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ORIGINAL ARTICLE

Three-dimensional printed immediate surgical obturator before maxillectomy: A pilot study

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ABSTRACT

Purpose: Surgical obturators improve patients' quality of life after maxillectomy by maintaining oral functions. As digital workflows are commonly used for planning maxillofacial surgeries and prostheses, the hypothesis of this study was that the fabrication of the immediate surgical obturator could benefit from the currently available open-source software. The aim of this study was to develop a protocol for fabricating before the surgery a prefabricated, personalized, and lightweight immediate surgical obturator with open-source software and limited amount of relining material.
Materials and methods: The protocol steps consisted of digital simulation of maxillectomy defect based on CBCT segmentation of cadavers' heads according to the surgical planning. Design of immediate surgical obturator by boolean subtraction tools using open-source software, scaling down the final designed immediate surgical obturator to 90%, and then 3D-printing it layer by layer in biocompatible resin to be relined and fitted intraorally after surgery.
Results: The developed protocol was successfully achieved. Maxillectomy defect interest areas were successfully segmented using open-source software. Immediate surgical obturator was also successfully designed and 3D printed using biocompatible resin materials. The immediate surgical obturator was thus adapted to the defect with limited amount of relining material.
Conclusions: This innovative method could give the patient an opportunity to benefit from a personalized, biocompatible and lightweight immediate surgical obturator. (*Int J Maxillofac Prosthetics 2021;4:18-24*)

Keywords

Stereolithography, computer-aided design/computer-assisted manufacturing, palatal obturators, immediate surgical obturator, maxillectomy.

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INTRODUCTION

Maxillectomy is an excisional surgery performed to treat tumor in the palate and maxilla, tumor extension, trauma or even necrosis. As a consequence, communication between nasal and oral cavities is expected, which alters various oral functions, such as speech, mastication, and swallowing. These functional deficiencies may also be associated with aesthetics and psychosocial impairments, impacting on the patient's daily quality of life.[1-3]

Immediate surgical obturator (ISO) can be fabricated preoperatively and placed during the surgery to maintain oral functions, to protect the surgical site from contamination and to guide the healing by providing a matrix for surgical packing. In addition, it reduces the hospitalization period and optimize condition for the realization of the following obturators.[4-8] The main limits of ISO are the logistical need for a prosthodontist to be in the operation room at the end of the surgery, the requirements for a lightweight and easy to remove obturator that reproduces palatal contours, and the financial need for cheap materials and procedures.

Conventionally, ISO is fabricated before the surgery on surgeon's request. Based on the model produced by maxillofacial prosthodontist, the surgeon can mark the planned surgical area and simulate the defect on the model. Maxillofacial prosthodontist can design and fabricate the ISO to be delivered to the operation room for insertion. ISO is usually fitted in the mouth for 3 weeks but up to 3 months. As the healing defect progress over time, a relining based on silicone or delayed-setting resin can be performed to close the gap between the obturator and the new margins.[6,9,10]

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In the last few years, the applications of digital technologies have generally been increased in maxillofacial prosthetics.[11-13] The use of computer aided design (CAD),[14, 15] computer aided manufacturing (CAM),[16-18] and virtual surgical planning (VSP)[19, 20] have advanced the field of oral and maxillofacial rehabilitation and offers new ways of design and reconstruction. This can potentially change the way maxillectomy and obturator production will be performed in the future. In specific, digital design can assist in a patient-specific modeling, while also allowing the obturator fabrication. When an ISO is printed pre-operatively, it is essential that it fits closely to the remaining tissue once the surgical defect is made.

As digital workflows are commonly used for planning maxillofacial surgeries and prostheses, the hypothesis of this study was that the fabrication of the immediate surgical obturator could benefit from the currently available open-source software. The aim of this study was to develop a protocol for fabricating before the surgery a prefabricated, personalized, and lightweight immediate surgical obturator with open-source software and limited amount of relining material.

MATERIALS AND METHODS

3D Data Acquisition and Processing

Three fresh cadavers' heads were chosen from the School of Surgery of the Bordeaux University. A pre-surgery imaging of the maxilla was performed for each cadaver head using a Cone Beam Computed Tomography (CBCT, NewTom 3D Imaging, Verona, Italy) and saved as a Digital Imaging and Communications in Medicine (DICOM) file format. The DICOM data set was imported for 3D segmentation into an open-source modeling software (ITK snap v3.8.0, USA) to produce 3D models. After discussion with the maxillofacial surgeon to choose the areas of interest, the minimum threshold was set to 890 Hounsfield units (HU) in order to visualize the soft tissues, such as sinus and palatal mucosa (Fig 1). To initiate automatic segmentation, bubbles were added and placed inside the area of interest. Speed and accuracy of the segmentation increase with the number of bubbles (Fig 2). The force and smoothness were left at normal values of 1 and 0.200, respectively. Once the segmentation has ended (Fig 3), the final rendered 3D maxilla models were then exported and saved as a binary standard triangle language (STL) file format.

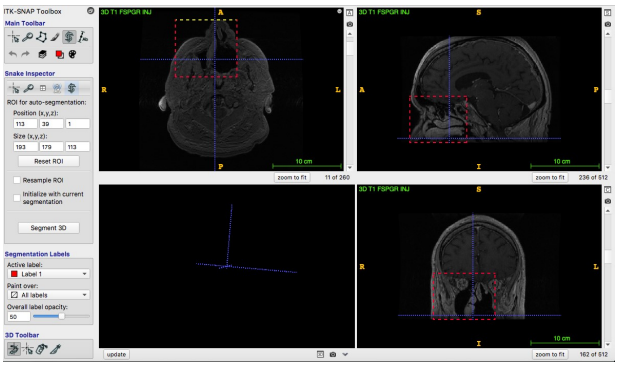


Fig 1. Choosing the areas of interest on the open-source 3D segmentation and modeling software.

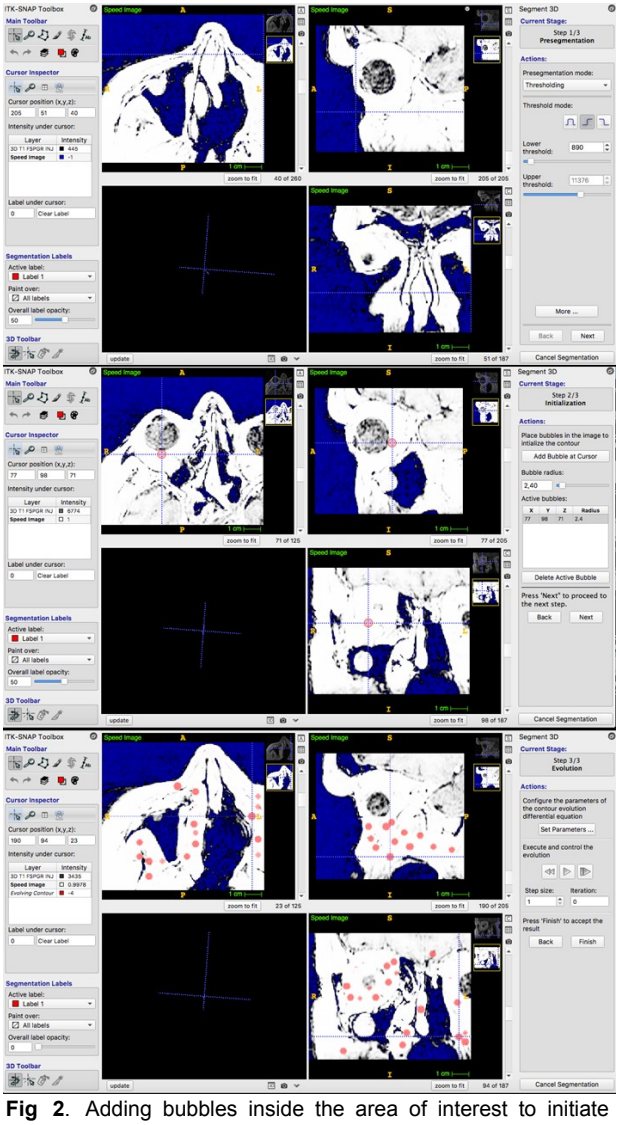


Fig 2. Adding bubbles inside the area of interest to initiate automatic segmentation.

Obturator Designing and Printing

All STL models were imported to open-source 3D-modeling software Autodesk Meshmixer software (Autodesk, Inc. CA) for data editing. In Meshmixer, a sphere was dropped in the scene, and placed to completely fill the maxillary defect (Fig 4).

To perform the boolean subtraction, the "designated" body was the defect model while the "active" body was the sphere. As a result, the volumes belonging to both the defect and the sphere were removed (Fig 5). The boolean difference resulted in the initial immediate

surgical obturator design, that needed to be cleaned up. Some undercuts, especially posterior areas, were left in order to promote retention (Fig 6). The overall ISO was undersized 2 mm and then hollowed, rafters were designed and added on the palatal side in order to offer some retention to an eventual relined palatal plate (Figs 7, 8). The final 3D ISO model was then imported and opened with the printer software Preform (v3.5, Formlabs, Somerville, MA, USA). The dimensions of the printing model was scaled down to 90%. The printing-necessary scaffolds were suggested and modified to make sure the support touch points were not on the intaglio surface (Fig 9). The file was then sent to a Form 2 stereolithographic printer (Formlabs, Somerville, MA, USA) to be fabricated layer by layer with a 250 mW laser using biocompatible resin (CE Class IIa, EN-ISO10993-1:2009/AC:2010) (Dental LT, Formlabs, Somerville, MA, USA). After the printing process has done, the ISO was then finished and polished (Fig 10).

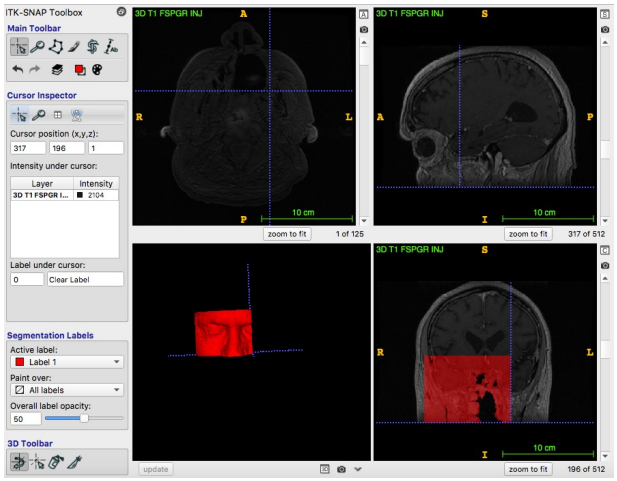


Fig 3. Complete of segmentation process and the final rendered 3D maxilla models is ready to be exported and saved as STL file.

Maxillectomy Preforming and Obturator Relining

With the help of a maxillofacial surgeon, three maxillectomy defect surgeries were performed on the cadaver heads to simulate Brown's maxillectomy defect, class 2b. The printed ISO was then placed into the cadaver's head after preformed of maxillectomy. As undersized ISO, a space was present between the obturator and the remaining tissues (Fig 11). A thin layer of putty silicone was applied on the obturator surface, and the composite was fitted in the defect (Fig 12).

RESULTS

The developed protocol for fabricating before the surgery a prefabricated, personalized, and lightweight immediate surgical obturator was successfully achieved.

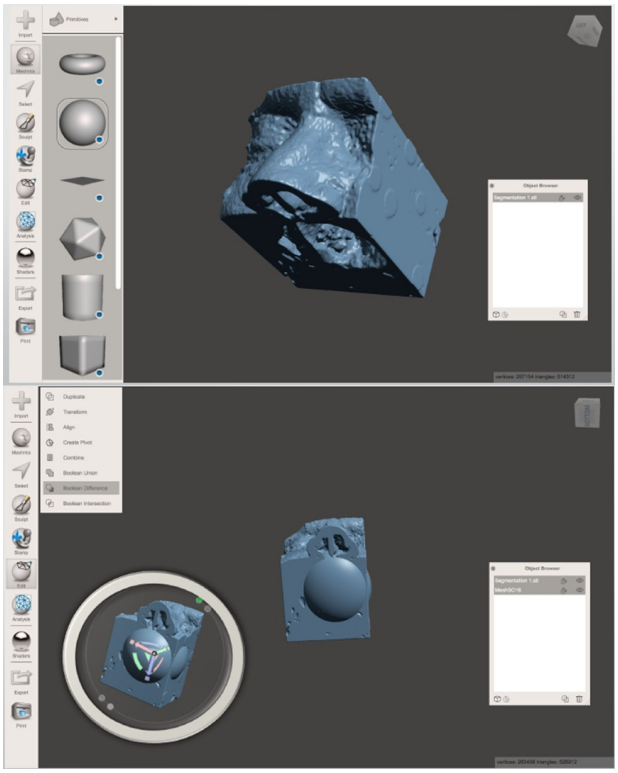


Fig 4. Using of open-source 3D modeling software for designing immediate surgical obturator.

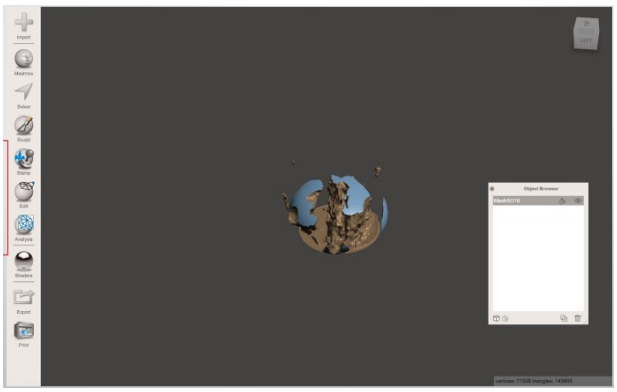


Fig 5. Shows the results of performing boolean subtraction to produce the immediate surgical obturator.

The areas of interest of the maxillectomy defects were successfully segmented using open-source software. IOS was also successfully designed using open-source software and 3D printed using biocompatible resin materials. The immediate surgical obturator was thus adapted to the defect with limited amount of relining material. Undersized obturator design had created a resin base, which was adjusted to Brown's maxillectomy class 2b after relining. The relining could be modified during the patient follow-up, as the resin obturator can be removed easily. In this designed ISO and through the rafters on the palatal side, a palatal plate could be used to support the ISO with delayed-setting resin.

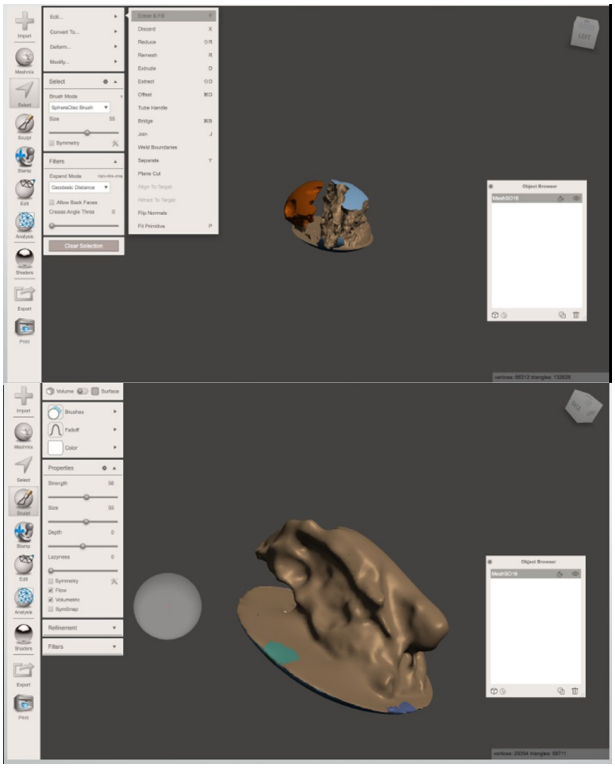


Fig 6. Shows the initial results of boolean subtraction and final finishing of the immediate surgical obturator design.

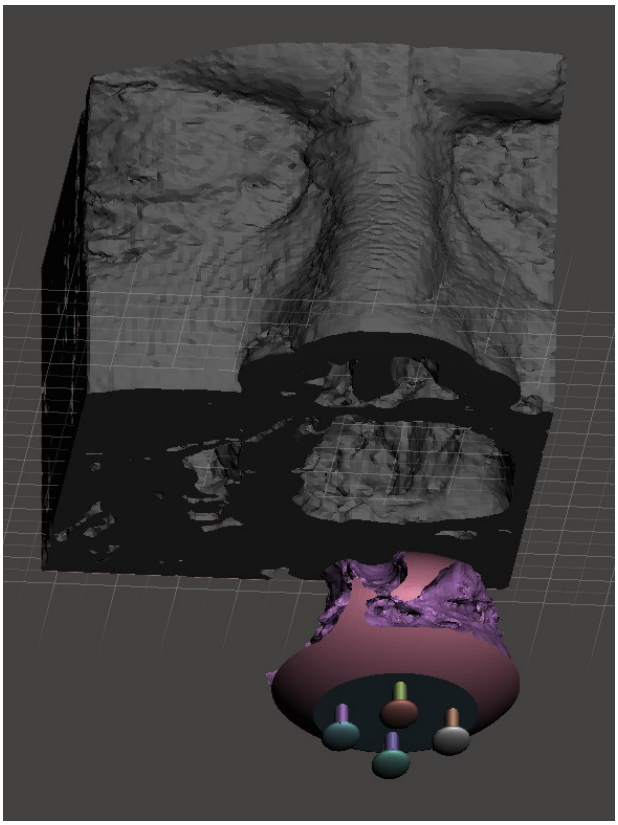


Fig 8. Designing and adding rafters on the palatal side in order to offer some retention to an eventual relined palatal plate.

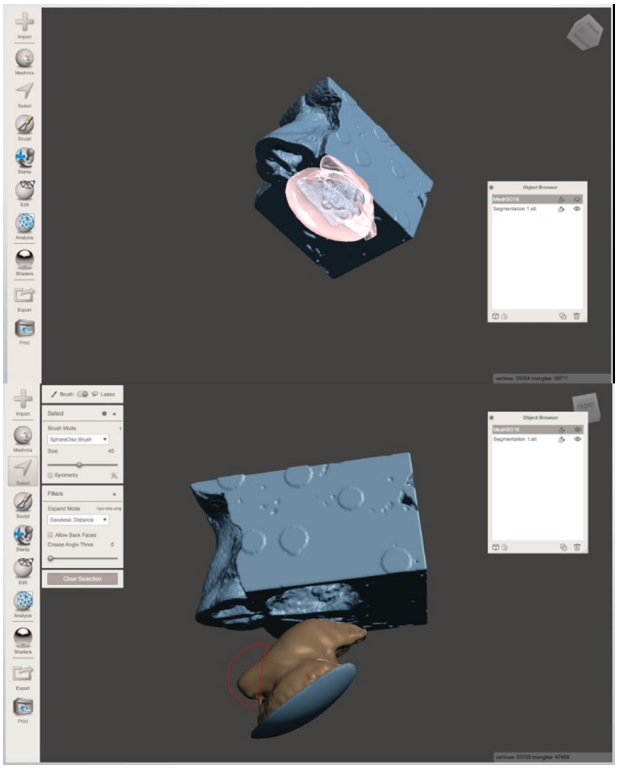


Fig 7. Undersizing the overall obturator design by 2 mm and hollowed.

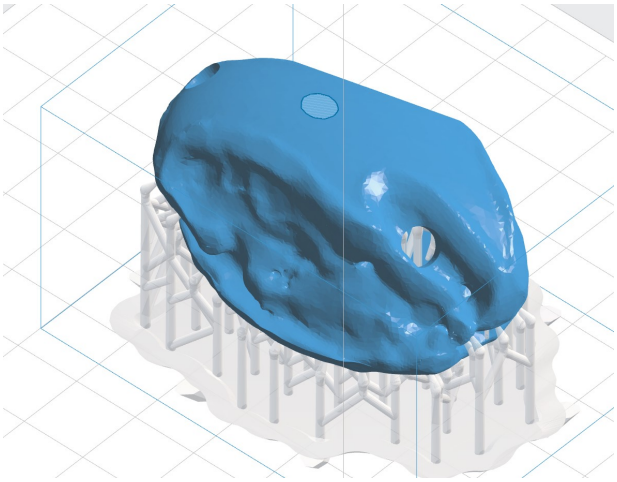


Fig 9. Scaling down the dimensions of the printing model and preparing the printing-necessary scaffolds.

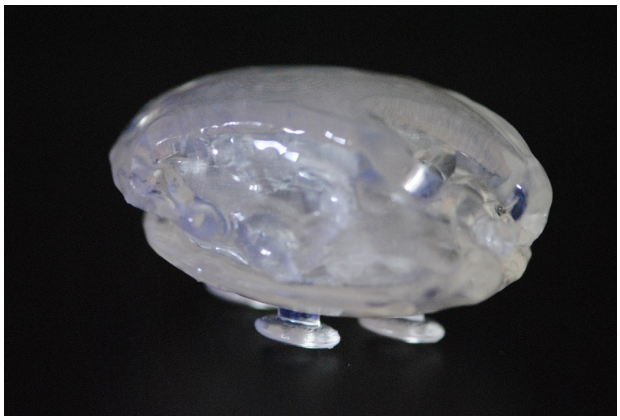


Fig 10. Shows the finished and polished final printed immediate surgical obturator in clear biocompatible resin.

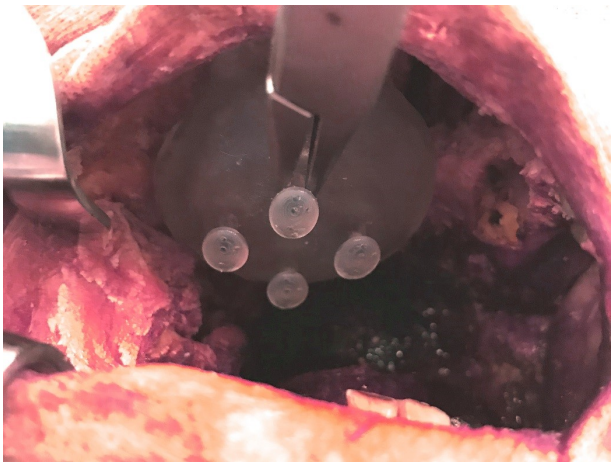


Fig 11. Fitting the undersized immediate surgical obturator into the cadaver's head maxillectomy defect.

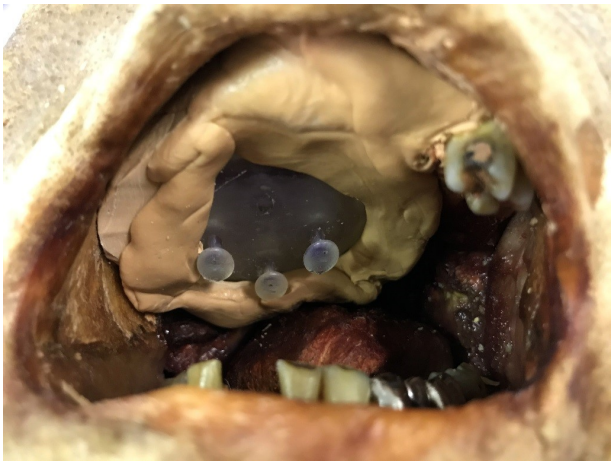


Fig 12. Appling a thin layer of putty silicone applied on the obturator surface and fitting it into the defect.

DISCUSSION

Based on the results of this study, the development of a protocol for a prefabricated ISO for maxillectomy defects is achievable with open-source software and limited amount of relining material. Therefore, the initial hypothesis was verified.

Maxillectomy defects can be of different types based on the tumor size and location. The most commonly used system for classification of maxillectomy defects in maxillofacial prosthetics is Aramany's classification,[21] although other classifications such as Brown's classification and Okay's et al classification are suitable for both surgeons and prosthodontists.[22-24] In this study, The Brown's maxillectomy class 2b has chosen and performed on the cadavers' heads, because it was the most frequently performed surgery, or at least the most frequently found in the maxillofacial surgical literature. However, this protocol can be tried with other types of maxillectomy classifications mentioned above, to prove its universal application.

In tumor surgical resection, the resected margins may vary between the preoperative planned resection and the actual resection. Within the operation and based on the situation, the surgeon may review the initial plan and include certain neighboring structures.[25] A relining of the surgical obturator is thus expected. Mukohyama et al.[26] have mentioned that the surgical obturators are very often too loose and not adapted to the contours of the resection.

To better predict the oncological limits, molecular imaging can jointly be used. Yu et al[27] have combined a preoperative CBCT of a patient with a positron emission tomography (PET) by production of F-fluorodeoxyglucose (FDG) for the computer planning of a maxillectomy. The FDG-PET scan identified abnormal regions based on glucose uptake and thus showed metabolic tumor volume to guide tumor resection. The coupled CBCT to PET scan allowed to select the arteries and veins that could be used for the anastomosis of the flap. The risks of cancer recurrence were thus better controlled.

In another study, Kortes et al.[17] have used two types of imaging, the CBCT data was coupled to the patient's MRI data as CBCT exhibited better accuracy for hard tissue, while MRI can better identify soft tissue and tumor expansion. In addition, the French Society of Stomatology, Oral Surgery, and Maxillofacial Surgery recommended merging CBCT images of the skull with the MRI images for the soft tissues and even to combine them with the optical impressions to create a virtual model of the face as precise as possible.[25] Thus, digital planning is improved.

Although DICOM based CBCT data were the main resource for segmentation using open-source software in this study, a non-artifact segmentation is often difficult to obtain from the CBCT of patient with metallic restorations in the mouth. Soft tissues may also be difficult to visualize on some imaging. For both scenarios, scanner software may require the selection of special acquisition modes before the reconstitution. These issues could be solved by matching an optical impression of the maxillary surface to the imaging of the maxilla defect. This data merging process could be done by using open-source software such as Meshmixer or Meshlab software, and would result in an accurate dentition and soft tissue recording, associated to an accurate defect imaging. In addition, polystyrene bites can be placed in the patient mouth to facilitate the segmentation of the soft tissues and teeth.

As any scientific study, the current study revealed some limitations. It is important to mention that these sample numbers are based on a very small subset of cadaver heads that had a one-sided maxillectomy defect. Therefore, it is to be expected that these samples may not be fully representative for the whole population of maxillectomy defects. Future research may aim to include maxillectomy defect patients with variety of defect classes. As for many other digital workflows, another limitation for this protocol is the time and experience necessary for its implementation. However, software is rapidly evolving and some former sophisticated protocols are now easy-to-use.

CONCLUSION

This study succeeded in developing a protocol for fabricating before the surgery an ISO with open-source software and limited amount of relining material. The reproducibility of these in vitro results on a patient seem to be guaranteed by the possible adaptation to changes in surgical limit during the procedures, when compared to planned limits. The retention of the obturator will however rely on the defect undercuts or on an additional palatal plate retained by dental clasps. This innovative method could give maxillectomy patient an opportunity to benefit from a personalized, biocompatible and lightweight immediate surgical obturator.

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