TAVR Valve Testing – Evolving From Idealized Models to Patient-Specific Replicas
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Introduction: Transcatheter aortic valve replacement (TAVR) is a minimally-invasive procedure to treat aortic valve stenosis. However the promise of TAVR is hampered by ensuing clinical complications (e.g. structural valve degeneration, leaflet thrombosis, regurgitant flows), which are influenced by device deployment in the patient-specific calcified anatomies. As computational models develop towards patient-specific geometries and scenarios, there is a widening gap in the concomitant development of in vitro models. Added complexity of patient-specific models should drive an effort towards verification and validation as well as complimentary testing in matched in vitro models that cannot be achieved clinically. Through a comprehensive battery of in vitro testing of TAVR devices in anatomically correct geometries and in silico models of procedural complications in patient-specific replicas, manufacturers can predict their TAVR devices performance and optimize their design before moving to costly preclinical animal testing and human subjects testing.

Materials and Methods: A novel polymeric TAVR valve (PolyV-1, PolyNova Cardiovascular Inc, Stony Brook, NY) was compared against two tissue (xenograft) valves: the Carpentier-Edwards Perimount Magna Ease (PME) surgical valve size 19mm (Edwards Lifesciences, CA) and the 20mm InnovaTAVR valve (Braile-Biomedica, Brazil). Baseline hydrodynamic performance (ISO-5840-3) was compared between the valves. FSI simulation of the polymeric TAVR and SAVR in an idealized geometry (circular annulus, no native leaflets) of a standard ISO 5840 left heart simulator (Vivitro Labs, Victoria, BC) and validated with said simulator \textsuperscript{1} (Fig. 1A). Performance of the valve under pathological conditions was evaluated in 5 patient specific calcified aortic root models (Vascular Simulations Inc, Stony Brook, NY) reconstructed from CT scans, and mounted in the Replicator simulator (Fig. 1B) that enables testing hydrodynamic performance by performing TAVR procedure with full major arterial tree and gather clinically relevant data and images (echo, angiography, cardiac CT and cardiac MR). MicroCT evaluation of the deployed valves allows detailed study of eccentric deployment and leak gaps causing regurgitant flows, which is unobtainable in the clinical setting (Fig. 1C).

Results and Discussion: Initial results of the valves effective orifice area (EOA) and transvalvular pressure drop, comparing the standard idealized geometries to a single patient-specific geometry show two different results\textsuperscript{2}. In the idealized geometry, all three valves had excellent performance characteristics (Figure 1A) and similar systolic pressure gradients, with the PolyV-1 (EOA 1.7cm$^2$ at 5LPM) performing on par with the gold-standard SAVR valve (EOA 1.6cm$^2$ at 5LPM). However, in the pathological geometry, the TAVR valves suffered a performance drop with the PolyV-1 falling below (EOA = 1.3cm$^2$) the SAVR (EOA = 1.4cm$^2$), showing the importance of studying the eccentric deployment in the pathological conditions. The SAVR valve performance was only impacted by the aortic geometry as native leaflets were removed. For further analysis, the patient-specific geometries will be fed back into patient-specific FSI simulations for complete capture of the device behavior.

Translational Impact: With the expanded battery of patient-specific testing, the preclinical testing of TAVR devices is elevated from testing benchmarks to a development tool to challenge the device design. Physical patient-specific models provide a reliable means to validate complex computational simulations, as well as testing clinical complications or failure modes, with greater clinical relevancy.

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