Single-Stage Percutaneous Tracheostomy Device

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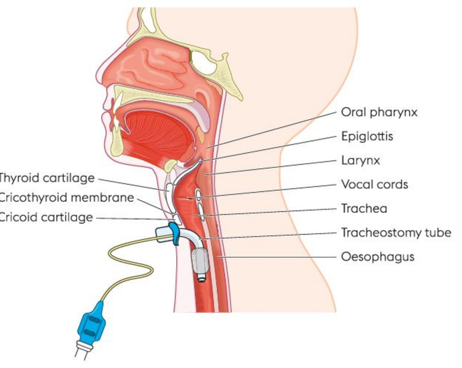
Background and Significance

What is a Tracheostomy?

Percutaneous tracheostomy is a procedure that circumvents airway obstruction by providing an alternative route through a deliberate opening in the trachea[1]. It is performed at the patient's bedside, as opposed to surgical tracheostomies which are performed in the operating room. Maintaining the patient's airway allows for ventilatory support and adequate perfusion until the native airway is restored.

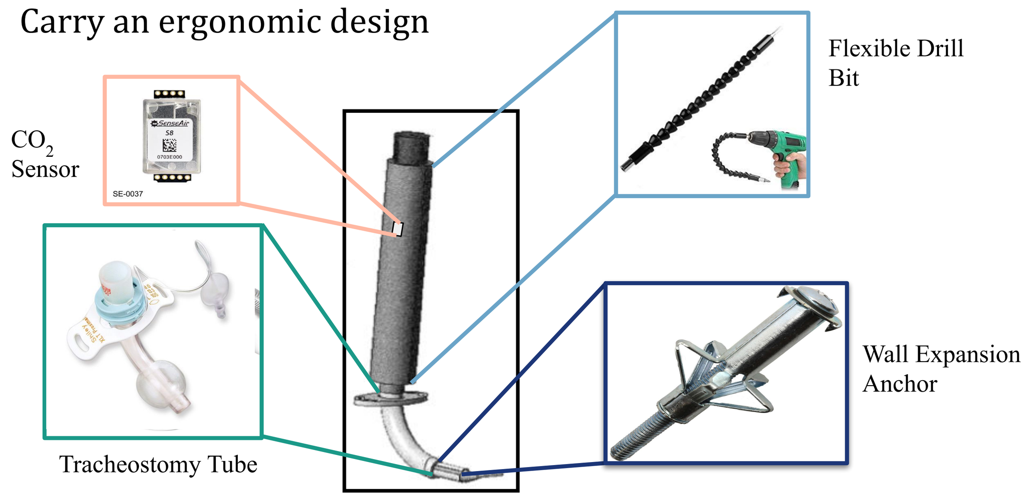


Clinical Need

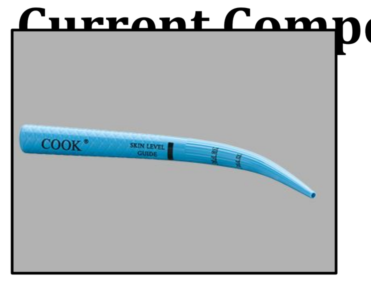
- Current methods require multiple rounds of instrumentation[2]:
  - Increased procedure time
  - Increased risk of infection
  - Increased risk of bleeding
- Minimal tactile feedback for the physician
- Inaccurate placement results in secondary complications[3]

Objectives

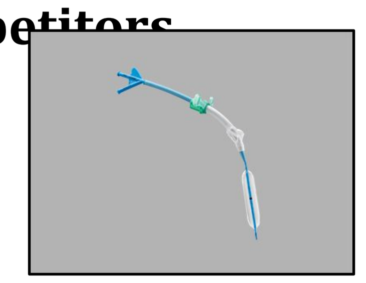
- Successfully dilate an opening of the trachea to 10 millimeters in diameter
- Employ a single instrument
- Detect correct placement
- Provide tactile feedback
- Carry an ergonomic design



Current Competitors



Blue Rhino



Blue Dolphin

Portex ULTRAperc

Methods and Results

Prototyping

Dilation Mechanism

A novel dilation mechanism is at the crux of our project, thus the first part of our prototyping process was to adapt a dilation mechanism. We tested the designs using larger-scale parts that are commercially available at hardware stores. After identifying flaws within each system, we were able to choose a wall-anchor like dilation method, and designed our components using 3D printing software. The wall anchor-like component is attached to a flexible drill bit that can be easily rotated by the physician to dilate the tracheal opening.

3D Printing

Our prototype design utilized a variety of printing techniques to formulate the various components, as well as an initial testing platform for our device. A rudimentary prototype was assembled with parts printed using the MakerBot 5th Generation series and Polylactic Acid filament (PLA). We identified the need for further mechanical considerations using this model, and redesigned and reprinted the parts in more various materials to better suit their intended functionality. A breakdown of key components and materials are given below:

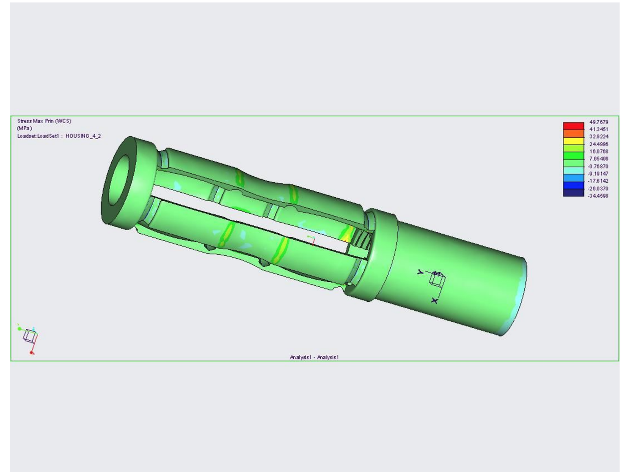
Flexible Drill Bit
- Printed in Flexible Resin

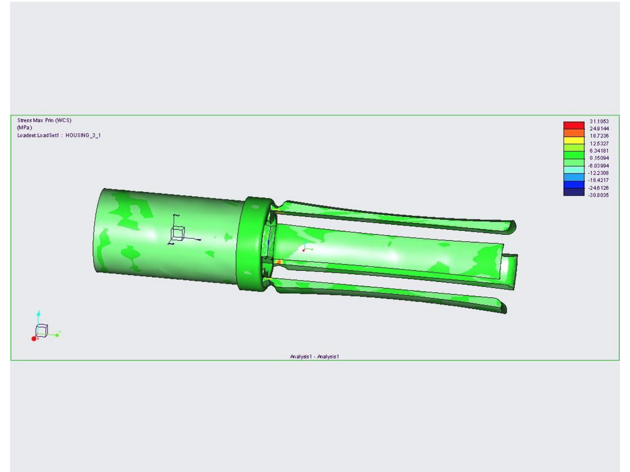
Rotating Knob
- Printed in PLA

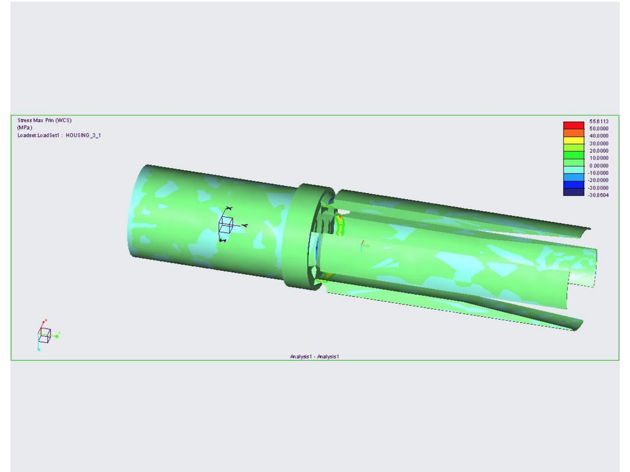
Screw Component
- Printed in Onyx, reinforced with Carbon Fiber

Finite Element Analysis (FEA) was conducted on three different designs for the expansion mechanism. Using these results we were able to choose the most stable design for printing and further development.

Maximum Stress Analysis

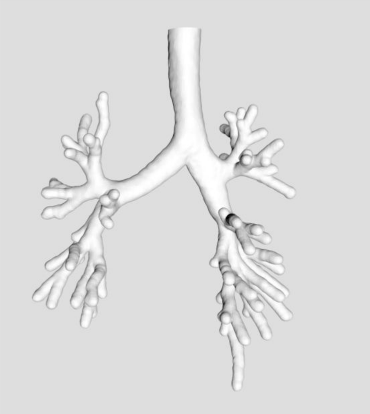




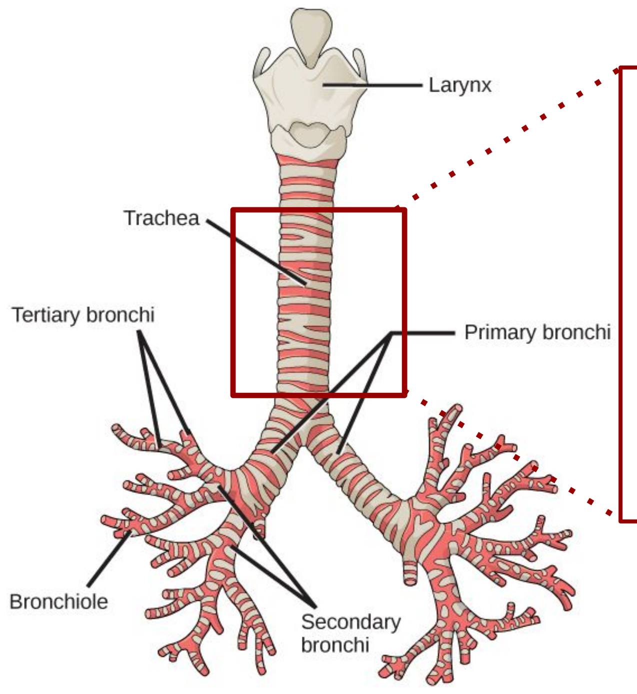


Tracheal Modelling

We used CT image data to construct a 3D model of an adult trachea, printed in a combination of materials to match the elastic modulus of the cartilaginous section of the trachea (approximately 1.74 MPa). 9g of the VeroGray, 16g of the Agilus30, and 5g of the Med610 materials were used in the final model, printed on the Objet500 Connex3 printer.



Patient Derived CT Scan



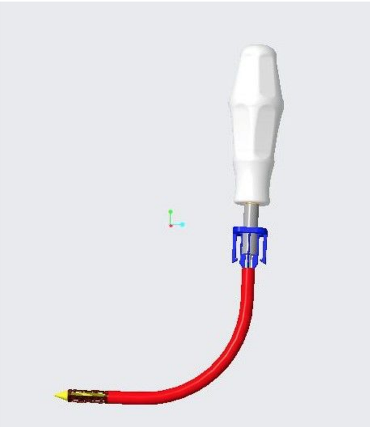
3D Printed Model

Ethical Implications

We intend to make a device that is cost-efficient and safer for patient use. In doing so we will improve accessibility, as well as patient outcomes. Initial prototyping has been conducted on 3D printed models to mitigate risk exposure of live subjects. Future analysis and studies using porcine models, and eventually patient data will require further implementation of ethical standards. Specific protocols designed with ideal conditions and proper treatment of subjects will be implemented and used with the same high ethical standards.

Conclusions

- Developed a **single stage** tracheostomy tube delivery system
  - Implements a novel dilation mechanism
  - Provides continuous tactile feedback
- Investigated various material components to develop a cost-effective, easily replicable design
- Demonstrated potential to create a device with additional components to sense placement through CO_2 sensors as well as determine trajectory



Future Work

We will proceed to testing our device on porcine models which are comparable to human tracheas once we have established efficacy in our 3D printed tracheal models. We then will test on cadavers to most closely replicate operating conditions before proceeding to clinical trials. Further collaboration with clinical faculty will allow us to develop a marketable and patentable design.

Significant References

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2. Cianchi, et al. "Comparison between Single-Step and Balloon Dilatational Tracheostomy in Intensive Care Unit: a Single-Centre, Randomized Controlled Study." *OUP Academic*, Oxford University Press, 21 Apr. 2010, academic.oup.com/bja/article/104/6/728/232461.
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Acknowledgements

We would like to extend our gratitude to our mentors Dr. John Fisher, Ph.D. and Dr. Joseph Rabin, MD for their continued support throughout our project. We would also like to thank Dr. Yang Tao, Ph.D, Dr. Lan Ma, Ph.D, and the Fischell Department of Bioengineering for their efforts.