Gastroesophageal reflux disease intervention testbed

Design Team
Avi Kurlantzick, Kenneth Love Villar
Ross Phillipps, Alina Visco

Design Advisor Sponsor
Prof. Jeffrey Ruberti N/A

Abstract
Gastroesophageal Reflux Disease (GERD) is a chronic condition characterized by the expulsion of stomach acid into the esophagus, affecting an estimated 10-20% of American adults. Established medicinal solutions tend to treat symptoms without reducing reflux. The development of implantable devices to supplement inadequate esophageal anatomy at the lower esophageal sphincter (LES) is hindered by a lack of ex vivo testing environments. This project encompasses the design and construction of a testbed to simulate the conditions experienced by ligature- (external) and valve-type (internal) anti-reflux devices. The testbed design features a floating piston "stomach" model to reproduce typical pressure waves and acid reflux, along with an anatomically correct LES junction and a rigid upper esophagus. This esophagus is designed to accomodate the type of acid-sensing probe commonly employed in clinical GERD diagnosis, as well as a separate fixture that simulates swallowing and ensures that food can pass through the device being tested.

For more information, please contact Jeffrey Ruberti (j.ruberti@neu.edu).
The Need for Project

A GERD testbed is needed to help researchers develop surgical interventions that stop reflux without impeding normal esophageal function.

GERD is a chronic condition affecting 10-20% of American adults (Ref. 19). Many patients opt for medicinal treatment that reduces stomach acidity, which causes the painful "heartburn" sensations associated with reflux, without reducing the frequency of reflux. This lower-acidity reflux can continue to cause damage to the esophagus over time (Ref. 32), potentially leading to serious complications.

At present, only a handful of anti-reflux surgeries have proven effective at combating reflux without impeding normal esophageal function. Only 2% of GERD patients currently opt for surgery. Of those, up to 62% continue to have symptoms severe enough to require medicinal treatment (Ref. 33). The creation of a GERD testbed would allow researchers and medical device manufacturers to investigate the effectiveness of new ligature- and valve-type surgical devices prior to human or animal testing.

The Design Project Objectives and Requirements

The GERD testbed shall test a device’s ability to prevent reflux through the LES without impairing normal esophageal function, such as swallowing and vomiting.

Design Objectives

The GERD testbed shall simulate the anatomy and function of a human esophagus, LES, and stomach (Rep. 4.1). The testbed shall accommodate and gauge the efficacy of ligature- or valve-type anti-reflux devices by detecting the travel of acid up the esophagus under varying stomach pressure conditions (Rep. 4.3). The testbed shall be able to simulate multiple body orientations, including upright, prone, and supine (Rep. 4.4.2).

Design Requirements

The upper esophagus section of the testbed shall approximate the geometry of a human esophagus 15-20 cm in length with an ID of 1.5 to 2 cm (Rep. 4.1.2). The LES section of the testbed shall be approximately 3 cm in length and have a resting closure pressure between 1.33 and 4.66 kPa, simulating the passive mechanical properties of a defective sphincter (Rep. 4.1.1). The testbed shall also include a test rig to simulate swallowing in the esophagus; to be considered valid, a device shall not cause the axial swallowing force to exceed 20 N (Rep. 4.2.5).

The stomach module shall simulate pressure profiles associated with gastric events (Rep. 4.1.3), e.g. reflux, vomit, belch (Rep. 4.2).
The testbed shall detect the presence of acid in the distal esophagus, as well as provide a record of the extent of acid travel during each testing cycle (Rep. 4.3.1). The testbed shall also detect and report axial and radial pressure exerted on the anti-reflux device (Rep. 4.3.2). All components exposed to HCl must be nonreactive with acid.

Design Concepts Considered

**Esophagus/LES**

Polymers, elastomers, and gels were considered for the LES, with either fabric or an esophageal stent as a backbone. Many elastomers and gels were eliminated due to acid reactivity. Certain opaque elastomers were both acid-resistant and cheaper than the polymers examined, but the polymers' transparency is preferable (Rep. 5.2.1).

**Stomach**

Pump, bladder, and piston systems were considered for the stomach component. An injector pump could easily control the volume and flow rate of expelled acid, but it would not be able to produce the pressure waves associated with vomiting and belching. An anatomically correct bladder could be custom-built at considerable cost, but stomach anatomy is highly variable in the adult population (Ref. 18), rendering any stomach of this type only nominally representative. The piston system, while not anatomically correct, provides precision for various gastric event pressure generation (Rep. 5.3.1).

**Swallow Testing**

Multiple design solutions were considered to simulate peristalsis, including elastic bands, viscous fluid, and roller balls. A non-peristaltic model was also considered, in which a linear force actuator propels the simulated food bolus downward (Rep. 5.1.1).

**Reflux Monitoring**

To detect and report acid travel up the esophagus, a layer of pH-sensitive dye, an array of pH sensors, a probe with a spray sensor, and a clinical acid monitoring system were considered. Due to its fine resolution and low cost, the pH-sensitive dye was the preferred design at first, but proved difficult to adhere to the flexible esophagus material. The pH sensor array and spray sensor probe are relatively inexpensive, but they would compromise resolution (Rep 5.4.1).
Recommended Design Concept

Following careful trade studies, a polymeric esophagus material was selected, with a separate test fixture to simulate swallowing. A piston will model stomach pressures. A clinical reflux monitoring system will record instances and severity of reflux during testing.

**Design Description**

A polymeric material was chosen for the LES region. It is acid-resistant and transparent. The distal portion of the esophagus will have a 2 cm flange to affix it to the piston stomach model (Rep. 5.2.2).

The stomach is modeled as a floating piston constructed of PVC. The outer cylinder has attachment interfaces at either end for the closing caps. The top cap has connection interfaces for a pressure transducer, an acid fill port, and air intake, and it captures the LES flange against the piston cylinder. A PVC piston head with two captive O-rings is actuated via controlled pressure changes in the lower half of the stomach. The bottom cap has connection interfaces for positive and negative pressure lines (Rep. 5.3.2).

The swallowing test esophagus is a separate module which is placed in a tensile testing machine. A spherical food bolus model is affixed to the machine’s load cell or linear actuator and passed through the esophagus. A rigid structure holds the tube in the machine without contacting the main body of the esophagus (Rep. 5.1.2).

The testbed accommodates a clinical acid reflux detection probe system, which tracks the presence and travel of acid in the esophagus by means of an array of pH and impedance sensors (Rep. 5.4.2).

**Analytical Investigation**

Ultimate strength and fatigue testing was completed on all testbed components. Each component passed testing with a factor of safety of at least 10. The Parker O-ring handbook was consulted for all O-ring calculations to mitigate the risk of acid leaks.

**Experimental Investigation**

Following assembly of the testbed prototype, the group will conduct testing to ensure that all components are chemically compatible with HCl and tightly sealed. The group will also develop calibration procedures for the air system driving the stomach piston.

**Key Advantages of Recommended Concept**

The piston stomach model allows for pressure simulation of various gastric events while remaining simple to machine. Having a rigid upper esophagus molded to a more flexible LES provides structural stability without compromising anatomical accuracy at the location of the anti-reflux device. The separate swallowing fixture
simplifies the removal of the simulated bolus from the LES after each swallowing test. Use of a clinical reflux detection probe allows testbed results to be correlated with patient data.

**Financial Issues**

Safety concerns related to the acidic contents of the testbed increased the overall cost of the project. Factors contributing to the cost of the testbed include the necessity of using only materials which are nonreactive with HCl and building all parts to tight tolerances to prevent leakage of acid vapor. Safety is of the utmost importance during testing of this project, so over $200 was spent on protective equipment alone.

**Recommended Improvements**

A location tracking system for the piston and a peristaltic esophagus model would improve the testbed. The testbed could be improved by implementing a dynamic location tracking system for the piston head, as the group did not have time to implement this feature. Additionally, a future phase of this project might develop a peristaltic swallowing system to more accurately simulate the forces on an anti-reflux device.