

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

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Background

- Occipital nerve stimulation (ONS) is an emergent treatment under investigation for a host of neuropathic pain and intractable headache disorders.
- Lead migration rates in previous investigations of ONS have ranged from 8% (1/13) to 53% (8/15).¹⁻⁶
- We report the procedural experience using the midline approach used in the PRISM study, a multi-center trial of occipital nerve stimulation (ONS) for drug-refractory migraine.

PRISM Trial Details

Results to be presented during General Session, Saturday, 05 Dec 2009, 3:20-3:40 PM

Migraine Subjects:

- Met the 2004 International Classification of Headache Disorders (ICHD-2) diagnostic criteria for migraine with aura, migraine without aura, and/or chronic migraine.
- Presented as drug-refractory (failed therapy with at least two acute and two preventive medications).
- Had ≥ 6 days per month of long-duration (≥ 4 hrs) migraine with moderate/severe pain (migraine day).

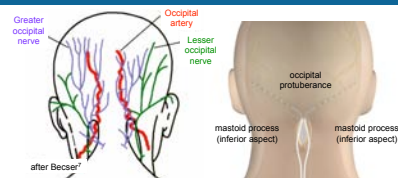
Study Design:

- Prospective, double-blind, randomized trial in 13 centers.
- During 12-week blinded period, subjects randomized 1:1 to receive bilateral active vs sham stimulation.
- Prior to permanent implant, all subjects received 5-10 days of percutaneous trial stimulation (with randomized settings) to evaluate predictive value on 12-week outcome.
- **Primary Endpoint:** Change from baseline in migraine days/month evaluated 12 weeks after implantation.
- After 12 weeks, sham subjects converted to active settings.

Implant and Fixation Procedure

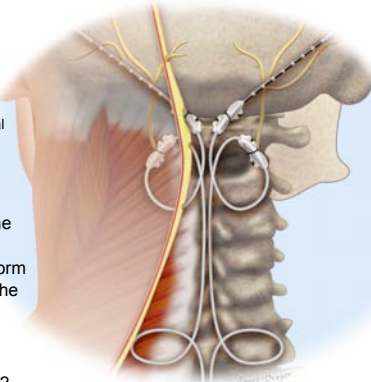
Landmark Visualization and Incision

- Vertical midline incision made extending ~4 cm caudal from a point 2 cm below the occipital protuberance.
- Bluntly dissect lateral pockets, exposing fascia for anchoring.
 - q Superficial incision avoids penetrating fascia covering trapezius muscle.
 - q Midline access avoids the occipital arteries and greater occipital nerves (5-28 mm lateral to midline⁷).



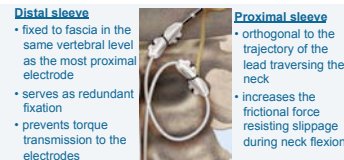
Lead Placement & Intra-operative Testing

- Insert curved Tuohy needle in subcutaneous fat plane at ~C1.
- Advance needle laterally until lead is 4-5 cm off midline.
 - q Tuohy needle can be curved with a French Bender to match the occipital curvature.
 - q Prevent engaging the dermis by facing needle bevel away from the dermal interface.
 - q Pinching superficial tissue away from the fascial layer helps guide needle within the subcutaneous fat.
 - q Avoid re-advancing needle to prevent edema and retain tissue integrity.
- Remove stylet and introduce lead, paying careful attention to the proximal lead tail to avoid contamination and risk of infection.
- Partially withdraw insertion needle exposing contacts, and perform intra-operative testing to confirm the occipital nerve lies under the proximal electrodes.



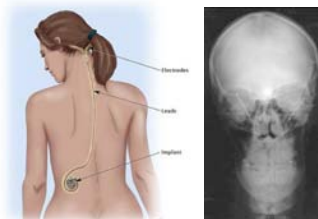
Lead Fixation Technique

- Secure each lead ipsilaterally to the lateral pocket fascia using 2 suture sleeves separated by a strain relief loop using migration-prevention geometry (see figure).
- Anchor each sleeve to the fascia with 3 sutures and intraluminal medical adhesive.
 - q Use non-absorbable braided sutures.
 - q 2 sutures to anchor the sleeve to the underlying fascia.
 - q 1 circumferential suture around the sleeve to anchor the sleeve to the lead.
 - q To minimize risk of slippage, inject medical adhesive in the sleeve lumen prior to cinching circumferential suture.

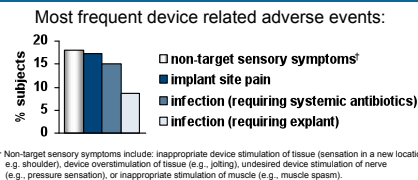


IPG Tunneling

- Additional strain relief loops placed at upper thoracic incision (T2-T4), at the implantable pulse generator (IPG), and at any other incisions.
- To prevent pain/discomfort at the area of the extension header, perform a small fasciotomy beneath the extension header, slip the header under the fascia, and close the fascia over the header.
- IPG placed in either infraclavicular, gluteal, or flank pocket depending on physician/patient preference.



2-Year Safety Data



Lead Migration

- Nine of 132 subjects (6.8%) implanted with a permanent system experienced lead migration requiring surgical revision or explant.
- The incidence of lead migration two years post implant was lower than other reported investigations in the literature.¹⁻⁶

Recommendations

Suggested Practices for Infection Mitigation

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

References

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