

3D Printing in Transcatheter Aortic Valve Replacement: A Review

Sergey Gurevich*

Department of Cardiology, University of Minnesota Fairview Medical Center
Minneapolis, Minnesota, USA

Abstract

Additive manufacturing, commonly known as 3 Dimensional (3D) printing, has revolutionized a number of industries since its development in 1981. In the last decade, however, its use has become more widespread and the technology more available. As the cost of both printers and printing materials dropped dramatically in price, its use has begun to transition to even personal households.

Keywords: Transcatheter aortic valve replacement; Paravalvular leak; 3D printing

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Description

Additive manufacturing, commonly known as 3 Dimensional (3D) printing, has revolutionized a number of industries since its development in 1981. In the last decade, however, its use has become more widespread and the technology more available. As the cost of both printers and printing materials dropped dramatically in price, its use has begun to transition to even personal households. The process of generating a 3D print is rather simple: 3D Digital Imaging and Communications in Medicine data (DICOM) is generated from a Computed Tomography (CT) scan or another similar imaging modality such as magnetic resonance imaging, 3D echocardiography, etc. The required anatomy is then extracted from the dataset using 3D image processing software such as Mimics (materialise NV) and a 3D digital model is generated. A 3D readable format such as stereolithography is then generated and fed into the printer. The 3D printer then generates the print with multiple additive layers using a robotic control in **Figure 1**.

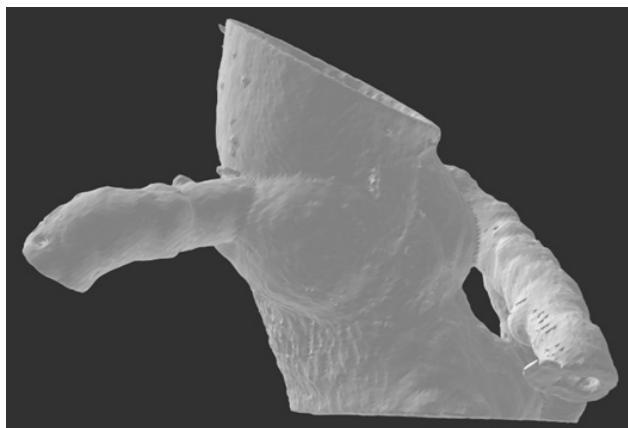


Figure 1: 3D printed model of the human aortic root generated from a stereolithography file of a DICOM dataset.

***Corresponding author:** Gurevich S, Department of Cardiology, University of Minnesota Fairview Medical Center Minneapolis, Minnesota, USA, Tel: 2123350724; E-mail: gure0011@umn.edu

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Despite its ease of use, there's a paucity of information on its use and benefits in healthcare and only a few case reports and case studies have evaluated anecdotal use in extreme anatomic cases. Novel and improved methods have allowed 3D printed models to mimic all parts of the anatomy through the use of different materials, mimicking the density of calcium and the elasticity of human aorta.

In structural cardiovascular procedures, just as in surgery, knowledge of the anatomy is of paramount importance to the success of the procedure. Growing interventional procedures such as transcatheter valvular repair rely on anatomic landmarks and quality intra-procedure visualization for guidance. Despite their wide success with almost a decade of randomized clinical trials showing non inferiority and, in certain risk groups, even superiority of Transcatheter Aortic Valve Replacement (TAVR), procedure related complications remain an obstacle [1,2]. Specifically, the big five have been listed as the most significant complications remaining [3]. With evidence growing for the use of TAVR in lower risk and younger patient, there is a strong argument for continuing to improve outcomes towards an event-free TAVR.

Each of the major remaining complications of TAVR places the patients at risk of increase mortality, stroke, and rehospitalization. A significant amount of research has been devoted to one particular complication: Paravalvular Leak (PVL). Early versions of both balloon and self-expanding valves had high incidence of mild and moderate PVL [4]. PARTNER 2 data showed that moderate or greater PVL is associated with increased mortality [5]. Beyond mortality, increased rates of PVL are responsible for early degeneration of TAVR valves and increased rates of repair and replacement. Evolution of the TAVR design has dramatically reduced the incidence of moderate PVL, but mild PVL remains

a significant complication with increased rates of stroke and mortality [6].

Given the mortality associated with PVL, a number of risk factors and predictors were identified that help operators improve procedural outcomes. Annulus size, annular calcium, and annular eccentricity index have all been proposed as predictors of PVL and have been marginally successful [7-9]. Although they increase the chance of predicting PVL, they cannot identify neither location nor severity. They are also unable to determine the solution to either reducing or preventing the event. 3D printing, however, has the additive advantage of not only accounting for the above mentioned predictors, but also identifying the location and magnitude of the PVL in **Figures 2-3**. Furthermore, the ability to choose different sizes, valves, and inflation volumes allows for solutions to be determined prior to the TAVR procedure itself [10].

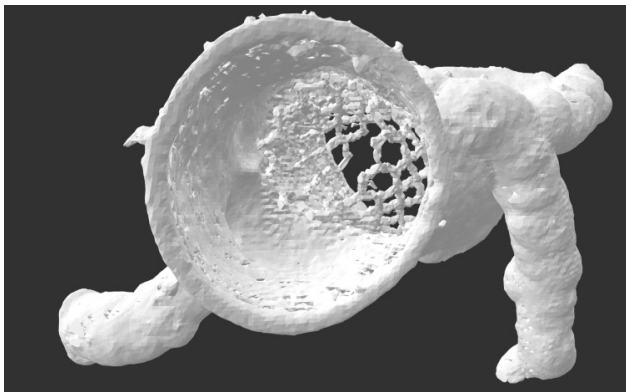


Figure 2: 3D printed model of a human aortic root implanted with a balloon-expandable TAVR stent frame.



Figure 3: 3D printed model of a human aortic root implanted with a TAVR stent frame showing an area of malapposition responsible for PVL.

3D printed models have been used to assist surgeons and interventional cardiologists alike with complex anatomy and cases. However, routine utilization of 3D printing in TAVR has also been shown to be useful in predicting complications such as PVL [10-12].

Conclusion

These studies utilized different methodologies for determining PVL including fluid loop modeling, computer simulations, and visual assessments. These 3D phantoms have also been compared

with traditional risk factors such as annulus size and eccentricity, and annular calcification and have been shown to be superior to both. Future direction of these models should be aimed at building a reliable, testable algorithm that can rapidly and cost efficiently produce models.

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