

BME Design

Multidimensional Imaging Based Model for Canine Cardiovascular Procedural Skills

BME 402 Spring 2025

April 30, 2025

Client: Dr. Sonja Tjsenheim

Advisor: Professor Tracy Jane Puccinelli

Team BVP:

Becca Poor (Leader)

Anna Balstad (Communicator)

Hunter Belting (BSAC)

Daisy Lang (BWIG & BPAG)

Table of Contents

Abstract	3
Introduction	4
Animals, Materials, and Methods	4
Model Development	4
Heart and Pulmonary Valve Segmentation	4
Jugular Vein	6
Pump	6
Full Model Assembly	6
Study Design	7
Subjects	7
Pre - Testing Likert Surveys	7
Testing with Model	7
Post - Testing Likert Surveys	8
Analysis	8
Results	9
Discussion	12
Study Limitations	13
Conclusion	14
References	15
Supplementary data	17
1 Project Design Specifications	17
2 Project Expense Report	24
3 Fabrication Protocols	24
3.1 Heart Segmentation	24
3.2 Printing Heart Wall, Jugular Vein, and Annulus	26
3.3 Jugular Vein	26
3.4 Model Stand	27
Jugular Fixture	27
Heart Box	28
4 Preliminary Testing Protocols	29
4.1 Valve Fatigue Test Protocol	29
4.2 MTS Elastic 50A Tensile Test Protocol	29
4.3 Surveys	29
5 Preliminary Testing Raw Data	31
5.1 MTS Elastic 50A Tensile Data	31
5.2 Elastic 50A Tensile Test Analysis Code	32
5.3 Pre and Post Testing Survey Results	35

Abstract

Introduction/Objectives

Currently, there are no procedural skills models to train cardiology residents in balloon valvuloplasty. The purpose of this study was to develop and evaluate the effectiveness of a multidimensional imaging based canine cardiology model in training veterinary cardiology residents in balloon valvuloplasty procedures.

Methods

The 3D canine heart model was segmented from a Computed Tomography Angiogram scan of a French Bulldog and 3D printed in Elastic 50A resin. The model's ability to simulate realistic balloon valvuloplasty procedures was assessed by 9 subjects. Subjects consisted of cardiology attendings, cardiology residents, and non-cardiology residents. The subjects were divided into two groups, experienced and inexperienced based on prior involvement with balloon valvuloplasty procedures. Before and after testing the model, subjects were asked to complete a pre-testing and post-testing Likert survey assessing the model's accuracy, their confidence level before and after testing, and their likelihood to recommend the model for training. Differences between responses of experienced and inexperienced users were assessed using a Wilcoxon Rank Sum Test ($p < 0.05$).

Results

No significant difference between experienced and inexperienced users was identified between any of the post-testing survey questions. Overall, 9/9 of the users believe the model is a useful tool for training cardiology residents and would recommend it be implemented into the training curriculum. Additionally, 100% of inexperienced users agreed that testing with the model increased their confidence in their ability to perform balloon valvuloplasty. 8/9 subjects agreed that the model provided realistic anatomy and accurately mimicked the experience of navigating a catheter through the heart.

Conclusions

Multidimensional imaging based canine cardiology models can be used to accurately mimic balloon valvuloplasty procedures. Implementation of these models can help inexperienced users increase their confidence in procedural skills and provide students with opportunities to practice and maintain these skills prior to real patient cases.

Introduction

Pulmonary valve stenosis (PS) is a congenital heart defect that causes the narrowing of the pulmonary valve. In most cases, PS is the result of valvular fusion or valvular malformation resulting in stenosis. Pulmonary valve stenosis is the most common congenital heart disease among canines and represents 31-34% of all canine congenital heart disease [1][2][3]. If left untreated, severe cases of PS can lead to exercise intolerance, exertional collapse, right-side congestive heart failure, and in rare cases, sudden death. Given the detrimental effects and high prevalence of PS, there is a need for veterinary cardiologists to be extensively trained in the procedures used to treat this disease.

The most widely accepted treatment for PS is balloon valvuloplasty (BVP) [4][5][6]. In this procedure a percutaneous transluminal angioplasty (PTA) balloon catheter is inserted through the external jugular vein, guided through the heart to the pulmonary valve, and inflated to tear apart the tethered leaflets [2]. This increases the effective orifice area of the pulmonary valve and improves blood flow from the heart to the lungs. Transcatheter procedures, such as BVP, are accompanied by steep learning curves and take ample exposure and practice to master. Models and other simulation training methods allow residents to develop and practice skills in a controlled low-stakes environment, reducing risk of harm to living patients. Simulator training using multidimensional imaging-based models can augment training provided in interventional labs and helps protect against fluctuating procedural caseload eroding skills. It also provides a more consistent experience for veterinary cardiology residents and provides an objective method of assessing individual progress amongst trainees.

A promising addition to current 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 device closure of patent ductus arteriosus and other procedures [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.

Currently, there are no canine simulation models for the purpose of training cardiology residents in BVP. The purpose of this study is to develop an anatomically accurate 3D model of a canine heart to simulate PS for veterinary cardiology residents to learn and practice BVP. The study will also assess the model's validity and ability to increase user confidence. The study team hypothesizes that creating a realistic canine heart model will enhance students' practical skills, understanding of balloon valvuloplasty, and confidence in their ability to perform BVP.

Animals, Materials, and Methods

Model Development

Heart Segmentation

The heart model was modeled from a Computed Tomography Angiography (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 (version 5.6.2) software (<https://www.slicer.orgsoftware>) to select the heart chamber walls, valves, and necessary vasculature (**Figure 1**). The CTA 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. To

reduce the difficulty of navigating the catheter around the right ventricular apex for practical use in trainees, the volume of the right ventricle was increased and the ventricular walls were smoothed by overlining the blood pool of the right ventricle.

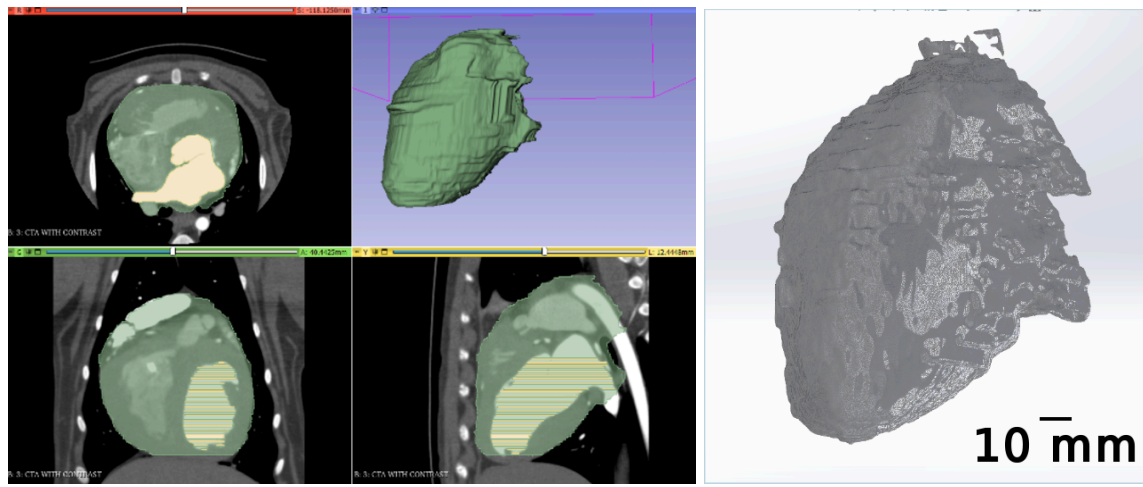


Figure 1. A CTA scan of a French Bulldog heart was segmented (as shown on the left) to create a 3D model of the heart.

After segmentation, STLs of the heart chambers and the annulus were generated and exported to MeshMixer (version 3.5) software (meshmixer.en.softonic.com). 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 software programs while preserving the details of the heart chambers. The STL file was then exported to Onshape. 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 (**Figure 2**). The pegs have a diameter of 8.89 mm and a height of 6.35 mm.

The heart chambers 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 Supplemental 3. 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 2.475 ± 0.156 MPa and maximum tensile strength of 0.87 ± 0.07 MPa. Further detail regarding the tensile testing including the analysis method and procedure can be found in Supplemental 5.2.

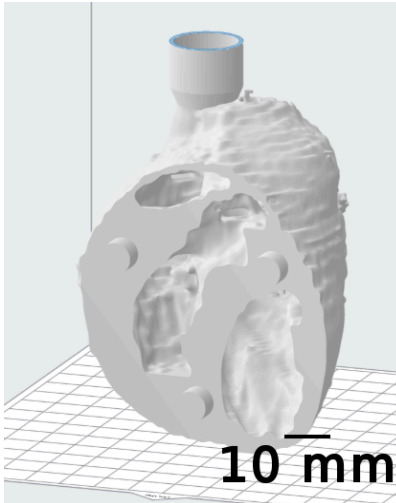


Figure 2. One half of the heart model after editing in OnShape. 3D pegs were added to the heart model to secure the two halves of the heart together. A connection piece was added to attach the jugular vein.

Jugular Vein

The jugular vein was created in SolidWorks and printed in Elastic 50A resin. 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 at the proximal end. The wall of the jugular vein is 1 mm thick. A connector between the jugular vein and cranial vena cava was added to the heart model in SolidWorks. The proximal end of the jugular vein fits inside the connector and is secured in place due to the dimensional tolerance of each component.

Pump

To replicate blood flow through the heart, a peristaltic pump was added to the model. 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]. The ideal flow rate to match native physiology for a French Bulldog is 1.15 mL per beat per kilogram of body weight [13]. The canine the model was built around weighs 9.8kg and the average heart 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 connects to the proximal end of the jugular vein at a 60 degree angle and is secured with a hose clamp (**Figure 3**). This ensured the fluid path was moving in the correct direction into the heart. 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.

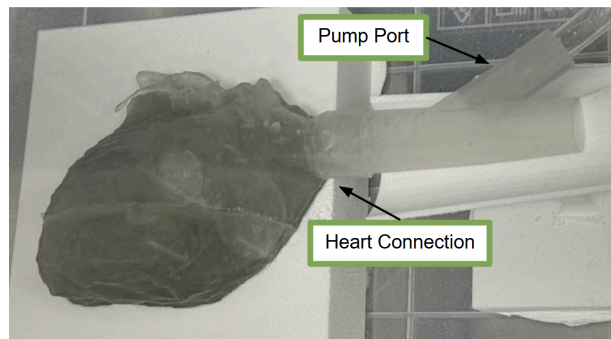


Figure 3. The pump port on the jugular vein attaches the tubing from the pump to the heart model. A connection piece between the jugular vein and heart was added.

Full Model Assembly

The final model consisted of seven main parts: the 3D printed heart, the 3D printed jugular vein, a video stand setup, a water basin to hold the model, a peristaltic pump to simulate blood flow, and heart and jugular vein supports (**Figure 4**).

Ancillary components to the model include the video stand system and heart and jugular vein supports. During a typical procedure, contrast is added to the vascular system and fluoroscopy is used to guide the catheter to the pulmonary valve. To replicate this, the stand holds a phone above the model and projects live footage of the model onto a monitor in front of the user. The phone connects to the monitor using a HDMI to USB-C or HDMI to Lightning cable. This replicates the fluoroscopy experience by ensuring the user looks at the screen rather than their hands. Additionally, the balloon catheter was filled with water colored with red dye to replicate the fluoroscopy and contrast, increasing visibility of the balloon through the model. The supports for the heart and jugular secure the model to prevent it from freely moving in the water basin. The support 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. Both supports are 3D printed out of polylactic acid (PLA) and ensure that the model stays in place during the procedure.

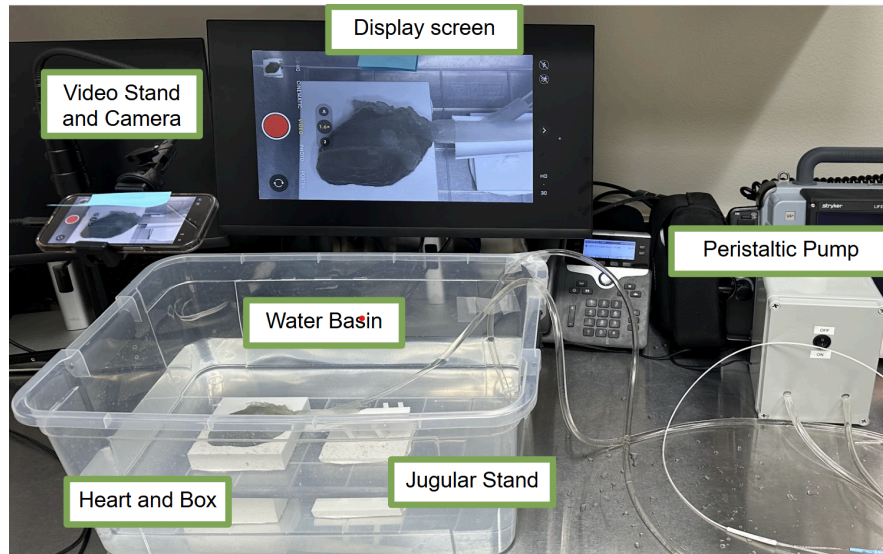


Figure 4. Full design assembly. The heart and jugular vein are secured into the system with 3D printed supports. The peristaltic pump allows fluid flow throughout the heart. The video stand, camera, and display screen mimic the use of fluoroscopy during the BVP procedure.

Study Design

Subjects

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, 3 cardiology attendings, and 3 residents from specialties other than cardiology (surgery, anesthesiology, and ophthalmology). This study was approved by the Institutional Review Board at the University of Wisconsin - Madison and was granted exempt status.

Pre - Testing Likert Surveys

Prior to interacting with the model, participants were asked to fill out a five question pre-testing survey. The first question on this survey asks for the participants' level of training – cardiology resident, non-cardiology resident, or cardiology attending. The second and third questions ask participants to quantify how many BVP procedures they have performed and observed. The last two questions ask participants to assess their confidence in their ability to perform BVP and their current understanding of catheter placement and cardiac anatomy using a Likert scale.

Testing with Model

Following the pre-testing survey, participants received a mini lesson on pulmonary stenosis, the balloon valvuloplasty procedure, and were shown images of each step in the procedure being performed on the model. 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 procedure trials on their own using the model. Each trial included inserting a wedge catheter into the model and navigating to the pulmonary valve, feeding the guide wire into the model through the wedge

catheter, removing the wedge catheter, then inserting the balloon catheter over the guide wire, and inflating the balloon once it has reached the pulmonary valve. Images of the wedge catheter, guide wire, and balloon catheter inside the model can be seen in **Figure 5**. The completion of one trial was marked by the inflation of the balloon catheter within the pulmonary valve. Participants were allowed to insert the wedge catheter and guidewire simultaneously as this is commonly done in the real procedure. Additionally, subjects were allowed to choose whether they wanted to use the balloon on the wedge catheter to help float the catheter through the ventricle. All equipment was removed from the model between trials. Given that balloon valvuloplasty requires two people to manage all the equipment being fed into the heart, a study team member served as first assistant to each participant during their interaction with the model. The same study team member assisted all of the participants. Each participant tested the model in a private room with only study team members present.



Figure 5. Wedge catheter, guide wire, and balloon catheter inserted in model (Left to Right)

Post - Testing Likert Surveys

After the participant completed three procedures, they were asked to answer a post-testing survey. The post-survey included eight questions. Two questions assessed how interaction with the model impacted the subject's confidence in their ability to perform BVP and their understanding of catheter placement and cardiac anatomy. Four questions asked subjects to assess the accuracy of cardiac anatomy, the experience of navigating the catheter, the fluid flow provided by the pump, and the video display screen. The final two questions asked subjects how likely they would be to recommend the model to their peers and if they believed it would be a useful training tool for cardiology residents. The post-surveys were 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 testing. When filling out the post-survey, participants were asked to select a survey code from an anonymous list and copy it both to the pre-survey and post-survey in order to match the pre-survey and post-survey to each other. Once the code had been selected, study team members were not permitted to view the survey. All surveys were placed in a locked room and results were not viewed until all testing was completed.

Analysis

After testing, the subjects were grouped based on their prior experience with BVP. Subjects in the experienced groups had served as the lead veterinarian on at least one BVP case ($n = 5$). The inexperienced group consisted of all subjects who did not have experience serving as the lead veterinarian on at least one BVP case ($n=4$). The pre- and post-testing Likert survey responses were converted to numerical values 1-5 (1 = strongly disagree, 5 = strongly agree) and compared between the experienced

and inexperienced group using a Wilcoxon Rank Sum Test using a significance level of $p < 0.05$. The statistical analysis was performed using Matlab.

Results

The first two questions on the pre-testing survey asked participants to quantify their experience and familiarity with BVP procedures. Based on these results, the participants in the study were divided into two groups: those who had first hand experience as the lead veterinarian during a BVP procedure (experienced) and those who had not (inexperienced). Among the non-cardiology residents, none had served as a lead during a BVP procedure, but two of the three had observed 1- 4 procedures. Within the cardiology residents, all had observed at least three cases. Two of these participants had assisted with at least 6 procedures and served as the lead veterinarian during at least one of these procedures. The other cardiology resident participant had assisted with 4 - 5 cases, but never served as the lead veterinarian. Finally, all three of the cardiology attendings have observed at least 6 BVP cases, assisted with at least 6 BVP procedures, and had served as the lead veterinarian during at least of these cases (**Table 1**).

Table 1: Participants grouped by experience serving as lead veterinarian during a balloon valvuloplasty procedure.

	Non-Cardiology Residents	Cardiology Residents	Cardiology Attendings	Total
Experienced	0	2	3	5
Inexperienced	3	1	0	4

The remaining two questions on the pre-testing survey asked subjects to rank their confidence in their ability to perform BVP and their understanding of cardiac anatomy and catheter placement on a Likert scale. The most common responses among the experienced and inexperienced groups are reported in **Table 2**. A significant difference was observed between experienced and inexperienced groups ($p = 0.02$) in terms of their confidence in BVP, with individuals in the experienced group reporting significantly higher levels of confidence in their ability to perform BVP than the inexperienced group. In terms of a subject's pre-testing understanding of cardiac anatomy and catheter placement, the experienced group reported significantly stronger understandings than the inexperienced groups ($p = 0.02$).

Table 2: Pre - Testing Survey Results

Question	Most Frequent Response: Total	Most Frequent Response: Experienced	Most Frequent Response: No Experience	p
I am confident in my ability to perform a balloon valvuloplasty to treat pulmonic stenosis.	Strongly Disagree	Strongly Agree	Strongly Disagree	0.02
I have a strong understanding of cardiac anatomy and catheter placement.	Strongly Agree	Strongly Agree	Strongly Disagree	0.02

Following interaction with the model, subjects were asked to complete a post-testing Likert survey to evaluate if they would recommend the model be used in cardiology resident training, the model's realism, and how the model impacted their confidence and understanding of BVP. The most frequent response among the experienced and inexperienced groups are shown in **Table 3**. No significant difference was observed between the responses of the experienced or inexperienced groups among the post-testing survey questions (**Table 3**).

In terms of the model's effectiveness as a teaching tool, all participants either agreed or strongly agreed that the model would be a useful tool in teaching cardiology residents. Additionally, all participants agreed or strongly agreed that they would recommend using the model for procedural skills training to their colleagues and peers.

Overall, 7 of the 9 participants agreed or strongly agreed that practice with the model improved their confidence in their ability to perform BVP. The other two participants neither agreed nor disagreed that the model helped to improve their confidence in BVP. Furthermore, 6/9 participants either agreed or strongly agreed that the model improved their understanding of cardiac anatomy and catheter placement. The other three participants all belonged to the experienced group and neither agreed nor disagreed in response to this question.

Finally, 8/9 participants agreed or strongly agreed that the heart anatomy was realistic, while one cardiology resident neither agreed nor disagreed. Additionally, 8/9 participants agreed or strongly agreed that the experience of navigating the catheter through the heart was realistic. The same cardiology resident that disagreed with the previous question disagreed with this question, stating that the experience of navigating the catheter was not realistic. In terms of the peristaltic pump to replicate fluid flow through the heart, 5 participants agreed or strongly agreed that the fluid flow was realistic. Of the remaining participants, 2 non-cardiology residents and 1 cardiology resident neither agree nor disagreed and 1 cardiology resident disagreed. It is important to note that only one participant, a cardiology attending, utilized the balloon feature on the wedge catheter to float the catheter to the pulmonary valve. Lastly, all participants either agreed or strongly agreed that the camera stand and video system adequately replicated the fluoroscopy monitors used in real cases.

Complete pre and post-testing survey results can be found in Supplemental 5.3.

Table 3: Post - Testing Survey Results

Question	Most Frequent Response: Total	Most Frequent Response: Experienced	Most Frequent Response: No Experience	p
I believe the model would be a useful training tool for cardiology residents.	Strongly Agree	Strongly Agree	Strongly Agree	0.56
I would recommend using the model for procedural skills training to other residents and/or fellows.	Strongly Agree	Agree	Strongly Agree	0.71
I am more confident in my ability to perform the balloon valvuloplasty catheter procedure after using the model.	Agree	Agree	Agree	1
The model improved my conceptual understanding of cardiac anatomy and catheter placement.	Agree	Neither Agree nor Disagree	Agree + Strongly Agree	0.10
The heart anatomy is realistic.	Agree	Agree + Strongly Agree	Agree	1
The experience of navigating the catheter was realistic.	Agree	Agree	Agree	0.97
The inclusion of forward fluid flow provides a realistic experience for floating a catheter through the cardiac structures.	Agree + Neither Agree nor Disagree	Agree	Agree + Neither Agree nor Disagree	0.91
Using the camera system prepared me to use fluoroscopic	Agree	Strongly Agree	Agree	0.24

imaging during a procedure.				
-----------------------------	--	--	--	--

Discussion

The objective of this study was to evaluate the effectiveness of a multidimensional imaging based model in providing resident and attending veterinarians with opportunities to learn and practice BVP. The survey results overall show that the model accurately mimics the BVP procedure, provides realistic anatomy, helps inexperienced users improve their confidence in BVP, and would be a useful tool for training cardiology residents.

First, the results showed that all but one user agreed that the heart anatomy and process of navigating the catheter through the heart model is realistic. Additionally, all users agreed that the display screen accurately mimicked how fluoroscopy is used in real procedures. One question regarding the model's accuracy, which received less agreement among study participants, evaluated the accuracy of the fluid flow provided by the pump. Just over half of subjects agreed that this component of the model was accurate. Although this is lower than the other three questions regarding the models' accuracy, 100% of cardiology attendings agreed that the fluid flow provided by the pump was accurate and these users have the most experience with BVP. The majority of the subjects who neither agree nor disagree came from the inexperienced group, indicating that these users may not be able to accurately assess this component of the model due to lack of experience. Overall, the responses to these questions demonstrate that multidimensional imaging based methods can be used to accurately replicate canine cardiac anatomy and realistically simulate BVP procedures.

Secondly, the post-testing results showed that 7/9 subjects agreed that testing with the model improved their confidence in their ability to perform BVP. More importantly, 100% of inexperienced users reported that they experienced this increase in confidence. The two users who neither agree nor disagree with this question came from the experienced group. These users may already have strong confidence in their ability to perform BVP and therefore did not experience an increase. Furthermore, 6/9 subjects agreed testing with the model improved their understanding of cardiac anatomy and catheter placement. Once again, 100% of the inexperienced users agreed to this question, and all other respondents neither agree nor disagree. This indicates users with more experience already have a strong understanding of cardiac anatomy and catheter placement, thus engagement with the model may not improve their understanding. Most importantly, these results show that this model increased the confidence of inexperienced users to complete the BVP procedure and they have an improved understanding of cardiac anatomy.

Finally, all users reported that they believe the model would be a beneficial addition to the current training program for cardiology residents and all subjects would recommend the model to their peers for teaching, learning, and practicing BVP. These results show that multidimensional imaging based models can be used to create useful teaching tools for cardiology residency programs.

Multidimensional image based modeling allows for fabrication of anatomically accurate patient-specific models in veterinary cardiology. These 3D models are beneficial in medical teaching, assessment of cardiac function, design and assessment of devices for interventional procedures, surgical planning, and education of the patient's owner [14]. The 3D printed model created in this study was proven to enhance education of cardiac anatomy and understanding of the BVP procedures. All students believed that the model would be a beneficial addition to their training program. Stieger-Vanegas et. al,

has shown the potential of cardiovascular 3D modeling by creating 3D patient specific models of different animals with varying heart conditions, highlighting the many future applications of 3D models [17]. In a similar study, Saunders et. al. evaluated a 3D model of a canine heart with patent ductus arteriosus for trainees to practice device placement and transcatheter closure. Diplomates and residents in their study agreed that the model provided a close representation of device placement in the clinical setting, and that using the model improved their confidence in completing the procedure [11]. This correlates with the results of our study where all inexperienced users responded that using the model improved their confidence in the BVP procedure. Overall, the use of 3D printed models in veterinary cardiology and medical training shows promise as students exhibit an increased understanding of anatomy and improved confidence in completing surgical procedures.

Study Limitations

There are two main limitations that must be considered for this study. The first limitation identified is due to the population, as there was variability in BVP procedure experience and understanding of canine cardiac anatomy across the participants. First, this study only consisted of nine total subjects, and the experienced and inexperienced groups consisted of five and four subjects respectively. The small number of subjects reduces the ability of the Wilcoxon Rank Sum test to identify the significant differences between the pre and post-survey responses. Future studies with more participants could build upon the results from this study and further increase confidence. Though the study size was small, the unanimous recommendation to implement the model as a tool for veterinary schools is a promising indication of the model's success.

Another limitation of the study was within the first step of the BVP procedure. In this step a wedge catheter is inserted through the jugular vein and subsequently traversed to the pulmonary valve by the physician. One method option the physician has is to “float” the catheter to the valve, meaning they inflate a balloon on the tip of the wedge catheter and the forward blood flow helps push the catheter towards the pulmonary valve. This technique is one of many different tools physicians use to get to the pulmonary value. However, the balloon in the wedge catheter provided was ruptured, and with no replacement the subjects were unable to implement this technique throughout the study. The main implication is the analysis of the fluid flow system in the model. The analysis of the forward flow can be most easily understood in this context as there is direct visual feedback while fluid flows around the balloon. The use of this technique could be isolated in future studies to better understand how the catheter is affected by the fluid flow of the model and determine how many, if any, subjects float the balloon.

Conclusion

PS is the most common congenital heart disease among canines. The treatment procedure for PS, BVP, is challenging to master and is accompanied by a steep learning curve. Currently, there are no models for students to learn and practice BVP. The purpose of this study was to develop a 3D printed heart model using multidimensional imaging based methods and evaluate the model's effectiveness in training users in the BVP procedure. The results of this showed that veterinary cardiology attendings, cardiology residents, and non-cardiology residents alike all believe that the 3D model accurately simulated the BVP procedure and would be a beneficial addition to the training programs for veterinary cardiology residents. Additionally, the model helped all inexperienced users increase their confidence in

their ability to perform BVP. Overall, this study demonstrates the effectiveness of using multidimensional imaging based methods to create a 3D cardiac canine model to simulate PS to train veterinary cardiology residents in BVP.

References

- [1] P. Oliveira *et al.*, “Retrospective review of congenital heart disease in 976 dogs,” *Journal of Veterinary Internal Medicine*, vol. 25, no. 3, pp. 477–483, Mar. 2011.
doi:10.1111/j.1939-1676.2011.0711.x
- [2] D. P. Schrope, “Prevalence of congenital heart disease in 76,301 mixed-breed dogs and 57,025 mixed-breed cats,” *Journal of Veterinary Cardiology*, vol. 17, no. 3, pp. 192–202, Sep. 2015.
doi:10.1016/j.jvc.2015.06.001
- [3] Brambilla, P. G., Polli, M., Pradelli, D., Papa, M., Rizzi, R., Bagardi, M., & Bussadori, C. (2020). Epidemiological study of congenital heart diseases in dogs: Prevalence, popularity, and volatility throughout twenty years of clinical practice. *PLOS ONE*, 15(7). doi:10.1371/journal.pone.0230160
- [4] Schrope, D. P. (2005). Balloon valvuloplasty of valvular pulmonic stenosis in the dog. *Clinical Techniques in Small Animal Practice*, 20(3), 182–195. doi:10.1053/j.ctsap.2005.05.007
- [5] B. A. Scansen, “Advances in the treatment of pulmonary valve stenosis,” *Veterinary Clinics of North America: Small Animal Practice*, vol. 53, no. 6, pp. 1393–1414, Nov. 2023.
doi:10.1016/j.cvsm.2023.05.013
- [6] T. P. Nguyenba and A. H. Tobias, “The AMPLATZ® canine duct occluder: A novel device for patent ductus arteriosus occlusion,” *Journal of Veterinary Cardiology*, vol. 9, no. 2, pp. 109–117, Nov. 2007.
doi:10.1016/j.jvc.2007.09.002
- [7] Jones, D. B., Sung, R., Weinberg, C., Korelitz, T., & Andrews, R. (2015). Three-dimensional modeling may improve surgical education and clinical practice. *Surgical Innovation*, 23(2), 189–195.
doi:10.1177/1553350615607641
- [8] Matyal, R., Montealegre-Gallegos, M., Mitchell, J. D., Kim, H., Bergman, R., Hawthorne, K. M., ... Mahmood, F. (2015). Manual skill acquisition during transesophageal echocardiography simulator training of cardiology fellows: A kinematic assessment. *Journal of Cardiothoracic and Vascular Anesthesia*, 29(6), 1504–1510. doi:10.1053/j.jvca.2015.05.198
- [9] Werz, S. M., Zeichner, S. J., Berg, B. -I., Zeilhofer, H. -F., & Thieringer, F. (2018). 3D printed surgical simulation models as educational tool by maxillofacial surgeons. *European Journal of Dental Education*, 22(3). doi:10.1111/eje.12332
- [10] Chahal, B., Aydin, A., & Ahmed, K. (2023). Virtual reality vs. physical models in surgical skills training. an update of the evidence. *Current Opinion in Urology*, 34(1), 32–36.
doi:10.1097/mou.0000000000001145
- [11] Saunders, A. B., Keefe, L., Birch, S. A., Wierzbicki, M. A., & Maitland, D. J. (2017a). Perceptions of transcatheter device closure of patent ductus arteriosus in veterinary cardiology and evaluation of a canine

model to simulate device placement: A preliminary study. *Journal of Veterinary Cardiology*, 19(3), 268–275. doi:10.1016/j.jvc.2017.04.002

[12] Man, J., Maessen, J., & Sardari Nia, P. (2020). The development of a flexible heart model for simulation-based training. *Interactive CardioVascular and Thoracic Surgery*, 32(2), 182–187. doi:10.1093/icvts/ivaa260

[13] Vurucu, M., Ekinci, G., & Gunes, V. (2021a). An echocardiographic study of breed-specific reference ranges in healthy French bulldogs. *Veterinary Radiology & Ultrasound*, 62(5), 573–582. doi:10.1111/vru.12997

[14] N. Hussein *et al.*, “Simulation of semilunar valve function: Computer-aided design, 3D printing and flow assessment with mr,” *3D Printing in Medicine*, vol. 6, no. 1, Feb. 2020. doi:10.1186/s41205-020-0057-8

[15] M. Vukicevic, B. Mosadegh, J. K. Min, and S. H. Little, “Cardiac 3D printing and its future directions,” *JACC: Cardiovascular Imaging*, vol. 10, no. 2, pp. 171–184, Feb. 2017. doi:10.1016/j.jcmg.2016.12.001

[16] L. M. Meier, M. Meineri, J. Qua Hiansen, and E. M. Horlick, “Structural and congenital heart disease interventions: The role of three-dimensional printing,” *Netherlands Heart Journal*, vol. 25, no. 2, pp. 65–75, Jan. 2017. doi:10.1007/s12471-016-0942-3

[17] S. M. Stieger-Vanegas and K. F. Scollan, “Development of three-dimensional cardiac models from computed tomography angiography,” *Journal of Veterinary Cardiology*, vol. 51, pp. 195–206, Feb. 2024. doi:10.1016/j.jvc.2023.11.017

Supplementary Data

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. Tjostheim 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.

References

- [1] M. Brložnik, A. Nemec Svete, V. Erjavec, and A. Domanjko Petrič, “Echocardiographic parameters in French bulldogs, Pugs and boston terriers with Brachycephalic Obstructive Airways syndrome,” *BMC Veterinary Research*, vol. 19, no. 1, Feb. 2023. doi:10.1186/s12917-023-03600-9
- [2] M. Vurucu, G. Ekinici, and V. Gunes, “An echocardiographic study of breed-specific reference ranges in healthy French bulldogs,” *Veterinary Radiology & Ultrasound*, vol. 62, no. 5, pp. 573–582, Jun. 2021. doi:10.1111/vru.12997
- [3] E. A. Stone and G. J. Stewart, “Architecture and structure of canine veins with special reference to confluences,” *The Anatomical Record*, vol. 222, no. 2, pp. 154–163, Oct. 1988. doi:10.1002/ar.1092220207
- [4] S.-J. Yoo, T. Spray, E. H. Austin, T.-J. Yun, and G. S. van Arsdell, “Hands-on surgical training of congenital heart surgery using 3-dimensional print models,” *The Journal of Thoracic and Cardiovascular Surgery*, vol. 153, no. 6, pp. 1530–1540, Jun. 2017. doi:10.1016/j.jtcvs.2016.12.054
- [5] Center for Devices and Radiological Health, “Classify your medical device,” U.S. Food and Drug Administration, <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device> (accessed Sep. 18, 2024).
- [6] D. Krishna, “FDA guidance on Computational Modeling and simulation in medical device submissions,” StarFish Medical, <https://starfishmedical.com/blog/fda-guidance-on-cms-in-medical-device-submissions/> (accessed Sep. 18, 2024).
- [7] “How to meet the new simulation testing requirements,” Medical Device and Diagnostic Industry, <https://www.mddionline.com/testing/how-to-meet-the-new-simulation-testing-requirements> (accessed Sep. 18, 2024).
- [8] T. Yamada et al., “Three-dimensional printing of life-like models for simulation and training of minimally invasive cardiac surgery,” *Innovations: Technology and Techniques in Cardiothoracic and Vascular Surgery*, vol. 12, no. 6, pp. 459–465, Nov. 2017. doi:10.1177/155698451701200615
- [9] A. B. Saunders, L. Keefe, S. A. Birch, M. A. Wierzbicki, and D. J. Maitland, “Perceptions of transcatheter device closure of patent ductus arteriosus in veterinary cardiology and evaluation of a canine model to simulate device placement: A preliminary study,” *Journal of Veterinary Cardiology*, vol. 19, no. 3, pp. 268–275, Jun. 2017. doi:10.1016/j.jvc.2017.04.002
- [10] L. E. Markovic, S. Nguyen, and S. Clouser, “Utility of three-dimensional virtual and printed models for veterinary student education in congenital heart disease,” *Education in the Health Professions*, vol. 6, no. 1, pp. 15–21, Jan. 2023. doi:10.4103/ehp.ehp_28_22

- Total Cost: \$616.07

4. Scroll 5-6 slices superior. Use the paintbrush tool to outline and color in the heart.

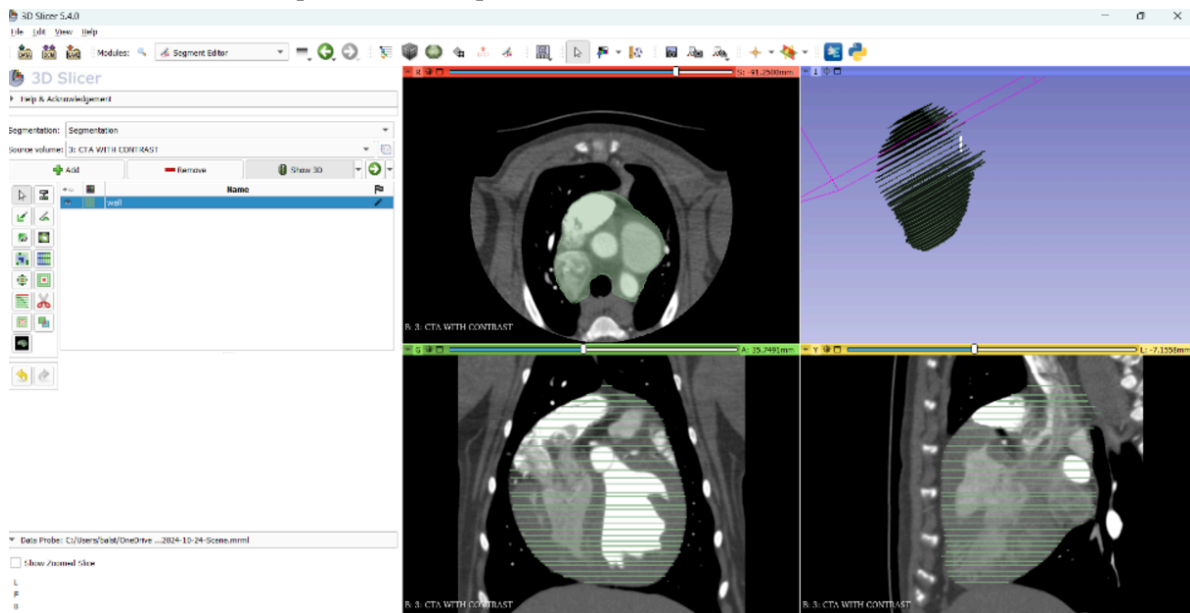


Figure 3.1.1: Heart segmentation after using the paintbrush tool to draw the heart every 5-6 layers

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.

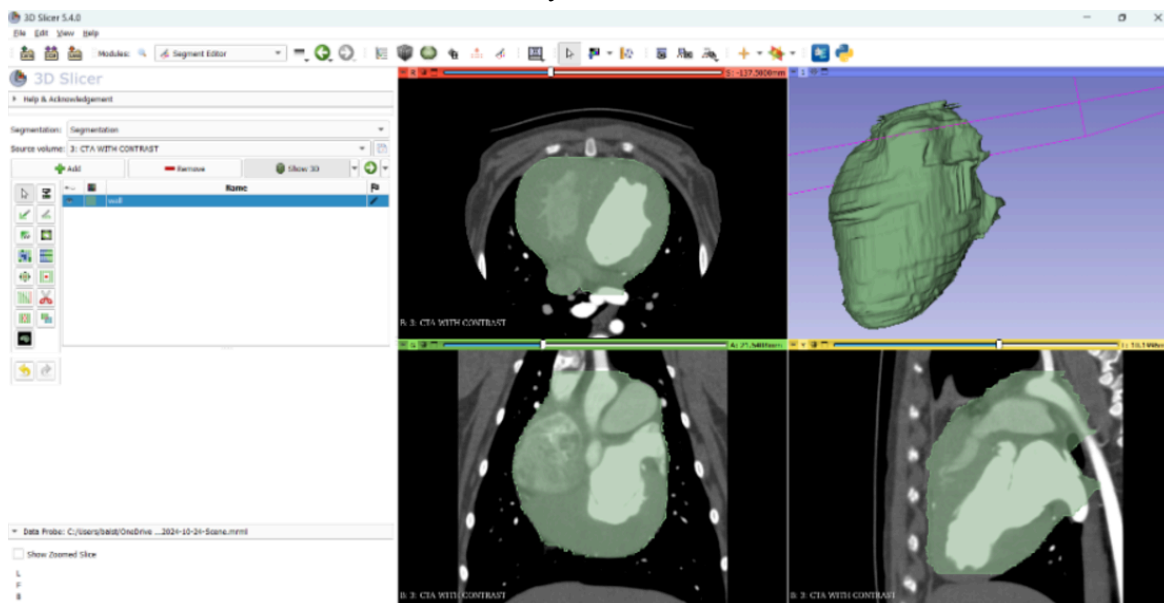


Figure 3.1.2: Heart segmentation after filling between layers

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.

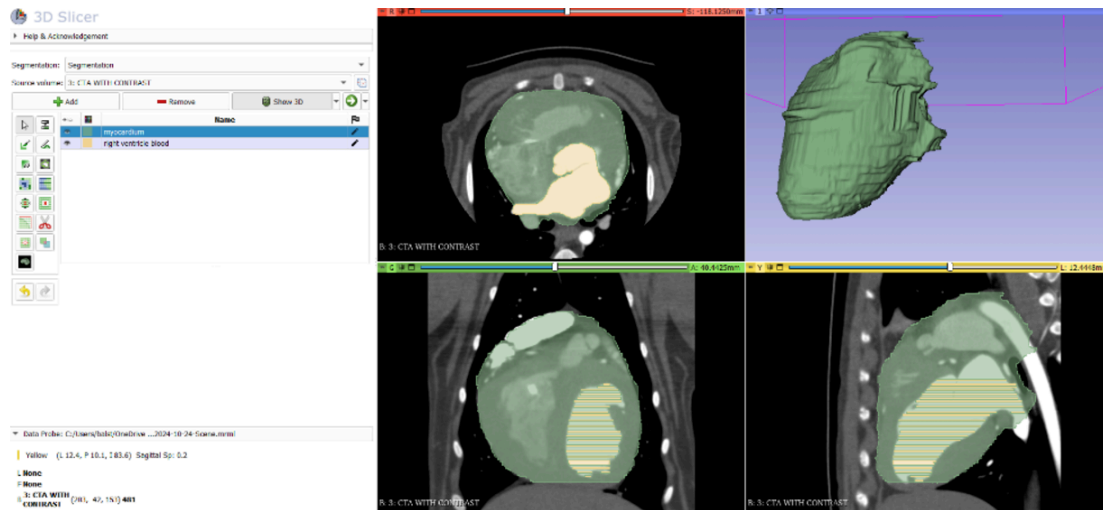


Figure 3.1.3: Heart segmentation during the process of segmenting the blood pools

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.

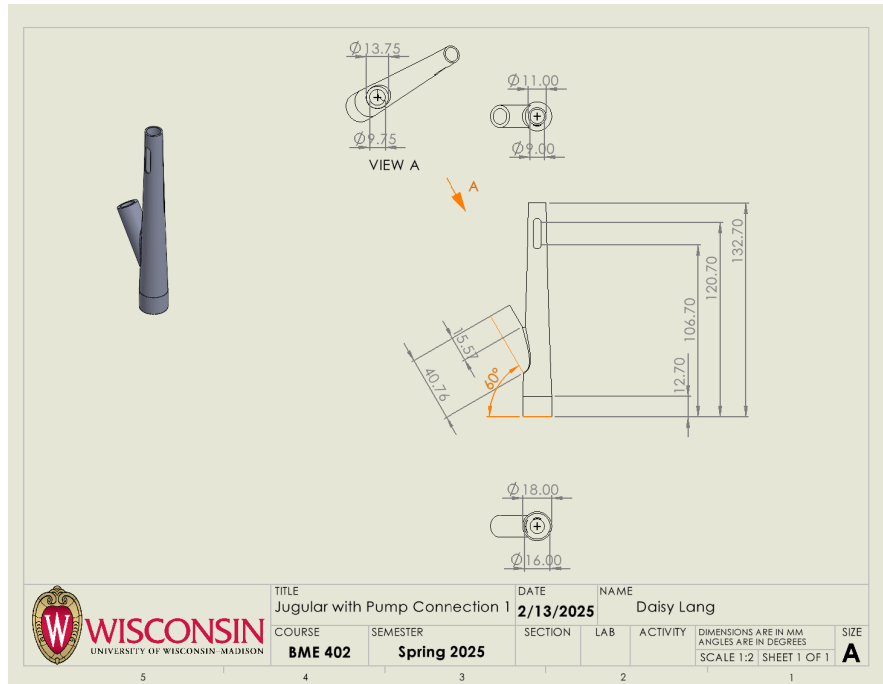


Figure 3.3.1: Jugular vein drawing

3.4 Model Stand

Jugular Fixture

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

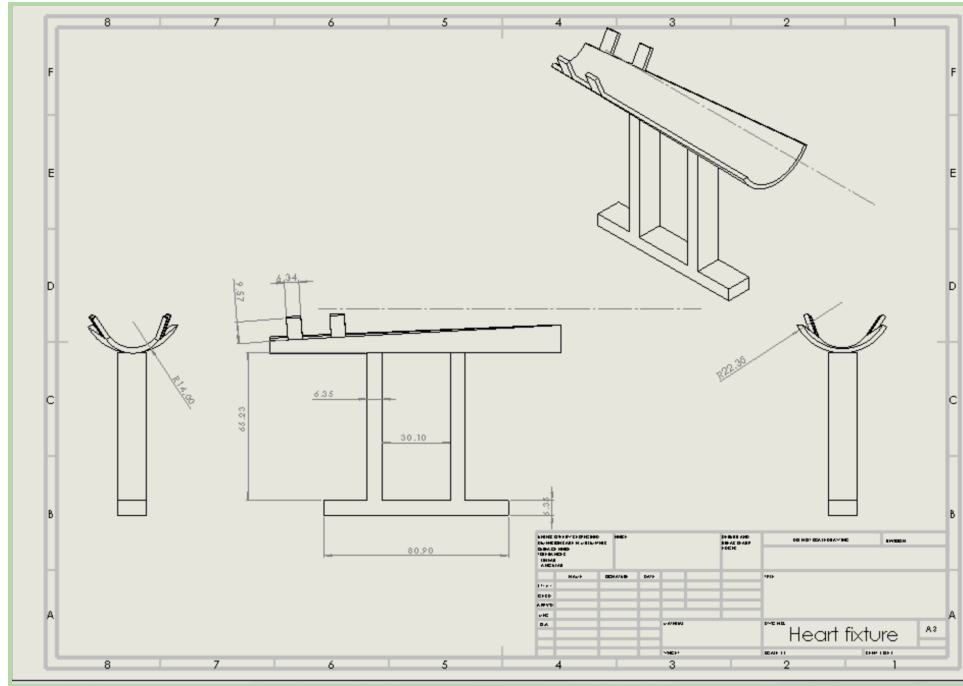


Figure 3.4.1: Jugular vein stand drawing

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.

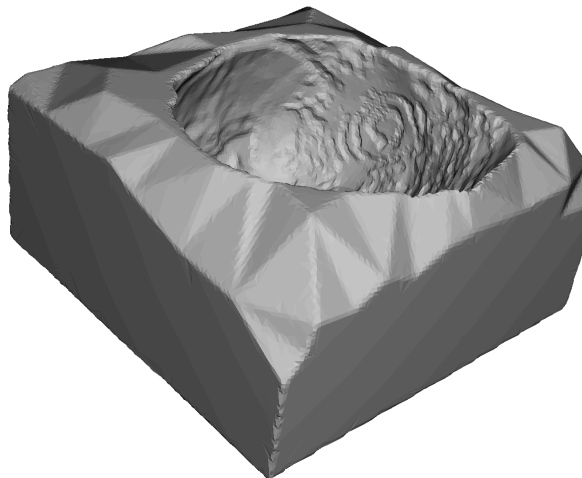


Figure 3.4.2: STL model of heart chamber base

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 with 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 on 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 tighten it, 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

Please check your level of training

- ☐ 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

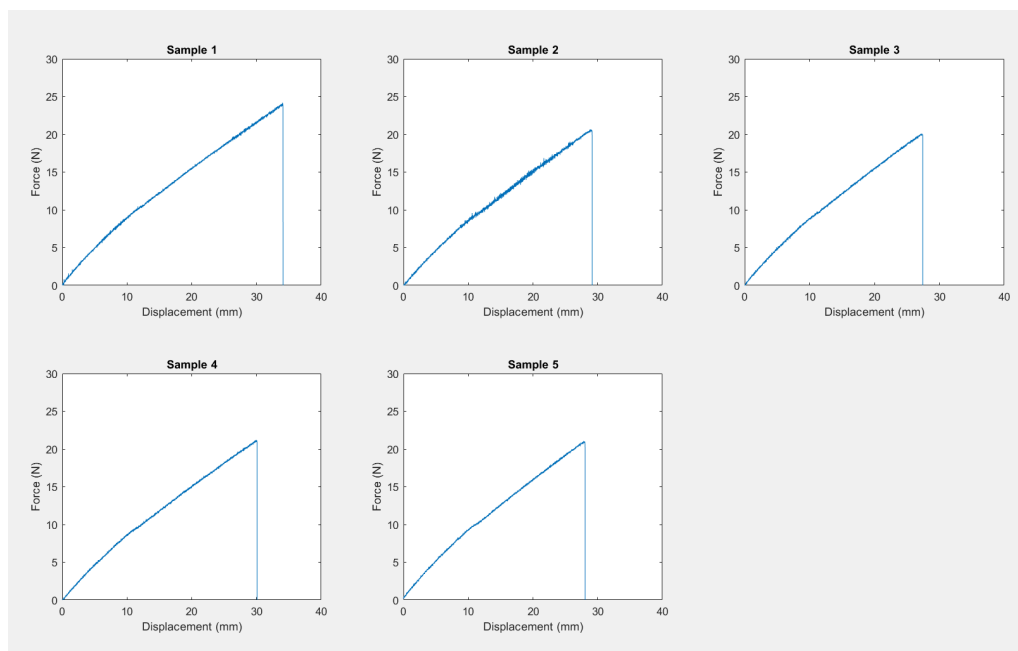


Figure 5.1.1: Force vs. Displacement graphs for tensile testing of Elastic 50A

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
forc1=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

```

5.3 Pre and Post Testing Survey Results

Level of Training	PreQ1	PreQ2	PreQ3	PreQ4	PostQ1	PostQ2	PostQ3	PostQ4	PostQ5	PostQ6	PostQ7	PostQ8	PostQ9
Cardiology Resident	3	2	4	3	5	4	4	4	4	3	4	4	5
Cardiology Resident	4	5	5	4	4	4	4	4	4	2	2	4	4
Cardiology Resident	4	4	5	5	4	4	3	3	2	4	3	4	4
Cardiology Attending	5	5	5	5	5	3	3	4	4	2	4	5	5
Cardiology Attending	5	5	5	5	5	4	4	5	5	3	5	5	5
Cardiology Attending	5	5	5	5	5	4	3	5	4	3	4	5	4
Non-Cardiology Resident	1	1	3	3	5	5	5	4	4	4	3	4	5
Non-Cardiology Resident	1	1	1	3	5	3	4	4	4	3	3	4	4
Non-Cardiology Resident	1	1	2	1	5	4	5	5	5	4	4	4	5
Level of Training	PreQ1	PreQ2	PreQ3	PreQ4	PostQ1	PostQ2	PostQ3	PostQ4	PostQ5	PostQ6	PostQ7	PostQ8	PostQ9
Inexperienced	1	1	3	3	5	5	5	4	4	4	3	4	5
Inexperienced	1	1	1	3	5	3	4	4	4	3	3	4	4
Inexperienced	1	1	2	1	5	4	5	5	5	4	4	4	5
Inexperienced	3	2	4	3	5	4	4	4	4	3	4	4	5
Experienced	4	5	5	4	4	4	4	4	4	2	2	4	4
Experienced	4	4	5	5	4	4	3	3	2	4	3	4	4
Experienced	5	5	5	5	5	3	3	4	4	2	4	5	5
Experienced	5	5	5	5	5	4	4	5	5	3	5	5	5
Experienced	5	5	5	5	5	4	3	5	4	3	4	5	4