

Closed-Loop SCS Therapy Outcomes at 3-months with Waveforms Optimized per Patient Preference

Ashwini Sharan, MD¹, Vahid Mohabbati, MD², Richard Sullivan, MBChB³, James Yu, MD⁴, Peter Georgius, MBBS⁵, Charles D Brooker, MBChB⁶, Malgorzata Straka, PhD¹, Andrew J Cleland, MD¹, Glenn Butler¹, Michelle Knight, BSc¹, Zachary Kyle-Little, BSc¹, Justin Morey¹, Nancy L McClelland, BSN¹, Charles Cain, PhD¹, Abi Franke, PhD¹, Marc A Russo, MBBS⁷

¹Medtronic, Minnesota, USA, ²Sydney Pain Research Centre, New South Wales, Australia, ³Precision Brain Spine and Pain Center, Victoria, Australia, ⁴Australian Medical Research, New South Wales, Australia, ⁵Sunshine Coast Clinical Research, Queensland, Australia ⁶Royal North Shore Hospital, New South Wales, Australia, ⁷Genesis Research Services, New South Wales, Australia

INTRODUCTION

- Closed-Loop SCS (CL-SCS) system adjusts amplitude, to account for changes in lead to cord distance, based on the measured physiologic response of the spinal cord – the evoked compound action potential (ECAP).¹
- CL-SCS aids in consistent delivery of dose to achieve analgesia. Here we report outcomes with CL-SCS with a variety of waveforms tailored to the patient's needs.

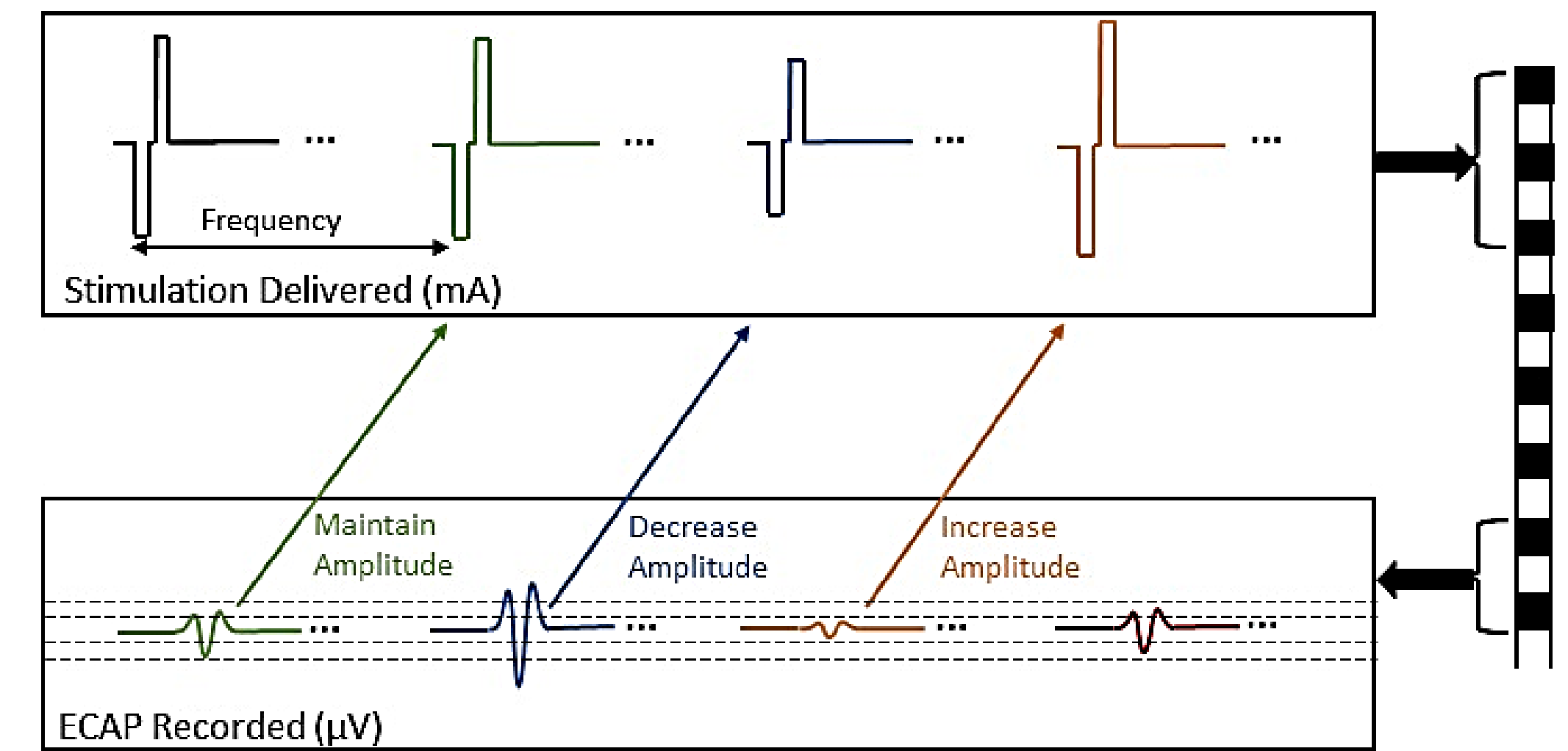


Figure 1. CL algorithm updates stim amplitude after each pulse.¹

METHODS

- Prospective, trial being conducted at 7 sites in Australia with study visits at 1-, 3-, 6-, 12-, 18-, and 24-months post device activation. Subjects with a successful SCS trial (≥50% reduction) were implanted with the study device. Each subject could have up to 4 optimization visits prior to the 1-month visit. (NCT05177354)
- Primary objective is to demonstrate reduction in overstimulation with the CL feature during randomized, single blind testing with an open-loop SCS control arm at 1-month. The primary analysis set (**PAS**) includes the **first 28 back/leg pain** subjects to complete the 1-month visit; stimulation amplitude was programmed at/above perception for this testing.
- Secondary objective is to characterize % of subjects with ≥50% reduction in overall, back/leg pain at 3 months; there is no control arm for this testing.
- **Data from 26 of the 28 subjects in the PAS** that completed the 3-month visit are presented here; 2/28 did not complete the 3-month visit – 1 missed visit and 1 due to an adverse event.

RESULTS

Table 1. Baseline Characteristics

Subject Characteristics	PAS (N=28)
Age (Years) – Mean (SD)	58.6 (13.5)
Female – n (%)	13 (46.4)
Primary Indication – n (%)	
DDD	14 (50.0)
FBSS/ PSPS type 2)	6 (21.4)
Radicular Pain Syndrome	4 (14.3)
CRPS	1 (3.6)
Post laminectomy Pain	1 (3.6)
Unsuccessful Disk Surgery	2 (7.1)
VAS (mm) – Mean (SD)	
Overall	79.5 (11.0)
Back	77.4 (15.7)
Leg	75.6 (17.8)
Severely disabled or worse – n (%)	24 (85.7)
Onset of Pain – Years, Mean (SD)	9.4 (9.5)
On Opioids – n (%)	14 (50.0)

Primary Endpoint: Closed-Loop Reduced Overstimulation in 89% of PAS Subjects (at 1-month)

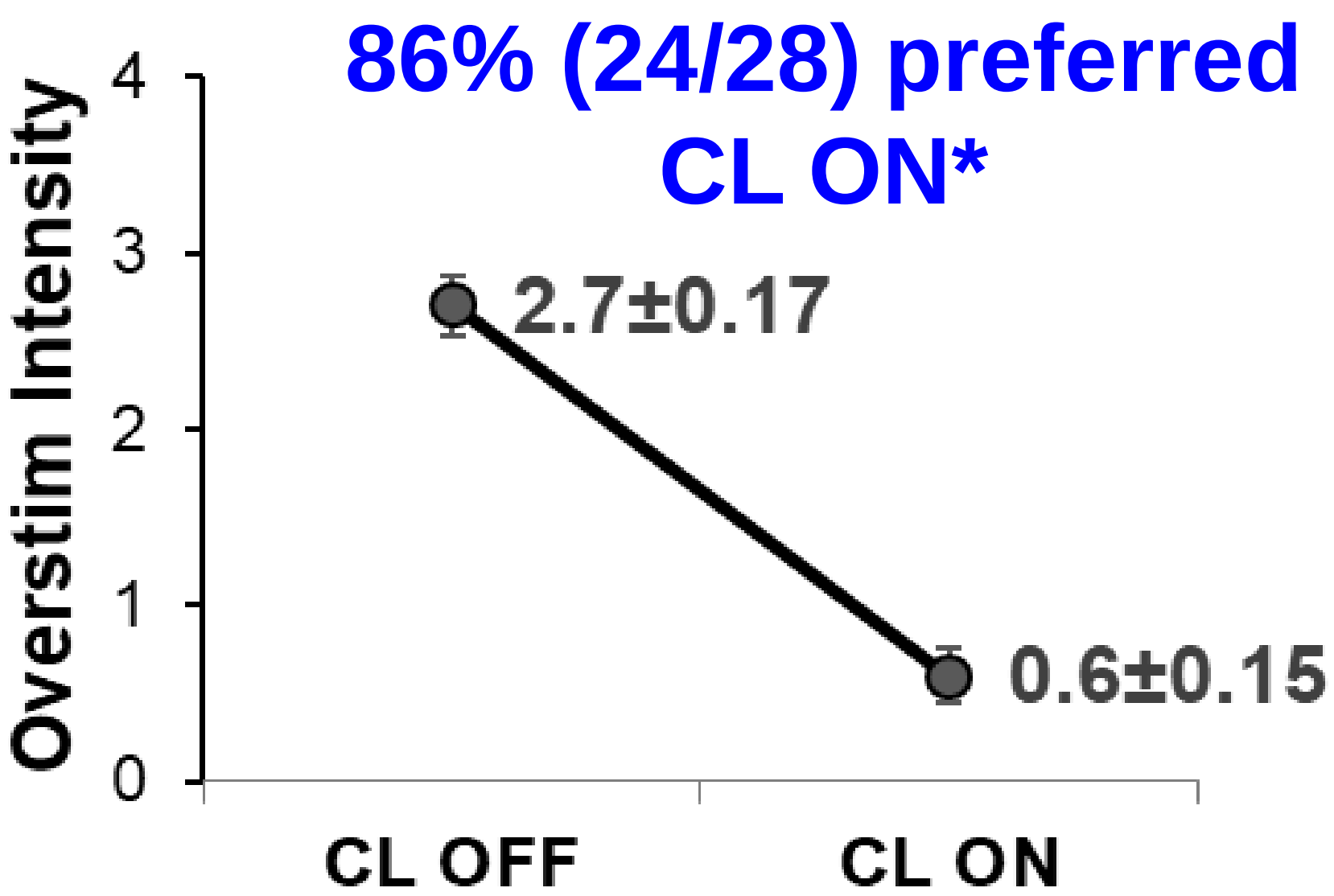


Figure 2. Intensity of overstimulation sensation on a 5-point Likert scale 0-4: No, Mild, Moderate, Strong and Very Strong overstimulation.*Preference reported during blinded testing.

Substantial reductions in Overall Back/Leg Pain was Observed at 3 months with Tailored Waveforms further Optimized with the CL feature

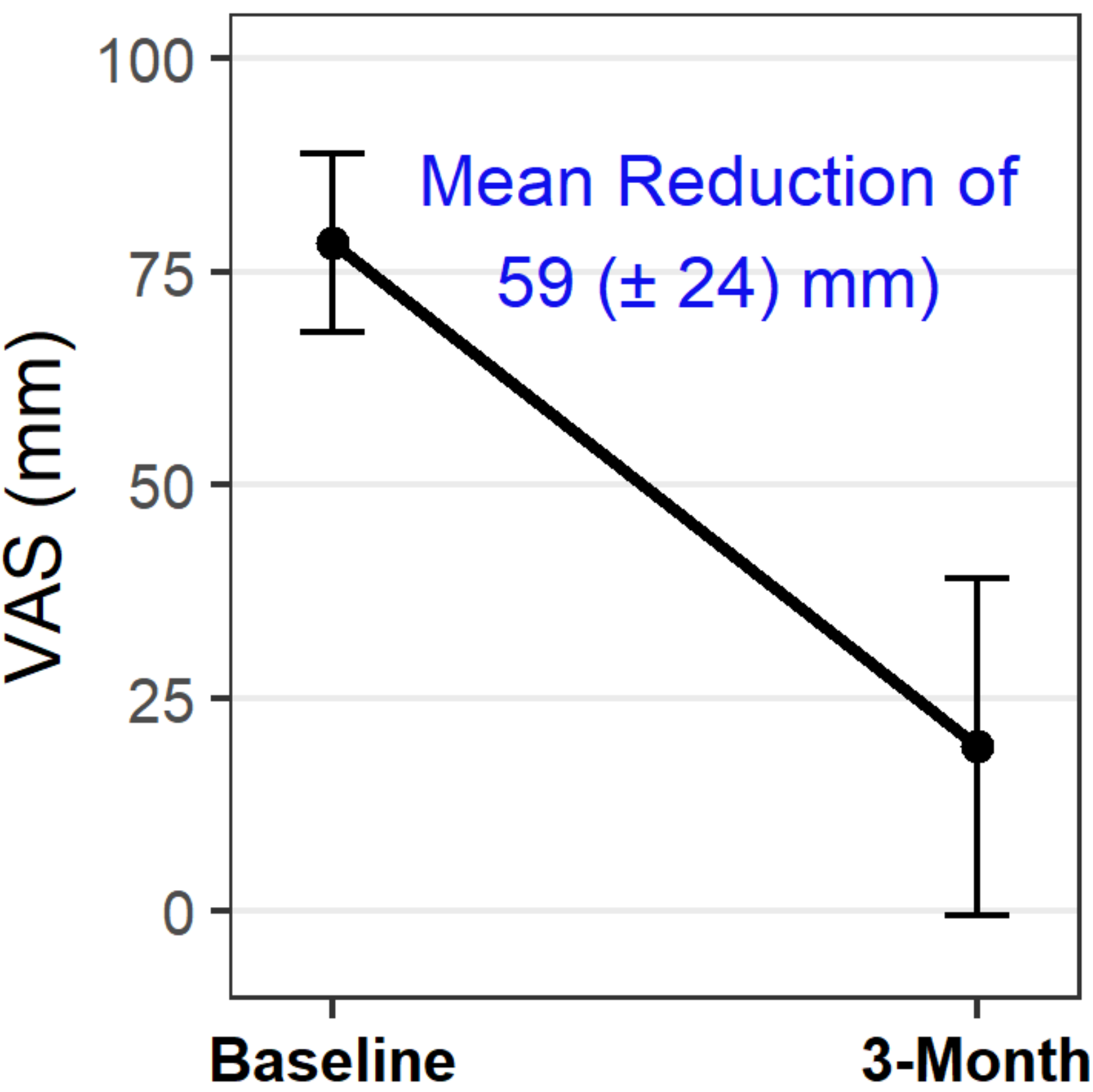
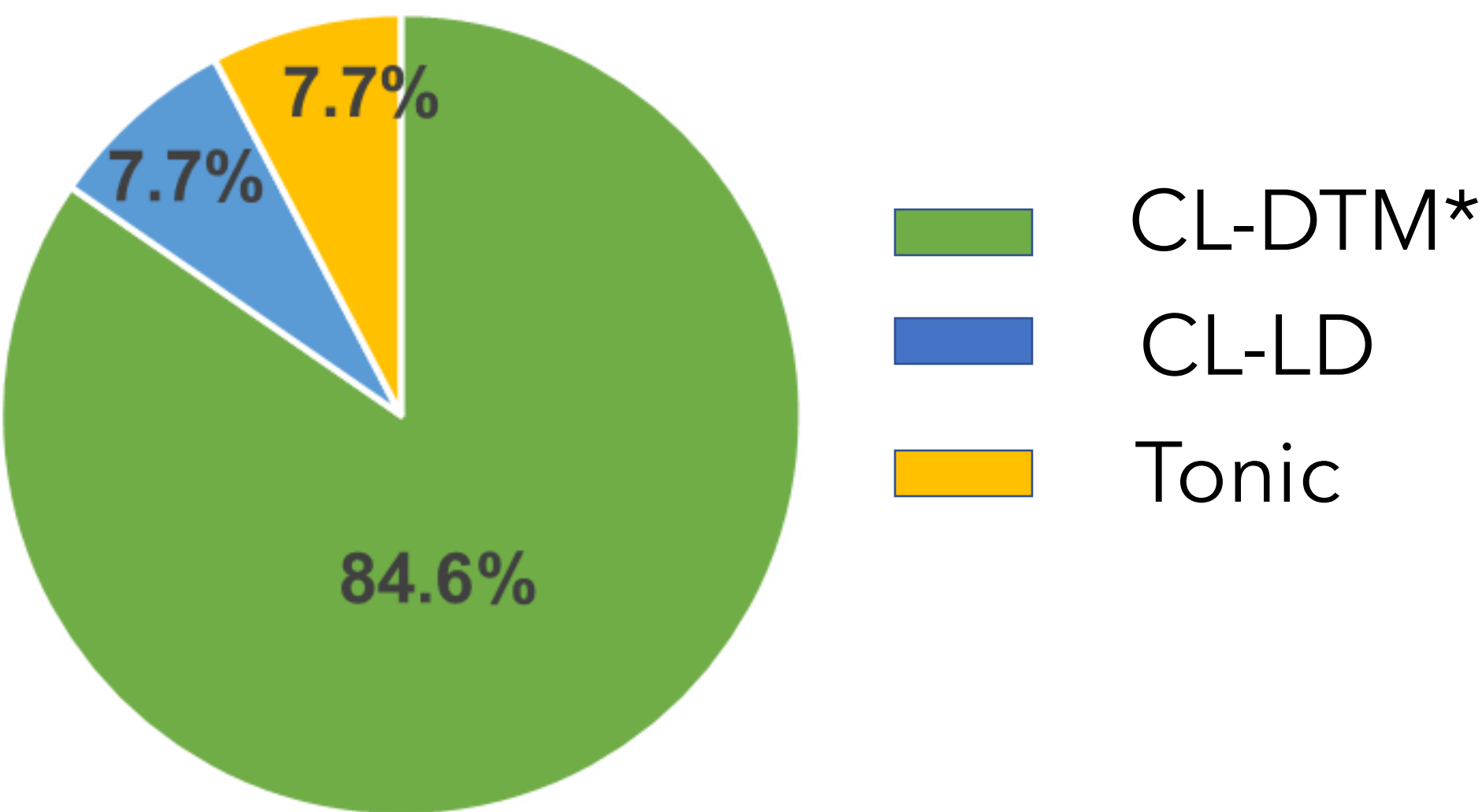
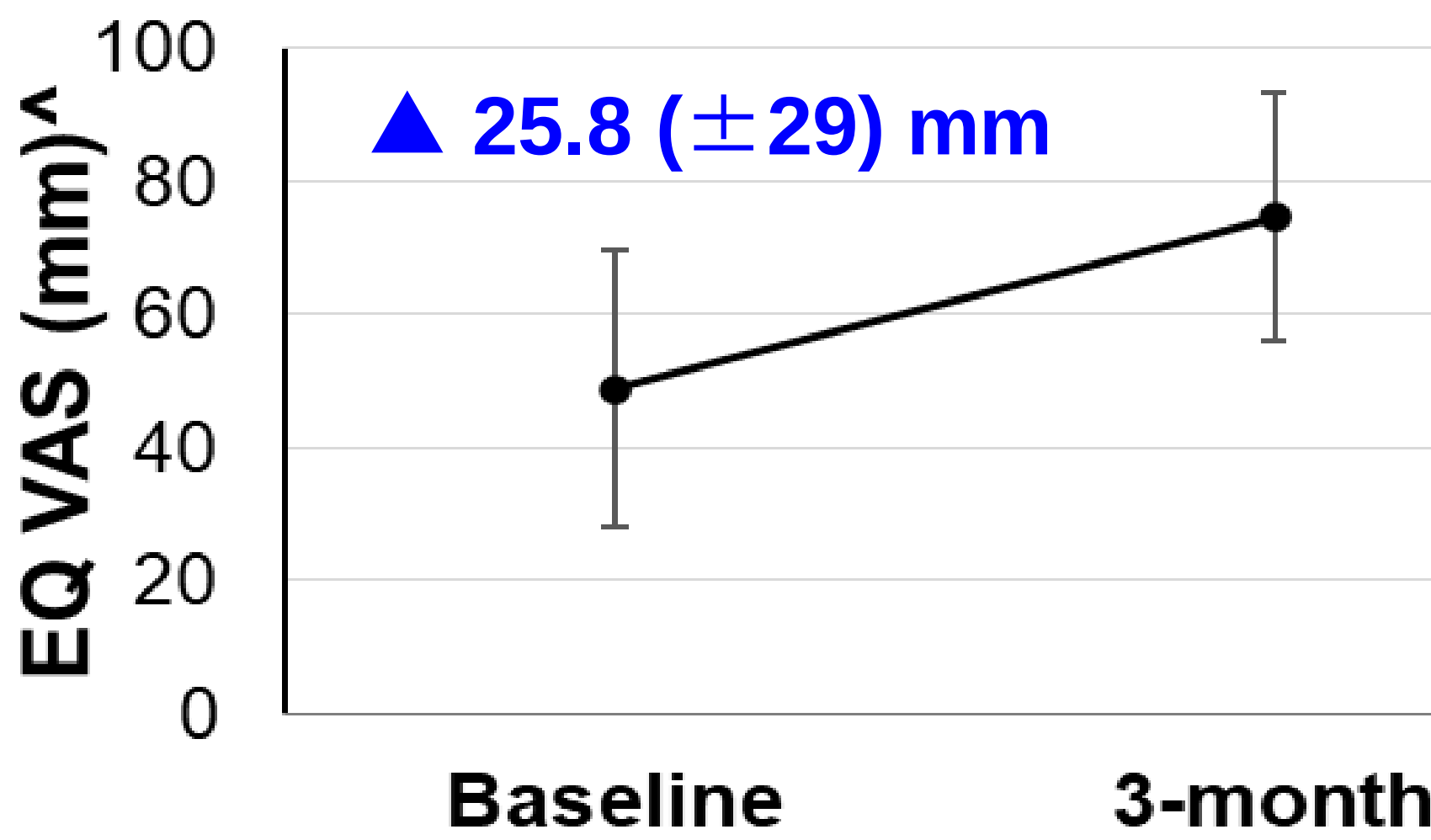


Figure 3. A. Overall VAS at Baseline and 3-month visits (n = 26). **B.** Most used waveforms.² *DTM includes 1 program at 50 Hz and the other at a rate between 200 – 900 Hz. LD includes one or two 50 Hz programs.



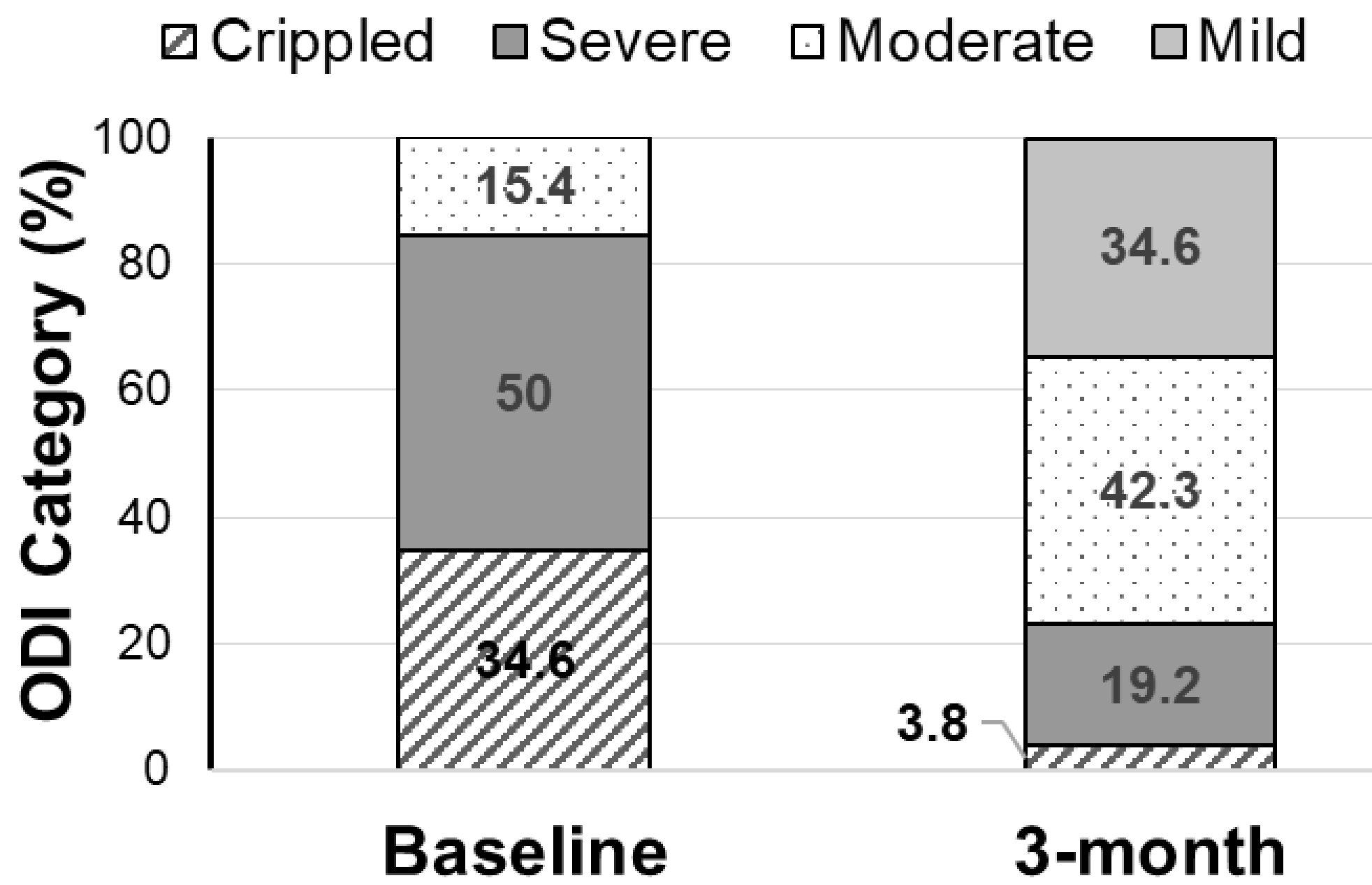
Health-Related QoL Improved Significantly (per EQ-5D)



81% (21/26) reported better Health State*

[^] EQ VAS improved at 3-mo.
^{*}The EQ-5D is better on ≥1 dimension and is no worse in any other.³

81% Of Subjects Improved their Physical Function (per ODI)



% with Severe disability or Worse reduced from 85% to 23%

Figure 4. Change in ODI category (n = 26).

CONCLUSIONS

- Patient Reported Outcomes are comparable to previous studies with CL-SCS and other modern waveforms.^{2, 4-6}
- 89% were a great deal better/better (per PGIC) and 100% reported being very satisfied/satisfied with the therapy (n = 26).

REFERENCES

1. Vallejo et al. Journal of Pain Research, 2021; vol.14, 3909 – 3918. 2. Fishman et al. Pain Practice, 2021; vol. 21, 912 – 923. 3. EQ-5D-5L User Guide Page 20: <https://tinyurl.com/EQ5D-User-guide>; accessed July 20, 2023. 4. Mekhail et al. Lancet Neurology, 2020; vol. 25, Suppl. page 9. 5. Wallace et al. Pain Management, 2023; vol. 13, 171 – 184. 6. Kapural et al. Anesthesiology, 2015; 123 – 132.

MAR and VM have consulted for Medtronic. VM, MAR, RS, PG, CDB and JY are participating investigators in this study. This study is sponsored by Medtronic.