Durability of Relief with Percutaneous Medial Branch PNS for the Treatment of Chronic Axial Low Back Pain

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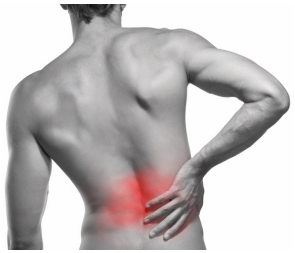
Introduction



Minimally Invasive, 60-day Percutaneous PNS:
Designed for use earlier in the treatment continuum:

- non-opioid
- non-destructive
- non-surgical

Chronic low back pain (LBP) is one of the most prevalent and challenging musculoskeletal conditions[1] and is the leading cause of disability in adults.

Goal: **Characterize responses to medial branch PNS in a prospective multicenter case series study in patients recalcitrant to multiple non-surgical treatments**

Materials & Methods

IRB-approved study; informed consent obtained from each subject.

Key Eligibility Criteria:

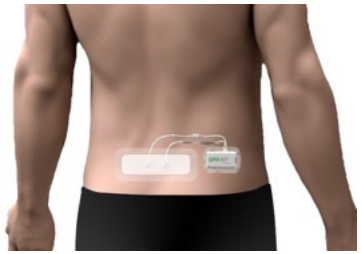
- Subjects with chronic axial LBP (≥ 3 months); no radicular pain
- Stable medication usage for ≥ 1 month prior to baseline
- No prior lumbar surgery or RFA within prior 6 months
- No anesthetic injections within prior 3 months
- Score of ≤ 20 on Beck Depression Inventory

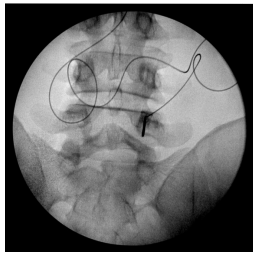
PNS Lead Implantation: Bilateral, percutaneous PNS leads, targeting medial branches of the dorsal ramus in the center of pain

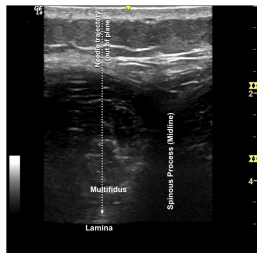
- *Image Guidance:* ultrasound and/or fluoroscopy
- *Confirmation:* Stimulation of medial branch confirmed by selective activation of multifidi

PNS Treatment: Stimulation for 6-12 hrs/day for up to 60 days

- Subjects continued normal activities
- Leads removed with gentle traction
- Long-term follow-up visits, up to 12 months after the 2-month PNS treatment





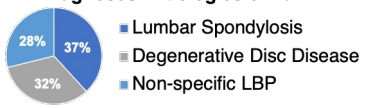


Results

Participant Demographics (n=74)

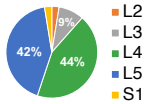
Age (years)	**56.3** (13.5)
Body Mass Index (BMI)	**29.4** (4.6)
LBP Duration (years)	**16.0** (13.0)
Sex (% Female)	**53%**
Baseline Opioid Usage (MME; n=20 on opioids at baseline)	**32.0** (37.1)
Previously Failed LBP Treatments:	
Non-opioid Analgesics	97%
Physical Therapy	89%
Opioid Analgesics	67%
TENS	65%
Anesthetic or Steroid Injections	57%
Epidural Injections	46%
Radiofrequency Ablation	23%

LBP Diagnoses / Etiologies of Pain:



Percutaneous PNS Implantation

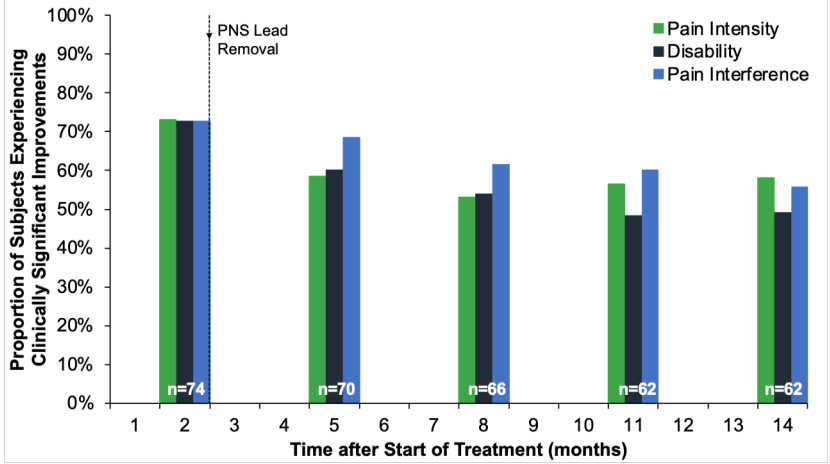
- 91% of participants received bilateral PNS leads
- L4 & L5 were the most commonly targeted spinal levels



Adverse Events: No serious or unanticipated adverse events (AEs).

- The most common AEs were mild skin irritation or pruritis (itching).

Proportion of subjects experiencing clinically significant reductions in Pain Intensity, Disability, and Pain Interference through 14 months after percutaneous PNS:



Proportion Reporting Clinically Meaningful Improvement in at Least 1 Outcome

- *Earlier publications described the results through the Primary Endpoint, this is the first report to completely describe the durability of relief with PNS in this cohort.*
- **Most participants reported clinically[2] and statistically significant reductions in pain, disability, and pain interference with percutaneous PNS**
- One-year post-treatment:
  - **77% participants experienced clinically meaningful improvement in at least one outcome**
  - **58% experienced clinically meaningful improvement in 2 or more outcomes.**

Reductions in Opioid Analgesic Medication Consumption:

- **Most subjects taking opioids at baseline (75%, n=15/20) reported reductions in opioid consumption in the months after PNS.**

Among those reducing opioids:

Study Timepoint	Avg. Opioid Consumption
Baseline (Before PNS)	28.5 MME
2 months (End of PNS treatment)	13.4 MME
14 months (1-year post-treatment)	5.1 MME

Conclusions

- 60-day Percutaneous PNS produced clinically meaningful relief for most participants through the 14 month follow up period without a permanent implant.
- Given the minimally invasive nature of percutaneous PNS and the significant benefits experienced by participants, percutaneous PNS provides an effective, first-line neurostimulation treatment option for patients with chronic axial LBP.

References:

[1] US Burden of Disease Collaborators. The State of US Health, 1990-2010 Burden of Diseases, Injuries, and Risk Factors. *JAMA*. 2013; 310(6):591-606.

[2] Dworkin et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain 2008; 9: 105-121.

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