MCEN 4085: Engineering for Social Innovation

Toobtek Intubation Trainer: End of Year Report

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1 Executive Summary

The purpose of the Toobtek intubation trainer project is to create an anatomically relevant fiberoptic intubation training model for medical professionals. The goal in creating this model is to better prepare medical professionals for cases of difficult airways, which arise due to underlying breathing complications, airway obstructions such as tumors and lesions, and other underlying health conditions. Difficult airway intubation procedures present challenges for medical professionals, as they do not have the adequate training to be able to handle these situations. This lack of training on difficult airways leads to improper intubation practice, which can prove fatal for patients. Examples of these complications include reduced blood oxygen levels and esophageal intubation, where the breathing tube is inserted into the esophagus instead of the trachea, both of which prove life-threatening. Intubation models are also cost-inaccessible for hospitals in the current economic climate, as they are currently experiencing financial struggles due to the COVID-19 pandemic. Finally, competing intubation models do not accurately represent the mechanical and geometric properties of human tissue, failing to accurately simulate the human airway.

The team's work during the Spring 2021 semester built upon the design from the Fall 2020 semester, which was centered around connecting a set of 3D printed respiratory components. The team used polyvinyl chloride (PVC) tubing and placed all the individual components into a black box to simulate the practice of fiberoptic intubation within a real human airway. The team's major areas of emphasis during the Spring 2021 semester were testing and data analysis, creating a viable tradeshow-ready prototype, and competing in the CU Boulder New Venture Challenge (NVC).

The first major area of emphasis was testing and data analysis, which the team approached through developing a test plan outlining the relevant tests to be performed on the device. This included comparing the prototype tracheas, stability testing, flexure testing, shore hardness testing, assembly and modularity testing, dimensional inspection, and collecting user feedback from medical professionals. The team then performed these tests, starting with the prototype trachea models, one translucent and one opaque. These prototypes were first printed using Agilus30 and VeroVivid as the print materials. Printing of these prototypes was completed through use of Stratasys J750 and J850 printers at both Robert MacCurdy's laboratory at CU Boulder and Medtronic. Once fabricated, testing commenced at Denver Health Medical Center with several CRNAs and anesthesiologists. Data was collected to on several key attributes such as color, hardness, and flexure, to see how well the models represented real human tissue. The main takeaways from the professional feedback included 1) the need for more pigmentation and color variation and 2) the need for more anatomical structures above the trachea in a finalized training model. The team also performed shore hardness testing of the trachea prototypes to assess whether they matched the desired values for real human tissue. When conducting this test, the team noticed that there was no way to use a Shore A hardness test for both the translucent and opaque trachea models. This forced the team to pivot in favor of a new sample, a rectangular sample that allowed for a Shore A hardness test. Performing this test yielded a trend in the residuals plot, indicating that the reported hardness values from Stratasys were calculated assuming a linear relationship between the constituent material properties.

The team then fabricated the full prototype and performed another series of tests on its properties and quality. The first of these tests was flexure testing on cylindrical samples, mimicking soft tissue and cartilage where the instantaneous elastic modulus of the device was measured through with help from the CU Boulder Tissue Biomechanics Laboratory. Testing revealed the instantaneous elastic modulus of the soft tissue and the cartilage were 1.25 MPa and 2 MPa respectively. These values were both are on the order of magnitude of soft tissue (0.5 MPa) and cartilage (1 MPa). The team believes that in subsequent design iterations, the overall hardness of the material can be reduced to ensure anatomical relevance of the model. Moreover, the team also conducted a second round of testing with Denver Health with the full prototype, observing significant improvements from the first round of testing. Medical professionals felt engaged in using our model as a training tool, giving it an 8/10 overall score, a point above the team's target of 7/10. While the team met its goal, we

believe that with continued testing and iteration, we can raise this score to 10/10 overall before the product is ready for full-scale production. Currently, testing is also being conducted to verify the stability of the model. For this test, the prototype is subjected to an external applied force of 5 *lbs* from an LCM 300 load cell sourced from the Integrated Teaching and Learning Laboratory (ITLL) at CU Boulder. Data is being collected on how the model responds to this force load in order to help the team better assess how long a medical professional can depend on this device to train consistently. Future testing will assess the modularity of the device to help understand the device's functionality as an interchangeable model that can be used to simulate a variety of airway management procedures.

The second major area of emphasis was re-designing the model to be a viable tradeshow-ready prototype. One of the major considerations was to reduce the number of components used in the complete device. One of the team's goals during the Fall 2020 semester was structural integrity of the device, which was to be achieved through the use of connection mechanisms both on the inside and the outside of each component. This was also meant to make it easier to view the fiberoptic scope while training, as this is important for medical professionals to gain the consistent practice that they desire. The team's work during the Spring 2021 semester changed this approach significantly, as the team focused on consolidating the subassemblies of the device to be single body components, reducing the complexity of the final assembly allowing the interchanging of components to be significantly easier. This was achieved through combing the anterior and posterior sections of the trachea and bronchi to create one trachea and two bronchus components, streamlining and consolidating the larynx from its right and left sections, and modifying the connections. These changes were made since the components are designed using a somewhat translucent material, meaning that inner connection features are not required. The overall results of the consolidated components were largely positive, as the the part count dropped significantly, the connections were much more stable, and the color was more aesthetically relevant. This redesigned model satisfied the team's goals of creating a modular and simple human respiratory model that is both capable of withstanding intensive use in different environments and anatomically relevant in reflecting the visual properties of the human airway.

The third and final major focus was competing in the NVC. Throughout the duration of this competition, the team was matched with various mentors and business experts within the Boulder community who helped address concerns with intellectual property (IP), go-to market strategy, and competitive positioning, as well as strengthened our business case for this device. The team also attended various workshops and presentations to guest judges to get an understanding of the expectations for the competition. Overall, the team performed very well in the competition, finishing in 3rd place among more than 150 competing teams and winning $\$16,000$ to pursue this solution as a business. The team is planning on using the funds to cover the filing the provisional and utility patent applications and to help cover the cost of materials to produce additional models that will address cases of difficult airways and other airway management practices, such as bronchoscopy and laryngoscopy.

Throughout this semester, the team remained on schedule with completing all deliverable items. The team also met regularly as a group and with its director to discuss updates on the product and to address upcoming design milestones and deliverables. Collectively, the team spent a total of 1312 engineering labor hours working on this project, translating into an internal labor cost of $\$81,411$ for this semester, as of April 19, 2021. The team estimates a total of 1344 labor hours to be completed at the end of the Spring 2021 semester. When accounting for a 5% contingency and a 40% overhead recovery and profit, the total estimated budget for this project is $\$125,437$. The team also estimates that materials expenses of $\$1,537$ for the entire project. This amount includes the cost of printing prototype models of the trachea for preliminary testing, the cost of the tubing connectors, the cost of printing the final model, and any additional costs that the team would encounter, such as the costs of the black box enclosure for the final model and materials for presenting at the Senior Design Expo.

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2 Background

2.1 Overview of Intubation Procedures

Intubation* is defined as a ventilation procedure involving the insertion of a tube into a patient's respiratory system to assist a patient in breathing [1]. It proves useful in providing ventilation to patients who are given general anaesthesia before surgery or have an illness causing difficulty with breathing, such as pneumonia, lung infections, or tuberculosis. While intubation can clearly be considered as a lifesaving procedure, it can prove fatal due to the subsequent complications it creates. The probability of survival for trauma patients drops by almost 22 percent when they have one or more complications resulting from endotracheal* intubation, a very common intubation procedure [2]. Such complications include: cardiac arrest, reduced oxygen levels in the blood, and damage to the esophagus due to esophageal intubation, or incorrect insertion of the tube into the esophagus instead of the trachea.

Standard intubation practices involving the insertion of a tube into the respiratory system are also limited in their capacity to address cases of difficult airways. Difficult intubation* is defined by the University of Iowa Health Care Center as a procedure involving "more than 3 attempts at intubation" or "nonstandard equipment or approaches" [3]. Difficult airway cases*, such as tumors obstructing the airway and broken jaws preventing free motion of the patient's mouth, require a more specialized intubation procedure called fiberoptic intubation.

Fiberoptic intubation* addresses difficult airway cases through on the insertion of a fiberoptic scope into the human respiratory system, as shown in Figure 1. This procedure allows for visualization of respiratory components beyond the depth of standard intubation tubes. According to the New England Journal of Medicine, fiberoptic intubation proves useful in dealing with both anticipated and unanticipated cases of difficult airways, providing medical professionals with strategies to more comprehensively treat intubation patients [4]. Fiberoptic intubation addresses difficult airway cases through on the insertion of a fiberoptic scope into the human respiratory system, allowing for visualization of respiratory components beyond the depth of standard intubation tubes.

Fiberoptic intubation is also currently the "accepted standard" when it comes to dealing with cases of difficult airways due to the decreased risks of performing intubation prior to the onset of anesthesia [5]. Given that the incidence of difficult intubations amounts to 37,500 occurrences per year in the United States alone, it is imperative to improve intubation training for medical professionals to address difficult airway cases [6].

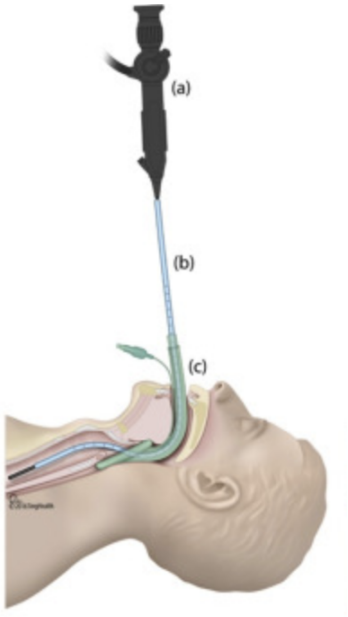

Figure 1: A diagram of fiberoptic intubation [7]

2.2 Product Overview

Toobtek's intubation training model is built on four major features. The first of these features is the anatomical relevance of the model. Through the materials research conducted, the team has identified materials that will replicate the mechanical properties of real human tissue, namely its shore hardness and flexure. Thus, each component of the final model shall resemble the characteristics that would be found in real human anatomy, providing medical students with a more realistic

*Definition can be found in Appendix A: Glossary

intubation simulator.

The second major feature is a tactile training approach to intubation training. The components of the human respiratory model will be enclosed within a black box, with a hole punctured in side of the box. This hole will serve as the opening for placement of a fiber optic scope, allowing for the student to practice intubation. The black box can be opened or closed at the user's leisure to give the user ample practice with observing where their scope is located, which will help them master the navigation of the human airway in a more comprehensive manner. Current intubation training models are focused around a traditional human dummy model, where the student can visually observe the placement of the scope within a model human head, or human dummy, and observe the effects. Toobtek's intubation training model is different in that the student doesn't always see where the scope is positioned, forcing the student to master the procedure of orienting the scope at all points within the model.

The third major feature is interchangeable respiratory components. This feature allows for the modeling of progressively more difficult airway situations within the same simulation device, such as broken jaws and tumors that create airway obstructions. Moreover, interchangeable components allow the model to account for differences in the anatomy of children and adults. Overall, interchangeable components allow the model to easily be modified to account for cases of difficult airways and differences in patient-specific anatomy. This provides intubation professionals the ability to modify the airway simulator, preparing them for the inherent complications that arise when intubating a patient.

The fourth major feature is the portability of Toobtek's intubation training model. Designing the model to be portable allows for it to be transported easily between different training sites. The weight savings realized through constructing a portable training model allow the team to optimize the overall functionality of the device, while alleviating materials expenses during the manufacturing process. Lower materials expenses during manufacturing allow for the team to produce a less expensive intubation training device. Thus, the team's goal of designing the final model to be portable will provide an affordable product to hospitals at a time when they face significant financial struggles. This will also allow the device to achieve significant market value in hospitals across the United States.

2.3 Summary of Final Design

The team's final design, shown in the photo below, will incorporate the tactile approach to intubation training that was a focal point of the Fall 2020 semester. It will consist of a set of human respiratory components, including the larynx, trachea, and bronchial trees, that will be connected using PVC tubing connectors and enclosed within a black box enclosure, which is structurally reinforce by foam that has been laser cut to fit around the airway components. This design meets the four major features discussed above in the product overview, which are anatomical relevance, a black box approach to intubation training, interchangeability, and portability. Through extensive quantitative and qualitative testing that has involved input from medical and tissue biomechanics experts, the team has verified that the device is indeed anatomically relevant. Through re-designing the model to reduce the overall part count and eliminating unnecessary additional components such as interior connection features, the team has also succeeded at making the components more interchangeable, as the model itself is composed of single body components that can be disassembled and reassembled as needed to mimic different airway procedures that medical professionals are training for. Further, the device is also portable and incorporates a tactile training approach, as the enclosure of the components within a black box ensures that the model can be easily transported between training sites, increasing its exposure to significantly more medical professionals, and can serve as a viable training tool for medical professionals through the easy opening and closing of the black box to check the scope's location at any point during the training period. Through redesigning the model to be significantly simpler in its part complexity and overall modularity, the team has succeeded in

creating a training device that medical professionals can depend on when training to administer this life-saving procedure.

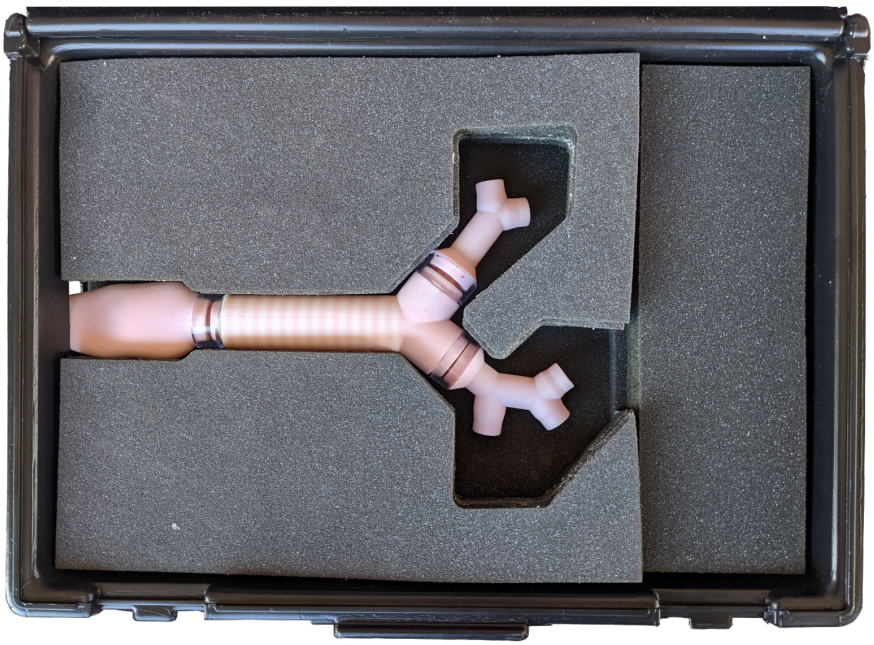

Figure 2: Picture of the final prototype

3 Market Demographics

3.1 Target Market

The team has identified all hospitals in the United States as our target market*. The American Hospital Association* finds in a 2018 study that there are 6,146 total hospitals in the United States [8]. This number accounts for hospitals in US communities, federal government hospitals, and non-federal psychiatric hospitals, as shown below in Figure 2. Selling the product to this market would allow for intubation professionals across the United States to become equipped to handle cases of difficult airways, the ultimate goal of this product. The team assumed a price point of $\$1500/unit$, which is consistent with competing models and 5 models per hospital, due to the current purchasing behavior of hospitals, which is between $\$5,000$ and $\$10,000$ for a comparable intubation training device. This gives our product a total addressable market value of $\$158.8 million$ for our base airway model alone, which is not accounting for additional models that will be produced at a higher price point to address cases of difficult airways and other airway management procedures, such as laryngoscopy and bronchoscopy. Pricing our model in this way allows us to sell more models to hospitals, equipping more medical professionals with the tools to be successful with fiberoptic intubation. With 37,500 difficult airway cases every year in the United States, as mentioned above, getting medical professionals trained in intubation practices and procedures is imperative in providing patients with appropriate treatment [6].

Total Number of All U.S. Hospitals	6,146
Number of U.S. **Community** [1] Hospitals	5,198
Number of Nongovernment Not-for-Profit Community Hospitals	2,937
Number of Investor-Owned (For-Profit) Community Hospitals	1,296
Number of State and Local Government Community Hospitals	965
Number of Federal Government Hospitals	209
Number of Nonfederal Psychiatric Hospitals	616
Other [2] Hospitals	123

Figure 3: Breakdown of hospitals across the United States [8]

3.2 Beachhead Market

The beachhead market* that the team has identified is hospitals in Colorado. Research that the team performed shows that there are about 100 hospitals in Colorado, and assuming that the team sells 5 models per hospital at a price point of $\$1500/unit$, this gives a total beachhead market value of $\$750,000$ [9]. The team feels confident in capturing this market due to our presence and network at Denver Health Medical Center, which has given us a viable launching point to establishing our brand in the Denver Metro Area, and eventually expanding across the state of Colorado.

3.3 Market Summary

The current state of the medical device market provides an opportunity for a less expensive intubation training model to realize significant market value, since demand for ventilator technology is growing due to the recent COVID-19 outbreak. Within the time period from 2019 to 2020, the market value of the global ventilators market is expected to grow from $2.4 billion to $12.1 billion [10]. As a result, educating medical professionals on intubation methods is becoming a more pressing need for hospitals. Furthermore, offering a less expensive intubation training solution will alleviate the current financial burden placed on hospitals due to their recent efforts to treat COVID-19 patients. According to the US Department of Health and Human Services*, hospitals currently face the reality of diminished revenues and increasing costs due to the COVID-19 pandemic [11]. The pandemic has forced hospitals to pull back on offering elective procedures like surgical implants and amputations in favor of purchasing medical equipment to respond to COVID-19 cases. Due to the current financial struggles of hospitals and the rising need for ventilation methods to treat this virus, Toobtek's intubation training model will prove useful to hospitals. It will provide a less expensive and accessible product for medical professionals to master the basic skills necessary to intubate successfully.

3.4 Competition

Current intubation training models range in price from under $100 to tens of thousands of dollars. These models that were researched fell in the price range between $73.95 and $13,364.85. The majority of the less expensive intubation training models were used for demonstrating the basics of intubating a patient. These products allow for students to visualize important features of intubation procedures, such as open and closed airways and the tilting of the patient's head. Models like these provide an overview of the basic types of intubation and orient students with the relevant anatomy of an intubation procedure. However, they do not allow for students to actually practice intubating a patient. These models also do not provide a method of assessing the user's ability to intubate, which limits their practicality as a training model for medical students. More expensive intubation training models differentiate themselves in this regard, providing both auditory and visual feedback for students. These visual and audible cues provide students with the ability to validate their intubation knowledge and assess their skills. Many of these models are also optimized for specific use cases, including Amyotrophic lateral sclerosis (ALS)* and edema*, providing a useful template for students to build their knowledge of common cases of difficult airways. Since these models have been optimized for specific difficult airway cases, they do not offer the ability to interchange respiratory components. These models also do not provide visual tracking of tube or scope placement throughout the intubation process. Rather, these models provide feedback only in response to certain triggers such as audible sounds when the user makes a mistake with scope placement, which serve to validate or invalidate the student's approach.

3.5 Customer Development

Over the course of this semester, the Toobtek team has conducted a series of customer development interviews regarding the final design. These interviews have helped shape the team's vision around the final product, while also illustrating the need for a less expensive and more anatomically-relevant intubation training device. Interviewees have included CRNA students who have experience practicing intubation using current methods, doctors who have experience with both demonstrating and administering intubation procedures, and industry experts who have experience building ventilation-based devices.

CRNA and medical student interviewees have expressed the need for more anatomical relevance in the simulators they use to practice intubation. They have also elaborated on the lack of a developed curriculum for learning intubation in medical school, which puts them at a disadvantage when it

comes to their experience with intubating patients prior to entering their profession. Industry experts have further elaborated on the need for a training simulator that accounts for cases of difficult airways, which are difficult to predict and respond to with current intubation models. Experts also stressed the importance of a device that can remain functional given different environmental conditions, such as an ambulance jostling the patient around due to an uneven road. These interviews have helped drive the team's focus towards building a model that is more anatomically-relevant and also more portable than competing models. These goals are achieved through through the use of interchangeable components and through the enclosure of respiratory components within a black box. The team hopes to continue subsequent rounds of customer development as further refinement of the product concept continues.

4 Product Requirements

4.1 Initial Requirements

In order to achieve our goal of alleviating user pain points, we have set forth specific requirements outlined in the Toobtek Product Requirements and Specifications sheet. By meeting each of our requirements, we will create an intubation training device that is anatomically relevant, with an emphasis on shape, color, and stiffness. The device will also be portable, accessible, and functional. These requirements were first established early on in the design process and have undergone iterations to ensure viability and customer satisfaction. One of these iterations included color matching the inside of the trachea using a human biologically similar trachea harvested from a cow. Qualitative data pertaining to flexure and hardness were also acquired via this method. Along with conducting qualitative analyses of our product, we also tested our requirements using sophisticated equipment and testing methods. The testing plan for these requirements is outlined in section 7.

4.2 Detailed Requirements

After conducting a series of customer interviews, we established the following design requirements that would allow for our final product to be completely user-centered.

4.2.1 Anatomical Relevance

In order to achieve our goal of anatomical relevance, the team conducted extensive materials research to identify three composite materials that when all combined, created an end product that both looked and felt like real human tissue. We determined the color of the respiratory components based on user testing and were able to incorporate it into the final model. We also created the individual respiratory components to have the same dimensions as real human anatomy based on an average sized adult male.

4.2.2 Interchangeability

We designed all of the individual components of the training model to be easily switched out in order to allow for our device to be used in a variety of different scenarios, including bronchoscopies and laryngoscopies, along with intubation. This design also allows for different airways to be exchanged for difficult ones to encapsulate procedures on patients that suffer from injuries, tumors, lesions, or other ailments.

4.2.3 Accessibility

This design requirement is based on Toobtek's value proposition to create a model that will not only provide more comprehensive training, but also provide increased training accessibility for a larger number of medical professionals. We found that many of our competitors do not offer models in a price range that allows for purchasing multiple training devices, creating a training barrier for many medical professionals. We designed our model to be priced at approximately a third of the price of the average comparable training model. This allows for multiple training devices to be purchased by hospitals for the same cost as a single unit from one of our competitors.

In addition to cost accessibility, Toobtek's intubation training device is also designed to be physically accessible. This means our device is lightweight and portable, allowing for it to be transported with minimal effort to different training sites.

4.2.4 Modular Training Approach

Not only does Toobtek strive to provide a better training experience for medical professionals, but also a more comprehensive one. In order to do so, the team incorporated a modular training approach that mimics the environment of an actual intubation procedure. To accomplish this, we designed our model to be easily opened up so the user can check his/her progress inside the model. In addition, when the model is completely closed, there is no visibility of the scope to the user, similar to what would be experienced during a real intubation procedure.

4.3 Regulatory Requirements

After conducting thorough research and consulting experts in the legal field, we found that according to Section 201[h] of the Food, Drug, and Cosmetic Act, our device is not classified or as a medical device. Therefore, we did not need to adhere to strict regulations set fourth by the FDA or other regulatory agencies. Due to the fact that our device is to be used in a hospital setting, we also specified the insurance codes that would be used to purchase our device. Our device will also adhere to the American Medical Association's (AHA's)* current procedural technology (CPT) insurance codes, which are AMA CPT 0558T-AMA CPT 0562T, which pertain to 3D printing human respiratory components

5 Design Overview

5.1 Motivation and Approach

Toobtek's mission is to provide medical professionals adequate training in order to perform fiberoptic intubation on patients with difficult airways with confidence. In order to meet this goal, the team has designed a human respiratory model that features anatomically relevant features to mimic geometries, tissue properties, and networks. Other necessary design considerations such as portability and interchangeability require the device to be lightweight, modular, and easily handled.

The device's features are centered around user pain points. Major considerations are simplicity and anatomical relevance. To achieve simplicity in assembly, the design minimizes the number of parts and connections. For anatomical relevance, the team conducted many hours of materials and 3D printing capabilities research to find material combinations that most accurately represented soft tissue, cartilage, etc. This material also is slightly translucent, allowing the user to get an exterior view of where they are in the simulation via the scope's guide light. The team also incorporated MRI DICOM data into the geometries of the device.

Finally, the product offers customization of each section, providing the user the opportunity to inspect difficult airways such as that of a child or an airway with lesions or tumors. By using MRI scans as a source for models, portions can be swapped out with almost any subject's specific airway geometries. The upper airway is the most likely candidate for this sort of customization because it's where professionals identify a majority of complications. This section is already based on MRI scans making this part is already easily customizable.

5.2 Anatomical Considerations

In order to provide proper training, the intubation training device needs to be anatomically relevant. This requires the device's networks to be identical to the human respiratory system's network, specifically requiring branching into 2 sections at the carina. The right side then further branches into 3 distinct lobar (secondary) bronchi while the left side features only 2 distinct lobar bronchi. In a human subject, these bronchi would continue branching off to tertiary, 4th degree, 5th degree, etc. bronchi, but for manufacturing and training purposes the secondary act as terminals of the respiratory network.

In order to best match the anatomy of a human respiratory system, research was completed concerning the dimensions of each of the various components. The measurements used are detailed in Table 1. It should be noted that while the values found in the source are in ISO units, values were converted to ANSI for CAD and design purposes.

Table 1: Male Human Respiratory Measurements

Feature	**Diameter [cm]**	**Uncertainty [cm]**
Upper Trachea Coronal	1.8	± 0.24
Lower Trachea Coronal	1.8	± 0.23
Upper Trachea Sagittal	2.06	± 0.27
Lower Trachea Sagittal	1.86	± 0.27
Left Main-Stem Bronchi	1.16	± 0.17
Right Main-Stem Bronchi	1.02	± 0.22

Additionally, materials research was conducted surrounding the properties of human tissue the team is attempting to represent based on the project requirements. These materials are detailed in Table 2; the cost associated with each material along with other possible material choices is detailed

in Table 3. Three materials will be purchased so that tests can be conducted on each to determine which material best matches our project goals. Once a material is chosen, the final model will be manufactured from the chosen material. Values for the Shore Hardness of our prototyping materials can be found in Table 2. Although the team has a target for instantaneous Elastic Modulus, this quantity is difficult to measure for viscoelastic materials, and thus manufacturers do not report it for these materials.

Table 2: Prototype Material Choices

Material	**Shore Hardness**	**Printer**	**Site**
FormLabs Flexible 80A Resin	80A	Form3	ITLL
Digital materials (emphasis on Agilus30)	$>$ 30A	Stratasys Objet J750	MacLab
Digital materials (emphasis on Agilus30)	$>$ 30A	Stratasys Objet J850	Medtronic

All materials in Table 2 are available in a translucent variety, which will allow for the customization of the final part color using resin dye.

5.3 Second Iteration Improvements

The design for Toobtek's intubation trainer between the first and second iterations undergone extensive rework. Major design changes include the removal of the rigid outer shell, the removal of the alignment pins, and the addition of standard connectors. These changes address the manufacturability and design aesthetic concerns with the first design iteration.

Originally, the outer shell was designed to keep the model in place and allow for interchangeable inlays, but the team pivoted from this idea due to its unrealistic stiffness. Additionally, the outer shell was removed in order to better match the Modulus of Elasticity* of human tissue, which is approximately 1 MPa. In lieu of this, the entire sub-assemblies are easily interchangeable. This will allow for the design to achieve the goal of having modular and customizable parts while retaining flexibility. Additionally, these changes reduce the complexity of the design without compromising functionality.

The next two major changes tackle the problem of alignment and connection of the parts. The alignment pins would not have allowed the design to the aesthetic or quality standards. Additionally, alignment pins increase the complexity of assembly. This complexity would reduce the overall ease of use and likely limit the customer satisfaction for this device. Toobtek has since standardized the connectors to both align pieces in each sub-assembly and connect different sub-assemblies together. These connectors would have been spaced to allow for the user to observe the fiber optic scope between components while using the device.

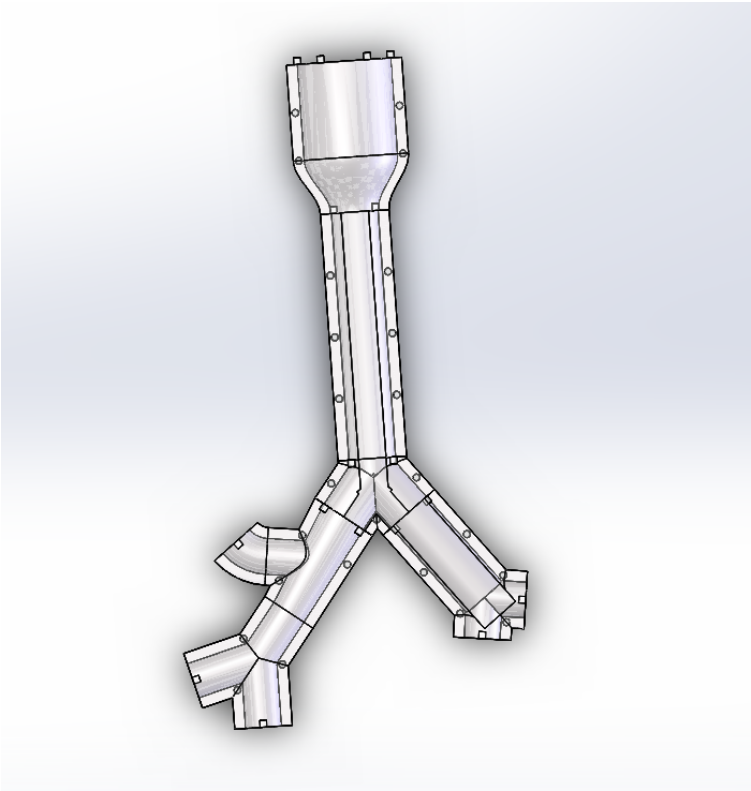

Figure 4: CAD model of the first iteration airway design of the product.

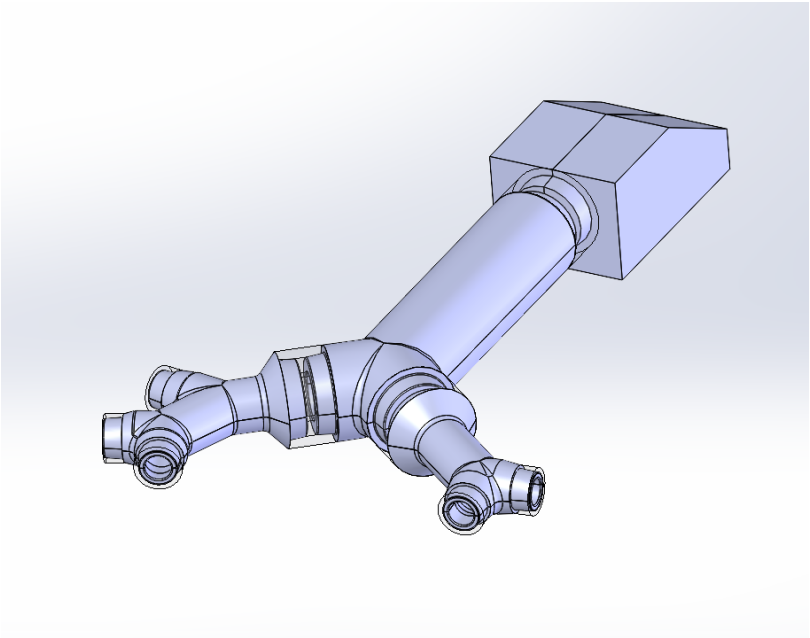

Figure 5: CAD model of the second iteration airway design of the product.

5.4 Final Design

For the final design of the prototype, all subassemblies were consolidated to be single body components. This means the anterior and posterior sections of the trachea and bronchi were combined to create one trachea and two bronchial components. The larynx was also consolidated from its right and left sections, while also receiving a much more streamlined profile. Between sections, the inner connectors were also removed, and the outer connections were shortened to remove the viewing window between components. Because the light from the fiberoptic scope is visible through each component, these viewing points were unnecessary.

With the consolidated components, the devices part count dropped significantly, meaning that the assembly process instantly became much easier. This also made the connections much more stable and capable of more intensive use. The color of the device was also tuned to make the overall aesthetic of the device to be much better than in previous iterations.

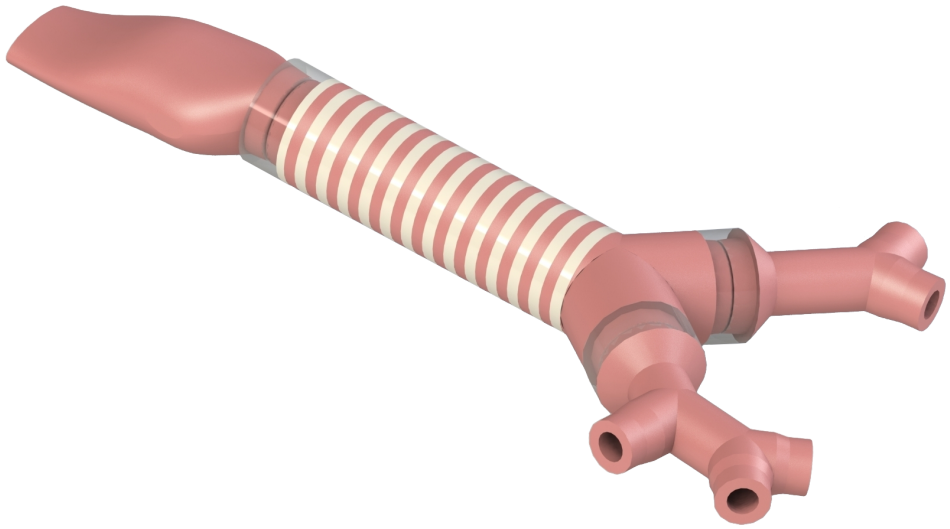

Figure 6: Render of the current airway design of the product as of 4/25/2021

6 Detailed Design

6.1 Trachea

The trachea section includes the carina and acts as the bridge between the other three components. It features an outer radius of 1.25in and includes cartilage rings represented by a fluctuating diameter and harder material along the length of the trachea to the carina junction. These cartilage rings have a maximum and minimum diameter of 0.875in and 0.850in, respectively. From the carina junction to the bronchial tree* connection points, the inner diameter is reduced to 0.500in. The trachea connects to the larynx and two bronchi via a press fit into the connectors (see subsection 6.5).

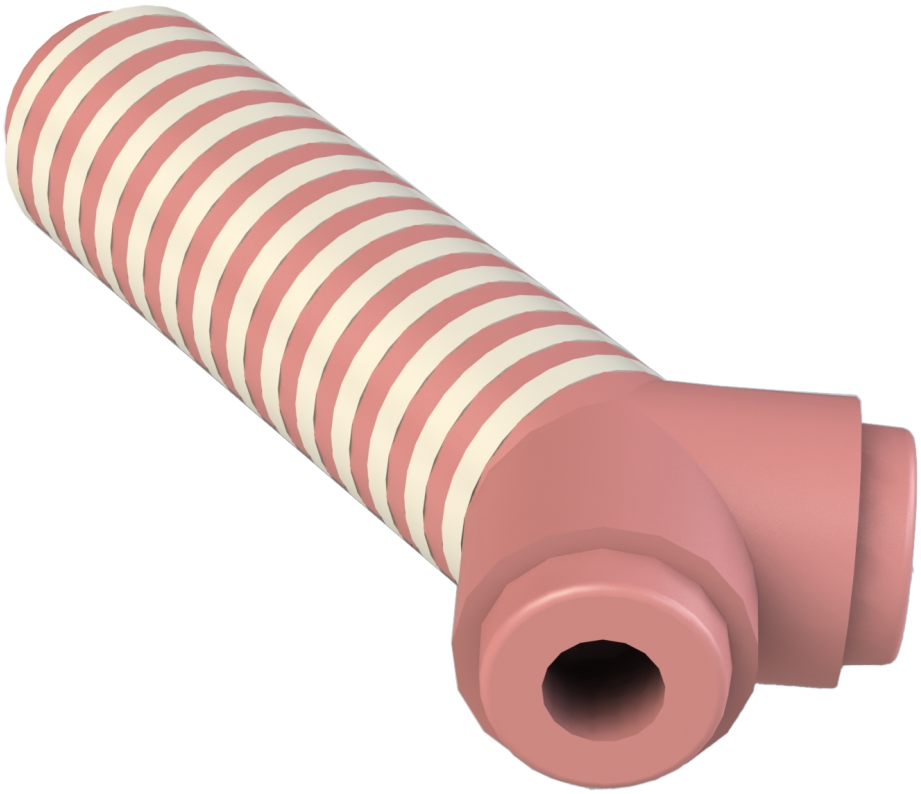

Figure 7: CAD model of the trachea component of the product.

The trachea also features the trachealis muscle*, represented by a small round protruding feature along the posterior wall, terminating at the connection to the larynx and the carina junction. The trachea includes both interior and exterior fillets of 0.10in radii at the carina junction. There are also three include 0.25in long connecting surfaces at each interface. These features allow the clear PVC tubing to fit tightly to the parts. Though the trachea looks symmetrical, the bronchi stems branch off at slightly different angles with the more inline one connecting to the right bronchi component.

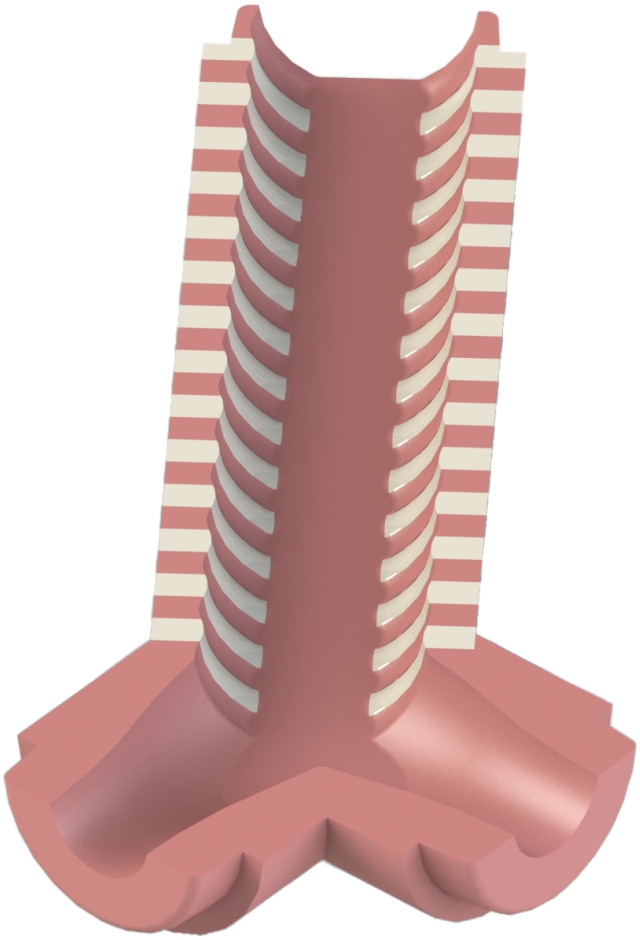

Figure 8: Cross section of the CAD model of the trachea component.

6.2 Right Bronchus

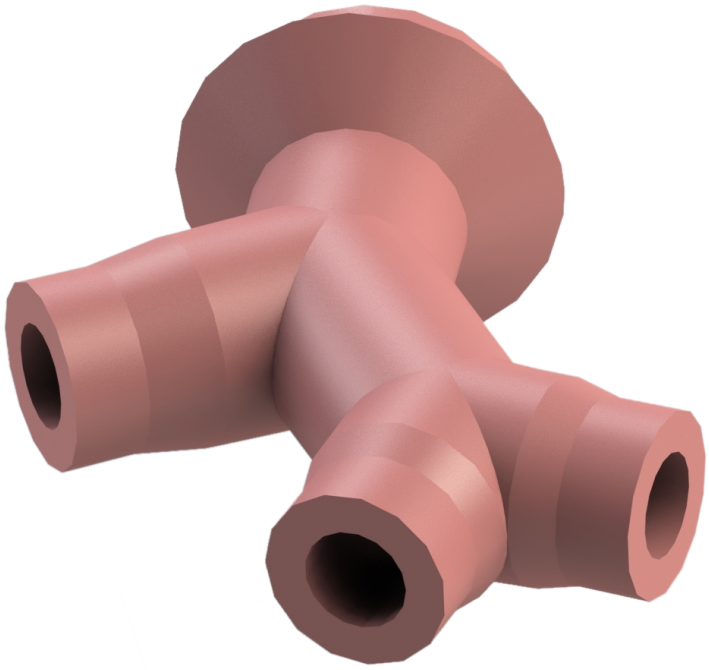

Figure 9: CAD model of the right bronchus component of the model.

The right bronchus connects to the trachea via its more inline bronchus stem. Unlike the trachea, the interior has a non-fluctuating diameter that reduces at each junction starting from the trachea connection point. The outer diameter begins at 1.00in to connect to the trachea and reduces to 0.70in before the first junction. All 3 branches have an ending diameter of 0.350in. As with the trachea, the part has a 0.25in long connection feature where the trachea meets the right bronchial tree. The part's material is uniform and utilizes the soft tissue representation.

6.3 Left Bronchus

The left bronchus connects to the trachea at the other of its bronchus stems. Like the right bronchus, this part has a non-fluctuating diameter that reduces after the single secondary bronchi junction. The outer diameter begins at 1.00in on the trachea connection end and reduces to 0.70in over 0.25in towards the junction. There is one connection feature similar to the other components to connect to the trachea via PVC tubing. The left Bronchus' material is also uniform and utilizes the soft tissue representation.

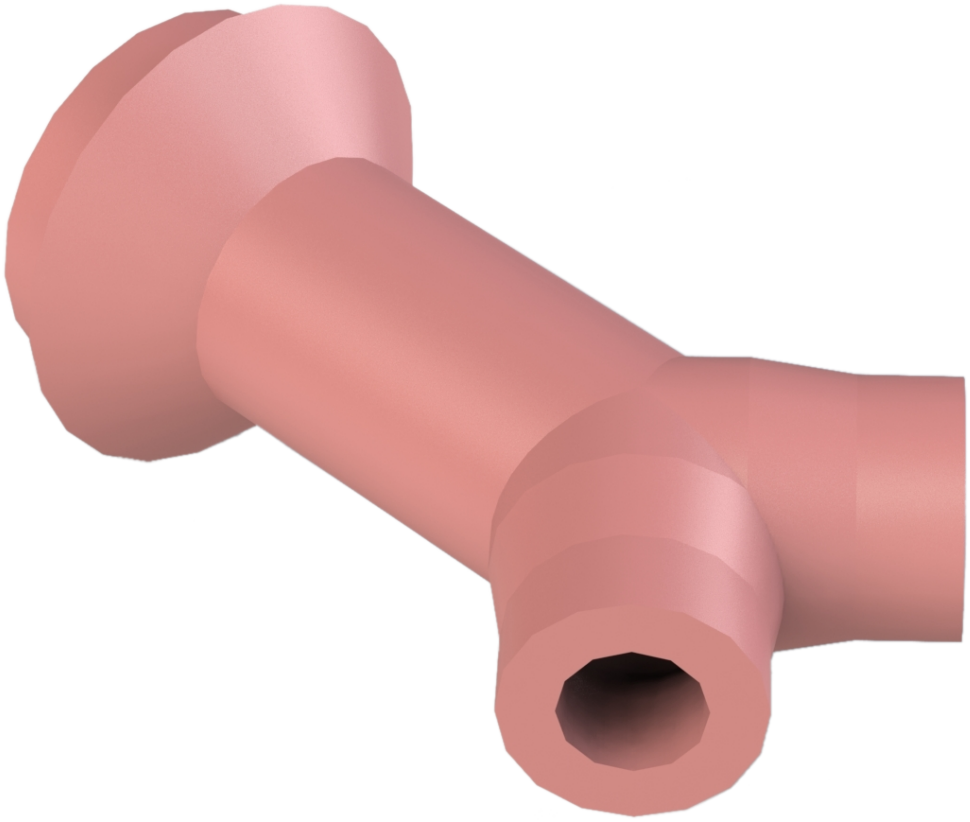

Figure 10: CAD model of the Left bronchus component of the model.

6.4 Larynx

The Larynx connects to the top of the trachea via the connection features and methods as stated before (see trachea section). This component features geometries such as the epiglottis and vocal cords*. The material for the trachea is the same soft tissue representation used for the bronchi components.

Due to the complicated geometries and many features, the larynx is deigned based on a MRI scan of a subject's head and neck. The MRI image conversion to a 3D model was accomplished using 3D Slicer and the model was edited in SolidWorks to be compatible with the other parts, particularly the connection points. Not only does this method allow the team to create a more anatomically relevant model, it also established a workflow for the customization of this section for specific use cases and difficult airways.

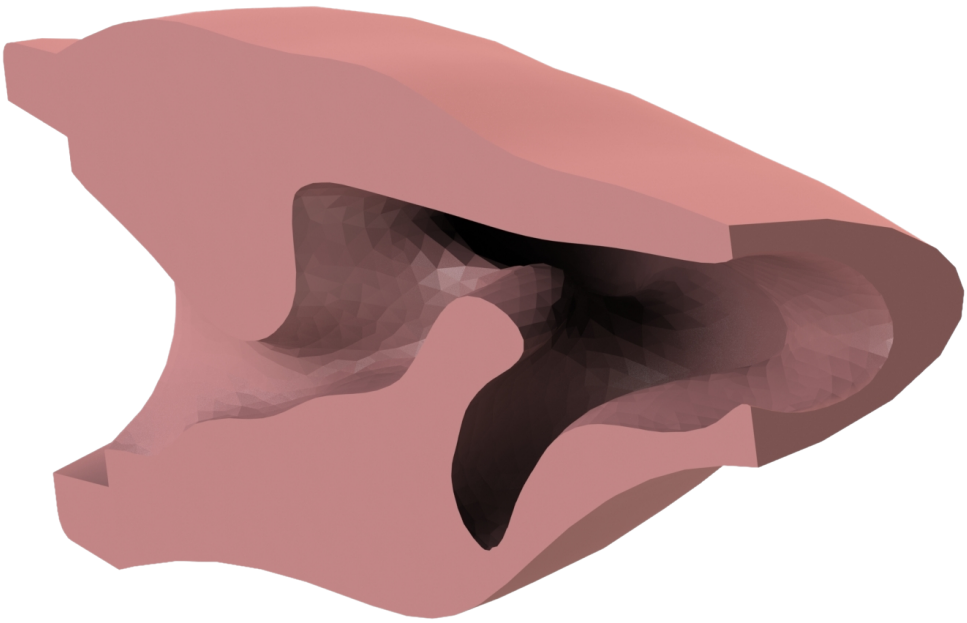

Figure 11: Cross section of the CAD model of the larynx. Note that the irregular geometries seen were derived from MRI data.

6.5 Connections

The connectors fasten the components together via a press fit method. The connectors will be made from clear, flexible PVC tubing. This tubing will have outer/inner diameters of 1.25/1.00in and will be 0.50in. While past iterations utilized the clear material to allow for trainees to track their progress throughout the model, they are only used as fasteners between the different components. The team decided on this material for our design because it is inexpensive, readily available, and makes for very stable connections. The choice of these connectors will allow Toobtek to focus its resources on the critical components and produce a more cost effective training device.

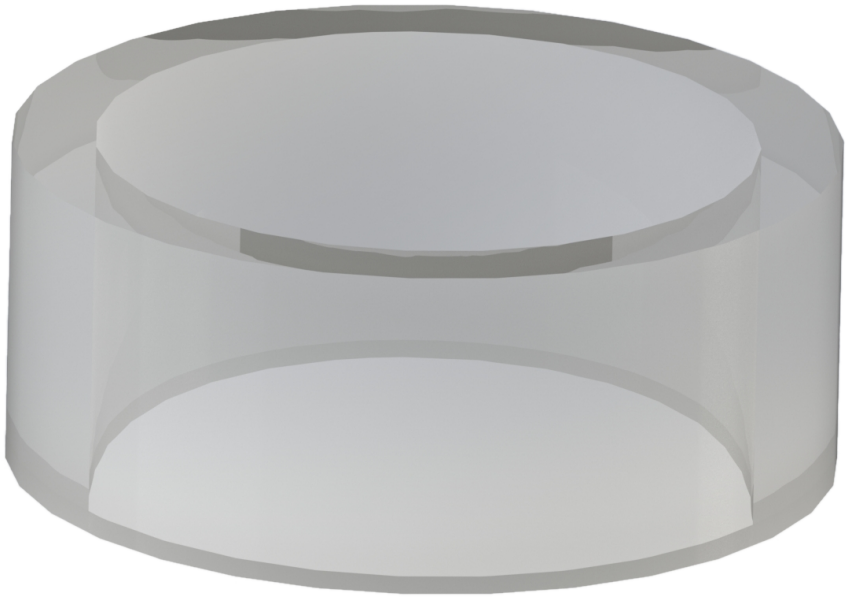

Figure 12: CAD model of the 1.25in OD tubing that is for connecting components of the device.

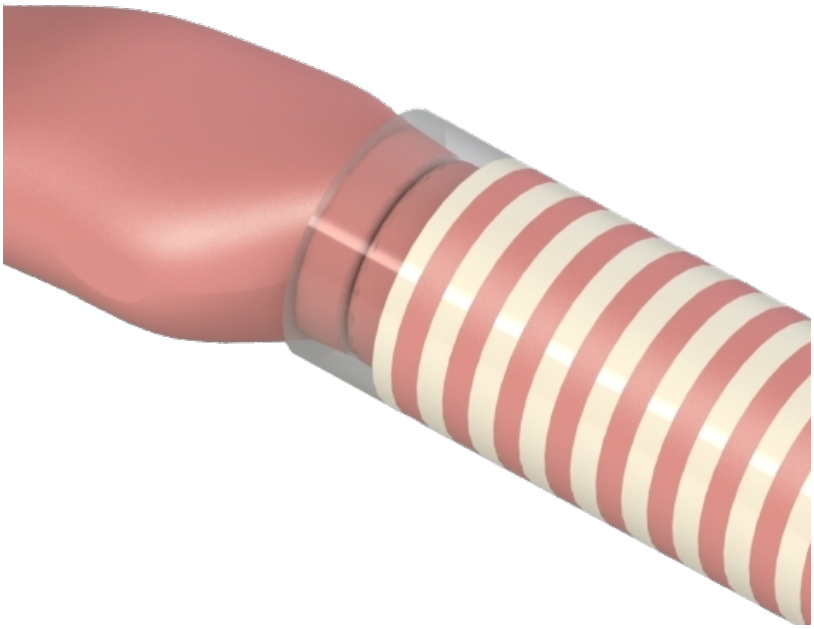

Figure 13: Render of the 1.25in OD tubing connecting the larynx and trachea components.

6.6 Enclosure

In order to meet our project requirement for portability, the entire assembly will be housed in a black box enclosure. The black box will include a hole on one end for the insertion of the fiberoptic scope while the box is in its closed or open state. Additionally, this setup will allow for training to be completed without the ability to track location, if desired. This "blind" traversal will allow for more realistic training. On the other hand, inexperienced users can leave the box open and will be able to easily identify where they are in the model by tracking the luminescence from the model's scope.

To maintain portability, the group determined the maximum dimensions for the enclosure to be 32in x 20in x 8in with a maximum weight of 27.5lbs. The device more than meets these requirements with the final prototype iteration. The enclosure will also include soft foam to hold the assembly as well as minimize the overall weight of the enclosure. On the exterior of the box, nonslip pads will keep the training device stationary while the device is in use.

Figure 14: Enclosure

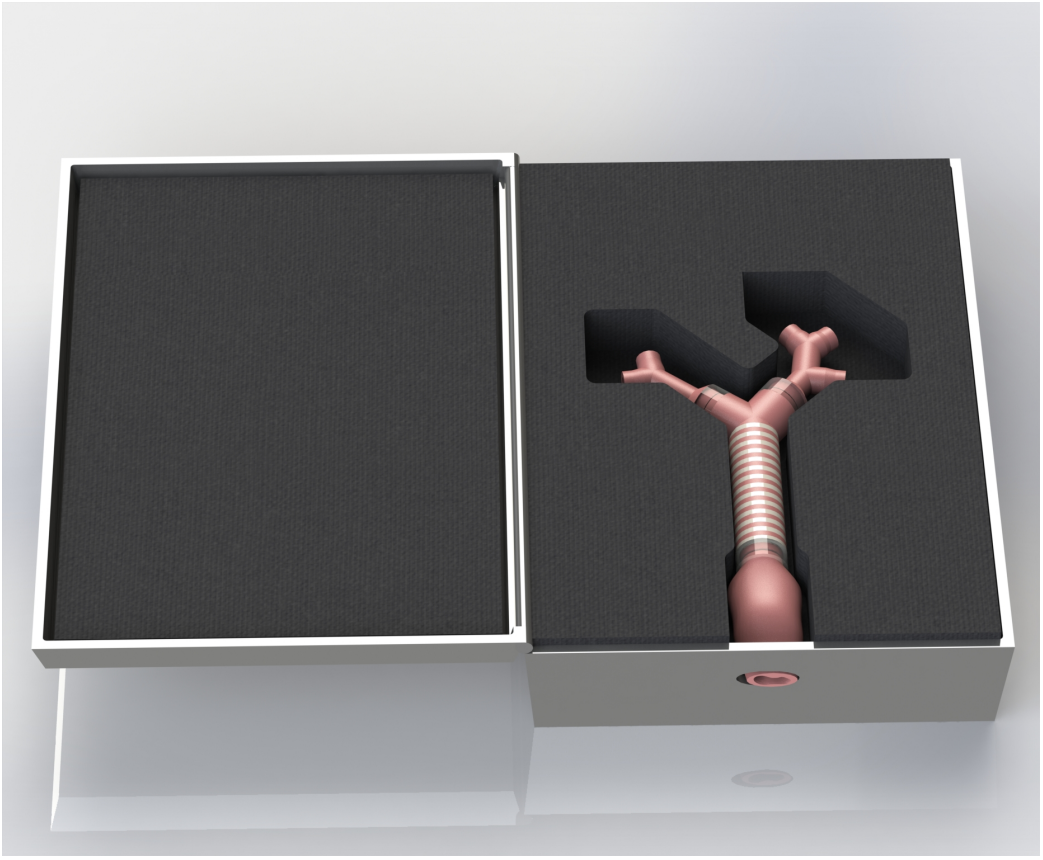

Figure 15: Render of the full assembly inside the black box enclosure enclosure.

6.7 Manufacturing Plan

For the method of manufacturing, the team decided on multi-material 3D printing. All manufacturing will be done using Stratasys J750 Multi-Material 3D printers. The materials used for this model are Agilus30 (white) and Vero Vivid (white and magenta) which are specific to the J750 printer and can be used in different ratios to achieve different hardness and flexibility values. With this precise control over material properties, the team came up with specific combinations for both soft tissue and cartilage representations. The time to print one full model is 15 hours. We do not have an estimate for the actual full print time including setup, as our printing was outsourced. The manufacturing schedule can be found in Figure 16 below.

The team also considered injection molding as an alternative manufacturing method. This would allow for a less expensive unit cost, but the ability to tune the material properties for specific regions of the device would be lost without customizing the molding process. Since the product is going to be produced in lower quantities at scale and quality is more important that production volume, injection molding was a less attractive option.

				PERIODS													
GOAL	BREAKDOWN	PLAN START	PLAN FINISH	12/14	12/21	12/28	1/4/21	1/11/21	1/18/21	1/25/21	2/1/21	2/8/21	2/15/21	2/22/21	3/1/21	3/8/21	3/15/21	3/22/21
Initial Trachea		12/14/20	1/25/21															
	Maccurdy	12/14/20	1/18/21															
	Medtronic	12/14/20	1/25/21															
	ITLL	12/14/20	1/11/21															
Connection		12/14/20	12/21/2020															
	Cut Tubing	12/14/20	12/21/2020															
Final Model		1/25/21	3/8/21															
	Healthy	1/25/21	2/22/21															
	Laceration	1/25/21	3/8/21															
	Tumor	1/25/21	3/8/21															

Figure 16: Manufacturing Schedule

7 Testing

Unless specified otherwise, data from these tests was compiled, analyzed, and visualized using MatLab. All 95% confidence intervals were calculated assuming a normal distribution.

7.1 Initial Testing

The Toobtek team has performed qualitative analysis regarding the flexure of the trachea using a human-biologically similar trachea harvested from a cow. Once a material is chosen for our prototype, we will be able to compare its flexure to the human-biologically similar trachea and adjust our material accordingly. This comparison will also be considered when choosing the prototype material for the airway.

In addition, a thorough dimensional inspection of each trachea sub-assembly was conducted to determine how precisely their respective 3D-printers modeled our input file. The types of inspection conducted are given in Tests 1.1.x, which can be found in the Appendix **??**.

7.1.1 Test A: Initial Trachea Comparison

2/5/2021

- **Operators:** Jacob Haimes and Kathryn Kubacki
- **Location:** Denver Health Medical Center

In order to determine the material of our model, as well as the group that would be printing it, we conducted a test with multiple medical professionals* at Denver Health. These medical professionals inspected two 3D-printed trachea sub-assemblies, which can be seen in Figure 17. After examining both, the participants were asked to fill out a survey designed to assess the similarity between our model and a real human trachea. An printable example of this survey can be found in Appendix C, although the survey was administered in an online format using Qualtrics XM, which was accessed via QR code. In total, we worked explicitly with 11 medical professionals, while many others listened, and occasionally gave their thoughts on the test.

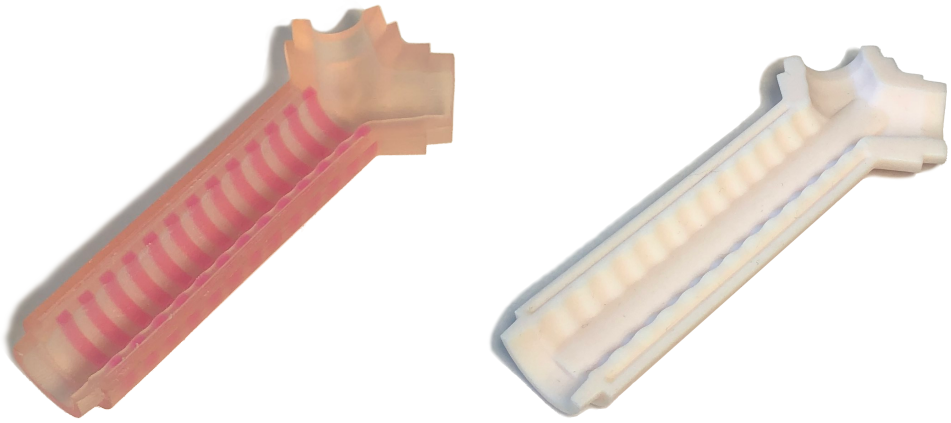

Figure 17: Portions of the translucent trachea sub-assembly (left) and the opaque trachea sub-assembly (right) used for Test A.

In order to increase the likelihood that our surveys were filled out, the participants were told that the written portion of the survey was not necessary. To compensate for this, notes regarding

qualitative feedback were taken throughout the test. One notable development during the test is that after approximately 3 medical professionals had been surveyed, a fibre optic scope was added to the test to help inspectors compare the parts to an average human trachea. There were 7 inspectors that filled out the 'Opaque' survey, whereas only 5 filled out the 'Translucent' survey. The results from this test can be seen in Figure 18.

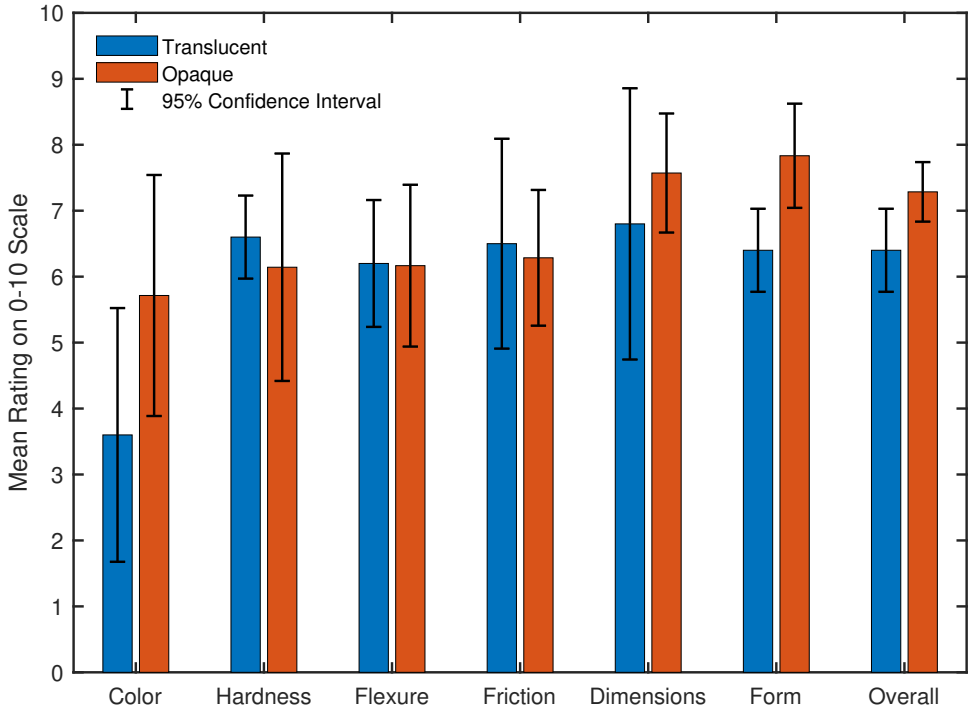

Figure 18: Results from the 2/5/2021 run of Test A at Denver Health. Due to low volume of inspectors, the calculated 95% confidence intervals are larger than desired, particularly regarding color, hardness, friction, and dimensions. Additionally, we note that "form" is the only category in which the 95% confidence intervals do not overlap.

In addition to the information displayed in Fig (18), the following sentiments were synthesized from the notes taken during the test.

- The opaque model looks like it is the trachea of a dead person. More pigment is needed for the soft tissue portion of both.
  - Ideally the model would be vascularized.
  - Including a color variation between cartilage and soft tissue would be nice.
- The following features should be changed to increase anatomical relevance:
  - The angle between the right mainstem and the current line of symmetry should be reduced
  - The muscle striation on the posterior of the trachea should:
    - Increase in width

    - Be made more flat
    - Extend further into the right and left mainstems

- Complications that would be useful to practice on include:
  - Angeoadima
  - The presence of foreign liquid(s), such as blood or vomit
  - The presence of a foreign object, such as a coin lodged in the the airway
- The epiglottis should be more floppy than the rest of the model.
- The mouth should be less stiff than the current model.
- Including anatomy above the trachea in a training device would be very helpful.

In future tests that require surveys, we will not include any questions that ask for a written response. We believe that this change will make inspectors more likely to take the time to fill out our survey. Additionally, there will be only one survey in the future, as having multiple QR codes was confusing and a deterrent to filling out the survey.

7.1.2 Test D: Shore Hardness Verification

The Shore Hardness of our product will be measured with a Shore Durometer, a device specifically designed to measure the hardness of materials such as elastomers, rubbers, thermosets, and thermoplastics. The durometer has a calibrated spring that applies a specific force to a point with standardized geometry, both of which are dependent on the type of Shore Hardness being measured. The Shore Hardness is then be determined with the depth of the resulting indentation [28]. We conducted this test in accordance with the ASTM D2240 standard [18].

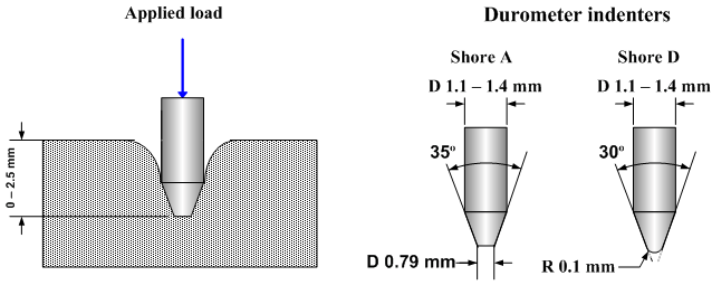

Figure 19: Illustration of a Shore Hardness test as well as the geometric differences between a Shore A and Shore D indenting point. When measuring Shore A hardness, a force of 1.812 lbs is applied, but when measuring Shore D hardness, a force of 10 lbs is applied [28].

2/11/2021

- **Operators:** Rebecca Jacobs
- **Distinction:** The initial trachea prints were measured directly

While executing this test, the operator realized that she couldn't take the Shore A hardness measurements appropriately for all desired locations on the initial trachea prints. Method A worked well for the opaque print, but could not measure the soft tissue portion of the translucent print easily. Method B, on the other hand, worked well for the translucent print, but could not measure

the soft tissue portion of the opaque print. Note that the translucent print did not have a muscle striation.

Because we lacked the ability to consistently measure the materials, the Toobtek team decided to conduct an additional round of Test D with a new sample. The new sample would be created such that taking Shore A measurements would not require multiple different methods in order to test each hardness. The sample used can be seen in Figure (21). Additionally, 10 measurements would be taken, instead of 5, to tighten the confidence intervals reported.

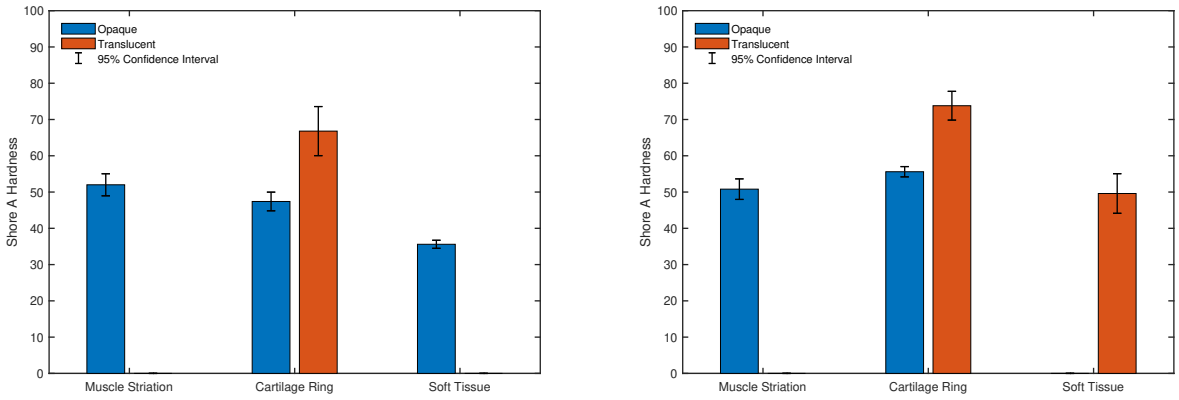

Figure 20: Hardness values measured on 2/11/2021 for multiple different material compositions and geometries on the initial trachea prints. Hardness was measured using method A (left) and method B (right). For both plots, the data for the opaque trachea is represented in blue, while the data for the translucent trachea is shown in orange. Note that the measured Shore A hardness for the cartilage rings seems to be dependant on the method used.

Figure 21: Image of the sample used in the 2/22/2021 run of Test D. The portions that are more translucent contain more Agilus30, while the sections that are more pink contain more VeroVivid Magenta. The target hardness values for each unique material combination are {40,50,60,70,85,95} (left to right).

2/22/2021

- **Operators:** Rebecca Jacobs
- **Distinction:** A sample made explicitly for this test was measured

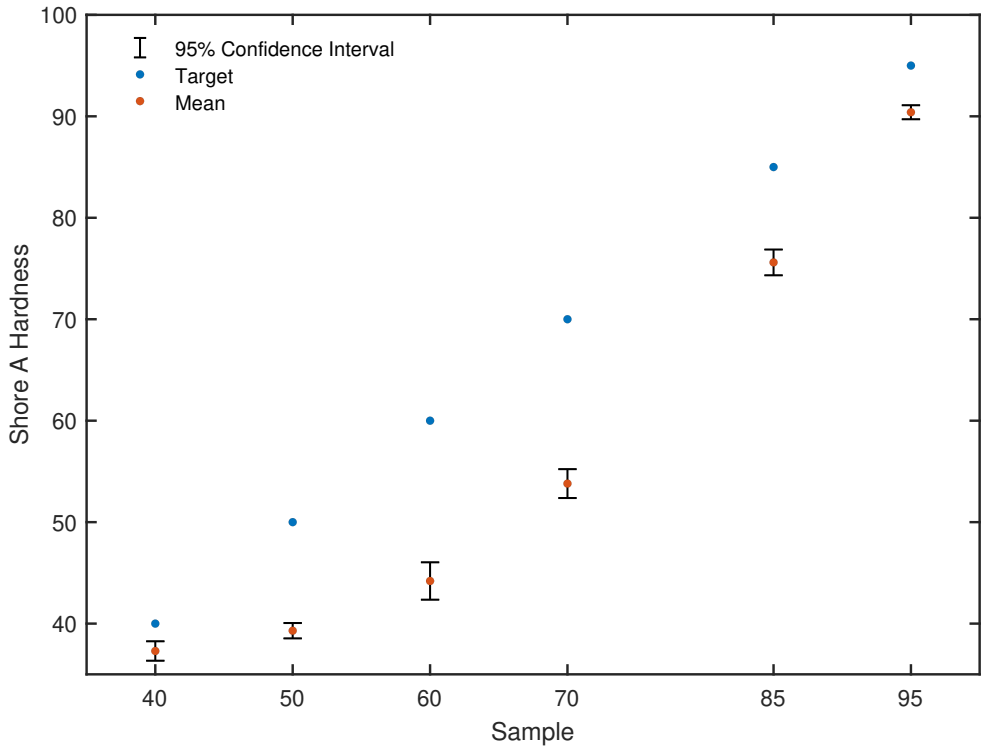

Figure 22: Hardness values measured by Toobtek on 2/22/2021 compared to the reported target value the 3D printer was set to. They are displayed with their target hardness in the *x-axis*, instead of the sample number, to help visualize the relationship between the reported and measured values.

Testing each material in the sample allowed Toobtek to get a better understanding of the trade-off between color of the print and its Shore A hardness. In Fig (22) we see that our measured hardness is significantly below the hardness reported by the Stratasys software. The difference by which the reported value and our measured value differs, visualized in Fig (23), follows a curved shape, reaching a maximum between the target values of Shore 60-70A. Due to the curved shape that our difference shows, Dr. Virginia Ferguson hypothesized that the reported Stratasys values were calculated assuming a linear relationship between the constituent material properties.

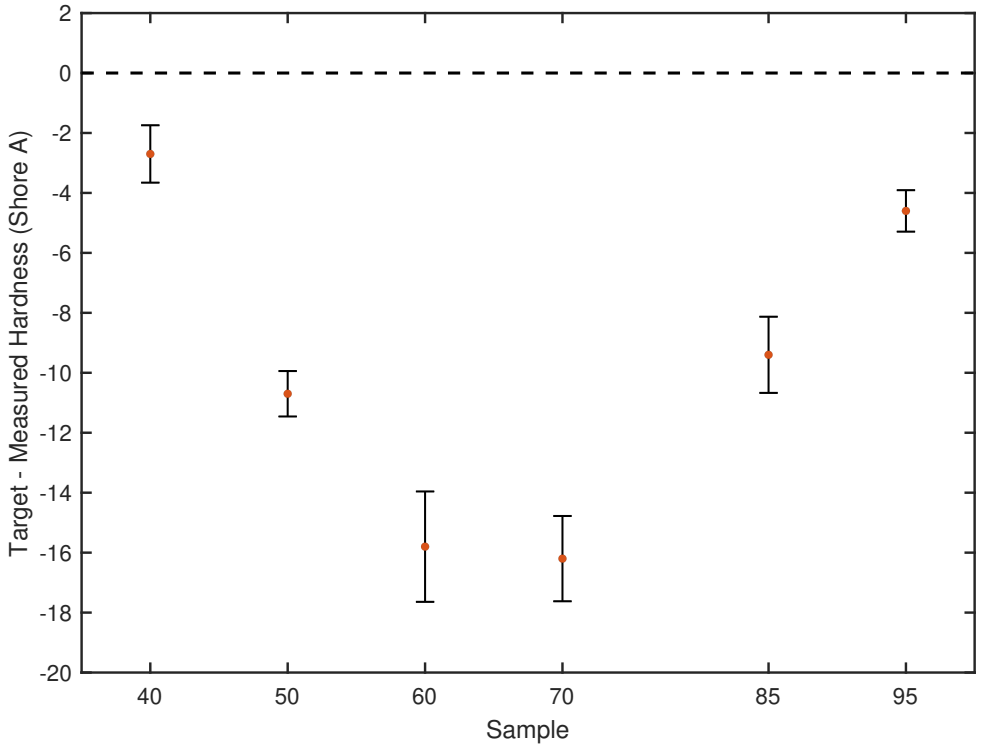

Figure 23: The difference between the reported target hardness given to the printer and the hardness measured by Toobtek. The dotted line represents the *x-axis*. This plot indicates a trend between these two values, as it is not homoscedastic.

7.2 Prototype Testing

7.2.1 Test C: Flexure

Prior to testing, a series of theoretical testing was conducted to confirm that the measurements we were interested in could not be accurately obtained using the INSTROM machine in the ITLL of CU Boulder. This pre-test analysis calculated approximate diameter of a sample that would be at 5% strain when exactly 10% of the maximum load capacity of several machines were applied [37]. The diameter can be found after assuming the Elastic Modulus of the material that is being tested. Although this may seem counter-intuitive, as Elastic Modulus is exactly what we will be measuring with Test C, this is simply to get an approximate diameter. Using Eq. (1) we can approximate a material's Elastic Modulus from it's Shore A hardness[36].

$$E \approx 10^6 * \exp(.0235 * H_{\text{ShoreA}} - .6402) \tag{1}$$

Using the hardness data from the 2/22 run of Test D, we approximated the diameter required to accurately test on the elastic modulus of the two material compositions that we had chosen to print with. One of these materials is a combination of Vero Magenta and Agilus30 White to create a material with target hardness of Shore 50A (soft tissue material), while the other is a combination of Vero White and Agilus30 White to create a material with target hardness of Shore 85A (cartilage material). We found that if we were to use the INSTROM machine in the ITLL, which has a maximum load of 50 kN, that we would need samples larger than half a foot in diameter. When

testing the Elastic Modulus of a sample, it's height should be greater than or equal to it's diameter [37]. This means that if we wanted to use the 50 kN INSTROM to get accurate Elastic Modulus measurements of our materials, each sample would cost at least $1500, and would most likely be closer to $10,000 in materials alone.

Dr. Ferguson's Lab, however, has similar machines with maximum loads of 2 kN and 200 kN. Using a similar workflow to before, we found that samples with a diameter and height equal to 3 cm could have their elastic moduli measured accurately on the 2 kN max load machine. The code for all of this analysis can be found in Appendix F.2.

We then asked Medtronic to print three cylindrical samples of each of our two material types. One of each of these samples was treated with the same process used to clean out the support material of the larynx, so that we could determine if this cleaning process, which includes a caustic solution bath followed by a water whirlpool, affected the material properties of the samples.

All six samples were then delivered to Victor Crespo, who ran the tests for us and sent over the data, which is visualized in Figures (24). Additional plots can be found in Appendix D.

3/30/2021

- **Operators:** Victor Crespo
- **Location:** Engineering Center

All values for elastic modulus we found using Eq. (2).

$$E_t = \frac{\sigma_t - \sigma_{t-\Delta t}}{\varepsilon_t - \varepsilon_{t-\Delta t}} \tag{2}$$

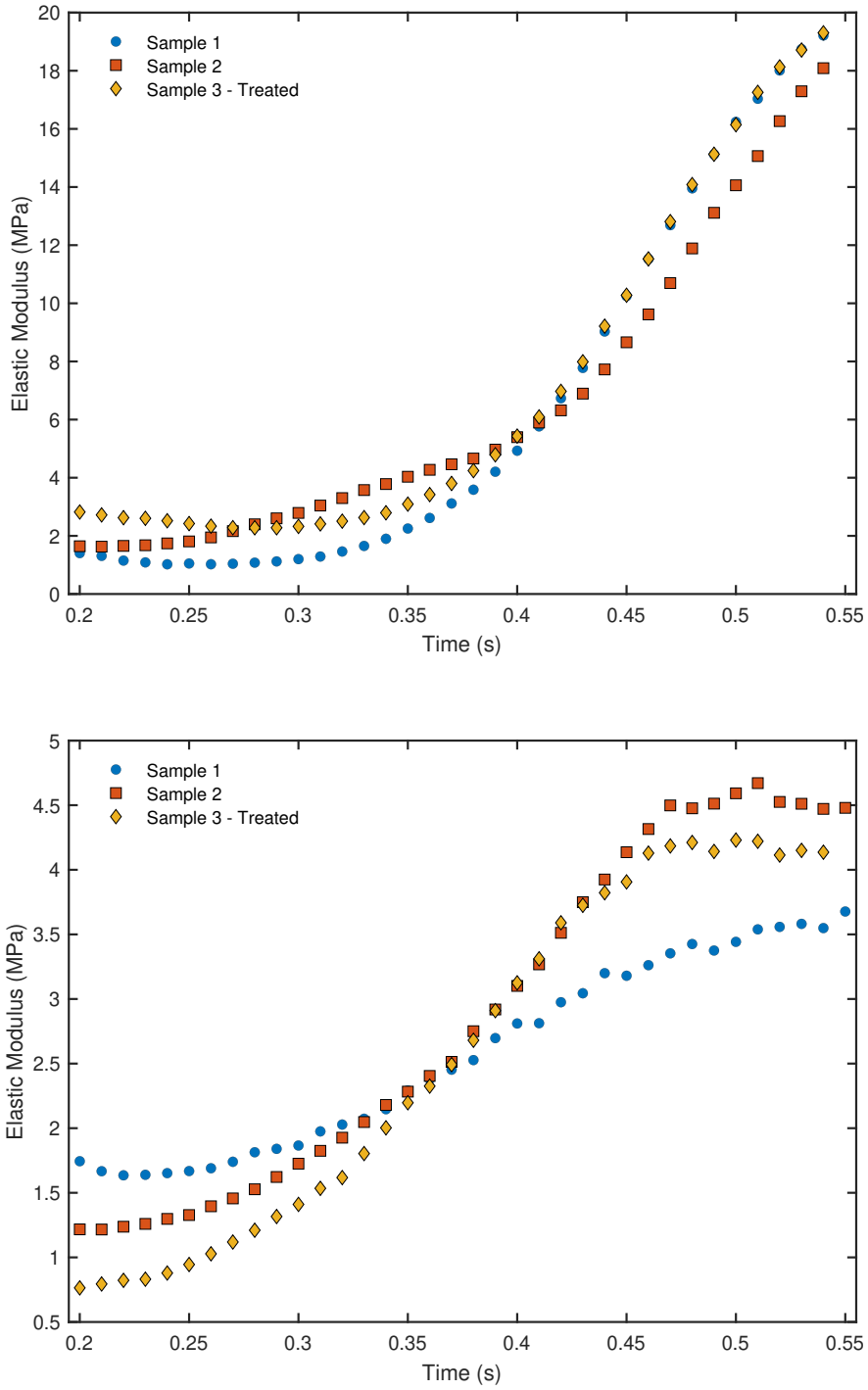

Figure 24: Calculated elastic modulus of the cartilage material samples (top) and the soft tissue material samples (bottom) using a Δt of .1 seconds. We see that the cartilage material has an instantaneous elastic modulus around 2 MPa, while the soft tissue material has an instantaneous elastic modulus of approximately 1.25 MPa.

7.2.2 Test E: Medical Professional Feedback

In addition to the quantitative tests conducted on the prototype, a second test was conducted with medical professionals from Denver Health, this time using the entire prototype. Unlike the trachea sub-assembly version of this test, which was used to determine which material the prototype airway would be comprised of, this test was administered to verify that our prototype meets requirements in the Toobtek PRS. Collectively, meeting these requirements would mean the medical professionals found our training device effective and anatomically relevant.

3/25/2021

- **Operators:** Jacob Haimes and Kathryn Kubacki
- **Location:** Denver Health Medical Center

For this test, we brought a full version of our prototype, which can be seen in Figure (25). Our experience during Test A allowed us to make multiple improvements to the survey and process. First, each medical professional was asked to fill out a single shortened feedback survey, which did encourage a better response rate. A printable example of this survey can be found in Appendix E, and an example survey can be seen at this link. The participants navigated through our training device using a fibre optic scope, and were then allowed to examine the 3D printed parts. Murphy can be seen here teaching one of his students about landmarks seen in intubation, as well as some insights regarding scope control.

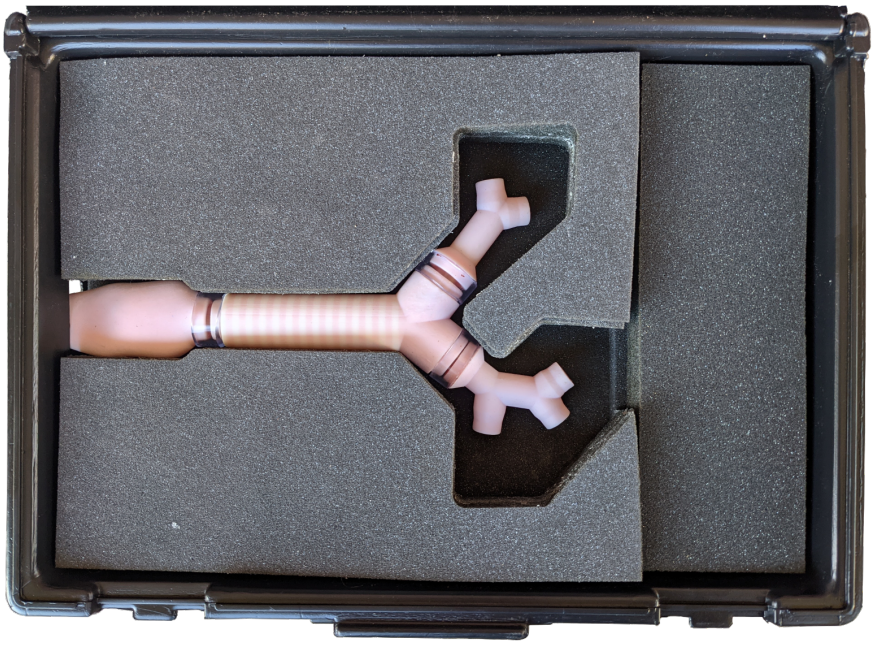

Figure 25: Bird's eye view of the device brought to the test on 3/25/2021 while it is open.

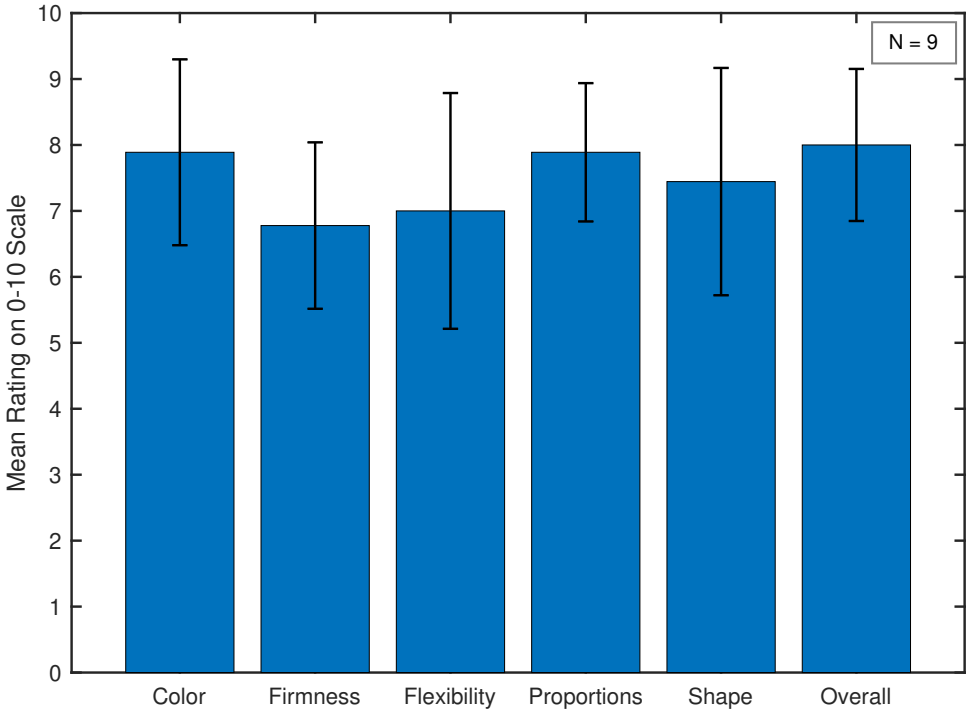

Figure 26: Results from the 3/25/2021 run of Test E at Denver Health. "Firmness" was the only classification to not obtain a score greater than or equal to 7, instead achieving a mean value of 6.78. For all categories, $1 < I_{95} < 2$, where I_{95} is the 95% confidence interval, which is visualized by the error bars in this plot. A total of 9 survey responses were recorded.

During the test, we also recorded the interviews and took notes on how the medical professionals thought we could improve our design. It was encouraging that the most common comment was that having more of the airway would be useful. Below is a summary of their thoughts on the model that are not captured in Fig (26).

- The geometry of each part is well within the limits of human anatomy
  - The angle of the right bronchus is good.
  - The bronchial tree length could be a little shorter
  - The trachea cartilage is a little firm
  - The larynx has resolution of newborn
  - The right upper takeoff is a little steep
    - Could be operator error
    - Well within limits
- Would be helpful to include tissue above the larynx
  - Could include collapsible tissue and a tongue
- Would be good to have external assembly cues

7.3 Future Testing

7.3.1 Test B: Stability

One somewhat unique requirement we have given our training device is Requirement 1.1.3. This requirement states that the box will not move when the closed training device is subjected to a purely horizontal force of less than 20 lbs. It was written in order to address a specific user pain point we discovered during our initial interviews which was that current training devices often slide much too easily, which can modify the quality of learning experience the training device provides a student. In order to accurately determine if we meet this requirement, a small horizontal force will be applied to a load cell attached to the closed training device that is sitting on a flat surface. The force will then increase in magnitude until the training device slips, at which point the test will be reset and re-administered. A total of 30 tests will be conducted.

The team was not able to accurately record the results of this test as of 4/25/2021, although a test was attempted. The load cell that was to be used, the FUTEK LCM300 (which can be seen in Fig (27)), requires at least two additional circuits in order to record data accurately with a DAQ. Specifically, these circuits are a filter, to remove noise from the reading, and an amplifier, to magnify the voltage range on the output of the sensor. The circuit setup that was used can be seen in Fig (28). Without these two circuits, accurate data acquisition is impossible, which was not clear to the team when designing this test. In the future, the team will make sure that we have a more thorough understanding of all sensors required for a test.

Figure 27: A picture of the LCM300 load cell (left) and it's experimental setup, as seen from the inside of the black box enclosure (right).

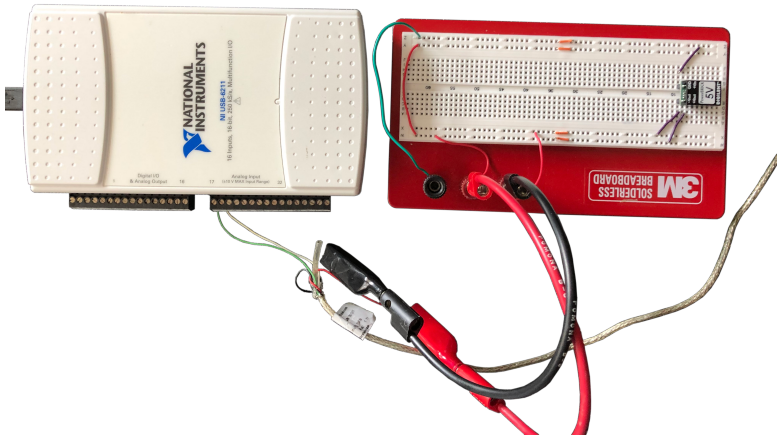

Figure 28: Picture of the circuit setup that was used for the attempted Test B. Note that the only circuit components other than the load cell is a power supply configured to provide an excitation voltage of 10V to the load cell.

7.3.2 Test F: Assembly and Modularity

To assess requirements 2.2.1 and 3.4.4, at least 10 people will be given instructions to partially disassemble (and possibly reassemble) our training device. These examiners will then be timed while they complete this task. After, they will repeat this process two more times, and all times will be recorded. These data will then be saved for further analysis as described in section 7.2.5.

8 Intellectual Property Discussion

As members of the Engineering for Social Innovation (ESI) section of senior design, our team will retain all intellectual property rights for this device. Upon discussion amongst the Toobtek team and with our director, Walter Wong, we have begun identifying areas of our device that will be important to protect against infringement. We have begun researching utility and design patents, as they will be most applicable for this design. Specifically, we are looking into pursuing a utility patent for the overall function of the device as a black-box fiberoptic intubation training simulator for medical professionals and a design patent for interchangeability of the respiratory components. The utility patent will protect the ability of the black box enclosure to permit the entry of a fiberoptic scope and the design patent will protect the geometric features of the respiratory components, which allows them to be interchangeable and replicate the properties found in real human tissue. Once we have finished prototyping and have a finalized product, we are planning to gather input from the Entrepreneurial Law Clinic and the Technology Transfer Office at CU Boulder to help further develop our plan for patent protection and gain assistance with filing patent applications. Currently, we are working with Mike McGaw at the Denver law firm McGaw Law to finalize and submit our provisional patent application. This will help the team take steps towards safeguarding its invention from any infringing competitors, and add value to our company as we ramp up our sales and begin to generate profit. The team also plans to use the funding from the CU Boulder New Venture Challenge to help fund the filing of a utility patent application that will come after the provisional patent application.

9 CU's New Venture Challenge (NVC) 14

9.1 Overview

The CU Boulder campus-wide New Venture Challenge is an annual entrepreneurship competition that brings together students across campus to pursue business ventures and compete for funding. This provides a great opportunity for taking an idea forward as a viable business, while also interacting with business experts and local entrepreneurs who help teams learn about the challenges that lie ahead for their business and volunteer their time to help strengthen CU's entrepreneurial community. Every year, the competition has three rounds, where all of the teams compete in Round 1, with a select number of teams advancing to Round 2 and the eventual NVC Championships. As a result of the COVID-19 pandemic, this year's NVC was made purely virtual, so presentations were delivered remotely to panels of judges.

9.2 Team Performance and Outcome

Toobtek was incredibly successful in this year's NVC in a few major ways. The first way was adding valuable business mentorship to our team, which helped us strengthen our business acumen. The team added mentors who have worked in both the biomedical field and the business consulting field, and both of these mentors helped us to improve our storytelling capability as a team, as well as in conducting further research on our product to help build the best business case for its implementation. The second way was in actual performance in the competition. Toobtek competed in all three rounds of the competition, and was among the top 6 teams in this NVC 14 Championships, a major feat considering that over 150 teams participated in this competition this year. Toobtek ended up finishing in 3rd place in the competition, winning $\$16,000$ which will be used to take our business forward and continue building on our strong product momentum.

10 Project Budget

10.1 Overview

We are currently on budget with our design and plan on achieving a finalized design within the budget allocated to our team from the university. Outlined below is the budget broken out in terms of labor, equipment, materials, and miscellaneous cost. A total of $71 has been spent so far on business development materials for each of our informational interview professionals as well on as a cow trachea for material properties testing.

10.2 Project Financial Status and Outline

Figure 29 shows the budget summary from the Toobtek cost control spreadsheet. This budget is an estimate encompassing projected labor costs based on anticipated tasks and their completion time. The estimated total budget of for this project including overhead and contingencies is $125,202. The labor costs associated with this estimate are reflective of the hours put in by the team, not the director or client. A breakdown of the material costs can be found below. At this time Toobtek is outsourcing labor to Medtronic and Dr. Robert MacCurdy, both whom have generously offered to manufacture our design at no cost, thus no external labor costs must be accounted for. The current projected project costs help account for unexpected costs.

Budget Summary					
Description	Estimated Costs (USD)				
	Labor Hours	Internal Labor	Contractor Labor	Materials	Totals
Design and Construction					
Equipment	0	$0	$0	$1,537	$1,537
Engineering	1,344	$83,773	$0	$21	$83,795
Subtotal Design and Construction Costs	**1,344**	**$83,773**	**$0**	**$1,558**	**$85,331**
Miscellaneous Costs					
Contingency	5.00000%				$4,267
TOTAL COSTS					**$89,598**
Overhead Recovery & Profit	40.0%				$35,839
TOTAL PRICE					**$125,437**

Figure 29: A screenshot of the budget summary

10.3 Estimated Materials Budget

The total estimated material cost for this project is $1537. The breakdown of the material budget can be seen in Tables 3.

Table 3: Projected Material Costs

Sub-Assembly/Section	Cost
Initial Trachea	$0.00
Connection Points	$33.33
Final Model	$0.00
Additional Costs	$1504.81
Total:	$1504.14

The breakdown of each of these sections can be found in Tables 4, 5, 6, and 7.

Table 4: Initial Trachea Model

Item	Material Info	Quantity	Cost	Vendor
Trachea	Agilus30 and VeroVivid	1	$0	Medtronic
Trachea	Agilus30 and VeroVivid	1	$0	MacLab

Table 4 lists all the items needed to construct our initial trachea model for testing purposes. This information was gathered to estimate a cost to conduct initial tests, which was found to be $0.00.

Table 5: Connection Points

Item	Material Info	Quantity	Cost	Vendor
Connection Points 1	PVC	10ft	$22.03	Home Depot
Connection Points 2	PVC	10ft	$9.84	Home Depot
Connection Points 3	PVC	2ft	$1.58	McGuckin Hardware

Table 5 lists all of the costs required to construct the 4 connection points. This cost is estimated to be $33.33. After design revisions, only Connection Point 1 was used in the final assembly.

Table 6: Final Prototype

Item	Material Info	Quantity	Cost	Vendor
Final Print	Agilus30 and VeroVivid	1	$0.00	MacLab

Table 6 lists the cost to print the tradeshow-ready final model. The cost to print the final design is $0.00.

Table 7: Additional Costs

Item	Material Info	Quantity	Cost	Vendor
Cow Trachea	Cow trachea	1	$50	BPO Parts
Black Box Enclosure	HDPE*	1	$4.63	Amazon/PFC
Greeting Cards	Paper	1	$21.25	FedEx
Nonslip Pad	Rubber	3	$9.83	McGuckin Hardware
Foam Sheets	Open Cell	1	$53.92	Grainger
Foam Adhesive	Spray Adhesive	1	$13.49	McGuckin Hardware
Tubing Cutter	Aluminum	1	$11.69	McGuckin Hardware
Additional Printing Materials	Agilus30 and VeroVivid	2	$1360	MacLab

Table 7 lists the additional items and costs associated with this project. The total additional costs associated with this project are $1504.81.

11 Project Schedule

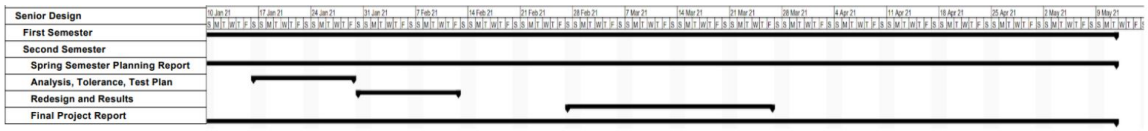

Table 8: Project Schedule Gantt Chart

We have completed fifteen major milestones as a team. In particular, we have worked through the Design Basis Document, Grant Proposal, Preliminary Design Review, Comprehensive Design Review, Manufacturing Review, End of Term Report for Fall, Test Plan, Prototype Test Results, Redesign, Redesign Test Results, New Venture Challenge, White Paper, Showcase, End of Year Report, and End of Year Presentation.

The project schedule focused on the completion of all deliverables. An overview of the schedule for the year can be seen in Table 8. A breakdown of Toobtek's spring and fall semesters schedule can be found in Appendices G and H.

11.1 Future Work

11.1.1 Design Requirements

In order to better match the geometry of the human respiratory system we will modify the design such that every component is created from an MRI scan. In addition, to we will work to create additional components including soft tissues above the larynx such as the tongue. This requirement was created based on feedback from medical professionals at Denver Health collected during the second round of testing.

11.1.2 Plan to Commercialize

Given the price point and nature of our product, we have identified our main points of contact for selling our device at most hospitals as the individuals who hold departmental head positions. For example, the Head of Anesthesiology would be our point of contact to purchase an intubation training model. In addition, we also have identified Group Purchasing Organizations (GPO's)* as a viable way to get our device into the hands of medical professionals. GPO's are responsible for purchasing medical training equipment, including educational tools, on behalf of a hospital. 97 percent of all hospitals are members of at least one GPO, and most hospitals are members of multiple GPO's. We plan to form professional connections with the key buyers of some of the large GPO's in order to penetrate the healthcare market.

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Appendices

A Glossary

American Hospital Association: A health care industry trade group that includes nearly 5,000 hospitals and health care providers..

Amyotrophic Lateral Sclerosis (ALS): A disease that affects nerve cells in the brain and spinal cord, which in-turn affects voluntary movement.

Anatomically Relevant: Similar to human anatomy in terms of aesthetics and feel.

Beachhead Market: A small market with specific characteristics that make it an ideal target market to sell a new product or service.

Black Box Approach: Intubation training method relying on placement of a human respiratory model within a black box enclosure.

Bronchial Tree: The branching system of bronchi and bronchioles, conducting air from the windpipe into the lungs.

Bronchus: Any of the major air passages of the lungs which diverge from the windpipe. Plural:Bronchi.

Carina: A cartilage situated at the point where the trachea (windpipe) divides into the two bronchi.

CDRH: "The Center for Devices and Radiological Health is the FDA center responsible for overseeing the medical device program." [29]

CRNA: Certified Registered Nurse Anesthetist.

CU Boulder: University of Colorado at Boulder.

DAQ: Data Acquisition system.

Difficult Airways: The clinical situation in which a conventionally trained anesthesiologist experiences difficulty with face mask ventilation of the upper airway, difficulty with tracheal intubation, or both.

Difficult Intubation: A procedure involving "more than 3 attempts at intubation" or "nonstandard equipment or approaches.

Edema: Swelling caused by fluid in the body's tissues.

Endotracheal: Occurring within or by way of the trachea.

Epiglottis: A flap of cartilage at the root of the tongue, which is depressed during swallowing to cover the opening of the windpipe.

FDA: "The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation." [29]

Fiberoptic Intubation: Procedure where a flexible endoscope with a a tracheal tube along its length is maneuvered through the epiglottis.

Flexure: Characteristic of a material experiencing deflection under a bending load.

Human-Biologically Similar: Similar to a human in terms of the makeup of organs, tissues, or other biological features of the body.

Group Purchasing Organization (GPO): Over 97% of all US hospitals are a part of at least one Group Purchasing Organization (GPO) and most are a member of more than one GPO. GPOs are an ideal sales arm for hospitals, as they market on behalf of the device companies who are members of their GPO. Additionally, they have direct access to the key decision makers and purchasing departments within the healthcare organizations.

HDPE: High Density Polyethylene.

Intubation: Medical procedure in which a tube is placed in the windpipe through the mouth or nose.

IRB: "...an Institutional Review Board is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects." [29]

Larynx: The hollow muscular organ forming an air passage to the lungs and holding the vocal cords in humans and other mammals; the voice box.

Magnetic Resonance Imaging (MRI): Radiology imaging used to produce images of different organs or processes in the body.

Medical Professionals: For our purposes, medical professionals are defined to be any persons meeting at least one of the following qualifications:

- Certified Registered Nurse Anesthetist
- Registered Nurse currently in a CRNA degree program and has been for at least 3 months
- Licensed Anesthesiologist
- Medical Doctor currently in an Anesthesiology residency program and has been for at least 3 months

Modulus of Elasticity: The ratio of the stress in a body to the corresponding strain (as in bulk modulus, shear modulus, and Young's modulus).

Pantone Color Matching: Color identification company dedicated to matching specific colors for a variety of products.

Shall: Indicates specifications strictly to be followed and from which no deviation permitted.

Target Market: A particular group of customers at which a product or service is aimed.

Trachea: A large membranous tube reinforced by rings of cartilage, extending from the larynx to the bronchial tubes and conveying air to and from the lungs; the windpipe.

Trachealis Muscle: A smooth muscle that bridges the gap between the free ends of C-shaped cartilages at the posterior border of the trachea, adjacent to the esophagus. The primary function of the trachealis muscle is to constrict the trachea, allowing air to be expelled with more force, e.g., during coughing.

US Department of Health and Human Services: "The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services." [32]

Vocal Cords: Folds of membranous tissue that project inward from the sides of the larynx to form a slit across the glottis in the throat, and whose edges vibrate in the airstream to produce the voice.

B Product Requirements and Specifications

A current version of all of our products requirements can be found in the *Product Requirements (current)* sheet of the Toobtek PRS. This appendix includes the most relevant sections of Revision I of this document. Note that the sources in these tables are independant from the sources in this report.

Requirement ID Naming Specifications			
1	**x**	**x**	Minimum Viable Product
2	**x**	**x**	ToobTek Satisfied
3	**x**	**x**	ToobTek Moonshot
x	**1**	**x**	Form
x	**2**	**x**	Anatomical Relevancy
x	**3**	**x**	Financial
x	**4**	**x**	Modularity
x	**5**	**x**	Customization
x	**6**	**x**	Education

Req. ID			Title	Description	Goal / Purpose	Verification
1	**1**	**1**	External Dimensions (Size)	While not in use, the entirety of the device will be no larger than 23"x 15.5"x 6" [1]	Increased portability allows for a more accessible device, which will reduce the barrier to practice	Inspection
1	**1**	**2**	Weight	The device will not exceed a weight of 27.5 [2] lbs	Increased portability allows for a more accessible device, which will reduce the barrier to practice	Inspection
1	**1**	**3**	Stability	While in use, the device will remain immobile when a horizontal force of less than 5 lbs is applied to it	Increased portability allows for a more accessible device, which will reduce the barrier to practice	Test and Analysis
1	**2**	**1**	Fiber Optic Clearance	Nominal diameter of the device's airway is larger than 1/10 of an inch [3]	Required for intubation training, scope is too large if the diameter is smaller than 2.5 mm	Inspection
1	**2**	**2**	Airway Diameter - Quantitative	Nominal diameter of the device's airway is within 1/8 inch [3] of the chosen demographic's airway size. Requirement 1.2.1 takes precedence if these two requirements conflict	A device that is as similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Inspection
1	**2**	**3**	Airway Edges - Quantitative	All edges inside of the airway will have a minimum radius of 1/10 of an inch	A device that has sharp edges that do not appear in a human body could teach incorrect practices or fallacies	Inspection
1	**2**	**4**	Airway Structure - Qualitative	Airway Structure will have a mean value greater than 7 on the Medical Professional Feedback Survey [8]	A device that seems similar to the real experience of fiber optic intubation is ideal to ensure training is effective	Test and Analysis

Req. ID			Title	Description	Goal / Purpose	Verification
2	**2**	**1**	Elastic Modulus (Cartilage) - Quantitative	The Elastic Modulus of the cartilage rings of our device will be on the order of magnitude of 1 MPa [10]	A device that is as similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Test and Analysis
2	**2**	**2**	Elastic Modulus (Tissue + Muscle) - Quantitative	The Elastic Modulus of the tissue and muscle of our device will be on the order of magnitude of 500 kPa [10]	A device that is as similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Test and Analysis
2	**2**	**3**	Hardness (Cartilage) - Quantitative	The hardness of the airway will be between Shore 60A and Shore 90A [4,5]	A device that is as similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Test and Analysis
2	**2**	**4**	Hardness (Tissue + Muscle) - Quantitative	The hardness of the airway will be between Shore 20A and Shore 60A [4,5]	A device that is as similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Test and Analysis
2	**2**	**5**	Color - Quantitative	The airway we create will be of similar color to that of a real human airway - Pantone 2030C and 2033C [7]	A device that is as similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Inspection
2	**2**	**6**	Color - Qualitative	Color will have a mean value greater than 7 on the Medical Professional Feedback Survey [8]	A device that seems similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Test and Analysis
2	**2**	**7**	Tissue Stiffness - Qualitative	Stiffness will have a mean value greater than 7 on the Medical Professional Feedback Survey [8]	A device that seems similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Test and Analysis
2	**3**	**1**	Cost	The total cost of manufacturing and materials for some version of the final intubation training device will be less than $250	Makes the device monetarily accessible, allowing for more users to access training for a perishable skill	Analysis
2	**6**	**1**	Scope Visibility	The question from Test 2.1.9 will have a mean value greater than 8.5	Being able to see where the camera is in the intubation trainer is important for teaching	Test and Analysis
2	**6**	**2**	Optional Scope Visibility	It will be possible to prevent visibility of the scope mentioned in Req 2.6.1, which will most likely manifest in closing the outer casing.	Being able to prevent a student from using resources they would not have in a real intubation is necessary for effective teaching	Inspection

Req. ID			Title	Description	Goal / Purpose	Verification
3	2	1	Surface Feel - Qualitative	Both wetness and friction will have a mean value greater than 7 on the Medical Professional Feedback Survey [8]	A device that seems similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Test and Analysis
3	2	2	Relectivity - Qualitative	Reflectivity will have a mean value greater than 7 on the Medical Professional Feedback Survey [8]	A device that seems similar to the real experience of fiberoptic intubation is ideal to ensure training is effective	Test and Analysis
3	3	1	Customization Cost	The total cost of manufacturing a custom version of the final intubation training device will be less than $2500	Makes the device monetarily accessible, allowing for more users to access training for a perishable skill, and allowing for easy further practice for specific difficult procedures	Analysis
3	3	2	Complication Cost	The total cost of manufacturing a version of an airway component that includes a complication will be less than $250	Makes the device monetarily accessible, allowing for more users to access training for a perishable skill, and allowing for easy further practice for specific difficult procedures	Analysis
3	4	1	Variety of Off-The-Shelf Models	The device will have at least 2 different configurations based on which interchangeable parts are used.	Training for more scenarios results in being more prepared for more scenarios	Design Verification*
3	4	2	Tumor Model	One of the configurations mentioned in requirement 3.4.1 will be of a patient with tumor insided their airway	Training in more scenarios creates more prepared medical personnel	Design Verification*
3	4	3	Laceration Model	One of the configurations mentioned in requirement 3.4.1 will be of a patient with a laceration somewhere inside their airway	Training in more scenarios creates more prepared medical personnel	Design Verification*
3	4	4	Easy Part Substitution	It will take no longer than 5 minutes for the device to be dissassembled enough such that any single airway (designated-interchangeable) component could be swapped out, and then reassembled again	Requirement to allow for interchangeable parts	Test and Analysis
3	5	1	Patient Specific Capabilities	The device will be able to be made in the form of any unique airway using MRI technology	Allowing for easy further practice for specific difficult procedures	Design Verification Professional Inspection

C Medical Professional Feedback Survey

The following page will be printed out and given to each medical professional examiner that participates in the initial prototype testing or the final prototype testing. For the first round of testing, each examiner will receive four of these surveys in succession, one for each different prototype that is being tested. There is also an online version created using qualtrics which can be viewed at the Toobtek Online Medical Professional Feedback Survey.

Toobtek Medical Professional Feedback Survey

Please indicate how similar you thought the artificial airway was to a human airway for each of the following properties.

	Completely different from a human airway				Resembling a human airway but has some flaws					Almost identical to a human airway
Color	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Other Visuals (How did the prototype reflect light? Were there any visual features missing?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Hardness (When you pressed on the prototype, how much 'give' did it have?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Flexure (Did the prototype bend appropriately?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Friction (How slippery was the prototype? Did the scope catch on the surface?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Dimensions (Were the sizes of the prototype features correct?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Form (Were the shapes of the prototype features correct?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Overall (What are your general thoughts on the prototype?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

Please note any aspects of the prototype that you appreciated:

Please note any aspects of the prototype that you did not like:
(this should include specific deficiencies as well as pain points)

D Stress Vs. Strain Curves from Test D

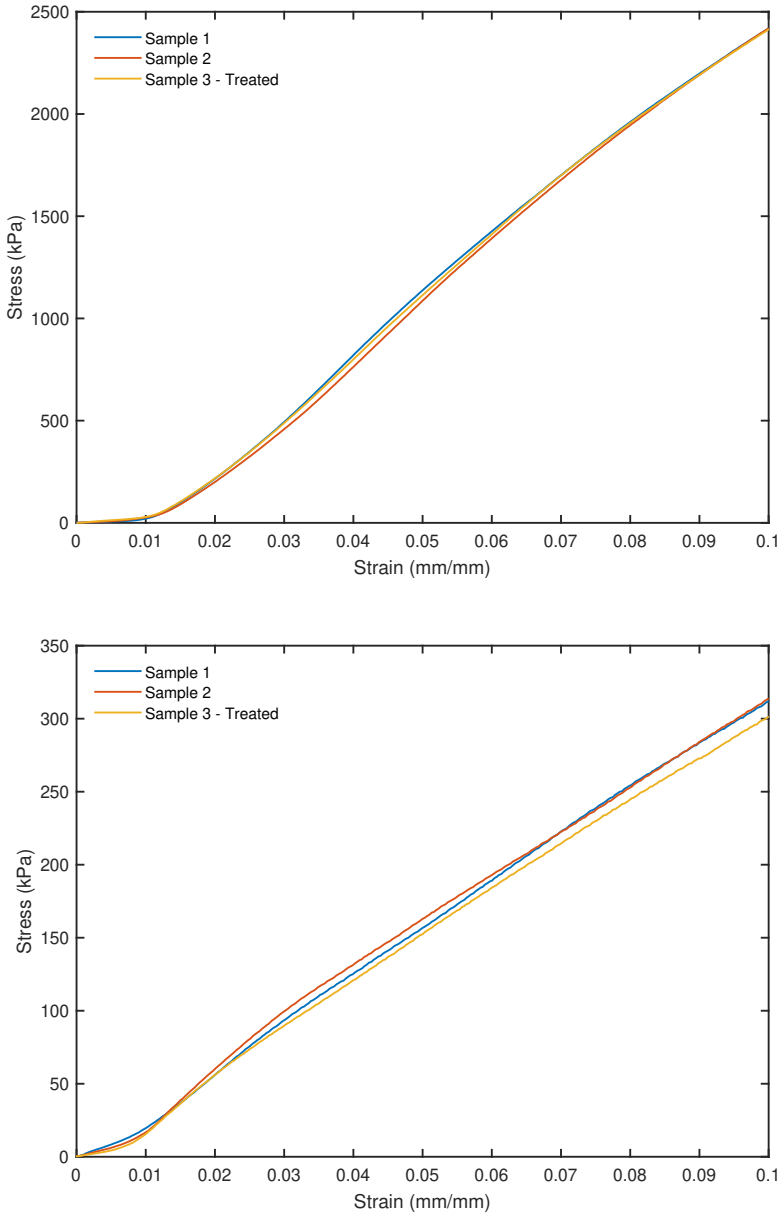


Figure 30: An additional representation of the data taken in Test C. Specifically, these plots show the stress vs. strain curves for the white samples (top) and the pink samples (bottom).

E Medical Professional Feedback Survey

A printout version of the survey used in Test E is on the following page.

Toobtek Medical Professional Feedback Survey

Please indicate how similar you thought the artificial airway was to a human airway for each of the following properties.

	Completely different from a human airway				Resembling a human airway but has some flaws					Almost identical to a human airway
Color	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Firmness (When you pressed on the prototype, how much 'give' did it have?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Flexibility (Did the prototype bend appropriately?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Proportions (Were the sizes of the prototype features correct?)	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Shape	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯
Overall	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

F MatLab Code

F.1 Test A Data Analysis

```
%% Read in and format data
% Translucent
opts = detectImportOptions(...
    'Toobtek_initialTracheaFeedbackSurvey_translucent_data.csv');
opts.SelectedVariableNames = 2:8;
nums_tr = readmatrix(...
    'Toobtek_initialTracheaFeedbackSurvey_translucent_data.csv',opts);

means_tr = mean(nums_tr,'omitnan');
std_tr = std(nums_tr,'omitnan');
n_tr = sum(~isnan(nums_tr));

opts.SelectedVariableNames = 9:15;
nps_tr = readmatrix(...
    'Toobtek_initialTracheaFeedbackSurvey_translucent_data.csv',opts);

% Opaque
opts = detectImportOptions(...
    'Toobtek_initialTracheaFeedbackSurvey_opaque_data.csv');
opts.SelectedVariableNames  = 2:8;
nums_op = readmatrix(...
    'Toobtek_initialTracheaFeedbackSurvey_opaque_data.csv',opts);

means_op = mean(nums_op,'omitnan');
std_op = std(nums_op,'omitnan');
n_op = sum(~isnan(nums_op));

opts.SelectedVariableNames  = 9:15;
nps_op = readmatrix(...
    'Toobtek_initialTracheaFeedbackSurvey_opaque_data.csv',opts);

means = [means_tr',means_op'];
S = [std_tr', std_op'];

ngroups = 7;
nbars = 2;
groupwidth = min(0.8, nbars/(nbars + 1.5));

nu_tr = n_tr - 1;
nu_op = n_op - 1;
t_95_vec = [tinv(.025,3),tinv(.025,5),tinv(.025,5),tinv(.025,6)];
```

```
I_95_tr = zeros(7,1);
I_95_op = zeros(7,1);

for i = 1:ngroups
    I_95_tr(i) = abs(t_95_vec(n_tr(i)-3) * std_tr(i) / sqrt(n_tr(i)));
    I_95_op(i) = abs(t_95_vec(n_op(i)-3) * std_op(i) / sqrt(n_op(i)));
end

I_95 = [I_95_tr I_95_op];

fig1 = figure('Name','Initial Trachea Comparison Bar Graph');
set(fig1, 'Position', [945 600 755 530]);
axes1 = axes('Parent',fig1);    hold(axes1,'on');
bar([means_tr',means_op']);
for i = 1:nbars
    x = (1:ngroups) - groupwidth/2 + (2*i-1) * groupwidth / (2*nbars);
    errorbar(x,means(:,i),I_95(:,i),'k','Linestyle','none',...
        'LineWidth',1.2,'CapSize',7.5);
end
set(gca,'XTickLabel',{'Color','Hardness',...
    'Flexure','Friction','Dimensions','Form','Overall'});
box(axes1,'on');                set(axes1,'FontSize',11,'LineWidth',1.2);
ylim([0,10]);                   ylabel('Mean Rating on 0-10 Scale');
lgd = legend({'Translucent','Opaque','95% Confidence Interval'},...
    'Location','northwest');
box(lgd,'off');                 hold off;
```

F.2 Test C Pre-Analysis

```
epsilon = .05;
max_load = [50*10^3 2*10^3 250]; %[N]
ten_percent_load = .1 * max_load;
shoreA = [37.3 39.3 44.2 53.8 75.6 90.4];

%% Create Simple Conversion Functions
A2Pa = @(x) exp(x * .0235 - .6403)*10^6;
MPa2psi = @(x) 145 * x;

%% Approximate E
E = A2Pa(shoreA); %[Pa]

%% Calculate D for various strain values
D_10 = zeros(3,6);
for i=1:3
    D_10(i,:) = sqrt( ...
        (4 * ten_percent_load(i)) ./ (pi * epsilon .* E) ); %[m]
end

%% Calculate Approximate Volume
% When (diameter / height) = 1
V_10 = pi * D_10.^3 / 4;

%% Cost Calculations
polymerized_density = 1.145 *(100/1)^3; %[g/cm^3]*[cm/m]^3=[g/m^3]
buying_cost = (1340 / 3.6) *(1/10^3); %[$/kg]*[kg/g]=[$/g]
cost_per_volume = ...
    polymerized_density * buying_cost; %[g/m^3]*[$/g]=[$/m^3]

C_10 = V_10'*cost_per_volume;

%% Change Units
D_10 = D_10' *1000; %[m]*[mm/m]=[mm]
V_10 = V_10' *(100/1)^3; %[m^3]*[cm^3/m^3]=[cm^3]

%% Display Results
disp(table(D_10,V_10,C_10))
```

F.3 Test C Data Analysis

```
for i = 1:6
    tempString = sprintf('%d.txt',i);
    opts = detectImportOptions(tempString);
    switch i
        case 1
            nums1 = readmatrix(tempString,opts);
            currFig = figure('Name','White Samples - Stress Vs. Strain');
            set(currFig, 'Position',[945 600 755 530]);
            currAxes = axes('Parent',currFig);  hold(currAxes,'on');
            plot(nums1(:,5),nums1(:,4),'LineWidth',1.2)
            box(currAxes,'on');
            set(currAxes,'FontSize',11,'LineWidth',1.2);
            xlabel('Strain (mm/mm)');           xlim([0,.1])
            ylabel('Stress (kPa)')
        case 2
            nums2 = readmatrix(tempString,opts);
            plot(nums2(:,5),nums2(:,4),'LineWidth',1.2)
        case 3
            nums3 = readmatrix(tempString,opts);
            plot(nums3(:,5),nums3(:,4),'LineWidth',1.2)
            currLgd = legend({'Sample 1','Sample 2',...
                'Sample 3 - Treated'},'Location','northwest');
            box(currLgd,'off')                  hold off;
        case 4
            nums4 = readmatrix(tempString,opts);
            currFig = figure('Name','Pink Samples - Stress Vs. Strain');
            set(currFig, 'Position',[945 600 755 530]);
            currAxes = axes('Parent',currFig);  hold(currAxes,'on');
            plot(nums4(:,5),nums4(:,4),'LineWidth',1.2)
            box(currAxes,'on');
            set(currAxes,'FontSize',11,'LineWidth',1.2);
            xlabel('Strain (mm/mm)')            xlim([0,.1])
            ylabel('Stress (kPa)')
        case 5
            nums5 = readmatrix(tempString,opts);
            plot(nums5(:,5),nums5(:,4),'LineWidth',1.2)
        case 6
            nums6 = readmatrix(tempString,opts);
            plot(nums6(:,5),nums6(:,4),'LineWidth',1.2)
            currLgd = legend({'Sample 1','Sample 2',...
                'Sample 3 - Treated'},'Location','northwest');
            box(currLgd,'off');                 hold off;
    end
end
```

```
start = 6;                finish = 51;              jump = 10;
elasticMod1 = (nums1(start+jump:finish,4)-nums1(start:finish-jump,4))...
    ./ (nums1(start+jump:finish,5)-nums1(start:finish-jump,5));
elasticMod2 = (nums2(start+jump:finish,4)-nums2(start:finish-jump,4))...
    ./ (nums2(start+jump:finish,5)-nums2(start:finish-jump,5));
elasticMod3 = (nums3(start+jump:finish,4)-nums3(start:finish-jump,4))...
    ./ (nums3(start+jump:finish,5)-nums3(start:finish-jump,5));
currFig = figure('Name','White Samples - Elastic Modulus Vs. Time');
set(currFig, 'Position',[945 600 755 530]);
currAxes = axes('Parent',currFig);                hold(currAxes,'on');
plot(nums1(start+jump:finish,2),elasticMod1/1000,'ok','MarkerSize',5.6,'
   MarkerFaceColor','#0072BD','LineWidth',.1)
plot(nums2(start+jump:finish,2),elasticMod2/1000,'sk','MarkerSize',7.1,'
   MarkerFaceColor','#D95319','LineWidth',.1)
plot(nums3(start+jump:finish,2),elasticMod3/1000,'dk','MarkerSize',6,'
   MarkerFaceColor','#EDB120','LineWidth',.1)
xlim([.195,.555])
xlabel('Time (s)');       ylabel('Elastic Modulus (MPa)')
box(currAxes,'on');       set(currAxes,'FontSize',11,'LineWidth',1.2);
currLgd = legend({'Sample 1','Sample 2','Sample 3 - Treated'},...
    'Location','northwest');
box(currLgd,'off');                               hold off;

start = 6;                finish = 51;              jump = 10;
elasticMod4 = (nums4(start+jump:finish,4)-nums4(start:finish-jump,4))...
    ./ (nums4(start+jump:finish,5)-nums4(start:finish-jump,5));
elasticMod5 = (nums5(start+jump:finish,4)-nums5(start:finish-jump,4))...
    ./ (nums5(start+jump:finish,5)-nums5(start:finish-jump,5));
elasticMod6 = (nums6(start+jump:finish,4)-nums6(start:finish-jump,4))...
    ./ (nums6(start+jump:finish,5)-nums6(start:finish-jump,5));
currFig = figure('Name','Pink Samples - Elastic Modulus Vs. Time');
set(currFig, 'Position',[945 600 755 530]);
currAxes = axes('Parent',currFig);                hold(currAxes,'on');
P4 = plot(nums4(start+jump:finish,2),elasticMod4/1000,'ok',...
    'MarkerSize',5.6,'MarkerFaceColor','#0072BD','LineWidth',.1);
P5 = plot(nums5(start+jump:finish,2),elasticMod5/1000,'sk',...
    'MarkerSize',7.1,'MarkerFaceColor','#D95319','LineWidth',.1);
P6 = plot(nums6(start+jump:finish,2),elasticMod6/1000,'dk',...
    'MarkerSize',6,'MarkerFaceColor','#EDB120','LineWidth',.1);
xlim([.195,.555])
xlabel('Time (s)');       ylabel('Elastic Modulus (MPa)')
box(currAxes,'on');       set(currAxes,'FontSize',11,'LineWidth',1.2);
currLgd = legend({'Sample 1','Sample 2','Sample 3 - Treated'},...
    'Location','northwest');
box(currLgd,'off');                               hold off;
```

```
%% Initial Averages
initAve1 = mean(elasticMod1(1:10));
initAve2 = mean(elasticMod2(1:10));
initAve3 = mean(elasticMod3(1:10));
initAve4 = mean(elasticMod4(1:10));
initAve5 = mean(elasticMod5(1:10));
initAve6 = mean(elasticMod6(1:10));
initWhiteOverall = mean([initAve1,initAve2,initAve3]);
initPinkOverall = mean([initAve4,initAve5,initAve6]);

fprintf('Sample #1, White -> %g (MPa)\n',initAve1)
fprintf('Sample #2, White -> %g (MPa)\n',initAve2)
fprintf('Sample #3, White -> %g (MPa)\n',initAve3)
fprintf('Overall, White -> %g (MPa)\n',initWhiteOverall)
fprintf('\n')
fprintf('Sample #4, Pink -> %g (MPa)\n',initAve4)
fprintf('Sample #5, Pink -> %g (MPa)\n',initAve5)
fprintf('Sample #6, Pink -> %g (MPa)\n',initAve6)
fprintf('Overall, Pink -> %g (MPa)\n',initPinkOverall)
fprintf('\n')
```

F.4 Test D Data Analysis (2/11/2021)

```
%% Input Data

% Method A
H_ms_ao = [50 53 53 49 55]';
H_cr_ao = [47 46 51 47 46]';
H_st_ao = [37 35 35 36 35]';
H_ms_at = [0 0 0 0 0]';
H_cr_at = [68 60 74 63 69]';
H_st_at = [0 0 0 0 0]';

% Method B
H_ms_bo = [51 47 51 53 52]';
H_cr_bo = [54 56 57 56 55]';
H_st_bo = [0 0 0 0 0]';
H_ms_bt = [0 0 0 0 0]';
H_cr_bt = [69 74 78 74 74]';
H_st_bt = [50 46 48 57 47]';

H_mat = [H_ms_ao  H_cr_ao  H_st_ao  H_ms_at  H_cr_at  H_st_at ...
         H_ms_bo  H_cr_bo  H_st_bo  H_ms_bt  H_cr_bt  H_st_bt];

H_means = mean(H_mat);
H_std = std(H_mat);
tval = tinv(.025,4);

I_95 = zeros(1,12);

for i = 1:length(H_std)
    I_95(i) = abs(tval * H_std(i) / sqrt(5));
end

ngroups = 3;
nbars = 2;
groupwidth = min(0.8, nbars/(nbars + 1.5));
```

```
fig1 = figure('Name','Initial Trachea Hardness Test - Method A');
set(fig1, 'Position', [945 600 755 530]);
axes1 = axes('Parent',fig1);    hold(axes1,'on');
bar([H_means(1:3)',H_means(4:6)']);
for i = 1:nbars
    x = (1:ngroups) - groupwidth/2 + (2*i-1) * groupwidth / (2*nbars);
    errorbar(x,H_means(1+(i-1)*3:1:i*3),I_95(1+(i-1)*3:1:i*3),...
        'k','Linestyle','none','LineWidth',1.2,'CapSize',7.5);
end
xticks([1,2,3])
set(gca, 'XTickLabel',...
    {'Muscle Striation','Cartilage Ring','Soft Tissue'});
box(axes1,'on');                set(axes1,'FontSize',11,'LineWidth',1.2);
ylim([0,100]);                  ylabel('Shore A Hardness');
lgd = legend({'Opaque','Translucent','95% Confidence Interval'},...
    'Location','northwest');
box(lgd,'off');                 hold off;

fig2 = figure('Name','Initial Trachea Hardness Test - Method B');
set(fig2, 'Position', [945 600 755 530]);
axes2 = axes('Parent',fig2);    hold(axes2,'on');
bar([H_means(7:9)',H_means(10:12)']);
for i = 1:nbars
    x = (1:ngroups) - groupwidth/2 + (2*i-1) * groupwidth / (2*nbars);
    errorbar(x,H_means(7+(i-1)*3:1:6+i*3),I_95(7+(i-1)*3:1:6+i*3),...
        'k','Linestyle','none','LineWidth',1.2,'CapSize',7.5);
end
xticks([1,2,3])
set(gca, 'XTickLabel',...
    {'Muscle Striation','Cartilage Ring','Soft Tissue'});
box(axes2,'on');                set(axes2,'FontSize',11,'LineWidth',1.2);
ylim([0,100]);                  ylabel('Shore A Hardness');
lgd = legend({'Opaque','Translucent','95% Confidence Interval'},...
    'Location','northwest');
box(lgd,'off');                 hold off;
```

F.5 Test D Data Analysis (2/22/2021)

```
%% Input Data
data = [...
    39  42      48      56      76      91;...
    39  39      49      55      75      91;...
    36  38      45      57      79      92;...
    39  39      44      53      74      91;...
    36  39      42      54      75      89;...
    38  39      41      51      73      89;...
    37  40      43      53      75      90;...
    37  39      44      55      78      91;...
    36  39      44      51      75      90;...
    36  39      42      53      76      90];

X = [40,50,60,70,85,95];

[N,sets] = size(data);
H_means = mean(data);
H_std = std(data);
tval = tinv(.025,N-1);

I_95 = zeros(1,sets);

for i = 1:sets
    I_95(i) = abs(tval * H_std(i) / sqrt(N));
end
```

```
fig1 = figure('Name','Sample Hardness Test');
set(fig1, 'Position', [945 600 755 530]);
axes1 = axes('Parent',fig1);    hold(axes1,'on');
title('Hardness Re-Testing Results')
meanPlot = plot(X,H_means(1:6),'ko','Linestyle','none',...
    'MarkerFaceColor','#D95319','MarkerSize',4,'LineWidth',.05);
confPlot = errorbar(X,H_means,I_95,'k','Linestyle','none',...
    'LineWidth',1,'CapSize',8.5);
targetPlot = plot(X,X,'ko','Linestyle','none',...
    'MarkerFaceColor','#0072BD','MarkerSize',4,'LineWidth',.05);
uistack(meanPlot,'top');
box(axes1,'on');
set(axes1,'FontSize',11,'LineWidth',1.2);
xlim([35,100]);                 xlabel('Sample')
ylim([35,100]);                 ylabel('Shore A Hardness');
xticks([40,50,60,70,85,95])
lgd1 = legend({'95% Confidence Interval','Target','Mean'},...
    'Location','northwest');
box(lgd1,'off');                hold off;

fig2 = figure('Name','Hardness Difference');
set(fig2, 'Position', [945 600 755 530]);
axes2 = axes('Parent',fig2);    hold(axes2,'on');
title('Hardness Re-Testing Residuals')
meanPlot = plot(X,H_means(1:6)-X,'ko','Linestyle','none',...
    'MarkerFaceColor','#D95319','MarkerSize',4,'LineWidth',.05);
confPlot = errorbar(X,H_means-X,I_95,'k','Linestyle','none',...
    'LineWidth',1,'CapSize',8.5);
plot([35,100],[0,0],'k--','LineWidth',1.5)
uistack(meanPlot,'top');
box(axes2,'on');
set(axes2,'FontSize',11,'LineWidth',1.2);
xlabel('Sample')
ylabel('Target - Measured Hardness (Shore A)');
xlim([35,100]);
ylim([-20,2]);
xticks([40,50,60,70,85,95]);    hold off;
```

F.6 Test E Data Analysis

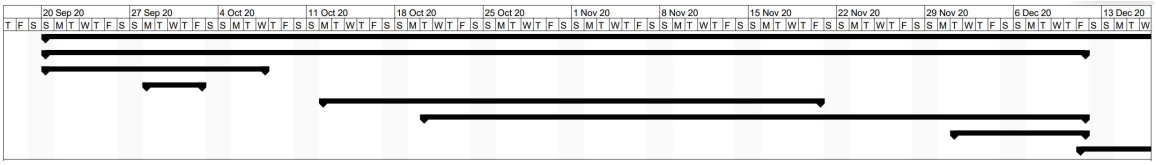
```
%% Read in and format data
opts = detectImportOptions('mprs_data.csv');
opts.SelectedVariableNames = 2:7;
nums = readmatrix('mprs_data.csv',opts);

means = mean(nums,'omitnan')';
std = std(nums,'omitnan')';
n = sum(~isnan(nums));

nu = n - 1;
I_95 = zeros(6,1);

I_95(:) = abs(tinv(.025,nu(:)) .* std(:) ./ sqrt(n(:)));

%% Standalone Plot
fig1 = figure('Name','MPRS Bar Graph');
set(fig1, 'Position', [945 600 755 530]);
axes1 = axes('Parent',fig1);    hold(axes1,'on');
bar(means','HandleVisibility','off');
errorbar(1:6,means,I_95,'k','Linestyle','none',...
    'LineWidth',1.2,'CapSize',7.5);
set(gca, 'XTickLabel',...
    {'Color','Firmness','Flexibility','Proportions','Shape','Overall'});
box(axes1,'on');                set(axes1,'FontSize',11,'LineWidth',1.2);
xlim([.2,6.8]);
ylim([0,10]);                   ylabel('Mean Rating on 0-10 Scale');
annotation(fig1,'textbox',...
    [0.824 0.86 0.073 0.051],...
    'VerticalAlignment','middle',...
    'String',{'N = 9'},...
    'LineWidth',1,...
    'HorizontalAlignment','center',...
    'EdgeColor',[0.502 0.502 0.502],...
    'BackgroundColor',[1 1 1]);
hold off;
```

G Project Schedule for First Semester

G.1 Fall Schedule Overview

Name	Duration	Start	Finish
Senior Design	**163 days?**	**9/20/20 ...**	**5/5/21 5:00 PM**
First Semester	**60 days?**	**9/20/20 ...**	**12/11/20 5:00 PM**
Grant Proposal	**13 days?**	**9/20/20 ...**	**10/7/20 5:00 PM**
Design Basis Document	**5 days?**	**9/28/20 ...**	**10/2/20 5:00 PM**
PDR	**30 days?**	**10/12/20...**	**11/20/20 5:00 PM**
CDR	**39 days?**	**10/20/20...**	**12/11/20 5:00 PM**
Revise CAD	**10 days?**	**11/5/20 ...**	**11/18/20 5:00 PM**
Presentation	18 days?	10/26/20 8...	11/18/20 5:00 PM
Paper	18 days?	10/26/20 8...	11/18/20 5:00 PM
Testing Documentation	39 days?	10/20/20 8...	12/11/20 5:00 PM
Manufacturing Review	**9 days?**	**12/1/20 ...**	**12/11/20 5:00 PM**
BOM	9 days?	12/1/20 8:...	12/11/20 5:00 PM
Drawings	9 days?	12/1/20 8:...	12/11/20 5:00 PM
Presentation	5 days?	12/7/20 8:...	12/11/20 5:00 PM
Manufacturing Schedule	9 days?	12/1/20 8:...	12/11/20 5:00 PM
Second Semester	**104 days?**	**12/11/20...**	**5/5/21 5:00 PM**

G.2 First Semester Gantt Chart



H Project Schedule for Second Semester

H.1 Spring Schedule Overview

Name	Duration	Start	Finish
SPR / Mid-Year Assess.	9 days?	1/19/21 8:00 AM	1/29/21 5:00 PM
Manufacture Trachea	9 days?	1/20/21 8:00 AM	2/1/21 5:00 PM
Grant Proposal	23 days?	1/3/21 8:00 AM	2/3/21 5:00 PM
Trachea Test Plan	8 days?	1/22/21 8:00 AM	2/2/21 5:00 PM
Qualitative Testing	3 days?	2/3/21 8:00 AM	2/5/21 5:00 PM
NVC Pitch Prepared	13 days?	1/29/21 8:00 AM	2/16/21 5:00 PM
Initial Website Completion	16 days?	1/26/21 8:00 AM	2/16/21 5:00 PM
Quantitative Testing	2 days?	2/18/21 8:00 AM	2/19/21 5:00 PM
Full Model Test Plan	9 days?	2/10/21 8:00 AM	2/22/21 5:00 PM
Founder's Agreement Finalized	10 days?	2/9/21 8:00 AM	2/22/21 5:00 PM
NVC Round One	2 days?	2/22/21 8:00 AM	2/23/21 5:00 PM
Form LLC	2 days?	2/22/21 8:00 AM	2/23/21 5:00 PM
Redesign	7 days?	2/21/21 8:00 AM	3/2/21 5:00 PM
NVC Round 2	1 day?	4/8/21 7:00 AM	4/8/21 5:00 PM
NVC Championships	0 days?	4/13/21 7:00 AM	4/13/21 8:00 AM
Manufacture Final Model	10 days?	3/2/21 8:00 AM	3/15/21 5:00 PM
Final Model Testing	16 days?	3/25/21 7:00 AM	4/15/21 5:00 PM
Videos and Supplemenetal Info	15 days?	3/23/21 8:00 AM	4/12/21 5:00 PM
Website Finalized	11 days?	3/29/21 8:00 AM	4/12/21 5:00 PM
White Paper	11 days?	4/5/21 8:00 AM	4/19/21 5:00 PM
Final Paper	17 days?	4/12/21 8:00 AM	5/4/21 5:00 PM

H.2 Second Semester Gantt Chart

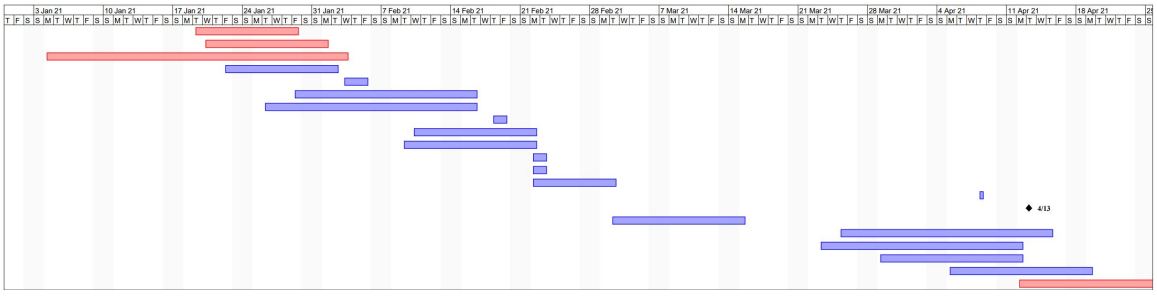


Table 9: Project Schedule Table (Note: The question marks included in the duration column are used by the Project Libre software denote the estimated time frame for completing each deliverable item)

Name	Duration	Start	Finish
Senior Design	**104 days?**	**12/11/20 8:00 AM**	**5/5/21 5:00 PM**
Second Semester	**104 days?**	**12/11/20 8:00 AM**	**5/5/21 5:00 PM**
Spring Semester...	**10 days?**	**1/16/21 8:00 AM**	**1/29/21 5:00 PM**
Background Recap	10 days?	1/16/21 8:00 AM	1/29/21 5:00 PM
Experimental Lay...	10 days?	1/16/21 8:00 AM	1/29/21 5:00 PM
Design Schedule	10 days?	1/16/21 8:00 AM	1/29/21 5:00 PM
Recovery Plan	10 days?	1/16/21 8:00 AM	1/29/21 5:00 PM
Test Plan	10 days?	1/16/21 8:00 AM	1/29/21 5:00 PM
Analysis, Toleran...	**10 days?**	**1/30/21 8:00 AM**	**2/12/21 5:00 PM**
Analysis	10 days?	1/30/21 8:00 AM	2/12/21 5:00 PM
Tolerance	10 days?	1/30/21 8:00 AM	2/12/21 5:00 PM
Test Plan	10 days?	1/30/21 8:00 AM	2/12/21 5:00 PM
Prototype Test Res...	10 days?	1/30/21 8:00 AM	2/12/21 5:00 PM
Redesign and Re...	**20 days?**	**2/27/21 8:00 AM**	**3/26/21 5:00 PM**
Redesign	10 days?	2/27/21 8:00 AM	3/12/21 5:00 PM
Redesign Test Re...	20 days?	2/27/21 8:00 AM	3/26/21 5:00 PM
Final Project Rep...	**104 days?**	**12/11/20 8:00 AM**	**5/5/21 5:00 PM**
Problem and Obj...	104 days?	12/11/20 8:00 AM	5/5/21 5:00 PM
Detailed Docume...	104 days?	12/11/20 8:00 AM	5/5/21 5:00 PM
Lab test plans an...	104 days?	12/11/20 8:00 AM	5/5/21 5:00 PM
Bil of Materials	104 days?	12/11/20 8:00 AM	5/5/21 5:00 PM
Gannt chart	104 days?	12/11/20 8:00 AM	5/5/21 5:00 PM
Ethical Considera...	104 days?	12/11/20 8:00 AM	5/5/21 5:00 PM
Safety and Oper...	104 days?	12/11/20 8:00 AM	5/5/21 5:00 PM
Conclusion	104 days?	12/11/20 8:00 AM	5/5/21 5:00 PM
Final Report	28 days?	3/27/21 8:00 AM	5/5/21 5:00 PM
Final Product	10 days?	4/10/21 8:00 AM	4/23/21 5:00 PM
White Paper	14 days?	4/5/21 8:00 AM	4/22/21 5:00 PM

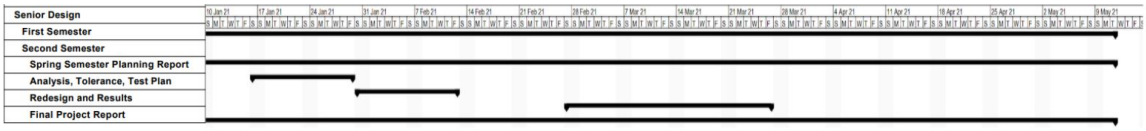


Table 10: Project Schedule Gantt Chart

I Revision History

Rev	Contributor(s)	Date	Description
A	Jacob Haimes, Rebecca Jacobs, Kaushik Kannan, Kathryn Kubacki, Judson Martin	December 1, 2020	Initial release of fall End of Term Report
B	Jacob Haimes, Rebecca Jacobs, Kaushik Kannan, Kathryn Kubacki, Judson Martin	December 10, 2020	Finished for fall End of Term Report deliverable
C	Jacob Haimes, Rebecca Jacobs, Kaushik Kannan, Kathryn Kubacki, Judson Martin	April 20, 2021	Initial release of spring End of Year Report
D	Jacob Haimes, Rebecca Jacobs, Kaushik Kannan, Kathryn Kubacki, Judson Martin	April 25, 2021	First iteration of spring End of Year Report, submitted for feedback
E	Jacob Haimes, Rebecca Jacobs, Kaushik Kannan, Kathryn Kubacki, Judson Martin	April 29, 2021	Final iteration of spring End of Year Report