Preformed vs Intraoperative Bending of Titanium Mesh for Orbital Reconstruction
E. Bradley Strong, Scott C. Fuller, David F. Wiley, Janina Zumbansen, M. D. Wilson and Marc C. Metzger

Otolaryngology -- Head and Neck Surgery 2013 149: 60 originally published online 12 March 2013
DOI: 10.1177/0194599813481430

The online version of this article can be found at:
http://oto.sagepub.com/content/149/1/60
Preformed vs Intraoperative Bending of Titanium Mesh for Orbital Reconstruction

E. Bradley Strong, MD1, Scott C. Fuller, MD1, David F. Wiley, PhD3, Janina Zumbansen, MD2, M. D. Wilson, PhD4, and Marc C. Metzger, MD, DMD, PhD2

Abstract
Objective. The most accurate orbital reconstructions result from an anatomic repair of the premorbid orbital architecture. Many different techniques and materials have been used; unfortunately, there is currently no optimal method. This study compares the use of preformed vs intraoperative bending of titanium mesh for orbital reconstruction in 2-wall orbital fractures.

Study Design. Cadaver-based study.

Setting. University hospital.

Subjects and Methods. Preinjury computed tomography scans were obtained in 15 cadaveric heads (30 orbits). Stereolithographic (STL) models were fabricated for 5 of the specimens (10 orbits). Two wall fractures (lamina papyracea and floor) were then generated in all orbits. Surgical reconstruction was performed in all orbits using 1 of 3 techniques (10 orbits each): (1) patient-specific implant molded from the preinjury STL model, (2) titanium mesh sheet bent freehand, and (3) preformed titanium mesh. Each technique was evaluated for orbital volume correction, contour accuracy, ease of use, and cost.

Results. No difference in volume restoration was found between the 3 techniques. Patient-specific implants had the greatest contour accuracy, poor ease of use, and highest cost. Freehand bending implants had the poorest contour accuracy, acceptable ease of use, and lowest cost. Preformed mesh implants had intermediate contour accuracy, excellent ease of use, and low cost.

Conclusion. All 3 techniques provide equivalent orbital volume correction. However, preformed mesh implants have many advantages based on contour accuracy, ease of use, and relative cost.

Keywords
orbit, orbital volume, trauma, orbital trauma, facial trauma, facial fracture, fracture, volume analysis, computer software, facial reconstruction, orbital reconstruction

Received January 2, 2013; revised January 29, 2013; accepted February 14, 2013.

Orbital fractures result in disruption of the complex internal orbital architecture. These injuries can result in enophthalmos, diplopia, and blindness. The goal of orbital reconstruction is an accurate repair of the premorbid orbital architecture. However, the complex geometry of the orbit makes this extremely challenging. Initially, bone grafts were used for orbital reconstruction. Alloplastic materials (ie, titanium and porous polyethylene) were then introduced and adopted by many surgeons. These materials are malleable, biocompatible, and more accurate than bone grafts for reconstruction of the internal orbital architecture. More recent developments in computer-aided design and manufacturing (CAD/CAM) have paved the way for preformed alloplastic implants that provide an even more accurate reconstruction of the internal orbit. This cadaver study compares the accuracy of orbital reconstruction in 2-wall fractures with titanium mesh using 3 different methods: patient-specific implants, freehand bending, and industrially machined preformed mesh.

Methods
Fifteen cadaveric heads (30 orbits) were obtained from the University of California, Davis donated body program. No institutional review board approval was required. All surgery was performed by a single surgeon (E.B.S.). Preinjury computed tomography (CT) scans were obtained in all specimens to document the baseline orbital anatomy. Orbital volume analysis was performed for each of the 30 orbits (Maxillo software; Stratovan Corporation, Sacramento, California). Five of the

1Department of Otolaryngology, University of California, Davis, California, USA
2Department of Maxillofacial Surgery, University of Freiburg, Germany
3Stratovan Corporation, Sacramento, California, USA
4Department of Public Health Sciences, Biostatistics, University of California, Davis, California, USA

Corresponding Author:
E. Bradley Strong, MD, Department of Otolaryngology, University of California, Davis School of Medicine, 2521 Stockton Blvd, Ste 7200, Sacramento, CA 95817, USA.
Email: edward.strong@ucdmc.ucdavis.edu

Downloaded from oto.sagepub.com at SOCIEDADE BRASILEIRA DE CIRUR on July 2, 2013
CT data sets were randomly selected and used to fabricate STL models of 10 orbits (2 orbits per STL model). A periosteal elevator was then inserted through a small stab incision in the lower eyelid and used to generate 2-wall fractures in all 30 orbits (ie, floor and medial wall). All orbits were then opened via a transconjunctival/transcaruncular incision. The entire floor and medial wall were exposed (Figure 1).

The specimens were then separated into 3 treatment groups (10 orbits in each group):

Patient-specific molding (group 1): Traditional titanium mesh sheeting was trimmed and molded onto the preinjury STL models and used for orbital reconstruction (Figure 2).

Freehand bending (group 2): Traditional titanium mesh sheeting was bent and trimmed by the surgeon intraoperatively without a template (Figure 3).

Preformed mesh (group 3): Industrially machined preformed titanium mesh sheets (Synthes, West Chester, Pennsylvania) were trimmed and inserted without alteration in the contour (Figure 4).

All implants were positioned within the orbital cavity to rest on the free bone edges of the orbital defect. All implants were fixated with 1 or 2 self-drilling bone screws.

Volume Analysis
Postrepair CT scans were obtained for all orbits. Preinjury and postrepair volumes were compared for each orbit. A 1-way analysis of variance test was performed to compare each mesh type and orbital volume. All statistical analyses were performed using SAS software version 9.3 (SAS Institute, Cary, North Carolina).

Contour Analysis
Preinjury and postrepair contour measurements were recorded for each orbit. Contour measurements were obtained by precisely overlaying the preinjury and postrepair CT data sets. A parasagittal plane 5 mm medial to and parallel with the lamina papyracea was evaluated in each orbit. Measurements between preinjury and postrepair contours were taken at the front, midpoint, and posterior edge of the orbital floor defect (Figure 5). A 1-way analysis of variance test was performed for each of the 3 contour measurements to identify differences between mesh types. All statistical analyses were performed using SAS software version 9.3 (SAS Institute).

Ease of Use
A subjective analysis was performed by the operating surgeon, taking into account implant availability, handling (ie, ease of cutting and bending), ease of insertion, and implant
stability. Each of these areas was rated excellent, acceptable, or poor.

Cost Analysis
The cost of each implant was compared.

Results
Volume Analysis
The raw orbital volume data are shown in Table 1. All results are reported as the difference between the preinjury and postrepair volumes for each orbit. Negative values indicate that the postrepair volume was smaller than the preinjury volume. Positive values indicate that the postrepair volume was larger than the preinjury volume. The preinjury CT data from specimen 4 were corrupted and had to be excluded from the analysis.

Patient-specific molding (group 1): All postrepair orbital volumes were smaller than the preinjury volumes. The range was −0.27 to −3.47 cc. The average reduction in volume was 2.18 cc. The standard deviation was 0.88 cc.

Freehand bending (group 2): All postrepair orbital volumes were smaller than the preinjury volumes. The range was −1.14 to −3.75 cc. The average reduction in volume was 2.56 cc. The standard deviation was 0.77 cc.

Preformed mesh (group 3): Postrepair volumes varied with 7 orbits being smaller and 3 orbits being larger. The range was −1.21 to 3.83 cc. The average change in volume was 1.72 cc. The standard deviation was 1.11 cc.

The 1-way analysis of variance test was not significant (P = .24). There was no evidence of differences between mesh type in terms of average preinjury/postrepair volumes.

Contour Analysis
One-way analysis of variance testing revealed statistically significant differences between each of the implant types for the front and middle orbit locations (P = .0007 and .0035, respectively). There was no difference noted in the posterior orbit measuring point (P = .46) (Table 2).

Ease of Use
Patient-specific molding (group 1): availability, poor; handling, acceptable; ease of insertion, poor; stability, excellent. Overall rating: acceptable.

Freehand bending (group 2): availability, excellent; handling, acceptable; ease of insertion, poor; stability, excellent. Overall rating: acceptable.

Preformed mesh (group 3): availability, excellent; handling, excellent; ease of insertion, excellent; stability, excellent. Overall rating: excellent.

Cost Analysis
Patient-specific molding (group 1): STL model: $750 to $1750, depending on material type. Orbital mesh: $1100 per sheet. Total cost $1850 to $2850.

Freehand bending (group 2): orbital mesh: $1100 per sheet.

Preformed mesh (group 3): preformed mesh: $1300 per sheet.

Cost values are approximate and vary between institutions.
Discussion

The literature is replete with different techniques for orbital reconstruction; however, the optimal implant materials and techniques remain controversial. The literature supports the use of alloplastic implants such as titanium mesh. These implants are generally molded intraoperatively using a free-hand technique, are rigidly fixated, and do not resorb. In an effort to increase precision, patient-specific STL models were used for intraoperative molding of the mesh. However, STL model fabrication is time-consuming and costly. More recently, CAD/CAM-generated preformed titanium mesh implants have been introduced. These implants provide an “ideal contour” generated from an analysis of over 300 normal CT data sets. This study compares the accuracy of orbital reconstruction with titanium mesh using 3 different methods: patient-specific implants, freehand bending, and industrially machined preformed mesh.

Volume Analysis

Because the patient-specific implants were molded to a preinjury STL model, the authors hypothesized that this group would have the greatest accuracy and smallest preinjury/postrepair volume difference, the freehand bending group would have the poorest accuracy and greatest preinjury/postrepair volume difference, and the preformed mesh group would fall somewhere in between. However, no significant volume differences could be documented between the 3 techniques. Although the 3 techniques may be equivalent, other possible explanations could include the following: (1) the patient-specific implant had the most accurate contour (see implant contour below), but the surgeon was not able to place the implant into the “ideal” position to precisely reproduce the preinjury volume and/or (2) the number of orbits analyzed was too small to detect a statistically significant volume difference.

A second finding was that all the postrepair orbital volumes were smaller than the preinjury volumes. The freehand bending (−2.56 cc) had the greatest volume reduction, followed by the patient-specific mesh (−2.18 cc) and the preformed mesh (−1.72 cc). One explanation for this finding could be that the internal orbital placement of the implants and the added thickness of the mesh resulted in an overall reduction in orbital volume. Because the patient-specific and freehand bending implants were bent intraoperatively, they were slightly larger in diameter than the preformed mesh implants. This increased size could have also played a role in the smaller postrepair volume for these 2 techniques.

Table 1. Preinjury and postrepair volume data.

<table>
<thead>
<tr>
<th>Specimen No.</th>
<th>Preinjury Volume—Right</th>
<th>Postrepair Volume—Right</th>
<th>Pre-Post Difference</th>
<th>Preinjury Volume—Left</th>
<th>Postrepair Volume—Left</th>
<th>Pre-Post Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (patient specific)</td>
<td>31.34</td>
<td>29.0968</td>
<td>−2.2432</td>
<td>30.2606</td>
<td>26.7884</td>
<td>−3.4722</td>
</tr>
<tr>
<td>2 (patient specific)</td>
<td>27.8054</td>
<td>24.8869</td>
<td>−2.9185</td>
<td>26.1888</td>
<td>24.4945</td>
<td>−1.6943</td>
</tr>
<tr>
<td>3 (patient specific)</td>
<td>25.6834</td>
<td>24.0735</td>
<td>−1.6099</td>
<td>26.0845</td>
<td>25.8103</td>
<td>−0.2742</td>
</tr>
<tr>
<td>4 (patient specific)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>6 (freehand bend)</td>
<td>35.68</td>
<td>33.1733</td>
<td>−2.5067</td>
<td>39.8435</td>
<td>36.629</td>
<td>−3.2145</td>
</tr>
<tr>
<td>7 (freehand bend)</td>
<td>30.2529</td>
<td>27.3532</td>
<td>−2.8997</td>
<td>30.7527</td>
<td>28.4233</td>
<td>−2.3294</td>
</tr>
<tr>
<td>8 (freehand bend)</td>
<td>23.9575</td>
<td>21.1479</td>
<td>−2.8096</td>
<td>23.19</td>
<td>19.969</td>
<td>−3.221</td>
</tr>
<tr>
<td>9 (freehand bend)</td>
<td>37.7919</td>
<td>34.0381</td>
<td>−3.7538</td>
<td>36.1711</td>
<td>33.881</td>
<td>−2.2901</td>
</tr>
<tr>
<td>10 (freehand bend)</td>
<td>31.7714</td>
<td>30.3719</td>
<td>−1.3995</td>
<td>30.5657</td>
<td>29.4237</td>
<td>−1.142</td>
</tr>
<tr>
<td>11 (preformed)</td>
<td>27.5859</td>
<td>26.3060</td>
<td>−1.2253</td>
<td>28.137</td>
<td>26.2976</td>
<td>−1.8394</td>
</tr>
<tr>
<td>12 (preformed)</td>
<td>28.8938</td>
<td>25.9385</td>
<td>−2.9553</td>
<td>28.9235</td>
<td>27.1029</td>
<td>−1.8206</td>
</tr>
<tr>
<td>13 (preformed)</td>
<td>27.3001</td>
<td>28.33</td>
<td>1.0299</td>
<td>28.5103</td>
<td>28.8321</td>
<td>0.3218</td>
</tr>
<tr>
<td>14 (preformed)</td>
<td>32.777</td>
<td>33.99</td>
<td>1.213</td>
<td>32.2082</td>
<td>32.0057</td>
<td>−0.2025</td>
</tr>
<tr>
<td>15 (preformed)</td>
<td>32.6914</td>
<td>29.9094</td>
<td>−2.7611</td>
<td>32.6026</td>
<td>28.5766</td>
<td>−3.8272</td>
</tr>
</tbody>
</table>

Table 2. Average preinjury and postrepair contour differences at the front, middle, and back of the orbital floor defect.

<table>
<thead>
<tr>
<th>Implant Type</th>
<th>Front, mm (Range)</th>
<th>Middle, mm (Range)</th>
<th>Back, mm (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid prototype</td>
<td>0.8* (0-1.8)</td>
<td>0.8* (0-1.7)</td>
<td>1.6 (0-4.2)</td>
</tr>
<tr>
<td>Freehand</td>
<td>3.9* (2.3-5.3)</td>
<td>4.0* (1.8-7.3)</td>
<td>2.3 (0-3.4)</td>
</tr>
<tr>
<td>Preformed</td>
<td>1.8* (0.7-3.2)</td>
<td>1.3* (0-2.8)</td>
<td>2.3 (0.8-4.4)</td>
</tr>
</tbody>
</table>

*Statistically significant difference between each of the 3 groups.

Downloaded from oto.sagepub.com at SOCIEDADE BRASILEIRA DE CIRUR on July 2, 2013
Contour Analysis

The analysis of orbital floor contour is methodologically challenging. The ideal analysis would evaluate thousands of corresponding points along the entire surface of the floor and medial wall of the preinjury and postrepair data sets. Because this was not feasible, a representative region of the orbital floor was chosen for analysis. The decision to analyze the contour in a sagittal plane 5 mm lateral to the lamina papyracea was based on work done by Kamer et al, showing that the medial bulge and “s-shaped” curve of the posterior orbital floor are key features to accurate orbital reconstruction.

Patient-Specific Molding (Group 1). The patient-specific mesh was noted to have the most accurate contour reconstruction. Error values in the front and middle of the orbital defects were the smallest of all 3 groups. The accuracy was found to be statistically greater than both the freehand bending and preformed mesh groups (\(P < .05\)). This can be explained by the fact that the mesh was fashioned onto an STL model that precisely reproduced the preinjury orbital contour. The posterior values showed no significant difference between the 3 groups (\(P > .05\)). This is most likely because the mesh was placed onto a stable posterior shelf, thus improving the accuracy of placement despite the implant type used. This finding may vary in the clinical setting, because there may be variations in the stability of the posterior shelf.

Freehand Bending (Group 2). The freehand bending group was noted to have the poorest contour accuracy of the 3 groups. Error values in the front and middle of the orbital defects were significantly larger than the other 2 groups (\(P < .05\)). This can be explained by the fact that the surgeon had no template to work from when fashioning the implant.

Preformed Mesh (Group 3). The preformed mesh group was noted to have intermediate accuracy when compared with the other 2 groups. Error values in the front and middle of the orbital defects were statistically more accurate than the freehand bending group but not as accurate as the patient-specific group (\(P < .05\)). The shape of the preformed mesh implant is based on the “average” contour of over 300 uninjured orbits and is not patient specific.

Ease of Use

Implant “ease of use” is subjective by its nature and therefore difficult to objectively quantify. This analysis was designed to evaluate some of the most common factors surgeons consider when choosing an implant: access to the material, handling, ease of insertion, and cost.

Patient-Specific Molding (Group 1). The patient-specific implant availability was rated poor because it required fabrication of an STL model weeks prior to the procedure (Figure 2). The handling was rated acceptable. The material is readily cut but does take more time to fashion than the preformed mesh. The ease of insertion was rated poor because despite meticulous technique, there are often sharp edges that catch the orbital fat (and potentially the extraocular muscles) when the implant is inserted or removed (Figure 6). The stability was rated excellent because the material had more than enough rigidity to maintain its shape after insertion.

Freehand Bending (Group 2). The freehand bent implant availability was rated excellent. It can be stocked sterile in the operating room and is readily available to the surgeon. The handling was rated acceptable. The material is readily cut but does take more time to fashion than the preformed mesh. The ease of insertion was rated poor because despite meticulous technique, there are often sharp edges that catch the orbital fat (and potentially the extraocular muscles) when the implant is inserted or removed. Given the fact that the implant may need to be inserted and removed 2 to 3 times before the best shape and orientation are determined, this can place the periorbital soft tissues at increased risk of iatrogenic injury. The stability was rated excellent. The implant held its shape well and had good rigidity when in place.

Preformed Mesh (Group 3). The preformed mesh implant availability was rated excellent. It can be stocked sterile in the operating room and is readily available to the surgeon. The handling was rated excellent. No contouring is required. Trimming the implant is rapid and simple. When 1 or more of the peripheral tabs needed to be removed, the fine interwoven mesh attachments were easily cut, leaving no rough edges (Figure 7). The ease of insertion was rated excellent due to its smooth edges, which did not catch on the orbital soft tissues. The stability was rated excellent because the material was quite stable when in place.
It should be noted that whether an implant is preformed or shaped by the surgeon, large 2-wall implants are challenging to accurately position. Although the ease of insertion varied for the different implant types, this does not imply that the risk of implant malposition or complications is reduced with any specific implant.

Cost Analysis

Patient-Specific Molding (Group 1). Rapid prototype models fabricated from CT data sets are available to surgeons. Common fabrication methods include stereolithography, 3-dimensional printing, fused deposition modeling, inkjet methods, laminated object manufacturing, and laser sintering. Stereolithography is the most commonly used technique for medical applications. Stereolithographic models are stable to moisture, have excellent accuracy (±0.005 inches), have a smooth surface, and are available in a wide range of materials. However, the fabrication cost can be prohibitive (range $750 to $1750 for a model limited to the midface/orbits), particularly when this cost may not be reimbursable.

Free hand bending (Group 2). Titanium mesh sheeting is one of the most common alloplastic implants used for orbital reconstruction. It is relatively easy to fabricate, sterilize, and store in the operating room. An average cost for a single sheet is approximately $1100.

Preformed mesh (Group 3). Although the preformed mesh sheeting is also made of titanium, fabrication requires that the material be machined to a precise contour. This results in a slightly increased cost when compared with flat orbital mesh sheets (approximately $1300).

Study Limitations

There are several limitations to this study. The first is a small sample size. A larger sample size might show a statistically significant volume difference between the treatment groups. Second is the use of a 2-dimensional analysis of orbital floor contour. It is possible that a true 3-dimensional analysis could give more accurate results for this portion of the study. Third is the subjective nature of the “ease of use” section. Because ease of use is subjective, actual ease-of-use determinations would need to be made by the individual surgeon. Finally, the study was performed in fresh cadavers, not in a clinical setting. A patient-specific model for intraoperative bending of an implant cannot be fabricated after the orbit has been fractured. Therefore, if this approach were to be used clinically, the patient-specific model would have to be generated from a mirror image of an uninjured, contralateral orbit.

Conclusion

There was no statistical difference in orbital volume repair with any of the 3 techniques studied. Evaluation of orbital floor contour showed the greatest accuracy for patient-specific molding, followed closely by preformed mesh and finally by freehand bending. In summary, although patient-specific implants offer the best reconstructive contour, they are expensive and time-consuming to fabricate. Freehand bent implants have the advantage of being cost-effective with years of clinical use; however, contour accuracy and ease of use were comparatively less. We feel that preformed mesh implants strike a middle ground with very good contour accuracy, moderate cost, and excellent ease of use. We conclude that preformed mesh implants have many advantages for 2-wall orbital fractures.

Author Contributions

E. Bradley Strong, study design, data collection, data analysis, manuscript preparation; Scott C. Fuller, study design, data collection; David F. Wiley, study design, data analysis; Janina Zumbansen, data analysis and interpretation; M. D. Wilson, data interpretation and statistical analysis; Marc C. Metzger, data analysis, data interpretation, manuscript preparation.

Disclosures

Competing interests: David F. Wiley is the chief technology officer of Stratovan Corporation and designer of Maxillo orbital volume software. Marc C. Metzger is a past consultant for Synthes.

Sponsorships: All mesh implants were donated for the study by DePuySynthes (West Chester, Pennsylvania). All rapid prototype models were donated by Medical Modeling (Golden, Colorado).

Funding source: Statistical analysis was supported by a grant from the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), through grant #UL1 TR000002.
References