PLANNED SURGERY, SURGICAL GUIDES AND CUSTOM IMPLANTS USING VIRTUAL PLANNING,DESIGN AND 3D ADDITIVE MANUFACTURING

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Abstract

This paper describes, through six clinical cases, the results and benefits of applying a comprehensive methodology for the simulation and planning of surgeries related to the restoration of bone structures that have suffered damage caused by various types of pathologies. Trials prior to interventions are performed with the support of 3D-printed test anatomical models. In addition, restorations or bone transformations are supported with implants made to measure for each case, and also with customized cutting guides. Appropriate polymeric materials are used and fused deposition is applied as the main additive manufacturing technique for obtaining the medical devices. The results obtained demonstrate the feasibility of applying such techniques, their advantages, and the possibilities of access to them in Ecuador.

Keywords: 3D printer; Cutting guide; Surgical planning; Additive manufacturing; Medical image; Reverse engineering

1. Introduction

Presented by the media as the third industrial revolution after mechanization and Taylorism, 3D printing has developed exponentially in the last twenty years. Various health sectors have been impacted by this new production method. There are several types of health products manufactured with 3D printing: medical devices, tissues, and artificial organs [1]. A recent review of the literature showed an exponential increase in publications on surgical applications of 3D-printing. Cranio-maxillofacial surgery represented the second-highest percentage of these publications. As additive manufacturing technology improves and becomes more affordable, its use in craniofacial plastic and reconstructive surgery has also expanded [2], [3]. The need to improve the visualization of surgical processes and results has fostered the emergence of anatomical test models, patient-specific surgical guides and customized 3D-printed prostheses [3]. The ability to customize surgical instruments and implants to match the complex shapes and three-dimensional structures, resulting from multiple pathologies or sequelae, has made 3D-printing a novel tool to address these challenging problems [4]. Virtual surgical planning, computer-aided design and manufacturing systems, along with three-dimensional printing, are powerful tools in cosmetic and reconstructive plastic surgery. The key elements in these processes are analysis, planning, virtual surgery, design, production of implants and post-operative analysis [5]. In the present work, six cases are exposed in which test anatomical models were applied for pre-surgical simulated surgery, designs of surgical cutting guides and personalized cranial and clavicular implants, manufactured with additive printing techniques.Through the analysis of the presented cases, it is intended to clarify some possible doubts expressed in the following questions: What are the advantages of this technology? Who is the true beneficiary of these advantages: the patient, the surgeon, and the health institutions? Are these advantages enough to outweigh the disadvantages associated with this technology?

2. Materials and Methods

For the digital three-dimensional reconstruction of a bone structure, a segmentation process is carried out that allows the anatomical model to be correlated. This model is filtered with the help of a post-process: to generate Standard Tessellation Language or Stereolithography (STL) files, exported from *3D Slicer* software (https://www.slicer.org), are rendered with the help of *Autodesk Meshmixer* software (https://www.meshmixer.com). For the segmentation of the tomographic images, a specific intensity is selected, called the Hounsfield Unit (HU), which measures the attenuation coefficient in the grey-scale for compact and soft tissues of the anatomical region of study [6]. A thresholding algorithm was applied to obtain a three-dimensional digital model of the anatomical area of interest, ready for printing. In the manufacture of the anatomical test model, for surgical planning, the additive manufacturing technology Fused Deposition Modeling (FDM) was applied, with the help of a *Creality CR-X Pro 3D* FDM printer (Shenzhen Creality 3D Technology Co., Ltd.). As printing material, the *HP PLA* 1.75 *mm Series* filament, from the Creality brand, was used. The reading, processing and generation of the route code, it was started from the STL file of the segmentation. And the printing itself was done with the help of open-source and free *Creality Slicer 1.2.3* software. When it is necessary to guarantee high standards of biocompatibility, other biomaterials are applied in the reproduction and restoration of bone structures. A comprehensive summary of these materials is reported in [7]. With the applied printing technology, the physical test model was obtained. And during manufacturing, supports are incorporated, which are then removed manually, trying not to alter the microstructure of the bone surface. Table 1 describes the characteristics of the FDM technology. The values of the manufacturing parameters are adjusted to obtain the best performance in the process.

Characteristics and manufacturing parameters	**Fused Deposition Modeling (FDM)**
Company and model	Creality CR-X Pro (2019 Updated)
Maximum build envelope	300 × 300 × 400 mm3
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

Table 1: FDM additive manufacturing characteristics and parameters

The printing parameters were set based on the geometric characteristics, size, surface quality, functionality of the anatomical model and type of material used. The mechanical characteristics of the polylactic acid (PLA) filament, that is not biocompatible, but that is used only for the manufacture of the anatomical test models, are described in Table 2.

Characteristics	**FDM-PLA**
Polymer	Thermoplastic PLA
Manufacturer	Creality HP-PLA
Commercial	HP-PLA
Colour	White (Bone)
Density	1.23kg m−3
Tensile strength	52 M P a
Print temperature	190 − 220◦C(± 5◦C)
Filament diameter	1.75 mm
Printed diameter	0.55 mm

Table 2: Characteristics of one of the material employed for this study, according to data sheet.

During the care process for each patient, the medical device design and simulated surgery phases are included. The design, which is based on the study of tomographic images, provides anatomical test models, patient-specific cutting guides and custom implants (if necessary). In other words, the segmentation algorithms facilitate the identification of the bone structure in need of restoration, and the performance of measurements to manufacture cutting guides for, for example, performing a tumour exeresis with negative margins, after a previous tomographic assessment. For the custom replacement implant model, repairs are made on sections of the three-dimensional digital model that includes the lesion. Thus, a new personalized model is obtained without flaws in the bone structure, which allows for avoiding structural failures.

2. Virtual surgical planning, computer-aided design and manufacturing technologies in clinical cases

This section describes the results obtained for six cases, with different pathologies and sequelae, which required some action related to the developed methodology.

2.1 Case 1: Skull trauma sequel

2.1.1Diagnosis and analysis

A 2-year-old female patient attended the consultation due to prominence in the temporal region as a result of cranioencephalic trauma. Physical examination reveals the prominence of the left temporal bone and ocular proptosis on the same side (Figure 1). A computerized axial tomography (CAT) with three-dimensional reconstruction shows a solution of bone continuity in the orbital roof and region of the left temporal squama, with front-orbital and temporal encephalocele (Figure 2).

Figure 1: Left temporoparietal prominence and ocular proptosis.

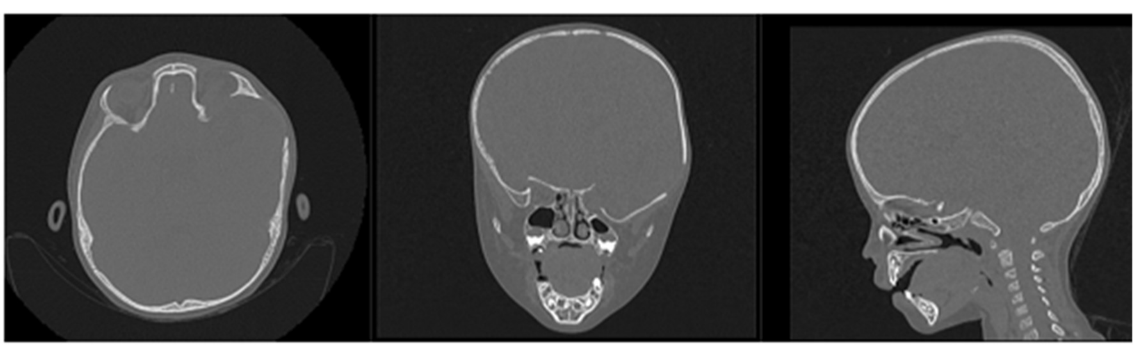

Figure 2: Computed Tomography (CAT). Left temporoparietal cranial defect, solution of continuity in the roof of the orbit and temporoparietal region.

2.1.2 Surgical planning

The defects found were corroborated both in the anamnesis, as well as in the physical examinations and tomography. The tomographic images were segmented to reconstruct the left temporo-parietal cranial bone tissue. A range of 180 to 2000 HU was used to establish the density of compact cranial tissue (Figure 3 and 4).

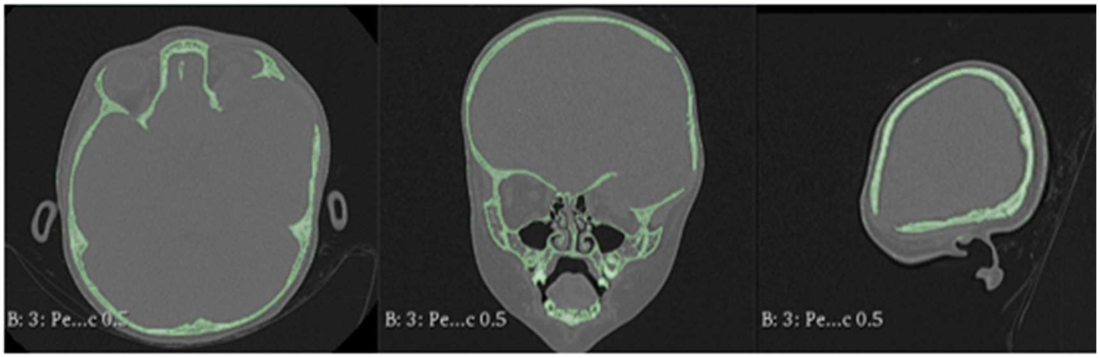

Figure 3: Selection of the HU intensity (corresponding to the necessary bone density) from the tomographic image.

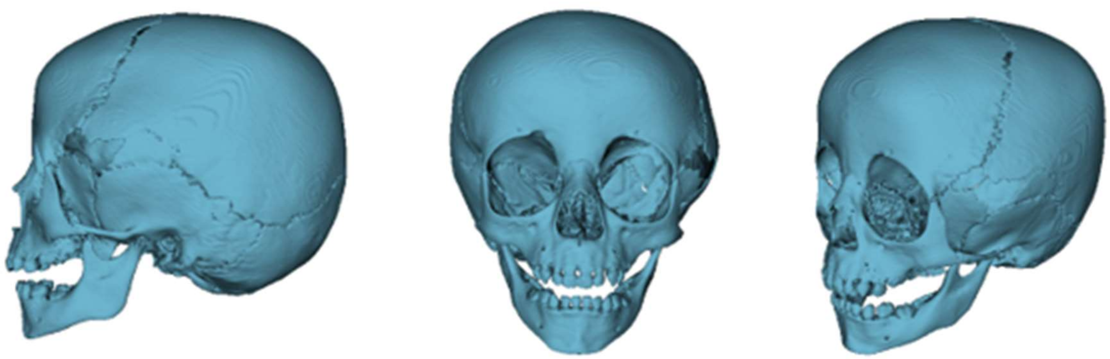

Figure 4: Bone segmentation of the anatomical model with the cranial defect.

2.1.3Planning and printing anatomical model

The segmentation process made it possible to correlate the digital anatomical model (in which the left temporoparietal defect was identified), and to obtain, with the applied printing technology, the physical anatomical model for simulated surgical planning (Figure 5 and 6).

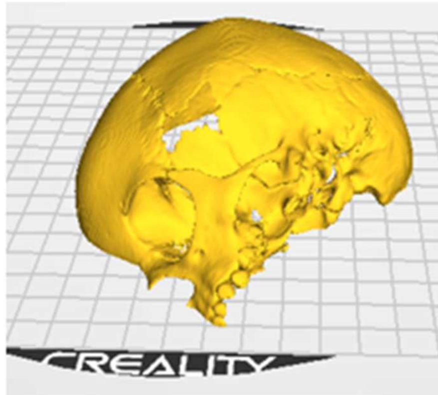

Figure 5: Preparation of the 3D-printing model.

Figure 6: 3D anatomical model of the skull and cuts planning

2.1.4 Intraoperative approach

Once the surgery has been tested and planned in the 3D model, the actual intervention is carried out with the previously chosen technique. During the surgical act (its main stages can be seen in Figure 7), cranial osteotomies were performed, as well as in bloc resection of the entire affected bone complex (orbital roof, zygomatic-temporal and temporoparietal region (red line in Figure 6). Then reconstructive osteotomies and placement of prosthesis or osteosynthesis material were performed, as needed (purple lines in Figure 6).

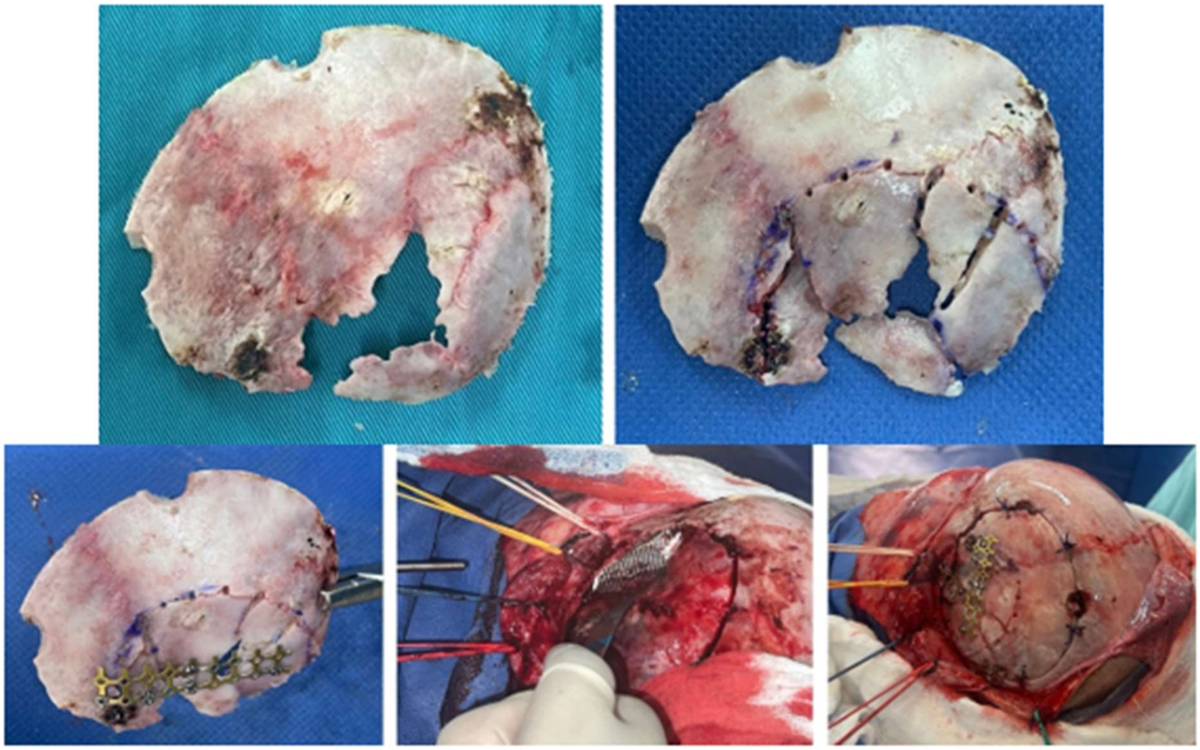

Figure 7: Resected bone complex (Top left). Bone complex with osteotomies (Top right). Union of osteotomies and reconstruction of the temporoparietal bone defect with osteosynthesis (Bottom left). Placement of orbital roof prosthesis for its reconstruction (Bottom centre). Placement of reconstructed bone complex (Bottom right)

2.1.5 Postoperative

The results of the surgery were verified through a tomographic study, digital photography and physical examination (Figure 8 and 9), stages included within the pre-surgical planning, which showed a significant improvement of the temporoparietal bone.

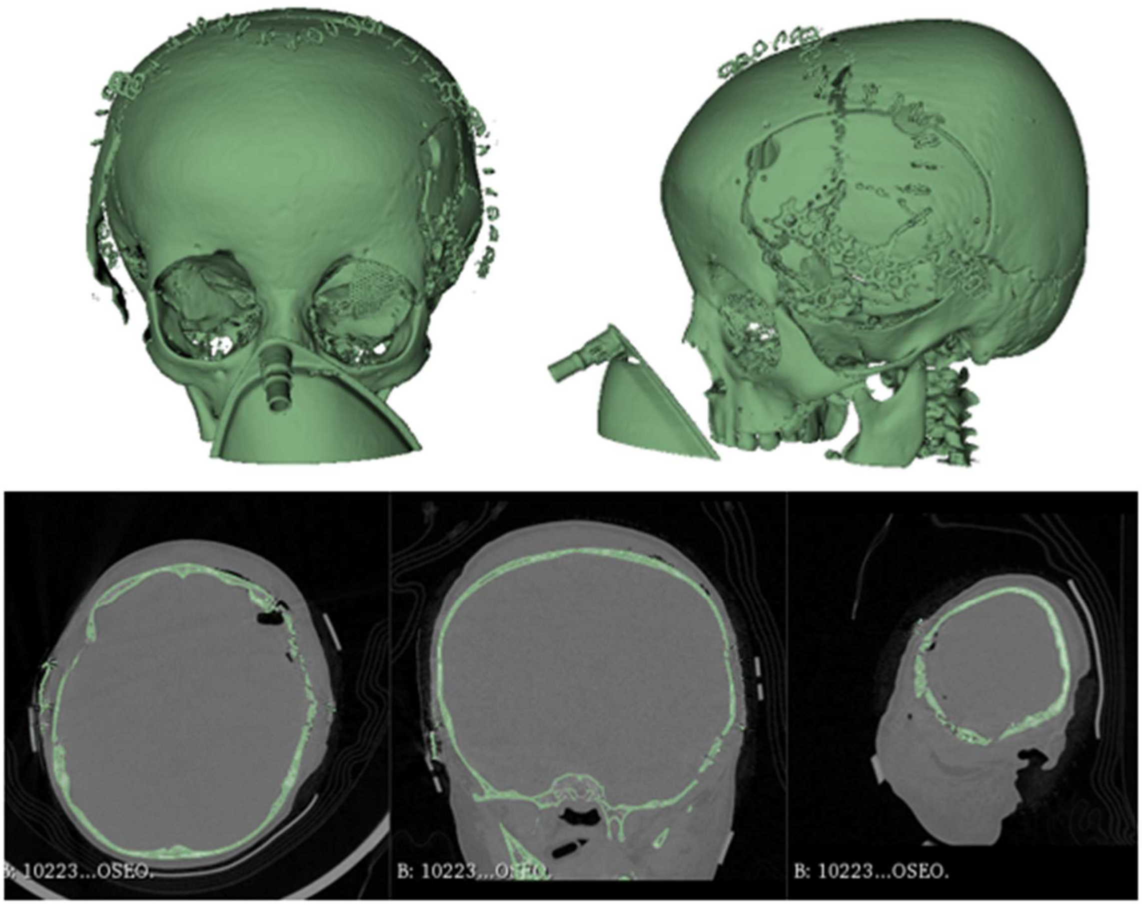

Figure 8: Immediate postoperative tomographic control. The correction of the cranial defect and the temporoparietal encephalocele and the roof of the orbit are observed.

Figure 9: Significant reduction of ocular proptosis and temporoparietal prominence.

2.2 Case 2: skull trauma sequel

2.2.1Diagnosis and analysis

10-year-old male patient, with a cranial collapse in the left temporal-parietal-occipital region, a sequel of cranioencephalic trauma with multiple surgical interventions. On physical examination, subsidence was confirmed in the temporo-parieto-occipital region, with multiple scars. Brain movement shines through to the skin (Figure 10). To the touch, irregular edges of a bone defect from anterior craniotomy are perceived. A CT scan with 3D reconstruction is performed, in which the solution of bone continuity in the affected area can be seen (Figure 11).

Figure 10: Collapse in the left temporo-parieto-occipital region.

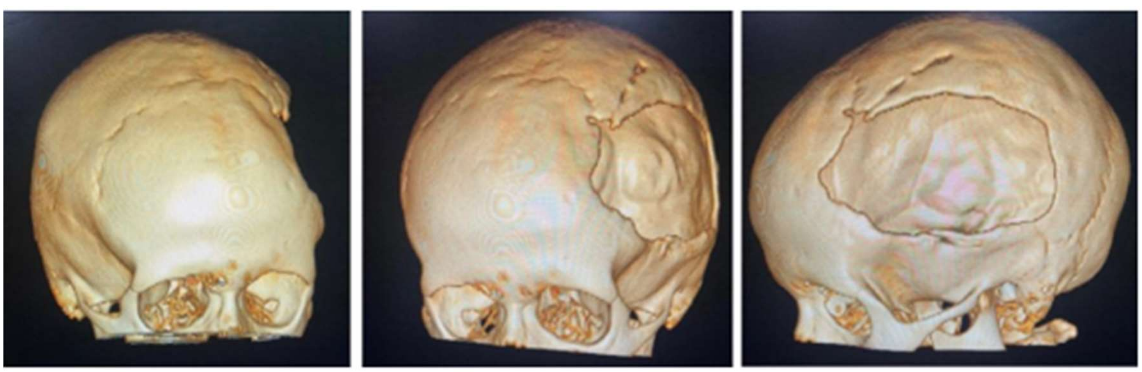

Figure 11: TAC: sinking in the temporo-parieto-occipital region (left). Solution of bone continuity in the affected area (centre-right).

2.2.2 Surgical planning

Reconstruction of the defects found, both in the anamnesis and in the physical and radiological examinations, applying 3D digital restoration (Figure 12), and manufacturing of the anatomical test models with the help of stereolithography.

Figure 12: Bone segmentation of the anatomical model from the tomographic image.

2.2.3 Printing of anatomical model

With the 1:1 scale digital model, it is possible to print an exact and individualized prosthesis for the specific bone defect and perform a reconstruction of the affected area without the need to establish a bone tissue donor area. Figure 13 shows the cranial anatomical model and the customized implant prototype placed in its position. For the design and manufacture of the prosthesis, the integral methodology described in [8] was followed.

Figure 13: 3D anatomical model of the skull and non-implantable prosthesis (only for planning).

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2.2.4 Intraoperative approach

The surgery was simulated, and in this trial, the prosthesis was tested in the 3D model. Surgery was then performed in vivo applying the chosen approach during simulation. During the surgical act, the final prosthesis was placed, manufactured with medical grade PMMA, and covered with the musculocutaneous flap. With this, the reconstruction of the bone defect and the recovery of the patient's cranial aesthetics were achieved. In Figure 14 moments of the surgery are observed.

Figure 14: 3D patient-specific implant placement (left). Resurfacing with temporal fascia flap (centre). Coverage of prosthesis with flap and acellular matrix (Right).

2.2.5 Post-operative results

The postoperative results were positive and verified with the help of a new tomography, digital photography and physical examination. Complete reconstruction of the bone defect was achieved (Figure 15 and 16).

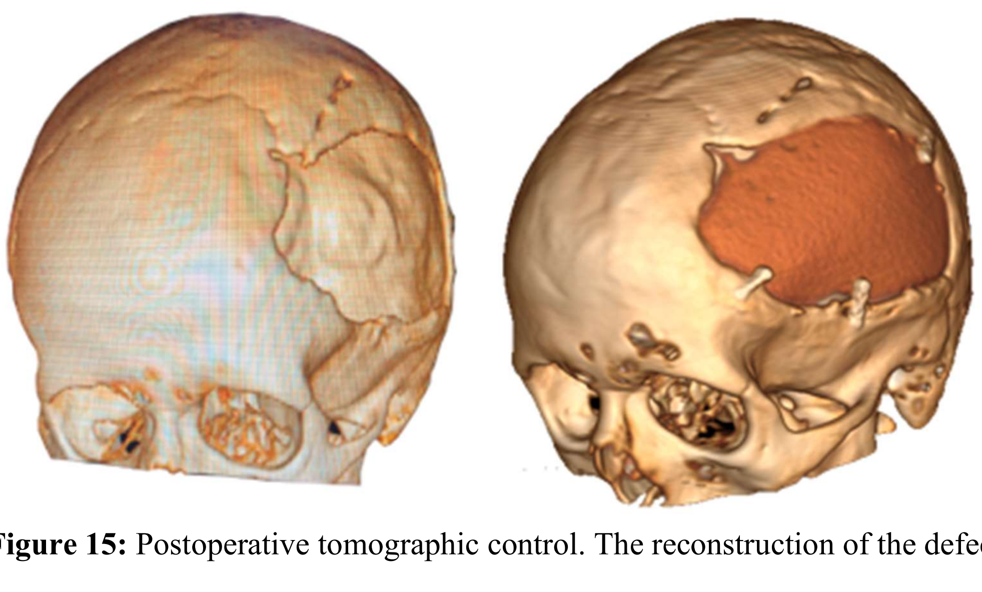

Figure 15: Postoperative tomographic control. The reconstruction of the defect is appreciable.

Figure 16: Resolution of the cranial deformity.

2.3 Case 3: Osteofibrous dysplasia

2.3.1 Diagnosis and analysis

An 11-year-old male patient, who for 4 years (before attending the consultation) had a hard, immobile, painless, progressively growing right frontal tumour. The tumour produced orbital deformity with ocular proptosis, enophthalmos and hypotropia (Figure 17, Figure 18, Figure 19).

Figure 17: Frontal tumour, ocular proptosis, enophthalmos.

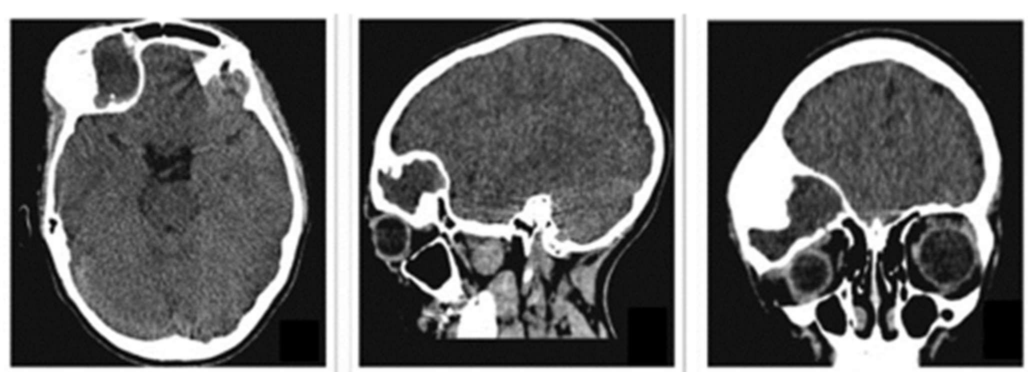

Figure 18: CAT: 5-cm bone lesion in the roof of the orbit, paranasal sinus, and anterior vault of the skull.

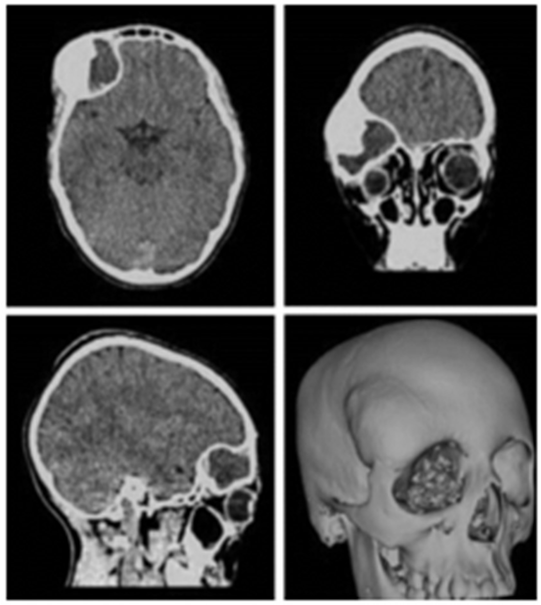

Figure 19: Exposure of cranial damage from the tomographic image, and three-dimensional model

2.3.2 Surgical planning

Reconstruction of the defects found, both in the anamnesis and in the physical and radiological examinations, applying 3D digital restoration (Figure 20), and manufacturing of the anatomical test models with the help of stereolithography.

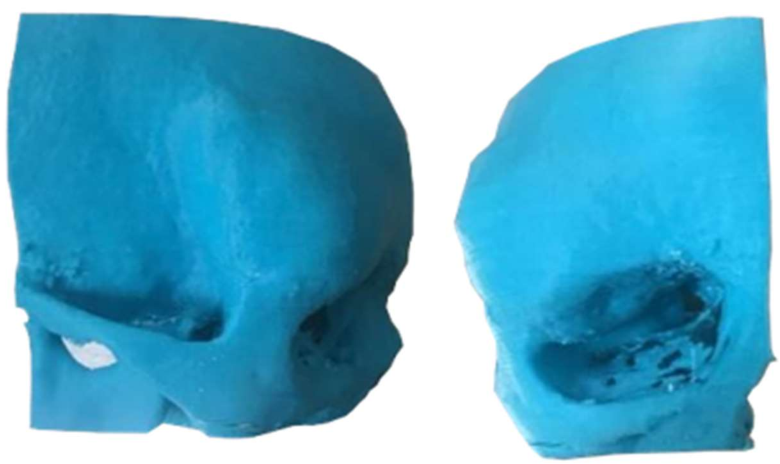

Figure 20: 3D printing of the anatomical model of the skull with the defect

2.3.3 Planning and printing anatomical models

For the segmentation, a thresholding algorithm was used, which allows for isolating the anatomical area of interest and creating the anatomical model for the simulated surgery.

2.3.4 Intraoperative approach

After the simulated surgery with the technique already selected, cranial osteotomie were performed, in bloc resection of the entire affected bone complex (orbital roof, zygomatic-frontal and temporal region), to perform reconstructive osteotomies, excision of the tumour and placement of the already restored bone complex. Fixation was performed with resorbable osteosynthesis material (Figure 21).

Figure 21: Skull fixation for actual surgery (Left). Placement of reconstructed bonecomplex (Right).

2.3.5 Post-operative results

Postoperative results were verified by new tomography, digital photography, and physical examination. It was possible to appreciate the complete reconstruction of the orbital roof, the anterior cranial vault, and the excision of the tumour, all in correspondence with the pre-surgical planning (Figure 22 and 23).

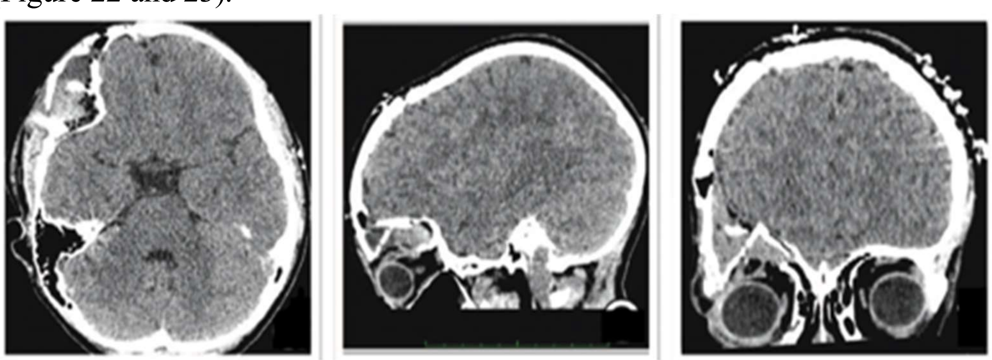

Figure 22: Post-surgical tomography. The removal of the intra-extra cranial tumour, the frontoparietal reconstruction and the roof of the orbit are observed.

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Figure 23: Resolution of ocular proptosis and frontal zygomatic prominence.

2.4 Case 4: right sternoclavicular joint tumour

2.4.1Diagnosis and analysis

A 55-year-old female patient with osteosarcoma of the right sternoclavicular joint causing pain in the joint and limiting the mobility of the right upper extremity (Figure 24).

Figure 24: Pre-surgical tomography.

2.4.2 Surgical planning

Tumour excision through simulated surgery, manufacture of a cutting guide to facilitate the intervention and manufacture of a 3D patient-specific prosthesis. For the phase of simulated surgery and the design of medical devices, a customized cutting guide was obtained from the study of tomographic images. For this, with the support of image segmentation algorithms, the digital model of the anatomical surface with osteosarcoma was generated, the bone structure was identified, and a 5 cm notch was made in the direction of the acromial extremity to facilitate cutting (Figure 25).

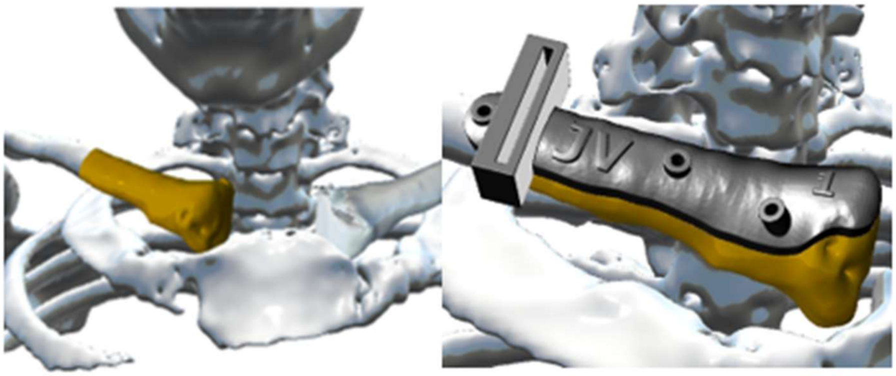

Figure 25: Virtual models. The virtual model of the anatomical defect (Left, yellow area). The virtual model of the custom cutting guide (Right, holes for fasteners and cutting slot shown).

For the virtual lower clavicular replacement model, the restoration was performed on the model with osteosarcoma. Thus, it was possible to obtain a personalized model without defects in the anatomy (geometry) of the bone, and with it avoid structural failure (Figure 26).

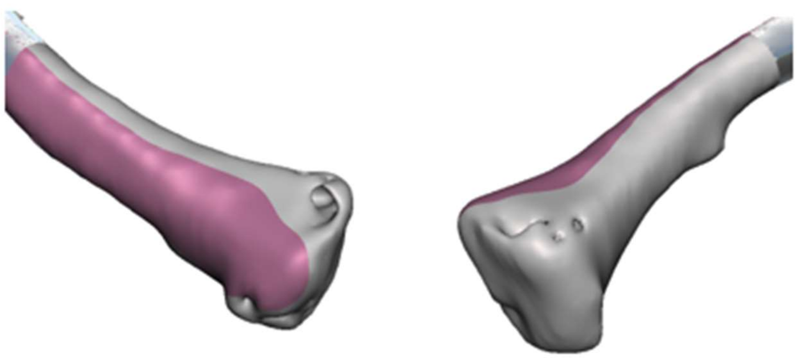

Figure 26: Anterior view (Left), showing joint damage. Posterior view (Right), defects caused by osteosarcoma.

Figure 27 shows the replacement clavicular virtual model, with the localized restorations, which was used to obtain, by 3D additive manufacturing, the implant prototype.

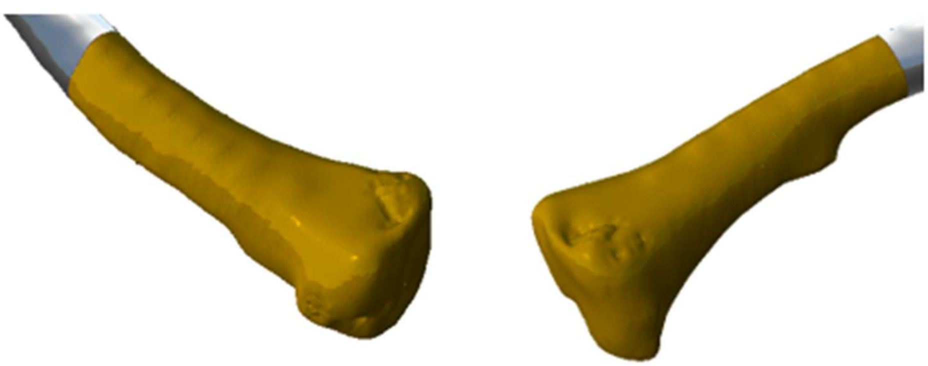

Figure 27: Repaired virtual model: Anterior view, undamaged joint (Left). Posterior view,

without osteosarcoma (Right).

2.4.3 Design and printing of anatomical models

The 3D printed cutting guide facilitated the exeresis of the tumour with negative margins previously assessed in the tomography (Figure 28).

Figure 28: Anatomical model, cutting guide and personalized prosthesis, printed in 3D

With the three-dimensional models, the 3D printing of the test anatomical model was carried out (PLA was used as impression material), and the manufacture of the personalized implant for the patient (PMMA was used as impression material) (Figure 29).

Figure 29: 3D printed implant anatomical model

2.4.4 Intraoperative approach

After simulating of the surgery, with the support of the 3D test models, the real surgery was programmed and carried out, consisting of clavicular osteotomies to perform the excision of the tumour. In this process, the cutting guide was used and the reconstruction of the bone structure was carried out: placement of the customized implant, which was fixed with osteosynthesis material and covered with muscle tissue. Figure 30 shows different moments of the surgery.

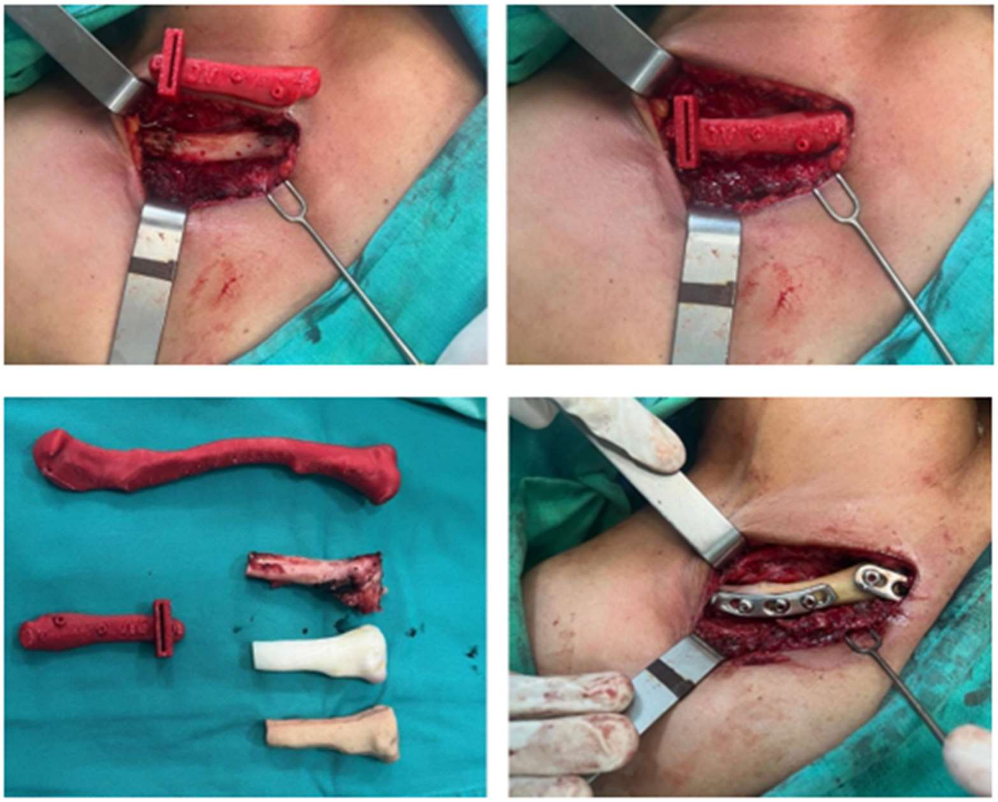

Figure 30: Moments of surgery. Positioning and fixing of the cutting guide (Above). Removed tumour alongside the anatomical test model and implant (Bottom left). Implant fixation elements (Bottom right).

2.4.5 Post-operative Results

Postoperative examinations (physical and tomographic) allowed to corroborate the total reconstruction of the bone structure and the recovery of the mobility of the affected extremity (Figure 31).

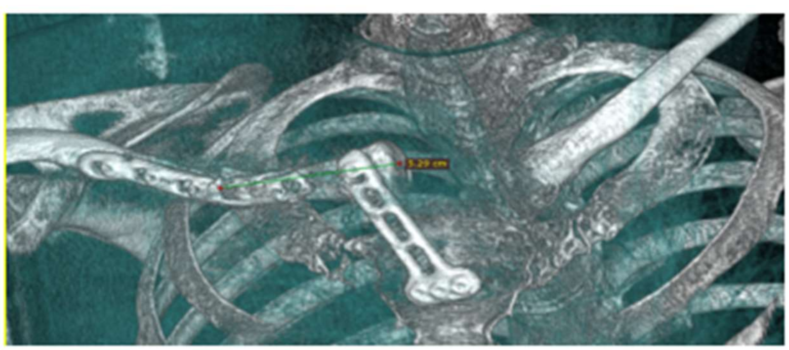

Figure 31: Post-surgical tomography. Reconstruction of the right sternoclavicular joint after tumour excision.

2.5 Case 5: Posterior chest tumour

2.5.1 Diagnosis and analysis

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70-year-old female patient, who was diagnosed with a tumour in the right thoracic region. The lesion affects the skin, subcutaneous cellular tissue, soft tissues, and rib grill with invasion of the pleura (Figure 32 and 33).

Figure 32: External views of the thoracic tumour.

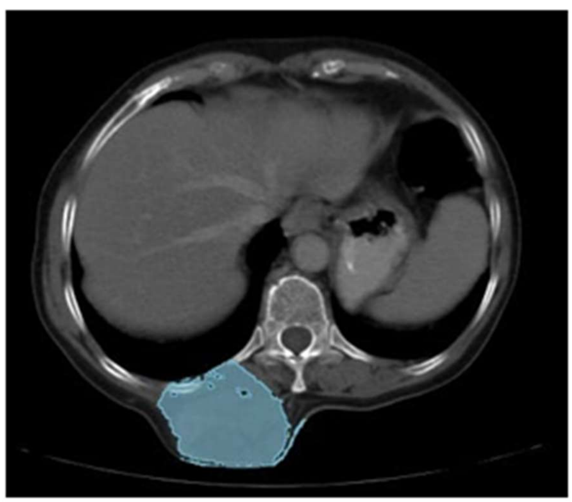

Figure 33: Tomographic image that reveals involvement of the skin, subcutaneous cellular tissue, soft tissues, and rib grill with invasion of the pleura.

2.5.2 Surgical planning

Excision of tumour from the right posterior chest wall through simulated surgery with the help of the anatomical test models printed in PLA (rib grill and cutting guide).

2.5.3 Design and printing of anatomical models

For the 3D manufacturing of the anatomical trial models and cutting guide, an Ender printer was used. Figure 34 shows an instant of the printing process and the cutting guide. While in Figure 35, another detail of the cutting guide is observed, and the anatomical test model includes the reproduction of the tumour.

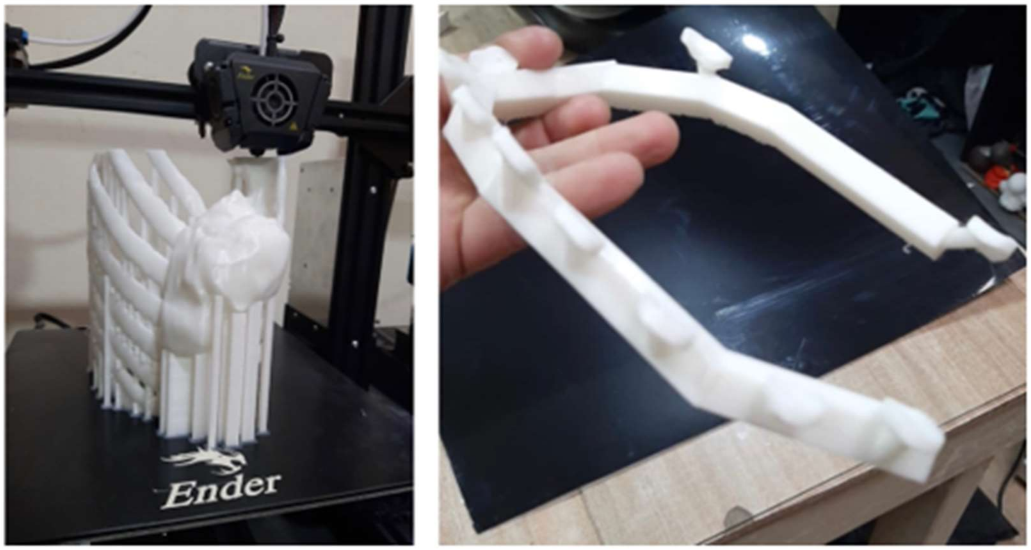

Figure 34: Printing process (Left). Cutting Guide (Right).

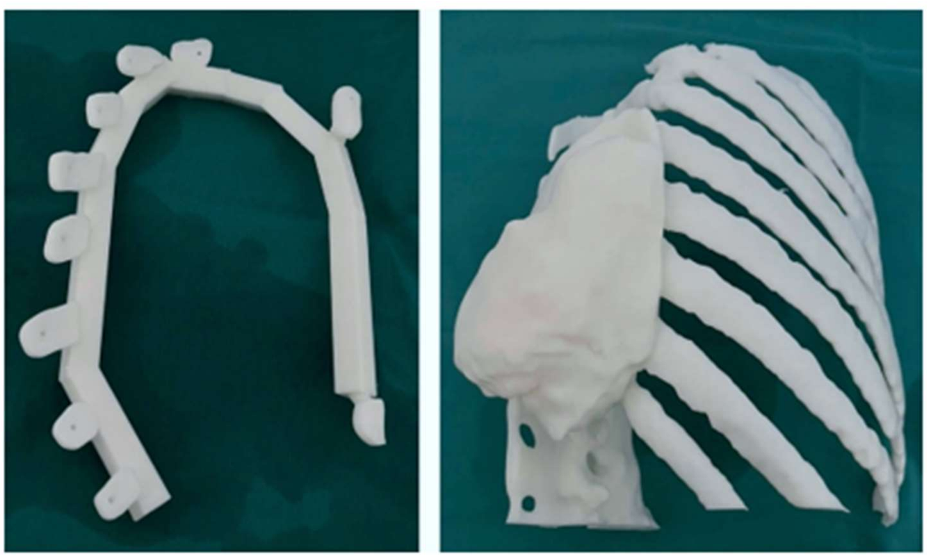

Figure 35: Detail of the cutting guide (Left). Anatomical test model with the tumour (Right).

2.5.4 Intraoperative approach

The simulation of the surgery, with the help of the 3D test models, facilitated the programming and performance of the actual intervention. In this, rib osteotomies are performed for excision of the tumour, in a bloc with the thoracic wall. This process was supported by the cutting guide. In Figure 36 photographic planes of the placement of the cutting guide can be seen.

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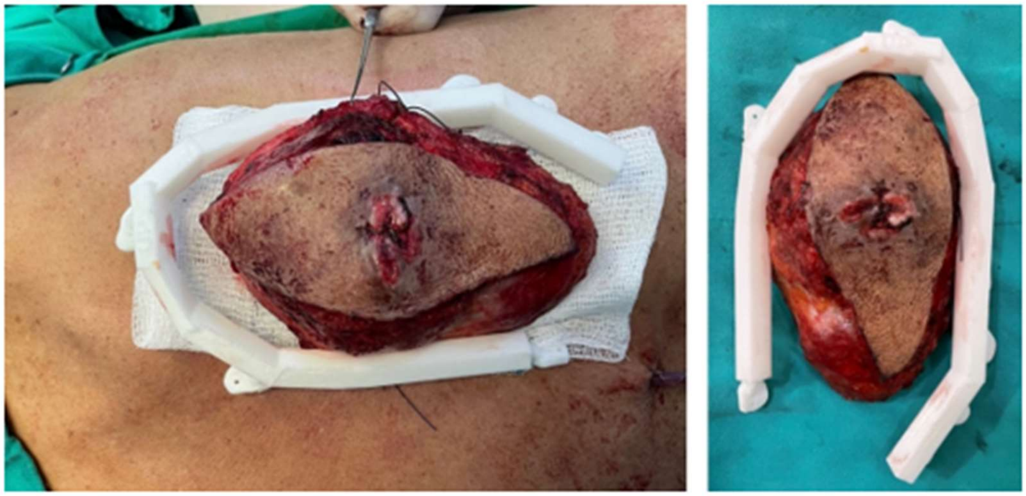

Figure 36: Excision of the tumour through limits marked by the cutting guide.

2.5.5 Post-operative results

Post-surgical examinations (tomography, digital photography and physical examination) allowed to corroborate the complete resection of the tumour with negative margins and to verify the total reconstruction of the rib grill. Figure 37 shows the state of the scar hours after surgery.

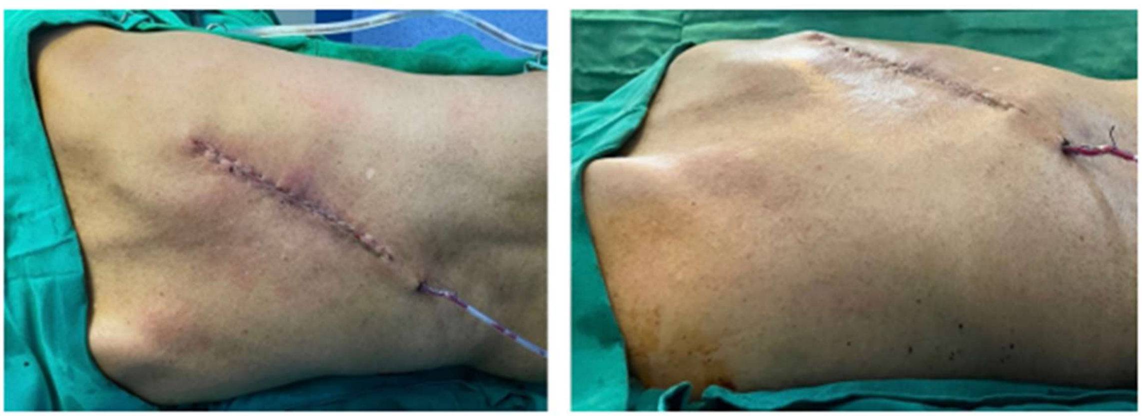

Figure 37: Reconstruction of the posterior chest wall.

2.5 Case 6: right sternoclavicular tumour

2.6.1 Diagnosis and analysis

A 55-year-old female patient was diagnosed with a tumour in the right sternoclavicular region, which compromised half of the sternal handle and the proximal third of the clavicle on the same side. As in the previous cases, from the tomographic images of the affected area, the three-dimensional digital model of the entire area is obtained. In Figure 38 part of the delimitation process of the damaged bone structure is observed.

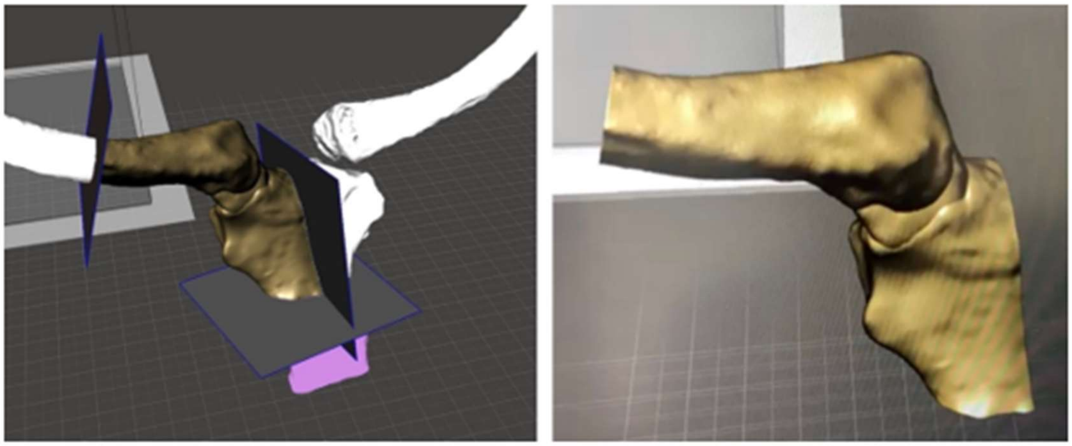

Figure 38: Isolation of the clavicular tumour (Left). Clavicle and sternum reconstruction model (Right).

2.6.2 Surgical planning

After the anatomical test models and cutting guide have been printed, the surgical process is planned and tested, which includes the excision of the tumour and reconstruction of the bony structure with a patient-specific 3D-printed implant. Figure 39 shows the cutting guide designed for this case and its placement.

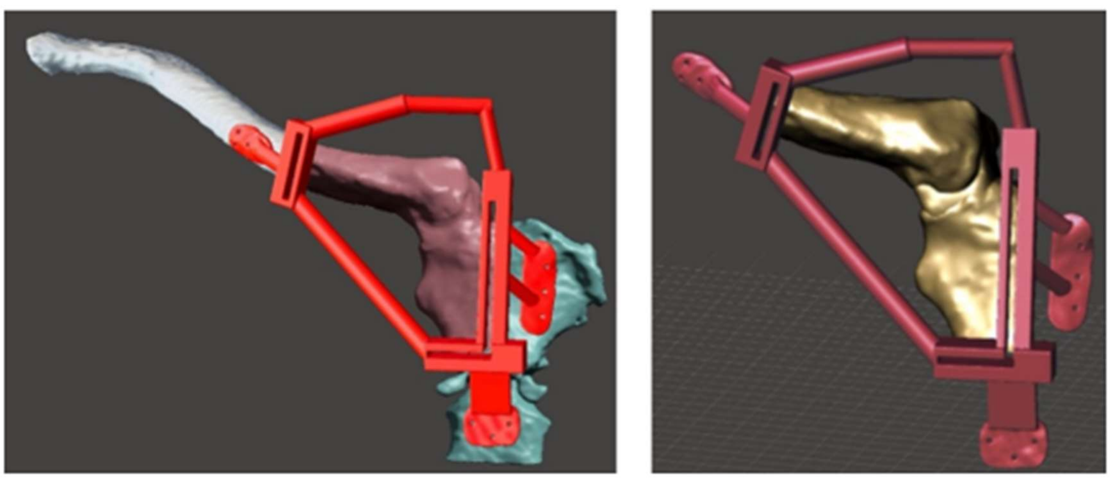

Figure 39: Bone segmentation model and anatomical reconstruction (Left). Anatomical positioning of the cutting guide (Right).

2.6.3 Design and printing of anatomical models

The simulation of the real surgery was carried out using the test anatomical model. Likewise, with the test model of the cutting guide, printed in 3D, the excision of the tumour was simulated with negative margins previously assessed in the tomography, which facilitated the placement of the personalized 3D implant, manufactured with PMMA. Figure 40 shows the anatomical test model, printed with PLA, the cutting guide manufactured with BioMed resin, and the personalized prosthesis printed in PMMA.

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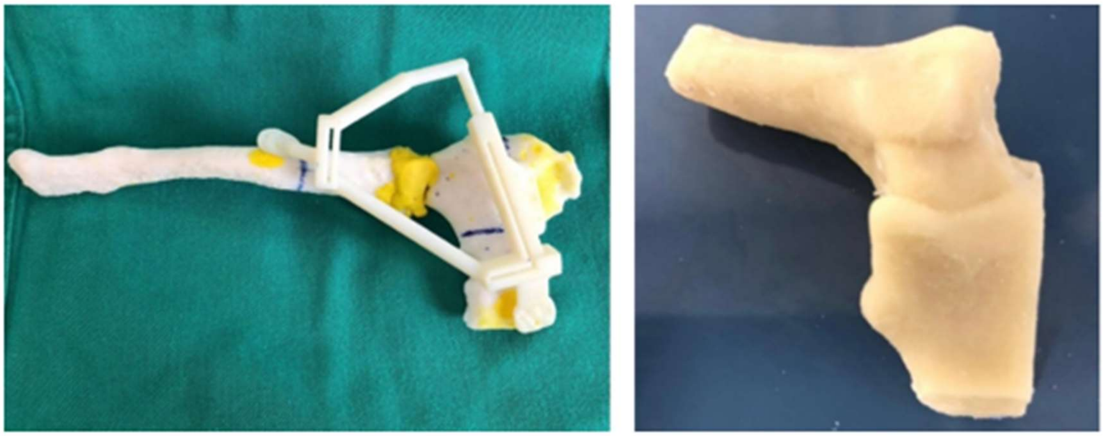

Figure 40: Anatomical model printed in PLA and BioMed White resin-based cutting guide (Left). PMMA-based custom implant (Right).

2.6.4 Intraoperative approach

After the simulated surgery with the help of the 3D models, the respective sternoclavicular osteotomies are programmed and executed for the excision of the tumour, now with the help of the cutting guide. After resecting the tumour, we proceeded with the reconstruction of the bone structure with the placement of the 3D prosthesis, fixing it with osteosynthesis material. The wound was closed and the prosthesis was covered with muscle tissue (Figure 41).

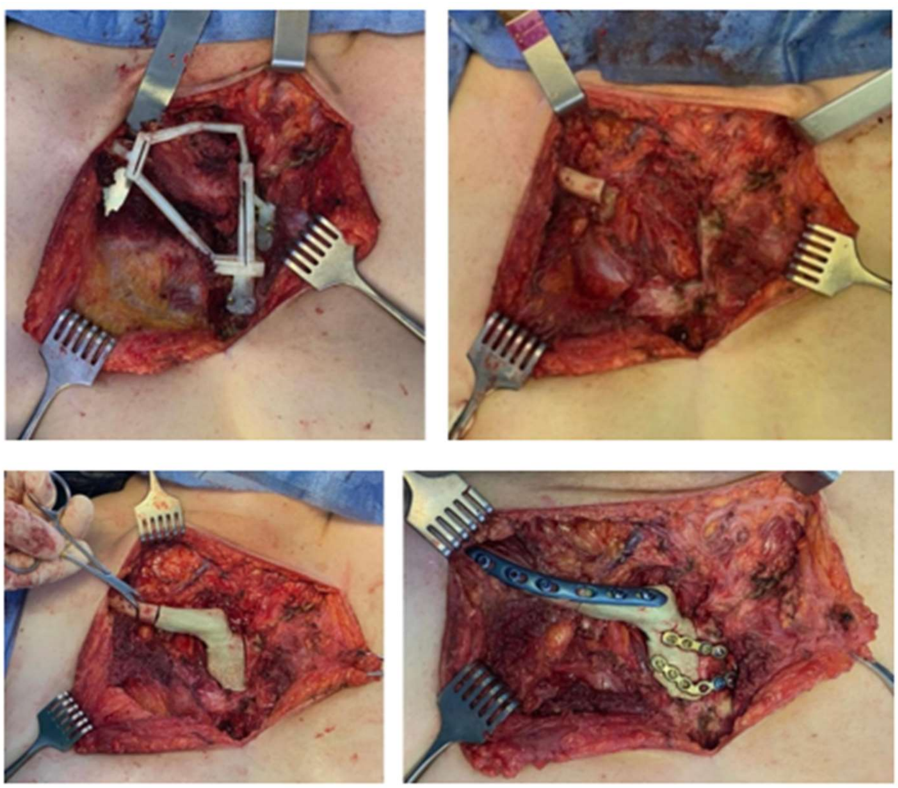

Figure 41: Surgery details. Positioning the cutting guide (Top, left). Space left by the excision of the tumour (Top, right). Placement of the custom implant (Bottom, left). Implant fixation (Bottom,

right)

2.6.5 Post-operative results

Postoperative tests (tomography, physical examination) showed complete resection of the tumour, with negative margins, and reconstruction of the sternoclavicular joint with adequate functionality (Figure 42).

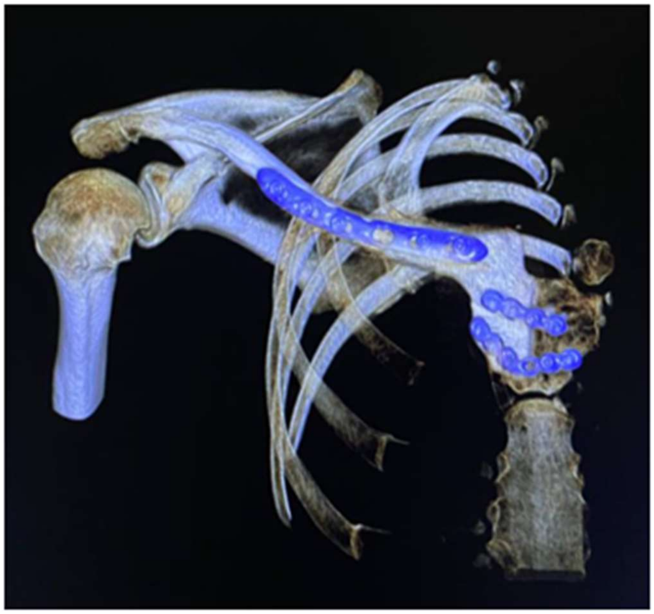

Figure 42: Right sternoclavicular reconstruction after tumour excision (tomographic image)

3. Results

There is a considerable volume of information on the benefits and limitations of 3D printing for medical applications. Results of surveys carried out on surgeons related to this activity have shown that the three main advantages of this technology are: the possibility of surgical planning, improvement in the quality of the surgical result and reduction of risks and complications for the patient. On the other hand, the three main factors that limit the use of 3D printing in public health are high costs, complexity of the organizational scheme to obtain the finished product and delivery time [1]. In [9] is reported that the main benefits of being able to perform a planned and personalized surgery are: safety, patient satisfaction and saving surgical time. Considering that the patient-safety is of the highest priority, being able to provide a predefined cutting guide and a personalized implant reduces the risks that could be derived, for example, from a procedure without such aids. The use of the 3D-printed cutting guide and implant saved approximately 30% of surgical time, a fact that is of great importance for health economics [8]. Other clinical advantages of maxillofacial surgical interventions, supported by manufacturing based on 3D printing techniques, are exposed in [10], [11], such as lower risk of injury and/or damage to the mandibular nerve, lower risk of mandibular fractures, lower risk of intra and postoperative bleeding less time in the operating room thanks to the simplification of the surgical procedure. In terms of costs, there are also advantages, in [12] it is concluded that, by using a consumer-grade

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3D printer, significant savings in costs and time in the operating room are estimated. In this study, it is reported that the annual operating room time saved was 58 hours, which represented a saving of USD 87, 000.00 in operating room costs. Likewise, not everything is favourable, at the moment, in terms of the medical applications described. In [13], [14], the authors allege that one of the disadvantages of using 3D-printed medical devices is related to cutting guides: possible errors when incorrectly placing the personalized guide on the bone to be manipulated. In correspondence with the results reported in this synthesis of cases, the importance of this technology for different medical applications is verified:

1. The use of scale 1:1 models for simulated surgery and trial-error test with the corresponding anatomical models, for the selection of an appropriate surgical approach and individualized planning of surgery for each patient.
2. The additive manufacturing of surgical guides favours the making of precise cuts, with adequate margins both for the oncological result and for the reconstruction of defects.
3. The manufacture of custom-made prostheses for bone reconstruction and restoration avoids both the morbidity of the donor site, as well as the increase in anaesthetic-surgical time that freehand manufacturing represents. The prosthesis is also exact for each patient's defect, which is why it represents an anatomical and aesthetic advantage.

All of the above translates into benefits for the patient. This procedure represents a decrease in hospital stay time, anaesthetic-surgical times, possible morbidity and mortality of the donor site, and the total final cost. In addition, it represents an improvement in the aesthetic and functional outcome.

4. Discussion

In [1] the contribution of 3D printing in the practice of surgeons is exposed. According to testimonials from various specialists, the reduction in operating time and the gain in precision in operating gestures are considerable. Similar testimonies are reported in [15], [16], [17], [18]. Regarding surgical planning, [19] shows how 3D technology has helped in many ways to improve medical procedures. In [20], a series of 6 cases are reported. Patients with various hemifacial asymmetries, for whom, after medical image processing, preoperative and postoperative masks were created. The authors took the unaffected hemifacial side to measure the volume of fat needed to fill the defect on the affected side. Although facial fat grafting generally requires making some subjective decisions, the use of 3D-printed masks to measure that volume achieved accuracies above 80%. In [21] the results obtained in the design, printing and placement of personalized bone implants are presented through three cases, under the guidance of a comprehensive methodology that covers all the aspects involved in this type of procedures.

5. Conclusions

Computer-aided design and additive manufacturing have proven to be effective tools in the design of custom implants. In the present work, the entire manufacturing process of 1:1 models for simulated surgery and surgical planning, cutting guides, and custom prostheses has been exposed, to perform personalized surgeries on six patients with different pathological scenarios. The general procedure (fabrication of the implant and surgical planning) was carried out according to the proposed methodology and with the support of open-source software for the segmentation and post-processing stages of medical images and digital models. This represented an advantageous factor, considering the level of economic development of the region where the methodology has been applied, and that an annual research license for a commercial package for the study, segmentation, and design of implants costs around USD 22,000.00 [4,5].

Another point of view on a cost and feasibility analysis is presented in [22]. It has also been clinically shown that custom implants fabricated with computer technologies improve the cosmetic appearance of the patient and minimize surgery time, blood loss and the risk of complications [16]. The proposed methodology offers better possibilities to surgeons for making decisions about the routes to follow, based on the requirements of each patient. Such decisions will be subject to the medical and surgical actions that result from each diagnosis. It is also important to keep in mind that, despite the many advantages of this technology, it should not replace clinical judgment or the technical skill of a surgeon, and does not guarantee an ideal or perfect result. However, when implemented correctly, virtual surgical planning, computer-aided design, and manufacturing improve efficiency, precision, reproducibility, and creativity in craniomaxillofacial and aesthetic plastic surgery.

These surgical procedures have been performed under the protection of the rules of the National Agency for Health Regulation, Control and Surveillance (ARCSA- acronym in Spanish), RESOLUTION No ARCSADE0262016YMIH, Article 20, items a, b, c and d.

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