MHSRS 2026

Breakout Session:
Preserving Warfighter Performance & Readiness
through Improved Battlefield Pain Control

60-Day Peripheral Nerve Stimulation Used for Treatment of Headache Facilitates Functional Improvements in Patients with Migraine

COL Steven P. Cohen, MD (RET)[1], CDR Steven R. Hanling, MD (RET)[2]; Genaro G. Gutierrez, MD[3]; Zachary L. McCormick, MD[4]; Mitchell P. Engle, MD[5]; Christopher A. Gilmore, MD[6]; Matthew J. Pingree, MD[7]; Narayan R. Kissoon, MD[7]; William J. Huffman, PhD[8]; Amorn Wongsarnpigoon, PhD[8]; Joseph W. Boggs, PhD[8]

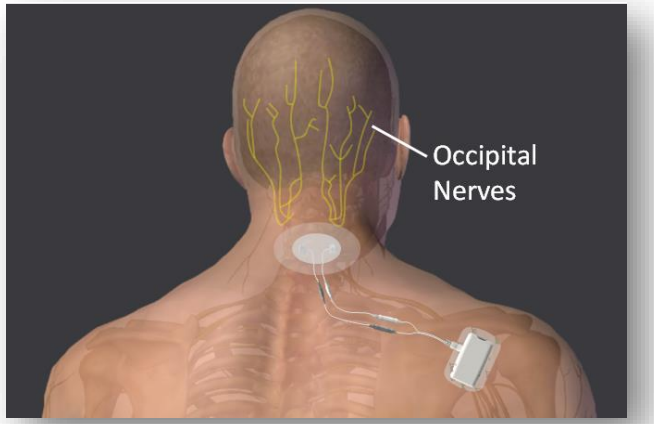
1. Northwestern University, Chicago, IL, USA
2. Piedmont Augusta, Augusta, GA, USA
3. Pain Specialists of America, Austin, TX, USA
4. University of Utah School of Medicine, Salt Lake City, UT, USA
5. Institute of Precision Pain Medicine, Corpus Christi, TX, USA
6. Center for Clinical Research, Winston-Salem, NC, USA
7. Mayo Clinic, Rochester, MN, USA; USA
8. SPR, Cleveland, OH, USA

Presenter Disclosures

- This study was funded by SPR
- Dr. Cohen is a consultant of Avanos, SPR, Persica, and Sword Health, and receives research funding paid to his institution from Avanos and Scilex
- *Additional relevant co-author disclosures:* Drs. McCormick, Gilmore, and Gutierrez have consulted for SPR, Drs. Huffman, Wongsarnpigoon, and Boggs are employees of SPR, and Drs. Wongsarnpigoon and Boggs have stock and/or stock options in SPR

Introduction

- Headaches resulting from Military-relevant injuries (e.g., blast injury, motor vehicle collisions, or repeated low-grade trauma from protective headgear) are a significant problem that can affect Military readiness
- Headache treatment can be complicated by the presence of primary headache conditions, including migraine which can preexist or develop consequent to injury
- Effective, durable headache relief may help Service Members improve combat readiness and facilitate return to full active-duty military service following head and neck trauma
- 60-day Peripheral Nerve Stimulation (PNS) has been shown to be effective for multiple Military-relevant types of pain including: shoulder, low back, post-traumatic, knee, and headache (non-migraine)[1,2,3]



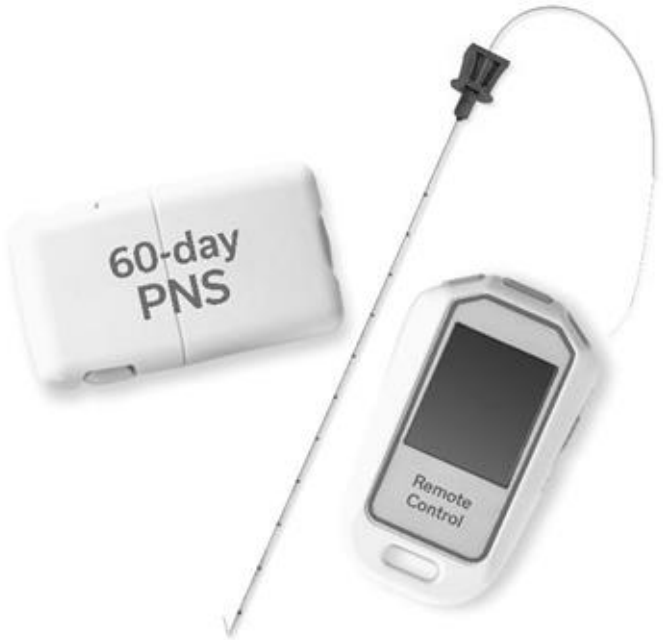
Illustrative use of 60-day PNS device placement during treatment

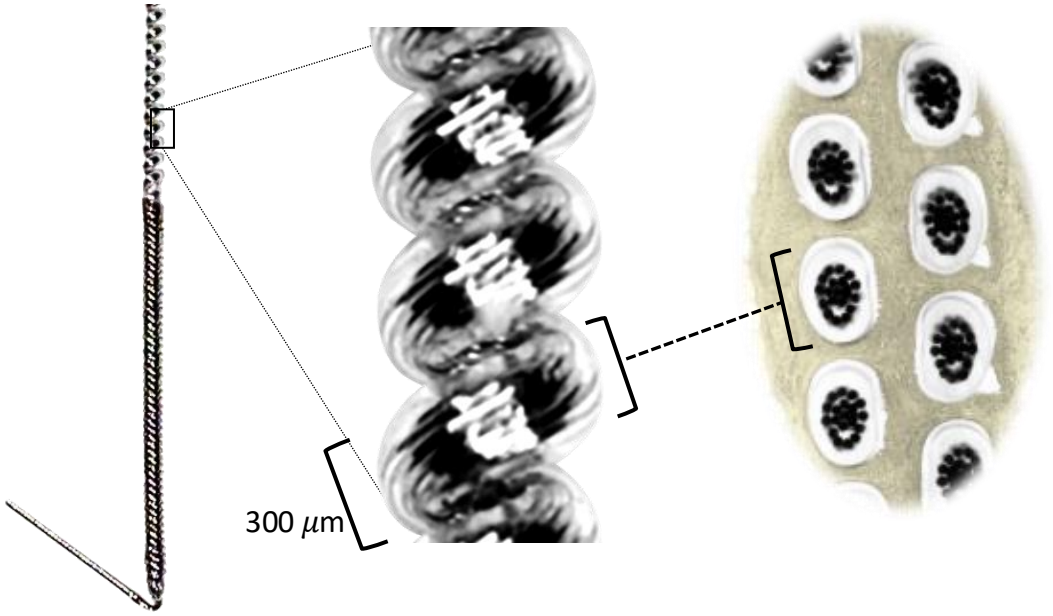
STUDY OBJECTIVES:

Collect data on the safety and efficacy of 60-day PNS targeting the greater occipital nerve and third occipital nerve for the treatment of disabling occipital headache in the presence of migraine.

1. Pritzlaff et al., Pain Management, 2024; 2. Goree et al., Pain Phys, 2024; McCormick et al., Pain Med., 2026; 3. Gutierrez et al., Headache, 2025

Minimally invasive percutaneous 60-day PNS system developed with DoD support[1]





Fibrotic ingrowth around the lead is intended to reduce pistoning and the ingress of contaminants

- **Designed to produce sustained pain relief after 60-day treatment period[2]**
- **No permanent implant**
- **U.S. DoD guidelines recommend 60-day PNS for Service Members who would like to remain on active duty[3]**

1. The present study was not supported by DoD. Previous funding associated with the development and clinical evaluation of the 60-day PNS device includes: W81XWH-18-C-0329, W81XWH-12-2-0132, W81XWH-17-C-0019, W81XWH-18-1-0799, W81XWH-18-1-0800

2. Example references demonstrating sustained relief: Chae et al 2013, Wilson et al. 2014, Gilmore et al. 2019, Cohen et al 2019, Gilmore et al. 2020, Gilmore et al. 2019, Gilmore et al. 2023, Goree et al., 2024, Gutierrez et al., 2025

3. McLean et al., RAPM, 2026

Materials & Methods

Study Design: IRB-approved, multi-center, prospective, single-arm study

Key Eligibility Criteria:

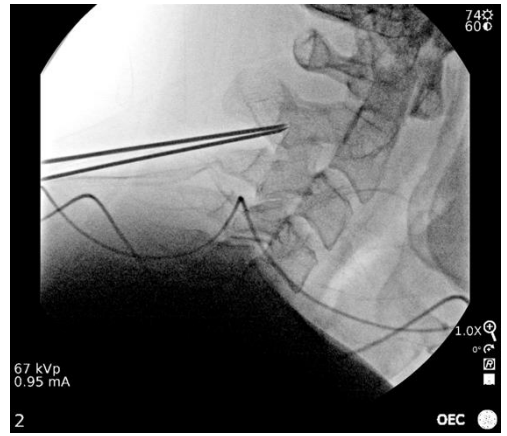
- Occipital head pain[#]
  - Previously diagnosed with cervicogenic headache or occipital neuralgia
  - ID Migraine Screener ≥2
- Average pain and pain interference scores ≥4/10 (evaluated by the Brief Pain Inventory Short Form [BPISF])

60-day PNS Treatment:

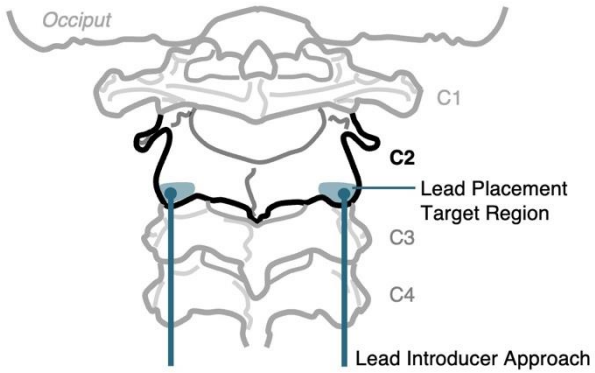
- Participants received two percutaneous leads targeting the greater and third occipital nerves with stimulation provided by an external pulse generator
- Leads were left in place for up to 60 days after which they were removed

Outcomes:

- **Key analysis:** proportion of participants with ≥50% reduction in pain intensity and/or pain interference at the end of treatment (EOT; i.e., 2 months from the start of treatment) and 3 months from start of treatment
- **Secondary outcomes:** Patient Global Impression of Change (PGIC), Migraine Disability Assessment (MIDAS), and Neck Disability Index (NDI)



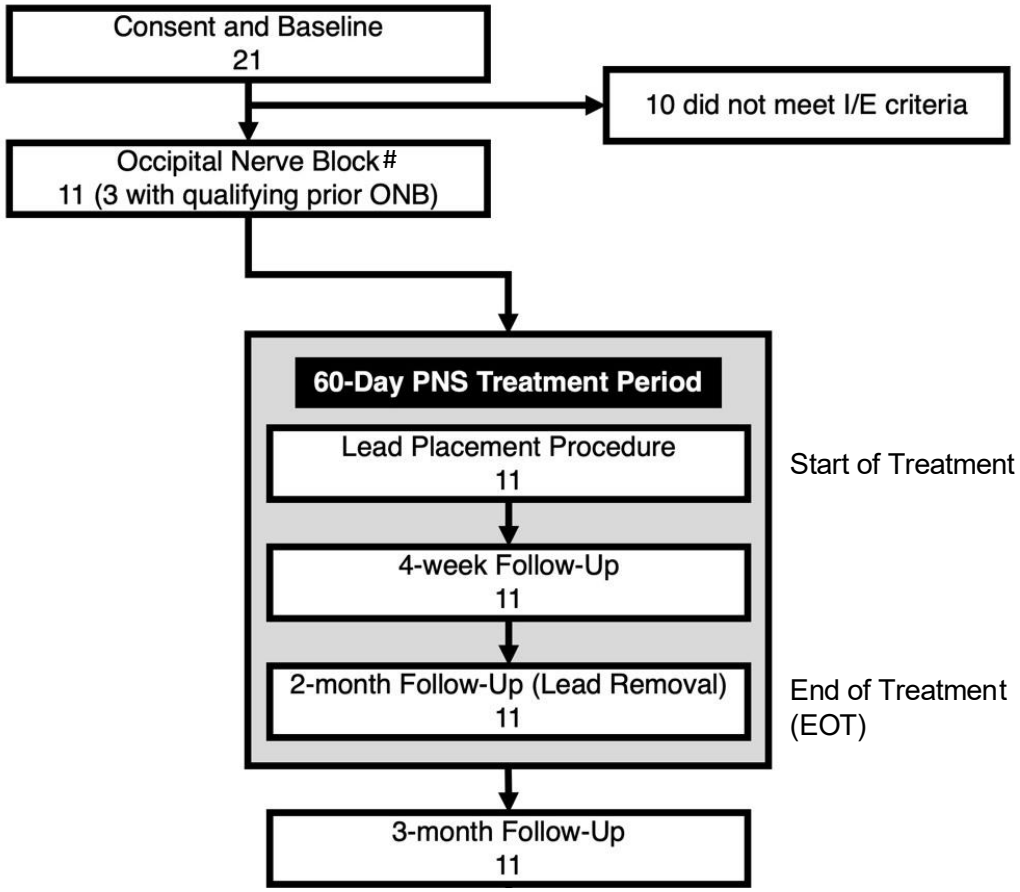
Lateral view of percutaneous lead placement



Illustrative A-P view of percutaneous lead placement

1. Pritzlaff et al., Pain Management, 2024; 2. Huntoon et al., Pain Phys, 2023; [#]Patients may have had migraine with occipital nerve tenderness

Study Participants



Consolidated Standards of Reporting Trials (CONSORT) participant flow diagram.

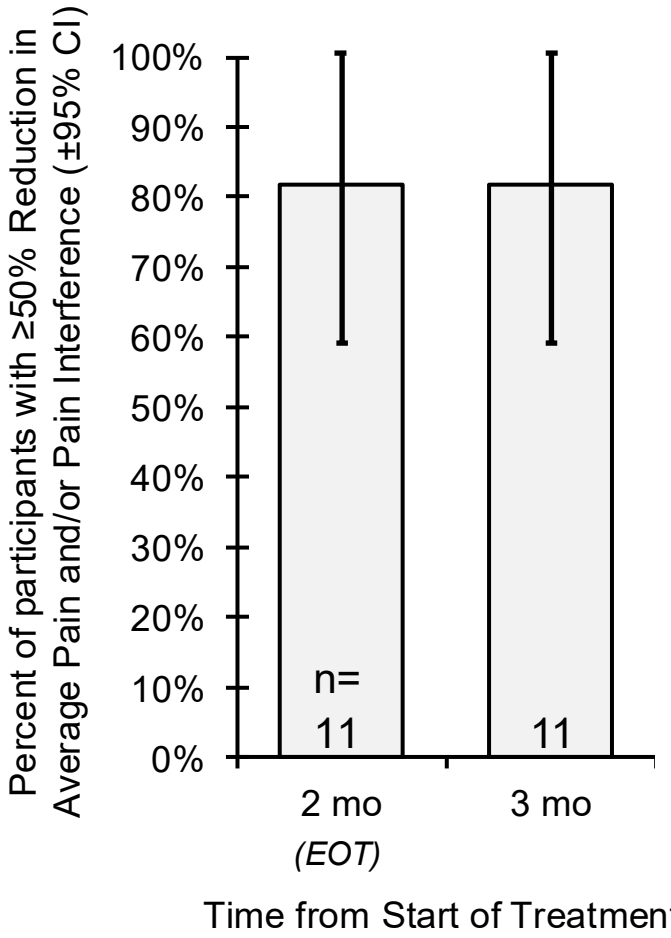
- Eleven participants were enrolled across 5 sites
- All participants (100%, n=11/11) had previously tried multiple treatments to control their headaches
- Common prior treatments were non-opioid medications, physical therapy, and injections (e.g., steroids, muscle relaxants, botulinum toxin)

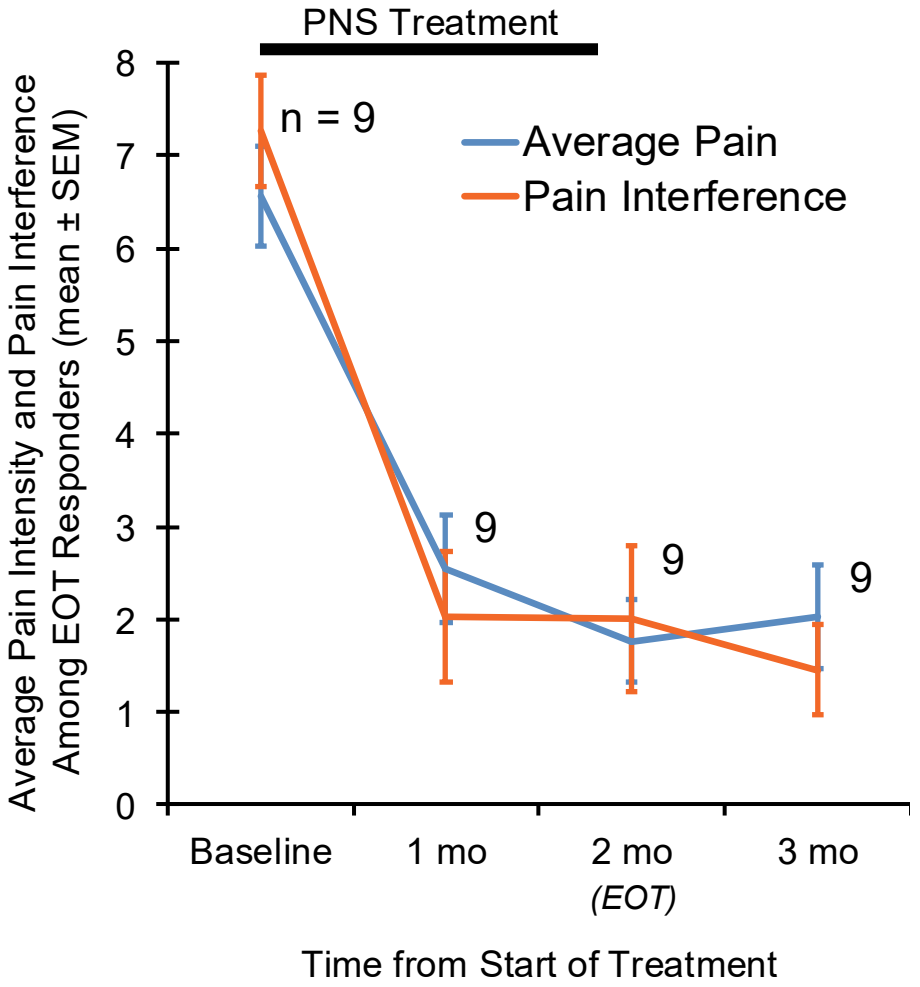
Participant Demographics (n=11)	**Value**
Age, years; mean (SEM)	50.6 (3.0)
Sex, female; n (%)	10 (91%)
Years of headache; mean (SEM)	14.1 (4.2)
Headache Diagnosis, n (%)	
Cervicogenic headache	7 (64%)
Occipital neuralgia	1 (9%)
Characteristics of both	3 (27%)
Treatment History, n (%)	
Used previous treatments/therapies, n(%)	11 (100%)
Count of previous treatments/therapies, median (minimum-maximum)	8 (3-11)

 # Occipital nerve block (ONB) performed to investigate potential relationships with PNS response.
All participants went on to receive 60-day PNS regardless of their ONB response (range: 14-100% relief).

Results: Relief from Headache

82% (9/11) of participants reported substantial reductions (≥50%) in average pain intensity and/or pain interference compared to baseline at 2 and 3 months





Responders at the end of treatment (EOT, n=9) had sustained relief from pain and pain interference through 3 months:

67%

mean reduction in average pain

80%

mean reduction in pain interference

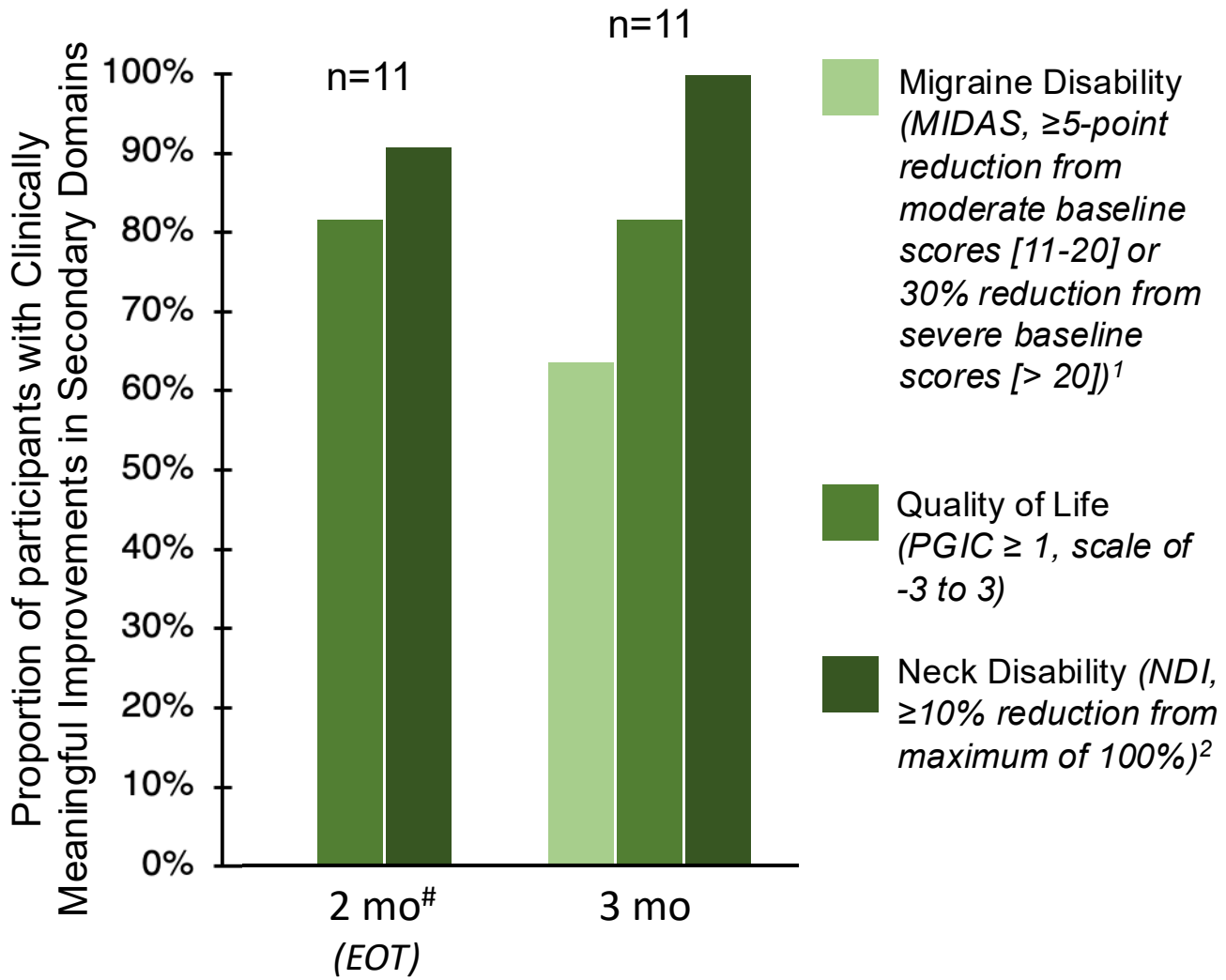
Results: Secondary Improvements

Headache relief facilitated improvements in quality of life and reductions in disability

Through 3 months, a majority of participants reported clinically meaningful improvements in secondary outcomes:

- **64%** had meaningful reductions in migraine disability (MIDAS)
- **82%** had at least minimally improved quality of life (PGIC)
- **100%** had clinically meaningful improvements in neck-based disability (NDI)

Safety: The most common AEs were skin irritation or itching. In this cohort, two infections were reported in two participants at the lead exit sites (1 classified as serious), and both resolved after a course of antibiotics with no sequalae.

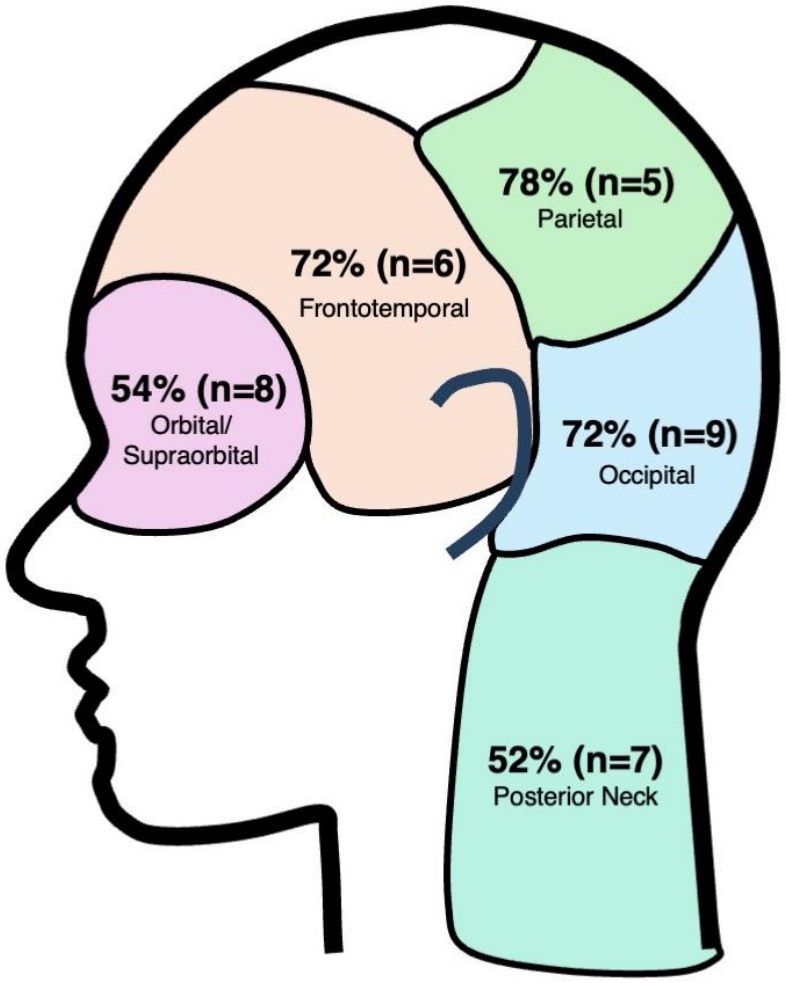


*MIDAS data not included at 2 months (EOT) because the instrument-defined 3-month recall period included time prior to start of PNS treatment.*

1. Stewart et al. 2001, 2. Vernon et al. 2008

Results: Pain Relief in Other Head Regions

Mean percent reductions in average pain intensity among EOT responders



- In addition to occipital pain, almost all participants (91%, n=10/11) reported at least moderate pain (≥4) in at least one additional head or neck region at baseline prior to treatment
- On average, EOT responders[#] also had >50% mean reductions in pain intensity in all other qualifying regions (range: 52-78%)

Note: The PNS leads are not intended to be implanted in the region innervated by the cranial and facial nerves, and use of the PNS system in the study was consistent with the indication statement for the device

[#]EOT Responder = ≥50% reduction in average pain intensity and/or pain interference

Summary and Conclusions

Study Outcomes

- Percutaneous 60-day PNS reduced pain and pain interference in a majority of patients with occipital head pain and concurrent migraine
  - Data collected through 3 months with further long-term follow-up data collection pending
- Pain relief facilitated improvements in additional domains:
  - Improved quality of life
  - Decreased neck-related disability
  - Decreased migraine-related disability

Military Applications

- These findings have important implications for Military healthcare, where rapid rehabilitation and return to duty are priorities
- Future research should evaluate PNS specifically in Military populations to optimize headache pain treatment protocols, better identify responders, and complement recently published evidence-based DoD guidelines for Service Member care[1]

This innovative, non-opioid, non-surgical pain management approach for Service members and Veterans may serve to increase Military readiness and reduce the Military's healthcare costs by reducing disabling headache following injury or trauma.

1. McLean et al., "US Department of Defense consensus guidelines on neuromodulation for pain management in an active-duty military population from a tri-service, multispecialty working group", RAPM, 2026

Questions?

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