Peripheral Nerve Stimulation of the Occipital Nerves for the Management of Headache Pain and Disability Associated with Chronic Migraine: Technical Considerations from a Prospective, Multicenter, Double-blinded, Controlled Study

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Introduction
Chronic migraine is a common and disabling complication that affects approximately 2% of the population (Manack et al., 2011). Peripheral nerve stimulation (PNS) of the occipital nerves is emerging as a potentially promising therapy for intractable chronic migraine patients. Identification of the risks and an understanding of the implant procedure are crucial given the novelty of this therapy. Implant and revision information is from a prospective, multicenter, double-blinded, controlled study is presented.

Study Design
Figure 1. In this IRB-approved prospective, multicenter, double-blinded, controlled study, patients were treated with a neuromodulation system (St. Jude Medical Neuromodulation Division, Plano, TX). Patients who had a successful trial (defined as at least 50% reduction in pain or adequate paresthesia coverage in the painful area) were implanted with a percutaneous system. Patients were then randomized to an Active or Control group for 12 weeks. Patients continued in an open-label phase with 24, 48, and 52 week evaluations.

Additional Surgery Descriptions
Additional surgeries for peripheral (occipital) nerve stimulation systems are divided into several categories depending on the underlying problem and goals that the patient and physician are trying to achieve. A ‘revision’ procedure is a surgery that utilizes the existing implanted devices and moves them to a new location (i.e. moving PNS from one side of the body to another or moving a lead that has migrated). A ‘reimplant’ procedure is a surgery that involves implanting a new device(s) for the patient. A ‘replacement’ procedure is a surgery where the existing implanted devices are removed from the patient and new devices are implanted.

Implant Procedure
Figure 2. At the initial surgery, 150 patients (95.5%) were implanted with two leads, 7 patients (4.5%) were implanted with one lead. Three leads were used in 8 patients (5.3%). The leads were placed adjacent to the occipital nerves. The illustration shows two leads (96, 116 cm). At the initial surgery, 13 patients (8.7%) had one IPG implanted while 137 patients (91.3%) had two IPGs implanted with two leads and 5 patients (3.3%) were implanted with one lead. The figures illustrates a bilateral implant.

Replacements, Revisions and Explants
Revises, Replace or Explant Lead/Extension Only

Revision, Replace or Explant IPG Only

Adverse Events

Summary and Conclusions
4 total of 157 systems were implanted
Nine total systems were replaced, 4 were revised, and 29 were explanted
0 of the 157 PNSs, 15 were replaced and 1 was explanted
Lead revision or replacement occurred in 23 patients
Leads were explanted in 15 patients.
Patients underwent additional surgery to revise, explant, or replace device components in 96 cases
The results from the study provide preliminary information on implantation techniques and revision rates for PNS in the occipital nerves for the management of headache pain and disability associated with intractable chronic migraines.

References