3D Printing for the Development of Palatal Defect Prosthetics

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Background: Three-dimensional (3D) printing has emerged as a promising new technology for the development of surgical prosthetics. Research in orthopedic surgery has demonstrated that using 3D printed customized prosthetics results in more precise implant placements and better patient outcomes. However, there has been little research on implementing customized 3D printed prosthetics in otolaryngology. The program sought to determine whether computed tomography (CT) serves as feasible templates to construct 3D printed palatal obturator prosthetics for defects in patients who have been treated for head and neck cancers.

Observations: A retrospective review of patients with palatal defects was conducted and identified 1 patient with high quality CTs compatible with 3D modeling. CTs of the patient's craniofacial anatomy were used to develop a 3D model and a Formlabs 3B+ printer printed the palatal prosthetic. We successfully developed and produced an individualized prosthetic using CTs from a veteran with head and neck deformities caused by cancer treatment who was previously treated at the Veterans Affairs Palo Alto Health Care System. This project was successful in printing patient-specific implants using CT reproductions of the patient's craniofacial anatomy, particularly of the palate. The program was a proof of concept and the implant we created was not used on the patient.

Conclusions: Customized 3D printed implants may allow otolaryngologists to enhance the performance and efficiency of surgeries and better rehabilitate and reconstruct craniofacial deformities to restore appearance and function to patients. Additional research will strive to enhance the therapeutic potential of these prosthetics to serve as low-cost, patient-specific implants.

Three-dimensional (3D) printing has become a promising area of innovation in biomedical research.[1,2] Previous research in orthopedic surgery has found that customized 3D printed implants, casts, orthoses, and prosthetics (eg, prosthetic hands) matched to an individual's unique anatomy can result in more precise placement and better surgical outcomes.[3-5] Customized prosthetics have also been found to lead to fewer complications.[3,6]

Recent advances in 3D printing technology has prompted investigation from surgeons to identify how this new tool may be incorporated into patient care.[1,7] One of the most common applications of 3D printing is during preoperative planning in which surgeons gain better insight into patient-specific anatomy by using patient-specific printed models.[8] Another promising application is the production of customized prosthetics suited to each patient's unique anatomy.[9] As a result, 3D printing has significantly impacted bone and cartilage restoration procedures and has the potential to completely transform the treatment of patients with debilitating musculoskeletal injuries.[3,10]

The potential surrounding 3D printed prosthetics has led to their adoption by several other specialties, including otolaryngology.[11] The most widely used application of 3D printing among otolaryngologists is preoperative planning, and the incorporation of printed prosthetics into reconstruction of the orbit, nasal septum, auricle, and palate has also been reported.[2,12,13] Patient-specific implants might allow otolaryngologists to better rehabilitate, reconstruct, and/or regenerate craniofacial defects using more humane procedures.[14]

Patients with palatomaxillary cancers are treated by prosthodontists or otolaryngologists. An impression is made with a resin–which can be painful for postoperative patients–and a prosthetic is manufactured and implanted.[15-17] Patients with cancer often see many specialists, though reconstructive care is a low priority. Many of these individuals also experience dynamic anatomic functional changes over time, leading to the need for multiple prothesis.

PALATOMAXILLARY PROSTHETICS

This program aims to use patients' previous computed tomography (CT) to tailor customized 3D printed palatomaxillary prosthetics to specifically fit their anatomy. Palatomaxillary defects are a source of profound disability for patients with head and neck cancers who are left with large anatomic defects as a direct result of treatment. Reconstruction of palatal defects poses unique challenges due to the complexity of patient anatomy.[18,19]

3D printed prosthetics for palatomaxillary defects have not been incorporated into patient care. We reviewed previous imaging

FIGURE Three Dimensional Printed Hard Palate Prosthetic

research to determine if it could be used to assist patients who struggle with their function and appearance following treatment for head and neck cancers. The primary aim was to investigate whether 3D printing was a feasible strategy for creating patient-specific palatomaxillary prosthetics. The secondary aim is to determine whether these prosthetics should be tested in the future for use in reconstruction of maxillary defects.

Data Acquisition

This study was conducted at the Veterans Affairs Palo Alto Health Care System (VAPAHCS) and was approved by the Stanford University Institutional Review Board (approval #28958, informed consent and patient contact excluded). A retrospective chart review was conducted on all patients with head and neck cancers who were treated at VAPAHCS from 2010 to 2022. Patients aged ≥ 18 years who had a palatomaxillary defect due to cancer treatment, had undergone a palatal resection, and who received treatment at any point from 2010 to 2022 were included in the review. CTs were not a specific inclusion criterion, though the quality of the scans was analyzed for eligible patients. Younger patients and those treated at VAPAHCS prior to 2010 were excluded.

There was no control group; all data was sourced from the US Department of Veterans Affairs (VA) imaging system database. Among the 3595 patients reviewed, 5 met inclusion criteria and the quality of their craniofacial anatomy CTs were analyzed. To maintain accurate craniofacial 3D modeling, CTs require a maximum of 1 mm slice thickness. Of the 5 patients who met the inclusion criteria, 4 were found to have variability in the quality of their CTs and severe defects not suitable for prosthetic reconstruction, which led to their exclusion from the study. One patient was investigated to demonstrate if making these prostheses was feasible. This patient was diagnosed with a malignant neoplasm of the hard palate, underwent a partial maxillectomy, and a palatal obturator was placed to cover the defect.

The primary data collected was patient identifiers as well as the gross anatomy and dimensions of the patients' craniofacial anatomy, as seen in previous imaging research.[20] Before the imaging analysis, all personal health information was removed and the dataset was de-identified to ensure patient anonymity and noninvolvement.

CT Segmentation and 3D Printing

Using CTs of the patient's craniofacial anatomy, we developed a model of the defects. This was achieved with deidentified CTs imported into the Food and Drug Administration (FDA)-approved computerized aid design (CAD) software, Materialise Mimics. The hard palate was segmented and isolated based off the presented scan and any holes in the image were filled using the CAD software. The model was subsequently mirrored in Materialise 3-matic to replicate an original anatomical hard palate prosthesis. The final product was converted into a 3D model and imported into Formlabs preform software to generate 3D printing supports and orient it for printing. The prosthetic was printed using FDA-approved Biocompatible Denture Base Resin by a Formlabs 3B+ printer at the Palo Alto VA Simulation Center. The 3D printed prosthesis was washed using Formlabs Form Wash 80% ethyl alcohol to remove excess resin and subsequently cured to harden the malleable resin. Supports were later removed, and the prosthesis was sanded.

The primary aim of this study was to investigate whether using CTs to create patient-specific prosthetic renderings for patients with head and neck cancer could be a

feasible strategy. The CTs from the patient were successfully used to generate a 3D printed prosthesis, and the prosthesis matched the original craniofacial anatomy seen in the patient's imaging (Figure). These results demonstrate that high quality CTs can be used as a template for 3D printed prostheses for mild to moderate palatomaxillary defects.

3D Printing Costs

One liter of Denture Base Resin costs $299; prostheses use about 5 mL of resin. The average annual salary of a 3D printing technician in the United States is $42,717, or $20.54 per hour.[21] For an experienced 3D printing technician, the time required to segment the hard palate and prepare it for 3D printing is 1 to 2 hours. The process may exceed 2 hours if the technician is presented with a lower quality CT or if the patient has a complex craniofacial anatomy.

The average time it takes to print a palatal prosthetic is 5 hours. An additional hour is needed for postprocessing, which includes washing and sanding. Therefore, the cost of the materials and labor for an average 3D printed prosthetic is about $150. A Formlabs 3B+ printer is competitively priced around $10,000. The cost for Materialise Mimics software varies, but is estimated at $16,000 at VAPAHCS. The prices for these 2 items are not included in our price estimation but should be taken into consideration.

Prosthodontist Process and Cost

The typical process of creating a palatal prosthesis by a prosthodontist begins by examining the patient, creating a stone model, then creating a wax model. Biocompatible materials are selected and processed into a mold that is trimmed and polished to the desired shape. This is followed by another patient visit to ensure the prosthesis fits properly. Follow-up care is also necessary for maintenance and comfort.

The average cost of a palatal prosthesis varies depending on the type needed (ie, metal implant, teeth replacement), the materials used, the region in which the patient is receiving care, and the complexity of the case. For complex and customizable options like those required for patients with cancer, the prostheses typically cost several thousands of dollars. The Healthcare Common Procedure Coding System code for a palatal lift prosthesis (D5955) lists prices ranging from $4000 to $8000 per prosthetic, not including the cost of the prosthodontist visits.[22,23]

DISCUSSION

This program sought to determine whether imaging studies of maxillary defects are effective templates for developing 3D printed prosthetics and whether these prosthetics should be tested for future use in reconstruction of palatomaxillary defects. Our program illustrated that CTs served as feasible templates for developing hard palate prostheses for patients with palatomaxillary defects. It is important to note the CTs used were from a newer and more modern scanner and therefore yielded detailed palatal structures with higher accuracy more suitable for 3D modeling. Lower-quality CTs from the 4 patients excluded from the program were not suitable for 3D modeling. This suggests that with high-quality imaging, 3D printed prosthesis may be a viable strategy to help patients who struggle with their function following treatment for head and neck cancers.

3D printed prosthesis may also be a more patient centered and convenient option. In the traditional prosthesis creation workflow, the patient must physically bite down onto a resin (alginate or silicone) to make an impression, a very painful postoperative process that is irritating to the raw edges of the surgical bed.[15,16] Prosthodontists then create a prosthetic minus the tumor and typically secure it with clips or glue.[17] Many patients also experience changes in their anatomy over time requiring them to have a new prostheses created. This is particularly important in veterans with palatomaxillary defects since many VA medical centers do not have a prosthodontist on staff, making accessibility to these specialists difficult. 3D printing provides a contactless prosthetic creation process. This convenience may reduce a patient's pain and the number of visits for which they need a specialist.

Future Directions

Additional research is needed to determine the full potential of 3D printed prosthetics. 3D printed prostheses have been effectively used for patient education in areas of presurgical planning, prosthesis creation, and trainee education.[24] This research represents an early step in the development of a new technology for use in otolaryngology. Specifically, many veterans with a history of head and neck cancers have sustained changes to their craniofacial

anatomy following treatment. Using imaging to create 3D printed prosthetics could be very effective for these patients. Prosthetics could improve a patient's quality of life by restoring/approximating their anatomy after cancer treatment.

Significant time and care must be taken by cancer and reconstructive surgeons to properly fit a prosthesis. Improperly fitting prosthetics leads to mucosal ulceration that then may lead to a need for fitting a new prosthetic. The advantage of 3D printed prosthetics is that they may more precisely fit the anatomy of each patient using CT results, thus potentially reducing the time needed to fit the prosthetic as well as the risk associated with an improperly fit prosthetic. 3D printed prosthesis could be used directly in the future, however, clinical trials are needed to verify its efficacy vs prosthodontic options.

Another consideration for potential future use of 3D printed prosthetics is cost. We estimated that the cost of the materials and labor of our 3D printed prosthetic to be about $150. Pricing of current molded prosthetics varies, but is often listed at several thousand dollars. Another consideration is the durability of 3D printed prosthetics vs standard prosthetics. Since we were unable to use the prosthetic in the patient, it was difficult to determine its durability. The significant cost of the 3D printer and software necessary for 3D printed prosthetics must also be considered and may be prohibitive. While many academic hospitals are considering the purchase of 3D printers and licenses, this may be challenging for resource-constrained institutions. 3D printing may also be difficult for groups without any prior experience in the field. Outsourcing to a third party is possible, though doing so adds more cost to the project. While we recognize there is a learning curve associated with adopting any new technology, it's equally important to note that 3D printing is being rapidly integrated and has already made significant advancements in personalized medicine.[8,25,26]

Limitations

This program had several limitations. First, we only obtained CTs of sufficient quality from 1 patient to generate a 3D printed prosthesis. Further research with additional patients is necessary to validate this process. Second, we were unable to trial the prosthesis in the patient because we did not have FDA approval. Additionally, it is difficult to calculate a true cost estimate for this process as materials and software costs vary dramatically across institutions as well as over time.

CONCLUSIONS

The purpose of this study was to demonstrate the possibility to develop prosthetics for the hard palate for patients suffering from palatomaxillary defects. A 3D printed prosthetic was generated that matched the patient's craniofacial anatomy. Future research should test the feasibility of these prosthetics in patient care against a traditional prosthodontic impression. Though this is a proof-of-concept study and no prosthetics were implanted as part of this investigation, we showcase the feasibility of printing prosthetics for palatomaxillary defects. The use of 3D printed prosthetics may be a more humane process, potentially lower cost, and be more accessible to veterans.

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