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PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. _____

INVENTOR(S)

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Additional inventors are being named on the _____ separately numbered sheets attached hereto.

TITLE OF THE INVENTION (500 characters max):

Distensible Endotracheal Tube

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☑ The address corresponding to Customer Number: 64574

OR

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Address

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ENCLOSED APPLICATION PARTS (*check all that apply*)

☐ Application Data Sheet. See 37 CFR 1.76.

☐ CD(s), Number of CDs _____

☑ Drawing(s) *Number of Sheets* 3

☑ Other (specify) Appendix A, Appendix B and Appendix C

☑ Specification (e.g., description of the invention) *Number of Pages* 15

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 2 of 2

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☑ No.

☐ Yes, the invention was made by an agency of the U.S. Government. The U.S. Government agency name is: _____

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SIGNATURE /Matthew J. Esserman/ DATE April 14, 2017

TYPED OR PRINTED NAME Matthew J. Esserman REGISTRATION NO. 41,536 (*if appropriate*)

TELEPHONE 215-569-5603 DOCKET NUMBER 150248-00101

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UNITED STATES PROVISIONAL PATENT APPLICATION

TITLE: **Distensible Endotracheal Tube**

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Appendices A-C are hereby incorporated herein and are part of this disclosure.

Government Sponsorship:

None.

Field

[0001] The embodiments disclosed herein are in the field of medical device tubes. More particularly, the embodiments disclosed herein relate to collapsible and distensible endotracheal tubes and methods of using same, which, *inter alia*, achieve a reduced outer diameter of the endotracheal tube via twisting of the endotracheal tube in order to ease intubation insertion and improve visualization during intubation, and then achieve an enlarged outer diameter of the endotracheal tube via distension of the endotracheal tube to enhance airflow. The endotracheal tube creates a universal size for endotracheal tubes. For example, in creating a tube that is collapsed to 2-3mm, hospitals will not need to stock multiple tube sizes, thereby drastically reducing inventory costs.

Background

[0002] Of the 51.7 million intubations that occur annually, 10% encounter complications, resulting in 5.3 million complications. These complications can mainly be attributed to poor visibility due to the large diameters of the endotracheal tubes (ETTs) necessary to maintain sufficient airflow to the lungs. Impaired visibility increases the chance of a failed intubation and that the clinician will damage the surrounding tissue. Failure to secure an airway could result in permanent brain damage or death. Injury to the soft tissues of the airway is a common cause of postoperative throat discomfort. The present novel device inserts at a small diameter to ease intubation and then distends

to enhance airflow, overcoming problems current ETTs lack by only accommodating a single diameter and not providing a physiological conduit to maintain respirations. The present collapsible design significantly decreases the diameter of the endotracheal tube to increase visibility around the ETT by 25%. This improved visibility will ease the process of intubation for clinicians, therefore improving patient outcomes.

[0003] Additional background information is described and shown in the Appendices.

[0004] It is desirable to provide an endotracheal tube and method of using same that, *inter alia*, are able to overcome the disadvantages mentioned in the Appendices.

[0005] These and other advantages of the present invention will become more fully apparent from the detailed description of the invention herein below and described in the Appendices.

Brief Description of the Drawings

[0006] This disclosure (including the Appendices) will be better understood when read in conjunction with any of the drawings disclosed herein (including those in the Appendices). For the purpose of illustration only, there is shown in the drawings certain embodiments. It's understood, however, that the inventive concepts disclosed herein are not limited to the precise arrangements and instrumentalities shown in the figures.

[0007] Figure 1 illustrates the pre-assembly view of the tubular sheet with longitudinal support structures (e.g., wires) adhered to the interior of the tubular sheet. The dotted lines within the proximal and distal tubes indicate the final location of the support structures embedded within the proximal and distal tubes thus affixing the support structures and the tubular sheet to both ends completing the passage.

[0008] Figure 2 illustrates the collapsed appearance of the tubular sheet endotracheal tube with an estimated actual outer diameter of, for example, 3mm. A pilot balloon tube is contained within the lumen of the endotracheal tube as well as raised tabs within the tube to facilitate deployment during removal of the stylet.

[0009] The method associated with the design is as follows: A patient is brought to the operating room in the standard fashion and is placed under general anesthesia. The universal (present invention) endotracheal tube is selected, the patient is paralyzed medically and intubated using standard techniques. Once the tube has passed at least partially through the vocal cords, the device expands. This may be initiated by a column of air from the ventilator or by removal of the sylet (via, for example, releasing from or breaking away from the tabs).

[0010] Figure 3 illustrates the distended state of the present invention endotracheal tube. In this configuration, airway pressure and resistance is decreased and the airflow to the lungs is more physiologic in nature.

[0011] Figure 4 illustrates the collapsed and distended views of the tube.

[0012] Figure 5 illustrates a cross-sectional view of a tubular sheet attachment portion to the (e.g., polyvinyl chloride (PVC)) endotracheal tube proximal and/or distal end. The tubular sheet with reinforced structure(s) (e.g., wire(s)) may be embedded within the proximal tube (i.e., the tube having the machine connector as part thereof) and/or distal tube (i.e., the tube having the cuff assembly as part thereof) or it may be superficial or internal to either tube or both tubes. Any connection of the tubular sheet with reinforced structure(s) to either tube may be made via any fastener mechanism such as glue, epoxy, embossing, welding, melting, stitching, tape, etc. In this figure, there are 9 wires and one tubular sheet which have ends that are embedded within the PVC tube.

[0013] Additional figures are disclosed in the Appendices and are hereby incorporated herein.

Detailed Description

[0014] The Appendices are hereby incorporated into this section of the disclosure, and any reference to information in this section may also refer to and/or incorporate the information in the Appendices.

[0015] It is to be understood that the figures and descriptions of the present invention may have been simplified to illustrate elements that are relevant for a clear understanding of the present embodiments, while eliminating, for purposes of clarity, other elements found in a typical endotracheal tube or typical method for using an endotracheal tube. Those of ordinary skill in the art will recognize that other elements may be desirable and/or required in order to implement the present embodiments. However, because such elements are well known in the art, and because they do not facilitate a better understanding of the present embodiments, a discussion of such elements is not provided herein. It is also to be understood that the drawings included herewith only provide diagrammatic representations of the presently preferred structures of the present invention and that structures falling within the scope of the present embodiments may include structures different than those shown in the drawings. Reference will now be made to the drawings wherein like structures are provided with like reference designations.

[0016] Before explaining at least one embodiment in detail, it should be understood that the concepts set forth herein are not limited in their application to the construction details or component arrangements set forth in the following description or illustrated in the drawings. It should also be understood that the phraseology and terminology employed herein are merely for descriptive purposes and should not be considered limiting.

[0017] It should further be understood that any one of the described features may be used separately or in combination with other features. Other embodiments of devices, systems, methods, features, and advantages described herein will be or become apparent to one with skill in the art upon examining the drawings and the detailed description herein. It's intended that all such additional devices, systems, methods, features, and advantages be protected by the accompanying claims.

[0018] For purposes of this disclosure, the term "wire" may include any elongated twistable support structure such as a cable, rod, ribbon, stick, pole, bar, etc. The wire may or may not comprise a shape memory-effect material. The wire material may comprise any twistable material such as a metal, metal alloy, plastic, polymer, or combination thereof.

[0019] Also, for purposes of this disclosure, the term "fluid" (i.e., used for inserting through the endotracheal tube) may include gas (e.g., air), liquid, or combination thereof.

[0020] Embodiments of the present application are directed to an endotracheal tube movable between a collapsed configuration and a distended configuration different from the collapsed configuration, the endotracheal tube comprising: a proximal end portion; a distal end portion; an intermediate portion longitudinally positioned between the proximal end portion and the distal end portion; at least one tubular sheet forming at least a part of the intermediate portion; and at least one wire connected substantially longitudinally along an interior of at least one of the at least one tubular sheet. The at least one tubular sheet and the at least one wire are twisted, whereby the at least one tubular sheet and the at least one wire are collapsed, thereby providing the at least one tubular sheet with a reduced outer diameter, when the endotracheal tube is in the collapsed configuration; and the at least one tubular sheet and the at least one wire are at least

partially untwisted, whereby the at least one tubular sheet and the at least one wire are distended, thereby providing the at least one tubular sheet with an enlarged outer diameter, when the endotracheal tube is in the distended configuration.

[0021] In an embodiment, the at least one wire comprises at least two wires.

[0022] In an embodiment, the endotracheal tube further comprises a cuff assembly comprising: a tip positioned at the distal end portion; and a cuff positioned between the tip and the at least one tubular sheet, wherein a distal end of the at least one tubular sheet is connected to the cuff assembly.

[0023] In an embodiment, the endotracheal tube further comprises a cuff inflation tube connecting the cuff to a pilot balloon, wherein the cuff inflation tube is positioned interiorly of the at least one tubular sheet.

[0024] In an embodiment, the at least one wire is positioned interiorly of the at least one tubular sheet.

[0025] In an embodiment, the endotracheal tube further comprises a machine connector assembly positioned at the proximal end portion, wherein a proximal end of the at least one tubular sheet is connected to the machine connector assembly.

[0026] In an embodiment, the endotracheal tube further comprises a stylet connected to the at least one wire and/or an interior surface of the at least one tubular sheet, when the endotracheal tube is in the collapsed configuration.

[0027] In an embodiment, the endotracheal tube is moved from the collapsed configuration to the distended configuration when fluid is transmitted through the at least one tubular sheet.

[0028] Embodiments of the present application are also directed to a method of using an endotracheal tube that is movable between a collapsed configuration and a distended configuration different from the collapsed configuration. The method comprises: providing an endotracheal tube comprising: a proximal end portion; a distal end portion; an intermediate portion longitudinally positioned between the proximal end portion and the distal end portion; at least one tubular sheet forming at least a part of the intermediate portion; and at least one wire connected substantially longitudinally along an interior of at least one of the at least one tubular sheet. The method also comprises providing the at least one tubular sheet and the at least one wire in a twisted configuration, whereby the at least one tubular sheet and the at least one wire are collapsed, thereby providing the at least one tubular sheet with a reduced outer diameter, when the endotracheal tube is in the collapsed configuration; and moving the at least one tubular sheet and the at least one wire from the twisted configuration to an at least partially untwisted configuration, whereby the at least one tubular sheet and the at least one wire are distended, thereby providing the at least one tubular sheet with an enlarged outer diameter, when the endotracheal tube is in the distended configuration.

[0029] In an embodiment of the method, the at least one wire comprises at least two wires.

[0030] In an embodiment of the method, the endotracheal tube further comprises a cuff assembly comprising: a tip positioned at the distal end portion; and a cuff positioned between the tip and the at least one tubular sheet, wherein a distal end of the at least one tubular sheet is connected to the cuff assembly.

[0031] In an embodiment of the method, the endotracheal tube further comprises a cuff inflation tube connecting the cuff to a pilot balloon, wherein the cuff inflation tube is positioned interiorly of the at least one tubular sheet.

[0032] In an embodiment of the method, the at least one wire is positioned interiorly of the at least one tubular sheet.

[0033] In an embodiment of the method, the endotracheal tube further comprises a machine connector assembly positioned at the proximal end portion, wherein a proximal end of the at least one tubular sheet is connected to the machine connector assembly.

[0034] In an embodiment of the method, the endotracheal tube further comprises a stylet connected to the at least one wire and/or an interior surface of the at least one tubular sheet, when the endotracheal tube is in the collapsed configuration, wherein the step of moving the at least one tubular sheet and the at least one wire from the twisted configuration to the at least partially untwisted configuration occurs by removing the stylet from the endotracheal tube.

[0035] In an embodiment of the method, the step of moving the at least one tubular sheet and the at least one wire from the twisted configuration to the at least partially untwisted configuration occurs when fluid is transmitted through the at least one tubular sheet.

[0036] The method steps in any of the embodiments described herein (or in the Appendices) are not restricted to being performed in any particular order. Also, structures mentioned in any of the method embodiments may utilize structures mentioned in any of the device embodiments. Such structures may be described in detail with respect to the device embodiments only but are applicable to any of the method embodiments.

[0037] Features in any of the embodiments described above (or in the Appendices) may be employed in combination with features in other embodiments described above (or in the Appendices), and such combinations are considered to be within the spirit and scope of the present invention. Such additions and/or alternatives are considered to be within the spirit and scope of the present invention, and may therefore utilize the advantages of the configurations and embodiments described above. The contemplated modifications and variations specifically mentioned above are considered to be within the spirit and scope of the present invention.

[0038] It's understood that the above description is intended to be illustrative, and not restrictive. The material has been presented to enable any person skilled in the art to make and use the concepts described herein, and is provided in the context of particular embodiments, variations of which will be readily apparent to those skilled in the art (e.g., some of the disclosed embodiments may be used in combination with each other). Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the embodiments herein therefore should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein."

What is Claimed is:

1. An endotracheal tube movable between a collapsed configuration and a distended configuration different from the collapsed configuration, the endotracheal tube comprising:

a proximal end portion;

a distal end portion;

an intermediate portion longitudinally positioned between the proximal end portion and the distal end portion;

at least one tubular sheet forming at least a part of the intermediate portion; and

at least one wire connected substantially longitudinally along an interior of at least one of the at least one tubular sheet;

wherein the at least one tubular sheet and the at least one wire are twisted, whereby the at least one tubular sheet and the at least one wire are collapsed, thereby providing the at least one tubular sheet with a reduced outer diameter, when the endotracheal tube is in the collapsed configuration; and

wherein the at least one tubular sheet and the at least one wire are at least partially untwisted, whereby the at least one tubular sheet and the at least one wire are distended, thereby providing the at least one tubular sheet with an enlarged outer diameter, when the endotracheal tube is in the distended configuration.

2. The endotracheal tube of claim 1, wherein the at least one wire comprises at least two wires.

3. The endotracheal tube of claim 1, further comprising:

a cuff assembly comprising:

a tip positioned at the distal end portion; and

a cuff positioned between the tip and the at least one tubular sheet, wherein a distal end of the at least one tubular sheet is connected to the cuff assembly.

4. The endotracheal tube of claim 1, wherein the endotracheal tube further comprises a cuff inflation tube connecting the cuff to a pilot balloon, and wherein the cuff inflation tube is positioned interiorly of the at least one tubular sheet.

5. The endotracheal tube of claim 1, wherein the at least one wire is positioned interiorly of the at least one tubular sheet.

6. The endotracheal tube of claim 1, further comprising:

a machine connector assembly positioned at the proximal end portion, wherein a proximal end of the at least one tubular sheet is connected to the machine connector assembly.

7. The endotracheal tube of claim 1, further comprising a stylet connected to the at least one wire and/or an interior surface of the at least one tubular sheet, when the endotracheal tube is in the collapsed configuration.

8. The endotracheal tube of claim 1, wherein the endotracheal tube is moved from the collapsed configuration to the distended configuration when fluid is transmitted through the at least one tubular sheet.

9. A method of using an endotracheal tube that is movable between a collapsed configuration and a distended configuration different from the collapsed configuration, the method comprising:

providing an endotracheal tube comprising:

a proximal end portion;

a distal end portion;

an intermediate portion longitudinally positioned between the proximal end portion and the distal end portion;

at least one tubular sheet forming at least a part of the intermediate portion; and

at least one wire connected substantially longitudinally along an interior of at least one of the at least one tubular sheet;

providing the at least one tubular sheet and the at least one wire in a twisted configuration, whereby the at least one tubular sheet and the at least one wire are collapsed, thereby providing the at least one tubular sheet with a reduced outer diameter, when the endotracheal tube is in the collapsed configuration; and

moving the at least one tubular sheet and the at least one wire from the twisted configuration to an at least partially untwisted configuration, whereby the at least one tubular sheet and the at least one wire are distended, thereby providing the at least one tubular sheet with an enlarged outer diameter, when the endotracheal tube is in the distended configuration.

10. The method of claim 9, wherein the at least one wire comprises at least two wires.

11. The method of claim 9, wherein the endotracheal tube further comprises:

a cuff assembly comprising:

a tip positioned at the distal end portion; and

a cuff positioned between the tip and the at least one tubular sheet, wherein a distal end of the at least one tubular sheet is connected to the cuff assembly.

12. The method of claim 9, wherein the endotracheal tube further comprises a cuff inflation tube connecting the cuff to a pilot balloon, and wherein the cuff inflation tube is positioned interiorly of the at least one tubular sheet.

13. The method of claim 9, wherein the at least one wire is positioned interiorly of the at least one tubular sheet.

14. The method of claim 9, wherein the endotracheal tube further comprises:

a machine connector assembly positioned at the proximal end portion, wherein a proximal end of the at least one tubular sheet is connected to the machine connector assembly.

15. The method of claim 9, wherein the endotracheal tube further comprises a stylet connected to the at least one wire and/or an interior surface of the at least one tubular sheet, when the endotracheal tube is in the collapsed configuration, and wherein the step of moving the at least one tubular sheet and the at least one wire from the twisted configuration to the at least partially untwisted configuration occurs by removing the stylet from the endotracheal tube.

16. The method of claim 9, wherein the step of moving the at least one tubular sheet and the at least one wire from the twisted configuration to the at least partially untwisted configuration occurs when fluid is transmitted through the at least one tubular sheet.

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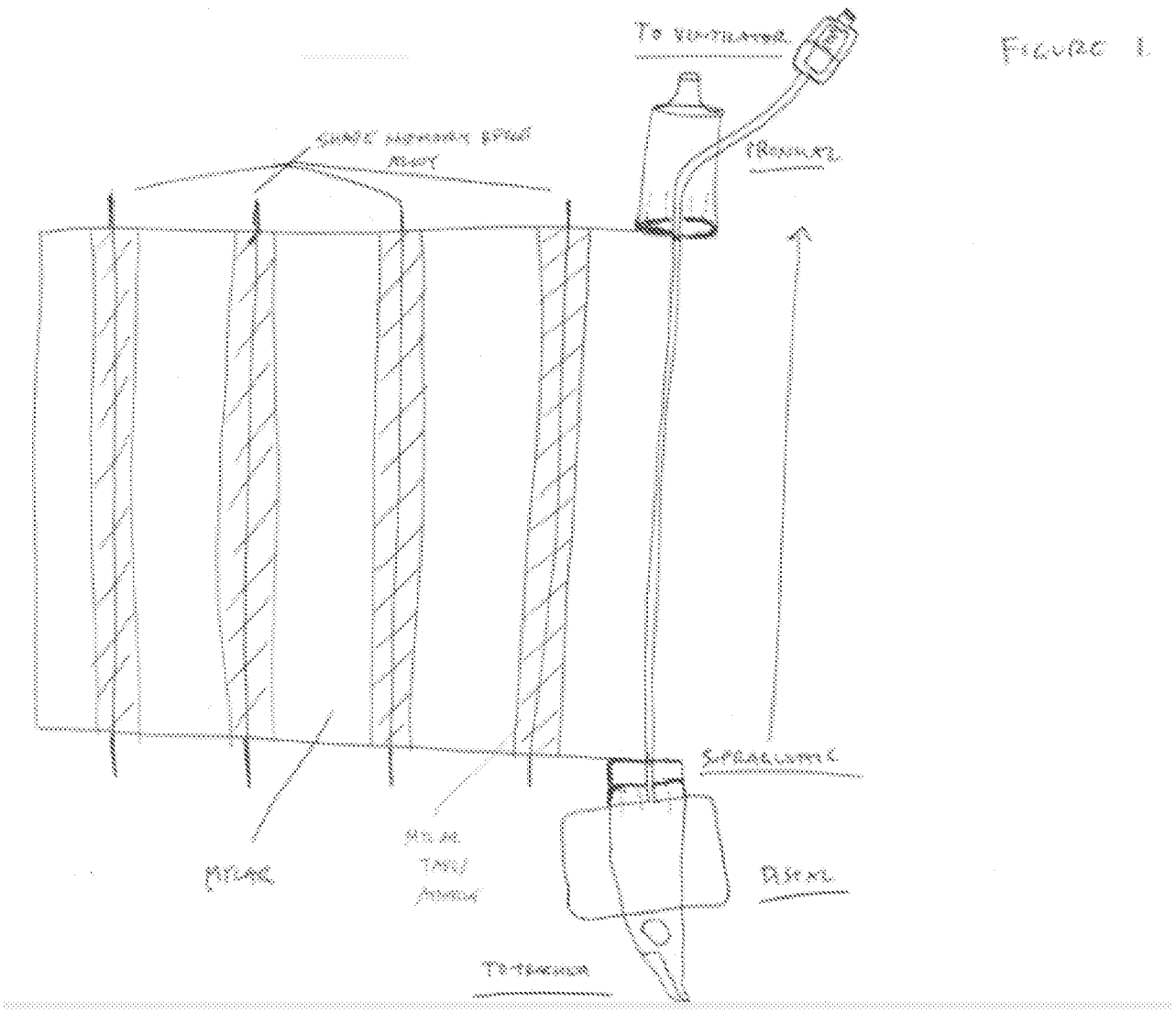

FIGURE 1.

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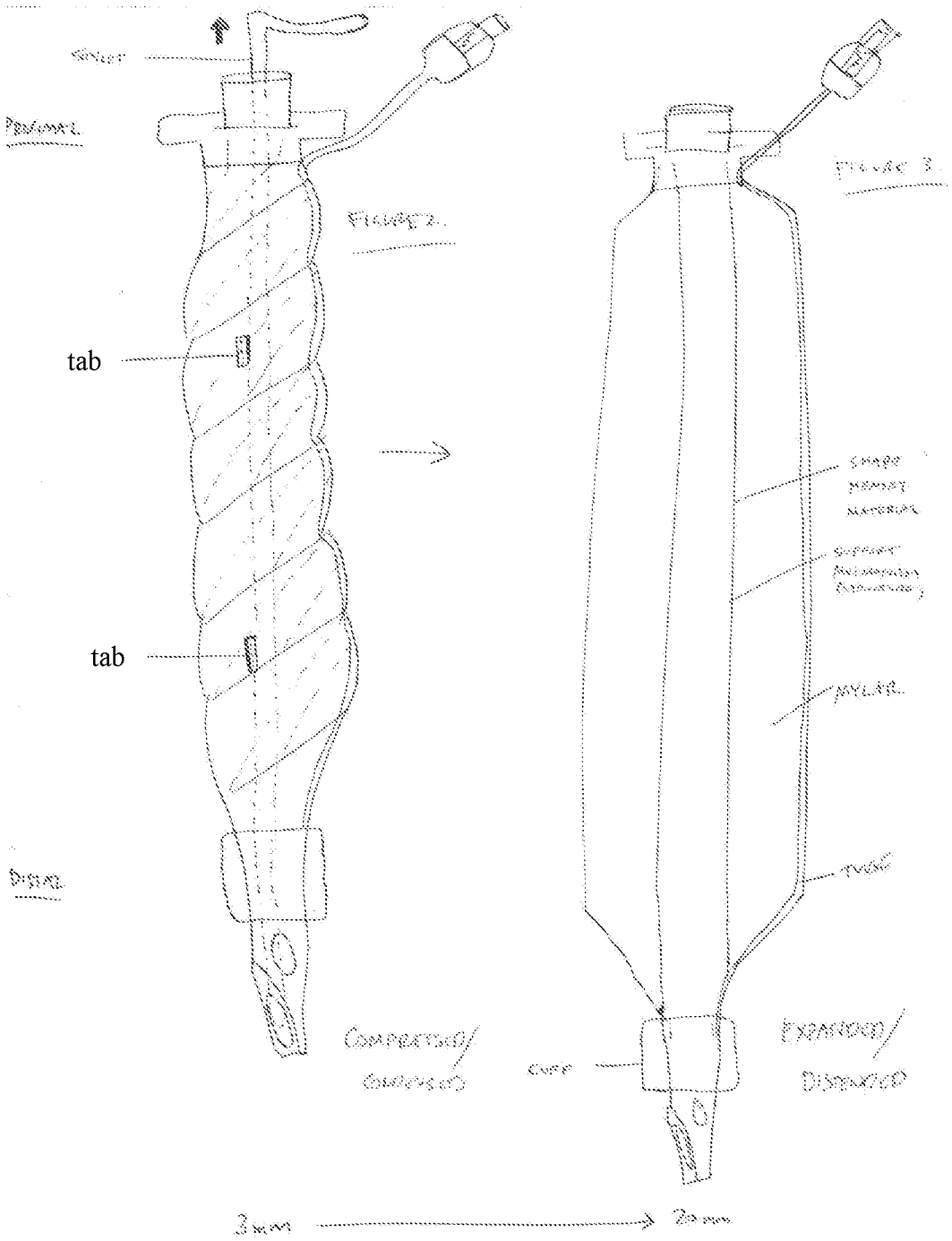

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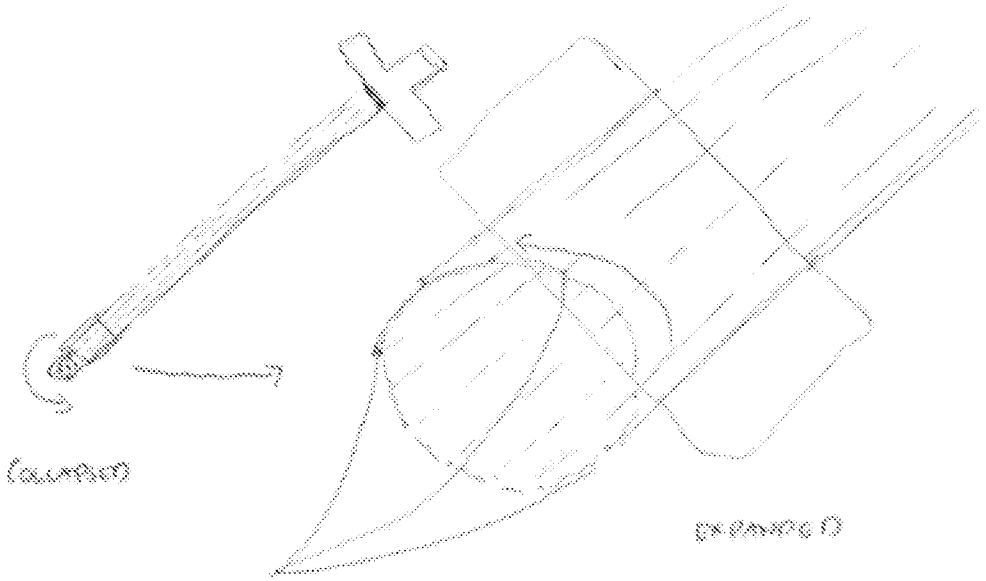
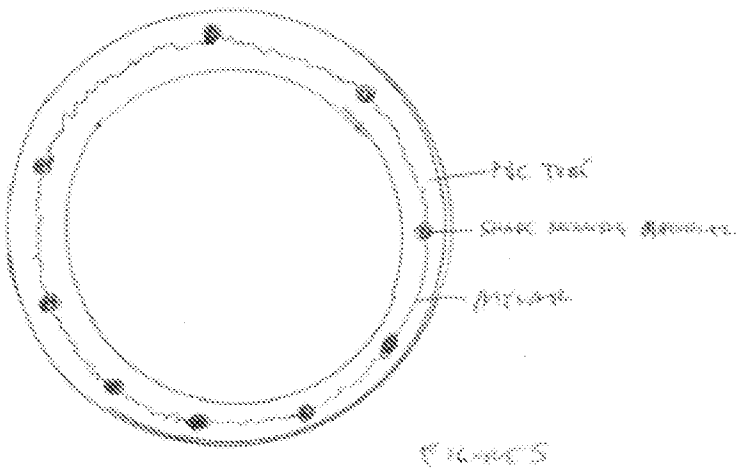




Appendix A

The present invention describes a novel endotracheal tube (ETT) that eases the process of intubation and improves patient outcomes by reducing the diameter of the ETT to improve visibility. The needs of this device are as follows:

- Current ETTs compromise between diameter and airflow, resulting in large diameters that impair visibility surrounding the device
- 10% of all intubations experience complications ranging from hitting the anatomy surrounding the trachea to intubating the esophagus
- No major modifications have been made to current ETTs in over 50 years

The present design must adhere to physiological constraints during surgery, which include:

- Diameter of the trachea and vocal cords
- Amount of air required by the lungs
- Threat of puncture in trauma patients
- Low cost of standard ETTs

After consulting with clinicians who perform intubation, the inventors have identified several design objectives and listed them in order of importance:

- Improve visibility for the clinician performing intubation
- Increase airflow to the patient's lungs
- Simple to deploy
- Resistant to puncture
- Similar in size to existing tubes

- Comparable in cost to existing tubes
- Biocompatible
- Sterilizable
- Laser-shielded

The present design seeks to address the shortcomings of current ETTs by being (e.g., radially) collapsible in order to increase visibility and ease of use during intubation and distensible in order to increase airflow to the lungs during surgery. The inventors focused on replacing the rigid PVC tubing characteristic of current ETTs with a material that is puncture resistant, yet able to collapse and expand with minimal deployment steps.

The inventors have developed a preliminary prototype made of wire-reinforced mylar tubular sheet that collapses (e.g., radially and optionally longitudinally) manually, and distends when connected to a ventilator (or, alternatively, when a stylette initially placed within the collapsed mylar tubular sheet is released from the endotracheal tube). The prototype design has been used for proof-of-concept testing involving intubation of a trainer model and delivery of air to the trainer model's lungs.

Introduction

Design Context Review

A Major Prevalence of Complications

Each year in the United States, an estimated 51.7 million endotracheal tubes (ETT) (i.e., determined using 5.5% annual growth rate of medical device market and 25.8 million endotracheal tubes sold in 2002) are used to deliver anesthesia or ventilate the lungs during

intubation for surgical procedures. 10.3% of intubations will experience a complication. Thus, 5.3 million intubations experience a complication each year, with patient outcomes ranging from persistent post-operative discomfort to death.

Intubation complications include aspiration of stomach contents into the lungs, esophageal intubation leading to hypoxemia, puncturing of tissues/collapsed lung (pneumothorax), dental trauma, twisting of the ETT, or puncture of tube components. These complications and their effects can be found in Table 4. Patients who incur such complications experience discomfort and may require additional health care. Furthermore, if mechanical complications occur, such as the puncture of a cuff, the ETT must be completely removed and the process repeated. Performing multiple intubations on one patient raises the risk for complications. The incidence of complications is further worsened in intubations of difficult airways (e.g. swollen tissue or severe oral trauma). In these cases, the airway entrances are narrower and current designs provide an inadequate line of sight due to the tube's large diameter, increasing the chance for complications. Ultimately, such complications become a major medical and financial burden to the patient.

Intubations and Anatomical Environment

Understanding of the design environment is fundamental to the design context and must be discussed first. As shown in Figure 1, Standard ETTs are comprised of a long tube with depth markings, an x-ray detectable radiopaque line along the length of the tube, an inflatable cuff, a pilot balloon that mirrors the pressure in the cuff, a beveled tip with a Murphy's Eye on the distal end, and a machine connector on the proximal end.

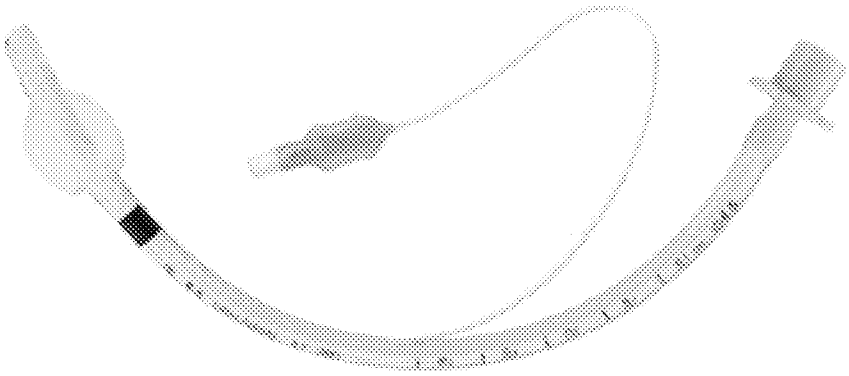


Fig. 1: Example of a standard ETT. Pictured: MedSource 6.5mm, cuffed (Model #: MS-23265).

During an intubation, the ETT is directed into the patient's trachea, the windpipe that connects the lungs to the larynx, using the beveled tip. The beveled tip is meant to increase visibility for the user as it is guided down the respiratory tract. Also found on the tip, the Murphy's Eye functions as a vent in case the bevel comes in contact with a wall and is unable to ventilate the patient. Once inserted into the trachea, the cuff is inflated past the larynx and vocal cords using an air-filled syringe. The inflated cuff secures the tube in position and creates a seal with the trachea. The machine connector is then connected to an anesthesia or oxygen source. The average trachea (shown in Figure 2c) is 2.4 centimeters wide. Its small size and the delicate anatomy surrounding it provides a challenge for the person performing the intubation. The tip of the ETT can be difficult to visualize and may prompt the handler to damage surrounding tissues. This damage leads to necrosis (premature tissue death) of the damaged tissue. Furthermore, enlarged airway anatomy, caused by cases such as infection, trauma, tumor or obstruction with a foreign object, also complicates the intubation procedure. Lastly, the esophagus, which is a comparable 2 centimeters wide, may be mistaken for the trachea and accidentally intubated. This

causes a complication known as esophageal intubation, where the ETT cuff forms a seal in the esophagus and obstructs the airway, resulting in low blood oxygen content (hypoxemia).

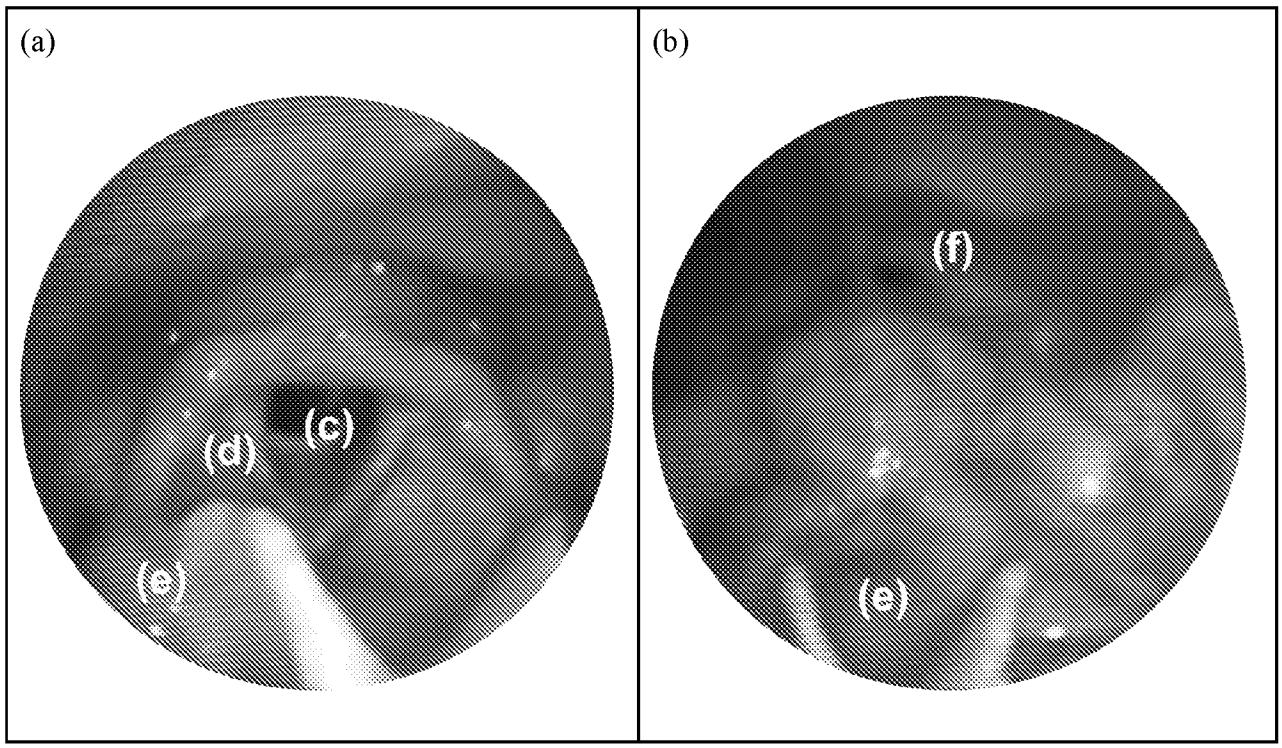


Fig. 2: Laryngoscopic images of the larynx. In (a), the trachea (c), vocal cords (d), and epiglottis (e), are visible. In (b), the larynx is shut during swallowing, showing how the epiglottis (e) contracts and forces the cartilages to shut thus revealing the esophagus (f).

Designs aiming to reduce complications must consider these challenges and more. The airflow through the device must be enough to effectively ventilate the lungs. Volumetric flow rate of air through an ETT may be modeled using Poiseuille Law, in which case the flow rate is proportional to the radius of the tube raised to the fourth power. Most ETTs remain in the trachea for an average of 7.5 hours. If the ETT has been in place for 48 hours, necrosis will begin to occur. Additionally, laryngoscopes or fiber optic scopes are often used in conjunction with ETTs

to gain a better, though limited, view of the trachea. These tools must also be considered when developing ETT designs.

A Clinical Perspective

Clinical knowledge of how ETT are used also provide design context. Intubations are most often performed by anesthesiologists and nurses to deliver anesthesia or ventilate the lungs for surgical procedures. When performing intubations, they often experience difficulty properly inserting the ETT into the trachea due to obfuscation of the trachea by the ETT itself. During intubation, doctors oftentimes secure the portion of the tube protruding from the mouth to one corner of the lips in order to operate on another area of the face. The tube is expected to remain connected to the external airway connection, and the cuff at the distal end of the tube is required to remain inflated beneath the vocal cords in order to secure the tube within the trachea and to prevent the aspiration of stomach contents. After the ETT has been removed, patients typically complain of sore throat and/or altered vocal quality.

Customers Prefer Inexpensive ETTs

Customers are central to any design and they must be considered. ETT customers are the hospitals that fund the operating rooms where intubations are performed. Hospitals typically purchase ETTs in bulk quantities and thus incur much of the cost associated with the tubes themselves. Because intubations are so commonly performed, hospitals do not want to invest substantial amounts of money into each ETT and prefer to purchase ETTs that fall in the lower part of that range.

The Present Device Will Address the Compromise Implicit in Current ETT Designs

Current designs rarely stray from the previously discussed standard design—varying mostly on material, sizes, and specialized components. However, all of the current designs include the traditional plastic tube and are manufactured in various inner diameters to accommodate different anatomies and airflow requirements. While a smaller diameter may be able to fit through a swollen airway, it will not deliver sufficient airflow. Conversely, correctly-sized ETTs are unable to fit through swollen airways. All current ETT designs must compromise on one of these features and no ideal solution exists. A need exists for a dynamic design that can fit through small airways and also deliver sufficient air to the lungs.

Regulations and Standards

ETT designs must comply with government regulations and standards in order to be safe for patient use. Relevant standards and regulations include FDA regulation number 868.5730, which defines a tracheal tube, and ISO 5361: 2002, which sets forth the industry standards governing criteria such as dimensions, radius of curvature, inflation system for the cuff, characteristics of the Murphy's eye, sterility assurance and packaging, kink resistance and radiopaque markers for ETTs, and ISO Standards 10993-1 for biocompatibility for devices in contact with mucous membranes and devices that act as a gas pathway. With respect to safety, appropriate sterilization of the device either by using an autoclave or ethylene oxide may be employed. Currently used biocompatible materials to produce ETTs include PVC, red rubber, and silicone, but PVC is overwhelmingly preferred. Furthermore, biocompatible coatings, such as Parylene, could also be employed in the present design.

Problem Statement

All current ETT designs must compromise between tube diameters that ease intubation and diameters that provide sufficient airflow to ventilate the lungs. Furthermore, these ETT designs lead to complications that ultimately become major medical and financial burdens to the patient. The present device that inserts at a small diameter and later expands (at least radially) to enhance airflow will improve patient outcomes by improving visualization, easing the intubation process, minimizing complications, and maintaining sufficient airflow to the lungs.

Market Analysis

The inventors' target population is people in the United States who receive intubation each year. The inventors aim to make the greatest impact possible with the present device, and accordingly this segment fully encompasses the entire spectrum of individuals who are directly affected by the use of ETTs. Given the markets for competitive products and the general lack of ETT design innovation, the inventors foresee a potential market share of 15%, which will yield a promising market opportunity of over $23 million a year.

In the selection of a target market for the present device, the inventors considered five criteria – the estimated market size, potential market share, competitive products and procedures, the customer's willingness to pay, and the predicted financial opportunity.

According to the "The World Medical Market Report 2003" published by Epsicom Business Intelligence in 2003, approximately 25.8 million ETTs were sold in the United States with annual market growth estimated to be 5.5%. The inventors assume that the annual market growth rate has remained constant since 2003 and that each sold ETT corresponds to a single

procedure. From this information, the estimated market size for all individuals who undergo intubation is a robust 51.7 million people.

The inventors then considered the market share for such a device. Although 51.7 million people require use of an ETT each year, the inventors must examine competing products and solutions that potential customers may consider and choose instead of intubation. The primary alternative options to intubation in the marketplace are the laryngeal mask airway (LMA), the Combitube, the continuous positive airway pressure (CPAP) mask, and tracheostomy. LMA is a supraglottic airway device that keeps a patient's airways open, but it suffers from compressibility of breathing tube and low cuff leak pressure. Combitube is a blind insertion airway device that functions without the use of a mask or tracheal intubation. While the Combitube can provide controlled airway ventilation even when used by untrained persons, it lacks a pediatric application and has been known to cause soft tissue perforation. CPAP uses mild air pressure to open the airways continuously. There are several CPAP delivery systems, such as face and nasal masks, but they are prone to air leakage due to difficulty maintaining an airtight seal. During a tracheostomy, a hole is cut into a patient's trachea, and often a tube is inserted to provide ventilation. Tracheostomies run the risk of infection, bleeding, airway loss, and even tracheal stenosis at the site of incision. Despite the alternative products and procedures, the ETT remains the prevailing device for ventilation during surgery. Additionally, the inventors estimate a potential 15% market share based on the prevalent uniform design of ETTs that the inventors aim to replace. The inventors anticipate that the inventors' novel device at a comparable, economically responsible price will garner a competitive share of the market.

For a patient receiving an intubation, willingness to pay can be framed in terms of the cost associated with an ETT. Depending on the general features and design of an endotracheal

tube, the cost of intubation can range from $3 to $200. Because the inventors want the present device to reach the widest population and be competitive with the currently prevalent ETTs on the market, the inventors define that customer's willingness to pay to be $3.

Other potential market segments considered include patients who undergo cardiac surgery, patients who become hospitalized due to severe pneumonia, patients who receive cholecystectomies (gallbladder removal surgery), and patients who undergo orthognathic surgery. In general, the inventors are focusing on patients who undergo procedures that involve general anesthesia and intubation. The customer's willingness to pay remains consistent across all of the potential market segments and is the same as previously mentioned ($3).

The market sizes for these segments are significantly smaller than that of all people who receive intubations. There are 7.5 million patients who undergo cardiac surgery, 600,000 cholecystectomies performed every year, more than 100,000 people are hospitalized due to pneumonia, and 13,500 patients (i.e., determined using 108,000 orthognathic surgeries over an eight year period, assuming that the number of procedures were evenly distributed by year over the period) who undergo orthognathic surgery each year.

Customer Needs

In order to produce a device that is commercially successful, it is essential to address market-specific customer needs. The inventors considered the needs of the patient, the anaesthesiologist intubating the patient, and the regulatory groups overseeing medical device implementation.

Based on clinical perspective and recent literature, the inventors identified seven key customer needs and justify them below. The complete list of Customer Needs can be found in Table 5.

First, the device must comply with ISO regulations for medical devices, anesthetic and respiratory equipment, and sterilization. In order to produce a medical device for commercial use, the device, above all else, must abide by federal and international standards. This need is of utmost importance - if unfulfilled, the device cannot be used for its intended purpose.

In accordance with its primary purpose of conducting air and/or anaesthesia during surgery, the device must allow for the passage of an adequate volume of air through itself. The new device could not serve as a replacement for the ETT if it could not perform this most basic function.

Third, the device must not malfunction or dislodge from the airway connection during the medical procedure following intubation. The cuff is largely responsible for this since it inflates just beneath the vocal cords to secure and seal the tube inside the trachea. Should the cuff deflate, the device would become loose in the trachea, potentially resulting in aspiration into the lungs.

The device must be rigid enough to be puncture- and kink-resistant while being flexible enough to accommodate differing patient anatomies. Because surgical tools are used in the same vicinity of the ETT, the present design must be puncture-resistant in the event a tool is errantly brought into contact with the device; similarly, bone fragments may also come into contact with the device in the event of severe injury. However, the new device must not be so rigid that it prevents bending within the trachea to facilitate insertion. The device must also be resistant to kinking so that airflow is not compromised.

Fifth, the device must not cause trauma to the patient. The most common current ETT design causes severe patient discomfort by changing the positioning of anatomical features within the throat, most notably the vocal cords. This is a key design element unmet by current designs.

The device must increase ease of implantation for the anesthesiologist or other medical professional performing the intubation. Although routine, intubations are difficult to perform because of limited visibility in the trachea around the ETT.

Finally, the tube must be cost-comparable to the current standard, which is $3. If it is not comparable and without significant improvements to the pre-existing design, it will handily be out competed.

Design Specifications

To address aforementioned customer needs, the inventors developed several measurable specifications. These specifications include the dimensions of the device, the hardness of the device, the sterility of the device, the visible area within the trachea, the cuff pressure, the device material's biocompatibility, and cost. An overview of these specifications can be found in Table 1. Each specification is elaborated upon below.

Table 1: Overview of design specifications.

Specification	*Competitive Value*	*Ideal Value*
Dimensions	L=35 cm; d=8mm	L=35 cm; d=10 mm
Hardness	Shore 85A	Shore 85A
Sterility	SAL < 10^{-6}	SAL < 10^{-6}
Visible Area in Trachea	3.5 cm^2	3.9 cm^2
Cuff Pressure	25 cmH_2O	25 cmH_2O
Biocompatibility	Comparable to PVC	Comparable to PVC
Price	$3	$3
Tidal Volumes	1 L	1.3 L
Ease of Use	3/5 on survey	3/5 on survey

Dimensions of the Device

For this specification, the inventors had to address ISO standards for tracheal tubes as well as the patient's anatomical constraints. For each individual, the length of the trachea varies, and an ETT that is too long would enter the lungs and fail to intubate the patient successfully. Furthermore, the length cannot be too short or the cuff cannot form a seal under the vocal cords, leading to ventilation issues. The diameter of the tube also cannot be too large because it would not fit inside the patient's trachea, or be too small because it would negatively affect the volumetric flow rate, which could lead to hypoxia. An average ETT has a length of 25 cm in compliance with ISO 5361: 2012 and an inner diameter of 8 mm, which constitute competitive

values. The ideal length would remain the same at 25 cm, but increase the diameter to 10 mm, which is closer to the diameter of the average trachea (24 mm).

Hardness

The hardness of the device directly relates to its puncture-resistance. Typical PVC ETTs have a hardness of Shore 85A, which is the competitive value as well as the inventors' ideal value considering puncture-risk is currently not a larger concern.

Sterility

Sterility is prescribed by AAMI standards for the well-being of the patient. They require that the device is sterilized, either by autoclave or ethylene oxide, which both have sterility assurance levels (SAL) of $<10^{-6}$.

Visible Area Within the Trachea

Current ETTs obstruct the view of the anaesthesiologist, which can lead to improper insertion. The current visible area (calculated using the cross-sectional area of the trachea and ETT), constitutes the inventors' estimated competitive value at 3.5 cm^2. The inventors would ideally increase this number by laterally collapsing the ETT on itself in order to decrease its diameter. The inventors hope to increase visibility to 4.34 cm^2.

Cuff Pressure

A sufficiently high cuff pressure is necessary to secure the ETT in place, but too large a pressure can cause necrosis of the surrounding tissue. Competitive values are around 25 cmH_2O. Marginal values would be 20 cmH_2O and 40 cmH_2O. The ideal value would preserve the competitive value of 25 cmH_2O.

Biocompatibility

The present device will comply with ISO 5361: 2012 standards for biocompatibility, including cytotoxicity, sensitization, irritation, genotoxicity, and implantation. Medical grade PVC, which is the material most commonly used, meets all these requirements and is the current gold standard that will ideally be mimicked in this regard in the inventors' design.

Price

Current ETTs range in price from a basic ETT for $3 (competitive value), to a steel reinforced for $200 (marginal value). The inventors aim for the inventors' design to have a price of $3.

Tidal Volumes

The most basic purpose of an ETT is to deliver air to the lungs, and an inability to do so could lead to hypoxia. Current ETTs when connected to a ventilator using standard settings are able to deliver 1 L of air to each lung. This constitutes the inventors' marginal value. The present device would ideally increase diameter in order to deliver a 33% volumetric increase in air -- 1.3 L air to each lung.

Ease of Use

One of the main goals of the inventors' design is to improve usability of ETTs. The inventors will measure this specification by giving an IRB-approved survey to clinicians to compare the inventors' design to a standard ETT. The inventors will request that clinicians rate the favorability of the present device on a 5 point scale, and due to the expected small sample size, hope to achieve a 3/5 rating for usability of the present device.

Design Strategy

Problem Decomposition

To facilitate pertinent and effective concept generation, understanding device design is essential. By identifying the different elements of a device and analyzing how each element contributes to the overall function, the inventors gained insight on how the device work and were then able to brainstorm concepts that contained components that met the required functions.

An endotracheal tube (ETT) is primarily used to keep a patient's lungs well-ventilated during a surgical procedure and/or to deliver general anesthesia to a patient's bloodstream via the lungs. The inventors defined the inventors' system as the ETT and the tracheal anatomy that surrounds it. The inventors' system has four subfunctions: to deliver airflow or anesthesia to the lungs, to create a seal between the device and the tracheal wall, to insert through the glottis, and to deploy inside the trachea (Figure 3).

First and foremost, an ETT must act as a conduit that delivers air to a patient's lungs. Airflow through the tube is essential to the patient's health and the success of the device. Thus, the inventors had to consider the diameter of the tube through which airflows when generating concepts and prototyping. Furthermore, the inventors had to guarantee the structural integrity of the tube in order for it to serve as a continuous conduit for airflow. Either air or anaesthetic vapour is input into this subfunction. For anaesthetic vapour, safe levels of pressure and flow of the gas mixture are regulated by an anaesthetic machine. The machine connector on the proximal end of the ETT connects to the anaesthetic machine. For air, the machine connector is detached and these levels are determined by the environment. Air travels from the proximal end of the

ETT to the distal end, where it released as an output in the trachea, en route to the lungs (Figure 1b).

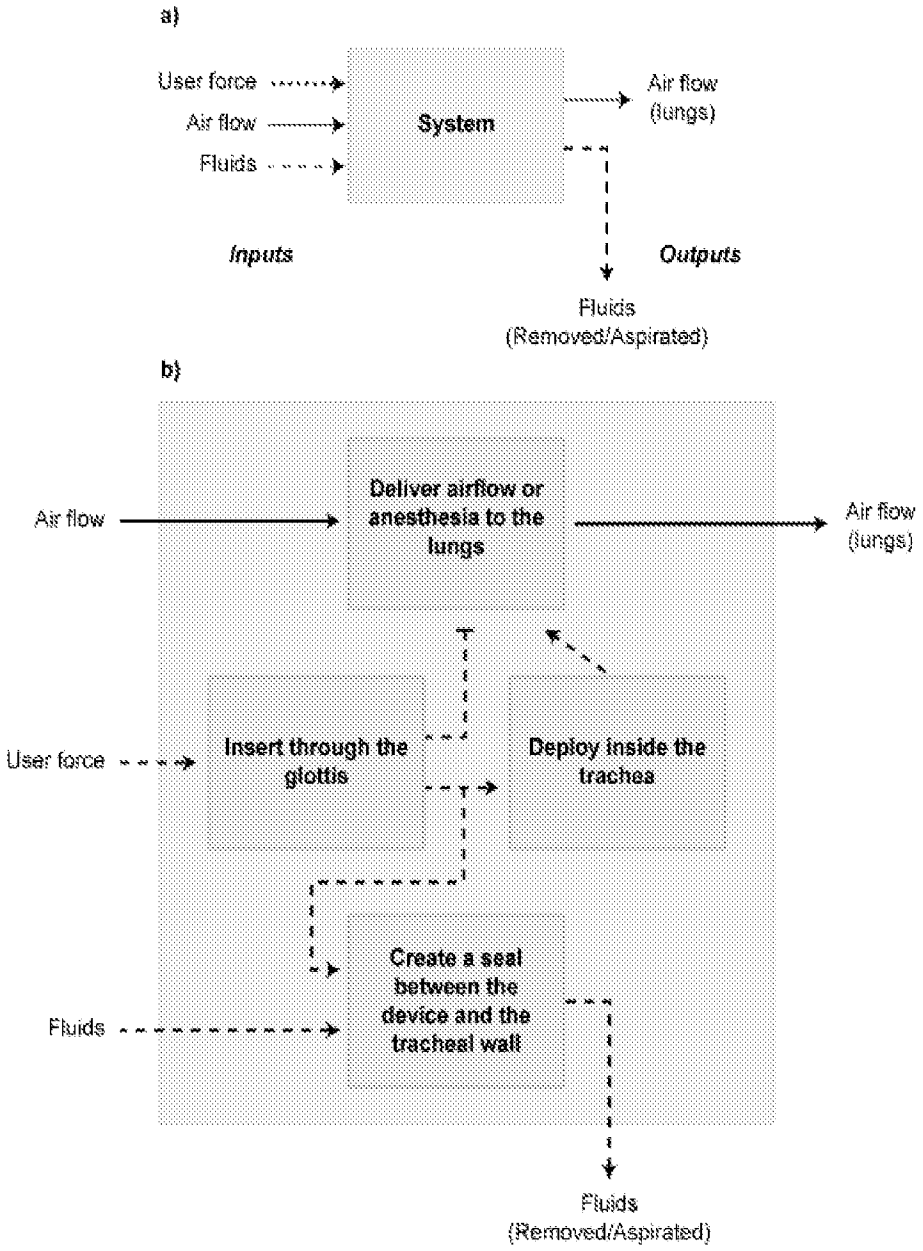


Fig. 3: Function diagram depicting functional decomposition. Inputs are represented by arrow heads and inhibition is represented by blunt end heads.

ETTs must insert through the glottis and then deploy inside the trachea. All current ETT designs must compromise between tube diameters that ease intubation and diameters that provide sufficient airflow to ventilate the lungs. Thus, in order to reach the inventors' goal of easing intubation while providing sufficient airflow, the inventors had to create a dynamic design that featured novel insertion and deployment functionalities as two separate subfunctions.

Inserting the ETT through the glottis requires decreased diameter to improve visualization and ease the process of intubation. The ETT is initially radially collapsed due to either its natural state or containment within a deployment mechanism. Therefore, the diameter and airflow through the ETT are temporarily reduced while the tube is quickly inserted through the glottis and into the trachea. The force required to maneuver the ETT into place is the input to this subfunction. The collapsed state of the tube inhibits airflow through the tube. Thus, inhibition of airflow and the inserted ETT serve as the outputs (Figure 3b).

At this point, the process of intubation has concluded and all that remains is to optimize airflow. Once inserted, deployment of the ETT is achieved by the components of the deployment mechanism. The deployment mechanism will either cease to contain the collapsed ETT or it will expand the ETT from its natural state to an expanded state, thus restoring the diameter and airflow through the ETT. The inserted ETT serves as the input to this subfunction and the expanded ETT serves as the output, restoring airflow (Figure 3b).

The ETT must also create a seal between the device and the tracheal wall to prevent aspiration of accumulative oral and gastric fluids from entering the lungs. Standard ETT designs employ an inflatable cuff at the distal end of the tube to apply radial pressure against the trachea to form a seal. The seal prevents fluid flow and reduces the occurrence of pulmonary aspiration,

which often leads to pneumonia. This subfunction directly affects patient health, and therefore a cuff or cuff equivalent must also be considered during concept generation. Oral and gastric fluids that accumulate above the cuff and the inserted ETT are the inputs to this subfunction. Fluid ideally remains blocked above the cuff during surgical procedures, since the cuff creates an impenetrable seal. When the surgical procedure is complete, the fluid is removed or aspirated from the body as an output upon extubation (Figure 3b).

Concept Generation

In order to ensure that the present design has the best performance with regard to the subfunctions in the functional decomposition, as well as to the challenges posed in the problem statement, the inventors brainstormed and prototyped as much as possible. The inventors ensured that airflow is not compromised, because it is the primary subfunction of an ETT. The design of the air conduit is essential because it directly impacts the conceptualization of the sealing and deployment subfunctions. After that, the inventors brainstormed possible deployment mechanisms because the inventors believed that each design likely had a unique set of deployment mechanisms that complemented its geometry. Finally, the inventors brainstormed various sealing mechanisms and cuff alternatives. During brainstorming, the inventors individually wrote concepts on index cards and passed them along to other group members for concept development and feedback. Then, the inventors vetted and consolidated the brainstorming concepts.

The brainstormed concepts were prototyped with paper or other simple materials to produce proof-of-concept prototypes. Then, the inventors researched appropriate materials and prototyping methods with which to create functional prototypes. Many combinations of design elements emerged.

Initial Combinations of Designs

After brainstorming, the inventors considered every combination of tube design, material, and deployment mechanism in a Morphological Chart (Table 2).

Table 2: Brainstormed concepts for each category.

	Option 1	**Option 2**	**Option 3**	**Option 4**
Material	PVC	Polyurethane	Silicone	
Designs	Stent	Accordion	Heart	Self-enveloped
Deployment Mechanism	Head scratcher	Sheath	String	

The inventors' first and simplest design was the heart design. This design was achieved by scoring the inside of a tube down an entire side and then folding inward along the incision (Figure 4). Despite being simple, it would closely mimic the anatomy of the vocal cords, theoretically allowing for easier insertion (Figure 4).

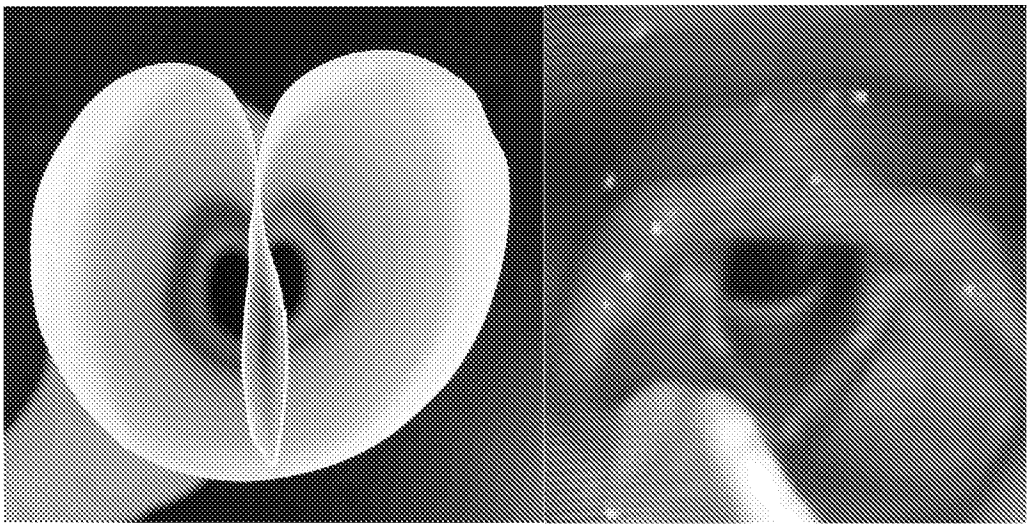


Fig. 4: Cross-section of heart design and vocal cords in trachea.

The inventors also considered an accordion design. This design was achieved via lateral scoring and folding (Figure 5). Scoring was more complex in this design because it was required on both sides of the material.

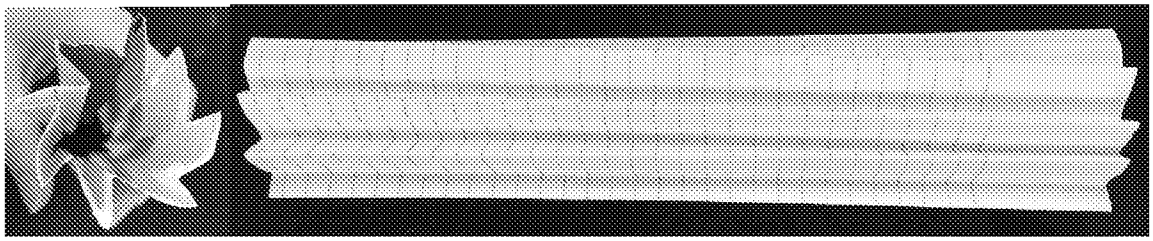


Fig. 5: Cross-sectional and side-views of the accordion design.

The most complex scoring was featured in the stent design (Figure 6). This design requires extensive geometric scoring and folding on both sides of the chosen material and would produce an intriguing, highly collapsible device. The geometric design has been adapted from paper origami applications.

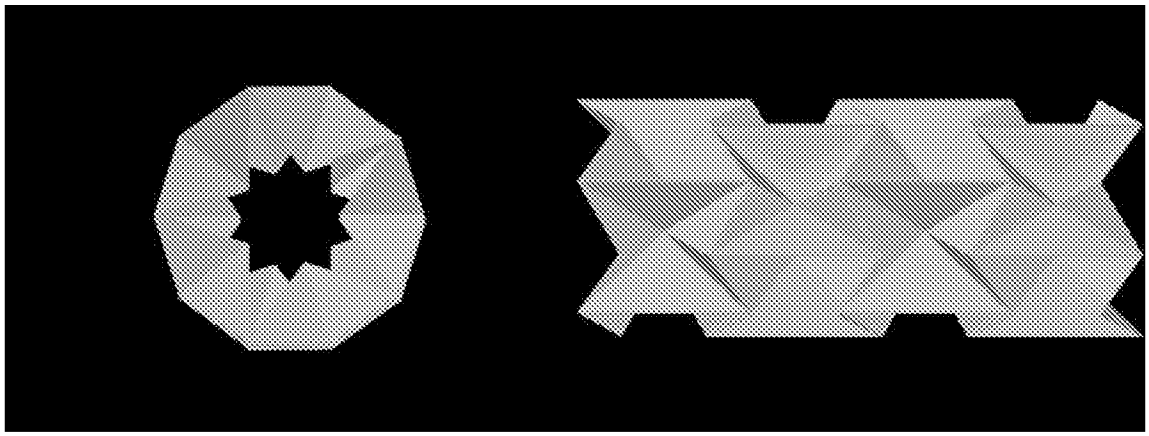


Fig. 6: Cross-sectional and side-views of the stent design.

Another design concept was the self-enveloping design (Figure 7). This design consisted of a radially helical, sliding tube geometry. Along half of the helix, an air tight tongue and groove that slides circumferentially along the inside of the tube provides radial expansion and contraction. The other half of the helix was solid to prevent further sliding and unwinding of the tube. The tongue was half of the circumferential length of the groove and was fused to the outer side of the helix. Similarly, the groove was fused to the inner side of the helix. Because of the complex radial structures, this design could not be scored and folded. It required an alternative shaping technique, such as molding.

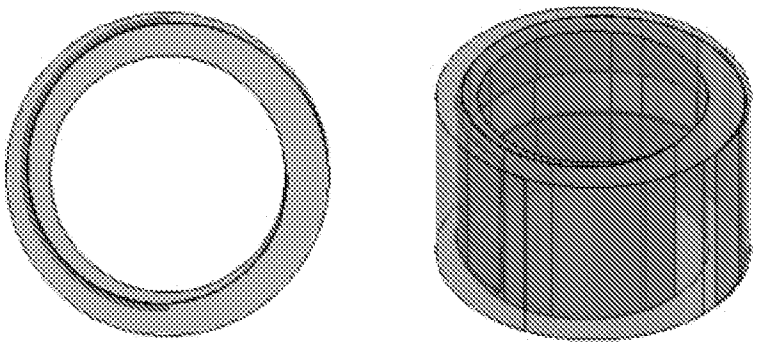


Fig. 7: Cross-sectional and isometric views of the self-enveloping design.

The designs were considered in conjunction with different materials, each of which had different benefits. PVC is the material traditionally used to produce ETTs, but cannot be laser cut since it produces toxic chlorine gas as a byproduct. PVC tubing has been the standard because of its appropriate hardness range (typically around 80A), its biocompatibility, low gas permeability, and cost. Polyurethane is a plastic with similar properties, with the exception of slightly higher gas permeability and cost. Furthermore, it is advantageous because it can be laser-cut safely. Finally the inventors considered silicone, which is slightly softer and has higher gas permeability. It may be cast into a 3D-printed mold.

The inventors considered three different deployment mechanisms for the inventors' designs: a head scratcher, sheath, and string mechanism. The head scratcher mechanism resembled a head scratcher in that it features long, thin rods that would provide outward forces to hold the device open from inside of the tube. The sheath mechanism was a simple plastic sheath that covers the device and produces inward forces to contract the tube design during insertion. When removed, the device expanded naturally due to material tensile forces. The string mechanism featured a single, long string that was woven into the device, providing inward forces that constricted the device. The string could be pulled from the proximal end, releasing the device and allowing it to expand due to natural material tensile forces.

Design Concept Screening

In order to select the most promising design concept combinations, the inventors then evaluated the combined concepts based on three criteria in a Screening Pugh Matrix (Table 3).

Table 3: Screening Pugh Matrix to evaluate brainstormed device combinations.

	PVC Heart Sheath	PVC S-E Either	PUR Stent Sheath	PUR Accordion Sheath	PUR Heart Sheath	PUR S-E Either	Sil Stent Sheath	Sil Accordion Sheath	Sil Heart Sheath	Sil S-E Either	Current PVC ETTs
Ease of Production (Given Material)	+	-	+	+	+	-	-	-	0	+	0
Complexity	+	-	-	0	+	-	-	0	+	-	0
Innovation	-	+	+	0	-	+	+	0	-	+	0
Theoretical Decrease in Diameter	-	0	+	+	-	0	+	+	-	0	0
Net Score	1	-1	2	2	0	-1	0	0	-1	1	0
Continue?	Yes	No	Yes	Maybe	No	No	No	No	No	Yes	

Abbreviations: PVC, polyvinyl chloride; PUR, polyurethane; Sil, silicone; S-E, self-enveloping.

Note: The inventors considered the sheath and string concepts equally for the S-E concept because they would be equally easy to incorporate and quick to deploy. The inventors reserved judgment until a prototype was produced for each.

Each design was evaluated using the following criteria: ease of production given material, ease of production given design, and innovation. Ease of production was defined as the ability to manufacture the design, given the material. For example, the self-enveloping design could theoretically be produced with PVC or polyurethane, but would be too complicated to produce given the tools at the inventors' disposal (precision knife, laser cutter). Devices with a high ease of production were given a (+). Complexity was defined as the degree of geometric manipulation that would be required to produce the design. Devices with high complexity were given a (-). Innovation was defined as the degree of novelty of a design given existing patents for

endotracheal tubes. For example, Patent US4141364A, Expandable Endotracheal or Urethral Tube, features a star-like expanding design, which is similar to the accordion concept. Other designs feature a locking mechanism (e.g., US20140238405 A1, US4722335 A), but have striking shortcomings that would be overcome with the inventors' design. Highly innovative designs were given a (+). The inventors finally considered the theoretical decrease in diameter based on the design. Designs that decreased diameter the most significantly were given a (+). The stent and accordion were anticipated to decrease diameter by 50-60%, the self-enveloping was anticipated to decrease diameter by 30-40%, and the heart was anticipated to decrease diameter by 15%-25%. For this screening matrix, non-reinforced PVC endotracheal tubes served as the inventors' baseline standard for comparison.

After evaluating the scores from the criteria, the inventors decided on three designs to prototype. While the polyurethane accordion with sheath was designated as another first choice by the Pugh Matrix, the inventors decided to instead select the PVC heart with sheath (originally fourth in line) as the inventors' third design to prototype. The inventors wanted to maximize the materials used in prototyping so that the inventors could better evaluate the performance of each in the future. The inventors decided to consider the polyurethane accordion with sheath as a design the inventors would later produce if time allowed or if the stent design became too difficult to prototype.

Cycle 3 Changes

A nitinol-reinforced mylar overlay design is preferred.

In any embodiment in this disclosure, the tubular sheet(s) may comprise material(s) other than mylar such as high density polyethylene, ultra high molecular weight polyethylene,

polyurethane, plastic or laminated metals (or alloys), graphene, stretchable material such as rubber, etc. Also, in any embodiment in this disclosure, the reinforcement (e.g., coil(s) or wire(s)) may comprise material(s) other than nitinol such as any material with elastic deformation capability (with or without shape memory effect), any twistable material such as a metal, metal alloy, plastic, polymer, or combination thereof, etc.

The mylar overlay design owed its radial collapsibility to a nitinol coil with outward tendency. The nitinol coiled through a rigid backbone and was sandwiched between mylar overlays. When a tab connected to the nitinol was pulled, the nitinol collapsed, bringing the mylar with it, effortlessly reducing tube diameter without compromising structural integrity. The tube was then sheathed to permit insertion of the narrowed tube. Removal of the sheath upon insertion permitted expansion to full diameter, enhancing airflow as compared to ETTs currently available on the market.

Fig. 8: Full length view of device in distended configuration, notably showing mylar overlay, pull tab, and cuff.

The tube could be divided into three major components: a collapsing mechanism, an anchoring backbone, and a mylar covering.

Fig. 9: Nitinol helix exposed and shown threaded through loops in backbone.

The primary actor in the collapsing mechanism was the nitinol coiling (Figure 9). Nitinol in 0.46 mm diameter was threaded through 1.5 mm wide loops connected to the backbone spaced 10mm apart. One end of the nitinol was secured to the backbone and the other was free at the distal end of the tube. The free end functioned as a pull-tab that tightened the nitinol coil when pulled. This tightened the mylar covering against the plastic backbone, thus reducing the outer diameter of the tube.

The expansive properties of nitinol made it ideal for use in the inventors' design. Once the nitinol pull-tab was released, the tightened coils expanded, returning to their original state. This expansion allowed for a sufficient amount of air to pass through the tube and to the lungs.

Fig. 10: The rigid backbone of the tube.

The nitinol coil connected to a rigid plastic backbone that provides structural support (Figure 10). The rigidity of the backbone facilitated insertion as well as served as an anchor for the nitinol. Evenly spaced loops were constructed into the backbone to form the nitinol into a coil and were constructed from durable plastic to prevent small pieces from breaking off and lodging into the lungs. The plastic was also smooth, in order to reduce friction as to best exploit the nitinol's expansive properties and prevent it from catching and failing to expand.

Fig. 11: A segment of the ETT showing the outer mylar overlay.

The final component of the collapsible tube was mylar (Figure 11). Two layers of mylar were used to envelop the backbone and coil, forming the ETT shape. The design features a double layer of mylar to give additional tension that prevents accumulation of fluids in between coil rings. The double layer also enhances the mechanical properties of mylar, making it more puncture resistant to medical tools.

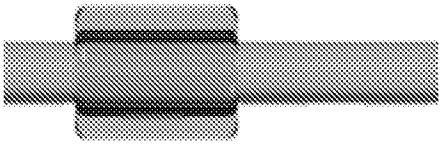


Fig. 12: The inflated cuff.

Additionally, the design featured an inflatable polyurethane cuff at the proximal end of the tube. The inflated cuff functioned similarly to commercially-available ETT cuffs, securing the tube in position and creating a seal with the trachea. Once the tube inserted past the larynx and vocal cords, the cuff inflated using an air-filled 20 mL syringe to a pressure of 25 cmH_2O in the trachea. The cuff had dimensions of 4 cm long and inflated to 9 mm away from the tube.

A polyurethane sheath was used to encase the entire ETT. The sheath covered the collapsed tube in order to increase visibility around the tube during intubation as well as to prevent the tube from accidental expansion. Once the ETT was in a patient's trachea, the sheath removed in order to deploy the tube, allowing air to flow into the lungs.

Cycle 4 Changes

The nitinol-reinforced mylar overlay design proved to be too difficult to produce as well. The thicker nitinol the inventors had was too rigid to form into a coil and the thinner nitinol coils would not collapse fully when pulled. Instead, the thin nitinol bunched up at the distal end and large amounts of force were required to continue pulling. The backbone also proved to be a challenge to produce. The inventors produced it using plastic mesh even though it was somewhat flimsy. The inventors decided to 3D print a sturdier backbone, which led to another version of the nitinol coil.

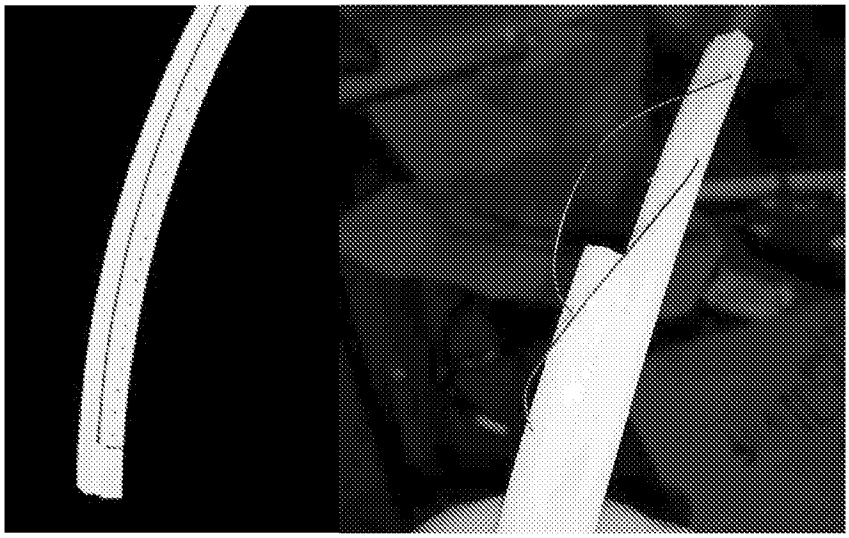


Fig. 13: 3D render of the new thick backbone and the nitinol ring replacement inside the 3D printed backbone.

The nitinol-reinforced mylar overlay design was replaced by a nitinol ring design (Figure 13). Instead of coils, the nitinol was cut and formed into rings. To fit the nitinol rings, the backbone changed from a plastic mesh to a pair of sliding rods with holes. Each ring along the length of the tube was attached at a hole in both rods.

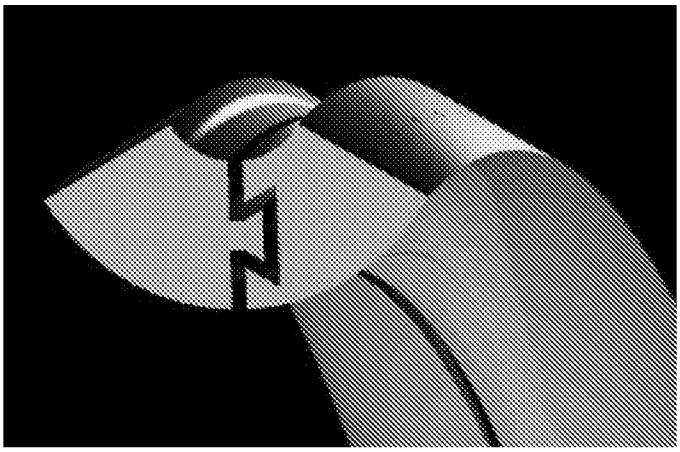


Fig. 14: 3D render of the sliding dovetail.

A sliding dovetail between both rods provided a shear force that pulled the nitinol rings longitudinally (Figure 14). This pull would cause the rings to stretch and the mylar that still enveloped the tube would collapse. The user would insert the tube in this collapsed state. Once the tube was inserted, the user would slide the two rods back to their normal, parallel position and the rings would return to a circular shape, expanding the tube again to deliver airflow.

An Emdodiment of the Present Design (the twistable, wire-reinforced mylar design)

In order to ease the intubation process, the inventors aimed to improve visibility during intubation by reducing tube diameter, which would therefore allow the physician to navigate the tube more deftly and prevent them from accidentally hitting and injuring the vocal cords and surrounding anatomy. This goal led to the development of the inventors' collapsible (i.e., radially and optionally longitudinally) ETT.

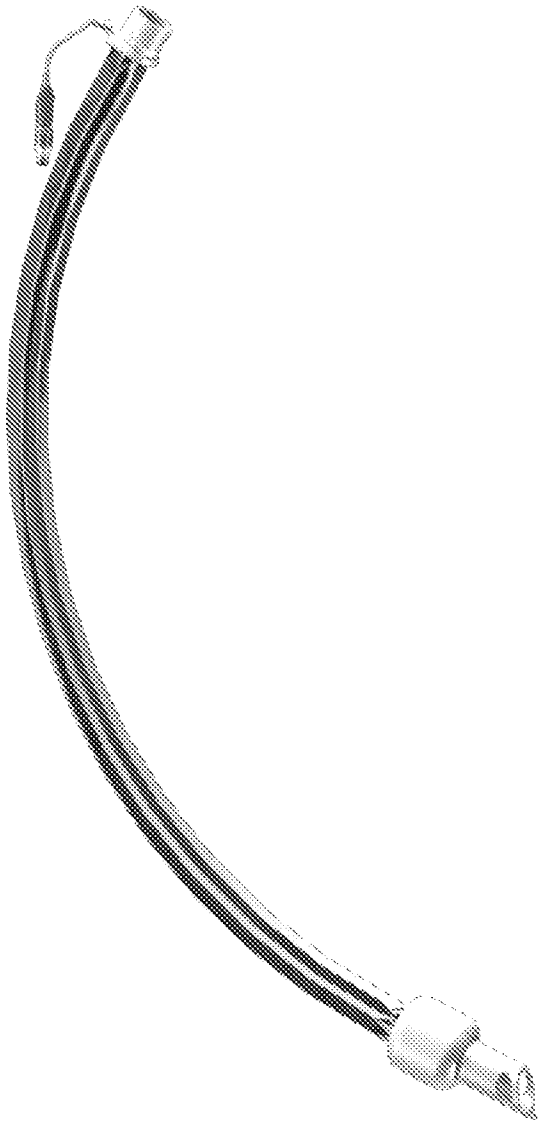


Fig. 15: Full length view of device, notably showing the mylar midsection, machine connector, pilot balloon, and cuff.

The inventors' twistable, wire-reinforced mylar design (Figure 15) has a mylar midsection reinforced by wires running along the longitudinal axis of the device. When the tube is twisted, the mylar and wires collapse, effortlessly reducing tube diameter without compromising structural integrity. In one embodiment, the wires have no outward tendency, so the tube remains in its collapsed state prior to insertion. After the tube has been inserted into the patient, the tube is connected to the ventilator, allowing the ventilator's positive pressure to

expand the tube to full diameter. This enhances airflow within the device compared to ETTs currently available on the market.

The inventors' tube can be divided into three major sections: a collapsing mechanism, machine connector and pilot balloon; and the Murphy's eye, inflatable cuff, and beveled tip.

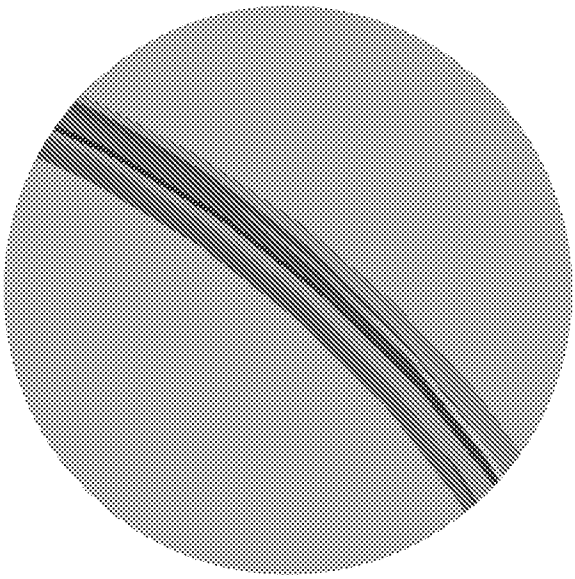


Fig. 16: Collapsible mylar midsection.

The primary actor in the collapsing mechanism is the mylar midsection (Figure 16). In an embodiment, the midsection is comprised of two 27 cm by 8 cm sheets of mylar, which sandwich 3 evenly-spaced wires that are 27 cm long. The edges of the sheets are sealed to form a cylindrical tube. The clinician can manually twist the tube to reduce the device to its collapsed configuration. As the walls of the device are quite thin, twisting the tube eliminates any free space in or around the device, thus reducing the outer diameter of the tube.

In an embodiment, there may be one or more tubular sheets.

The thinness of the wire-mylar combination makes these materials ideal for use in the inventors' design. The device is able to collapse to an outer diameter (of the mylar tube) substantially equivalent to the composite diameter of the reinforcing wires, which is, for

example, as low as approximately 2 millimeters. Once air begins cycling through the tube, the walls of the device expand, returning the tube to its original state having, for example, an outer diameter of up to approximately 5cm. This expansion allows for a sufficient amount of air to pass through the tube and to the lungs. Using an optional double layer is also advantageous because it enhances the mechanical properties of mylar. Because ETTs are often used alongside sharp medical tools, the tube must be puncture resistant.

In another embodiment, the at least one wire may comprise memory-effect material where the natural tendency of the wires would be in the distended configuration. In this scenario a stylette would be employed initially (releasably) connected to the interior of the mylar sheet (via releasable attachment mechanism(s) such as breakable or removable tabs, velcro, glue, epoxy, embossing, stitching, tape, etc.) while the endotracheal tube is in the collapsed configuration. Once the endotracheal tube is in its final position (e.g., at least partly within the trachea), the user would pull the stylette disconnecting it from the mylar sheet via breaking/releasing the tabs and removing it from the entirety of the endotracheal tube. The wires would then expand to their biased distended configuration resulting in the mylar sheet also being in a distended configuration with an enlarged outer diameter.

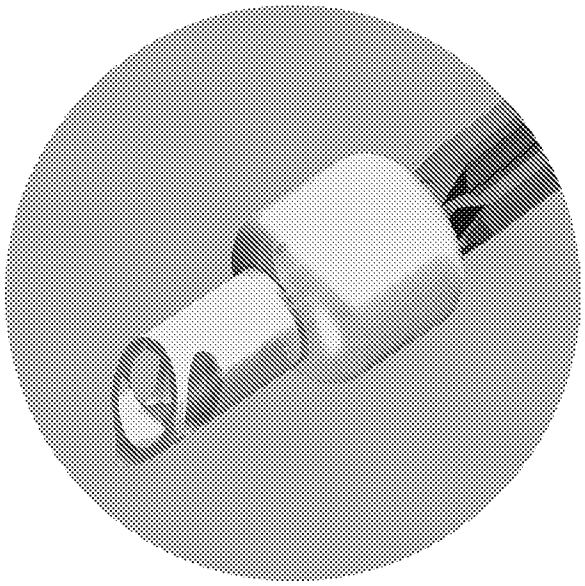


Fig. 17: The Murphy's eye, cuff, and beveled tip.

In either embodiment, the base of the cylindrical tube is fused to the proximal tip of a conventional endotracheal tube, which is comprised of a Murphy's eye, cuff, and beveled tip (Figure 17). The functions of each of these components have previously been detailed in the Design Context Review above. The cuff is connected to the pilot balloon by a small tube, which directs the air from the syringe filling the pilot balloon to the cuff. This small tube is sandwiched between the two mylar sheets, maintaining even spacing with the reinforcing wires. The small tube and/or the at least one wire may alternatively be positioned interiorly of the innermost mylar tubular sheet. If only one tubular sheet is employed, the small tube and/or the at least one wire may be positioned interiorly of the tubular sheet as well. Once the tube is inserted into the trachea past the larynx and vocal cords, the cuff is inflated using an air-filled 20 mL syringe to a pressure of 25 cmH_2O. The cuff has dimensions of 4 cm long and inflating to 9 mm away from the tube. The at least one wire may be connected to the tubular sheet via any fastening mechanism such as glue, epoxy, embossing, stitching, tape, etc.

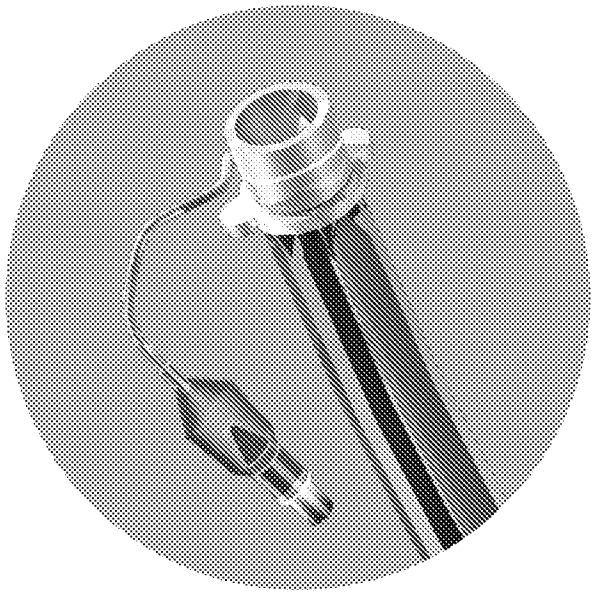


Fig. 18: The machine connector and pilot balloon.

The device also features a machine connector and pilot balloon from a conventional endotracheal tube (Figure 18).

Testing and Results

Testing Plan

Specification 1: Dimensions of Device

The dimensions of the device must be measured in order to assure the device fits appropriately into the patient's throat. The dimensions to be measured will be the length of the expanded device (as applicable), diameter of expanded and collapsed tube, and thickness of the tube. These measurements will be performed using a ruler (length) and micrometer (diameter and thickness) according to manufacturer instructions. Each measurement will be taken 3 times for each of 3 devices, to ensure that the measurements are precise and that there is no variation due to manufacturing. The inventors will create two-sided 85% Confidence Intervals (CIs) with

bounds at 34 cm and 36.0 cm for length, 9.0 mm and 11.0 mm for diameter, and 0.40 mm and 0.60 mm for thickness.

Specification 2: Deviation from Ideal Hardness

Hardness, a measure of puncture resistance, will be assessed in a position paper that will consider the manufacturer's tolerance for the reported material hardness.

Specification 3: Sterility

Sterility, an FDA requirement necessary to prevent contamination of the present device, will be assessed in a position paper that will validate the chosen sterilization method for the present device.

Specification 4: Improved Visibility in Throat Around Device

Improved visibility is a defining aspect of the novelty of the present device. It is hereby defined as the difference between the cross-sectional of an average trachea and the cross-sectional area of the collapsed device. Cross-sectional area of device calculated from the collapsed dimensions of device. Cross-sectional area of an average trachea determined from literature values (based on a diameter of 2.4 cm and the assumption of a circular cross-section). Improvement is calculated as percent increase from the competitive value of 3.55 cm^2. The inventors will create a one-sided 80% CI for increase in cross-sectional area with a lower bound of 15% increase.

Specification 5: Seal Pressure on Wall

Pressure in cuff must be high enough to create a seal with the airway, but low enough to prevent necrosis of tissue. It will be assessed in a position paper that will validate the pressure in the cuff from a standard ETT extracted for integration in the inventors' design.

Specification 6: Biocompatibility

Biocompatibility is essential to ensure the surrounding tissue does not react adversely to the insertion of the present device. It will be assessed in a position paper that will validate the material chosen for the present device.

Specification 7: Total Cost

Total cost is determined by summing the cost of raw materials used to produce the device as well as labor costs, and must be low enough to ensure that the inventors' tube will be successful commercially. Meeting this specification is defined as being less than $25 in total cost.

Specification 8: Increased Tidal Volume

A high enough tidal volume is required to prevent patient hypoxia. It will be measured using the accompanying software for the Laerdal SimMan. The SimMan will be set according to manufacturer instructions for standard air delivery to the lungs: a positive end pressure (PEEP) of 5 cmH_2O. Tidal volume will be measured 3 times for 3 devices to create a one-sided 85% CI with a lower bound of 0.92 L.

Specification 9: Ease of Use

High ease of use is another major anticipated benefit of the inventors' design and is the inventors' novel improvement. It will be determined by responses to the inventors' anesthesiologist survey. The survey will be administered to anesthesiologists after they have tested the inventors' novel ETT for deployment success rate and deployment time. Each question asks respondents to evaluate statements regarding ease of use of the present device on a scale of

1-5. Based on their responses, the inventors will generate one-sided 80% CIs with a lower bound of 3 for each question.

Testing Results

Specification 1: Dimensions of Device

The present device averaged 35.1±0.6 cm in length, 10.1±0.1 mm in expanded diameter, and 0.54±0.1 mm in thickness. 85% CIs created based on these data had bounds at 34.8 and 35.5 cm in length, 10.0 and 10.2 mm in expanded diameter, and 0.47 and 0.60 mm in thickness, fully meeting the inventors' specifications for dimensions. Table 6 contains the full dataset for this specification.

Specification 2: Deviation from Ideal Hardness

Commercially available mylar has a hardness of 92 Shore A according to manufacturer specifications. The inventors have no reason to assume the inventors' lot of mylar has a different hardness. 92 Shore A exceeds the inventors' specified 85 Shore A, indicating that mylar has higher puncture resistance than the PVC used in standard ETTs.

Specification 3: Sterility

The present device would be sterilized using ethylene oxide, which does not melt plastic or harm mylar, the two material components of the present device, but still provides a SAL of $<10^{-6}$, which is the standard for sterilization.

Specification 4: Improved Visibility in Throat Around Device

The present device had an average visibility of 4.49±0.016 cm^2, which translates to a 26.5±0.45% improvement in visibility. 80% CI created for this measurement had a lower bound at 4.48 cm^2, which translates to a 26.2% increase in visibility, which is much higher than the inventors' 15% lower bound specification. Table 7 contains the measurements that indicated improvement in visibility.

Specification 5: Seal Pressure on the Wall

Standard ETTs require 10 mL of air to fill to a pressure of 25 cmH_2O, which matches the inventors' specification. Assuming the clinician follows manufacturer's instructions and the cuff has not been compromised, this value should be accurate. If in further iterations of the inventors' design the inventors decide to have a custom-made cuff, the inventors will need to measure the cuff pressure with a manometer to determine the ideal volume of air to achieve a pressure of 25 cmH_2O.

Specification 6: Biocompatibility

While mylar is not currently approved with regard to biocompatibility with airways, Parylene, a biocompatible coating, is FDA-rated with a USP XXII, Class VI biocompatibility rating, which is sufficient for the inventors' application. In future iterations of the present device, the inventors would work with manufacturers in order to best coat the present device with Parylene.

Specification 7: Total Cost

Total cost was determined to be $7.31, according to a Labor, Burden, and Materials Cost Analysis. While this does not meet the inventors' ideal value, the cost of the present device still falls below the inventors' specified value of $25.

Specification 8: Increased Tidal Volume

The present device had an average of 1.16±0.089 L tidal volume. This translated to a 80% CI with lower bound of 1.12 L, which is much higher than the inventors' specification, but doesn't meet the inventors' ideal value of 1.33 L. This value could potentially be increased by increasing the expanded diameter of the tube, provided this does not significantly increase the collapsed diameter. Measurements for tidal volume can be found in Table 8.

Specification 9: Ease of Use

Notably, the present device averaged 4.6±0.55 out of 5 with regard to ease of use, and 5±0 out of 5 with regard to successful intubation, translating to a 4.5% and 4.2% increase compared to the corresponding results for a standard ETT.

While the inventors' results are slightly better than standard ETTs, this is still significant because these clinicians are experts at intubating with a standard ETT. This means that they were able to intubate just as well with an ETT they had never seen before, indicating that the learning curve is likely to be much smaller, which could save time training future clinicians, allowing them to focus on more complicated procedures.

Summary and Recommendations

The inventors' design replaces the PVC tubing of standard ETTs with wire-reinforced mylar. This mylar component allows the device to radially collapse from 10 mm to 2 mm,

affording unprecedented visibility around the ETT and delivers more air to the lungs compared to standard ETTs. The use of mylar also affords the device increased hardness without increasing thickness, flame retarding ability, and radiopacity. Wire reinforcement enhances maneuverability of the mylar tube.

The inventors have exceeded the inventors' design criteria for improving visibility and simple deployment, and have surpassed standard ETTs with regard to ease of use, tidal volumes measured within the tube, and puncture resistance, despite failing to meet the inventors' more ambitious design criteria, including reduced cost, biocompatibility, and sterility.

In future design iterations, the inventors suggest that the proximal end be reinforced. During testing of the present device at UTHealth Medical School the inventors were informed by clinicians that patients often bite down on ETTs when they are coming out of anesthesia. Biting down on the ETT may block the airway, leading to serious complications. As such, the inventors suggest that the distal end be reinforced with a less deformable material that does not break the patient's teeth, should they bite down following surgery. By reinforcing only the distal end, the present device would preserve its increased visibility since the portion of the tube inside the trachea would still be collapsible. Reinforcing the distal end would also prevent kinking of the device when it is connected to the ventilator. While the present device's length allows it to accommodate a larger spectrum of anatomies, the inventors found that it bent at the weight of the connected ventilator and blocked airflow to the lungs if it was not held up vertically. Reinforcing the distal end would address both of these potential failure modes.

To increase airflow to the lungs, the inventors would suggest increasing the diameter of the tube so that it may expand to fully meet the diameter of the patient's trachea. This characteristic must be carefully optimized with regard to amount of material (wire, mylar) in

order to collapse to a small enough diameter without using too few wires and compromising maneuverability, and to expand to a large enough diameter to have a significant improvement of airflow. Failure modes associated with having a larger diameter, including the possibly increased incidence of twisting and kinks and increased contact between the device and the sensitive tissues of the trachea and surrounding area, must also be taken into consideration and addressed.

Finally, the inventors recommend collaboration with manufacturers in order to address limitations in production. The inventors' prototype is limited because of the inconsistency of gluing parts together, which can lead to leaks that decrease air delivered to the lungs, and the addition of unnecessary bulk to the present device due to thickly applied glue. Additionally, hand cutting mylar can lead to inconsistencies and also jagged edges that can easily rip the mylar tube, again leading to leaks. Finally, because the inventors' prototype is made using recovered cuffs and proximal ends from standard ETTs, to use a smaller end means using a smaller cuff that doesn't necessarily fit the patient. Increasing cuff size relative to the PVC tubing or designing a new cuff that is customizable to the patient's anatomy in a way similar to the inventors' tube design, would improve the seal across patients.

Table 4: Intubation Complications.

	Complication	*Cause(s)*	*Effect(s)*	*Severity (Catastrophic-Negligible)*
1	**Vomit/stomach acid entering lungs (pulmonary aspiration)**	**Poor seal below vocal cords, punctured pilot balloon, faulty connection to syringe,**	**Lung infection (pneumonia), chemical pneumonitis, asphyxiation**	**Significant**
2	**Blocking the airway**	**Esophageal intubation**	**Low oxygen in blood (hypoxemia), coma, or death**	**Catastrophic**
3	**Twisting or kinking of endotracheal tube**	**Improper insertion, weak plastic**	**Air flow is compromised, removal and re-intubation**	**Significant**
4	**Puncturing of pilot balloon, cuff, or tube**	**Weak plastic, difficult airways, surgical mistakes, poor manufacturing**	**Removal and re-intubation, puncture increases potential for aspiration**	**Significant**
5	**Puncturing of tissues via insertion**	**Improper insertion of beveled tip, multiple intubation attempts, excessive force, difficult airways**	**Collapsed lungs due to air leakage into the space between the lungs and chest wall (pneumothorax), necrosis of tissues**	**Significant**
6	**Trauma to lips, teeth, tongue, and nose**	**Improper insertion, insufficient lubrication, excessive force**	**Patient discomfort, permanent anatomical damage**	**Significant**

Table 5: Customer Needs.

Need	Priority
User Needs	
The device is rigid enough to withstand puncture, while being flexible enough to work properly in a variety of patients	**4**
The device increases ease of implantation for anesthesiologist	**6**
The device does not alter throat anatomy/harm throat	**5**
The device allows for the passage of an adequate volume of air through itself	**2**
The device must not malfunction/dislodge from airway connection during procedure	**3**
Payer Needs	
The tube is similar in manufacturing cost to current tube designs	**7**
Regulatory/Standards Needs	
The device must comply with ISO regulations for medical devices, anaesthetic and respiratory devices (ISO 5361), sterilization	**1**

Table 6: Dimensions of Device.

	Length (cm)	Thickness (mm)	Diameter (cm)
	34.6	0.39	10.1
	34.5	0.4	10.1
Tube 1	34.4	0.39	10.1
	35	0.54	10.1
	35	0.55	10
Tube 2	35.1	0.55	9.9
	35.9	0.67	10.3
	35.8	0.65	10.2
Tube 3	36.2	0.68	10.3
Average	35.1±0.76	0.54±0.14	10.1±0.15

Table 7: Visibility Around the Tube.

Standard ETT - Available Cross-Sectional Area: 3.57 cm^2

	Tube 1 (cm^2)	**Tube 2 (cm^2)**	**Tube 3 (cm^2)**
Trial 1	4.49	4.46	4.5
Trial 2	4.48	4.47	4.5
Trial 3	4.5	4.49	4.51
Average	4.49±0.02	4.47±0.02	4.50±0.01

Table 8: Tidal Volume.

	Tube 1 (mL)	**Tube 2 (mL)**	**Tube 3 (mL)**
Trial 1	1260	1130	1163
Trial 2	1300	1071	1127
Trial 3	1175	1193.5	1010
Average	1245±63.8	1131.5 ± 61.3	1100 ± 80

Appendix B

Introduction

5*1.7 million* intubations are performed annually in the US

10.3% experience complications

5.3 *million* complications need to be addressed

Goal: Ease the process of intubation to improve patient outcomes

Method to Achieve Goal: Reduce the diameter of endotracheal tube to improve visibility

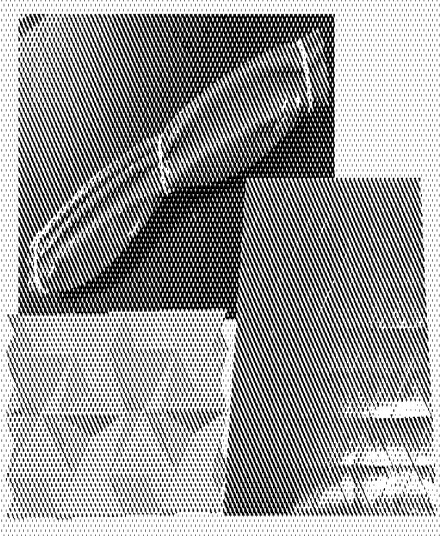
Design Iteration Timeline

Cycle 1

- Brainstorming
- Research
- Materials

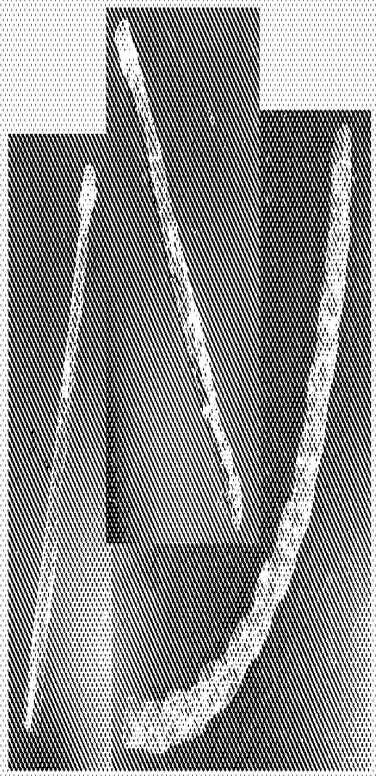
Cycle 2

- Designs involving scoring and folding of polyurethane
  - Stent
  - Accordion
  - Heart
  - Self-enveloped



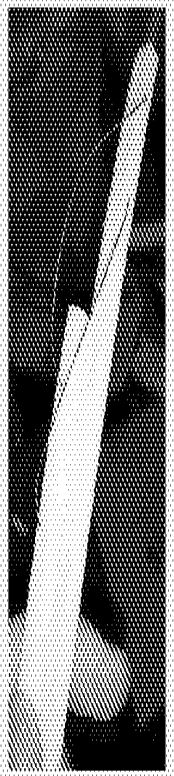
Cycle 3

- Designs involving transparency sheets and first nitinol coil design



Cycle 4

- Designs involving a backbone, mylar sheath, and nitinol coils or rings



TUBE MUCH

Radially Collapsible Endotracheal Tube

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teamtubemuch@gmail.com

RICE UTHealth

PURPOSE

Design a dynamic Endotracheal Tube (ETT) that collapses to increase visibility around the tube, easing the process of intubation, and expands to deliver sufficient air volumes.

PROBLEM

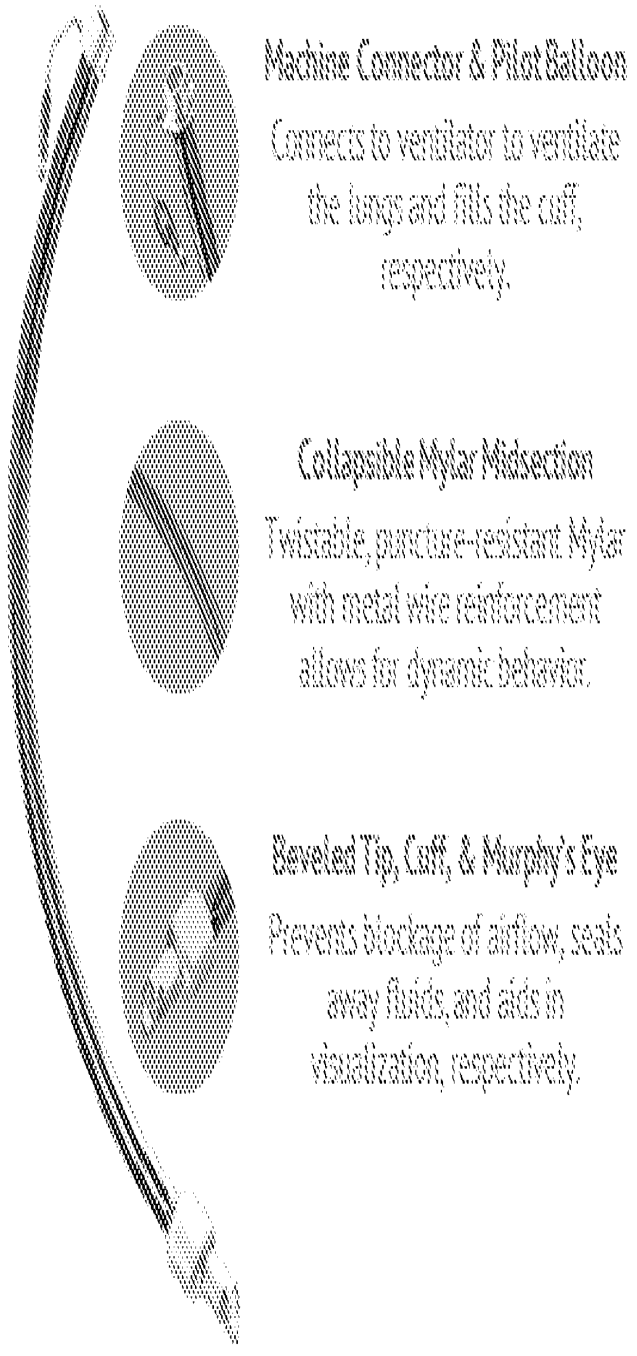
- 5.7 million intubations performed annually in the US[1]
- 10.3% experience complications[2]
- 5.3 million complications need to be addressed

By increasing visibility and ease of use, complications are theoretically less likely to occur.

RESULTS

- Visibility increased by 25.8%
- Increased tidal volume by 13%
- Ease of use increased by 4.5%
- Mylar hardness makes tubes highly puncture resistant

DESIGN



Machine Connector & Pilot Balloon

Connects to ventilator to ventilate the lungs and fills the cuff, respectively.

Collapsible Mylar Midsection

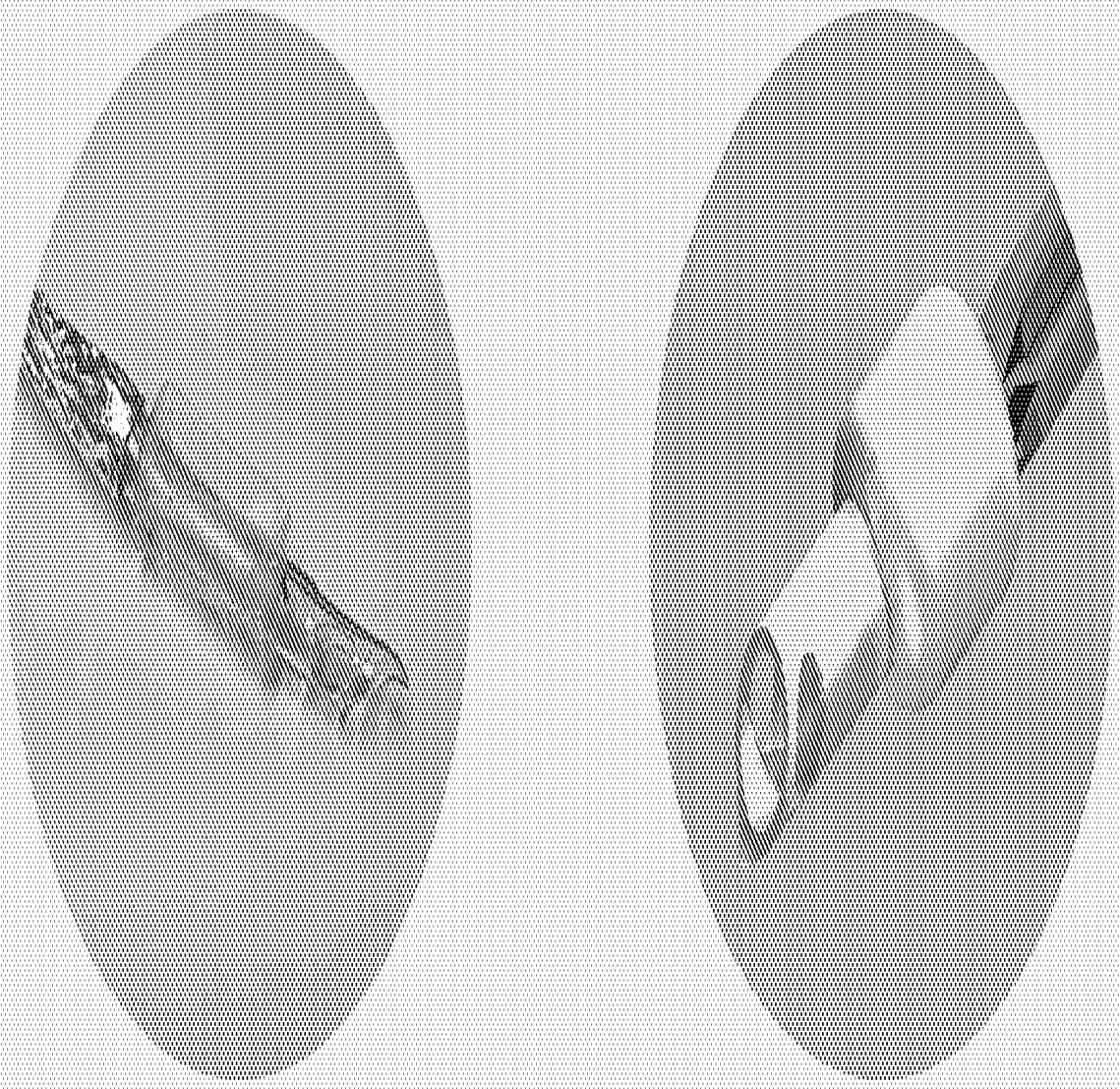
Twistable, puncture-resistant Mylar with metal wire reinforcement allows for dynamic behavior.

Beveled Tip, Cuff, & Murphy's Eye

Prevents blockage of airflow, seals away fluids, and aids in visualization, respectively.

Integrate Cuff, Pilot Balloon, and Murphy's Eye

Cuff, pilot balloon, & Murphy's eye acquired from existing ETTs



SCHOOL
TAVERN

Priority	Design Requirements / Task	Spec 1	Spec 2	Spec 3	Spec 4	Spec 5	Spec 6	Spec 7	Spec 8	Spec 9
		Dimensions of device	Deviation from ideal hardness	Sterility	Improved visibility around device	Seal pressure on wall	Biocompatibility	Total cost	Improved air flow	Ease of use
1	The device must comply with ISO regulations for medical devices, anaesthetic and respiratory devices (ISO 5361) sterilization	X		X			X		X	
2	The device allows for the passage of an adequate volume of air through itself	X							X	
3	The device must not malfunction/dislodge from airway connection during procedure	X				X				
4	The device is rigid enough to withstand puncture, while being flexible enough to work properly in a variety of patients		X							
5	The device does not alter throat anatomy/harm throat	X	X	X		X	X			
6	The device increases ease of implantation for anesthesiologist	X	X		X					X
7	The tube is similar in manufacturing cost to current tube designs							X		

	Spec 1	Spec 2	Spec 3	Spec 4	Spec 5	Spec 6	Spec 7	Spec 8	Spec 9	
	Dimensions of device	Deviation from ideal hardness	Sterility	Improved visibility around device	Seal pressure on wall	Biocompatibility	Total cost	Improved air flow	Ease of use	
Reference Part Comparison	High (4)	Med. (3)	Low	High (1)	Med.	Low	Med.	Med. (2)	Med.	
Competitive Values	8 mm (d), 35 cm (l), 1.2 mm (t)	Shore A85	SAL < 10^-6	3.55 cm^2	25 cm H2O	Same as PVC	$3	1.00 L	3/5	
Marginal Values	8 mm (d), 35 cm (l), 1.2 mm (t)	Shore A85	SAL < 10^-6	3.55 cm^2 (0% improv.)	30 cm H2O < x < 40 cm H2O	Same as PVC	$58	1.00 L (0% improv.)	3/5	
Test Values	10 mm (d), 35 cm (l), 0.5 mm (t)	Shore A85	SAL < 10^-6	4.34 cm^2 (22% improv.)	25 cm H2O	Same as PVC	$3	1.33 L/min (33% improv.)	3/5	
Test Measured Values	10.1 mm (d), 35.1 mm (l), 0.54 mm (t)	Shore 92A	SAL < 10^-6	4.49 cm^2 (25.8% improv.)	25 cm H2O	Parylene	$7.31	1.16 L (13% improv.)	4.6/5	TOTAL POINTS
Potential Point Values	150	50	50	250	100	100	100	200	200	1200

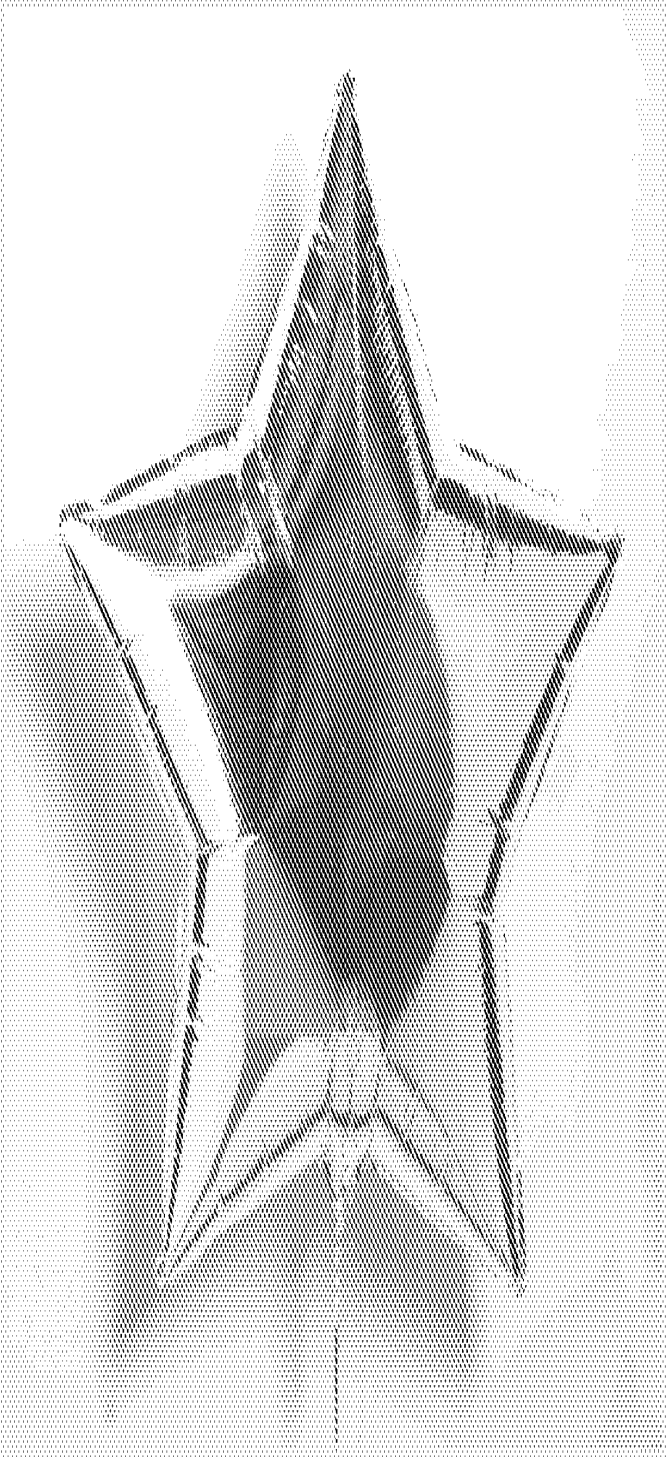
	Spec #1	Spec #2	Spec #3	Spec #4	Spec #5	Spec #6	Spec #7	Spec #8	Spec #9	
	Dimensions of device	Deviation from ideal hardness	Sterility	Improved visibility around device	Seal pressure on wall	Biocompatibility	Total cost	Improved air flow	Ease of use	
Technical Risk/Complexity	High (4)	Med. (3)	Low	High (1)	Med.	Low	Med.	Med. (2)	Med.	
Competitive Values	[illegible]	[illegible]	SAL < 10^-6	[illegible]	25 cm H2O	Same as PVC	$3	1.00 L	3/5	
Marginal Values	[illegible]	[illegible]	SAL < 10^-6	[illegible]	30 cm H2O < x < 40 cm H2O	Same as PVC	$58	1.08 L (8% improv.)	3/5	
Ideal Values	[illegible]	[illegible]	SAL < 10^-6	[illegible]	25 cm H2O	Same as PVC	$3	1.33 L/min (33% improv.)	3/5	
Final Measured Values	[illegible]	[illegible]	SAL < 10^-6	[illegible]	25 cm H2O	Parylene	$7.31	1.16 L (13% improv.)	4.6/5	TOTAL POINTS
Potential Point Values	150	50	50	250	100	100	100	200	200	1200

Dimensions of device

	Length	Expanded Diameter	Thickness
Ideal	35 cm	10 mm	0.50 mm
Measured	35.1 ± 0.6 cm	10.1 ± 0.1 mm	0.54 ± 0.1 mm

Deviation from ideal hardness

- Ideal: 85 A
- Measured: 92 A

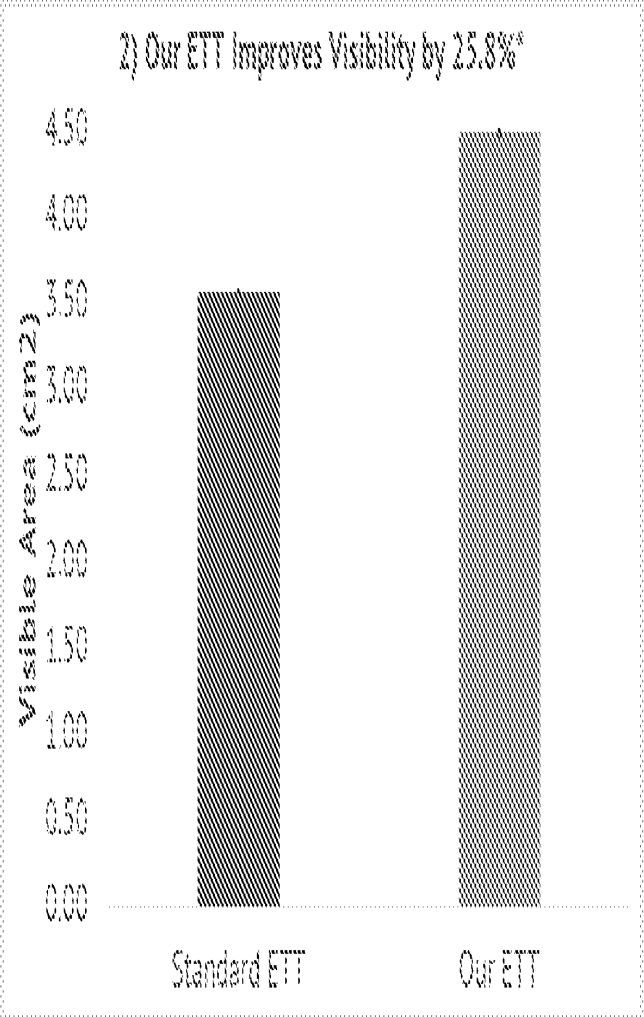


Sterility

- Ethylene oxide
- Ideal: SAL 10^-6
- Anticipated: SAL 10^-6

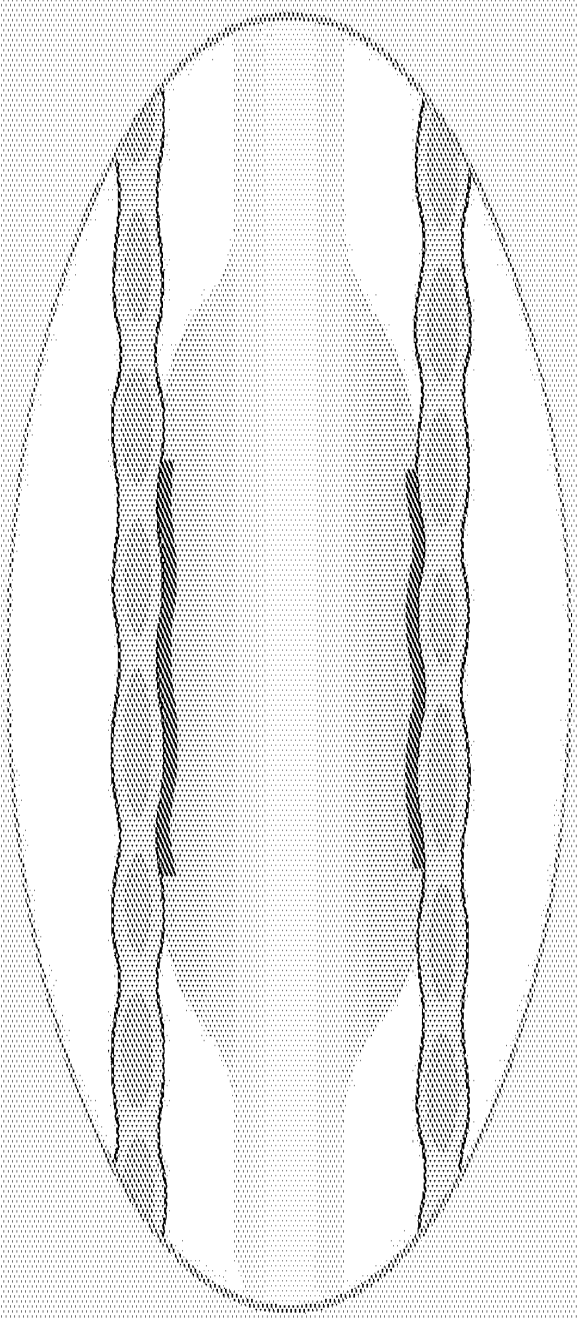
Improved visibility around device

- Ideal: 22% increase
- Measured: 25.8 ± 0.45% increase



Seal pressure on wall

- Ideal: 25 cmH_2O
- Anticipated: 25 cmH_2O



Biocompatibility

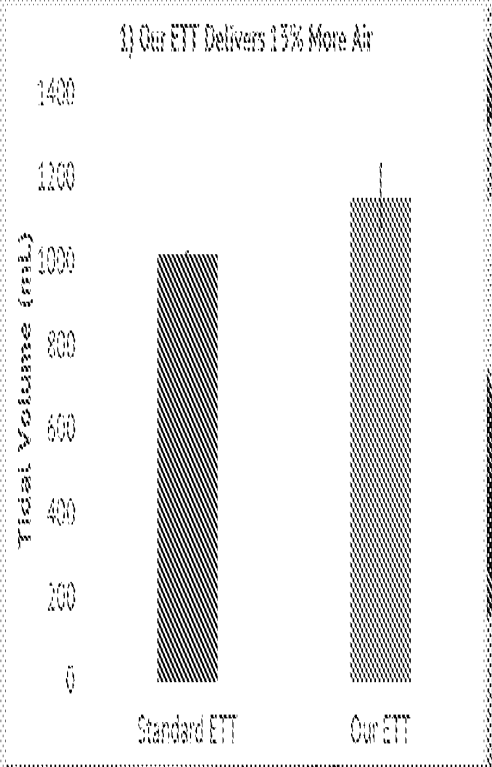
- Ideal: comparable to PVC
- Anticipated: work with manufacturer to select biocompatible coating
  - Compatible with mucosal membranes (ISO 10993)
  - Compatible for surface contact, durations on the order of hours (ideally weeks for long-term use)
  - Moisture resistant
  - Thin enough to preserve collapsibility of mylar component
  - Must be able to adhere to mylar

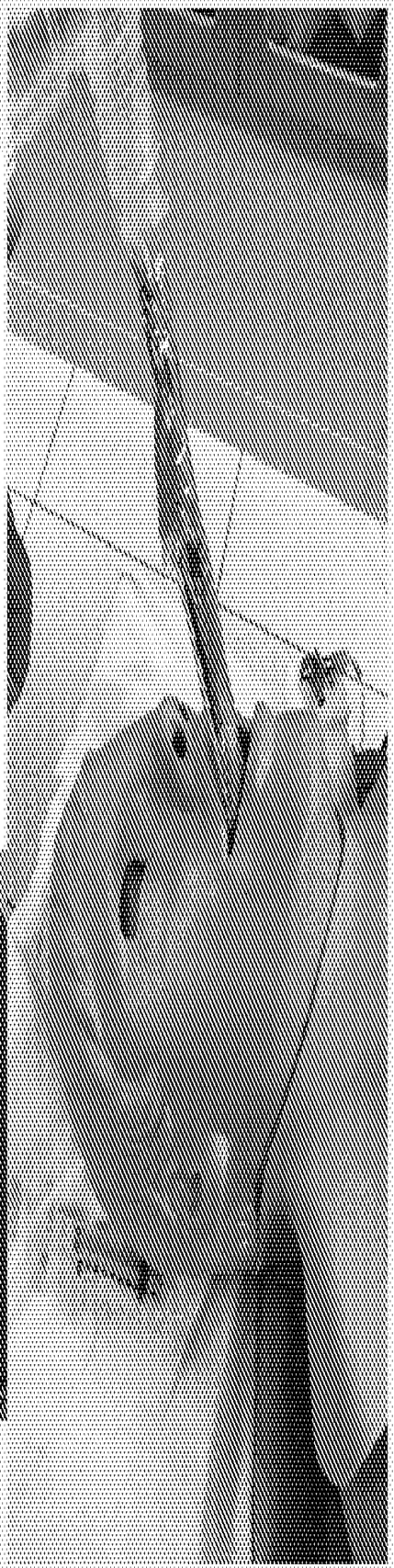
Process Step	Material	Quantity		Duration of Task	
Securing mylar tube to machine connector and cuff	Hot glue stick	1		1 min	
	Machine connector, cuff, & remainder of tube	0.5			
Constructing mylar tube	Mylar sheet	1.57×10^{-1}		30 sec	
	Pipe cleaners	4		5 min	
	Contact cement	1.58×10^{-3}		30 sec	

Total cost expected to **significantly decrease** under streamlined manufacturing

Improved tidal volumes

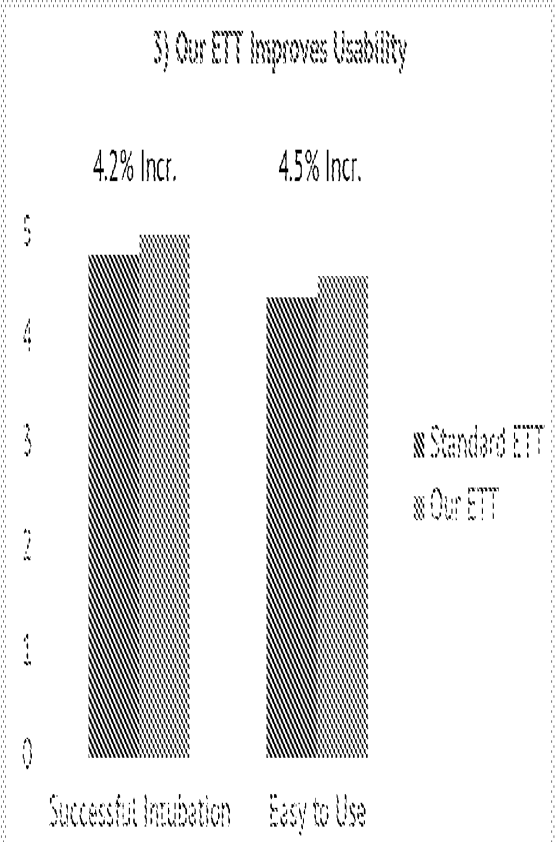
- Measured using SimMan software, averaged tidal volume in each lung
- Marginal: 1.0 L
- Ideal: 1.3 L
- Measured: 1.16 ± 0.089 L

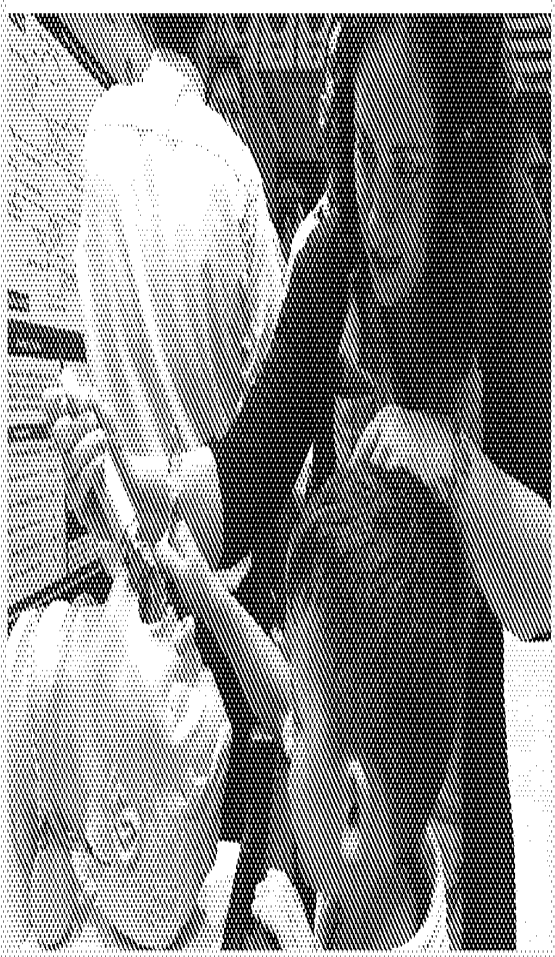




Ease of use

- Ideal: 3/5
- Measured (our device): 4.6 ± 0.55 out of 5
- Measured (standard ETT): 4.4 ± 0.55 out of 5
- Improvements to ease of use study:
  - Modify range to prevent "maxing out"
  - Control for human error





So easy, a child could use it!

Tidal Volumes (Raw Data)

	Tube 1 (mL)	Tube 2 (mL)	Tube 3 (mL)
Trial 1	1260	1130	1163
Trial 2	1300	1071	1127
Trial 3	1175	1193.5	1010
AVG	1245	1131.5	1100
STDEV	63.836	61.264	79.994

Dimensions (Raw Data)

	Length (cm)	Thickness (mm)	Diameter (cm)
Tube 1	34.6	0.39	10.1
	34.5	0.40	10.1
	34.4	0.54	10.1
Tube 2	35.0	0.54	10.1
	35.0	0.55	10.0
	35.1	0.55	9.9
Tube 3	35.9	0.67	10.3
	35.8	0.65	10.2
	36.2	0.68	10.3
AVG	35.1	0.54	10.1
STDEV	0.7638	0.135	0.1528

Visibility (Raw Data)

	Tube 1 (cm^2)	Tube 2 (cm^2)	Tube 3 (cm^2)
Trial 1	4.49	4.46	4.5
Trial 2	4.48	4.47	4.5
Trial 3	4.50	4.49	4.51
AVG	4.490	4.473	4.503
STDEV	0.01000	0.01528	0.005774

Appendix C

Failure Mode and Effects Analysis (FMEA)

	Potential Failure Mode	*Cause(s)*	*Effect(s)*	*Probability of Occurrence (Frequent-Improbable)*	*Severity (Catastrophic-Negligible)*	*Risk Index*	*Acceptable?*	*Mitigation Plan*
	e.g. Dislodgement of electrode from chest	Poor surface preparation, excessive sweat, hair, cord pulled, patient movement	Poor to no electrical signal, patient no longer monitored	Frequent	Significant	3	No	Select stronger, water-resistant adhesive for electrode design
1	Vomit/stomach acid entering lungs (pulmonary aspiration)	Poor seal below vocal cords, punctured pilot balloon, and faulty connection to syringe.	Lung infection (pneumonia), chemical pneumonitis, asphyxiation	Probable, 2.8% of all intubations [3]	Significant	5	Unacceptable	Include pilot balloon (or equivalent design) to inflate the cuff and seal off airway. Design should allow for seal pressure equivalent to that of existing technologies (25 cm H2O).
2	Blocking the airway	Esophageal intubation	Air flow is compromised, removal and re-intubation is required, low oxygen in blood (hypoxemia), coma, or death.	Occasional, 1.3% of all intubations [3]	Catastrophic (if undetected)	4	Unacceptable	Final tube design should provide larger degree of visibility around itself to theoretically decrease the chance of esophageal intubations. Ensure that the tube is able to have a radius of curvature comparable to existing technologies (140 mm). Include a beveled tip.
3	Kinking of endotracheal tube	Improper insertion, patient biting down on tube, unreinforced material due to poor Mylar-to-wire ratio	Air flow is compromised, removal and re-intubation is required, low oxygen in blood (hypoxemia), coma, or death.	Remote (detectable)	Catastrophic (if undetected)	8	Undesirable	Longitudinal metallic wires provide rigidity and maintain shape during insertion and when expanded inside the trachea. Further testing to optimize our design will reveal optimal balance of Mylar and wiring to allow for ideal collapse. Use of stylet during insertion helps add additional rigidity. Including a bite guard in future designs would prevent patients from blocking their airway when they come out of anesthesia.
4	Puncturing of pilot balloon, cuff, or tube	Weak plastic, difficult airways, surgical mistakes, poor manufacturing	Removal and re-intubation, puncture increases potential for aspiration	Occasional	Significant	6	Undesirable	The selected material, Mylar, is puncture resistant due to its hardness. Inner and outer layers of Mylar help further increase puncture resistance. Optimizing the thickness of cuff and pilot balloon during manufacturing would reduce the chance of puncture.
5	Puncturing of tissues during insertion	Improper insertion of beveled tip, multiple intubation attempts, excessive force, difficult airways	Collapsed lungs due to air leakage into the space between the lungs and chest wall (pneumothorax), necrosis of tissues	Remote, 0.1% of intubations [3]	Significant	10	Yes, with quality assurance review	Develop a less-pointed bevel tip. Improve visibility around the device to increase the probability of successful intubations.
6	Trauma to lips, teeth, tongue, and nose	Improper insertion, insufficient lubrication, excessive force	Patient discomfort, permanent anatomical damage	Remote, 0.2% of intubations [3]	Significant	10	Yes, with quality assurance review	Develop a less-pointed bevel tip. Improve visibility around the device to increase the probability of successful intubations.
7	Holes in the tube	Poor manufacturing leads to holes in the mylar midsection of the contact points of the mylar and the tip ot machine connector.	Air flow is compromised, removal and re-intubation, low oxygen in blood (hypoxemia).	Remote	Significant (if undetected)	10	Yes, with quality assurance review	Streamlined manufacturing would provide proper sealing so that holes are not likely to form. Choosing the right adhesives for Mylar and proper pleating are key considerations.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	Distensible Endotracheal Tube
First Named Inventor/Applicant Name:	Jonathon S. Jundt
Filer:	Matthew J. Esserman/Kristin Lawson
Attorney Docket Number:	150248-00101

Filed as Small Entity

Filing Fees for Provisional

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
PROVISIONAL APPLICATION FILING FEE	2005	1	130	130
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**130**

Electronic Acknowledgement Receipt

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Application Number:	62485595
International Application Number:	
Confirmation Number:	1125
Title of Invention:	Distensible Endotracheal Tube
First Named Inventor/Applicant Name:	Jonathon S. Jundt
Customer Number:	64574
Filer:	Matthew J. Esserman/Kristin Lawson
Filer Authorized By:	Matthew J. Esserman
Attorney Docket Number:	150248-00101
Receipt Date:	14-APR-2017
Filing Date:	
Time Stamp:	15:12:53
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$130
RAM confirmation Number	041717INTEFSW15141700
Deposit Account	022555
Authorized User	Kristin Lawson
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.19 (Document supply fees) 37 CFR 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Provisional Cover Sheet (SB16)	150248_00101_Prov_Cover_Sheet_executed.pdf	303733 5523e2949b1ef721000034f2596ab0da3d4d1c34	no	3
Warnings:					
This is not a USPTO supplied Provisional Cover Sheet SB16 form.					
Information:					
2		150248_00101_Prov_Specification.pdf	520243 a127ec5c94800bf19d5b8762c44ef102042049d5	yes	18

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	11
Claims	12	15
Drawings-other than black and white line drawings	16	18

Warnings:					
Information:					
3	Appendix to the Specification	150248_00101_Appendix_A.pdf	1484279 dd46d70c07e20725cd5ef5276166e05520ce5022	no	45
Warnings:					
Information:					
4	Appendix to the Specification	150248_00101_Appendix_B.pdf	2043209 3af4e910e28722027b1b02395edb7b12fc4cea37	no	20
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5	Appendix to the Specification	150248_00101_Appendix_C.pdf	81813 a10206679afa0435ad305629376571a57db9288e	no	1
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			Total Files Size (in bytes):	4463054	

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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