

Interim Clinical Data on Treatment of Axial Back Pain with Nevro System

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Background

Failed Back Surgery Syndrome (FBSS) is characterized by back and/or leg pain following surgery¹. Spinal Cord Stimulation (SCS) is a preferred treatment modality for patients with FBSS² as it is minimally invasive and reversible. While reduction of the leg pain component of FBSS is well documented, treatment of axial low back pain with traditional SCS has proven difficult³. Here, we conducted a prospective study to evaluate the safety and efficacy of a new neuromodulation system (Nevro Corporation, Menlo Park, CA) in a population of mostly axial back pain patients.

Study Measurements

Following a successful trial, the subject was implanted with a permanent device and evaluated for safety and efficacy at 1-, 3- and 6-months. Key outcomes measured included:

- Back pain and leg pain reduction as measured by VAS.
- Functional improvement and opioid analgesic usage.
- Stimulation changes with body movement and postural changes.

Methods

Percutaneous leads were placed at the midline. Due to the nature of stimulation and **no sensation of paresthesia, intraoperative paresthesia mappings were not required**. Reliance on intraoperative patient feedback while undergoing surgery was negated because leads did not have to be adjusted for paresthesia coverage.

Interim Results

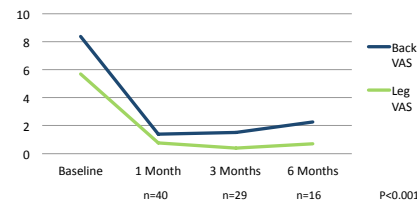
This is an ongoing multi-center European study. Presented here are interim data from 66 patients who have undergone a "trial phase" with Nevro System.

- **Predominant Pain:** Back (84%), Leg (16%)
- **Prior Back Surgery:** Yes (80%), No (20%)

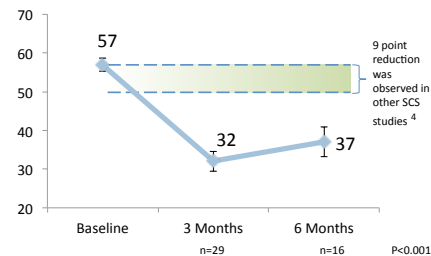
Nevro Trial Phase Success

- 59 out of 66 subjects (89%) met the trial success criteria (>50% pain relief as compared to baseline).
- Subjects that previously **failed conventional SCS therapies** also had similar trial phase success rate. 11 out of 14 subjects had successful trials with Nevro SCS.

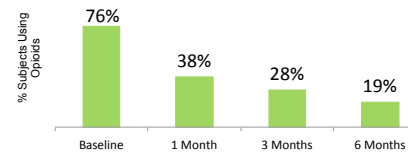
Back and Leg Pain Reduction



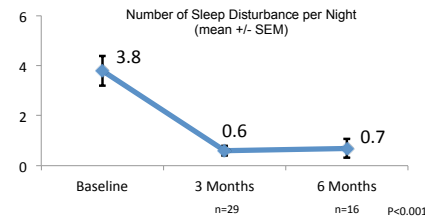
Oswestry Disability Index Improvements



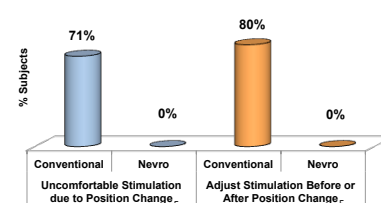
Opioid Reduction



Sleep Disturbance Reduction



Elimination of Uncomfortable Stimulation⁵



Conclusions

Functionality

- Subjects do **not** experience sensation of paresthesia.
- Anatomical placement of leads eliminates the need for intra-operative paresthesia mapping.
- Subjects do **not** experience unpleasant movement-induced change in paresthesia⁵.

Efficacy

- Sustained-analgesia in axial back pain patient cohort. (>70% back pain relief at 6 months).
- Improved patient functionality and restoration of sleep.
- Significant reduction and elimination of opioid usage to control pain
- High overall trial success rate – success rate is similar for patients who have failed prior conventional SCS therapy.

Safety

- Proportion and type of adverse events are consistent with other studies conducted.

References

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