Catheter Insertion & Watchman Procedure Medical Simulation Device

Trine University
Biomedical Engineering

Kanny Huang[1], Jack Konicek[1], Lilly Speier[1], Oliver Zhao[1], Melanie G. Watson Ph.D.[1]

[1]Bock Department of Biomedical Engineering, Trine University, Angola, Indiana 46703

Introduction & Motivation

Atrial fibrillation (AF) is a serious heart condition causing irregular heartbeat, arrhythmia, and blood clots, affecting over 5 million people in the United States [1]. AF causes improper blood flow within the left atrial appendage (LAA), resulting in blood clots accumulating in the LAA, which ultimately increases a patient's chance of stroke by 500% [2].

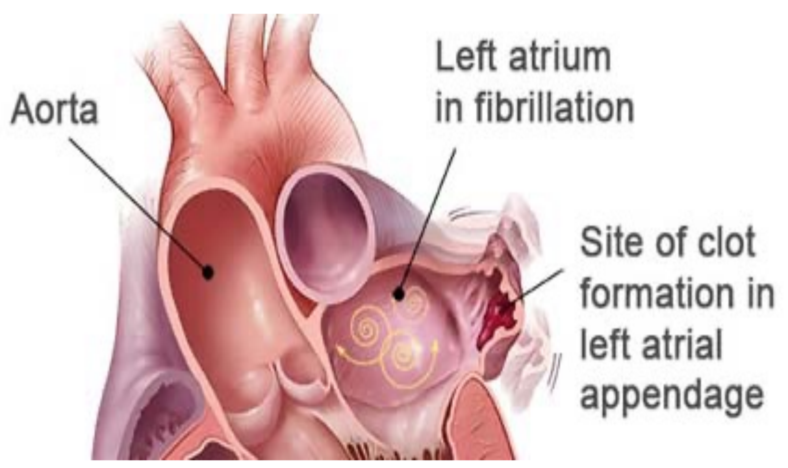

Figure 1. Schematic of how AF impacts the LAA [3]

The Watchman procedure is a widely accepted solution to treat AF and prevent blood clot accumulation in the LAA. This technique uses a catheter to guide a closure device into the LAA, sealing it off from the rest of the heart. Heart tissue grows over the Watchman device implant and permanently seals the LAA, reducing a patient's overall risk of stroke [4].

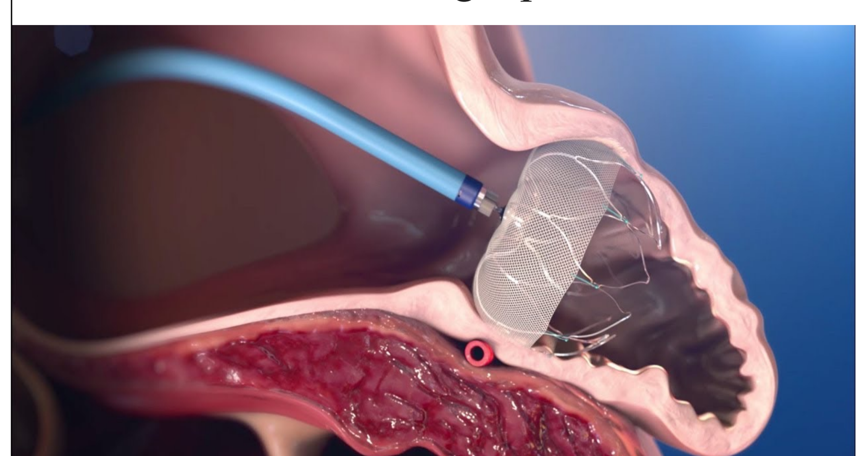

Figure 2. Illustration of the Watchman device being deployed into the LAA [5].

Cardiac catheterization procedures can be very dangerous if performed by inexperienced physicians, but there are few medical simulation devices available for training. Available devices are expensive, do not provide patient specificity, and cannot simulate physiologically accurate fluid flow.

Phase 1 Prototype

This project is a continuation of a senior design project from last year, aiming to create a medical simulation device to practice cardiac catheterization surgeries, such as the Watchman procedure. Phase one developed the foundation for all of the electrical components involved in the device and inspired the cart organization within the final product. Phase two aimed to improve leaks, electrical safety, and appearance.

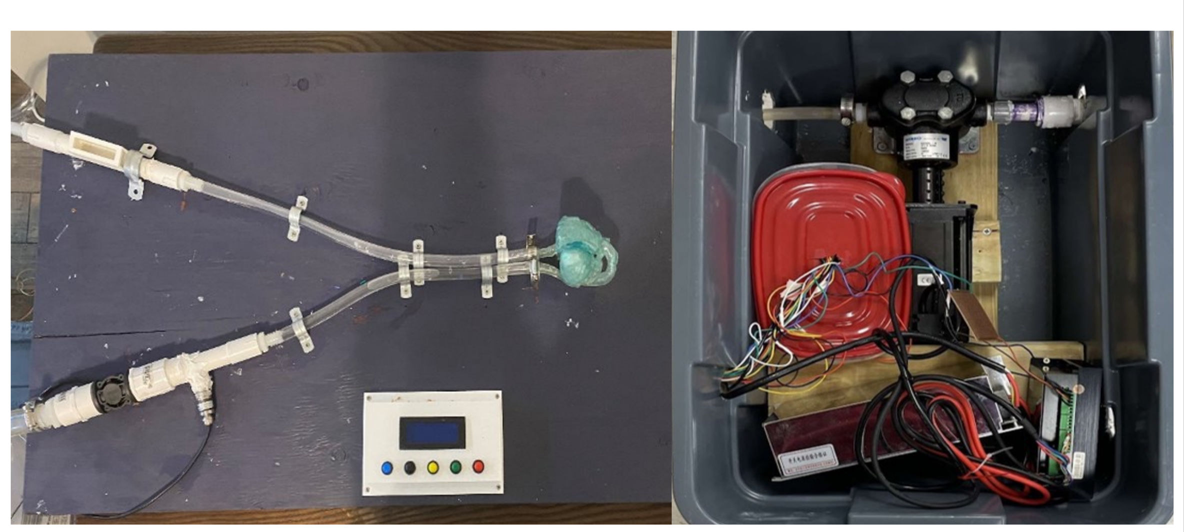

Figure 3. Phase one prototype on plywood cart (left), and electrical components housed in Rubbermaid container (right).

Cart Organization

Figure 4. Schematic describing new cart organization [6].

The Cath Lab Trainer 2.0 product is presented on a commercially available utility cart featuring three shelves. The top shelf contains a patient-specific heart model, vinyl tubing vasculature, protective chest plate cover, and LCD screen to adjust simulated heart rate and units displayed. The middle shelf houses a five-gallon mineral oil reservoir, where mineral oil is used to mimic the viscosity of blood observed *in vivo*. Inside the supporting pillars of each floor holds the tubing for fluid and electrical wires. The bottom shelf contains a Hydro 5330C-X piston pump, stepper driver, power supply, and an Arduino Mega 2560 microcontroller board. Lastly, electrical wires and vinyl tubing vasculature are contained inside separate pillars of the cart system, found between cart shelves. This new cart organization improves both electrical safety and aesthetic appeal of the phase one prototype.

Electrical System

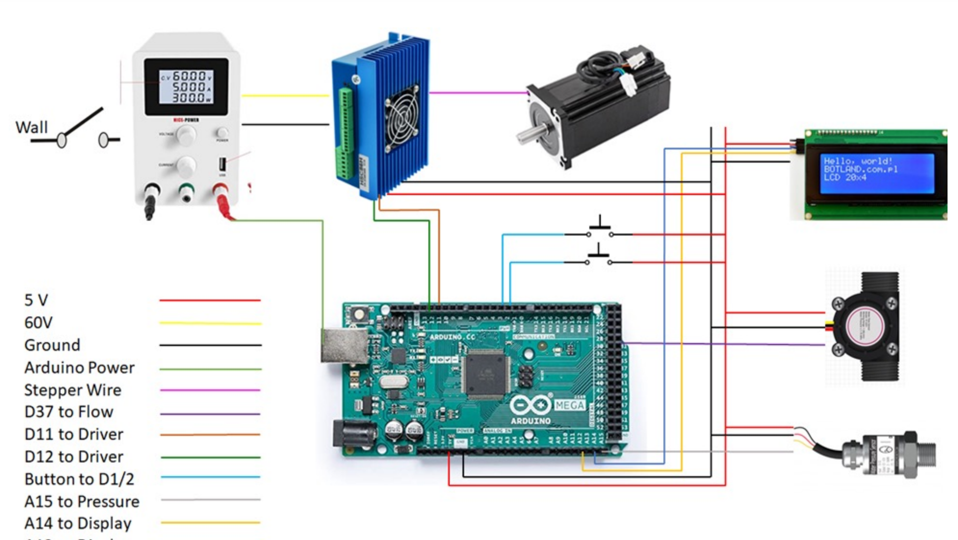

Figure 5. Circuit diagram for final product.

The circuitry above controls the stepper driver, piston pump, LCD screen, sensors, and buttons. These are all coded by the Arduino Mega 2560 microcontroller, which is plugged into a wall outlet with an on/off switch for easy system control.

***Blue:** Change flow rate units*
***Black:** Change velocity units, initiate continuous flow*
***Yellow:** Change pressure units, initiate pumping sequence*
***Green**: Decrease heart rate*
***Red**: Increase heart rate*

Figure 6. Startup message displayed on LCD screen.

The LCD screen uses 10k Ω resistors within a breadboard to control the buttons shown above. This design allows the user to increase or decrease heart rate, or change units of pressure, velocity, and fluid flow. Additionally, this system can switch between simulating Womersley or simple continuous flow.

Computer Aided Design

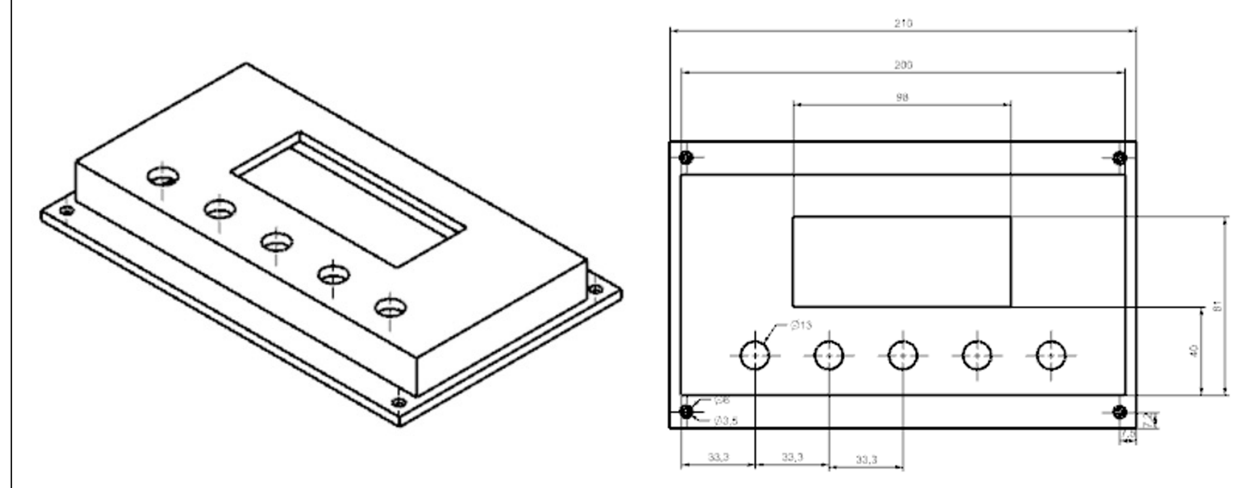

Figure 7. CAD used to 3D print LCD screen casing.

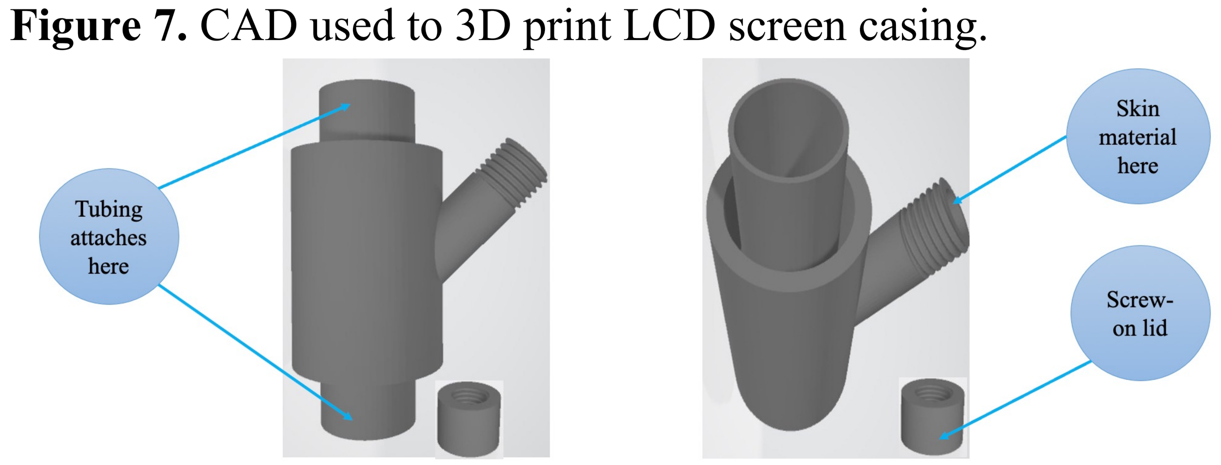

Figure 8. CAD used to 3D print catheter insertion pieces, where 2mm thick sheets of Elastico resin are used to mimic human skin.

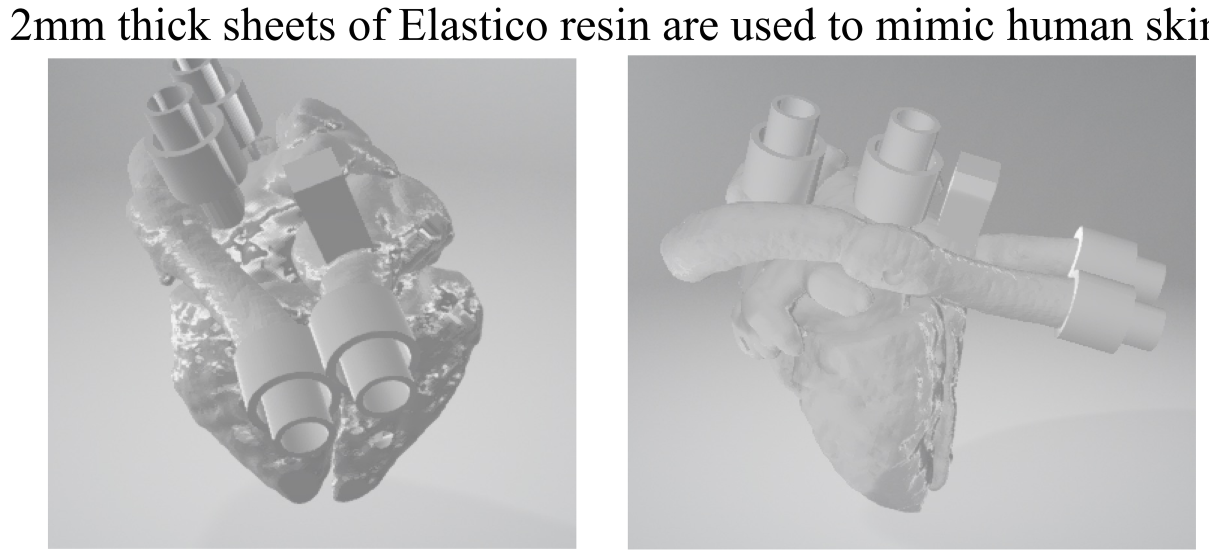

Figure 9. CT scanned patient-specific heart model with custom insertion pieces to ensure secure connections with vinyl tubing. The heart model was printed with Formlabs Flexible 80A resin.

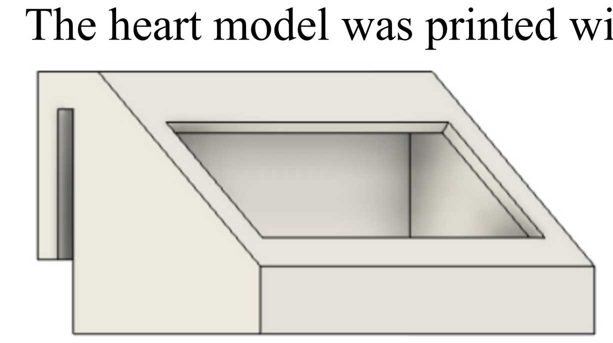

Figure 10. CAD used to 3D print a ledge to hold the LCD screen user interface, shown on the left.

Testing

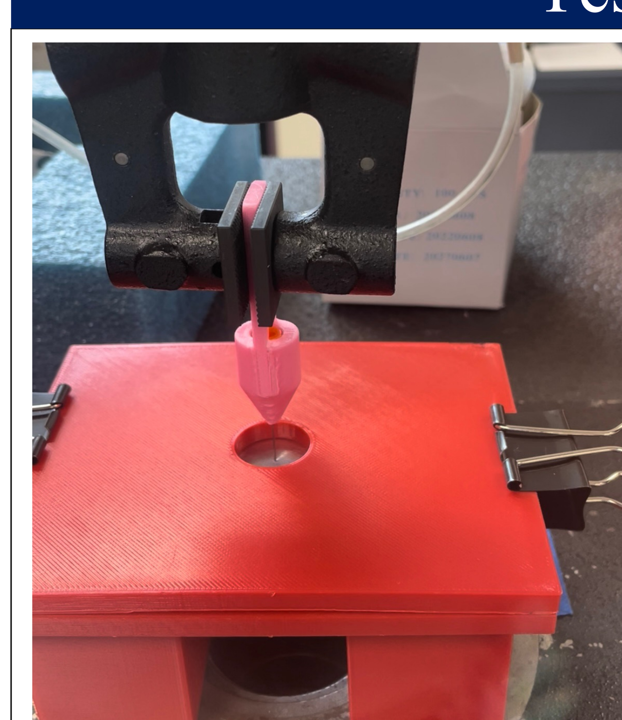

Figure 11. Custom puncture testing apparatus with a 3D printed base and syringe-holding mechanism, fit for 25-gauge needles.

Puncture testing was performed on 2 mm thick sheets of Elastico 3D printed resin material according to ASTM standard F2878: Protective Clothing Material Resistance to Hypodermic Needle Puncture. The average force required to puncture human skin is 0.5 - 1 N, and the average force required to puncture an Elastico sheet was 1.018 N; therefore, Elastico was deemed an appropriate model for skin within the product's catheter insertion point mechanism [7].

Conclusions

- Simulated Womersley flow, as observed *in vivo*
- Utilized clear vinyl tubing to visualize fluid flow within the cardiovascular system
- Delivered a product with adjustable testing parameters and a patient-specific heart model
- Created a closed system that does not exhibit leaking
- Redesigned the catheter insertion piece to more accurately mimic human anatomy
- Improved electrical safety and overall aesthetic appeal of the prototype developed during phase one of the project

Future Directions

- Integrate additional insertion pieces and vasculature to model additional catheterization procedures, such as extracorporeal membrane oxygenation (ECMO)
- Add force sensors and buzzers to give feedback on the success of the simulated surgery, in real-time
- Incorporate angiographic projections, which allow surgeons to orient themselves within the heart model
- Make the operating height of the cart adjustable
- Adjust button functions to automatically inject red dye, allowing for better visualization of fluid flow

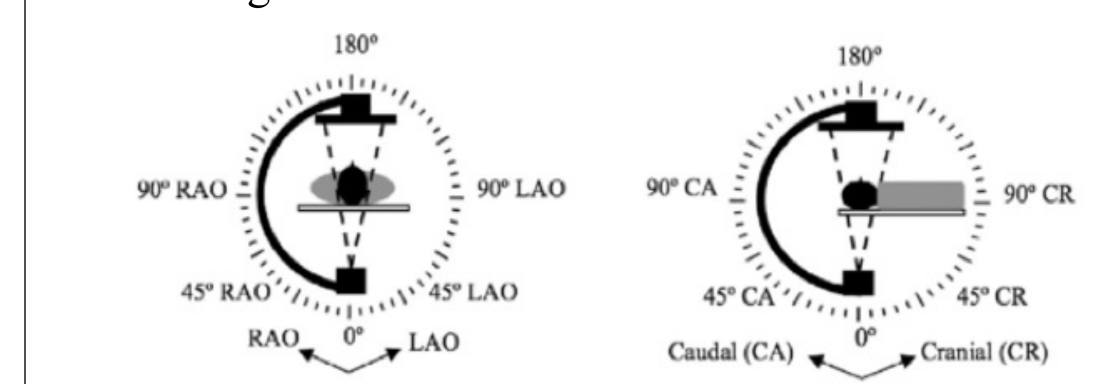

Figure 12. Angiographic projections: right (RAO) and left anterior obliques (LAO), caudal and cranial orientations [8].

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Contacts

Kanny Huang: khuang17@my.trine.edu
Jack Konicek: jpkonicek19@my.trine.edu
Lilly Speier: ljspeier18@my.trine.edu
Oliver Zhao: ozhao19@my.trine.edu