ASRA PAIN MEDICINE
22nd Annual Pain Medicine Meeting
November 10-11, 2023 | New Orleans, Louisiana
#ASRAFall23

Abstract: 5049

Scientific Abstracts > Chronic Pain

# AN IMPLANTABLE SCS SYSTEM WITH AUTOMATIC DAILY REMOTE MONITORING AND REMOTE PROGRAMMING: FIRST-IN-HUMAN EXPERIENCE

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## Introduction

Most spinal cord stimulation (SCS) systems require frequent in-person reprogramming to achieve optimal pain management. Recent technological advances in the capabilities of SCS devices have presented the opportunity for remote SCS device management.1 While results of an SCS teleprogramming pilot study have been reported previously,2 to our knowledge, BENEFIT-03 (NCT04683718) is the world's first long-term study of an SCS system with automatic daily transmission of objective device monitoring data with remote programming. Here, we report analysis of remote device management outcomes from BENEFIT-03, an ongoing 2-year study designed to assess an implantable SCS system with multiphase stimulation, automatic daily remote monitoring, and remote programming capabilities.

## Materials and Methods

BENEFIT-03 is a prospective, multicenter, single-arm, first-in-human study with 24-month follow-up, ongoing at Australian clinical sites with Ethics Committee approval. All participants provide written informed consent prior to study procedures. Key inclusion criteria: 1) chronic low back and/or leg pain, 2) baseline pain intensity ≥60mm by Visual Analog Scale (VAS). Post-implant follow-up consists of in-office visits (3, 6, 12 and 24 months) and remote visits as required, which may be initiated by participants, investigators, proactive care triggers (based on automatic daily device monitoring), or patient-reported outcomes (PROs). Primary endpoints are responder rate (≥50% overall pain relief, VAS) and freedom from device-related complications at 6 months. Additional outcome measures include Oswestry Disability Index, opioid usage, PROMIS-29, Patient Global Impression of Change, daily PROs (numeric rating scale [NRS] for pain intensity and sleep quality via diary assessments; collected for 28 days following the 3-, 6-, and 12-month visits), and other questionnaires (including participant and clinician experiences with remote management)

## Results/Case Report

BENEFIT-03 was initiated with the first participant consented in September 2021. As of this analysis, remote management data were available for 34 trial participants and 31 implanted participants. From October 2021 to May 2023, the overall daily device monitoring data transmission rate for trialed and implanted participants was 93%, and a total of 100 remote device management sessions were conducted. Six-month questionnaire data regarding experience with remote device management were available for 28 implanted participants and the clinicians of 23 participants. Of the participants surveyed, 100% found the process of remote device management follow-up easy or very easy and 93% agreed or strongly agreed they would choose a device with remote capabilities. Clinicians responded that remote device management benefited 83% of participants and reduced staff burdens in the management of 55% of participants.

## Discussion

This interim analysis showed remote device management to be a highly useful tool well-received by both SCS participants and their clinicians. Participants were satisfied with remote management of their SCS system and clinicians reported that remote management benefited participants and reduced staff burden.

## References

1. Staats P, Deer T, Levy R, et al. Expert Panel Recommendations on Remote Monitoring in the Field of Spinal Cord Stimulation (SCS). Poster presented at the New York & New Jersey Pain Medicine Symposium; November 3 6, 2022; Jersey City, NJ.
2. Deer TR, Esposito MF, Cornidez EG, Okaro U, Fahey ME, Chapman KB. Teleprogramming Service Provides Safe and Remote Stimulation Options for Patients with DRG-S and SCS Implants. J Pain Res. 2021 Oct 14;14:3259-65.

## Disclosures

Yes

## Tables / Images

# An Implantable SCS System With Automatic Daily Remote Monitoring and Remote Programming: First-In-Human Experience (114/130 characters)


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**ABSTRACT** (443/1000 word limit)

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**References** (maximum 5):

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