Pain Relief for Axial Back Pain Patients

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Objective & Introduction

Spinal Cord Stimulation (SCS) is a preferred treatment modality for patients with FBSS[1], but treatment of axial low back pain with traditional SCS has proven difficult[2]. This study evaluates the safety and efficacy of a new SCS system in a patients with axial back pain.

Materials & Methods

This is an ongoing, prospective European trial conducted in Belgium and the United Kingdom. Institutional Review Board (IRB) approval was obtained from both sites prior to patient enrollment.

At baseline, patients had back pain VAS ≥ 5.0 cm as measured on a 10 cm VAS for pain (0 cm = no pain, 10 cm = worst pain imaginable).

After a successful screening trial phase, patients were implanted with a novel SCS system (Nevro, Menlo Park, CA) that consisted of dual octapolar, percutaneous electrodes and rechargeable IPG. Leads were placed anatomically near the midline between T8-T11. Programming parameters consisted of pulse rate of up to 10kHz.

Patients were and will be evaluated at 1-, 3-, and 6-months. Measurements at these visits include:

- Back Pain VAS, Leg Pain VAS, Oswestry Disability Index (ODI), and Pain Medication

Demographics

- Mean age ± SD: 50 ± 10 years
- Gender: 58% female
- Predominant Pain: Back (87%), Leg (13%)
- Prior Back Surgery: Yes (80%), No (20%)

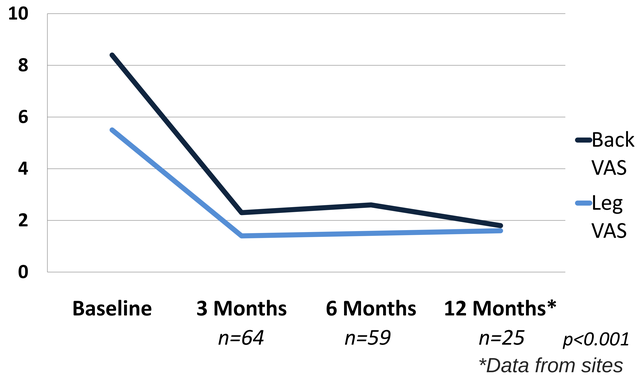
Interim Results

To date, 72 out of 82 subjects (88%) met the screening trial success criteria (e.g., ≥ 50% pain relief as compared to baseline).

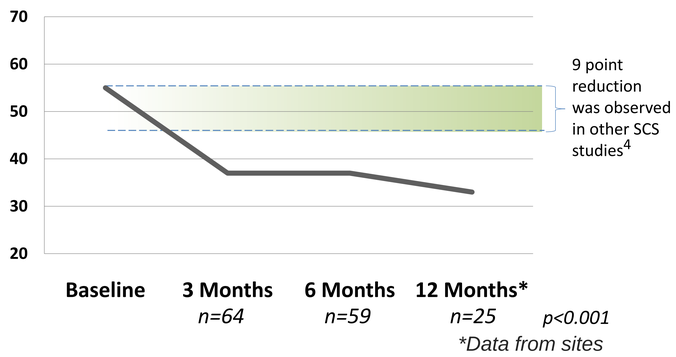
This is an ongoing study and interim results are shown since not all patients have passed 1-, 3-, and 6-months time points. Also, after IPG implant, there is no loss to follow-up and only 1 patient withdrew from the study.

Serious adverse events related to the study after IPG implant are: pocket pain (n=4), lead migration (n=1), wound infection (n=1). Other device-related complications were consistent with rates reported in the literature[3].

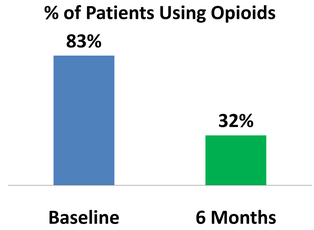
Back and Leg Pain Reduction



ODI Improvements

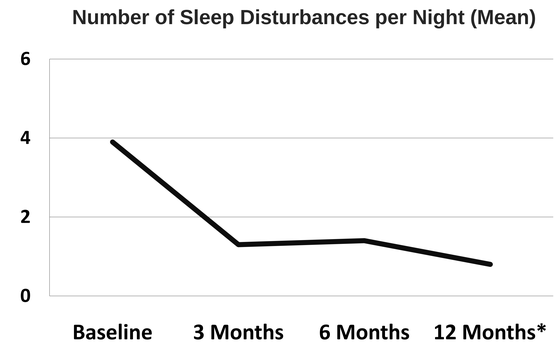


Opioid Elimination

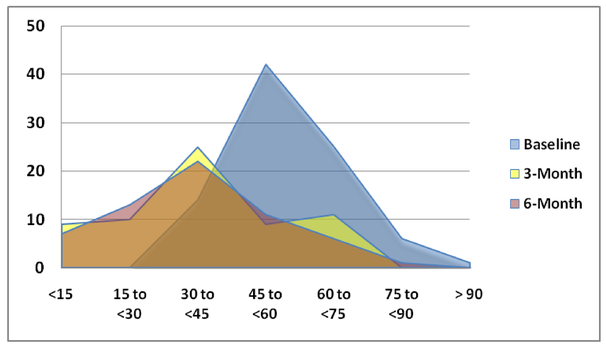


- 49 of 59 patients (83%) who passed 6 months were on opioids at baseline
- 19 of 59 patients (32%) were on opioids at 6 Months

Sleep Disturbance Reduction



ODI Population Change



Discussion and Summary

Back pain relief has been a challenge for SCS[5]. This system provides excellent long-term relief for both back and leg pain in a difficult-to-treat, axial back pain patient population. Notably, patients do not experience paresthesia, thereby eliminating movement-associated dysesthesia as seen with conventional SCS[6].

Furthermore, this system offers procedural efficiencies by making lead placement anatomic and eliminating the need for intra-operative mapping.

In summary, reduction in both back pain and leg pain is sustained at 12 months. This is supported by:

- ≥70% reduction of VAS compared to baseline
- 21 point reduction in Oswestry Disability Index
- Significant reduction in mean number of sleep disturbances per night

References

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