Patient-specific pediatric silicone heart valve models based on 3D ultrasound

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ABSTRACT

PURPOSE: Patient-specific heart and valve models have shown promise as training and planning tools for heart surgery, but physically realistic valve models remain elusive. Available proprietary, simulation-focused heart valve models are generic adult mitral valves and do not allow for patient-specific modeling as may be needed for rare diseases such as congenitally abnormal valves. We propose creating silicone valve models from a 3D-printed plastic mold as a solution that can be adapted to any individual patient and heart valve at a fraction of the cost of direct 3D-printing using soft materials.

METHODS: Leaflets of a pediatric mitral valve, a tricuspid valve in a patient with hypoplastic left heart syndrome, and a complete atrioventricular canal valve were segmented from ultrasound images. A custom software was developed to automatically generate molds for each valve based on the segmentation. These molds were 3D-printed and used to make silicone valve models. The models were designed with cylindrical rims of different sizes surrounding the leaflets, to show the outline of the valve and add rigidity. Pediatric cardiac surgeons practiced suturing on the models and evaluated them for use as surgical planning and training tools.

RESULTS: Five out of six surgeons reported that the valve models would be very useful as training tools for cardiac surgery. In this first iteration of valve models, leaflets were felt to be unrealistically thick or stiff compared to real pediatric leaflets. A thin tube rim was preferred for valve flexibility.

CONCLUSION: The valve models were well received and considered to be valuable and accessible tools for heart valve surgery training. Further improvements will be made based on surgeons' feedback.

Keywords: surgery, training, heart valve models, pediatric, patient-specific, 3D-printing, congenital heart disease, mitral valve, tricuspid valve, complete atrioventricular canal defect, ultrasound

1. INTRODUCTION

Heart valve surgery is a difficult procedure, and it is considered best practice to train for surgery by assisting with procedures in the operating room and practicing surgical skills in laboratory[1]. Cardiac surgeons spend almost a decade learning surgery techniques through observation, but there is little opportunity to practice complex repairs, particularly in small children, because of the associated risk and expectation that the attending surgeon is performing these difficult procedures.

As such, across surgical disciplines there has been increasing interest and validation of using patient-specific simulation for training and to improve outcomes in complex cases[2,3]. When it is impossible to practice heart surgery in vivo, practicing on a phantom model can be useful for learning and improving on surgical skills. For example, practicing on a generic mitral valve model has been shown to improve accuracy in mitral valve surgery and shorten the procedure[4]. Although it is possible to purchase generic valve models of the most commonly studied adult heart valves, there are no generic models for pediatric sized valves or congenitally abnormal valves. Pediatric valve repair is gaining interest as an alternative to valve replacement, as valve replacement in children requires serial replacement and in some cases anticoagulation[5]. Valve surgery is also a major component of more complex cardiac repairs with significant room for improvement in outcomes. For example, approximately 30% of patients who undergo complete atrioventricular canal (CAVC) repair must undergo a second surgery for recurrent atrioventricular valve regurgitation[6]. There is no simple and accessible implementation for simulating rare and difficult repairs in pediatric patients or patients with congenital heart disease in a patient-specific manner.

Several studies have looked into direct 3D-printing with flexible materials as a means of physically modeling heart valves based on 3D ultrasound. So far, this has been done for two of the most commonly studied valves: the mitral valve and the aortic valve[7,8]. Although effective at replicating the shape of the valves, direct 3D-printing with “soft” materials has several limitations. This method requires access to 3D printers capable of printing directly with soft materials, which can be a limiting factor for hospitals and cardiac surgery training centers. Most importantly, currently available flexible materials for even very high-end printers result in models that are relatively stiff, brittle, and overall are not sufficiently realistic for suturing and realistic surgical simulation.

An accessible method for creating physical valve models will be valuable for both patient-specific simulation and batch manufacturing of valves for education and training. We propose creating realistic silicone models using 3D-printed molds as an inexpensive and accessible approach to fabrication of patient-specific, 3D-ultrasound-derived valves for surgical simulation.

2. METHODS

Patient-specific heart anatomy was acquired from ultrasound images. The valve of interest was manually segmented and a 3D surface representation of the valve was created. A rim, skirt, and orientation markers were added to the valve representation and a mold was created as the inverse of the valve. This process was used to design molds for a mitral, a tricuspid, and a CAVC valve. The molds were used to create several silicone model copies of each valve. Pediatric cardiac surgeons practiced suturing on the silicone valve models and completed a questionnaire to assess their resemblance to real valves and their use as surgical training or planning tools. IRB approval was obtained for this study.

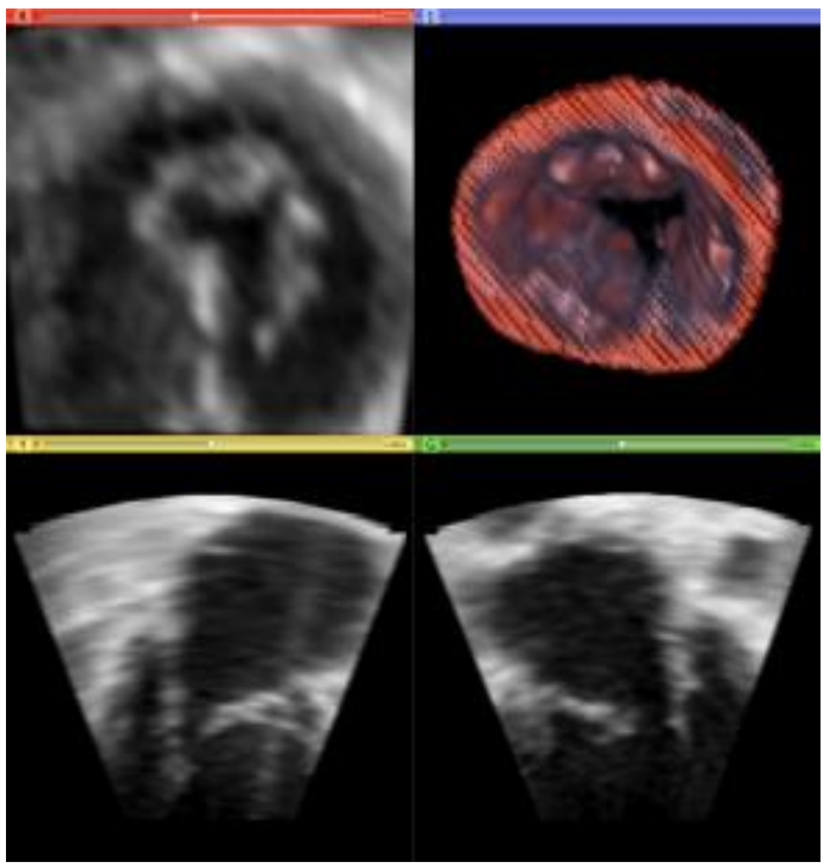

Figure 1. Volume rendering of a pediatric heart (case B) with axial, sagittal and coronal slice views. The annulus contour of the valve was determined from 2D slices taken from the ultrasound volume.

2.1 Imaging

Image acquisition was performed on a Philips IE33 utilizing transthoracic X5 and X7 probes (Philips Medical, Andover, MA) from apical position in clinic patients or the operating room. Full volume gated and 3D zoom acquisitions were obtained for A) a mitral valve in a 15-year-old patient, B) a tricuspid valve in a 4-year-old patient with hypoplastic left heart syndrome (HLHS) and C) a CAVC valve in a 3.3-month-old patient. Segmentations were performed in mid-systole phase. IRB approval for the study was obtained at the Children’s Hospital of Philadelphia.

2.2 Segmentation

An outline of the annulus contour was created by selecting evenly spaced points along the rim of the valve from 2D ultrasound slices extracted from the ultrasound volume. This annulus contour was used to create a cropping volume for volume rendering (Figure 1) and for creating a mask for segmentation.

Next, thresholding was applied to the image and a spherical 3D brush was used to segment the valve leaflets using a different color for each leaflet (Figure 2). The leaflets were manually thinned to about 1.0 mm thickness to mimic the thickness of pediatric valves, as suggested by surgeons. The surface of the leaflets was smoothed by convolution with a Gaussian kernel with a standard deviation of 3.0 mm. A 3D surface was created from the leaflet segmentation (Figure 3).

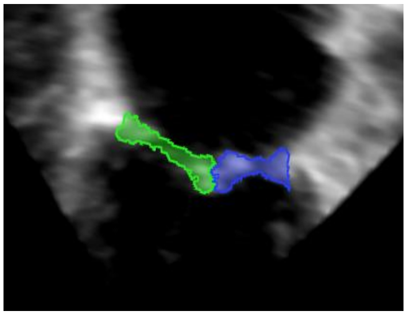

Figure 2. Segmentation of leaflets based on ultrasound image (case B).

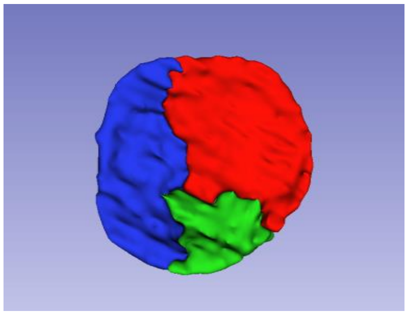

Figure 3. Smoothed 3D surface created from leaflet segmentation (case B).

2.3 Mold design

Several structures were added automatically to the valve model surrounding the 3D representation of the leaflets. A cylindrical rim was added around the valve model following the annulus contour to mark the outline of the valve and provide stiffness to the model. A flat skirt was created around the valve for holding the valve in commercially available simulated valve holders. Orientation markers “R” and “S” were manually drawn onto the skirt, representing the right and superior anatomical directions (Figure 4).

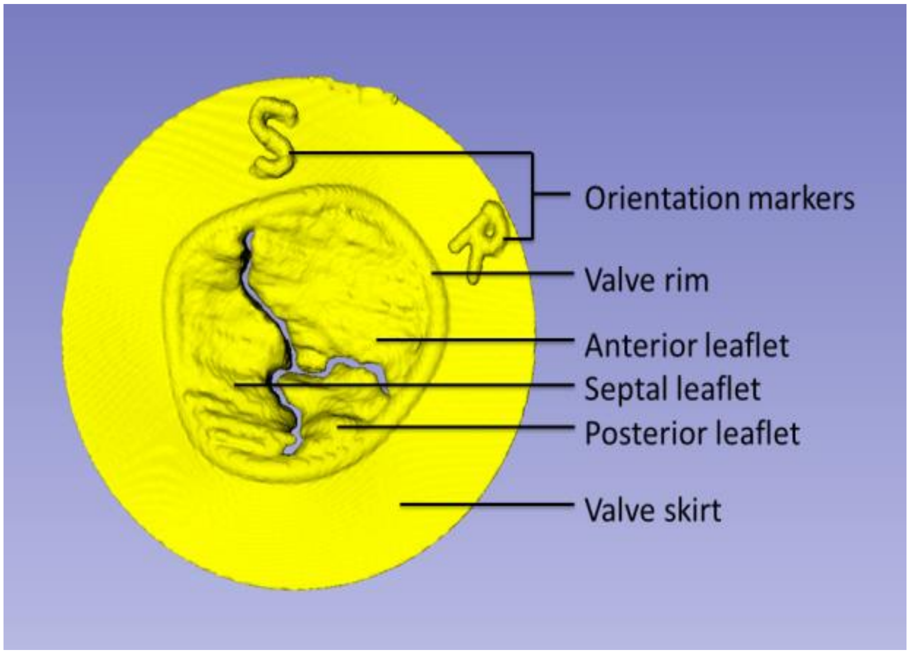

Figure 4. Valve model of a tricuspid valve (case B). A mold is created from the inverse of this model.

Top and bottom mold models were created as the inverse of the valve model (Figure 5). Tunnels with a radius of 1 mm were manually drawn in the top mold along the rim and skirt to allow air bubbles to escape when closing the filled mold. Air tunnels were not added inside the valve as this could affect the shape of the leaflets. The two mold pieces were printed of ABS plastic using a Dimension 3D printer (Stratasys, Eden Prairie, MN) with a layer thickness of 0.254 mm (Figure 6).

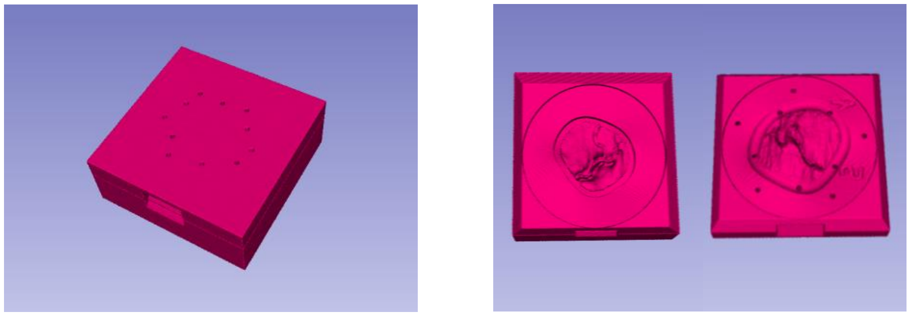

Figure 5. 3D mold model for a tricuspid valve (case B) viewed in 3D Slicer: assembled (left), and disassembled (right).

Figure 6. 3D-printed mold for a tricuspid valve (case B): assembled (left), and disassembled (right).

2.4 Silicone valve creation and evaluation

Silicone valve samples with five different degrees of firmness were made using varying amounts of softener additive. These were sent to pediatric surgeons for evaluation, allowing the surgeons to choose the material that felt most lifelike and practical for practicing suturing. Once the preferred firmness was selected (2 parts Dragon Skin® Part A, 2 parts Dragon Skin® Part B, 1 part Slacker® tactile mutator, 1 drop Silc Pig® flesh tone silicone pigment), a mold was created for each of the tricuspid, mitral and CAVC valves (Smooth On, Inc., Macungie, PA, USA).

Figure 7. Silicone valves in order from left to right: tricuspid, CAVC, mitral.

The molds were used to create silicone heart valve models (Figure 7). After waiting 75 minutes for the silicone to set, the valves were removed from the molds and any extra silicone was trimmed. A commercial valve holder (Adjustable Mitral Valve Base, LifeLike BioTissue, London, Canada) was used to hold the valves in place.

For simulating repair of a CAVC, a ventricular septal model was positioned below the valve. The septal model is a thin flat silicone model that will be pulled up and sutured to the CAVC valve to simulate separating the left and right chambers of the heart during CAVC repair. A separate holder for the ventricular septum model was designed in SolidWorks 2015 SP03 (Dassault Systèmes SOLIDWORKS Corp., Waltham, MA, USA) and 3D-printed to position the ventricular septum model below the CAVC valve (Figure 8).

Figure 8. Setup for CAVC repair simulation: a CAVC valve model is secured at the top of the valve holder. A silicone ventricular septal model is secured below the valve with a separate 3D-printed holder.

Six pediatric cardiac surgeons (three attending surgeons and three fellows) practiced suturing on these valves and answered a questionnaire for evaluation of the valves' fidelity and usefulness in training and surgery planning.

2.5 Software implementation

3D Slicer is a free open source software for visualization and medical image analysis[9]. We have developed custom modules for 3D Slicer for importing 4D ultrasound sequences and valve visualization (they are already in the publicly available, open-source SlicerHeart extension), segmentation, advanced visualization, valve annulus and leaflet quantification, and automated valve model design (these modules are going to be publicly released in the near future).

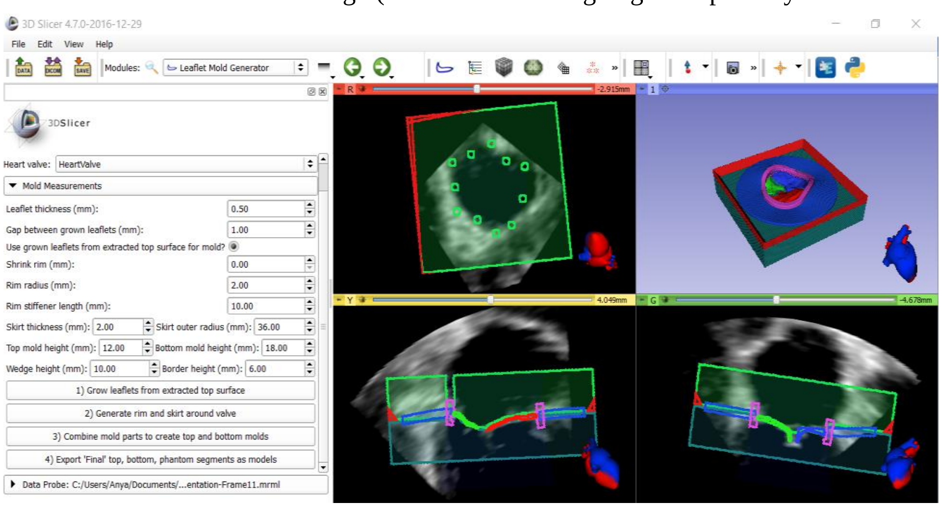

Figure 10. Screenshot of the Leaflet Mold Generator module in SlicerHeart used to create top and bottom mold pieces.

3. RESULTS AND DISCUSSION

3.1 Valve use, valve material, and resemblance to human heart valves

All six surgeons considered the models to be useful for training for cardiac surgery and practicing difficult cardiac surgery cases (Table 1). They found the silicone material cuts and holds sutures well, but may be more rigid than real leaflets (Figure 9). A thin annulus rim with a 2 mm radius was preferred over a rim with 3 mm radius, as it shows the outline of the valve while giving more flexibility to the model than thicker rims. Alternatively, one surgeon suggested that it may be more realistic to include no rim at all.

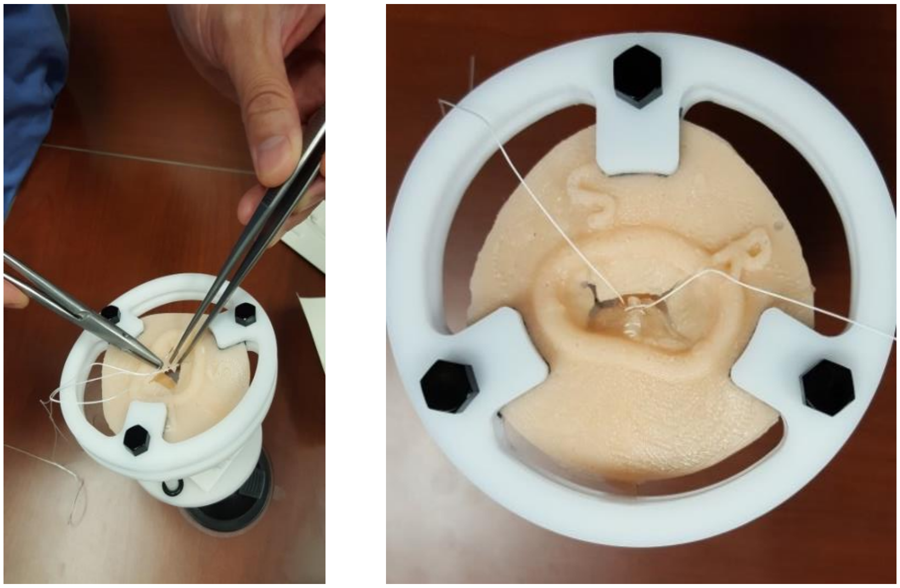

Figure 9. A surgeon practices suturing techniques on a valve model. Chosen silicone material holds sutures well.

Mimicking the appearance and feel of real heart valves creates a more realistic tool for valve repair training. Choosing a soft and durable material is important for valve models to imitate human heart tissue. Dragon Skin® silicone used for this study is a good material for valve creation because it is easy to use, does not tear easily, and is well suited for practicing suturing. The silicone's flexibility can be manipulated by adjusting levels of softening additive, allowing us to achieve desired softness in the valve models.

Table 1. Results from questionnaire filled out by six pediatric cardiac surgeons evaluating the silicone valve models.

	Very unrealistic / Not at all useful	Somewhat unrealistic / Not very useful	Neutral	Somewhat realistic / Somewhat useful	Very realistic / Very useful
VALVE MODEL					
Upon visual inspection, how realistic is the heart valve?	0	0	0	5	1
Is the thickness of the leaflets realistic?	0	3	2	1	0
How realistic is the rigidity of the leaflets?	0	0	2	3	1
Is the annular rim model realistic?	0	0	0	5	1
VALVE MATERIAL					
Is suturing the material realistic?	0	0	1	4	0
How realistic is cutting the material?	0	0	2	3	1
VALVE USABILITY					
Will the model be useful for practicing for difficult cases?	0	0	0	3	3
Will the model serve as a useful training tool for trainees?	0	0	0	1	5

3.2 Leaflet thickness

Surgeons noted that that the valve leaflets appear thicker than what they subjectively considered realistic, despite the leaflets having already been made to be thinner than they appear in the ultrasound image. This may be due to limitations of ultrasound imaging, as thin structures may appear thicker on ultrasound due to finite axial resolution, lateral beam width and reverberation artifacts and may depend on gain settings[10]. Since valve thickness may be affected by valve disease, it will be important to find a more accurate way of measuring true valve thickness.

3.2 Time and cost for valve fabrication

The process of creating a physical valve model using this method takes one to two days. The most time-consuming step of the process is the manual segmentation of the leaflets. Manually segmenting the leaflets from the ultrasound took two to six hours per valve, depending on the size of the valve. Better segmentation tools will reduce the time required to segment these very thin leaflets, and fully automatic segmentation of adult mitral heart valves has been demonstrated[11]. After leaflet segmentation, SlicerHeart software was used to create mold components which needed to be manually edited to conform to the shape of the valve model (Figure 12). Editing the molds took one to two hours per valve. We are currently working to automate the separation of the mold parts and all manual steps after leaflet segmentation in our software module, which will eliminate time spent editing the mold. Once the mold model was 3D-printed, preparing the silicone mixture, filling the mold and allowing the silicone to cure all took less two hours, with only fifteen minutes of hands-on time.

The material cost for the 8cm x 8cm x 3cm molds cost $50-100 (US) per mold, and cost of silicone material required for each valve was less than a dollar. The commercial Mitral Valve Base holder purchased from LifeLike BioTissue cost $100 (US).

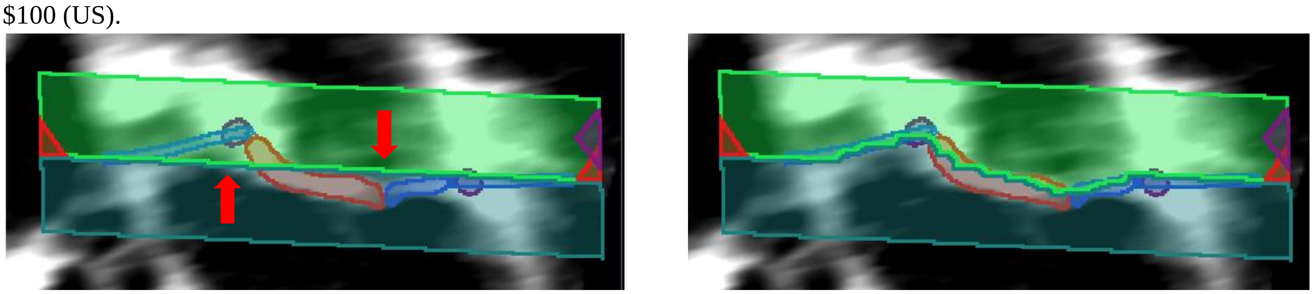

Figure 12. Top and bottom mold models pictured in SlicerHeart before (left) and after (right) manual editing to fit the shape of the valve model. Automating mold separation will reduce mold creation time.

This process of creating heart valve models based on a patient's ultrasound will allow surgeons to quickly create physical valve models to prepare for upcoming surgeries. Using these models, the surgeon can practice several different approaches for the surgery before operating on a live patient, which may be especially useful for rare or difficult cases. The low cost of making valve models using 3D-printed molds makes these tools accessible to most pediatric cardiac centers.

4. CONCLUSION

Silicone valve models created from 3D-printed molds were well-received by pediatric cardiac surgeons. All surgeons expressed that these models will be a useful tool for pediatric cardiac surgery training and may also be beneficial for planning difficult surgeries. Creating silicone valve models from 3D-printed molds shows promise as an easy and accessible method for creating patient-specific valve models. Feedback from this study will be used to improve the valve models so the described method can start being used in an educational setting.

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