Prospective, Multicenter Study of Percutaneous Medial Branch PNS for the Treatment of Chronic Axial Low Back Pain

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Introduction

- 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.

Minimally Invasive, 60-day Percutaneous PNS:
A promising non-opioid, non-destructive, and non-surgical treatment for chronic axial LBP, designed for use earlier in the treatment continuum than conventional neurostimulation.

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

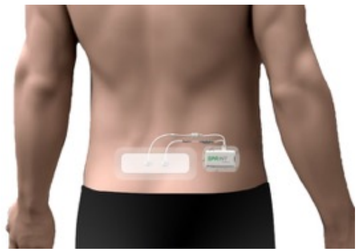
Materials & Methods

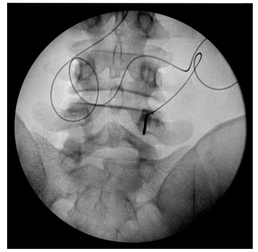
Ongoing IRB-approved study; informed consent obtained from each subject.

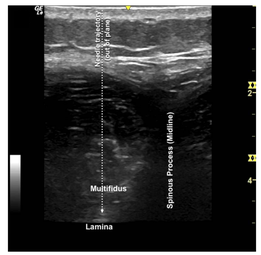
Key Eligibility Criteria:
- Subjects with chronic axial LBP (≥ 3 months); no radicular pain
- Stable medication usage for ≥ 1 month prior to baseline
- No prior lumbar surgery or RFA within prior 6 months
- No anesthetic injections within prior 3 months
- Score of ≤ 20 on Beck Depression Inventory

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 (ongoing)





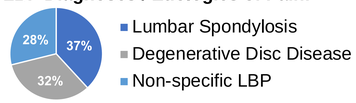


Results

Participant Demographics (n=74)

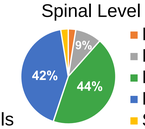
Age (years)	**56.3** (13.5)
Body Mass Index (BMI)	**29.4** (4.6)
LBP Duration (years)	**16.0** (13.0)
Sex (% Female)	**53%**
Baseline Opioid Usage (MME; n=20 on opioids at baseline)	**32.0** (37.1)
Previously Failed LBP Treatments:	
Non-opioid Analgesics	97%
Physical Therapy	89%
Opioid Analgesics	67%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

LBP Diagnoses / Etiologies of Pain:



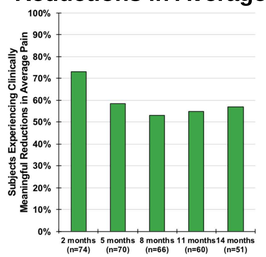
Percutaneous PNS Implantation
- 91% of participants received bilateral PNS leads
- L4 & L5 were the most commonly targeted spinal levels

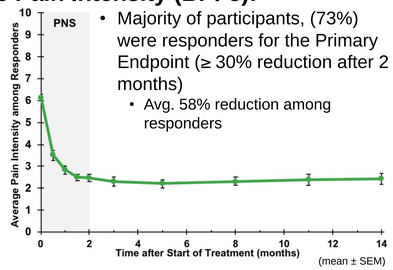
Spinal Level



Adverse Events: No serious or unanticipated adverse events (AEs).
- The most common AEs were mild skin irritation or pruritis (itching).

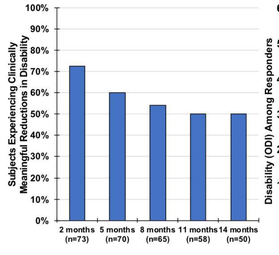
Reductions in Average Pain Intensity (BPI-5):

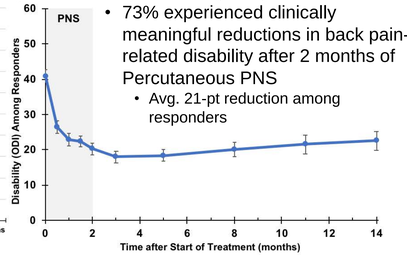




- Majority of participants, (73%) were responders for the Primary Endpoint (≥ 30% reduction after 2 months)
  - Avg. 58% reduction among responders

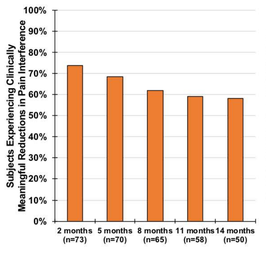
Reductions in Oswestry Disability Index (ODI):

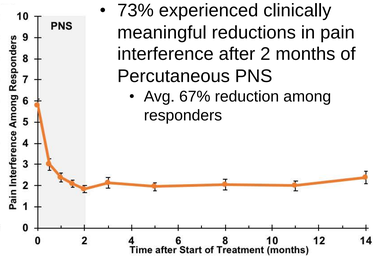




- 73% experienced clinically meaningful reductions in back pain-related disability after 2 months of Percutaneous PNS
  - Avg. 21-pt reduction among responders

Reductions in Pain Interference (BPI-9):



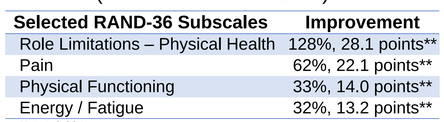


- 73% experienced clinically meaningful reductions in pain interference after 2 months of Percutaneous PNS
  - Avg. 67% reduction among responders

Majority of participants reported clinically[2] and statistically significant reductions in pain, disability, and pain interference with percutaneous PNS.
- Reductions were sustained through at least 14 months among a majority of participants.

Majority of participants reported statistically significant improvements in health-related quality of life (QoL)
- 91% reported QoL improvements with PNS:

Patient Global Impression of Change (PGIC)

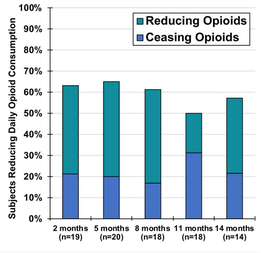


- Statistically significant improvements in QoL with PNS (measured via RAND-36):

Selected RAND-36 Subscales	Improvement
Role Limitations – Physical Health	128%, 28.1 points**
Pain	62%, 22.1 points**
Physical Functioning	33%, 14.0 points**
Energy / Fatigue	32%, 13.2 points**

** p < 0.001

Reductions in Opioid Analgesic Usage:



- 63% reduced opioids (avg. 65% reduction), with 21% reporting complete cessation
- Opioid reductions were sustained through 14 months
  - 57% reported opioid reductions and 21% reporting complete cessation at 14 months

Conclusions

- Clinically meaningful and statistically significant reductions in pain, disability, and pain interference were reported by a majority of participants who completed the Primary Endpoint and each of the long-term follow up visits.
- Given the minimally invasive, non-destructive nature of percutaneous PNS and the significant benefits, percutaneous PNS may provide a promising first-line neurostimulation treatment 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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