Device for Dilating Esophageal Strictures

Final Design Report

28 April 2006

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TABLE OF CONTENTS

ABSTRACT:

The objective of this project is to construct a computer interface compatible with the Alliance™ II Inflation System and CRE™ Fixed Wire Balloon Dilator. The interface will collect esophageal tissue compliance data from esophageal dilations in the form of a pressure versus volume graph. This device should be low cost, safe, easy to use by the client, and capable of producing accurate data. The interface will help our client improve the effectiveness, safety, and speed of the esophageal dilation procedure, allowing patients to have better results with fewer return trips to the hospital. Our final design incorporates a pressure transducer and a linear potentiometer connected to a computer to generate a graphical display of esophageal tissue compliance. Due to difficulties in obtaining the linear potentiometer from AD Electronics, the testing of the final design still needs to be completed to check for accuracy.

BACKGROUND:

Problem Statement

The goal of our project is to develop a safer method of treating esophageal strictures. An esophageal stricture is a collection of scar tissue partially blocking the esophagus pathway limiting food flow and giving the patient a choking sensation. Currently, a pressurized balloon dilation method is used to break the strictures, but can lead to tearing of the esophagus. We intend to instrument the esophageal dilation system to obtain accurate measurements of balloon pressure and volume during dilation. The instrumented system and a computer-readout of the results would be available to the surgeon during the dilation. By measuring the pressure on the esophagus, the surgeon may avoid over-pressurization and prevent the tearing of the esophagus tissue.

Problem Overview

The design needs to be safe, meaning that it must reduce the frequency of esophageal perforations and emergency surgeries. This device must measure and monitor stricture compliance via a computer interface during the procedure. The dilating apparatus and computer interface must be easy to use and read. Also, this device must provide accurate and reliable information for every procedure. The balloon must be dispensable and low cost, while the inflating gun must be reusable.

Problem Motivation

The device would reduce the frequency of esophageal perforations compared to the current methods. By measuring the tissue compliance (the flexibility and resiliency of the stricture with respect to pressure and volume) of the stricture as the balloon is inflated, the procedure can be closely monitored as the pressure on the esophagus approaches the perforation point. This idea of a perforation point of the esophageal lining is not a known or defined value, but a device that could measure tissue compliance could

help define this point and reduce the number of perforations that occur during esophageal dilations. An audio-visual signal on the device will alert the doctor to abort the procedure to avoid perforation. Knowing the compliance of the stricture would also allow the doctor to adjust the procedure for a specific degree of compliance. If the doctor knows that the stricture is highly compliant, then the stricture can be safely dilated at a faster rate. A highly compliant stricture can also be dilated to a larger diameter without risk of perforation, therefore decreasing the number of procedures needed to fully dilate the stricture.

Esophageal Strictures

Esophageal strictures are a build-up of scar tissue that results in a narrowing of the distal portion of the esophagus (Figure 1). Strictures are relatively common, affecting two in every 1,000 people [7]. The most common symptom of a stricture is a feeling of choking. Several causes of esophageal strictures are benign fibrous tissue formation, achalasia (the inability of the sphincter muscles to relax), ingestion of caustic agents, gastrointestinal reflux, and cancer [9].

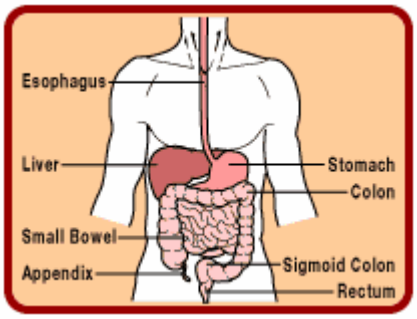

Figure 1. Diagram of the human esophagus anatomy [9].

Treatment for Esophageal Strictures

Treatment options for esophageal strictures are limited to surgery and dilation. There are several different types of surgeries that have been performed to remedy esophageal strictures. These include esophagomyotomy[1], partial or segmented esophageal resection, and mucosal fenestration[2] [2, 11]. However, these surgical procedures are complicated, time consuming, and risky. A more commonly used treatment for esophageal strictures is dilation. Dilating the esophagus involves the use of an inflatable balloon or rubber tube to expand the esophagus (Figure 2).

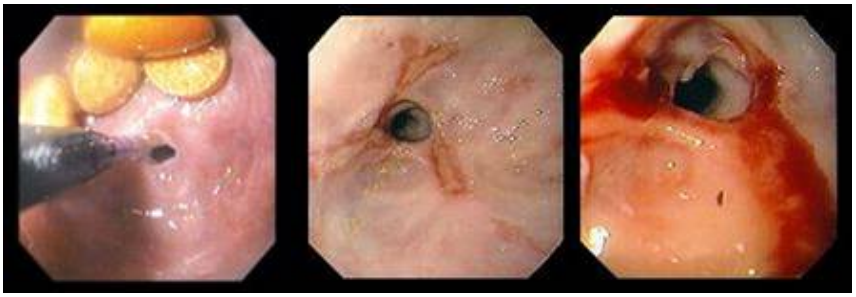

Figure 2. Dilation of a human esophageal stricuture using a balloon dilator [3].

[1] Treatment of esophageal achalasia by a longitudinal division of the lowest part of the esophageal muscle down to the submucosal layer.

[2] An opening in the membrane surface.

Esophageal Dilators

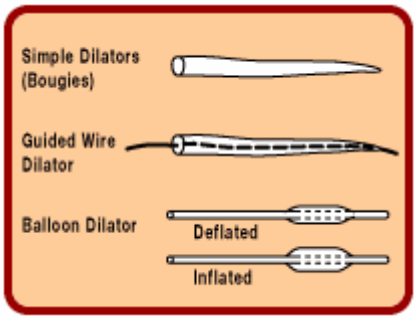

Figure 3. Different types of esophageal dilators [9].

Mechanical and balloon dilators are the two main types of dilators currently used in the procedure. Mechanical (push-type) dilators exert forces from both the top and the inside of the stricture opening [5]. A common mechanical dilator is the bougie dilator. Bougie dilators are simply dense rubber tubes that taper at one end and are hollow in the middle, allowing an endoscope to pass through into the esophagus. Other types of mechanical dilators are the Eder-Puestow and Savary dilators. These two dilators are inserted into the esophagus using a guide wire. However, the potential for perforation is increased by the use of the wire.

The second type of dilator, the balloon dilator, functions by inserting a collapsed balloon into the opening of the stricture and inflating the balloon to break the stricture. These dilators must either be passed over a guide wire or through an endoscope (also referred to as TTS for "through the scope"). Balloon dilators, unlike mechanical dilators, can be used for more complex strictures. Theoretically, these dilators can decrease perforation risks and dilate more intricate strictures since they only apply radial forces on the esophagus lining; mechanical dilators also use sheer forces that increase risk of perforation. Disadvantages to this method include higher cost and the reduction of tactile feedback, since the balloon could potentially go past the stricture unless an endoscope is used for guidance.

Stricture Size and Compliance

Little work has been done to learn more about stricture size and the effects of these various esophageal treatments on the diameter of the esophagus [6]. One study used radiological techniques to measure the stricture size, but the results showed that these techniques were only marginally more informative than using endoscopes alone [6]. Esophagrams[3] are typically used to determine the number, location, and length of strictures in the esophagus [8]. However, little work has been done examining tissue compliance in the esophagus or stricture size measurements made by the inflatable catheter balloon.

Design Constraints

The computer interface system must be compatible with the client's current device. Changes should be made with minimal alterations to the functionality and handling of the current device. This means that the added computer interface system must not interfere with the dilation procedure and should not require additional attention by the person performing the procedure. The device must be ergonomic, easy to use, and require

[3] A series of x-rays of the esophagus. The x-ray pictures are taken after the patient drinks a solution that coats and outlines the walls of the esophagus.

minimal training and maintenance. The computer interface must provide clear, accurate, and interpretable data in the form of a pressure versus volume (PV) graph.

All materials and components must be durable, secure, and must not be easily dislodged. Any materials enclosing the inflating fluid must be capable of withstanding pressures up to six atmospheres. The interface needs to be reusable and last for several years since the electrical and computer components are expensive. Materials and components must be able to undergo multiple procedures a day.

Additional constraints apply to any materials that will be inserted into the esophagus. They must be non-toxic, flexible, and functional inside the human body, which is normally a moist, acidic environment at 37 degrees Celsius. If the inserted parts are reusable they must be able to withstand either autoclave sterilization or another sterilization process. Furthermore, all device surfaces must be smooth and contain no sharp corners or edges, as rough or sharp surfaces will increase the frequency of perforating the esophagus.

Any electrical components used in the design must not harm the patient. For example, electric currents could pose potential shock and any wires must be concealed to prevent perforation of the esophageal lining. All electrical sensors and components must obtain accurate pressure and volume readings and display a smooth PV curve with minimal interference.

The completed device will need to be tested to ensure that it is safe for procedures on humans and that it produces accurate data. Before testing can begin, appropriate protocols and research proposals will need to be written and submitted for approval to the Institutional Animal Care and Use Committee (IACUC) for animal testing or the Human Institutional Review Board (HIRB) for human studies.

Current Device

Our client currently uses a CRE™ Fixed Wire Balloon Dilator (Figure 4) and the Alliance™ II Inflation System (Figure 5) purchased from Boston Scientific to perform esophageal dilation However, this current system does not provide any visual feedback on esophageal tissue compliance during the procedure. The client must manually record readings for pressure and volume from the inflation system, which can be tedious.

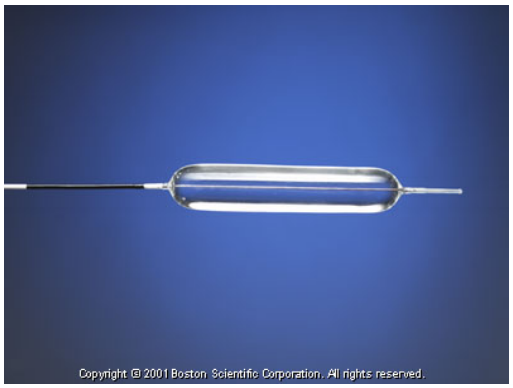

Figure 4. CRE™ Fixed Wire Balloon Dilator [4].

Figure 5. Alliance™ II Inflation System [4].

A biomedical engineering group from 2002 previously worked with our client on a similar project. The group's final design consisted of two syringes connected to each other (Figure 6). As one syringe was depressed, both syringes would displace equal volumes. The syringes were connected by tubing to a Sensym Inc. pressure transducer. One syringe was filled with water and was connected to a differential pressure sensor to measure the pressure inside the balloon. The second syringe was filled with air and hooked up to an absolute sensor to measure the volume change in the syringe. These sensors were connected to a 5-volt energy source and to ground. The Biobench interface system was then used to monitor the sensors. Their system was tested once, but the group was unable to differentiate between the pressure being recorded from the balloon and from the esophagus. Also, the pressure-volume graphs generated by their design were not very accurate. The generated graphs did not produce a smooth curve, showing that a lot of background noise was present.

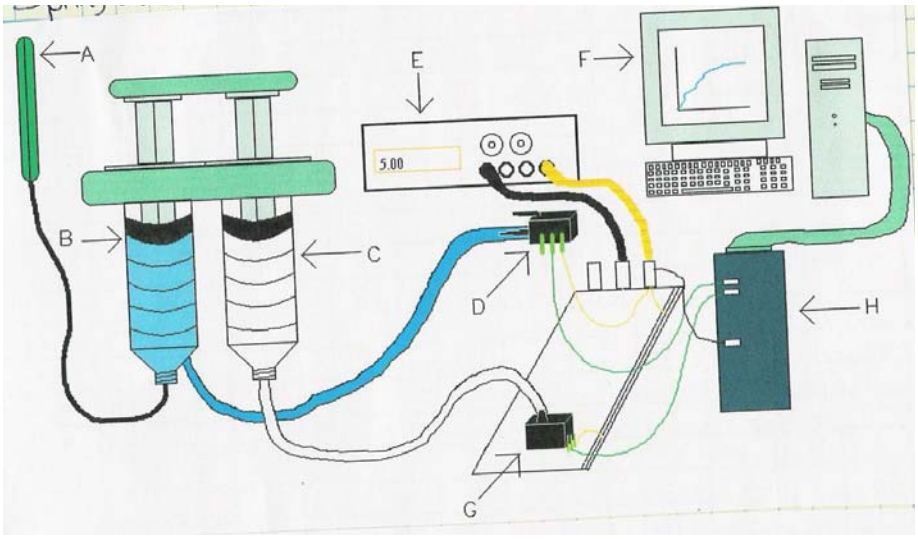

Figure 6. Schematic of prototype from Spring 2002 group: A=Balloon, B=Water-filled syringe, C=Air-filled syringe, D=Differential pressure transducer, E=Power supply, F=Computer output, G=Absolute pressure transducer, H=Biobench interface [10].

Competition

Dilation system competition is mainly limited to previous methods and previous research in the field. Older methods of dilating using Savary dilators are still practiced, but rarely. Our client has admitted to difficulty in receiving grant money for research on dilation compliance.

While compliance graphs have been created in previous studies, no device has been developed specifically for the automated computing of an esophageal compliance graph. Two different studies proposed a computerized graph for bladder compliance using a barostat and manometric catheters (Figure 7), but all of their data was manually entered [12, 13].

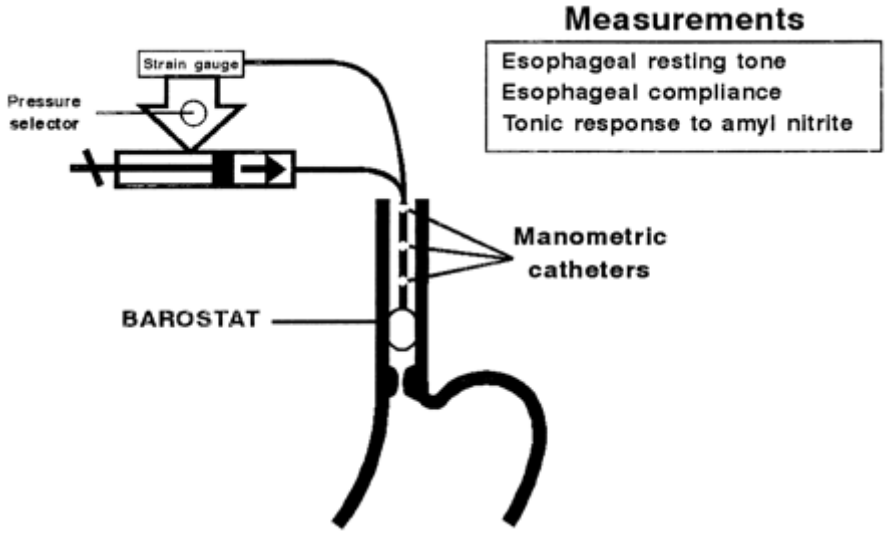

Figure 7. Diagram of the esophageal barostat and attached manometric catheters allowing simultaneous recording of tonic and phasic esophageal motor activity [12].

MATERIALS:

Our design for a compliance measurement device relies on the use of the inflation system and the adjoining catheter balloon [4]. The inflation system consists of a controlled manual injection mechanism, a replaceable syringe, and an analog pressure gauge. The balloon is attached to the injection end of the syringe and is the only part that contacts the patient's esophagus. A linear potentiometer is attached to the outside of the syringe to measure the injected volume. A rigid bar connects the slide of the linear potentiometer to the plunger of the syringe. Connecting barbs, stopcocks, and low compliance tubing are necessary to provide continuous, accurate input to the pressure sensor.

A pressure sensor (Model AST4100, American Sensor Technologies) is connected to the balloon using tubing and a T-piece. The pressure sensor can read up to 6.8 atm of pressure. In conjunction with the pressure sensor and linear potentiometer, an analog to digital converter (PMD-1208LS, Measurement Computing) interprets the information received. The computer supplies the 5+ Volt power requirement for the system through the converter. To interpret the digital signal into a graphical computer output, a LabView program is used to display the pressure vs. volume compliance curve.

FUTURE RESEARCH:

After completion of our design, an animal protocol and research proposal must be developed in order to proceed with testing. The animals used in testing will be cats or opossums, whose esophageal characteristics closely resemble the human esophagus. This testing must confirm that the device is safe, accurate, and capable of reproducible data. During the testing, we hope to find a relationship between esophageal compliance data and perforation.

ALTERNATE DESIGNS:

Linear Position Transducer

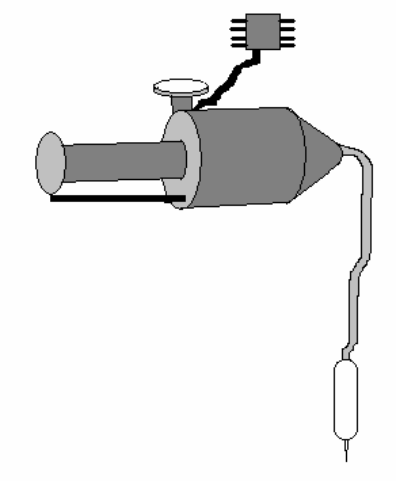

Figure 8. Linear Position Transducer.

The first design is the Linear Position Transducer (Figure 8). In this design, the plunger of the syringe would be attached to a linear position transducer. This transducer records the distance that the plunger moves with each consecutive push. Using the position data collected by the transducer, the change in volume can be found. A pressure transducer would be added near the pressure gauge on the syringe to record the internal fluid pressure. The pressure gauge is left intact as a fail-safe device. Using the positional data collected by both transducers, a computer interface program would generate a pressure versus volume curve, allowing doctors to see the pressure on the esophagus.

The Linear Position Transducer has several advantages. First, adding the pressure transducer requires little or no adjustment to the existing pressure gauge, allowing the user to verify accuracy of computer data. Additionally, this design would be easy for our client to use, produce accurate data, and be the relatively inexpensive. This design would also be feasible to construct. However, the only disadvantage to this design is that the linear position transducer may be bulky.

Flow Meter

The second design is the Flow Meter (Figure 9). This design would incorporate a pressure transducer by removing the current pressure gauge. The pressure gauge must be removed to create space for flow meter installation. The transducer would directly record the pressure into a computer interface program and eliminate the need for doctors to manually read the pressure. On the front end of the syringe a flow meter would be attached. This meter would record the flow of the liquid as it passes through the catheter, which can be converted to volume. The meter would also be connected to a computer interface to electronically record the flow in the syringe and balloon. Using this data, the program would generate a pressure versus volume curve.

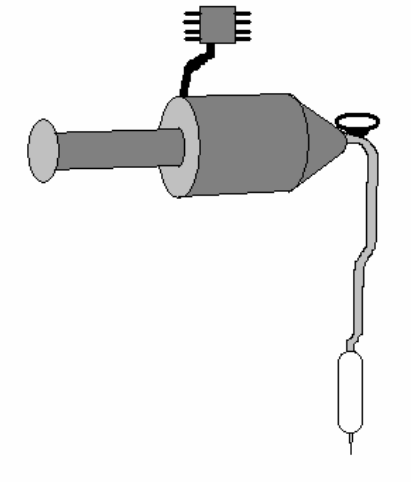

Figure 9. Flow Meter.

The device would be easy for our client to use

and produce accurate data. However, attaching a flow meter could reduce the durability of our prototype since the flow meter could be bulky and broken off from the device.

T-Piece and Ultrasonic

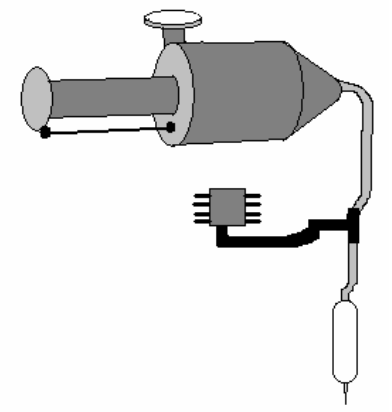

Figure 10. T-Piece and Ultrasonic.

The third design is the T-Piece and Ultrasonic (Figure 10). This design is similar to the Linear Position Transducer design; however an ultrasonic sensor would replace the linear position transducer. As the syringe pump is pressed, the ultrasound sensor would record the distance the plunger moves. This distance could be converted into volume of both the syringe and balloon using cross-sectional area. A pressure transducer would be attached to the tubing connected to the balloon, forming a T-piece junction. Once the data has been collected from both transducers, a computer interface program can generate a pressure versus volume curve.

Although the T-Piece and Ultrasonic design would produce accurate data and requires no tampering with the current pressure gauge, it may be difficult to securely mount the ultrasonic sensors to the device. Also, the sensors may not record accurate data at small distances.

Hand Click

The fourth design is the Hand Click (Figure 11). In this design, a pressure sensor would be added to the pressure gauge. This would electronically record pressure, as well as allow the client to view the pressure. There would be no attachment to record volume. The user would pump a known volume into the syringe each time the handle on the gun is compressed. After each volume increment, the hand click component must be pressed by the user to transmit the volume data to the computer.

While the device would record the pressure, the Hand Click design relies on the doctor to record the volume in the syringe and balloon at any known time. Furthermore, the volume and pressure data are collected incrementally and will not create a smooth, continuous PV curve. It would be the least expensive design, but it would not produce accurate data.

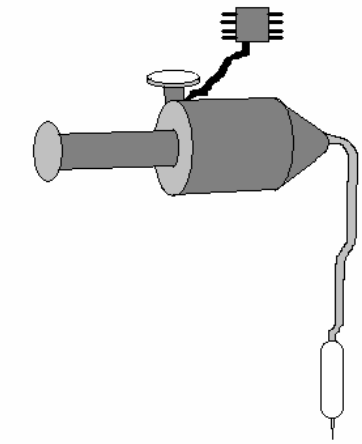

Figure 11. Hand Click.

DESIGN MATRIX:

In this design matrix, accuracy and safety were weighted the heaviest of all the design features because they are most important to the client. Each design was assessed

and given a point value for each category in the features column. As shown in the matrix, design one (the linear position transducer design) received the best score.

Feature (Possible Points)	Design 1	Design 2	Design 3	Design 4
Size (5)	4	5	3	4
Ease of Use (6)	6	6	5	2
Cost (12)	9	6	9	10
Accuracy (20)	15	15	15	5
Reproducibility (8)	7	7	7	3
Durability (10)	8	7	5	9
Aesthetics (4)	3	3	3	4
Feasibility (15)	14	5	10	14
Safety (20)	20	20	20	3
TOTALS:	**86**	**74**	**77**	**54**

FINAL DESIGN:

The final design uses measurements of balloon pressure and volume to monitor esophageal tissue compliance (Figure 12). It provides this feedback in the form of a pressure versus volume graph that will be displayed on a laptop computer. It incorporates aspects from both the Linear Position Transducer and T-Piece and Ultrasonic alternate designs.

The volume is measured by a linear potentiometer mounted on top of the syringe. The potentiometer slide will be connected to the back end of the gun by a rigid bar so that the displacement of the syringe plunger coincides with the displacement of the potentiometer slide. The change in distance measured by the potentiometer can than be multiplied by the cross sectional area of the syringe to obtain the volume injected into the balloon.

Pressure in the balloon is measured by a pressure transducer. A three-way, luer stopcock is inserted inline below the existing analog pressure gauge and low compliance tubing will connect it to a pressure transducer. Since the fluid pressure is the same throughout the device, the transducer provides an accurate way of measuring balloon pressure.

Both the linear potentiometer and the pressure transducer will provide an analog voltage output. These signals will then be sent to a laptop computer using a PMD-1208LS USB digital to analog converter. A LabView program takes the input signals and outputs the corresponding pressure and volume values in both numerical and graphical representations. The program also creates the pressure versus volume graph to show esophageal compliance. If the pressure on the esophagus approaches the perforation point an audio-visual alarm will alert the doctor to halt the procedure.

The computer interface system does not affect the operation of the current dilating device. Very few resources are needed to retrofit the current device with the new interface and additional maintenance is not required between procedures. Once the syringe gun is fitted with the linear potentiometer, it remains attached to the gun and does

not need to be removed between procedures. The stopcock splitter that leads to the pressure transducer can be simply connected inline between the balloon and existing pressure gauge with the standard luer connections.

The cost estimate for the final design is $250. Most of this cost is from the pressure transducer ($130) and the converter ($110). The linear potentiometer ($2), connection pieces ($6), and tubing ($2) are inexpensive.

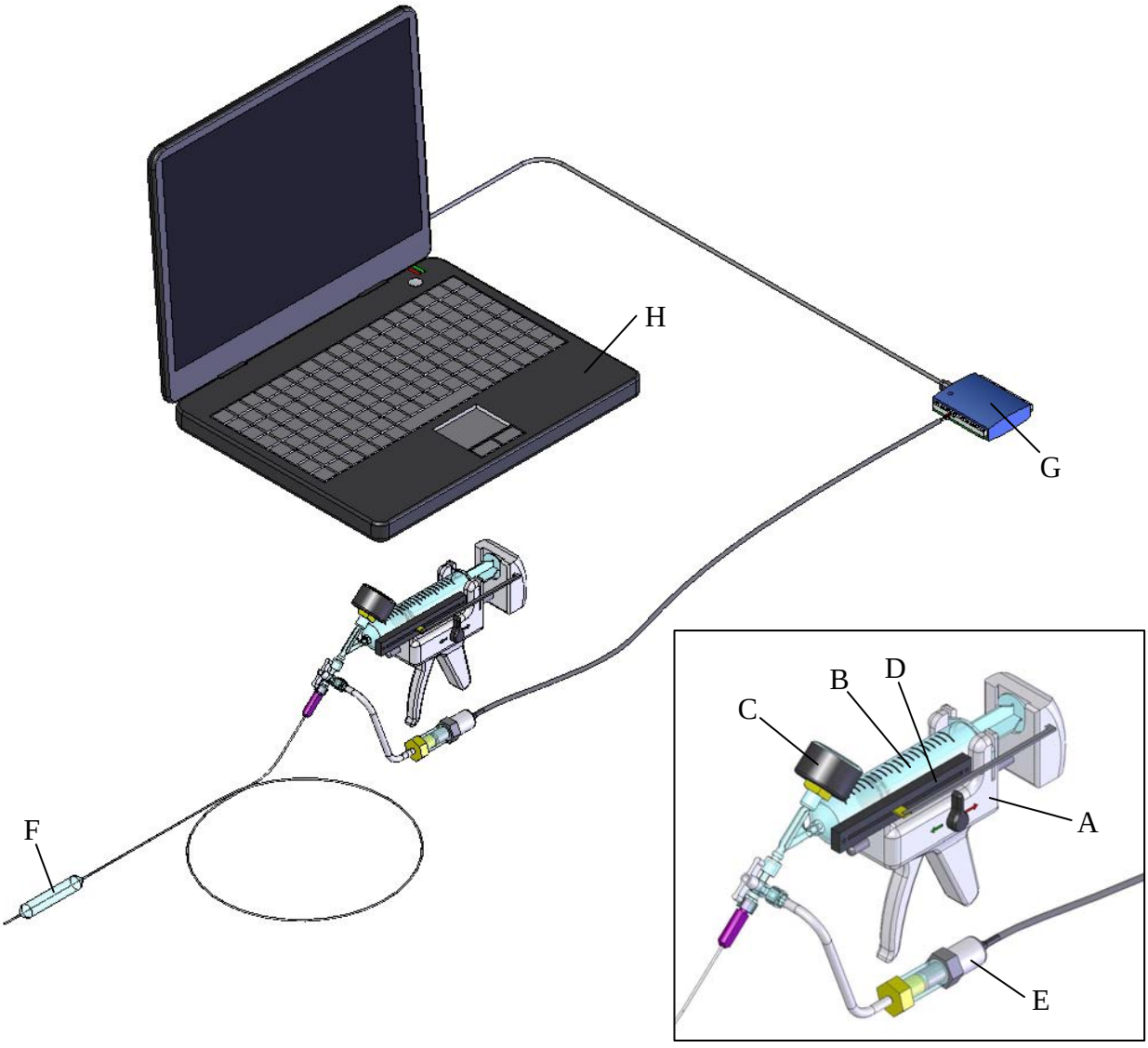

Figure 12. Computer interface final design.
A. AllianceTM II Inflation System (syringe gun), B. Syringe, C. Analog pressure gauge, D. Linear potentiometer, E. Pressure transducer, F. CRETM Fixed Wire Balloon Dilator, G. Digital to analog converter, H. Laptop computer

TESTING AND RESULTS:

Due to complications with AD Electronics, we were unable to obtain the linear slide potentiometer and finish constructing our prototype prior to completion of this paper. Since the potentiometer is needed to measure volume, esophageal tissue compliance could not be generated.

ETHICAL CONCERNS:

Several ethical considerations guided the design of the compliance measurement system. An ethical concern of our design project was patent infringement. Because we do not aim to sell any replicates of our prototype and are only using it in the testing stages, we are not violating any patents. The design and its objectives have been discussed with a Boston Scientific representative.

Methods for testing became another ethical concern of the project. Our client suggested that we test on animals, possibly pigs or cats. All members of the group enrolled in the animal research ethics seminar. We have decided to test the final prototype on a pseudo-esophagus. Finally, the work we have performed over the course of this design project is governed by the University of Wisconsin-Madison's intellectual property laws.

FUTURE WORK:

Once we receive our potentiometer, we need to finish constructing our prototype. We also need to figure out a way to separate tissue compliance from balloon compliance. Since we will be measuring the pressure and volume in the balloon and not the actual force exerted on the balloon from the esophagus, we must eliminate the balloon's effect on the compliance.

Simulated testing and possibly animal testing will also be done after our prototype is complete. Testing using simulated esophageal tissue, such as liquid latex and plastic tubing, will be needed to test the functionality and accuracy of our prototype. After our prototype is complete and initial tests have been run, animal testing is a possibility. This requires submitting a protocol to IACUC for approval.

After affirming that our design works, we need to make our design more aesthetically pleasing if we want to market it. The marketable design would require minimal number of easily obtained or manufactured parts. Cost efficiency would also need to be taken into account.

APPENDIX A - References

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