



60-Day Peripheral Nerve Stimulation Provides Durable Relief from Occipital Head Pain: 12-Month Outcomes from a Prospective, Single-Arm Study

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Introduction

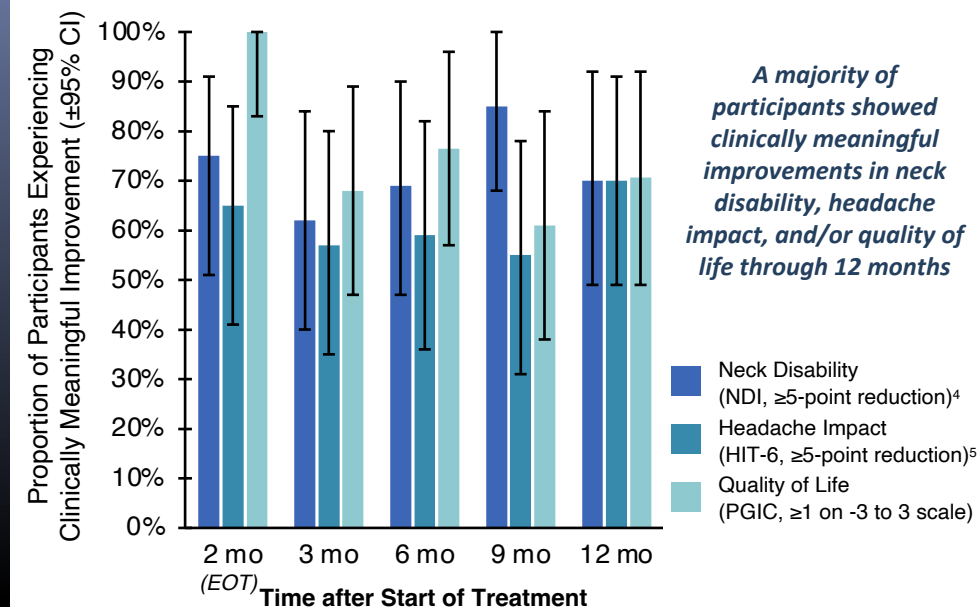
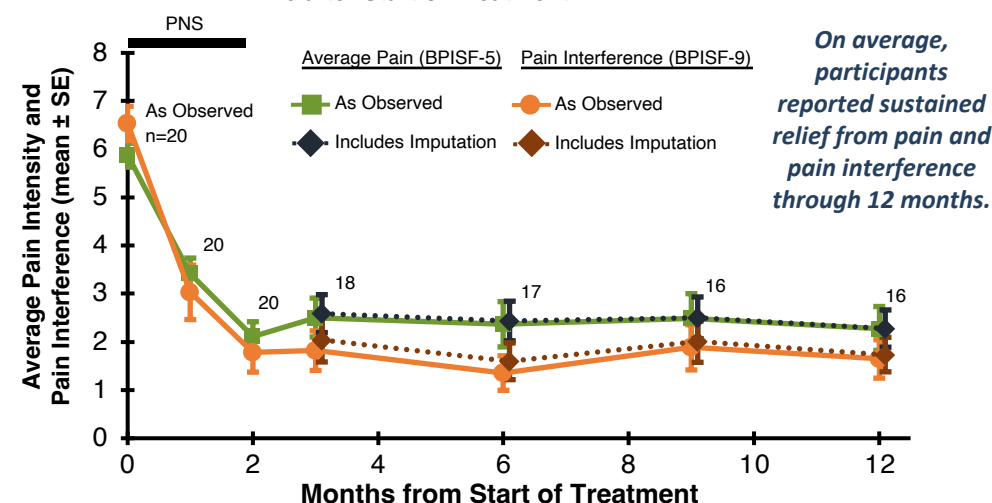
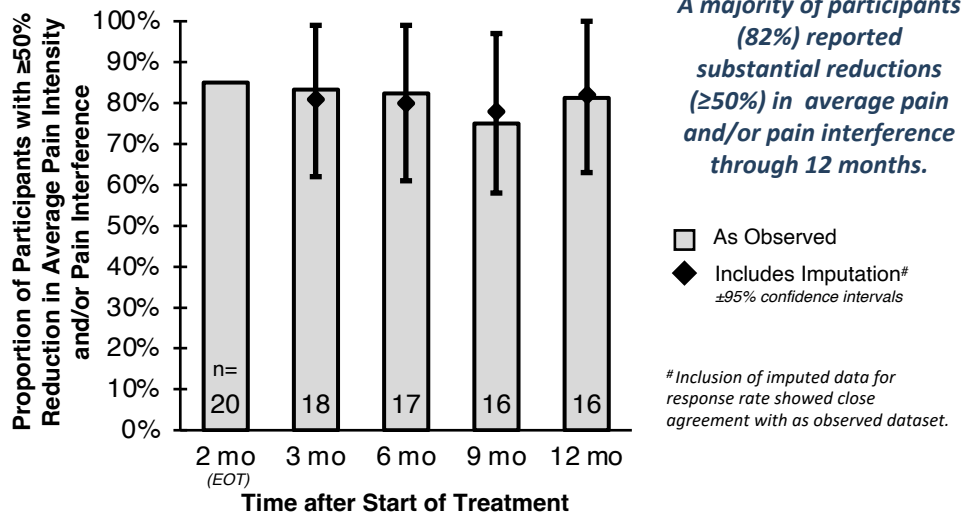
- Over 15% of patients with chronic headache have occipital head pain, including from cervicogenic headache (CGH) and occipital neuralgia (ON).^{1,2}
- CGH and ON can be significantly debilitating, impacting physical function, social function, sleep, and headache-related quality of life.
- Recently published data included evidence of pain relief in participants with CGH or ON following percutaneous 60-day peripheral nerve stimulation (PNS) through 3 months from the start of treatment.³
- Here, the study cohort is followed through 12 months to determine the sustained effects of 60-day PNS used for treatment of occipital head pain.

METHODS

- IRB-approved, multicenter, prospective case series (5 sites, n=20).
- Key eligibility criteria: occipital head pain due to CGH and/or ON, baseline average pain and pain interference $\geq 4/10$, lack of migraine-like features, 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.
- Sustained relief is presented as the proportion of participants with $\geq 50\%$ reduction in average pain intensity and/or pain interference at study visits following end of treatment (EOT) including through 12 months.
- Secondary outcomes: Patient Global Impression of Change (PGIC), Neck Disability Index (NDI), and Headache Impact Test (HIT-6).
- Missing data were addressed using multiple imputation with predictive mean matching performed by an independent third-party statistician group (WCG, Cary, NC).



RESULTS



Safety: Within this cohort, 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 12 months in a large 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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This work was supported by SPR. Disclosures: CG, ZM, 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 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.