3D Printing Airway Trainers

Final Report

BME 400

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Client

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Abstract

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 limits 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. Airway models were generated from MR scans, segmented using 3D Slicer, and refined in Autodesk Fusion 360. The final design was casted from a 3D printed mold using the negative space of the airway. Compression testing revealed that Ecoflex™ 00-30 silicone closely replicated the softness of TruCorp rubber, while also withstanding over 50 intubations with minimal damage. After casting, the airway was integrated onto a silicone mouth and 3D printed base and tested for intubation, simulating clinical conditions. This process demonstrates the feasibility of producing low-cost, reusable, anatomically accurate, patient-specific trainers to improve anesthesiologist preparedness and reduce complications in airway management. Future iterations aim to enhance anatomical accuracy during segmentation and integrate fully customizable manikins. This technology offers a scalable solution for personalized intubation training and holds promise for improving clinical outcomes in complex airway scenarios.

Body of Report

Introduction

Motivation

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].

Current Methods and Existing Devices

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. There are a multitude of airway trainers that exist on the market, but they lack functionality in crucial areas for effective medical resident learning. The major limitation of many competing designs on the market is that they only represent one airway abnormality. The company 7-Sigma makes different airway management training tools, but these trainers lack significant modularity that can make them useful for medical residents beyond very specific use cases [4]. One of these trainers also costs around $2000, which can price out certain potential clients that require many different airway trainers to practice on [4]. The Laerdal Airway Management Trainer is the current airway management device used at the UW Health University Hospital. Much like the 7-Sigma trainer, the Laerdal device lacks the ability to remove the airway and place another in its place, strongly limiting the usability of the device. These tools also cost around $3000, which can once again

price out potential clients looking to develop a library of difficult airways to practice on [5]. Laerdal does also make a $272 Airway Demonstration Model, but this device is purely an airway with the lower portion of the mandible, lacking the full face and functional lungs shown in Figure 1 [6].

Figure 1: Laerdal Airway Management Trainer [5]

Recently, a more novel approach to airway trainer design has reached the market with Decent Simulators. While retaining the normal facial structure and anatomical design used by other companies making airway management trainers, Decent Simulators differs by including significant modularity in their design. These trainers have the ability to swap airways seamlessly, as well as including a library of difficult airways that are commonly seen in the field. Decent Simulators trainers also include crucial landmarks in the upper airway with vocal cords and an epiglottis [7]. While developing a library of difficult airways is an important aspect of the team's work, our main objective, and what differentiates our design as compared to Decent Simulators is the ability to generate patient specific airways that can be used preoperatively. A trainer from Decent Simulators also costs around $1,700, which is significantly more expensive than what our current design process costs [7].

Figure 2: Decent Simulators Trainer Showing Modularity [7]

Problem Statement

Standard airway trainers that exist on the market are limited in their usability beyond very simple ETI training. Some trainers do exist that mimic abnormal airways that could be seen by emergency medical technicians and surgeons, but these trainers are expensive and only mimic one facet of an abnormal airway. Abnormal airway intubation training has been shown to improve patient outcomes, as the level of intubation practice is directly correlated to ability for clinicians and EMTs in the United States. There currently exists no method for transforming magnetic resonance imaging (MRI) into a stereolithography (STL) file that can be 3D printed, but the team believes that this can be done using an advanced segmentation process to generate a high resolution 3D render. This would require segmenting the different slices of the MRI to assure that the printed airway has a >90% anatomical accuracy to make the device clinically relevant.

Background

Biology and Physiology

Ensuring physiological accuracy is fundamental to this device and its intended use. The device must be specific and precise to the individual in question, specifically with regards to important factors for intubation. Craniofacial factors that affect intubation include tongue size, adequacy of the mouth opening, condition and presence of the teeth and uvula, the presence of an overbite, and thyromental distance, which refers to the distance from the chin to the thyroid notch in the neck [8]. A larger tongue, a smaller mouth opening, an overbite, and a short thyromental distance can all lead to a more difficult intubation procedure. On an idealized airway trainer, these craniofacial factors would be adjustable by allowing for variation in mandible positioning, thyromental distance, and tongue size.

Airway anomalies must also be taken into account, as an accurate device would match the upper airway and trachea of varying individuals, with some of the following conditions. Pyriform aperture stenosis is the narrowing of the nasal airway due to bony overgrowth, which makes nasal intubation nearly impossible [9]. A laryngeal cleft is the abnormal connection between the larynx and esophagus, which can cause accidental esophageal intubation, which can be deadly if not recognized quickly. Laryngeal stenosis, webs, and atresia refer to a spectrum of abnormalities within the larynx that can make breathing and intubation difficult. Stenosis refers to a narrowing of the larynx, webs partially constrict the airway, and atresia is a complete

blockage of the airway. Finally, a complete, or circular tracheal ring, rather than a typical C-shaped ring, can lead to tracheal stenosis, which makes both breathing and intubation more difficult.

Mechanical properties are also an important factor to consider when designing an airway model, to ensure physiological conditions are met. The trachea is a C-shaped ring, made up of cartilage, which provides structural integrity, and smooth muscle and connective tissue that provide flexibility [10]. The range of Young's Modulus within the linear-elastic range for connective tissue is typically 2.4 ± 1.2 MPa, and smooth muscle is 1.2 ± .5 MPa. That being said, smooth muscle and connective tissue increase non linearly, with a higher slope as strain increases further as seen in Figure 2 below. A typical range for the Young's Modulus for the cartilage is 16.92 ± 8.76 MPa, but it can range from 5 to 39 MPa depending on age, as cartilage stiffness increases with age due to ossification [10].

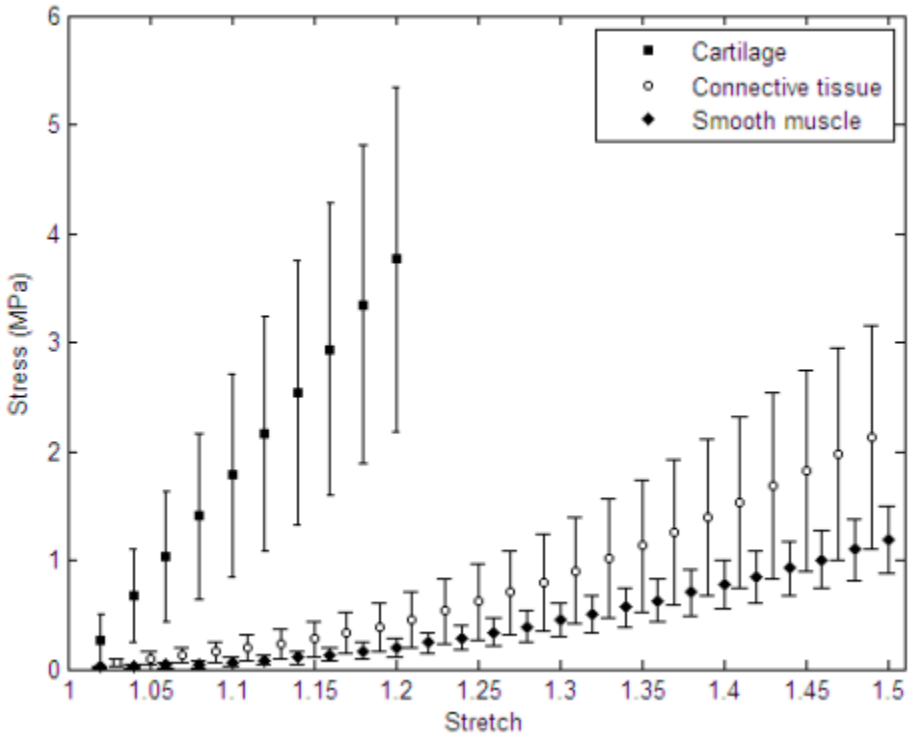


Figure 3: Stress-strain data for cartilage, smooth muscle, and connective tissue samples; expressed as mean ± STD [10]

Magnetic Resonance Imaging

Magnetic resonance imaging is a non-invasive imaging technique that produces three dimensional anatomical images [11]. MRI uses strong magnets to generate powerful magnetic fields that interact with protons in the body and forces them to align to this potent field. Radiofrequency currents are then sent through tissues to stimulate the aligned protons, forcing them out of their alignment with the magnetic field [11]. Once these frequencies are no longer being sent through the body and the protons are able to realign with the powerful magnetic field, energy is released by these molecules and sensed by the MRI sensors. Since different tissues have different properties that impact the speed of realignment and the energy released by each proton, conclusions can be drawn from this data to determine which tissue is which in the image [11]. To obtain an image, patients are placed into a large magnet and are told to hold very still so as to not blur the image [11]. MR scanners are most commonly used to image soft tissue in the body and differ from computed tomography scans (CT) as they do not use radiation to generate the images [11]. The lack of radiation in MRI is a hallmark of the technique, and one of the key factors when determining whether to use MRI or CT. Frequent scans will be taken using MRI as the patient will be protected from the possibly harmful radiation that they may be exposed to during a CT scan [11]. It should be noted that while there is no radiation used in MRI, the strength of the applied magnetic field will interact with implants in the body, especially those containing iron, so individuals with pacemakers or implantable defibrillators are advised to not enter MRI machines [11].

Segmentation and 3D Printing

An integral part of going from scan to print is the process of segmentation. This process involves isolating anatomical structures from scan data to generate 3D renders that can then be exported as STL files and printed [12]. Some of the major challenges with segmentation relates to the slice thickness of the imaging. Thicker slices capture less fine detail which can obscure the anatomical structures being segmented, and lead to a lower resolution render. Taking thinner slices captures more of the final details of the structure being segmented, not only enhancing the accuracy of the segmentation, but also producing much higher quality meshes [10]. While different segmentation softwares can produce higher resolution and quality renders than others, the team is limited to resources available to the team through the University of Wisconsin and free online software. With this in mind, the team used the 3D Slicer software. 3D Slicer is a free, open source software for visualization, processing, segmentation, registration, and analysis of medical, biomedical, and other 3D images and meshes [13]. In the context of this project, the

software allows for MR scans to be parsed and converted into models that can be used in many applications, namely 3D printing.

Another software considered was ITK-SNAP, a free, open source software for visualization and segmentation. There exists an algorithm in the ITK-SNAP software that can complete automatic segmentation, which uses the contrast of the MRI to differentiate the voxels of tissue, but there are also capabilities for manual segmentation [14]. The manual segmentation component of the software has both a polygon tool and paintbrush tool for fine object refinement and definition. Once a render is generated on ITK-SNAP, it can then be transferred to another resource for further refinement and processing.

For 3D printing, the printer will depend on the type of material selected for prototyping. In general, 3D printing in medical applications uses the Stereolithography (SLA) method. This method uses a bath of photosensitive resin with a UV laser to cure the resin. The UV laser is directed onto the resin slice by slice using a computer controlled mirror that directs the exposure path of the UV light to sequentially generate the slices of material that bind to form a solid object [15].

Since thermoplastic polyurethane (TPU) was a possible material for the final design, it is also important to briefly explain fused deposition modeling (FDM) printing. FDM printing builds the print layer by layer by depositing melted thermoplastic polymers that eventually form final physical objects [16]. FDM machines are loaded with spools of thermoplastic material, and once the nozzle has reached the melting point of the chosen polymer, the printer begins to feed the filament through an extrusion head [17]. The material then cools and solidifies to form the desired shape of the print. To fill a larger area, multiple passes are often used, analogous to coloring in an object [16]. While FDM printing is useful for low-cost and quick prototyping, it lacks the accuracy and resolution required for ensuring anatomical accuracy of a printed airway [17]. SLA printing is considered to provide the greatest accuracy of the types of 3D printing used in medical applications, so this was the team's chosen method for fabricating our airway.

Client Information

Dr. Kristopher Schroeder is a UW Health anesthesiologist and a professor in the Department of Anesthesiology at the University of Wisconsin School of Medicine and Public Health. He also serves as interim vice chair of education and vice chair of faculty development in the Department of Anesthesiology.

Design Specifications

The design specifications for this project have been shaped by client input and requirements for a final device. While the scope of the current semester's work is to generate a proof of concept airway and focus on defining a concrete method for going from MRI to STL, it is still important to establish specifications for future airway printing.

To ensure clinical relevancy of a printed airway, biomechanical properties were selected to mimic standard airway anatomy. The desired Young's Modulus for the airway is 2.3-23 MPa, based on the material mechanics of tracheal cartilage in a standard human airway [18]. The Shore hardness of the airway should be 60-91 A, but can vary depending on the selected infill of the print and material choice [19]. For the life in service of a fabricated airway trainer, an amount of 20,000 intubation cycles was deemed feasible and comparable to other trainers on the market [20]. Based on client input, the airway must also match a human airway in both look and texture to eliminate any variation between trainer and real airway, and to simulate the true experience of ETI for medical residents and trainees utilizing the device.

The client also gave the team a budget of $750, but minimizing the process cost is integral for establishing the team's method as superior to existing devices, so the team will look to the $272 Laerdal Airway Demonstration Model as a target cost [6]. While minimizing cost is a major factor of the requirements outlined by the client, another is to keep the process of transforming a scan into a printed airway to under 72 hours. This will ensure selected patients with difficult airways can have their airway printed and practiced on by the surgeon prior to operation.

Codes and Standards

Since the project involves extracting personal information from patients through MRI, the protections placed on this information through the Health Insurance Portability and Accountability Act (HIPAA) must be considered. Any scan must be anonymized prior to being used on any 3D rendering software as to comply with the protections placed on this information through HIPAA [21]. Another standard that was considered by the team was ISO 15223-1:2021. This standard specifies the requirements for symbols on medical devices and is applicable to all symbols used in a broad spectrum of medical devices [22]. Symbols can be placed on the medical device itself, on the packaging, or in any accompanying information that is used to explain how to operate the device [22].

Preliminary Designs

Design Choice #1 - Adjustable Blocks Design

This design consists of 3D printed blocks of varying sizes that would be placed under the manikin's head to allow for modulation of the neck angle in the sagittal plane only. This angle change influences the thyromental distance, or the distance between the chin and neck. A smaller thyromental distance causes a more difficult intubation, so the varying blocks would create varying difficulty levels. These blocks are contoured to the head shape of the manikin to increase stability as much as possible, and velcro or suctions would be used at their base to further this stability. The simple nature of this design allows the user to quickly swap between difficulty levels without the use of additional tools, and the stability of the blocks allows the user to intubate with full pressure without unnecessary movement of the manikin.

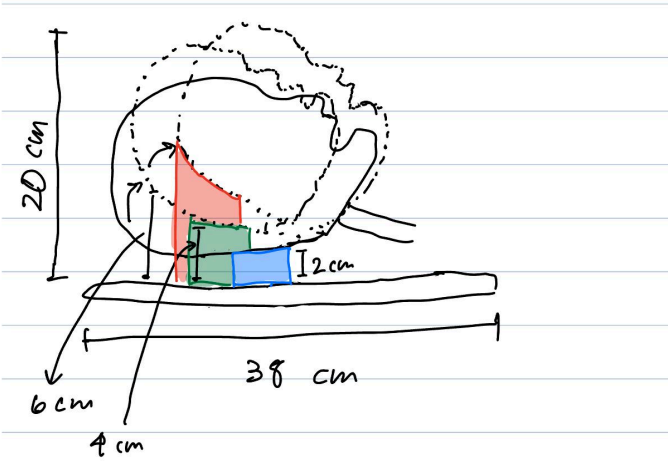


Figure 4: Adjustable Blocks Design

Material Choice #2 - Flexible Lamp Design

This design consists of a flexible lamp arm that is implemented within the neck and screwed into the skull of the manikin. This allows for three degrees of freedom of movement, as it permits movement in the sagittal and coronal planes, as well as rotation around the vertical axis, very closely matching the freedom of movement seen in humans. Each end of the lamp rod has a threaded portion designed to screw into the base of the head as well as the back of the neck to secure the rod in place while the neck angle is being adjusted. This design is not very stable and would benefit with the implementation of a mechanism such as design one to provide support under the head of the manikin while intubating. The stability mechanism is not limited to design one and could be as simple as researching another way to lock the rod in place during intubation training.

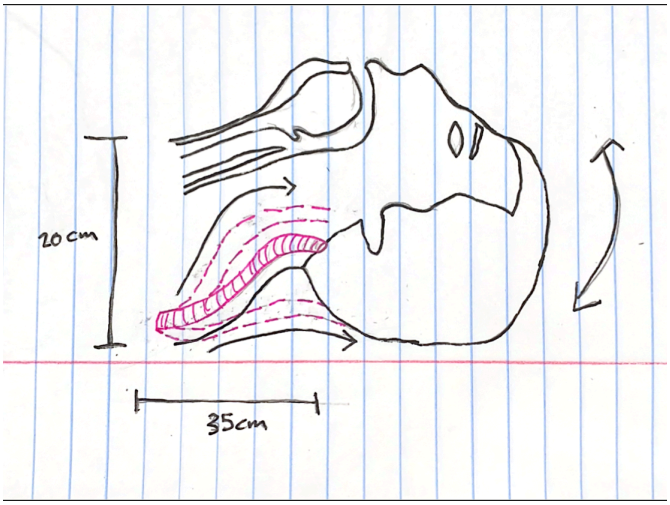


Figure 5: Flexible Lamp Design

Material Choice #3 - Rotating Pin Design

The pin design utilizes a system similar to adjustable gym equipment. The head of the manikin will have one hole that rotates to align with a series of holes on the base. A pin can be removed to allow freedom of movement in the manikin's sagittal plan, then reinserted when the manikin is at the desired position. The rack of pin holes will be fastened to the base of the trainer, and made of stainless steel to provide reliable stability. Once the pin is inserted, the manikin's head should have negligible movement in any plane. A foreseen drawback of this design is a small number of possible positions. The pin and holes should be as small and as close together as possible to improve the precision of neck angle.

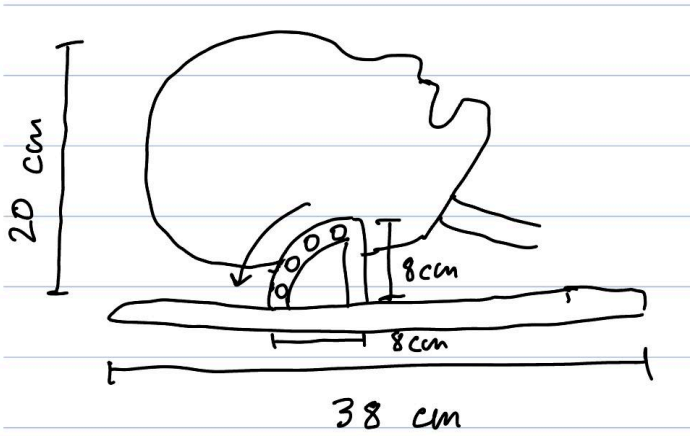


Figure 6: Rotating Pin Design

Preliminary Design Evaluation

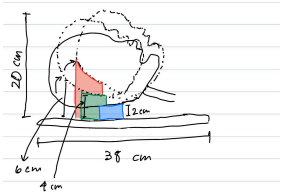
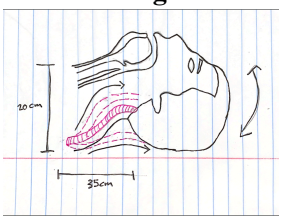
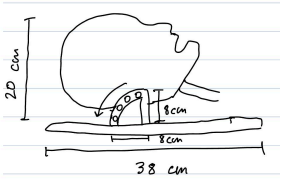
Design Criteria (Weight)	Design 1: Adjustable Blocks Design 		Design 2: Flexible Lamp Design 		Design 3: Rotating Pin Design 	
Ease of Use (20)	4/5	16	5/5	20	4/5	16
Stability (20)	2/5	8	2/5	8	5/5	20
Durability (15)	5/5	15	3/5	9	5/5	15
Precision (15)	3/5	9	5/5	15	3/5	9
Ease of Fabrication (10)	5/5	10	4/5	8	3/5	6
Cost (10)	5/5	10	5/5	10	2/5	4
Safety (10)	5/5	10	5/5	10	4/5	8
Total Score (100)	**78**		**80**		**78**	

Table 1: Material Design Matrix

Ease of Use: An individual with experience intubating on airway manikins should be able to use the design without any instruction. The user should be able to adjust the head and neck position in less than 10 seconds to allow for efficient practice.

Stability: There is significant downward force placed on a manikin during intubation. The head must be supported from below to prevent downward movement. This is reflective of a clinical intubation scenario. The manikin head must not be too flexible in the frontal plane to prevent rotation of the neck. However, during intubation there should not be significant forces applied in the frontal plane so this does not need as much attention as support from below. The final manikin should stay secure and in place during use unless forces exceed those experienced in clinical application.

Durability: The printed airway should be able to withstand at least 50 intubations. However, the manikin is intended to be used for multiple different airways that get swapped in and out. The manikin should withstand up to 20,000 intubations, similar to other manikins on the market. There should be very minimal wear and tear on the manikin over extended periods. This includes being used repeatedly as well as being left on a shelf untouched for months at a time.

Precision: The design that modulates the neck and head position should allow for a high degree of precision. This includes a wide range of angles as well as multiple specific angles within that range. The manikin must also be representative of human anatomy and be able to achieve the angles seen during clinical intubation.

Ease of Fabrication: This refers to how difficult the design is to incorporate into the assembly of a manikin. One manikin can be used for a long time since the airway is meant to be interchangeable. Because of this, the manikin only needs to be built once, so the ease of fabrication does not need to be taken heavily into consideration.

Cost: The cost includes all materials used to construct the manikin except for the airway. This is not weighted very high in the design matrix because manikins cost in the hundreds to thousands range to build. Everything besides the airway is a one time purchase.

Safety: It is difficult to get injured using an airway trainer manikin. Safety in this case refers to patients of those who train on the mankin. The manikin needs to be reflective of human anatomy and real life intubation conditions. This allows clinicians to be adequately prepared to intubate on live patients without causing them harm.

Proposed Final Design: Based on examination of the criteria above, the flexible lamp design is the best choice for our prototype. It is intuitive and easily adjustable to any desired position. The design is also cheap and does not leave room for injury. A lamp rod can be incorporated into a multitude of potential designs without causing disruption or needing to be worked around. The downside of this design is its lack of support and stability at the back of the head. This can be remedied by incorporating the block's design into the manikin or by building the manikin around a sturdy base.

Fabrication

Materials

TPU was chosen to be the final material for the 3D mold. However, Formlabs Flexible Resin and Formlabs Elastic Resin which have a Shore hardness of 80A and 50A respectively were also used to print a prototype airway in the previous semester. Previously, the team fabricated three airways, each identical in shape and size, but printed with a different material, as seen in Figure 6. These are listed as TPU2, Flexible1, and Elastic1 in Appendix B. Having three different materials allowed for the determination of which mechanical properties are best suited for repeated intubation.

Figure 7: Three Printed Airways, Material from left to right: Elastic Resin, Flexible Resin, TPU

The work conducted this semester focused on a different method for fabrication. While the printing of the physical airway was shown to be effective, the team aimed to accelerate the fabrication process, while also improving the overall accuracy of the final airway. To accomplish this, the team first printed a mold made out of PLA, as well as supporting materials that defined

the negative space of the airway so silicone could be poured into the mold to create our final design. The team elected to use Ecoflex™ 00-30 silicone for its flexibility and fast cure time, as well as familiarity with the casting process [23].

Figure 8: Silicone Mold Casting

MRI & Segmentation

To obtain MR scans that accurately depict the airway in a position seen in intubation, the patient was directed to assume a sniffing position, aided with a headrest as shown in Figure 9 below. Multiple scans were taken to ensure accuracy of the model, and once taken, they were exported as DICOM files for manipulation. A full protocol regarding MR scans is available in Appendix C.

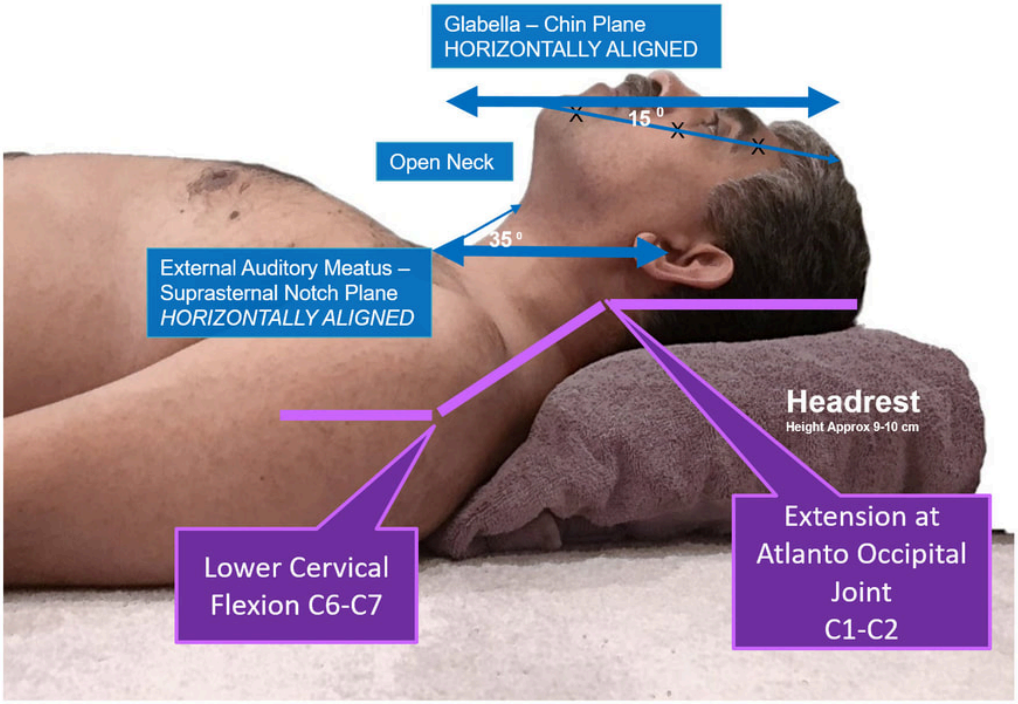


Figure 9: Sniffing Position in Adults [34]

Once DICOM files were received by the team, they were imported into the 3D Slicer software for segmentation. These scans differentiate tissue with a grayscale gradient that shows how the protons within each material respond to the magnetic field. This allows especially for clear differentiation between air and tissue, as the air appears black on an MR scan. Using this property, the team utilized the thresholding feature of 3D Slicer to include all voxels within a very low brightness and exclude all other voxels. This allowed for the air within the airway, as well as lots of extra spaces around it, to be formed as a solid, which could then be cleaned up using 3D Slicer features such as Scissors and Islands, as demonstrated in Appendix D. With an isolated lumen of air, the surrounding tissue could be added using features such as Copy, Add, and Grow to result in an stl mesh file as shown in Figure 10 below, which could be further processed in Autodesk Fusion 360.

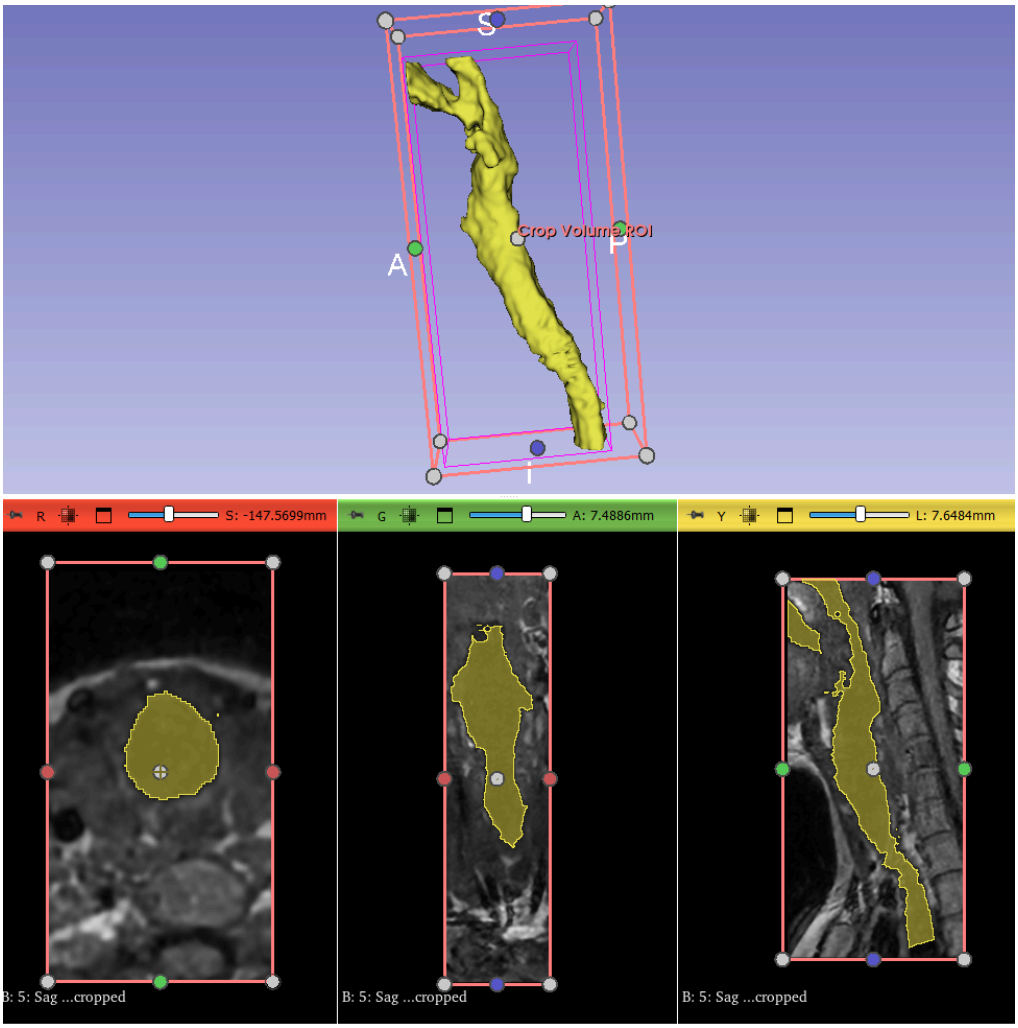


Figure 10: Segmentation of the Airway in 3D Slicer

Conversion & Printing

The segmented mesh developed in 3D Slicer was brought into Autodesk Fusion 360, a 3D modeling software. In Fusion, the imported .stl file opened as a mesh, or a 3D structure consisting solely of vertices, edges, and faces known as facets. The mesh body of the airway is seen below in Figure 11. A mesh has no depth or volume and therefore cannot be 3D-printed. Therefore, the mesh had to be converted into a solid body before being able to be printed.

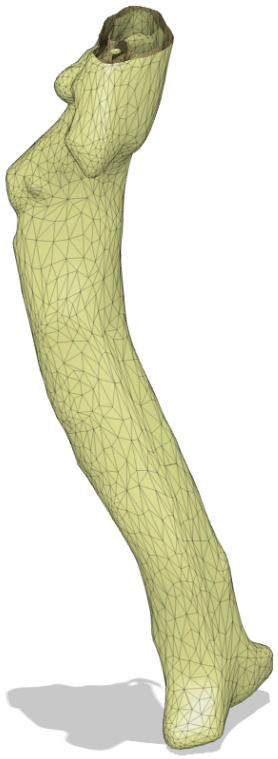


Figure 11: Airway Mesh

Per the protocol in Appendix E, Fusion tools were used to repair inconsistencies in the mesh, alter the resolution, and ultimately convert the mesh into a solid object. Once in the form of a solid object, the airway was scaled up by a factor of 25% and holes to accept pegs from the mold were added. This was accomplished using modeling tools in the steps outlined in Appendix E.

Figure 12: Assembly of Airway Mold Parts

Next, a cylindrical mold shell was created to cast the airway. The mold was fitted to the anatomical size of the neck and pegs were added in calculated locations to attach the airway and the lamp rod spine(a channel for the spine was created by printing a cylinder of equal diameter and attaching it to the mold shell with pegs).

Figure 13: Airway Solid Body

The modified airway and mold parts were exported out of Fusion in the form of a .3mf file, which could then be imported into a pre-printing slicing software called PreForm. The slicing software allows for the adjustment of print orientation, support structure, scaling, and other settings that can affect the print quality. Once sliced, the files were sent to an FDM 3D printer to be printed in PLA.

Final Prototype

The final prototype for this semester consisted of a silicone based mouth which was created from open source data. The mouth was then attached to the casted airway generated from MR data with zip ties and silicone sealant. While this connection was sufficient for intubation demonstration and practice, in the future the team would hope to cast both pieces of silicone as one so that this connection point is not a possible mode of failure. The flexible lamp rod from the design matrix was then attached through the neck portion of the airway and drilled into the head to further stabilize the connection. The face used on the manikin came from an airway trainer given to the team by our client. The manikin base came from work completed two semesters

prior and allowed for minor neck mobility as well as placement of the airway manikin in the sniffing position.

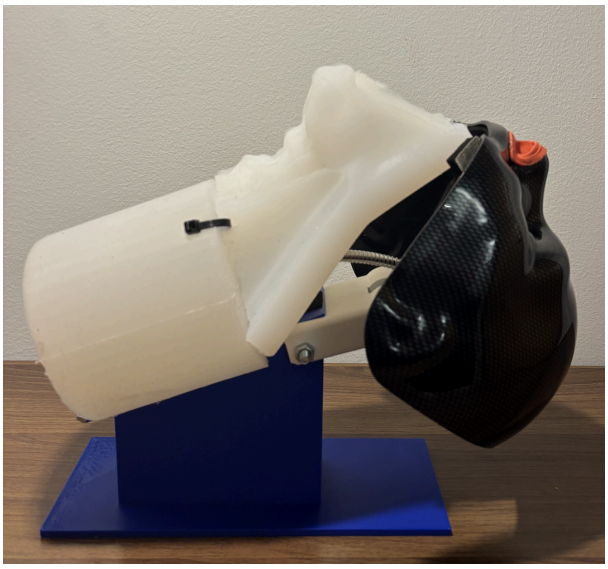


Figure 14: Airway Manikin Prototype

Testing and Results

Compression Testing

Figure 15: Silicone Test Coupon Before Compression

Figure 16: Silicone Test Coupon After Compression

The stiffness of each of the printed materials was measured using Material Test System (MTS) compression testing, allowing the team to compare the printed materials to an existing

trainer made of silicone. The airways of each material (silicone, elastic resin, flexible resin, and TPU) were placed between the compressive attachments and compressed in the frontal plane to a load of roughly 24.5 Newtons, a typical load experienced during intubation [35]. The team used a test coupon piece of EcoFlex silicone to measure the stiffness of the material of the airway used for this semester's work. The deformation was recorded at this load and used to calculate the stiffness of each material in N/mm, and results are shown in Figure 17 below. The EcoFlex silicone most closely matched the stiffness of the TruCorp Rubber airway given to the team by our client. The full compression testing protocol is available in Appendix G.

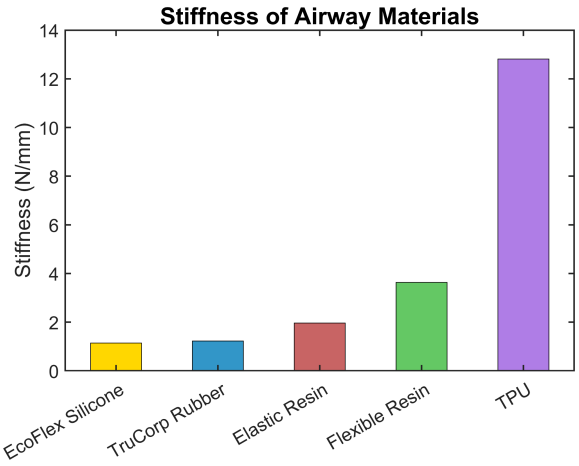


Figure 17: Stiffness of Airway Materials During Compression Testing

Durability Testing

The materials' durability was tested via repeated intubation using a laryngoscope and a bougie until damage occurred, or until 50 intubations were performed. The precise protocol is listed in Appendix H. This was a valuable test to understand how well each material can withstand the forces incurred during intubation, especially in critical points that bear the most forces such as the opening into the trachea. Slight damage was seen at that point after relatively few intubation attempts on both the elastic resin and flexible resin, while the TPU, EcoFlex silicone and TruCorp rubber were able to withstand 50 attempts with no or minimal damage.

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 2: Durability Results For All Materials During Intubation

Discussion

Testing results reveal that resin 3D prints are susceptible to tearing when stretched, despite being highly compressible. TPU on the other hand does not compress as easily and does not tear when stretched. Elastic Resin is the most compliant of the three materials that were printed with, but EcoFlex silicone was the most compliant of all the materials tested on. Previous work has shown that directly matching the mechanics of the airway is independent of the utility of the trainer, so the testing conducted this semester was more applicable to matching the stiffness of the TruCorp rubber. TPU is too stiff and allows for almost no freedom of movement when intubating. In future testing, it is vital that the airway opening is wider than a laryngoscope. This will avoid immediate tears like the ones observed during durability testing. Since the trainer's first mode of utility is for patient specific training, 50 cycles is a practical benchmark for durability testing. Further testing should also include more than 50 repetitions of intubation if the trainer is being used for non-patient specific practice. The typical airway trainer will undergo up to 20,000 intubations in its lifetime [33]. When designing something used to train medical professionals, it is necessary to simulate accurate anatomy so that professionals do not have misconceptions when it comes to performing their practice in the field. The device should specify to the user any mechanical differences between the printed airway and a typical human since in cases like this it is not reasonable for the training device to be perfectly accurate. Intubation testing was performed by students with no formal training. It is unlikely that this led to significant differences in results observed than if professionals performed the same tests, but it is a possible source of error to consider when drawing conclusions.

Conclusion

There currently exists no way to practice intubation on specific airways that present difficulties during intubation. The goal of this project was to develop a process to 3D print patient specific airway trainers. This was accomplished originally by first taking an MR image and then transforming it into an STL file that was printed using Formlabs 50A Elastic resin. Once printed, the model airway was integrated onto a prototype airway trainer where it was used to simulate intubation. This semester, the team elected to pursue an alternative method for airway fabrication. The team printed out a mold, as well as the corresponding negative space of the airway to then cast silicone over. Pursuing this method as opposed to directly printing the airway

proved to be more efficient and effective and will be the team's method moving forward. This process was to ensure anatomical accuracy of the patient and allow for an anesthesiologist to familiarize themselves with the airway before surgery, as well as decrease the time needed between scan and final airway.

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. Once the airway was casted it was then attached to the silicone mouth and 3D printed base so that it was able to be successfully intubated on. The team was able to integrate the work of the past three semesters in the creation of our final design and generated an airway manikin that included many aspects of other intubation trainers on the market, but was patient specific. The stiffness of the Ecoflex™ 00-30 silicone most closely matched that of the TruCorp rubber manikin given to the team by our client which was a major goal.

In the future, the team hopes to continue working on developing a method to cast the silicone as one continuous piece to eliminate potential modes of failure at the current connection points. The team would then like to integrate the final casted airway onto a manikin completely fabricated by the team so that other factors that can alter difficulty of intubation such as tongue size, mandible position, and neck angle could be considered. More work must be done to successfully incorporate more modes of intubation failure on the manikin, as well as to effectively integrate each aspect of modularity much like other trainers on the market. The team made a major leap this semester and hopes to have a manikin fully fabricated by the end of next semester to integrate all the work done over the past year and a half.

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Appendix

Appendix A: Product Design Specifications

Function

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]. 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]. To combat the difficulties caused by the variation in airways that can lead to inadequate training for many clinicians, this project seeks to prove the feasibility of a method for transforming CT scans or MRIs of a patient's endotracheal fanatomy into a 3D printed airway trainer so that clinicians can practice on high-risk scenarios. Establishing a concrete method for taking a CT scan or MRI and 3D printing a >90% anatomically accurate airway will ensure that clinicians will receive ample practice.

Client Requirements

- Prove the feasibility of taking an MRI or CT scan and 3D printing the airway with 90% anatomical and physiological accuracy.
- Create airways that can be swapped in and out of a universal trainer for the use of medical residents.
    - The focus of the work currently is to generate a concrete method for taking a scan and printing an airway, but once the method is proven to be feasible then the team could look to print different abnormal airways.
    - The team must also consider the modulation of airways from different positions of a patient’s neck.
- A hypothetical model must be flexible, represent accurate physiological biomechanics, and be made of a material that can resist water based lubricants as these are the typical compounds used during ETI procedures [4].
- Replicate accurate facial anatomy on a finalized model.

- Differentiate tissues in the airway by using unique materials to assist medical resident learning.

Design Requirements

1. Physical and Operational Characteristics

a. Performance requirements

The device will be used up to 50 times in a single session, with these sessions occurring frequently during medical student training periods. It must be adjustable to various positions, capable of holding them indefinitely, and easily readjustable at any time. Additionally, the device must endure thousands of intubation cycles under typical use conditions without wear or loss of functionality. Typical use consists of inserting a laryngoscope blade into the mouth to lift the epiglottis, followed by the insertion of an endotracheal tube into the larynx and then the trachea [5]. Once airflow is confirmed, the blade is removed, followed by the endotracheal tube. Furthermore, the fabrication process should be repeatable and precise, allowing for the consistent production of airway models representative of individuals with various airway abnormalities.

b. Safety

The device should be made up completely of non-toxic materials and avoid substances such as latex to maximize the number of individuals that can utilize the airway trainer. The most significant safety consideration for this device is to ensure its accuracy and reliability as outlined in the next section. Inaccurate airway trainers lead to inadequate intubation skills, eventually resulting in failed intubations and patient injury.

c. Accuracy and Reliability

The device should have a maximum percentage error of 5% for key measurements. These measurements include tongue to posterior pharyngeal wall (PPW), tip of tongue to vallecula, uvula to epiglottis, and more [6]. All measurements and specific values are in Section A of the appendix. Since the device is designed to model individual airway variations, certain measurements may deviate from those in the cited study. In such cases, dimensions will be determined on a case-by-case basis to ensure anatomical accuracy. To validate production precision, multiple devices representing different airway conditions must demonstrate accuracy and consistency. Additionally, the device's material must follow a typical tracheal Young's modulus of 16.92 MPa ± 8.76 MPa, depending upon the patient's age and condition, to ensure a realistic intubation experience [7].

d. Life in Service

To compete with existing airway trainers, namely the AirSim Pierre Robin X, the device must be able to withstand at least 20,000 cycles while maintaining accuracy [8]. If significant wear is seen primarily in a specific component of the device, this component must be easily replaceable without requiring a full device replacement. All portions of the device should be accessible and/or removable to allow for regular cleaning and maintenance.

e. Shelf Life

The required shelf life of the device depends upon the chosen design. If a device is made to mimic a specific patient's airway, a long storage time is not necessary, as it will only be used for a short period. However, if the device is made to mimic a certain condition, it will need to withstand typical storage conditions in a hospital for up to 20 years. Throughout storage, there should be no statistically significant changes to the measurable properties of the device.

f. Operating Environment

The device is meant to mimic a hospital setting with favorable conditions; room temp of 22 degrees Celsius and a relative humidity of 40-60% [9]. A water based lubricant is often used with airway trainers to mimic physiological conditions. Water based lubricants are standard to use with tracheal tubes and should not harm the 3D printed airway [10]. The airway will require cleaning after each session of use to prevent buildup of lubricant.

g. Ergonomics

The printed airway should withstand typical forces applied during intubation. It will not be expected to withstand unnecessary strain during use. The product should be capable of withstanding a force of more than 61.6 N, which is the maximum force applied by inexperienced intubators [11].

h. Size

The size of the product will be representative of the size of the patient's airway. It will span the length of the mouth opening to the carina which is typically 23.5 cm in men and 22.4 cm in women. This distance can range from 17 to 29 cm in adults depending on age and sex [12]. The diameter of a typical trachea is 22 to 24 mm in females and 24 to 26 mm in males [13]. Variations in airway length may affect the 3D printing process if the patient's airway is too large to fit on the available 3D printer. In this case, the use of a larger printer will be required. The printed airway will be fixed to an apparatus that accurately reflects the size of a head, neck, and upper thoracic cavity which is about 55cm x 35cm x 25cm in size [14,15].

i. Weight

While the weight of an airway manikin is not the primary concern during the design process, the weight should be considered in order to make the trainer as realistic as possible and match the feel of using a typical airway manikin. 10.87 kg is typical for a common airway trainer and should be a target weight for this product [16].

j. Materials

In order to preserve the functional value of this product, the materials chosen for the printable airways must share the mechanical properties of biological airways. Of the many properties of biological tissue, Young's modulus and Shore hardness present as the most important material properties to accurately convey in the airway models. The Young's modulus of airway tissues varies with tissue type. For tracheal mucosa membrane (TMM), the modulus ranges from 4-18 KPa, while cartilage within the airway ranges from 3.2-23 MPa [17]. Other mechanical properties of airway tissue include shore hardness, which is a measure of a material's flexibility. TMM has a shore hardness of 35-40 A while the hardness of airway cartilage typically lies between 59.6-91 A [18]. Airway properties vary between individuals, especially between patients with airway abnormalities. Quantitative MRI scans have proven to be useful in noninvasively determining tissue qualities and properties, so examining the initial airway scan of the patient to inform the material choices for that specific patient could help improve the accuracy of the printed airway [19]. While it may be difficult to exactly replicate the mechanical properties of each of the desired airways in the 3D-printed airways, it is integral to the efficacy of the trainer that the correct materials are used.

To house the printed airway and create a dynamic craniofacial structure, one or more heads and cervical regions of the spine may need to be fabricated to complete the trainer. Typical airway trainers are made of 3D-printed or injection molded plastics covered by silicone outer layers. While acquiring these materials and fabricating a functional trainer using them could prove difficult, they seem to be the most cost-effective method for creating realistic and functional manikins.

k. Aesthetics, Appearance, and Finish

To maximize the training efficacy of the airway and manikin, they should look as life-like as possible. In the airway, the color and texture should resemble the inside of the airway as accurately as possible. This may mean adjusting 3D-printing resolution to yield more refined textures. When looking down the airway directly or through a video laryngoscope while intubating, the printed airway should have proper coloring to put the trainee in the most likely environment that they will encounter in the actual patient. Color of the airway can change due to certain conditions or diseases such as cystic fibrosis, in which mucus lining the airway can swell and change to a greenish color [20]. These factors should be accounted for during the 3D-printing process to ensure an accurate model.

The physical manikin should also resemble the patient's craniofacial structure accurately. There are many conditions that can affect an individual's facial structure and can lead to complications during intubation. Craniofacial clefts, Pierre Robin sequence, craniosynostosis, achondroplasia, and Down syndrome are a few of the many conditions that can result in abnormal craniofacial anatomies and should be represented in the final design [21].

2. Production Characteristics

a. Quantity

The client has requested the team generate a proof of concept using the CT scan or MRI provided by the client. More focus has been placed on confirming the method for taking a CT scan or MRI and 3D printing the airway, but the client did suggest that the team have one model created by the end of the design process.

b. Target Product Cost

The client did not have a set budget for the team to follow, but based on the work of the team in a prior semester, the team will seek to stay below $750. The price for a standard airway management trainer made by the company Laerdal is $2,950 [22]. By creating a smaller section of the airway, and not the entire manikin from the standard airway management trainer from Laerdal, the product cost can be more closely related to the $272 Laerdal Airway Demonstration Model [23].

3. Miscellaneous

a. Standards and Specifications

i. ISO/IEC 3532-1:2023 – Information Technology — Medical Image-Based Modelling for 3D Printing — Part 1: General Requirements [24]
    1. This standard specifies the requirements for medical image-based modelling for 3D printing for medical applications. It concerns accurate 3D data modelling in the medical field using medical image data generated from computed tomography (CT) devices.

ii. ISO/IEC 3532-2:2024 – Information Technology — Medical Image-Based Modelling for 3D Printing — Part 2: Segmentation [25]
    1. This standard provides an overview of the segmentation process for medical image-based modelling of human bone. It specifies a standardized process to improve the performance of human bone segmentation, but it is also applicable to medical 3D printing systems that include medical 3D modelling capabilities.

iii. Patent CN105616043A – 3D printing and injection molding based silicone individualized airway stent preparation technology [26]
    1. This patent describes a technology integrating both 3D printing and silicone injection molding to create custom airway stent molds.
    2. The patent discusses the process of using a specific patient's CT scans to develop silicone molds for stents, and how this process is patented may complicate the patentability of our design.

iv. Patent US10850442B1 – Medical devices and methods for producing the same [27]

1. The patent describes the production of medical devices, such as airway stents, through additive manufacturing processes- specifically fused deposition modeling (FDM) and polycarbonate urethane (PCU).
2. The patent discusses the specifics of 3D-printing medical devices, specifically airway stents which the design may infringe on.

v. ISO 15223-1:2021 – Medical devices — Symbols to be used with information to be supplied by the manufacturer [28]
1. This standard specifies symbols used to express information for a medical device. It is applicable to symbols used in a broad spectrum of medical devices, and would pertain to an airway trainer. These symbols can be used on the medical device itself, on its packaging or in the accompanying information.

b. Customer

Potential customers for this device include teaching hospitals, EMS services, and medical schools. During this semester of work the client will be the only customer, as he will validate the anatomy and viability of the printed airway trainer before any products would be put to market. If the client did want to expand the reach of the product, it would likely be to peers at UW-Health in the anesthesia department. The client wants the team to solidify the process for transforming a scan of an airway into a printed airway, so an actual product will only be to prove the feasibility of the process.

c. Patient-related concerns

Since this product will never come into contact with the patients, there are very limited patient related concerns. One concern to consider is the use of personal information through MRI. To comply with HIPAA, there must be precautions taken when scanning patient airways and using this personal information to generate a 3D print. Scans must be anonymized before being used on any rendering software as to comply with the protections placed on personal information [29]. The main users of this product will be the clinicians and medical residents practicing their intubation skills. With that in mind, it should be noted that the tools used in practice on these trainers must not come into contact with any substances that would cause them to deteriorate before being used on a patient. An example for this would be the product must not contain any materials that could be potentially corrosive to metal as the laryngoscope is not able to be put in the autoclave after this interaction [30].

d. Competition

i. Laerdal Airway Management Trainer [31]
1. A lifelike adult manikin that can be used to practice ventilation, intubation, and suction techniques.
2. Includes features like induced vomiting, pressure sensitive teeth, and separate handheld anatomical models.
3. Used by UW-Health and the Anesthesia department to train residents.
4. Costs nearly $3,000 which is a reasonable price compared to what else is on the market.

ii. Seven Sigma Airway Trainers [32]

1. Parts are able to be removed and replaced to emulate different intubation scenarios. Typical adult airways can be used as well as airways of a patient who is swollen, a child, or has burn trauma. There are also different manikins for different races.
2. Solves the problem of allowing practice on difficult and abnormal airways, but is not patient specific.

iii. Trucorp Airway Trainers [33]
1. Offer three different manikins including an adult and child version with more coming soon. All of which are meant to imitate an abnormal airway that is difficult to intubate.
2. Feature an inflatable tongue to replicate conditions like obesity, down syndrome, and craniofacial abnormalities. Manikins also have adjustable mobility in the neck and spine as well as the ability to displace the larynx.

iv. Difficult Endotracheal Intubation Simulator [34]
1. This model has 3 modifications that can be made to make intubating more challenging.
    a. The manikin has upper incisors which are longer than average and are able to be removed.
    b. The manikin includes a sliding mandible that can allow for 0 to 10 mm of movement which can simulate an overbite.
    c. The mandible can be locked in place to restrict opening of the mouth. The inter-incisor distance can be reduced to 3 cm.

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Appendix

Appendix A: Anatomical Measurements

Measurement	**Mean, mm (SD)**	**Measurement**	**Mean, mm (SD)**
Tongue to PPW	12.22 (5.42)	Base of epiglottis to PPW	11.84 (3.1)
Epiglottis to PPW	7.94 (3.35)	Vertical distance of soft palate	26.50 (7.71)
Tip of tongue to vallecula	71.49 (6.01)	Soft palate to laryngeal inlet	60.64 (9.97)
Tip of tongue to tongue dorsum	34.38 (5.25)	Uvula to epiglottis	21.40 (7.88)
Vallecula to epiglottis	14.64 (4.2)		

Appendix B: Finance Table

Item	**Description**	**Manufacturer**	**Mft Pt#**	**Vendor**	**Vendor Cat#**	**Date**	**QTY**	**Cost Each**	**Total**	**Link**
Prints										
TPU1	First TPU print - Dr. Garcia STL	n/a	n/a	n/a	n/a	3/18	1	$1.09	$1.09	n/a
TPU2	Team's model TPU print	n/a	n/a	n/a	n/a	4/15	1	$1.72	$1.72	n/a
Flexible1	First flexible resin print using team model	n/a	n/a	n/a	n/a	4/15	1	$22.98	$22.98	n/a
Elastic1	First elastic resin print using team model	n/a	n/a	n/a	n/a	4/15	1	$21.23	$21.23	n/a
FlexibleFi	Final flexible	n/a	n/a	n/a	n/a	4/21	1	$26.98	$26.9	n/a

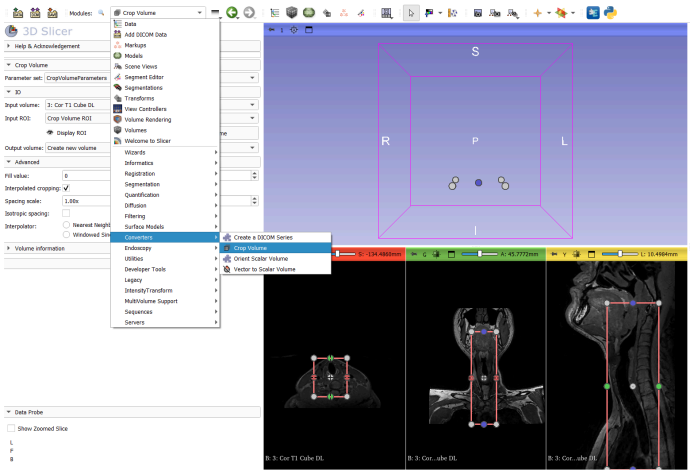
nal	print using updated team model								8	
								TOTAL:	**$74.00**	

Appendix C: MR Scanning Protocol

- Spacers were put into the MRI head coil to allow for neck extension
- Foam pads put under the neck and upper back to get volunteer into the sniffing position
- Body coil placed over the upper chest
- Blanket put over volunteer to keep warm
- Scan window focused over mouth, airway, and upper chest
- 1mm x 1mm voxel size
- Mouth closed scan ~3 minutes
- Mouth open scan ~5 minutes
- MRI done in coronal plane, but can be reformatted for axial or transverse planes for slicing/segmentation purposes

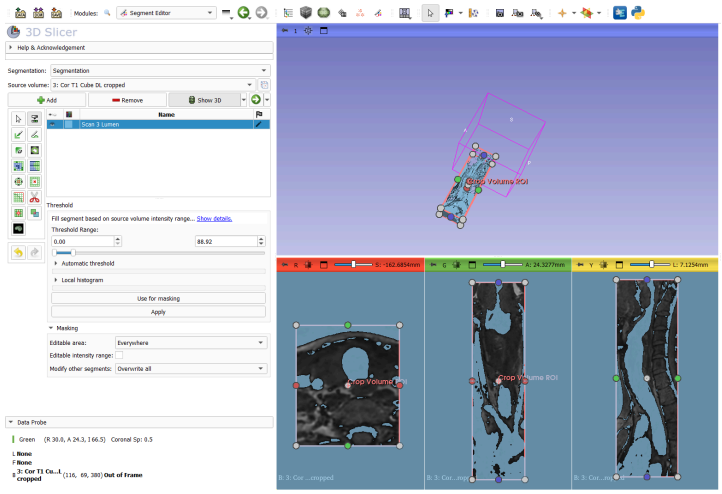
Appendix D: 3D Slicer Segmentation Protocol

1. Upload DICOM files from MR scans by selecting add DICOM data, and select desired scan by double clicking
2. Look through the three views (coronal, sagittal, and transverse) to ensure that the scan looks good, and use the crop volume module to crop the scan to only include the airway from just superior to the epiglottis to just inferior to the carina(split in the trachea). In this module you will need to select "Create New ROI", choose the desired region, and then select apply to create the new cropped volume.

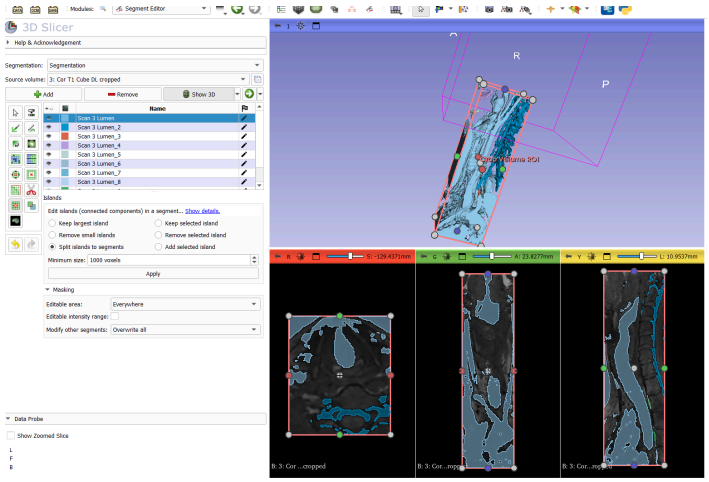


3. Under the segment editor module, select the source volume that you just created (should say the scan name and then cropped), and select Add to create a new segmentation. Rename this segment to something you will remember represents the air (I used Scan 3 Lumen). Then select Threshold from the options on the left side and change the low end

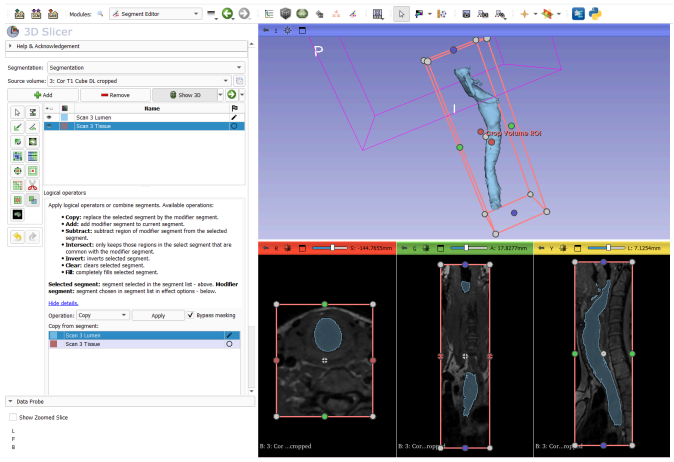
of the range to 0, and the high end to something around 90. This will depend on the scan, so look through each view to ensure that all air within the airway is highlighted. When the thresholding looks good, press Apply.



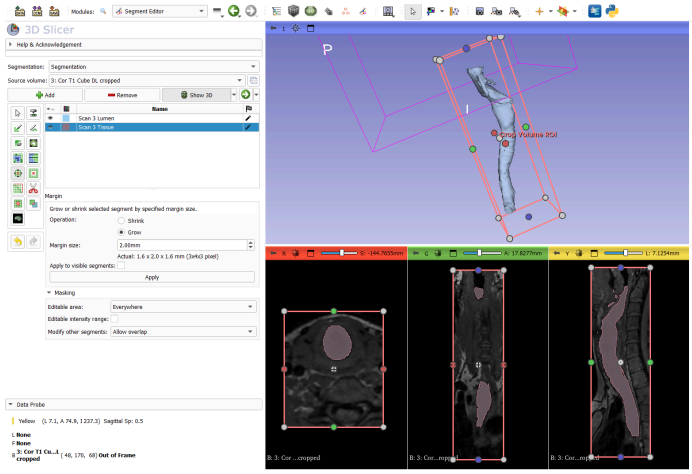
4. To begin cleaning up the segment, select Islands from the left side, and then Split islands to segments. You can adjust the minimum voxel size to include more islands. Once you split it into segments, you can remove any segments that are not part of the main airway.



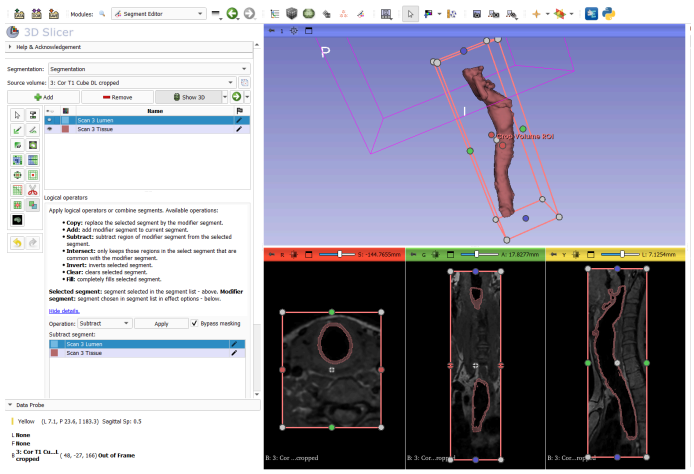
5. At this point, there will still be a lot of undesired segments still included, so you will need to use the Scissors tool to cut out sections that should not be included. This can be done by cutting small parts where the desired and undesired portions are connected to create an island, and then using the Split islands to segments feature from step 4 to remove them. This will be the longest step.
6. Once the airway is cleaned up, you will need to make the tissue around it. To do this, you need to go to logical operators, and then press Add to create a new segment, and name it something like Scan 3 Tissue. Then press Copy, and select Scan 3 Tissue up above, and Scan 3 Lumen below, then press Apply. At this point, you should have 2 identical segments.



7. Next, take this new segment and go to Margin on the left side, select Grow, and make the margin size 2 mm. Then make sure to select Allow overlap under modify other segments at the bottom! Then press Apply, and this segment should be slightly bigger than the other one.



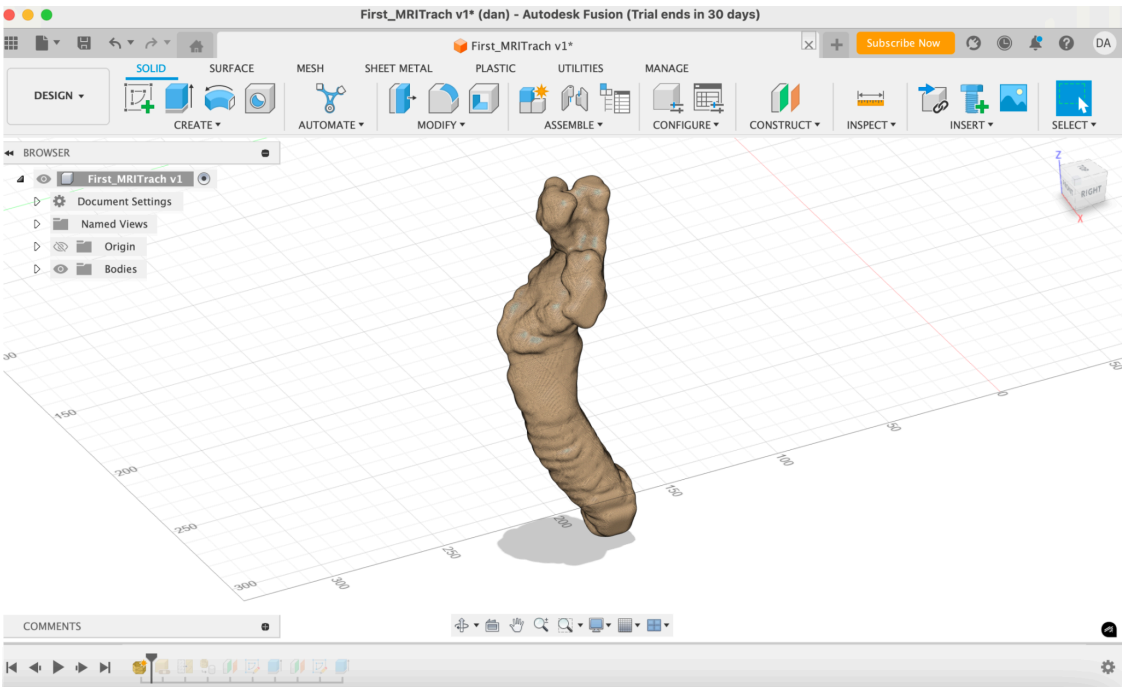
8. Finally, in Logical Operators, select subtract, and select the tissue as your chosen segment at the top and subtract the air from the tissue. This should leave you with a hollow shell of the airway!



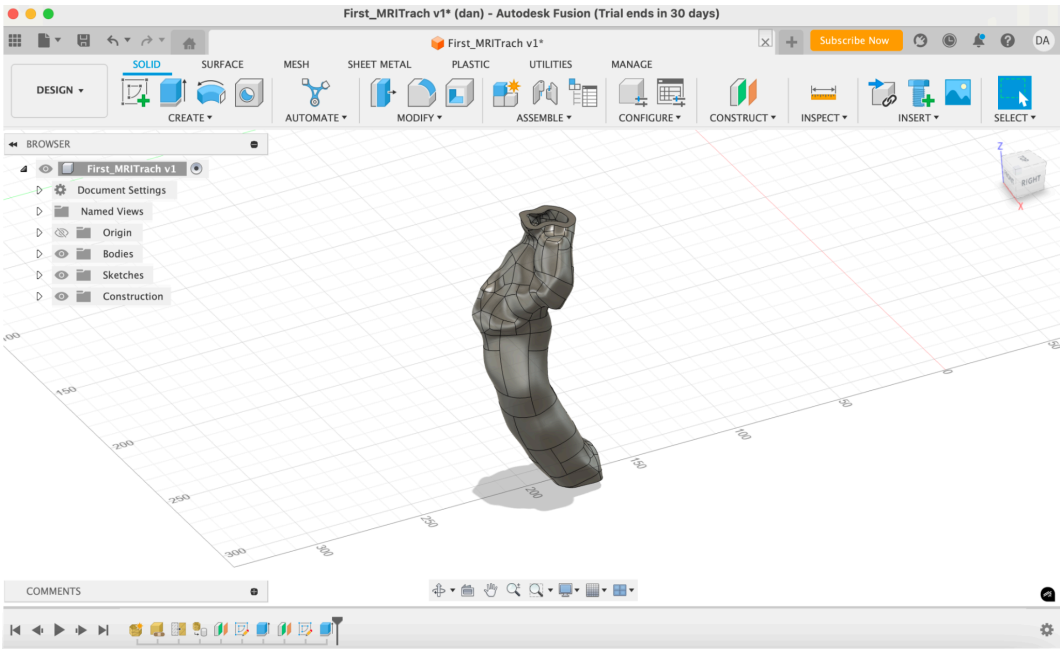
9. Next, go to the Segmentations module, and under Export/Import models and labelmaps, select Export and Models and then Export to the desired folder.
10. Finally, go to the Data module, select the Airway, and export as an STL file.

Appendix E: 3D Printing Prep Protocol

1. Load .stl file from segmentation into Fusion 360



2. "Insert Mesh" → choose mm
3. "Prepare" → "Repair"
4. "Modify" → "Reduce" → 9950 facets
5. "Modify" → "Convert Mesh" → "Parametric" → "Organic"
6. Cut ends (create offset plane, then sketch + cut)



7. Extrude the two ends of the airway and fillet end to create a wider opening(particularly at the top of the airway)
8. Create offset plane just inferior to the epiglottis
9. Create elliptical sketch in the offset plane and cut through bottom of the airway
10. Create sketch in the sagittal plane at the midline of the airway → create three point curve starting at the elliptical sketch and traveling down and away from the airway
11. Create an ellipse sketch 1.5 mm larger(in all directions) than the first ellipse sketch on the same plane
12. Use the “Sweep” feature to extrude the area between the ellipses(should be an elliptical ring) along the three point curve sketched in step 10 → this should result in an esophagus
13. Use the “Fillet” and “Offset Faces” tools to clean up any uneven surfaces and protruding extrusions

14. Export as .3mf or .stl

Appendix F: 3D Printing Protocol

- The file to be printed is transferred from a mesh to a 3mf as part of the 3D Printing Prep Protocol
- Put the file onto a flash drive
- Remove the file from the flash drive onto the makerspace computer, or another compatible computer that is being used
- Open the file with Bambu software for TPU or Preform software for Formlabs Resin
- Select appropriate infill, thickness, and material
- Orient the file and apply supports
- Print to the desired printer
- Return to collect part and remove supports

Appendix G: Compression Testing Protocol

- Swap tensile clamps for compression attachment on MTS machine.
- Open TestSuite software on computer
- Place airway on the bottom attachment so that compression can be done in the sagittal plane
- Lower the upper attachment until it begins touching the airway, and then zero the force and the displacement.
- Lower the upper attachment until the force value reaches roughly 24.5 Newtons and record the displacement value.
- Repeat for all airways

Appendix H: Durability Testing Protocol

- One repetition involves inserting a metal laryngoscope into the airway roughly 3cm or to where the airway would split into the trachea and esophagus and holding it with upward force for about 5 seconds.
- This process was repeated until significant damage to the airway occurred or until roughly 50 intubations
- Only the laryngoscope was used because the other materials used to intubate were observed to not scratch or stretch the airway
- The laryngoscope was in the airway for 5 seconds because it is removed quickly into the intubation process which takes at least 15 seconds