DESIGN OF MEDICAL IMPLANTS FOR UNDERGRADUATE BIOMEDICAL ENGINEERING RESEARCH

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Abstract: Undertaking research projects, applying the theory learnt and working on design problems at an undergraduate level lay a good foundation for learning design and product development. Undergraduate research is not mandatory in many Biomedical Engineering (BME) programs, especially in 4-year colleges. However, getting involved with a research project for academic credit or for gaining research experience will be very beneficial to students in the BME program. With respect to product design, medical implantables offer a complex and interesting challenge for BME students. The need to understand the three-dimensional form of the constituent parts and how they fit in the sub-assembly and in the main product, with the help of modern techniques such as 3D Rapid Prototyping could be highly rewarding to BME undergraduate students. This type of pedagogical approach is not extensively adopted in BME Design courses. The objective of the present undergraduate research project is to study, design, build a prototype and analyze the design of a medical implantable.

The selected implantable for the study is a prosthetic aortic valve. The commonly reported defects are aortic stenosis and aortic regurgitation. Replacement of the defective natural valve is usually done with a prosthetic aortic valve. The design of the prosthetic aortic valve is crucial to ensure that it has the right form and it fits and functions properly. Having BME students design medical implantables enables them to better appreciate the importance of 3D structure and dimensions of the implantable product.

The initial step is to create concept sketches of the prosthetic aortic valve. The conceptual design of the aortic valve is reviewed and iteratively refined. 3D models of the prosthetic aortic valve are then created using SolidWorks. The 3D CAD model is used to assess the structural feasibility and suitability of the designed part/sub-assembly. Since designing is an iterative process, revised versions of the prosthetic aortic valve were created based on engineering reviews. This approach leads to a better final design and ascertains a more thorough understanding of the form and fit of the prosthetic aortic valve. Subsequently, with the help of a 3D Rapid Prototyping machine, a prototype of the design was fabricated and analyzed. The first prototype did not account for spacing between two moving parts and resulted in a static model. A revised version was fabricated taking the moving parts into consideration to make it a dynamic prototype. Future work is planned to design a suitable test fixture to perform pseudo in-vitro testing of the prototype aortic valve. The subsequent phase of the project could involve controlled testing of the prosthetic aortic valve on a specially designed test fixture or implanted in an animal to validate safe and proper functioning of the prototype

In conclusion, utilizing SolidWorks to design and 3D Rapid Prototyping in BME design courses could improve engineering design learning outcomes for BME students while giving them a preliminary experience in doing research.

Keywords: *Undergraduate Research Project, Biomedical Engineering design education, Prosthetic Aortic Valve, Rapid Prototyping*

Introduction

It was reported that the overall rate of death attributable to cardiovascular disease (CVD) was 245 per 10,000 [1]. Approximately 90,000 valve substitutes are now implanted in the United States and 280,000 worldwide each year; about half are mechanical valves [2]. One reason why the heart fails is when the natural aortic valve (Figure 1) does not work the way it should. While the prosthetic valve is an efficient and common replacement for the aortic valve, it still has the issue of causing clotting, damaging blood cells and disrupting the natural flow of blood. According to a clinical investigation published in the Texas Heart Institute Journal, "The ideal prosthetic heart valve should possess qualities that include good hemodynamic performance and durability, ease of insertion, and freedom from thromboembolic events. Although valve manufacturers aim for these objectives, no prosthetic valve has yet achieved a perfect performance profile in accordance with these criteria" [3]. Hence, a study on the design of heart valves seems to be a worthwhile research project for undergraduate BME students and with the help of modern technologies such as 3D Rapid Prototyping, getting involved with such a research project for academic credit or for gaining research experience will be highly beneficial for the students. Furthermore, it will improve the students' knowledge about prosthetic medical implantables while giving them experience in solving a complex real-life biomedical engineering problem, such as aortic valve replacement.

The objective of the present undergraduate research project is to design a prosthetic aortic valve by making a 3D design on CAD software and employing rapid prototyping to fabricate a prototype of the prosthetic valve to analyze the design and make necessary improvements iteratively.

Background

Valvular Stenosis (narrowing of the valve) and Valvular Insufficiency or Regurgitation (leakage/ backflow of the valve) are two common types of heart valve disease. Occasionally the defective aortic valve can be repaired but often valve replacement is required. While there are other replacement options such as bovine heart valves or porcine heart valves, the focus of the project is on the prosthetic aortic valve. During a heart surgery, the natural aortic valve is replaced with a prosthetic, mechanical valve that would imitate each function of the natural aortic valve. Prosthetic mechanical valves, which are composed primarily of metal or carbon alloys, are classified according to their structure as caged-ball, single-tilting-disk, or bileaflet-tilting-disk valves [4]. An example of a prosthetic aortic valve currently in use is St. Jude Medical™ Masters Series valve.

3D Rapid Prototyping (3D RP) is a technique used to fabricate a physical model of a three-dimensional CAD drawing. In the undergraduate design course, BME students can create a 3D model of a medical implantable device, such as a prosthetic aortic valve. The prosthetic aortic heart valve is a small implant and has intricate detail. Once the 3D model is designed, a prototype can be built. Using a traditional machining method to fabricate this part is tedious and time-consuming. With RP, the process of fabrication is shortened and the part is created quickly. The part can then be studied, changes can be made immediately and the part can be re-fabricated. Rapid Prototyping is a technology that speeds the iterative product development process. This makes it very useful for the study of the design and manufacture of implants. Some advantages of Rapid Prototyping include processing time reduction up to 75%, better visualization and high design flexibility to enable short-term component modifications and cost-effective component production for demonstration purposes, and functional test samples [5]. The evolution of RP techniques was a result of a marriage between computer graphics software and various materials technologies, which allowed layered formation [6].

Prosthetic Aortic Valve Design and Fabrication

The ideal valve substitute should mimic the characteristics of a normal native valve. In particular, it should have excellent hemodynamics, long durability, high thromboresistance, and excellent implantability [2]. The design is the most crucial step when fabricating a prosthetic aortic valve because the design is what determines the form and fit of the implantable. The dimensions of the valve need to be precisely the same as the natural aortic valve so that the amount of blood flow through the valve remains constant. If the prosthetic valve is not designed properly, it may not fit properly and it may not function properly. To ensure the best design, BME students will need to follow the design process when creating the prosthetic aortic valve. The first step is to make concept sketches. When considering design sketches, a simplistic, working model was considered. The purpose was to see if it was possible to create a simple prosthetic aortic valve quickly. With concept sketches, students will be able to creatively come up with designs that may or may not work. Considering alternative solutions is an aspect of design activity that involves thinking of potential solutions (or parts of potential solutions), experimenting with solution ideas, and thinking of ways to get around an impasse [7]. The design of the constituent was accomplished using SolidWorks 2012. The various parts of the prosthetic aortic valve are described in the following sections.

The leaflet on the prototype aortic valve must replicate the function of the leaflets on the natural aortic valve. While the natural aortic valve has three leaflets, the prosthetic aortic valve is designed with two leaflets (Figure 2), symmetric to each other about the center of the valve. The diameter of the leaflet is 20mm. The hinges have a diameter of 1mm and span a length of 18mm. The hinges are located 6mm from the flat (right side) edge of the leaflet. From a design consideration, this seemed to provide a stable axis of rotation while allowing the leaflet to rotate freely. The leaflets open upwards at an angle of ~85° when the blood pressure rises in the ventricle and pushes the blood through the aorta.

The holding ring, shown in Figure 3, is a critical structure of the prosthesis. It supports the leaflets and provides a stable platform for the leaflets to pivot about. It needs to be biocompatible, strong and light in weight. The holding ring has an outer diameter of 23mm and an inner diameter of 20mm. The design of the holding ring was made so that it would hold both the leaflets and allow them to rotate about a pivot. The leaflets need to open and close based on pressure change but there needs to be a support so that the leaflets do not rotate more than they need to. The holding ring provides a stopper so that the leaflets open and close only till a certain limit and no more.

The main function of the Suture Ring is to allow the surgeons to stitch the prosthetic valve into the heart. The suture ring is what connects the prosthetic valve to the interior wall of the aorta. The suture ring is designed to encircle the holding ring which is why the outer diameter of the holding ring is the same as the inner diameter of the suture ring.

Once each part is designed, the constituent can be put into a prosthetic aortic valve assembly (Figure 4). The constituent parts are shown in Figure 6 in different colors in order to differentiate one part from another in the design and drawing phases. The design is then converted to a .STL file format and is now ready for fabrication. The prototype of the prosthetic aortic valve was created using the Zprinter 310 Plus at the Manufacturing Center at Wentworth Institute of Technology. This machine offers the option of feeding an .STL CAD file of the 3D design of the prosthetic aortic valve into the machine and then proceeds to fabricate it. The machine produces a monochrome fabrication, which means the prototype is made from only one material - ABS plastic. The most preferred biomaterial for heart valves is LTI Carbon (pyrolytic carbon). The LTI carbon exhibit excellent blood compatibility, biocompatibility as well as wear and fatigue resistance [8]. However, with rapid prototyping, the material of the fabricated prototype is based on the configuration of the prototyping machine.

Results and Discussion

The prototype of the prosthetic aortic valve was fabricated successfully. The SMK4 prosthetic aortic valve, shown in Figure 6, was the first fabricated prototype made from ABS Plastic. While the prototype yielded encouraging results, many improvements could have been made to the design of the valve. Firstly, the leaflets of the prosthetic aortic valve have to be able to open and close. The leaflets in the SMK4 prosthetic valve were static because the space between the hinge on the leaflets and hole on the holding ring did not exist. This meant that the two parts were touching each other and when the design was fed into the rapid prototyping machine, it recognized the design as one part because the leaflets and the holding were in contact with each other. This required the design to be revised to allow for some space between the leaflets and the holding ring. Once this was sorted, the revised design was sent to the Manufacturing Center and another prototype was fabricated - the SMK5 prototype, shown in Figure 7. Unfortunately, according to the configuration of the rapid prototyping machine, the tolerance between two moving parts on the prototype has to be at least 0.5 mm. This is difficult to achieve on the full sized model of the prosthetic valves which is why the prototypes shown in Figure 6 & 7 show the prosthetic aortic valve in the open position. The fact that the two prototypes were static models was a constraint in the project. To work around this constraint the design of the prosthetic aortic valve would have to be scaled up in size. At this stage in the project, a prototype with the revised design has not been fabricated.

An purpose of the project was to understand how the design would be created and subsequently fabricated using a rapid prototyping machine. To create a design from scratch, students will need to understand each aspect of the part, each detail in the design and the functioning of the part itself. As the undergraduate student team follows the design process while creating a prosthetic aortic valve, they develop an understanding of the problem, realize potential alternatives and decide on a final solution to the problem. This project involved a mechanical engineering student and a biomedical engineering student. The mechanical engineering student was exposed to the physiological aspect of the heart and the biomedical engineering student learnt 3D designing using SolidWorks. Both students were introduced to 3D Rapid Prototyping. With the guidance of a biomedical and electrical engineer the students were involved in a collaborative undergraduate project. This approach is what BME design courses coupled with research need to focus on. In a design course that spans one semester, student teams will need to design, prototype and analyze a medical implantable. The introduction of 3D CAD will help the student learn designing and the importance of the design process. This, coupled with fabrication of the 3D design using 3D RP will allow students to not only learn the design aspect of engineering but also the medical significance of the implantable device.

Future Work

As part of the design process, students need to perform the testing of the prototype. This would require the building of a test fixture to test the prototype of the prosthetic medical implantable. Initial testing could involve a simple, transparent cylindrical tube with the valve placed in the middle. Then a liquid can be passed through the tube to check if the leaflets open properly. A more sophisticated test fixture can be adopted that would allow pulsatile flow of a liquid across the valve. This would give an indication as to whether the prototype can withstand the pressure change across the valve. The next step could involve the use of two chambers with the valve in between them, to replicate the natural left ventricle and aorta. This coupled with an accurate pulsatile flow of a liquid, with the same viscoelasticity as blood, could throughly test the prototype of the aortic valve, giving the student a detailed physiological representation of blood flow through a prosthetic aortic valve in patients who have undergone aortic valve replacement surgery.

It is intended to study the effect of flap positioning and geometry with respect to blood flow during the systolic phase. The mechanical aortic valve has served as a suitable and feasible solution for patients with aortic stenosis and regurgitation. However, the replacement procedure is extremely invasive and requires opening the chest to access the heart, leaving a permanent scar on the chest while being susceptible to infections and clotting within the heart. This is inconvenient for patients who cannot undergo surgeries due to various surgical risks. Research is in progress on emerging techniques to explore alternate methods for replacing the natural aortic valve. The Transcatheter Aortic Valve Replacement is proving to be the future of aortic valve replacement surgery. The procedure for replacing the aortic valve using a catheter is simpler and less invasive. This approach also eliminates the need for cardiopulmonary bypass because the heart can continue to beat during the procedure [9]. The Transcatheter Aortic Valve Replacement procedure can serve as a replacement for the standard aortic valve replacement surgery once certain issues are conclusively solved.

Conclusion

In conclusion, computer-aided design couple with 3D RP has the potential to become a great approach to learning product design. The preliminary results are encouraging. With 3D Rapid Prototyping, iterative changes can be made to a design to suit the form and fit features, when designing medical implantables. It has the potential to innovate teaching engineering design and enhance learning outcomes for BME students.

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Figures

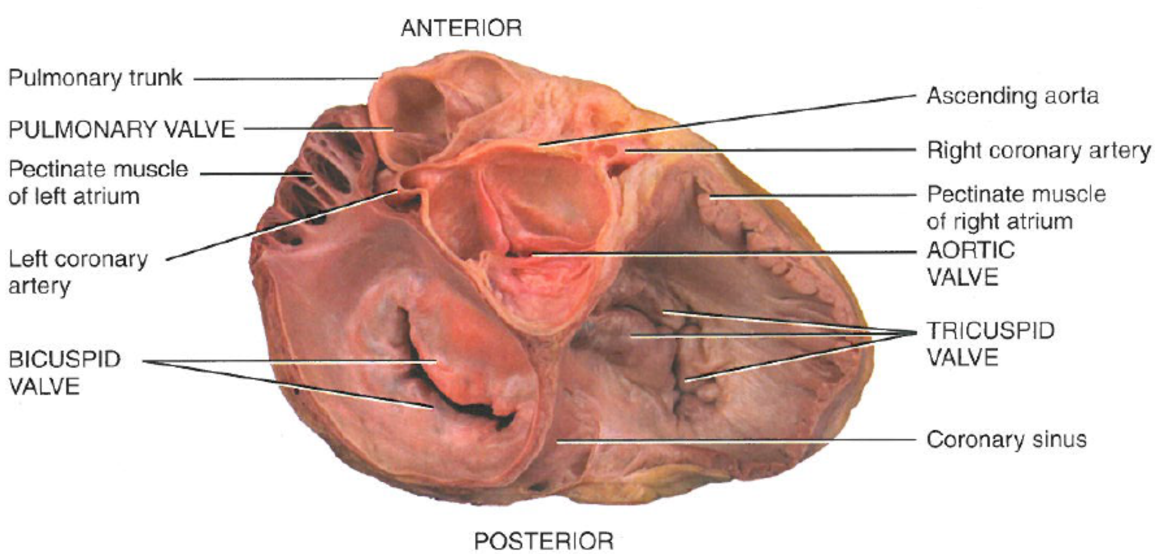

Figure 1. The cross sectional view of the heart showing the heart valves [10]

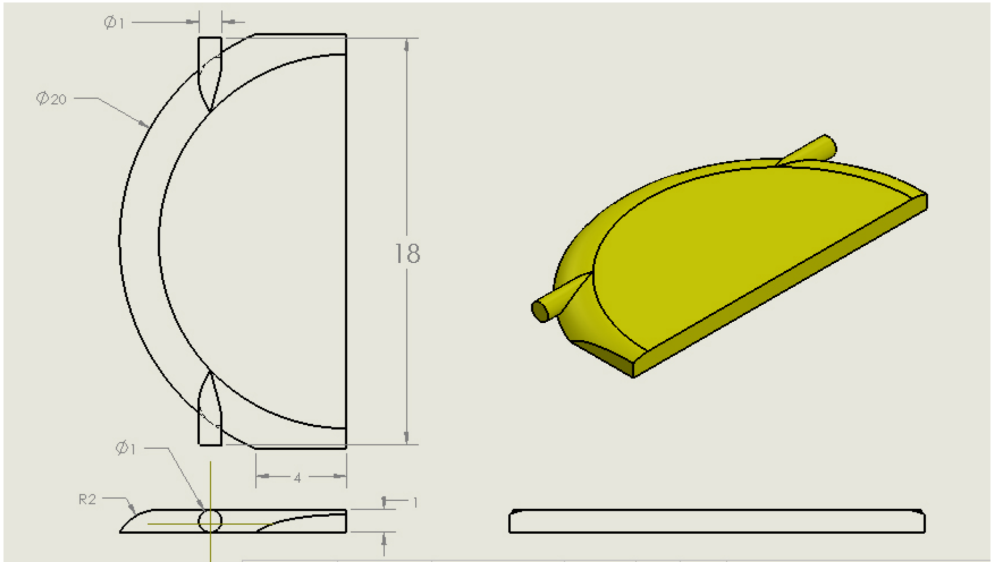

Figure 2. The CAD dimensional drawing of the prosthetic aortic valve leaflet

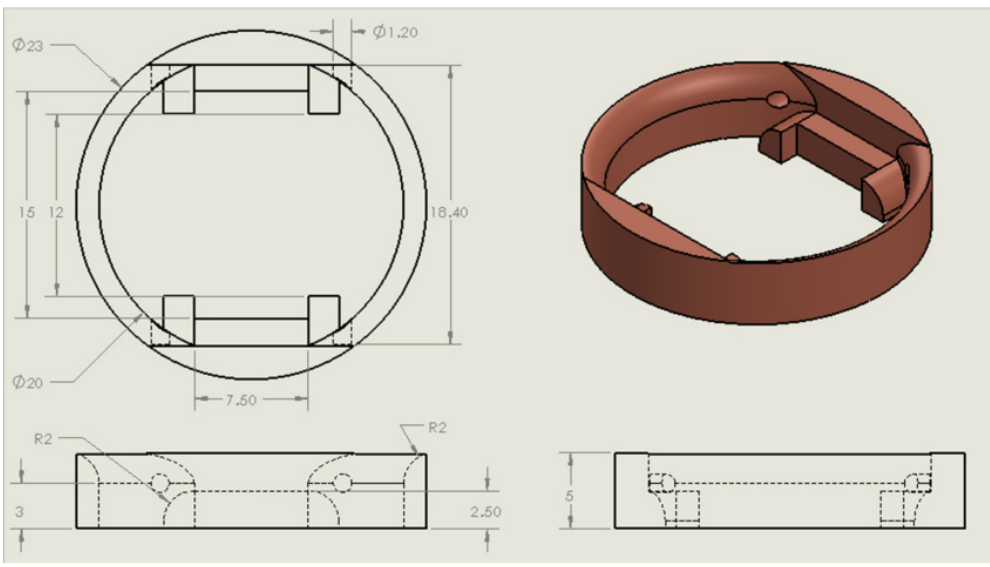

Figure 3. The CAD dimensional drawing of the prosthetic aortic valve holding ring

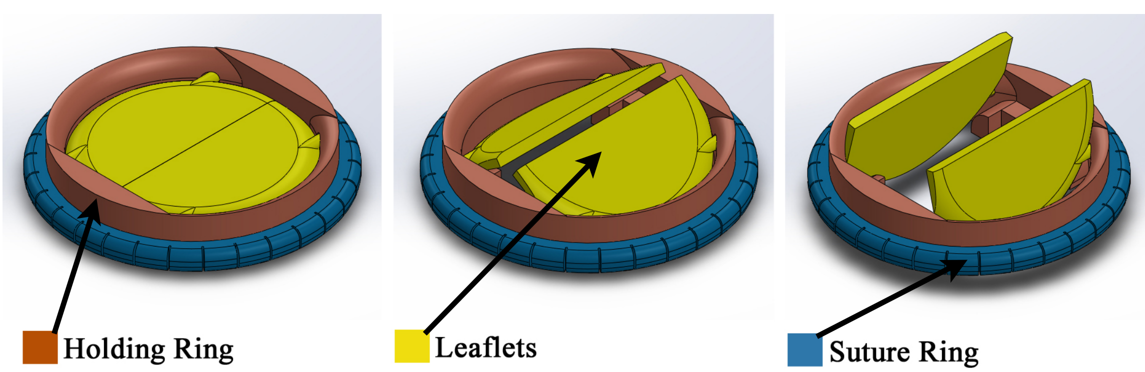

Figure 4. The prosthetic aortic valve in the closed, mid-way and open positions

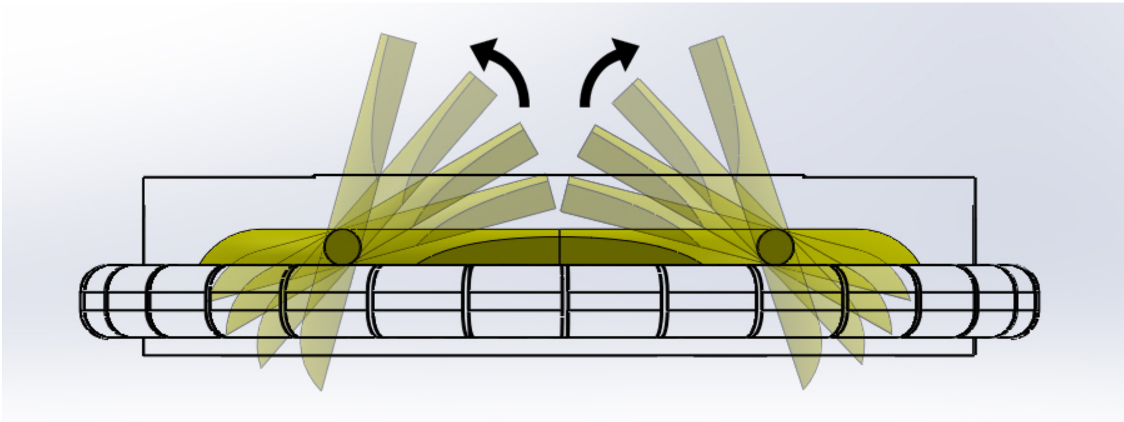

Figure 5. The path of the leaflets of the prosthetic aortic valve in the systolic phase

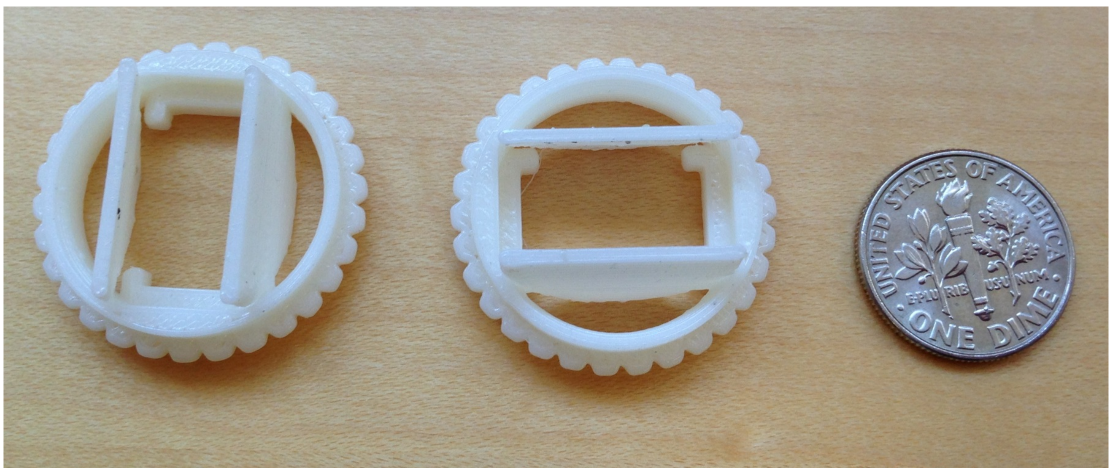

Figure 6. The prosthetic aortic valve prototype SMK4

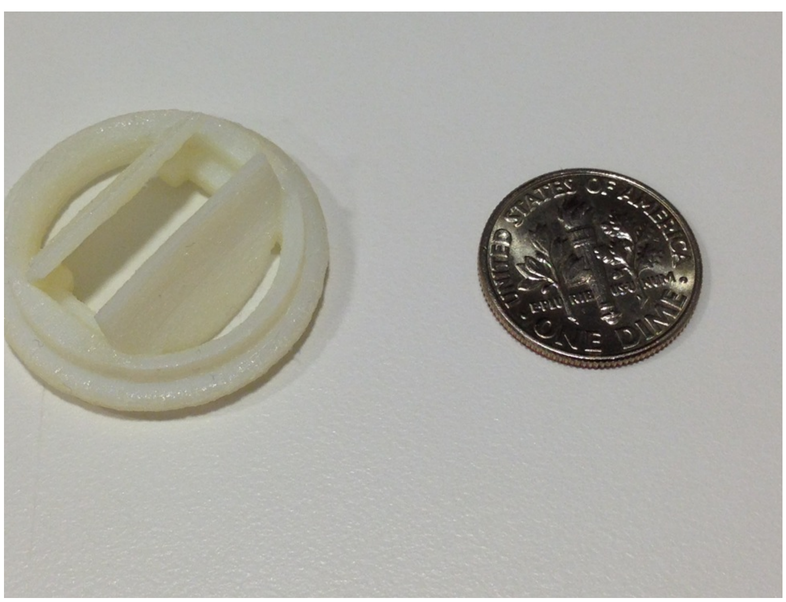

Figure 7. The prosthetic aortic valve prototype SMK5