

Specific Aims Overview

Many factors impact the successful intubation of the human airway during hospital procedures. These include, but are not limited to, technology availability, clinician competency, and natural and unnatural variations in the anatomy of a given patient. The general aim of this research is to develop an automated intubation system that is not solely dependent on human manipulation, while still giving the physician full control of the procedure. Over the course of the 2021-2022 academic year, an Ohio State University capstone team developed a prototype that would achieve this aim (figure 3). The device utilizes an actuation method novel to the health-care community, twisted and coiled polymers (TCP), to guide the intubation tube into the proper location in the airway of the patient, before being extracted by the acting physician.

Current technology is limited primarily to direct and video laryngoscopes, as well as fiber optic intubation. These methods, while improving the visibility of the patient's anatomical features, require holistically manual control from the physician. This dependency leads to a large reliance on operator skill and judgment, giving way to increased chances for human error. There are multiple automated intubation systems currently in development, but none support the portability and automated extrusion that the prototype being discussed here can boast. By using the TCP actuation method, we are confident we can create a fully autonomous intubation method with the possibility for both manual and autonomous control, which also supports extrusion and retraction-based actuation.

The completed timeline for the project is shown in Figure 1, and is better explained in each of the individual Specific Aims sections.

0.1 Aim 1: TCP Fabrication, Modeling, and Control

Because of the unique properties of the actuation material, and for the purpose of data collection, the TCP material will be made in house. In the past, the material was created using a manually spun hand drill and imprecise counter-weight setup. With the intent of consistent recreation of the necessary string, the setup will be automated and configurable electronically. This step is very important to the overall performance of the project as consistency in the TCP material will be the difference between project success and project failure.

Once the desired fabrication setup is complete, the arguably most difficult portion of the design process will begin. Here, the researchers will build symbolic kinematic modeling equations such that the TCP end effector can be simulated and controlled using an optimal feedback controller. This will guarantee minimal error in intended versus actual movement. The system will be tested using inputs from a manual joystick controller, as well as with a predetermined path in order to simulate the inputs of the artificial intelligence system before it is officially ready for implementation (Aim 3).

0.2 Aim 2: Design of End Effector and Core Tubing

In parallel to the modeling process, another objective is to design and implement the end effector and core tubing components. Since the end effector is objectively the highest risk component of the device, it will be designed to be completely removable from the rest of the core tubing. This will allow for easy replacement steps to be taken in the event of a broken end effector. With electrical connections set at designated positions, and held in place via a magnet and small locking mechanism. This is also where the camera at the end of the end effector (similar to the fiber optic camera) will be introduced and connected.

The remainder of the core tubing design is composed of an outer shell, electrical wiring to each of the four TCP, and electrical wiring to the camera. These components will be developed separately from the end effector with the exception of the connection point, and will be light weight, with the objective of minimizing the diameter of the final tube, this step is not seen as a primary obstacle. Note that the outer tubing of both portions of the continuum component must be compatible with the human anatomy.

0.3 Aim 3: Integration Between Neural Network and Controller

In the fall of the 2021-2022 academic year the original capstone team, composed of mechanical and biomedical engineering students, and based out of the Biomedical Engineering Department, created a separate project for the creation of a neural network which can identify the human airway anatomy. The intent was to develop software which would eventually guide the continuum robot by identifying anatomical features in the mouth of a patient. This project was largely successful due to the cooperation of the Computer Science and Engineering (CSE) Department, and the software created is ready for implementation with a finished prototype.

Aim 3 of this project is to merge a final product with the artificial intelligence system created by the CSE team in the spring of 2022. This will consist of training a larger sample size of data, checking data conversions between the network and the main controller, and selecting a set of parameters which will be most useful in guiding the robot to the proper location.

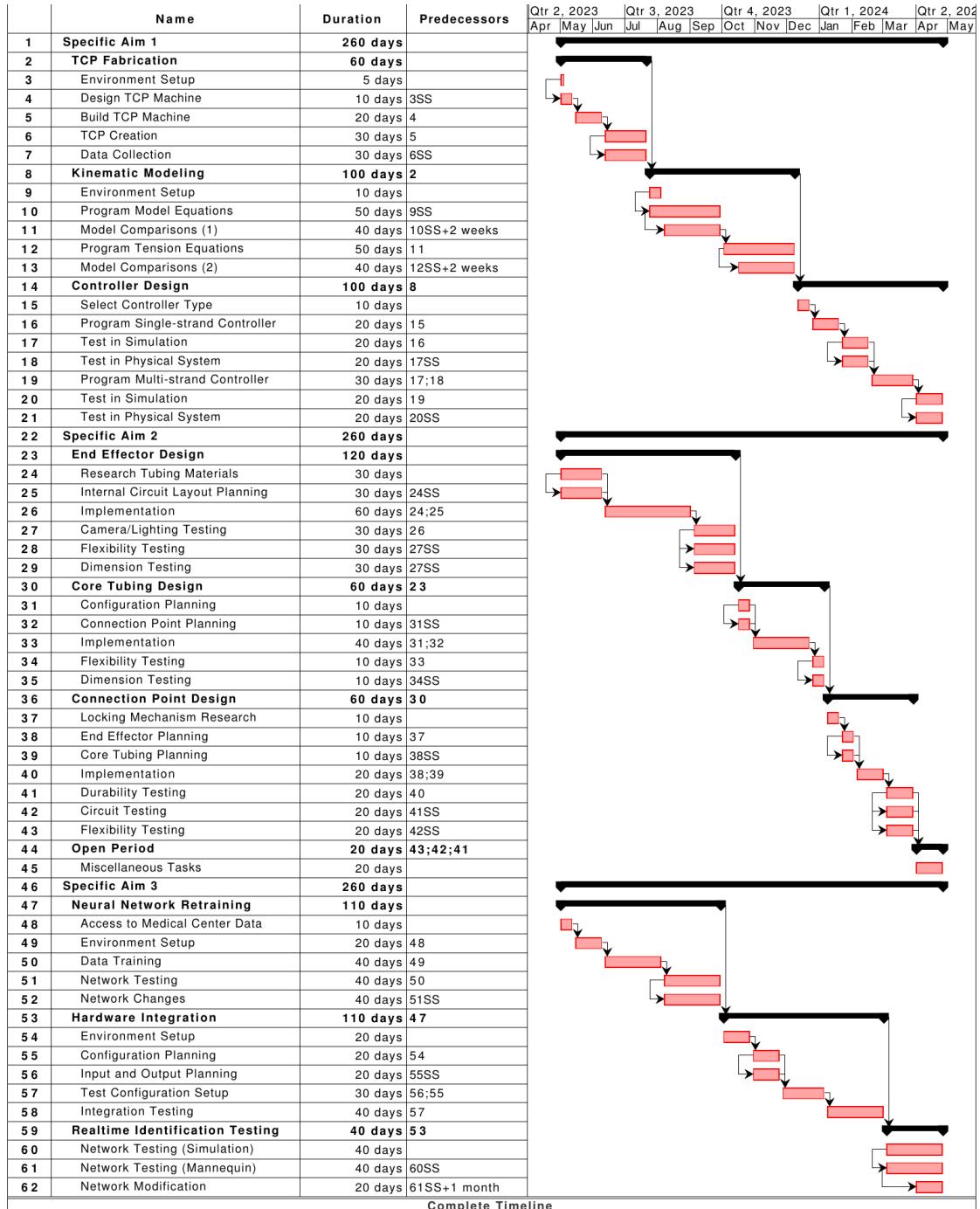


Figure 1: Full AEI Project Timeline

Specific Aim 1: Breakdown

1.1 Rationale

Aim 1 is centered around the creation and modeling of the TCP material. There are multiple methods used to make this process consistent and reliable. Most notably those described in [1], where the TCP actuation method is used to manipulate a humanoid hand. With the purpose of simplification of the creation/modeling process, a precursor fiber with similar specifications to that of the aforementioned article will be purchased.

In order to achieve a consistent fabrication process, the TCP will be spun using an automated system; similar to that of a rope making machine. The system will be configurable to a set number of rotations, and a set RPM speed, as well as having connections for an adjustable counter-weight which will be used as the third and final configuration input when making the material. Once the fabrication process is created and checked for consistency, data will be collected on the actuation capabilities of the string with varying configuration inputs. A setup will be chosen based on the data collected.

The next step is to derive a control model formula which can represent the tension exhibited by a single strand of the TCP with inputs of current [*Amps*] and over a predetermined length of time [*seconds*]. The constant parameters of the system will ideally be the same as the parameters used when creating the TCP string, but will require more testing to legitimize. Because TCP is actuated via heat generation, the system dynamics will be time-dependent, and will be discussed in the next section.

Finally, a controller will be implemented (figure 2), ideally using the aforementioned model formula. The current plan is to utilize an optimal control policy with the inclusion of an accurate model. In cases where the model cannot be applied, a simpler sub-optimal policy may be used instead. Both options are feasible. Model predictive control (MPC) will be considered because of its ability to look into future states, and accurately account for time-dependent variables when given a reliable and accurate model and cost function.

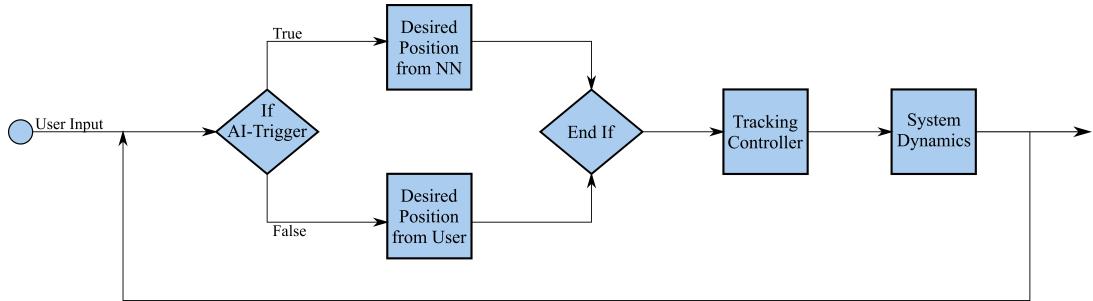


Figure 2: AEI System Control Diagram

Figure 2 shows the planned controller structure. The user-input block is a set of parameters received from the user during runtime. This will tell the device whether the user is in manual or automated operation modes, and will split into two similarly structured decision branches. With a desired trajectory chosen, the tracking controller will decide the necessary current value before uploading the results to the system dynamics and continuing.

1.2 Approach

1.2.1 Timeline

The fabrication of the TCP material will be facilitated through a modular and controllable stepper motor circuit. The wire of choice will be silver-coated nylon 6/6 precursor fiber, similar to that used in the initial prototype. The control board used for TCP creation will be an Arduino Uno, and will be used to control the RPM of the machine, as well as the total number of spins. The counter-weight attached to the machine can also be adjusted for further variations, but will likely follow similar mechanics to those used in [1, 2, 3]. For consistency, the length of the TCP created during a given test will be held constant, and will be heat-treated and trained using the research verified by [1, 2]. The fabrication process is currently designated about 25% of total project time. That is, if the project spans a single year, the fabrication process would be given 3[months]. The bulk of this time period will be spent creating new material and collecting the data points outlined in Section 1.2.2.

Modeling of the TCP actuation will be completed in parallel to Aims 2 and 3, and will be appointed about 40% of the Aim 1 project schedule, meaning for a year-long project modeling will be given approximately

4.5[months]. The system of equations discussed in Section 1.2.2 from [1] make the assumption that the load place on the TCP is constant. For the purpose of implementation with the AEI system, this assumption cannot be made. The purpose of this portion of the project will be to implement a variable load into the system of equations, as well as merge the system with the continuum robot modeling techniques used in [4]. It should also be noted that some of this period will also be inevitably spent creating more TCP for the testing process.

The controller for the system will ideally be model-dependent. It is understood that model-dependent controllers, when accurately tuned, can create optimal systems and are more reliable and robust than model-independent alternatives. Considering the time-dependence of the TCP system variables, the use of model predictive control (MPC) will be considered because of its ability to look into future states and solve for the optimal set of inputs at a given point in time. MPC is a control method commonly used in the robotics community for like-wise scenarios and has proven to be one of the most ideal control policies in the field. That said, there are other similarly effective model-independent controller alternatives in the event that an optimal policy is not able to be constructed. Because of the importance of this portion of the project, it will similarly be allocated 40% of the total project time.

The completed timeline, as well as those constructed for Aim 2 and 3, is shown in Figure 1.

1.2.2 Modeling Techniques

The following section describes the steps taken for TCP modeling as derived in *Modeling of twisted and coiled polymers (TCP) muscle based on phenomenological approach* by Farzad Karami and Yonas Tadesse. The following equations are used to approximate the temperature and displacement of the material based on a given current [A], load [N] and string dimensions.

The change in resistance with respect to temperature is shown in Equation 1 below.

$$R(T) = R_0(1 + \alpha(T - T_0)) \quad (1)$$

Where $R(T)$ represents the current resistance in [ohms], R_0 is the resistance at a reference temperature, T_0 , and T is the current temperature of the TCP. α is the coefficient of resistivity which is defined more accurately in [5] and is closely related to the coefficient of thermal expansion (CTE). For the purpose of manipulating tension using the TCP mechanics, a material with a negative CTE was chosen. It is further explored that the elastic modulus, E , is also determined by temperature.

For equation 1 to be used accurately during modeling the change in temperature must also be approximated. This is completed below.

$$T - T_\infty = -\frac{R_0 i^2}{-hA + R_0 i_2 \alpha} \left(1 - \exp^{\frac{-hA + R_0 i_2 \alpha}{mc_p} t} \right) \quad (2)$$

Where T_∞ is the ambient temperature, i is the operating current, h is the coefficient of heat convection, A is the exposed TCP surface area, m is the TCP mass, c_p is the specific heat capacity, and t is the time-passed. This is used to approximate the temperature, T , of the TCP with respect to a given current, i , and time, t .

Using Equation 2 in combination with the function for E (equation 3 and along with the dimensions of the TCP material, the displacement of the TCP can be calculated using the set of equations shown below.

$$E(T) = a_1 T^{a_2} + a_3 \quad (3)$$

$$\Delta_{el} = \frac{F}{k} \quad (4)$$

$$\Delta_{th} = \delta H = \frac{L\delta L - \pi D \delta D}{\sqrt{L^2 - \pi D^2}} = \frac{L_0^2}{H_0} \alpha_L (T - T_0) - \frac{pi D_0^2}{H_0} \alpha_T (T - T_0) \quad (5)$$

$$\Delta H = H_0 - \Delta_{th} + \Delta_{el} \quad (6)$$

Equation 3 represents a fitted function for the elastic modulus of a single string of TCP at a given temperature. Equation 4 is the displacement of the TCP with respect to the load and equation 5 is the displacement based on the CTE and heat generation via electrical current. Finally, (6) is the sum of all displacement methods highlighted in the previous two equations.

Here, a_1 , a_2 and a_3 are the fitted curve coefficients, F is the load on the TCP, k is the elastic coefficient (not derived here), L_0 is the initial TCP stretched length, H_0 is the initial TCP coiled length, D_0 is the

diameter of the coiled wire, α_L is the longitudinal CTE, and α_T is the transverse CTE. The use of these equations allow for the approximation of the TCP length at a given point in time.

The issue that arises here is the assumption that the load, F , is constant. For the purpose of implementation in AEI, the tension must be dynamic in the modeling. This issue will be addressed during the modeling

1.2.3 Experimental Process

Verifying the controller system will be completed parallel to its programming. Once the fabrication method for the TCP is finalized, a few weeks will be designated to creating TCP and collecting data over its behavior when supplied with varying levels of current, constant counterweight magnitudes and with differing ply-numbers. The collected data points will include, but will not be limited to, TCP temperature, displacement and resistance trends. In the schedule shown in Figure 1 these tasks are represented by items 1-8.

With the load-static model verified, the system of equations will either be adjusted for variable load, or a method of numerically approximating the tension in the TCP will be implemented. The goal of this step will be to create a conversion from current TCP temperature to string tension. Modeling for tension will allow the researcher to design a single-strand controller which is capable of holding a desired displacement by manipulating the tension in the TCP wires. The items span 9-13 in the comprehensive schedule (Figure 1).

With this, the system can be expanded to continuum robot modeling using the piecewise constant-curvature method, better explained in [4]. The controller can also be expanded to 3-D continuum robot actuation by similarly manipulating current to control deflection via the tension in the TCP (schedule items 15-21).

At this step, the internal position sensing system will be addressed and there are multiple options available on the market. The intent with this component is to understand in real-time the position of the end effector, and compare to the model. These include electromagnetic sensing, explained thoroughly in [6], and optical sensing. Preliminary research suggests the former will be more viable for the purpose of the device and to the hospital environment.

1.3 Risks and Alternatives

It is understood that all of the steps taken in this portion of the development process are subject to considerable obstacles. That said, each of the discussed approaches have alternative methods of attack which should still achieve the overarching goals of the research.

In the case of fabrication, there are multiple methods for twisting, annealing, and training the TCP wires. This process is well documented in the aforementioned articles and is unlikely to be problematic, but if the creation process does not work as intended, there are many alternatives to twisting the string and prepping it for annealing and training. The TCP essentially requires a small-scale rope-making machine, and thus has many vehicles for a consistent system.

While methods of modeling the TCP behavior have been discussed, and are proven to be reliable, there is still a chance that a comprehensive model of the TCP will not be as easily generated as predicted. In the event that a model-based optimal controller cannot be constructed accurately, it is also possible to train a model-free neural network to produce the intended controller behavior. This would involve considerably more data on configuration details, but is very possible and has been done for likewise projects in the past [7, 8].

Specific Aim 2: Breakdown

2.1 Rationale

In aim 2, the design of the end effector and core tubing circuitry is addressed. In this portion of the project, the end effector will be engineered to house the TCP such that it is not exposed, can be replaced when necessary, does not limit its range of motion, and also allows for the installment of the camera and light. To achieve this, the four strands of TCP will be lined in parallel to the center tube, which contains the necessary assortment of circuit components. It should be noted that this task is not dependent on the completion on Aim 1, as the TCP wires can be replicated with past test wire or thick string, and can be given a maximum TCP diameter which satisfies the constraint that the full prototype fits in the endotracheal tube.

The core tubing, which is extruded from the housing module and connects to the end effector via a specially designed clip, will likewise need to house the necessary wires which lead to the TCP, light and camera. This portion of the tubing will be relatively simple in configuration, with the primary limiting factor being the diameter of the tube.

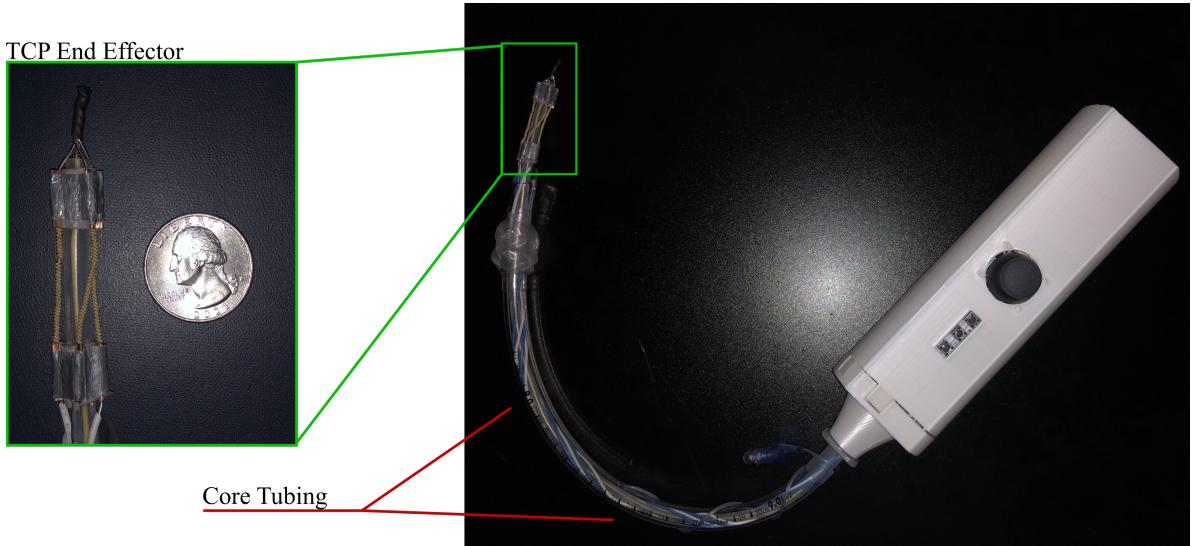


Figure 3: Prototype Assembly Developed in 2021-2022 Academic Year by OSU Capstone Team

Figure 3 shows the prototype designed and assembled by the aforementioned OSU capstone team. This prototype was specifically designed with the intent to prove functionality, and thus many quality-of-life features were not included. The most noticeable example of this being the exposed wiring at the prototype end effector, and the imprecise method of connection to the TCP ground wire. As this is the project being expanded upon, the previous prototype will be used as a reference for the general configuration of the tubing but will be largely redesigned.

2.2 Approach

2.2.1 Timeline

The timeline for the design and creation of the continuum snake will likely be more sequential than in Aim 1. Each of the components; the end effector, the core tubing and the connection between them, will be broken into itemized sections. More specifically, the end effector design segment, will most likely require close to 40% of the total project time. That is, for a year-long project, the end effector would be designated approximately 5[months]. This time is primarily split between researching airway-compatible flexible materials, and designing the internal layout for the TCP, camera and light configuration. It should be noted here that the circuit which controls the current to the individual TCP wires (without the camera/light) was created during the OSU capstone project, and will likely not be changed dramatically here. This circuit can be seen in Figure 4. The steps for this task are highlighted in lines 23-29 of Figure 1.

In the next segment, about 25% of project time will be appropriated to the design and creation of the core tubing (about 3[months] for a year-long project). This portion of the project is fundamentally simpler when compared to the first task, and is not seen as a large risk to project time. That said, the connection mechanism which allows for the smooth replacement of the end effector in the event of a breakage will be extremely important since the end effector is dependent on the wire connections and must be properly secured (shown in lines 30-35 of the Full Timeline).

The design of the connection mechanism will occur after both the end effector and core tubing are completed, and is appointed 25% of the total project time (3[months] for a year-long project). This is because of the importance of this feature to the fast application necessary in the emergency environment. The remaining 10% of the project will be left open in the event that one or more of the sections requires slightly more time to be completed to the necessary standard.

The completed timeline, as well as those constructed for Aim 1 and 3, is shown in Figure 1.

2.2.2 Tubing/Circuitry Techniques

The end effector will be constructed with the intent of a two-layer configuration. The center will be comprised of the ground wire and the camera, similar to the prototype made during the OSU capstone project with an insulating tube surrounding the components (layer 1). Next, the TCP will be connected in parallel

around the center shaft and connected to the common ground wire. Each string will also be connected to an individual active wire which is used to control the current supplied to the TCP from the main controller. The TCP will then be surrounded by another layer of insulated tubing (layer 2). It is also possible that a third intermediate layer will be introduced to insulate the individual TCP string from one another, this will hopefully be avoidable though as it would unnecessarily increase the diameter of the assembled system. This portion of the device will only span one to two inches in length. Note that the controller need not be completed for testing, in initial scenarios, a simple user-defined analog signal can be used to test motion.

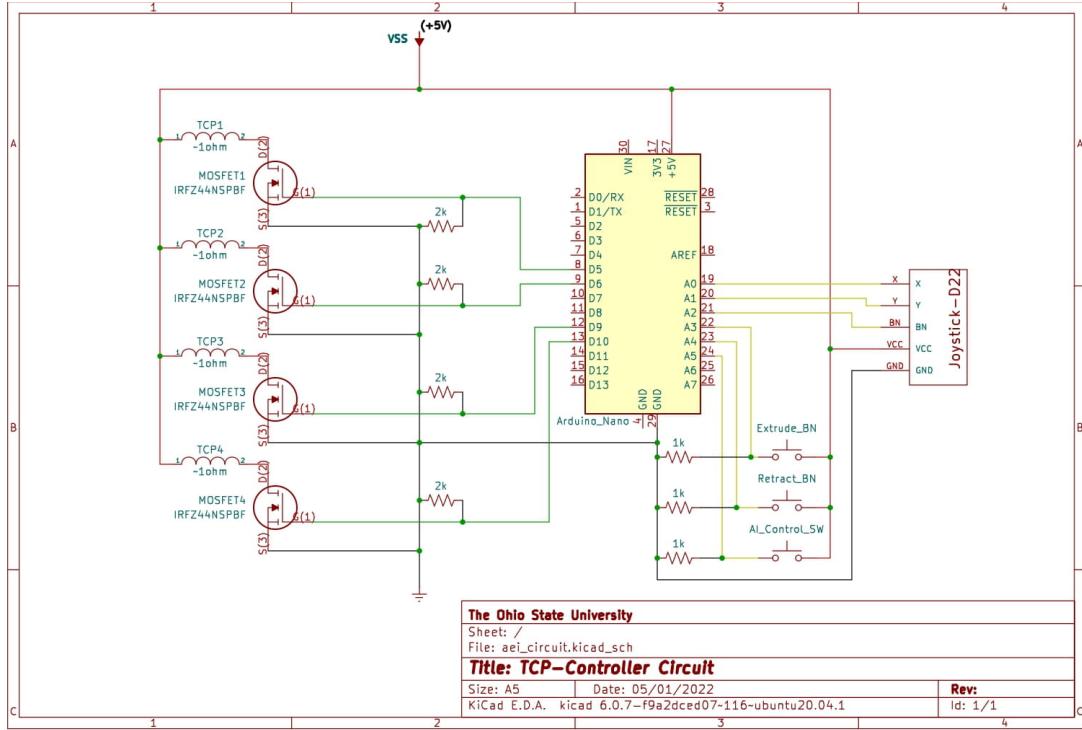


Figure 4: TCP Circuit Created in OSU Capstone Project

The TCP circuit is made up of three primary components; the four TCP strands and their designated MOSFET transistor which controls the variable current magnitude, the joystick which acts as a vehicle for manual operation of the end effector, and three buttons which control the extrusion, retraction, and AI features. The bulk of these items are housed in the control module (shown in Figure 3), leaving the TCP as the only remaining item which must be included in the end effector.

The core tubing will be considerably simpler to assemble and can be stylized to a single airway-compatible tube housing the necessary wires which will each be individually insulated. This is similar to every day USB pin-out wiring and other related cords. Because of its simplicity, the core tubing is not likely to break or have technical issues after being assembled. For this reason, the end effector and core tubing will be design separately and connected together via a locking mechanism. This way, if the end effector malfunctions, it can be replaced relatively easily, and without affecting the rest of the assembly. It may also be necessary to incorporate a aesthetic center-line down both components such that they can be attached to one another in a consistent configuration.

2.2.3 Experimental Process

The experimental process practiced here will primarily be focused on patient compatibility, end effector flexibility, and dimension fitting. Since the prototype is obsolete if the end effector does not fit within the confines of the intubation tube, this specification will be prioritized. TCP string is known for its high degree of flexibility, one reason why it is ideal for working in such a tight environment [2]. That said, the inner components will most likely have to be optimized such that the dimension tests can be fulfilled reliably.

Flexibility tests will occur for the two main components seperately, as well as for the final assembly, and are represneted by schedule items 28, 34 and 43 in Figure 1. The end effector must be able to freely stretch in all directions in the full assembly while the core tubing should be slightly more rigid, allowing it

to be extruded from the control module reliably. Pass/fail parameters for these tests will be defined more thoroughly before the project start.

The final test is the compatibility test and will likely be non-pervasive, which is why it is not referenced directly on the project timeline. This test is to ensure the materials being utilized are compatible with the human airway anatomy, and do not pose any form of danger to the patient. To account for this during the design process, only pre-approved anatomy-compatible materials will be considered for the composition of the end effector, core tubing and connector segments. For this reason, the testing of the materials is not given scheduling time.

2.3 Risks and Alternatives

The largest risk being addressed in this portion of development is the hard constraint for the diameter of the tubing. The most complex portion of the tubing, the end effector, must fit within the confines of commonly used intubating tubes. For development purposes, the constraint can be relaxed to the smallest adult-specific tube available (8[mm] diameter). This will likely be more than enough room for the current configuration since the OSU capstone project final design was very close to fitting comfortably, despite having many imperfections in the design of the end effector.

It should also be noted that the circuit diagram referenced in Figure 4 does not include the end effector light or camera, meaning it will have to be incorporated during the project planning period. The system will likely resemble the current flexible intubation scope camera/light system, although more research is required before making the final adjustments to the circuit.

Specific Aim 3: Breakdown

3.1 Rationale

The primary goal of Aim 3 will be to integrate the on-board micro-controller with the neural network developed in the Spring of 2022 by the computer science and engineering capstone team after it is trained on real anatomical footage. Their system utilizes a trained neural network to identify and trace the anatomical features of the airway from video records. The outputs of the identifier are boxes which encapsulate the feature, as well as a confidence interval value which relays how likely it is that the feature was identified correctly.

The automation component of the device is wholly dependent on the system discussed here. It will most likely be implemented on board the device, but depending on its weight and specifications, it may be run on a separate unit, with a more complex communication system. Either way, the device will be capable of this feature with the addition of the camera to the end effector.

Figure 5 shows a demonstration of the CSE team's newtork in progress. The results among all test were relatively similar, with some difficulty noticed as the camera approached the airway. That said, with more training the network should be able to overcome this issue. The footage referenced is currently held by the Wexner Medical Center under a XXX disclosure agreement, and will be released to this project for the express purpose of training the network.

3.2 Approach

3.2.1 Timeline

During the 2022 Spring semester, the BME department at the OSU commisioned a CSE department capstone project with the intent to develop a functional AI system. This network can be used to identify the anatomical features of the human mouth and airway. For the purpose of the project, the network was limited to identification of features on a mannequin, and the videos taken were processed and put through the network after they were taken. That said, the network developed was capable of identifying the uvula, epiglottis and vocal chords as shown in Figure 5.

To expand off of this project, three main tasks will be completed. First, the network will be retrained on the real-anatomy data set already collected by the Wexner Medical Center. This process will most likely be given about 40% of the total project time, i.e. 5[months] in a year-long project, and are stated in lines 47-52 of Figure 1.

The network will then be integrated with the main controller hardware. This will most likely involve a communication system between the external network and the controller being programmed on for Aim 1 and

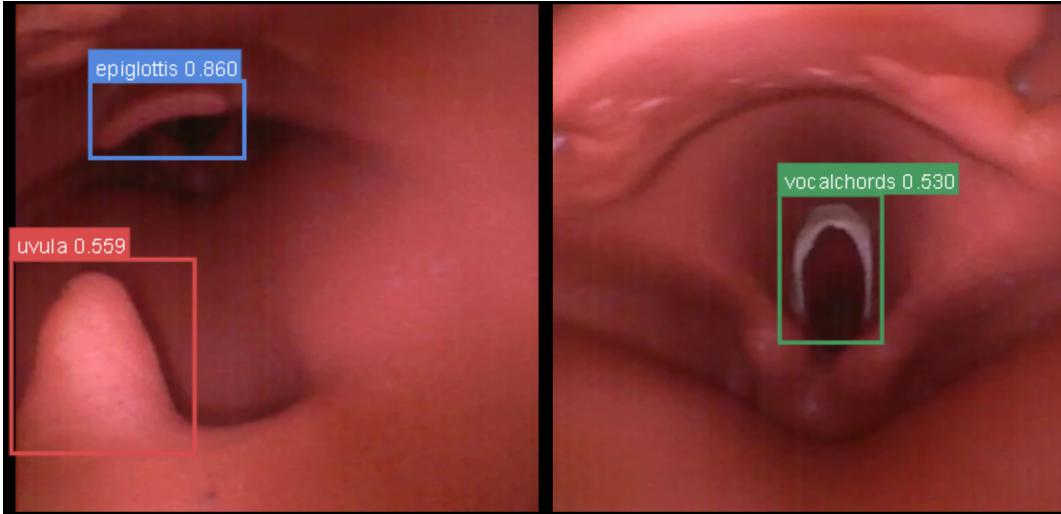


Figure 5: Anatomy Identification Network on Human Mannequin

the camera system. It is currently unclear how exactly this will be implemented, but time will be set aside specifically to problem solve this requirement. This process will also be given approximately 40% of the total project time. It should be noted that Specific Aim 1 need not be completed for this process to be completed. As long as it can be proven that the hardware is able to read and utilize the output of the controller (even if that is simply outputting results to the screen), the test will be considered complete (lines 53-58 of Figure 1).

The final test will consist of verifying that the identification software can be utilized in real time using the on-board camera. These tests will likely require the use of the mannequin, but will eventually be demonstrated on cadaver subjects as well (although the cadaver tests are unlikely to occur in this time frame). Again, these tests have no dependency on Aim 1 or 2 since the only system being verified is the identification system. This portion of the project will be given the remaining 20% of the project timeline (around 2[months]). Shown in lines 59-62 of the Full Project Timeline.

The completed timeline, as well as those constructed for Aim 1 and 2, is shown in Figure 1.

3.2.2 Network Testing and Integration

The neural network referenced here is largely sitting in a completed state. It is currently trained on a set of human mannequin example videos and performs to a high degree of accuracy. Once access is granted for the human intubation procedure videos housed on the Ohio State University Wexner Medical Center computer system, the network can be retrained for real human anatomy. The work done by the CSE department capstone team will be used to streamline this process as the neural network layers were setup in a reusable manner.

Once the network is trained, a communication system between the on-board micro-controller and the NN will be developed. The current plan is to evaluate the run-time needs of the neural network and quantify whether it can be run from within the housing module, or if it should be run externally and communicate via a wired connection. It should be noted that the control system from Aim 1 does not need to be finished to test this communication system. As long as the outputs from the network match the inputs to the controller, they can be developed in parallel. This means that at the beginning of both processes, the communication point will be defined thoroughly to alleviate any difficulties down the road, this task will likely be completed during the Environment Setup period.

3.2.3 Experimental Process

The testing of the NN will initially be repeated over the set of mannequin video data as a way of checking that the environment is setup properly. Once the environment is verified, and access is granted for the intubation procedure data, the NN will be retrained. Testing will occur in parallel to the network tuning, somewhat similar to the process described in Section 1.2.3. The precise criteria for suitable confidence levels, etc. will be better described at the beginning of this process and with considerable research on other self-guiding projects.

As for the communication portion of the aim, the tests performed will be less subjective. The primary goal here will be to verify that the AI is able to publish feature locations to the main controller at an acceptable rate. The following time period will consist of real-time mannequin tests, as well as various cadaver tests which fall outside the scope of this time frame.

3.3 Risks and Alternatives

The largest risk in the development of the neural network is defining the level of confidence which the controller will allow before deciding a motion is safe. In other words, how low of a confidence is acceptable before the controller refuses to move in that direction. Setting this value too low factors in an obvious level of risk to the patient, as the device may navigate towards incorrectly identified features. Setting this setting too high may put the device at risk of stalling, i.e. reaching a point where no features are identifiable and not being able to make a decision. Ideally, a fail-safe will be implemented to account for this but it is also important to remember that the device as a whole is being designed with the intent that the practitioner is never absent from the procedure. They are required to watch the approach of the robot into the airway, and in these rare instances they would easily be able to manually override the neural network and move the robot in the proper direction.

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