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PATIENT-SPECIFIC THREE-DIMENSIONAL COMPUTATIONAL HEART MODELING AND PRINTING TO ENHANCE CLINICAL UNDERSTANDINGS AND TREATMENT PLANNING: CONGENITAL RECURRENT PULMONARY ARTERY STENOSIS AND TRANSCATHETER PULMONARY VALVE REPLACEMENT

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ABSTRACT

Advances in the surgical and interventional management of children with congenital heart disease has improved survival and outcomes. Each such patient is born with specific anatomical variations which call for detailed evaluations so to plan for appropriate patient-specific management. Significant progress has been made in commercially available two-dimensional imaging – i.e. echocardiogram, CT, and MRI – yet using such, three-dimensional anatomical details can be difficult to accurately represent. In addressing this concern, it has been shown that patient-specific three-dimensional modeling can be useful for interventional procedural or surgical planning [1]. Here we present two cases for which patient-specific anatomical three-dimensional modeling and printing were utilized for (1) the pre-sizing and placement of stents within a complex bifurcation pulmonary artery stenosis; and (2) evaluating the candidacy of the patient's anatomy for a transcatheter pulmonary valve placement. Detailed within this technical brief are de-identified case information, workflows for model generations, and results regarding clinical usage. In conclusion, we found these patient-specific models to be an advantageous resource for treatment planning in these two pediatric congenital heart disease cases.

Keywords: 3D printing, patient-specific 3D modeling, congenital heart disease (CHD), pediatrics, pulmonary artery stenosis, TPVR, tetralogy of Fallot (TOF)

NOMENCLATURE

3D	three-dimensional
CHD	congenital heart disease/defect
DICOM	digital imaging and communications in medicine
PLA	polylactic acid
CT	computed tomography
PA	pulmonary artery
PV	pulmonary valve
RVOT	right ventricular outflow tract
TOF	tetralogy of Fallot
TPVR	transcatheter pulmonary valve replacement
SVC	superior vena cava
RV	right ventricle
LV	left ventricle
Ao	aorta

1. INTRODUCTION

Annually in the United States, around 40,000 live births are affected by congenital heart disease (CHD) [2]. Around 10,000 of these newborns may require interventions within their first year of life for continued survival or to ensure enhanced quality of life. In addition to this subset of newborns, children with CHD may need additional interventions throughout their lives. This

means that annual numbers of corrective procedures for pediatric CHD in the United States easily surpasses 10,000. These congenital anatomies are complex and vary significantly from one patient to another. For this reason, precision medicine in the form of patient-specific three-dimensional (3D) modeling has been shown to be particularly useful for understanding the complex associated anatomies and informing treatment options, as well as providing valuable resources for both patient/family and trainee education [1]. Here we present two unique cases for which patient-specific computational 3D anatomical models and prints were utilized, as well we discuss their similarities and differences in both usages and utilities.

2. MATERIALS AND METHODS

For both cases discussed, clinical diagnostic images (pre-procedural CT scans in DICOM format) were imported into Materialise Mimics® software, through which the areas of interest in each case were segmented through Hounsfield-unit thresholding for the creation and analyses of multiple masks. These masks were then further refined and segmented by hand to create the best representative 3D models. Once appropriately segmented anatomical 3D reconstructions were created in Mimics®, they were imported into Materialise 3-matic®. This program was then used to further smooth and optimize the models; subsequent 3D meshes were reduced in size to allow for both better 3D printing and end-user visualizations. From here, models were then printed at 100% scale using an Ultimaker© 3 Extended as well as a Stratasys© J750 digital anatomy printer.

2.1 PA Stenosis Case

In the first clinical case, a patient-specific 3D print was made for an 18-year-old female who was born with truncus arteriosus type-I and had undergone her initial surgery as an infant, with placement of a right ventricular-to-pulmonary arterial confluence conduit. Throughout her lifetime, this patient continued to experience both recurrent conduit and branch pulmonary arteries stenoses, even after multiple surgical and interventional procedures. For this reason, a 3D model was requested to clarify the anatomy and plan for transcatheter interventions. Additionally, we intended to use the model to facilitate patient/family's counseling.

The resultant 3D models were for the patient's right ventricular outflow tract (RVOT) conduit and branch pulmonary arteries (PA). These models were created from the blood volumes in the areas of interest, as opposed to tissue models created from direct tissue segmentation. An additional model was also created, which contained models of the stents already present within the PA branches of the patient prior to her upcoming procedure. Three final prints were created from these models, shown in Figure 1: a 1mm shell model printed using polylactic acid (PLA) filament on the Ultimaker© 3 Extended printer, a 1mm shell model of flexible plastic printed by Stratasys©, and a translucent solid model with embedded stent models (oriented as shown from patient scans) also printed by Stratasys©.

FIGURE 1: 3D PRINTED MODELS FOR PA STENOSIS CASE. (A) HOLLOW PLA, (B) HOLLOW FLEXIBLE PLASTIC, (C) SOLID FIRM PLASTIC WITH EMBEDDED STENT MODELS.

2.2 Candidacy for Transcatheter Pulmonary Valve Replacement (TPVR)

In the second cardiac case, a patient-specific 3D-printed model was generated for the heart of an eight-year-old girl who had been diagnosed with tetralogy of Fallot (TOF), whose initial surgical repair required the use of a transannular patch. However, the patient subsequently developed pulmonary valve insufficiency and right ventricular enlargement; hence she was referred for TPVR. In order to better evaluate the patient's appropriateness for TPVR, a hollow 3D print of the patient's cardiac anatomy was requested. Uniquely in this case, it was especially important to be able to evaluate whether valve implantation would cause compression on the left anterior descending (LAD) coronary artery, as this is a major cause for concern in regards to pursuing this treatment strategy for such a patient.

To address these concerns, three prints were generated, all detailing various aspects of this patient's whole heart: 1) a solid blood volume model, 2) a hollow 2mm shell model of the blood volume, and 3) a hollow tissue model. The resultant 3-matic® models are presented in Figure 2. The tissue model was adjusted such that the thinnest wall was at least 2mm, to ensure structural integrity of the print. Note, this model was still considered to be anatomically relevant, since this did not affect the main area of interest (pulmonary valve annulus and coronary arteries). The solid model was printed using PLA filament with an Ultimaker© 3 Extended printer, while both hollow models were printed using a Stratasys© J750 digital anatomy printer to best emulate the native anatomical environment for potential valve deployment.

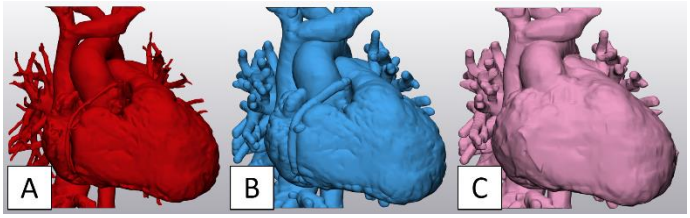

FIGURE 2: 3D MODELS FOR TPVR CANDIDATE. (A) SOLID BLOOD VOLUME, (B) 2MM EXTERNALLY SHELLED BLOOD VOLUME, (C) TISSUE MODEL WITH MINIMUM 2MM THICKNESS.

3. RESULTS AND DISCUSSION

It was recognized that in both clinical cases pre-procedural planning was aided by patient-specific 3D models, but for differing purposes. In the PA stenosis case, the model was

desired for: 1) understanding the complexities of the pulmonary artery anatomy; 2) interventional planning such as balloon and stent sizing; and 3) patient/family counseling. For the TPVR candidate, the model was desired for: 1) better understanding of the patient's anatomies, and 2) practicing deployments in a physical model for visualizing the potential impacts of the implanted valve on adjacent structures, especially the coronary arteries. For these varying purposes between clinical needs, varying models were created – illustrating the range in applicability for patient-specific 3D modeling and printing.

3.1: PA Stenosis Model and Outcomes

For the PA stenosis case, a 3D printed whole heart model was not considered as needed, for the only procedurally relevant anatomical structures were the RVOT and PA. Thus, the model and resultant prints were only for these structures. As such, the model was printed at 100% scale for each print shown in Figure 1: i.e., in order to best understand the relative sizing of these structures and visualize the stents already within the PA.

It should be noted that the final model for this stenosis case had a minor error in comparison to the patient actual anatomy: the stent model was printed to be completely embedded in the surrounding shelled blood volume model, when in actuality there was a portion of extravascular stent material near the left pulmonary artery ostium, which also caused this area to be occluded. This occlusion can be seen in Figure 3. This points out that such complex anatomies require both anatomical expertise and extensive manual segmentation: hence, close interactions between the clinician and the individuals working on the computation segmentations are needed.

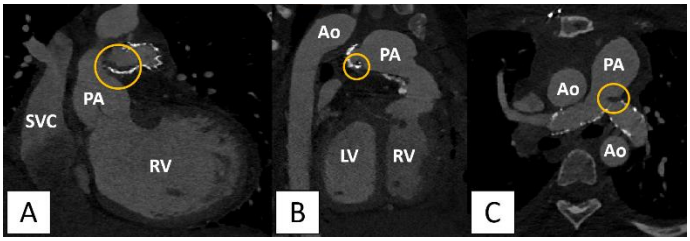

FIGURE 3: (A) CORONAL, (B) SAGITTAL, AND (C) AXIAL VIEWS FROM THE PATIENT CT SCAN, ILLUSTRATING EXTRAVASCULAR STENT MATERIAL AND RESULTANT VESSEL OCCLUSION.

Despite this known small error, the resultant models were considered very useful for the clinical care team. The initial utilities of these models were for gaining better understandings of this patient's unique cardiac anatomy for planning the bifurcation stents to use for treatment. In addition, these models were especially useful in discussing the diagnosis and treatment options with the patient/family, who were then given the models to keep after the procedure. The procedure itself was successful by way of a demonstrated immediate increase in blood flow through the occluded area (with a resultant decrease in right ventricular pressure) and patient-noted resolution of symptoms and improved exertional capacity. The imaging, 3D-printed models, and associated clinical information will also be useful as educational resources [3,4].

When considering continuing these modeling protocol for future cases, we the authors also note that it is critical to maintain ongoing dialogue between the engineering and clinical care teams to ensure needed qualities, accuracies, and ultimate usefulness of generated patient-specific 3D models.

3.2: TPVR Candidate Model and Anticipated Outcomes

As stated previously, the main purposes for the generated models for this clinical case were twofold: 1) to examine the RVOT for sizing of the stented valve to be deployed, and 2) to evaluate the potential interactions between the proposed prosthesis and associated anatomical structures, especially the aortic root and the coronary arteries. For these reasons, three distinct whole heart models were created. Although the specific areas of interest were primarily the PV annulus and the LAD and right coronary arteries, a whole heart model was desired in order to best simulate the environment in which the valve was to be deployed. Thus, a solid blood volume model was created in order to show the blood flow paths through the heart, as well as the relative locations of and distances between the areas of interest. This model also served as the basis to generate and hollow out the other two models and ensure that they properly emulated the interior areas of this patient's heart.

Similarly, as described above, a 2mm shell model was created from this original blood volume model, and it was utilized for easier visualizations of the altered anatomies after the valve deployment. Because these prior models do not entirely emulate the actual anatomies of the patient, especially when considering local connective tissues between vessels, a third model and print were generated. This third model was created through segmentations of the cardiovascular tissues themselves from the CT scans. This model was adjusted such that the minimum outer wall thickness was 4 pixels, or about 2mm, again to improve structural integrity of the print itself – thus, this model is referred to as a "hybrid" tissue model. Note, this change did not cause narrowing or occlusion of any area, as this shelling technique does not impact interior surfaces. A comparison of masks from each model, as shown in the Materialise Mimics® models, can be seen in Figure 4. Of note is the separation between vessels, in the 2mm shelled blood volume model (shown in blue) and the full encapsulation of vessels within the tissue model (shown in pink).

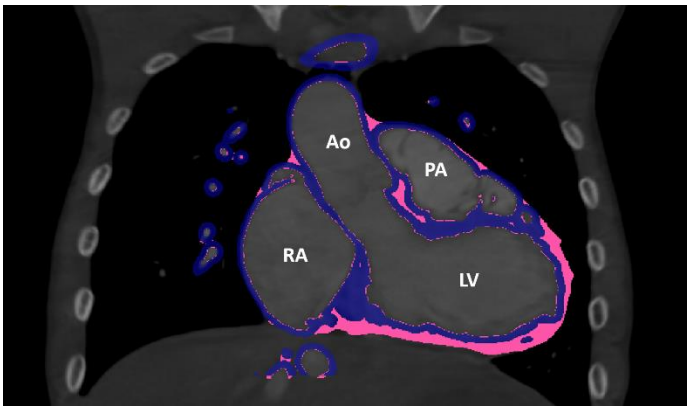

FIGURE 4: COMPARISON OF MASKS OF SHELLED BLOOD VOLUME MODEL AND HYBRID TISSUE MODEL. BLUE INDICATES 2MM SHELL MODEL AND PINK INDICATES HYBRID TISSUE MODEL.

In subsequent studies, these prints will be compared to assess potential differences in outcomes from valve deployments. The results from such assessments will then be used to analyze model generations and printing for future cases: i.e., when deciding the necessity of an exact tissue model in comparison to a shelled blood volume model for physiological relevance.

4. CONCLUSION

Patient-specific 3D anatomical models can serve multiple, varying purposes for different clinical case presentations, particularly in pediatric congenital heart disease. Additionally, there is significant value in utilizing patient-specific 3D models to aid in patient-doctor communications, for which our group has first-hand experiences. We will continue to strive for advancing the utilities of and applications for patient-specific 3D models in pediatric congenital heart disease diagnoses, treatments, communications, and education.

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