

# **Barostat to Measure Esophageal Strictures**

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TABLE OF CONTENTS:

1. Abstract.....	3
2. Design Problem.....	3
3. Background.....	3
a. Esophagus	
b. Gastrointestinal Reflux Disorder (GERD)	
c. Tissue Compliance	
4. Current Treatment.....	5
a. Balloon Dilation	
b. Bougie Dilation	
5. Design Alternatives.....	7
a. Crossing Wires	
b. Barium Swallow	
c. Sonar	
d. Plastic Balloon that holds shape	
6. Final Design.....	8
7. Patent Search.....	14
8. Testing.....	14
9. Conclusion.....	16
a. Ethics	
b. Future Work	
10. Appendices.....	19
a. References	
b. Preliminary Design Specifications	
c. Design Alternatives	
d. Budget	

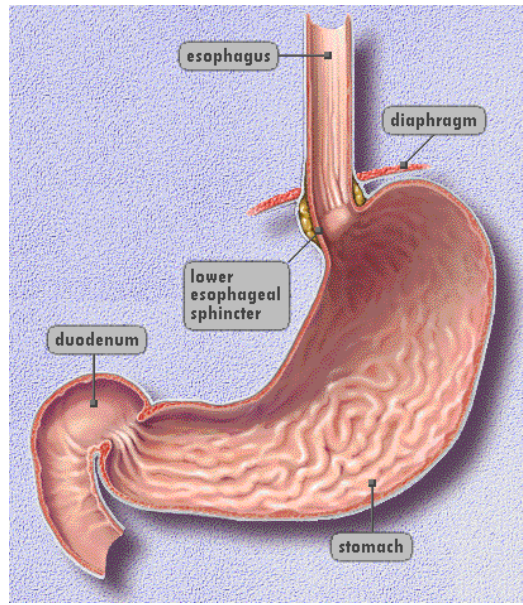
**Abstract** The goal of this project is to design a device to measure the size and compliance of an esophageal stricture. Ideally the device will be an addition to the devices currently used. Important requirements include simplicity, cost, and patient concern. Our design alternatives include a wire device, barium swallow, sonar, and foam or plastic balloon to measure size and compliance. We chose a design that measures pressure and volume of liquid injected into a balloon device with pressure transducers. Two transducers are used, one to measure pressure inside the balloon, using water, and one to measure volume compressed, using air. The slope of the pressure vs. volume graph will vary depending on tissue compliance. Future work on the project includes continued testing for standard curves and appropriate user interface that would work in a standard hospital setting.

### **Design Problem:**

The project is to design a device to measure both the size of a stricture inside the esophagus and the compliance of the stricture tissue (the stress-strain behavior). Ideally the device would measure both these components and be able to attach to the current equipment used to stretch strictures.

### **Background**

The esophagus is a muscular tube that extends from the pharynx through the esophageal hiatus of the diaphragm. The upper third of the esophagus consists of striated muscle, and the lower two-thirds consists of smooth muscle. After a meal, the lower esophageal sphincter (LES) usually remains closed (Figure 1). When it relaxes at an inappropriate time, it allows acid and food particles to reflux into the esophagus.



Source: AstraZeneca LP [Online]

**Figure 1-Gastrointestinal System**

The reflux of stomach acid into the esophagus is one of the most common GI ailments. The usual symptom is heartburn, an uncomfortable burning sensation behind the breastbone. Evidence indicates that up to 36% of otherwise healthy Americans suffer from heartburn at least once a month, and that 7% experience heartburn as often as once a day (AstraZeneca LP, 2002). One consequence of reflux is the formation of scar tissue, which forms abnormally stiff regions of esophageal tissue.

Acid reflux is intensified by certain factors so avoiding these can indirectly prevent reformation of strictures (or at least slow down their reformation). Common things to avoid in preventing acid reflux may be alcohol, nicotine, fried or fatty foods, chocolate, coffee, pregnancy, citrus juices, and overeating. Sleeping more upright has also shown improvement in acid reflux severity as well.

Although acid reflux is the main cause of esophageal strictures, many factors or diseases can contribute to the formation of strictures. These include gastroesophageal reflux disease (GERD), cancer of the esophagus, bulimia, consumption of corrosive

liquids, lung problems and genetics. There are very few methods for either diagnosing or treating this disorder. Two different measurements that would be useful from a clinical point of view are the size of stricture and compliance of stricture tissue.

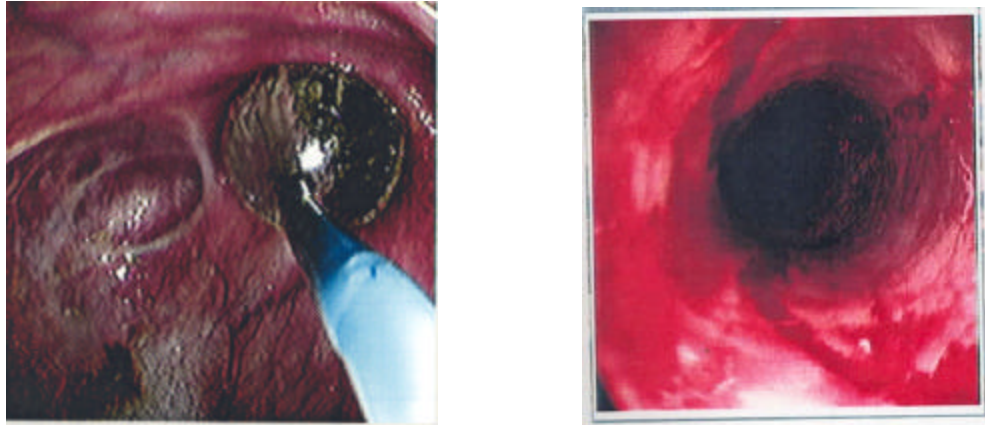
Tissue compliance is defined as the change in volume divided by the change in pressure (Klabunde, 2002). In a lab setting, tissue compliance is measured by stretching a piece of tissue across four probes that have force measurement sensors on them (Nicosia, 2002). The probes pull the tissue, measuring the force and distance. In turn, tissue compliance can be calculated. It would be advantageous to be able to measure tissue compliance in order to know the characteristics of an esophageal stricture. This would allow better estimations from the doctors of severity and predictions of future treatments.

### **Current Treatment**

Currently only a few effective treatment methods exist. The majority of cases are treated through dilation of the stricture, which involves stretching and breaking the stricture in order to return the diameter of the esophagus to the desired size. Dilation can be done in different ways with the same overall result. This is usually done as an outpatient procedure. Surgery is also an option, although not as common due to the complexity involved and the increased risk.

One of the most common methods is balloon dilation. With any dilation technique, the patient's esophagus is numbed with some anesthetic and they are sedated. With this technique, a sausage-shaped balloon is passed into the stricture, and it is filled with distilled water until the esophageal diameter is expanded to the desired size (Figure 2b). Balloon dilation is usually done in conjunction with upper endoscopy. The video

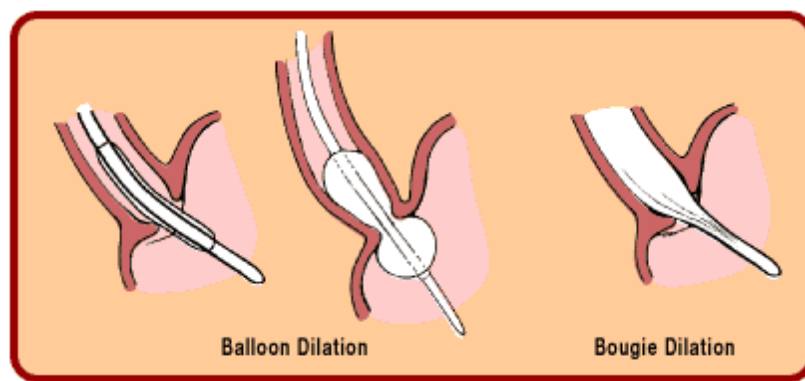
endoscope is passed to the esophagus through the mouth and the balloon is then passed through the scope (Figure 2a). The balloons vary in maximum diameter size and thus different sizes are available for use.



Source: UW-Hospital, Dr. Mark Reichelderfer

**Figure 2: a) Balloon in esophagus during procedure. b) Open esophagus after stretching procedure.**

Another technique used is Bougie dilation, in which a series of increasingly larger, rubber or soft plastic dilators are moved across the stricture. These dilators require a guide wire to first be placed down the esophagus for the dilators to travel over. Bougie dilation is used in cases in which the stricture is longer and takes up a larger portion of the esophagus. This procedure is typically not used unless it is needed because of the increased discomfort associated with the larger dilators. The two main dilation techniques are shown in Figure 3.



Source: Jackson Gastroenterology

**Figure 3- Dilation Techniques**

Even though the current treatments are effective, preventative treatment still presents the best option. In the case of acid reflux, working to decrease the severity of the disease is the best approach.

### **Design Alternatives (see also Appendix III)**

Although the design specifications required a system to measure both the compliance and size of the stricture only two of the six designs alternatives meet both requirements. These designs include: wires crossing, and modification of the existing pressure sensor to digital readout. The other four alternatives include: foam, sonar, opaque x-ray, and a form fitting plastic balloon.

#### *Design 1*

Our first alternative uses two wires crossing inside a balloon, controlled mechanically from outside (Figure 4). The wires would be added into the current balloon and the procedure would be done simultaneously with the dilation. The wires would be interfaced to constantly measure the force exerted. Since the force exerted would remain relatively constant until it reached an obstruction, the stricture's diameter could be approximated at the first point where force drastically changes. The next part of the graph would be analyzed to determine compliance of the stricture. A major drawback of this design is our ethical responsibility as engineers. The wires could potentially rip a hole in the side of the balloon, causing tissue in the esophagus to be torn. Further complicating this design is the interface required to mechanically control the wires and record force. Final disadvantages to this design are the cost and complications involved with retrofitting each balloon before the procedure.

### *Design 2*

Using a method already familiar to radiologists, this design would use opaque barium markers to chart the size and length of the stricture. Using these markers would give the doctor a detailed picture of the size and location of the stricture, but does not give a compliance measurement. Another disadvantage of this design includes the costs associated with adding another doctor and procedure for each trial.

### *Design 3*

This design would use sonar technology to constantly record the size of the balloon throughout the dilation (Figure 5). This design would alter the current balloon, and add an additional interface for the nurse to become familiar working with. Although this device would accurately measure the size, it would not give the more important measurement, compliance. Another major drawback is the cost associated with using this technology is beyond our allowed budget.

### *Design 4*

This design would inject hardening foam into a balloon similar to the one used for dilation. The balloon would slide down the endoscope's channel prior to the procedure and foam would be injected down the same channel. The foam would then mold to the shape of the stricture (Figure 6). This would give a detailed map of the stricture while in the body, but complications would arise while trying to remove the device from the body without changing the shape. Without measuring compliance, this alternative does not give the information needed.

### *Design 5*

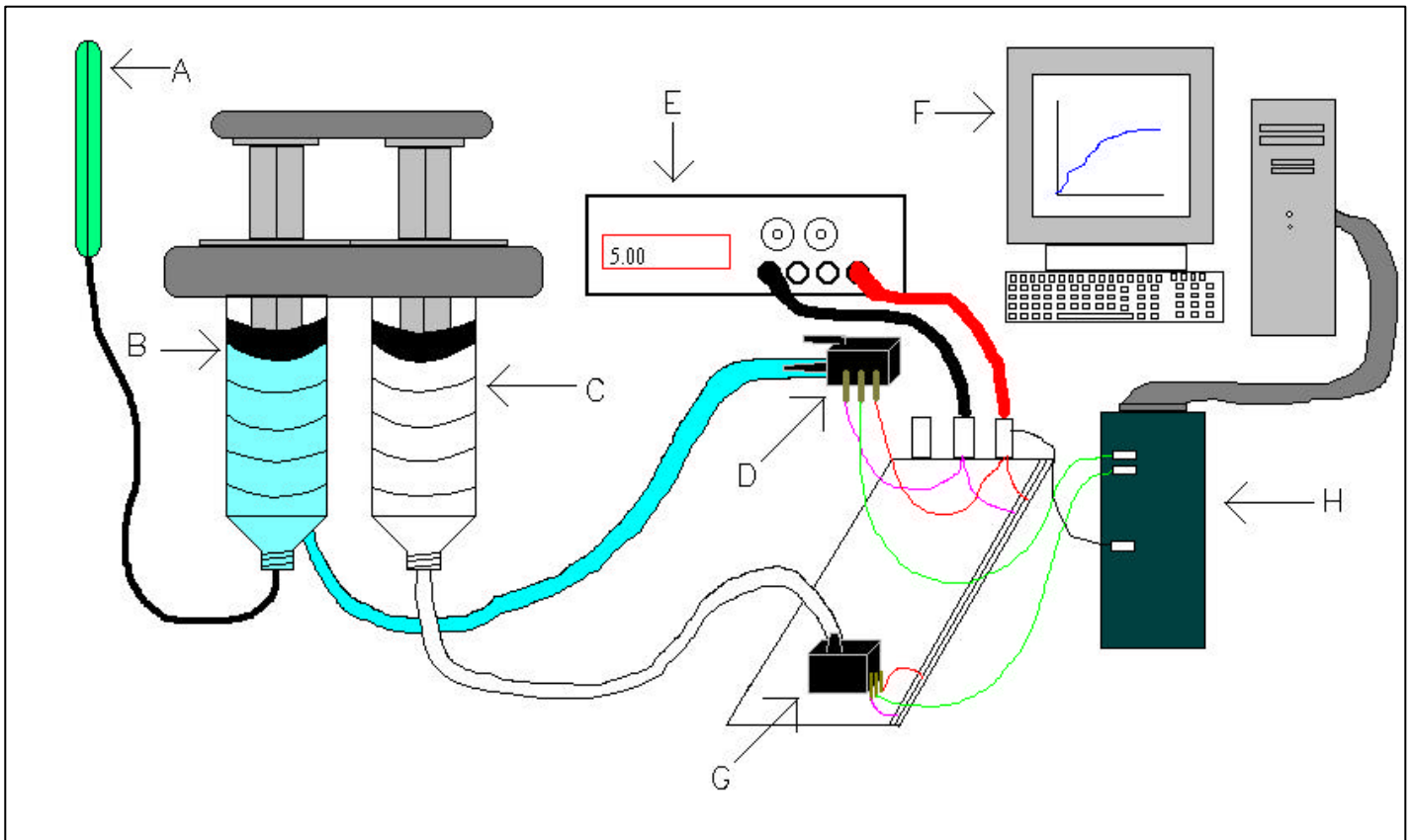
This design would use a new balloon fabricated out of a material that holds its shape while deflated. This balloon would slide down the endoscope's channel and be inflated using the same basic procedure as the dilation, but would not stretch the stricture. Use of a device like this would give a very detailed description of the stricture. In addition to manufacturing a new balloon dilator, the complications of designing and testing the material provide a major drawback. A few other major disadvantages of this design include the lack of compliance measurement, and an additional procedure for the patient.

### *Design 6*

This design modifies the current syringe used during the procedure to digitally record pressure and volume, which could be converted to compliance through testing. This device would be interfaced to a computer, and would require the nurse in the room to tell the computer when to start recording information. Using time as a constant, pressure and volume measurements could then be graphed to analyze the dilation. This device would not require any additional procedure from the patient, and the additional knowledge from the nurse would be minimal. The most complicated part of this design would be interfacing the device into a computer. One such interface that can be hooked up to a computer to record pressure costs about \$3,700. Other digital pressure sensors are available that can be. The only major drawback at this point is the estimated cost of an interface that works with a computer, but we are hoping the university has something that will be useful.

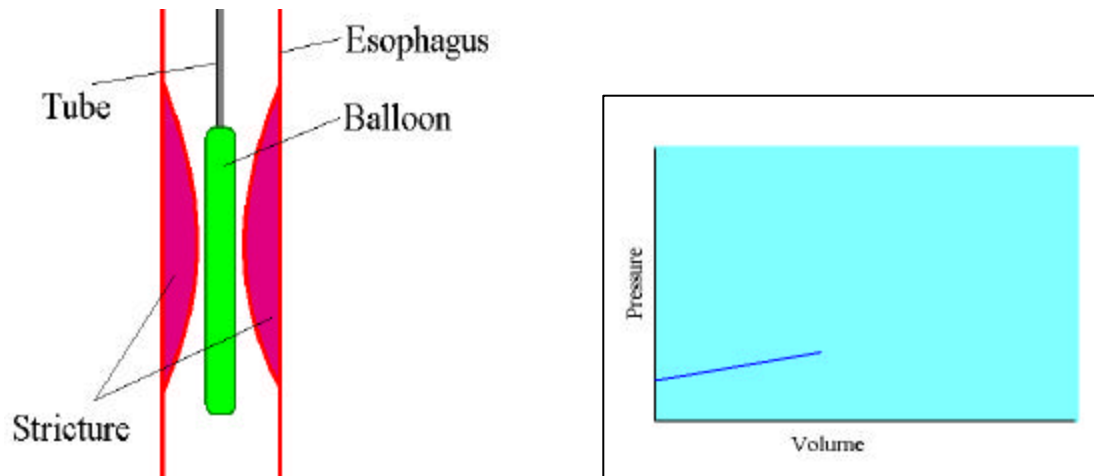
### **Final Design:**

For our final design (Figure 7), we utilized the basic structure from our midsemester preliminary design. The main components of our final design were two syringes connected to each other so that when the top handle was pressed down, both syringes displaced equal volumes. Each syringe was connected via tubing to a Sensym Inc. pressure transducer. The first syringe was used to inflate the balloon and was filled with water and also connected to a differential pressure sensor. This measured the change in pressure inside the balloon. The other syringe was filled with air and connected to an absolute sensor. This sensor was used to measure the volume change in both syringes. Both sensors were connected to a voltage source set at 5 volts and also to the ground. Biobench interface system was used to monitor the output of each sensor. The output of each sensor was in volts, so we needed to convert to pressure change and volume change in order to create the graphical output.



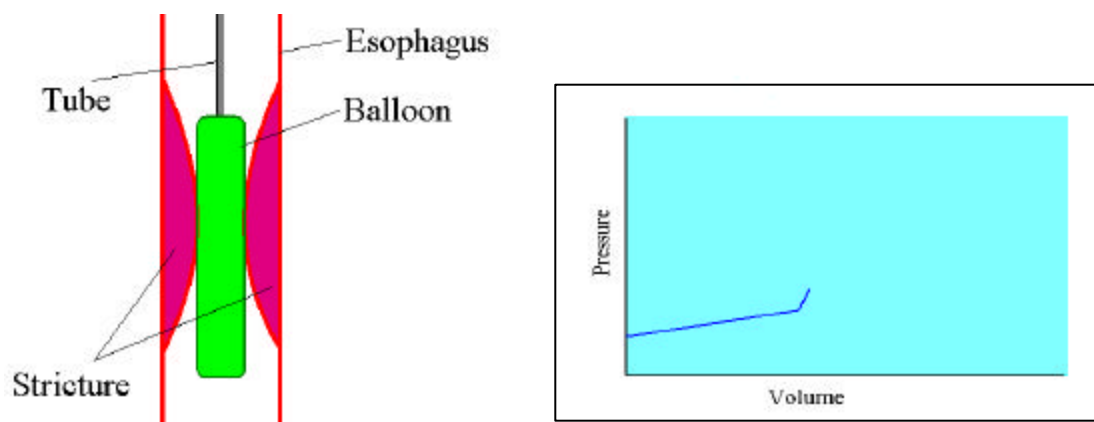
**Figure 7- Final Design: Components: A-Balloon, B-Water-filled syringe, C-Air-filled syringe, D-Differential pressure transducer, E-Power supply, F-Computer output, G-Absolute pressure transducer, H-Biobench interface.**

The following represents the predicted graphical output that would be analyzed to determine volume and compliance of the stricture. As the balloon is inflated, the pressure will increase linearly until the balloon contacts the stricture. Because the balloon is inflated using fluid, the volume reading should not be distorted. When the device is placed within a stricture, this linear relationship will be observed as the balloon inflates until it the balloon reaches the constricted walls of the stricture (Figure 8).



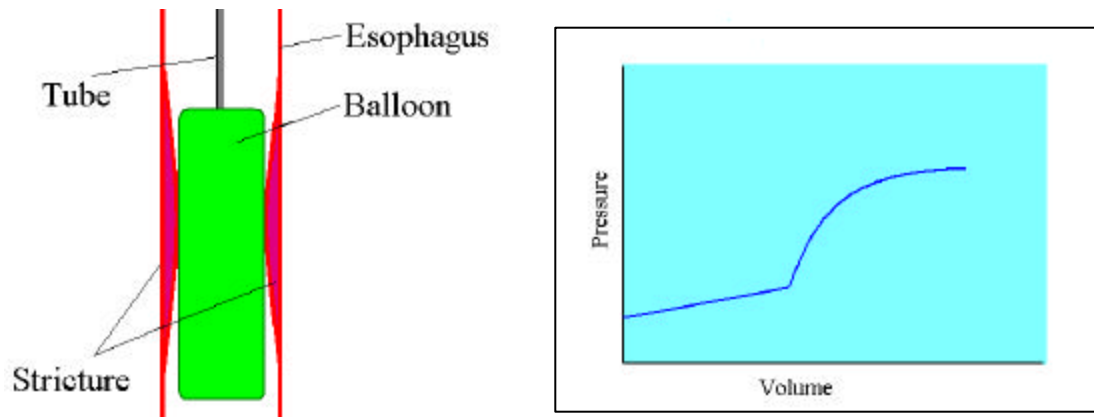
**Figure 8-Partially inflated balloon in esophagus and graph of expected output**

As soon as the balloon comes in contact with the walls of the stricture, the pressure needed to inflate it will begin to increase at a greater rate. It is at this point on the graph that the size of the stricture can be determined. At the point of increase, the volume transducer will provide a number for the volume of fluid pumped into the balloon. Based on the geometry of the balloon, its radius can be determined. This radius would be the size of the esophageal opening within the stricture (Figure 9).



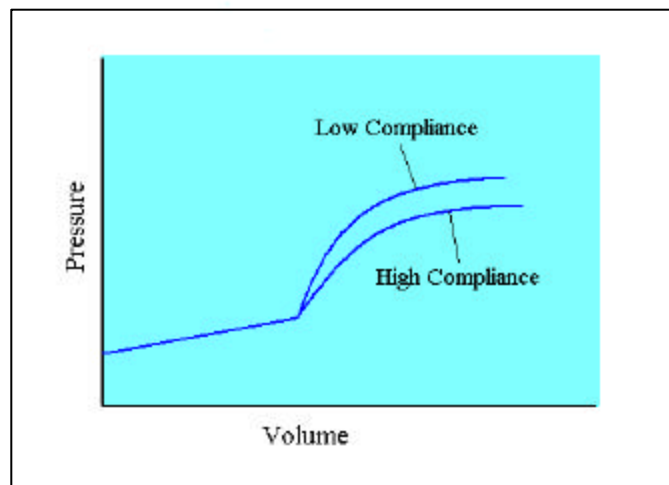
**Figure 9-Balloon inflated to wall of stricture and expected graphical output. On graph, point of increase indicates volume at walls of stricture, indicating size of stricture.**

As the balloon inflated to its final size, the final portion of the graph would be produced. From this portion, the compliance can be determined (Figure 10).



**Figure 10-Balloon fully inflated and expected graphical output. On graph, slope of line after increase point indicates compliance of tissue.**

A stricture that is very compliant would require less pressure per unit of volume to inflate the balloon and the slope of the graph would be less. A very non-compliant stricture would require more pressure per unit of volume and thus the slope would be greater (Figure 11).



**Figure 11-Graphical representation of high vs. low compliance**

We chose this design based on a few key specifications. First, this design would be very easy to use. The procedure is the same as the current procedure for opening a stricture, meaning a doctor would not have to learn to use any new machines or techniques. Second, since this design is based off of the old balloon, the safety factor is

the same. This design is just as safe as the model currently being used. Finally, this device allows for the measurements of both the size of the stricture and its compliance. This feature makes this design preferable because it requires no other equipment for measurement. In the testing section, we will discuss the actual outputs from our tests.

### **Patent Search**

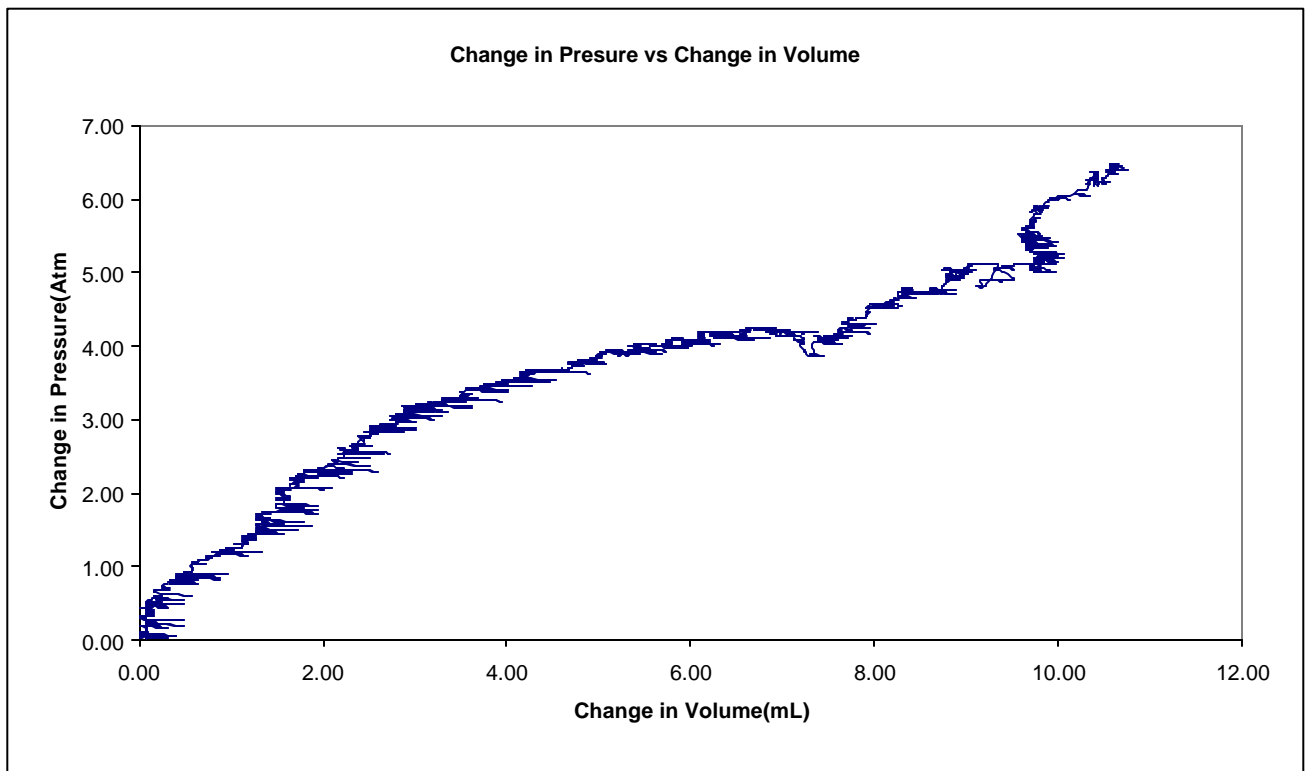
The US patent database was searched via their website ([www.uspto.gov](http://www.uspto.gov)) to determine whether any related products existed. After searching through 253 entries containing the keywords “esophagus” and “compliance”, we could find no product that measured the compliance esophageal strictures.

### **Testing**

Testing was performed with the prototype connected directly to a BioBench© interface and software. The first series of tests were performed with a 12mm diameter MaxForce TTS™ balloon dilation catheter from Boston Scientific, with a 5.00 V supply connected to each pressure sensor. During each trial the balloon was filled to capacity, the data was logged in Biobench©, and then exported to Microsoft Excel for analysis. While analyzing the data from our first tests we realized that an initial volume reading of the air syringe was essential to obtain any useful data. Although these tests did not give any quantitative data, both output voltages were graphed to see if a relationship existed. With voltage output from the pressure sensor on the balloon graphed against voltage output of the pressure sensor on the air syringe a linear relationship was observed.

The second series of trials was performed with identical procedures but with a 16mm diameter MaxForce TTS™ balloon dilation catheter from Boston Scientific. These tests were designed to obtain a normalized curve from dilation without anything

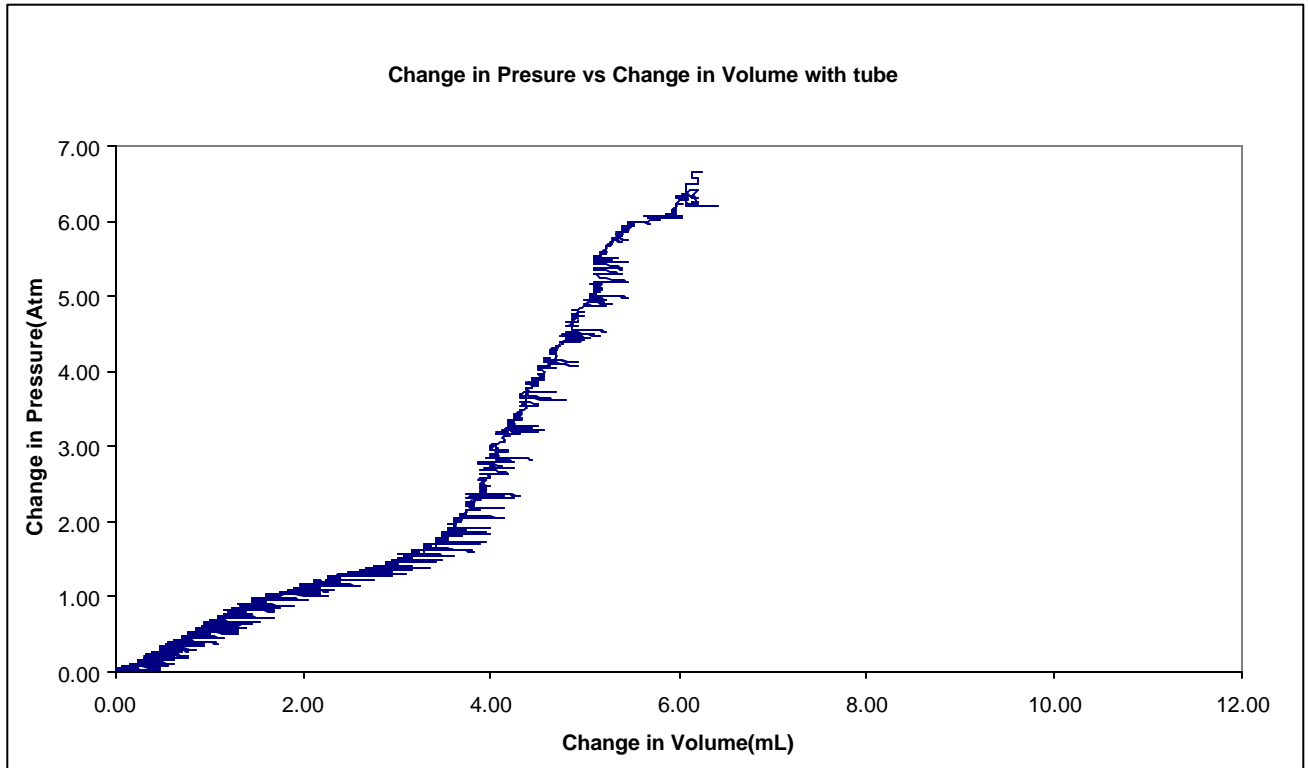
obstructing the balloon. An initial volume was recorded for each trial so the data could be converted to pressure and volume. The initial volume of the syringe was 36.50 mL. It is known that a change of one PSI is equal to 40 mV (Online SenSym ICT, 2002). Using this fact, readings from the water pressure sensor were converted from volts into pressure. Change in volume in the syringe with air was calculated using the measured pressure and the ideal gas law ( $PV=nRT$ ). We then graphed the change in pressure in the balloon filled with water vs. change in volume. A definite increase in slope could be seen in the graph when the balloon filled to a maximum volume (Figures 12).



**Figure 12- Graph of balloon inflation without restrictive tubing**

A final trial was performed exactly as the ones in the second series of trials, but with a rigid piece of plastic tubing obstructing the balloon. The initial volume in the syringe was 36.50 mL. This trial (Figure 13) shows a change in slope earlier than the

graphs obtained during the tests without an obstruction. The graph from this trial is similar to our projected outcome (Figure 6). More tests will have to be performed using this same technique to obtain reliable quantitative data.



**Figure 13- Graph of balloon inflation with restrictive tubing**

## **Conclusion**

### *Ethical Issues*

Ethics is an important issue to consider when looking at a device that will be used on humans. Materials and procedures that could potentially cause harm should not be used on patients. This brings into consideration the issue of testing, both animal and human. Animal testing has always been used in order to initially screen for any mishaps or potential problems. In the future we plan on testing on animals and in doing so must also get approval from the UW Animal Care and Use Committee (ACUC). At least one

doctor of veterinary medicine, one practicing scientist experienced in research involving animals, and one public member to represent general community interests in the proper care and use of animals should be on a committee to approve of the animal testing. All guidelines must be followed, including rationale for testing, housing, operational procedures and a safe work environment (UW Animal Care and Use Committee, 2002). Our application for testing must pass the committee to evaluate if it is ethical.

Once we test on animals and conclude our device is safe, we can then move on to human testing. We must apply to the UW Institutional Review Board for Human Testing Protection (Reichelderfer, 2002), who would consider if our research would be ethical on humans. If approved, testing must follow the procedures of the UW Multiple Project Assurance. All consenting patients would have to be informed of the possible risks of participating and minimal harm must be done. All medical records would have to be kept confidential.

#### *Future Work*

Although our current prototype is functional and it successfully shows the pressure-volume relationship as the balloon is inflated, much work is needed to improve, refine, and test it.

The first of these proposed improvements to our design would incorporate our two-syringe system that is hand-depressed into a syringe-depressing gun similar to the one that is currently used by medical personnel. The gun currently used to blow up the esophageal balloons while stretching strictures requires minimal force on the part of the nurse, technician, or physician. Our device, on the other hand, requires a great amount of force to fully inflate the balloon. In many cases, it is likely that the pressure within the

balloon could not be reached with our current design. By incorporating the gun into our device, a mechanical advantage would make the balloon much easier to fill, even at the high pressures. This simple alteration of the gun platform would allow not only be helpful to the person depressing the syringe, but will also help create smoother curves in the readout (which will be easier to interpret).

Another thing that needs to be considered is the accuracy of our pressure sensors. If the accuracy is not what it needs to be, better pressure sensors can easily be obtained to replace the current ones. After some testing is done, more will be known about the accuracy that is required to give a good readout.

One of the most important steps in the future development of this device is testing. Confirming our predicted results is very important to ensure that it will work as we have planned. Initially, testing will be done on dogs or pigs to check the predicted results and also to make sure that no unexpected problems arise during its use. Safety is a huge issue and initial testing on dogs or pigs will ensure no casualties or injury to human subjects will occur later. After this preliminary testing stage is completed successfully, the next step is human-subject testing. In order to do this, there are various approvals we must meet. The first step is to file an Investigation Device Exemption (IDE) form with the FDA for approval. After receiving FDA approval, our testing methodology must also be approved by the UW-Hospital Institution Research Board. After this is done, the consent of the patients will be sought before any tests are conducted.

## Appendix I- References

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## Appendix II- Product Design Specification

# Product Design Specification

## Barostat To Measure Esophageal Strictures

Team: Julie Sauer, Hannah Kirking, Kevin Wright, Steve Trier

Date: 5/10/02

**Function:** A device to measure the size of the stricture (the percent reduction in radius of the stricture) and the compliance of the tissue (the stress-strain behavior).

### **Client requirements:**

- Allow for easy and quick of interpretation of information of device

### **Design requirements:**

#### **Physical and Operational Characteristics**

- Performance requirements:* If cost and time effective, device would be used in every procedure. Must measure size of stricture and compliance of tissue during the procedure.
- Safety:* Can't be toxic in body. Needs to be small enough to fit down esophagus and be of a flexible material as not to puncture esophageal walls. Must not have parts that may fall off into esophagus.
- Accuracy and Reliability:* Must measure within 1mm of actual size. Must be able to measure the size of a structure between 2mm to 25 mm.
- Life in Service:* Dependent upon cost
- Shelf Life:* 2-5 years
- Operating Environment:* Inside esophagus-approx 37 degrees C, wet, acidic environment. Also in typically hospital environment.
- Ergonomics:* Easy to learn and use, not complicated.
- Size:* Needs to fit through opening in camera tube and down the esophagus of patient. As small as possible is best in order to allow for maximum comfort of patient.
- Weight:* Must not put unneeded pressure on esophageal walls.

- j. *Materials:* Non-toxic materials, safe to use in body. Flexible material, can alter size, volume (like balloon). Blunt as not to puncture balloon or esophagus.
- k. *Aesthetics, Appearance, and Finish:* Smooth edges. It will be similar to other instruments currently used in the esophagus (such as balloons or guidewires).

### **Production Characteristics**

- a. *Quantity:* One per procedure room in hospital.
- b. *Target Product Cost:* approx. \$150-pressure transducers \$60, extra syringe and tubing \$20, device to interface from transducers to computer \$80

### **Miscellaneous**

- a. *Standards and Specifications:* Must follow current human testing guidelines.
- b. *Customer/Patient-related concerns:* Reasonable cost, small as possible, no added procedure.
- c. *Competition:* none

### Appendix III- Design alternatives

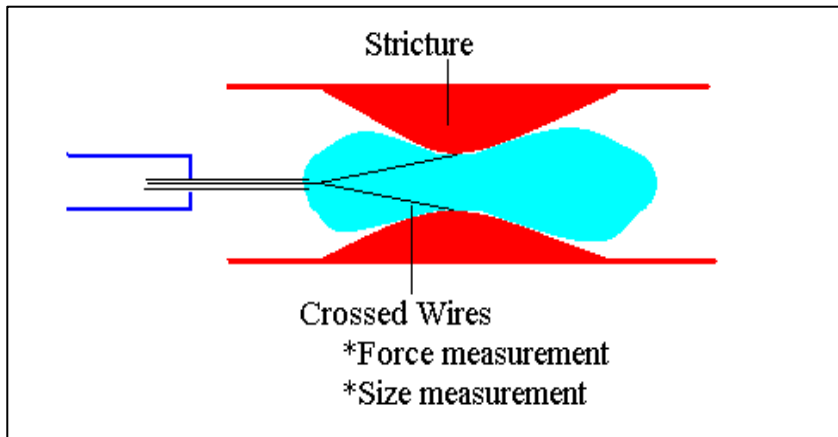


Figure 4- Crossed wire alternative device

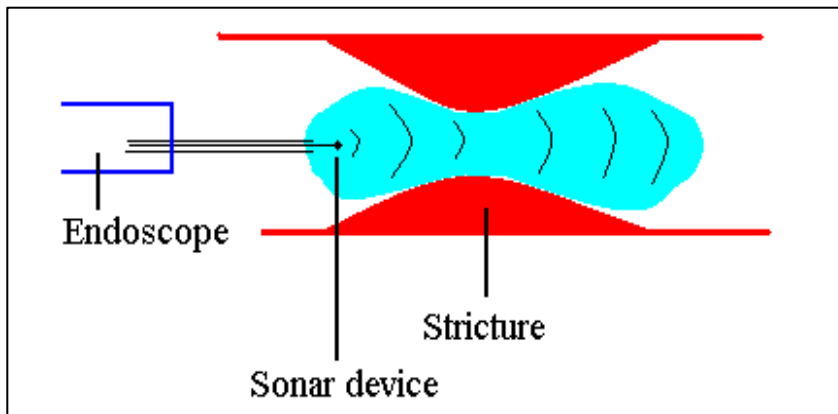


Figure 5- Sonar alternative device

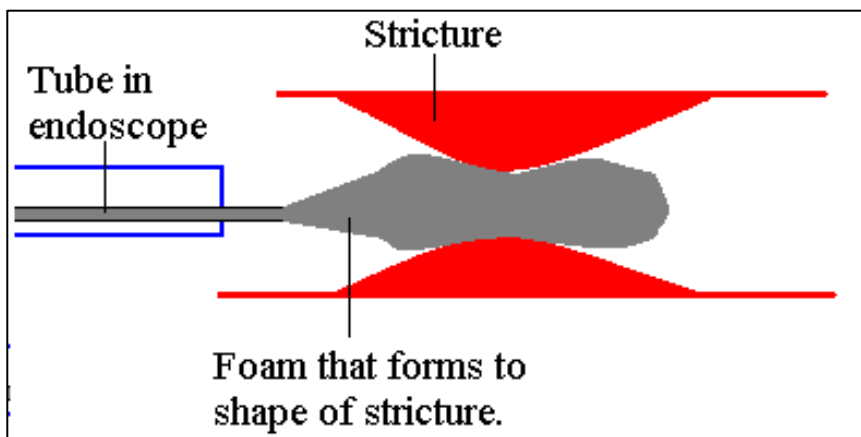


Figure 6- Foam alternative device

<b>Idea</b>	<b>Compliance measurement</b>	<b>Size Measurement</b>	<b>Patient concerns</b>	<b>Ease of use</b>	<b>Cost/ plausibility</b>
1 Two wires crossing inside balloon, controlled mechanically from outside. This procedure would be done with the same balloon used to dilate the stricture, right before procedure is completed. (Figure 4)	Taken as a continuous force measurement. The actual compliancy measurement comes where the force exerted changes.	Gives the radius of the stricture, right when the force measurement begins to increase.	No additional information asked from the patient. The wires could potentially rip a hole in the side of the balloon, causing tissue in the esophagus to be torn.	One extra step in the procedure, which would probably take less than 5 minutes total. Force and size would be recorded continuously on a computer.	Interface to record and mechanically control the wires would be relatively expensive and hard to design at this point in our career, but reusable. Each balloon would need to be retrofitted before procedure.
2 Using x-ray to see barium swallowed by patient	None	Gives a detailed measurement for size of opening and length of stricture.	Not many people would be willing to put themselves through an extra procedure without incentive.	Procedure already exists, but is time consuming and involves more doctors.	Each procedure is very expensive and not plausible, since a compliancy measurement is not taken.
3 Sonar inside balloon (Figure 5)	None	Measurement would be taken as a function of time and converted to diameter.	No patient concerns, since nothing additional is performed.	No additional procedure, just an additional interface for the nurse to become familiar working with.	Interface would be very expensive and the procedure is not plausible, since a compliancy measurement is not taken.

4	Foam injected into stricture through a tube in a similar manner as the balloon. Foam would mold to the shape of the stricture. (Figure 6)	None	Size would be measured while inside of body, but getting the foam out of the esophagus in the same shape and size would be a challenge	Performed at the same time as the dilation, but would require being sedated longer.	Additional procedure for the nurse and doctor to learn.	Inexpensive depending on foam used. Not a plausible solution, since it doesn't measure compliance of tissue.
5	Construct same type of balloon using a plastic that stretches to the shape of the stricture, and holds the shape when deflated.	None	Accurate and detailed description of the shape of the stricture.	Performed in the same visit as the dilation, but would require being sedated longer.	Extra procedure, but would be very similar to the one currently used to stretch the stricture.	The cost of manufacturing and designing the materials and balloon outweigh the benefit of getting a precise volume measurement. Also will not measure compliance.
6	Change the pressure and volume measurements on the syringe to digital form. This would give a digital readout measuring volume injected and pressure attached to the syringe.	Pressure inside the balloon would be continuously recorded on a computer and interpretation of the graph would give a compliance measurement.	Volume would be measured digitally and graphed against the pressure measurement using time as a constant between both measurements. The point where the pressure curves change would give the volume in which the diameter could be calculated.	No additional procedure or safety concerns. It just modifies the current procedure to give a useful measurement.	Procedure would be the same as before, the only operational changes would be using the interface and computer software.	An interface already exists. One such interface that can be hooked up to a computer to record pressure costs about \$3,700. Other digital pressure volume sensors can be hooked up to the existing syringe.

## Appendix IV-Money Spent on Project

Table 1: Summary of money spent on project

Item	Cost
Air Pressure Sensor from Digi-Key	\$28.00
Supplies from Home Depot-tubing	\$1.50
Water Pressure Sensor from Digi-Key	\$38.00
Supplies from Home Depot-wood, paint, tubing	\$12.00
Total	\$79.50