Defining the breaking point: Benefits and pitfalls of modeling long-term durability of a third-generation transcatheter valve in an era of short-term data

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As the indications for transcatheter aortic valve replacement (TAVR) continue to expand to lower-risk patients, understanding the tradeoffs between reducing procedure-related morbidity, and longer-term concerns of durability and structural failure, becomes increasingly salient (Table 1). The Edwards SAPIEN 3 valve (Edwards Lifesciences Corp, Irvine, Calif) is currently being evaluated for use in low-risk surgical patients with aortic stenosis in the Placement of Aortic Transcatheter Valves randomized trial (PARTNER) 3. Currently, there are limited data on the modes of failure of transcatheter bioprosthetic valves, with one systematic review identifying only 87 cases of failure between 2002 and 2014.¹ Five-year follow-up of PARTNER 1 subjects showed no evidence of valve deterioration on echocardiographic examination, but is likely biased by its survival rate of 27.4%.²

While awaiting more clinical data on the outcomes of TAVR in a population with increased projected survival, Xuan et al³ provide a critical framework for identifying potential mechanisms of long-term failure of a 26-mm

SAPIEN 3 valve, in an elegant study analyzing the distribution of stress across the valve components. Using the computational method of finite element analysis (FEA), the authors used primary data on the material properties of the bovine pericardium valve leaflets to simulate the deformation of the SAPIEN 3 valve in a closed configuration in systole and diastole. Using this model, areas subjected to the greatest maximum principal stress (tension/tearing force) and minimum principal stress (compression/bending force) have been localized to the leaflets' sutured edge at the commissure and might indicate potential foci of calcification and leaflet degeneration.⁴

Computational models for bioprosthetic valve durability prediction.

Central Message

Advanced computational models of transcatheter aortic valves provide a preliminary platform that can eventually integrate clinical data to more accurately predict valve degeneration patterns.

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TABLE 1. Evolution of Edwards transcatheter bioprosthetic aortic valves

	First-generation	Second-generation	Third-generation
Name	SAPIEN THV	SAPIEN XT	SAPIEN 3
Delivery catheter (transfemoral)	22-F or 24-F	18-F or 16-F	14-F
Design implementations	Stainless steel stent	Cobalt chromium stent	Cobalt chromium frame structure redesigned; outer seal skirt added
Problems addressed		More compressible frame results in fewer vascular bleeding complications	New frame allows access to coronary arteries for future procedures; outer sealing skirt reduces risk of moderate or severe paravalvular leaks; lower profile further reduces vascular complications
Issues	Large sheath size required; cannot be repositioned	Sheath size still results in some complications; cannot be repositioned	Outer seal skirt might affect bundle branches in some patients and result in higher frequency of pacemaker implantation; cannot be repositioned

SAPIEN valves are from Edwards Lifesciences Corp (Irvine, Calif). F, French.

To fully understand the implications of the FEA model developed in this study, it is important to note the limitations of this method, which omits blood flow dynamics, thereby ignoring variation in pressure load and flow-induced shear stress on the leaflets.⁵ An alternative method of dynamic simulation, fluid–structure interaction analysis, couples the structural and fluid domains of the valve. This characterizes the stress distribution across the valve as well as the kinematics of leaflet deformation during the cardiac cycle, but might oversimplify the modeling of the structural domain.^{6,7} FEA, as used in this study, satisfactorily represents the nonlinear stress–strain relationship and mechanical anisotropy of valve leaflets, especially in the newly deployed configuration before degeneration. Follow-up studies that incorporate the effects of calcification and degeneration of the valve over time, might benefit from the additional use of fluid–structure interaction techniques to better elucidate abnormal hemodynamics.

As TAVR continues to rapidly evolve, it is important to consider new metrics to define success. If valve-in-valve options prove to be a satisfactory method of reintervention in cases of structural valve failure, the durability of transcatheter aortic valves need not achieve the same standards as surgically implanted valves. However, alternative modes of failure, such as valve thrombosis, late embolization, and endocarditis, will likely require continued refinement of procedural techniques and

evolution of valve design. Xuan et al³ have provided a solid framework by which to identify expected areas of structural failure in the SAPIEN 3, and further clinical data will further improve the accuracy and prediction potential of computational models, with great implications for eventual development of a simulation-based tool to select the most appropriate patients for TAVR.

References

1. Mylotte D, Andalib A, Theriault-Lauzier P, Dorfmeister M, Girgis M, Alharbi W, et al. Transcatheter heart valve failure: a systematic review. *Eur Heart J*. 2015;36:1306-27.
2. Kapadia S, Leon M, Makkar R, Tuzcu EM, Svensson LG, Kodali S, et al. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet*. 2015;385:2485-91.
3. Xuan Y, Dvir D, Wang Z, Mizoguchi T, Ye J, Guccione JM, et al. Stent and leaflet stresses in 26-mm, third-generation, balloon-expandable transcatheter aortic valve. *J Thorac Cardiovasc Surg*. 2019;157:528-36.
4. Rodriguez-Gabella T, Voisine P, Puri R, Pibarot P, Rodes-Cabau J. Aortic bioprosthetic valve durability: incidence, mechanisms, predictors, and management of surgical and transcatheter valve degeneration. *J Am Coll Cardiol*. 2017;70:1013-28.
5. Luraghi G, Wu W, De Gaetano F, Rodriguez Matas JF, Moggridge GD, Serrani M, et al. Evaluation of an aortic valve prosthesis: fluid-structure interaction or structural simulation? *J Biomech*. 2017;58:45-51.
6. Wu W, Pott D, Mazza B, Sironi T, Dordoni E, Chiastra C, et al. Fluid-structure interaction model of a percutaneous aortic valve: comparison with an in vitro test and feasibility study in a patient-specific case. *Ann Biomed Eng*. 2016;44:590-603.
7. Chandran KB. Role of computational simulations in heart valve dynamics and design of valvular prostheses. *Cardiovasc Eng Technol*. 2010;1:18-38.