Customized Orbit and Frontal Bone Implants

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Abstract

Orbitocranial reconstruction objectives include creation of a solid barrier between intracranial contents and the environment allowing restoration of physiologic homeostasis and restoration of aesthetic craniofacial contours. Historically, bone grafts have been used for reconstruction but were fraught with unpredictable resorption and imperfect contouring given the complex anatomy of the orbitofrontal bones. With advances in three-dimensional modeling technology, alloplastic custom implants in orbital and frontal bone reconstruction have allowed for rapid fixation reducing surgical times and improved cosmesis.

Keywords
- cranioplasty
- frontal
- orbital
- patient-specific implant

The bony orbit can be affected by many pathologies including trauma, ablative resection of benign and malignant tumors, and infectious etiologies. Orbital trauma accounts for 40% of all craniofacial trauma.[1] In many cases where fronto-orbital osteotomies are necessary for tumor extirpation, replacement at the conclusion of the case affords no significant deformity. However, in cases where significant bony loss occurs, bone grafting with rigid fixation historically was utilized to restore such defects. Resorption and imperfect alignment of bone grafts (iliac crest, rib, calvaria) have limited aesthetic reproducible and functional results. The slight variability in the three-dimensional (3D) contour of the orbit with flat or slightly curved bone grafts can have a significant aesthetic effect on outcome.

Traditional techniques in alloplast have included application of titanium plates, either standard with intraoperative bending or prebent. Proper fixation of such plates remains a challenge given the narrow operative field. Additionally, while titanium mesh is inert and easily malleable, revision surgery may be challenging given ingrowth of soft tissue. With advancements in computer-aided design technology, 3D printing, and polymer technology, patient-specific implants (PSIs) have been successfully reported in facial reconstruction.[2–9]

Orbital and Frontal Anatomy

The orbital cavity is composed of the following seven bones: sphenoid, frontal, zygomatic, ethmoid, lacrimal, maxilla, and palatine. Its complex anatomical shape is conical but irregular. The orbital apex lies approximately 40 to 45 mm from the medial orbital rim. The thickened bone of the rim provides resistance to traumatic forces, while thinner bones of the walls particularly the medial wall and orbital floor are more prone to fracture. Inferomedially the nasolacrimal canal houses the nasolacrimal duct just posterior to the anterior medial canthal attachments. Posterior to the canal lies the posterior medial canthal attachments along the lacrimal bone. The anterior and posterior ethmoidal arteries enter the orbit along the junction of the frontal and ethmoid bones medially. Whitnall's tubercle marks the protuberance 1 cm posterior to the lateral orbital rim and is the natural attachment of the lateral canthus.

3D Planning

Use of patient-specific 3D printed implants was reported relatively recently, approximately a decade ago. Indications for secondary revision of orbital fractures include presence of diplopia, enophthalmos > 2 mm, restrictive strabismus, hypoglobus > 1 mm, and extraocular muscle entrapment. A review of the primary literature indicates that volumetric differences between affected, or fractured sides, and the contralateral uninvolved sides range between 1.6 to 2.4 cm.[3,10–12] For these reasons, precise correction of the orbital shape is necessary and traditional techniques have led to unpredictable outcomes

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in inexperienced hands. Chepurnyi et al reported high efficacy of PSI for orbital volume in the correction of residual enophthalmos with 0.74 cm^3 mean difference in orbital volumes after surgery with 3.7% incidence of residual enophthalmos.[12]

Much progress toward PSIs arose from refinements in orbital fracture repair. Hoffmann et al reported the first use of individualized glass ceramic implants for orbital reconstruction designed on stereolithographic models in the 1990s, however dismissed routine use of this technology given extensive preparation time necessary.[1] Challenges in intraoperative bending of orbital plates have led commercial companies, such as Stryker (Kalamazoo, MI), Depuy Synthes (West Chester, PA), and KLS Martin (Jacksonville, FL), to produce prebent plates based on averaged geometries of hundreds of patients' orbital scans. Population based prebent implants have been shown to have improved outcomes compared with conventional two-dimensional (2D) implants.[13–16] Huempfner-Hierl et al found that while preformed plates conformed highly to an average orbit, major differences in slope and geometry were noted among companies.[17] Since the take-off of 3D printing, the first report described 3D printing a patient's intact orbit or skull, either mirrored contralateral or reconstituted affected side followed by manual adaptation of a titanium plate to the patient-specific mold.[18,19]

A barrier to wider acceptance of PSI use in isolated orbital fractures as discussed by Mahoney et al is that outcomes of isolated orbital fracture repair without navigation are already excellent and the benefits of custom implants requires further study to justify the cost associated with the technology.[20] Commercial companies now offer planning sessions and fabrication of implants based on preoperative computed tomography (CT) scans with relatively quick turnaround. The utilization of these implants in combined defects of the orbit and frontal bone may be more justified given the anatomic complexity of the defect; however, studies are lacking and limited to some case reports.[21,22]

Implant Material

Alloplastic materials have been well accepted for the treatment of calvarial defects. Xenografts, autografts, and various metals and alloys such as aluminum were used initially. Acrylics, such as methyl methacrylate, are the most widely used material.[23] Hydroxyapatite has also been utilized alone or in combination with titanium mesh with decreased tissue reactions and osseointegration. More recently, polyetheretherketone (PEEK) is a polymer with ideal alloplastic properties: nonconductive, biocompatible, and stable in the setting of long-term exposure to bodily fluids, elasticity is similar to native cortical bone, and light material makes it suitable for even large defects. In the era of 3D printable technologies, PEEK has become popular for PSI. One of the advantages of PSI in frontal cranioplasty not discussed in the orbital reconstruction literature is the decreased risk of progressive scalp thinning over the entire area of the mesh reported by multiple authors and hypothesized by Yoshioka and Tominaga as atmospheric and intracranial pressure fluctuations.[24–26]

Operative Technique

The senior author (Y.D.) prefers approaching the orbital floor for PSI placement through a transconjunctival retroseptal approach. The implant is slid along the floor and fixated with one monocortical screw along the floor just beyond the orbital rim to avoid palpable hardware. See ►**Fig. 1(A–F)** for patient case examples. Approach to fronto-orbital cranioplasty is typically performed from a coronal incision as per the senior author. When the frontal sinus is violated, either obliteration or cranialization is generally necessary with plugging of the frontal sinus outflow tract with temporalis muscle. The anterior skull base is reconstructed with a pericranial flap if available to completely seal off the intracranial and upper aerodigestive tract. Other regional or free tissue transfer may be necessary to accomplish. A titanium mesh construct is molded intraoperatively to fit the approximate shape of the fronto-orbital bony

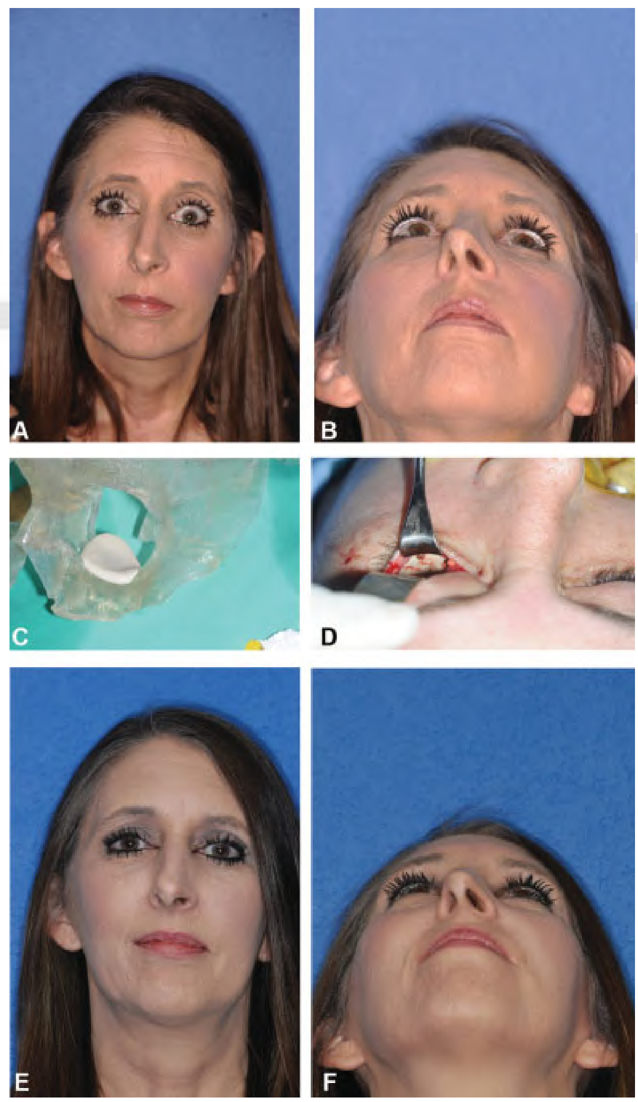

Fig. 1 (**A**) Patient with left enophthalmos (preoperative frontal view). (**B**) Same patient in the preoperative basal view. (**C**) PEEK orbital floor implant was designed based off preoperative CT scans. (**D**) Intraoperative placement of PEEK implant via the transconjunctival retroseptal approach. (**E**) Six-month postoperative frontal view with improved enophthalmos. (**F**) Six-month postoperative basal view. CT, computed tomography; PEEK, polyetheretherketone.

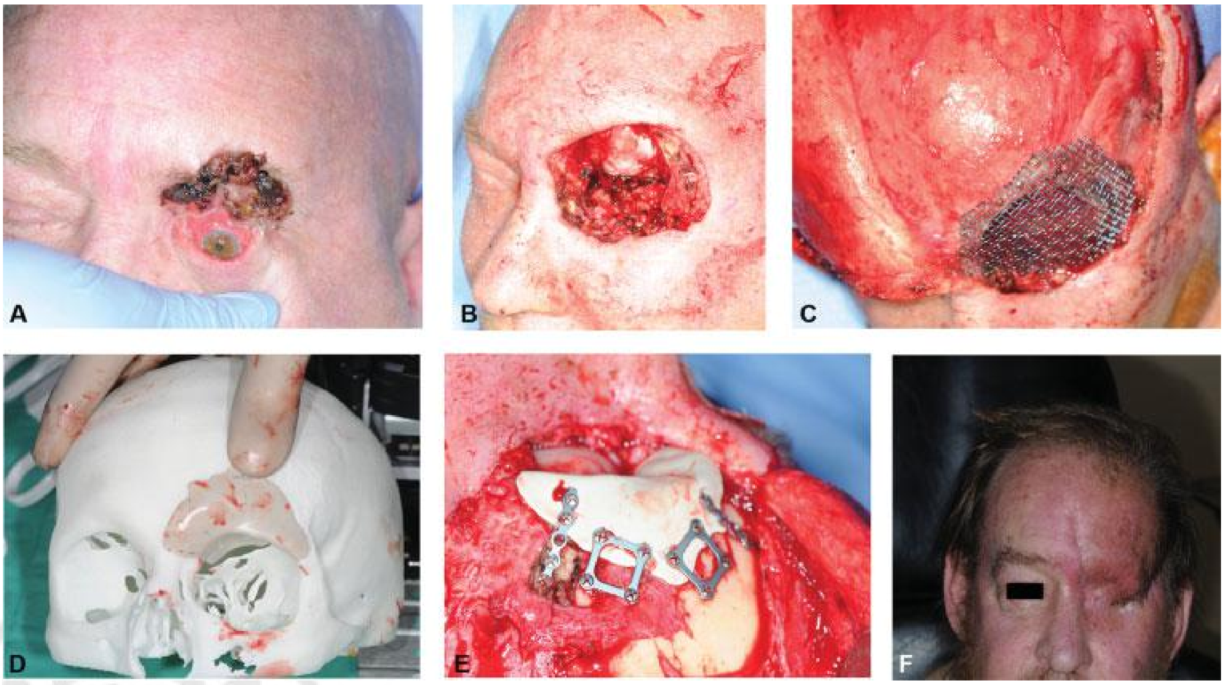

Fig. 2 (**A**) Patient with cutaneous malignancy involving the left upper brow invading the eye. (**B**) Same patient who underwent exenteration with fronto-orbital craniotomy, and free tissue transfer. (**C**) Interim cranioplasty with titanium mesh was performed. (**D**) Several weeks following initial reconstruction, the patient undergoes titanium mesh removal, definitive cranioplasty with PEEK implant as a second stage. (**E**) PEEK implant secured with miniplates. (**F**) Postoperative outcome with aesthetic superior orbital rim contour. PEEK, polyetheretherketone.

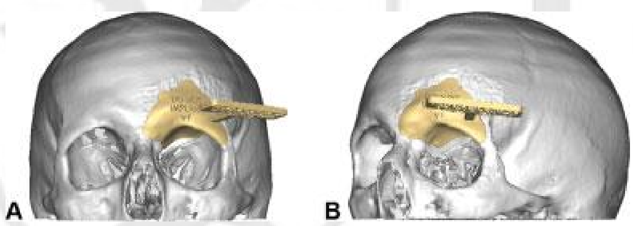

Fig. 3 (**A**) Postoperative CT scans following titanium mesh placement for the previously discussed patient utilized for PSI implant fabrication (fontal view). (**B**) Oblique view with planned PSI implant. CT, computed tomography. PSI, patient-specific implant.

defect and secured to the surrounding bone with monocortical screws. The coronal flap is draped over the cranioplasty and incision is closed with drains that are removed just before discharge from the hospital, typically just a few days postoperatively if course is uncomplicated. Should frontal or orbital overlying soft tissue be removed for tumor ablation, regional or free-flap reconstruction may be indicated. See ►**Fig. 2(A–F)** for patient case. Immediate postoperative CT scan is obtained with 1 mm thick cuts through the craniotomy defect and utilized for virtual surgical planning (VSP) of PSI (see ►**Fig. 3A, B**). Following healing of the soft tissue envelope, typically 8 weeks postoperatively, the patient is brought back for removal of mesh cranioplasty followed by implantation of PSI. PSI is secured to the surrounding bone with several miniplates and monocortical screws.

Outcomes

Outcomes of PSI are still emerging. Isolated orbital PSI results demonstrate efficacy in enophthalmos repair with a residual rate of 3.7% as per Chepurnyi et al.[12] Additional benefits are reported as decreased durations of surgery. No randomized trials are available to compare PSI and existing prebent plates or standard 2D plates bent intraoperatively. Additionally, the indications for PSI are controversial and have been utilized for primary repair as well as secondary or tertiary trauma. Strong et al found no difference in volume restoration among PSI implants, titanium mesh sheeting manually bent, and preformed titanium mesh in a cadaveric study. PSI had the greatest contour accuracy but poor ease of use and highest cost compared with preformed mesh implants, which had excellent ease of use, low cost, and intermediate accuracy.[27]

Several limitations to 3D implants include the prohibitive cost in some areas in the world. Access to these technologies is available commercially, but professionally made custom implants can cost over $10,000 depending on the size and material of the construct. Researchers have reported on use of a low-cost 3D printer to make PSI cranioplasty molds.[28] Callahan et al reported a low-cost 3D printing of orbital implant templates for secondary orbital reconstruction.[29] These workarounds may decrease the economic burden on the health care system but the increased turnaround time of implant design and preoperative planning and fabrication investment by the surgeon may be prohibitive for routine utilization for many.

When bony defects of the fronto-orbital region necessitate extensive bone grafting, PSI alloplastic options have the benefit of significantly decreased operative times and improved aesthetic contour as well as lack of donor-site morbidity. Secondary reconstruction of orbital cavities can be particularly difficult due to malunion of prior fractures, scarring, and loss of anatomic landmarks.[30] In these challenging cases, PSI may be of significant benefit as VSP may offer more precise and predictable results. While the technology of VSP has shifted the focus of surgery from intraoperative adjustment to preoperative digital workflow, widespread utilization and acceptance of this are dependent on surgeons' familiarity with such a technology. Further studies are necessary to assess the cost–benefit analysis of this emerging technology.

Conclusion

With advances in 3D printing technology, PSI is beginning to revolutionize surgical reconstruction for orbital and frontal bone defects. Preoperative workflow is leading to decreased operative times and improved aesthetic contours with precise and predictable postoperative results. Its role at present is not properly elucidated and may be limited to secondary reconstruction of complicated defects. Cost–benefit analyses are needed.

Conflict of Interest
None.

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