Barostat to Measure Esophageal Strictures

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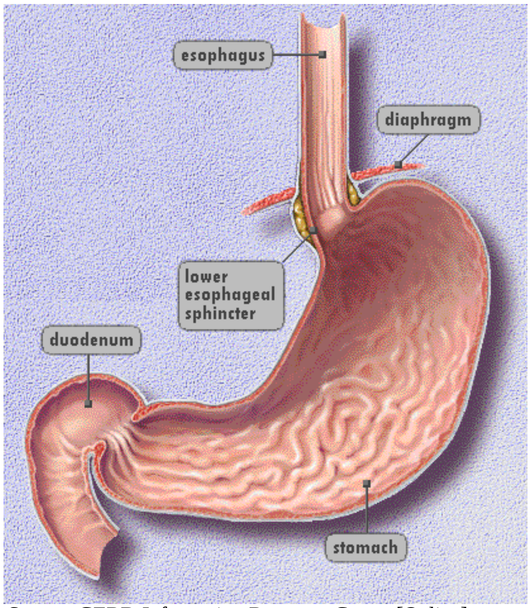
Abstract The goal of this project is to design a device to measure the size and compliance of an esophageal stricture. Ideally the device will be an addition to the current devices used. Important requirements include simplicity, cost, and patient concern. Our design alternatives include a wire device, 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 to calculate the desired components. Future work on the project includes finding a specific device that will measure pressure and volume, and an interface and software that will output correct results.

Design Problem:

The project is to design a device to measure both the size of a stricture inside the esophagus along with 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 (See Figure 1). When it relaxes at an inappropriate time, it allows acid and food particles to reflux into the esophagus.



Source: GERD Information Resource Center [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). 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.

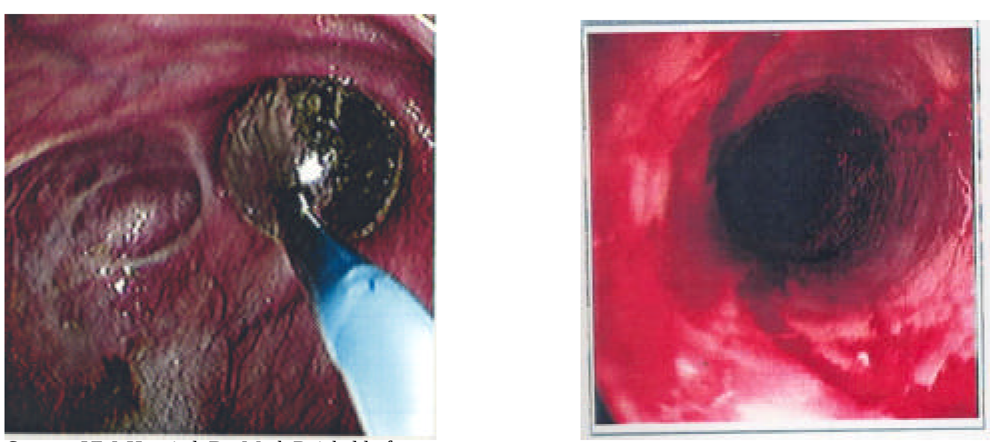
Although acid reflux is the main cause of esophageal strictures, many factors or diseases can contribute to the formation of strictures. These include gastroesophageal reflux disease (GERD), cancer of the esophagus, bulimia, consumption of corrosive liquids, lung problems and genetics. There are very 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). In a lab setting, tissue compliance is measured by stretching a piece of tissue across four probes that have force measurement sensors on them. 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.

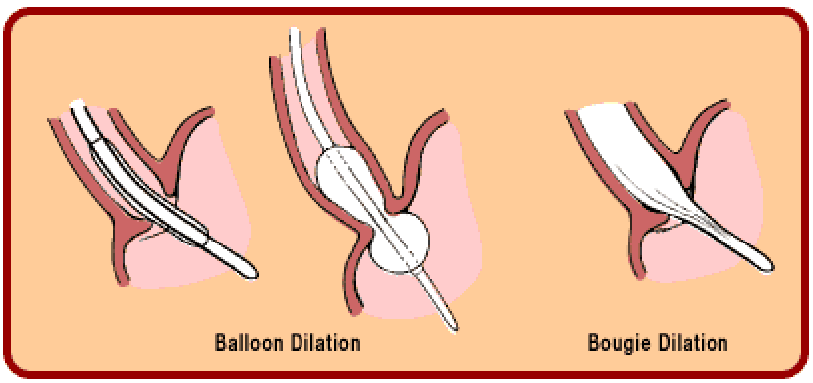
One of the most common methods is balloon dilation. With any dilation technique, the patient's esophagus is numbed with some anesthetic and they are sedated. With this technique, a sausage-shaped balloon is passed into the stricture, and it is filled with distilled water until the esophageal diameter 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 (Appendix III)

	Idea	Compliance measurement	Size Measurement	Patient concerns	Ease of use	Cost/ plausibility
1	Two wires crossing inside balloon, controlled mechanically from outside. This procedure would be done	Taken as a continuous force measurement. The actual compliancy measurement comes where	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	One extra step in the procedure, which would probably take less than 5 minutes total. Force and size	Interface to record and mechanically control the wires would be relatively expensive and hard to design at

	with the same balloon used to dilate the stricture, right before procedure is completed. (Figure 11)	the force exerted changes.		side of the balloon, causing tissue in the esophagus to be torn.	would be recorded continuously on a computer.	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 10)	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 9)	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.

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 compliancy 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.

Final Design:

For our final design, we incorporated aspects from some of our alternate designs as well as the current system used to open the strictures. We took the original balloon and tube device and attached two separate components to it. The first component consists of a volume transducer attached to the tube opposite the balloon. This device will allow for a constant rate of inflation along with a known volume at any given time. The second component is a pressure gauge also attached opposite the balloon end. Both of these devices would be interfaced to a computer, which would be able to monitor pressure and volume measurements at the same time. As the balloon inflates, the computer processes the two signals and graphs them comparatively. Figure 4 shows our device.

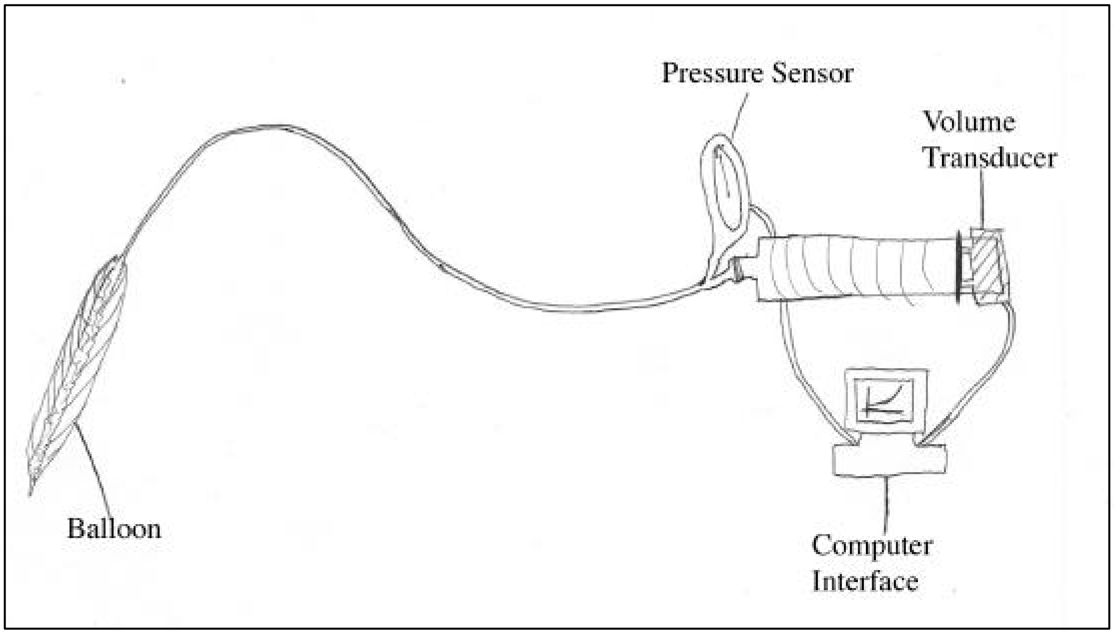


Figure 4-Final design

The graphical output is what is analyzed to determine volume and compliance of the stricture. As the balloon is inflated, the pressure will increase linearly until the balloon is completely inflated. Because the balloon is inflated using fluid, the pressure 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 5).

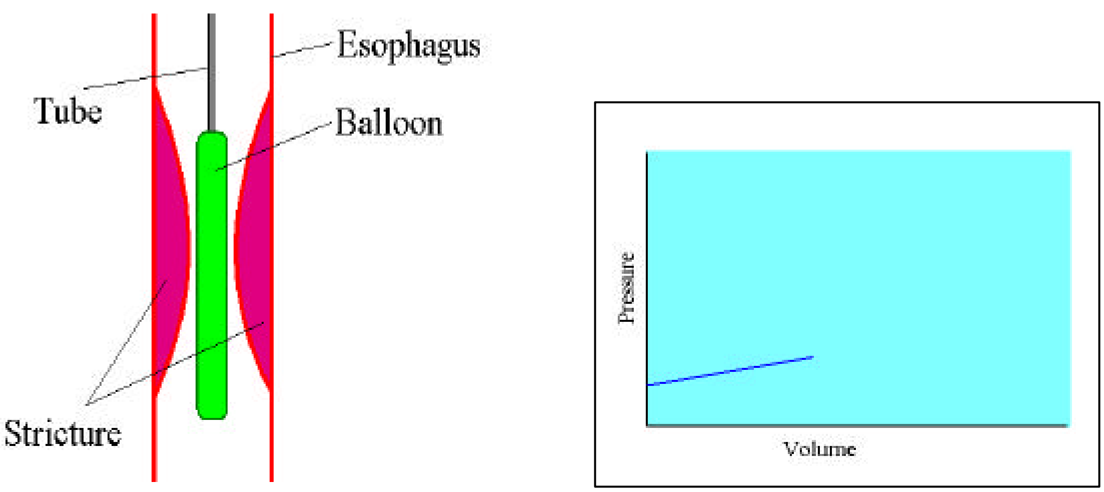


Figure 5-Partially inflated balloon in esophagus and graph of expected output

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 6).

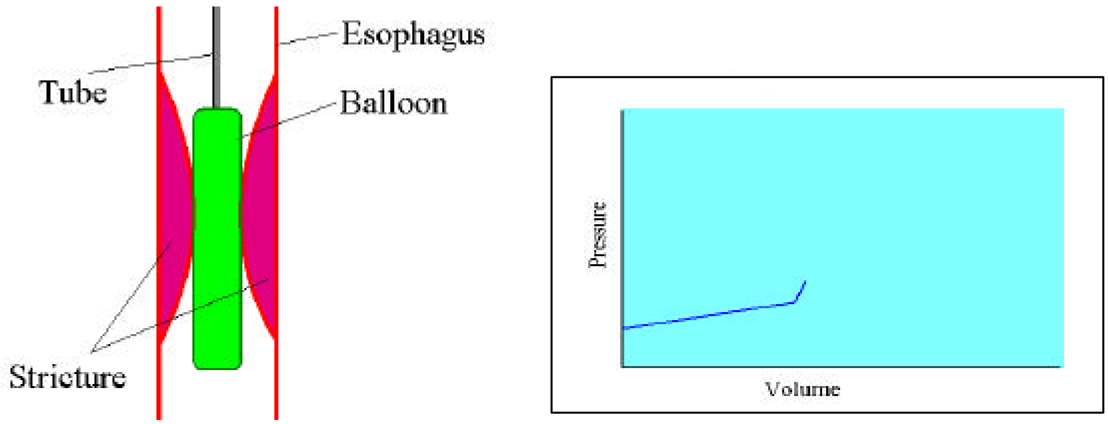


Figure 6-Balloon inflated to wall of stricture and expected graphical output

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 7).

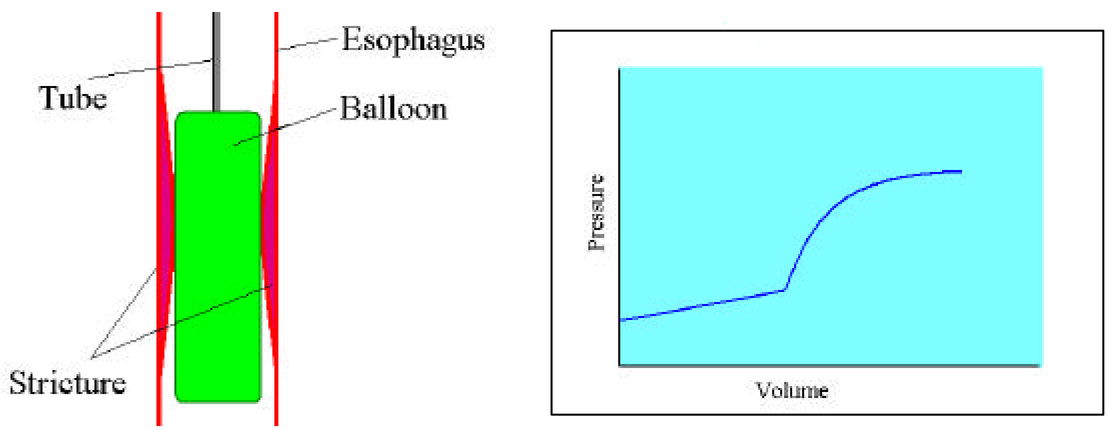


Figure 7-Balloon fully inflated and expected graphical output

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 8).

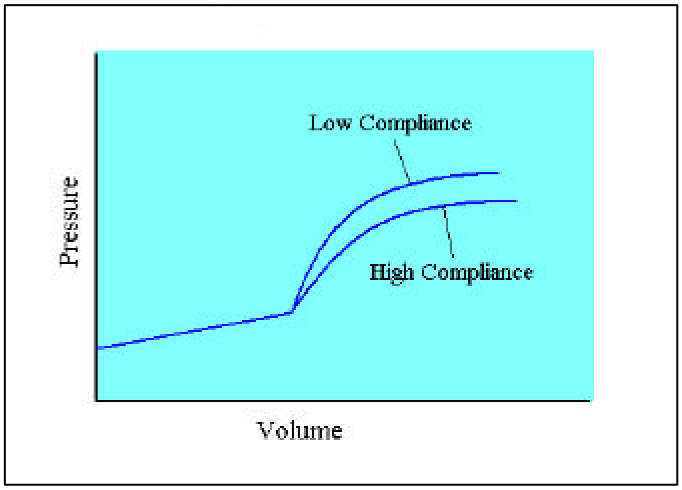


Figure 8-Graphical representation of high vs. low compliance

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.

Future Work

Some difficulties that may be encountered with this device would come when interpreting the graphical outputs. A number of tests would need to be conducted, on esophagi with strictures and those without. It would need to be tested on those without strictures in order produce a standard curve for the balloon inflation. A doctor could compare this curve to the curve generated from a stricture in order to determine the key points on the graph. Also, these standard curves would need to be created a number of times to account for differences in various people's esophagi.

Appendix I- References

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Nicosia M. 2002. Lecturer. Department of Biomedical Engineering, University of Wisconsin, Madison, WI 53706. Pers. Comm.

Reichelderfer M. 2002. M.D. and Professor (CHS). Department of Medicine-Gastroenterology Division, University of Wisconsin, Madison, WI 53706. Pers. Comm.

Appendix II- Product Design Specification

Product Design Specification

Barostat To Measure Esophageal Strictures

Team: Julie Sauer, Hannah Kirking, Kevin Wright, Steve Trier
Date: 3/15/02

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

a. *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.

b. *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.

c. *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.

d. *Life in Service*: Dependent upon cost

e. *Shelf Life*: 2-5 years

f. *Operating Environment*: Inside esophagus-approx 37 degrees C, wet, acidic environment. Also in typically hospital environment.

g. *Ergonomics*: Easy to learn and use, not complicated.

h. *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.

i. *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:* Depends on disposability, how well it works, expense.

b. *Target Product Cost:* Not specified

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

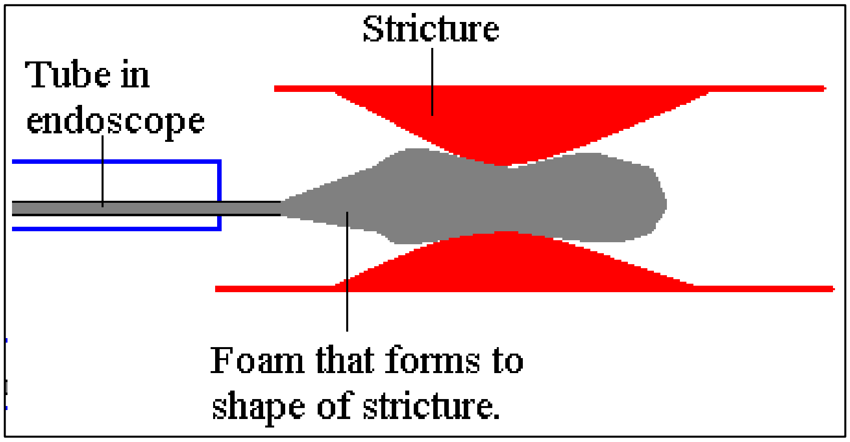

Figure 9- Foam alternative device

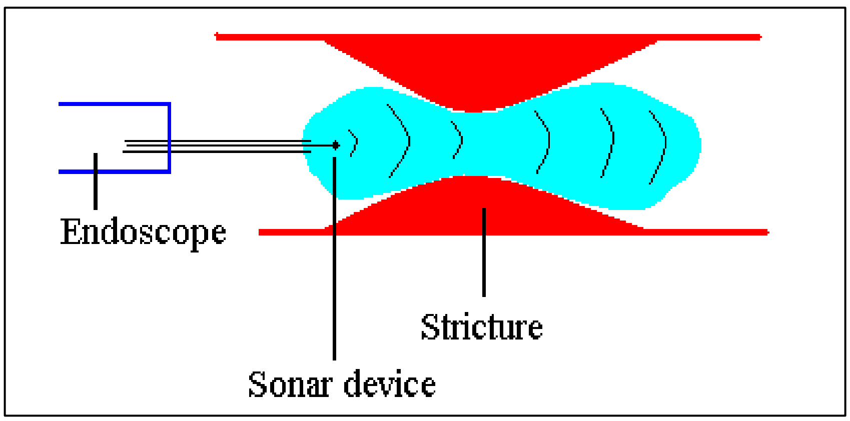

Figure 10- Sonar alternative device

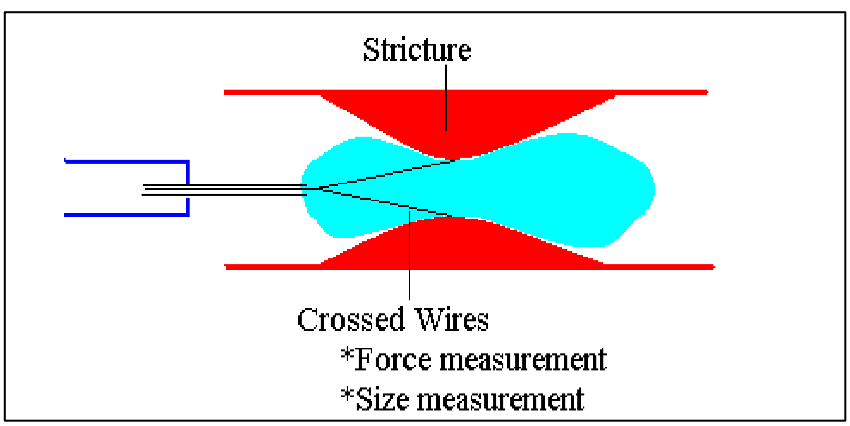

Figure 11- Crossed wire alternative device