

*Article*

CLINICAL APPLICATION OF A PATIENT-SPECIFIC 3D PRINTED MEDICAL DEVICE: SURGICAL PLANNING AND FINITE ELEMENT ANALYSIS OF CRANIAL IMPLANT MANUFACTURED WITH PMMA AND PEEK

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**Abstract:** The article reports on a patient who required a cranial protection system. Using additive 1 manufacturing techniques and surgical planning with the help of bio-models, a patient-specific bone 2 implant solution was proposed that allows aesthetic restoration of the affected area and provides 3 an adequate level of protection. In addition, through a comparative analysis with finite elements, 4 the mechanical response to external actions of the medical device, printed with two materials: 5 polymethylmethacrylate (PMMA) and polyether-ether-ketone (PEEK), is simulated. The tested 6 materials have recognized biocompatibility properties, but their costs on the market differ significantly. 7 The results obtained demonstrate the similarities in the responses of both materials. It offers the 8 possibility that low-income people can access these devices, guaranteeing adequate biomechanical 9 safety, considering that PMMA is a much cheaper material than PEEK. 10

**Keywords:** polymethylmethacrylate; polyether-ether-ketone; custom medical device; finite element 11

analysis. 12

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1. **Introduction** 13

The research does not stop on the possibilities on the use of the Polyether-ether-ketone 14

(PEEK) polymer, as a biomaterial for the development of custom-made bone prostheses 15

and other types of applications in the field of medicine; since it has been proven to be an 16

ideal replacement for metallic materials such as titanium and its alloys, and polymers such 17

as Polymethylmethacrylate (PMMA). The advantages of PEEK revolve around its lightness, 18

its modulus of elasticity close to that of natural bone and its good biocompatibility. If the 19

biological, mechanical and manufacturing properties of the PEEK are compared with the 20

above mentioned materials the PEEK has supremacy at the moment. 21

22

For example, in [[1](#_bookmark18)] a study carried out with 45 patients with unilateral post-traumatic 23

defect of the orbital wall, who received subsequent treatment with personalized reconstruc- 24

tions with PEEK, or with pre-bent titanium plates, is reported. The patients were divided 25

into two groups, the obtained results showed that there was no infection, no inflammation, 26

nor decreased vision in any of the groups. On the other hand, diplopia did not appear 27

in 82.1% of the patients treated with PEEK, compared to 70.6% of those treated with tita- 28

nium (control group). The mean surgery time was 54.25 *±* 16.8 *min* with the application 29

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of personalized PEEK-based implants, compared to 82.9 10.8 *min* for the control group. 30 The mean difference between intact and damaged orbital volume was 1.9 1.4 *cm*3 in the 31 control group versus 0.74 0.6 *cm*3 in the PEEK group (*p <* 0.05). Thus, the best results 32 were obtained for PEEK in terms of restoring the volume and shape of the damaged orbit. 33

*±*

*±*

*±*

34

In [[2](#_bookmark19)], is presented a comparison between properties of PEEK elements printed in 3D 35 applying Fused Deposition Modeling (FDM), and elements milled with the same material. 36 The surface treatment technique used yielded better results (elimination of manufacturing 37 defects and roughness for better cell adhesion and distribution in 3D printed devices). In 38 addition, no toxicity was observed in the subsequent 48 hours, during the evaluation of 39 adhesion assessed by the cultivation of primary human endothelial cells and osteoblasts. 40 On the other hand, considering the limitations of PEEK due to its bio-inertness, hydropho- 41 bicity and susceptibility to microbial infections, in [[3](#_bookmark20)] is reported on the review of some 42 modification strategies, such as the superficial one and the incorporation of materials in the 43 base matrix, which can increase the biological activity of the material and its antibacterial 44 and bio-active performance. Another promising approach, regarding the improvement 45 of the surface bio-activity of custom 3D printed PEEK implants by fused deposition, is 46 reported in [[4](#_bookmark21)]. The authors of this research obtained encouraging results by immersing the 47 material for two minutes in concentrated sulfuric acid to obtain the so-called sulfonated 48 PEEK. 49

50

From the point of view of design and bio-mechanics, studies have been carried out 51

on the behaviour of human bones manufactured from PEEK; finding similarities between 52

the mechanical response of the artificial element and that of the natural one [[5](#_bookmark22)]. Fracture 53

mechanisms have been revealed and the material’s response to prolonged exposure to 54

high temperatures has been studied [[6](#_bookmark23)]. The authors of [[7](#_bookmark24)] design micro-structures with 55

PEEK and its compounds to improve implant compatibility. A homogenization process is 56

carried out, controlling the isotropic lattice structure, with the help of reduced graphene 57

oxide (rGO) and calcium hydroxyapatite (cHAp). With the improved design it is possible 58

to eliminate light imperfections, increasing the stability of the structure. The controlled 59

homogenization, porosity, and particle size distribution help increase cellular infiltration 60

and biological integration of the PEEK, rGO and cHAp compounds. 61

62

Regarding the manufacturing techniques that are most applied, 3D FDM printing 63

predominates. The authors of [[8](#_bookmark25)], show the supremacy of the 3D FDM technique over 64

subtractive manufacturing processes such as Computerized Numerical Control (CNC) 65

milling, and show results achieved at the University Hospital of Basel, despite the diffi- 66

culties involved in the medical certification of this workflow. Likewise, in [[9](#_bookmark26)], the first 3D 67

printed scaphoid prosthesis is described, at the Cantonal Hospital Baselland, Switzerland, 68

using medical grade PEEK with fused filament manufacturing (FFF) technology. This same 69

technique is analyzed in [[10](#_bookmark27)], and the favourable temperature conditions during 3D print- 70

ing are highlighted, compared to processes such as selective laser sintering and injection 71

moulding. 3D printing overcomes many of the restrictions of other related techniques and 72

allows to offer better solutions that are structurally adapted to the needs of the patient. 73

Then, in [[11](#_bookmark28)], the process of solving a defect in cranioplasty caused by a deficiency of the 74

titanium mesh used initially is described, which weakened the arch of the left eyebrow and 75

caused a deformation of a sinus path. The problem was corrected by applying an additively 76

manufactured cranial implant with PEEK for the new cranioplasty. 77

78

In [[12](#_bookmark29)], it is reported on experimentation with PEEK sheets, manufactured by Single 79

Point Incremental Forming (SPIF), which is a flexible and matrix-free forming technology 80

that allows complex shapes to be obtained. In addition, it is of great economic profitability 81

in reduced production. The results of the SPIF tests allowed the development of analyses 82

in terms of formability, failure modes, temperature, forming force and geometry precision; 83

and thus, evaluate optimal parameters and methodologies for the manufacture of prosthe- 84 ses. All the above allowed us to verify the potential of manufacturing personalized medical 85 devices through incremental sheet formation (ISF) processes in combination with advanced 86 biocompatible polymers such as PEEK. 87

88

Many reports have also been published on the results of the application of surgical 89

techniques and intervention planning, and follow-up of implanted patients. For example, 90

in [[13](#_bookmark30)], the evolution of six patients operated on for intraosseous meningiomas is reflected. 91

The resection strategy was planned and discussed with the manufacturer of the custom 92

PEEK bone implant used in the reconstructive phase. The authors of the paper state that 93

*“the described technique is simple, precise and effective to achieve good results in disease control, as* 94

*well as in aesthetic and functional restoration”*. In [[14](#_bookmark31)], is described a patient in whom a PEEK 95

implant was applied as a solution for the remodelling of the skeleton and soft tissues in 96

facial aesthetic plastic surgery. The surgeons thus responded to the patient’s complaints 97

about hypoplasia of the malar area, after three operations of placement and replacement 98

of silicone implants. The person expressed dissatisfaction regarding the symmetry and 99

sensation through the skin of the lower eyelid, at the edge of the prostheses. After the 100

application of the PEEK variant, no complications were reported and the results seem to be 101

satisfactory for both parties. 102

103

A very complete summary of the benefits and potential of PEEK has been published 104

by Abid Haleem and his collaborators in a letter to the Editor [[15](#_bookmark32)]: the material in question 105

is suitable for artificial bone replacements because it is biocompatible, non-toxic, and non- 106

inflammatory and osteoconductive. Its low molecular weight makes it ideal in orthopaedics 107

for fracture fixation and osteotomies, spinal fusions, and ligament reconstructions. Its high 108

resistance provides it better mechanical properties compared to other traditionally used 109

materials, since it supports the loads generated in the human body. It also helps to evaluate 110

the evolution of fractures, thanks to the fact that it is radiolucent in radiographs. And it is 111

compatible with Computerized tomography (CT) and Magnetic resonance imaging (MRI) 112

technologies, that is, PEEK does not interfere with these imaging techniques. 113

114

Before the appearance of PEEK, another polymer used in this type of surgical proce- 115

dure and treatment of bone conditions was PMMA. In the review article [[16](#_bookmark33)] a section is 116

dedicated to the comparison between both materials, in terms of advantages and disadvan- 117

tages in implantology applications. As for PMMA, it polymerizes through an exothermic 118

reaction that can be harmful to overlying soft tissues [[17](#_bookmark34)]. Implants based on this material 119

cannot be infiltrated by new bone tissue due to its lack of porosity, it interferes with os- 120

teoconduction and vascularization, it does not interact with the surrounding tissue, and it 121

may be susceptible to higher infection rates ([[18](#_bookmark35)]; [[19](#_bookmark36)]; [[20](#_bookmark37)]; [[21](#_bookmark38)]). On the other hand, four 122

studies ([[22](#_bookmark39)]; [[23](#_bookmark40)]; [[24](#_bookmark41)]; [[25](#_bookmark42)]) report similarities between PEEK and PMMA in terms of the 123

success rate of treatment and rate of complications. 124

125

This paper reports on a planned and materialized cranioplasty with PMMA in a health 126

institution in southern Ecuador. And as part of the investigation, the performance of the 127

customized bone implant, manufactured with PEEK and with PMMA, is compared at 128

the level of simulation of the mechanical response. This considering the advantage of 129

PMMA over PEEK in terms of cost. A random internet search found the value of PMMA 130

to be between USD 1.99 and USD 3.80 per *kg*. While the price of medical-grade PEEK 131

resin is between USD 1450 and USD 1470 per *kg*. A limitation of PEEK technology is 132

the requirement for support structures, which incurs additional costs. Considering the 133

above, and that the average purchasing power of the inhabitants of this area is low, the 134

PMMA-based variant of implants remains a viable option for many people who do not 135

have the necessary resources to afford the best PEEK-based solution. 136

1. **Materials and Methods** 137
   1. *Data acquisition Medical Imaging and Segmentation* 138

A computed tomography of the patient was performed, and the images were saved in 139

a high-resolution Digital Imaging and Communications in Medicine (DICOM) file, with 140

voxels of 512 512 *Z*, where *Z* varies from 150 to 520 slices. The images were then pro- 141

*× ×*

cessed using the open-source software *3D Slicer* ([https://www.slicer.org](https://www.slicer.org/)) to generate the 142

Standard Tessellation Language or Stereolithography (STL) file of the anatomy of interest. 143

144

The tomographic images were segmented with a specific intensity, called Hounsfield 145

Unit (HU), which measures the attenuation coefficient on the grey scale for compact tissues, 146

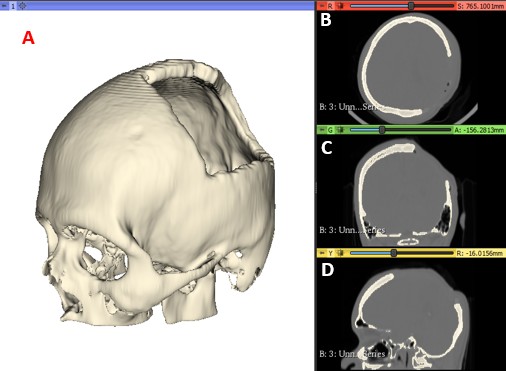
in this case of the target anatomical region of the patient. 147

148

For the present study, values of 211.73 2755.0 HU are used to segment the cranial 149

*−*

compact bone model. In Figure [1](#_bookmark0) the medical images and segmentation are shown. 150



**Figure 1.** CT Scan Images: segmented model (**A**), axial view (**B**), coronal view (**C**) and sagittal view (**D**).

* 1. *Finite Element Method* 151
     1. Cranial Model 152

To obtain the three-dimensional geometry of the patient’s cranial model, the STL file 153

was processed by treatment of meshes and cloud of points, with reverse engineering tools 154

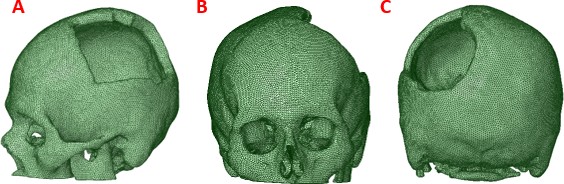
provided by the *Autodesk Meshmixer* software ([https://www.meshmixer.com](https://www.meshmixer.com/)), and Ansys 155

Workbench. 156

157

This process was applied to the anatomical model of the patient to obtain a precise 3D 158

model of his anatomy, which was then used for finite element analysis (FEM). (Figure [2](#_bookmark1)) 159



**Figure 2.** Computational model of the skull: (**A**) Lateral view, showing damage or trauma to the local parietal bone. (**B**) Front view of the cranial model, the defect is observed, and the lack of symmetry.

(**C**) Posterior view of the cranial model.

* + 1. Customized Implant Model 160

The post-processed model of the skull with the defect was used for the reconstruction 161

with the cranial implant, using the *Autodesk Meshmixer* software. A symmetrical reference 162

plane was created in the three-dimensional model. For the restoration of the affected area 163

(missing cranial bone), the structural symmetry of the human body was assumed. With the 164

editing tools of the software, the healthy side of the structure is inverted, creating a mirror 165

image that can be superimposed on the area to be restored. Both parts of the structure are 166

assembled to fill the cavity. Subsequently, the Boolean subtraction tool is applied to obtain 167

the required custom implant design (Figure [3](#_bookmark2)). 168



**Figure 3.** Reconstruction of the cranial 3D model with the help of the customized implant to simulate the clinical scenario: (**A**) Geometric model of the implant to cover the defect in the patient’s parietal area. (**B**) Geometric model of the customized implant, coronal contour perimeter zone. (**C**) 3D view of the implant, showing the internal shape and the variation of the angulation of the contact interface along the contour.

* + 1. Assembly of the skull model and medical device 169

Figure [4](#_bookmark3) shows the reconstructed cranial model of the patient. The design of the 170

implant was carried out in a personalized way, and when the person receiving the medical 171

device requires it (in extreme cases), this model is also useful for simulations. For example, 172

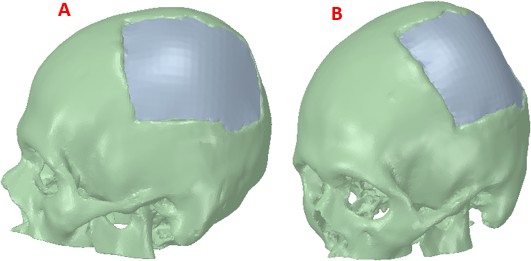
in high-performance sports activity, failures of implanted medical devices have been evi- 173

denced, causing structural and physiological damage to the bone. An adequate simulation 174

study can contribute to the determination of the mechanical parameters that personalized 175

medical devices must present to be able to withstand certain static loads, also simulating 176

events that may take place during the performance of these types of activities [[26](#_bookmark43)]. 177



**Figure 4.** Reconstruction of the skull: (**A**) Lateral view of the skull and customized implant, showing the reconstruction. (**B**) Frontal View, defect covered by the cranial implant.

For the simulation studies in this case, the materials used for the computational analy- 178

sis were two: one of low cost, widely used in operating rooms for immediate cranioplasties, 179 and in the dental sector, PMMA. And the second, of high performance and high cost, 180 although with better biocompatibility properties, industrial grade PEEK, is used in Latin 181 American countries for medical purposes. 182

* + 1. Coupling Details 183

For the successful fixation of the implant, it is important to detail the interface contours 184

of the cranial profile, and the location of the implant. For this, the perimeter area of the 185

damage is studied and how the stress transfer occurs under considered external load con- 186

ditions. In the article [[27](#_bookmark44)] the relevance of analyzing the contacts of natural bone-implant 187

interfaces is highlighted, in addition, its authors corroborate that the edges of the defect 188

must have a surgical preparation at positive angles, while the edges of the device to be 189

implanted must have opposite angles, in such a way that the “fit” will be the best possible, 190

thus contributing to the coupling safety. 191

192

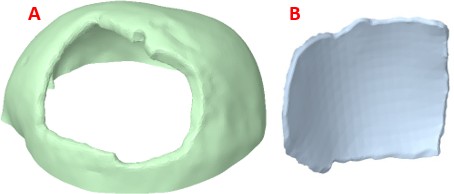
If the implant does not have support on the cranial bone, in the presence of external 193

loads, stresses are transferred to the fixing elements, which endangers the integrity of the 194

system. High stresses would potentially compromise the bone morphology required for 195

anchorage. For the case reported in this paper, the fixation systems were not analyzed since 196

full support of the implant was achieved on the cranial damage perimeter. (Figure [5](#_bookmark4)) 197



**Figure 5.** Configuration of the model to simulate the clinical scenario, highlighting the contour of the defect and adjustment of the implant: (**A**) Geometric model of the location of the defect in the left lateral parietal area of the patient. (**B**) Geometric model of the customized implant, showing the contours of the perimeter adaptation to the cranial bone.

* + 1. Boundary conditions 198

For the analysis using the finite element method, the structural static modulus was 199

considered. The established loading conditions were assigned to the external surface of the 200

implant. An external load of 8000 *N* was applied to the centre of the implant [[28](#_bookmark45)], which 201

simulates the static load of a collision with some foreign object. And a 2000 *N* load was 202

also applied to the top left of the implant, simulating what happens during rest. 203

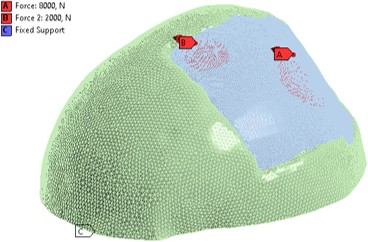
204

For reducing the computational load in the simulation, the cranial model was adjusted 205

in such a way that the number of mesh elements was reduced, and the simulation time 206

decreased. An embedment condition called “Fixed Support” was also assigned at the base 207

of the axial slice of the skull with zero displacements and rotations (Figure [6](#_bookmark5)). 208



**Figure 6.** Loading conditions: (**A**) 8000 *N* force acting on the central area of the implant. (**B**) 2000 *N* force, acting on the upper left parietal part of the implant. (**C**) Fixed Support, embedment at the base of the skull.

* + 1. Mesh Conditions 209

The simulation was carried out with the help of the *ANSYS WORKBENCH R21.1* 210

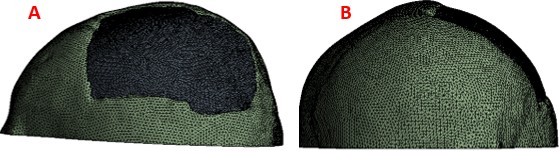
software (ANSYS Inc., Canonsburg, Pennsylvania, USA). The selected mesh was made up 211

of tetrahedral elements (SOLID185). The mesh refinement tests yielded a 7% convergence 212

guarantee. The model is composed of 329898 nodes and 178488 elements of size 5 *mm*. 213

“Bonded contact” was also considered for border conditions at the implant-cortical bone 214

interface, the most realistic according to [[29](#_bookmark46)]. Details of the mesh can be seen in Figure [7](#_bookmark6). 215



**Figure 7.** Mesh elements: (**A**) Mesh of the implant with fixation towards the skull. (**B**) The meshing of the cranial model with the implant.

* 1. *Material properties* 216

In the computational model, the materials were assumed to be isotropic, homogeneous 217

and linearly elastic, by [[30](#_bookmark47)]; [[31](#_bookmark48)]. The custom medical device was made of PMMA and 218

PEEK. Table [1](#_bookmark7) presents the mechanical properties of each material used in the simulations. 219

**Table 1.** Material properties of components used in the simulation of the assembly model 3D.

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Cranial cortical bone** | **PMMA** | **PEEK** |
| *Young’s modulus* | *Eb* = 15000 *MPa* | *EPMMA* = 3000 *MPa* | *EPEEK* = 3600 *MPa* |
| *Poisson’s ratio* | *µb* = 0.3 | *µPMMA* = 0.38 | *µPEEK* = 0.39 |
| *Ultimate tensile* | *σu*,*b* = 130 *MPa* | —– | *σu*,*PEEK* = 172 *MPa* |
| *Yield strength* | —– | *σy*,*PMMA* = 72 *MPa* | *σy*,*PEEK* = 90 *MPa* |
| *Reference* | [[32](#_bookmark49)] | [[33](#_bookmark50)] | [[33](#_bookmark50)] |

Once the mechanical properties of the components were introduced, FEA simulations 220 were carried out to study the behaviour of the cranial model under external static loads, 221 which are useful to understand how the stresses are distributed in the cranial area during 222 the performance of the considered activities. 223

* 1. *Surgical Planning and Manufacturing* 224

In the manufacture of the anatomical test model, for surgical planning, the additive 225

manufacturing technology Fused Deposition Modeling (FDM) was applied, with the help 226

of a *Creality CR-X Pro 3D FDM* printer (Shenzhen Creality 3D Technology Co., Ltd.). 227

228

As printing material, Creality’s HP PLA 1.75 *mm* Series filament was used. The STL 229

file was used as the basis for reading, processing and obtaining the route code, while for the 230

3D printing process, the *Creality Slicer 1.2.3* software was used. The support material was 231

removed manually, paying special attention not to affect the surface of the bone structure. 232

Table [2](#_bookmark8) presents the characteristics of the FDM technology. 233

**Table 2.** FDM additive manufacturing characteristics and parameters.

**Characteristics and manufacturing parameters Fused Deposition Modeling**

*Company and model* Creality CR-X Pro (2019 Updated)

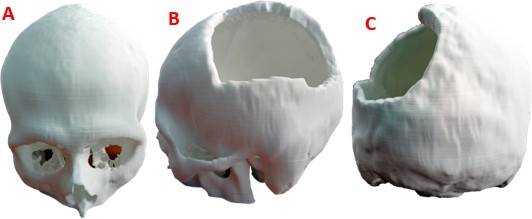
*Maximum build envelope* 300 300 400 *mm*3 *Nozzle diameter* 0.4 *mm*

*× ×*

*Positioning resolution (X/Y/Z)* 1.25 *µm*/1.25 *µm*/1 *µm Selected layer thickness* 0.10 *mm*

*Printed filament line width* 0.4 *mm*

The 3D version of the test anatomical model, printed on a 1:1 scale, can be seen in 234 Figure [8](#_bookmark9). The level of damage in the left parietal area of the patient is considerable, so the 235 results of the finite element analysis offer the necessary support for the medical device to 236 withstand demand loads. 237

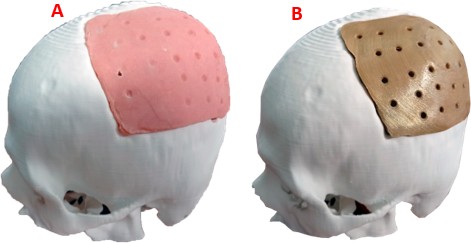


**Figure 8.** Cranial model for surgical planning: (**A**) Frontal view. (**B**) Lateral view, area of damage. (**C**) Back view.

The trial anatomical model was used by the surgeon in the preoperative evaluation 238

and surgical planning, thus verifying the functionality of the customized device. The test 239

model of the customized implant was also used to obtain a sterile mold of thermosetting 240 material, with which the final PMMA-based implant was made. For its part, the customized 241 implant model, in industrial PEEK, was manufactured with the help of a *FUNMAT PRO 410* 242 printer, applying FFF additive technology. Subsequently, the definitive test of the implant 243 was carried out on the cranial anatomical model and it was verified that the shape was 244 consistent with the virtual models (Figure [9](#_bookmark10)). 245



**Figure 9.** Cranial model with the patient-specific implant: (**A**) Cranial bio-model with the PMMA implant coupled. (**B**) Cranial bio-model with the PEEK implant coupled.

1. **Results** 246

Four simulation cum-shots were performed under the “Force” load condition of 247

2000 *N* applied to the external surface of the cranial bone-coupled PMMA-based custom 248

implant model, and with the same condition applied also on the external surface of the 249

personalized implant model based on PEEK coupled to the cranial bone. The geometry of 250

the personalized implants, for both materials, presents variable thicknesses. Towards the 251

central point, where the 2000 *N* load was applied, the thickness is 2.58 *mm*; while at the 252

point where the 8000 *N* load is applied, the thickness is 3.02 *mm*. 253

254

Likewise, for the load condition “Force” of 8000 *N* applied in the central zone of the 255

external surface of the model of the personalized PMMA implant, coupled to the cranial 256

bone. And the same load condition was applied to the central area of the external surface 257

of the custom PEEK implant model, coupled to the cranial bone. This allowed us to 258

obtain the von Mises stress distribution for the implant and the cranial bone, and the total 259

deformations (Table [3](#_bookmark11)). 260

**Table 3.** Von Mises stresses and total deformation of the structures1.

**Structure Material von Mises**

**Total Deformation [***mm***]**

**Load State [***N***]**

*Skull Cortical bone* 40 *±* 10 0.080 *±* 0.001 2000

**Stress [***MPa***]**

*Implant PMMA* 40 *±* 7 0.56 *±* 0.02 2000

*Skull Cortical bone* 36 *±* 8 0.073 *±* 0.001 2000

*Implant PEEK* 44 *±* 5 0.42 *±* 0.08 2000

*Skull Cortical bone* 83 *±* 7 0.210 *±* 0.008 8000

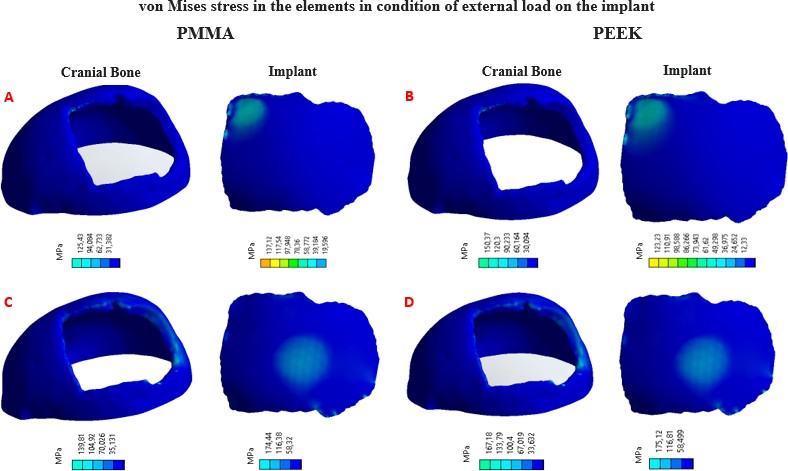
*Implant PMMA* 103 *±* 20 2.71 *±* 0.21 8000

*Skull Cortical bone* 59 *±* 22 0.21 *±* 0.01 8000

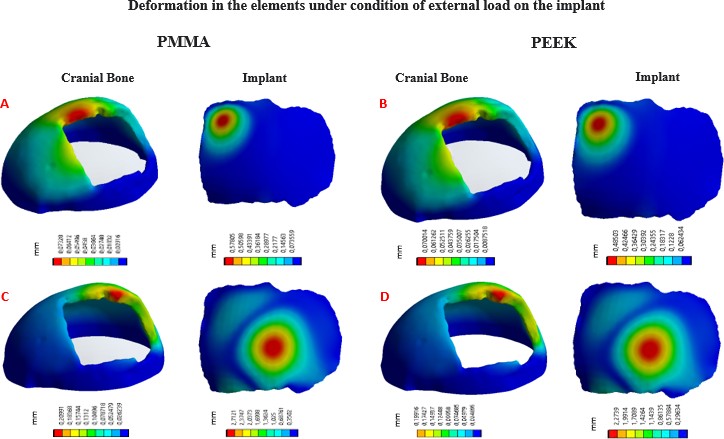
*Implant PEEK* 99 *±* 11 2.30 *±* 0.03 8000

1 Each load state was applied to the external surface of the implant. The effort with the deformation generated in the cranial structure is the result of the coupling and transfer of the load on the implant.

In Figure [10](#_bookmark12), the von Mises stress distribution for each element can be seen, according 261 to the state of external load. In Figure [11](#_bookmark13), the total deformations generated by the states of 262 external loads, in the implant and the cranial bone, are detailed. 263



**Figure 10.** von Mises stress distribution in the implant and cranial bone: (**A**) Load condition “Force” 2000 *N*, implant with PMMA. (**B**) Load condition “Force” 2000 *N*, implant with PEEK. (**C**) Load condition “Force” 8000 *N*, implant with PMMA. (**D**) Load condition “Force” 8000 *N*, implant with PEEK.



**Figure 11.** Deformation in the implant and cranial bone: (**A**) Load condition “Force” 2000 *N*, implant with PMMA. (**B**) Load condition “Force” 2000 *N*, implant with PEEK. (**C**) Load condition “Force” 8000 *N*, implant with PMMA. (**D**) Load condition “Force” 8000 *N*, implant with PEEK..

* 1. *Statistic Analysis* 264

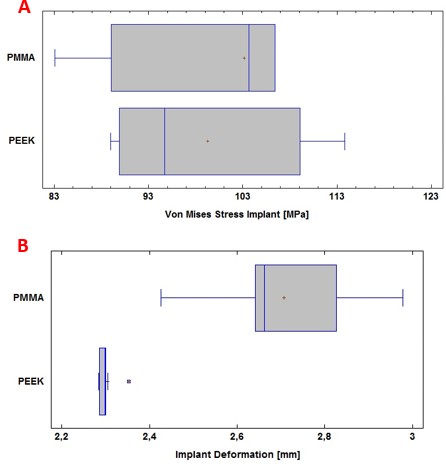
The statistical analysis of the computational results was carried out by applying the 265

analysis of variance of one factor (ANOVA), with the help of the *SPSS Statistics* software 266

(SPSS, Inc., Chicago, IL, USA). In Figure [12](#_bookmark14) (A), the von Mises stress levels for the per- 267

sonalized implant with PMMA and PEEK are observed. Figure [12](#_bookmark14) (B) shows the total 268

deformation of the implant with each material under the load condition “Force” 8000 *N*. 269



**Figure 12.** Statistical analysis: (**A**) von Mises stresses of the PMMA and PEEK implants, respectively.

(**B**) Deformation of the PMMA and PEEK implants, respectively.

In this computational study, the effect of using PMMA and PEEK for the protection 270

of the skull against the action of a static load of 8000 *N* on the surface of the device was 271 examined. The mean and standard deviation of the von Mises stress analysis for the PMMA 272 implant was 103 20 *MPa*; while for the PEEK implant, it was 99 11 *MPa*. In this case, 273 no significant differences are observed (*p >* 0.05), with a confidence level of 95 %. 274

*± ±*

275

The total deformation of the PMMA implant was also examined, where the mean 276

and standard deviation of the analysis were 2.71 0.22 *mm*; while for the PEEK implant, 277

*±*

2.30 0.03 *mm* was obtained. In this case, significant differences were observed (*p <* 0.05), 278

*±*

with a confidence level of 95 %. 279

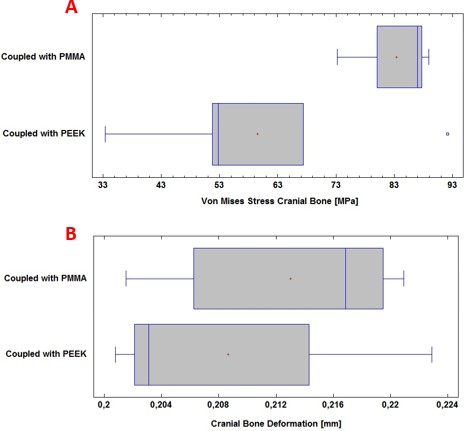
280

In Figure [13](#_bookmark15) (A), the von Mises stress levels in the cranial bone are observed, resulting 281

from the couplings of the PMMA and PEEK implants, respectively. Whereas, in Figure [13](#_bookmark15) 282

(B), the total deformation of the cranial bone caused by the coupling of the implant is 283

presented. All of the above under the application of a load “Force” 8000 *N*. 284



**Figure 13.** Statistical analysis: (**A**) von Mises stresses in the cranial bone. (**B**) Deformation of the cranial bone.

During the computational analysis, the effect of using PMMA and PEEK implants, 285

respectively, coupled to the cranial bone, was examined to achieve the necessary protection 286 of the internal structures and tissues, before a static load of 8000 *N* on the external surface 287 of the implant. The mean and standard deviation of the von Mises stress analysis for the 288 cranial bone was 83 7 *MPa* with PMMA. While with PEEK 59 22 *MPa* was obtained. 289 In this case, significant differences were observed (*p <* 0.05), with a confidence level of 95 %. 290

*± ±*

291

The total deformation of the cranial bone when coupled with the PMMA implant 292

was also examined. The values for the mean and standard deviation of the analysis were 293

0.213 0.008 *mm*. For PEEK, in the same situation, 0.208 0.009 *mm* was obtained. No 294

*± ±*

significant differences are observed (*p >* 0.05), with a confidence level of 95 %. 295

296

The analysis has focused only on the case of the greater load, because the safety of 297

the personalized implant will depend on this action. The load of 2000 *N* simulates the inci- 298

dence during the rest-activity; in such a situation, failures will not occur, since the stresses 299

generated in the implant do not exceed the yield stress of either of the two materials ([[28](#_bookmark45)]; 300

[[34](#_bookmark51)]). 301

302

* 1. *Post-operative* 303

The implant manufactured in PMMA was successfully placed in the patient. The 304

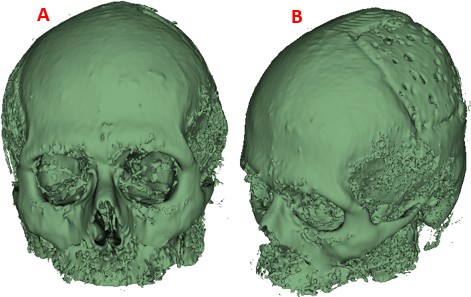
postoperative evolution was satisfactory, there were no complications of any kind, and the 305

person left the hospital facility 48 hours after the intervention. In addition, for follow-up, a 306

visit was scheduled 14 days after surgery. In Figure [14](#_bookmark16) the symmetry achieved with the 307

cranial reconstruction is visible. There were also no difficulties with healing, the aesthetic 308

and functional result was as expected and complete patient’s satisfaction. 309



**Figure 14.** CT scan of the patient, with the custom PMMA implant, 14 days post-surgery: (**A**) Image of the skull with the PMMA implant attached, front view. (**B**) Image of the skull with the attached PMMA implant, 3D view.

* + 1. Postoperative follow-up 310

Computer-Aided Design and Additive Manufacturing have proven to be effective 311

tools in the design of custom implants. The results presented describe the entire custom 312

manufacturing process, surgical planning, finite element analysis and 3D manufacturing, 313

which facilitated the performance of cranioplasty in a patient affected by skull bone cancer. 314 The general procedure (fabrication of the implant and surgical planning) was carried out ac- 315 cording to the proposed methodology and using open-source and commercial software for 316

the segmentation, post-processing and mechanical design stages. The use of free software, 317

whenever possible, was an advantageous factor considering the economic possibilities of 318

the region where the methodology has been applied. In Figure [15](#_bookmark17) the final results of the 319

entire process can be seen. 320



**Figure 15.** Patient benefited from the personalized PMMA implant.

1. **Discussion and Conclusions** 321

Through the presentation of a real case, the usefulness of the proposed method for 322

the analysis of clinical cases in the area of neurosurgery and reconstruction of cranial 323

defects with a complex surgical approach has been demonstrated. Through a finite element 324

study, the level of von Mises stresses and total deformations that take place in the coupling 325

of the bone-implant system under static loads were determined, which is established as 326

one more criterion for the design of medical devices for the cranioplasty treatment with 327

biocompatible materials such as PMMA and PEEK. 328

329

Four computational analysis were developed under a static external load of 2000 *N*, 330

which was applied to the upper left part of the implant, simulating an external action that 331

this area of the head would receive during rest-activity; and a load of 8000 *N*, applied in 332

the centre of the implant, simulating a static impact action. All of the above to determine 333

the stress levels and total deformations of the implant-cranial bone system. 334

335

In this investigation it was found that there are no significant differences between the 336

PMMA personalized medical device and the PEEK one, concerning to the total deforma- 337

tions caused by the load of 8000 *N*, considering the state of load as maximum. Significant 338

differences were found in the von Mises stress distribution. 339

340

The decision to know which device to use for cranioplasty treatment will depend on 341

the magnitude of the damage and the patient’s financial availability. In Eastern European 342

and Asian countries, PMMA is currently used as an alternative material for cranioplasty. In 343

[[35](#_bookmark52)] is reported on the use of locally developed polylactic acid and polymethyl methacrylate 344

molds to perform cranioplasties for bone defects in technically demanding areas of the 345

skull, while ensuring good aesthetic results and functional recovery. According to the 346

authors, no surgical complications occurred in 14 patients. In addition, the subjective and 347

objective evaluation revealed a significant improvement in the results. There were also 348

no postoperative complications during a 6-month follow-up period, except in one patient 349

who presented a late infection. Studies like this validate the use of acrylic materials as an 350

alternative for cranioplasty treatment. 351

352

Late infection rates from the use of PMMA in custom-made bone implants are fre- 353

quently increased by improper handling of sterilization protocols for manufactured devices, 354

or by bacterial contamination during handling. 355

356

In the study presented in [[36](#_bookmark53)], intolerance reactions to resin prostheses are evaluated. 357

The placement of a prosthesis, with the load acting on the supporting tissue; the lining 358

of the oral mucosa; and direct contact with the material often causes a non-physiological 359

situation. As a rule, oral tissues tolerate this situation. However, in some cases, reactions 360

of intolerance to the prosthesis appear. In its triggering, and the appearance of possi- 361

ble mucosal disorders, various factors intervene or interact. Due to the etiological and 362

pathogenic complexity of these complications, the literature does not reflect a uniform 363

opinion regarding the definition, classification and appearance of these clinical pictures. 364

365

It has also happened that, in patients who have undergone successive surgery to 366

remove and replace implants, the capillary tissue has lost healing properties, causing the 367

decubitus effect and with it the proliferation of bacteria that contaminate the implanted 368

device. Even so, the cranioplasty surgeries that have been performed in this area of Ecuador 369

have had an approximate average cost of USD 450. In addition, the preoperative prepara- 370

tion with the anatomical test models has helped to reduce the duration of the interventions 371

and the time the patient remains under the effects of anaesthesia, also reducing the risks 372

of surgical complications. A similar scenario is described in [[35](#_bookmark52)], [[37](#_bookmark54)]. As reported, the 373

investment in a PMMA implant was USD 50. 374

375

The manufacturing process with PEEK has an approximate cost of USD 5000, inacces- 376

sible to the economy of many people. In the present study, however, the simulation results 377

showed that both materials are equal in terms of security and structural integrity that they 378

provide in the event of static load events: they do not exceed the yield point, so under 379

the same demands, they are capable of responding without failure. Regarding the total 380

deformations suffered, no significant differences were observed. In addition, the possible 381

scope of the finite element method has been verified in terms of optimizing the structural 382 properties of the implant to maximize resistance and durability and minimize weight and 383 volume. 384

385

In some public and private hospitals in the Republic of Ecuador, a country located in 386

the northwestern region of South America, the introduction of advanced medical technolo- 387

gies, such as 3D printing, has been fundamentally limited for economic reasons and a lack 388

of investment in research and development. However, in a certain way, these limitations 389

have been overcome by applying viable alternatives. For example, keeping PMMA as a fea- 390

sible option in terms of biocompatibility and mechanical performance, and advantageous 391

in economic terms. 392

393

In three health institutions in the region, since July 2020, 5 surgeries have been per- 394 formed that required customized bone replacement (the last one made in September 2022). 395 Three cranioplasties, one clavicular implant and one for the sternum-clavicle. All medical 396

devices placed in these patients were manufactured with PMMA. Follow-up has been 397

maintained on each of them up to the present, and in none of the cases has there been any 398

complication. These surgical procedures have been performed under the protection of the 399

rules of the [National Agency for Health Regulation, Control and Surveillance](https://www.gob.ec/sites/default/files/regulations/2020-08/Documento_Buenas_Pr%C3%A1cticas_Almacenamiento_Distribuci%C3%B3n_y_Transporte_para_Establecimientos_Farmac%C3%A9uticos_y_Establecimiento_Dispositivos_M%C3%A9dicos_0.pdf) (ARCSA- 400

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*through the use of surgical guides and additive manufacturing. Phase II: additive manufacturing with PEEK* 416

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