BME Design

The Product Design Specifications (PDS)

Multidimensional imaging-based models for cardiovascular procedural skills training

Fall 2024 BME 400

September 19, 2024

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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.
- 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. 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.

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.

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.

Weight: The model will be an adequate weight to be transported by one person. The maximum weight of the model is 50 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 material will simulate native anatomy flexibility and must not be tacky to the user.

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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