EML 4905 Senior Design Project

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PREPARED IN PARTIAL FULFILLMENT OF THE
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BACHELOR OF SCIENCE
IN
MECHANICAL ENGINEERING

Experimental Verification of Optimized Cooling of Human Hearts for Transplant Surgery

100% Report

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Ethics Statement and Signatures

The work submitted in this B.S. thesis is solely prepared by a team consisting of Patricia Matthews, Rebekah Santana, Rafael Sanz, and Marcelo Torrentes and it is original. Excerpts from others' work have been clearly identified, their work acknowledged within the text and listed in the list of references. All of the engineering drawings, computer programs, formulations, design work, prototype development and testing reported in this document are also original and prepared by the same team of students.

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Abstract

This paper presents the progression and process of developing and testing an artificial heart, with thermal and geometrical properties as close as possible to those of a real human heart, for the purpose of experimentally verifying a computer model for heart cooling. Upon the failure of the artificial heart model, the team obtained approval to conduct testing on a porcine heart. Information pertaining to research, funding, design, fabrication, and testing necessary for the execution of this project are included, along with the design of the cooling system and testing apparatus. Several other relevant observations and explanations concerning necessary simplifications in the heart model are also included. In the end, the computational model was not able to be verified, but valuable insight into the design of a system for such verification was gained, as well as knowledge pertaining to the human circulatory system.

Introduction

Problem Statement

With current technology, human hearts fit for transplant are only viable for approximately four hours. However, an improved cooling method could increase the lifespan of the heart, which would give medical personnel a better opportunity to transport the heart in time to save a life. Research shows that there is an optimal cooling rate for each type of tissue that maximizes cell survival, but external cooling alone is not sufficient to achieve it. With external cooling only, there is an uneven temperature gradient caused by the outer tissue being cooled more quickly than the inner tissue. This temperature gradient causes thermal stresses and is linked to an increase rate of tissue decay.

Before an internal cooling system can be designed successfully, it is necessary to first run simulations of the heart in computer models. The results yielded by such simulations can then be verified with physical experiments using artificial or animal hearts. Computer models for human hearts have been developed, and simulations for cooling human hearts in this way are currently under development by Ph. D candidate Mr. Abas Abdoli. The purpose of this senior project is to design a physical experimental model in order to help verify his computer simulations, compare the effects of external cooling alone as opposed to internal and external cooling, and better understand the behavior of a heart undergoing cooling.

Project Objectives

1. Construct an approximate geometric model of the human heart from a material which emulates its thermal properties accurately.
    - The use of a manufactured model is ideal because the material properties would be homogenous throughout the model, which would be consistent with the computer model being used as reference.
    - If a heart cannot be successfully manufactured, a pig heart will be used. Pig hearts are very similar to human hearts but are not as easy to predict computationally.
2. Develop a testing apparatus suitable for housing the model heart. This apparatus will include the pump, containers, hoses, and attachments of the cooling system, and thermocouples and flow meter necessary to track the temperature and flow rate of the cooling fluid through the model and temperature of the model itself at various points.
3. Test the artificial (or animal) heart with external cooling alone and with internal and external cooling together, and compare results first to each other, and then to data gathered from similar studies done on computer models.

Motivation

The process of organ preservation has long been a key issue for doctors and surgeons attempting to provide suitable organs to patients in need. Current methods of preservation have short shelf lives and run the risk of tissue degradation due to oxygen deprivation. The falling number of viable donors suggests that more sustainable techniques are needed to offset demand. By producing an apparatus that can efficiently and uniformly cool the human heart, it may be possible to increase the amount of time that the heart remains useable and the distance that it can be transported to a recipient, ultimately increasing the overall availability of organs fit for transplantation. The purpose of this preliminary project is to contribute valuable information and observations to the research necessary for such an undertaking.

Summary of Global Considerations

According to the U.S. Department of Health & Human Services there are approximately 3,000 people on the waiting list for a heart transplant at any given time in the United States alone ("What to expect,"). The scope of this project however, goes far beyond our borders, as analogous organizations from other countries show. The Australian government's Heart Foundation, for example, reports that its waiting list contains over a hundred patients who often wait up to two years for a transplant organ ("Heart transplants,"). In the United Kingdom, the National Health Services Blood and Transplant Organization states that three patients die every day waiting for a suitable heart ("Organ tissue donation,"). The most alarming statistic discovered while researching this challenge comes from an article published on InsideScience.org which said that "about 70 percent of donated hearts are not accepted for transplantation," (Gwynne, 2012, para. 15) due in part to deterioration during transport. The global impact of our project is both simple and important. Verifying that optimized preservation

by internal as well as external cooling would improve the viability of a donated heart would open the doors to new technology that could save lives around the world.

We have strived throughout the course of our research and testing to carefully document our approach so that this work can be easily repeated and continued. The end of the paper includes a section of recommendations to further facilitate this.

Literature Survey

Background

The first human-to-human cardiac transplantation was performed in South Africa on December 3, 1967 by surgeon Christian Barnard using the experimental work developed by Norman E. Shumway. This event marked the beginning of heart transplantations worldwide and necessitated the development of several methods and techniques for preserving organs outside of the body. These techniques fall into two major categories: keeping the heart in human physiological state and cooling the heart until transplant (Brink & Hassoulas, 2009).

Relevant Research

The most widely used method for transporting organs is a standard ice cooler. Cold static preservation is still the most prominently used method for organ transportation because it is simple and easily reproduced. The organ is submerged in a sterile liquid solution and surrounded by ice packs at approximately 4 degrees Celsius. This method, however, has drawbacks; studies have shown that external cooling of organs is a vastly ineffective method of preservation due to the lack of uniform cooling that occurs when using ice packs. Additionally, ice packs alone may be insufficient in cooling an organ down to a target temperature rapidly enough (Dennis, Eberhart, Dulikravich & Radons, 2003).

More technological developments have been made in recent years. In 2010, a research team at the University of California Berkley's Ronald Reagan Medical Center developed a device capable of preserving a human heart in near perfect physiological state. The medical device developed by TransMedics restores the donor's heart back into a beating state by pumping oxygenated blood through the system at stable temperatures all while monitoring the heart's functionality (Albin, 2010). As recently as March 2013, the first ever "warmed liver"

transplant was performed in London, England by a surgical team at King's College Hospital. The new innovation is the result of 20 years of research and work done by engineers at Oxford University. The device used to preserve the liver works by pumping blood through the capillaries of the liver, causing the organ to regain and retain color and normal functionality (Walsh, 2013).

While promising, these technologies are new and still under development. The alternative of internally and externally cooling the heart presents a few unique advantages. First, in order to preserve the heart in a virtually physiological state, blood of the same type as the recipient must be readily available and attached to the system. By using a generic, bio-friendly liquid as a coolant, such as a saline solution, the time lost in finding and retrieving the appropriate blood could be saved. Second, the cooling system is less complex than the physiological system which translates to fewer opportunities for complications.

However, there are some challenges in cooling the heart this way. The process of cryogenics is delicate, as uneven cooling rates in donor organs can cause strong residual thermal stresses which may severely damage organ tissue, and low cooling rates may lead to chemical decomposition of the organ. Research shows that for structures of impure chemical composition, such as muscle tissue, the physical phase changing process occurs over a wide range of temperatures as opposed to any single temperature (Dennis & Dulikravich, 2000). Studies have been conducted to determine the optimal local freezing rate of an organ; that is, the quickest freezing rate that can be obtained while keeping the amount of local thermal stresses endured by the specimen below the limit where fracture occurs.

Sophisticated computer simulation programs have been developed to determine the variation of unsteady three-dimensional temperature distributions on the walls of different organs and these results have been verified experimentally. For example, tests were done using various

materials with similar size and shape of a kidney. The tests showed that damages due to thermoelastic stresses could be controlled by manipulating and minimizing the temperature distribution on the surfaces of the freezing container used in preserving the organ (Dennis, Dulikravich & Rabin, 2000).

Synthetic Material Selection for Artificial Heart

To ensure accuracy, the physical model of the heart was made from a polymer that best emulates the thermal properties of human heart tissue. A few materials are available that emulate different properties of heart tissue. For example, researchers at Imperial College London have synthesized a material called poly(glycerol sebacate) (PGS) which, at a range of temperatures, yields mechanical properties similar to that of myocardium, the muscle substance of the heart. Their findings are summarized and compared to data for human heart tissue, which will heretofore be referred to by its proper medical name, myocardium, below:

Synthetic Cardiovascular Materials		
Properties	**PGS**	**Myocardium**
Density	1.1277 to 1.1394 g/cm3	approx. 1.055 g/cm3
Young's Modulus	0.04 to 1.2 MPa	10 to 500 kPa
Tensile Strength	0.2 to 0.5 MPa	--

Table 1: Properties of Synthetic Polymers

Since the Young's modulus for PGS is similar to that of a real heart throughout diastole, PGS is a promising material substitute for myocardium in terms of mechanical properties (Chen, Bismarck, Hansen, Junaid, Tran, Harding, Ali & Boccaccini, 2008) (Vinnakota & Bassingthwaighte, 2003). It was hoped that PGS would be sufficiently close in thermal properties to be a suitable material for our purposes so that thermal and mechanical properties could be tested, but PGS's one strength is in its mechanical characteristics.

Research shows that a protein found in insects known as resilin is capable of having similar elasticity to human muscle tissue (Cebe, Hu, Kaplan, and Qin). This was another appealing alternative, but the thermal properties were again insufficient.

Another considered material was PVC-P. It is an easily manufactured material with simple handling procedures and a long life cycle. This material emulates the thermal and optical

properties of fat very well, and is extremely practical (Rodrigo et al., 2013). Unfortunately, the heart is primarily muscle.

Finally, a material was found that sufficiently matches the thermal properties of myocardium when it is prepared correctly. This material is agar gel. Agar is a powder that can be dissolved in water to form a gel with similar thermal properties to muscle tissue. Agar powder is cheap and easily attained, but has a relatively short life cycle. Salt can be added to the gel, which would alter the thermal properties to make them even more similar to those of muscle tissue (Rodrigo et al., 2013). Agar powder is the material of choice for the heart model due to the substance's affordability, availability, ability to be molded, and flexibility in mimicking the thermal properties of muscle tissue. For comparison, data for agar is shown alongside data for myocardium below (Table 2 and 3):

Tissue	Thermal Conductivity (W/mK)	Specific Heat (J/gK)
Fat	0.203	2.678
Muscle	0.529	3.684

Table 2: Thermal Properties of Agar

Phantom	Thermal Conductivity (W/mK)	Specific Heat (J/gK)
Pure	0.48 ± 0.02	4.63 ± 0.05
100 g/l NaCl	0.49± 0.02	3.96 ± 0.04
200 g/l NaCl	0.52 ± 0.03	4.40 ± 0.04

Table 3: Thermal Properties of Heart Tissues

Design Aspects of Artificial Heart

Considerations and Necessary Assumptions for Manufactured Model

Designing and manufacturing a replica of the human heart presented unique and difficult challenges in terms of geometry, thermal properties, budget, and time. The heart is a completely solid, enclosed body that is watertight, not constant in size or shape, almost completely asymmetrical, and very complex. It contains three types of muscle tissue: pericardium, myocardium, and endocardium. Each of these tissues has different thermal and mechanical properties. The heart itself is located in a pericardial sack which contains two layers of pericardium and each layer has a different texture. While the types of tissue and general characteristics can be found in any biology, anatomy, or physiology book pertaining to the human body, the exact thermal properties are not readily available and usually based on approximations using other animal tissues such as porcine and canine hearts. Thus, certain simplifying assumptions were made for the manufactured model and are as follows:

1. Myocardium is the dominant muscle tissue in the heart and is representative of the heart as a whole thermally.
2. The inner cavities of the heart can be simplified and still yield valuable information in terms of cooling and heating.
3. The valves between the atria and ventricles can be modeled as orifices.
4. A representative size of the heart can be used as well as thicknesses of the heart walls since heart sizes vary from person to person.
5. Fat around the heart is negligible since the heart is primarily lean.
6. Agar gel, which while not identical in thermal properties, is sufficiently close to simulate myocardium.

Verification of Assumptions

These assumptions and the results obtained were to be tested against a computer model developed by Mr. Abas Abdoli, a Ph.D. student under the guidance of Professor George Dulikravich in the mechanical engineering department of Florida International University and discussed. The computer model made the same assumption about the nature of the heart tissue being virtually identical to myocardium. One major difference was that the computer model had near perfect geometry as opposed to the manufactured heart, which required simplified geometry in order to fit within budget. Even with geometrical difference, trends could have still been confirmed between the computational and physical method. Unfortunately, at this stage in the project, the manufactured heart failed and was not able to be tested. All information related to failure is included in the section "Manufacturing of Artificial Heart."

Considerations Using Agar Gel

Other challenges in manufacturing arose with the use of agar gel. While it is the best tissue phantom available, it only has a life of one week before it begins decomposition. Agar is an organic material and decays with time until it is unusable. Therefore, the manufacturing and testing of this cycle was different from most senior design projects. A great deal of testing was done before the artificial heart was made, as the heart was only useful for a week until another had to be made. Each heart costs approximately ninety dollars. The testing apparatus was also designed and tested first, and the material was tested to confirm correct preparation and properties. Once those tasks were completed, everything was pre-prepared so that the heart could be inserted, and tested immediately in order to minimize the degradation of the material. Due to material failure, this testing step was never reached. Also, because of budgeting, it was not always possible to have a heart available since the manufacturing of each heart was expensive.

Lastly, the properties of the agar gel were never confirmed since the artificial heart failed and the testing of thermal conductivity was quoted at $250.00 per sample. These tests were only valuable if an artificial heart was successfully made. If the thermal properties had varied significantly from those of the human heart, the computer model values would have been changed accordingly and meaningful comparisons still made.

Geometric Design of Artificial Heart

Original Designs

It was originally planned to completely design the artificial heart in one solid piece or assembly, and three prototypes were developed. The first two were extremely simple in order to determine what simplifications were feasible and which were unacceptable. Once those options were considered, "Design 3" was developed which was far more complicated than the first two models but still very simple. At this point in the design process the material had not been chosen and this design was the best since it was the most accurate and still producible.

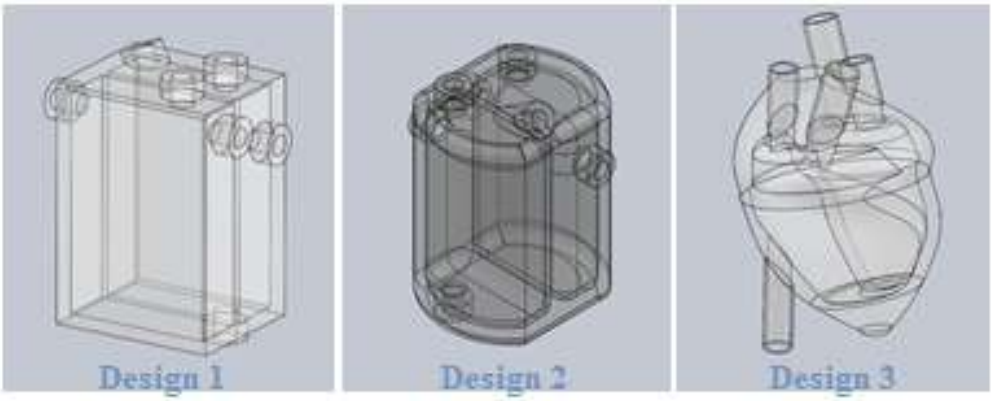


Figure 1: Original Artificial Heart Designs

Issues with Original Designs

All three models, however, overly simplified the heart into two major chambers instead of four without any consideration for the valve openings between chambers. This was done because the geometry of the heart chambers is very difficult to measure and duplicate. Up to this point in the design process, it was the best that could be generated. Later, an MRI scan converted to a stereolithography file was donated to the team from which measurements could be taken and better approximations made.

MRI Model

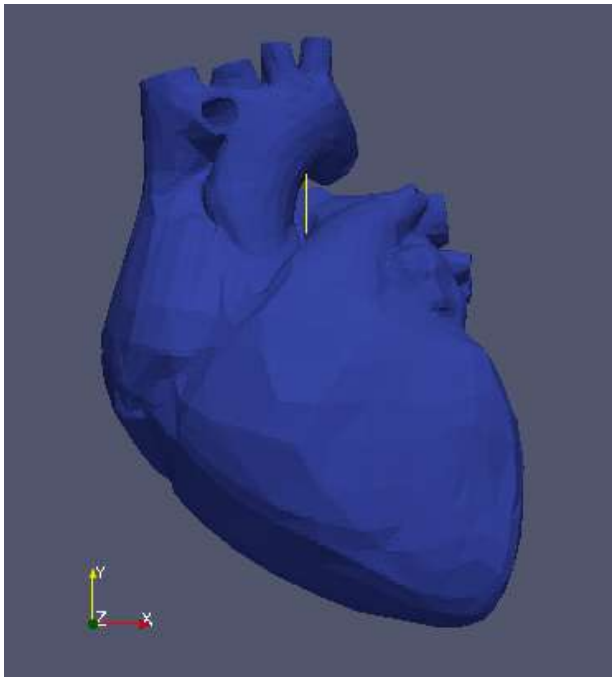


Figure 2: STL file of Human Heart

The stereolithography file presented the closest match to an actual heart possible. While it was still an approximation, as can be seen from Figure 2, the approximation is nearly perfect. Constructing a model identical to this MRI would have been ideal and was pursued aggressively. Unfortunately, manufacturing an identical replica heart proved impossible in terms of team finances and manufacturing capabilities at Florida International University.

Issues with the MRI Model

At first, it was expected that a 3-D print could be made and then a mold made from the print which agar gel could be poured into and then removed from. As this method was pursued, issues arose that proved it would not be possible. On the following page is a summary of what needed to be done and the issues associated each certain step.

The design process for the model was originally as follows:

1. Fix the errors in the donated MRI .stl file (resize to proper scale, remove misplaced facets, etc.).
2. Make a sample of agar material to better choose an appropriate molding process.
3. Find a suitable parting line for molding in STL file.
4. 3-D print the resulting sections individually.
5. Create mold sections from 3-D prints.
6. Assemble the mold.
7. Create multiple physical models to be tested.

Unfortunately, the manufacturing of a usable mold based on the MRI was too complex to be feasible. The issue arose at "Step 3." There is no single mold release line that would facilitate the accurate shaping of the inside features. In order to produce the inside features of the heart it would have had to be molded in multiple pieces and then joined into the finished model, which would have caused discontinuities throughout and likely leakage. In addition, the parting lines could not be inserted into the CAD model as it is not a true solid surface but rather a collection of facets. The inside cavity cannot be printed as a solid piece around which the synthetic material can be molded for the same reason. Also, there is no guarantee that conversion of the file to a solid shape that can be manipulated beyond resizing and cutting is even possible, let alone within budget. Software capable of doing so generally sells for at least one thousand dollars.

Additionally, a lost wax method was considered. By this method, the MRI would be 3D printed without any modifications, and then cut into sections that would be surrounded by wax. Once the wax pieces were reassembled into a single mass from which the shape of the heart was missing, the appropriate molding material could be poured and allowed to solidify inside of it.

The temperature of the construction would then be raised and the wax could be removed easily from the outside and drained from the inside, leaving behind all of the delicate internal features that proved so troublesome to achieve in previous methods considered. This seemed the best approach until a sample of the chosen molding material was produced, and the melting temperature proved too low to withstand this. The agar gel melts at the boiling point of water: 100 Celsius.

A hybrid method was considered in which a 3-D print of the entire heart would be made as a solid piece and used to create a cast. The synthetic material would then be poured into the cast, with a series of tubing and balloons inserted to create the valves and chambers. This method, however, is undesirable because there would be a considerable loss of detail; the internal features would be so crude that it would not be worth the cost involved to keep the outside shape so realistic.

More options were explored and extensive research was done online to determine whether it was possible to print with agar or a substitute and retain both the model's full geometry and the material's thermal properties. If agar gel is to be printed with the appropriate properties it must undergo a very precise preparation that lasts approximately six hours and includes vacuum chambers and magnetic stirrers (outlined in section: Prototype Development). Unsurprisingly, no 3-D printer could be found that works with agar gel. So far as substitutes are concerned, no 3-D printable material with thermal properties close to myocardium could be found. 3-D systems and Stratsys (two leading companies in 3-D printing) were called, and neither was aware of a suitable printing material with which we could make the heart in one process. Additionally, no information on the internet of successful printing of gel could be found.

The Medical Replica Heart

Before arriving at the final design, using a replica heart used for teaching anatomy was considered such as the one shown below:

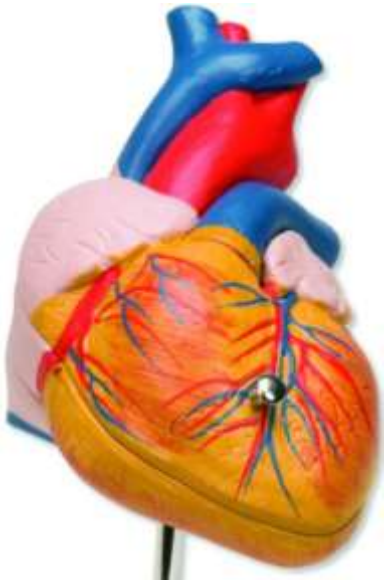


Figure 3: Model Heart (3B Scientific G08 2 Part Classic Heart Model)

Molding a model such as this one which pulls apart would be beneficial and inexpensive, but it would have to be molded in sections and then assembled which would likely result in leakage. Further objections were similar to those which arose with the lost wax method.

Final Artificial Heart Design – A Combination of the Heart Replica and 3D Printing

Each manufacturing method was discussed with Professor Dulikravich and Mr. Richard Zicarelli, Director of the Engineering Manufacturing Center, and no option alone was deemed suitable. Finally, a solution was found. The heart replica used for teaching was used to create the outer mold. CAD files were made in SolidWorks of the internal features of both the MRI and heart replica. The CAD file of the replica heart was naturally the better fit and more practical in terms of printing. The following two pages contain Figures 4-7 and explanations as to why the

MRI was unusable. Once the internal features were decided upon and placed in the mold, the agar gel was poured into the mold around the 3-D print and allowed to solidify. Once hardened and of a rubberlike consistency, the heart was to be squeezed, causing the internal 3-D print to fall apart, and then once completely demolished, the 3-D print was to be removed through the arterial openings in the heart. It was assumed the agar gel could withstand the pressure, but it did not. A more detailed explanation of the process is given in "Manufacturing of Artificial Heart." What follows are the approximations of the MRI scans and the challenges they posed. The first two are taken directly from the MRI and the rest are the Solidworks loft that resulted from these cross-sections.

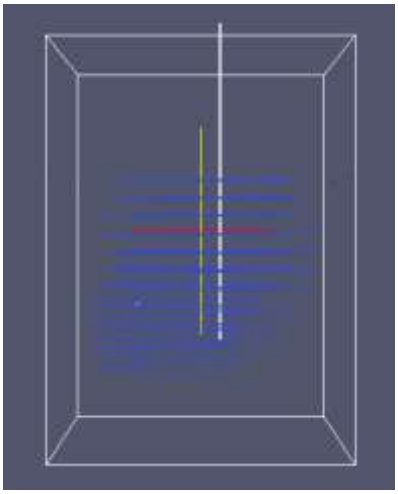


Figure 4: MRI Approximation – Construction Planes – Front View

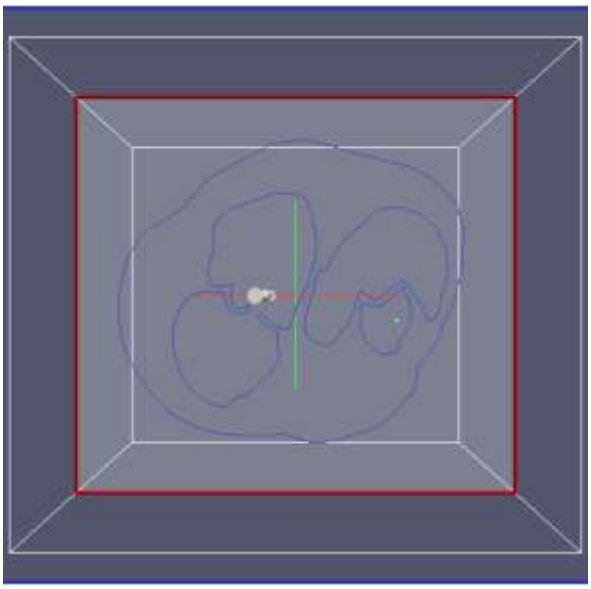


Figure 5: MRI Approximation – Cross Section - Top View

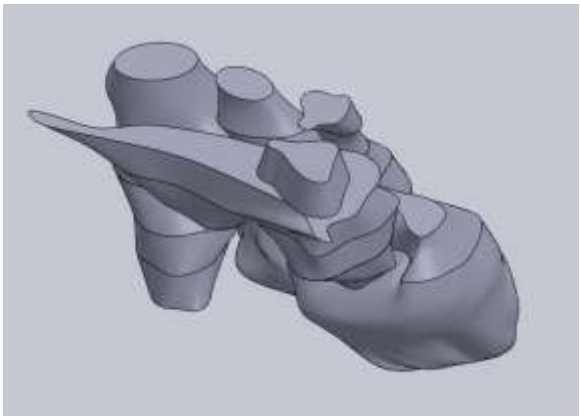


Figure 6: MRI Approximation – Isometric View

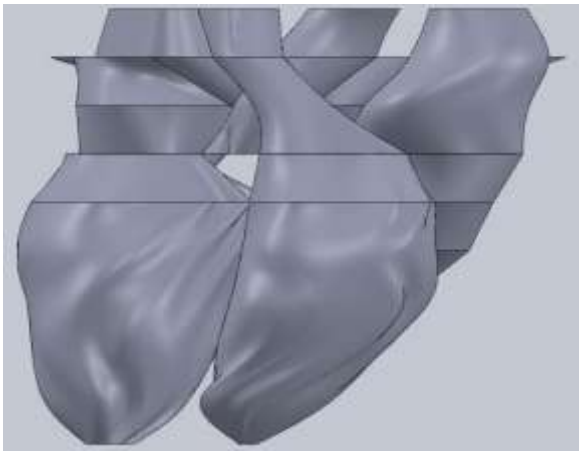


Figure 7: MRI Approximation – Front View

It is apparent from the images above that the MRI was too intricate to model correctly. While the realism of the MRI is what made it appealing, the geometry was difficult to 3D print since different bodies started at different heights. Each body would have had to been printed separately and hollow so that they could attach then be crushed. However, since they needed to be very thin, they would have been extremely fragile and difficult to assemble. Furthermore, 3D printing is expensive and it could not be certain that the MRI geometry was going to fit appropriately within the outer mold of the replica heart.

Artificial Heart Material Prototyping

Sample Material Fabrication

In order to determine if agar (our preferred material) was a viable molding material, we created several samples of the gel solution using various procedures and methods. The samples were created using three methods: boiling, as per the instructions on the product label, and two methods through the process of an oven curing, which was detailed in a paper by Dr. Basto, with whom we first discussed the use of agar.

Procedure: Boiling Method

Using the label directions, our methodology was as follows:

1) Measure and obtain 5 grams of agar powder into a small pot using a digital scale.
2) Pour 96 mL of distilled water into the same pot for a total density of 52 g/L.
3) Turn on the stove to ‘medium’ and place the pot with the mixture on the stove top, heating until boiling occurs.
4) Once boiling occurs, stir the agar solution with a metallic spoon consistently for approximately one minute (measured using a stopwatch).
5) Remove the pot containing the agar solution from the heated stove top and pour mixture immediately into plastic mold container and cover.
6) Add water after the gel has set to protect the gel from drying up and losing its elasticity. This step should be completed within an hour after removing from heat.

Results - Boiling Method

Using the method listed above, the process yielded a moderately flexible solid which took the features of the container it cooled in well. It should be noted that in using this method, a lot of air bubbles were trapped within the gel, leaving the final product with several small voids. This was undesirable but was mostly resolved by constant, slow stirring.

Procedure: Approximate Dr. Basto Method

The team then proceeded to create a sample with a modified version of the instructions from Dr. Basto's paper, due to the lack of equipment and materials available to the team's disposal. Our revised method was as follows:

1) Measure and obtain 5 grams of agar powder into a small glass bowl using a digital scale.
2) Pour 96 mL of distilled water into the same small glass bowl.
3) Stir mixture for ten minutes with a spoon until the solution is uniform in texture and color.
4) Put glass bowl into a pre-heated oven at 170°F for four hours. Place bowl in the center of the oven rack to ensure even distribution of heat.
5) After four hours have passed, pour agar solution into plastic immediately into a mold and cover.

Results – Approximate Dr. Basto Method

There are several things that should be noted about this process. The first is that during baking, it appeared that the mixture had begun to separate, and the water rose to the top of the solution. The second is that the agar solution never set into a solid, even after the end of its shelf life (Fig. 8). Finally, the original instructions called for a magnetic stirrer and a vacuum chamber,

which were not used due to the lack of resources but acquired later thanks to the biology department of Florida International University, the Advanced Materials Engineering Research Institute, and our own construction (next page).

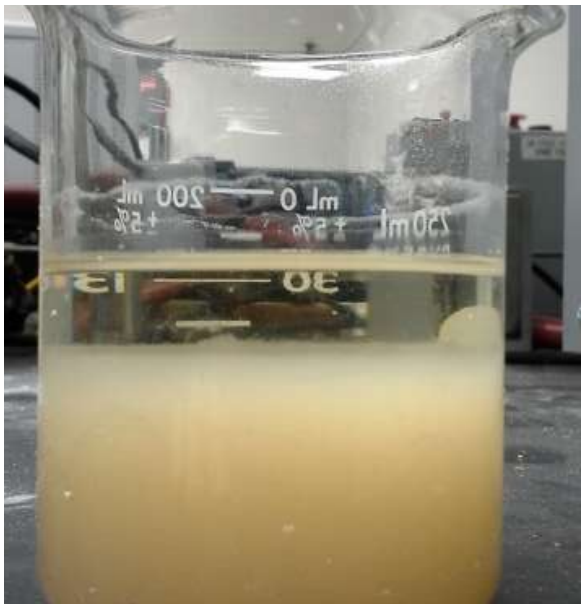


Figure 8: Modified Oven Method Result

Design of Magnetic Stirrer

A magnetic stirrer consists of two portions: the magnet in the beaker that stirs the solution and the electric motor with attached magnets that spins the magnet in the beaker. The stirrer was not available at first, so the team constructed its own. A small fan with a motor attached was used to drive the rare earth magnets, therefore causing the magnet in the beaker to spin. The fan was connected to a switch and a power source. The casing was selected to be very thin so as not to inhibit the magnetic field. Also, the fan was placed as near the top the case as possible. Below (Fig. 9) is the schematic is presented and in (Fig. 10) the actual stirrer is shown. The stirrer is powerful enough to spin the magnet when there is approximately 2 inches in water pressure. This is sufficient to stir the amount of mixture need to mold the heart.

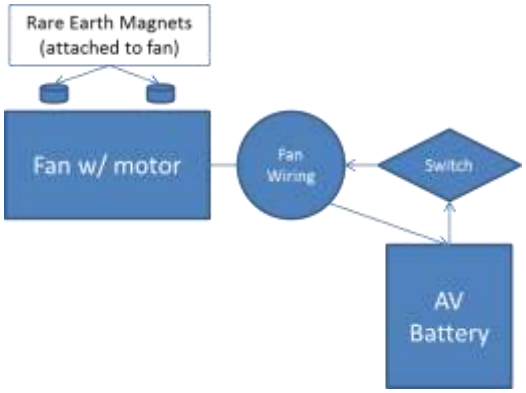


Figure 9: Stirrer Schematic

Figure 10: Stirrer

Procedure: Dr. Basto Method 1

After consulting with the faculty at the Advanced Materials Engineering Research Institute (AMERI), the team was granted access of a vacuum chamber and GC lab conduction oven to create more samples of the agar gel. A magnetic stirrer was also built by the team to eliminate the process of manual stirring. The 1st Dr. Basto method is as follows:

1) Place 300 mL of distilled water in a beaker.
2) Place 15.6 g of Agar powder in the beaker (concentration is now 52 g/L).
3) Blend the mixture with a magnetic stirrer for 10 minutes.
4) Remove the mixture from the magnetic stirrer and place it in a vacuum chamber for 1 hour.
5) Remove the mixture from the vacuum chamber and place in a preheated oven at 75 C for four hours.
6) Remove the mixture from the oven (if mixture is not homogeneous, stir slowly with a glass rod) and slowly pour mixture into mold while avoiding the formation of bubbles.
7) Use a glass plate and seal top of the mold in order to yield a straight flat surface.
8) Remove glass plate and let mixture air for 20 minutes. To preserve the phantom (mixture), place it in aqueous solution with same composition as the phantom.

Results – Dr. Basto Method 1

Three hours after removing the agar solution from the oven, no solidification was evident in the mixture. The agar gel failed to achieve a desirable consistency and was rendered unacceptable for the needs of this project (Figure 11). Dr. Basto was consulted and he suggested a superior method labeled “Dr. Basto Method 2” on the following page.

Figure 11: Dr. Basto Method 1 Results

Procedure: Dr. Basto Method 2

1) Place 300 mL of distilled water in a beaker.
2) Place 15.6 g of Agar powder in the beaker (concentration is now 52 g/L).
3) Blend the mixture with a magnetic stirrer for 1 hour.
4) Remove the mixture from the magnetic stirrer and place in a vacuum chamber for 2-3 hours.
5) Remove the mixture from the vacuum chamber and place it in a preheated oven at 70 C for one hour.
6) Remove the mixture from the oven (if the mixture is not homogeneous, stir slowly with a glass rod) and slowly pour the mixture into mold while avoiding the formation of bubbles.
7) Use a glass plate and seal top of mold in order to yield a straight flat surface.
8) Remove glass plate and let mixture air for 20 minutes. To preserve the phantom (mixture), place it in aqueous solution with same composition as the phantom.

Results – Dr. Basto Method 2

The solution did not solidify in the beaker after five hours of being placed at room temperature. After four hours part of the solution was poured across a receipt in order to also test transparency and allowed to sit for a half hour with no significant solidification (Figure 12). That portion of it hardened some. The rest of the solution was allowed to sit overnight and was checked at 2 pm the next day for a total 19 hrs at room temperature. It still had not solidified and was unusable as a mold material (Figure 13).

Figure 12: Dr. Basto Method 2 (5 hrs Left; 30 min Right)

Figure 13: Dr. Basto Method 2 - 19 Hrs

Conclusion

Dr. Basto was asked for clarification as to his method after each method was unsuccessful. He provided some, but the team was not able to duplicate his results. More clarification was requested, but Dr. Basto was unresponsive. The team needed to move forward and decided to use the boiling method with Dr. Basto's ratios of agar and water. The plan was to test the thermal properties after the artificial heart was made in order to determine what thermal conductivity was reached and use that value in the computer simulations. Several hours were spent attempting to get AMERI's thermal conductivity tester, Microflash 300, running but the team was unsuccessful. Regardless, the artificial heart was never successfully manufactured so the next step of measuring the thermal properties was never needed.

Artificial Heart Fabrication

Development of CAD Model

As discussed earlier, a design using the geometry of an educational model was chosen for this project. An obvious concern of this method was that the internal features must fit inside of the educational model with sufficient clearance to resemble a real human heart. In other words, it had to be certain that the CAD model of the heart cavities fit within the model as 3D printing is expensive in terms of both finances and time. To ensure a correct fit, the outer bounds of the educational model heart were modeled in SolidWorks. Below, Figure 14 shows the front (orange) and right (grey) views of the outside surfaces of the model heart. Dimensioned views are included in the following pages.

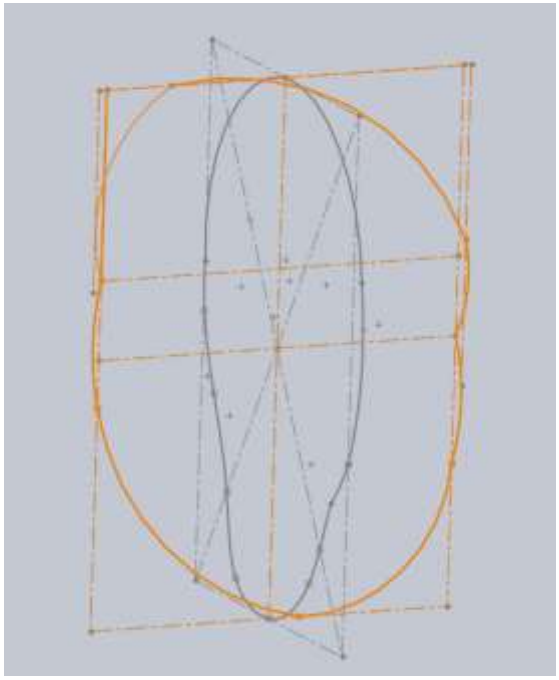


Figure 14: Outer Mold Bounds

A more detailed, dimensioned view of these outside bounds is shown below in centimeters (Figures 15 and 16).

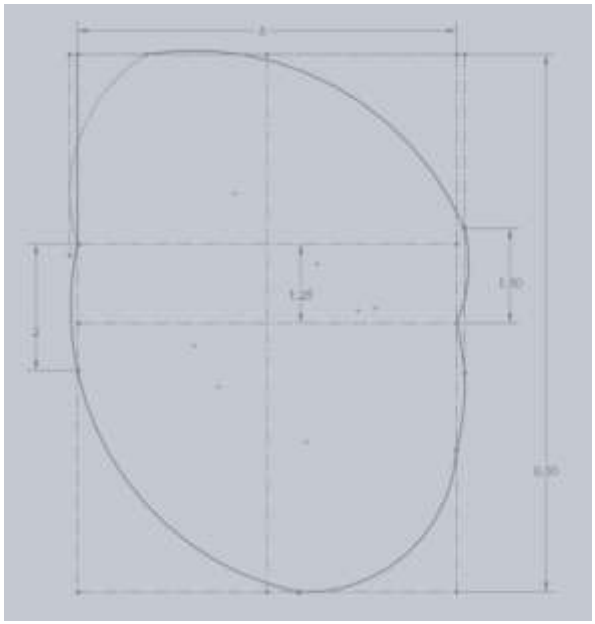


Figure 15: Dimensioned Front View of Outer Mold Bounds

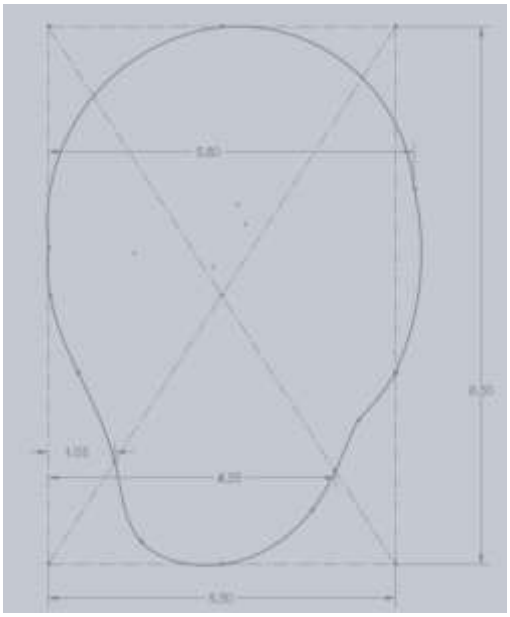


Figure 16: Dimensioned Side View of Outer Mold Bounds

Next, further measurements were taken from the physical model and used to create two lofted solids; one to represent the left atrium and ventricle, and another to represent the right atrium and ventricle.

Figure 17 is representative of what would be seen in the master mold. The horizontal lines in the image were measured at 1cm intervals along the height of the heart, and then additional detail was added at key inflection points of the model. The lines in Figure 17 were concerned with the left side of the model, and would be used to create planes in the next step.

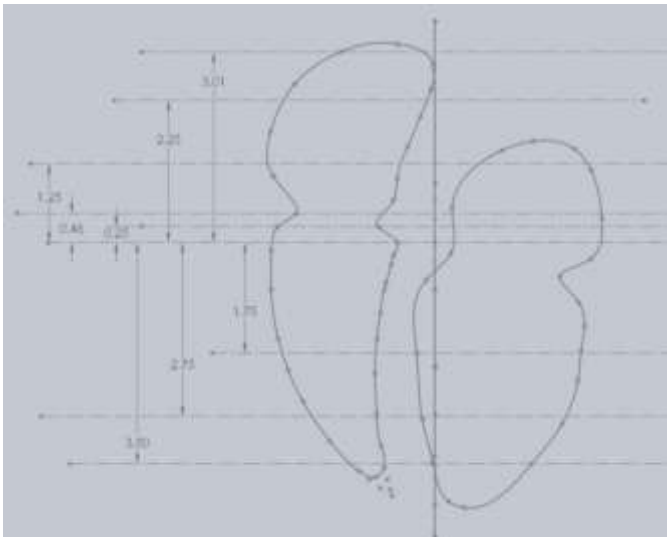


Figure 17: Loft Plane Lines for the Left Side of the Model

The first image below (Figure 18) shows the planes used to create the lofts of the internal chambers of the heart. These are set perpendicular to the cross section shown above. A solid of the right atrium and ventricle was lofted along these ovals to form a solid shape with the same dimensions as the master mold (Figure 19).

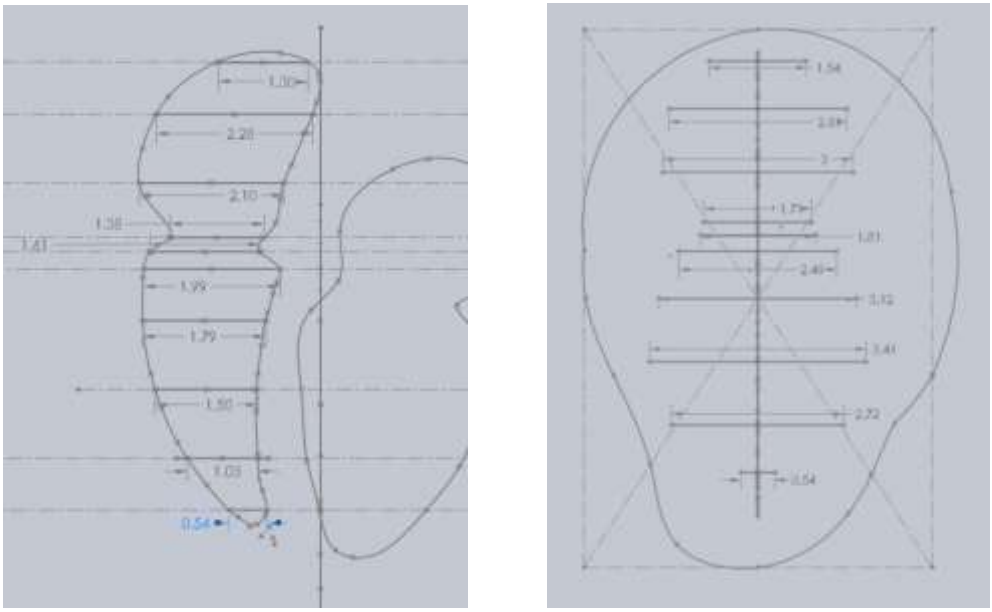


Figure 18: Master Mold with Representative Ovals Front (Left) and Side (Right) - Left

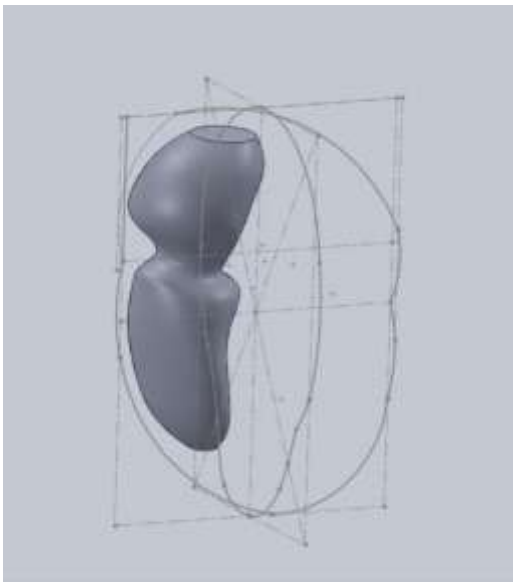


Figure 19: Lofted Internal Chambers – Left

The same process was completed for the right side of the mold. The images for the right side modeling are shown below. Figure 20 shows the left atrium and ventricle contour and Figure 21 shows the dimensions of the cross sections used. Figure 22 shows the final lofted shape.

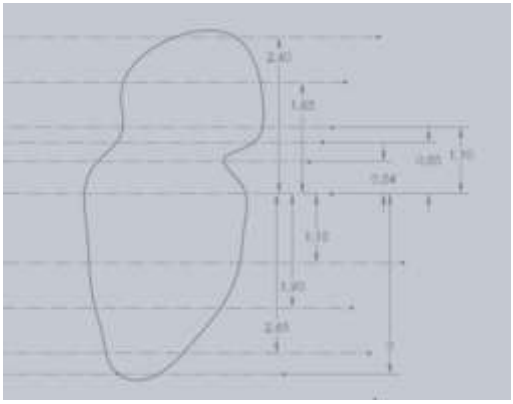


Figure 20: Atrium-Ventricle Dimensions – Right

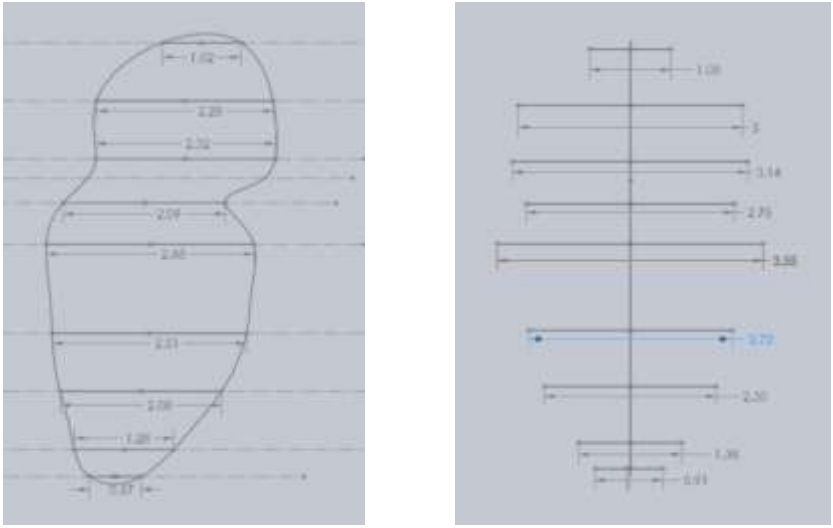


Figure 21: Master Mold with Representative Ovals Front (Left) and Side (Right) – Right

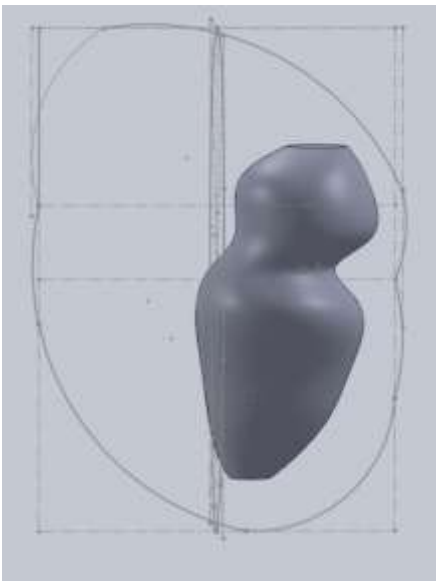


Figure 22: Lofted Internal Chambers - Right

Below, Figure 23 shows both halves of the heart relative to each other and the lofted nature of the pieces. The 0.014” loft was very thin but still allowed for the pieces to stand under their own weight and be handled.

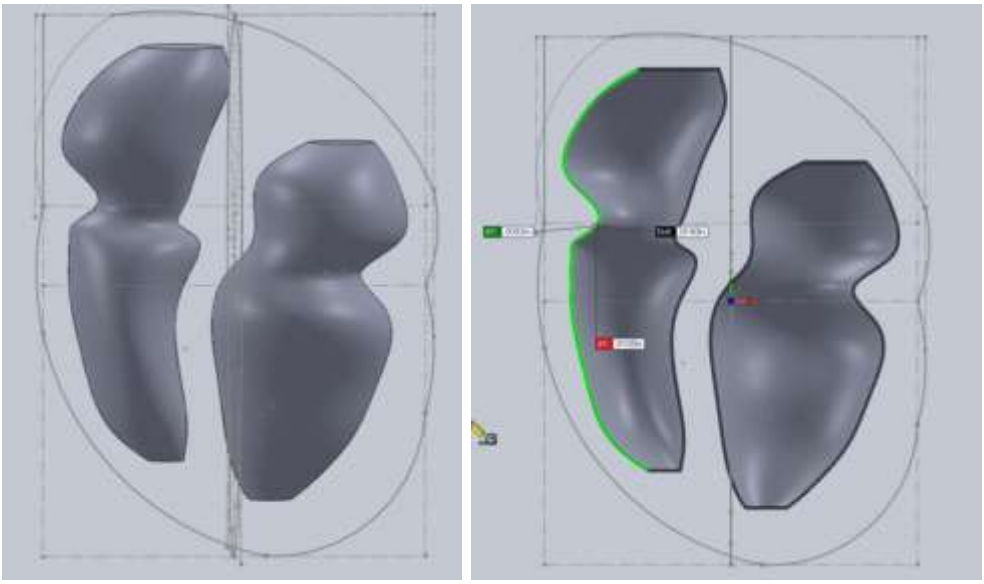


Figure 23: Lofted Internal Chambers

3D Printing of Internal Chambers

Figure 24 shows the 3D prints that were created using the CAD file previously presented. Two sets were printed in case one was damaged during manufacturing, as the print furthest to the right was. Since the pieces are so thin, they are extremely fragile, as intended, and susceptible to failure. The print furthest to the right, the left atrium and ventricle, had its stem fall off. The stem was originally meant to be used in suspending the models, but an alternative method was used involving metal pins that will be explained in the following section. Some gaps were developed during printing that proved problematic since the agar gel could possibly flow into the cavities once it was poured into the mold. In order to avoid this, super glue was used to seal the cracks and any larger holes were covered in clear tape. This method of sealing the cracks was successful and no agar gel seeped into the 3D prints.

Figure 24: Internal Feature 3D Prints

Mold Production

At this point, all of the solid figures necessary to create the final mold were available, so the production of the mold itself began. First, a material was chosen to create the mold. The team faced a choice between silicon rtv and urethane. One advantage of silicon is that it does not require the use of mold release, and the clay used in the molding process can be of any sort, while urethane does require mold release and necessitates the use of a special sulfate free clay that will not interfere with the curing process. Silicon also retains detail better and only takes about four hours to cure, but is considerably more expensive and difficult to work with than urethane. Silicon comes in two parts: Side A, which is the silicon rubber itslef, and Side B, the vulcanizing or curing agent. These two parts must be thoroughly mixed to ensure good results. This is difficult because Side B is a small amount of thin liquid that must be added to a large volume of Side A, which has a viscosicty similar to peanut butter. Urethane on the other hand retains less detail than silicone and requires at least 24 hours to set, but is very affordable. Urethane also comes separated into a rubber and a vulcanizing agent, but is much easier to mix properly; the two parts have a similar low viscosity and are mixed on a one-to-one ratio. Additionally, urethane does not require a vacuum to release any air bubbles formed during the mixing process while silicon does.

Initially the team chose and ordered silicon, because of its better retention of detail. Furthermore, it was found that a vacuum was not needed as long as the liquid was poured in a thin stream at a significant distance above the molding. However, because the listing was given by weight and not volume, a miscalulation in the density of the silicone products resulted in the team purchasing an insufficient amount of silicon. Purchasing enough silicon to complete the project was out of budjet, so urethane was used instead.

Production of the mold followed a standard approach. To create a mold of the outside of the heart, the team purchased five acrylic sheets cut to form an open-topped box. The acrylic sheets were sized so that there would be a minimum half inch clearance between the educational model and the walls of the box. The dimensions of the sheets were as follows:

Acrylic Sheet Dimensions	
Number	**Size**
2	4" x 6.5"
2	4" x 5.5"
1	5" x 6"

Table 4: Acrylic Sheet Dimensions

The assembled box is shown below (Figure 25) with the educational model inside of it to show clearances.

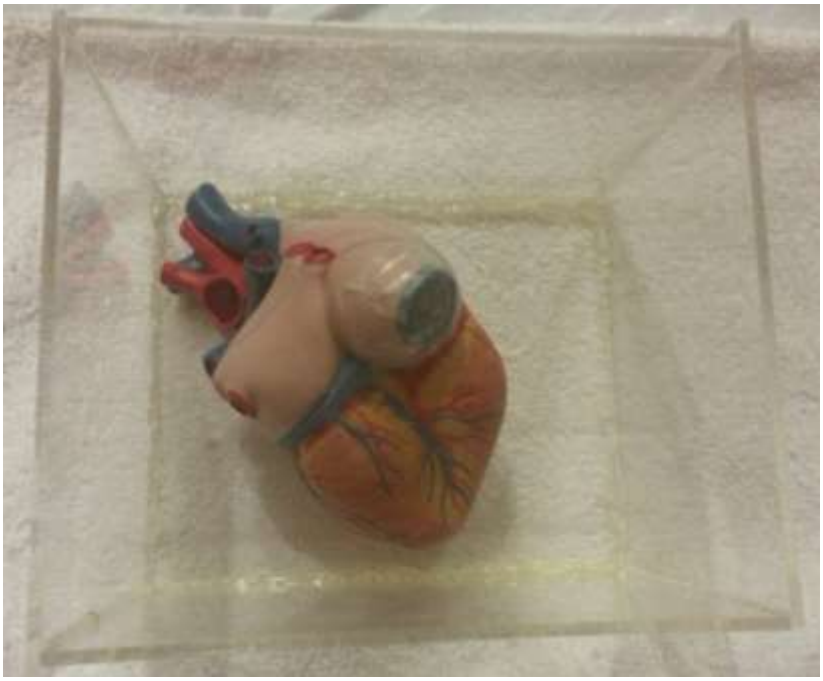


Figure 25: Box - Post Construction

The box was assembled with hot glue and filled halfway with clay. The purchased heart model, which will be refered to from this point forward as the master, was examined for holes or edges that would be inadvertently filled during the mold-making process. These holes were filled

or covered with clay and tape, a parting line was found, clay was wrapped around the parting line, and then the master was pressed into the clay and the entire construction was coated evenly with mold release. The clay was fitted with indentations to aid with alignment of the final mold; the indentations would fill with the mold material and create a keyhole effect with the other side of the mold. Figures 26 and 27 show to essentail parts of the molding process, establishing the molding line, which must be symmetric and minimize undercuts, and the filling to the mold line which should be as uniform as possible.

Figure 26: Heart w/ Parting Line

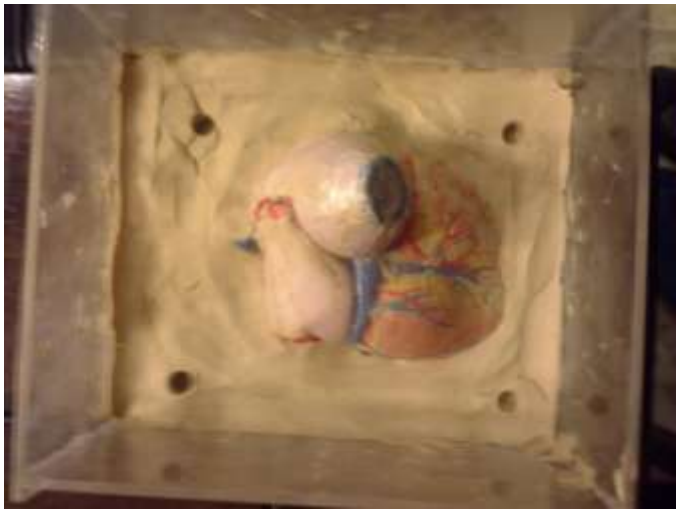


Figure 27: Heart Buried to Parting Line

The mold material, urethane, was mixed in a one-to-one ratio by volume and poured into the acrylic box over the clay and master and allowed to cure. After 24 hours, the acrylic box was disassembled and the clay was removed from the master and the finished half of the mold. The acrylic box was reformed around the finished half of the mold, and mold release was again applied evenly to coat all surfaces inside of the arcylic box. Utherene was again poured into the box and allowed to cure. The following photos show the mold in various stages of production. Figure 28 - Left shows the mold with the acrylic and clay removed once the first half of the eurethane had cured. Figure 28 - Right shows the mold with the acrylic reconstructed around it and the solidified urethane on the bottom, ready for the next step. Figure 29 shows the newly poured second layer of erethane and the clay. During this step a severe leak was present that was stopped with the use of clay and hot glue. Fortunately the leak was stopped right before the urethane fell below the master mold. This resulted in a thin layer over some surfaces of the master mold which was later reinforced with Loctite G02 adhesive.

Figure 28 Left – Heart after First Application of Urethane; Right – Reapplication of Acrylic Panels

Figure 29: Second Layer of Urethane

Once the second half of the mold had cured, the mold was removed from the acrylic box and carefully separated (Figure 30). The heart was removed, and then a hole was drilled into the mold so that the agar could be poured for the final model. The hole was placed in line with one of the arteries leading into the heart so that it wouldn't interfere with any of the external features (red arrow).

Figure 30: Separation of Mold Halves

Next, the internal features of the mold were inserted. Thin metal rods which could be easily removed and filled after molding were placed (red arrow) in the urethane and carefully hot glued to the internal structures. The half of the urethane mold with the internal features inserted is shown in Figure 31 and 32 below. The 3D prints were spaced approximately with the master mold as a reference.

Figure 31: Left Atrium and Ventricle w/ Support

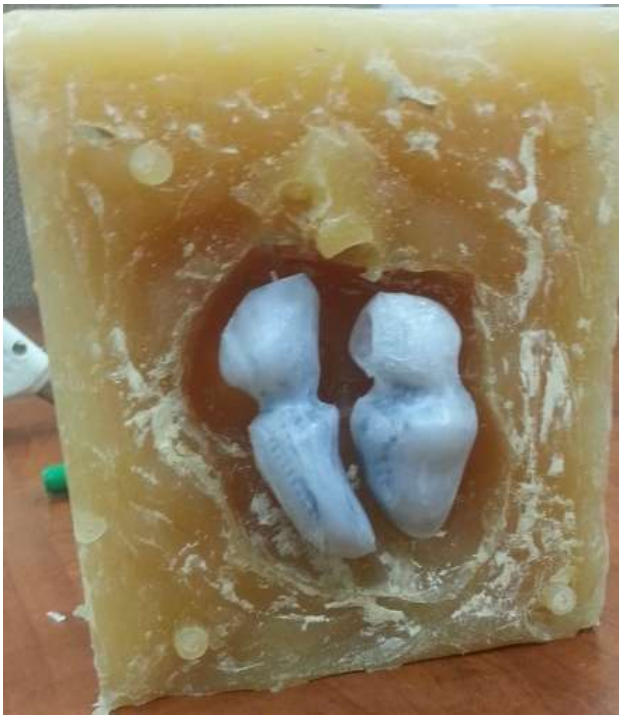


Figure 32: Mold with Both Halves of Heart

Finally, both sides of the mold were placed back together. The sides of the mold were reinforced with the acrylic sheets used to make the box earlier, and masking tape was used to hold everything tightly in place. A funnel was placed in the hole in the top of the mold to pour the agar. This configuration is shown in Figure 33.

Figure 33: Mold Ready for Pouring

The acrylic bracing was also necessary because of a thin area in the urethane mold. A large bubble had come through as a result of the leak that occurred during the fabrication of the second part of the mold. This thin area was patched with glue, but the team felt that a more substantial reinforcement was necessary to make sure the heart was molded properly.

Model Production

Agar gel was mixed and heated using the boiling method described earlier in this paper, and poured into the mold. Although the gel had set in just a few minutes in the trial runs with the material, the urethane mold acted as an insulator, so the gel was left to cool for over two hours. The first attempt at removing the model from the mold, shown below, was unsuccessful. The low parting line on the mold made the stem of the heart weak, and it tore during removal. In the photos, the internal print is clearly visible through the tear in the model, where there should have been no opening.

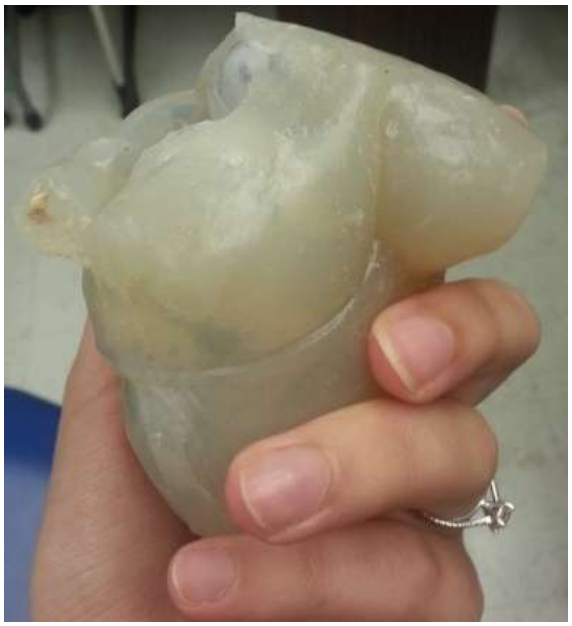


Figure 34: First Attempt at Molding Agar

The second attempt at removing an agar heart replica from the mold proved more successful. The first attempt was again placed within the mold and boiling agar was re-applied so that the stem (area around the aortic arch) did not fill completely and was not so difficult to remove. This area was only given an hour to cool since the amount was much less and there was

more ventilation through the top of the mold since it wasn't full. This resulted in a mold that was externally correct and much more easily removed.

Figures 35 and 36 display the successful attempt in terms of molding. The area near the aortic arch (red arrow) is still slightly more transparent since it has not solidified as long as the rest of the heart.

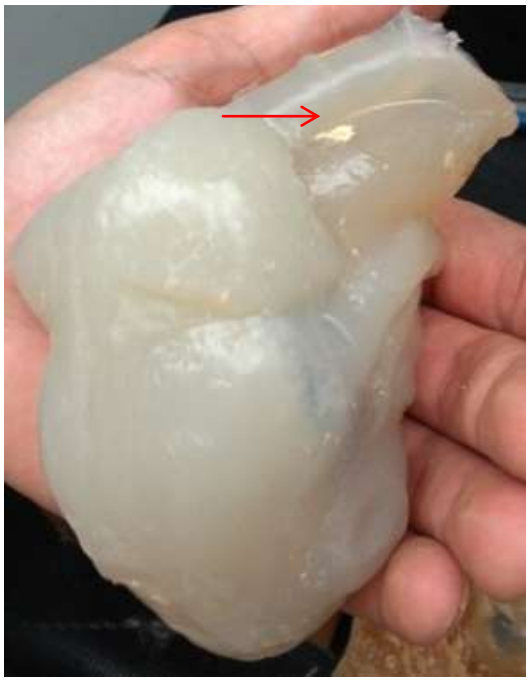


Figure 35: Second Attempt Front View

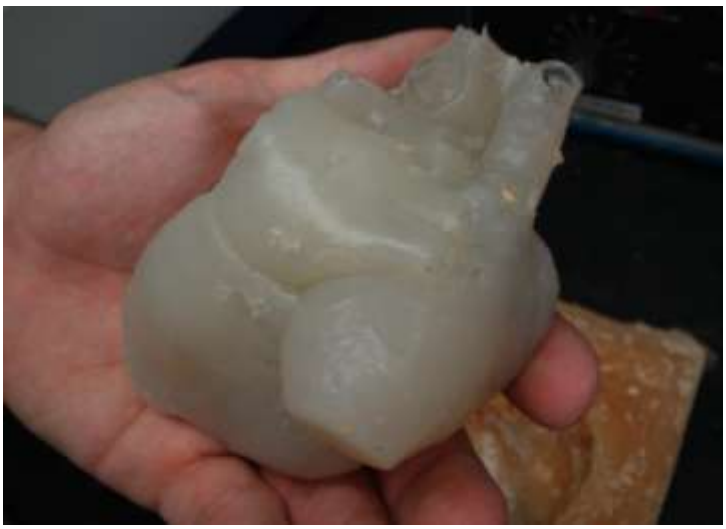


Figure 36: Second Attempt Rear View

Figure 37: Model Heart w/ Size Reference

Figure 37 demonstrates that the mold was comparable in size to an actual human heart. This second attempt used a set of the 3D prints in order to determine whether or not the internal 3D print could be successfully crushed within the model. Once crushed, holes would be drilled following the major arteries and veins attached to the chambers and the 3D print particles would be removed. Those same holes were to be used in attaching the pump apparatus and running cold fluid through the inside of the heart. A few observations were immediately made about the material. First, during the preliminary tests of the material, it was relatively clear when thin, but in the final mold, multiple thin layers resulted in an opaque appearance. Furthermore, unexpected stress concentrations developed due to the geometry of the mold and material was not as resilient as expected. The mold felt very unstable.

A feeling, however, is not enough to determine whether or not the design was a success. It was necessary to apply pressure until the 3D prints that made the internal cavities fell apart. Pressure was applied in several locations uniformly in order to minimize the possibility of the agar gel coming apart. Unfortunately, once the 3D print caved, the mold did as well (Figure 38).

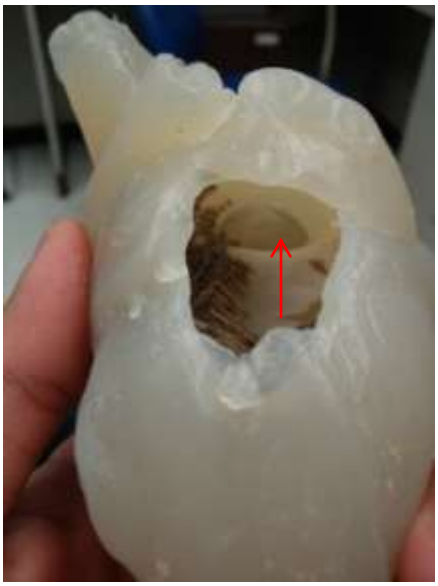


Figure 38: Mold Failure

The inner black portions in the cavity are residue left over from the 3D printing process. The clear bump (red arrow) demonstrates that during the pouring of the material, both 3D prints came into contact, which was undesired. Even so, a layer of agar gel could have been added after and covered the bump. The geometry, however, would have been less accurate.

Conclusions about Mold

Since the mold failed mechanically, little can be done. Any modification to the material would necessarily change its properties and require another round of testing that would call for more time than is left for the completion of this project. Each 3D print cost $25 dollars and multiple prints might have been needed if failures like this continued to occur. That would have be a high cost that was not affordable due to budget constraints. One last option remained, and

that was to utilize a porcine heart. Although it was not be homogenous like the computer model, it was cheaper than producing more artificial samples and more similar to the human heart thermally and mechanically. The one disadvantage of using a pig heart was that its properties were not be able to be measured exactly and used in the computational model. Even so, the pig heart allowed for much more realistic testing and forced the team to modify the apparatus for a biological tissue which was much more difficult to manage than an artificial heart. In turn, the testing apparatus was superior after the utilization of the porcine heart which is presented in the following sections.

Validity of Using a Pig Heart

There is a general acceptance in pertinent literature that a porcine heart is anatomically similar to that of man's. A detailed comparative study between human and pig hearts was conducted in 2005 which showed that although there are some differences in the anatomical details between pig and human hearts, the similarities are so great that they should be structurally compatible with each other (Rodriguez et al, 2005). In fact, porcine hearts are so similar to human hearts that porcine tissue is sometimes used in artificial heart valves; the company Edwards Lifesciences, which advertises itself as "the global leader in the science of heart valves," has several porcine derived models available (Edwards Lifesciences).

While there may be some differences that would be significant in a xenotransplantation between a pig and a human, for the purposes of this project the geometry and properties of the porcine heart are adequate (Crick et al, 1998). That is to say, if combined internal and external cooling of a porcine heart produce better results than external cooling alone, the physiological differences between the two species is not so significant that the results would not translate to a human heart as well. Furthermore, the human and porcine heart are sufficiently similar so that the validity of a computerized system could still be assessed. There are slight differences between any two hearts, and extending those expectations of differences to encompass the minor deviations between human and porcine hearts is acceptable for the purposes of this project.

The images on the following page are a great visual representation of the parallels between porcine and human hearts. Although the photos are taken at slightly different angles and are not to scale, it is clear that the basic anatomical structure is extremely similar. The table below shows various properties of human and porcine hearts.

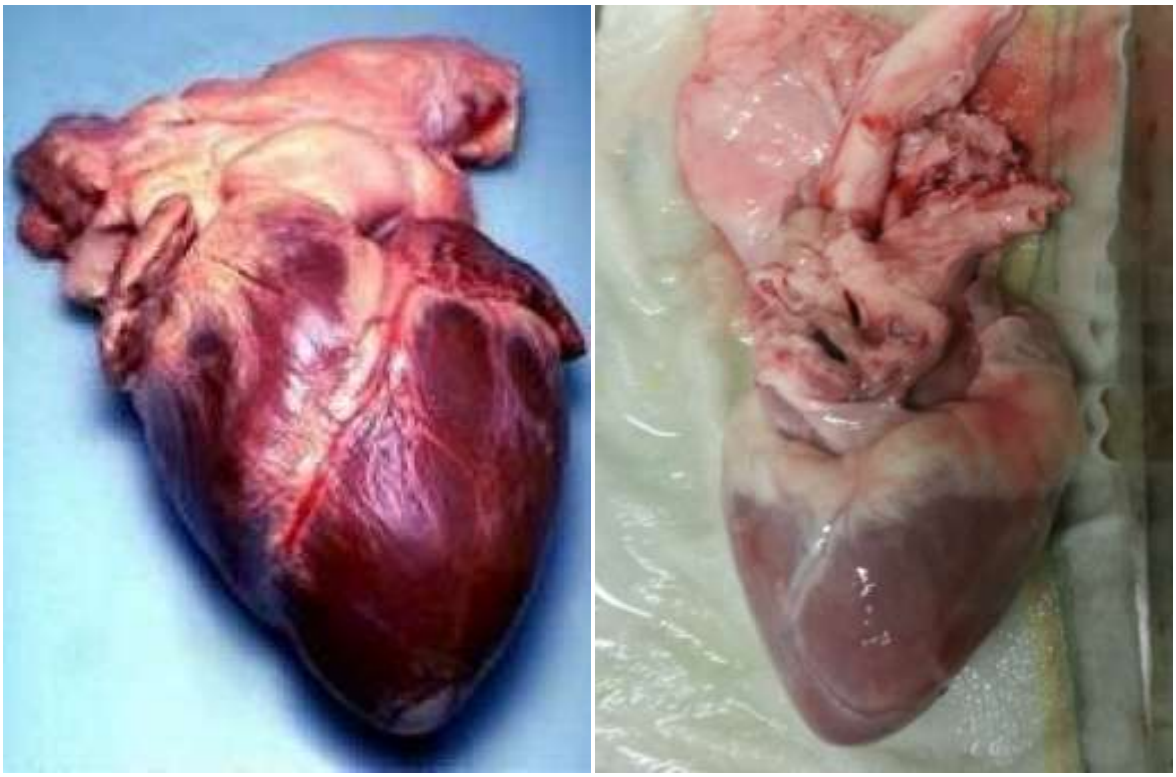


Figure 39: Human Heart (Left) [Taken from health-advisors.org] and Porcine Heart (Right)

Properties	Human Heart	Porcine Heart
Thermal Conductivity	0.48-0.59 W/m·K	0.59-0.78 W/m·K
Mass	250-350 g	250-350 g
Blood Pressure	120 mm Hg	128 mm Hg
Heart Rate	60 bpm	70 bpm

Table 5: Heart Property Comparison - Human and Porcine

It is important to note that the lower range of the thermal conductivity values for porcine hearts is relevant to hearts measured with epicardial fat present, while the upper range was measured without epicardial fat (Koncan, 2000). Therefore, if the porcine heart used in testing still has epicardial fat attached to it, the thermal properties of the heart will match up extremely well to the measured values of the thermal conductivity of a human heart (Zhang, 2009). The blood pressures and heart rates between species is also quite similar, so flow settings used during the testing process should have similar physical consequences for both species as well ("Animal Longevity and Scale,").

Training and Approval

Before testing can be conducted using animal tissue, the appropriate steps must be taken to obtain the required certifications and approval by the supervising authorities. An application must be submitted and reviewed by the Institutional Animal Care and Use Committee (IACUC) which is mandated by the federal government to be established by research institutions to oversee and evaluate the use of animals in laboratories. The application required the team to indicate the purpose of experiment, principal investigator supervising the study, tissue type desired to be tested, location of lab on campus where testing will be conducted, and a credible, USDA federal plant where the animal tissue will be purchased. After these items are listed, the application is submitted and reviewed by IACUC and ultimately approved within approximately 5 days.

In addition to obtain approval to conduct on campus testing using animal tissue, the team was also required to complete the FIU Environmental Health & Safety (EHS) Laboratory Safety Awareness and Working with the FIU IACUC online course. These courses went through the proper laboratory etiquette and procedures in handling hazardous materials, as well as the responsibilities of lab managers, principal investigators, and all personnel working in the testing area. It is the duty of all authorized personnel to become familiar with the dangers that are associated with working in FIU labs and a series of tests must be completed after reading each online module in order to receive certification. Upon reception of the online curriculum completion report, the team was given full permission to enter FIU labs and begin testing involving animal tissue.

To test on a pig heart, it must be purchased from a U.S. Department of Agriculture (USDA) certified and inspected plant that follows humane, ethical, and federal protocols. The

pig hearts were obtained at Mary's Ranch/Cabera's Slaughterhouse located in Hialeah, Florida. A letter to the USDA explaining the experimental intent was submitted to the slaughterhouse with an official FIU letter head and an application was completed with information of the institution, tissue requested, and simple overview of how the tissue will be used.

Once approval was granted and the hearts were purchased, testing could begin. Before the testing process is described in this paper, a detailed review of the design and implementation of the pumping apparatus is included.

Testing Apparatus Fabrication

Design Requirements

The human heart pumps an average of 5 liters per minute during the day. The pump apparatus is intended to mimic this phenomenon in order to induce internal cooling of the heart. The heart consists of a right and left atrium and ventricle. Both atria receive blood and the ventricles expel it. The left ventricle pumps blood at a greater rate than the right ventricle. The right ventricle pumps blood at approximately half the maximum flow velocity. The maximum blood velocity has been measured at 120cm/sec during strenuous physical activity. Accordingly, the right ventricle cannot have a flow velocity greater than 30-50cm/sec without out causing damaging to the muscle tissue. All of the data concerning blood flow through the heart was provided by Mr. Abas Abdoli. These flow rates requirements will determine the final design of the pumping apparatus.

First Pump Apparatus Design

In this section the design and fabrication of the cooling system is presented in addition to a list of materials with costs per part (Table 6: List of Materials – Pump). The system was carefully designed to control flow rates between 0 liters/min and 5 liters/min using a valve without overwhelming the constant-flow pump.

List of Materials- Pump Apparatus		
Component	**Quantity**	**Cost (per unit)**
3/8” OD x 1/4" ID x 10’ Vinyl Tube	1	$2.69
1/2” OD x 3/8” ID x 20’ Vinyl Tube	1	$6.26
3/4” PVC Female Adapter	4	$0.47
3/4" PVC Male Adapter	2	$0.46
1/2” x 2’ PVC Pipe	1	$1.14
3/4" x 2’ PVC Pipe	1	$1.34
2” PVC Bushing	1	$1.97

PTFE Thread Seal Tape	1	$1.47
12V Marine Utility Pump	1	$37.99
TOKYO BBK05002 Water Flow Meter 0-5 L/min	1	$56.75
3/4" x 1/2" MPT Brass Male Adapter	3	$2.23
3/4" SGL Union Ball Valve	1	$8.54
	Total Cost	$127.64

Table 6: List of Materials - Pump

The following figures are the schematic for the recirculating system (Figure 40: Cooling System Schematic) as well as the actual cooling system developed (Figure 41: Cooling System). The "3" in the figure is the recirculating system. The water container "6" will be switched out in the future for a container that allows for easy addition of ice in order to better control the temperature of the cooling fluid, cold water.

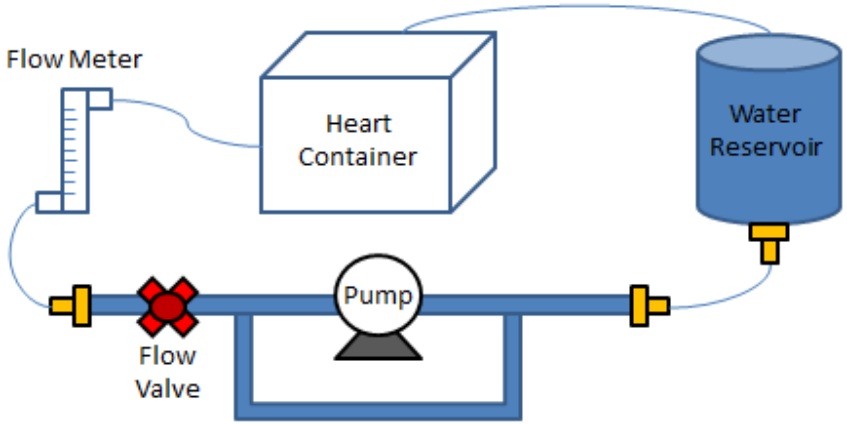


Figure 40: Cooling System Schematic

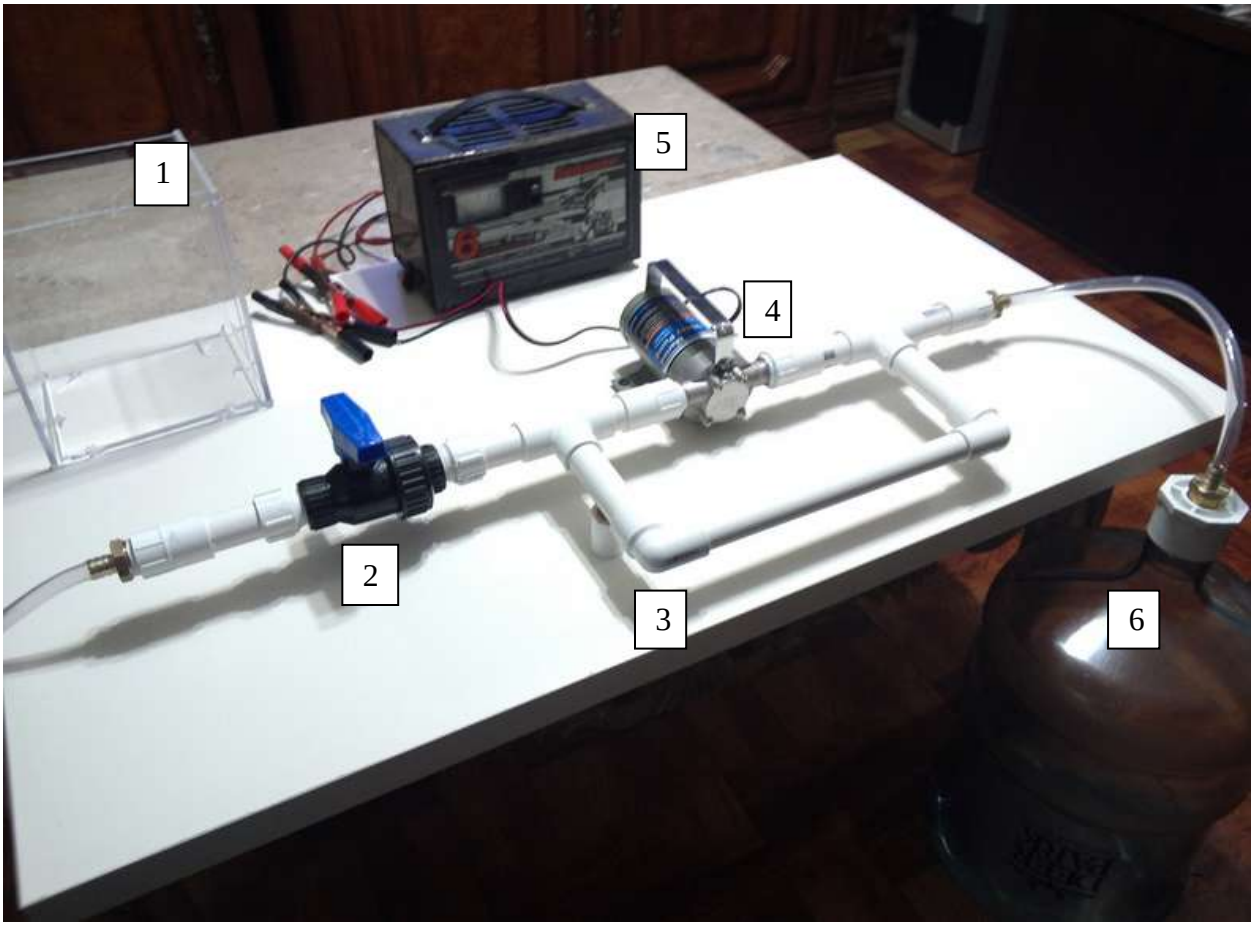


Figure 41: Cooling System

A description of the parts numbered in Figure 41 above follows:

1) Acrylic shatterproof heart container: stores the transplant heart at low temperatures.
2) Union ball valve: controls the amount of coolant flowing into the heart container based on the handle position.
3) PVC redirection pipe system: circulates the coolant fluid through the pump when the flow valve is completed closed off. This is done in order to avoid damaging the single speed pump through excessive back pressure when the fluid is being supplied to the heart at low flow rates.

4) 12V marine utility water pump: most essential component of the pumping apparatus. It initiates and sustains a water flow once it is connected to the 6V/12V power supply. The pump at full power runs at a maximum flow rate of 200 GPH and 50 psi.
5) G Solid State Auto battery charger: serves as the power supply to the utility pump.
6) 5 gallon water reservoir: stores the coolant that will be pumped through the PVC pipe system and ultimately into the heart. The water reservoir will also be the location where the fluid temperature is controlled by adding ice to the existing water mass.

The following page contains Figure 42, Figure 43, and Figure 44, which are closer shots of the parts in order to better see the details of each component.

Figure 42: Flow Control Valve

Figure 43: 12V Utility Pump and Power Supply

Figure 44: Flow Meter

The TOKYO water flow meter (Figure 44) was purchased to measure the amount of water flow entering the heart at any given point during testing. The flow meter is capable of measuring from 0 to 5 liters per minute. This meter was suitable for the project's objective and application since it is desirable to maintain the coolant flow rate below or equal to the physiological blood flow rate of a live human heart of 5 liters per minute. The coolant flow enters through the bottom of the device and exists through the top. The black control knob regulates the water flow through the meter.

Heart Container Leak Test

An image of the heart container (Figure 45) follows.

Figure 45: Heart Container with Silicone Sealant

Silicone sealant was applied to all of the edges of the acrylic container in order to prevent leaks from occurring. To ensure proper sealing of the container, the surfaces were cleaned and dried off prior to applying the sealant to each corner. Excess sealant was removed with a cotton swab and then allowed to dry for an hour. The silicone sealant was then set to cure for a full 24 hours. After the silicone had completely solidified, a leak test (as described on next page) was conducted to ensure that the container could enclose a fixed volume.

Procedure

1) Fill the container with approximately 3.5 liters of water.
2) Observe the edges of the container, especially the corners, for fifteen minutes and note any leaks.
3) Empty the container of water and check for any dissolution of sealant or expansion of the container.

Results

The acrylic container is made up of 5 rectangular panels and has an approximate empty space volume of 222 in^3, or 3.64 liters. Thus, the container was too near full capacity to avoid spilling over and confusing a drip for a leak. It was evident that leaks were present in the edges of the base acrylic plate. Additional silicone sealant was reapplied at the areas where leaking was present and the container did not fail the test a second time.

Conclusion

In order to prevent leaks from occurring during testing, it is important to apply the silicone sealant evenly in the corners and gaps of the final acrylic container and the appropriate amount of time must be allowed for the sealant to cure and properly settle. When done successfully, no leaks will occur once the fluid and heart is added into the container. A wait time of fifteen minutes is suitable since the final presentation last approximately ten minutes. If leaks occur during testing, they can quickly be patched, but leaking during a presentation is not suitable. Just in case, a secondary container will be available should an unforeseen leak occur that is not easily patched. An extra container will also be present during presentations.

Flow Rate Testing

Below is a picture of the reference volume (Figure 46) and a description of the test procedure and results.

Figure 46: Container with Known Volume for Flow Rate Testing

	t(s)	t(min)	Volume (L)	Flow rate (L/min)
Trial 1	20.96	0.3493	2	5.725
Trial 2	20.55	0.3425	2	5.839
Trial 3	19.05	0.3175	2	6.299
			Average	5.954

Table 7: Flow Rate Trials (without flow meter)

Procedure for Fully Open Valve:

1) Connect the utility pump to the 12V power supply and run at full speed (valve completely open).
2) Hold the outlet hose (3/8 inch inner diameter) above and into the container shown above.
3) Using a stopwatch, record the time taken to fill the container to 2 L as designated by bottom of the black tape in Figure 46.
4) Empty the container.
5) Repeat steps 3-5 twice.
6) Tabulate data.

Conclusions

The flow rate is relatively consistent and acceptable for the purposes of the test. A live reading should be taken during testing. This will be done with the use of the flow meter which is validated in the next test.

First Pump Apparatus Design: Flow Meter Validation

After the flow rates were tested using the method above, the measurements were then conducted with the flow meter installed to the pump apparatus. The flow meter is capable of maintaining the coolant flow rate between 0 to 5 liters per minute. The flow meter's outlet hose line has an inner diameter of ¼ inch which assists in limiting the coolant flow rate into the synthetic heart.

Procedure for Flow Meter Validation

1) Connect flow meter on the outlet side of the 12V utility pump.
2) Attach hose with ¼" inner diameter to the outlet nozzle of the flow meter and insert opposite end into the reservoir tank.
3) Connect the pump to the power supply and allow the coolant to flow through the entire system.
4) Once the flow meter measurement reaches a constant level, use a stop watch to record the time it takes to fill up a 2 L container.
5) Use the time measurement to calculate the rate of flow and compare the results to the flow rate displayed by the flow meter.

Results

After conducting the testing, the average flow rate of the water running through the pipe system with the flow valve opened at full capacity was 5.954 L/min. With the flow meter installed, the flow measurement conducted with the stop watch and water container averaged at a flow rate of 3.982 L/min compared to the averaged flow rate read by the flow meter of 4.050 L/min. Images of the flow meter reading results follow.

	t(s)	t(min)	Volume (L)	Flow rate (L/min)	Flow meter reading (L/min)
Trial 1	30.18	0.5030	2	3.976	3.90
Trial 2	30.09	0.5015	2	3.988	4.20
			Average	3.982	4.05

Table 8: Flow Rate Trials (with flow meter)

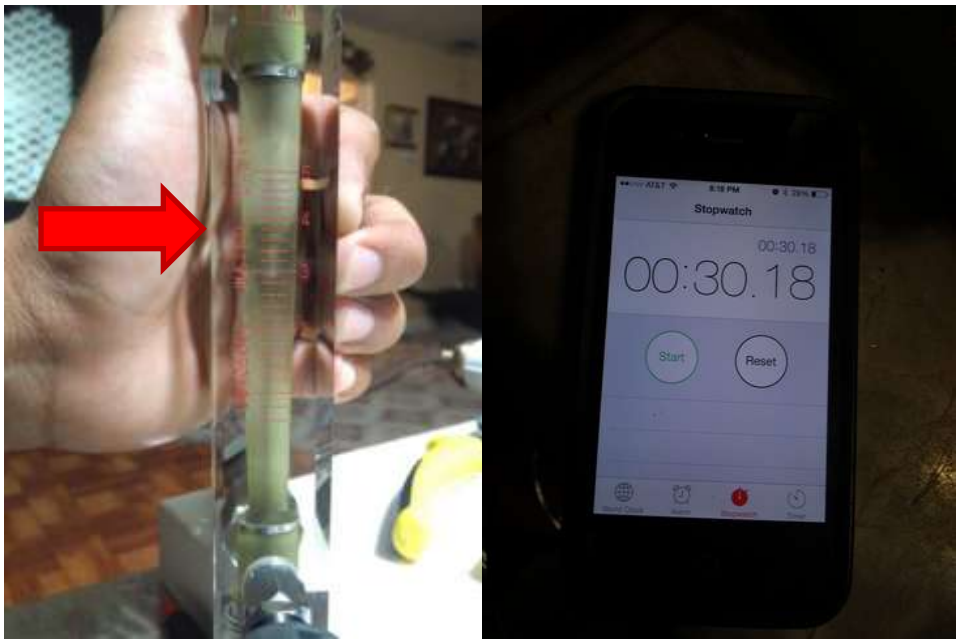


Figure 47: Flow Meter Validation Picture 1

Figure 48: Flow Rate Validation Picture 2

Conclusion

These preliminary flow tests and leak tests confirm that the test apparatus is reliable and produces flow in the required range of 0-5 L/min. An extra advantage of the system is that it draws from its own water supply, so the pressure and flow rate will not fluctuate like other system do when they are attached to a faucet in a building in which the water pressures regularly vary. Some modifications were made to the system; these are detailed in the next section. These changes pertain to the fact that in order to better simulate flow in a heart, at least two inlets are necessary. What follows is a description of how this was accomplished and the testing of the new system.

Revisions to Pump Apparatus

The pump apparatus was redesigned to incorporate a dual flow path in order to deliver fluid to the right and left ventricles of our heart specimen. The structure consists of two outlet nozzles with ½ inner diameters where the coolant will flow out of and into the flexible hose line system as shown in Figure 49. Figures 50 and 51 highlight different components of the system. Located right before the straight connector nozzles are flow valves that serve to regulate the flow of fluid as it is supplied to the system. Due to the anatomy of the human heart, the rate of blood pumped through the left ventricle of the heart is typically twice that of the flow rate through the right ventricle. The left ventricle is responsible for pumping oxygenated blood into the aorta, which is the body's largest artery. This supplies the entire body with blood. The right ventricle is responsible for pumping deoxygenated blood to the pulmonary artery where it is carried to the lungs. Since the right ventricle does not work as hard as the left, it pumps blood at a lower rate. The human heart pumps blood to the body at approximately 5 liters per minute. This valve was used as our upper baseline limit when designing the cooling apparatus. With all of this information known, it was essential to reconstruct the pumping system so that one nozzle had twice as much flow than the second at any given time and that it should not exceed a total volumetric flow of 5 liters per minute during experimentation.

A piping subsystem was added to the apparatus to alleviate any back pressure build up that could occur when the system is operating at low flow rates. A flow valve is attached to the secondary piping system to allow flow to redirect back to the pump inlet, creating a closed loop with the circulating coolant.

Second Pump Apparatus Design

Figure 49: Redesigned Pump Apparatus with Dual Outlet Nozzle Configuration

Figure 50: Dual Outlet Nozzles A and B

Figure 51: Markings on Flow Valve Handle Indicating Degrees of Rotation

Second Pump Apparatus Design: Flow Rate Testing

Due to the fact that the pump apparatus was redesigned to have two outlet ports for the coolant as opposed to one, a new set of flow rates tests were done to find the appropriate configuration where Outlet A had a flow rate was twice as great as Outlet B shown in Figure 50. The tests were conducted by having the flow valve on Outlet A completely opened for each trial and slowly increasing the amount of flow coming out of Outlet B. A new flow meter, shown in Figure 52, was selected and purchased to accurately control and monitor multiple flow rates simultaneously; however, due to the location from which the part is being delivered, the new device has not been received and installed in the pump apparatus. To overcome this obstacle, the original flow meter was left attached to Outlet A and the fluid flow from Outlet B was measured using a two liter container and the elapsed time was recorded using a stopwatch. Table 9 consists of the results of each trial at different valve openings at Outlet B.

	Flow Rate Testing						
	Outlet A	**Outlet B**					**Flow Ratio**
Test	**Flow Rate (L/min)**	**Flow Valve Opening (Rotations)**	**Volume measured (L)**	**Time (sec)**	**Time (min)**	**Calculated Flow Rate (L/min)**	**Outlet A: Outlet B**
1	3.2	0.750	2.000	34	0.567	3.529	0.907
2	3.4	0.667	2.000	44	0.733	2.727	1.247
3	3.7	0.583	2.000	71	1.183	1.690	2.189
4	4	0.542	2.000	96	1.600	1.250	3.200
5	4	0.500	2.000	188	3.133	0.638	6.267

Table 9: Flow Rate Trials for dual outlet nozzles (with flow meter)

Based on the results, in order to achieve the desired 2 to 1 flow ratio between outlets A and B, two configurations can be used. Tests 3 and 4 show that by rotating the flow valve handle by approximately 0.667 and 0.583 rotations, we obtain a 1.247 and 2.189 to 1 respectively.

Figure 52: Flow SysMatic Model FSML-200M Water Flow Regulator

With the intention of regulating the fluid flow of two separate lines at two different rates, the Flow SysMatic Model FSML-200M Water Flow Regulator was purchased due to its precision in water control. The device's initial design intent is to serve as a cooling system for molds. The flow meter consists of flow tubes made of polyamide nylon material with engraved flow readings incremented at half liters per minute. Adjustable reference rings and brass float cones are assembled to each channel which allows the user to read the flow rates of each separate line up ten liters per minute.

Final Pump Apparatus Design

The final iteration of the pumping apparatus consists of the Flow SysMatic Model FSML-200M Water Flow Regulator which is capable of measuring and controlling the inlet flow rates of two separate lines simultaneously which fits the necessary testing parameters. This was the greatest change done to the system since it will be the source of flow control. Due to the orientation of the meter and location of the inlet and outlet hose lines, a testing fixture was assembled with openings in the top surface to allow the flexible tubing to provide coolant to the

heart and return back to the flow meter. The water exiting the heart is directed back to the flow meter and ultimately channeled into the reservoir tank and cycled. The meter reading is supplied by the exiting heart fluid. Testing is done under the assumption that the flow entering the heart is equivalent to the fluid exiting the heart specimen. In Figure 53, the bottom two knobs are used to control the amount of flow entering the heart and the top two knobs control the water leaving the heart. Since we only desire to adjust the inlet flow, the top two controls were kept completely rotated to the left and provided no resistance to the exiting flow.

Figure 53: Flow meter controls

Based on the sizes of the superior vena cava, pulmonary trunk, pulmonary veins, and aorta, brass fittings were purchased to properly secure the incisions on the heart sample and prevent as much leakage as possible. Matching fittings were paired for the inlet and outlet hose lines. Channel 1 was assigned to supply fluid to the left ventricle and the tubing was fixed with 1/2” x 3/4” brass expansion couplings. Channel 2 was assigned to the right ventricle and limited to low flow. 1/2” x 3/8” brass reduction couplings were attached to the tube endings in order to abide by the flow velocity restrictions. Four fuel injection hose line clamps were fastened to the bottom of the device to ensure that no leakage would occur once fluid flow was commenced.

Figure 54: Activated Brass float Cones under Constant Flow

Figure 54 shows the brass cone floats that begin to float based on the rate at which the water is enters the device.

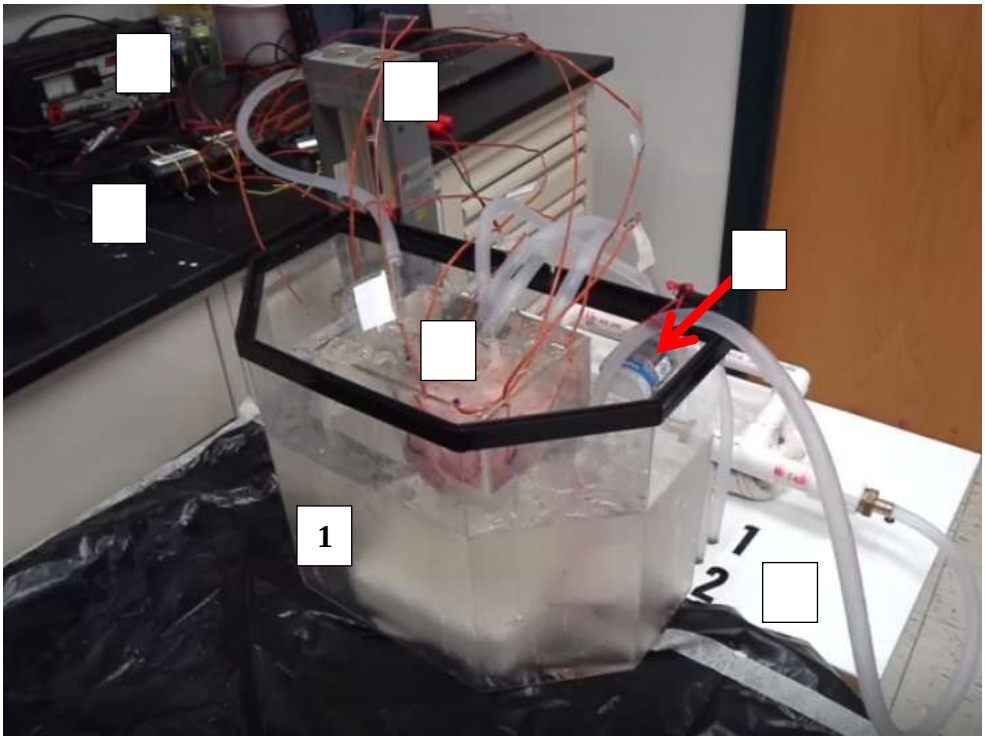


Figure 55: Isometric View of Pump Apparatus

A description of the parts numbered in Figure 55 above of the final testing pump apparatus is as follows:

1) Five gallon fish tank: serves as a water reservoir to store the coolant that will be pumped through the PVC pipe system and ultimately into the heart. The water reservoir will also be the location where the fluid temperature is controlled by adding ice to the existing water mass.
2) Acrylic shatterproof heart container: stores the transplant heart at low temperatures.
3) Testing fixture base: wooded plank with labeled hose line configuration, mounted pump and PVC system and flow meter. The base is support by four metallic legs.
4) Flow SysMatic Model FSML-200M Water Flow Regulator: will control and measure the fluid flow through the heart specimen.
5) USB data acquisition module: thermocouples will be connected to the module and the temperature readings will be logged into the laptop where the thermocouples signals will be processed.
6) G Solid State Auto battery charger: serves as the power supply to the utility pump.
7) 12V marine utility water pump: most essential component of the pumping apparatus. It initiates and sustains a water flow once it is connected to the 6V/12V power supply. The pump at full power runs at a maximum flow rate of 200 GPH and 50 psi.

Final Pump Apparatus Design: Flow Meter Verification

To ensure and maximize the amount of accuracy during testing, a series of flow tests were conducted to verify the accuracy of the Flow SysMatic Model FSML-200M Water Flow Regulator. The same procedures were followed as listed in previously in this report. Each individual channel was tested at various flow rates settings and the outlet water was collected, measured, and the time elapsed for each trial was recorded. Channel 1 was initially set to output a flow of 1 liter per minute while Channel 2 was completely shut off. The flow was increased each subsequent trial and the same was then repeated for Channel 2. Tables 10 and 11 below are the results:

Channel 1 Flow Meter Accuracy Test Results				
Instrumental Reading (L/min)	Volume (L)	Time (min)	Actual Flow Rate (L/min)	% error
1	2	1.217	1.643	64.339
2	2	0.800	2.500	25.000
3	2	0.550	3.636	21.212
4	2	0.417	4.796	19.904
5	2	0.350	5.714	14.286

Table 10: Channel 1 Flow meter Accuracy Test Results

Channel 2 Flow Meter Accuracy Test Results				
Instrumental Reading (L/min)	Volume (L)	Time (min)	Actual Flow Rate (L/min)	% error
1	2	1.367	1.463	46.306
2	2	0.783	2.554	27.714
3	2	0.567	3.527	17.578
4	2	0.433	4.619	15.473
5	2	0.350	5.714	14.286

Table 11: Channel 2 Flow meter Accuracy Test Results

The test results show that the flow meter control settings did not yield accurate flow measurements. At low flow settings, each channel displayed high amounts of errors and both channels exhibited similar trends in which the error gradually decreased as the flow was

increased. The flow rate tests indicated that a calibration of the system and measurements taken need to be done the cooling experimentation to accurately note the flow entering the heart. To do this, the instrumental readings for each channel were plotted versus their respective experimental results and a line of best fit was computed for each set of results as plotted in Figure 56.The equation of each linear function was then used to calculate the actual flow rate of the device based on the output readings during cooling tests.

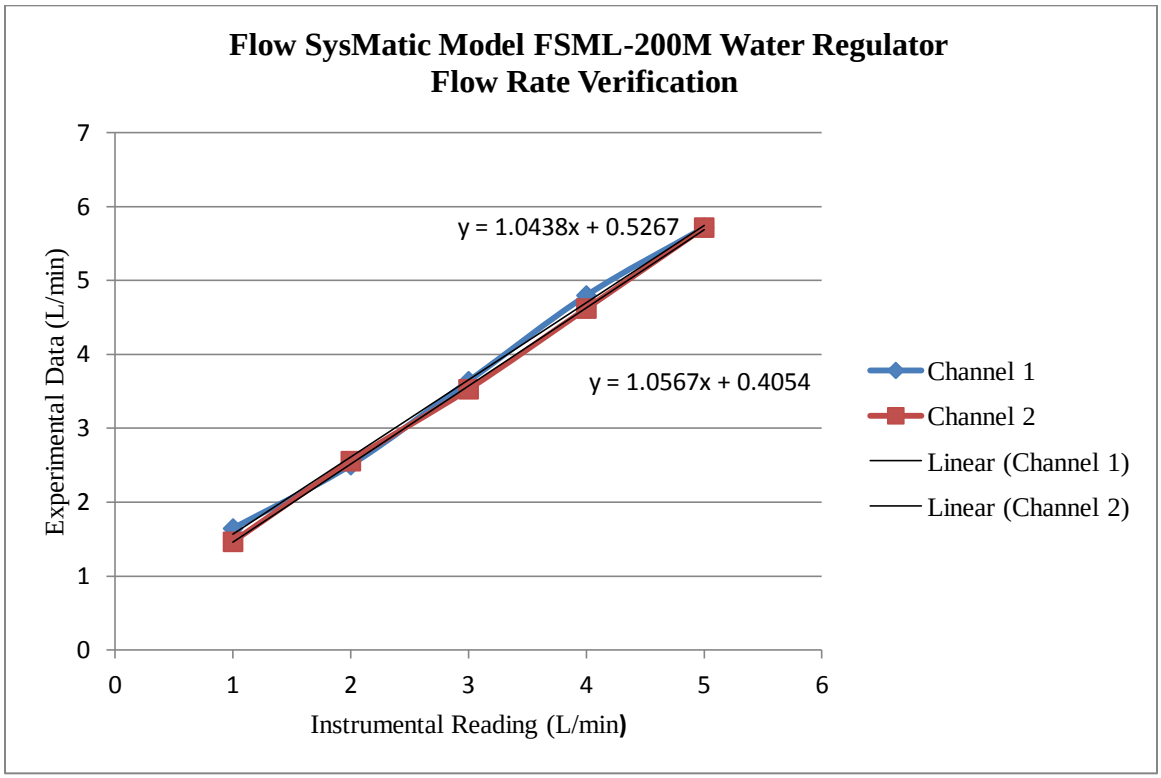


Figure 56: Linear Regression Analysis

Maximum Flow Rate Calculations

The pump is capable of supplying coolant at a maximum flow rate of about 10 liters per minute. Knowing this, selecting the appropriate hose lines with specific inner diameters can achieve the recommended flow velocities for the right and left ventricles. A standardized hose line with an inner diameter of 0.25 inches was purchased and assembled to the pump apparatus. Since the flow rate obtained are all in metric units, the hose inner diameter converts approximately to 0.653 centimeters. Calculating flow velocity can be done by using and rearranging the formula:

$$Q = AV,$$

where Q represents volumetric flow, A is the cross-sectional area of the hose line, and V is the fluid velocity. The following sequence of calculations and conversions were conducted to determine the appropriate hose sizes:

Hose Line Outlet Area

d1=0.25in = 0.653cm --> $A1 = \frac{\pi d1^2}{4} = \frac{\pi(0.653cm)^2}{4} = 0.335cm^2$

Current Maximum Flow Rate

1 liter = 1000cm3

Qmax = 5 liters/min = 83.333cm3/sec

Calculated Flow Velocity

$$Q = AV \rightarrow V = \frac{Q}{A}$$

$$V1 = \frac{83.333cm^3/sec}{0.335cm^2} = 248.755\frac{cm}{sec}$$

Based on the calculations above, the coolant line supplying fluid to the heart specimen with an inner diameter of 0.25 inches at the maximum possible flow rate allowable yields a flow

velocity greater than the heart should anatomically withstand. Initially, finding the upper limit of flow we can use during testing can solved using the following:

$$Q_{test\ max} = AV = (0.335cm^2)\left(120\frac{cm}{sec}\right) = 40.2\ cm/sec = 2.412\ liters/min$$

The maximum restriction calculated of 2.412 liters per minute is solely based on the 0.25 inner diameter of the hose, however, the maximum flow velocity of 120 liters per minute is based on the fluid supplied to the left ventricle. The brass expansion coupling attached to the pulmonary vein as a diameter of 0.75 inches. Additionally, the limit of flow velocity to the right ventricle can be calculated using the 0.375 inches from the reduction coupling. Recalculating to find the upper limits is can be as concluded:

Left and Right Ventricle Maximum Flow

$$d_{left\ venticle} = 0.75in = 1.905cm \rightarrow\ A1 = \frac{\pi d1^2}{4} = \frac{\pi(1.905cm)^2}{4} = 2.8520cm^2$$

$$d_{right\ venticle} = 0.375in = 09525cm \rightarrow\ A1 = \frac{\pi d1^2}{4} = \frac{\pi(0.9525cm)^2}{4} = 0.7096cm^2$$

$$Q_{left\ ventricle\ max} = AV = (2.8520cm^2)\left(120\frac{cm}{sec}\right) = 342.24\ cm^3/sec = 20.534\ liters/min$$

$$Q_{right\ ventricle\ max} = AV = (0.7096cm^2)\left(50\frac{cm}{sec}\right) = 35.48\ cm^3/sec = 2.129\ liters/min$$

Flow limitations will be done using the lowest value from the right ventricle of 2.129 liters per minute. For testing, fluid flow to the left ventricle will not be greater than twice this value, which equates to 4.258 liters per minute.

Failure Modes

It is important to never operate the pump apparatus without first filling the system with coolant. If the pump is turned on dry, it can overheat and become damaged. A second concern operating the pump stems from altering the flow at the nozzle outlet ports. As the flow valves are closed to produce a low flow rates, water begins to be built up into the pump and creates large back pressure. Measures will be taken in the design of the system to insure that these things do not happen, such as properly starting system already filled with water. The system will also fail to properly recirculate fluid if the connections between the hose lines and heart are not completely fastened and secure.

Summary of Testing Components and Purpose

Container

A clear, acrylic container was constructed to vertically house the heart being tested. Approximately one inch clearance between the heart and container wall was designed so that a more uniform temperature field would be developed while still allowing room for ice-water around the heart. The container was fixed to the testing system for stability and mobility.

Cooling System

A pumping system with two outlets was developed that provides stable flow rates within the range necessary for the tests. The ability to vary and measure flow rates is essential for comparison with the computer model and heat transfer analysis. The computer model must be run at different flow rates and compared with experimental tests for any meaningful comparisons to be made. Lastly, the rate of heat transfer is dependent on the Nusselt number which is a function of the Reynolds number which is a function of flow rate. The velocity of the fluid affects the rate at which heat is transferred.

OMB-DAQ-54 System

T-type thermocouples are attached to the data acquisition module for thermocouple process signals which is connected to a computer equipped with OMB-DAQ-54 via USB. T-type thermocouples were utilized since they are suited for temperatures far below and above operating range for this test. T-type thermocouples are rated for ranges from -250 C to 350 C. Once the team is ready to test on a porcine heart, temperatures tested will be between 4 C and 36 C. T-type thermocouples are also accurate and durable enough for the purposes of this test. 16 thermocouples will be used and placed throughout the inside and outside of the heart where

temperature concentrations exist and along the inner walls of the box to measure ambient temperature.

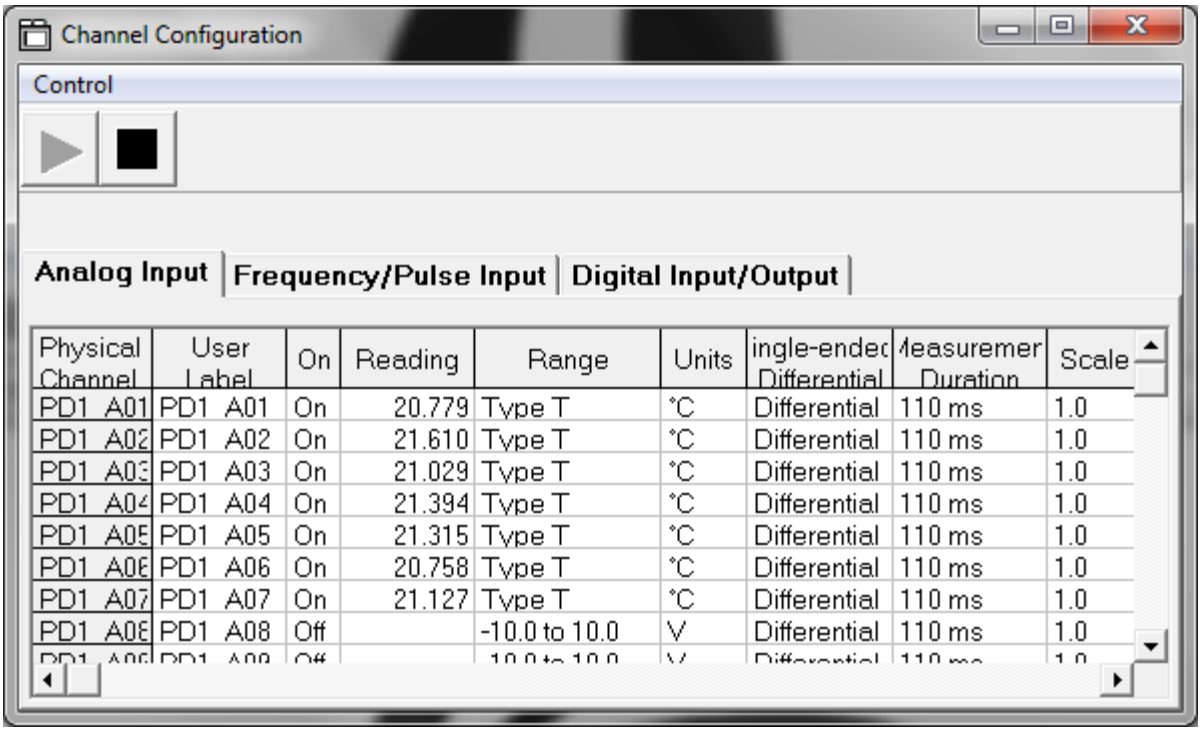
Preparation of Porcine Heart for Testing

Mass Measurement

After the heart was rinsed and trimmed of extra blood and tissue, it was weighed on a small scale at 281g.

Thermocouple Placement

Figure 57: Thermocouple Data Acquisition System



Physical Channel	User Label	On	Reading	Range	Units	ingle-endec Differential	Measuremer Duration	Scale
PD1_A01	PD1_A01	On	20.779	Type T	°C	Differential	110 ms	1.0
PD1_A02	PD1_A02	On	21.610	Type T	°C	Differential	110 ms	1.0
PD1_A03	PD1_A03	On	21.029	Type T	°C	Differential	110 ms	1.0
PD1_A04	PD1_A04	On	21.394	Type T	°C	Differential	110 ms	1.0
PD1_A05	PD1_A05	On	21.315	Type T	°C	Differential	110 ms	1.0
PD1_A06	PD1_A06	On	20.758	Type T	°C	Differential	110 ms	1.0
PD1_A07	PD1_A07	On	21.127	Type T	°C	Differential	110 ms	1.0
PD1_A08	PD1_A08	Off		-10.0 to 10.0	V	Differential	110 ms	1.0

Table 12: Thermocouple Live Feed

The data acquisition system in the Figure 57 on the previous page served as an intermediate between the thermocouples and the computer on which the data was saved. The six thermocouples visible in the image (Table 12) were placed in the heart (thermocouples 1 through 5) and in the cold water baths (thermocouples 6 and 7). The live reading in the figure above shows the thermocouple readings at room temperature.

When determining the placement of the thermocouples for testing, it was important to choose locations spaced at a sufficient distance from each other to obtain unique data without interference from the other thermocouples. Each thermocouple required a slit to be made for insertion and adhesive placed around it to keep it in place. Applying too many thermocouples in the same region would have significantly changed the thermal properties of that region. It was also important not to place the thermocouples so deep within the myocardial tissue that they puncture through to the internal chambers of the heart and are exposed to the cold water flowing inside. Such a puncture could cause a fluid leak in addition to incorrect data, as the thermocouple would be reading the water temperature and not the temperature of the heart. It was decided that even considering the stretching of the heart walls due to pressure from the pumping system, thermocouple depths ranging from 5 to 10 mm should suffice. A consistent depth of approximately 5 mm was used. Figure 58 shows the placement of the thermocouples relative to the heart.

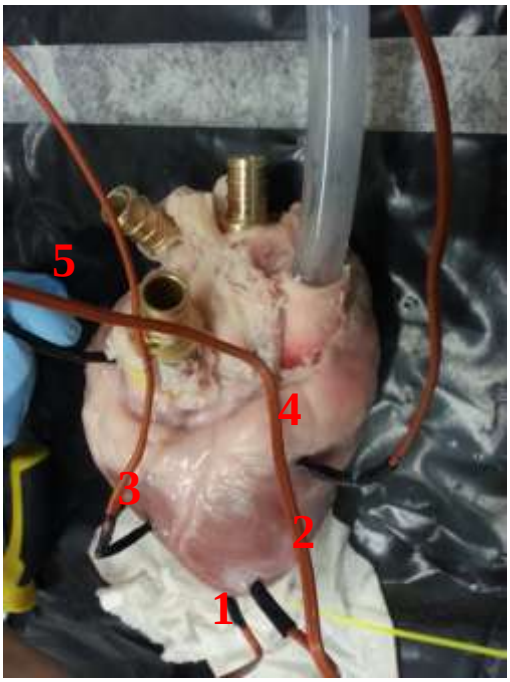


Figure 58: Combined Cooling - Thermocouple Placement

Hardware Hookup for Internal Flow

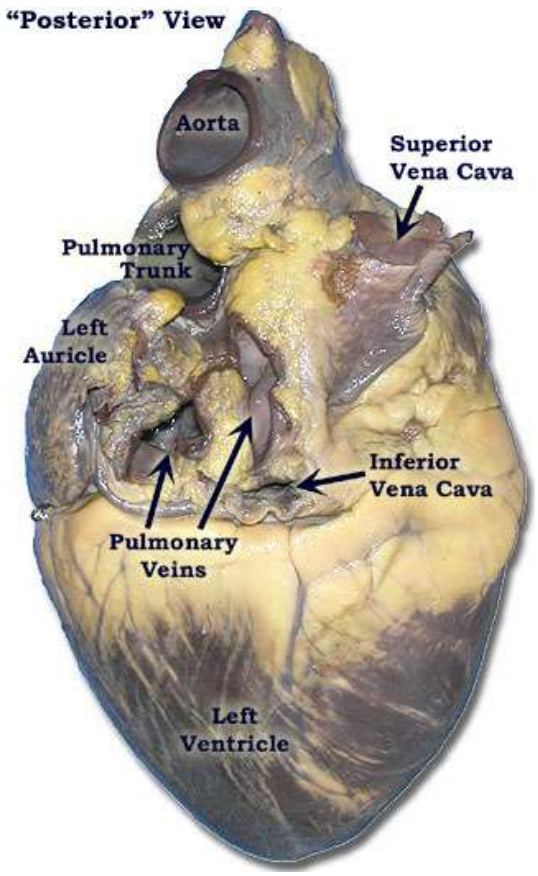


Figure 59: Labeled Porcine Heart

Figure 59 above represents what one could expect to see when they receive a pig heart from a slaughterhouse (Savalli, 2005). There are two main lines of fluid flow through the heart: one in which the blood flows from the body through the heart and into the lungs, and one in which blood flows back from the lungs through the heart and back into the body. The pumping system connects to each of these sections individually.

Unoxygenated blood enters the heart through the superior and inferior vena cava into the right atrium, through the right ventricle, and out of the pulmonary trunk to be delivered to the lungs. For our experiment, a brass fitting was adhered to the superior vena cava with super glue.

The inferior vena cava was closed shut, held again by a form of super glue – Krazy glue ™ and Gorilla Glue ™ were used. Another brass fitting was installed at the pulmonary trunk. The superior vena cava is the heart inlet for flow line 2 of the pumping apparatus, and the pulmonary trunk is the outlet. Figure 60 below illustrates this setup.

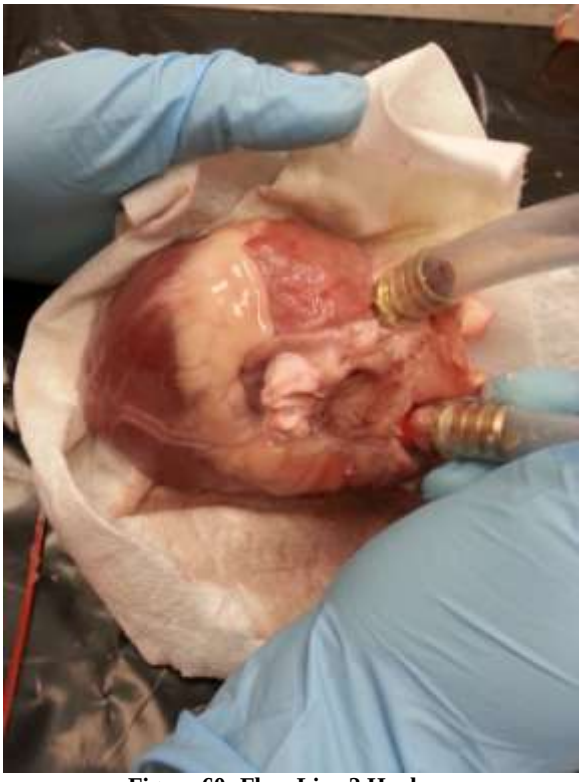


Figure 60: Flow Line 2 Hookup

When blood returns from the lungs, it enters the heart through the pulmonary veins and exits through the aorta. Again, a brass fitting was installed at one inlet (a pulmonary vein), while the other was sealed off. Another fitting was installed at the aorta, or the outlet for the left chambers of the heart. This path is connected to flow line 1, which runs at a higher flow rate, as the left chambers of the heart are larger and have a higher demand than the right chambers. Figure 61 shows the heart with all fittings and hoses attached.

Figure 61: Heart with all Hose Attachments

Due to the differences in sizes of the different major veins and arteries leading to and from the heart, different brass fittings were used at each connection to better fit the geometry of the heart. These fittings are shown in the figure below.

Figure 62: Brass Fittings

The ½” to ¾” connections (left) fit into the pulmonary vein and aorta, while the ½” to ⅜” connections (right) were fitted into the superior vena cava and pulmonary trunk.

Leak Checking

Before testing could begin, the heart had to have all inlets and outlets not attached to the hosing system sealed to prevent flow leaks. The inferior vena cava, for example, was sealed off using super glue. Super glue was the adhesive of choice for sealing the heart tissue because only a small amount of glue is needed to create a strong bond. Super glue was used during the Vietnam War for first-aid and it works well in the damp, moist heart tissue (Hayes, 2004).

There was severe leaking in the heart because of a tear through the superior vena cava, across the entire right atrium, and down into the inferior vena cava. Several measures were taken over the course of the leak check to try and correct this problem. First, the tear was super glued back together; however, the glue was not able to withstand the expansion during pumping. Next, a heart tissue graph was performed by cutting a small strip of tissue from the aorta and gluing it over the tear in the right atrium. This also proved insufficient. Finally, a section of the aorta was cut and slipped over the hosing, and then the edges of the tear in the right atrium were glued around it. This progression is shown in Figures 63-64. After those figures, there is an additional image of other leaks found on the heart (Figure 65).

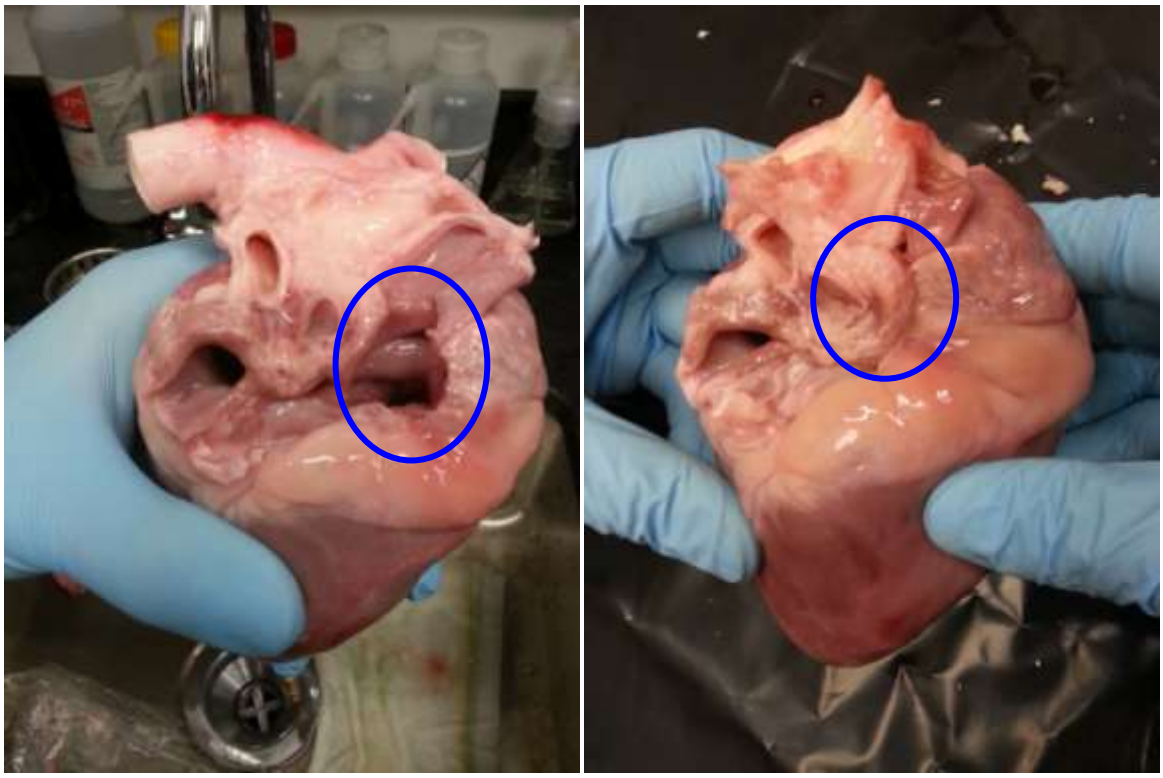


Figure 63: Large Lesion Visible in Right Atrium and Sealing with Glue

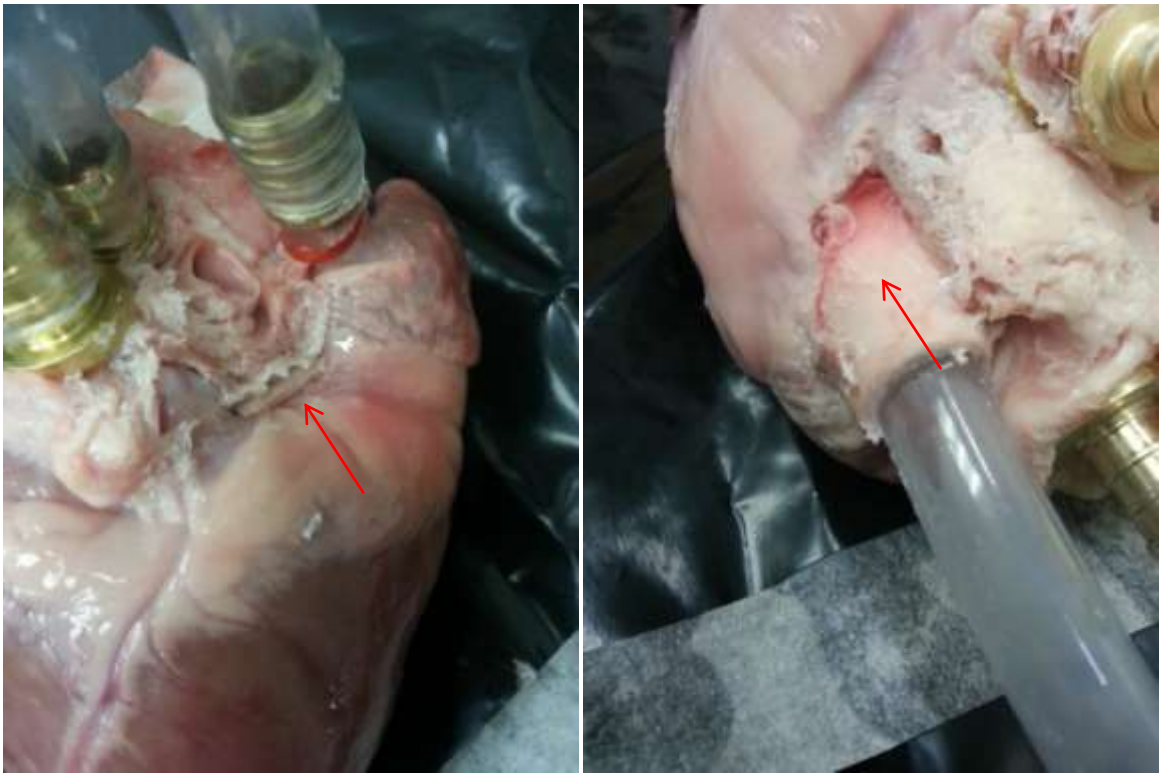


Figure 64: Left – Patches from Aorta used in Sealing Large Lesion after Glue Failure

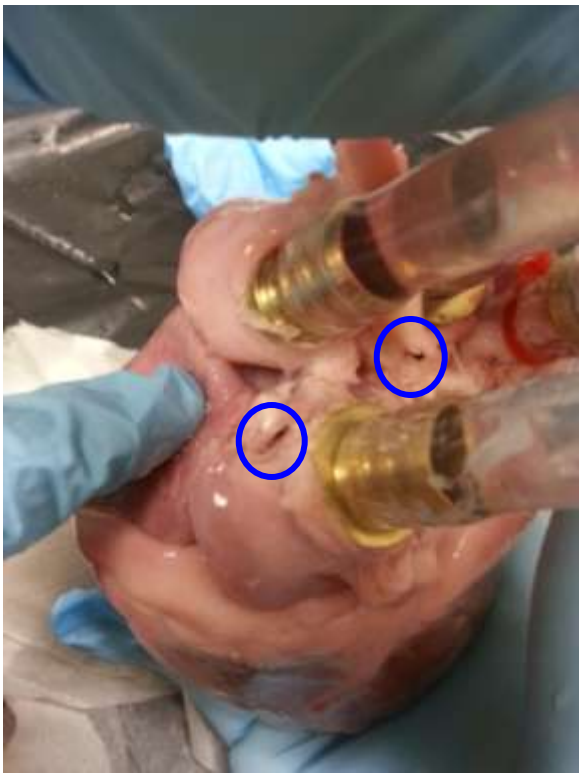


Figure 65: Leak near Pulmonary Trunk (left) and Aorta (right)

It should be noted that several leaks developed over the course of testing for flow continuity. The super glue was suitable for only closing small openings. Larger openings required either a patch and adhesive or a zip-tie. It took over nine hours to successfully seal the heart shown in Figures 63-65.

Porcine Heart Testing

Once the heart was correctly connected to the pumping apparatus and checked for major leaks, it was submerged into an ice water bath in a two chambered system. We were unable to successfully seal the heart from all leaks, but steady flow through the apparatus was achieved. The pumping system was left on for 75 minutes while the data acquisition system recorded temperature data. Ice was added to the reservoir chamber at fifteen minute temperatures to ensure steady, cold operating conditions. Figure 66 shows the heart within the cooling system. A double chamber was used since the inner chamber is smaller and elevated to minimize the tension on the heart and keep it isolated from the inlets and outlets of them pump. The outer chamber serves to help insulate the inner chamber and ensure a more uniform, cold surrounding for the heart.

Figure 66 shows the heart and a thermocouple that became loose. Figure 67 shows the pump set up used.

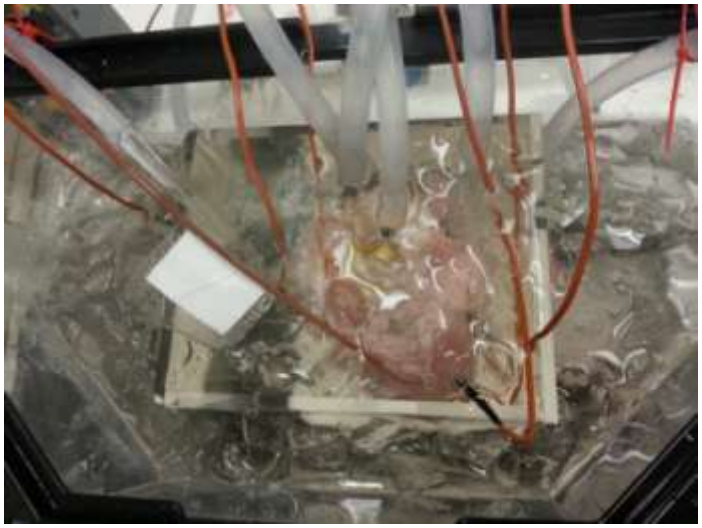


Figure 66: Heart within Two-Chamber System

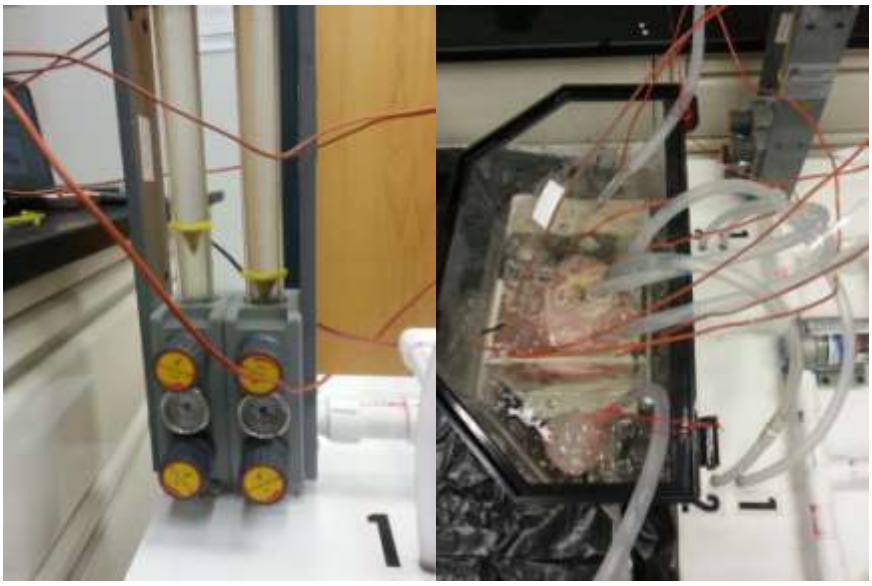


Figure 67: Flow Meter (left) and System Configuration (right)

There was unsuppressed leaking in the heart, but steady flow was established through both flow lines, so the test was still able to be conducted. In Figure 68 below, there is visible turbulence on the surface of the water due to a fairly large leak around the aorta.

Figure 68: Turbulence in Water due to Leak

Data and Results

For the combined cooling test, the flow meter measured channel one's flow rate to be 2.55 liters per minute and channel two to be approximately 0.75 liters per minute. After calibration, the actual flow through channel one and channel two are 3.19 liters per minute and 1.20 liters per minute, respectively, which is under our maximum flow rate specifications.

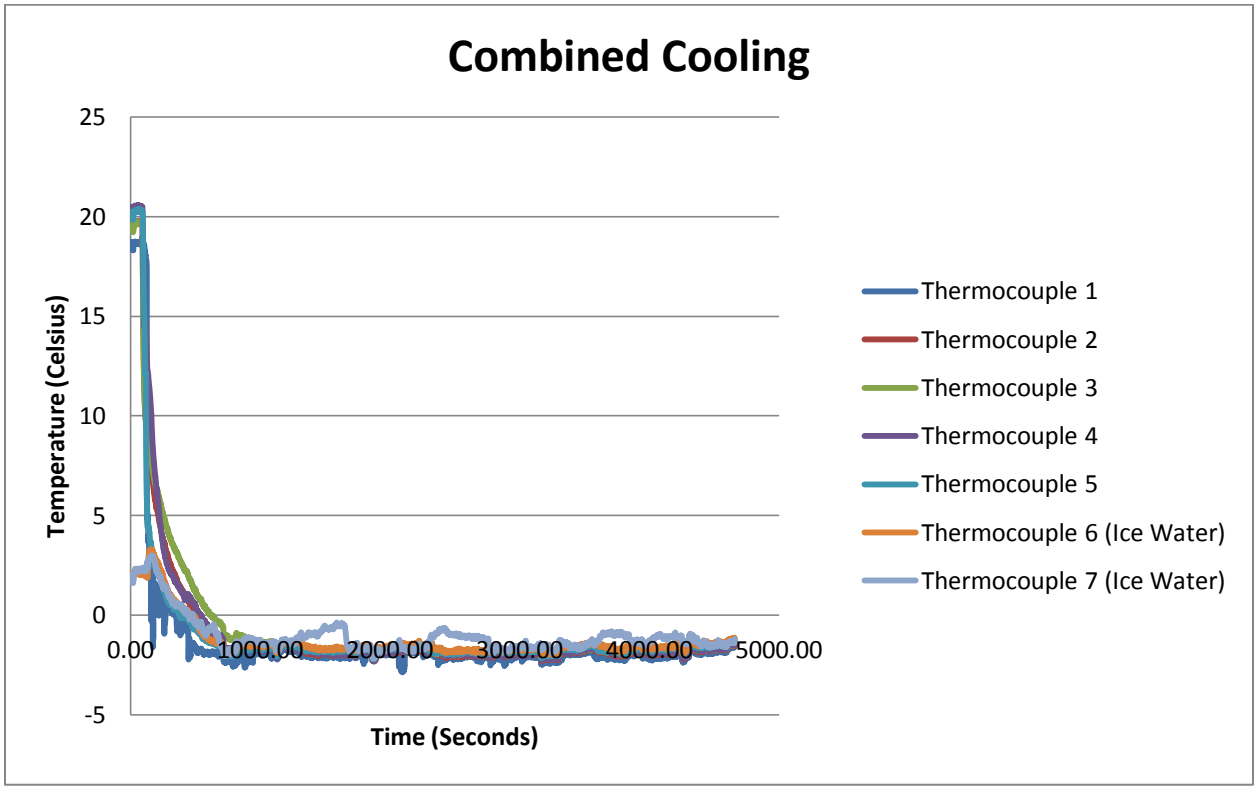


Figure 69: Combined Cooling - Entire Test

Figure 69 suggests the time needed for the heart to reach roughly zero degrees is 1000 seconds. However, the possibility of leaking is high and presents challenges in directly confirming computational results. Thermocouple 7 seems to have touched the wall around 1800 seconds and 2500 seconds increasing its temperature and then resettled in its original position. This shift may have occurred during the addition of ice. An analysis of the first five minutes follows in Figure 70.

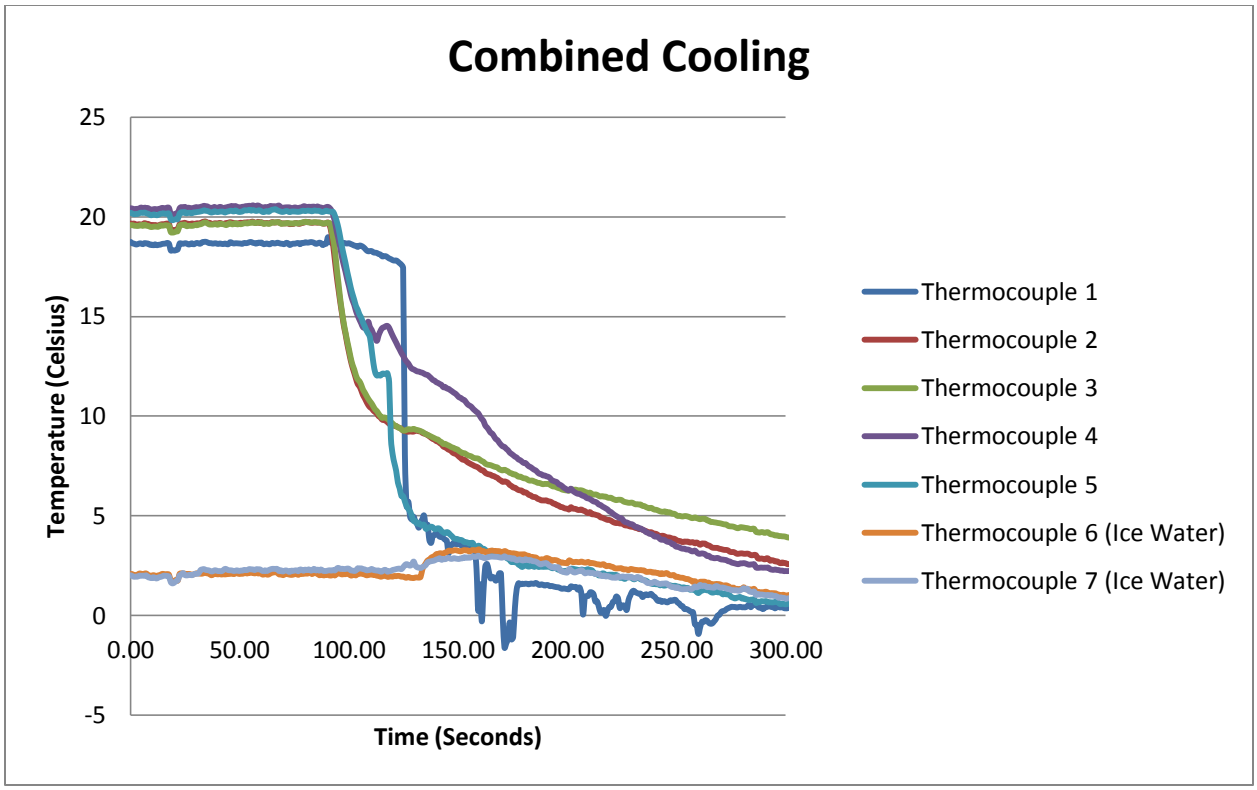


Figure 70: Combined Cooling - First Five Minutes

Considering the first five minutes shows that the drop is much too dramatic between 100-150 seconds. During the first one hundred seconds of the test, the heart was still suspended above the cold water and the pump was not turned on. The heart was then placed within the chamber and the pump was started. A rapid decrease in temperature ensued that is not likely due to tissue readings alone. The most likely cause for this temperature decrease is that cold water rushed into small gaps around the thermocouples that were generated through the expansion of the heart due to the pump. This water rapidly cooled the sensor while slightly heating up because of the tissue. For this reason, it is likely that the steadier slow drop from 10 deg Celsius to 0 deg Celsius for some of the thermocouples was the cooling within the pocket of water around them.

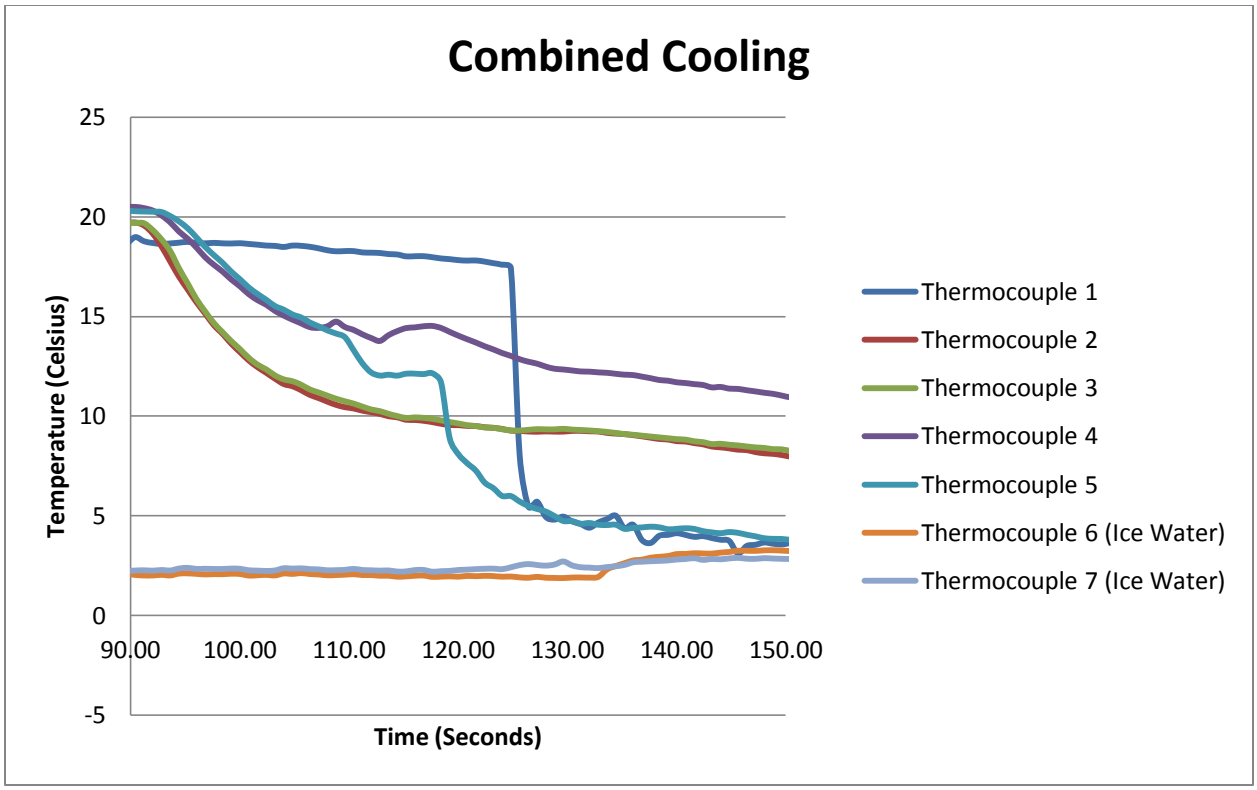


Figure 71: Combined Cooling - First Minute of Exposure

Figure 71 shows that cooling patterns were very sporadic for the first minute of submersion and internal perfusion. Sharp drops in temperature are recorded for two of the thermocouples. This suggests that the method of sealing the thermocouples was not always sufficient to block out the water. If the method was not always sufficient, then it is possible that even for the steadier graphs, unwanted effects of direct water contact were recorded. Unfortunately, none of the data can be proved to be exclusively from the tissue and not from the cooling water.

Sources of Error

There were several factors that contributed to the inconclusiveness of the test results. The first and largest source of error is in the thermocouples. When the thermocouples were first embedded into the heart, a small slit was made through the pericardial tissue and the thermocouples were inserted to their proposed depth. They were then secured with super glue. This setup resulted in several problems: susceptibility to the effects of expansion, inaccurate placement, and the opportunity for leakage. As stated earlier, the depth of the thermocouples is significant because placing the thermocouples too deep could rupture the heart chambers and cause leaking and invalid data. An effect that was not considered, however, was the degree of expansion. While the hearts were attached to the pumping apparatus they underwent massive expansion; the chamber walls stretched and thinned, making the effective thermocouple depth more shallow than intended and straining the glue bonds. This allowed water to enter the incisions and flow around the tips of the thermocouples. In one case, a thermocouple was completely dislodged from the heart.

Another major problem with the cooling system was the propensity towards leaking. Even without unexpected damages to the heart during the butchering process, such as the tear to the right atrium of the heart, there was still a lot of modification to be done to prepare the organ for implementation in the cooling system. All of the minor arteries and veins that had been cut had to be sealed. Some of the smaller blood vessels were hard to locate before leak-checking the system, and there was always the chance that a poor sealing job would result in the reopening of the sealed vessel. There was also the possibility of a bad seal between the brass fittings and the vessels. This is especially important when you consider that all hearts have slight differences in size and geometry, yet standard size fittings were used. There was no guarantee of a perfect fit.

Significant leaks could lead to improper flow rate readings and cause the test results to vary drastically with the computer simulated model.

A final source for error is in the cooling system itself. Even if a good seal is achieved between the heart's vessels and the brass fittings, there will be discrepancies between the computer and physical models. In the computer model, there is a clean starting plane for the inlet flows, but even under the best conditions, the starting position for the flow on a real heart using the methods described throughout this paper would be inconsistent between trials. Another source of error inherent in the system is temperature fluctuation. In the combined cooling trials, temperatures were kept near freezing by periodically adding ice to the reservoir tank. In a computer system, however, the input temperatures for simulation are constant.

Conclusions

- The experimental set up is not sufficient to validate any computational models since flooding likely occurred on all the thermocouples rendering temperature measurements unusable.
- The system can adequately pump water through porcine hearts and cool them internally and externally.
- Flow rates can be accurately approximated and controlled through both inlets and outlets of the pump apparatus.
- If flooding is stopped, the thermocouples would be able to yield meaningful values for computational comparison.
- The pump apparatus can run constantly for over an hour.
- The pump system can successfully attach to porcine hearts in an average adult human size range.

Recommendations for Future Improvements

Since testing failed because of the thermocouples, our strongest recommendation for future improvement is the implementation of finer and more precise thermocouples that can be adequately sealed. Ideally, the thermocouples used would be thin enough to pierce the pericardium without using a razor, and would stay imbedded within the myocardial tissue with minimal or no adhesive. This would greatly mitigate the risk of the thermocouples picking up readings from the cooling fluid instead of the myocardial tissue.

Another area in which major improvements could be made is in the interface between the cooling apparatus and the heart. A better design for the interface between the testing apparatus and the heart would be extremely beneficial because it would prevent leaks and make the device more user-friendly. Ideally, the interface would consist of flexible fittings that could adjust to any size valve with a strong seal. This would help ensure proper flow throughout the heart. In the same vein, a more accurate measurement and simulation of flow could be achieved if the more minor blood vessels, such as the inferior vena cava and unused pulmonary veins, were also fitted to the pumping system for fluid flow.

A third area for improvement would be the development of a sophisticated controlled temperature system in which fluid conditions could be kept as stable and homogenous as possible. This would result in more uniform cooling and better correlation to simulated results.

Finally, this project would benefit from a larger test sample size so that extraneous data could be ignored and strong trends could be analyzed in a meaningful way. The team spent much time developing an artificial heart, but porcine hearts are superior and much cheaper while giving the best approximation of the human heart possible. By the time porcine testing began, there was only enough time to test on a single sample before the deadline of this report.

Success Meeting Design Objectives

The project objectives were:

1. Construct an approximate geometric model of the human heart from a material which emulates its thermal properties accurately.
    - The use of a manufactured model is ideal because the material properties would be homogenous throughout the model, which would be consistent with the computer model being used as reference.
    - If a heart cannot be successfully manufactured, a pig heart will be used. Pig hearts are very similar to human hearts but are not as easy to predict computationally.

2. Develop a testing apparatus suitable for housing the model heart. This apparatus will include the pump, containers, hoses, and attachments of the cooling system, and thermocouples and flow meter necessary to track the temperature and flow rate of the cooling fluid through the model and temperature of the model itself at various points.

3. Test the artificial (or animal) heart with external cooling alone and with internal and external cooling together, and compare results first to each other, and then to data gathered from similar studies done on computer models.

The purpose of Objective 1 was to find or construct an adequate heart or heart model to test on. This was completed through the use of a porcine heart after taking the required training courses and receiving the proper approvals for animal tissue testing.

The purpose of Objective 2 was to design a system that could produce internal and external cooling which could monitor and control flow rates and measure temperatures. This was completed through the design and construction of the pump apparatus.

The purpose of Objective 3 was to test on the system alone and comparae results to computational calculations. This was partially completed through the three trials consisting of external cooling alone and combined cooling. While the tests were conducted, they were not able to be compared with computer simulations.

Project Management

Timelines

Below in Tables 10-12 the different predicted timelines throughout the course of project are presented.

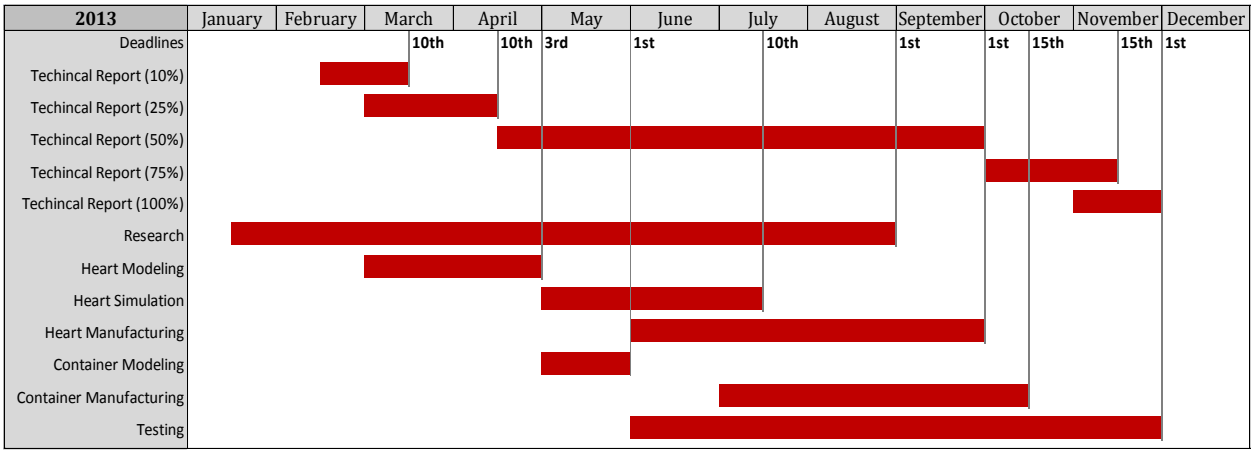


Table 13: Project Timeline (Initial Estimation)

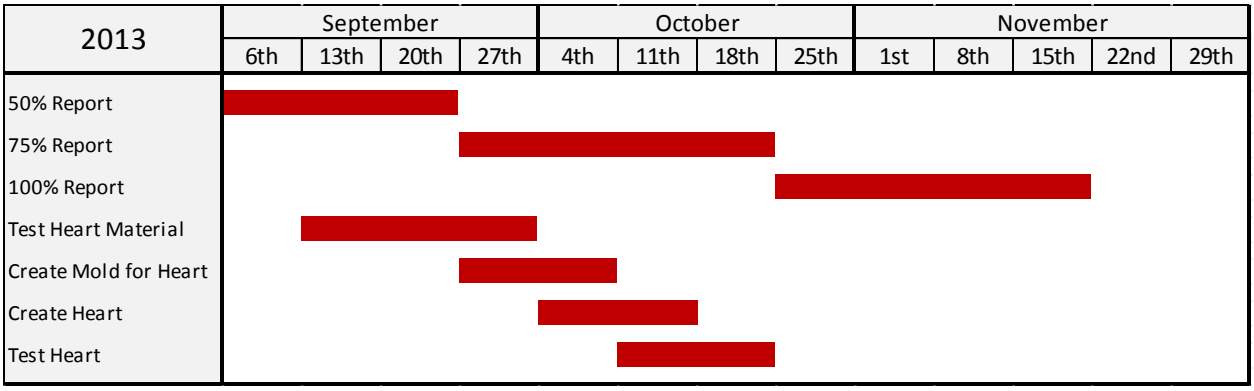


Table 14: Project Timeline (Second Estimation)

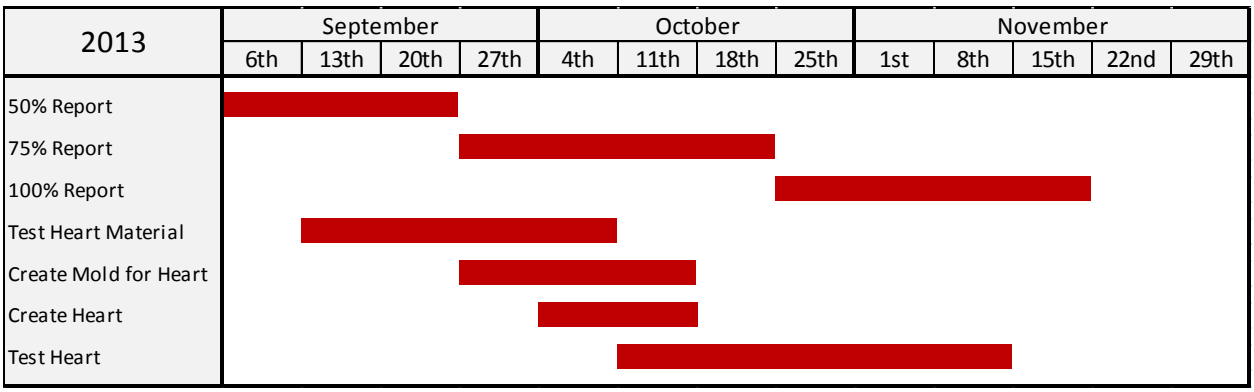


Table 15: Project Timeline (Current Estimation)

Comments Concerning Project Timelines

For the most part, the team has stayed on course to finish on time with the project. Some aspects of the project were reconsidered during the summer as a response to suggestions from the IAB and Professor Dulikravich, our advisor. The team decided to focus on the thermal aspects of the heart only, and not include other aspects such as mechanical tests that would have monitored pressure and deformation. It was not possible to complete all of those tests within budget and schedule constraints. Also, the team was no longer to perform computer simulations, but to compare tests results with a simulation already prepared by Mr. Abas Abdoli. These simplifications to the project were necessary and natural as engineering projects often must be reevaluated and redefined.

The one major change from the second estimation to the third was the setback in testing since the artificial heart failed. The team manufactured and was ready to test the artificial heart on October 20th 2013. Had all things gone well, the testing phase of the project would have been complete and the team would have stayed on schedule. Now that a pig heart was tested, further research was needed prior to testing. The research was not as burdensome as the one required for the artificial heart, but certain new steps were taken. The team was approved to test on animal tissue and undergo the required trainings. This took 2-3 weeks and forced the team to test right before the final senior report was due. In summary, the necessity of testing on a pig heart set the team behind a month. Even so, the team finished the project on time, albeit with a much smaller sample size than desired.

Breakdown of Responsibilities

To date, each member of the team has logged approximately 250 hours of work on this project. Tables 13 and 14 show the breakdown of responsibilities and their changes.

Tasks	Rebekah Santana	Patricia Matthews	Marcelo Torrentes	Rafael Sanz
Modeling				
Research				
Fabrication				
Design				
Material Selection				
Simulation				
Fundraising				
Record Keeping				
Testing Apparatus				

Table 16: Breakdown of Responsibilities (Original)

Tasks	Rebekah Santana	Patricia Matthews	Marcelo Torrentes	Rafael Sanz
Material Manufacturing				
Material Testing				
Mold Design				
Testing Apparatus Design				
Testing Apparatus Construction				
Testing Apparatus Validation				
LabVIEW				
Heart Manufacturing				
Heart Testing				
Data Analysis				

Table 17: Breakdown of Responsibilities (Updated)

Comments Concerning Breakdown of Responsibilities

As different work has needed to be done at different stages, responsibilities were also changed. As previously mentioned, simulations were no longer necessary on behalf of the team. Thus simulations were removed. Each member contributed to the data analysis so that each person provided their own insight and made their own observations.

Cost Analysis

Sources of Cost

Over the course of the project there have been four major sources of cost. The first source of cost was presentation materials. During the development of the design several reports, summaries, and a poster were printed. Travel costs are also a significant source of cost. Third, prototype costs were slightly under budget but still significant. Over $1000 was spent by the team on materials and fabrication. Had certain equipment not been lent to the team or free assistance been given, the team would have ended even further over budget than it did.

Design Cost

Design costs usually consist of overhead costs and salaries. Since this team is composed of students, the costs can be considered time costs exclusively in terms of how many man hours each team member put in. The man hours were listed in terms of research, modeling, testing, report writing, and presentation preparation and delivery.

Prototype Cost Analysis

There are two essential prototypes for this project: the heart and the testing apparatus. A general overview of each is considered in this section and specifics are presented the “Expenses to Date” table.

The attempted synthetic heart generated three primary sources of cost. First a replica heart was purchased in order to be used as a mold for the exterior of the heart. Several hearts were available for purchase, some even for hundreds of dollars, but for the sake of this project, only an accurate exterior was needed. This allowed the team to find a relatively inexpensive model heart that was used only for its exterior and for approximation of the inner chambers. The fine intricacies were insignificant since the model was used in a mold which would not have

been able to catch every minute detail. Second, the mold supplies such as the putty, acrylic side panels, and agar gel were also expenses. In addition, the 3-D printed interiors were expensive and some were destroyed in the process of fabrication. Both sets were originally priced at $120 dollars, but were reduced to $90.00 dollars after one chamber contained a defect. The porcine hearts eventually used for testing cost $10.00 apiece.

The testing apparatus had several expenses. A pump was purchased in addition to several hoses, fittings, valves, containers, flow meters, and other miscellaneous items. It was originally planned to use a variable speed pump for ease of flow control. An alternative was chosen that significantly lowered cost and was equally effective. A constant speed pump was placed in a recycling piping system from which flow could be released by a valve and controlled in that manner. Substituting a simple pump for the variable speed pump cut the price by approximately two-thirds. The pipes and hoses were made of the cheapest options available since pressures will be minimal and a complex analysis of the piping system is not essential for this project. What was of primary importance was that the temperature of the fluid entering and exiting the pipes is recorded so that a careful study of temperature profiles can be carried out. As for the fluid being used in the testing apparatus, it was simply an ice-water solution. The ice-water solution was adequate as cooling is the only property required and the current method of transporting hearts for transplants is simply an icebox. For this reason, using ice-water in the testing apparatus allows for a closer comparison between the current method and the method being tested– internal and external cooling.

Travel Costs

Travel to and from school to work as a team was a significant source of cost, as each member lives an average of forty minutes away. Occasionally, the team had to meet at a certain member's house which resulted in some other members driving an hour and a half. . Each time the team met, a total of approximately $32.00 dollars in fuel was spent, not including tolls

Funding and Assistance

There was no direct funding given to the team for the completion of the project by any outside sources. It was difficult to sell this project since it is very preliminary in nature. There was assistance, however, in terms of equipment. A magnetic stir rod was lent by the biology department; Temperature measurement equipment, roughly $1000 in cost, was lent to the team for usage by the mechanical engineering department; AMERI granted use of a Microflash 300 thermal diffusivity and conductivity tester as well as their laboratories; and Cordis offered to lend equipment if necessary. Mr. Zicarelli, director of the manufacturing center, offered free consultation and low prices for 3D prints. Several friends offered assistance in locating equipment online and generally offering a helping hand. Without the assistance the team received, the project would not have gone nearly as well as it did.

Projected and Actual Costs

Tables 15-18, shown below, contain information pertaining to original time and money cost estimates and actual time and money costs to date.

Category	Task	Time (hours)	Category Total
Research and Design	General Heart Research	80	440
	Heart Mechanical Properties Research	40	
	Heart Thermal Properties Research	40	
	Artificial Heart Manufacturing Research	30	
	Material Research	50	
	Research of Testing Methods	40	
	Conceptual Designs	30	
	SolidWorks Modeling	30	
	Comparison of Designs	10	
	Heart Container Research	30	
	Heart Container Design	20	
	Heart Design Completion	20	
	Container Design Completion	20	
Analysis, Assembly, and Testing	Computer Simulations	25	175
	Assembly of Heart and Container	30	
	Test Probe Placement and Testing	20	
	Physical Testing	40	
	Analysis of Data	40	
	Testing Completion	20	
Reports and Presentations	Senior Reports	80	150
	Presentations & Rehearsals	30	
	Engineering Drawings	20	
	Poster	20	
		Total Time	**765**

Table 18: Original Projected Time Cost

Category	Task	Time (hours)	Category Total
Research and Design	General Heart Research	80	613
	Porcine Heart Research	3	
	Heart Mechanical Properties Research	50	
	Heart Thermal Properties Research	50	
	Artificial Heart Manufacturing Research	50	
	Material Research	55	
	Research of Testing Methods	65	
	Conceptual Designs	45	
	SolidWorks Modeling	60	
	Comparison of Designs	30	
	Heart Container Research	35	
	Heart Container Design	25	
	Heart Design Modifications	20	
	Container Design Modifications	45	
Analysis, Assembly, and Testing	Obtaining Tissue Use Approval	16	178
	Assembly of Model Heart and Container	40	
	Test Probe Placement and Testing	36	
	Physical Testing	44	
	Analysis of Data	7	
	Testing Optimization	35	
Reports and Presentations	Senior Reports	65	110
	Presentations & Rehearsals	25	
	Engineering Drawings	5	
	Poster	15	
		Total Time	901

Table 19: Actual Time Cost to Date

Some differences occurred between the predicted time cost for the design project and the actual time worked on the project. Several hours were spent working on different variations of the pump apparatus and consulting with manufacturing and materials on methods on how to produce the synthetic heart model.

Project Section	Item	Cost
Materials and Components	Heart material (Polymer/Gelatin/Plastic)	$100.00
	3-D Printing	$300.00
	Thermistors	$20.00
	Clamps	$10.00
	Tubing	$20.00
	Electrical Wiring	$20.00
	Coolant (Water or Saline Solution)	$5.00
	Polycarbonate Sheets	$20.00
	Pump	$100.00
	Power supply (salvaged)	$0.00
Report and Presentation	Poster	$80.00
	Reports	$20.00
	Miscellaneous (props, supplies, etc.)	$10.00
	Projected Total Cost	**$705.00**

Table 20: Projected Monetary Cost

Project Section	List of Materials			
	Component	**Quantity**	**Unit Price**	**Subtotal**
Pump System and Testing	1 Gallon distilled water	1	$1.29	$1.29
	1/2" x 3/8 in Pex Brass Coupling	1	$3.77	$4.03
	1/2” OD x 3/8” ID x 20’ Vinyl Tube	1	$6.26	$6.26
	1/2” x 2’ PVC Pipe	1	$1.14	$1.14
	1/2” x 3/8” PEX Brass Reduction Coupling	2	$1.88	$3.76
	12V Marine Utility Pump	1	$37.99	$37.99
	2” PVC Bushing	1	$1.97	$1.97
	3/16 x 1/4 Brass Adapter Barb x MIP LF	1	$5.60	$5.99
	3/4 x 1/2 in Pex Brass Coupling LF	1	$1.98	$2.12
	3/4" PVC Male Adapter	2	$0.46	$0.92
	3/4" SGL Union Ball Valve	1	$8.54	$8.54
	3/4" x 1/2" MPT Brass Male Adapter	3	$2.23	$6.69
	3/4" x 2’ PVC Pipe	1	$1.34	$1.34
	3/4” Gate Valve	3	$8.39	$25.17
	3/4” PVC Female Adapter	1	$0.47	$0.47
	3/4” PVC Female Adapter	4	$0.47	$1.88
	3/4” PVC Male Adapter	2	$0.46	$0.92
	3/4” PVC Tee	1	$0.47	$0.47
	3/8” OD x 1/4" ID x 10’ Vinyl Tube	1	$2.69	$2.69
	3/8” x 3/8” Barbed Fittings	2	$1.89	$3.78
	7/16"-1/2" Fuel injection hose clamps	1	$2.99	$2.99
	8 oz PVC Cement/Primer COMBO	1	$8.00	$8.00
	Acetone	1	$1.99	$1.99
	Alkaline 9V Battery	1	$6.99	$6.99
	Blue Nitrile Gloves 10 Pk - FG	1	$5.14	$5.50
	Electrical Tape	1	$1.99	$1.99
	Flow SysMatic Water Flow Regulator	1	$69.00	$69.00
	FQ Utility Knife	1	$5.79	$6.20
	Gorilla Glue Super Glue	1	$5.97	$6.39
	Krazy Glue	1	$3.49	$3.73
	Pig Hearts	1	$10.00	$10.00
	PTFE Thread Seal Tape	1	$1.47	$1.47
	TOKYO BBK05002 Water Flow Meter	1	$56.75	$56.75
	Zip ties	1	$1.37	$1.37
Synthetic Model	3D Prints of Heart Chambers	1	$95.00	$95.00
	7”x5”x3” Projection Box	1	$7.49	$7.49
	Acrylic Sheets	1	$23.48	$23.48
	Acrylics sheets	1	$30.01	$30.01
	Agar powder, Reagent Grade 100 g	2	$29.58	$59.16
	Heart model	1	$36.21	$36.21
	Molding Clay	1	$18.82	$18.82
	Rubbermaid Food Storage Container	1	$3.29	$3.29
	Silicone	1	$35.05	$35.05
	Urethane Casting Solution	1	$55.81	$55.81

Miscellaneous	80 mm Long Life Bearing Case Fan	1	$3.99	$3.99
	9V Bat Clips	1	$2.99	$2.99
	Micro Magnet	1	$2.99	$2.99
	Panasonic CR2450 Battery	1	$3.80	$3.80
	SPST Rocker Switch	1	$3.49	$3.49
Report & Presentation	Poster	2	$168.00	$336.00
	10% Report	1	$2.40	$2.40
	25% Report	1	$3.00	$3.00
	50% Report	1	$10.00	$10.00
	75% Report	1	$12.50	$12.50
	100% Report	1	$16.50	$16.50
		Current Total Cost		$1,061.77

As the team has reached the end of the design project timeline, all of the main components have been purchased and steps were taken to reduce costs through design iterations and obtaining valuable connections with third party resources. In attempting to reduce costs, some major successes were made. One area where cost was reduced was in redesigning the pump apparatus from using a variable speed pump that can cost up to $200 to implementing a single speed utility pump which costs about $40.00. The thermocouples and electrical wiring were also provided to the team by the mechanical engineering department at Florida International University for the thermal study the test heart. The donation of the temperature measurement equipment was the greatest reducer of cost as the entire system with licenses would have cost $1000.00.

Unexpected costs arose during the course of the project such as the magnetic stirrer and extra, unused mold materials. Essentially, the entire design of the artificial heart was a major expense that could have been avoided had the team known it would fail. Unfortunately, such things cannot be discovered until they happen. Regardless, valuable information and learning was accomplished in the design of the artificial heart.

As of today, total costs have reached approximately 152% of the projected costs estimated at the start of the project in April of 2013. That means that the team has surpassed the original budget for the project. It was expected that the budget may be passed and the absolute limit was decided to be $1000.00 which is a cost of $250.00 per team member. The team completed testing just under this budget, but the final costs of printing the final report and a second poster amounted to $184.50. Figure 78 shows the final makeup of expenses.

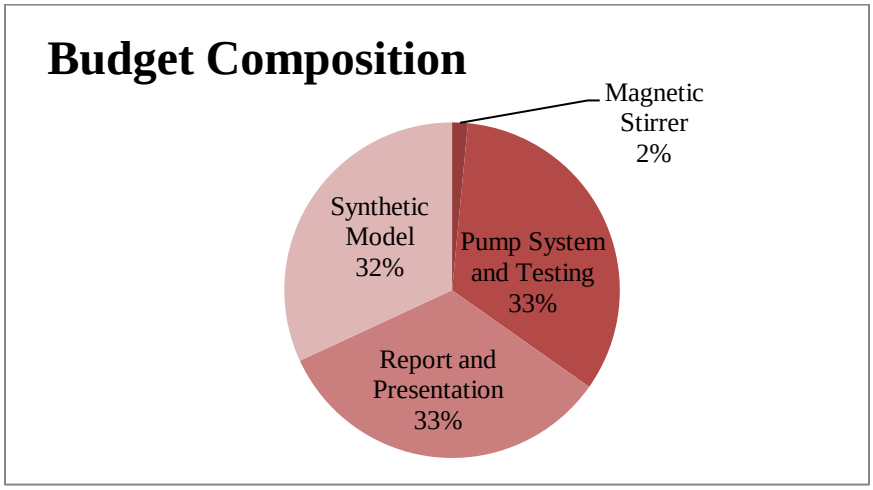


Figure 72: Budget Composition

Final Remarks

The team is satisfied with the outcome of this ambitious senior design project. This biomedical project was chosen out of interest in learning more about the cardiovascular system and for the challenge in first learning about something new and then designing accordingly. Throughout the various phases of the project, much was learned about the human cardiovascular system, pump systems, thermocouples, data acquisition system, and mold making. While we would have loved to be able to verify the computer model, we are pleased with the progress we did make on a limited budget in terms of time and finances. We are grateful to FIU for our education and for the opportunity to work on such a project as this one.

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