ECAP-Controlled EVOKE Closed-Loop Spinal Cord Stimulation (CL SCS):
Double-Blind, Randomized Trial for the Treatment of Chronic Pain – 24-month Outcomes

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ABSTRACT

Introduction:
Evoked compound action potential (ECAP) recording provides an objective measure of spinal cord (SC) activation during SCS and can assist in programming of the SCS system. ECAP-controlled EVOKE CL SCS, in which the stimulation output is automatically adjusted to maintain a desired ECAP amplitude, has been shown to provide effective pain relief in an open-label study (ACTRN12615000713594) (Brooker 2021).

Objective:
This double-blind randomized controlled trial (RCT) was conducted under an Investigational Device Exemption to compare the safety and efficacy of ECAP-controlled EVOKE CL stimulation (investigational group) with open-loop (fixed output) stimulation (OL, control) to treat chronic back and leg pain (NCT02924129) (Mekhail 2019).

Methods:
134 subjects were enrolled and randomized after trial leads were implanted. The primary endpoint evaluated ≥50% reduction in overall back and leg pain measured by the Visual Analog Scale (VAS). Opioid usage and other patient-reported outcomes (PROs) including emotional/physical functioning, sleep quality, and quality of life were also collected. Additionally, objective neurophysiological data, including SC activation and time spent in the therapeutic range, were collected.

Results:
Herein the Evoke Study Group reports the 24-month outcomes from this ongoing RCT. The proportion of implanted subjects with ≥50% overall back and leg pain reduction at 24 months was statistically superior in the EVOKE CL vs. EVOKE OL group (84.0% vs. 65.9% subjects, respectively; p=0.040). Long-term improvements in all other PROs, including POMS, ODI, PSQI, EQ-5D-5L, and SF-12, were also demonstrated. Opioids were reduced or eliminated in
66.7% (EVOKE CL) and 60.9% (EVOKE OL), respectively. The most frequent level of SC activation was three times greater for EVOKE CL (median ECAP Amplitude: 22.5µV CL vs. 7.5µV OL). SC activation was better maintained within the therapeutic range with EVOKE CL (median: 93.9% CL vs. 46.1% OL). There were no differences in the safety profiles between treatment groups, and the type, nature, and severity of adverse events were similar to other SCS studies.

**Conclusion:**
In this ongoing study, ECAP-controlled EVOKE CL SCS provided statistically superior pain relief and greater improvement in other PROs compared with EVOKE OL SCS at 24 months. EVOKE CL delivered greater levels of SC activation and better maintained SC activation in the subject’s therapeutic range.

**Conclusion Statement From Your Research Findings:**
The level and consistency of SC activation may be mechanistically important for outcomes with SCS.