Transcatheter Aortic Valve Oversizing Adversely Impacts Leaflet Kinematics, Flow Field, and Durability

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Statement of Purpose: Proper stent deployment is essential for successful transcatheter aortic valve (TAV) implantation. It has been proposed that transcatheter aortic valves must be slightly larger than the aortic annulus to decrease the degree of perivalvular aortic regurgitation and achieve appropriate valve anchoring[1]. Currently, patients with an aortic annulus diameter of 18 to 21 mm may be considered for placement of 23mm Edwards SAPIEN prosthesis while the 26mm SAPIEN prosthesis is sized for an annulus of 21 to 24 mm. However, oversizing leads to TAV leaflet distortion due to excess pericardial tissue relatively to stent orifice area. Leaflet distortion increases stress on one or more leaflets and may result in premature failure of the TAV. The aim of this study was to determine the impact of TAV oversizing on leaflet kinematics and flow field.

Methods: Nine TAVs designed to mimic the 23mm Edwards SAPIEN valve were created using stainless steel stents and three pericardial valve leaflets. TAVs were implanted in 19, 21, and 23mm Carpentier-Edwards bioprostheses in a pulse duplicator (n=3 each). Bioprosthetic valves provided a well-controlled and consistent environment to examine the effect of TAV oversizing. Physiologic circulation was simulated through viscoelastic ventricular contraction, blood-simulating fluid, and control of local compliance and peripheral resistance. Pulse duplicator input parameters were used to match ISO 5840 and FDA standards for testing heart valves: heart rate of 70 beats/min, systolic duration of cycle period of 35%, mean atrial and aortic pressures of 10 and 100mmHg, and cardiac output of 5 L/min. Hemodynamic parameters were maintained constant throughout the study. Leaflet kinematics was visualized using a high-speed camera (1000 frames/sec). A 2D particle image velocimetry system was used to map velocity field as well as shear and Reynolds stresses after TAV implantation.

Results: The three 23mm TAVs made in the laboratory demonstrated similar hemodynamics to the Edwards SAPIEN valve. After implantation of 23mm TAVs within 23mm bioprostheses, the hemodynamics were excellent. Mean pressure gradient was 8.3 ± 1.2 mmHg and no leaflet distortion was observed after implantation.

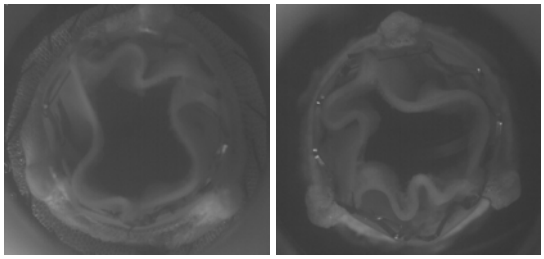

Figure 1: Incomplete opening of 23mm TAV implanted in (a)21mm and (b)19mm bioprostheses at peak flow.

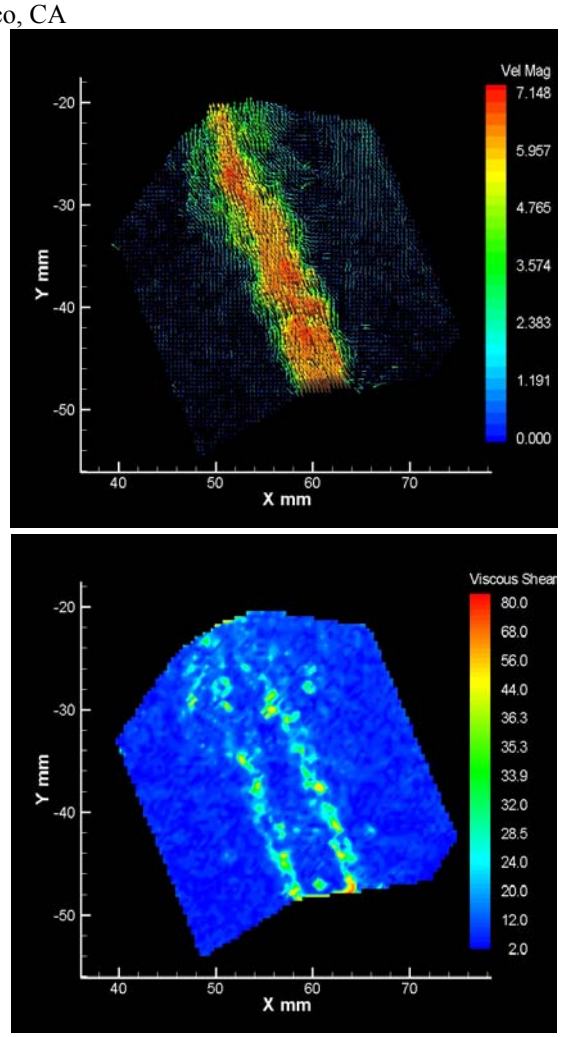

Figure 2: Instantaneous peak flow velocity and shear stress after implantation of TAV in 19mm bioprosthesis.

However, after TAV implantation within 19 and 21mm Edwards bioprostheses, TAV leaflets were distorted and asymmetric TAV leaflet kinematics were observed (Figure 1). A mean pressure gradient after implantation within 21 and 19mm bioprostheses of 28.0±12.8 and 44.0±14.9 mmHg was obtained, respectively. In 19 and 21mm bioprostheses, the oversized TAV significantly reduced the central orifice area, giving rise to higher central axial flow and high shear stress regions potentially leading to platelet damage (Figure 2).

Conclusions: Optimal sizing remains a critical issue for TAVs. Small aortic diameter could constrain an oversized TAV and lead to TAV leaflet distortion. TAV oversizing adversely impacts the leaflet kinematics and flow field, and may affect the long-term durability of TAVs.

References: Zajarias A. and Cribier A. JACC. 2009; 53:1830-36.