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# Cranioplasty following decompressive craniectomy – Analysis of complication rates and neurological outcomes: A single center study

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## ABSTRACT

Background: Cranioplasty is the surgical intervention to repair cranial defects in both cosmetic and functional ways. Despite the fact that cranioplasty is a simple procedure, it is still associated with a relatively high complication rate, ranging between series from 12% to 50%.

Methods: The author did a prospective cohort study of patients from August 2015 to December 2017, who had undergone decompressive craniectomy followed by cranioplasty after 6 weeks at our institution. All patients were followed up to 6 months after cranioplasty and complications were recorded both by imaging and clinically. The complications were classified as minor (subgaleal collection, seizures) who did not require the second surgery and major (hydrocephalus, bone flap infection) who required the second surgery. To find out neurological outcome, Glasgow coma score (GCS) and Glasgow outcome scale extended (GOSE) were recorded at 1 month, 3 months, and 6 months.

Results: Overall complication rate in this study was 22.4% (16/72). Subgaleal collection was the most common complication (5.6%), followed by hydrocephalus (4.2%), seizure (4.2%), bone flap infection (2.8%), intracerebral hematoma (2.8%), empyema (1.4%), and subdural hematoma (SDH) (1.4%). Of these, 8.4% (n = 6/72) were major complication (hydrocephalus n = 3, bone flap infection n = 2, and SDH n = 1) which required the second surgery. GCS and GOSE were assessed preoperatively and in postoperative period at 1 month, 3 months, and 6 months. Both mean values of GCS and GOSE showed a significant improvement at 3 and 6 months after cranioplasty.

Conclusion: Cranioplasty after decompressive craniectomy is associated with higher complication rate, but good neurological outcome after surgery always outweighs the complications.

Keywords: Cranioplasty, Hydrocephalus, Infection, Seizure

Key Message: Cranioplasty after decompressive craniectomy is associated with higher complication rate, but good neurological outcome after surgery always outweighs the complications. However, complications rate can be brought down by meticulous timing of cranioplasty in a patient of well-controlled comorbidities and precise surgical techniques. However, storing bone in bone bank is not an additional factor for any postcranioplasty complications which was considered previously.

# **INTRODUCTION**

Cranioplasty is the surgical procedure for repairing cranial defects in both cosmetic and functional ways. The history of cranioplasty dates back to 7000 B.C.<sup>[14]</sup> Inorganic materials were

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used in previous times for cranioplasty which was replaced by organic materials later on.<sup>[14]</sup> Bone from different donor sites such as ribs or tibia also was utilized since the 19<sup>th</sup> century.

Despite being a simple, safe, and clean procedure, it is still associated with a high complication rate, ranging from 12% to 50%.<sup>[2,3,5-8,10-12]</sup> Several parameters such as the initial underlying pathology, type of bone graft, timing of surgery, patient comorbidity, and the technical aspects of the cranioplasty technique have been associated with the occurrence of complications which ultimately affect neurological output.

Cranioplasty also helps to optimize neurological recovery, both physiologically and/or clinically in patients of decompressive craniectomy.<sup>[4,9,13,15,17]</sup> As almost all patients surviving a decompressive craniectomy will require cranioplasty, the complications and neurological outcome of cranioplasty following decompressive craniectomy should be acknowledged.

By this prospective study, we aim to review the complications and neurological outcome of cranioplasty following decompressive craniectomy.

## MATERIALS AND METHODS

Consecutive patients of decompressive craniectomy at our institution were considered for the study. The study was conducted from August 2015 to December 2017. We conducted a prospective observational cohort study of 72 patients of cranioplasty following decompressive craniectomy. For the purpose of calculation of sample, complication rate has been considered as primary variable. Allowing an error of 10% either side, the sample size came to 67 with confidence level 95%. The formula used for calculating the sample size was as follows:

 $n=Z2a/2 \pi (1-\pi)/L2$ 

Where,  $\pi = 0.116$ ; L= 0.10; and za/2=1.96.

## Inclusion criteria

All adult patients above 18 years who underwent decompressive craniectomy for raised intracranial pressure due to various indications – nonpenetrating traumatic brain injury, intracerebral hematoma (ICH), subdural hematoma (SDH), and ischemic stroke, abscess, and tumor, were included in our study population.

## **Exclusion criteria**

Patients not willing to participate in the study were excluded from the study.

## Data collection methods

Data were collected prospectively when the patient was in individual participant data in the form of demographic profile at the time of cranioplasty (age, sex, indication of decompressive craniectomy, and laterality of decompressive craniectomy), comorbidity (hypertension, diabetes mellitus [DM], and use of antiplatelet drug), Glasgow coma score (GCS) and Glasgow outcome scale extended (GOSE) at the time of cranioplasty, intraoperative blood loss (ml), operative time (minute), and duration from decompressive craniectomy (days). All patients were followed up to 6 months of cranioplasty and complications were recorded. The complications were classified as minor who did not require the second surgery and major who required the second surgery. Postoperative computed tomography (CT) scan was done in all patients and findings were recorded. CT finding of the patient who developed complications was recorded separately. To find out neurological outcome, GCS and GOSE were recorded at 1 month, 3 months, and 6 months.

#### Methods of the measurement of outcome of interest

## Primary outcome

To find out complications, all patients were followed at 1 month, 3 months, and 6 months and radiological assessment was done whenever required by CT scan.

Statistical analysis was done to find out relation of complication with gender, comorbidity (hypertension, DM, use of antiplatelet drug, and intraoperative events [blood loss and operative time]), and duration from decompressive craniectomy.

## Secondary outcome

To review neurological outcome, all patients were followed and GCS and GOSE scale were recorded at time of admission, at 1 month, 3 months, and 6 months after cranioplasty.

## Statistical analysis

Analysis was done by Student's *t*-test, Chi-square tests, and Fisher's exact tests and the results computed.

## RESULTS

There were 74 patients who underwent cranioplasty during the study period, of which two were lost to follow-up after surgery. Remaining 72 patients were included in the study.

Of 72 patients, 58 were male (80.6%) and 14 were female. Mean age at the time of cranioplasty was  $51.13 \pm 16.96$  (mean  $\pm$  standard deviation) years. Majority (n = 67) had unilateral defect (93.05%) while 5 patients (6.95%) had bifrontal defect as a result of bifrontal decompressive craniectomy. The left side (n = 36) was more common (50%) than (n = 31) the right side (43.05%). Majority of patient had hypertension (65.3%) while 27.8% of patients were having DM. Thirteen patients (18.05%) were taking antiplatelets on regular basis [Table 1]. The most common indication for decompressive craniectomy was ICH (hypertensive n = 33) and the second most common indication was head injury (multiple contusion, SDH n = 19). Other indication includes acute SDH (spontaneous) (n = 9), chronic SDH (recurrent) (n = 1), middle cerebral artery infarct (n = 7), tumor (n = 1), brain abscess (n = 1), and venous sinus thrombosis (n = 3)[Table 2]. Majority of patient's bone flap was stored in bone bank (98.5%, n = 70) while one patient who was operated (decompressive craniectomy) in some other hospital had bone flap in his abdomen (1.5%). Autologous bone was used for cranioplasty in most of the patients (98.6%). For one patient whose bone flap was lost as he was operated outside, we used methyl methacrylate (1.4%) [Table 1]. Minimum GCS at the time of cranioplasty was 7 and maximum GCS was 15. Minimum GOSE at the time of cranioplasty was 3 and maximum GOSE was 8. Mean GCS at the time of cranioplasty was 13.08  $\pm$  2.37 while mean GOSE score was 3.40  $\pm$  1.33 [Table 1]. Mean operative time was 111.55 ± 20.63 min while mean blood loss was  $165.83 \pm 47.34$ ml [Table 1]. The overall complication rate was 22.4%. The most common complication was subgaleal collection (5.6%), followed by hydrocephalus (4.2%), seizure (4.2%), bone flap infection (2.8%), intracerebral hematoma (2.8%), empyema (1.4%), and SDH (1.4%) [Table 3]. Associated comorbidities such as hypertension, DM, and coronary artery disease increase the risk of both major and minor complications after cranioplasty. However, statistical significance cannot be proven in our study [Table 3]. Intra operative events like blood loss and operative time also assessed in relation to complications which came out as statistically insignificant [Table 4].

#### Neurological outcome

Patients had mean GCS of  $13.08 \pm 2.37at$  the time of cranioplasty,  $13.15 \pm 2.377$  after 1 month of cranioplasty,  $13.36 \pm 2.241$  after 3 months of cranioplasty, and  $13.53 \pm 2.22$  6 months after cranioplasty. Statistical analysis was done to find out difference of GCS at 1 month, 3 months, and 6 months which showed that there was a significant difference (improvement) of GCS at 1 month, 3 months, and 6 months (*P* < 0.05) after cranioplasty [Table 5].

Patient had mean GOSE at time of cranioplasty  $3.40 \pm 1.34$ ,  $3.68 \pm 1.432$  after 1 month of cranioplasty,  $4.17 \pm 1.869$  after 3 months of cranioplasty, and  $4.42 \pm 1.97$  after 6 months of cranioplasty. Statistical analysis was done to find out difference of GOSE at 1 month, 3 months, and 6 months

Characteristic	Number of patients (%)
Number of patients	72
Male	58 (80.6)
Female	14 (19.4)
Туре	
Unilateral (left)	36 (50)
Unilateral (right)	31 (43.5)
Bifrontal	5 (6.95)
Type of graft	
Autologous	71 (98.6)
Synthetic	1 (1.4)
Storage of bone flap	
Bone bank	70
Autologous	1
Comorbidity	
Hypertension	49 (65.3)
Diabetes mellitus	20 (27.8)
On antiplatelet	13 (18.05)
GCS and GOSE	
Mean GCS at time of CP	$13.08 \pm 2.37$
Mean GOSE at time of CP	3.40±1.33
Intraoperative	
Mean operative time	111.55±20.63 min
Mean blood loss	165.83±47.34 ml

GCS: Glasgow coma score, CP: Cerebral palsy, GOSE: Glasgow outcome scale extended

 Table 2: Indication of DC.

Indication of DC	Number (%)			
Head injury	17 (23.6)			
CSDH	1 (1.4)			
ASDH	9 (12.5)			
ICH	33 (45.8)			
MCA infarct	7 (9.7)			
Abscess	1 (1.4)			
Tumor	1 (1.4)			
Venous thrombosis	3 (7.2)			
Total	72 (100)			
ICH: Intracerebral hematoma, SDH: Subdural hematoma				

which showed that there was a significant difference (improvement) of GOSE at 1 month, 3 months, and 6 months (P < 0.05) after cranioplasty [Table 6].

## DISCUSSION

Cranioplasty is necessary for optimal neurological recovery after decompressive craniotomy. Anatomical reconstruction of skull after decompression always restructures the physiological balance of brain and its circulation. Along with technical aspects, emphasis on postoperative complications following cranioplasty should be given.<sup>[7]</sup>

Complication	N (%)	DM (+)	P value	Antiplatelet (+)	P value	HTN	P value
Complication	19 (70)	DM(+)	r value	Antiplatelet (+)	r value	11110	r value
Subgaleal collection	4 (5.6)	0	0.570	0	1.00	3	0.132
Hydrocephalus	3 (4.2)	1	1.00	1	1.00	2	0.052
Seizure	3 (4.2)	2	0.185	1	0.455	2	0.052
Bone flap infection	2 (2.8)	2	0.074	0	1.00	2	0.966
Empyema	1 (1.4)	0	1.00	0	1.00	1	0.476
SDH	1 (1.4)	0	1.00	1	0.181	1	0.476
ICH	2 (2.8)	0	1.00	1	0.331	2	0.966
Total	16 (22.4)						

**Table 4:** Relation of intraoperative time and blood loss with complication.

	Result	n	Intraoperative time			Blood loss
			Mean	<i>P</i> value ( <i>t</i> -test for equality of means)	Mean	<i>P</i> value ( <i>t</i> -test for equality of means)
Seizure	YES	3	116.67	0.066	96.67	0.198
	NO	69	167.97		112.32	
SGC	YES	4	162.50	0.886	107.50	0.679
	NO	68	166.03		111.91	
НСР	YES	3	216.67	0.057	113.33	0.887
	NO	69	163.62		111.59	
BFI	YES	2	190.00	0.468	115.00	0.818
	NO	70	165.14		111.57	
Empyema	YES	1	150.00	0.739	120.00	0.686
	NO	71	166.06		111.55	
SDH	YES	1	250.00	0.073	120.00	0.686
	NO	71	164.65		111.55	
ICH	YES	2	175.00	0.783	130.00	0.202
ICH: Intracer	ebral hemator	ma, SDH	[: Subdural h	ematoma		

Table 5	Table 5: Difference of GCS at time of CP, at 1 month, 3 months, and 6 months.								
	Pair	Paired differences					t	df	P value
		Mean	Std. deviation	Std. error mean	95% confidence interval of the difference				
					Lower	Upper			
Pair 1	GCS at time of CP – GCS 1 month	-0.069	0.256	0.30	-0.130	-0.09	-2.302	71	0.024
Pair 2	GCS at time of CP – GCS 3 months	-0.278	0.587	0.069	-0.416	-0.140	-4.017	71	0.000
Pair 3	GCS at time of CP – GCS 6 months	-0.444	0.854	0.101	-0.645	-0.244	-4.416	71	0.000
GCS: Gl	GCS: Glasgow coma score, CP: Cerebral palsy								

Overall complication rate in our study was 22.4% (16/72). Subgaleal collection was the most common (5.6%, n = 4) complication. All patients were managed conservatively. Repeated aspiration followed by crepe bandage application was done in three patients while one patient required lumber drain. Culture of aspirated fluid was sent in all cases which were sterile.

Two patients developed seizures (4.2%) (one patient had partial seizure and one patient had generalized tonic-clonic

seizure). Both episodes occurred on the 1<sup>st</sup> postoperative day. CT head was done in both the patients, but there was no evidence of any contusion or hematoma. Antiepileptic drugs were modified in all patients and there were no further episodes till the last follow-up.

Two patients developed intracerebral hematoma which was detected on routine postoperative CT head. The size of hematoma was small and both patients did not develop new neurological deficit so they were managed conservatively.

Table 6	Table 6: Difference of GOSE at time of CP, at 1 month, 3 months, and 6 months.								
	Pair		Paired differences				t	df	P value
		Mean	Std. deviation	Std. error mean	95% confidence interval of the difference		-		
					Lower	Upper			
Pair 1 Pair 2	GOSE at time of CP – GOSE 1 month GOSE at time of CP – GOSE 3 months	-0.278 -0.764	0.562 1.216	0.066 0.143	$-0.410 \\ -1.050$	$-0.146 \\ -0.478$	-4.192 -5.330	71 71	0.000 0.000
Pair 3	GOSE at time of CP – GOSE 6 months	-1.014	1.429	0.168	-1.350	-0.678	-6.020	71	0.000
CP: Cere	CP: Cerebral palsy, GOSE: Glasgow outcome scale extended								

One patient (1.4%) developed empyema on the  $10^{th}$  postoperative day. He presented with complaints of cystic swelling at operative site with high-grade fever. Aspiration of swelling was done which showed frank pus, it was sent for culture and sensitivity. Culture report showed *Staphylococcus aureus*. Intravenous antibiotics were started according to culture sensitivity report and intravenous antibiotic was given for 2 weeks.

Basheer *et al.*<sup>[1]</sup> reported complication rate of 23% in which the most common complication was bone flap infection. Other complications in this study were epidural hematoma, subdural hematoma, parietal contusion, bone resorption, sunken bone, deep venous thrombosis (DVT), and pneumonitis.

Gooch *et al.*<sup>[7]</sup> had complication rate of 34% and reoperation rate was 26%. The most common complication in this series was wound infection followed by bone resorption, DVT, hydrocephalus, and status epilepticus. Even uncomplicated nature of procedure cannot prevent the complications following cranioplasty. However, in his series, postoperative cranioplasty is associated with high complication rate and bifrontal craniectomy is associated with a significant increase in complications.

Zain *et al.*<sup>[16]</sup> had overall complication rate of 36.5%. About 26% of patients (n = 25) had minor complications which included breakthrough seizures (15.6%, n = 15), subgaleal collections (3.1%, n = 3), and superficial wound infections (3.1%, n = 3), whereas major complications (10.4%, n = 10) included hydrocephalus (3.1%, n = 3), transient neurological deficits (3.1%, n = 3), and osteomyelitis (2.1%, n = 2).

Statistical analyses were done to find out relation of complication with comorbidities such as hypertension, DM, and use of antiplatelet drug. Intraoperative events such as blood loss and operative time also assessed in relation to complications [Table 4]. Although the presence of risk factors increases the chances of postoperative complications, it was not significant in our study (P > 0.05).

## Timing of cranioplasty

In our study, we found that the patients who were operated before 84 days (12 weeks) had higher rate of hydrocephalus,

seizure, empyema, subdural hematoma, and intracerebral hematoma while patents who were operated after 84 days (12 weeks) had higher rate of bone flap infection and subgaleal collection, but these findings were not statistically significant (P > 0.05).

Our results are slightly similar to a study done by Walcott *et al.*<sup>[18]</sup> who concluded that patients who were operated before 90 days had higher rate of cranioplasty associated complication.

Basheer *et al.*<sup>[1]</sup> concluded that patients who underwent cranioplasty after 24 weeks had more complications as compared to the ones who had gone before 24 weeks. However, they have not mentioned individual complication and its relation with duration from decompressive craniectomy.

The advantage of timely cranioplasty is easier tissue dissection due to well-maintained plane between dura mater and subgaleal till 4 and 5 months postcraniectomy. It also counters negative postcraniectomy complications such as hydrocephalus and syndrome of trephine.

#### Complication requiring resurgery

In our study, six patients (8.4%) had to be reoperated due to complications. The most common indication for reoperation was hydrocephalus accounting for three patients. Two patients of bone flap infection and one patient of SDH required reoperation.

Among the patient having hydrocephalus, two patients presented with headache while one patient presented with decrease level of consciousness and elevation of bone flap. All patients were got operated and Codman Hakim programmable shunt was placed in all patients.

Two patients (2.8%) developed bone flap infection both were reoperated and bone flap was removed and cranioplasty was done later on using polymethyl methacrylate cranioplasty.

Our reoperation rate was 8.4% which was significantly lower as compared to the previous study Basheer *et al.*<sup>[1]</sup> who had reoperation rate of 14%. The most common complication for reoperation in Basheer *et al.*<sup>[1]</sup> was bone flap infection followed by epidural hematoma and subdural hematoma.

Gooch *et al.*<sup>[7]</sup> had reoperation rate of 26% and the most common indication for reoperation was wound infection. Zain *et al.*<sup>[16]</sup> had reoperation rate of 7% which was less as compared to our study (8.4%). Table 7 is showing comparison of various studies with author study.

In our series, 70 of 72 patients were having cranioplasty from the bone placed in bone bank.

Still, our complication rate and reoperation rate were much less than other studies. Hence, bone storage in bone bank as compared to abdomen is not a factor for increase in complication rate. However, as per our experience, storing bone in bone bank avoids unnecessary abdominal incision, blood loss and it decreases operating time also.

#### Neurological outcome

Clinical outcome in terms of GCS and GOSE was compared precranioplasty, 1 month, 3 months, and 6 months postcranioplasty in our series. Both mean values of GCS and GOSE showed a significant improvement at 3 months and 6 months postcranioplasty compared to precranioplasty. These clinical data were corresponding to the studies done by Chibbaro *et al.*,<sup>[16]</sup> whereby remarkable neurological and cognitive improvement has been recorded at postcranioplasty. However, in their studies, the sample populations were limited to those with severe head injury and undergoing early reconstructive cranioplasty. Therefore, cranioplasty was effective not only for cosmoses.

#### How to improve results for upcoming neurosurgeons

As cranioplasty is an elective and rewarding procedure, here are some effective ways to handle it with best positive results. Patient should be given necessary time to control his hypertension and uncontrolled DM. Blood thinners should be stopped 7 days before operative procedure to correct dysfunctional coagulation parameters. Intraoperative good blood pressure control is also necessary. These measures usually avoid subdural or epidural hematoma. Shortening intraoperative time and diminishing blood loss give better results for patients. Intraoperative use of antibiotic (vancomycin) containing solution for irrigation is the most beneficial method to avoid bone flap infection,

Table 7: Comparison of various studies.							
Study	<b>Complications (%)</b>	Reoperation (%)					
Gooch et al. <sup>[7]</sup>	33	26					
Basheer et al. <sup>[1]</sup>	23	14					
Zain et al. <sup>[16]</sup>	36.5	7					
Author study	22.4	8.4					

abscess, or empyema. If vancomycin is not available, then usage of any broad-spectrum antibiotic having good Grampositive bacterial coverage will give good results. Meticulous intermittent closure of subgaleal and skin with a negative suction subgaleal drain for 48 hour is also very helpful in avoiding subgaleal collection or infection. After drain removal, crepe bandage application with moderate pressure for 7 days is also helpful in giving good results in my recent cases. Subgaleal and skin closure over the bone flap should be tension free and stretching should be avoided. Tension bound approximation leads to flap ischemia and necrosis. Unhealthy and irregular bony edges should be nibbled, especially along sphenoid ridge to avoid stretching. Intraoperatively, meticulous dissection should be done between subgaleal and dura to avoid dural breach and cerebrospinal fluid leak. Ideally, cranioplasty should be done between 12 and 16 weeks. Otherwise longer time interval between primary surgery and cranioplasty will lead to dense adhesions making it difficult to obtain the right plane. Bone flap should always be autoclaved before keeping it back. In case of infection or suspicion of contamination, antibiotics should be stepped up. Abscess or empyema should be drained and bone flap should be removed as early as possible and replacement should be done with bone cement. Utilizing these methods, we are getting better results in our recent cases.

## CONCLUSION

Cranioplasty after decompressive craniectomy is associated with higher complication rate, but good neurological outcome after surgery always outweighs the complications. However, complications rate can be brought down by meticulous timing of cranioplasty in a patient of wellcontrolled comorbidities and precise surgical techniques. However, storing bone in bone bank is not an additional factor for any postcranioplasty complications which was considered previously.

#### Recommendation

As cranioplasty is a relatively simple procedure, a relatively high complication rate in literature needs larger studies to find the associations of complications with comorbidity, intraoperative events, and timing of cranioplasty to minimize the risk of complications.

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#### **Conflicts of interest**

There are no conflicts of interest.

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