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Original Research Article

Development of a 3D printed paranasal sinus system prototype for endoscopic surgery training

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Abstract: Functional endoscopic sinus surgery (FESS) stands as a crucial treatment method in otolaryngology, necessitating sophisticated training models for effective skill acquisition. Addressing this need, an additively manufactured prototype of the paranasal sinus system for endoscopic training was developed. Critical in the development process was the identification and integration of tissue-equivalent materials simulating mucosa, cartilage, and bone tissue. A comprehensive AM material evaluation encompassing multiple iterations was conducted, focusing on haptic fidelity and visual resemblance. A training environment with an excess through the left nostril was produced using fused deposition modeling (FDM) printing as well as stereolithography (SLA). Ultimately, a flexible resin, crafted through SLA printing, and a silicone mixture emerged as the optimal choice for mimicking the anatomical structure of the paranasal sinus system. By carrying out various operation steps of the FESS, practitioners were able to assess the suitability of the prototype and, in particular, the materials used. While overall feedback was positive, refinement opportunities, notably regarding mucosal thickness, were identified. Looking ahead, insights gained from this additive manufactured training model could be used to develop a comprehensive training model tailored to clinical needs.

I. Introduction

The examination and treatment of pathologies of the paranasal sinuses is considered extremely challenging. The functional endoscopic sinus surgery (FESS) for example is a complex operation used in otorhinolaryngology. With the help of this treatment method, pathologies in the nasal cavity and paranasal sinuses can be treated in a minimally invasive manner. With the help of endoscopes, doctors are able to examine and analyze the inside of the nose. Optimal hand-eye coordination of the practitioners is essential for this, as surgical instruments have to be handled parallel to the endoscope.

Realistic training on practice models can help ensuring optimal preparation of new clinicians [1]. Currently, the main training opportunity, if available at all, is on body donations (corpses) or sometimes through simulated operations. The few physical nasal training models available on the market, e.g. from Fusetec (Adelaide, South Australia) or Phacon Sinus Assistant (Phacon GmbH, Germany), do not fulfil all the special requirements for the FESS, e.g. to reproduce the important tissue structures in the paranasal sinuses in terms of haptics and optics [1]. For instance, procedures may involve removing polyps, widening the ostia of the sinuses, or accessing the maxillary sinus by removing the processus uncinatus with a reverse cutting Blakesley punch. Consequently, the model must incorporate various tissue types. The commercial models are also too expensive for student training courses.

Furthermore, desired pathologies are not always present in donated bodies. In order to train the operation and navigation skills through the complex paranasal sinus system, a physical training models is required that can realistically simulate the various processes during the FESS.

II. Material and methods

The development process was based on the VDI 2221 [2] with adaptions made by Wegner et al**.** [3] regarding the development of medical models. In this application case it

involves a detailed material analysis to find substitutes for mucous membrane, cartilage and bone.

Following collaborative requirements gathering with otorhinolaryngology experts, an in-depth analysis of the fundamental process involved in performing FESS for maxillary sinus polyp removal was conducted. Subsequently, a delineation of the required steps for incorporation into the training model was achieved. Moreover, a hierarchical functional framework for the paranasal sinus training model was devised, ensuring a systematic development approach.

As the next step the substitute material testing was conducted with medical experts. Testing was divided into three different test phases. At the beginning, suitable tissue-equivalent substitute materials were researched and collected. This included a broad selection of 3D printed materials (flexible resin as well as polylactid), silicon mixtures of different shore hardness, liquid latex, agarose and gelatin. In the first test phase, this large number of possible substitute materials were tested and unsuitable ones were sorted out. Evaluating them according to five criteria, each on a one to five scale, with a maximum achievable total score of 25 points. The test criteria were pullability, stampability, deformability and optical representation as well as what kind of tissue it represents the most and to what degree. The test setup is depicted in Figure 1, consisting of a side cover, base, nose cover (Figure 1a) and the material sample on a slidable material sled (Figure 1d), for quick conversion. The material sample with a size of 12mm x 8mm x 5mm (see Figure 1b) were placed inside of the 3D printed setup, produced with fused deposition modeling (FDM) and stereolithography (SLA). The nose cover was constructed on the basis of a 3D nose model taken from the online database free3d.com. This test setup was used to conceal the test material and represent a more realistic test environment.

The most suitable materials for cartilage and bone from this first test were a polylactid (ecoPLA by Niceshops GmbH, Paldau, Austria) and Flexible 80A (Formlabs Inc., Massachusetts, United States). Printed with an Ultimaker S5 (Ultimaker B.V., Geldermalsen, The Netherlands) and a Formlabs Form 3 (Formlabs Inc., Somerville, MA, United States). For mucous membrane a two-component silicone with a shore hardness of Shore 00 mixed with 50 wt.% silicone oil (Silikonfabrik.de, Germany) was rated with the highest points, 23 out of 25.

The materials with the highest total points passed to the next round. In the second test phase two 3D printed paranasal sinus test models were manufactured using the two eligible bone materials. The two models can be seen in Figure 2. The aim was to assess and classify the material behavior in a more anatomical structure, since parameters like material thickness have a major influence on the haptic material properties.

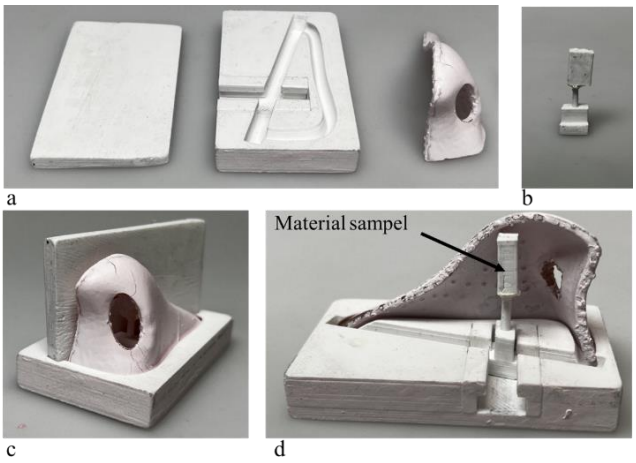

Figure 1: a Components of the test setup for the first material sample testing phase. Side cover, base, nose cover. b material sample. c Assembled setup. d View from the side without the side cover.

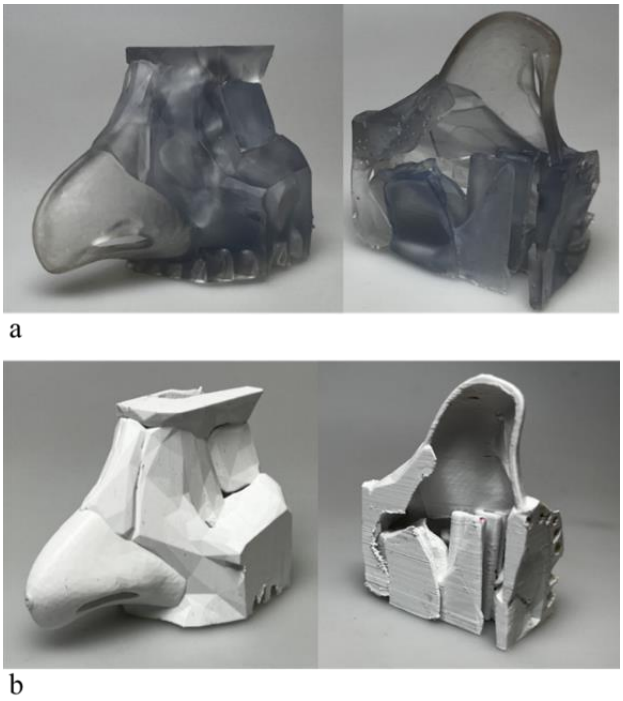

Figure 2: 3D printed anatomical test models for the second test phase. a See-through Flexible 80A. b White PLA.

To achieve a precise modeling of the maxillary sinus and its anatomical intricacies, including the processus uncinatus, middle turbinate, and inferior turbinate a STL model derived from a CT scan, available through emboli3D.com, was used [3]. Cartilaginous landmarks were added in consultation with the doctors to evaluate them during the testing phase. The models were then evaluated for the test criteria using surgical instruments. During which the flexible model received the highest score. And was thus selected for the paranasal prototype.

In the final material test phase suitable coating processes and the color matching of the mucous membrane were tested and evaluated. The color was desired to be in the reddish-pink range. Various colors were tested, such as

color pigments, acrylic paint, spray paint and flexible acrylic paint. Furthermore, different application techniques of the silicon mixture onto the 3D printed model were tested, like brush coating or dipping. The highest visual representation scores were received by using HexFlex flexible paint in pink (Poly-Props Materials International LTD. Dublin, Ireland) mixed into the silicon mixture (00 Sh with 50 wt.% silicone oil) and apply it onto the 3D model using dipping.

Finally, the prototype was designed and manufactured. Based on the test models the final prototype was designed in Autodesk Inventor (Autodesk, Inc., San Rafael, CA, United States). The prototype can be divided into two basic modules, the paranasal sinus module, see Figure 3, and the training environment, see Figure 4. These two modules in turn consist of individual components. The sinus module, was separated into three individual components and a frame, see Figure 3a. This division was necessary in order to fully coat the sinus cavity with the selected colored silicone mixture. The training environment consist of a FDM printed box as base and an SLA printed nose cover (Figure 4a), it thus represents the platform in which different sinus modules can be placed. To have a more realistic skin tone the model was spray painted after printing.

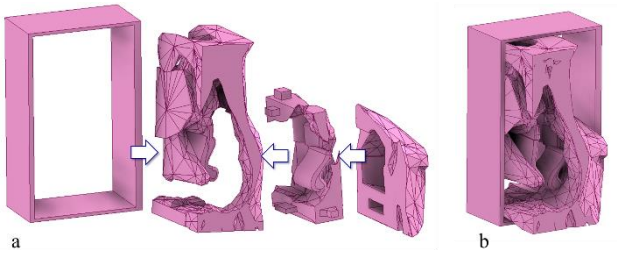

Figure 3: CAD images of the paranasal sinus module. a Components and assembly. b Sinus system model.

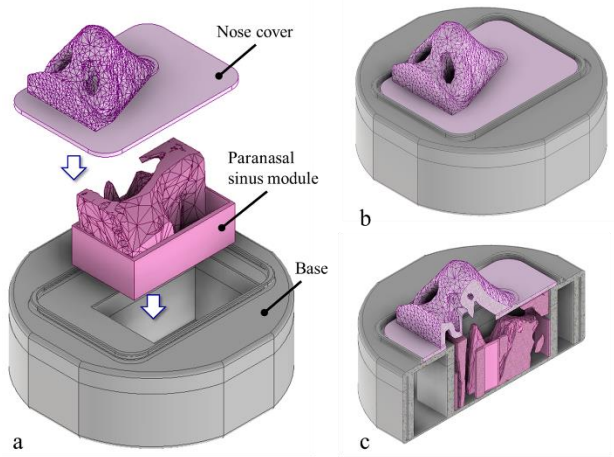

Figure 4: CAD images of the whole training model. a Assembly of the paranasal sinus module in the training environment, b Training environment consisting of nose cover and base module, c Sectional view into the training model.

III. Results and discussion

Once the prototype had been manufactured, see Figure 5, it was tested and evaluated at the otorhinolaryngology department. Certain surgical steps were performed on the prototype using various surgical instruments, like removing the processus uncinatus with a reverse cutting Blakesley punch. In this way, the doctors were able to assess the suitability of the prototype and in particular the materials used. The evaluation of the developed paranasal sinus prototype was carried out using an evaluation form. An endoscope (ENF-VH) with an integrated camera and linked light source (Visera elite CLV-S190) by Olympus (Olympus Europa SE&Co. KG, Hamburg, Germany) was used to visualize and document the simulated endonasal view. Initially, the overall haptics of the prototype were evaluated in general, while the individual procedural steps of an operation, such as pullability, were evaluated later on. Finally, the realism and suitability of the prototype as a training model was assessed. At the end of the evaluation form, comments could be written to provide further suggestions for improvement or general feedback. With the help of these additional findings, a more precise evaluation should be given on the one hand and further optimization suggestions collected on the other.

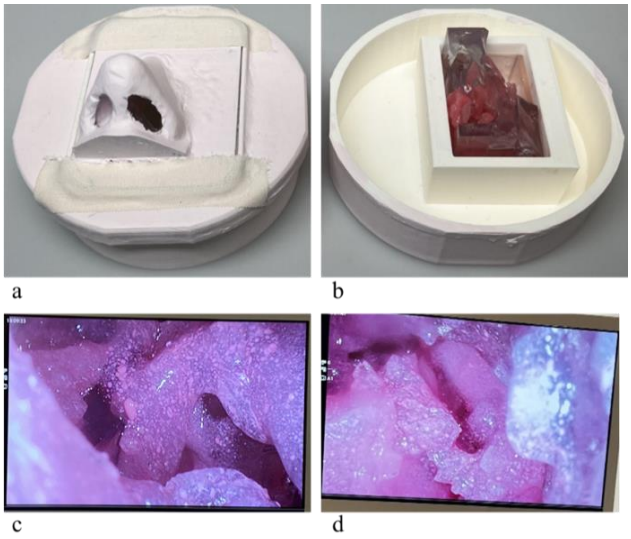

Figure 5: a,b Final prototype of the training model. c,d Endoscopic images.

In summary, the prototype fulfils most of the requirements. The model depicts the left maxillary sinus with the surrounding features, which is accessible through the left half of the nose (cf. Figure 5). The proportions of the prototype allowed the insertion and use of various endoscopes and surgical instruments. In addition, the paranasal sinus can be removed from the training environment and reinserted, which ensures quick and easy replacement of the processed materials.

The overall feel of the prototype was rated four out of five points and thus categorized as very good. According to the practitioners, the pullability and deformability of the

materials were easy to implement and were each awarded four points. The stampability, which describes the ease with which a material can undergo the stamping process without defects, was evaluated using a reverse cutting Blakesley punch. The material performed very well and was rated with five points. No metric measurements such as tensile strength or compression were performed, the haptics were only assed on an ordinal scale.

The coating of the mucosa only received three points as it was not well attached and could be removed too quickly during training. To avoid this, the attachment of the mucosal coating should be optimized. In addition, the layer thickness was too thick in some places and too thin in others, which meant that some of the surrounding features of the maxillary sinus were not easily recognizable. As a result, the visual appearance was only rated with three points due to visual restrictions caused by the mucosal coating.

Commercially available sinus models can cost around $2,260. In contrast, 3D printing this sinus model in-house cost us approximately €100, factoring material costs, printer operation, and labor. While the initial investment in a 3D printer and occasional maintenance add to the overall cost, in-house production remains significantly cheaper for small-scale projects, like this. Another advantage is the reusability of the model and the option to adapt the sinus system with different pathologies.

IV. Conclusions

In this work a 3D printed prototype of the paranasal sinus system for endoscopic training purposes was developed. Surrogate materials for mucous membrane, cartilage and bone were evaluated through a variety of materials tested in several test phases for haptics and appearance. The final choice of tissue-equivalent replacement materials for the mucosa, cartilage and bone were integrated into a prototype, tested and evaluated. Overall, the prototype for the paranasal sinus system training model was manufactured using direct additive manufacturing [4] only the coating of the mucosa was added using a dipping process.

By performing the FESS the suitability of the prototype and, in particular, the materials used were analyzed using a questionnaire. In conclusion, the evaluation was positive, although the thickness of the mucosa, among other things, should be optimized in a next step.

A throw training evaluation with a broad training group include a selection of experts, intermediates and novices like in Suzuki et al. [1] or Leong et al. [5] should be performed in the future to evaluate the models applicability. In this study, two experts and one intermediate took part in the evaluation. The models analysis could also be done in comparisons to other training models as well. In future, the training model should further integrate different pathologies, like different polyps in various positions. The integration of complications that can occur during a FESS should also be addressed in order to optimally prepare young physicians for the complex procedure. The paranasal sinus system could then be used not only in student training but also in remote training courses across the globe, like in [6].

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AUTHOR'S STATEMENT

Conflict of interest: Authors state no conflict of interest. Animal models: No animal experiments were carried out. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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