



Randomized Controlled Clinical Trial Evaluating the Safety & Effectiveness of 10 kHz High Frequency & Traditional Low Frequency Stimulation for the Treatment of Chronic Back & Leg Pain: 18-month Results

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Introduction

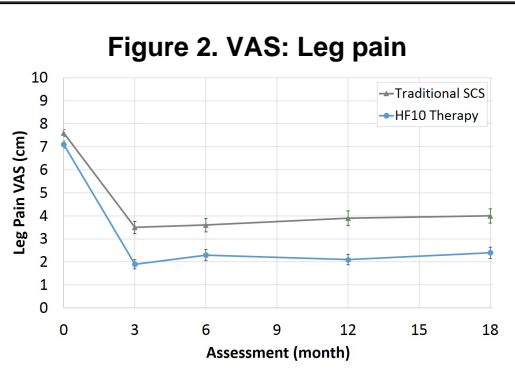
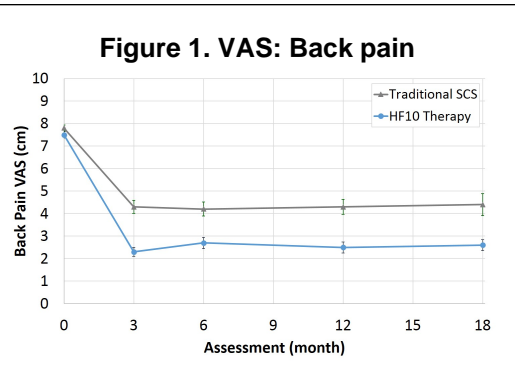
A randomized controlled trial with appropriate statistical power and long term outcomes is the hallmark of Level 1 clinical evidence. The SENZA-RCT multi-center pivotal study was powered to directly compare high frequency spinal cord stimulation (SCS) at 10 kHz (HF10™ therapy) and traditional low frequency (~50 Hz) SCS. The comparative efficacy of these modalities for the treatment of chronic back and leg pain for 18 months is presented.

Methods

Baseline assessments were performed prior to randomization of 198 patients. 171 patients responded during a trial phase of the assigned SCS system and were implanted. 18 month results were available for 165 of these patients. Responders were defined as having at least 50% pain reduction, while pain remitters were defined as having a VAS pain score of 2.5 or less out of 10.

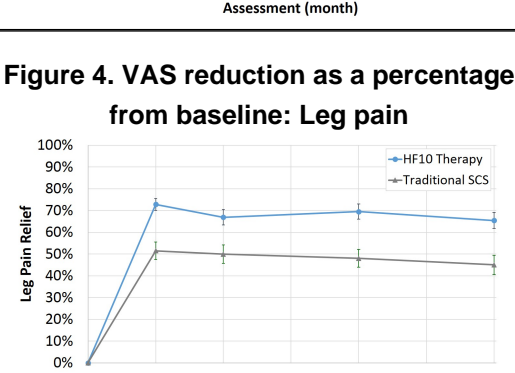
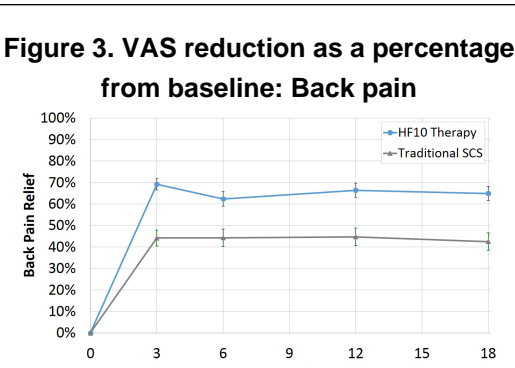
Results: Changes in VAS (cm)

At 18 months, back pain decreased to a greater degree for patients receiving HF10 therapy (64.9%±30.8%) than with traditional SCS (42.5%±35.9%), $p<0.001$ (Figure 1). Similarly, leg pain decreased to a greater degree for HF10 therapy patients (65.4%±35.2%) than with traditional



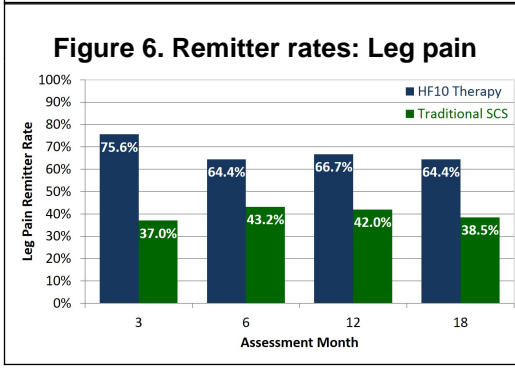
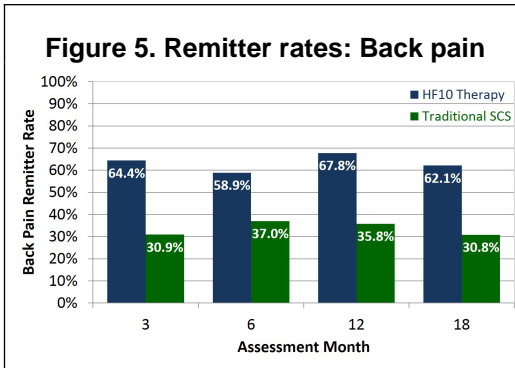
Results: Changes in VAS (%)

More patients were pain responders to HF10 therapy than traditional SCS (Back pain: 75.9% for HF10 therapy, 47.7% for traditional SCS, $p<0.001$ (Figure 3); Leg pain: 77.0% for HF10 therapy, 53.8% for traditional SCS, $p<0.001$) (Figure 4).



Results: Remitters (VAS≤2.5 cm)

More patients were also pain remitters with HF10 therapy than traditional SCS (Back pain: 62.1% for HF10 therapy, 30.8% for traditional SCS, $p<0.001$; Leg pain: 64.4% for HF10 therapy, 38.5% for traditional SCS, $p<0.001$). Patients classified as remitters in both groups combined had a back pain score of 1.2 ± 0.8 and a leg pain score of 1.0 ± 0.8 . Safety profiles were similar.



Conclusions

The SENZA-RCT study provides strong Level 1 evidence in support of long-term use HF10 therapy as compared with traditional low-frequency SCS for the treatment of chronic back and leg pain.

References

- ClinicalTrials.gov identifier NCT01609972

Learning Objectives

- Understand the differences between 10 kHz high frequency and traditional low frequency (~50 Hz) spinal cord stimulation.
- Understand the comparative safety and efficacy these to SCS modalities in treating chronic back and leg pain over an 18 month period.