Gastro-Esophageal Reflux Test Bed

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Abstract
This project addresses the need for a test bed to provide experimentation to reduce the hardship from Gastro-Esophageal Reflux Disease (GERD). GERD is a condition where the contents of the stomach rise into the esophagus and erode the esophageal lining, which can lead to Barrett’s Esophagus and then cancer. This test bed will be utilized in coordination with Draper Labs and Brigham and Women's Hospital to perfect an endoscopic valve that will reduce the effects of GERD in patients. Throughout normal activity the upper portions of the digestive tract undergo various muscle contractions, pressures, and volumes. The GERD test bed design will need to correctly simulate these variable pressures and the rates at which they occur. The test bed will utilize a polyethylene tube to simulate the last 10cm of the esophagus, but it will also be removable so that a cadaver or porcine esophagus can also be used. The stomach pressure waves will be simulated using a linear motor, which will be controlled and monitored by a series of pressure transducers, pushing up on the bottom plate to generate the necessary pressures within the stomach chamber.

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The Need for Project

In order to be able to test their anti-reflux valve, Draper and Brigham and Women’s need to have a way to test it. Right now, there is nothing on the market to fulfill their testing needs. By creating a test bed that can simulate stomach pressures on the lower esophageal sphincter, the valve would then be able to be tested under the conditions that it will normally go through inside of the human esophagus.

This test bed will ensure that the valves being tested in it qualify to be put into a human being. Leading to the valve functioning the way it was intended and stopping reflux and users from developing esophageal cancer.

The Design Project Objectives and Requirements

Design Objectives

The main objective of the group was to create a prototype that met the sponsor specifications such as, creating the pressures that occur daily in the upper digestive system in people with GERD so that they could have a testing device for their valve. The group also wanted to create a product that could be easily manufactured so it could be sold commercially.

Design Requirements

The design must accurately simulate the pressures that occur in the human stomach during different functions such as belching, coughing and vomiting. The pressures that are seen normally in the average human stomach vary between 0-100 mmHg. The system must also simulate the rates at which the pressure rises so that the testers can see if the valve can withstand the pressures.

The product must also have a removable esophagus so that other types of esophagus’ can be used such as porcine. The entire system must also be portable and able to pivot, so that the testing can be done at whatever orientation that the tester desires. Also the materials used to build the system must be HCl resistant because the contents of the stomach must also be simulated during the testing procedures.
**Design Concepts Considered**

Alternate design concepts considered variations in pressure generation as well as ease of manipulation for variable user inputs.

Multiple design concepts were developed in order to fulfill the design requirements. The key component of the system was to expose the valve being tested to the pressure wave forms of vomiting, coughing, belching, and normal/resting.

One design concept considered was a chamber with a bladder extending from the esophagus opening to the drain at the bottom of the chamber. The chamber was to be pressurized with variable pressures subsequently collapsing the stomach bladder and exposing the valve in the esophagus to a similar pressure. The pressures generated by pressurizing the stomach chamber however, would not follow a typical waveform that may be seen as the collapses of the bladder could not be well controlled. As a result of this another concept was considered which employed a series of rotating cams. The four cams used would each generate one of the four pressure waves of vomiting, coughing, normal/resting and burping. The stomach chamber would be collapsible with the rotating cam pushing up on the bottom of the chamber reducing the volume of the chamber and generating the pressure wave. In order for the system to change wave form desired the entire chamber would have to be moved into a fixed position over the corresponding cam. The cam concept makes it difficult to model the variation in each type of wave form, as for instance normal pressures may fluctuate differently from patient to patient. As a result, in order to change the cam to model a slightly different wave form, the cam would have to be physically manipulated. A more effective way to manipulate the pressure waves was considered in the leading and final candidate in which the motor with rotating cams is replaced by a linear motor which pushed on the bottom of a collapsing chamber. The linear motor is supplied with wave forms from a PLC controller which allow the user to not only select the type of wave form but also tune the waveforms without changing the system.
Recommended Design Concept

The GERD test bed contains a collapsible, HCl resistant stomach chamber coupled with a linear motor which can generate multiple wave forms. The linear motor, pivot case, adjustable LES band and clamped esophagus tube allow for high customization by the user.

Design Description

The GERD test bed was developed to replicate the conditions seen by the lower esophageal sphincter during GERD and variable pressure conditions. The system from bottom to top starts with a programmable and controlled linear motor which follows programmed wave forms. The motor oscillates up and down pressing on the bottom of the collapsible stomach chamber. The stomach chambers consists of two high density polyethylene plates, which are resistant to HCl and have a high strength preventing deformation under the forces and pressure of the system (Rep. 4.6). The collapsible side wall of the stomach is made up of ethylene propylene diene monomer (EPDM) which has a high modulus of elasticity and strength allowing it to withstand the conditions of all the programmed scenarios (Rep. 4.5). The stomach pressure is measured and controlled through a pressure sensor which sits flush with the top plate. A Teflon tube simulating the esophagus sits over a ring on the top plate and is secured with a tube clamp. An incrementing band is wrapped around the simulated esophagus, just above the clamp, to simulate the lower esophageal sphincter. The entire system is secured by three shafts that bolt directly into the top plate, the bottom plate is fitted with three precise linear bearings which slide over the shafts during oscillations, and the shafts are secured into the bottom of a clear containing Lexan chamber. The chamber allows the system to sit in between two legs which allow the system to pivot and simulate upright and laying down positions.

Key Advantages of Recommended Concept

There are multiple advantages of using the recommended concept over the other designs considered. One advantage is that using a linear motor allows the user to manipulate the input wave forms without altering the mechanical system. In addition, clamping the esophagus tube to the system allows the user to change the type of material or tubing being used to simulate the esophagus which lets the user to further customize the system. The adjustable, incremental band which represents the lower esophageal sphincter, allows the user to regulate the tightness and test at healthy, weakened and other sphincter strengths. Continued adjustability is offered to the user through the
pivot which the system sits in, allows the system to be run at vertical, horizontal, and variable angles.

Financial Issues

This product is intended to later be mass produced. The intended commercial cost at this time is not known. The final cost of the chosen design in the end will be close to $5,000. This is mostly because of the linear motor chosen. With more research a much more affordable motor can be chosen and lower the cost of producing this design considerably.

After all the work put into the design, the group believes that it is worth continuing with project. Adjustments could be made to tailor to other tests, so this test bed could be used for other medical testing and not just for the sponsor valve. The test bed would then be more desirable for other hospitals and medical companies.

Recommended Improvements

The addition of expandable rings and subsequently peristaltic motion would result in a better simulation of the conditions which would be felt by the tested valve. An improvement which could be made to the system would be to pursue an expandable ring concept for the lower esophageal sphincter. This concept could result in more adjustability for the user in order to better simulate conditions from patient to patient. In addition to the aforementioned benefit, when multiple rings are used in series there is the possibility of simulating the esophagus's peristaltic motion. The development of peristaltic motion in the esophagus would expose the tested valve to a more anatomically correct simulation of esophageal and LES motility.