A pilot study to see the effectiveness of high density spinal cord stimulation for intractable lumbar radiculopathy on virgin-backs

UK single Centre Interim data

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Objectives

Spinal Cord Stimulation (SCS) is increasingly being used in patients with intractable neuropathic pain who have not undergone previous spinal surgery; however, data in the use of paraesthesia-free stimulation in this population is limited.
We aim to investigate the clinical response following SCS implant with High Density programming and the effect on quality of life.

Methods

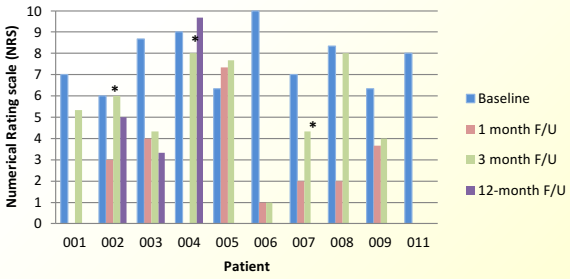
An open label, single-centre pilot study (n=20).
This study is recruiting patients with intractable neuropathic pain (n=20) due to undergo SCS with Medtronic RestoreSensor™ as part of their standard NHS treatment.
The following self-report data will be collected pre-implant and at 1, 3 and 12 months 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)

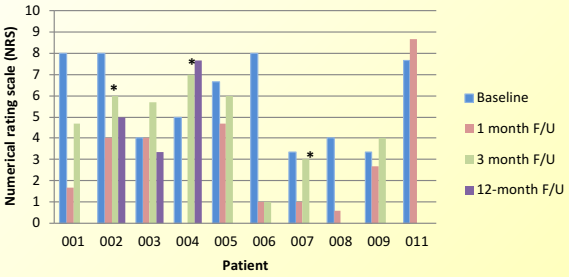
Interim Results

11 patients (10 female, 1 male) have been enrolled. 1 patient consented but baseline outcomes not yet completed.
At **baseline** (n=10), the mean NRS score for lower back pain and leg pain were 7.67±1.33 and 5.80±2.06 respectively.
1-month (n=10), post-implant, the average reduction in lower back pain is 5.37±3.18 (−66.75% vs. baseline) and 2.97±2.67 (-50.84% vs. baseline) for leg pain.
3-months (n=10), post-implant – average back pain reduction is 2.8 ± 3.39 (-33.28% vs. baseline) and 2.07 ± 3.40 (27.22% vs. baseline).
12-months *(n=4)* post-implant - average back pain reduction is 3.17 ± 3.60 (-42.70% vs. baseline) and 3.83 ± 2.73 (-57.28% vs. baseline).

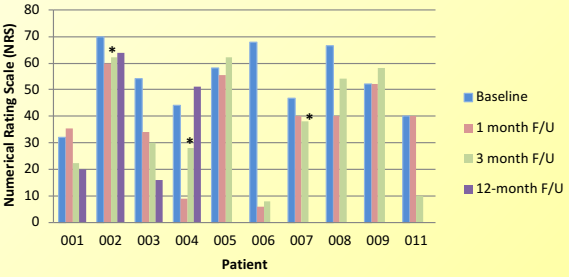
NRS: Low Back Pain



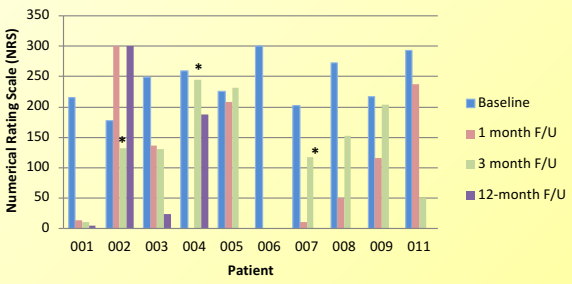
NRS: Leg Pain



ODI



PSQ



***Adverse events**
Patient 002 – fall prior to 3 month visit.
Patient 004 – had fall prior to 3 month visit. Poor pain control continues at 12-months after revision of leads
Patient 007 – unable to charge IPG at 3 months and required revision

Conclusions

Currently, the interim data of this study demonstrates High Density SCS may be an effective therapy to reduce lower back and leg pain in patients who have not previously undergone spinal surgery.

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