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MANUFACTURE OF SILICONE NASAL PROSTHESES WITH DIGITAL TOOLS AND 3D-PRINTED MOLDS

Bruno Benegra Denadai
UTFPR - Universidade Tecnológica Federal do Paraná – Curitiba
http://lattes.cnpq.br/7595114058853579

Felipe Mateus Franco
UTFPR - Universidade Tecnológica Federal do Paraná – Curitiba
http://lattes.cnpq.br/3096835710799443

Karin Barczyszyn
HAC - Hospital Angelina Caron
https://lattes.cnpq.br/8199746251782270

José Aguiomar Foggiatto
UTFPR - Universidade Tecnológica Federal do Paraná – Curitiba
http://lattes.cnpq.br/8013863352635494

Abstract: Facial mutilations can result from trauma, congenital diseases, surgical sequelae of malignant diseases and infections. Although medicine has achieved excellent technological and surgical resources in recent decades, in many cases bucomaxillofacial rehabilitation with prostheses is still necessary, which is often the best option for the patient, if not the only one; allowing the reintegration of the individual to their social and family environment, directly impacting their entire quality of life. The conventional method of manufacturing nasal prostheses is laborious, time consuming and highly dependent on the artistic skills of the prosthetists. This study aims to describe the making of a silicone nasal prosthesis using digital tools and 3D printed molds. Decreasing the professional's artistic dependence, ensuring repeatability, good adaptation and high quality of the final prosthesis. The entire procedure was carried out in partnership with the Additive Manufacturing and Tooling Group (NUFER) of the Universidade Tecnológica Federal do Paraná (UTFPR) with Clinirad (Oncology Clinic) at Angelina Caron Hospital (HAC).
Keywords: Facial prosthetics, 3D Printing, Molds for facial prostheses.

INTRODUCTION

Facial defects can result from many causes, such as traumatic losses, congenital anomalies, infections, burns, but mainly from surgical resections in the fight against cancer [1]. Despite all medical technology with early diagnostic tests and preventive campaigns, cases of this disease continue to increase significantly year after year worldwide. According to data from INCA (National Cancer Institute), for the three-year period 2023-2025, 704 thousand new cases are expected in Brazil, 70% in the South and Southeast regions. Non-melanoma skin cancer is the most frequent, reaching 31.3% of all cases. In addition to the aggravating factor of skin cancer, these data also include the 6th position in the world ranking occupied by head and neck cancer, a modality also strongly associated with facial mutilations, resulting from the low socioeconomic conditions of the patients. These anomalies can be embarrassing for the bearer and often make these individuals traumatized, embarrassed and psychologically debilitated [2-10].

After surgical treatment, chemotherapy and radiotherapy are associated with most of the more advanced cases, leading to sequelae that may make reconstruction by plastic surgery impossible due to skin complications caused by ionizing radiation that induces tissue fibrosis and difficulty in regeneration, which contraindicates more invasive surgeries due to the risk of skin graft failure and osteoradionecrosis [11-15]. In these cases, prosthetic restoration is recommended, allowing the individual's immediate reintegration into their social and family environment, and directly impacting their entire quality of life [16].

The conventional method of manufacturing nasal prostheses is laborious, time consuming and highly dependent on the artistic skills of the prosthetists [17]. The process also requires modeling the patient's face, usually done using alginate and plaster, which causes discomfort and does not always provide good geometric accuracy [18]. Opposing these negative points, studies show that the use of digital technologies reduces manufacturing time, reduces the cost and automates the process, reducing the professional's artistic dependence, ensuring repeatability, good adaptation and high quality of the final prosthesis [19-20].

Additive manufacturing (AM – Additive Manufacturing), commonly called 3D printing, is widely used in the medical field to manufacture biomodels for preoperative planning, intraoperative guides and medical education with didactic models [21-23]. All over the world, researchers use it to discover new ways to solve problems due to its power to provide several benefits, such as personalization of medical products and equipment, rapid prototyping and the possibility of manufacturing complex geometries, a suitable tool for manufacturing anatomical molds [24-26].

This study aims to describe the making of a silicone nasal prosthesis using digital tools and 3D printed molds. The procedure was carried out in a partnership between the Nucleus of Additive and Tooling Manufacturing (NUFER) of the ''Universidade Tecnológica Federal do Paraná" (UTFPR) and Hospital Angelina Caron (HAC).

METHODOLOGY

The fabrication method is subdivided into four main phases: the acquisition of the patient's facial geometry, the modeling of the prosthesis, the modeling and manufacture of the molds that give it its physical shape, and the manufacture of the silicone prostheses using the molds.

INITIAL PHASE - ACQUISITION OF THE PATIENT'S FACIAL GEOMETRY

The first phase consists of obtaining patient data so that they can be entered and worked on in the available digital modeling tools. Initially, patients undergo a Computed Tomography (CT) scan, a procedure that divides the region of interest into hundreds of sectional images forming a file in DICOM (Digital Imaging and Communications in Medicine) format. This file makes it possible to start the reconstruction process using the Brazilian program InVesalius®, which reads the images and provides a 3D visualization of the CT scan. It is possible to make a selection of the region of interest according to its density. In this case, as these are nasal prostheses, the chosen density must cover the entire region of the face, which is why the "adult epithelial tissue" range was selected (Figure 1). Once reconstructed, the surface of the face is then exported in STL (STereoLithography) format.

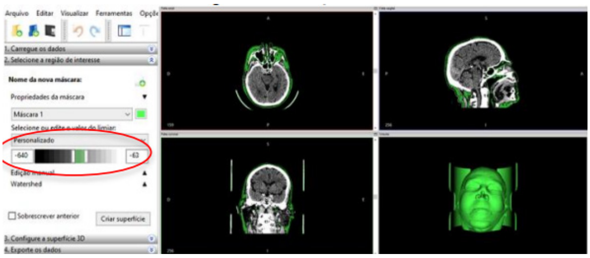

Figure 1 - Density used to create the patient's three-dimensional face.

PHASE 2 - PROSTHESIS MODELING

This phase can be considered the main phase, as it consists of modeling the prosthesis and adapting it to the patient's face, using the Meshmixer® program (Autodesk®). The face model exported by the InVesalius® program contains the entire surface referring to the chosen density range, which may have elements that are not necessary for modeling, such as parts of the tomograph bed, for example. For a better visualization and to minimize computer processing time, the first step is the selection and isolation of the region of interest. Then the patient and the prosthodontist choose a model of nose among those available in a library of noses provided free of charge by NUFER. After choosing, the selected model is positioned and modeled on the virtual face, so that it covers the entire mutilated region (Figure 2a). The junction of the two geometries is done so that the nose of the library is the front part of the prosthesis and the geometry of the face itself is the back part, guaranteeing a natural appearance and perfect adaptation to the face (Figure 2b). The last step is the modeling of the parting surface that will divide the mold into two parts. The surface must pass through the prosthesis and out through the edges, ensuring correct separation of the lower and upper parts. This is done by adding a flat surface in the program and modeling it with the available tools, until the described characteristics are achieved (Figure 2c).

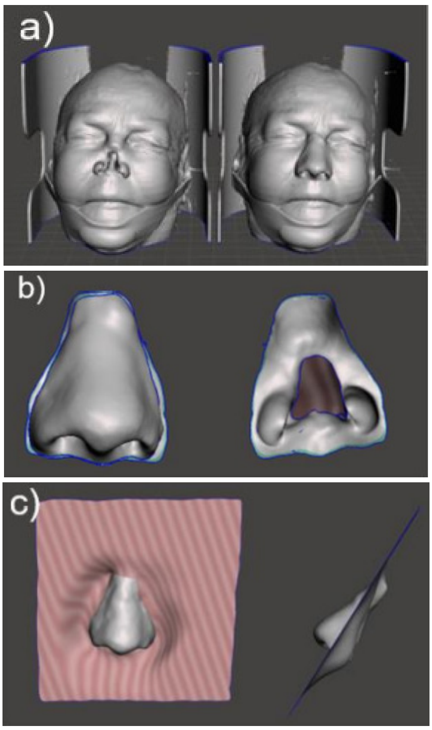

Figure 2 - Prosthesis modeling.

PHASE 3 - MODELING AND MANUFACTURING OF MOLDS

The prosthesis, in STL format, is opened as a solid body in the SolidWorks® program (Dassault Systèmes). A plane is created and the cross section of the mold is drawn on it, encompassing the geometry of the prosthesis inside. The mold extrusion is always done with the "merge results" option unchecked, so that it is not fused with the prosthesis. Next, the Boolean subtraction of the prosthesis geometry inside the mold is performed, leaving an empty region, which will be filled with silicone in the future. With the "split" tool, the previously modeled parting surface is used as a cutting tool to divide the mold in two (Figure 3). The two parts are exported in STL format to be able to manufacture them by 3D printing. The Ultimaker Cura process planning program was used to define the manufacturing parameters. The parts were printed on PLA material (3D FILA®) using the ENDER 3 PRO® Printer (Creality) according to the printing parameters shown in Table 1.

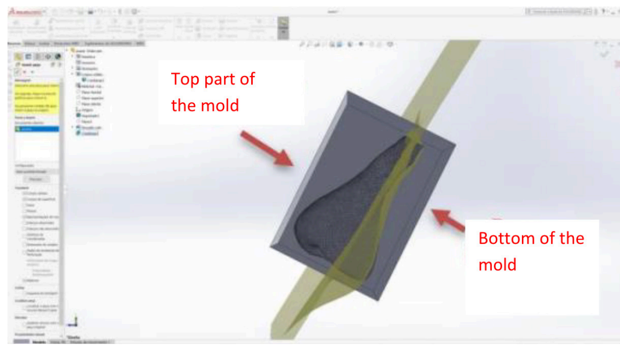

Figure 3 - Mold partition.

Layer height (mm)	0,1
Filling (%)	10
Table temperature (°C)	60
Nozzle temperature (°C)	200
Print speed (mm/s)	45
Support angle (°)	60

Table 1 – Printing Parameters.

FINAL STAGE - MANUFACTURING THE PROSTHESES IN SILICONE USING THE MOLDS.

After receiving the molds of the prostheses sent by UTFPR, production of the prosthesis begins at the Hospital Angelina Caron, with medical grade silicone, used worldwide and with greater indication, following the same manufacturing principles of conventional prostheses made in flasks of plaster. In this study, Silicone Dragon Skin Fast 10 by Smooth On (East Texas, PA, USA®) was used, which was pigmented with mineral pigments and Silk Pig pigments (East Texas, PA, USA®), smooth's platinum silicone curing accelerator. On (Plat Cat) and the extrinsic characterization done with the platinum silicone paint base (Psycho Paint by Smooth On).

The process of intrinsic silicone characterization involves, in addition to choosing the color, mimicking the texture and spots of the patient's skin, performed with flocking powder together with the aforementioned pigments. The insertion of the silicone in the areas with larger recesses can be done with a disposable syringe or with a brush to avoid the formation of bubbles. After the first layer with the proper characterizations (done in a similar way to the conventional technique in plaster muffle), the rest of the base silicone is applied, carefully poured throughout the mold. The mold is closed and left under pressure with the aid of a manual press, waiting for the silicone to vulcanize during the period stipulated by the manufacturer (75 min), at room temperature.

After this step, the prosthesis is removed from the mold and its adaptation to the patient's face is verified, as well as the characterization. If any color adjustment is necessary, the same can be done by performing the extrinsic pigmentation following the conventional technique, and the piece must be washed with silicone pre-painting fluid, from the same Smooth On line and using the platinum silicone paint base (Psycho Paint by Smooth On) duly pigmented according to what is desired. It must be noted that the working time of Psycho Paint is 20 min and the curing time is 2 hours, following the manufacturer's guidelines.

RESULTS

In this study, the methodology was applied to manufacture a nasal prosthesis for a patient with facial multilation due to surgical sequelae.

During the modeling phase, it is noted that the process depends a lot on the quality of the tomography, since all the modeling is done based on the surface generated by it. Patients with slightly looser skin may have significant differences in their facial expression when lying down compared to standing up. Therefore, the examination must always be performed with the patient in the most natural position possible. The printing time for the set of molds was 12h and 23min, using approximately 40g of filament (Figure 4).

The facial prosthesis was analyzed by Dr. Karin Barczyszyn, a dentist at Angelina Caron Hospital with expertise in facial prosthetics. Overall, it got a very positive and promising review, thus validating the proposed workflow. Figure 5 illustrates the result obtained in the patient assisted by the SUS at Angelina Caron Hospital. This work was submitted to CEP (Ethics and Research Committee) and registered under CAAE 48174521.3.0000.5226.

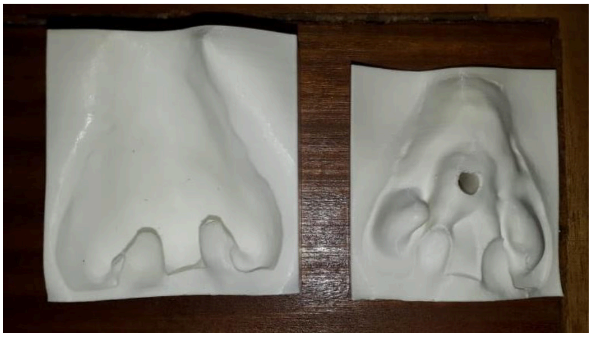

Figure 4 - Printed templates.

Figure 5 - Completed prosthesis.

CONCLUSION

The results obtained in the research showed that the proposed method worked properly and has many advantages compared to the manual method:

- Reduces modeling time, as virtual modeling is faster to perform and correct.
- Reduces manufacturing time: The molds take an average of 12 hours to be printed with the maximum quality of the printer used (Ender 3 Pro). Manual modeling takes, on average, days to be done and several attempts.
- Repeatability. The mold is not disposable, therefore, numerous prostheses can be made from it, exactly the same without additional modeling work.
- Perfection of the reproduced anatomy, excellent adaptation of the part to the facial defect, reliability of the silicone prosthesis with a virtually projected model and naturalness.

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