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Design of a Pressure Measuring Syringe

Alexander H. Slocum, Jr.[1], Samuel C. Duffley[1], Jaime Moreu Gamazo[1], Adrienne Watral[1], Joan E. Spiegel, MD[2], Alexander H. Slocum, PhD[1]

[1]*Department of Mechanical Engineering, MIT, Cambridge, MA 02139*
[2]*Department of Anesthesiology, Beth Israel Deaconess Medical Center, Boston, MA 02215*

Abstract
It is known that excessive pressures within endotracheal tube cuffs and tracheostomy tubes are correlated with serious complications such as tracheal erosions, tracheo-esophageal fistulae and tracheal stenosis. Proper inflation of an endotracheal tube cuff relies upon the use of a manometer to ensure safe pressures. Conventional methods of measuring intra-cuff pressure include the use of a 3-way stopcock and an aneroid manometer, or by simple pilot balloon palpation. Because the former method is cumbersome and expensive, and the latter inaccurate, we have devised an integrated syringe-manometer that allows for simultaneous cuff inflation and visual indication of intra-cuff pressure. The design maintains the feel and look of a traditional syringe with only the internal components altered to accommodate a silicone rubber bellows, of which the load-deflection relationship has been modeled using finite element analysis, and also verified experimentally. A pressure-measuring syringe has been designed, tested, and verified to meet the health-care professional (customer) requirements: the data show a close correlation to the finite-element bellows model (to within +/- 5 percent up to 50% elongation), and the syringe presented here can be used to accurately measure endotracheal tube intra-cuff pressures up to 50 cmH_20.

1. Introduction

Endotracheal intubation is a common practice amongst emergency personnel and physicians whereby a tube is inserted into a patient's lungs for the purpose of ventilation and/or the delivery of anesthetic gases. A cuff located at the distal end of the tube is inflated using an air-filled syringe. The subsequent measurement of intra-cuff pressure is a standard practice intended to reduce the frequency of hyper- or hypo-inflation. Hyper-inflation of the cuff may result in nerve palsy, tissue necrosis and tracheal stenosis while hypo-inflation may allow gastric secretions to contaminate lung tissue, and/or hinder proper aeration of the lungs during positive pressure ventilation.

New data confirms that overblown cuffs are common during surgery [1]. In fact, most are inflated to a pressure greater than what is recommended; 25 cmH_20 is generally accepted as normal [2]. Studies on chronically intubated patients in the critical care setting corroborate these observations [3]. An accurate, pressure-sensing syringe that gives physicians a tool to help avoid both hyper- and hypo-inflation of the endotracheal tube cuff was constructed to replace expensive and bulky, traditional aneroid and electronic manometers.

2. Methods

A deterministic design process was used beginning with the development of a set of functional requirements (FRs) for a syringe capable of in-line pressure-measurement. The FRs were developed through conversations with practicing anesthesiologists, as well as a literature search which was performed in order to determine both the status of prior art, and the results of current and past studies relating to intra-cuff pressure monitoring.

The response from practicing anesthesiologists was that current technology was cumbersome and difficult to use well. The analog manometer pictured in Figure 1a is designed such that it must be primed with air prior to measuring intra-cuff pressure, which is time-consuming and can lead to inaccurate readings. Other options, including the diaphragm-based in-line pressure indicator, pictured in Figure 1b, or the hand-held manometer/inflator pictured in Figure 1c, are either large and bulky, or have also been shown to be not accurate enough [4].

Figure 1a: Analog manometer.

Figure 1b: BSmart™ pressure indicator (www.concertmedical.com

Figure 1c: Posey Cufflator™ (left, www.posey.com) and Rusch Endo Test (right, www.rusch.com).

Thusly, the goal was to develop a *simple* and *inexpensive* way for a health care professional to easily, rapidly, and accurately measure the pressure within the endotracheal tube cuff.

2.1 Functional Requirements

The device's functional requirements are shown in Table 1. Potential design parameters are presented as well in order to foreshadow certain design features that were used in the final prototype.

Table 1: Functional Requirements for a Pressure Measuring Syringe

Functional Requirements	**Design Parameters**
Integrated, in-line pressure measurement	Pressure sensing components inside syringe body
Measure cuff pressures between 5-50 cm H_2O	Tuned stiffness of silicon rubber bellows
Maintain pressure measurement	Plunger must maintain seal inside syringe
Maintain geometry and ergonomics of current syringe.	Stiffness of plunger in syringe must be identical to standard syringe
Compatible with current syringes	Modified plunger has pre-determined outer diameter
Inexpensive and disposable	Injection molded components

The alpha-prototype pressure-measuring syringe is shown in Figure 2. Its critical components are as follows:

1. *Syringe body* – this contains the plunger and allows for pressure development.
2. *Plunger* – this contains the bellows; this is the component on which an operator pushes.
3. *Seal* – this maintains the pressure within the bellows; identical to current syringe seals.
4. *Bellows* – this element indicates the pressure within the endotracheal tube cuff.

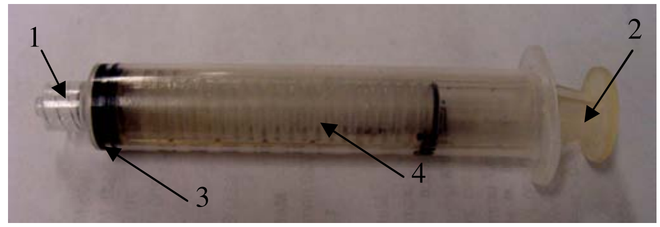

Figure 2: Alpha prototype pressure-measuring syringe with silicone-rubber bellows.

2.2 Design Iteration I

The first syringe design iteration used a bellows which was compressed upon actuation of the plunger and inflation of the cuff. The plunger maintained a seal to the inside of the syringe through the use of an o-ring. This concept can be seen in Figure 3. During a design review, it was suggested that the bellows be flipped in order to simplify the design and combine the two seals (the bellows and o-ring), as can be seen in Figure 4. This resulted in more efficient use of the elasto-mechanics of the bellows, also gave the syringe a greater range, and also reduced the complexity of the device by combining two seals into one.

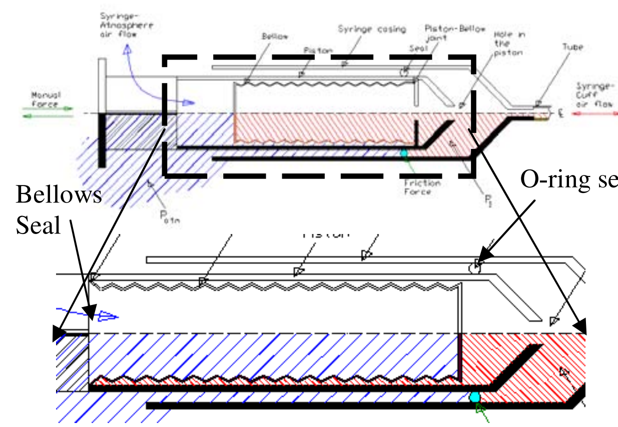

Figure 3: Bellows design concept with 2 seals.

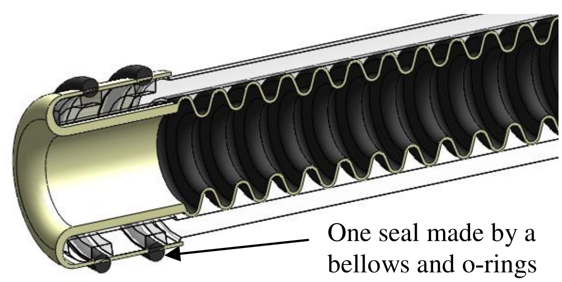

Figure 4: Bellows design concept with 1 seal.

The first attempt at manufacturing the alpha prototype was to 3-D print the components. However, the nature of the 3-D printing process which was available[1] was such that it yielded a bellows whose performance was severely limited

[1] An Object Connex500 was used to print the components out of TangoPlus material.

due to process artifacts remaining inside of the bellows; removal of these artifacts would have torn the thin membrane of the bellows, rendering it useless.

Because of the limited success obtained with 3-D printing, the manufacture of the bellows was outsourced. After a design review and consultation with the manufacturer[2], it was decided to manufacture the bellows out of silicone rubber. Figure 5 shows the silicone rubber bellows, and the alpha prototype with this bellows is shown in Figure 2 above.

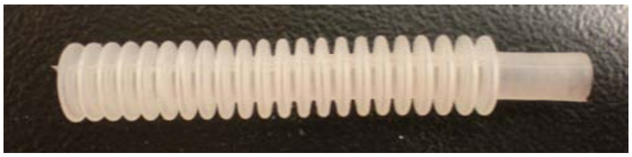

Figure 5: Silicone rubber bellows produced by Columbia Engineered Rubber in Dayton, Ohio.

The design of the pressure sensing syringe maintains most of the traditional syringe design, in that only the plunger is modified to accommodate the bellows. The components of the syringe are also scalable, in order to allow the design to be utilized for other pressure sensitive procedures outside of the range appropriate for endotracheal tube cuffs. The current iteration of the syringe can accurately measure pressure within a range of 5-40 cm H_20.

2.3 Bellows Deflection Model

It will be shown that the bellows design can be modeled and thus accurately tuned by varying parameters of the finite-element model so as to give the desired stiffness and pressure measurement range. This leads to an increase in both the design's scalability and the control which a design engineer has over the bellows performance.

Figure 6 shows a free-body diagram of the silicon rubber bellows. P_{cuff} is the pressure in the ET tube cuff, A_b is the cross-sectional area of the bellows, and F_b is the reaction force from the bellows. The model is good for both tension and compression of the bellows; however the stiffness $k_{bellows}$ must be matched with the compressive or tensile elastic modulus of the silicone rubber. Specifically, the tensile elastic modulus is far more strain dependent than the compressive modulus. The parameter $k_{bellows}$ determines the pressure measurement range of the bellows.

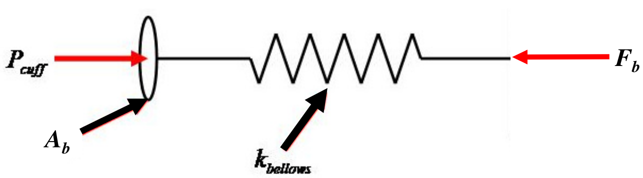

Figure 6: Free body diagram of bellows.

[2] Columbia Engineered Rubber (www.columbiaerd.com).

While the free-body diagram provides a simple model for the bellows design, Figure 7 shows a finite element meshing in ADINA™ (a finite element modeling program), used to represent a single convolution of the bellows geometry. Figure 8 shows the resulting distribution of stress in the convolutions under a load of 6 kPa (60 cmH_20).

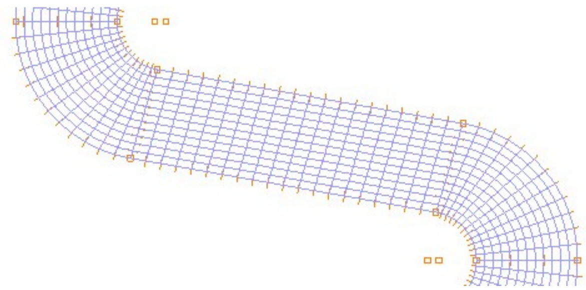

Figure 7: Adina mesh of final convolution geometry.

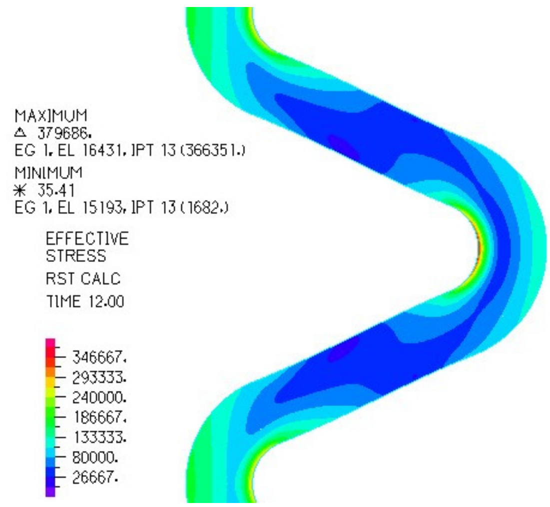

Figure 8: Stress distribution for 60 cmH_20 applied pressure.

2.4 Design Iteration II

In the final prototoype, the plunger is a combination of two identical injection molded parts. A silicone bellows inside the body of the plunger acts as a single elasto-mechanical measurement device and allows for highly repeatable measurements. Figure 9 shows a solid model of the β-prototype pressure-measuring syringe.

3. Results and Discussion

The calculated pressure-deflection relationship of the bellows was experimentally verified, as can be seen in Figure 10, further demonstrating the scalability of the design. The results obtained from the load-cell testing showed a close correlation between the load-deflection relationship for both the slow and fast tests. The model for the bellows was within +/- 5% up to about 50% deflection, which shows that the bellows geometry was accurately modeled using ADINA™.

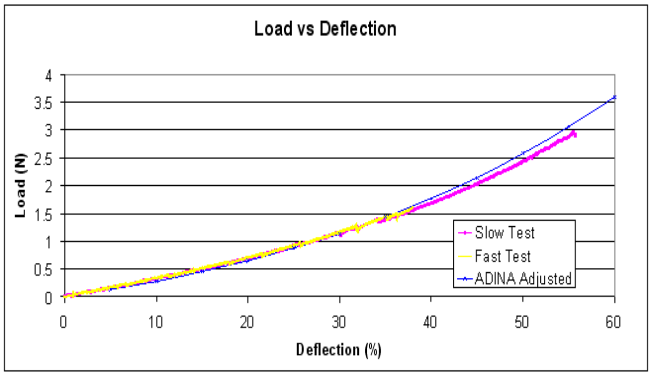

Figure 10: Plot of load vs. deflection for the simulation (solid blue line) as well as two tests: slow (pink) and fast (yellow).

The significance of the experimental results indicates that the bellows geometry can be engineered to meet the needs of a specific application. Changes in thickness or size of the convolutions would lead to changes in bellows stiffness. This will also allow the bellows to be "tuned" to meet the requirements of a wide range of medical applications where integrated pressure measurement is required.

4. Conclusions and Further Work

Thus far, the plunger has been re-designed for manufacturing and units have been injection molded by ProtoMold (www.protomold.com). The bellows was also re-designed and units are currently being produced by NT Medical (www.ntmedical.com). At publication, the β-prototype was not completed, but will be presented in-person at the presentation of this paper at the Design of Medical Devices Conference at the University of Minnesota, April 13-15, 2010.

In conclusion, a simple, cost-effective integrated-syringe-manometer has been developed that both controls and accurately measures air pressure in endotracheal tube cuffs.

Acknowledgments

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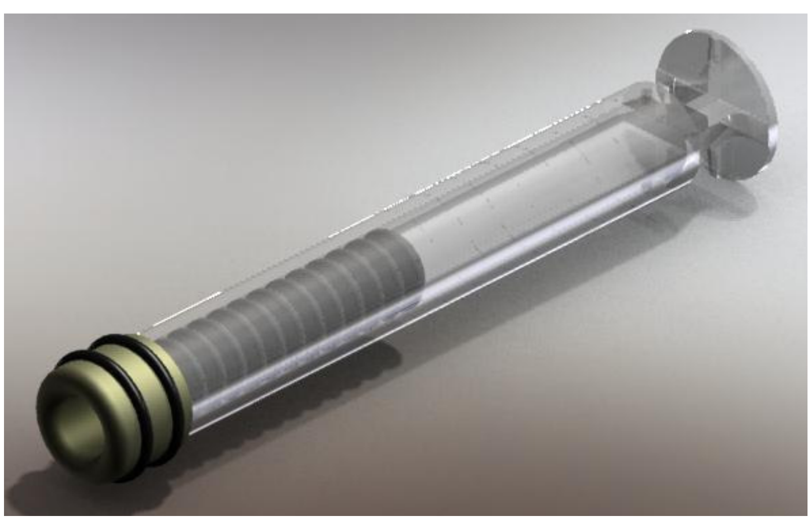

Figure 9: Solid model of the β-prototype pressure-measuring syringe.