Esophageal Simulator

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Abstract

Eso-technologies came to us asking us to design an esophageal simulator that will allow them to test and develop their cardiac monitoring device without the need for patient interaction. After weeks of brainstorming, and researching we have decided upon a single tube pressure design that will express the pressure waves within the esophagus by pumping either liquid or gas into a flexible tube. Our design will not be extremely difficult to fabricate, so our main focus is to purchase and program a pumping system that will fluctuate as the body does.

Problem Statement

Eso technologies is currently developing a new, less invasive device to replace the pulmonary artery catheter (PAC). The PAC measures cardiac pressures and heart conditions during surgery. The PAC, despite its benefits, caused ~40000 heart related complications in patients last year. Eso tech's new device will monitor the heart and respiratory function via the esophagus. The device is still in development and testing has been performed on patients. However, the device is limited to 40 patient tests by the FDA. Our goal is to design an esophageal simulator that minimizes patient interaction while allowing quicker testing and refinement of the device. Our device needs to be able to replicate the dynamic pressure from the heart and lungs as well as the static pressure of the esophagus.

Introduction to Eso-technologies

Eso-technologies is a small, growing biomedical engineering company from Middleton, Wisconsin. Currently Eso-technologies has patents on several designs, including an esophageal cardiac monitoring system, that is designed to replace the PAC. The new design will be less invasive complications, cost less, and easier be easier to handle.

The device will monitor the cardiac pressure, specifically the left atrium, lung pressure, esophageal static pressure and peristalsis. The new device makes use of our human anatomy to read required

Figure 1: An image including the esophagus, heart and lungs [1].

pressures. The wall of the left atrium of the heart is in direct contact with the wall of the esophagus, so any pressure developed in the atrium will be translated through these membranes into the esophagus, where the push onto the probe will equate to a specific pressure. In Figure 1 above, the esophagus is the small opening right in the middle of the picture, the left atrium is the dark cavity that contains a little of the teal coloring. The esophagus resides within the chest cavity and therefore the static pressure in the esophagus will be manipulated to oscillate with the positive and negative pressure waves of the lungs. In the picture above, the lungs can be seen on either side of the heart, taking the majority of the chest cavity. This allows the Eso-Technologies' device to less invasive while monitoring the same areas as the PAC because their device does not need to be implanted into the heart causing additional stress.

Current Testing Methods

The Eso-technologies device is still in the refinement process. To determine areas where the device requires improvement, the device needs to be tested in the correct environment. The best way to do this is in patients during clinical trials. However, the problem with this method is that the FDA has limited each probe to just 40 clinical trials, requiring more probes to be fabricated which delays the refinement process and is a lag on costs for the new company. Therefore, if a device can be designed to replicate the testing environment, more tests can be run per probe which increases refinement turnaround and decreases the need to fabricate a large number of probes.

Client Requirements

The most important aspect of this design is the simulation of cardiac pressure (Figure 2). In order to do this, a programmable pump will be used. With the data provided by the client, the pump will be used to recreate the pressure waveforms of the heart, specifically the left atrium. In addition to this, it is important that other pressures of the thoracic cavity are produced, one of which is the static pressure of the esophagus. Because the esophagus is essentially a deflated tube when resting, it will exert pressure on anything that is it, including Eso-technologies' probe. The top trace is of an EKG and the bottom trace shows the esophageal waveforms. Another pressure generating component of the thoracic cavity is respiration. During respiration, a negative pressure process causes air to enter and leave the lungs. The air, or lack thereof, causes pressure changes in the chest that can be measured in the esophagus. One final pressure that needs to be accounted for is the esophageal pressure during peristalsis. When swallowing occurs, a wave of contraction occurs down the esophagus, resulting in pressure exertion on the probe. Although this is an important pressure wave to generate, it may be out of the scope of the first semester of the design.

Figure 2: Sample Waveforms provided by Eso-Technologies [2]

Before choosing materials to use, ranges and frequencies of the previously mentioned pressures must be known. With the help of Dr. Reikersdorfer, we were able to gain quantitative values for these pressures (Table 1).

Anatomical Structure	**Pressure Range**	**Frequency**
Left Atrium	0-30 mmHg	40-140 per min
Chest Cavity	-10-30 cmH20	0-20 per min
Esophagus (static)	0-50 mmHg	Constant
Esophagus (dynamic)	0-100 mmHg	0-10 per min

Table 1: Required Pressure Ranges

In order to generate these pressures, several different mechanical and software components must be used. Although the clients do not require any specific components or programs, it is required that the pressures may be independently varied and also changed in frequency in order to simulate different situations. In addition, a system must be put in place to measure the generated pressure, to verify that the pressure output as calculated by the program actually matches what the probe is sensing. This system will also provide a feedback loop to make any necessary corrections.

Design Alternatives

Pressure Tube

The first possible design is a rigid tube with an inflatable inside that replicates the pressure waveforms from the chest cavity. The inside tubing would be flexible and mimic the properties of an esophagus. The inflexible outside tube could be made of inexpensive PVC tubing. The inside flexible tubing would wrap around each end of the rigid outside tubing and be sealed off to prevent air loss with a clamp. A pressure generator or pump would be attached to the rigid tubing pumping air between the outside and inside tubing (Figure 3). Also, a pressure measurement device would be attached to the tubing system to read what pressure is being delivered to the esophageal probe. The measurement of the delivered pressure can be used to make a closed loop system (Figure 4). The input and output pressures could be used to calculate the error and adjust automatically. Two simulators could be placed in line so each pressure bulb on the probe is reading a different pressure. One simulator would generate the respiratory and static pressures while other would generate the same pressures as well as the cardiac pressure waveforms. This would allow both bulbs on the probe to be tested separately. One positive aspect of this design is the simplicity of construction and maintainability while still delivering the correct pressure waves to the esophageal probe. A negative aspect of this design is the programming of the motor driving the air into the system, since all three pressure waveforms are delivered from one source.

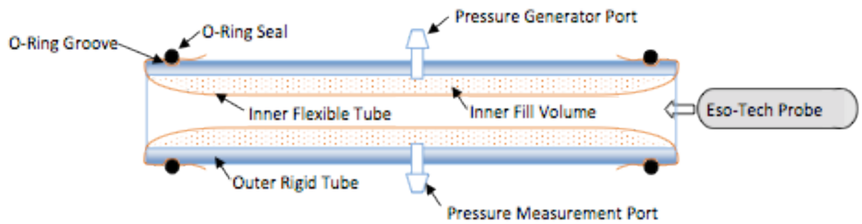

Figure 3: Pressure Tube Design [3]

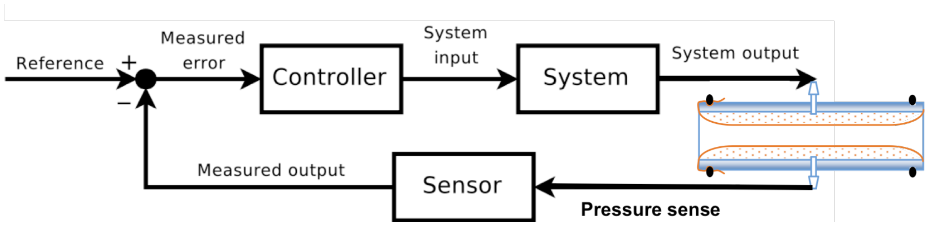

Figure 4: Closed Loop System [3]

<u>Thoracic Cavity</u>

The second design idea tries to replicate the anatomy of heart in relation to the esophagus (Figure 5). The design consists of a rigid box containing a flexible tube, replicating the esophagus. A fluid filled sac would be placed next to the esophagus and impinge on it, acting like the heart in a human. The "heart" would have its own pump allowing it to have a separate waveform than the respiratory pressure. To hold the esophagus in place, a rigid "back bone" could be placed behind it, like in the human body. Pressurizing the rigid box and regulating the flow of air with a pump would generate the pressure from the lungs. The static pressure is also provided by the pressurization of the rigid box. A positive aspect of

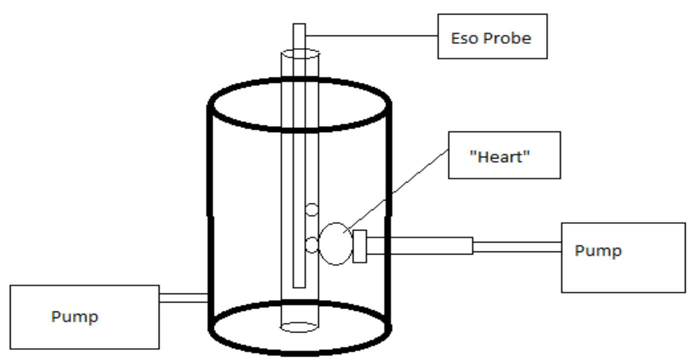

Figure 5: Thoracic Cavity Design

this design is the low complexity in programming the pumps. Also, the anatomy is closer to what is seen in a human body. Our client may in the future want to test the device with real organs, allowing this design to be modified later. The heart provides a contact pressure on the esophagus, just like in the chest. A negative aspect to this design is the complex construction and maintenance. The rigid container must be sealed, which may be difficult with the esophagus tubing exiting from each end. In addition, keeping the heart in a specific position may be difficult. Possibly making a rigid tube that extends from the inside wall to the esophagus may be a solution to the problem. The probe also must face a specific direction and be placed a specific distance down the tube. This may cause inconsistent results from testing, causing the simulator to be less accurate if all that needs to be tested is the pressure sensors on the probe.

<u>Double Bladder Apparatus</u>

The third design alternative is the double bladder apparatus (Shown in Figure 6). In this design, the pressure sources are the two liquid filled bladders, shown in black in Figure 6. These sacs are made of a strong, elastic material, capable of frequent expansion and contraction while undergoing contact pressure from the surrounding apparatus. The bladders are connected to a separate glass syringes, each filled with enough fluid to simulate the required pressures. The upper bladder impinges on the reference balloon and will be used to generate the static pressure of the esophagus and respiratory pressure simultaneously. The lower bladder will simulate cardiac, respiratory, and

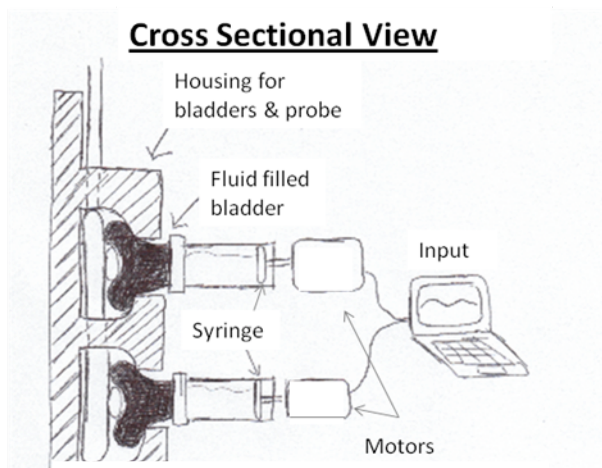

Figure 6. Cross-Sectional View of the Double Bladder Apparatus

esophageal pressures simultaneously. The two bladders and the probe are held firmly in place by the rigid support apparatus (cross-hatched structure in Figure 6). The glass syringes are each driven by their own motor, which will in turn create the respective pressures of the two fluid filled sacs. These two motors will receive input from data programmed into LabView.

The advantages of this design are its two fluid filled bladders permits simultaneous data collection of the reference and left atrial pressure sensors. This allows the program to subtract the pressures applied to the reference sensor from the pressures on the left atrial sensor and in theory, leave only the cardiac pressures. Also the implementation of the liquid filled balloons versus air filled allows for a more accurate representation of the contact pressure of the left atrium in a human because the heart is a liquid filled organ. This design also incorporates the rigid housing that will hold the probe and bladders in place. This housing will prevent the bladders and probe from moving relative to each other during testing, allowing for more reproducible results.

However, this design has some drawbacks as well. One issue with this design is that the bladders create a unidirectional pressure on the probe's sensors; therefore, if the bladders are not positioned so they are uniformly distributed over the sensor, the pressure readings will be skewed. This design is also anatomically inaccurate because it lacks an esophageal analog and each bladder generates multiple pressure waves, instead of having a separate system for each waveform. Straying from an anatomically correct design disallows for future expansion of the design through the incorporation of real organs and tissues. This design uses two motors to generate the pressure waveforms, which create the possibility of synchronization issues. This includes lag between the two motors due to a programming error or a mechanical malfunction of one of the motors; this would cause inaccurate readings of the pressure waves.

In addition, the overall fabrication of this design would be difficult because the rigid support apparatus (cross-hatched structure in Figure 6) is complicated to construct.

Design Matrix

To evaluate which design would best fulfill the client's requirements, a design matrix (Figure 7) was created. This matrix evaluates each design on five categories: the accuracy of the pressures produced, the reproducibility of the pressure measurements, the cost of each design, the simplicity or ease of construction of the designs and lastly how anatomically correct each design is. Each category was allotted a certain number of points for a total of 100 points between the five categories. The accuracy of the generated pressures was given the highest point allowance at 40 because it is most important for the design to create pressure waveforms of the correct magnitude and frequency so that the data collected by the probe is representative of the pressures found in a human body. The reproducibility of the measurements was allotted the next highest point total at 25 because it is imperative that the probe experiences the same pressures from trial to trial so that malfunctions or design flaws of the probe can be detected by obtaining results that deviate from the norm. The simplicity or ease of construction was given a point total of 20 because the design should be feasible to build in a timely manner so that testing with the probe can get underway. The anatomical accuracy of each design accounted for 10 points out of the 100 because an anatomically correct design allows for future expansion by incorporating real organs and tissues. Also an anatomically accurate design may account for pressure losses or other phenomenon that occur in the human body as the waveforms are translated through the various tissues before they reach the esophagus. Lastly the cost of the design was weighted at 5 points out of 100. Cost was least important out of all the categories because many of the materials and devices required to build the designs can be donated by Eso-technologies and their affiliates. In addition to this many of the components needed will be inexpensive compared to the $500 allotted budget. These point allowances are based off the clients design specifications point allowances are based off the clients design specifications.

	Design Matrix					
	accuracy 40	**reproducibility 25**	**Cost 5**	**Simplicity (ease of construction) 20**	**Anatomy 10**	**Totals**
Pressure Tube	35	23	5	18	5	86
Thoracic Cavity	30	15	2	10	10	67
Frame w/two balloons	30	20	4	13	5	72

Figure 7: Design Matrix based on our clients design specifications

After evaluating each design against all five categories, it became apparent that the pressure tube design would best fulfill Eso-technologies design specifications. The thoracic cavity, even though it is anatomically correct and produces fairly accurate pressure waveforms, would have major issues producing consistent results due to the interaction of so many dynamic systems. In addition, the design would be costly and difficult to build and therefore scored the lowest out of all three designs. The double bladder apparatus scored moderately across all categories with the exception of anatomical accuracy due to its simpler design. However, the pressure tube was found to produce the most accurate and reproducible waveforms as well as being the cheapest and easiest to fabricate. Therefore, the best design for Eso-technologies esophageal simulator is the pressure tube.

Future Work

After deciding upon the pressure tube design, we met with our clients to discuss specifications about this design and plan out our next steps. We will first need to decide on the materials for the design and then order them. For the esophagus, we will use a material that most closely represents the elasticity of a real human esophagus; a penrose drain may be the best alternative for the esophagus due to its structure and elasticity resembling that of a human esophagus. We will also need to find a motor as well as proper input and release valves that will allow the generation of the proper waveforms in the pressure tube. Once we have the materials, we will need to construct the design. After fabrication, a computer program will be created in LabVIEW that will drive the motor to create the desired pressure waves. This program will allow the user to adjust the magnitude and frequency of all three waveforms individually. Once the design is operable, we will design a feedback loop using a pressure transducer located on the pressure tube that will collect data and relay it back to the program in LabVIEW. This feedback loop will allow us to ensure that our inputs are creating the desired outputs and if not, how we can adjust accordingly. Once this is complete, testing with Eso-technologies probe in our esophageal pressure tube can begin.

References

[1] *Visible Human Server*. Web. 13 Oct. 2010. <http://visiblehuman.epfl.ch/>.

[2] Eso-Technologies Inc. *An Esophageal Simulator with Cardiothoracic Pressure Signals*. Sept 9, 20210.

[3] Gorski, Steve. Company Memorandum. Eso-Technologies Inc. Oct 4, 2010.

Acknowledgements

We would like to thank the following people for their help during the project:

- Bonnie Reinke and Stephen Gorski of Eso-Technologies
- Dr. Chris Reikersdorfer
- John Webster-Advisor
- Dennis Bahr

Appendix A- Product Design Specifications

Project Title: Esophageal Simulator

Team members: Joel Schmocker, Luke Juckett, Ian Linsmeier, Tyler Klann

Function: Eso-Technologies is currently in the process of developing a pressure sensing device that will measure the cardiac pressure from the left atrium. Because they have limited testing sessions on patients, they have requested that a pressure simulator be constructed. The device needs to have a programmable pump that can reproduce and vary the frequency and size of the pressures generated by the heart, lungs, and esophagus.

Client requirements: Shown below are the required pressure ranges.

Left Atrium	0-30 mmHg	40-140 per min
Chest Cavity	-10-30 cmH20	0-20 per min
Esophagus (static)	0-50 mmHg	Constant
Esophagus (dynamic)	0-100 mmHg	0-10 per min

In addition to this, the device must be able to independently read the pressures to provide feedback to the pump.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device needs to be able to produce pressure waves from the esophagus, heart, and lungs. The pressure waves must also be able to be varied in both magnitude and frequency.

b. *Accuracy and Reliability*: It is very important that the pressures exerted on the probe are correct. In order to do this, real measurement provided by Eso-Technologies will be programmed into the system. In addition there will need to be an external pressure sensor to ensure the correct pressure and to provide feedback when necessary.

c. *Life in Service*: The device will be used as new developments of the probe occur and need to be tested.

d. *Shelf Life*: During normal use, the device will last very long. However, different materials will likely be placed into the tube to simulate the esophagus.

e. *Operating Environment*: The system will be used in a lab. It will not need any special materials to prevent wear and tear from the environment.

f. *Size*: The pressure tube will likely be a small size, because a small contact point is needed for the probe. In order to be portable, a laptop computer could be used as the source of the pump information

g. *Materials*: The material in the tube should mimic the esophagus, as the probe will be placed in the esophagus. Currently a penrose drain is a suitable option for this.

2. Production Characteristics

a. *Quantity*: There is a need for one system, with an option to replace the material inside the tube.

b. *Target Product Cost*: The budget is allowed up to $500

3. Miscellaneous

a. *Competition*: Currently there is no device that reproduces pressures in order to test an esophageal probe