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Original Article

Oculopalpebral prosthesis prototype design using the additive manufacturing technique: A case study

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ABSTRACT

Three-dimensional (3D) printing technology has advanced for applications in the field of reconstructive surgery. This study reports the application of a comprehensive methodology to obtain an anatomical model, using computed tomography and 3D printing, to treat a patient with cancer who designed a prototype oculopalpebral prosthesis for the reconstruction of the affected area of the face (left eye). A personalized prototype was obtained, which adapted to the face of the person, and improved the aesthetics and quality of life. The applied techniques helped to make definitive prostheses using materials that could be permanent. The training and tests carried out in this study favored the understanding and assimilation of the technology and the possibility of applying it to patients in need of facial prosthetic rehabilitation.

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Introduction

Patients who have lost parts of their body due to congenital causes, accidents, or ablative oncological surgery, and those who cannot be rehabilitated by surgical means or anaplastology (fusion of science and art) need help in reducing their psychological trauma and facilitating their social reintegration.[1]

In Ecuador, the demand for facial and somatic prostheses has been increasing and people who require a prosthesis often cannot obtain it either because of its high cost or the lack of resources in the country.

The removal of important anatomical structures leaves a marked aesthetic and functional deformity in the patient. Some patients are treated using radiation protocols after tumor resection; in such cases, complications due to collateral damage to the surrounding hard and soft tissues can occur.[2]

The new three-dimensional (3D) printing technologies and application of computational engineering tools have enabled the national medical sector to develop procedures for the reconstruction of anatomical structures from 3D bio-models that were generated from two-dimensional medical images.[3,4]

Therefore, 3D printing, combined with the sublimation technique, has been applied to manufacture eyeball prostheses. The results obtained and the corresponding comparison with manually manufactured eyeballs have been reported in patients who could preserve their eyelids and the complete ocular cavity. Furthermore, aspects related to the biological and physicochemical safety of the prostheses and the satisfaction of the treated patients were addressed.[5-7] The molding was carried out without the impression of the anophthalmic cavity.

Other studies have reported the 3D design of geometric models without printing for ocular prostheses, by applying a low-dose cone beam computed tomography (CT) as a starting point, for ex vivo anophthalmic socket models.[8] Moreover, in terms of manufacturing via 3D printing, different models of ideal eyeballs for the estimation of intraocular pressure were based on corneal thickness, and this technique could be a promising alternative to the conventional porcine eye model.[9]

This report describes the design of an oculopalpebral prosthesis prototype for a patient who required the reconstruction of the anatomical structure of the left eye and its contour. By using medical images and reverse engineering techniques, the 3D model for the application was obtained using a printing technique. Moreover, by carrying out prototype adaptation tests, the restoration of the affected area was achieved.

Materials and methods

Case description

A 70-year-old patient who lost his left eye in an accident several years ago had a prosthetic eyeball. He underwent surgery for the resection of a pigmented lesion that affected the conjunctiva at the bottom of the anophthalmic cavity, tarsal conjunctiva of the eyelids, and conjunctiva of the semilunar fold and caruncle. Histopathology reports indicated that a 2-mm thick invasive melanoma had developed on melanosis (Breslow III), in the vertical growth phase, without ulceration and with a compromised surgical limit. On physical examination, no pigmented lesions were observed. No cervical lymphadenopathy was identified. Staging tomography was negative for other lesions. Since it was a vertically growing melanoma with compromised resection edges and no evident previous resection lesion or scar, it was decided to perform a left ocular exenteration and apply a free skin graft to cover the orbital cavity. No PET or CT scan was performed; however, only a simple and contrast-enhanced CT of the chest, abdomen, and pelvis was carried out. The surgery was satisfactory. The histopathological results revealed that the recession margins were free and no residual tumor was found in the tissue, so the patient was placed under surveillance without chemotherapy. However, immunotherapy was not considered (see Figure 1).

After the necessary assessment, and with the express wish of the patient, the process to obtain a prototype of the personalized oculopalpebral prosthesis was carried out.

Figure 1. Condition of the patient before the adaptation of the ocular prosthesis prototype: frontal view, defect in the left eye.

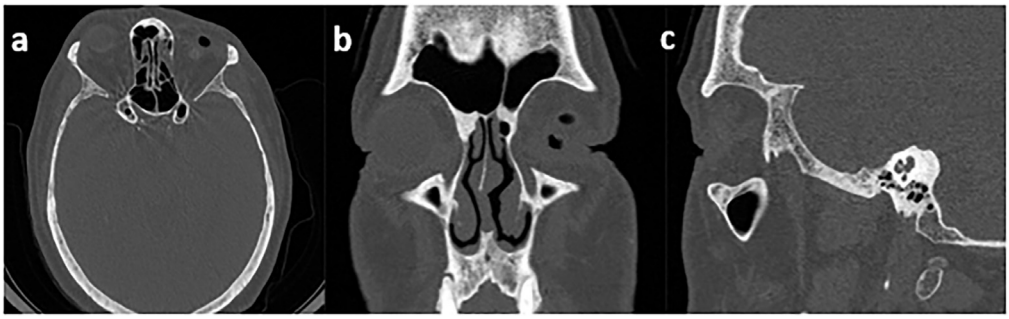

Figure 2. CT scan images: axial section (a), coronal section (b), and sagittal section (c).

Data acquisition

The CT scan data of the patient were acquired as digital imaging and communications in medicine (DICOM) files. High-resolution CT scans with a resolution of 512 × 512 x Z voxels, where Z ranges from 40 to 500, were considered. The data were then processed using the free and open-source software *3D Slicer* (https://www.slicer.org) to generate the *standard tessellation language or stereolithography* (STL) model for the required anatomy. Figure 2 presents the CT data in the three section planes and absence of the eyeball due to the surgical intervention.

Medical imaging and segmentation

Computerized tomography in face reconstruction cosmetic surgery is used to evaluate and treat congenital or acquired facial deformities (craniofacial malformations, post-oncological sequelae). Computerized tomography scans have helped to obtain complete and detailed view of the affected bone structure and soft tissues, giving way to personalized treatment plans and greater precision in reconstruction.[10] The medical images (tomographic study of the patient) were stored in DICOM format to carry out the segmentation process, and based on this, the modeling for the reconstruction of the area of interest and planning of the ocular prototype design were carried out. To achieve this objective, the 3D Slicer software (v.4.11) was used. This open-source and free license tool provides functionalities similar to those of other commercial softwares and has great versatility for identification of soft tissues and bones.[11-13]

The tomographic images were segmented to reconstruct the external skin, close to the affected area, and obtain the replica of the patient's superficial anomaly on a real scale. The segmentation strategy was to apply a mask that occupies the soft and hard tissues ranging from of -264.00 to 2976.00 Hounsfield units in the grayscale. With complete segmentation, it is possible to model all the external profiles of the patient's face, and make the necessary repairs on the segmented model, elim-

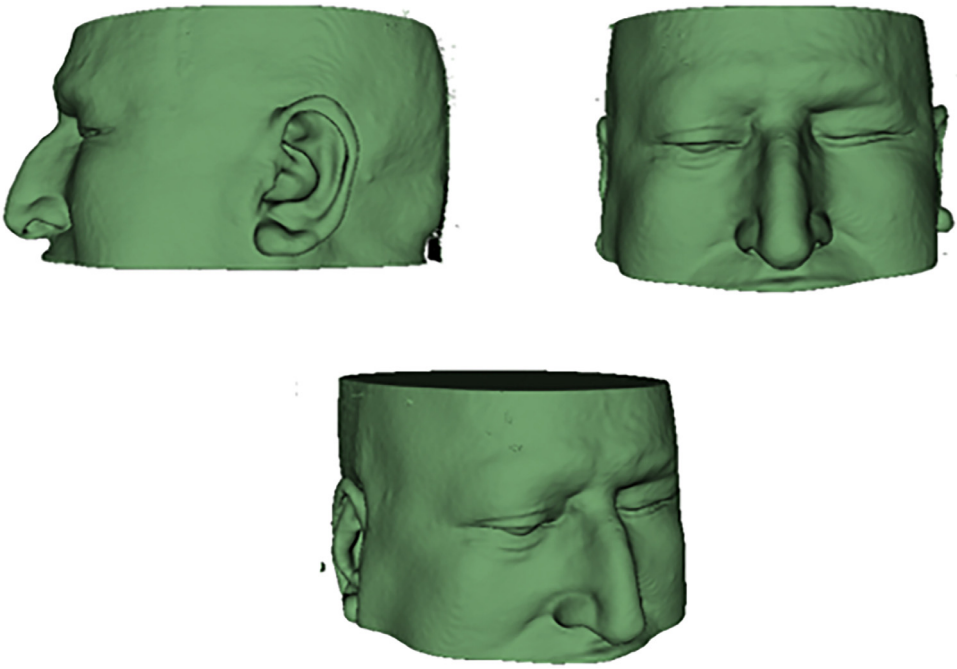

Figure 3. Different views of post-processing of the segmentation model. The presence of noise on the perimeter surface of the patient's skull and face is identified.

inating the noise captured during the tomographic procedure. The applied methodology is described in.[10] The resulting high-definition model was exported to STL format.

Reconstruction of the model and preparation for 3D printing

When anatomical reconstructions are made using CT data, it is important to preserve the topology of the surfaces because they provide precise information about the shapes, especially in the craniomaxillofacial area.[1] A virtual study is not sufficient for medical or surgical purposes. High standards of anatomical correlation and exact location of structures are required for cosmetic restoration. This information is obtained using advanced tools to obtain 3D physical models and a reconstruction protocol is needed for the area of interest in the human body. For the case described, denoising was performed on the computational model of the complete skull. Figure 3 shows the three views obtained after removing the orbital arch, but unnecessary artifacts captured in the tomography could still be observed, which were removed with the help of complex geometry reconstruction and the repair software *Autodesk Meshmixer* (https://www.meshmixer.com), version 3.5.

The edition of the model in STL format was developed using basic commands: *select*, to perform the separation of tissues; *invert, plane,* and *cut*, to divide the model, obtain the volume of interest, and prepare the 3D additive manufacturing, respectively.[10] Figure 4 shows the critical path of the process to obtain the 3D digital prototype model, with a filling density of 10% and a resolution of 0.05 mm. This procedure helps to minimize misfits during the design of the custom external implant.

Characteristics of 3D printing technology

For 3D printing, FDM technology was applied with the help of a *Creality CR-X Pro 3D* printer (Shenzhen Creality 3D Technology Co., Ltd.), and Creality HP PLA 1.75 mm Series filament was used. For the reading, processing, and generation of the routing code, the STL file was handled with the *Creality*

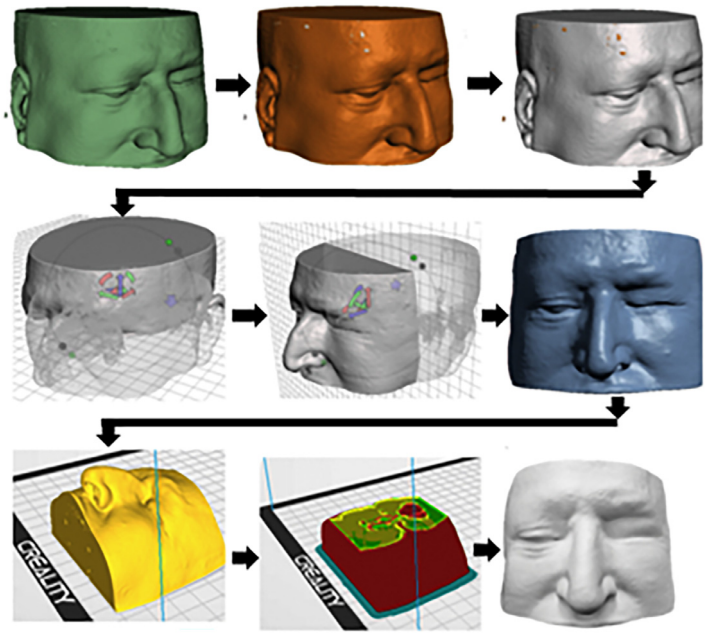

Figure 4. Critical path of the process to obtain the digital model of the 3D prototype.

Table 1
FDM additive manufacturing characteristics and parameters

Characteristics and manufacturing parameters	Fused Deposition Modeling Technology
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

Slicer Cx software. The incorporated supports were removed manually, paying special attention not to affect the surface of the facial microstructure.

Table 1 presents the characteristics of the FDM technology and the adjusted manufacturing parameters to obtain the best performance in the printing process.

The printing parameters were established based on the geometric characteristics, size, surface quality, functionality of the anatomical model, and type of material used. Table 2 shows the mechanical characteristics of the impression material and parameters supported by other studies on anatomical models.[10]

Results

Design and validation of prototype in vivo using 3D printing models

The manufacture of the oculopalpebral prosthesis prototype followed a routine of clinical care, laboratory procedures, and preservation of local hygiene with the instruments used. A visual description of the manufacturing process is represented in Figure 5.

The prosthesis prototype was manually carved and tested directly on the anatomical model of the patient, to adapt the shape, size, position, and aesthetics. The material used was cold porcelain

Table 2
Characteristics of the material used

Material characteristics	FDM technology
Polymer	Thermoplastic PLA
Manufacturer	Creality HP -PLA
Commercial	HP PLA
Color	White
Density	1.23 kg/m^3
Tensile strength	52 MPa
Print temperature	190-220°C (+/- 5)
Filament diameter	1.75 mm
Printed diameter	0.15 mm

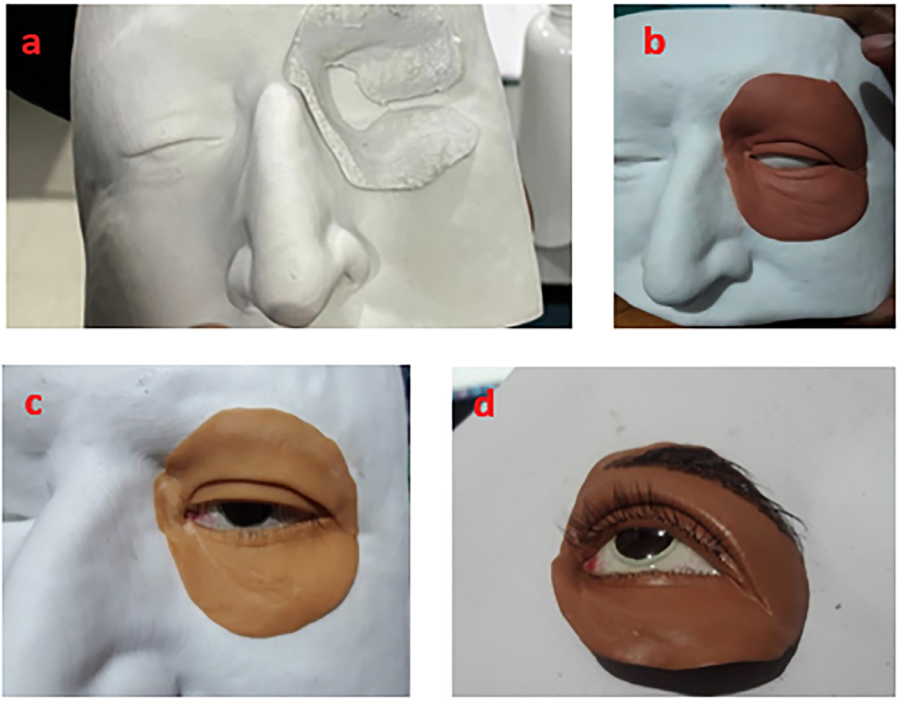

Figure 5. Stages of the prosthetic protocol: (a) development of the prototype of the customized oculopalpebral prosthesis adaptation from the patient's anatomical model. (b) reconstruction of the oculopalpebral prototype, based on the details of the healthy eye. (c) taking of base color and placement of eyebrows and main detail of the view. (d) Final prototype of the customized oculopalpebral prosthesis.

(flexible paste), mixed with acrylic paint to obtain a homogeneous mass with a color similar to that of the patient's face. Similarly, for the eyeball, porcelain mass was mixed with white titanium acrylic paint. Added details included eyelashes, eyebrows, and facial features. Later, to protect the prototype, a layer of matt lacquer was applied. Figure 6 shows the prototype incorporated into the patient.

The patient received instructions regarding local hygiene, which consisted of daily cleaning of the vision perimeter and not sleeping with the prosthesis. Quarterly controls were carried out.

Discussion

The objective of this study was to evaluate a strategy for manufacturing a prototype for the rehabilitation of oculopalpebral deformity in a specific patient. For this, the comprehensive methodology

Figure 6. Final test of the oculopalpebral prosthesis prototype.

proposed in[10] was adopted. The necessary craniomaxillofacial tomographic study of the patient was developed. With the help of free platform medical software, soft tissue segmentation was achieved with good correlation, a process validated by the treating physician.

FDM 3D printing technology has helped to replicate complex surfaces and facial features of the patient, using polylactic acid (PLA), a polymeric material. The manufacturing costs of the anatomical model were not representative, compared to those of other types of processes, such as the use of plaster casts. For such an option, molding with the plaster mixture is performed on the patient.

The process developed to obtain the oculopalpebral prosthesis prototype has contributed to improving the psychological state of the patient, owing to their social reintegration and self-esteem elevation.

The applied methodology avoids the inconvenience associated with systems that apply screwed metallic structures to an implanted base or fastening using magnets. In addition, the risk of chronic inflammation of the soft tissues is reduced.

Moreover, local hygiene is a primary factor for maintaining the health of tissues surrounding the implant; therefore, patients might prefer the simplicity of the proposed variant over the greater stability provided by metallic fixation systems. To obtain more information on the previous factors, the cited studies can be referred.[14-18]

The fixation of the oculopalpebral prosthesis prototype, once sterilized, was performed using surgical glue. During the follow-up period, the patients did not report any discomfort.

Conclusions

The design and clinical development of facial prostheses requires a multidisciplinary team, including a reconstructive surgeon, a design engineer, and an anaplastologist, to provide patients with aesthetically and structurally appropriate facial prostheses. The development of technology, including computer-aided design and 3D printing, has contributed to the availability of facial prostheses by eliminating several stages involved in the handmade prototyping process. In addition, the application of improved materials will result in greater durability of these devices.

The use of 3D printing technology also reduces the execution times for the manufacture of personalized prosthesis prototype and minimizes invasive processes for the patient, when compared with plaster molding. Implant materials must be carefully evaluated to ensure the necessary safety.

The results show the possibility of obtaining an acceptable restoration, from an aesthetic point of view, of the facial oval of patients with considerable damage to the bone structure and tissues surrounding their eyes, with total loss of eyelids. Such conditions make it difficult to place an eyeball prosthesis.

The proposed procedure is semi-manual, because it avoids a major part of manipulation involved in the procedure that is traditionally applied in the few health institutions in the country with this

facility. In addition, its great advantage lies in cost reduction when compared with the application of the sublimation technique presented in other studies.[5-8] Moreover, the possibility of complications of cytotoxicity and intradermal reaction are not a cause for concern, since the prosthesis is placed over a deep cavity completely covered by healthy skin. The device can be removed and replaced whenever the wearer wishes, for hygiene or rest purposes. Notably, it is crucial to test for possible skin sensitivity of the patient to the polymeric material with which the prosthesis is manufactured.

In public and private hospitals in the Republic of Ecuador, the adoption of advanced medical technologies, such as 3D printing, is limited due to factors such a lack of resources and low investment in research and development. Thus, personalized medical devices are being developed and applied with the help of academia, to transfer new technology to the medical sector.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

Author contribution statement

Bohorquez-Vivas, Diana Denisse; Pablo Gerardo Peña-Tapia: Performed the experiments, analyzed and interpreted the data, contributed reagents, materials, analysis tools, or data. Efrén Vázquez-Silva; Freddy Patricio Moncayo-Matute: Analyzed and interpreted the data, contributed reagents, materials, analysis tools, or data. Diana Patricia Moya-Loaiza; Paúl Bolívar Torres-Jara: Reviewed and corrected the manuscript. Efrén Vázquez-Silva: Wrote the paper.

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Protection of people and animals

The authors declare that the procedures followed conform to the ethical standards of the responsible human experimentation committee under the World Medical Association and the Declaration of Helsinki.

Data confidentiality

The authors declare that they have followed the protocols of the country and its institutions regarding the publication of patient data.

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Right to privacy and informed consent

The authors have obtained the informed consent of the patient referred to in the article. This document is in possession of the corresponding author. In this document, the patient declares that he authorizes the use of the information and photographs related to his case.

Ethical approval statement

These 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. ARC-SADE0262016YMIH, Article 20, items a, b, c and d. (Custom-made medical devices do not require a health record. The informed consent of the person who receives it is sufficient)

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