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Cranioplasty of Calvarial Skull Defects: A Comparative Study between Using Three Dimensional Custom-Made Cranioprostheses versus Hand-Made Bone Cement in Restoring Skull Configuration

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Abstract

Introduction: Cranioplasty is the surgical repair of a bony defect or deformity in the skull that is caused after cranial surgery or trauma. It carries cosmetic and protective benefits. Many types of materials are allowed. The subject of this study is to compare the outcome of two different manufacturing processes in reconstruction of calvarial skull defects by using 3D custom-made cranioprostheses versus hand-made bone cement implants. **Patient and Methods:** This is a prospective comparative study conducted on 20 patients of calvarial skull defects of different etiologies, sites and sizes, admitted in the neurosurgical departments of Cairo and Fayoum Universities in the period from August 2017 to February 2018. Patients are divided into two study groups: (group 1) 10 patients operated upon by 3D custom-made implant; (group 2) operated upon by hand-made bone cement implant. Statistical Analysis Used: Mann-Whitney test and Chi-square test. **Results:** Craniotomy using 3D custom-made implants gives better results than using bone cement in the functional restoration of skull shape and cranial protection with shorter operative time and less rate of postoperative complications. There is no statistically significant difference between the two study groups regarding cosmetic outcome. **Conclusion:** 3D custom-made implant is recommended for large and complex skull defects. Further and large studies might be needed.

Keywords

Cranioplasty, Custom-Made Implant, Bone Cement

1. 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 [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 it aspires to neurologic recovery and relief of symptoms due to craniotomy defect such as described in syndrome of the trephined [3].

The material most commonly 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, or may be due to post-traumatic fragmented bone defect. When this occurs, the original bone flap often has to 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 dilatability with heat, low cost and ready to use. There are also many techniques that have been described to achieve the best result after cranioplasty procedures [5].

The aim of this study is to compare two different manufacturing processes in reconstruction of calvarial skull defects, using custom-made 3D designed cranioprostheses versus hand-made bone cement implants, and to compare outcomes of them.

2. Patients and Methods

This is a prospective comparative study on twenty patients with calvarial skull defects of different etiologies, sites and sizes. Patients have been admitted and operated in neurosurgery departments of Cairo and Fayoum University hospitals in the period from August 2017 to February 2018.

This study included all patients with residual calvarial skull defects which needed cranial reconstruction and Patients of both genders and all age groups above 10 years old. We excluded 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 and Patients under age 10 years old.

Complete medical history was carefully assessed with special attention to the

following items; age, sex, history of head trauma, time of craniotomy in primary operation, history of previous cranioplasty operation and history of chronic illnesses. In this study we examined the defect to determine site, size and shape of the defect and to detect any signs of inflammations, erosions or pigmentation in the overlying skin .It also includes examination of brain pulsations (if they are seen by inspection and felt by palpation, felt by palpation only or couldn't be seen or felt). Also assessment of scar of primary operation; its length, shape and healing was accomplished.

Preoperative CT scans with bone window & 3D reconstruction have been done for all the patients to demonstrate the defect and to detect any underlying brain pathology. But in group 1, in which we used 3D custom made implant, special characters of preoperative CT scan had to be included. Thickness between axial cuts should be less than 0.5 mm, Patient should be well centralized, Imaging should include all skull dimensions from vertex to mandible.

Preparation of prefabricated 3D custom-made implant

To produce the custom-made cranioplasty implants, a spiral CT scan of the head was performed as the first step with special characters as mentioned before. A virtual 3D model of the skull was obtained using a 3D reconstruction program (Materialize Mimics version 21) then a cranioplasty implant was designed using mirror image from other side as a guide for the reconstruction with another software (Materialise 3 matic version 11). By using selective laser sintering (Sinter Station 2000, 3D System, Darmstadt, Germany) the virtual models (of the calvarial defect and the custom-made implant) were transformed into physical models.

The designed implant was well suited for the defect, which was not needed for further manual processing. Polyamide (PA-2200) material, which is a fine white powder, has been used as the reconstruction material. On the surface of implants, there are many holes to prevent development of an epidural hematoma and to facilitate easy fixation of implants. They were sterilized by using autoclave due to their thermal stability.

Surgical technique

All the patients were operated upon under general anesthesia; the head was positioned according to the site of the defect and with the plane of the defect parallel to the horizontal. On the operating table, the head was supported on a head ring. At induction of anesthesia, a single dose of a broad-spectrum antibiotic agent was given to all patients intravenously. The patient's hair was removed with a margin of at least 3 cm from the incision line using a propriety hair shaver.

Scalp incision was designed over the previous scar if it is sufficient for exposure of all margins of the defect with or without minimal extension of the wound, and it should be behind the hair line to minimize cosmetic disfigurement of patients. In case of frontal defects (anterior to the hair line) a bi-coronal (Sutar) scalp incision has been done. Skin incision was designed with a broad flap base to accommodate the vascular supply to the area of skin within the flap.

Proper sterilization of the wound using povidone iodine was done. Intradermal injection of adrenaline 1:200,000 with 10 ml of 0.5% Xylocaine was administered all over the planned skin incision to induce vasoconstriction and minimize bleeding from the skin.

The wound was then opened using a scalpel and sharp dissection of pericranium and adhesions was done, surgical gauze was placed along all sides of the incision. In temporal defects, once the scalp flap was reflected, the temporalis muscle was usually dissected from the dura and reflected laterally. The defect margins were then fully exposed, then trial of fine dissection of underlying adherent dura from the bony margin was done with great care not to do dura tear to avoid CSF leak complications.

In group 1: Patients with 3D Custom-made prosthesis: We performed 4 - 5 holes around defect margins, 1 cm away from the edge with a diameter of 1 mm for the hole using surgical drill, with careful protection of dura and brain tissue by applying spatula undersurface of defect margin.

Sterilized prefabricated custom-made implants were applied. The implant was fixed with silk or prolene sutures to holes in bony margins of the defect to provide more stability. The designed implant was well suited for the defect, which was not needed for further manual processing (**Figure 1**).

In group 2: Patients with hand-made bone cement flaps: A pre-polymerized powder of antibiotic-impregnated methyl methacrylate will be hand-mixed with the liquid monomer intraoperative, with a liquid to powder ratio: 0.5 mL/gm.

A piece of prolene mesh was placed over the dura before placing the methyl methacrylate and molding it to fit with the defect. It was continuously irrigated with cold saline to protect the brain from the excess heat produced. Then the graft was fixed in place using non-absorbable monofilaments sutures. In temporal defects, fixation was reinforced with overlying temporalis muscle (**Figure 2**).

Subgaleal drain was positioned in large wounds. The wound was closed in a layer with 2-0 Vicryl sutures for subcutaneous tissues and 2-0 prolene sutures for skin closure.

Drains were removed after 24 - 48 hours postoperative.An intravenous antibiotic course continued for 3 days, and then patient continued for about 7 days after discharge on oral antibiotic till removal of sutures. Routine postoperative dressings were changed every 48 hours, and the sutures were removed 10 - 14 days after the operation.

Post-operative imaging by CT brain on the 2nd day postoperative to assess any early complications in form of epidural or subgaleal collection. Patients were discharged after stabilization of their condition with regular follow up in outpatient clinic CT brain was done after 7 - 10 days of discharge and after 3 months later or if patient developed any complications.

Cosmetic and functional outcomes were assessed according to Honeybul *et al.* [4] (**Table 1**, **Table 2**).

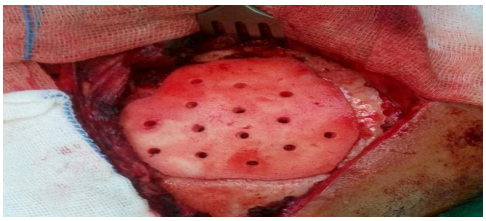

Figure 1. Intraoperative image of outer surface of the prosthesis after implantation and how it perfectly fits to the skull defect.

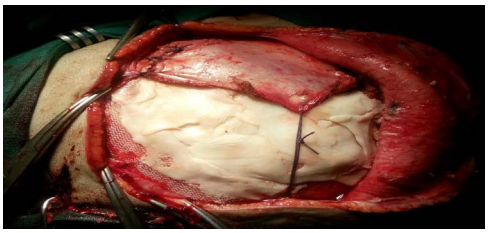

Figure 2. An intraoperative image following resection of frontal meningioma eroding overlying bone, the defect operated upon by cranioplasty using bone cement flap over a prolene mesh.

Table 1. Assessment of cosmetic appearance [4].

Assessment	Clinical	Patient
Complete success	Acceptable cosmetic appearance even on close inspection (minor temporal hollowing allowed)	Satisfied with appearance (minor temporal hollowing allowed)
Partial success	Minor cosmetic failure only noted on closer inspection	Minor cosmetic problem only noted on close inspection
Satisfactory	Satisfied but cosmetically noticeable	Satisfied with appearance but not ideal
Partial failure	Cosmetically poor result; may need revision but could be left	Unhappy with appearance; may want revision but possibly could be left
Complete failure	Cosmetically poor results & requires revision	Unhappy with appearance & definitely wants revision

Table 2. Functional assessment [4].

Assessment	Clinical	Patient
Complete success	Complete restoration of cranial coverage on clinical palpation	Completely satisfied with coverage on clinical palpation
Partial success	Minor defects only noticed on clinical palpation; not clinically significant	Minor defects only noticed on clinical palpation
Satisfactory	Satisfactory coverage but not ideal	Satisfied with coverage but not ideal
Partial failure	Failure to restore coverage; may need revision but could be left	Unhappy with coverage; patient may want revision but possibly could be left
Complete failure	Failure to restore coverage & definitely need revision	Unhappy with coverage & definitely patient wants revision

In the postoperative period complications assessed if present such as; Epidural, subdural and subgaleal collections, CSF leak Seizures, Late infection and Extrusion and migration of the implant.

Statistical Analysis:

Data were collected and coded to facilitate data manipulation and double entered into Microsoft Access and data analysis was performed using Statistical Package of Social Science (SPSS) software version 18 in windows 7. Simple descriptive analysis in the form of numbers and percentages for qualitative data, and arithmetic means as central tendency measurement, standard deviations as measure of dispersion for quantitative parametric data. Quantitative data included in the study was first tested for normality by One-Sample Kolmogorov-Smirnov test in each study group then inferential statistic tests were selected. For quantitative non-parametric data: Mann-Whitney test in comparing two independent groups and For qualitative data: Chi square test to compare two of more than two qualitative groups. The P-value ≤ 0.05 was considered the cut-off value for significance.

3. Results

On comparing the demographics between the study groups we found that the mean age among group 1 ranged between 12 and 49 years with mean/SD (25.7 ± 12.9). The mean age among group 2 ranged between 11 and 50 years with mean/SD (26.8 ± 14.8). There is no statistically significant difference with p-value > 0.05 as regards age, which indicated proper matching between both procedures.

As regarding sex, Group 1 has 10 males with no females while group 2 included 4 males and 6 females. There is statistically significant difference with p-value < 0.05 between study groups as regards sex distribution with high percentage of males among group 1 (Table 3).

In group 1, size of defects (in cm^2) showed mean/SD (20.4 ± 18.6) while in group 2, it showed mean/SD (31.6 ± 29.4). There is no statistically significant difference with p-value > 0.05 between study groups as regards skull defects size which indicated proper matching between both procedures.

Table 3. Demographics of both study groups.

Variables	Group 1 Custom-made Implant (n = 10)		Group 2 Bone cement (n = 10)		p-value	Sig.
Age (years)						
Mean /SD	25.7	12.9	26.8	14.8	0.9	NS
Sex						
Male	10	100%	4	40%	0.01	S
Female	0	0%	6	60%		

*S: significant, *NS: Non significant.

Group 1 included 3 patients (30%) with frontal defects, 2 patients (20%) with parietal defects, 4 patients (40%) with temporal defects and 1 patient (10%) with occipital defect. Group 2 included 2 patients (20%) with frontal defects, 5 patients (50%) with parietal defects, 1 patient (10%) with temporal defects and 2 patients (30%) with occipital defect. There is no statistically significant difference with p-value > 0.05 between study groups as regards skull defects sites which indicated proper matching between both procedures.

Regarding causes of skull defects we found that in group 1, 8 patients (80%) with traumatic cause, one patient (10%) with defect due to skull bone osteomyelitis followed an intracerebral abscess and one patient (10%) with defect post decompressive craniectomy for management of massive cerebral infarction. Group 2 included 4 patients (40%) with traumatic cause, 6 patients (60%) with defects due to neoplastic causes 5 of them were meningiomas invading overlying bones and 1 case was osteoma. There is statistically significant difference with p-value < 0.05 between study groups as regards skull defects etiologies with high percentage of trauma etiology among group PA-2200 and neoplastic etiology among group of bone cement.

In group 1, mean/SD of duration of operation is 72.5 ± 16.8, while in group 2, mean/SD of duration of operation is 101 ± 17.1. There is statistically significant difference with p-value < 0.05 between study groups as regards duration of operation with shorter duration among group 1.

In group 1: according to doctor assessment, there are 6 patients (60%) with complete success, 3 patients (30%) with partial success and only one patient (10%) with satisfactory result. In group 2: according to doctor assessment, there are 3 patients (30%) with complete success, 5 patients (50%) with partial success and 2 patients (20%) with satisfactory result. In group 1: according to patient assessment, there are 4 patients (40%) with complete success, 5 patients (50%) with partial success and only one patient (10%) with satisfactory result. In group 2: according to patient assessment, there is one patient (10%) with complete success, 6 patients (60%) with partial success and 3 patients (30%) with satisfactory result.

There is no statistically significant difference with p-value > 0.05 between study groups as regards cosmetic assessment by doctor and patients which indicated that both procedures had the same cosmetic outcome (**Table 4**).

In group 1: according to doctor assessment, there are 6 patients (60%) with complete success and 4 patients (40%) with partial success. In group 2: according to doctor assessment, there are 5 patients (50%) with partial success, 4 patients (40%) with satisfactory result and one patient with partial failure. In group 1: according to patient assessment, there are 2 patients (20%) with complete success, 7 patients (70%) with partial success and only one patient (10%) with satisfactory result. In group 2: according to patient assessment, there are 3 patients (30%) with partial success, 6 patients (60%) with satisfactory result and one patient with partial failure.

Table 4. Cosmetic outcome in both study groups.

Variables	Group 1 Custom-made (n = 10)		Group 2 Bone cement (n = 10)		p-value	Sig.
	No.	%	No.	%		
Doctor cosmetic assessment						
Satisfactory	1	10%	2	20%	0.4	NS
Partial success	3	30%	5	50%		
Complete success	6	60%	3	30%		
Patient cosmetic assessment						
Patient cosmetic assessment						
Satisfactory	1	10%	6	60%	0.2	**NS**
Partial success	5	50%	3	30%		
Complete success	4	40%	1	10%		

Statistically significant difference (p-value < 0.05) was noted between the two groups as regards functional assessment by doctor and patients with higher percentage of success among group 1, which indicates that cranioplasty using 3D custom-made implant provides better functional outcome (Table 5).

According to group 1, 2 patients (20%) had subgaleal collection and one patient (10%) had epidural & subgaleal collections. According to group 2, 3 patients (30%) had subgaleal collection, one patient (10%) with early postoperative infection (within 1st week) and one patient (10%) with epidural & subgaleal collection. There is no statistically significant difference with p-value > 0.05 between study groups as regards early complications, which indicates that both procedures had the same percentage of early complications.

According to group 1, no one had reported any complications through the follow up period (3 - 6 months). According to group 2, one patient (10%) had subgaleal collection & late infection but infection subsided on medical treatment, one patient (10%) with late infection & patient needed flap removal, one patient (10%) with late infection which led to hydrocephalus & patient needed flap removal and two patients (20%) with late infection led to flap exposure& patients needed flap removal. Statistically significant difference (p-value < 0.05) was noted between the two groups as regards late complication with no complication among group of custom-made implants which indicated this procedure had better results.

4. Discussion

Cranioplasty is a reconstructive procedure used to repair skull defects and restore skull anatomy. It is a challenge for neurosurgeons to perform optimal skull reconstruction, and the achievement of the best result remains a topic of debate [1].

Table 5. Functional outcome in our study groups.

Variables	Group 1 Custom-made (n = 10)		Group 2 Bone cement (n = 10)		p-value	Sig.
	No.	%	No.	%		
Function assessment by doctor						
Partial failure	0	0%	1	10%	0.01	S
Satisfactory	0	0%	4	40%		
Partial success	4	40%	5	50%		
Complete success	6	60%	0	0%		
Function assessment by patient						
Partial failure	0	0%	1	10%	0.04	**S**
Satisfactory	1	10%	6	60%		
Partial success	7	70%	3	30%		
Complete success	2	20%	0	0%		

In this study, cranioplasty was mainly aimed to restore cosmetic appearance and to provide well cerebral protection and functions. So, our aim here is to describe two different manufacturing processes in reconstruction of calvarial skull defects by using custom-made 3D designed cranioprostheses versus hand-made bone cement implants and to compare outcomes of them.

Regarding sex of patients, 14 of our patients (70%) were males and the remaining six patients (40%) were females. The male prevalence had also been noted in the study done by Staffa *et al.* [6] with predominance of men with a percentage equals (64. 4%). And also a study by Honeybul *et al.* [4] which included 45 male patients (64.2%) of total 70 patients while the remaining (35.8%) were females. This predominance may be explained by high percentage of traumatic etiology in our study which accounts for (60%) of cranial defects in our study that goes with the above mentioned study by Staffa *et al.* [6] Traumatic causes were either due to fight or road traffic accident that mostly related to males more than females.

In our study, other causes that lead to removal of skull bones resulting in cranial defects include 6 patients (30%) with neoplasms, one patient (5%) with cerebral abscess with overlying bone osteomyelitis and one patient (5%) with massive cerebral infarction.

This disagrees with a study by Jonkergouw *et al.* [7] 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.* (84) 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 parietal region (35%), followed by the frontal region (25%), temporal re-

gion (25%) and occipital region (15%). This disagrees with the findings made by Andrea Mareira *et al.* [8] (53.2% of total cases) and Alexander Van Gool *et al.* [9] (46.7% of total cases) who found that the most common site was the frontal region. Moreira-Gonzalez *et al.* [8] who also found that the main site of cranioplasy in his study was the frontal region in (53.2%) of cases, followed by temporal region in (23.4%). While, the parietal and mastoid regions, when combined, made up (23.4%) of the reconstructed sites

The main preoperative imaging done for all patients in our study was CT scan with bone window and 3D reconstruction to show the defect and help in preoperative manufacture of the custom-made implant. This radiological investigation had been used in a previous mentioned study by Staffa *et al.* [6] which used it for preparation and production of custom made devices in synthetic porous hydroxy-apatite (HA) from processing of CT images.

Three-dimensional reconstruction of computer tomography images was first described in the mid-1980s, with various groups describing its utility in preoperative planning for craniofacial surgery using prefabricated flaps [10].

As regards the Duration between craniectomy and cranioplasty operations, our study groups showed that in group 1, mean duration was 16.9 months. While in group 2, mean duration was 24.2 months, with no statistically significant difference (with p-value > 0.05).

Jonkergouw *et al.* [7] 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.* [11] in 1979, 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 assumed 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 3D custom-made cranioprostheses (mean 72 min) than hand-made bone cement implant (mean 101 min). As it is well prepared preoperatively which saved more time, also it had multiple holes to prevent epidural collection and to facilitate easy and perfect flap fixation. This comes in agreement with Staffa *et al.* [6] who confirmed that the mean time in the operating theatre was reduced from around 150 min with implants produced in the operating theatre to 90 min with the pre-manufactured hydroxyapatite prosthesis. Short operation time saves efforts, costs and decrease incidence of infection.

In our study, we assessed the patients to record early complications within 1st 3 weeks postoperative between both groups. In our study, 3 patients in group 1 (30%) developed subgaleal and epidural collections. Five patients in group 2 (50%) developed subgaleal and epidural collections and one of them (5%) had

immediate postoperative infection. 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 1, which was operated with 3D custom-made implants, we didn't notice any late complications postoperatively and through time of follow up. That goes in agreement with Rotaru *et al.* [12] who analyzed custom-made implants on 10 patients and found that during the recovery period, there were no signs of infection, plate rejection or wound dehiscence in any case.

In group 2, 5 out of 10 patients operated with bone cement flap, developed late infections despite all infection control precautions we had taken. Four of them (40%) needed another operation for flap removal. Which disagrees with a low rate of infection in study reported by Moreira-Gonzalez *et al.* [8] who noticed 7 cases of infections (9.3%) out of total 75 patients operated with bone cement flap. This revealed that there is statistically significant difference (with p-value < 0.05) between both study groups as regards late complications. So that, the low incidence of infection with custom made implants gives them a high priority on choosing the proper procedure preoperatively.

As we mentioned above, cranioplasty aims mainly to restore the cosmetic appearance and to provide well cerebral protection and functions. To be completely successful cosmetically, the cranioplasty material has to 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 [4].

In this study, we found that there is no statistically significant difference (with p-value > 0.05) between both study groups as regards cosmetic assessment by doctor and patients which indicated that both procedures had nearly the same cosmetic outcome.

In group 1, 6 patients (60%) showed complete success (accepted cosmetic appearance even in close inspection) and 3 patients (30% (showed partial success (minor cosmetic failure only noted on closer inspection) according to the doctors' opinion. While in group 2, which operated with hand-made bone cement flaps, doctors noticed only 3 patients (30%) with complete success and 5 patients (50%) with partial success. All cases in this study showed either complete, partial orsatis factory results with absence of complete cosmetic failure that need mandatory revision.

This goes in agreement with Honeybul *et al.* [4] who compared autologous cranioplasty with custom-made implants cranioplasty and showed that (78%) of patients in custom-made implants group had complete success while (34%) of patients in autologous cranioplasty group had complete success with absence of a partial or complete cranioplasty failure at 12 months of follow-up.

According to functional assessment of implants, cranial coverage must be complete, with no defects felt on clinical palpation. In this study, cranioplasty

with custom-made implants showed (60%) complete success (Complete restoration of cranial coverage on clinical palpation) and (40%) partial success (Minor defects only noticed on clinical palpation; not clinically significant). While in cranioplasty with bone cement flaps, it showed (50%) partial success, (40%) satisfactory results (Satisfactory coverage but not ideal) and (10%) partial failure (Failure to restore coverage which may needs revision but could be left).

A statistically significant difference (p-value < 0.05) was noted between both study groups as regards functional assessment of implants by doctor and patients with higher percentage of success among group 1using custom-made implants. This difference between both procedures is due to the accurate nature of the computer aided custom-made implant that perfectly fits the original defect and preserves good skull symmetry. This comes in agreement with Rotaru *et al.* [12] who noticed that the 3Dreconstructed CT examination in his study showed that symmetry was achieved in all 10 cases and there were no secondary effects on the cerebral mass or soft tissues.

5. Conclusion

Cranioplasty using prefabricated 3D custom-made implants gives better results than using bone cement in the reconstruction of calvarial skull defects despite their different etiologies. Prefabricated 3D custom-made implants provide shorter operative time and less rate of complication than bone cement flaps. There is a statistically significant difference in functional restoration of the skull shape and cranial protection with better outcome after using 3D custom-made implants. So the procedure is recommended for repairing large and complex-shaped cranial defects. While there is no statistically significant difference between our study groups regarding cosmetic outcome.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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