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ORIGINAL ARTICLE

Frontal bone tumor resection and parietal bone defect repair with immediate cranioplasty surgery using additive manufacturing–customized Ti-6Al-4V alloy implants

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Abstract

Purpose This paper reports the case of a female patient, with a bone tumor in the frontal region and bone defect in the parietal side of the skull, who underwent one-step cranioplasty surgery.

Methods Preoperative surgical planning was performed via virtual 3D modeling of the patient's computed tomography, and biomodels consistent with the skull's geometry were produced. The surgery was conducted using customized implants made up of additively manufactured Ti-6Al-4V alloys, and the postoperative results were obtained.

Results The bone cancer was completely eliminated, the bone portion of the frontal bone and left orbital roof were removed, and the eyeball was leveled. Additively manufactured implants allow the fabrication of perfectly fit implants that reconstruct the patient's complex bone structure and provide skull protection. In addition, additively manufactured biomodels and implants facilitate surgical planning with greater precision.

Conclusion Cranioplasty performed with customized implants enables complete healing with optimal aesthetic results, making it an attractive approach for large craniofacial repair.

Keywords Tumor · Computed tomography · Modeling · Rapid prototyping · Craniomaxillofacial

Introduction

Cranioplasty is a well-established procedure applied in skull bone defect surgeries to repair an injured area and protect intracranial contents (Rios-Vicil et al. 2022; Sahoo et al. 2021) with aesthetic importance. Most cranioplasty indications comprise trauma sequelae or patients previously submitted to craniotomies for the treatment of neoplasms, intracranial hypertension, or other conditions that lead to a cranial defect due to bone resection (Dujovny et al. 1997; Matsuno et al. 2006; Moreira-Gonzalez et al. 2003; Reid Gooch et al. 2009).

In bone tumor cases, tumor cells destroy the patient's bone tissue, requiring treatments, such as radiotherapy and surgical excision for tumor removal, followed by cranioplasty (Mohan et al. 2022; Perng et al. 2021). Clinical evidence has verified a favorable impact on the functional recovery of brain tissue after cranioplasty; the improvement of symptoms, such as headache and epileptic seizures; the recovery of cognitive neurological deficits; and an improvement in the level of consciousness in patients undergoing

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the reparative procedure (Agner et al. 2002; Dujovny et al. 1997; Liang et al. (2007); Sakamoto et al. 2006), including the morphological reconstitution of the injured area, physical barrier to protect the brain, and aesthetic importance.

Surgeries are often carried out with the implantation of self-polymerization acrylic resins based on poly(methyl methacrylate) (PMMA) (Rios-Vicil et al. 2022). However, this leads to several disadvantages, including an increase in the leading time of the surgeon to manipulate the material and achieve fitting accuracy towing to the different structures of each patient's bone (Antonini et al., 2020; Azarmehr et al. 2017; Rotaru et al. 2012; Thakur et al. 2019; Yeolekar and Qadri 2018).

Implants based on titanium and its alloys are being customized and are effective alternatives for repairing maxillofacial defects because of their numerous properties, such as a reduced modulus of elasticity than other metals (Las et al. 2021; Pilliar 1991), biocompatibility, (Kaur and Singh 2019), and corrosion resistance due to the formation of an oxide passive layer that promotes osseointegration (de Viteri and Fuentes 2013). In addition, titanium-based implants exhibit long-term stability (Cabraja et al. 2009; Heissler et al. 1998) and low infection rates (Hassan et al. 2019).

The difficulties related to the complex skull bone structure are currently being addressed by medical imaging techniques from the patient's injury area, followed by virtual reconstruction to obtain biomodels for surgical planning. These are commonly made of polymers and customized implants processed by additive manufacturing (AM) techniques (Moiduddin et al. 2022), including a one-step surgery that minimizes complications (Rios-Vicil et al. 2022). First, the patient's injury area is scanned by computed tomography (CT) or magnetic resonance imaging (MRI) to obtain a 3D virtual image reconstruction of the injured area, which is converted into a standard triangulation language (STL) file to manufacture the customized implant. Moreover, when dealing with large defects, the use of digital subtraction mirror imaging is crucial to obtain the accurate geometry of the bone defect to be repaired (Goh et al. 2010).

AM processes are currently replacing conventional machining processes in obtaining customized implants with an accurate geometry for the patient's bone structure. One such AM process is the powder bed fusion (PBF), which adopts an electron or laser beam to fuse fine powders of different materials layer by layer, to produce customized bone repair implants (Lei et al. 2022; Zhang et al. 2021). Post-processing operations, such as heat treatment and polishing, may be required in the PBF technique to achieve the desired implant quality (Sagbas 2020). However, AM methods reduce surgery time and costs and facilitate the planning of patient-specific implant characteristics with superior precision (Chacón et al. 2022).

This study presents a case report of a female patient with a large cranial defect. It includes cancer removal and bone defect repairs, with immediate cranioplasty surgery, using customized additively manufactured implants. Hence, a study merging medical imaging data with virtual design, planning, and manufacturing of biomodels and implants was conducted in this case.

Materials and methods

Patient data

The female patient was treated at the Clinical Hospital of the University of Campinas. Prior to undergoing treatments, the patient exhibited bone segment loss in the parietal area due to previous neoplasm removal surgery (30 years prior) and developed an osteoblastoma tumor in the frontal region, causing cranial vault bulging and eye depression.

Three-dimensional virtual modeling and manufacturing of biomodel and implants

To produce the biomodel and implants, a helical craniofacial CT scan of the patient was obtained using a standard fine-cut protocol with 1 mm increments in each section, with 0° inclination in the orientation of the gantry. Subsequently, CT scans were converted and segmented. First, using MIMICS version 16.0 software (Materialise, Belgium), the DICOM format was exported to STL format. Then, Magics 14.0 software (Materialise, Belgium) increased the surface quality. Finally, SolidWorks version 2012 software (SolidWorks, USA) was used to create the design of the final implants in the CAD images.

The biomodel was fabricated with polyamide powder (PA 2200, nylon) using a 3D Formiga P110 (EOS GmbH, Germany) and blasted with glass beads. Ti-6Al-4V ELI medical grade alloy implants were fabricated using virgin titanium alloy powder via the PBF process and the EOSINT M270 3D AM system with a 170-W laser power, 30 µm layer thickness, and 1250 mm/s scan speed, under an argon atmosphere at the Biofabris Institute (INCT-BIOFABRIS). The implants were subjected to stress-relief heat treatment at 650 °C for 3 h, followed by polishing with a disc finishing machine (model CF 2×18-SP, Otec Prazisionsfinish GmbH, Germany) and autoclave sterilization (Getinge HS66 turbo, temperature 135 °C, during 53 min).

Surgical procedures

This study was approved by the Research Ethics Committee of the University of Campinas (UNICAMP)

(CAAE:0876.0.146.000–11, Approval: 970/2011), and the participant signed an informed consent agreement.

The surgery was conducted at the Surgical Center of the Clinical Hospital of the University of Campinas, Brazil.

Results

Preoperative evaluation

Before the surgical procedure, the patient underwent routine preoperative medical evaluation comprising standard cardiological and hematological workouts that revealed no abnormality. The radiological evaluation consisted of cranial MRI and craniofacial CT scans, as detailed above. Figure 1a and b presents the frontal and oblique views of the craniofacial defect, respectively. Figure 1c illustrates a 3D CAD virtual model based on CT scans detailing the tumor region.

Design of the biomodels and implants

CT images of the patient's skull were converted and segmented to design the biomodels and implants. Accordingly, the digital imaging and communication in medicine (DICOM) files were converted into 3D CAD models, which allowed virtual planning. Figure 2a presents a 3D CAD virtual model based on CT scans showing the region and dimensions of the previous cranioplasty defect.

Figure 3a illustrates the virtual surgical planning with a customized tumor resection guide template in the frontal (Fig. 3b) and oblique (Fig. 3c) views. Finally, Fig. 3d presents a virtual model of the skull after resection.

The virtual design was obtained to understand the cranioplasty surgery, plan the alignment of the implant with the skull, evaluate the fitting of the two implants, assess how to fix the implants, and determine the tumor area to be removed. Owing to the complexity of bone geometry and tumor removal, one implant was designed for the frontal area and another one for the parietal area. According to the CAD modeling, the frontal and parietal implants measured approximately 95 mm × 69 mm and 101 mm × 92 mm, respectively. Figure 3 presents the different views of 3D CAD models of cranioplasty implants.

Additive manufacturing of the biomodel and implants

Figure 4 illustrates the biomodel and implants fabricated via AM. As illustrated in Fig. 4a, the biomodel exhibited previous bone segment loss in the parietal area. Figure 4b illustrates the tumor resection guide template, while Fig. 4c presents the biomodel with the discarded tumor area. Finally,

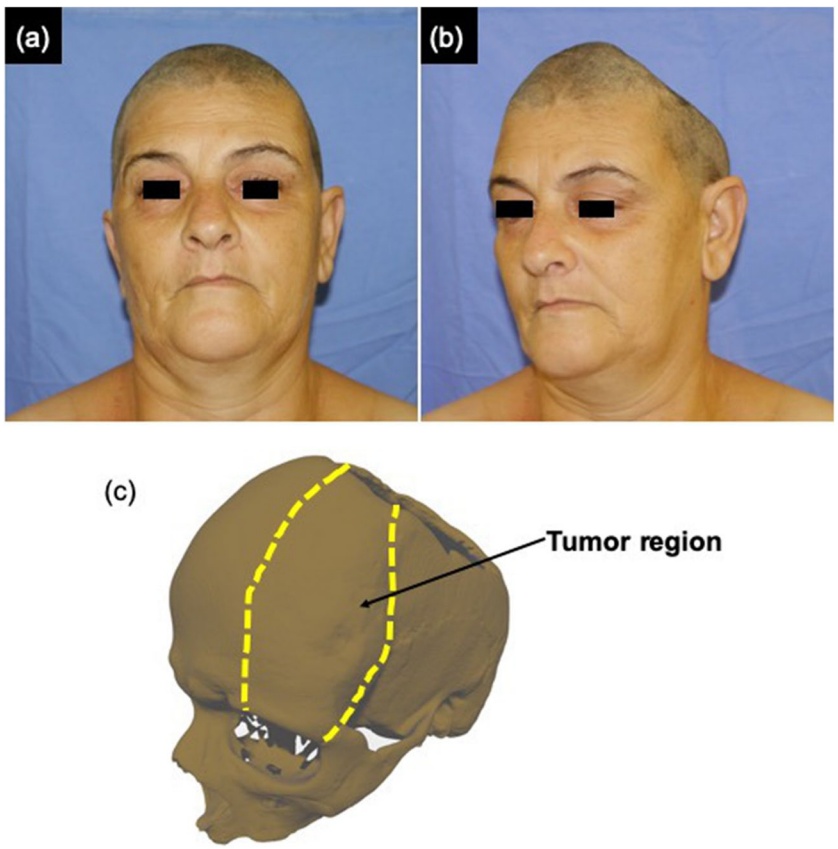

Fig. 1 Pictures of the patient in the preoperative period. **a** Frontal and **b** oblique views. **c** 3D CAD virtual model based on CT scans showing tumor region

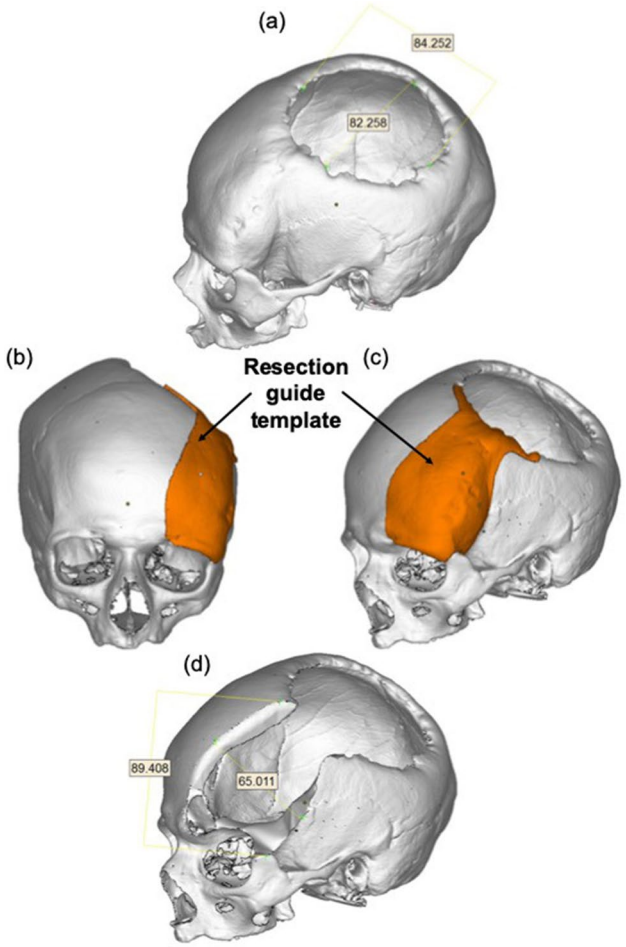

Fig. 2 **a** 3D CAD virtual model based on CT scans showing region and dimensions of the previous cranioplasty. Virtual surgical planning with the tumor resection guide template in **b** frontal and **c** oblique views. **d** The virtual model of the skull after resection. Dimensions in mm

Fig. 4d–f presents AM implants in the parietal region, and that fitted in the injured area.

Surgical procedure

The procedure was performed under general venous anesthesia, with the patient in the supine position and head turned to the right while resting on a soft head holder. After drawing the incisions on the scalp (Fig. 5a), the first steps of the procedure comprised incising and separating the scalp from the underlying skull in the anterior aspects of the surgical field and the dura mater in the posterior regions, with careful dissection and identification of the borders of the existing cranial defect in the left parietal region. After superposition of the surgical guide template (Fig. 5b), previously produced based on the limits of the tumor obtained via the preoperative CT scan, the left front-orbital skull tumor was resected using a high-speed low-profile craniotome, leading to an orbitofrontal defect (Fig. 5c). Accordingly, meticulous epidural hemostasis was performed, and subsequently, the dura mater was elevated with polypropylene 4.0 stitches at the edges of the craniotomy. The two implants were then fixed to the skull using commercial surgical screws of the Ti-6Al-4V ELI alloy measuring Ø 1.5 mm × 5 mm and Ø 1.5 mm × 10 mm, first in the parietal region (Fig. 5d) and then in the frontal region (Fig. 5e), thereby completing the cranioplasty procedure (Fig. 5f). Closure was performed as usual with subcutaneous separated absorbable stitches (Vicryl 2.0) and continuous cutaneous sutures with nylon 3.0. A subgaleal drain (Portovac 3.2) was left in place for 24 h.

Postoperative results

Postoperative evaluation was performed via clinical examination during recovery after surgery and after an 11-month follow-up period.

The postoperative results are presented in Fig. 6. Figure 6a illustrates the dissected tumor piece, while Fig. 6b presents its superimposition on the biomodel. Figure 6c, d presents the results in the postoperative period after 11 months, showing the frontal (a) and oblique (b) views of the patient.

Discussion

This paper reports the case of a female patient with a previous bone tumor removal and consequent cranial defect in the left parietal region, who underwent a surgical procedure comprising the resection of a new skull tumor in the left front-orbital region and immediate cranioplasty with customized implants produced by additive manufacturing.

CAD models of parietal and frontal bone defects were designed based on CT scans, and customized implants made of Ti-6Al-4V alloys were fabricated by AM. The bone defects were designed using the digital subtraction mirror imaging method, the most successful repair method with customized implants (Goh et al. 2010). The customized 3D polyamide biomodels were fundamental, showing the tumor area to be removed, and assisted in marking for incision and resection based on the limits of the tumor on the CT scan. Considering the patient's bone defects and planning the patient-specific implant characteristics, the surgical guide template helped in defining the margins of the bone resection during the surgical procedure. It allowed a reduction in the frontal bone removal time. This technique also permitted greater certainty for the neurosurgeon that the tumor (bone portion of the left orbital roof and frontal region) was completely removed, and the prosthesis was promptly placed in

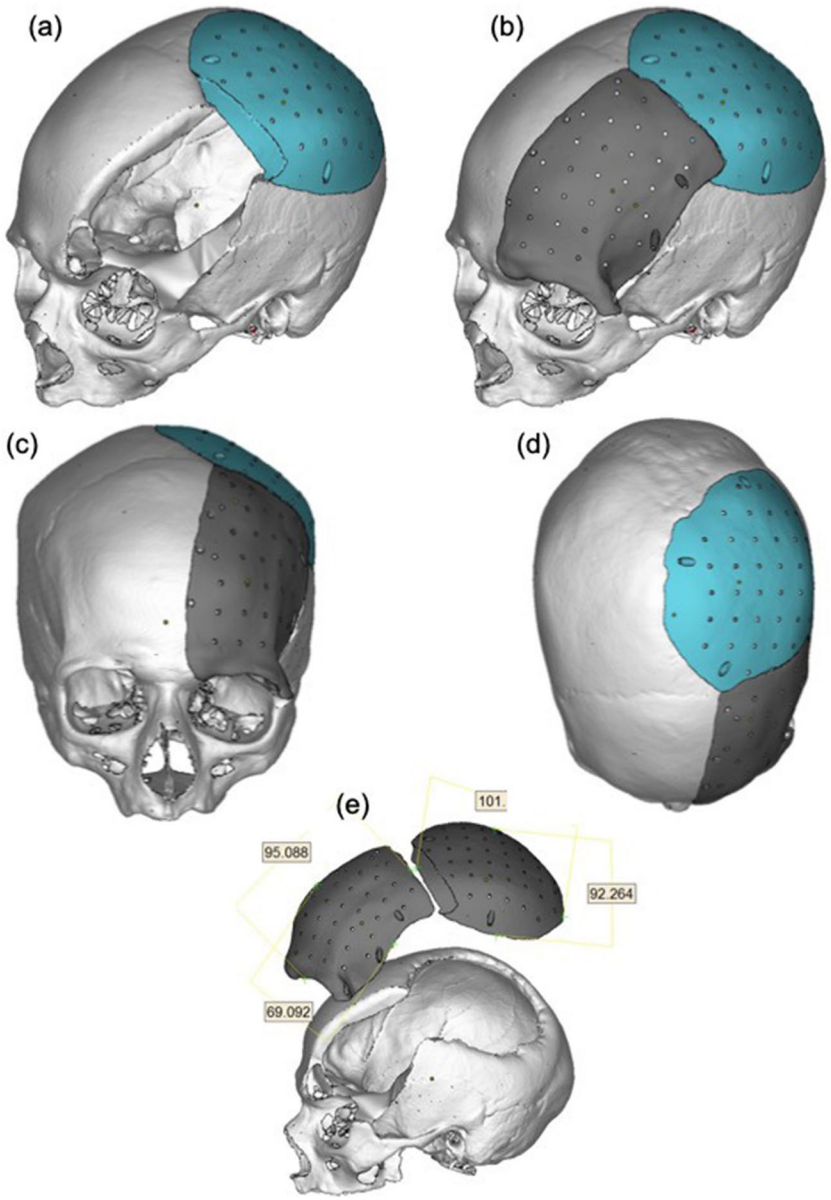

Fig. 3 **a**–**e** Virtual surgical planning showing 3D CAD models of the cranioplasty implants in several views. Dimensions in mm

an optimal position, thereby preserving the eyeball leveling, visual acuity, and external eye movements.

The implant was fixed in the parietal region and facilitated the correction of the bone defect with protection of the intracranial structures. It is important to highlight that fixing the implants with screws eliminated any nodulation on the edges of the implants that could generate future discomfort for patients. Accordingly, perfect fitting of both implants was observed with optimal aesthetic results. Finally, the success of any craniofacial repair surgery also depends on the aesthetic results in the postoperative period (Parthasarathy 2014). The patient developed a hematoma below the prosthesis on the third postoperative day, despite the closed drains. The drainage was reopened, leading to a favorable outcome. Three years later, the patient underwent fat grafting in the temporal region to correct minor muscle atrophy. To date, she has reported no complaints.

Implants based on Ti-6Al-4V alloys are effective alternatives for repairing maxillofacial defects due to their mechanical properties, biocompatibility, and corrosion resistance. AM implants with porous structures can be tailored to mimic the mechanical properties of natural bone (Koju et al. 2022). The use of Ti-6Al-4V alloys can have variable properties depending on their microstructure, which is influenced by the manufacturing process and heat treatments (Zhang et al. 2024). These factors can impact the implant's performance. Ti-6Al-4V alloy implants are well documented. Our research group has carried out other cranioplasty surgery using titanium alloys, with good outcomes (Jardini et al. 2021).

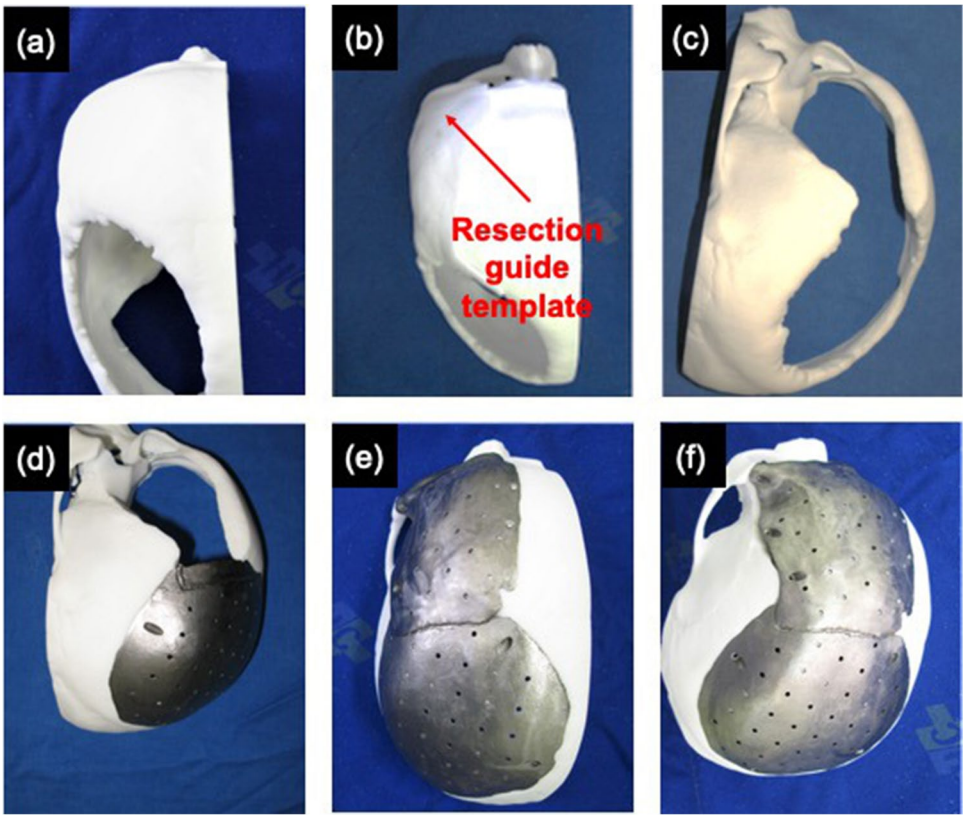

Fig. 4 Skull additively manufactured biomodel with **a** tumor, **b** tumor resection guide template, and **c** after tumor resection. **d–f** Customized additively manufactured cranioplasty implants

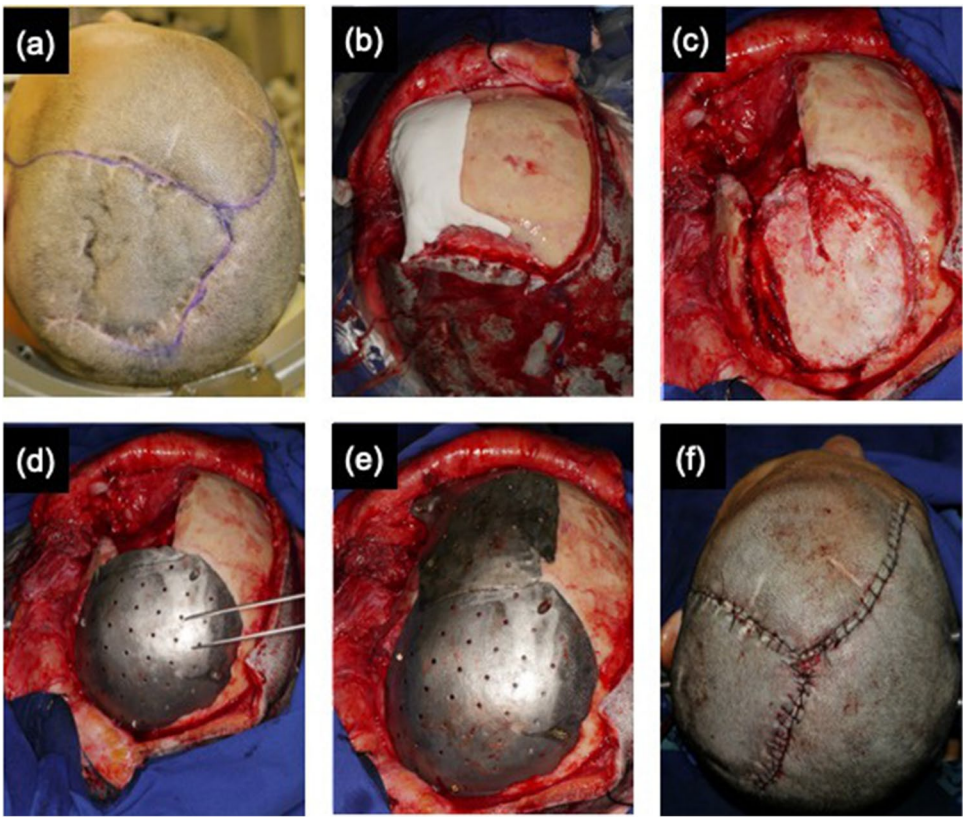

Fig. 5 Surgical procedures at different stages. At the beginning with the incision markings (**a**), followed by superposition of the guide template on the tumor to be resected (**b**) and after front-orbital skull tumor resection (**c**). The installation of additively manufactured parietal (**d**) and frontal (**e**) implants and the immediate postoperative view (**f**)

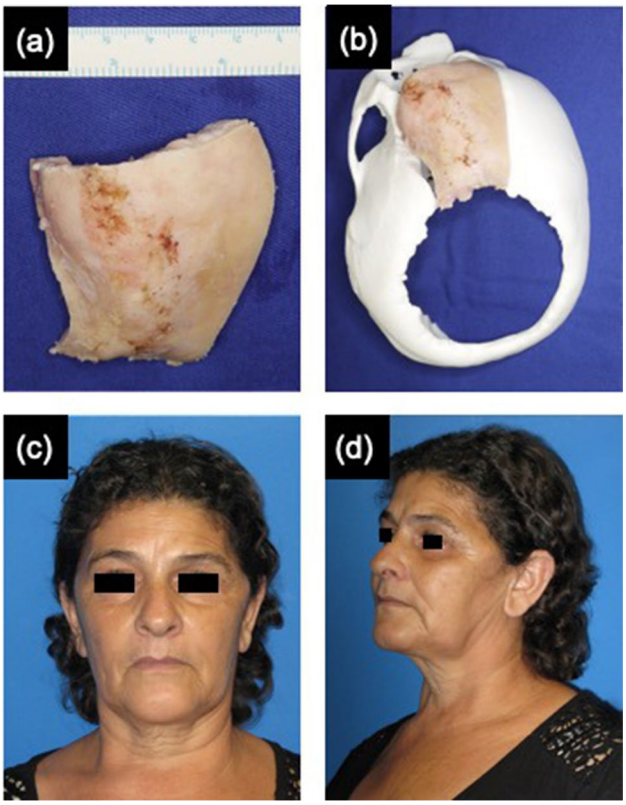

Fig. 6 **a** Tumor resected and **b** fit with biomodel. **c** The postoperative period after 11 months showing the patient in frontal (**a**) and oblique (**b**) views

Osteoblastoma is a rare tumor accounting for 0.8 to 1% of all bone tumors, with a preponderance in young male adults (Ohkawa et al., 1997). It mainly affects the axial and vertebral skeleton, thereby affecting the skull 14–20% of the time in the maxillary, temporal, sphenoid, occipital, ethmoid, and frontal regions (Clutter et al. 1984).

Autologous bone grafting is considered the "gold standard" for post-craniotomy reconstruction; however, the size of the defects and anatomical conformation of the frontal bone made this case particularly challenging. Therefore, the best option in this scenario is to employ a customized implant.

The outcomes of placing customized implants can be enhanced by combining them with techniques like intraoperative in situ tissue engineering (Krasilnikova et al. 2022). This approach allows for the collection and minimal processing of cells directly in the operating room. Bone marrow–derived mononuclear cells, which can promote angiogenesis in the implantation area (Umemura et al. 2006), and stromal vascular fraction cells, which have been shown to improve the effectiveness of osteoinductive scaffolds in treating critical-size cranial defects in mice, are excellent options for these cases (Nyberg et al. 2019).

This single-step surgery allowed tumor removal with immediate leveling of the frontal and parietal regions with customized prosthesis implantation, thereby reducing the time and cost of surgery, postoperative time, and patient recovery. In addition, customized implants proved to be suitable for the repair of bone defects. In the present case, a follow-up exhibited excellent clinical results in restoring the craniofacial architecture; the left eye was leveled with preserved eye movement, and no infections were detected.

It is essential to highlight that this was a case report presented to the Brazilian Health Regulatory Authority (ANVISA) with ultramodern customized medical devices in Brazil. Accordingly, a standard (Diário Oficial da União, 2019) was published in September 2019, regulating the manufacture and commercialization of customized medical devices.

Conclusion

In summary, a large cranial defect and bone tumor removal in a patient who underwent one-step cranioplasty surgery were presented. In addition, the design, manufacturing, and implantation of customized additively manufactured implants were presented. Biomodels are fundamental for repairing the patient's complex bone structure, allowing surgical planning, and manufacturing of customized implants. These, combined with AM, allowed neurosurgeons greater certainty in the removal of the entire tumor, allowing the repair of bone defects with a customized geometry that reproduced the original craniofacial geometry, with optimal aesthetic results and improved quality of life for the patient.

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Declarations

Competing interests The authors declare no competing interests.

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