BME Design

Multidimensional Imaging Based Model for Canine Cardiovascular Procedural Skills

Spring 2025 BME 402

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Client: Dr. Sonja Tjsotheim

Advisor: Professor Tracy Jane Puccinelli

Team BVP:

Becca Poor (Leader)

Anna Balstad (Communicator)

Hunter Belting (BSAC)

Daisy Lang (BWIG & BPAG)

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The purpose of this study was to build a canine heart model to simulate pulmonary valve stenosis and to aid veterinary cardiology residents in practicing transcatheter balloon valvuloplasty procedures.

Methods

The final model consisted of six main parts: a 3D printed heart, a 3D printed jugular vein attachment, a removable 3D printed pulmonary valve, a video stand setup, a basin for the model and a peristaltic pump to simulate blood flow through the model. The heart and pulmonary valve were segmented from the CTA scan of a French Bulldog. All 3D printed components were printed in Elastic 50A resin. The model's ability to simulate realistic balloon valvuloplasty procedures was assessed by veterinary residents and veterinary cardiology attendings. Subjects were taught how to use the model, allowed to perform three balloon valvuloplasty procedures, then were asked to fill out a Likert scale survey to assess the model's performance.

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Introduction

Pulmonary valve stenosis (PS) is a congenital heart defect that causes the narrowing of the pulmonary valve. PS is the most common congenital heart disease among canines and represents 31-34% of all canine congenital heart disease diagnoses [1][2][3]. If left untreated, severe cases of PS can lead to right-side congestive heart failure. Given the large prevalence of this disease, there is a need for veterinarians trained to treat PS.

The most widely accepted treatment for PS is balloon valvuloplasty [4][5][6]. In this procedure a balloon catheter is inserted through the external jugular vein, guided to the pulmonary valve and inflated to spread apart the valve leaflets [2]. This increases the diameter of the pulmonary valve and improves blood flow from the heart to the lungs. Transcatheter procedures, such as balloon valvuloplasty, are accompanied by steep learning curves and take ample exposure and practice to master. Unfortunately, there are often very few training opportunities for trainees beyond performing a minimum number of procedures, and these opportunities are dramatically reduced in hospitals experiencing staffing shortages and reduced hours of operation.

A promising solution to the lack of training opportunities are 3D simulation models. Previous studies on human surgical procedures have found that training with 3D simulation models can improve both surgical and clinical practices [7][8][9][10]. Additionally, other 3D models of canine hearts have been found to be effective in training veterinary students in spatial awareness of cardiovascular anatomy and increasing confidence with the procedure [11][12]. To better prepare veterinary cardiology trainees to perform transcatheter procedures, there is a need for canine heart simulation models to allow them to learn and maintain these skills.

The purpose of this study was to develop an anatomically accurate 3D model of a canine heart to simulate PS for veterinary cardiology residents to learn and practice balloon valvuloplasty. Creating a realistic canine heart model will enhance students' practical skills and understanding of balloon valvuloplasty, providing a deep understanding of the procedure and opportunities to practice the procedure prior to performing it on live animals.

Animals/Materials/Methods

Model Development

Full Model Assembly

The final model consisted of six main parts: a 3D printed heart, a 3D printed jugular vein attachment, a removable 3D printed pulmonary valve, a video stand setup, a basin for the model and a peristaltic pump to simulate blood flow through the model. The heart and pulmonary valve were segmented from the computed tomography angiography (CTA) scan of a French Bulldog and all 3D printed components were printed in Elastic 50A resin. The heart and jugular vein are secured to a base that is printed out of polylactic acid (PLA) and ensures that the model stays in place during the procedure.

The Elastic 50A resin from Formlabs was chosen for a multitude of reasons, including in-house 3-D printing capabilities and anatomical accuracy to the native soft tissues being modeled. In addition, the Elastic 50A is transparent, which is an important aspect of the model design. Mechanical tensile testing was completed to determine the elastic modulus and ultimate tensile stress of the material. The resulting testing yielded an elastic modulus of 2.47 ± 0.156 MPa and maximum tensile strength of 0.87 ± 0.07 MPa. Further detail regarding the tensile testing including the raw data and procedure can be found in Appendix 5.2. The Elastic 50A resin was sufficient to be implemented for use with the anatomical aspects of the model based on the mechanical tensile testing and feedback from experts at the UW-Madison Veterinary Hospital.

Ancillary components to the model include the jugular vein base, heart stand, and the video stand system. During a typical procedure, contrast is added to the vascular system and fluoroscopy is used to guide the catheter to the pulmonary valve. Having a display integrated into the model provides a view that is more realistic to the procedure as the trainee is focused on the screen instead of the model, developing a greater feel for how to manipulate the catheter in vivo. A phone is placed into the stand and connected to a monitor using a HDMI to USB-C cable. The base for the heart and jugular secures the model to prevent it from freely moving in the water basin. The base holds the jugular vein above the water level for palpation and insertion of the catheter. The base for the heart is a cavity that is made from the negative of the heart and the base for the jugular vein is a half pipe that tapers down similarly to the shape of the printed vein. The final component of the jugular base is the prongs that stick out of the sides. The prongs hold a thin manikin skin-like material over the top of the distal end of the jugular vein, allowing users to palpate and insert the needle in a realistic manner.

Heart and Pulmonary Valve Segmentation

The heart model was modeled from a CTA scan of a french bulldog with pulmonary valve stenosis that was seen for treatment at the University of Wisconsin School of Veterinary Medicine. The CTA was segmented using 3D Slicer software to select the heart chamber walls, valves, and necessary vasculature. The CT scan was first uploaded as a DICOM file. The volume of the DICOM file was then cropped to focus on the heart. Using the axial view, the heart was manually segmented with the paint tool. The myocardium and blood pools were segmented separately to ensure an accurate heart model. In the axial view, the pulmonary valve annulus and leaflets were then carefully outlined using the paintbrush tool. To reduce the difficulty of the model for trainee use, the volume of the right ventricle was increased and the ventricular walls were smoothed by overlining the blood pool of the right ventricle. This aims to reduce the difficulty of navigating the catheter around the right ventricular apex. After segmentation, STLs of the heart chambers and the annulus were generated and exported to MeshMixer. In MeshMixer, the heart chambers STL was made into a solid body and the number of triangles was reduced. Reducing the STL decreases the file size to make the file more manageable in other softwares while preserving the details of the heart chambers. The STL file was then exported to Onshape, where the heart chambers were cut vertically, ensuring that the planar cut split the area where the pulmonary valve is located. In Onshape, three peg and hole connectors were added to the heart chamber walls to secure the two halves of the heart together. The pegs have a diameter of 8.89 mm and a height of 6.35 mm.

The heart chambers and valve were printed on a Formlabs 3B printer with Formlabs Elastic 50A resin. The components were post-processed through a washing and curing phase. The Elastic 50A resin was washed in 99% isopropyl alcohol for ten minutes, dried for ten minutes, and washed for another ten minutes to remove supports. To cure the Elastic 50A resin, the parts were put into a UV-transparent container filled with water and cured at seventy degrees celsius for thirty minutes. Full details of the fabrication are described in Appendix 3.

To ensure the annulus and valve would not stretch with continued use, a fatigue test was performed. For the testing, a balloon catheter was inserted into the valve and inflated 150 times. Over the course of the testing slight expansion was observed, however, the expansion was minimal and the valve may be easily replaced. Full details of the valve fatigue testing and results can be found in Appendix 5.1.

Jugular Vein

The jugular vein consists of three different components: the vein, the manikin skin that covers the region of the jugular vein where the catheter is inserted, and the cranial vena cava connector. The dimensions of the jugular vein were based on measurements made by a veterinary radiologist from a neck CTA scan of a French Bulldog. The jugular vein is 132.7 mm in length. The distal end of the jugular vein has an inner diameter of 9 mm and tapers out to an inner diameter of 16 mm where it connects to the cranial vena cava connector. The wall of the jugular vein is 1 mm thick. In order to simulate puncturing the needle through the skin, a hole was cut into the distal end of the jugular vein and covered with replaceable manikin skin. With this addition residents can puncture the IV needle through the manikin skin and into the jugular vein without ripping the model. Additionally, residents can practice palpating the skin in order to find the correct insertion area. The last component, the cranial vena cava connector, is directly modeled into and printed as a part of the heart model. The proximal end of the jugular vein fits inside the connector and is secured in place due to the dimensions of each component.

Pump

The pump generates flow through the heart, directing the balloon catheter through the chambers to the valve in a similar manner to blood circulation. It is commonly seen during procedures to “float” the catheter tip using the blood flow to reach the pulmonic valve; The pump simulates the flow to assist in reaching the valve [4]. Also, using a pump during the training procedure creates a more realistic model. The ideal flow rate to match native physiology for a french bulldog is 1.15 mL per beat per kilogram of body weight for the canine [13]. The canine the model was built around weighs 9.8kg and the average flow rate in a canine during the procedure is approximately 80 beats per minute. Based on the flow rate, weight of the canine, and the heart rate, the flow rate for the pump needs to be approximately 902 mL per minute. The pump used in the model is a peristaltic 900 mL/min high flow pump. It requires 12 volts DC power at 1.5 amps. To simplify the system, the pump was integrated with other electrical components, enabling it to be powered by a wall outlet and a switch.

To connect the pump to the heart a 6.35 mm inner diameter and 9.525 mm outer diameter clear polyvinyl chloride tubing was used. The tubing from the outlet valve on the pump connected to the proximal end of the jugular vein at a 60 degree angle and was secured with a hose clamp. This ensured the fluid path was moving in the correct direction into the heart. Additional tubing was fastened to the output of the pulmonary artery and the tubing was directed to the bottom of the fluid basin to ensure the water surface remained undisturbed. The water inlet valve on the pump was secured with tubing that stretched into the bottom of the water tank to pull in the fluid.

Study Design

In order to test the functionality of the final model, veterinary residents and cardiology attendings at the University of Wisconsin Madison School of Veterinary Medicine were asked to voluntarily participate in testing. Participants consisted of 3 cardiology residents, 4 cardiology attendings, and 4 residents from specialties other than cardiology.

Prior to interacting with the model, participants were asked to fill out a pre testing survey. The initial survey asks for the participants' level of training – cardiology resident, resident in a department other than cardiology, or cardiology attending. The questions in the survey focused on the participant's exposure to balloon valvuloplasty to treat pulmonic stenosis while shadowing or assisting along with their overall knowledge and confidence to complete the procedure.

Following the pre testing survey, participants received a lesson on pulmonary stenosis and balloon valvuloplasty from a current cardiology attending. This lesson was followed by a demonstration of a balloon valvuloplasty procedure on the 3D model. Then, participants were asked to use the model to perform three separate balloon valvuloplasty procedures on their own using the model. Each participant tested the model in a private room with only study team members present.

After the participant completed three procedures and felt comfortable with the model, they were asked to answer a post testing survey. The post survey asked the participant questions about whether using the model improved their confidence and conceptual understanding of the balloon valvuloplasty procedure. Participants were also asked to assess the realism of the anatomy, their experience navigating the catheter, and the accuracy of the vascular access procedure. Additionally, they evaluated how well the forward fluid flow simulated the actual procedure. Final questions on the survey asked if the user would recommend the model and if it would be a useful training tool for cardiology residents. The post survey was administered in the private testing room immediately after the conclusion of testing. All surveys were anonymous and participants were asked to not discuss their experience with the model with other participants until the completion of all testing.

After testing, the results from each subject group – non-cardiology residents, cardiology residents, and cardiology attendings – were analyzed and compared. The survey responses were scored on a Likert scale with numerical values 1-5. To analyze the results, a paired t-test was used to determine if there were significant differences between the subject groups' responses using a significance level of $p<0.05$. The statistical analysis was performed using Microsoft Excel. This study was approved by the University of Wisconsin Madison Institutional Review Board.

Results

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Discussion

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Study Limitations

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Conclusion

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Appendix

1 Project Design Specifications

BME Design

The Product Design Specifications (PDS)

Multidimensional imaging-based models for cardiovascular procedural skills training

Spring 2024 BME 402

February 26, 2024

Client: Dr. Sonya Tjostheim

Advisor: Dr. Tracy Puccinelli

Team:

Becca Poor (Leader)

Anna Balstad (Communicator)

Daisy Lang (BPAG & BWIG)

Hunter Belting (BSAC)

Function

Interventional cardiology is continuously expanding as a field, especially in veterinary medicine as new methods, techniques and procedures are developed to treat common congenital heart diseases. As a consequence, it is imperative to develop training models to support the learning and understanding of surgeries by veterinary trainees and improve outcomes for patients. The ability to quickly and accurately place balloon catheters or stents is of the utmost importance as complications can lead to harmful outcomes. For this project, the focus is on creating an accurate model of a canine heart to allow training simulations for pulmonary valve stenosis (PS) via a 3-D rendering from a computed tomography angiography (CTA) scan. The model should mimic both the anatomy of the canine cardiovascular CTA scan and have similar material properties to that of the in vivo environment. Currently in the University of Wisconsin School of Veterinary Medicine, the caseload for interventional procedures has been lower, making it difficult to provide opportunities for the resident training program. The development of a 3-D model would allow a low-risk environment for learners to practice placing the balloon catheter or stent and provide ample opportunities for residents to practice these skills before performing the procedure on a live patient.

Client Requirements

- Create a 3-dimensional silicone model of a canine heart with PS using CTA scans.
- Trainees should be able to practice passing the catheter through the right ventricle and atrium and inflating a balloon or placing a stent without looking at their hands.
- The model should be based on a specific case of PS, most likely a French Bulldog due to the prevalence of PS in this breed comparatively.
- The model should be transparent or partially open to allow for visualization of the catheter or stent passing through the model.
- The silicone used for the model should allow for a smooth, realistic feel when inserting and passing the catheter/stent through the model.
- The models should be able to withstand multiple uses by trainees.
- The design should be capable of being implemented into a fluid flow system.

Physical and Operational Characteristics

Performance Requirements: The model for cardiovascular procedural skills training for balloon valvuloplasty procedures on canines should accurately represent the heart structure of a canine and model the pulmonary stenosis of the selected patient. The model will be created from CT Angiography scans of one patient selected by the client. Accuracy of the model will provide the most effective learning experience for users. The material of the model should have similar surface properties to that of cardiac muscle When the user is placing a catheter in the model, the resistance felt by the user should simulate that felt in vivo. The model must be able to withstand at least 100 uses. A pump should be integrated into the system to create a fluid flow system similar to blood flow in the heart. The pump should have a flow rate of 800 mL/min to replicate the heart rate and flow volume of a french bulldog [1,2]. A typical use of the model includes the insertion of a catheter into the right heart and deployment of a balloon in the pulmonary valve or placement of a stent near the pulmonary valve, along with retraction of the catheter. This use should not damage the surface or structure of the model. The model should be either translucent or have part of the heart wall removed to allow the user to see the catheter's tip during practice.

Safety: The materials used in creating the model will be non-toxic and pose no significant risk to the users. Any electric components for the camera used to simulate the use of fluoroscopic imaging to guide the user will be safely contained and have appropriate warning labels. Similarly, the electric components for the heart pump will be safely contained to minimize hazards.

Accuracy and Reliability: The model must be able to accurately represent a canine heart with PS. The client will be providing CT angiography scans to create the model to model the heart after. The fluid flow system should pump water at a rate similar to that of blood flow in the french bulldog during the procedure.

Life in Service: The client would like this model to be used for at least one year of training. This includes supervised lab once or twice a year for seven trainees plus individual practice time. A single use would include one user performing the insertion of a catheter and the deployment of a balloon or stent. Therefore the model should be able to withstand at least 100 uses.

Shelf Life: The model, while not in use, will be stored in an office setting at a temperature of 20-22 °C and at a relative humidity between 30% and 50%. The model should not deteriorate while stored in these conditions. The model may be stored on a shelf for 1-2 years.

Operating Environment: The model will be used by trainees in veterinary school and practicing doctors of veterinary medicine to learn and practice the balloon valvuloplasty procedure to treat PS. The model will be submerged in tap water during use. The water will be within a temperature range of 15-27 °C. The model will be submerged in water for up to 6 hours at a time. Therefore it is important that the model is water resistant and does not deteriorate with prolonged exposure to fluid. If adhesives are used for the model, they must be water resistant. The model will be removed from the water and allowed to air dry completely between training sessions. Future improvements to the model include the addition of a pump to circulate water through the heart to mimic blood flow.

Ergonomics: The model will be placed on a table at an appropriate height to ensure proper ergonomics for the user. The heart model itself does not pose any ergonomic concerns. The camera system that will be used to simulate fluoroscopic imaging will be positioned to minimize any ergonomic difficulties.

Size: The model will be stored in an office and needs to be able to be transported by itself. There are no size restrictions to the complete model but the heart model will be similar to native anatomy size for a canine cardiac system. The internal dimension of the left ventricle of a french bulldog is 21.23 mm during systole and 33.5 mm at end-diastole.

Weight: The model will be an adequate weight to be transported by one person. The maximum weight of the model is 20 lbs to ensure easy transferability of the model between lab spaces and storage.

Materials: The heart model will be fabricated from Formlabs Elastic 50A resin. The stand to support the model will be 3D printed from PETG. The platform for the stand will be acrylic. A cyanoacrylate glue will be used to secure the heart stand to the acrylic. The camera system will be a commercially available camera and camera stand. The heart pump will be a commercially available pump. The material will not be radiopaque to ensure the balloon or stent is visible under fluoroscopy. The material will simulate native anatomy flexibility and must not be tacky to the user.

Aesthetics, Appearance, and Finish: The model will be transparent to allow the user to visualize the balloon during a procedure. The 3D model will include ridges to replicate native heart texture drawn from the CTA scans. The model will not include any sharp or rough edges to guarantee the balloon and stent have a smooth insertion. The jugular vein in the model will be a smooth texture [3].

Production Characteristics

Quantity: One model will be designed and manufactured.

Target Product Cost: The model and system combined will cost less than $1000. 3D printing filament and plastic will be the main cost components of the model. A camera and fixture for the camera will be the main cost components of the recording system. Cardiac models of native human hearts that are 3D printed cost ~$60 per heart [4].

Miscellaneous

Standards and Specifications: The model is classified as a Class I Medical Device by the Food and Drug Administration (FDA) and must adhere to the standards set for Class I Medical Devices [5]. This includes adhering to the FDA standards for Computer Modeling and Simulation. These standards require that our model be validated both quantitatively and qualitatively. Quantitative validation must involve an analysis between results from testing our model and data collected from similar in vitro models and in vivo procedures. Qualitative validation requires that an experienced clinician use our device and compare the user experience and interface to living patient procedures [6]. Additionally, the Good Manufacturing Practice (GMP) sets standards for Simulation Testing. These standards require that our model mimics the anatomy and physiology of the canine heart and be made from a material that feels the same as the human tissues included in the model. In our model specifically, all blood vessels must mimic any changes caused due to pulmonary stenosis within the arteries. Additionally, the GMP standards require that all geometry within the model must be derived from real patient scans [7]. Lastly, the materials chosen in our model must match the elastic modulus and breaking strength of the cardiac tissue that is designed to represent. The general standards for cardiac models require an elastic modulus of 0.17 MPa and a breaking strength of 0.17 MPa [8].

Customer: Our customer is Dr. Sonja Tjostheim, a Clinical Assistant Professor of Cardiology for the Department of Medical Sciences at the UW School of Veterinary Medicine. Dr. Tijostheim would like to use this device to train her Cardiology residents within the Veterinary School. She has asked us to focus our model on PS as this is the most common procedure that her trainees need to practice. During the first semester, she would like the model to focus on pulmonary valve balloon valvuloplasty. Next semester, depending on progress, she would like the model to also be conducive for stent placement procedures. Additionally, Dr. Tjostheim would like the model to be based on the physiology of French Bull Dogs, as this is the most common patient for these procedures.

Patient-related concerns: The model imaging system must not require fluoroscopic imaging, as the client would like to reduce exposure to users.

Competition:

1. AATS 3-Dimensional Print Model [4]
    - Utilized original CT scans from patients to create a 3D model and converted to STL model.
    - Model printed on Objet Connex 260 printer using TangoPlus FullCure resin for the heart and VeroWhite for the platform and stools and immersed in sodium hydroxide solution to remove supports.
    - The elasticity of the material was found to be different from native heart anatomy creating a difficult model to utilize for simulation runs.
2. Canine Model for Patent Ductus Arteriosus Occlusion in Dogs [9]
    - Model based on 17-month-old male Miniature Schnauzer and utilized CT scans to develop a 3D model.
    - The model was printed in soluble thermoplastic at 1.5 times the normal size and then covered in a polydimethylsiloxane coating. The soluble thermoplastic was dissolved in a heated alkaline solution, leaving a polydimethylsiloxane hollow structure.
    - The majority of participants reported that the model was representative of device placement in clinical settings. Suggested improvements to the model include extending the aorta cranially and caudally, expanding the model to include the entire heart, and using more flexible materials.
3. Three-Dimensional Virtual and Printed Models for Veterinary Student Education in Congenital Heart Disease [10]
    - Computed tomography angiography datasets from canine patent ductus arteriosus were segmented using Materialise Mimics Innovation Suite and printed on a Formlabs Form2 printer to create a 3D model. used to create 3D models. The patent ductus arteriosus was printed in dyed resin, and the other structures were clear.
    - A virtual overlay of the 3D model onto 3D lateral and 2D ventrodorsal thoracic radiographs was also used to test the effectiveness of virtual overlays in enhancing cardiac education.
    - The 3D printed model and 3D digital model were perceived as significantly more helpful than the 2D radiograph. All students stated that these models provided a valuable learning opportunity.
    - These models show the value of using 3D printed heart models in veterinary medicine education. However, these models are for patent ductus arteriosus, not pulmonary stenosis. In addition, the models only displayed the region near the patent ductus arteriosus, not the full heart. This model was also not used for skills training.

4. A 3-D human model of complex cardiac arrhythmias [11]
    - Human 3D microtissues were generated by seeding hydrogel-embedded hiPSC-CMs and cardiac fibroblasts into an established microwell system designed to enable active and passive force assessment.
    - Cell-cell signaling was disrupted using methyl-beta cyclodextrin (MBCD), previously shown to disassemble cardiac gap junctions. The model demonstrated that arrhythmias were progressive and present in all microtissues within 5 days of treatment. Arrhythmic

tissues exhibited reduced conduction velocity, an increased number of distinct action potentials, and reduced action potential cycle length.

- The implementation of the dual electrophysiology camera system allowed the detection of 3D differential effects in action potential propagation in an *in vitro* setting for the first time. Arrhythmias could be controlled to become complex in their electrophysiological nature with multiple wavefronts.
- Though this model was to study arrhythmias, it demonstrates that even cell scaffold models are possible to further understand complex issues in the cardiovascular system. The resulting conclusion is that though it is more complex, it is possible to create a cell scaffold structure to model different issues with the heart.

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2 Project Expense Report

Item	Description	Manufacturer	Manufacture Part Number	Vendor	Date	QTY	Cost Each	Total	Link
3D Printed Materials									
Elastic 50A	Heart and Jugular Material	Formlabs	RS-CFG-ELCL-02	Formlabs	10/14/2024	1	$208.57	$208.57	https://formlabs.com/store/materials/elastic-50a-resin-v2/
Flexible 80A	Orignial Material for Heart	Formlabs	RS-CFG-FL80-01	Formlabs	10/14/2024	1	$208.57	$208.57	https://formlabs.com/store/materials/flexible-80a-resin
Model Stand Materials									
Super Glue	Secure Jugular to Heart and Stand to Base Plate: 0.07 oz Tube	The Original Super Glue Corporation	SGH2J	Makerspace	11/19/2024	2	$2.42	$4.84	https://supergluecorp.com/product/super-glue-tube/
3D Printed Stand	PLA Prints of stand to hold the Jugular and Heart	N/A	N/A	Makerspace	11/19/2024	2	$8.00	$8.00	N/A
Acrylic Base Plate	Secure the Model	N.A	N/A	Makerspace	11/19/2024	1	$0.00	$0.00	N/A
Phone Stand	Phone Tripod Stand, 85" Tall Cellphone Tripod with Gooseneck Remote, Flexible Tripod Stand for iphone, Portable Phone Stand Tripod for Recording, Compatible with iPhone 14 13 12 pro Android Cell phone	Vivtiv	p18-353	Amazon	2/13/2025	1	$21.99	$21.99	https://www.amazon.com/Cellphone-Gooseneck-Flexible-Recordin
Pump Materials									
Perisaltic Pump	900ml/min high Flow peristaltic Pump 12V dc Brush Motor Liquid dosing Pump with BPT Tube	Kamoer	KPHM900-HB-B24	Amazon	2/7/2025	1	$58.88	$58.88	https://www.amazon.com/dp/B0BB75XPRX/ref=sspa_dk_detail_1?
Tubing	10 Feet - 1/4" ID x 3/8" OD Clear Vinyl Tubing, Translucent Plastic PVC Tubing Hose Pipe for Water Air Pump	Kesoto	601279606865	Amazon	2/13/2025	1	$6.99	$6.99	https://www.amazon.com/Kesoto-Clear-Translucent-Plastic-Tubing
Hose Clamps	3/8" Heavy Duty Double Snap Grip Nylon Hose Clamps Several Ratcheting Adjustable Clamp	Quickun	767065462036	Amazon	2/13/2025	1	$11.59	$11.59	https://www.amazon.com/Quickun-Double-Several-Ratcheting-Adjustable/dp/B08P3S7NHT/ref=asc_df_B08P3S7NHT?mcid=82869f5d75ac3ec79ec60d8c10e56129&hvocijid=14693359646575673253-B08P3S7NHT-&hvexpln=73&tag=hyprod-20&linkCode=df0&hvadid=730312820598&hvpos=&hvnetw=g&hvrand=14693359646575673253&hvp=undefined&th=1)
Circuit Switch	6A 250V/ 10A 125V Circuit Switch	ELMA	39122226	Makerspace	2/18/2025	1	$0.20	$0.20	https://www.yorklighting.com/brand-satco-products-inc/hi-low-metal-round-rocker-switch-w-diode-2-circuit-rated%3A-6a-250v-10a-125v/sku-V27-80-2101
Power Adaptor	12V DC 1.5A-2A Converter Adapter Power Supply Power Cord Power Cable Charger DC Power Supply Plug 5.5mm x 2.5mm	ShenZhen Moveforest Electric Appliance Industry Co.,LTD	9553171318326	Amazon	2/18/2025	1	$7.89	$7.98	https://www.amazon.com/1-5A-2A-Converter-Adapter-Supply-Charger/dp/B0CNV6BHL7/ref=asc_df_B0CNV6BHL7?mcid=c2c6f93d820b3e4584d2d0f5ce88bdd4&hvocijid=4882312312521876959-B0CNV6BHL7-&hvexpln=73&tag=hyprod-20&linkCode=df0&hvadid=730312820598&hvpos=&hvnetw=g&hvrand=4882312312521876959&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9018944&hvtargid=pla-2281435178298&psc=1
							TOTAL:	**$537.61**	

Figure 2.1: Project Expenses

3 Fabrication Protocols

3.1 Heart Segmentation

3D Slicer software was used to segment the CT scan. This is an open source software. The CT Angiogram from the client can be uploaded and segmented to create an STL of the desired anatomy.

Steps:

1. Add DICOM data
2. Use the Crop Volume tool to focus the segmentation window on the heart and remove some of the extra components
3. Begin at the bottom of the heart in the axial view. Use the paintbrush tool to outline and color in the heart.
4. Scroll 5-6 slices superior. Use the paintbrush tool to outline and color in the heart.

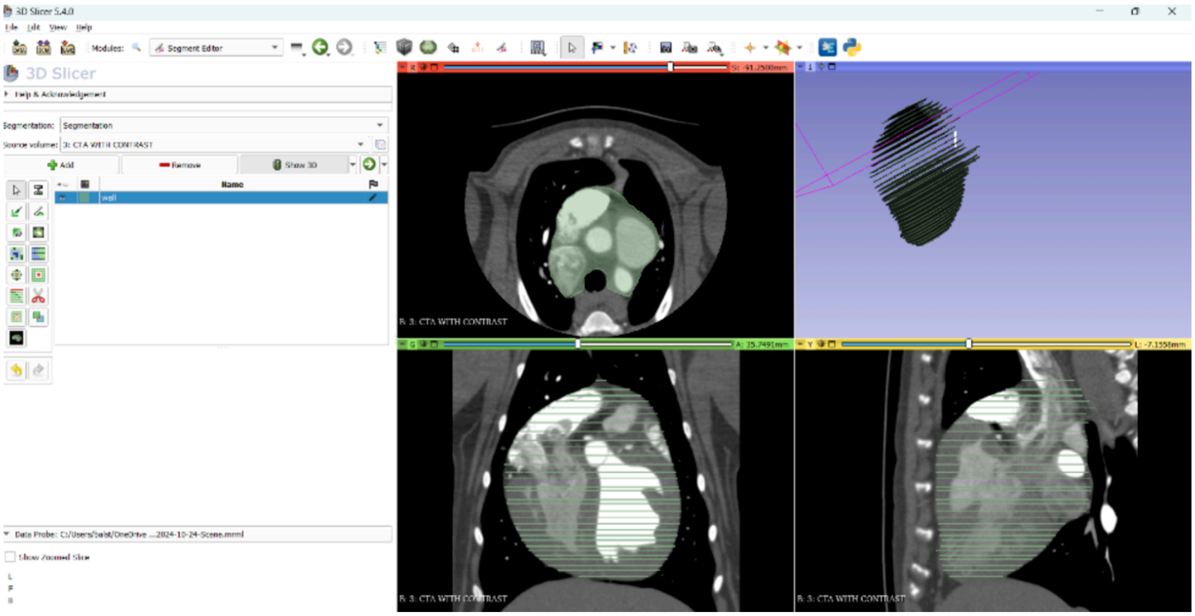

Figure 3.1.1: Heart segmentation after using the paintbrush tool to draw the heart every 5-6 layers

5. Repeat steps 3 and 4 until you have reached the top of the heart. Then use the fill between slices tool. This will fill between the slices that you have drawn.

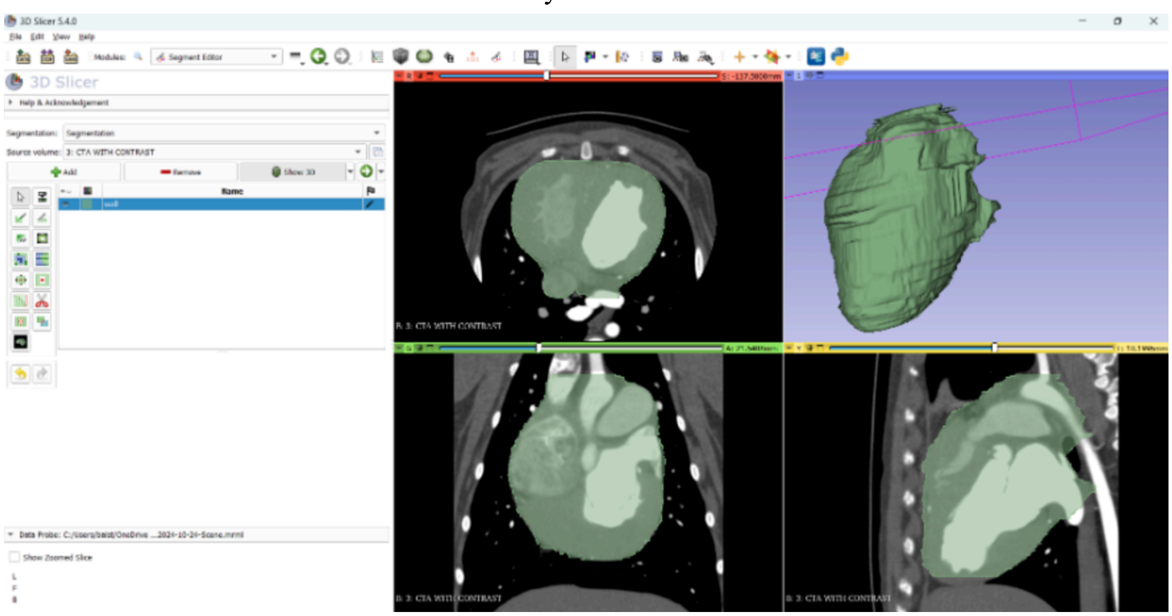

Figure 3.1.2: Heart segmentation after filling between layers

6. Next create a new segmentation. This will be the inside of the heart.
7. Start at the bottom of the heart in the axial view again. Outline and color in the blood pools in the heart.
8. Scroll 5-6 layers and color in the blood pools again.

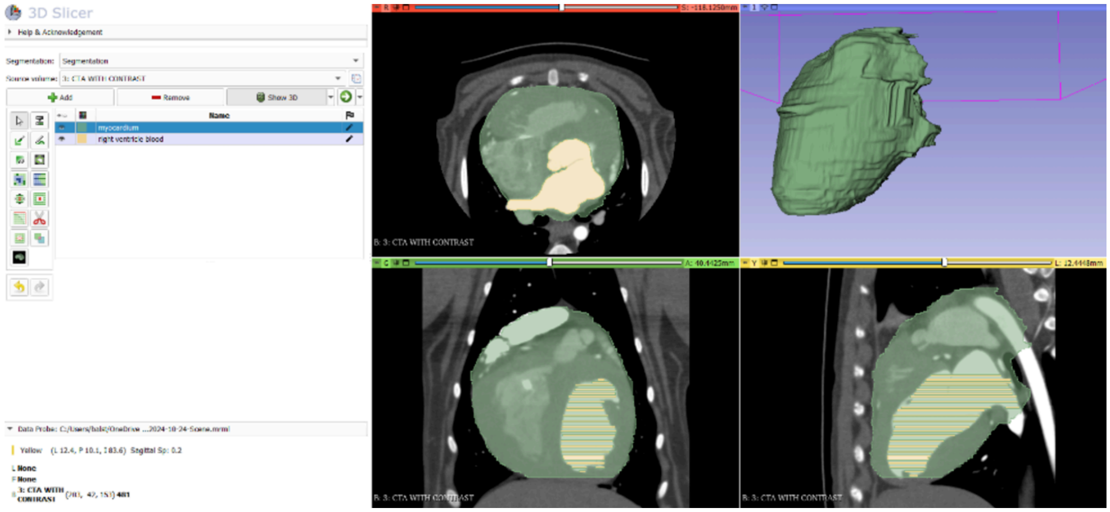

Figure 3.1.3: Heart segmentation during the process of segmenting the blood pools

9. Fill between layers.
10. The fill between layers is not entirely accurate. You will now need to go through every layer of the heart, alternating between the two segmentation paint brush and eraser tools to improve the accuracy of the heart.
11. Use the smoothing tool to smooth out edges. Smooth value was set to 0.35.
12. Export the STL.

3.2 Printing Heart Wall, Jugular Vein, and Annulus

1. Import the stl file to be printed into the Formlabs PreForm software.
2. Ensure that the print has no internal support by selecting that option, this allows for simplification of part cleanup.
3. Send the print file to the Formlabs 3B 3-D printer and add the correct material cartridge/tank to the printer so that it can begin.
4. Once print has finished, remove the platform which the parts are on and inspect parts for print defects to determine if a reprint is necessary.
5. The Elastic 50A material will be washed once for ten minutes with 99% IPA, then allowed to dry for ten minutes. Once dry the support will be taken off and it will be washed once more again in the wash station with the 99% IPA.
6. Allow the parts to dry before placing them in the curing station. Again the cure steps can differ depending on the material. The Elastic 50A prints are placed in a UV-transparent container that is filled with water. The cure station is set to preheated to 70 degrees celsius. Once preheated the parts can be put in for 30 minutes.
7. Take parts out of the cure station, if supports are still on the part they can be removed at this time.
8. Inspect parts for issues that may have been missed or that arose during the previous steps.

3.3 Jugular Vein

1. Design jugular vein in SolidWorks.

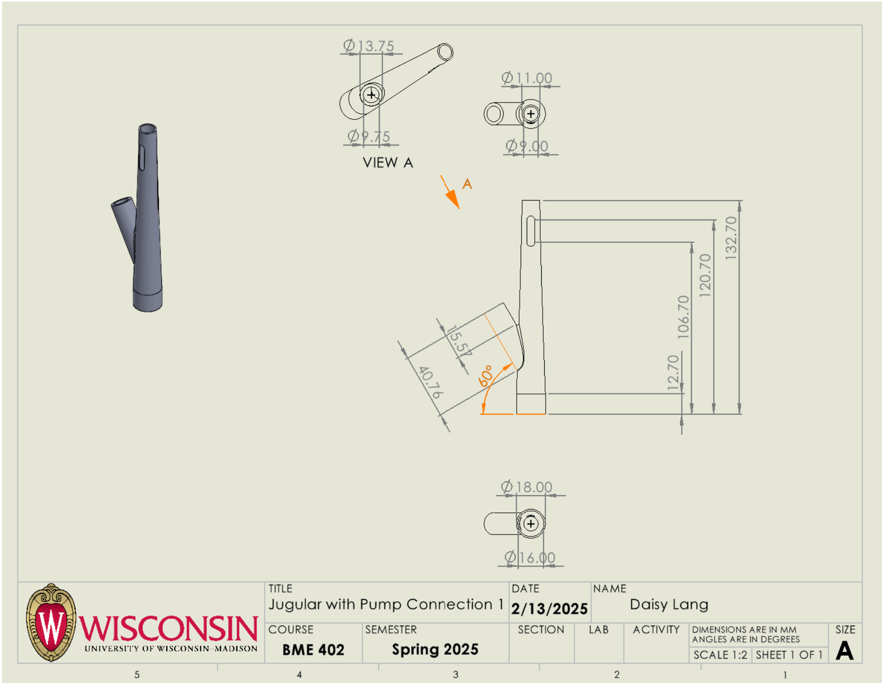

Figure 3.3.1: Jugular vein drawing

3.4 Model Stand

Jugular Fixture

1. Design jugular fixture in SolidWorks.
2. Print in white resin using FormLabs printer.

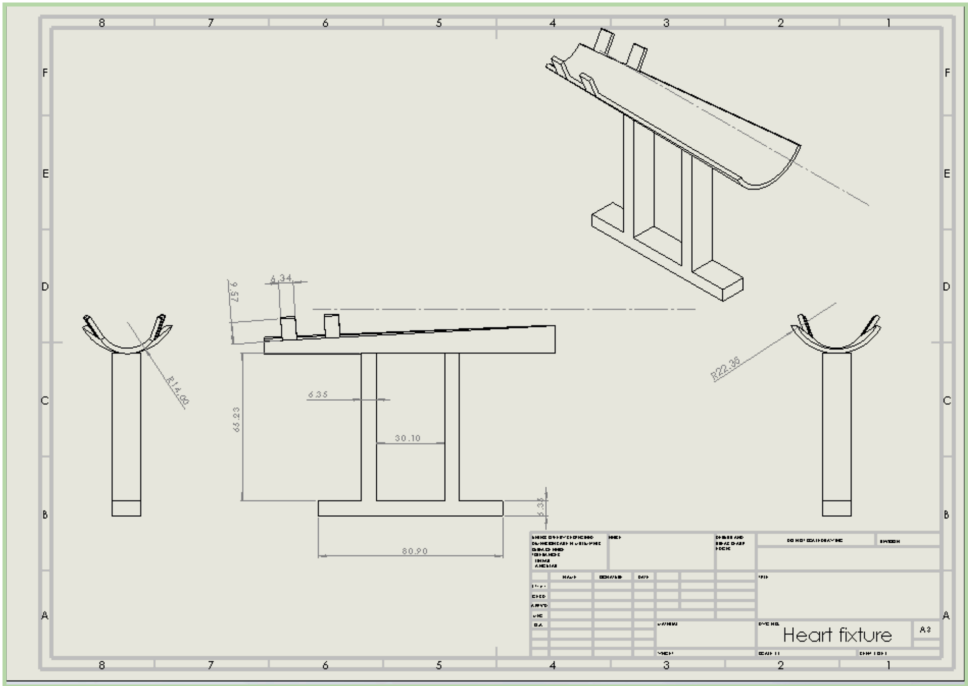

Figure 3.4.1: Jugular vein stand drawing

Heart Box

1. Draw box in MeshMixer.
2. Import heart STL and place it in the correct orientation.
3. Subtract outline of heart from box.
4. Export box into Blender to remove remaining heart ventricles.
5. Export back into MeshMixer.
6. Apply smooth and reducing function to decrease the number of triangles in STL.
7. Export from MeshMixer as STL.
8. Print heart mold using PETG on Bambu Printer.

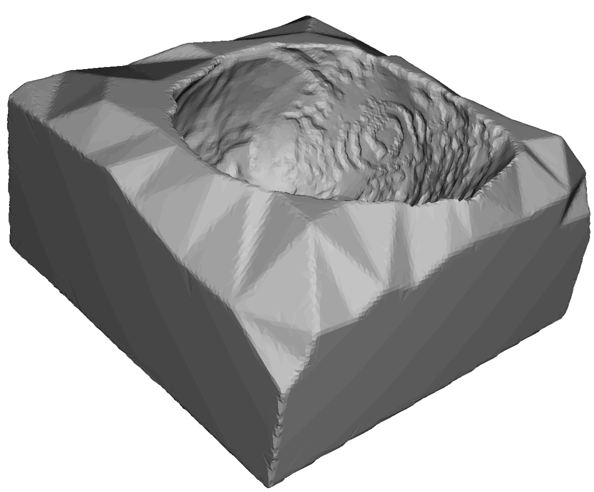

Figure 3.4.2: STL model of heart chamber base

4 Preliminary Testing Protocols

4.1 Valve Fatigue Test Protocol

The annulus is 3D printed from Formlabs Elastic 50A resin. This is a clear, flexible material. The balloon catheter used for the testing is a client provided catheter that is typically used for the balloon valvuloplasty procedure that are focused on.

1. Obtain initial measurements of the annulus -- horizontal distance across the top, middle, and bottom of the inside of the annulus and vertical distance of the inside of the annulus.
2. Fill the balloon catheter with 30 mL of water.
3. Feed the catheter into the 3D printed annulus such that the annulus is around the middle of the balloon.
4. Inflate the balloon catheter to a pressure of 3 atm. Pause for a second or two, then deflate. Repeat 10 times, ensuring that will each inflation, the valve leaflets are being pushed open.
5. After completing 10 inflation/deflation cycles, repeat the initial measurements.
6. Complete 150 cycles, measuring every 10 cycles.
7. Analyze any changes in dimension of the annulus.

150 cycles is an adequate testing length as the model is expected to be used roughly 100 times per year.

4.2 MTS Elastic 50A Tensile Test Protocol

1. Calibrate calipers and set to zero.
2. Use calipers to measure the width and thickness of the middle section of each dog bone.
3. Turn the MTS machine one and initiate “BME 315 Tensile Testing Protocol” in TWE
4. Set the strain rate to 5 mm/min
5. Load the sample into the bottom clamp of the MTS machine. Ensure that the bottom of the sample is aligned with the bottom edge of the clamp, then tighten the clamp.
6. Load the sample into the top clamp and tightentin, ensuring that the position needles on the left and right of the top and bottom clamp are aligned with each other. This ensures that the sample is perfectly vertical in the MTS machine.
7. Remove all slack in the sample by manually raising the top clamp of the MTS machine.
8. Measure the gauge length of the sample.
9. Zero both the load and crosshead.
10. Hit “Run” and enter the width and thickness of the sample into the MTS computer.
11. Once the sample ruptures, ensure that the data was collected and exported correctly.
12. Remove the sample from both clamps.
13. Select “Return to Zero” to return the top MTS clamp to its original position.
14. Repeat for all 8 samples.

4.3 Surveys

Balloon Valvuloplasty Procedural Skills Model Assessment

<u>Please check your level of training</u>

☐ Cardiology resident

☐ Resident in department other than cardiology

☐ Cardiology attending

Initial Questionnaire

Please answer the following questions before using the balloon valvuloplasty model.

1. I am confident in my ability to perform a balloon valvuloplasty to treat pulmonic stenosis.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

2. Please select the number balloon valvuloplasty cases to treat pulmonic stenosis that you have assisted with

   ☐ 0 cases ☐ 1 - cases ☐ 3 - 4 cases ☐ 4 - 5 cases ☐ 6+ cases

3. Please select the number of balloon valvuloplasty cases to treat pulmonic stenosis that you have observed

   ☐ 0 cases ☐ 1 - cases ☐ 3 - 4 cases ☐ 4 - 5 cases ☐ 6+ cases

4. I have a strong understanding of cardiac anatomy and catheter placement.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

Follow Up Questionnaire

Please answer the following questions after using the balloon valvuloplasty model.

1. I believe the model would be a useful training tool for cardiology residents.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

2. I am more confident in my ability to perform the balloon valvuloplasty catheter procedure after using the model.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

3. The model improved my conceptual understanding of cardiac anatomy and catheter placement.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

4. The heart anatomy is realistic.

☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

5. The experience of navigating the catheter was realistic.

☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

6. The jugular vein model simulates vascular access adequately.

☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

7. The inclusion of forward fluid flow provides a realistic experience for floating a catheter through the cardiac structures.

☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

8. Using the camera system prepared me to use fluoroscopic imaging during a procedure.

☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

9. I would recommend using the model for procedural skills training to other residents and/or fellows.

☐ Strongly Disagree ☐ Disagree ☐ Neither Agree/Disagree ☐ Agree ☐ Strongly Agree

5 Preliminary Testing Raw Data

5.1 MTS Elastic 50A Tensile Data

Table 5.1.1 Elastic 50A type IV dimensions for elastic modulus testing

Sample #	Width (mm)	Thickness (mm)	Gauge Length (mm)	X-Sectional Area (mm^2)
1	6.66	3.69	70	24.58
2	6.88	3.66	70	25.18
3	6.86	3.64	70	24.97
4	6.83	3.59	70	24.52
5	6.82	3.58	70	24.42

Table 5.1.2 Elastic 50A mechanical properties from tensile testing

Sample #	Elastic Modulus (MPa)	Maximum Stress (MPa)
1	2.655241403	0.984000539
2	2.334854114	0.820829226
3	2.310819761	0.804649585
4	2.462719274	0.86462805
5	2.61018899	0.861888358
Average:	2.474764708	0.867199152
Std:	0.156132625	0.070249551

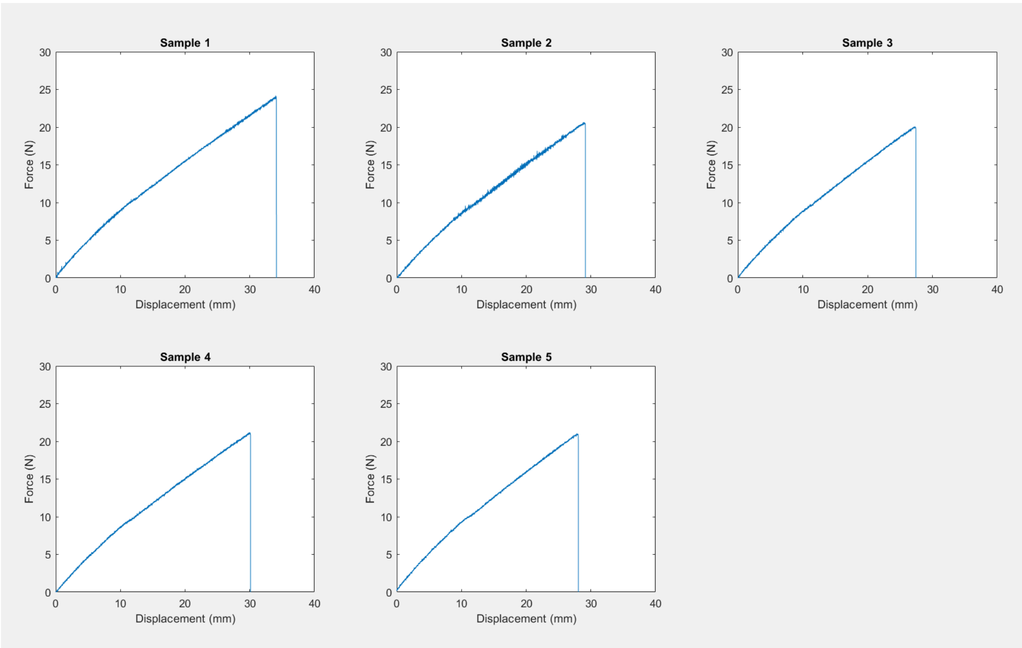

Figure 5.1.1: Force vs. Displacement graphs for tensile testing of Elastic 50A

5.2 Elastic 50A Tensile Test Analysis Code

```
%% BME 402 MTS Analysis
% Import the raw data as a numeric matrix
% Close figures and clear out other variables that have been assigned
clear all
close all
% Extract the columns of interest from your data
disp1=Test_1(:,1); %mm
force1=Test_1(:,2); %Newtons
disp2=Test_2(:,1); %mm
```

```
force2=Test_2(:,2); %Newtons
disp3=Test_3(:,1); %mm
force3=Test_3(:,2); %Newtons
disp4=Test_4(:,1); %mm
force4=Test_4(:,2); %Newtons
disp5=Test_5(:,1); %mm
force5=Test_5(:,2); %Newtons
% Plot your raw data and inspect it to make sure it looks as you expect
hold on
figure(1);
subplot(2,3,1);
plot(disp1, force1);
title('Sample 1')
xlabel('Displacement (mm)')
ylabel('Force (N)')
xlim([0 40]);
ylim([0 30]);
subplot(2,3,2);
plot(disp2, force2);
title('Sample 2')
xlabel('Displacement (mm)')
ylabel('Force (N)')
xlim([0 40]);
ylim([0 30]);
subplot(2,3,3);
plot(disp3, force3);
title('Sample 3')
xlabel('Displacement (mm)')
ylabel('Force (N)')
xlim([0 40]);
ylim([0 30]);
subplot(2,3,4);
plot(disp4, force4);
title('Sample 4')
xlabel('Displacement (mm)')
ylabel('Force (N)')
xlim([0 40]);
ylim([0 30]);
subplot(2,3,5);
plot(disp5, force5);
title('Sample 5')
xlabel('Displacement (mm)')
ylabel('Force (N)')
xlim([0 40]);
ylim([0 30]);
hold off
%% Find the Linear Region
j1=input('Enter first frame of the linear region of the loading curve');
j2=input('Enter last frame of the linear region of the loading curve');
```

```
Lo=input('Enter the gauge length');
A1=input('Enter the cross-sectional area of your specimen');
A2=input('Enter the cross-sectional area of your specimen');
A3=input('Enter the cross-sectional area of your specimen');
A4=input('Enter the cross-sectional area of your specimen');
A5=input('Enter the cross-sectional area of your specimen');
%% Calculate tendon stress and strain, being careful to use consistent units.
stress1 = force1/A1;
strain1 = disp1/Lo;
Em1 = (stress1(j2)-stress1(j1))/(strain1(j2)-strain1(j1));
maxforce1 = max(stress1);
stress2 = force2/A2;
strain2 = disp2/Lo;
Em2 = (stress2(j2)-stress2(j1))/(strain2(j2)-strain2(j1));
maxforce2 = max(stress2);
stress3 = force3/A3;
strain3 = disp3/Lo;
Em3 = (stress3(j2)-stress3(j1))/(strain3(j2)-strain3(j1));;
maxforce3 = max(stress3);
stress4 = force4/A4;
strain4 = disp4/Lo;
Em4 = (stress4(j2)-stress4(j1))/(strain4(j2)-strain4(j1));;
maxforce4 = max(stress4);
stress5 = force5/A5;
strain5 = disp5/Lo;
Em5 = (stress5(j2)-stress5(j1))/(strain5(j2)-strain5(j1));;
maxforce5 = max(stress5);
Emtot = (Em1 + Em2 + Em3 + Em4 + Em5) / 5;
maxtot = (maxforce1 + maxforce2 + maxforce3 + maxforce4 + maxforce5) / 5;
Emstd = std([Em1 Em2 Em3 Em4 Em5]);
stdtot = std([maxforce5 maxforce4 maxforce3 maxforce2 maxforce1]);
% Plot Stress Strain Curve
figure(6);
hold on
plot(strain1, stress1, '.', strain1(j1:j2),stress1(j1:j2),'.');
%plot(strain2(j1:j2),stress2(j1:j2),'.');
%plot(strain3(j1:j2),stress3(j1:j2),'.');
%plot(strain4(j1:j2),stress4(j1:j2),'.');
%plot(strain5(j1:j2),stress5(j1:j2),'.');
title('Stress vs Strain - Elastic 50A')
xlabel('Strain')
ylabel('Stress (MPa)')
legend("Test 1", "Test 2", "Test 3", "Test 4", "Test 5")
hold off
```