

Original Article

Surgical Outcome of Cranioplasty between Frozen Autologous Bone Flap versus Synthetic Acrylic Cement Flap.

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Background:

Cranioplasty (CPL) is a surgical procedure performed to restore a defect on the cranial vault after a previous decompressive craniectomy made for traumatic brain injury, ischemic or hemorrhagic disease or even after the removal of cranial tumors. Although apparently it may resemble an easy and routine surgical procedure, cranioplasty has several complications. The most frequently reported complications are infections, autologous bone flap resorption, cerebrospinal fluid leak, subdural effusion, seizures, syndrome of the trephined, hematomas & poor cosmetic result. The objectives of cranioplasty are (1) to restore the earlier contour of skull bone (2) to protect the underlying brain and (3) to diminish the complications of a craniectomy. Readily available and traditionally used frozen autologous bone graft for primary reconstruction is associated with complications. Recent reports suggest that synthetic acrylic cement flap might have better surgical outcome.

Aims: The objective of the study was to compare the surgical outcome of cranioplasty between frozen autologous bone flap and synthetic acrylic cement flap.

Methods: This cross-sectional analytical study was carried out in the department of Neurosurgery, Dhaka Medical College and Hospital, Dhaka. Total 70 samples were taken and allocated equally into two group- Group-A (35 patients with frozen autologous bone flap) and Group-B (35 patients with synthetic acrylic cement flap). The data regarding socio- demographic, clinical, bio-chemical, imaging and surgical outcome were recorded processed and analyzed with the Statistical Package for Social Science (SPSS) version-22.0 and Microsoft Excel. Quantitative data expressed as mean standard deviation and qualitative data as frequency and percentage. Comparison was done by tabulation and graphical presentation in the form of tables, pie chart, graphs, bar diagrams, histogram & charts etc.

Results: Study demonstrates that maximum number of patients (e.g., 31.4%) were between 31-40 years' age group. Mean age of the patient was 32.37 ± 11.50 years in group-A and 33.31 ± 16.86 years in group-B. Male and female ratio was 4.8:1. Although recovery rate was predominant in group-B patients, but the difference was non-significant ($p = 0.176$). Study shows that 20.0% of the patients in group-A developed complication after surgery, whereas complication rate was 8.5% in group-B patients. Study revealed that superficial incisional SSI was 11.4% patients in group-A & 5.7% in group-B, deep incisional SSI was 2.9% patients in group-A & none of case in group-B, cerebrospinal fluid leak was 5.7% in group-A & 2.9% in group-B. Bone resorption was 2.9% in group A & none of case in group B.

Conclusions: This study revealed that synthetic acrylic cement flap cranioplasty is associated with better surgical outcome than frozen autologous bone flap.

Keywords: CPL(Cranioplasty), PMMA(Polymethylmethacrylate), BFR (Bone flap resorption), GCS (Glasgow coma scale), GOS (Glasgow outcome score), DC (Decompressive craniectomy),

Introduction

Cranioplasty (CPL) is a secondary surgical procedure performed to restore a defect on the cranial vault after a previous operation made with the removal of skull bone flap. This commonly happens when a decompressive craniectomy is needed for brain edema due to traumatic injury, ischemic or hemorrhagic stroke, after the removal of cranio-dural tumors, or even after the correction of skull malformations¹. Cranioplasty offers cosmetic and protective benefits for patients with cranial defects².

For cranial reconstruction, many types of materials can be used; however, autologous bone flap replacement using the previously removed bone flap is traditionally performed. Autologous bone grafts are preferred because this method reduces foreign materials being introduced into the body, and because the bone flap can be readily accepted by the host and integrated back into the skull².

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Polymethylmethacrylate (PMMA) is a very reliable thermoplastic that can be prefabricated or even molded intraoperatively to create an adequate prosthesis. Preformed PMMA implants made by hand have been superseded by newer 3-D printed implants, but this is accompanied by higher costs and timing issues, apart from having limited availability in developing and third-world countries³. PMMA is used as bone cement (i.e., polymerized in situ from methyl methacrylate monomer and polymer powder mixture) and as a bulk polymer implant material. PMMA, when used in bulk polymer form, is considered a reliable and inexpensive implant material, which showed better long-term outcomes compared with frozen autograft. PMMA, when used as bone cement, causes local toxic reactions, and the material becomes encapsulated by fibrous tissues. The optimal timing of cranioplasty and numerous associated risk factors predicting complications are unknown and synthetic materials for cranial bone defect reconstruction exhibit more promising outcomes compared with autograft. There were differences in survival rates among synthetic materials⁴. Therefore, aim of the study was to compare the surgical outcome of cranioplasty between frozen autologous bone flap and synthetic acrylic cement flap.

Methodology

This cross-sectional analytical study was carried out on 70 patients diagnosed with bony defect in Department of Neurosurgery of Dhaka Medical College, Bangladesh, during March, 2018 to August, 2019. Ethical clearance for the study was taken from the Department of Neurosurgery and IRB, Dhaka Medical College and informed written consent was taken from each patient. Preoperatively thorough neurological examination was done. The patients were divided purposively into two equal groups (group-A & group-B) each having 35 patients and underwent reconstruction either with frozen autologous bone flap or synthetic acrylic cement having skull bone defect (>4cm²). This study excluded patients who had not undergone cranioplasty for previous craniectomy, but rather some other related procedure (i.e., operation for craniosynostosis or a maxillofacial reconstruction).

Autogenous bone flaps was stored at -80°C under sterile conditions until reimplantation. Intra-abdominal placements were not performed. During the study period, synthetic acrylic cement flap was used for skull bone reconstruction.

Infection prophylaxis with intravenous antibiotics given according to department-specific protocols. Follow-up outcome was measured at the following time points: 3rd POD, 7th POD and 1 month.

The following events after cranioplasty were recorded: superficial incisional surgical site infection (SSI), deep incisional SSI, epidural hematoma, cerebrospinal fluid leak, hydrocephalus, exposure of implant, resorption, implant breakage, implant migration, and cosmetic appearance.

All the collected data were checked very carefully to identify errors in collecting data. Data processing work consisted of registration of schedules, editing, coding and computerization, preparation of dummy tables, analysis and matching data. The technical matters of editing, encoding and computerization looked by researcher.

All data were presented in suitable table or graph according to their affinity. A description of each table and graph was given to understand them clearly. All statistical analysis was performed using the statistical package for social science (SPSS) program version 22.0, and Microsoft Excel. Continuous parameters were expressed as mean \pm SD and categorical parameters as frequency and percentage. Comparisons between groups (continuous parameters) were done by unpaired-t test. Categorical parameters compared by Chi-Square and Fisher exact test. The significance of the results as determined in 95.0% confidence interval and value of $p < 0.05$ was considered as statistically significant.

Observations and results

Table I: Distribution of the study subjects according to age (N=70)

Age (years)	Group A(n=35) n (%)	Group B (n=35) n (%)	p-value
1 - 10	1 (2.9)	3 (8.6)	
11 - 20	7 (20.0)	9 (25.7)	
21 - 30	7 (20.0)	2 (5.7)	
31 - 40	11 (31.4)	11 (31.4)	
41 - 50	8 (22.9)	4 (11.4)	
51 - 60	1 (2.9)	6 (17.1)	
Mean \pm SD	32.37 \pm 11.50	33.31 \pm 16.86	0.786
Range	8-56	8-60	

Unpaired t test was done to measure the level of significance

Table II: Distribution of the study subjects according to gender (N=70)

Gender	Group A(n=35) n (%)	Group B(n=35) n (%)	p-value
Male	29 (82.9)	29 (82.9)	1.000
Female	6 (17.1)	6 (17.1)	

Chi-square test was done to measure the level of significance

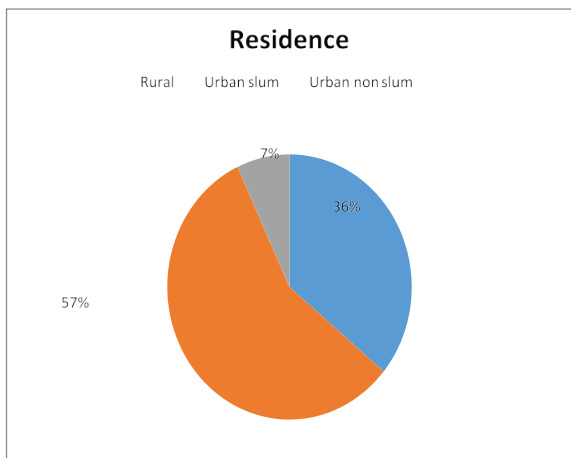


Figure- 1: Distribution of patients in urban and rural area (N=70)

Table III: Distribution of the study subjects according to preoperative variables (N=70)

	Group A (n=35)	Group B (n=35)	p-value
Time of cranioplasty following DC (months)			
Mean±SD	4.29 ± 0.04	4.28 ± 0.04	0.299
Range (month)	3 – 9	3 - 8	
Defect size (cm ²)			
Mean±SD	9.2 ± 2.5	9.3 ± 2.7	0.872
Range (cm ²)	5 – 14	6 - 17	

Unpaired t test was done to measure the level of significance

Table IV: Distribution of the study subjects according to GCS on admission (N=70)

GCS	Group A (n=35) n (%)	Group B (n=35) n (%)	p-value
9-11	0	0	0.932
12-13	3 (8.57)	2 (5.71)	
14-15	32 (91.4)	33 (94.2)	
Mean ± SD	14.0 ± 0.2	14.0 ± 0.1	

Table V: Comparison of complications between groups (N=70)

Complications	Group A(n=35) n (%)	Group B(n=35) n (%)	p-value
Superficial incisional SSI	4 (11.4)	2 (5.7)	0.397
Deep incisional SSI	1 (2.9)	0 (0.0)	1.000
Epidural hematoma	1 (2.9)	0 (0.0)	1.000
Cerebrospinal fluid leak	2 (5.7)	1 (2.9)	0.852
Hydrocephalus	1 (2.9)	0 (0.0)	1.000
Bone resorption	1 (2.9)	0 (0.0)	1.000
Exposure of implant	1 (2.9)	2 (5.7)	0.614
Implant breakage	0 (0.0)	1 (2.9)	1.000
Death	0 (0.0)	1 (2.9)	1.000

*Multiple responses

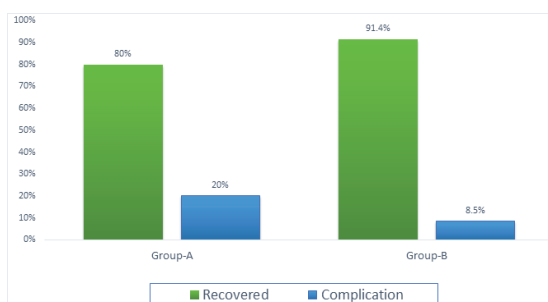


Figure-2 : Comparison of overall outcome between groups (N =70).

Table VI: Distribution of cases according to multiple & Single complications (N=70)

Complications	Group A (n=35) n (%)	Group B (n=35) n (%)
<i>Multiple complications</i>		
Superficial incisional SSI+ Exposure ofimplant	1	1
Superficial incisional SSI+ Cerebrospinal fluid leak	2	0
Superficial incisional SSI+ Exposure ofimplant + Cerebrospinal fluid leak	0	1
Hydrocephalus+ Bone resorption	1	0
<i>Single complications</i>		
Superficial incisional SSI	1	0
Deep incisional SSI	1	0
Epidural hematoma	1	0
Implant breakage	0	1

Chi-square test was done to measure the level of significance

Table VII: Distribution of cases according to GCS on admission, 3rd , 7th POD & 1 month follow up (N=70)

GCS (Mean ± SD)	Group A (n=35) n (%)	Group B (n=35) n (%)	p-value
Baseline	14.0 ± 0.2	14.0 ± 0.1	0.096
Range	12-15	12-15	
3rd POD	14.5 ± 0.1	14.8 ± 0.1	
Range	13-14	13-15	
7th POD	14.0 ± 0.2	14.0 ± 0.1	
Range	14-15	14-15	
1 month	15.0 ± 0.0	15.0 ± 0	
Range	15	15	

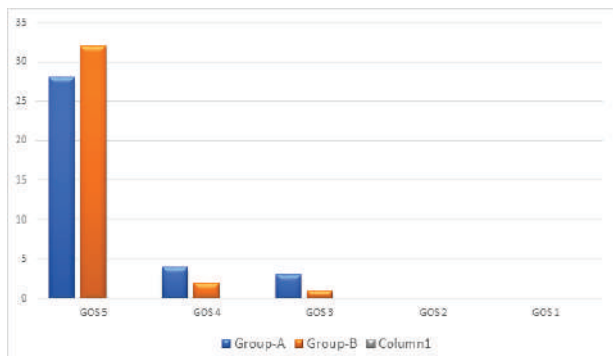


Figure -3 : Assessment of Glasgow Outcome Score at 1 month follow up (N=70)

Table VIII: Association of Defect size (cm²) with complication rate (N=70)

	Mean defect size of total study population (n=60) Mean±SD	Mean defect size in patients with complications (n=10) Mean±SD	p-value
Group-A	9.2 ± 2.5	12.8 ± 3.7	< 0.0001
Group-B	9.3 ± 2.7	11.9 ± 3.1	0.0004

Unpaired t test was done to measure the level of significance

Discussion

This study was carried out to investigate the surgical outcome of cranioplasty between frozen autologous bone flap and synthetic acrylic cement flap. Study demonstrates that about one third of patients (e.g., 31.4%) were between 31-40 years’ age group. Mean age of the patient was 32.37 ± 11.50 years in group-A and 33.31 ± 16.86 years in group-B. Male and female ratio was 4.8:1.

These findings consistent with result of other study^{3,5}.

Operative variables of craniotomy surgery revealed, time interval between craniectomy and reconstruction and defect size was non-significant between groups. Although recovery rate was predominant in group-B, but the difference was statistically non-significant. Present study shows that 20.0% of the patients in group- A developed complication after surgery, whereas complication rate was 8.5% in group-B patients. In a study 64 patients were enrolled and randomized to receive either their own bone or a primary titanium cranioplasty. There were no primary infections in either arm of the trial.

Among the 31 patients who had an autologous cranioplasty, 7 patients (22%) had complete resorption of the autologous bone such that it was deemed a complete failure. Partial or complete autologous bone resorption appeared to be more common among young patients than older patients⁵. In a retrospective review show that, 32.0% of patients developed complication. Infection, epidural hematomas, CSF leak and hydrocephalus were most common complications. A minor complication occurred in 13 patients (13.0%), whereas 19 patients (19.0%) developed a major complication. The survival of the autograft subgroup was lower compared with other subgroups of synthetic materials⁴.

In synthetic materials groups, fewer complications were observed compared with the autograft group. Synthetic materials for cranial bone defect reconstruction exhibit more promising outcomes compared with autograft. There were differences in survival rates among synthetic materials⁴.

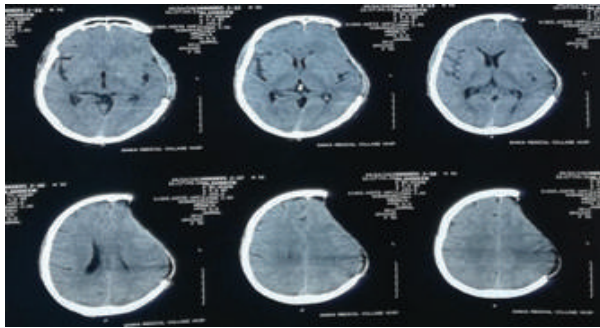
The overall complication rate for cranioplasty after DC was 10% to 40%¹. These complications include infections, reoperations, intracranial hemorrhage, extra-axial fluid collection, hydrocephalus, seizures and bone resorptions⁶. In this study single patient developed bone resorption which is usually 2.7 to 44.4%^{5,7}.

The bone flap infection rate after cranioplasty was 2% to 20%¹. Risk factors include long operative times, craniectomy with temporalis muscle resection, and presence of preoperative subgaleal fluid collection(s), and postoperative wound disruption. Bone resorption indicates bone tissue resorption by osteoclast, which break down bone tissue and releases minerals from bone tissue to the blood. Resorption after cranioplasty means decreased bone volume or bone mineral density after autologous cranioplasty. The reported rates were between 2.7% and 44.4% (Cho et al., 2017).

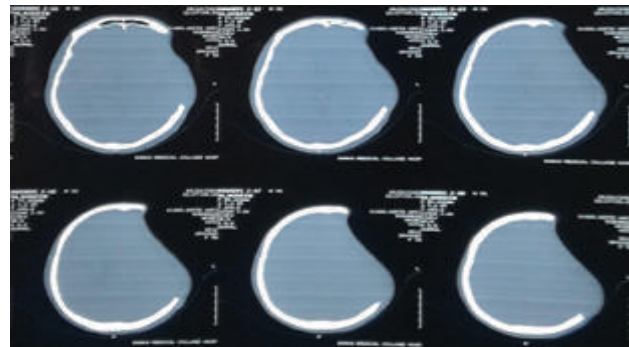
Present study revealed that superficial incisional SSI was 11.4% patients in group-A & 5.7% in group-B, Deep incisional SSI was 2.9% patients in group-A & none of case in group-B, Cerebrospinal fluid leak was 5.7% patients in group-A & 2.9% in group-

B. Bone resorption was 2.9% in group-A. In this study none of the patients in group-B developed epidural hematoma, hydrocephalus & bone resorption. The difference between group was non-significant at p >0.05. In this study, single patient expired.

In the present study, after cranioplasty was



Photograph 1: CT scan of head (soft tissue window) showing left fronto-temporo-parietal cranial defect

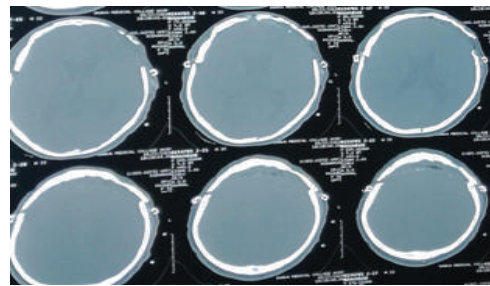


Photograph 2: CT scan of head (Bone window) showing left fronto-temporo-parietal cranial defect

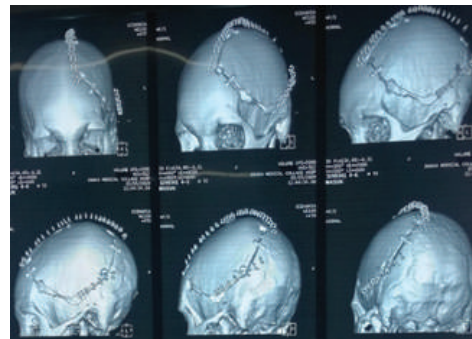
performed with autograft, SSI was 11.4% patients deep incisional SSI was 2.9% patients. This rate is parallel to more recent publications and it is considerably higher compared with earlier studies⁸. Similar study reported that, 45.5% (5 of 11) of cranioplasties performed with PMMA bone cement were to be removed; 3 patients presented with SSI, and 2 patients presented with displaced alloplast (Piitulainen et al., 2015). In earlier studies, the optimal timing of cranioplasty was debated.

In this study, though the improvement of GCS in both group was similar but it was better in group B patient.

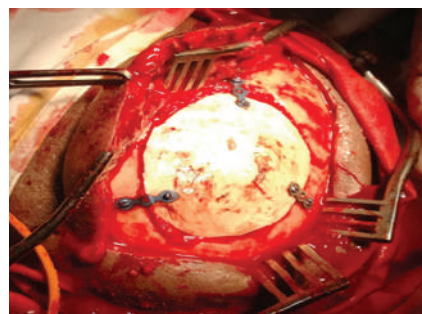
In this study, cranioplasties performed with synthetic materials showed a limited number of complications. However, this finding did not reach statistical significance which is similar to other study⁴ but a higher infection rate was observed among patients who had an alloplast reconstruction performed⁹. Also, results of this study did not suggest preoperative infection as a predisposing factor for alloplast material extrusion. A meta-analysis of 18 studies concluded that implant material has no effect on the cranioplasty infection rate or overall complication rate¹⁰. Taking into consideration the small sample size and prospective nature of this study, it is not within the scope of this study to draw conclusions of the best performing currently available material. Cryopreserved bone is readily available and remains the first-choice method for many surgeons. However, the overall outcomes were non-significant in both groups; post-operative complications were less in patient's surgery with synthetic acrylic cement flap. Therefore, this study can consider any of two techniques, but first choice can be synthetic acrylic cement reconstruction in selective cases.



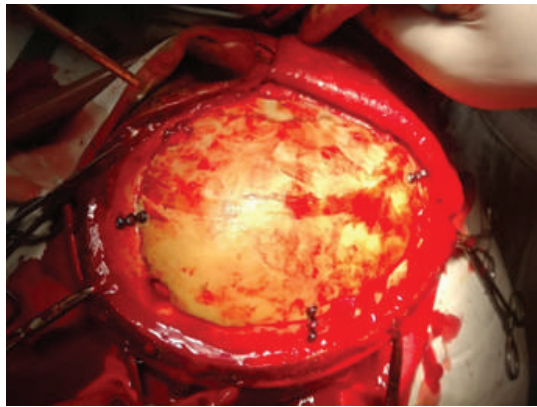
Photograph 3: Post-operative CT scan of head in axial view.



Photograph 4: Post-operative CT scan of head with 3D reconstruction view.



Photograph 8: Fixation of synthetic acrylic cement flap with mini-plates and screws



Photograph 9: Fixation of frozen autologous bone by mini-plates and screws

2. Surgery and preoperative assessment was done by various surgeons
3. Lack of ultra-low deep freeze (temperature -80°C) facility in neurosurgery department of DMCH

Conclusion

After analyzing all the results, cranioplasty with synthetic acrylic cement flap exhibit more promising outcomes compared with frozen autologous bone graft in relations to complications like wound infection, Cerebrospinal fluid leak and bone resorption.

Limitations

1. It was a single centre study. Only patients being admitted in the department of neurosurgery, Dhaka Medical College Hospital, Dhaka were taken for the study. So this not reflect the overall picture of the country. A large-scale study needs to be conducted to reach to a definitive conclusion

Recommendations

Further studies can be undertaken by including large number of patients in different hospitals. Considering easy availability and use in practice, synthetic acrylic cement flap can be used in the management of cranioplasty. An ultra-low deep freeze will be needed for cryopreservation in neurosurgery department of DMCH

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