

## Cranioplasty with a low-cost customized polymethylmethacrylate implant using a desktop 3D printer

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**OBJECTIVE** Cranioplasty implants should be widely available, low in cost, and customized or easy to mold during surgery. Although autologous bone remains the first choice for repair, it cannot always be used due to infection, fragmentation, bone resorption, or other causes, which led to use of synthetic alternatives. The most frequently used allogenic material for cranial reconstructions with long-term results is polymethylmethacrylate (PMMA). Three-dimensional printing technology has allowed the production of increasingly popular customized, prefabricated implants. The authors describe their method and experience with a customized PMMA prosthesis using a precise and reliable low-cost implant that can be customized at any institution with open-source or low-cost software and desktop 3D printers.

**METHODS** A review of 22 consecutive patients undergoing CT-based, low-cost, customized PMMA cranioplasty over a 1-year period at a university teaching hospital was performed. Preoperative data included patient sex and age; CT modeling parameters, including the surface area of the implant (defect); reason for craniectomy; date(s) of injury and/or resections; the complexity of the defect; and associated comorbidities. Postoperative data included morbidity and complications, such as implant exposure, infection, hematoma, seroma, implant failure, and seizures; the cost of the implant; and cosmetic outcome.

**RESULTS** Indications for the primary craniectomy were traumatic brain injury (16, 73%), tumor resection (3, 14%), infection (1, 4%), and vascular (2, 9%). The median interval between previous surgery and PMMA cranioplasty was 12 months. The operation time ranged from 90 to 150 minutes (mean 126 minutes). The average cranial defect measured 65.16 cm<sup>2</sup> (range 29.31–131.06 cm<sup>2</sup>). During the recovery period, there was no sign of infection, implant rejection, or wound dehiscence, and none of the implants had to be removed over a follow-up ranging from 1 to 6 months. The aesthetic appearance of all patients was significantly improved, and the implant fit was excellent.

**CONCLUSIONS** The use of a customized PMMA was associated with excellent patient, family, and surgeon satisfaction at follow-up at a fraction of the cost associated with commercially available implants. This technique could be an attractive option to all patients undergoing cranioplasty.

<https://thejns.org/doi/abs/10.3171/2017.12.JNS172574>

**KEYWORDS** cranioplasty; custom polymethylmethacrylate mold; 3D printing; surgical technique

THE evolution of cranioplasty parallels the development of technology, the growth of our collective imagination, and our desire to provide maximum benefit with minimum risk and the smallest footprint.<sup>12</sup> Throughout history, numerous and diverse techniques and novel materials are continuously being developed or improved to properly treat this complex problem.<sup>6</sup> Ideally,

implants should be widely available, low in cost, and customized or easy to mold during surgery.<sup>17</sup>

Although autologous bone remains the first choice for repair, it cannot always be used due to infection, fragmentation, bone resorption, or other causes,<sup>28</sup> which had led to the use of synthetic alternatives (metals, ceramics, plastics, resorbable polymers, and biomaterials).<sup>17</sup>

**ABBREVIATIONS** GCS = Glasgow Coma Scale; PMMA = polymethylmethacrylate; TBI = traumatic brain injury.

**SUBMITTED** October 18, 2017. **ACCEPTED** December 11, 2017.

**INCLUDE WHEN CITING** Published online June 15, 2018; DOI: 10.3171/2017.12.JNS172574.

The most frequently used allogenic material for cranial reconstructions with long-term results is polymethylmethacrylate (PMMA).<sup>12</sup> Initially manufactured as an industrial material, it was repurposed for use in human calvarial repair by Zander in 1940 and popularized in the published work of Gurdjian et al. soon thereafter<sup>4,12,15</sup> due to its biocompatibility, availability, low cost, strength, and ability to be remolded.<sup>2</sup>

The advent of computer-assisted design and 3D printing technology has allowed the production of increasingly popular customized, prefabricated implants.<sup>4,12</sup> Although precise, the use of this technology has not been widely adopted due to limited access to expensive commercial and industrial 3D printers<sup>31</sup> or expensive commercial customized implants. The addition of increasingly affordable or open-source 3D technology and software makes it possible for neurosurgeons to create in-office, patient-tailored implants.

Our design process for cranioplasty is low cost and feasible in comparison with other described methods. We use open-source image-editing software and desktop 3D printers, and the process innovation we create is efficient in terms of time and resources in order to make it possible for the consultant neurosurgeon to create in-office, patient-tailored implants.

The aim of this study is to share our method and experience with customized PMMA prostheses using a precise and reliable low-cost implant that can be customized at any institution with open-source or low-cost software and a desktop 3D printer.

## Methods

### Patient Population

We performed a review of 22 consecutive patients undergoing CT-based, low-cost, customized PMMA cranioplasty over a 1-year period at a university teaching hospital (Facultad de Medicina y Hospital Universitario “Dr. José Eleuterio González,” Universidad Autónoma de Nuevo León). Institutional review board approval and patient or caregiver consent for photographs were obtained prior to the study’s initiation.

### Preoperative and Intraoperative Data

Preoperative data included patient sex and age; CT modeling parameters, including surface area of implant (defect); reason for craniectomy; date(s) of injury and/or resections; complexity of defect; and associated comorbidities. Intraoperative data included surgical technique, location of surgery, drain use, type of closure, and PMMA implant modifications.

### Postoperative Data

Postoperative data included morbidities and complications, such as implant exposure, infection, hematoma, seroma, implant failure, and seizures; cost of the implant; and cosmetic outcome. In addition to the clinical monitoring in the outpatient clinic, patients or their families were contacted by phone to obtain follow-up information and to complete a telephone questionnaire regarding their satisfaction with the PMMA cranioplasty after 1 to 6 months.

We used a simple ordinal rating scale to rate patient or primary caregiver satisfaction with the cosmetic result of the PMMA patient-specific implant as follows: 1, very dissatisfied; 2, somewhat dissatisfied; 3, neutral; 4, somewhat satisfied; and 5, very satisfied.<sup>15</sup>

### Modeling Technique

Cranioplasty CT scanning was performed using a helical scanner. Contiguous 1-mm reconstructed slices were produced from the data volume. The data were then downloaded from the scanner workstation for editing in open-source image-editing software. We use open-source image-editing software and desktop 3D printers, which are briefly described below.

InVesalius is an open-source software that generates 3D medical imaging reconstructions based on a sequence of 2D DICOM files acquired with CT or MRI equipment; the software is internationalized and multiplatform (GNU Linux, Windows, and Macintosh OS). Blender is another free software that we use for modeling the prosthesis; it is cross-platform and runs well on Linux, Windows, and Macintosh computers. MeshLab and MeshMixer are both open-source software that provide tools for editing, cleaning, texturing, and converting the mesh in order to repair them, if necessary. The 2 desktop 3D printers we use are Formlabs Form 2 (Formlabs Inc., from US\$3499.00) and Ultimaker 2+ (from US\$2499.00).

The defects repaired with this process are, in most cases, windows with irregular borders in various anatomical locations. The first step, once the 3D model of the patient’s skull is generated, is to obtain the contour of the defect by sketching a line over the external diameter of the craniectomy, or planned craniectomy when needed, and then apply this same step to the internal border. These steps will help in the creation of a precise final piece that matches perfectly with the defect or planned craniectomy (Fig. 1).

Reference curves are drawn to obtain the precise convex form of the external and internal faces of the piece. When the case allows it and there is a healthy side of the skull, reference curves can be mirrored. Once the reference curves are made, a patch is made to form a closed surface or a solid part.

The implant is verified to match perfectly with the skull’s perimeter. The next step is to model the mold for the implant using the same open-source image-editing software. When finished, the mold must be exported to a stereolithography format for printing. Then the mold is sterilized, and the implant is customized during or before surgery, pressing the PMMA into the mold when it is in its plastic phase until its complete polymerization. The design process typically lasts between 4 and 5 hours, and the 3D mold printing lasts on average 10 hours.

### Cranioplasty

Cranioplasty was performed in the standard fashion, the PMMA implant was secured to the skull with self-tapping titanium screws and miniplates, and a Jackson-Pratt wound drain was placed in the subgaleal plane in all cases. When part of the temporal muscle could not be dissected, the temporal part of the implant was modified with ron-

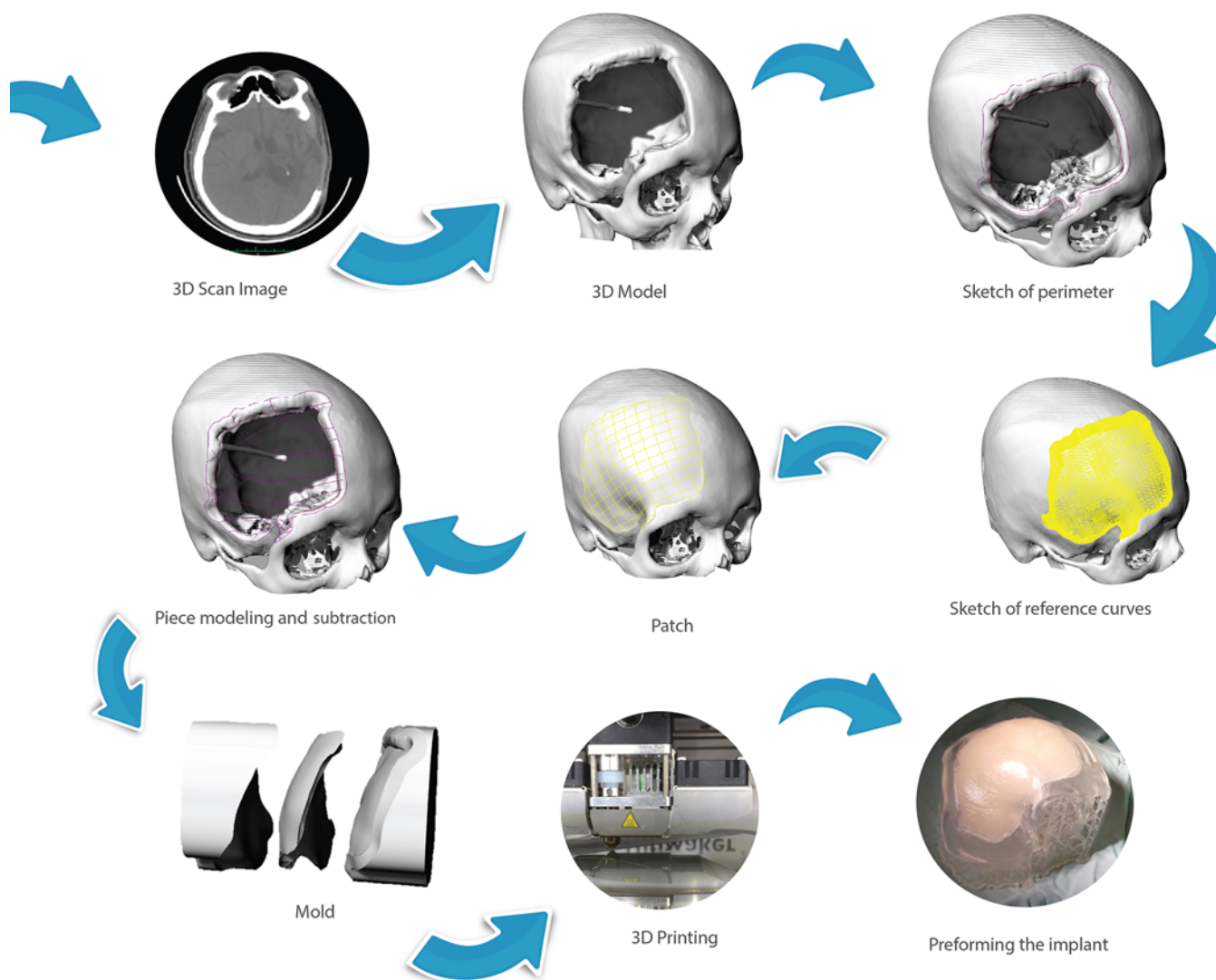


FIG. 1. Implant remodeling process. Figure is available in color online only.

geur. All patients received preoperative antibiotics, and a postoperative CT scan was obtained in all patients, usually on the 1st postoperative day.

## Results

A total of 22 consecutive patients were included. Table 1 and Fig. 2 show baseline characteristics. The mean age of the participants was 35.40 years, ranging from 3 to 73 years. Sixteen male and 6 female patients were included. About half of the patients presented with 1 symptom (10, 50%). At preoperative examination, 15 (68%) patients had a Glasgow Coma Scale (GCS) score of 15, and 7 (32%) had a score of 13–14. Indications for the primary craniectomy were traumatic brain injury (TBI) (16, 73%), tumor resection (3, 14%), infection (1, 4%), and stroke (2, 9%). The median interval between previous surgery and PMMA cranioplasty was 12 months. The operative time ranged from 90 to 150 minutes (mean 126 minutes). The average cranial defect measured 65.16 cm<sup>2</sup> (range 29.31–131.06

cm<sup>2</sup>). At postoperative examination, 17 (77%) patients had a GCS score of 15, and 5 (23%) had a score of 13–14. The postoperative follow-up period ranged from 1 to 6 months. The costs for the implant ranged from US\$135.23 to US\$444.44 (mean US\$307.79).

## Complications After Cranioplasty

During the recovery period, there was no sign of infection, implant rejection, or wound dehiscence. None of the implants had to be removed.

## Cosmetic Results

The aesthetic appearance of all patients was significantly improved. Of all 22 participating patients, 14 (63.64%) were very satisfied with the aesthetic result, and 8 patients (36.36%) were somewhat satisfied with the aesthetic result. Seven patients were somewhat satisfied because of temporalis muscle atrophy, and 1 patient was somewhat satisfied due to the elevation in the skin caused by the implanted

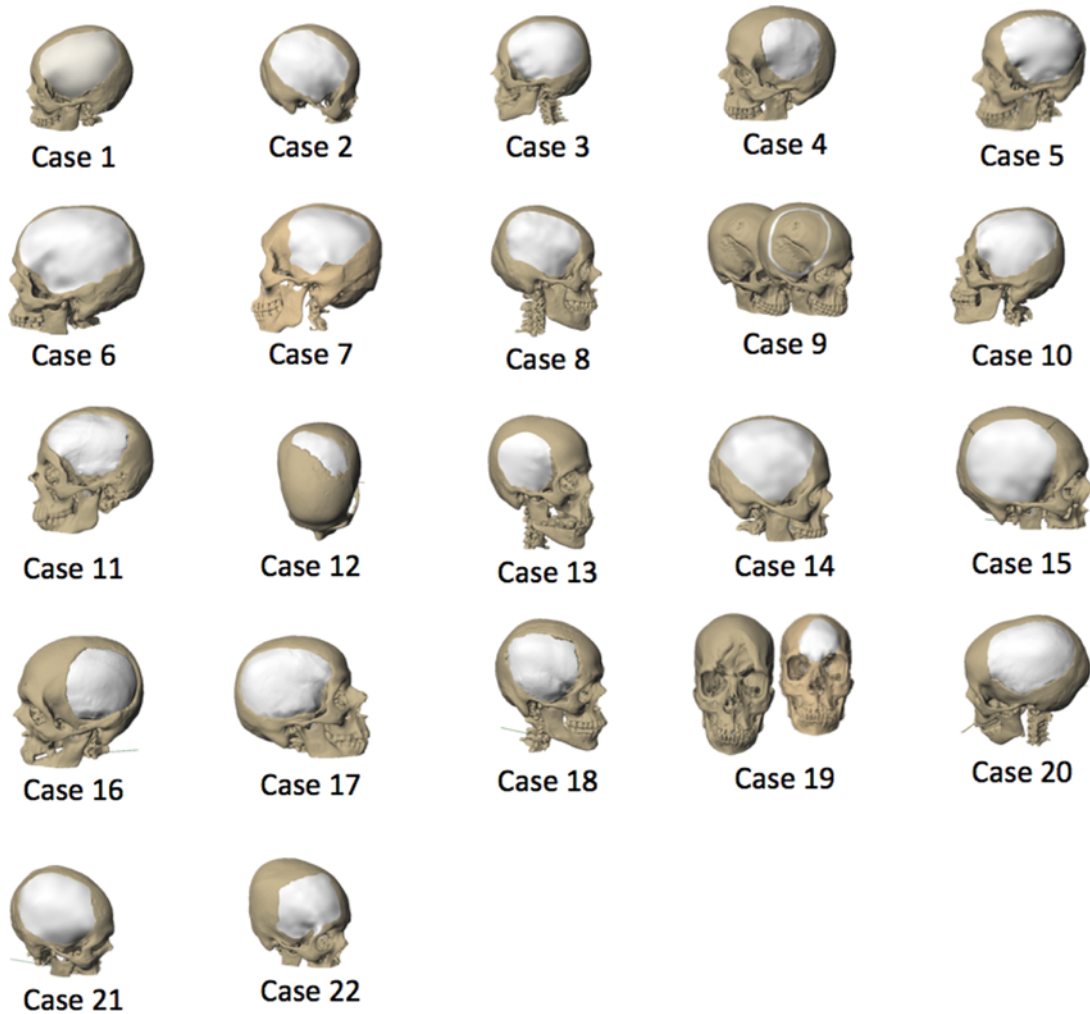


FIG. 2. Illustrations showing the customized polymethylmethacrylate implants for each patient. Figure is available in color online only.

miniplate. In general, we evaluated the postoperative appearance 6 months after surgery (Fig. 3). The surgeons reported that the implant fit was excellent and that the results were good in all cases.

## Discussion

Alloplastic cranioplasty techniques using PMMA are a common method of restoring lost cranial bone.<sup>11</sup> These techniques require modeling of the plastic during its polymerization. This can be difficult with respect to the shape of the skull and thus the aesthetic outcome. One major problem is that, under surgical conditions, free modeling of a large PMMA plastic is difficult. Thus, the process of customizing an implant's design and fabrication has dramatically evolved in just a few decades, from free-hand molding to computer-assisted molding.<sup>18</sup>

Advantages of computer-designed, prefabricated implants have been demonstrated and include improved cosmetic outcome as well as minimization of the procedure time needed for implant insertion.<sup>16</sup> However, in most series, expensive commercial and industrial 3D printers (approximately US\$37,000–US\$310,000) or expensive com-

mercial implants (approximately US\$10,000)<sup>3,5,8,13,18,21,22,26,30–32</sup> were used, which are prohibitive for use in low- and middle-income countries.

To our knowledge, there is no report of computer-designed customized cranioplasty usage in low- and middle-income countries where the incidence of cranioplasty should be expected to be higher.<sup>23,24,27,29</sup> In a high-income country, it is expected that the implant would be offered without cost to the patient but not in most middle- and low-income countries.

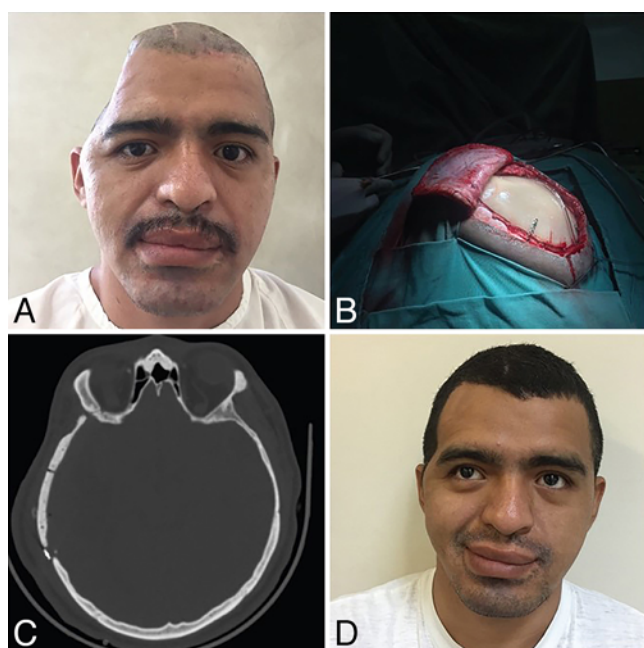
Different techniques have been reported for customizing a cost-effective implant, with most using the head of the patient prior to or during the surgery and casting.<sup>2,5,7,9,19,20,30,31,33</sup> However, despite their low associated cost, these techniques are not precise or reliable, the original bone flap is needed, and the procedure involves many time-consuming steps. Recently, Abdel Hay et al. published 2 cases in which a template of the external surface was used to mold the implant by hand.<sup>1</sup> We think that a negative 2-part mold (i.e., inner and outer surfaces) will provide a better result because the polymer takes the precise form planned on the computer.



TABLE 1. Baseline characteristics

Case No.	Age (yrs), Sex	Diagnosis	Preop GCS Score	Location	Defect Dimension (cm)	Defect Area (cm <sup>2</sup> )	Price (US\$)
1	13, M	TBI	15	Lt FP	13.00 × 11.00	71.5	362.00
2	17, F	TBI	15	Rt FTP	12.39 × 10.79	66.84	362.00
3	12, M	TBI	15	Lt FTP	18.46 × 14.20	131.06	444.44
4	40, M	AVM	15	Lt FTP	8.56 × 8.80	37.66	161.11
5	25, M	TBI	15	Lt FTP	12.30 × 9.10	55.96	362.00
6	47, M	TBI	14	Lt FTP	15.00 × 11.80	88.50	444.44
7	50, M	TBI	13	Lt FTP	11.32 × 9.10	51.50	300.00
8	45, F	Ischemic stroke	15	Rt FTP	11.55 × 9.92	57.28	300.00
9	49, F	Meningioma	15	Rt FP	9.90 × 11.00	54.45	161.11
10	54, M	TBI	14	Lt FTP	13.30 × 10.40	69.16	305.55
11	38, M	TBI	15	Lt FTP	12.11 × 11.32	68.54	255.12
12	16, M	Empyema	15	Parietal bilat	12.21 × 11.01	67.21	297.29
13	63, F	Meningioma	15	Rt FTP	10.95 × 11.26	61.64	294.44
14	23, M	TBI	15	Rt FTP	14.80 × 12.00	88.8	444.44
15	15, M	TBI	15	Rt FTP	13.41 × 12.60	84.48	398.80
16	3, M	TBI	14	Lt FTP	11.29 × 10.12	57.12	305.55
17	26, M	TBI	14	Rt FTP	12.47 × 10.23	63.78	311.00
18	28, M	TBI	15	Rt FTP	12.94 × 10.76	69.61	338.88
19	73, M	Mucocele	14	Frontal	8.20 × 7.15	29.31	135.23
20	45, F	TBI	15	Lt FTP	11.30 × 10.10	57.06	298.34
21	34, M	TBI	14	Rt FTP	10.95 × 11.26	61.64	305.55
22	63, F	TBI	15	Rt FTP	9.00 × 9.00	40.5	290.34

AVM = arteriovenous malformation; FP = frontoparietal; FTP = frontotemporoparietal.



**FIG. 3.** This 23-year-old patient, who was involved in a motorcycle accident, was diagnosed with an acute subdural hematoma for which a craniectomy was performed. A customized cranioplasty was applied 7 months later with the results shown. Figure is available in color online only.

The 3D printer used in this study costs approximately US\$2500–US\$3500, and the software is open-source, with 48 hours to produce the implant. The process of implant fabrication should be simple, and we condensed steps to create not only a precise implant but also a method that can print surgical guides for planned craniotomy and skull reconstruction after resection of bone tumors in a single surgical session.

To our knowledge, this is the first report that has described a customized PMMA implant designed using open-source planning tools and a desktop 3D printer.<sup>31</sup> Despite the advent of affordable 3D technology, little attention has been paid to the democratization of technology that open-source and low-cost software and a desktop 3D printer could effect to empower global neurosurgery.<sup>10,25</sup> Nevertheless, by sharing our experience using a reliable and low-cost method that can be performed in any institution with open-source or low-cost software and a desktop 3D printer, we hope to facilitate the advancement of customized cranioplasty. In the end, the democratization of technology will help every novel and creative spirit to develop and embark on future directions in world neurosurgery.

## Conclusions

In our series, the use of customized PMMA was associated with excellent patient, family, and surgeon satisfaction at follow-up at a fraction of the cost associated with commercially available implants. This technique could be an attractive option to all patients undergoing cranioplasty.

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## Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

## Author Contributions

Conception and design: Morales-Gómez. Acquisition of data: Morales-Gómez, García-Estrada, Leos-Bortoni, Delgado-Brito, Flores-Huerta, De La Cruz-Arriaga. Analysis and interpretation of data: Morales-Gómez, García-Estrada, Leos-Bortoni. Drafting the article: Morales-Gómez, García-Estrada, Leos-Bortoni. Criti-

cally revising the article: Morales-Gómez, Garcia-Estrada, Leos-Bortoni. Reviewed submitted version of manuscript: Morales-Gómez, Garcia-Estrada, Leos-Bortoni. Approved the final version of the manuscript on behalf of all authors: Morales-Gómez. Statistical analysis: Morales-Gómez, Garcia-Estrada, Leos-Bortoni. Administrative/technical/material support: Morales-Gómez, Delgado-Brito, Flores-Huerta, De La Cruz-Arriaga, Torres-Díaz,

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