Editorial Comment

Three-Dimensional Printing and the Auricle: Predicting Future Events?

Stephen H. Little, MD, and Muhamed Saric, MD, *Houston, Texas; and New York, New York*

It is now well established that occlusion of the left atrial appendage (LAA) in appropriate patients with chronic atrial fibrillation is an effective method to reduce stroke risk. However, the LAA, or more historically the auricle, is an anatomic curiosity that is so notoriously patient specific in its size and geometry that either computed tomography (CT) or transesophageal echocardiography (TEE) must be used to characterize its dimensions and anatomic shape prior to LAA occluder implantation.

During LAA device implantation the correct size device must be chosen and then tested to ensure effectiveness and safety. This device performance checklist is often referred to as the PASS criteria, referring to the device position, anchor, size, and seal. If the implanted device fails the PASS criteria then it must be repositioned, or removed and replaced, an outcome that is associated with increased procedure time, expense, and patient risk. As preprocedural imaging improves, and as digital and physical modeling continue to rapidly develop, perhaps now it is time to revisit this procedural strategy.

Over the last decade there have been seismic advances within the highly technical field of three-dimensional (3D) printing. Within cardiovascular medicine alone, 3D printing has increasingly been applied to create teaching models, to recreate valve pathology and dysfunction, to plan complex surgical interventions, and most recently to evaluate proposed device performance following catheter-based intracardiac interventions.[1] The principal attraction of 3D printed modeling is that the anatomy replicated is entirely patient specific, allowing procedures to be practiced, and wherever possible perfected, with little added cost and no additional patient risk.

Cardiac 3D printing can be performed based on any electrocardiogram-gated volumetric data set of high quality. Magnetic resonance imaging, CT, and 3D echocardiographic data have all been used to create specific cardiac models.[2] The main steps to create a model include the following: (1) select the cardiac cycle phase, (2) export the DICOM image data to a segmentation software package, (3) segment the large-volume data down to a region of anatomic interest, (4) convert the digital model into a file format compatible with 3D printers (typically.STL), and (5) select the 3D print materials to replicate the desired mechanical properties (and colors) for the model. Early-generation models were often created from a single rigid material; however, 3D printers today can blend together multiple materials (in any color) with different physical properties (e.g., hard, soft, elastic, rigid), with resolution to <1 mm.[2] However, the quality of anatomic replication is limited by the resolution of the imaging modality used and by our limited knowledge of the in vivo material properties of normal and pathologic cardiac tissues.

In this issue of the journal, Fan and colleagues describe a unique study.[3] In a population of patients undergoing LAA occluder therapy (Watchman device, Boston Scientific, Marlborough, MA), they compared a collection of clinical and echocardiographic outcomes based on whether a 3D printed model had been used for device sizing prior to the procedure. They describe two importantly different patient populations. In the first population ($n = 72$), 3D printed models of the LAA were created from 3D TEE images acquired prior to the LAA occlusion procedure. These models were used for benchtop implantation and sizing of occluders and compared in a retrospective but blinded fashion to the clinical occluder outcomes. In the second population ($n = 32$), the device selection was prospectively guided by the use of such 3D printed models. The impact of the strategy of choosing a device size based on patient-specific physical models was evaluated by comparing the clinical and echocardiographic outcome between these two patient cohorts. The authors introduce the concept of device size match (or mismatch) based on the performance of the device subjected to the PASS criteria after implantation within the patient-specific LAA model. Across both study populations, all patients with model-match device sizing achieved implant success without the need for resizing. In contrast, patients with model-mismatch sizing experienced longer procedure time, more deployment attempts, device resizing, implant failures, and more procedure-related complications. The study authors report that for patients undergoing LAA occlusion, a strategy of device size selection made in agreement with 3D-printed model-based sizing is associated with reduced procedure time, greater safety, and improved overall efficacy of the procedure. They conclude that preprocedural device sizing with the use of patient-specific 3D models in addition to intraprocedural imaging guidance may lead to superior clinical outcomes.

This application of preprocedure volumetric imaging data for the prediction of interventional outcomes is novel and demonstrates important advances. The term “patient-specific modeling” is often used when discussing 3D print replication of anatomy. But depending on the intended application for the model, the degree of patient specificity that is actually replicated may or may not be important. In this study by Fan *et al.*, the internal anatomic geometry of the LAA is patient specific since the internal volume and all cross-sectional dimensions are usually very well defined by either volumetric echo or CT methods. However, the wall thickness of the LAA was standardized at 1 mm for all patients. Likewise, the 3D print material used to create the models was consistent for all patients and was chosen to represent a reasonable (but not patient specific) replication of LAA wall tissue mechanical properties. This effort to replicate the mechanical property of cardiac tissue is one of the key developments that separates digital image models from physical models.

For digital-only models there is currently no commercially available software that will simulate deformation of the implanted device by the constraining tissue nor the deformation of the tissue by an expanding device. This lack of bidirectional deformation modeling is

From the Houston Methodist DeBakey Heart and Vascular Center, Weill Cornell Medicine (S.H.L.), Houston, Texas; and Langone Health (M.S.), New York University, New York, New York.

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Reprint requests: Stephen H. Little, MD, Houston Methodist DeBakey Heart and Vascular Center, 6550 Fannin Street, SM-1801, Houston, TX 77030 (E-mail: *shlittle@houstonmethodist.org*).

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currently a significant limitation for all software modeling of device implantation (including transcatheter aortic valve replacement, mitral repair, and LAA occlusion). In this study, an important finding was that because the LAA 3D printed models were constructed from material that was sufficiently pliable to undergo shape deformation, the asymmetric LAA orifice dimension became more symmetric (circular) after occluder implantation. This simple observation demonstrates an important potential advantage of 3D physical modeling (printing) over digital only modeling—namely, the ability to model tissue deformation by the implanted device. Clearly this is only a first step, and more validation of material property targets and replication is needed, but the technical ability to deform patient-specific anatomy (even if replicated from imaging data) is an important development that may have far-reaching implications for several other structural heart procedures.

Currently, LAA sizing relies primarily on two-dimensional (2D) TEE or CT measurements. On 2D TEE, four standard views are used for LAA sizing: 0°, 45°, 90°, and 135°. At each angle, the landing-zone LAA orifice diameter and LAA depth are measured independently.[4] Although routine, the measurements obtained in this fashion have significant shortcomings.

Due to a lack of clear anatomic markers at each standard TEE angle, one cannot be sure that the landing-zone LAA orifice diameters are measured along the same plane in each view. Similarly, LAA depth measured in each view may not represent the maximum depth available. Moreover, while 2D TEE imaging may visualize the overall shape of the LAA, finer details of LAA anatomy such as additional LAA lobes may not be fully demonstrated. Three-dimensional modeling of the LAA overcomes many of the shortcomings of 2D imaging as one can measure the landing-zone LAA orifice diameters on the same plane, the exact shape of the landing zone can be fully appreciated, and the LAA depth as well as the LAA anatomic shape can be demonstrated clearly.

The data presented in this issue of the journal clearly indicate that 3D print modeling may have advantages over 3D TEE-based characterization of the LAA for device implantation. However, previously published work by Wang *et al.*[5] compared characterization of the LAA by 2D or 3D TEE to CT-based characterization and showed significant advantage for the CT (volumetric) method. So far it appears that for the clinical dilemma of LAA size and shape characterization, contrast CT as a volumetric imaging modality may be better than 2D or 3D TEE, and 3D printed models (based on 3D TEE) are superior to 3D TEE images alone. As yet, we do not know whether 3D printed models (based on either 3D TEE or CT) are superior to digital CT image data alone for the prediction of LAA occluder size selection and subsequent procedural and clinical outcomes.

In centuries gone by, the Oracle was a classic figure associated with insightful counsel, prophetic predictions, or precognition of the future. Today, as we consider patients with chronic atrial fibrillation, we are generally more concerned about the left atrial auricle—but we are just as interested in the prediction of future events. Patient-specific 3D print modeling is a tool we can now employ to at least enhance the predictability of proposed structural heart interventions.

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