Incorporating 3D RP Process in Biomedical Engineering Design

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Abstract

Design, prototyping and analysis are vital skills to be obtained by Biomedical Engineering (BME) students. These skills should be taught to the BME students during their design courses. Introducing the design process with prototypes gives students a better visualization of a final product in three dimensions. While machining the designed part would be the ideal method, it is not always practical within the confines of an academic term. The most effective alternative to machining a part within the confines of a semester is to use a three-dimensional rapid prototype (3D RP) system to fabricate the part. This is a practical method to quickly and accurately establish the proof of concept. The primary objective of this paper is to study, design, and build an artificial mitral heart valve with 3D RP and to explore the feasibility of including 3D RP process in BME design courses.

In most engineering projects the product designs are conceptualized, fabricated, tested, analyzed, and refined. The rapid prototyping system uses three dimensional Computer Aided Design (3D CAD) files to fabricate a physical model. These models are usually made from ABS-plastics, starch, rubber, or another suitable material. This project looks into the design of an artificial heart valve using 3D modeling software, flow simulation, and rapid prototyping. Using a 3D CAD to 3D RP in biomedical design will enable us to create a number of complicated parts.

In order to better understand the form and function of a mitral valve, a preliminary study was conducted. Several versions of heart valves were designed using the 3D CAD software in SolidWorks. These models were further modified after observing how they performed within a flow simulation in SolidWorks's COSMOS. The data files for the modified models were then exported to the 3D RP machine. The 3D RP machine then produced physical models which could be held, viewed and further analyzed.

With the techniques of 3D RP, BME students will acquire a better understanding of the process taken from the design concept to the final product. With the model in hand, students had a better understanding of how the mitral valve functions and then they were able to justify why the part was designed in a specific configuration. Initial results are encouraging for not only the prototype valve but also the application of 3D rapid design in the educational environment.

In conclusion, the design of this artificial mitral heart valve and its fabrication in 3D RP shows the feasibility and potential benefits for the use of rapid prototyping process in engineering education with a particular emphasis on Biomedical Engineering design courses.

Introduction

Design, prototyping, and analysis are vital skills to be gained by BME students. Design courses which include CAD and 3D RP are important in all engineering disciplines, including the multi-disciplinary field of Biomedical Engineering. Current students who lack these skills are at a disadvantage when entering the workforce and working with design teams. In order to produce more competitive engineering graduates, engineering education must include more practical applications and techniques. Skills like these should be taught to the BME students during their design courses in the undergraduate program of study. However, most college engineering programs do not adequately cover the different types of prototyping in their design courses. Introducing the design process with prototypes gives students a better visualization of a product in three-dimensions. While machining the designed part would be the ideal, it is not always practical within the limits of an academic term. Using 3D RP system to fabricate a part would be the most effective alternative to machining a part.

Cardiac valve diseases result in over one-hundred thousand valve replacement surgeries worldwide every year. The mitral and aortic valves are two common cardiac valves which can become deficient, thus resulting in regurgitation or stenosis. The high levels of stress to the left side of the heart is a major contribution to valve failures.[1, 2] One replacement option is an artificial mechanical valve which would mimic the functions of a natural heart valve. A mechanical valve is an effective and frequently used solution, but unfortunately they do have their limitations.

The aim of this study is to present an available process to teach product design through 3D RP techniques, including going through the steps of design, prototyping, and simulation testing. Through this study we will be merging many aspects of the Biomedical and Mechanical Engineering fields ranging from biological systems to fluid mechanics. The objectives of this study are:

i) to design a mitral valve using 3D RP techniques
ii) to prototype a mitral valve based on increased fluid flow
iii) to assess the benefits and limitations of this new valve design
iv) to explore the benefits of rapid prototyping process for inclusion in instruction of BME design courses.[3]

Background

Traditionally, engineering design begins with the assessment of the requirements of a system. From the assessed needs, solutions are then conceived and incorporated into a new design. Modern technology allows engineers to prototype and test products before the actual production. This allows the system to be modified pre-production which reduces costs. Programs such as SolidWorks allows for three-dimensional models to be created, tested, and analyzed. Once approved, the model can then be exported to a rapid prototyping system which will produce a physical part. With this tool set engineers can eliminate many issues with their designs before significant resources are put into a project. Furthermore, testing and analysis can then be done on a system to ensure that the changes are beneficial.

Presently, there are three main types of artificial, mechanical valves in the medical market: ball-and-cage, tilting disk, and the Bi-leaflet valve. Each valve has its own advantages and disadvantages. The ball-and-cage design was the first to be created. This mechanical valve has many issues with hemolysis and thromboembolic complications.[4] The next mechanical valve was the tilting disk, which improved the flow velocity. The last major mechanical valve design was the Bi-leaflet valve. The Bi-leaflet valve allowed for parallel flow with less resistance.

The main drive to improve these models is to decrease resistance while minimalizing reverse flow and biological trauma. In addition, there is a need for a quiet, mechanical movement. Currently the two most frequently used mechanical valves for mitral valves patients are the Bi-leaflet valve and the single-leaflet valve. Unfortunately, the mechanical components of these valves damage blood cells and require the use of anticoagulants.[1,3,5] Stress on the heart can also occur if the valve design is inefficient and requires the heart to pump more frequently in order to sustain proper blood flow.

Design

The new design of the SMK2 mitral valve aims to maintain the shape and structure of the classic Bi-leaflet valve. Ideally, the new valve design would have a similar exterior so it can be easily interchangeable with the current industry- standard valve. The use of two leaflets allow for ordinary blood flow similar to a natural valve. In order to create the prototype model, the first step would be to design the artificial heart valve in a computer-aided 3D design program. SolidWorks was chosen to generate the 3D models due to its compatibility with the available 3D printers and its fluid flow simulation capabilities.

As a basis for the design of the new replacement valves, the natural valves functionality was used as a reference. The natural mitral valve leaflets close at the center of the exterior walls by the chordae tendineae and blood pressure. In the case of the artificial valve, the chordae tendineae are no longer utilized and only blood pressure is used to open and close the mechanical leaflets.[6]

The new valve design is based upon the theory of fluid dynamics.[7] Flow velocity is greatest at the center of a valve or tube due to the friction from the wall. The center of the natural mitral valve is unobstructed allowing for the fastest blood flow with the least resistance. Current designs of artificial mitral valves restrict flow in the center of the valves due to the location of their leaflet pivot joints. Bi-leaflet valves use the center of the valve to position their joints, thus allowing for the most blood flow on the edges of the valve. Single and ball valves obstruct the flow of blood in general. This new design utilizes the concept of a Bi-leaflet valve. With the new design, instead of putting the pivot points in the middle of the valve, the pivot points are offset to the middle of the leaflets. This design change allows blood to flow without obstruction in the middle of the stream and thereby allows for a higher velocity of blood.

This design would position joints at the center of each leaflet (Figure 2) allowing for a ninety degree maximum range of movement from fully open to the closed position. In order for the valve to automatically close when the pressure difference drops, a stop edge would be needed to ensure that the maximum angle would not be greater than eighty-five degrees. With this reduced angle, when fully open, about forty-seven percent of the valve cavities are at the midpoint, allowing for a large volume of blood to flow unhindered.

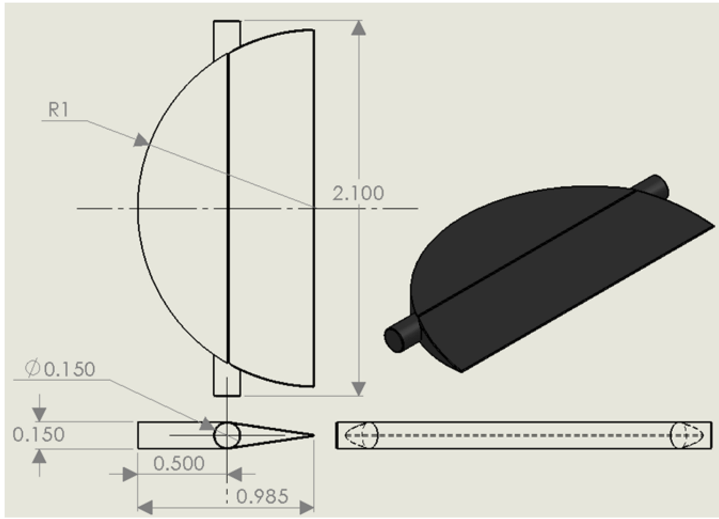

Figure 1: Artificial SMK2 Mitral Valve (all dimensions in mm)

As a result of the new location of the pivot point (centered in the leaflet), the centroid is now located by the pivot point. By this design, when the pressure is placed on the leaflet, it is slow to turn due to location of the moment of inertia. In order to overcome this problem, the leaflets have also been tapered. By tapering the valves the moment of inertia is shifted, which allows the valves to close more quickly. The reduction to the valve can be seen in Figure 1. A minimum thickness should be maintained so that the leaflets are still durable to withstand the frequent opening and closing of the valves.

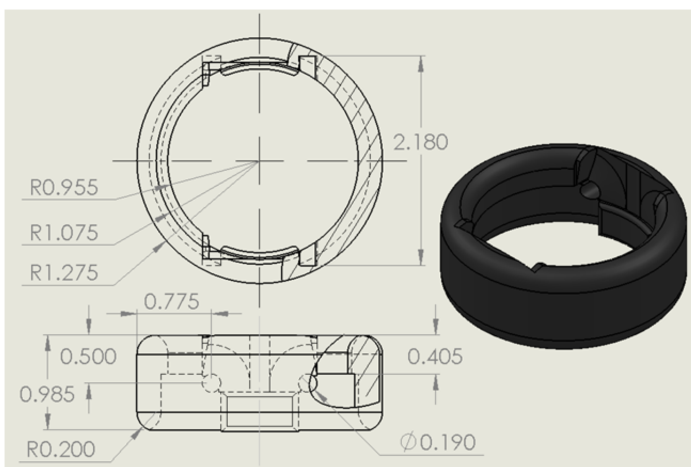

Figure 2: Artificial SMK2 Mitral Valve (all dimensions in mm)

The edges within the valve ring were added to prevent the leaflets from passing beyond an eighty-five degree range of motion and to seal the valve walls from backflow. Incisions were made to the interior wall to allow the movement of the leaflets so that their motion would not be prohibited by intersecting the inner wall. The contours and inner designs of the valve ring walls are shown in Figure 2.

The dimensions of each valve would vary depending on the individual patient's heart and valve orifice size. The dimension of the Middle-Joint Bi-leaflet Valve is listed in the Table I.[4] A tolerance of 0.03 mm was built into the design to allow the parts to have full movement after the parts were printed.

Table I: Typical Mitral Valve Size Data

Component	Maximum	Minimum	SMK2 Design
Orifice	4.09 cm^2	2.22 cm^2	3.4 cm^2
Tissue Annulus/ Flare Diameter	30 mm	19 mm	25.5 mm
Internal diameter	24 mm	20 mm	21.5 mm
Overall height	15 mm	12 mm	10 mm
Sewing Ring Diameter	36 mm	24 mm	29.5 mm
Sewing Ring Height	9 mm	4 mm	4 mm

The resources used in the design of this heart valve were chosen based on currently accepted materials for artificial heart valves. Available materials are limited due to the possible reactions within the body to foreign objects. The leaflets and inner ring would be made from pyrolytic carbon which has properties that reduce blood clots from forming. The valve's outer ring would be constructed out of strong and biocompatible titanium. The suture ring would be made from double velour polyester.

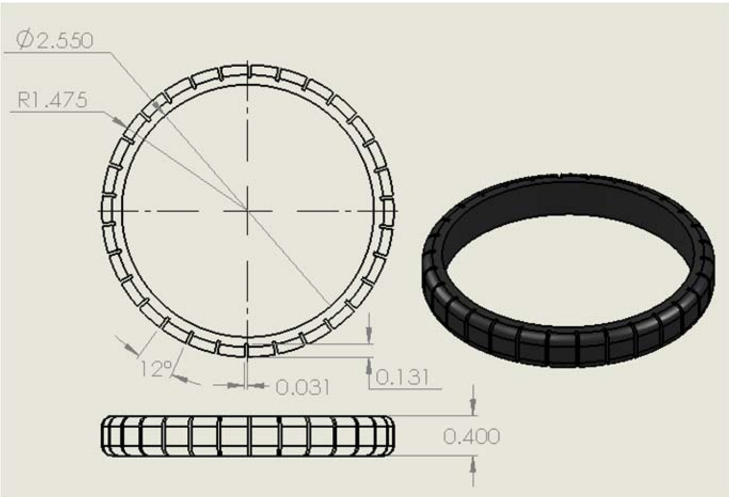

Figure 3: Suture Ring (all dimensions in mm)

Implementing a tool such as SolidWorks will enable an engineer to better explain his or her design and help the engineer to create drawings for use during fabrication.

Results

Three dimensional rapid prototyping of the mitral valve

With the drawings created in the previous section, a model was exported to a stereo lithography file or STL. This file is used by a 3D RP machine to print out a physical model in ABS plastic or powder and resin.

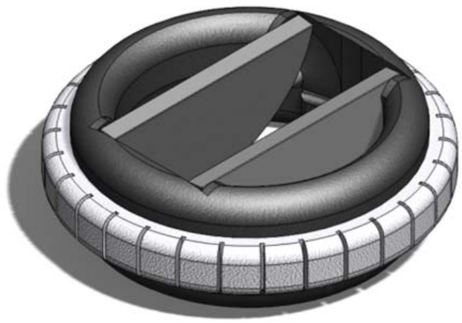

Figure 4: Assembly of Valve

The first example was produced with the ZPrinter 310 rapid prototyping machine.[8] This printer puts down a layer of subset and then prints a resin into this subset. After each printing, another layer of subset is applied, so that over time the whole model is printed and leaves a finished model contained in the subset material. A vacuum and compressed air are used to remove all of the excess subset. A fully printed clean model can be seen in Figures 5.

Figure 5: Traditional Bi-leaflet SMK2 Mitral Valve 1:3 Scale Printed out of Starch Front and Back Views

The second example was produced with the Dimension bst768 rapid prototyping machine. This machine is special because it prints using ABS plastic, which allows for a much more durable model. In the case of this printer, printing a subset every time is not generally required; subset printing is only needed if an overhang or unstable feature is being constructed. In such an event, the printer will produce a gray support substrate to support the model as seen in Figure 6. The support material is removed after construction is complete by physically peeling it off.

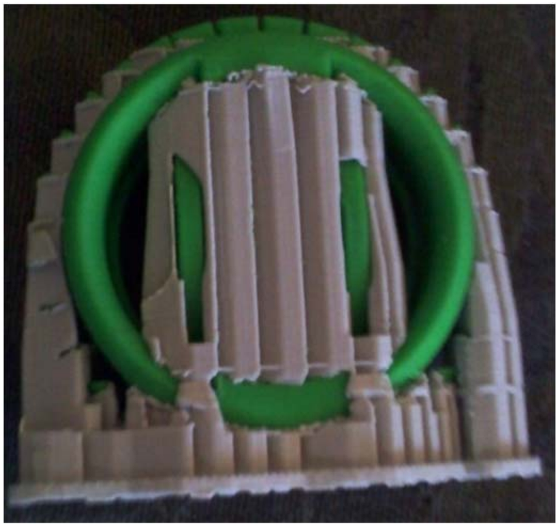

Figure 6: SMK2 Mitral Valve in ABS Plastic shown with subset

Figure 7: SMK2 Mitral Valve Assembly with Suture Ring in
ABS Plastic 1:1 Scale Top, Bottom and Closed View

The Middle-Joint Bi-leaflet Valve was printed in both resin enforced starch and ABS plastic for display and testing purposes. The model is functional as a result of the additional tolerances used in the spacing between the parts. The final ABS plastic model printed to scale can be seen in Figure 7. The valve fabricated in ABS plastic could be used in fluid testing due to the water resistant properties of ABS plastic while the starch model would just dissolve.

Flow simulation of the SMK2 mitral valve

The simulation tool set COSMOS within SolidWorks was used to simulate the blood flow through the Middle-Joint Bi-leaflet Valve.[9] The flow plug-in allows the user to set the parameters of the fluid flowing through the valve. The program had blood as a possible fluid option and it required fluid velocity and pressures to simulate the flow through the valves.

In the SolidWorks fluid simulation, values for flow-velocity, temperature, and pressure were chosen. These values were chosen based off the peak and initial diastolic phase for the left atrium. The average human body temperature was chosen at 98.6 degrees Fahrenheit. The peak flow velocity from the left atrium was 72 cm/sec.[10] The pressure in the left atrium was chosen to be 10 mm Hg.

Flow velocity and pressure data were generated through mesh analysis and this data was used to generate images. These tests were run on both the Middle-Joint Bi-leaflet Valve and a classic Bi-leaflet valve. Their results were compared, with the size difference taken into consideration.

The purpose of the Middle-Joint Bi-leaflet Valve was to increase the blood flow rate into the left ventricle and decrease the resistance. The design met the criteria selected at the beginning of the research. With about forty-seven percent of the valve opening at the center of flow, a large amount of blood can move without obstruction or diversion.

The mechanical valve was simulated and the cross section of the flow velocity and pressure through the open valve at multiple angles were collected. At eighty-five degrees, the flow velocity was the highest through the center point. Figure 11 is an image of the flow velocity data at this angle. The flow's velocity ranged from 130 cm/sec to 150 cm/sec. The further from the center of the valve, the slower the flow velocity was. Flow velocity was maintained at about 92 cm/sec throughout the valve.

A flow simulation was then run on a traditional valve with leaflet opened near the center of the valve to make a general comparison between the two. In the case of the SMK1 mitral valve, the flow velocity was reduced and higher turbulence was caused to the flow around the valve.

Figure 8: SMK1 Mitral Valve at 90° Pressure Flow Simulation

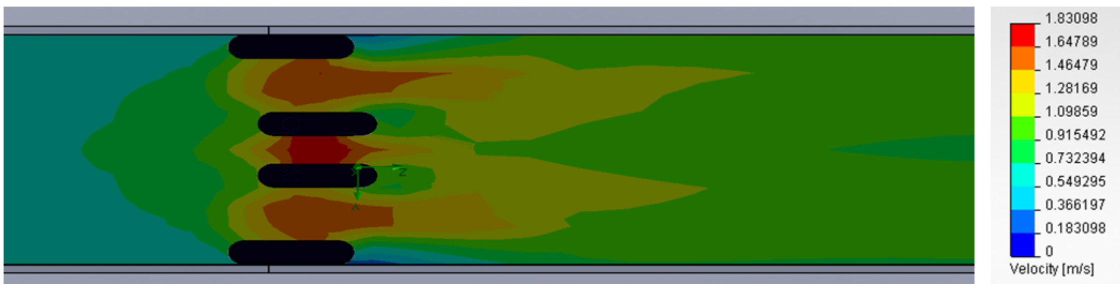

Figure 9: SMK1 Mitral Valve at 90° Velocity Flow Simulation

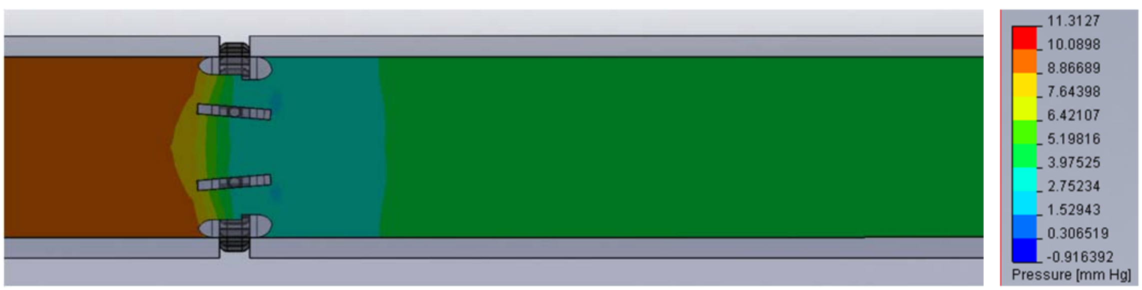

Figure 10: SMK2 Mitral Valve at 85° Pressure Flow Simulation

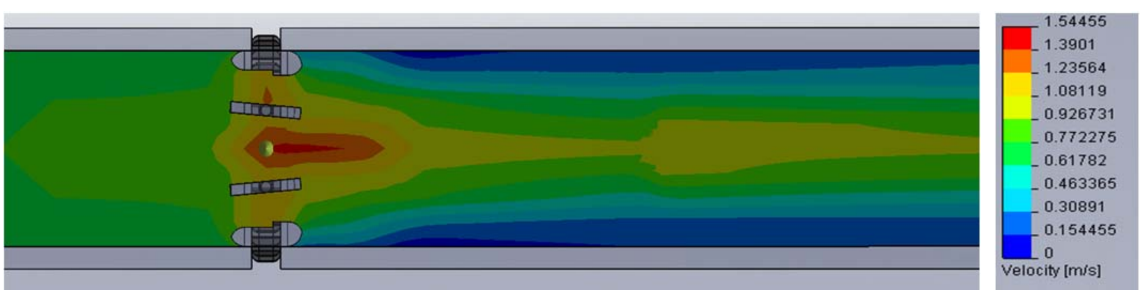

Figure 11: SMK2 Mitral Valve at 85° Velocity Flow Simulation

Discussion

It was interesting to note that the 3D RP models of the mitral valve were designed and successfully created. The interactive process in creating design improvements provided a valuable learning experience for the students. Throughout this project several problems were encountered in the design. These problems primarily relate to initial assumptions that were later determined to be inaccurate. As a result of these problems, students were able to gain a better overall understanding of how the system works. Along the design path many issues were noticed, to which corrections were implemented.

Several problems were overlooked in order to ensure that the key point of the research could be accomplished. One of these issues was the placement of the pivot joint. In order to ensure perfectly round interior walls, the pivot joint would have to be located at the largest cross section of the valve interior. If the pivot joint were located at any other location, the sides of the leaflets in the closed position would interfere with the walls in the open position. To resolve this interference with the interior walls, a relief had to be carved out where the leaflets would pivot. This part would be nearly impossible to machine and then casting would be necessary. Likewise, this would cause biological complications due to when the blood would pass it could cause clotting and additional drag in these areas. If a clot was significant enough, it may cause the valve to fail. Additionally, unnecessary features may cause more complications in flow and should be avoided if possible.

For the purpose of this paper, determining the ideal location for the leaflets and placement of the joints was inconclusive. The middle of the leaflet was chosen to allow more flow in the center while not having to fundamentally change the design of the Bi-leaflet valve. It was determined that by moving the pivot point to the middle many changes would have to be made to accommodate the new movement. A more efficient location could have been determined by making a relationship between the moment of inertia of the leaflets and the volumetric flow rate through the valve. This way, the optimal location of the pivot point could be determined based upon the maximum speed of leaflet rotation and the maximum volumetric flow rate.

Another issue encountered was allowing the valve to close automatically. The angle of eighty-five degrees was chosen because it was closest to ninety degrees, but will still allow the valve to close during back flow. Further testing would be required to determine if this angle would be the most efficient angle based on differential pressures which accrue during back flow.

There should also be a study of the forces at the pivot points during opening and closing. The valve must be thick enough to sustain the load which was applied to the pivot points when the valve is in motion. This is a critical problem because as the size of the leaflets increase its mass also increases, which will reduce the rate at which it accelerates. If the valve does not close rapidly enough, a significant amount of blood will escape causing the heart to be ineffective.

Finally, further improvements could be made to the shape of the valve. For the sake of simplicity a cylindrical valve was chosen. This valve was placed into a cylindrical shaped socket. It was noted that in the current market, more efficient designs exist. The difference between a conceptual design and an implemented design may be a difficult notion for many students to grasp. Therefore, BME students would benefit from labs which focus on prototyping. Students would then better understand the limitations and problems of producing a final product.

With the aid of rapid prototyping and simulation, the assessment as well as the optimization of a design can be done earlier. Students will be able to make improvements to their final designs and notice unforeseen issues with relative ease. Use of 3D RP is critical for research and design of implantable devices.

Conclusion

Methods of education dealing with problem solving and creative solutions pertaining to design can be difficult to convey. The most encouraging, yet difficult steps in the design process lie in the final product or prototype. By way of illustration, 3D CAD models of the mechanical heart valve were completed and the valve designs were fabricated via a 3D printer to support the proposed applications of rapid prototyping within the instruction of BME design concerns. The results obtained provided support for 3D RP. The process of creating 3D RP is beneficial in both the educational and production settings, particularly when used for implantable devices. The students and teachers can benefit from the inclusion of 3D RP.

In conclusion, the design of the artificial mitral heart valve and the fabrication of 3D RP models strongly support the concept of enhancing engineering education via the rapid prototyping process. Special application of rapid prototyping cannot be overstated for BME design courses.

Bibliography

1. Parlikar, Tushar, and George Verghese. “A Simple Cycle-Averaged Model for Cardiovascular Dynamics.” *Massachusetts Institute of Technology* (Sept. 2005).
2. Pierrakos, Olga. “Hemodynamic Flow Characterization of St. Jude Medical Bi-leaflet Mechanical and Bioprosthetic Heart Valve Prostheses in a Left Ventricular Model via Digital Particle Image Velocimetry.” *Virginia Polytechnic Institute and State University* (Nov. 2002).
3. Yoganathan, Ajit. “Cardiac Valve Prostheses.” *Georgia Institute of Technology* 127 (2000).
4. On-X Life Technologies, Inc. Web. 07 Apr. 2011. <http://www.onxlti.com/>.
   Palladino, Joseph. “Physiological Modeling, Simulation, and Control.” *Trinity College* (2006).
5. Yoganathan, Ajit, Jack Lemmon, and Jeffrey Ellis. “Heart Valve Dynamics.” *Biomedical Engineering Fundamentals* 3rd Edition.
6. Chen, Tiffany. “Cardiac Output Estimation from Arterial Blood Pressure Waveforms using the MIMIC II Database.” Massachusetts Institute of Technology (June 2009).
7. “Heart Valve Dynamics.” *The Biomedical Engineering Hand Book:* (2000): 20.1 29.2.
8. “Zprinter® 310 plus hardware manual.” *Zcorp:* (2002)
9. "Simulation Software Advantages | SolidWorks." Simulation Software Advantages | SolidWorks. N.p., n.d. Web. 10 June 2011. <http://www.cosmosm.com>
10. Rossvoll, Ole. “Pulmonary Venous Flow Velocities Recorded by Transthoracic Doppler Ultrasound: Relation to Left Ventricular Diastolic Pressures.” *JACC* 21 (June 1993).

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