Reductions in Opioid Consumption with Percutaneous Peripheral Nerve Stimulation (PNS) for Chronic Low Back Pain

Christopher Gilmore, MD[1], Leonardo Kapural, MD, PhD[1], Thomas Hopkins MD, MBA[2], Mehul Desai, MD, MPH[3], Sean Li, MD[4], Michael DePalma, MD[5], Abram Burgher, MD[6], Timothy Deer, MD[7], Meredith McGee, PhD[8], Joseph Boggs, PhD[8]

[1] Center for Clinical Research, Winston Salem, NC, [2] Duke University, Durham, NC, [3] International Spine, Pain and Performance Center, Washington, DC, [4] Premier Pain Centers, Shrewsbury, NJ, [5] Virginia iSpine Physicians, Richmond, VA, [6] The Pain Center, Phoenix, AZ, [7] The Spine and Nerve Center of The Virginias, Charleston, WV, [8] SPR Therapeutics, Inc, Cleveland, OH

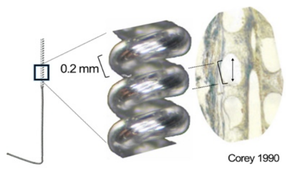
INTRODUCTION

- 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.
- An alternative to conventional neurostimulation and radiofrequency ablation is needed.

	Radiofrequency Ablation	Conventional Neurostimulation	Percutaneous PNS
Avoid Tissue Destruction?	✗	✓	✓
Avoid Permanent Implant?	✓	✗	✓

PERCUTANEOUS Peripheral Nerve Stimulation (PNS):

- Wearable stimulator and percutaneous fine-wire, coiled lead (designed to anchor in tissue with excellent safety profile[2])



Goal: Evaluate feasibility of 60-day percutaneous PNS to reduce opioid use in patients with chronic LBP.

METHODS

Ongoing IRB approved study; informed consent was obtained from each participant.

Key Eligibility Criteria:

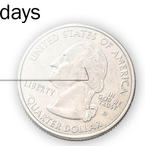
- Participants with chronic LBP (≥ 3 mos); no radicular pain
- Stable medication usage at least 1 mo prior to baseline
- No prior lumbar surgery or RFA within prior 6 months
- No anesthetic injections within prior 3 months
- Score of ≤ 20 on Beck Depression Inventory

Small Wearable Stimulator

Wireless Hand-held Remote

Percutaneous Peripheral Nerve Stimulation (PNS) Treatment:

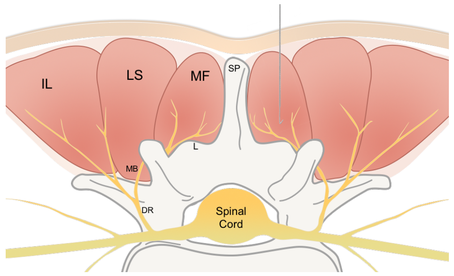
- Stimulation for 6-12 hrs/day for up to 60 days
- Participants continued normal activities
- Leads removed with gentle traction
- Participants return for long-term follow-up visits



PNS LEAD PLACEMENT

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

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



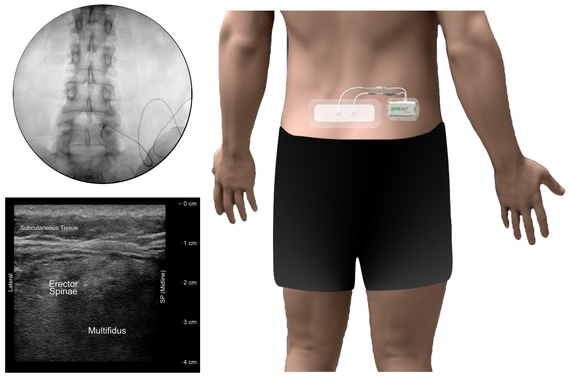


Figure Abbreviations: Dorsal Ramus (DR), Iliocostalis (IL), Lamina (L), Longissimus (LS), Medial Branch (MB), Multifidus (MF), Spinous Process (SP).

PARTICIPANT DEMOGRAPHICS

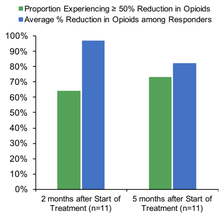
Participants Taking Opioids at Baseline (n = 11):

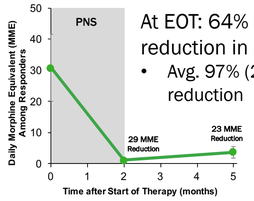
- Average Age: 60.8 years (40.1 – 82.1)
- Average Baseline Pain Score: 6.3 (BPI-5)
- Average Baseline Opioid Consumption mg Morphine Equivalent: 26.9 MME
- Average Duration of LBP: 17.0 years
- Spinal Level of Lead Placement:
  L2 (n=1), L3 (n=1), L4 (n=6), L5 (n=3)

RESULTS

Substantial Reductions in Opioid Analgesic Consumption with PNS among Those Taking Opioids:

Participant	Baseline mg Morphine Equivalent (MME)	End of Treatment (EOT)			3-mo Post-EOT		
		MME	MME Reduction from Baseline	% MME Reduction	MME	MME Reduction from Baseline	% MME Reduction
1	80.0	0.0	80.0	100%	0.0	80.0	100%
2	22.1	2.9	19.3	87%	0.0	22.1	100%
3	3.6	0.0	3.6	99%	2.9	0.7	19%
4	13.6	0.0	13.6	100%	6.4	7.1	53%
5	66.4	47.1	19.3	29%	57.8	8.6	13%
6	10.0	9.3	0.7	7%	10.0	0.0	0%
7	3.2	4.3	-1.1	-34%	1.1	2.1	67%
8	1.4	1.4	0.0	0%	0.0	1.4	100%
9	57.9	4.3	53.6	93%	15.0	42.9	74%
10	7.1	0.0	7.1	100%	1.4	5.7	80%
11	31.0	0.5	30.5	98%	5.8	25.2	81%
Average All Participants	*26.9*	*6.3*	*20.6*	*62%*	*9.1*	*17.8*	*63%*





At EOT: 64% had ≥50% reduction in opioids

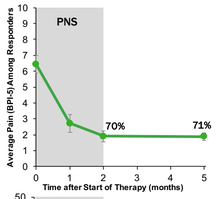
- Avg. 97% (29.7 MME) reduction

Clinically Significant[3] Reductions in Average Pain Intensity, Disability, and Pain Interference with PNS:

Average Pain Intensity (BPI-5):

64% of subjects had ≥ 50% pain relief

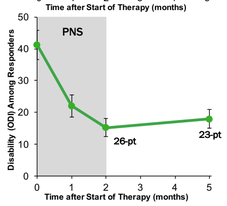
- Avg. 70% reduction among responders



Disability (ODI):

82% of subjects had ≥ 10-pt reduction

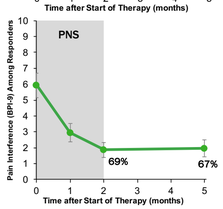
- Avg. 26-pt reduction among responders



Pain Interference (BPI-9):

82% of subjects had ≥ 30% reduction

- Avg. 69% reduction among responders



OUTCOMES

- At End of Treatment (EOT) 64% reported ≥ 50% reduction in opioid consumption with PNS (n=7/11)
  - *Avg. 29.7 mg morphine equivalent (MME) reduction (97%) among responders at EOT*
- At 3 months post EOT, 73% reported ≥ 50% reduction in opioids (n=8/11)
  - *Avg. 23.1 MME reduction (82%) among responders at 3 months post-EOT*
- Majority of participants experienced clinically-significant reductions in average pain intensity, disability, and pain interference.
  - *64% (n=7/11) had ≥ 50% reduction BPI-5*
  - *82% (n=9/11) had ≥ 10-pt reduction ODI*
  - *82% (n=9/11) had ≥ 30% reduction BPI-9*

Safety: No serious or unanticipated device-related adverse events.

CONCLUSIONS

- Percutaneous PNS treatment for up to 60 days can substantially reduce usage of opioid analgesic medications in patients with chronic LBP.
- These results support earlier findings in other pain indications that percutaneous PNS for up to 60 days can relieve chronic LBP, which leads to improvement in disability and quality of life.
- Percutaneous PNS can be implemented without requiring tissue destruction or a permanently implanted device.

REFERENCES & ACKNOWLEDGEMENT

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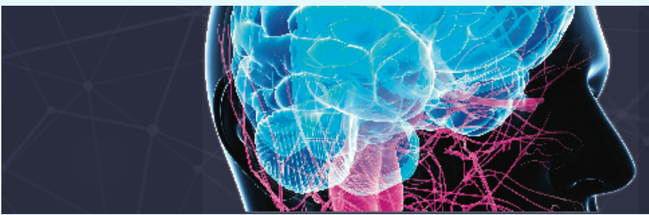
Funding:
This study was funded by SPR Therapeutics, Inc.



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