Single-Step Resection and Reconstruction Using Patient-Specific Implants in the Treatment of Benign Cranio-Orbital Tumors

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Purpose: The aim of this study was to evaluate surgical outcomes using patient-specific prostheses produced by computer-aided design and manufacturing for primary reconstruction in patients with benign cranio-orbital tumors. Polyetheretherketone was used to manufacture the implants.

Materials and Methods: The present study included 3 patients who underwent fronto-orbito-pterional craniotomy using individual custom-made surgical guides. Patient-specific polyetheretherketone prostheses were used for reconstruction during the same surgery. All patients underwent esthetic examination (facial and orbital symmetry, globe projection and position), ophthalmologic examination (diplopia with the Hess-Lancaster test, visual field and acuity), and radiologic evaluations (computed tomography and magnetic resonance imaging) during the preoperative and follow-up periods. Operating time and short- and long-term complications were recorded.

Results: The immediate and long-term morphologic results were satisfactory; in particular, ocular globe position and projection were correct. After 25 to 31 months, none of the patients developed implant-related complications, such as infection, extrusion, or malposition. Two-year postoperative computed tomograms and magnetic resonance images showed no recurrences.

Conclusion: Single-step resection and reconstruction with computer-aided designed and manufactured implants is a challenging new technique that decreases operative time and morbidity. The implants adequately restore an anatomically complex area with satisfactory cosmetic results.

Benign lesions of the cranio-orbital region require resection followed by reconstruction for cerebral and orbital protection. Restoration of anatomic and functional cranial and orbital contouring represents a challenge for the surgical team when attempting an appropriate cosmetic repair. The natural curvature of the orbital rims and frontal convexity are difficult to re-create precisely.

An appropriate reconstruction of orbital walls is needed to restore correct globe position and prevent postoperative restriction of extraocular muscles.1-4 Several materials and different techniques have been used to reconstruct the cranio-orbital bone defect in a cosmetically sufficient manner, including autograft bone, allograft bone, xenograft bone, and bone substitutes.5-20 Each material has advantages and
disadvantages, and the search for an ideal calvarial replacement continues. Since 1995, improvements in medical imaging and computational modeling have allowed the development of various computer-aided prefabricated patient-specific implants (PSIs). In delayed (secondary) reconstruction procedures, PSIs enable excellent functional and cosmetic results with a shorter operating time. In single-step (primary) resection and reconstruction procedures, the transfer of a treatment plan to an intraoperative site depends on the experience of the individual surgeon.

Computer-designed prostheses have been made of titanium, methylmethacrylate, hydroxyapatites, porous polyethylene, hard tissue replacement polymethylmethacrylate-polyhydroxyethyl-calcium hydroxide-coated patient-matched implants, and polyetheretherketone (PEEK).

In this report, the authors describe the surgical planning and technique and esthetic and functional outcomes of custom-made prefabricated PEEK PSIs (Synthes Maxillofacial, Oberdorf, Switzerland) using computer-aided design and computer-aided manufacturing for primary reconstruction in patients with cranio-orbital tumors.

**Materials and Methods**

From June through December 2010, 3 patients with benign cranio-orbital tumors underwent combined maxillofacial and neurosurgical treatment at the Division of Maxillofacial Surgery and Division of Neurosurgery, San Giovanni Battista Hospital, University of Turin (Turin, Italy; Table 1). In all cases, PEEK implants were used successfully for cranio-orbital reconstruction during the same surgical procedure.

All patients gave their written informed consent. This study was performed in agreement with the local institutional review board. This study followed the Declaration of Helsinki guidelines.

### Table 1. DETAILS OF PATIENTS WHO UNDERWENT SINGLE-STEP RESECTION AND CRANIO-ORBITAL RECONSTRUCTION WITH PREFABRICATED COMPUTER-AIDED DESIGNED AND MANUFACTURED PEEK IMPLANTS

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yr)/Gender</th>
<th>Signs/Symptoms</th>
<th>Diagnosis</th>
<th>Site</th>
<th>PEEK Implant and Cutting Guide: Site and Shape</th>
<th>PEEK Implant: Site and Shape</th>
<th>Follow-Up (mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>54/F</td>
<td>exophthalmos, dystopia</td>
<td>meningioma (WHO grade I)</td>
<td>right anterior-middle skull base: roof/lateral walls of orbit, great sphenoid wing, temporal bone, frontal bone</td>
<td><img src="image1" alt="3D Model" /></td>
<td><img src="image2" alt="3D Model" /></td>
<td>31</td>
</tr>
<tr>
<td>2</td>
<td>56/M</td>
<td>exophthalmos, proptosis, diplopia, slight visual impairment (40/100)</td>
<td>meningioma (WHO grade I)</td>
<td>right anterior skull base: roof/lateral walls of orbit, anterior clinoid, lesser sphenoid wing, temporal bone, frontal bone</td>
<td><img src="image3" alt="3D Model" /></td>
<td><img src="image4" alt="3D Model" /></td>
<td>29</td>
</tr>
<tr>
<td>3</td>
<td>46/F</td>
<td>dystopia, right roof orbit swelling</td>
<td>hemangioma</td>
<td>right: roof wall orbit, frontal bone</td>
<td><img src="image5" alt="3D Model" /></td>
<td><img src="image6" alt="3D Model" /></td>
<td>25</td>
</tr>
</tbody>
</table>

Abbreviations: F, female; M, male; PEEK, polyetheretherketone; WHO, World Health Organization.

* Three-dimensional models based on data from computed tomograms (green, cutting guide; red, custom-made implant).

1 Three-dimensional models based on data from computed tomograms (red, custom-made implant).
All patients underwent clinical examinations during the preoperative period. Facial and orbital symmetry, globe projection and position, visual acuity, and diplopia were recorded. Results of the Hess-Lancaster test and digital visual field were obtained. Preoperative radiologic evaluations included computed tomography (CT) and magnetic resonance (MR) imaging with and without gadolinium enhancement.Operating time and short- and long-term complications were recorded.

POSTOPERATIVE FOLLOW-UP PERIOD

All patients were followed with standardized serial clinical and radiologic examinations (mean, 28.3 months; range, 25 to 31 months). Follow-up appointments were scheduled every week in the first postoperative month, every month in the first year, and then every 3 months.

Standardized clinical evaluation consisted of esthetic evaluation (facial and orbital symmetry, globe projection and position) and ophthalmologic evaluation (diplopia with the Hess-Lancaster test, visual field and acuity). The esthetic results were listed as poor (major defects were present, evident to the patient, no operation required), or satisfactory (almost no defects present, the patient and the surgeon satisfied with the result).

Axial, coronal, and 3-dimensional (3D) CT scans were taken immediately postoperatively; 1 and 2 years later, CT and MR imaging with and without gadolinium enhancement were repeated.

SURGICAL PLANNING

Spiral CT datasets (Somatom Sensation 16 scanner, Siemens, Erlangen, Germany), with 16 × 0.75 collimation, 0.55-pitch increment, 1-mm slice thickness, and 0° gantry tilt, were acquired for preoperative planning and surgery on a computer.

Images in Digital Imaging and Communications in Medicine format were sent by compact disk to the manufacturer (Synthes Maxillofacial) for processing. The 3D CT images were returned by the Web to the surgeon with software that allowed rotation, cropping, and manipulation of the images.

In a Web conference with the engineer, the surgeon simulated on the computer screen the osteotomies for planned tumor resection.
A custom-made implant was designed, taking into account the individual anatomy of the patient. Once the virtual planning was completed, custom-made surgical guides for the planned resection were designed. These patient-specific surgical guides aided the transfer of the virtual planned craniotomy to the operating field, allowing reconstruction with a perfectly matching custom-made implant for shape and size. The surgeon reviewed and approved the guides.

Surgical guides and implants for reconstruction were produced using rapid prototyping technologies. Then, the custom-made prefabricated PEEK implants and surgical guides were returned to the surgeon for further approval or additional editing. If satisfactory, a nonsterile prefabricated PEEK implant and cutting guides were delivered and sterilized by heat at the authors’ hospital facility.

Results

The patients’ demographic and pathologic features are presented in Table 1.

All patients underwent a coronal flap procedure. Fronto-orbito-pterional craniotomy was performed by the maxillofacial and neurosurgical teams using the individual custom-made surgical guides as a template for the bone flap.

In patients 1 and 2, temporary orbito-zygomatic osteotomies were performed to allow greater reflection of the temporalis muscle. The zygoma was left pedicled to the masseter muscle. This was useful for improving access for the pterional craniotomy and for orbital lateral wall osteotomy, according to the surgical guides. After completion of the neurosurgical procedure and fixation of the implants, the osteotomized zygoma was fixed with miniplates.

In each patient, the scalp was elevated carefully; the tumor and dysplastic bone were removed, taking great care to avoid injury to the orbital contents, and were sent for histologic analysis. An intraoperative navigation system (VectorVision Cranial 7.8, BrainLAB AG, Heimstetten, Germany) was used during the operation to check for deep tumor resection margins and to preserve vital structures.
In patient 2, the skull base approach allowed extradural optic canal unroofing and optic nerve decompression, without any morbidity.

In patient 3, the resection included the lateral aspect of the frontal sinus, which was preserved and sealed with a pericranial flap. On postoperative day 7, a cerebrospinal fluid leak was noted and the patient underwent a second surgical intervention. Abdominal fat was harvested and used directly on the dura, over the pericranial flap.
The frontal sinus was preserved. The cerebrospinal fluid leak ceased and no other complications were registered.

The implant was checked for fit and then fixed with 2.0-mm titanium miniplates and screws. If necessary, contouring was performed using a high-speed drill with a cutting burr. The pericranial flap was used as a watertight seal to protect the dura and the implant. The dura was secured to the implant, which had premade holes, to prevent epidural hematoma formation. One drainage tube was placed and the skin was closed in a 2-layer fashion.

During the immediate postoperative period, all patients complained of some degree of diplopia. This resolved spontaneously within 1 month. The vision of patient 2 recovered from 40/100 to 70/100. The postoperative course was uneventful from a reconstructive standpoint, with no implants requiring removal because of infection.

FIGURE 2 (cont’d). Patient 2. C, Reconstruction with polyetheretherketone patient-specific implant perfectly fits the bone defect. t, temporal muscle.


FIGURE 2 (cont’d). Patient 2. D, Postoperative 3-dimensional computed tomogram shows good reconstruction.

The immediate and long-term morphologic and esthetic results were satisfactory in all 3 patients. In particular, ocular globe position and projection were correct. Postoperative CT scans showed that PEEK PSIs re-established correct orbital rim and wall morphology (Figs 1 through 3).

Postoperative CT scans and MR images showed no recurrences 2 years later.

Discussion

Cranio-orbital reconstruction after tumor resection can prove challenging from technical and esthetic standpoints. Reconstruction of the bone defect during the same surgical procedure is a complex procedure, especially for large defects or defects involving the fronto-orbito-temporal region.\(^{13,20,30}\) However, primary reconstruction has been suggested to provide biomechanical stability, cerebral protection, optimal cosmetic results, and landmarks for postoperative imaging.\(^{32,38}\)

The problem of finding the ideal material and technique for craniofacial reconstruction has been addressed in several publications and numerous solutions have been proposed, with acceptable results.\(^{4,39}\)

In patients with defects involving esthetically relevant regions, such as the convexity of the frontal bone and the orbital rims, the use of autogenous tissue for primary reconstruction is particularly complex because of the amount of donor tissue needed and the increased difficulty and time required for shaping bone or alloplastic grafts.\(^{1,2,19,20,33}\)

Computer-designed alloplastic implants have revolutionized the conceptualization and approach to complex cranioplasty and have become a reliable alternative. These implants have the advantage of being preoperatively tailored to the exact size of the cranial defect, thus allowing a shorter operating time, improved postoperative stability, and incomparable cosmetic results.\(^{21-33}\)

If a primary reconstruction procedure is planned, determining the tailoring of the approach and the exact size of the craniotomy is the main difficulty. It is of the utmost importance to ensure that the planned defect corresponds to the true defect, so that the custom implant correctly fits into the defect.
The implants in the present study were patient specific and custom generated by validated software that allowed mirroring of the contralateral uninjured fronto-orbital region. The advantages of an implant generated with mirroring procedures, in terms of esthetic reconstruction and shorter operating time, are maintained only if minor intraoperative revision of the implant is needed.

In the present series, the preoperative determination of the craniotomy and orbital resection size was performed virtually using 3D CT images, whereas Eppley et al., Eppley, Vougioukas et al., and Pritz and Burgett reported planning of the resection on stereolithographic models. In accordance with Eppley, the authors suggest that the estimation of the amount of bone to be excised be generous to avoid a time-consuming procedure of bridging gaps between the implant and bone resection edges in case of underestimated osseous infiltration. Transfer of the preoperative plan to the operative field is the key to success.

In this case series, the authors used computer-generated cutting guides for the exact guidance of craniotomy and orbital rim resection. These cutting guides must be solid and must fit in a precise position on the skull. To have a precise fit and stability of the template, the authors planned cutting guides with arms within the orbit for 1 cm around the bony rims (Fig 4). Other investigators have used different methods, such as navigation-guided craniotomy, rubber, or aluminum templates fixed to the skull with bone and screws.

The deep resection margins for sphenoid wing meningiomas near the orbital apex were determined with the help of intraoperative navigation and by the individual skills of the surgeon.

In this series, the planned margins of the craniotomy were adequate and only minor adjustments of the implants and bone edges were necessary. In all cases, fixation of the implant required less than 30 minutes. A shorter operative time was achieved and morbidity related to the reconstruction procedure was minimal.

The Web conference for planning required approximately 1 hour and the entire planning process lasted 20 to 35 days.

The use of PEEK implants for cranio-orbital reconstruction after tumor resection has been documented in the literature. Before the introduction of PEEK implants for craniofacial reconstruction, the
FIGURE 4. Cutting guides are built with arms around the orbital rims to fit in a precise position on the skull. Arms help to orient the position of the template (green, cutting guide; red, custom-made implant; blue, tumor).


FIGURE 5. Patient 1. A, B, Preoperative facial views of right exophthalmos and dystopia. (Fig 5 continued on next page.)

major medical use of PEEK was in vertebral fusion cage implants and hip replacement implants.\textsuperscript{41} PEEK is a semicrystalline thermoplastic biocompatible material with numerous physical characteristics that are favorable for use in calvarial reconstruction. PEEK polymers have ideal imaging properties (they are translucent to x-rays and nonmagnetic so they do not create artifacts on CT or MR images, facilitating postoperative diagnostic monitoring), good stiffness, durability, light weight, fatigue and chemical

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\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{d.png}
\caption{Patient 1. D, Intraoperative use of cutting guide to outline the area of resection that matches the size of the polyethere-therketone implant. \textit{t}, temporal muscle; \textit{m}, meningioma; \textit{Or}, right orbit. \textit{(Fig 5 continued on next page.)} Gerbino et al. Treatment of Cranio-Orbital Tumor J Oral Maxillofac Surg 2013.}
\end{figure}
resistance, and can be repeatedly sterilized without degradation of their mechanical properties. Furthermore, their modulus may be adapted to closely match that of cortical bone, which is important to avoid shielding and modulus mismatch against the cortical bone. PEEK implants are also nonallergenic. PEEK is easily contoured with high-speed burrs and easily fixed with a conventional plate and screw system, which are important features for single-step resection and reconstruction procedures.

Lethaus et al\textsuperscript{33} reported that, unlike titanium, the absence of a bioactive potential is the major disadvantage of pure PEEK. A common disadvantage, as for all alloplastic materials, is related to the potential for postoperative infection.\textsuperscript{35-37,41} In the 3 present cases, no infection of the implant was observed. PEEK implant use after infection has been reported in the literature.\textsuperscript{53,56,57}

An important consideration in cranial reconstruction is the frontal sinus. Eppley\textsuperscript{2} reported that any sinus exposure to the defect site likely will result in eventual implant infection. Cranialization of the sinus and exclusion of the frontonasal ducts is strongly advocated.\textsuperscript{1,2} This statement is appropriate in cases in which porous implants, such as methylmethacrylate, hard tissue replacement patient-matched implants, and MEDPOR (Stryker, Kalamazoo, MI), are used.

For titanium implants and meshes and PEEK implants that have no porous structure and are resistant to infections, the authors believe that the interposition of vascularized tissue between the implant and a physiologically aerated sinus system is adequate. For an infected sinus, cranialization and obliteration of the nasofrontal recess is mandatory. In patient 3, the implant was in contact with a pedicled pericranial flap interposed between the implant and the lateral recess of a physiologically pneumatized frontal sinus. No infection has been reported in 2 years of follow-up.

Diplopia occurred in all patients but resolved spontaneously. Diplopia was considered to be caused by a minor imbalance of the extraocular muscles rather than by paralysis of the muscles, which is thought to be caused by tumor displacement, surgical resection, or nerve displacement. The extraocular muscles in the present patients were intact postoperatively. Patient 2, who had slight visual impairment at presentation, recovered his visual loss, as documented by ophthalmologic evaluation. No signs of restricted gaze in the right eye were observed postoperatively.

The esthetic results were satisfactory, with no asymmetries of the orbital rim and cranial convexity. Preoperative exophthalmos was corrected in all patients. In patients 1 and 2, the implants were designed with incomplete reconstruction of the lateral wall, thus simulating a 1-wall orbital decompression (Figs 2C, 5, 6).

In conclusion, there are several advantages of the present technique: 1) the preoperative model allows the surgeon to plan the resection and reconstruction before surgery; 2) single-step resection and reconstruction shortens operative time and decreases morbidity; and 3) the implant accurately restores the complex 3D structure of the resected bone and minimal or no additional adjustments are needed to position it. The use of custom-made implants and cutting guides results in adequate reconstruction of an anatomically complex area, with good functional globe position, satisfactory extraocular muscle function, and excellent postoperative cosmetic appearance. Therefore, this method is indicated in selected cases in which complex reconstruction is required. Conventional methods might be preferable for cost-related reasons when the resected area is small and does not involve a large portion of the orbital rims and walls. Furthermore, the PEEK implants were well tolerated; neither infections of the implant material nor failures were observed in the 3 present cases.

The main limitation of this study is the small sample. More experience and further long-term follow-up studies are needed to evaluate a much larger patient population with better control over the variables. Nevertheless, this specific technique appears to be a promising option for primary reconstruction of cranio-orbital defects after benign tumor resection.

References


