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Cranioplasty: Surgical Research

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Authors' contributions

This work was carried out in collaboration among all authors. Author MAA designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors EAAE and EEEG managed the analyses of the study. Author AISE managed the literature searches. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Background: Cranioplasty involves the repair of a cranial defect or deformation for cosmetic reasons, as well as long-term protection of the brain from the external environment. This work aims to evaluate and compare the efficacy, advantages and limitations of different materials used in cranioplasty.

Methods: Prospective study of twenty-five patients who underwent cranioplasty for a skull bone defect by using different materials from March 2018 to March 2020.

Results: The study included 13 males and 12 females. The defect was post-traumatic in 11 patient neoplastic in 13 patients and 1 patient was after decompressive craniectomy for malignant ischemia .When the defect was less than 80 cm² bone cement was used in 54.5%. When the defect was \geq 80 cm² titanium mesh was used in 71.4 % of those cases. 72.0% of the patients (18 of 25) reported excellent cosmetic results, 24% (6 of 25) good, 4.0% (1 of 25) poor results.

Conclusion: When the original bone flap is not available for cranioplasty titanium mesh is suitable for the large calverial bone defects. it is strong but hard to shape while bone cement is more suitable for small defects near the skull base as it is easy to shape but weak. Medpore and hydroxyapetite powder are better for pediatric defects as they don't hinder bone growth. Prefabricated bone flaps are effective but expensive and can't be used if cranioplasty is planned in the same operation.

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Keywords: Cranioplasty; hydroxyapatite; prefabricated; titanium mesh; bone cement.

1. INTRODUCTION

Cranioplasty is the surgical repair of a skull defect for restoring the contour of the skull with the original skull piece or a custom contoured graft [1].

The most common causes of skull defects include trauma, bone neoplasm, iatrogenic after decompression for uncontrolled intracranial hypertension in traumatic brain injury or malignant hemispheric stroke [2].

The patient with the bone defect may complain of cosmetic problems, headache or fits [3]. CT bone window with 3D reconstruction is a gold standard imaging technique for evaluation of the defect and planning of the best treatment [4].

Cranioplasty is important for cosmetic reason, as well as long-term protection of the brain from the external environment. Materials commonly used for cranioplasty include Methyl methacrylate (MMA), titanium, bone ceramics or autolegous bone graft [5]. Titanium mesh cranioplasty with or without (MMA) is currently in wide use and is considered a good substitute for skull bone defects [6].

Titanium mesh is hard to shape, relatively expensive & bioacceptable. It also shows less rate of infection, even when in contact with the paranasal sinuses. Methyl methacrylate (MMA) easy to shape but is weak and associated with high infection rate. Recently, titanium meshes were used as a support to cement materials. In this way, the strong resistance against mechanical stress of the titanium and the ability to remodeling of the cement materials were combined [7].

2. PATIENTS AND METHODS

This study was conducted in The Department of Neurosurgery at Tanta University, from March 2018 to March 2020. It included Twenty-five patients who underwent cranioplasty for a skull bone defect by using different materials.

2.1 Patient Population

2.1.1 Inclusion criteria

All patients having large bone defect causing deformity or neurological manifestation.

2.1.2 Exclusion criteria

- Unhealthy or atrophic scalp.
- Osteomyelitis.
- Bad general condition which could interfere with anesthesia.
- Small skull defect which does not cause any cosmetic or neurological disturbances.

2.2 Preoperative Protocol

All patients were subjected to full history taking, general and neurological examination and local examination of the bone defect to determine the site and the size of the defect, detect any signs of inflammation and the quality of the overlying skin to determine the possibility of intervention.

2.3 Investigations

CT scan bone window with 3D reconstruction were done in all cases to evaluate the defect and contrast was injected to detect underling infection or neoplasm.

2.4 Surgical Technique

The steps, costs, technique and follow up methods were explained to the patient or first degree relatives before any surgical intervention. And informed consent including assignment for participating in the research work was taken.

(A) **Titanium mesh:** Titanium mesh is stiff and rectangular in shape, so it needs to be customized to fit the size and contour of the defect and fixed to the skull by miniscrews.

B) Methyl-methacrylate: It is a monomere in powder form and needs a specific liquid to become stony hard after polymerization and liberating heat. The powder and liquid are mixed in flask very well till its texture becomes coherent, then an adequate amount fills the gap and molded till we get suitable curvature, during this process, we irrigate cold saline to cool down the flap to avoid thermal effect on underlying tissues.

C) Hydroxyapetite: After bone margins were identified it should be trimmed to allow the fusion of the particle with the bone.



Fig. 1. Exposure of the margin of the bone defect



Fig. 2. Titanium mesh preparation



Fig. 3. Ttanium mesh fixed by mini screws



Fig. 4. Preparation of MMA

D) 3D Printed flap: The flap is printed by using a 3D printer for a thin slice CT bone window with 1mm. The used material is poly-laurine-lactam. The prefabricated flap is fenestrated to avoid any collection of blood beneath the flap. Then, the flap can be fixed to the skull bone using mini plates and screws.

2.5 Polyethylene

This material is available as smooth sheets of various thicknesses or as sheets with conical projections to add bulk if desired.

- It can be trimmed with a scissor to fit and cover the cranial defect.
- An allowance was made for molding and edge approximation by cutting the implant slightly larger than the template. Fixation is performed by placing titanium screws directly through the implant into the bone or suturing the implant to the surrounding pericranium.

2.6 Auto-graft

 The original bone flap was preserved in the abdominal wall.

- The bone flap is washed and cleaned with a physiological saline solution.
- The flap is then soaked in a 10% betadine/saline solution for 15 min. undiluted betadine is toxic to bone and

hence should always be diluted for this technique.

• The flap is placed into the surgical site and fixed with titanium miniscrews and plates.



Fig. 5. The methyl-methacrylate molded to fit the bone defect



Fig. 6. Hydroxyapatite particles

Fig. 7. Hydroxyapetite covering the dura



Fig. 8. 3D flap after fixation by using mini screws and plate



Fig. 9. The bone flap after its fixation with miniscrews and plates

Postoperative: CT brain with 3D reconstruction done for the assessment of the flap. All patients and relatives were asked for their satisfaction with cosmetic results and seizure control.

3. RESULTS

This study included 25 patients operated for cranioplasty .The defect was post-traumatic in 11 patient, neoplastic in 13 patients and 1 patient was after decompressive craniectomy for malignant ischemia.

Age distribution is shown in Table 1.

The pathology in the neoplastic cases was meningioma en plaque for 5 patients, 4 cases with metastatic lesion and 4 patient with eroded bone by meningioma.

The causes in traumatic defect were 7 patients (63.6%) due to compound depressed fracture, 3 patients had ASDH (27.3%) and one patient (9.1%) was post-operative osteomyelitis after EDH evacuation Table 2.

The defect was related to the skull vault in 20 patients and related to the skull base in 5 patients Fig. 12.

15 patient were presented by cosmetic problem, 10 patient were complaining of headache and only one patient presented by fits Table 3.

Hydroxyapatite was used in 2 patients, Titanium mesh was used in 12 patients, 3D prefabricated flap was used in 2 patients, Bone cement was used in 8 patients and medpore was used in 1 patients Table 2.

Only one patient was not satisfied with the cranioplasty as he developed wound infection due to SCF leakage, in this patient the material used was titanium mesh Table 2.

The bone cement was used in 54.5% in all patient with defect less than 80 cm², 18.2% for hydroxyapatite and 27.27% titanium mesh while 3Dprefabricated medpore were not used. The titanium mesh was used when the defect was \geq 80 cm² 71.4% of those cases Table 4.

All patients with skull base defects were treated by using bone cement while in the vault defects the most commonly used material was titanium mesh in 11 patients Table 6.

72.0% of the patients (18 of 25) reported excellent cosmetic results, 24% (6 of 25) good results Table 5.

		Trauma group (n = 11)	Tumor group (n = 13)	Ischemic (n = 1)
Age	Range	3-73	34-60	45
(years)	<30 y	8 (72.8%)	0 (0%)	0 (0%)
	≥ 30 y	3 (27.3%)	13 (100%)	1 (100%)

Table 1. Age of different groups

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Fig. 10. Follow up CT brain post-operative (A. Shows titanium mesh, B. Shows methylmethacrylate, C. Shows hydroxyapetite, D. Shows 3D printed flap using poly-laurine-lactam)



Fig. 11. The site of bone defect in all patients

Patients (n = 25)			
Cause	Trauma	11(44.0%)	
	Tumor	13 (52.0%)	
	Ischemic	1 (4.0%)	
Unilaterality	Unilateral	24 (96.0 %)	
-	Bifrontal	1 (4.0 %)	
Material	Hydroxyapatite	2 (8.0%)	
	Titanium mesh	11 (44.0%)	
	3Dprefabricated	2(8.0%)	
	Bone cement	8 (32.0%)	
	Medpore	1 (4.0%)	
	Autograft	1 (4.0%)	
Complications	No	24 (96.0%)	
	CSF leak	1 (4.0%)	
	followed by Infection	х <i>у</i>	
Satisfaction	Satisfied	24 (96.0%)	
	Not satisfied	1 (4.0%)	

Table 2. Cause of defect, unilaterality, material, complications and outcome in all studied patients

Table 3. Clinical presentation

Clinical presentations	Patients (n = 25)			
		No.	%	
Cosmetic unacceptance	15		60%	
Headache	10		40%	
Epilepsy	1		4%	

Table 4. Material to the size of defect of all studied patients

Material	Size		
	< 80 cm ²	≥ 80 cm²	
hydroxyapatite	2 (18.18%)	0 (0%)	
Titanium mesh	3 (27.27%)	10 (71.4%)	
3Dprefabricated	0 (0 %)	1 (7.1%)	
Bone cement	6 (54.54%)	2 (14.3%)	
Medpore	0 (0%)	1 (7.1%)	
	Patient (n=11)	Patient (n=14)	

Table 5. Satisfaction on visual analogue scale

Degree	(%) (n = 25)	
Excellent	18 (72.0%)	
Good	6 (24.0%)	
Fair	0 (0.0 %)	
Poor	1 (4.0 %)	

3.1 Selected Cases

Case 1: A female patient aged 45 years old presented with long-standing headache and gradual progressive left eye proptosis with no affection on the visual acuity CT brain and MRI

brain with contrast were done and revealed meningioma en plaque causing hyperosteosis of the orbital roof, lateral orbital wall, and temporal bone. Orbital roof lateral orbital wall and temporal bone were removed and reconstruction was done by bone cement at the same operation. Aboushehata et al.; JAMMR, 33(11): 38-52, 2021; Article no.JAMMR.68261

Site	Used materials	Patients (n = 25)	
Skull base (n=5)	Bone cement	5 (100%)	
Vault (n=20)	Titanium mesh	11 (55.0%)	
	3D prefabricated	2 (10.0%)	
	Bone cement	3 (15.0%)	
	Medpore	1 (5.0%)	
	Autograft	1 (5.0%)	
	Hydroxyapatite	2 (10.0%)	

Table 6. Used materials in different sites

Table 7. Used materials according to age

Age group	Used materials	Patients (n = 25)
Pediatric (n=4)	Hydroxyapatite	2 (50.0%)
	3D prefabricated	1 (25.0%)
	Medpore	1 (25.0%)
Adults (n=21)	Titanium mesh	11 (52.4%)
	Bone cement	8 (38.1%)
	Autograft	1 (4.7%)
	3D prefabricated	1 (4.7%)



Fig. 12. MRI brain with contrast meningioma enplaque with bony affection

Case 2: A female patient aged 56 years old presented with headache and blurred vision with a history of HCC. CT brain revealed metastatic HCC eroding the overlying bone. The tumor and affected bone were removed and cranioplasty was done by using titanium mesh at the same operation.

Case 3: Male patient aged 4 years old presented to ER after a road traffic accident with GCS was 11, CT brain was done and revealed acute subdural hematoma which was

evacuated and the patient admitted to ICU till full recovery . 1 month later the patient came to our outpatient clinic with sinus discharging pus, CT brain with contrast revealed a pus collection and bone flap osteomyelitis. The bone flap was discarded. 6 months later on the cranioplasty was done with medpore.

4. DISCUSSION

It is well known that decompressive craniotomy (DC) has been associated with disturbances of

cerebrospinal fluid (CSF) circulation. furthermore, [8]. DC causes significant changes in the dynamics of local cerebral blood flow, as well as the cerebral metabolic rate of oxygen and glucose changes, which affect normal brain function and metabolism [9].

Thus, the performance of cranioplasty may theoretically restore all the altered conditions and improve the patient's overall neurological condition as it is not just cosmetic surgery [10]. A total of 25 patients who were admitted to the Neurosurgical Department Tanta University Hospital and had undergone cranioplasty from March 2018 to March 2020 were included in the study.

The mean age of all included patients was 39 years while the mean age of traumatic group was 9 years and tumor group was 45.5 years. Among all the patients, 52.0% (n = 13) were males and 48.0% (n = 12) were females.



Fig. 13. Axial view of CT brain post-operative



Fig. 14. 3D reconstruction of CT brain post-operative



Fig. 15. Axial MRI brain sowing metastatic HCC eroding the bone



Fig. 16. Post-operative axial CT brain for cranioplasty with titanium mesh

Hamandi et al. [11] reported in their study that 85.7% (n = 12) were males and 14.3% were females, which is somewhat in accordance with our study as the males are more liable to the trauma which is the most common cause for skull bone defect.

The initial diagnosis of the patients included traumatic causes including (RTA, FFH, and physical assault) or neoplastic caused skull bone defect and iatrogenic craniectomy due to brain edema. The most common cause of the bone flap removal was tumor caused by 52.0%

(*n* = 13) while the traumatic cause represented 44.0 % (*n* =12) and 4.0% for ischemic patient. In trumatic group (n = 11) the compound depressed fracture formed 63.6% (*n* = 7), ASDH 27.3% (*n* = 3) and EDH 9.1% (*n* = 1).

Hamandi et al. [11] in their study reported the cause of bone flap removal at 57.15% (n = 8) due to penetrating injuries and 35.70% (n = 5) due to depressed, While in our study we didn't have cases after a penetrating injury as most of those patients died or have a small not significant defect.

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Fig. 17. Axial CT brain with contrast showing subdural collection of pus



Fig. 18. Pre-operative axial CT brain showing bone defect



Fig. 19. Post-operative axial CT brain showing the closure of the defect with medpore

Regarding laterality of the defect, the most common cranial defect was unilateral (96.0%, n = 18), only one patient had bifrontal defect 4.0 %,(n = 1). Various studies on cranioplasty have shown that unilateral defect is the most common cranial defect.

Basheer et al. [12] in their study of 114 patients reported that 90.35% (n = 103) were unilateral, 5.26% (n = 6) were bilateral, and 4.39% (n = 5) were bifrontal, which is somewhat in accordance to our study.

We used bone cement in all patients with skull base defect as it is easy to shape, while in the vault defect we used titanium mesh in 52.4 % of those patients as it is strong and hard to shape.

We used hydroxyapetite powder in 2 (50.0%) pediatric cases as the hydroxyapetite induces bone osteocoduction without affecting the growth of the skull and it gives a good cosmetic results. We used 3D fabricated bone flap in two patients.

In our study we have done cranioplasty for 5 patients with a skull base tumor 20.0% (n = 5) meningioma en plaque all of them were female 100.0% (n = 5), and the main age was 47. The cranioplasty was done in all of them by using bone cement as it is easy to shape, as the reconstruction of the temporal fossa; orbital roof and lateral orbital wall need a malleable material to have a good result and satisfying cosmetic outcome.

There was no post-operative deterioration of vision. The preoperative proptosis improved with no transmitted brain pulsation to the eye globe which could be one of the most annoying complaints.

Freeman et al. [13] in their study agreed with us as they found that twenty-five patients were included; 92% of participants were women. The mean age was 51 years. Proptosis significantly improved. To date, all treated patients are progression free.

Complications were noted in 4.0 % (n = 1) in all studied patients as there was CSF leak followed by wound infection and pus discharged from the wound. The complication happened in the only patient who received radiotherapy.

Walcott et al. in their study reported that wound infection 12.13% (n = 29) was the most common complication following cranioplasty. They had a

net complication rate of 23.85% (n = 57). The main complication is the implant failure rate within 6 months. The implant failure was defined as infection or implant exposure after cranioplasty that removal of the implant was necessary [14].

This is higher than our results in this study as they have a large group in the study and they performed cranioplasty at the same operation in traumatic patients which is associated with a higher risk of infection as the wound in compound skull fracture is usually contaminated. The implant will harbor bacteria and cause infection. We had a smaller sample and cranioplasty was performed in a separate session after ensuring the absence of infection by clinical and laboratory follow-up.

An empiric antimicrobial treatment covering Gram-positive and Gram-negative germs was started. The appropriate response to therapy was ascertained and followed over time, monitoring systemic and local clinical signs [15].

Walcott et al. [14] also reported that patient age, location of cranioplasty, presence of an intracranial device, bone flap preservation method and cranioplasty material were not predictive of the development of cranioplasty infection. Poor nutritional status has been shown to increase surgical infection risk [16].

Most of the patients 56.0% (n = 14) were operated on within 9 –28 weeks after the primary procedure. The reasons for delayed cranioplasty include patients deemed medically or neurologically unstable until the point of intervention or nonresolution of cerebral edema or centralized nature of neurosurgical care at our place where there are logistic difficulties in operating patients early.

The optimal timing of cranioplasty following craniectomy is intensely debated. Studies have been performed that either support or refuse its influence on post-cranioplasty infection [17]. Commonly, performing cranioplasty 3 months after craniectomy is recommended; if the patient has a history of intracranial infection or open craniocerebral injury, the procedure can be delayed for at least 6 months after the first surgery [18].

However, some authors have advanced the idea of early cranioplasty after decompressive craniectomy to alleviate complications from craniectomy [19]. Early cranioplasty performed before massive scar formation reduces operative time by facilitating soft tissue dissection. Liang et al. reported that early cranioplasty was safe and assisted in improving patient's neurological function and prognosis [20].

Chun and Yi [19], in their study concluded that early cranioplasty provides satisfactory securing of dissection plane during operative procedures compared with later cranioplasty, without causing additional complications, including infection, subdural hygroma, and brain parenchymal damage in selected cases.

Borger et al. [21] in their study determined the criteria for early cranioplasty to 3 months. The advantages of early cranioplasty were reported in their study, including shorter dissection and operation time, fewer blood loss, cost reduction, and better functional outcomes. However, the disadvantages of early cranioplasty have also been reported, including epidural, wound healing disturbance, hydrocephalus, infection and bone resorption.

Others reported that early cranioplasty is associated with increasing morbidity and complication because of interruption of wound healing and the performance of a second procedure on just recovering from initial insult, and possibility of leakage of cerebrospinal fluid. Chang etal. study found a significantly lower rate of infection in patients undergoing early (≤3 months) cranioplasty compared with those undergoing cranioplasty after 3 months. And other studies showed similar results [22].

The delayed cranioplasty means that the average bone preservation period is longer than that of early cranioplasty. As the preserving period for autograft bone flap is longer, the chance of flap contamination is increased [22].

Some authors assert that flaps stored beyond 10 months should be resterilized or discarded [23].

We used titanium mesh in 13 patients (52.0%) of all studied patients and 8 of those patient had a large defect larger than 80 cm².Titanium is, however, expensive, difficult to pre-fabricate, and hardly affordable by many patients, Titanium appears to be the most biocompatible metal available at present. It is biologically and chemically inert [24].

The use of antibiotic-impregnated methyl methacrylate has proved to be more superior than using one not impregnated with antibiotics.

[25]. In our study we added vancomycin powder to bone cement to reduce the infection chance.

The use of titanium mesh has the advantage of being more resistant to fracture, and less likely to develop when compared infection to methylmethacrylate in the study of Broughton E et al. that included 45 cases only 2 were reported to be infected and required flap removal. All cases were operated upon using Methylmethacrylate for the repair [26].

Andrabi, S et al. [27], found in their study that the most common method of bone storage was frozen bone bank 80.51% (n = 190) while we preserved the original bone flap in the abdominal wall in many cases and most of those cases had infected abdominal wound and osteomyelitis of the bone flap [27].

5. CONCLUSION

This study revealed the efficacy, advantages and limitations of different methods used in cranioplasty. By comparing different modalities we found out that the best material used in large skull bone defect which doesn't need a significant curvature was titanium mesh, while the best materials for the defect in skull base and need to fabricate it to give a good curvature like temporal fossa was bone cement, while the best choice for children was hydroxyapatite.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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