Final Design Report
Bernoulli Heart Valve - Project 13

Bella Barbera Suzy Ellis Cameron Henry
Stephen Paige Vishal Vijayakumar
College of Engineering and Mathematical Sciences
The University of Vermont

May 10th, 2021

Date	Revision	Release Notes
05/10/2021	01	First Draft

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1 Project Handoff

Both the disclaimer form and project memo are provided at the beginning of this documentation.

2 Project Design Details

2.1 Abstract

The problem at hand is that current mechanical heart valve designs have a high risk of clot formation due to platelet activation and/or hemolysis, red blood cell death, when compared to biological heart valves.[4] To generate a mechanical heart valve that can open to 90 degrees during forward flow and close fully during backward flow. The leaflets have an airfoil geometry to create a pressure differential sufficient enough for this to occur. Computational fluid dynamic simulations are used to validate this process for 2D computer models. Additionally, 3D printed physical models are used concurrently with the simulations to strengthen evidence. Results from the 2D and 3D static computational simulations suggest the airfoil shaped leaflets induce a sufficient pressure gradient that would help ensure proper closure of the valve from the fully open 90 ° position. The wall and leaflet shear results also show promise in remaining below the acceptable threshold to prevent hemolysis and further complications. The physical model also demonstrated ability to open and close sufficiently in response to pulsatile flow in the testing apparatus. All of these results advocate for further development of this novel design as the results show evidence that the airfoil leaflets do allow for an improved opening angle from the current bi-leaflet mechanical heart valve. To progress with this model, dynamic simulations should be performed to increase confidence in the exact behavior of the leaflets throughout the pulsatile flow cycle. Additionally, physical

testing was performed that mimics the conditions of the heart chamber as closely as possible and then compared to computational modeling results.

2.2 Problem Statement

Create a heart valve, using airfoil leaflets, that opens to 90 degrees during forward flow and reliably close during back flow. This would reduce the high flow gradient that is common in current mechanical heart valves. When there is a high flow gradient present, it causes more hemolysis, thus amplifying blood clotting. Minimizing the flow gradient will reduce the shear of red blood cells (RBC) and reduce the need for blood thinners. This allows the individual to worry less about bleeding out if injured during high risk activities. The valve geometry must create a sufficient pressure differential to initiate the closing action during back flow. It must be engineered using a biocompatible material to not cause bodily rejection. It must also be able to open to 90 degrees.

2.3 Client Requirements

1. Open to 90 degrees which allows for reliable blood flow.
2. Generates flow field that is analogous to the flow field of blood within a natural human heart.
3. Uses airfoil geometry which allows the leaflet to open fully to 90 degrees due to the pressure gradients providing a sufficient pressure difference.
4. Minimizes hemolysis and thus decreases blood clotting. RBCs shear when their velocity is too high when coming in contact with the leaflet and walls of the domain. The proteins released from ruptured RBCs induces more blood coagulation. This requires the

individual to take blood thinners which impedes their lifestyle as they must minimize high-risk activities that could cause injury leading to dangerous hemorrhaging.

The inability for current bi-leaflet mechanical heart valves to open to 90 ° negatively affects the patient by further restricting blood flow through the valve. This can lead to increased coagulation and hemolysis and requires the patient to take blood-thinner medication, but it necessary to provide reliable closing of the valve. Therefore, one of the most critical improvements this design provides is to have the leaflets open to 90 ° to in theory reduce the need for blood thinners. To be able to open to 90 ° the airfoil leaflet must be able to induce a pressure gradient that is sufficient to ensure proper closing. All of the client requirements listed above work together to make the wider opening angle possible.

2.4 Working Design Concept

The novel bi-leaflet mechanical heart valve is designed to passively open to 90 degrees and close to 180 degrees with normal cyclical cardiac rhythm. The leaflets are designed to have airfoil-like geometries to initiate pressure differentials and utilize the Bernoulli principle as the mechanism of action to initiate closing. To validate this design, the concept is tested via computational fluids methods as well as physical testing of 3D prototypes. Therefore, the working design concept consists of 2D and 3D computational models as well as a 3D printed prototype. The product consists of a metal aperture, in which two leaflets may freely rotate on hinges spanning their diameter. A suture ring made of dacron is located outside of the aperture. It is the suture ring that is sewn into the heart muscle of the patient.

Figures 1 through 4 show the working design concept for the computational side of the project. Figures 1 and 2 show the 2D CAD that was employed for 2D simulations while Figures 3 and 4 show the 3D CAD used for 3D simulations. As you can see the first figure for 2D shows the leaflets open to 0 ° and the second 2D CAD Figure shows the leaflets after having rotated 90 ° which is the most important concept of the working design. The same concept is shown in the 3D CAD as well with the leaflets open to 0 ° and closed at 90 °.

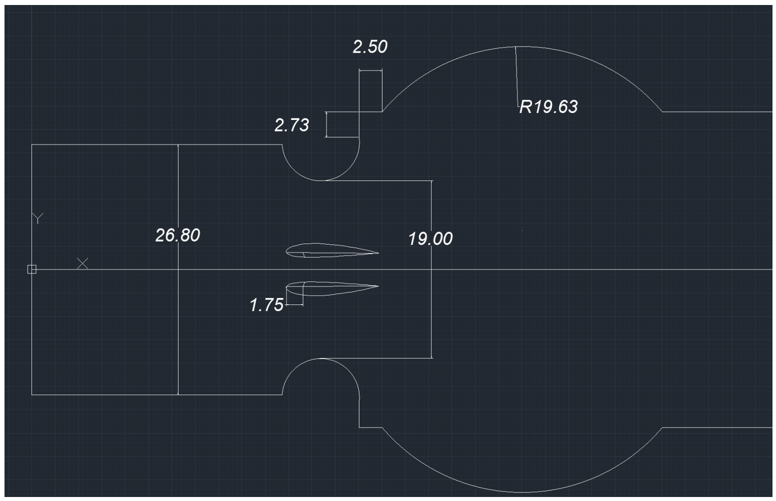


Figure 1: 2D Valve fully open at 0° (All units in millimeters)

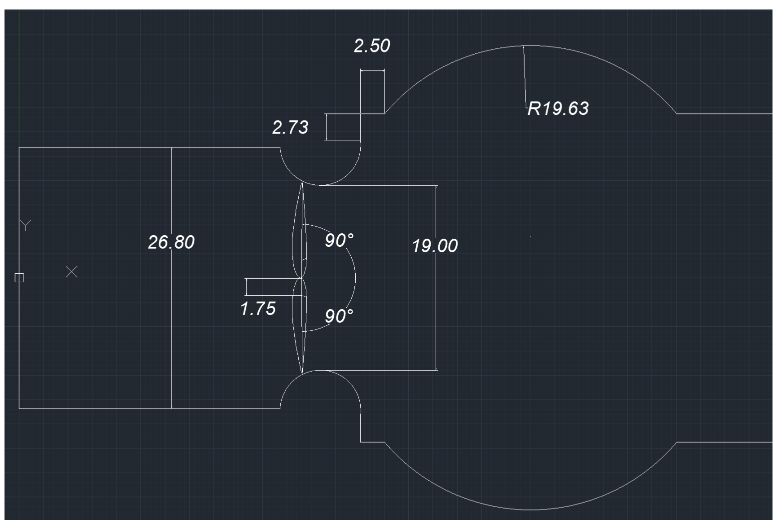


Figure 2: 2D Valve fully closed at 90° (All units in millimeters)

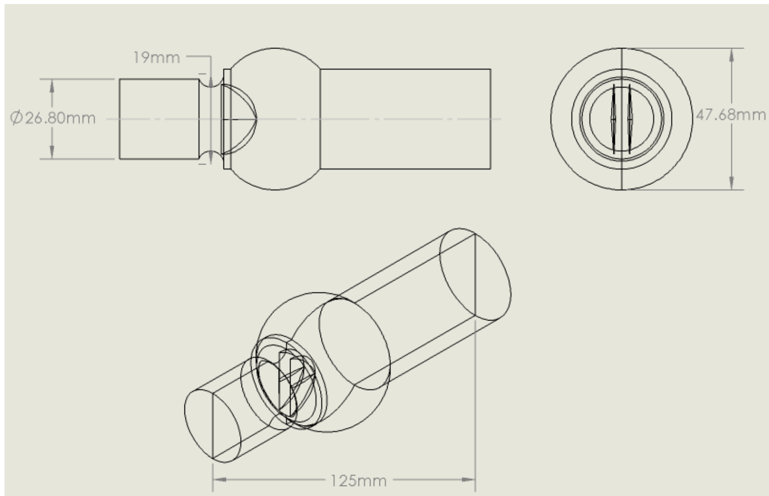


Figure 3: 3D Valve fully open at 0° (All units in millimeters)

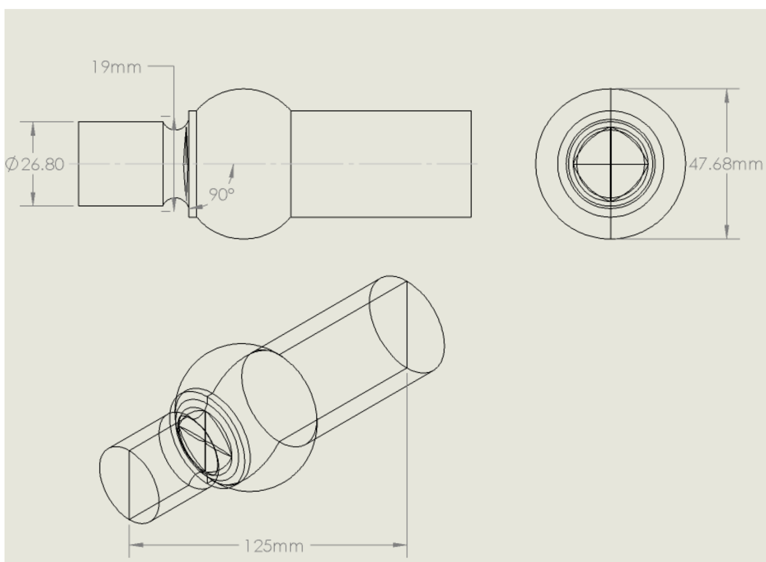


Figure 4: 3D Valve fully closed at 90° (All units in millimeters)

The major function of the valve is possible as a result of the leaflet geometry. For the leaflets to be open fully at 0 ° to the horizontal, there must be a pressure gradient induced somehow across the leaflet by the reverse flow to force the leaflet closed. With previous flat and curved leaflet designs being open fully to 90 ° was not possible due to their then inability to close. The airfoil-like geometry forces the flow to move at a greater velocity over the top of the leaflet resulting in a lower pressure above the geometry as seen in Figure 5.

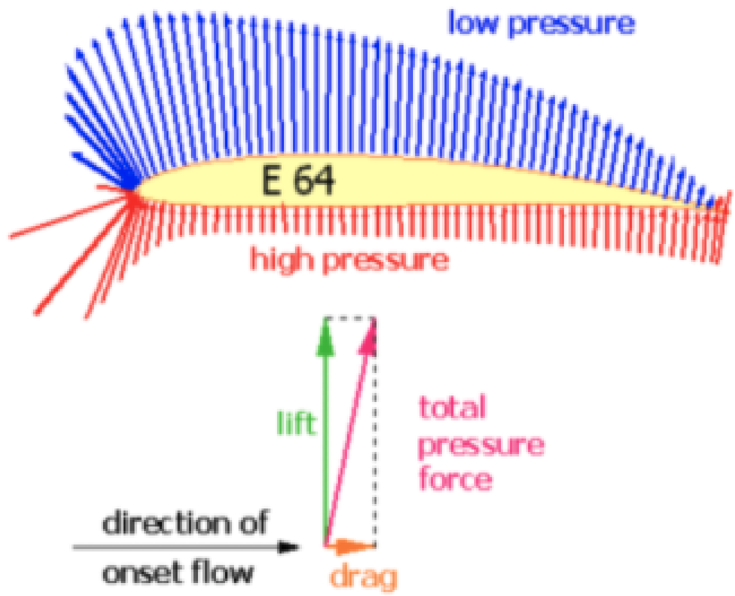


Figure 5: Airfoil Concept Explanation

This means the lower velocity below the leaflet causes a greater pressure beneath it which will force the leaflet to rotate about its hinge to the closed position 90 ° from the horizontal. This accomplishes the major desired functions of the leaflet to open fully to 0 ° as well as close reliably. Other minor functions are satisfied as well as a result of the major function being successful. The purpose of opening to 0 ° is to minimize hemolysis and therefore blood clotting, which would be accomplished as a result of the major function.

2.5 Analyses

A number of analyses were performed by each team member to provide further information on the working design concept. These are the following analyses:(1) the effect of airfoil leaflet geometry on parameters, (2) determining the correct flow: Newtonian vs. non-Newtonian, (3) effect of leaflet angle on shear and axial velocity, (4) pressure gradient formation with respect to backflow on the airfoil leaflet, and (5) determination of material selection.

2.5.1 The Effect of Airfoil Leaflet Geometry on Parameters

Currently, heart valves employ a flat or curved leaflet geometry. However, these designs do not allow for the leaflets to open fully to 90 degrees. For the leaflets to open to 90 degrees, they must induce a proper pressure gradient that ensures closure. To accomplish this, one pair of the leaflets are designed with an airfoil-like geometry that takes advantage of the Bernoulli Effect to help close the leaflets from their 90 degree opened position. The shape of the Bernoulli leaflet is larger in the center and tapered towards the edges. Thicker leaflets generate a greater velocity difference of the blood flow between the upper camber and lower camber surfaces because the fluid travels faster on the upper camber. However, increasing the thickness essentially decreases the opening angle because the projected area of the leaflets is increased. Therefore, an analysis of leaflet thickness must be conducted to determine the minimum thickness necessary to begin valve closing during diastole while not being too thick as to decrease the angle of opening. As this is a novel application of the Bernoulli principle, the consistency of performance is also an unknown quantity. During systole when the valve is opening, the valve should theoretically operate exactly as current bileaflet valves do. The uncertainty however lies during diastole, when the valve is closing. The initial point of closing when the valve is still close to 90 degrees is what is determined from the Bernoulli effect and the consistency and rates of closing requires analysis to determine how reliable this principle is performing.

Analysis Method

The flat and airfoil leaflet geometries are compared against each other by analyzing differences in wall shear, leaflet shear, axial velocity and turbulent kinetic energy. These parameters will be obtained from computational fluid dynamic simulations. The first step to obtain these results is to create the computational domain using 2D CAD, in this case the surrounding domain modeled was the aorta surrounding the leaflets. From there, the geometry can be implemented into a meshing software in order to properly divide the geometry into finite volumes for analysis. Visuals for this process can be seen in the section earlier: Functions - Computational. Lastly, the refined mesh can be brought into the fluid simulation software, where means of obtaining the desired parameters can be set up to get values for axial velocity, shear and turbulent kinetic energy. Within ANSYS Fluent, the computational fluids software, the density and viscosity of blood were assumed to be 1050 $\frac{kg}{m^3}$ and 0.002 $Pa(s)$ respectively. The "inlet velocity" or velocity at which the flow is initialized at is assumed to be 1 m/s as the average velocity of blood through the aortic valve is 0.3-0.8 m/s. The higher end of this velocity range was used in the analysis to capture the time when hemolysis and shearing would most likely occur. ANSYS Fluent uses a control-volume-based approach to adapt a general scalar transport equation to an algebraic equation that can be solved numerically. This control volume approach subsists of integrating the transport equation about each control volume, which yields a discrete equation that expresses the conservation law bases around a control-volume technique. The following unsteady conservation equation for transport of a scalar quantity can be seen below:

$$\int_V \frac{\partial \rho\phi}{\partial t} dV + \oint \rho\phi\vec{v}\cdot d\vec{A} = \oint \Gamma_\phi \Delta\phi \cdot \vec{A} + \int_V S_\phi dV \tag{1}$$

Where ϕ is the scalar quantity being transported, ρ is density, $\vec{v}$ is a velocity vector, $\vec{A}$ is a surface area vector, Γ_ϕ is a diffusion coefficient of ϕ, Δ_ϕ is a gradient of ϕ, and S_ϕ is the source of ϕ per unit volume. It is this equation that is applied to each and every control volume in the computational domain. With regards to the turbulent aspects of the flow, a $k-\omega$ turbulence model was employed which is applicable to wall bounded flows such as this one. It is based off of model transport equations for the turbulent kinetic energy and specific dissipation rate. The turbulent kinetic energy k and the specific dissipation rate, ω are obtained from the transport equations below:

$$\frac{\partial}{\partial t}(\rho k) + \frac{\partial}{\partial x_i}(\rho k u_i) = \frac{\partial}{\partial x_j}(\Gamma_k \frac{\partial k}{\partial x_j}) + G_k - Y_k + S_k \tag{2}$$

$$\frac{\partial}{\partial t}(\rho \omega) + \frac{\partial}{\partial x_i}(\rho \omega u_i) = \frac{\partial}{\partial x_j}(\Gamma_\omega \frac{\partial \omega}{\partial x_j}) + G_\omega - Y_\omega + S_\omega \tag{3}$$

Where G_k is the generation of turbulence kinetic energy due to mean velocity gradients and G_ω represents the generation of ω. Γ_k and Γ_ω represent the dissipation of k and ω due to turbulence, and S_k and S_ω are user defined source terms. There are many more equations that further define the turbulence model, but these were deemed the most relevant.[1]

Interpretation

The first property contrasted between the flat and airfoil leaflet in order to determine differences was axial velocity. In Figures 6, flat leaflet, and 7, airfoil leaflet, the flow as it reacts passing through the leaflets at an angle of 25 degrees and the profile that develops afterwards as a result can be seen.

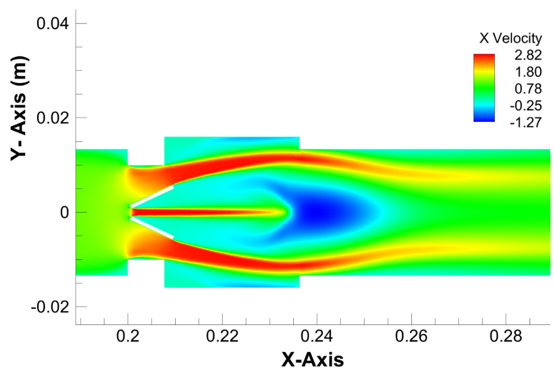


Figure 6: Axial Velocity of Flat Leaflet

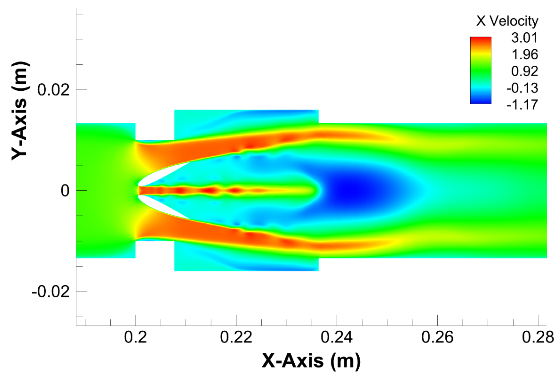


Figure 7: Axial Velocity of Airfoil leaflet

The axial velocity plots are almost identical in magnitude and distribution. Looking closely at Figure 7 however, there is much more unsteadiness within the flow surrounding the airfoil leaflet, most likely caused by the vortices induced by the geometry. This can be observed as the wrinkles or waves present in Figure 7 which are not seen in Figure 6. Looking at the averaged values of axial velocity along the profile in Table 10, the airfoil and flat leaflet produce essentially the same values. Therefore, axial velocity is not something that needs to currently be further improved moving from flat to an airfoil leaflet.

The next two images seen in Figures 8 and 9, compare TKE or turbulent kinetic energy, which is the mean kinetic energy per unit mass associated with eddies in turbulent flow.

Much literature suggested that points of hemolysis coincided with locations of turbulence eddies, and that hemolysis approximations could be made as a result, which is why turbulent kinetic energy is also observed. Only one angle is shown here to highlight the difference in geometries of the leaflets, as varying angles will be discussed next. The values of turbulent kinetic energy prove to be essentially the same when comparing the flat and wing-like leaflet and therefore did not currently influence any design considerations.

The values that shaped the direction of the project most from these analyses was the

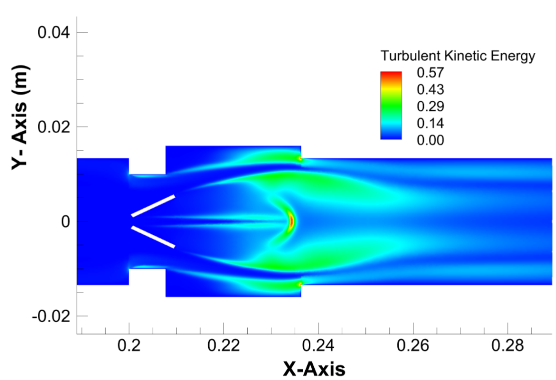


Figure 8: Flat Leaflet 25 °

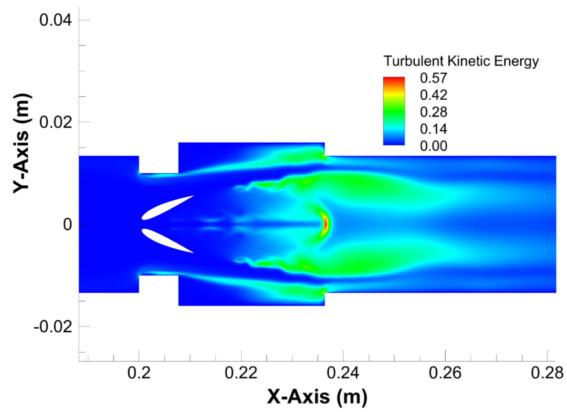


Figure 9: Airfoil leaflet 25 °

leaflet shear. While the average wall shear sees a slight increase on the magnitude of about 1 pascal from the flat to the airfoil shape, it is not a significant difference. However, the leaflet shear on the airfoil shape proves to be much greater when strictly compared to the flat leaflet. A comparison of these values can be seen below in Table 10.

Quantitative Analysis (Shear and Velocity)		
	Flat Leaflet	Airfoil Leaflet
Average Wall Shear (Pa)	6.30851	7.00501
Average Leaflet Shear (Pa)	61.39451	138.9531437
Axial Velocity (m/s)	0.70150	0.700640325

Figure 10: Table Containing Analysis of Leaflet Shear and Velocity of Varying Leaflet Geometries

Results - Accuracy and Future Directions

As previously stated, the shear results prompt more analysis with regards to the airfoil curvature and camber and hinge orientation to see if the team can reduce the leaflet shear as well as prove its success in closing from 90 degrees. This will be done using reverse flow with dynamic leaflets, preliminary experiments could be performed with static. It is important to keep in mind that this is a static simulation. In the future, the simulation will be improved to employ dynamic leaflets which could alter the values the team previously obtained. However, when dealing with computational fluid simulations, it is important to start simple and slowly then increase complexities to ensure accuracy. With regards to accuracy, to set up the most accurate fluid simulation, a sufficient amount of literature was consulted to determine numerical methods and models (e.g. turbulence) as well as flow parameters such as (density and viscosity). The simulation complexity, as mentioned, is also slowly increasing (i.e. dynamic leaflets, pulsatile flow, 3D) to allow more parameters to be analyzed. In addition to this, the mentor for the project Dr. Dubief as well as the CFD Professor Dr. Louisos both who are well versed in fluid simulation analysis, were often consulted.

2.5.2 Determining The Correct Flow: Newtonian vs. Non-Newtonian

There are multiple models that can be used to simulate blood flow due to blood being a shear-thinning non-Newtonian fluid. In general, it is easier to simulate flow using a Newtonian model because it reduces the amount of errors in the calculation. However, the properties of blood breakdowns the Newtonian model when blood flow is on the order of magnitude of -2. When simulating the blood flow in this application, the blood flow is on an order of magnitude of -1, meaning the Newtonian model does not break down. This makes calculating the velocity and shear values easier because errors are minimized.

Analysis Method

To minimize error and computational time, in general, it is better to use Newtonian models when applicable as they produce less errors in the calculations. However, due to the small scale of the simulation and smaller parameter values such as velocity and shear, the Newtonian model has potential to break down. Therefore, is was critical to perform an analysis to determine which fluid model to use when running simulations. The simulation software, ANSYS Fluent, uses a Newtonian model by default and it assumes the kinetic and dynamic viscosities are constant; they do not depend on shear rate.[1] The non-Newtonian flow was simulated using the Carreau Model using this formula:

$$\nu = \nu_\infty + (\nu_0 - \nu_\infty)[1 + (k\dot{\gamma})^a]^{(n-1)/a} \tag{4}$$

Where ν indicates the viscosity of the fluid, ν_0 is the viscosity at zero shear rate, ν_∞ is viscosity at infinite shear rate, k is the relaxation period in seconds, $\dot{\gamma}$ is the shear rate, a has the default value of 2 indicating change from linear to power law behavior, and n is the power index.[?]

A study conducting a similar analysis on modeling blood flow, concluded that the model type depends on the blood velocities. The following graphs are pulled from Reference 4,[5] Figure 11 shows how a Newtonian model is not as accurate as the non-Newtonian models when blood flow speed is at an order of magnitude of -2. However, the graph on the right in Figure 11 shows that there is no difference between the Newtonian model and Carreau model when blood flow has an order of magnitude of -1. Additionally, the blood velocities in a heart range from 0.3 to 0.8 m/s, thus the velocity values have an order of magnitude of -1 meaning that it is more conducive to use a Newtonian model when simulating blood flow.[5]

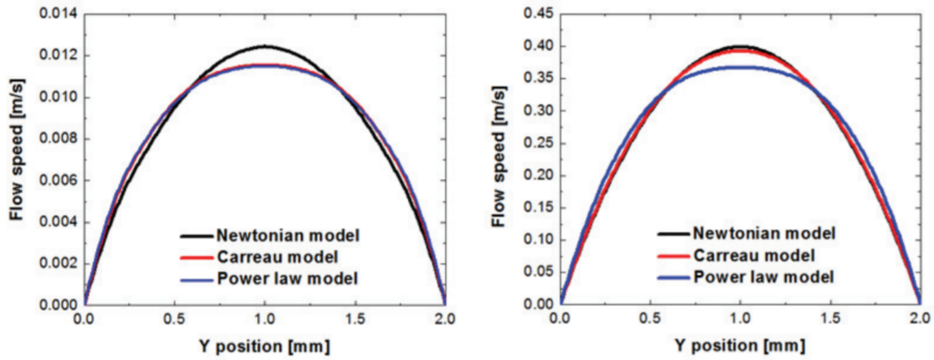


Figure 11: Comparing Blood Flow Values of Fluid Models at Varying Magnitudes.[5]

Interpretation

The results of the simulations indicated that it is more beneficial to run blood flow using a Newtonian model. Referring to Figures 12 and 13, the contour plots show that there is not much of a difference between the two models when looking at the x-velocity profile. The only notable difference is Figure 13 has a more gradual gradient of velocities, when looking at the orange trails, than Figure 12. Additionally, the blue zone is shorter for the non-Newtonian than the Newtonian. Figure 14 shows the values of the parameters extracted from the simulations. Note that non-Newtonian values were slightly higher than the Newtonian values. This can be attributed to errors in the calculations from the simulations performed.

	Newtonian	Non-Newtonian
Lealet Shear (Pa)	29.76293	33.81809013
Wall Shear (Pa)	4.4563132	5.13810826
Axial Velocity (m/s)	0.7018364	0.701692596

Figure 14: Comparing Parameters of Shear and Velocity Between the Models

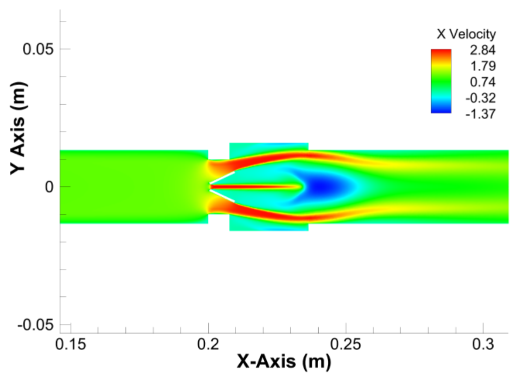


Figure 12: Contour plot of the x-velocity of the domain for Newtonian flow.

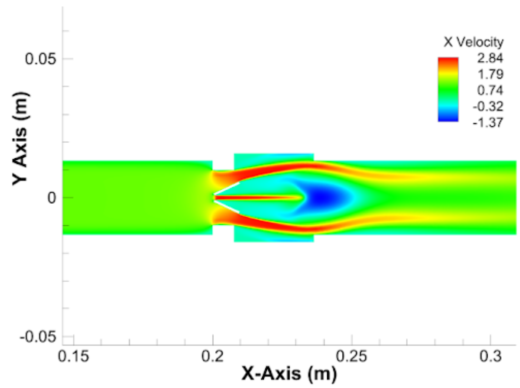


Figure 13: Contour plot of the x-velocity of the domain for non-Newtonian flow.

Results - Accuracy and Future Directions

These results showed that the simulations can use a Newtonian fluid model over a non-Newtonian model due to the flow speed being on order of magnitude of -1. The specific application of these simulations do not use low enough flow speeds that using a Newtonian model does not affect the values when calculating shear stress. Therefore, a Newtonian model was used in all future simulations and will continue to be used.

2.5.3 Effect of Leaflet Angle on Shear and Axial Velocity

Leaflets within heart valves have a wide range of motion, being able to be in a fully closed or open position, as well as any angle in between those two states. Flow affected by these leaflets are studied to determine wall and leaflet shear as previously discussed, however, these results are heavily impacted by the angle that the leaflets are at. Therefore, it was of utmost importance to analyze the properties of interest at various leaflet angles to thereby obtain results at all positions and points in time regarding the dynamic cycle of the leaflets.

Analysis Method

To achieve this analysis the three geometries, flat, curved, and airfoil, were each analyzed at five different leaflet angles in order to characterize the complete range of motion for the leaflets. This analysis is performed using ANSYS Fluent. The first step to obtain these results was to use the created computational domain of the three geometries using 2D CAD. Then in CAD, each of the leaflets were rotated to the specific degree that Team 13 wanted to analyze. From here, each of the geometries (15 total) was imported into a meshing software (Workbench) to properly divide the geometry into finite volumes to begin computational analysis. The newly refined meshes for each case were then read into ANSYS Fluent, so that the desired results could be obtained at each angle of interest. Further detail on this process can be located in earlier sections of the report: ”Functions - Computational”.

Interpretation

The results from this analysis were that leaflet angle has a significant effect on shear and axial velocity. Figures 15 and 16 show the effect that varied leaflet angles have on wall and leaflet shear. It is easily observed from these graphs that around the 30 - 40° range, there was a shift in how much wall shear was present in both the domain and the leaflet. However, from these same graphs, it could be interpreted that no matter the opening angle, the flat leaflet constantly maintained less shear than the two other leaflet geometries. At the highest opening angle of 55°, the curved leaflet had the greatest amount of wall shear while the airfoil leaflet resulted in bearing the most leaflet shear.

Figures 17a, 17b, and 17c, display the results of axial velocity at five different positions along the domain of each geometry at a different leaflet angle. The flat and airfoil leaflet have

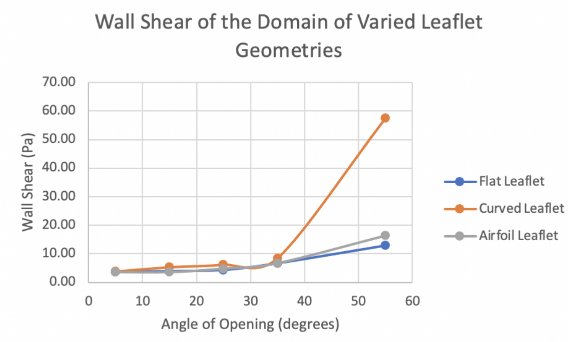


Figure 15: Wall Shear of Domain

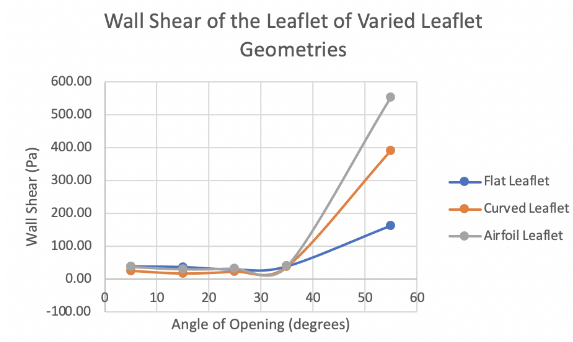
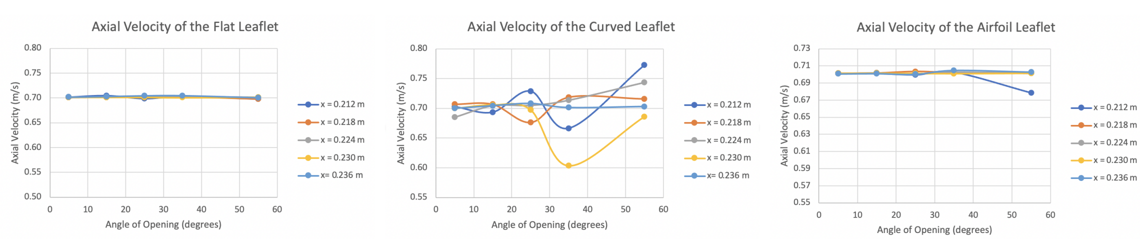


Figure 16: Wall Shear of Leaflets

certain similarities, mainly being that they both remained almost constant for each opening angle and also for the location where the velocity was calculated. The only exception to this interpretation is that the airfoil leaflet axial velocity dips at the highest opening angle at the positions closest to the leaflet. It was assumed that this occurred because at such a high opening angle, the velocity is still steadily increasing at the first location past the leaflet, which the plots indicate, and once the flow reaches the second position, it retains a constant value for the rest of the domain. For the curved leaflet, Figure 17b, the opening angle did not matter for the position farthest from the leaflet. However, the axial velocity did fluctuate in each of the four other positions at the five different opening angles.

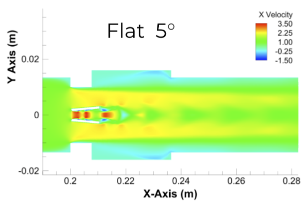


(a) Flat Leaflet **(b)** Curved Leaflet **(c)** Airfoil Leaflet

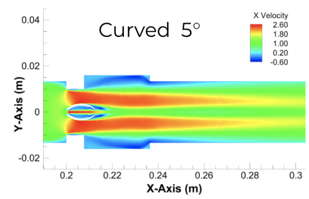
Figure 17: Axial Velocity Graphs of Flat, Curved, and Airfoil Leaflets

Figure 18 are Tecplot images of the same axial velocity simulation data presented in

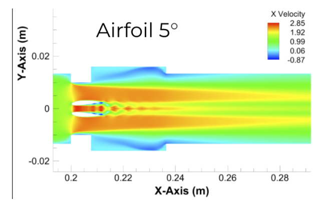
Figure 17. Figures 25, 18b, 18c display the axial velocity of the flat, curved and airfoil leaflets at 5° while Figures 18d, 18e, and 18f show the same leaflets but at 55°. It is important to examine the difference in the flow speed displayed in these plots. There are clear changes, the change in color, between the 5° and 55° images through the domain of each of the leaflet geometries. From the results, it is clear that the parameters of interest, wall shear and axial velocity, vary based on the orientation angle of the leaflet. Therefore, this confirms the prediction that performing simulations that employ dynamic leaflets are not only necessary, but will provide more accuracy when quantifying the parameters of interest.



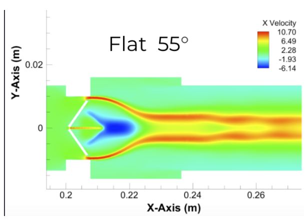
(a) Flat Leaflet at 5°



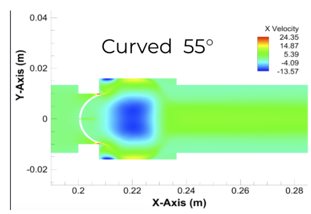
(b) Curved Leaflet at 5°



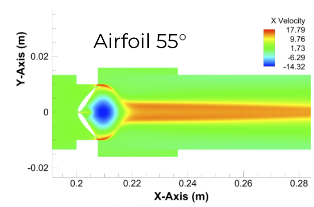
(c) Airfoil Leaflet at 5°



(d) Flat Leaflet at 55°



(e) Curved Leaflet at 55°



(f) Airfoil Leaflet at 55°

Figure 18: Axial Velocity at Three Leaflet Geometries and Two Opening Angles

Results - Accuracy and Future Directions

The results prove that opening angle of the leaflets affect the flow, and thereby results in different values of shear force as well as axial velocity for each opening angle. Therefore, it is clear that in the future more opening angles will be studied to gain a better understanding of the hemodynamics at each of those specific angles as to better ascertain the most valid range of opening angles. In regards to accuracy, to maintain some form of consistency, the geometry and meshes used in this analysis were the same as the previously analyses. The key difference between them was that in this specific analysis, each of the leaflets were simply rotated to 5, 15, 25, 35, and 55 degrees in the 2D CAD drawings. Furthermore, as mentioned previously, multiple sources of literature were consulted before determining models and methods.

2.5.4 Pressure Gradient Formation with respect to Backflow on Airfoil Leaflet

As mentioned earlier, for the leaflets to be able to open to 90 °, a proper pressure gradient must be induced from the backflow to ensure closure. This is accomplished in current mechanical valves with the help of hinge placement. Heart valve leaflet hinges are not symmetrical. They are not placed exactly in the middle of the hinge, and this is done to create an area difference with one side of the leaflet being larger than the other. The more area resisting flow, the more force is created, so the larger side of the leaflet is oriented to resist the blood flow in the desired direction so that it may open in that direction. Therefore, a reverse flow analysis had to be performed in order to predict the behavior of the airfoil leaflet when in contact with back flow.

Analysis Method

In the analyses before this: Newtonian flow and Leaflet Geometry Effects, the process of creating a simulation has been explained in great detail. Therefore, to avoid repetition the process specifically related to this analysis will be discussed but the general set-up will not be outlined again. It can be known that the same computational domain and meshing conditions were employed in this study as previous. To see how the pressure gradient develops around the airfoil leaflet, two angles, 5 ° and 35 ° were tested to see how the pressure distribution would evolve as the leaflets continued to close. The flow, once again simulated as close to blood as possible, is initialized from the right hand side of the domain to represent back flow during diastole. The following pressure contour plots were then created in order to analyze how the pressure differential formed on either side of the airfoil leaflet.

Interpretation

The contour plots of pressure can be seen below in Figures 19 and 20. The results are promising, as they exhibit evidence of stronger pressure levels on the underside of the leaflets (in the area between the two leaflets) when compared to the area above the leaflets which is desired. Looking at the 5 ° oriented leaflet, the pressure values on the bottom are considerably higher in magnitude when contrasted with those upper portion. It can then be hypothesized that the greater pressure magnitude in between the leaflets will force them to close in the outward direction, as desired, from their almost 90 ° open position. This theory is further enforced by Figure 20, where at a later phase of closure, 35 °, the pressure gradient again supports closure. This can be seen by observing the extreme pressure differential on either side of the leaflet where the red areas show higher pressures and the blue/green areas show lower pressures. The force of pressure is acting in the direction that would close the leaflets.

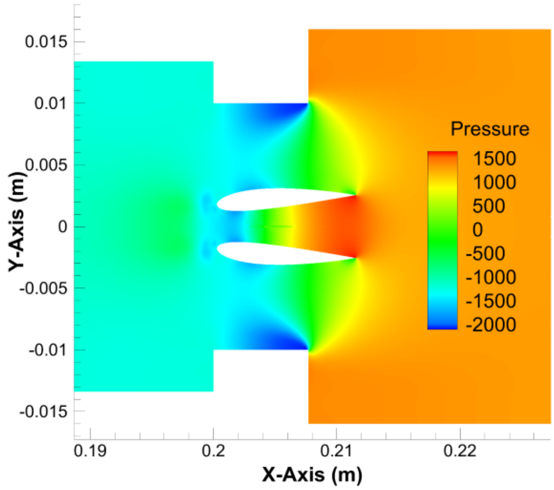


Figure 19: Pressure Distribution over Airfoil Leaflet 5 °

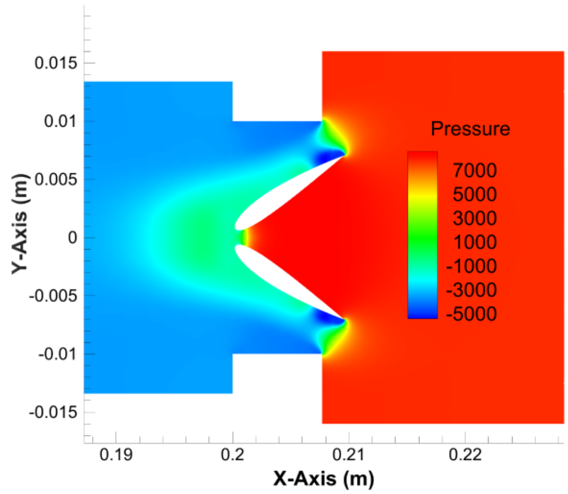


Figure 20: Pressure Distribution over Airfoil Leaflet 35 °

Results - Accuracy and Future Directions

The analysis results are promising as they suggest the wing-like geometry of the leaflet is capable supporting closure from an open angle of 90 °. Therefore going forward this theory will be further tested by implementing dynamic leaflets as well as pulsatile flow to more accurately simulate the conditions within the aorta. The exact curvature and camber of the leaflet will also be tested to figure out the optimal compromise between thickness (creating a greater gradient) and keeping as much room for flow to pass when open at 90 °. Hinge location also influences the ability for the leaflets to change. As a result, the exact location of the hinge will also be investigated in the future.

2.5.5 Determination of Material Selection

The surface of a bioprosthesis is the only material that the body comes into contact with, and while bulk properties remain important, the surface properties of the valve are the most crucial in determining biocompatibility. The material cannot trigger an immune response or amplify blood coagulation, therefore, an analysis of materials must be conducted. There are many biologically inert materials already generally understood, but research must be conducted to determine the optimal material for this purpose as well as investigating any possible coatings or micro texturing. Depending on the surface features of the heart valve, it can minimize protein adsorption, (proteins sticking to the surface), which then decreases the onset of thrombosis. When a biomedical device is implanted into the body and comes into contact with blood, proteins in the blood that trigger coagulation will adsorb onto the valve and signal the body to form a blood clot.

Analysis Method

Current mechanical heart valves are constructed out of either titanium or carbon, two materials that have been used for a long time for their bioinertness/biocompatibility properties. While gold is another well-understood biomaterial that is generally nonreactive in the body and is commonly used for medical purposes, it was not the primary option for this design in efforts to minimize costs for consumers/patients.

The component of the valve with the highest potential to initiate rejection mechanisms is the fabric ring surrounding the valve used to suture the valve to the tissue of the heart wall. Dacron is the material that has shown the most resemblance to normal physiology and mimics the native aortic annulus, (fibrous ring of the heart valve), via its geometry and dynamics. It is also biocompatible and is the industry standard for suture rings. Other studies mention the usage of polyurethane films and ultrananocrystalline coatings on the heat valve. These methods are effective because the polyurethane film is highly modifiable, but there is more room for improvement. Additionally, the ultrananocrystalline coating is low cost and has good mechanical properties, but it is difficult to manufacture the coating. Poly-ethylene glycol is another coating polymer that has been a topic of interest for researchers. It forms a "water-shield" around the item that coats which aids in preventing protein adsorption and RBC interactions. However, it is not permanent and its breakdown can lead to toxicity. Since this is a long-term prosthesis polymer breakdown is likely and this option was also disregarded.

The main method of analyzing different materials is though performing multiple literature searches on current and novel materials that are approved or will be approved by the FDA. The method of designing a new material is not apart of the scope of the project due to creating novel materials being a time-consuming and expensive process. The best method of deciding which material to use is through the usage of a benefits and drawbacks list that states the effectiveness of the materials for this specific application.

Interpretation

The previously listed characteristics of a prosthesis are important when considering devices to be implanted into the body. Due the drawbacks of many novel and current techniques, it best to keep the materials usage simple. The usage of a carbon as the bulk of the material and coating the device in titanium provides optimal results by having a desired lack of surface interactions with Ti and low mass bulk properties from carbon fibers. The titanium will have a modified surface, fluorinated nanotubes, that creates a barrier between the blood and coating. This creates a superhemophobic surface, minimizing protein adsorption and coagulation cascade, thus creating a heart valve that uses less blood thinners.[3] The usage of blood thinners cannot be completely eradicated at this stage of technology because there will be a degree of protein adsorption.

Results - Accuracy and Future Directions

Using these results, the surface material type of the simulated valve will be titanium and the bulk material will be carbon. Different layer thicknesses of titanium will be assessed to determine leaflet mobility effectiveness and if any degradation occurs from blood to ensure the coating can last a lifetime. The heart valve, particularly the leaflets, have potential to be hollow with titanium as the material blood will interact with. Another study could be performed if a hollow titanium valve can withstand the environmental pressures of the heart. The thought process is to generate leaflets that are as light as possible to minimize the force they need to open. Less force is required to rotate lighter leaflets, which would transversely decrease the shear and impact forces on RBCs.

2.6 Engineering Specifications

The full Engineering Specification document located in appendix for reference. With confidence that the final design will successfully allow for opening to 0 °, the product is able to meet nearly all of the engineering specifications. The design allows for the leaflets to open fully to 0 ° with respect to the horizontal due to the airfoil leaflets. It is the leaflets that induce a pressure gradient even when fully open to 0 ° that will force the leaflets closed. Despite the change in leaflet geometry the diameter of the valve was able to remain 19mm in the designs as well as remain below the acceptable shear threshold of 150 Pa.[4] These specifications were confirmed with CAD modeling and CFD simulations. Finite element analysis was able to confirm that the chosen valve geometry would withstand 33.3 kPa with a safety factor of 1.4. This was deemed as appropriate for the expected pressures that would be encountered within the heart. Aside from physical engineering specifications, the product was analyzed for a sterility assurance and financial feasibility.[2] Due to the minimal change in the leaflet geometry, the product remained fairly similar to existing models and was able to be compared regarding these two specifications.[6]

The engineering specifications had a relative pass percentage of 90 %, and all of the client constraints were met. The only specification that failed and was not completed was the sufficient valve sealing in the physical 3D printed model, that that was due to limitations in the printing tolerances and in a higher quality model, i.e. if it ere CNC'd out of titanium or carbon, this would not be an issue. The team know that that would not be a problem because valves that are currently made using these processes do not have this issue, and manufacturing of Team 13's valve would be very similar to those already on the market with just a slight geometry alteration.

The only failed engineering specification was that the valve shall seal properly to avoid leakage, which was tested using some of the physical prototypes. Due to the limitations of 3D printing, the valve did not fit snugly into the testing apparatus and the leaflets did not easily rotate within the aperture which did result in leakage. This could be remedied by machining a heart valve out of a cheap metal such as aluminum to allow for exact dimensional and proper hinge fillets that can rotate the leaflets with ease. This would also increase the validity of physical testing. The full engineering specification document with each specification and verification results filled out can be found in the appendix.

2.7 Conclusions

Dr. E. Taylor Haring came to the UVM SEED program with an innovative idea to improve the bi-leaflet mechanical heart valve and SEED Team 13 worked hard to make the dream a reality. Overall the Bernoulli heart valve project should certainly be considered a success. The ultimate goal of the project is to reduce the need for blood thinners taken by patients. Due to the increased flow velocity through mechanical heart valves and their inability to open fully to 0 °, the patients rely on blood thinners to prevent clotting. To accomplish this Dr. Haring suggested designing a heart valve that can open fully to reduce hemolysis and clotting. The final design of the project employed airfoil leaflets that successfully induced a pressure gradient across them in the fully open position at 0 °. These results suggested the leaflets would reliably close from this position and overall the design would be a success because this would in theory decrease hemolysis and clotting within the valve.[4] Therefore with regards to the problem statement as well as Dr. Harings requirements, the project certainly meets the expectations. Outside of the actual working design of the project the client also expects a paper draft which will be provided to him at the close of the semester.

The client was satisfied with the overall status of the product both after each sprint, and the final outcome. He was impressed at the engineering required for the CFD simulations, and each time he was shown contour plots of various flow parameters and metrics such as pressure, velocity, or shear. He understood that there were some institutional limitations with the resources at hand, but was encouraged by the results that were achieved. The clients satisfaction can also be quantified as he always gave 5's for the team during every sprint review. Most recently he expressed his enthusiasm about the results by suggesting he may try to publish a paper with them or attend a conference.

The most important future recommendation for further development on this project would be dynamic simulations, where the leaflets respond to the fluid forces. This would provide a more accurate representation as to how the leaflets would respond to blood forces in vivo. A secondary recommendation would be to continue on with physical testing, but with higher quality apparatus with a valve and leaflets made of a metal instead of a 3D printed polymer. This would allow for comparison of physical and computational results which is crucial in determining the feasibility of the project.

2.8 Citations

All references and citations for the Project Design Details as well as the rest of the Final Design Report can be found in Section 7: References.

3 Project Reflection

With any project, it is important to look back and reflect upon the process to evaluate what went well and what the team could learn from. The main lessons learned was to setup realistic goals and provide adequate time for different verification methods

3.1 Impact Statement

Decision 1

The valve needed to be manufacturable at a comparable total cost to valves that are currently on the market. A valve made at exorbitant cost to the patient just for profit maximization would be exploitative and professionally unethical. Designing and manufacturing the product is only part of the engineers responsibility. Without addressing the cost implications of the design, the product could be unable to be attained by those who are in need of it. Therefore it is critical for the engineer to keep economical perspective when designing the product to ensure it will be affordable for those who it is being designed for. It was decided that the valve would be able to be manufactured using processes that are already currently used. The major components of the valve remained very similar to the existing models, save for the leaflet geometry, which allowed it to be nearly the same price as existing models. Using already established manufacturing processes allowed the product to be as simplistic as possible with the fewest possible modes of failure. It satisfied the clients desire for a cost-effective valve design and minimized the patient's financial burden as much as possible. Keeping the newly designed valve as accessible to the patient as possible prevents any extra economical or societal strain in getting the product where it needs to be.

Decision 2

To ensure credibility of results and methodology used throughout the project, many outside resources were utilized including third party publications and experts in the field of computation fluid dynamics were consulted. These steps were taken by the team as a professional responsibility to instill confidence in decisions made regarding the project. Prior art research was required for this project because valve design has an extensive history with many geometry variations being explored. It needed to be verified that airfoil leaflets had not been researched or attempted previously, to avoid any possible shortcomings they may have had. Regarding CFD, the team's knowledge limitations needed to be acknowledged and overreaching could lead to invalid results. Professors, or those with more expertise in the field, were consulted during points of concerns in developing simulations to avoid taking on aspects of the project that were too complex or beyond the teams knowledge base. Consulting professors, or those with more expertise in the field was integral in keeping the project realistic and credible. This limited the progression of the project, but helped ensure the quality of results that were obtained. Although this caused some goals to need to be adjusted, it was for the overall benefit of the project as a whole.

3.2 Lessons Learned

The team had an overall positive experience with the project. Communication and team dynamics were smooth and cohesive, and there was a positive relationship with the client with encouraging and supportive feedback. Most goals were achieved and each sprint the processes were evaluated and adjusted accordingly. There were some hurdles to overcome, but they were learned from, and overall experience in the course was considered successful.

Initially, the goals set were too ambitious for the time frames that were given. For example, 3D dynamic leaflet motion wherein the leaflets react specifically to the fluid flow proved to be more difficult the initially expected. This caused a some overwhelmedness, but also challenged the team and their problem solving methods. The goals were then readjusted while staying cognizant of limitations and strengths. This increased the team's efficiency to allow more effort to be put into simpler goals to provide stronger results. The second lesson learned was that the team needed to provide adequate time for different verification methods. The CFD simulations hit a wall where the team found it difficult to improve upon the simulations. But then enough information initially but then a physical model was needed to further validate results, when running 3D dynamic simulations became difficult to run. Limitations of physical manufacturing methods caused some delays in the physical testing because the FabLab was overrun with projects.

The physical testing was not an overall hindrance to the project's performance, although a higher quality model would have contributed to project verification and proof of concept. The greatest challenge that was experienced was just the complexity of the CFD models. It was challenging to precisely simulate leaflet response to realistic fluid forces, which if successful, would have had an enormous positive impact to accuracy.

Future engineering steps for the project come in 2 parts:

1. Physical testing

    - Create a higher quality physical model that is not reliant or contingent on FabLab 3D printing resolution. Preferably a CNC model could be created using aluminum, titanium, or carbon fiber and placed in a fluid tunnel to observe leaflet rotation.

2. CFD testing

    - Reach out to experts in the field of using ANSYS to better understand how to have a body respond to fluid forces to aid in simulation.

3.2.1 Lesson #1: Keeping Goals Realistic

Initially, the team set their goals too ambitiously. This caused the team to be overwhelmed from stretching themselves too thin, but it also challenged the team and their method of problem solving. The team readjusted their goal setting to keep in mind their limitations and strengths to maintain level-headed. This increased the team's efficiency allowing them to put more effort into the team's goals and provide stronger results. For future implications, it would be more beneficial to keep the team's goals realistic from the beginning to avoid stress and maximize efficiency.

3.2.2 Lesson #2: Provide Adequate Time for Different Verification Methods

The CFD simulations hit a wall where the team found it difficult to improve upon the simulations. The simulations provided enough information initially but then a physical model was needed to further validate results, when running 3D dynamic simulations became difficult to run. Limitations of physical manufacturing methods caused some delays in the physical testing because the FabLab was overrun with projects. Additionally, the quality of the prototype being printed did not meet standards. The heart valve did not have the fine detail it needed to provide proper closure. Future implications, start using physical testing earlier to adjust the design to account for fabrication issues.

4 Project Retrospective

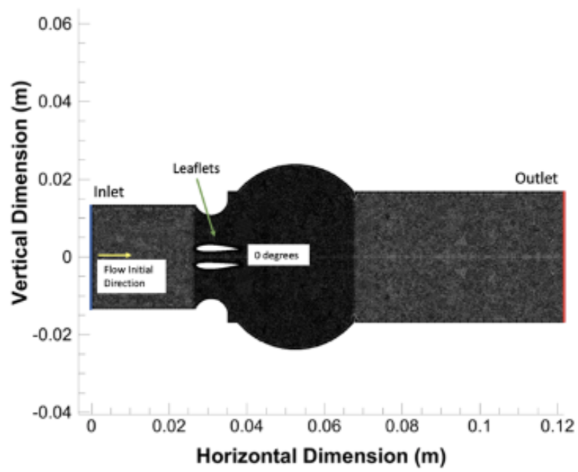
The most impactful kaizen the team choose was to be able to recognize what work could be shared among deliverables, client requirements, and the team's own testing. The team chose this kaizen because by being more cognizant of what work could shared between each of them, the group could become more efficient and therefore deliver more professional and completed work in each. This had a direct impact on the team's overall performance because it allowed the team to manipulate the work into each product that was required, from the Final Design Presentation to the client's hopeful publication. The best aspect of SCRUM was having the structure that it offered to the team. The group met three times a week and always had open communication within the group if a team member was unable to attend. There were always lines of open communication to continue the work outside of meetings as well. SCRUM also allowed the team to fully realize that each member of the group had strengths and weakness that it could leverage to make the best product possible. Work and tasks were always delegated to certain group members that could provide the team with the greatest possible end result. One aspect of SCRUM that did not always work too well were how the SCRUM roles were applied to each team member. In the beginning it was nice to have specific roles and therefore specific people to go to for tasks. For example, Stephen Paige was the Financial Officer and so whenever the team needed to purchase something, he was contacted. However, overtime this became a bit taxing because the team realized that the roles segregated the group more than it was helping. By the spring semester, however, the team naturally just worked together on any task and were no longer dependent on just one individual for a certain task. This allowed each member of the team to understand how each role worked and it made the output more efficient as well. A recommendation would be to modify how the roles are realized in a SCRUM team. Instead of one person being solely responsible for their role, the team believed it would be vital that each team member understands each job at least at its base level.

5 Product Review

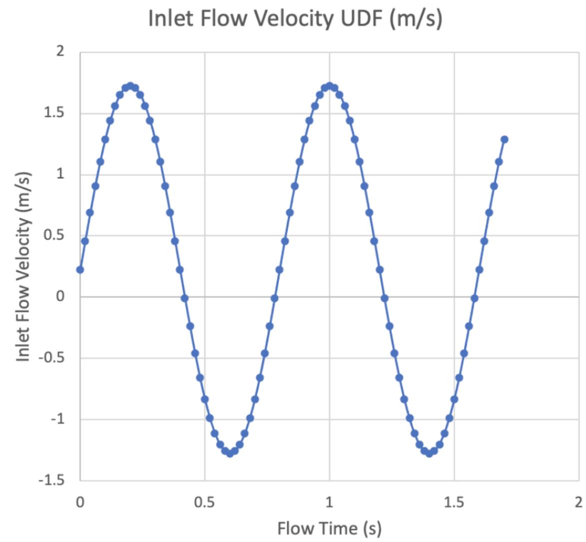
During the course of Capstone Design II there were four sprints each with their respective sprint goals. The client's satisfaction levels were at a maximum score of 5 for every sprint in both the fall and spring semesters. The development team was also satisfied as they always delivered the sprint goal that was outlined in the Sprint Planning documentation at the beginning of each sprint.

Throughout the course there were never any discrepancies between team and client satisfaction levels. This is most probably due to the clear and constant communication that was continued with the client. The client's rationale behind his satisfaction could be because the team always delivered what was asked for and what the team set out to do.

For Sprint 4, the goal was to implement a bulbous domain as to emulate a human heart Figure valve and also to implement pulsatile flow. 21a shows this new bulbous domain while Figure 21b graphs the the pulsatile flow which was created using a User Defined Function in Ansys Fluent. Both of these sprint goals were accomplished.



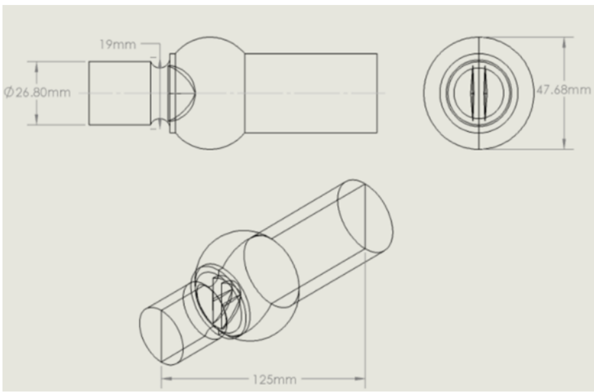
(a) New Bulbous Valve Domain



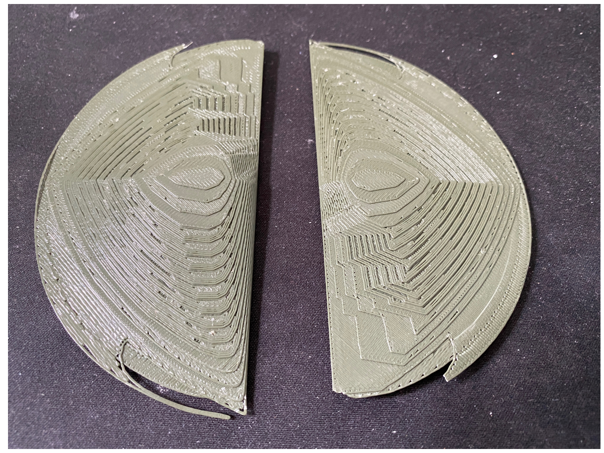
(b) Pulsatile Flow

Figure 21: Sprint 4 Goals

In Sprint 5 the goals were to create a 3D static heart valve domain Figure 22a and create the team's preliminary physical prototype Figure 22b. Shifting to 3D was very important as 2D can lack accuracy with regards to geometry and gradient effects. The latest 3D printed airfoil leaflets were closest to those being used in the 3D model to keep physical and computational testing in line. Both of these sprint goals were accomplished.



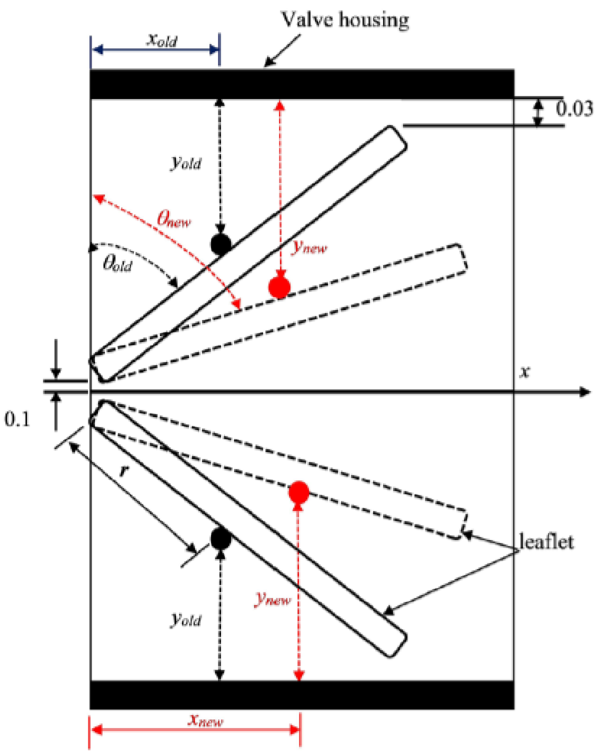
(a) 3D static heart valve domain



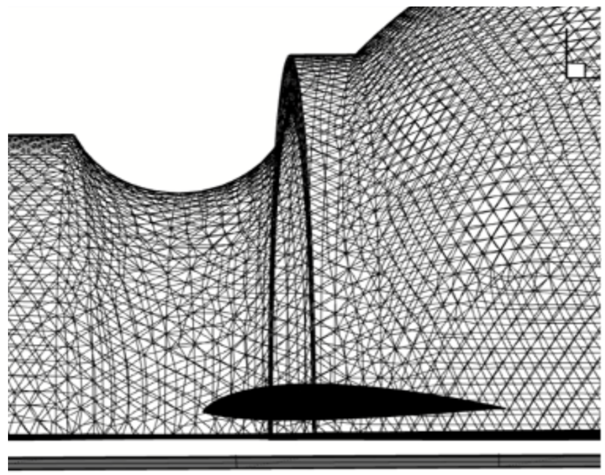
(b) Airfoil Leaflet Updated Design

Figure 22: Sprint 5 Goals

In Sprint 6 the goals were to gain major headway in trying to implement 2D dynamic leaflets as seen in Figure 23a and to also implement the novel airfoil geometry into the 3D static model from Sprint 5, as seen in Figure 23b. Implementing dynamic leaflets is critical for understanding how the the leaflets move in response to the flow. Both of these sprint goals were accomplished.



(a) Complexities Surrounding Dynamic Leaflets



(b) First 3D Mesh with Novel Airfoil

Figure 23: Sprint 6 Goals

Lastly in Sprint 7, Team 13 ran the updated 3D static model with the new leaflet design as to ascertain data for the senior design night poster as well as the publication Dr. Haring wanted the team to write, which can be seen in Figure 24. This sprint goal was accomplished.

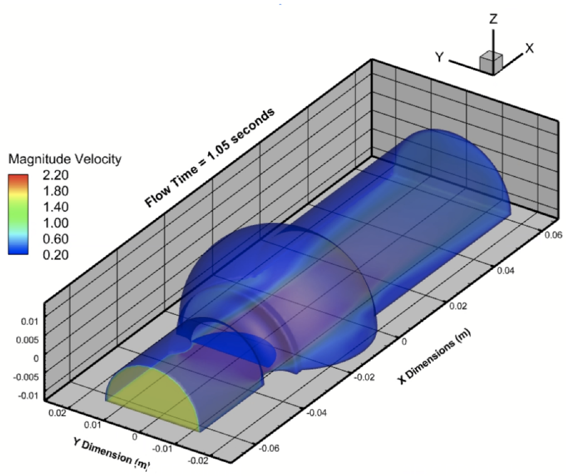


Figure 24: 3D Static Valve in Tecplot

6 Budget

6.1 Allotted Budget

Approximately half of the total budget was spent: $422.33 spent with $577.67 remaining. Half of the total expenditure was spent on data management in the form of a Samsung T5 high speed SSD for the transfer and backup storage of CFD data and case files. The rest of the team's spending was allocated to the physical modeling apparatus including iterations on the fluid chamber, tubing, and 2 different water pumps. An Arduino to create pulsatile flow had already been acquired, and the 3D printed valves were created in the Fab Lab, at no cost to the team.

6.2 Budget Management

Given that less than half of the teams maximum budget was spent, budget management was considered successful. All of the spending by the team came in the spring semester, since the fall semester was primarily focused on CFD modeling using software provided by the university. A third party workstation was utilized in the spring semester, which necessitated the purchase of external storage, and physical modeling design also began in the spring semester.

6.3 Budget Reflection

There were no restrictions on spending throughout this project, as there was always additional funds in reserve. But since there were additional resources, in retrospect the team would have perhaps spent more of their budget on a higher-quality physical model. Instead of 3D printing using the University's resources, this manufacturing would have been outsources to a third-party company, or a model could have been CNC'd out of titanium, carbon fiber, or aluminum.

6.4 Expenses List

Item	Account	Category	Quantity	Price	Total
small box	Project Estimated Costs	Parts	1	$12.99	$12.99
big box	Project Estimated Costs	Parts	1	$16.99	$16.99
Power adapter	Project Estimated Costs	Parts	1	$7.99	$7.99
10 ft tubing	Project Estimated Costs	Parts	1	$9.99	$9.99
Small Pump	Project Estimated Costs	Parts	1	$11.99	$11.99
SSD	Project Estimated Costs	Parts	1	$230.26	$230.26
DC House 42 Series Upgrade Water Diaphragm Pressure Pump, 5.0 GPM 55 PSI 12V DC Self Priming Water Pump	Project Estimated Costs	Parts	1	$69.99	$69.99
Food Coloring	Project Estimated Costs	Parts	1	$14.98	$14.98
Charlotte Pipe Cap	Project Estimated Costs	Parts	1	$20.90	$20.90
Fixture Displays Clear Acrylic Tube	Project Estimated Costs	Parts	1	$26.25	$26.25

Figure 25: List of all expenses

7 References

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A Appendix

A.1 Remaining Product Backlog

1. 2D Dynamic Leaflet Simulations

2. 3D Dynamic Leaflet Simulations

Simulating dynamic leaflets is crucial in calling this project a complete success. Static simulations only allowed for limited analyses as the method remained far from representing an actual mechanical heart valve. Although they work well to provide preliminary insight and rapid results, the data obtained from static simulations must be taken with a grain of salt. Any effect that the leaflets have on the flow due to their rotation is not able to be modeled with the static simulations. Therefore it is critical to implement dynamic leaflets into the simulations to account for the rotational dynamic effects the leaflets exert on the flow. Secondly, with static simulations it is unclear if the leaflets will behave as expected. Consequently, the hypothesized behavior of the airfoil leaflets can only be inferred from suggestive results. If the leaflets were able to be dynamically simulated, then their behavior could be more confidently characterized. As always, 2D dynamic simulations should be approached before attempting 3D to methodically increase complexity.

A.2 Completed Engineering Specification

The Engineering Specification Tab can be found attached to the end of this Final Design Report.