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High-Frequency Surpasses Traditional Spinal Cord Stimulation in First Controlled Trial Comparing Technologies

March 19, 2015, NATIONAL HARBOR, Md. – The first-ever randomized, controlled trial to compare spinal cord stimulation (SCS) technologies found that high-frequency SCS using 10 kHz (HF10) exceeded lower-frequency, traditional SCS in response rate and pain relief. Further, this was achieved without the paresthesia that may cause discomfort with traditional SCS, the researchers reported today in a scientific poster at the 31st Annual Meeting of the American Academy of Pain Medicine.

Traditional SCS low-frequency (~50 Hz) stimulation is an attempt to mask the sensation of pain with a tingling or buzzing sensation, known as paresthesia. Therefore, the therapeutic goal with traditional SCS is to cover the areas of pain with paresthesias, explained B. Todd Sitzman, M.D., M.P.H., medical director of Advanced Pain Therapy, PLLC, in Hattiesburg, Miss.

In contrast, “high-frequency HF10 therapy utilizes a stimulation frequency that is orders of magnitude higher than traditional SCS,” Sitzman said. “HF10 therapy does not produce paresthesias and achieves superior back and leg pain relief.”

More importantly, HF10 therapy was shown to be superior to traditional SCS in all of the study-related primary and secondary endpoints, including response rate and pain relief. The magnitude of back pain relief was consistent with previous European research of HF10 therapy (Van Buyten et al, Neuromodulation 2013;16(1):59-65; Al-Kaisy et al, Pain Med 2014;15(3):347-54).

The use of SCS, introduced in 1967, has expanded as a treatment for difficult pain syndromes, encompassing peripheral neuropathies, complex regional pain syndromes, peripheral vascular disease and other disorders in addition to failed back surgery syndrome (Deer, Techniques in Regional Anesthesia and Pain Management 1998 2(3):161-7).

Traditional low-frequency SCS systems are widely used in clinical practice. However, the scientific literature indicates that achieving back pain coverage with traditional SCS is technically difficult and is often not sustained over time. (North et al, Neurosurgery 2005;57(5):990-62005; Frey et al, Pain Physician 2009;12(2):379-97). According to one report, 71 percent of patients who received an implant with traditional SCS experienced discomfort.

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from the stimulation of paresthesia (Kuechmann et al, Abstract. Pain in Europe VI [EFIC], Lisbon, Portugal: Sept. 9-12, 2009). In the current study, 44 percent of patients receiving traditional SCS reported uncomfortable stimulation.

The study was a prospective, randomized, multicenter, comparative trial of the investigational HF10 vs. the standard SCS therapy, designed in consultation with and monitored by the FDA. Institutional review board approval was obtained for each study site.

The 12-month follow-up data indicated that the responder rate with HF10 therapy was twice that with traditional SCS for both back and leg pain. Also, the average degree of pain relief with HF10 therapy was more than 50 percent greater than with traditional SCS. The level-1 evidence with 12-month follow-up meets today’s rigorous standards for evidence-based healthcare and complies with regulatory agency and payer preference for comparative effectiveness, the investigators said.

“These results provide important comparative effectiveness data for healthcare providers and clinically relevant information for pain physicians, patients and payers,” Sitzman said.

At present, HF10 therapy is investigational in the United States. The manufacturer of the device, Nevro Corp., which funded this study, anticipates obtaining market approval from the FDA by mid-2015.

*Poster 140 – Rationale for the SENZA-RCT Study Design and Comparative Outcomes*

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