Abstract: Heart diseases lead to a large number of deaths globally. Some of these diseases can be a result of mechanical, electrical, or biochemical complications within the heart. Among heart valve diseases, mitral valve diseases are common. A diseased mitral valve negatively affects the amount of blood that fills the left ventricle, thus decreasing cardiac output. It is reported that over 2 million Americans suffer from mitral valve regurgitation, and a large number of patients suffer from Rheumatic heart disease, leading to mitral stenosis in over 3 million patients. While the mitral valve can be repaired in many cases, surgical replacement of the valve with a prosthetic valve is often performed. Prosthetic heart valves are used to replace the diseased mitral valve, allowing the patient’s heart to function regularly. Before a prosthetic is utilized, it goes through a design process. The design of a prosthetic valve can be accomplished by collaborative work involving different disciplines. The objective of the present undergraduate research project is to design a prosthetic mitral valve, involving collaborative effort of biomedical and mechanical engineering students, employing CAD and 3D printing and prototyping a prosthetic mitral valve.

The requirements for a prosthetic mitral valve are to match the structure and function of the natural mitral valve. Literature on structure of existing mitral valves, including the caged ball valve, single disc valve, bi-leaflet valve, and the tilting disc valve were reviewed. Each configuration of the prosthetic mitral valve had its advantages and disadvantages. Considering functional similarity with the natural valve, a bi-leaflet valve configuration was selected.

The design process began with concept sketches of the mitral valve. Through the collaborative team of biomedical engineering and mechanical engineering students, integrating the knowledge of the anatomical and physiological aspects of the heart chambers and valves with computer aided design techniques such as SolidWorks, a 3D model of the mitral valve was created based on the conceptual design. After iterative design reviews and corresponding improvements, the design was finalized. The components of the final design of the prosthetic mitral valve consisted of a holding ring (20 mm diameter and 4mm thickness) and a suture ring (22 mm diameter). The leaflets (10 mm diameter) were hinged within the holding ring. 3D drawings and .STL files were prepared to provide input to 3D Printing machine. Based on iterative improvements in valve design, a few prototypes of the 3D model were fabricated using 3D rapid prototyping.

Upon examining the fourth version prototype of the prosthetic mitral valve, the feasibility of the approach was shown. In the future, it is hoped to explore the development of an enhanced mitral valve using flexible material. It is also hoped to develop a mitral valve suitable for a minimally invasive method for implantation, such as a transcatheter technique.

In conclusion, with a collaborative team of biomedical and mechanical engineering students, a prosthetic mitral valve was designed using 3D CAD tools. Design reviews, iterative improvements, and corresponding 3D rapid prototypes were made. The feasibility of the design and fabrication approach illustrated the achievements of learning outcomes through this research project, supporting the idea of increasing collaboration and research at undergraduate levels.

Keywords: 3D rapid prototyping, prosthetic valve design, mitral valve
Introduction

Heart disease is one of the leading causes of death in the world. These diseases can occur because of faults with the biochemical, electrical, or mechanical activity of the heart. Of the diseases that affect the heart valves, mitral valve disease is common. A heart that contains a diseased mitral valve can have a negative impact on cardiac output. Many Americans suffer from mitral valve disease, with over 2 million affected by mitral regurgitation and 3 million affected by mitral stenosis [11]. A diseased mitral valve can be repaired. However, surgical replacement does take place frequently. Prosthetic heart valves play a great role in saving the lives of those whose valves are not functioning properly. However, before prosthetic heart valves are implanted in the heart, they go through stages of design development. The stages of design are performed through the collaboration of various engineering disciplines. Prototypes of the heart valve are made to check if they will properly meet the patient’s needs. These prototypes are created by the engineer first coming up with a design for the heart valve. The design is then made through computer assisted design (CAD). The design is then made into a prototype through 3D rapid prototyping [5]. 3D rapid prototyping is a very important step in the design process of heart valves because it is only through this technique that engineers are able to make their ideas tangible.

There are complications that can occur with the heart valves from diseases that affect the heart’s function. The heart valve that is most commonly affected is the mitral valve (shown in Figure 1). It is understandable that any complications with the mitral valve can cause serious malfunction of blood pumping. Common complications are mitral valve regurgitation and mitral stenosis. With mitral valve regurgitation, blood from the left ventricle leaks into the left atrium. This can be due to several factors: the leaflets function regularly, but there is annular dilation or leaflet perforation; leaflet prolapse that occurs due to papillary muscle damage or lengthening, or; leaflet motion is restricted [1]. These complications result in reduced cardiac output, hence less blood being supplied to tissues throughout the body. Over 2 million Americans suffer with this condition [11]. Another complication is mitral valve stenosis, or narrowing of the mitral valve. The major cause of mitral stenosis is rheumatic heart disease (RHD). It is reported by the American Heart Association that 15.6 million people worldwide have RHD [6]. Mitral stenosis can lead to heart enlargement due to pressure buildup within the left atrium, atrial fibrillation, or left-sided heart failure if not treated over a given period of time. The patient can undergo medical treatment if these symptoms are acted upon immediately. However, if too much time elapses, valve replacement surgery will be needed.

Malfunctioning mitral valve can impact ventricular filling and cardiac output, thus affecting the amount of blood pumped throughout the body. One thing to note is that cardiac muscles do not regenerate. In this case, the defective mitral valve is not able to heal fully on its own. Until the diseased mitral valve is tended to, the heart will continue to produce a reduced cardiac output. The only solution is to replace the diseased mitral valve. The objective of the present undergraduate research project is to design a prosthetic mitral valve, involving collaborative effort of biomedical and mechanical engineering students employing CAD and 3D printing and prototyping a prosthetic mitral valve.
Background

The need for effective prosthetic mitral valve designs is great. It is reported that 300,000 patients undergo mitral valve surgery worldwide, with 44,000 in America alone [8]. In order to get an idea for an effective design for a prosthetic mitral valve, it is useful to review the commercially available prosthetic mitral valves. An early design of a heart valve prosthesis used was the caged ball valve, consisting of a suture ring, a ball, and a cage around the ball. It is efficient in the sense that it can perform the function of the mitral valve. The ball moves in the direction the force of blood pressure pushes it, which allows blood to flow, and prevents backflow. Although it does perform the function of a mitral valve, it still has major downsides. The downsides are ironically due to the ball. Because the ball is present, the blood now has to be pumped around the ball, whereas before the replacement, the blood simply went through the valve. In order for blood to go around the ball, higher amounts of energy must be spent by the myocardium. One thing to take into consideration is that the ball will be in contact with blood cells. With the ball moving around, there will be collisions between the ball and the blood cells. This, in turn, kills red blood cells on impact. In addition, dislocation may occur due to calcification of the annulus if the prosthesis is not placed perfectly [9]. These errors need to be eliminated in order to make a valve that is more efficient in allowing blood to flow and preventing backflow without destruction or causing the heart to work harder.

Another mitral valve configuration is that of a single leaflet valve. This design consists of a suture ring, a single disc, and two steel struts that keep the disc in place. This function of this valve is similar to the caged ball valve, except there is now a disc in place of the ball. Atrial contraction increases chamber pressure, pushing down on the disc, and the struts catch the disc in order to keep it within the ventricle. With the disc there, the blood can flow through the valve and into the ventricle. With ventricular contraction and increase in pressure with respect to the atrium, the disc is pushed up into the atrium. The suture ring catches the disc in order to prevent any backflow into the atrium. While the valve seems to mimic the functions of the mitral valve, still there are some constraints. Like the caged ball valve, the disc is moved around by the pressure created by the blood. Due to the presence of the disc, blood must be pumped around the disc in order to move into the ventricle. This leads to the heart doing more work. Another major setback is the fact that there is a high risk of thromboembolism, which is a blood clot in a blood vessel and can obstruct blood flow to the heart.

The bi-leaflet valve consists of a suture ring, and it has two leaflets. This function differs from the aforementioned functions, seeing as they function by the leaflets rotating when pressure is applied. When the left atrium contracts, blood pressure will push down on the leaflets, causing the valve to open and allow blood flow. When the left ventricle contracts, blood pressure will push the leaflets up into the atrium. This will in turn cause the valve to close and prevent backflow of blood. With this technique, this allows a great amount of central flow of blood. The only downfall of this design is that there is some backflow of blood.

Another type of valve configuration is the tilting leaflet valve. This valve consists of a suture ring, a disk, and metal struts that are structured in a way that supports one side of the disk and leaves the other side free, giving the disk the ability to tilt. When the atrium contracts, blood pressure pushes down on the half of the disc that is not supported by the
metal struts. This allows the blood to flow through the valve into the ventricle. When the
ventricle contracts, the blood pressure pushes up against the tilted part of the disk. The disc
will then rotate on the metal struts, forcing it to close. Aside from the fact that this valve does
allow a little bit of backflow of blood, it performs the function of a mitral valve very
accurately.

**Design and Fabrication**

In order for a prosthetic mitral valve to function the same way as a patient’s own
mitral valve, the structure of the prosthetic mitral valve must be similar to that of the natural
valve. The mitral (bicuspid) valve has two leaflets. It is reasonable to base the design of the
prosthetic (SMKM6) valve with two leaflets.

After creating a conceptual sketch of the design of the prosthetic valve, SolidWorks
was used to make the 3D model of each of the components. The components of the natural
mitral valve consist of the mitral valve leaflets and the mitral annulus. The chordae tendineae
(the muscle that attaches the flaps to the mitral annulus) are not considered when taking into
account that the mitral valve will be replaced as a whole. The diameter of the mitral annulus
is estimated as 22 mm. Considering that most mitral valve disorders occur in individuals 60
years and older, the thickness of the mitral valve ring must be comparable to the thickness of
the mitral valve rings belonging to patients within the age group. The thickness is about 4 mm
[10].

The components of the prosthetic mitral valve consists of leaflets (Figure 2), a holding
ring (Figure 3), and a suture ring (Figure 4). Each component of the prosthetic valve plays a
role in helping the valve to function and allowing blood flow. Each leaflet has a set of two
legs, one on each side of the leaflet. The inner holding ring has holes for the legs of the
leaflets so that they can rotate when pressure is applied to them. The inner holding ring also
contains protruding legs positioned above and slightly behind the holes for the legs of the
leaflets. This configuration is selected so that when pressure pushes downward on the leaflets,
they do not rotate a complete 90°, but instead about 75°. When force pushes upward on the
valves when the ventricle contracts, the valves will receive an increase in pressure and cause
the valve to close. If the leaflets tilt 90°, they are less likely to close from the blood pressure.

With all of these components and features taken into consideration, a 3D model of the
assembly of the components was created (Figure 5). Upon completion of the 3D assembly, the
model underwent 3D rapid prototyping, being composed of ABS, plastic, and resin.

**Results and Discussion**

Several prototypes were made based on initial design and improved versions. The
prototype SMKM6 was created successfully (Figure 6). The 3D printer efficiently printed out
each component of the prototype successfully. The leaflets of the valve are able to move when
force is applied to them and the movements are regulated by the struts. The plastic struts
(which protrude 2 mm from the inner ring) are able to regulate the angle at which the leaflets
rotate, which suggests that successful flow will possibly be achievable.

The dimensions of each component were fabricated accurately. However, there were
some setbacks when it came to the function of the flaps. The flaps were designed to have a 20
mm diameter so that they fit in the holding ring. However, as the flaps rotated downward, the
front ends of the flaps moved from the center of the holding ring to where the diameter was
less than 20 mm. As a result, there was an overlap between the flap and the holding ring in the
CAD. To fix this, the sides of the front end of the flaps were flattened in order to prevent overlapping and to allow non-restricted rotation of the flaps. With this adjustment being made, a prosthetic mitral valve was designed and the corresponding prototype, SMKM6, showed promise to be a valve that would function efficiently.

Through the collaboration of a mechanical engineer and a biomedical engineer, along with the supervision of a biomedical engineering professor, fabricating various prototypes of the mitral valve with 3D printing was possible. This has also helped in expanding knowledge of CAD through SolidWorks. Also, the engineering students gained a substantial knowledge on 3D design and assemblies. As a result of this project, collaborative learning was experienced with an example of knowledge of 3D rapid prototyping.

Future Work

In the future, we hope to develop a modified version of the prosthetic mitral valve by trying different materials with greater flexibility.

There are also hopes for increasing the utility of 3D rapid prototyping. 3D rapid prototyping can possibly be used to print a scaffold to be used in tissue engineering. As different designs and concepts are created, 3D rapid prototyping will bring these ideas to fruition.

Another thought to keep in mind is that implantation of prosthetic heart valves is very invasive and depending on the age and health condition of the patient, they may not be able to undergo the procedure needed. A newer technique used to implant prosthetic heart valves is a transcatheter approach. Using this technique, the patient does not have to go through open heart surgery, which is both invasive and can cause complications. During the testing phase and subsequent phase of trial with implanting in animal bodies, many other minimally invasive techniques may be explored to increase the efficiency of the operation of the valve.

Conclusion

The design of the mitral valve prosthetic was made to closely resemble the anatomy and function of a biological mitral valve. Through CAD and 3D printing, the prototype was made. Through observation, the dimensions of the prototype matched that of a biological valve. Preliminary results are encouraging and they support the effort to design and prototype a heart valve, work collaboratively, and gain knowledge of 3D rapid prototyping for a real application.

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References

Appendix

Figure 1: Components of the Heart (Source: Marieb, Elaine; Katja, Hoehn. *Human Anatomy & Physiology: Eighth Edition*. CA: Pearson, 2010.)
Figure 2: CAD dimensional drawing of SMKM6 mitral valve leaflet

Figure 3: CAD dimensional drawing of SMKM6 mitral valve annulus
Figure 4: CAD dimensional drawing of SMKM6 suture ring

Figure 5: CAD dimensional drawing of SMKM6
Figure 6: 3D printed prosthetic SMK3 mitral valve