3D Printing Airway Trainers

Product Design Specifications (PDS)

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Client

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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.

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

Appendix A: Anatomical Measurements

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