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# Use of a Single Standard Skull Model for Preparation of PMMA-Based Cranioplasty Flap: A Novel Low-Cost Technique

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## ABSTRACT

**AIM:** To introduce a novel, low-cost technique for cranioplasty using a single standard polyvinyl chloride plastic skull model as a guide for cranioplasty flap development; to observe and to compare the functional and cosmetic outcomes.

**MATERIAL and METHODS:** We conducted an observational, retrospective, cohort study that included 20 patients who underwent cranioplasty at the Department of Neurosurgery, RMLIMS, Lucknow from September 2020 to September 2021. The patients were evaluated based on postoperative cosmesis and symptomatic relief.

**RESULTS:** A total of 20 patients were included in this study. All procedures were performed without any intraoperative or long-term complications noted on follow-up. None of the patients required reoperation. We observed no evidence of bleeding, infection, or poor scar formation. The patients and their families were satisfied with the cosmetic results of the procedure.

**CONCLUSION:** Our technique provided excellent functional outcomes, cosmetic appearance, and improved clinical symptoms. This technique is currently the most cost-effective alternative available.

**KEYWORDS:** Cranioplasty, Three-dimensional printing, Polymethyl methacrylate, Reconstruction, Defects of skull

**ABBREVIATIONS: HA:** Hydroxyapatite, **PMMA:** Polymethylmethacrylate, **PEEK:** Polyetheretherketone, **3D:** Three-dimensional, **PVC:** Polyvinyl chloride, **CT:** Computed tomography

## INTRODUCTION

Cranioplasty is one of the most common neurosurgical procedures performed worldwide for the reconstruction of cranial defects. Cranioplasty provides a protective cover to the brain, as well as cosmetic benefits, which in turn provide psychological relief and increased social performance for patients. Cranioplasty also reduces the risk of epilepsy and improves electroencephalographic abnormalities and cerebral blood flow, as well as other neurological benefits (2).

Cranioplasty is one of the oldest surgical procedures, with a history dating as far back as 2000 BC, when a thin gold plate was used for the first time to reconstruct a cranial defect in a Peruvian skull with a left frontal defect (14). Since then, many materials have been used for cranioplasty, with varying advantages and disadvantages.

Allografts from animal origins and cadavers have been used previously, although were abandoned because of high infection, low calcification, and high bone resorption rates (14). The use of autologous cranium bone grafts has become widespread, especially in pediatric patients, owing to their easy reintegration. Autologous bone must be preserved either in cryoprecipitate or a subcutaneous pocket in the abdominal wall, each with certain disadvantages (14). Cryoprecipitate destroys the tissue matrix where osteoprogenitor cells enter and take root. Graft placement in abdominal wall pockets

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leads to local site infection and bone resorption. Autologous implants have the benefits of a low-cost reconstruction option and low infection rates compared with allografts and better cosmesis, although a high resorption rate and reduced strength and malleability, leading to the continued search for more resilient synthetic implants (14).

Various cranioplasty materials are available, ranging from biological sources such as demineralized bone matrix, hydroxyapatite (HA), bone morphogenetic proteins, and metallic sources such as aluminum, silver, gold, and titanium, to synthetic polymers such as polymethylmethacrylate (PMMA) and polyetheretherketone (PEEK). These materials have varying advantages and disadvantages that make them useful for particular cases.

However, the availability of an ideal cranioplasty implant is far from reality. The ideal cranioplasty graft material should have a low infection rate and heat conduction and should be nonmagnetic, radiolucent, durable, shapable, and inexpensive, with good tissue compatibility and mechanical resistance. PMMA is one such material that checks most of these boxes for an ideal implant. Its strength is comparable to that of bone; it is inert, does not conduct heat, and is durable, shapable, inexpensive, and widely available.

With favorable material such as PMMA, the development of a cranioplasty flap that nearly fits the cranial defect, maintains the curves and contours of the natural skull, and provides satisfactory cosmesis is a daunting task. Many techniques are available for this purpose, among which the most popular is three-dimensional (3D) printing; however, it is not only more costly than the technique described here, but also time consuming. In addition, the cosmetic results are not significantly superior to those observed in the current study. Several studies have demonstrated the feasibility of producing low-cost custom implants that offer significant cost-saving potential and improved aesthetic results and quality of life.

In this study, we introduced a novel, low-cost technique for cranioplasty using a single standard polyvinyl chloride (PVC) plastic skull model as a guide for cranioplasty flap development and observed and compared the functional and cosmetic outcomes with its expensive counterparts through an extensive literature review.

## MATERIAL and METHODS

This observational retrospective cohort study was conducted at Department of Neurosurgery, RMLIMS, Lucknow. This study included 20 patients with large craniectomy defects (> 25 $cm^2$) following surgery for various pathologies who were admitted for a cranioplasty procedure between September 2020 and September 2021. All cranioplasties were performed at least 3 months after the initial craniectomy to minimize the infection risk.

### Preoperative Preparation

All patients underwent routine blood investigations and a high-resolution computed tomography (CT) scan of the head (1-mm thickness). The bone window was selected to define the craniotomy margins in detail. We performed 3D reconstruction of the CT scan to infer the defect size and contour.

### Material Details

PMMA is a type of polyester developed from acrylic acid polymerization that was discovered in 1939 during World War II. The medicinal use of PMMA was not initiated until 1970 (6). Its strength is comparable to that of bone and shows good results in compression and torsion tests. When combined with a titanium mesh, PMMA can also resist fractures. Furthermore, PMMA is heat resistant, radiolucent, inert, inexpensive, and readily available. However, this material also has its shortcomings, such as high risk of extrusion, decomposition, and infection. Infection rates vary from 5% in general cases to 23% in patients with previous reconstruction site infection. PMMA generally adheres to the bone edges although sometimes requires titanium miniplates and screws for anchorage (3).

The preparation of PMMA involves an exothermic reaction. The temperature can be as high as 80–100 °C for 8–10 minutes, otherwise it might cause burn injuries to the underlying tissues (9). Compared with titanium, which has an elastic modulus of 1.10 GPa, PMMA has an elastic modulus of 3 GPa (10). Hence, there is less stress shielding and loosening of the fixation devices over time. With an impact strength of 5.27 kJ/$m^2$, a PMMA implant provides an impact strength similar to that of normal cranial bone. PMMA has better compression and stress resistance than hydroxyapatite and has also been shown to adhere to the dura mater without any reaction to the underlying tissue (17).

### Implant Preparation

A single standard PVC plastic skull model was used as a guide for cranioplasty flap development in all 20 patients in this study. The CT and reconstructed 3D images were used to mark the cranioplasty flap on the skull model. PMMA (Rapid Repair, PYRAX®, Uttarakhand, India) for commercial use is comprised of two components: a powder and liquid component (Figure 1A). The powder component contains the acrylic polymer, and the liquid component contains the solvent. An adequate amount of powder was placed in a sterile bowl, and the liquid component was mixed until a semisolid dough was created (Figure 1B). Gentamycin (Genticyn, Abbott Healthcare Pvt Ltd., Mumbai, India), an antibiotic, was added to the mixture to prevent infections. This dough was then flattened to a thickness of approximately 5–7 mm and spread nearly to the size of the craniectomy defect. The craniectomy defect size and precise location were inferred from the 3D reconstruction model of the CT scan (Figures 1C, 2A, 2B, 3A, and 3B). The defect was marked on the 3D skull model while palpating the bone margins on the patient (Figures 1D, 1E, and 1F) using the CT 3D reconstruction images. When the dough was still in a semisolid phase and shapeable, it was placed on the life-size 3D skull model, which acts as a scaffold covered with liquid paraffin at the craniectomy defect site, and molded according to the standard contour of the skull model (Figure 1G). This created a precise implant for the patient (Figure 1H). The prepared implant was autoclaved at 121 °C and 15 pounds

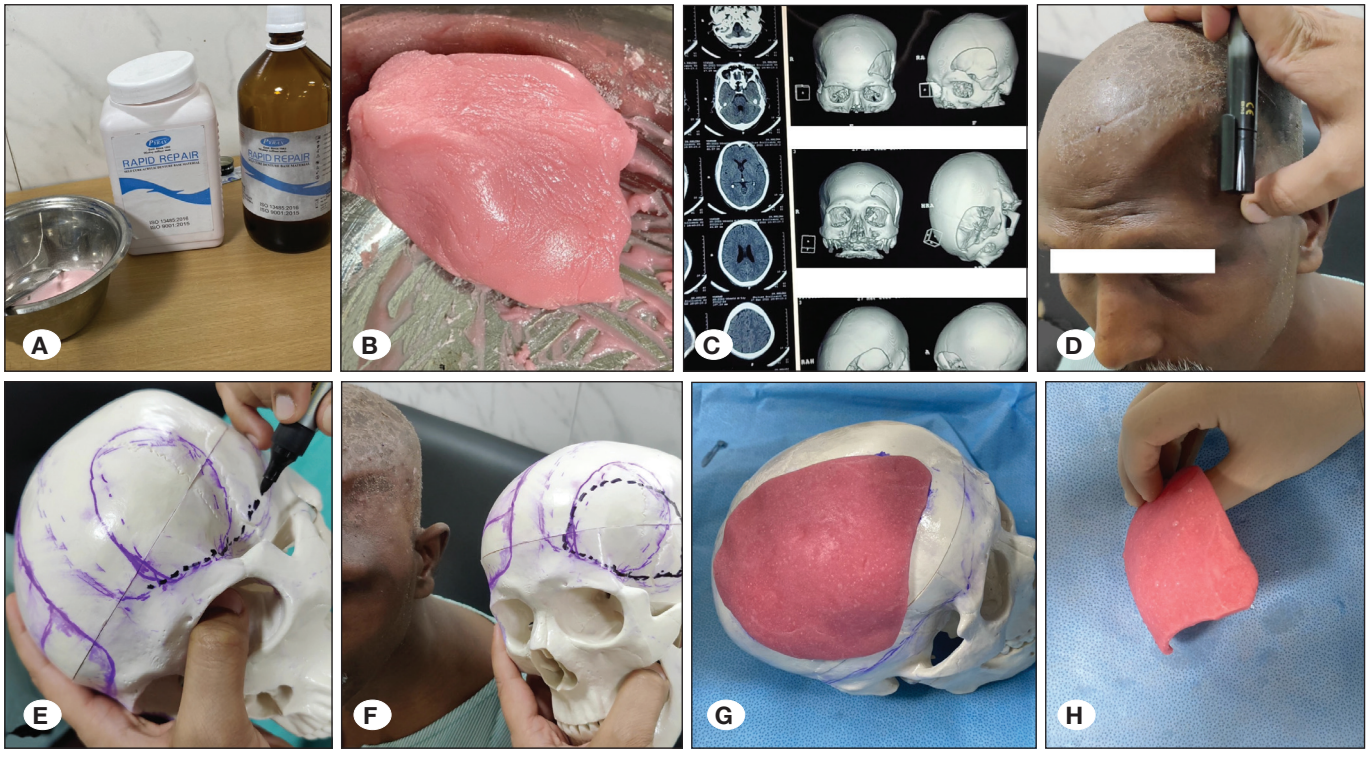


**Figure 1: A)** PMMA for commercial use with two components- the powder component and the liquid component. The powder component contains the acrylic polymer and the liquid component consists of the solvent. **B)** A semisolid dough is created after mixing an adequate amount of powder and the liquid component. **C)** The size of the craniectomy defect and its precise location is inferred from the 3D reconstruction model of the CT scan. **D)** the bony margins of the defect is palpated directly on the patient. **E)** along with palpation, the defect is marked on the skull model matching the precise location. **F)** Defect on the skull model is matched alongside the patients defect. **G)** When the dough is still in a semi-solid phase and can be shaped, it is placed on the life-size 3D model of the skull on which the marking is done which acts as a scaffold covered with liquid paraffin and molded according to the standard contour of the skull model. **H)** This gives the precise implant for the patient. Rest of the fine trimming is done during surgey.

per square inch of pressure for 30 minutes and used under sterile conditions during surgery.

### Intraoperative Steps

Anesthesia induction, patient positioning, and part preparation were routinely performed. A skin incision was made on the previous surgical scar in all patients. The skin flap was raised with meticulous dissection of the pseudomembranous plane between the dura and galea. The craniectomy margins were exposed, and soft tissue was cleaned off (Figures 2C and 3C). Multiple random 1-mm holes were made in the prepared PMMA implant. Finally, it was placed over the defect, and the uneven edges were trimmed off with a motorized drill to facilitate a snug fit with the defect. The implant was dipped in antibiotic solution for a 5-10 minutes before it was finally placed on the skull. The implant was fixed to the skull with titanium miniplates and screws (Figures 2D and 3D).

### Postoperative Period

A subgaleal tissue drain was placed under the skin flap for 24–48 hours. A high-resolution CT scan with 3D reconstruction was performed to assess the implant cosmesis and symmetry (Figures 2E, 2F, 3E, and 3F). The patients were discharged on postoperative days 3–7.

### Follow-up

The average follow-up period was 8 months, ranging from 3–14 months. No complications or cosmetic deformities were observed in any of the patients. The patients and their families were satisfied with the cosmetic results, which improved their quality of life. Cosmetic and functional outcomes were assessed according to the study by Honeybul et al. as follows: complete success, partial success, satisfactory partial failure, and complete failure (12).

## RESULTS

Patient details, such as sex; age; occupation; defect cause, size, and location; surgery time; complications; and outcomes are presented in Table I. All procedures were performed without any intraoperative or long-term complications observed on follow-up. The mean surgery duration was approximately 95 minutes. None of the patients required reoperation, and there was no evidence of bleeding, infection, or poor scar formation. The patients and their family members were satisfied with the cosmetic results of the procedure. This technique was able to provide satisfactory postoperative cosmesis at follow-up as compared with the patients' preoperative deformities (Figures 2G, 2H, 3G, and 3H). According to Honeybul et al.'s

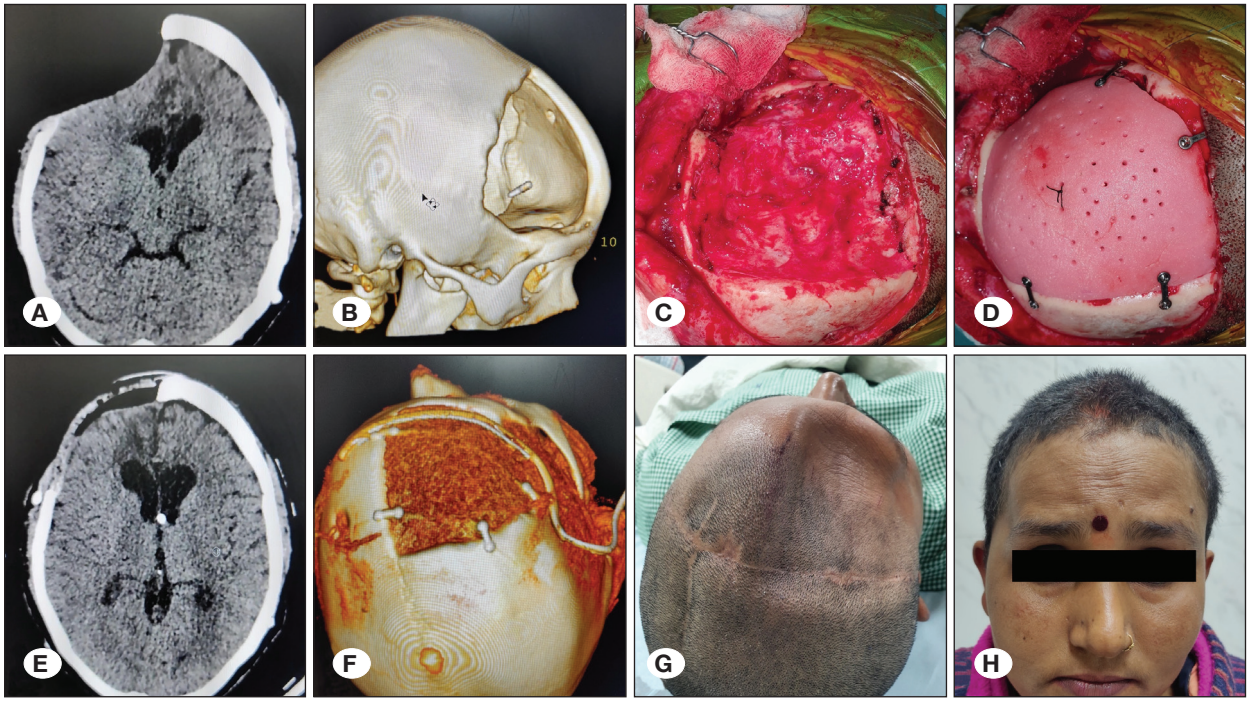


**Figure 2:** Case of a 36-year-old female with decompressive craniectomy for intracranial aneurysm treated with clipping. **A)** preoperative axial CT scan showing the craniectomy defect. **B)** 3D reconstruction CT image showing the contour and size of the defect. **C)** intraoperative image showing the craniectomy margins. **D)** intraoperative image with the placement of the PMMA cranioplasty flap with multiple holes to promote tissue in-growth. **E)** postoperative CT scan showing the prosthesis in place. **F)** postoperative 3D reconstruction showing prosthesis providing perfect contour to the skull. **G)** preoperative cranial defect. **H)** postoperative cosmesis to the patient.

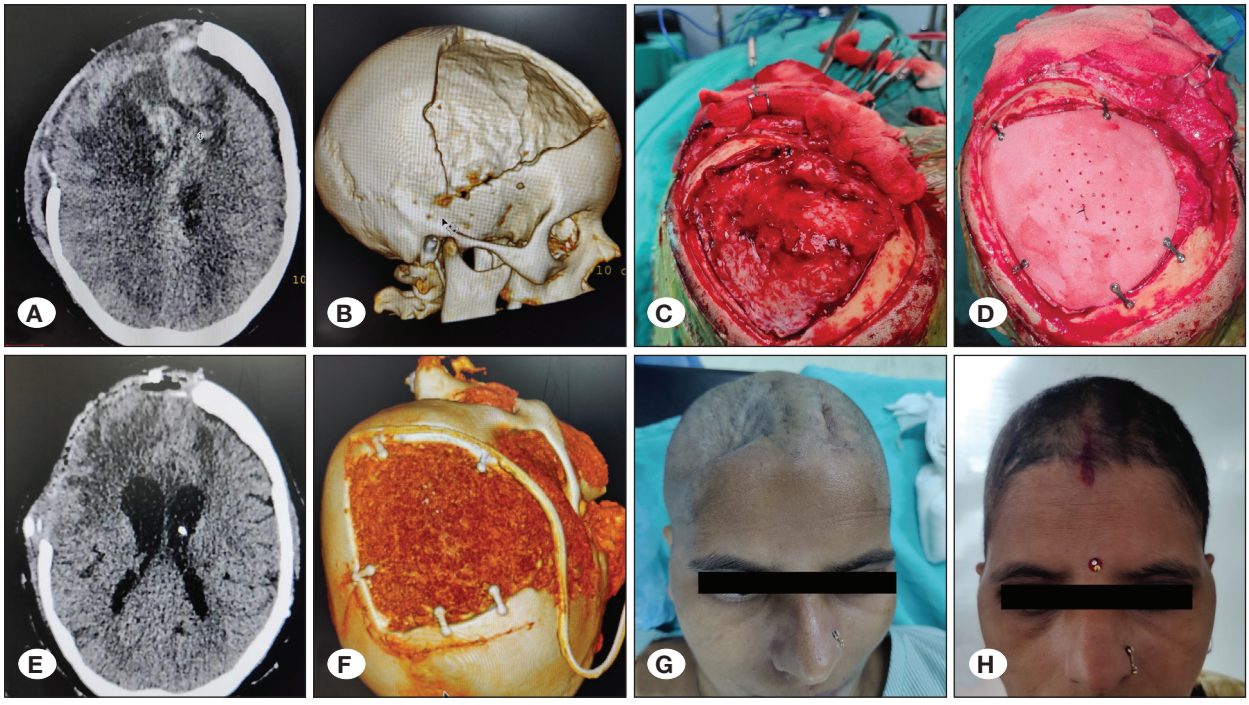


**Figure 3.** Case of a 41-year-old female with decompressive craniectomy for intracranial atypical meningioma involving the bone. **A)** preoperative axial CT scan showing the craniectomy defect. **B)** 3D reconstruction CT image showing the contour and size of the defect. **C)** intraoperative image showing the craniectomy margins. **D)** intraoperative image with the placement of the PMMA cranioplasty flap with multiple holes to promote tissue in-growth. **E)** postoperative CT scan showing the prosthesis in place. **F)** postoperative 3D reconstruction showing prosthesis providing perfect contour to the skull. **G)** preoperative cranial defect. **H)** postoperative cosmesis to the patient.

**Table I:** Patient Details

| Patient no. | Age/Sex | Diagnosis | Location of defect | Size of defect (cm x cm) | Duration of surgery (minutes) |
|---|---|---|---|---|---|
| 1 | 11/F | Left frontoparietal Arteriovenous Malformation | Left frontoparietal | 10 x 9 | 90 |
| 2 | 21/F | Right frontoparietal Arteriovenous Malformation | Right frontoparietal | 11 x 9.1 | 88 |
| 3 | 68/F | Left supraclinoid aneurysm | Left fronto-temporoparietal | 15 x 13 | 100 |
| 4 | 29/M | Right frontoparietal infarct | Right fronto-temporoparietal | 14 x 13.5 | 110 |
| 5 | 28/M | Left frontal glioma | Left frontoparietal | 12 x 10 | 85 |
| 6 | 49/F | Right parietal contusion | Right fronto-temporoparietal | 15 x 13.2 | 98 |
| 7 | 18/M | Left parietal Arteriovenous Malformation | Left fronto-temporoparietal | 13 x 10 | 90 |
| 8 | 45/M | Left parietal infarction | Left fronto-temporoparietal | 14 x 11.5 | 105 |
| 9 | 49/M | Olfactory groove meningioma | Right frontotemporal | 11 x 9.5 | 78 |
| 10 | 26/M | Right frontoparietal infarct | Right fronto-temporoparietal | 14.5 x 12.2 | 92 |
| 11 | 43/F | Falcine meningioma | Bifrontal | 13 x 10 | 90 |
| 12 | 53/M | Right acute fronto-temporoparietal subdural hematoma | Right fronto-temporoparietal | 15 x 13 | 112 |
| 13 | 38/F | Right middle cerebral artery aneurysm | Right fronto-temporoparietal | 14 x 12 | 98 |
| 14 | 22/M | Right Frontal contusion | Right frontotemporal | 12 x 9 | 90 |
| 15 | 35/F | Left middle cerebral artery aneurysm | Left fronto-temporoparietal | 14 x 11 | 100 |
| 16 | 42/M | Right fronto-parietal convexity meningioma | Right frontoparietal | 11 x 9 | 78 |
| 17 | 38/M | Right frontoparietal infarct | Right fronto-temporoparietal | 15 x 12 | 104 |
| 18 | 28/F | Right parietal contusion | Right frontoparietal | 12 x 10 | 96 |
| 19 | 23/M | Left parietal arteriovenous malformation | Left fronto-temporoparietal | 15 x 11 | 110 |
| 20 | 48/M | Right frontoparietal infarct | Left fronto-temporoparietal | 14 x 11 | 98 |

assessment method, 14 patients had complete success and 6 patients had partial success. None of the patients experienced partial or complete failure.

## DISCUSSION

Cranioplasty is one of the most common neurological surgeries performed worldwide for the reconstruction of cranial defects. It provides a protective cover for the brain and helps patients psychologically and increases their social performance. Sinking skin flap syndrome is a serious neurological disability that occurs months after a large craniectomy and is characterized by headache, vertigo, loss of concentration, memory loss, depression, and convulsions (1). Cranioplasty provides relief from these symptoms.

The ideal cranioplasty graft material should have a low infection rate and heat conduction and should be nonmagnetic, radiolucent, durable, shapable, and inexpensive, with good tissue biocompatibility and mechanical resistance (5). Various materials have been used and developed for this purpose. However, the search for an ideal calvarial replacement method continues. Titanium, PEEK, and PMMA are among the most commonly used materials.

Titanium is a strong, noncorrosive, noninflammatory bioactive material with great potential for osseointegration and has a lower infection rate (2.6%) than that of cranioplasty (15). Titanium cranioplasty implants have been widely used in recent times with the introduction of 3D printing technology and computer-aided design. These 3D-modeled titanium meshes provide excellent cranioplasty implants for large cranial defects (21). However, they also have drawbacks compared with acrylic implants. Titanium implants are more costly than acrylic implants, with varying availability.

Darwish et al. compared the clinical outcomes and complications of titanium mesh and acrylic bone cement cranioplasty

implants among 40 patients. The authors found no statistically significant differences between groups in functional outcomes, cosmetic appearance, and improvement of clinical symptoms as assessed by the doctor as well as the patient (8). This finding is consistent with that of similar studies by other authors. However, the risk of postoperative complications in defects >25cm$^2$ was higher in patients in which acrylic bone cement was used. In contrast, William et al. found that among 151 patients who underwent titanium mesh cranioplasty, 25.8% had early and late complications in the form of seromas and infections (24).

In our study of acrylic implants, we found no early or late complications in any of our patients. In addition, all patients, as well as their family members, were satisfied with the cosmetic results.

Formulating a PMMA cranioplasty graft is a daunting task. Many techniques are available for the development of a cranioplasty flap that nearly fits the cranial defect and maintains the curves and contours of the individual skull. Obtaining a well-fitted cranial implant is possible using the PMMA casting method (23). However, this increases the procedure time as well as the risk of tissue necrosis owing to the exothermic hardening of acrylic bone cement. In their study on 16 patients, Erasmo Barros et al. found that customized 3D PMMA molds and implants achieved symmetric and aesthetic results with low complication rates (7). However, high production costs and delayed availability were major drawbacks to this study.

Other popular techniques include 3D printing and computer-aided design technology.

Moreover, 3D printing technology has become popular for the creation of patient-tailored implants (4). However, the availability of this technology in countries such as India is limited, and the high costs and technical difficulties limit its use in the general population. A quality 3D printer that can provide decent results costs anywhere from 2000–3000 USD and take longer than 48 hours to manufacture an implant (19). In general, a 3D-printed implant costs approximately five times more than a simple, noncustomized implant. Our technique incurs a fraction of this expense and saves time and money.

The cost of a prefabricated PEEK or titanium implant has ranged from 5000–12000 USD in various studies worldwide. The total cost incurred using our technique was approximately 300 USD, including all materials required for surgery, postoperative medicines, and hospital charges, which is considerably lower than the cost of commercially available prefabricated implants. These commercial implants account for 64% of the total cost of cranioplasties (16). The use of a single PVC plastic skull model as a guide to developing the cranioplasty flap in our study greatly contributed to reduced procedure costs.

Low-cost treatment options are direly needed in countries such as India, which is a developing country with 80 million people (6.7%) below the poverty line (income ≤ 1.25 USD per day) (United Nations report). In India, the average out-of-pocket expenditures are much higher than the World Health Organization's estimate for developing countries, mainly due to failed insurance schemes. Although many government-sponsored programs such as Rashtriya Swasthya Bima Yojana and Ayushman Bharat are available to provide financial health support for the poorest 40% of the Indian population, failure to properly implement these programs and lack of coverage for outpatient expenses are major drawbacks.

The use of brand-based prefabricated cranioplasty implants including those made of titanium mesh, ceramics, and polymers is costly, and most patients belong to the middle and lower socioeconomic groups (13). Many patients prefer to live their lives with cranial defects rather than pursuing costly prosthetic implants (19).

Infection remains the most common complication of cranioplasty, with variable incidence rates. Regardless of the selection method, many factors affect the complication risks, including the timing of surgery, patient performance, choice of material, and surgical duration (22).

The overall complication and infection rates were 5–25% and 5–20%, respectively, in various studies (20). Matsuno et al. reported an infection rate of 25.9% with autologous grafts compared with synthetic implants such as those made of PMMA and titanium (18). Moreira Gonzalez et al. found that the use of bone cement was associated with a high rate of complications, especially for large defects (20). Similar results were reported by Zins et al. in their study of 16 patients, in which 8 patients (50%) developed postoperative complications (25).

Although similar complications, including infections and seroma formation, were not observed in our study in the early or late follow-up periods, a long-term follow-up study may reveal different results.

The cosmetic results observed in this study are comparable and, in some instances, superior to those of other techniques and materials used for cranioplasty. Morales-Gomez et al. reported a 100% satisfaction rate regarding cosmetic outcomes in their 2019 study of 22 patients using PMMA casts made by a 3D printer (19). A similar study by Fisher et al. (2012) reported an 82.6% satisfaction rate. In our study, the satisfaction rate was 100%, and our low-cost technique was performed without the use of 3D printing and computer-aided design techniques, which are not only costly but also scantly available (11).

## CONCLUSION

Cranioplasty is a common neurosurgical procedure that is performed worldwide to treat various intracranial pathologies. With several options for cranioplasty materials available, PMMA appears to be a promising option. We have introduced a new technique, in which a single standard PVC plastic skull model was used to make cranioplasty flaps in all patients with satisfactory cosmetic outcomes. This technique has been proved to be not only cost-effective, but also time-saving and easily reproduced, which may be significantly relevant in countries such as India, where the financial burden of healthcare is very high. Our technique provided excellent functional outcomes, cosmetic appearance, and improved

clinical symptoms, which is equal, if not superior to its expensive counterparts without complications. Although a large number of long-term follow-up studies are still needed to validate our results, this technique is currently the most cost-effective alternative available.

**AUTHORSHIP CONTRIBUTION**

Study conception and design: DKS, DS
Data collection: DS
Analysis and interpretation of results: DKS, DS
Draft manuscript preparation: DKS, DS
Critical revision of the article: DKS, DS, KY, MK, RKS
Other (study supervision, fundings, materials, etc...): KY, RKS
All authors (DKS, DS, KY, MK, RKS) reviewed the results and approved the final version of the manuscript.

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