Stent and leaflet stresses in 26-mm, third-generation, balloon-expandable transcatheter aortic valve

Yue Xuan, PhD,^a Danny Dvir, MD,^b Zhongjie Wang, PhD,^a Trek Mizoguchi, BS,^a Jian Ye, MD,^c Julius M. Guccione, PhD,^a Liang Ge, PhD,^a and Elaine E. Tseng, MD^a

ABSTRACT

Objectives: Transcatheter aortic valve replacement has proven successful in treating intermediate-risk, high-risk, and inoperable patients with severe aortic stenosis. Third-generation, balloon-expandable transcatheter aortic valves were developed with an outer sealing skirt to reduce paravalvular leakage. As transcatheter aortic valve replacement use expands, long-term durability questions remain. Valve design influences durability, where regions of increased leaflet stress are vulnerable to early degeneration. However, third-generation transcatheter aortic valve stresses are unknown. Our goals were to determine the stent and leaflet stresses of third-generation, balloon-expandable transcatheter aortic valves.

Methods: The commercial 26-mm Edwards SAPIEN 3 valve (Edwards Lifesciences, Inc, Irvine, Calif) underwent high-resolution micro-computed tomography scanning to develop a precise 3-dimensional geometric mesh of the stent and valve. Leaflet material properties were obtained from surgical bioprostheses, and stent material properties were based on cobalt-chromium. Simulations of systemic pressure loading were performed, and stress was calculated using finite element analyses.

Results: At diastole, maximum and minimum principal stresses on transcatheter aortic valve leaflets were 2.7 MPa and -0.47 MPa, respectively. Peak leaflet stresses were observed at upper leaflet commissures, at their connection to the stent. Maximum and minimum principal stresses for the stent were 38.2 MPa and -44.4 MPa, respectively, at 80 mm Hg and were located just below the commissural stent.

Conclusions: Stress analysis of the 26-mm SAPIEN 3 valve using exact geometry from high-resolution scans demonstrated that peak stresses for both transcatheter aortic valve stent and leaflets were present at commissural tips where leaflets were attached. These regions would be most likely to initiate degeneration. The Dacron skirt had minimal effect on stresses on leaflets and stent. (*J Thorac Cardiovasc Surg* 2019;157:528-36)

SAPIEN 3 valve (Edwards Lifesciences, Inc, Irvine, Calif).

Central Message

The current-generation SAPIEN 3 valve (Edwards Lifesciences, Inc, Irvine, Calif) has peak stresses at commissures and sutured areas below, which may initiate eventual bioprosthetic calcification and degeneration.

Perspective

Durability is a concern as transcatheter valves move toward lower-risk younger patients. Stress analyses are important for evaluating relative durability compared with transcatheter or surgical bioprostheses. We showed that peak leaflet stresses in the current-generation SAPIEN 3 valve (Edwards Lifesciences, Inc, Irvine, Calif) occurred at leaflet commissures at stent attachment sites, suggesting regions prone to initiating degeneration.

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Transcatheter aortic valve replacement (TAVR) has proven effective for treating severe aortic stenosis (AS) in intermediate- and high-risk surgical patients and inoperable

patients.¹⁻³ The third-generation, balloon-expandable transcatheter aortic valve (TAV) SAPIEN 3 (Edwards Lifesciences, Inc, Irvine, Calif) was introduced commercially

From the ^aDepartment of Surgery, University of California San Francisco and San Francisco VA Medical Centers, San Francisco, Calif; ^bDivision of Cardiology, University of Washington, Seattle, Wash; and ^cDivision of Cardiovascular Surgery, St Paul's Hospital and Vancouver General Hospital, Vancouver, British Columbia, Canada.

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Address for reprints: Elaine E. Tseng, MD, San Francisco VA Medical Center, 500 Parnassus Ave, Suite 405W, Box 0118, San Francisco, CA 94143-0118 (E-mail: Elaine.Tseng@ucsf.edu).

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Abbreviations and Acronyms

AS	= aortic stenosis
FE	= finite element
FEA	= finite element analysis
PET	= polyethylene terephthalate
PVL	= paravalvular leakage
SAVR	= surgical aortic valve replacement
TAV	= transcatheter aortic valve
TAVR	= transcatheter aortic valve replacement

Scanning this QR code will take you to a supplemental video for the article.

in January 2014 in Europe and in June 2015 in the United States. The SAPIEN 3 was the first TAVR device to receive US Food and Drug Administration approval for the expanded indication to intermediate-risk surgical patients with severe symptomatic AS. A key improvement in valve design over prior second-generation SAPIEN XT was inclusion of an outer polyethylene terephthalate (PET) sealing cuff at the base of the stent to significantly reduce paravalvular leakage (PVL). In addition to the standard 23-mm, 26-mm, and 29-mm sizes, a 20-mm diameter SAPIEN 3 became available for smaller annulus sizes and valve-in-valve implantation. Major alterations in stent configuration also occurred for the SAPIEN 3, which carried important clinical implications: (1) a significantly reduced profile for the crimped valve that allowed insertion within a 14F or 16F expandable sheath, (2) much larger cells distally to allow easier access for future coronary catheterization through the cell struts, and (3) an increase in overall stent length.⁴ Changes in stent configuration revolutionized vascular access for TAVR to allow routine transfemoral percutaneous access.

Concerns regarding TAVR durability have not been a major concern for the original clinical trials involving high-risk and inoperable patients who were typically octogenarians.⁵⁻⁹ However, as lower-risk younger patients become enrolled, the question of TAVR durability rises to the forefront. The Placement of Aortic Transcatheter Valves randomized trial 3 has been recruiting patients since April 2016 to test the safety and efficacy of SAPIEN 3 in low-risk surgical patients with AS. Valve design affects long-term durability. Regions of increased leaflet stresses correlate with areas of calcific degeneration and tearing.¹⁰⁻¹⁵ Therefore, understanding TAV leaflet stresses is important for determining relative durability of TAVs compared with other devices or bioprostheses. We have previously used finite element

analysis (FEA) to examine leaflet stresses in the first-generation Edwards SAPIEN and second-generation SAPIEN XT valves.^{16,17} FEA is an established method to determine essential data about complicated biological systems that would otherwise be impossible to directly measure in vivo. FEA in physiologic studies is particularly valuable when used to estimate device durability by determining stresses and failure modes. Finite element (FE) models require accurate 3-dimensional geometry in zero-pressure state, detailed assembly, material properties, and physiologic loading conditions. Because of the important changes altering valve design, stresses on the most recent third-generation, balloon-expandable TAV are unknown. The goal of this study was to determine TAV stent and leaflet stresses in a 26-mm, third-generation Edwards SAPIEN 3 valve.

MATERIALS AND METHODS

The commercial 26-mm Edwards SAPIEN 3 (external diameter 25.8 mm, height 20 mm) was obtained. TAV assembly consisted of 4 components: bovine pericardial leaflets, cobalt-chromium stent, Dacron covering, and outer PET sealing skirt. Physical measurements were taken, and suture connections between different components were studied to enable accurate modeling of the assembly with its connections. Overview of this process to determine TAV stress distribution includes (1) development of TAV mesh using 3-dimensional geometry; (2) FEA using FE explicit solver; and (3) postprocessing and data analysis to determine stresses on leaflets and stent.

SAPIEN 3 Transcatheter Aortic Valve Mesh Generation

The SAPIEN 3 (26 mm) was imaged with a desktop cone-beam micro-computed tomography scanner (microCT-40; Scanco Medical AG, Baseldorf, Switzerland) in different orientations, including along the short axis for leaflet and long axis for stent reconstruction, and intensities to distinguish stent and leaflet geometries. Scan settings used were as follows: X-ray energy = 45 kVp, X-ray current = 200 μ A, filter = 0.5 mm aluminum, field of view = 50 mm, voxel size = 50 μ m, and integration time = 200 ms. High-resolution Digital Imaging and Communications in Medicine radiologic images (voxel size 50 $\times$ 50 $\times$ 50 μ m) were imported into MeVisLab, an open source surface reconstruction software (<http://www.mevislab.de/>). Digital Imaging and Communications in Medicine files were scanned individually to separate TAV stent versus leaflets materials to obtain the most accurate representation of their respective geometries. Stent and leaflet surfaces were combined using suture lines. The reconstructed surface was then imported into GeoMagic Design (3D Systems, Rock Hill, SC), where the geometries were created and refined (Figure 1, B). The finalized surface was then imported into Truegrid (XYZ Scientific Applications, Pleasant Hills, Calif) to generate a volume mesh with accurate size and thickness ex vivo. The total number of elements used was 20,988 for leaflets and 6167 for stent, 4320 for Dacron, and 4272 for skirt (Figure 1, C).

Finite Element Analyses

The SAPIEN 3 uses leaflets made of specially treated bovine pericardium to resist calcification, and that proprietary process is the same as for corresponding surgical Carpentier-Edwards pericardial valves (Edwards Lifesciences, Inc). We previously performed biaxial stretch testing of surgical bovine pericardial valves (Edwards Lifesciences, Inc) to determine material properties of TAV leaflets, to avoid destroying leaflets of the 26-mm SAPIEN 3.¹⁸ The methods of biaxial stretching

FIGURE 1. A, Subregions of the SAPIEN 3 (Edwards Lifesciences, Inc, Irvine, Calif) leaflet. B, Micro-computed tomography scanned geometry of leaflets. C, Mesh of the leaflets, stent, and skirt based on micro-computed tomography scanned images. D, Material property of bioprosthetic leaflets.

and the hyperelastic material model have been described.¹⁹ Averaged leaflet material properties from 12 bioprosthetic valves (35 leaflets) were used in this study, and the stress-strain curve of the averaged leaflet material property is presented in Figure 1, D.

FE simulations were performed using ABAQUS solver (Dassault Systems, Waltham, Mass). Stent geometry was modeled using 3-dimensional brick elements, whereas leaflet geometry was modeled using nonlinear shell elements. Mesh convergence studies were performed to determine the ideal mesh size for the balance of cost and accuracy. Contact definitions between leaflets and between leaflet and stent were investigated to choose one most accurately representing the overall behavior. Leaflet nodes were connected to the stent using a “TIE” contact (coefficient of friction value 0.1). TAV leaflet geometries were sutured to Dacron at the bottom and tied to stent geometry at the top. TAV leaflet mesh was subdivided into 4 distinct regions to study stress distribution due to pressure loading: (1) upper commissure, (2) lower commissure, (3) upper free leaflet region, and (4) lower leaflet belly region (Figure 1, A).

Simulations were performed to determine TAV stresses based on arterial loading conditions on commercial TAV without crimping and balloon expansion. Pressure loading was applied to outer surfaces of leaflets and stent to 80 and 120 mm Hg with quasi-static loading conditions. Diastole results in highest pressure differential between aortic and left ventricular pressure; therefore, closed leaflet configurations were analyzed to assess leaflet stresses. Boundary conditions were applied to the stent to prevent any shifting of the stent. To simulate the deployed geometry, the stent was pulled along the radial direction to reach the desired diameter of 24 mm, 25 mm, and 26.5 mm, respectively.

RESULTS

Maximum and minimum principal stresses for the entire leaflet assembly, as well as each TAV component, were determined at 80 and 120 mm Hg. High stress concentration locations were determined. Maximum principal stresses for the SAPIEN 3 stent were 38.2 MPa and 57.3 MPa at 80

and 120 mm Hg, respectively (Figure 2, A). Peak stresses occurred in the cells just below the commissure stents where the stent contacted the diseased aortic valve and was confined. Minimum principal stresses, which indicated the bending force on TAV stent, were -44.4 MPa and -66.6 MPa at 80 and 120 mm Hg, respectively (Figure 2, A). These stresses were similarly located in the cells just below the commissure stents, but also along the top of the stent in crossover points that met with the commissure struts.

Maximum principal stresses across the entire leaflet were 2.7 MPa and 3.0 MPa at 80 and 120 mm Hg, respectively (Figure 2, B, and Video 1). Peak stresses occurred at the upper leaflet edge where the leaflets were sutured to the stent at the commissures. Minimum principal stresses across the entire leaflet were -0.5 MPa and -0.6 MPa at 80 and 120 mm Hg, respectively. These stresses occurred at locations similar to maximum stresses: on the upper sutured edge of the leaflets close to the commissure (Figure 2, B). Upper sutured leaflet edges (region 1) contained maximum and minimum principal stresses for the entire leaflet assembly. Lower sutured leaflet edges (region 2) had the second highest peak stresses of 2.1 MPa and 2.6 MPa at 80 and 120 mm Hg, respectively. Minimum principal stresses in region 2 were -0.13 MPa and -0.14 MPa. Upper free leaflet edges (region 3) had maximum stresses of 1.1 MPa and 1.5 MPa at 80 and 120 mm Hg, respectively, and minimum stresses of -0.18 MPa and -0.48 MPa at 80 and 120 mm Hg, respectively. Lower leaflet belly (region 4) had slightly higher maximum principal stresses of 1.2 MPa and

FIGURE 2. A, At 80 mm Hg diastolic pressure, maximum (a) and minimum (b) principal stresses on the stent are shown. At 120 mm Hg systolic pressure, maximum (c) and minimum (d) principal stresses are shown. B, At 80 mm Hg, maximum (a) and minimum (b) principal stresses on entire leaflet assembly are shown. At 120 mm Hg, maximum (c) and minimum (d) principal stresses on the entire leaflet are shown.

1.7 MPa at 80 and 120 mm Hg, respectively, than the upper leaflet region, but the magnitude of minimum principal stresses was lower (-0.19 and -0.28 MPa at 80 and 120 mm Hg, respectively).

Addition of the outer skirt varied stress distributions in the subregions, although none reached statistically significant differences compared with without the skirt (Figure 3, $P > .05$). Without the sealing skirt, maximum principal

stresses on the stent were reduced to 35.5 MPa and 53.0 MPa at 80 and 120 mm Hg, respectively, and minimum principal stresses were reduced to -32.6 MPa and -48.6 MPa at 80 and 120 mm Hg, respectively. In contrast, without the sealing skirt, maximum principal stresses on the leaflets occurred in the same regions of the upper commissure area but increased to 2.9 MPa and 3.2 MPa at 80 and 120 mm Hg, respectively (Figure 3).

VIDEO 1. Maximum principal stress on the leaflet of the SAPIEN 3 valve (Edwards Lifesciences, Inc, Irvine, Calif) at diastole. Video available at: [https://www.jtcvs.org/article/S0022-5223\(18\)31268-6/fulltext](https://www.jtcvs.org/article/S0022-5223(18)31268-6/fulltext).

Minimum principal stresses on the leaflets decreased to -0.38 MPa and -0.60 MPa located at the upper commissural sutured edge at 80 and 120 mm Hg, respectively. In the lower commissural sutured edges, maximum principal stresses were 1.4 MPa and 2.3 MPa, at 80 and 120 mm Hg, respectively, and minimum principal stresses were -0.098 MPa and -0.10 MPa, at 80 and 120 mm Hg, respectively. Upper leaflet and lower belly

FIGURE 3. Comparison of (A) maximum principal stress and (B) minimum principal stress on different leaflet regions with and without the outer skirt at diastole.

FIGURE 4. Comparison of maximum principal stress on leaflets within different deployed geometries of a 26-mm TAVR at diastole.

had less than half of maximum and minimum principal stresses compared with region 1.

TAVR is typically not deployed in the fully expanded nominal geometry; therefore, we simulated the under-expanded and overexpanded geometries in addition to nominal expansion. The deployed underexpanded geometry of 24 mm and 25 mm and the overexpanded geometry of 26.5 mm were studied. Peak leaflet stresses were 2.1 MPa for 24 mm, 2.3 MPa for 25 mm, and 3.1 MPa for 26.5 mm, with increasing stresses with larger deployed geometries (Figure 4). Peak stresses and deformation were primarily observed in the commissure area in all the deployed geometries (Figure 5).

DISCUSSION

In this study, we demonstrated that for the stent of the 26-mm SAPIEN 3, maximum and minimum principal stresses occurred in the cells just below the commissural stent posts as well as the crosslinking stents that adjoined the commissure. For the leaflets, maximum and minimum principal stresses occurred at the commissures where the leaflets attached to the stent. From the durability perspective, leaflet as opposed to stent stresses is more critical, because the stent material is much stronger and less prone to fracture, whereas valve failure results from leaflet tearing or calcification. Maximum principal stress is the tension/tearing force, and minimum principal stress is the compression/bending force. Both stresses are of clinical importance because areas of high stress have been correlated as initiation sites for calcification and leaflet degeneration.¹²⁻¹⁵ High stress regions on the leaflets reflect areas that with hundreds of millions of cycles of opening and closing would be prone to initiating degeneration.

We previously examined stent and leaflet stresses in the earlier first- and second-generation balloon-expandable TAVs. However, notable design changes were implemented for the SAPIEN 3 compared with prior devices. An outer

FIGURE 5. Maximum principal stress distribution on leaflets within different deployed annulus sizes of TAVR at diastole.

PET sealing skirt was added to reduce PVL. Stent configuration was modified, which allowed a lower profile delivery system and easier access for percutaneous coronary interventions. Leaflet design also altered the configuration of the stent and leaflet interface at the commissures. Clinical results from the SAPIEN 3 at 1 year via the nested registry in the Placement of Aortic Transcatheter Valves II trial were excellent, with very low all-cause mortality and high overall survival 85.6% at 1 year.²⁰ With the outer sealing skirt, no severe PVL occurred and only a 2.7% rate of moderate PVL. With the reduction in delivery profile, transfemoral access rate was high, 84%. Likewise, the SAPIEN Aortic Bioprosthesis European Outcome 3 registry at 1-year follow-up showed 98.3% success of implantation with 12.6% all-cause mortality at 1 year with 87.1% transfemoral access. Again, there was no severe PVL, and moderate PVL was low at 2.6%.²¹ For intermediate-risk patients, all-cause mortality at 1 year follow-up further declined with the SAPIEN 3 to 7.4% with moderate or severe PVL in 2%.²²

Outer Sealing Cuff and Paravalvular Leakage

Moderate and severe PVL after TAVR are associated with increased mortality.⁵⁻⁹ To minimize post-TAVR PVL, an outer sealing skirt was added, which did exert effects on

both stent and leaflet stresses albeit not statistically significantly. On the one hand, the skirt reduced leaflet peak stresses. Maximum principal stresses on the leaflet were decreased by 5.9% at 120 mm Hg and 6.3% at 80 mm Hg. On the other hand, additional pressure on the skirt increased peak stresses on the stent. Maximum principal stresses on the stent increased by 7.19% at 120 mm Hg and 8.73% at 80 mm Hg. From a durability perspective, the addition of an outer skirt appears to be beneficial by balancing out some of stresses on the leaflets. Nonetheless, peak stress levels clinically will be affected by TAVR shape after patient-specific deployment, based on deployed location and native valve calcification, which may negate some of these benefits.

Comparison of Surgical Aortic Valve Replacement and Transcatheter Aortic Valve Replacement Simulations

Durability is the Achilles heel of bioprosthetic valves, whether TAVR or surgical aortic valve replacement (SAVR). Valve durability is influenced primarily by structural valve dysfunction, resulting from bioprosthetic valve degeneration. Pathologically, bioprosthetic degeneration involves leaflet cusp calcification and stiffening, and leaflet tearing. Recently, valve thrombosis has been highlighted as another potential mode of failure.²³ For

surgical bioprostheses, degeneration by calcification or leaflet tearing correlated with areas of high tensile and compressive stresses,^{11,24} and cyclic flexural fatigue and bending.^{10,25} Previously, the 25-mm Edwards bovine pericardial valve was investigated by FEA, using leaflet material properties from those valves and exact valve geometry under 120 mm Hg quasi-static loading conditions.¹¹ Maximum in-plane stress ranged from 544.7 to 663.2 kPa; however, leaflet and stent interactions were not specifically described. Leaflet stresses were greatest near the commissures and least near the free edge. For surgical bioprostheses, FEA of high stress regions correlated well with sites of bioprosthetic leaflet calcification and degeneration. In our study, maximum principal stresses for the 26-mm SAPIEN 3 were significantly higher than reported for surgical bioprosthesis of comparable size. Differences in leaflet geometry and thickness may account for this. To crimp the SAPIEN 3 or other TAV designs into low-profile delivery systems, a thinner bovine or porcine pericardium is required.²⁶ This leaflet thickness reduction translates to higher leaflet stresses, where stress is inversely proportional to leaflet thickness in an approximately linear fashion assuming similar material properties. Given that TAVR leaflets are approximately one half the thickness of SAVR leaflets, increased leaflet stress is to be expected. Increased TAVR rather than SAVR leaflet stresses may reflect an earlier tendency for degeneration, which should be closely followed clinically.

Computational TAV simulations that examined stress on leaflets have been limited. One recent study based on the 26-mm SAPIEN-XT reported average Von Mises stresses of the 1% of elements experiencing greatest stress to be 1.54 MPa under 13 KPa pressure in a patient-specific deployed model.²⁷ However, the model was not based on exact leaflet geometry, but rather an estimate, and used the second-generation SAPIEN-XT. Maximum stress also was not reported. Another study with a homemade 23-mm TAV reported maximum principal stress of 2.5 MPa²⁸ in diastole, and another study reported maximum principal stress of 0.87 MPa for a leaflet shape optimized from 500 designs and reported high stress regions in the leaflet belly.²⁹ Neither study used exact geometry or a fully assembled TAV, including leaflets, stent, Dacron, skirt, and sutures, as in the current study. We examined maximum principal stresses of current third-generation, balloon-expandable SAPIEN 3 using exact leaflet geometry and thickness, and incorporated the stent, Dacron, and skirt with leaflet interactions in our simulations. In comparison with our prior work on the same-sized 26-mm Edwards SAPIEN, leaflet stresses in the SAPIEN 3 (2.7 MPa) were slightly higher than in the first-generation design (2.5 MPa). Our leaflet stress results for SAPIEN 3 were also higher than those for the larger 29-mm SAPIEN-XT

(1.6 MPa). Compared with earlier generations, the SAPIEN 3 has a different design in how the leaflet is sutured to the stent at the commissure area. The first 2 generations of SAPIEN were sutured to a side bar along the radial direction, whereas the SAPIEN 3 is sutured to the circumferential bar on the stent and there are no radial side bars. In this manner, the suture moves away radially from the center of the valve. The leaflet configuration directly affects peak principal stresses and stress distribution. In general, stresses can be reduced by increasing leaflet thickness, aligning the material orientation, and optimizing leaflet shape computationally.^{26,30,31}

The latest generation of valve design was optimized to meet pressing clinical needs of reducing PVL and lowering delivery system profile for transfemoral access. FEA stress analyses of surgical bioprostheses have shown correlation of high stress regions with sites of leaflet calcification initiation and degeneration.^{10,11,24,25} Our results suggest that for the SAPIEN 3, commissural leaflet regions will be most prone to leaflet degeneration, and given the higher stresses than surgical valves, the SAPIEN 3 may be prone to earlier degeneration. Presently, because the majority of TAVR recipients are elderly (average age 80 years), we have insufficient TAVR failure data to correlate stresses with degeneration. However, as TAVR moves to younger patients, whether low risk or intermediate risk, such durability data will be important to correlate with our stress analysis predictions.

Study Limitations

Our study did not take into account the crimping and ballooning process that occurs during TAVR. Crimping physically damages TAV leaflets and may weaken leaflets and increase leaflet stress.^{32,33} We did not destroy our TAV to test its leaflets for exact material properties given the rarity of obtaining TAVs and need for future TAV experimental in vitro tests. As such, we used excised leaflets from surgical bioprostheses to determine material properties for TAV leaflets.¹⁸ Although the treatment processes for both Edwards valves are expected to be the same, thinner pericardial leaflets used in TAVR may have different material properties than were represented here. The current model presents the stress on the initial implantation without the effect of degeneration over time and the material property changes. Progressive leaflet degeneration is expected to be localized and most likely starts from the locations with high stress concentrations as indicated in our current study. With more clinical evidence of TAVR leaflet degeneration, further work modeling containing time factor and material changes of degeneration would be beneficial. We studied only 1 commercial SAPIEN 3 valve because of limited availability of the clinical valve product for our research, which did not include additional sizes. The impact of valve size and

deployment on the stent and leaflet stresses were beyond the scope of this study and may be included in future studies based on valve availability. We assumed strict standards with high reproducibility and quality controls during the manufacturing of these Food and Drug Administration–approved clinical TAVs by industry such that study of more samples would not yield statistically significant results. Our detailed FEA of SAPIEN 3 provides fundamental knowledge for future studies, such as valve-in-valve implantation or comparison of SAPIEN 3 with other TAVR designs, such as the Medtronic CoreValve (Minneapolis, Minn). Valve-in-valve implantation requires patient-specific geometry of the surgical valve and deployed geometry of SAPIEN 3 within with interactions are defined between the 2 valves, which is beyond the scope of the current study. Last, complex fluid–structure interaction simulations were not incorporated and beyond the present scope of this study.

CONCLUSIONS

We determined TAV stent and leaflet stresses on the 26-mm SAPIEN 3 using micro-computed tomography scanned geometry. We demonstrated that maximum stresses occurred at the cells of the stent just below the commissure and as the struts adjoined to the commissure, whereas for leaflets, maximum stresses occurred at the leaflet commissures where they attached to the stent. These leaflet regions will likely be areas where degeneration initiates. Future comparisons with surgical bioprostheses or other TAV devices will be necessary to compare relative durability based on valve design. Nevertheless, stress magnitude differences suggest higher stresses in the SAPIEN 3 relative to surgical bioprostheses, which may affect durability.

Conflict of Interest Statement

Dr Dvir serves as a consultant for Edward Life Sciences. Dr Ge is co-founder of ReValve Med, Inc, and reports grants from the National Institutes of Health during the conduct of the study. Dr Tseng is co-founder of ReValve Med, Inc, and reports grants from the National Institutes of Health during the conduct of the study. Dr Xuan reports grants from the American Heart Association for a postdoctoral fellowship during the conduct of this study. Dr Ye serves as a consultant for Edward Life Sciences. All other authors have nothing to disclose with regard to commercial support.

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Key Words: transcatheter aortic valve, leaflet, stress, durability

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