



Contents lists available at ScienceDirect

## Journal of Cranio-Maxillo-Facial Surgery

journal homepage: [www.jcmfs.com](http://www.jcmfs.com)

## Outcome in patient-specific PEEK cranioplasty: A two-center cohort study of 40 implants

J. Jonkergouw<sup>a, b, 1</sup>, S.E.C.M. van de Vijfeijken<sup>c, d, \*, 1</sup>, E. Nout<sup>a</sup>, T. Theys<sup>e</sup>, E. Van de Castele<sup>f</sup>, H. Folkersma<sup>g</sup>, P.R.A.M. Depauw<sup>h</sup>, A.G. Becking<sup>c, d</sup><sup>a</sup> Department of Oral and Maxillofacial Surgery Tilburg, Hilvarenbeekseweg 60, 5022 GC, Tilburg, The Netherlands<sup>b</sup> Department of Oral and Maxillofacial Surgery, University Hospitals Leuven, Herestraat 49, 3000, Leuven, Belgium<sup>c</sup> Department of Oral and Maxillofacial Surgery, Academic Medical Center, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands<sup>d</sup> Academic Centre of Dentistry Amsterdam (ACTA), Gustav Mahlerlaan 3004, 1081 LA, Amsterdam, The Netherlands<sup>e</sup> Department of Neurosurgery, University Hospitals Leuven, Herestraat 49, 3000, Leuven, Belgium<sup>f</sup> iMinds-Vision Lab, Department of Physics, University of Antwerp, Belgium<sup>g</sup> Neurosurgical Center Amsterdam, Academic Medical Center, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands<sup>h</sup> Department of Neurosurgery Tilburg, Hilvarenbeekseweg 60, 5022 GC, Tilburg, The Netherlands

## ARTICLE INFO

## Article history:

Paper received 6 March 2016

Accepted 1 July 2016

Available online xxx

## Keywords:

Cranioplasty

Craniectomy

Patient specific implant

PEEK

Computer aided-design and modelling

Cranial vault reconstruction

## 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 modelling of polyetheretherketone (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 haematoma (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 favourably to recent literature reports on cranial vault reconstruction.

© 2016 European Association for Cranio-Maxillo-Facial Surgery. Published by Elsevier Ltd. All rights reserved.

## 1. 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 (Rifkinson-Mann, 1988). In the 16th century Fallopius also recommended repair with gold plates (Sanan and Haines, 1997) 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 canine skull (Sanan and Haines, 1997).

Cranioplasty provides protection to the underlying brain and is performed for both functional and aesthetic reasons. It aspires to neurologic recovery, as described with reconstruction for the sinking scalp flap or syndrome of the trephined (Dujovny et al., 1997a, 1999; Goldstein et al., 2013; Kuo et al., 2004; Stula, 1982; Winkler et al., 2000). Disadvantages to delayed cranioplasty involve a temporarily unprotected brain as well as an aesthetic deformity (Kshetry et al., 2012). Timing seems to be important in the neurological outcome of patients but also in avoiding complications (Yadla et al., 2011). Cranioplasty is most commonly performed after previous craniectomy for traumatic brain injury, stroke, after intracranial tumour surgery and intracranial infections

\* Corresponding author. Department of Oral and Maxillofacial Surgery, Academic Medical Center, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands.

E-mail address: [s.e.vandevijfeijken@amc.uva.nl](mailto:s.e.vandevijfeijken@amc.uva.nl) (S.E.C.M. van de Vijfeijken).

<sup>1</sup> Both authors contributed equally to the manuscript.

(Diedler et al., 2009; Honeybul and Ho, 2013; Kakar et al., 2009; Mak et al., 2013; Morley et al., 2002; Perez-Bovet et al., 2012; Schirmer et al., 2007; Schwab et al., 1998; Vahedi et al., 2007; Whitfield et al., 2001; Winter et al., 2005).

Material choice for cranioplasty is still controversial, which brings complexity to this seemingly straightforward procedure (Klinger et al., 2014; Sahoo et al., 2010; Walcott et al., 2013; Yadla et al., 2011). Harvest sites for autologous bone grafts include iliac crest, rib, sternum, scapula and the skull (Shah et al., 2014). 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 (Grant et al., 2004). 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 (Cheng et al., 2014; Goldstein et al., 2013; Matsuno et al., 2006; Schoekler and Trummer, 2014; Walcott et al., 2013; Yadla et al., 2011). At present, there are primarily 3 classes of allografts: metal, ceramic and polymer (Bonda et al., 2015). Titanium is the only metal still in use, it is a biocompatible material with a low infection rate (Lethaus et al., 2012). Nonetheless titanium has certain disadvantages: the material is expensive and leads to artifacts on imaging (Hill et al., 2012; Matsuno et al., 2006). 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 (Lethaus et al., 2012). Hydroxyapatite is a ceramic, which is known to be a good scaffolding material for bony ingrowth (Bonda et al., 2015). Unfortunately, it is rather limited for use in larger defects because of its brittleness and low tensile strength (Ducic, 2002; Dujovny et al., 1997b). Polymethyl 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 (Blum et al., 1997; Matsuno et al., 2006).

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 (Bonda et al., 2015). Recently, computer-assisted 3-dimensional modelling of polyetheretherketone (PEEK), another polymer, has been successfully introduced for cranial reconstruction (Hanasono et al., 2009; Kurtz and Devine, 2007). 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). The elasticity and energy-absorbing properties of PEEK match closer to bone than the mechanical properties of titanium. And in contrast to titanium, PEEK is a radiolucent non-magnetic material, facilitating post-operative imaging (Kurtz and Devine, 2007; Lethaus et al., 2011, 2012, 2014; Shah et al., 2014). PEEK has a few disadvantages, but it has no bioactive potential and the costs related to the manufacturing of a PEEK PSI are high (Lethaus et al., 2014).

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.

## 2. Material and methods

### 2.1. 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 using PSIs. 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).

### 2.2. 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, tumour, 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, operation time and the size of the defect. Defect size was measured with the use of 3D software (Maxilim<sup>®</sup> software (Medicim NV, Mechelen, Belgium) and Autodesk 3ds Max 2012 (Autodesk Inc., USA)), which takes into account the curvature of the skull. Fig. 1.

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

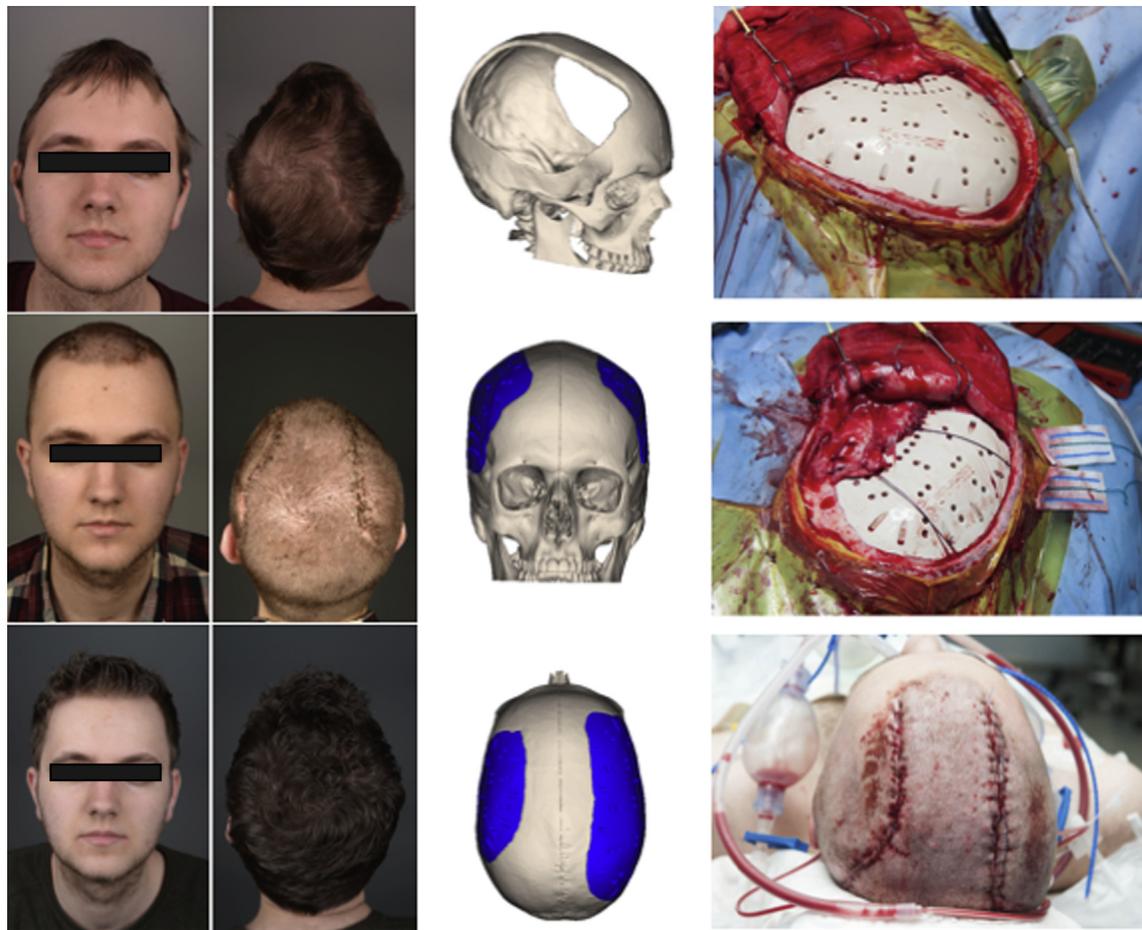
Follow-up reports of the neurological status of patients were studied. Patients who had a normal neurological status before and after PEEK cranioplasty were excluded. Patients or their relatives were contacted by phone to obtain a subjective evaluation of the evolution of the neurological status after 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.

### 2.3. 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).

### 2.4. Surgical procedure

Prophylactic antibiotics (intravenous Cefazolin 2000 mg) were administered 30 min 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 (Fig. 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



**Fig. 1.** Clinical illustration. *Left panel:* Preoperative (top), early (middle) and late (bottom) postoperative photographs. *Middle panel:* 3D CT reconstruction of cranium and defect illustrating planning of PEEK reconstruction (blue). *Right panel:* Intra-operative photographs showing right (top) and left (middle) PEEK cranioplasty nicely adapting to the contours of the defect; intra-operative photograph after closure (bottom).

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 post-operative care.

### 2.5. 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  $\leq 0.05$  was considered statistically significant. Data analysis was performed using SPSS 23.0.

## 3. Results

### 3.1. 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). 15 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. 10 patients (26%) were smokers at the time of cranioplasty. Indications for the primary craniectomy were stroke (39%), trauma (34%), tumour resection (21%) and infection (5%). Craniectomy resulted in unilateral convexity defects in 32 patients (84%), bilateral convexity defects in 2 patients (5%, Fig. 1) and frontal defects in 4 patients (11%). Frontal sinus involvement was present in 1 patient.

### 3.2. Time to cranioplasty

Fig. 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  $-80^\circ$ . These bone grafts failed due to infection ( $n = 11$ ) or resorption ( $n = 11$ ). 10 of the 11 infected bone grafts were treated with debridement and delayed cranioplasty. 10 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 tumour tissue ( $n = 4$ ), brain swelling or haemorrhage

**Table 1**  
Summary.

	N (%)	Mean ( $\pm$ SD)	N of complications (%)
<b>Patient characteristics</b>			
38 patients			
<b>Gender</b>			
Male	23 (61)		7 (30)
Female	15 (40)		4 (27)
Age (years)		43.2 $\pm$ 18.1	
<b>Comorbidities</b>			
Diabetes	2 (5)		0 (0)
Cardiovascular disease	10 (26)		4 (40)
Obesity	7 (18)		0 (0)
Preoperative radiotherapy	0 (0)		0 (0)
Smoking	10 (26)		4 (40)
<b>Initial diagnosis</b>			
Trauma	13 (34)		4 (31)
Stroke	15 (39)		6 (40)
Infection	2 (5)		0 (0)
Tumour	8 (21)		1 (13)
<b>Defect site</b>			
Unilateral convexity	32 (84)		9 (28)
Bilateral convexity	2 (5)		1 (50)
Frontal	4 (11)		1 (25)
<b>Time to PEEK cranioplasty</b>			
40 implants			
<b>Timing of cranioplasty</b>			
Immediate cranioplasty	15 (38)		2 (13)
Delayed cranioplasty	25 (63)		9 (36)
<b>Previous cranioplasty</b>			
With autologous bone graft	22 (55)		5 (23)
Without autologous bone graft	18 (45)		6 (33)
Number of previous surgeries		1.9 $\pm$ 1.1	
<b>Surgery-specific characteristics</b>			
40 implants			
Defect size (cm <sup>2</sup> )		106.3 $\pm$ 46.1	
Shaving	25 (63)		5 (20)
Additional incision	5 (13)		2 (40)
Suspension of temporal muscle	20 (50)		6 (30)
Drain	22 (55)		8 (36)
Operation time (min)		126.0 $\pm$ 60.4	

N = number; SD = standard deviation.

( $n = 3$ ). 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 tumour (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  $1.9 \pm 1.1$  (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.

### 3.3. Surgery-specific characteristics

The average cranial defect measured  $106.3 \pm 46.1$  cm<sup>2</sup> (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 surgical procedures. The mean operation time was  $126 \pm 60.4$  min (median 111, range 40–337).

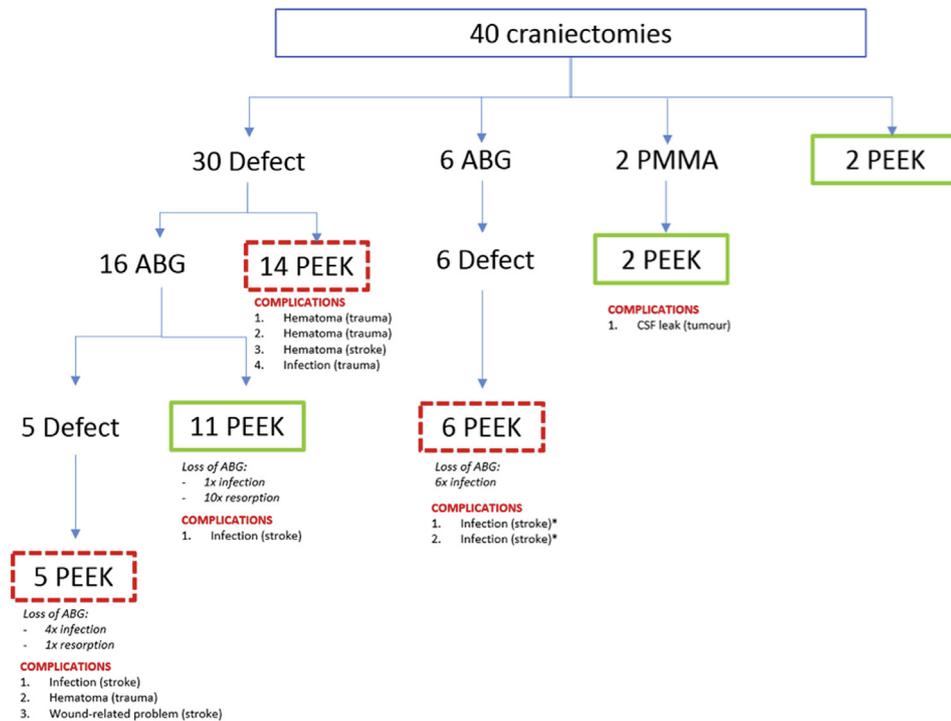
### 3.4. Overall complications

Twenty-nine PEEK implants (73%) were without any complication. 11 complications were seen in 11 patients. Complications

(28%) consisted of infection ( $n = 5$ ), haematoma ( $n = 4$ ), CSF leak ( $n = 1$ ) and wound-related problems ( $n = 1$ ). Ten cranioplasties (25%) required additional surgery. Three (epidural) haematomas 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-implantation 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) haematoma 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).

### 3.5. 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.

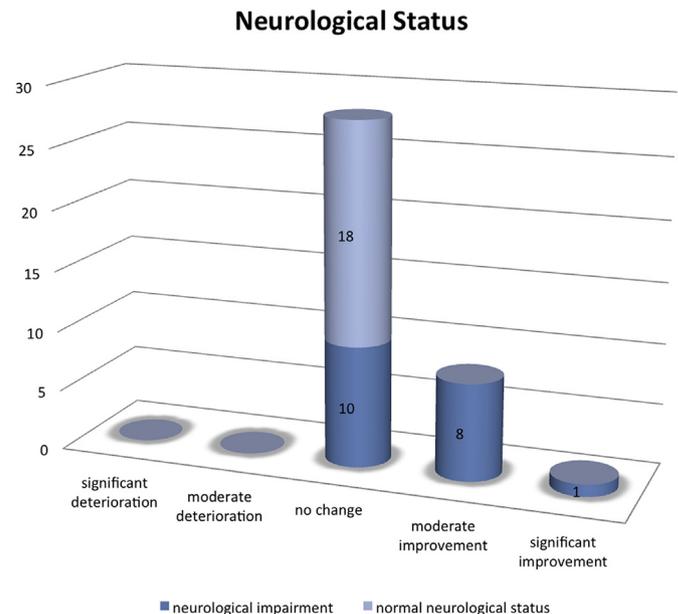


**Fig. 2.** Schematic overview regarding cranioplasty timing. The complications after PEEK cranioplasty are given with the initial indication of craniectomy between brackets. *Solid border*: immediate PEEK cranioplasty; 2 complications were seen in 15 cranioplasties. *Dashed border*: delayed cranioplasty; 9 complications were seen in 25 cranioplasties (ABG = autologous bone graft; \*: Final loss of PEEK cranioplasty).

There was no significant difference in mean age between patients who developed a complication ( $50 \pm 18$  years) and those who did not ( $40 \pm 18$  years). The presence of comorbidity did not seem to be related to a higher complication 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 behaviour (40% vs. 25%). Concerning the original indication for craniectomy, tumour 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 PSIs with InterFix technology and other PEEK PSIs we did not find a significant difference in the complication rate (28% vs. 27%).

### 3.6. Neurological status assessment

Neurological status assessment is summarized in Fig. 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 of the neurological status following PEEK cranioplasty. There were no patients showing neurological deterioration after PEEK reconstruction.



**Fig. 3.** Neurological status assessment.

## 4. 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 (Cheng et al., 2008; Gooch et al., 2009; Klinger et al., 2014; Matsuno et al., 2006). Literature to date mainly focuses on failure rates and reoperation 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) (Honeybul and Ho, 2012; Lee et al., 2012; Matsuno et al., 2006; Piitulainen et al., 2015; Sundseth et al., 2014). 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 (Klinger et al., 2014; Matsuno et al., 2006; Yadla et al., 2011). In line with the literature, *S. aureus* appeared to be the most common pathogenic microorganism (Cheng et al., 2008; Goh et al., 2010; Rosenthal et al., 2014). Although infection rates in this study were comparable to infection rates after autologous cranioplasties, PEEK has the important advantage of being repeatedly sterilized with no significant changes in its mechanical behaviour (Kurtz and Devine, 2007). 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-implantation (5%).

#### 4.1. Patient characteristics

A non-significant, but positive correlation between age, vascular comorbidities, smoking behaviour 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 (Chang et al., 2010; Zanaty et al., 2015). Conflicting results on associations with medical comorbidities have been reported in the literature (Lee et al., 2012; Matsuno et al., 2006; Zanaty et al., 2015).

With regard to the initial indication for craniectomy, stroke patients were more likely to get complications, in particular infections after PEEK cranioplasty; this is consistent with literature findings and most likely reflects age in combination with (vascular) comorbidities (Chang et al., 2010; Zanaty et al., 2015). Remarkably, cranioplasty in tumour patients was associated with a trend towards a lower infection rate, which contrasts to the literature reporting higher complication rates in tumour patients due to perioperative corticosteroid treatment, nutritional problems and chemo- and/or radiotherapy (Chang et al., 2010; Klinger et al., 2014). Tumour patients in our series however had a meningioma and did not receive chemotherapy nor radiotherapy.

#### 4.2. 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 (Chang et al., 2010; Gooch et al., 2009; Yadla et al., 2011). 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 (Kim et al., 2013; Yadla et al., 2011). 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 (Cheng et al., 2008; Lee et al., 2012), a finding we could not confirm in this study.

#### 4.3. 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 (Kim et al., 2013; Lee et al., 2012; Matsuno et al., 2006), 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 haematoma on the one hand, nor to the development of a post-operative infection on the other hand (Chang et al., 2010; Klinger et al., 2014). Moreover the indication for drain placement can be biased towards more complex cases.

#### 4.4. Neurological status assessment

Although the rating scale used for neurological assessment after PEEK cranioplasty was a simple ordinal scale based on subjective judgement, 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 (Dujovny et al., 1999; Kuo et al., 2004; Winkler et al., 2000). A cranioplasty can thereby improve cerebral blood flow, resulting in an improvement of the neurological status and recovery (Kuo et al., 2004; Winkler et al., 2000). 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.

#### 4.5. 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.

### 5. 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 favourably because of the advantage of re-sterilization and the possibility of reuse.

#### Financial support

None.

#### Conflict of interest

The authors report no conflict of interest.

## Acknowledgement

The authors thank L. Dubois, MD, DDS, PhD for participating in the surgical management of some of the patient.

## References

- Blum KS, Schneider SJ, Rosenthal AD: Methyl methacrylate cranioplasty in children: long-term results. *Pediatr Neurosurg* 26: 33–35, 1997
- Bonda DJ, Manjila S, Selman WR, Dean D: The recent revolution in the design and manufacture of cranial implants: modern advancements and future directions. *Neurosurgery* 77: 814–824, 2015
- Chang V, Hartzfeld P, Langlois M, Mahmood A, Seyfried D: Outcomes of cranial repair after craniectomy. *J Neurosurg* 112: 1120–1124, 2010
- Cheng CH, Lee HC, Chen CC, Cho DY, Lin HL: Cryopreservation versus subcutaneous preservation of autologous bone flaps for cranioplasty: comparison of the surgical site infection and bone resorption rates. *Clin Neurol Neurosurg* 124: 85–89, 2014
- Cheng YK, Weng HH, Yang JT, Lee MH, Wang TC, Chang CN: Factors affecting graft infection after cranioplasty. *J Clin Neurosci* 15: 1115–1119, 2008
- Diedler J, Sykora M, Blatow M, Juttler E, Unterberg A, Hacke W: Decompressive surgery for severe brain edema. *J Intensive Care Med* 24: 168–178, 2009
- Ducic Y: Titanium mesh and hydroxyapatite cement cranioplasty: a report of 20 cases. *J Oral Maxillofac Surg* 60: 272–276, 2002
- Dujovny M, Agner C, Aviles A: Syndrome of the trephined: theory and facts. *Crit Rev Neurosurg* 9: 271–278, 1999
- Dujovny M, Aviles A, Agner C, Fernandez P, Charbel FT: Cranioplasty: cosmetic or therapeutic? *Surg Neurol* 47: 238–241, 1997a
- Dujovny M, Aviles A, Anger C: An innovative approach for cranioplasty using hydroxyapatite cement. *Surg Neurol* 48: 294–297, 1997b
- Goh RC, Chang CN, Lin CL, Lo IJ: Customised fabricated implants after previous failed cranioplasty. *J Plast Reconstr Aesthet Surg* 63: 1479–1484, 2010
- Goldstein JA, Paliga JT, Bartlett SP: Cranioplasty: indications and advances. *Curr Opin Otolaryngol Head Neck Surg* 21: 400–409, 2013
- Gooch MR, Gin GE, Kenning TJ, German JW: Complications of cranioplasty following decompressive craniectomy: analysis of 62 cases. *Neurosurg Focus* 26: E9, 2009
- Grant GA, Jolley M, Ellenbogen RG, Roberts TS, Gruss JR, Loeser JD: Failure of autologous bone-assisted cranioplasty following decompressive craniectomy in children and adolescents. *J Neurosurg* 100: 163–168, 2004
- Hanasono MM, Goel N, DeMonte F: Calvarial reconstruction with polyetheretherketone implants. *Ann Plast Surg* 62: 653–655, 2009
- Hill CS, Luoma AM, Wilson SR, Kitchen N: Titanium cranioplasty and the prediction of complications. *Br J Neurosurg* 26: 832–837, 2012
- Honeybul S, Ho KM: How “successful” is calvarial reconstruction using frozen autologous bone? *Plast Reconstr Surg* 130: 1110–1117, 2012
- Honeybul S, Ho KM: The current role of decompressive craniectomy in the management of neurological emergencies. *Brain Inj* 27: 979–991, 2013
- Kakar V, Nagaria J, John Kirkpatrick P: The current status of decompressive craniectomy. *Br J Neurosurg* 23: 147–157, 2009
- Kim H, Sung SO, Kim SJ, Kim SR, Park IS, Jo KW: Analysis of the factors affecting graft infection after cranioplasty. *Acta Neurochir (Wien)* 155: 2171–2176, 2013
- Klinger DR, Madden C, Beshay J, White J, Gambrell K, Rickert K: Autologous and acrylic cranioplasty: a review of 10 years and 258 cases. *World Neurosurg* 82: e525–e530, 2014
- Kshetry VR, Hardy S, Weil RJ, Angelov L, Barnett GH: Immediate titanium cranioplasty after debridement and craniectomy for postcraniotomy surgical site infection. *Neurosurgery* 70: 8–14, 2012 discussion 14–15
- Kuo JR, Wang CC, Chio CC, Cheng TJ: Neurological improvement after cranioplasty – analysis by transcranial doppler ultrasonography. *J Clin Neurosci* 11: 486–489, 2004
- Kurtz SM, Devine JN: PEEK biomaterials in trauma, orthopedic, and spinal implants. *Biomaterials* 28: 4845–4869, 2007
- Lee CH, Chung YS, Lee SH, Yang HJ, Son YJ: Analysis of the factors influencing bone graft infection after cranioplasty. *J Trauma Acute Care Surg* 73: 255–260, 2012
- Lethaus B, Bloebaum M, Essers B, ter Laak MP, Steiner T, Kessler P: Patient-specific implants compared with stored bone grafts for patients with interval cranioplasty. *J Craniofac Surg* 25: 206–209, 2014
- Lethaus B, Safi Y, ter Laak-Poort M, Kloss-Brandstatter A, Banki F, Robbenmenke C, et al: Cranioplasty with customized titanium and PEEK implants in a mechanical stress model. *J Neurotrauma* 29: 1077–1083, 2012
- Lethaus B, Ter Laak MP, Laeven P, Beerens M, Koper D, Poukens J, et al: A treatment algorithm for patients with large skull bone defects and first results. *J Craniofac Surg* 39: 435–440, 2011
- Mak CH, Lu YY, Wong GK: Review and recommendations on management of refractory raised intracranial pressure in aneurysmal subarachnoid hemorrhage. *Vasc Health Risk Manag* 9: 353–359, 2013
- Matsuno A, Tanaka H, Iwamuro H, Takashi S, Miyawaki S, Nakashima M, et al: Analyses of the factors influencing bone graft infection after delayed cranioplasty. *Acta Neurochir (Wien)* 148: 535–540, 2006 discussion 540
- Morley NC, Berge E, Cruz-Flores S, Whittle IR: Surgical decompression for cerebral oedema in acute ischaemic stroke. *Cochrane Database Syst Rev*: CD003435, 2002
- Perez-Bovet J, Garcia-Armengol R, Buxo-Pujolras M, Lorite-Diaz N, Narvaez-Martinez Y, Caro-Cardera JL, et al: Decompressive craniectomy for encephalitis with brain herniation: case report and review of the literature. *Acta Neurochir (Wien)* 154: 1717–1724, 2012
- Piitulainen JM, Kauko T, Aitasalo KM, Vuorinen V, Vallittu PK, Posti JP: Outcomes of cranioplasty with synthetic materials and autologous bone grafts. *World Neurosurg* 83: 708–714, 2015
- Rifkinson-Mann S: Cranial surgery in ancient Peru. *Neurosurgery* 23: 411–416, 1988
- Rosenthal G, Ng I, Moscovici S, Lee KK, Lay T, Martin C, et al: Polyetheretherketone implants for the repair of large cranial defects: a 3-center experience. *Neurosurgery* 75: 523–529, 2014
- Sahoo N, Roy ID, Desai AP, Gupta V: Comparative evaluation of autogenous calvarial bone graft and alloplastic materials for secondary reconstruction of cranial defects. *J Craniofac Surg* 21: 79–82, 2010
- Sanan A, Haines SJ: Repairing holes in the head: a history of cranioplasty. *Neurosurg* 40: 588–603, 1997
- Schirmer CM, Hoit DA, Malek AM: Decompressive hemicraniectomy for the treatment of intractable intracranial hypertension after aneurysmal subarachnoid hemorrhage. *Stroke* 38: 987–992, 2007
- Schoekler B, Trummer M: Prediction parameters of bone flap resorption following cranioplasty with autologous bone. *Clin Neurol Neurosurg* 120: 64–67, 2014
- Schwab S, Steiner T, Aschoff A, Schwarz S, Steiner HH, Jansen O, et al: Early hemicraniectomy in patients with complete middle cerebral artery infarction. *Stroke* 29: 1888–1893, 1998
- Shah AM, Jung H, Skirboll S: Materials used in cranioplasty: a history and analysis. *Neurosurg Focus* 36: E19, 2014
- Stula D: The problem of the “sinking skin-flap syndrome” in cranioplasty. *J Maxillofac Surg* 10: 142–145, 1982
- Sundseth J, Sundseth A, Berg-Johnsen J, Sorteberg W, Lindegaard KF: Cranioplasty with autologous cryopreserved bone after decompressive craniectomy. Complications and risk factors for developing surgical site infection. *Acta Neurochir (Wien)* 156: 805–811, 2014 discussion 811
- Vahedi K, Hofmeijer J, Jüttler E, Vicaut E, George B, Algra A, et al: Early decompressive surgery in malignant infarction of the middle cerebral artery: a pooled analysis of three randomised controlled trials. *Lancet Neurol* 6: 215–222, 2007
- Walcott BP, Kwon CS, Sheth SA, Fehnel CR, Koffie RM, Asaad WF, et al: Predictors of cranioplasty complications in stroke and trauma patients. *J Neurosurg* 118: 757–762, 2013
- Whitfield PC, Kirkpatrick PJ, Czosnyka M, Pickard JD: Management of severe traumatic brain injury by decompressive craniectomy. *Neurosurgery* 49: 225–226, 2001
- Winkler PA, Stummer W, Linke R, Krishnan KG, Tatsch K: Influence of cranioplasty on postural blood flow regulation, cerebrovascular reserve capacity, and cerebral glucose metabolism. *J Neurosurg* 93: 53–61, 2000
- Winter CD, Adamides A, Rosenfeld JV: The role of decompressive craniectomy in the management of traumatic brain injury: a critical review. *J Clin Neurosci* 12: 619–623, 2005
- Yadla S, Campbell PG, Chitale R, Maltenfort MG, Jabbour P, Sharan AD: Effect of early surgery, material, and method of flap preservation on cranioplasty infections: a systematic review. *Neurosurgery* 68: 1124–1129, 2011 discussion 1130
- Zanaty M, Chalouhi N, Starke RM, Clark SW, Bovenzi CD, Saigh M, et al: Complications following cranioplasty: incidence and predictors in 348 cases. *J Neurosurg*: 1–7, 2015