# 3D Printing Airway Trainers

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# ABSTRACT

Intubation is an invasive airway management method to ensure a patent airway. It is used during operations and emergencies when a medical provider must control a patient's ventilation. Abnormal anatomy, such as sublingual tonsils or subglottic stenosis, combined with other physical conditions like obesity, can make airway management difficult. Failure to secure an airway risks poor perfusion and death. Training for these situations is essential for safe airway management. Existing airway trainers on the market replicate standard anatomy under challenging conditions but do not represent abnormal airways with shifted anatomical landmarks, unexpected lesions, or modified anatomy due to prior surgery. This project aims to create a 3D-printed, patient-specific airway trainer using imaging of an abnormal airway. Custom trainers can provide preoperative training and teach healthcare providers to intubate complex airways. This project outlines a method to convert imaging into printable files and develops a base compatible with multiple airways. The material chosen for the airway was subjected to a material tensile test to ensure biomechanical accuracy of the printed airways. The trainer base underwent a finite element analysis of the maximum forces applied during intubation, and a test was performed to ensure the range of motion in the trainer was consistent with that of existing airway trainers.

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# 1 INTRODUCTION

## 1.1 Motivation

Airway management is a critical medical procedure to restore or maintain a patient's ability to breathe properly. This procedure is common in the medical field and is frequently performed on patients with anaphylaxis, respiratory arrest, or airway obstruction, as well as many other conditions; in the U.S., airway management occurs approximately 400,000 times a year in emergency settings. Despite airway management occurring at a relatively high rate, 12.7% of initial intubation attempts in emergency airway management situations are unsuccessful. A failed first intubation attempt is linked to a higher likelihood of negative outcomes for a patient, such as aspiration, hypoxia, and even cardiac arrest [1]. These potential complications highlight the importance of first-pass success and thus underscore the need for medical professionals to be able to refine and practice the complex techniques of intubation, including laryngoscopy and endotracheal tube placement. Due to the high-risk nature of intubating patients in critical condition, it is ideal for clinicians to practice airway management in a safe and controlled environment.

A proposed method to allow for this training environment is the airway trainer. A trainer is a mannequin designed to replicate the human airway's anatomical structure offering healthcare providers a repeatable and low-risk setting where they can learn the nuances of different intubation techniques. Regular practice with airway trainers helps clinicians build confidence and familiarity with the steps of airway management procedures and reduces the likelihood of error when performing intubation in an emergency setting. Although existing airway trainers can possess a variety of advanced features, they also tend to present obstacles because of their extremely high cost, extensive delivery time, and inability to simulate a wide anatomical variety of patient airways [2]. This project aims to produce an airway trainer that can be purchased more affordably, obtained more quickly, and replicate patient-specific anatomy.

## 1.2 Existing Devices & Current Methods

Through a combined effort of the client's previous experience and the team's research, multiple existing airway trainer devices were researched. The field of airway management trainers is vast, with large companies like Ambu and Laerdal making everything from complex trainers to simple head-and-neck-only trainers that can be purchased on Amazon [3, 4]. The varying level of complexity of these trainers allows the clinicians to replicate a variety of situations in which intubation is necessary. For example, the Laerdal Airway Management Trainer replicates standard anatomy and physiology through lifelike materials, and an anatomically correct head and neck are shown in Figure 1 [4].


**Figure 1:** Laerdal Airway Management Trainer [4]

The client's main goal is to train on non-standard airways that have a higher chance of perioperative failure or problems arising. TruCorp is a UK-based company that creates difficult airway trainers to simulate some common conditions during which intubation may be necessary to keep an airway patent. The TruCorp Airsim Difficult Airway Trainer can simulate laryngospasm (a sudden closing of the vocal cords) and increased edema or swelling in the airway due to anaphylaxis or a similar reaction. This airway management can be made difficult with these conditions; however, the client's goal is not to replicate standard anatomy in substandard conditions. Instead, it is to train on complex and nonstandard anatomy. Figures 2 and 3 show the trainer and the ability to simulate laryngospasm [5].


**Figures 2 and 3:** TruCorp Airsim Difficult Airway Trainer and the simulated laryngospasm it can produce [5]

The existing designs presented above are commercially available products but lack specific details crucial for this project. Section 3.1 Design 1 provides further explanation. In that section, the reasons why none of the existing trainers available could meet the client's needs were assessed numerically as the team decided on the project's scope.

## 1.3 Problem Statement

Current airway trainers present several issues that decrease their effectiveness in preparing medical professionals for real-world intubation situations. The majority of existing commercial airway trainers are highly expensive and, due to their specialized manufacturing processes, often have lengthy delivery times, both of which serve as obstacles in their procurement. Another significant drawback in trainer models is they typically have standardized anatomical structures that lack the variability present in the actual patient population. Airway anatomy can differ dramatically depending on factors such as the patient's age, BMI, pathology, and any previous medical procedures. The one-size-fits-all anatomy common in existing trainers can make it difficult for clinicians to prepare for the intricate airway conditions they may encounter. This can result in clinicians not being fully equipped to handle challenges specific to patients with whom they are working, which is possibly a contributing factor to the high percentage of unsuccessful initial intubation attempts currently observed in emergency situations [1].

The objective is to create an airway training device that overcomes these aforementioned limitations through the medium of 3D printing. The group plans to utilize computed tomography (CT) scans of patients to print the airway anatomy of a trainer so that it may mimic specific pathologies and offer a more realistic training experience. This customization will allow clinicians to practice on models that closely replicate the airways of patients they may have to intubate.

# 2 BACKGROUND

## 2.1 Anatomy and Physiology

The human airway is composed of several different components which are necessary for respiration. The upper airway starts with the mouth, after which is an open cavity referred to as the oral cavity. This cavity leads into the larynx through the pharynx, which is the mucous membrane-lined portion of the airway between the base of the skull and the esophagus and is composed of both the oropharynx and nasopharynx. At the bottom of the oral cavity, a large muscular organ called the tongue plays a role in the passage of air through the mouth, capable of preventing airflow to the oropharynx. Just below the pharynx is a piece of cartilage called the epiglottis, responsible for preventing foreign objects from entering the lower airway. Beneath this is the larynx, also known as the voice box. The larynx contains vocal cords and is surrounded by the cricoid and thyroid cartilage. This section leads to the trachea which is the passageway leading to the rest of the airway, composed of cartilage rings lined with mucosa [6].

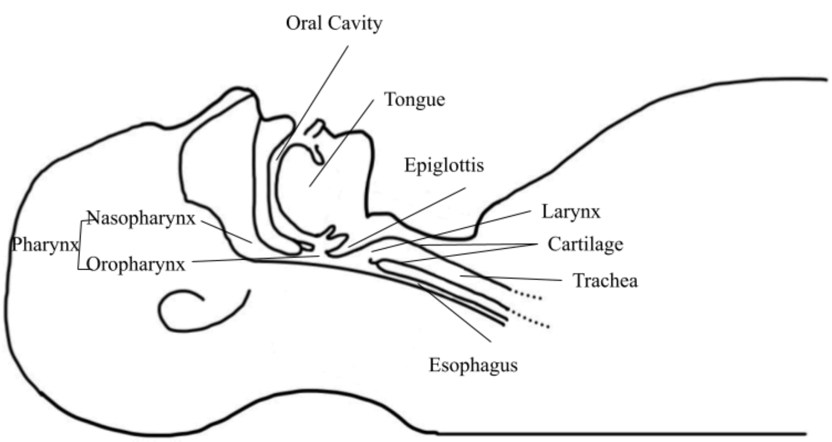



**Figure 4**: Diagram labeling the major components of the airway

Many conditions are capable of causing airway obstruction or limiting airway access. Among these are obesity and subglottic stenosis. Obesity is characterized by excessive fatty tissue in certain body areas, including the mouth and pharynx. This excessive tissue is capable of endangering the patency of the airway or making intubation difficult [7]. Subglottic stenosis is characterized by the narrowing of the airway in the region beneath vocal folds to the lower portion of the cricoid cartilage [8]. This condition is likewise capable of making airway access via intubation difficult.

## 2.2 Client Information

Dr. Schroeder is an anesthesiologist and a professor at the University of Wisconsin School of Medicine and Public Health. He serves as Vice Chair of Faculty Development and is interim Vice Chair of Education in the Department of Anesthesiology.

## 2.3 Product Design Specification

The product design specifications for this project have been shaped by information combined from client requirements, research, standards, and ongoing client input. The client is requesting an intubation trainer mannequin that can provide patient-specific pathology to practice intubation of a difficult airway prior to the operation. These trainers can be used preoperatively as well as postoperatively to train individuals throughout the Department of Anesthesia and UW-Health.

Due to health and safety reasons, certain materials should not be used to create the trainer, such as latex, as this is a common allergen. Additionally, the trainer must have a success rate around the 97% mark due to this being the global average intubation success rate [9]. This will be a difficult airway trainer, so the expected success rate is lower. In order to provide the most realistic trainer possible, ergonomics must be designed to exhibit similar forces that a standard human airway would [10]. Multiple biomechanical properties were considered when choosing the methods and materials for structuring this project. These include the Shore Hardness being within 50A to 80A and a Young's Modulus of 16 MPa $\mp$ 8 MPa to replicate the standard human airway properties [11, 12]. Specifically, shore hardness was included as a criterion to represent how difficult the model would be to initially deform under the force of the laryngoscope. This deformation included aspects of shore hardness as well as Young's Modulus. These ranges are due to age, pathophysiology, as well as other factors, such as if the patient has had previous surgery on the throat or is a victim of smoke inhalation. Because of this, these ranges have been set as a goal, but it will ultimately be up to the client to provide the final input on the material characteristics of certain airways.

The budget for a single airway trainer is $750, given by the Department of Anesthesia. This may change throughout the semester depending on the quantity of trainers requested and if the final product fits the client's needs. Other requirements that must be considered include the maximum size and weight of the product. Airway trainers must be able to be moved around and stored by a single person and thus cannot be heavier than 10 to 15 kgs, which is approximately the weight of current trainers on the market [13, 14]. Size must also be considered as well, with the size of the trainer replicating the upper torso of a standard human body. The trainer cannot be larger than 0.55 m x 0.35 m x 0.25 m to adequately simulate the clinician standing at the head of a patient [14, 15]. Additional product design specifications and the full, unabridged version of the PDS can be found in Appendix 8.1.

# 3 PRELIMINARY DESIGNS

## 3.1 Design 1 - Commercial Difficult Airway Trainer

The first design scope of the project sought to determine if any commercially available airway trainers met our client's needs. After initially realizing that no company created custom, patient-specific airway trainers, the team turned to utilizing this project scope idea to empirically prove that none of the existing airway trainers on the market fulfilled the client's needs.

Many companies create airway trainers that allow for intubation simulation as well as other airway procedures like a cricothyrotomy, the use of an oropharyngeal or nasopharyngeal airway, or even the use of double lumen endotracheal tubes [16 - 19]. These airway trainers often represent or mimic certain situations or conditions due to environmental exposure rather than pathological conditions or abnormal anatomy; because of this, commercial airway trainers have two main flaws. First, these simulators replicate a situation rather than a condition. Seven Sigma Simulation Systems has a trainer that can replicate smoke inhalation and airway burns, which is incredibly useful to practice for those situations, however, this is not providing the client with the practice that he needs in order to intubate patients who have abnormal anatomy or conditions. Secondly, these trainers are extraordinarily expensive, with the cheaper end being ~$2000 and the TruCorp Airsim Difficult Airway Trainer priced around $6000 [16]. Due to these factors, the existing devices are not sufficient and do not meet the client's requirements. Additional discussion will be provided in Section 4.1: Design Matrix.

Figure 5, below, shows an individual intubating a Decent Simulators Airway Task Trainer. This trainer has adjustable neck flexibility and narrows the trachea but cannot have modifications made to the underlying anatomy.

**Figure 5:** Decent Simulators adjustable difficulty airway trainer [18]

Figure 6 shows a replaceable airway present in a Seven Sigma Simulation Systems product that can be replaced with different anatomy. This modularity would allow the client to utilize one base chest and head anatomy while offering different airways, such as a patient suffering from anaphylactic shock or the airway of a geriatric patient.

**Figure 6:** Seven Sigma Simulation Systems swappable airway anatomy demonstration [19]

In summary, the client has reiterated to the team that although these commercial designs present thoughtfully and accurately created difficult intubation scenarios, they are not the same scenarios needed to practice for patients who may have extra weight, subglottic stenosis, sublingual tonsils, modified anatomy from a previous surgery, or a birth defect.

## 3.2 Design 2 - Modification to TruCorp Airsim Airway Trainer

The second project scope features the idea of modifying an airway trainer that is also already commercially available and being used for training the procedure of intubation by medical personnel, as seen in Figure 7. The TruCorp Airsim Airway Trainer was offered by the client to be modified with different airways for intubation practice. In this TruCorp trainer, the airway from the pharynx to the bronchi can be easily removed. From there, real scans of patient airways with various complications, such as subglottic stenosis or sublingual tonsils, will be used to create physical models that are then retrofitted into the airway trainer frame. This process will be able to occur for unlimited adaptability in a specialized airway trainer. The addition of patient-specific airways makes this trainer highly versatile in the medical field, as the TruCorp Trainer features other pathologies, such as the ability to simulate edema with a swollen tongue [20]. It is important that many different pathologies are able to be used in intubation training before the real pathologies of a patient are attempted to be intubated. The TruCorp frame is already suitable for intubation training; therefore, it is highly advantageous to maintain the shape of the majority of the airway trainer except for a few specific pieces of airway anatomy. Figure 7 shows an example of how this modularity might be possible.

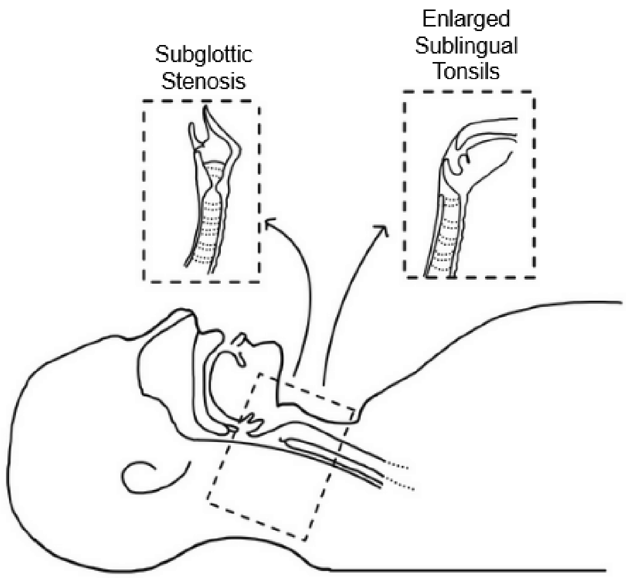



**Figure 7:** Modular airway trainer with replaceable difficult airways

## 3.3 Design 3 - 3D Printed Modular Airway with Patient-Specific Anatomy

The third project scope design is 3D printing a modular airway using patient-specific anatomy. This method features the use of segmentation software to identify important anatomical landmarks from patient imaging. Imaging selected for this process would include pathologies or anatomy that create difficult airway management. Figure 8 shows a depiction of a printed airway based on imaging of a patient with subglottic stenosis or a narrowing of the airway just below the epiglottis. This technique would allow for the patient-specific airway to be translated to a Standard Tessellation Language (.stl) file to be 3D printed using resins or silicones. Once an airway is constructed, a framework to hold the airway in place would be designed. The framework must be able to hold all difficult airways created using this segmentation method and allow medical professionals to practice various procedures. To increase the procedural versatility of this model, the framework should also include surrounding anatomy such as the mouth, nose, and bronchial tubes. This method allows for the trainer to be fabricated at a low cost, with similar methods being used to create airways for as low as $105 per airway [21]. The ability of this trainer to be patient-specific is a major advantage that could allow for advancements in how medical professionals train for airway management. One possible application is the ability to practice procedures in a pre-operative environment using a trainer with a patient's specific anatomy.

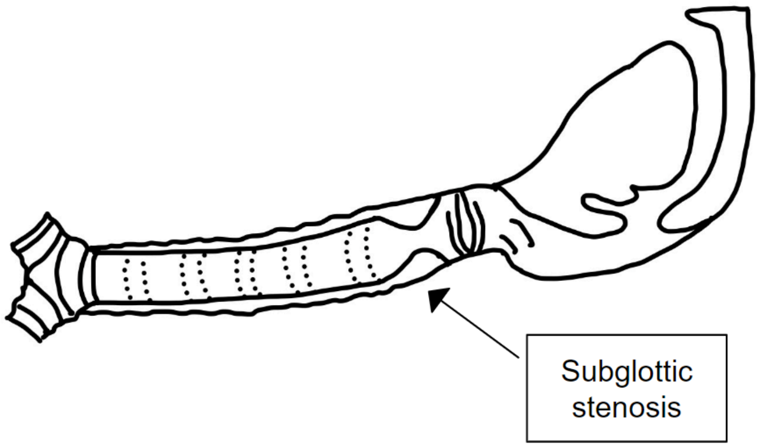


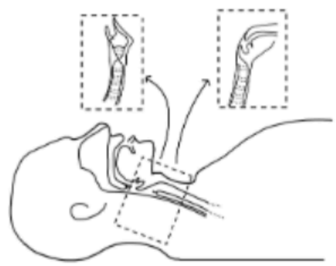

**Figure 8:** Depiction of a modular airway 3D printed using pathological patient imaging

# 4 PRELIMINARY DESIGN EVALUATION

## 4.1 Design Matrix

Table 1 shows the project scope design matrix, which explains the rankings below.

**Table 1:** A design matrix created by the team used to rank the three preliminary designs. Each category is rated by importance and is used to determine an overall score for each design.

| Design Criteria | Commercial Difficult Airway Trainers  TruCorp AirSim Difficult Airway Trainer | | Modifications to Existing Trainers  | | 3D Printed Modular Airway with Patient-Specific Anatomy  | |
|---|---|---|---|---|---|---|
| **Physiological Accuracy (25)** | **4/5** | 20 | **3/5** | 15 | **5/5** | 25 |
| **Complexity (20)** | **4/5** | 16 | **2/5** | 8 | **3/5** | 12 |
| **Cost (20)** | **2/5** | 8 | **1/5** | 4 | **5/5** | 20 |
| **Ease of Use (15)** | **4/5** | 12 | **2/5** | 6 | **3/5** | 9 |
| **Versatility (10)** | **2/5** | 4 | **3/5** | 6 | **4/5** | 8 |
| **Durability (10)** | **4/5** | 8 | **2/5** | 4 | **3/5** | 6 |
| **Total (100)** | **70/100** | | **41/100** | | **80/100** | |

## Reasonings for Scores

### Physiological Accuracy

Physiological accuracy is defined as the ability of the trainer to accurately replicate the anatomy of a difficult airway management case. This is weighted the highest because it is a direct representation of how well the trainer prepares professionals for realistic difficult airway situations that could be encountered in their practice.

### Complexity

The complexity of the design measures the likelihood that a medical professional would be able to practice and perform medical procedures on the trainer produced by a certain method. Complexity also takes into consideration the number of changes that would need to be made to the airway anatomy to achieve a trainer on which intubation can be practiced. This is weighted highly as it demonstrates the ability of the trainer to act as an effective educational tool.

### Cost

Cost is another important factor to consider. This is weighted highly as keeping the cost of each airway low allows for training on a wide range of difficult airway scenarios to be more affordable and accessible. This could greatly improve the ability of professionals to manage airways in many difficult airway scenarios.

### Ease of Use

Ease of use is defined as the ability of the trainer to aid the user through training during different procedures. This is weighted somewhat highly as it includes features important to the development of the airway management skills a medical professional might need when a patient presents with a difficult airway.

### Versatility

Versatility defines the ability of the trainer to provide a wide range of patient pathologies. This is important to consider as medical professionals will encounter many different pathologies in their practice and they must know how to appropriately manage each one.

### Durability

Durability shows the ability of the trainer to withstand repeated training without losing qualities necessary for an accurately represented difficult airway. This is weighted the lowest because while it is important to consider, it is more dependent on material choice than choice of methods.

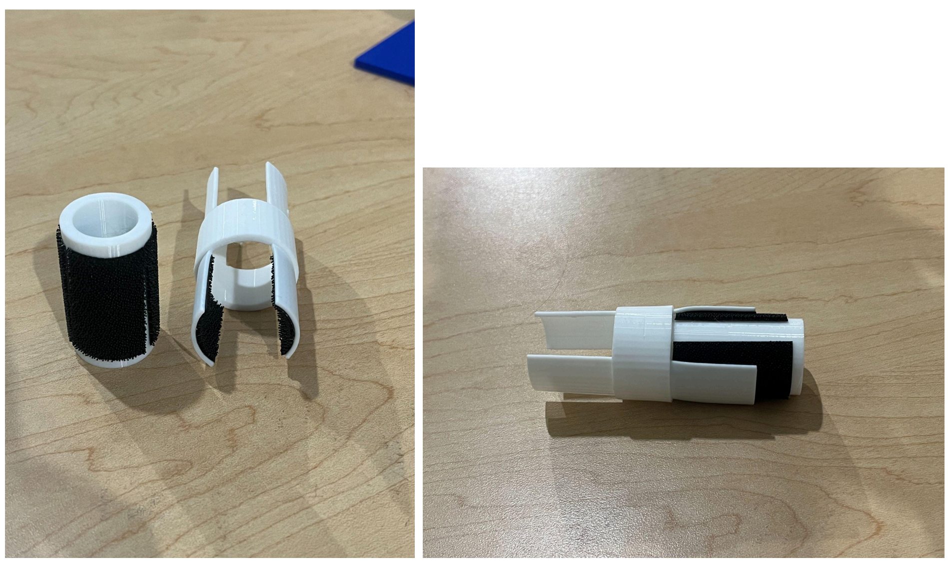
## 4.2 Proposed Final Design

The proposed final design is the 3D-printed modular airway with patient-specific anatomy. The decision to create patient-specific anatomy for the airway trainer was based on the first design matrix proposed, where it scored highest. Particularly, the design's physiological accuracy, low cost, and versatility were the primary reasons why it was picked. The physiological accuracy of the model is a distinct feature in that it enables the molding of patient-specific anatomy, which can better reflect anatomical nuances. Similarly, the versatility of this design comes from the fact that it can provide a variety of patient pathologies, widening the applications of its use to complex intubations from simple intubations because of the ability to control the entire airway anatomy rather than only a portion or none at all compared to the other two designs. Because the design will be within the provided budget of $750, it's cost-efficient, which is an additional strength. A drawback to using this model is the complexity of its design. This design will reflect patient-specific anatomy and more anatomical analyses will be done, requiring careful design. However, after considering all the aspects in the decision matrix, this was the winning project scope, and this is the direction the team will continue in. The next decision matrix will be covered in Section 5.2 Materials Design Matrix.

# 5 DEVELOPMENT PROCESS

## 5.1 Design Updates and Design Remodels

The base of the airway trainer has undergone significant remodeling since the preliminary design proposal. Key updates focused on optimizing the dimensions of the base, adjusting the angle of depression of the raised platform relative to the base, and determining the mechanism for attachment of the printed airway to the base. Initially, a large slit running down the center of the raised platform was intended to facilitate the attachment and removal of the patient-specific airways. However, the team identified a major inefficiency with this method: reaching underneath the trainer each time the airway needed to be replaced was inefficient. To address this, the team explored alternative solutions, including using magnets and a spring-loaded latch. While these options showed potential, they were ultimately deemed overly complex. The chosen solution was mushroom cap Velcro (brand name: Dual Lock by 3M [21] ), which proved to be a more effective and straightforward mechanism. This design balances ease of use with reliability and streamlines the process of airway attachment and removal without compromising any functionality. Additionally, a white connector piece was fabricated to provide an easy swapping mechanism for various airways. This piece would assume that the upper airway would remain constant between models and is made for applications where only the lower airway has special conditions. This is pictured alongside and attached to the hinge below in Figures 9 and 10.



**Figures 9 and 10**: Airway connector pieces attached and disassembled

Another significant design consideration involved modeling and printing additional anatomy for the airway trainer. Initially, the team planned to 3D scan the head of an existing airway trainer and print it as part of the model. However, it was advised that this approach would involve an extremely lengthy post-processing phase, requiring significant time and effort to refine the scanned model for use. The faster alternative proposed was to instead simply use a preexisting scan of a head from an online database. Given the short time available, the team decided to move forward with this plan.

The product's overall workflow has also seen considerable change from the original structure due to the group's inability to leverage commercially available software tools that would have dramatically simplified the process of segmenting CT scans. This has tasked the group with using less advanced software to segment the CT, but the high complexity and intricacy of human airways and pathologies make this task extremely difficult for an undergraduate design team. As a result, the workflow has shifted from a standardized approach to a more flexible, case-by-case process, allowing the final product to be more tailored to each patient. There is a greater discussion of this changed process in Sections 5.3 and 5.4 and in Section 8: Discussion.

## 5.2 Materials Design Matrix

Table 2, below, shows a second design matrix which was created after defining the scope of the project with Table 1. After deciding to create a fully custom airway, the proper material needed to be chosen, which is what this design matrix assisted with.

**Table 2**: A design matrix created to rank three different materials. Each category is rated by importance and is used to determine an overall score for each design.

| Design Criteria | Material #1: Silicone 3D Printed Resin 60-75A, ~2 MPa | | Material #2: Formlabs 80A Resin 80 A, ~4 MPa | | Material #3: Liquid Silicone | |
|---|---|---|---|---|---|---|
| **Biomechanical Properties (25)** | **3/5** | 15 | **4/5** | 20 | **2/5** | 10 |
| **Durability (20)** | **3/5** | 12 | **3/5** | 12 | **2/5** | 8 |
| **Ease of Fabrication (20)** | **4/5** | 16 | **4/5** | 16 | **2/5** | 8 |
| **Reliability (15)** | **4/5** | 12 | **5/5** | 15 | **3/5** | 9 |
| **Cost (10)** | **4/5** | 8 | **2/5** | 4 | **3/5** | 6 |
| **Compatibility with Training Materials (10)** | **2/5** | 4 | **4/5** | 8 | **2/5** | 4 |
| **Total (100)** | **67/100** | | **75/100** | | **45/100** | |

**<u>Reasoning for Scores</u>**

### Biomechanical Properties

The biomechanical properties indicate how well the material mimics the properties of the human airway, being that the material falls as close to the range 16.92 ± 8.76 MPa for its Young's Modulus, the range used for the cartilage in a human airway and within 50-80A for Shore Hardness [10, 11]. A higher score represents a closer value in either of these properties to the given range. This is weighted the highest as in order for an airway trainer to be effective it must accurately simulate a human airway.

### Durability

Durability indicates the strength of the material or how well it would hold up against intubation attempts. A higher score indicates a more durable material. This is ranked highly as in order for an airway trainer to be effective, it must be able to tolerate several intubation attempts.

**Ease of Fabrication**

Ease of fabrication is measured by the simplicity with which it takes to make an airway trainer. A higher score indicates a material that is more easily and more quickly converted into the desired product. This is weighted highly as a material with a greater ease of fabrication that would allow for the quick creation of different anatomy of the airway.

**Reliability**

Reliability indicates how prone the material is to flaws. A higher score indicates a material less prone to flaws. This criteria is weighted relatively important as a material that can form a design with very few flaws is ideal.

**Cost**

Cost refers to the price per volume of the material. A higher score indicates the material is less expensive. This is rated lower as most materials considered are relatively inexpensive.

**Compatibility with training materials**

Compatibility with training materials refers to the materials' compatibility with lubricants used in intubation. A higher score indicates a more compatible material. This is ranked low as lubricants exist that are compatible with all the materials considered.

## 5.3 Materials

The trainer consists of a 3D-printed segment of the airway made out of Formlabs 50A v2 resin. Formlabs 50A has a stated Young's Modulus of ~1.7 MPa and a Shore Hardness of 55A [22]. This material is resilient to most lubricants to be utilized for airway practice using typical airway equipment. Although Young's Modulus is out of range of the ideal that was stated above, the ideal range includes the hardness and mechanical properties of the tracheal cartilaginous rings, which are not the focus of this chosen material. However, future models may mix materials to more accurately imitate different components of the trachea, such as including components of different materials like Formlabs 80A to simulate tracheal rings with properties similar to those found in the literature.

All structural components of the base were designed to handle the 63 N of force associated with the maximum amount of force demonstrated during intubation [23]. These components include a base component, a hinge, and a top jaw printed out of PLA due to its ease of printing and relatively low cost. A bottom jaw was also printed out of PLA and attached via

TPU torsional springs. TPU was used for springs as it has a strong fatigue resistance and demonstrates materials similar to that of the springs present in the AirSim trainer model [24,25].

Future materials may be added to add specific properties where required. Additional materials are available in the Makerspace with slight variations in properties that may be utilized in testing. See Appendix 11.1 (Product Design Specifications) and 11.2 (Expense Spreadsheet) for more detailed info on materials and budget.

## 5.4 Methods

The first step to 3D printing a patient-specific, difficult airway is to obtain a Digital Imaging and Communication in Medicine (DICOM) file of an airway that includes a pathology that results in difficult airway management. This file will then be segmented using segmentation software such as 3D Slicer [26, 27]. Segmentation is a process in which 3D imaging from procedures such as a CT or MRI is broken into layers. Each layer of the image is sectioned and labeled as different anatomical structures. When the slices are compiled back together, the segments create accurate representations of the volume and shape of an anatomical structure. This data is converted into a .stl file format [27]. The .stl file is then imported into OnShape, where an intersection of the model and a cylinder around the desired portion of the model is taken. This intersection is then used to form a shell of the model whose thickness can be increased by exporting and reimporting the file as a .jt file before forming the shell. The top and bottom of the shell are cut off to form the desired shape of the model before the file is exported as a .stl. See Appendix 11.3B (Airway Fabrication) for a more in-depth guide for the formation of the shell model using OnShape as well as the processing that occurs in 3DSlicer to create the .stl that was imported into OnShape. This file can then be 3D printed using materials replicating a human airway's biomechanics. See Figure 11 for each step in the airway fabrication process. In addition to the airway, an airway holder must be designed and fabricated using computer-aided design (CAD) software such as SolidWorks [28]. After using CAD to model the holder, it will be converted into a .stl file and 3D printed.

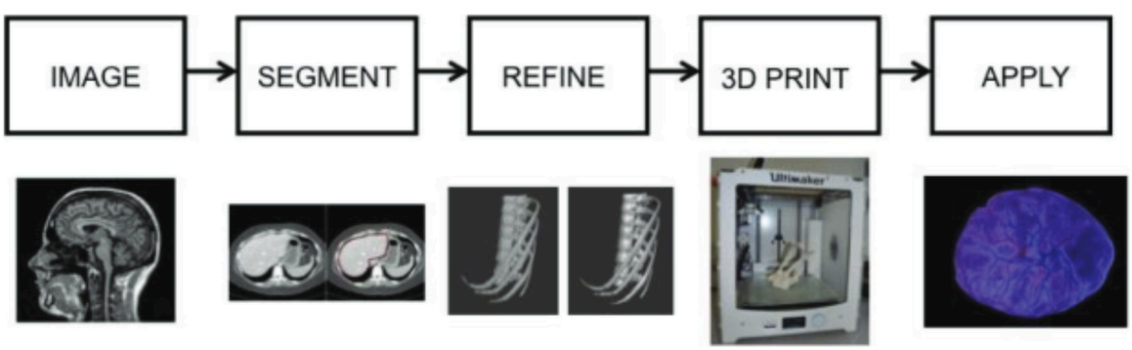



**Figure 11:** Outline of fabrication of a patient-specific model from imaging [29]

# 6 TESTING

## 6.1 Finite Element Analysis Test

The primary objective of this testing was to evaluate whether the components of the airway trainer base could withstand the forces typically exerted during intubation without structural failure. Literature indicated that the maximum force applied during intubation is approximately 63 Newtons [23]. Applying this force to the base component was replicated using finite element analysis software in SOLIDWORKS. The base was separated into the bottom jaw, top jaw, neck hinge, and the base piece. A force of 63 Newtons was applied to the top, right, and a combination of both positions for each of these pieces. A Factor of Safety (FOS) of 5 or below was considered a failure in this test because it falls below the acceptable design threshold for safe and repeated use. A high FOS was chosen to ensure that any inconsistency in manufacturing due to 3D printing, such as variations in infill and printing orientation, were accounted for. The necessity for this increased precaution was influenced by the mechanical failure of the first prototype of the bottom jaw piece. The results of this test were informative to the reliability of the new airway trainer and whether it simulates a successful human airway intubation.

## 6.2 Neck Range of Motion Test

The airway trainer needs to accurately represent the range of motion of a patient's head. Although flexion (head moving toward the chest) and extension (head moving upward) of the head are expected during the intubation process, extension ranks higher in importance as the head must be extended to open the airway and allow for optimal positioning of a laryngoscope. Inaccurate levels of flexion and extension diminish the airway trainer's ability to realistically model the intubation of a patient. Inaccuracy in the trainer's range of motion can potentially lead to injury of the patient. The AirSim trainer provided by the client was used to gather a reference for the values of flexion and extension. The maximum flexion of the AirSim was measured to 50°, and extension was measured to 45°. It was later discovered that the AirSim trainer was likely missing screws, leading to the 45° measure of extension to be significantly higher than realistic extension, causing hyperextension.

## 6.3 Material Tensile Test

The mechanical properties of the material used to create the 3D-printed airway were tested through a series of tensile tests. ASTM-D638 Type IV Dogbone samples were used for this test, and Figure 12 below depicts the testing setup [30]. The MTS machine collected data on the relationship between the force exerted on the Type IV dogbone and the resulting displacement of the material. In addition to this data, constants such as gauge length and cross-sectional area were recorded for each individual testing sample to ensure accurate analysis. This raw information was subsequently processed using MATLAB to generate data illustrating the relationship between the stress ($N/mm^2$) and strain (mm/mm) experienced by the part under tensile loading. Determining the Young's Modulus of the material, Formlabs 50A resin, was crucial in determining the realism and accuracy of the biomechanical properties of the airway replica. Available literature quantified a human airway to have a Young's Modulus of 16 MPa $\mp$ 8 MPa depending on the patient's age or current condition [11]. The samples were tested with a 1 kN load on the MTS machines in the Biomedical Engineering teaching labs. The data given from that was then used to calculate stress and strain from force and displacement, and then Young's Modulus from the slope of the stress versus strain was calculated.

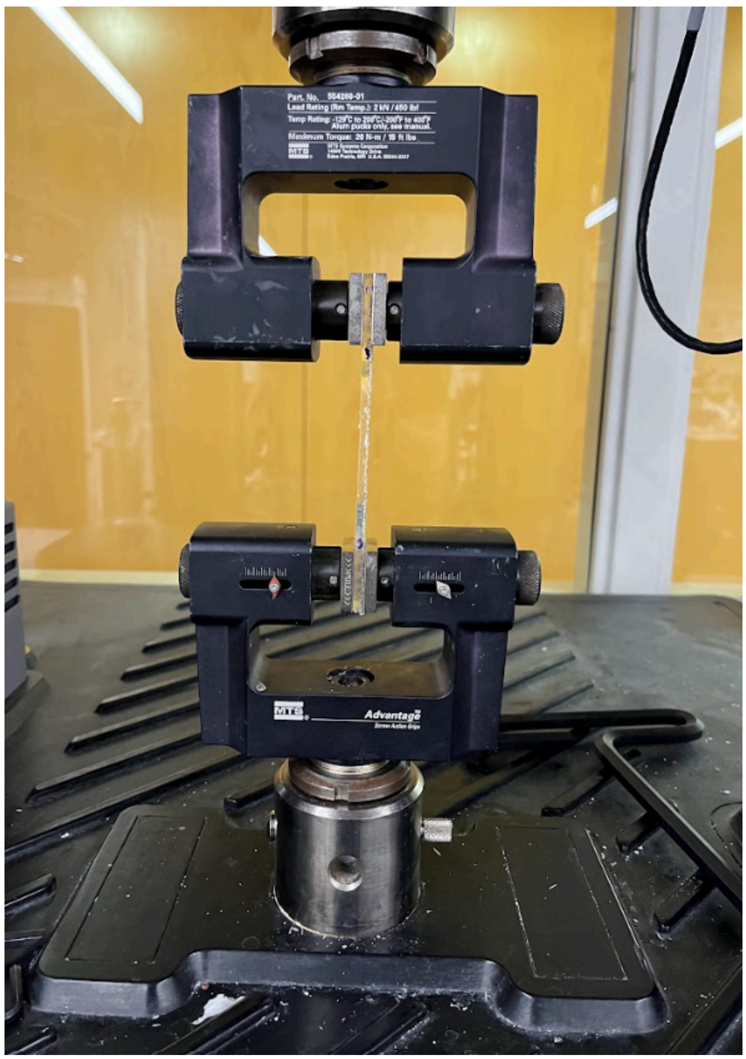



**Figure 12:** MTS tensile testing on Type IV dogbone

# 7 RESULTS

## 7.1 Finite Element Analysis Results

The Finite Element Analysis Test yielded important findings concerning the prototype. The base piece and neck hinge successfully passed each of the three FEA tests. However, the top jaw and bottom jaw experienced failure when a 63 N force was simultaneously applied to the top and right sections of each part, as well as when a 63 N force was applied only to the top area of each part. These failures are visible in Table 3 below and indicate that the top jaw and bottom jaw had a factor of safety of less than 5. Future modifications are needed for the prototype to have appropriate strength.

**Table 3:** Results of the FEA Test, with green indicating a pass and red indicating failure

| Area Force Applied | Base Piece | Neck Hinge | Top Jaw | Bottom Jaw |
|---|---|---|---|---|
| Top | ✔ | ✔ | X | X |
| Right | ✔ | ✔ | ✔ | ✔ |
| Both | ✔ | ✔ | X | X |

Figure 13 depicts explicitly the gradient of stress experienced by the bottom jaw during the FEA testing it underwent. The blue, green, and red regions indicate areas on the part experiencing low, moderate, and high stress, respectively. The area where the model experiences the highest stress is where the body of the mandible meets the descending portion of the jaw.

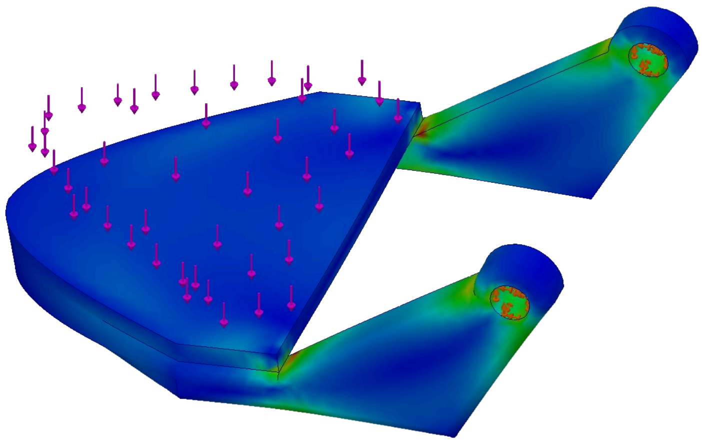


**Figure 13:** Stress experienced by Bottom Jaw during the FEA Test

## 7.2 Neck Range of Motion Results

The range of motion testing conducted demonstrated the maximum flexion and extension of the airway trainer's neck hinge to be 55° and 27°, respectively. The hinge's flexion is adequate, falling in a range similar to that of the Airsim Airway Management Trainer, a premium commercially available model that has a maximum flexion of 50° [16]. Figure 14 below depicts the hinge piece in its state of maximum flexion. However, the hinge piece's extension, arguably the more important of the two metrics, falls short of the Airsim Trainer's 45° maximum extension. Figure 15 exhibits the maximum extension capability of the team's final hinge piece.

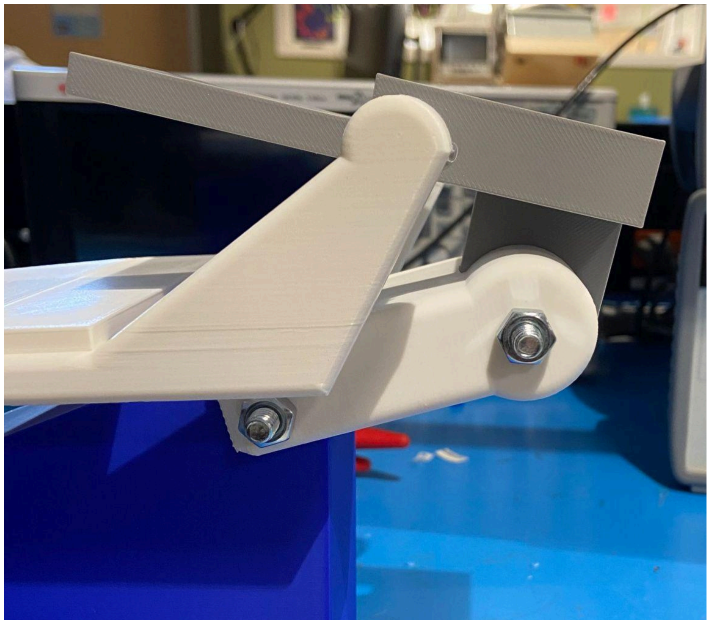


**Figure 14**: The maximum flexion of the final hinge piece

**Figure 15:** The maximum extension of the final hinge piece

## 7.3 Material Tensile Test Results

The Young's Modulus for each dogbone was calculated through the MTS testing from the linear region of each stress vs. strain graph (Figure 16). This value was then compared to the datasheet obtained from Formlabs. The Young's Modulus value yielded by the dogbone testing was 0.91 MPa, stated as 1.59 MPa, with a standard deviation of 0.109 MPa [31]. Full data from the MTS testing can be found in the Appendix, Section 11.5C. Some variation in the dog bone's Young's Modulus value was seen due to the removal of the supports made during the dog bone's 3D printing. Dog bone samples immediately after a print with the supports still attached can be seen in Figure 17 below. This post-printing removal process tended to harm the model, and methods of printing without supports should be further explored. Finally, Figure 18 shows how much the material elongated during the test and demonstrates that it failed cleanly in the same plane as its cross-sectional area.

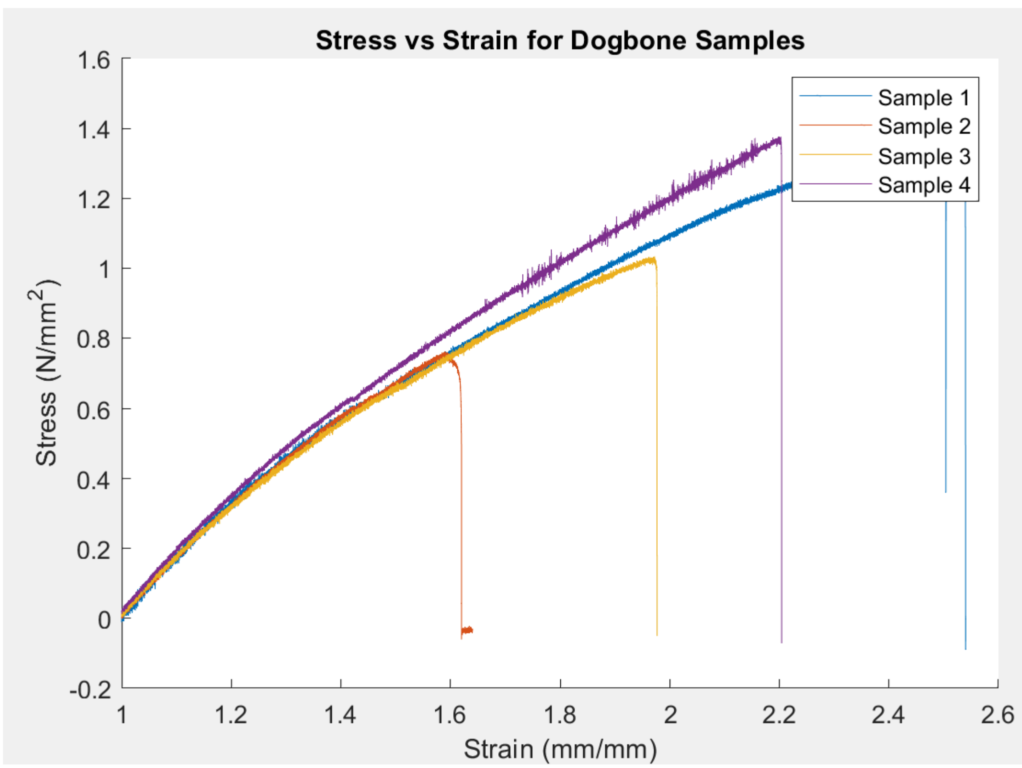



**Figure 16:** Graph depicting tensile testing data for the dogbone samples


**Figure 17:** Type IV dogbones with 3D-printed support structures still attached

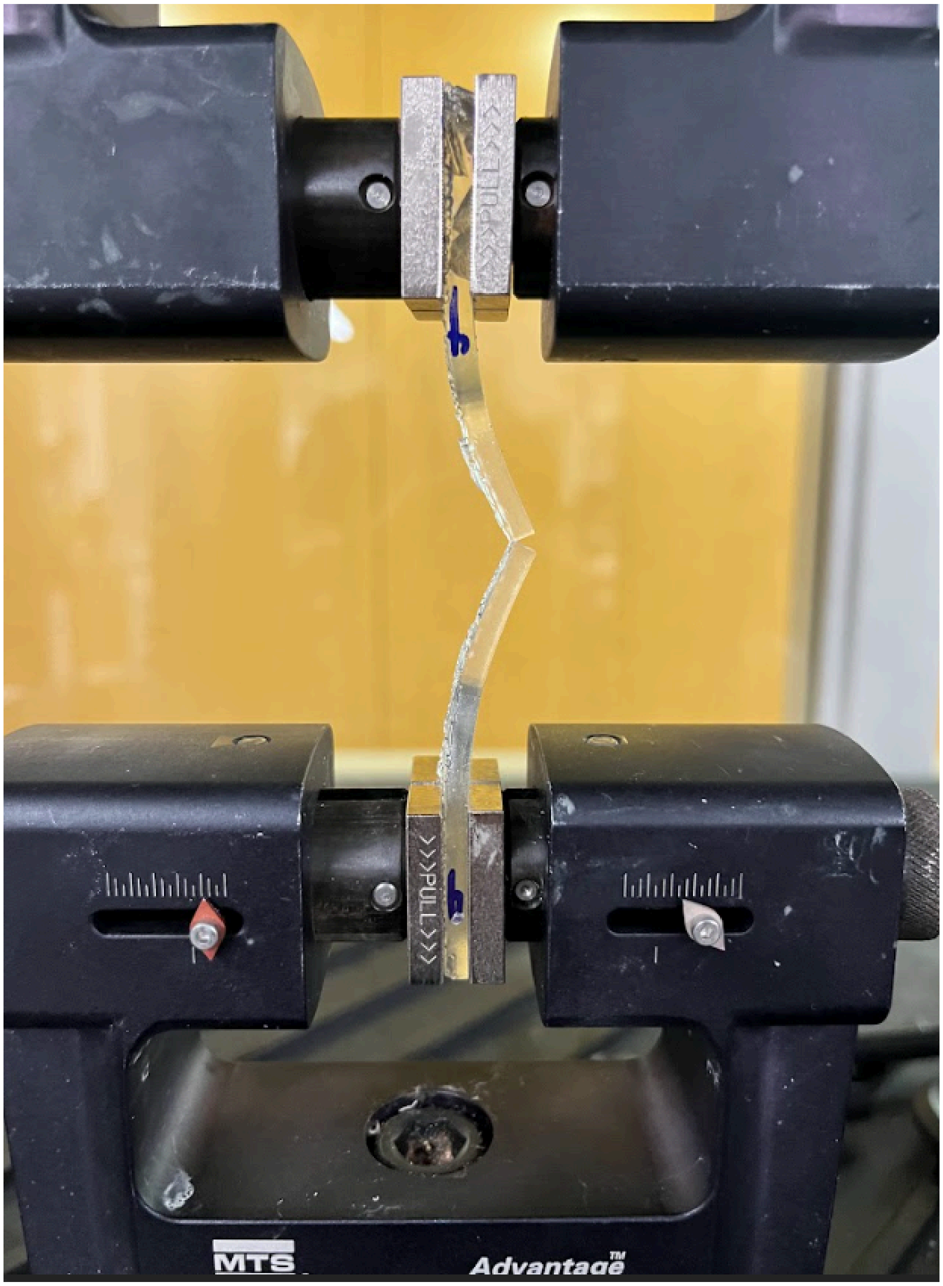



**Figure 18:** Dogbone sample failure during MTS testing

# 8 DISCUSSION

Creating a novel airway trainer for physicians to practice intubations is critical to improving modern intubation procedures. The novel trainer prototype has attempted to underscore the variety of patient anatomies that current trainers have not represented. Thus, while extensive intubation testing has not been completed with the prototype, it has the potential to be useful in the clinical setting.

However, to proceed, specific changes for the trainer are required. The Finite Element Analysis (FEA) completed shows that a stronger material for the lower jaw would be appropriate. Because both jaw components failed to withstand a test force of 63N, using a stronger material is the next step. Specifically, using ABS or PETG to print these portions of the trainer would ensure they are stronger than the current PLA models [32]. Next, a continued search for a base connection mechanism is necessary as the current model is strained. Likewise, additional research surrounding accurate flexion and extension angles would improve the prototype as suggested by the Neck Range of Motion Test (ROM), as it showed accurate flexion angles (relative to current trainer models) but slightly different extension angles. As briefly mentioned in the results of this test, the AirSim model potentially exhibited hyperextension due to a broken piece of plastic serving as a range-limiting stopper. Therefore, to give more context to any future ROM tests, additional research needs to be done relating to both the expected ROM of the AirSim as well as the standard flexion and extension values that a patient's head would be able to undergo during intubation.

Furthermore, an important modification would be to include more airway anatomy as a more detailed anatomical model, leading to more realistic procedure results during intubation. For the trainer's base, 3D scanning could be utilized to create a base model. Using scans that fail to represent the full population or only represent a portion of the population can lead to inaccurate models, increasing the risk of injury and raising ethical concerns, as inadequate trainers may harm patients. To move forward with this approach, the team would need to access accurate data about population-specific anatomy to make the trainer as applicable as possible ensuring that the clinicians training on this model are appropriately prepared to practice on the patient demographics they will serve.

Imaging is a powerful tool for analyzing structures such as a human organ via CT scans. Due to difficulties in obtaining adequate CT scans for imaging, the use of this technique was limited during the fabrication of the current prototype. Ensuring quick access to such scans would be beneficial to the final design. A patient CT was not delivered by the client, and only sample data that was found through 3DSlicer was able to be used. The client was unaware of the need for an IRB for this project and could not find anonymized scans through industry partners. Nonetheless, the sample chest CT available was treated as a real patient scan and processed using the methodology outlined in Appendices 11.3B.1 and 11.3B.2. This did limit the ability to replicate the facial anatomy as no scan was available to base the upper portion of the airway off of along with the oral cavity anatomy. This also limited the group's ability to accurately connect the airway model that was being created with supporting maxillofacial anatomy to create a cohesive trainer.

Next, segmentation of these scans is important to create accurate anatomical models. Collaboration with the Anesthesia department at the UW-School of Medicine and Public Health would be ideal for segmentation support, enhancing the design's accurate anatomical representation. Furthermore, reaching out to a variety of companies with autosegmentation software would improve the design. Due to decisions made earlier in the semester based on the client's expected lead time, PDS criteria, and the team's familiarity with abnormal airway anatomy, the choice was made to utilize auto-segmentation software. Unfortunately, despite much effort, the team was unable to access more advanced software and get in contact with a radiology department willing to help with the project. In the future, establishing a connection between UW-Health's Radiology department and this project would allow their expertise in segmentation and abnormal anatomy to create the best model possible that accurately represents the patient's anatomy.

Material choice and subsequent testing of the flexible resin reflect the balance needed to replicate patient biomechanics yet not hinder the model by requiring additional processing before use. As discussed in Section 5.3 Materials, the final chosen material was Formlabs 50A resin, which did not match the original biomechanical properties that the research suggested; these biomechanical properties represented tracheal cartilage more accurately rather than the soft tissue, so a material with a much lower Young's Modulus and Shore A hardness was chosen. 50A resin was selected due to its malleability compared to other softer materials, such as 80A resin. The team utilized Makerspace 3D printers during this testing and prototyping, which encountered numerous errors. After printing over half a dozen models, none of the flexible 50A parts printed without failing. The team was then notified flexible parts were placed on hold due to resin and printer incompatibility. With a flexible material, the supports could have been cured directly to the model, as shown in Figure 17, where there is a slab of support material cured to the dogbone samples, which was difficult to remove. This caused two problems. First, this meant added difficulty removing these supports before use in the trainer. Second, this meant that removal of the supports could negatively impact the model's biomechanical properties due to the unintended removal of some of the model material rather than the support material. This likely occurred during MTS testing and potentially caused the variability seen in Figure 16. A potential solution is to work with a contract 3D printing company that can ensure the prints are handled correctly and sent with the post-processing completed. After the failure of the prints, Makerspace Staff alerted the team that they had updated to Formlabs 50A v2 resin, which began printing without failure. Continuing to utilize the Makerspace for future projects may be possible, but more testing of the Formlabs 50A v2 resin should be completed before continuing.

Creating an airway trainer that reflects the anatomical features of the population is critical. The potential for harm is high when creating such devices due to variability, which must be evaluated. If a medical professional practices on a model that fails to represent a realistic airway management situation, they will fail to learn the skills to perform safe and effective intubation. Therefore, conducting more detailed research, especially CT scan segmentation, is important. The team reached out to another BME Design Group (Rising Against Cancer) to learn how they were able to accurately replicate a pelvic phantom. They discussed using MeshMixer as well as using Mimics Materialize to better segment the model [33]. Additionally, modifying the trainer base would ensure an accurate and safe trainer device for use by physicians. Currently, the prototype has potential for application in the clinical setting after proper improvements are made to ensure an anatomically correct and population-specific airway trainer to allow the client to improve training and provide safer and more effective care to his patients.

# 9 CONCLUSION

Current trainers on the market lack versatility in the difficult airway management situations they represent, but medical professionals need to be prepared to intubate regardless of patient abnormalities and pathologies. To master these difficult airway management situations, medical professionals must have extensive practice and repetition that only an anatomically accurate and well-designed trainer can provide. Therefore, creating a novel airway trainer device that can reflect the complexity of patient-specific anatomy while allowing for versatility in the difficulty and pathologies that can be practiced would be a step towards increasing airway management proficiency and improving outcomes of patients. The final design focuses on achieving these two main objectives by fabricating an airway trainer base with the ability to interchange 3D printed airways and creating a printable airway derived from patient imaging.

While the final design creates a solid foundation for the creation of 3D-printed patient-specific airway trainers, both the airway trainer base and the printed airway have drawbacks and require continued future work. The current method of printing an airway based on imaging requires a highly complex system of post-processing that could not be easily achieved by anyone unfamiliar with the software (SOLIDWORKS, OnShape, 3DSlicer, etc.). In addition, the auto-segmentation process makes some size alterations, affecting the accuracy of this method in representing anatomy. These alterations impact the ability of the model to represent the airway in a highly meaningful way for training. To address these drawbacks, a few next steps should be taken. First, collaborating with the client to obtain early access to scans is essential in accurately representing patient-specific anatomy. Once a scan is obtained, it would be important to reach out to radiologists for support with segmentation. This would allow the design to move away from auto segmentation and the accompanying challenges, such as post-processing and inconsistencies in methods between airways. Another future consideration is further exploring and accessing available software and technology to aid segmentation or post-processing.

The final design of the airway trainer base also requires continued work and refinement. Improvement of the surrounding anatomy represented by the airway trainer base is an area for growth. By improving and adding facial anatomy (nose, mouth, and teeth), the trainer base can improve the ability to create a realistic training experience for intubation and increase the number of advanced airway procedures that can be practiced using the model. In addition, the FEA Test showed that the materials for the Top Jaw and Bottom Jaw pieces should be reconsidered, and the range of motion should be altered to be more consistent with the AirSim model, as shown by the Range of Motion Test.

Overall, the premise of these projects and the achievements of the final design of the airway and the airway trainer base provide the groundwork for the exciting possibility of 3D-printed airway trainers. With the refinement of these methods and continued work, the possibility of a patient-specific trainer promises an exciting change in how medical professionals train and prepare for complex airway management.

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# 11 APPENDIX

## 11.1 Product Design Specification

**Project Function:**

Many people worldwide suffer from medical conditions caused by damaged or blocked airways. These medical pathologies can often lead to shortness of breath in those affected, which can eventually lead to severe outcomes. To ensure a patent airway regardless of the present pathology, endotracheal intubations (ETIs) are performed. Over 400,000 Americans are intubated annually, with a chance of an unsuccessful first attempt success at 12.7% [1]. These procedures involve placing a tube in a patient's trachea to aid in breathing. ETIs, while effective, take considerable practice and bring inherent risk. Medical residents often use airway trainers as tools to practice ETIs and gain the necessary experience and knowledge of endotracheal anatomy. While some current airway trainer models provide adequate ETI practice, many do not simulate the actual endotracheal environment that can vary from patient to patient, especially suboptimal anatomy, such as allergic reactions, inhalation burns, or trauma to the upper airway [2]. Current models (often created using 3D printing to make molds to pour silicone into) usually need more complexity that reflects patient anatomy in difficult airway situations. This can lead to difficulties in the ETI learning process, which can have a detrimental impact in the clinical setting when time and oxygenation of the patient are critical. This project attempts to create a 3D-printed airway trainer with swappable anatomy that can simulate a wide range of difficult airway situations to provide healthcare professionals with a more accurate and challenging practice method. A model supporting multiple anatomy types can provide healthcare professionals with the ability to practice multiple high-risk scenarios throughout training to ensure they receive realistic practice before performing the procedure in a time-critical situation on a patient without a patent airway.

**Client Requirements:**

- Create a 3D-printed airway trainer model that improves on the weaknesses of current models.
- The model must incorporate swappable anatomy to reflect the complex nature of the endotracheal airway region and allow for altering of simulations for healthcare providers.
- The model must be flexible, represent physiological biomechanics, and resist water-based lubricants, as these compounds are often used on tools during ETI procedures [3].
- The model must be adaptable to specific patient needs (for example, obesity, structural abnormalities, etc.) to ensure trainer accuracy regardless of patient condition. Additionally, the client would prefer the ability to swap in real patient anatomy created from CT or MRI scans.
  - According to the client, specific components of the airways that might differ between patients include:

- Presence or absence of a narrowed trachea (Subglottic Stenosis)
- Moved tonsils (Sublingual Tonsils)
- Obesity and the associated neck mobility
- Cancer or lesions that may impact the size or properties of the trachea, epiglottis, or other airway structures
- Swelling due to diseases or injuries in different places in the upper and lower airways

**Design Requirements**

1. **Physical and Operational Characteristics**
    a. Performance Requirements: The device must be durable and support extended daily use by medical personnel learning the intubation process. It must also allow the intubation process to be completed in 45 seconds or less to prevent patient hypoxia [3]. A successful intubation means end-tidal carbon dioxide must be able to be measured to confirm placement in the trachea. [5]. The device's material must be flexible and lubricated with conventional water-based lubricants [3].
        i. Specific biomechanical properties that must be followed to ensure that the model has a life-like intubation experience are a Young's Modulus of 16 MPa ∓ 8 MPa depending on the patient's age or current condition and a Shore A Hardness of 80 to represent how a laryngoscope would interact with the tissue inside the airway [7, 8].
    b. Safety: To maximize accessibility to device training, the airway trainer must be made of non-toxic substances and consider allergens such as latex. The Standards and Specifications section of this document presents a specific standard dictating which materials are safe in medical devices. Additionally, the performance of this device must model safe intubation, as failure to do so could endanger future patients being intubated by professionals who were trained with this device.
    c. Accuracy and Reliability: This device must allow for successful ETI at least 96.8% of the time, as represented by the global success rate [6]. In order to ensure accuracy, the material characteristics of each model must fall within the appropriate range of Young's Modulus and Shore A Hardness for the patient. These values may fall out of the listed range above, but if multiple models are made of the same airway, their properties must be identical to ensure that no matter which trainer is used, they both accurately represent the anatomy.
    d. Life in Service: The airway portion of the design is made to be able to support 20,000 intubation cycles, consistent with the AirSim Pierre Robin X model with the use of standard intubation lubricants [9]. Upon failure of the device, the model

will be designed for easy replacement of the airway portion to reduce cost and waste.

e. Shelf Life: The airway trainer should be stored with protection from severe values of pressure (1 atm), humidity ( <70%), and temperature (0 ℃ - 22℃) [10,11]. The design's material will be vastly silicone-based, and silicone maintains its material properties for a minimum of 2 years with no statistically significant change [12].
f. Operating Environment: The product is designed to mimic ideal conditions consistent with the hospital setting [13]. This range of conditions includes humidity values less than 85% and low subjectivity to substances other than typical water-based lubricant [14-16]. The model is designed to be resilient to typical forces associated with typical intubation techniques, around 42 N on average but can vary based on the patient's size and weight [17].
g. Ergonomics: The product is designed to simulate intubation processes on patients with complex and uncommon airway conditions. Replicating the ergonomics of actual intubation will allow for a decrease in intubation-related injury, such as dysphagia (43%), pain (38%), or hoarseness (27%) [18]. The product will be designed for practice intubations to allow more opportunities to practice low occurrence, high acuity situations for healthcare providers. The product is thus designed for only such forces associated with intubation and not to put unnecessary strain on the medical provider while practicing [19].
h. Size: The device should replicate the size of an adult head, neck, and upper thoracic cavity. Existing airway trainers already on the market that possess a build similar to what this device should have been constructed with dimensions of approximately 0.55m x 0.35m x 0.25m [20, 21]. This will enable users to realistically simulate the experience of conducting airway management on a patient. There will be a regular adult model and a bariatric adult model, which will be larger if time allows. The thoracic piece of both models will be detachable from the head and neck portion, allowing different airway pathologies to be substituted, thus increasing the model's versatility.
i. Weight: The airway trainer should be light enough to be easily transferred to different locations and used by different individuals if need be. The majority of existing airway trainers that are currently sold by major distributors weigh 5 to 19 kg [22, 23]. The trainer should ideally be in the range of 10 to 15 kg so that it is sturdy enough to not shift around when airway management training is occurring, but to also prevent it from being so heavy that it loses its portability.
j. Materials: The trainer must be made of materials that find a balance between providing a realistic feel of the airway while also having flexibility and durability. The goal for the materials is to fit within the Young's Modulus and Shore A Hardness thresholds discussed above, but the client will make the final decision on the level of realism each material has. The trainer must also be resistant to the

water-based lubricant that would likely be applied to the airway management equipment. Materials that fit these criteria and are common in popular airway trainers include polyvinyl chloride and silicone, which are able to handle the wear and tear that accompanies airway training while still providing a lifelike feel [24, 25].

k. Aesthetics, Appearance, and Finish: The product will have a professional-grade finish and clearly resemble a human head, neck, and upper thoracic cavity. The head will have distinguishable facial features and the overall texture and color of the design will be similar to that of human skin. The product will also contain thorough instructions on proper use.

2. **Production Characteristics**
   a. Quantity: The goal set by the client is one airway management trainer or airway model that can be used in conjunction with an airway management trainer. This product should accurately represent the anatomy of a common pathology that causes difficult airway management. If required for future use, the methods and design should be easily replicated and manufactured for widespread use and application to a broader range of pathologies.

   b. Target Product Cost: The client provided the team with a budget of $750. The current price of a standard airway management trainer from Laerdal is $2,799 [26]. By creating a modular section to be slotted into the more complex trainer, the goal product cost would be similar to that of more simplistic trainers, such as the Laerdal Airway Demonstration Model, which costs $259 [27].

3. **Miscellaneous**
   a. Standards and Specifications:
      i. ISO/IEC 3532-1:2023: Information technology - Medical image-based modeling for 3D printing - Part 1: General Requirements [28]
         1. This standard sets forth the requirements of accurate medical modeling for patient care. This ensures that the data that is recorded from a CT or MRI machine is accurately read and processed by a slicing software, such as 3DSlicer.
      ii. ISO/IEC 3532-2:2024: Information technology - Medical image-based modeling for 3D printing - Part 2: Segmentation [29]
         1. This standard sets the requirements for the process of slicing, augmenting, and 3D printing modeling of human bone for use in surgery. It also provides a process to increase the performance of bone segmentation.

iii. ISO 15223-2:2010: Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied [30]
    1. This standard helps ensure that symbols produced in accordance with a similar standard (ISO 15223-1) are easily understood by the target audience. Following this standard will help limit the damage and harm to both the product as well as the user.

iv. ISO 20417:2021: Medical devices – Information to be supplied by the manufacturer [31]
    1. This standard informs the manufacturer of a medical device about the required documents, identification, and labels that must be present on the device itself, packaging, and any supporting documentation. This standard does not specify how this information must be communicated to the end consumer, but just outlines the requirements of which data must be included.

v. ISO 22442-3:2007: Medical devices utilizing animal tissues and their derivatives [32]
    1. This standard ensures that any use of animal tissue or products in any medical devices undergoes proper elimination of any viruses present which could harm the patient or care team. This is particularly interesting because in finding the right material to make the product out of, the client mentioned a product which may contain animal byproducts to replicate the feel of human tissue.

vi. CFR 177.2600 [33]
    1. This Code of Federal Regulations sets forth standards that must be met for the materials of medical devices. It states explicitly that if latex is to be used, it cannot be made of more than 0.02% latex by weight. Additionally, it regulates which materials can be used to cure resins. However, with 3D printed resins, UV light will be used.

b. Customer: The potential customers for this device include teaching hospitals, research labs, EMS services, medical schools, and any other sector of medicine whose scope of practice encompasses advanced airway procedures. Currently, the client will be the only customer of the product to test and validate its ability to mimic the anatomy, complications, and maneuvers before its release to additional customers, starting within UW-Health. The customer is leaning towards a device that can keep costs down with a modular design to provide the widest variety of anatomically correct simulations while purchasing the least amount of trainers.

c. Patient-related concerns: The product will not directly be in contact with patients or be part of the patient care setting. This device will be used to train individuals providing care to the patient before the patient interaction starts. However, the tools and devices used to perform advanced airway procedures must not be exposed to harmful substances or environments that cause them to deteriorate before being used to treat the patient. For example, the product cannot contain any material that is corrosive to metal due to the inability to autoclave the laryngoscope after this interaction occurs [34].

d. Competition:
   - i. Competing design #1 - Laerdal Airway Trainer [35]
     1. This airway trainer is what UW-Health and the Anesthesia department use to practice and train their residents. The anatomy is functional and replicates the mechanical properties of a patent airway.
     2. The simulator has a removable airway but is not exchangeable for a more complex anatomical situation.
     3. The client thinks this product is effective, but his main concern is the ~$3000 cost per simulator.
   - ii. Competing design #2 - Decent Simulators Airway Management Task Trainer [36]
     1. This airway trainer features an anatomically accurate airway with additional features such as adjustable difficulty and neck stiffness.
     2. It cannot accurately represent various pathologies that contribute to the difficulty of airway management cases.
   - iii. Competing design #3 - Seven Sigma Airway trainers [37]
     1. 7-SIGMA Simulation Systems ($7S^3$) create highly realistic simulators focusing on difficult airway management situations.
     2. These mannequins are segmented by race and airway condition (regular, burned, swollen), and they can swap out airway modules to make intubation more difficult.
     3. These trainers appear to fit most of the client's requirements; however, they are not customizable to patient-specific anatomy and do not list public prices due to prices being negotiated on a contract basis; however, one trainer has a listed price of $5,900.

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## 11.2 Expense Spreadsheet

| Item | Description | Manufacturer | Mft Pt# | Vendor | Vendor Cat # | Date | QTY | Cost Each | Total | Link |
|---|---|---|---|---|---|---|---|---|---|---|
| **Purchased Supplies** | | | | | | | | | | |
| Dual Lock reclosable fastener | Attachment mechanism for airway to base | 3M | 51111976364 | | B007OXK330 | 11/7/2024 | 1 | $22.36 | $22.36 | https://www.amazon.com/3M-Dual-Lock-Reclosable-Fastener/dp/B007OXK330?sr=8-8 |
| **3D Printing Expenses** | | | | | | | | | | |
| | 50A and 80A Test Print | Makerspace | N/A | Makerspace | N/A | 10/14/2024 | 1 | $23.04 | $23.04 | |
| | Biomed Clear Test Print | Makerspace | N/A | Makerspace | N/A | 10/18/2024 | 1 | $10.44 | $10.44 | |
| | Jaw V1, PLA | Makerspace | N/A | Makerspace | N/A | 10/29/2024 | 1 | $1.95 | $1.95 | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | First Test Print of negative model | Makerspace | N/A | Makerspace | N/A | 11/15/2024 | 1 | $29.00 | $29.00 | |
| | Trainer stand | Makerspace | N/A | Makerspace | N/A | 11/15/2024 | 1 | $3.15 | $3.15 | |
| | First Test Print of offset model | Makerspace | N/A | Makerspace | N/A | 11/19/2024 | 1 | $4.43 | $4.43 | |
| | TPU Springs V1 | Makerspace | N/A | Makerspace | N/A | 11/20/2024 | 1 | $0.60 | $0.60 | |
| | PLA Bottom Jaw | Makerspace | N/A | Makerspace | N/A | 11/22/2024 | 1 | $3.25 | $3.25 | |
| | Dogbone Samples, offset model V2, and negative model V2 | Makerspace | N/A | Makerspace | N/A | 11/22/2024 | 1 | $74.52 | $74.52 | |
| | TPU Springs V2 | Makerspace | N/A | Makerspace | N/A | 11/26/2024 | 1 | $1.60 | $1.60 | |
| | Offset model V3 (Final), ABS Jaw | Makerspace | N/A | Makerspace | N/A | 11/27/2024 | 1 | $5.40 | $5.40 | |
| | TPU Springs V3 | Makerspace | N/A | Makerspace | N/A | 12/2/2024 | 1 | $2.70 | $2.70 | |
| | Connector Pieces | Makerspace | N/A | Makerspace | N/A | 12/4/2024 | 1 | $5.75 | $5.75 | |
| | | | | | | | | **TOTAL:** | **$188.19** | |

## 11.3 Fabrication Protocol

### 11.3A Framework Fabrication

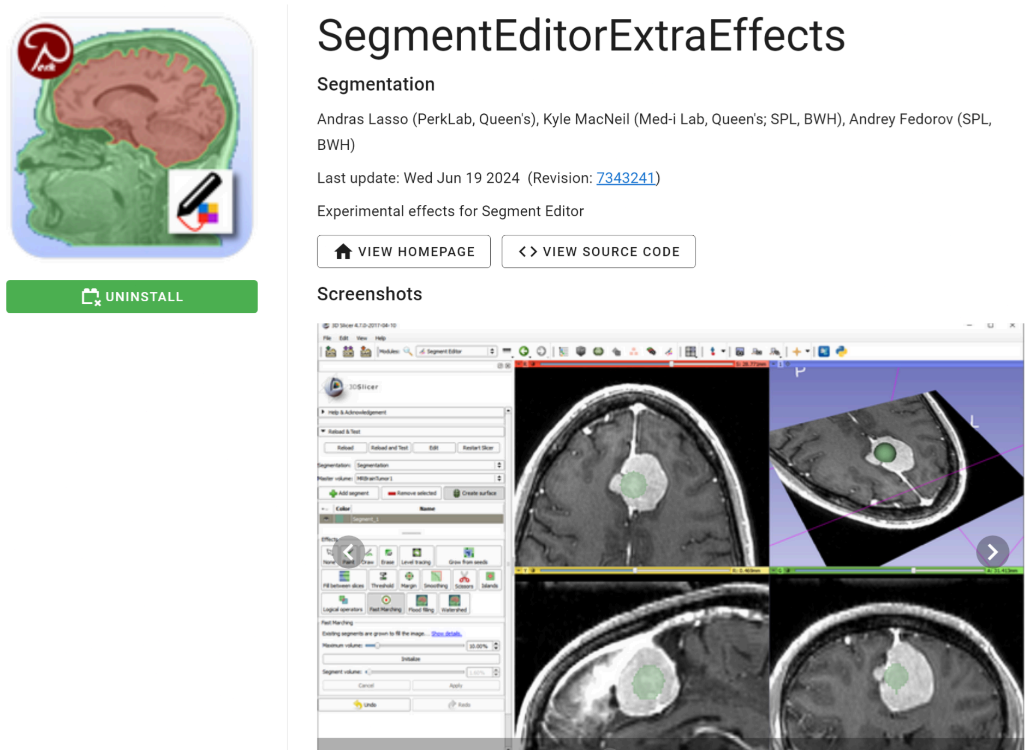
1. Obtain a caliper and take measurements on the base, bottom jaw, top jaw, and neck hinge of the AirSim airway trainer.
2. Using the measurements taken on the AirSim trainer, design the simplified base within SOLIDWORKS using the measured dimensions.
3. To ensure the pieces fit correctly, a tolerance should be added. This tolerance was in the range of 2-5 mm in each of the dimensions measured.
4. Once the base is created, the neck hinge will be the next piece fabricated. The measurements from the AirSim trainer are used again.
5. After replicating the neck hinge piece using the AirSim dimensions, the design will diverge from that seen in the AirSim. This design modification is done by using the mirror function to create a singular neck hinge piece whereas the AirSim’s neck hinge used two symmetrical pieces.
6. Model the top and bottom jaws using the AirSim dimensions and the SOLIDWORKS features: Extrude, Extrude Cut, Mirror, Loft, etc.

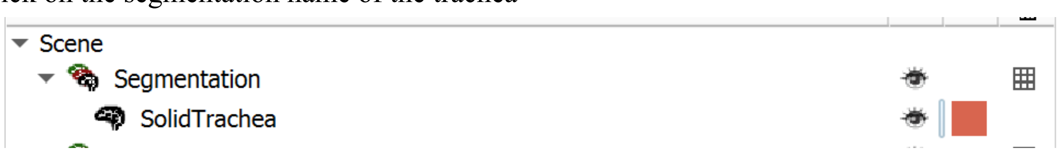
7. With the base, top jaw, bottom jaw, and neck hinge modeled start an assembly and add these four parts into the assembly. Use the Mate feature to ensure that each piece fits together correctly.
8. Convert each SOLIDWORKS part file to an stl file that can be 3D printed.
9. The material used was Bambu Lab's PLA filament. Use Bambu Slicer software to select the material and a compatible printing orientation.
10. Print the pieces using Bambu Lab's 3D printer.
11. After printing follow any necessary post-processing instructions and remove the supports.
12. Next use SOLIDWORKS to model the torsional springs needed to connect the jaw pieces. Use the dimensions:
    a. Diameter of ends: 5 mm
    b. Diameter of center: 3 mm
    c. Length of piece: 7.5 mm
13. Convert these files to a stl file. Print using the same process as listed in steps 9-11. The material used for these pieces is TPU.
14. Obtain all materials required for the assembly of the airway trainer base:
    a. Printed pieces (base, bottom jaw, top jaw, neck hinge, and TPU torsional springs)
    b. Two bolts and four nuts (ensure that they can fit in the holes on the base and neck hinge)
    c. Super glue
    d. Dual lock fastener tape
15. Use the bolts and nuts to connect the base piece with the neck hinge so that the inside face of the hinge is flush with the base. Then connect the neck hinge with the top jaw in the same manner.
16. Use the super glue to adhere the torsional springs to the top and bottom jaw. Be careful to align the jaw pieces properly.
17. Carefully place an 8 cm piece of Dual Lock fastener tape on the sloped surface of the base.

## 11.3B Airway Fabrication

### 11.3B.1 3DSlicer Instructions:

1. Import the DICOM to slice
    a. For now it is the sample chest CT
2. Open 3DSlicer and install the SegmentEditorExtraEffects extension




3. Follow [this video](), defining only the trachea, and keep smoothing on
    a. Follow the steps from 0:04 to 1:08
    b. Do not do the Optional Steps listed at the end of the video
4. Ensure that the solid model of the trachea is the only object appearing in the top right window of 3DSlicer
5. Select the data window from the top dropdown
6. Right-click on the segmentation name of the trachea
    a. 

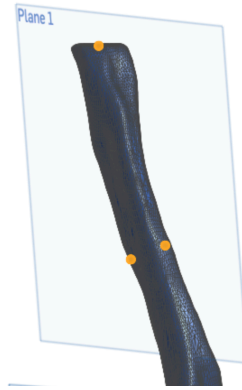
    b. Ensure that it has the eye showing, meaning it is visible
7. Select “Export visible segments to models”
8. This will create a new folder and model in the data viewer
    a. 

    b. Right-click on the model now and click “Export to File” and select .STL file
9. Once exported, open the STL file in SOLIDWORKS and begin post-processing

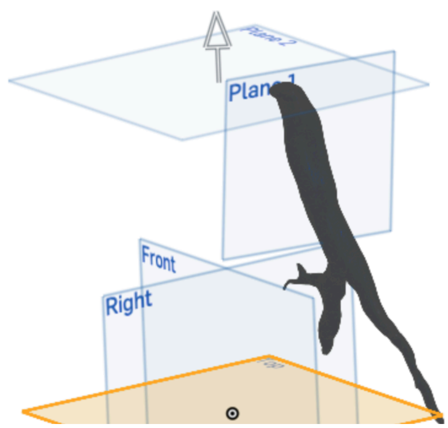
11.3B.2 OnShape Instructions

1. (1: Shell Trachea Fabrication) Import trachea into OnShape in <u>millimeters</u>

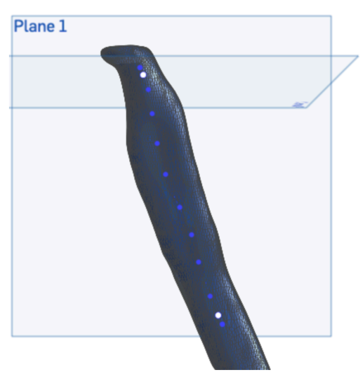
2. Create a plane that bisects the trachea from the pts front to back using the three point mode of the plane tool. This will be Plane 1.
    a. The recommended three points to select are one on top of the trachea, one on the front, and one on the back



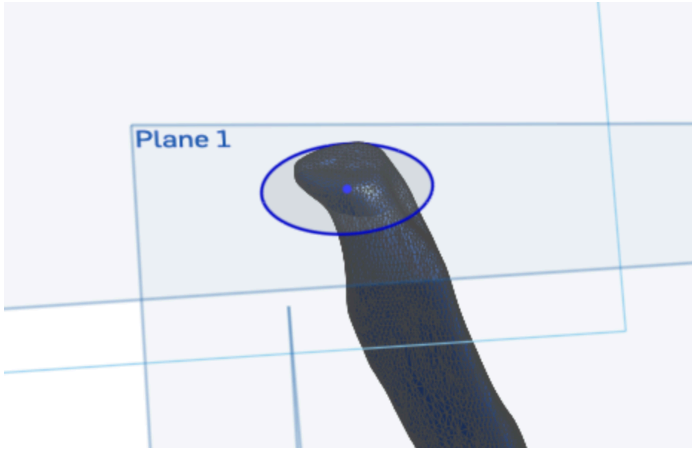

3. Create a second plane using the plane tool and the offset mode. Select the Top plane and offset the Top plane to the top of the trachea model. This will be Plane 2.



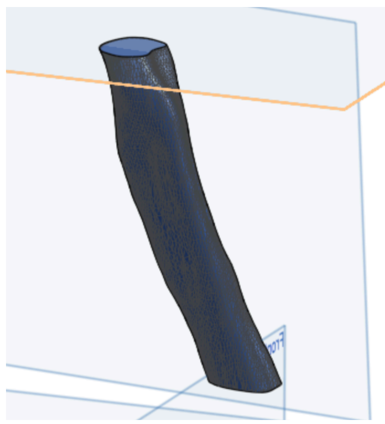

4. Going back to Plane 1, select the plane and make a sketch. Before accepting the sketch, select the spline tool. Starting with a dot just below the very top of the trachea, make a series of dots down the center until reaching the end of the area desired to copy. Press escape to get out of spline mode. Save the sketch.



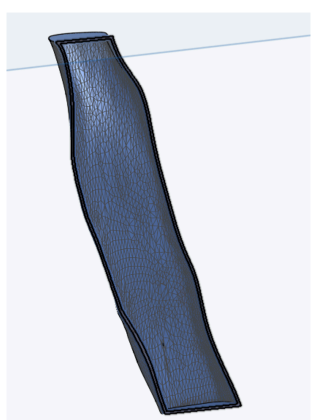

5. On Plane 2, create a sketch. In this sketch use the circle tool to draw a circle directly over the top of the trachea large enough to encompass the entire trachea. Save the sketch.




6. Select the sweep tool, set it to the intersect tab, and then select the circle for the region to sweep and the spline for the sweep path.

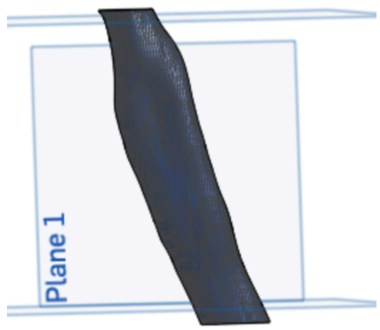


7. If only a 5 mm shell is desired then step 8 may be skipped
8. Export the file as a JT and import the this file into a new project
9. Select the shell tool, select the hollow checkbox, and click on the trachea. Set the Shell thickness to 0.0015-0.0016 mm or 0.0011 mm or 0.00136 mm (values specific to airway model)

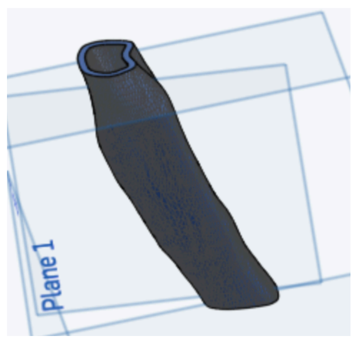


(Section view of interior)

10. Using the same process as in step 3, create 2 more planes just above the bottom of the model and just below the top

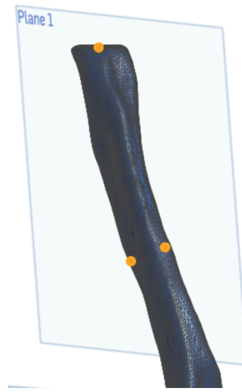



11. Using the split tool, click on the trachea to use for the part field and select a plane for the entity field. Click the arrows at the bottom of the window to ensure the trachea part of the model is saved.
12. Repeat this process for the other plane

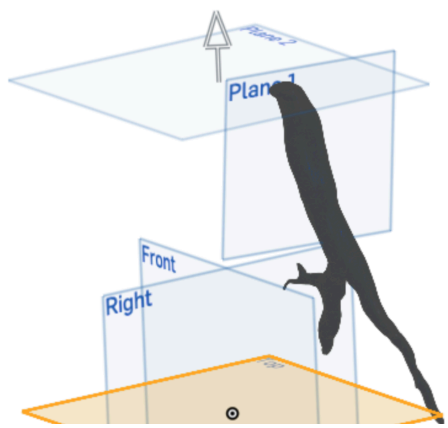



13. Export file as stl and print

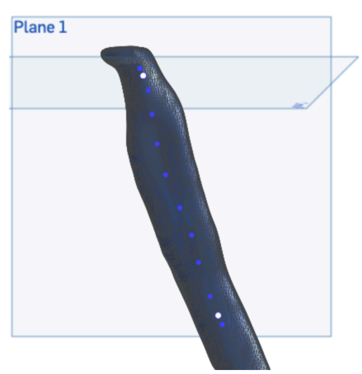
1. (2: Hollow Trachea Fabrication) Import trachea into OnShape in <u>millimeters</u>
2. Create a plane that bisects the trachea from the pts front to back using the <u>three point</u> mode of the <u>plane</u> tool. This will be Plane 1.
    a. The recommended three points to select are one on top of the trachea, one on the front, and one on the back



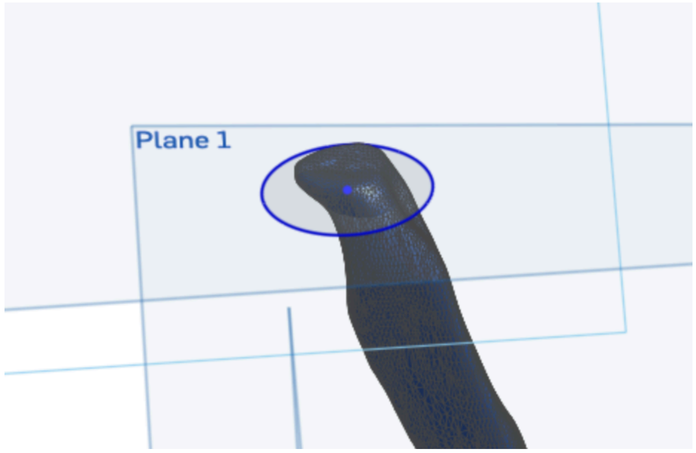

3. Create a second plane using the <u>plane</u> tool and the <u>offset</u> mode. Select the Top plane and offset the Top plane to the top of the trachea model. This will be Plane 2.



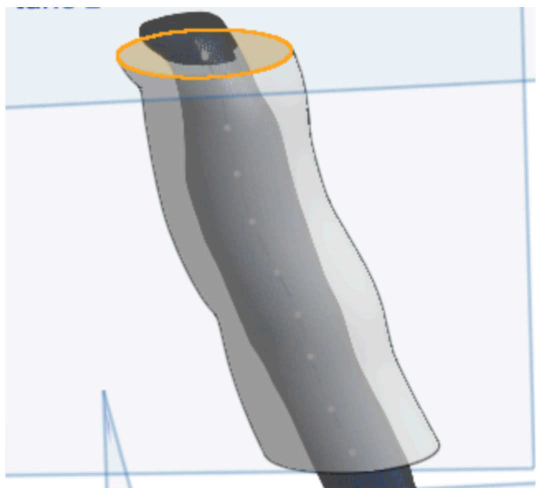

4. Going back to Plane 1, select the plane and make a <u>sketch</u>. Before accepting the sketch, select the <u>spline</u> tool. Starting with a dot just below the very top of the trachea, make a series of dots down the center until reaching the end of the area desired to copy. Press escape to get out of spline mode. Save the sketch.



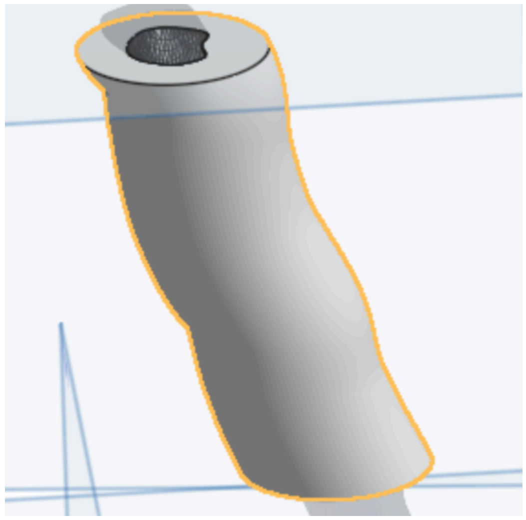
5. On Plane 2, create a sketch. In this sketch use the circle tool to draw a circle directly over the top of the trachea large enough to encompass the entire trachea. Save the sketch.




6. Select the sweep tool, set it to the new tab, and then select the circle for the region to sweep and the spline for the sweep path.



7. Select the boolean tool, set it to the subtract tab, click on the trachea for the tool field and select the sweep for the target field



8. Export file as stl and print.

## 11.4 Experimental Protocol

### 11.4A Finite Element Analysis Protocol

1. Open the base, neck hinge, bottom jaw, and top jaw parts in SOLIDWORKS.
2. Make sure that each of the pieces is made of the correct material (PLA). If PLA is not in the SOLIDWORKS Material Library, create a custom plastic using the mechanical properties and values listed in the Bambu Labs PLA filament datasheet.
3. Press Evaluate > SimulationXpress Analysis Wizard.
4. This should start the appropriate software required for the finite element analysis.
5. Follow the prompts to select fixtures. Select any faces that will be secured during the use of the airway trainer base.
6. Hit next, and follow the prompts to add forces to faces. Start by applying a force of 63 N to the top of the piece.
7. Run the simulation. Ensure that the displacement animation is consistent with the expected deformation. Record the outputted Factor of Safety.
8. Repeat this process changing only the placement of the forces to the right plane and a combination of both right and top planes. Record the Factor of Safety for all simulations.
9. Repeat Steps 3-8 for each of the PLA parts of the airway trainer base.

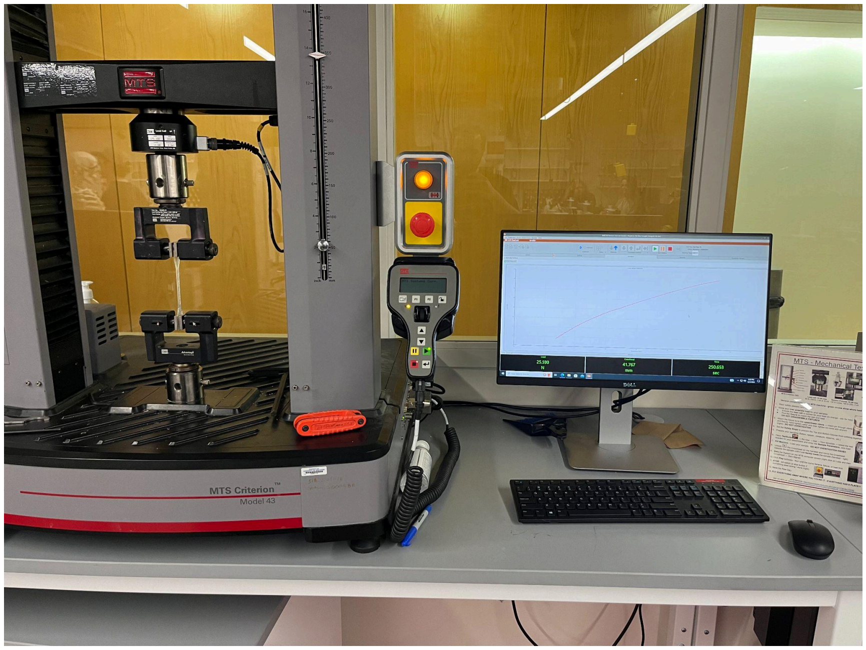
### 11.4B Range of Motion Testing Protocol

1. Acquire the final prototype and ensure the entire neck hinge mechanism is fully assembled
2. Ensure the bolts that hold the model together are firmly screwed together to limit play within the connections

3. Rotate the white and grey (bottom and top jaw pieces, respectively) pieces until they are approximately horizontal
4. Attach the modular connector to the dual lock on the blue-sloped surface of the trainer
5. Take a phone or any other device that is able to internally measure angles
6. Place the device along the thick back portion of the top jaw mechanism and ensure it reads approximately 0. This is the reference plane, replicating a neutral neck position
7. Rotate the head fully forward (flexion) and backward (extension) as shown in Figures 11 and 12 above
8. Record the maximum angles that can be reached from these maneuvers and this is the range of motion of the model

## 11.4C MTS Test Protocol

1. Load the tensile testing jaws into the grey MTS machine in the BME shared teaching lab in ECB
2. Log into the computer and open the BME 315 rat tendon tensile test file. This is preprogrammed to achieve a variable strain rate ultimate tensile test which limits the amount of extra work needed to be done
3. Turn on the MTS machine and ensure the load cell is connected and data can be read from the computer
4. Remove supports from the dogbone samples that were printed at the Makerspace
5. Place the dogbone sample into the jaws of the MTS machine, ensuring that the part is securely gripped on both ends
6. Ensure that the entire thinner portion of the sample is not clamped as this will be the gauge length
7. Measure the cross-sectional area of the thinner section. This can change as support material may remain or some of the model's material may have been removed during the support removal process
8. Change the strain rate to 10mm/min and begin the test. The testing setup should look like this picture




9. Export each run as a seperate data set and ensure that force, displacement, and time are all exported
10. Repeat the test as many times as desired
11. Safely shut down the MTS machine, and return the tensile testing aparatus to the case, and log off of the computer
12. Process the MTS data using the Matlab code found in section 11.5B

## 11.5 Testing Raw Data

### 11.5A FEA Analysis Data

Numbers represent the Factor of Safety that resulted from each test

| Where Force was Applied | Base Piece | Neck Hinge | Top Jaw | Bottom Jaw |
|---|---|---|---|---|
| Top | 131.427 | 139.702 | 3.17467 | 4.02414 |
| Right | 111.911 | 50.0847 | 16.9 | 16.8553 |
| Both | 116.451 | 49.8 | 2.9559 | 3.30452 |

### 11.5B Matlab Code for MTS Data Analysis

```
%%Reading the modified data file the MTS machine exported and extracting
```

```
% time, distance, and load during the test
%Can run multiple times without closing the figure window to stack data
data_coords = readmatrix("C:\Users\jwspe\OneDrive\Desktop\BME 315\BME300\4-FullFailure\4.xlsx");
time = data_coords(:,3);
distance = data_coords(:,1);
load = data_coords(:,2);
%%These are the standard width and depth measurements for the ASTM D638
% type IV dogbone. These will probably fluctuate based on how the support
% material is removed, however we are assuming proper size, which is what
% the client will be assuming as well when they are printing future models
width = 6; %mm
depth = 3.4; %mm
%This is used to calculate strain as it demonstrates how much elongation
%occured. Note: this is assuming only the thin, ~33mm distance is the part
%elongating and not any of the other material placed outside of the clamp.
gaugeLength = 33; %mm
%%Calculations for graphing
area = width * depth;
stress = load / area;
strain = (gaugeLength + distance) / gaugeLength;
%Graphing logic
figure(1)
hold on
plot(strain, stress)
xlabel("Strain (mm/mm)")
ylabel("Stress (N/mm^2)")
title("Stress vs Strain for Dogbone Samples")
legend("Sample 1", "Sample 2", "Sample 3", "Sample 4");
hold off
```

## 11.5C Raw Young's Modulus Data

| Sample Number | Stress and Strain Values used, respectively | Young's Modulus |
|---|---|---|
| 1 | (2.00, 1.20) and (1.31, 0.503) | 0.98 MPa |
| 2 | (1.41, 0.59) and (1.09, 0.167) | 0.76 MPa |
| 3 | (1.76, 0.89) and (1.21, 0.34) | 1.00 MPa |
| 4 | (2.01, 1.25) and (1.17, 0.32) | 0.90 MPa |