Esophageal Stricture Compliance Device

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Abstract

Esophageal strictures are the narrowing of the esophagus due to the build-up of scar tissue. Dilation is used to treat the stricture by increasing the diameter of the esophagus. Currently, there is very little known about the compliance of esophageal strictures. Our objective is to create a device that can measure the compliance of esophageal strictures. Currently, a linear potentiometer and pressure sensor record the volume and pressure of saline in the balloon and record the data in real time on a graph via a LabVIEW VI. Several latex esophagi were used to generate compliance curves. From these, it was determined that as the thickness of a stricture increases and the diameter decreases, the slope of the compliance curve increases, indicating a decrease in overall compliance. Future work of the project should focus on obtaining curves from human subjects and an A/D converter that can work with LabVIEW so the device can be made compact and ready for hospital use.

Background/Motivation

Esophageal strictures are the narrowing of the esophagus due to the build-up of scar tissue following healing from previous injury. The injury of the esophagus is known to be caused by one of 3 general categories: (1) intrinsic diseases that narrows the esophageal lumen through inflammation, fibrosis, or neoplasia, (2) extrinsic diseases that alter the lumen via intrusion leading to lymph node enlargement, (3) or diseases that disrupt the control and innervation of the smooth esophageal muscles and the lower esophageal sphincter [1]. The most common cause of esophageal strictures is the side effect of untreated gastrointestinal reflux disorder (GERD). GERD left untreated causes continual damage to the esophagus from the regurgitation of stomach acid entering the lumen of the esophagus [2]. The epithelium lining the esophagus is not designed to be in contact with acid from the stomach and is injured. Repetitive injury causes build-up of scar tissue from previous healings which gradually narrow the luminal diameter of the esophagus.

Esophageal strictures are associated with dysphagia or difficulty with eating, since the esophagus is narrowing from about 25 mm to 10-22 mm [3]. Esophageal strictures are treated using balloon dilation, in which the strictures are slowly stretched through a radially inflated balloon, in an attempt to restore normal luminal diameters. Dilation is typically performed multiple times during a patient's lifetime to best alleviate symptoms [4]. While dilation improves dysphagia, it can be dangerous if perforations are incurred during the procedure leading to costly hospital expenses, infection, death and malpractice law suits.

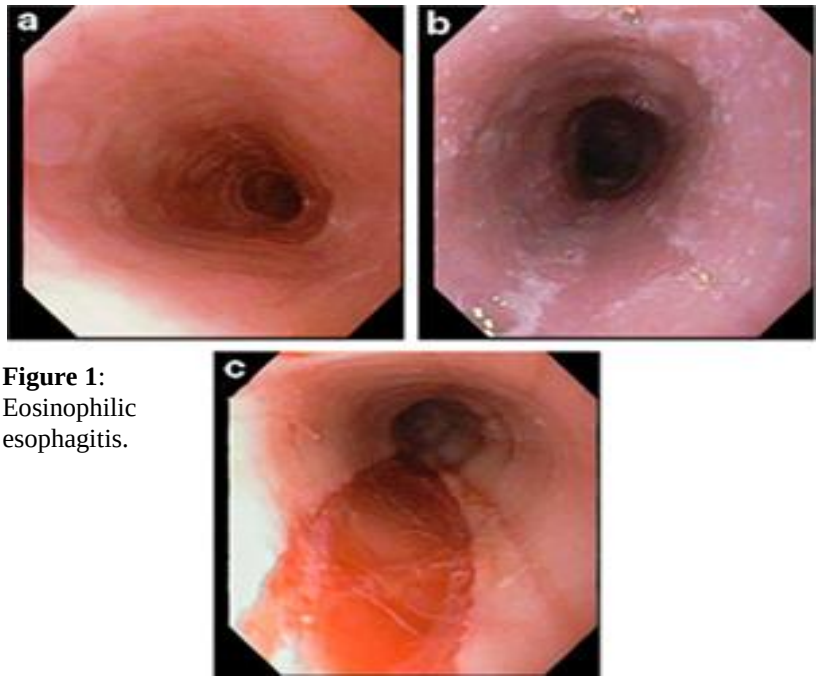

Figure 1: Eosinophilic esophagitis.

Recently, eosinophilic esophagitis has been found to be increasingly important in the formation of esophageal strictures. This is a growing concern since eosinophilic esophagitis is associated with a higher rate of mucosal tearings and perforations during balloon dilation. The rate of perforations and mucosal tearing is based on the equipment used and the skill of the clinician. Dilation is performed either with mechanical dilators or balloon dilation. Dilation with balloon dilators reduces the shear stress on the esophageal lumens through radial dilation, thus reducing the risk of perforations [3]. Our client a specialist in balloon

dilation admitted that even in his department at the UW hospital 1or 2 patients are perforated each year during this procedure. Although perforations rarely occur at the UW clinic, the expertise and the experience in smaller areas is thought to increase the rate of perforations. A long-term goal is to implement a real-time pressure volume compliance curve with the current equipment, to alert the clinician to a potential mucosal tears or perforation.

Problem Statement

Currently, there is very little known about the compliance of esophageal strictures. With more research and work on this subject, particularly in understanding compliance trends with different size strictures, clinicians would be able to categorize them and this would lead to more and better treatment options. There are currently no devices on the market that measure esophageal stricture compliance. Our objective is to create a device that can measure the compliance of esophageal strictures. This device must be able to accurately measure the pressure in the balloon and simultaneously measure the volume of saline in the balloon. This data must then be displayed to the clinician in real time, so that any unsafe changes in the compliance curve can be detected and action taken. Secondly it must be tested to ensure that it performs as desired. Finally, the device must be made in a way that is aesthetically pleasing and equipped to work within a hospital operating room environment before it can be commercialized.

Design Requirements and Restraints

There are certain functions the device and its accompanying software must be able to perform to properly monitor what is happening during the esophageal dilation procedure. Its basic function is to measure the injected volume of saline into the dilation balloon and the corresponding pressure the balloon exerts on the walls of the esophagus. Secondly it must

display the data obtained as a tissue compliance curve in real time. This display must be easy to comprehend, since the curve will determine the clinician's decisions throughout the procedure. A sufficient sampling rate of 1Hz is necessary to create the real time compliance curve. Therefore the amplitude resolution of the analog digital converter must at least be 4 bits.

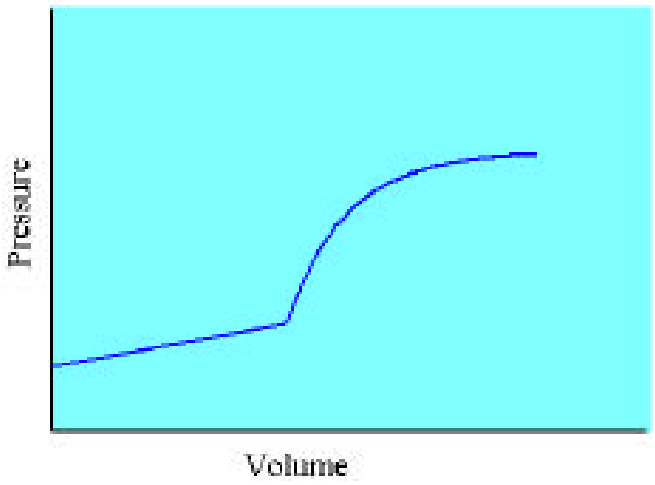

Figure 2. This example compliance curve shows the ideal curve that our device will be able to obtain. The sharp increase in the slope of the curve occurs when the balloon contacts the walls of the esophagus.

The output display the clinician would view during the procedure is theoretically displayed in figure 2. Once tested and finalized, the data should be accurate to three significant figures.

Some of the other design constraints have to do with keeping the device easy to use and compatible with the current operation procedure. There should be no need to add to the complexity of the procedure, and for this reason, the device should be able to work with the current equipment and methods already being used. This will provide the clinician with critical information about what is happening without requiring additional training or difficultly to the process. Since the procedure is already being performed, and this upgrade merely provides additional information, there is no added risk involved to

the patient. However, to enhance the safety of the procedure, the device will provide a warning if the esophagus is tearing or on the verge of tearing. Finally, the device must be able to run on the computer or laptops already being used at hospitals today eliminating the purchase of new expensive equipment. With the addition of the analog to digital converter, allowing a more compact the design, the device becomes less bulky and more convenient for use in the operating room.

Previous Work

Past work done on the device includes creating the caulk-gun like casing which pushes saline out of the syringe. Last semester, a new pressure sensor was purchased to replace one that had been previously broken. Also, there is a linear potentiometer on the gun which is calibrated so that its voltage output corresponds with a volume of saline that has been injected into the balloon.

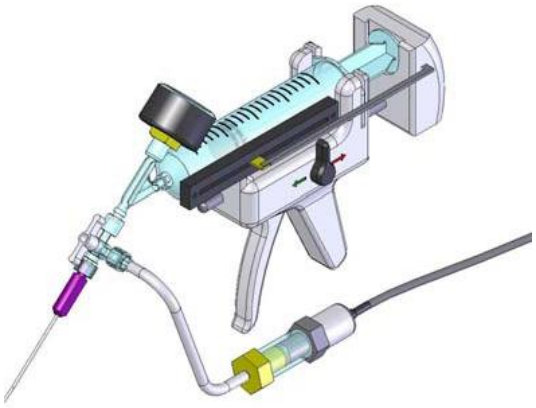

Figure 3. The device shown with linear potentiometer, pressure transducer, and disposable syringe.

Both the potentiometer and the pressure transducer in the past have been connected to the National Instruments ELVIS board to collect data. The data was then displayed using LabVIEW to provide real time graphing. Last semester the LabVIEW circuit was finalized to work with the two inputs, one from the potentiometer and one from the

pressure sensor, to provide the necessary data points to create a real time compliance curve of the esophageal stricture.

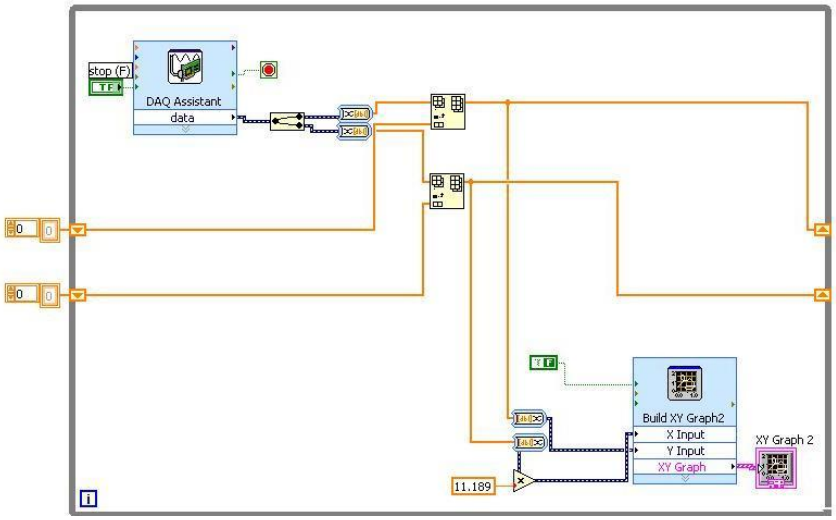

Figure 4. LabVIEW circuit which takes in two inputs and graphs them.

Analog-Digital- Converters

The current system uses the National Instruments ELVIS board to connect to the computer. This system then interfaces with the LabVIEW DAQmx to display the voltage readings from the sensors. This board however, is not optimal for a hospital setting due to its cost and bulk. The ELVIS board costs around $7000, which would make it a costly burden for smaller hospitals to purchase. In addition, its size would clutter the procedure area, which could affect the procedure. For this reason, a more compact analog-to-digital signal converter is needed.

Option 1

The first option is the LabJack ™ U12 from LabJack ™. This model runs off a power supply generated from the USB connection to the computer. It is capable of receiving +/- 10 V inputs and can also supply +5V. Both the pressure sensor and the linear potentiometer have an input range of 0 to 5V which falls in the range of the lab jack. The power lead from the linear potentiometer and the pressure sensor can be attached to the 5V source, so an external power supply will not be needed. The resolution of 12 bits is adequate for the amplitude resolution needed. The pin connections are clearly labeled on the front of the jack. Most importantly, the software driver is compatible with LabVIEW. Last semester it was determined that LabVIEW would be the best software option in which to design a circuit to graph the data in real time.

Unfortunately, the LabJack ™ device is semi-expensive at a price of $130. In the unlikely event of finding a less expensive option with the same attributions, it should be looked at prior to the purchase of this product. Also, the device does not supply a -5V source. The pressure sensor needs both a plus and negative 5V source to run. The LabJack ™ does have multiple pins for supplying power. An inverting amplifying circuit could be used. This would add unnecessary noise to the circuit and add the need of a printed circuit.

Option 2

The second analog to digital convertor is the PMD-1208LS from Measurement Computing. Much like the U12, this model has a +/-10V input range, which is sufficient for the sensors. The PMD is also compatible with LabVIEW and can supply +5V to the sensors.

Similar to the LabJack ™, it does not have a -5V power source, adding the complications discussed previously. The pins on the PMD are also poorly labeled with numbers instead of the function of the pin. This could cause problems in the event that a wire became unattached during a procedure. Someone unfamiliar with the device may not be able to reattach the wire in a reasonable amount of time, causing the loss of data from the procedure. However this could be compensated through the implantation of the PMD into a mounting dock with labeled ported.

Option 3

The final option is the UE9 which is also from LabJack ™. It has all the same capabilities as the previous devices but also has the added feature of wireless data communication. With the feature, all components could be fit inside a single case and there would be no wires running to a computer. This would allow more movement around the room for the clinician, as the gun could move independently of the laptop. However, the added weight of the lab jack might affect the accuracy of the procedure as the clinician would not be used to holding a larger weight. In addition, the delay and added noise of the wireless data transmission would have to be evaluated in the procedural setting. If the esophagus was to perforate, the transmission of this data would need to be instantaneous and distinguishable to stop the procedure. Regardless of the delay rate, this device is well out of the budget for this project, with a cost of around $500. In the continuation of this project in future years, when more funding is possible, this should be a considered option.

Design Matrix

To decide between the three lab jacks, a design matrix was constructed. The categories consisted of power supply, inputs, user interface, LabVIEW compatibility, size and cost. Power supply, inputs and LabVIEW compatibility where chosen to be most important. All products scored the same marks in each of the three categories as none of the jacks were able to supply -5V power, all had a good input range, and were LabVIEW compatible. The deciding factors were user interface and cost. The U12 and UE9 scored high in user interface because all pins were labeled directly on the device. The PMD is not labeled so it scored poorly. The U12 and UE9 however, scored low in the cost category where as PMD scored nearly perfect. After scoring all the categories, the PMD 1208LS had the highest score and this will be the chosen lab jack for the project.

	Weight	U12	PMD	UE9
Power Supply	25	16	16	16
Inputs	20	20	20	20
User friendly	10	8	5	9
LabVIEW	20	20	20	20
Size	15	13	13	9
Cost	10	5	9	0
Total	100	82	83	74

Figure 5: Design matrix for LabJack ™.

Pressure Sensor Sealants

The second design problem arose when the old pressure sensor was replaced with the

new sensor. Figure 6 shows the connection between the adaptor and the pressure sensor. The connection between the new sensor and the adapter tube is inadequate to with stand the necessary ten atmospheres as it currently can only take two atmospheres before the sensor pops off the adapter. The use of thread sealant has been the solution elected for this issue. After researching possible adhesives, it was narrowed down to three possible choices.

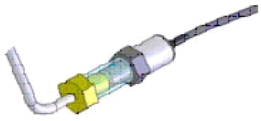

Figure 6: Illustration of the adaptor pressure sensor connector.

Option 1

The first option discovered was the adhesive MK 1325. It is listed as a high strength, low viscosity thread sealant. However, it is irreversible. Error in application could ruin both the pressure sensor and the adapter. Another issue with this sealant is that it would have to be ordered from a company in Germany. Shipment could potentially take an unnecessarily long amount of time, when we have only a limited time to work on the device.

Option 2

For the second option, we looked for a sealant that would be more readily available and reliable. Gorilla Glue was what was found next. This adhesive is marketed as waterproof glue good for adhering dissimilar materials to each other. Since the pressure sensor is metal and the adapter is plastic, this is a very good trait. However, Gorilla Glue has an unpredictable glue expansion and this could make application difficult.

Option 3

The third option discovered was the thread sealant, MegaLoc. This sealant is reported to have strength of 1200 psi which is more than perfect for the device. Also, MegaLoc is nontoxic and inexpensive, while being easy enough to obtain.

Design Matrix

In an attempt to organize the important factors of each sealant, weighted, numerical values were assigned to most valued attributes. Each sealant was then evaluated on how well is fulfilled the specifications. The most important qualities, which were weighted most heavily, were strength, toxicity, reversibility and cost. Toxicity was heavily weighted as to provide a safe environment for construction. Below is how each option faired in the design matrix.

	Weight	MK 1325	Gorilla	Megaloc
Strength	50	50	30	45
Reversibility	10	0	5	3
Toxicity	20	20	20	20
Ease of use	5	4	5	5
Availability	5	1	5	3
Cost	10	?	9	9
Total	100	75	74	85

Figure 7: Design matrix of adhesive.

MegaLoc won over all as it possessed the strongest sealant while still being safe, affordable and easy to obtain. The availability and reversibility of MK 1325 and the strength of Gorilla Glue is what harmed these adhesives' chances of being selected.

Neither of the above methods was utilized in the formation of the pressure sensor seal. Rather a brass pipe ¼" threaded pipe formed the connection between the pressure sensor and the medical tubing.

Final Prototype

The device and the LabVIEW circuit are fully functioning for the first time. The device consists of a syringe held in place by an adjustable gun, which can be used to either inject or take back in the saline inside of the syringe. When the saline leaves the syringe, it flows into a dilation balloon and the pressure and volume of the balloon are measured. Both the balloon and the syringe elements of the device are easily replaceable. Currently, the prototype uses the Utah Medical pressure sensor along with a linear potentiometer to obtain the pressure and volume readings. The AST pressure sensor proved to be extremely difficult to use, and so as a temporary solution, the Utah Medical sensor was used. After testing with this sensor, it was found that it could withstand pressures of up to 5.5 atm, which far exceeded the 1 atm pressure which was originally thought to be its maximum. The 5.5 atm pressure range must be expanded in the future, but for the current state of the project it was an adequate range to allow testing. The output from this sensor is on the order of millivolts, and therefore has to be amplified. A circuit to perform this amplification is used.

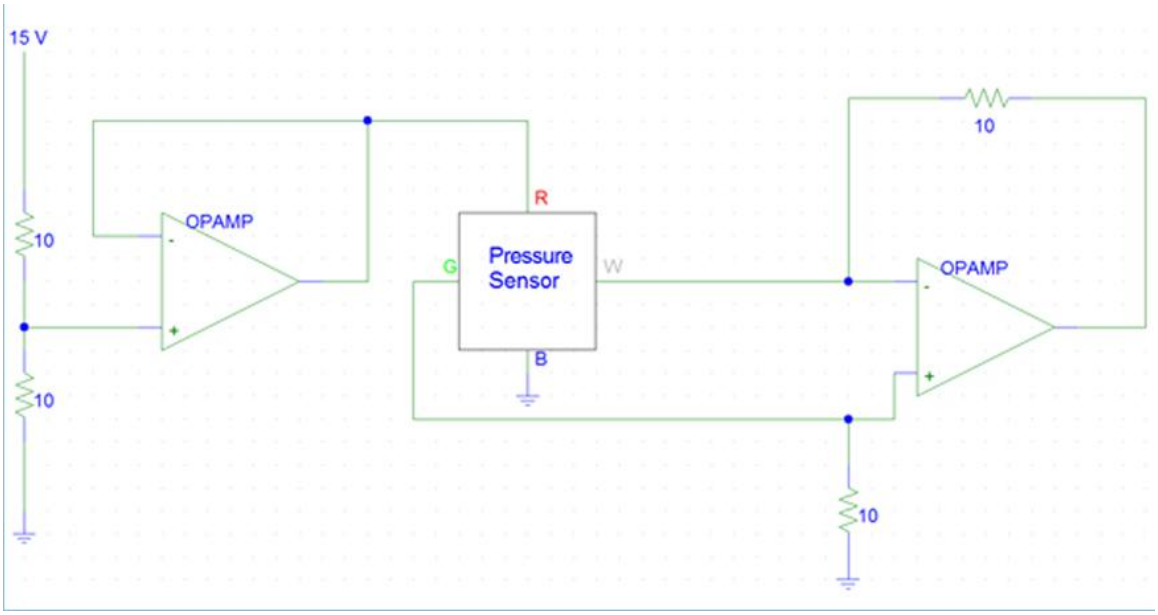

Figure 8. The amplification circuit used for the Utah Medical pressure sensor.

The outputs of the pressure sensor and the linear potentiometer are currently attached to separate channels on a National Instruments Educational Laboratory Virtual Instrumentation Suite (ELVIS) device. In the future it will be necessary to replace this with a portable A/D converter. From here the signals are analyzed by LabVIEW. The software program was configured to capture the signals using a Data Acquisition element. When placed in the LabVIEW block diagram, the element processes the input signals. The number of input channels can be selected and the sample rate can be set to capture at a rate fast enough to read all the data points. From here, the signal is split into two, one from the pressure transducer and one from the linear potentiometer. In order to convert the voltage signal to the correct units of volume and pressure, the signals were run through a mathematical operator. The operators were assigned a constant that corresponded to the number of volts per milliliter or atmosphere. These calibrated readings create an accurate graph when testing the device. The LabVIEW software was created to display a curve with volume in mL on the x-axis and pressure in atm on the y-

axis. A while loop is also used so that a continuous curve is generated, instead of just the current point being processed.

Testing

To test the device, the team used several mock esophagi constructed out of liquid latex. This material was determined to most closely model real human esophagi by previous groups. They were constructed by wrapping wax paper around pipes with different diameters. The thickness of each esophagus was also varied by applying varying layer amounts of the liquid latex. Eight esophagi were constructed in total. Unfortunately, only four of these esophagi were capable of production graphs. The other four esophagi had diameters that were too large for the balloon sizes the group had. The esophagi tested were labeled 5, 6, A and B. They had thicknesses of 1.21 mm, 0.94 mm, 1.58 mm and 1.02 mm respectively and diameters of 15.02 mm, 20.28 mm, 16.05 mm and 8.21 mm respectively. The first step was to calibrate both the pressure sensor and the linear potentiometer so the output voltages could be converted into atmospheres of pressure and milliliters of saline. This was done by hooking the pressure senor up to a blood pressure gauge. The voltage reading was taken at 20 mmHg intervals and the relationship was graphed as seen below.

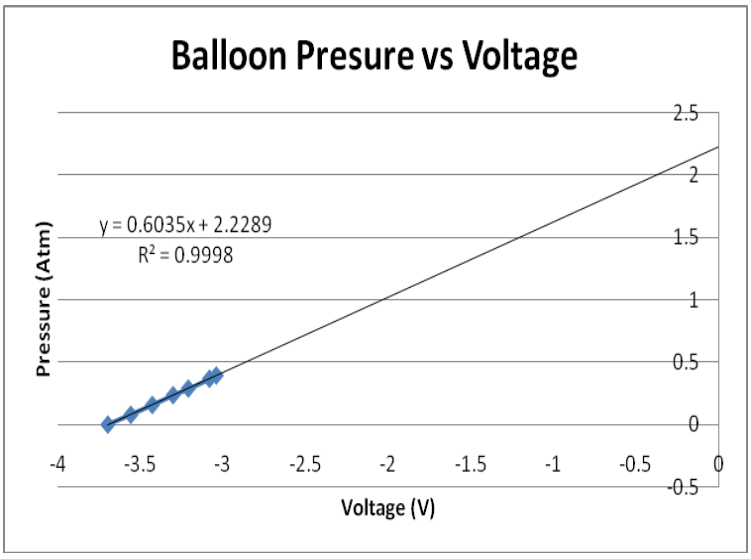

Figure 9: The calibration data for the pressure sensor.

The voltage at zero pressure was not quite zero thus the y-intercept is not zero. The relationship is linear thus it can be expanded to all pressures that may be passed through the sensor. These readings were also compared to the analog pressure gauge that exists on the syringe, and they were very close to the computer generated readings. The linear potentiometer was calibrated in much the same way with voltage readings being taken for every 5 mL of saline that was pushed in to the balloon. The data for this is represented below.

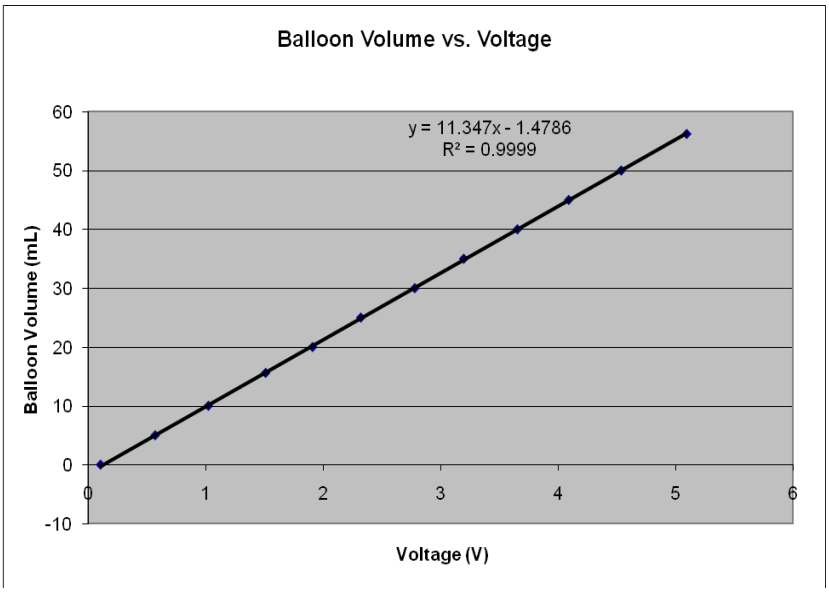

Figure 10: The calibration data for the linear potentiometer.

This was also a linear relationship with a nonzero voltage for zero milliliters of fluid. These relationships are amplification specific so they would need to be updated if the amplification of the differential operational amplifier was changed or a different pressure sensor was used.

With these relationships entered into the LabVIEW VI, the testing could begin. The same balloon was used for each esophagi to keep the procedure the same for each test. The balloon was inserted into the esophagi and inflated with all the contents of the syringe. A screen shot was taken of the LabVIEW graph and the data was plotted in an excel graph for later analysis.

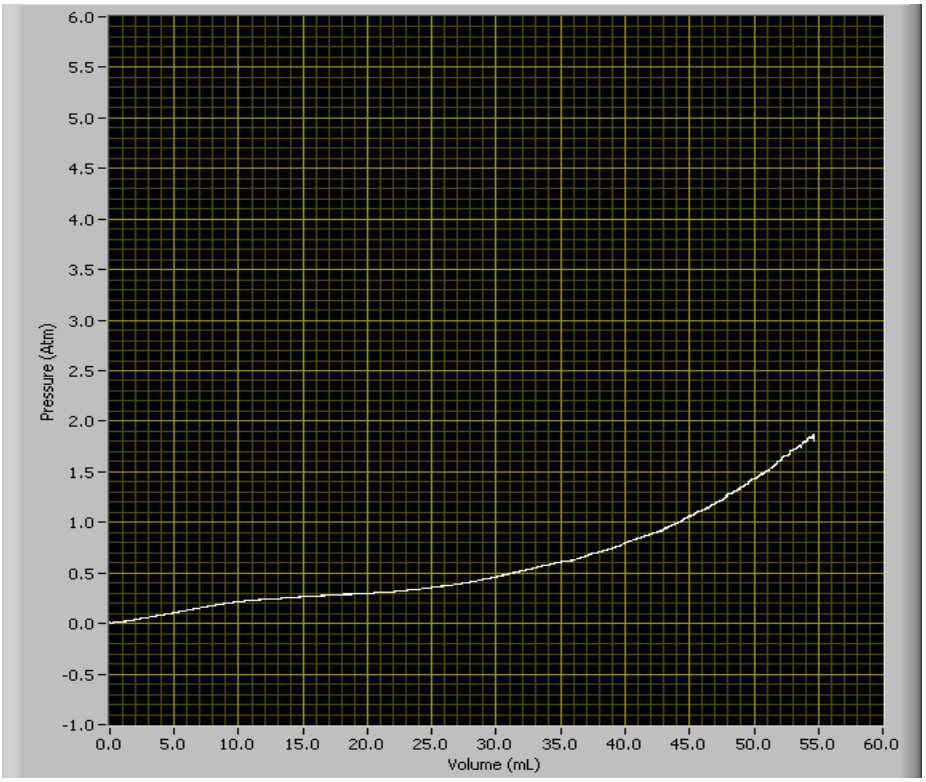

Figure 11: The real time volume graph generated with one of the mock esophagi. It would be visible to the clinician during the procedure so they could monitor the pressure and volume.

The procedure was carried out on all four esophagi explained above. The resulting composite graph is shown below.

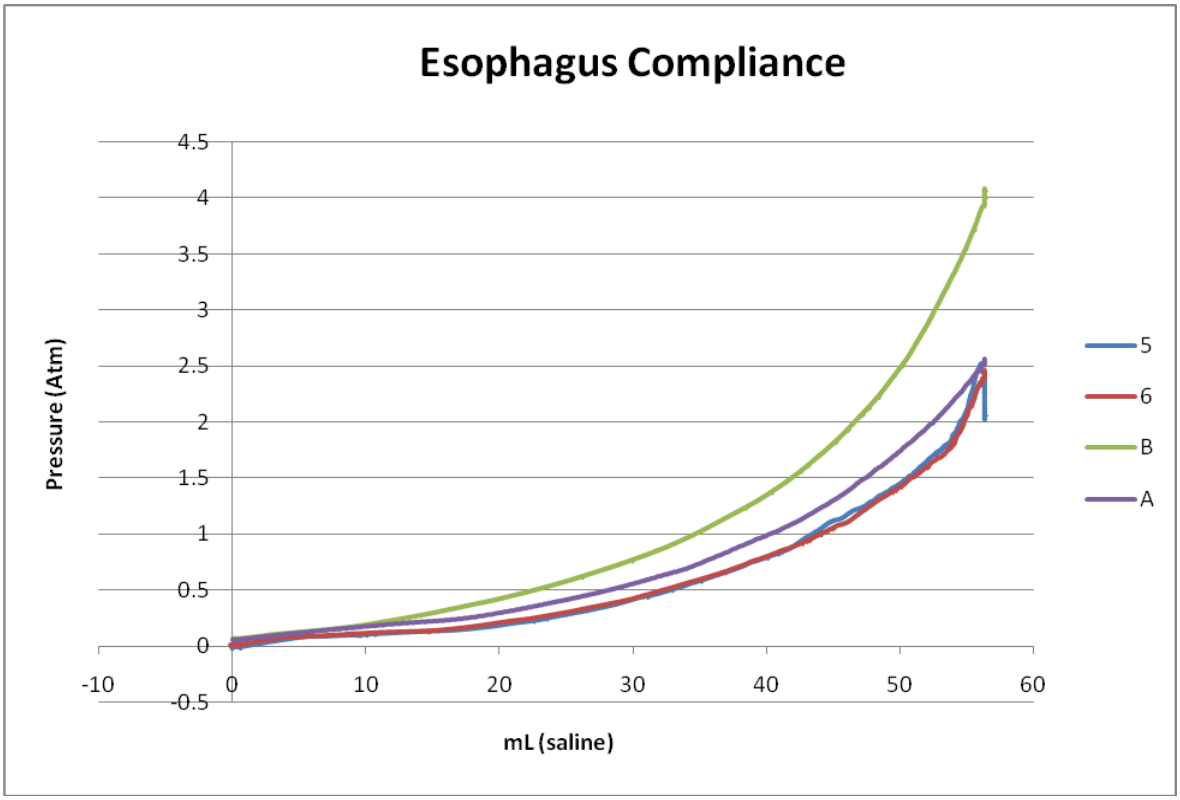

Figure 12: Compliance data from esophagi 5, 6, A and B.
Esophagus 5 had a thickness of 1.21 mm and diameter 15.02mm, esophagus 6 had a thickness of 0.94 mm and diameter 20.28mm, esophagus A had a thickness of 1.58 mm and diameter 16.05 mm, and esophagus B had a thickness of 1.02 mm and diameter 8.21 mm.

The graph suggests that there indeed is a relationship between stricture size and compliance. As the diameter of the mock esophagi decreased, the slope of the compliance curve increased, indicating a decrease in compliance of the esophagus. In the same respect, as the diameter was held nearly constant and the thickness of the esophagi was increased, the compliance curve slope also increased, indicating a decrease in compliance. The difference in the compliance curve was noticeable even when the dimensions of the esophagi were varied by less than a millimeter. This suggests that real esophageal strictures could be characterized by the shape of their compliance curves.

These results are promising for the future and justify the collection of data from a wider population of animal and human models.

In order to test the future possibilities of the perforation alarm, an esophagus was perforated and the graph was recorded. The largest balloon was inserted in the smallest diameter esophagus and inflated to a maximum. The graph and the esophagus were watched for signs of perforation. As visual evidence of esophageal perforation occurred, there was noticeable drop in pressure on the compliance graph. The pressure then built until another area of the esophagus perforated, which is shown as the second drop in pressure. The point of pressure drop must be analyzed in the future for its possible use in a perforation alarm.

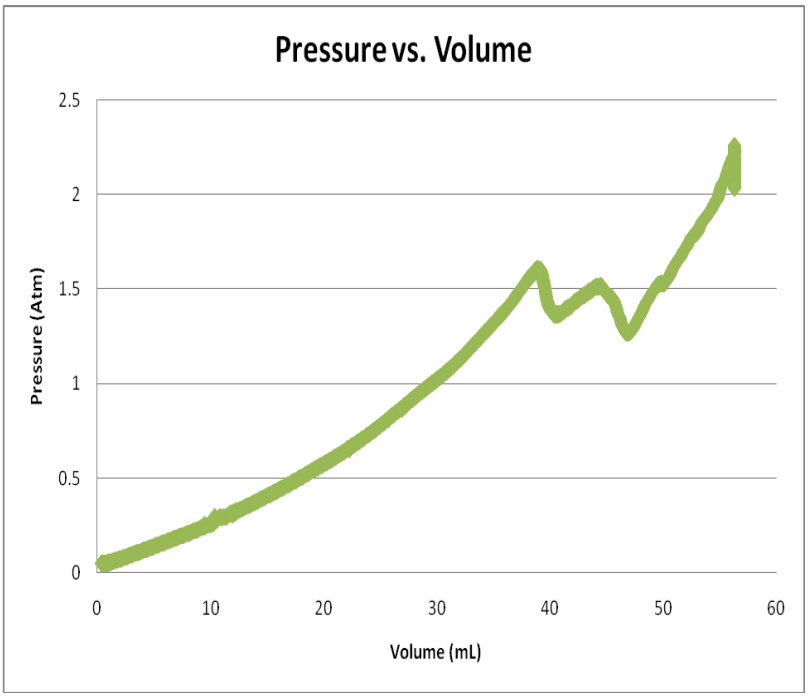

Figure 13: The graph shows the perforation of esophagus B. The drops in pressure represent tears in the esophagus.

Further testing of this device should focus on generating curve when the filling of the balloon is not constant. When this was tested, there was a spike in pressure that fell down to a constant pressure, making the compliance graph very jagged. This will complicate the addition of a compliance alarm. Future work should focus on a possible

filter to record the maximum pressure obtain by the pressure spike and one that records the minimum pressure that the graph returns to after the spike. These graphs could be graphed together for the surgeon to watch and an alarm could be calibrated for both. Otherwise, a motorized syringe gun should be explored to apply a constant rate of filling to produce a smooth curve.

Future Work

As the design has approached the final stretch in prototype development, the last few steps to be taken have been identified. A fundamental challenge yet to be accomplished includes purchasing a pressure sensor that can withstand ten atmospheres of pressure. This pressure allotment was suggested by the client as it is above the maximum pressure feedback observed during dilation procedure. The sensor employed within the last weeks of the semester was only suited for five atmospheres and required the creation of a supplemental operational amplifier. Utilization of the initial AST sensor would be ideal as it contains an internal voltage amplification system. However, further correspondence with the sensor company may be needed and the wiring schematic better deciphered as to prevent continuous damage of more sensors.

Along with obtaining a new pressure sensor, a LabVIEW compatible analog-digital converter will need to be utilized. This converter, once configured to the hospital laptop, will allow computer-device communication and enable the collection of compliance data. The converter will permit elimination of the desktop computer and the use of a more accessible and convenient laptop. The current PMD model is not cooperating with LabVIEW as the product description implied it would. Further research into a cost-

effective, practical converter would be needed. Potentially, a wireless converter could be used as to optimize ease of use and organization.

As to further simplify the device, incorporating and condensing the pressure sensor and power supply into a compact form for the hospital setting would be needed for practicality and successful marketing.

Through testing, it was realized that using saline syringe gun, instead of one steady pump, created a very noisy compliance curve. Ideas of making the syringe motorized as to eliminate the rapid, dramatic pressure changes and create a more controlled procedure have come to notion and should be further deliberated. Creating this device would not only make the compliancy curves easier to distinguish but it would decrease the amount of variables in the dilating procedure.

As the main goal of this entire project is to compile and study compliance curves of esophageal strictures as to be able to predict and prevent the perforation of the esophagus lining, the last design hurdle to achieve is this safety mechanism. Developing an alarm system, sensitive to specific compliancy curve changes and trends that could stop dilation or even automatically deflate the balloon upon the alarm activation would be on track with initial goals of this project.

Finally, extensive testing on animals and humans will be needed in order to develop a library of compliancy curves so patterns can hopefully be recognized as to help in the prediction of particular esophagi mechanical properties. This collection of data could be intertwined with the development of a perforation alarm.

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Appendix

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Device for Dilating Esophageal Strictures

Function: The current prototype is designed to measure the tissue compliance of an esophageal stricture during balloon dilation. A syringe gun is used to inject saline in a balloon. As the syringe is depressed, a sensor attached to the side of the gun and to the top of the syringe measures the change in volume. The potentiometer measures the change in volts as the arm of the sensor gets shorter. The pressure sensor is attached at a T-joint at the end of the syringe. Saline is then able to go into the pressure sensor and the balloon. The two sensors are attached to a computer, which can store the data. The data is collected, analyzed, and displayed in real time using the LabView software. The graph measures pressure versus volume which is tissue compliance.

Client Requirements: The client has three goals for the project. The first goal is to gain approval for human testing. This requires writing an IRB protocol and gaining approval from the IRB board. The second is to design an alarm program that will accompany the software to alert the doctor and nurses of perforation of the esophagus. The last is to make the design aesthetically pleasing. This will get the device ready to be used in a hospital setting. This includes putting the sensors in a plastic casing and binding the wires into a single wire.

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:* The data recording will be added on to a device that is already in common use in hospitals. The addition of the sensors must not interfere with the procedure and should be capable of being implemented in any GI procedure room in the country. The device must measure the full volume of the syringe, which is 60 mL. The device must also read up to 10 atm of pressure.

b. *Safety:* The sensor device is essentially a no risk addition to the procedure. The operation is already being done and the device only measures the surgery and does not change it.

c. *Accuracy and Reliability:* The pressure and volume sensors need to be able to make a smooth graph that is readable to the operating team. The device should be significant to 1 significant figure after the decimal.

d. *Life in Service:* The sensors will be good for the lifetime guaranteed by the manufacture. The syringes are replaced as needed readily from hospital supply. A new balloon dilator is used with every patient.

e. *Ergonomics:* The only restriction on the device is the length of the wires connecting it to the computer and the force needed to pull the trigger of the syringe gun.

f. *Size:* The device has to be able to be held in one hand or mounted and capable of being moved around the operating room.

g. *Aesthetics, Appearance, and Finish:* The final product should be similar in color and texture to the syringe gun the sensor is mounted on.

2. Production Characteristics:

a. *Quantity:* The current goal is to produce one prototype. The future goal is to have the device available and in every GI procedure room in the country.

b. *Target Product Cost:* The materials for the sensors cost around $100. The syringe gun is the most expensive of the prototype at around $500. The syringe and balloon dilator are bought in mass quantities and are disposable.

3. Miscellaneous

a. *Standards and Specifications:* With one of the goals to begin human testing, approval from the UW-Madison Institutional Review Board will be necessary to incorporate the device into the procedure.

b. *Patient-related Concerns:* All team members will need to be HIPAA certified to work with the data collected. Each patient will be assigned a number and the list of the names and numbers will be kept inside a locked box where only the doctor can access it. People working with the data will only be able to see the number of the patient.