

Is high-frequency spinal cord stimulation a disease-modifying treatment for diabetic neuropathy?

Aims: To investigate whether treatment with high-frequency (10 kHz) spinal cord stimulation (SCS) has beneficial long-term effects on protective sensation in people with painful diabetic neuropathy (pDN).

Methods: Multicenter, prospective, randomized, open-label clinical trial including 216 participants with pDN who were randomized to receive either conventional medical management (CMM) alone or 10 kHz SCS plus CMM with optional treatment crossover after 6 months. Protective sensation corresponding to risk of foot ulceration was evaluated by quantitative assessment of 10 g monofilament tests at 10 sites per foot. The examination was performed at baseline, 3, 6, 12, and 24 months.

Results: Participants in the 10 kHz SCS group were able to detect more 10 g monofilament stimuli compared to CMM alone and to preimplantation at each post-randomization visit, which translated into an increased proportion of participants at low foot risk for foot ulceration in the 10 kHz SCS group. The proportion of low-risk participants approximately doubled from pre-implantation to 3 months post-implantation and remained stable through 24 months.

Conclusions: 10 kHz SCS treatment may exert beneficial long-term effects on protective sensation in people with pDN.

Comments. There is increasing evidence that high-frequency spinal cord stimulation is effective for providing pain relief in patients with painful diabetic neuropathy. However, it is currently unclear, whether it provides other beneficial effects beyond masking peripheral pain signals before they reach the brain. In the present clinical trial (SENZA-DPN), standardized 10 g monofilament tests were performed as an exploratory endpoint to quantitatively assess protective sensation and to assess foot ulceration risk, whereas the evaluation of motor and sensory nerve function as part of the main study endpoints published before seemed to rely more on individual clinical judgment.

In the present study, an increased number of 10 g monofilament stimuli was detected at the first follow-up visit 3 months post-implantation that was maintained throughout the 24-month observation period, suggesting an increased protective sensation equivalent to a lower risk of developing neuropathic foot ulcers. Whether these participants actually developed fewer neuropathic foot ulcers during or after the course of the study is not currently reported.

The mechanistic reasons for the improved touch sensation associated with electrical stimulation remain unclear and future studies are needed to clarify whether the observed test results represent true disease-modifying effects or other electrophysiological or psychophysical phenomena.

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Reference. Argoff CE, Armstrong DG, Kagan ZB, Jaasma MJ, Bharara M, Bradley K, Caraway DL, Petersen EA; for Investigators. Improvement in Protective Sensation: Clinical Evidence From a Randomized Controlled Trial for Treatment of Painful Diabetic Neuropathy With 10 kHz Spinal Cord Stimulation. *J Diabetes Sci Technol.* 2024 Jan 9:19322968231222271. doi: 10.1177/19322968231222271. Epub ahead of print. PMID: 38193426.

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