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### **Occipital Nerve Stimulation: Surgical Technique and Outcomes from the PRISM Study of ONS for Drug-Refractory Migraine**

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*Abstract:*

#### **Introduction**

While occipital nerve stimulation (ONS) is an emergent treatment under investigation for a host of neuropathic pain and intractable headache disorders, few reports of surgical technique, outcomes, and best practices are found in the literature. We report the procedural experience from the PRISM study, a randomized controlled trial of ONS for drug refractory migraine.

#### **Methods**

Percutaneous leads were bilaterally placed in the subcutaneous layer superficial to the greater occipital nerve via a midline vertical incision extending 4 cm caudal from a point 2 cm below the occipital protuberance. The lead was introduced using a curved Tuohy needle, inserted at the midline incision at about C1 and advanced laterally at an angle. Each lead was secured ipsilaterally using 2 suture sleeves fixed by 3 sutures and intraluminal medical adhesive (see Figure). The proximal sleeve was orthogonal to the trajectory of the lead traversing the neck, increasing the frictional force resisting slippage during neck flexion. The distal sleeve, connected by a loop, was collinear to the electrodes and adjacent to the proximal electrode, preventing

torque transmission to the electrodes and serving as redundant fixation. Intra-operative testing confirmed the nerve to be under the proximal electrodes. Additional strain relief loops were placed at an upper thoracic incision (T2-T4), at the pulse generator, and at any other incisions.

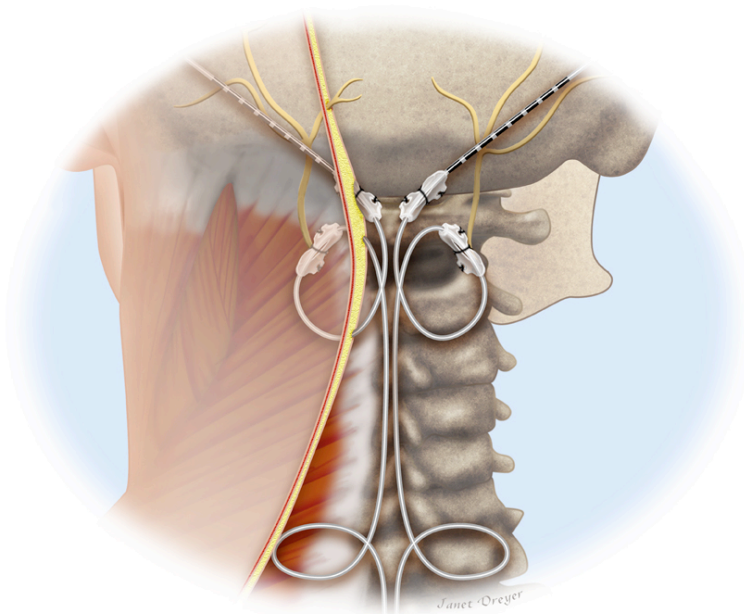
### Results

Of 138 subjects implanted with an externalized trial system, 132 received a permanent system, 125 completed 12-week follow-up, and 74 completed 2-year follow-up. Nine of 132 subjects (6.8%) implanted with a permanent system experienced lead migration requiring surgical revision or explant. Two-year aggregate safety data revealed non-target area sensory symptoms (18.0%), implant site pain (17.3%), and infection (15.1% requiring systemic antibiotics, 8.6% requiring explant) as the most-frequent device related adverse events.

### Conclusions

The incidence of lead migration two years post implant was substantially lower than other reported investigations. Recommended surgical practices to mitigate infection include:

1. Occipital area hair clipping with electric shaver 48 hrs preop and prophylactic IV antibiotic 30-45 minutes preop.
2. Hair washing the night before and morning of surgery with an antiseptic shampoo.
3. Postoperative antibiotics x14 days after permanent implant.
4. Antiseptic soap and bactroban TID x10-14 days with dressing change QD x3-5 days postop.
5. Non-braided suture removal 10-14 days postop, after antiseptic soap application.
6. If temporary lead is used for trial stimulation,  $\geq 3$  weeks should separate temporary lead removal and permanent lead implantation.



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