75th AAN ANNUAL MEETING ABSTRACT

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Abstract Title: 10 kHz SCS Provides Durable Pain Relief and Neurological Improvements for Patients with Painful Diabetic Neuropathy: 24-Month RCT Results

Press Release Title: Spinal Cord Stimulation May Help Diabetic Neuropathy

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Objective: To evaluate the long-term safety and effectiveness of 10 kHz spinal cord stimulation (SCS) for the treatment of painful diabetic neuropathy (PDN).

Background: Approximately 37 million Americans have diabetes,[1] and ~ 25% of these patients experience PDN.[2] Conventional medical management (CMM), which includes pharmacotherapies, is ineffective for many PDN patients.[2] Here we report outcomes through 24-month (24M) follow-up for high-frequency (10 kHz) SCS treatment of PDN.

Design/Methods: In this RCT, patients had PDN symptoms ≥12M refractory to medications, lower limb pain intensity ≥5cm (0-10cm visual analog scale [VAS]), and hemoglobin A1c ≤10%. Patients (n=216) were randomized 1:1 to 10 kHz SCS plus CMM or CMM alone, with optional treatment crossover at 6M.

Results: At 6M, patients receiving 10 kHz SCS experienced average pain relief of 76%, while patients receiving CMM alone experienced average pain increase of 2%. At 6M, no 10 kHz SCS patients crossed over to CMM, while 93% of eligible CMM patients elected to cross over to 10 kHz SCS. Pain relief with 10 kHz SCS was durable as patients experienced average pain relief of 80% at 24M.

At 6M, clinician-assessed neurological improvements were observed in 62% of patients in the 10 kHz SCS arm and 3% in the CMM arm. Neurological improvements were durable as 66% of patients receiving 10 kHz SCS had improvement at 24M.

There were no device explants due to lack of efficacy. There were eight (5.2%) study-related infections (n=3 resolved; n=5 (3.2%) explanted), which is within the range reported across all/non-diabetic SCS patients (2.5-10%).[3]

Conclusions: The results demonstrate that 10 kHz SCS provides durable pain relief with acceptable safety. The improvements in neurological function highlight the unique disease-modifying potential of 10 kHz SCS for PDN.

References: [1]CDC. National Diabetes Statistics Report; May 2022. [2]Shillo et al. Curr Diab Rep 2019; 14(2):162-73. [3]Eldabe et al. Pain Med 2016; 17(2):325-36.

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