Esophageal Stricture Compliance Measuring Device

Biomedical Engineering Design 200/300

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Abstract

Esophageal strictures occur in the lower esophagus just above the cardiac sphincter. The main cause of strictures is acid reflux disease but they can also be caused by cancer and genetics. Larger strictures cause the opening of the esophagus to shrink, making difficult to swallow. The goal of this project is create a device that can measure the compliance of esophageal strictures by measure the pressure of the stricture against the dilation balloon and the volume of liquid inside the balloon. LabView will be used to design a program that can display a real time pressure vs. volume graph from which compliance can be measured. In the future, this data will be used to analyze different esophageal strictures and better understand how they form and work.

Background

The esophagus (Figure 2) is the tubular structure connecting the throat to the stomach. A specialized muscle called the lower esophageal sphincter (LES, Figure 1) and located at

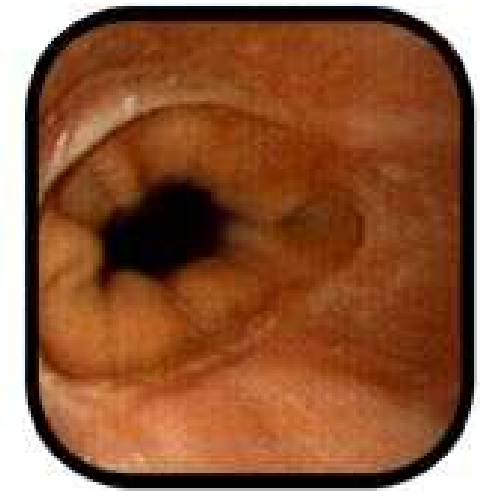

Figure 1: Lower Esophageal Sphincter (from:http://www.gicare.com/pated/eiegnmle.htm)

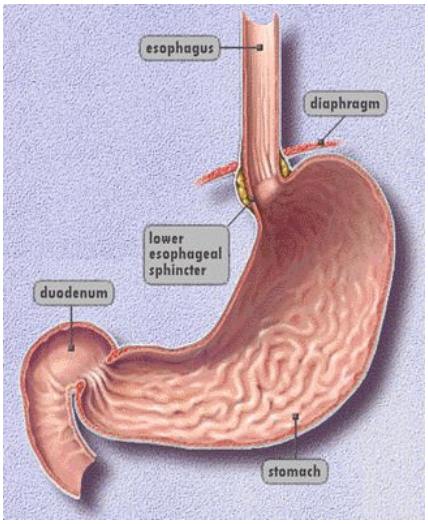

Figure 2: Stomach and Esophagus (from: http://intmed.muhealth.org/gast/patient_resource/anatomy_function/esophagus.html)

the distal end of the esophagus regulates the

passage of food and liquid into the stomach. When working properly, the LES relaxes to allow foods and liquids to pass into the stomach and then contracts to prevent stomach acids and the digested food to move back up the esophagus.

Occasionally, the LES fails to contract properly and allows digestive enzymes and stomach acids to reflux into the esophagus. This acid reflux damages the tissue of the lower esophagus. When damage occurs frequently, repeated healing cycles cause scar tissue to build up in the esophagus. This scarring causes a narrowing of the esophagus called an esophageal stricture (Figure 3). About 70-80% of esophageal strictures are caused by this type of gastroephageal reflux (Vasudeva, 2006). Other causes of these strictures include the ingestion of corrosive substances like cleaning solution, damage caused by endoscopy, and infection by bacteria or viruses, but each of these accounts for only a small fraction of stricture occurrences.

A person with an esophageal stricture will experience some difficulty swallowing, called dysphagia. In mild cases, this dysphagia is limited to the swallowing of solid foods, but in more severe cases even swallowing liquids can be extremely painful.

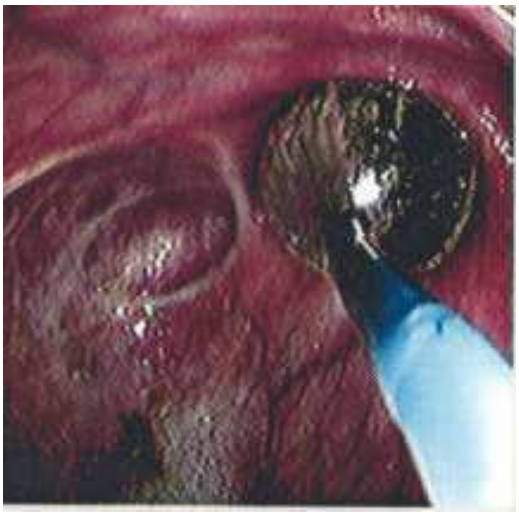

Figure 3: Balloon Dilation of an Esophageal Stricture

The most common treatment method for these strictures is called balloon dilation (Figure 3). This procedure utilizes a balloon attached to a syringe via a narrow plastic tube. The balloon

is pushed through the esophagus and into the narrow stricture opening. Saline solution is then delivered to the balloon from the syringe to gradually widen the area of the stricture. Typically, the diameter stricture is widened anywhere from 5-20mm (Vasudeva, 2006). Though this procedure widens the stricture, there is a large rate of stricture recurrence, and any single patient may have to undergo this procedure many times in his or her lifetime.

Most of the time this procedure is safe, but in some cases, the dilation can cause a perforation of the tissue of the esophagus. These cases of perforation can be very dangerous as they can lead to infections and even death. A study of the compliance (the change in volume per unit of applied pressure) of the esophageal stricture could provide valuable insight into the kinds of applied pressures that generally cause perforation. If compliance could be measured effectively, these dangerous cases could be minimized or even eliminated.

Problem Statement

Little work has been done with the compliance of esophageal strictures. If more was known about the compliance of different size strictures, doctors could categorize them and develop trends that would lead to more efficient treatment options. Currently, there are no devices on the market that measure 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. The output of the device should provide a real time graph of compliance that can be viewed during the procedure and also be capable of altering the procedure team to any perforation of the esophagus that requires immediate action.

Design Requirements and Constraints

The device and the software used to display information while using it require some capabilities which are critical when monitoring what is happening during an esophageal dilation surgery. Quite simply, it must measure volume of saline that is being injected into the dilation balloon and also the pressure the balloon exerts on the esophagus. With this, it must then graph in real time these results, creating a tissue compliance curve that can be used by the physician to maintain a safe dilation process.

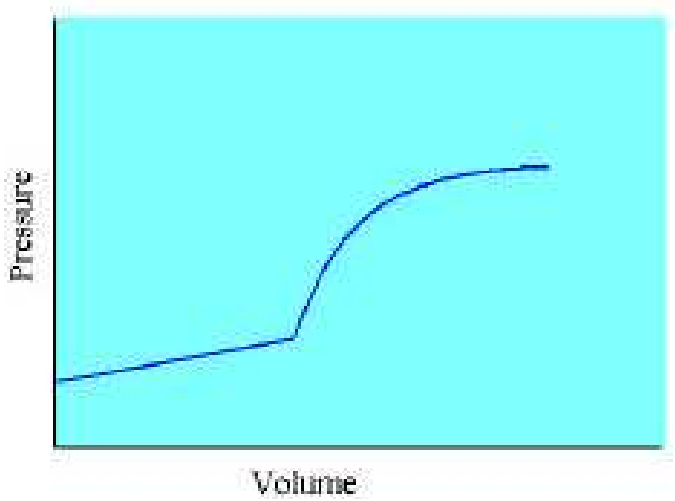

Figure 4. This graph shows an example curve with volume and pressure measurements. The sharp increase in the slope of the curve occurs when the balloon comes into contact with the walls of the esophagus.

This curve is an example of what our software may display to the physicians in real time. Eventually, the compliance data should be accurate to three significant figures past the decimal.

Other design requirements have to do with maintaining the simplicity of the procedure for the physician, and not adding on to the process of dilation that they are already

performing. This means that the device is an addition to the procedure, and will not change what the doctor does at all, just give more information about what is happening during the procedure. One thing that the design must be capable of doing is to inform the physician of a perforation in the esophagus, and provide a warning to stop immediately. This adds safety to the procedure. In addition, the software must be able to be run on the computers already being used in hospital GI units. This eliminates the need for hospitals to spend money on new equipment when it is possible to use what they already possess. Finally, the design needs to be able to be easily used in a hospital setting. This means that it must be compact as to not get in the way during surgery, and also it must be aesthetically pleasing for when it becomes commercially available.

Though safety is usually a major issue when dealing with devices that collect data on humans, it is not a large factor in the design requirements. This is simply because the data collection does not add any more risk to the patient. The dilation surgery is already being performed, and the addition of a data collection device is just providing means to analyze the surgery as it is happening. Any risk from contamination or from damage to the esophagus from the balloon inserted is a result of the surgery itself, and not from the device.

Design Option 1: LabView

LabView is a software program developed by National Instruments for graphing, measuring and analyzing. It uses an image based programming language where the user chooses the desire function for a menu and drags it onto a back panel. The back panel is used for designing the program while the front panel displays the actual program,

including graphs and controls. The program also contains linear operators that can convert the signal inputs into different units and then display these converted units in a graph. LabView also has the ability to filter the incoming signal and display the graph on the filtered information.

LabView has many advantages that would help with the project. The first is its ability to graph in real time. The client has specified that the data must be displayed in real time so he can view the data during the procedure and have a warning of sharp decreases in slope to alert him of a perforation of the esophagus. Along with this, LabView can graph two inputs on the same graph: one on each axis. Even if the program did real time graphing, it would be of no use if it could only graph on input at a time. Secondly, the program can convert easily from volts into units of pressure and volume. This is important because nurses and doctors will not have to do any converting in the procedure room or after the surgery is complete. The graph can be printed as is and studied without needing to do many, time consuming conversions.

LabView's disadvantages lie in the actual writing of the program. While it is image based and no computer code language is needed, the amount of images and programming options is large. The knowledge assumed of the programmer is higher than that of a second or third year undergrad with no programming experience. Thus, the amount of time needed to spend learning the program is great and may be too much for the scope of this project. A meeting with Amit Nimunkar was held to discuss LabView and how to go about writing out program. After the meeting, it seemed that it would be possible to write

the program. National Instruments is also teaching a class on LabView in the coming week which will be helpful in learning to use LabView properly. This will help immensely in writing the program. The only other disadvantage of LabView is its cost of $1199 for base, $2399 for full and $4099 for professional. If it is necessary to buy separate licenses for each computer being used, it could become quite expensive. LabView professional may have an application distribution option that would allow one program to be purchased and then installed on many computers. This would be ideal for use in a hospital setting.

Design Option 2: BioBench

BioBench is software application program designed specifically for physiological data acquisition and analysis by National Instruments. It is used for graphing and analysis of data, particularly from the fields of the life sciences. The software is designed so that no programming language or know-how is required, and it is compatible on nearly any PC, whether it is a desktop or a laptop. A feature called "Playback Mode" enables the user to be able to watch any previously acquired data trends as necessary, which allows for deeper analysis of the data. Overall, the software is useful for acquiring, storing, displaying and analyzing data in the life sciences fields.

BioBench has some advantages that were considered in the decision making process. Something that is important to any potential users of the device would be the simplicity and amount of background knowledge required in order to work the software along with the device itself. BioBench is a turnkey application, which means that no programming is required at all. This is important because anyone could simply acquire the software

and begin collecting data immediately. Because a major goal of the project is to not interfere with the surgery being done by using complicated software, this is very advantageous. Also, another advantage to the software comes in the form of multiple inputs, and BioBench is capable of using sixteen input channels. For the device, two inputs would be necessary, one for pressure and the other for volume of saline displaced from the syringe. Though the device only requires two, the fact that BioBench supports sixteen is another advantage of the software. Perhaps the biggest advantage of this software is its affordability. The program runs at $995.00 for a Windows based application. However, this can be used on any PC, which is economically beneficial.

BioBench also has some disadvantages which were considered when choosing the final design. Unlike LabView, BioBench does not possess a unit conversion function. This is important because it cannot translate volts into units for pressure and volume. Doctors or nurses should not have to do this themselves, or have another other program to do it for them because that adds to the complexity of the surgical process, and again keeping the surgery as easy as possible for the physicians is very important. Also, BioBench may have a playback mode, but it lacks a graphing function. All data must be exported into Microsoft Excel and then may be graphed using that program. This means that real time graphing is not a possibility with BioBench. Because this is the client's main design requirement, the lack of the real time graphing feature is a major disadvantage for this software. Having to convert units with another program adds more complications to the dilation surgery, and not being able to detect sharp changes in graphs that may mean esophageal perforation immediately adds risk.

Design Option 3: Pasco

Pasco's DataStudio software is a tool for data collection and analysis. The software is designed to have "plug-and-play" data collection capabilities. Using Pasco's PasPort sensors and computer interface devices, one can connect a sensor directly to a computer and record data in real time. The software itself allows such manipulations as customizing scaling and displays, statistical data analysis, and importing and exporting data. This software and sensor technology is often used in introductory biology and physics laboratories to demonstrate principles of physical and biological principles.

Despite its ease of use and real time collection capabilities, there are a number of drawbacks that make Pasco's software insufficient for our purposes. First, the software is only capable of collecting from sensors manufactured by Pasco. Though the list of sensors they manufacture includes a pressure sensor, their pressure sensor is not usable for measuring liquid pressure. Also, though easy to use, the software lacks advanced programming capabilities that would allow us to program perforation warnings into the data collection process. Finally, the use of Pasco would require that all hospitals using our device purchase Pasco's interfacing system in addition to their software, adding an extra and ultimately excessive cost to our design.

Design Matrix

The design matrix (Figure 5) was created to aid in the decision making about what software program to use to write the program to graph volume vs. pressure. The categories were chosen based on the design constraints mentioned. Each category was given a weighting out of 100 total points according to its importance. Real time graphing

was given the highest weighting of the four categories because the completed prototype needs to be able to graph the information in real time. Inputs and unit conversion were ranked next in importance. If the program was not capable of working with the sensors of the prototype, then it could not be used, even if it could graph in real time. Ease of use refers to the writing of the needed program. This, and cost, where least important because they have less to do with the actual functioning of the software program. After adding together the scores of each software program, the design matrix indicated that LabView is the best program because it has the best real time graphing and is compatible with the inputs.

	Weight (out of 100)	**LabView**	**BioBench**	**Pasco**
Graphing Capability	70	70	10	60
Ease of Use	5	2	3	4
Inputs	10	9	9	0
Unit Conversion	10	8	1	6
Cost	5	1	2	5
Total	100	90	25	75

Figure 5: Design matrix of the three design options

Future Work

The future work of the project consists of a few main steps. The first is to complete the software program that is capable of graphing the two inputs on one graph in the desired units of volume and pressure. From work already done with LabView, graphs of the inputs from the pressure sensor and the linear potentiometer have been made. A standard curve was made from the readings of the linear potentiometer at volumes spaced ten milliliters apart. This will be used to convert volts into milliliters for the final volume vs. pressure graph. Along the same lines, the conversion of volts to units of pressure also needs to be done. The conversion from previous papers differs so new calculations will need to be made to determine the correct conversion factor. Investigate into the volume of liquid in the tube running to the pressure sensor from the t joint and how it might affect the reading of the graph needs to be researched. If so it will alter the data, the volume of liquid in the tube will need to be determined and added to the graph so that the graph can start at a zeroed point.

The next step is to complete the circuit that will be used to amplify the signals from the sensors and input them into the computer. The circuit will use an op amp to amplify the signal from the pressure transducer. The signal from the linear potentiometer will require no amplification. The correct level of amplification still needs to be determined for the pressure transducer signal. After this, it may be necessary to pass the signal through a filter to filter out any noise caused by the amplification or surrounding electronics. In the long run, after the desired circuit is designed, it will be necessary to have the circuit printed. This will reduce the overall size of the circuit, eliminate the excess wires, cutting

down on noise, and stop individual components from coming unplugged from the bread board, increasing reliability.

Next, the completed device will need to be tested. Previous groups have lain out methods to construct testing materials to determine if the sensors and graph work correctly. These include creating an imitation esophagus from liquid latex. The number of coats of latex will determine how hard to imitation esophagus is, mimicking different levels of compliance of a stricture. Standard curves can be produced for each coat of latex used. Once testing is done in humans, these can be compared to the graphs achieved to do further research. The base amount of pressure in the balloon as it is filled without exerting any pressure it will also need to be determined. If there is a significant pressure, this will need to be added to the equation for the graph to make it start as a zeroed amount. After completing this testing, it may be applicable to start testing in humans. Because the procedure is already in standard use and the addition of the data recording device does not pose any additional risk to the patient, it may not be necessary to first test the device on animals. A meeting with the client will be needed to go over the testing results and to determine the next course of action.

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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 distilled water 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. Water 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. Currently the data is stored in mV and needs to be inputted in a separate program after collection, such as Xcel to get output readings of mL or m^3 for the volume and Atmosphere or Pascal for the pressure. The readings can be stored on any computer that is capable of readings inputs from the sensors and running the BioBench program.

Client Requirements: The client has three goals for the project. The first 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. The second is to write a software program that can measure the pressure and the volume in real time and make a graph on the computer screen. An alarm program will accompany this software to alter the doctor and nurses to perforation of the esophagus. The last goal is to gain approval for human testing. This requires writing an IRB protocol and gaining approval from the IRB board.

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.
    - **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 3 significant figures 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.