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Improvement in Protective Sensation: Clinical Evidence From a Randomized Controlled Trial for Treatment of Painful Diabetic Neuropathy With 10 kHz Spinal Cord Stimulation

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Abstract

Background: Painful diabetic neuropathy (PDN) can result in the loss of protective sensation, in which people are at twice the likelihood of foot ulceration and three times the risk of lower extremity amputation. Here, we evaluated the long-term effects of high-frequency (10 kHz) paresthesia-independent spinal cord stimulation (SCS) on protective sensation in the feet and the associated risk of foot ulceration for individuals with PDN.

Methods: The SENZA-PDN clinical study was a randomized, controlled trial in which 216 participants with PDN were randomized to receive either conventional medical management (CMM) alone or 10 kHz SCS plus CMM, with optional treatment crossover after 6 months. At study visits (baseline through 24 months), 10-g monofilament sensory assessments were conducted at 10 locations per foot. Two published methods were used to evaluate protective sensation via classifying risk of foot ulceration.

Results: Participants in the 10 kHz SCS group reported increased numbers of sensate locations as compared to CMM alone ($P < .001$) and to preimplantation ($P < .01$) and were significantly more likely to be at low risk of foot ulceration using both classification methods. The proportion of low-risk participants approximately doubled from preimplantation to 3 months postimplantation and remained stable through 24 months ($P \leq .01$).

Conclusions: Significant improvements were observed in protective sensation from preimplantation to 24 months postimplantation for the 10 kHz SCS group. With this unique, disease-modifying improvement in sensory function, 10 kHz SCS provides the potential to reduce ulceration, amputation, and other severe sequelae of PDN.

Trial Registration: The SENZA-PDN study is registered on ClinicalTrials.gov with identifier NCT03228420.

Keywords

neuropathy, diabetes, neuromodulation, chronic pain

Background

Worldwide there are 537 million adults with diabetes, approximately 25% of whom will experience painful diabetic neuropathy (PDN).[1-3] While pain is often the primary motivation for patients to seek treatment for PDN, these patients often also suffer from reduced sensory function.[4] Intact sensory function of the foot, particularly of the plantar surface, is critically important in preventing loss of protective sensation

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