Endotracheal Tube Cuff Pressure Indicator

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Abstract

Endotracheal intubation is required for most invasive surgeries. The current tubes used on adults have cuffs attached at the end of the tube that when inflated create an airtight seal inside the trachea to prevent aspiration. However, this cuff system is not suitable for pediatric intubations since it can cause injury and scarring to the tissue of the trachea if over inflated. The goal of the new design was to add a pressure indicator as a visual cue for regulating cuff pressure so that it may be implemented in pediatric cases. A prototype was constructed that consists of a mechanical spring system designed to measure air pressure and alert users of the current level. However, the prototype is scaled up to demonstrate proof of concept. A set of tests has been performed which show the device exhibits reproducible and predictable stem displacement with discrete pressure application with a small margin of error. Continued work on this project would involve the design and production of a scaled down device demonstrating accurate, reproducible readings at the specified pressure scale while decreasing the effect of static friction.

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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

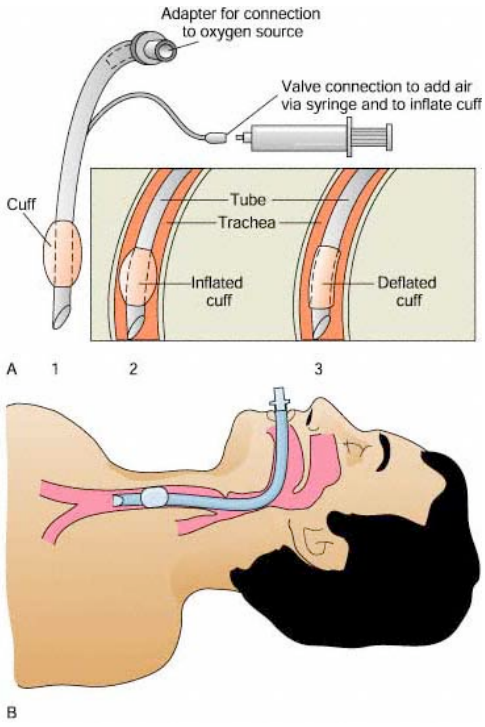

Figure 1: Endotracheal Tube Placement [Source: http://connection.lww.com/]

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).

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. Over inflation 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.

Problem Statement

Our client, Dr. Lester Proctor, has charged us with the task of designing an endotracheal tube cuff system that would indicate the cuff pressure for purposes of regulation. Dr. Proctor is 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.

Current Devices

Several patents with ideas for intracuff pressure-regulating systems exist as well, although none have been seriously marketed. Most of the patented ideas consist of designs that include either bulky, expensive, electronic components or non-disposable components. The goal of this semester's project is to produce a working prototype that is inexpensive, and easy to use. (A summary of current patents can be found in ***Appendix A***.)

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. It is not suitable for use in pediatrics, however due to its availability for adult use only.

Design Constraints

This semester's design must adhere to several requirements that have been specified by the client. Singularly most important among the design specification is that

any modification cannot negatively impact the performance of the existing endotracheal tube. FDA approval for use in human pediatrics is required in order to successfully market and produce the product. Indication of, or a way to maintain intracuff pressure at 25 cm H2O must be reliable to +/- 2 cm water pressure, and will be the most important modification to the existing device. The complete system (consisting of the tube, cuff and valve) must last for the duration of the patient's intubation and will be disposed of when it is no longer in use. The system must have a shelf life of one year, in optimal conditions with little outside exposure. Use in both Emergency Room and Operating Room settings will occur, so the materials of the product should not decrease MRI or CT compatibility. The finished product should be clean, with a white finish for high visibility. The semester goal is to produce a working prototype without adding more than one dollar to the current cost of approximately five dollars. Because the client already has a means by which to inflate the cuff, the design should focus on installation of an indicator of the intracuff pressure. Finally, the modification must be able to be bypassed in order to accommodate unforeseen situations. (A full product design specification is available in ***Appendix B***.)

Ethics and Safety

As with any medical device or dealing with material and human interaction, safety plays a major role in the selection and production of the design. The main goal of this semester's project, as stated previously, was to design and produce a device that would either automatically regulate the amount of pressure in the endotracheal tube cuff or allow the person inflating the cuff to regulate this pressure. The damage caused by

over-inflation of the cuff was the main problem to overcome. Research on the issue suggests that a pressure of about 25 centimeters H_2O has been determined to be the maximum allowable intracuff pressure to maintain a satisfactory safety level of inflation (Veyckemans, 1999). Therefore, the device should be effective at this pressure level since no damage to the tissues of the trachea would occur. Sterility of the device is necessary because the device would be widely used in operating rooms and in direct contact with hospital patients.

Food and Drug Administration (FDA) approval is required in order for the device to be used in hospitals with patients. Based on our research, this semester's medical device needs to follow class two requirements. This is a lengthy process, but it is necessary to ensure that the device is safe for use in humans, especially pediatrics. Another safety concern is compatibility with magnetic resonance imaging (MRI), computed tomography (CT), and other machines used in the hospital setting. Only certain materials are compatible with all of the machines used; therefore, the final materials need to be carefully selected. Some materials may even be compatible with the machines and still create interference, which is also unsafe (Grady, 1996). Interference with any of these machines could lead to an incorrect diagnosis, incorrect treatment options, and many other negative scenarios for the patient. The final safety concern involves the ability of the person inflating the cuff to override the modification. In order to be sure that the device is applicable in any situation or setting, a means of override is necessary.

Design Alternatives

Design 1: Electrical Design

Overview

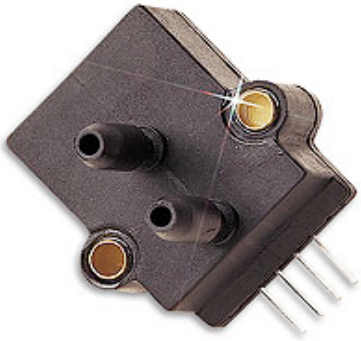

Figure 2: PX-138 Pressure Transducer [source: omega.com]

The first design is an electrical approach at creating an endotracheal tube cuff pressure indicator. The fundamental basis of this design is a pre-existing electrical pressure transducer manufactured by Omega Engineering, Inc **(Figure 2)**. The use micro-machined silicon pressure sensors to produce highly accurate pressure readings. The PX-138 is capable of measuring pressures in the range of 1 pounds per square inch, or 70.31 cm H2O +/- .3% which would cover the safe operating pressure range of the endotracheal tube cuff.

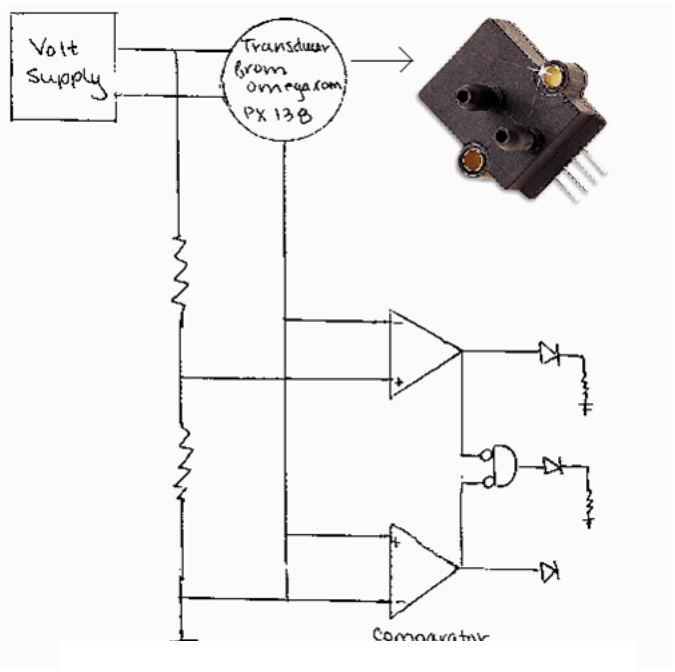

Figure 3: Electric Circuit [Source: Tim Shedd]

Electrical transducers function by converting pressure into a fraction of the supplied voltage. The output voltage can than be applied to various functions; In this case, a simple circuit composed of a power source, the transducer, and a set of comparators **(Figure 3)**. The comparators interpret the output voltages from the transducer and power a set of LEDs in such a way that they would illuminate corresponding to three different intra-cuff pressure ranges, namely when the cuff is

inflated to less than 20 cm of H2O pressure, between 20 and 30 cm H2O, and greater than 30 cm H2O. In addition, the LEDs would be color coordinated: yellow would represent under-inflation; green, ideal pressure; and red, over-inflation.

The transducer, circuit, and LEDs would be attached to the endotracheal tube near the pilot balloon. At this location they could be easily be read by the physician at the time of inflation.

Advantages and Disadvantages

A great benefit to this design is its accuracy. As previously mentioned, the transducer can produce precise measurements within our relatively low working pressure range. The device is also very user friendly. Since it utilizes three different colored LEDs to display the pressure to the administrator, it is difficult to misread the pressure within the cuff. This minimizes the chance of user error.

However, there are some problems associated with this design, the most prominent being price. The cost per unit for an electrical pressure indicator would be well above the target allowance established by the client. The pre-manufactured transducer alone costs $85.00. Even at an estimated bulk discount of $10 per transducer, the electric design would still be overwhelmingly more expensive than the allotted price increase of $.1-$1 over the price of the base endotracheal tube. Another disadvantage of this design is the electrical approach itself. The problem is that any form of electronic device has the potential to interfere with other medical equipment in the operating room.

Design 2: Mechanical Design

Overview

Whereas the first design relied almost entirely on electrical means of reading and displaying the pressure, the second utilizes a mechanical approach. It is essentially a small-scale pressure gauge, utilizing the same concepts as those used in measuring the pressure inside automobile tires.

Similar to the electrical device, the gauge would be connected to the cuff air supply tube near the pilot balloon so that it could measure the pressure within the cuff at the time of inflation. The air pressure in the system would act on a piston inside of the device **(Figure 4)**. The force of the air would push on one side of the piston, moving it as the pressure increased. On the other side of the sealed piston, there would be some form of calculated resistance to the force of the air pressure. The original design called for the use of a metal spring, however, due to the design specification of MRI compatibility, a non-metallic form of resistance will need to be used.

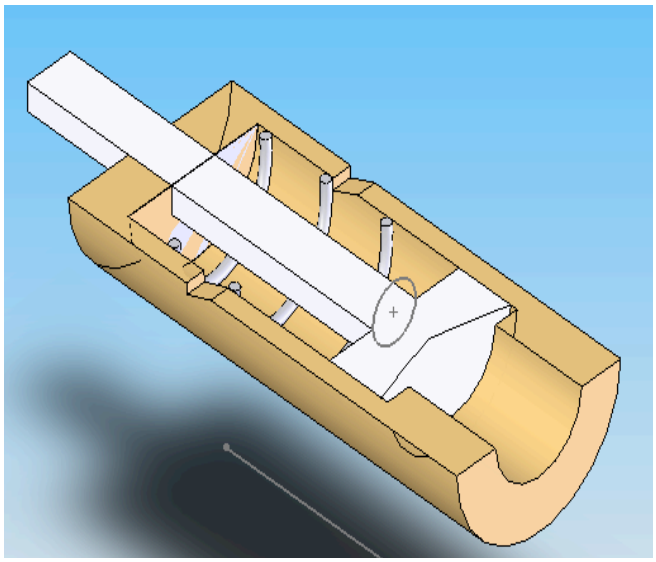

Figure 4: Inner workings of design

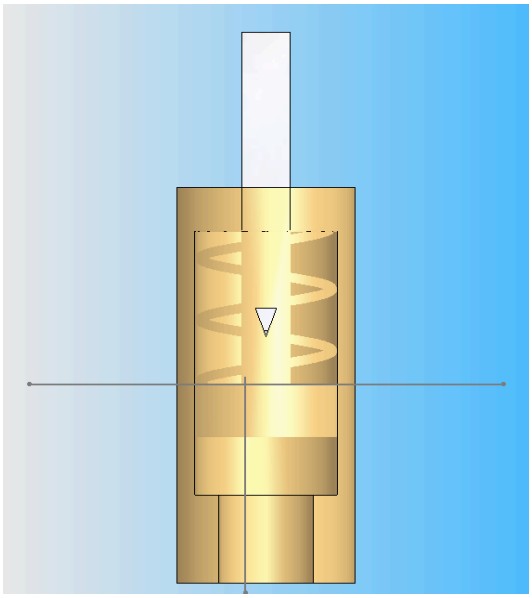

Figure 5: Protrusion of indicating stem

As the pressure increases and the piston increasingly recedes into the body of the device (moved in the direction away from the air supply), it will protrude an indicating stem. This indicating stem will extend to a length proportional to the intracuff pressure. **(Figure 5)**. The stem will be equipped with a color-coded pressure scale printed on its outside, which will be calibrated to reflect the respective pressures inside the cuff, and subsequently give a reading of the intracuff pressure to the physician.

Advantages and Disadvantages

An advantage of this design is that it is economical. Whereas the electrical design is way out of the prescribed price range, this approach is estimated to be, at max, $5 over the suggested unit price. The savings in unit price would come at the price of the level of precision, but the device can be calibrated to perform within the specified accuracy criteria. Because it's made mostly of plastic (which is relatively low-cost and requires less labor to fabricate with compared to other materials), in mass-production, its unit price should fall within the ideal range. Another advantage to this design is that the device would be versatile. Since it reads pressures through a range of values rather than at specific predetermined intervals, physicians could choose exactly pressure to which they would like to inflate the cuff. This allows for physicians to use different pressures for different situations at their digression, permitting them to compensate for factors such as the size, gender and age of the patient.

This design does have its setbacks, however. It will be challenging to calibrate this device to the required accuracy, which means initial design testing could be grueling.

Also, because it has to be MRI compatible, a traditional metallic spring will not suffice, so an alternative form of resistance will need to be implemented.

Design 3: Relief Valve

Overview

This design involves the attachment of a one-way pressure relief valve inline with the current one-way intake valve on the endotracheal tube (**Figure 6**). 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 cm water pressure, the pressure release valve will open to rid the cuff of excess pressure and the release valve will close again once the pressure returns to slightly below 25 cm water pressure. Another modification required in this design is the manual override clamp.

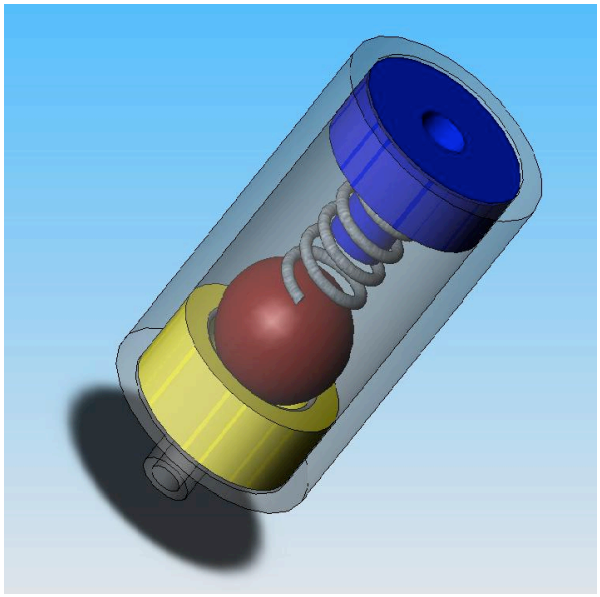

Figure 6: Schematic for pressure relief valve

Since Dr. Proctor requires the ability to countermand the pressure release for emergency purposes, the clamp would be used to bypass the relief valve, rendering it 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.

Advantages and Disadvantages

One main advantage of this design is its ability to reliably release pressure. Also, this design has the ability to work in the background of the hospital facility. This implies that the valve can function without user or physician intervention. The additional relief valve should be relatively inexpensive to manufacture because they are already in production for other medical applications.

There are a few drawbacks including MRI and CT compatibility. Aside from having to find a MRI compatible material for the spring, there is also a need for precision manufacturing. This is due to the fact that there is high precision and accuracy required in this pressure relief valve and a minute amount of pressure to work with. Finally, this design was pursued last semester, which is why it is included, however is not exactly what the client is looking for now.

Design Matrix

In order to compare the designs, a design matrix (**Table 1**) was created to grade each option on its merits in five critical categories: Safety, Client Preference, Ease of Use, Effectiveness, and Price. Safety, Client Preference and Price were deemed the most important and weight on a higher scale of ten. Safety takes into account the likelihood of failure, and is extremely important for an *in vivo* medical product. Similarly, Client Preference is crucial, as the product must fit the specifications laid out by our client Dr. Proctor, an experienced clinician with insight into how the product would be used in practice. Price is important because the product will be used for a short time before being disposed and should be affordable to ensure high usage. Finally, Effectiveness 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 while a human life is on the line.

	Safety (10)	Client Preference (10)	Ease of Use (5)	Effectiveness (5)	Price (10)	Total (40)
Electrical	9	1	5	4	1	20
Mechanical	8	10	4	4	10	36
Relief Valve	10	6	5	3	7	31

Table 1: Design Matrix

The electrical design is the easiest device for physicians to work with, but its circuitry makes it too expensive. This design also has the potential to cause numerous problems regarding interference with other medical devices and treatment possibilities. The mechanical design is by far the most like our clients proposed project, but adding a pressure relief system may prove difficult. Being the safest, the relief valve was given a perfect score for safety and a fairly high score for projected price, but lost points in the other categories because it cannot be easily manufactured when one takes into account MRI compatibility and the precision manufacturing/calibration required. The relief valve also lost some point in the Effectiveness category because it has no way of indicating the pressure, it can only regulate. In the end, the mechanical design garnered the most points, and will be the design pursued for prototyping and production.

Final Design

The final design **(Figure 7)** is composed of two main elements. The first component is the indicator, which is a mechanical means to visually display the pressure inside the cuff to the physician. The second element is an attachment from the indicator to existing endotracheal tubes. This design is composed of modifications to the current cuff inflation system.

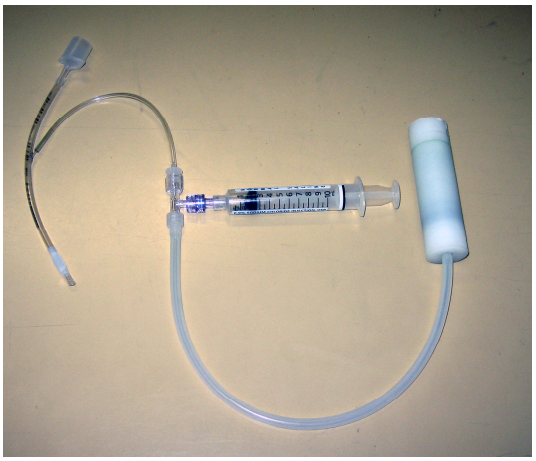

Figure 7: Final Design

The alterations made to the existing system to create the new system included cutting off the pilot balloon and replacing it with a new "T" valve **(Figure 8)**. This allows the cuff air supply tube to be inflated via a one-way valve with a more universal syringe (a standard 10 mL syringe without a needle) while also permitting the indicator to be attached inline with the endotracheal tube (ET) cuff. The important aspect of this part of the design and its current configuration is that the system is connected in a way that allows the pressure in the indicator to be equal to the pressure in the cuff. Establishment of this equality was vital in the theoretical basis of the design, and was required in order to create a product capable of producing meaningful pressure readings.

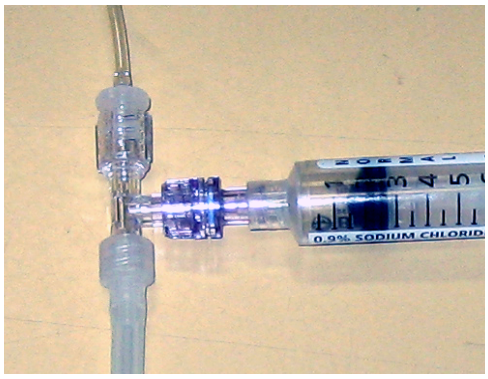

Figure 8: T-Valve and connector

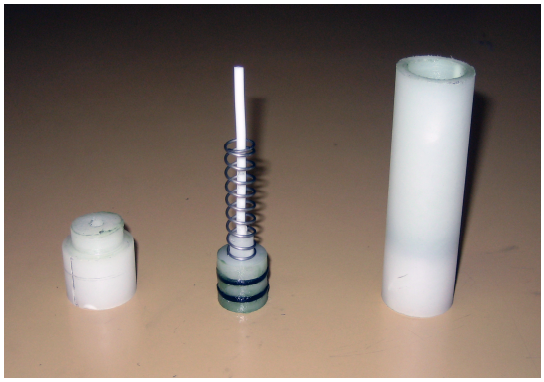

Figure 9: Three components

The pressure indicator is a compilation of multiple parts **(Figure 9)**. The three major components of the assembly are the external cylinder, a piston, and a spring. The external cylinder contributes the bulk of the design, and is made out of a Food and Drug Administration (FDA) compliant polypropylene rod. It serves as the casing for the device and houses the internal parts, namely the piston, indicating stem, and spring. A hole in the end is attached to the air supply tube in order to connect the air in the system to an internal chamber of the device. The hollow external cylinder outlines this internal chamber and the piston is housed inside of it. The piston was constructed from polypropylene and is machined to fit tightly inside of the cylinder. Two rubber O-rings are also affixed onto the piston in order to create an airtight seal between the piston and the cylinder (**Figure 10**).

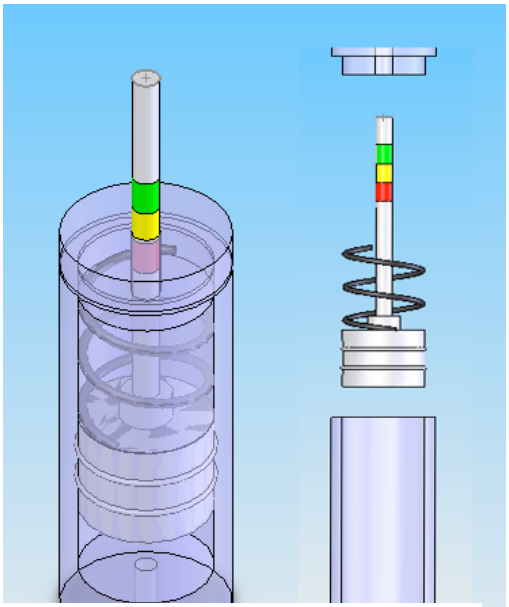

Figure 10: Final design schematic [SolidWorks]

As air from the syringe enters the internal chamber, the piston is driven upwards. Attached to the piston is an indicating stem, which protrudes from the device when the piston is forced up by the pressure inside of the system. A spring fits over the indicating stem, which is made of Teflon PolyTetraFluoroEthylene (PTFE), and is encased inside the

external cylinder between the piston and a polypropylene end cap. The end cap is locked down on the end of the apparatus and designed so that it holds the spring securely inside while allowing the indicating stem to extend out through a hole in the cap's center (**Figure 11**). The length of stem displacement outside of the device indicates the pressure inside the cuff.

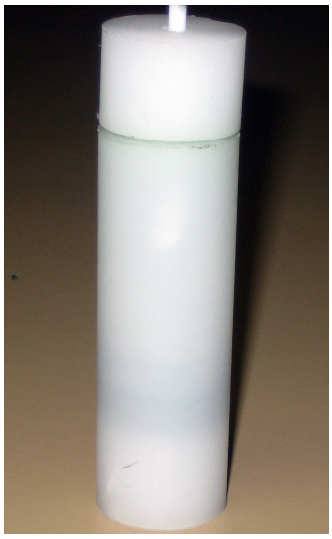

Figure 11: Assembled cylinder with protruding stem

As the pressure inside the cuff increases, it creates a force, which acts on the piston, compressing the spring and protruding the indicating stem. The key concept in the design is that the pressure inside of the cuff directly correlates to the compression of the spring, and thus directly correlates to the displacement of the stem. Testing results of our prototype confirm this effect.

Testing: Friction, Pressure, and Stem Displacement

Upon completing construction of the first device, it proved to have quite a bit of initial static friction to overcome before the piston could slide. As a result, two smaller devices were machined in order to see if decreasing the piston diameter could reduce friction. In theory, this would reduce the surface area in contact with the housing wall and thus reduce the total friction of the system. Additionally, lubrication and o-rings were added to further reduce friction and ensure an airtight seal. In total, there were three iterations machined: a one inch diameter piston with one o-ring, a 0.73 inch diameter piston with one o-ring, and a 0.75 inch diameter piston with two o-rings.

In order to test the static friction in each of the three devices, eyehooks were attached to the end of the indicating stem. These hooks were then pulled with a spring scale and the force required to move the piston was recorded. This was repeated twenty times for each prototype. The data showed that the 0.75-inch diameter device with two o-rings had the least amount of static friction to overcome with an average static friction of 0.97 +/- 0.2 pounds. This is largely due to the fact that when machining, the piston was trimmed down so that nothing except the o-ring was in contact with the inner wall of the housing.

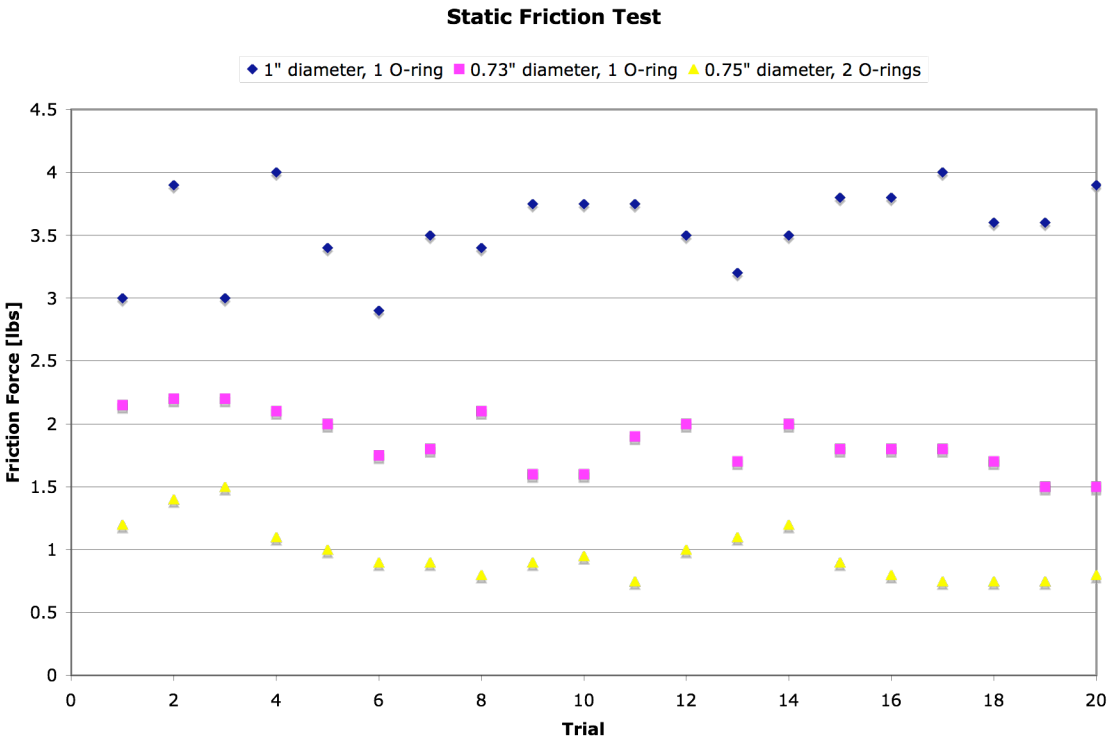

Figure 12: Static Friction Test in three iterations of design using spring scale

Once the 0.75" diameter iteration of the design was chosen as the final prototype, the pressure versus stem displacement was tested with the help of Jim Maynard. The device was attached to a pressurized air tank and a manometer. As certain pressures were

applied via the air tank, the stem displacement was measured and recorded. After a thorough analysis of the data, it was found that there was a strong linear relationship between the two with an R squared value of 0.98 and a standard error of +/- 0.039 millimeters within the predicted values given by the calibration curve.

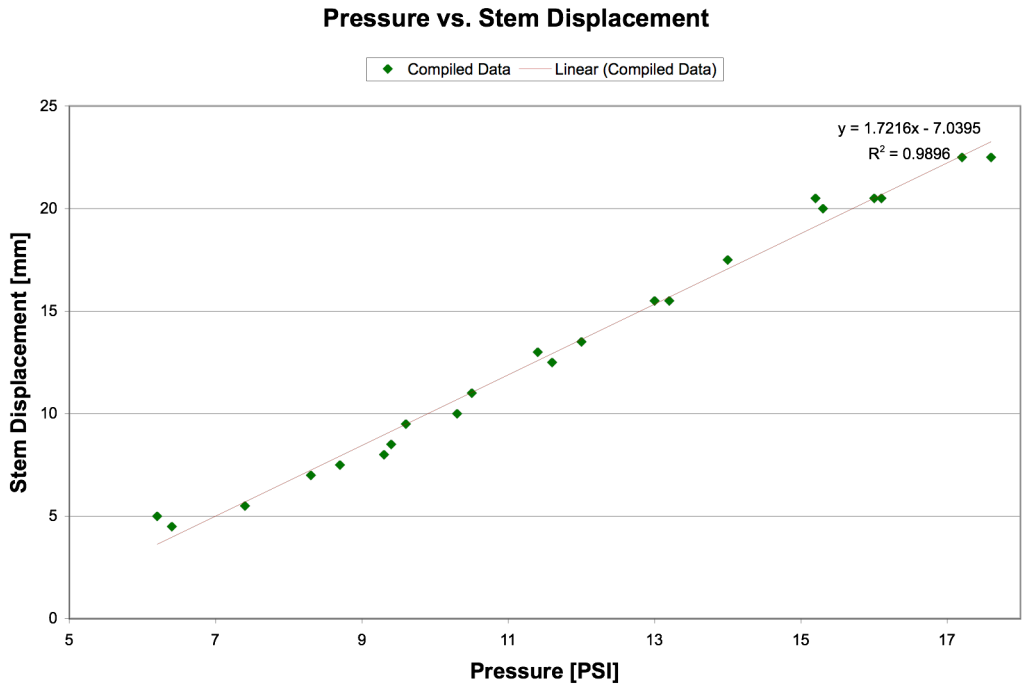

Figure 13: Pressure versus stem displacement test using pressurized air

Discussion

The static friction forces encountered are about two orders of magnitude higher than the minimum value required for the design to work properly in the pressure range of 0-50 cm H_2O specified in the design criteria. To overcome an initial static friction force of 0.97lbs with a piston diameter of 0.75 inches requires a pressure of at least 2.19 psi. As the required force to start the piston moving is greater than the operating pressure range, resolution of pressures in that range is currently not possible. Initial static friction forces would have to be overcome at 2.5 cm H_2O, or 0.0356 psi in order to get an approximate

5% error margin on the 0-50 cm H_2O pressure range. Correspondingly, the static friction force would have to be less than 0.015lbs in the final product.

A cursory evaluation of the sources of static friction leads us to the conclusion that the largest contribution to static friction was due to imperfections as a result of the machining process itself. Shaping the bulk polypropylene required various drilling and boring techniques. Static friction could be reduced greatly if the surface imperfections left after boreing the outer cylinder were eliminated. This could be accomplished by molding the indicator rather than machining, an option discussed in the future work section of this paper. Investigating a means of lubrication that works best with plastics and custom manufacturing o-rings for use specifically with our design could further reduce static friction.

In order to overcome static friction and show a direct relationship between intracuff pressure and stem displacement, a stronger spring was used in the test set up. As it is the spring constant that determines the viable operating pressure range, the test prototype showed displacements at significantly higher pressures; pressures high enough to get resolution of stem displacement with a one pound static friction force. The plot of pressure versus stem displacement shows that stem displacement has a strong linear dependence on the pressure in the system, and is therefore a viable method of measuring intracuff pressures. This observation fits with the theoretical calculations of stem displacement at discrete pressures (**Table 2**).

Cuff Pressure (cm H2O)	Stem Displacement (in)	Load (lbs)	Volume (mL)
0	0	0	0
2	0.019041456	0.012567361	0.137852203
4	0.038082912	0.025134722	0.275704406
6	0.057124368	0.037702083	0.413556609
8	0.076165824	0.050269444	0.551408813
10	0.09520728	0.062836805	0.689261016
12	0.114248735	0.075404165	0.827113219
14	0.133290191	0.087971526	0.964965422
16	0.152331647	0.100538887	1.102817625
18	0.171373103	0.113106248	1.240669828
20	0.190414559	0.125673609	1.378522032
22	0.209456015	0.13824097	1.516374235
24	0.228497471	0.150808331	1.654226438
26	0.247538927	0.163375692	1.792078641
28	0.266580383	0.175943053	1.929930844
30	0.285621839	0.188510414	2.067783047
32	0.304663295	0.201077774	2.205635251
34	0.323704751	0.213645135	2.343487454
36	0.342746206	0.226212496	2.481339657
38	0.361787662	0.238779857	2.61919186
40	0.380829118	0.251347218	2.757044063
42	0.399870574	0.263914579	2.894896266
44	0.41891203	0.27648194	3.03274847
46	0.437953486	0.289049301	3.170600673
48	0.456994942	0.301616662	3.308452876
50	0.476036398	0.314184023	3.446305079

Table 2: Theoretical stem displacement for given pressure with a spring constant of 0.66 lbs/in. and a piston diameter of 0.75 in.

With a reduction of static friction, springs with lower spring constants could be implemented. While springs with appropriate spring constants were purchased for use with the prototype, they were ultimately replaced by the stronger springs because the former did not have the strength to reset the piston to zero displacement after pressure was relieved. Spring type also has an effect on indicator function. We cannot be certain that the springs obtained follow Hooke's law perfectly, therefore all iterations of the pressure indicator would require extensive calibration testing to ascertain a model of

predicting behavior, but the strong linear relationship obtained from the prototype shows that creating a precise model is possible.

Future Work

With an established proof of concept, the spring and piston design must now be scaled down to be effective in the 0-50 centimeter H_2O range. The current static friction force of approximately one pound must be reduced by two orders of magnitude. Further research must be conducted concerning materials, manufacturing, and lubrication to find the most efficient way to reduce friction. Lack of experience in machining caused the current prototypes to have rough faces and skewed dimensions. The two o-ring design along with excessive amounts of silicon-based lubrication have temporarily reduced some of the friction, but is still not small enough to accomplish readings of 0-50 centimeters H_2O.

Injection molding could provide smoother, more exact prototypes, reducing much of the unnecessary friction. Alternatives in materials and lubrication offer another opportunity to reduce friction. Delrin is a polymer often used in paintball markers for its low cost, adequate strength, lightweight, and self-lubricating properties. These same properties might make it a more effective bulk material than the current polypropylene (DuPont, 2006). Coating the existing material with a low resistance polymer such as Teflon can also reduce friction. LabView or other analytical software will be crucial in pressure and force testing in order to quantitatively compare all of the possibilities.

It is important to note that any option to lower the static friction must not sacrifice the prototype's MRI compatibility. Although the current prototype is constructed with all

MRI friendly material, (polypropylene, rubber, and non-ferrous metal) it must be tested further to make sure it is completely safe. There is also the possibility of replacing the stainless steel spring with a different material so that the device will no longer leave a footprint.

Eventually, this design will be integrated with a t-tube system with one end directly connected to the endotracheal tube, replacing the pilot balloon, and the other equipped with a luer-lock fitting for a syringe. The device would come packaged with the endotracheal tube so that it comes ready to use upon arrival.

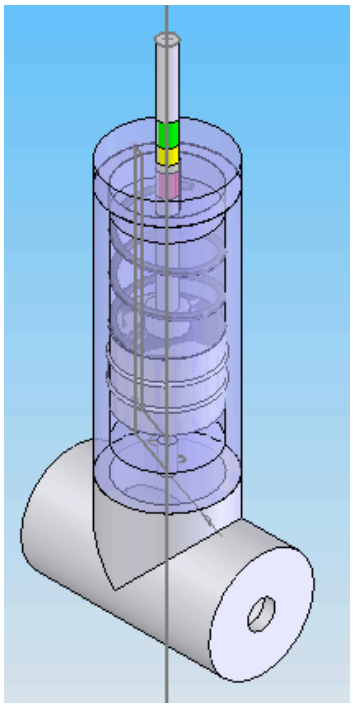

Figure 14: Integrated T-tube system with one end acting as air inlet and one end attached to endotracheal tube

The simplicity of the device makes it easy to adapt for different sizes and brands of endotracheal tubes. If this design is finalized within the desired pressure ranges, the huge demand for such a product will likely gather some attention. Both physicians and manufacturers will be attracted to this cheap and effective solution to a largely unmet problem.

Conclusion

It is clear from the earlier discussion that the device created has great potential to function as a successful pediatric, cuffed endotracheal tube. While several problems were encountered, from valves to developing testing techniques, this is simply the process of engineering. With timelines and budget constraints weighing heavily on this project, valuable knowledge and improved both technical and interpersonal skills have been gained. Ideally we would like to refine, rebuild, and completely finish this design to

the point where it can be proposed to a manufacturing company. We would love to gain rights to the intellectual property that we have created and are planning to disclose for a patent. Dr. Lester Proctor, our client, has been very cooperative throughout the semester in terms of providing equipment and constructive input to our ideas. If we were to have the opportunity to work on this project again, we would begin immediately building a new prototype from the ground up, finding custom manufactures, and pursuing a patent. It is our belief, that while there have been some setbacks, pursuing this further and perfecting the accuracy and precision on endotracheal tubes would benefit millions of patients.

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Appendix A

Current Patents

US Patent Number 5235973
A tracheal tube is equipped with two air lines to the inflatable cuff, one for monitoring cuff pressure and another of larger diameter for inflating the cuff. Intracuff pressure monitored via the smaller diameter line is continuously displayed. A cuff pressure control system allows independent adjustment of cuff pressure via the larger diameter line from high pressure during inspiration to low pressure during expiration. The switchover point is determined by a detecting pressure monitor in the mechanical ventilator inspiration line. The circuit also adjusts automatically to changes in the baseline expiration pressure. The output of a bidirectional mass flow sensor tracks airflow in the cuff inflation line and is integrated to indicate volume. Volume into the cuff is then compared to volume out of the cuff to detect cuff leakage.

US Patent Number 7018359
The patented component consists of a clear, plastic cylinder that locks onto the pilot balloon and is delimited with marks that correspond to the intracuff pressure. When attached to the pilot balloon a small piece juts out and opens the inflation valve. Air enters the cylinder and depresses a bellows that acts like a piston. The distal end of the bellows is open to the atmosphere so pressure differences between the cuff and atmosphere cause the piston head of the bellows to move proportionally to the intracuff pressure. Using the calibrated markings on the outside of the cylinder, a close pressure measurement can be taken.

US Patent Number 5487383
This idea uses a unique integration of two tubes of different diameters going into the endotracheal tube cuff. The larger diameter tube is used for rapid inflation of the cuff, while the smaller tube is used for monitoring and adjusting the pressure. The goal of this invention is to achieve a monitoring and control system that delivers constant cuff pressures high enough to prevent aspiration without causing any damage to the tracheal mucosa. With the two tube system, this devise is constantly inflating and deflating the cuff to monitor and control pressure. This feature can ensure a constant seal during the inspiration/ expiration of a mechanical ventilator. Pressure is displayed on a CRT or a LED bar graph. Pressure is controlled by the use of two solenoid release valves hooked up in series on the smaller deflation tube.

US Patent Number 4924862
This system has 2 parts: the release valve and the excess pressure flow monitor. The release valve is a 2-way valve and is adjustable. It has an inlet and outlet connected in series between the cuff and the source of inflation. Two relief valves are used: a low pressure valve in series with a high pressure valve. There is an exhalation drive line connected to the tube, and this controls the low pressure release valve. The flow detector is located in the cuff inflation line and produces some kind of electrical signal if excess airflow occurs. This device involves an attachment and a two-way release valve.

US Patent Number 4617015

This device is a bottlecap-shaped addition to the cuff air supply tube that is added in-line near the valve for the syringe. It visually indicates pressure to the anesthesiologist. As pressure increases, a diaphragm flexes, and that flexing indicates pressure levels. The price of this design is a relatively greater value compared to other more expensive methods of indicating pressure. The overall idea of this device is similar to that of a tire pressure gauge—as pressure increases, a stem or rod protrudes from the device indicating inflation of the cuff and ideally, an actual value for the amount of pressure inside the cuff.

Appendix B

Product Design Specification

Problem Statement:

Develop a method of indicating the intracuff pressure of an endotracheal tube to operators.

Client Requirements:

- Intracuff pressure must reach 25 cm H2O pressure.
- Intracuff pressure must be known or released at 25 cm H2O pressure.
- Modification can be bypassed to accommodate unforeseen situations.

Design Requirements

1. **Physical and Operational Characteristics**
    a. *Performance requirements*: Must perform at level consistent with existing endotracheal tubes (i.e. intubation for surgery, through recovery).
    b. *Safety*: Must be FDA approved for humans under the class two medical device requirements. Performance specifications are unknown at this time.
    c. *Accuracy and Reliability*: Must maintain or indicate intracuff pressure of 25 cm H2O.
    d. *Life in Service*: Must last for duration of patient intubation, (short or long term). Disposable.
    e. *Shelf Life*: Storage in optimal conditions for one year.
    f. *Operating Environment*: The system will be used in both E.R. and O.R. settings. When not in use, it will be stored with little outside exposure.
    g. *Size*: Cannot add noticeable amount of size to existing tube system, less than 6 inches long, two inches deep, and two inches wide.
    h. *Weight*: Cannot add noticeable amount of weight to existing tube system, less than 100 grams.
    i. *Materials*: MRI and CT compatible.
    j. *Aesthetics*, *Appearance, and Finish*: Clean, with white finish for high visibility.

2. **Production Characteristics**
    a. *Quantity*: Working prototype
    b. *Target Product Cost*: < $1 over base ET tube which is approximately five dollars.

3. **Miscellaneous**

a. *Standards and Specifications*: FDA approval for use in human pediatrics.
b. *Customer*: Customer already has means to inflate cuff. Needs indicator of intracuff pressure.
c. *Competition*: Lanz® brand endotracheal tubes (30 cm H_2O)