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Design and construction of a flexible pharyngeal phantom

A. Ibbeken[1*], C. Hagen[1], F. Zell[1], A. Steffen[2], U. Grzyska[3], A. Frydrychowicz[3] and T. M. Buzug[1]

[1] *Institute of Medical Engineering, Universität zu Lübeck, Lübeck, Germany*
[2] *Department of Ear, Nose and Throat Medicine, Universitätsklinikum Schleswig-Holstein, Lübeck, Germany*
[3] *Department of Radiology and Nuclear Medicine, Universitätsklinikum Schleswig-Holstein, Lübeck, Germany*
[*] *Corresponding author, email: ibbeken@imt.uni-luebeck.de*

Abstract: Obstructive sleep apnea (OSA) is a common sleep disorder characterized by episodes of partial or complete obstruction of the upper airway during sleep. In order to experimentally examine the causes that lead to OSA, a flexible pharyngeal phantom of the upper airway geometry of an OSA patient was fabricated using additive manufacturing and silicone casting techniques. The result of each manufacturing step was recorded and examined with a control CT scan, the deviation of the phantom from the digital model was measured and evaluated.

I. Introduction

Obstructive sleep apnea (OSA) is a common sleep disorder characterized by repeated partial or complete obstruction of the upper airway due to a shift of soft tissue. Regarding to a meta-analysis [1], the overall population prevalence of OSA ranges between 9% and 38%. Since OSA can lead to a range of secondary diseases, e.g., diabetes, hypertension, and cardiovascular disease, it is important to provide appropriate treatment. Experimental examination of obstructive sleep apnea can improve and support diagnosis and therapy and is required for the validation of simulations of digital models. Deformation measurements on flexible pharyngeal phantoms of OSA patients can provide important information about the causes and pathophysiological mechanisms of OSA. For this reason, we fabricated an anatomical upper airway phantom with additive manufacturing methods based on magnetic resonance (MR) imaging data of an OSA patient. Several computed tomography (CT) control scans were acquired during the manufacturing process to record the results of each manufacturing step.

II. Material and methods

A flexible pharyngeal phantom was fabricated using additive manufacturing and casting techniques. The upper airway geometry, including the airway, tongue, soft palate, the lateral pharyngeal walls and fat pads, was segmented from an MR image (3T MR system, Ingenia, Philips, Amsterdam, Netherlands; MR parameters: TR = 700 ms, TE = 35 ms, flip angle = 90°, pixel spacing = 0.58 x 0.58 mm^2, slice thickness = 1 mm) of a sleep apnea patient by physicians using ITK-SNAP (www.itksnap.org) [2]. The segmented geometry can be exported as standard triangulation language file (STL) for further processing. A digital model, shown in Fig. 1, was designed based on the segmentations. For this purpose, the soft tissue components mentioned above were merged together to improve feasibility and will be referred to as soft tissue in the following. The surface of the soft tissue and the airway were smoothed in Meshmixer (Autodesk, Mill Valley, California, USA) and the STL files were reduced to 20000 triangles for further processing.

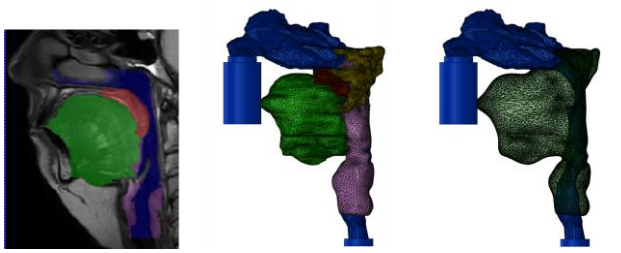

Figure 1: Left: MR image with segmentation of upper airway parts. Middle: Post-processed segmented parts: airway with pipe connections (blue), lateral pharyngeal walls (purple), tongue (green), soft palate (red) and fat pads (yellow). Right: merged soft tissue components and airway.

A three-part mold, shown in Fig. 2, was designed in SolidWorks (Dassault Systèmes, Vélizy-Villacoublay, France), in which the soft tissue and airway structure are integrated. An Ultimaker 3 (Ultimaker, Gendermalsen, Netherlands), a fused deposition modeling 3D printer, was used to print the parts with a layer height of 0.1 mm using PLA, while the airway structure was printed with water-soluble material (Premium PLA Filament and Atlas PVA Filament, FormFutura, Nijmegen, Netherlands). After the mold was assembled, a silicone cast was made using the two-component silicone Sylgard 527 (Sylgard 527 Silicone Dielectric Gel, Dow Corning, Midland, Michigan, USA). Before casting, the silicone was degassed in a vacuum chamber. According to [3], the Youngs modulus of Sylgard 527 is 5 kPa for a mixing ratio of 1:1 and thus is in the range of pharyngeal soft tissue elasticity values [4, 5]. For rapid

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curing, the casted phantom was placed in an oven at 60°C for four hours. The water-soluble airway was then dissolved by placing the phantom in a water bath for two weeks. Three CT control scans were acquired during the manufacturing process (Pixel spacing: 0.18 x 0.18 x 0.18 mm^3). The first after assembling the casting mold and the second after casting and curing of the silicone. The last scan was taken after the wash-out process of the water-soluble material. The soft tissue and airway structure of the phantom were segmented by threshold and manual segmentation and registered with a rigid transformation to perform distance measurements to the digital model as a measure of quality.

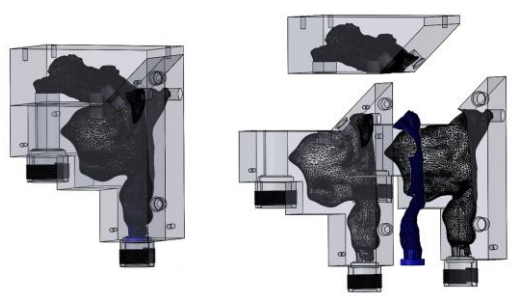

Figure 2: Casting mold (left) with integrated soft tissue and water-soluble airway (blue) and explosion view (right).

III. Results and discussion

Fig. 3 shows the acquired distance measurements of the segmented CT scans from the digital model. The mean absolute distance of the casting mold is 0.7 mm ± 0.5 mm, while the mean absolute distance of the casted phantom is 0.9 mm ± 0.7 mm. The mean absolute distance of the airway structure from the digital model after the wash-out process is 0.3 mm ± 0.3 mm. The higher mean distance and standard deviation of the casted phantom might result from a slight warp of the 3D printed material due to curing the phantom in the oven at 60°C, which has also been observed at the inlet and outlet of the phantom. Nevertheless, the deviation of the casted phantom from the digital model is still in the range of MR image resolution.

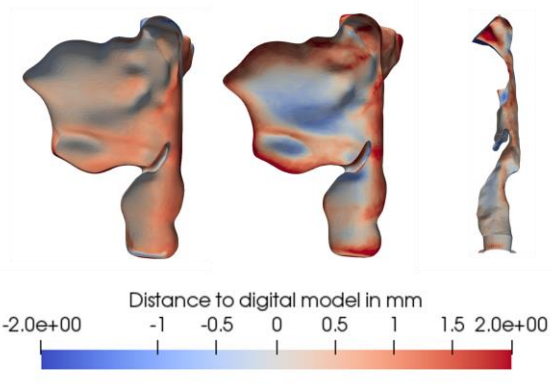

Figure 3: Distances between the digital model and the CT segmentation of the casting mold (left), the casted and cured phantom (middle) and the airway after the wash-out process (right).

The curing procedure also led to the formation of air bubbles, shown in Fig. 4, which probably occurred when the silicone contracted during cooling. In order to prevent warping and the formation of air bubbles in the future, the curing of the silicone will be carried out at room temperature. The third CT scan showed that the water-soluble material did not dissolve completely, leading to the conclusion that a longer solving time is necessary.

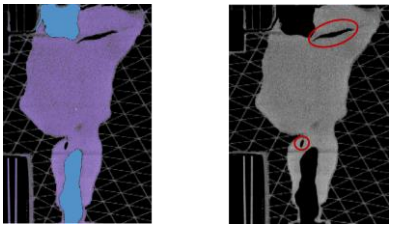

Figure 4: CT image of the casted phantom with soft tissue replica (purple) and airway (blue). Two air bubbles formed in the area of the epiglottis and near the transition to the nose (red markings).

IV. Conclusions

A workflow to fabricate a flexible upper airway phantom of an OSA patient was successfully developed. Additive manufacturing and silicone casting techniques were used for fabrication. The final phantom showed slight deviations from the digital model presumably due to warping of the printed material by the curing process of the silicone at 60°C. This leads to the conclusion that for future phantom manufacturing curing at room temperature should be preferred. The final CT scan showed that some water-soluble material had not been dissolved, which also illustrates the need for CT control scans during phantom preparation. In summary, the quality of the phantom is considered to be of sufficient quality, as the deviation from the digital model is still in the range of image resolution. The phantom will be used for flow and deformation measurements to examine causes that lead to OSA.

Acknowledgments

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Author's statement

Conflict of interest: Authors state no conflict of interest. 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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