1. **Patient-Specific 3D Printed Airway Models for Applications in Anesthesiology**
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3. Abstract (3400 character limit)

Background: Effective airway management is a critical responsibility of anesthesiologists, who use airway trainers to practice intubation. These trainers prepare anesthesiologists for normal airway anatomies, but when presented with an abnormal airway, intubation becomes more difficult. While difficult trainers exist, they focus on craniofacial abnormalities, not internal airway irregularities. This limitation reduces their effectiveness in preparing clinicians for atypical anatomies, making it more difficult to manage difficult airways and increasing the risk of complications during procedures. This project aimed to develop a novel process for creating patient-specific airway trainers using MR imaging, segmentation, and 3D printing.

Methods: Airway models were generated from MR scans of the patients' upper airway while in the sniffing position. The DICOM files were segmented using 3D Slicer, and refined in Autodesk Fusion 360. Once converted to .3mf files, the airways were printed in various materials and tested in compression to determine the optimal material choice. In later iterations, an existing airway mold negative was adapted in Fusion to support difficult feature implementation including vocal cord inflammation, stenosis, and upper airway growths. This design was then casted in silicone before being integrated into a 3D printed base and tested for intubation, simulating clinical conditions.

Results: (Add in after testing)

Conclusions: This process demonstrates the feasibility of producing airway trainers that result from segmentation of patient MR imaging, but many difficulties persist in the use of MR

imaging. The reduction in resolution resulting from conversion into a printable file causes a loss in physiological accuracy, and certain landmarks, such as the esophagus and tongue, cannot be effectively modeled using a segmented MRI scan. However, a customizable manikin that can be manipulated to represent complex airway scenarios fills a clinical gap that can be used to improve clinical outcome.

4. Introduction

4.1 Background and Need

Emergency airway management is crucial during instances of respiratory distress, as clinicians typically only have on average 15-30 seconds to secure an airway before possible onset of hypoxia and brain damage [1]. Over 400,000 Americans each year are intubated in these emergency settings, with 12.7% of these intubations failing on the first attempt. For difficult airways, upwards of 50% of intubations fail on the first attempt [1]. The failure to successfully intubate a patient on the first attempt leads to a 33% increase in likelihood for patients to experience complications from lack of oxygen [1]. Since the amount of endotracheal intubation (ETI) training for a clinician and not necessarily the type of clinician performing the procedure might be more important for a successful ETI, it has become increasingly important to create a wide range of airway trainers for clinicians to practice on [2].

While some current airway trainers can provide adequate ETI practice for clinicians, these trainers are not able to successfully simulate the varying endotracheal environments of the many patients clinicians will see each day. These trainers specifically struggle to simulate the anatomy observed during allergic reactions, inhalation burns, or trauma in the upper airway [3]. Improperly simulating the endotracheal anatomy of patients can lead to problems in the learning process for medical residents, leading them to be less prepared for emergency ETI and therefore at a greater risk for failure on their first attempt.

4.2 Previous Work

There have been limited attempts to use 3D printing as a means for creating lifelike models for airway management. Previous attempts to integrate 3D printing into airway management involved taking computed tomography (CT scans). In Malackany et al. they successfully printed out a model of a patient's tracheobronchial tree to help visualize the specific anatomy and develop an airway management plan [4]. The authors concluded that adequate preoperative planning is crucial in patients with potentially difficult airways to decrease complications [4]. In A Iliff et al, the authors proved the feasibility of creating 3D models from reconstructed CT imaging using PolyJet 3D printing techniques with a photopolymer and thermoplastic polyurethane in addition to filament printing [5]. In Cardell et al. a feasibility study was conducted on utilizing multimodal 3D printing to augment a commercial manikin for patient specific intubatable design, but no further results were posted beyond the outline of the study [6].

4.3 Outline and Summary

In section 5.1 we outline the author's original plan for fabricating patient specific airway trainers by using Magnetic Resonance Imaging (MRI) of a volunteer in the "sniffing position" and then directly printing out that segmented portion of the airway. It should be noted that the authors have since changed the method for airway fabrication and have instead moved to take the negative of the airway space to then 3D print a mold from which a silicone model can be casted. One of the major difficulties of the initial fabrication technique was that the first scans collected by the authors did not reflect the opening of the airway when segmented, requiring an artificial opening to be created on the final model which was not reflective of patient anatomy. There were also difficulties in transferring the segmented airway model between the 3D Slicer software and Fusion Autodesk 360, which caused variations in anatomy due to the difference in resolution. In section 5.2 we describe the current fabrication technique and how this difference has led to significant improvements in ease of fabrication as well as with segmenting the DICOM files for the final design. In section 5.5 there is discussion of the testing that is being conducted with airway management professionals for qualitative feedback on the final airway management prototype, as well as the time to intubate for individuals with varying degrees of experience with intubation.

5. Materials and Methods

5.1 The authors collected MRI data from a volunteer at the University of Wisconsin Hospital to determine the feasibility of directly printing a patient specific airway. Using the MRI data, 3DSlicer was used to segment the data, isolating the cartilage and muscular tissue surrounding the airway. This segmentation, shown in Figure 2 below, was done with the help of thresholding based on density of the tissue, and cleaned up using smoothing features on 3DSlicer. This was then converted to a solid body using Autodesk Fusion and into a printable file using SolidWorks. This file was then printed out of Thermoplastic Polyurethane (TPU), Flexible Resin, and Elastic Resin. This printing process proved difficult and fickle due to the complex geometries and thin walls of the airway. Supports from these prints were difficult to remove, and each print failed multiple times before a successful print was seen.

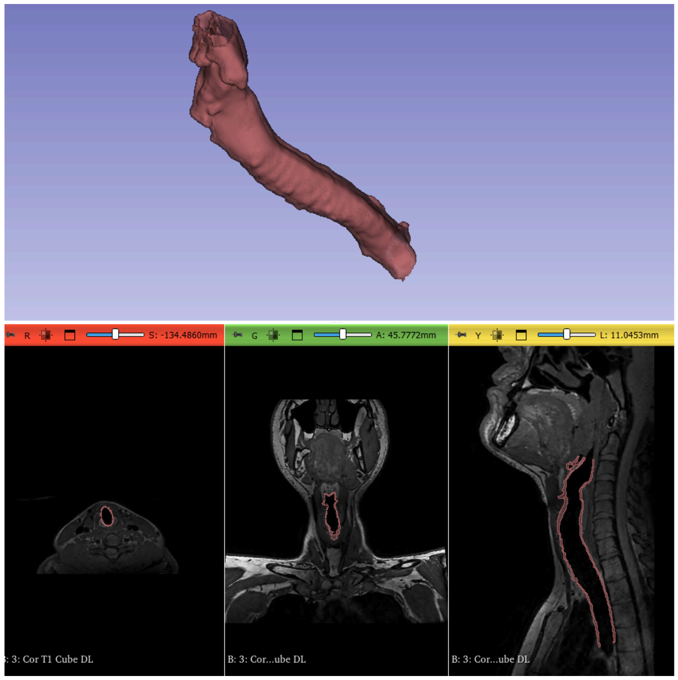

Figure 2: Segmentation of Volunteer Airway using 3D Slicer

5.2 The second method utilized new volunteer scans, in which the volunteer assumed a sniffing position, or intubating position throughout the duration of the scan. This allowed for slightly improved airway modeling, as this position opens up the airway to a position seen during intubation. With this new airway, the same segmentation protocol was followed in 3D Slicer, with one adjustment. Rather than isolating the tissue surrounding the airway, the empty space within the airway was isolated and thus converted into a solid body in Autodesk Fusion and into a printable file in SolidWorks, similarly to the prior method.

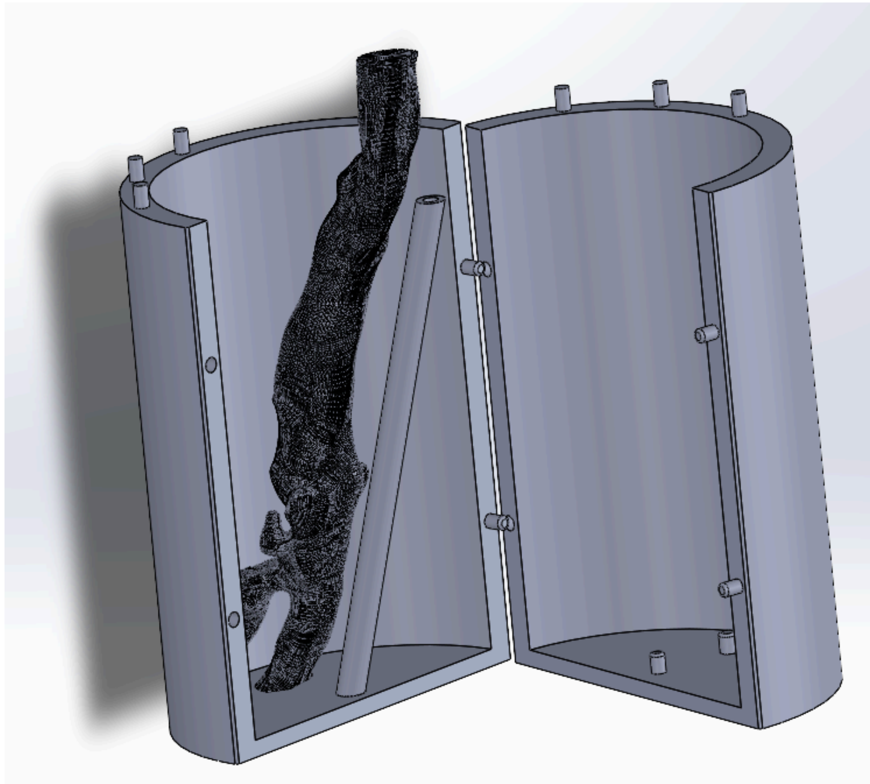

Figure 3: 3D Render of Airway Mold and Outer Shell

5.3 Two additional parts were designed in SolidWorks to create a mold into which silicone could be poured. The outer shell created the neck of the intubation trainer, and the smaller cylinder was a mold into which a flexible lamp rod could be inserted, imitating a flexible spine of a human. All three parts, shown in Figure 3 above, were printed out of polylactic acid (PLA). These prints were faster, cheaper, and more reproducible than the prior prints, and printed without fail multiple times. Silicone was poured into this mold and upon hardening, all of the PLA parts were removed, leaving just the silicone behind. This silicone was integrated with an existing mouth and upper airway mold and attached to a base as shown in Figure 4 to allow for intubation to be practiced.

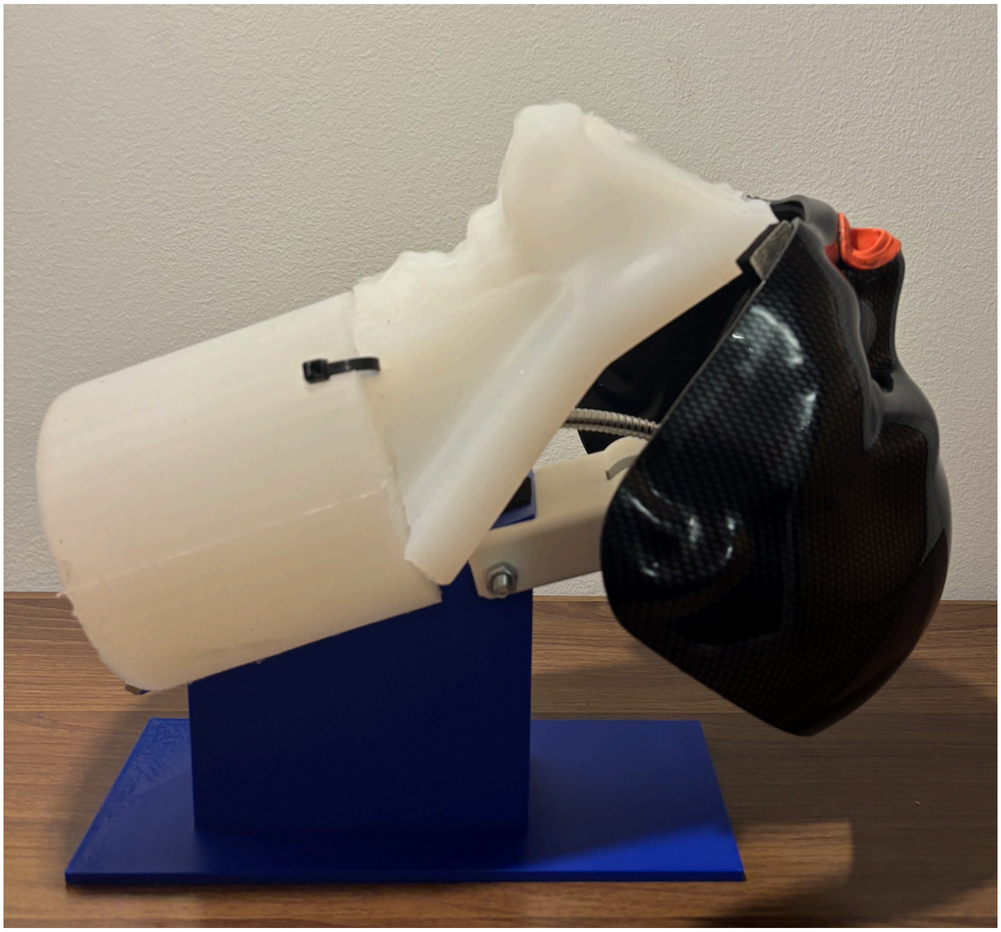

Figure 4: Airway Manikin Prototype

5.3 Multiple materials were considered for use during design in order to optimize the airway for accuracy during intubation. The materials considered were TPU, Flexible Resin, Elastic Resin, and EcoFlex Silicone. Compression and durability testing was performed on each of these materials to determine similarities and differences to human tissue. The compression testing utilized MTS (Material Testing System) to determine the stiffness of each material. The material, printed in the shape of the volunteer's airway, was placed sideways in the MTS machine and compressed until 25N, a typical load experienced during intubation. This testing was not possible to perform on the EcoFlex Silicone, as it was molded in a geometry that differed greatly from the other designs, which would cause large impacts to compression testing. Durability testing consisted of repeated intubation using a laryngoscope and an endotracheal tube until visible damage was seen, or until 50 trials were performed.

Figure 5: Compression Testing of Flexible Resin Material

5.4 The team plans to perform qualitative tests to gather data on the device's ease of use and general effectiveness. This data will be obtained by having users adjust the manikin’s features and remove and replace the manikin’s airway if applicable. Users of various intubation skill levels will perform a number of intuitions on the manikin. The stability, durability, and anatomical precision will be assessed based on feedback from users and observation of performed intubations. Feedback from experienced incubators will be vital in assessing the effectiveness of the device.

6. Results

6.1 Initial material testing revealed that TPU, followed by flexible resin, elastic resin, and EcoFlex silicon, is the least compressive of the materials tested. The team also tested the TruCorp rubber from an airway training manikin which had a similar stiffness to silicone.

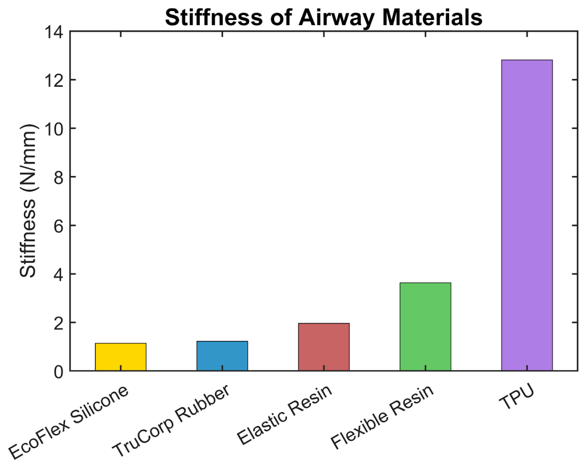

Figure 5: Graph Depicting Stiffness of Different Materials

Durability testing revealed that TPU and EcoFlex resin experienced the smallest change in natural shape after repeated intubation. Elastic and flexible resin experienced tearing after minimal intubations. The TruCorp Rubber also experienced no change in shape or properties after over 50 intubations.

Material	**EcoFlex Silicone**	**TruCorp Rubber**	**Elastic Resin**	**Flexible Resin**	**TPU**
Intubations until damaged	>50 - Minimal Damage	>50 - No Damage	4	7	>50 - No Damage

Table 1: Durability Results For All Materials During Intubation

Although the hardness of TPU most closely matches that of airway cartilage, the material is not practical for use in an airway trainer. The tested material that allows for the best quality of intubation training is EcoFlex. The silicone material does not tear under significant pressure or during repeated use. However, the material deforms greater amounts than human tissue under typical intubation conditions. These factors make EcoFlex the most ideal material for creating an airway training manikin, although it must be noted that in a human intubation, the maximum force applied before airway damage will be lower than during training.

7. Discussion

We outline the process to convert MR imaging of patient airways to patient-specific intubation trainers to improve airway management outcomes. This project identified several difficulties in designing and fabricating patient-specific airway trainers from MR imaging. MR imaging of the volunteer airways in the sniffing position, even with anaesthesiologist assistance, did not yield functional airway models. While the MR imaging achieved accurate airway size and represented patient-specific anatomy, the imaging failed to deliver a distinguishable esophagus and tongue, and required significant smoothing during segmentation to produce a single airway mesh. In early iterations of the design, the lack of an esophagus was remedied through manual modeling of an esophageal tube in an estimated location based on landmarks on the airway model and in the segmentation interface. While this addition created a necessary failure mode for the model during intubation, the guesswork involved in this step jeopardized the accuracy and realism of the model to the extent that the team felt uncomfortable using this process moving forward. Additionally, reduction of the mesh in Fusion before converting to a solid body resulted in a diminished resolution. When imported to Fusion, the airway meshes had between 25,000-30,000 faces which was too complex for the modeling software to compute and convert directly to a solid body. The necessary reduction to <10,000 faces leveled the topography of the tissue and led to a reduced anatomical accuracy of the model. Another hurdle encountered during this study was the direct 3D printing of airways in early interactions of the design. Though 3D printing has extreme potential in tissue modeling applications due to a wide variety of materials and variable infill density parameters, its integration into our MRI-driven process did not yield the best results. Additionally, physically creating a manikin with a seamless integration of 3D printed airways proved difficult. Distinguishing how much of the manikin should be rooted in patient-specific MR imaging versus constructed separately as a modular or adjustable base was a persistent challenge. Ultimately, the team chose to use preoperative MR imaging solely to determine the difficulties in the patient's airway, then adjust an all-in-one, adjustable, modular manikin to represent the airway as accurately as possible.

8. Conclusions

- The first method for airway trainer fabrication was not appropriately reflective of patient anatomy and provided the authors with many difficulties that reduced team productivity. As a result, this method was scrapped.
- The new method for fabrication established a more feasible way for directly mimicking patient airway anatomy through the use of the negative space in the airway to create a mold which could then be cast out of silicone.
- Initial material testing was conducted during both phases. After discussion with the author's client it was determined that matching the material properties to trainers that exist on the market was more useful than attempting to directly match airway mechanical properties.
- Qualitative testing gave us this info (fill in once done)
- Time to intubate testing gave us this info (fill in once done)
- Fidelity testing proved (whatever it proved)
- The team successfully developed a method for taking an MR scan of an individual and converting it into a 3D printable file through the use of Autodesk Fusion.

9. References

[1] S. Maguire, P. R. Schmitt, E. Sternlicht, and C. M. Kofron, “Endotracheal Intubation of Difficult Airways in Emergency Settings: A Guide for Innovators,” Medical Devices : Evidence and Research, vol. Volume 16, pp. 183–199, Jul. 2023, doi: https://doi.org/10.2147/mder.s419715.

[2] P. F. Fouche, P. M. Middleton, and K. M. Zverinova, “Training and experience are more important than the type of practitioner for intubation success,” Critical Care, vol. 17, no. 1, p. 412, 2013, doi: https://doi.org/10.1186/cc11924.

[3] B. A. Traylor and A. McCutchan, “Unanticipated Difficult Intubation In An Adult Patient,” PubMed, 2021. https://www.ncbi.nlm.nih.gov/books/NBK572134/

[4] N. Malackany *et al.*, “Successful Management of Previously Failed Difficult Airway Using a 3D Printed Airway Model,” *Journal of Cardiothoracic and Vascular Anesthesia*, vol. 37, no. 8, pp. 1474–1477, Aug. 2023, doi: https://doi.org/10.1053/j.jvca.2023.04.009.

[5]H. A. Iliff, I. Ahmad, S. Evans, J. Ingham, G. Rees, and C. Woodford, “Utilising 3D printing in assessment of anticipated difficult airways,” Anaesthesia Reports, vol. 11, no. 1, Jan. 2023, doi: https://doi.org/10.1002/anr3.12232.

[6] A. Cardell, S. Dunham, and A. Aghera, “31EMF Intubatable 3D Printed Airway Manikin: A Feasibility Study for Replicating Real Patient Anatomy,” Annals of Emergency Medicine, vol. 80, no. 4, p. S14, Oct. 2022, doi: https://doi.org/10.1016/j.annemergmed.2022.08.054.