Project Proposal

A System to Quantify Heart Valve Leaflet Strain

Team #10
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Project for Client: Dr. Wei Sun

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Executive Summary

Replacement heart valves are part of a growing medical division which has the potential to save the lives of many patients. Transcatheter aortic valves and bioprosthetic valves are used as replacement of heart valves. However, the necessary testing to make sure these heart valves are suitable to be used in patients has not yet been mastered. The main objective was to create a strain measuring system which will have the ability to see how the valve leaflets are affected under varying applied pressures. A special technique of testing these valve leaflets will be used to get accurate data when different loads are presented to the valves. The three valve leaflets have been sub-divided into six different regions with the use of special 3D imaging devices in order to receive data about the valve which was not available before. Previous experiments had too many leaks which could not hold the desired pressures that needed to be used on the valves. The device also has an extremely easy and effective setup and cleaning design for the user. This design sets itself apart from others because it is able to measure the strains on not only surgical valves but also on transcatheter tissue valves.

1 Introduction

1.1 Background

The client Dr. Wei Sun is an associate professor in the mechanical and biomedical department of the University of Connecticut since 2007. Dr. Sun received his Ph.D. in 2003 from the Bioengineering Department of the University of Pittsburgh. The research areas that Dr. Sun has devoted his studies to are Soft tissue mechanics, computational biomechanics, and medical device design. His research focuses on the experimental study and constitutive modeling of cardiovascular biomaterials, and on the study of tissue and organ function using computational tools. His research background includes such projects as designing of new heart valve and annuloplasty prosthesis, modeling of biomimetic fibre scaffold materials as artery substitutes, and study of biomechanics of heart valve biomaterials. His previous employment included working as a Postdoctoral Fellow in the Mechanical Engineering Department at the Georgia Institute of Technology and as a staff engineer in the Heart Valve Therapy R&D Department at Edwards Lifesciences LLC, Irvine. Currently, Dr. Sun is interested in having a testing device that will quantify the 3D deformation of a bioprosthetic heart valve leaflet when exposed to various fluid loading conditions. From this device he will be able to obtain data that is a crucial application his current research projects.
1.2 Purpose of the project

Presently, more than 1 in 3 adults have some form of cardiovascular disease; some of these include Aortic Valve, Mitral valve Disease, valvular stenosis, and valvular insufficiency. Heart valves are involved in the one-way blood flow by opening and closing with each heartbeat. The valves need to close tightly in order to prevent backflow of blood. In addition, the closing and opening of the valve are directly dependent on the pressure changes behind and in front of the valves. When the heart valves start having problems when their main function is when disease arises and the patient becomes at risk of heart attack or other deadly consequences. Aortic valve disease refers to damage to the aortic valve, causing it not to function properly. Valvular insufficiency happens when a valve does not close tightly which then causes blood leaks backward instead of moving in the proper one-way flow. Ultimately cause the heart to become enlarged and will pump less blood through the body. Valvular stenosis is due to the leaflets not opening wide enough consequently only a small amount of blood can flow through the valve. Then the heart must work harder to pump the sufficient blood through the body. Heart valve replacement surgeries have become the most invasive option for the treatment of heart valve disease.

Figure 1: Main Function of a Heart Valve
http://www.bidmc.org/CentersandDepartments/Departments/Surgery/CardiacSurgery.aspx

1.3 Previous Work Done by Others

1.3.1 Products
Biomedical Device Consultants & Laboratories, LLC uses a hydrodynamic testing device that utilizes a dual chamber heart valve test system to copy the hemodynamics of ventricle and atrial muscle contraction and relaxation. In addition it includes a stable flow field that meets ISO 5840 requirements for assessment and performance of aortic and mitral heart valves. The HDT-200 Pulsatile Hydrodynamic Dual Chamber Heart Valve Test System has been designed to test pressure differences, effective orifice area, regurgitant volumes, leakage rates, and velocity flow fields for both surgically implanted and transcatheter heart valve devices. The device is accompanied by Statys™ HDT control and monitoring software. The software has been developed to give the unique feature of absolute control over the pulse duplicator excitation waveform. The Statys™ HDT software provides real-time data collection and analysis of the device parameters of interest, such as pressure differences.

![HDT-200 System](http://www.bdclabs.com/testing-equipment/pulsatile-hydrodynamic-system.php)

**Specifications**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Working Fluid</th>
<th>Stroke Volume</th>
<th>Flow Rate</th>
<th>Flow Monitoring</th>
<th>Waveforms</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-8 Hz</td>
<td>Water, PBS, Blood Analog</td>
<td>0-300 ml</td>
<td>0-10 L/min</td>
<td>Ultrasonic Technology</td>
<td>Sinusoidal and Arbitrary</td>
</tr>
</tbody>
</table>

Figure 2: The HDT-200 Pulsatile Hydrodynamic Dual Chamber Heart Valve Test System

1.3.2 Patent Search Results

Patent number: 5961549 for *Multi-leaflet Bioprosthetic Heart Valve*, obtained by Nguyen et al in Oct 5, 1999. The device has an apparatus for testing heart valve leaflets where each leaflet has a measured deflection response within 0.030 inches of the other leaflets upon application of a load sufficient to stress each of the leaflets between 300 and 600 kPa. The
apparatus includes a leaflet framing assembly including a holder with an indentation for receiving a leaflet to be tested, accompanied by a frame that holds the cusps of the leaflet still. The frame includes a plurality of needles which will act as markers that are pointed ends downward. Furthermore, the indentation in the holder has receptor holes for the needles as the cusp of the leaflet is secured against movement at the discrete points defined by the needles. A stress load sufficient to stress the leaflets within a high modulus region of their stress/strain characteristic is applied to each leaflet. Then leaflets within a predetermined observed deflection range of each other are grouped together. The strain response to an applied load is designed to simulate physiological pressures within the heart.

Patent number: 5531784, *Test device for and method of testing rapid assembly tissue heart valve* obtained by Love, Charles in July 2, 1996. The testing device consists of a chamber made of a material which allows the user of the chamber to visualize the sides and top-end view of a mounted heart valve. Also, the chamber will be displacing a volume of solution through the valve that will test both the opening and closing of the valve in addition to determining the amount of leakage at the closed position. Ultimately, this device is testing heart valves that will be used for valve replacement surgery. The surgeon will implant the valve by the usage of a holder and then suturing the acceptable heart valve to annulus.

### 2.1 Objective

The goal of this project is to design a device that is used to test both transcatheter and bioprosthetic leaflets valves to see how they react under specific amounts of strain. The device will be built so that pressure is pumped to the valves in order to quantify the leaflets deformation. These artificial valves go through a lot of testing in order for them to be cleared for usage. This system will be used as one of the testing mechanisms that the valves need to pass first before they move on to other rigorous testing. Some of the tests that are performed on both the transcatheter and bioprosthetic leaflets are very time consuming and the user needs to make sure that these valves are worth to continue testing before they undergo them. This is one of the first tests that these valves need to be able to pass. The device will be designed so that there is a place to house the artificial tissue valve with an attached pressurized hydrostatic loading tube. In order to accurately quantify the deformations in the three leaflets, the use of boreoscopic lenses will be used. The objective of these lenses is to give the user a 3D view of the entire valve. It is nearly impossible for the user to be able to see the valve deformations and to be able to accurately see how the valves are closed without any scientific help. A problem that was encountered in this design in the past was leaks which caused the system to not hold the desired pressure in order to get adequate testing. Another objective in this device is to have an easy setup and cleaning design. When the artificial tissue valve is being housed in the saline solution it is very difficult for the tester to remove the saline solution from the system without adjusting the heart valve and possibly damaging the whole set up. The goal is to have a very easy and convenient way for the
user to utilize this device. The setup for previous design was very time consuming and a hassle for the tester to use this device so our objective is to simplify the design.

2.2 Methods

The device will contain two main chambers that will be designed using a 3D CAD software program, either SolidWorks or NX 8.0. One will be a holding tank which will maintain a solution temperature of 37°C Celsius. The transcatheter valves must be tested with water around human body temperature to ensure the correct mechanical properties of the Nitinol stents. The two chambers will be connected by plastic tubing. If the holding taking is not needed it may be disconnected from the system. Both chambers will be easily dismantled for trouble free cleaning.

The second chamber will be the actual testing chamber, where the valve will be mounted. The chamber will be designed to have as many up-close viewing angles of the valve as possible using clear Plexiglas. The testing chamber must be designed to ensure the valve and area around it can be lit during testing using conventional lamps.

The platform for the valve will have a hole to allow for water to leak through the valve. It is crucial that no leakage will come between the holder and the valve. The hole may also be opened or closed depending on what stage in testing. When filling the chambers with water the hole will be closed and during testing will be open. There will be a tube leading from the hole which will empty into a collecting jar. The collecting jar will be used to determine the actual amount of leakage that is coming through the valve with respect to time and pressure. The valve holder will allow for each valve to be used interchangeably with little to no preparation.

Two cameras with rigid borescope lenses will be used during the testing of the valves. This lens will help focus and magnify desired regions of each leaflet. Dragon skin will be used around the lens going into the chamber to maintain pressure and prevent any leakage. The cameras need to be calibrated before each test so the system will have a calibration cube that will sit over the valve. The cameras will then be calibrated and the cube will be retracted and taken out of view.

Figure 1: Image of a rigid borescope lens.
Six different regions of each leaflet will be monitored for stress and strain. Each region will be marked with five graphite markers or permanent ink. The cameras will have different viewing angles of the same region on each leaflet. The device will be designed in a way to capture all the different regions of the leaflet without having to reposition the valve by emptying and filling the tank after each testing cycle.

Figure 2: Example of a leaflet with six different regions that each contains five markers.

Two different valves will be tested in the device, so there must be appropriate fitting for the surgical and transcatheter aortic valve. The valve holder will have interchangeable silicone molds that correspond to either the surgical or transcatheter valve. The mold for the surgical valve will have a slot where the cloth ring will fit in. The transcatheter valve will have a cylindrical mold where the stent will compress into. The mold will be designed to be able to accommodate multiple sizes of annulus for both valves. The transcatheter aortic valves’ have a stent which partially partial view of the leaflets, so appropriate testing angle must be determined.

Figure 3: On left is the Edwards CEP Valve and the right is the Edwards Sapien XT

The chamber will be able to hold pressure but importantly a steady pressure to plus or minus 5 mmHg. The desired pressure for testing will range from 40 mmHg to 200 mmHg. A pressure sensor will be placed near the platform of the valve to record accurate pressure readings. The device can be pressurized using a hand pump and a mechanical pump. The mechanical pump will have a digital readout of the desired pressure. The mechanical pump will increase the accuracy of the pressure inside the tank. It must be able to reach all pressures in the desired range as well maintain that pressure.

Once the valve is mounted inside the testing chamber, both chambers will be filled with a warm saline solution. The tank will be sealed and then pressurized. Since there will be water
leakage through the valve the pump must be able to counteract the pressure drop as best as possible. This will help maintain an accurate pressure reading. When the tank starts to become pressurized that will cause the leaflets of the valve to close.

Figure 4: Sequence of pictures showing how a native aortic valve leaflets will close with pressure.

The outputs of the pressure sensor as well as the images captured by the CDC or high speed camera will be analyzed using a LabVIEW program. The program is able to manipulate the images to determine the strain and stress of a captured portion of the leaflet. The computer program will be able to take the two dimensional images collected from the cameras and construct a three dimensional view of the leaflet.

3 Budget

The budget needed for this design as of now is just an estimate. This is because Dr. Sun is allowing us to use his engineering lab. In this lab most of the needed components needed for our design is already been purchased for the lab. If any of these components turn out to not function well in our design then our budget may increase. Also, there is a chance that there is something that can be used in the lab in exchange for purchasing some of these components. Table 1 Below is the materials needed in this design with the expected costs.

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<thead>
<tr>
<th>Parts Needed</th>
<th>Average Price</th>
<th>Expected Cost</th>
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<tbody>
<tr>
<td>2 Borescopic Lenses</td>
<td>$200.00</td>
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<tr>
<td>CDC/Highspeed Camera</td>
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<td>Aluminum Scrap Metal</td>
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<tr>
<td>Clear Acrylic Plexiglass Tube 6&quot; OD X 5.75 ID X 11-</td>
<td>$50.00</td>
<td>$50.00</td>
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<td>7/8</td>
<td></td>
<td></td>
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<tr>
<td>----------------------------------------------------------------------</td>
<td>-------</td>
<td>-------</td>
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<tr>
<td><strong>1953 Bumper bolt and nut, low dome stainless steel cap</strong></td>
<td>$1.89</td>
<td>$18.90</td>
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<td><strong>Pressure Hand Pump</strong></td>
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<tr>
<td><strong>Valve/Fittings</strong></td>
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<td>$25.00</td>
</tr>
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</table>

Table 1 – Expected products and Budget for the design

4 Conclusion

With the completion of this project proposal the system will be able to quantify heart valve leaflet strain for both surgical and transcatheter aortic valves. The system will build off of a previously designed project that will not leak, have better results and easier to clean. It will also be pressurized using a mechanical pump with a consistent pressure output. The new device will allow for easy rotation and viewing of the three different leaflets on each valve. These changes will allow for testing of multiple valves much faster than before and with better accuracy.
Works Cited


