Comparison of Polyetheretherketone and Titanium Cranioplasty after Decompressive Craniectomy

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Key words
- Complication
- Cranioplasty
- Implant exposure
- PEEK
- Polyetheretherketone
- Titanium

Abbreviations and Acronyms
PEEK: Polyetheretherketone

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OBJECTIVE: **To characterize complication and failure rates and outcomes of patients who underwent cranioplasty with polyetheretherketone (PEEK) and titanium implants and to compare complication and failure rates between the 2 implants.**

METHODS: **A retrospective cohort study of patients who underwent cranioplasty with PEEK patient-specific implant (PEEK Optima-LT) and preformed titanium mesh at the National Neuroscience Institute, Singapore, between January 2001 and February 2012 was performed. Data related to initial decompressive craniectomy and cranioplasty, associated complications after cranioplasty, and indication for revision or removal of implants were collected. Cranioplasty failure was defined as revision or removal of a patient's implant.**

RESULTS: **Overall complication rates for PEEK and titanium cranioplasty were 25.0% and 27.8%, respectively. The combined complication rate was 27.3%. A trend toward increase in exposed implant in titanium cranioplasty compared with PEEK cranioplasty was observed ($P = 0.074$). There were 3 of 24 (12.5%) cranioplasty failures with PEEK, and 27 of 108 (25%) cranioplasty failures with titanium ($P = 0.129$). Previous deep infection in patients after decompressive craniectomy was associated with cranioplasty complications (odds ratio, 23.3; confidence interval, 3.00—180.5; $P = 0.003$) and failure (odds ratio, 22.5; confidence interval, 2.82—179.0; $P = 0.003$).**

CONCLUSIONS: **The findings from this study highlight that cranioplasty is associated with significant complications, including the necessity for reoperation. It is hoped that the information in this study will provide better understanding of the risks associated with PEEK and titanium cranioplasty and contribute to decision making by the clinician and patient.**

INTRODUCTION

Decompressive craniectomy is commonly used to treat medically refractory intracranial hypertension in trauma, cerebral infarction, and intracranial hemorrhage of various causes. After decompressive craniectomy, patients may require cranioplasty, a delayed procedure to reconstruct their cranial defect. Various materials ranging from autografts to xenografts and bone substitutes, including polymethyl methacrylate, hydroxyapatite, calcium phosphate, porous polyethylene, and titanium, have been used for the reconstruction of these cranial defects (17). Polyetheretherketone (PEEK), a well-known and widely used material in spine surgery, has been used more recently in cranioplasty.

The use of titanium in cranioplasty was first described in a small case series in 1964 (20). Titanium has been proven to be biocompatible and provides good cosmetic and functional results (21). However, it is not strong enough for brain protection in cases with large frontal defects that are prone to impact forces (5, 13), and it has been reported to cause thinning of soft tissues and extrusion (5). PEEK is an aromatic polymer with ether and ketone chains. It is currently available as a prefabricated patient-specific implant for cranioplasty. Prefabrication involves obtaining a fine-cut spiral computed tomography scan and creation of a digital model of the cranial defect and surrounding craniomaxillofacial skeleton. A digital model implant is produced, and final construction of the implant is accomplished after approval of the model. As a computer-assisted generated implant, the PEEK implant is said to have the advantage of being a precise fit to the cranial defect. In addition to its resistance to high temperatures, chemicals, radiation, and biologic inertness, PEEK has been reported to have other numerous advantages over other alloplastic materials in terms of strength, stiffness, durability, biocompatibility, thermal conductivity, and radiographic translucency. The elasticity and energy-absorbing properties of PEEK, which resemble bone more closely than titanium, provide better protection for cranioplasty in patients compared with titanium (14). To date, PEEK cranioplasty appears to be very promising with reports (1, 8, 19) showing good outcomes in terms of excellent cosmetic results, comparable strength to native bone, and low rates of infection. However, no long-term results in PEEK cranioplasty and comparison with titanium cranioplasty are available.

The present study characterizes complication and failure rates and outcomes of patients who underwent cranioplasty with PEEK and titanium implants. We also

compared complication and failure rates between the 2 implants.

METHODS

A retrospective cohort study of patients who underwent cranioplasty with PEEK patient-specific implant (PEEK Optima-LT; Synthes, Inc, West Chester, Pennsylvania, USA) and preformed titanium mesh that was peened to fit the patient intraoperatively at the National Neuroscience Institute, Singapore, between January 2001 and February 2012 was performed. In our institute, cranioplasty is performed at least 8 weeks after decompressive craniectomy provided that clinically the patient is medically well with no ongoing issues such as sepsis and the brain swelling has resolved. The decision for the type of implant used is made by the surgeon. Cranioplasty with autologous bone is not performed at our institution. We started performing cranioplasty with PEEK patient-specific implant in 2008. Approval for this study was obtained from the local centralized institutional review board.

Study subjects included patients with decompressive craniectomies who required cranioplasty using titanium or PEEK. Patients with incomplete data and patients who did not have a minimum of 1 outpatient follow-up examination were excluded. Data collected included age at time of cranioplasty; sex; significant past medical history; and parameters from initial decompressive craniectomy including indication, site, size, associated postoperative complications, Glasgow Outcome Scale score, time interval from decompressive craniectomy to cranioplasty, and length of follow-up. Complications after cranioplasty and indication for revision or removal of implants were also recorded. Cranioplasty failure was defined as revision or removal of a patient's implant. Superficial infection was defined as infection involving skin and subcutaneous tissue of the incision site. Deep infection was defined as cranial infection involving deep soft tissue, spaces, or brain. Exposed implant was defined as exposure or extrusion of implant because of erosion of the skin.

SPSS version 20 (IBM Corporation, Armonk, New York, USA) was used to perform all statistical analyses. Differences in proportions and means between the 2 groups were tested using Fisher exact test and Student t test for categorical and continuous variables, respectively. Analyses employing univariate and multivariate logistic regression models were also done. One patient with an exposed titanium implant who declined treatment was analyzed on an intention-to-treat basis. The level of statistical significance was set at $P < 0.05$. Values represent mean ± SEM.

RESULTS

Patient Demographics and Characteristics

This study comprised 132 patients who underwent decompressive craniectomy and subsequent cranioplasty with PEEK and titanium implants (Table 1). Patients who underwent PEEK cranioplasty tended to be younger than patients who had titanium cranioplasty. There is also a significant difference in follow-up length between the 2 groups because our institution started performing PEEK cranioplasty in 2008.

Cranioplasty Complications and Failure

Overall complication rates for PEEK and titanium cranioplasty were 25.0% and 27.8%, respectively, with a combined complication rate of 27.3%. The occurrence of superficial infection (PEEK [4.2%] vs. titanium [2.8%], $P = 0.758$), deep infection (PEEK [4.2%] vs. titanium [8.3%], $P = 0.404$), exposed implant (PEEK [4.2%] vs. titanium [13.9%], $P = 0.074$), new seizures (PEEK [8.3%] vs. titanium [1.9%], $P = 0.283$), and extradural

Table 1. Patient Demographics and Characteristics

	PEEK ($n = 24$)	Titanium ($n = 108$)	*P* Value
Number of males	13 (54.0%)	72 (67.0%)	0.279
Mean age (years)	35.0 ± 16.0	43.5 ± 15.5	0.023*
Mean GOS score	4.2 ± 0.9	4.0 ± 0.9	0.353
Mean DC size (cm^2)	80.8 ± 47.5	63.3 ± 28.9	0.095
Site of DC			
Left	9 (37.5%)	57 (52.8%)	0.259
Right	11 (45.8%)	41 (38.0%)	0.496
Bifrontal	3 (12.5%)	6 (5.6%)	0.209
Bilateral	1 (4.2%)	4 (3.7%)	1.000
Indications for DC			
Trauma	13 (54.2%)	55 (50.9%)	0.824
Intracranial hemorrhage	10 (41.7%)	33 (30.6%)	0.338
Ischemic stroke	1 (4.2%)	12 (11.1%)	0.461
Tumor resection	0	8 (7.4%)	0.350
Past medical history			
Previous superficial infection	2 (8.3%)	4 (3.7%)	0.299
Previous deep infection	3 (12.5%)	8 (7.4%)	0.420
Multiple cranial operations on same site	0	2 (1.9%)	1.000
Previous cranial radiotherapy	0	3 (2.8%)	1.000
Immunosuppression (DM, previous CT)	0	12 (11.1%)	0.122
Redo cranioplasty	1 (4.2%)	2 (1.9%)	0.455
Mean time interval between DC and CP (months)	8.3 ± 5.2	11.2 ± 16.4	0.126
Length of follow-up (months)	16.9 ± 14.4	43.1 ± 35.1	0.000*

PEEK, polyetheretherketone; GOS, Glasgow Outcome Scale; DC, decompressive craniectomy; DM, diabetes mellitus; CT, chemotherapy; CP, cranioplasty.
*Significant difference.

hemorrhage (PEEK [4.2%] vs. titanium [0.9%], P = 0.455) was characterized (Table 2). A trend toward increase in exposed implant in titanium cranioplasty compared with PEEK cranioplasty was observed, but this was not significant. The time interval from cranioplasty to the complication of exposed implant for PEEK was 1.6 months, and the mean time interval for titanium was 33.6 months (range, 0.26–83.06 months).

PEEK had 3 of 24 (12.5%) cranioplasty failures, whereas titanium had 27 of 108 (25%) cranioplasty failures. The difference between the 2 groups was statistically insignificant (P = 0.129). Kaplan-Meier plot (Figure 1) showed that PEEK cranioplasty tended to fail early (<3 months). This early failure was mainly due to infection. However, cranioplasties that did not fail tended to follow a stable curve with >85% of PEEK cranioplasties surviving at 3 years. In contrast, titanium cranioplasty showed a smaller proportion of early failures but followed a down-trending curve. At 3 years, 82% of titanium cranioplasties survived, but the longer follow-up time for titanium showed that it continued to fail at a steady rate thereafter.

Of 132 (22.7%) implants, 30 had either infection or exposure that required revision or removal, and 29 procedures (1 patient declined) were performed. Removal of the cranioplasty implant was performed in 14 of 14 patients experiencing infectious complications. Primary closure was achievable in all cases except for 1 patient with superficial infection who required a trapezius flap and 1 patient with deep infection who required a latissimus dorsi flap for closure.

Of the 15 patients with exposed cranioplasty implants who underwent a procedure, 10 patients had implant removal, 2 patients had implant revision, and 2 patients had wound débridement and closure. Primary closure was achievable in 7 of 14 patients; 6 patients required a local advancement flap, and 1 patient required an anterolateral thigh flap. One patient had mild exposure and underwent low-power laser therapy with good healing and closure of the skin defect.

Table 2. Complication and Failure Rates of PEEK and Titanium Cranioplasty

	PEEK (n = 24)	Titanium (n = 108)	P Value
Overall complications	6 (25.0%)	30 (27.8%)	0.783
Superficial infection	1 (4.2%)	3 (2.8%)	0.758
Deep infection	1 (4.2%)	9 (8.3%)	0.404
Exposed implant	1 (4.2%)	15 (13.9%)	0.074
New seizures	2 (8.3%)	2 (1.9%)	0.283
Extradural hemorrhage	1 (4.2%)	1 (0.9%)	0.455
Implant failure (requiring revision or removal)	3 (12.5)	27 (25)	0.129

PEEK, polyetheretherketone.

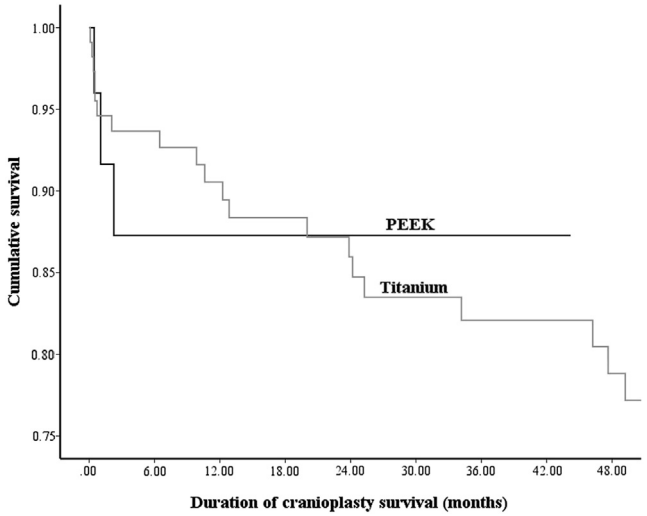

Figure 1. Kaplan-Meier graph of cranioplasty survival comparing polyetheretherketone and titanium implants. PEEK, polyetheretherketone.

Factors Affecting Cranioplasty Complications and Failure

Logistic regression analyses were performed to evaluate the effects of primary indications for decompressive craniectomy, medical history, implant material used, site and size of cranioplasty, and mean time interval from decompressive craniectomy to cranioplasty on cranioplasty complications and failure. The only factor associated with cranioplasty complications (odds ratio, 23.3; confidence interval, 3.00–180.5; P = 0.003) and failure (odds ratio, 22.5; confidence interval, 2.82–179.0; P = 0.003) was previous deep infection after decompressive craniectomy.

DISCUSSION

Although much has been written on cranioplasty and the various alloplastic implant materials used, publications of PEEK cranioplasty have been limited to case reports and small series (1, 8, 19). To our knowledge, this retrospective study is the largest comparison involving PEEK and titanium cranioplasty to date.

Complication and Failure Rates

The combined cranioplasty complication rate of 27.3% in this study is comparable to prior findings in the literature involving the use of polymethyl methacrylate or titanium (7, 23, 24). When stratifying to type of implant material, the complication rate of 27.8% for titanium was commensurate with many studies (Table 3) with complication rates ranging from 0–37.5% (4, 6, 9, 11, 12, 24, 26). There were no short-term or long-term results in cranioplasty with PEEK for comparison.

Our infection rate of 10.6% lies within current findings reported in the literature, which range from 0% (4, 15) to 22.2% (2, 3). On comparison with other materials used, the infection rate was similar to cranioplasty with autologous bone (8%) (10) but higher compared with hydroxyapatite implants (2.05%) (22). We further

Table 3. Complications After Titanium Cranioplasty

Study	Complication (%)	Infection (%)	Exposure (%)
Eurfinger and Saylor, 2001 (4)	4.5	0	4.5
Gear et al., 2002 (6)	2.3	2.3	0
Heissler et al., 1998 (9)	20	6.7	0
Joffee et al., 1999 (11)	0.7	0.7	0
Kuttenberger and Hardt, 2001 (12)	0	0	0
Vahtsevanos et al., 2007 (24)	37.5	16.7	—
Wiggins et al., 2013 (26)	29	16	—

characterized the level of infection as either superficial or deep. The exposed implant rate of 12.1% is higher than the rate reported by Eufinger and Saylor (4); this was the main complication found in our study. Only 1 of our patients (4.2%) with cranioplasty using a PEEK implant had an exposed implant, which occurred 1.6 months after implantation. Mean time interval between cranioplasty and occurrence of exposed implant in titanium implants was 33.6 months (range, 0.26–83.06 months). These findings illustrate that the length of follow-up after cranioplasty needs to be taken into consideration, and patients need to be monitored for this possible long-term complication.

The number of infected or exposed implants that required revision or removal was similar to that reported by Gooch et al. (7). However, our implant removal rate of 18.9% is higher than that reported by Neovius and Engstrand (16), where in 0–6.7% of titanium implants infection or wound dehiscence led to implant removal. These findings highlight that although cranioplasty is considered a simple procedure conceptually, there are significant risks of which clinicians should be vigilant when considering this procedure.

Factors Affecting Cranioplasty Complications and Failure

A more recent study (18) of the effect of timing of cranioplasty on postoperative complications reported that early cranioplasty, the presence of ventriculoperitoneal shunt, and primary indication for decompressive craniectomy of intracerebral hemorrhage were significant associations for the occurrence of postoperative complications after cranioplasty. In another study, Walcott et al. (25) showed that cranioplasty infection rates were predicted by the occurrence of reoperation and indication for decompressive craniectomy of stroke. In our study, we found that previous deep infection after decompressive craniectomy was associated with the development of cranioplasty complications and failure. Type of implant material used was shown not to affect complication and failure outcomes.

Comparison Between PEEK and Titanium Cranioplasty

Complication rates of 25.0% and 27.8% for PEEK and titanium cranioplasty, respectively, were identified; this difference was not statistically significant. There was a trend toward increase in exposed implant in titanium cranioplasty compared with PEEK cranioplasty, but this was not significant (13.9% vs. 4.2%, $P = 0.074$). This incidence of exposure shows that thinning of soft tissues and extrusion of implants remains an issue in titanium and may be an issue in PEEK cranioplasty. In Singapore, there is a substantial price difference between the 2 implants (PEEK [USD 4500] vs. titanium [USD 1700]). At the present time, our results do not justify the higher cost of using PEEK cranioplasty.

Limitations of Study

This was a retrospective study and was subject to shortcomings commonly related to this format, including loss of patient data and inadequate follow-up. These results represent only a single-center experience. However, our standardized protocol and large number of patients may outweigh our shortcomings.

CONCLUSIONS

We provided detailed data on complication and failure rates associated with PEEK and titanium cranioplasty after decompressive craniectomy. Despite its limitations, our study highlights that cranioplasty is associated with significant complications, including the necessity for reoperation. The most important factor for complication or failure of cranioplasty was previous deep infection after decompressive craniectomy. There were no differences in the complication rates between the titanium and PEEK cranioplasty. It is hoped that the information in this study will provide better understanding of the risks associated with PEEK and titanium cranioplasty and will be useful in clinician decision making and patient choice of a cranioplasty implant.

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