A prospective single centre pilot study to investigate the response to 1000Hz frequency in patients with spinal cord stimulation with intractable neuropathic pain who have not undergone spinal surgery (virgin back).

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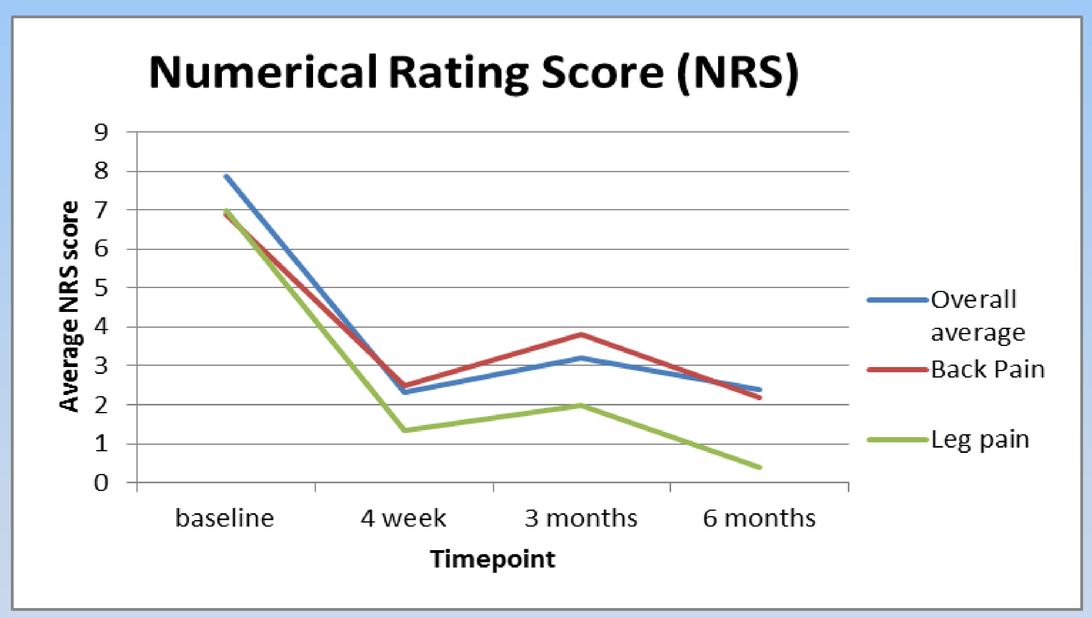
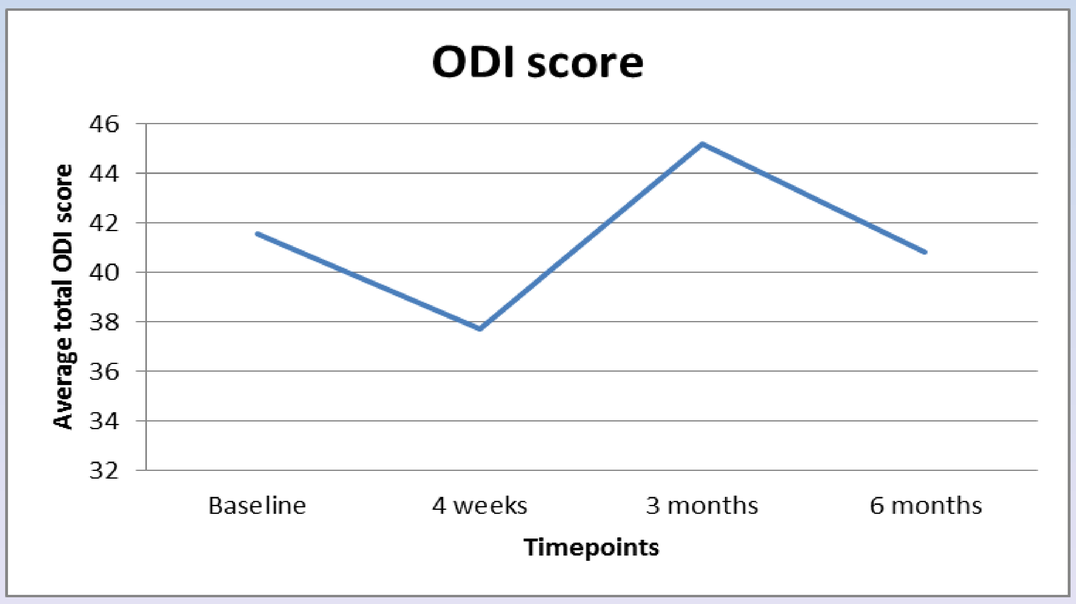
Introduction

Spinal cord stimulation (SCS) is a successful treatment in patients with intractable neuropathic pain. This therapy is most commonly used in patients who have chronic neuropathic pain following failed back surgery syndrome (FBSS). However, SCS is increasingly being used in patients with intractable neuropathic pain who have not undergone previous spinal surgery. Nevertheless, data for the use of higher frequency stimulation in the virgin back population is limited.

Objectives: The primary objective is to investigate the clinical response following implantation of the Boston Scientific Wavewriter and higher frequency (1,000Hz) neurostimulation in patients who have neuropathic pain and who have not undergone any spinal surgery. The secondary objective will be to investigate the effect on functionality, quality of life, and adverse events in the study population.

Methods: This study is a single-centre pilot study. Patients with intractable neuropathic pain (n=30) due to undergo SCS with Boston Scientific Wavewriter as part of their standard treatment are being recruited. Pain scores (Numerical Rating Scale, NRS) and data from self-report questionnaires (Oswestry Disability Index (ODI), Pain and Sleep Questionnaire (PSQ), Patient Global Impression of Change), EQ-5D-5L and an economic resource questionnaire are collected at baseline , 4 weeks, 3 months, 6 months, 12 months and 24 months post-implant.





Interim Results: At present, 9 patients (6 Females and 3 Males) have been implanted and 1 withdrawn in this study. Five patients have completed 4 week, 12 week and 6 months follow-up questionnaires.

Baseline (n=8), the mean NRS for back and leg is 6.9 (±1.36) and 7 (± 1.85) respectively.

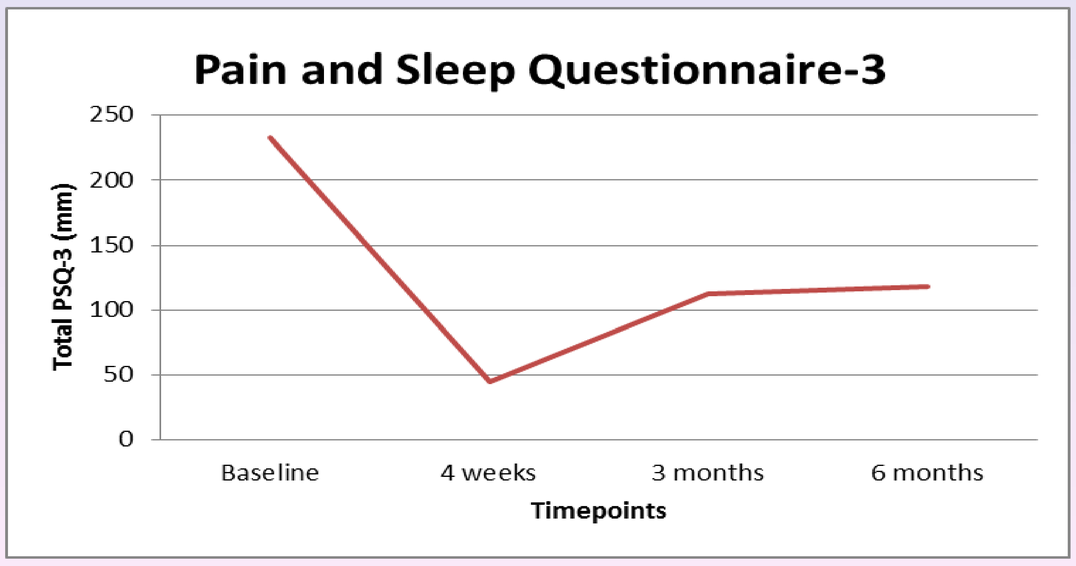
4 weeks (n=6), the average back pain was 2.5±1.38(-97.5% vs. baseline) and leg pain 1.33±1.51 (-98.6 % vs. baseline).

3 months (n=5), the average back pain differed by some points, 3.8±2.39 (-96.2% vs. baseline) and leg pain 2±3.08 (-98% vs. baseline).

6 months (n=5), further reductions were observed with average back pain 2.2±1.64 (-97.8% vs. baseline) and leg pain 0.4±0.89 (-99.6% vs. baseline).

Improvements in sleep were seen mainly at 4 weeks (-55%) whilst at 3 months (-12.8%) and 6 months (-18%) when compared to baseline. Additionally, a reduction in ODI scores were seen 4 weeks 37.7±25.6 (-9.4%) and 6 months 40.8±9.4 (-1.9%). However at 3 months 45.2±26 (8%) indicated an increase.

Overall results show an increase at 3 months due to programming issues in which patients had a slight increase in pain.



Conclusion: The interim data for this study suggests HF-SCS may be an effective therapy to reduce lower back and leg pain and improve daily living for patients who have not previously undergone spinal surgery.