3D Printing Airway Trainers

Preliminary Report

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Client

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Abstract

Airway management is a critical aspect of any medical procedure and is one of the primary responsibilities of anesthesiologists during operations. Anesthesiologists use airway trainers to practice intubation, one of the foundational techniques of airway management. These trainers prepare anesthesiologists for normal airway anatomies, but when presented with an abnormal airway, intubation becomes more difficult. While difficult airway trainers exist, they focus more on craniofacial abnormalities that complicate intubation rather than the varying anatomies of the airway itself, which does not adequately prepare anaesthesiologists for intubation of irregular airways. This project aims to develop a process for making patient-specific airway trainers to improve anesthesiologist preparedness for procedures involving difficult airways. Creating a patient-specific airway trainer begins by scanning the airway of a patient suspected to have an abnormal airway, then segmenting the scan to convert it to a printable format. The airway is then printed in TPU, a low-cost filament with material properties similar to biological airway tissue. Once printed, the airway is implemented into an adaptable airway trainer where adjustments to the mandible position, tongue size, and neck position can be tailored to the manikin to the patient's anatomy. The airway materials and manikin adjustments will be tested thoroughly to ensure anatomical accuracy, durability, and usability before finalization of the design. Once completed, the airway trainer represents a functional, patient-specific, and anatomically correct model for intubation practice. The trainers will enable anesthesiologists to be better prepared to manage irregular airways and will ultimately reduce complications and improve patient outcomes.

Introduction

Motivation

Emergency airway management is crucial during instances of respiratory distress, as clinicians typically only have on average 15-30 seconds to secure an airway before possible onset of hypoxia and brain damage [1]. Over 400,000 Americans each year are intubated in these emergency settings, with 12.7% of these intubations failing on the first attempt. For difficult airways, upwards of 50% of intubations fail on the first attempt [1]. The failure to successfully intubate a patient on the first attempt leads to a 33% increase in likelihood for patients to experience complications from lack of oxygen. Since the amount of endotracheal intubation (ETI) training for a clinician and not necessarily the type of clinician performing the procedure might be more important for a successful ETI, it has become increasingly important to create a wide range of airway trainers for clinicians to practice on [2]. While some current airway trainers can provide adequate ETI practice for clinicians, these trainers are not able to successfully simulate the varying endotracheal environments of the many patients clinicians will see each day. These trainers specifically struggle to simulate the anatomy observed during allergic reactions, inhalation burns, or trauma in the upper airway [3].

Current Methods and Existing Devices

The current standard for creating airway trainers involves 3D printing molds that will have silicone poured into them, but this method also does not reflect the complexity of airways observed in the clinical setting. Not properly simulating the endotracheal anatomy of patients can lead to problems in the learning process for medical residents, leading them to be less prepared for emergency ETI and therefore at a greater risk for failure on their first attempt. There are a multitude of airway trainers that exist on the market, but they lack functionality in crucial areas for effective medical resident learning. The major limitation of many competing designs on the market is that they only represent one airway abnormality. The company 7-Sigma makes different airway management training tools, but these trainers lack significant modularity that can make them useful for medical residents beyond very specific use cases. One of these trainers also costs around $2000, which can price out certain potential clients that require many different airway trainers to practice on [4]. The Laerdal Airway Management Trainer is the current airway management device used at the UW Health University Hospital. Much like the 7-Sigma trainer, the Laerdal device lacks the ability to remove the airway and place another in its place, strongly limiting the usability of the device. These tools also cost around $3000, which can once again price out potential clients looking to develop a library of difficult airways to practice on [5].

Figure 1: *Laerdal Airway Management Trainer [5]*

Problem Statement

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

Background

Biology and Physiology

Ensuring physiological accuracy is fundamental to this device and its intended use. The device must be specific and precise to the individual in question, specifically with regards to important factors for intubation. Craniofacial factors that affect intubation include tongue size, adequacy of the mouth opening, condition and presence of the teeth and uvula, the presence of an overbite, and thyromental distance, which refers to the distance from the chin to the thyroid notch in the neck [6]. A larger tongue, a smaller mouth opening, an overbite, and a short thyromental distance can all lead to a more difficult intubation procedure. On an airway trainer, these craniofacial factors would be adjustable by allowing for adjustable mandible positioning, thyromental distance, and tongue size.

Airway anomalies must also be taken into account, as an accurate device would match the upper airway and trachea of varying individuals, with some of the following conditions. Pyriform aperture stenosis is the narrowing of the nasal airway due to bony overgrowth, which makes nasal intubation nearly impossible. A laryngeal cleft is the abnormal connection between the larynx and esophagus, which can cause accidental esophageal intubation, which can be deadly if not recognized quickly. Laryngeal stenosis, webs, and atresia refer to a spectrum of abnormalities within the larynx that can make breathing and intubation difficult. Stenosis refers to a narrowing of the larynx, webs partially constrict the airway, and atresia is a complete blockage of the airway. Finally, a complete, or circular tracheal ring, rather than a typical C-shaped ring, can lead to tracheal stenosis, which makes both breathing and intubation more difficult [7].

Mechanical properties are also an important factor to consider when designing an airway model, to ensure physiological conditions are met. The trachea is a C-shaped ring, made up of cartilage, which provides structural integrity, and smooth muscle and connective tissue that provide flexibility. The range of Young's Modulus within the linear-elastic range for connective tissue is typically 2.4 ± 1.2 MPa, and smooth muscle is 1.2 ± .5 MPa [8]. That being said, smooth muscle and connective tissue increase non linearly, with a higher slope as strain increases further as seen in Figure 2 below. A typical range for the Young's Modulus for the cartilage is 16.92 ±

8.76 MPa, but it can range from 5 to 39 MPa depending on age, as cartilage stiffness increases with age due to ossification.

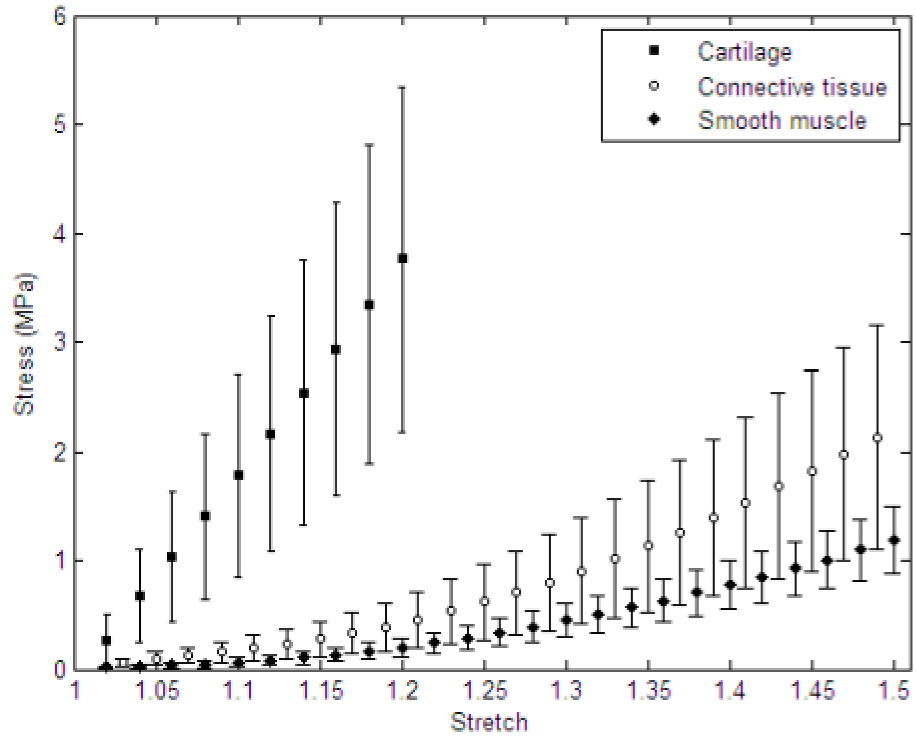

Figure 2: *Stress-strain data for cartilage, smooth muscle, and connective tissue samples; expressed as mean ± STD*

Segmentation and 3D Printing

An integral part of going from scan to print is the process of segmentation. This process involves isolating anatomical structures from scan data to generate 3D renders that can then be exported as STL files and printed [9]. Some of the major challenges with segmentation relates to the slice thickness of the imaging. Thicker slices capture less fine detail which can obscure the anatomical structures being segmented, and lead to a lower resolution render. Taking thinner slices captures more of the final details of the structure being segmented, not only enhancing the accuracy of the segmentation, but also producing much higher quality meshes [9]. While different segmentation softwares can produce higher resolution and quality renders than others, the team is limited to resources available to us through the University of Wisconsin and free online software. With this in mind, the team is likely to use the ITK-SNAP software, a free resource available to download on any computer. While ITK-SNAP is not as advanced as the Mimics software shown to the team in our meeting with Dr. Sylvana Garcia-Rodriguez of the University of Wisconsin Hospital Department of Radiology, ITK-SNAP is still capable of producing high quality renders. There exists an algorithm in the ITK-SNAP software that can complete automatic segmentation, which could be a focus of the team's work as segmenting an airway is not as involved as segmenting different tissues, but there are also capabilities for manual segmentation [10]. The manual segmentation component of the software has both a polygon tool and paintbrush tool for fine object refinement and definition. Once a render is generated on ITK-SNAP, it can then be transferred to another resource for further refinement and processing. As shown to the team in our meeting with Dr. Garcia, it is integral to complete two rounds of post processing on renders before they are downloaded as STL files as this will greatly improve the resolution and smoothness of the print. 3D slicer, another free application from the internet will likely be used as the secondary processing tool [11].

For 3D printing, the printer will depend on the type of material selected for prototyping. In general, 3D printing in medical applications uses the Stereolithography (SLA) method. This method uses a bath of photosensitive resin with a UV laser to cure the resin. The UV laser is directed onto the resin slice by slice using a computer controlled mirror that directs the exposure path of the UV light to sequentially generate the slices of material that bind to form a solid object [12]. SL printing is considered to provide the greatest accuracy of the types of 3D printing used in medical applications, so this will be the team's chosen method for fabricating our airway.

Client Information

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

Design Specifications

The design specifications for this project have been shaped by client input and requirements for a final device. While the scope of the current semester's work is to generate a proof of concept airway and focus on defining a concrete method for going from MRI to STL, it is still important to establish specifications for future airway printing. To ensure clinical relevancy of a printed airway, biomechanical properties were selected to mimic standard airway anatomy. The desired Young's Modulus for the airway is 2.3-23 MPa, based on the material mechanics of tracheal cartilage in a standard human airway [13]. The Shore hardness of the airway should be 60-91 A, but can vary depending on the selected infill of the print and material choice [14]. For the life in service of a fabricated airway trainer, an amount of 20,000 intubation cycles was deemed feasible and comparable to other trainers on the market [15]. Based on client input, the airway must also match a human airway in both look and texture to eliminate any variation between trainer and real airway, and to simulate the true experience of ETI for medical residents and trainees utilizing the device. The client also gave the team a budget of $750, but minimizing the process cost is integral for establishing the team's method as superior to existing devices, so the team will look to the $272 Laerdal Airway Demonstration Model as a target cost [16]. While minimizing cost is a major factor of the requirements outlined by the client, another is to keep the process of transforming a scan into a printed airway to under 48 hours. This will ensure selected patients with difficult airways can have their airway printed and practiced on by the surgeon prior to operation.

Preliminary Design Materials

Material Choice #1 - Formlabs Flexible Resin

Formlabs Flexible Resin is a highly durable and stiff-yet-flexible SLA resin. The greatest advantage of this material is that it has ideal material properties for this application as the Young's modulus of 8.9 MPa and Shore hardness of 80.0 A are in the desired range outlined in the design specifications [17]. One disadvantage of the material is that because the resin is proprietary to Formlabs, it is only compatible with Formlabs printers and therefore may be relatively inaccessible. Another disadvantage is the cost of the material. The resin is relatively expensive, costing $0.29/g at the UW Makerspace [18]. Lastly, because the resin is translucent, in order to achieve the life-like look of airway tissue, the resin needs to be dyed before printing. Formlabs Flexible Resin is a very ideal material for this application due to its material properties, but its inaccessibility and relatively high cost could prove to be prohibitive.

***Figure 3**: Formlabs Flexible Resin Sample Print [19]*

Material Choice #2 - EcoFlex 00-50 Liquid Silicone

EcoFlex 00-50 Liquid Silicone is a two-part, versatile silicone rubber mixture that is both strong and flexible. If this material were to be selected, the 3D printer would not print directly with silicone. Instead, a negative of the desired part would be printed in a basic filament like PLA. The PLA mold would then be used to cast the airway in liquid silicone. However, due to the geometry of an airway, creating and casting a mold would likely prove fairly difficult. Another disadvantage of silicone is its material properties, which fall well outside the desired range for the project. The Young's modulus of liquid silicone is 82.7 kPa and the Shore hardness is roughly 10A [20]. Despite its lacking mechanical properties, silicone is relatively inexpensive as it costs roughly $0.05/g [21], and when factoring in the cost of a mold filament which also costs $0.05/g [18], results in an accessible material selection. Silicone presents an interesting, low-cost alternative to 3D printed filaments but lacks ideal material properties and can be difficult to fabricate.

***Figure 4**: Liquid Silicone Cast [22]*

Material Choice #3 - Thermoplastic Polyurethane (TPU)

Thermoplastic polyurethane or TPU is a plastic from the thermoplastic elastomer and is a very common 3D printing filament. TPU is generally flexible, very durable, and abrasion resistant. One of the upsides of TPU is its ease of use as it can be printed in any color on most FDM(fused deposition modeling) 3D printers. Once printed, TPU also has ideal material properties for this application as the Young's modulus of 9.8±0.7 MPa is right in the desired range [23]. While the Shore hardness of 95A is slightly outside of the desired range, this can be adjusted for during slicing by decreasing the infill density [24]. Another advantage of TPU is the cost, as TPU filament costs $0.05/g at the UW Makerspace which highlights its usability as prototyping material. Overall, TPU is an accessible, low-cost material with desirable material properties for use in printing airways.

Figure 5*: TPU Print [25]*

Preliminary Design Evaluation

Design Criteria (Weight)	**Design 1:** Formlabs Resin 		**Design 2:** Silicone Casting 		**Design 3:** Thermoplastic Polyurethane (TPU) 	
Mechanical Properties (25)	5/5	25	2/5	10	4/5	20
Cost (20)	2/5	8	4/5	20	5/5	20
Ease of Fabrication (20)	3/5	12	1/5	4	4/5	16
Durability (15)	5/5	15	3/5	9	4/5	12
Resemblance to Trachea (10)	3/5	6	5/5	10	4/5	8
Printer Availability (10)	2/5	4	5/5	10	4/5	8
Total Score (100)	**70**		**59**		**84**	

Table 1*: Material Design Matrix*

The design matrix evaluates the strengths and weaknesses of the 3 previously proposed materials. The material used must have similar mechanical properties to an airway in order to accurately mimic intubation conditions. The young's modulus and Shore hardness of Formlabs Resin best replicate the strength and flexibility of an airway. It is also important that cost is kept low since each patient will require a newly printed airway. Thermoplastic Polyurethane is the cheapest, making it the best option for practical use. Ease of fabrication refers to the simplicity of printing each material as well as the accuracy with which it can be printed. Silicone casting has a complex process requiring the printing of a mold followed by the pouring and curing of silicone. Formlabs Resin is printed in a top to bottom fashion which is generally more precise than the more commonly used fused deposition modeling (FDM) method used with TPU which prints layer on top of layer [26]. However, part of the printing process with Formlabs Resin includes an intensive and specific curing process which is why TPU scores higher in this category [27]. Typical airway trainers can be used for up to 20,000 intubations [28]. The 3D printed airways are intended to be used for far fewer repetitions, but still need to hold up under extended use as well as withstand pressure from sharp objects. Formlabs Resin is the stiffest of the 3 materials and the most resistant to abrasion making it the most durable. It is important for the color and texture of the printed airway to resemble a typical airway in order for the user to familiarize themself. Silicone is commonly used in practicum and can be easily dyed to resemble the color of a trachea. Formlabs Resin requires a more complex dyeing process and TPU can be purchased in a proper color. When it comes to printing, not every material can be used with every printer. It is important for the entire process to be streamlined and accessible and not every hospital may have access to a specific 3D printer. The silicone casting process can work with any 3D printer because the mold can be made of the simplest materials. Formlab materials require specific Formlab printers, whereas most FDM printers can be used to print TPU.

Proposed Final Design

Based on examination of the criteria above, TPU is the best material choice to use for a fully developed 3D printing process. The material is both cost effective and accessible, while also demonstrating the physiological properties of an airway. The team plans to print a prototype using both TPU and Formlabs Resin in order to gather more data while testing and also to receive further feedback from the client.

Fabrication Methods

To outline the project process, a patient with a potentially abnormal airway scheduled for a procedure will get an MRI scan of their airway in the sniffing position. That scan will be segmented using image processing software to convert the scan into an STL file. The STL file will then get sliced and prepared for printing. During this process, infill densities and infill patterns will be selected to yield the most accurate print based on testing of mechanical properties. The sliced file will be sent to a 3D printer where it will be printed in the selected material. Once the airway is printed, the part will be cleaned and will then be ready for integration into the airway trainer. From there, anesthesiologists and medical professionals can practice intubation on the airway to ensure preparedness for the actual procedure.

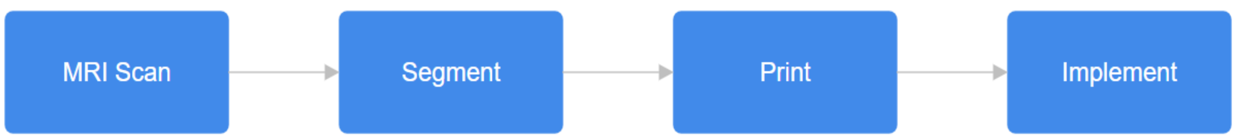

Figure 6: *Process Flow Chart*

Testing and Results

The team will be performing multiple tests to determine the accuracy and efficacy of the airway trainer device. With regards to anatomical accuracy of the airway, the team will measure volume using a water displacement test, and compare this value to volume values from the segmented MRI scan to ensure accuracy. Additionally, airway width, length, and geometry will be compared to the segmented scan. These tests will give the team confidence in the accuracy of the full process from MRI to 3D printed model. To test durability of the airway, the team will perform puncture resistance tests on the printed material. This will involve pressing the laryngoscope onto the material using an MTS machine to test the average value that is required to cause puncture. This will allow the team to understand if the device can withstand typical use conditions, and what may cause failure. The team will also perform cyclic loading tests, ideally of 20,000 cycles, under typical intubation conditions to determine if any degradation is seen, giving the team insight into the durability of the device. Finally, the team will compare intubation time for individuals, varying from novice to expert, on the printed device when compared to a control group. This test will ensure the team that the new device is functional, and intubation can be performed in a similar manner and time frame to an existing airway trainer device.

Conclusion

There currently exists no way to practice intubation on specific airways that present particular difficulties. The goal of this project is to develop a process to 3D print patient specific airway trainers. This will be accomplished by first taking an MRI image and then transforming it to an STL file that can be printed. Once printed, the model airway will be integrated onto an airway trainer manikin where it can be used to practice intubation. This process will ensure anatomical accuracy of the patient at hand and allow for an anesthesiologist to familiarize themselves with the airway before surgery.

In the future, the team plans to follow this process to print 2 prototypes. One will be printed with Formlabs 80A Resin and the other with Thermoplastic Polyurethane. These will be used for initial testing. The team also hopes to design an airway trainer manikin that has modular capabilities such as adjustable mandible position and neck flexion as well as a size adjustable tongue. These adjustments will allow for further specification of the patients airway and can produce a more difficult intubation scenario to practice with.

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Appendix

Appendix A: Product Design Specifications

Function

Emergency airway management is crucial during instances of respiratory distress, as clinicians typically only have on average 15-30 seconds to secure an airway before possible onset of hypoxia and brain damage [1]. Since the amount of endotracheal intubation (ETI) training for a clinician and not necessarily the type of clinician performing the procedure might be more important for a successful ETI, it has become increasingly important to create a wide range of airway trainers for clinicians to practice on [2]. While some current airway trainers can provide adequate ETI practice for clinicians, these trainers are not able to successfully simulate the varying endotracheal environments of the many patients clinicians will see each day. These trainers specifically struggle to simulate the anatomy observed during allergic reactions, inhalation burns, or trauma in the upper airway [3]. To combat the difficulties caused by the variation in airways that can lead to inadequate training for many clinicians, this project seeks to prove the feasibility of a method for transforming CT scans or MRIs of a patient's endotracheal anatomy into a 3D printed airway trainer so that clinicians can practice on high-risk scenarios. Establishing a concrete method for taking a CT scan or MRI and 3D printing a >90% anatomically accurate airway will ensure that clinicians will receive ample practice.

Client Requirements

- Prove the feasibility of taking an MRI or CT scan and 3D printing the airway with 90% anatomical and physiological accuracy.
- Create airways that can be swapped in and out of a universal trainer for the use of medical residents.
    - The focus of the work currently is to generate a concrete method for taking a scan and printing an airway, but once the method is proven to be feasible then the team could look to print different abnormal airways.
    - The team must also consider the modulation of airways from different positions of a patient’s neck.

- A hypothetical model must be flexible, represent accurate physiological biomechanics, and be made of a material that can resist water based lubricants as these are the typical compounds used during ETI procedures [4].
- Replicate accurate facial anatomy on a finalized model.
- Differentiate tissues in the airway by using unique materials to assist medical resident learning.

Design Requirements

1. Physical and Operational Characteristics

a. Performance requirements

The device will be used up to 50 times in a single session, with these sessions occurring frequently during medical student training periods. It must be adjustable to various positions, capable of holding them indefinitely, and easily readjustable at any time. Additionally, the device must endure at least 20,000 intubation cycles under typical use conditions without wear or loss of functionality. Under typical use, the device will have to withstand the insertion of a laryngoscope blade as well as an endotracheal tube [5]. Furthermore, the fabrication process should be repeatable and precise, allowing for the consistent production of airway models representative of individuals with various airway abnormalities.

b. Safety

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

c. Accuracy and Reliability

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

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

d. Life in Service

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

e. Shelf Life

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

f. Operating Environment

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

g. Ergonomics

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

h. Size

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

i. Weight

While the weight of an airway manikin is not the primary concern during the design process, the weight should be considered in order to make the trainer as realistic as possible and match the feel of using a typical airway manikin. 10-12 kg is typical for a common airway trainer and should be a target weight for this product [16].

j. Materials

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

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

k. Aesthetics, Appearance, and Finish

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

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

2. Production Characteristics

a. Quantity

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

b. Target Product Cost

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

3. Miscellaneous

a. Standards and Specifications

i. ISO/IEC 3532-1:2023 – Information Technology — Medical Image-Based Modelling for 3D Printing — Part 1: General Requirements [24]

        1. This standard specifies the requirements for medical image-based modelling for 3D printing for medical applications. It concerns accurate 3D data modelling in the medical field using medical image data generated from computed tomography (CT) devices.

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

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

    iv. Patent US10850442B1 – Medical devices and methods for producing the same [27]
        1. The patent describes the production of medical devices, such as airway stents, through additive manufacturing processes- specifically fused deposition modeling (FDM) and polycarbonate urethane (PCU).
        2. The patent discusses the specifics of 3D printing medical devices, specifically airway stents which the design may infringe on.

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

b. Customer

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

c. *Patient-related concerns*

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

d. *Competition*

- i. Laerdal Airway Management Trainer [31]
    1. A lifelike adult manikin that can be used to practice ventilation, intubation, and suction techniques.
    2. Includes features like induced vomiting, pressure sensitive teeth, and separate handheld anatomical models.
    3. Used by UW-Health and the Anesthesia department to train residents.
    4. Costs nearly $3,000 which is a reasonable price compared to what else is on the market.
- ii. Seven Sigma Airway Trainers [32]
    1. Parts are able to be removed and replaced to emulate different intubation scenarios. Typical adult airways can be used as well as airways of a patient who is swollen, a child, or has burn trauma. There are also different manikins for different races.
    2. Solves the problem of allowing practice on difficult and abnormal airways, but is not patient specific.
- iii. Trucorp Airway Trainers [33]
    1. Offer three different manikins including an adult and child version with more coming soon. All of which are meant to imitate an abnormal airway that is difficult to intubate.
    2. Feature an adjustable tongue to replicate conditions like obesity, down syndrome, and craniofacial abnormalities. Manikins also have adjustable mobility in the neck and spine as well as the ability to displace the larynx.
- iv. Difficult Endotracheal Intubation Simulator [34]
    1. This model has 3 modifications that can be made to make intubating more challenging.

a. The manikin has upper incisors which are longer than average and are able to be removed.
b. The manikin includes a sliding mandible that can allow for 0 to 10 mm of movement which can simulate an overbite.
c. The mandible can be locked in place to restrict opening of the mouth. The inter-incisor distance can be reduced to 3 cm.

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Appendix B: Finance Table

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Category 1										
									$0.00	
									$0.00	
Category 2										
									$0.00	
									$0.00	
								TOTAL:	**$0.00**	