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Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform

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Objective: The purpose of the multicenter, randomized, unblinded, crossover Success Using Neuromodulation with BURST (SUNBURST) study was to determine the safety and efficacy of a device delivering both traditional tonic stimulation and burst stimulation to patients with chronic pain of the trunk and/or limbs.

Methods: Following a successful tonic trial, 100 subjects were randomized to receive one stimulation mode for the first 12 weeks, and then the other stimulation mode for the next 12 weeks. The primary endpoint assessed the noninferiority of the within-subject difference between tonic and burst for the mean daily overall VAS score. An intention-to-treat analysis was conducted using data at the 12- and 24-week visits. Subjects then used the stimulation mode of their choice and were followed for one year. Descriptive statistics were used analyze additional endpoints and to characterize the safety profile of the device.

Results: The SUNBURST study demonstrated that burst stimulation is noninferior to tonic stimulation ($p < 0.001$). Superiority of burst was also achieved ($p < 0.017$). Significantly more subjects (70.8%) preferred burst stimulation over tonic stimulation ($p < 0.001$). Preference was sustained through one year: 68.2% of subjects preferred burst stimulation, 23.9% of subjects preferred tonic, and 8.0% of subjects had no preference. No unanticipated adverse events were reported and the safety profile was similar to other spinal cord stimulation studies.

Conclusions: The SUNBURST study demonstrated that burst spinal cord stimulation is safe and effective. Burst stimulation was not only noninferior but also superior to tonic stimulation for the treatment of chronic pain. A multimodal stimulation device has advantages.

Keywords: Burst stimulation, chronic pain, spinal cord stimulation, tonic stimulation, waveform

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