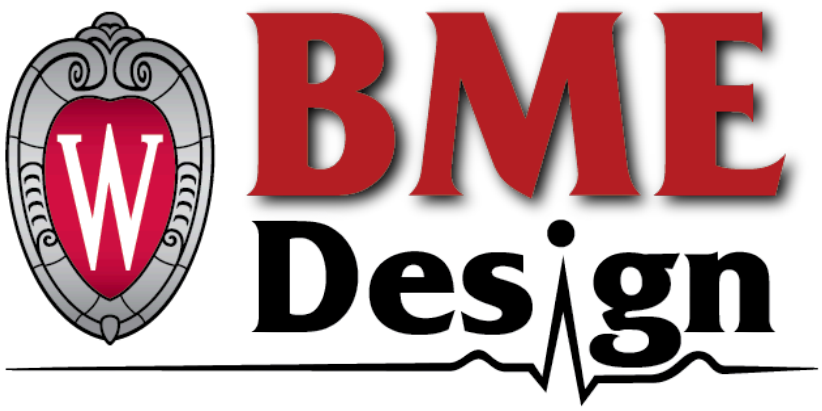

3D Printing Airway Trainers

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BME 200/300 Design Project

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Project Function:

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

Client Requirements:

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

- Cancer or lesions that may impact the size or properties of the trachea, epiglottis, or other airway structures
- Swelling due to diseases or injuries in different places in the upper and lower airways

Design Requirements

1. **Physical and Operational Characteristics**
    a. Performance Requirements: The device must be durable and support extended daily use by medical personnel learning the intubation process. It must also allow the intubation process to be completed in 45 seconds or less to prevent patient hypoxia [3]. A successful intubation means end-tidal carbon dioxide must be able to be measured to confirm placement in the trachea. [5]. The device's material must be flexible and lubricated with conventional water-based lubricants [3].
        i. Specific biomechanical properties that must be followed in order to ensure that the model has a life-like intubation experience are a Young's Modulus of 16 MPa ∓ 8 MPa depending on the patient's age or current condition and a Shore A Hardness of 80 to represent how a laryngoscope would interact with the tissue inside the airway [7, 8].
    b. Safety: To maximize accessibility to device training, the airway trainer must be made of non-toxic substances and consider allergens such as latex. The Standards and Specifications section of this document presents a specific standard dictating which materials are safe in medical devices. Additionally, the performance of this device must model safe intubation, as failure to do so could endanger future patients being intubated by professionals who were trained with this device.
    c. Accuracy and Reliability: This device must allow for successful ETI at least 96.8% of the time, as represented by the global success rate [6]. In order to ensure accuracy, the material characteristics of each model must fall within the appropriate range of Young's Modulus and Shore A Hardness for the patient. These values may fall out of the listed range above, but if multiple models are made of the same airway, their properties must be identical to ensure that no matter which trainer is used, they both accurately represent the anatomy.
    d. Life in Service: The airway portion of the design is made to be able to support 20,000 intubation cycles, consistent with the AirSim Pierre Robin X model with the use of standard intubation lubricants [9]. Upon failure of the device, the model will be designed for easy replacement of the airway portion to reduce cost and waste.
    e. Shelf Life: The airway trainer should be stored with protection from severe values of pressure (1 atm), humidity (<70%), and temperature (0 ℃ - 22℃) [10,11]. The

design's material will be vastly silicone-based, and silicone maintains its material properties for a minimum of 2 years with no statistically significant change [12].

f. Operating Environment: The product is designed to mimic ideal conditions consistent with the hospital setting [13]. This range of conditions includes humidity values less than 85% and low subjectivity to substances other than typical water-based lubricant [14-16]. The model is designed to be resilient to typical forces associated with typical intubation techniques, around 42 N on average but can very based on the patient's size and weight [17].
g. Ergonomics: The product is designed to simulate intubation processes on patients with complex and uncommon airway conditions. Replicating the ergonomics of actual intubation will allow for a decrease in intubation-related injury, such as dysphagia (43%), pain (38%), or hoarseness (27%) [18]. The product will be designed for practice intubations to allow more opportunities to practice low occurrence, high acuity situations for healthcare providers. The product is thus designed for only such forces associated with intubation and not to put unnecessary strain on the medical provider while practicing [19].
h. Size: The device should replicate the size of an adult head, neck, and upper thoracic cavity. Existing airway trainers already on the market that possess a build similar to what this device should have been constructed with dimensions of approximately 0.55m x 0.35m x 0.25m [20, 21]. This will enable users to realistically simulate the experience of conducting airway management on a patient. There will be a regular adult model and a bariatric adult model, which will be larger if time allows. The thoracic piece of both models will be detachable from the head and neck portion, allowing different airway pathologies to be substituted, thus increasing the model's versatility.
i. Weight: The airway trainer should be light enough to be easily transferred to different locations and used by different individuals if need be. The majority of existing airway trainers that are currently sold by major distributors weigh 5 to 19 kg [22, 23]. The trainer should ideally be in the range of 10 to 15 kg so that it is sturdy enough to not shift around when airway management training is occurring, but to also prevent it being so heavy that it loses its portability.
j. Materials: The trainer must be made of materials that find a balance between providing a realistic feel of the airway while also having flexibility and durability. The goal for the materials is to fit within the Young's Modulus and Shore A Hardness thresholds discussed above, but the client will make the final decision on the level of realism each material has. The trainer must also be resistant to the water-based lubricant that would likely be applied to the airway management equipment. Materials that fit these criteria and are common in popular airway trainers include polyvinyl chloride and silicone, which are able to handle the wear

and tear that accompanies airway training while still providing a lifelike feel [24, 25].

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

2. Production Characteristics

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

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

3. Miscellaneous

a. Standards and Specifications:
   i. ISO/IEC 3532-1:2023: Information technology - Medical image-based modeling for 3D printing - Part 1: General Requirements [28]
      1. This standard sets forth the requirements of accurate medical modeling for patient care. This ensures that the data that is recorded from a CT or MRI machine is accurately read and processed by a slicing software, such as 3DSlicer.
   ii. ISO/IEC 3532-2:2024: Information technology - Medical image-based modeling for 3D printing - Part 2: Segmentation [29]
      1. This standard sets the requirements for the process of slicing, augmenting, and 3D printing modeling of human bone for use in surgery. It also provides a process to increase the performance of bone segmentation.
   iii. ISO 15223-2:2010: Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied [30]
      1. This standard helps ensure that symbols produced in accordance with a similar standard (ISO 15223-1) are easily understood by the

target audience. Following this standard will help limit the damage and harm to both the product as well as the user.

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

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

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

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

c. Patient-related concerns: The product will not directly be in contact with patients or be part of the patient care setting. This device will be used to train individuals providing care to the patient before the patient interaction starts. However, the tools and devices used to perform advanced airway procedures must not be exposed to harmful substances or environments that cause them to deteriorate

before being used to treat the patient. For example, the product cannot contain any material that is corrosive to metal due to the inability to autoclave the laryngoscope after this interaction occurs [34].

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

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