



## Research article

# Surgical planning and finite element analysis for the neurocranial protection in cranioplasty with PMMA: A case study



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## ARTICLE INFO

## ABSTRACT

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New developments in terms of additive manufacturing, computational tools and mathematical simulation techniques have favored the development of successful methodologies for the restoration or restitution of bone structures in the human body. Likewise, achievements in Materials Science have allowed the development of biocompatible composites capable of achieving mechanical characteristics and biological similarities comparable to those of natural bone. Without considering the advantages and disadvantages of some biomaterials with respect to others, this research aims to evaluate the surgical planning, the design process, the impact resistance and the critical deflection of a customized cranial implant manufactured from polymethylmethacrylate (PMMA). With the support of finite element methods (FEM), the level of neurocranial protection offered by the implant is assessed.

## 1. Introduction

At present, the use of different types of materials in bone correction and reconstruction interventions has reached a significant boom, placing as an essential premise for this a high degree of bio-compatibility of the composite used. Among the materials used are metals and their alloys (pioneers in such implementations), polymers, ceramics and combinations between them. In the review article by Gibon and his collaborators [1], the authors analyze information on the biological response and foreign body reaction to the by-products of compounds that are

used to replace joints, specifically polyethylene, ceramics and polymethylmethacrylate (PMMA).

PMMA does not always reach the necessary degree of biocompatibility to remain in contact with human tissue. In [2] the authors report on the long-term post-surgical difficulties that can occur with a kerato-prosthesis, in which a grafted cornea comes into contact with the central optic made of polymethylmethacrylate. The results of this research spin around the solution of such a problem by modifying the surface of the inert biomaterial. The researchers demonstrated that a coating of calcium phosphate (CaP) deposited on dopamine-activated PMMA sheets

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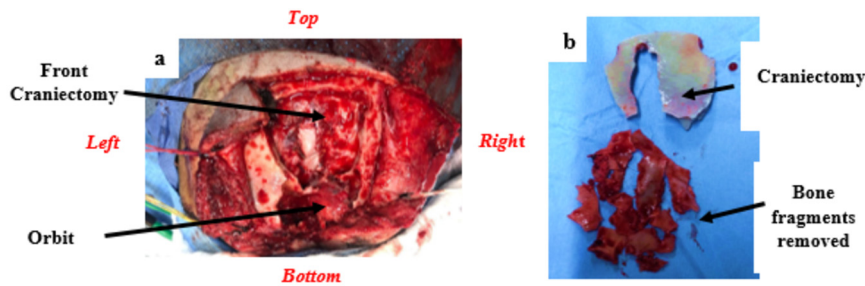


Fig. 1. Left fronto-orbital damage (a). Results of the craniectomy and cleaning of the affected area (b).

improves adhesion to type I collagen (the main component of corneal replacement). Also with the help of a new method by immersion, the creation of cavities is achieved to fix nanoparticles of hydroxyapatite on the surface of the polymeric compound, and thus avoid possible delamination.

Cranioplasty is an operative technique that is applied to restore cranial-bone defects or deformities caused by trauma or surgical intervention, or after a decompressive craniectomy. In formal terms, in this paper the definition provided by Sanan and Haines is accepted as valid: “cranioplasty implies reconstruction with alloplastic materials or autologous tissues in order to provide the best protection to the intracranial content, reestablish the limits between intra and extra structures and restore the craniofacial contour, providing support for the overlying soft tissues” [3].

The medical applications of bone restoration are also complemented by the advances achieved by the different additive manufacturing techniques. For those that are based on the extrusion of materials, the most suitable in this case are thermoplastics, but these depend on the temperature and the loading rate. For these reasons it is important to study how these parameters affect the mechanical properties of the material. The authors of [4] report on this. Dynamic mechanical analyzes were carried out with different materials, including PMMA, to determine the application temperature range, as well as traction tests at different speeds. One of the relevant results of this research is that polymethylmethacrylate, once implanted, is not sensitive to internal temperature changes in the human body. In [5] a cost-effective technique to obtain personalized cranial bone implants based on PMMA is described, with the use of prefabricated molds in polylactic acid, printed in 3D.

The debate about how and when to proceed with a cranioplasty for delayed reconstruction is also open. In [6] an analysis based on experience is presented, regarding which techniques, at what time after the occurrence of the trauma and which biomaterials would be appropriate in such situations.

From the point of view of the mechanical behavior of a customized implant, such an analysis is commonly performed by applying the study of finite elements (FEM). Authors Dhanopia and Bhargava, in [7], present results related to the fixation behavior, in a fractured human femur, of a thermoplastic polymethylmethacrylate prosthetic plate in the mid-axis position under static load conditions. The calculated mechanical resistance is compared with the closest value of the resistances of the natural biological material of the femur, and to demonstrate that PMMA is the most suitable material, they compare the minimum value of the Von Mises stress, the maximum total deformation, the maximum and minimum principal stresses, with respect to other biomaterials, that is, the mechanical integrity of the composite is verified.

The segmentation process of the tomographic image obtained from the affected area, after healing from the initial surgery, is also described. An analysis FEM makes it possible to verify the resistance of the implant against possible impacts (without considering the fixation system and the interaction with the natural bone), and based on the obtained results, to estimate the mechanical performance, such as the permissible stress limits supported by the implant, as well as the verification of its maximum deformation. In the present work, the performance of a late

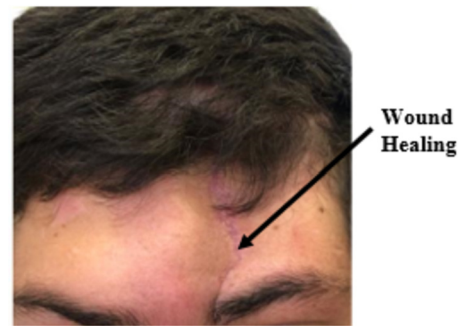


Fig. 2. Trauma without reconstruction, with residual defect.

cranioplasty is exposed, in which the additive manufacturing technique by extrusion is applied for the materialization of a personalized implant based on PMMA, with the aim of correcting a deformation caused by an accident with firearm.

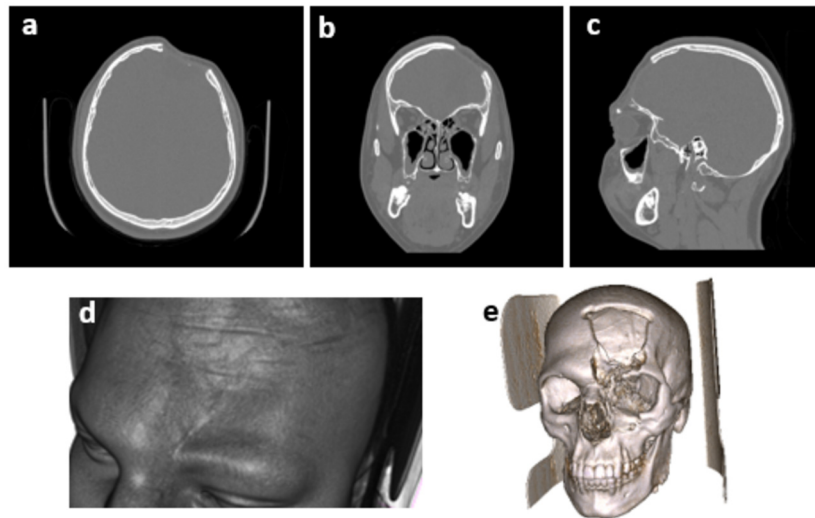
## 2. Materials and methods

From a computed tomography of the affected region of the skull, the process is developed that allows obtaining the three-dimensional model to develop the design, manufacture the personalized implant and carry out an analysis FEM to mechanically characterize the device. The second surgical stage (reconstructive surgery) and the results observed during the follow-up of the patient are also described.

For the development of the present investigation, the informed consent of the patient was obtained for the publication of the images and the results of the entire process. In addition, from an ethical point of view, the medical and surgical process was carried out under the regulations of the National Agency for Sanitary Regulation, Control and Surveillance (ARCSA-acronym in Spanish) of Ecuador.

### 2.1. Clinical case

A 19-year-old patient presents with a gunshot wound to the left fronto-orbital region. Initial imaging studies indicate damage to the roof, superior orbital rim, and frontal bone, as well as foreign bodies and bone fragments embedded in the frontal lobe. After evaluating the damage, a craniectomy and surgical cleaning were performed. The vision of the left eye was severely affected. Fig. 1 shows the damage suffered by the patient and the extracted bone remains, the greatest affectation took place in the upper edge of the orbit and the left frontal lobe. Fourteen weeks after surgery, trauma is assessed without primary reconstruction. The residual defect can be seen (Fig. 2). The patient does not present any other medical or psychological complication that could exclude him from a reconstruction treatment. After the corresponding protocols of medical ethics, and with the informed consent of the person, reconstructive surgery was performed with a personalized implant to return the facial oval to its original appearance.



**Fig. 3.** CT Scan images in three orientations: Axial view (a). Coronal view (b). Sagittal view (c). 3D model reconstructed (d) with the rendered volume module (e).

**2.2. Image processing**

The computed tomography CT Scan data of the patient as a Digital Imaging and Communications in Medicine (DICOM) file is acquired. Only high-resolution CT scans with a voxel resolution of  $512 \times 512 \times Z$ , where  $Z$  ranges from 48 to 498 were used. The CT data is then processed using the open-source software *3D Slicer* (<https://www.slicer.org>) [8], to generate the STL model for the required anatomy. Fig. 3 shows, from different angles, the magnitude of the missing bone tissue. These images were also useful for making preliminary measurements from which the corresponding implant is designed. The *3D Slicer* software allows bone exploration, planning of the procedure and, with the appropriate tools, the correct interpolation of the geometric shape of the damage and the contour of the personalized implant.

**2.3. Bone segmentation process**

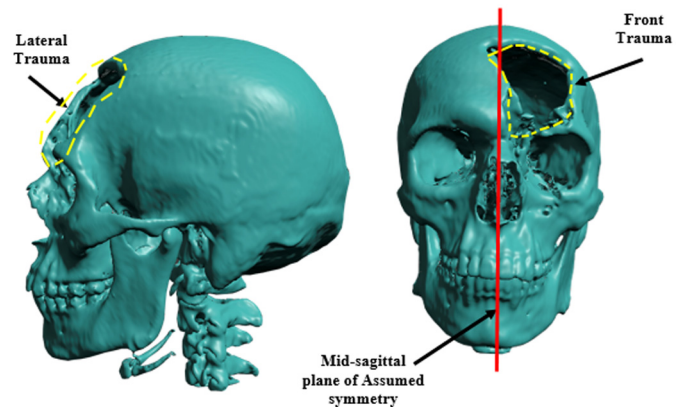
The segmentation of CT 2 images is performed with the selection in the film of the specific intensities (Hounsfield units: HU) that measure the attenuation coefficient in the gray scale for tissues, bones, skin and muscles of the anatomical region of interest [9]. The segmentation process is carried out using a thresholding algorithm, with which it is possible to delimit the area of anatomical interest. The highest HU values correspond to bone tissue. For the present study, values in the range of 188.06 – 3071.0 HU were used.

**2.4. Post processing of anatomical models**

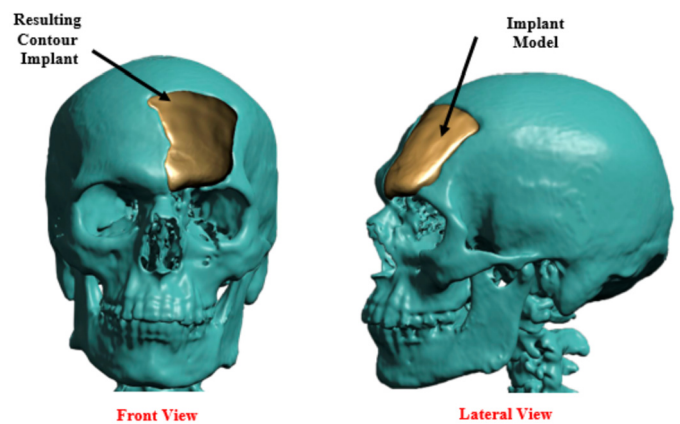
Before the design of the personalized implant, the stl model, exported from the *3D Slicer* software, is interpreted with another open-source software for the repair and design of anatomical models: *Autodesk Meshmixer* (<https://www.meshmixer.com>). It is necessary to minimize the differences or geometric errors between the topologies of the implant and the cranial bone in the affected area. Fig. 4 shows the computational model of the skull with the trauma.

**2.5. Customized implant design**

For bone reconstruction it is assumed that the structure of the human body is symmetrical. With the help of editing tools, the right side (healthy bone) is inverted, generating a mirror image that is superimposed on the left side (bone with trauma). Both halves are merged with the help of the *Autodesk Meshmixer* software tool called “boolean subtraction” (see Fig. 5), filling the cavity. In the computational model,



**Fig. 4.** CT assisted 3D representation of the traumatized skull, front and lateral view.



**Fig. 5.** Design of custom cranial implant.

all the surrounding bone tissue is “removed”, keeping only the portion that corresponds to the damaged and covered area. The cranial implant is designed in such a way that the external edges reach the largest contact surface with the edges of the damaged part of the skull, this allows the defect to be virtually “covered”.





Fig. 6. Evaluation of the 3D printed implant, directly on the patient.

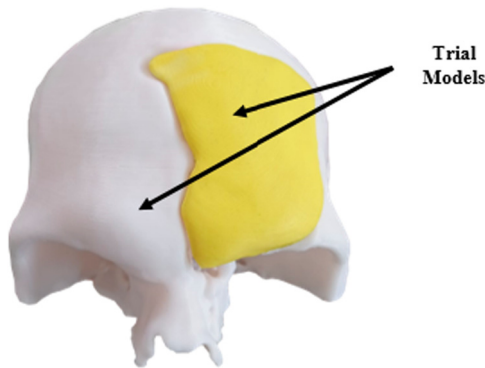


Fig. 7. Complete anatomical model for surgical planning.

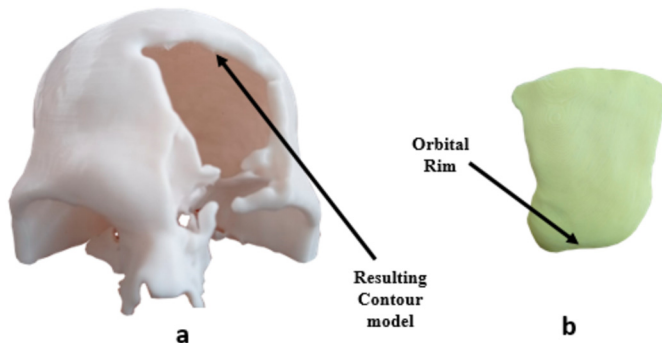


Fig. 8. Anatomical Models. Trial cranial model (a). Implant trial model (b).

### 2.6. Pre-surgical phase and surgical planning

The anatomical models of both the patient's skull and the implant were manufactured using the fused deposition modeling technique. The material used for printing was Polylactic Acid (PLA), at a 1 : 1 scale. With these models it was possible to better understand the magnitude of the damage to the cranial tissue and plan the surgical approach (Fig. 6). With the anatomical trial models, the fit between the contour of the damaged area and the contour of the implant is verified (Fig. 7).

The thickness of the implant was estimated based on the mirror measurement made of the healthy lateral portion of the skull. The designed implant covers areas corresponding to frontal bone tissue, rim and orbital roof (Fig. 8).

### 2.7. Application of the finite element method

With the help of simulation tools, the computational model of the implant was subjected to a pressure load of 50N, distributed in a central area of the implant (yellow area in Fig. 9), of 314 mm<sup>2</sup>. In [10] physical

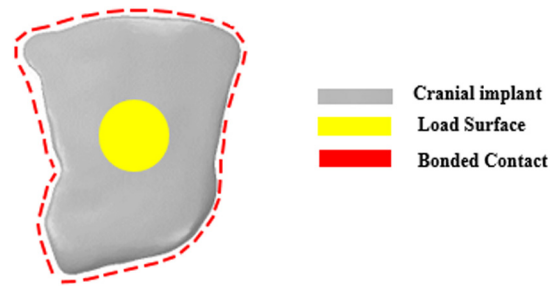


Fig. 9. FEM Cranial Implant Model: front View.

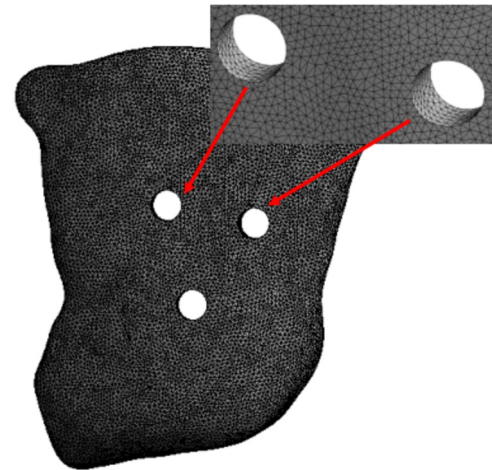


Fig. 10. Cranial implant meshing.

Table 1. Mechanical properties of implant material. Source: [11].

Material	Modulus of elasticity (MPa)	Poisson's ratio
PMMA	2944	0.375

properties of the human head are provided: mass, center of gravity and moment of inertia, information with which the value of the load to be applied in the simulation was obtained. The constraint condition was performed around the entire perimeter of the implant, simulating a fixed contact with the skull interface.

The size and type of the mesh elements for the implant were determined by a sensitivity and convergence analysis based on a result of equivalent Von - Misses efforts (EQV), which guarantees that the post-process value does not vary in a higher range at 5%. In [11] the ideal parameters for FEM analysis in cranial implants are reported. The characteristics of the applied mesh are as follows: 420110 tetrahedral elements, the largest element 2.3 mm, the smallest element 0.66 mm.

With the application of refinement methods, a fine mesh transition was obtained in the implant model. The material is considered isotropic, according to [12], which is why the implant must not exceed the yield stress. This guarantees a homogeneous behavior and enables the use of a linear model (Fig. 10).

For the manufacture of the permanent device, the biopolymer Polymethylmethacrylate (PMMA) was used. Information on the mechanical properties of this material, for FEM studies, can be found in [13], [14], [15] and [16]. These works report on linear analyzes to obtain EQV, implant deformations and structural performance under impact loads.

The study, in this case, focuses only on the functionality of the implant, therefore, the skull-implant interface fixation system is not considered in the simulation model. The mechanical properties of PMMA are presented in Table 1.

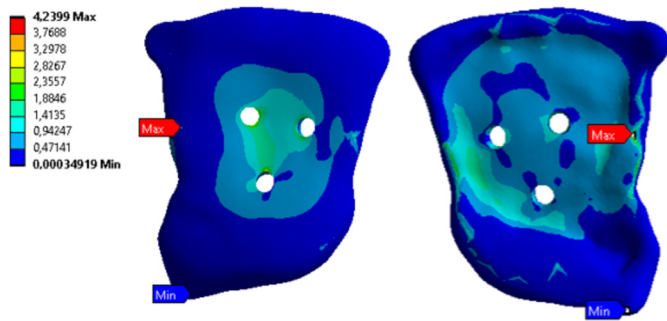


Fig. 11. Equivalent Von - Misses stresses of the implant. Outside the implant (right). Inside the implant, in contact with the internal cranial tissues (left).

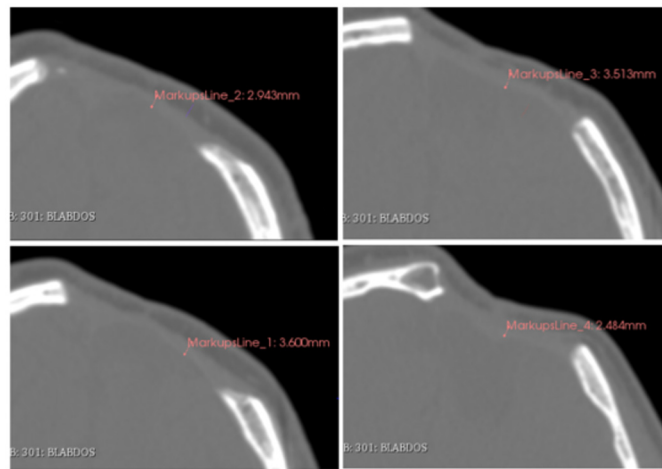


Fig. 12. Pre-surgical measurements from the outer cerebral rim to the meninges.

### 2.8. Determination of the implant mechanical behavior

The mechanical behavior is analyzed for two different situations: implant with pattern and without pattern of holes.

#### 2.8.1. Mechanical strength with hole pattern

With the help of the FEM analysis of the personalized implant, it is possible to observe the equivalent Von-Mises forces. The concentration of these stresses can be seen in the central part of the implant, an action that only locally affects the global resistance of the device. As shown in Fig. 11, the stresses reached were 3.29 MPa (minimum stress on the inner part of the implant) and 4.23 MPa (maximum stress on the outer part of the implant) respectively.

Based on the EQV analysis and the stress contours, it is decided to place the fixing elements at the upper right and lower left ends, taking as reference the center of the device or the load application point (see Fig. 11 (right) and Fig. 11 (left)). Such a decision is in correspondence with the absence of efforts in that area.

#### 2.8.2. Critical deflection with hole pattern

Another important parameter during the structural performance of the implant is the deflection, taking into consideration that its location is close to the meninges and the brain mass. Thus, it is necessary to avoid possible neurocranial damage caused by the implant, as it yields to external pressure. Directional deviation and pressure could induce a greater effort, associated with contusions or other trauma, on brain tissue [17], [18].

Fig. 12 shows the tomographic images used to estimate the critical deflection of the implant from measurements in the axial direction of the trauma area, so that, once placed, it is possible to compare the

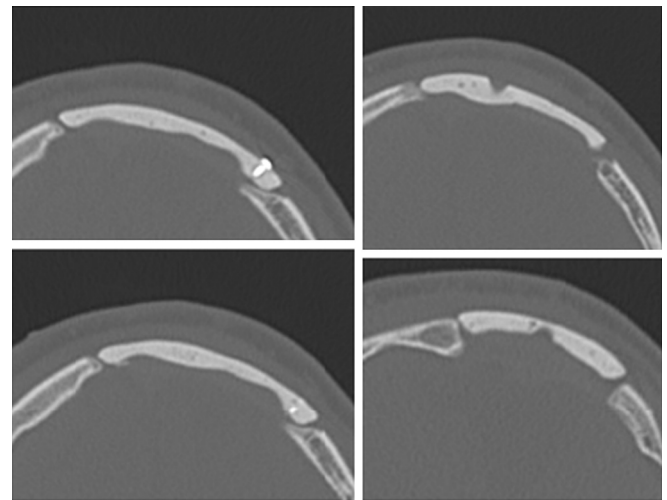


Fig. 13. Post-surgical axial tomographic images: correction of tissue deformation and position.

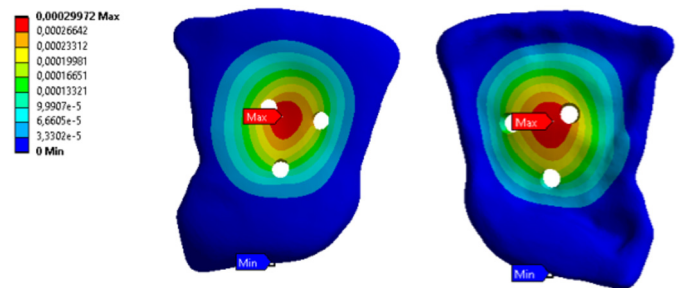


Fig. 14. Directional deflection of the implant.

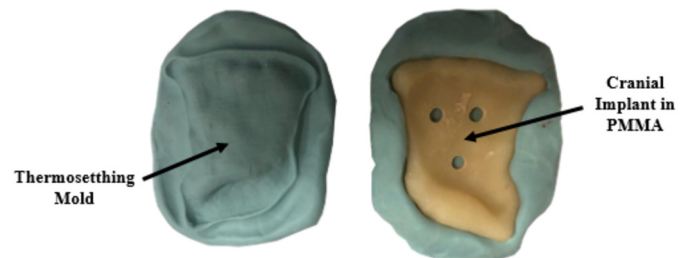


Fig. 15. Thermosetting mold for the manufacture of the definitive implant.

deflection of the device, caused by the estimated load, and verify that there is no damage or pressure on the meninges.

Fig. 13 shows the result of the replacement of the internal tissues and the recovery of the facial curve, once the implant has been placed. It is also observed that the implant does not exert compression on the brain mass or on the meninges.

The simulated global directional deflections can be seen in Fig. 14. Given the applied load, they reach values of 0.00023 mm and 0.00029 mm, measured from the outside and inside of the device, respectively. In both cases, the critical value that could induce some intracranial trauma (3.60 mm) is not exceeded. Other analyzes that involve the deflections caused by the action of external load, can be consulted in [19].

#### 2.8.3. Cranial implant manufacturing

The 3D printing models served as the basis for obtaining a thermostable mold used for the manufacture of the definitive PMMA-based implant (see Fig. 15). The device has a built-in hole pattern.



Fig. 16. Implant tests on the cranial model.

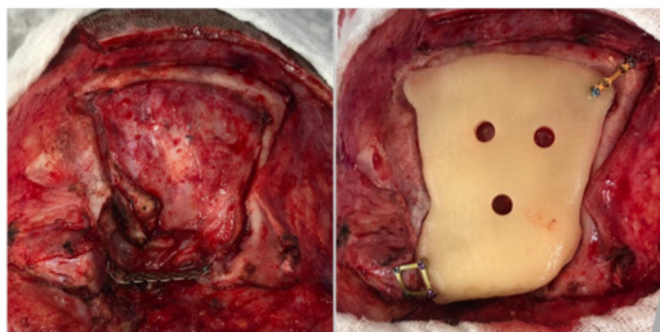


Fig. 17. Surgical intervention: cranial implant placement and fixation.

The additive techniques applied were Fused Deposition Modeling (FDM) technology to generate the anatomical trial models, and pouring of the liquid PMMA material into the mold cavity to obtain the definitive implant.

The medical assessment is then carried out with the help of the anatomical test models (Fig. 16), verifying the almost perfect fit of the implant in the replacement area, and the corresponding planning and surgical simulation. In this step, the decision on the fixation system to be used was also made.

Then the device is sterilized at low temperature with Hydrogen Peroxide with the STERIS Healthcare equipment.

Table 2. Comparative mechanical results of the simulation with and without hole pattern. Source: The authors.

Implant	Mechanical strength (MPa)	Critical deflection (mm)
Hole pattern	3.29 – 4.23	$2.7 \times 10^{-4}$
No hole pattern	2.82 – 3.63	$1.7 \times 10^{-2}$

### 2.9. Intraoperative phase

During the surgical intervention, the cranioplasty was successfully performed. The replacement device was correctly adapted to the cranial cavity, as planned, and there was no need for corrections (see Fig. 17).

The customized implant was fixed at 2 points using a titanium system for cranial flaps (Zimmer Biomet microplates and screws). The operative time was 60 minutes.

### 2.10. Postoperative phase

In the postoperative evaluation no neurological complications were observed, the medical discharge occurred 48 hours after the intervention. Fig. 18 shows the patient’s condition during a follow-up visit two months after surgery. And a tomography to verify the status of the implant.

## 3. Results

In addition to the planning of the surgery with the help of the anatomical models, the evaluation of the implant from the mechanical point of view, and its manufacture, the simulation of the mechanical behavior (under the same conditions) of the implant without the hole pattern was also carried out. Table 2 shows the comparison between the results obtained in both situations.

The mechanical stress is lower for the implant without the hole pattern, while the deflection is higher. This second is explained because the deformation occurs globally; while when holes are present, the deformation occurs in a localized way.

The mechanical behavior of the implant is also determined by its geometry, which in turn is governed by the specific anatomical structure of the person receiving the implanted device.

## 4. Discussion

Anatomical bio models manufactured with 3D printing were very useful for surgeons in planning the surgical approach.

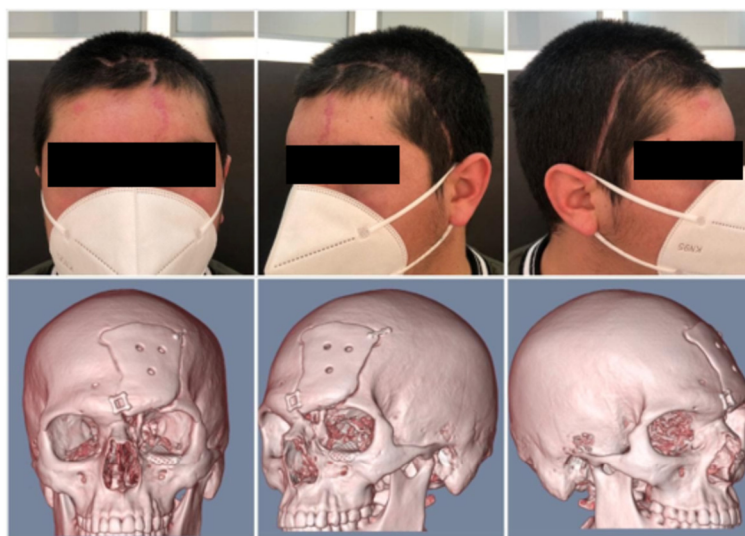


Fig. 18. External aspect of the patient two months after surgery (above). Post-Surgical tomography (below).



The personalized implant was designed with PMMA for cranial reconstruction, which was evaluated with the help of simulation, under a static load of 50N according to studies reported in [10]. The distribution of stresses and deflections in the implant was verified, the biomechanical results were evaluated regarding the planning of the anatomical reconstruction. The greatest stresses generated in the implant are in the range of 3.29 MPa to 4.23 MPa, values below the yield limit of the material, which guarantees the functionality of the implanted device. The unitary strain of the implant is  $650\mu\epsilon$  at most, also below the maximum non-physiological limit of  $3000\mu\epsilon$ , supported by the results of Frost [20].

The comparison was made, in terms of Von-Misses efforts, between the implant with and without the pattern of holes (the latter allows the evacuation of fluids and favors osseointegration). In the absence of this pattern, lower stresses were obtained, in the range of 2.82 MPa to 3.63 MPa, therefore, greater resistance of the implant against external impacts. However, because of the physiological advantages of escape routes, the medical advantage prevails over the mechanical one. Also, the presence of the holes causes less deflection of the device, increasing its safety, since it reduces the risk of affecting internal structures.

The experience of applying the methodology presented in [21] is manifested in this study.

For the conformation and fixation of the implant designed in this case, Polylactic Acid (PLA) was used to print the anatomical trial model, which in turn allowed for surgical planning. Thus, biocompatibility is not necessary for this model of the patient's skull. For the manufacture of the final personalized implant, a medical grade silicone mold was used, which does not need to have biocompatibility properties either. This mold allows obtaining the geometric and surface characteristics of the prototype. In addition, the internal surface (in contact with the PMMA) is covered with a release agent. The definitive device was manufactured with PMMA, and it is known from previous studies that this polymeric material can reach a degree of biocompatibility of up to 95%. On this it is possible to consult the results presented in, for example, in [22], [23], [24], [25]. During the placement surgery, the personalized implant was properly sterilized before being placed.

A system of titanium micro plates and micro screws is used to fix the device to the bone. This metal presents a proven biocompatible response when in contact with the internal tissue of the human body. However, the resistance of Titanium to corrosion is also of importance because the release of ions from the surface can cause, among other phenomena, toxicity. A reference study on the behavior of Titanium against the phenomenon of corrosion, can be consulted at [26]. In the reported case, considering that the implant is immersed in a complex living environment and that the surface of the micro plates were not processed, what has prevailed has been medical follow-up for a considerable time after surgery. There were no complications. The medical team also learned that the patient emigrated, and did so under the proper recommendations for maintaining observation and medical control over the status of the implant.

## 5. Conclusions

From an engineering perspective, the reconstruction of cranial defects should aim at optimizing custom implant designs, heterogeneously distributing the biomaterial based on the Von-Misses forces required, according to the desired functionality. This implies considering, within the design parameters, the magnitude and direction of the loads to be supported by the bio-anatomical ensemble.

In cases of cranial reconstruction, the larger the defect, the greater the complexity of the design in terms of strength, mechanical stability and aesthetic-functional requirements.

The application of finite elements allows a better understanding of the biomechanical performance of the implant, and thus determine more realistic scopes in terms of the level of recovery from the con-

dition prior to the trauma, especially for people who perform intense physical activity.

In the surgical process, unexplored scenarios could be presented (anatomical complexity, type of clinical approach not reported) and virtual images could not be enough help for the success of the surgery. In such scenarios, personalized 3D printed anatomical models facilitate preoperative planning, favor speed and precision with minimization of surgical execution times, and better post-surgical results.

A line of work that remains open in this type of applications is related to the study of the interaction between the forces generated by the cranial model (implanted material – natural bone structure), in the face of the absorption of forces generated, for example, due to an impact or other external action. Controlling unitary deformations would be important, since bone degradation due to non-physiological changes would be minimized. From the mathematical point of view, in such situations nonlinear simulation models are required to estimate the failure limits of the assembly.

This research with a practical approach describes the application of computational analysis, rapid prototyping by 3D printing with FDM technology, and multidisciplinary evaluation for the treatment of cranial defects with personalized bone reconstructions.

In this work, which reports on the application of already established techniques but typical of regions with a high economic development, it is also evidenced on the level reached in the ecuadorian austro region, where it is already possible to carry out this type of intervention following a methodology that describes the entire process, from computerized axial tomography or magnetic resonance imaging, to the materialization of the personalized bone implant, regardless of the additive manufacturing techniques used or the biomaterials that are decided to be used (with prevalence of medical criteria for make such decisions).

It is also possible to highlight that, for example, compared to the procedures proposed and reported in [27], [28] the applied methodology could reduce the effective total time for obtaining and placing a personalized bone implant by a certain percentage (approximately 5%, although this data has not been strictly verified yet), considering the simplification of the workflow (from the point of view of the computational tools used) in relation to the flows described in the previous articles.

## Declarations

### Author contribution statement

Freddy Patricio Moncayo-Matute; Pablo Gerardo Peña-Tapia; Paúl Bolívar Torres-Jara: Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

Efrén Vázquez-Silva: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Diana Patricia Moya-Loaiza; Gabriela Abad-Farfán; Andrés Fernando Andrade-Galarza: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

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### Data availability statement

Data included in article/supplementary material/referenced in article.

### Declaration of interests statement

The authors declare no conflict of interest.

### Additional information

No additional information is available for this paper.

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