Project Statement & Specifications

Fabrication of Percutaneous Transvenous Mitral Annuloplasty Testing Device

Team 19

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Project for Dr. Wei Sun

Client Contact: Dr. Wei Sun, Tissue Mechanics Lab, Bronwell 203, (860)-486-0369
Statement of Need:

Millions of patients nationwide are affected by mitral valve regurgitation, a condition in which there is leaking of the mitral valve within the heart. Current treatments are invasive and risky. In order to rectify this, noninvasive correction procedures are being researched. Dr. Wei Sun is conducting research which focuses on the initial effects of a constriction device on the tissue surrounding the valve. In order to observe the physical effects of such a procedure, a testing device is needed.

The project is to fabricate this testing device. The device will function in supporting the heart while providing it with an environment that simulates the conditions found within the body. These conditions include temperature and the dynamic pressure of blood flow. Additionally, means of acquiring physical data that measure strain, stress, and physical deformation must be captured, recorded, and analyzed through the use of software engineering.

Introduction & Overview:

The purpose of designing a PTMA testing device is to enable the client to conduct research concerning the initial response of the heart to the implantation of the constriction device. The constriction device addresses mitral regurgitation, which is the back flow of blood from the left ventricle to the left atrium. The regurgitation is the result of mitral valve prolapse, a condition in which a gap exists between the anteromedial leaflet and the posterolateral leaflet. The presence of the gap is due to the widening of the mitral valve annulus. This condition affects 10% of the population.

The currently practiced method of treating the condition is open heart surgery. Problems with the current method include death of the patient and reoccurrence of the condition. The problems are more pronounced in the elderly, who are the most susceptible to this condition. Additionally, their weakened physical state prevents surgery from being a safe and viable option, and those who do attempt surgery face a difficult recovery due to their age.

In an effort to avoid open heart surgery and the associated complications, noninvasive methods are currently being developed. One such method is the percutaneous implantation of a memory alloy bridge anchored by two stents. The device is inserted into coronary sinus and acts to counteract widening of the annulus by constricting the wall around the posterolateral leaflet of the mitral valve. By constricting the wall, it reduces space between the leaflets and thereby reduces regurgitation. The bridge portion of the device is constructed using a shape-memory alloy, which allows the bridge to return to its pre-determined shape post-insertion, thus allowing constriction of the valve. The shape is determined by the geometry of the valve in such a manner that the bridge will force leaflets closer together.

In order to test the effect of the device on the heart tissue, Dr. Wei Sun has requested the fabrication of a testing chamber. The chamber will contain various components which will allow the tissue’s response to the initial deployment of the stent to be simultaneously tested and recorded. The client has requested that
the chamber consists of both an inner chamber and an outer chamber. The outer chamber will need to circulate temperature controlled water around the inner chamber in an effort to mimic body temperature. The inner chamber will shield the heart from the pressure and movement caused by the circulation of water in the outer chamber. In addition, the inner chamber will need to support hearts of varying shapes and sizes, and therefore, will need to be fabricated in such a way that it can accommodate such differences. In order to accurately test the tissue’s response to the device, heart beat and blood flow need to be simulated in the test specimen. Simulation will be achieved by way of pressurized water flow into the tissue from an external water source. Tubing will be used to connect the external water source to the tissue, and therefore, the inner chamber must contain inlets and outlets.

The tissue’s response will be analyzed by measuring the strain on the coronary sinus, the deformation of the mitral valve, and the internal geometries of the valve and coronary sinus. The strain on the coronary sinus will be measured with strain gages which will be applied directly to the outer wall of the coronary sinus in the longitudinal direction. Two digital cameras will be used to capture the deformation of the mitral valve. The use of two cameras will enable the capture of deformation in the x, y, and z planes. The cameras will track deformation through the use of tracking markers that will be applied directly to the heart tissue. The ultrasound machine will be used to capture the geometries of the coronary sinus and the mitral valve before, during, and after deployment of the constriction device. The data collected by the different components will be synchronized using programming software.

**Realistic Constraints:**

Economic constraints surrounding the fabrication of the testing apparatus involve the need to control the pressure of the water being used to stimulate blood flow and heartbeat. To control the pressure, ideally, a programmable pump would be required. The costs of the pump are excessive and therefore, most likely beyond the predicted budget range. Alternatively, a more economic solution would be to modify a pump that is currently owned by the lab. However, the costs and ease of altering the pump have not been determined.

Another constraint is the need for multiple stents in order to determine the functionality of the PTMA testing device. Whether fabricated or purchased, the repeated cost of acquiring the stents will have an economic impact.

Health and safety constraints are a major concern for the project. The heart tissue will be in an open container and precautions must be taken in order to prevent any sort of health hazard to the user or damage to the tissue.

**Other Information:**

Dr. Wei Sun’s laboratory is located on the Storrs campus, in Bronwell 311. The majority of the design and testing will be conducted in this lab. We will be closely collaborating with Thuy Pham, a graduate
student, who has completed finite element models of this system and is hoping that physical results will support her findings.

**Questions:**

- What is our budget?
- Which parts of the heart need to be pressurized?
- What are the specifications concerning flow through the mitral valve?
  - Will the opening and closing action be repetitive or just one cycle?
  - Will the flow and pressure match or exceed real life?
- Will the CS pressure be constant or follow a realistic flow pattern?
- How does the client want to use the ultrasound machine?
  - Will it be fixed in place, moved by hand or controlled by some other means?
- What are the client’s intentions and wishes concerning other areas of the heart such as the right side or the aorta?
- How will stents be acquired?
  - Will they be made or purchased?
  - What will their design and specifications be?
- Is there any software restrictions regarding the processing of the ultrasound image on an external platform such as a desktop?
- Are there any issues or restrictions in integrating software from camera, strain gauge, ultrasound machine, and pressure gauges?
- What will be used for the programming?
- Are there any programs already made that may be of use?
- How will the water be heated and circulated through the apparatus?
- What safety devices must be in place to prevent injury, spilling, or contamination?
- What are the size constraints on the device as a whole?
  - What are the size constraints on the components of the device?

**Technical Specifications:**

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<thead>
<tr>
<th>Physical:</th>
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<tbody>
<tr>
<td>Chamber Material:</td>
<td>Clear plastic polymer</td>
</tr>
<tr>
<td>Metal supports within chamber:</td>
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<tr>
<td><strong>Mechanical:</strong></td>
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<tr>
<td>Inner Chamber Size:</td>
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<td>Plastic Thickness:</td>
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<tr>
<td>Pressure within Heart:</td>
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<td>Proximal Stent Diameter:</td>
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<td>Ultrasound Machine:</td>
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<tr>
<td>Strain Gauges:</td>
<td>Water-proof, able to detect a wide range of strains over a wide range of temperatures</td>
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