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Enhancement of the SynCardia Total Artificial Heart for Pediatric Use

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Biomedical Engineering Senior Design Project

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ABBREVIATIONS

Body Surface Area	BSA
Concept Failure Mode and Effects Analysis	C-FMEA
Computational Fluid Dynamics	CFD
Design Failure Mode and Effects Analysis	D-FMEA
Failure Mode and Effects Analysis	FMEA
Food and Drug Administration	FDA
Quality Functional Deployment	QFD
Total Artificial Heart	TAH
Ventricular Assist Device	VAD

ABSTRACT

Pediatric patients with disorders and diseases of the heart have limited options with regards to implantable devices. Many of these implants are ventricular assist devices, which is not always suitable for a patient. Total artificial hearts (TAHs) have supported many adult patients until transplantation, and we believe that they could do the same for pediatric patients. SynCardia has the only Food and Drug Administration (FDA) approved TAH devices. Since SynCardia is the only company with FDA approved TAHs, we decided to modify the design of the SynCardia TAH for use in pediatric patients without compromising the function of the

current device. This paper reports on the process for the design modification to the TAH. The project resulted in detailed drawings of our proposed device, a risk mitigation summary, and a partial verification report.

INTRODUCTION

SynCardia has the only Food and Drug Administration (FDA) approved TAH devices [1]. The larger 70 cc device has primarily been used in larger patients, so the company created a smaller 50 cc TAH device which was just approved by the FDA in 2020 [1]. Both of these are too big for many children who could benefit from a TAH. There are other TAH devices that are being studied such as BiVacor and OregonHeart. The BiVacor device is “small enough for a child, powerful enough for an adult” [2]. Although the BiVacor device may be able to fit in a child, it is not yet approved by the FDA. The OregonHeart TAH is aimed to fit in patients 10 years and older and is still in animal studies [3]. Ventricular assist devices (VADs) are also becoming available for bridge to transplant applications, but TAHs are the better solution for biventricular heart failure.

Since SynCardia is the only company with FDA approved TAHs, we modified the design of the SynCardia TAH for use in pediatric patients without compromising the function of the current device. Specifically, we enhanced the internal mechanics of the *in situ* ventricular system in the current TAH for patients between the ages of six and ten. Our design enhancement focused on the ventricular system and not on the other components such as the external driver.

In redesigning the TAH, we compared three sizes: 30 cc, 32.5 cc, and 35 cc. The 35 cc volume was chosen because it had the least potential risk. SOLIDWORKS was used to create 3D models for the device. Only the left ventricle was created, as the left and right ventricles are similar in design. A prototype was 3D printed for our initial design. The final models were analyzed using computational fluid dynamics (CFD) and SOLIDWORKS to ensure that they met our target ranges for our engineering requirements.

The project resulted in detailed drawings of our proposed device, a risk mitigation summary, and a partial verification report. Going through the design process, which was specifically adapted from the FDA medical device design process for the senior design capstone projects, allowed us to further understand the steps it takes to design and develop a medical device. We further developed communication, conflict management, and team management skills through working as a team. In completion of design, we also learned about the various tools engineers and others use in the creation of a product such as Quality Functional Deployment (QFD), Failure Mode and Effects Analysis (FMEA), CFD, and 3D modeling using SOLIDWORKS.

PROBLEM BACKGROUND

Over five hundred heart transplants are performed on pediatric patients every year, and patients in the age range of six to ten years old have the highest rejection rates of all pediatric patients [4]. Commonly, TAHs are used in cases of severe heart failure, biventricular failure, intractable arrhythmias, irreparable ventricular defects, or ventricular failure due to previous mechanical valve support [5]. Multiple mechanical circulatory support devices exist to treat

heart problems, but are limited in their applications, especially for children. Between 1999 and 2006, 533 (17%) children under the age of 18 died waiting for a heart transplant [6]. The current artificial heart models approved by the FDA are too large for many pediatric patients. For older and adolescent children, mechanical assist devices have an 80% success rate as a bridge to transplantation [7].

The SynCardia TAH 70 cc and 50 cc designs (formerly known as Cardiowest) are the only commercially available TAH devices in America [1]. Because of this, we chose SynCardia's TAH device to enhance and expand to serve pediatric patients. Of the 1596 implantations of the SynCardia TAH devices as of 5/11/2016, 12% are women and less than 5% are pediatric [8]. The 70 cc design was made to fit in patients with a body surface area (BSA) greater than 1.7 m^2 and a minimum anteroposterior length of 10 cm from the sternum to the tenth thoracic vertebra; the 50 cc design was made to fit in patients with a BSA between 1.2 m^2 and 1.7 m^2 with a anteroposterior length of less than 10 cm [8]. These dimensions are estimates and with virtual surgery tools and improved medical imaging, device implantations outside of those ranges are possible [8]. Our proposed device was developed to expand upon these two TAH sizes and increase the availability of life saving devices to children.

PROJECT SCOPE

The goal of this project was to enhance the internal mechanics of the *in situ* ventricular system of the SynCardia TAH by modifying the design so that it can fit in a six to ten year old without compromising function. We did not attempt to modify any aspect of the SynCardia driver system, which pumps air into the system, or any materials used in the device.

METHODOLOGY

We followed the Senior Capstone Design Process, adapted from the FDA medical device design process [9]. This design process included five stages: user needs, design input, design (preliminary) process, design output, and medical device prototype. In the user needs stage, we conducted sufficient research on the anatomy of the heart, SynCardia 50 cc and 70 cc designs, TAH competitors, FDA documentation, and cardiovascular pathologies. We investigated the circumstances in which patients are recommended the use of TAHs.

Next, we used a Quality Functional Deployment (QFD) to determine the customer requirements, derive the engineering requirements (including the engineering targets), and document how the SynCardia TAHs compared to other products. When comparing to the other devices, such as BiVacor and OregonHeart, we accepted that some of these competitors may have better products due to factors such as continuous flow. Even with this being the case, SynCardia has the only FDA approved, commercially available TAHs. Engineering requirements were defined based on the customer requirements and were assigned specified target values. Finally, we determined the risks of the product by creating Failure Mode and Effects Analysis (FMEA) for the concept and design. We found that the greatest risks are hemolysis and inadequate blood flow.

Our design focused on the scale-down of the TAH so that it could be suitable for pediatrics. For this iteration of the design, we focused on the mechanics of the ventricular system. The D-FMEA was also conducted in this stage. We assessed the risks associated with

our design and determined a risk priority number (RPN) for each risk based on severity, probability of occurrence, and detectability.

In the design output phase, part and assembly drawings were prepared, a verification process was developed, and assembly instructions were compiled. The engineering requirements were verified against the final design using computational fluid dynamics and SOLIDWORKS. Models and drawings were created for our 35 cc modification of the SynCardia TAH design.

DESIGN REQUIREMENTS

The finished product will extend the population that can benefit from the ventricular system of the SynCardia TAH so that it can effectively function as a heart in six to ten year old pediatric patients. The product must provide adequate blood flow and not put the pediatric patient at a greater risk for hemolysis than the SynCardia TAH does for older patients. The size of the product must be small enough to be implanted in the average six to ten year old pediatric patient. These essential conditions were explicitly defined in four customer requirements: appropriate ejection fraction, sufficient cardiac output, low hemolysis, and appropriate size (Table I-1, Appendix I). Each of the customer requirements had a corresponding engineering requirement and target value/range to verify the design (Table I-2, Appendix I). The target for the first requirement was a minimum left ventricular ejection fraction of 0.61 [10-12]. The next target was a cardiac output in the range of 2.6 - 5.4 L/min [13]. The third requirement of low shear stress on red blood cells had two possible targets: the shear rates should not exceed 2% of the maximum in the SynCardia 50 cc TAH or exceed the maximum shear stress of 150 Pa [14]. Note that only one of the criteria had to be met for the verification of low hemolysis. The last

target range indicated that the external volume of the 35 cc TAH design shall be within the range of 230.0 mL and 318.1 mL [15].

The functions that could be a source of risk to our total artificial heart design enhancement were compiled (Table 1). Key elements were that the TAH should provide sufficient blood circulation, cause minimal damage to red blood cells, and fit comfortably with the patients in our target range of six to ten years old. Each function could lead to failure of the device and therefore failure modes, the effects of failure, and the mechanisms of failure were compiled. All of this had to be taken into account when designing our device concepts.

Table 1: Essential Device Functions

1.	Sufficient Blood Circulation	The TAH should be able to provide adequate blood flow to the vital organs so that it can effectively function as a heart.
2.	Minimal damage to Red Blood Cells (RBC)	The TAH should provide sufficient blood flow that does not damage or shear the RBCs.
3.	Decreasing the volume of the device	This design enhancement is focusing on decreasing the overall size of the TAH ventricles so that it can comfortably fit within the chest cavities of our average patient in our range of six to ten years old.

DESIGN CONCEPTS

We determined the specifications of our preliminary design and specific components by assessing three concept designs for the device: 30 cc, 32.5 cc, and 35 cc. After weighing the

advantages and disadvantages of each of the alternative concepts, we concluded that the 35 cc would be the best design. This concept was selected because it was the largest of the three, meaning it would provide the most ample blood flow, fit between the specified range of 230 mL and 318.1 mL, and created the least amount of shear on RBCs. Using dimensions from literature and conducting brute calculations, we put together rough specifications and designs for the 35 cc TAH device [16]. The first design iteration (Figure 1) was based solely on images that we had seen on SynCardia's website [1].

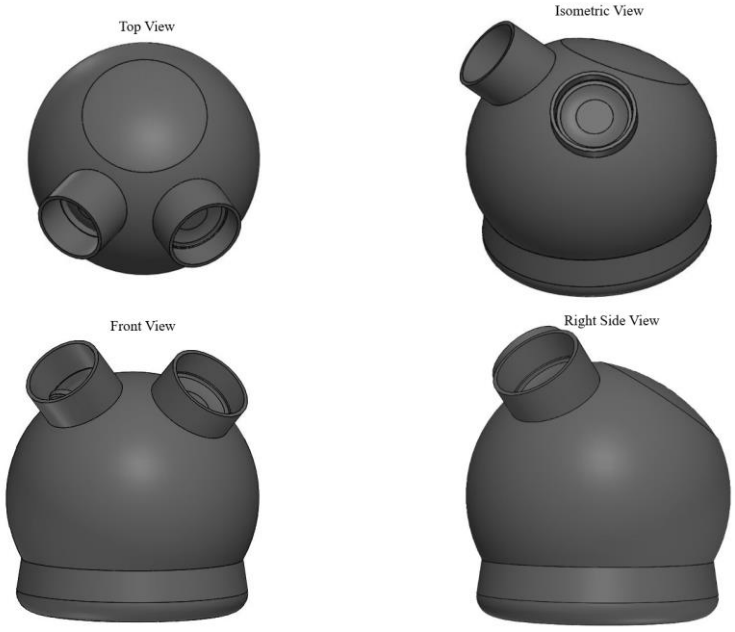

Figure 1. Original Left Ventricle Assembly Model

After meeting with Joe Giampietro, a Lead Clinical Specialist at SynCardia, and seeing the SynCardia 50 cc TAH, we realized that our original models did not accurately represent the device. In altering the design, the left ventricle housing, the end cap, and the diaphragm were reconceptualized. The end cap, which was originally thought to be flat on the bottom surface, was modified to be curved. In our initial design, the diaphragm had been modeled to have

curvature, when it is actually flat and only balloons when air pressure forces it. The design of the diaphragm was adjusted accordingly. Lastly, the left ventricle housing was modified. When comparing our prototype with SynCardia's 50 cc TAH, our prototype was larger, which should not have been the case. To rectify this, the spherical body of the left ventricle housing was adapted to be smaller. In an attempt to more closely match the shape of the SynCardia 50 cc TAH, the inlet and outlet channels were moved closer to the outside circumference of the left ventricle housing and adjusted to be almost vertical.

A final SOLIDWORKS model was created for each of the components and it was assembled (Figures 2).

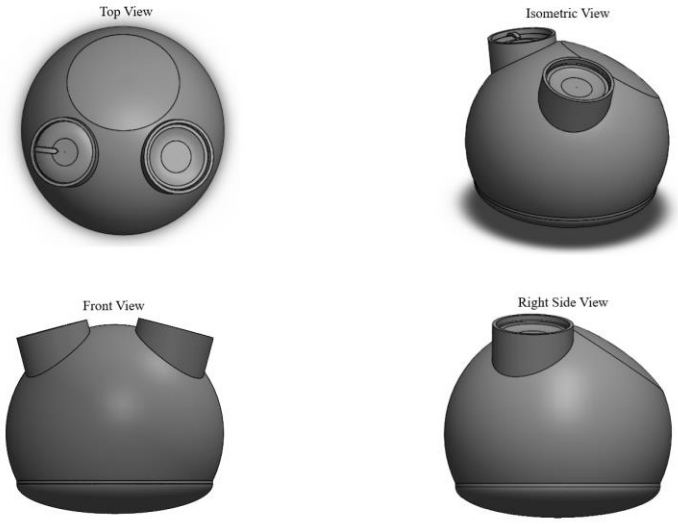

Figure 2. Final Left Ventricle Assembly Model

RISK ASSESSMENT

Through this process, we assessed the risks associated with our design through the creation of a C-FMEA and a D-FMEA. When determining the size of our TAH device, we

assessed the risks of insufficient blood flow, hemolysis, and improper size for our target age group of six to ten years old. Through alternative concepts and the D-FMEA we determined that a 35 cc TAH decreased the risks of these instances occurring.

Overall, the benefits outweighed the risks and identified future foci of the risk mitigation process. The team identified insufficient blood flow and hemolysis as high risks that could be properly mitigated with medications while the improper size risk was deemed not a significant risk. Through a risk mitigation summary, we clearly specified these risks and the appropriate mitigations, indicating that the benefits of the medications outweigh the risks of side effects.

At the conclusion of the risk mitigation summary we identified risks to focus on in the future. An important risk associated with the size change of the design is external driver compatibility with our smaller device. For example, the driver could supply too much power and increase the risk of hemolysis. We accept that the driver electronics may need to be altered with this new design. If this device enhancement were to be successful, testing with the driver would need to be conducted to validate that the 35 cc design is feasible with the current driver, else the driver would have to be altered as well. Another future risk is the long-term viability of the device. Currently, the SynCardia TAH 70 cc device is only approved for short-term use as a bridge to transplant. The mean average time of usage as of 2011 was 554 days [17]. The viability length of this proposed 35 cc TAH device should be assessed in the future.

With appropriate mitigations, we have concluded that the benefits of the device outweigh the risks. This device has the possibility to save a child's life. It can provide a child with heart failure or congenital heart disease a semi-normal life while waiting on a transplant. We believe the risk is greater for a child with bi-ventricular heart failure to wait for a transplant without a

supporting device than the risk of our 35 cc TAH. In addition, the child has the possibility to live outside of a hospital. All of these benefits outweigh the risks that the size may not be correct, the blood flow may not be sufficient, and hemolysis. Each of the high risks can be sufficiently mitigated to validate that the benefits of the 35 cc TAH device outweigh the risks.

VERIFICATION

In order to ensure that our design met our engineering requirements, verifications were completed using CFD and SOLIDWORKS. Verification tests were conducted on our last two engineering requirements of low hemolysis and appropriate size. The target passing ranges were mentioned previously, in the Design Requirements section.

In the verification of low hemolysis, two tubes were modeled to simulate the arterial outflow of the left ventricle. One tube had a diameter matching the outlet of the left ventricle housing for the 35 cc and the other matched the 50 cc outlet. We used blood velocities ranging between1.3 and 1.8 m/s to verify the low shear stress on red blood cells. The results of this CFD analysis indicated that the shear stress varied from 23.6 to 32.9 Pa for the 35 cc modeled capillary and 21.4 to 28.9 Pa for the 50 cc capillary. Therefore, the design passed one criteria of the low hemolysis requirement, that the shear stress does not exceed 150 Pa. For the other criteria of the 35 cc design not exceeding 2% of the maximum shear stress of the 50 cc design, the 35 cc design failed. However, since the 35 cc design only needed to pass one of the defined criteria, the 35 cc design has an acceptable amount of shear stress on red blood cells.

The volume of the 35 cc TAH device was verified using SOLIDWORKS. The results found that the device had an external volume of 260.3 mL which fits within the required passing range of 230.0 mL to 318.1 mL. The other two verification tests for ejection fraction and cardiac output were not conducted but the exact verification procedures for each engineering requirement is shown in Appendix II.

DELIVERABLES

As TAHs are expensive to manufacture and have many facets, including an external pump and a moving diaphragm, it was not feasible to create an operational prototype. Since the left ventricle is the main ventricle we used for verifications and it is very close in size to the right ventricle, we 3D printed the left ventricle assembly. To create this inoperable prototype, Mr. Trexler of the University of Akron's Mechanical Engineering Department was provided with our SOLIDWORKS files. All of the left ventricle components were printed separately using polyurethane filament. The diaphragm was specifically made out of flexible thermoplastic polyurethane so that it would closely mirror the SynCardia design. The 3D print (Figure 3A) was based on our first iteration SOLIDWORKS design. As stated previously, the design was altered after meeting with Joe Giampietro, a Lead Clinical Specialist at SynCardia, and comparing the prototype to the actual TAH (Figure 3B).

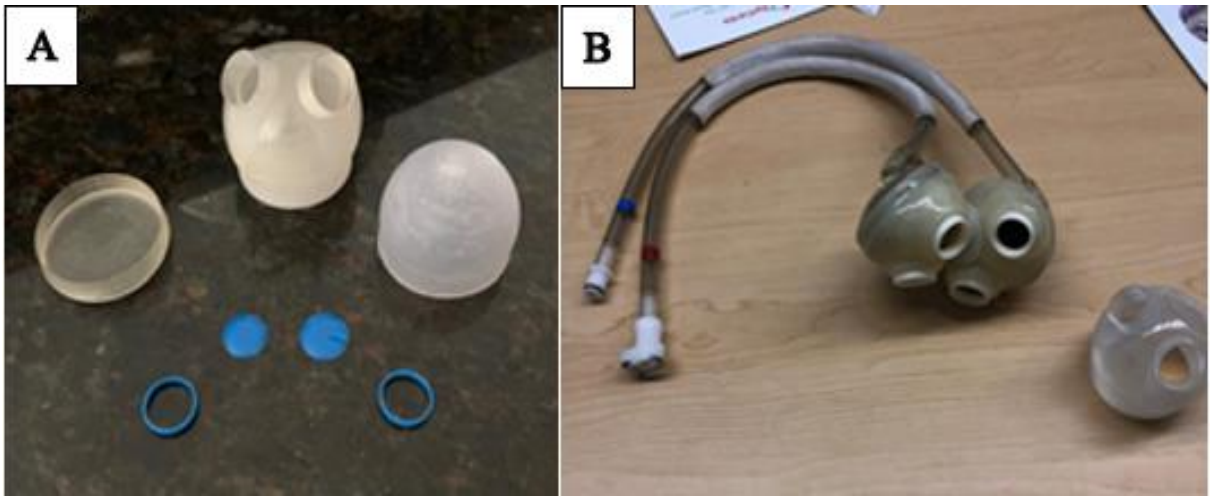

Figure 3: 3D prints of the design, where (A) was based on the original SOLIDWORKS design and (B) compared the print to the 50cc TAH

LESSONS LEARNED & NEXT STEPS

To redesign the device for pediatric patients, the team learned about TAHs, the FDA medical device design process, and the complications of developing a design modification to a product. Communication, or lack thereof, between different companies, departments, and even individuals can cause a huge delay in productivity and design quality. These same entities are likely to disagree on requirements because of differing areas of expertise. Conflict management is extremely important in teamwork and compromises must be made often.

Furthermore, the team learned that many revisions and iterations at each step is needed to meet the required goal at the end of each stage; sometimes this meant returning to a previous stage to revise the design or target value. To improve our design, we would compare our device shape and materials used to other TAHs that are in development. The device that we created is

relatively rigid and does not mimic the flexibility of cardiac tissue. It would not be capable of flexible movement or electrical conductivity like an actual human heart. To rectify this, we could test soft materials for conductivity, biocompatibility, and feasibility of manufacture. Mechanical testing would also be necessary to determine strength and durability of a material under the forces generated by the human body and human movement.

We would also research alternative connection fasteners to determine whether SynCardia's current solution of using Velcro is the best way to hold the ventricles together. In lieu of using a fastener, the design could be altered to combine the separate ventricles into one device. This integrated design would mitigate any concern of the devices becoming separated inside of a patient but would make the product more functionally complex to manufacture. Tensile testing could be used to determine the force required to disconnect the ventricles, and an appropriate solution would be chosen accordingly.

One shortcoming of our design, which would need to be rectified, is our lack of a fail-safe. While we hope for the device to work all of the time, that is not going to happen. In case of failure in the left ventricle, a mechanism must be designed into the system to counteract nonperformance. This aspect should be further researched and implemented into our design.

In the future, more work should be completed to analyze CFD of the 3D model and verify the engineering requirements of proper ejection fraction and appropriate cardiac output, ensuring that the design is tested to meet all targeted specifications. A more realistic, working prototype should be developed. For the TAH to be complete, a right ventricle would have to be modeled. Creating an operational prototype would allow for physical testing (i.e. pumping blood through the TAH) to take place.

After a realistic prototype has been developed, more testing would be required. The presence of metal on the device would warrant corrosion testing, as the body is an extremely adverse environment. ASTM International Standard F2129 provides guidelines and is commonly used for corrosion testing medical implants [17]. Ex vivo experimentation, using human tissue, and in vivo animal studies could help to identify any complications that might arise upon implantation or use of the TAH. While these methods would not exactly simulate human body interactions, they could indicate where our design would fail or need improvements.

CONCLUSION

At the conclusion of this project, a risk mitigation summary, detailed drawings and models, and a partial verification report of the 35 cc TAH were completed. This project sought to expand the market of SynCardia's TAHs by decreasing the size of the devices in order to fit in pediatric patients between the ages of six and ten. Going through the FDA medical device design process, our team defined our clinical problem, created requirements for the design that can be feasibly met, went through design iterations, verified some of our requirements, and assessed the risk throughout the process. In doing this, we created a feasible design that has thus far been verified through two tests and does not have significant risks.

In the assessment of the risks, the team determined that the risk of the 35 cc TAH being the incorrect size was not high and verified that the dimensions of the device would fit in a patient our age group. During this verification of size, we reassessed our design and had to make it smaller. Since one aspect of our hemolysis verification testing passed, we did not determine that the design needed to be altered with this risk. We were unable to complete the verification of

proper blood flow, so we did not alter our design in regard to this risk. Although we did not change our design for the risks of insufficient blood flow or hemolysis, we postulated that these high risks could be mitigated with medications, just as SynCardia did with their current devices [18].

All in all, we believe that our device design would help to expand the TAH market to include pediatric patients. While the design would need to be refined, it provides an initial concept which shows that a smaller device than those currently on the market is feasible. The creation of a TAH for pediatric patients would provide an alternative to ventricular assist devices and potentially save lives.

PROFESSIONAL AND ETHICAL RESPONSIBILITIES

When developing the design, we considered the impact of the 35 cc TAH on the global, economic, environmental, and social environments. We focused on how the 35 cc design compared to the two other concepts of 30 cc and 32.5 cc. Compared to the other concepts listed, our design was worse due to the fact that it was larger since this leads to more material that will be disposed of after the device is used and higher possibility of pain. In the broader context, compared to the SynCardia 70 cc and 50 cc, our design should rank higher.

From an ethical standpoint, the 35 cc device is smaller than the current SynCardia TAHs, to provide a more comfortable fit within a pediatric patient in our age range of six to ten years old. There may be patients within our target group that may have pain or discomfort due to a

large size. We accept this consideration and hope that doctors will take this into consideration when implanting.

In the social context, the device may be limiting to the daily routines of a patient. The patients will have to carry their external freedom driver with them wherever they go. Although for some, this is not as limiting given the condition they were before surgery. According to Joe Giampietro, a Lead Clinical Specialist at SynCardia, a former patient was able to hike a few miles in the woods with just his external driver in his backpack. This device could help children with severe heart failure to live improved lives while they wait for a transplant.

From an environmental standpoint, the proposed device will not be able to be reused or recycled, as the device is considered a biohazard once implanted. The 35 cc TAH device is fairly small in size and has a reduced environmental imprint than the 50 cc and 70 cc TAH devices at SynCardia. Although the 35 cc device is a temporary fix to heart failure as a bridge to transplant and will eventually end up in a landfill, it has the potential to save a lot of children's lives.

INDIVIDUAL CONTRIBUTIONS

Rachel Barendt was assigned as the systems engineer. She was responsible for completing background research, finding past and current patents for TAHs, and developing and editing the customer and engineering requirements. She also worked on developing the prototype sizing, designing the SOLIDWORKS component models, and testing of the final prototype using ANSYS to validate that it met the customer and engineering requirements and the proper documentation of the verification procedure.

Margaret Clark was assigned as the project manager and is responsible for administrative tasks in addition to engineering tasks. Her administrative tasks include keeping the group on schedule, contacting advisors, contacting SynCardia, and assigning tasks on a Gantt chart. Her engineering tasks include background research, compiling customer and engineering requirements, compiling information for the QFD and FMEA, writing plans and procedures for verification and prototype assemblies, and finishing the risk assessment. She also wrote a significant portion of this report while other members were conducting computational fluid dynamics.

Madison Marks was assigned as the quality engineer and has been responsible for many duties including, background research, FDA documentation, compiling customer and engineering requirements, gathering information for the QFD and FMEA, and designing the SOLIDWORKS models. She also completed verification of Engineering Requirement #4 using SOLIDWORKS.

Gabby Zuschak was assigned the function of marketing. She has conducted many tasks including researching competitors and the problem, helped brainstorm customer and engineering requirements, engineering requirements target values based upon research done, compiled risks, concept FMEA risk mitigation/control, reaching out to SynCardia to define the target value for engineering requirement number 3, in the QFD matrix researched design concepts and alternative concepts, major components list, systems diagram with specifications, CFD research and contacting ANSYS, recording results and preliminary documentation of report, verification report, and 3D printing of left ventricle.

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APPENDICES

Appendix I. Customer and Engineering Requirements

Table I-1: User Requirements/Customer Needs

		Description	Validation
1.	Internal Enhancement	The product will enhance the internal mechanics of the in situ ventricular system of the SynCardia Total Artificial Heart so that it can effectively function as a heart in a six to ten year old pediatric patient.	We will complete an analysis of the product to verify that the enhancement did not compromise cardiac function and addressed the clinical need.
2.	Blood Flow	The product will provide adequate blood flow to the six to ten year old pediatric patient.	We will complete computational fluid dynamics analysis on the product and compare flow rates to normal ranges of blood flow for the appropriate ages.
3.	Hemolysis	The product will not put the pediatric patient at severe risk for hemolysis nor will it pose a greater risk for hemolysis than the 50 cc SynCardia Total Artificial Heart does for older patients.	We will complete computational fluid dynamics analysis on the product to determine the shear rates of blood.
4.	Dimensions	The size of the product will be small enough to be implanted in the average six to ten year old pediatric patient.	We will measure the dimensions of the product model to ensure that it fits within the parameters of the average six to ten year old pericardial cavity.

Table I-2: Engineering Requirements

		Description	Validation
1.	Internal Enhancement	The in situ ventricular system of the current SynCardia Total Artificial Heart (TAH) shall have a minimum left ventricular ejection fraction of 0.61 [10-12].	We will perform computational fluid dynamics on the SynCardia 35 cc to ensure that the TAH's ejection fraction is consistently above 0.61.
2.	Blood Flow	The SynCardia TAH heart design shall provide an adjustable cardiac output in the range of 2.6 - 5.4 L/min [13].	We will perform computational fluid dynamics on the SynCardia 35 cc to ensure that the TAH's average cardiac output is consistently in the range of 2.6-5.4 L/min.
3.	Hemolysis	The SynCardia TAH heart design shall not generate shear forces on the red blood cells that exceed 2% of the maximum shear stress of the SynCardia 50 cc TAH or exceed the maximum shear stress of 150 Pa [14].	1. We will perform computational fluid dynamics on the SynCardia 35 cc and SynCardia 50 cc to ensure that the shear stress on whole blood for the 35 cc is within 2% of the 50 cc's shear stress on whole blood. 2.We will perform computational fluid dynamics on the SynCardia 35 cc to ensure that the shear stress on whole blood caused by the TAH is always $\leq$ 150 Pa.
4.	Dimensions	The SynCardia TAH heart design external volume shall be within the range of 230.0 mL and 318.1 mL [15].	We will measure the SynCardia 35 cc model in SOLIDWORKS to make sure that the volume of the ventricular system is within the range of 230.0 mL and 318.1 mL.

Appendix II. Verification Procedure

Verification Procedure:

1. **Verification of minimum left ventricular ejection fraction of 0.61.**

   - ❑ Equipment: SOLIDWORKS 3D model assembly of 35 cc design, ANSYS software
   - ❑ Set-up/Configuration Instructions:1) Create the 35 cc TAH design using dimensions found in literature and appropriate approximations. This will be done using SOLIDWORKS software.
   - ❑ Step-by-Step Procedures:
     - ❑ Open up ANSYS workbench
     - ❑ Create a Fluid Flow (Fluent) Analysis System
     - ❑ Create Geometry (created using SOLIDWORKS and saved as a STEP file then import into ANSYS)
     - ❑ Set up boundary conditions for each part of the geometry (for example we would select for all parts involved with the pathway of the fluid flow; inner housing, inlets, and outlets and define the velocities in each. Run flow at a rate of >9L/min.)
     - ❑ Retrieve a solution- insert results want to output. Then run calculations for ___ amount cardiac cycles or BPM. Solve. Run multiple tests at different velocities repeating this procedure. We will then use the ejection fraction formula to calculate ejection fraction. Performing this procedure multiple times will assure us that our target ejection fraction is obtained.

     Acceptance Criteria for Pass/Fail Determination:

     - ❑ Pass:35 cc model has an ejection fraction of 0.61
     - ❑ Fail: 35 cc model has an ejection fraction of less than 0.61.

2. **Verification of adjustable cardiac output in the range of 2.6-5.4 L/min.**

   - ❑ Equipment: SOLIDWORKS 3D model assembly of 35 cc design, ANSYS software
   - ❑ Set-up/Configuration Instructions: 1) Create the 35 cc TAH design using dimensions found in literature and appropriate approximations. This will be done using SOLIDWORKS software. Find the rate at which blood flows

- ❑ Step-by-Step Procedures:
  - ❑ Open up ANSYS workbench
  - ❑ Create a Fluid Flow (Fluent) Analysis System
  - ❑ Create Geometry (created using SOLIDWORKS and saved as a STEP file then import into ANSYS)
  - ❑ Set up boundary conditions for each part of the geometry (for example we would select for all parts involved with the pathway of the fluid flow; inner housing, inlets, and outlets and define the velocities in each.)
  - ❑ Retrieve a solution- insert results want to output. Then run calculations for ___ cardiac cycles or BPM. Solve.
  - ❑ Run multiple tests at different velocities repeating this procedure to compare different cardiac outputs.

Acceptance Criteria for Pass/Fail Determination:

- ❑ Pass: 35 cc model has cardiac output range of 2.6-5.4 L/min
- ❑ Fail: if outside 2.6-5.4 L/min

3. Verification of the appropriate shear stress on red blood cells:

- ✓ Equipment: SOLIDWORKS files of tubes for shear stress for 35 and 50cc, ANSYS software
- ✓ Set-up/Configuration Instructions: Select the boundary conditions of the inlet and outlet surfaces on each of the tubes. Input the characteristics of the blood, blood velocity, and temperature. Solve for the shear stresses on the vessel wall.

Step-by-Step Procedures:

- ✓ Create a Fluid Flow (Fluent) Analysis System in ANSYS
- ✓ Import SOLIDWORKS part file of tubes for shear stress 50 cc TAH (saved as a Parasolid file) under Geometry
- ✓ Open up Design Modeler to generate a mesh of the tube
- ✓ Under the Part, Details of Body, select Fluid
- ✓ Generate a mesh of the tube using an element size of .0005 m.

- ✓ Create Named Selections for the blood_inlet, blood_outlet, and wall
- ✓ Close Design Modeler and update the Mesh in ANSYS Workbench
- ✓ Open ANSYS Fluent
- ✓ Turn on Energy Equation under Models and change Viscous-Laminar to a standard k-epsilon equation
- ✓ Add blood as a fluid material
    - ✓ Density = 1060 kg/m^3
    - ✓ Specific heat = 3513 j/kg-k
    - ✓ Thermal conductivity = 0.44 w/m-k
    - ✓ Viscosity = 0.003 kg/m-s
- ✓ Change Cell Zone Conditions to blood
- ✓ Boundary Conditions
    - ✓ Blood_inlet
        - ✓ Type: velocity-inlet, input velocity of blood (1.3 m/s, 1.5m/s, and 1.8m/s), and change temperature to 310 K
    - ✓ Interior Part
        - ✓ Type: solid
    - ✓ Blood_outlet
        - ✓ Type: pressure-outlet
    - ✓ Wall
        - ✓ Type: wall
- ✓ Initialize the Solution
- ✓ Run Calculation with 150 iterations (repeat for each value of blood velocity)
- ✓ Create a contour for wall fluxes to find shear stress on the wall
- ✓ Run calculations and solve to get a value in Pa

- ✓ Repeat steps i-xvi for 35 cc design
- ✓ Confirm the solutions pass the criteria

Acceptance Criteria for Pass/Fail Determination:

- ✓ *Pass:* **1)** 35 cc model has shear forces at or below 2% of the stress in the 50 cc model **2)** 35 cc model has shear forces at or below 150 Pa
- ✓ *Fail:* **1)** 35 cc model exceeds 2% of the shear stress in the 50 cc model **2)** 35 cc model exceeds the maximum shear force of 150 Pa

(note: the device failed 1) below %2 of the 50 cc model and passed 2) the model does not exceed 150 Pa)

4. Verification of the maximum external design:

- ✓ Equipment: SOLIDWORKS 3D model of 35 cc TAH design
- ✓ Set-up/Configuration Instructions: 1) Create the 35 cc TAH design using dimensions found in literature and appropriate approximations. This will be done using SOLIDWORKS software. The two ventricles will be created separately. 2) The two ventricles will be assembled into one design—representing the *in situ* ventricular system
- ✓ Step-by-Step Procedures:
  - ✓ Open the assembly design of the 35 cc ventricular system in SolidWorks
  - ✓ Select the top faces of the outer "quick connects" and the diaphragm of the left ventricle
  - ✓ Press the Intersect button to create an intersecting solid in the void space between the diaphragm and the walls of the ventricle
  - ✓ Go to Tools
  - ✓ Click Mass Properties
  - ✓ Select the intersect solid
  - ✓ Observe and record the volume of the internal space
  - ✓ Deselect the intersect solid and select the left ventricle body
  - ✓ Observe and record the volume of the external material
  - ✓ Sum the two values to get the external volume

- ✓ Double the summation to account for the right ventricle, which is approximately the same size

✓ <u>Acceptance Criteria for Pass/Fail Determination:</u>

- ✓ *Pass:* The external volume is within 230.0 mL and 318.1 mL.
- ❑ *Fail:* The external volume is below 230.0 mL or above 318.1 mL