



Scan to Learn More

Significant Relief of Headache Pain Following 60-Day PNS: Three-Month Outcomes From a Prospective, Single-Arm Study

N Kisson, MD¹; GG Gutierrez, MD², ZL McCormick, MD³; M Engle, MD⁴; C Gilmore, MD⁵, M Pingree, MD¹; J Pope, MD⁶;
D DiBenedetto, MD⁷; P Sayal, MD⁴; WJ Huffman, PhD⁸; CA Zurn, MS⁸; ND Crosby, PhD⁸; JW Boggs, PhD⁸

¹Mayo Clinic, Rochester, MN; ²Pain Specialists of America, Austin, TX; ³University of Utah School of Medicine, Salt Lake City, UT; ⁴Institute of Precision Pain Medicine, Corpus Christi, TX;
⁵Center for Clinical Research, Winston-Salem, NC; ⁶Evolve Restorative Center, Santa Rosa, CA; ⁷MedVadis Research, Waltham, MA; ⁸SPR Therapeutics, Cleveland, OH

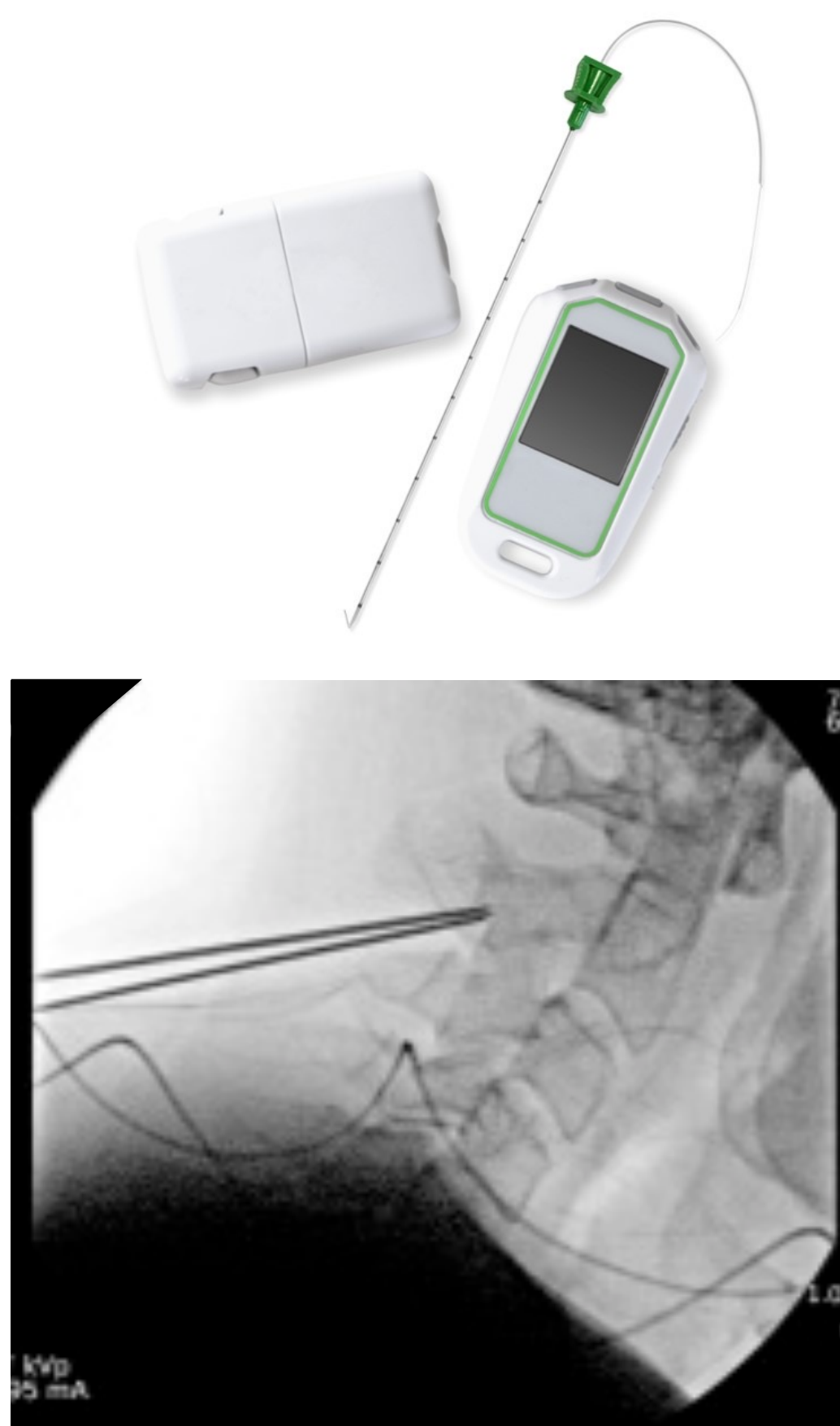


RATIONALE

- Background:** Occipital head pain, including cervicogenic headache (CGH) and occipital neuralgia (ON), is estimated to affect over 15-20% of patients with chronic headaches.¹
- 60-day peripheral nerve stimulation (PNS) treatment has shown positive results for the treatment of various pain conditions, including following stimulation of the occipital nerves.^{2,3}
- This study is the first prospective evaluation of 60-day PNS for headache pain.
- Objectives:** Collect data on the safety and efficacy of 60-day PNS targeting the greater occipital nerve (GON) and third occipital nerve (TON) for the treatment of CGH and ON.

METHODS

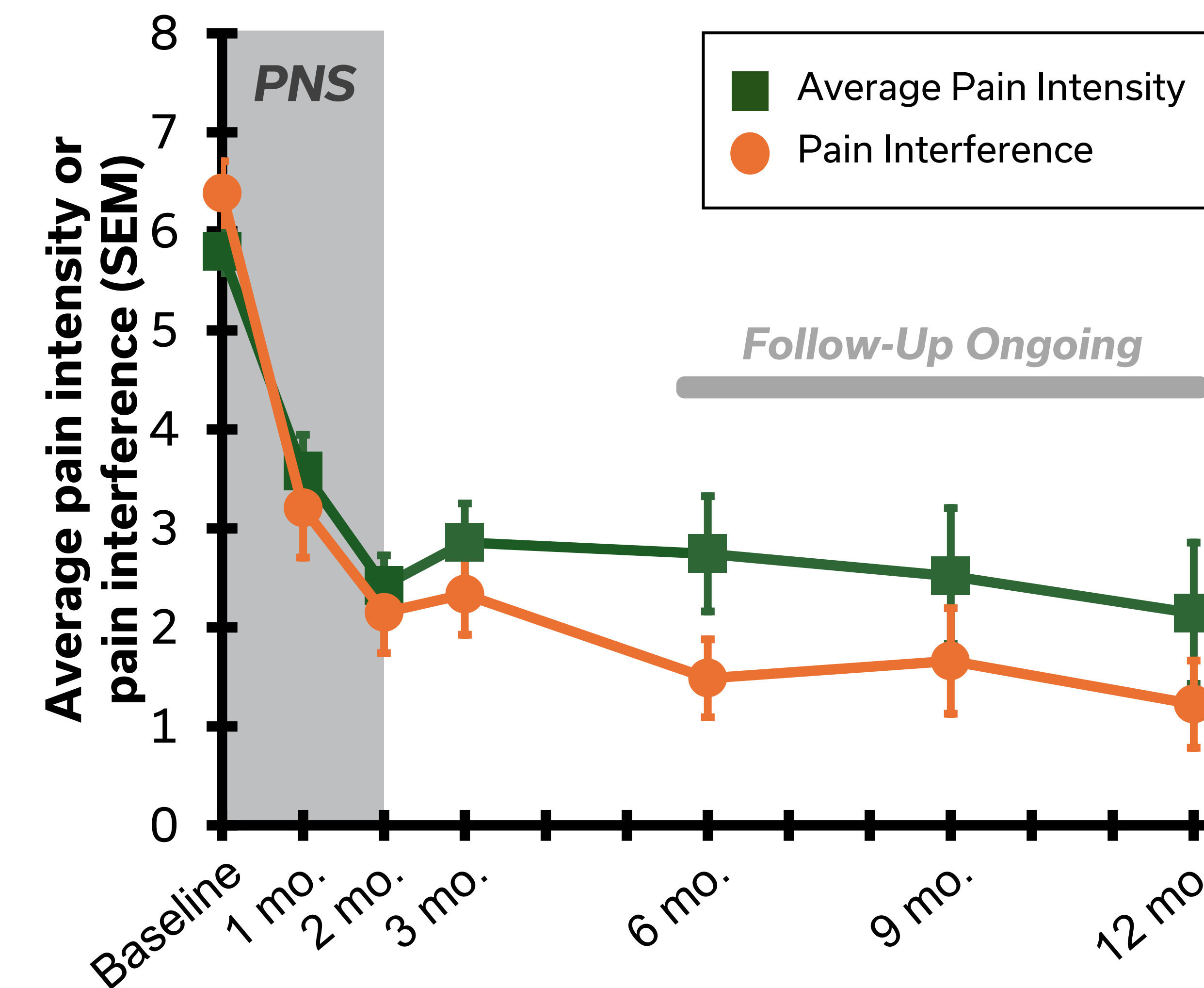
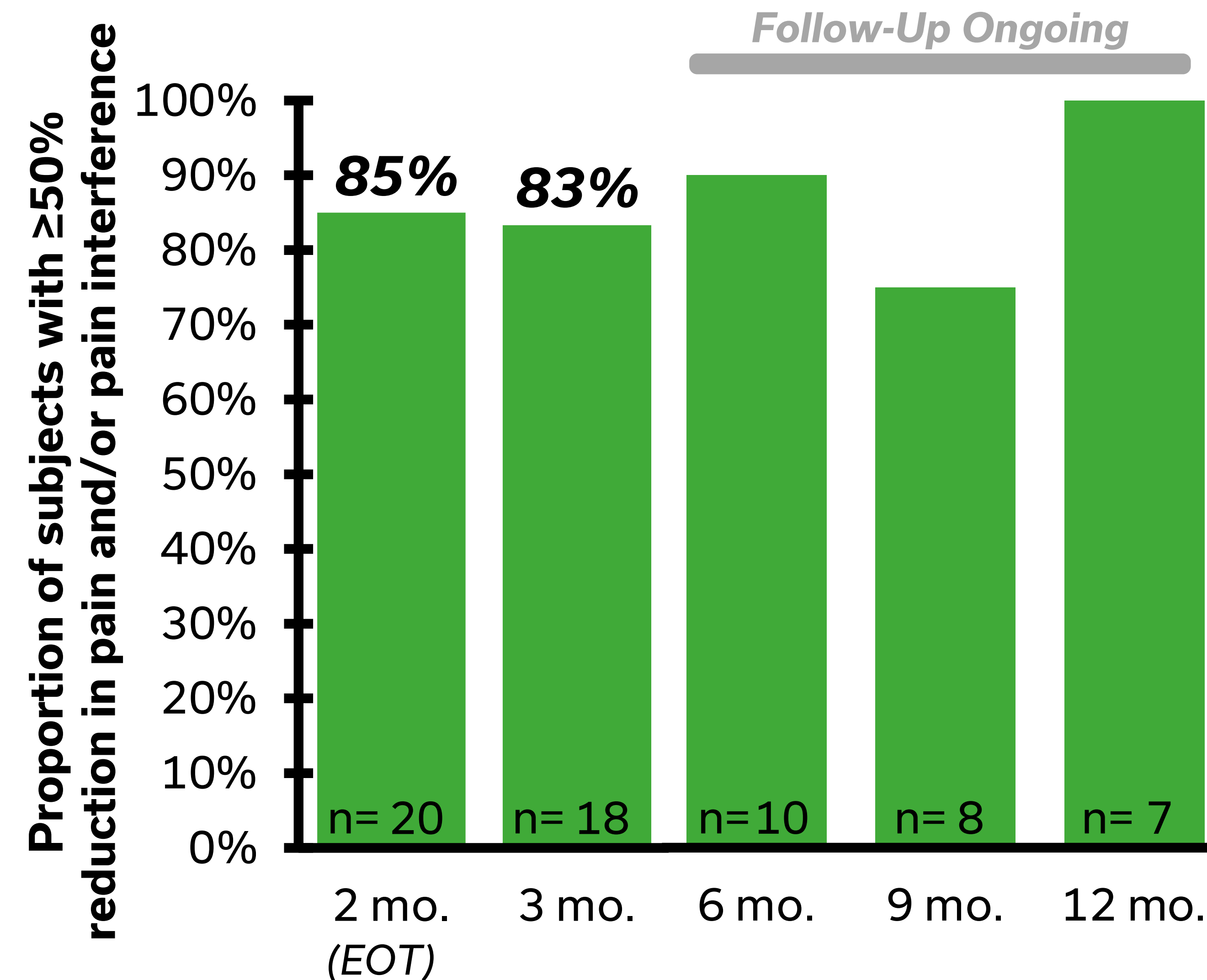
- This study is an IRB-approved, multicenter, prospective case series (n=20).
- Key eligibility criteria: occipital head pain due to CGH and/or ON, baseline average pain and pain interference $\geq 4/10$, lack of migraine-like features, Beck Depression Inventory ≤ 20 .
- Percutaneous leads targeting GON and TON at the C2 vertebral level were placed percutaneously for 8 weeks, up to 60 days.
- Proportion of subjects with $\geq 30\%$ and $\geq 50\%$ reductions in average pain intensity and/or pain interference evaluated at end of treatment (EOT) and 3 months.
- Additional outcomes: Patient Global Impression of Change (PGIC), Headache Impact Test (HIT-6), Neck Disability Index (NDI).
- EOT and 3-month data for all subjects are presented. Prospective follow up through 24 months is ongoing.



Top: The percutaneous PNS device enables patient-directed treatment using an external pulse generator and a Bluetooth-enabled remote. Bottom: Lateral fluoroscopic view of stimulating probes during placement of percutaneous leads, entering over the C4/C5 level and targeting the C2 lamina.

RESULTS & DISCUSSION

Over 80% of Subjects Reported $\geq 50\%$ Reduction in Pain and/or Pain Interference at 3-months



Demographics (n=20)

- Gender: 14 Female, 6 Male
- Age: 55 ± 17 years
- BMI: 29 ± 6
- Duration of Pain: 5.6 ± 6.8 years

Clinically Significant Quality of Life and Functional Improvements at 3 mo.

- 67% of subjects reported quality of life improvement (PGIC ≥ 1)
- 61% of subjects reported NDI improvement (≥ 5 pt)
- 56% of subjects reported HIT-6 improvement (≥ 5 pt)

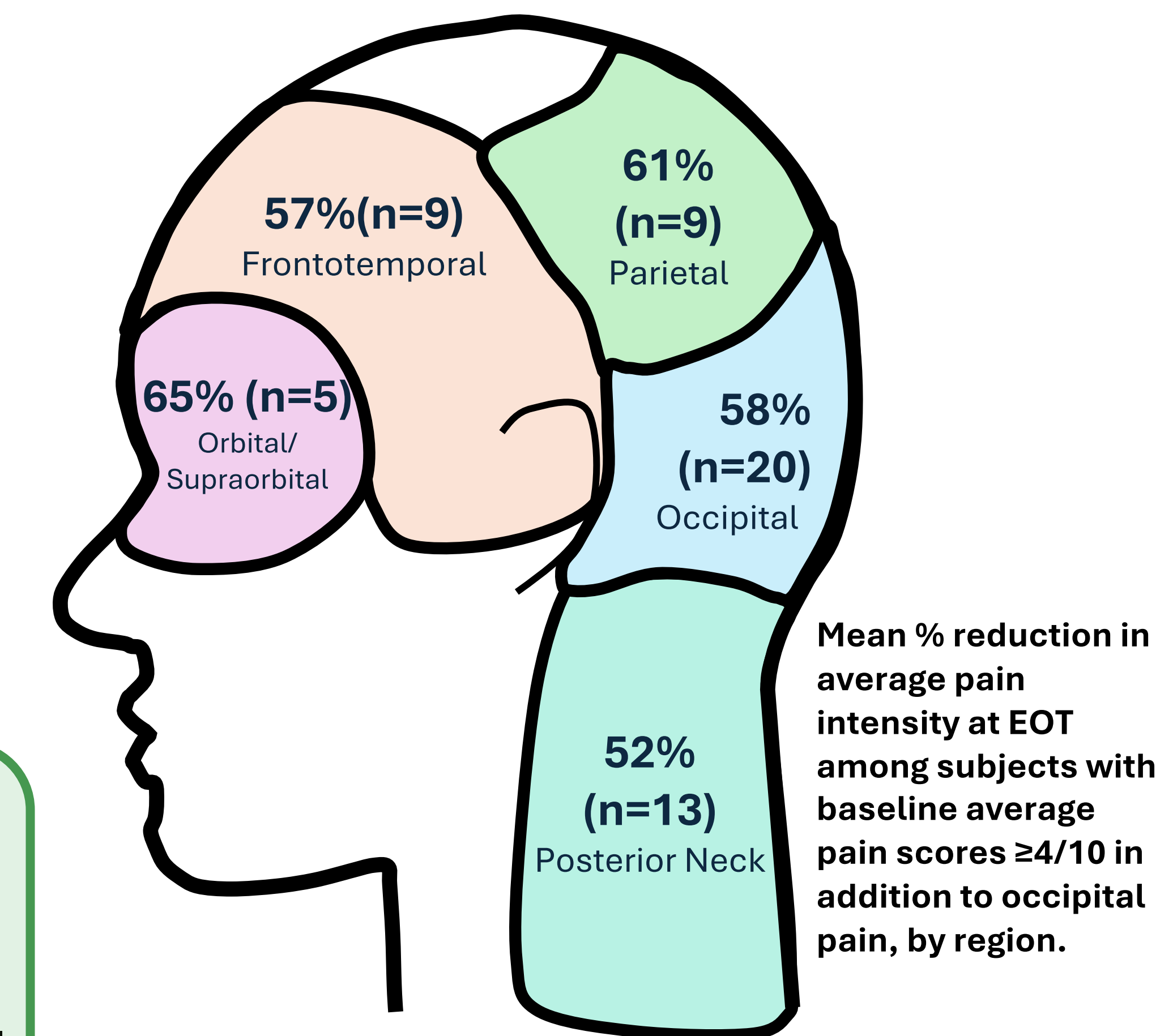
Safety

All study-related adverse events (AEs, 23 in total) were non-serious. The most common AEs included skin irritation (8 events in 5 pts), discomfort/pain from stimulation (5 in 3 pts), and itching (4 in 3 pts). No infections were reported.

Primary Endpoint (PE)

90% of subjects reported clinically significant ($\geq 30\%$) reductions in pain and/or pain interference at EOT (n=18/20, 95% CI: 77-100%).

Average Pain Intensity Also Decreased Outside of the Occipital Region[†]



[†] The percutaneous PNS device is not intended to be placed in the region innervated by the cranial and facial nerves.

CONCLUSIONS

- 60-day PNS may safely and effectively relieve pain due to occipital neuralgia and/or cervicogenic headache, resulting in functional improvements and reduced the impact of headache pain and neck disability.
- Subjects experienced substantial headache pain relief and reductions in pain interference, headache impact, and pain-related neck disability.
- Prospective follow-up is ongoing, and preliminary outcomes to-date show sustained reductions in pain and pain interference in a majority of subjects.

REFERENCES

1. Fabry et al., *Neuroradiology* 2023.
2. Huntoon et al., *Pain Physician* 2023.
3. Sheth et al., *ASRA Annual Meeting* 2022.

This study was funded by SPR Therapeutics. GG, CG, JP, and PS are consultants for SPR Therapeutics. JP, NDC, and JWB have stock options/equity in SPR Therapeutics. WJH, CAZ, NDC, and JWB are employees of SPR Therapeutics.