Endotracheal Tube Cuff Valve

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Client
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Abstract

Endotracheal intubation is required for most invasive surgeries. The current tubes used in adults are generally cuffed, but this cuff system is not suitable for pediatric intubations since it can cause scarring and injury to the tissues. The goal of the new product is to modify the existing tube-cuff-valve system to allow regulation of the pressure in the cuff, in order to permit safe use in children. Three design ideas have been generated, and after evaluation of all designs, a final design has been chosen. The team plans to proceed with more research and the creation of a working prototype

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Problem Statement

Our client, Dr. Lester Proctor, has charged us with the task of designing an endotracheal tube cuff valve that would systematically and predictably fail when an operator attempted to inflate the cuff past 25 centimeters H_2O pressure. Dr. Proctor is a practicing anesthesiologist and professor working in the University of Wisconsin hospitals. One of the duties he must perform is the intubation of patients undergoing invasive surgical procedures. Normally, he uses a cuffed endotracheal tube for the intubation, but for all the advantages the cuff provides there are several risks associated with it that make it unsafe for use with pediatrics. The smaller diameter endotracheal tube used in pediatric cases traditionally does not even have a cuff at its end. Accordingly, Dr. Proctor would like us to design an endotracheal tube that is also cuffed so in future procedures the child will benefit from all the advantages of a cuffed tube, without the possibility of harm due to excess cuff pressure.

Background Information

Every year the UW hospital system performs upwards of 20,000 operations. 25% of those procedures are on children over the age of five, and 75% of those children are intubated using an uncuffed endotracheal tube (Proctor, 2006).

When an adult patient is intubated, a cuffed endotracheal tube is used. In this process, a plastic tube is inserted into the patient's trachea, past the larynx (Figure 1), where it will serve to provide oxygen and other various medical gasses to the anesthetized patient. A cuff at the posterior end of the endotracheal tube is then inflated with air. The cuff is a simple balloon that encircles the end of the endotracheal tube which, when inflated,

pushes against the tracheal wall. This provides several advantages to the doctors and patients. First, it anchors the endotracheal tube in the trachea. This is important in the progression of the surgery, so that the tube does not become accidentally dislodged. Second, the cuff creates an airtight seal between the respiratory machine and the lungs. The seal allows for more accurate delivery of oxygen at lower pressures, as well as prevents pollution of the air from medical gasses. Finally, the cuff prevents patient aspiration. Aspiration occurs when foreign matter, be it bacteria laden mucous or vomit, enters the lungs (Spray *et al.*, 1976). Normally, the foreign matter would be dispelled from the lungs via an involuntary reflex, usually coughing, but the anesthetized patient is unable to cough due to the various paralyzing agents used in surgery. Foreign matter that remains in the lungs for an extended period of time can ultimately cause infection and pneumonia. Adults receiving mechanical ventilation have an incidence of Ventilator Associated Pneumonia of up to 60% with an attributed death rate of 27% (Fagon *et al.*, 1993).

QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.

Figure 1: Endotracheal Tube Placement [Source: http://connection.lww.com/]

The cuff is inflated with air via a one-way valve attached to the cuff through a separate tube that runs the length of the endotracheal tube. A syringe is inserted into the

valve and depressed until a suitable intracuff pressure is reached. *Sengupta et al.*, (2004) has shown that cuff pressure is highly variable among patients. 27% of their sample population had endotracheal tube cuffs inflated past 40 centimeters H_2O. Overinflation of the cuff past the optimal range of 20 – 30 centimeters H_2O is associated with the risk of Ischemia in the trachea. Ischemia is a shortage of blood supply to an organ or tissue (Wikipedia, 2006), in this case due to pressure exerted on blood vessels in the tracheal wall. Extended shortages of blood supply can lead to necrosis in the area, scarring, and even closure of the trachea. Children are particularly susceptible to ischemia, which is why anesthesiologists use the uncuffed endotracheal tube.

Current Devices

Currently one product exists on the market with a pressure-regulating system designed for the endotracheal tube cuff. This is the Hi-Lo® Tracheal Tube With Lanz® Pressure Regulating Valve. This design is not suitable for children, however, and our client is interested in using a regulating system in pediatric intubations.

Design Constraints

The design must follow several specific requirements, some of which have been detailed by the client. The new system must perform at the same level as the existing endotracheal tube system. Improvements should be made on the existing design, incorporating the changes set forth by our client and the industry. FDA approval for use in human pediatrics is required for the entire apparatus, in order to be able to successfully market the product. Failure at 25 cm H_2O +/- 0.25 cm H_2O pressure is mandatory and

must be very reliable, as this is the most important modification to the existing device. Failure cannot occur before or after 25 cm H_2O. The tube, cuff, and valve must be able to last for the duration of the patient intubation, and will be disposed of when they are no longer in use. In optimal conditions, the shelf life should be one year, with little outside exposure. Use in both Emergency Room and Operating Room settings will occur. Materials used should not increase visibility of the tube in MRI situations. The finished product should be clean, with a white finish for high visibility. Our goal is to produce a working prototype without adding more than five dollars to the current cost. Because our client already has the means to inflate the cuff, our modifications should focus on a means to bypass the valve. The failure of the cuff at 25 centimeters H_2O must be able to be overridden to accommodate unforeseen and emergency situations. (A full product design specification is available **Appendix A**.)

Design 1: T-Valve

Overview

The T-Valve (Figure 2) is a simple design adding another valve on the pilot balloon that allows for pressure release. The new valve will be added to the original existing valve system, separating the outtake and intake parts of the valve. The new added valve will be used as a safety valve, releasing excess pressure when pressure inside valve (directly correlating with cuff pressure) exceeds 25 centimeters H_2O. The release valve will be a one-way outtake valve that is held shut by a spring, much like the current intake valve found on the endotracheal tube made to inflate only by means of inserting the syringe. When the pressure in the valve reaches 25 centimeters H_2O, the spring will

no longer be able to hold the valve closed, releasing the pressure in the valve until it falls to safer levels.

Modifications such as a readable gauge, a manometer, can also be applied to this design.

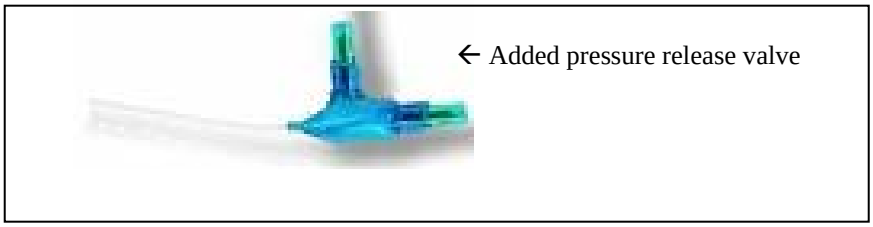

Figure 2. Schematic for T-valve system
[Source: http://greatcare.ec51.com/images/bank/1098801555.jpg].

Advantages and Disadvantages

The most noticeable advantage of this device is its extremely simple design. With not much being changed, this design would retain most, if not all, of the advantages of the original device without adding too many new variables to be accounted for i.e. federal approvals, unforeseen problems or failures, etc. Furthermore, it'd be more familiar to the doctors who would operate this device compared to our other designs.

A safety advantage of this design is that it's constrained to one place, providing only one place on the design to look out for problems occurring. Another advantage is the ability to modify the design by adding a readable gauge, much like a tire gauge, or a balloon that regulates pressure.

A disadvantage of this design compared to our other designs is that a manual override of the system (needed when an unforeseen situation occurs) is not as straightforward. Also, if it sticks, preventing proper failure, overriding it would be tricky.

Another disadvantage is the fabrication this device. With it being one whole piece, the whole device would have to be custom made from scratch.

Design 2: Clip Valve

Overview

The Clip Valve design (Figure 3) is a basic one-piece lever system. This design works exclusively with the pilot balloon. A clip (which could be fashioned out of plastic, metal, etc.) with two protrusions, one to close the release valve and one in contact with the pilot balloon, will be attached on the exterior of existing valve and be spring loaded to keep the valve shut when the pilot balloon is deflated and pressure is below 25cm H_2O. When pilot balloon (which inflating with the cuff balloon) reaches the pressure/size of 25cm H_2O, it will be able to push the end of the clip up far enough in which the release valve, previously shut by the clip, will open, releasing pressure. When pressure drops enough for the lever to fall back in place, release valve is closed allowing for continued inflation if desired.

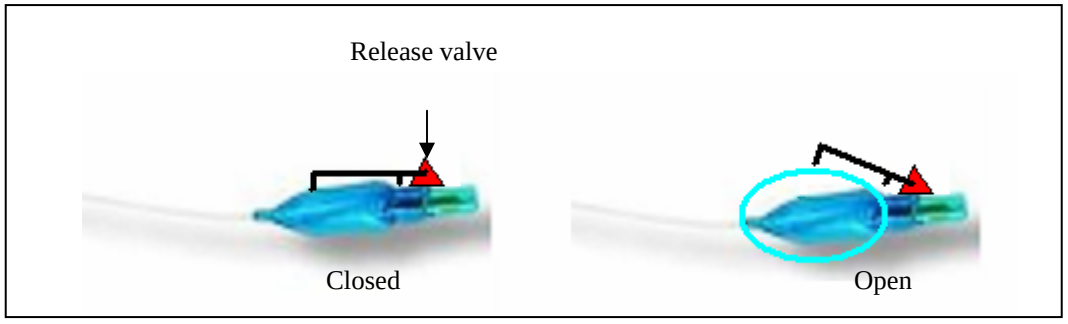

Figure 3. Schematic for clip valve system
[Source: http://greatcare.ec51.com/images/bank/1098801555.jpg].

Advantages and Disadvantages

This device can be very easily overridden, both to keep the valve open or closed. To keep it open, just lift up clip up. To keep it closed, just hold it down. One could also keep it closed by holding it down with a rubber band or a clamp of some kind. The ability for it to reset and re-fail repeatedly is also advantageous because it makes it self-maintained.

A primary disadvantages however, is that this clip device will be on the exterior of the valve. This means that the device is exposed to the surroundings and could easily get caught on something or be damaged. Moreover, this device could be damaged in two critical spots. One is at the spring and another is at the release valve itself. Damage to either of these spots could lead to malfunction.

Design 3: Two-Valve System and Clamp

Overview

While this system operates similar to current design, there are several modifications to consider. This design involves the attachment of a second pilot tube and pilot balloon to the existing pilot balloon (**Figure 4**). Because the pressure inside the cuff is equal to the pressure inside the pilot balloon, the new one-way release valve will respond to the pressure in the original balloon and new tube. Once the pressure exceeds 25 centimeters water pressure, the pressure release valve will open to rid the cuff of extra pressure and the release valve will close again when the pressure is about 25 centimeters water pressure. Another modification required in this design is the manual override clamp.

Since Dr. Proctor requires the ability to countermand the pressure release for emergency purposes, the clamp would be used to force the outtake valve to be ineffective. The design would allow for the use of any medical clamp commonly found in emergency vehicles and hospitals. Slide clamps, plastic tube clamps, and roller clamps similar to those on IV's are being considered as possible override mechanisms.

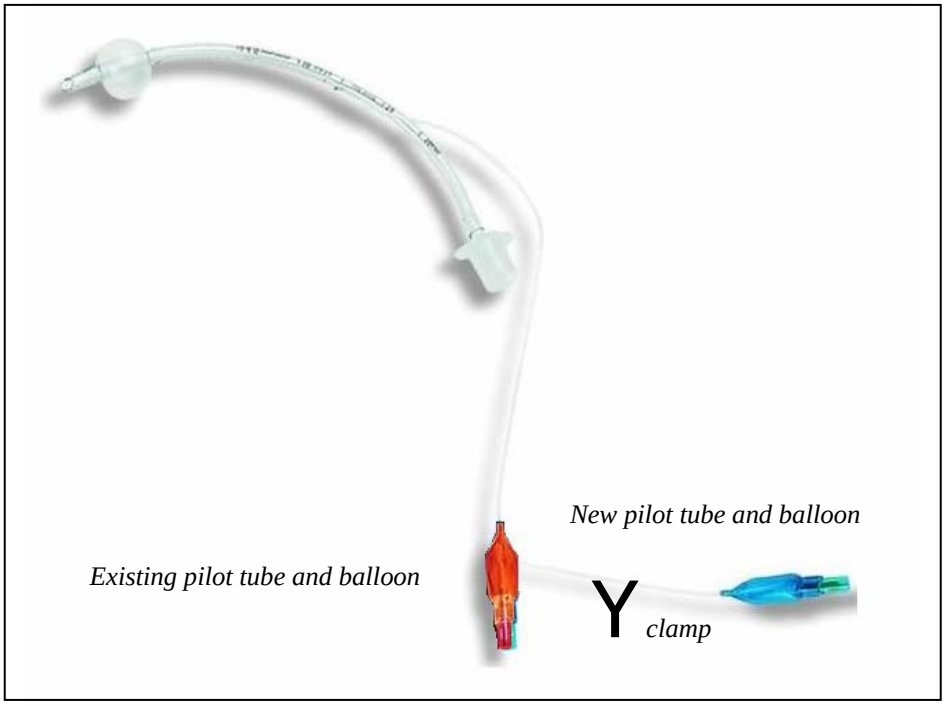

Figure 4. Schematic for two-valve system with clamp capabilities [Source: http://greatcare.ec51.com/images/bank/1098801555.jpg].

Advantages and Disadvantages

One main advantage to this design is its ability to consistently fail by having the ability to override the device. Also, this design has the ability to fail, reset, and re-fail numerous times. The additional pilot tube and balloon should be relatively easy to manufacture because they are already in production for the current design.

There are a few minor drawbacks including possible clamp failure. The size of the extension has the possibility of becoming in the way of a procedure. Also, the seamless manufacturing from one pilot tube to two pilot balloons may present some roadblocks. This addresses the possibility for inexplicable valve error, which is currently seen.

Design Matrix

In order to evaluate the designs, a design matrix (Table 1) was created to grade each on its merits in five categories that are relevant to the project: Safety, Effectiveness, Simplicity, Ease of Use, and Price. Safety takes into account the incidence of failure, extremely important for an *in vivo* medical product so it was weighted higher than the other categories with 10 being a perfect score. Similarly, Effectiveness was rated out of 10, as the product must perform its duties while a human life is on the line. Simplicity and Ease of Use of the design are important because the circumstances under which the product will be used may be hectic, and the less time that goes into figuring out how the product functions the more effective it may be. Finally Price is important, as the product will be used for a short time before being disposed of.

	Safety (10)	**Effectiveness (10)**	**Simplicity (5)**	**Ease of use (5)**	**Price (5)**	**Total (35)**
T-Valve	**9**	**6**	**5**	**4**	**5**	**29**
Clip	**7**	**6**	**2**	**5**	**1**	**21**
Clamp	**10**	**10**	**4**	**4**	**3**	**31**

Table 1: Design Matrix

Being the most simple design, the T-valve was given a perfect score for simplicity and projected price, but lost points in the other categories because it cannot be easily bypassed. The clip valve is the easiest mechanism to work with, but its multiple moving

parts make it too complex, expensive and prone to failure. The clamp design is by far the safest and most effective of the designs, but it lost some points due to form factors and the possibility of mistaking the two valves. In the end, the clamp design garnered the most points, and will be the design pursued for prototyping and production.

Future Work

There is a copious amount of future work needed to validate and develop the new design for an endotracheal tube. Dr. Proctor has supplied many specifications and design constraints. One task will be to finalize the proposed design, which must meet the client's requirements found in the Project Design Specifications (**Appendix A**). Also, a broader knowledge base of pressure thresholds will aid in the designing process. More extensive research will need to be conducted to locate and obtain information on manufacturing companies. There are a few companies that work with small-scale pressure release valves. Contact needs to be made and possibly estimate large-scale manufacturing for economic production. Given budget constraints the total cost must be investigated and minimized to facilitate a viable design.

In order to accomplish the desired pressure, testing needs to be done. While Dr. Proctor donated current versions of the endotracheal tubes, research in how to test the design is also necessary. One idea involving PVC tubes is a possibility for testing as well as calibration, but unfortunately adds to expenses and does not demonstrate the ability to override. Error testing will also be necessary in order to articulate types of misuse and their effects on the endotracheal tube cuff valve. This information could also be helpful in creating the training tools and cautionary section of the user's manual.

References

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Appendix A

Product Design Specification

Client Requirements:

- Cuff cannot fail before reaching 25 cm H_2O pressure.
- Cuff must fail after 25 cm H_2O pressure**.**
- Cuff failure can be bypassed to accommodate unforeseen situations.

Design Requirements

1. **Physical and Operational Characteristics**
    a. *Performance requirements*: Must perform at level consistent of existing endotracheal tubes (i.e. intubation for surgery, through recovery).
    b. *Safety*: Must be FDA approved for humans. No need to be autoclavable.
    c. *Accuracy and Reliability*: Must fail at 25 cm H_2O +/- .25 cm H_2O
    d. *Life in Service*: Must last for duration of patient intubation, whether short term or long. Will be disposed of when no longer in use.
    e. *Shelf Life*: Should be able to be stored in optimal conditions for 1 year.
    f. *Operating Environment*: During use, the cuff valve will be used in both E.R. and O.R. settings. During storage, it will be held on a shelf with little outside exposure.
    g. *Materials*: Should not increase MRI visibility of endotracheal tube.
    h. *Aesthetics, Appearance, and Finish*: Should be clean, with white finish for high visibility.
2. **Production Characteristics**
    a. *Quantity*: Working prototype
    b. *Target Product Cost*: < $10
3. **Miscellaneous**
    a. *Standards and Specifications*: FDA approval for use in human pediatrics.
    b. *Customer*: Customer already has means to inflate cuff. Must have means to bypass valve.

Competition: Lanz® brand endotracheal tubes (30 cm H_2O)