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. The objective of the client and the team is to create a device that can measure the compliance of esophageal strictures. At this time, a linear potentiometer and pressure sensor record the volume and pressure of saline in the balloon. This data is then displayed on a real time graph using the LabVIEW. The focus of the current work is adding a compact and affordable labjack and creating a seal between the pressure sensor and its adapter capable of withstanding ten atmospheres.

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 the acidic 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 25mm to 10-22mm[3]. Esophageal strictures are treated using balloon dilation, in which the strictures are slowly stretched

through a radially inflation 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.

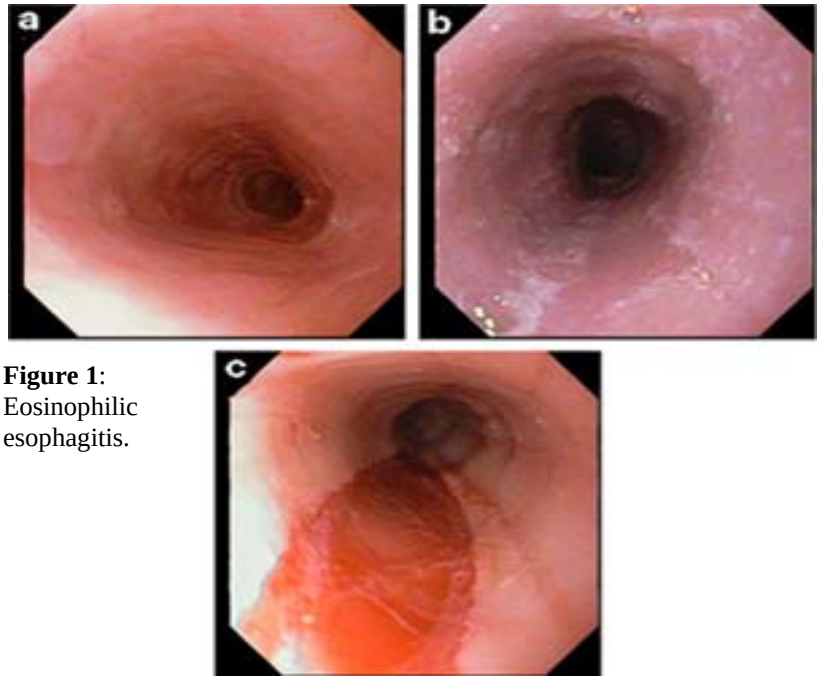

Figure 1: Eosinophilic esophagitis.

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 dilating radially thus reducing the risk of perforations [3]. Our client uses balloon dilation and specializes in this area, but admitted that even in his department at the UW hospital 1or 2 patients are perforated each year during this procedure. This rate may appear low at this clinic, but in smaller areas, where clinicians are not as specialized nor have as much

experience, the number of perforations increases. A long-term goal is to implement a real-time pressure volume compliance curve with the current equipment, to alert the clinician to an upcoming 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. The objective of the client and the team 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 the software with which it runs must be able to perform in order to properly monitor what is happening during the esophageal dilation procedure. The basic function that it must perform is to measure volume of saline that is being injected into the dilation balloon and the pressure the balloon exerts on the esophagus. It must then take this data and create a displayable tissue compliance curve in real time, which can be monitored by the clinician ensure that the procedure remains safe. A sufficient

sampling rate of 1Hz is necessary to create the real time compliance curve. Therefore the resolution of the analog digital converter must at least be 4 bits.

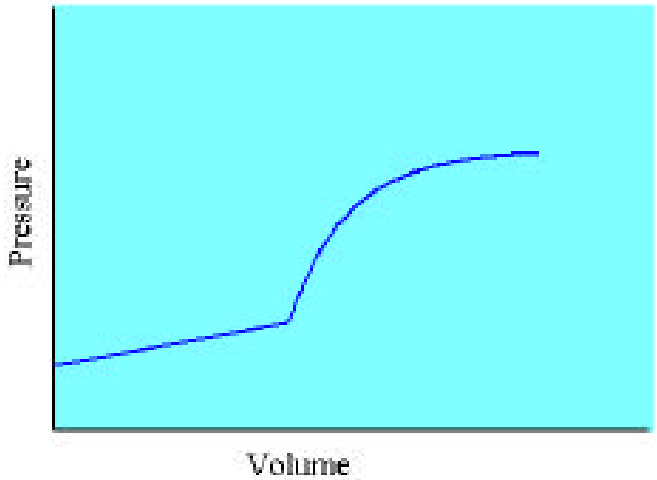

Figure 2. This example compliance curve shows the ideal curve that our device will be able to obtain. The sharp increase in the slope of the curve occurs when the balloon contacts the walls of the esophagus.

This would be the type of output the clinician would see while performing the operation. 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. This eliminates the need for additional funding for new expensive equipment. With the

addition of the labjack for a more compact design, the device becomes less bulky and more convenient for use in an 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.

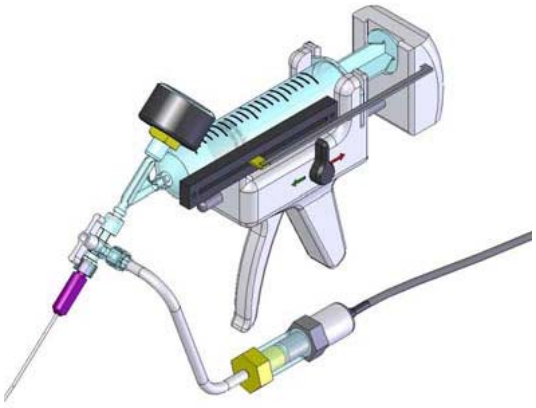

Figure 3. The device shown with linear potentiometer, pressure transducer, and disposable syringe.

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.

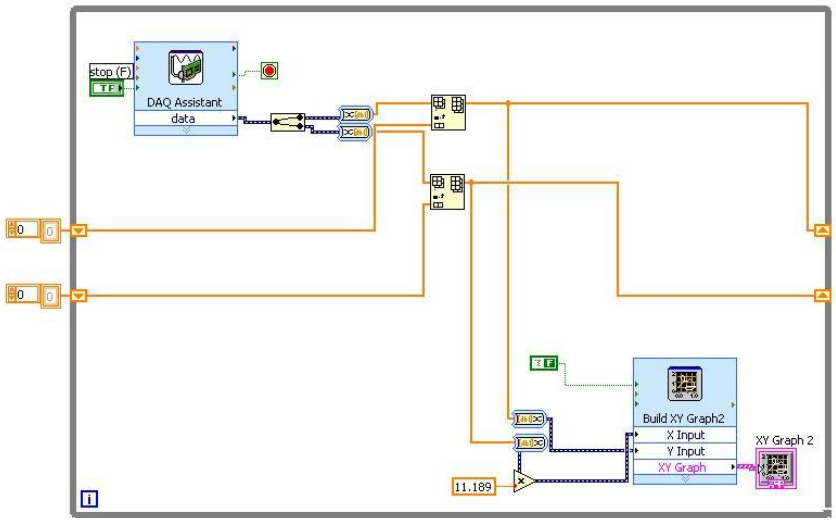

Figure 4. LabVIEW circuit which takes in two inputs and graphs them.

Lab Jacks

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 data sampling rate 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 device is semi-expensive at a price of $130. If a less expensive option can be found with the same attributions, it should be looked at first. Also, the device does not supply a -5V[5]. The pressure sensor needs both a plus and negative 5V source to run. The lab jack 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 lab jack option 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. But again, like the first lab jack, 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[6]. 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. For initial testing purposes, the function of each pin could be written on to the device but in the long run, it would be necessary to have a schematic of the pin setup in every hospital room. If the sheet were to become misplaced, it could ruin data logging for several procedures until the device could be fixed.

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 in wireless data transmission would have to be evaluated. If the esophagus was to perforate, the transmission of this data would need to be instantaneous so the procedure could be stopped. Regardless of the delay rate, this device is well out of the budget for this project, with a cost of around $500[7]. In the continuation of this project in future years, when more funding is possible, this should be a considered option.

Design Matrix

In order 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 labjacks.

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 [8].

Option 2

For the second option, we looked for a sealant that would be more readily available and still get the job done. 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 [9].

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 [10].

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 much it matched to what was desired. 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.

Future Work

Now that the solutions to the design problems have been solved, progress should come more quickly in the upcoming weeks. Now that the connection between the pressure sensor and the adapter can be strengthened to withstand 10 atmospheres, focus can be shifted into figuring out why the pressure sensor is not working properly. Currently, the sensor does not respond to the pressure changes of the syringe. Correspondence with the sensor manufacturer will be necessary in determining whether the sensor is broken or if there is some miscommunication in the interpretation of the sensor documentation. Depending on the outcome, a new sensor may need to be purchased. Although, the

potentiometer has been calibrated previously, poor connections have resulted in re-soldering the circuit requiring this calibration to be checked. Before continuation, the relationships of the potentiometer and pressure sensor must be calibrated to attain reliable results. LabVIEW must successfully be applied to the hospital's laptop and tested with the current LabVIEW and circuit. Following successful testing with the laptop and the current circuit, the chosen labjack must be configured with the hospital's laptop and tested with the LabVIEW circuit.

After all these components are working and have been calibrated, testing can begin. First, tests should be run with the latex esophagi replicas to see how the graphs vary with different thicknesses. The thicknesses of the esophagi are altered by the number of layers of latex applied during their construction. This testing should reveal distinct curves for the varying thickness and compliance of the esophagi. These results will be of use when testing extends to live dilations. After gaining IRB approval, comparison of the curves from the latex esophagi and the curves obtained from human testing will aid in future research. Comparison will hopefully lead to understanding how each stricture varies and the maximum pressure each stricture can take without rupturing the esophagus.

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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.