Journal of Cardiothoracic and Vascular Anesthesia ▮ (▮▮▮▮) ▮▮▮–▮▮▮

Contents lists available at ScienceDirect

ScienceDirect

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Emerging Technology Review

Modeling Patient-Specific Deformable Mitral Valves

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Medical imaging has advanced enormously over the last few decades, revolutionizing patient diagnostics and care. At the same time, additive manufacturing has emerged as a means of reproducing physical shapes and models previously not possible. In combination, they have given rise to 3-dimensional (3D) modeling, an entirely new technology for physicians. In an era in which 3D imaging has become a standard for aiding in the diagnosis and treatment of cardiac disease, this visualization now can be taken further by bringing the patient's anatomy into physical reality as a model. The authors describe the generalized process of creating a model of cardiac anatomy from patient images and their experience creating patient-specific dynamic mitral valve models. This involves a combination of image processing software and 3D printing technology. In this article, the complexity of 3D modeling is described and the decision-making process for cardiac anesthesiologists is summarized. The management of cardiac disease has been altered with the emergence of 3D echocardiography, and 3D modeling represents the next paradigm shift.

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Key Words: mitral valve; cardiovascular models; 3-dimensional printing; transesophageal echocardiography

THE NUMBER OF mitral valve (MV) repair interventions, both surgical and catheter-based, is rapidly growing, improving patient outcomes and providing patient-specific care. Similar to many medical fields, cardiac teams are turning to 3-dimensional (3D) modeling as a planning and training tool to deliver the best standard of care. The development of 3D modeling is a result of advances in both additive manufacturing, better known as 3D printing, and cardiac imaging technologies, particularly transesophageal echocardiography (TEE). Physical models of cardiac anatomy have been used in a wide variety of applications, from sizing replacement valve stents to assessing postintervention hemodynamics to training. However, modeling the heart is a particularly arduous task, as are cardiac interventions, and the difficulty in both processes can be attributed to the heart's dynamic morphology and behavior.

There are a number of characteristics a model of cardiac anatomy must accommodate, including the following: complex patient pathologies; tissue properties; and in the case of dynamic models, flexibility of material and accurate hemodynamics. Even though dynamic models are not always necessary, MV pathologies are best understood and identified in a dynamic environment. MV regurgitation, the most standard measure of MV competency, can only be measured in a realistic hemodynamic environment, using models with sufficiently accurate tissue-mimicking properties. This poses a

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Funding for this work was provided by a Canadian Institutes for Health Research foundation grant (#143232) and a Canadian Foundation for Innovation grant (#33487).

D. Bainbridge, J. Moore, and T. Peters own shares in Archetype Medical, London, Ontario, Canada, which manufactures a flow pump for testing valve models.

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http://dx.doi.org/10.1053/j.jvca.2017.09.005
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substantial challenge for standard additive manufacturing technologies because most 3D printers only work with rigid or only partially flexible materials. Furthermore, even printers capable of using flexible materials cannot match the tissue strength and echogenicity of the MV.

Despite these limitations, additive manufacturing still can be used as part of a workflow to create patient-specific, dynamic deformable mitral valve models (DMVMs) to enable cardiac teams to understand patient-specific anatomy and better plan interventions. Patient-specific models, integrated into a suitable flow pump, then can form the basis for both training clinicians, planning of particularly complex or novel MV interventions, and assessing repair and replacement options.

Patient-specific DMVMs can be integrated into the existing standard of care for patients with complex mitral pathology. The clinical workflow can be straightforward and relatively inexpensive:

- 2D and 3D TEE images are acquired from the patient, who could have a particularly complex pathology or who may be a candidate for a catheter-based device.
- Images are processed to create a mathematical model that is readable by an inexpensive 3D printer.
- A negative-molding technique is used to form an accurate yet flexible model of the patient's valve.
- This model then is integrated into an appropriate hemodynamic model (pulse duplicator) to permit MV motion.
- The cardiac team then can use the model as a planning tool to simulate intervention and potentially as a learning opportunity for trainees.
- The course of treatment for the patient would proceed using insights gained from simulated interventions.

The process of replicating a model, or multiple models, takes no more than 1 week from acquiring the diagnostic TEE data.

In this article, the authors discuss the general process of creating dynamic models and provide an overview of the methodology for producing patient-specific DMVMs as an example of the modeling process.

General Template for Cardiac Modeling

Image Collection and Processing

Figure 1 describes an overview of the full workflow for creating DMVMs. Ideally, patient-specific DMVMs should fit into existing standard of care practice as much as possible. In most cases, diagnostic TEE data are collected from patients considered for MV interventions. TEE provides excellent enface imaging for MV morphology and regurgitation. However, despite its strengths, TEE does have some limitations including visualization of subvalvular anatomy in the case of MVs and difficulty imaging objects that lie parallel to the direction of the ultrasound beam (signal dropout), such as the leaflets during diastole. Other imaging options such as computed tomography and cardiac magnetic resonance exist for generating 3D models but typically are not part of the standard of care workflow. Cardiac magnetic resonance is least frequently incorporated into the standard of care due its expense and breath-hold demand and therefore is not easy to use.

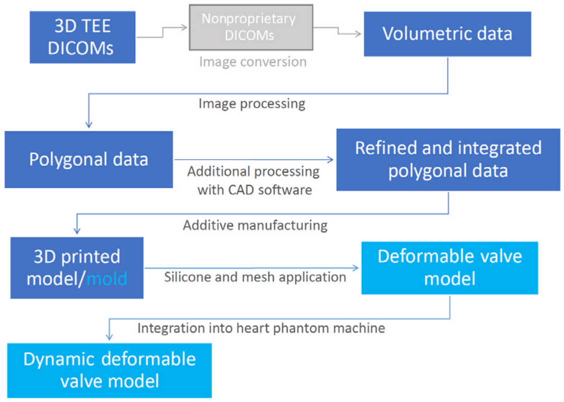

Fig 1. General workflow chart for creating deformable mitral valve models. CAD, computer assisted design; DICOM, digital imaging and communications in medicine; TEE, transesophageal echocardiography.

Volumetric image data exported from a TEE machine typically are in a DICOM format, which involves the organization of many voxels (3D pixels) assigned a specific gray scale value to create an image of the patient's anatomy. Depending on the TEE manufacturer, sometimes it is necessary to convert the TEE DICOM files from a closed proprietary format to an open, nonproprietary format (such as Cartesian DICOM). In this case, the TEE machine company must provide the appropriate software for the conversion.

Before creating a 3D printed model, it is necessary to define the actual tissue boundary and shape to be printed. This entails using software to create a polygonal mesh (usually consisting of connected triangles) that defines the tissue boundary—a process called "image segmentation." Segmentation software ranges from manual to fully automatic, and the algorithms on which it is based vary widely depending on the application. There are many open source segmentation software programs available (eg, 3D Slicer [https://www.slicer.org/] and ITK Snap [http://www.itksnap.org/pmwiki/pmwiki.php]). Regardless of which application is used, the software must be able to import the TEE volumetric data, identify the desired anatomy (usually involving some degree of user input), and then output the "polydata," typically in the standard tessellation language file format that is most commonly used by 3D printers.

After the segmentation process isolates and converts the relevant image data, additional processing may be used to further refine the model of the patient's anatomy. For most basic segmentation algorithms, 3D TEE imaging generates irregular surfaces due to its inherent image quality, and depending on the application the clinician intends for the model, this might have a negative effect on the model's use and therefore may require additional processing. Beyond this, the segmented MV must be adapted for integration into a flow pump. Several commercial devices are available for assessment of replacement valves, but modeling the subvalvular

Please cite this article as: Ginty O, et al. (2017), http://dx.doi.org/10.1053/j.jvca.2017.09.005

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