Optimal Design #17 Report

Development of a Pulsatile Left Heart Simulator

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Team #17

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1 Optimal Design Project #17

1.1 Introduction

The purpose of the project is to build a pulsatile flow loop that allows for implementation and testing of mechanical and bioprosthetic valves while accurately simulating the hemodynamic pressure and flow conditions of the left side of the heart. The optimal design includes an easier, more successful method for implementing a biological aortic root into the flow loop, as requested by the client, Dr. Sun. The flow loop is oriented horizontally to prevent an increase in pressure throughout the system when the longer aortic root is implemented. The whole system is composed of Plexiglas to enable the mitral and aortic valve functions to be observed through viewing ports at both the inlet and outlet sides of the valves. The ventricle chamber is set up as a square, allowing the fluid to enter and exist at a right angle. Cameras are mounted on both sides of the ventricle, allowing visualization of the valves simultaneously. It is also important that this design does not affect the physiological waveforms produced by the function of the heart valves.

A model of the optimal design is shown below in Fig. 1 and a flow chart of the path of fluid flow throughout the system can be seen in Fig. 2. The fluid enters the system through the atrium, a large chamber functioning to hold excess water not currently in use by the system. The open-top design allows for a fluctuation in volume without causing an increase in pressure throughout the system. A heat reservoir also encases the atrium chamber to heat the fluid to 37°C in order to simulate the \textit{in vivo} environment. The fluid next flows from the atrium through the mitral valve. The mitral valve incorporates a system of set-screws that adjust so that various sized mitral valves can be mounted into the system for testing. Next, the fluid flows through the mitral valve down to the ventricle. The ventricle consists of an inflatable latex sack in an airtight housing. A pulsatile air pump is used to control the pressure of the system. An intake of air causes the ventricle to inflate, whereas a pump of air causes the ventricle to contract, closing the mitral valve and forcing fluid through the aortic valve. The design for the aortic valve mount is very similar to that of the mitral valve and also incorporates adjustable set-screws so that a variety of aortic valves can be mounted into the device.

The fluid flows from the aortic valve out into the ascending aorta, which is a series of tubing. After traveling through the ascending aorta the fluid must pass through a compliance chamber, simulating the resistance of the body on blood flow. The compliance chamber is a rubber compartment contained within a Plexiglas tube so that the pressure applied to the flow at this point is variable. The fluid then returns to the atrium through another series of tubing. Pressure sensors are present at each of the components to measure the pressure in each segment. A flow meter is also present following the mitral and aortic valves to measure and record the fluid flow rate through the valves. This enables the generation of physiological waveforms of the simulated heart cycle, as well as the detection of regurgitation in the valves or other mechanical problems.

This optimal design is superior to the two alternative designs due to the valve mounting method. This mounting device is the easiest design and it also allows for greater versatility of the device because valves of many different diameters and lengths can easily be mounted into
the device for testing. This design also incorporates the heat reservoir from a different optimal design because it will provide an environment more comparable to the conditions present in the human heart.

Figure 1: SolidWorks Model of the Optimal Design

Figure 2: Schematic of Optimal Design
1.2 Subunits

1.2.1 Atrium Chamber

The first component of the pulsatile flow loop is the atrium chamber. Water supplied to the flow loop, from the water source in the laboratory, first enters the system through the atrium. The main purpose of the atrium chamber is to serve as a reservoir, holding excess water not currently used by the system. Figure 3 shows the design of the atrium previously built by a graduate student of Dr. Sun’s research team with an addition of a surrounding heat reservoir. The original atrium is implemented in the optimal design because it has successfully held and supplied water to the system in Dr. Sun’s previous tests. The atrium design consists of a 5.75” by 12.25” by 3.25” open topped chamber of Plexiglas. The large open-topped chamber allows for a fluctuation in volume without causing a drastic increase in pressure throughout the rest of the system. This is important because an increase in pressure occurring at the beginning of the loop would be experienced throughout the rest of the system. As a result, pressure readings obtained at the mitral and aortic valves would be inaccurate, as would the physiological waveforms of the system. The water in surrounding heat reservoir will be heated by a water heater. This modification will implement a temperature of 37°C, resulting in a more accurate representation of the in vivo environment. A hole at the base of the atrium opens up to a tube connecting to the mitral valve chamber. The valve chamber will be compression fit against the side of the output of the atrium. The compression will prevent leaks around the valve resulting in the correct pressurizations in the chambers.

Before a complete test of the system can be administered, each component must be individually tested for success. Water will be pumped into the atrium and the flow rate into the mitral valve will be tested using a flow meter. A slow rate will indicate a blockage within the atrium exists. The atrium will also be inspected for leakage, which would affect the pressure in the system and ultimately result in inaccurate physiological waveforms.
1.2.2 Mitral Valve

The mitral valve is a key aspect of this flow loop because it acts as a doorway for fluid to flow through to the ventricle so it can then be pumped throughout the system. The mitral valve is a one way valve. As fluid is pulled into the ventricle, the two valve leaflets open allowing fluid passage. When the ventricle contracts pushing fluid out, the pressure of the two leaflets pushes them backwards, closing off the path. The mitral valve used in this design is already constructed and available in Dr. Sun’s laboratory. Valves are manufactured and sold to hospitals, making it very difficult and expensive to obtain new ones.

One of the key goals of this project is to be able to incorporate different sizes and types of valves into the mitral and aortic positions. The design of the valve housing reflects this issue. The housing consists of a solid aluminum rectangle with a hole bored into it with a diameter as large as the widest valve used in this type of testing. This hole will extend through the majority of the rectangle until the end where a smaller hole will be drilled, allowing the valve to rest against a flat surface. The first type of valve that may be implemented in this position is a bioprosthetic valve. This valve type consists of a sewing ring or annulus at the base that is supporting three struts. Between these supports are three tissue leaflets that meet in the middle. A crucial characteristic when attaching one of these valves is that the three struts must have a small amount of space to flex as the valve opens. To fix this valve in place, a thin-walled steel cylinder with an outer diameter the same as the diameter of the larger hole will slide down onto the valve once it has been placed in the chamber. The cylinder will be pushed down to compress the valve in place to prevent sliding. Along the rectangle four holes will be drilled...
from each edge face. Set-screws will be used to hold the cylinder in place, holding the valve steady in the process.

The mechanical valves present a different problem. They are cylindrical and the sewing ring runs up along the side of the valve. This type cannot be secured using a top down compression mechanism. Instead, this valve will be held in place using compression plates from the sides. Four small curved aluminum sections will be cut and fixed to sections of a compressible gasket, as shown in Fig.4. Each of these four sections will attach to one of the drilled holes for the set-screws. These sections will be attached to screws of their own and will be moved inwards towards the valve until the valve is compressed and stable. Using this method will result in an easy process allowing different valve types to be changed out without removing or building too many different parts.

![Figure 4: SolidWorks Mitral Valve Mount Model](image)

1.2.3 Pulsatile Air Pump

A pulsatile air pump is attached to the bottom of the ventricle chamber to pump fluid through the system simulating that of a heartbeat. The pump currently used in Dr. Sun’s laboratory will be implemented as it has accurately pumped fluid through the original flow loop in previous tests. It was able to generate proper pressure and fluid rates to produce
physiological waveforms resembling those produced by a human heart. The pump has two knobs that control the systolic and diastolic pressures applied to the left ventricle. Also, a control on the pump is used to regulate the number of simulated heart beats per minute, which in turn controls the number of systole/diastole cycles per minute. Additionally, a control on the pump can be used to regulate the duration of the systolic phase in milliseconds.

1.2.4 Ventricular Chamber

In the human body, the left ventricle is responsible for pumping blood through the aortic valve into the ascending aorta and out to the rest of the body. In this flow loop, the ventricle will pump fluid through the system powered by a pulsatile air pump described in Section 1.2.3. The ventricle design is adopted from the preexisting ventricle developed by Dr. Sun’s research team, consisting of a latex sack housed in an airtight chamber. The pulsatile air pump is connected to the bottom of the chamber. As seen in Fig. 5, the ventricle chamber is designed as a square, with the flow entering then leaving in a right angle. This square design allows visualization of the mitral and aortic valves while the system is running. Cameras can be mounted on two of the sides of the ventricle which will allow visualization of both valves simultaneously without affecting the overall physiological flow waveforms. The two paths of view cross along the center of the ventricle and continue through the valve chambers until they reach view windows at either the exit from the atrium, or the entrance to the compliance chambers.

Each heartbeat simulated by the pulsatile air pump will pump an amount of fluid through the system determined by the systolic and diastolic pressures applied by the pump to the left ventricle. The human heart contracts during the systolic phase of the heartbeat. To implement the systolic phase into the flow loop, the pump pushes air through a tube into the airtight chamber housing the ventricle, directly influencing the internal pressure. As a result, the ventricle collapses on itself, pushing fluid through the aortic valve. Simultaneously, this contraction of the ventricle will apply pressure to the mitral valve which will close it, preventing water from entering the atrium via this route. In contrast, the diastolic phase of the heartbeat is when the ventricle relaxes and fluid flows through the mitral valve to refill the ventricle. To simulate the diastolic phase, the pump draws air from the ventricular housing chamber, creating a vacuum. As a result, the sack inflates to its original size and is filled with fluid from the atrium through the one way mitral valve. This process accurately simulates the muscle contraction and relaxation periods of the human heart, enabling the valve function to be focused on during testing.
1.2.5 Aortic Valve

The aortic valve is the section of the flow loop that receives fluid as it leaves the ventricle. Although entirely different in the human body, the aortic and mitral valves used in this flow loop for study are very similar. Manufactured mitral and aortic valves differ only slightly and these differences are negligible in this design. The aortic valve housing chamber is identical to that of the mitral valve chamber and secures the valves using the same methods.

The main difference in this section is that two different interchangeable housing chambers will be built to serve very different purposes. One will be designed to house the mechanical and bioprosthetic valves and the other will be designed to fit a biological porcine or bovine aortic valve and a section of the ascending aorta. The design of this section will depend on additional outside research currently being conducted by Dr. Sun’s research team. The section below the native leaflets is not uniform and is very difficult to mount. A process is being developed outside of this design group to determine the best method of attachment. When this is decided, a new housing chamber will be built so that it can be easily exchanged for the other chamber. This section will be the last feature implemented into the design. The flow loop must be run and be calibrated using the original valves before the second design can be implemented.
1.2.6 Ascending Aorta

The ascending aorta is the component of the heart that pumps the oxygenated blood coming from the heart out to the entire body. The ascending aorta is the largest artery in the body and it splits into smaller portions as it moves further away from the heart. In the flow loop, this component is made up of a series of tubing to simulate the separation of the blood into different sections to travel throughout the body. The tubing used for the ascending aorta is Urebrade Reinforced Polyurethane Tubing, with an inner diameter of 0.25” and an outer diameter of 0.47”, which is designed to resist weathering and tearing. It is a very tough and resilient material that can withstand high pressures so it is not very elastic. Since the arteries in the body actually have an elastic component, the flow loop must compensate for the rigidity of this tubing, which is done using the compliance chamber.

1.2.7 Compliance Chamber

The compliance chamber is the portion of the flow loop that maintains the accuracy of the waveforms produced by the device. After leaving the aortic valve and while passing
through the ascending aorta, the fluid encounters the compliance chamber. Compliance exists in the heart, therefore it must also exist in the design of the device. Compliance is defined by:

\[
\text{Compliance} = \frac{\Delta S}{\Delta P} = \frac{\Delta S}{\Delta P_{\text{systolic}} - \Delta P_{\text{diastolic}}}
\]

where \(\Delta S\) is the change in the aortic cross-sectional area and \(\Delta P\) is the change in pressure [1]. Compliance indicates the ability of the walls of arteries and veins to contract and expand as the interior pressure changes. There must be a component to compensate for the requirement to expand and contract according to the arterial pressure since the material used for the ascending aorta is so rigid.

This is accomplished using a rubber compartment contained within a cylindrical Plexiglas structure, as shown below in Fig. 7. The tube is approximately six inches in length and has a inner diameter of three inches and an outer diameter of three and a half inches. It is connected to a controllable pressure pump and gauge so that as the pressure within the tube changes, the size of the rubber compartment changes accordingly. The device has this feature because the pressure at which the best waveforms will be produced is unknown. The ability to adjust the amount of compliance applied to the system will provide a method for adjustment in troubleshooting if the waveforms obtained at first are not quite similar to the expected results.

This compliance chamber is connected in the loop between the ascending aorta and the throttle valve. The fluid flows through the rubber compartment within tube so that the pressure can adequately impact the flow. As seen in Fig. 8, the rubber component is attached to the tube at both ends so that the portion between the rubber and the tubing has no openings to the outside, other than the opening leading to the pressure pump and gauge. The specific type of material that will be used for the rubber compartment has not been decided yet because the amount of stretch and contraction required of the compartment is not known. Part of the building and troubleshooting process will include testing of different sizes and strengths of balloons to decide which type of balloon will work best for this device.
Figure 7: SolidWorks Model - Inside View of Compliance Chamber

Figure 8: SolidWorks Model of Compliance Chamber 2
1.2.8 Data Acquisition

There will be two types of data acquisition devices used in this flow loop system. One is a flow meter and the other is a pressure sensor. The electronic flow meter will be mounted right before the aortic valve chamber. Ideally, it will be positioned as close to the annulus of the valve as possible so that the waveforms obtained can be used to detect problems, such as the regurgitation rate and back flow of the valve. To measure the pressure in the system, many small close-able ports will be built into the chambers at various locations. These ports will consist of small tubes running from the desired location inside a specific chamber to the exterior where they will be attached to hose valves. These valves will allow for the attachment of electronic pressure sensors which will take the desired pressure waveforms from the system. At a minimum, pressure ports will be located before the mitral valve, inside the ventricle, before and after the aortic valve, and one along the path of the compliance. The exact locations of these ports will be decided upon after completion of the flow loops main components.

2 Realistic Constraints

2.1 Engineering Standards

As requested by the client, the final pulsatile flow loop model must allow implementation of mechanical and bioprosthetic valves of various sizes while producing accurate physiological waveforms resembling those produced by the human heart. Each component of the flow loop must be compression fit as to not leak or alter the pressure or fluid flow rate of the entire system. If the waveforms are inaccurate or if a problem exists with the valve function, such as regurgitation, the system must be re-evaluated to find a solution to the problem. This may include modifications to the valve mountings or ventricle set-up. Also, to mimic the in vivo environment, the heat reservoir must maintain a temperature of 37°C. If the temperature fluctuated, the model would no longer resemble the environment in the body. Thus, the whole system must be constantly monitored to locate and prevent problems.

2.2 Economic Constraints

Although the client is quite generous with the budget, we must keep it in mind at all times. We will be ordering blocks of aluminum and Plexiglas, and it is important that we don’t overspend. We must also be aware of the possibility of failure in the early trial period of testing, which may result in reconstruction of components, thus additional ordering.
2.3 Environmental Constraints

To the extent of our design, the flow loop will only contain water running through it. Although the water will be supplied by Dr. Sun’s laboratory, we can reuse the water flowing through the system multiple times as to not take advantage of the supply. If there ever comes the time that simulated body fluid would be implemented into the system, we would have to be conscious of leakage due to its high expense. We will also be limited to the water heater in the laboratory so we will have to share it if any other teams are using it as well.

2.4 Sustainability

Due to the fact that in the trial and error period of testing the system will be running countless times a day, it is important that our design is stable and resilient. The Plexiglas of the previous flow loop design cracked at the location of the screw insertions over time. To avoid this problem, our design will implement smaller screws, enabling the Plexiglas to withstand the pressure of the system.

More importantly, it is crucial that the replacement valves remain in good condition and continue to function properly. Because the valves currently used in experimentation are about five years old, we must constantly monitor their function. If one of the valves is no longer suitable for testing, it may be necessary to order a new valve which would be very expensive.

It is also important that the pulsatile air pump functions properly throughout the trial runs. This is because if the correct systolic or diastolic pressure isn’t implemented into the system from the beginning, it is not possible for the accurate physiological waveforms to be produced. It would also be very expensive to replace such a crucial component of this system.

2.5 Manufacturability

Although much of the material will be provided by the Tissue Mechanics Lab, it will be necessary to construct a few of the components from Plexiglas and aluminum. The valve mountings, as well as the compression fit ventricle chamber will be machined in the UConn Machine Shop. If the proposed design hinders accurate physiological waveforms in any way, it may be necessary to redesign specific components. More specifically, if the sharp angles of the square ventricle design impedes fluid flow, it may have to be altered to a V-shape. However, due to the requested view ports on the inlet and outlet sides of the valves, the possible alterations to the design may be limited in order for clear images to be obtained. The worst case scenario may include a sacrifice in the field of vision in order maintain the proper physiological waveforms of the fluid running through the valves.

It may also be necessary to change the compliance back to two Plexiglas cylinders as in the original design if the rubber tubing does not produce efficient resistance.
2.6 Social Constraints

Once the initial design is constructed, it is expected that troubleshooting and modifications will be necessary to achieve the appropriate cardiovascular waveform results. Therefore, time will be a great constraint the second semester if a large amount of modifications must be made. Each group member must be able to sacrifice and manage their time so that the completes project will be successful and of satisfaction to the client.

3 Safety Issues

This project is designed and implemented in a safe, controlled environment so minimal safety issues exist. The only electronic components involved with the device are the flow meters which are connected to a computer to read and record data. In the existing device, one of the major issues is that there are several interfaces that are not perfectly sealed and the water flowing through the loop leaks. Since water is the only fluid that is used to test the device, the leaks to not cause a health or safety issue unless the water leaks uncontrollably.

Initial testing will be performed using mechanical valves and water flowing through the loop. However, later on in the process, mechanical valves will be replaced with bioprosthetic valves to test their ability to function in the device. As mentioned previously, the current device has several locations that are not sealed correctly and the water leaks out. This alone does not cause a safety issue but once the valves, made up of biological tissues, are introduced, the leaking water could cause a biological hazard.

Also, many of the flow loop components must be machined into specific dimensions or drilled into for screw insertion. Two of the three members will be machine shop certified to perform these tasks, following the necessary safety precautions.

4 Impact of Engineering Solutions

The device itself will not have a direct impact on society because it is a model of a heart, as opposed to a device that will, for example, be designed, tested, and implanted into an individual. At the same time, the implications of this device are potentially great. When it is complete, several different mechanical and bioprosthetic heart valves and heart stents can be mounted and tested using the device. The device will also be used to observe how the aortic and mitral heart valves function during the cardiac cycle by imaging the heart valves from the inlet and outlet sides. This will help gather additional information about heart valves to help improve their design and create additional solutions to the problem of heart disease.

Because heart valve replacement surgery is quite common, testing of bioprosthetic heart valves for success in the *in vitro* environment will provide surgeons with the confidence that the valves will function properly in a patient. Patients will be able to understand that their
new valve will function like their original valve, alleviating the fear that it might fail or that they might have to undergo another surgery to have it fixed.

Currently, ViVitro Labs Inc. in Canada has developed the world-wide known ViVitro Pulse Duplicator in which they rent out to companies and surgeons to test their replacement heart valves. Additionally, companies and surgeons have the option of sending their heart valves to ViVitro to have technicians complete the testing. Ideally, if our pulsatile left heart simulator could be easily manufactured and marketed, companies or surgeons in need of testing replacement heart valves could purchase a flow loop for themselves. This way, it would be less of a hassle and companies could test the replacement valves regularly. An increase in heart valve replacement research would result, aiming for the ability to improve the lives of those suffering from heart valve disease.

5 Life-Long Learning

Through researching and designing modifications for the existing pulsatile flow loop, we acquired knowledge and experience that will be of great use in future projects and ultimately in industry. Because an understanding of how the components of the flow loop combine to function properly was obtained from the existing model, the main aspect of this project was to design alterations for improvement. The ability to work together as a team to generate innovative ideas is a necessary skill to become a successful engineer. Brainstorming various ways to accomplish the same task tested our creativity. Another crucial aspect of working as a team is the ability to accept criticism of one’s own ideas while at the same time understanding that a different idea may be more feasible and effective. The process of trial and error was executed in order to produce the optimal design. This is another key factor necessary to become a successful engineer.

Most importantly, the team experienced production deadlines. A large amount of work was expected to be completed in a short period of time. This forced each team member to successfully manage his or her time in order to do a sufficient job while pulling an equal amount of weight in the group. This skill is important in any work setting. Also, it was expected of the team to become proficient in writing professional reports. The reports were graded so that we could learn the correct way to write each section. This knowledge will be extremely helpful when writing reports for future projects.

Another important aspect of this project is the ability to work within a budget. The team was encouraged to use the resources already available in the client’s lab and only buy materials that are required outside of these resources. When buying additional products, the team was also encouraged to find the most cost-effective sources to purchase items from. The client required a reliable device so the materials had to be inexpensive without sacrificing quality. This aspect of the project taught economical skills which is important in any industry. It is important to perform any task using the best cost-effective sources because it saves money and other resources for the company or sponsor of the project.
More specifically, the team acquired additional detailed knowledge of the human heart cycle. It was necessary to know the anatomy of the left side of the heart along with the mechanical properties of the mitral and aortic valves in order to generate appropriate designs. As a biomedical engineer, an important goal is to be able to apply mechanical and physical processes to human body functions. The team also learned how to use SolidWorks and Microsoft Visio 2010, which are both common software programs used in industry to design three-dimensional models.

Looking forward into the design process, the team will learn technical skills while constructing the actual device. Building the device will test the team’s proficiency with machinery and engineering. There will most likely be several different designs of certain components of the system as the current designs are implemented and adjustments need to be made. It is important to have a good plan before the building process begins but the nature of this device will force a great deal of trial and error. The team will have to keep this in mind so that the changes are expected and deadlines are not missed because of unexpected problems. This is applicable to any work setting, specifically in an engineering job, because managers will not be interested in why a device is not working when the deadline comes up. They will but upset that the deadline is not met and that they do not have a working device in time.

### 6 Budget

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b) Clear, Acrylic, Plexiglass 3” (ID, 3.5” OD) by 12” | a) $26.59  
b) $29.82 |
| Tubing         | a) Superthane Ester Based Tubing  
Outer Diameter (OD) = 0.125”  
Inner Diameter (ID) = 0.0625”  
b) Urebrade Reinforced Polyurethane Tubing  
OD= 0.47”  
ID= 0.25” | a) ($0.11/ft)(25 ft)  
b) ($1.34/ft)(25 ft) | a) $2.75  
b) $33.50 |
<p>| Valve Mounting | a) 6061 Aluminum | a) $115.02 |</p>
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7 References