

A Placebo-Controlled Surgical Trial of the Treatment of Migraine Headaches

Jeffrey E. Janis, M.D.

Dallas, Texas

This article, simply put, represents the definitive proof that surgical decompression of peripheral trigger points in the treatment of migraine headaches is a valid concept. It has come a long way since the original two patients who Dr. Guyuron saw in his office after cosmetic endoscopic brow lifts 9 years ago touted their improvement in their migraine headache symptoms—an unexpected and even surprising “side effect” from surgery. Those two patients led Dr. Guyuron and his colleagues to review their historical experience with cosmetic corrugator resection to see whether this had been the case all along and had just gone unnoticed. When they published their first report on the subject in 2000 using a retrospective questionnaire to show that nearly 80 percent of patients had improvement in their migraine symptoms as compared with their baseline preoperative status,¹ who would have thought that the pathway would eventually lead to a prospective study involving sham surgery with a 1-year follow-up that demonstrates without doubt that surgery is a legitimate form of treatment for migraineurs?

The robust study design requires special commendation. A sham surgery study design hopes to overcome the placebo effect seen in the literature dealing mostly with pharmacotherapy.² As one might expect, sham surgery in human beings is not an easy study design for which to gain institutional review board approval at any institution, let alone voluntary participation by patients. That is obviously why there is a dearth of this type of study in the world literature on any surgical subject. Nevertheless, in the alternative treatment of migraine headaches, there actually now exist five of these sham studies: three on the use of acupuncture,^{3–5} one on the closure of patent foramen ovale,⁶ and now this addition on surgical decompression of peripheral trigger points. Dr. Guyuron and his team’s pursuit of academic

integrity and the highest level of evidence to support this hypothesis is to be applauded.

As with any quality science, the results of this study raise some interesting questions and answer others. For instance, how can one explain that one of the 26 patients undergoing sham surgery actually had complete elimination of migraine headaches at 1 year? It has been this author’s experience, and Dr. Guyuron’s, that most if not all patients experience improvement immediately after surgery irrespective of the longer term result. This may be attributed to the surgical undermining of flaps, neurapraxias from nerve manipulation, or the placebo effect. However, for the beneficial effect to persist at 1 year is a surprising finding, and one that warrants further investigation.

Conversely, eight of 49 patients who underwent actual surgery had no change in their migraine headache symptoms after surgery. Although the authors point out that this result may reflect the fact that only one trigger point was addressed, potentially leaving others untreated, the fact is that there exists a small subpopulation of nonresponders in *all* available clinical studies on this subject reported in the peer-reviewed literature.^{7–10} The implication, of course, is that there are more trigger points as yet undescribed, or even that perhaps the surgical technique for comprehensive decompression of these nerves requires further refinement. The translational research model allows us to take this clinical issue back to the laboratory for investigation, which is currently underway at multiple centers across the country, and whose preliminary anatomical results are to be reported in the very near future.^{11–14} For instance, in the occipital region, whereas we originally thought there was a single point of nerve compression at its intersection with the semispinalis muscle,¹⁵ there may be as many as six points of compression along the course of the greater oc-

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capital nerve.¹¹ This greater understanding of anatomy, derived in actuality from surgical failures, may result in improved outcomes through advanced techniques of decompression.

Another question that is raised in the discussion of this study concerns how to more accurately determine the primary trigger point. As this study points out, “when the failed cases were analyzed, it appeared that the predominant migraine headache trigger site was incorrectly assigned in some instances.” Given that proper and accurate diagnosis is the foundation for successful treatment, what information can be gleaned from this to decrease surgical failures? An algorithm for treatment has been previously published,⁸ and others have been able to reproduce consistent results using this method.^{9,10} The primary trigger point is determined by patient history, specifically, where the patient describes the headache as originating from. Perhaps in some cases there may be “masking” occurring, where the pain from one site overshadows another site that is almost equal in intensity. Alternatively, is it possible for trigger points to change over time, especially after being addressed with either botulinum toxin or surgery? Again, more questions remain than answers.

Finally, Dr. Guyuron reported in this study that 22 of the 26 sham surgery patients were returned to the operating room for actual surgical decompression after serving as controls for 1 year. The follow-up on these patients, using themselves as internal controls, would be most intriguing and powerful.

In sum, this study represents a definitive step toward the legitimization of the concept initially put forth 9 years ago by Dr. Guyuron and colleagues. Through its robust study design and statistically significant results, our understanding of how to more successfully surgically treat an affliction that affects 28 million Americans,¹⁶ and that has a higher prevalence than asthma and diabetes combined,¹⁷ has been greatly enhanced. The questions raised will be surely answered with future investigation, only to be replaced by others, though, as the odyssey toward a definitive cure continues.

Jeffrey E. Janis, M.D.

Department of Plastic Surgery
University of Texas Southwestern Medical Center
Dallas, Texas 75390-9132
jeffrey.janis@utsouthwestern.edu

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