Five-Year Outcome of Surgical Treatment of Migraine Headaches

Bahman Guyuron, M.D.
Jennifer S. Kriegler, M.D.
Janine Davis, R.N.
Saeid B. Amini, Ph.D., M.B.A., J.D.

Cleveland, Ohio

Background: This study was designed to assess the long-term efficacy of surgical deactivation of migraine headache trigger sites.
Methods: One hundred twenty-five volunteers were randomly assigned to the treatment ($n = 100$) or control group ($n = 25$) after examination by the team neurologist to ensure a diagnosis of migraine headache. Patients were asked to complete the Medical Outcomes Study 36-Item Short Form Health Survey, Migraine-Specific Quality of Life, and Migraine Disability Assessment questionnaires before treatment and at 12- and 60-month postoperative follow-up. The treatment group received botulinum toxin to confirm the trigger sites; controls received saline injections. Treated patients underwent surgical deactivation of trigger site(s). Results were analyzed at 1 year (previously published) and 5 years postoperatively (the subject of this report).
Results: Eighty-nine of 100 patients in the treatment group underwent surgery, and 79 were followed for 5 years. Ten patients underwent deactivation of additional (different) trigger sites during the follow-up period and were not included in the data analysis. The final outcome with or without inclusion of these 10 patients was not statistically different. Sixty-one (88 percent) of 69 patients have experienced a positive response to the surgery after 5 years. Twenty (29 percent) reported complete elimination of migraine headache, 41 (59 percent) noticed a significant decrease, and eight (12 percent) experienced no significant change. When compared with the baseline values, all measured variables at 60 months improved significantly ($p < 0.0001$).
Conclusion: Based on the 5-year follow-up data, there is strong evidence that surgical manipulation of one or more migraine trigger sites can successfully eliminate or reduce the frequency, duration, and intensity of migraine headache in a lasting manner. (*Plast. Reconstr. Surg.* 127: 603, 2011.)

More than 30,000,000 Americans (18 percent of females and 6 percent of males) suffer from migraine headaches that often interfere with their job performance and interpersonal relationships.[1–4] It is estimated that about one in every four households has someone who suffers from this condition.[1] The prevalence and disabling nature of migraine headache make it a topic of interest to many, yet the condition remains largely underdiagnosed and undertreated.[1]

From the Department of Plastic Surgery, Case Western Reserve University, and the Center for Headache and Pain, Cleveland Clinic.
Received for publication May 7, 2010; accepted August 11, 2010.
Presented at the American Society of Plastic Surgeons/Plastic Surgery Educational Foundation Annual Meeting, in Seattle, Washington, October 24, 2009.

DOI: 10.1097/PRS.0b013e3181fed456

Furthermore, approximately one-third of migraine sufferers are not helped by standard therapies.[5] The preventive and abortive pharmaceutical agents have associated adverse effects and are often very costly. Migraine headaches present an enormous economic burden to the individual sufferer and society in general due to missed work (a collective 112 million workdays per year) and loss of productivity totaling $14 billion annually in the United States.[6] The total annual costs associated with migraine headache and its treatment total $13 billion to $17 billion annually, with the cost of medications for migraine headache alone accounting for $1.5 billion.[7,8]

The senior author (B.G.) has developed surgical techniques to deactivate migraine headache

Disclosure: *The authors have no financial interest to declare in relation to the content of this artcle.*

trigger sites. The research team has been investigating its efficacy over the last 10 years.[9–12] Our retrospective,[9] pilot prospective,[10] and anatomical studies[13–16] have all provided a foundation for this more comprehensive investigation to assess the effectiveness of this technique over a 5-year follow-up period. Our in-depth, previously published study of the surgical treatment of the four most common migraine trigger sites[11] reported the outcome of the treatment at 1-year follow-up and compared the treatment group with controls who did not undergo surgery. The efficacy of this treatment was further documented with our single trigger site study, which incorporated a sham surgery control group.[12] Other research groups have also demonstrated positive results with the surgical treatment of migraine headache.[17–19] The purpose of this prospective study was to investigate the 5-year outcome in patients who underwent surgical treatment of migraine headache in one to four common trigger sites.

PATIENTS AND METHODS

Patient Selection

Institutional review board approval was obtained from two separate institutions. The recruited volunteers were examined by the neurologist (J.S.K.) of the research team to ensure the diagnosis of migraine headache in accordance with the guidelines established by the International Headache Society. A total of 125 volunteers met the initial criteria. Patients underwent detailed evaluation to identify their trigger sites. They were asked about the most common focal site of onset of their migraine headache (migraine trigger sites). These trigger sites were palpated to detect any tenderness. For the nasal trigger site, examination of the internal nose was undertaken to observe the septum and the inferior turbinates; if applicable, the presence of enlarged turbinates and the type of septal deviation were documented. The observed intranasal pathology was confirmed with a computed tomography scan. Of the 125 patients diagnosed with migraine headache, 100 were randomly assigned to the treatment group and 25 served as controls. This control group sample size was selected by the biostatistician based on the results of the previous studies. Patients in the treatment group received injection of botulinum toxin A (Botox; Allergan, Irvine, Calif.) into three of the four trigger sites (frontal, temporal, and occipital) in a logical, stepwise manner; the most prominent site was injected first to provide confirmation. A total of up to four trigger points were identified in a variety of combinations for each patient, based on the constellation of symptoms, physical examination, and patient response to botulinum toxin A. Initially, the 25 control patients were injected with 0.5 ml of saline. After 1 year, the control group had the option to undergo surgical treatment. Of the 19 control group patients who completed the 1-year follow-up, 17 underwent identification and deactivation of their trigger sites.

All patients enrolled in the study were asked to complete the Medical Outcomes Study 36-Item Short Form Health Survey, Migraine-Specific Quality of Life, and Migraine Disability Assessment questionnaires before treatment and at the postoperative follow-up visits at 1 and 5 years. In addition, all patients continued to maintain a diary documenting the frequency (migraines per month), intensity (rated on a visual analogue scale from 0 to 10, with 10 being the most severe), and duration (in days) of any migraine headache experienced, associated symptoms, and possible triggers for 5 years. The recorded information for each visit also included calculation of a migraine index using the following formula: ($intensity \times frequency \times duration$).

Surgical Procedures

Based on the identified trigger sites, surgery included any one of the following as a single procedure or in combination (in the same setting): removal of the glabellar muscle group, including the corrugator supercilii, depressor supercilii, and the lateral portion of the procerus muscles to decompress the supraorbital and supratrochlear nerves for the frontal trigger site (trigger site I); avulsion of a small portion of the zygomaticotemporal branch of the trigeminal nerve for the temporal trigger site (trigger site II); septoplasty and turbinectomy for the intranasal trigger site (trigger site III); and removal of a small segment of the semispinalis capitis muscle and shielding of the nerve with a subcutaneous flap to fully decompress the greater occipital nerve for the occipital trigger site (trigger site IV). For a detailed description of these procedures, refer to our previously published reports.[10–12,20,21]

Data Analysis

Statistix Version 8 (Analytical Software, Inc., Tallahassee, Fla.), and StatView Version 5 (SAS Institute, Inc., Cary, N.C.) were used for statistical analysis of the data. Descriptive statistics were computed for all variables. A migraine headache index was calculated by multiplying together the fre-

quency, intensity, and duration of migraine headache, and this was compared with the baseline migraine headache index. Two-tailed paired *t* tests were used to compare the mean frequency, intensity, and duration of migraine headaches and the migraine headache index measured before surgery (baseline) and at the last visit (60 months postoperatively). Repeated-measures analysis of variance was used to compare the mean frequency, intensity, and duration of migraines over time (0, 3, 6, 9, 12, 15, 18, 21, 24, 36, 48, and 60 months). If necessary, adjustments for multiple comparisons were made through Bonferroni correction. Chi-square analyses were performed to test for a relationship between categorical variables such as surgical sites and patients' improvement status. A p value less than 0.05 was considered significant. Reduction of at least 50 percent in migraine headache frequency, intensity, and/or duration compared with baseline values was used to define significant improvement.

RESULTS

Study Population

Of the original 100 patients randomized to the treatment group, 91 had successful detection and confirmation of the trigger sites and underwent surgery, 89 were followed for 1 year,[11] and 79 completed follow-up requirements for the entire 5-year period. There were 73 women and six men in the study. Their mean age was 43.6 years (range, 21 to 63 years). Fifty-nine patients experienced migraine headache without aura, 14 experienced migraine headache with aura, and six experienced migraine headache with and without aura. Of these 79 patients, 10 who underwent deactivation of additional (different) trigger sites during the 5-year follow-up period to provide them additional relief were not included in the final analysis to avoid extra confounding factors affecting the results. All 10 of these patients had already observed significant improvement (at least 50 percent reduction) before the second procedure. Of the remaining 69 patients, six had surgery on one trigger site, 15 underwent surgery on two trigger sites, 30 were subject of surgery on three trigger sites, and 18 underwent surgery on all four trigger sites (Table 1).

Table 1. Summary of Surgical Procedures Offered to Patients ($n = 69$)

No. of Surgery Sites		No. of Patients	
1	6 (8.7%)	Trigger site I	2
		Trigger site II	1
		Trigger site III	3
2	15 (21.7%)	Trigger sites I, II	9
		Trigger sites I, III	4
		Trigger sites I, IV	1
		Trigger sites III, IV	1
3	30 (43.5%)	Trigger sites I, II, III	25
		Trigger sites I, II, IV	5
4	18 (26.1%)		

Trigger site I, frontal area; trigger site II, temporal area; trigger site III, intranasal area; trigger site IV, occipital area.

Outcome at 5 Years Compared with Baseline

The mean change from baseline in the frequency, intensity, and duration of migraine headache, as well as the average migraine headache index, at the 5-year follow-up is listed in Table 2. When compared with the baseline values, all measured variables improved significantly at 12 months, and this improvement was maintained at 60 months ($p < 0.0001$). The mean migraine frequency was 10.9 ± 7.46 at baseline compared with 4.0 ± 5.34 at 60 months ($p < 0.0001$). The mean migraine intensity was 8.5 ± 1.23 at baseline compared with 4.5 ± 3.18 at 60 months ($p < 0.0001$). The mean migraine duration was 1.4 ± 1.40 days at baseline compared with 0.31 ± 0.87 days at 60 months ($p < 0.0001$). Finally, the mean migraine headache index was 90.3 ± 80.10 at baseline compared with 11.4 ± 29.92 at 60 months ($p < 0.0001$).

Overall Surgical Outcome

Based on the criteria of at least 50 percent reduction in baseline migraine frequency, intensity, or duration, 61 of the 69 patients (88 percent) in the treatment group had benefited from surgery and have maintained an overall improvement. Twenty (29 percent) reported elimination of migraines, and 41 (59 percent) experienced a significant decrease. When we include the 10 patients who had undergone surgery in additional trigger sites during the follow-up period, 71 of 79 (90 percent) maintained the initial positive response to the surgery, with 22 (28 percent) experiencing elimination of migraines and 49 (62 percent) experiencing a significant decrease. There was no statistically significant difference in the final outcome with or without the inclusion of these 10 patients.

Analysis by Trigger Site

Considering specific trigger sites, 64 of 69 patients (93 percent) had a frontal migraine headache trigger site, 57 of 69 (83 percent) had a temporal migraine headache trigger site, 52 of

Table 2. Baseline, 1-Year Follow-Up, 5-Year Follow-Up, and Mean Change from Baseline at 5 Years

Variable	Baseline	1 Year	5 Years	Mean Change (Baseline to 5 Years)	*p**
Frequency, MH/month	10.9 ± 7.46	4.0 ± 6.39	4.0 ± 5.34	6.9 ± 7.57	<0.0001
Intensity (analog scale 0–10)	8.5 ± 1.23	4.0 ± 3.27	4.5 ± 3.18	4.0 ± 3.18	<0.0001
Duration (days)	1.4 ± 1.40	0.42 ± 0.76	0.31 ± 0.87	1.04 ± 1.21	<0.0001
MH index (*frequency* × *intensity* × *duration*)	90.3 ± 80.10	10.5 ± 16.66	11.4 ± 29.92	78.9 ± 76.42	<0.0001
MIDAS	3.6 ± 0.72	1.8 ± 1.37	1.7 ± 1.55	1.9 ± 1.56	<0.0001
MSQEM (Mental Migraine Score)	47.0 ± 24.72	83.3 ± 23.61	82.0 ± 26.39	34.9 ± 29.52	<0.0001
MSQPRE	65.7 ± 20.06	88.1 ± 15.98	86.4 ± 20.13	20.7 ± 21.53	<0.0001
MSQRES	45.1 ± 18.21	79.6 ± 21.81	78.7 ± 22.03	33.5 ± 25.37	<0.0001
SFMEN	43.2 ± 11.09	47.8 ± 9.00	48.4 ± 10.56	5.2 ± 5.34	<0.0001
SFPH	43.7 ± 9.66	51.1 ± 9.15	47.7 ± 9.87	4.0 ± 5.34	<0.0001

MH, migraine headache; MIDAS, Migraine Disability Assessment; MSQEM, Migraine-Specific Questionnaire; MSQPRE, Migraine-Specific Questionnaire, Preventive; MSQRES, Migraine-Specific Questionnaire, Restrictive; SFMEN, Medical Outcomes Study 36-Item Short Form Health Survey, Mental; SFPH, Medical Outcomes Study 36-Item Short Form Health Survey, Physical.
All values are mean ± SD.
*The *p* values were obtained from paired *t* test and confirmed by Wilcoxon signed rank test.

69 (75 percent) had an intranasal migraine headache trigger site, and 25 of 69 (36 percent) had an occipital migraine headache trigger site either in isolation or in conjunction with other trigger sites.

Adverse Events

The surgical complications and their frequency are listed in Table 3. At 5 years, no patients had persistent intense itching or uneven brow movement. Twenty patients reported very occasional itching. Hair thinning at the site of the endoscopic incision was observed in three patients. Two patients reported hypersensitivity, two patients experienced hyposensitivity along the course of the supraorbital or supratrochlear nerves, and two patients reported numbness in the same areas at the 5-year follow-up. Three patients reported some mild occipital stiffness or weakness. One patient had injury to the temporal branch of the facial nerve which recovered completely.

DISCUSSION

This study was designed to assess the long-term success of surgical deactivation of migraine headache trigger points. The 5-year follow-up data reported here provide strong evidence that surgical deactivation of one or more trigger sites can successfully eliminate or reduce the frequency, duration, and intensity of migraine headache, and the results are enduring. Compared with baseline values, 61 of 69 patients (88 percent) have demonstrated significant improvements on all variables that have been sustained at the minimum of 60 months.

Table 3. Surgical Complications

Nature of Adverse Event	*n*	Percent (% per Trigger Site)	Related Trigger Site
Temporal nerve injury	1	1.7	Temporal
Occasional neck stiffness	1	4	Occipital
Occasional neck weakness	2	8	Occipital
Skin numbness	2	3	Frontal
Hypersensitivity	2	3	Frontal
Hyposensitivity	2	3	Frontal

There is a high placebo response rate in migraineurs.[22] Placebo responsiveness, however, is short-lived, and an 88 percent placebo effect lasting 5 years has never been documented. This article, coupled with our previous studies that have demonstrated between 83 and 92 percent positive outcomes, reduces the potential for the placebo effect playing a significant role in the outcome.

We have discussed the rationale for elimination or improvement of migraine headache following surgical treatment in our previous publications.[9–12,20,21] Although the initial discovery of an improvement in migraine headache was merely serendipitous, our research team has made a concerted effort to find anatomical reasons for this improvement. We have designed surgical techniques and investigated why surgery may play a role in the amelioration of this disabling condition.[13–16] There are still many unanswered questions, and our team continues its efforts to find more logical pathophysiological reasons for the surgical success that our patients have been enjoying.

Although the percentage of patients who observed complete elimination of migraine headache is not substantial in this study, our analysis of more recent results yields insight regarding improved surgical response, including

elimination of migraine headache. The incidence of a positive response (at least 50 percent reduction) is currently over 90 percent, with over 70 percent showing complete elimination. We attribute this improvement in the outcomes to a series of factors. The most significant is the consequence of more accurate identification of migraine trigger sites. It was the failure to detect and deactivate the primary trigger sites that reduced the overall success rate. Better detection and deactivation of specific trigger sites has dramatically increased the success rate over the last 5 years. In addition, with experience more complete elimination of the triggering element has been possible. Specifically, the corrugator muscle group is being removed more thoroughly, and the nasal contact points and concomitant intranasal pathology, such as concha bullosa, are dealt with more aggressively. At the occipital trigger site, the crossover or entanglement between the occipital artery and the greater occipital nerves is eliminated by better exposure and removal of the occipital artery, if necessary. Furthermore, more attention is devoted by our team to identify patients with rebound headaches and narcotic dependency because, regardless of how successful the surgery may seem, the patients may still experience rebound headaches or could complain of pain due to addiction to opiates. Success of surgery is measured by its efficacy and taking into consideration the associated risks. Every adverse effect has been carefully documented throughout the study period. The recorded complications are listed in Table 3.

Beyond the four trigger sites discussed here, there are less common migraine headache entities involving the auriculotemporal branch of the trigeminal and lesser occipital nerves. The auriculotemporal trigger site is managed by removing the temporal artery[23] as advocated by Sultaneh,[24] and the lesser occipital site is dealt with by neurectomy and burying the tied end of the nerve in the muscle and injection of triamcinolone to reduce the potential for neuroma formation.

The results of this 5-year analysis were not compared with the control group who were only followed for 1 year. Based on the design of the initial study, most patients in the control group underwent surgical treatment at 1 year.

CONCLUSION

This study not only confirms our findings from previous studies that the surgical treatment of migraine headaches in properly selected patients is likely to succeed but it also provides evidence that the obtained results are enduring.

Bahman Guyuron, M.D.
29017 Cedar Road
Cleveland (Lyndhurst), Ohio 44124
bguyuron@aol.com

REFERENCES

1. SynerMed Communications. 21st century prevention and management of migraine headaches. *Clin Courier* 2001;19: 1–15.
2. Lipton RB, Bigal ME, Diamond M, Freitag F, Reed ML, Steward WF. Migraine prevalence, disease burden, and the need for preventive therapy. *Neurology* 2007;68:343–349.
3. Lipton RB, Stewart WF, Diamond S, et al. Prevalence and burden of migraine in the United States: Data from the American Migraine Study II. *Headache* 2001;41:646–657.
4. Stewart WF, Shechter A, Rasmussen BK. Migraine prevalence: A review of population-based studies. *Neurology* 1994; 44(6 Suppl. 4):S17–S23.
5. Dodick DW. Triptan nonresponder studies: Implications for clinical practice. *Headache* 2005;45:156–162.
6. Hu XH, Markson LE, Lipton RB, et al. Burden of migraine in the United States: Disability and economic costs. *Arch Intern Med.* 1999;159:813–818.
7. Goldberg LD. The cost of migraine and its treatment. *Am J Manag Care* 2005;11(Suppl 2.):S62–S67.
8. 2002 Pharmacy Benchmarks. *Trends in Pharmacy Benefit Management for Commercial Plans.* Sacramento, Calif.: Pharmacy Care Network; 2002.
9. Guyuron B, Varghai A, Michelow BJ, et al. Corrugator supercilii muscle resection and migraine headaches. *Plast Reconstr Surg.* 2000;106:429–434.
10. Guyuron B, Tucker T, Davis J. Surgical treatment of migraine headaches. *Plast Reconstr Surg.* 2003;112(Suppl.):164S–170S.
11. Guyuron B, Kriegler JS, Davis J. Comprehensive surgical treatment of migraine headaches. *Plast Reconstr Surg.* 2005; 115:1–9.
12. Guyuron B, Reed D, Kriegler JS, Davis J, Pashmini N, Amini S. A placebo controlled surgical trial for the treatment of migraine headaches. *Plast Reconstr Surg.* 2009;124:461–468.
13. Totonchi A, Pashmini N, Guyuron B. The zygomaticotemporal branch of the trigeminal nerve: An anatomical study. *Plast Reconstr Surg.* 2005;115:273–277.
14. Mosser SW, Guyuron B, Janis JE. The anatomy of the greater occipital nerve: Implications for the etiology of migraine headaches. *Plast Reconstr Surg.* 2004;113:693–697.
15. Dash K, Janis J, Guyuron B. The lesser and third occipital nerves and migraine headaches. *Plast Reconstr Surg.* 2005; 115:1752–1758.
16. Janis JE, Ghavami A, Lemmon JA, Leedy JE, Guyuron B. Anatomy of the corrugator supercilii muscle: Part I. Corrugator topography. *Plast Reconstr Surg.* 2007;120:1647–1653.
17. Dirnberger F, Becker K. Surgical treatment of migraine headaches by corrugator muscle resection. *Plast Reconstr Surg.* 2004;114:652–657.
18. Poggi JT, Grizzell BE, Helmer SD. Confirmation of surgical decompression to relieve migraine headaches. *Plast Reconstr Surg.* 2008;122:115–122.
19. Behin F, Behin B, Behin D, Baredes S. Surgical management of contact point headaches. *Headache* 2005;45:204–210.

20. Guyuron B, Becker DB. Surgical management of migraine headaches. In: Guyuron B, Eriksson E, Persing JA, et al., eds. *Plastic Surgery: Indications and Practice*. New York: Elsevier; 2009.
21. Guyuron B, DiNardo LA. Forehead/brow/soft tissue surgery for migraines. In: Evans G, Persing L, eds. *Soft-Tissue Surgery of the Craniofacial Region*. New York: Informa Healthcare USA; 2007:93–112.
22. Diener HC, Schorn CF, Binge IU, Dodick DW. The importance of placebo in headache research. *Cephalagia* 2008;28:1003–1011.
23. Janis JE, Hatef DA, Ducic I, et al. Anatomy of the auriculotemporal nerve: Variations in its relationship to the superficial temporal artery and implications for the treatment of migraine headaches. *Plast Reconstr Surg*. 2010;125:1422–1428.
24. Sultaneh A. Migraine: New surgical treatment. Paper presented at: Congress of Neurological Surgeons; September 29 to October 4, 2001; San Diego, Calif.

American Society of Plastic Surgeons Mission Statement

The mission of the American Society of Plastic Surgeons® is to support its members in their efforts to provide the highest quality patient care and maintain professional and ethical standards through education, research, and advocacy of socioeconomic and other professional activities.