Polyetheretherketone Implants for the Repair of Large Cranial Defects: A 3-Center Experience

BACKGROUND: Calvarial reconstruction of large cranial defects following decompressive surgery is challenging. Autologous bone cannot always be used due to infection, fragmentation, bone resorption, and other causes. Polyetheretherketone (PEEK) is a synthetic material that has many advantages in cranial-repair surgery, including strength, stiffness, durability, and inertness.

OBJECTIVE: To describe our experience with custom-made PEEK implants for the repair of large cranial defects in 3 institutions: San Francisco General Hospital, Hadassah-Hebrew University Hospital, and the National Neuroscience Institute, Singapore.

METHODS: A preoperative high-resolution computed tomography scan was obtained for each patient for design of the PEEK implant. Cranioplasty was performed via standard technique with the use of self-tapping titanium screws and miniplates.

RESULTS: Between 2006 and 2012, 66 cranioplasties with PEEK implants were performed in 65 patients (46 men, 19 women, mean age 35 ± 14 years) for repair of large cranial defects. There were 5 infections of implants and 1 wound breakdown requiring removal of the implant (infection and surgical removal rates of 7.6% and 9.1%, respectively). Two patients required drainage of postoperative hematoma (overall surgical complication rate, 12.7%). Nonsurgical complications in 5 patients included seizures, nonoperative collection, and cerebrospinal fluid rhinorrhea that resolved spontaneously. Overall median patient or family satisfaction with the cranioplasty and aesthetic result was good, 4 on a scale of 5. Temporal wasting was the main aesthetic concern.

CONCLUSION: Custom-designed PEEK implants are a good option for patients with large cranial defects. The rate of complications is comparable to other implants or autologous bone. Given the large size of these defects, the aesthetic results are good.

KEY WORDS: Cranial repair, Cranioplasty, PEEK patient-specific implants

Large decompressive craniectomies are used to treat intractable elevated intracranial pressure as a result of severe traumatic brain injury, stroke, and other pathologies. Calvarial reconstruction of these extended defects remains a challenge. Although autologous bone remains the first choice for repair of the defect, it cannot always be used owing to infection, fragmentation, bone resorption, and other causes. Recently, computer-assisted 3-dimensional modeling has been used to design custom-made synthetic implants for large cranial defects by using materials such as methylmethacrylate, hydroxyapatite, titanium, and others. Polyetheretherketone (PEEK) is a synthetic material that has many advantages in cranial-repair surgery, including strength, stiffness, chemical inertness, and durability. We report our clinical experience at 3 institutions with custom-made PEEK implants for the repair of large cranial defects.

METHODS

The Department of Neurosurgery at 3 institutions (San Francisco General Hospital, Hadassah-Hebrew University Medical Center, and the National Neuroscience Institute, Singapore) participated in this
RESULTS

Sixty-six cranioplasties with PEEK implants were performed in 65 patients. Patient characteristics for all study patients (all 3 centers) are detailed in Table. A good fit of the patient-specific cranial implant to repair the cranial large defect was usually obtained at surgery as demonstrated in Figure 1.

SFGH Series

Twenty-six patients (23 men, 3 women) with a mean age of 38 ± 13 years underwent 27 PEEK cranioplasties at SF GH. In 24 patients, the initial indication for decompressive craniectomy was trauma. Other initial indications for surgery were tumor resection and cerebral abscess. In 24 patients the decompressive craniectomy was unilateral (12 right-sided, 12 left-sided) and in 2 patients bifrontal decompression was performed. Postoperative complications were seen in 5 patients. Three patients presented with signs of infection at the PEEK cranioplasty site, necessitating removal of the implant. In all 3 patients the organism isolated from cultures was methicillin-resistant Staphylococcus aureus (MRSA). One patient presented with an epidural collection that was drained without removal of the implant. One patient was readmitted after cranioplasty with seizure. Of the 3 patients that experienced infection in the SF GH series, 1 patient had a repeat PEEK cranioplasty that was successful and did not result in another infection or other complications.

Hadassah Series

Sixteen patients (9 men, 7 women) with a mean age of 32 ± 15 years underwent PEEK cranioplasty. In 11 patients, the initial indication for decompression was cranial trauma. Other indications included a gunshot wound to the neck with subsequent internal carotid artery infarction, stroke, large intracerebral hematoma from an arteriovenous malformation rupture during pregnancy, and interhemispheric subdural empyema. In 13 patients, the decompressive craniectomy was unilateral (6 right-sided, 7 left-sided), in 2 patients bifrontal, and in 1 patient midline to allow an interhemispheric approach. One patient in the Hadassah series had an epidural empyema necessitating removal of

<p>| TABLE. Characteristics of 65 Patients Who Underwent Cranioplasty With Patient-Specific PEEK Implants* |</p>
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Age</th>
<th>Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Male 46, Female 19</td>
</tr>
<tr>
<td>Initial diagnosis</td>
<td>Trauma</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td>Aneurysm/AVM</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Ischemic stroke</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>ICH</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Abscess/empyema</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Tumor/postbiopsy bleeding</td>
<td>2</td>
</tr>
<tr>
<td>Interval between craniectomy and PEEK cranioplasty, mo, median (IQR)</td>
<td>9 (6-14)</td>
<td></td>
</tr>
<tr>
<td>Length of hospital stay, days, median (IQR)</td>
<td>4 (3-7)</td>
<td></td>
</tr>
<tr>
<td>Mean follow-up after PEEK cranioplasty, mo</td>
<td>24 ± 16</td>
<td></td>
</tr>
</tbody>
</table>

*PEEK, polyetheretherketone; AVM, arteriovenous malformation; ICH, intracerebral hemorrhage; IQR, interquartile range.
the PEEK implant. The offending organism was MRSA. Two patients had other postoperative complications: one with a small subdural hematoma not requiring surgical intervention, and another who presented with CSF rhinorrhea 3 months after PEEK cranioplasty. In this patient endoscopy with fluorescein was performed, but the site of leak could not be identified. The patient was treated with 1 week of lumbar drainage without recurrence of CSF leak during 2 years of follow-up.

National Neuroscience Institute, Singapore Series

Twenty-three patients (14 men, 9 women) with a mean age of 32 ± 6 years underwent PEEK cranioplasty. In 12 patients, the initial indication for surgery was trauma, whereas other indications included bleeding from aneurysm, arteriovenous malformation, hemorrhagic and ischemic stroke, and bleeding after brain biopsy. In 19 patients, the decompressive craniectomy was unilateral (13 right-sided, 6 left-sided), in 3 patients bifrontal, and in 1 patient bilateral. Two patients had their PEEK implant removed, 1 because of infection (MRSA) and another patient because of a CSF leak that required wound revision leading to wound breakdown over the implant. One patient had a postoperative epidural hematoma requiring surgical evacuation with retention of the PEEK flap. Two patients had seizures after cranioplasty.

Complication Rates

The overall infection rate for the PEEK implants was 7.6% (5 of 66 cases). The overall removal rate for the PEEK implant (5 infections, 1 wound breakdown) was 9.1% (Figure 2A). Of the implants removed, 2 were bifrontal (National Neuroscience Institute, Singapore [NNI] series) and 4 were unilateral (SFGH and Hadassah series). The overall rate of postoperative complications requiring surgical intervention (6 removals of implants and 2 postoperative hematomas requiring surgery) was 12.1% (Figure 2A). Of the patients who developed infection only one had postoperative extra-axial hematoma. There was no significant difference in mean age between patients who developed infection (30 ± 8 years) vs those who did not (35 ± 15 years, P = .37). In this series, all infections were due to MRSA, indicating the importance of antibiotic-resistant organisms as an etiological agent of infection in this patient group. The overall rate of

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nonsurgical complications (seizure, nonsurgical hematomas, and CSF leak likely not related to surgery and not requiring surgical intervention) was 7.6% (Figure 2B). There was no 30-day perioperative mortality. Mean follow-up in all study patients was 24 ± 16 months (range, 6–60). During follow-up of up to 5 years following cranioplasty, 2 patients died, all in the SFGH series. One patient died after sustaining another severe traumatic brain injury (TBI) and another of an apparent drug overdose. Seven patients (10.7%) required placement of a ventriculoperitoneal shunt after cranioplasty for treatment of hydrocephalus. No movement of the implant was noted in any patients, and no fractures of implants occurred during follow-up.

We assessed the social status of patients to determine whether social factors may influence the risk of complications after cranioplasty. We were able to assess whether patients had a history of drug use (intravenous drug or cocaine use) and whether they were homeless. In the Hadassah and NNI patient populations, no patients were homeless or had a history of drug use. In contrast, in the SFGH series, 11 patients (42%) had a history of homelessness or drug use. Of the 3 patients that sustained infections after PEEK cranioplasty in the SFGH series, 1 patient had a history of drug use. This finding does not indicate that homelessness or drug use is a statistical predictor of infection.

Patient Satisfaction and Aesthetic Results

We assessed patient satisfaction with the PEEK cranioplasty by oral interview and structured questionnaire. The overall satisfaction, the patient assessment of the aesthetic result, and an evaluation of temporal wasting were assessed on a scale 1 to 5.

We obtained follow-up in 53 patients. Overall satisfaction with the cranioplasty in 37 patients who self-reported was 4 or 5 in 81% of patients, whereas 16% rated neutral, and 1 patient (3%) was very dissatisfied (Figure 3). In those patients whose neurological condition precluded response, the primary caregiver, usually the closest family member, answered this question. In these 16 cases, 56% were very satisfied, 25% were somewhat satisfied, 1 (6%) was neutral, and 12% were very dissatisfied (Figure 3). Satisfaction with the cosmetic results of cranioplasty was rated as very satisfied (47%) or somewhat satisfied (37%) by 84% of respondents, but 12% and 4% of respondents, respectively, were neutral or somewhat dissatisfied with the cosmetic results of surgery. However, temporal wasting was a concern that was at least mildly distressing in 14 of 47 (30%) patients or family members who responded to this question. Eleven patients (16.9%) reported some degree of neurological improvement after cranioplasty.

DISCUSSION

Our results indicate that cranioplasty with PEEK implants is a good option for patients with large cranial defects. Given the large size of most of these defects, the aesthetic results are good and the rate of complications is comparable to other implants or autologous bone reported in recent large series. Rates of complications following cranioplasty for large cranial defects are much higher than in other elective neurosurgical procedures. In a recent large series of 280 patients who underwent cranioplasty with autologous bone after large decompressive craniectomy mostly following TBI, stroke, or subarachnoid hemorrhage, Schuss and colleagues reported an overall complication rate of 16.4%. Gooch et al. reported a series of 62 patients that underwent cranioplasty following decompressive craniectomy and found that complications requiring surgical intervention occurred in 14.7% of cases. Chang et al. reported on 212 patients who underwent cranioplasty with either autologous bone or allograft with an overall complication rate of 16.4%. In that series those patients that had cranial repair with allograft had a higher rate of infection (18.4%) than those who underwent cranioplasty with autologous bone. Goh et al. reported on 31 patients who had custom-made methylmethacrylate implants for cranial repair after failed cranioplasty with autologous bone, reporting a surgical complication rate of 12.1% and an infection rate of 9.7%. Wiggins et al. reported a series of 127 cranioplasties with custom-made titanium implants in 113 patients who had undergone bifrontal craniectomy or unilateral decompressive hemicraniectomy and found an infection rate of 16%. The large size of the implants needed for cranial repair following decompressive craniectomy may contribute to the relatively high rates of infection observed in most series.

Most previous studies of cranioplasty after large decompressive craniectomy have not detailed the organisms responsible for infection. An important finding of this study is that all infections in this series were caused by an antibiotic-resistant S. aureus (MRSA). This finding is somewhat surprising since...
infections in other cranial operations that involve implantation of a foreign body, such as insertion of a ventriculoperitoneal shunt, are usually caused by skin pathogens such as *Staphylococcus epidermidis*. However, patients that undergo cranioplasty following decompressive craniectomy are different, because all have, by definition, undergone previous hospitalization. Many endured a long hospital course or multiple hospitalizations that included infectious complications treated with antibiotics, increasing the risk of subsequent colonization with antibiotic-resistant organisms such as MRSA. MRSA commonly colonizes the respiratory tract, open wounds, intravenous catheters, or the urinary tract of hospitalized patients previously exposed to antibiotics. Interestingly, Goh and colleagues' study of 31 patients operated on over a 10-year period who underwent cranioplasty with customized fabricated implants after failed cranioplasty also found that, in all 3 cases of infection, the pathogen isolated on culture was *S. aureus*. However, the authors did not report the antibiotic resistance profile of the offending organism. Cheng and colleagues' reported a series of 84 cranioplasties in 75 patients with either autologous bone or polymethylmethacrylate and reported 9 infections (10.7%). They provide detailed microbiological data in 7 of these 9 cases. The most common organism isolated from the wound culture was oxacillin-resistant *S. aureus*, found in 3 cases. Other organisms cultured were coagulase-negative *Staphylococcus*, *Enterobacter cloacae*, and *Pseudomonas aeruginosa*, each isolated in 1 case, whereas in 1 case no organism was identified on culture. Our findings together with those of Cheng et al suggest that consideration should be given to obtaining preoperative culture swabs in select patients scheduled for cranioplasty such as those that have endured a long hospital course or have had previous serious infections treated with antibiotics. In patients found to be colonized with MRSA or other resistant organisms, one may consider either delaying the cranioplasty or administering an antibiotic appropriate for resistant organisms (such as vancomycin in the case of MRSA) for preoperative prophylaxis. The rate of seizures observed after cranioplasty (4.5%) is also notable. Prospective studies to examine whether antiseizure prophylaxis should be given in the immediate postoperative period after cranioplasty would be clinically useful.

PEEK is one of several materials available for repair of cranial defects utilizing 3-dimensional reconstruction, including methylmethacrylate, hydroxyapatite, and titanium. All prefashioned patient-specific implants have the advantage of providing a good fit for the calvarial defect. Like methylmethacrylate and hydroxyapatite, PEEK is translucent to x-rays and nonferromagnetic so that it does not produce artifacts on postoperative CT or magnetic resonance imaging. PEEK has the advantage of being compatible with self-tapping titanium screws and plates, allowing for firm and stable fixation to the cranium. Notably, in our series no patient had loosening or movement of the implant and no fractures of the implant occurred. Fractures of hydroxyapatite implants have been reported and the strength of PEEK is an important advantage in this respect. Previous series reporting on PEEK implants for cranioplasty have been small. Hanasono et al described 6 cases in which PEEK implants were used to repair large cranial defects without any infectious complications and with good aesthetic results. Scolozzi et al reported one case of PEEK cranioplasty without complications. Our series presents data from different institutions with a varied patient population and different etiologies as the original indication for surgery. Overall, the large majority of patients (75%) had a decompressive craniectomy performed owing to trauma, but other etiologies including stroke, hemorrhage, and infection were also among the indications for the initial surgery. Interestingly, when infection did occur, the most common organism responsible was MRSA. This finding underscores the importance of antibiotic-resistant organisms that are likely hospital acquired in the etiology of postsurgical infections that involve synthetic implants. Future efforts need to focus on preventing infections with nosocomial organisms. The highest rate of infection was seen in the SFGH series (11.1%). The patient population in this series had high rates of homelessness and drug use (42%), but we did not find that these parameters were a direct predictor of infection. Although there was no perioperative mortality, 2 patients in the SFGH series (both with a history of drug use and homelessness) died at long-term follow-up, 1 of a repeat TBI, emphasizing the risks to this patient population.

Although the rating scale used to rate satisfaction with PEEK cranioplasty is a simple ordinal scale and is limited by the lack of any previous validation, the results seem to indicate overall satisfaction with the aesthetic results of cranioplasty. However, the results also indicate that temporal wasting is a concern for patients and family members. In patients who return to good functional capacity, this can be a cause for distress due to issues of appearance to others and self-perception. The degree to which temporal wasting may affect overall patient satisfaction with the aesthetic results of cranial repair surgery has not been well addressed in the literature and deserves further study. Although 3-dimensional construction of a synthetic implant can account extremely well for the cranial bony defect, it does not offset for lack of symmetry in the soft tissues. Unfortunately, current technology does not allow for the design of implants that can compensate for soft-tissue asymmetry. Technological advances that would aid in designing implants with true 3-dimensional symmetry would be a welcome step forward and should be a goal of future developments in implant design.

In 2 institutions in this series (SFGH and Hadassah), PEEK implants were usually used when a previous cranioplasty resulted in infection of the patients native bone flap, bone resorption occurred, or the initial injury resulted in a fragmented or an obviously infected bone flap. At the NNI, local regulations prevent storage of biological materials, thus preempting the use of autologous bone for cranioplasty. Given the comparability of our observed infections with those reported in the literature for autologous bone cranioplasties of similar size, and given that the use of autologous bone is less costly, we feel that the use of PEEK...
patient-specific implants should generally be reserved for those patients for whom the autologous bone is not available or not suitable for implantation.

Limitations

This is an observational study that retrospectively analyzes prospectively collected data that have several limitations. Despite pooling data from 3 centers, the number of patients is still too small to determine specific risk factors for infection after cranioplasty with PEEK. We did not include a direct comparison with an autologous bone cranioplasty series in our study, because it was not our intention to perform a case-control study. Such a comparison would be inherently limited by the fact that many patients in the SFGH and Hadassah series underwent cranioplasty with PEEK patient-specific implants after the failure of autologous bone cranioplasty, whereas patients at the NNI do not undergo autologous bone cranioplasty because of regulatory restrictions. In addition, no comparison was made to cranioplasty with other materials used for patient-specific implants. A cost-benefit analysis of the various implants currently available for cranial repair surgery would be a helpful addition to the literature. Ideally, a randomized controlled trial of these implants and autologous bone could determine which material is best suited for the repair of large cranial defects.

CONCLUSION

Patient-specific PEEK implants are a reasonable option for repair of large cranial defects but should not replace the use of autologous bone when it is available. Rates of complications are comparable to those reported with other implants, and overall aesthetic results are good. Temporal wasting is the main aesthetic concern after cranioplasty.

Disclosures

Dr Manley has taught at Neurotrauma courses sponsored by the Synthes Corporation for which he has received honoraria. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

REFERENCES


Acknowledgment

The authors thank Mathieu Laroche, MD, MSc, FRCS(C), for providing the intraoperative image.

COMMENTS

This article is important and interesting for a number of reasons. It is the largest series of PEEK cranioplasties performed to date, having pooled results from 3 neurosurgical centers. It is noteworthy and reassuring that they found a complication rate similar to that described for cranioplasty performed with the patients’ native bone. The authors’ recognition of the high rate of perioperative seizures and recommendation to consider seizure prophylaxis is also noteworthy. Likewise, the fact that MRSA was the sole organism responsible for postimplantation infections is important—although this was consistent with previous reports, it was surprising to me given the preponderance of S. epidermidis in shunt-related infections. Last but not least the authors have devised a pair of simple rating scales that may have utility in future research.

In my opinion, the major question related to these custom implants is whether their precise fit leads to a cosmetic result that is clearly superior in the context of the unavoidable temporalis wasting that accompanies a craniectomy and subsequent cranioplasty of any type. Demonstration of superior cosmesis would help to justify the high cost of custom implants. The present study was not intent on addressing this question, although they present a nice discussion of the issue. Certainly, custom implants are more convenient for neurosurgeons than the mesh and methylmethacrylate I was brought up with. Placing a compensatory volume of methylmethacrylate beneath the wasted temporalis seemed to

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increase patient satisfaction—one potential advantage of this less elegant approach.

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The authors have performed a multicenter observational study of PEEK cranioplasty, involving 66 patients between 3 centers worldwide. This represents the largest series in the literature. The primary value of this article relates to complication rates, and one unexpected finding concerning cosmesis. The former represents valuable information to counsel patients as to the likelihood of complications, which fortunately appear no worse than when autologous bone is used. The latter is a fairly newly described issue, concerning temporalis atrophy. It is possible to have made custom implants that compensate for this. The overall infection rate in this series is 7.6%. I wonder, in the future, if this rate can be reduced by applying antibiotic solutions or powder to the wound and implants, prior to closure, as has been reported in the spine literature. Despite the availability of PEEK custom cranial implants, it is surprising that very little has been written in the neurosurgical literature about this method up to this point.

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The authors should be commended for their collaborative efforts in the largest single effort to date reporting the use of PEEK implants in cranioplasty procedures. In this retrospective study reviewing 66 cranioplastics, the reported overall complication rate was 12.7%, and the infection rate was 7.6%. Historically, routine practice has consisted of the use of native bone owing to the perception of lower costs and lower infection rates relative to the use of custom foreign body implants. Improved technology, such as 3-dimensional printing, as well as infection prophylaxis standards, has brought increased attention to the use of custom cranioplasty implants. In the present study, the overall findings of complication rates were very similar to prior reports1-3 despite the inclusion of centers from the United States, Singapore, and Israel. This is despite institutional variations in implant preservation, infection prophylaxis, or other hospital-specific practices that could not be accounted for. Furthermore, one recent meta-analysis by Yadla et al4 found no difference in infection rate or overall complication rate between the use of autograft and allograft materials. Complication rates with cranioplasty procedures remain to be a significant problem—further studies with larger populations will be needed to determine specific high-risk factors, as the populations in this study are heterogeneous.

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