Clinical relevance of current materials for cranial implants
Towards an optimal patient-specific implant material
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Outcome in patient-specific PEEK cranioplasty: A two-center cohort study of 40 implants

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ABSTRACT

Objective: The best material choice for cranioplasty following craniectomy remains a subject to discussion. Complication rates after cranioplasty tend to be high. Computer-assisted 3-dimensional modeling of poly(ether ether ketone) (PEEK) was recently introduced for cranial reconstruction. The aim of this study was to evaluate patient- and surgery-related characteristics and risk factors that predispose patients to cranioplasty complications.

Material and methods: This retrospective study included a total of 40 cranial PEEK implants in 38 patients, performed at two reference centers in the Netherlands from 2011 to 2014. Complications were registered and patient- and surgery-related data were carefully analysed.

Results: The overall complication rate of PEEK cranioplasty was 28%. Complications included infection (13 %), postoperative hematoma (10 %), cerebrospinal fluid leak (2.5 %) and wound-related problems (2.5 %). All postoperative infections required removal of the implant. Nonetheless removed implants could be successfully re-used after re-sterilization.

Conclusion: Although overall complication rates after PEEK cranioplasty remain high, outcomes are satisfactory, as our results compare favorably to recent literature reports on cranial vault reconstruction.
INTRODUCTION

Cranioplasty aims to repair a defect in the cranium and is one of the oldest neurosurgical procedures. Archeological evidence dates back to 3000 BC and suggests that the Incas performed skull reconstruction using gold plates. In the 16th century Fallopius also recommended repair with gold plates and one century later, in 1668, the Dutch surgeon van Meekeren reported on the repair of a cranial defect in a Russian soldier with bone derived from a dog skull.

Cranioplasty provides protection to the underlying brain and is performed for both functional and esthetic reasons. It aspires neurologic recovery, as described with reconstruction for the sinking scalp flap or syndrome of the trephined. Disadvantages to delayed cranioplasty involve a temporarily unprotected brain as well as an aesthetic deformity. Timing seems to be important in the neurological outcome of patients but also in avoiding complications. Cranioplasty is most commonly performed after previous craniectomy for traumatic brain injury, stroke, after intracranial tumor surgery and intracranial infections.

Material choice for cranioplasty is still controversial, which brings complexity to this seemingly straightforward procedure. Harvest sites for autologous bone grafts include iliac crest, rib, sternum, scapula and the skull. At present, autologous bone flap replacement using the previously removed bone flap is the most common practice. Autologous bone does not exert immune rejection and is effective as a substrate for bone ingrowth and revascularization. Besides this autologous bone reconstruction has relatively low costs. However, there is a risk of infection, resorption and in this case its strength gradually reduces. This has led to a search for synthetic materials. At present, there are primarily 3 classes of allografts: metal, ceramic and polymer. Titanium is the only metal still in use. It is a biocompatible material with a low infection rate. Nonetheless titanium has certain disadvantages: the material is expensive and leads to artifacts on imaging. Furthermore, it is a very strong material that shows no deflection in cases of traumatic stress and consequently it has no protective energy-absorbing properties. Hydroxyapatite is a ceramic, which is known to be a good scaffolding material for bony ingrowth. Unfortunately, it is rather limited for use in larger defects because of its brittleness and low tensile strength. Poly(methyl methacrylate) (PMMA), a polymer, has been widely used because of its low cost, radiolucency and lack of thermoconduction. Nonetheless it is associated with complications such as infection, fragmentation and a lack of incorporation.
Computer-assisted design (CAD) and computer-assisted manufacturing (CAM) has been used to make titanium, hydroxyapatite and PMMA implants. Prefabrication of a patient-specific implant (PSI) reduces operation time and produces superb cosmetic results. Recently, computer-assisted 3-dimensional modeling of poly (ether ether ketone) (PEEK), another polymer, has been successfully introduced for cranial reconstruction. It is a strong and highly thermoplastic material. It resembles titanium in its perfect intraoperative fitting and its resistance to aggressive sterilization procedures (heat and ionizing radiation). On the contrary, the elasticity and energy-absorbing properties of PEEK match closer to bone than the mechanical properties of titanium. And unlike titanium, it is a radiolucent and a non-magnetic material, facilitating postoperative imaging. PEEK has a few disadvantages: it has no bioactive potential and the costs related to the manufacturing of a PSI are high.

The aim of this study is to evaluate patient- and surgery-related characteristics and risk factors that predispose patients to an increased risk of complications after PEEK cranioplasty.

MATERIAL AND METHODS

Study design and patient population
This retrospective study included 38 consecutive patients who underwent 40 PEEK cranioplasties from 2011 to 2014 in the Academic Medical Center Amsterdam (24 cranioplasties) and the St. Elisabeth Hospital Tilburg (16 cranioplasties). Both centers used identical protocols and procedures for skull reconstruction by means of PSI. The current series included all patients who underwent PEEK cranioplasty. No patients were excluded. The study protocol was approved by the local medical-ethical review board (local protocol no. L87.2015; METC no. Nw 2015-38).
Data collection

Data collection included the following patient parameters: gender, age at time of PEEK cranioplasty, medical comorbidities (diabetes, cardiovascular disease, obesity (body mass index > 30), preoperative radiotherapy, smoking, indication for craniectomy (trauma, stroke, tumor, infection) and side of surgery (unilateral, bilateral, frontal). Surgical reports were carefully analysed with regard to the timing of cranioplasty. A difference was made between immediate and delayed cranioplasty. Cranioplasty was defined as 'immediate' when there was no interval between craniectomy or removal of previous cranioplasty with autologous bone or PMMA. Delayed PEEK cranioplasty was performed after an interval of wound healing, leaving the brain temporarily unprotected. The time between previous surgery (craniectomy or cranioplasty) and PEEK cranioplasty was listed, as well as the number of surgeries prior to PEEK cranioplasty and the complication-rate after previous cranioplasty using autologous bone or PMMA. Other surgery-related data that were collected included preoperative shaving of the surgery site, incorporation of the previous scar into the skin incision or use of additional incisions, suspension of the temporal muscle, intraoperative placement of a subgaleal drain and operation time and the size of the defect. Defect size was measured with the use of 3D software (Maxilim software (Medicim NV, Mechelen, Belgium) and Autodesk 3ds Max 2012 (Autodesk Inc. USA)), which takes into account the curvature of the skull (Figure 1).

The main outcome parameters were defined as the presence of any complication after PEEK cranioplasty (infection, hematoma, cerebrospinal fluid (CSF) leak, wound-related problems) and the need for any medical (use of antibiotics) or surgical intervention (drainage of a hematoma, surgical repair of a CSF leak, use of a reconstructive skin flap, removal of the implant) after cranioplasty.

Follow-up reports of the neurological status of patients were studied. Patients who had a normal neurological status before and after PEEK cranioplasty were excluded. Patients or their relatives were contacted by phone to obtain a subjective evaluation of the evolution of the neurological status after PEEK cranioplasty. A simple rating scale was scored as follows: 1: significant neurological deterioration; 2: moderate deterioration; 3: no change; 4: moderate improvement; 5: significant improvement.
Preoperative planning
Computed tomography (CT) scans of the cranium were acquired using a high-resolution protocol as required for preoperative 3D planning and design of the PEEK implant (Xilloc Medical BV, Maastricht, the Netherlands, 29 cranioplasties; DePuy Synthes, Zuchwil, Switzerland, 7 cranioplasties; 3di GmbH, Jena, Germany, 4 cranioplasties).

Surgical procedure
Prophylactic antibiotics (intravenous Cefazolin 2000 mg) were administered 30 minutes before incision. A skin flap was raised and if present, an autologous bone flap or PMMA PSI was removed. After dural exposure the bony edges of the skull defect were exposed to fit the PEEK PSI (Figure 1). Pre-formed holes in the PSI were used for dural tack-up sutures. In recent PEEK cranioplasties, the need for additional miniplate fixation could be eliminated with the tangential InterFix technology (Xilloc), in which case the screws were tangentially directed into the bone edges. If indicated, the temporal muscle was suspended to the PSI through the pre-formed holes. In selected cases a subgaleal drain was placed. There was no consensus about the placement of a drain, so the decision was left to the preference of the surgeon and the present conditions. The skin was closed in two layers and a circumferential pressure bandage was applied. All patients underwent standard postoperative care.

Statistical analysis
Categorical data are presented as absolute values and percentages, continuous, normally distributed data as means and standard deviations (SD), while time intervals are presented as medians and interquartile ranges (IQR). Potential risk factors associated with complications after the use of PSI were extracted with Chi-square tests. A p-value ≤ 0.05 was considered statistically significant. Data analysis was performed using SPSS 23.0.
RESULTS

Patient characteristics

Table 1 lists a detailed summary of patient and surgery-specific factors. In total 40 PEEK cranioplasties were performed in 38 patients. Two patients had bilateral cranial defects. The median follow-up period was 19.1 months (IQR 12.5-30.6). The average age at PEEK cranioplasty was $43.2 \pm 18.1$ years (range 8-84) with a male predominance (61% male). Fifteen patients (39%) had one or more associated comorbidities: cardiovascular disease in 10 (26%), obesity in 7 (18%) and diabetes in 2 (5%) patients. No patient had received radiotherapy. Ten patients (26%) were smokers at the time of cranioplasty. Indications for the primary craniectomy were stroke (39%), trauma (34%), tumor resection (21%) and infection (5%). Craniectomy resulted in unilateral convexity defects in 32 patients (84%), bilateral convexity defects in 2 patients (5%, Figure 1) and frontal defects in 4 patients (11%). Frontal sinus involvement was present in 1 patient.
Time to cranioplasty

Figure 2 gives a schematic overview of the management until final PEEK cranioplasty.

Twenty-two (55%) out of 40 autologous bone grafts were replaced, 6 of them at the time of craniectomy and 16 of them in a delayed fashion after preservation at -80°C. These bone grafts failed due to infection \( (n = 11) \) or resorption \( (n = 11) \). Ten of the 11 infected bone grafts were treated with debridement and delayed cranioplasty. Ten out of 11 bone graft failures due to resorption were treated with immediate cranioplasty.

Eighteen (45%) of the 40 autologous bone grafts could not be replaced due to damage caused by trauma \( (n = 11) \), the presence of intra-osseous tumor tissue \( (n = 4) \), brain swelling or hemorrhage \( (n = 3) \). In two of these 18 cases, PMMA was used for reconstruction of the defect at the time of craniectomy. These implants failed due to a subcutaneous CSF collection. Two PSIs were placed at the time of craniectomy with removal of an intra-osseous tumor (meningioma) and 14 PEEK cranioplasties occurred in a delayed fashion.

The median interval between previous surgery and PEEK cranioplasty was 4.7 months (IQR 0-7.7). The mean number of surgeries prior to PEEK was 1.9 ± 1.1 (median 2.0, range 0-4). In 25 cases (63%) the implant sites were considered complex because more than one surgery was performed prior to PEEK cranioplasty.

Surgery-specific characteristics

The average cranial defect measured 106.3 ± 46.1 cm² (range 11-181). The largest craniectomy defects were found in stroke patients and after severe brain trauma. The operative field was shaved in 63% of surgeries. The previous scar was fully reused in 88%. An additional incision was made in 13% with a new incision in 8% and a partial reuse of the scar in 5%. In 50% of cases the temporal muscle was suspended to the PSI. A subgaleal drain was placed in 55% of the surgical procedures. The mean operation time was 126 ± 60.4 minutes (median 111, range 40-337).
ABG = autologous bone graft*: Final loss of PEEK cranioplasty

**Figure 2.** Schematic overview regarding cranioplasty timing

The complications after PEEK cranioplasty are given with the initial indication of craniectomy between brackets. Solid border: immediate PEEK cranioplasty; 2 complications were seen in 15 cranioplasties. Dashed border: delayed cranioplasty; 9 complications were seen in 25 cranioplasties.

**Overall complications**

Twenty-nine PEEK implants (73%) were without any complication. 11 complications were seen in 11 patients. Complications (28%) consisted of infection (n = 5), hematoma (n = 4), CSF leak (n = 1) and wound-related problems (n = 1). Ten cranioplasties (25%) required additional surgery. Three (epidural) hematomas were surgically evacuated, one CSF leak needed surgical repair and one patient had a skin flap necrosis, which was reconstructed with a latissimus dorsi flap. Five PEEK implants (12.5%) were removed due to infection. In three of these patients the same PSI was re-used after sterilization after 1.8, 3.8 and 8.0 months, without further complications. Two patients refused re-operation and consequently a permanent loss of PEEK cranioplasty was seen in 5%. There was no mortality observed within six months after PEEK cranioplasty. The overall infection rate after cranioplasty was 13%. *Staphylococcus aureus* was the predominant pathogenic microorganism in four of these five cases. One patient with a postoperative (subgaleal) hematoma received conservative treatment, without the need for additional surgical intervention. Postoperative subcutaneous seroma formation was observed in four cases and resolved spontaneously in all. The median time between PEEK cranioplasty and the presentation of complications was 35 days (n = 11, IQR 4.5-90.5).
Chapter 5

Complication predicting factors
The number of complications associated with the patient- and surgery-specific factors is listed in Table 1. Statistical analysis of the different risk factors did not show a significant increase in complication rates.

There was no significant difference in mean age between patients who developed a complication (50 ± 18 years) and those who did not (40 ± 18 years). The presence of comorbidity did not seem to be related to a higher complications rate, except for patients with vascular comorbidity. They were more likely to get any complication than patients without vascular disease (40% vs. 25%). This was also found for smoking behavior (40% vs. 25%). Concerning the original indication for craniectomy, tumor patients were less likely to develop complications (13% vs. 33%) and stroke patients were more likely to get complications (40% vs. 22%). Although cranioplasty timing did not show statistical significance, we observed 9 of 11 complications (82%) in the delayed cranioplasty group. After previous cranioplasty with autologous bone, and even in those cases where autologous bone was lost due to infection, no association with higher complication rates was found. One case of skin flap necrosis was observed in a patient where additional incisions were made. When comparing PEEK PSI’s with InterFix technology and other PSIs we did not find a significant difference in the complication rate (28% vs. 27%).

Neurological status assessment
Neurological status assessment is summarized in Figure 3. One patient was lost to follow-up (N/A). Eighteen patients had a normal neurological status before and after cranioplasty. Ten patients (53%) with neurological impairment showed no change in neurological status after PEEK cranioplasty. Eight patients (42%) showed a moderate improvement and one patient (5%) showed a significant improvement of the neurological status following PEEK cranioplasty. There were no patients showing neurological deterioration after PEEK reconstruction.
### Table 1: Detailed summary of included patient and surgery-specific factors

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>N (%)</th>
<th>Mean (± SD)</th>
<th>N of complications (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>23 (61)</td>
<td>7 (30)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>15 (40)</td>
<td>4 (27)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td>43 ± 18.1</td>
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<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>2 (5)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>10 (26)</td>
<td>4 (40)</td>
<td></td>
</tr>
<tr>
<td>Obesity</td>
<td>7 (18)</td>
<td>0 (0)</td>
<td></td>
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<tr>
<td>Preoperative radiotherapy</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>10 (26)</td>
<td>4 (40)</td>
<td></td>
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<tr>
<td>Initial diagnosis</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Trauma</td>
<td>13 (34)</td>
<td>4 (31)</td>
<td></td>
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<tr>
<td>Stroke</td>
<td>15 (39)</td>
<td>6 (40)</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>2 (5)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Tumor</td>
<td>8 (21)</td>
<td>1 (13)</td>
<td></td>
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<tr>
<td>Defect site</td>
<td></td>
<td></td>
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<tr>
<td>Unilateral convexity</td>
<td>32 (84)</td>
<td>9 (28)</td>
<td></td>
</tr>
<tr>
<td>Bilateral convexity</td>
<td>2 (5)</td>
<td>1 (25)</td>
<td></td>
</tr>
<tr>
<td>Frontal</td>
<td>4 (11)</td>
<td>1 (25)</td>
<td></td>
</tr>
<tr>
<td>Time to PEEK cranioplasty</td>
<td>40 implants</td>
<td>1.9 ± 1.1</td>
<td></td>
</tr>
<tr>
<td>Timing of cranioplasty</td>
<td></td>
<td></td>
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<tr>
<td>Immediate cranioplasty</td>
<td>15 (38)</td>
<td>2 (13)</td>
<td></td>
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<tr>
<td>Delayed cranioplasty</td>
<td>25 (63)</td>
<td>9 (36)</td>
<td></td>
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<tr>
<td>Previous cranioplasty</td>
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<tr>
<td>With autologous bone graft</td>
<td>22 (55)</td>
<td>5 (23)</td>
<td></td>
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<tr>
<td>Without autologous bone graft</td>
<td>18 (45)</td>
<td>6 (33)</td>
<td></td>
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<tr>
<td>Number of previous surgeries</td>
<td>1.9 ± 1.1</td>
<td></td>
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<tr>
<td>Surgery-specific characteristics</td>
<td>40 implants</td>
<td>106 ± 46.1</td>
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<tr>
<td>Defect size (cm²)</td>
<td></td>
<td></td>
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<tr>
<td>Shaving</td>
<td>25 (63)</td>
<td>5 (20)</td>
<td></td>
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<tr>
<td>Additional incision</td>
<td>5 (13)</td>
<td>2 (40)</td>
<td></td>
</tr>
<tr>
<td>Suspension of temporal muscle</td>
<td>20 (50)</td>
<td>6 (30)</td>
<td></td>
</tr>
<tr>
<td>Drain</td>
<td>22 (55)</td>
<td>8 (36)</td>
<td></td>
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<tr>
<td>Operation time (min)</td>
<td></td>
<td>126 ± 60.4</td>
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</table>
DISCUSSION

Although the surgical technique of cranioplasty has been established a long time ago, complication rates are still relatively high and the best method to reconstruct large skull defects remains a matter of debate. This study describes our experience with PEEK cranioplasties.

In line with findings from previous large studies, we found that PEEK cranioplasty is associated with a significant risk of post-operative complications. Literature to date mainly focuses on failure rates and re-operation rates are rarely reported.
Large studies on autologous cranial grafts report failure rates up to 40% due to resorption or infection (defined as an infection requiring removal of the bone graft)\textsuperscript{27,40-43}. Resorption did not occur with PEEK cranioplasty. The infection rate in our series (defined as the invasion and multiplication of micro-organisms that are not normally present within the body) was 13\%, which is comparable to the reported infection rates after autologous and allograft cranioplasties\textsuperscript{20,22,27}. In line with the literature, \textit{S. aureus} appeared to be the most common pathogenic microorganism\textsuperscript{44-46}. Although infection rates in this study were comparable to infection rates after autologous cranioplasties, PEEK has the important advantage of the possibility to be repeatedly sterilized with no significant changes in its mechanical behavior\textsuperscript{37}. Therefore most of the implants could be replaced after a period of time and final loss was only recorded in two patients who refused re-operation (5\%).

\textbf{Patient characteristics}

A non-significant, but positive relation between age, vascular comorbidities, smoking behavior and complications was found in our study. A relationship with other medical comorbidities was not found. The association between age and complication rates is well known\textsuperscript{47,48}. Conflicting results on associations with medical comorbidities have been reported in the literature\textsuperscript{27,40,48}.

With regard to the initial indication for craniectomy, stroke patients were more likely to get complications after PEEK cranioplasty; this is consistent with literature findings and most likely reflects age in combination with (vascular) comorbidities\textsuperscript{47,48}. Remarkably, cranioplasty in tumor patients was associated with a trend towards a lower infection rate, which contrasts to the literature reporting higher complication rates in tumor patients due to perioperative corticosteroid treatment, nutritional problems and chemo- and/or radiotherapy\textsuperscript{22,47}. Tumor patients in our series however had a meningioma and did not receive chemotherapy nor radiotherapy.
Time to cranioplasty

Timing of cranioplasty is a controversial issue. The main argument for early cranioplasty is to avoid the syndrome of the sinking scalp flap. Furthermore, early cranioplasty is often advised because of easier tissue dissection and the possibility of early active rehabilitation, but can be contraindicated in contaminated wounds. Likewise we performed a delayed cranioplasty when the autologous bone graft was lost due to infection and immediate cranioplasty when the autologous bone graft was lost due to resorption. Recent literature reports however did not show a difference in complication rates between early and late cranioplasties. In our series, delayed cranioplasty tends to predispose to an increased risk of complications in comparison to immediate cranioplasty. One explanation could point towards the more arduous tissue dissection due to the formation of adhesions between the dura and subcutaneous tissues. Current literature also reports higher complication rates in patients who have had two or more previous surgeries, a finding we could not confirm in this study.

Surgery-specific characteristics

No association was found between the complication rate and defect size, shaving of the operation site and suspension of the temporal muscle. Due to an extensive vascularization, scalp wounds usually heal well and are not very susceptible to necrosis. We recorded one case of skin flap necrosis as a result of multiple previous surgeries with additional incisions compromising blood supply. In contrast with the literature, an increased operation time was not associated with an increased complication rate. We could not relate the placement of a drain to the formation of a postoperative hematoma on the one hand, nor to the development of a postoperative infection on the other hand. Moreover the indication for drain placement can be biased towards more complex cases.
**Neurological status assessment**

Although the rating scale used for neurological assessment after PEEK cranioplasty was a simple ordinal scale based on subjective judgment, our results suggest a (moderate) improvement of the neurological status in several cases. An unprotected brain has to function under the atmospheric pressure which can result in a local vascular dysfunction, also known as the syndrome of the sinking scalp flap or syndrome of the trephined 3,5,6. A cranioplasty can thereby improve cerebral blood flow, resulting in an improvement of the neurological status and recovery5,6. Consequently, cranioplasty may not only be useful for cerebral protection and aesthetic improvement, but the current data also suggest that cranioplasty can result in neurological improvement.

**Limitations**

The small sample size leads to an inherent low statistical power and therefore no firm conclusions can be drawn. No direct comparison with different cranioplasty techniques was made. The present study also poses certain limitations due to its retrospective nature; complications were necessarily obtained from file studies. Prospective trials are needed to further elucidate the relationship between specific risk factors and the outcome after PEEK cranioplasty.

**CONCLUSION**

Cranioplasty carries a significant risk of postoperative complications, not infrequently requiring reoperation. PEEK cranioplasty showed comparable complication rates to the literature reporting on cranioplasties using autologous bone grafts or allografts. Outcomes after cranial vault reconstruction using PEEK implants however compared favorably because of the advantage of re-sterilization and possibility of reuse.

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REFERENCES


