Modeling Energy Demands of a Reduced-Energy Derivative of DTM™ Stimulation on Rechargeable and Recharge-Free SCS Systems

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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 DTM™ SCS are being investigated to understand opportunities to further tailor therapy approaches for different patients.
- A recent feasibility study demonstrated that a DTM™ SCS derivative (DTM™ endurance therapy) provided significant reduction in energy usage while offering a similar degree of pain relief and therapy satisfaction to patients compared to prior SCS therapy[2].

Objectives

Data collected from a prospective, multi-center study of DTM™ endurance therapy (NCT04601454) has been used to estimate device longevity for recharge-free devices as well as recharge requirements on rechargeable devices. Patients with chronic intractable back and/or leg pain were enrolled and followed-up for 12-months

Materials & Methods

- Programming data from the 3-month, 6-month and 12-month follow-ups were used to calculate the charge delivered per second by the implanted neurostimulator (Intellis™, Medtronic) using Equation 1:

$$\sum frequncy\ (s^{-1}) \times amplitude\ (A) \times pulsewidth\ (\mu s) \times therapy\ cycling\ ON\ time\ proportion$$

- Recharge interval was determined by configuring a rechargeable Intellis™ neurostimulator - attached to a lead submerged in a saline solution (active electrode impedance 900 Ω) - with study settings on a validated "Energy Usage" calculator available on the Clinician Programmer Application.
- Longevity was determined by configuring a recharge-free Vanta™ neurostimulator with study settings on a validated "Estimate Battery Longevity" calculator on the Clinician Programmer Application. The calculator accounts for intrinsic characteristics of the Vanta™ neurostimulator such as overall battery capacity, instantaneous current drainage based on settings, and typical impedance ranges.
- Results are shown for subjects programmed to DTM™ endurance therapy settings with or without cycling at the specified follow-up. Subjects needed to be on DTM™ endurance settings for over 90% of their study duration to be included in the analysis.

Results

- 57 subjects were enrolled at 12 US sites from November 2020 through June 2021.
- Current usage (Figure 1) and amplitude ranges (Table 1) for DTM™ endurance therapy are reported at 3-, 6-, and 12-month follow-up visits.
- Longevity for different sample impedances (Figure 2) and recharge interval and duration (Table 2) using DTM™ endurance at 12-month follow-up are reported.

Figure 1: Current Usage

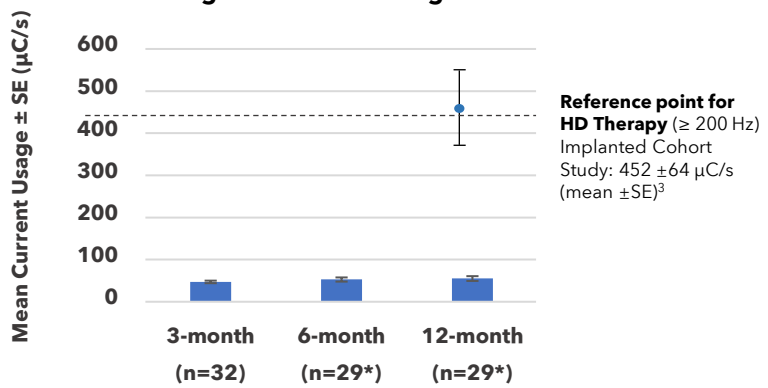


Table 1: Amplitude Ranges

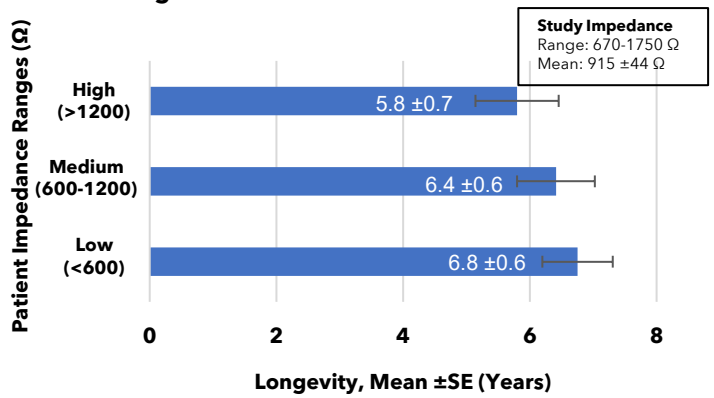
	3-mo (n=32)	6-mo (n=29*)	12-mo (n=29*)
Amplitude Range (Mean ±Standard Deviation), mA	1.0 - 5.0 (2.6 ±0.2)	1.0 - 5.8 (2.8 ±0.2)	0.7-7.3 (2.7 ±0.3)

**Subjects were excluded from analysis at 6- and 12-months due to programming changes from DTM™ SCS endurance therapy (N=1) and due to study exit (N=1). An additional subject (N=1) was unable to have longevity calculated due to amplitude being set to zero at some point during the follow-up period.*

Table 2: Recharge Modeling on Intellis™ Rechargeable Neurostimulator (n=29)

60 min recharge every 12.2 ±0.6 days
-or-
5.5 ±0.5 minutes of daily recharge

Figure 2: Longevity Modeling on Vanta™ Recharge-free Neurostimulator at 12 Months



Conclusions

Advanced SCS patterns can employ energy conserving programming approaches through therapy cycling as well as manipulations of amplitude, frequency, and pulse width. This study quantifies the energy usage of DTM™ endurance therapy, a reduced-energy DTM™ SCS derivative and uses real patient data to estimate device longevity for recharge-free devices and recharge requirements on rechargeable devices. Energy conserving stimulation patterns have the potential to provide clinical benefit along with impacting the patient experience through either reduced recharge requirements or by providing increased longevity on recharge-free devices. Further research into energy dosing is warranted to increase understanding of the therapeutic window and mechanism of action, which may improve therapy efficacy or durability, and reduce side effects.

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.
2. Fishman M, Hatheway J, Will A, et al. Utilization of Different Energy Profiles of Differential Target Multiplexed™ Spinal Cord Stimulation. American Society of Pain & Neuroscience (ASPN); July 22-25, 2021; Miami, FL. Abstract.

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