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7	Cranioplasty in the Sultanate of Oman
8	A retrospective review of cases from the National Craniofacial Center 2012-
9	2022
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17	Abstract
18	Objectives: Cranioplasty is a complex craniofacial and neurosurgical procedure, which aims to
19	reinstate the architecture of the cranial vault and elevate both aesthetic and neurological function.
20	Several reconstructive materials have been thoroughly explored in the search for the optimal
21	solution for cranioplasty. Methods: A retrospective analysis was carried out on all cranioplasty
22	procedures performed at Khoula Hospital from 2012 to 2022. This study encompassed a total of
23	47 patients. The data collection process involved gathering demographic information, the
24	characteristics of the cranial defect, and any complications that occurred post-operatively. Results:
25	The most common cause of cranial defects is craniectomy following traumatic head injury
26	(70.2%), along with excision of fibrous dysplasia (10.6%). The most frequently utilized material
27	for cranial repair was autologous bone graft (n=28), followed by PEEK (n=14). Interestingly, the
28	replacement of bone graft from previous craniectomy showed a notably high resorption rate
29	(71.4%), in contrast to split calvarial grafts (0%) and other types of bone grafts (14.3%).
30	Additionally, delayed graft infection was observed in 3.6% of the bone graft group and 7.1% of

- 31 the PEEK group. *Conclusion:* Patient-specific alloplastic implants such as PEEK, have gained
- 32 popularity for large and complex cranioplasty, as they provide excellent aesthetic outcomes and
- 33 leave no donor site morbidity. In contrast, bone graft remains the gold stander for small to medium
- 34 sized cranial defects.
- *Keywords:* Cranial Reconstruction; Cranioplasty; bone graft; PEEK

Advances in knowledge

- 1. This study provides detailed description about the causes of cranial defects in Oman, considering road traffic accidents are one of the leading causes of traumatic cranial defects hence highlighting the importance of road traffic accident safety precautions.
- 2. This study emphasizes on material selection case to case based.

Application to Patient Care

- 1. This study provides a better understanding of the causes of cranial defects in Oman, which helps in designing better prevention strategies, and preparing the health care system in Oman.
- 2. It provides a guide for the craniofacial plastic surgeons on the material selection for cranial reconstruction.
- 3. The importance of a strict preservation conditions for the autologous bone grafts.
 - 4. The importance of a strict infection prevention protocols during the cranial reconstruction surgeries.

Introduction

The human skull is a unique bony structure that plays an essential role in the distinctive appearance of an individual. It also acts as a protective vault for the central nervous system. However, this sophisticated structure can be disrupted by multiple disease processes, such as trauma and malignancies, leading to cranial defects. Defects in the skull can be caused by trauma, decompressive craniectomies, congenital anomalies, or tumor resections. This loss of bone compromises the skull's function as a brain guard and leaves the brain vulnerable to further physical trauma. In addition, the absence of sizeable calvarial bone leads to several physiological and psychological complications. 1–4

The skull shape contributes significantly to personal appearance, meaning that any defect in this area will result in extreme disfigurement. Pruzinsky illustrated that individuals with major craniofacial abnormalities might undergo social withdrawal and develop psychological and emotional distress. Among the other complications of absent cranial bony coverage is the "syndrome of trephine," described in 1939 by Grant & Norcross. Patients experience a cluster of symptoms, including headache, insomnia, behavioral changes, vertigo, tinnitus, and fatigue. The "Sinking Scalp Flap syndrome" has also been used to describe focal motor deficits in patients who have undergone craniectomy and have a persistent hemi-cranial defect. It is also known as motor trephine syndrome. Because of the many complications of cranial defects, cranial reconstruction is performed. 1,8

The main goal of cranioplasty is to restore the function of the skull shield, provide symptom relief, and enhance the patient's aesthetics. 1,3,8,9 A study involving 62 patients demonstrated that cranioplasty significantly improved the quality of life in all aspects during a 24-month follow-up. 10 This improvement was measured using SF-36, an assessment tool consisting of eight main domains (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). 10,111 Moreover, numerous studies have observed that cranioplasty enhances cerebral blood flow (CBF) in both hemispheres. 12–16 This increase in CBF appears to be a significant contributor to the symptomatic relief experienced by patients after reconstruction, including the resolution of headaches. Another study, utilizing objective measurement tools such as GOS, FAB, and MMSE, demonstrated cognitive recovery in 92% of participants during a 6-month follow-up. 12 Consequently, it was concluded that cranioplasty plays a vital role in the neurological and psychosocial rehabilitation of patients with skull defects. 9,16,17

Several reconstructive materials have been developed and used to close cranial defects. These materials are broadly categorized into two main groups: biological and synthetic materials. Biological materials include autologous grafts, allografts, and xenografts. The first documented use of a bone xenograft dates back to 1668 when van Meekeren reported the use of canine bone for the reconstruction of the skull of a Russian noble. Later, Walther conducted the first successful case of autologous bone graft in 1821. However, xenografts were greatly

discouraged later on due to their high infection, rejection, and resorption rates. ²⁰ It was not until the early 20th century that the use of autografts became widely practiced for their advantages, such as high biogenic compatibility (resulting in a low rejection rate) and their molding and integration ability into bones, especially in the pediatric age group where bones are still growing. ^{18,21} Several synthetic materials have been used, starting with acrylic after World War II. Subsequently, many other materials were developed and employed. However, due to associated side effects, technical difficulties, and limited accessibility, these materials are not utilized in current practice. ^{22–24} Nonetheless, materials such as Polyetheretherketone (PEEK), titanium mesh, and alumina ceramics are widely employed in contemporary practice, demonstrating favorable outcomes, including a low infection rate, shorter operation time, low resorption rate, and enhanced strength. ^{25,26}

The complication rate among cranial reconstructive materials differs. For instance, both bone xenograft and allograft have a high rate of infection and resorption. ^{19,20} Bone autograft is the gold standard to close small and medium cranial defects after the decompressive procedure because of its low infection rate and cost, and it is readily available. However, it carries a high risk of bone resorption and breakdown, especially in children. 18,27,28 Synthetic materials show a lower infection rate, resorption, and need for revision surgery, along with favorable cosmetic outcomes due to constant advancements in computer-based customization and 3-dimensional printing. 21,25,26 Furthermore, among different synthetic materials, titanium mesh has the lowest infection rate and a higher cosmetic outcome. However, it is also found to be heat-conductive and considered to be more costly. 18,25,29 Methyl methacrylate (MMA) is considered strong, radiolucent, and nonconductive to heat but is unfortunately associated with a high infection rate. ^{18,25,30,31} The use of Hydroxyapatite is limited because of its high infection rate, limited osteointegration, and low tensile strength leading to fragmentation, although its flexibility and expansion properties make it favorable for use in the pediatric age group. 18,32 Alumina ceramics and PEEK have the desired strength, low infection rate, a favorable cosmetic outcome, and are chemically stable but are considered the most expensive materials and lack osteogenic properties. 18,23,25,33

In the Sultanate of Oman, the vast majority of cranioplasties are performed at the national trauma center, Khoula Hospital. Cases of cranial reconstruction involving the replacement of bone from

previous craniectomy procedures are exclusively handled by neurosurgeons. In contrast, instances of cranioplasty using other types of bone grafts or allograft materials, as well as those involving complex cranial defects, are mainly undertaken by the craniofacial plastic team. While there has been one study published on Oman's experience with PEEK cranioplasty, there are no reports of cranial reconstruction using other materials. Hence, this study was conducted. ³⁴

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Methods

A cross-sectional study was conducted to examine all cases of cranial reconstruction that were operated on in Khoula Hospital, the Sultanate of Oman, between February 2012 and December 2022.

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The initial participant list was retrieved from the medical electronic files of Khoula Hospital (Al Shifa 3 Plus) using keywords such as (cranioplasty, cranial reconstruction, PEEK, Titanium, bone graft, etc.). After thoroughly reviewing the initial list, only patients who satisfied the inclusion criteria were incorporated into the final version. Patients who underwent immediate cranioplasty post-craniotomy and cases of reduction of cranial bone fractures were excluded.

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47 cases were found eligible. The electronic medical records of these patients were extensively 141 142 examined to extract study parameters. Demographic information, such as age and gender, was 143 collected. Details regarding cranial defects, including the mechanism, location, size, and any prior 144 reconstruction, were recorded. Cranial reconstruction parameters included the type of material, 145 operative time, and hospital stay. Additionally, immediate and delayed postoperative 146 complications were identified. Delayed adverse outcomes were defined as complications that 147 occurred after the patient is discharged postoperatively. The screened complications included 148 wound infection, seizure, hydrocephalus, hematoma, significant seroma requiring aspiration, 149 subdural hygroma, wound gaping, bone resorption, implant exposure, hardware failure, and 150 revision surgery. To mitigate bias, data were independently collected by two trained researchers. 151 All data were coded and stored in a password-protected computer, consolidated in a single Excel 152 sheet.

This study was approved by the Khoula Hospital Ethical Board. This study was conducted in accordance with the Declaration of Helsinki. Patient Consent Patients have signed a written consent to share their data and use their photos in the manuscript.

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Results

During the study period from 2012 to 2022, forty-six (47) cases of cranial defects underwent cranioplasty using various cranial reconstruction materials. Most cases had no known medical comorbidities, except for 3 patients with hypertension, two patients with multi-suture craniosynostosis who had been previously operated on, and one diabetic patient.

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- The most common cause of cranial defects was found to be traumatic, accounting for 33 cases
- 165 (70.2%), with 26 defects developing post-motor vehicle accidents, 6 cases post-falls, and 1 case
- caused by a gunshot injury. Five cases had cranial defects after fibrous dysplasia excision (10.6%).
- Other causes of cranial defects in our series included excision of Langerhans cell histiocytosis
- 168 (4.26%), squamous cell carcinoma (4.26%), neurofibroma (2.1%), frontal encephalocele (2.1%),
- 169 cleidocranial dystocia (2.1%), post-debridement of osteomyelitis area (4.26%), and decompression
- craniotomy for brain abscess drainage (2.1%).

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- 172 Thirteen patients had a prior history of cranial reconstruction. Among these 13 patients, seven were
- 173 reconstructed using bone autograft, one with titanium mesh, and 5 with other methods, including
- elevation of the fractured segment and fixation, fronto-orbital advancement, and cranial vault
- expansion. Most cranial reconstructions in our cases were done using bone autograft in 28 cases
- 176 (59.6%). In the bone graft category, 14 cases were reconstructed using split-thickness calvarial
- bone, 7 cases using bone from previous craniectomy (known as bone replacement), and another 7
- cases utilizing bone graft from other locations such as the iliac crest and rib. PEEK was used for
- 179 14 cases (29.8%), 2 cases were reconstructed with bone cement (4.26%), 2 cases with titanium
- 180 mesh (4.26%), and 1 case with acrylic (2.1%).

- In terms of the locations of these cranial defects in our sample, eleven of the defects were fronto-
- temporo-parietal (23.4%) in location, ten with frontal defects (21.3%), six with fronto-parietal
- defects (12.8%), and four were found with defects in the fronto-temporal area (8.5%). There were

five cases of parietal defects (10.6%), and other defects were seen with the following percentages: occipital (6.4%), temporal (2.1%), parieto-occipital (8.5%), and temporo-parietal (4.26%). The mean size of the defects was 80.6 cm². The largest defect among our cases was 300 cm², whereas the smallest was 5.25 cm².

There were no intra-operative complications in all cases, and the mean operation time was 3 hours and 56 minutes. Furthermore, we investigated the average operation time for each used material and found that the longest average time for performing cranial reconstruction was using bone autograft; 3 hours and 57 minutes. The average hospital stay was 10.8 days. Further details about average operation time and hospital stay across different used materials are shown in Table 1.

Immediate post-operative complications were observed in 4 cases (8.5%). Three cases developed a hematoma, and 1 case had a wound infection. Delayed complications developed in 40.4% of the cases, with some cases experiencing multiple adverse outcomes. The most frequent delayed complications were significant bone graft resorption (n=6) and residual deformity (n=5). The majority of bone graft loss occurred in cases where bone from previous craniectomy was used (71.4%). Adverse outcomes are summarized in Table 2.

Discussion

In our study, we included 47 cases of cranial defects that underwent cranioplasty between 2012 and 2022. The most common cause of cranial defects was traumatic, predominantly post road traffic accidents (RTA). In 2012, road traffic crashes were reported to be the top cause of injuries, disabilities, and deaths in Oman, according to an official report by the Omani Ministry of Health (MoH). In a subsequent analytic study, the rate of RTAs was observed to have a minimal decline until 2018. Posti et al conducted a retrospective observational study to assess the operative outcomes of cranioplasty after severe traumatic brain injury treated with decompressive craniectomy. They reported that a successful cranioplasty predicts favorable patient outcomes one year after the procedure. Moreover, it was reported that the appearance of traumatic subarachnoid hemorrhage on imaging is a major risk factor for implant removal. They reported that the appearance of traumatic subarachnoid hemorrhage on imaging is a major risk factor for implant removal.

215 As the ideal material for cranial defect reconstruction remains a matter of debate, our study 216 utilized different materials, with decisions made based on various factors, including but not 217 limited to the size and location of the defect, availability of materials, and surgeon preference. 218 Overall, bone autograft was the most frequently used material in our center, accounting for 219 59.6% of cases. Most of these patients underwent calvarial split-thickness bone grafting, and 220 78.5% of them had a small to medium-sized defect (<100 cm²). Among the 28 patients who 221 underwent bone autografting for cranial defects, 6 experienced bone graft resorption (21.4%), 222 and graft migration was observed in 2 cases. Cranial reconstruction with bone graft stored from 223 the previous craniectomy, also known as bone replacement, exhibited the highest resorption rate 224 compared to other types of bone autograft, with a percentage of 71.4% (Figure 1). One case, with 225 a prior history of regional radiotherapy, underwent repair using a rib bone graft and was 226 complicated by multiple infections and bone resorption, ultimately leading to graft removal. 227 However, all other bone autograft sources showed no resorption after a 1-year follow-up. In a 228 meta-analysis published in 2016, the resorption rate was found to be 9.7% after decompressive 229 craniotomy, with an average storage duration of 69.9 days and a mean freezing temperature of -57°C. ³⁸ . In addition, bone graft resorption can still occur beyond 12 months postoperative. For 230 231 example, a randomized controlled trial that followed up with 31 patients having a Titanium 232 cranial implant and 31 patients undergoing autologous bone cranioplasty for a period of 24 months showed bone resorption during long-term follow-up. ³⁹ Cobbad et al concluded in one of 233 234 their papers that autologous bone is still the most reliable, safe, and cost-effective material. It 235 remains the gold standard due to its excellent biocompatibility and osteogenesis ability (Figure 236 2). However, its use is hindered by its tendency for resorption and the need for preservation. It is usually either preserved at freezing temperatures (-70°C) or within the abdominal wall.⁴⁰ When 237 238 comparing the two methods of preservation, Corliss et al found no statistically significant differences in terms of infection, resorption, and reoperation rates..³⁸ However, most centers 239 240 nowadays avoid opening the abdominal wall for preservation to minimize additional surgery, scarring, and the patient's comorbidities. In our center, the current neurosurgical practice is to 241 242 preserve the bone graft from craniectomy in freezer of -5 degree C temperature. In addition, a 243 recently published study suggested a new way of preserving bone graft in the freezer to reduce 244 infection later. Their novel cryopreservation approach involved placing the bone graft in gauze 245 saturated with 80mg of gentamicin and 2g of nafcillin within a three-layer sterile bag system.

They managed to reduced infection rate from 18.7% using the traditional wet cryopreservation method to 5.6% using the new dry cryopreservation method. 41 Furthermore, the majority of these cases involve complicated MVC victims who undergo cranioplasty late, during which the bone remains in place for an extended period, exceeding a year in most instances. This delay in reconstruction and suboptimal preservation might explain the high rate of resorption observed in cranioplasty with bone replacement. In a study conducted in South Korea investigating risk factors for bone resorption, it was concluded that the pediatric age group, larger skull defect, the gap between the bone flap and bone edge, and heat sterilization of autologous bone could be contributing factors for bone resorption.⁴² Additionally, a multicenter study reported that it takes two years to stabilize the bone flap and therefore recommends a two-year follow-up as an optimal length.⁴³ Custom-made PEEK implants exhibit superior aesthetic outcomes as it is patient-specific (Figure 3). An analysis of 12 patients with PEEK implants, using root mean square error (RMSE) between the presurgical virtual position and the postoperative actual position of the implant, revealed that PEEK implants manufactured in a patient-specific style demonstrate highly accurate positioning. This, in turn, results in superior aesthetic outcomes.⁴⁴ In addition to its cost, PEEK implants lack osteogenic properties and the ability to integrate with surrounding bones, which might increase the risk of infection, local inflammation, and dislodgment. 18,21,26 Patientspecific PEEK implants were used in 14 cases (29.8%), with no intra-operative and/or immediate complications. However, seroma was noted in 4 cases (28.6%), implant migration in 1 case (7.1%), and 2 cases developed seizures (14.3%). When comparing our results with Punchak et al.'s meta-analysis, our incidence tends to fall within the international range.⁴⁵ The incidence of infection post-cranioplasty ranges from 5% to 33% worldwide, and our rate was 6.4% across all used materials and 7.1% with PEEK implants. 46-50 The case of the infected PEEK implant involved a 44-year-old male with fibrous dysplasia. This patient underwent left frontal bone and superior orbital resection, along with frontal sinuses obliteration. Simultaneously, two PEEK PSIs were used for reconstruction. The patient initially recovered well without complications. However, on a 4-year follow-up, the patient developed intermittent clear nasal discharge. CT scans and other laboratory tests were conducted. CSF rhinorrhea was ruled out, and no clinical or laboratory findings suggested infection. The patient continues conservative management. Our

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277 low infection rate could be explained by our strict protocol, which was published in a previous 278 study. It consists of intravenous cefazolin for a total of five days, in addition to frequent and 279 extensive head washing with chlorhexidine preoperatively. 51 280 281 Regarding the size, the largest defect among our cases was 300 cm², whereas the smallest was 282 5.25 cm². The mean operative time for all cases in the study was 3 hours and 56 minutes. 283 Multiple studies, including the one published by Sedney et al., argued that a larger craniectomy size improves survival without the risk of increased complications.⁵² On the other hand, larger 284 285 defects may require more meticulous surgical techniques, leading to longer operative times that 286 may increase the risk of surgical site infection, as proven by Shibahashi K and his group. They 287 stated that the estimated two-year surgical site infection risk was 31.3% for the long operative time (> 1 hour and 38 minutes).⁵³ 288 289 290 In our current craniofacial protocol, we advise against using preserved bone graft from previous 291 craniectomy to reconstruct large cranial defects, especially if the graft was not stored in an optimal environment, as it carries a high resorption rate. Alternatively, we recommend the use of 292 293 a patient-specific PEEK implant for large defect cranioplasty, as it has superior aesthetic 294 outcomes and excellent survival. In contrast, split calvarial bone graft is an optimal option for the 295 reconstruction of small to medium defects. 296 297 In terms of follow-up, our protocol involves close interval monitoring during the first 6 months 298 postoperative and subsequently on a yearly basis. According to some studies, the standard follow-up is recommended at 3 months.⁵⁴ However, certain complications can still arise in the 299 long term, such as bone resorption or delayed implant infection.³⁹ Therefore, we adhere to a 300 301 rigorous long-term follow-up, extending up to 5 years in some cases. Concerning imaging 302 investigations, CT maxillofacial with 3D reconstruction is performed on the 3rd day 303 postoperative, followed by additional assessments at 3 and 6 months postoperative. Moreover, 304 delayed CT scans can be conducted to evaluate for late complications, such as assessing the

extent of bone resorption beyond the 12-month follow-up period.

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307 **Conclusion**

- 308 In conclusion, cranial reconstruction remains a debatable matter given the wide variety of
- available materials and their variable success and complication rates. Thus, material selection
- 310 should be tailored based on the defect characteristics. Additionally, there is a need to develop
- more optimal materials that offer good biocompatibility, infection resistance, a high survival
- rate, and provide a satisfying aesthetic outcome.

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314 Authors' Contribution

- 315 KA, SS and TB conceptualized and designed the study. KA, SS and TB were responsible for
- project coordination. KA collected the data. AF analyzed the data. KA, AF, MS, AJ drafted the
- manuscript. SS and TB revised the manuscript and supervised the work. All authors approved the
- final version of the manuscript.

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Conflict of interest

325 The authors declare no competing interests.

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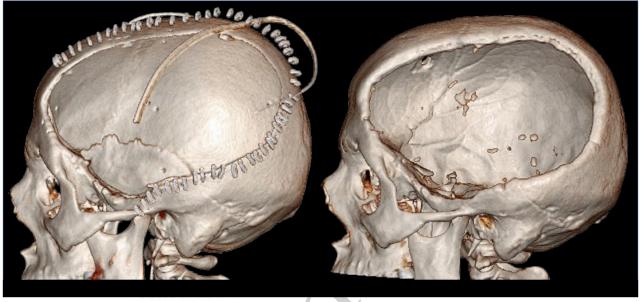
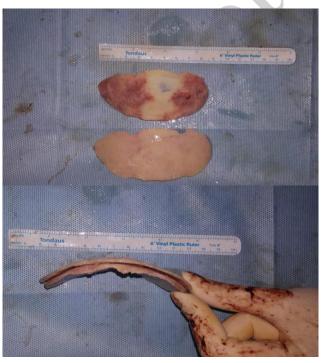


Figure 1: Right side: 3rd day post cranioplasty with bone graft replacement (bone from previous craniectomy). Left side: 9 months post operative. The picture illustrates severe resorption of the bone graft (>98).





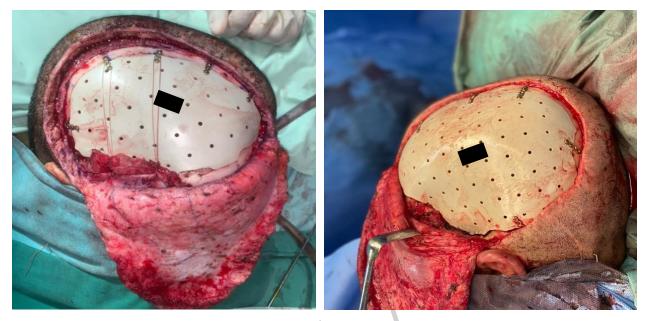


Figure 3: PEEK patient-specific cranial implants, patients' identifications have been concealed. The implants are fixed with titanium plates and screws. On the left picture, temporalis muscle is being suspended over the implant.

		Mean Operation Time	Mean Hospital Stay (Days)
Bone Autograft	Calvarial Split Bone Graft	4 hours 47 minute	7
	BG From Craniotomy	2 hours 10 minute	25
	Rib BG	4 hours 50 minute	8
	Iliac Crest BG	2 hours 40 minute	14
PEEK		3 hours 51 minute	8
Cement		5 hours	7
Titanium		2 hours	not known
Acrylic		2 hours	3

Table 2: Crosstabling between used materials and observed complications (with the percantage of the complication within the material)

Number Immediate of Cases Complications

Late Complications

				Wound Infection	Hematoma	Bone Resorption	Delayed graft infection	Graft migration	Residual Deformity	Seroma	Seizure
Bone Autograft	Calvaria	al STBG	14	0	2 (14.3%)	0	0	0	1 (7.1%)	0	0
	BG craniect	from omy	7	1 (14.3%)	0	5 (71.4%)	1 (14.3%)	1 (14.3%)	0	1 (14.3%)	0
	Other BG	distant	7	0	0	1 (14.3%)	0	1 (14.3%)	0	0	0
PEEK			14	0	0	0	1 (7.1%)	1 (7.1%)	2 (14.3%)	4 (28.6%)	2 (14.3%)
Titanium M	esh		2	0	0	0	1 (50%)	1 (50%)	0	0	0
Acrylic			1	0	0	0	0	1 (100%)	0	0	0
Bone Ceme	nt		2	0	0	0	0	0	1 (50%)	0	0