BME Design

Multidimensional Imaging Based Model for Canine Cardiovascular Procedural Skills

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Abstract

In recent years, the University of Wisconsin Madison School of Veterinary Medicine has experienced a shortage of patients suffering from Pulmonary Stenosis (PS) due to staffing shortages and reduced hours of operation. As a result, veterinary students have fewer opportunities to practice transcather procedures to treat PS. In order to ensure students can learn this procedure, a 3D canine heart model was developed to simulate transcatheter balloon valvuloplasty for the treatment of PS. Similar models have been developed by other academic groups and veterinary schools, but currently there are no canine procedural heart models available on the market. The proposed model includes a 3D printed anatomically accurate canine heart, jugular vein, and pulmonary valve. The canine heart and valve were developed through segmentation of a computer tomography angiography (CTA) scan of a french bulldog with PS and the jugular vein was created in SolidWorks based on dimensions collected from CTA scans and consultation by a veterinary radiologist. Three tests were used to evaluate the model: the stiffness of the model materials was evaluated in MTS tensile testing and compared to the stiffnesses of native tissue, the deformation of the pulmonary valve annulus was measured over the course of 150 balloon catheter inflations, and the full functionality of the model was qualitatively assessed by the client. Based on these results, the material used for the jugular vein and annulus were approved. Additionally, the results showed that the heart chambers must undergo improvements before the model is fully functional.

1 Introduction

1.1 Motivation

Pulmonary valve stenosis (PS) is a congenital heart defect that causes the narrowing of the pulmonary valve [1]. In PS, the leaflets of the pulmonary valve are thickened or partially fused, obstructing blood flow from the heart to the lungs [2]. PS is the most common congenital heart disease among canines and represents 31-34% of all canine congenital heart disease diagnoses [3]. Canines with PS may experience exercise intolerance, collapsing, and heart arrhythmias [2]. If left untreated, severe cases of PS can lead to right-sided congestive heart failure [4]. Any species of canine can develop PS, but it is most prevalent in French Bulldogs [4]. Given the rising popularity of this dog breed and the increasing number of PS cases reported, there is a need for veterinarians trained to treat PS [5].

There are two main methods of treating PS; minimally invasive transcatheter procedures and surgical intervention. Of the two, transcatheter procedures are the preferred method of treating PS because they are significantly less expensive than surgical operations, have shorter procedural times, and faster recovery times [6][7]. Additionally, most pet owners do not purchase pet insurance and cannot afford surgical intervention, leaving transcatheter procedures as the only option available to treat their pets [8]. Even if a pet owner elects to have surgery on their canine, veterinary cardiothoracic surgeons are not widely available at every animal hospital [8]. For these reasons, transcatheter procedures are performed almost exclusively over surgical operations, driving the high demand for veterinarians trained in transcatheter procedures [6].

In recent years, the University of Wisconsin Madison School of Veterinary Medicine has experienced a decreased caseload of patients with PS, due to a staffing shortage that has limited the hours of operation of the emergency clinic [8]. This decreased caseload has eliminated opportunities for veterinary students to practice transcatheter procedures and has created the need for alternative methods for students to learn and practice these skills. Prior studies have found that training simulators are the most effective way for veterinary students to learn new procedures [9][10]. Additionally, students who utilize training simulators report improved technical performance as compared to students who did not use training simulators to learn the same skill [11]. In order for veterinary students to improve their transcatheter procedural skills amidst the decreased caseload of PS patients, there is a need for a training model for PS treatment.

1.2 Existing Devices & Current Methods

Currently, there are no canine heart training models commercially available. However, many universities have created cardiac models for their associated veterinary programs. One example is the Canine Model for Patent Ductus Arteriosus Occlusions at the College of Veterinary Medicine and Biomedical Sciences at Texas A&M University [12]. This group developed a CAD model of the patent ductus arteriosus from a CTA scan of a canine heart. They then 3D printed the model in a soluble thermoplastic, coated the model in a polydimethylsiloxane solution, and dissolved the thermoplastic in an alkaline solution to end with a hollow shell of their model [12]. Students then used this model to practice repairing patent ductus arteriosus occlusions. Similarly, another group created multiple 3D models of common congenital heart defects using CTA scans of a canine heart. This group 3D printed the vasculature and arteries involved in the defect in a stiff clear resin from Formlabs [13]. Veterinary students were provided with these models during cardiology anatomy lessons [13].

These existing simulators provide a framework for converting 2D CTA scans into 3D CAD models. Additionally, both of these models reported that students who utilized the 3D models during their training felt more confident in their skills and knowledge than those who did not use the 3D models [12][13]. However, these models only include specific vasculature within the heart, and a model to simulate PS must include all related vasculature and the right ventricle and atrium.

1.3 Problem Statement

Due to the decreased caseload of patients with PS at the University of Wisconsin Madison School of Veterinary Medicine, veterinary students have fewer opportunities to practice transcatheter procedures to treat PS. For most pet owners, transcatheter procedures are the only affordable option to treat their canines with PS, creating a high demand for veterinarians trained to perform these procedures. The goal of this project is to create a 3D model of a canine heart to simulate PS for veterinary students to practice transcatheter procedures. The model will simulate inserting a catheter into the jugular vein, feeding through the right ventricle and atrium into the pulmonary valve, and inflating the catheter to expand the annulus leaflets. This will allow students to learn and practice transcatheter procedures amidst the decreased caseload experienced by the School of Veterinary Medicine.

2 Background

2.1 Anatomy and Physiology

A canine heart and a human heart have many similarities. A canine heart is ovoid in shape compared to a human heart that is more elliptical or round [14]. The apex in a canine is more blunt than in a human heart and is formed entirely by the left ventricle. Also, the heart placement in the chest is more medial than in humans which is similar to other four-legged mammals. For a human heart, the ratio of heart weight to body weight is 6.95g/kg but for a canine it is 5g/kg making it much lighter compared to the body weight of the patient [14]. Furthermore, canine hearts lack an inferoseptal recess resulting in a larger proportion of the atrioventricular conduction axis within the subaortic outflow tract [15]. As for the jugular vein, the walls contain about 5-10 layers of smooth muscle and collagen [16]. The cluster of smooth muscle cells forms around the area where the valve leaflets join with the vein. Throughout the vein, there is a smooth texture that blends into the heart [16].

The flow of blood throughout the heart is an integral part of the physiology of the heart. The blood coming from the veins is drained into the right atrium through the tricuspid valve and into the right ventricle [17]. The right ventricle pushes the blood to the lungs through the pulmonic valve and into the pulmonary artery to be oxygenated. The pulmonary valve has three leaflets, or cusps, that open and close to control blood flow. The cusps attach to a tough, fibrous ring of connective tissue called the annulus [17]. The blood then flows through capillaries that are spread across the lungs to pick up oxygen. Once oxygenated, the blood drains through the pulmonary vein into the left atrium, through the atrium, and into the left ventricle [17]. From the left ventricle, the blood begins its descent through the aorta and into the rest of the body [17]. The path of blood in the heart is shown in Figure 1.

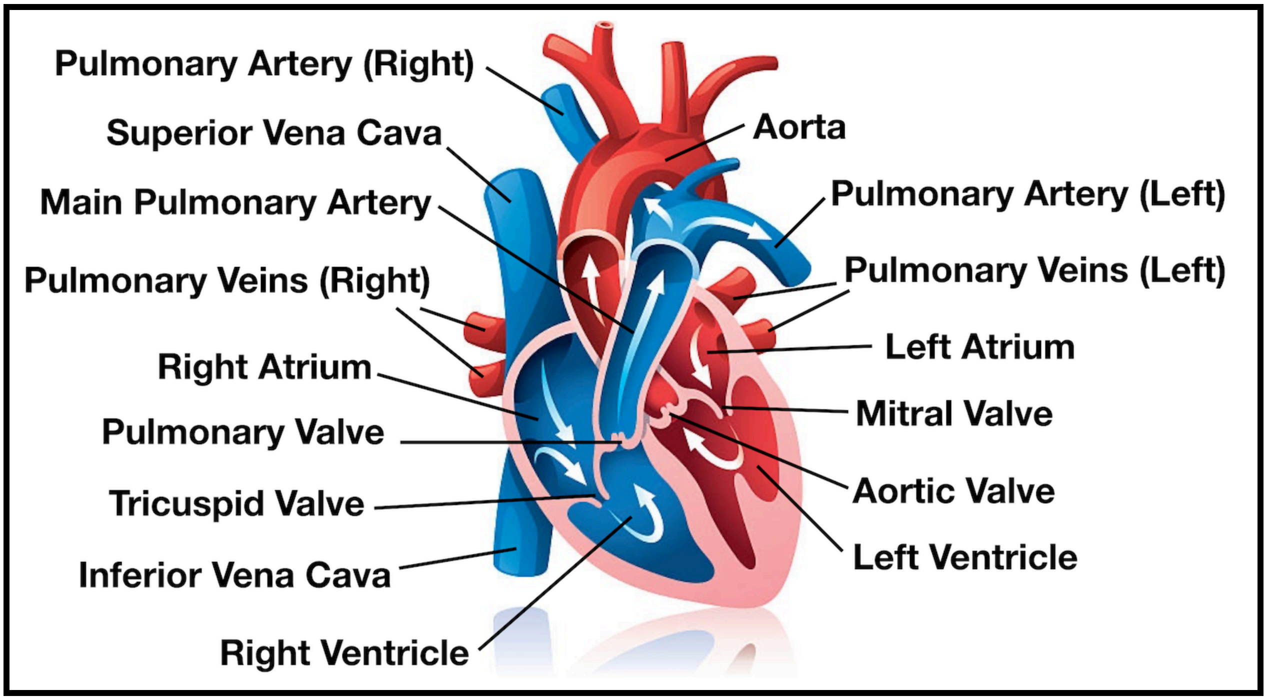


Figure 1: Path of Blood through the Heart [18]

The jugular vein is located along the neck, beginning at the base of the neck and extending to the back of the mandible. The jugular vein carries blood from the neck to the right atrium of the heart to become reoxygenated. Transcatheter procedures to correct PS require a balloon catheter to be inserted through the jugular vein at the neck and follow this path to enter the heart. The path of the jugular vein into the heart is shown in Figure 2.

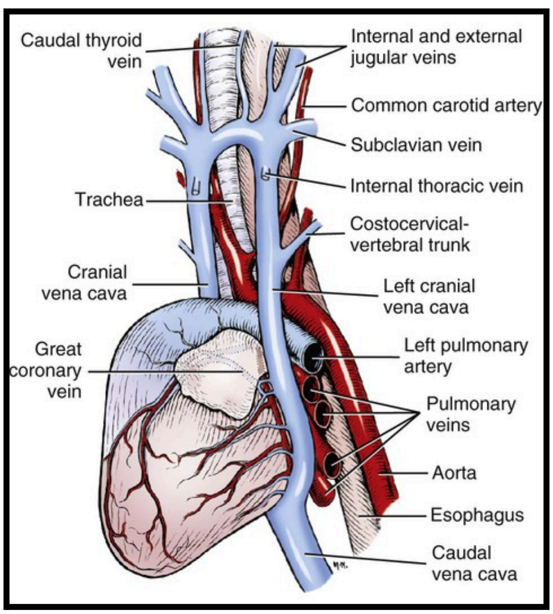


Figure 2: Path of Jugular Vein to Heart in Canine [19]

The device described in this report will model the heart and jugular vein of a French Bulldog with PS. PS is a congenital heart defect causing narrowing or misshaping of the pulmonary valve [20]. A visual representation of PS is shown in Figure 3. This defect is seen in 0.1%-1% of the canine general population and approximately 40 cases are seen per year at the UW School of Veterinary Medicine [21]. PS can cause different levels of blockage in the heart, specifically the right ventricle outflow tract. This is mainly due to isolated pulmonic valve stenosis as a defect of the pulmonic valve. These defects include varying fibrosis, thickening, and commissural fusion causing a bileaflet or unileaflet [20]. Many patients with PS do not experience any symptoms beyond a mild heart murmur, but patients with severe cases can experience life-threatening symptoms that lead to fatality if not treated [20].

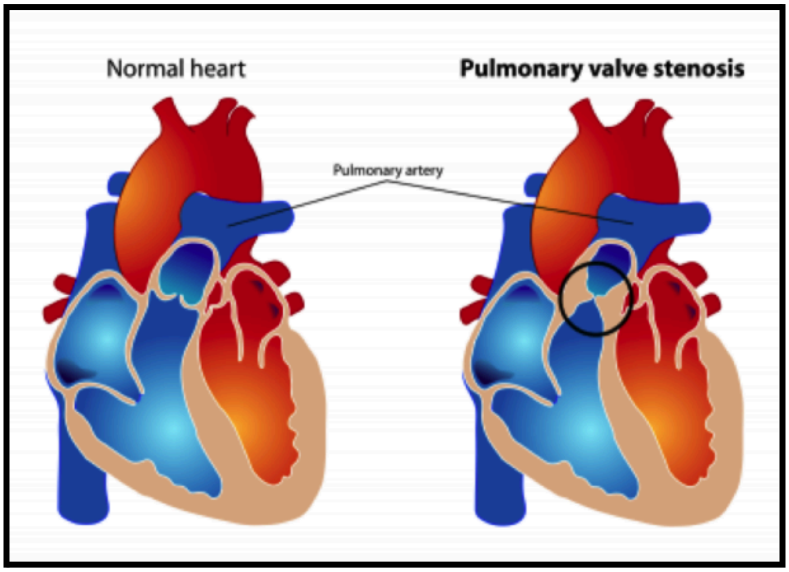


Figure 3: Pulmonary Valve Stenosis in a Canine Heart [17]

2.2 Balloon Valvuloplasty and Stent Placement

There are two main types of procedures used to treat PS; balloon valvuloplasty and stent placement. Treatment selection depends on the condition of the pulmonary valve leaflets [1]. Using an echocardiogram, a veterinarian can assess the severity of the PS. The severity of PS is based on the thickness of the leaflets and the reduced diameter of the pulmonary valve. Balloon valvuloplasty is the preferred method of treatment for canines with moderate to severe PS [22]. During this procedure, a catheter with a balloon tip is inserted through the jugular vein, near the canine's neck. The balloon catheter is guided to the pulmonary valve and oriented across the valve. The balloon is then inflated to tear apart the valve leaflets, increasing the diameter of the opening in the pulmonary valve and improving blood flow from the heart to the lungs [22]. The procedure is illustrated below in Figure 4. Although balloon valvuloplasty is the ideal method of treatment for many dogs with PS, there is a steep learning curve associated with the procedure, and students must spend considerable time learning and practicing the procedure [23].

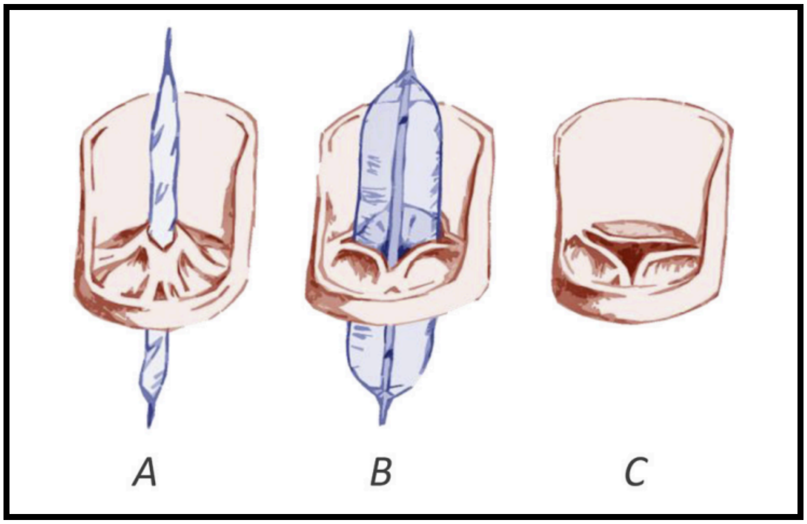


Figure 4: Balloon Valvuloplasty of Pulmonary Valve [22]

Stents are used to treat severe cases of pulmonary valve stenosis. This process is similar to balloon valvuloplasty, except the balloon catheter contains a premounted stent on the outside [24]. Once the catheter is inserted across the pulmonary valve, the balloon is inflated to expand the stent. The catheter is then removed, leaving the stent across the valve [24]. This procedure is only used in severe cases of PS, as it leaves the pulmonary valve permanently open and allows for small amounts of blood to flow backward across the valve [8]. The device described in this report will primarily focus on balloon valvuloplasty, as it is the more common procedure. Future iterations of the device will be compatible with stent placement.

2.3 Client Information

Dr. Sonya Tjostheim is a Doctor of Veterinary Medicine and Diplomate of the American College of Internal Veterinary Medicine. Currently, she is a Clinical Assistant Professor of Cardiology for the Department of Medical Sciences at UW-Madison where she teaches cardiovascular medicine to 3rd year students and clinical cardiology to 4th year students.

2.4 Product Design Specifications

The largest requirement of this device is that it must accurately simulate the native anatomy of a French Bulldog heart. Additionally, the model will be developed from CTA scans of the heart and must accurately represent the native anatomy of the heart within 10% of the dimensions retained from a patient's CTA scans. The model will be used an estimated 100 times per year and must have a life of service of 10 years. Between uses, the device will be stored in an office environment at a temperature of 20-22 °C.

In terms of size, the model will reflect the native anatomy of a heart with a vertebral heart size (VHS) of approximately 11.0 - 14.12 [25]. VHS is a method that is used across physicians to measure and assess a canine's heart size. It is measured using radiographic measurements. The model will be secured in a casing with maximum dimensions of 30 cm X 30 cm X 30 cm. The entire device will weigh less than 12 kg to allow the model to be easily transferred around the clinic and teaching classrooms. To allow for optimized learning, the model must be transparent to ensure that students can see the balloon and catheter during inflation and insertion within the annulus.

The materials used within the model must mimic the properties of natural cardiac tissue. First, the material must match the coefficient of friction of the jugular vein, which is 0.05 [26]. A material with a low coefficient of friction is incredibly important to the model as a tacky material will cause the catheter to get stuck while being fed through the model. Second, the material for the annulus and jugular vein must match the elastic modulus of native tissue (0.17MPa and 1.6MPa respectively) within 10% [27][28]. An accurate elastic modulus will ensure that the 3D printed heart walls will deform similarly to myocardium during surgery. Lastly, the material chosen for the annulus must match the fatigue limit of the natural cardiac tissue and must not plastically deform due to continuous strain from the balloon inflating and expanding the material [29]. Within the lifecycle of 100 uses, the pulmonary valve must not deform more than 15%. The platform for the model will be fabricated from acrylic or clear hard resin to provide a rigid base for the model to be secured.

The budget for this project is $1000, which includes material and fabrication costs. This model will not be made for the commercial market and therefore the entirety of the budget can be spent on building one model. The client primarily wants a model that can simulate balloon valvuloplasty procedures, as this is the most common procedure her students will be performing. Once a model compatible with balloon valvuloplasty has been developed, the client would like the model to be adapted to also be compatible with stent placement.

Finally, this proposed model is classified as a Class I Medical Device by the Food and Drug Administration (FDA) and must follow all standards in place for these devices [30]. 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 [31]. Additionally, the model must adhere to the standards set by the Good Manufacturing Practices (GMP), which indicate that the device must be derived from real patient scans, and the materials utilized must mimic cardiac tissue [32].

The full, unabridged version of the Product Design Specifications can be found in Appendix 11.1.

3 Preliminary Designs

3.1 Full Design Models

3.1a 3D Printed One Piece

The 3D printed one piece model will be a model of the right heart, pulmonary valve, and jugular vein and will be fabricated in one print. The model will be fabricated from one material. This model will have a singular annulus design within the chambers of the heart that would not be interchangeable. Material options for this design include a variety of resins, thermoplastics, and other polymers. The model will be printed from a stereolithography (STL) file that will be constructed from a patient's CTA scan. Consideration will be required in the placement of structural supports in printing this design to ensure supports will not alter the functionality of the model.

Figure 5: Example of 3D printed heart model [33]

3.1b Molded One Piece

Similar to the 3D printed one piece model, this model will consist of a single mold and will be made from a flexible silicone material. To fabricate the Molded One Piece heart model, a mold will be 3D printed and then be filled with a silicone material. The molds will be constructed from a resin or thermoplastic. The mold will consist of an outer mold that the silicone material will be poured into and a negative-space mold to make the heart hollow. Additional printed components may be needed to properly mold inner components including the annulus and valve leaflets.

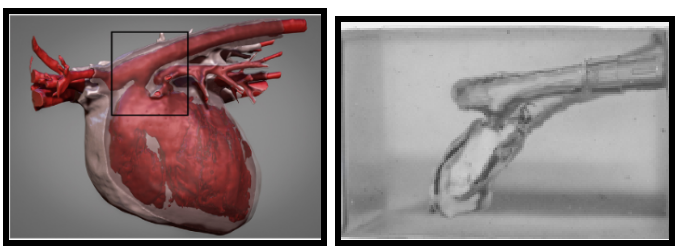


Figure 6: Example of arteries of the heart molded from a silicone material using 3D printed molds [34]

3.1c 3D Printed Four Piece

The 3D Printed Four-piece model will be created out of two different materials and contain four separate components. The four components include the top and bottom halves of the heart, the annulus, and the jugular vein. The heart chambers will be made of a stiff material and the jugular vein and annulus will be made of a more flexible material. The jugular vein will be permanently attached to the heart chambers using a waterproof adhesive. The annulus will be toleranced so that it fits securely within the bottom half of the heart chamber, but will not be permanently fixed to allow the client to exchange the annulus if needed. The top and bottom half of the heart will fit together with extruded pegs. The top half of the heart will have three extruded pegs that fit in the matching indents on the bottom half of the heart. The extruded pegs will be over toleranced so they fit snugly within the indents on the bottom half of the heart. The main benefit of the 3D Printed Four Piece model is the ability to manufacture various components from different materials. Using different materials for each component will allow the model to more accurately match the surface finish, compliance, and other important factors for this training model.

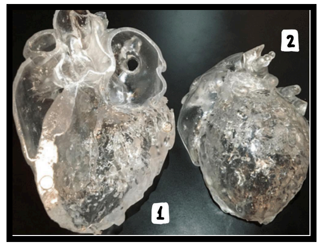


Figure 7: Example of two halves of a 3D printed heart [35]

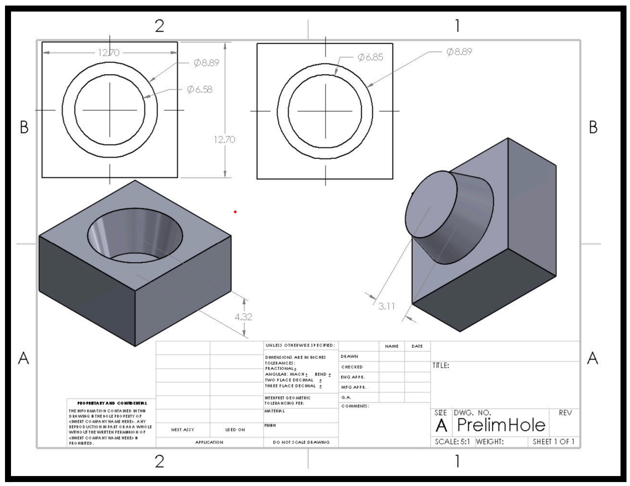


Figure 8: Extruded pegs to connect two halves of heart

3.2 Jugular Vein and Annulus Materials

3.2a Elastic 50A Resin - Formlabs

Elastic 50A Resin from Formlabs is a SLA (stereolithography) that is used for engineering applications. It is a translucent material with a ultimate tensile strength of 3.4 MPa and 160.0% elongation at break. It has a shore hardness of 55.0A and is compatible with a range of printers including Form 3, Form 3+, Form 3B, Form 3B+, Form 3BL, Form 4, and Form 4B. It is commonly used for creating parts with a feel similar to softer rubbers and silicones. Elastic 50A Resin will spring back quickly when compressed and stretched [36].

3.2b Flexible 80A - Formlabs

Flexible 80A Resin from Formlabs is a SLA that is a stiff elastomer that has a soft-touch. It is translucent with an ultimate tensile strength of 8.9 MPa and 120.0% elongation at break. The shore hardness is 80.0A making it a stiffer material. It is compatible with a Form 2, Form 3, Form 3+, Form 3B, Form 3B+, Form 3L, Form 3BL, and Form 4 printer. It withstands bending and flexing with a flexibility similar to hard rubber [37].

3.2c NinjaFlex TPU - NinjaTek

NinjaFlex TPU from NinjaTek is a TPU (thermoplastic polyurethane) with minimal tackiness. It has abrasion and chemical resistance built into polyurethane with 20% better abrasion resistance than ABS and 68% better than PLA. This TPU has a shore hardness of 85A with 660% elongation. It has good vibration reduction and a low friction exterior making it an ideal material for fabrication. NinjaFlex requires an extruder temperature of 225°C – 250°C [38].

3.3 Heart Chambers Materials

3.3a Clear Resin V5 - Formlabs

Clear Resin V5 from Formlabs is a SLA used for a variety of applications. One of its main properties is that it is very stiff and strong. It has a flexural strength of 105.0 MPa, 8.0% elongation at break, and 60.0 MPa ultimate tensile strength. It is only compatible with a Form 4 and Form 4B printer. It is very clear and the appearance is similar to acrylic [39].

3.3b Flexible 80A - Formlabs

Flexible 80A Resin from Formlabs is a SLA that is a stiff elastomer that has a soft-touch. It is translucent with an ultimate tensile strength of 8.9 MPa and 120.0% elongation at break. The shore hardness is 80.0A making it a stiffer material. It is compatible with a Form 2, Form 3, Form 3+, Form 3B, Form 3B+, Form 3L, Form 3BL, and Form 4 printer. It withstands bending and flexing with a flexibility similar to hard rubber [37].

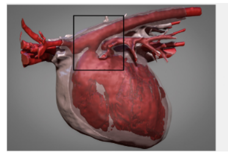
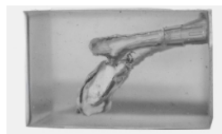
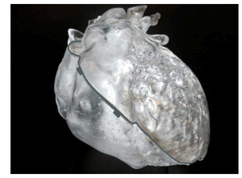
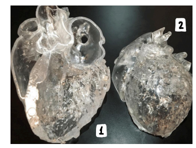
3.3c PolyJet Photopolymer - Stratasys

PolyJet Photopolymer from Stratasys is commonly used to make anatomical models. The material is printed on a Stratasys J750 Digital Anatomy 3D printer. The properties of the material are within the same range of porcine myocardium or slightly stiffer. The stiffness is relative to the thickness of the material. The elasticity ranges from 0.262 to 0.536 MPa and the elastic modulus is roughly 0.327 N/m2. The polymer has a sticky surface finish [40].

4 Preliminary Design Evaluation

4.1 Full Design Model Design Matrix

Table 1. Design matrix to evaluate full heart design and fabrication ideas.

Design Criteria	3D Printed One Piece 		Molded One Piece  		3D Printed Four Piece  	
Anatomical Accuracy (25)	3/5	15	2/5	10	**4/5**	**20**
Ease of Fabrication (20)	**4/5**	**16**	1/5	4	3/5	12
Durability (15)	3/5	9	2/5	6	**4/5**	**12**
Modularity (15)	1/5	3	1/5	3	**5/5**	**15**
Ease of Use (10)	**4/5**	**8**	3/5	6	2/5	4
Cost (10)	3/5	3	**4/5**	**8**	2/5	4
Safety (5)	4/5	4	**5/5**	**5**	4/5	4
Total (100)	58/100		42/100		**71/100**	

4.1a Matrix Criteria and Point Explanations

Anatomical Accuracy (25/100)

Anatomical accuracy refers to the level of detail included in the design to represent the anatomical features. It is the most important criterion of the design as the model will be used to train veterinary students on cardiac procedures. If the model does not match the anatomy of a canine heart, it will be an ineffective training tool and will not prepare students for real procedures on their patients.

The 3D Printed Four Piece model scored the highest in this category with a (4/5) because its many parts will be printed separately, allowing for more detail. The 3D Printed One Piece model received the second-highest score of (3/5) because printing the whole model together will not allow the same level of detail as the Four Piece because supports may be added to ensure stability during printing. The Molded Model scored a (2/5) because silicone molding is less precise than 3D printing.

Ease of Fabrication (20/100)

Ease of fabrication refers to the feasibility and complexity of fabrication. This was ranked as the second most important criterion as the model must be able to be created using the resources available on campus and within the time frame of two semesters.

The 3D Printed One Piece Model won this category with a (4/5) because the single piece can be printed all at once by using strategic placement of supports and material selection making it easier to design than a Four Piece Model. Additionally, multiple similar models have utilized a one-piece design and there is ample literature available on how to 3D print the heart in one piece. The Four-Piece Model received the second-highest score (3/5) in the category because although 3D printing is easier than silicone modeling, the four separate pieces will require four separate CAD models that need to be designed to fit together geometrically. Lastly, the Molded Model scored the lowest in the category with a (1/5) because building a mold and then constructing the silicone model from the mold is the most time-consuming process and has the highest chance of failure in design.

Durability (15/100)

Durability refers to the ability of the design to withstand damage and misuse and is tied for the third most important criterion because the model must withstand a minimum of 100 times per year and resist mistakes that students may make while practicing procedures that could damage the model.

The 3D Printed Four Piece Model won this category with a (4/5) because the Four Piece model has multiple pieces that are easy to replace if damage occurs to the device. In contrast, if damage occurs to the One Piece Model, the entire design must be replaced, which led to its score of (3/5) in this category. Both of the 3D printed designs scored higher than the Molded Design, which scored a (2/5), because silicone is much softer and more fragile than the thermoplastics that would be used in 3D printing.

Modularity (15/100)

Modularity refers to the ability of the annulus and jugular vein to be exchanged within the device. Modularity is also tied for the third most important criterion because the device must be compatible with different patients' annuli and jugular veins in order to allow students to practice procedures for different breeds of dogs and various severities of PS.

The 3D Printed Four Piece Model won this category with a (5/5) because it is the only design where the annulus and jugular vein are not attached to the heart model and can be easily exchanged. The

3D Printed One Piece and Molded Models both received a (1/5) because the entire model will be one piece and the entire model must be remade to change the type of annulus and jugular vein.

Ease of Use (10/100)

Ease of Use refers to the complexity of the user interface and how easily a catheter can be passed through the material. As students may use the model to practice unsupervised, it is important that the user interface is as simple and straightforward as possible. Given that all three design ideas have similar user interfaces, this criterion was not weighted highly.

The 3D Printed One Piece Model scored the highest in this category with a score of (4/5). Both of the One Piece Models scored higher than the Four Piece Model (2/5) because the singular piece does not require assembly and no pieces could go missing or have assembly issues. Both 3D models scored higher than the Molded Model because silicone often has a tacky surface finish, which would make it more challenging for the students to pass the catheter through the model.

Cost (10/100)

Cost refers to how much money it will cost to purchase materials and manufacture the model. Given the large budget of the project ($1000) and that the model is a one time device that will not be produced commercially, cost was not given high priority within the design matrix.

The Molded Model scored the highest in this category with a (4/5) because silicone is much cheaper than the thermoplastics that will be used in the 3D models. The 3D Printed One Piece Model scored the second highest with a (3/5) and the 3D Printed Four Piece Model scored the lowest with a (2/5). Although both will be made of the same material, the Four Piece Model will be more expensive to make as it will require four pieces and the pieces can be much more detailed, causing it to use more material.

Safety (5/100)

The final criterion, Safety, refers to any safety concerns to the user while using the device. This category was weighted the lowest within the design matrix because none of the designs subjected the user to any relevant safety risks.

The Molded Model won this category with a score of (5/5) because in the event that the model breaks, a silicone model will not have any sharp pieces that could potentially harm the user. The two 3D models tied in this category with a score of (4/5) because they will be made out of plastic and could have sharper pieces if the model were to break.

4.2 Jugular Vein and Annulus Materials Design Matrix

Table 2. Design matrix to evaluate three material options to 3D print the jugular vein and annulus from.

Design Criteria	Elastic 50A Resin - Formlabs [34] 		Flexible 80A - Formlabs [35] 		NinjaFlex TPU - NinjaTek [36] 	
Compliance (25)	**5/5**	**25**	2/5	10	1/5	5
Surface Finish (20)	2/5	8	3/5	12	**4/5**	**16**
Transparency (20)	**5/5**	**15**	4/5	12	1/5	3
Ease of Fabrication (15)	2/5	12	**4/5**	**12**	1/5	3
Cost (10)	3/5	6	3/5	6	**4/5**	**8**
Durability (5)	2/5	4	3/5	6	**4/5**	**8**
Resolution (5)	**4/5**	**4**	**4/5**	**4**	2/5	2
Total (100)	**68/100**		**62/100**		**45/100**	

4.2a Matrix Criteria and Point Explanations

Compliance (25/100)

Compliance refers to the material's ability to change shape and deform when a force is applied to it. The compliance of the material for the jugular vein and the annulus is very important to the client, earning it a weight of 25. Accurate compliance will ensure that the feel of resistance against the catheter in the model replicates that of the canine heart in vivo to provide an adequate training experience. The young's modulus of the jugular vein is 4 MPa, meaning it is a softer, more rubber-like material. The Elastic 50A scored the highest in this category (5/5) because it has the lowest shore hardness, making it the most compliant and similar to the jugular vein. The Flexible 80A Formlabs scored the second highest (2/5) with a shore hardness of 80A, and the NinjaFlex TPU was scored the lowest (1/5) because it has a shore hardness of 85A.

Surface Finish (20/100)

Surface finish refers to whether the surface is tacky or slick. Surface finish was weighted at 20 because it is important that the material for the jugular vein and annulus be slick and not create an abundance of friction when the user is inserting the catheter. Because the NinjaFlex TPU is a harder material it is least likely to create friction against the catheter, and thus scored the highest (4/5). The Flexible 80A material is described as a soft-touch, rubber-like material, making it less slick than the TPU. Therefore the Flexible 80A earned a (3/5) for surface finish. Finally, the Elastic 50A resin scored the lowest (2/5) because it is described as similar to an elastic material, which is least similar to the surface finish of the jugular vein.

Transparency (20/100)

Transparency was weighted at 20 because client requests that the heart model be transparent for users to be able to see the progression of the catheter through the heart during training. The Elastic 50A resin scored the highest (5/5) because it is marketed as translucent and example prints of Elastic 50A appear the most transparent. Similarly, the Flexible 80A material is marketed as translucent, however the example prints appear less transparent than the Elastic 50A; Therefore, the flexible 80A was scored just below the Elastic (80A), given a (4/5) . The NinjaFlex TPU is sold in a "water translucent" color, however, the images of sample prints of this filament appear more opaque, so it was scored the lowest for transparency (1/5).

Ease of Fabrication (15/100)

The jugular vein and annulus will be 3D printed. Therefore, ease of fabrication is related to how easy the material is to print. The Flexible 80A scored the highest for ease of fabrication (4/5) because it is a harder resin. Harder resins are easier to print because they have more stability during printing, more layer adhesion, and are less prone to warping than softer resins. The Elastic 50A resin is a softer resin, making it more challenging to print (2/5). NinjaFlex TPU scored the lowest for ease of fabrication because of the difficulty of printing thermoplastics and because the team does not have easy access to a printer that is capable of printing TPU.

Cost (10/100)

Cost includes the price of purchasing the material and printing the components. Cost has a lower weighting in the matrix because of the relatively low cost of printing these smaller components of the model and the large budget. NinjaFlex TPU scored the highest (4/5) for cost because it is the most affordable option. NinjaFlex TPU costs $99.67 for 1 kg of material. Elastic 50A and Flexible 80A both cost $199 for 1 kg of material, so they were scored equally (3/5).

Durability (5/100)

Durability refers to the wear resistance of the material. While it is important that the material does not wear with use, the model is expected to be used for at least one year of training, and the materials selected are unlikely to show excessive wear with that number of uses, so durability was weighted lower. The NinjaFlex TPU scored highest for durability (4/5) because of its high abrasion resistance. The Flexible 80A material scored (3/5) for durability because of its relatively high durability and ability to return to its originally printed shape after small deformations. The Elastic 50A scored the lowest for durability (2/5) as it is softer and may show stretching or degradation with continued use.

Resolution (5/100)

Resolution includes the amount of surface detail and accuracy that can be achieved when printing with the given material. Resolution was weighted lower in the design matrix because for this model it is more important that the jugular vein and annulus provide the correct feel for the user when inserting and inflating a balloon catheter than the visual details of the print. The Elastic 50A and Flexible 80A both have a resolution of 25 microns, so they both scored (4/5). NinjaFlex TPU has a resolution of 100 microns, earning it a score of (2/5).

4.3 Heart Chambers Materials Design Matrix

Table 3. Design matrix to evaluate material options to print the heart chambers from.

Design Criteria	Clear Resin V5 - Formlabs [37] 		Flexible 80A - Formlabs [35] 		PolyJet Photopolymer - Stratasys [38] 	
Compliance (25)	1/5	5	4/5	20	**5/5**	**25**
Surface Finish (25)	2/5	10	**4/5**	**20**	1/5	5
Transparency (20)	**5/5**	**20**	4/5	16	2/5	8
Ease of Fabrication (15)	**5/5**	**20**	4/5	16	1/5	4
Resolution (10)	4/5	**8**	4/5	8	**5/5**	**10**
Cost (5)	**5/5**	**5**	5/5	5	1/5	1
Total (100)	**68/100**		**84/100**		**53/100**	

4.3a Matrix Criteria and Point Explanations

Compliance (25/100)

Compliance refers to the material's ability to change shape and deform when a force is applied to it. The compliance of the material for the heart chambers is of great importance for the model to be accurate as well as durable, earning it a weight of 25. Accurate compliance will ensure that the feel of resistance against the catheter in the model replicates that of the canine heart in vivo to provide an adequate training experience. The PolyJet Photopolymer from Stratasys scored the highest in this category (5/5) because it mimics the compliance of the heart chambers the best, especially given the range of shore values from 30 to 95. Flexible 80A from Formlabs came second (4/5) due to its shore hardness of 80 which provides a material that isn't too compliant and models the heart well. The last material was Clear Resin V5 from Formlabs which received a (1/5) due to the fact that the material is a hard plastic with little to no compliance.

Surface Finish (25/100)

Surface finish refers to whether the surface is tacky or slick. Surface finish was weighted at 25 because it is important that the material modeling the heart chambers is slick and does not create an abundance of friction when the user is inserting the catheter through the chambers. The highest scoring material (4/5), the Flexible 80A material is described as a soft-touch, rubber-like material, making it fairly slick especially after post processing. Next was the Clear Resin V5 from Formlabs which scored a (2/5) due to its hard surface which can have some tackiness due to the curing of the resin. Lastly was the PolyJet Photopolymer from Stratasys (1/5) due to the description of the material being similar to fatty tissue, fibrotic tissue, soft organs and tumors.

Transparency (20/100)

Transparency was weighted at 20 because the client requests that the heart model be transparent for users to be able to see the progression of the catheter through the heart during training. The Clear V5 resin scored the highest (5/5) because it is marketed as being almost as transparent as glass. Similarly, the Flexible 80A material is marketed as translucent, however, the example prints appear less transparent than the Clear V5 resin. Therefore, the flexible 80A was scored just below the Clear V5 resin, given a (4/5) . The PolyJet Photopolymer from Stratasys scored the lowest due to its yellow tinged translucent appearance after printing, giving it a (2/5).

Ease of Fabrication (15/100)

The heart chambers will be 3D printed. Therefore, ease of fabrication is related to how easy the material is to print. The Clear V5 resin scored the highest for ease of fabrication (5/5) because it is the hardest resin of the three. Harder resins are easier to print because they have more stability during printing, more layer adhesion, and are less prone to warping than softer resins. The Flexible 80A resin is a softer resin, making it more challenging to print (4/5). The PolyJet Photopolymer scored the lowest (1/5) for ease of fabrication because of the difficulty of printing softer materials. Also, the team does not have easy access to a printer that is capable of printing the PloyJet material due to it being a Stratasys product.

Resolution (10/100)

Resolution includes the amount of surface detail and accuracy that can be achieved when printing with the given material. Resolution was weighted lower in the design matrix because for this model it is more important that the heart chambers provide the correct compliance and surface finish compared to marginally better resolution that may allow a slightly more accurate model. The Clear V5 and Flexible 80A both have a resolution of 25 microns, so they both scored (4/5). The PolyJet Photopolymer that is printed on stratasys printers is recommended to have a resolution of 17 microns, earning it the highest score of (5/5).

Cost (5/100)

Cost includes the price of purchasing the material and printing the components. Cost has a lower weighting in the matrix because of the relatively low cost of printing these smaller components of the model and the large budget given by the client ($1000). The Clear V5 and Flexible 80A both are printed off of the Formlabs printers which the design team has access to, making it more affordable; However, the Clear V5 is $99 compared to the Flexible 80A which is $199. Due to this fact the Clear V5 received the highest score (5/5) while the Flexible 80A received a (4/5). The PolyJet Photopolymer received the lowest score (1/5) due to the lack of accessibility to a Stratasys printer, meaning the printing would have to be outsourced along with the material costs associated.

5 Final Design

5.1 Final Design Selection

5.1a Full Model Final Design

The final design for the heart model is the 3D-printed four-piece model. This model scored the highest in the design matrix in Table 1 with a final score of 71/100. The key features of this design are the ability to use different materials for the jugular vein, annulus, and heart chambers, the increased anatomical accuracy that can be achieved by printing the heart as two parts, and the ability to design different annuli with unique presentation of PS and exchange them within the model. These advantages outweigh the increased cost and complexity of fabrication due to the four separate pieces.

5.1b Annulus and Jugular Vein Material Final Design

Given that the final model will consist of four separate pieces, the material for the jugular vein and annulus will be different from the material used to create the chambers. From Table 2, Elastic 50A Resin won the design matrix for the annulus and jugular vein material with a score of 68/100. Of all materials evaluated, Elastic 50A resin has the lowest shore hardness score, making it the most compliant and similar to the highly elastic jugular vein and annulus tissue. Although Elastic 50A Resin scored the lowest in the category of surface finish, the material was presented to the client who stated that it was not tacky enough to impact the passage of the catheter through the model. The material is also the most transparent out of the three material options which will allow students to see the location of the cather as it passes through the model.

5.1c Heart Chambers Material Final Design

The heart chambers in the final design will be made from Flexible 80A as it won the design matrix in Table 3 with a score of 84/100. Flexible 80A won the category of surface finish, because it is the least tacky and least likely to affect the catheter sliding through the model. Flexible 80A is the second most compliant and second hardest material of the three evaluated, making it the best option to 3D print while still being relatively flexible. Additionally, the Flexible 80A is less compliant than the Elastic 50A that will be used in the jugular vein and annulus, which allows for more precise printing and better anatomical accuracy.

5.2 Heart Chamber

To create the heart chambers, the STL generated from the segmentation of the client-provided CTA scan of a French Bulldog was imported into OnShape. Once the STL was brought into OnShape additions and changes could be made to the whole heart. The first update was to separate the heart into two halves, splitting along the dorsal plane. Then, three pegs were added to the outer rim of the top half of the heart to secure the halves of the heart together. The initial design of the pegs had a diameter of 8.89 mm and height of 3.11 mm. The corresponding holes had a diameter of 8.89 mm and a depth of 4.32 mm. Both the pegs and holes had a matching 15 degree draft angle to aid in connection between the two heart halves. Three of these identical pegs and holes were set in locations on the two halves to allow for the greatest depth. The pegs were placed in a triangular shape around the heart to provide a strong and uniform connection. The heart halves were then printed out of a hard resin to create an initial prototype. This prototype showed that the peg connections were not tight enough to hold the two heart halves together. As a result of this print, the connections went through a second phase of development which eliminated the draft angle entirely, increased the hole depth to 6.86 mm and the peg height to 6.35 mm, and decreased the hole diameter to 8.839 mm while keeping the peg diameter at 8.89 mm. Due to the flexibility and compliance of the Elastic 80A, the under-toleranced hole fits snugly around the pegs and holds the two halves tightly together.

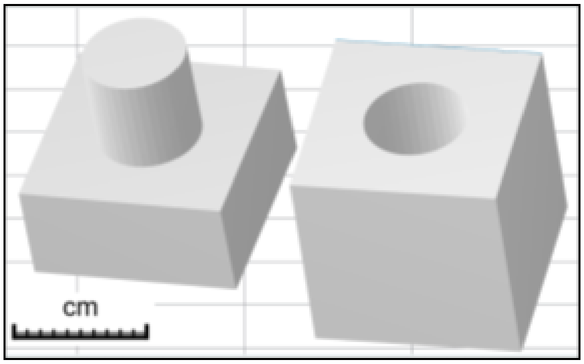


Figure 9: Isolated view of the final peg and hole connections for the heart chambers (left) and the final design of the heart halves (right)

5.3 Jugular Vein

The jugular vein consists of three different components: the vein itself, the cranial vena cava connector between the heart and jugular vein, and the manikin skin flap that covers the region of the jugular vein where the catheter is inserted. The dimensions of the jugular vein were provided by a veterinary radiologist at the UW Veterinary Hospital based on a head and neck CTA scan of a French Bulldog. 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 first step in balloon valvuloplasty involves inserting an IV needed into the jugular vein. The client requested that this process be as realistic as possible and wants students to puncture the IV needle through the vein, rather than inserting it through the open end of the jugular vein. In order to fulfill these requirements and simultaneously prevent damage to the jugular vein material, a hole was cut into the distal end of the jugular vein and covered with replaceable manikin skin. This allows students to puncture the IV needle through the manikin skin and into the hole in the jugular vein without damaging the jugular vein material itself. This reduces the risk of tearing the jugular vein, the more expensive component of the model compared to the manikin skin. Additionally, the manikin skin is opaque and allows students to practice palpating the skin in order to find the correct insertion area. Originally, the hole in the jugular vein was rectangular, but the sharp corners caused the material to tear apart easily when a catheter was pushed through. To remedy this flaw, the edges of the hole were rounded to mitigate the risk of material tears during future catheter insertions. The last component of the design connects the heart to the jugular vein. The connector is directly modeled into and printed as a part of the heart, acting as an augmented cranial vena cava. The proximal end of the jugular vein fits inside the connector and will be secured in place with cyanoacrylate adhesive in the final prototype.

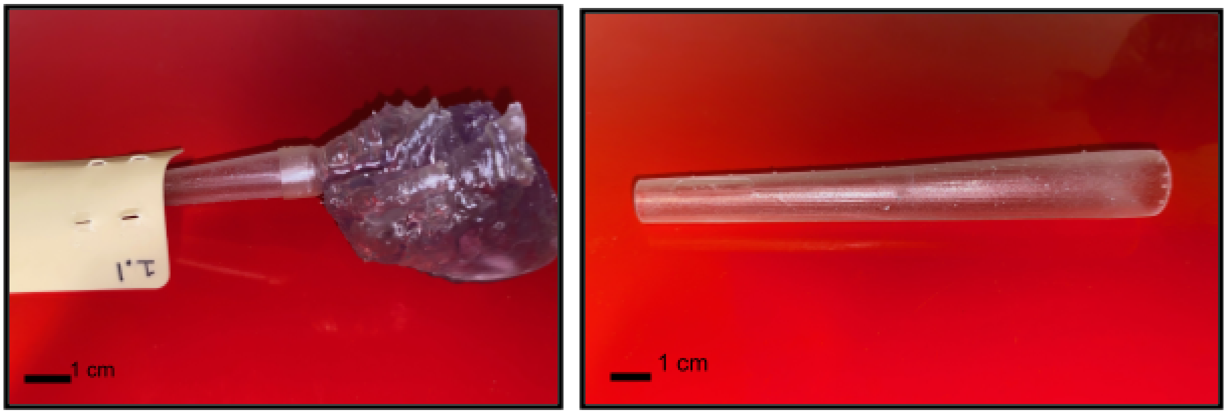


Figure 10: Jugular vein connected to the heart and overlaid with the manikin skin (left). Jugular vein with slot for catheter insertion (right)

5.4 Pulmonary Valve

The model pulmonary valve includes the annulus and the leaflets. During the CTA segmentation of the heart chambers, the valve structure was identified, segmented from the heart chambers, and printed separately in Elastic 50A. The valve securely fits within the bottom half of the heart model as it is held in place via a press fitting. The valve is easily removable and replaceable if damage occurs or if a new variation of valve is required. The wall of the heart chambers sufficiently captures the valve and allows a balloon catheter to be inflated and deflated multiple times without dislodging the valve from the heart chambers.

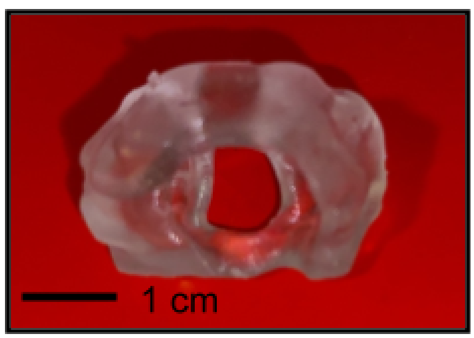


Figure 11: Annulus with the leaflets visible on the interior of the valve

5.5 Heart Stand

The heart model stand includes the heart chamber base, jugular vein stand, and acrylic plate. First, the heart chamber base consists of a polyethylene terephthalate glycol (PETG) box with a hole in the shape of the heart chambers. The heart chambers sit snugly within the box which prevents movement of the heart during the procedure. Second, the jugular stand elevates the jugular vein and aligns it with the cranial vena cava. The stand is made of PETG and has 2 flanges that extend from each side on the distal end. Slits in the manikin skin fit over the flanges and hold the manikin skin flush against the jugular vein during insertion. Lastly, the heart chamber base and jugular vein stand are attached to the acrylic base to create a rigid and sturdy base during use of the model.

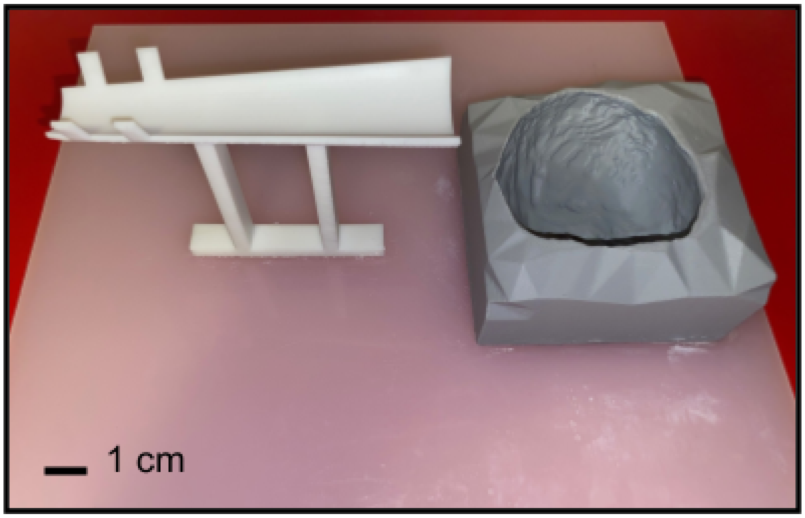


Figure 12: Heart model stand and base attached to the acrylic plate

5.6 Full Model Assembly

The full assembly takes all of the components and combines them into a fully functional heart model. The user goes step by step through the procedure, inserting the catheter through the manikin skin over the jugular vein, navigating through the heart to the valve and inflating/deflating the balloon to simulate the treatment of the pulmonary stenosis. The user has the ability to take the model apart to replace components such as the annulus and manikin skin as needed. The heart model can also be opened during use to help students better understand the procedure, anatomy, and navigate through the arches in the heart chambers.

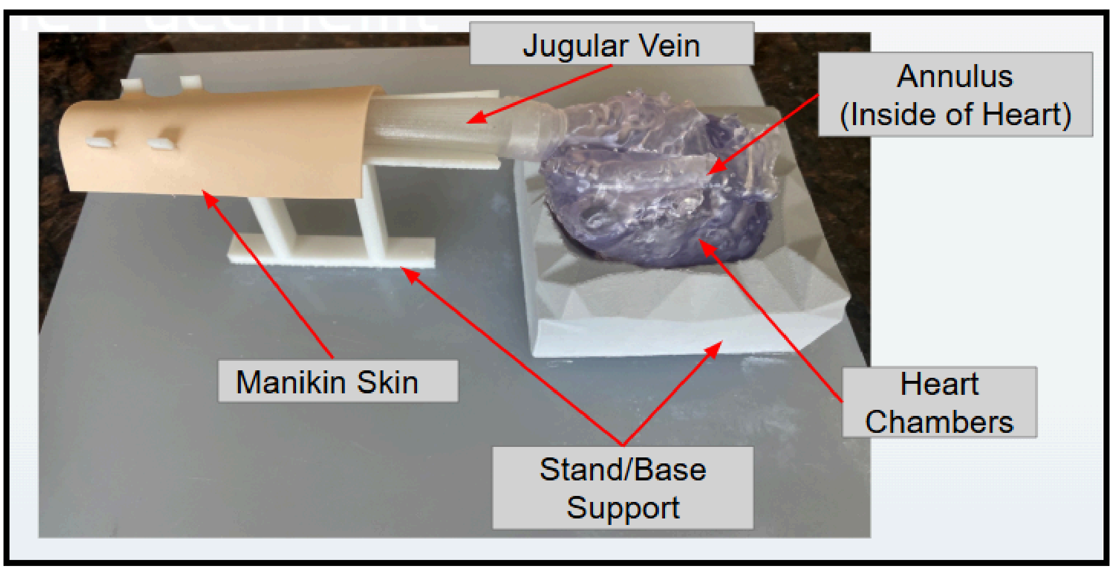


Figure 13: Final model design fully assembled into the base and stand supports

6 Fabrication

5.2a Heart Chambers and Annulus

The heart chambers and annulus were modeled from a client provided CTA of a french bulldog with pulmonary valve stenosis. The CTA was segmented using 3D Slicer software to select the heart chamber walls, valves, and necessary vasculature. Using the axial view, the pulmonary valve annulus and leaflets were segmented separately by carefully outlining the structures using the paintbrush tool. After segmentation, STLs of the heart chambers and the annulus were generated and exported to MeshMixer. In MeshMixer, the heart chambers STL 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. In Onshape, the heart chambers were cut vertically, ensuring that the planar cut split the area where the pulmonary valve is located. Three peg and hole connectors were added to the heart chamber walls. The pegs have a diameter of 8.89 mm and a height of 6.35 mm. The dimensions of the holes for the pegs are about 50 thousands of an mm smaller. This negative clearance ensures a secure fit between the chamber halves. The heart chambers were printed on a Formlabs 3B printer with Formlabs Flexible 80A resin. The annulus was printed on the same printer with Formlabs Elastic 50A resin. The components were post-processed through a washing and curing phase. The Elastic 50A resin is washed in 99% isopropyl alcohol for ten minutes, then allowed to dry for ten minutes and washed one more time for ten minutes again with the supports on the part removed. 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. The Flexible 80A resin is also washed in a ten plus ten minute wash cycle but the supports stay on the part for both washes. The curing cycle is set at sixty degrees celsius for ten minutes for maximal mechanical performance. Full details of the fabrication are described in Appendix 11.3b.

5.2b Jugular Vein

The jugular vein was designed using SolidWorks 3D modeling. The jugular vein is tapered with an inner diameter of 9 mm at the distal end and 16 mm where the jugular vein connects to the cranial vena cava. The walls of the jugular vein are 1 mm thick. These dimensions were verified from a CTA scan read by a veterinary radiologist at the UW-Madison School of Veterinary Medicine. The jugular vein is 150 mm long. At the 9 mm end, a 20 x 5 mm long oval is cut out of the jugular vein. This is where the catheter will be inserted into the jugular vein. A complete drawing of the jugular vein can be found in Appendix 11.3c.

Additionally, the jugular vein will be inserted into the heart through an extruded cylinder around the cranial vena cava. The extruded cylinder has an inner diameter of 18.05 mm, allowing for a 0.025 mm tolerance on each side between its inner wall and jugular vein. The extruded cylinder has a wall thickness of 1 mm. Cyanoacrylate adhesive secures the jugular vein to the extruded cylinder. The jugular vein will be made of Elastic 50A and the extruded cylinder will be made of Flexible 80A and will be printed attached to the heart chambers. A complete drawing of the heart connection piece can be found in Appendix 11.3c.

5.2d Model Stand

The jugular stand was designed in SolidWorks. See Appendix 11.3d for drawing. The stand has an overall height of 65.23 mm. The half cylinder is designed to have a tolerance of 20% of the outer diameter of the jugular vein model. The distal radius is 14.00 mm and the proximal radius of the half cylinder is 22.35 mm. The flanges on the distal end of the jugular stand at 9.57 mm long and 6.24 mm wide. The stand was printed on a FormLabs Form 4 printer in the MakerSpace out of White Resin V5.

Furthermore, the heart box was created using MeshMixer. A box was drawn in MeshMixer then the STL of the heart was placed in the correct orientation within the box. The heart outline was subtracted from the internal area of the box with a 0.75 mm buffer. This model was imported into Blender to subtract the remainder of the heart ventricles from the center of the mold. The model was then imported back to MeshMixer. A smoothing and reducing function was applied to decrease the number of triangles in the STL. The mold was then exported as an STL file to be printed. The heart mold was printed in PETG using a Bambu printer.

A white acrylic piece with thickness of 6.35 mm, width of 304.8 mm, and length of 304.8 mm was cut to be the base of the model. The base ensures the model does not tip over or move while the procedure is being performed. The heart mold and jugular holder were attached to the acrylic base by placing cyanoacrylate glue on the interfacing side. The model was pressed against the base for approximately 60 seconds to ensure the glue was dry.

6 Testing

6.1 Elastic Modulus Testing

In accordance with the design specifications, the materials within the model must mimic the natural properties of cardiac tissue, specifically the elastic modulus. The two selected materials, Elastic 50A and Flexible 80A, underwent tensile MTS testing to determine the elastic modulus. Both are anisotropic and were tested in the longitudinal fiber orientation, as this orientation aligns with the path of the catheter as it is fed through the jugular vein. If the catheter were to stretch the jugular vein or heart chambers, it would be in the longitudinal direction.

First, 4 dog bone samples of each material were printed. The dimensions of the dog bones followed the parameters described for by ASTM D638 Type 1 samples for tensile testing of plastic materials (Figure 14) [41]. The width and thickness of each sample were measured using calipers. Each sample was loaded into the MTS machine and the gauge length was measured. Per ASTM D638, each sample was loaded at a rate of 5 mm/min until rupture [41]. In every test, the sample broke at the MTS clamp point before plastic deformation could occur in the middle of the sample, so a true yield strength could not be determined (Figure 15). Regardless, enough data was collected to determine the elastic modulus.

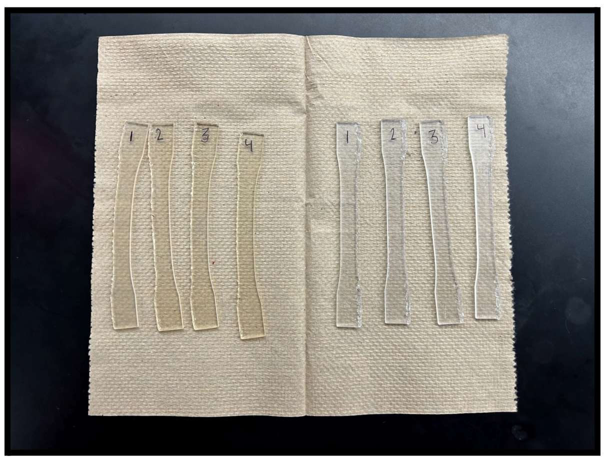


Figure 14: Dog bone samples of Flexible 80A (left) and Elastic 50A (right)

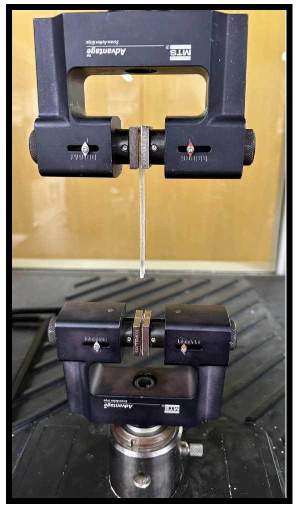


Figure 15: Sample rupture near clamp connection

6.2 Annulus Valve Fatigue Test

The 3D printed annulus and valve leaflets were tested to ensure that they could endure repeated expansion from the balloon catheter during use of the model. With each use of the model, the annulus will be expanded by the balloon catheter, which may cause deformation or stretching of the 3D printed component over the lifetime of the model. To test the fatigue lifespan of the annulus, the balloon catheter was fed through the annulus and inflated and deflated 150 times. For each cycle, the balloon catheter was inflated to a pressure of 3 atm. The inner dimensions of the annulus were measured in 3 different locations before testing and after every 10 cycles of inflation and deflation. Measurements were performed using images taken during testing in ImageJ software. The full testing protocol is in Appendix 11.4b.

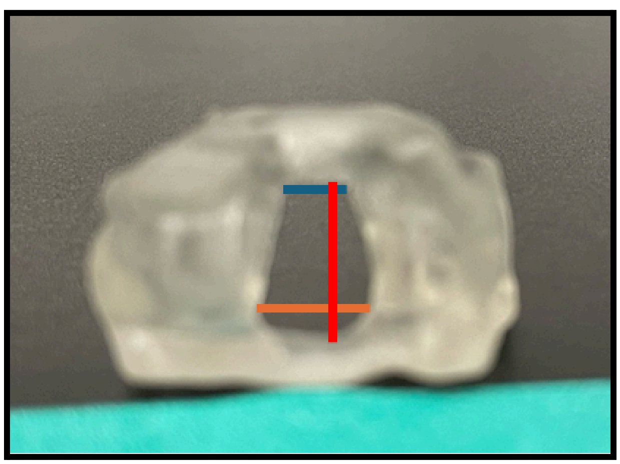


Figure 16: Annulus during fatigue testing. The top diameter (blue), bottom diameter (orange), and height (red) were measured in ImageJ after every 10 cycles.

6.3 Full Model Function Test

The entire model and stand were evaluated based on their ability to replicate native anatomy and tissue. They were also tested to determine the functionality of the whole system. To evaluate model functionality, the client practiced a balloon valvuloplasty procedure on the model and evaluated its performance in 5 categories: feel of the model compared to native anatomy, the movement of the leaflets of the balloon, visibility through the model, insertion process, and ease of use. The full protocol is in Appendix 11.4c.

First, the feel of the model compared to native anatomy was evaluated. The client placed the model in a water bath, creating a more lifelike scenario, and traversed a catheter through the jugular vein into the right atrium. The client struggled to maneuver the catheter around the base of the right ventricle into the pulmonary valve. The client tried a combination of catheters, wires, and balloon catheters to reach the pulmonary valve. Due to the lack of correctly sized tools, jagged edges in the model, and inflexibility of heart walls, the client was unable to reach the pulmonary valve.

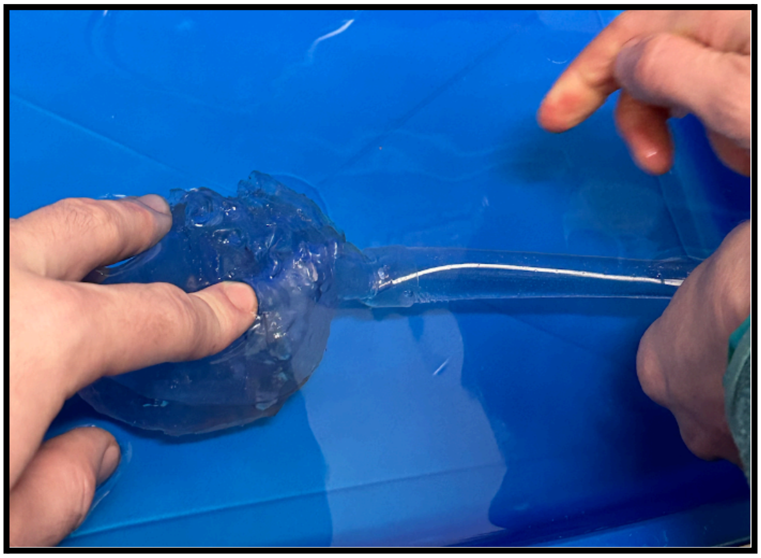


Figure 17: Client traversing balloon tipped catheter through the model

Next, the valve leaflets were tested to see how similar their response to a balloon inflation were to native anatomy. The balloon was placed directly into the valve without following the native path as shown in Figure 18. The balloon was inflated three times, per procedure, then removed from the valve. See Figure 19.

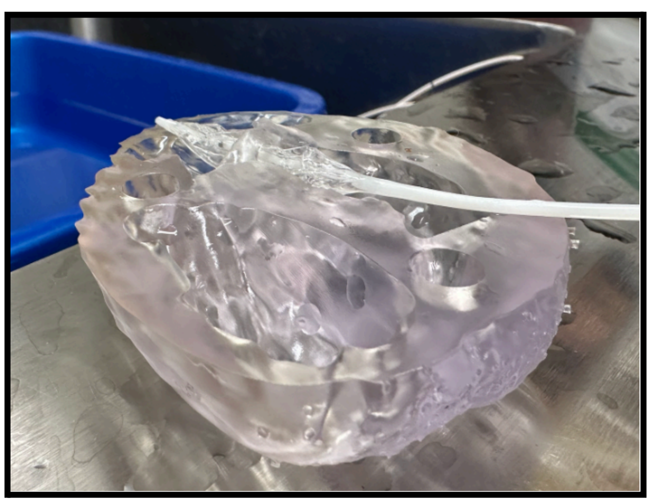


Figure 18: Balloon catheter positioned in pulmonary valve in model

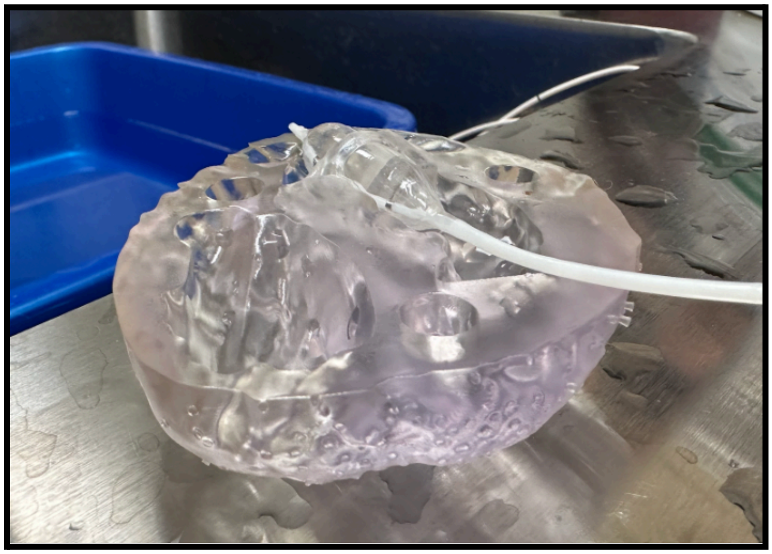


Figure 19: Balloon catheter inflated in pulmonary valve in model

The third criteria that was tested was the visibility through the model. The end goal is to have a recording system projecting the movement of the catheter through the model onto a screen. To ensure the catheter is visible, a catheter was placed in the deepest part of the heart, right ventricle, and was evaluated on its visibility. The catheter placed in the heart is shown in Figure 20.

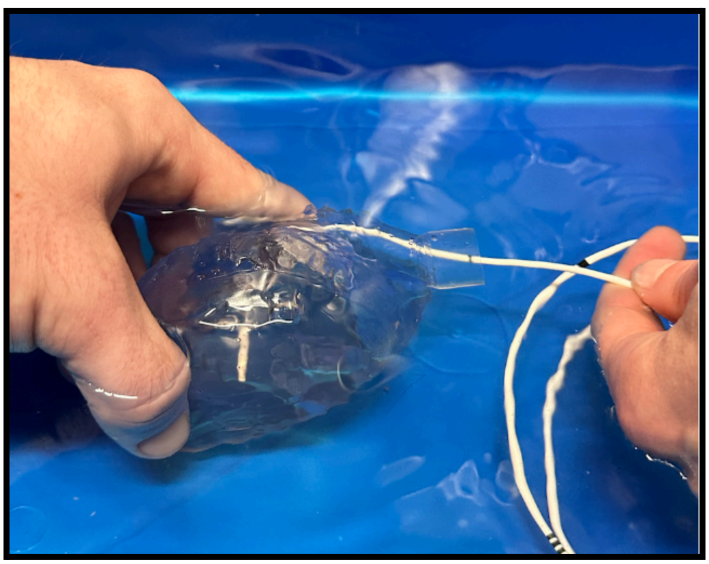


Figure 20: Catheter placed in right ventricle of heart model in water basin

The insertion process of the IV catheter was performed out of the water tank. The jugular vein model was placed into the stand and the manekin skin was placed on top. The client used an IV needle during the procedure to pierce through the manekin skin into the jugular opening, simulating the insertion process. The remainder of the needle was removed with the path needle left in the model as shown in Figure 21.

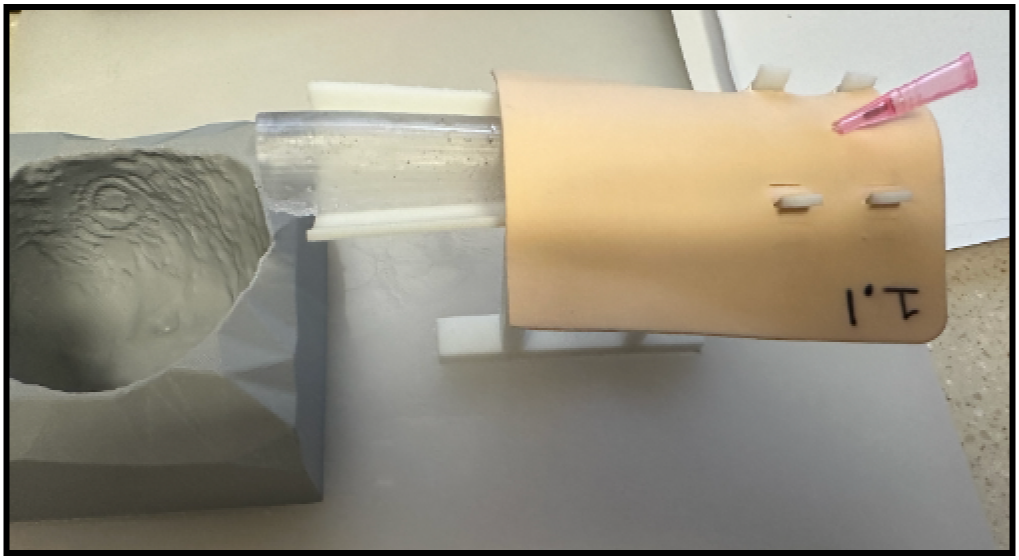


Figure 21: Jugular vein with simulation skin in model was needle inserted post procedure

The last criteria to be evaluated was the ease of use of the model assembly including the heart model, the valve, the jugular vein, and the stand. The client placed the valve into the heart model then pushed both halves of the heart model together. She then placed the jugular vein into the heart model and placed it within the stand. The client then placed the simulation skin onto the model.

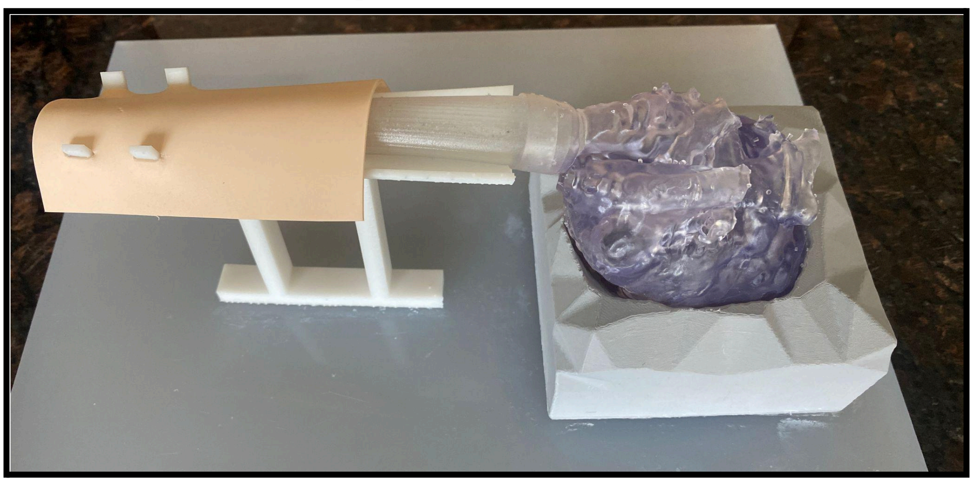


Figure 22: Model placed inside the stand with complete assembly

7 Results

7.1 Elastic Modulus Test Results

For each material sample, the stress and strain were recorded by the MTS machine and then exported and plotted in MATLAB (Figure 23). A linear equation was fitted to the linear region of each graph to calculate the elastic modulus of the sample. The average elastic modulus for the Elastic 50A samples was 1.678 ∓ 0.084 MPa. The average elastic modulus for the four Flexible 80A samples was 2.505 ∓ 0.321 MPa. The full testing protocol, testing data, and graph for each sample can be found in Appendix 11.4a and 11.5a.

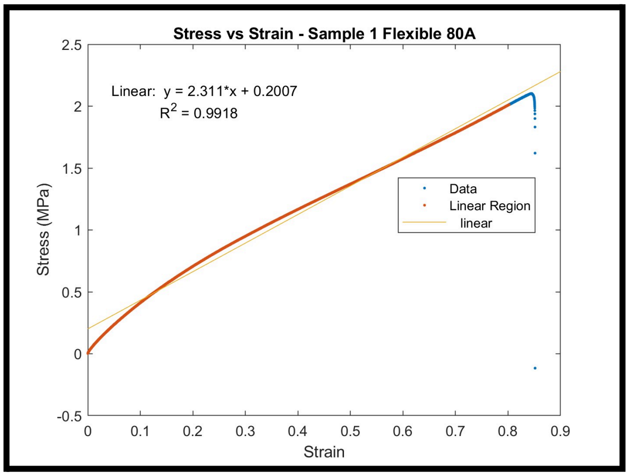


Figure 23: Example stress vs strain curve for Flexible 80A sample with linear equation fit

7.2 Annulus Valve Fatigue Results

The 3D printed annulus was measured before testing and after every 10 cycles of inflation and deflation. The annulus was measured in 3 locations using ImageJ software. The top diameter was measured horizontally at the top inner portion of the annulus. The bottom diameter was measured horizontally along the bottom of the annulus. The height of the annulus was measured on the inner diameter vertically. Changes in these dimensions during testing will indicate if the 3D printed material is stretching during testing.

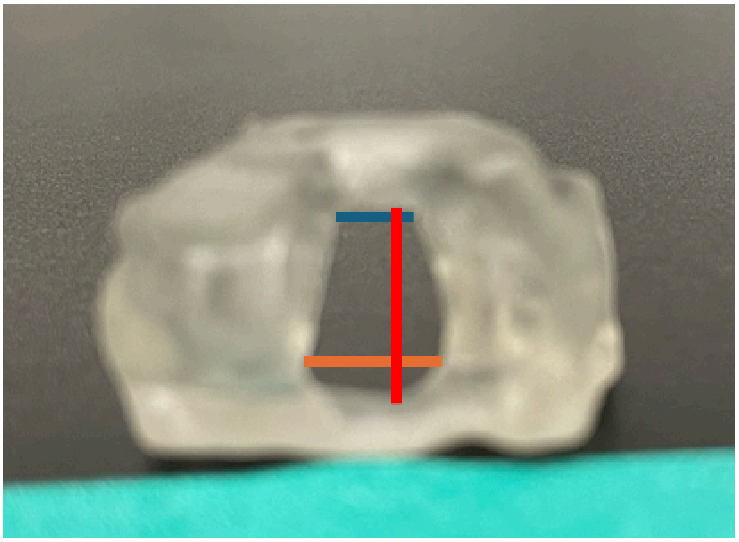


Figure 24: Image taken during annulus valve fatigue testing showing measurement locations – top diameter (blue), bottom diameter (orange), height (red)

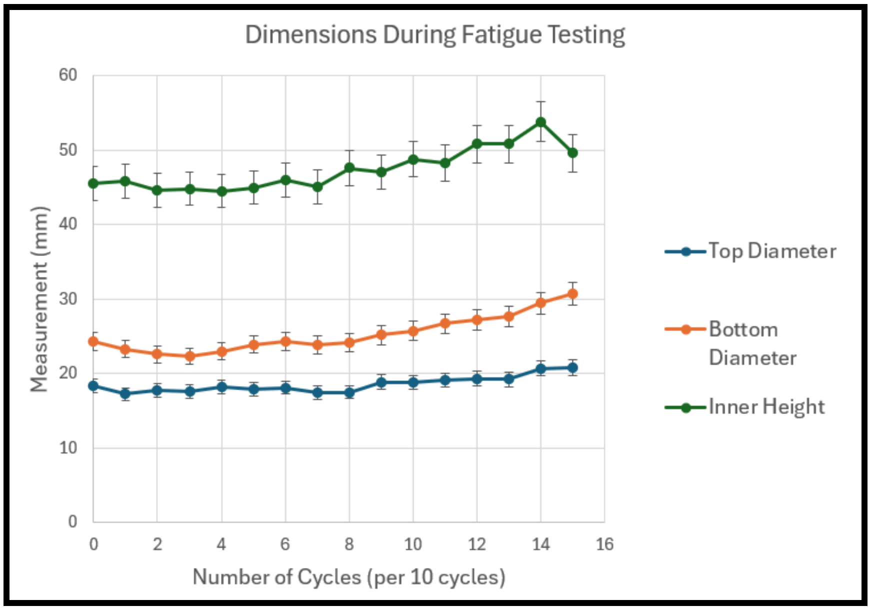


Figure 25: Dimensions recorded during fatigue testing of the annulus.

The measurements were then plotted and analyzed. The dimensions all showed a gradual increase throughout testing. This indicates that the annulus did stretch during testing. The percent change in the top diameter was calculated as 13.2%. The bottom diameter increased by 26.0%, and the inner height increased by 9.0%. The full results of the test are shown in Appendix 11.5c.

7.3 Full Model Function Results

The five criteria that were evaluated for the full model function test were the feel of the model compared to native anatomy, the movement of the valve leaflets with balloon inflation, visibility through the model, insertion process, and ease of use. Each of the five criteria were evaluated by the client as either meeting expectations or needing improvement. The movement of the valve leaflets meets expectations as the leaflets move in a similar fashion to native tissue with the balloon inflation. The visibility through the model meets expectations. The catheter was visible through the model even in the deepest part of the model, the right ventricle. The insertion process also meets the client's expectations. The ease of use criteria was evaluated as needing improvements. The client struggled to place the heart model into the heart mold on the base due to the tight tolerance between the mold and the heart model. The feel of the model compared to native anatomy was also determined to need improvements based on the client's evaluation. The client was unable to traverse the catheter to the heart using the catheter that was available. Overall, the model anatomy was deemed too challenging, as the jagged edges within the right ventricle and stiffness of the heart walls made it impossible to transverse the catheter through the chambers into the pulmonary valve. The results of the full model function test are shown in Appendix 11.5d.

8 Discussion

8.1 Elastic Modulus Testing

The elastic modulus of the venus tissue that makes up the jugular vein is dependent upon the pressure of the fluid that flows through the vein [42]. In canines, when the pressure of the fluid is 0.001 atm, 0.05 atm, and 0.07 atm, the longitudinal elastic modulus of the jugular vein is 0.12 ∓ 0.018 MPa, 1.18 ∓ 0.21 MPa, 4.6 ∓ 1.3 MPa respectively [42]. The elastic modulus of the Elastic 50A was found to be 1.678 ∓ 0.084 MPa. The percent error between the Elastic 50A elastic modulus and canine venus tissue is 1281.66% at 0.001 atm, 40.51% at 0.05 atm, and -63.52% at 0.07 atm. Based on these values, Elastic 50A does not accurately mimic the elastic modulus of the jugular vein in canines within 10%, as required by the design specifications. This test has two big takeaways. First, the pressure of the fluid in the valve dictates the elastic modulus of the jugular vein, so to accurately simulate the elastic modulus using Elastic 50A, the fluid in the model would need to be kept at a pressure between 0.05 and 0.07 atm. Second, it is important to note that biological tissues are viscoelastic while plastic polymers are elastic. Because Elastic 50A has no fluid-like response in its mechanical behavior, it is not possible to perfectly mimic the behavior of a biological tissue using a plastic material. At this time, the client is pleased with the material choice for the jugular vein and feels that it accurately represents the native tissue to the extent needed for teaching students with this model.

Additionally, the overall elastic modulus of ventricular myocardial tissue is 0.108 ∓ .229 MPa [43]. The percent error of the Flexible 80A in comparison to the ventricular myocardium is 2231.19%. These results indicate that Flexible 80A does not accurately mimic the elastic modulus of the ventricular myocardium within 10%. The client is pleased with the transparency of Flexible 80A but noted that the high stiffness makes it challenging to pass a catheter through the heart chambers as the wall of the heart should deform with the force of the catheter. Next semester, the heart chambers will be printed in Elastic 50A as the stiffness more closely matches the elastic modulus of myocardial tissue and provides more compliant heart walls.

8.2 Annulus Valve Fatigue

Due to the diameters of the annulus gradually increasing throughout the testing, the heart valve may expand with prolonged use. This fatigue testing was performed for more cycles than are expected in the intended use of the model. During normal use, the expansion should be minimal. In addition, the annulus will be confined within the heart, which will counteract some of the stretching that was seen in the testing. Therefore, this testing will be repeated with the annulus secured within the full heart model. To address this potential expansion of the annulus that was observed in testing, multiple annuli can be 3D printed and provided to the client. The annulus is not permanently attached to the model, so the annulus can be replaced as needed when fatigue is observed by the users.

8.3 Full Model Function

The valve and the insertion process met the design criteria outlined by the client and do not need to be updated. Although the visibility through the model met expectations the client would like to test the visibility through the model with the balloon catheter filled with colored dye. This may help to improve the visualization of the balloon as it navigates through the heart model. Due to ease of use needing more improvements the tolerance between the heart model and the heart mold on the base needs to be increased. This will allow for an easier placement of the heart model in the base when setting up the model assembly. As the client was unable to advance the balloon catheter to the pulmonary valve due to the model's complexity, the anatomy will need to be modified by expanding the size of the right heart chambers and smoothing out the edges along the heart wall. While the client notes that the challenges she faced while feeding the catheter through the heart chambers are realistic to real life procedures, the model may be too challenging for students learning the procedure for the first time. This justifies altering the native anatomy to assist students learning and practicing the procedure. Additionally, in real life procedures, the veterinarian will use the blood flow through the heart to help push the catheter through the heart. The current model is a static system that does not have blood flow, attributing to the challenges in maneuvering the catheter. Future updates will be necessary to enable the students and the client to successfully complete the procedure using the model.

9 Conclusion

Recently, the UW Veterinary Hospital has experienced a decreased caseload of patients with pulmonary stenosis. As a result, veterinary students have fewer opportunities to learn and practice the transcatheter procedures used to treat this condition. To solve this problem, a canine heart model was built to allow students to learn and practice balloon valvuloplasty in the absence of living patients with this condition. The final design of this model consists of the canine heart chambers, a removable pulmonary valve, jugular vein, a stand and base to support the model, and manikin skin for simulation skin.

A functional prototype of the model was created and tested to evaluate the design based on the design specifications and client requirements. The three tests performed on the model included material stiffness testing, valve deformation testing, and a full model functionality test. From these tests, two main aspects were identified as needing improvement. First, during the material stiffness characterization test, the results showed the material used to make the heart chambers was insufficiently compliant. Additionally, during the full model functionality test, the geometry of the heart chambers and sharp edges within the chambers made it extremely difficult to pass the catheter through the heart. To address the stiffness of the heart chambers, the material will be changed from Flexible 80A to Elastic 50A. In order to address the challenging geometry, the wall thickness of the right ventricle will be decreased to create larger heart chambers and the sharp edges within the right ventricle will be smoothed.

In the future, the model will be placed in a dynamic fluid filled system. Currently, the heart model is in a static fluid environment, which does not simulate blood flowing in the model. To improve the physiological accuracy of the model and to simplify the process of navigating the catheter to the valve, a pump system will be developed. This will simulate blood flow through the heart and allow students to practice using the blood flow to direct the catheter through the heart to the annulus, where the balloon will be inflated. Additionally, a video platform will be incorporated into the model stand. During procedures on real patients, veterinarians view the location of the catheter by viewing an x-ray screen that tracks the catheter with fluoroscopy. In order to replicate this scenario, a camera will be held above the model and project a video of the model on a monitor screen. This will allow students to practice the procedure while looking at a screen rather than their hands.

In terms of future testing that must be performed on the model, coefficient of friction testing of the Elastic 50A material will be executed. It is important that the material in the model does not impose significant friction to the balloon catheter. If the coefficient of friction is significantly greater than that of native tissue, baby soap will be added to the fluid system to reduce the friction between the catheter and Elastic 50A material. Additionally, the annulus valve fatigue test will also be repeated with the valve constrained in the heart chamber. This will result in a more accurate test setup as during normal use the valve will only be inflated when it is inside the heart chambers. By restricting the valve the overall size should not increase as significantly as when it is unconstrained, generating passing results. Overall, the initial heart model developed proved balloon valvuloplasty procedure can be simulated using 3D printed components from CTA scans, done so in an anatomically and procedurally accurate design.

In conclusion, the first prototype of the model showed a successful simulation of pulmonary stenosis and balloon valvuloplasty. Future changes to the heart chamber material and geometry will eliminate the current challenges with navigating the catheter through the heart and create a simpler model better suited for students. Additionally, the addition of a dynamic fluid flow system and video display will increase the model's similarity to real life procedures. Following these changes, the model will be ready for use in training veterinary students in balloon valvuloplasty to treat pulmonary stenosis.

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11 Appendix

11.1 Product Design Specifications

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 students 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 students 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, therefore, the dimensions of the model should be within 10% of the dimensions measured on the CT scan. 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 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.

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. The model should be accurate to within 10% of the dimensions of the heart's dimensions as measured in the patient's CT scan.

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 30 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 [10].

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 two 3D printing resins. The jugular vein and annulus will be printed using Formlabs Elastic 50A. The heart chambers will be 3D printed from Formlabs Flexible 80A. 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 the fixture will be fabricated from 3D resin. 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 [1].

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 [2].

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 [3]. 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 [4]. 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 [5]. Lastly, the materials chosen in our model must match the elastic modulus and breaking strength of the cardiac tissue that is designed to represent within 10%. The general standards for cardiac models require an elastic modulus of 0.17 MPa and a breaking strength of 0.17 MPa [6].

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 students 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 Bulldogs, 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 [2]
    - Utilized original CT scans of a patient 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 [7]
    - 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 [8]
    - 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 into 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 [9]
    - 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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11.2 Expense Spreadsheet

Item	Description	Manufacturer	Date	QTY	Cost Each	Total	Link
Category 1 3D Printed Material							
Elastic 50A Resin	Material for Jugular Vein and Annulus	Formlabs	10/14/24	1L	$208.57	$208.57	https://formlabs.com/store/materials/elastic-50a-resin-v2
Flexible 80A Resin	MAterial for Heart Chambers	Formlabs	10/14/24	1L	$208.57	$208.57	https://formlabs.com/store/materials/flexible-80a-resin
Category 2 Fabrication Materials							
Super Glue	Secure Jugular Vein to Heart	The Original Super Glue Corporation	11/19/24	2 x 0.07 oz	$1.21	$2.42	https://supergluecorp.com/
Stand Print	Model Holder Stand	MakerSpace	11/20/24	2	$8.00	$16.00	N/A
					TOTAL:	**$435.56**	

11.3 Fabrication Protocols

11.3a 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.

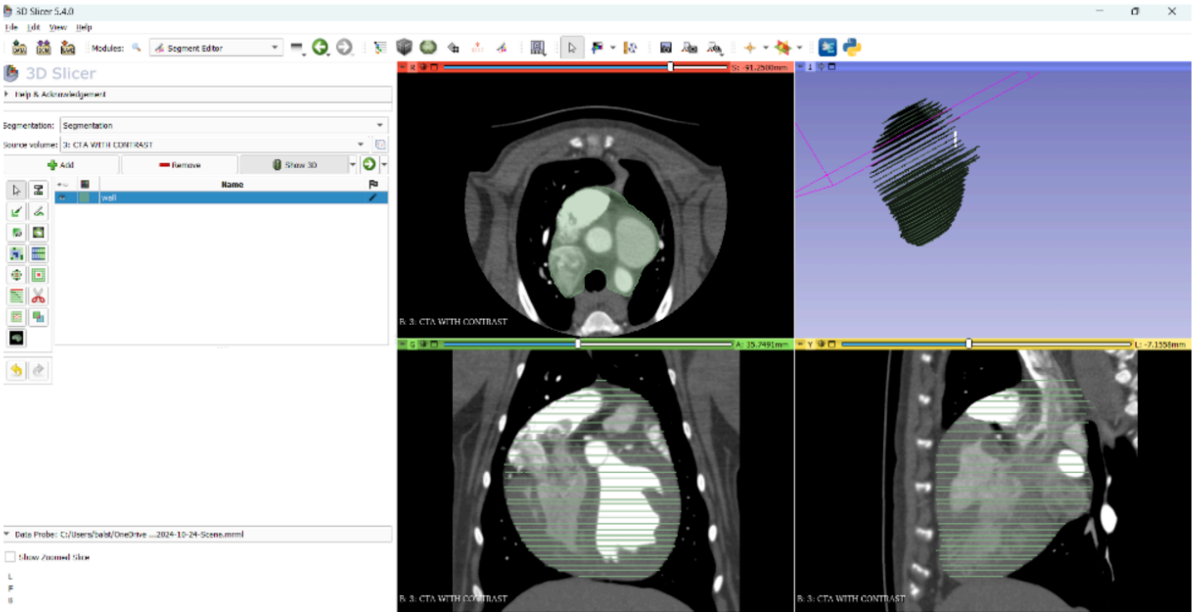


Figure 26: Heart segmentation after using the paintbrush tool to draw the heart every 5-6 layers

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.

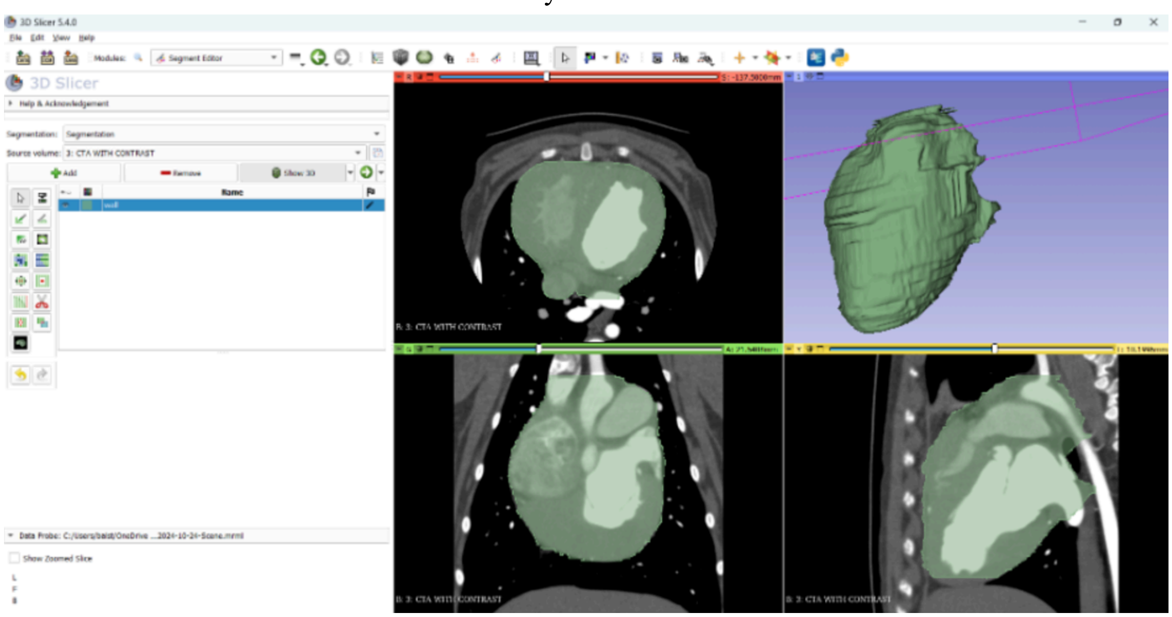


Figure 27: Heart segmentation after filling between layers

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.

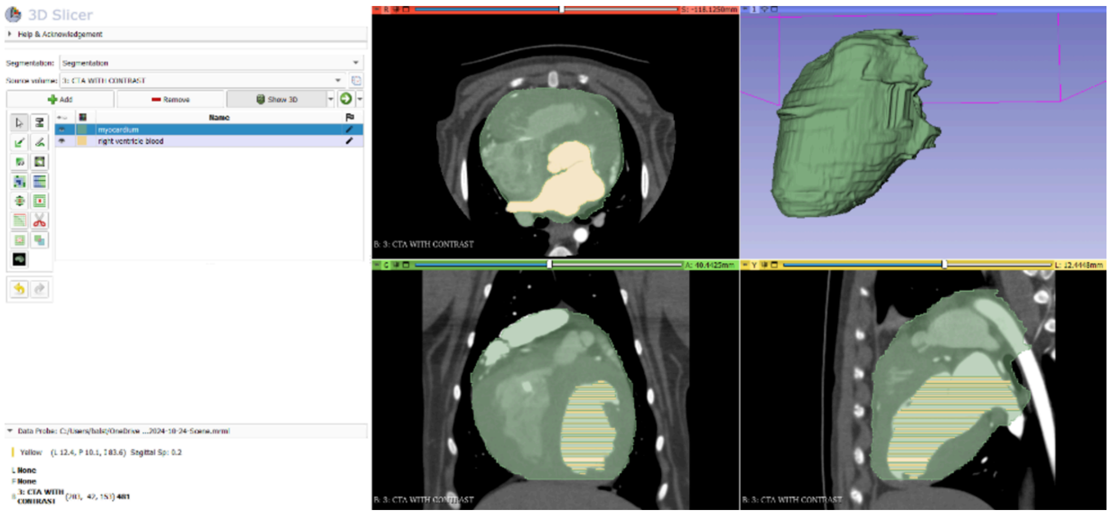


Figure 28: Heart segmentation during the process of segmenting the blood pools

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.

11.3b Printing Heart Walls, Annulus and Jugular Vein

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. Depending on the material chosen, the wash steps can differ.
    a. For the Elastic 50A material it 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.
    b. For the Flexible 80A material the steps are the same except the supports stay on for the second wash as well.
6. Allow the parts to dry before placing them in the curing station. Again the cure steps can differ depending on the material.
    a. 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.
    b. The Flexible 80A prints are placed directly in the cure station which has been preheated to 60 degrees celsius. The parts are then left to cure for 10 minutes in the station.
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.

9. If there are no issues the printing process is complete otherwise a reprint should be considered for the part, in which the steps above would be repeated.

11.3c Jugular Vein

Jugular Vein Drawing:

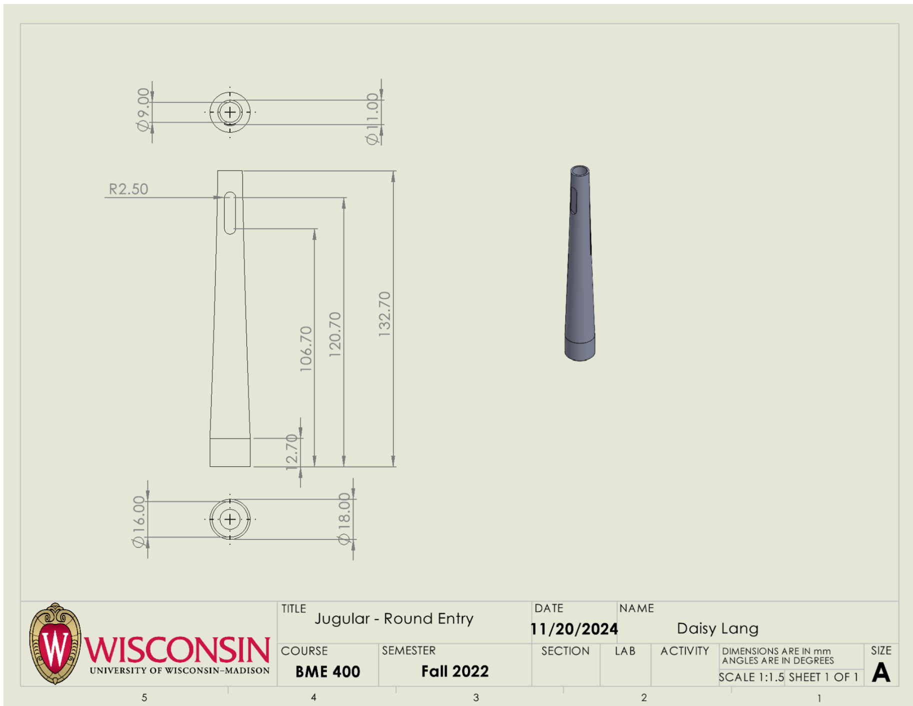


Figure 29: Jugular vein model drawing

Heart Connector Drawing:

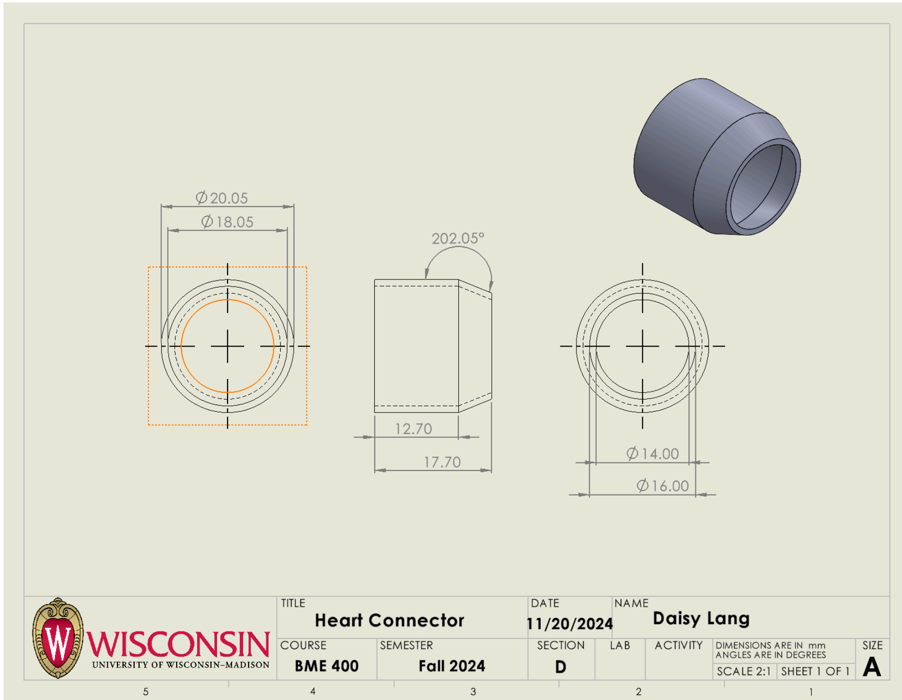


Figure 30: Jugular vein connection model drawing

11.3d Model Stand

JUGULAR FIXTURE

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

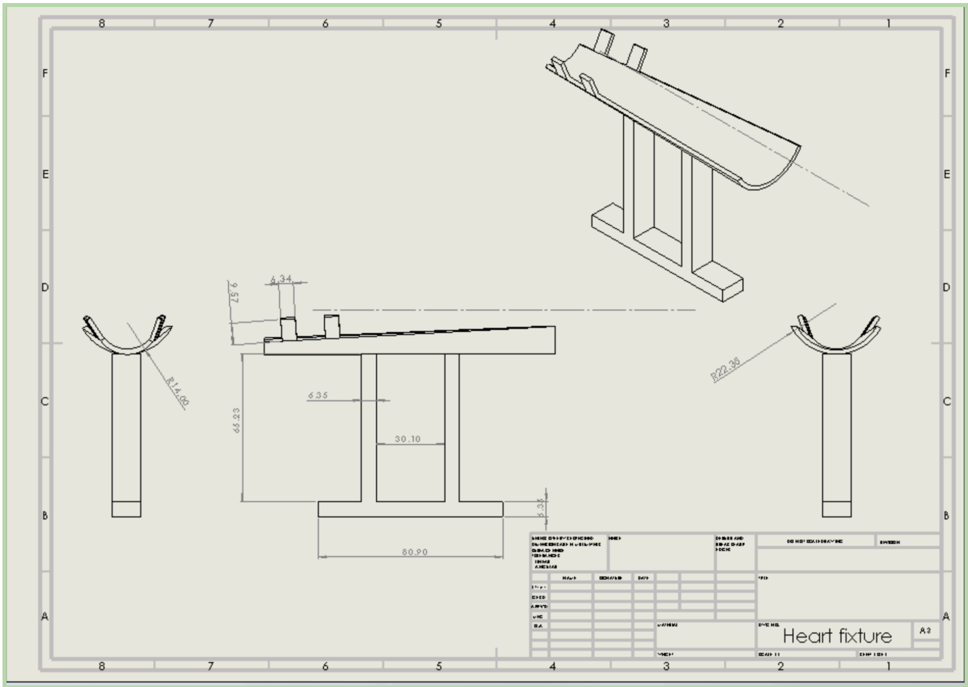


Figure 31: Jugular vein stand drawing

HEART MOLD

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

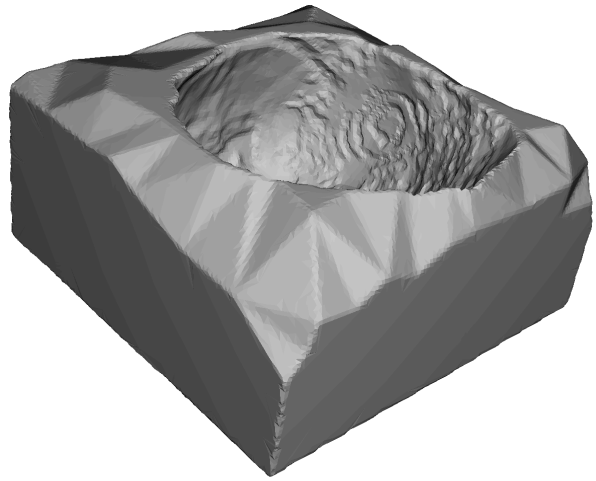


Figure 32: STL model of heart chamber base

MODEL STAND ASSEMBLY

11. Place cyanoacrylate glue (super glue) on each interfacing feature between the acrylic base and the heart mold
12. Hold together for 60 seconds to ensure glue is dry
13. Place cyanoacrylate glue (super glue) on each interfacing feature between the acrylic base and the jugular stand

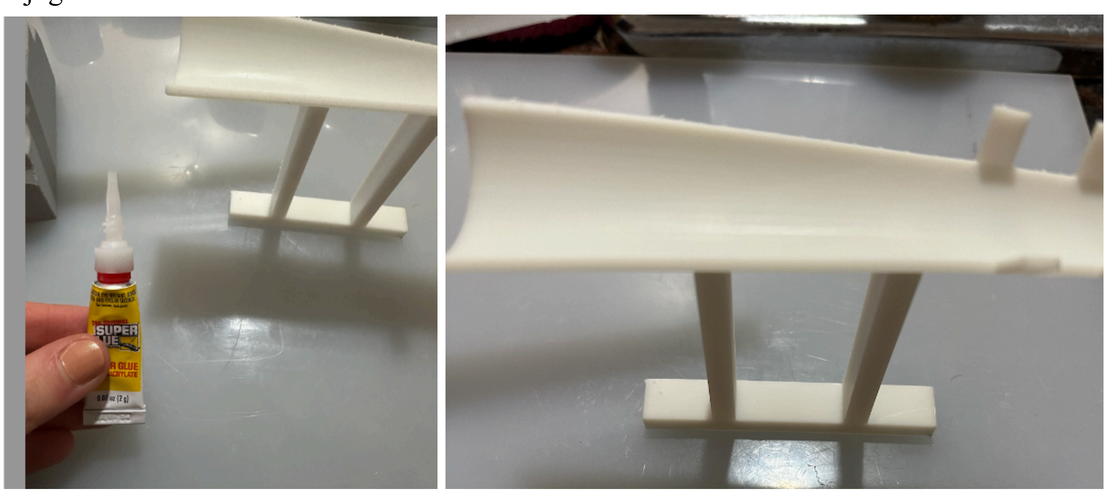


Figure 33: Application of glue to jugular stand and acrylic base

14. Hold together for 60 seconds to ensure glue is dry

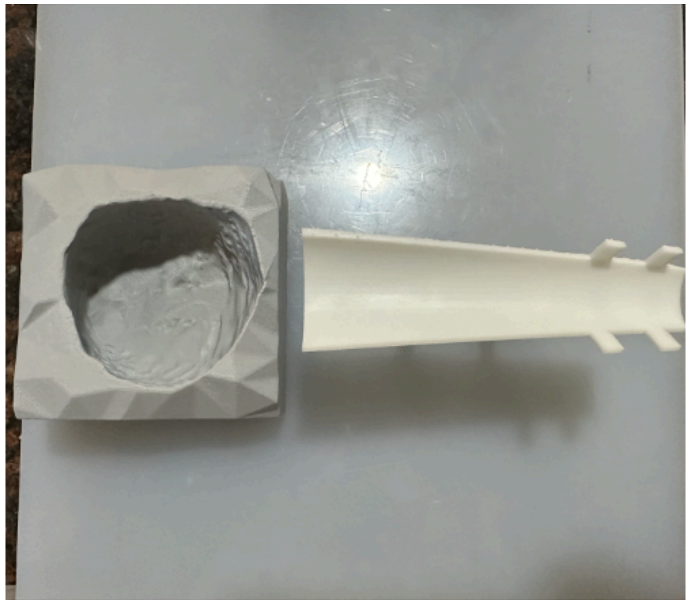


Figure 34: Jugular vein stand and heart chamber base fixtured to acrylic base

11.4 Experimental Protocols

11.4a Elastic Modulus Testing 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.

11.4b Annulus Wear 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 according to the client.

11.4c Full Model Function Test Protocol

Entire test protocol executed by client.

Movement of Valve Leaflets with Inflation:

1. Insert the balloon catheter through the valve
2. Inflate the balloon, deflate the balloon, inflate the balloon, deflate the balloon
3. Client evaluate the movement of the valve in comparison to native anatomy

Visibility Through the Model

1. Place the model in a tank of water (will end up being a fluid filled system)
2. Place a wire and catheter into the heart
3. Client evaluate the visibility through the model

Insertion Process

1. Place the jugular and heart into the mold and stand
2. Place the simulation skin onto the model
3. Place an IV through the simulation skin into the jugular
4. Client evaluate the similarity to native insertion

Ease of Use of the Model

1. Place the valve into the heart
2. Place both heart halves together
3. Place jugular into the heart
4. Place heart into heart stand mold and lie the jugular into the stand
5. Place the skin layer onto the stand in the slots
6. Client evaluates the ease of use of the process

Feel of the Model Compared to Native Anatomy

1. Place the model with the valve inserted into a water bath
2. Run a catheter line through the heart and try to place the balloon through the valve
3. Client evaluates the similarity to native anatomy and tissue

11.5 Raw Testing Data

11.5a Elastic Modulus Testing Data

Elastic 50A Sample Dimensions:

Sample	Width (mm)	Thickness (mm)	Gauge Length (mm)
1	10.04	2.36	77.04
2	10.01	2.35	78.58
3	10.10	2.35	77.83
4	10.11	2.37	77.85

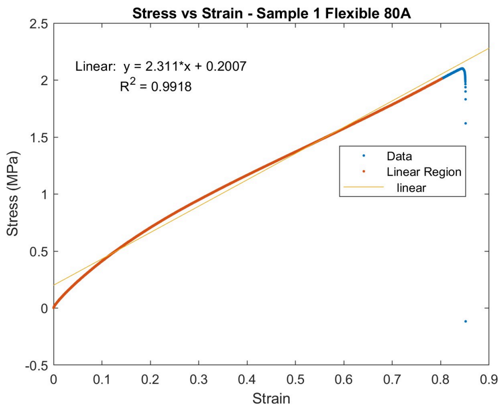
Flexible 80A Sample Dimensions:

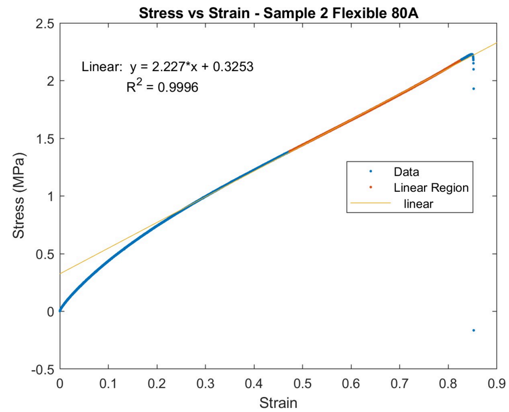
Sample	Width (mm)	Thickness (mm)	Gauge Length (mm)
1	10.05	2.35	79.54
2	10.09	2.37	79.54
3	10.09	2.32	79.54
4	10.04	2.35	79.54

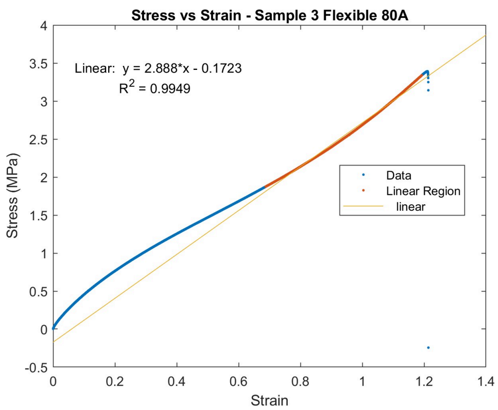
Average Elastic Modulus and Standard Deviation:

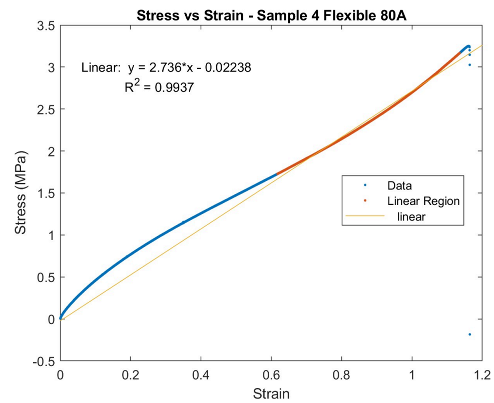
Material Type	Sample 1	Sample 2	Sample 3	Sample 4	Mean	STD
Elastic 50A	1.703 MPa	1.649 MPa	1.780 MPa	1.581 MPa	1.678 MPa	0.084
Flexible 80A	2.311 MPa	2.227 MPa	2.888 MPa	2.736 MPa	2.505 MPa	0.321

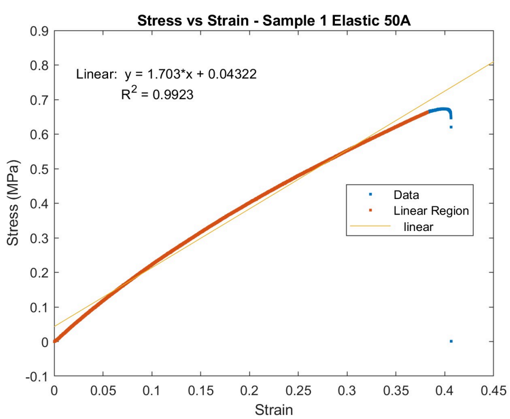
Stress vs Strain Curves for Each Sample:

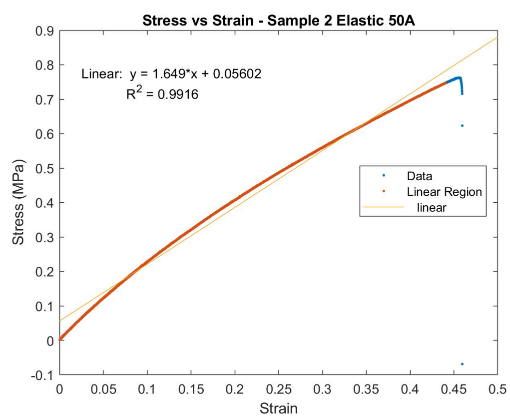












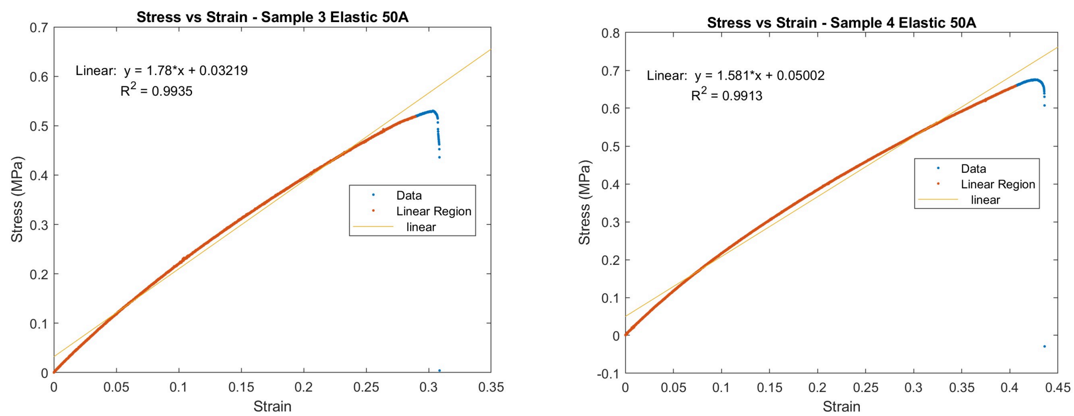


Figure 35: Stress strain curves for all test samples

11.5b Elastic Modulus MATLAB Code

```
%% BME 400 MTS Analysis
% Load your data file, replacing the '...' below with your filename
file = 'Sample1J.txt';
data=load(file);
% Extract the columns of interest from your data
disp=data(:,1); %Displacement in mm
force=data(:,2); %Force in Newtons
time=data(:,3); %Time in sec
% Plot your raw data and inspect it to make sure it looks as you expect
figure;
plot(force);
%% 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');
A=input('Enter the cross-sectional area of your specimen');
%% Calculate tendon stress and strain, being careful to use consistent units.
stress= force/A ; % Stress in MPa
strain = (disp) /Lo ; % Strain (unitless)
% Plot Stress Strain Curve
plot(strain,stress,'.', strain(j1:j2),stress(j1:j2),'.');
title('Stress vs Strain - Sample 4 Elastic 50A')
xlabel('Strain')
```

```
ylabel('Stress (MPa)')
legend( 'Data', 'Linear Region')
```

11.5c Annulus Wear Testing Data

Time Point	Scale		Top Diameter		Middle Diameter		Bottom Diameter		Inner Height	
	Pixels	Scale Ratio	Pixels	mm	Pixels	mm	Pixels	mm	Pixels	mm
0	203	3.82297552	70.03	18.31819212	100	26.15764	93	24.32660099	174	45.51429
1	219	4.12429379	71.063	17.23034384	108	26.1863	96	23.27671233	189	45.82603
2	219	4.12429379	73	17.7	109	26.42877	93	22.54931507	184	44.6137
3	224	4.21845574	74	17.54196429	111	26.31295	94.2	22.33044643	189	44.80313
4	222	4.18079096	76	18.17837838	110	26.31081	96	22.96216216	186	44.48919
5	229	4.3126177	77.06	17.86849782	118	27.36157	103	23.88340611	194	44.98428
6	223	4.19962335	76	18.09686099	113	26.90717	102	24.28789238	193	45.9565
7	238	4.48210923	78.03	17.40921429	118	26.32689	107	23.87268908	202	45.06807
8	222	4.18079096	73	17.46081081	113	27.02838	101	24.15810811	199	47.59865
9	228	4.29378531	81	18.86447368	118	27.48158	108	25.15263158	202	47.04474
10	223	4.19962335	79	18.81121076	115	27.38341	108	25.71659193	205	48.8139
11	209	3.93596987	75	19.05502392	108	27.43923	105	26.67703349	190	48.27273
12	209	3.93596987	76	19.30909091	111	28.20144	107	27.18516746	200	50.8134
13	213	4.01129944	77	19.19577465	116	28.91831	111	27.67183099	204	50.85634
14	213	4.01129944	83	20.6915493	116	28.91831	118	29.41690141	216	53.84789
15	213	4.01129944	83.2	20.74140845	112	27.92113	123	30.66338028	199	49.60986
Percent Difference				13.22846882		6.741784		26.04876571		8.998435

Figure 36: Annulus wear testing measurements

11.5d Full Model Function Testing Data

Model Criteria	Evaluation
Movement of Valve Leaflets	Meets Expectations
Visibility through Model	Meets Expectations
Insertion Process	Meets Expectations
Ease of Use	Needs Improvement
Feel of Model compared to Native Anatomy	Needs Improvement