BME Design

Multidimensional Imaging Based Models for Canine Cardiovascular Procedural Skills

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Client: Dr. Sonja Tjsotheim

Advisor: Dr. Tracy Jane Puccinelli

Team Checking the Beat:

Hunter Belting (Leader)

Anna Balstad (Communicator)

Becca Poor (BSAC)

Daisy Lang (BWIG & BPAG)

Abstract

Pulmonary valve stenosis is a congenital heart defect that leads to narrowing of the pulmonary valve, restricting blood flow from the heart to the lungs [1]. Pulmonic stenosis is caused by thickening or fusion of the pulmonary valve leaflets. This congenital disorder is most often identified in brachycephalic dogs, primarily French Bulldogs [1]. Canines with advanced disease may experience exercise intolerance, collapsing, arrhythmias, or heart failure [1]. Balloon valvuloplasty is the preferred treatment for pulmonic stenosis. To perform this procedure, a small incision is made in the dog's neck and a catheter is fed through the jugular vein into the dog's heart. Then a balloon catheter is placed across the pulmonic valve and the balloon is inflated to tear apart the valve leaflets, creating a larger opening to allow blood to flow more easily from the heart to the lungs [2]. The University of Wisconsin School of Veterinary Medicine is experiencing a decreased caseload of patients with pulmonary stenosis (PS), decreasing the training opportunities for students. In addition, there are currently no models of canine PS available with the intended use of transcatheter procedure skills training on the market. Simulator training with a multidimensional imaging-based model of PS allows students to learn and practice essential skills such as handling guidewires and catheters, balloon positioning and inflation, and communication between veterinary interventionists. This report outlines the plans for an anatomically accurate model of canine PS, created from Computed Tomography Angiography (CTA) scans and 3D printing.

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1 Introduction

1.1 Motivation

Pulmonary valve stenosis (PS) is a congenital heart defect that causes the narrowing of the pulmonary valve [3]. In PS, the leaflets of the pulmonary valve are thickened or partially fused, obstructing blood flow from the heart to the lungs [1]. PS is the most common congenital heart disease among canines and represents 31-34% of all canine congenital heart disease diagnoses [4]. Canines with PS may experience exercise intolerance, collapsing, and heart arrhythmias [1]. If left untreated, severe cases of PS can lead to right-sided congestive heart failure [5]. Any species of canine can develop PS, but it is most commonly seen in French Bulldogs [5]. Given the rising popularity of this dog breed, there is a need for veterinarians trained to treat PS [6].

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 [7]. Given that most pet owners do not purchase pet insurance, most owners cannot afford surgical intervention and transcatheter procedures are the only option available to treat their pets [8]. Two types of transcatheter procedures are used on canines with PS; balloon valvuloplasty and stent placement [7]. These transcatheter procedures are performed almost exclusively over surgical operations and for this reason, there is a high demand for veterinarians trained in transcatheter procedures to treat PS [7].

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 opportunities 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 simulator for PS treatment.

1.2 Existing Devices and Current Methods

Currently, there are no canine heart training simulators 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 soluble thermoplastics, 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, both of these models only include specific vasculature within the heart, and a model to simulate PS must include both 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. This model will allow students to learn how to perform transcatheter procedures and provide them with the opportunity to practice these skills 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 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. In a healthy dog, the pressure gradient of the pulmonic valve is less than 20 mmHg, but a dog with PS may have a pressure gradient above 80mmHg [17].

This 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 [18]. A visual representation of PS is shown in Figure 1. 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 [19]. 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 [18]. 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 [18].

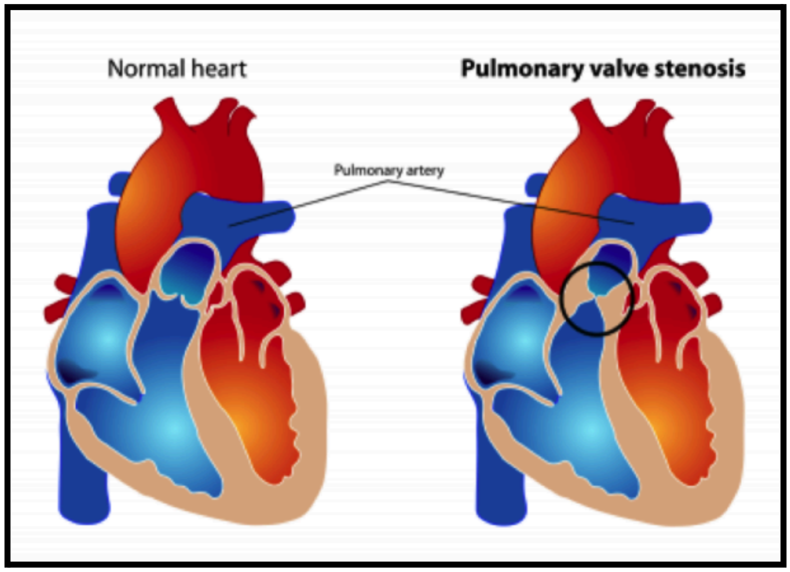


Figure 1. Pulmonary Valve Stenosis in a Canine Heart. [17]

There are multiple different treatments for PS including balloon valvuloplasty and stent placement. Balloon valvuloplasty is normally chosen for the treatment of PS, but treatment selection depends on the condition of the pulmonary valve leaflets [1]. Using an echocardiogram, a canine can be assessed on if the procedure will be successful or not. During a balloon valvuloplasty, the patient is under general anesthesia [1]. When a veterinarian is evaluating if a patient is a fit for balloon valvuloplasty, they look at factors such as the severity of PS, concurrent cardiac defects, and other cardiac diseases. If the dog has a systolic gradient of <50mmHg then they can live a normal life span with minimal symptoms throughout their life [20].

2.2 Balloon Valvuloplasty and Stent Placement

There are two main types of procedures used to treat PS; balloon valvuloplasty and stent placement. Balloon valvuloplasty is the preferred method of treatment for canines with moderate to severe PS [21]. 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 annulus. 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 [21]. The procedure is illustrated below in Figure 2. 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 [20].

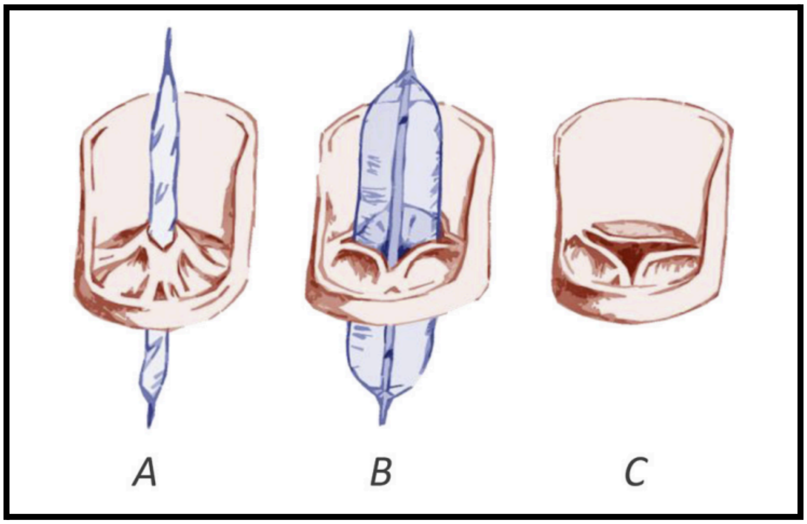


Figure 2: Balloon Valvuloplasty of Pulmonary Valve [20]

Stents are also used to treat severe cases of pulmonary valve stenosis. This product is very similar to balloon valvuloplasty, except the stent balloon catheter contains a premounted stent on the outside [22]. 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 [22]. 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. She currently 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 following product design specifications were created based on the client preferences, research, and standards for surgical skills models. The largest requirement of the 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 a minimum of 30 times per year and must have a life of service of 10 years. Between uses, the device will be stored in an office environment and must withstand a temperature of 20-22 °C for this duration.

In terms of size, the model will reflect the native anatomy of a heart with a VHS score of approximately 11.0 - 14.12 [23]. The model will be secured in a casing with maximum dimensions of 12 in X 12 in X 12 in. The entire device will weigh less than 25 pounds 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 [24]. 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 (0.17 MPa), max stress (1.5 MPa), and max strain (1.10) of natural cardiac tissue [25][26]. 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. The standard for fatigue limits for synthetic vasculature is 400 million cycles [27]. The platform for the model will be fabricated from Delrin 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 customer for the project is the client, Dr. Sonja Tjostheim, who 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 [28]. 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 [29]. 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 [30].

The full, unabridged version of the Product Design Specifications can be found in Appendix 8.1.

3 Preliminary Designs

3.1 Full Design Models

Three different designs for the full model were created. These included the 3D Printed One Piece model, the Molded model, and the 3D Printed Four Piece Model.

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 that 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 computed tomography (CT) 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 3: Example of 3D printed heart model [31]

3.1b Molded One Piece

To fabricate the Molded One Piece heart model, a mold will be 3D printed to then be filled with a silicone-type material to model the heart. The molded one piece model will be made of a flexible silicone material. The molds will be constructed from a resin or thermoplastic. The mold will consist of an outer mold that the silicone/rubber 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.

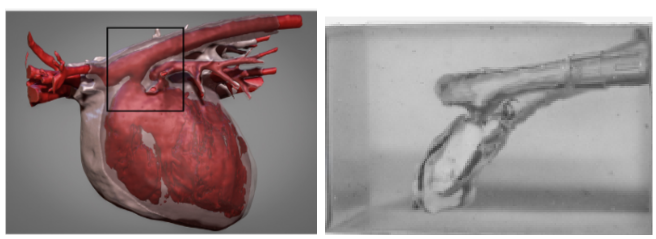


Figure 4: Example of arteries of the heart molded from a silicone material using 3D printed molds [32]

3.1c 3D Printed Four Piece

The 3D Printed Four Piece model will be created out of three different materials and four separate components. The four components include the top and bottom halves of the heart, the annulus and pulmonary valve, and the jugular vein. The jugular vein will be permanently attached to the heart chambers. The annulus and pulmonary valve will be secured within the chambers of the heart with 3D printed structures. There will be a ridge surrounding the top and bottom half of the heart with three snaps around the exterior of the heart to secure the entire heart model together. The main benefit of the 3D Printed Four Piece model is the ability to manufacture the 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.

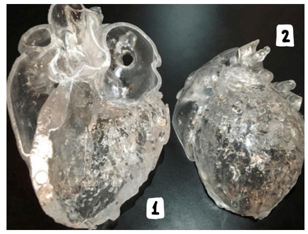


Figure 5: Two halves of a 3D printed heart [33]

3.2 Jugular Vein and Annulus Materials

Three possible materials to form the jugular vein and annulus were considered: Elastic 50A Resin, Flexible 80A Resin, and NinjaFlex TPU.

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 [34].

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 [35].

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 low friction exterior making it an easier material for fabrication. NinjaFlex requires an extruder temperature of 225°C – 250°C [36].

3.3 Heart Chambers Materials

Three materials for the heart chambers within the model were considered: Clear Resin V5, Flexible 80A, and PloyJet Photopolymer.

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 [37].

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 [35]

3.3c PolyJet Photopolymer - Stratasys

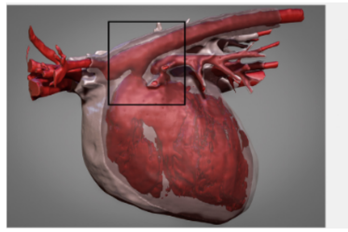
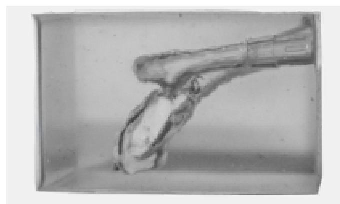
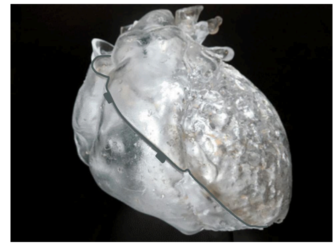
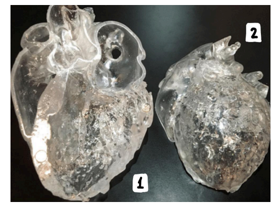
PolyJet Photopolymer from Stratasys is commonly used to make anatomical models. The material is printed on a Stratasys J750 Digital Anatomy 3D printer. The properties of the material are within the same range of porcine myocardium or they are slightly stiffer. The stiffness is relative to the thickness of the material. The elasticity ranges from 0.262 to 0.536 MPa and the young's modulus was around 0.327 N/m2. The material is easier to cut through when placing sutures than porcine myocardium but has similar failure mechanisms when undergoing puncture testing. The polymer has a sticky surface finish [38].

4 Preliminary Design Evaluation

4.1 Full Design Model Design Matrix

Table 1 shows the evaluation of the three full model designs. These models were assessed on seven different criteria: anatomical accuracy, ease of fabrication, durability, modularity, ease of use, cost, and safety.

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 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 30 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 even though the Four Piece and One Piece Models will be made out of the same material, 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 shows the evaluation of the three materials for the annulus and jugular vein. These models were assessed on seven different criteria: compliance, surface finish, transparency, ease of fabrication, cost, durability, and resolution.

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 [4], 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 is 85A [5]

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 [2]. 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 [1]. 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 shows the evaluation of the three materials for the heat chambers. These models were assessed on five different criteria: compliance, surface finish, transparency, ease of fabrication, cost. .

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 [2]. 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 [8].

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 [6]. 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 [9], 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 Discussion

5.1 Final Design Selection

5.1a Full Model Final Design

The final proposed design for the PS 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 annuluses 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 can be different from the material used to create the chambers. From Table 2, Elastic 40A 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 is passed through the model.

5.1c Heart Chambers Material Final Design

Finally, the heart chambers in the final design will be made from Flexible 80A as it won the design matrix is 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 interact with the catheter sliding through the model. Additionally, Flexible 80A balances ease of fabrication and compliance with the best of three materials. 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 a relatively flexible model. 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 anatomically accuracy.

5.2 Future Work

5.2a Fabrication Plans

This project will involve two main stages of fabrication. The first phase is translating the CTA imaging into STL files. Once the cardiac CTA is transferred into an STL file, it must then be sectioned and sliced into the four components. The four components are the jugular vein, top half of the heart, the bottom half of the heart, and the annulus. In addition to sectioning the heart components, clasps must be designed to secure the chambers of the heart together. The second phase of fabrication involves 3D printing the model on Formlabs 3D printer in the selected materials. Prior to printing the desired materials, the models will be printed in a less expensive material to ensure that the STL design has included the correct printing supports. This strategy will help eliminate the waste of costly materials and keep the project within the budget.

5.2b Testing Plans

Two main tests will be performed on the model. First, after a preliminary version of the design is printed with the correct materials, the client will use the model and assess how well the model compares to real-life procedures. The two main aspects of the design that will be assessed during this test are the surface finish and anatomical accuracy. During this test, the client will assess how well the catheter glides through the model and how well the key features of the heart are represented in the model.

The second test performed will evaluate the compliance of the annulus. In this test, multiple versions and sizes of the annulus will be printed in the correct material. Then, balloon catheters of various sizes will be placed in these and inflated to expand the annulus. The diameter of the annulus will be measured prior to inflation, while the balloon is in place and inflated, and after the balloon is deflated and removed. The goal of this test is to ensure that the annulus has a significant increase in diameter during balloon inflation and is able to return to its original shape after the balloon is removed. The measurements gathered in the test will be evaluated using a Student T-test.

6 Conclusion

PS is a congenital heart defect characterized by thickened or partially fused leaflets of the pulmonary valve that obstruct blood flow from the heart to the lungs. Balloon valvuloplasty is the preferred method of treating PS in canines leading to a high demand for veterinarians that are properly trained in this procedure. The University of Wisconsin Madison School of Veterinary Medicine has experienced a decreased caseload of patients with PS, thus reducing the number of opportunities for training and skills practice in transcather procedures. The goal of this project is to create a multidimensional imaging-based model of a canine heart with PS to allow veterinary students to practice balloon valvuloplasty procedures for PS. The proposed design for this project, the four piece 3D printed model, will provide accurate simulation experience of balloon valvuloplasty to treat PS with the use of materials that resemble native tissue, accurate patient-specific anatomy, and the opportunity to repeatedly practice their skills. The jugular vein and annulus will be 3D printed with Elastic 50A resin from Formlabs, a transparent and compliant material with a low coefficient of friction to prevent resistance when students practice inserting the catheter. The heart chambers will be 3D printed in two components to prevent additional 3D printed support material and to allow the addition of alternate annulus and valve leaflet designs in the future. The heart chambers will be 3D printed with Flexible 80A resin from Formlabs that will provide moderate compliance, transparency, and accurate appearance. This model will give students opportunities to learn the procedure on an anatomically accurate model and practice their skills for balloon valvuloplasty to treat PS. Future work for this project includes segmenting the CTA scan to create an STL of the patient's anatomy, modification of the 3D design to include attachment points for the heart chambers, material testing, and finally 3D printing and assembly.

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8 Appendix

8.1 Product Design Specification

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.
- Even though it is not a requirement, 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 30 uses per year. 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. On the shelf the model will last up to 5 years minimum.

Operating Environment: The model will be used in a laboratory or office environment for training and practice purposes. This environment will include a room temperature of 20-22 °C and a relative humidity between 30% and 50%. 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 may be incorporated into fluids so ensuring all materials are water tight and are compatible with fluids.

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, specific to the patient Popcorn a french bulldog.

Weight: The model will be an adequate weight to be transported by one person. The maximum weight of the model is 15 lbs to ensure easy transferability of the model between lab spaces and storage.

Materials: The heart model will be fabricated using a 3D printing filament. The platform for the heart to be secured will be fabricated from Delrin or a 3D printing filament. 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 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 [10]. 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 (0.17 MPa), max stress (1.5 MPa), and max strain (1.10) of natural cardiac tissue [11][12]. 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. The standard for fatigue limits for synthetic vascular is 400 million cycles [13]. The material used for the annulus and jugular vein is a flexible 50A resin from Formlabs and the material for the heart chambers is a flexible 80A resin from Formlabs.

Aesthetics, Appearance, and Finish: The model will be transparent or include windows in the model to allow the user to visualize the stent or 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 andy 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. 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 Bull Dogs, as this is the most common patient for these procedures.

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

Competition:

1. AATS 3-Dimensional Print Model [2]
    - Utilized original CT scans from patient to create a 3D model and converted to STL model.
    - Model printed on Object 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 than native heart anatomy creating a difficult model to utilize for simulation runs.
2. Canine Model for Patent Ductus Arteriosus Occultuion 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 hallow 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 onto 3D lateral and 2D ventrodorsal thoracic radiographs was also used to test the effectiveness of virtual overlays in enhancing cardiac education.
    - The 3D printed model and 3D digital model were perceived as significantly more helpful than the 2D radiograph. All students stated that these models provided a valuable learning opportunity.
    - These models show the value of using 3D printed heart models in veterinary medicine education. However, these models are for patent ductus arteriosus, not pulmonary stenosis. In addition, the models only displayed the region near the patent ductus arteriosus, not the full heart. This model was also not used for skills training.

4. A 3-D human model of complex cardiac arrhythmias [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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