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TECHNOLOGY AT THE NEURAL INTERFACE

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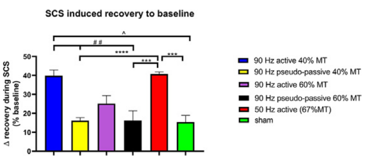

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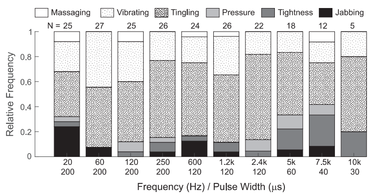

The boundaries of sensory perception of spinal corfd stimulation are not well defined. The BENEFIT-01 study aimed to create a map of perceptual threshold responses across a broad range of SCS parameters and programming to inform sub-perception therapy design. This multicenter study was conducted at 7 US sites. A total of 43 patients with low back and/or leg pain who completed a percutaneous commercial SCS trial were enrolled. Test stimulation was delivered via trial leads for ~90 minutes before removal. SCS parameters, including amplitude, frequency, pulse width (PW), electrode configuration, cycling, and multi-frequency stimulation were varied during testing. Perception threshold (PT), comfort level (CL), perceptual coverage area and paresthesia quality (via patient selection of keywords) were collected. Differences were evaluated with ANOVA followed by post hoc multiple comparisons using t-tests with Bonferroni correction.

PT was primarily determined by PW and was insensitive to frequency for constant frequency stimulation (range: 20 Hz–10 kHz; $F(1,284) = 69.58$, $p < 0.0001$). For all tests, CL was ~25% higher than PT. The dominant variable that influenced perception quality was frequency. Sensations described as comfortable and tingling were most common for frequencies between 60 Hz–2.4 kHz; unpleasant sensations were generally more common outside this range. Increasing distance between active electrodes from 7 mm to 14 mm, or cycling the SCS waveform at 1 Hz, decreased PT ($p < 0.0001$). Finally, PT for a low-frequency stimulus (ie, 60 Hz) was unaffected by mixing with a sub-PT high-frequency stimulus.

Clinical Science

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