Use of Customized Polyetheretherketone (PEEK) Implants in the Reconstruction of Complex Maxillofacial Defects

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xtensive maxillofacial defects resulting from trauma or oncologic resection present reconstructive challenges. Various autografts and alloplastic materials in conjunction with standard soft-tissue techniques have been used in the reconstruction of these types of defects. Polyetheretherketone (PEEK) is a semicrystalline polyaromatic linear polymer exhibiting an excellent combination of strength, stiffness, durability, and environmental resistance. Recent investigations of PEEK as a biomaterial resulted in the successful treatment of cervical disk disease. We describe a series of 4 patients whose defects were reconstructed using customized PEEK implants. All had excellent postoperative aesthetic and functional results without complications such as infections or extrusions. Because PEEK implants are customizable, easily workable, inert, and nonporous, they represent an ideal alloplastic material for maxillofacial reconstruction. *Arch Facial Plast Surg. 2009;11(1):53-57*

> Numerous autogenous and alloplastic materials have been used in maxillofacial reconstruction. Most commonly, autogenous bone grafts, free tissue transfer, methylmethacrylate, different types of bone cement, or Silastic porous polyethylene (Medpor; Porex Surgical Products Group, Newnan, Georgia) are used for reconstructing such defects. All have associated disadvantages. Autogenous bone grafts and free tissue transfer (eg, fibula osteocutaneous free flaps) exhibit resorption and donor site morbidity.1 Silastic implants and methylmethacrylate can elicit foreign body reactions, resulting in high infection and extrusion rates.² Bone cements such as carbonated calcium phosphate paste (Norian Corporation, Cupertino, California) and hydroxyapatite cement (Mimix; Biomet Microfixation, Jacksonville, Florida) exhibit poor workability and need to be sculpted during surgery to achieve a satisfactory aesthetic result.

> Because of the disadvantages associated with commonly used materials, the search

Author Affiliations: Department of Otolaryngology–Head and Neck Surgery (Drs Kim, Boahene, and Byrne) and Division of Facial Plastic and Reconstructive Surgery (Drs Boahene and Byrne), The Johns Hopkins University School of Medicine, Baltimore, Maryland. for the ideal implant continues. A potential candidate is polyetheretherketone (PEEK). PEEK is a semicrystalline polyaromatic linear polymer that exhibits an excellent combination of strength, stiffness, durability, and environmental resistance. For these reasons, the material has been used in the aerospace, automotive, and electrical industries for more than 20 years.

More recently, the biocompatibility of PEEK has been established,³⁻⁵ and subsequent medical applications of the material have followed. Most prominently, PEEK has shown preliminary success in the treatment of cervical disk disease. Specifically, PEEK has served as a substitute for autogenous bone grafts and titanium cages in anterocervical fusion.⁶⁻¹⁰

Reports of the use of PEEK in the reconstruction of maxillofacial defects have been limited.¹¹ However, we believe that PEEK—coupled with a prefabrication process that can produce patient-specific implants (PSIs)—may represent an ideal strategy in the reconstruction of challenging maxillofacial defects. In addition, because PEEK implants are durable, workable, and biocompatible, the use of the implant may become more popular in the future.

| Patient No./ Sex/Age, y | Primary Disease Process | Defect Description | Time Since Surgery, mo |
|----------------------------|---|------------------------------------|---------------------------|
| 1/F/29 | Esthesioneuroblastoma and resection with multiple failed reconstructions | Orbitomaxillary | 16 |
| 2/M/19 | Blunt trauma from motor vehicle crash | Anterior table of frontal sinus | 14 |
| 3/F/11 | Hemangioma after resection | Superior orbitocranial | 19 |
| 4/F/17 | Blunt trauma from motor vehicle crash | Orbitomaxillary | 20 |

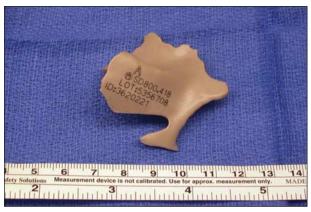


Figure 2. Polyetheretherketone patient-specific implant for patient 1.

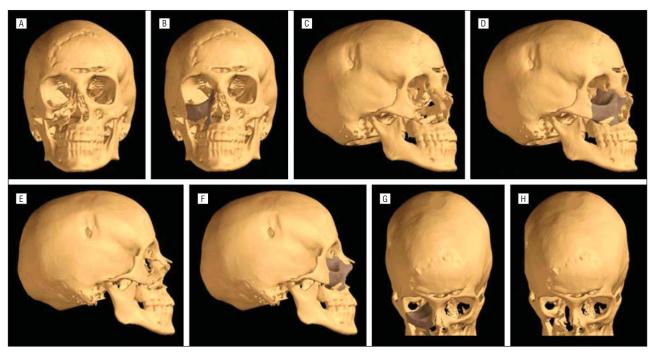


Figure 1. Three-dimensional computed tomographic images of patient 1 using the polyetheretherketone patient-specific implant protocol. A, Preoperative frontal view. B, Frontal view with the proposed implant. C, Preoperative right oblique view. D, Right oblique view with the proposed implant. E, Preoperative right lateral view. F, Right lateral view with the proposed implant. G, Preoperative superior view. H, Superior view with the proposed implant.

METHODS

In 2006, 4 patients with residual maxillofacial defects from trauma or surgical extirpation of neoplasms were evaluated at The Johns Hopkins Hospital, Baltimore, Maryland, by 2 of us (K.D.O.B. and P.J.B.) (**Table**). Based on thorough examinations and review of computed tomographic (CT) images, the patients exhibited maxillofacial defects for which prospective reconstruction posed surgical challenges. As such, the patients were deemed to be candidates for undergoing reconstructive surgery with the use of PEEK PSIs (Synthes CMF, West Chester, Pennsylvania). Informed consent regarding the use of PEEK in their reconstruction was obtained from each patient or guardian.

The patients then underwent imaging using a proprietary 3-dimensional CT imaging protocol.¹² Subsequently, the PEEK PSI was fabricated at the manufacturer's facility and was sent to The Johns Hopkins Hospital. All 4 patients underwent surgical exposure of their maxillofacial defects and had implantation performed. Implants underwent minor intraoperative

modifications and were fixated to surrounding native bone with standard titanium hardware used in facial reconstruction.

REPORT OF CASES

CASE 1

A 29-year-old woman had undergone craniofacial resection of a right facial esthesioneuroblastoma at an outside institution 10 years previously, followed by radiation therapy. Multiple attempts at reconstruction, including the use of split calvarial bone grafts, failed. She was initially seen at our clinic for evaluation of persistent facial asymmetry. On physical examination, the patient had significant right maxillary hypoplasia, enophthalmos, and mild hypoglobus. Glabellar depression and alar retraction were also present as a result of her previous operations. Palpation revealed a significant lack of

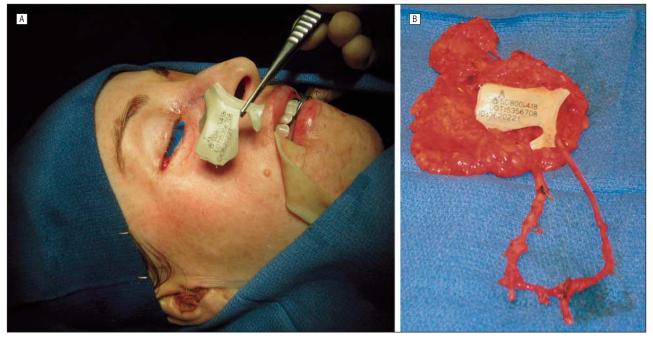


Figure 3. Intraoperative views of patient 1 before polyetheretherketone (PEEK) implantation. A, Preimplantation view with the PEEK implant in the correct position. B, PEEK implant with the radial forearm free flap.

bony structure of the right inferomedial orbital rim and floor. Computed tomographic images confirmed these findings, and magnetic resonance imaging revealed an inadequacy of overlying soft tissue. Therefore, the decision was made to perform free tissue transfer in conjunction with a PEEK PSI. The patient underwent the PEEK PSI CT protocol (**Figure 1**), with subsequent implant fabrication (**Figure 2**).

Surgical exposure of the defect was obtained through a combined transconjunctival (with lateral cantholysis) and sublabial approach. The PEEK PSI was slightly modified and then fixated using standard plating techniques. Subsequent additional soft-tissue coverage was obtained through the use of a radial forearm fascial free flap (**Figure 3**). On postoperative day 5, the patient had more than expected facial edema. As a result, she underwent surgical reexploration to rule out a seroma or hematoma that could compromise the free flap. No fluid collection was encountered during reexploration.

Six weeks after surgery, an intranasal examination exhibited a small area of dehiscence. Because of the potential communication between the nose and the implant site, the patient underwent endoscopic debridement and repair of the intranasal dehiscence. The dehiscence was identified and closed using local flap coverage. Subsequent postoperative visits revealed improved postoperative bony and soft-tissue facial contours and decreased enophthalmos (**Figure 4**).

CASE 2

A 19-year-old healthy young man was seen at an outside hospital after being involved in a motor vehicle crash. He was in a coma and required mechanical ventilatory assistance. In addition, the patient sustained nasal fractures and a fracture of the anterior table of the frontal sinus. Repair of his nasal fracture was attempted 5 days later, while the frontal sinus fracture was managed expectantly (observed).

The patient was seen at our institution 5 months later with persistent nasal obstruction, postnasal drip, and a residual depression on his forehead. On physical examination, the patient had a severely twisted nose with significant septal deviation and associated bilateral internal nasal valve stenosis. In addition, he exhibited a depression in the glabella overlying the area of his original frontal sinus fracture. Attempts made to elicit a possible cerebrospinal fluid leak were negative. Subsequent maxillofacial CT images were obtained that confirmed our examination findings and ruled out the presence of skull base fractures or nasofrontal duct trauma. The frontal sinus was well aerated, despite the frontal sinus fracture.

The patient underwent the PEEK PSI CT protocol, with subsequent implant fabrication. Eleven months after the initial injury, he underwent revision septorhinoplasty with major septal repair and cranioplasty using the PEEK implant through a bicoronal incision. After surgery, the patient exhibited improved glabellar contour and nasal patency. He had no signs or symptoms of chronic sinusitis or postnasal drainage.

CASE 3

An 11-year-old girl was born with a hemangioma obstructing the vision of her right eye. Despite undergoing 2 separate operations as an infant to remove the hemangioma, she developed limited right-sided vision. She was seen at our clinic years later because of significant facial scarring and residual facial asymmetry. On physical examination, the right superomedial brow exhibited a palpable and visible bony concavity. A depressed wide scar ran from her

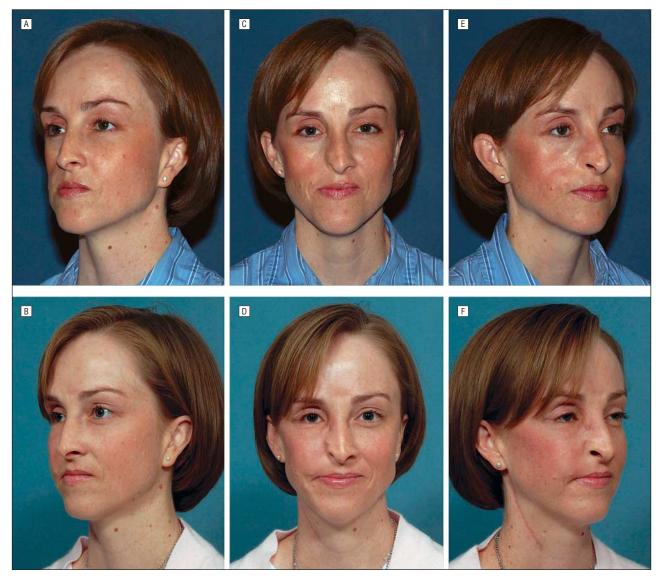


Figure 4. Views of patient 1 before surgery and 6 months after surgery. A, Preoperative left oblique. B, Postoperative left oblique. C, Preoperative frontal. D, Postoperative frontal. E, Preoperative right oblique. F, Postoperative right oblique.

right forehead in a vertical direction toward her eyebrow and continued diagonally in a medial direction to ultimately involve the right medial canthus. This scarring had resulted in significant contracture of her right upper eyelid, with notching and minor lagophthalmos.

The patient underwent the PEEK PSI CT protocol, with subsequent implant fabrication. Surgery was then performed and included scar revision and repair of the right upper eyelid retraction using a full-thickness skin graft obtained from the contralateral upper eyelid. Exposure of the bony defect was performed by softtissue undermining through the scar revision site. Subsequent placement and fixation of the PEEK PSI was performed. A small area of residual deformity was encountered after PEEK implantation; therefore, additional bone cement was applied to improve the reconstructive contour.

Her postoperative visit 4 months later revealed significant improvement of her orbital contour. However, the vertical forehead and eyebrow portion of her scar revision once again healed with a depressed wide scar. Therefore, the patient underwent additional scar revision via geometric broken-line closure 6 months later.

CASE 4

A 17-year-old girl had sustained a comminuted left malar fracture and orbital floor fracture 4 years previously as a result of a motor vehicle crash. At that time, she underwent open reduction and internal fixation of her malar fracture at an outside institution. Orbital floor reconstruction was deferred. The operation was complicated by the development of a postoperative hematoma and infection. Four months later, the patient was seen at our clinic with facial asymmetry, enophthalmos, and clear rhinorrhea suggestive of a cerebrospinal fluid leak. Further examination and a CT image revealed a fracture of the cribriform plate and an injury to the left nasofrontal duct. She subsequently returned to the operating room for orbital floor reconstruction and cerebrospinal fluid leak repair of the anterior skull base. The frontal sinus was also addressed with the use of an osteoplastic flap and obliteration of the frontal sinus using free fascia grafting and bone cement. This was performed through a bicoronal approach.

Despite these reconstructive efforts, the patient returned 4 years later with a persistent relative lack of projection in the left infraorbital region and an overprojection of the left zygomatic arch. The results of the physical examination confirmed hypoglobus and moderate leftsided enophthalmos. Secondary orbitomaxillary reconstruction using a PEEK PSI was offered. The patient was motivated to proceed, and she underwent the PEEK PSI CT protocol, with subsequent implant fabrication.

Implantation of the PEEK PSI was performed without difficulty. Subsequent postoperative visits revealed overall aesthetic improvement in bony and soft-tissue facial contours and correction of enophthalmos.

COMMENT

Maxillofacial defects can result from various conditions, including trauma and following resection of neoplastic disease. Because some resultant defects are complex, surgeons have turned to different autogenous and alloplastic materials to rebuild the support mechanisms of the facial skeleton. All materials exhibit distinct disadvantages, as it is generally accepted that "there is no perfect implant."

In our article, we described a series of patients whose reconstruction included the use of PEEK PSIs. After a follow-up period of 16 to 20 months, none of the patients experienced implant-related complications such as infection, extrusion, or malposition, while all improved with respect to aesthetics or function.

The durable yet malleable physical properties of PEEK as a biomaterial provide surgeons with another material with which complex maxillofacial defects can be reconstructed. The material is durable, yet intraoperative modifications can be performed with ease. In addition, the ability to prefabricate an implant based on the patient's anatomy can result in decreased operative time and a more "accurate" custom fit.

More experience and further studies are needed with this material. However, it appears at first glance that PEEK implants show great promise as another weapon in the reconstructive armamentarium. Accepted for Publication: April 22, 2008.

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