Med. J. Cairo Univ., Vol. 90, No. 1, March: 345-350, 2022
www.medicaljournalofcairouniversity.net

The Use of Prefabricated 3D Printed PEEK Implants for Repair of Skull Defects

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Abstract

Background: Skull defects may occur following trauma, infection, tumor invasion and neurosurgical procedures like decompressive craniectomy. Large defects should be reconstructed for brain protection and normalization of cerebral hemodynamics.

Aim of Study: To evaluate the use of prefabricated customized 3D printed implants for cranioplasty of skull defects >4cm in diameter.

Patients and Methods: The study included 20 patients with skull defects >4cm in diameter operated upon by cranioplasty using prefabricated 3D printed PEEK implants in the period from March 2017 to April 2018. Patients were assessed for cosmetic results, cost, operative time and complications. Pre and post-operative CT scans with 3D reconstruction were performed in all patients. Patients were followed-up clinically and radiologically for 6 months following surgery.

Results: The study included 15 males and 5 females with an average age of 39.4 years. The cause of skull defect was trauma in 9, tumor invasion in 7, decompressive hemicraniectomy in 2 and infection in 2 patients. The average defect size was 7.6cm in diameter. Good cosmetic results were achieved in all patients. No complications were encountered except for superficial wound infection in 1 patient and small extradural hematoma in another patient.

Conclusion: Use of 3D printed implants for cranioplasty provides excellent cosmetic results with less operative time, blood loss and complications when compared to conventional methods but at a higher cost.

Key Words: *Cranioplasty – Implant – Polyetheretherketone – Repair.*

Introduction

SKULL defects may result from trauma, infection, invading tumors or neurosurgical procedures such as decompressive craniectomy. Reconstruction of large sized defects is required for cosmetic reasons as well as to protect the underlying brain and normalize the cerebral hemodynamics [1]. Cranioplasty is considered among the oldest neurosurgical procedures, performed since 3000 B C [2]. The ideal cranioplasty material should be resistant to infection, radiolucent, not dilated with heat, easy to shape, strong to biomechanical processes, ready to use, not expensive and properly fits the cranial defect [3].

Throughout history, numerous different materials were used for repair of skull defects. Despite the variety in materials and techniques of cranioplasty, there is no consensus about the ideal material and researches continue to develop the ideal reconstruction material [4].

The most commonly used synthetic materials for cranioplasty include polymethylmethacrylate (PMMA), hydroxyapatite, ceramic, titanium and polyetheretherketone (PEEK) [5]. The use of PEEK allograft for cranioplasty is increasing specially in the last decade [6]. Outstanding regards density and mechanical strength, it also doesn't interfere CT and MRI and easily designed according to custom order [5,7,8].

The development of computer-assisted designs and three-dimensional printing technology has allowed the production of patient-specific, prefabricated, customized cranioplasty implants. Although the technique is more precise than conventional cranioplasty, it has not been widely used due to

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Abbreviations:

CAD/CAM : Computer aided design/computer aided manufacturing.
cm : Centimetre.
CSF : Cerebrospinal fluid.
CT : Computerized Tomography.
GCS : Glasgow Coma Scale.
IV : Intravenous.
MCA : Middle cerebral artery.
MRI : Magnetic resonance imaging.
PEEK : Polyetheretherketone.
PMMA : Polymethylmethacrylate.
SDH : Subdural hematoma.

the high expenses of the 3D printers and customized implants [9].

The aim of this study was to evaluate the use of prefabricated customized 3D printed PEEK implants for cranioplasty of skull defects larger than 4cm in diameter as regards cosmetic results, post-operative complications, duration of operation and cost-effectiveness.

Patients and Methods

The study was conducted on 20 patients with skull defects larger than 4 cm in diameter operated upon by cranioplasty using patient-specific prefabricated customized 3D printed PEEK implants in the period from March 2017 to April 2018 in Neurosurgery Department, Faculty of Medicine, Cairo University Hospitals. Patients with defects less than 4cm in diameter, bilateral defects, hydrocephalus, infected flaps, unfit for general anesthesia, with disturbed conscious level (GCS <15) and patients older than 65 years were excluded from the study.

Preoperative 1mm thick spiral CT brain with 3D reconstruction was used to manufacture the PEEK implant using computer aided design / computer aided manufacturing (CAD/CAM) technology with the use of a 3D printer utilizing information from the normal side of the skull (contralateral to the defect).

Surgery was performed under general anesthesia. After positioning of the patient, shaving of the hair and sterilization of the wound, the scar of the previous operation was opened and bone margins were clearly exposed with proper dissection of the temporalis muscle form the underlying dura. Care was taken to avoid unnecessary opening of the dura which may lead to CSF leak later on. The prefabricated implant was then placed in position and several dural stitches to the implant were performed to avoid the later collection of an extradural hematoma. The implant was then fixed to the surrounding bone margins by self-tapping screws and miniplates (Fig. 1). After proper hemostasis, the wound was closed in layers leaving a subgaleal drain that was removed 24 hours postoperatively.

Patients were followed-up clinically and radiologically for 6 months following surgery (Fig. 2). Follow-up CT scan with 3D reconstruction was performed the next day after surgery to assess the placement of the construct and detect any complications like hemorrhage or edema. Another CT was performed at 6 month follow-up to assess the cosmetic results. Patients were assessed for cosmetic results, operative time and complications including infection, seroma, exposure of the construct, hemorrhage, CSF leak, new onset seizures and need for reoperation or removal of the implant. For assessment of cosmetic results, the patient and his family were asked at 6 month follow-up to describe the cosmetic appearance as either complete success, partial success, satisfactory, partial failure or complete failure. The first three options were considered good cosmetic results whereas the last two were considered poor cosmetic results.

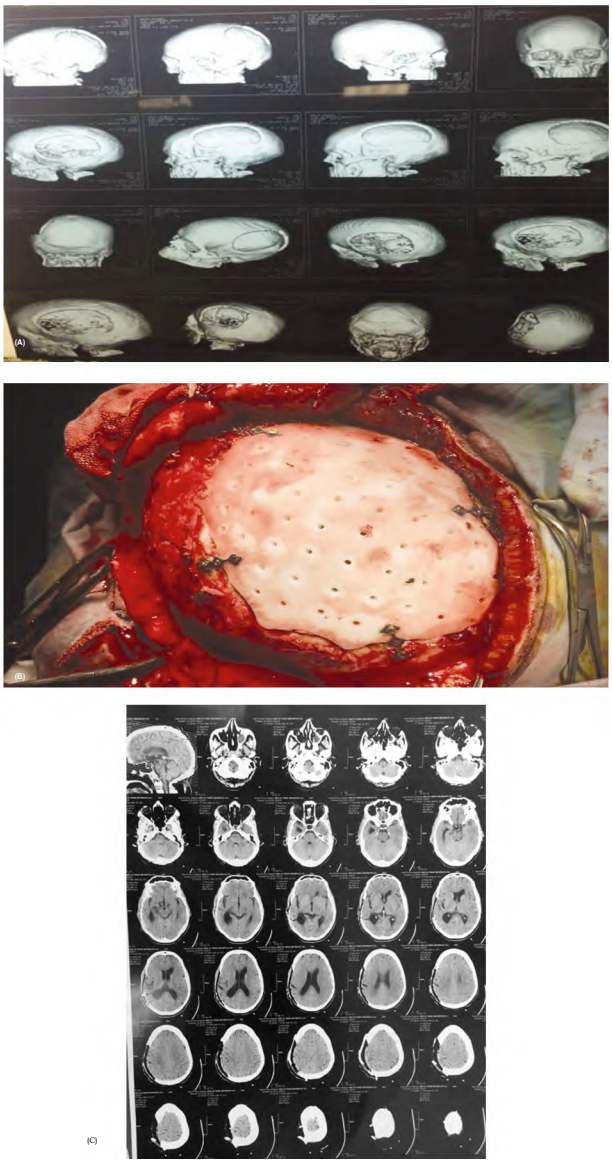
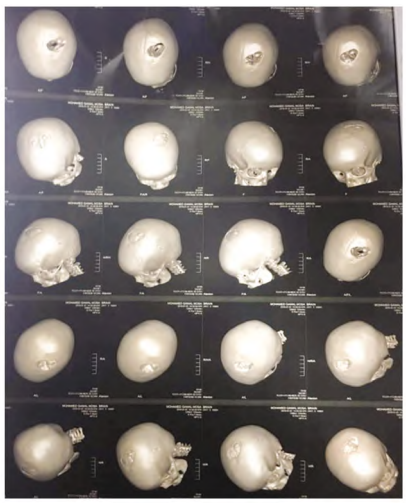
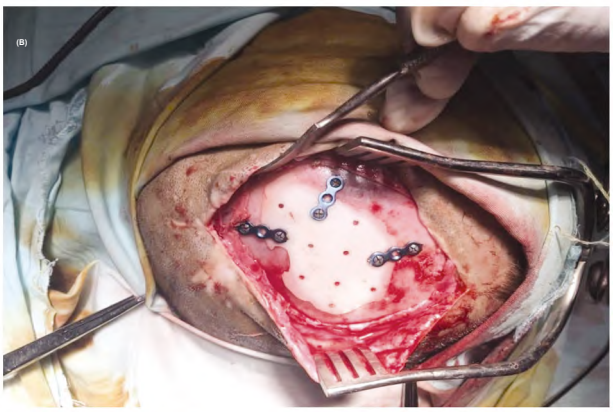


Fig. (1): 44 years old male patient with history of chronic brain abscess operated upon by excision 1 year prior to admission followed by osteomyelitis 1 year prior to admission, (A) Preoperative CT 3D reconstruction showing large right fronto-parietal defect (B) Intraoperative placement of the PEEK implant and fixation to bone margins with miniplates and screws (C) Follow-up axial CT showing proper fitting of the construct.

(A)





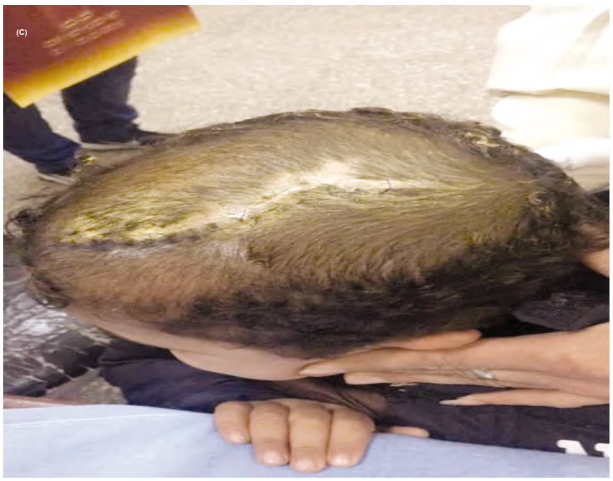


Fig. (2): 6 years old boy with history of compound depressed skull fracture operated upon by removal of comminuted fragments 6 months prior to admission (A) CT 3D reconstruction showing the skull defect (B) Intraoperative application of the construct (C) The patient at follow up after restoration of normal skull contour.

Results

The study included 15 (75%) males and 5 (25%) females whose age ranged from 6-61 years with a mean age of 39.4 years. Trauma and tumor invasion were the most common causes of the initial bone defect where trauma was the aetiology in 9 (45%) patients and tumor invasion in 7 (35%) patients. Other causes were decompressive hemicraniectomy in 2 (10%) and infection in 2 (10%) patients (Table 1). The interval between previous surgery and cranioplasty ranged from 5-16 months with an average of 10.4 months. The size of the defect ranged from 4.4 to 14.5cm in diameter with an average of 7.6cm. The mean operative time was 79.2 minutes and the mean postoperative hospital stay was 2.5 days.

Table (1): Aetiology of skull defect.

Cause	No.	Percentage
Trauma	9	45
Tumor invasion	7	35
Decompressive craniectomy	2	10
Infection	2	10

Good cosmetic results were achieved in all patients. At 6 months follow-up, the process was considered cosmetically a complete success by 11 (55%) patients, partial success by 5 (25%) patients and satisfactory by 4 (20%) patients. No cases were reported as partial or complete failure (Table 3).

Regarding complications, no complications were encountered except for superficial wound infection in one patient who was managed conservatively with repeated dressing and IV antibiotics after culture and sensitivity with no need for removal of the implant. Another patient developed a small extradural hematoma which resolved in follow-up and didn't require surgical evacuation. None of the patients developed complications requiring reoperation or removal of the implant.

Table (2): Cosmetic results at 6 months follow-up.

Complete Success	Satisfied with appearance	11 (55%)
Partial Success	Minor cosmetic problem	5 (25%)
Satisfactory	Satisfied but not ideal	4 (20%)
Partial Failure	Unhappy with appearance but could be left	0 (0%)
Complete Failure	Unhappy with appearance and wants revision	0 (0%)

Discussion

Cranioplasty is defined as the surgical repair of skull defects caused by trauma, infection or surgery like decompressive craniectomy **[10]**. The operation has cosmetic purpose for restoration of normal shape of the skull and functional purpose

to protect the brain, regulate CSF dynamics and reduce headache caused by previous trauma or surgery [11]. The patient's own bone is the most common material used for cranial reconstruction. Advantages are that it is cheap, strong, radiolucent and has an ideal contour [12]. On the other hand, using autologous bone was found to be associated with high rate of infection and bone resorption and in this case the flap has to be removed and replaced by alloplastic alternative [13].

In the past, the most commonly used alloplastic material for repairing skull defects when the autologous bone was not available was PMMA (bone cement). It has the advantages of being cheap, heat resistant, strong with ease of use. However, bone cement has a high rate of infection, extrusion, fracture and cosmetic dissatisfaction to the patient [3,14,15]. More recently, other materials were used the most common of which are titanium and PEEK. Titanium is strong and malleable and provides good cosmetic results. It has the lowest rate of infection among materials used for cranioplasty [15]. The disadvantages of titanium is that it is expensive and produces image artifact on postoperative imaging [3]. PEEK on the other hand doesn't produce artifacts on imaging. It is also light in weight making it more comfortable to the patient and, unlike the metallic implants, doesn't conduct temperature [16]. The main disadvantages of PEEK implants are the high cost, lack of osteointegrative properties making it liable to extrusion and the high risk of infection [3].

Our study was performed on 20 patients with skull defects where the original bone was not available. Cranioplasty was done using prefabricated PEEK implants in all patients. The aetiology of the skull defects in these patients was either following trauma requiring removal of the bone flap to decompress the cortex as in large acute SDH and massive brain oedema or due to a compound depressed fracture where the fractured bone fragments were too small to be repositioned. Other aetiologies included tumor invasion by invasive meningioma as in the case of meningioma en plaque, iatrogenic following decompressive hemicraniectomy for massive MCA infarction and osteomyelitis of the skull bone following previous surgery. The interval between previous surgery and cranioplasty was lower in cases following trauma and decompressive craniectomy (usually 5-7 months) while it was highest in cases following infection (ranging from 12-16 months).

Good cosmetic results were achieved in all patients in our study. 80% of patients described the surgery as either complete or partial success while 20% considered it satisfactory. The two most common causes for non-complete satisfaction of the later group were temporalis muscle atrophy which was not corrected by the PEEK implant and non-cosmetic appearance of the scalp wound specially if it reached areas not covered by hair. Good cosmetic results were also described in other studies where prefabricated implants were used for cranioplasty [17,18,19]. On the other hand, numerous studies have shown less favorable cosmetic results with the use of autologous bone, bone cement and conventional titanium mesh [20-23].

The operative time was markedly reduced when compared with other methods of cranioplasty (especially PMMA cranioplasty). Numerous other studies reported similar results [17,18,19]. The reduced surgical time is valuable in numerous aspects, the most important of which is that may lower surgical complications particularly the infection rate. The study performed by Lee et al., [24] suggested that reduced operative time significantly reduces the risk of bone graft infection. It may also help in compensation of the high cost of the prefabricated implant [19,25].

Only one patient developed wound infection in our series representing 5% of cases. This may be considered a low incidence as the infection rate following cranioplasty in the literature ranges from 2 to 21.4% [26,27]. Other studies using prefabricated implants have similarly shown low infection rates [14,16-19]. The low infection rate with customized implants is probably related to the short operative time, less handling of the implant, avoidance of long term preservation of the autogenous flap and the toxic gas produced during PMMA cranioplasty. Another complication encountered in our series was an extradural hematoma in one patient which resolved spontaneously in follow-up scans. We recommend to always apply dural tuck-up stitches to the bone margins as well as to the under surface of the implant to minimize the risk of extradural hemorrhage later on.

None of our patients during the 6 month follow up period developed exposure, resorption or failure of the implant. This is promising as these complications are common with conventional cranioplasty procedures including autologous bone and PMMA. Other studies have also shown superiority of prefabricated implants over conventional techniques regarding complications related to the construct and need for reoperation [5,17,18,28]. Ng et al., [29] compared prefabricated implants made of PEEK with those made of titanium. Complications regard-

ing implant exposure and failure were significantly higher in the titanium group and suggested that PEEK is superior to titanium as a cranioplastic implant. On the other hand, Oliver et al., **[30]** performed a systematic review on four methods of alloplastic cranioplasty and stated that PEEK implants showed the highest rate of local complications and highest ultimate failure rate when compared with PMMA, titanium and Norian implants.

Our results suggest that the use of prefabricated PEEK implants provides better cosmetic results with less complications than other methods of cranioplasty. The high cost of the implant remains a challenge specially in developing countries. We believe that it is particularly valuable in patients with previous failed cranioplasty surgery in addition to children, young women, very large skull defects and defects in areas of the skull not covered totally by hair particularly the frontal region. We recommend further prospective studies with larger number of patients and for longer follow-up periods for better assessment of the cost-effectiveness of this technique and for detection of possible late complications specially in children with growing skulls.

Conclusion:

Use of prefabricated PEEK implants for reconstruction of large skull defects has shown promising results. It produces better cosmetic results with less side effects than conventional methods of cranioplasty. The high cost of the implant requires accurate patient selection specially in developing countries.

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إستخدام شرائح الكيتون إيثر متعدد الإيثر مسبقة الصنع عن طريق الطابعة ثلاثية الأبعاد فى عمليات رأب القحف

أجريت هذه الدراسة على عشرين مريض يعانون من وجود عيب بعظام الجمجمة نتيجة إصابة أو إلتهاب أو ورم أو جراحة سابقة حيث تم إجراء جراحة رأب القحف لتجميل عظام الجمجمة بإستخدام شرائح الكيتون إيثر متعدد الإيثر مسبقة الصنع عن طريق الكمبيوتر والطابعة ثلاثية الأبعاد. وقد إجريت الجراحة للمرضى فى عمليات جراحة المخ والأعصاب بكلية الطب جامعة القاهرة وتم متابعة المرضى لمدة ستة أشهر بعد إجراء الجراحة إكلينيكياً وعن طريق الأشعة المقطعية ثلاثية الأبعاد على المخ وذلك لمتابعة النتائج التجميلية للجراحة ومتابعة حدوث أى مضاعفات للجراحة مثل الإلتهاب أو النزيف أو الحاجة إلى إزالة الشريحة. وقد أظهرت نتائج البحث أن استخدام شرائح الكيتون إيثر متعدد الإيثر له نتائج مبشره فى عمليات رأب القحف حيث أن النتائج التجميلية كانت أفضل من الطرق التقليدية لرأب القحف مثل استخدام أسمنت العظام أو الشبكة التيتانيوم التقليدية إلى جانب أن نسبة حدوث المضاعفات كانت أقل مع استخدام شرائح الكيتون إيثر متعدد الإيثر وتقليل زمن الجراحة. ولكن نظراً للتكلفة العالية لهذه الشرائح فإنه يوصى بأن يتم دراسة كل مريض على حده وذلك لإختيار الحالات الأكثر احتمالية للإستفادة من هذه التقنية مثل الأطفال والنساء صغيرات السن وحالات فشل جراحة رأب القحف باستخدام الوسائل الأخرى وذلك لتحقيق الفعالية من حيث التكلفة. كما يوصى بعمل المزيد من الدراسات تضمن أعداد أكبر من المرضى مع زيادة فترة المتابعة للوصول لنتائج أكثر دقة ومتابعة حدوث أى مضاعفات متأخرة قد تحدث مع استخدام تلك التقنية فى جراحات تجميل عظام الجمجمة.