Barostat To Measure Esophageal Strictures

Team members: Kevin Wright, Steve Trier, Julie Sauer, Hannah Kirking
Clients: Dr. Mark Reichelderfer, UW Hospital
Date: 4/30/02-5/7/02
Problem Statement:

The reflux of stomach acid into the esophagus is one of the most common GI ailments. One consequence of such reflux is the formation of scar tissue which forms abnormally stiff regions of esophageal tissue, sometimes leading to obstructive swallowing disorders. There are very few methods for either diagnosing or treating this disorder. There are two different measures which would be useful from a clinical point of view:

a. a device to measure the size of the stricture i.e., the percent reduction in radius of the stricture
b. a device to measure the compliance of the tissue i.e., the stress-strain behavior

Restatement of Team Goals:

1. Get the pressure sensor.
2. Finish putting together the entire prototype before class on Friday.
3. Hook up and interface the prototype with the oscilliscope and computer on Friday and test to see if the output is what is desired/expected. Also test to see how accurate we can be at manually increasing the volume.
4. Prepare poster and final paper.
5. Get all materials and setups together to have for our presentation next Friday.
2. Meet with Dr. Reichelderfer.

Summary of Accomplishments:

Main Accomplishments:

1. First and foremost-we met with Dr. Reichelderfer Monday and discussed what we have and what his plans/wishes were. Topics included the project in the future, pig and human testing of the device, and our actual design. Dr. Reichelderfer WILL be at the poster session Friday so we will show him then what we have and get more input from him then.
2. We got the second pressure sensor.
3. Our device is totally built and painted (we DID end up including the second pressure sensor) and we took some initial testing data using the BioBench software on computers in a BME Instrumentation lab coupled with a analog-digital converter. The pressures/volumes still need to be calculated to make the graph appear the way we want it to.
4. We have planned what our poster area will look like Friday and are getting all the things that we need for it together. We are hoping to have an all inclusive area, including an oscilloscope, some examples of our tested graph (the computer with

the BioBench program probably won't be there), a model of the digestive tract, our device, and of course, the poster.
seeing as we have less than two weeks to finish. Steve checked out some displacement sensors online but didn't come up with anything that looked like they would work AND were within our price range. We decided that unless we have any huge breakthroughs, we may end up manually controlling volume flow for the prototype with the assumption that the real device would have a volume transducer or some kind of motor for pumping a constant volume. We can displace a constant volume manually with fairly good accuracy and we decided that this would work for at least testing our prototype to see if it gives the predicted results.

5. We also put together the syringe part of the device. It included drilling another hole near the end of it, through which a piece of plastic tubing was attached. Two outputs are needed: the balloon on one of them and the pressure sensor on the other. When the pressure sensor arrives, it will be attached to the end of the added output/tubing so that the pressure if even through the chamber of the device.
6. We found a piece of tubing that is just about the exact right size for testing purposes. It is simply a clear, plastic tube but will work well because you can see the balloon being inflated. It will work very well for our demonstration.
7. An initial design and outline for our poster presentation was discussed. We hope to have a model of the associated anatomy (upper digestive tract), our prototype with the oscilliscope, computer, and power source, and a setup showing how a water pump will someday ideally replace the manual pump (all of this along with the poster behind us).
8. And last but most importantly…we heard back from Kathy at the hospital. We are setting up a time to meet with Dr. Reichelderfer this week.

Statement of Team Goals:

6.

Project Schedule:

Week	Date	Lecture Topic	Activities
1	**25 Jan.**	**Introduction and course expectation**	**Formed groups, select project, contacted client.**
2	**1 Feb.**	**Overview of the design process**	**Literature searched; met with client, watched endoscopic procedure**
3	**8 Feb.**	**Outline of PDS**	**Developed PDS**
4	**15 Feb.**	**Discussed brainstorming, did**	**Reviewed lit. and brainstorm**

		activity	direction
5	**22 Feb.**		**Discussed where to go from here**
6	**1 Mar.**		**Brainstormed and discussed ideas, Met with Mark Nicosia to gain more knowledge on compliance**
7	**8 Mar.**	**Discussed presentation and paper requirements**	**Continued brainstorming- then concentrated on narrowing down to the best ideas**
8	**15 Mar.**	**Gave mid-semester Presentations -handed in notebooks**	**Listened to presentations**
9	**22 Mar.**	**Went over improvements that could be made on paper and presentation**	**Got evaluation back from paper and presentation- discussed results and where to go from here**
10	**29 Mar.**		**Spring Break**
11	**5 Apr.**		**Worked on design- Discussed possible transducers - Steve's correspondence with FISCO**
12	**12 Apr.**	**Discussed planning our time for the rest of the semester**	**Worked on design- brainstormed ideas for pressure sensor and volume pump**
13	**19 Apr.**		**Ordered pressure sensor – Bought a water volume pump – checked on oscilliscope for interfacing**
14	**26 Apr.**	**Engineering ethics**	**Tested water pump and pressure**

			sensor-reordered pressure sensor, built prototype
15	**3 May**	**Filled out evals**	**Worked on final design prototype and testing and interfacing**
16	**10 May**		**Hand in final report and notebook to advisor**
17	**17 May**		**Final meetings with advisors**

Difficulties:

Activities:

1. Class meeting (2.5 hours each)
2. Shopping for supplies and building prototype (approx. 4.5 hours each)
3. Steve-BSAC meeting (approx. 1 hour)
4. Meeting with client (approx. 0.5 hours each)

Total: Previous: approx. 162 hrs.
New: approx. 193 hrs.

Appendix 1

Product Design Specification

Barostat To Measure Esophageal Strictures

Team: Julie Sauer, Hannah Kirking, Kevin Wright, Steve Trier
Date: 3/5/02

Function: A device to measure the size of the stricture (the percent reduction in radius of the stricture) and the compliance of the tissue (the stress-strain behavior).

Client requirements:

- Allow for easy and quick of interpretation of information of device

Design requirements:
Physical and Operational Characteristics

a. *Performance requirements*: If cost and time effective, device would be used in every procedure. Must measure size of stricture and compliance of tissue during the procedure.

b. *Safety*: Can't be toxic in body. Needs to be small enough to fit down esophagus and be of a flexible material as not to puncture esophageal walls. Must not have parts that may fall off into esophagus.

c. *Accuracy and Reliability*: Must measure within 1mm of actual size. Must be able to measure the size of a structure between 2mm to 25 mm.

d. *Life in Service*: Dependent upon cost

e. *Shelf Life*: 2-3 years?

f. *Operating Environment*: Inside esophagus-approx 37 degrees C, wet, acidic environment.

g. *Ergonomics*: Easy to learn and use, not complicated.

h. *Size*: Needs to fit through opening in camera tube and down the esophagus of patient. As small as possible is best in order to allow for maximum comfort of patient.

i. *Weight*: Dependent upon design-must not be so heavy as to put unneeded pressure on esophageal walls.

j. *Materials*: Non-toxic materials, safe to use in body. Flexible material, can alter size, volume (like balloon). Blunt as not to puncture balloon or esophagus.

k. *Aesthetics, Appearance, and Finish*: Smooth edges. It will be similar to other instruments currently used in the esophagus (such as balloons or guidewires).

Production Characteristics

a. Quantity: Depends on disposability, how well it works, expense.

b. Target Product Cost: ?

Miscellaneous

a. Standards and Specifications:

b. Customer/Patient-related concerns: : Reasonable cost, small as possible

c. Competition: none known

Appendix 2

Description of Device/Idea		Benefits	Questions Involved, Possible Challenges
1	FOR SIZE-Use some kind of foam that would be squirted into the esophagus through a tube inserted in a way similar to the balloon. The foam would “harden” (or at least become more firm) in the form of the stricture.	-Creates a representative model of the stricture -Easy to measure size -Inexpensive-dependent upon material type	-Research needs to be done on finding a foam type that may work. -Material must harden but still remain flexible -How will device pass through the “corner” at the meeting of the esophagus and mouth? -Must also involve camera to know when to squirt foam in (When is device actually in stricture?)
2	FOR SIZE-Modified balloon-use the same balloon procedure that is used to stretch stricture but make balloon out of a plastic material that will stretch out but not recoil to original size or shape. Then, when the balloon is deflated and removed, it will hold the form of the stricture to be reinflated for viewing by doctor.	-Easy procedure -Little modification needed for entrance of device (same technique as current balloon would be used) -Removal wouldn’t be a problem because “model” would be deflated upon removal from esophagus	-Availability of a plastic material of this description -When reinflated for viewing, balloon must not be overinflated or model will be ruined
3	FOR SIZE-Couple barium swallow and X-ray to manually see size of stricture	-Technology already exists -Equipment would already be available to most doctors	-Most patients not wanting to swallow barium -Expensive -Somewhat tedious for doctor
4	FOR SIZE-Use some type of sonar device that when placed in the center of the stricture, it would be able to return the size of the opening	-Very accurate -Could be automated to give readout almost immediately	-Very expensive -Would require good understanding of sonar abilities -Challenge of making the device small enough and getting it into the esophagus
5	FOR COMPLIANCE-Modify the current syringe used to inflate balloon to give us a pressure readout that would indirectly represent tissue compliance	-Design of actual device would be fairly easy (not counting interfacing) -Would require a modification to the equipment currently used	-Would require some kind of interfacing system-could be very challenging -Requires research on the varying pressures and how they relate to compliance (Which pressure values correspond to which compliance?)
6	FOR COMPLIANCE-Design device using fiberoptic pressure sensor by FISCO (possibly place the sensor inside of current balloon to monitor pressure)	-Very small in size -Interfacing system already available (also from FISCO) -Immediate readout of pressure, which could probably be altered to give a compliance readout	-VERY expensive (for interfacing system) -Alteration of readout needed-convert pressure readings to compliance -Requires relationship between pressure and compliance