Long-term Efficacy of Biomodeled Polymethyl Methacrylate Implants for Orbitofacial Defects

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Objective: To report the long-term efficacy of custom polymethyl methacrylate implants using high-resolution computed tomographic modeling in the reconstruction of complex orbitofacial defects secondary to trauma.

Methods: Nine patients with complex orbitofacial bone defects after trauma were evaluated for this retrospective, nonrandomized, noncomparative study. All the patients underwent reconstruction using custom, heat-cured polymethyl methacrylate implants. Patients were followed up postoperatively and evaluated for complications.

Results: Nine consecutive patients (5 men and 4 women) aged 28 to 63 years who underwent surgical reconstruction using prefabricated, heat-cured polymethyl methacrylate implants were included in the study. The interval between injury and presentation ranged from 1 month to 40 years. There were no significant complications, including infection, extrusion, or displacement of the implant. In all of the patients, wound healing was uneventful, with antibiotic drugs administered perioperatively. Mean follow-up was 4.3 years from the first visit (range, 6 months to 10 years).

Conclusions: Computed tomographic biomodeled, prefabricated, heat-cured polymethyl methacrylate implants are well tolerated in the long term. Their advantages include customized design, long-term biocompatibility, and excellent aesthetic results.

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The accurate replication of complex human anatomy has long been sought for patients with severe orbitofacial defects. These abnormalities could result from trauma, congenital defects, or iatrogenic defects such as tumor removal. The main objective of reconstruction of orbitofacial defects is to restore anatomical integrity, providing proper eyelid and facial function and cosmetic improvement. Secondary reconstructions pose a particular challenge to the surgeon. Severe trauma and the resultant multicontoured disruption of tissues causes extensive scarring, loss of anatomical landmarks, and loss of functional tissue. Secondary reconstruction can exacerbate all of these conditions.

Many autologous and allogenic implant materials have been used with varying success and indications. In general, autologous and alloplastic materials, which are modeled intraoperatively, have failed to create ideal 3-dimensional (3-D) facial and orbital contours. In contrast, high-resolution preoperative modeling facilitates precise implant construction and placement, thus providing improved facial contour and implant stability. Concerns regarding alloplastic material placement include long-term implant stability and risk of infection.1 Herein we report the successful long-term efficacy of custom polymethyl methacrylate (PMMA) implants using high-resolution computed tomographic (CT) modeling in the reconstruction of complex orbitofacial defects secondary to trauma.

Methods

Patients

Nine consecutive patients who underwent reconstruction of orbitofacial defects secondary to trauma using CT biomodeled implants were included in the study. Criteria for the use of a custom CT biomodel included severe bony trauma with multicontoured orbitofacial defects and unsatisfactory primary reconstruction. Preoperative considerations included the degree of trauma, previous surgery, tissue volume, and functional deficits. Measurements of the pupillary distance, degree of enophthalmos, displacement of zygoma, and orbital rim were included. In all of the cases, patients underwent 3-D CT of the orbits and construction of a custom PMMA implant to duplicate the anatomical defect.

High-Resolution CT Biomodeled Custom PMMA Implants

Acquisition by CT and transfer and evaluation of patient data were performed according
to principles established in preliminary studies on geometrically standardized models and the production of implants for bony models.2 Generation of a physical model (BMI Biomedical Modeling Inc, Boston, Mass) from CT data required 4 basic steps. The first step was acquisition of CT data using specified protocols (Figure 1). The second step was delineation of a CT data subset, which described the model itself (Figure 2). The third step involved data translation into a rapid prototyping machine to form the 3-D model. Using these data, an accurate prefabricated PMMA implant was constructed using a 6-step process.2 For best results, strict protocols on patient movement and technical considerations were followed (a copy of the BMI Biomedical Modeling Inc protocol can be obtained via e-mail at http://www.biomodel.com). Actual scanning time was kept as short as possible, with 0.5- to 1.0-mm slices.

**DATA TRANSLATION**

The technician identified the 3-D region of data describing the model, and the slices were reconstructed into a 3-D object. The reconstruction also interpolated between the slices, filling in the “gaps” within each single slice and producing a smoother model.

**IMPLANT FABRICATION TECHNIQUE**

Generation of an accurate PMMA implant from the 3-D CT model required several steps. Briefly, a thin layer of dental die stone was painted on the bony tissue side of the wax. After the die stone hardened, the mold was separated and the cavity was thoroughly cleaned. The PMMA non–cross-linked acrylic mono-
mer and polymer were processed and packed into the stone mold. The mold was subjected to a 3-stage water bath heating unit for 15 hours. Finally, the newly custom-fabricated, accurate PMMA implant and the 3-D CT biomodel were sterilized using ethylene oxide gas followed by aeration for at least 72 hours to remove residual ethylene oxide.

SURGERY

All the procedures were performed by 2 of us (M.J.G. and R.A.G.). The goal of surgery was to restore anatomical function, orbital volume, and facial contour. During reconstruction of the orbitofacial defects, care was taken to ensure precise implant placement. It was important that the implant did not rest on any high points of bone because this could dramatically alter orbital volume or contour. Appearance of a thin meniscus of fluid between the bone implant interfaces was indicative of proper placement of the implant (Figure 3A), with an even distribution of fluid over the entire surface of the bone under the clear implant (Figure 3B). If any high points were noted from either the PMMA implant or the bone, these were trimmed down at the time of surgery. After surgery, patients were observed for any signs of complications, including orbital hemorrhage, severe pain, displacement, and extrusion of the implant.

RESULTS

Nine consecutive patients with complex orbitofacial bone and soft tissue injuries secondary to trauma were evaluated for reconstructive surgery. Their ages ranged from 28 to 63 years (mean, 48.7 years). There were 5 men and 4 women. The interval between injury and presentation was 1 month to 40 years (Table 1), during which time all of the patients underwent surgical reconstruction elsewhere. Procedures before reconstruction with PMMA included the use of autologous bone graft (2 patients), porous polyethylene implants (2 patients), titanium plate implants (2 patients), and soft tissue reconstruction with hard-palate eyelid grafting and silicone injection (1 patient each) (Table 2).

All of the patients demonstrated signs and symptoms of severe orbital trauma and cicatrisation, including facial asymmetry (3 patients), orbital asymmetry including hypoglobus (6 patients), and diplopia (5 patients). Patient characteristics and details of their injuries are summarized in Table 1. Ocular and orbital examination revealed decreased visual acuity in 6 of 8 patients, hypoglobus in 6, restrictive strabismus in 5, lower eyelid ectropion in 5, and enophthalmos in 4. Upper eyelid ptosis was present in 3 patients, superior sulcus deformity in 2, and exposure keratopathy in 2. One patient had traumatic mydriasis, aphakia, retnopathy and optic neuropathy, and frontal nerve hypoesthesia (Figure 4). After reconstruction using custom PMMA implants, no surgical complications were reported. Two procedures required minor intraoperative modification, such as grinding off excessive PMMA implant or cutting high points of bone. All of the implants were fixed using screws that were counter-fitted (below the level of the implant). This prevents any projection of the screws, thus eliminating palpation externally. The surgical details are included in Table 2.

Figure 3. Intraoperative photographs showing accurate placement of the prefabricated polymethyl methacrylate (PMMA) implant. A, Formation of a thin meniscus of fluid between the bone implant interface is seen, which confirms proper placement of the PMMA implant over the anatomical defect. B, Clear distribution of fluid is seen over the bone under the transparent PMMA implant.

Figure 5 demonstrates signs of orbitofacial deformity and scarring secondary to a boating accident 3 years earlier. Orbital trauma included a right blowout fracture, a right tripod fracture, and lateral bowing of the medial wall of the maxillary antrum with the absence of its superior wall, in addition to multiple facial injuries. Previous surgical reconstruction included multiple eyelid operations and scleral buckling for retinal detachment. Preoperative assessment demonstrated 2 mm of right enophthalms. Eyelid examination revealed 1 mm of right lower eyelid ectropion, with 2 mm of inferior displacement of the right lateral canthal angle, superior sulcus deformity, and cicatricial orbitopathy. The patient underwent high-resolution CT biomodeling and custom implant construction. Surgical reconstruction using a PMMA implant included right orbital reconstruction with repair of the orbital blowout fracture and orbital rim fracture. Additional procedures included right upper eyelid ptosis repair and right inferior conjunctivoplasty using a free hard-palate mucous membrane graft with right canthoplasty. Intraoperatively, constant comparison was made between the patient’s anatomy and that of the model, which was placed on the table adjacent to the operating field. The implant fit well, with minor modification necessary along the posterior and medial aspects of the orbital floor. The motility of the eye was constantly checked during the procedure to prevent...
entrapment of the septae or extraocular muscle. The postoperative photograph demonstrates good improvement of the superior sulcus defect and improvement of enophthalmos and eyelid contour and function (Figure 6).

**Figure 7** A shows a patient with severe facial and orbital trauma after a fall from a 50-ft height. Extensive orbital trauma included fractures of the right frontal bone, orbital floor, and zygomatic arch (posterior and lateral displacement consistent with trimalar fracture) and inferior displacement of orbital soft tissue. Preoperative assessment of the right eye revealed 3.5 mm of hypoglobus, with depression of malar eminence, superior sulcus deformity, and

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**Table 1. Characteristics of Patients Who Underwent Reconstructive Procedures Using Custom, Prefabricated PMMA Implants**

<table>
<thead>
<tr>
<th>Patient No./Sex/ Age, y</th>
<th>Year of Trauma</th>
<th>Type of Trauma</th>
<th>Interval Between Trauma and First Visit</th>
<th>Symptoms</th>
<th>Eye Affected</th>
<th>Injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/F/28 1991</td>
<td>Boating accident 3 y</td>
<td>Facial symmetry and loss of vision</td>
<td>Right</td>
<td>Blowout fracture, tripod fracture, penetrating injury to the orbit, retinal detachment, and eyelid laceration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2/F/42 1977</td>
<td>Motor vehicle crash 16 y</td>
<td>Diplopia</td>
<td>Right</td>
<td>Fractures (orbital rim, floor, zygoma, maxilla) and crush injuries, right side of face</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/M/28 1997</td>
<td>Snowboarding accident 10 mo</td>
<td>Diplopia and sunken eye</td>
<td>Right</td>
<td>Fractures (orbital rim and floor)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4/M/41 1992</td>
<td>Fall from 50-ft height 1 mo</td>
<td>Diplopia and asymmetry of eyes</td>
<td>Right</td>
<td>Fractures (orbital rim and floor), eyelid laceration, and contusive injuries to the brain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5/F/48 1998</td>
<td>Motor vehicle crash 1 y</td>
<td>Diplopia, asymmetry of eyes, sunken eye, and drooping of the upper eyelid</td>
<td>Right</td>
<td>Fractures (orbital rim, floor, maxilla, and malar), bilateral fracture zygoma, and severe midface contusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6/F/62 1964</td>
<td>Fall on left side of face 40 y</td>
<td>Improper eye closure and severe deformity of the lower eyelid and left cheek</td>
<td>Left</td>
<td>Fractures (zygoma and malar complex) and midface deformity with concavity of the maxilla</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7/M/63 1990</td>
<td>Blunt injuries 9 y</td>
<td>Facial asymmetry</td>
<td>Left</td>
<td>Fractures (orbital rim and zygoma)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8/M/59 1995</td>
<td>Motor vehicle crash 2 y</td>
<td>Diplopia and facial asymmetry</td>
<td>Right</td>
<td>Fractures (orbital floor, zygoma, and malar complex)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9/M/48 2002</td>
<td>Motor vehicle crash 1 y</td>
<td>Facial asymmetry, numbness, and tingling</td>
<td>Right</td>
<td>Blowout fracture and collapsed fracture of the maxilla</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviation:** PMMA, polymethyl methacrylate.

**Table 2. Surgical Data of Patients Who Underwent Reconstruction Using PMMA Implants**

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Previous Procedures</th>
<th>Previous Implant</th>
<th>Date of Surgery, mo/d/y</th>
<th>Surgical Procedure†</th>
<th>Intraoperative Adjustments</th>
<th>Follow-up, y</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Scleral buckling and eyelid procedures</td>
<td>No</td>
<td>9/5/1995</td>
<td>Roof + rim + facial implant</td>
<td>None</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>Multiple orbital reconstructive procedures and strabismus correction</td>
<td>Bone grafts</td>
<td>8/1/1994</td>
<td>Floor + rim</td>
<td>None</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>Multiple orbital reconstructive procedures</td>
<td>No</td>
<td>6/29/1998</td>
<td>Floor + rim</td>
<td>Trimming of the implant</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Eyebrow laceration repair</td>
<td>No</td>
<td>7/27/1993</td>
<td>Floor + rim</td>
<td>Grinding off of excessive PMMA</td>
<td>6</td>
</tr>
<tr>
<td>5</td>
<td>Orbital floor implantation and eyelid reconstruction</td>
<td>Titanium mesh and Medpore and hard palate mucous membrane graft</td>
<td>2/14/2000</td>
<td>Floor + rim + facial + removal of old implant</td>
<td>None</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>Midface reconstruction and orbital rim and floor implantation</td>
<td>Cheek implant, silicone injection, and titanium implant</td>
<td>5/31/2005</td>
<td>Floor + facial + removal of old implant</td>
<td>None</td>
<td>0.5</td>
</tr>
<tr>
<td>7</td>
<td>Reconstruction of the left eyelid and left midface</td>
<td>No</td>
<td>8/5/1999</td>
<td>Floor + volume enhancer</td>
<td>None</td>
<td>6</td>
</tr>
<tr>
<td>8</td>
<td>Multiple orbital reconstructive procedures</td>
<td>Autologous bone and Medpore implant</td>
<td>2/6/1997</td>
<td>Roof + floor + removal of old implant</td>
<td>None</td>
<td>5</td>
</tr>
<tr>
<td>9</td>
<td>Upper eyelid laceration repair</td>
<td>No</td>
<td>5/14/2003</td>
<td>Roof + zygoma + maxilla</td>
<td>None</td>
<td>2</td>
</tr>
</tbody>
</table>

**Abbreviation:** PMMA, polymethyl methacrylate.

*All of the patients had placement of screws and no complications.
†Reconstruction of the orbitofacial defect using custom PMMA implants.
orbital volume deficit with 3 mm of enophthalmos. There was hypoesthesia of the ophthalmic division of the trigeminal cranial nerve. Motility examination showed limitation of upgaze and downgaze in the right eye. The patient underwent CT biomodeling and custom implant construction. The orbital anatomical reconstructions with implants are demonstrated in Figure 8A. Because the patient had a superior orbital rim defect and an inferior orbital floor defect, 2 implants were designed (Figure 8B and C). Figure 8D demonstrates typical lock-and-key fit to anatomical structures. The same precise fit was achieved intraoperatively. A superior eyelid crease incision and an inferior transconjunctival incision with subperiosteal dissection were used to achieve access to the bony defects (Figure 9 and Figure 10). Postoperative assessment demonstrates significant improvement of the hypoglobus, superior sulcus defect, and enophthalmos (Figure 7B and C).

Figure 11 demonstrates preoperative and postoperative photographs of a patient who underwent PMMA implant reconstruction of multiple bony injuries and eyelid lacerations after a motor vehicle crash 1 year before presentation. On examination, he demonstrated a healed malar fracture with hypoglobus and enophthalmos of 2 mm each in addition to some degree of midface
Descent and hollowing of the right malar and submalar regions (Figure 11A). The CT scan demonstrated a comminuted fracture of the right maxilla involving the anterior ramus of the orbital floor (Figure 12). A CT biomodel was designed that clearly illustrated the areas of bony defect in the orbital floor (Figure 13A). Accordingly, a PMMA implant was constructed (Figure 13A inset) to fully conceal the fracture site (Figure 13B). The patient withstood the surgery well and showed marked improvement after surgery (Figure 11B).

Long-term data demonstrate that placement of orbital implants achieves reliable stability and long-term improvement in function with minimal risk of extrusion or implant infection. None of the patients in this study developed significant complications, including infection, extrusion, or displacement of the implant. All of the patients had minimal postoperative pain, and none developed hematoma or seroma. No surgical drains were used. In all of the patients, wound healing was uneventful, with antibiotics given perioperatively. Mean follow-up after reconstruction was 4.3 years (range, 6 months to 10 years). All of the patients had a routine follow-up with complete ophthalmologic evaluation once a week for a month, followed by once every 2 months for 6 months and quarterly annual visits thereafter.
COMMENT

Many types of implant materials have been used for reconstructive orbitofacial surgery. Distinction between the use of autogenous bone grafts and alloplastic materials has largely been based on issues concerning biocompatibility and availability. Autogenous materials such as bone grafts provide many advantages, including excellent biocompatibility and low infection and extrusion rates. However, these materials have pertinent limitations, such as the potential...
for a prolonged operative procedure, limited supply, significant resorption, donor site morbidity, and minimal malleability and customization. Craniofacial implants have been successfully made from materials such as PMMA and silicone polymers for more than 45 years. Prefabrication of PMMA offers customization while using an established biocompatible material. In 2 of the present patients, the previous autologous bone grafts had to be removed owing to significant resorption or displacement. Customizing autografts intraoperatively is difficult, and it is technically impossible to achieve ideal precision for eyelid and facial symmetry. Small asymmetries of 1 to 3 mm are not only aesthetically noticeable but can compromise eyelid function. In the patients described herein, periorbital facial symmetry was improved, as was eyelid function. Use of CT biomodeling for alloplastic materials is convenient and provides precise and functional reconstruction.

Prefabricated computer-generated implants made from carbon fiber–reinforced polymer and prebent titanium plates have also been used for cranioplasty but are expensive. The ideal alloplastic material should be biocompatible, inert, lightweight, rigid, and inexpensive. Overall, PMMA is well suited to custom orbital implantation and generates minimal thermal, electrical, and magnetic conductivity.

Previous literature has raised concerns that alloplastic implants are prone to infection and explantation in the long term. A study by Jordan et al reported that the incidence of early and delayed complications varies from 0.4% to 7.0% with alloplastic implants. A study of 37 orbital reconstructions using titanium implants reported complications such as undercorrection, symptomatically palpable implants, and orbital infection requiring explantation. In another study, a 7% complication rate included tight orbital fit, gaze limitation, and eventual development of enophthalmos. Infections usually develop as a sequela to floor and medial wall orbital fractures. The proximity and disruption of the paranasal sinuses seem too significant for infection. Bioactive glass has been used in the reconstruction of the orbital floor. The authors noted complications such as ectropion and infraorbital nerve hypoesthesia in 2 of 28 patients in their series. Orbital abscess, recurrent infection leading to implant removal, postoperative infraorbital anesthesia, and palpable screws were some of the complications encountered in other studies using alloplastic implants, such as porous polyethylene and silicone. In addition, 2 case reports described orbital fracture reconstruction using woven polyamide, followed by fistula formation from the maxillary antrum and ethmoid air cells. Both cases were cured by removal of the implant and surrounding tissue. In the present study, although the sinuses were involved in 6 of 8 cases, no such complication occurred. The incidence of perioperative infection has been remarkably low for porous hydroxyapatite. This resistance has been attributed to antibiotic-containing blood filling the pores of the implant, thus preventing normal and pathologic flora from establishing infection in the implant. However, cases with hydroxyapatite implants have been reported to develop clinically significant deep-tissue infection. Although the number of patients in this study is too small to address the issue of infection rate, all of these cases were secondary recon-

![Figure 12](http://archfacial.jamanetwork.com/pdfaccess.ashx?url=/data/journals/faci/11782/)  
**Figure 12.** Coronal computed tomographic scan of the face demonstrating a comminuted fracture of the right maxillary anterior wall with hemorrhagic opacification of the right maxillary sinus. Also seen is the fracture of the right orbital floor involving the anterior ramus.

![Figure 13](http://archfacial.jamanetwork.com/pdfaccess.ashx?url=/data/journals/faci/11782/)  
**Figure 13.** Photographs of the computed tomographic biomodel and custom prefabricated implant for reconstruction of an orbitofacial defect. A, Computed tomographic biomodel prepared for the patient with an orbital floor fracture. The polymethyl methacrylate implant is shown in the inset. B, Photograph showing accurate placement of the polymethyl methacrylate implant over the orbital floor defect.
In the present study, all of the patients were first seen many years after the trauma and primary reconstruction (1 patient presented 40 years after the trauma) with facial asymmetry and deformity. Reconstruction with custom biomodeled implants offered a practical alternative in complex cases. It requires preoperative CT according to specific parameters and can be accomplished in almost all radiology centers. Model construction is straightforward, with reduced operative time. All of the patients demonstrated long-term sustained improvement of facial deformities.

We conclude that biomodeled PMMA implants are well tolerated in the long term. Although this study is relatively small, it is the first time long-term data have been presented regarding the applicability of biomodeled PMMA implants. We believe that the advantages of customization and long-term efficacy reported in this article far outweigh potential complications in complex orbital reconstruction, which requires precise implant customization to provide function improvement.

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REFERENCES