Population Preferences for Surgical Treatment of Refractory Migraine Headache: A Utility Outcomes Study

Radbeh Torabi, MD; Jacob Veith, BS; Lynn Bourn, BS; Ahmed Ibrahim, MD, PhD; Oren Tessler, MD

BACKGROUND: Migraines affect 28 million people in the United States. Surgical treatment for migraine headaches refractory to medical treatment has grown recently for patient with limited options. Utility scores are standardized tools offering validated means of measuring the health state preference of a health condition or disease state. The aim of this study was to prospectively determine the impact of the health state burden prior to surgical treatment, to characterize the quality of life for this patient population.

METHODS: Twenty consecutive patients [1 male (5%), 19 females (95%)], age of 47.2 years (SD=14.9) undergoing surgery for migraines were prospectively assessed to establish utility scores [visual analogue scale (VAS), time-trade off (TTO), and standard gamble (SG)] and migraine specific symptoms and disability (MSSD), prior to surgical treatment. Utility scores for monocular and binocular blindness were used as a control for validation and comparison.

RESULTS: Despite medical treatment, MSSD demonstrated mean 15.2 headaches per month (SD=8.7), lasting 14.2 hours (SD=9.7) per episode, with a mean pain level of 8.1 (SD=1.8) for patients prior to surgical treatment. Utility scores (VAS, TTO, SG) for migraine headaches were 0.54 (SD=0.26), 0.76 (SD=0.26), and 0.73 (SD=0.27) respectively; similar to those for monocular blindness (0.52, 0.80, 0.80) but higher than binocular blindness (0.24, 0.55, 0.57).

CONCLUSION: Migraine headaches refractory to medical treatment can be objectively assessed using utility scores. Utility scores for migraine headaches were comparable to previously published data for unilateral facial paralysis and lower extremity lymphedema, and worse in comparison to common cosmetic deformities such as breast ptosis and an aging neck. We have described the health state burden, in a prospective manner, in order to expand the benefits of surgical treatment of refractory migraine headaches, and express the debility for this patient population.

Targeted Peripheral Nerve-Directed Onabotulinumtoxin A Injection is an Effective Long-Term Therapy for Migraine Headache

Jenny C. Barker, MD, PhD; Jeffrey E. Janis, MD, FACS

BACKGROUND: Onabotulinumtoxin A (BOTOX®) is an FDA-approved treatment for chronic migraine headaches that involves on-label, high-dose administration across 31 anatomic sites. Anatomically-specific peripheral nerve trigger sites have been identified that contribute to migraine headache pathogenesis and are amenable to both BOTOX® injection and surgical decompression. These sites do not always correlate with the on-label FDA-approved injection pattern, but represent a more targeted approach. The efficacy of targeted peripheral nerve trigger site BOTOX® injection as an independent long-term therapeutic option has not been investigated.

METHODS: A retrospective review was completed for 223 patients with migraine headaches. Sixty-six patients elected to proceed with diagnostic BOTOX® injections. Of these, 24 continued long-term therapeutic BOTOX® injections while 42 matriculated to surgery. Outcomes were tracked.

RESULTS: Therapeutic long-term targeted trigger site-directed BOTOX® injection resulted in significant improvement in migraine headache index (MHI) (53.5 +/- 83.0, p<0.006), headache days/month (9.2 +/- 12.7, p<0.0009) and migraine severity (2.6 +/- 2.5, p<0.00008) versus baseline. MHI improved from the initiation of diagnostic injections to the establishment of steady-state injections (p<0.002), and further improved over time (p<0.05, mean follow-up 615 days) with no desensitization observed. Decompressive surgery resulted in significant improvement in MHI (100.8 +/- 109.7, p<0.0000005), headache days/month (10.8 +/- 12.7, p<0.000002), migraine severity (3.0 +/- 3.8, p<0.00001), and migraine duration in hours (16.8 +/- 21.6, p<0.0007). MHI improvement with surgery was better than long-term BOTOX® injections (p<0.05).

CONCLUSIONS: Though inferior to surgical decompression, targeted peripheral nerve trigger site-directed BOTOX® injection is an effective primary therapy for migraine headache representing a possible alternative to non-directed BOTOX® injection with decreased dosage requirements and the potential for decreased cost.

DISCLOSURE/FINANCIAL SUPPORT: None
BREAST SESSION 1

Acellular Dermal Matrix in Immediate Expander/Implant Breast Reconstruction: A Multicenter Assessment of Risks and Benefits

Michael Sorkin, MD; Ji Qi, MS; Hyungjin M. Kim, ScD; Jennifer B. Hamill, MPH; Jeffrey H. Kozlow, MD; Andrea L. Pusic, MD; Edwin G. Wilkins, MD

INTRODUCTION: Acellular dermal matrix (ADM) has gained widespread acceptance in immediate expander/implant reconstruction, due to perceived benefits of improved aesthetic outcomes and superior tissue expansion dynamics. Although previous investigators have evaluated its risks, few studies have assessed the impact of ADM on other outcomes, including patient-report measures.1-3 The objective of this study was to evaluate the effects of ADM use on complications, time to exchange, and patient-report outcomes (PRO) in immediate expander/implant reconstruction.

METHODS: The Mastectomy Reconstruction Outcomes Consortium (MROC) Study used a prospective cohort design to evaluate patients undergoing post-mastectomy reconstruction from 11 centers and 57 participating surgeons. The current analysis focused on women receiving immediate tissue expander reconstruction following mastectomies for cancer treatment or prophylaxis. Medical records and PRO data were collected preoperatively and at three months and one year postoperatively. The PRO measures included the BREAST-Q and Numeric Pain Rating Scale (NPRS). Bivariate analyses and mixed effect logistic regression models were used to assess the effects of ADM use on complication rates, time to exchange, and patient satisfaction with breasts, postoperative pain and other PROs.

RESULTS: A total of 1,107 patients were evaluated, including 546 (49.3%) with ADM and 561 (50.7%) without ADM. Controlling for demographic and clinical covariates, there were no statistically significant differences between the ADM and non-ADM cohorts in overall complication rates (19.9% vs. 18.3%, p=0.40), major wound infections (3.6% vs. 1.9%, p=0.12)[3] or reconstructive failures (2.2% vs 1.0%, p=0.59) at one year following reconstruction. There were also no significant differences between the cohorts in the time to expander/implant exchange (p=0.89) or in one year post-operative PRO scores, including satisfaction with breast (p=0.14), psychosocial well-being (p=0.40), physical well-being (p=0.93) and postoperative pain (p=0.29).

CONCLUSION: In our multicenter, prospective analysis, we found no significant ADM effects on complications in immediate expander/implant breast reconstruction. Our analyses also noted no statistically significant differences between ADM and non-ADM cohorts for other outcomes, including time to exchange and PROs. The results of this study call into question the utility and value of ADM in immediate expander/implant reconstruction and suggest a need for further critical reassessment of ADM use in this setting.

DISCLOSURE/FINANCIAL SUPPORT: Supported by NCI grant 1R01CA152192. None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

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Surgeon-Controlled Study and Meta-Analysis Comparing FlexHD and AlloDerm in Immediate Breast Reconstruction Outcomes

Nikhil Sobti; Eric C. Liao, MD, PhD

INTRODUCTION: The use of acellular dermal matrix (ADM) has facilitated immediate prosthesis-based breast reconstruction and holds select applications in cosmetic breast surgery. Despite widespread adoption, there remain concerns regarding the differences in post-operative complication rates among the available ADM products. Few studies directly compare outcomes following ADM-based reconstruction with two of the most commonly available ADM materials, AlloDerm and FlexHD. Those studies that are available often do not adequately control for the surgeon as a variable. We hypothesize that complication rates