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# ECAP-CONTROLLED CLOSED-LOOP SCS FOR THE TREATMENT OF CHRONIC PAIN: 36-MONTH EVOKE STUDY OUTCOMES

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## Introduction

A novel SCS system delivers evoked-compound action potentials (ECAPs)-based therapy to 1) Guide programming and confirm activation of the intended target (i.e., ECAP-guided programming); and 2) Deliver closed-loop therapy to maintain accurate and consistent neural activation on every stimulus (i.e., ECAP-controlled closed-loop SCS [CL-SCS]). This therapy has now been studied through 36-months.

## Materials and Methods

The EVOKE double-blind RCT was designed to evaluate the safety and efficacy of ECAP-based therapy to treat chronic back and leg pain (NCT02924129) (1,2). The study was conducted at 13 investigation sites throughout the United States under an Investigational Device Exemption to gain US Food and Drug Administration (FDA) approval. The protocol was approved by each participating site's institutional review board and all patients provided written informed consent. Herein we report on the cohort that were assigned to and remained in CL-SCS at 36-months. Overall back and leg pain (VAS), opioid usage, and patient-reported outcomes including ODI, POMS, PSQI, and EQ-5D were collected. Treatment response was evaluated considering attainment of minimal clinically important differences (MCIDs) in impaired domains (baseline scores worse than normative US values). Objective neurophysiological data, including spinal cord activation, were measured.

## Results/Case Report

Forty-one patients randomized to CL-SCS remained in their treatment allocation and were followed-up through 36-months. Most patients obtained ≥50% reduction (83% [34/41]) and ≥80% reduction (59% [24/41]) in overall back and leg pain. Most patients with baseline impairment in a domain obtained ≥1 MCID response for ODI (85% [35/41]), EQ-5D (81% [33/41]), PSQI (68% [25/37]) and POMS (81% [21/26]). All patients (100% [41/41]) achieved ≥1 MCID response in at least 1 domain, 93% (38/41) in at least 2, 85% (35/41) in at least 3, 60% (24/40) in at least 4 and 57% (13/23) in 5 domains. Opioid reduction or elimination was observed in 55% (11/20) of patients who were taking opioids prior to CL-SCS. Therapy accuracy was within 3.7μV from the ECAP target. Device utilization was 80% and percent time stimulating above ECAP threshold was 98%. There were no explants due to loss of efficacy through 36-months.

## Discussion

ECAP-based SCS therapy enables real-time collection of continuous, objective, in-vivo neurophysiological data. This provides accurate evaluation of the therapy and interpretation of the clinical outcomes, and when ECAP-controlled CL-SCS is employed, results in a level of evidence unmatched in neuromodulation. ECAP-guided programming and ECAP-controlled closed-loop neural activation resulted in sustained, durable pain relief and holistic treatment response at 36-months. ECAP-based therapy provides a transparent, objective approach to SCS by which therapy can be monitored and adjusted to improve patients' lives.

## References

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; 19: 123-134.
2. Mekhail N, et al. Durability of Clinical and Quality-of-Life Outcomes of Closed-Loop Spinal Cord Stimulation for Chronic Back and Leg Pain: A Secondary Analysis of the Evoke Randomized Clinical Trial. JAMA Neurol 2022; 79: 251-260.

## Disclosures

Yes

## Tables / Images