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Patient-specific palatal obturator prosthesis from DICOM files through low-cost 3D printing: a case study

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Abstract

This work aims to define an accessible workflow for the design and manufacturing of maxillofacial obturator prostheses from DICOM files for patients with reduced mobility of the oral cavity. Starting from a case study, the STL file of the injured area was generated to develop the parametric 3D model of the mold. The mold was then manufactured with a low-cost 3D printer, and the palatal obturator was obtained by silicone casting. The patient has improved his quality of life by recovering some vital functions. This workflow may overcome conventional processes, leading to develop new patient-specific prostheses in critical situations.

Keywords: indirect 3D printing; fused deposition modeling; silicone casting; parametric design; maxillofacial external prosthesis; design for additive manufacturing;

1. Introduction

Maxillectomy implies the partial or total removal of the maxilla bone, and it can be used to treat cancers. It can cause maxillary defects such as oronasal fistulas, loss of cheek and lip support, as well as cosmetic defects in the middle third of the face, impaired phonation, and swallowing [1–4]. Treatment includes reconstructive surgery or rehabilitation with an obturator prosthesis. The different approaches depend on the extent of the defect and its location, the number of remaining teeth, and the quality and quantity of the supporting tissue [5,6]. An obturator prosthesis can be planned for temporary or permanent treatment [7,8], or in combination with other interventions [7]. Obturators can promote healing [9] and help to eliminate problems related to phonation and swallowing [10]. With obturator prostheses, oral impairments can be eliminated or, at least, reduced immediately, limiting the sequelae of surgical tumor removal [11,12]. Aesthetic deformities are also reduced by providing the missing teeth and appropriately supporting the upper lip and cheeks. The immediacy and effectiveness of the rehabilitation spur the patients to respond to the situation they are facing. Obturators can be classified as immediate, temporary, or definitive [13]. The definitive obturator prosthesis, in addition to performing the obturator function, allows the rehabilitation of the aesthetic, phonatory, and masticatory functions thanks to the presence of the teeth and the reconstruction of the palatal structure.

Different manufacturing technologies can be used to fabricate obturator prostheses, ranging from more conventional and artisanal processes to integrated digital workflows [14]. Among those, Additive Manufacturing (AM) or 3D printing has strongly contributed to simplifying their production, including low-cost processes [15]. Since its origins, AM has been employed in healthcare thanks to its intrinsic flexibility to create patient-specific solutions [16,17]. 3D printed orthoses and prostheses often derive from intraoral scanners or imaging files, i.e., from computed tomography (CT) [18,19]. AM has shown some similarities with the most widespread patient imaging techniques. From literature, several studies aimed to develop customized prostheses such as articular orthoses and facial prostheses from imaging files, i.e., DICOM, obtaining a patient-specific 3D model mesh to be manufactured through 3D printing [20–22].

Although several studies linked AM and imaging techniques for the development of patient-specific prostheses in different medical fields, this approach is primarily related to the realization of customized pre-surgical models, aesthetic solutions, or internal prostheses [23–25]. Recently, some works have been focusing on fabricating patient-specific obturator prostheses for the rehabilitation of maxillectomy defects [26–28], as well as on new workflows for

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maxillofacial obturators [29–33]. However, these kinds of approaches are not well-established for those critical cases that cannot rely on conventional methods, i.e., for reduced mobility of the oral cavity. Furthermore, a workflow that integrates expertise from design and engineering fields has not completely been established, yet. Hence, some technical aspects such as usability, weight, and shape optimization are not always considered within clinical practice.

This paper aims to define an accessible workflow for the design and manufacturing of maxillofacial obturator prostheses from DICOM files for low-cost 3D printers. Starting from a case study with reduced mobility of the oral cavity, a STL mesh file of the injured area was generated to develop the parametric 3D model of the mold, following the Design for Additive Manufacturing principles [34]. This mold was then manufactured with a low-cost 3D printer, and the patient-specific obturator was obtained by silicone casting. Thanks to this obturator prosthesis, the patient improved his quality of life by recovering some vital functions, i.e., speaking, eating, drinking. This workflow may overcome conventional processes, leading to the development of patient-specific prostheses for critical situations.

2. Materials and Methods

2.1. Clinical Case Study

This work referred to a clinical case study of a 75-year-old male patient diagnosed with carcinoma of the palatine salivary glands in 2003. The patient underwent surgical resection and postoperative radiation therapy. On imaging, extensive oro-nasal-antral communication is visible due to extensive bone loss involving much of the hard palate and the entire floor of the left maxillary sinus. In November 2020, the patient underwent an additional control CT scan, an examination acquired for planning 3D reconstruction surgery of the palate and floor of the left maxillary sinus. From the imaging study, it appears that this is a critical case study. The patient, who underwent postoperative radiotherapy, reported lockjaw that prevented a physiological oral cavity opening of 50 mm as an effect of late radiation toxicity. The maximum opening was 2.5 mm, and it was impossible to take impressions with traditional techniques or intraoral scanners because of these extreme limitations due to mandibular tightening from cancer therapies. The patient was no longer able to wear the previous obturator prosthesis due to its shape and the rigidity of the material. Hence, the patient complained of discomfort in phonation and swallowing, which also affected the psychological profile.

2.2. Materials

Low-cost Fused Filament Fabrication (FFF) 3D printing was selected as the primary AM technology for the experimentation of this work. The 3D printed mold of the obturator prosthesis was manufactured by using polylactic acid (PLA) 3D printing filaments from Eumakers (Rigenera, Barletta, Italy). Silicone rubber was cast into the 3D printed mold to obtain the patient-specific obturator prosthesis. Conventional maxillofacial silicone materials were not considered due to their high viscosity and/or hardness. These factors could affect the shape fidelity of the obturator, i.e., partial filling of the mold cavity, as well as its insertion in cases of reduced opening of the oral cavity [35]. Silplay 184/30, hereinafter called Silplay, was chosen to fabricate the first version of the obturator prosthesis (Prochima Srl, Colli al Metauro, Italy) thanks to its low hardness and viscosity (30 Shore A and 9.000±2.000 mPa.s, respectively).

Mechanical tensile properties of Silplay were evaluated by following the ASTM standard test method D412-16 for vulcanized rubber and thermoplastic elastomers [36]. A set of five dumbbell specimens was prepared by pouring the silicone into 3D printed molds. The specimens have a thickness of 2 mm, a width of 25 mm, an overall length of 115 mm, and a nominal gauge length of 33 mm, following the “Die C” shape. Tensile tests were performed with a Zwick Roell Z010 (ZwickRoell GmbH & Co., Ulm, Germany) with a 10 kN cell load, setting the speed to 500 mm/min.

2.3. 3D modeling of the STL from DICOM files

The 3D visualization of the injured area was obtained from the DICOM file of a CT scan. The imaging file was then processed to prepare the STL mesh file of the maxillectomy defect. In turn, it was used to design the optimized shape of the obturator and the corresponding mold for the fabrication. Fig. 1 resumes the design workflow of the patient-specific obturator prosthesis and the different software used within the design process. The DICOM file was processed with 3D Slicer. This open-source software for the visualization and manipulation of imaging files contributed to defining the injured area by marking the cross-sections (Fig. 1a, yellow line). The different marked cross-sections were combined to obtain the STL mesh file of the injured area (Fig. 1b).

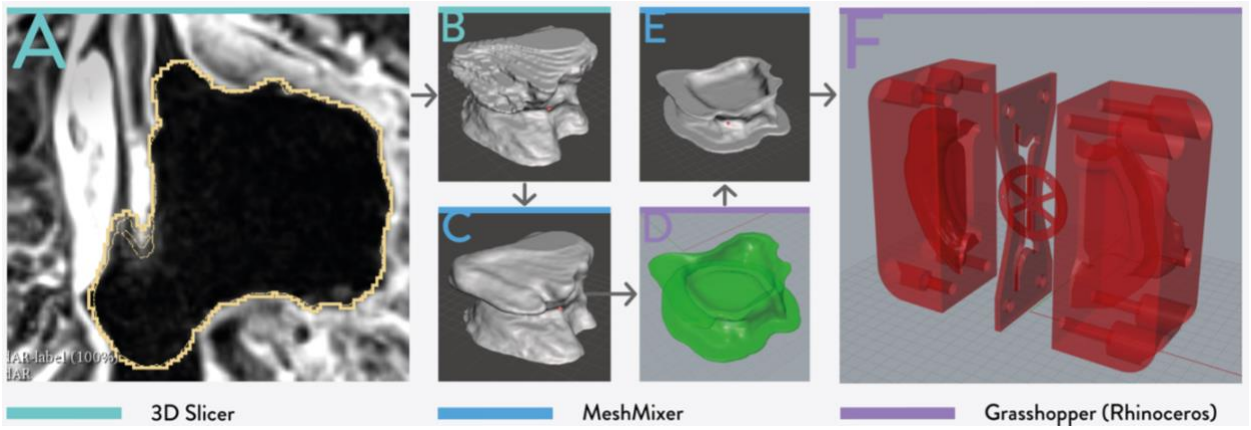


Fig. 1. Design workflow of the patient-specific palatal obturator: check of the DICOM file and definition of the injured area highlighted with the yellow line (a), generation of the rough mesh from the DICOM file (b), refinement of the rough mesh (c), design of the obturator mesh (d), refinement of the obturator mesh (e), generation of the parametric mold parts (f).

The resulting rough mesh was refined by using the open-source software Meshmixer (Autodesk, San Rafael, CA, USA). This step contributed to obtaining a smooth STL file without the mesh defects from the 3D model generation process in 3D Slicer, i.e., eliminating sharp corners, non-manifold geometries, layer-by-layer segmentation appearance from the DICOM file (Fig. 1c). The shape of the obturator prosthesis was then designed using Rhinoceros, a 3D modeling software (Robert McNeel & Associates, Seattle, WA, USA). In detail, Grasshopper plugin was used to set the parametrization of the obturator shape, i.e., by reducing its weight and setting an algorithmic definition to be used for other patient-specific obturators (Fig. 1d). The STL file of the parametrized obturator was imported in Meshmixer to further refine the mesh surface, i.e., rounding sharp corners to facilitate the silicone casting (Fig. 1e). Grasshopper algorithmic definitions were finally used to design the parametric 3D models of the mold. In this way, the mold could be adapted in its dimensions to fabricate a wide range of obturators, i.e., through time on a specific maxillectomy defect, or for different patients. The manufacturing features for casting were added during this step (Fig. 1f).

2.4. Manufacturing of the obturator prosthesis through low-cost 3D printing

The patient-specific obturator prosthesis was manufactured by using low-cost accessible 3D printing equipment for the fabrication of the casting mold. This approach is also known as “Indirect 3D printing” since AM is used to indirectly obtain the final shape, i.e., through the fabrication of molds, tools, inserts [24].

Fig. 2 shows the manufacturing workflow of the patient-specific obturator prosthesis and its different fabrication steps. The STL mesh file of the mold was imported into the open-source slicing software Prusa Slicer (Prusa Research, Prague, Czech Republic) to set the Gcode file for the 3D printer (Fig. 2a). The parts of the mold were then manufactured in PLA with a low-cost desktop size FFF 3D printer (Prusa i3 MK3S 3D printer, Prusa Research, Prague, Czech Republic) and a nozzle diameter of 0.4 mm (Fig. 2b). Afterward, the obturator prosthesis could be fabricated by silicone casting. The inner cavity of the mold was coated with a release wax agent to facilitate the silicone removal and to reduce the layer-by-layer effect of 3D printing onto the obturator surface (Prochima Srl, Colli al Metauro, Italy).

The final version of the obturator consisted of the main body made of silicone with an embedded 3D printed PLA insert connected to a nylon thread. This configuration facilitates the insertion and extraction of the obturator for the user. Hence, the insert was embedded into the silicone during the manufacturing workflow by positioning the insert onto the first half of the casting mold through specific parts fixed with metric screws. This step allowed to cast the Silplay silicon into the first half of the mold, helping to fix the insert position (Fig. 2c). After the complete curing of Silplay (24h at room temperature), the insert holders were removed to check the final positioning of the insert (Fig. 2d). The mold was then closed by fixing its second half through metric screws, and the casting process was completed by filling the second half of the mold (Fig. 2e). As in the previous step, the mold was opened after the complete curing of the silicone by removing the metric screws. The obturator prosthesis was removed from the two halves of the mold thanks to the elastic properties of the silicone, which allowed to fabricate a complex shape with functional geometrical overhangs through casting (Fig. 2f).

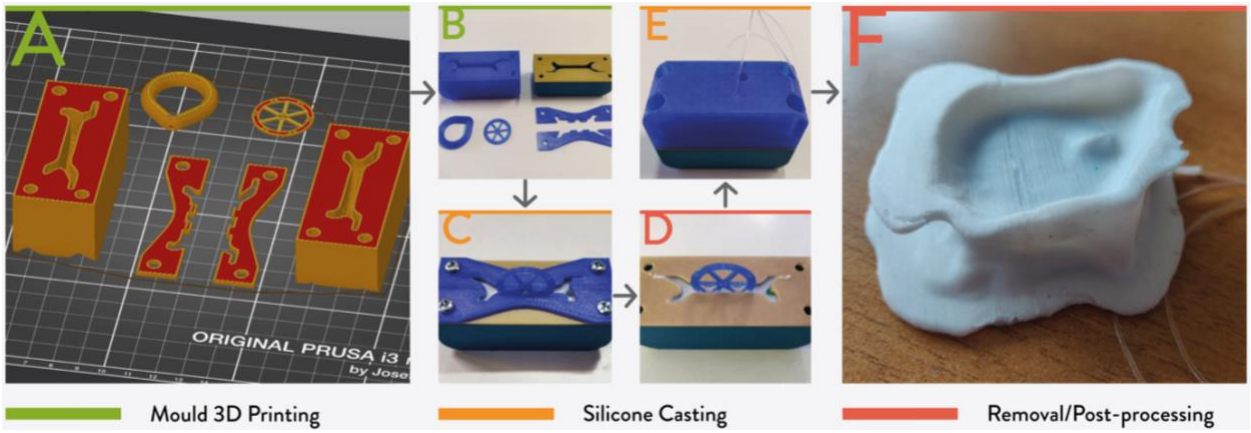


Fig. 2. Manufacturing workflow of the patient-specific palatal obturator: generation of the Gcode file of the mold parts (a), 3D printing of the mold parts (b), positioning of the insert in the insert holder, and silicone casting in the first mold half (c), removal of the insert holder (d), closing of the mold and silicone casting in the second mold half (e), opening of the mold and removal of the patient-specific palatal obturator (f).

3. Results and discussion

3.1. Mechanical characterization of Silplay silicone

The results of the tensile tests are resumed in Table 1 and were obtained by following the parameters described in the previous section. Some comparisons can be made with other commercial silicone rubbers for maxillofacial applications to verify the mechanical appropriateness of Silplay for obturators [35]. The ultimate tensile strength is comparable to the values of the commercial solutions, which mainly range from 2.5 to 4.5 MPa. Contrarily, the elongation at break is lower in comparison with the other commercial silicones with values higher than 500 % of elongation. However, the modulus of Silplay increases at 200% elongation and at break, showing a slightly stiffer behavior close to the failure. Silplay allows higher strain at lower elongations, i.e., 100 % and 200 %, and this behavior could presumably be beneficial for the obturator prosthesis developed in this work. First, this mechanical behavior could help the user to insert and extract the obturator prosthesis in case of reduced mobility of the oral cavity. In fact, Silplay allows the user to slightly bend the obturator during these specific actions, and to retain its original shape when worn. Moreover, the removal of the obturator from the casting mold could be facilitated for the same reason, avoiding accidental ruptures despite the geometrical overhangs of the shape. Finally, the hardness of Silplay is comparable to the values of some of the commercial solutions, suggesting the possible appropriateness of its mechanical properties for this specific application.

Table 1. Mechanical properties of Silplay from the experimental tensile tests: ultimate tensile strength (S_M), elongation at break (ε_M), Modulus of elasticity at 100 % elongation, 200 % elongation, and at break (E).

S_M (MPa)	ε_M (%)	E at 100% Elongation (MPa)	E at 200% Elongation (MPa)	E at Break (MPa)
4,08 ± 0,50	344,96 ± 34,73	0,62 ± 0,02	0,92 ± 0,04	1,18 ± 0,06

3.2. Patient-specific 3D model from DICOM file

This case study validated the design workflow of the patient-specific 3D model of the obturator prosthesis described in the previous section. Conventional impressions could not be used considering the patient's reduced mobility of the oral cavity (2.5 mm of maximum opening), as well as intraoral scanning techniques. This constraint required the use of medical imaging systems, i.e., CT scan, as a starting point to digitalize the specific maxillectomy defect. At the same time, inaccuracies or errors related to the impression or scanning processes could be mitigated by using a more accurate data source, which is the DICOM file. Conventional workflows may be compared to artisanal processes that rely on the experience from the professionals of clinical prosthesis practice [32]. Thanks to the design workflow of this work, the area of the maxillectomy defect was defined and converted in a 3D model file more reliably and accurately, allowing to use it as a starting point to design the customized obturator.



Fig. 3. Patient-specific palatal obturator: previews of the 3D model (a) and the final part obtained by silicone casting into the 3D printed mold (b).

Fig. 3a shows the final design of the patient-specific obturator prosthesis at the end of the design workflow. Working on the mesh resulted in the optimization of its shape by considering not only the clinical constraints but also the usability of the prosthesis, as well as the optimization of its technical aspects, i.e., weight reduction, flexibility, and overall dimensions according to the maximum opening of the oral cavity. In this case study, the stability of the prosthesis is mainly ensured by its external patient-specific shape, its capability to adapt to the surrounding healthy tissues, and its fixing through geometrical overhangs or undercuts. For these reasons, the internal area of the maxillectomy defect was discarded, and some internal and external geometrical features were added to the prosthesis, i.e., the internal wall separation and insert, the upper and lower overhang surfaces. Furthermore, the flexible behavior of the prosthesis was designed by combining the thickness and geometries of the external walls with the properties of Silplay silicone from the tensile tests, as shown in the final part (Fig. 3b).

3.3. Patient-specific obturator through low-cost 3D printing

Similarly, this case study also validated the manufacturing workflow of the obturator prosthesis, as well as the design of its mold. This indirect approach allows the professionals to obtain an accurate casting mold without manual or artisanal steps, requiring less practical experience in comparison with conventional processes, i.e., only for casting. Moreover, identical copies of the obturator may be realized with the same mold, which may also be fabricated more than once, i.e., in case of damages. The components of the mold (upper and lower halves, insert holder) and of the thread insert (insert and handle) are shown in Fig. 4a and can be entirely manufactured through low-cost FFF processes. The design of the 3D printed mold helps in fabricating a complex patient-specific obturator with an embedded insert that facilitates its insertion/extraction in case of reduced mobility of the oral cavity.

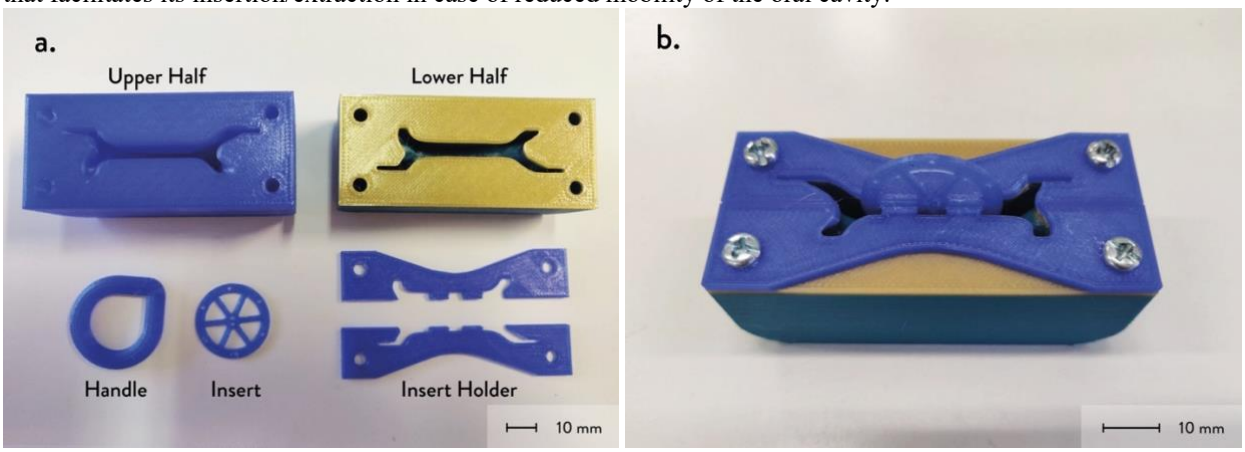


Fig. 4. 3D printed mold of the patient-specific obturator: 3D printed components (a), sub-assembly of the insert holder before the first casting (b).

The cavity of the mold was manufactured to avoid complex overhangs in the building plate direction, hence tricky supports to be removed. This advantage was facilitated by following the Design for Additive Manufacturing principles during the design phase and the Gcode file setting [34]. Moreover, the design of the mold helped in positioning the insert into the obturator, avoiding misalignments during the casting. By splitting the casting process into two steps, the insert could be placed in the right position through the insert holder (Fig. 4b). The second casting step finalizes the position of the insert and the thread, allowing the use of the opposite side of the thread to extract the prosthesis after its use. Finally, the shape and the flexibility of the material helped in removing the prosthesis from its mold despite the geometrical undercuts of the obturator. To sum up, low-cost 3D printing could be an effective way to fabricate patient-specific obturators although a new set of skills linked to digital technologies is required to use the workflows presented in this work.

3.4. Use of the patient-specific prosthesis for the clinical case study

The obturator prosthesis of this work was tested by the patient. In particular, the patient was able to insert and extract the obturator thanks to the flexibility given by its geometry and material, as well as the thread linked to the embedded insert (Fig. 5a). Silplay silicone allows for easy insertion/extraction by the patient, which is also simplified by the thread connected to the insert. As shown in Fig. 5b and 5c, the external walls of the obturator can be easily bent by the user to facilitate the insertion of the prosthesis despite the limited opening of the oral cavity. The patient also recovered some vital functions, i.e., speaking, drinking, eating, while using this obturator. In general, the surgical resection from maxillectomy causes oronasal communication that involves problems such as the inability to swallow, defects in phonation, and difficulty in chewing, affecting the patients' quality of life. Rehabilitation of these patients by means of obturators helps to overcome the post-surgical sequelae by eliminating the oronasal communication. Hence, the test of the obturator prosthesis of this work preliminary validated its design and technical features.

In addition to surgical resection, many patients with carcinomas of the head and neck region undergo postoperative radiation or chemotherapy (or both), which can lead to problems related to late radiation toxicity. In clinical prosthetic practice, the most significant side effect is lockjaw, which limits the physiological opening of the oral cavity. These effects also impact the realization of an obturator prosthesis of the palate. In traditional practice, obturators are fabricated starting from impressions obtained with traditional techniques or intraoral scanners. However, the opening of the oral cavity can be drastically reduced by the mandibular clamping resulting from cancer therapies, as for this case study. Therefore, a way to overcome these problems may be the use of the patient's DICOM files for the 3D view and the 3D model of the defect. The workflow reported in this work helps in overcoming the above-mentioned issues by developing a patient-specific palatal obturator prosthesis from the DICOM file of the CT scan.

4. Conclusions

This paper resumed an integrated workflow for the design and manufacturing of patient-specific maxillofacial palatal obturators with low-cost 3D printers. The STL mesh file of the maxillectomy defect was obtained starting from the DICOM files of a case study, enabling the design of the patient-specific obturator.

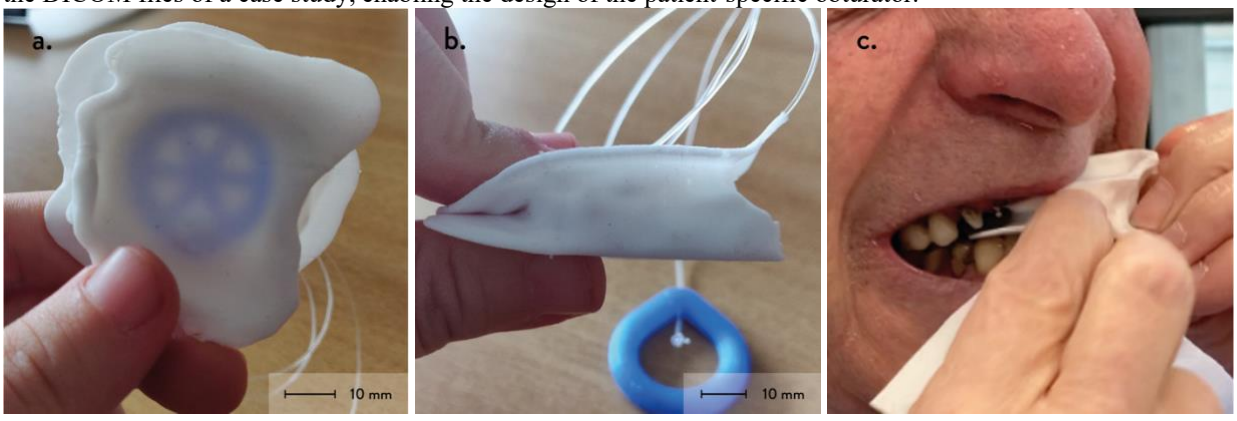


Fig. 5. Preliminary validation of the patient-specific palatal obturator prosthesis: main view of the final shape with the position of the insert (a), check of the flexible behavior of the obturator external walls (b), insertion of the prosthesis by the patient (c).

Its mold was then fabricated through FFF 3D printing, and soft silicone was cast into the mold cavity. Preliminary validation of the steps was carried out within a case study of a patient with reduced opening of the oral cavity. The use of this palatal obturator helped the patient to recover some vital functions. This workflow may lead to optimized prostheses by integrating design and engineering knowledge. Digital technologies may be seen as tools for clinical prosthesis practice, especially in critical situations. However, this workflow should be further tested to be fully validated, and new collaborations should be fostered to fully exploit it, i.e., with the design and engineering fields.

The next work steps are focusing on the use of maxillofacial commercial silicones and patient's comfort. A new obturator is being fabricated with a specific silicone for maxillofacial applications (Dropstil F556 from Prevent Transformation, Châteauneuf-sur-Isère, France). Hence, the obturator shape is being modified according to the different material behavior, keeping its technical features and a good adaptation to the patient's maxillectomy defect.

Acknowledgments

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