Watchman Procedure Heart Catheter Trainer

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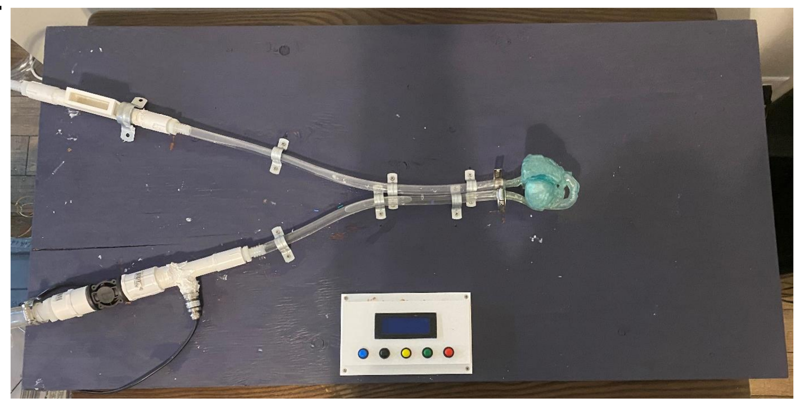
Introduction and Motivation

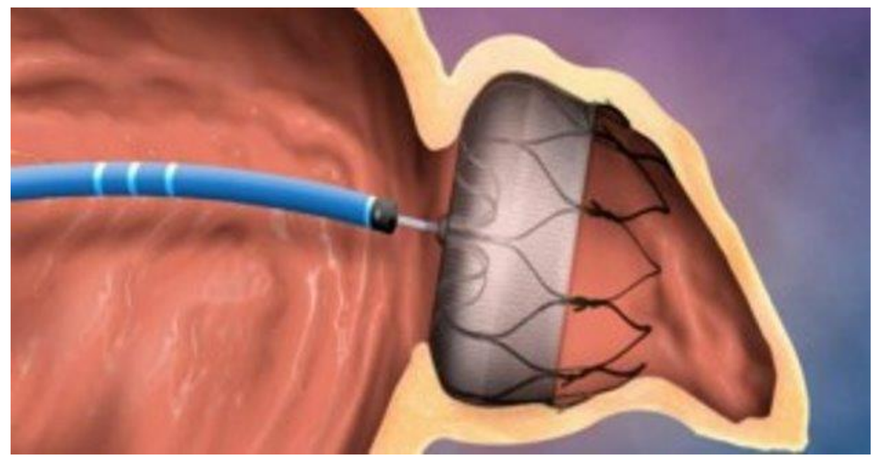
The purpose of the project is to create a trainer for the Watchman atrial occlusion procedure for Parkview Health. This procedure helps to minimize the risk of blood clots forming that eventually cause strokes in patients with atrial fibrillation. Currently, there are some digital trainers which offer little customization of the procedure as well as physical trainers that can cost upwards of $20,000. The team used 3-D modeling software to edit hearts to fit the apparatus and an Arduino driven pump system able to create pulsatile flow.

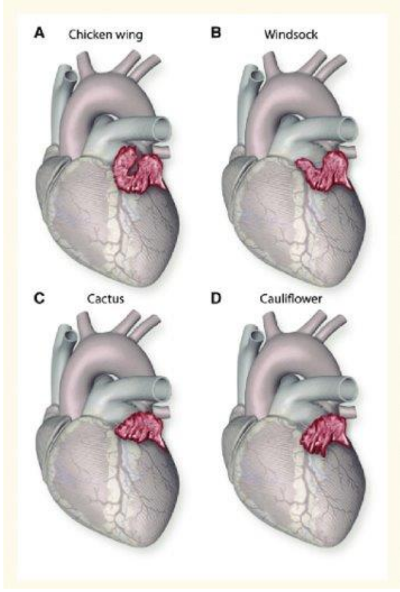
The device utilizes a set of vinyl and PVC pipes to mimic the vasculature of the aorta and vena cava. The heart itself is from a scan of a patient's heart resulting in a detailed mesh. The heart was then edited using a variety of different 3-D modeling software's in order to incorporate the heart into the piping. Pulsatile flow is used to mimic the beating of the heart. Flow is driven by a piston pump driven by a NEMA 34 stepper motor controlled by an Arduino microcontroller. The microcontroller also takes inputs from a flowmeter and water pressure sensor. These values are then fed to an LCD display with adjustable units. The microcontroller also allows for different pulse settings to create varying heart rates for the trainer. The device has also left space on the apparatus and within the program to allow for modifications to be made for practice different procedures.



Watchman Procedure

Atrial Fibrillation (AF) is a common arrhythmia affecting over 33 million individuals worldwide. [1] A common treatment for AF utilizes the Watchman catheter device to close the left atrial appendage (LAA) reducing symptoms attributed to AF including strokes. Parkview Health has tasked the design group with creating a heart catheter trainer for the Mirro Center of Research and Innovation. The trainer will allow for new physicians to be trained on the procedure as well as experienced physicians to practice for upcoming procedures.

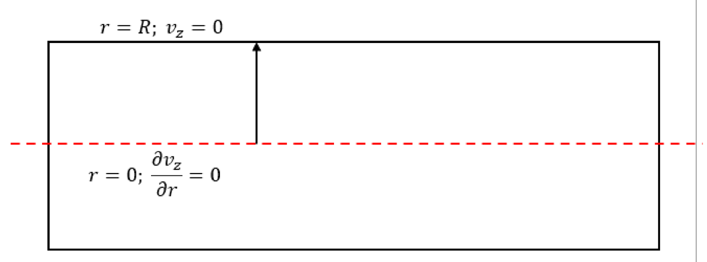




Left atrial occlusion is a procedure in which the LAA is closed off using devices delivered via catheters inserted through the right femoral vein, passing through the inferior Vena Cava into the left atrium where a transeptal puncture is used to pass the catheter into the left atrium and LAA. [3] [4] The Watchman Left Atrial Appendage System is a device designed to close off the LAA by establishing a porous membrane across the LAA opening that promotes cardiac tissue ingrowth. [4] [2] These shapes include chicken wing (A), cactus (C), cauliflower (D), and windsock (B). [5]

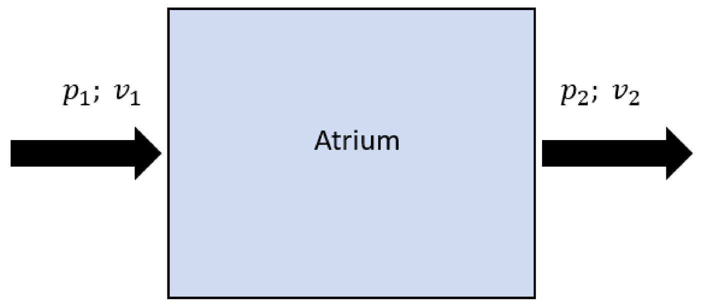
Mathematical Model

Vessel model:
Assumptions:
- Pseudo-steady state
- Oscillating flow
- Cylindrical coordinates
- Incompressible fluid
- Newtonian fluid
- Fully developed flow
- Edge effects neglected
- Laminar flow
- No external forces
- No-slip boundary condition



$$v_z = \frac{\Delta p R^2}{4\mu L}\left(1 - \left(\frac{r}{R}\right)^2\right)\cos(\omega t)$$

Atria model:
Assumptions:
- Steady State
- Incompressible fluid
- Newtonian fluid
- No external forces

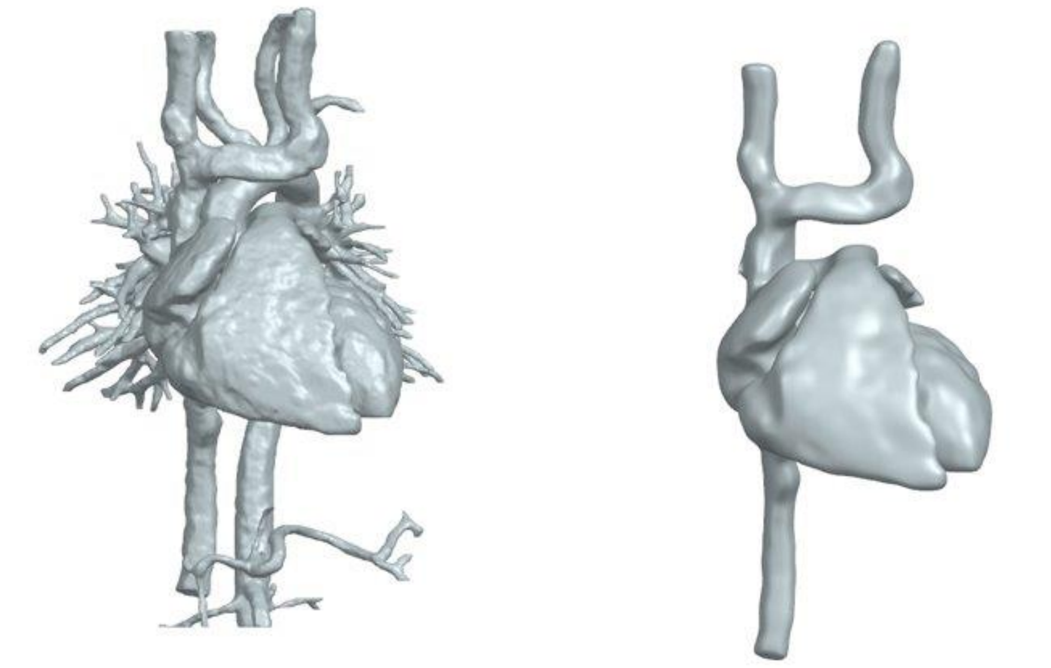


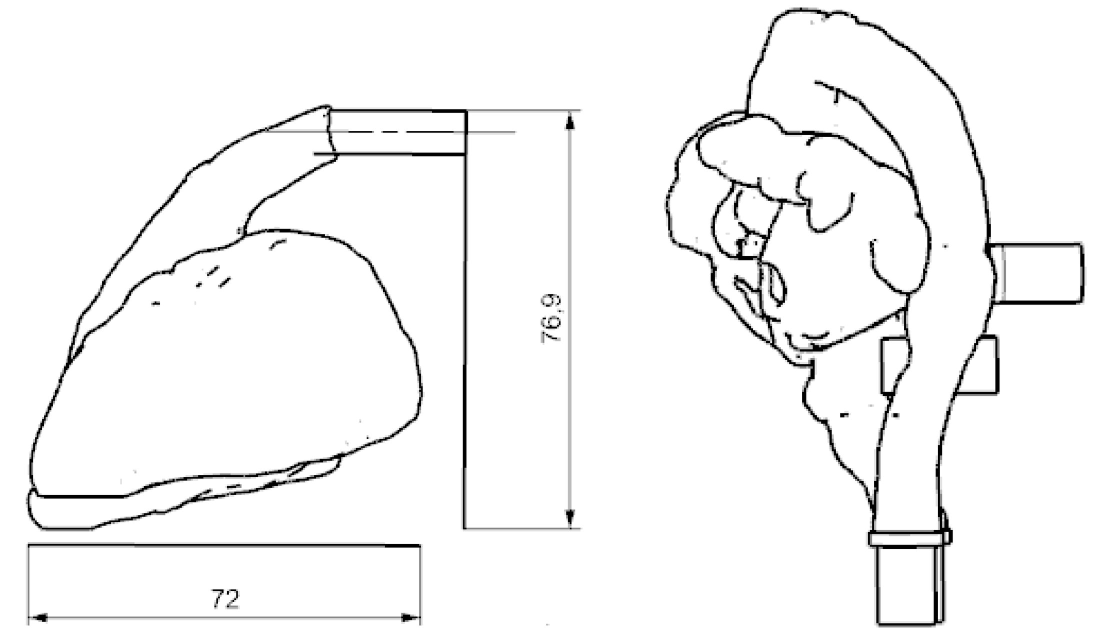
$$\Delta p = -\frac{\rho}{2}\left(v_2^2 - v_1^2\right)$$

Mathematical models such as those shown above are used in software processes such as FEA and creating the pump code. Use of mathematical models in software provides estimate output values for pressure and velocity gradients of fluid flow. In specific case of FEA, these models provide virtual simulation resulting in points of high stress or failure in an imported CAD model. Coding Using the model for oscillating blood flow allows the pump to produce a flow with oscillating characteristics.

Computer Aided Design

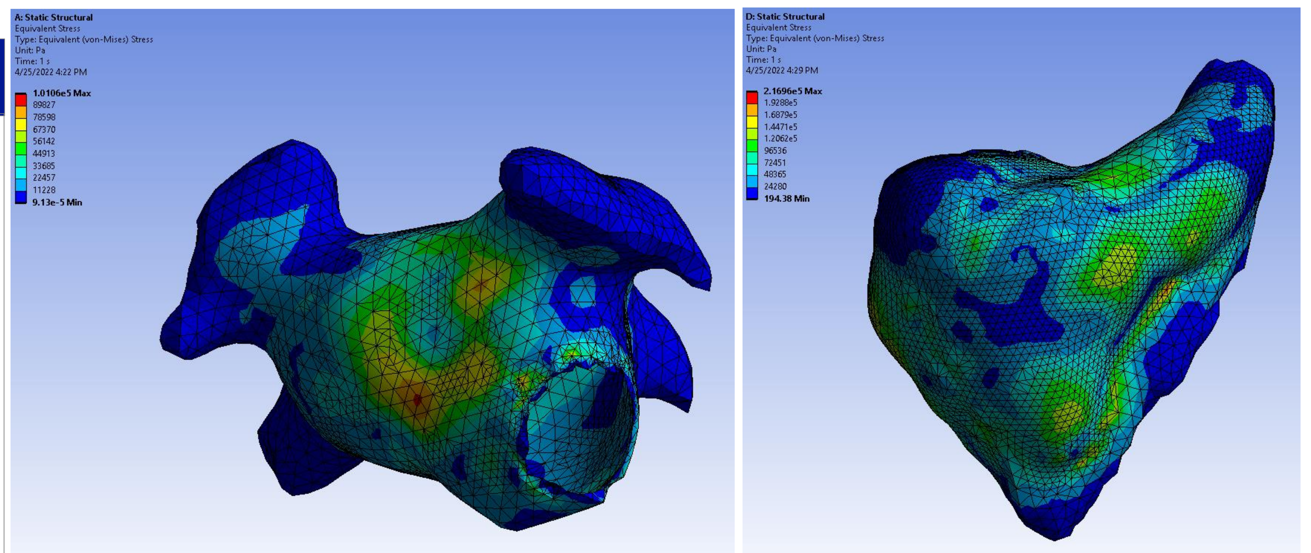
The CAD was created using a mix of NX 12.0 and Mesh mixer to maintain and accurate internal geometry complete with interconnected heart compartments. These models where created in two



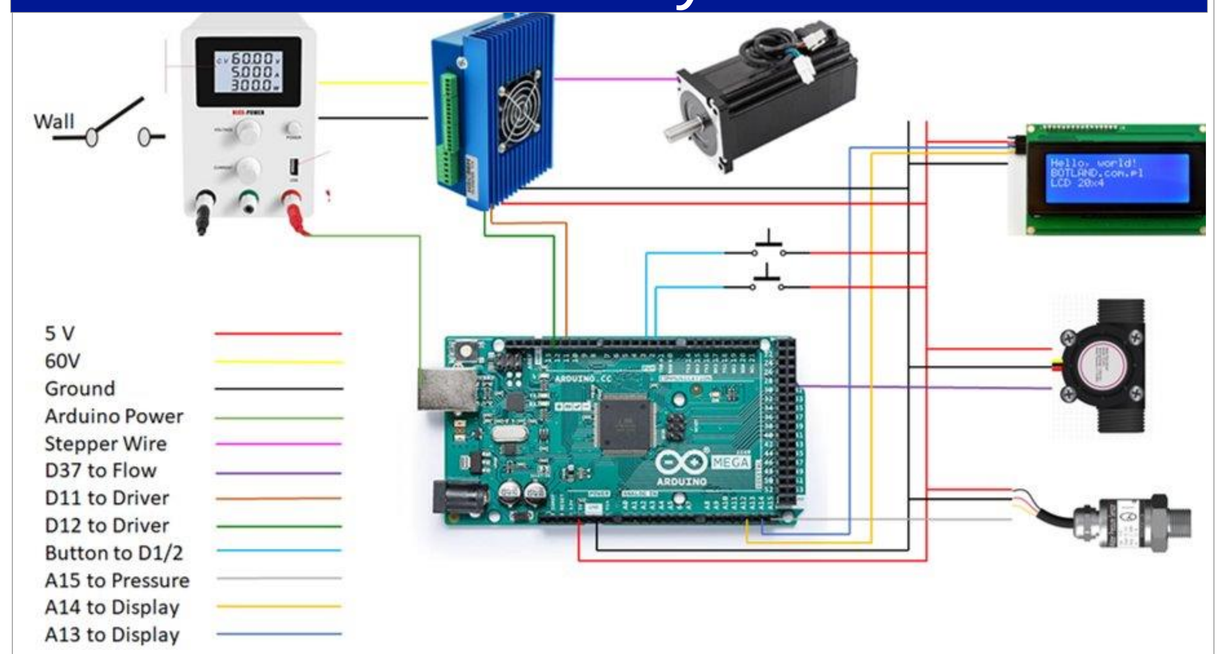


Finite Element Analysis

Finite element analysis was used to determine the minimum force requirements that will be absorbed by the heart to determine its thickness and material needs. The tests were conducted using ANSYS workbench and ANSYS Discovery to run fluid and pressure test. Unfortunately, only 1 of the fluids tests was run successfully but these provided a pressure value of 620 Pa that was applied to the internal surfaces of all heart component. This showed that a minimum thickness of 1 mm is required for hard resign materials and 2 mm for soft resin materials.



Electrical Systems



Circuit design shown above for controlling the motor, buttons, screen and sensors originates from an Arduino Mega microcontroller. The system can be plugged into the wall, but a safety kill switch must be turned on in order for the voltage source to be powered safely. The voltage source will be set between 50V and 60V and directly power a stepper motor that drives a piston pump. A 5V USB plug will connect the voltage source to the Arduino which will power the remaining components.

Testing

Three major tests were performed to ensure the success of the project consisting of testing silicone insertions, printed heart material, and precision and accuracy of pump system. Silicone Testing showed some leaks when catheter was inserted resulting in redesign with thicker silicone. Material testing showed Siraya Blue to be the most structurally sound material for printing the heart while still maintaining translucency. Pump tests showed promising results with major concerns due to leaking that has since been resolved.

Mean of Means	11.149
STD	2.59295
Count	30
SEM	0.473406
dof	29
Hypothesized Mean	10
T-statisitc	2.427346
P-value	0.010825

Conclusions

- *Created pulsatile flow through a clear tubing system with adjustable pulse rate.*
- *Successfully edited and 3-D printed a scan of a human heart that could be integrated into tubing system*
- *Tubing and silicone insertion points allow for needles and catheters to be placed within the system for practice Watchman procedures to be performed.*
- *Leaking throughout the system proved to be a problem, but was fixed for the finished product*
- *The final device design consistently brings itself to biologically accurate flow rates.*

Future Directions

- Add a second insertion point
- Streamline CAD process
- Create Womersly flow
- Expand trainer for more procedures (ECMO)
- Create biologically accurate pressure within the system

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