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Poly Methyl Methacrylate Versus Prefabricated Customized 3D Printed Poly Ethyl Ether Ketone Implants in Cranioplasty: Comparative Study

HUSSEIN A. ZAKARIA RABIE, M.D.; ALI MOHAMED Y. ELKADY, M.D. and MOHAMED AMR GOUDA, M.D.

The Department of Neurosurgery, Faculty of Medicine, Cairo University,

Abstract

Background: Cranioplasty is a surgical procedure used to treat bony defects or calvarial skull deformities. Till now, there has been little consensus on the standard-of-care for implant materials used in the procedure. Implant materials should have proper mechanical strength to protect the brain and support bone growth. The perfect implant material should be individualized to the contours of the defect to ensure a proper cosmetic result for each patient.

Aim of Study: The paper aimed to assess the use of Poly Methyl Methacrylate and the prefabricated customized 3D printed PEEK implants in the repair of skull bony defects assessing the biocompatibility features, cosmetic results and post-operative complications.

Patients and Methods: This study was carried out on Thirty patients with post traumatic and post neurosurgical procedures skull defects randomly divided into 2 groups operated upon by cranioplasty with Poly Methyl Methacrylate or 3D printed PEEK implants at Cairo University Hospitals.

Results: Prefabricated customized 3D printed PEEK implants showed better outcome regarding cosmetic outcome and lower incidence of postoperative complications.

Conclusion: 3D prefabricated PEEK implants showed several advantages compared to Poly Methyl Methacrylate as it is more malleable and therefore easier to place at areas of skull convexities and orbital walls and decrease the incidence of post operative complications.

Key Words: *Cranioplasty – PEEK – Poly Methyl Methacrylate – Skull bony defects.*

Introduction

THE most common causes causing calvarial skull defects include traumatic depressed fractures of the skull, decompressive craniectomies, tumor infiltration of skull bones, congenital deformities and inflammatory lesions **[1].**

Indications for cranioplasty procedure include mainly brain protection, aesthetic reasons, and management of trephine syndrome. Epilepsy management has been debatable indication since the forties. Studies have shown that cranioplasty has an important role in improving cerebral blood flow and cerebral metabolism **[2].**

There are several techniques for repair of the cranial vault defects that can be broadly divided according to the graft used into autologous bone cranioplasty and allograft cranioplasty. The ideal implant material for cranioplasty should show biocompatibility features like tissue tolerance, simplicity of design, ease of sterilization, low heat conductivity, radiolucency, light weight, resistance to infections, no dilatability with heat, low cost and ready to use. There are also many techniques have been described to achieve the best result after cranioplasty procedures **[3].**

Patients and Methods

This retrospective cohort comparative study carried out on fifty patients with post traumatic and post neurosurgical procedures skull defects operated upon at Cairo University Hospitals by cranioplasty.

The study was conducted at Cairo University hospitals in Egypt from June 2024 – April 2025.

Ethical approval and consent to participate:

All procedures performed in the study involving human participants were in accordance with the ethical standards of the institution and approved by the Ethics Committee of Cairo University.

Correspondence to: Dr. Hussein A. Zakaria Rabie,
E-Mail: Husseinzakaria1990@gmail.com

Statistical analysis:

- Microsoft excel 2013 will be used for data entry and the statistical package for social science (SPSS version 24) will be used for data analysis.
- Arithmetic mean and standard deviation will be used for summary of normal quantitative data, median and interquartile range will be used for summary of abnormal quantitative data, and frequencies will be used for qualitative data.
- Bivariate relationship will be displayed in cross tabulations and comparison of proportions will be performed using the chi-square and Fisher's exact tests where appropriate.
- *t*-independent will be used to compare normally distributed quantitative data and Mann-Whitney for skewed data.
- *p*-value will be calculated to assess statistical significance, a value less than 0.05 will be considered statistically significant.

Methodology in details:

Thirty patients with post traumatic and post neurosurgical procedures skull defects operated upon at Cairo University Hospitals by cranioplasty during the period from June 2024 to April 2025.

All 50 patients were subjected to thorough history taking, clinical examination and radiological examination and divided into 2 groups:

- Group (A): 25 patients using Poly Methyl Methacrylate construct for cranioplasty.
- Group (B): 25 patients using 3D printed PEEK molds cranioplasty.

Preoperative full neurological examination was done, adequate radiological assessment with CT scan of the brain with 3D reconstruction for the skull was done as the main imaging criteria for assessing primary deformity, underlying parenchymal injuries and to assess post-operative reconstruction.

1- Clinical history was taken. The etiology of the skull defect was determined from the history given by the patient.

2- Pre and post-operative General and neurological examinations were done on all patients. The general examination includes examination of the defect to determine site and size of the defect and to detect any postoperative complications.

3- A preoperative and post-operative CT with 3D reconstruction was done when available for most of the patients.

Intra-operative technique:

- General anesthesia.
- Position according to site of previous craniectomy.
- Prophylactic 3rd generation cephalosporin was given to all patients, active against staphylococcus species, because the Poly Methyl Methacrylate construct and prefabricated 3D implant are foreign implants.
- Scalp incisions was designed to be outside the defect, behind the hair line, never parallel to previous incisions or scars to avoid ischemic necrosis, and with a broad flap base to accommodate the vascular supply to the flap or through opening of the previous scar if coopting to defect, in case of frontal defects (anterior to the hair line) a bi-coronal scalp incision was done.
- Proper sterilization of the skin using povidone iodine is to be done. Injection of adrenaline 1:200000 (5 mcg: ml) mixed with 10ml of 0.5% xylocaine to minimize bleeding from the skin. After injection, the wound re-sterilized.
- At the end of both procedures closure of the skin and underlying galea with insertion of sub-galeal drain.

Operative procedures:

Group (A):

- Manual trial to mold portion from the Poly Methyl Methacrylate to fill the bony gap and creating contours for cosmetic purpose.
- The construct put in place with trimming its lateral edges to coop with the healthy bony edges.

Group (B):

- Creating a space between healthy bones and dura.
- Using a manual or electronic drill small holes created in healthy bones and adjacent part of prefabricated 3D implant.
- Fixing the healthy bones to construct using mini-plates and screws.

Postoperative care:

- Surgical wound care was done using povidone iodine daily for 10 days and A.B. (third generation cephalosporin).
- Stitches were removed for all patients within two weeks of surgery.
- Drain was left for 48-72 hours following surgery. Clinical follow-up was done for all patients up to 6 months.

Postoperative assessment of aesthetic outcome was measured subjectively by the patients' satisfaction on a scale of 1 to 10, 1-3 means fair outcome, 4-7 means good outcome while 8-10 means excellent outcome.

Postoperative assessment of postsurgical complications.

Results

Age and sex: Regarding age distribution of our cases, it ranged between (6 and 54 years), the largest proportion of cases encountered during 3rd decade of life 20 cases constituting 40%.

Regarding Sex Difference between both groups, there was 35 (70%) males in and 15 females in group statistical insignificant difference between both groups.

The Etiology of skull defects: 40 cases of skull defects were post traumatic in the form of compound depressed fracture. Five cases were post-tumor excision and five were from decompressive craniectomy.

Table (1): Different etiologies of skull defects.

Etiology	Number of patients	% Percent
Trauma (Depressed fractures)	40	80
Post Tumors Excision	5	10
Decompressive Craniectomy	5	10
Total	50	100

Outcome of the patients regarding cosmetic appearance: Regarding the cosmetic outcome we found that it was 12 cases (80%) with good and excellent outcomes, 3 cases (20%) with fair outcome in group A, compared to 15 (100%) with good and excellent outcome in Group B, with statistically significant difference (*p*-value=0.04).

Table (2): Different cosmetic outcomes between both groups.

Group	Excellent	Good	Fair
Group A	17 cases (68%)	3 cases (12%)	5 cases (20%)
Group B	19 cases (76%)	6 cases (24%)	0 case (6.66%)
p-value		0.04 (Significant)	

Complications: Regarding the complications encountered to the 50 patients during the hospital stay and the follow-up in the next 6 months, there were no complications encountered in 38 cases (76%), 5 cases (10%) developed exposure of the implant or mainly the miniplates in case of prefabricated implants that had been managed conservatively in 3 cases "proper dressing after trimming of the edges" and two of them managed by implant removal after failure of conservative management and appearance of skin necrosis, 2 cases (4%) developed infection one of them was managed conservatively by parenteral antibiotic for 10 days, the other one was managed by implant removal, 5 cases (10%) developed seroma that had been followed-up in outpatient clinic till it subsided within 1.5 month.

Table (3): Table of complications.

Complication	Number	Percent
Exposure, managed conservatively	3	6
Exposure, removed	2	4
Infection, managed conservatively	1	2
Infection, removed	1	2
Seroma	5	10
No	12	24

3 cases (6%) developed exposure of the implant, 3 case developed infection (6%), 3 cases developed seroma (6%) and 2 cases (4%) needed to be reoperated in group A, while in group B only one case (2%) exposed and needed to be removed, 2 cases (4%) developed seroma, with statistical significant difference (*p*-value=0.047).

Table (4): Comparison between complications occurred in both groups.

Complication	Group A & its percentage	Group B & its percentage	*p*-value
Exposure, managed conservatively	2 (4%)	0	
Exposure, removed	1 (2%)	1 (2%)	
Infection, managed conservatively	2 (4%)	0	0.047 (Significant)
Infection, removed	1 (2%)	0	
Seroma	3 (6%)	2 (4%)	
Total	9 (12%)	3 (6%)	

Discussion

In our study, Cranioplasty mainly aimed to restore cosmetic appearance and to provide cerebral protection and functions. Our aim is to describe two different manufacturing processes in reconstruction of calvarial skull defects by using hand molded Poly Methyl Methacrylate construct versus 3D printed prefabricated PEEK implants and to compare outcomes of them.

In our study, 35 of our patients (70%) were males and the remaining 15 patients (30%) were females. Staffa et al. **[5]** found male predominance with a percentage equals (64.4%). While Honeybul et al. **[4]** found 45 male percentage (64.2%) of total 70 patients while the remaining (35.8%) were females.

The male predominance may be explained by high percentage of traumatic etiology in our study which accounts for (80%) of cranial defects.

In our study, Trauma accounts for 40 cases (80%) were either due to fight or road traffic accident that mostly related to males more than females, while in the study by Staffa et al. **[5]** found that 60% of the cases are traumatic cases.

In our study, other non-traumatic causes that lead to removal of skull bones resulting in cranial defects include 5 patients (10%) with neoplasms, 5 cases (10%) after decompressive craniectomies.

This disagrees with a study by Jonkergouw et al. **[6]** who found that the most common indication for the primary craniectomy was stroke (39%), followed by trauma (34%), tumor resection (21%) and infection (5%). Also, Andrea Mareira et al. **[7]** found post-tumor resection to be the most common cause of the defect.

In our study, we reported in group A, which was operated by hand molded Poly Methyl Methacrylate construct implants, we noticed that that 3 cases (6%) developed implant exposure that had been managed conservatively in 2 cases (4%) and one needed to be removed, three cases (6%) developed infections two of them managed conservatively and the other needed implant removal, while in group B, 1 patients (2%) developed exposure of the implant which was managed by reoperation to be removad. In the study by Victor Chang et al. **[8]** involving 212 cases with different methods of cranioplasty, mostly used method was autologous bone graft over a period of 13 years, infection was reported in 15 cases of the 15 cases, 7 cases (18.9%) out of a total of 37 patients, had repaired by Poly Methyl Methacrylate construct.

In our study, infection occurred only in 3 cases (6%) in group A, while Rotaru et al. **[9]** who analyzed custom-made implants on 10 patients and found that during the recovery period, there were no signs of infection, plate rejection or wound dehiscence in any case.

In our study, we found that there is statistically significant difference (with *p*-value >0.05) between both study groups as regards cosmetic subjective assessment by patients which indicated that group B has better cosmetic outcome.

In group A, 17 patients (68%) showed excellent, 3 patients (12%) showed good outcome, and 5 patients (20%) showed fair outcome according to the patient's opinion. While in group B all cases showed either excellent or good outcomes postoperatively.

This goes in agreement with Honeybul et al. **[4]** who compared autologous cranioplasty with custom-made implants cranioplasty and showed that (78%) of patients in custommade implants group had complete success while (34%) of patients in autologous cranioplasty group had complete success with absence of a partial or complete cranioplasty failure at 12 months of follow-up, while Rotaru et al. **[9]** found that the 3D reconstructed CT examination in his study showed that symmetry was achieved in all 10 cases and there were no secondary effects on the cerebral mass or soft tissues.

A statistically significant difference (*p*-value <0.05) was noted between both study groups as regards cosmetic assessment of implants by patients with higher percentage of success among group B using custom-made implants. This difference between both procedures is due to the accurate nature of the computer aided custom-made implant that perfectly fits the original defect and preserves good skull symmetry.

Limitations of the study:

1- Small sample size as compared to other similar studies.

2- Limited resources and foundation.

Conclusion:

3D prefabricated PEEK prosthesis showed several advantages when compared to Poly Methyl Methacrylate construct as it is more malleable and therefore easier to place at areas of skull convexities and orbital walls, shorten the time of surgery and decrease the incidence of post-operative complications.

Cases of cranial defect with inflammatory conditions should be well assessed preoperatively to make sure that there is no overlying condition that should cause prosthesis failure. Also, in cases where the defect was following a decompressive craniotomy, care must be taken not to perform the cranioplasty before complete normalization of the intracranial pressure.

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غرسات بولي ميثيل ميثاكريلات مقابل غرسات بولي إيثيل إيثر كيتون المطبوعة ثلاثية الأبعاد والمصنعة مسبقًا فى جراحة رأب الجمجمة: دراسة مقارنة

فى هذه الدراسة قمنا بعرض التفاصيل التشريحية لقبة الجمجمة وأسباب فجوات الجمجمة المختلفة. قمنا أيضا بشرح الأهمية الفسيولوجية لسلامة عظام الجمجمة وطرق دواعى اللجوء للجراحة لإصلاح فجوات الجمجمة وموانعها. ناقشنا. إصلاح فجوات قبة الجمجمة.

بالإضافة إلى ذلك فقد قمنا بإدراج خمسين حالة يعانون من فجوات بالجمجمة التى تتطلب الإصلاح الناتجة عن أسباب مختلفة وعرضنا نتائجها.

وقد تم تثبيت طرف اصطناعى PEEK ثلاثى الأبعاد مُصنّع مسبقًا بمفرده او باستخدام المسامير او بناء بولى ميثيل ميثاكريلات.

وقد قمنا فى هذه الدراسة بعرض طريقه فريدة لتثبيت طرف اصطناعى PEEK ثلاثى الأبعاد مُصنّع مسبقًا وعرض نتائجها وبمقارنة نتائجنا فقد تبين الجدوى التجميلية لاستخدام PEEK كما تبين ايضا تقارب مستوى حدوث العدوى بين استخدام PEEK والميثاكريلات.