

Specific Aims

Many factors impact the successful management 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 a 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 has been developing a prototype that will 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.

<p>Specific Aim 1:</p> <ul style="list-style-type: none"> ● Fabrication <ul style="list-style-type: none"> – Rope-making machine – Data collection ● Modeling <ul style="list-style-type: none"> – Reference [ARTICLE] – Inputs: Current, Load – Outputs: Temp, Displacement Inductance, Tension ● Control (see right) 	
<p>Specific Aim 2:</p> <ul style="list-style-type: none"> ● Select maximum TCP diameter ● Design End Effector (see right) <ul style="list-style-type: none"> – 4x TCP wires – 1x Camera – 1x Light ● Design Core Tubing (see right) <ul style="list-style-type: none"> – 4x TCP power-wires – 1x TCP ground-wire – Camera wires – Light wires 	
<p>Specific Aim 2:</p> <ul style="list-style-type: none"> ● Setup and install CSE NN ● Gain access to OSU Wexner Medical Center Database Images ● Re-train data on real anatomical features ● Evaluate Performance: <ul style="list-style-type: none"> – Confidence in identification – Type I and Type II errors 	

Fig. 1: Aim 1, 2 and 3 Objectives and Images

1 Aim 1: Develop Method of 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).

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.

3 Aim 3: Integration Between Neural Network and Main 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.

Approach

4 Aim 1

4.1 Rationale

In the first step of Aim 1, the fabrication process of the TCP will be developed to a point of consistent and accurate creation. Once this process is proven to be consistent and reliable, the next steps will be modeling the system, and choosing a control architecture which can maintain a consistent configuration of the TCP with little-to-no error.

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 parameters 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 set to current and voltage. 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 a control architecture similar to model predictive control (MPC) which would create the most accurate system available. MPC, and its alternatives will be more thoroughly discussed in the next section.

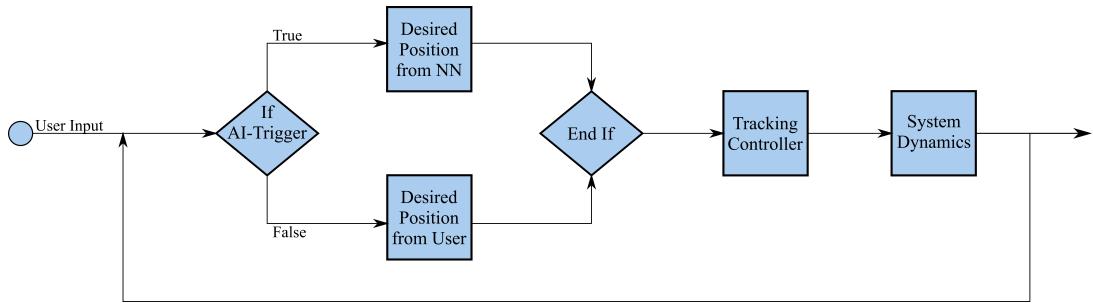


Fig. 2: AEI System Control Diagram

4.2 Approach

4.2.1 Hypothesis/Timeline

The fabrication of the TCP material will be facilitated through an in-house rope making machine which are standard and can be automated relatively easily. The wire of choice will be silver-coated nylon 66 wire, similar to that used in the initial prototype. The control board of choice for the automation will be an Arduino Uno, and will be used to control the RPM of the machine, as well as the number of spins. The counter-weight attached to the machine can also be adjusted for further variations. For consistency, the length of the TCP created at a given time will be held constant, and will be heat-treated and trained using the research verified by [CITE SOURCE FOR FABRICATION].

Modeling of the TCP system will be the most difficult of the steps discussed in this research. Here, the formula for the TCP dynamics will be simplified to take the inputs current and voltage, and output the tension created after a certain period of time. This is achieved in the research conducted here [CITE MODELING ARTICLE]. The model will be compared to the real TCP using a tension measurement device, and by holding the current and voltage constant over the intended period of time. In this way, the error between the model and the real system can be evaluated at varying configuration settings. With tension calculated, the system then be directly compared to a solely tension-driven actuation system. This effectively turns the model from a current (input) to tension (output) calculation, to a current (input) to motion (output) formula.

The controller for the system will ideally be model-dependent. It is understood that model-dependent controllers, when accurately tuned, create the most effective system controllers and are more reliable and robust

then model-independent alternatives. Also, considering the time-dependence of the TCP system, the use of MPC will be prioritized because of its ability to look into future states and solve for the optimal set of inputs at a given point in time.

4.3 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 project.

In the case of the fabrication. It is likely that the TCP string may be too thin, inconsistent string could be purchased, or the machine itself may be too intricate to make/program in-house. In the scenario of thin or inconsistent string, there are many companies that make the intended wire and ordering thicker/more consistent silver-coated polymer wire is possible. Once a certain brand of wire proves sufficient, it will be ordered in bulk and used for the remainder of the project. If the machine proves too intricate to make by hand, it is also possible to order small scale rope making machines online.

Since TCP is a relatively new form of actuation and is time-dependent, verified methods of modeling are not easily found. Here, the equations derived from the research of Farzad Karami and Yonas Tadesse in [CITE MODELING ARTICLE] will be used to supplement the formulations found in-house. In the extreme case that the model cannot be derived analytically, it is also possible to train a neural network to produce the intended behavior. This would involve considerably more data on configuration details, but is very possible and has been done for likewise projects in the past [SE3-nets ARTICLE, YANG AND MENG ARTICLE].

5 Aim 2

5.1 Rationale

In aim 2, the design of the end effector, and the core tubing is addressed. In this portion of the project, the end effector will be designed to house the TCP such that it is not exposed, can be replaced when necessary, and does not limit its range of motion. To achieve this, the four strands of TCP will be lined in parallel to the center tube, which contains the ground wire, as well as the camera. 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 regular thick string.

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

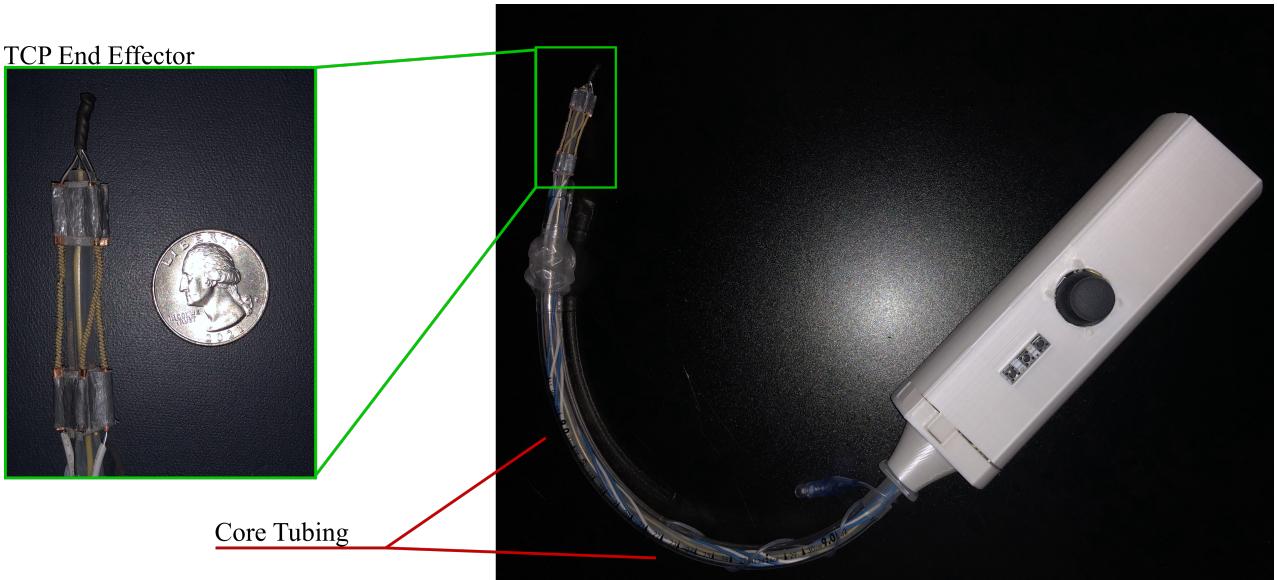


Fig. 3: Prototype Assembly Developed in 2021-2022 Academic Year by OSU Capstone Team

5.2 Approach

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.

The core tubing will be considerably simpler to assemble and can be stylized to a single tube housing the necessary wires which will each be individually insulated. This is similar to every day USB pin-out wiring and other related devices. 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. It may also be necessary to incorporate a center-line down both components such that they can be attached to one another in a consistent configuration.

5.3 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) instead of tubes used in children. That said, in the event that the TCP and other components do not fit within these constraints, alternatives to this configuration will have to be researched.

6 Aim 3

6.1 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. 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.

6.2 Approach

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 they setup the neural network layers efficiently and were able to identify the anatomical features from human mannequin footage. The same network can thus be used for the real system.

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.

6.3 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.

7 Experimental Procedure

7.1 Aim 1

1. Construct TCP-making machine

- (a) Assemble small-scale rope-making machine to create/test TCP strings in-house
- (b) Required Components:
 - Nema-17 Stepper Motor
 - Arduino Uno (or equivalent)
 - LCD for Configuration UI
 - Assorted adjustable dials
 - Counterweights
 - Pulley
 - Assorted Bearings
 - Table clamp

2. Collect data on TCP configurations:

- Various configurations of the assembly from Step 1 will be created for data collection
- Configuration Parameters:
 - (a) **Rotation speed [RPM]**
 - (b) Counterweight [kg]
 - (c) **Initial TCP length [mm]**
 - (d) Annealing Process:
 - Counterweight
 - **Duty Cycle**
 - (e) Training Process
 - Counterweight
 - **Duty Cycle**
- **Evaluated Results:**
 - (a) Final diameter [mm]
 - (b) Inductance [H]
 - (c) Final TCP length [mm]

3. Model the chosen TCP configuration (single strand):

- Reference [ARTICLE ON MODELING] for many of the necessary equations
- Derive equations for tension?
- Evaluate the performance of the model:
 - (a) Modeling Inputs:
 - Current
 - Load (counterweight)
 - (b) Modeling Outputs:
 - Temperature [C] - Equation 7
 - Displacement [mm] - Equation 24
 - Inductance [H] - Equation 28
 - **Tension [N]** - Equation ?

8 Aim 2

1.