3D Printing Airway Trainers

Preliminary Report

BME 301
October 13, 2025

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 elastic resin, a material with properties similar to biological airway tissue, and flexible enough to practice intubating on. 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. 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]. The company Decent Simulators makes airway management trainers that are more closely related to the ultimate goal of this project. The Decent Simulators V2 Airway Management Task Trainer costs around $1,700, a significant decrease in price from the Laerdal tools currently used at the UW Hospital. The Decent Simulators trainer is designed to be fully modular, with airways that can be swapped in and out of the trainer in seconds. This trainer also includes different difficult airways that can be leveraged for high value practice for medical residents of all skill levels [5].

Figure 1*: Decent Simulators V2 Airway Management Trainer [5]*

Problem Statement

Many standard airway trainers that exist on the market are limited in their utility 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 or 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. By taking an MRI of a patient's airway as they lay in the sniffing position, the DICOM files can be sliced using a segmentation software to eventually generate an STL file that can be 3D printed. By segmenting each different slice of the MRI, the team can 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. Patient positioning is also crucial for successful intubation, specifically the patient's neck angle. Since favorable positioning has been correlated to improved success rate for intubation it is absolutely necessary to consider neck angle alteration for a final design [7]. This can be accomplished in many ways, but most important is allowing for movements in different planes to ensure optimal training conditions.

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 [8].

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 [9]. 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.

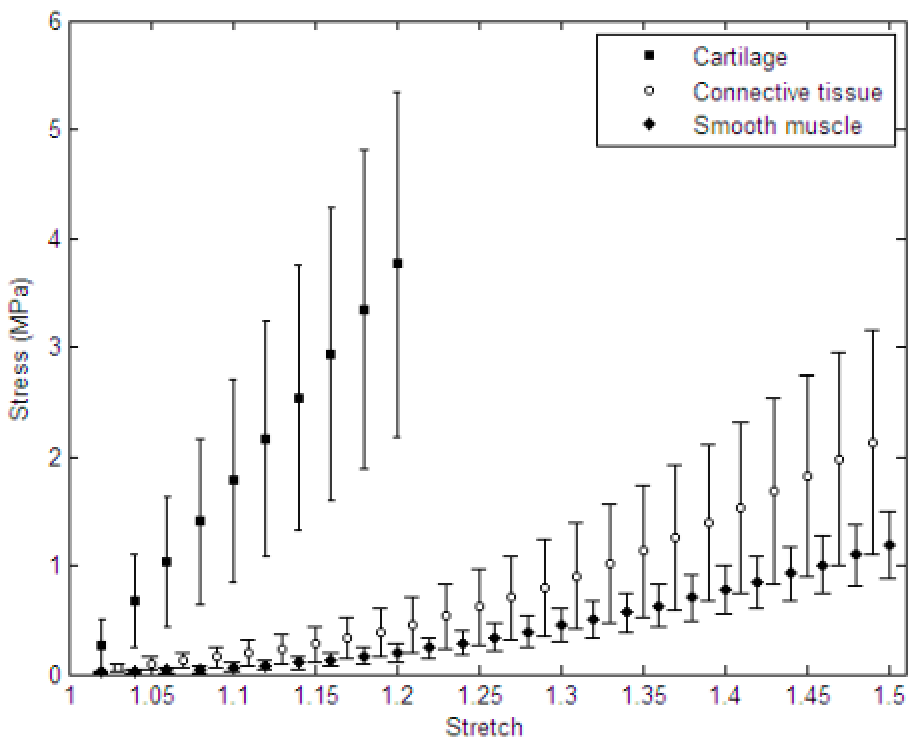


Figure 2*: Stress-strain data for cartilage, smooth muscle, and connective tissue samples; expressed as mean ± STD*

Magnetic Resonance Imaging

Magnetic resonance imaging is a non-invasive imaging technique that produces three dimensional anatomical images [10]. MRI uses strong magnets to generate powerful magnetic fields that interact with protons in the body and forces them to align to this potent field.

Radiofrequency currents are then sent through tissues to stimulate the aligned protons, forcing them out of their alignment with the magnetic field [10]. Once these frequencies are no longer being sent through the body and the protons are able to realign with the powerful magnetic field, energy is released by these molecules and sensed by the MRI sensors. Since different tissues have different properties that impact the speed of realignment and the energy released by each proton, conclusions can be drawn from this data to determine which tissue is which in the image [10]. To obtain an image, patients are placed into a large magnet and are told to hold very still so as to not blur the image [10]. MR scanners are most commonly used to image soft tissue in the body and differ from computed tomography scans (CT) as they do not use radiation to generate the images [10]. The lack of radiation in MRI is a hallmark of the technique, and one of the key factors when determining whether to use MRI or CT. Frequent scans will be taken using MRI as the patient will be protected from the possibly harmful radiation that they may be exposed to during a CT scan [10]. It should be noted that while there is no radiation used in MRI, the strength of the applied magnetic field will interact with implants in the body, especially those containing iron, so individuals with pacemakers or implantable defibrillators are advised to not enter MRI machines [10].

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 [11]. 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 the team through the University of Wisconsin and free online software. With this in mind, the team used the 3D Slicer software. 3D Slicer is a free, open source software for visualization, processing, segmentation, registration, and analysis of medical, biomedical, and other 3D images and meshes [12]. In the context of this project, the software allows for MR scans to be parsed and converted into models that can be used in many applications, namely 3D printing.

Another software considered was ITK-SNAP, a free, open source software for visualization and segmentation. There exists an algorithm in the ITK-SNAP software that can complete automatic segmentation, which uses the contrast of the MRI to differentiate the voxels of tissue, but there are also capabilities for manual segmentation [13]. The manual segmentation component of the software has both a polygon tool and paintbrush tool for fine object refinement and definition. Once a render is generated on ITK-SNAP, it can then be transferred to another resource for further refinement and processing.

For 3D printing, the printer will depend on the type of material selected for prototyping. In general, 3D printing in medical applications uses the Stereolithography (SLA) method. This method uses a bath of photosensitive resin with a UV laser to cure the resin. The UV laser is directed onto the resin slice by slice using a computer controlled mirror that directs the exposure path of the UV light to sequentially generate the slices of material that bind to form a solid object [14].

Since thermoplastic polyurethane (TPU) was a possible material for the final design, it is also important to briefly explain fused deposition modeling (FDM) printing. FDM printing builds the print layer by layer by depositing melted thermoplastic polymers that eventually form final physical objects [15]. FDM machines are loaded with spools of thermoplastic material, and once the nozzle has reached the melting point of the chosen polymer, the printer begins to feed the filament through an extrusion head [15]. The material then cools and solidifies to form the desired shape of the print. To fill a larger area, multiple passes are often used, analogous to coloring in an object [15]. While FDM printing is useful for low-cost and quick prototyping, it lacks the accuracy and resolution required for ensuring anatomical accuracy of a printed airway [16]. SLA printing is considered to provide the greatest accuracy of the types of 3D printing used in medical applications, so this was the team's chosen method for fabricating our airway.

Client Information

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

Design Specifications

The design specifications for this project have been shaped by client input and requirements for a final device. The scope of the current semester's work is to design and fabricate a functional airway training manikin that has modular capabilities. The neck angle, tongue size, and mandible position should be adjustable to represent a wide range of patients, and the airway portion should be removable and replaceable. This modulation should be rapid, able to occur in less than a minute to ensure there is no barrier towards adjustment of the device. 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 [17]. 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 [18]. 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.

Codes and Standards

Since the project involves extracting personal information from patients through MRI, the protections placed on this information through the Health Insurance Portability and Accountability Act (HIPAA) must be considered. Any scan must be anonymized prior to being used on any 3D rendering software as to comply with the protections placed on this information through HIPAA [19]. Another standard that was considered by the team was ISO 15223-1:2021. This standard specifies the requirements for symbols on medical devices and is applicable to all symbols used in a broad spectrum of medical devices [20]. Symbols can be placed on the medical device itself, on the packaging, or in any accompanying information that is used to explain how to operate the device [20].

Preliminary Designs

Design #1 - Adjustable Blocks

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

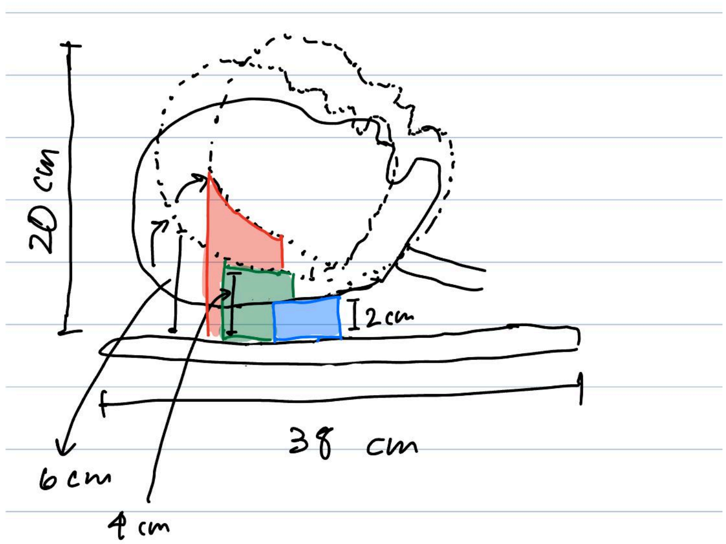


***Figure 3**: Sketch of Blocks Design*

Design #2 - Flexible Lamp Design

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

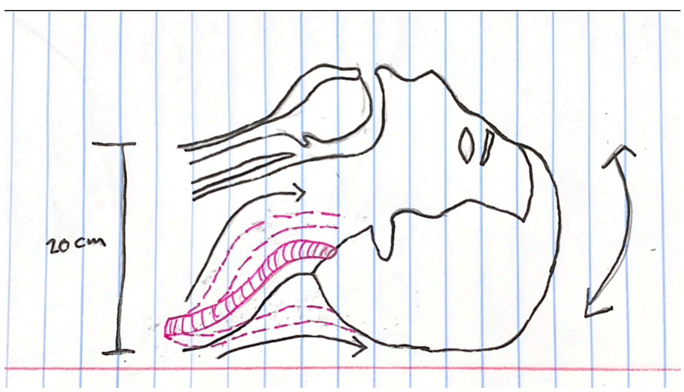


Figure 4*: Sketch of Flexible Lamp Design*

Design #3 - Rotating Pin Design

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

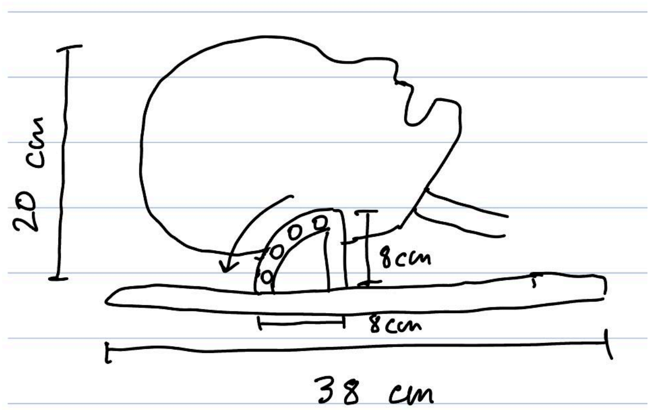


Figure 5*: Sketch of Rotating Pin Design*

Preliminary Design Evaluation

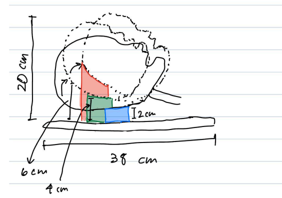
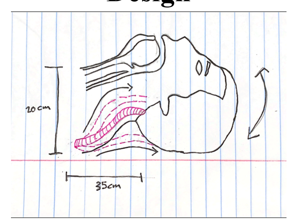
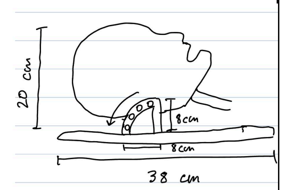
Design Criteria (Weight)	Design 1: Blocks		Design 2: Flexible Lamp Design		Design 3: Pin Design	
						
Ease of Use (20)	4/5	16	5/5	20	4/5	16
Stability (20)	2/5	8	2/5	8	5/5	20
Durability (15)	5/5	15	3/5	9	5/5	15
Precision (15)	3/5	9	5/5	15	3/5	9
Ease of Fabrication (10)	5/5	10	4/5	8	3/5	6
Cost (10)	5/5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

Table 1: *Preliminary Design Matrix*

The design matrix evaluates the strengths and weaknesses of the three previously proposed designs. All three designs focus on the manikin's adjustability of the neck. The goal of this design matrix is to find the best design when scored against seven different criteria: Ease of usability of the mechanism, the ability of the design to remain in place and stable during use, durability after repetitive intubations, precision representative of human anatomy, ease of fabrication, cost, and safety. Ease of use is weighted the heaviest at twenty points due to the team's main priority: making the manikin as easy to use by clinicians and students for training purposes as possible. Ease of fabrication, cost, and safety are all weighted at ten points due to the year long time line to fabricate, a target cost of $750, and the low probability of the clinician or student being unsafe while intubating. Design 1: Blocks scored highest in durability, ease of fabrication, cost, and safety. This design is made up of multiple 3D printed blocks that vary in size and can withstand multiple intubations without being damaged in any way. The blocks are 3D printed and for that reason they are easy to make as well as cost effective. The design of the

3D printed blocks will conform to the back of the head or neck to provide stability and allow clinicians to practice on an accurate model therefore increasing safety of the patient during surgery. Design 2: Flexible Lamp Design scored highest in ease of use, precision, cost, and safety. This design has the greatest adjustability of all three designs. The flexible rod mechanism makes this design easy to manipulate into different neck positions as well as help in the precision of the anatomically correct neck position due to its capability to make small adjustments to the neck angle. The flexible lamp rod is very cost effective, with parts being sold online at low prices. Due to the precision of this design the clinician will be able to practice a safe intubation procedure. Design 3: Pin Design scored highest in stability and durability. This design is able to lock in place with a pin that helps in stability of the entire manikin when intubating. Stainless steel will be used for the pin design and will therefore be extremely durable when undergoing multiple intubation procedures.

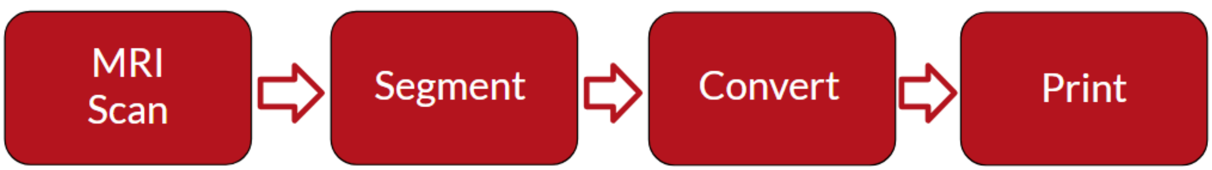
Proposed Final Design

Based on examination of the criteria above, the flexible lamp design is the best choice for a manikin with a modular neck. It is intuitive and precise, while also being affordable, safe, and simple to build. Some adjustments will be necessary in order to make up for the main downside of the design, which is a lack of support from below the head. The blocks design provides support that effectively counteracts the downward force experienced during intubation. A combination of the two designs will allow for a stable and easily adjustable training manikin.

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*



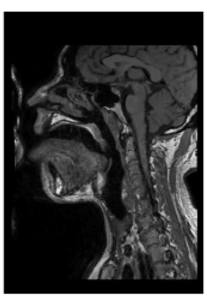


Figure 7: *MRI Scan*

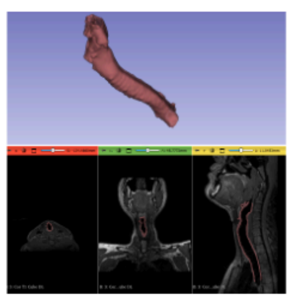


Figure 8: *3D Slicer Segmentation*

Figure 9: *3D Render*

Figure 10: *Solid Body*

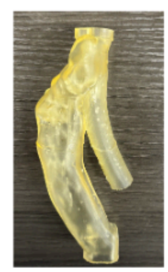


Figure 11: *3D Print*

To house the printed airways and provide additional difficulty factors, the team will be designing and fabricating an airway manikin. To do this, a silicone mouth and upper airway will be cast using a 3D-printed mold, the files for which are available on the Decent Simulators website. The mold is to be printed out of PLA and cast in platinum cure silicone rubber. This mouth and upper airway will be integrated into the manikin using a 3D printed craniofacial structure, which will also have features to support the adjustability of the mandible position. The team anticipates using basic filaments like PLA and ABS for this purpose due to their low cost, availability, and sufficient mechanical properties. The 3D printed and silicone head assembly will be further secured by a flexible metal rod which will act to create an adjustable neck angle. The rod will be integrated through a custom-printed mount to the skull and will also attach to the manikin baseplate. Additional adjustments like mandible positioning will be accomplished through fabrication of a separate jaw from the skull and creating various positions for the jaw to hinge. The team anticipates using 3D printing and any necessary hardware to fabricate this part of the trainer. Lastly, the team is looking to incorporate adjustable tongue size, which will either be done through an inflatable balloon method or with interchangeable tongues. This will likely be done by casting more silicone into custom-designed 3d printed molds. In conclusion, 3D printing will constitute the majority of the fabrication process, with silicone casting and hardware integration processes supplementing where needed.

Testing and Results

The team will be performing multiple tests to determine the efficacy of the airway trainer device. 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. Cyclic loading tests will also be done on the modulation of the device, to ensure that degradation is not seen with repeated swapping of airways or adjustment of neck angle, mandible position, or tongue size. Additionally, the time to adjust the manikin to these different conditions will be tested. This will involve testing the time required to swap airways, adjust neck angle, mandible position, and tongue size. 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 develop their own airway training manikin. The manikin should have modular capabilities including adjustable mandible position and neck flexion as well as a size adjustable tongue. The manikin should also have the ability to remove and replace airways. This way, multiple airways can be scanned and printed using the previously developed process, and used on the same airway trainer. The summation of these adjustments will allow for further specification of the patient's 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]. 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]. 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. 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 an anatomically accurate airway will ensure that clinicians will receive ample practice. Being able to attach these anatomically accurate airways to a lifelike manikin with modular neck position, an inflatable tongue balloon, and removable teeth would ensure that training is representative of realistic intubation scenarios.

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.
    - Generate a concrete method for taking a scan and converting it to a printable airway.
    - Print different types of abnormal airways to create a library of difficult airways for intubation practice.
    - Consider the modulation of the manikin to further increase the number of clinical scenarios for practice.
- A hypothetical model must be flexible, and represent accurate physiological biomechanics.
    - This model also must 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 manikin.
- 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. The neck of the manikin must be adjustable to various positions and capable of holding them indefinitely. The manikin must also have an adjustable mandible to create variation in craniofacial anatomy. The manakin will include a mechanism to add the obstacle of pressure sensitive teeth during intubation. The addition of an inflatable tongue and an ability for the manikin to vomit would also create further variation during intubation situations. The process of swapping out airways for one another must be repeatable, and the device must withstand thousands of iterations of this process. The device must also endure thousands of intubation cycles under typical use conditions without wear or loss of functionality. Typical use consists of inserting a laryngoscope blade into the mouth to lift the epiglottis, followed by the insertion of an endotracheal tube into the larynx and then the trachea [5]. Once airflow is confirmed, the blade is removed, followed by the endotracheal tube.

Furthermore, the fabrication process should be repeatable and precise, allowing for the consistent production of airway models representative of individuals with various airway abnormalities.

b. Safety

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

c. Accuracy and Reliability

The device should have a maximum percentage error of 5% for key measurements. These measurements include tongue to posterior pharyngeal wall (PPW), tip of tongue to vallecula, uvula to epiglottis, and more [6]. All measurements and specific values are in Section A of the appendix. Since the device is designed to model individual airway variations, certain measurements may deviate from those in the cited study. In such cases, dimensions will be determined on a case-by-case basis to ensure anatomical accuracy. To validate production precision, multiple devices representing different airway conditions must demonstrate accuracy and consistency. Additionally, the device's material must follow a typical tracheal Young's modulus of 16.92 MPa ± 8.76 MPa, depending upon the patient's age and condition, to ensure a realistic intubation experience [7]. The device should specify to the user any mechanical differences between the 3D printed airway and a typical human airway.

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)		

Table X: *Anatomical Measurements*

d. Life in Service

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

e. Shelf Life

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

f. Operating Environment

The device is meant to mimic a hospital setting with favorable conditions; room temp of 22°C 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 will not harm the 3D printed airway [10]. The airway will require routine cleaning 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 0.55m x 0.35m x 0.25m in size [14,15].

i. Weight

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

j. Materials

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

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

k. *Aesthetics, Appearance, and Finish*

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

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

2. Production Characteristics

a. *Quantity*

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

b. *Target Product Cost*

The client did not have a set budget for the team to follow, however based on the work done in previous semesters, the team will seek to stay below $750. The price for a standard airway management trainer made by the company Decent Simulators is $1,700 [22]. Creating a smaller section of the airway the product cost of just the airway 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. 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 [29].

d. *Competition*

i. Laerdal Airway Management Trainer [30]
   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 dollars which is a reasonable price compared to what else is on the market.

ii. Seven Sigma Airway Trainers [31]
   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 [32]
   1. Offer three different manikins including an adult and child version with more coming soon. All of which are meant to imitate an abnormal airway that is difficult to intubate.
   2. Feature an inflatable tongue to replicate conditions like obesity, down syndrome, and craniofacial abnormalities. Manikins also have adjustable mobility in the neck and spine as well as the ability to displace the larynx.

iv. Difficult Endotracheal Intubation Simulator [33]
   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 zero 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.

v. Decent Simulators [22]
   1. Fully modular manikin. Airways and other parts can be efficiently replaced within a training session.

2. MRI data used to recreate anatomical features with extreme accuracy
3. Allows for practice with difficult airways and various intubation positions, and includes features such as vocal cords and an interarytenoid notch.
4. The V2 airway management trainer costs 1,700 dollars, which is much cheaper than the Laerdal trainer.

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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**	