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Original Article

Functional and aesthetic evaluation after cranial reconstruction with polymethyl methacrylate prostheses using low-cost 3D printing templates in patients with cranial defects secondary to decompressive craniectomies: A prospective study

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Abstract

Background: Cranial reconstruction surgery is a procedure used as an attempt to reestablish the cranial bone anatomy. This study evaluates the symptomatic and aesthetic improvement of patients with cranial defects secondary to decompressive craniectomies after cranial reconstruction with customized polymethyl methacrylate (PMMA) prostheses. Secondly, we aim to divide our experience in the production of these prostheses with a low-cost method.

Methods: A prospective study was carried out with patients submitted to cranioplasty at the Hospital da Restauração between 2014 and 2017. A total of 63 cranioplasties were performed using customized PMMA prosthesis produced by 3D impression molds. All patients underwent a functional and aesthetic evaluation questionnaire in the preoperative period and in the sixth postoperative month.

Results: Sixty-three patients underwent cranioplasty with a mean age of 33 years, ranging from 13 to 58 years, 55 males and 8 females. The mean area of the defect was 147 cm^2. The mean postoperative follow-up of the patients was 21 months, ranging from 6 to 33 months. Fifty-five patients attended the 6-month postoperative consultation. All patients presented symptomatic improvement after reconstruction of the skull. The infection rate was 3.2%, 4.8% of extrusion, 1.6% of prosthesis

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fracture, 7.9% of extradural hematoma, 17.4% of reoperation, 5% of wound dehiscence, and 4.8% of removal of the prosthesis.

Conclusion: Cranioplasty, with a customized PMMA prosthesis, improved the symptoms and aesthetic appearance of all operated patients. The use of prototypes to customize cranial prostheses facilitated the operative technique and allowed the recovery of a cranial contour very close to normal.

Key Words: Cranial defects, cranial reconstruction, cranioplasty, decompressive craniectomies, methyl methacrylate

INTRODUCTION

Decompressive craniectomy is a surgical procedure indicated for the treatment of severe and refractory intracranial hypertension related to conditions such as traumatic brain injury, subarachnoid hemorrhage, intracranial hemorrhage, and ischemic stroke.[1,7,16,17,32] This surgery not only reduces mortality, but also implies neurological, social, and psychic repercussions resulting from the absence of the cranial bone. After regression of cerebral edema and when the patient has good clinical conditions, cranioplasty is indicated.[15]

Cranial reconstruction aims to reacquire cerebral protection against trauma, to recover the cranial contour, and to improve neurological symptoms with the reestablishment of intracranial physiological pressure.[5,29,39] Restoration of the anatomic barrier between intracranial structures and the environment normalizes cerebrospinal fluid and cerebral blood flow dynamics. The set of signs and symptoms that result from partial loss of the cranial bone is called Syndrome of the trephined.[20,27]

Cranioplasty is performed with autologous bone or with alloplastic materials.[5,19] The autologous bone has a higher resistance to infection and a lower probability of extrusion, but presents a variable absorption rate.[5,9,10,13] The parietal bone graft is the first choice whenever it is possible. In reconstructions after decompressive craniectomy, the size of the defect precludes this option due to the lack of donor area. The alloplastic materials have an excellent contour, but a higher risk of infection and extrusion. Its most used types are polymethyl methacrylate (PMMA), hydroxyapatite (HA), and titanium.[10,13,39]

PMMA molds can be performed preoperatively or intraoperatively. During surgery, it can be molded manually or with molds built with 3D printing (additive manufacturing). Through a partnership with the Renato Archer Information Technology Center in Campinas, São Paulo, we sent CT scan of the patients who would undergo cranial reconstruction to make 3D models, which allow the molding of a personalized cranial prosthesis with PMMA.

This study demonstrates the improvement of neurological symptoms and the aesthetic aspect of patients submitted to cranial reconstruction, with customized PMMA prosthesis through 3D printing after decompressive craniectomy. Second, we share our experience with a low-cost method of manufacturing these prostheses.

METHODS

This is a clinical trial performed by the Plastic Surgery and Neurosurgery Service of the Hospital da Restauração (HR) in Recife – PE, between 2014 and 2017. It included 63 patients, previously submitted to decompressive craniectomy as a consequence of severe traumatic brain injury, stroke, and neoplasia; and released by neurosurgery to perform a plastic surgery. These 63 patients underwent cranial reconstruction with PMMA prosthesis using 3D impression molds and followed up for at least 3 months postoperatively.

All patients were attended at the Neurosurgery and Plastic Surgery of the Hospital and were operated in the HR. Participants signed the free and informed consent term and the study was approved by the CAAE of HR under number 128551/2017. Patients with bone defects underwent CT scan (SOMATOM Definition AS 64 slice, Siemens®) with cuts ≤1 mm and the exams were recorded in DICOM format on a DVD. These files were sent via Dropbox® to the Renato Archer Information Technology Center (CTI RA) in Campinas – SP. Scanned images are handled in the software InVesalius® (open source software and developed by CTI Renato Archer) for the models to be developed and later printed by a 3D printer (SLS HiQ, 3D System®).

Three prototypes were developed:

1: Defective skull [Figure 1a].
2: Missing part of the defective skull [Figure 1b].
3: Two shapes (two pieces) of molds that allow us to make a perfect copy of prototype 2 [Figure 1c].

The prototypes were printed by the Polyamide Plastic Material Sintering (PA12) technology, are not biocompatible, and cannot be implanted in humans. Thus, the prototype 3 allows the molding of the cranial prosthesis in biocompatible material during the surgery.

All prototypes were sterilized by steam autoclave at 134°C for 5 min and sent to the operating room.

After anesthetic induction, the customized prosthesis is made with PMMA and it is inserted in solution with antibiotic and saline, until reaching the ambient temperature [Figure 2]. The surgical approach is done in the previous scar of the craniectomy, without resection of the cicatricial borders, to avoid tension during closure. The defect is exposed with elevation of the scalp, in the plane just above the dura mater, leaving the cover as thick as possible [Figure 3a]. The prosthesis is then fitted into the defect [Figure 3b] and fixed with titanium plates and screws (Bioplate®, 1.6-hole 2-plate system). A Blake® silicone tubular continuous suction drain is positioned, and the surgical wound is closed in the galeal plane with Capofril® 2-0, and in the skin plane with Mononylon® 2-0, in separate locations. After surgery, the patient is referred to the Advanced Neurosurgery Support Unit (USAN), where a CT scan is performed within the first 12 h. The drain is withdrawn when the flow rate is <50 ml in the last 12 h and hospital discharge usually occurs within 48 h.

An evaluation of the signs and symptoms of the Syndrome of the trefinado was performed through a questionnaire, for all patients, in the pre- and sixth postoperative month. The reported complaints were local discomfort, headache, dizziness, tinnitus, insomnia, fatigue, irritability, depression, insecurity, intolerance to vibration, seizures, paresis, dysphasia, dyspraxia, attention deficit, memory deficit, and worsening symptoms in orthostatic position or with Valsalva maneuver. In the sixth postoperative month, the patients also answered about the aesthetic result of the surgery (excellent, very good, good, regular, and bad). We analyzed postoperative data and postoperative evolution. Complications within the follow-up period were assessed by the Landriel Ibanez classification system.[24] This system grades complications in four grades [grade 1: no invasive treatment required; grade 2: invasive treatment required, but not intensive care unit (ICU); grade 3: invasive treatment required and ICU admission; grade 4: death].

The number of patients operated during the study period determined the sample size. The Chi-square test was used to calculate the proportions. The *P* value considered statistically significant was <0.05.

RESULTS

Sixty-three consecutive cranioplasties were performed between 2014 and 2017 in patients with a mean age of 33 years, ranging from 13 to 58 years, 55 males and 8 females. All of these patients were followed up until the third postoperative month and 55 (87.3%) attended the medical appointment in the sixth month to respond to the symptom questionnaire. We considered the *N*

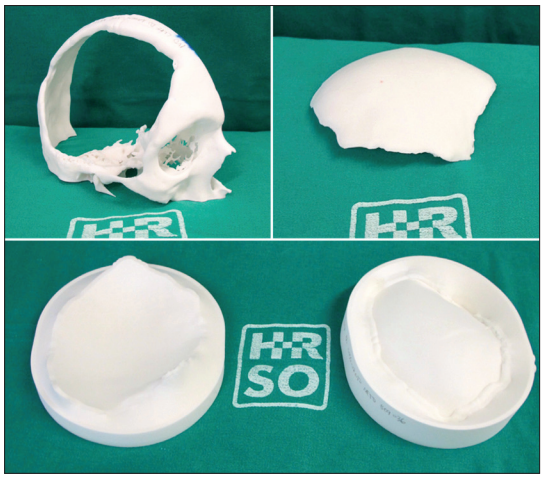

Figure 1: Prototypes of the cranial prosthesis

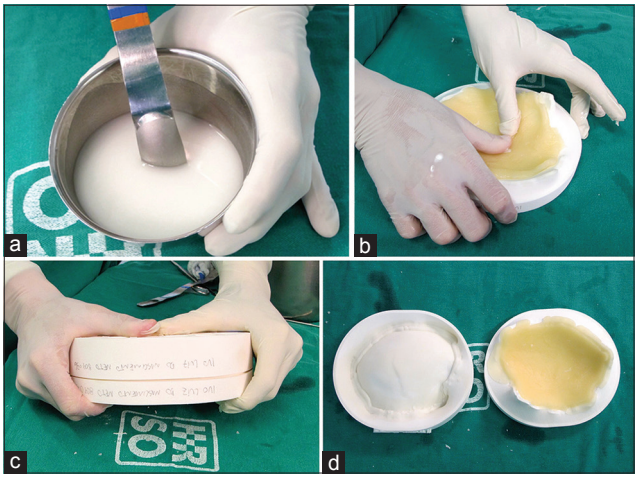

Figure 2: (a) Preparation of bone cement; (b) polymethyl methacrylate manual molding in prototype molds; (c) engagement of the two complementary halves of the molds; (d) final prosthesis with the same dimensions of the initial prototype

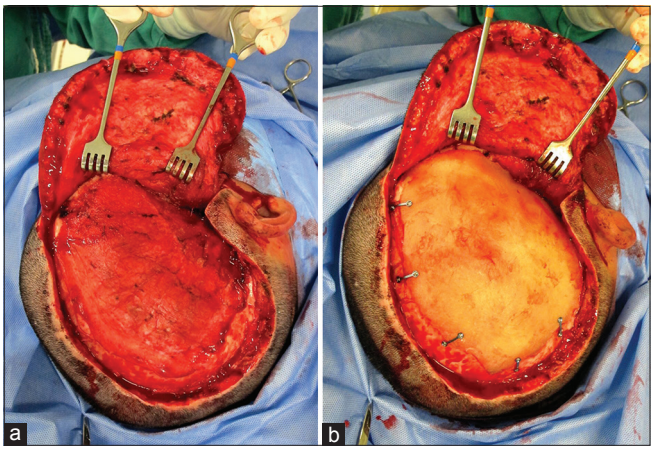

Figure 3: (a) Defect exposed after the elevation of the scalp; (b) fixation of the prosthesis into the defect

Table 1: Signs and symptoms of the Syndrome of the trephined in the pre- and postoperative period of cranial reconstructions (*n*=55)

Signs and symptoms presented	Preoperative, *n* (%)	Postoperative			*P*[1]
		Resolution, *n* (%)	Improvement (%)	Maintenance, *n* (%)	
Local discomfort	46 (83.6)	35 (76.1)	11 (23.9)	0 (0.0)	–
Headache	42 (76.4)	29 (69.0)	12 (28.6)	1 (2.4)	<0.001
Dizziness	24 (43.6)	17 (70.8)	6 (25.0)	1 (4.2)	<0.001
Buzz	10 (18.2)	7 (70.0)	2 (20.0)	1 (10.0)	0.011
Insomnia	22 (40.0)	9 (40.9)	9 (40.9)	4 (18.2)	0.003
Cansaço	30 (54.5)	11 (36.7)	14 (46.7)	5 (16.6)	<0.001
Irritability	41 (74.5)	9 (21.9)	15 (36.6)	17 (41.5)	0.274
Depression	16 (29.1)	8 (50.0)	5 (31.3)	3 (18.7)	0.012
Insecurity	44 (80.0)	28 (63.7)	10 (22.7)	6 (13.6)	<0.001
Vibration intolerance	22 (40.0)	20 (90.9)	2 (9.1)	0 (0.0)	–
Seizures	15 (27.3)	12 (80.0)	3 (20.0)	0 (0.0)	–
Paresias	34 (61.8)	5 (14.7)	22 (64.7)	7 (20.6)	0.001
Dysphasia	41 (74.5)	16 (39.0)	21 (51.2)	4 (9.8)	<0.001
Dyspraxia	32 (58.2)	8 (25.0)	19 (59.4)	5 (15.6)	<0.001
Attention deficit	34 (61.8)	7 (20.6)	21 (61.8)	6 (17.6)	<0.001
Memory deficit	40 (72.7)	6 (15.0)	19 (47.5)	15 (37.5)	0.114
Worsening of standing or Valsalva symptoms	19 (34.5)	16 (84.2)	2 (10.5)	1 (5.3)	<0.001

of 63 for evaluations of complications and *N* of 55 for evaluation of functional and aesthetic outcome. Mean postoperative follow-up was 21 months, ranging from 3 to 33 months. The mean area of the defect was 147 cm^2. All patients showed improvement of symptoms after reconstruction of the skull bone [Table 1]. Furthermore, the proportion-comparison test was significant in all evaluated signs/symptoms, except for irritability (*P*-value = 0.274) and memory deficit (*P* value = 0.114), indicating that after 6 months of treatment all signs/symptoms were resolved or improved in the vast majority of cases. The number of patients who persisted with irritability and memory loss in the postoperative period was statistically similar to those who showed improvement of these symptoms. These are possibly symptoms related to baseline disease.

All 55 reconstructions had a satisfactory aesthetic result. Forty-nine (89.09%) found the result excellent and six patients (10.90%) found the result very good. Five patients had extradural hematoma (7.9%): two asymptomatic extradura and three symptomatic hematomas. Forty-one patients (65.1%) had seroma and three (4.8%) had dehiscence. There were 11 reoperations (17.4%): five drainage of extradural hematoma, two successful closures of extrusions, two removals of prostheses by infection, one removal of prosthesis by refractory extrusion, and one replacement of prosthesis by fracture of the same. Six patients (9.5%) had a seizure in the first 12 h postoperatively. There was a neurological sequel in one of the patients (2%) of extradural hematoma [Table 2].

DISCUSSION

Cranioplasty with the use of PMMA is a method that has been increasingly consolidated in neurosurgical practice.[11,37] Since the 1940s, this has been the most commonly used material for secondary cranial reconstruction.[42] PMMA consists of a thermoplastic material with high biocompatibility, mechanical resistance, and wide use in the medical environment.[21,23] The study had no group control. We compare with the previous status of the patients before cranial reconstruction. The questionnaires of symptomatic and aesthetic evaluation were applied in the pre- and the sixth postoperative month, only with simple direct questions to the patient and his companion. No internationally accepted cognitive, motor, or quality-of-life tests have been used. The questionnaires were applied in the medical consultation by the same team that operated the patient. These are the limitations and possible biases of this study.

The use of customized prosthesis through 3D impression molds in cranial reconstruction has an advantage to facilitate the surgical technique and the excellent cranial contour [Figure 4]. Through the technique proposed in this article and the use of PMMA as an implant material, the intraoperative modeling of the final implant is completed within a few minutes. Customizing the prosthesis in the prefabricated molds through the 3D printer avoids the likelihood of tissue damage due to the exothermic reaction during the polymerization process and provides accurate implants that exactly fit the defects.

Table 2: Complications of patients submitted to cranial reconstruction with customized prosthesis (*n*=63)

Complication	Landriel Ibanez classification system[24]	Value, *n* (%)	*P*-value
Seroma		41 (65.1)	–
Seizures in the first 12 h	1	6 (9.5)	–
Reoperation:	3	11 (17.4)	–
a) Extradural hematoma	3	5 (7.9)	–
b) Extrusion	2	3 (4.8)	–
c) Fracture of the prosthesis	2	1 (1.6)	–
d) Infection	2	2 (3.2)	–
Dehiscence	2	3 (4.8)	–
Removal of prosthesis	1	1 (1.6)	–
Neurological sequela	1	0 (0.0)	–
CSF fistula			

[1]*P*-value of the Chi-square test for comparison of the proportion (if *P* value<0.05 the prevalence differ significantly)

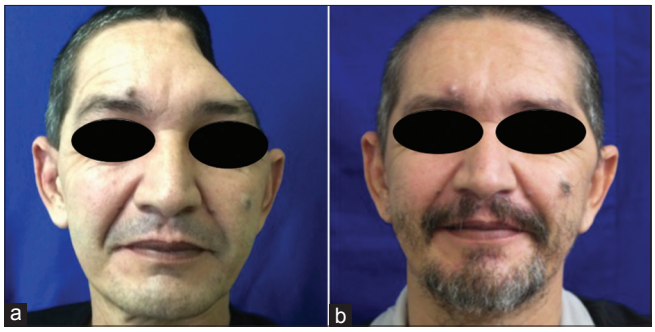

Figure 4: (a) Before cranial reconstruction using the proposed technique; (b) after implantation of the polymethyl methacrylate prosthesis

In addition to PMMA, other materials can be modeled for cranioplasty with the aid of a 3D printer, such as titanium,[4,8,36] carbon fiber reinforced polymer,[30,38] and HA.[26,28,34] Regarding implant manufacturing costs, which is a very important detail in the underdeveloped countries, the PMMA presents an unquestionable advantage when compared to outsourcing the production of other types of materials. In our experience, our alternative method of transoperative customization allowed a reduction of 70 times in the total value of the surgical procedure. The drastic reduction in the cost of this procedure allowed the accomplishment of this procedure in a public hospital of Brazil.

Recent studies suggest that cranioplasty contributes to neurological recovery in craniectomized patients.[3,29] Neurological signs and symptoms of the patients with post-craniectomy defects may be due to traumatic brain injury or the absence of bone. The lack of bone is related to changes in the circulation of cerebrospinal fluid, to the effect of atmospheric pressure compressing the cortex, and to the reduction of venous return caused by the obliteration of the subarachnoid space.[29] In 1945, Farrington[12] had already realized the improvement of the neurological function after cranioplasty, which was confirmed by many other authors afterwards[2,12,14,18,22,31,33,35,40] and by our study, where all patients had symptomatic improvement after cranial reconstruction.

We also compared our results to previous studies documenting secondary cranial reconstruction with PMMA. Zanaty *et al.*[41] reported an overall complication rate of 31.32%, with an overall infection rate of 26.43%, 6.90% of surgical site hematoma rate, and 3.16% of death rate. In another study by Broughton *et al.*,[6] the authors reported an overall complication rate of 30.0%, an overall infection rate of 10.3%, and one mortality of 2.3%. In our series of cases, we had a considerably lower incidence of overall infection 3.2%, a slightly higher incidence of surgical site hematoma (7.9%), and no related deaths. As compared with these reports, we have experienced a global incidence of seromas of 43%, whose incidence throughout the series was reduced through the accomplishment of adhesion points between the prosthesis and the pericranium, as previously described by Maricevich *et al.*[25] Regarding the type of incision (Becker or Kempe), in our experience we did not observe any difference between them in relation to the difficulty of surgical reconstruction.

Therefore, this is a technique with functional gains where the aesthetic factor has a significant impact on the social reintegration of the patients. Although all patients in this study considered the new cranial contour as excellent or very good, there is often a variable asymmetry in the temporal region. This prosthesis achieves excellent bone symmetry, and we believe that it happens for two reasons: the lack of repositioning of the temporal muscle at the end of the decompressive surgery and the atrophy of this muscle by the time it remained disinserted from the temporal fossa. Consequently, the temporal muscle tends to become less bulky and "retract" caudally, creating a bulge above the zygomatic arch.

CONCLUSION

The cranial reconstruction with customized PMMA prosthesis promoted the improvement of the neurological symptoms and aesthetic appearance of all operated patients. Finally, by sharing our experience using a reliable and a low-cost method with the use of a 3D printer, we hope to make this surgical technique easily accessible and reproducible in any institution.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be

made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest
There are no conflicts of interest.

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