


# Durable, 24-Month Headache Relief Observed Following 60-Day Peripheral Nerve Stimulation:
## A Prospective Feasibility Study

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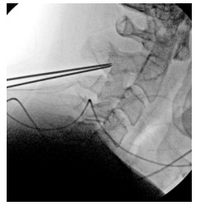
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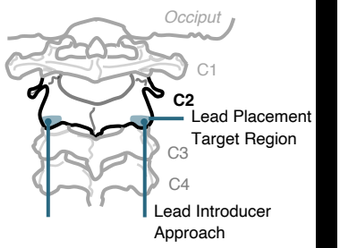
## INTRODUCTION

- Over 15% of patients with chronic headache have occipital head pain, including from cervicogenic headache (CGH) and occipital neuralgia (ON).[1,2]
- CGH and ON can be significantly debilitating, impacting 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 12 months from the start of treatment.[3,4]
- **OBJECTIVE:** Determine if the effects of percutaneous 60-day PNS for the treatment of occipital headache are sustained through 24 months.

## METHODS

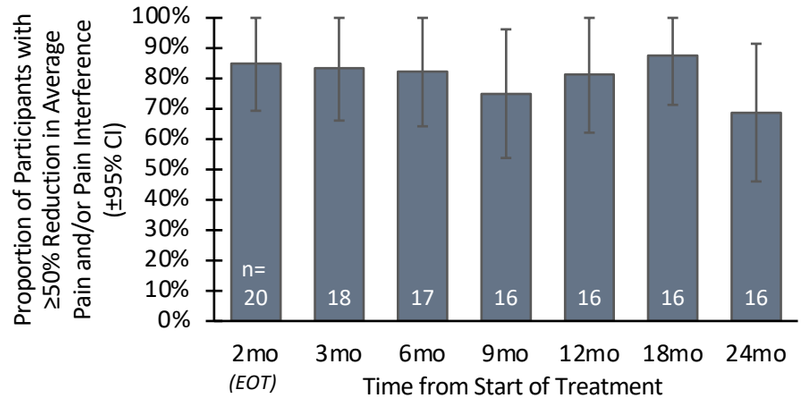
- IRB-approved, multicenter, prospective case series (5 sites, n=20).
- **Key eligibility criteria**: Age ≥18, occipital head pain due to CGH and/or ON, absence of migraine and migraine-like features baseline average pain and pain interference ≥4/10, and Beck Depression Inventory ≤20.
- Flexible, percutaneous leads were placed to target the greater and third occipital nerves (e.g., at the C2 lamina) for up to 60 days.
- Participants controlled stimulation intensity using a handheld remote.
- The prospectively defined endpoint was the proportion of participants with ≥30% reduction in average pain and/or pain interference at end of treatment (EOT).
- In this analysis, sustained relief was evaluated as the proportion of participants with ≥50% reduction in average pain intensity and/or pain interference following EOT.
- Secondary outcomes: Patient Global Impression of Change (PGIC), Neck Disability Index (NDI), and Headache Impact Test (HIT-6).



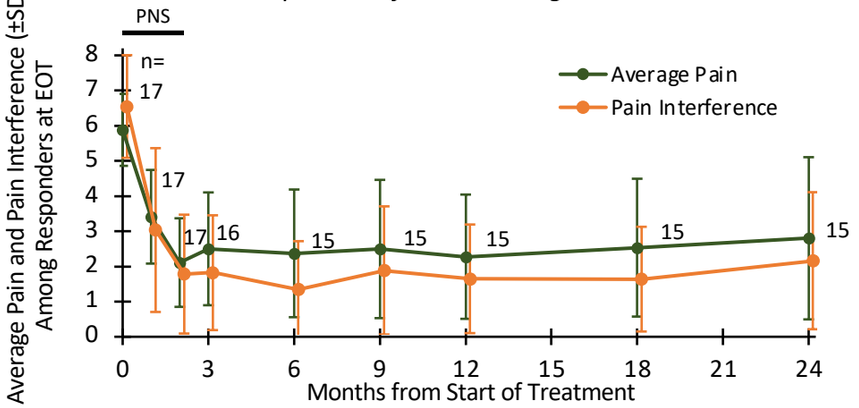



## RESULTS

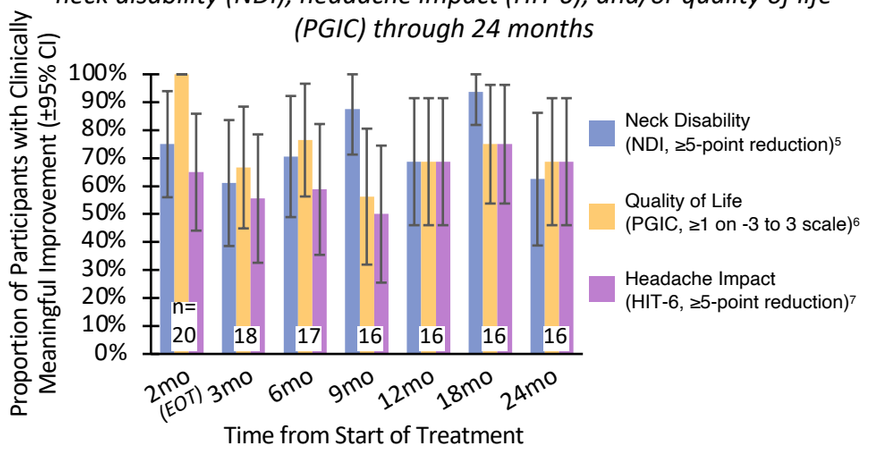
*A majority of participants reported substantial reductions (≥50%) in average pain and/or pain interference through 24 months*




*On average, responders at EOT reported sustained relief from pain and pain interference through 24 months*




*A majority of participants had clinically meaningful improvements in neck disability (NDI), headache impact (HIT-6), and/or quality of life (PGIC) through 24 months*




Safety: All study-related AEs were non-serious with the most common events being skin irritation from bandages and post-procedural discomfort. No new device-related adverse events were reported in the follow-up period.

## CONCLUSIONS

- Percutaneous 60-day PNS safely and effectively relieved occipital headache pain, and relief was sustained through 24 months in a majority of participants.
- Pain relief facilitated improvements in multiple headache-related domains including reduced impact of head pain with daily activities, improved quality of life, and reduced neck pain-related disability.

## REFERENCES AND ACKNOWLEDGMENTS

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