An investigation into frequency parameters and variable electrode array response with Medtronic Restore Sensor technology in patients with intractable neuropathic pain who have not had spinal surgery
UK Single Centre Interim Data

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Background

Spinal cord stimulation (SCS) is traditionally used for patients with neuropathic pain following failed back surgery syndrome. Data in the use of paraesthesia-free stimulation in patients with intractable neuropathic pain who have not undergone previous spinal surgery is limited.

Objectives

- To investigate the clinical response following implant with the Medtronic Restore Sensor neurostimulator system and High Density SCS in patients with lumbar radiculopathy who have not undergone any spinal surgery.
- Secondary objectives will be to investigate the effect on quality of life and adverse events.

Methods

Design: open label, single-centre pilot study.
Patients with intractable neuropathic pain (n=20) due to undergo SCS as part of their standard treatment for lumbar neuropathic pain are being recruited.
The following self-report data will be collected pre-implant and at 1, 4, 12 month post-implant:

- Numerical Rating Scale (NRS)
- Oswestry Disability Index (ODI) for low back pain
- Pain and Sleep Questionnaire (PSQ-3)
- Patient Global Impression of Change (PGIC)

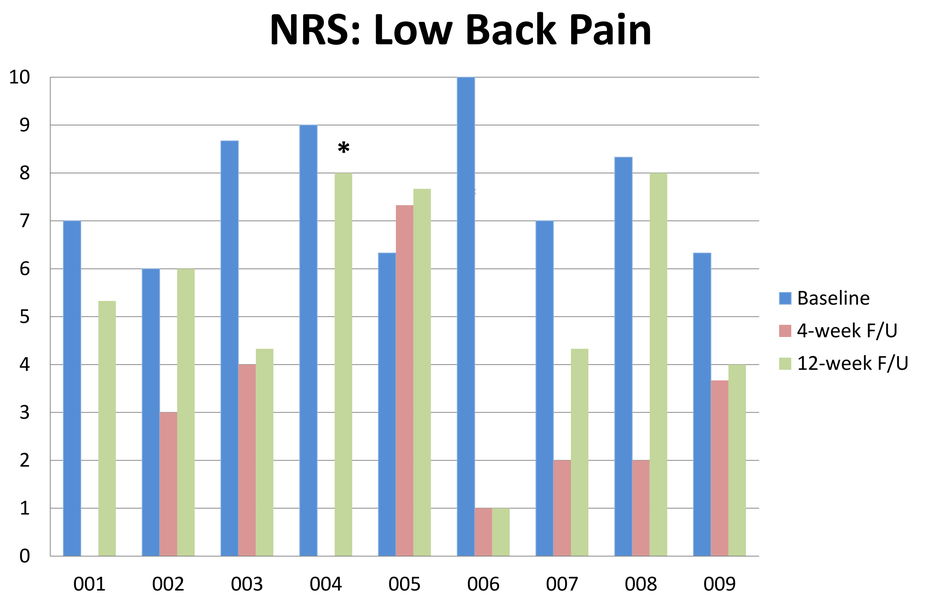
Interim Results

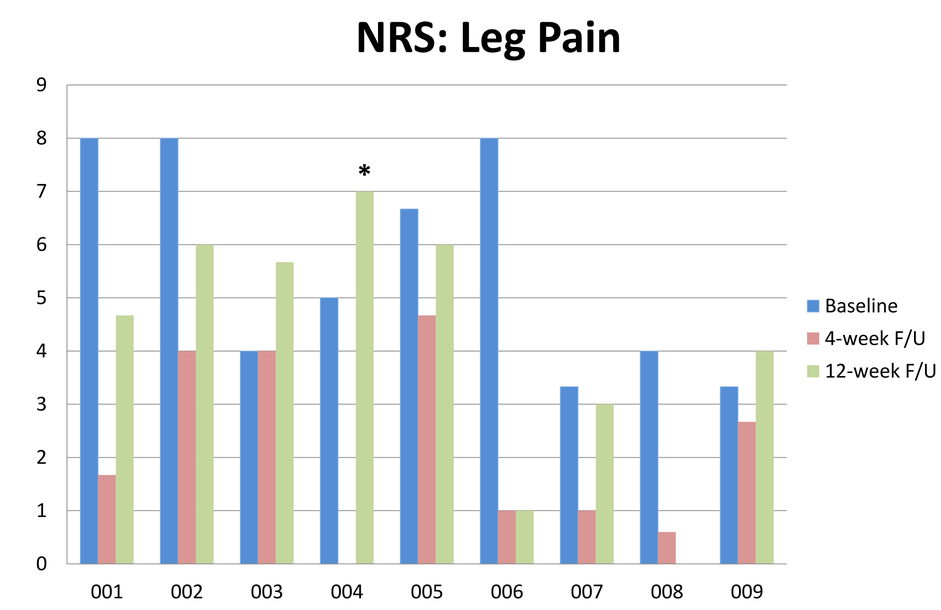
9 patients (8 female, 1 male) have been enrolled into the study so far. All have completed 12-week follow-up visits.

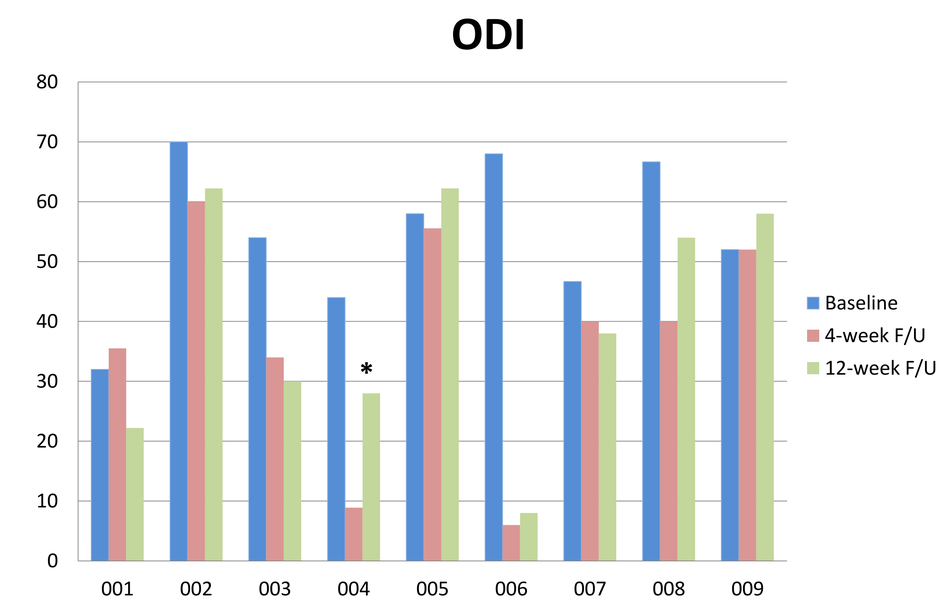
Baseline mean NRS scores for lower back pain and leg pain were 7.67 ± 1.33 and 5.80 ± 2.06 respectively. At 4-weeks post-implant, the average reduction in lower back pain is 5.07 ± 3.23 (−63.06% vs. baseline) and 3.41 ± 2.41 (-57.93% vs. baseline) for leg pain. At 12-weeks the average reduction is 2.22 ± 3.03 (-25.86% vs. baseline) and 1.44 ± 2.94 (19.13% vs. baseline).
*Adverse event for Patient 004 – had fall and required revision.

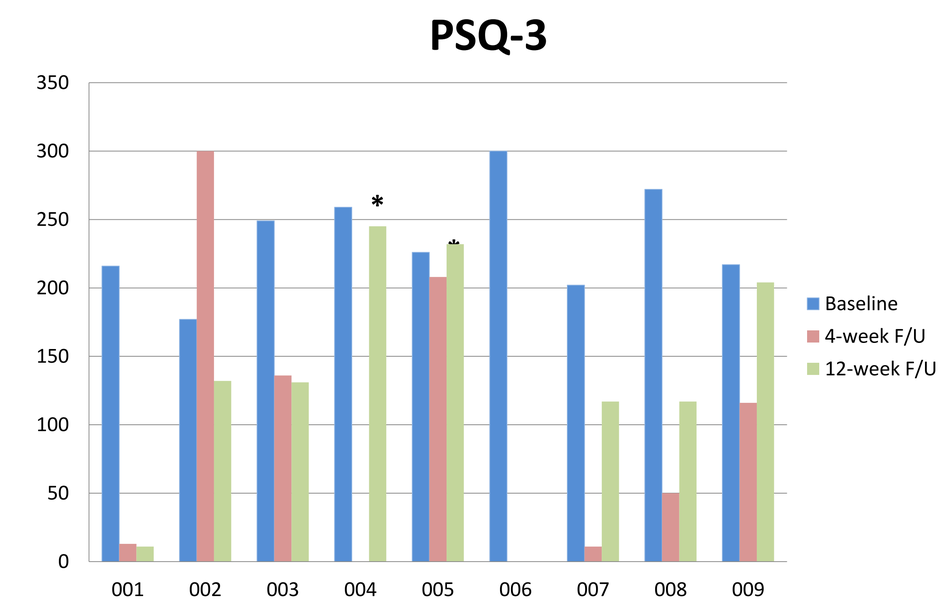
Conclusion

Our interim data demonstrates paraesthesia-free SCS may be an effective therapy to reduce lower back and leg pain in patients who have not undergone previous spinal surgery. We intend to continue data collection up to 1-year post-implant.









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