Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain

The SENZA-RCT Randomized Controlled Trial

Leonardo Kapural, M.D., Ph.D., Cong Yu, M.D., Matthew W. Doust, M.D., Bradford E. Gliner, M.S., Ricardo Vallejo, M.D., Ph.D., B. Todd Sitzman, M.D., M.P.H., Kasra Amirdelfan, M.D., Donna M. Morgan, M.D., Lora L. Brown, M.D., Thomas L. Yearwood, M.D., Ph.D., Richard Bundschu, M.D., Allen W. Burton, M.D., Thomas Yang, M.D., Ramsin Benyamin, M.D., Abram H. Burgher, M.D.
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**ABSTRACT**

**Background:** Current treatments for chronic pain have limited effectiveness and commonly known side effects. Given the prevalence and burden of intractable pain, additional therapeutic approaches are desired. Spinal cord stimulation (SCS) delivered at 10 kHz (as in HF10 therapy) may provide pain relief without the paresthesias typical of traditional low-frequency SCS. The objective of this randomized, parallel-arm, noninferiority study was to compare long-term safety and efficacy of SCS therapies in patients with back and leg pain.

**Methods:** A total of 198 subjects with both back and leg pain were randomized in a 1:1 ratio to a treatment group across 10 comprehensive pain treatment centers. Of these, 171 passed a temporary trial and were implanted with an SCS system. Responders (the primary outcome) were defined as having 50% or greater back pain reduction with no stimulation-related neurological deficit.

**Results:** At 3 months, 84.5% of implanted HF10 therapy subjects were responders for back pain and 83.1% for leg pain, and 43.8% of traditional SCS subjects were responders for back pain and 55.5% for leg pain (P < 0.001 for both back and leg pain comparisons). The relative ratio for responders was 1.9 (95% CI, 1.4 to 2.5) for back pain and 1.5 (95% CI, 1.2 to 1.9) for leg pain. The superiority of HF10 therapy over traditional SCS for leg and back pain was sustained through 12 months (P < 0.001). HF10 therapy subjects did not experience paresthesias.

**Conclusion:** HF10 therapy promises to substantially impact the management of back and leg pain with broad applicability to patients, physicians, and payers. (Anesthesiology 2015; 123:00-00)