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Research paper

3D printing based on cardiac CT assists anatomic visualization prior to transcatheter aortic valve replacement

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ABSTRACT

Background: 3D printing is a promising technique that may have applications in medicine, and there is expanding interest in the use of patient-specific 3D models to guide surgical interventions.
Objective: To determine the feasibility of using cardiac CT to print individual models of the aortic root complex for transcatheter aortic valve replacement (TAVR) planning as well as to determine the ability to predict paravalvular aortic regurgitation (PAR).
Methods: This retrospective study included 16 patients (9 with PAR identified on blinded interpretation of post-procedure trans-thoracic echocardiography and 7 age, sex, and valve size-matched controls with no PAR). 3D printed models of the aortic root were created from pre-TAVR cardiac computed tomography data. These models were fitted with printed valves and predictions regarding post-implant PAR were made using a light transmission test.
Results: Aortic root 3D models were highly accurate, with excellent agreement between annulus measurements made on 3D models and those made on corresponding 2D data (mean difference of −0.34 mm, 95% limits of agreement: ± 1.3 mm). The 3D printed valve models were within 0.1 mm of their designed dimensions. Examination of the fit of valves within patient-specific aortic root models correctly predicted PAR in 6 of 9 patients (6 true positive, 3 false negative) and absence of PAR in 5 of 7 patients (5 true negative, 2 false positive).
Conclusions: Pre-TAVR 3D-printing based on cardiac CT provides a unique patient-specific method to assess the physical interplay of the aortic root and implanted valves. With additional optimization, 3D models may complement traditional techniques used for predicting which patients are more likely to develop PAR.

1. Introduction

Transcatheter aortic valve replacement (TAVR) utilizes a catheter-based delivery system to deliver a prosthetic valve mounted within a stent into a diseased aortic valve. While TAVR is a safe alternative to surgery in appropriately selected patients with aortic stenosis,[1] there are known limitations. For instance, there is no direct access to the patient's anatomy to provide precise prosthesis sizing and the complex three-dimensional anatomy of the aortic root makes it difficult to predict how the prosthetic valve will adapt in situ.[2] Moreover, the prosthetic valve is secured at the annular plane in a sutureless fashion and failure to achieve a circumferential seal can result in paravalvular aortic regurgitation (PAR).[3] PAR is the most frequent complication after TAVR and carries increased morbidity and mortality.[4,5] Therefore, meticulous pre-procedural imaging with transthoracic

Abbreviations: PAR, paraaortic regurgitation; TAVR, transcatheter aortic valve replacement; 3D, three-dimensional; STL, standard tessellation language; CCT, cardiac CT; TTE, transthoracic echocardiography.

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echocardiography (TTE), transesophageal echocardiography (TEE), and/or cardiac computed tomography (cardiac CT) is required to ensure the most optimal fit.

Three-dimensional (3D) printing can provide personalized models of patient-specific anatomy for pre-surgical planning and surgical device design. To date, 3D printing has been used for pre-procedural planning in a small number of cardiovascular cases involving coronary arteries,[6] intracardiac defects,[7–9] mitral[10–14] and pulmonic valves.[15,16] To our knowledge, however, there is no published data regarding the utility of 3D printing to guide TAVR.

In this proof-of-concept study, we aimed to determine whether patient-specific 3D printed models could be used to visualize the fit between the native aortic valve complex and TAVR prosthetic valves, and thus predict the occurrence of post-procedural PAR.

2. Methods

2.1. Study population

In a retrospective fashion, we examined 16 patients in whom pre-TAVR cardiac CT and post-TAVR TTE were available (Table 1). Eight patients with clinically documented PAR were initially selected from a larger database based on the following criteria: (1) patients had an ECG-gated pre-procedure CCT with multiphase acquisition to ensure coverage during the systolic phase of the cardiac cycle and (2) they had a follow-up transthoracic echo (TTE) within 1 month of the procedure that demonstrated at least mild PAR. Subsequently, 8 TAVR patients without PAR were matched for age, sex and size of implanted valve.

The presence or absence of PAR on the post-procedure TTE was confirmed by two experienced cardiologists with level III training in echocardiography (M.C. and A.G.), blinded to all patient data. This review led to the reassignment of one control patient (patient 3) to the PAR group based on consensus from both readers, resulting in a

Table 1
Demographics of patients with correctly and incorrectly predicted paravalvular aortic regurgitation. Italicized lines correspond to patients in which paravalvular aortic regurgitation was incorrectly predicted as absent (false negative) or incorrectly predicted as present (false positive).

PAR	Predicted leak? [amount] (Location)	PAR severity (location)	Approach	Valve size (mm)	Gender	Age, yrs	Valve type	Re-ballooned?	Annular calcs? (visual grades for sectors)
+	*No*	*Moderate (5:00)*	*femoral*	*26*	*F*	*74*	*Sapien*	*Yes*	*Yes (1,2,0)*
+	*No*	*Mild (6:00)*	*apical*	*29*	*M*	*85*	*Sapien XT*	*No*	*Yes (2,1,0)*
+	*No*	*Mild (6:00-8:00)*	*apical*	*26*	*F*	*79*	*Sapien*	*Yes*	*Yes (0,0,1)*
+	Yes [3%] (1:00-3:00)	Mild (1:00-2:00)	femoral	26	M	87	Sapien XT	Yes	No (0,0,0)
+	Yes [1%] (11:00)	Moderate (1:00-3:00)	femoral	26	F	74	Sapien 3	Yes	Yes (0,2,0)
+	Yes [2.6%] (2:00-3:00)	Mild (3:00-5:00)	aortic	26	M	79	Sapien	No	No (0,0,0)
+	Yes [0.8%] (10:00-11:00)	Mild (12:00)	femoral	29	M	88	Sapien XT	No	No (0,0,0)
+	Yes [1.3%] (7:00-8:00)	Mild (6:00 & 9:00)	femoral	29	M	85	Sapien 3	Yes	No (0,0,0)
+	Yes [4.7%] (5:00-7:00)	Mild (12:00)	femoral	26	M	69	Sapien 3	No	No (0,0,0)
-	*Yes [0.8%] (8:00)*	*None*	*femoral*	*26*	*M*	*89*	*Sapien*	*No*	*Yes (0,1,2)*
-	*Yes [1.3%] (6:00)*	*None*	*aortic*	*26*	*M*	*89*	*Sapien*	*No*	*No (0,0,0)*
-	No	None	femoral	23	F	91	Sapien	No	No (0,0,0)
-	No	None	femoral	26	M	78	Sapien 3	Yes	Yes (0,2,2)
-	No	None	aortic	29	M	86	Sapien 3	No	Yes (0,1,0)
-	No	None	aortic	26	F	77	Sapien	No	Yes (0,1,2)
-	No	None	femoral	29	M	87	Sapien XT	No	No (0,0,0)

Column 1. PAR: para-aortic regurgitation. + indicates patients with confirmed PAR, while − indicates patients without PAR. In column 2, quantification of predicted PAR is reported as a percentage of the total area of the annulus and is indicated in [brackets]. The predicted clock face position is reported in (parentheses). In column 9, re-ballooned refers to cases where the interventionalist chose to balloon open the TAVR valve twice during the placement of the valve. This was done at the discretion of the interventionalist. In column 10, the presence or absence of annular calcifications is reported, and is graded as grade 0, no calcification; grade 1, small (<1 mm) non-protruding calcification; grade 2, calcium protruding > 1 mm into the annulus or extensive (>50% of cusp sector) calcification; grade 3, protruding calcium (>1 mm) and extensive (>50% of cusp sector) calcification.[26] Grades are reported in the order (right coronary sector, left coronary sector, noncoronary sector).