

# 12-month Outcomes with a Flexible Closed Loop Spinal Cord Stimulation System

Vahid Mohabbati, MD,<sup>1</sup> Richard Sullivan, MBChB,<sup>2</sup> James Yu, MD,<sup>3</sup> Peter Georgius, MBBS,<sup>4</sup> Charles D Brooker, MBChB,<sup>5</sup> Malgorzata Straka, PhD,<sup>6</sup> Andrew Cleland, MD,<sup>6</sup> Glenn Butler,<sup>6</sup>

Michelle Knight, BSc,<sup>6</sup> Justin Morey,<sup>6</sup> Nancy L McClelland, BSN,<sup>6</sup> Xiaoxi Sun, MA,<sup>6</sup> Abi Franke, PhD,<sup>6</sup> Marc A Russo, MBBS<sup>7</sup>

<sup>1</sup>Sydney Pain Research Center, Sydney, NSW; <sup>2</sup>Precision Brain Spine & Pain Centre, Kew, VIC; <sup>3</sup>Australian Medical Research, Hurstville, NSW; <sup>4</sup>Sunshine Coast Clinical Research, Noosa Heads, QLD;

<sup>5</sup>Royal North Shore Hospital, St. Leonards, NSW; <sup>6</sup>Medtronic Neuromodulation, Minneapolis, MN; <sup>7</sup>Genesis Research Services, Broadmeadow, NSW



## Background

•A double-blind survey of a representative sample of 100 SCS patients showed that inconsistent dosing (e.g., over- or under stimulation) occurs in over 50% of patients with fixed-output devices, regardless of the waveform.<sup>1</sup>

•Inconsistent dosing results from changes in lead-to-cord distance during activities of daily living. The closed-loop (CL) algorithm in the study device adjusts amplitude based on the measured physiologic response of the spinal cord – the evoked compound action potential (ECAP).<sup>2</sup>

•Here we report outcomes with CL-SCS and multiplexed waveforms tailored to the patient's needs (e.g., above/below perception, low dose etc. ).<sup>2</sup>

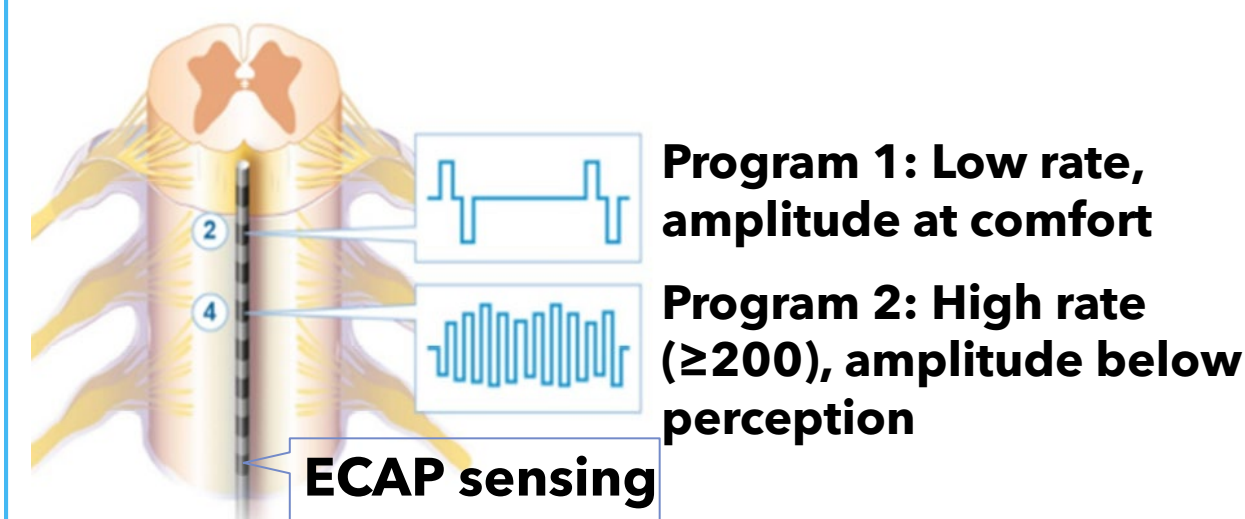


**Figure 1. Illustration of CL programming for multiplexed waveforms like DTM**  
Program 1 generates the ECAP signal. Additional therapy can be provided on Program 2. CL makes adjusts both program amplitudes ratiometrically.

## Methods

•Prospective study being conducted at 7 sites in Australia (NCT05177354). The study has 2 parts: a) in-clinic, randomized, cross-over, single blind, testing for Primary Endpoint at 1-month and b) long-term, single-arm follow-up for pain outcomes at 3-, 6-, 12-, 18- and 24-months post Device Activation.

•**Primary objective** is to demonstrate reduction in overstimulation with the CL-SCS relative to OL-SCS. The primary analysis set (**PAS**) includes the first **28 back/leg pain** subjects to complete the 1-month visit with measurable ECAPs (see inset in **Figure 2**).

•**Secondary objective** is to characterize % of subjects with ≥50% reduction in overall, back/leg pain at 3 months.

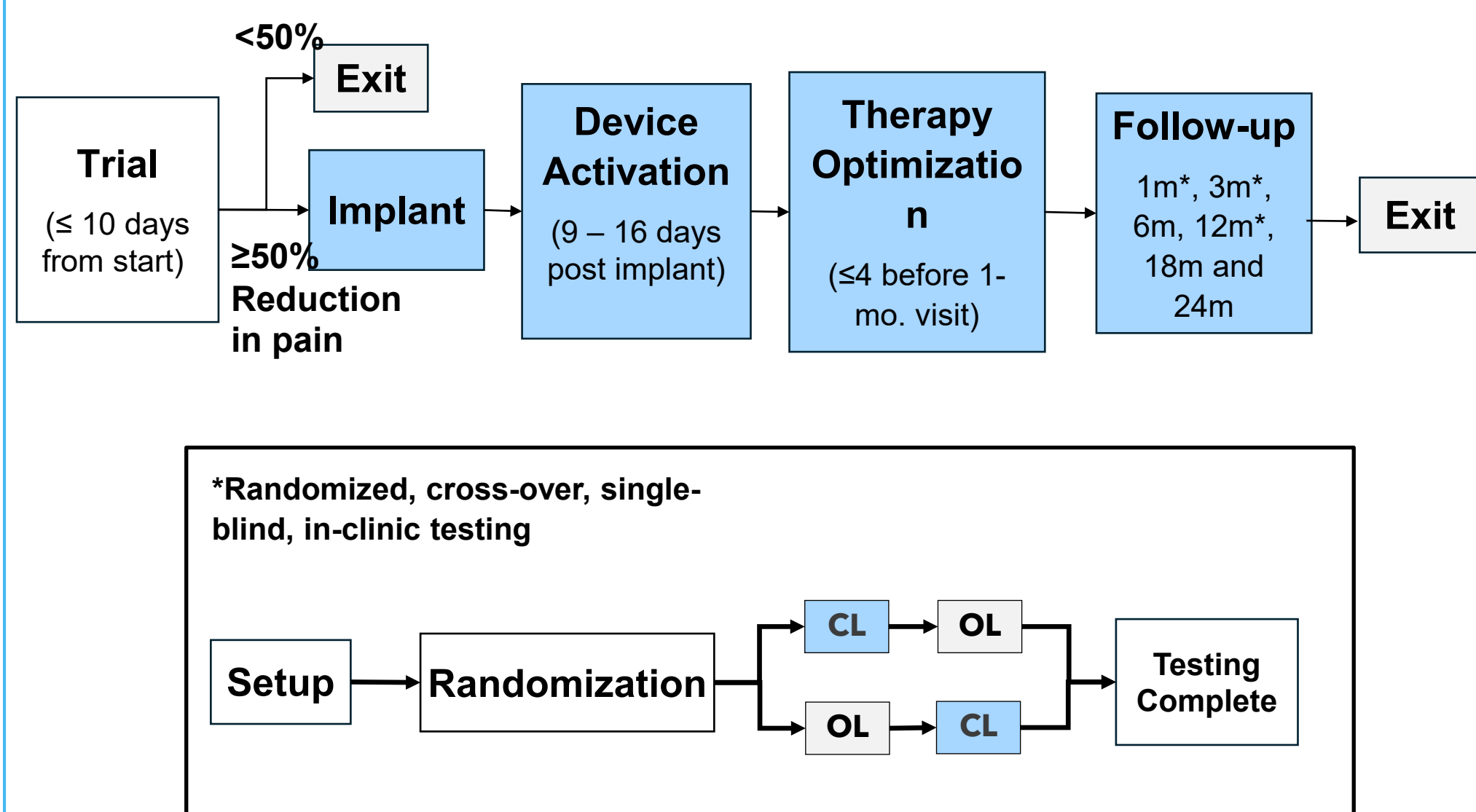


**Figure 2.** Study visits through the 24-month follow-up. The randomized in-clinic testing at 1-, 3- and 12-month visits is shown as an inset.

## Results and Discussion

**CL is effective in addressing inconsistent dosing and related side effects, thereby providing a more comfortable overall experience.**

### In-clinic testing of CL Performance at 12-months

**91%** Had reduced overstimulation with CL-SCS at 12M (n = 43)

**88%** Expressed preference for CL-SCS vs. OL-SCS during blinded testing (n = 43)

**Figure 4.** In-clinic, randomized cross-over testing of CL performance in reducing overstimulation. Intensity of overstimulation sensation was reduced significantly with CL-SCS (inset Figure 2). All subjects that completed the 12-month visit and had usable ECAPs were included in the in-clinic testing.

**Fewer manual adjustments with CL-SCS vs. OL-SCS during at-home use**

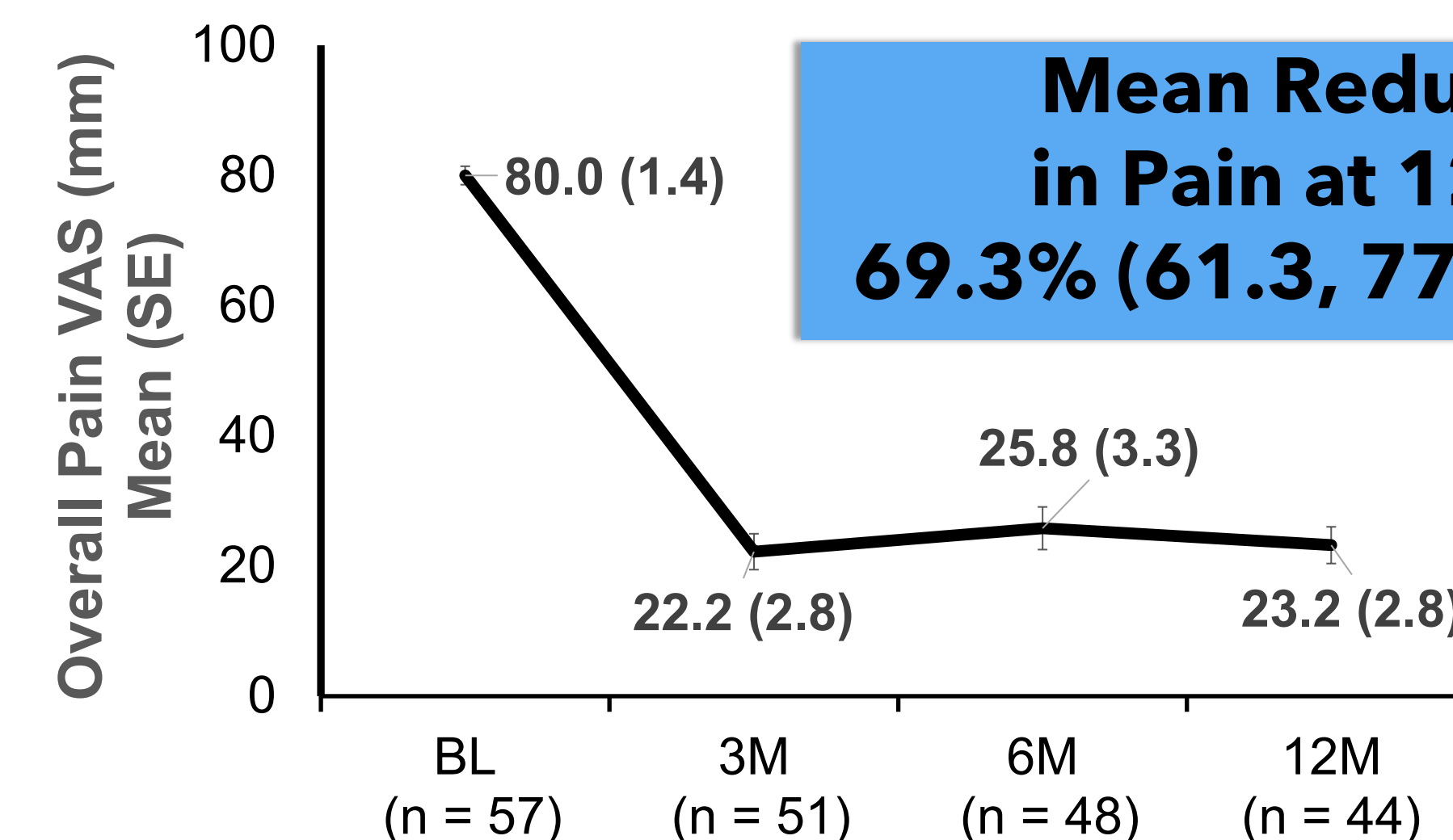


**1 stimulation amplitude adjustment per month with CL-SCS (median over 30 days prior to 12M visit)**

**50%**

**of survey participants made adjustments once per week to ≥1 per day with OL-SCS<sup>1</sup>**

**Sustained and significant improvements in low-back/leg Pain and composite outcomes were seen through the 12-month visit**



**98%**

Would definitely or probably recommend therapy to family or friends (n = 44)

**100%**

Expressed Satisfaction with therapy (n = 44)



**Quality of Life**  
EQ5D increased ≥0.074



**Mood**  
POMS reduction ≥10



**Physical Function**  
ODI reduction ≥10



**Sleep**  
PSQI reduction ≥3.0



**Pain VAS**  
reduction ≥30%

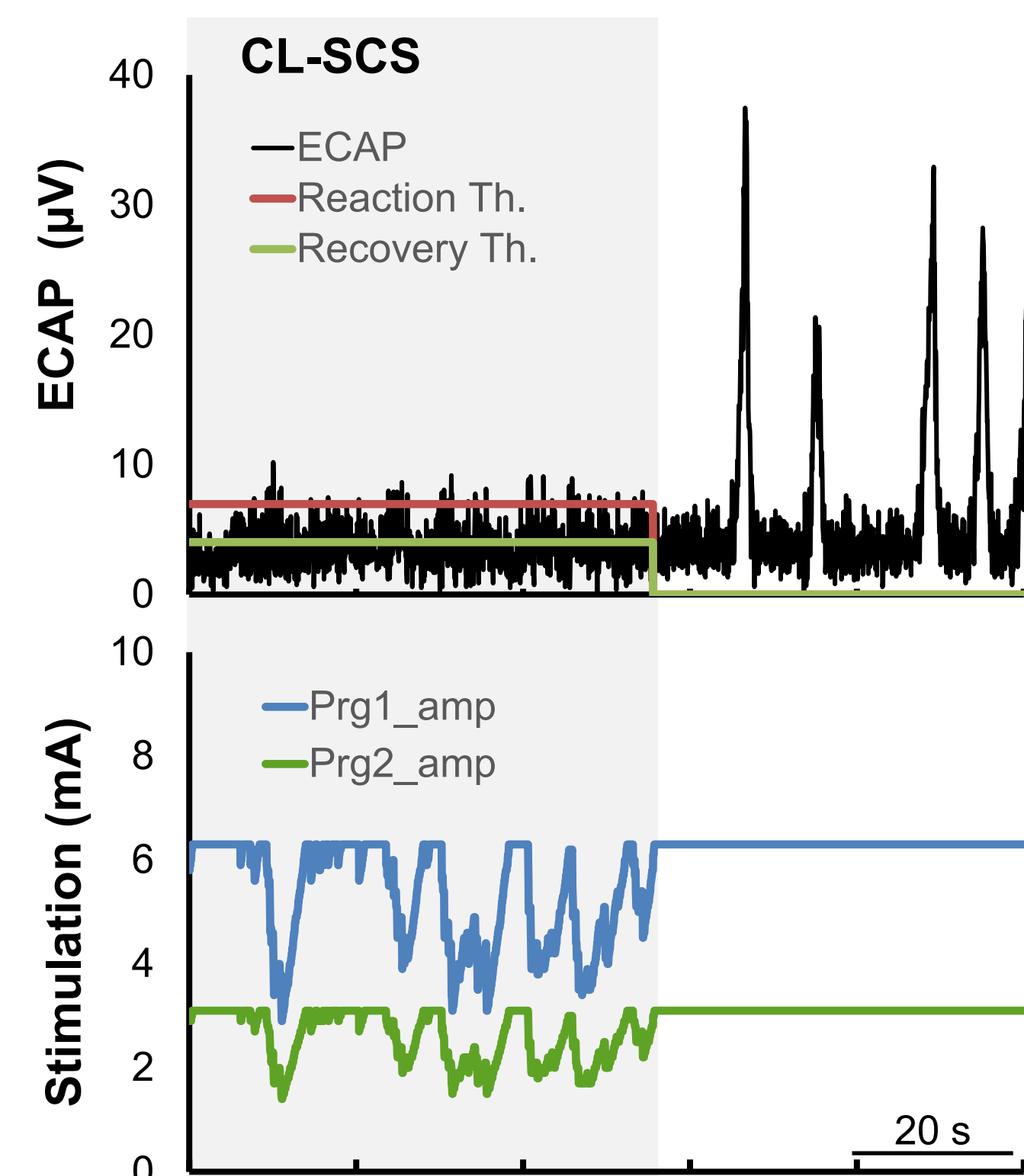
•8/10 improved by MCID or more in 3 or more of the domains listed to the right

•Average 2X MCID in Overall Pain, QoL and Physical Function

The number of subjects meeting a minimal clinically important difference (MCID) in various outcomes was assessed. A composite outcome assessed the number of subjects improving in 3 domains.<sup>3</sup>

## Flexible CL feature that works with Sub- or Supra-Perception Waveforms

### 3a. No ECAPs at rest (below perception)



### 3b. ECAPs at rest (above perception)

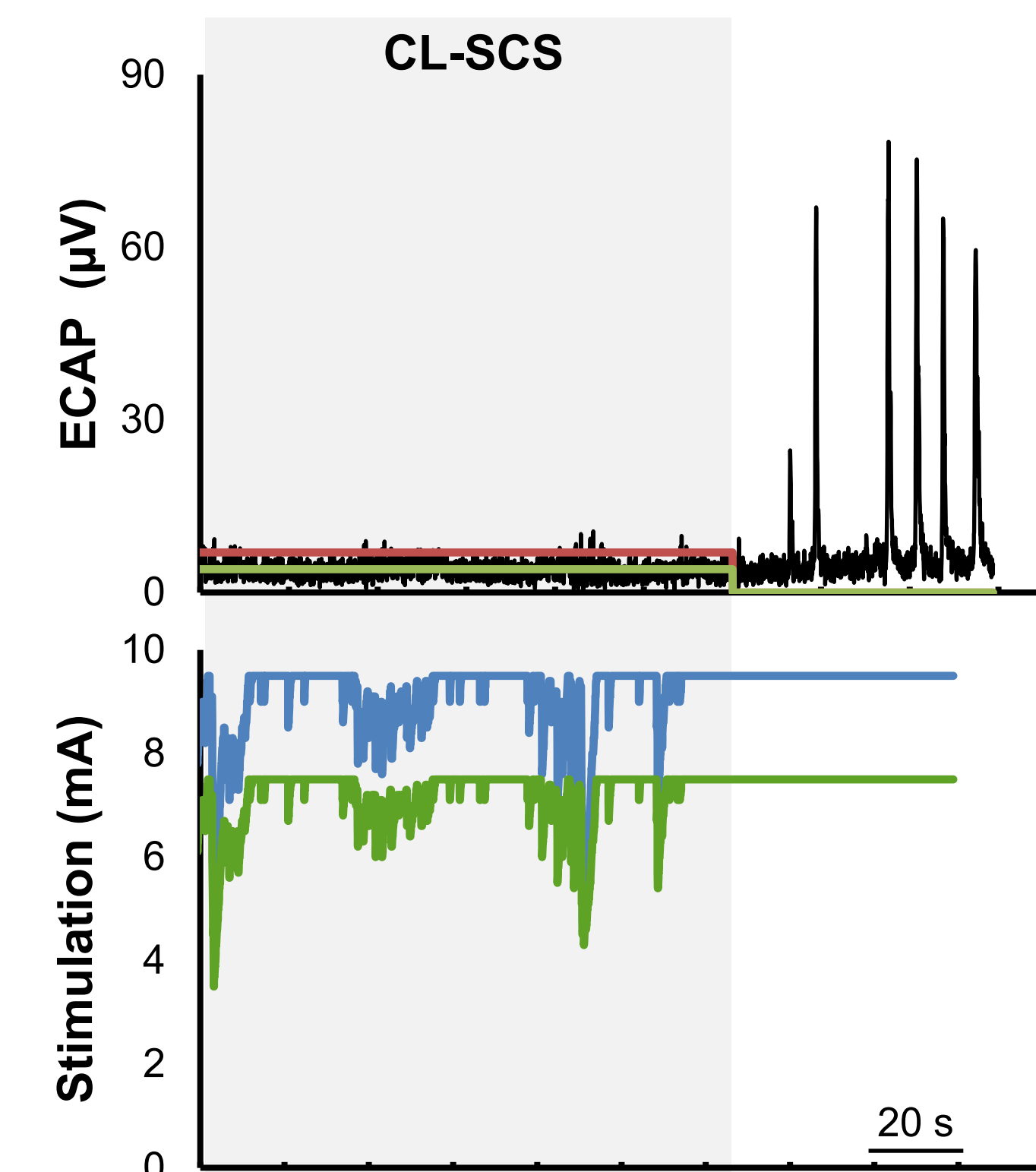


**Figure 3.** Examples (from different subjects) for the CL feature adjusting stimulation amplitude during 12-month in-clinic visit for **a.** below or **b.** above perception waveforms. Large changes in ECAP amplitude with OL-SCS during movement can be seen in both examples; for the below-perception therapy the CL feature will react when ECAPs appear during movement.

## SUMMARY

- CL-SCS reduced overstimulation and the need for manual adjustments, thereby improving the overall therapy experience.
- Significant and sustained improvements were observed in Pain, Physical Function, and Quality of Life through 12-months.
- Follow-ups are ongoing to evaluate the long-term benefits of CL-SCS with customized, multiplexed waveforms.

References:  
1. US SCS Patient Market Research Conducted in June/July 2023 by StrataMark LLC, an independent 3rd party market research agency (N=100, double-blinded, 20-minute online survey).  
2. Vallejo et al. Journal of Pain Research, 2021; vol.14, 3909 – 3918.  
3. Mekhail et al. Reg Anesth Pain Med, 2024; vol 49 (5): 346 - 354.

Disclosures:  
MAR and VM have consulted for Medtronic. VM, MAR, RS, PG, CDB and JY are participating investigators in this study.

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