Automated Endotracheal Intubation (AEI)

Team 6.2 (AEI)

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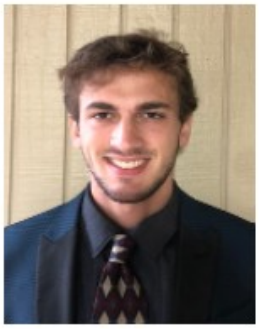
Abstract:

Endotracheal intubation is an often performed procedure which is critical to the health and safety of patients in both the elective and emergency environments. Its purpose is to give the anesthesiologist access to the lungs during various procedures and allows them to control the patient's breathing while they are under operation, or unable to do so themselves. That said, in the worst case scenarios faulty intubation tube placements can cause severe trauma, and often times death, and it can be difficult to prepare trainees for the variations in differing patient's airways. Current placement strategies mostly depend on moving anatiomical features out of the way and visualizing the path to the airway via a camera, but none combine the best visualization practices with the ability to control navigation of the tube accurately and autonomously. The goal of this project is to develop a device which facilitates the placement of the endotracheal tube such that the first-pass success (FPS) rate increases, and the possibility of trauma to the patients airway decreases. To achieve this, a novel device was created. This device utlizes twisted and coiled polymers (TCP) to guide the end effector in to the airway. The device is used to create a path for the intubating physician to slide the endotracheal tube into the proper location, before removing the device from the patient completely. The novelty of this device lies in the TCP acuation method which operates independent of its distance from the housing module, which gives it the capability to be machine-driven. This is unlike any other method currently in the market today, and opens avenues for robustly increasing the accuracy and safety of this complex and fast procedure.

Team Members:



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Acknowledgments:

First, we would like to thank Dr. Mark Ruegsegger who has been instrumental in the advancement of this project. We are grateful for his guidance and the interest he shows in helping us complete our goals.

Likewise, we would like to express our gratitude to Dr. Hamdy Awad for his guidance and expertise in anesthesiology and in demonstrating to us the need for and importance of the new method of endotracheal intubation being developed.

We are also thankful for the support of Nate Ames, along with the rest of the Center for Design and Manufacturing Excellence Department, for their services in beginning this process, and their continued help in advancing our agenda.

Finally, the Innovation Studio, who has graciously gifted us $250 for prototyping, which we are excited to utilize with their supervision.

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Chapter 1

1. Introduction

Endotracheal intubation (EI) may come off as a simple procedure when looking at the big picture, but it is a critical procedure performed by anesthesiologists and emergency medical specialists. A plastic tube is manually inserted into the mouth, pushed down the throat, and eventually enters the patient's airway. Figure 1 below depicts a modern intubation in a hospital. While many times it is this simple with the current tools and adequate amount of skill possessed by the person performing the procedure, failed attempts and complications still occur more frequently than desired. Optimized technology for this procedure has still not been innovated and there is a lot of room for improvement. Currently, we are still using technology and techniques that were first invented in the late 19th century. Slight modifications and improvements have been made to them, but the same general procedure remains. This report was created to define the current problems in EI, and pinpoint what a future medical device needs to find solutions to the many shortcomings in the field. To do this, we gathered a vast amount of information regarding the clinical procedure, as well as current medical devices used to complete it. To fix something, it is imperative to understand the problem from many different angles and ensure that nothing is missed, especially when it comes to keeping a person alive while they cannot breathe on their own. The group's focus is to innovate an autonomous device that successfully inserts the endotracheal tube into a patient's trachea. For simplification and feasibility, the group will be focused on patients with non-complicated airways. Ideally, if the patient enters the procedure with a healthy airway, then the EI procedure should not change that. As a team, we hope to use the research and knowledge acquired in this report to find "gaps" in the current EI field and devise our device to specifically address those, keeping traditional strategies in mind as well. In the end, to be successful, our automated EI device must include novel features, as well as have a success rate that is higher than manual intubation, or at the very least equivalent with other advantages to offer.

Figure 1: Endotracheal intubation being performed on a patient in a clinical setting.

2. Problem Definition

a). Clinical background

Endotracheal intubation was first attempted in 1858 to avoid traditional methods of tracheotomy. At the time, tracheotomy was used to relieve laryngeal obstruction (Dobell, 1994). Later, physicians discovered they were able to visualize the glottis by depressing the epiglottis, which is crucial for successful tube placement. Victor Eisenmenger is attributed to the final version of the inflatable cuff on the actual tube itself for sufficient pressure buildup in the lungs (Dobell, 1994). The inflatable cuff, which can be seen in Figure 2, is still a necessary part of modern endotracheal tubes. In 1895, Alfred Kirsten introduced the laryngoscope. This was a huge advancement because the person performing the intubation no longer had to depress the epiglottis with their finger (Dobell, 1994). Robert Macintosh designed a laryngoscope that incorporates a blade that is continuously curved, protecting the patient's upper teeth while still depressing the tongue (Pantano, 2015). The Macintosh blade is still used to this day.

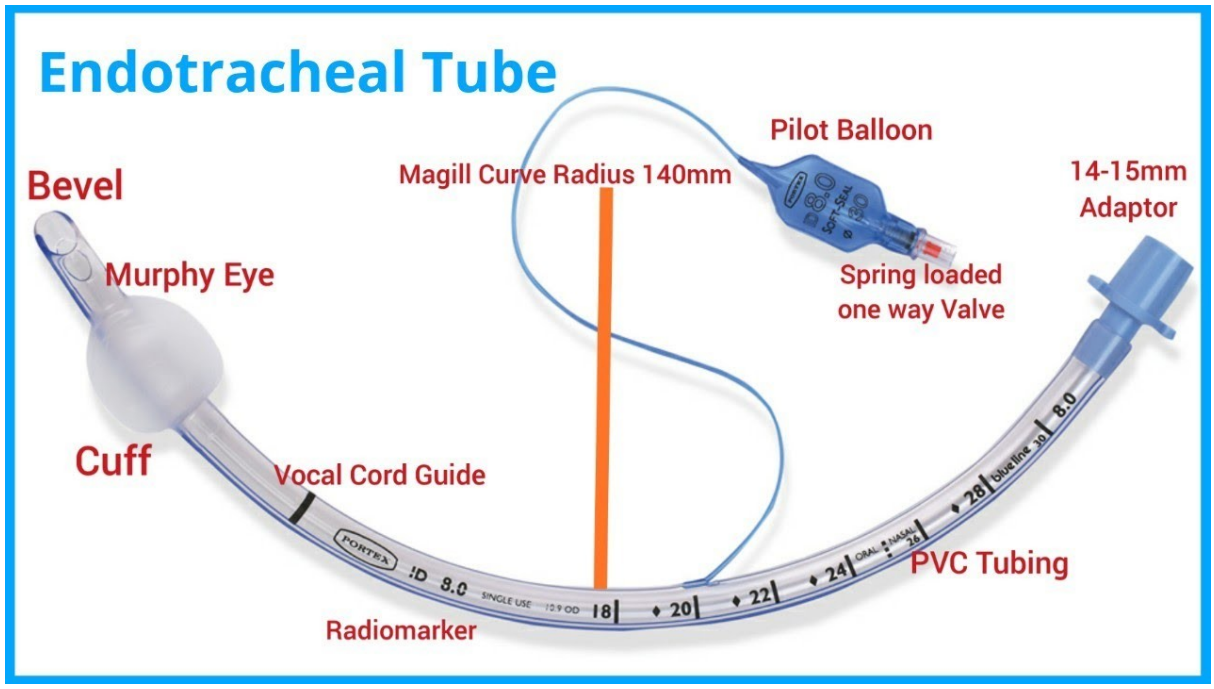

Figure 2: The currently used endotracheal tube with important features labeled.

Intubation is considered one of the most important skills in anesthesiology (Hemmerling et al., 2012). Respiratory intubation (and mechanical ventilation) was the third most common procedure performed at hospitals in 2011 (Pfuntner et al., 2021) with 13-20 million intubations are performed each year in the United States (Nadeem et al., 2017). Most intubations will be performed through endotracheal intubation as it is the gold standard in emergency airway management. The placement of the endotracheal tube with relevant anatomical features labeled

can be seen in Figure 3 below. Airway management is vital for the health and safety of the patient; quickly securing the airway is a primary concern for physicians (Nadeem et al., 2017). The gravity of the situation necessitates the need for a high first-pass success (FPS) rate regarding intubation. Historically, endotracheal intubation has been terminated for several reasons, including ineffective removal of tracheobronchial secretions, trouble swallowing, and fear of permanent larynx injury (Stauffer et al., 1981). Each additional attempt at intubating a patient or the overall pass success (OPS) rate increases the risk of damage to the patient dramatically. Numerous adverse risks are likely to present themselves with the additional time taken to intubate the patient, including oxygen desaturation, laryngospasm, pneumothorax, hypotension, etc. (Sakles, et al.,2013). Currently, endotracheal intubation is performed by multiple skilled medical specialists which can introduce a wide range of human errors (Alvarado & Panakos, 2021). When executed by a medical specialist, the intubation procedure is composed of multiple, time-consuming steps such as airway preparation, pre-oxygenation, and laryngoscopy (Alvarado & Panakos, 2021).

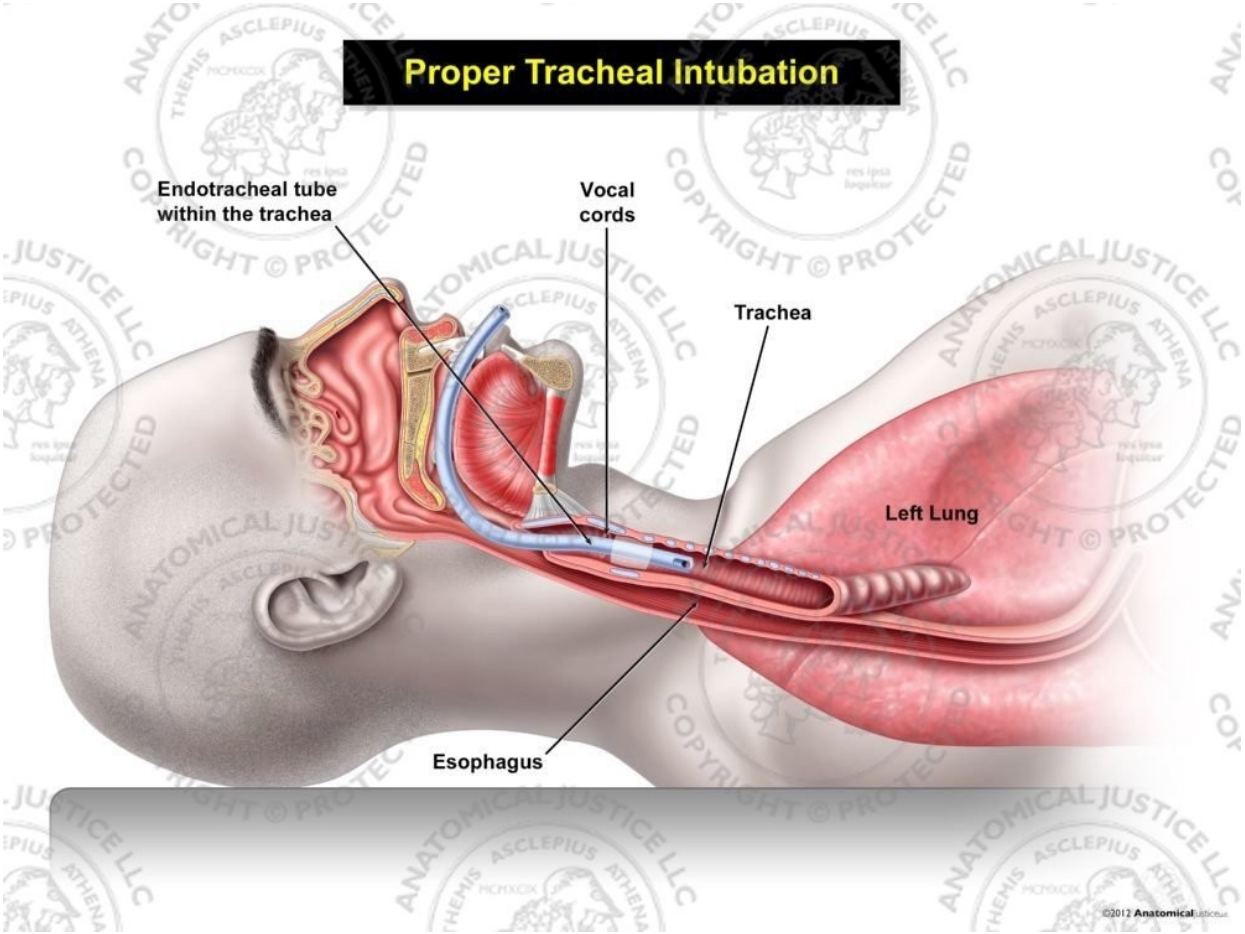

Figure 3: Proper placement of endotracheal tube.

The choice of laryngoscopy is frequently accompanied by a variety of backup strategies due to the lower than optimal OPS rate (Alvarado & Panakos, 2021). As intubation is a common procedure, it is performed in a variety of settings by various healthcare professionals. Not differentiating by the intubation method used, the FPS rate for intubation is 46.4% to 77.2% for paramedics, 71.2% to 87.5% for prehospital physicians, and 60.7% to 97.3% for in-hospital physicians (Bernhard et al., 2015). Anatomical differences and obesity can pose a challenge regarding intubation and may result in a lower chance of successful intubation (Nicholson, 2014). In addition, operator-related differences may influence an individual's skill set regarding intubation (Hemmerling et al., 2012). The success rates have also been found to differ in various settings. The emergency department can exhibit success rates as low as 70% on the first attempt and 89% on the second attempt, which is considerably less successful than in anesthesia departments (Hemmerling et al., 2012).

b). Device Background

As stated previously, endotracheal intubations remain one of the most often practiced procedures in the hospital environment, the importance of an updated and more efficient system is imperative. The proposed solution will be created with the overarching goal of increasing the average FPS rate from the industry standards, which range between 75% to 85% depending on the clinical environment where the patient is being intubated (Bernhard et al., 2015). It is also worth mentioning that the OPS rate ranges typically average to around 95% or higher for prehospital and in hospital physicians, and 85% or higher for prehospital paramedics (Bernhard et al., 2015). These may seem like acceptable success rates, but the real damage occurs after the first pass to the patient. Statistics show that the more passes needed, the more likely the patient is to suffer from injuries including hypoxemia, esophageal intubation, aspiration, and even cardiac arrest. A 2014 study even states that the likelihood of injury increases 4-fold with any more than one intubation attempt (Bernhard et al., 2015).

The need for an intubation method that optimizes the FPS rate is necessary for the increased safety of any patient being operated on. For the scope of the intubation device being discussed here, the target population will be patients with healthy airways, i.e., the scope will not include patients who have predetermined issues with their airway.

The clinical environment currently has three primary methods for intubation, with the three of them being performed a combined 50 million times every year in the United States (Kitzmann, 2020). These methods include direct laryngoscopy, video laryngoscopy, and flexible intubation scope, and can be seen in Figure 4 below. Direct laryngoscopy utilizes the Macintosh blade to visualize the larynx and while it is primarily used during the intubation process, it is also applicable to any surgical procedure that requires access to the larynx including resuscitations (Peterson et al., 2021). Video laryngoscopy is very similar to the previously mentioned direct method with the exception that an internal camera, connected to an external screen, which is used to visualize the larynx, glottis, and epiglottis, among other applicable anatomical features. Both tools are used to physically depress the tongue and glottis so that the operator can visualize the airway more easily. The final tool, the flexible intubation scope, or flexible bronchoscope is another effective visualization method that allows the practicing physician to insert and guide the intubation tube into the patient when direct, or video laryngoscopy would be otherwise difficult,

or impossible to perform. This process is centered around an insertion cord which is tied back to a camera and external monitor which allows the physician to clearly see the inside of the patient's airway during intubation, thus assisting in guiding the tube to the correct location ("Awake Bronchoscope Intubation," 2012). All these tools are completely removed from the patient when the intubation tube is deemed in the correct location.

Figure 4: Three most common tools for endotracheal intubation.

It is worth noting that a review article published in 2015 (Lewis et al.) investigated 64 studies which found that video laryngoscopy resulted in significantly fewer failed intubations than direct laryngoscopy. The authors concluded that this is likely due to the improved view of the glottis. However, the study did not find a significant difference regarding the number of intubation attempts (i.e., OPS) and the time required to intubate between these two methods. Flexible intubation scopes are thought of as an advanced intubation method and require more experience and training which may lead to underutilization in practice (Nicholson, 2014).

There are currently several different types of endotracheal intubation devices that have established a patent either in their utility or design. Regarding utility patents, they mostly concentrate on the smart navigation or features of the intubation device. For example, recently a device was patented by the Ohio State Inventors which intubated patients based on guidance from an audio-vibratory architecture. Another recent utility patent was a light-guided endotracheal intubation system that uses an autonomous modulated light source to navigate. Both devices' weaknesses are their slow installation time and difficulty of usage. Regarding design patents, there have been several designs of endotracheal tubes and handles recorded. With that said, they do not limit any new designs that can be created in the future due to the possibilities of the implied design space.

There is also an innovative new design planned to come to market at the end of next year which utilizes a vine robot to quickly and accurately place the intubation tube while also closing off the esophagus (Hawks et al., 2021). The intubation method itself is being catered to

emergency related intubations, for example in ambulances, or for military applications, but it is not difficult to see its application in the hospital environment.

c). The New Device

With the overarching goal of increasing the first-pass success rate (FPS), the objective for the new device can be seen in the bulleted list below. These requirements were chosen from discussions between the anesthesiologists and nurses whom the device is being designed for and are intended to encompass their wants and needs.

List of Objectives:

1. Is handheld
2. Is light weight
3. Is safe to reuse, or modular
    3.a Is environmentally conscience
4. Is reliable
5. Is accurate
6. Is easy to use
7. Is ergonomic
8. Is controllable by a single person

Noteworthy items in the list above include the need for the device to be either reusable, or modular. The device will either be sterilized post-procedure, or the portion of the device will be replaced after the installation of the intubation tube.

The device also has an important hard constraint which is the portion that enters the patient must have a maximum diameter of 1 cm.

Chapter 2

1. Engineering Functions

The engineering functions for the new device can be found below. They were developed with the guidance, and discussion from anesthesiologist, Dr. Hamdy Awad. They include mandatory functions, which are required for the success of the overall project, and optional functions which will be considered during the design process, but not prioritized.

a). Mandatory Functions

1. Can fit within the dimensions of the human airway.
2. Can navigate the human airway.
3. Can visualize its surroundings.
4. Can properly place the currently used tracheal tube.
5. Can perform intubation in an appropriate amount of time.
6. Can operate successfully on a noncomplicated airway.
7. Can be inputted into human airway without causing damage.
8. Can be removed without causing damage.
9. Can be used in the place of the current intubation system.
10. Can be powered through the length of the procedure.

b). Optional Functions

1. Can be operated in both manual and automatic mode.
2. Can deliver appropriate medication.
3. Under $40,000 end cost to user

2. Standards

There are multiple standards for medical devices that deal with anesthesiology/airway management. The international organization for standardization (ISO) has developed multiple documents detailing medical equipment in general (*11.040.*01 - *Medical Equipment in General*, 2021*)*, the quality management of design and manufacture of medical devices (*ISO 13485:2016*, 2020), 6 subcommittees under ISO/TC 121 for anesthetic and respiratory equipment with 105 current published standards with more under development (*Standards by ISO/TC 121*, 2021). The subcommittee topics include breathing attachments and anesthetic machines, airways and related equipment, medical gas supply systems, and more.

American Society for Testing and Materials (ASTM) has developed a standard regarding the decommissioning and disposal of medical equipment (ASTM International, 2018). There were standards regarding rigid laryngoscopes, but they have since been withdrawn.

The FDA is a big regulator of medical equipment in America. The code of federal regulations, title 21, governs food and drugs. Specifically, the 800 series is for medical devices. Here we have listed some specific parts that deal with the regulations of anesthesiology devices (Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act

(the act), 2020), tracheal tubes (Tracheal Tube, 2020), rigid laryngoscopes (Rigid Laryngoscope, 2020), and flexible laryngoscopes (Flexible Laryngoscope, 2020).

3. Stakeholders/Users

By observing Figure 5 we can see combined, the Manufacturer, Users, Vendors, and Government are the stakeholders which each have a critical role. The manufacturer, as the creator of the device, must ensure that it is manufactured to meet the required standards of safety and performance. The user should make sure that he/she has qualifications and training in the proper use of the device. The vendor provides an interface between the product and the user and should ensure that the products sold comply with regulatory health requirements. The government has the responsibility to oversee the efforts of manufacturers and vendors and ensure the medical devices are made available with safety and effectiveness.

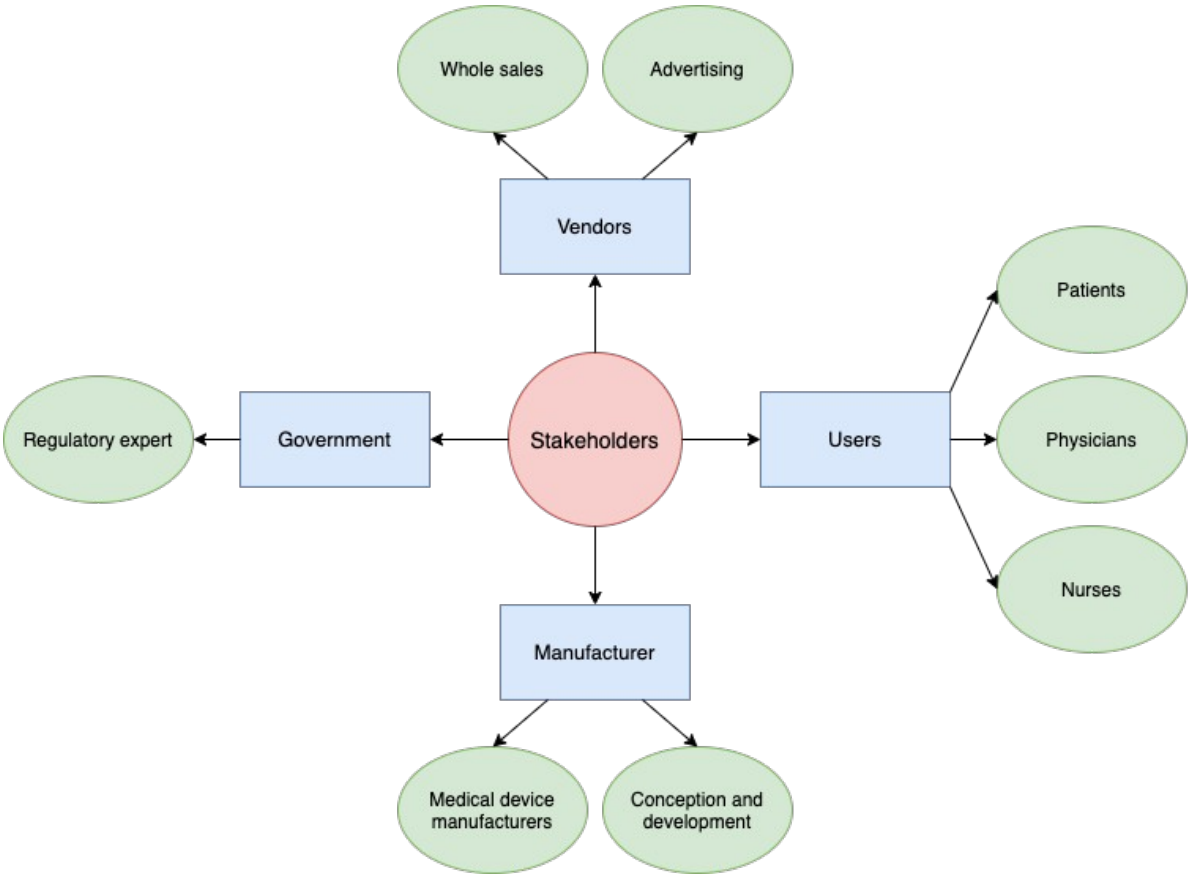

Figure 5: Diagram Map of Stakeholders

4. Sustainability

The sustainability of the endotracheal intubation device can be achieved by investing in smart material choices for the device. The medical device should be reusable which will save the environment from disposable endotracheal tubes. Its reusability with sterilization methods will decrease environmental harm. With that said, for the device to be reusable, it must have durable properties and be sterilized without high energy requirements. Another point to increase sustainability, by using sustainable and efficient materials it can be recycled or reprocessed. If instead the device is designed to be modular, the hope is that compatible recyclable materials can be found that lie in the necessary standards for patient safety.

Chapter 3

1. Concept Selection

a). Development of Initial Concepts

The team formulated and improved upon many innovative ideas that were eventually implemented into our concept designs via collaboration within the group, as well as with our clinical mentor Dr. Hamdy Awad (and affiliated colleagues).

However, this could not have been possible without the individual efforts of Team 6.2's group members in brainstorming novel and potentially effective features. This entailed searching for relevant literature relating to endotracheal intubation, continuum robots, and modes of actuation. After reading current literature, Team 6.2 pinpointed what was advantageous to the associated concept, in addition to what could be improved upon with the team's future device and concept design.

Upon completion of the research and collaboration stage, Team 6.2 was ready to transform verbal concepts into concrete visualizations. The team accomplished this by composing a total of twenty "Device Design Sketches". This process required a large amount of free sketching and proactive brainstorming from individual members of the team. To aid in this process, when the team experienced a degree of stagnation in their design sketches, similar to "writer's block", we turned to the team's collaborators for advice. Nate Ames, the executive director of Ohio State's Center for Design and Manufacturing Excellence, informed the team how to find and implement new ideas into concept designs. He told the team not to confine the device sketches to what is currently used or "expected" of an endotracheal intubation device. He mentioned how potential features of your device could be developed from almost anything we visualize or use in our day-to-day life. The team was given suggestions such as conducting a Google search for "art museum sculptures". Following this advice led the team to novel and unique features that we implemented into the initial concepts, as well as the selected "final" design.

To complete the development of initial concepts, each team member presented their device design sketches, sharing what their favorite aspects and features were of the associated design. During this process, other members of the team would provide the presenting teammate with "applause" or constructive criticism for a particular design. A list of desired features was compiled from this process. The team made sure that the feature list contributed to the device functions that were previously created as it is anticipated that the final device will be able to accomplish a majority of them.

Figure 6: 3D Abstract Sculpture from the Richard Erdman Studio

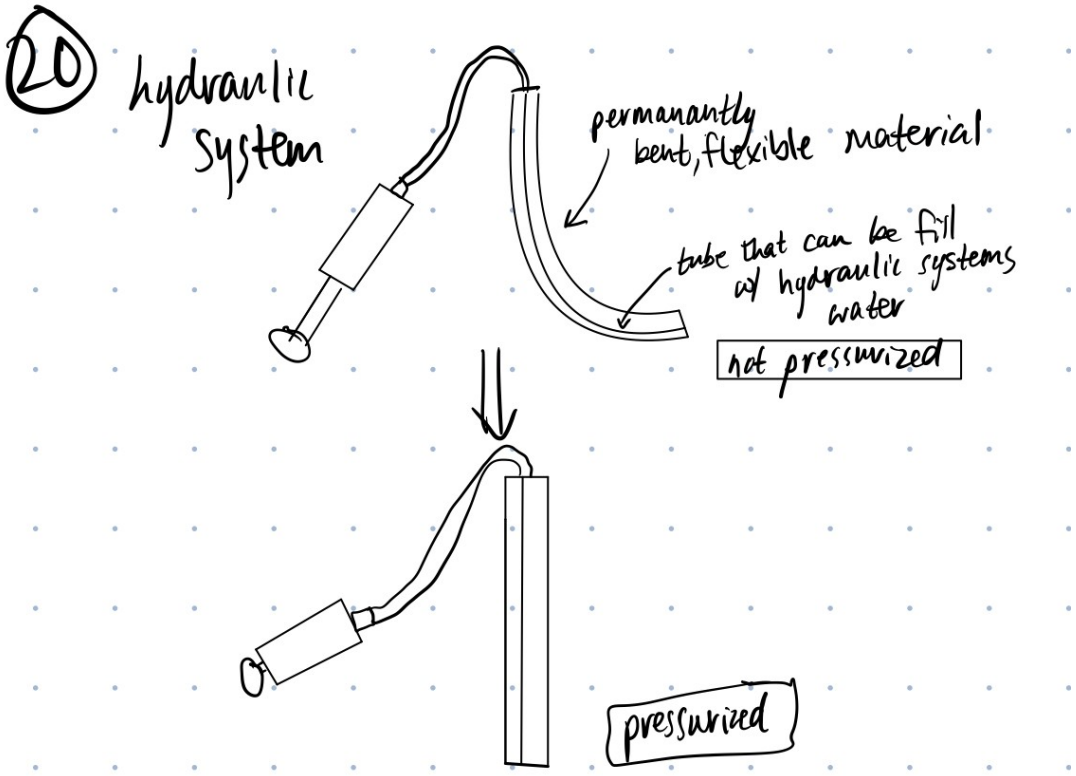

Figure 7: Initial Design for Hydraulic Action Concept

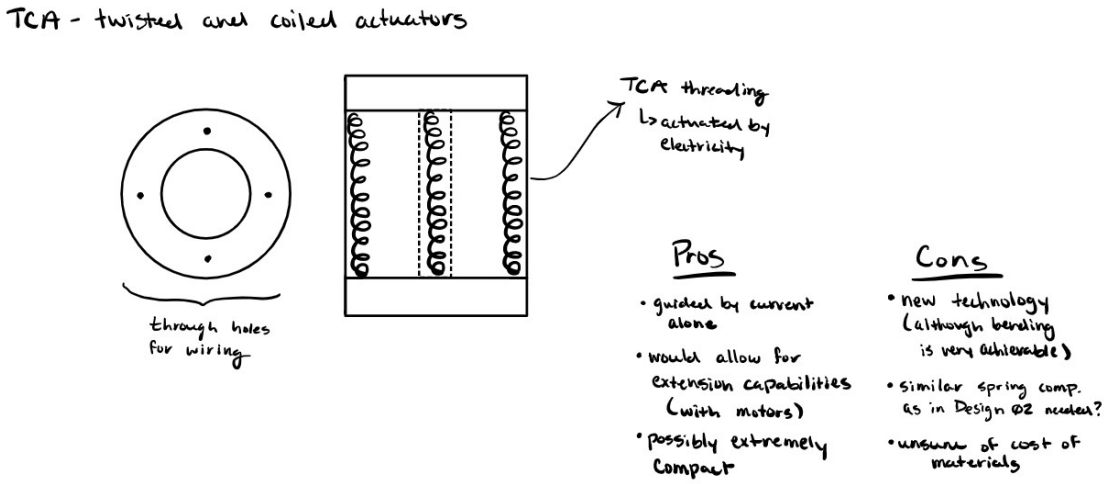

Figure 8: Initial Design for TCA String Concept

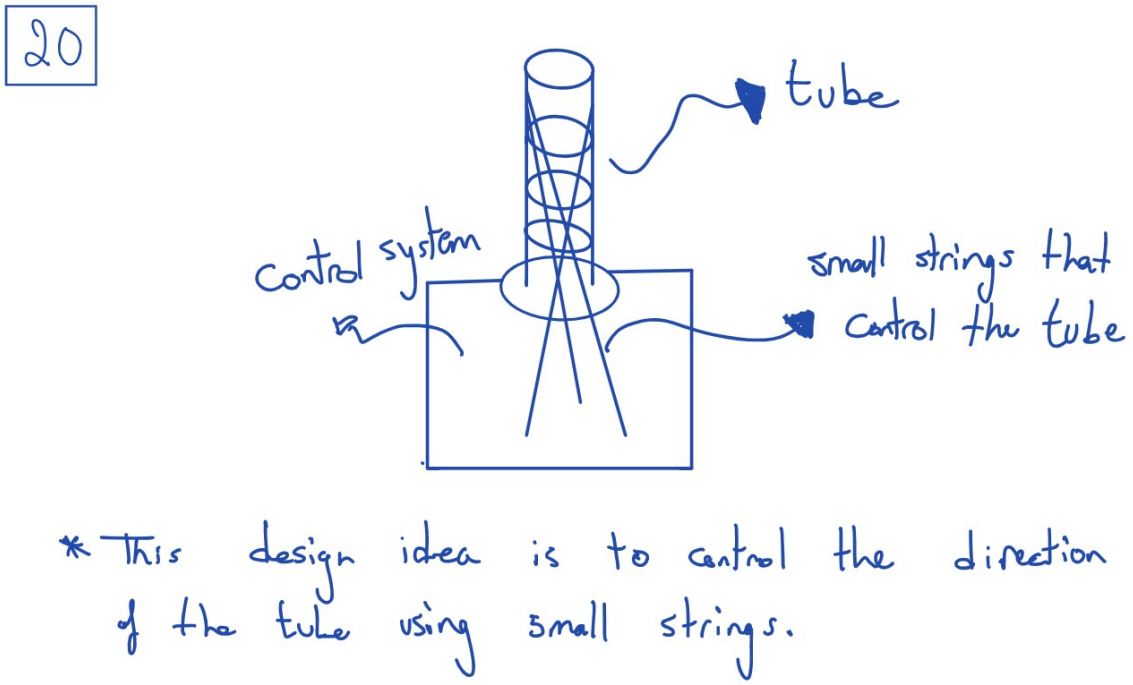

Figure 9: Initial Design for Tension Actuation Concept

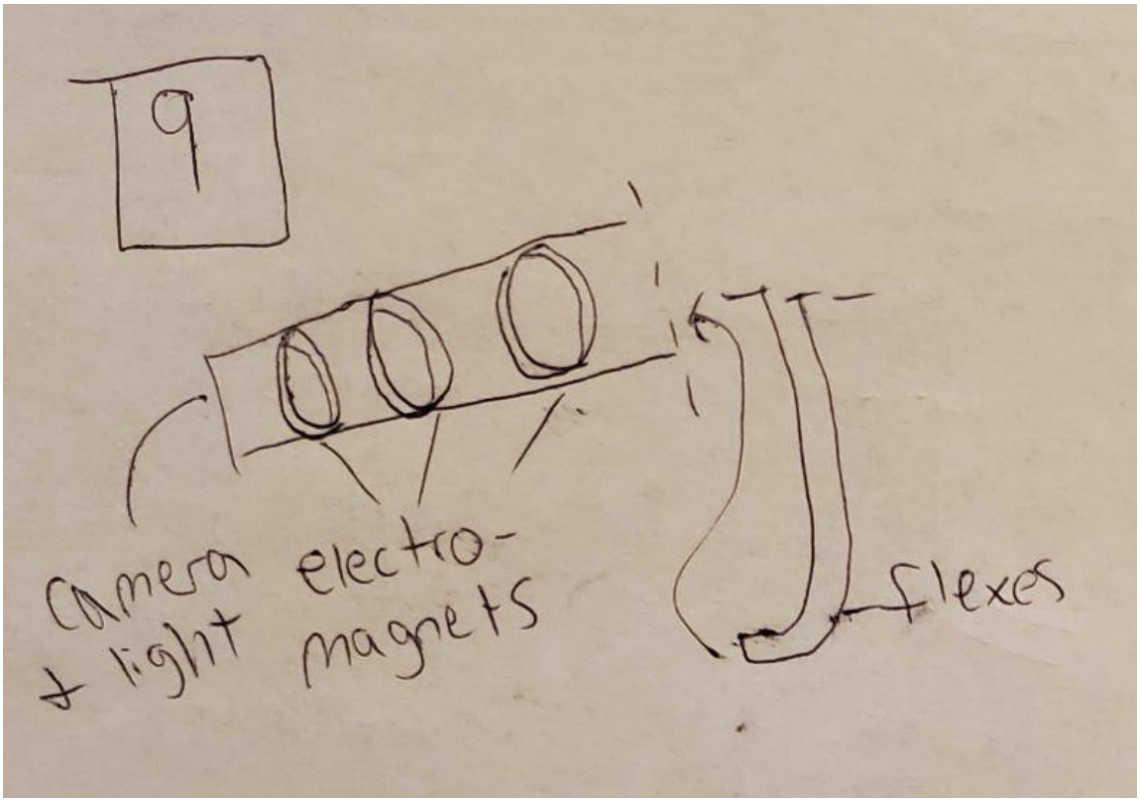

Figure 10: Initial Design for Magnetic Actuation

b). Concept Screening

After the team finished each of their preliminary design sketches. The designs were categorized into actuation, subcomponents, and shape. The objective of the designs was to focus on controlling the endotracheal intubation tube meeting size constraint requirements. Each team member explained their designs to the whole team where opinions and comments were exchanged on each design concept. The team then began to analyze the different solutions and started to select the best practical actuation methods that can be suitable for the goal of the device.

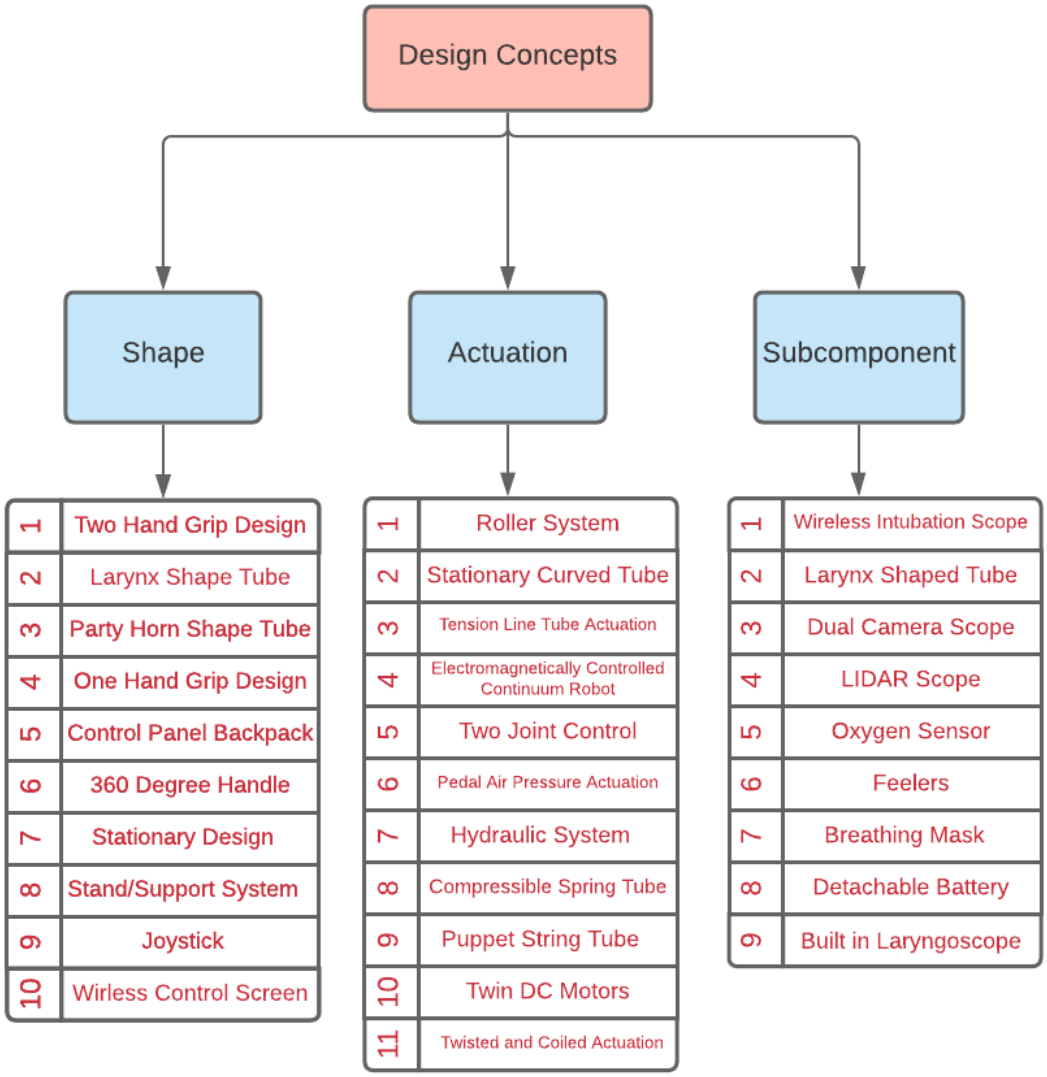

Figure 11: Design Concept Map

After the team's discussions through meetings with Dr. Awad and Nate Ames. The team decided to choose three options from the designs that were done. The first option was to use twisted and coiled actuator/polymers. The second option was to use a hydraulic system pressured with either air or liquid and the third option was to use tension actuators.

c). Conceptual Designs

Below are the three alternative solutions that our team came up with. All of the solutions involve an actuation device, or scope, being inserted into the currently used endotracheal tube that houses a camera at the tip. The placement of the scope into the proper location (by utilizing the actuation) in the trachea will precede the placement of the endotracheal tube into the patient. This functions in a very similar manner to currently used flexible intubation scopes. All of the solutions will then be removed from the patient, leaving behind the ETT. Again, this is similar to currently used flexible intubation scopes.

Hydraulic actuation:

The first proposed solution is to utilize an in compressible fluid, such as oil or water, to actuate the tip of a tube. With no hydraulic force being imposed on the tube, the tip (referring to the last 2-3 centimeters of the tube) will be in one configuration (curved or straight). When a force is applied to the tube the tip will transform into the other configuration. By modulating the force applied to the tube, the angle of the tip can be controlled. This, in conjunction with the person controlling the device being able to raise/lower and rotate the device, allows for the proper range of motion to access the trachea. By implementing software to control the movement of the tip, manual and assisted steering might be possible.

Twisted and coiled actuators:

The second proposed solution is to utilize biomimetic actuation. Twisted and coiled actuators (TCA) are a novel type of soft robotic actuator. They are constructed of polymer fibers and twisted in a coil to allow for contraction when subjected to heat (Wu, 2020). By utilizing three or four equally spaced TCA aligning with the long axis at the tip of a tube, bending in any direction could be achieved. This already allows for a higher range of motion than hydraulic actuation. In addition to this, the nature of this actuation mechanism allows for the implementation of motorized feeding and retraction of the tube. The actuators only require movement in the portion of the material that they are in, the wires feeding the actuators with electricity, to generate heat, do not need to move during actuation. We think that a spool or roll of wire can be extruded out of a handheld machine that has TCA configuration at the tip of a scope. No longer would the operator be required to manually feed the tube into the patient during intubation. Finally, since all the movements necessary for intubation are electronically controlled, this opens the opportunity for machine-driven intubation. Not only could automated steering be added but automated feeding is also possible with this design.

Tension Actuation:

Our third and final proposed solution is to add on to the currently used tension-driven continuum robots that power flexible intubation scopes with automated steering. The current systems have two control wires that allow tip movement in one plane (Berkow & Sakles, 2015).

Using the camera at the tip of the scope and a computer vision algorithm, the tip of the scope could be steered in the necessary direction for proper intubation.

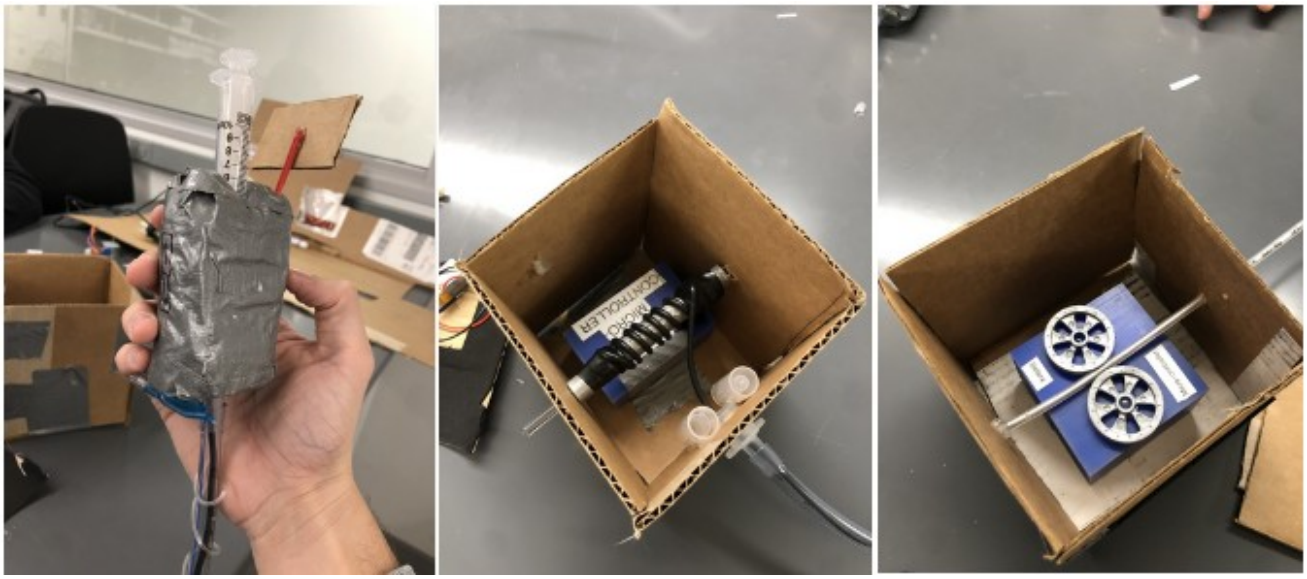

Figure 12: Preliminary Design Mockups

From left to right shown is the Hydraulic, TCA, and Tension actuation systems

d). Selection Process

The three designs were then compared via a 5-point ranking system that covered the mandatory engineering functions discussed in Chapter 2. These rankings were then multiplied by a predetermined weight that corresponded to that engineering functions importance to the functionality of the product. To decide the appropriate weights, a Pairwise Comparison Table (PCT) was used. The table and subsequent rankings can be seen in Table 1.

Table 1: Pairwise Comparison Table (PCT)

	Handheld	Light Weight	Reuse	Modular	Reliable	Accurate	Easy to Use	Ergonomic	Single Operator	DOF
Handheld	x	0	0	0	1	1	1	0	1	1
Light Weight	1	x	0	0	1	1	1	0	1	1
Reuse	1	1	x	1	1	1	1	1	1	1
Modular	1	1	0	x	1	1	1	1	1	1
Reliable	0	0	0	0	x	1	0	0	0	0
Accurate	0	0	0	0	0	x	0	0	0	0
Easy to Use	0	0	0	0	1	1	x	0	1	1
Ergonomic	1	1	0	0	1	1	1	x	1	1
Single Operator	0	0	0	0	1	1	0	0	x	0
DOF	0	0	0	0	1	1	0	0	1	x
Total	4	3	0	1	8	9	5	2	7	6

The PCT works to compare the importance of individual engineering functions to one another such that the sum of the column corresponds to its importance to the intended device. For example, in Table 1, when Handheld was compared to Light Weight, the conclusion was drawn that it was more important for the device to be Handheld. Thus, the Handheld column got a 1 (for true) in the Lightweight row. Once this process was completed for all elements of the table, the columns were summed, and the subsequent value was the ranking for the function.

Through this process, it was calculated that Accuracy, Reliability, and the Single Operator functions were the three most concerns for the future prototype. The least crucial functions were Reusability, Modularity, and Ergonomics and were ranked with the lowest weight in the summary table. It should be noted that Reusability did not get any points through the PCT, and thus does not have any actual impact on the final design decision.

The resulting rankings of each engineering function was then used as the weight in the summary comparison table, which can be seen in Table 2. Each device was given a score ranging from 1 to 5, with 1 being the lowest possible, and 5 being the highest, then multiplied by the ranking as determined in Table 2. This resulted in a maximum score of 225.

Table 2: Summary Comparison Table

Scores: 1-5	Importance	TCA	Tension	Hydraulic
Handheld	4	4	1	2
Light Weight	3	4	4	2
Reuse	0	1	1	1
Modular	1	5	1	3
Reliable	8	4	4	3
Accurate	9	2	4	3
Easy to Use	5	2	2	4
Ergonomic	2	3	2	2
Single Operator	7	2	2	2
DOF	6	5	4	2
Total	225	143	137	118

As can be seen in Table 2, the TCA design scored the highest with a total of 143. The tension actuated design scored second with 137, and Hydraulic was in third with 118. The primary strength of the TCA design is its ability to be directly extruded from the base of the intended control module, as well as its compact required actuator. For these purposes the TCA actuation approach will be pursued for the intended prototype. It should be noted that tension scored similarly to TCA but lost overall due to the bulkiness of its required actuators, and the inability to be extruded from the base.

e). Description of Preliminary Design

As mentioned in the previous section, the chosen actuation method will be twisted and coiled actuator (TCA) string. This will be guided by a microcontroller located in the body of the device alongside a power supply module which will be similarly located. The power supply will be initially prototyped externally, with the intent of relocating it to the internal system after

initial testing proves successful. Figure X on the next page shows the second 3D printed mockup of the device.

The string will be coiled around a center shaft pre-extrusion and, once actuated, will move out the hole located at the center and bottom of the body. Current methods available, as well as products that were intended for the market did not have this feature, giving the device a novelty when compared to similar prototypes.

Figure 13: TCA Mockup 2 – Middle section removed for visibility of inner components.

The power supply component will be stored in a removable lid to the device for easy replacement, or recharging capabilities. This allows the control module to be reused indefinitely, increasing the environmentally friendly facet of the device.

Controlled via a joystick, and three to five buttons, the device will have both manual and automatic capabilities. The operator will have the choice to guide in the lengths of the actuated segments. With the operator's overview, the device can also be set into automatic mode. This will be monitored by the intubating physician, and requires that said physician holds down a button/trigger during the entire process. This is to guarantee oversight on the operations of the device.

Another novelty is in the possibility of having the actuated segments removable from the main body. This is possible because the guiding wires are electrically actuated, meaning they can be cut off and reunited with the circuit without affecting the functionality of the segments.

Chapter 4

1. Testing and Evaluation Plan

a). Analysis 1

The first analysis of the device will be to ensure the device operates within certain standards of movement. The test will consist of measuring the motion of the TCP wires in the vertical and horizontal planes. Supplying varying current values to the TCP will be achieved using the controller circuit constructed for the housing unit. The criteria for passing this analysis will be a yes/no decision grid which will be used to verify the successful movement of the end effector in each of the predetermined directions, see Table 3, for an example of the grid.

Table 3: Proposed Decision Grid for TCP Movement Analysis

DIRECTION	RIGHT	LEFT	UP	DOWN
PASS/FAIL	---	---	---	---

The resources required to fulfill this task are the circuit previously mentioned, and a finished configuration for the end effector. People required to complete this task are solely the capstone team members; Michael Napoli, Tag Stork, Connor Gantt, and Hossam Montasser. The circuit creation and programming will be completed by Michael Napoli, and the TCP fabrication and configuration will be completed as a group effort.

b). Analysis 2

The second analysis is to ensure that our device complies with an ISO/ANSI/AAMI/DIS standard. The team decided to select standard ISO/DIS 8600-4 which deals with the maximal width of the inserted portion on an endoscope. It is imperative that the portion of our device that will be guiding the endotracheal tube past the vocal cords and into the trachea complies with this standard as the final device will have a camera at the end and be considered an endoscope. We will need to address this standard in the fabrication of the endoscope or snake portion of our device. The snake consists of two components, the bulk extrusion/retraction material and the engineered one-inch end effector (EE). The bulk extrusion/retraction material will only need to consist of the core material and circuit wiring. However, the EE will be more complicated to fabricate because it needs to incorporate the four TCP actuators, core material, camera, and circuitry wiring. The team was unable to get full access to the standard website, so there is no quantitative number associated with the maximal width previously mentioned, but the team decided to use the dimension of an approved endotracheal tube (9 mm). This was chosen because, for the team's intended device to function as anticipated, it will need to fit inside of the endotracheal tube, which has already been approved for use in the human airway. Therefore,

when the EE prototype is completed, the team will measure its final width and confirm it is less than the one associated with standard ISO/DIS 8600-4.

The device creators (capstone team) will be responsible for the construction of the device and successfully complying with the standard. The physical resources needed in this process are silver coated nylon yarn for the TCP, hollow silicone tubing for the core material, and essential circuitry components. A camera and associated wiring will also be needed in the final product, but the team's initial prototype will not include this. Each team member will be expected to contribute to innovating and optimizing the EE portion of the prototype device. As mentioned above, it is vital to ensure that all necessary components are included in the device and the maximal width is less than the number associated with the standard.

c). Analysis 3

The third analysis is a clinical test. The specific design specification being tested here is the user feedback of the device. This information is essential as none of the team members are the targeted end-user of this device. We would like feedback on how someone who would be using a device like our prototype feels about specific aspects. Therefore, we conducted a survey to evaluate this standard. Our survey currently is composed of five questions that all can be answered on a scale from 1 to 5. An example of how this would work follows. The first question may be "How intuitive are the controls on the device?" where the clinician needs to rate it on a scale where 1 is not intuitive at all and 5 is very intuitive. We will use this same rating scale for all questions. The other questions we have created are "How comfortable would you be using this device with an external monitor to view the camera?", "How capable do you feel that you can hold this device steady during intubation?", "What is the likelihood that you would use a device like this in the future for endotracheal intubation?", and "How comfortable are you with the speed that the device actuates the effector at?". Again, for the final question, 1 represents not comfortable at all, and 5 represents very comfortable.

We plan to administer this survey to a variety of clinicians that intubate patients frequently as part of their job. To evaluate this standard our team has decided that the average score from all the participants must be at least 70 percent of the maximum possible points (greater than or equal to 70% average). To carry out this analysis our team needs the previously mentioned clinicians and a survey. Additionally, the role of the team members in the evaluation is to create and revise the survey as well as recruit clinicians to administer the survey too.

2. Device Evaluation and Analysis

a). Analysis 1

The first analysis, or the movement test, was 75% successful (see Table 4). The device exhibited slow movement in three of the four desired directions. The primary concern with the motion witness was the lack of speed in actuation, and the small range of motion.

Table 4: Completed Decision Grid for TCP Movement Analysis

DIRECTION	RIGHT	LEFT	UP	DOWN
PASS/FAIL	PASS	PASS	FAIL	PASS

Since TCP utilizes heat generation to create tension in the individual strings, the process for applying tension is relatively slow when compared to tension driven actuation. With that said, the team was able to quickly actuate larger pieces of TCP in previous single-DOF movement tests. This leads the team to believe fast application of the actuation method is a strong possibility.

Another limitation witnessed was the small range of motion of the EE. This was primarily due to the lack of consistent tension between the differing TCP strings. With more time, a more stable and consistent method of adhering the TCP string to the core tubing could have been prioritized, and this issue would have been much less prevalent. It should also be noted that the test string was relatively short, and a longer piece of TCP would have a larger range of motion.

b). Analysis 2

The second analysis, or the standards test, was performed as mentioned above in the previous section. When inserting the device's snake portion into a 9 mm endotracheal tube, the team concluded that only the central tubing section complied with standard ISO/DIS 8600-4. As the team was nearing the end of the device fabrication, the four TCP actuators had to be adhered to the core tubing material via duct tape due to time constraints and material availability. This was not optimal as it led to a bulky end effector, as well as potential unwanted slippage with actuation. Therefore, since this analysis was defined as a pass/fail test, the team's device failed to comply with standard ISO/DIS 8600-4. Technically, the device had a 50% pass/50% fail result with the central tubing section sufficiently fitting inside the endotracheal tube.

After reflecting on the failed analysis and brainstorming areas for improvement regarding the end effector, we concluded that we need find a way to embed the TCP and its associated crimps into the core material. This would produce a snake that has a consistent diameter that fits

into the endotracheal tube. In turn, this would result in our device complying with standard ISO/DIS 8600-4 and passing the analysis with no issues.

c). Analysis 3

The third analysis, or the clinical test, was administered as planned in the above section. Our team was able to administer our survey to two of our mentors. The average score was 19.5/25 or 78 percent. Based on the criteria we defined earlier, this score would constitute a pass as the average score from all the participants was greater than or equal to 70 percent. The lowest scoring question out of the five was "How comfortable are you with the speed that the device actuates the effector at?" with an average score of 2.5/5. One mentor left comments stating that the device in its current form is too slow to use in emergency situations.

Chapter 5

1. Summary, Design Refinements, Recommendations

Title: Automated Endotracheal Intubation (AEI)

Goal: Facilitate endotracheal intubation with a hand-held electronically controlled device.

Picture:

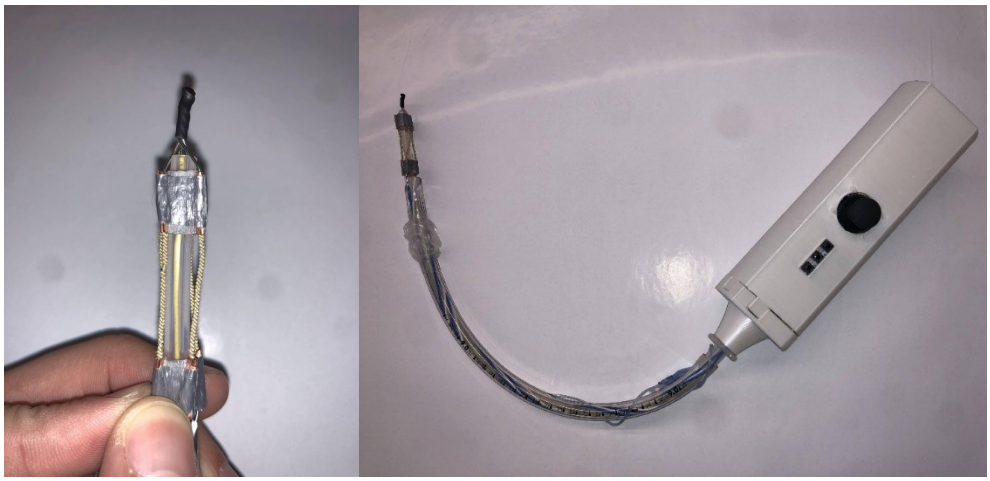

Figure 14: Image of End Effector and Final Prototype

Summary: Endotracheal intubation is an often performed procedure which is critical to the health and safety of patients in both the elective and emergency environments. Its purpose is to give the anesthesiologist access to the lungs during various procedures and allows them to control the patient's breathing while they are under operation, or unable to do so themselves. That said, in the worst case scenarios faulty intubation tube placements can cause severe trauma, and often times death, and it can be difficult to prepare trainees for the variations in differing patient's airways. Current placement strategies mostly depend on moving anatiomical features out of the way and visualizing the path to the airway via a camera, but none combine the best visualization practices with the ability to control navigation of the tube accurately and autonomously. The goal of this project is to develop a device which facilitates the placement of the endotracheal tube such that the first-pass success (FPS) rate increases, and the possibility of trauma to the patients airway decreases. To achieve this, the device shown in Figure 14 was created. This device utlizes twisted and coiled polymers (TCP) to guide the end effector in to the airway. The device is used to create a path for the intubating physician to slide the endotracheal tube into the proper location, before removing the device from the patient completely. The novelty of this device lies in the TCP acuation method which operates independent of its distance from the housing module, which gives it the capability to be machine-driven. This is unlike any other method currently in the market today, and opens avenues for robustly increasing the accuracy and safety of this complex and fast procedure.

2. Improvements and Extensions of Current Design

a). TCP Fabrication Process

Over the course of the last semester the team spent a large percentage of their time creating a consistent method of fabricating the TCP used on the end effector component. While the fabrication process was successful for small quantities of test material, it is unclear how the process would perform when scaled to a manufacturing environment, or when completed by a single researcher.

For this reason, the first improvement suggested is a more streamlined method of fabricating the test material. This would most likely be achieved by methodically controlling the spin of the TCP material with a predetermined speed, and number of rotations during fabrication. In this way, the individual would be able to select a configuration that best suited their needs, and consistently be able to replicate the process in the future.

b). End Effector to Core Tubing Adherence

The next suggested improvement would be a more dependable method of adhering the TCP to the core tubing. This is fundamentally crucial to the performance of the TCP in application, and thus should be prioritized moving forward. The largest issue observed with respect to TCP adherence was the lack of consistent tension between the individual strings on the end effector. This caused difficulties in controlling the motion of the end effector, because two opposing strings would have unequal base-level tensions and would thus require differing levels of current to create movement or would not be able to move at all.

c). Kinematic Modelling and Control

The current system of control for the end effector is subjective to the qualitative observations made by the user. In other words, there is no system to assist the user in controlling the movement of the TCP, as well as maintain safe operating current levels. For instance, if the user in question is moving from a position all the way to the left of center, to a position to the right of center, there is no model currently that allows for a safe adjustment. The user could easily attempt to make the adjustment, be dissatisfied with the speed of the actuator, and subsequently ramp up the operating current to unsafe levels to move the EE faster but overshooting the desired position in the process. Not only does this increase the error in positioning, but also the risk to the device as too rapid of a change or too high of a current can snap the strands of TCP. Furthermore, while the TCP will be contained within an insulated sheath, the unnecessary increase in heat and current could be harmful to the patient, and thus should be avoided when possible.

While the “remote control” model of the end effector was adequate in testing the fundamental components of the device, a more consistent method of safely moving the end effector to a designated position should be developed. This could consist of a simple

proportional-integral-derivative (PID) controller or, with the creation of an accurate model, a more complex optimal controller. The inputs to the system would consist of the current to each of the TCP strands, and the output would be the position of the tip of the end effector.

d). End Effector and Core Tubing Extrusion/Retraction

As previously mentioned in this report, the fundamental novelty of this actuation method is the ability for the snake and end effector to be extruded from the housing module. The team was not able to approach this implementation because of time restraints, but the implementation of the driving motor that would perform this task would not be difficult to complete if the snake was in a finalized state.

It should be noted that, while extrusion will be the primary goal of this portion of the device, retraction back into the housing module is just as important. Without the retraction feature, the snake would have no ability to move back into the housing module; whether that be to prepare the device for another intubation, or simply for storage purposes.

e). Camera, Monitor, Lighting, and Automation

The ability to extrude the end effector from the housing module leads to the capability of automation of the placement of the endotracheal tube. This would require multiple integrations but would primarily center around the installation of a camera and lighting unit that connects to the tip of the end effector, as well as a monitor to view the footage on.

Cameras for this purpose are already commonplace in the healthcare community and can be seen used in most endoscopic devices including flexible intubation scopes. The implementation of the camera, along with a monitor connected to the housing unit (similar to those seen in Figure 4), would both increase the visibility of the airway to the physician, and lead to the implementation of the automated guidance system.

f). Team Reflection

It goes without saying that more time on the project would have been beneficial to its overall success. While the team is very happy with the performance of the current device given the time/cost restraints of the OSU capstone program, there are still many possible objectives to be completed by future groups. The actuation method chosen here is novel, and very promising but to be tested, manufactured, and sold on a large scale, much work still needs to be done.

Appendix A - Project Gantt Chart

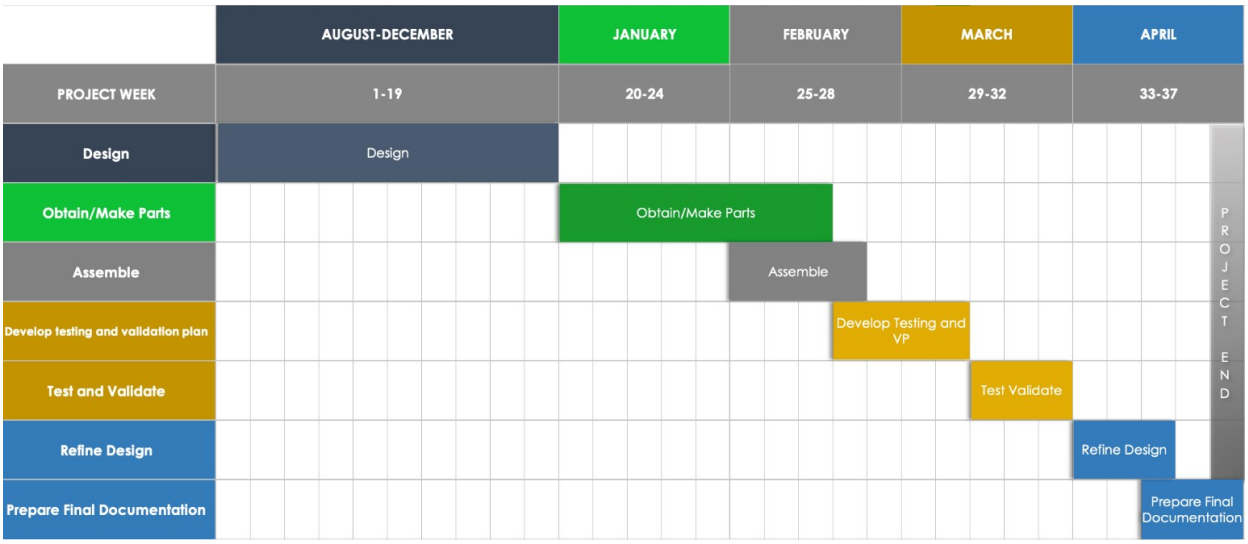

Figure 15: Project Gantt Chart for the 2021-2022 academic year

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