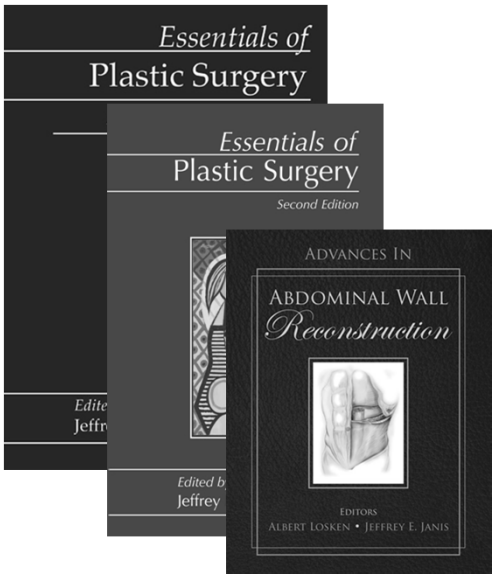
The Surgical Treatment of Migraine Headaches

Jeffrey E. Janis, MD, FACS
Professor of Plastic Surgery, Neurosurgery, Neurology and Surgery
Executive Vice-Chairman, Department of Plastic Surgery
Chief of Plastic Surgery, University Hospitals
The Ohio State University Wexner Medical Center

Disclosures

- **Royalties – Quality Medical Publishing/CRC Press**
- **Consultant – LifeCell**
- **Honorarium – Pacira**



Migraine Headaches

- 35 million people in the U.S. alone
- Affect 18% of women
- Affect 6% of men
- Cumulative lifetime incidence:
  - 43% women
  - 18% men
- 1 in 4 households have at least one person who suffers from migraine headaches

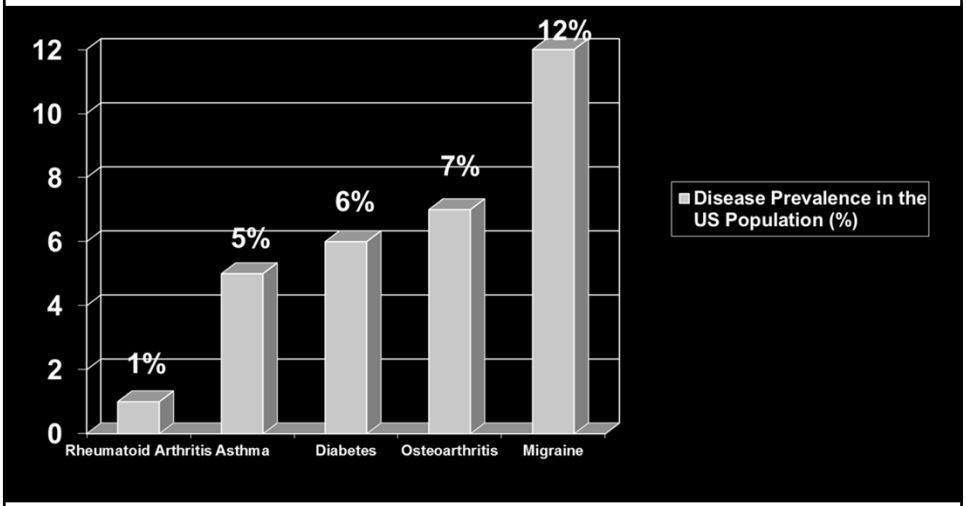
Lipton RB, Stewart WF, Diamond S, Diamond ML, Reed M. Prevalence and burden of migraine in the United States: Data from the American migraine study II. Headache. 2001; 41: 646-657.
Stewart WF, Wood C, Reed ML, Roy J, RB Lipton; AMPP Advisory Group. Cumulative lifetime migraine incidence in women and men. *Cephalagia* 2008;28:1170-8.

Impact of Migraines

- Single most disabling neurologic disorder
- 5th leading cause of visits to the emergency room
  - 4 million emergency room visits annually
- 6 million prescriptions for anti-migraine drugs

Leonardi M, Raggi A. Burden of migraine: International perspectives. *NeurolSci* 2013;34:S117-8.
Smitherman TA, Burch R, Sheikh H, Loder E. The prevalence, impact, and treatment of migraine and severe headaches in the United States: A review of statistics from national surveillance studies. *Headache* 2013;53:427-36.

Migraine Headaches

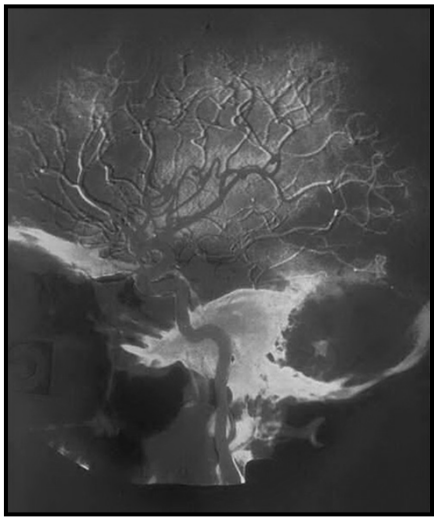


Migraine is more common than asthma and diabetes combined

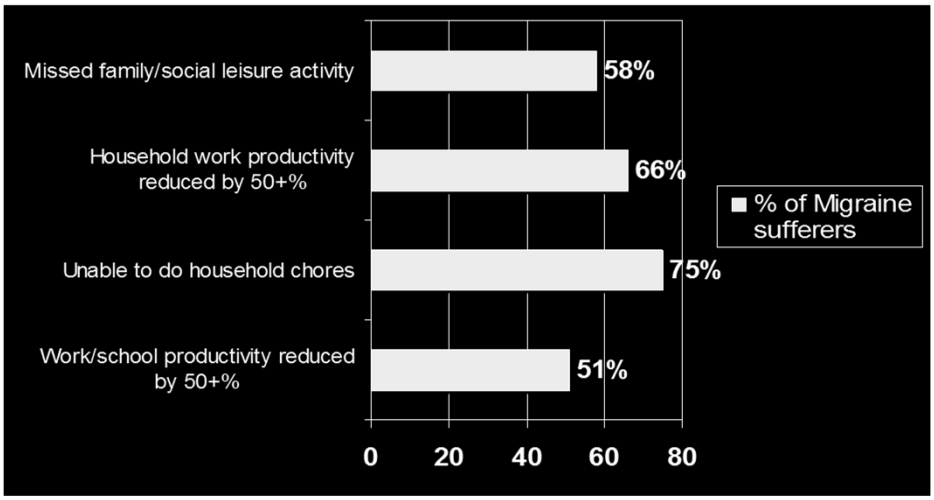
Data from the Centers of Disease Control and Prevention. U.S. Census Bureau, and the Arthrtitis Foundation

Migraine Headaches

- **1/3 of the patients are not helped by standard therapies**
- **Even the most efficacious medications only reduce their severity and frequency, rather than eliminate them**



Migraines Affect Patients' Abilities to Perform ADL's



Lipton RB, Stewart WF, Diamond S, Diamond ML, Reed M. Prevalence and burden of migraine in the United States: Data from the American migraine study II. Headache. 2001; 41: 646-657.

Economic Consequences

- **112 million collective workdays lost**
- **$14-$17 billion in productivity lost**

Author: TaxRebate.org.uk

Hu XH, Markson LE, Lipton RB, Stewart WF, Berger ML. Burden of migraine in the United States. Arch Internal Med. 1999; 159: 813-818.
Goldberg LD. The cost of migraine and its treatment. *Am J Manag Care* 2005;11:S62-7.

Traditional Treatments

- **Abortive**
  - **<u>Goal:</u> To prevent a migraine attack or to stop it once it starts**
- **Preventative**
  - **<u>Goal:</u> To lessen the frequency and severity of the migraine attacks.**

Traditional Treatments

- **Abortive Examples**
  - **Sumatriptan (Imitrex)**
  - **Zolmitriptan (Zomig)**
  - **Eletriptan (Relpax)**
  - **Naratriptan (Amerge, Naramig)**
  - **Rizatriptan (Maxalt)**
  - **Frovatriptan (Frova)**
  - **Almotriptan (Axert)**

Traditional Treatments

- **Preventative Examples**
  - **Beta-blockers (propanolol [Inderal])**
  - **Calcium channel blockers (verapamil [Covera])**
  - **Antidepressants - Amitriptyline (Elavil), nortriptyline (Pamelor)**
  - **Antiseizure medications – Gabapentin (Neurontin), valproic acid (Depakote), topiramate (Topamax)**
  - **Some antihistimines and anti-allergy drugs, including diphenhydrapmine (Benadryl) and cyproheptadine (Periactin)**

Traditional Treatment Disadvantages

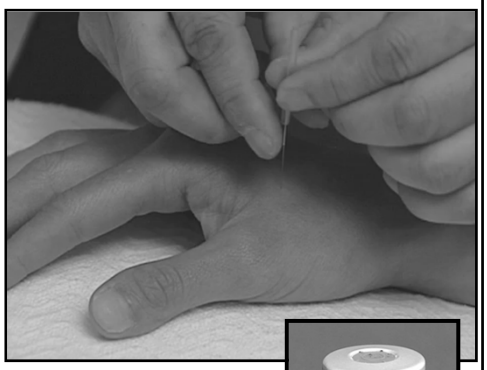
- **Must be taken on a regular basis**
- **Can be expensive, even with co-pays**
- **Time to take effect**

Traditional Treatment Disadvantages

- Can have side effects
  - Drowsiness
  - Weight gain
  - Hair loss
  - Difficulty concentrating/memory issues
- Contraindications:
  - Some contraindicated with pregnancy, history of coronary artery disease, stroke, etc.

Alternative Treatments

- Acupuncture
- Menthol patches
- Electrical Stimulation
- Magnesium
- Massage therapy
- Chiropractor
- Biofeedback
- Botulinum toxin
- Nerve Blocks
- Surgery



History of Botox and Surgery for Migraines

- 1st 2 patients in 2000
  - Dr. Bahman Guyuron – Case Western Reserve University
  - Unexpected outcome after cosmetic browlifts – improvement of migraine headaches

Evolution of Thought

- *"Carpal tunnel syndrome of the head"*
  - Nerve compression, irritation, entrapment by surrounding tissues
  - Thought to be supraorbital and supratrochlear nerve entrapment by the corrugator supercilli muscle

Etiology of Migraine Headaches

- Traditional
  - Centrally-mediated neurovascular phenomenon
- New Concept
  - Peripherally-mediated "trigger points"
    - –Branches of the trigeminal nerve and their muscular investments

First Publication

Guyuron B, Varghai A, Michelow BJ, Thomas T, Davis J. Corrugator supercilii muscle resection and migraine headaches. Plast. Reconstr. Surg. 2000; 106: 429-434

First Publication

Cosmetic

Corrugator Supercilii Muscle Resection and Migraine Headaches

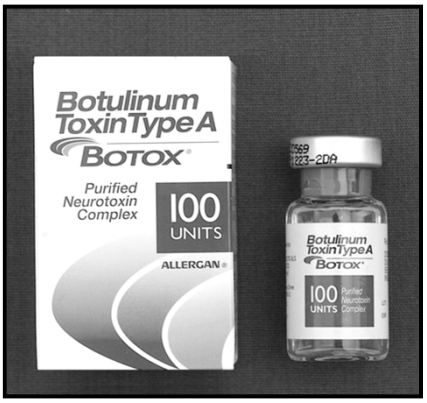
Bahman Guyuron, M.D., F.A.C.S., Amin Varghai, B.S., Bryan J. Michelow, M.D., F.R.C.S., Theresa Thomas, C.L.P.N., and Janine Davis, R.N.

Cleveland, Ohio

- Retrospective Questionnaire
  - Sent to 314 patients who had undergone resection of corrugator for cosmetic reasons
  - Found 79.5% of those patients who had pre-op migraines had elimination or improvement

Evolution of Technique

- Can't perform corrugator resection on everyone with a migraine headache
- Introduction of botulinum toxin as a test



Translational Anatomical Investigation

- Migraine patients tend to have pain in typical locations:
  - Periorbital area
    - –Supraorbital and supratrochlear nerves (SON/STN)
  - Temples
    - –Zygomaticotemporal branch of the trigeminal nerve (ZTN)
  - Back of neck
    - –Greater, lesser, and third occipital nerves (GON, LON, TON)

Major Peripheral Trigger Points

- Supraorbital
- Supratrochlear

} Muscle, Fascia, Bone, Vessel

- Zygomaticotemporal – Muscle, Fascia
- Greater Occipital Nerve – Muscle, Fascia, Vessel
- Nasoseptal (SPG) - Cartilage

Minor Peripheral Trigger Points

- Auriculotemporal
- Lesser Occipital Nerve
- Third Occipital Nerve

Putting It All Together

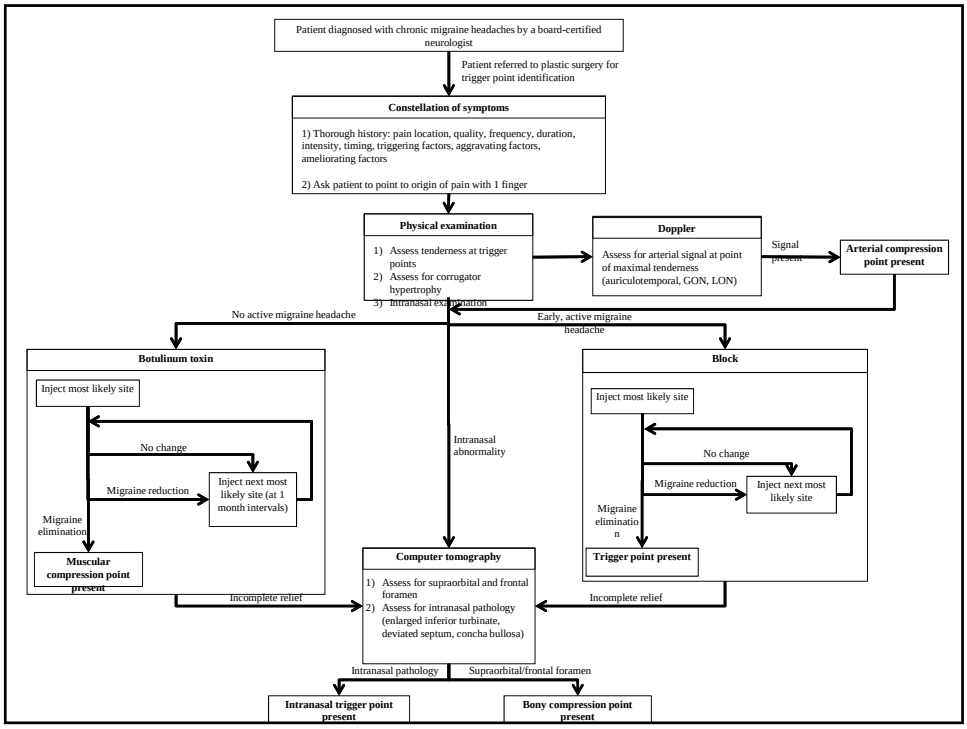
- Patient Selection
  - Officially diagnosed with migraine headaches by a neurologist
  - Failure or intolerance of traditional medications
  - Disability

Choosing Injection Sites

- Guided primarily by where the headaches usually begin:
  - Periorbital region
  - Temple
  - Back of neck
    - GON/LON/TON
  - Retroorbital

Choosing Injection Sites

- Augmented by use of:
  - Nerve blocks
  - CT scan
  - Doppler

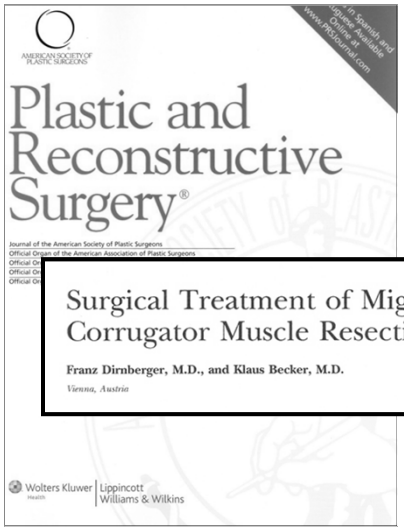


Surgery

- **Endoscopic or transpalpebral glabellar muscle resection**
- **Zygomaticotemporal nerve avulsion**
- **Greater occipital nerve release with fat flap transposition**
- **Septoplasty with ITR/outfracture**

Evidence and Outcomes

Further Publications



- PRS Sept 2004
- Austrian experience

Dirnberger F, Becker K. Surgical treatment of migraine headaches by corrugator muscle resection. Plast. Reconstr. Surg. 2004; 114: 652-657

Surgical Treatment of Migraine Headaches by Corrugator Muscle Resection

Franz Dirnberger, M.D., and Klaus Becker, M.D.

Vienna, Austria

- Prospective study on 60 patients who underwent migraine surgery
  - 28.3% complete elimination
  - 40% significant improvement
  - 31.7% minimal to no change

The Early Landmark Publication

- PRS Jan 2005
- Prospective study on migraine surgery

Comprehensive Surgical Treatment of Migraine Headaches

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

Cleveland, Ohio

Guyuron B, Kriegler JS, Davis J, Amini SB. Comprehensive surgical treatment of migraine headaches. Plast. Reconstr. Surg. 2005; 115: 1-9

Comprehensive Surgical Treatment of Migraine Headaches

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

Cleveland, Ohio

- 89 patients underwent surgery
- 25 patients were controls (no surgery)
- 92% who underwent surgery had benefit
  - 35% complete elimination
  - 57% significant improvement
- Only 15.8% of controls had benefit
  - 0% elimination

Guyuron B, Kriegler JS, Davis J, Amini SB. Comprehensive surgical treatment of migraine headaches. Plast. Reconstr. Surg. 2005; 115: 1-9

Comprehensive Surgical Treatment of Migraine Headaches

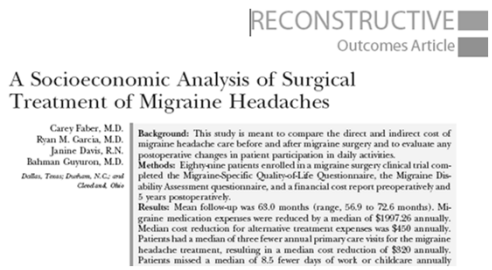
Bahman Guyuron, M.D., Jennifer S. Kriegler, M.D., Janine Davis, R.N., and Saeid B. Amini, Ph.D., M.B.A., J.D.

Cleveland, Ohio

- Mean follow-up 396 days
- Mean annualized cost for migraine care:
  - Treatment group: $925
  - Control group: $5,530
  - Baseline: $7,612
- Mean # of days lost/month from work:
  - Treatment group: 1.2
  - Control group: 4.4
  - Baseline: 4.41

Guyuron B, Kriegler JS, Davis J, Amini SB. Comprehensive surgical treatment of migraine headaches. Plast. Reconstr. Surg. 2005; 115: 1-9

Proven Socioeconomic Benefit



RECONSTRUCTIVE
Outcomes Article

A Socioeconomic Analysis of Surgical Treatment of Migraine Headaches

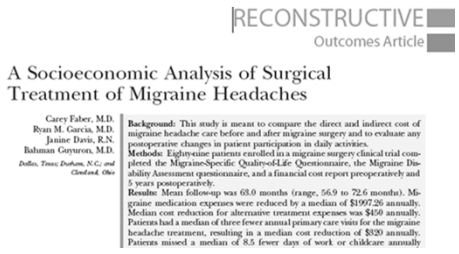
Carey Faber, M.D.
Ryan M. Garcia, M.D.
Janine Davis, R.N.
Bahman Guyuron, M.D.
Dallas, Texas; Durham, N.C.; and Cleveland, Ohio

Background: This study is meant to compare the direct and indirect cost of migraine headache care before and after migraine surgery and to evaluate any postoperative changes in patient participation in daily activities.
Methods: Eighty-nine patients enrolled in a migraine surgery clinical trial completed the Migraine-Specific Quality-of-Life Questionnaire, the Migraine Disability Assessment questionnaire, and a financial cost report preoperatively and 5 years postoperatively.
Results: Mean follow-up was 68.0 months (range, 56.9 to 72.6 months). Migraine medication expenses were reduced by a median of $1997.26 annually. Median cost reduction for alternative treatment expenses was $450 annually. Patients had a median of three fewer annual primary care visits for the migraine headache treatment, resulting in a median cost reduction of $820 annually. Patients missed a median of 8.5 fewer days of work or childcare annually

- Median total cost reduction of $3,949/year
  - ↓ med costs
  - ↓ primary care visits
  - ↓ # of work days missed with regained productivity time

Faber, C., et al., A socioeconomic analysis of surgical treatment of migraine headaches. Plast Reconstr Surg, 2012. 129(4): p. 871-7

Proven Socioeconomic Benefit



RECONSTRUCTIVE
Outcomes Article

A Socioeconomic Analysis of Surgical Treatment of Migraine Headaches

Carey Faber, M.D.
Ryan M. Garcia, M.D.
Janine Davis, R.N.
Bahman Guyuron, M.D.
Dallas, Texas; Durham, N.C.; and Cleveland, Ohio

Background: This study is meant to compare the direct and indirect cost of migraine headache care before and after migraine surgery and to evaluate any postoperative changes in patient participation in daily activities.
Methods: Eighty-nine patients enrolled in a migraine surgery clinical trial completed the Migraine-Specific Quality-of-Life Questionnaire, the Migraine Disability Assessment questionnaire, and a financial cost report preoperatively and 5 years postoperatively.
Results: Mean follow-up was 68.0 months (range, 56.9 to 72.6 months). Migraine medication expenses were reduced by a median of $1997.26 annually. Median cost reduction for alternative treatment expenses was $450 annually. Patients had a median of three fewer annual primary care visits for the migraine headache treatment, resulting in a median cost reduction of $820 annually. Patients missed a median of 8.5 fewer days of work or childcare annually

- Average surgical cost: $8,378
- Expense of medical management exceeded up-front cost of surgery shortly after 2 years post-operatively

Faber, C., et al., A socioeconomic analysis of surgical treatment of migraine headaches. Plast Reconstr Surg, 2012. 129(4): p. 871-7.

Corroborative Evidence

RECONSTRUCTIVE

Confirmation of Surgical Decompression to Relieve Migraine Headaches

Joseph T. Poggi, M.D.
Brett E. Grizzell, M.D.
Stephen D. Helmer, Ph.D.
Wichita, Kan.

Background: Surgical decompression of various trigger sites has been shown by two authors to relieve migraine headaches. The purpose of this study was to evaluate the effectiveness of surgical decompression of multiple migraine trigger sites in a clinical practice setting, and to compare the results to those previously published.
Methods: A retrospective, descriptive analysis was performed on 18 consecutive patients who had undergone various combinations of surgical decompression of the supraorbital, supratrochlear, and greater occipital nerves and zygomaticotemporal neurectomy performed by a single surgeon. All patients had been diagnosed with migraine headaches according to neurologic evaluation and had undergone identification of trigger sites by botulinum toxin type A injections.
Results: The number of migraines per month and the pain intensity of migraine headaches decreased significantly. Three patients (17 percent) had complete relief of their migraines, and 50 percent of patients (nine of 18) had at least a 75 percent reduction in the frequency, duration, or intensity of migraines. Thirty-nine percent of patients have discontinued all migraine medications. Mean follow-up was 16 months (range, 6 to 41 months) after surgery. One hundred percent of participants stated they would repeat the surgical procedure.
Conclusions: This study confirms prior published results and supports the theory that peripheral nerve compression triggers a migraine cascade. The authors have verified a reduction in duration, intensity, and frequency of migraine headaches by surgical decompression of the supraorbital, supratrochlear, zygomaticotemporal, and greater occipital nerves. A significant amount of patient screening is required for proper patient selection and trigger site identification for surgical success. (*Plast. Reconstr. Surg.* 122: 115, 2008.)

Migraine headache prevalence in the United States is estimated at 11.7 percent (5.6 percent for men and 17.1 percent for women). Most individuals (62.7 percent) suffer one to four migraine headache days per month, and 53 percent report severe impairment or the need for bed rest.[1] Previous studies estimate the indirect cost burden of migraine headache in the workplace to be $12 billion annually. Eighty-one percent of this value ($9.66 billion) is attributable to absenteeism.[2] Traditional therapy has been targeted at abortive prescription medication and prevention directed at the central theory of migraine propagation. Recently, studies concerning the peripheral theory (certain trigger points outside the brain start reactions that migrate centrally) have shown promising results. This theory postulates that peripheral trigger points can be eliminated by surgery. This leads to elimination of sites of nerve compression, stopping a migraine cascade. Dr. Guyuron and other researchers have shown that up to 92 percent of patients, when properly selected, can benefit from migraine surgery.[3,4] Of this group, 35

From the Department of Surgery, The University of Kansas School of Medicine–Wichita.
Received for publication July 19, 2007; accepted October 25, 2007.

DOI: 10.1097/PRS.0b013e31817742da

Disclosure: *None of the authors has any financial interests or commercial interests in any product or company associated with or referred to in this research. Furthermore, the authors do not have any associations, including consultancies, stock ownership or other equity interests, patent licensing arrangements, or payments, for conducting or publicizing any study described in this article.*

- PRS July 2008
- Poggi et al demonstrated reproducibility
- Retrospective review of 18 surgical patients

Poggi JT, Grizzell BE, Helmer, SD. Confirmation of surgical decompression to relieve migraine headaches. Plast. Reconstr. Surg. 2008; 122: 115-122

Corroborative Evidence

RECONSTRUCTIVE

Confirmation of Surgical Decompression to Relieve Migraine Headaches

Joseph T. Poggi, M.D.
Brett E. Grizzell, M.D.
Stephen D. Helmer, Ph.D.
Wichita, Kan.

Background: Surgical decompression of various trigger sites has been shown by two authors to relieve migraine headaches. The purpose of this study was to evaluate the effectiveness of surgical decompression of multiple migraine trigger sites in a clinical practice setting, and to compare the results to those previously published.
Methods: A retrospective, descriptive analysis was performed on 18 consecutive patients who had undergone various combinations of surgical decompression of the supraorbital, supratrochlear, and greater occipital nerves and zygomaticotemporal neurectomy performed by a single surgeon. All patients had been diagnosed with migraine headaches according to neurologic evaluation and had undergone identification of trigger sites by botulinum toxin type A injections.
Results: The number of migraines per month and the pain intensity of migraine headaches decreased significantly. Three patients (17 percent) had complete relief of their migraines, and 50 percent of patients (nine of 18) had at least a 75 percent reduction in the frequency, duration, or intensity of migraines. Thirty-nine percent of patients have discontinued all migraine medications. Mean follow-up was 16 months (range, 6 to 41 months) after surgery. One hundred percent of participants stated they would repeat the surgical procedure.
Conclusions: This study confirms prior published results and supports the theory that peripheral nerve compression triggers a migraine cascade. The authors have verified a reduction in duration, intensity, and frequency of migraine headaches by surgical decompression of the supraorbital, supratrochlear, zygomaticotemporal, and greater occipital nerves. A significant amount of patient screening is required for proper patient selection and trigger site identification for surgical success. (*Plast. Reconstr. Surg.* 122: 115, 2008.)

Migraine headache prevalence in the United States is estimated at 11.7 percent (5.6 percent for men and 17.1 percent for women). Most individuals (62.7 percent) suffer one to four migraine headache days per month, and 53 percent report severe impairment or the need for bed rest.[1] Previous studies estimate the indirect cost burden of migraine headache in the workplace to be $12 billion annually. Eighty-one percent of this value ($9.66 billion) is attributable to absenteeism.[2] Traditional therapy has been targeted at abortive prescription medication and prevention directed at the central theory of migraine propagation. Recently, studies concerning the peripheral theory (certain trigger points outside the brain start reactions that migrate centrally) have shown promising results. This theory postulates that peripheral trigger points can be eliminated by surgery. This leads to elimination of sites of nerve compression, stopping a migraine cascade. Dr. Guyuron and other researchers have shown that up to 92 percent of patients, when properly selected, can benefit from migraine surgery.[3,4] Of this group, 35

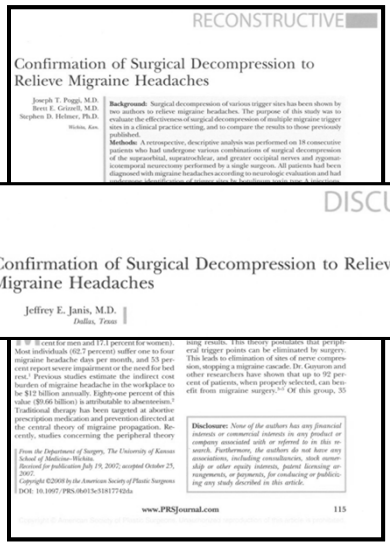
From the Department of Surgery, The University of Kansas School of Medicine–Wichita.
Received for publication July 19, 2007; accepted October 25, 2007.

DOI: 10.1097/PRS.0b013e31817742da

Disclosure: *None of the authors has any financial interests or commercial interests in any product or company associated with or referred to in this research. Furthermore, the authors do not have any associations, including consultancies, stock ownership or other equity interests, patent licensing arrangements, or payments, for conducting or publicizing any study described in this article.*

- 17% elimination
- 50% significant improvement
- 33% minimal to no change
- Mean follow up: 16 months

Corroborative Evidence



RECONSTRUCTIVE

Confirmation of Surgical Decompression to Relieve Migraine Headaches

Joseph T. Poggi, M.D.
Brett E. Grinnell, M.D.
Stephen D. Helmer, Ph.D.
Wichita, Kan.

Background: Surgical decompression of various trigger sites has been shown by two authors to relieve migraine headaches. The purpose of this study was to evaluate the effectiveness of surgical decompression of multiple migraine trigger sites in a clinical practice setting, and to compare the results to those previously published.

Methods: A retrospective, descriptive analysis was performed on 18 consecutive patients who had undergone various combinations of surgical decompression of the supraorbital, supratrochlear, and greater occipital nerves and zygomaticotemporal neurectomy performed by a single surgeon. All patients had been diagnosed with migraine headaches according to neurologic evaluation and had

DISCUSSION

Confirmation of Surgical Decompression to Relieve Migraine Headaches

Jeffrey E. Janis, M.D.
Dallas, Texas

cent for men and 17.1 percent for women). Most individuals (62.7 percent) suffer one to four migraine headache days per month, and 33 percent report severe impairment or the need for bed rest.[1] Previous studies estimate the indirect cost burden of migraine headache in the workplace to be $12 billion annually. Eighty-one percent of this value ($9.66 billion) is attributable to absenteeism.[2] Traditional therapy has been targeted at abortive prescription medication and prevention directed at the central theory of migraine propagation. Recently, studies concerning the peripheral theory

ising results. This theory postulates that peripheral trigger points can be eliminated by surgery. This leads to elimination of sites of nerve compression, stopping a migraine cascade. Dr. Guyuron and other researchers have shown that up to 92 percent of patients, when properly selected, can benefit from migraine surgery.[3,4] Of this group, 35

Disclosure: *None of the authors has any financial interests or commercial interests in any product or company associated with or referred to in this research. Furthermore, the authors do not have any associations, including consultancies, stock ownership or other equity interests, patent licensing arrangements, or payments, for conducting or publicizing any study described in this article.*

From the Department of Surgery, The University of Kansas School of Medicine-Wichita.
Received for publication July 19, 2007; accepted October 25, 2007.
Copyright ©2008 by the American Society of Plastic Surgeons
DOI: 10.1097/PRS.0b013e31817742da

www.PRSJournal.com 115

- The nasoseptal trigger point was not addressed in this cohort, which may have led to artificially low success rate
- Still an invaluable addition to the literature

Janis, J.E.. *Discussion: Confirmation of Surgical Decompression to Relieve Migraine Headaches.* by Poggi, J.Y. et. al. Plast Reconstr Surg. 122(1):123-124, 2008.

Corroborative Evidence

RECONSTRUCTIVE

Validation of the Peripheral Trigger Point Theory of Migraine Headaches: Single-Surgeon Experience Using Botulinum Toxin and Surgical Decompression

Jeffrey E. Janis, M.D.
Arjun Dhanik
Jessica H. Howard, B.A., P.A.-S.
Dallas, Texas, and St. Louis, Mo.

Background: Migraine headache is a widespread neurovascular disorder that is often suboptimally or incompletely treated. This article confirms the efficacy of botulinum toxin treatment with surgical decompression as a deactivator of migraine headache trigger sites through the retrospective analysis of a single surgeon's experience.

Methods: A retrospective chart review was performed on 24 patients presenting with the diagnosis of migraine headache. Botulinum toxin type A injections were used to identify frontal, temporal, and/or occipital trigger points. The nasal trigger point was diagnosed with a decongestant trial, intranasal examination, and computed tomographic scan. Those patients with more than one trigger point underwent multiple surgical procedures, which were performed concomitantly during the same operation. All botulinum toxin injections, surgical procedures, and patient meetings were conducted by the principal investigator (J.E.J.), minimizing intrapatient treatment variability and multiprovider bias.

Results: Patient progress was tracked by consolidating migraine frequency, severity, and duration as a Migraine Headache Index. Nineteen patients (79.2 percent) benefited from surgery. Two patients (8.3 percent) reported migraine elimination and 17 patients (70.8 percent) reported significant improvement of their migraine symptoms. Among those patients who responded to surgery, average improvement from baseline levels was 96.9 percent. Among the entire patient population, average improvement was 78.2 percent from baseline. The mean postsurgical follow-up was 661 days.

Conclusion: This study found botulinum toxin treatment with surgical decompression to be a potent deactivator of migraine headache trigger sites, corroborating the findings of the current literature in the field and underlining the reproducibility of the treatment. (*Plast. Reconstr. Surg.* 128: 123, 2011.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

THERAPEUTIC

Migraine headache affects 28 million individuals in the United States, 17.1 percent of women and 5.6 percent of men,[1] and is more prevalent than asthma and diabetes combined.[2] Direct medical costs for migraine headaches are approximately $1 billion annually, with an estimated $13 billion annually in lost productivity,[3] causing enormous economic difficulties and personal suffering.

Traditionally, abortive and preventative pharmaceuticals have been the preferred means of migraine management. Despite advancements in pharmaceutical treatment, medications are not always effective, often have severe side effects, and can be expensive.[3,4]

In 2000, Guyuron et al. first reported an association between corrugator supercilii muscle resection and elimination or significant improvement of migraine headache symptoms: 51 of 59 patients experienced elimination or significant improvement after corrugator resection, a 79.5 percent

From the Department of Plastic Surgery, University of Texas Southwestern Medical Center, and Washington University in St. Louis.
Received for publication August 6, 2010; accepted January 21, 2011.
Copyright ©2011 by the American Society of Plastic Surgeons
DOI: 10.1097/PRS.0b013e3182175b64

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

www.PRSJournal.com 123

- Single surgeon study
- 2005-2009
- 96 patients
- 24 operations
- 63 trigger sites decompressed

Janis J.E., Dhanik A, Howard J.H. Validation of the Peripheral Trigger Point Theory of Migraine Headaches: Single-Surgeon Experience Using Botulinum Toxin and Surgical Decompression. Plast Reconstr Surg. 128(1):123-131, 2011.

Corroborative Evidence

RECONSTRUCTIVE

Validation of the Peripheral Trigger Point Theory of Migraine Headaches: Single-Surgeon Experience Using Botulinum Toxin and Surgical Decompression

Jeffrey E. Janis, M.D.
Arjun Dhanik
Jessica H. Howard, B.A., P.A.S.

Dallas, Texas; and St. Louis, Mo.

Background: Migraine headache is a widespread neurovascular disorder that is often suboptimally or incompletely treated. This article confirms the efficacy of botulinum toxin treatment with surgical decompression as a deactivator of migraine headache trigger sites through the retrospective analysis of a single surgeon's experience.

Methods: A retrospective chart review was performed on 24 patients presenting with the diagnosis of migraine headache. Botulinum toxin type A injections were used to identify frontal, temporal, and/or occipital trigger points. The nasal trigger point was diagnosed with a decongestant trial, intranasal examination, and computed tomographic scan. Those patients with more than one trigger point underwent multiple surgical procedures, which were performed concomitantly during the same operation. All botulinum toxin injections, surgical procedures, and patient meetings were conducted by the principal investigator (J.E.J.), minimizing intrapatient treatment variability and multiprovider bias.

Results: Patient progress was tracked by consolidating migraine frequency, severity, and duration as a Migraine Headache Index. Nineteen patients (79.2 percent) benefited from surgery. Two patients (8.3 percent) reported migraine elimination and 17 patients (70.8 percent) reported significant improvement of their migraine symptoms. Among those patients who responded to surgery, average improvement from baseline levels was 96.9 percent. Among the entire patient population, average improvement was 78.2 percent from baseline. The mean postsurgical follow-up was 661 days.

Conclusion: This study found botulinum toxin treatment with surgical decompression to be a potent deactivator of migraine headache trigger sites, corroborating the findings of the current literature in the field and underlining the reproducibility of the treatment. (*Plast. Reconstr. Surg.* 128: 123, 2011.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

THERAPEUTIC

Migraine headache affects 28 million individuals in the United States,[1] 17.1 percent of women and 5.6 percent of men,[2] and is more prevalent than asthma and diabetes combined.[3] Direct medical costs for migraine headaches are approximately $1 billion annually, with an estimated $13 billion annually in lost productivity,[4] causing enormous economic difficulties and personal suffering.

Traditionally, abortive and preventative pharmaceuticals have been the preferred means of migraine management. Despite advancements in pharmaceutical treatment, medications are not always effective, often have severe side effects, and can be expensive.[5,6]

In 2006, Guyuron et al. first reported an association between corrugator supercilii muscle resection and elimination or significant improvement of migraine headache symptoms: 31 of 39 patients experienced elimination or significant improvement after corrugator resection, a 79.5 percent

From the Department of Plastic Surgery, University of Texas Southwestern Medical Center, and Washington University in St. Louis.
Received for publication August 6, 2010; accepted January 21, 2011.
Copyright ©2011 by the American Society of Plastic Surgeons
DOI: 10.1097/PRS.0b013e3182175d64

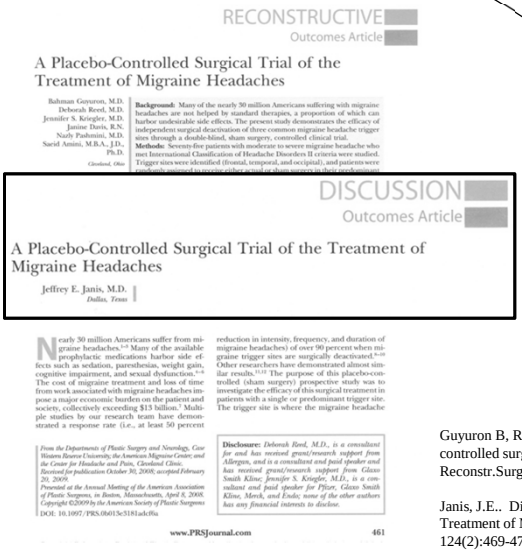
Disclosure: *The authors have no financial interest to declare in relation to the content of this article.*

www.PRSJournal.com 123

- **100%** response rate to Botox
  - Average of 87.5% improvement in MHI over baseline
- **80%** response rate to surgery
  - Average of 96.6% improvement in MHI over baseline

Janis J.E., Dhanik A, Howard J.H. Validation of the Peripheral Trigger Point Theory of Migraine Headaches: Single-Surgeon Experience Using Botulinum Toxin and Surgical Decompression. Plast Reconstr Surg. 128(1):123-131, 2011.

The Definitive Publication



RECONSTRUCTIVE
Outcomes Article

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

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

Cleveland, Ohio

Background: Many of the nearly 30 million Americans suffering with migraine headaches are not helped by standard therapies, a proportion of which can harbor undesirable side effects. The present study demonstrates the efficacy of independent surgical deactivation of three common migraine headache trigger sites through a double-blind, sham surgery, controlled clinical trial.

Methods: Seventy-five patients with moderate to severe migraine headache who met International Classification of Headache Disorders II criteria were studied. Trigger sites were identified (frontal, temporal, and occipital), and patients were randomly assigned to receive either actual or sham surgery in their predominant

DISCUSSION
Outcomes Article

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

Jeffrey E. Janis, M.D.
Dallas, Texas

Nearly 30 million Americans suffer from migraine headaches.[1–3] Many of the available prophylactic medications harbor side effects such as sedation, paresthesias, weight gain, cognitive impairment, and sexual dysfunction.[4–6] The cost of migraine treatment and loss of time from work associated with migraine headaches impose a major economic burden on the patient and society, collectively exceeding $13 billion.[7] Multiple studies by our research team have demonstrated a response rate (i.e., at least 50 percent reduction in intensity, frequency, and duration of migraine headaches) of over 90 percent when migraine trigger sites are surgically deactivated.[8–10] Other researchers have demonstrated almost similar results.[11,12] The purpose of this placebo-controlled (sham surgery) prospective study was to investigate the efficacy of this surgical treatment in patients with a single or predominant trigger site. The trigger site is where the migraine headache

From the Departments of Plastic Surgery and Neurology, Case Western Reserve University, the American Migraine Center, and the Center for Headache and Pain, Cleveland Clinic.
Received for publication October 30, 2008; accepted February 20, 2009.
Presented at the Annual Meeting of the American Association of Plastic Surgeons, in Boston, Massachusetts, April 8, 2008.
Copyright ©2009 by the American Society of Plastic Surgeons
DOI: 10.1097/PRS.0b013e3181adcf0a

Disclosure: *Deborah Reed, M.D., is a consultant for and has received grant/research support from Allergan, and is a consultant and paid speaker and has received grant/research support from Glaxo Smith Kline; Jennifer S. Kriegler, M.D., is a consultant and paid speaker for Pfizer, Glaxo Smith Kline, Merck, and Endo; none of the other authors has any financial interests to disclose.*

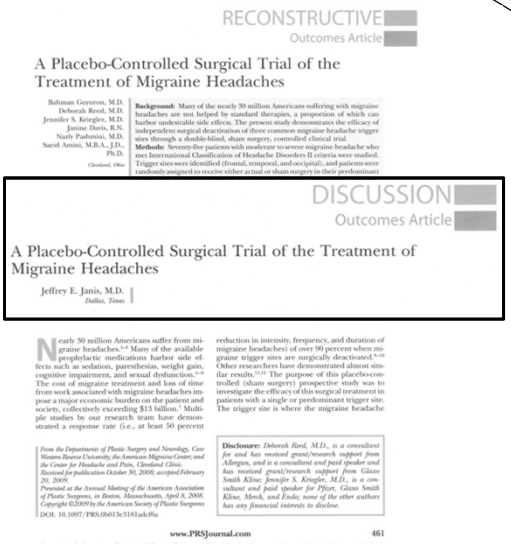
www.PRSJournal.com 461

- PRS August 2009
- IRB-approved prospective sham surgery study
- 75 patients
  - 26 sham surgery/49 actual

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

Janis, J.E.. Discussion: A Placebo Controlled Surgical Trial for the Treatment of Migraine Headaches. by Guyuron, B. Plast Reconstr Surg. 124(2):469-470, 2009.

The Definitive Publication



RECONSTRUCTIVE
Outcomes Article

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

Bahman Guyuron, M.D.
Deborah Reed, M.D.
Jennifer S. Kriegler, M.D.
Janine Davis, R.N.
Nazly Pashmini, M.D.
Saeid Amini, M.B.A., J.D., Ph.D.
Cleveland, Ohio

Background: Many of the nearly 30 million Americans suffering with migraine headaches are not helped by standard therapies, a proportion of which can harbor undesirable side effects. The present study demonstrates the efficacy of independent surgical deactivation of three common migraine headache trigger sites through a double-blind, sham surgery, controlled clinical trial.
Methods: Seventy-five patients with moderate to severe migraine headache who met International Classification of Headache Disorders II criteria were studied. Trigger sites were identified (frontal, temporal, and occipital), and patients were randomly assigned to receive either actual or sham surgery in their predominant

DISCUSSION
Outcomes Article

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

Jeffrey E. Janis, M.D.
Dallas, Texas

Nearly 30 million Americans suffer from migraine headaches.[1–3] Many of the available prophylactic medications harbor side effects such as sedation, paresthesias, weight gain, cognitive impairment, and sexual dysfunction.[4–6] The cost of migraine treatment and loss of time from work associated with migraine headaches impose a major economic burden on the patient and society, collectively exceeding $15 billion.[7] Multiple studies by our research team have demonstrated a response rate (i.e., at least 50 percent reduction in intensity, frequency, and duration of migraine headaches) of over 90 percent when migraine trigger sites are surgically deactivated.[8–10] Other researchers have demonstrated almost similar results.[11,12] The purpose of this placebo-controlled (sham surgery) prospective study was to investigate the efficacy of this surgical treatment in patients with a single or predominant trigger site. The trigger site is where the migraine headache

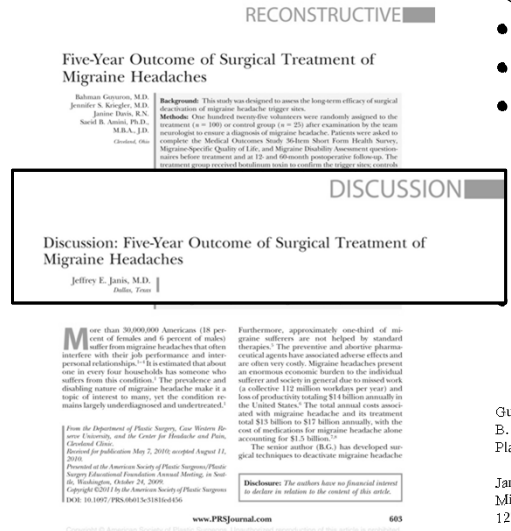
From the Departments of Plastic Surgery and Neurology, Case Western Reserve University, the American Migraine Center, and the Center for Headache and Pain, Cleveland Clinic.
Received for publication October 30, 2008; accepted February 20, 2009.
Presented at the Annual Meeting of the American Association of Plastic Surgeons, in Boston, Massachusetts, April 8, 2008.

DOI: 10.1097/PRS.0b013e3181adcf6a

Disclosure: *Deborah Reed, M.D., is a consultant for and has received grant/research support from Allergan, and is a consultant and paid speaker and has received grant/research support from Glaxo Smith Kline; Jennifer S. Kriegler, M.D., is a consultant and paid speaker for Pfizer, Glaxo Smith Kline, Merck, and Endo; none of the other authors has any financial interests to disclose.*

- 57.1% **complete elimination** in actual surgery vs. 3.8% in sham surgery ($p<0.001$)
- 83.7% **significant improvement** in actual surgery vs. 57.7% in sham surgery ($p<0.05$)

Longevity Addressed



RECONSTRUCTIVE

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 seventy-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

DISCUSSION

Discussion: Five-Year Outcome of Surgical Treatment of Migraine Headaches

Jeffrey E. Janis, M.D.
Dallas, Texas

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.[1–3] 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.[2]

Furthermore, approximately one-third of migraine sufferers are not helped by standard therapies.[2] 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.[4] The total annual costs associated with migraine headache and its treatment total $15 billion to $17 billion annually, with the cost of medications for migraine headache alone accounting for $1.5 billion.[5,6]

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

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

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

- PRS Feb 2011
- **5 year follow-up**
- 61/69 (88%) - positive response to the surgery after 5 years
  - 20 (29%) - complete elimination
  - 41 (59%) - significant decrease
  - 8 (11%) - no significant change
- All measured variables at 60 months improved significantly **($p<0.0001$)**

Guyuron, Bahman; Kriegler, Jennifer S.; Davis, Janine; Amini, Saeid B. Five-Year Outcome of Surgical Treatment of Migraine Headaches. Plastic & Reconstructive Surgery. 127(2):603-608, 2011.

Janis, J.E.. Discussion: Five-Year Outcome of Surgical Treatment of Migraine Headaches. by Guyuron, B. Plast Reconstr Surg. 127(2):609-610, 2011.

Factors for Success and Failure

RECONSTRUCTIVE

Factors Contributing to Migraine Headache Surgery Failure and Success

Kelsey Larson, B.A.
Michelle Lee, M.D.
Janine Davis, R.N.
Bahman Guyuron, M.D.
Cleveland, Ohio

Background: The purpose of this study was to identify factors that contribute to migraine headache surgery failure and success.
Methods: A retrospective chart review was conducted of patients who underwent surgery for migraine headaches performed by the senior author (B.G.) and had at least 11 months of follow-up. The study population included three groups: migraine surgery success, improvement, and failure. Thirty-six unique data points were collected for each patient.
Results: A total of 169 patients met inclusion criteria. Of these, 66 patients comprised the migraine surgery success group (S, complete elimination of migraine headaches); 67 comprised the migraine surgery improvement group (I, >50 percent reduction in migraine frequency, intensity, or duration); and 36 comprised the migraine surgery failure group (F, <50 percent reduction in migraine frequency, intensity, or duration). Significant differences among the groups included age at surgery ($S > I$, $p = 0.02$), migraine frequency ($S < I$, $p = 0.02$), age of migraine onset ($S > I$, $p = 0.003$; $S > F$, $p = 0.04$), history of head or neck injury ($S < I$, $p = 0.04$), daily use of over-the-counter migraine medications ($S < I$, $p = 0.05$), visual symptoms ($S > I$, $p = 0.02$), increased intraoperative bleeding ($S < F$, $p = 0.04$; $I < F$, $p = 0.04$), site I ($S > F$, $p = 0.0006$; $I > F$, $p = 0.0004$), site II ($S > F$, $p = 0.015$), single operative site ($S < F$, $p = 0.005$), one to two operative sites ($S < F$, $p = 0.04$; $I < F$, $p = 0.01$), and four operative sites ($S > I$, $p = 0.05$; $S > F$, $p = 0.04$).
Conclusions: Factors associated with migraine surgery failure include increased intraoperative bleeding and surgery on fewer trigger sites. Factors associated with migraine surgery success are older age of migraine onset, higher rate of visual symptoms versus improvement group, surgery at site I or II, and deactivating all four operative sites. (*Plast. Reconstr. Surg.* 128: 1069, 2011.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Risk, III.

RISK

Migraine headaches affect over 28 million Americans[1] and approximately 324.1 million people worldwide.[2] They commonly interfere with daily function and are the twentieth leading cause of years lost due to disability around the world.[2] They are also the ninth leading cause of disability in women around the globe.[3]

The most common treatments available for migraine headaches today include a combination of avoidance of common migraine triggers, prophylactic pharmacologic interventions, acute abortive therapy, and acute analgesic therapy. Pharmacologic substances commonly used to treat migraine headache include beta blockers, antidepressants, anticonvulsants, calcium channel blockers, and serotonin antagonists.[4] Although medical therapy provides patients and physicians some control over their migraine headaches, complete elimination of migraine headaches for prolonged periods of time is often not possible. In addition, pharmacologic intervention has numerous side effects and comorbidities, such as fatigue, dizziness, cardiovascular arrhythmias, and hepatotoxicity.[5] Alternative treatment options, such as injections of botulinum toxin type A

From the Department of Plastic Surgery, Case Western Reserve University.
Received for publication November 24, 2010; accepted May 11, 2011.
Presented at Plastic Surgery 2010, the Annual Meeting of the American Society of Plastic Surgeons/Plastic Surgery Foundation, in Toronto, Ontario, Canada, October 1 through 5, 2010.

DOI: 10.1097/PRS.0b013e31822fb61a1

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

- Success:
  - Older age of migraine onset
  - No lightheadedness or sensitivity to bright light/loud noises
  - Surgery on SON/STN/ZT
  - Deactivating all four operative sites at same time

Larson, Kelsey; Lee, Michelle; Davis, Janine; Guyuron, Bahman
Factors Contributing to Migraine Headache Surgery Failure and Success
Plastic & Reconstructive Surgery. 128(5):1069-1075, November 2011.

Factors for Success and Failure

RECONSTRUCTIVE

Factors Contributing to Migraine Headache Surgery Failure and Success

Kelsey Larson, B.A.
Michelle Lee, M.D.
Janine Davis, R.N.
Bahman Guyuron, M.D.
Cleveland, Ohio

Background: The purpose of this study was to identify factors that contribute to migraine headache surgery failure and success.
Methods: A retrospective chart review was conducted of patients who underwent surgery for migraine headaches performed by the senior author (B.G.) and had at least 11 months of follow-up. The study population included three groups: migraine surgery success, improvement, and failure. Thirty-six unique data points were collected for each patient.
Results: A total of 169 patients met inclusion criteria. Of these, 66 patients comprised the migraine surgery success group (S, complete elimination of migraine headaches); 67 comprised the migraine surgery improvement group (I, >50 percent reduction in migraine frequency, intensity, or duration); and 36 comprised the migraine surgery failure group (F, <50 percent reduction in migraine frequency, intensity, or duration). Significant differences among the groups included age at surgery ($S > I$, $p = 0.02$), migraine frequency ($S < I$, $p = 0.02$), age of migraine onset ($S > I$, $p = 0.003$; $S > F$, $p = 0.04$), history of head or neck injury ($S < I$, $p = 0.04$), daily use of over-the-counter migraine medications ($S < I$, $p = 0.05$), visual symptoms ($S > I$, $p = 0.02$), increased intraoperative bleeding ($S < F$, $p = 0.04$; $I < F$, $p = 0.04$), site I ($S > F$, $p = 0.0006$; $I > F$, $p = 0.0004$), site II ($S > F$, $p = 0.015$), single operative site ($S < F$, $p = 0.005$), one to two operative sites ($S < F$, $p = 0.04$; $I < F$, $p = 0.01$), and four operative sites ($S > I$, $p = 0.05$; $S > F$, $p = 0.04$).
Conclusions: Factors associated with migraine surgery failure include increased intraoperative bleeding and surgery on fewer trigger sites. Factors associated with migraine surgery success are older age of migraine onset, higher rate of visual symptoms versus improvement group, surgery at site I or II, and deactivating all four operative sites. (*Plast. Reconstr. Surg.* 128: 1069, 2011.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Risk, III.

RISK

Migraine headaches affect over 28 million Americans[1] and approximately 324.1 million people worldwide.[2] They commonly interfere with daily function and are the twentieth leading cause of years lost due to disability around the world.[2] They are also the ninth leading cause of disability in women around the globe.[3]

The most common treatments available for migraine headaches today include a combination of avoidance of common migraine triggers, prophylactic pharmacologic interventions, acute abortive therapy, and acute analgesic therapy. Pharmacologic substances commonly used to treat migraine headache include beta blockers, antidepressants, anticonvulsants, calcium channel blockers, and serotonin antagonists.[4] Although medical therapy provides patients and physicians some control over their migraine headaches, complete elimination of migraine headaches for prolonged periods of time is often not possible. In addition, pharmacologic intervention has numerous side effects and comorbidities, such as fatigue, dizziness, cardiovascular arrhythmias, and hepatotoxicity.[5] Alternative treatment options, such as injections of botulinum toxin type A

From the Department of Plastic Surgery, Case Western Reserve University.
Received for publication November 24, 2010; accepted May 11, 2011.
Presented at Plastic Surgery 2010, the Annual Meeting of the American Society of Plastic Surgeons/Plastic Surgery Foundation, in Toronto, Ontario, Canada, October 1 through 5, 2010.
Copyright ©2011 by the American Society of Plastic Surgeons
DOI: 10.1097/PRS.0b013e31822fb61a1

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

www.PRSJournal.com 1069

- Failure:
  - Increased intraoperative bleeding
  - Surgery on fewer trigger sites (1-2 vs. 3-4)

Larson, Kelsey; Lee, Michelle; Davis, Janine; Guyuron, Bahman
Factors Contributing to Migraine Headache Surgery Failure and Success
Plastic & Reconstructive Surgery. 128(5):1069-1075, November 2011.

Anatomical Conclusions

- Complete CSM resection (and portion of procerus and depressor)
- Branch patterns and asymmetries can lead to failures (SON/STN/ZT/GON)
- Release of foramen or notch, as indicated
- Complete release of GON
- Compression can take different forms (muscle, fascia, bone, vascular, etc.)

Current Body of Evidence

- **3 case series**
- **8 retrospective cohort studies**
- **3 prospective cohort studies**
- **2 randomized controlled trials**

Janis, J.E., Barker, J.C., Javadi, C., Ducic, I., Hagan, R., Guyuron, B. A Review of Current Evidence in the Surgical Treatment of Migraine Headaches. Accepted for publication, Plast Recon Surg

Summary of 17 Clinical Studies

- Average success rate: 90%
  - Either elimination or >50% improvement
- Reproduced by multiple surgeons
- Reproduced at multiple institutions

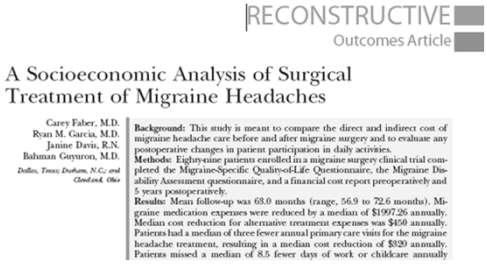
Janis, J.E., Barker, J.C., Javadi, C., Ducic, I., Hagan, R., Guyuron, B. A Review of Current Evidence in the Surgical Treatment of Migraine Headaches. Accepted for publication, Plast Recon Surg

Summary of 17 Clinical Studies

- F/U > 1 year in all but 1 retrospective study
- Adverse events reported in 10/17 studies

Janis, J.E., Barker, J.C., Javadi, C., Ducic, I., Hagan, R., Guyuron, B. A Review of Current Evidence in the Surgical Treatment of Migraine Headaches. Accepted for publication, Plast Recon Surg

Proven Socioeconomic Benefit



RECONSTRUCTIVE
Outcomes Article

A Socioeconomic Analysis of Surgical Treatment of Migraine Headaches

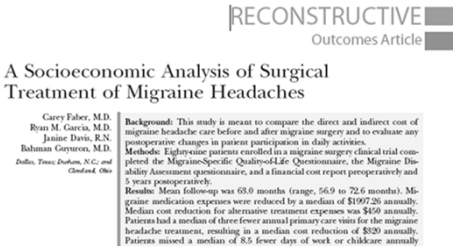
Carey Faber, M.D.
Ryan M. Garcia, M.D.
Janine Davis, R.N.
Bahman Guyuron, M.D.
Dallas, Texas; Durham, N.C.; and Cleveland, Ohio

Background: This study is meant to compare the direct and indirect cost of migraine headache care before and after migraine surgery and to evaluate any postoperative changes in patient participation in daily activities.
Methods: Eighty-nine patients enrolled in a migraine surgery clinical trial completed the Migraine-Specific Quality-of-Life Questionnaire, the Migraine Disability Assessment questionnaire, and a financial cost report preoperatively and 5 years postoperatively.
Results: Mean follow-up was 68.0 months (range, 56.9 to 72.6 months). Migraine medication expenses were reduced by a median of $1997.26 annually. Median cost reduction for alternative treatment expenses was $450 annually. Patients had a median of three fewer annual primary care visits for the migraine headache treatment, resulting in a median cost reduction of $820 annually. Patients missed a median of 8.5 fewer days of work or childcare annually

- **Median total cost reduction of $3,949/year**
  - **↓ med costs**
  - **↓ primary care visits**
  - **↓ # of work days missed with regained productivity time**

Faber, C., et al., A socioeconomic analysis of surgical treatment of migraine headaches. Plast Reconstr Surg, 2012. 129(4): p. 871-7

Proven Socioeconomic Benefit



RECONSTRUCTIVE
Outcomes Article

A Socioeconomic Analysis of Surgical Treatment of Migraine Headaches

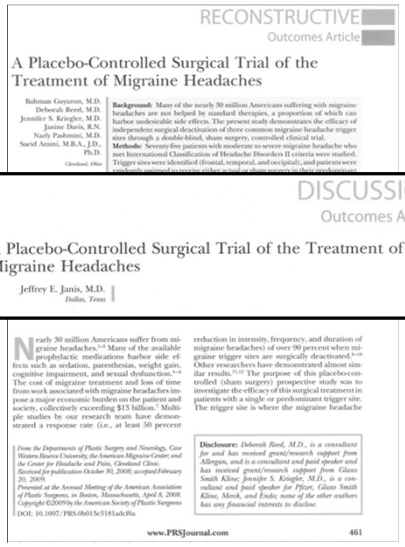
Carey Faber, M.D.
Ryan M. Garcia, M.D.
Janine Davis, R.N.
Bahman Guyuron, M.D.
Dallas, Texas; Durham, N.C.; and Cleveland, Ohio

Background: This study is meant to compare the direct and indirect cost of migraine headache care before and after migraine surgery and to evaluate any postoperative changes in patient participation in daily activities.
Methods: Eighty-nine patients enrolled in a migraine surgery clinical trial completed the Migraine-Specific Quality-of-Life Questionnaire, the Migraine Disability Assessment questionnaire, and a financial cost report preoperatively and 5 years postoperatively.
Results: Mean follow-up was 68.0 months (range, 56.9 to 72.6 months). Migraine medication expenses were reduced by a median of $1997.26 annually. Median cost reduction for alternative treatment expenses was $450 annually. Patients had a median of three fewer annual primary care visits for the migraine headache treatment, resulting in a median cost reduction of $820 annually. Patients missed a median of 8.5 fewer days of work or childcare annually

- **Average surgical cost: $8,378**
- **Expense of medical management exceeded up-front cost of surgery shortly after 2 years post-operatively**

Faber, C., et al., A socioeconomic analysis of surgical treatment of migraine headaches. Plast Reconstr Surg, 2012. 129(4): p. 871-7.

The Definitive Publication


RECONSTRUCTIVE
Outcomes Article

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

DISCUSSION
Outcomes Article

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

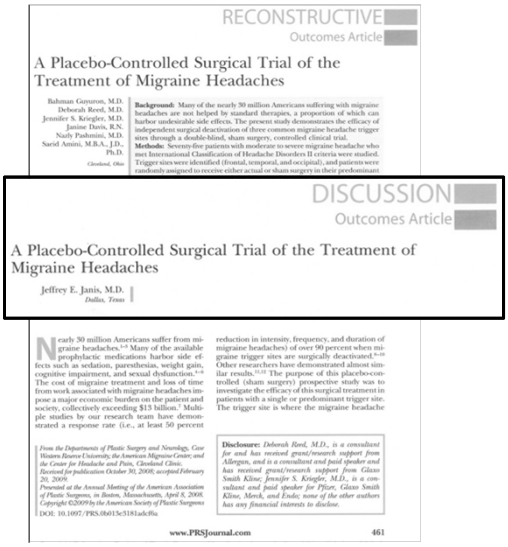
Jeffrey E. Janis, M.D.
Dallas, Texas

- PRS August 2009
- IRB-approved prospective sham surgery study
- 75 patients
  - 26 sham surgery/49 actual

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

Janis, J.E.. Discussion: A Placebo Controlled Surgical Trial for the Treatment of Migraine Headaches. by Guyuron, B. Plast Reconstr Surg. 124(2):469-470, 2009.

The Definitive Publication


RECONSTRUCTIVE
Outcomes Article

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

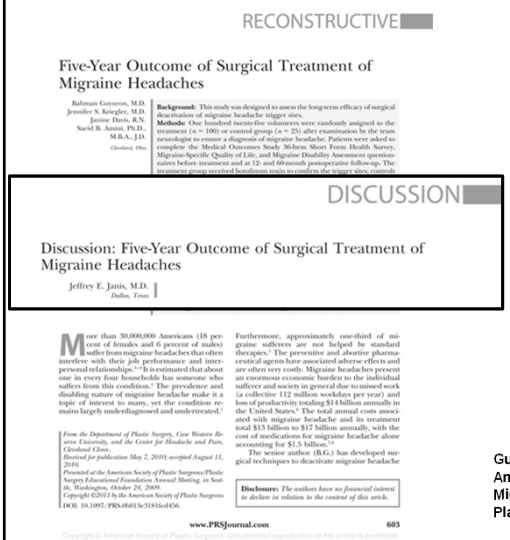
DISCUSSION
Outcomes Article

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

Jeffrey E. Janis, M.D.
Dallas, Texas

- 57.1% <u>complete elimination</u> in actual surgery vs. 3.8% in sham surgery ($p<0.001$)
- 83.7% <u>significant improvement</u> in actual surgery vs. 57.7% in sham surgery ($p<0.05$)

Longevity Addressed



RECONSTRUCTIVE

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

DISCUSSION

Discussion: Five-Year Outcome of Surgical Treatment of Migraine Headaches

Jeffrey E. Janis, M.D.
Dallas, Texas

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]

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

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

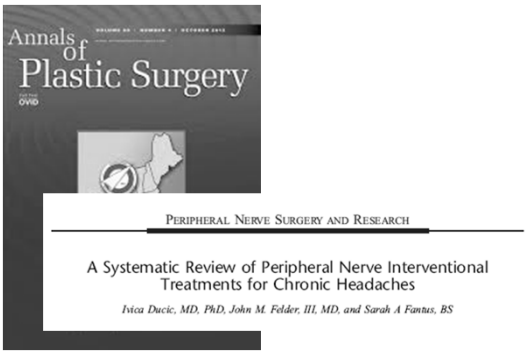
Disclosure: *The authors have no financial interest to declare in relation to the content of this article.*

- **PRS Feb 2011**
- **5 year follow-up**
- **61/69 (88%) - positive response to the surgery after 5 years**
  - **20 (29%) - complete elimination**
  - **41 (59%) - significant decrease**
  - **8 (11%) - no significant change**
- **All measured variables at 60 months improved significantly (p<0.0001)**

Guyuron, Bahman; Kriegler, Jennifer S.; Davis, Janine; Amini, Saeid B. Five-Year Outcome of Surgical Treatment of Migraine Headaches.
Plastic & Reconstructive Surgery. 127(2):603-608, 2011.

Janis, J.E.. Discussion: Five-Year Outcome of Surgical Treatment of Migraine Headaches. by Guyuron, B. Plast Reconstr Surg. 127(2):609-610, 2011.

Systematic Review



Annals of Plastic Surgery

PERIPHERAL NERVE SURGERY AND RESEARCH

A Systematic Review of Peripheral Nerve Interventional Treatments for Chronic Headaches

Ivica Ducic, MD, PhD, John M. Felder, III, MD, and Sarah A Fantus, BS

- **Examined prevalence, efficacy and complication rates**
  - **Peripheral nerve decompression – 86%**
  - **Radiofrequency therapy – 55%**
  - **Peripheral nerve stimulation – 68%**
- **Decompression with highest success and lowest complication rate**

Ducic, I., J.M. Felder, 3rd, and S.A. Fantus, A Systematic Review of Peripheral Nerve Interventional Treatments for Chronic Headaches. Ann Plast Surg, 2013.

Conclusions

- **Botox, blocks, and constellation of symptoms can be used to diagnose peripheral trigger points**
- **Surgical decompression is effective in the treatment of migraine headaches**

Developments in Plastic Surgery

Rajiv Chandawarkar, MD
Director of Plastic Surgery, University Hospital East
Associate Professor of Plastic Surgery
Adjunct Associate Professor of Orthopedics
Department of Plastic Surgery
The Ohio State University Wexner Medical Center

Mission

"We restore and make whole those parts which nature or ill fortune have taken away,

not so much to delight the eye, but to buoy up the spirit of the afflicted."

Gaspare Tagliacozzi, 1597

The Clinical Need

Common diagnoses that threaten limbs include:

- **Diabetic foot ulcers**
- **Vascular disease**
- **Surgery especially high risk patients with joint replacements**
- **Chronic osteomyelitis with open wounds,**
- **Non-healing ulcers (vascular or neuropathic) and**
- **Tumors both acute and chronic trauma**

The Clinical Need: Fast Facts

One in four diabetic individuals develops peripheral vascular disease that, when severe, may require amputation

More than 60 percent of non-traumatic lower-limb amputations occur in people with diabetes.

Incidence of initial amputation due to diabetes would be 179 per 100,000 person-years (compared to amputation in peripheral arterial disease in non-diabetic individuals is 10 per 100,000 person-years).

What is the CWC Limb Preservation Program?

- **Multidisciplinary Team**
  - **Said Atway- Podiatry**
  - **Rajiv Chandawarkar – Plastic Surgery**
  - **Michael Go -Vascular Surgery**
  - **Jeff Janis – Plastic Surgery**
  - **Gayle Gordillo – Plastic Surgery**
  - **Richard Schlanger – General Surgery**
- **Objective – prevent amputations**
- **Patient-Centered Care**
  - **Combined Vascular and Podiatry evaluation**
  - **PT, orthotist, labs, dietician – available on site**
  - **Wound care expertise**
  - **Complex Plastic Surgical reconstruction for limb preservation**

Significance

- **A COMBINED TEAM APPROACH is the best treatment strategy.**
- **Vascular restoration: accurate evaluation and minimally invasive repair (interventional techniques)**
- **Orthopedic debridement and salvage**
- **Plastic Reconstructive Surgery:The soft tissue surrounding the bone injury is the vascular envelope - nurturing bone back to health**
- **Wound Care**
- **Hyperbaric O2**

Principles

- **Step 1: identify nature of the defect: Characterize Vascular, Orthopedic and Soft Tissue needs**
- **Step 2: Outline a treatment plan that simultaneously treats blood supply, bone and soft tissue synergistically.**
- **ASK THE CRITICAL QUESTIONS**

Principles

CRITICAL QUESTIONS

- **Is the limb salvageable**
- **If so, what is the algorithm of reconstruction**

Amputation Versus Salvage

- **In complex extremity injuries, the treating physician must always first determine whether limb salvage is feasible.**
- **Are neurovascular structures are injured, are they repairable?**
- **Is normal sensation obtainable?**

Amputation Versus Salvage

- **Does a compartment syndrome exist? Unless a compartment syndrome is recognized and treated, muscle ischemia and muscle death will occur, converting potentially viable soft tissue to infarcted muscle and scar**
- **Is the FINAL outcome functional?**
- **Will the patient tolerate rehabilitation?**

Amputation Versus Salvage

"A fantastic operation not worth doing, is not worth doing well."

- Ashok Shaha MD, MSKCC

Plastic & Reconstructive Service Timing of Soft Tissue Reconstruction

- Early soft tissue reconstruction reduces the nosocomial contamination and secondary necrosis of exposed tissues.
- Late soft tissue reconstruction is associated with a significantly higher infection and flap complication rate – but allows for wound and patient stability.

Timing of Soft Tissue Reconstruction

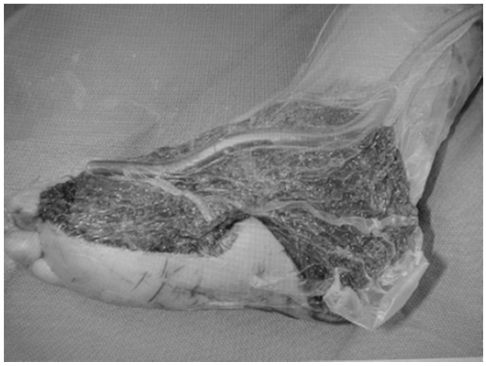
INITIAL Debridement is a must. If soft tissue reconstruction needs delayed, employ well established temporizing measures.

Timing of Soft Tissue Reconstruction

- Vacuum-assisted closure (VAC)
  - Seals the wound
  - Exposes a wound to sub-atmospheric pressure.
  - It is extremely effective in treating a wide spectrum of wounds including traumatic wounds as well as dehisced incisions with or without exposed hardware
- Hyperbaric oxygen (HBO)
  - Promotes formation of granulation tissue and stimulate angiogenesis in wounds that are compromised, usually by impaired arterial inflow or venous outflow

Timing of Soft Tissue Reconstruction

– Vacuum-assisted closure (VAC)



WOUND CLOSURE

- Composite free flaps (e.g osteocutaneous fibula flap
- Free flaps e.g. Gracilis flap
- Perforator flaps e.g. Propeller flap
- Pedicled regional flaps e.g. Pectoralis major flap
- Local fasciocutaneous flaps
- Full thickness skin graft
- Split skin graft
- Direct closure
- Healing by secondary intention (+/- negative pressure therapy)

WOUND CLOSURE

- **This is a continuum of procedures ranging from the simplest to the most complex (free flap transplantation.**
- **As a general principle the procedure with the greatest chance of success and lowest risk is chosen, often being one of the simpler techniques.**
- **The more complex procedures are required in larger wounds with exposed bone, fixation devices or poorly vascularized tissues.**

WOUND CLOSURE

- Muscle Flaps
- Fasciocutaneous Flaps

EACH HAS ADVANTAGES

WOUND CLOSURE

- Muscle Flaps
  - Compromises donor function
  - Bulky, many times non-pliable
  - Usually microvascular surgery
  - Typically needs skin cover/graft
  - Complex, time consuming and resource-rich

WOUND CLOSURE

- **Muscle Flaps**
  - **Compromises donor function**
  - **Bulky, many times non-pliable**
  - **Usually microvascular surgery**
  - **Typically needs skin cover/graft**
  - **Complex, time consuming and resource-rich**

WOUND CLOSURE

- **Fasciocutaneous Flaps**
  - **Easier to perform**
  - **Skin is composite to the flap**
  - **Less expensive**
  - **Donor function is preserved**
  - **Needs local vascular supply**

TEAM APPROACH TO EXTREMITY RECONSTRUCTION

- Reconstruction is a coordinated effort among orthopaedic surgeons, vascular surgeons, traumatologists, infectious disease and plastic surgeons.
- Subsequent involvement of rehabilitation specialists and prostheticians

TEAM APPROACH TO EXTREMITY RECONSTRUCTION

- It is not uncommon in practice for an orthopaedic traumatologist to stabilize a fracture, a vascular surgeon to perform an arterial interposition graft, and a microsurgeon to do a free tissue transfer.

TEAM APPROACH TO EXTREMITY RECONSTRUCTION

- Communication and careful preoperative planning are important to ensure successful reconstruction.
- The ability of the reconstructive plastic surgeon to deliver the correct tissue at the correct time with the correct composite nature enhances limb salvage.

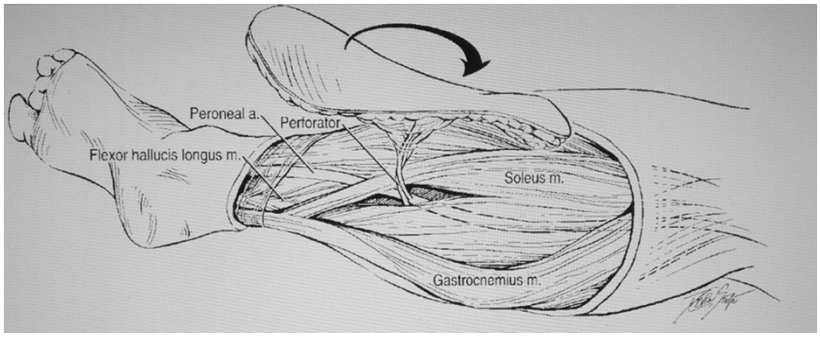
Novel Fasciocutaneous Flaps for the Reconstruction of Complicated Lower Extremity Wounds

- Fasciocutaneous perforator flaps can be used as an elegant alternative to other local or free flaps to treat the loss of tissues of the leg, once risk, benefits and expected results are understood.
- Novel fasciocutaneous flaps nourished by perforator vessels have been developed and are increasingly used as a valuable local alternative to the local flaps, with their high complication rates, and to the microsurgical flaps, with their more difficult and specialized technique.
- They provide local tissue, replacing like with like, but they harvest it from a distant, undamaged, region of the leg, which means healthy and well-vascularized tissue.

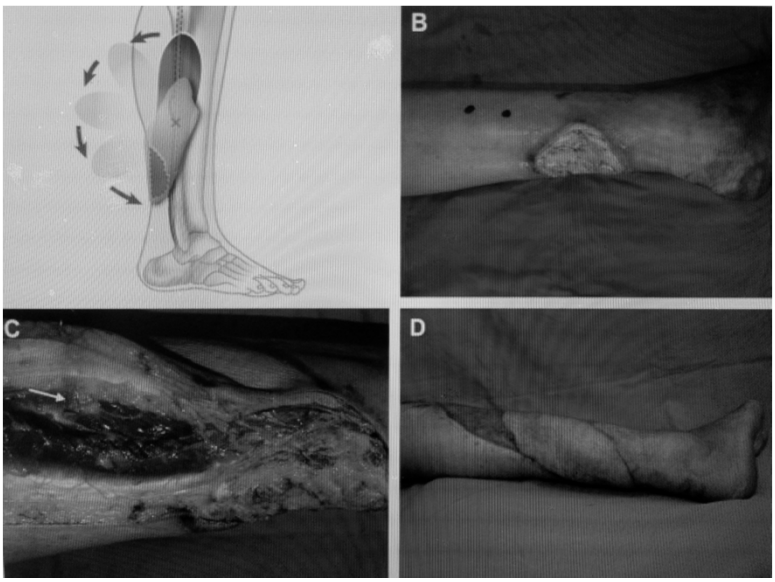
Novel Fasciocutaneous Flaps for the Reconstruction of Complicated Lower Extremity Wounds

- They do not need microsurgical facilities and skills, which may not be available everywhere. However, it is vital that the vessels are handled with great care and meticulous attention to detail in their preparation for the rotation.
- The known anatomic exiting sites of the perforator from the fascial plane will guide the planning of the flap, aided by the Doppler ultrasound and an exploratory incision. the surgical technique of perforator flaps harvesting and flap design, complications and solutions.

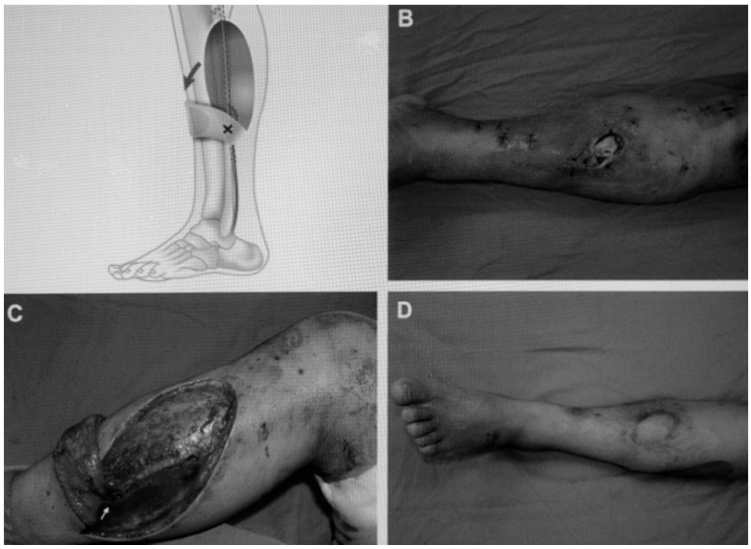
Sural Flaps



Sural Flaps

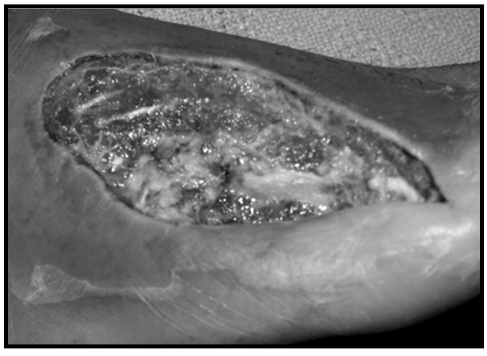


Sural Flaps

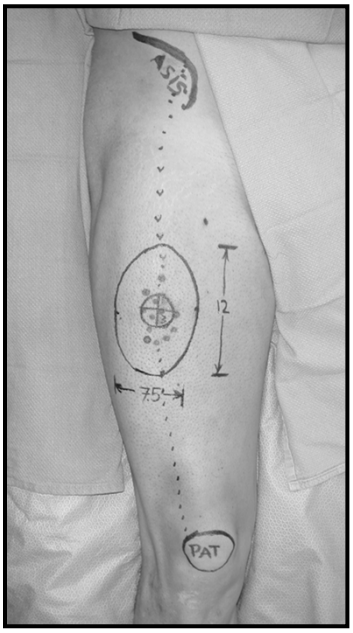


Photos courtesy of Rajiv Chandawarkar, MD

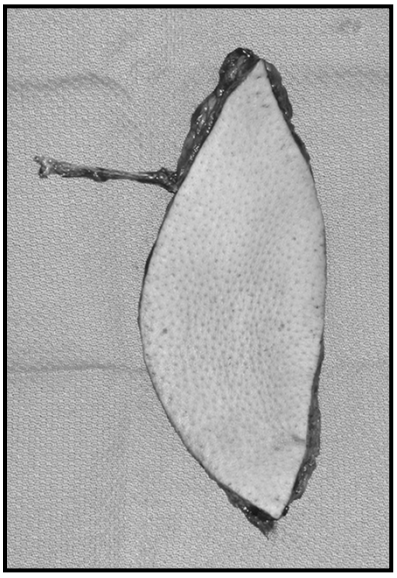
Free ALT Perforator Flap

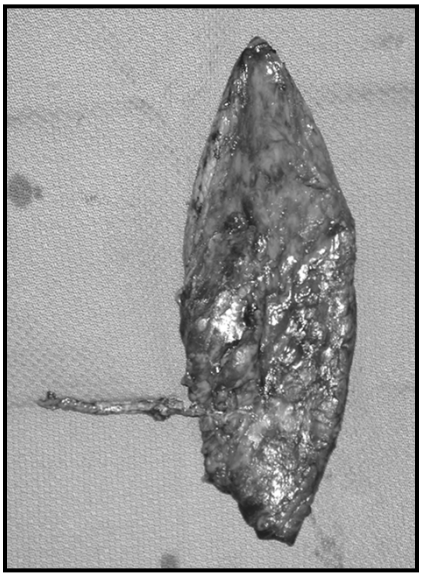


Photos courtesy of Jeffrey Janis, MD

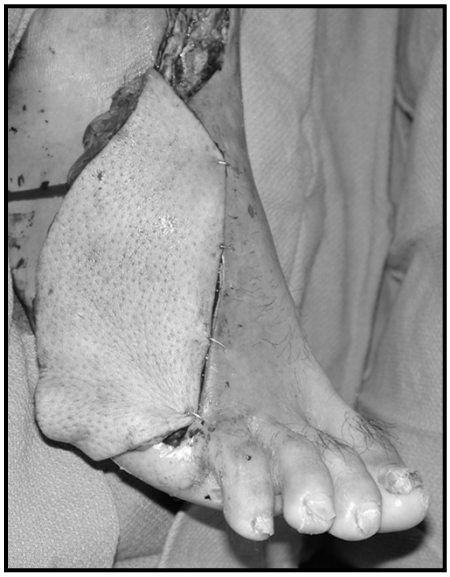


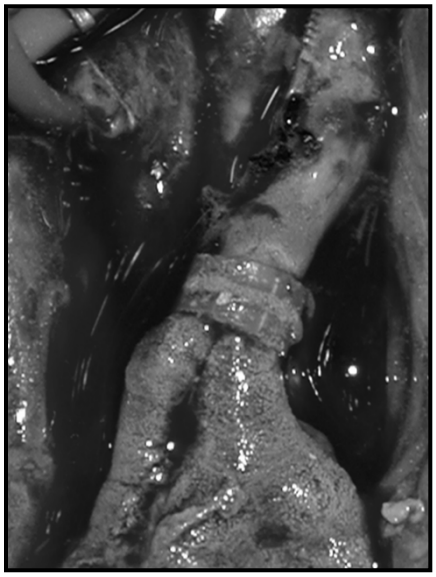
Photos courtesy of Jeffrey Janis, MD



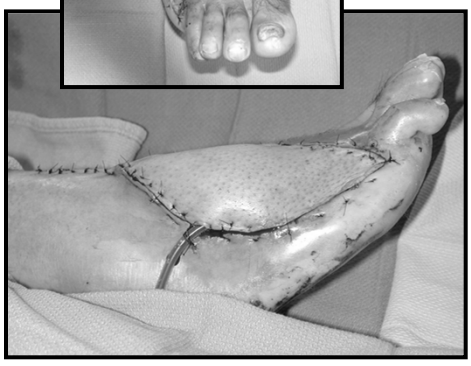


Photos courtesy of Jeffrey Janis, MD





Photos courtesy of Jeffrey Janis, MD



Photos courtesy of Jeffrey Janis, MD

Photos courtesy of
Jeffrey Janis, MD

Overall Challenge

THINK CREATIVELY ON DISEASE MANAGEMENT RATHER THAN EPISODE MANAGEMENT

EMPLOY INNOVATIVE COST CUTTING – QUALITY ENHANCING METHODS

MONITOR/MEASURE/INCENTIVIZE

SAVE 700B IN 10 YEARS……
……WHOSE COST CURVE WILL BE BENT