WHEN PAIN WON'T QUIT

Is Peripheral Nerve Stimulation the Missing Piece?

A clinical update on evidence, patient selection, and multimodal integration

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Interventional Pain Medicine | Axis Spine Center

Disclosures

SPR-Consulting

Boston Scientific-Research, Consulting

Discgenics-Research

Why This Matters Now

3 in 10

US adults live with chronic pain

50+ yrs

PNS has existed as a concept — but only recently became practical

2015

FDA cleared percutaneous PNS leads, changing accessibility

The push toward non-opioid, minimally invasive, reversible options has moved PNS from a niche last resort to a mainstream part of the interventional toolbox.

Learning Objectives

1. Review the current evidence supporting peripheral nerve stimulation for select chronic pain conditions.

2. Identify patients who are most likely to benefit from referral for peripheral nerve stimulation.

3. Incorporate peripheral nerve stimulation into evidence-based, multimodal chronic pain management.

Today's Roadmap

1. **The Science** — Mechanism, history, and delivery systems
2. **The Evidence** — Condition-by-condition review of the data
3. **Patient Selection** — Indications, contraindications, and the trial process
4. **Practice Integration** — Multimodal fit, referral pathway, and a case example

The Science

Mechanism, history, and how delivery has evolved

How PNS Works: The Gate Control Theory

- A small electrode is placed near a target peripheral nerve.
- Low-level electrical current selectively activates large, fast-conducting A-beta fibers.
- A-beta activation inhibits transmission of nociceptive signals carried by A-delta and C fibers at the dorsal horn.
- Net effect: pain signal is "gated" before it reaches conscious perception, without destroying the nerve.

Reversible. Non-destructive. Targeted.

Unlike ablation or neurolysis, PNS does not damage the nerve. Stimulation parameters can be adjusted or the device removed entirely — an important discussion point for patients weighing their options.

Contrast with:

- Spinal cord stimulation — targets dorsal columns, broader field
- Radiofrequency ablation — destructive, not reversible
- Nerve blocks — diagnostic/short-acting, not a long-term solution alone

From Electric Eels to Ultrasound-Guided Leads

A rapid evolution in delivery, not concept

Ancient Rome

Electric fish applied to painful body parts — the earliest recorded electroanalgesia

1960s–70s

First surgical PNS implants for neuropathic limb pain and trigeminal neuralgia

2015

FDA clears percutaneous, ultrasound-guided PNS leads — no open surgery required

Today

Two practical delivery models used side-by-side in clinic

Temporary / 60-Day System

- Percutaneous coiled lead, wearable external stimulator
- Left in place up to 60 days, then removed in-office
- No permanent implant — lower up-front risk and cost

Traditional Implantable System

- Short trial (~7 days) followed by permanent IPG implant if successful
- Fully internalized system, patient-controlled settings
- Better fit for durable, well-localized single-nerve pain

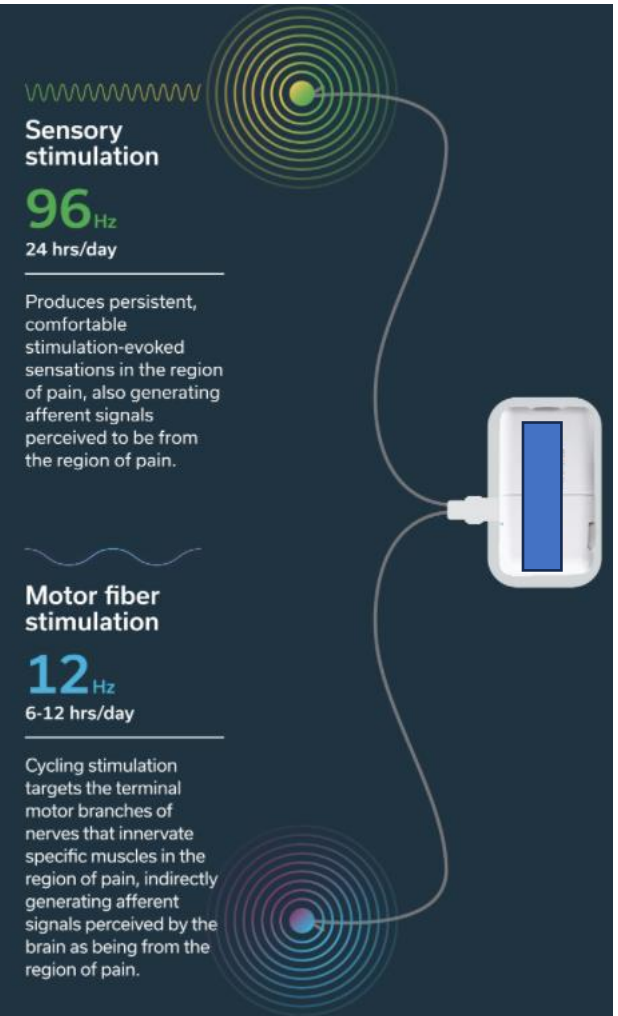
A comprehensive approach to pain

Bimodal PNS treatment combines the benefits of two validated stimulation techniques — sensory and motor fiber activation — providing tailored coverage with the potential to address multiple types of underlying pain.

How Bimodal PNS treatment works

Two leads are implanted percutaneously in complementary target locations, such as the suprascapular nerve and the axillary nerve at the deltoid in the shoulder region.

When treatment is initiated, the two leads deliver simultaneous yet different stimulation modalities. This activates afferent signals from two targeted locations and physiological sources, resulting in tailored coverage in the area of pain and leveraging two complementary pain relief mechanisms for the promotion of pain relief.*



Sensory stimulation

96 Hz

24 hrs/day

Produces persistent, comfortable stimulation-evoked sensations in the region of pain, also generating afferent signals perceived to be from the region of pain.

Motor fiber stimulation

12 Hz

6-12 hrs/day

Cycling stimulation targets the terminal motor branches of nerves that innervate specific muscles in the region of pain, indirectly generating afferent signals perceived by the brain as being from the region of pain.

Potential targets

Shoulder posterior and superior pain

96 Hz neurostimulation to the suprascapular nerve

Shoulder anterior and lateral pain

12 Hz neurostimulation to the axillary nerve at the deltoid



Head and neck pain

96 Hz neurostimulation to the occipital nerve

12 Hz neurostimulation to the cervical medial branch at multifidus

Back and leg pain

96 Hz neurostimulation to the lumbar spinal nerve (e.g., L5)

12 Hz neurostimulation to the lumbar medial branch nerve at multifidus

Knee pain

96 Hz neurostimulation to the femoral nerve

12 Hz neurostimulation to the femoral nerve at vastus medialis oblique

The Evidence

What the data show, condition by condition

The Big Picture: What Recent Reviews Show

2025 Systematic Review & Meta-Analysis of RCTs (Pain Physician)

Across RCTs spanning 1966–Feb 2025: fair (Level III) evidence, moderate certainty, moderate strength of recommendation for implantable PNS following a trial, selective lumbar medial branch stimulation without a trial, and temporary 60-day PNS.

2025 Meta-Analysis of Durability, up to 24 Months (106 studies, n = 9,272)

Implantable PNS provides persistent, clinically meaningful analgesia sustained up to 24 months. Largest effect sizes seen in pelvic and upper-extremity pain; smallest in truncal pain. Certainty of evidence rated low-to-moderate given reliance on observational data.

Honest framing: this is real, reproducible signal — not Level I proof across the board. Quality of evidence varies significantly by condition, which is exactly why we're reviewing them individually.

Migraine & Occipital Neuralgia

STRONGEST EVIDENCE

- PNS of occipital nerves has the most mature evidence base in the field, including multiple double-blinded randomized controlled trials.
- One RCT: 12 weeks randomized, then 40 weeks open-label. Active PNS reduced headache days by 8.5 days/month vs. baseline ($p < 0.0001$).
- 30% and 50% responder rates of 60% and 35% respectively at one year.
- Occipital and trigeminal PNS for neuralgia: Level III evidence, but most observational series show >50% relief in the majority of patients.

Level I–II

evidence for migraine specifically — the best-supported indication in this talk

Effective Treatment of Occipital Head Pain in the Presence of Migraine Using Percutaneous 60-Day Peripheral Nerve Stimulation: Results from a Prospective, Single-Arm, Multicenter Study

Matthew Pingree[1], Narayan Kissoon MD[1], Genaro Gutierrez[2], Zachary McCormick MD[3], Christopher Gilmore MD[4], Mitchell Engle MD[5], William Huffman PhD[6], Nathan Crosby PhD[6], Joseph Boggs[6]

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Scan to Learn More About the Clinical Evidence for 60-Day PNS

ASPN AMERICAN SOCIETY of PAIN & NEUROSCIENCE

OBJECTIVE

- Migraine-like features (e.g., photophobia, nausea) commonly occur alongside refractory pain due to cervicogenic headache (CGH) or occipital neuralgia (ON), compounding the negative effects of headache on function and quality of life.[1-2]
- Percutaneous 60-day peripheral nerve stimulation (PNS) has shown effectiveness in occipital head pain disorders including CGH and ON. A recent prospective, single-arm study found that patients with ON or CGH can achieve significant reductions in pain and pain interference following 60-day PNS[3], but that study excluded patients with migraine-like features.
- The present study presents data on the efficacy and safety of the 60-day PNS treatment among patients with ON or CGH along with concurrent migraine.

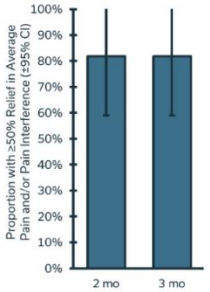
METHODS

- IRB-approved, multicenter, prospective study (n=11). All participants followed through 3 months to-date with additional prospective follow-up ongoing.
- Key criteria: diagnosed CGH and/or ON and presence of migraine-like features (based on prior diagnosis and ID Migraine score ≥ 2), baseline average pain and pain interference ≥4/10, and Beck Depression Inventory ≤20.
- Participants received percutaneous leads targeting the greater and third occipital nerves (e.g., at the C2 lamina) for 8 weeks (i.e., up to 60 days).
- This analysis reports treatment responders as the proportion of participants with ≥50% reduction in average pain intensity and/or pain interference.
- Additional outcomes: Patient Global Impression of Change (PGIC), Headache Days per Week, Neck Disability Index (NDI) and Migraine Disability Assessment (MIDAS).
- Safety was assessed by summarizing study-related Adverse Events (AEs).

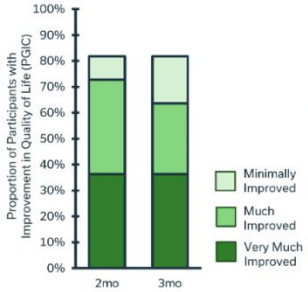


RESULTS

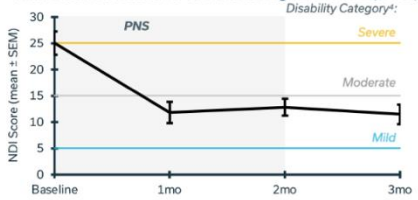
82% (9/11) reported ≥50% reductions in average pain and/or pain interference through 3 months



Improvements in quality of life were similarly sustained through 3 months in a majority of participants (n=11)



Average Neck Pain-Related Disability (NDI) decreased from Severe at Baseline to Mild through 3 months (n=11)



Additional outcomes at 3 months:

64% Clinically meaningful reductions in **migraine-related disability**†

2.2 Average **additional headache-free days** per week

† 5-point or 30% reduction in Migraine Disability Assessment (MIDAS) for moderate or severe baseline values[5]

Safety: The most common AEs were skin irritation or itching. Two infections were reported at lead exit sites (one classified as serious), and both resolved after a course of antibiotics.

CONCLUSIONS

- Sixty-day PNS provided substantial relief from pain and pain interference among participants with CGH/ON and migraine.
- Occipital pain relief facilitated improvements in neck pain-related disability, migraine-related disability, and quality of life.
- Participants also reported more headache-free days per week on average.
- Prospective follow-up is ongoing.

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This work was supported by SPR. Disclosures: GG, ZM, and CG have consulted for SPR. WJH, NDC, and JWB are employees of SPR. The authors thank the site clinical coordinators and research staff for their contributions to the study. The authors are also grateful for the dedication and effort of the Clinical Affairs team at SPR, including Dana Crowe, Sara Anderson, and Rosemary Zang.

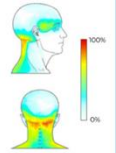
Percutaneous Sixty-Day Peripheral Nerve Stimulation Provides Durable Relief from Occipital Headache: A Prospective Single-Arm Study

Christopher Gilmore MD[1], Zachary McCormick MD[2], Genaro Gutierrez[3] MD, Mitchell Engle MD[4], Matthew Pingree MD[2], Jason Pope MD[5], David DiBenedetto MD[2], Narayan Kissoon MD[2], William Huffman PhD[6], Nathan Crosby PhD[6], Joseph Boggs PhD[6]

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Introduction

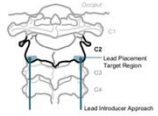
- An estimated 15-20% of patients with chronic headaches have occipital head pain, including from cervicogenic headache (CCH) and occipital neuralgia (ON).[1,2]
- CGH and ON can be significantly debilitating, impacting domains like physical function, social function, sleep, and headache-related quality of life.
- Recently published data included evidence of pain relief in participants with CGH or ON following percutaneous 60-day peripheral nerve stimulation (PNS) through 3 months from the start of treatment.[3]
- **Goal: present data on the sustained effects of 60-day PNS used for treatment of occipital head pain through 12 months.**



Distribution of pain frequency in cervicogenic headache[4]

Methods

- This IRB-approved, prospective single-arm study enrolled participants with occipital head pain due to CGH and/or ON and a lack of migraine-like features as assessed by the ID Migraine screener (score <2).
- Participants received percutaneous leads targeting the greater and third occipital nerves near the C2 lamina with stimulation for up to 60 days.





Lateral view of percutaneous lead placement

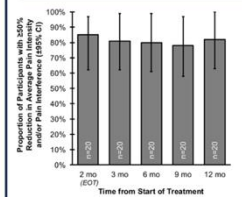
- Primary analysis: Reduction in average pain and/or pain interference at end of treatment (EOT) and follow-up visits through 12 months.
- Secondary outcomes: Patient Global Impression of Change (PGIC), Headache Impact Test (HIT-6), and Neck Disability Index (NDI)
- Multiple imputation (predictive mean matching) was performed to account for attrition.



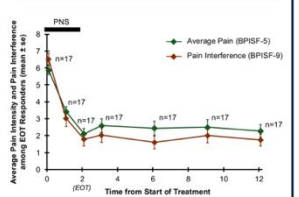
Illustrative use of 60-day PNS device placement during treatment

Results

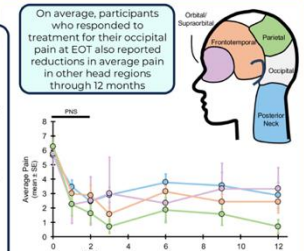
A majority of participants reported ≥50% reductions in pain and/or pain interference through 12 months.



On average, participants who were responders at EOT reported sustained reductions in pain and pain interference through 12 months.



On average, participants who responded to treatment for their occipital pain at EOT also reported reductions in average pain in other head regions through 12 months

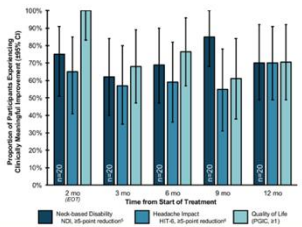


Mean pain intensity shown among participants who met the EOT responder definition and had at least 4/10 pain at baseline in a given region. At baseline, n ranges from 4 to 11. At 12 months, n ranges from 3 to 9)

Participants had occipital pain refractory to at least 2 different treatment types.

Previous Conservative Therapies (n, % of N=20)	
Non-opioid pain medications	19 (95%)
Physical therapy	18 (90%)
Chiropractic treatment/spinal manipulation	13 (65%)
Injections (nerve block and/or corticosteroid)	13 (65%)
Massage Therapy	13 (65%)
Acupuncture/dry needling	12 (60%)
Opioid pain medications	12 (60%)
Exercise Therapy	11 (55%)
TENS	10 (50%)
Radiofrequency ablation	8 (40%)
Botox injections	4 (20%)

A majority of participants had clinically meaningful improvements in neck disability, headache impact, and/or quality of life through 12 months.



Safety: Among this cohort, all study-related adverse events were non-serious, and the most common events were skin irritation, itching, and post-procedural pain.

Conclusions

- 60-day PNS may safely and effectively provide sustained relief of occipital headache pain due to occipital neuralgia or cervicogenic headache
- Participants experienced sustained headache relief and/or reductions in pain interference, including pain in areas outside of the occipital region
- Headache reductions facilitated meaningful improvements in additional domains.
  - Neck Disability
  - Headache Impact
  - Quality of Life

References & Acknowledgments

1. Fabry et al., *Neuroradiology*, 2024. 2. Robinson et al., *Cephalalgia*, 2025. 3. Gutierrez et al., *Headache*, 2025. 4. Uthaikhup et al., *Pain Med* 2020. 5. Vernon et al., *J Manipulative Physiol Ther*, 2008. 6. Kosinski et al., *Qual Life Res*, 2003

This work was supported by SPR. CG, GG, and JP have consulted for SPR. WJH, NDC, and JWB are employees of SPR. The authors thank the site clinical coordinators and research staff for their contributions to the execution of the study and express gratitude for the efforts of the Clinical Affairs team at SPR, including Dana Crowe, Sara Anderson, and Rosemary Zang.

NANS2026 ANNUAL MEETING
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Chronic Low Back Pain

MODERATE EVIDENCE

- Multicenter RCT: subcutaneous nerve stimulation + conventional medical management (CMM) vs. CMM alone in failed back surgery syndrome (FBSS) — 38 vs. 36 patients.
- Selective lumbar medial branch stimulation can be trialed without a formal trial period per 2025 GRADE synthesis — a practical, lower-friction pathway.
- 60-day percutaneous PNS shows durable, clinically significant improvement in pain and pain interference for many low back etiologies, including post-surgical and non-specific mechanical pain.
- Best candidates: pain not amenable to further surgical correction, with a clear, localizable nerve target (e.g., cluneal or medial branch distribution) rather than diffuse axial pain.

Level III

fair evidence, moderate certainty per 2025 GRADE-based synthesis

Observations from the RESET RCT: A Post-Hoc Per Protocol Analysis of Clinical Outcomes with Percutaneous 60-Day Medial Branch PNS in Chronic Low Back Pain

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ASPN 2026

Recently Published Manuscript

BACKGROUND



- The RESET Clinical Trial[1] is an RCT comparing percutaneous 60-day peripheral nerve stimulation (PNS)[2] to usual care with standard interventional management (e.g., ablations, injections, physical therapy)[3,4] for chronic low back pain (CLBP).
- Primary Endpoint results for the Full Analysis Set were recently published in 2025[1].

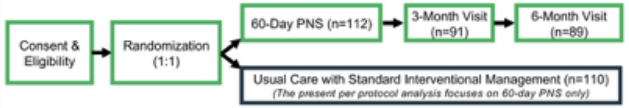
This post-hoc analysis aimed to characterize the relationships between baseline variables, treatment delivery, and 60-day PNS outcomes.

- Additional goals included exploring how outcomes vary among patients with facetogenic or discovertebral pain features.

RESET Low Back Pain

RCT DESIGN AND METHODS

Patients with moderate to severe CLBP confined to the lumbar region without radiation to the extremities were included (*key exclusion: RFA within ≤6 months, radicular leg pain, BMI >40, prior lumbar surgery*).

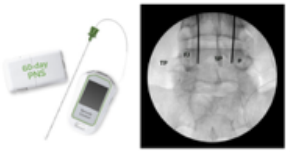


Participant demographic and clinical characteristics (Full Analysis Set; n=112)	
Age (years), mean ± SD	55 ± 14
CLBP duration (years), mean ± SD	14 ± 13
Female, % (n)	53% (59)
Baseline scores	
Average pain Intensity, BPI5, mean ± SD	6.0 ± 1.2
Pain interference, BPI9, mean ± SD	6.2 ± 1.4
Oswestry Disability Index, ODI, mean ± SD	42 ± 16
Per Protocol utilization (among n=93 participants who completed treatment)	
Completed treatment as prescribed, % (n)	72% (67)

PERCUTANEOUS 60-DAY PNS

Bilateral percutaneous 60-day PNS targeting the lumbar medial branches (SPRINT® PNS System, SPR).

- 12 Hz, 0-30mA, 10-200µs
- Leads removed after up to 60 days



OUTCOMES AT 3 MONTHS

PER PROTOCOL 60-DAY PNS TREATMENT DELIVERY

✓ Bilateral stimulation usage of 6-12 hours per day for 56-60 days

✓ Stimulation sensations overlapping >50% of the painful area (assessed at lead implant, 1-month visit, and end of treatment)

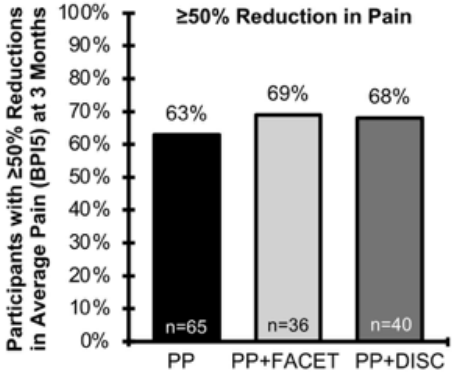
Univariate logistic regressions (alpha=0.05) evaluated associations between variables (baseline and treatment characteristics) and responder rate (≥50% reduction in average pain at 3 months).

Odds Ratios (ORs) for Assessed Clinical Variables

	Full Analysis Set (n=112)		Per Protocol Set (n=65)	
	OR [95% CI]	p-value	OR [95% CI]	p-value
Per protocol device utilization				
completed treatment as prescribed	3.04 [1.16, 7.93]	0.023	n/a	n/a
Participant demographics				
Age (years)	1.00 [0.97, 1.03]	0.934	1.01 [0.97, 1.05]	0.716
Back pain duration (years)	1.00 [0.97, 1.04]	0.865	1.00 [0.95, 1.04]	0.818
Gender (female)	1.33 [0.57, 3.11]	0.503	0.77 [0.27, 2.15]	0.614
Baseline scores				
Average pain Intensity, BPI5	1.09 [0.77, 1.54]	0.620	1.08 [0.71, 1.64]	0.712
Pain interference, BPI9	1.09 [0.80, 1.48]	0.586	0.87 [0.61, 1.25]	0.456
Oswestry Disability Index, ODI	1.01 [0.98, 1.04]	0.589	1.01 [0.97, 1.06]	0.495
Diagnostics				
≥80% relief from single MBB	2.34 [0.97, 5.66]	0.058	2.21 [0.77, 6.32]	0.139

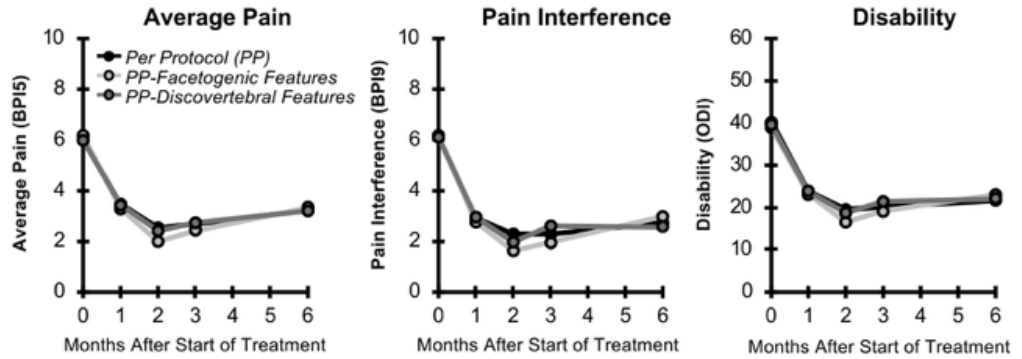
- **Per protocol treatment delivery was associated with achieving meaningful pain relief**, as those participants had **3.04 times higher odds of achieving ≥50% reduction in average pain** (n=65; p=0.023).
- Baseline characteristics, diagnostic imaging, and response to a MBB did not have a significant association with treatment response.

Responder rates are shown for cohorts with **facetogenic features** (PP+FACET; determined via clinical exam or ≥80% relief from a medial branch block) and **discovertebral features** (PP+DISC; determined via clinical exam or moderate to severe findings on medical imaging) **within the Per Protocol Set** (PP).



DURABILITY OF RELIEF THROUGH 6 MONTHS

Reductions in pain extended to improvements in pain interference and disability, with sustained benefits sustained for the Per Protocol (n=65), facetogenic (n=36), and discovertebral (n=40) cohorts.



Safety *No serious, unanticipated study-related adverse events (AEs) occurred for any participant. The most common AEs related to percutaneous 60-day PNS were mild skin irritation or itching at the bandage.*

CONCLUSIONS

- In this study, **per protocol treatment delivery of 60-day PNS was significantly associated with achieving meaningful pain relief** (3.04 times higher odds of achieving ≥50% pain reduction at 3 months).
- Baseline characteristics, diagnostic imaging, and response to a medial branch block were not significantly associated with 60-day PNS outcomes.
- Exploratory cohort analyses **demonstrated effectiveness among patients with facetogenic or discovertebral pain features**, with improvements sustained through 6 months (follow-up ongoing).
- These findings suggest that 60-day PNS treatment delivery is an important determinant of outcomes, **underscoring the role of proper lead implantation, patient education, and treatment adherence**.

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McCormick et al. 2025[1]
Findings from the Full Analysis Set

Hemiplegic & Chronic Shoulder Pain

GOOD EVIDENCE, UNDERUSED

- Three RCTs specifically in hemiplegic (post-stroke) shoulder pain demonstrate safe, effective, practical application.
- Wilson et al. prospective RCT (n=25): average pain reduction from 7.5 to 3.2 on NRS.
- Oswald et al. prospective case series (n=42 implants): 78% of patients reported significant improvement, 71% average pain reduction, 72% improvement in activity level.
- Responder rates in contemporary post-stroke shoulder and osteoarthritis cohorts now regularly exceed 80% in some series.
- A genuinely underutilized indication — many stroke and orthopedic patients with refractory shoulder pain never hear about this option.

>80%

responder rates reported in some contemporary shoulder pain series

Chronic Knee Pain (OA & Post-TKA)

EMERGING EVIDENCE

- 2025 retrospective analysis of 60-day PNS in 18 patients with chronic knee pain, compared to conventional medical management controls.
- Growing role for patients with osteoarthritis who are poor surgical candidates, or with persistent post-total-knee-arthroplasty pain.
- PNS targets genicular or femoral/sciatic branches depending on pain distribution — again, a localizable-nerve-target requirement.
- Positioned as a bridge or alternative for patients wanting to avoid or delay further knee surgery, or who have pain despite a technically successful TKA.

New in 2025

growing literature base; still smaller sample sizes than back, shoulder, or headache data

Percutaneous 60-Day Peripheral Nerve Stimulation (PNS) Relieves Postoperative Pain After Total Knee Arthroplasty (TKA): Crossover Outcomes Through 12 Months

G. Lawson Smith,[1] J. Goree,[1] SA Grant,[2] DM Dickerson,[3,4] Y Eshraghi,[5] S Vaid,[6] AK Valimahomed,[7] JJ Finneran,[8] JR Shah,[1] NN Shah,[3,4] MN Guirguis,[9] MS Eckmann,[9] AB Antony,[10] BJ Ohlendorf,[11] M Gupta,[12] JE Gilbert,[13] A Wongsarnpigoon,[14] JW Boggs[15]

[1]University of Arkansas for Medical Sciences, [2]University of North Carolina at Chapel Hill, [3]Endeavor Health, [4]University of Chicago, [5]Ochsner Medical Center, [6]Better Health Clinical Research, [7]Gramercy Pain Center, [8]University of California San Diego [9]University of Texas San Antonio, [10]The Orthopaedic Institute, [11]Duke University, [12]Neuroscience Research Center, [13]SPR

More Clinical Evidence for Percutaneous 60-Day PNS

Objective

- Total knee arthroplasty (TKA) is an effective procedure for treating end-stage knee osteoarthritis, and > 1.2M TKAs per year are expected in the U.S. by 2040 [1].
- Up to 10-20% of patients continue to experience persistent intractable postoperative pain despite a technically successful surgery and no obvious surgical issues [2].
- If not effectively treated, persistent intractable postoperative pain can impair function and interfere with daily activities.
- Recently published results found that Percutaneous 60-day PNS significantly reduced persistent intractable postoperative pain after TKA, resulting in improved function compared to sham (placebo) treatment at the end of treatment (EOT) [3].

Study Goal: *The present analysis evaluated the efficacy of Percutaneous 60-day PNS in relieving persistent postoperative pain following TKA in participants who initially received placebo treatment before crossing over to Percutaneous 60-day PNS in a multicenter, double-blinded, placebo-controlled RCT.*

RCT Design and Methods

Percutaneous 60-Day PNS: *Minimally invasive treatment (no permanent implant) capable of producing sustained pain relief lasting more than 4 years across different indications [4,5].*

- Post-market, multicenter, double-blind, randomized placebo-controlled trial.
- Institutional review board (IRB)-approved and prospectively registered (NCT04341948) [3].
- Leads placed in a minimally-invasive ultrasound-guided procedure with single needle insertion per lead.
- Leads targeted the femoral and sciatic nerves in the upper thigh [3].
- Participants received active or placebo (sham) stimulation for 24 hours/day for up to 60 days.

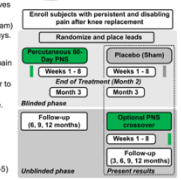


Key Eligibility Criteria:

- Persistent and stable moderate to severe pain after TKA (BPI-5 ≥5).
- Stable medication usage for ≥4 weeks prior to baseline visit.
- Opioids ≤ 90 mg morphine equivalent dose.
- No contraindicated conditions.
- Age ≥ 21 years.
- BMI ≤ 40 kg/m^2
- No diagnosis of diabetes.

Outcomes:

- Brief Pain Inventory Short Form: pain (BPI-5) weekly recall.



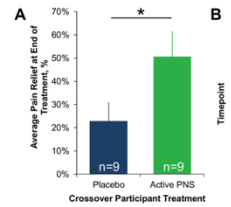
Results

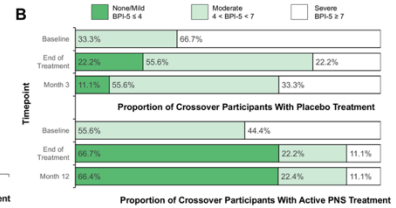
Successful primary endpoint: *The PNS group had significantly more responders (≥50% pain relief during weeks 5-8 of treatment) than the placebo group (PNS=60% vs. Placebo=24%; p=0.03) [3].*

Optional crossover‡: *9 participants treated with placebo (sham) then completed Percutaneous 60-Day PNS treatment during optional crossover.*

A) Participants who received placebo first, then crossed over to 60-day PNS, reported **significantly greater pain relief with 60-day PNS** at EOT compared to placebo

B) A minority of participants had mild or no pain **after placebo** treatment (top) compared with **a majority after 60-day PNS** (bottom). **The proportion of participants with mild or no pain remained stable** at the Month 12 follow-up following 60-day PNS





* $p < 0.05$ (paired t-test); error bars show standard deviation

§16 of 20 participants elected to crossover to 60-day PNS following placebo (sham) stimulation. One participant discontinued after Week 2 and was excluded from the analysis per the prespecified analysis protocol. One participant was lost to follow up after the Month 6 visit and missing data were imputed using a mixed effects model. Month 9 and Month 12 outcomes were derived from the combined observed and imputed data.

Baseline information: *Median time since surgery: 2.8 years.*

Safety: *No study-related serious or unanticipated adverse events. Skin irritation was the most common adverse event.*

Key Takeaways

Percutaneous 60-Day PNS is a minimally invasive treatment option for persistent intractable postoperative pain with:

- A strong safety profile
- Significantly greater pain relief compared to placebo (sham) stimulation at the end of treatment among crossover participants.
- A majority of crossover participants reporting sustained mild pain scores out to Month 12.

Acknowledgments

Funding: The vast majority of funding for this study was provided by the Department of Defense (DoD, The Office of the Assistant Secretary of Defense for Health Affairs, through the Peer Reviewed Orthopaedic Research Program under Award No. W81XWH1810799). Opinions, interpretations, conclusions and recommendations are those of the authors and are not necessarily endorsed by the DoD. Additional support was provided by SPR.

Relevant Disclosures: MA, GJG, VP, JJH, DJDG, and RKB have consulting agreements with SPR. JEG, AW, and JWB are employees of SPR and have ownership/options interests in SPR.

Other Contributions: Thank you to site research staff and the Clinical Affairs team at SPR, including Ryan Begun, Alexis Kunzel, Sara Anderson, and Rosemary Zang.

References: [1] Shichman et al. JB JS Open Access 2023 [2] Wylde et al. EFORT Open Rev. 2018. [3] Goree et al., Neuromodulation, 2024. [4] Vorenkamp et al. Pain and Therapy 2025. [5] Gilmore et al. Pain and Therapy 2025.

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JANUARY 22-25 | LAS VEGAS, NV

Percutaneous 60-Day Peripheral Nerve Stimulation used for treating chronic knee pain: Outcomes from a multi-center, retrospective chart review

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Scan to Learn More

Objective

- Knee pain impacts approximately 25% of adults and adversely affects function and mobility, and pain relief can enable rehabilitation and functional recovery [1].
- Conventional pain treatment options often lack sustained efficacy and can produce unwanted side effects [2, 3].
- A recent double-blind randomized controlled trial found Percutaneous 60-Day Peripheral Nerve Stimulation (PNS) can reduce knee pain and improve function [4]. The present study evaluates real world experience using the same system.

Study: IRB-approved retrospective review of multiple centers' experience using Percutaneous 60-Day PNS to treat chronic knee pain.

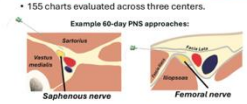
Methods

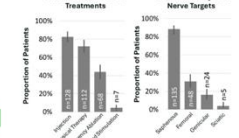


- Treatment with Percutaneous 60-Day PNS device with lead(s) connected to body-worn external pulse generator.
- Leads removed after end of treatment (typically after 60 days of treatment).
- Data were extracted from electronic medical records and supplemented by data available for patients who opted in to provide outcomes to the device manufacturer's database.
- Patient characteristics included demographic data, clinical characteristics related to their knee pain (diagnosis, other treatments used, etc.), and treatment outcomes.
- The proportion of patients who reported clinically substantial (≥50%) pain relief was evaluated at end of treatment (EOT).

Prior interventions and 60-day PNS

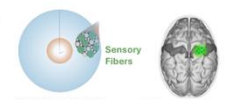
- 155 charts evaluated across three centers.





Proposed Mechanism

- *Consistent pain relief across knee pain causes, including in patients with multiple knee pain causes, lends support to a convergent central mechanism for PNS*
- *Remote selective targeting of the peripheral nerves with percutaneous PNS helps recondition the underlying centralized pain state [5].*



Percutaneous PNS robustly activates sensory fibers

Robust activation reconditions the CNS

Results

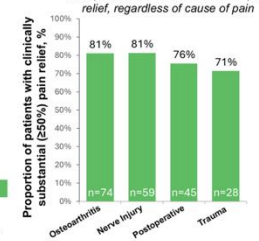
A majority of patients reported clinically substantial relief of knee pain following Percutaneous 60-Day PNS

76% Proportion with clinically substantial (≥50%) pain relief[#]

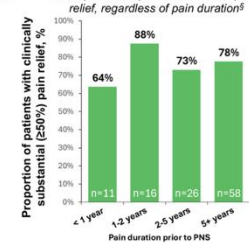
72% Average pain relief among patients with clinically substantial relief

71% Proportion with improved quality of life[‡]

Most patients achieved substantial pain relief, regardless of cause of pain



Most patients reported substantial pain relief, regardless of pain duration§



Postoperative: *included n=36 patients with post-TKA pain with 75% (n=27 of 36) reporting clinically substantial pain relief [4].*

Safety: *No adverse events were serious or unanticipated.*

[#] n=149 of 155 patients had available outcomes at the end of treatment
[‡] n=92 of 155 patients had available outcomes at the end of treatment
[§] n=38 patients did not report a duration of pain; among these patients, 76% (n=28 of 37 with available outcomes) reported clinically substantial relief

Key Takeaways

Percutaneous PNS provided meaningful relief of chronic knee pain in a multi-center chart review.

High responder rates and pain relief were consistent across:

- **Different causes of knee pain.**
- **Different durations of pain before treatment.**

Acknowledgments

Funding: Support for this study was provided by SPR.

Relevant Disclosures: MA, GJG, VP, JJH, DJDG, and RKB have consulting agreements with SPR. JEG, AW, and JWB are employees of SPR and have ownership/options interests in SPR.

Other Contributions: Thank you to site research staff and the Clinical Affairs team at SPR, including Ryan Begun, Sara Anderson, and Rosemary Zang.

References: [1] U. S. Nguyen et al., Ann Intern Med, 2011. [2] R. Benyamin et al., Pain physician, 2008. [3] N. Bellamy et al., Cochrane Database Syst Rev, 2006. [4] J. H. Goree et al., Neuromodulation, 2024. [5] T. R. Deer et al., J Pain Res, 2021.

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Durable Knee Pain Relief After 60-Day Peripheral Nerve Stimulation (PNS): Cross-Sectional Survey Outcomes Out to Five Years

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More Clinical Evidence for 60-Day PNS

Objective

- Knee pain impacts approximately 25% of adults and adversely affects function and mobility, and pain reduction can enable rehabilitation and functional recovery [1].
- A recent double-blind randomized controlled trial found Percutaneous 60-Day Peripheral Nerve Stimulation (PNS) can reduce knee pain and improve function [2].
- Real-world data can help elucidate the impact of treatments in routine clinical care [3], and Percutaneous 60-Day PNS has produced durable long-term pain relief that has been shown to last more than 4 years in several indications [4,5].

Study Goal: *Evaluate durability of knee pain relief following Percutaneous 60-Day PNS treatment.*

Methods





- IRB-approved cross-sectional follow-up survey of patients who underwent 60-day PNS treatment used for knee pain and:
  - were at least 6 months from the start of treatment
  - responded with ≥50% pain relief at the end of treatment (EOT)
  - had opted in at the time of treatment to provide information to the device manufacturer
- Patient-reported outcomes:
  - Patient-reported percent pain relief
  - Average and worst pain scores
  - Patient global impression of change (PGIC) in quality of life, physical function, mood, and sleep.
  - Use or avoidance of other treatments and interventions for their knee pain since 60-day PNS treatment including changes in medications.
- Continuous data: mean ± SD.

Results

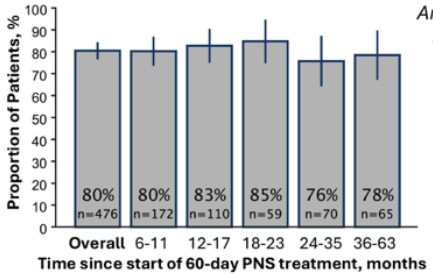
Overall Respondent Characteristics

Demographics (n=476)	
Sex	69% F
Age, years	65 ± 14
Baseline Average Pain (0-10 NRS)	5.7 ± 2.1
Baseline Worst Pain (0-10 NRS)	8.6 ± 1.6
Months from Start of 60-Day PNS, n (%)	
6-11 Months	172 (36%)
12-17 Months	110 (23%)
18-23 Months	59 (12%)
24-35 Months	70 (15%)
36-63 Months	65 (14%)
Causes of Knee Pain, n (%) Patients selected all that apply.	
Osteoarthritis	245 (51%)
Postoperative	183 (38%)
Injury/Trauma	133 (28%)
Nerve/Neuralgia	62 (13%)
Unsure/Unknown	26 (5%)

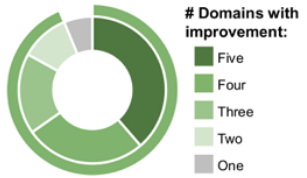
NRS: Numerical Rating Scale

Safety: As a follow-up survey, safety outcomes were not directly assessed for this study

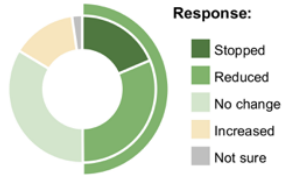
A majority of survey respondents were durable responders §



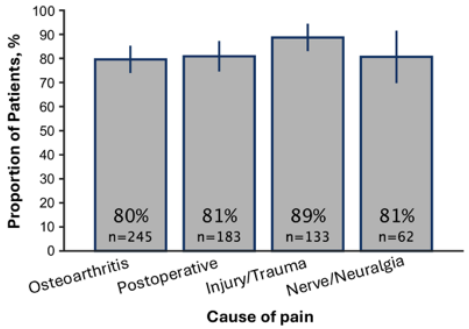
Among durable responders (n=383), ***94% reported improvements in multiple domains***



Among patients taking medications (n=441), ***50% stopped or reduced their medications***

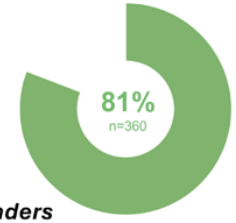


Durable responders across pain etiology §



76% of survey respondents *(n=360 of 476)* ***also reported avoiding subsequent major interventions:***

- *Surgery,*
- *Radiofrequency ablation,*
- *Permanent neurostimulator implants*



81% (n=291 of 360) of these patients were durable responders

§ ***Durable responders:*** *Pain relief ≥50% and/or improvement in quality of life, physical function, mood, and/or sleep ≥1 on a 7-point (-3 to 3) PGIC scale.*

Key Takeaway

Percutaneous 60-Day PNS is a minimally invasive treatment that can provide patients with durable knee pain relief out to 5 years.

Acknowledgments

Funding: Support provided by SPR.
Relevant Disclosures: SE, HM, NS and RB are consultants for SPR. JEG, AW, and JWB are employees of SPR and have ownership/options interests with SPR.
Other Contributions: Thank you to the Patient Support and Clinical Affairs teams at SPR, including Ryan Begun, Joey Wellman, Regina Bellian, Jacqui Lingler, and Rosemary Zang.
References: [1] U. S. Nguyen et al., Ann Intern Med, 2011 [2] Goree et al., Neuromodulation, 2024. [3] Chakravarthy et al., Pain Phys, 2018 [4] Vorenkamp et al. Pain and Therapy 2025. [5] Gilmore et al. Pain and Therapy 2025.

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Neuropathic Pain & Phantom Limb Pain

MIXED / SELECT INDICATIONS

- Systematic review of implantable PNS for peripheral neuropathic pain: phantom limb pain was the only indication reaching moderate-level evidence.
- Other neuropathic indications (CRPS, painful mononeuropathy, post-herpetic neuralgia, ilioinguinal/genitofemoral neuralgia) supported mostly by case series and small cohorts.
- Peripheral field stimulation and dorsal column stimulation remain reasonable alternatives or adjuncts when PNS access to the specific nerve is not feasible.
- Future prospective, adequately powered trials are still needed across most of these individual neuropathic subtypes.

Phantom Limb

the one neuropathic indication with moderate-level evidence in systematic review

Perioperative & Postoperative Pain

RAPIDLY GROWING

- Over 18 million orthopedic procedures performed annually in the US, with pharmacologic management still the primary analgesic mode.
- 2025 systematic review: 11 articles from 9 distinct studies (6 RCTs) on temporary PNS after knee, shoulder, hip, foot, and ankle surgery.
- Used both in the acute perioperative phase and for chronic postoperative pain, with a non-opioid, non-addictive mechanism.
- Represents a meaningful opioid-sparing strategy for orthopedic and surgical partners — a strong collaborative opportunity for pain medicine.

6 RCTs

included in a 2025 systematic review of temporary PNS in orthopedic surgery

Patient Selection

Who to consider, who to avoid, and how the trial works

The Core Candidate Profile

Core Indications

- Chronic pain lasting more than 3 months
- Documented failure of less invasive treatments (medications, physical therapy, nerve blocks)
- Pain localized to the distribution of a single, identifiable peripheral nerve
- Absence of surgical / procedural contraindications
- No further corrective surgical options exist, or patient wishes to avoid/delay surgery

Contraindications & Exclusions

- Active or uncontrolled coagulopathy
- Active local or systemic infection
- Diffuse, non-localized neuropathy (poor target for a single-nerve therapy)
- Anatomy or pathology better suited to dorsal column / dorsal root stimulation
- Unaddressed significant psychiatric or substance use comorbidity that would impair trial interpretation

The Trial-to-Implant Pathway

1	**Confirm the target**	Diagnostic nerve block confirms the pain generator and predicts stimulation response.
2	**Place the trial lead**	Percutaneous, ultrasound-guided lead placement — an office-based procedure, no incision.
3	**Trial period**	5–7 days (implantable pathway) or up to 60 days (temporary system), with patient-reported outcomes tracked daily.
4	**Evaluate response**	Meaningful threshold is typically ≥50% pain reduction plus functional improvement, not pain score alone.
5	**Decide & proceed**	Responder → permanent implant (if using implantable system) or trial lead simply removed (60-day system, no further step).

Risk Profile: Favorable, but Not Zero

Infection	Low incidence; higher with longer indwelling time (60-day system) — monitor site closely.
Lead migration / fracture	Most common device-related complication; often correctable without surgery.
Nerve irritation or injury	Uncommon with ultrasound guidance; typically transient if it occurs.
Device-related discomfort	Some patients report uncomfortable stimulation sensations requiring reprogramming.
No permanent destructive injury to the nerve itself	A key safety differentiator vs. ablative techniques.

Practice Integration

Where PNS fits in a multimodal plan, and how to refer

PNS in the Multimodal Pain Ladder

Foundation	Medication optimization, physical therapy, sleep, activity pacing, behavioral health support
Diagnostic clarity	Targeted diagnostic blocks to confirm the pain generator before escalating
Reversible neuromodulation	PNS trial as a low-risk, non-destructive next step when a single nerve is implicated
More invasive / permanent options	Ablation, spinal cord stimulation, or surgery reserved for appropriate, confirmed candidates

PNS is not a replacement for the foundation — it's most effective layered on top of ongoing conservative and behavioral care.

A Quick Referral Checklist

- ✓ Pain present > 3 months and refractory to appropriate conservative care
- ✓ Pain localizes to a single, identifiable peripheral nerve distribution
- ✓ No uncontrolled coagulopathy or active infection
- ✓ Reasonable expectations discussed — this is a trial-first, reversible therapy
- ✓ Consider PNS earlier for migraine/occipital neuralgia, hemiplegic shoulder pain, and post-op orthopedic pain — the strongest evidence indications

Case Vignette: Tying It Together

- **62-year-old with hemiplegic shoulder pain, 18 months post-stroke**
- Failed: sling support, physical therapy, oral analgesics, and two corticosteroid injections
- Diagnostic axillary nerve block → 80% transient relief, confirming the pain generator
- Percutaneous PNS trial placed near terminal branches of the axillary nerve to the deltoid
- 7-day trial: pain reduced from 8/10 to 2/10; sleep and range-of-motion both improved
- Proceeded to permanent implant; sustained benefit reported at 6-month follow-up, now weaning off scheduled analgesics

Key Takeaways

The evidence is real but uneven: strongest for migraine/occipital neuralgia and hemiplegic shoulder pain, solid and growing for low back and perioperative pain, earlier-stage for knee and most neuropathic pain.

PNS is reversible and non-destructive — a genuine 'trial before you commit' option that lowers the stakes of trying.

The best candidates have pain confined to a single, identifiable peripheral nerve and have failed appropriate conservative care.

PNS works best as one layer of a multimodal plan — not a replacement for medication management, PT, or behavioral health.

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Thank You

Questions & Discussion

Jessica Jameson, MD | Axis Spine Center