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Original Article

Three dimensional custom-made PEEK cranioplasty

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ABSTRACT

Background: An optimal reconstruction of calvarial skull defects is a challenge for neurosurgeons, and the strategy used to achieve the best result remains debatable. Therefore, we conducted this study to compare the esthetic and functional outcome of custom-made three-dimensional (3D) cranioprostheses to handmade bone cement in reconstructing calvarial skull defects.

Methods: We included 66 patients above 10 years of age with calvarial skull defects and undergoing reconstruction: 33 were enrolled in the custom-made 3D implants group and 33 in the handmade implants group in the period from August 2017 to December 2020 in the neurosurgery department of Fayoum University Hospital.

Results: Complete success of the esthetic end-point was insignificantly higher in the custom-made 3D prostheses group based on the doctor's and patients' assessment (60.6% vs. 42.4%; 33.3% vs. 9.1%, $P > 0.05$), respectively. Complete success of the functional end-point was significantly higher in the custom-made 3D group compared to the handmade cement bone group according to the doctor's and patients' assessment (60.6% vs. 0%; 21.2% vs. 0%, $P < 0.05$). There were no late complications noted in the custom-made 3D prosthesis group, whereas 50% of the handmade bone group had late complications ($P < 0.05$). Full improvement of the symptoms of the "syndrome of trephined" was achieved in the 3D custom-made group compared to the handmade bone cement group (20% vs. 0%).

Conclusion: Cranioplasty using three dimensional customs made PEEK prosthesis is a reliable method which saves operative time, lowers cost and provides less complications if compared with other cranioplasty techniques. Custom-made 3D cranioprostheses are better than handmade bone cement in reconstructing calvarial defects in terms of esthetic and functional outcome as well as complications.

Keywords: Bone cement, Cranioplasty, Custom-made, Implant

INTRODUCTION

Reconstruction of calvarial skull defects remains a particular challenge to the craniofacial surgeons and neurosurgeons.[12] The most common causes leading to such defects include depressed fractures of the skull bone, decompressive craniectomies, tumor infiltration of calvarial bones, congenital deformities, and inflammatory lesions.[3-5] It may also occur due to bone flap loss as a consequence from infection.[13] Besides the cosmetic appearance due to soft tissue and skeletal structures involvement, such defects would expose a significant area of the brain.[6] Most of the scientific contribution found in the literature focuses mainly on bone replacement involving the whole cranial thickness to correct most of these defects.

However, only a limited number of studies reported the use of materials for calvarial reshaping.[12]

Cranioplasty is a procedure performed primarily to improve the symmetry and/or shape of the head. It involves resection, remolding, and movement of the bones of the head.[20] Patients with calvarial defects usually complain from headache, dizziness, irritability, loss of concentration, depression, anxiety, intolerance to noise, and motor weakness. This status is usually known as "syndrome of the trephined."[10] Therefore, it is essential to reconstruct calvarium contour like a closed safe to keep brain protected from surrounding environmental hazardous factors.

The goal of cranioplasty is to restore normal morphology through obtaining a stable, permanent, non-injurious results with both satisfactory esthetic outcome and sufficient mechanical/functional outcome to ensure adequate protection of the endo-cranial structures.[12] Selection of the cranioprosthesis or the implant material used for reconstruction remain controversial.[16] Despite the lack of consensus in the literature on the ideal material for such reconstructive surgery, autogenous bone usage has been considered the standard among various other materials,[11] and neurosurgeons have traditionally chosen bone as the most natural substrate.[19]

Being genetically identical with less susceptibility to infection, bone grafts are usually preferred. Moreover, these grafts are non-foreign bodies with easy accessibility to contour and also have fewer later complications.[2] That being said, autogenous bone usage has its own drawbacks, some of which are that the harvesting procedure prolongs the operative time and requires time to heal and more importantly is that there is a limited supply of bone available for autografts.[14] Therefore, various alloplastic materials have been used in craniofacial reconstructions.[9,14]

Polymethylmethacrylate (PMMA) is the most commonly recognized materials, being cheaper and easier as well as easy to use. Most alloplastic cranioplasties are performed by this material.[14,18] PMMA is popular due to the material strength and its unique restoration of the skull defects with no distortion.[8] Since there are only a limited number of reports on hand-made implants as well as custom-made three-dimensional (3D) cranioprostheses in reconstructing calvarial skull defects, we conducted this prospective comparative study in order to compare the aesthetic and functional outcome of both implants.

MATERIALS AND METHODS

We performed a prospective randomized comparative study in the period from August 2017 to December 2020 on 66 patients with calvarial skull defects of various etiologies, sites and sizes, who underwent calvarial reconstruction at the Neurosurgery department, Fayoum university hospital, Fayoum, Egypt. All patients above 10 years old with residual calvarial skull defects which required cranial reconstruction were asked to participate in our study. All patients who met the inclusion criteria and accepted to join the study were enrolled. A written consent was taken from each eligible patient before initiation of the study. Individuals with a history of graft failure or rejection or with a history of local infection, immune-compromised patients, patients undergoing radiotherapy or with residual disease of recipient site, or those under the age of 10 were excluded from the study. Recruited patients were divided into two groups based on the type of the manufacturing process in reconstructing the skull defect. Group 1 consisted of 33 patients who had undergone cranioplasty using 3D custom-made cranioprostheses which were manufactured before the surgery; however, Group 2 incorporated 33 patients on whom we used hand-made bone cement implant which was formed intraoperatively by the operating surgeon where PMMA was used as the reconstruction material. The research approval was obtained from the Institutional Review Board before conducting the study.

A complete medical history including age, gender, occupation, residence, etiology of the skull defect and duration of primary craniotomy operation was taken from each patient. History of past head trauma, seizures, progressive weakness or deterioration of consciousness, chronic illness, previous cranioplasty operation, was also taken from every participating patient.

The general condition of patients undergoing restoration of skull configuration was clinically assessed for surgical fitness through a full neurological as well as local examination. Local examination was held to estimate the size, site, and shape of the defect and to detect any signs of local inflammation, erosions or pigmentations in the overlying skin, in addition to examination of the scar of the primary operation; length, shape, and healing.

In our study, all patients underwent pre-operative CT brain with 3 dimensional skull reconstruction and bone window pre and post-operative. However, in Group 1, special care for small details in pre-operative CT scan had been considered: Well centralization of patients; Axial cuts thickness should be less than 0.5 mm; All skull dimensions should be included from the mandible up to the vertex. Furthermore, to prepare the 3D implant, a virtual 3D model of the skull was obtained using a 3D reconstruction program (Materialize Mimics Version 21) and then mirror image from the other side of skull was established for the implant to use it as a guide for the reconstruction with another software (Materialise 3-matic version 11). On using selective laser sintering (Sinter Station 2000, 3D system, Darmstadt, Germany) the virtual models (of the calvarial defects and the custom-

made implants) were transformed into physical models. All designed implants were well-suited for the defect and required no further manual processing. Polyamide (PA-2200) material was used as the reconstructing material. On the surface of all implants, they are many holes to prevent occurrence of epidural hematoma as well as to facilitate the fixation of these implants. All implants were sterilized using autoclave due to their thermal stability.

All patients were administered general anesthesia. A single dose broad-spectrum antibiotic was given intravenously at induction of anesthesia. Povidone Iodine was used for proper wound sterilization. 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. In case of frontal defects (anterior to the hair line), a bi-coronal (Sutar) scalp incision was performed, whereas in case of temporal defect, once the scalp flap was reflected, we used to dissect temporalis muscle from the pericranium and reflect it laterally.

In Group 1, four to five holes were made in the bone around the defect margins, 1 cm away from the edge with a diameter of 1 mm, to which the implant was fixed using silk or prolene sutures. In Group 2, a pre-polymerized powder of antibiotic-impregnated methyl methacrylate was hand-mixed with the liquid monomer intra-operative with a liquid to powder ratio of 0.5 mL/g. A piece of prolene mesh was placed over the dura before placing the implant. Simultaneously, it was irrigated with cold saline to protect the brain from over-heat. Then, the graft was fixed using non-absorbable monofilaments sutures. Subgaleal drain was positioned in large wounds. Drains were removed 24–48 h postoperatively, where intravenous antibiotic course was continued for 3 days and for 7 more days on oral antibiotic after discharge. Routine dressings were changed every 48 h and the sutures were removed 10–14 days after the operative. The patients were followed for 3 months after discharge. CT was performed on the 2nd post-operative day as well as 7–10 days after discharge and 3 months later to assess any complications. Acceptable cosmetic appearance after prosthesis insertion was considered as complete success, cosmetically. On the other hand, complete restoration of cranial coverage on clinical palpation was considered as complete success, functionally.

Statistical analysis

Data were collected, coded, and entered into Microsoft Access. Data analysis was performed using Statistical Package of Social Science -Version 18. The mean and standard deviation of assessed variable were presented. We expressed categorical variables in the form of percentages and numbers. Qualitative data were tested for normality using One-Sample Kolmogorov-Smirnov test. Mann-Whitney test was used to compare two independent groups and Chi square test (χ^2) was used to compare more than two groups. $P \leq 0.05$ was considered the cut-off point for statistical significance.

RESULTS

A total of 66 patients were included in the final analysis: 33 in Group 1 who had custom-made 3D cranioprostheses; 33 in Group 2 who had handmade implants. In Group 1, 24 patients were males while 9 were females with a mean age of 25.7 (12.9). However, in Group 2, 13 patients were males while 20 were females with a mean age of 26.8 (14.8). The patient characteristics are shown in [Table 1].

Regarding skull defect size (cm^2), Group 1 showed a mean size of 20.4 (18.6), while Group 2 showed a mean size of 31.6 (29.4). There is no statistically significant difference in skull defect size in both groups ($P > 0.05$). On comparing the various skull defect sites in both groups, there was no statistically significant difference as regards defect sites between both groups ($P > 0.05$). Group 1 consisted of 12 patients with frontal defects, seven with parietal defects, 12 with temporal defects, and two patient with occipital defect. On the other hand, Group 2 consisted of nine patients with frontal defect, 16 with parietal defects, five with temporal defects, and three patients with occipital defects.

Based on the etiological background of the skull defect, the analysis revealed a statistically significant difference between study groups as regards skull defect etiologies ($P = 0.02$). The most common etiology in Group 1 was trauma followed by neoplastic, post-decompressive craniotomy and bone osteomyelitis, respectively (69.7%, 18.2%, 9.1%, 3%). On the other hand, Neoplasm was the most common cause in Group 2 followed by trauma, respectively (48.5%, 39.4%). Various etiologies and their percentages in each group are presented in the [Table 2].

The duration (months) between craniectomy and cranioplasty differed insignificantly between both groups ($P > 0.05$): Group 1 had a mean duration of 16.9 (12.5), while Group 2 had a mean duration of 24.2 (23.3). Surprisingly, Group 2 had significantly higher mean duration (minutes)

Table 1: Comparison of age and sex in both study groups.

Variables	Group 1 Custom-made implant (*n*=33)		Group 2 Bone cement (*n*=33)		*P*-value	Sig.
Age (years)						
Mean/standard deviation	25.7	12.9	26.8	14.8	0.9	NS
Sex						
Male	24	72.7%	13	39.4%	**0.01**	S
Female	9	27.3%	**20**	**60.6%**		

*S: Significant

of cranioplasty operation compared to Group 1 (101 vs 72.5, $P = 0.01$).

The outcome of the cranio-prosthesis inserted was determined based on two factors: the cosmetic appearance and the functionality of the implant, based on the surgeon and patients' assessment. Based on the cosmetic outcome, in Group 1, complete success was achieved in 60.6% of patients according to doctor's assessment, while only 42.4% showed complete success according to patient's assessment. On the other hand, only 33.3% of patients in group 2 achieved complete success according to doctor's assessment while only 9.1% showed complete success according to the patient's assessment. There is no statistically significant difference ($P > 0.05$) between the study groups as regards cosmetic assessment from the doctor's as well as the patient's perspective [Table 3].

As regards functional outcome of the implant used, 60.6% of patients in Group 1 achieved complete functional success according to the doctor's assessment; however, according to patients' assessment, only 21.2% reached complete success. Noteworthy, none of the patients in Group 2 who underwent cranioplasty using the handmade bone cement achieved a complete functional success according to both the doctor's and patients' assessment. Surprisingly, the analysis revealed a statistically significant difference ($P < 0.05$) between both group according to both the doctor's and patients' assessment as regards the functional outcome of the implant, pointing that 3D custom-made implants provided much better functional outcome in these patients [Table 4].

Complications of cranioplasty were subdivided into early complications (within the 1st 3 days post-operative) and late complications (during the follow-up period from 3 to 6 months). Regarding early complications, two patients in Group 1 had sub-galeal collection while one patient had epidural and sub-galeal collections. On the other hand, three patients in Group 2 had sub-galeal collection, while only one patients had epidural and sub-galeal collection and one patient had early post-operative infection. Both groups revealed no significant difference ($P > 0.05$). In terms of long-term complications (late), Group 1 was free from any long-term complications, whereas, in Group 2, one patient had sub-galeal collection and late infection which subsided with medical treatment, one patient had late infection and needed flap removal, one patient presenting with late infection that led to hydrocephalus which required flap removal, and two patients presented with late infection which led

Table 2: Comparison of various skull defect etiologies in our study groups.

Variables	Custom-made (*n*=33)		Bone cement (*n*=33)		*P*-value	Sig.
	No.	%	No.	%		
Trauma	**23**	**69.7**	13	39.4	**0.02**	S
Bone osteomyelitis	1	3	1	3		
Post Decompressive craniectomy	3	9.1	3	9.1		
Neoplasm	6	18.2	**16**	**48.5**		

*Sig: Significance

Table 3: Comparison of the cosmetic outcome in our study groups.

Variables	Group 1 Custom-made (*n*=33)		Group 2 Bone cement (*n*=33)		*P*-value	Sig.
	No.	%	No.	%		
Doctor cosmetic assessment						
Satisfactory	3	9.1	6	18.2	0.4	NS
Partial success	10	30.3	16	48.5		
Complete success	20	60.6	11	33.3		
Patient cosmetic assessment						
Satisfactory	3	9.1	10	30.3	0.2	NS
Partial success	16	48.5	20	60.6		
Complete success	14	42.4	3	9.1		

*NS: Non-significant

Table 4: Comparison of the functional outcome in our study groups.

Variables	Group 1 Custom-made (*n*=33)		Group 2 Bone cement (*n*=33)		*P*-value	Sig.
	No.	%	No.	%		
Function assessment by doctor						
Partial failure	0	0	3	9.1	0.01	S
Satisfactory	0	0	13	39.4		
Partial success	13	39.4	17	51.5		
Complete success	20	60.6	0	0		
Function assessment by patient						
Partial failure	0	0	3	9.1	0.04	S
Satisfactory	3	9.1	20	60.6		
Partial success	23	69.7	10	30.3		
Complete success	7	21.2	0	0		

to flap exposure and undergone flap removal. The analysis revealed a statistically significant difference regarding late complications in the favor of the custom-made implant group which showed much reduction in the incidence of late complications [Table 5].

Many patients with skull defects complain of various symptoms known as "syndrome of the trephined" which consists of a range of poorly defined symptoms including headache, anxiety, depression, fatigue, lack of concentration, memory problems, and dizziness.[7] Before cranioplasty, seven patients in group 1 had syndrome of trephined symptoms-from which two patients showed full improvement after cranioplasty. On the other hand, five patients in Group 2 had syndrome of trephined symptoms before cranioplasty, however, none of them showed full improvement. The results showed no significant difference in terms of clinical assessment of syndrome of trephined symptoms between the study groups ($P > 0.05$) [Table 6].

Case presentation

This case presented with right temporal skull defect (6 × 3 cm) following compound depressed fracture which was operated upon 8 months earlier. Custom-made 3D implant was used to restore skull configuration. In the 12th day after discharge, the patient came for follow-up and reported satisfaction with the operation results [Figure 1].

DISCUSSION

Cranioplasty is a widely used procedure in the process of reconstructing skull configuration in cases of calvarial skull defects. Optimal reconstruction results remain a challenge for neurosurgeons, and the way to achieve the best results remains highly debatable.[1] The primary end-points of such procedure is to restore the esthetic appearance as well as to functionally protect the brain and correct intracranial ventricular collapse due to exposure to atmospheric pressure.[22] However, the appropriate timing of post-craniectomy cranioplasty is unknown.[17]

Our study population comprised of 37 male patients and 29 females. This has also been noted in Staffa *et al*. population where male patients accounted for more than 60% of their population.[23] The same pattern was also noted in Honeybul

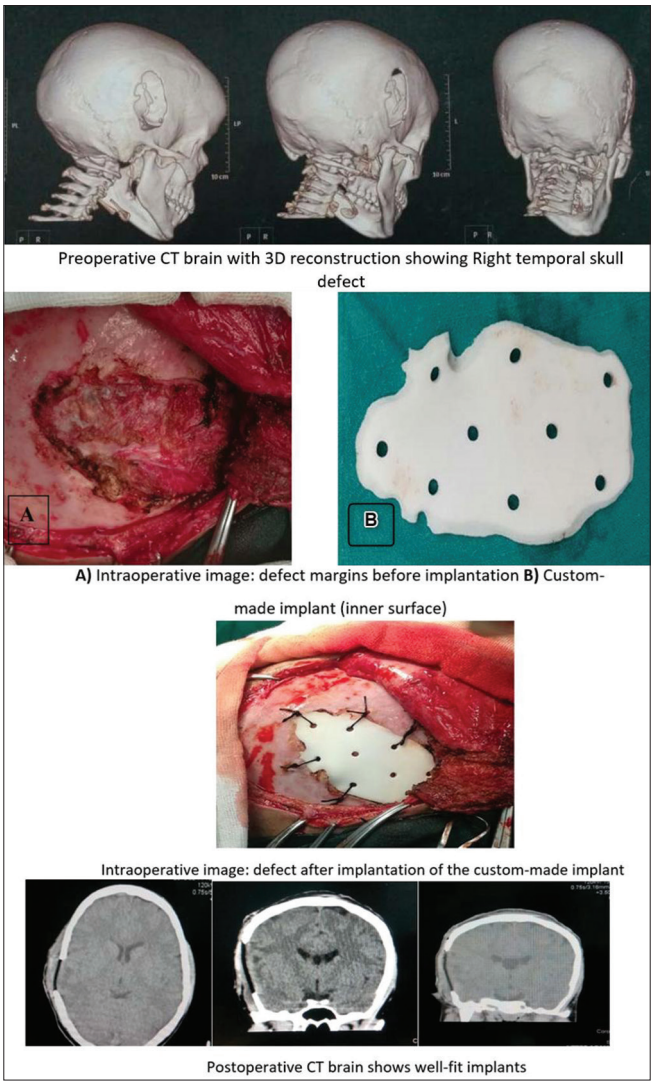

Figure 1: Pre-, intra-, and post-operative imaging of the three-dimensional custom-made implant.

Table 5: Comparison of late complications in both study groups.

Variables	Group 1 Custom-made (n=10)		Group 2 Bone cement (n=10)		P-value	Sig.
	No.	%	No.	%		
Late complications						
No late complications	10	100	5	50	**0.02**	**S**
Subgaleal collection and late infection with no need for flap removal	0	0	1	10		
Late infection and need flap removal	0	0	1	10		
Late infection, hydrocephalous and need flap removal	0	0	1	10		
Late infection, flap exposure and need flap removal	0	0	2	20		

Table 6: Comparisons of syndrome of trephined symptoms before and after operation in our study groups.

Variables	Custom-made (*n*=10)		Bone cement (*n*=10)		*P*-value	Sig.
	No.	%	No.	%		
Syndrome before operation						
Absent	3	30	5	50	0.7	NS
Present	7	70	5	50		
Final syndrome outcome after operation						
No improvement	1	14.3	2	40	0.2	NS
Partial improvement	4	57.1	3	60		
Full improvement	2	28.6	0	0		

*NS: Non-significant

et al. study.[15] Such male predominance in our population could be attributed to the high frequency of traumatic etiology of these defects as trauma accounted for 55% of cranial defects in our population. Traumatic etiology was either due to road accidents or fights. This goes in line with the literature.[23]

As regards the cosmetic outcome in our population, complete success- according to doctor's assessment, was higher in patients who underwent reconstruction with the custom-made 3D cranioprostheses compared to those who were handled with handmade bone cement, however, this finding is insignificant. Noteworthy, all cases in this study showed complete, partial or satisfactory results with absence of complete cosmetic failure that would need mandatory revision. This goes in line with a study comparing autologous cranioplasty with custom-made implants cranioplasty which showed that 78% of patients in the custom-made implants group had complete success, whereas only 34% of patients in the autologous cranioplasty group had complete success. Furthermore, there was no report of even a single case with partial or complete cranioplasty failure within the 12 months of follow-up after the operation.[15]

Our analysis revealed that, from a functional perspective, that custom-made cranioprostheses had significantly higher complete success rates compared to the hand-made bone cement implants. This finding goes in line with what has been reported by Rotaru *et al*. who noticed that the 3D reconstruction in their population showed that symmetry was achieved in all of his cases with no secondary effects on the cerebral mass or soft tissues.[21] The difference in this outcome could be attributable to the accurate nature of the computer aided custom-made implants that perfectly fit the original calvarial defect and preserves good skull symmetry.

Custom-made cranioprostheses has been reported to have good functional outcome with minimal late complications. A study found that during the recovery period from reconstructive surgery that there were no signs of infection, plate rejection or wound dehiscence in any of the included cases.[21] Our results revealed a similar finding where no one of the patients in the custom-made 3D implants showed any late complications during the follow-up period of 3–6 months. As regards the handmade bone cement group, half of the patients developed late infections despite all the taken infection control preventive measure. Controversially, another report revealed a low infection rate of 9.3% in patients operated with bone cement flap.[19] PMMA material is highly exothermic, generating temperature up to 100°C,[8] thus any tissue that comes in contact with the cement becomes susceptible to thermal necrosis. Therefore, PMMA can significantly induce an inflammatory response resulting in late infection.[23] This could possibly be the reason behind the high rate of infection in this group in our study. Eventually, custom-made implants outrank handmade implants in terms of less complications rates which make choosing the 3D implants a better choice for reconstructing calvarial skull defects of various etiologies.

The most patients with skull defects, especially large ones, complain of many symptoms described as the "syndrome of the trephined," which consists of a range of poorly defined symptoms including headache, anxiety, depression, fatigue, lack of concentration, memory problems, and dizziness.[7] The incidence of these symptoms in the custom-made 3D prostheses group was higher than the handmade bone cement group. Full improvement of these symptoms, in our study, was higher in the custom-made implant group than the handmade implant group; however, this finding is not significant.

Our findings favor the custom-made 3D implants in the reconstruction of calvarial skull defects in terms of esthetic and functional outcomes. They also show less short-term and long-term complications. Nevertheless, the small sample size of our study makes the findings of our analysis not generalizable.

CONCLUSION

Prefabricated 3D custom-made implants give better results in terms of esthetic and functional outcome in comparison to the handmade bone cement implant. They provide shorter operative time with less complication rates. Therefore, they are highly recommended for repairing large and complex-shaped cranial defects.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

There are no conflicts of interest

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