Cuffed Pediatric Endotracheal Tubes

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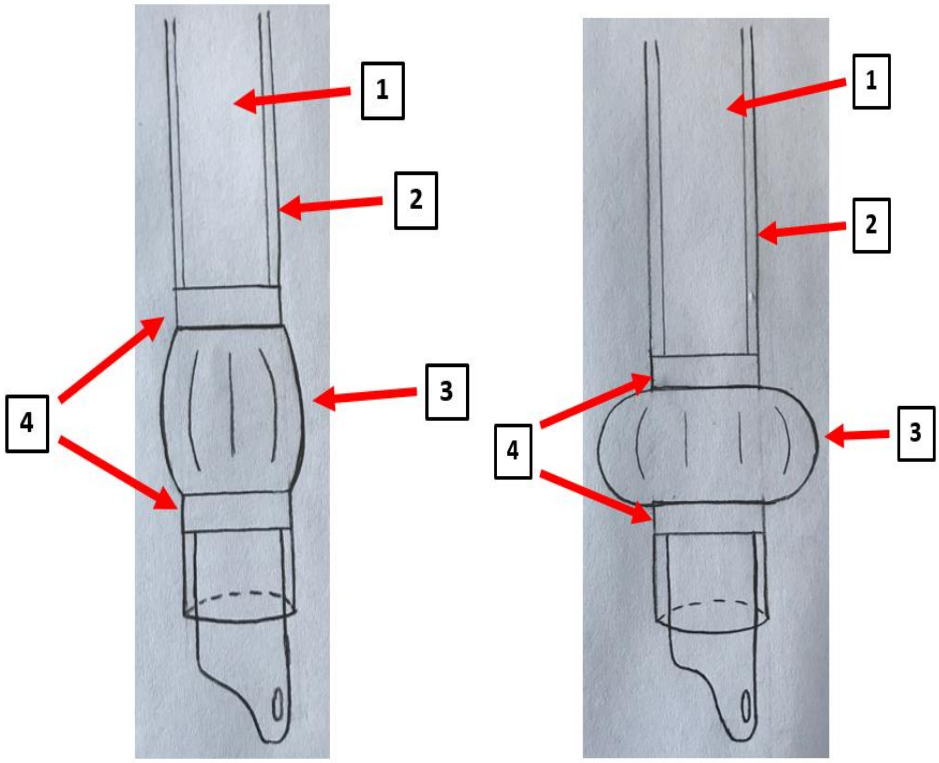

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CONTENT

BACKGROUND:

Overview

Endotracheal tubes (ET) are used to provide patients with an adequate airway when they are unable to breathe on their own. The process of placing an ET tube into the trachea of a patient is known as an endotracheal intubation [1]. For a more detailed description of endotracheal intubations, see Appendix A-1. Endotracheal intubations can be done in hospitals, intensive care units, and in the field. The primary users of ET tubes often include nurses, paramedics, physicians, or anesthesiologists. In emergency situations, nurses and paramedics are commonly responsible for performing endotracheal intubations, as the ET tube needs to be placed as quickly as possible to maintain the patient's airway in a timely manner.

ET tubes are used to provide proper ventilation during emergency situations, surgical procedures, and on-floor intubations. Endotracheal tubes are usually made out of polyvinylchloride (PVC) with major components including a cuff (optional), bevel, tube, radio-opaque line, pilot balloon, pilot line, and connector, as seen in Figure 1 below [2].

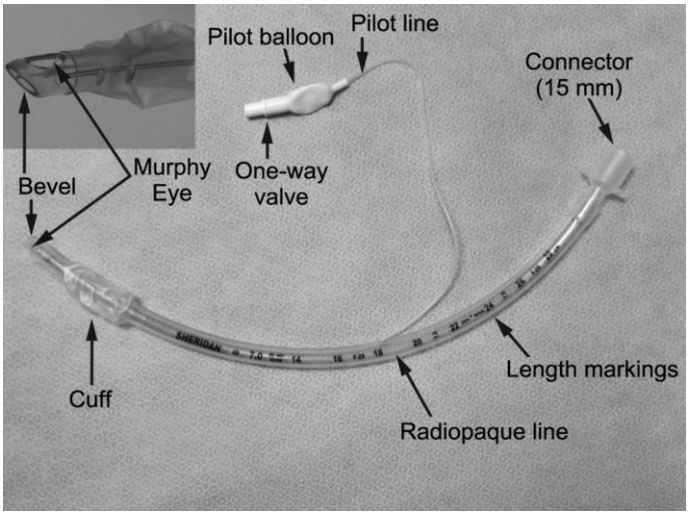


Figure 1. Cuffed endotracheal tube with labelled parts [2]

The cuff, located at the end of the tube, is a balloon that is inflated and monitored by the pilot balloon, which remains outside of the body. The air for the cuff is commonly supplied by a syringe. The syringe is attached to the one-way valve and supplies pressurized air to both the pilot balloon and the cuff [2]. After the cuff is filled, the syringe is removed and the air stays inside the cuff due to the one-way valve [2]. If the cuff is losing pressure then the pilot balloon will deflate, allowing the user to realize that something has gone wrong [2]. The cuff provides proper tracheal sealing to prevent stomach contents or subglottic secretions from getting into the lungs, which is commonly known as aspiration [3]. The cuff also prevents air leakage, which will be further discussed in detail. The radiopaque line allows the tube to be seen on chest x-rays as the tube cannot normally be seen in radiographic images [2]. The bevel helps the users navigate the tube around the vocal cords and the Murphy eye is a safety feature for situations when the end of the tube gets stuck against the wall of the trachea [2]. If this were to occur, the Murphy eye will provide an alternative way for air to get through the tube. The length markings are designed to help the user know how far the ET tube has been placed into the trachea. Lastly, the connector shown at the top of the tube, is used to connect the ET tube to breathing systems, such as a ventilator or bag-valve mask. ET tubes can also be connected to a catheter mount to provide more flexibility when connecting the tube to breathing equipment [2]. The connector has an outer diameter of 15mm, which is the standard for all ET tubes [2].

Cuffed vs. Uncuffed ET Tubes

Although endotracheal tubes play an important role in supporting and sustaining patients by providing an adequate airway, there are risks that accompany the process of using cuffed and uncuffed tubes, especially in children. Over 1,000,000 pediatric endotracheal intubations occur

each year in the United States and 150,000 of these procedures leave pediatric patients with stridor or hoarse voice [4,5,6]. Stridor is often temporary; however, the condition indicates that damage has been caused to the underdeveloped mucosal tissues in a child's throat [7]. To avoid causing injury to pediatric patients, physicians often opt for uncuffed endotracheal tubes despite the advantages that cuffed ET tubes can provide [8]. Uncuffed pediatric ET tubes are less abrasive; however, they often slip out of place and have higher amounts of air leakage during volume-controlled ventilation [3,6]. Slippage can be a major factor in causing airway trauma and is often a complication that many users encounter despite basic airway management training [9]. Uncuffed ET tubes also have the disadvantage of excessive air leakage. The air leakage around the tube is exacerbated by the position of the patient's head and degree of neuromuscular relaxation during surgical procedures [3,10]. Initially, when the uncuffed tube is placed, the air leakage is limited to an extent; however, as anesthetics are administered or as time progresses, the position of the tube can change causing improper ventilation [10]. Complications from air leakage can include reductions in lung volume, lung compliance, and functional residual capacity [6]. Improper ventilation levels could prove to be fatal for children.

Unlike uncuffed ET tubes, cuffed ET tubes have the benefit of reducing slippage and providing a proper seal for the airway to prevent aspiration and air leakage. Despite these advantages, cuffed ET tubes are often not used in children under the age of 8 due to the undeveloped structures in the child's throat [10]. In children, the epiglottis is more flexible, the larynx and trachea are not fully calcified, and the mucous membranes are loosely attached to the sides of the throat [1,11]. See Appendix A-2 for a graphic comparing the tracheal anatomy of a child to that of an adult. Cuffed pediatric ET tubes can exert pressure on the trachea mucosa leading to tissue

hypoperfusion, which causes decreased blood flow in the vessels surrounding the throat [10]. It can also cause subglottic stenosis, which is the narrowing of the area below the vocal cords due to scar tissue buildup [10]. The fragile nature of the laryngeal tract in children makes it difficult for physicians to efficiently seal the airway using a cuffed ET tube, as pressure generated by the cuff can cause damage to the mucosal wall of the larynx.

During emergency situations, nurses and paramedics have to place ET tubes in children while under pressure, and can therefore find the intubation process to be difficult with current ET tubes. In a high stress situation, selecting a properly sized tube and placing the tube correctly on the first try can be problematic. As a result, paramedics and nurses often opt for uncuffed tubes for patients younger than 8 years old as they are less likely to cause injury and are easier to place. One study found that the margin of safety while using cuffed ET tubes is reduced by 50%, due to the tracheal anatomy of children [12]. The length of the trachea is smaller in children and can easily be damaged by improperly sized cuffed ET tubes. It was reported that 82% of airway traumas in pediatrics were associated with the use of excessively large endotracheal tubes [12]. There are different formulas used to calculate the size of tubes that should be used in patients; however, these calculations are often inaccurate and can lead to improper sizing and frequent tube changes in children.

Current Technology & Patents

The cost of endotracheal tubes can vary among competitors due to differences in features. Top vendors for current endotracheal tubes include ConvaTec, GE Healthcare, Medtronic, and Teleflex [13]. However, there are some patents regarding technology that could significantly

change the problems seen today with pediatric endotracheal tubes. For example, there are patents that have focused on incorporating pressure sensors into cuffed ET tubes, as shown in Figure 2.

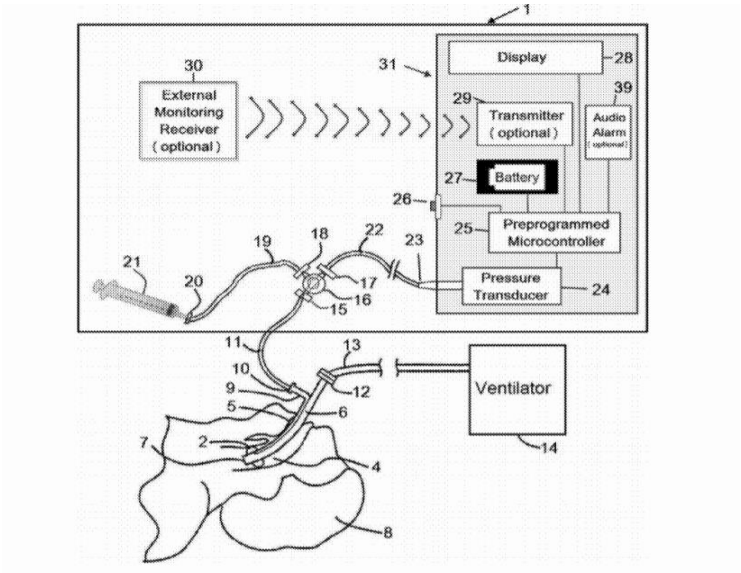


Figure 2. Patent US 0188084 by Nolan D. Shipman demonstrating the pressure regulation system that can be used to monitor the inflation of cuffs in ET tubes [14].

The tube coming from the trachea (6) splits into a Y shape and connects to a ventilator and a three-port stopcock (16). This stopcock connects the electronic system to the syringe (19), and to the pressure transducer (24), which is powered by a lithium battery (27). These numerous parts work together to monitor and regulate the pressure applied to the tracheal wall of a patient.

Despite the novel pressure system described in the patent above, there are several devices on the market that can monitor cuff pressure, some of which also inflate and deflate the cuff. These devices include the VBM cuff manometer, which can be used without an energy source [15]. This device has a green range that informs the user when the cuff is in the ideal pressure range, a release valve to adjust the pressure, and a vacuum valve to fully deflate the cuff [15]. This device comes in a variety of different options in order to satisfy users with different needs. One of the most common VBM cuff manometers can be seen in Figure 3 below.

Figure 3. VBM cuff manometer used to monitor the pressure in the cuff of an ET tube [15].

Although cuff pressure can be closely monitored, the use of cuffed ET tubes in pediatric patients remains unpopular due to the risks and complications the cuff can cause. The technology solutions currently on the market have failed to change the dogma of using uncuffed ET tubes in children.

MAIN FOCUS

There are several issues currently seen with ET tubes, as described above. The difficulties with cuff pressure, improper tube sizing, and placement were considered when designing the first iterations for an improved cuffed pediatric endotracheal tube. With those parameters in mind, we further narrowed our focus to improving the ease of use and efficiency of cuffed pediatric ET tubes as these are two major problems that arise when intubating trauma patients. Quick oxygenation is needed for such patients as delays can result in a ten-fold increase in mortality rate [16]. The nurses and paramedics who perform intubation procedures in emergency situations are under high amounts of stress, which can lead to complications when using cuffed ET tubes.

One study found that 30.4% of pediatric patients require multiple intubation attempts during critical care transport [25]. We would hope that our device could be used on all patients but we are specifically focusing on children as there are larger needs that must be addressed in current cuffed pediatric ET tubes.

PROBLEM STATEMENT

Due to the difficulties associated with placing cuffed pediatric endotracheal tubes during emergency situations, there is a need to develop cuffed endotracheal tubes that will be quick and easy for nurses and paramedics to use while reducing the risk of causing tracheal damage, such as stridor, in pediatric patients under the age of 8.

DESIGN OBJECTIVES

The primary objectives for the cuffed pediatric endotracheal tube are safety, reliability, and convenience. Safety is the main priority for our design solution. The endotracheal tube components must be biocompatible, meaning the device will not cause harm to the body or inflict an immunological response during the intubation period. The endotracheal tube components will be made from a biocompatible material, such as PVC, TPE or Polyurethane. The ET tube must also be smooth to avoid causing harm to patients during the intubation process. Similarly, the ET tube must be safe for patients during the intubation period as the device must be able to seal the airway, prevent aspiration, and reduce the risk of causing damage to internal tissues. In addition to safety, the device must be reliable as the tube needs to remain stable in the trachea during the entire intubation period. The device must be convenient, meaning the ET tube can be easily placed during emergency situations. The ET tube must be ready to use

with minimal preparation after it has been removed from packaging and the device must be able to attach to a variety of devices such as ventilators and manual oxygen bags. Table 1 below gives a summary of the primary objectives and a weighted objective tree can be seen in Appendix A-3.

Table 1. Objectives for cuffed pediatric endotracheal tube.

Main Objective	**Safe**	**Convenient**	**Reliable**
Subsections of Objective	Low risk of injury to patient	Ready to use with minimal prep after package removal	Stable in throat during intubation period
	Biocompatible	Compatible with different attachments	
		Easy/Quick to place	

FUNCTIONS AND SPECIFICATIONS

The primary functions for cuffed pediatric ET tubes include: providing an airway for gas exchange, protecting internal tissues from damage, applying minimal pressure to the tissues in the trachea, and protecting the lungs from aspiration and air leakage. These functions revolve around the main objectives of keeping the patient safe and having a reliable device that is convenient to use in trauma situations. There are formulas, such as the Khines formula described in Appendix A-4, that can be used to calculate the internal diameter of a cuffed pediatric ET tube in relation to a patient's age [23]. The safe internal diameter for pediatric patients falls between 3-6mm [10]. In addition, the cuff must exert a pressure less than 15cmH_2O on the trachea with an added marginal value of 5cmH_2O, to provide room for adjustment depending on the internal diameter of the trachea [12]. This will allow for a cuff expansion that reduces tracheal damage,

while providing zero gap area for unwanted air leakage or aspiration. The pediatric ET tubes will be able to connect to a maximum of 5 different attachments. Table 2 describes the ideal and marginal specifications for the ET tube based on the functions discussed.

Table 2. Functions and specifications for cuffed pediatric ET tubes.

Function	**Metric**	**Unit**	**Marginal Value**	**Ideal Value**
Provides an airway [10]	Diameter	mm	3.0 - 6.0	2.5 - 6.5
Protects internal tissues from damage [18]	Pressure	cmH_2O	20	</=15
Protects lungs from aspiration [26]	Volume of fluid that leaks around cuff	mL	0 - 2	0
Seals against air leakage [27]	Flow volume of exhaled air	ml/min	(.001/6L) = $1.6*10^{-7}$	0
Connects to attachments	Number of attachments	#	3	5

DESIGN REQUIREMENTS

Customer needs discovered at Albany Medical Center primarily focused on concerns about the disadvantages of uncuffed ET tubes and the pressure-related damage caused by cuffed ET tubes in pediatric patients. Keeping these concerns in mind, the requirements for the design solutions combine the benefits of a cuffed ET tube with improved patient safety for children under the age of 8 years old.

For the cuffed ET tube, the cuff must maintain a pressure less than 15cmH_2O to minimize tracheal damage [12]. The pressure of the cuff can be periodically monitored using pressure sensors or manometers to ensure that this threshold is not surpassed and ultimately keep the patient safe [17]. The cuff must also seal the airway to prevent aspiration and air leakage. The maximum allowable space between the trachea and cuff is 0.0005mm^2 with 0 to 1.6*10^{-7}ml/min for air leakage flow [27]. In addition, the internal diameter of the tube must be between the well-researched and safe range of 3-6mm to provide an airway for gas exchange [10]. The tube must also be placed within 30 seconds to ensure quick and proper ventilation during emergency situations [18]. The design requirements mentioned above were driven primarily by the need to improve patient safety. Through these requirements, the cuffed pediatric ET tube solution described below aims to maintain an airway, seal against air leakage and aspiration, and prevent pressure-related damage to the trachea. For more information on the design requirements and how the cuffed pediatric ET tube design meets the needs of patients, see Table 3 below.

Table 3. Design requirements for improved cuffed pediatric ET tube.

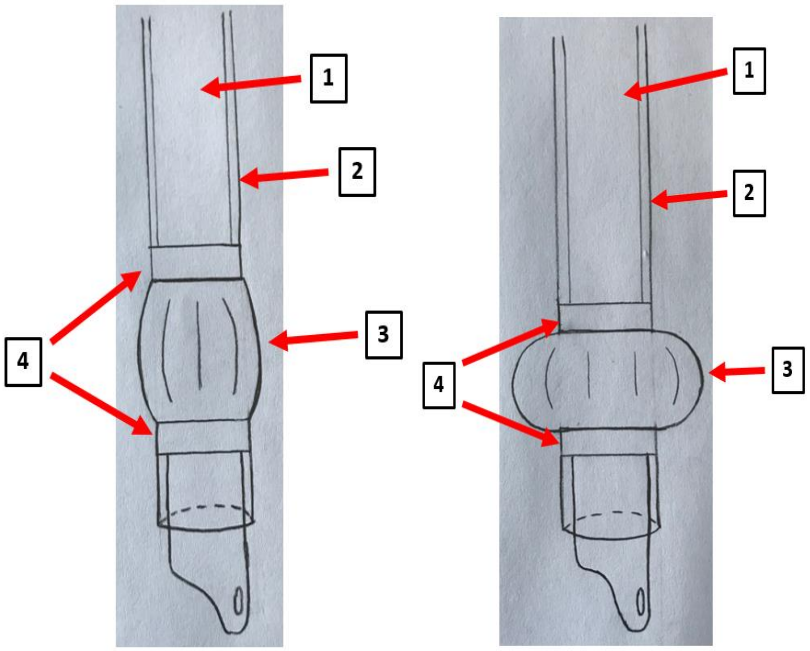
Design Requirement	**Test Method**	**Customer Need**	**Performance Improvement**
Cuff pressure must be less than 15 cmH20 while the ET tube is in use [12].	Use tube lined with pressure paper to simulate the tracheal walls. Place cuffed ET tube inside tube and expand cuff. The pressure paper will indicate how much pressure the cuff exerts at different expansion levels.	Need a cuffed ET tube that will seal the airway without putting pressure on fragile internal structures in the throat	Reduced pressure-related injuries to pediatric patients.
ET tube maintains a constant internal diameter between 3.0-6.0mm (depending on the child's age) [10]	Measure internal diameter of tube and measure airflow through the tube to ensure the device provides a proper airway.	Need a cuffed ET tube that will provide adequate gas exchange for the patient.	Reduced risk of oxygen deprivation and ventilation complications for the patient.
ET tube is accurately placed within 30 seconds [18]	Perform approximately 5 time trials for placing ET tube into manikin.	Need a cuffed ET tube that is easy to place in the correct location	Be able to accurately place ET tube in emergency situations to reduce the amount of time it takes to open the airway
ET tube has a 15 mm connector for attachments [2]	Attach bag-valve mask to connector of ET tube to verify that the connector-to-tube connection does not leak	Need a cuffed ET tube that is compatible with different attachments, such as a ventilator and bag-valve mask	Can provide mechanical or active ventilation to a patient without having to change the ET tube

PROPOSED DESIGN SOLUTION

Sheath Mechanism

The following design was created based on the need for a cuffed pediatric ET tube that is quick and easy to place. The proposed design solution, as seen in Figure 4 below, uses an outer sheath surrounding the ET tube to control the expansion and contraction of the cuff. More specifically, the outer sheath can be pushed down or pulled up to expand or contract the cuff, respectively.

For this mechanism to work, the cuff is secured to the sheath by two supports. The top support can move based on the force that is applied to the sheath, while the bottom support remains stationary and is secured to the bottom of the ET tube. The user controls the movement of the sheath from the top of the ET tube, the portion that is outside of the patient's body. While the ET tube is being inserted, the cuff is collapsed and flush to the sides of the tube. After insertion, the sheath is moved downward to expand the cuff. The cuff, which is made out of a separate material from the sheath, is inflated to a fixed volume during the manufacturing process. The material of the cuff will be similar to the material used in conventional cuffed ET tubes, such as polyurethane.



(A) (B)

Figure 4. Current design solution for cuffed pediatric endotracheal tube, with labels of its respective components. The unexpanded cuff (A) can be compared to the expanded cuff (B). The device consists of an ET tube (1) surrounded by an outer sheath (2). The outer sheath controls the expansion and contraction of the cuff (3). The top of the cuff is secured to the sheath, while the bottom of the cuff is secured to the ET tube, as shown by the supports (4).

The design solution also consists of a tick mark system, as seen in Figure 5, that allows the user to know how far the cuff is expanded and how much pressure the cuff is exerting on the trachea. Inside the top of the sheath, there are several tick marks that correspond to different expansion levels for the cuff. As the sheath is moved downward, the cuff will expand outward. With this design, there is a complementary piece on the ET tube that corresponds to the shape of the tick marks inside the sheath. The tick mark system serves as an added feature to help the user control the movement of the sheath, while knowing the precise expansion level of the cuff. An image of the full prototype can be seen in Appendix A-4.

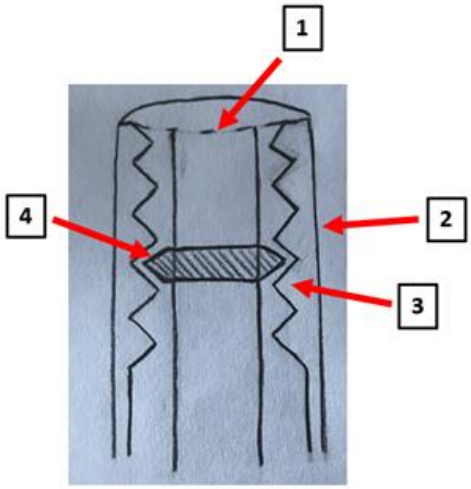


Figure 5. Image showing the tick mark system that will serve as a feedback mechanism for the user. The ET tube (1) is surrounded by the outer sheath (2), which contains tick marks (3) that correspond to different levels of expansion for the cuff. For the tick mechanism to work, there is a corresponding piece (4) on the ET tube that fits into the grooves within the sheath.

Unlike the current cuffed ET tubes on the market, the design described above eliminates the step of using a syringe to inflate the cuff. The user simply expands the cuff by moving the outer sheath accordingly. Removing the use of a syringe reduces the amount of time it takes to properly intubate patients. In addition, the cuff in the design described above contains a controlled volume of air. The volume of air inside the cuff is related to the pressure the cuff

exerts on the tracheal walls. The cuff is designed so that at maximum expansion levels, the pressure never exceeds the limit of 15cmH_2O. By having a pre-existing controlled volume within the cuff, there is no risk of over-inflation or exerting excessive amounts of pressure on the internal tissues of the trachea.

VALIDATION OF DESIGN

To validate the safety and ease of use of our design, we performed a series of tests on our prototype. The major validations were designed to verify that the device could provide an airway, prevent aspiration and air leakage, apply minimal pressure to the internal tissues of the throat, and ensure compatibility with attachments, such as breathing equipment.

Air Delivery

To measure the adequacy of air travel through the ET tube, we used a volumetric exerciser and balloons. We initially conducted a binary test to measure air flow through the tube by attaching a balloon to the bottom of the ET tube and observing the inflation of the balloon as we blew air into the top of the ET tube. The results confirmed that air could travel through the ET tube. We performed a quantitative analysis on our prototype to determine if the amount of air going into the ET tube matched the amount of air coming out of the tube. The 750 mL of air put into the ET tube was measured using a balloon that was blown up to the same diameter for each trial. The results demonstrated that a sufficient amount of air was able to make it through the ET tube for the given amount of air that was put into the tube. The results of the binary and quantitative tests can be seen in Table 4. There were limitations for this validation such as air leakage around the

balloons and air leakage during transfer to the volumetric exerciser that contributed to the results. Further testing with more precise equipment could be used in future validations.

Table 4. Binary and quantitative test results measuring air flow through the ET tube.

Air Flow		
Binary (Y/N)	Quantity of Air IN(mL)	Quantity of Air OUT (mL)
Y	750	750
Y	750	700
Y	750	750
Y	750	600
Y	750	750
N/A	N/A	Average: 710

Prevents Aspiration

We measured the ability of the cuff to seal against aspiration by using a tube to mimic the trachea and a small beaker to measure the water that passed around the cuff. The setup of the experiment can be seen in Figure 6 below. The ET tube was inserted into the tracheal tube and the cuff was expanded so that it touched all sides of the tracheal tubing. Water was poured into the space between the ET tube and the tracheal tube and subsequently measured at the bottom of the tracheal tube. The binary and quantitative tests, seen in Table 5, demonstrated that no water could pass around the cuff and therefore the device was sufficient at preventing aspiration.

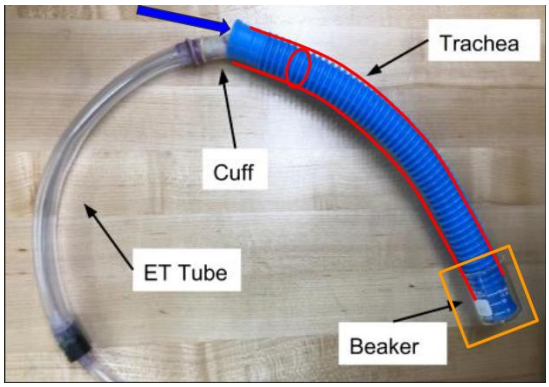


Figure 6. Experimental setup for measuring the ability of the cuff to prevent aspiration. The ET tube was inserted into the blue "tracheal" tube and the cuff was expanded to touch all sides of the tracheal tube. Water was poured into the top of the tracheal tube, as indicated by the blue arrow, and subsequently measured at the bottom of the tracheal tube using a small beaker.

Table 5. Binary and quantitative results for tests measuring the ability of the cuff to prevent aspiration.

Seals Against Aspiration		
Binary (Y/N)	Quantity of Water IN (mL)	Quantity of Water OUT (mL)
Y	5	0
Y	5	0
Y	5	0
Y	5	0
Y	5	0

Prevents Air Leakage

Similar to the validation for preventing aspiration, we conducted a series of trials to test the ability of the cuff to prevent air leakage. To perform the validation, we inserted the prototype into a tube to mimic the trachea and expanded the cuff so that it touched all sides of the tracheal tube. We then blew air into one end of the tracheal tube and measured the amount of air that came out the other side. The amount of air going into the tracheal tube was based on lung capacity. In both the binary and quantitative validations seen in Table 6, no air was able to pass around the cuff and therefore our device was able to prevent air leakage.

Table 6. Binary and quantitative results measuring the ability of the cuff to prevent air leakage.

Seals Against Air Leakage		
Binary (Y/N)	Quantity of Air IN	Quantity of Air OUT (mL)
Y	6L	0
Y	6L	0
Y	6L	0
Y	6L	0
Y	6L	0

Applies Minimal Pressure to Internal Tissues

We used a sample of pressure paper to conduct a binary test to measure the amount of pressure the cuff exerts on the tracheal walls. The sample of pressure paper was designed to measure between 2 PSI and 200 PSI; however, the cuff on a pediatric ET tube exerts approximately 0.2 PSI and below. Due to this limitation, we could only confirm that our prototype exerts less than 2

PSI. We performed the validation by lining our tracheal tube with the pressure paper and inserting our ET tube into the tracheal tube. We expanded the cuff so that it touched all sides of the tracheal tube lined with pressure paper. We observed no color change on the pressure paper and therefore verified that the cuff on our prototype exerts less than 0.2 PSI. Future validations could be performed with more sensitive pressure sensors to confirm the specific amount of pressure the cuff exerts on the tracheal walls.

Compatibility to Other Attachments

We were able to confirm the compatibility of our prototype with other attachments without performing any specific validation tests as we used a connector from an existing ET tube. The standard connector size is 15 mm in diameter and thus our device is compatible with ventilatory devices, such as a bag-valve mask or mechanical ventilator.

MEDICAL REGULATORY PATHWAY

Description: Indicated and Intended Use

Our "Breath of Life" prototype for an improved cuffed pediatric ET tube, is a medium risk device. ET tubes have the intended use of airway management when patients cannot maintain their airway during medical situations. From the FDA medical devices database, we found two Class II tracheal devices that our prototype proved substantially equivalent to.

Substantial Equivalence

Table 7 below describes the different aspects and characteristics in which our prototype is substantially equivalent to in predicate devices.

Table 7. Substantial Equivalence Comparison

Items	**Prototype: "Breath of Life" Cuffed Pediatric ET Tube**	**Predicate Device: Kimberly-Clark Microcuff Pediatric ET Tubes (2008) [19]**	**Predicate Device: Rusch Oral/Nasal Tracheal Tube, Cuffed- Magil/Murphy (1996) [20]**
[1] Classification: Name/Number 510 (K) Number	Tracheal Tube II	Tracheal Tube II K080821	Tracheal Tube N/A K961837
[2] Indication for use	Designed for oral intubation and airway management	Designed for oral/nasal intubation and are indicated for airway management	Intended for oral or nasal intubation and airway management
[3] Specifications	Cuffed ET Tube range of internal diameters range for pediatric patients	Cuffed ET Tube range of internal diameter pediatric patient range	Cuffed ET Tube range of internal diameter for different general patient range
[4] Materials	PVC & Polyurethane	Polyurethane	PVC
[5] Structure and composition	Cuffed Tube - Main Tube - Cuff - Inflating System- Sheath & Ticking Mechanism	Cuffed Tube - Main Tube - Cuff - Inflating system: pilot balloon and syringe)	Cuffed Tube - Main Tube - Cuff - Inflating System: pilot balloon and syringe)

From the table, it can be seen that the intended use of our prototype, which is supported by our validation tests, and characteristics of predicate devices are the same. Thus, our cuffed pediatric ET tube would take a very similar path to navigating the FDA review process as other ET tubes have in the past. Our 510(k) submission would be similar to those of the cuffed ET tubes mentioned above, such as the 510(k) number K080821 for the Kimberly-Clark Corp. This device had a product code of BTR and was described as a tracheal tube [19]. The 510K review panel for this device was in the Division of Anesthesiology [19]. Specifically, it was under the Office of

Device Evaluation, division of anesthesiology, general hospital, respiratory, infection control and dental devices [19]. Under its regulation number, 868.5730, it was stated that "a tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway" [19]. Based on this description, the product was classified as a Class II device [19]. Thus, when trying to get FDA clearance for our device we would follow a similar process as was done with the device described above. One part of our device that would be different is that there will not be an uncuffed version as it is only for oral intubations and the cuff would not be considered a microcuff. We would also include an explanation for the cuff expansion mechanism of our design and tick mark system, as these two parameters set our design apart from the predicates. Despite these novel additions, the classification, intended use, specifications, material, and general structure of our design is similar to the predicates mentioned above and therefore we should not have much difficulty receiving clearance.

SUMMARY

It can be seen that there are many complications associated with the pediatric cuffed endotracheal tubes on the market today. As a result, our device is focused on being quick and efficient, while exerting minimal cuff pressure to prevent tracheal damage. In addition to these advantages, our device performs similarly to other ET tubes on the market and provides an airway to patients while preventing aspiration and air leakage. The ticking system makes the device easy to use and the outer sheath removes the need to use a syringe during the intubation process. With more time, we would have enhanced the manufacturing process to improve the ticking system, made our device completely biocompatible, changed the material for the cuff, and scaled down the device to the desired size. Despite the limitations we encountered, the cuff

expansion mechanism and tick mark feedback system we created serve as novel features provide advantages over the current pediatric cuffed ET tubes seen on the market.

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APPENDIX

A-1: Endotracheal Intubation

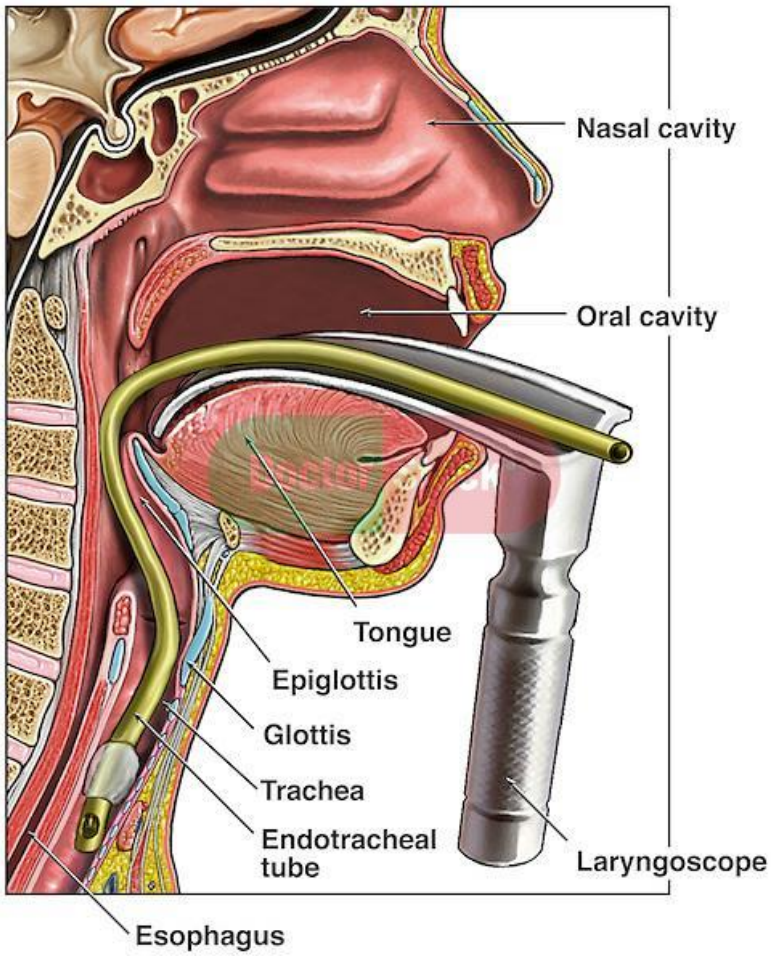

Figure 7. To insert an endotracheal tube for an endotracheal intubation a laryngoscope is inserted into the mouth of the patient to pull the epiglottis back and provide a wider opening for the tube to travel through [9] This is usually done with the users left hand [9]. With the user's right hand or other hand, the tube is then placed on top of the laryngoscope and inserted all the way down the throat until the desired length marking on the ET tube is reached [9]. This length marking will be determined for each individual based on previous calculated formulas and data [9]. Once the tube has reached the desired depth the laryngoscope will be removed and the tube with be left in place. If the ET tube is a cuffed tube it will be inflated at this point.

A-2: Anatomy of throat

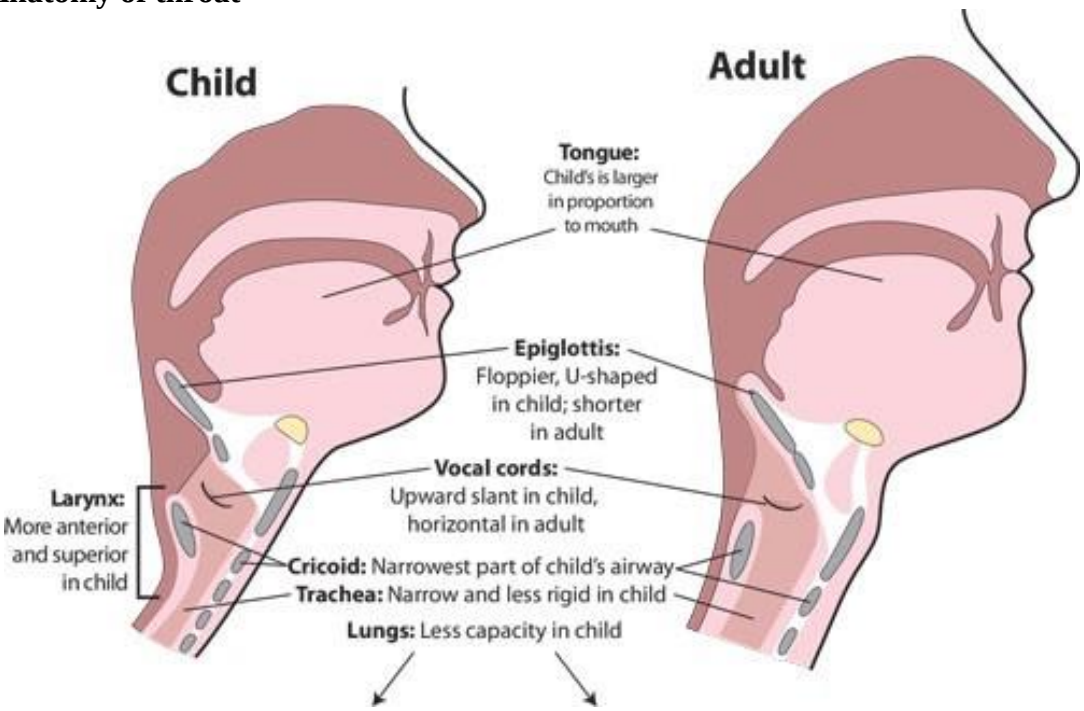

Figure 8. Image showing the labelled anatomical structures of the throat for a child and an adult. Children have a funnel-shaped larynx that can be difficult to navigate around, especially due to the narrowing of the cricoid cartilage. Children also have a floppier epiglottis and upward slanted vocal cords that can make placement of the ET tube difficult [6].

A-3: Objective Tree (Weighted)

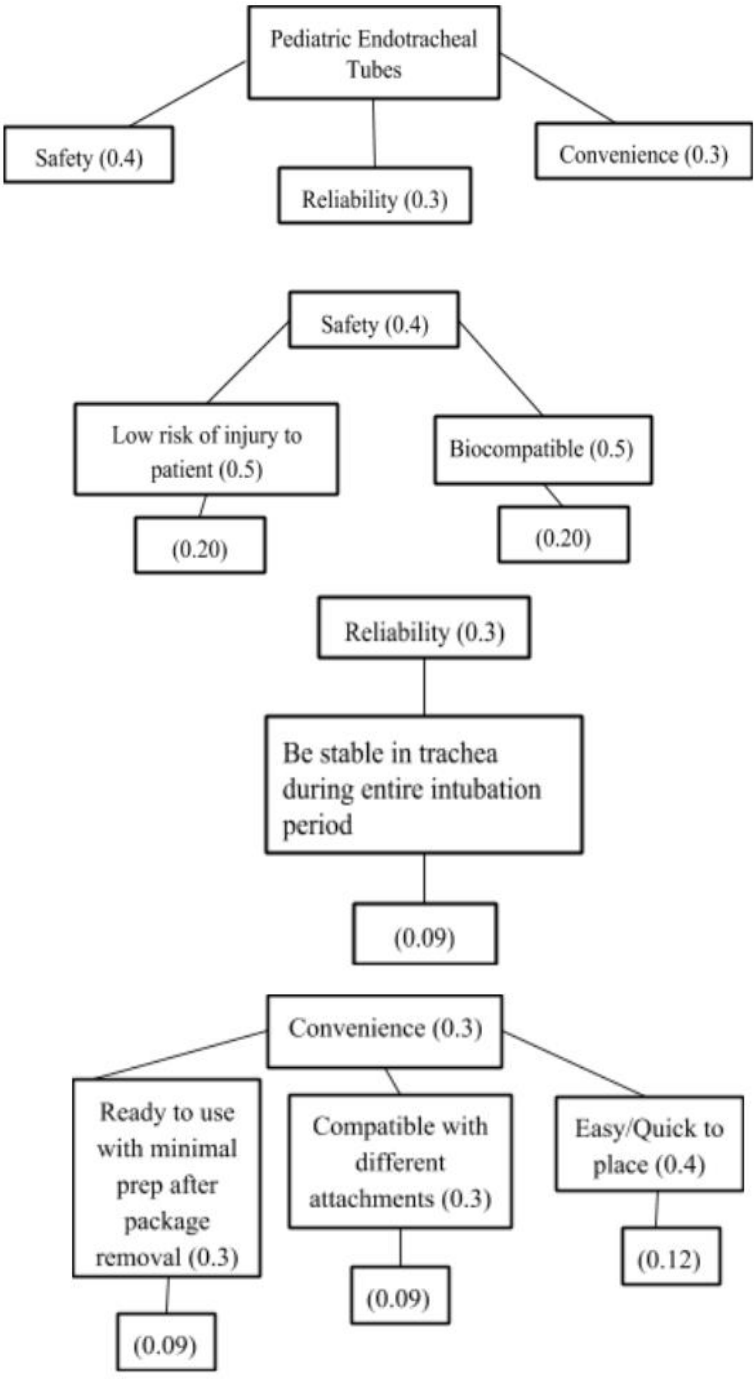

Figure 9. Weighted objective tree for the cuffed pediatric ET tube.

A-4: Khines Formula and Full Prototype

Khine Formula:

ID for CET = [age (years)/4 + 3]

The Khine Formula is used to predict the internal diameter of cuffed ET tubes used in children. The formula takes into account the child's age to alter the diameter of the cuffed ET tube accordingly [23]. The Khine formula serves as a prediction for the sizing of cuffed ET tubes in children and therefore is not always accurate given the child's size or tracheal anatomy. Improper tube sizing can cause tracheal damage to the underdeveloped tissues in the trachea of children [7].

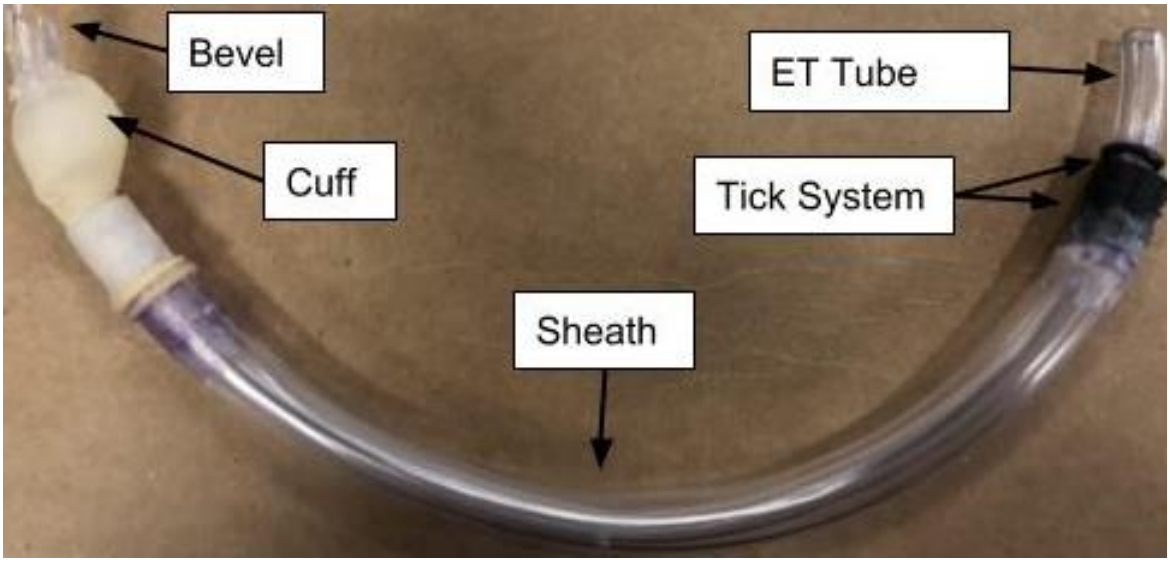

Figure 10. Full prototype of the cuffed pediatric ET tube. The ET tube is surrounded by an outer sheath, which controls the expansion and contraction of the cuff. Both tubes are made out of PVC. The cuff, seen at the bottom of the tube, is made from latex balloons and expands and contracts accordingly with the movement of the outer sheath. The tick mark system, seen at the top of the tube, is 3D printed from TPE and serves as a feedback mechanism for the user. The tick marks system allows the user to control the movement of the sheath, while knowing the expansion level of the cuff. The design maintains the beveled tip seen in current cuffed ET tubes as this feature helps the user navigate the tube around the vocal cords. With more time, the design seen above would be made from biocompatible materials.