3D Printing Airway Trainers

BME 200/300
University of Wisconsin-Madison
Department of Biomedical Engineering
10/09/2024

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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 patient's oxygenation and ventilation must be controlled by a healthcare professional. Abnormal anatomy, such as sublingual tonsils or subglottic stenosis, combined with other physical conditions like obesity, can make an airway very difficult to intubate. The inability to secure an airway can lead to poor perfusion and death, so training for these situations is commonplace for healthcare workers who manage airways. Existing airway trainers on the market replicate standard anatomy under challenging conditions, such as during anaphylaxis, but cannot simulate the nuances of an abnormal airway, like shifted anatomical landmarks, unexpected lesions, or modified anatomy due to prior surgery. This project aims to create a 3D-printed custom airway trainer based on a patient's CT or MRI scan, which appropriately replicates a specific abnormal airway that would otherwise be unable to be represented. These custom trainers would serve as a preoperative training tool and be used for broader educational purposes to teach healthcare providers how to intubate a complex airway without the pressure of human life on the line. After the trainer is created, the client will intubate the model and determine how realistic the experience is. By following relevant biomechanical properties through picking an adequate material to manufacture the trainer, the team can provide a highly realistic, biomechanically accurate model to help medical professionals provide better patient care and reduce adverse outcomes during difficult airway management.

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1 INTRODUCTION

1.1 Motivation

Airway management is a critical medical procedure done to restore or maintain a patient's ability to breathe properly. This procedure is very common in the medical field and is frequently performed on patients with anaphylaxis, respiratory arrest, or an 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 these airway management situations are unsuccessful. An unsuccessful first intubation is linked to a higher likelihood of negative outcomes for the patient, which can include 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 that exists when intubating patients who are in critical condition, it is ideal for clinicians to be able 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 that offers 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. However, although existing airway trainers can possess a variety of advanced features, they also tend to present obstacles in the form of their extremely high cost, extensive delivery time, and their inability to simulate a wide anatomical variety of patient airways [2]. The goal of this project is 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 is 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 is able to 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 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, which will be discussed later. 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 of this. There, the reasons why none of the existing trainers available can fit the needs of the client were assessed numerically as the team decided the scope of the project.

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 that is common in existing trainers can make it difficult for clinicians to prepare for the intricate airway conditions that 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 referred to as 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 referred to as 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 both 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].

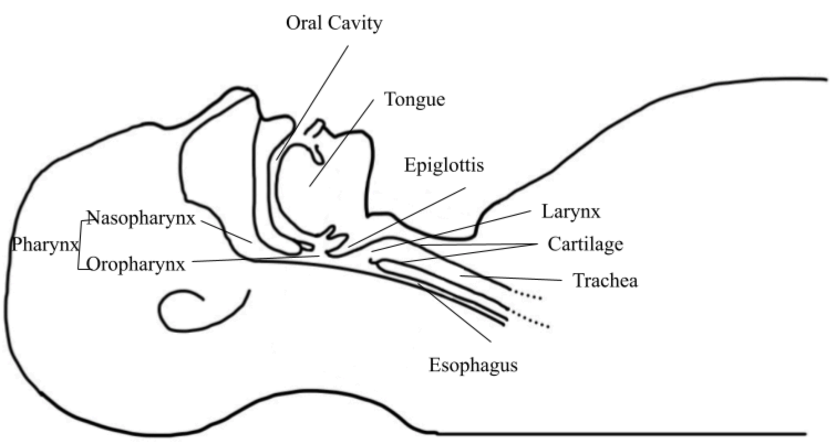


Figure 4: Diagram labeling the major components of the airway

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 areas of the body, 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 which can provide patient specific pathology in order 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 within 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. 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 [9]. 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 [10, 11]. 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 [12, 13]. 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 [13, 14]. 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 [15 - 18]. 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, the 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 [15]. 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 [17]

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 [18]

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 [19]. 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.

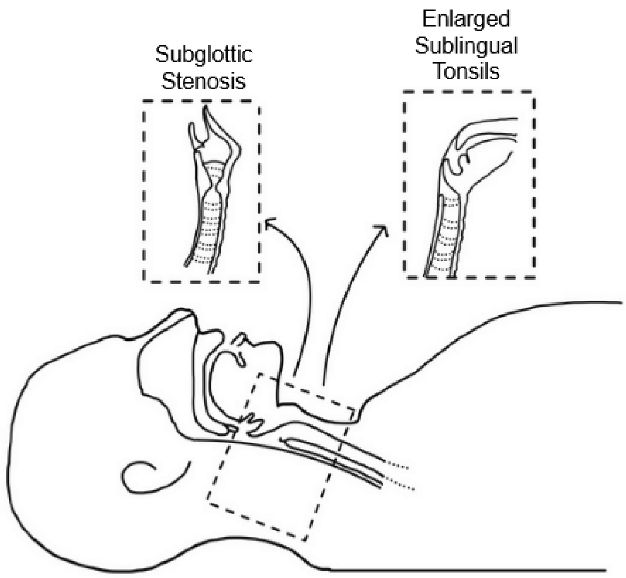


Figure 7: Modular airway trainer with replaceable difficult airways

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 for medical professionals to practice a variety of 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 [20]. The ability of this trainer to be patient specific is a major advantage which could allow for advancements in the way that 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.

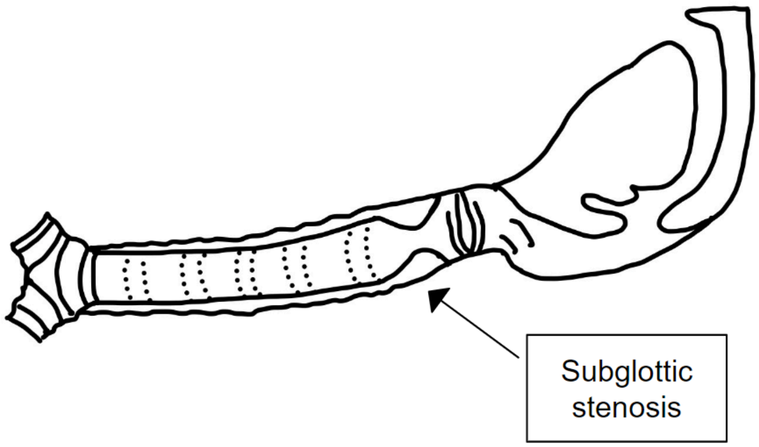


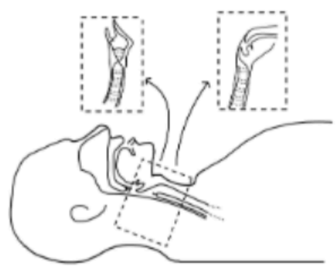
Figure 8: Depiction of a modular airway 3D printed using pathological patient imaging

4 PRELIMINARY DESIGN EVALUATION

4.1 Design Matrix

Table 1 shows the project scope design matrix, which has the rankings explained 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**	

Reasoning**s** 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 taking into consideration 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 5.1 Materials Design Matrix.

5 DEVELOPMENT PROCESS

5.1 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.

5.2 Materials

The trainer will consist of a 3D printed segment of the airway made out of Formlabs 80A resin. Formlabs 80A has a Young's Modulus of ~4 MPa and a Shore Hardness of 80A. This material will be resilient to most lubricants to be utilized for airway practice using typical airway equipment. Although this 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. 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 8.1 (Product Design Specifications) and 8.2 (Expense Spreadsheet) for more detailed info on materials and budget.

5.3 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 a segmentation software such as 3D Slicer [21]. 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 an .stl file format [22]. Next, this file must be refined using software such as Blender [23]. This file can then be 3D printed using materials that replicate the biomechanics of a human airway. See Figure 12 for each step in the airway fabrication process. In addition to the airway, an airway holder must be designed and fabricated using a computer aided design (CAD) software such as SolidWorks [24]. After using CAD to model the holder, it will be converted into an .stl file and 3D printed.

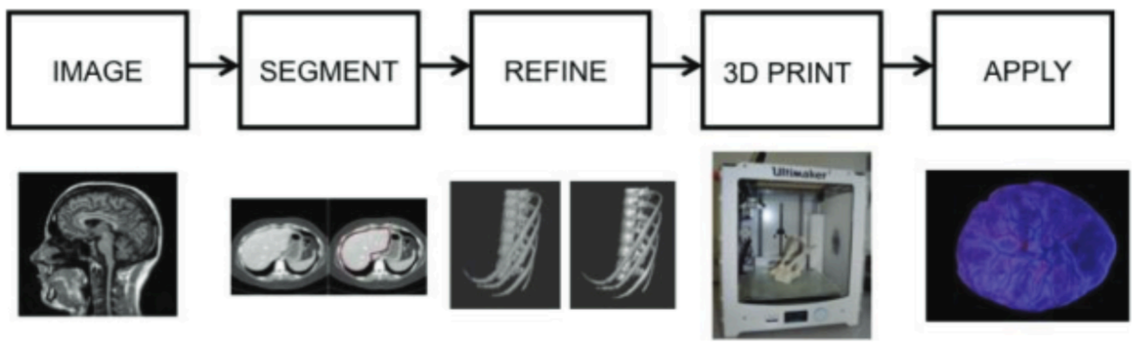


Figure 9: Outline of fabrication of a patient specific model from imaging [25]

5.4 Testing

After development of the airway trainer, its accuracy will be assessed in three ways. First, the biomechanical properties of the trainer's material will be tested. This will be assessed by the client and by a materials testing lab within the College of Engineering if needed. Next, the trainer will be tested by performing test intubations. The client and potentially other anesthesiologists will be conducting these. Lastly, a comparison of the DICOM image of the airway anatomy will be compared to the printed anatomy. This will be done through taking measurements on the slicing software and confirming those match on the model. The biomechanical properties of the airway anatomy will be analyzed by testing the Shore Hardness and Young's Modulus of the material. These values must be within the range of 50-80A for Shore Hardness and 16MPa ± 8MPa for the Young's Modulus [10, 11]. Maintaining Shore Hardness and Young's Modulus within these ranges ensure that the biomechanics of real airway anatomy have been replicated in our trainer as they are reflective of real airway properties. Testing the Shore Hardness of the material can be done using a durometer, a tool which presses into the material producing an indentation (hardness) value [26]. Young's modulus can be tested utilizing an atomic force microscope (AFM) which uses a sharp tip to map down on the material, measuring how the material deforms under pressure [27]. Next, the trainer will be tested with a test intubation. Test intubations performed on the trainer must last a maximum of 45 seconds [28]. This threshold is reflective of the current intubation test standard and must be met to ensure optimal performance. After printing, the trainer anatomy will be compared to the DICOM images used to create anatomical outlines. The images and the trainer will be compared thoroughly to observe differences. If differences found influence factors such as the biomechanics or intubation performance the trainer may need to be reprinted.

6 CONCLUSION

The process of endotracheal intubation is vastly prevalent in the field of medicine. The process itself is difficult to master, yet it is vital that medical professionals performing these procedures feel they have had adequate training before attempting this procedure in a life-threatening scenario. The 3D printed modular airway with patient-specific anatomy will attempt to minimize the uncertainty in endotracheal intubation by allowing for intubation to be practiced on a model with the anatomical accuracy of the real patient. This design is relatively low-cost and highly versatile because of its ability to form physiologically accurate airway models. Once the patient-specific airway segment is developed, a frame including the mouth, nose, and bronchi will need to be constructed.

Future work will be to test Formlabs 80A resin to determine if it is the best fit for the modular airway. A material with the physical properties most similar to that of a human airway will be selected. From there, the Shore Hardness and the Young's modulus of the modular airway will be tested to certify the most accurate biomechanics of an airway model. Additionally, the team is working with the client to locate real patient airway scans that are viable for slicing and becoming .stl files that are 3D printable. Finally, the modular airway will be tested by a medical professional who will attempt to intubate and verify its accuracy and validity.

7 REFERENCES

[1] Maguire, Samantha, et al. “Endotracheal Intubation of Difficult Airways in Emergency Settings: A Guide for Innovators.” Medical Devices (Auckland, N.Z.), vol. 16, July 2023, pp. 183–99. PubMed Central, https://doi.org/10.2147/MDER.S419715.

[2] Tanya, Stuti, and Adam Dubrowski. “Development of a Cost-Effective Pediatric Intubation Task Trainer for Rural Medical Education.” Cureus, vol. 12, no. 1, p. e6604. PubMed Central, https://doi.org/10.7759/cureus.6604. Accessed 9 Oct. 2024.

[3] “Ambu Airway Management Trainer (A186002000).” GTSimulators.Com, https://www.gtsimulators.com/products/ambu-airway-management-trainer-a186002000-ab186-002. Accessed 15 Sept. 2024.

[4] “Airway Management Trainer,” Laerdal Medical. Accessed: Sep. 20, 2024. [Online]. Available: https://laerdal.com/us/products/skills-proficiency/airway-management-trainers/laerdal-airway-management-trainer/

[5] “AirSim Difficult Airway with Bronchi,” Trucorp. Accessed: Oct. 02, 2024. [Online]. Available: https://trucorp.com/en/produto/airsim-difficult-airway-with-bronchi/

[6] M. Ball, M. Hossain, and D. Padalia, “Anatomy, Airwa,” 2023, Accessed: Oct. 09, 2024. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK459258

[7] P. Aceto, V. Perilli, C. Modesti, P. Ciocchetti, F. Vitale, and L. Sollazzi, “Airway management in obese patients,” Surgery for Obesity and Related Diseases, vol. 9, no. 5, pp. 809–815, Sep. 2013, doi: 10.1016/j.soard.2013.04.013.

[8] N. D. Jefferson, A. P. Cohen, and M. J. Rutter, “Subglottic stenosis,” Seminars in Pediatric Surgery, vol. 25, no. 3, pp. 138–143, Jun. 2016, doi: 10.1053/j.sempedsurg.2016.02.006.

[9] B. McGuire and K. Hodge, “Tracheal intubation,” Anaesthesia & Intensive Care Medicine, vol. 23, no. 11, pp. 661–666, Nov. 2022, doi: 10.1016/j.mpaic.2022.08.002.

[10] [7] T. Agbiki et al., “Fabrication and assessment of a bio-inspired synthetic tracheal tissue model for tracheal tube cuff leakage testing,” BJA Open, vol. 10, p. 100290, Jun. 2024. doi:10.1016/j.bjao.2024.100290

[11] F. Safshekan, M. Tafazzoli-Shadpour, M. Abdouss, and M. B. Shadmehr, “Mechanical Characterization and Constitutive Modeling of Human Trachea: Age and Gender Dependency,” Materials (Basel), vol. 9, no. 6, p. 456, Jun. 2016, doi: 10.3390/ma9060456.

[12] “Airway Management Training Model.” GTSimulators.Com, https://www.gtsimulators.com/products/airway-management-training-model-bt-csie-t. Accessed 15 Sept. 2024.

[13] “Critical Airway Management Trainer. [101-060].” Nasco Healthcare, https://shop.nascohealthcare.com/products/101-060. Accessed 15 Sept. 2024.

[14] “Ambu Airway Management Trainer (A186002000).” GTSimulators.Com, https://www.gtsimulators.com/products/ambu-airway-management-trainer-a186002000-ab186-002. Accessed 15 Sept. 2024.

[15] “Difficult Airway Trainers,” Trucorp. Accessed: Sep. 25, 2024. [Online]. Available: https://trucorp.com/en/procedure/difficult-airway-trainers/

[16] “Airway Management Trainer,” Laerdal Medical. Accessed: Sep. 20, 2024. [Online]. Available: https://laerdal.com/us/products/skills-proficiency/airway-management-trainers/laerdal-airway-management-trainer/

[17] “Decent Simulators | medical task trainers,” Decent Simulators. Accessed: Sep. 20, 2024. [Online]. Available: https://www.decentsimulators.com

[18] “African American Burn Victim Skills Torso Airway Trainer,” 7S3. Accessed: Sep. 20, 2024. [Online]. Available: https://7-s3.com/product/african-american-burn-victim-skills-torso-airway-trainer/

[19] “AirSim: Adult Airway Training by TruCorp,” Trucorp. Accessed: Oct. 03, 2024. [Online]. Available: https://trucorp.com/en/product/airsim/

[20] B. H. K. Ho et al., “Multi-material three dimensional printed models for simulation of bronchoscopy - BMC Medical Education,” BioMed Central, https://bmcmededuc.biomedcentral.com/articles/10.1186/s12909-019-1677-9

[21] “3D slicer image computing platform,” 3D Slicer, https://www.slicer.org/ (accessed Oct. 9, 2024).

[22] D. I. Nikitichev et al., “Patient-specific 3D printed models for education, research and surgical simulation,” 3D Printing, Oct. 2018. doi:10.5772/intechopen.79667

[23] B. Foundation, “Home of the blender project - free and open 3D creation software,” blender.org, https://www.blender.org/ (accessed Oct. 9, 2024).

[24] “3D CAD Design Software,” SOLIDWORKS, https://www.solidworks.com/ (accessed Oct. 9, 2024).

[25] D. I. Nikitichev et al., “Patient-specific 3D printed models for education, research and surgical simulation,” 3D Printing, Oct. 2018. doi:10.5772/intechopen.79667

[26] S. W. ISM, “What is Durometer? – Elastomer and Plastic Hardness.” Accessed: Oct. 10, 2024. [Online]. Available: https://www.industrialspec.com/about-us/blog/detail/what-is-durometer-elastomer-and-plastic-hardness

[27]“How do you measure Young’s Modulus with an AFM?,” Oxford Instruments. Accessed: Oct. 10, 2024. [Online]. Available: https://afm.oxinst.com/outreach/how-do-you-measure-youngs-modulus-with-an-afm

[28] C. Vincent-Lambert and R. Loftus, “Time taken to perform a rapid sequence intubation within a simulated prehospital environment,” Southern African Journal of Critical Care, vol. 35, no. 2, p. 70, Nov. 2019, doi: https://doi.org/10.7196/sajcc.2019.v35i2.368.

8 APPENDIX

8.1 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 in order to ensure that the model has a life-like intubation experience are a Young's Modulus of 16 MPa $\mp$ 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 very 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 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.

References

[1] Maguire, Samantha, et al. "Endotracheal Intubation of Difficult Airways in Emergency Settings: A Guide for Innovators." Medical Devices (Auckland, N.Z.), vol. 16, July 2023, pp. 183–99. PubMed Central, https://doi.org/10.2147/MDER.S419715.

[2] B. A. Traylor and A. McCutchan, "Unanticipated Difficult Intubation in an Adult Patient," in StatPearls, Treasure Island (FL): StatPearls Publishing, 2024. Accessed: Sep. 18, 2024. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK572134/

[3] "Intersurgical - Lubricant." Accessed: Sep. 18, 2024. [Online]. Available: https://www.intersurgical.com/products/airway-management/lubricant

[4] C. Vincent-Lambert and R. Loftus, "Time taken to perform a rapid sequence intubation within a simulated prehospital environment," Southern African Journal of Critical Care, vol. 35, no. 2, p. 70, Nov. 2019, doi: https://doi.org/10.7196/sajcc.2019.v35i2.368.

[5] A. C. Alvarado and P. Panakos, "Endotracheal tube intubation techniques," PubMed, 2023. https://www.ncbi.nlm.nih.gov/books/NBK560730/

[6] Michèle Min Chan, Christophe Fehlmann, M. Pasquier, L. Suppan, and Georges Louis Savoldelli, "Endotracheal Intubation Success Rate in an Urban, Supervised, Resident-Staffed Emergency Mobile System: An 11-Year Retrospective Cohort Study," Journal of Clinical Medicine, vol. 9, no. 1, pp. 238–238, Jan. 2020, doi: https://doi.org/10.3390/jcm9010238.

[7] T. Agbiki et al., "Fabrication and assessment of a bio-inspired synthetic tracheal tissue model for tracheal tube cuff leakage testing," BJA Open, vol. 10, p. 100290, Jun. 2024. doi:10.1016/j.bjao.2024.100290

[8] F. Safshekan, M. Tafazzoli-Shadpour, M. Abdouss, and M. B. Shadmehr, "Mechanical Characterization and Constitutive Modeling of Human Trachea: Age and Gender Dependency," Materials (Basel), vol. 9, no. 6, p. 456, Jun. 2016, doi: 10.3390/ma9060456.

[9] "AirSim Pierre Robin X difficult airway trainer (Light Skin Tone) | Limbs & Things US & Canada." Accessed: Sep. 18, 2024. [Online]. Available: https://limbsandthings.com/us/products/tcpr10000x/tcpr10000x-airsim-pierre-robin-x-light-skin-tone/

[10] R. Nolan, "Safe Storage of Rubber Products," Aero Rubber Company®, Inc. Accessed: Oct. 09, 2024. [Online]. Available: https://aerorubber.com/2020/10/08/safe-storage-of-rubber-products/

[11] "News - Storage Knowledge of Silicone Sealant in High Temperature and Humidity Climate," https://www.siwaysealants.com/. Accessed: Oct. 09, 2024. [Online]. Available: https://www.siwaysealants.com/news/storage-knowledge-of-silicone-sealant-in-high-temperature-and-humidity-climate/

[12] C. André and C. Jim, "Silicone Biomaterials: History and Chemistry & Medical Applications of Silicones," Biomaterials Science, vol. 52, no. 2, pp. 1–20, Accessed: Sep. 18, 2024. [Online]. Available:

chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.pentasil.eu/images/Silicone%20Biomaterials.pdf

[13] D. M. Gnugnoli, A. Singh, and K. Shafer, "EMS Field Intubation," in StatPearls, Treasure Island (FL): StatPearls Publishing, 2024. Accessed: Sep. 18, 2024. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK538221/

[14] A. Kochanke, K. Krämer, C. Üffing, and A. Hartwig, "Influence of high-temperature and high-humidity aging on the material and adhesive properties of addition curing silicone adhesives," International Journal of Adhesion and Adhesives, vol. 111, p. 102980, Dec. 2021, doi: 10.1016/j.ijadhadh.2021.102980.

[15] K. Christopher, T. Todd, S. Gary, and W. Ron, "Orotracheal Intubation," The New England Journal of Medicine, pp. 1–4, [Online]. Available: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://ubccriticalcaremedicine.ca/docs/procedures/Orotracheal%20Intubation.pdf

[16] E. Kim, S. M. Yang, S. J. Yoon, J.-H. Bahk, and J.-H. Seo, "The effects of water lubrication of tracheal tubes on post-intubation airway complications: study protocol for a randomized controlled trial," Trials, vol. 17, p. 562, Nov. 2016, doi: 10.1186/s13063-016-1699-0.

[17] B. J. Hindman, F. Dexter, B. C. Gadomski, and M. J. Bucx, "Sex-Specific Intubation Biomechanics: Intubation Forces Are Greater in Male Than in Female Patients, Independent of Body Weight," Cureus, vol. 12, no. 6, p. e8749, doi: 10.7759/cureus.8749.

[18] M. B. Brodsky et al., "Laryngeal Injury and Upper Airway Symptoms after Endotracheal Intubation During Surgery: A Systematic Review and Meta-Analysis," Anesth Analg, vol. 132, no. 4, pp. 1023–1032, Apr. 2021, doi: 10.1213/ANE.0000000000005276.

[19] B. McGuire and K. Hodge, "Tracheal intubation," Anaesthesia & Intensive Care Medicine, vol. 23, no. 11, pp. 661–666, Nov. 2022, doi: 10.1016/j.mpaic.2022.08.002.

[20] "Adult Airway Management Trainer [SKU: 101-501]." Nasco Healthcare, https://shop.nascohealthcare.com/products/101-501. Accessed 15 Sept. 2024.

[21] "Ambu Airway Management Trainer (A186002000)." GTSimulators.Com, https://www.gtsimulators.com/products/ambu-airway-management-trainer-a186002000-ab186-002. Accessed 15 Sept. 2024.

[22] "Airway Management Training Model." GTSimulators.Com, https://www.gtsimulators.com/products/airway-management-training-model-bt-csie-t. Accessed 15 Sept. 2024.

[23] "Critical Airway Management Trainer. [101-060]." Nasco Healthcare, https://shop.nascohealthcare.com/products/101-060. Accessed 15 Sept. 2024.

[124] "Medical Compounds and Tubing for Airway Management Products." Tekni-Plex, https://teknigives.tekni-plex.com/tekni-plex-medical/applications/airway-management/. Accessed 15 Sept. 2024.

[25] Silicone Training Manikin - All Medical Device Manufacturers. https://www.medicalexpo.com/medical-manufacturer/silicone-training-manikin-61076.html. Accessed 15 Sept. 2024.

[26] "Laerdal Airway Management Trainer," Laerdal®, https://laerdal.com/us/doc/2163/Laerdal-Airway-Management-Trainer

[27] "Airway Demonstration Model," Laerdal, https://laerdal.com/us/item/252500

[28]14:00-17:00, "ISO/IEC 3532-1:2023," ISO. Accessed: Sep. 18, 2024. [Online]. Available: https://www.iso.org/standard/79624.html

[29]14:00-17:00, "ISO/IEC 3532-2:2024," ISO. Accessed: Sep. 18, 2024. [Online]. Available: https://www.iso.org/standard/79625.html

[30]14:00-17:00, "ISO 15223-2:2010," ISO. Accessed: Sep. 18, 2024. [Online]. Available: https://www.iso.org/standard/42343.html

[31]14:00-17:00, "ISO 20417:2021," ISO. Accessed: Sep. 18, 2024. [Online]. Available: https://www.iso.org/standard/67943.html

[32]14:00-17:00, "ISO 22442-3:2007," ISO. Accessed: Sep. 18, 2024. [Online]. Available: https://www.iso.org/standard/39351.html

[33] "CFR - Code of Federal Regulations Title 21." Accessed: Oct. 09, 2024. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=177.2600

[34] yasminlp, "Autoclave Guide: What Can & Can't Be Autoclaved," TOMY. Accessed: Sep. 18, 2024. [Online]. Available: https://tomy.amuzainc.com/blog/autoclave-guide/

[35]"Airway Management Trainer," Laerdal Medical. Accessed: Sep. 18, 2024. [Online]. Available: https://laerdal.com/us/products/skills-proficiency/airway-management-trainers/laerdal-airway-management-trainer/

[36]"Airway management," Decent Simulators, https://www.decentsimulators.com/airway-management

[37]"About 7S3 | 7-SIGMA Simulation Systems," 7S3. Accessed: Sep. 18, 2024. [Online]. Available: https://7-s3.com/about-7-sigma/

8.2 Expense Spreadsheet

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Makerspace 3D Printing Costs										
Formlabs 80A test print	Test print of an airway or heart to determine if material properties are sufficient					Estimated 10/11	1	$25.00	$25.00	
									$0.00	
Other Supporting Purchases										
									$0.00	
									$0.00	
								TOTAL:	$25.00	
								Budget:	$750.00	
								Financial Standing:	GOOD	