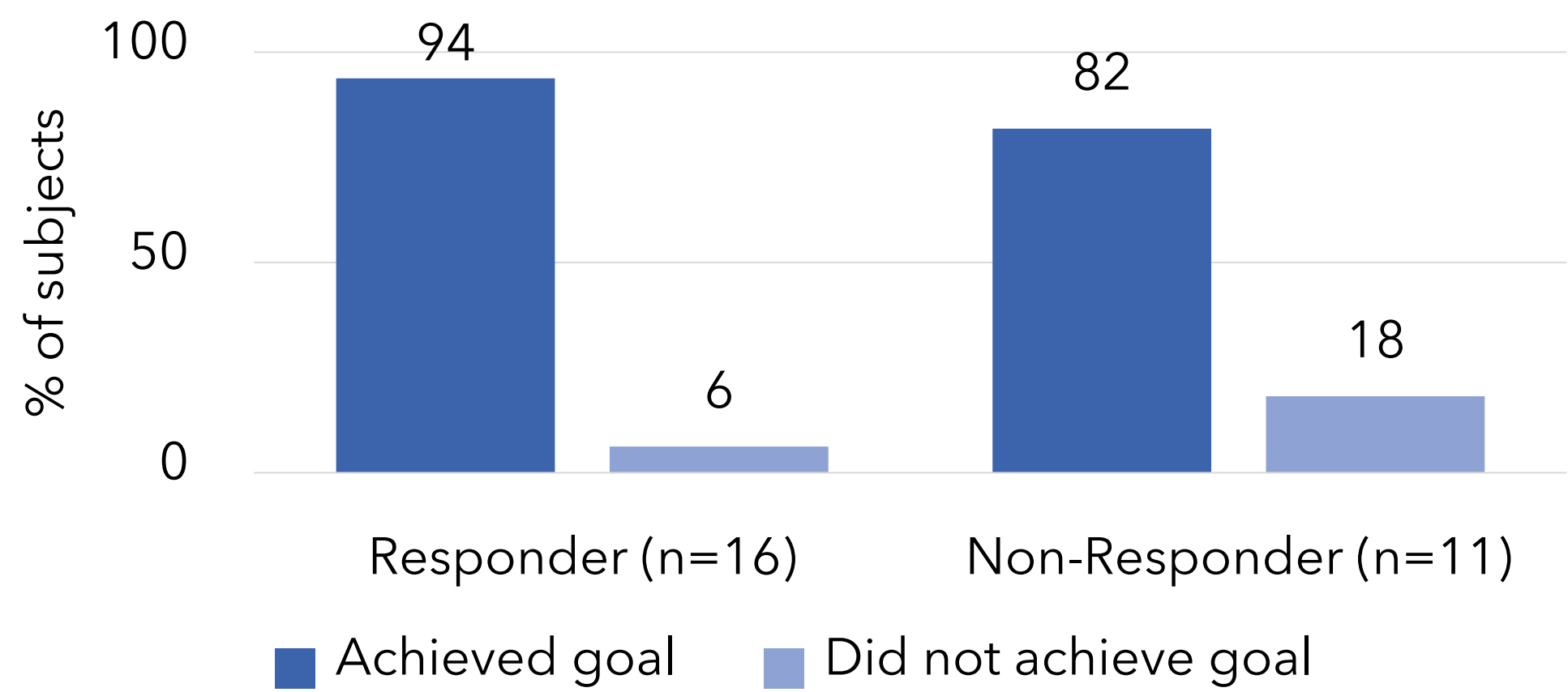
Table 2. Activity goals set at baseline or at 1- and 3-month follow-up that were achieved by the 12-month final study visit.

Category	Goals Set at Baseline*			Goals Set at 1- and 3-month Follow-Up**		
	# of goals set	# of goals achieved by 12mo	% of goals achieved by 12mo	# of goals set	# of goals achieved by 12mo	% of goals achieved by 12mo
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%

*Each subject set 1 goal at baseline

**At 1- and 3-month follow-ups, each subject could set between 0 and 2 goals.

Figure 4. Bar graph showing percent of responder subjects that achieved a goal set at baseline by 12-month follow-up. DTM™ endurance responders experienced ≥50% pain relief (VAS scores) at 12-months.



Conclusions

- 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.
- Although a set of subjects did not achieve the conventional benchmark of ≥50% pain relief, an overwhelming majority of subjects successfully achieved their personalized activity goals.
- These findings imply a nuanced relationship between pain relief and the ability to engage in daily activities.
- Addressing the complexity of pain and its impact on activity will be critical in creating patient-centric therapies and a promising area of future research.
- Goal attainment should be more objectively measured in the future as this may enhance therapy compliance and conversations related to overall therapy satisfaction.