Early Experience with Closed-Loop SCS During In-clinic Testing

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Background

Spinal cord stimulation (SCS) is a treatment for chronic pain, typically of the back and extremities. Movement of the spinal cord relative to the leads may result in an electrical dose that is either below, or exceeds, the dose intended for the patient. In the case of excessive dose—which may result from instances of decreased separation between the cord and the leads, such as a back arch or a cough—the patient may compensate by adjusting the therapy amplitude to a lower setting. This may in turn result in sub-optimal pain relief.[1] Evoked compound action potentials (ECAPs), a measure of neural activation, can be used to adjust for this inconsistent dosing in real time (**Figure 1**). This process is referred to as closed-loop SCS (CL-SCS), in contrast to the fixed-amplitude, "open-loop" SCS in wide commercial use to-date.

Closed-Loop SCS with contemporary multiplexed waveforms

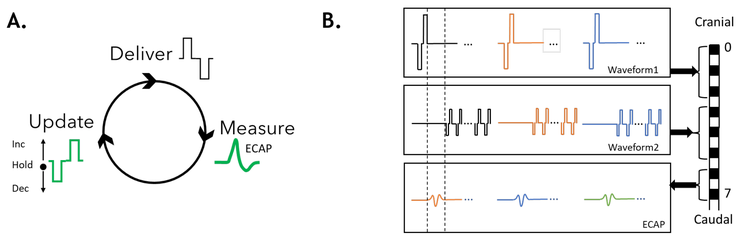


Figure 1. The algorithm updates stimulation amplitude, for Waveforms 1 and 2, 50 times per second.[2] A. Closed-Loop SCS algorithm. **B.** Schematic showing the timing of stimulation with Waveform1 to elicit ECAP, sensing the ECAP, and the inclusion of a 2nd waveform. The algorithm adjusts both waveforms ratiometrically after each measurement of the ECAP signal.

Study Design

Objective: optimize workflow to efficiently program CL-SCS with contemporary waveforms (e.g., DTM™ SCS[3], DTM Endurance[4]).

The study is being conducted at 5 sites in the US. The externalized trials leads are connected to an investigational, external neurostimulator capable of stimulating, sensing and adjusting stimulation amplitudes based on measured ECAP signal.

Key Eligibility Criteria:

1. Candidate for or undergoing Medtronic SCS device trial for labeled indication.
2. Is not being trialed with a permanent implant lead and extension.

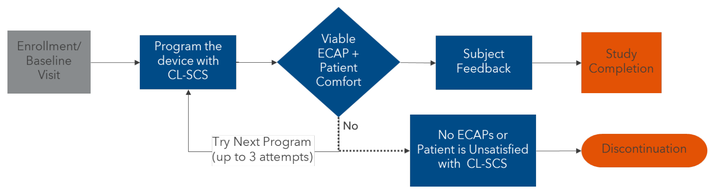
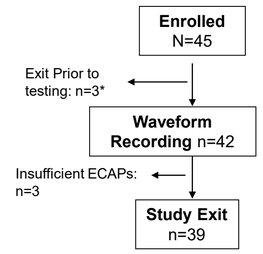


Figure 2. Study Design. SCS trial was done per the site's standard of care and is not part of the study.

Results

Figure 3. Subject Disposition



*2 subjects withdrew consent and 1 was exited by PI.

Table 1. Baseline Characteristics

Variable	Subjects (N = 39)
Age – mean(SD) years	59.1 (10.6)
Female – n (%)	20 (51.3%)
Location – n (%)	
Low back and/or Leg	25 (64.1%)
Upper Limb and/or Neck	12 (30.8%)
Etiology – n (%)	
Post laminectomy pain	14 (35.9%)
Degenerative Disc Disease	6 (15.4%)
Failed back surgery syndrome	3 (7.7%)
Radicular pain	7 (17.9%)
Complex Regional Pain Syndrome	2 (5.1%)
Other	7 (17.9%)

CL-SCS Programming

Figure 4. All subjects could be programmed with CL-SCS with multiplexed waveforms.

Each therapy setting took a median of 9 (2 – 38) minutes to program. Programming for Cervical leads was faster than for Thoracic locations [median(min – max)]: 8(2,14) vs. 11(2,38) minutes. ^ Other includes multiplexed waveforms with Waveform1 at 50 Hz and Waveform2 at frequencies between 50 and 300 Hz.

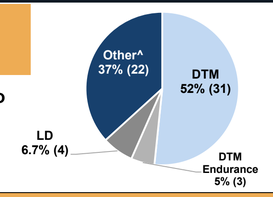


Figure 5. A. Perception Thresholds (PT) are higher in the thoracic region due to the greater cerebrospinal fluid thickness. **B.** Figure from Levy et al showing the variability of dorsal cerebrospinal fluid thickness along the spine.[5]

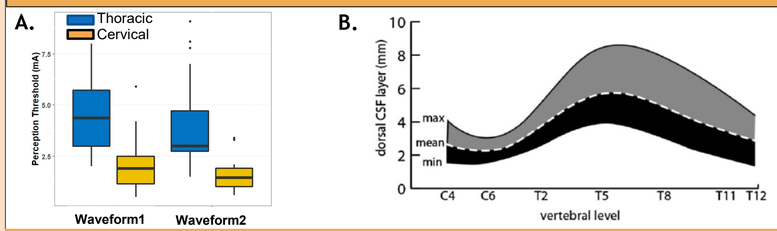
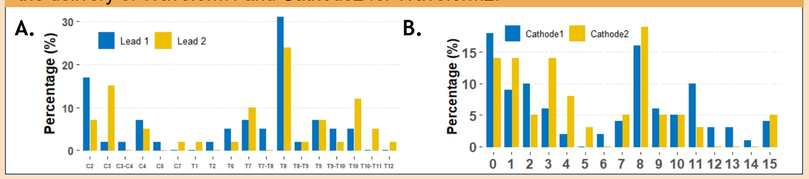


Figure 6. **A.** SCS lead tip locations. **B.** Electrode for Stimulation Delivery. Cathode1 is for the delivery of Waveform1 and Cathode2 for Waveform2.



Results

Figure 7. Waveform1 amplitude as a % of PT is shown. Both Sub- and supra-perception CL-SCS settings could be programmed depending on patient comfort.

Stimulation amplitude was programmed to a median of 103 (min-max: 68 - 230)% of PT for Waveform1 and 67 (36 - 145)% for Waveform2. Subjects were programmed to a "comfortable" amplitude for Waveform1.

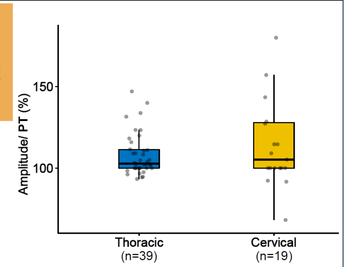
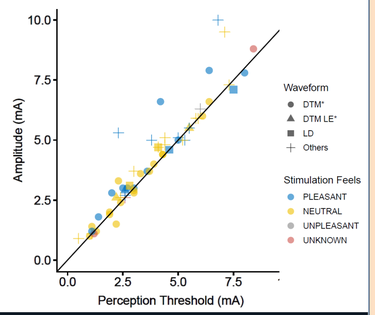


Figure 8. Subjects reported that 95% (55/58) of settings had a pleasant/ neutral sensation. Waveform1 amplitude and PT are shown.

Subjects with successful programming reported their experience during actions replicating activities of daily living was the same/ better than during commercial trial with 86% (50/58) of settings.

Note: 41% of patients had more than one setting programmed. New/ additional groups were programmed if viable ECAPs could not be sensed at the location of the preferred setting or if time permitted to try other settings.



Discussion

- The data from this study supports the feasibility of programming CL-SCS based on measured ECAP signals with contemporary multiplexed waveforms efficiently (median of 9 minutes).
- Programming was feasible with a variety of lead placements, combination of electrodes and with sub- and supra-perception settings.

References

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Acknowledgements

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