

ECAP-CONTROLLED CLOSED-LOOP SCS WITH A SINGLE LEAD

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Introduction

Evoked compound action potential (ECAP)-controlled closed-loop spinal cord stimulation (SCS) has been proven to show superior pain relief compared to traditional 'open-loop' SCS due to its ability to maintain consistent and accurate activation of the spinal cord (1,2). Here, we present a single-center case-series in which ECAP-controlled closed-loop SCS was delivered using a single percutaneous lead to treat chronic pain.

Materials and Methods

N=8 patients with persistent spinal pain syndrome (PSPS) type 2 (5F; 3M; 55.3 years (mean)) were implanted with a single-percutaneous 12-contact lead (2 patients had two leads but only one lead was programmed) guided by intraoperative paresthesia-based testing and coupled to an ECAP-controlled closed-loop SCS system (Evoke® SmartSCS™, Saluda Medical, Australia). All patients were suffering from pain in at least 2 areas of their body (Fig.1). Pain relief was assessed using the verbal numerical rating scale (NRS) and objective neurophysiology was collected at the follow-up visits. Additionally, the EQ-5D-5L a standardised instrument for measuring health-related quality of life states were investigated.

	Pain location left	Pain location right
Patient 1	Foot, Lower Leg, Upper Leg, Buttock, Lower Back, Groin	Foot, Lower Leg, Upper Leg, Buttock, Lower Back, Groin
Patient 2	Foot, Lower Leg, Upper Leg, Buttock, Lower Back	Foot, Lower Leg, Upper Leg, Buttock, Lower Back
Patient 3	Foot, Lower Leg, Upper Leg, Lower Back	Foot, Lower Leg, Upper Leg, Lower Back
Patient 4	Upper Leg, Buttock, Lower Back	Buttock, Lower Back
Patient 5	Foot, Lower Leg, Upper Leg, Buttock, Lower Back	Foot, Lower Leg, Upper Leg, Buttock, Lower Back
Patient 6	Lower Leg, Upper Leg, Buttock, Lower Back	Buttock, Lower Back
Patient 7	Upper Leg, Lower Back	Lower Back
Patient 8	Lower Leg, Lower Back	Lower Leg, Lower Back
Patient 9	Lower Leg, Upper Leg, Buttock, Lower Back	Buttock, Lower Back

Table.1: Pain location.

Results (Interim Analysis)

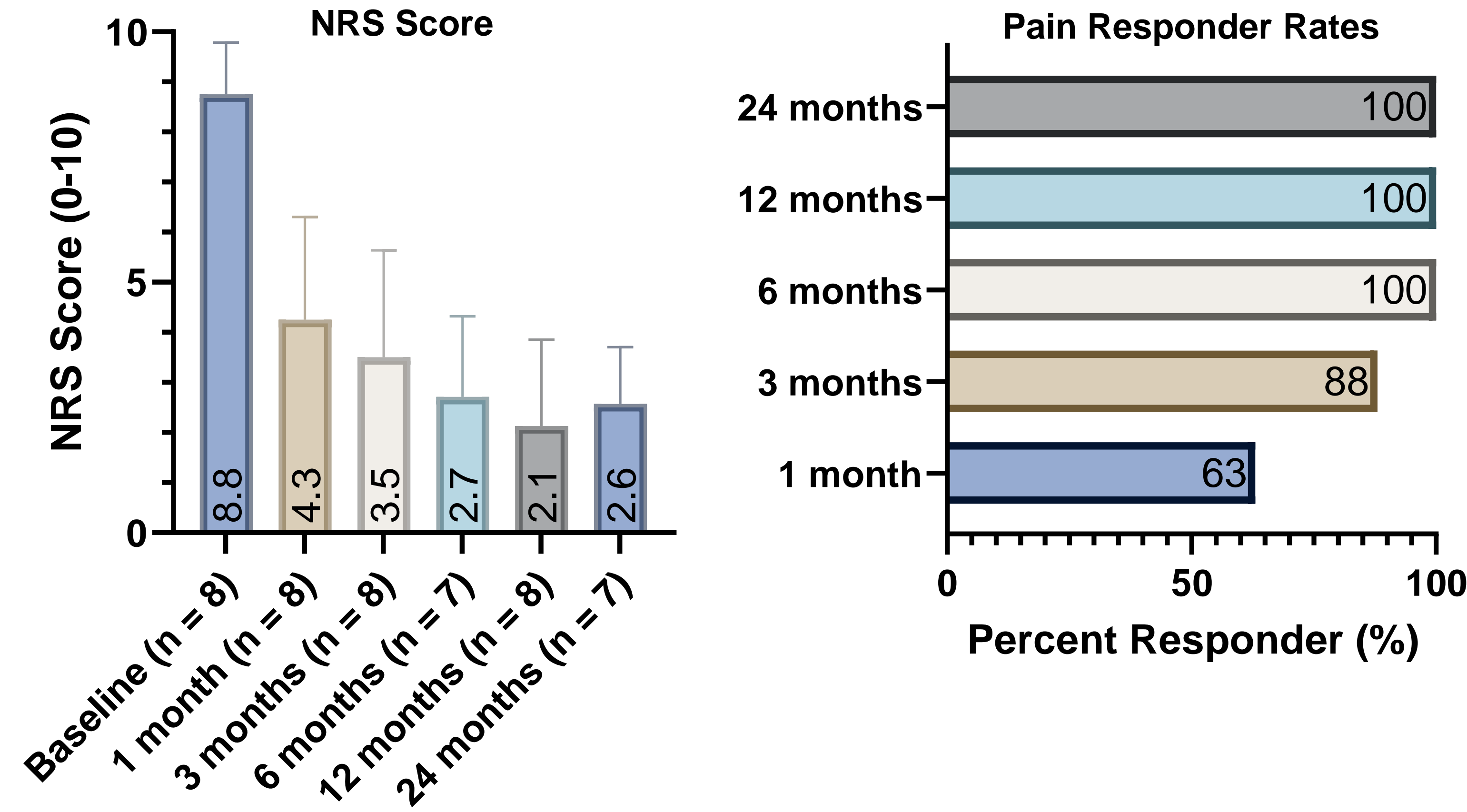


Fig. 1 NRS score and Responder rate over time. Mean (±SD) Baseline (n = 8) pain scores (NRS) were 8.8 ± 1.0 and at 24 months (n = 7) scores decreased to 2.6 ± 1.1. Patients who reported ≥50.0% pain relief were defined as responders. At 24 months, there were 100.0% responders

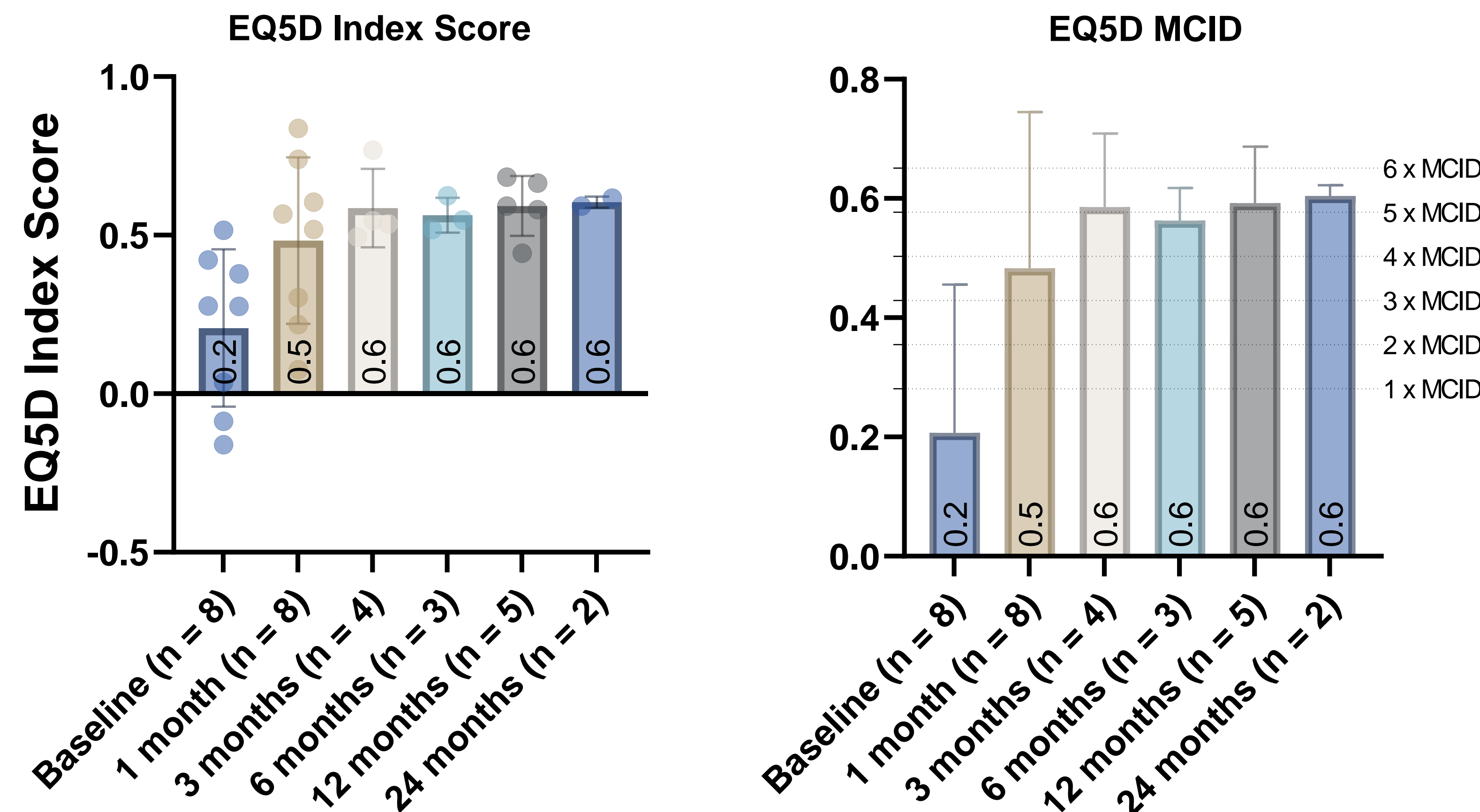


Fig. 3- EQ5D Index Score and MCID. Mean (±SD) Baseline (n = 8) EQ5D scores were 0.2 ± 0.3 and at 12 months (n = 5) scores increased to 0.6 ± 0.7. More than 5xMCID (0.074) improvement were observed at 12 months and 24 months.

Results (Interim Analysis)

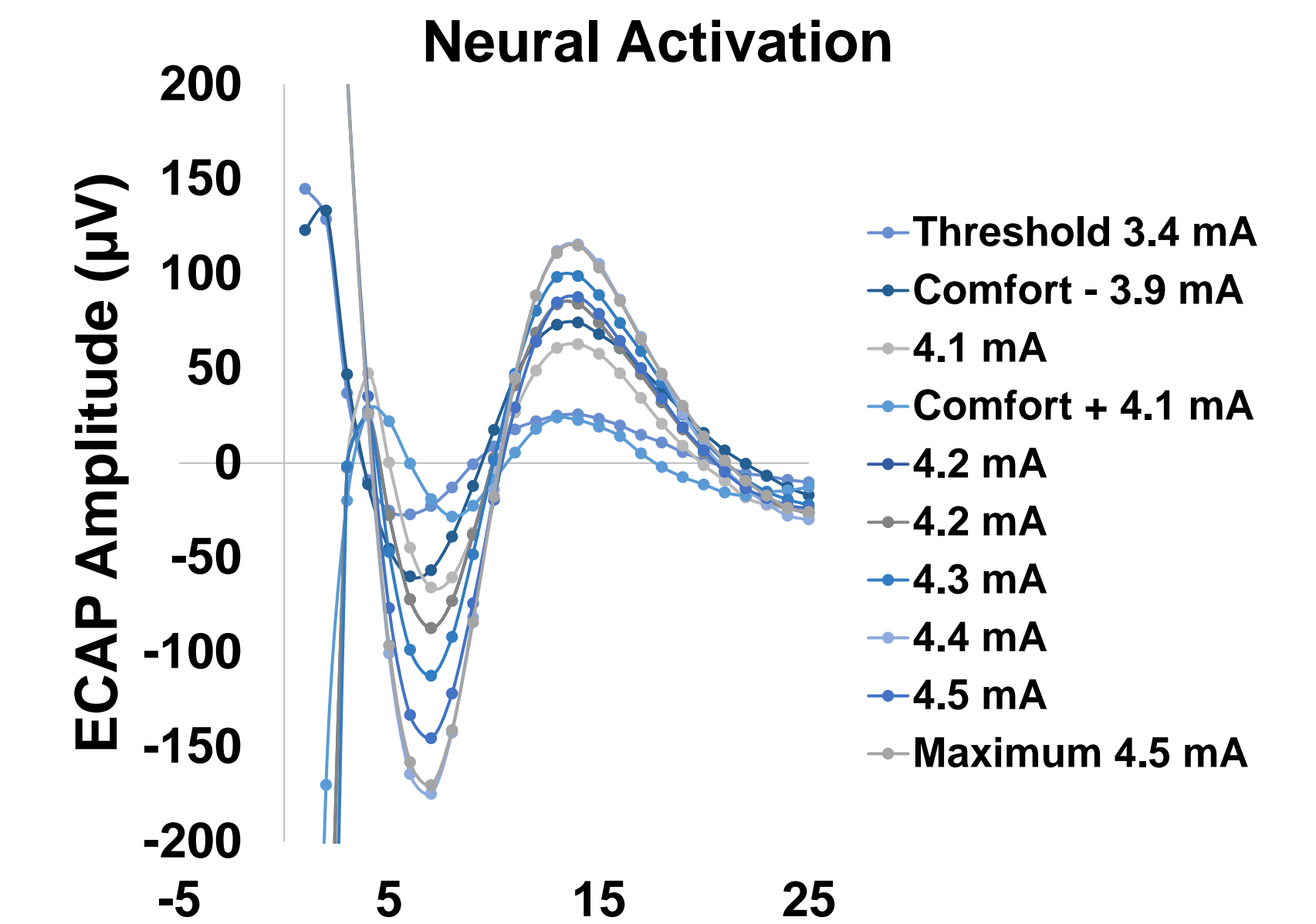


Fig. 4 ECAP Amplitude. Example of an individual activation plot from an individual patient. The recorded neural signal consisted of a positive P1 peak followed by a negative N1 peak and a second positive P2 peak. The ECAP amplitude (µV) grew as current increased.

In- and Out-Of-Clinic Activation

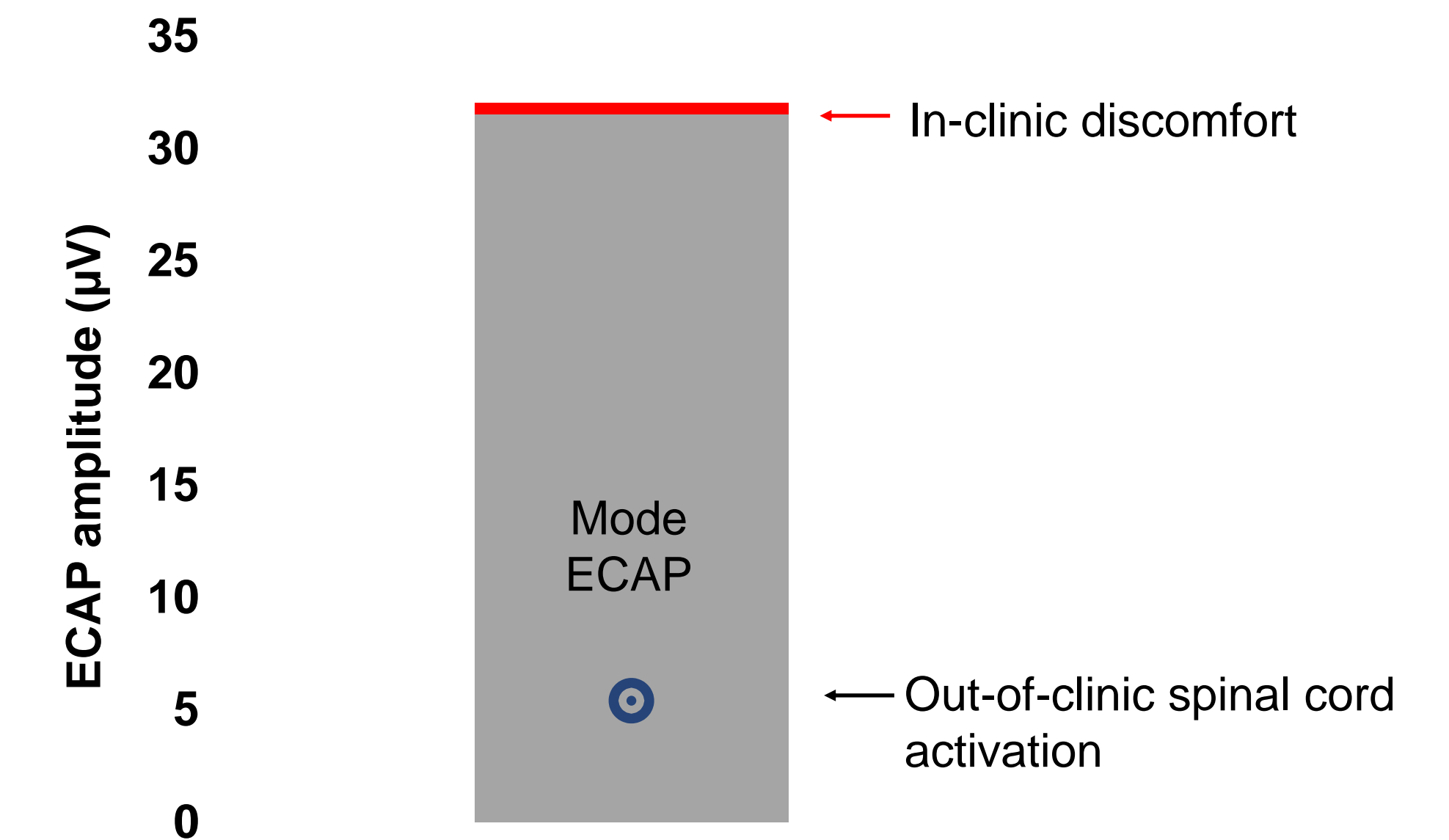


Fig. 5 In-clinic and out-of-clinic spinal cord activation. Recording and measurement of ECAPs from the patient in-clinic and out-of-clinic- The patient used their closed-loop SCS above ECAP threshold and (Neural Activation Level; Mode ECAP: 5.4 µV)

Conclusion

Neurophysiology-based programming and accurate neural activation enabled by pulse-pulse monitoring and control have been shown to provide superior, effective, and durable pain relief (1,2).

Initial data from this single-center case-series indicated the feasibility of using single-lead placements for treating chronic pain in patients suffering from pain in at least two areas of their body, with the ECAP-controlled closed-loop SCS system. Further research is required to validate these preliminary findings using single-lead placements.

1) Mekhail N et al. Long-term safety, and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. Lancet Neurol. 2020.
2) Russo M et al. Sustained Long-Term Outcomes with Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study. Neurosurgery. 2020.