24-month results from the prospective, open-label trial investigating spinal cord stimulation in chronic non-surgical back pain: Maiden Back study

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Introduction

Persistent non-operative low back of neuropathic origin has profound negative impacts on everyday life. Spinal cord stimulation (SCS) is an approved treatment for chronic pain of neuropathic origin.

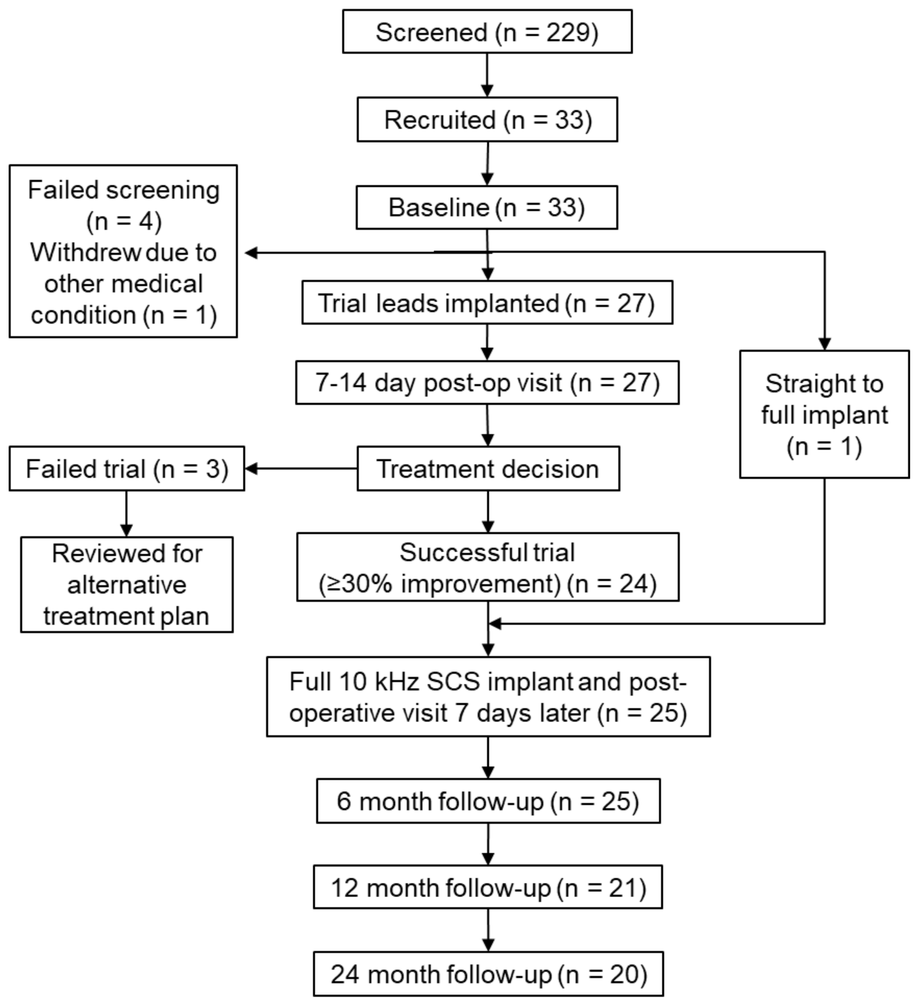
Aim: This prospective, open label trial with five-year follow-up aimed to explore the use of SCS in patients with chronic non-surgical back pain. The 24-month results are presented.

Materials and methods

Twenty-five patients with back pain and hyperalgesia or allodynia without prior spinal surgery were fully implanted with SCS (frequency: 10 kHz; pulse width: 30 µs). Patients attended follow-up visits after 6 (n = 25), 12 (n = 21) and 24 (n = 20) months of SCS.

At baseline, the presence of neuropathic features (S-LANSS and PainDETECT), back and leg pain (visual analogue scales, VAS), health-related quality of life (HRQoL, EQ-5D-5L) and pain-related disability (Oswestry Disability Index, ODI) were ascertained.

At follow-up, back and leg pain (VAS), HRQoL (EQ-5D-5L), pain-related disability (ODI), patient global impression of change (PGIC), medication, adverse events and programming data were ascertained.



Statistical analysis: The 24-month data for leg and back pain, HRQoL and pain-related disability were analysed by intention-to-treat (n = 25) using repeated measure ANOVAs/Friedman tests with Bonferroni pairwise comparisons. Counts and percentages were generated for pain response (≥30% reduction in back pain VAS) and pain-related disability response (≥10-point reduction in ODI)

Results

Table 1 summarises the characteristics of the 25 patients who had a fully implanted system.

Gender	8 males and 17 females
Age (years)	48 (9)
BMI (kg/m^2)	29 (5)
S-LANSS score	15 (6)
PainDETECT score	19 (8)
Pain duration (years)	7 (5)

Table 1: Summary of characteristics. Data presented as counts (n) for gender and mean (SD) for remaining measures.

Back pain was significantly higher at baseline compared to 6 months (mean difference: 3.58, $p < 0.001$), 12 months (mean difference: 3.86, $p < 0.001$) and 24 months (mean difference: 2.67, $p = 0.013$). 32% (8 of 25) of patients reported a reduction in back pain (VAS) ≥ 50%.

Leg pain did not significant change ($p > 0.05$).

HRQoL was significantly lower at baseline compared to 6 months (mean difference: -0.21, $p = 0.006$) and 12 months (mean difference: -0.19, $p = 0.001$), but not 24 months (mean difference: -0.16, $p > 0.05$).

Pain-related disability was significantly impaired at baseline compared to 6 months (mean difference: 23.80, $p < 0.001$), 12 months (mean difference: 18.36, $p < 0.001$) and 24 months (mean difference: 13.72, $p = 0.020$). 48% (12 of 25) of patients reported a reduction in pain-related disability (ODI) score ≥ 10 points.

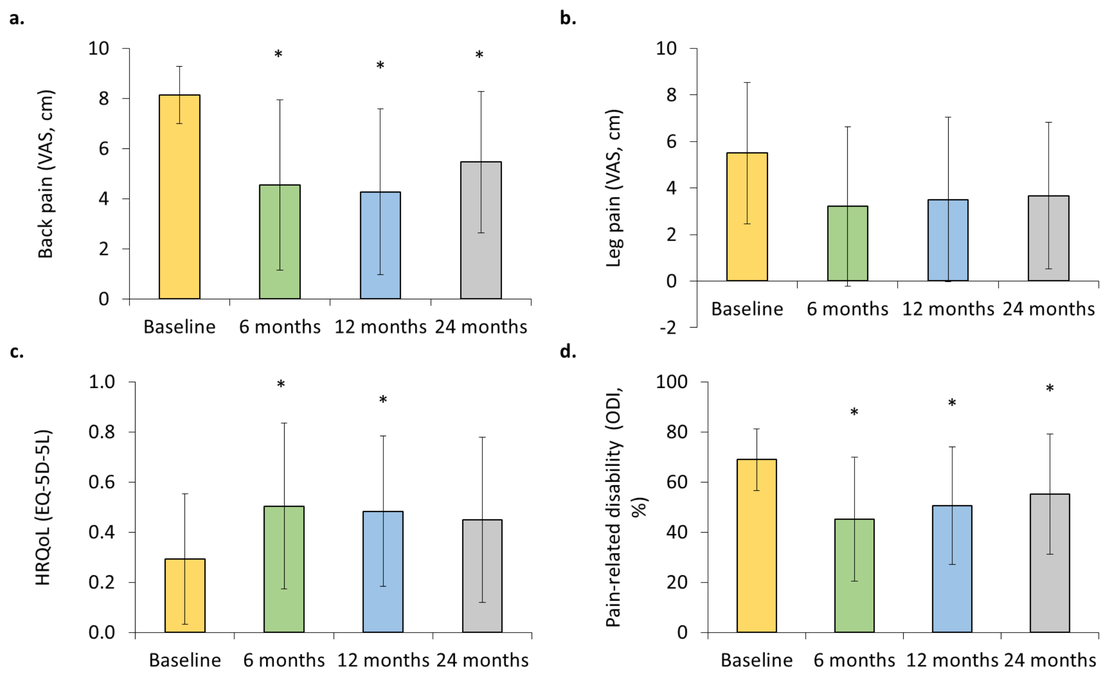


*Figure 1: Back pain (a), leg pain (b), HRQoL (c) and pain-related disability (d) during baseline, 6, 12 and 24 months for the 25 fully implanted patients. * = significantly different to baseline.*

Discussion and conclusion

SCS in patients with chronic non-surgical back pain was associated with significant improvements in back pain, HRQoL and pain-related disability at 24 months.

The five-year follow-up period will help in assessing the long-term effectiveness and safety of treating this pain condition using SCS. The final patient is scheduled to complete their final visit by the end of this year and the five-year results will be written and published.

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