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Outcome of 3D Reconstructed Acrylic Cranioplasty

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ABSTRACT

Background: Cranioplasty is required for post-craniectomy rehabilitation. Its outcomes depend on multiple factors; this study aims to evaluate the impact of size and the anatomic location of cranial defect on patient satisfaction. **Methods:** A prospective observational study was conducted on 70 patients who underwent cranioplasty. A defect size ranging from 12cm^2 to 168cm^2 was included in the study and was categorized into four anatomic groups (Frontotemporal, Trauma flap, Occipital, and Bifrontal). A 10-point Likert scale was used to assess patient satisfaction scores. A One-way ANOVA test, a Kruskal-Wallis's test, and a Logistic Regression were performed to evaluate these defect characteristics and their effect on the cosmetic satisfaction. **Results:** Among the participants, 90% were satisfied with the cosmetic outcome following cranioplasty. The study found no significant association between the defect size and patient satisfaction (P-value 0.309 and Exb (B)= 1.014). Also, no significant impact of anatomical location was observed on patient satisfaction (Anova: F (3, 3) = 1.41, P-value 0.249). **Conclusion:** The study found no significant effect of the cranial defect sizes or their anatomical location on the overall patient cosmetic satisfaction.

INTRODUCTION

Cranioplasty is a surgical procedure that is executed to repair a defect or deformity in the skull. This defect is a consequence of a traumatic injury, tumor resection, congenital defects, or decompressive craniectomy performed to treat cerebral edema and other pathologies (1). It is a minimally complex procedure that improves function, cranial protection, and cosmetic appearance following craniectomy (2). Hence, its importance is underscored because it is vital to functional and cosmetic rehabilitation, which augments patients' psychological and social well-being (3).

Various materials are being implemented for cranioplasty procedures, including implant materials like titanium, polymethyl methacrylate (PMMA), and polyetheretherketone (PEEK) (4) (5). All these materials have some benefits and drawbacks and are employed depending on the patient's requirements and clinical demands. However, their long-term prognosis remains controversial (2). The increased demand for customization and better precision led to the advent of in-house fabrication of patient-specific bone implants. The artificial bone flaps were customized by 3D printing and proved effective at covering the skull defect with fewer complications than the conventional methods (6), (7). This 3D printer-assisted technique offers a better anatomical fit and precise measurement of artificial implants for cranioplasty.

Dabandi et al demonstrated the cost-effectiveness of 3D printed polymethyl methacrylate implants by three clinical cases. The PMMA implants accurately fitted the cranial defect and were an affordable option for people with low socioeconomic backgrounds (8). Another case series outlined morbidity rates, cosmetic satisfaction, and affordability of 3D printed cranial implants. It studied 31 patients, 80% of whom were cosmetically satisfied following cranioplasty (9). To date, little light has been shed on the aspect of patient cosmetic satisfaction with 3D printer-assisted cranioplasty. This subject is of particular relevance for a country like Pakistan, where neurotrauma

resulting from road traffic accidents is quite common, making procedures like craniectomy and cranioplasty often inevitable. To our knowledge, scarce data are available in Pakistan regarding this matter, thus, our study aims to examine the cosmetic results and patient satisfaction following 3D printer-guided cranioplasty.

MATERIALS AND METHODS

This was a prospective analytical observational study performed on patients who had undergone decompressive craniectomy due to trauma, brain tumors or other pathologies. These patients thereafter received cranioplasty with a polymethyl methacrylate implant using 3D printing. The study was conducted in the Department of Neurosurgery Unit II, Punjab Institute of Neurosciences, Lahore, after receiving the ethical letter from the Institutional Review Board- Punjab Institute of Neurosciences. The study was completed in four months, from February 13, 2025 to June 12, 2025. A sample size of 70 patients was calculated using a 95% confidence level, 10% margin of error, and an expected percentage of patient satisfaction of 80% (9). A non-probability consecutive sampling technique was employed by performing 3D-guided cranioplasty on all eligible craniectomy-treated patients during the study duration. The study included both male and female patients aged 20-50 years who had undergone craniectomy due to traumatic brain injury (TBI), space-occupying lesion (SOL), or infarcts involving bone flap removal. A cranial defect of greater than 3×3cm was included. Patients who had unresolved cerebral edema, hydrocephalus, or signs of active infection (e.g., discharge or erythema at the wound site) were excluded to ensure an optimum and complication-free cranioplasty procedure.

Following ethical approval, patients who fell into the inclusion criteria were enrolled from the ward. The surgical procedure and nature of the study were explained to the patients, and written informed consent was taken from them. Baseline variables like age, gender, duration, cause of defect, and hemisphere were recorded. Before cranioplasty, a CT scan (Siemens Somatom Definition Edge 128 Slice) was run for every patient, firstly to rule out hydrocephalus and brain edema. Secondly, the size and shape of the defect were assessed; 3×3cm to 14×12cm were included in the study. The cranial defects were individualized into four categories according to their anatomic locations: Occipital (defect on posterior skull), Bifrontal (defect extending between both frontal bones), Frontotemporal (involving both frontal and temporal bones), and Trauma flap (defect involving frontal, temporal, and parietal bones). Thirdly, DICOM data was used to reconstruct the missing part of the skull, and a virtual implant was created. A prototype implant was then made and checked for fit and contour on the 3D printed hemiskull model. After proper reshaping and modification, a final Polymethyl methacrylate (G21, PMMA) implant was fabricated. This implant was sterilized before use in surgery.

After following the pre-operative surgical protocols, an NPO patient was administered prophylactic antibiotics and was placed under general anesthesia. The surgical site was shaved and disinfected to ensure aseptic conditions. An incision was made on the previous craniectomy scar mark, and a skin flap was reflected by dissecting the scalp from the dura. Then the temporalis muscle was relieved from the dura to make the bony margins evident. The sterilized PMMA implant was then placed over the defect and was properly aligned, burr holes were drilled in the implant to prevent epidural fluid collection, and it was anchored to the skull by titanium mini-plates and screws. The muscles were then reattached to the pericranium with absorbable Vicryl 2/0 suture (Surgicryl Monofast). A subgaleal drain was placed, and the galea was approximated using Vicryl 2/0 suture (Surgicryl Monofast). The skin was then sutured with a Prolene 1 (DemeLENE) vertical mattress suture to ensure optimum wound edge approximation. The patient was then shifted to post-operative care and was observed for two weeks. The subgaleal drain was retained for 3-4 days and was removed when minimal to no discharge was found. Between the 10th and 12th day following surgery, the suture removal was carried out, and the patient was discharged in a stable condition. All patients were recalled 2 weeks post-operatively for follow-up and cosmesis satisfaction analysis. 5 patients had wound dehiscence and were excluded from the study, so in total, 65 patients were assessed for cosmetic satisfaction. A 10-point Likert scale was used to assess the cosmetic satisfaction of the patients, in which '7-10' was considered satisfied, and '<7' was considered 'unsatisfied' (9).

Data Analysis

Data was recorded and analyzed using Statistical Package for Social Sciences (SPSS) version 21. The frequency percentages of baseline variables like age groups (20-34 years, 35-50 years), gender, and location of defects were depicted in a table format. The area of defects was computed by calculating 'length × width', and a line graph was made by keeping 'patient number' on the X-axis and 'defect area' on the Y-axis. To assess the effect of the location of defects on the cosmetic satisfaction, One-Way ANOVA was run between defect location and Likert scale scores, considering a P-value of <0.05 as significant. To further strengthen the results, a non-parametric Kruskal-Wallis Test was run. To assess the effect of the anatomic location of the defect on cosmetic satisfaction, logistic regression was run. The Likert scores were categorized into two groups, i.e.,>7 was satisfied and < 7 was not satisfied; the defect area was taken as a continuous independent variable. Wald statistics, odds ratio, standard error, and P-value were quoted.

RESULTS

The patients presented with variable cranial defect sizes ranging from 12cm^2 to 168 cm^2. 52.3% of participants were young adults, belonging to the 20-34 age group. 47.7% were middle-aged people (35-50 years). Most of the participants were males, 95.3%. Most of the patients presented with the Trauma flap defect (66.2%), followed by the Frontotemporal defect (23.1%).

Figure 1 shows a pre-operative CT scan that highlights the size, shape, and anatomic location of the cranial defect. A 3D-designed virtual model of the flap is evident, concealing the previously shown cranial defect in Figure 2.

The intraoperative image shows the precise placement of the PMMA flap with holes drilled in it and is secured using titanium screws in figure 3. The clinical pre-operative and post-operative comparison of the patient shows a notable improvement in the cranial contour and the cosmetic esthetic of patient in figure 4.

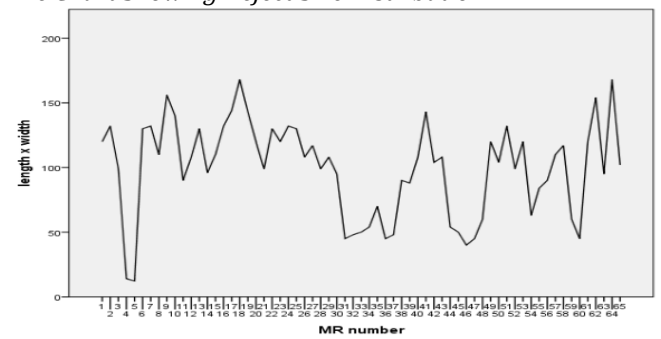
Table 1

Baseline Characteristics of the Study Participants

Variable		Frequency (%)
Age (years)	20-34	34 (52.3)
	35-50	31 (47.7)
Gender	Male	62 (95.3)
	Female	3 (4.6)
Location of defect	Frontotemporal	15 (23.1)
	Trauma flap	43 (66.2)
	Occipital	2 (3.1)
	Bifrontal	5 (7.7)

Graph 1

Line Chart Showing Defect Size Distribution



Graph 2

Bar Chart Comparing Frequency of Satisfied Patients with Unsatisfied Patients

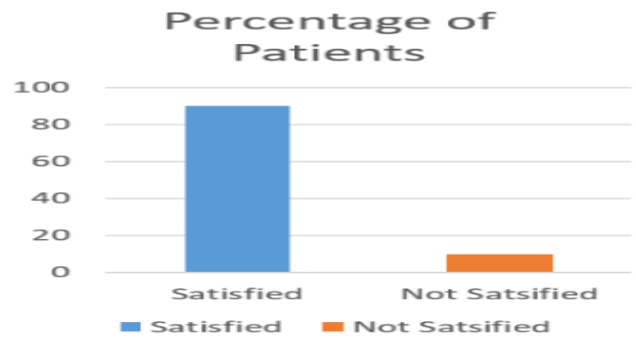


Figure 1

3D Reconstructed Image Showing Cranial Defect- Pre Operative.

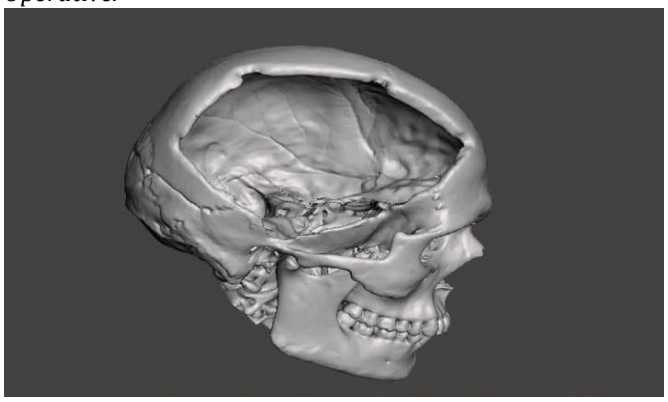


Figure 2

3d Reconstructed Image Showing Cranioplasty Graft Designed to Fit Defect

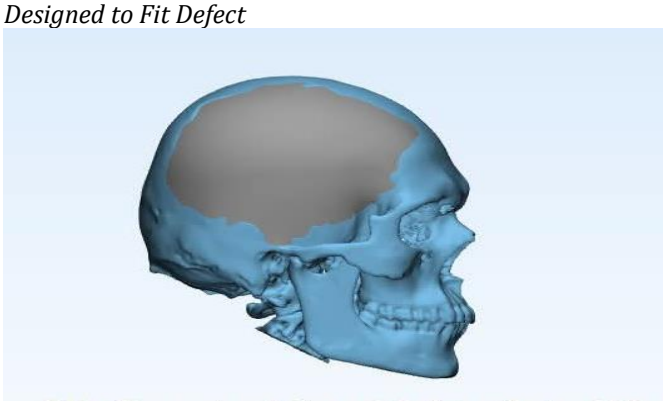


Figure 3

Intra-Operative Photograph of 3D Cranioplasty Graft Placed and Secured with Mini-Plates.

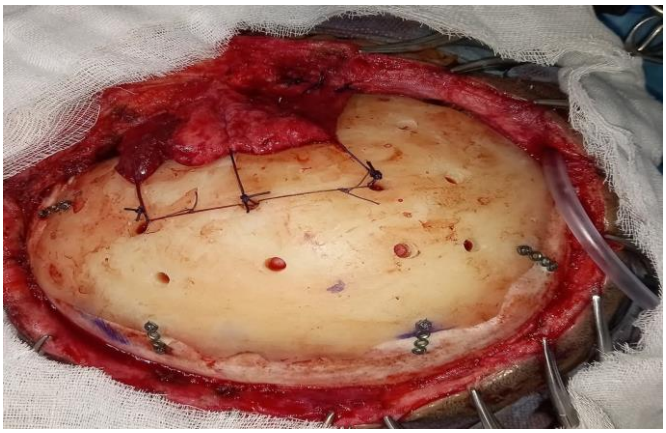
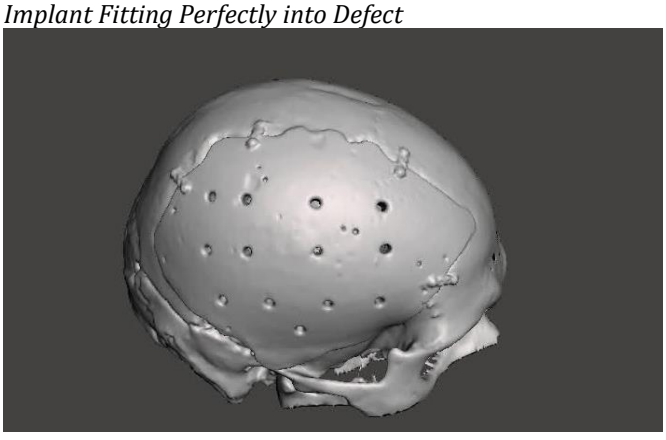


Figure 4

Photographs of Patient (Taken with Permission Showing Pre-Operative and Post-Operative Status for Comparison.

Figure 5

Post-Operative 3D CT Scan Showing 3D Cranioplasty Implant Fitting Perfectly into Defect



There is no notable difference in the mean scores among all defects, although there is a slight trend towards higher satisfaction in patients with the occipital defects (M=10.0). One-way ANOVA test shows no significant variation in the mean cosmetic satisfaction between groups (F (3, 3) = 1.41, P value 0.249). As the assumption of normality was not fully reached, so a non-parametric Kruskal-Wallis Test was employed, which ensured that the type of anatomic location of the cranial defect does not significantly impact the cosmetic satisfaction of the patients (H (3) = 3.17, P-value 0.366)

Table 2

Statistical Impact of Anatomic Location of the Cranial Defect on the Cosmetic Satisfaction Scores.

Defect Location	Mean (SD)
Frontotemporal	9.0 (1.2)
Trauma flap	9.1 (1.4)
Occipital	10.0 (0.0)
Bifrontal	7.8 (2.7)
Anova: F (3, 3) = 1.41, P=value= 0.249	
Kruskal Wallis Test: H (3) = 3.17, P=value= 0.366	

The logistic regression inferred no significant association between the defect size (area/ cm^2) and patient satisfaction. Exb (B) value of 1.014 does show a minor increase in odds of satisfaction with increasing defect size, but this is not significant as the P-value is 0.309. The P-value of 0.017 shows the baseline odds when the defect area is 0.

Table 3

Statistical Impact of the Defect Area on the Cosmetic Satisfaction Scores.

Variable	B	SE	Wald	df	P-value	Exb (B)
Defect Area	0.014	0.013	1.034	1	0.309	1.014
Constant	-3.732	1.569	5.660	1	0.017	0.024

DISCUSSION

Craniofacial cosmesis is entirely subjective, and it is challenging to measure it objectively (10). It is a crucial part of patient rehabilitation following the decompressive craniectomy in restoring functional, cosmetic, and psychological domains (11). It is employed to reconstruct a large cranial defect that, if left untreated, would affect the facial aesthetics and quality of life. Uygur S et. al. proposed a categorization for the size of cranial defect, i.e., a defect less than $25cm^2$ was called 'small defect' and the one larger than $200cm^2$ was said 'large defect'. Additionally, it proposed a methyl methacrylate, polyethylene, or autoclaved bone cranioplasty for the large defects (12). In the present study, the subjects who underwent cranioplasty had variable-sized skull defects ranging from $12cm^2$ to $168cm^2$. The present paper involved patients of all ages; 52.3% were young adults, who fell into the age bracket of 20-34 years, and the others were middle-aged patients. Moreover, the participation is dominated by males by 95.3% (Table 1). A Saudi study assessed the outcomes of cranioplasty, with a 57.4% male and 42.6% female participation, and 78% of patients were over 18 years, and the other 21% were pediatric (13).

The present paper highlights the rehabilitation of the occipital, trauma flap, frontotemporal, and bifrontal cranial defects with PMMA implants. 66.2% of defects were frontal-temporal-parietal defects (trauma flaps), followed by frontal-temporal cranial defects, 23.1% (Table 1). Comparatively, the Saudi study targeted an anatomically wider classification, involving frontal-parietal defects (10.3%), parietal-temporal defects (7.4%), etc. (13).

A total of 70 patients were enrolled in the study, out of which 65 qualified till the stage of follow-up. These patients had post-craniectomy defects of different anatomic locations and dimensions, and all were assessed for cosmesis satisfaction 2 weeks post-cranioplasty. Figures 1-5 provide a clinical demonstration of a trauma flap craniectomy defect that underwent cranioplasty. 3D printing was performed to reconstruct the patient's digital 3D skull and to fabricate an accurately fitting PMMA implant. The pre-op and Post-op photographs emphasize the cosmetic improvement and the patient's satisfaction. The illustrated bar chart inferred that 90% of the patients were cosmetically satisfied with the outcomes of cranioplasty. Likewise, the clinical workflow described in the Swiss study shows an improvement in the cranial contours and symmetry following the PMMA cranioplasty. The study also reported satisfactory results in 80% of the patients (9).

Our study has explored the impact of the anatomical location of skull defects and their size on the cosmetic satisfaction of the patient. The mean scores (SD) of all anatomical groups were in an elevated range, that is, 9.0 (1.2) for the frontotemporal defect, 9.1 (1.4) for the trauma flap defect, 10.0 (0.0) for the occipital defect, and 7.8 (2.7) for the bifrontal defect. A one-way ANOVA test was employed to study the difference in mean scores across the anatomical location groups; a P-value of 0.249 inferred no significant association in satisfaction of the patients with different anatomically located cranial defects. Given that the assumptions of normality were not fully met, a further non-parametric Kruskal-Wallis test was employed. This test also revealed no significant difference in the satisfaction scores among the four anatomical groups, H (3) = 3.17, P-value 0.366. Likewise, Ilbel et al reported no significant variability among the satisfaction scores across different anatomical groups. The mean satisfaction scores were as follows: 7.7 ± 1.6 for frontal-temporal-parietal defects, 7.6 ± 1.5 for frontal-temporal with orbital involvement, 8.3 ± 2.1 for frontal-temporal without orbital involvement, and 8 for bifrontal. Although the satisfaction scores showed a positive trend towards satisfaction, the difference was not statistically significant (P-value 0.886) (9).

The present paper has analyzed patients with skull defects of different sizes, ranging from 3.5cm x 3.5cm ($12cm^2$) to 14cm x 12cm ($168cm^2$). A logistic regression test was employed to assess the impact of defect sizes on the patients' cosmetic satisfaction. An insignificant P-value of 0.309 and Exb (B) of 1.014 inferred that defect size was not a major determinant of cosmetic satisfaction. A study presented their experience of restoring a skullcap defect with acrylic implants, using both manually fabricated and 3D printed implants. While the study did not directly assess the impact of defect sizes on cosmetic satisfaction, as determined in the present paper, their decision to select the fabrication technique was influenced by the size of the

defect. A large cranial defect measuring > 200cm^2 was rehabilitated using a 3D printed acrylic implant, emphasizing the importance of defect size (14). Another study analyzed 101 patients with a mean defect size of 104.6 cm^2, this study deduced that larger defect sizes were associated with scalp atrophy over time (15). It can also be derived from this finding that such gradual change can indirectly affect the cosmetic outcome of cranioplasty by damaging the contour and skin integrity on the implant site.

Although the present paper found no statistically significant impact of location and size of defect on the patient satisfaction post-cranioplasty, it was one of the few studies that have explored this association, which has been largely overlooked in the previous pieces of literature. This study has focused on the patient-perceived aesthetic outcomes relative to the defect characteristics, which can be considered the strength of this study as well as a weakness, as it has not touched the other aspects of cranioplasty, including post-operative complications, implant material, and surgical techniques, etc. Further research needs to be done on the other aspects of cranioplasty and other parameters that can determine the cosmetic satisfaction of patients.

CONCLUSION

This study is among the few to assess the association of cranial defect sizes and anatomic location on the patient's cosmetic satisfaction. It found no significant association between these defect characteristics and patient satisfaction.

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