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# POLICY STATEMENT

## Migraine Headache Surgery

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### Background

The ASPS is committed to patient safety, advancing the quality of care, innovative treatments, and practicing medicine based upon the best available scientific evidence. Due to the growing interest regarding the migraine headache surgery, the ASPS Health Policy's Patient Safety Subcommittee created a task force to examine the safety and efficacy of peripheral nerve/trigger site surgery for refractory chronic migraine headache (MH). The task force examined the available evidence on best practices for peripheral nerve/trigger site surgery for refractory chronic MH. This statement summarizes their findings and recommendations.

### Definitions

#### *Headache*

Headache is pain in any region of the head. Headaches may occur on one or both sides of the head, be isolated to a certain location, radiate across the head from one point, or have a viselike quality. A headache may appear as a sharp pain, a throbbing sensation or a dull ache. Headaches can develop gradually or suddenly, and may last from less than an hour to several days.

#### *Migraine*

A condition marked by recurring moderate to severe headache with throbbing pain that usually lasts from four hours to three days, typically begins on one side of the head but may spread to both sides, is often accompanied by nausea, vomiting, and sensitivity to light or sound, and is sometimes preceded by an aura and is often followed by fatigue.

#### *Peripheral nerve/trigger site surgery*

A minimally invasive peripheral nerve surgery applied to relieve pressure of a nerve.

## **INTRODUCTION**

Migraine headache (MH) is a debilitating disease that leads to significant functional limitations in affected patient. Based on the most recent prevalence data in the US, MH affects between 17% and 23% of the population. The annual cost for treatment of chronic MH is over \$10,000 per year, with an estimated annual cost to society of over \$13 billion. In addition, loss of productivity and lost time at work contributes to the societal burden of MH.

For a long time, analgesics comprised the mainstay of medical MH treatment. In the 1990's, the serotonin stimulating triptans were introduced and approved by the FDA as first-line MH treatment. Since then, many other abortive and preventive medications, injectables and medical devices have been used to treat MH with limited success. In up to one third of cases, traditional therapies fail to relieve symptoms, are contraindicated, or cause side effects that are not tolerated well by patients.

MH has classically been described as a neurovascular disorder originating in the central nervous system. However, more recently, strong data supports the addition of peripheral/extracranial sensory nerve compression or irritation within head and neck muscular, fascial, bony, and vascular sites as potential triggers for MH. When such a stimulus occurs in a genetically and structurally susceptible individual (e.g. one with a baseline central diminished threshold for cortical depolarization), these peripherally-generated/centrally-conducted stimuli are believed to activate MH pathology. Although peripheral nerve irritation can present spontaneously, this mechanism can also evolve from post-traumatic, post-operative, or a chronic occipital/trigeminal neuralgia source. Any of these inciting conditions can directly or indirectly traumatize peripheral nerves/surrounding tissue in the head and neck and establish an effective MH trigger site.

Numerous anatomic studies have confirmed predictable patterns of nerve entrapment in surrounding tissues. Potential peripheral trigger sites include the frontal (supratrochlear and supraorbital nerves), temporal (zygomaticotemporal and auriculotemporal nerves), occipital (greater, lesser, and third occipital nerves), nasal regions (branches of the sphenopalatine ganglion), and nummular headaches.

In addition to anatomic studies, basic scientific research has proven the existence of extracranial pathology in migraineurs undergoing surgery. Electron microscopy and proteomics of nerves

removed during migraine surgery show axonal abnormality and deregulation of the myelination process in patients with MH versus control. In addition, the calvarial periosteum of migraine surgery patients demonstrates increased expression of pro-inflammatory markers and decreased expression of anti-inflammatory markers. Both animal and human studies have shown that sensory and pain fibers cross the calvarial bones through cranial sutures and connect intracranial and extracranial axons. This suggests communication between peripheral and central structures. Vessel involvement has also been studied and, while vascular triggers exist, it has been shown that occipital artery vasculitis is not contributory to the pathogenesis of headaches in patients undergoing migraine surgery.

In 2000, Guyuron et. al. first reported his experience with amelioration of MH symptoms in patients who underwent browlift surgery, with excision of the corrugator muscle. He postulated that muscle resection effectively decompressed the supraorbital and supratrochlear nerves and was analogous to carpal tunnel release on median nerve compression.

Several years later (2010), the Food and Drug Administration (FDA) approved BOTOX (onabotulinumtoxin A) for prophylaxis of chronic MH, defined as equal to or greater than 15 days per month with headaches lasting equal to or greater than 4 hours a day. Several randomized, placebo controlled trials have since then shown efficacy of botulinum toxin in the treatment of MH. The efficacy of targeted botulinum toxin injections in MH treatment further supports Guyuron's original theory of peripheral nerve compression. Building on his work, a significant body of evidence has been published demonstrating a correlation between targeted weakening of muscles with botulinum toxin and nerve decompression with a demonstrated decrease in MH frequency, duration and pain in select patients. Janis et al. showed an average improvement of 73% (in MHI) with a targeted approach to Botox injection of peripheral nerve trigger sites with an average follow up of 615 days. Based on these studies, chemodenervation can be utilized mostly as a diagnostic tool or alternatively as a treatment option for those patients who have trigger sites that are primarily muscular in origin and either do not want, or are not candidates for, surgery. Although treatment of chronic MH with botulinum toxin is effective, its efficacy is temporary and repeated treatments can contribute to increased cost of care over the long term. If Botox is to be used as a treatment, an anatomically-based, targeted approach is recommended with an interval of 85 days between injections.

Subsequent studies have refined and expanded our understanding of the role of peripheral nerve compression as it contributes to headaches. Additional triggers have been identified and their means of detection have improved with selected use of physical exam, doppler, imaging, Botox, and nerve blocks. Consequently, surgical techniques have evolved to address all peripheral triggers. Above all, an accurate history, anatomical knowledge, and skilled localization/identification of the offending trigger(s) is essential to surgical treatment success.

Numerous national and international groups have demonstrated that peripheral trigger site surgery in the head and neck is associated with a low complication rate and is a predictably efficacious treatment for properly selected migraineurs. Some clinical guidelines continue to identify any migraine surgery as “experimental” despite the strong scientific foundation that supports the mechanism, efficacy, and safety of this treatment.

## **RESULTS**

The general theory behind successful surgical management of MH is that mechanical irritation of peripheral nerves by vessels, muscle, fascia bone and/or contact points between structures inside the nose contribute to the pathogenesis of MH pain in select patients. Resection of muscle/fascia/bone, ablation of vessels, detachment or transection of peripheral nerves, and elimination of the rhinogenic contact points reduce the centrally transmitted stimuli and thus reduce the likelihood for MH pain to occur.

The field of surgical treatment of MH began with an anecdotal report of a serendipitous incidental post-operative finding (45). Nearly 20 years following that initial published report, there exists an extensive body of peer-reviewed studies evaluating the efficacy and safety of surgical treatment of MH.

### *Clinical Outcomes*

Guyuron et. al.’s initial report of surgical MH treatment demonstrated improvement of MH in 31 out of 39 endoscopic browlift patients with corrugator muscle resection. This initial study prompted Guyuron et al. to design a prospective cohort study that demonstrated treatment success in 21 of 22 patients who underwent corrugator and zygomaticotemporal nerve resection, with 11 patients having complete elimination of headaches. Success was defined as a greater than 50% reduction in symptoms, with a mean follow-up of nearly a year. Reproducibility of the technique

was demonstrated by Dirnberger et. al. who showed elimination or significant improvement in MH in 41 of 60 patients who had decompression of the frontal trigger site with a mean follow-up of 13 months.

In 2005, Guyuron et al. described the comprehensive treatment of MH. In this study, 82 out of 89 (92%) patients noticed at least a 50% improvement in frequency, intensity or duration of MHs postoperatively ( $p < 0.0001$ ). 31 (35%) had complete elimination of symptoms and 51 (57%) were improved. In comparison, none of the 19 patients in the control group reported elimination of symptoms, and only three controls noted  $>50\%$  improvement of symptoms ( $p < 0.0001$ ) (63).

A retrospective cohort study by Poggi et. al. showed possibility of complete relief of MH, reduction of MH symptoms, and elimination of need for MH medication with surgical deactivation of trigger sites identified by preoperative botulinum toxin injection.

A study of great importance is the prospective, randomized, placebo controlled trial by Guyuron et, al that demonstrated success of surgical techniques in the treatment of MH. The group reported on 125 patients using a 4:1 allocation for the surgical treatment and control arms. Of note, this type of IRB-approved study is very restricted in surgery and therefore rarely performed in surgical research. An allocation of 4:1 was chosen as this was considered the most ethical distribution of true versus sham surgical patients. Specific trigger points/surgical techniques were determined by preoperative response to botulinum toxin injection. This study demonstrated that 41 of 49 (84%) patients who underwent nerve decompression experienced significant improvement or complete elimination of their MH, versus 15 of 26 (58%) patients in the placebo surgery control group. The difference between experimental and control groups was statistically significant ( $p < 0.05$ ). More importantly, 28 of 49 (57%) patients who underwent peripheral trigger deactivation reported complete elimination of MH compared to only 1 out of 26 (4%) in the sham surgery/placebo group(66). A 5-year follow-up of these patients and found that 61 of the 69 patients available for follow up had experienced substantial improvement to complete elimination of their symptoms, which overcomes the placebo effect that may have been seen in some patients in the original study.

The largest clinical trial was reported by Guyuron and his research team. Successful treatment, defined as a greater than 50% improvement in frontal MH specific scores with greater than 1 year follow up, was achieved in 86% of the 270 studied patients. MH days per month were decreased

in 84% of patients. Complete elimination of frontal MH symptoms was achieved in 57% of patients.

A recent study by Gfrerer et al. focused on functional outcome/ disability in migraine surgery patients. It shows that migraine surgery candidates are severely disabled by their disease, but pain intensity/ disability from MH is improved by 112% (on average) postoperatively.

A 2014 systematic review by Janis et al analyzed the clinical outcome of 17 published clinical trial and summarized the current evidence. Successful migraine surgery outcomes were reported between 68 and 95%.

Janis et al. demonstrated that peripheral nerve decompression surgery was more effective than long term Botox administration in patients with chronic MH, with more patients experiencing either elimination of symptoms or >90% improvement in the surgical arm of the study vs. >50% improvement in the Botox arm with follow-up in both arms > 1 year.

Further, a recent meta-analysis on efficacy of interventional therapies for the treatment of chronic headaches by Ducic et al. noted that pooled surgical success rates were approximately 85%. Success for alternative interventional treatment methods was much lower, at 68% for neuromodulation and 55% for radiofrequency ablation.

### *Surgical Techniques*

With regard to refinement of the most efficacious surgical techniques, a 2011 study of 169 patients by Larson et. al. found that surgery was most successful when all four trigger sites were addressed. Janis confirmed these findings in a report where 19 of 24 patients who underwent peripheral nerve surgery directed to trigger sites relieved by botulinum toxin in the face, head, and neck achieved significant improvement (97% improvement in MHI in those who responded to surgery) to complete elimination of symptoms.

Enhancement of technique has occurred related to trigger site-specific anomalies. The frontal trigger site is the most commonly reported. Chepla et. al. demonstrated that muscle resection with supraorbital foraminotomy was superior to muscle resection alone, with a significant reduction in Migraine Headache Index (frequency in days/month x intensity on a scale of 1-10 x duration as a fraction of 24 hours). The addition of the foraminotomy or decompression of the orbital rim

consistently for both the supraorbital and supratrochlear nerves was further developed by Hagan et. al. showing improved outcomes. This surgical refinement was based on anatomic studies and was supported by traditional peripheral nerve literature that advocates complete decompression of all fixed anatomic points of compression involved along the course of an affected nerve. Further, multiple authors have documented improvement in frontal MH symptoms with open/transpalpebral or endoscopic approaches to treatment of the corrugator complex and supraorbital rim with minimal to no complications. The use of validated tools such as the Migraine Disability Assessment Score (MIDAS) as a patient reported outcome measure has become commonplace. Similar developments in technique have been described for the temporal nerves.

A small subset of migraine surgery patients who fail primary occipital nerve decompression Subsequent GON resection (neurectomy) has been shown to improve symptoms in 70% of these patients. Treatment failures in these patients appear likely due to nerve injury from prolonged compression or direct destruction of involved nerves by previous trauma or craniotomy, minimizing the role of decompression. Similarly, post-traumatic or post-operative direct damage to occipital or frontal nerves that have caused true neuromas, generally necessitate neurectomy. In these scenarios requiring nerve excision, additional procedures such as implantation of the nerve into muscle (neurotization), or nerve end reconstruction are performed to minimize potential symptomatic neuroma formation. Nerve transection has also been described for smaller sensory nerves. For the auriculotemporal and zygomaticotemporal nerves, as well as third occipital nerve, neurectomy instead of decompression is often anatomically more suitable. Thus, depending on the specific clinical scenario, anatomical location, and type of nerve injury, surgical intervention can include nerve decompression, transection, reconstruction, and any combination of the above, even in the same patient on the same operative date.

The techniques reported above are efficacious and reasonable surgical interventions on a very challenging subgroup of MH patients – particularly when previous medical or interventional treatments have failed.

## **DISCUSSION/CONCLUSIONS**

Based on a comprehensive literature search and review of a large body of peer-reviewed scientific evidence, peripheral nerve/trigger site surgery for refractory chronic MH is safe and effective in

the treatment of patients with a suspected peripherally-generated/centrally-conducted MH etiology.

There is substantial, extensively replicated, clinical data that demonstrates a significant reduction in MH symptoms and frequency (even complete elimination of headache pain) following trigger site surgery.

Compelling evidence for the extracranial origin of MH in select migraineurs continues to be elucidated in the clinical and basic scientific literature.

Critics of peripheral nerve trigger surgery for the treatment of MH utilize the position that the body of peer-reviewed studies demonstrating efficacy owe their success to the placebo effect. However, the long-term effects of surgical intervention for MH cannot be reasonably attributed to placebo. After all, it was the patient who first observed and reported improvements in their MH after cosmetic surgery and the neither the surgeon nor the patient could have anticipated this outcome. Further, the first previously mentioned retrospective study by Guyruon et al. surveyed patients without disclosing the study intentions, simply asking if patients had MH prior to and after forehead surgery. Nonetheless, results showed a decrease in MH in patients undergoing corrugator resection. An 88% response lasting 5 years cannot be the result of a placebo effect. When comparing the results of the first quarter of the postoperative period to the subsequent quarters in Guyruon's above mentioned comprehensive study, there was a steady and statistically significant improvement in the results, which is contrary to what one would expect from a placebo effect, where the initial higher success rate would decline over time. Multiple studies and reviews have shown the long-term efficacy of MH surgical intervention.

It is the position of the American Society of Plastic Surgeons that peripheral nerve trigger surgery for treatment of refractory chronic migraine headache in properly selected patients is not an experimental treatment and is considered a standard, accepted treatment given nearly 20 years of peer-reviewed published evidence in high impact factor journals. Targeted surgical deactivation should be integrated into the stratified care model for the treatment of chronic migraine patients and represent a covered service by all insurance carriers.

Now is the time for all involved specialties to come together for the benefit of the patient, and to embrace surgical treatment of MH in properly selected patients.



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