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A Comparative Study between Using Titanium Mesh Versus Hand-Made Bone Cement Implants in Restoring Skull Configuration

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Abstract

Background: We describe two different techniques in reconstruction of calvarial skull defects and to compare outcomes of using titanium mesh versus hand-made bone cement implant.

Aim of Study: The aim of this study is to describe two different types of technique in reconstruction of calvarial skull defects and to compare outcomes of using titanium mesh versus hand-made bone cement implant.

Patients and Methods: The present study is a comparative study that was done for 30 patients who underwent cranioplasty in Cairo and Bani suef university hospitals, between January 2019 and December 2020. The patients were divided in two groups 15 in each, group A in which patients operated upon by cranioplasty with titanium mesh and group B in which patients operated upon by cranioplasty using handmade bone cement. In this study, The patient was then followed for three months in the outpatient clinic with the first visit 14 days from discharge, one month later then at the end of the three months to determine the cosmetic outcome and the patient satisfaction and also to make sure that no complications occurred " wound dehiscence, exposure of implant, infection, overlying skin maceration or inflammatory signs, seizures, CSF leak, epidural or subdural haemorrhage.

Results: As regards cosmetic outcome, there is statistically insignificant difference between both study groups and analysis of results showed that bone cement had slightly better cosmetic outcome. As regards duration of surgery, there is statistically significant difference between both study groups and analysis of results showed that bone cement cranioplasty had shorter operative period. As regards complication rate, there is statistically insignificant difference between both study groups and analysis of results showed that bone cement had higher rate of post-operative infection.

Conclusion: When comparing both materials we found that the results were statistically significant as the duration of surgery (bone cement had shorter operative time). Other results showed statistically insignificant differences as cosmetic outcome (bone cement had slightly better cosmetic outcome) and post-operative complications (bone cement had higher rate of post-operative infection).

Key Words: *Cranioplasty – Titanium mesh – Bone cement.*

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Introduction

CRANIOPLASTY is a reconstructive procedure used to restore skull anatomy and repair skull defects. Optimal skull reconstruction is a challenge for neurosurgeons, and the strategy used to achieve the best result remains a topic of debate **[1].**

The most common causes leading to calvarial skull defects include depressed fractures of the skull, decompressive craniectomies (DC), tumor infiltration of calvarial bones, congenital deformities and inflammatory lesions and primary bone tumors **[2].**

Cranioplasty provides protection to the underlying brain and is performed for both functional and aesthetic reasons. It is important for cosmesis as well as for neurologic recovery and relief of symptoms due to craniotomy defect such as described in syndrome of the trephined (which was first described in the French literature during World War I, and consisted of: Headache and sometimes pulsatile pain, amnesia, inability to concentrate and insomnia) **[3].**

The material most used for reconstruction has been the patient's own bone that has been stored in a refrigerated sterile container or in an abdominal pocket at the time of craniectomy. The rationale for this is that autologous bone fulfills many of the requirements of an ideal reconstructive material. However, it has been demonstrated that the use of

autologous bone is associated with a high failure rate due to infection and bony resorption. When this occurs, the original bone flap often must be discarded, and consideration must be given to alternative alloplastic material **[4]**.

Many characteristics have been suggested to describe the ideal alloplastic material for cranioplasty: Biocompatibility features such as tissue tolerance, simplicity of manufacture, ease of sterilization, low thermal conductivity, radiolucency, light weight, resistance to infections, no expandability with heat, low cost and ready to use. There are also many techniques that have been described to achieve the best result after cranioplastic procedures **[5]**.

Patients and Methods

This is a randomized comparative study conducted in Cairo University Hospitals and Bani suef University Hospitals, in the department of neurosurgery. All patients were reviewed for detailed history, clinical examination, and investigations. The operations were performed on those who had skull bony defect of different causes e.g. post traumatic, post infectious and post tumor resection.

This study is designed to include 2 groups. Group A includes 15 patients with cranioplasty using titanium mesh while Group B includes 15 patients with cranioplasty using handmade bone cement implants with total number of 30 patients of both groups. Inclusion criteria were patients with residual calvarial skull defects which need cranial reconstruction with no specific gender. Exclusion criteria were Immuno-compromised patients, Cases with history of graft failure or rejection, Recipient site with residual disease, History of recent local infection, Patients planned for radiotherapy, Patients under age 10 years old.

All patients were subjected to thorough history taking and clinical examination with special attention to age, gender, neurological deficits include history of seizures weakness, sensory changes, history of chronic illness, steroid therapy or radiation therapy, and special habits e.g. smoking, alcoholism.

Clinical findings include assessment of general condition of the patient, assessment of surgical fitness and neurological examination: Motor function (power, superficial & deep reflexes), sensory affection (anaesthesia with sensory level or hypoesthesia).

Radiological investigations include CT brain and skull with 3d reconstruction.

Patients were assigned into two groups:

- Group (1): 15 patients in which their skull defect was surgically reconstructed by titanium mesh cranioplasty.
- Group (2): 15 patients in which their skull defect was surgically reconstructed using hand-made bone cement implant.

Postoperative medical treatment includes antibiotics, analgesics, gastric protecting drugs, IV fluids and neurotropic drugs.

Early follow-up includes post-operative neurological status, radiological evaluation of the graft used for cranioplasty. Later follow-up after 2 weeks was done for assessment of the wound and the cosmetic appearance of the patient then after 1 month and at the end of 3 months duration.

Results

In all patients, the etiology of the skull defect was post-traumatic defect in the form of compound depressed fracture in all of them (21 cases). Eight cases had post tumor excision skull defects (four cases were post osteoma excision and four cases post meningioma excision). One case of decompressive craniectomy following ASDH evacuation.

Table (1): Different aetiologies of cranial defects.

Etiology	Number of patients	% Percent
Trauma (Depressed fractures)	21	70.0
Post Tumors Excision	8	26.7
Decompressive Craniectomy	1	3.3
Total	30	100

Table (2): Different etiologies between both groups.

Group	Post Traumatic & its %	Post Tumor Excision & its %	Post decompressive craniectomy & its %
Group A	11 cases (73.34%)	4 cases (26.7%)	0 cases (0.0%)
Group B	10 cases (66.7%)	4 cases (26.7%)	1 case (6.66%)
p-value		0.592	

Regarding the site of the defect, 13 cases (43.3%) had frontal defects, 12 cases (40.0%) presented with parietal defects, 4 cases (13.3) presented with fronto-parietal defects and one case (3.3%) presented with occipital defect.

Table (3): Sites of skull defects.

	Frequency	Percent
Frontal	13	43.3
Parietal	12	40.0
Occipital	1	3.3
Fronto-parietal	4	13.3
Total	30	100.0

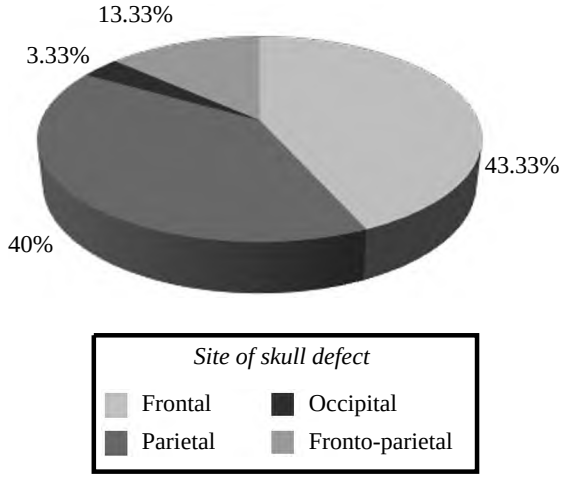

Fig. (1): Pie chart showing different sites of skull defect.

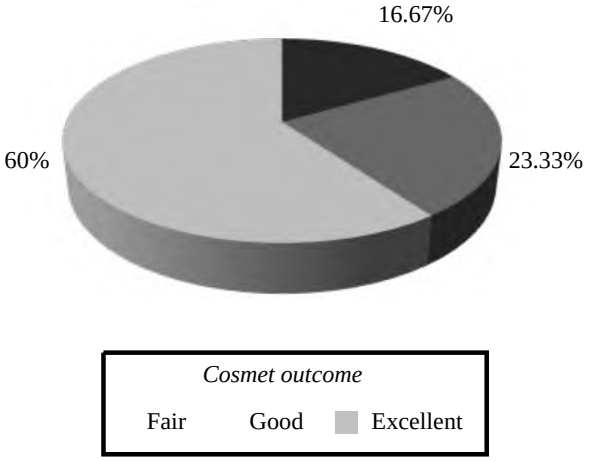

Fig. (2): Pie chart showing cosmetic outcome of both groups.

Outcome of the patients:

Method of assessment of post-operative cosmetic outcome.

Table (4): How to assess clinical and patient's outcome.

Assessment	Clinical	Patient
Excellent (complete success)	- Acceptable cosmetic appearance even on close inspection	- Satisfied with appearance
Good (partial success)	- Minor cosmetic failure only noted on close inspection	- Minor cosmetic problem only noted on close inspection
Satisfactory	- Satisfied but cosmetically noticeable	- Satisfied with appearance but not ideal
Fair (partial failure)	- Cosmetically poor result: may need revision but could be left	- Unhappy with appearance; may want revision but possibly could be left
Poor (complete failure)	- Cosmetically poor result and require revision	- Unhappy with appearance and wants revision

As shown in the table below: 18 cases (60.0%) had excellent outcome, 7 cases (23.3%) had good outcome and 5 cases (16.7%) had fair outcome.

Table (5): Outcome of patients.

Outcome	Number	Percent
Excellent	18 cases	60.0
Good	7 cases	23.3
Fair	5 cases	16.7

Table (6): Different outcomes between both groups.

Group	Excellent	Good	Fair
Group A	8 cases (53.3%)	4 cases (26.7%)	3 cases (20%)
Group B	10 cases (66.7%)	3 cases (20%)	2 case (13.3%)
p-value	0.754		

Regarding the cosmetic outcome: In group A, 8 patients (53.3%) had excellent outcome, 4 patients (26.7%) had good outcome while 3 patients (20%) had fair outcome.

In group B, 10 patients (66.7%) had excellent outcomes, 3 patients (20%) had good outcome while 2 patients (13.3%) had fair outcome.

There was an insignificant statistical difference (*p*-value =0.754) between the two groups.

By comparing the outcome of both groups, statistics showed slightly better cosmetic outcome (good and excellent) 86.7% in group B than group (A) 80%.

Regarding the complications encountered in the thirty patients during the hospital stay period and the 3 month follow-up period, there were no complications encountered in 20 cases (66.7%). Three cases (10%) developed exposure of the implant; all of them were managed by implant removal after failure of conservative management. Four cases (13.3%) developed infection, all of them failed to be conservatively managed and needed implant removal. Three cases (10%) developed seroma that had been followed up in outpatient clinic till it had subsided within 1.5 month without any need for hospital readmission.

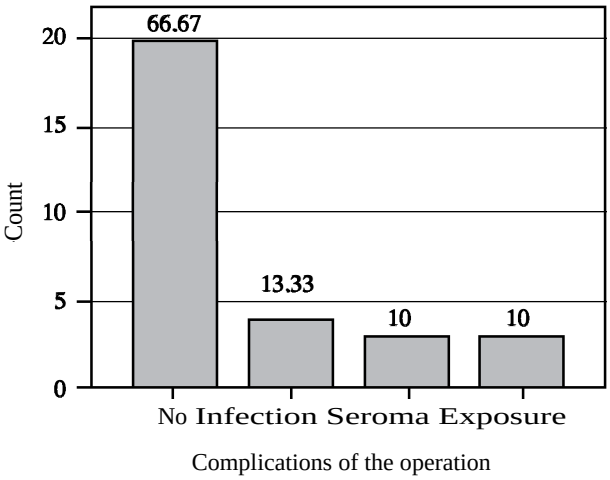

Fig. (3): Bar Chart for complications.

Table (7): Table of complications.

Complication	Number	Percent
Exposure (implant removed)	3	10
Infection (implant removed)	4	13.3
Seroma (conservative)	3	10
No complications	20	66.7

Table (8): Comparison between complications that had occurred in both groups.

Complication	Group A	Group B	p-value
Exposure	2 (13.3%)	1 (6.7%)	0.601
Infection	1 (6.7%)	3 (20%)	
Seroma	1 (6.7%)	2 (13.3%)	
Total	4 (26.7%)	6 (40%)	

Regarding the complications encountered, 2 cases (13.3%) developed exposure of the implant, 1 case developed infection (6.7%), 1 case developed seroma (6.7%) and 3 cases (20%) needed to be removed in group A, while in group B only one case (6.7%) had implant exposure, 3 cases developed infection (20%), 2 cases (13.3%) developed seroma and 4 cases (26.7%) needed to be removed, with statistical insignificant difference (p-value=0.601).

In group A, mean/SD of duration of operation was 46.67±4.791, while in group B, mean/SD of duration of operation was 36.13±5.410.

Table (9): Table of Operative Duration in minutes in Both Groups.

Group	Mean	Standard deviation	p-value
Group A	46.67	4.791	<0.001
Group B	36.13	5.410	

There was statistically significant difference with p-value <0.001 between study groups as regards duration of operation with shorter duration in group B.

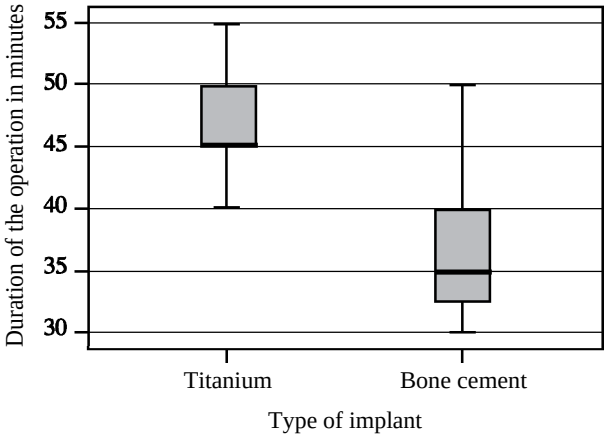

Fig. (4): Bar chart representing duration of operation in minutes in all study cases.

In group A, mean/SD of duration between craniectomy and cranioplasty is (44.80±58.767), while in group B, mean/SD of duration between craniectomy and cranioplasty is (23.27±40.019).

Table (10): Time interval between craniectomy and cranioplasty in both groups.

Group	Mean	Standard deviation	p-value
Group A	44.80	58.767	0.252
Group B	23.27	40.019	

There was statistically insignificant difference with p-value 0.252 between study groups as regards Time interval between craniectomy and cranioplasty.

Discussion

Cranioplasty is a reconstructive procedure used to restore skull anatomy and repair skull defects. Optimal skull reconstruction is a challenge for neurosurgeons, and the strategy used to achieve the best result remains a topic of debate.

In this study, cranioplasty was mainly aimed to restore cosmetic appearance and cerebral protection. So, our aim here is to describe two different procedures of reconstruction of calvarial skull defects by using titanium mesh versus hand-made bone cement implants and to compare outcomes of them.

Regarding the gender of patients included in this study, 20 of our patients (66.7%) were males and the remaining 10 patients (33.3%) were females. The

male prevalence had also been noted in the study done by Staffa et al., with predominance of men with a percentage of 64.4%. And a study by Honeybul et al., which included 45 male patients (64.2%) of total 70 patients. This predominance may be explained by high percentage of traumatic etiology in our study which accounts for (70%) of cranial defects in this study that goes with the above-mentioned study by Staffa et al., Traumatic causes were either due to fight or road traffic accident that are mostly related to males more than females.

In our study, other causes that led to removal of skull bones resulting in cranial defects include neoplasms in 8 patients (26.7%) and acute subdural hematoma in one patient (3.3%).

This disagrees with a study by Jonkergouw et al., who showed that the most common indication for the primary craniectomy was stroke (39%), followed by trauma (34%), tumor resection (21%) and infection (5%). Also, there is Andrea Mareira et al., who listed post-tumor resection to be the most common cause of the defect.

In the present study, we found that the most common site of cranial defects was the frontal region (43.3%), followed by the parietal region (40.0%), fronto-parietal defects (13.3%) and occipital region (3.3%). This agrees with the findings made by Andrea Mareira et al., (53.2% of total cases) and Alexander VanGool et al., (46.7% of total cases) who found that the most common site was the frontal region. Moreira-Gonzalez et al., also found that the main site of cranioplasty in his study was the frontal region in (53.2%) of cases.

As regards the Duration between craniectomy and cranioplasty operation, patients in group A of this study had mean duration of 44.8 months, while in group B, the mean duration was 23.27 months, with no statistically significant difference (with *p*-value >0.05). Jonkergouw et al., demonstrated that delayed cranioplasty tends to predispose to an increased risk of complications in comparison to immediate cranioplasty. One explanation could point towards the more difficult tissue dissection due to the formation of adhesions between the dura and subcutaneous tissues.

In another study reported by Rish et al., cranioplasties taking place 1-6 months after craniectomy had the highest complication rate (7.9%) and those performed 12-18 months after craniectomy had the lowest complication rate (4.5%). The purported advantage of this waiting period includes avoidance of operating on a potentially contaminated wound.

Regarding duration of operation, we found statistically significant difference (with *p*-value <0.05) between both groups, with shorter duration among group operated with hand-made bone cement (mean 36.13 minutes) than Titanium mesh (mean 46.67 minutes). Short operation time saves effort, cost and decrease incidence of infection.

Because of having a shorter operative time, bone cement cranioplasty is more suitable for patients with high-risk anaesthesia than titanium mesh cranioplasty.

In this study, we reported the patient's complications at time of hospital stay "average three days". In our study 1 patient in group A (6.7%) developed subgaleal collection. Two patients in group B (13.33%) developed subgaleal and epidural collections. This revealed that there is no statistically significant difference between both groups (with *p*-value >0.05).

We also assessed patients of both groups to record late complications. In group A, which was operated using Titanium Mesh implants, we noticed that those 2 cases (13.3%) developed implant exposure both had been removed, 1 case (6.7%) developed infection which needed implant removal after failure of conservative management. In another study by Victor Chang et al., involving 212 cases with different methods of cranioplasty, mostly used method was autologous bone graft over a period of 13 years, infection was reported in 7 cases (18.9%) out of a total of 37 patients, had repaired by titanium mesh.

That disagrees with the complications encountered in our study 4 cases (26.7%) out of 15. However, infection occurred only in 1 case (6.7%) and that agrees with the same study regarding percentage of infected cases only.

In group B, 1 patient developed exposure of the implant which needed to be removed, 3 patients (20%) developed infections in all of them conservative management failed, and implants needed to be removed. Moreira-Gonzalez et al., reported 7 cases of infections (9.3%) out of total 75 patients operated with bone cement flap, and they only had a lower infection rate in comparison to our results.

Regarding exposure of titanium mesh cases, one of them occurred 4 months postoperative and the second occurred 6 months postoperative and both were removed immediately after exposure while the bone cement exposed case occurred 5 months postoperative and removed immediately after exposure.

Regarding the onset of infection in bone cement cases, they occurred 3,4,6 months postoperative respectively and removal was done 10 days after failure of conservative management while the only case of titanium infection occurred 5 months postoperative and removed 10 days after failure of conservative management.

Cranioplasty aims mainly to restore the cosmetic appearance and provide cerebral protection. To be

completely successful cosmetically, the cranioplasty material must be unnoticed, even on close inspection. A minor degree of temporal hollowing was deemed allowable, as this is really a consequence of the initial decompression rather than the restorative material. In addition, there are elements of cosmetic outcome that are unrelated to the cranioplasty material, such as skin thickness, hair length and density, and the position of the skull defect.

In this study, we found that there is statistically insignificant difference (with *p*-value more than 0.05) between both study groups as regards cosmetic outcome, Analysis of the results showed that group B has slightly better cosmetic outcome.

In group A, 8 patients (53.3%) showed excellent outcome (accepted cosmetic appearance even in close inspection), 4 patients (26.7%) showed good outcome (minor cosmetic failure only noted on closer inspection) and 3 patients (20%) showed fair outcome.

While in group B, 10 cases (66.7%) showed excellent outcome, 3 cases (20%) showed good outcome and 2 cases (13.3) showed fair outcome.

All cases in this study showed either excellent, good or fair results with absence of complete cosmetic failure that need mandatory revision.

In our study, there was statistically significant difference with *p*-value <0.01 between study groups as regards duration of operation with shorter duration among group B.

Conclusion:

Most cranial defects are acquired because of trauma. Repair of skull defects with either titanium mesh or Methylmethacrylate cranioplasty is relatively safe, provides an acceptable cosmetic reconstructive option and contributes to neurological improvement in treatment of cranial defects.

As regards cosmetic outcome, there is statistically insignificant difference between both study groups and analysis of results showed that bone cement had slightly better cosmetic outcome.

As regards duration of surgery, there is statistically significant difference between both study groups and analysis of results showed that bone cement cranioplasty had shorter operative period.

As regards complication rate, there is statistically insignificant difference between both study groups and analysis of results showed that bone cement had higher rate of post-operative infection.

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دراسة مقارنة بين استخدام شبكة التيتانيوم والاسمنت العظمى المشكل يدوياً فى استعادة تكوين الجمجمة

لقد قمنا فى هذه الدراسة باستعراض تشريح عظام الجمجمة، واسباب عيوب الجمجمة والدواعي والموانع لإصلاح هذه العيوب كما تم مقارنة خصائص العديد من المواد التى تستخدم فى عمليات تجميل عظام الجمجمة والخصائص المثالية للمادة المستخدمة فى هذه العمليات بشكل عام.

وقد اجريت الدراسة على ثلاثين مريضاً يعانون من عيوب بعظام الجمجمة لأسباب مختلفة مثل اصابات الرأس واستئصال اورام الجمجمة وقد اجريت الجراحة لهذه الحالات باستخدام شبكة التيتانيوم فى ١٥ حالة والاسمنت العظمى المشكل يدوياً فى ١٥ حالة اخرى. وبعد مقارنة نتائج كلا من المادتين وجدنا ان هناك نتائج ذات دلالة احصائية مثل مدة العملية الجراحية (حيث وجد ان الاسمنت العظمى اقل فى مدة الجراحة)٠ كما اظهرت الدراسة نتائج اخرى حيث اتضح ان الاسمنت العظمى يبدو متناسقاً أكثر من الناحية التجميلية، ولكنه ذو معدل اعلى من شبكة التيتانيوم فى حدوث عدوى ما بعد الجراحة.