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Leaflet stress and strain distributions following incomplete transcatheter aortic valve expansion

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ABSTRACT

Transcatheter aortic valve replacement (TAVR) is an established treatment alternative to surgical valve replacement in high-risk patients with severe symptomatic aortic stenosis. The current guidelines for TAVR are to upsize transcatheter aortic valve (TAV) relative to the native annulus to secure the device and minimize paravalvular leakage. Unlike surgical stented bioprosthetic valves where leaflets are attached to a rigid frame, TAVs must expand to fit within the native annulus. Fully-expanded circular TAVs have consistent leaflet kinematics; however, subtle variations in the degree of stent expansion may affect leaflet coaptation. The objective of this study was to determine the impact of incomplete TAV expansion on leaflet stress and strain distributions. In this study, we developed finite element models of a 23 mm homemade TAV expanded to diameters ranging from 18 to 23 mm in 1 mm increments. Through dynamic finite element simulations, we found that leaflet stress and strain distributions were dependent on the diameter of the inflated TAV. After complete expansion of the TAV to 23 mm, high stress and strain regions were observed primarily in the commissures during diastole. However, 2–3 mm incomplete TAV stent expansion induced localized high stress regions within the TAV commissures, while 4–5 mm incomplete stent expansion induced localized high stress regions within the belly of the TAV leaflets during the diastolic phase of the cardiac cycle. Increased mechanical stress and flexural deformation on TAV leaflets due to incomplete stent expansion may lead to accelerated tissue degeneration and diminished long-term valve durability.

1. Introduction

Transcatheter aortic valve replacement (TAVR) is an established and effective treatment alternative to surgical valve replacement in inoperable and high-risk patients with severe aortic stenosis (Adams et al., 2014; Leon et al., 2010; Smith et al., 2011). The use of this new treatment has rapidly spread worldwide since 2002, and to date, TAVR has been used in over 40 countries accumulating to >60,000 implantations. TAVR stands to significantly alter the paradigm from surgical to transcatheter treatment if the indications can be safely expanded to lower-risk younger patients. However, long-term durability of transcatheter aortic valves (TAVs) is currently unknown. To expand TAV technology to lower risk younger patients for whom surgical results are excellent, TAV durability must match with that of surgical bioprostheses. Therefore, proper evaluation of TAV long-term durability is crucial for potential expansion of TAVR to lower-risk patients.

Pathophysiologic mechanism of bioprosthetic tissue degeneration is multifactorial (Schoen, 2012; Schoen and Levy, 1999). Two distinct yet potentially synergistic processes that account for limited durability are widely considered to be (1) calcification and (2) non-calcific tissue degeneration (Schoen and Levy, 1999). Leaflet calcification plays a key role in the failure of bioprosthetic valves. Calcification is initiated primarily within residual connective tissue cells that were not removed by fixation procedures (Schoen, 2012; Schoen et al., 1985, 1986). Furthermore, elastin and collagen fibers can act as nucleation sites for calcium-phosphate minerals (Bailey et al., 2003; Schoen and Levy, 2005). Moreover, it is widely accepted that mechanical stress stimulates calcification by damaging the structural integrity of tissue. It has been shown that regions of calcification correlate with leaflet high stress regions (Levy et al., 1983; Schoen and Levy, 1999; Schoen et al., 1985; Thubrikar et al., 1983).

In addition to calcification, it has been shown that non-calcific tissue degeneration due to fatigue induced structural deterioration could be a cause of structural damage in surgical bioprostheses (Sacks and Schoen, 2002; Schoen and Levy, 1999). Following tissue fixation procedure, the entire extracellular matrix is highly bonded, essentially eliminates the ability for tissue fibers to slide

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relative to each other (Connolly et al., 2005; Lovekamp et al., 2006; Sacks et al., 2006; Vyavahare et al., 1999). Non-calcific damage is likely induced by shearing and fiber debonding (Sacks and Schoen, 2002). It has been shown that high stress and bending moment regions in stented bioprostheses correlate with regions of mechanical damage (Ferrans et al., 1978; Sacks, 2001; Sacks and Schoen, 2002).

Although TAV manufacturers use a similar biologic leaflets as surgical bioprostheses and therefore it would be expected to degenerate via similar mechanisms, TAV design and implantation configuration are substantially different than surgical bioprostheses (Bourantas and Serruys, 2014; Rodes-Cabau, 2012). Unlike surgical valves, the degree of TAV expansion varies from patient to patient, and depends upon annulus size and specific calcified valve geometry (Delgado et al., 2010). Furthermore, the current guidelines for TAVR are to upsize the TAV relative to the native annulus to secure the device and minimize paravalvular leakage. The range of annulus size for TAVR suggests that not all patients will achieve complete TAV expansion to the manufactured size, and some degree of incomplete stent expansion may exist (Binder et al., 2013; Schultz et al., 2009). Such alterations in the degree of stent expansion may lead to distorted leaflet coaptation which over time can negatively influence long-term durability. The impact of incomplete TAV expansion on leaflet stress distribution and ultimately long-term valve durability is not known. The objective of this study was to determine the impact of incomplete TAV stent expansion on TAV leaflet stress and strain distributions. Increased mechanical stress and flexural deformation on TAV leaflets may lead to accelerated tissue degeneration and diminished long-term durability (Ferrans et al., 1978; Levy et al., 1983; Sacks, 2001; Sacks and Schoen, 2002; Schoen and Levy, 1999; Schoen et al., 1985; Thubrikar et al., 1983). In this study, computational simulation results of incompletely expanded TAVs were compared to fully-expanded circular TAVs.

2. Materials and methods

2.1. Transcatheter aortic valve

A 23 mm TAV was created based on the Edwards SAPIEN XT valve design (Fig. 1). Three leaflets were cut from a bovine pericardium patch (Edwards Lifesciences, Irvine, CA). The lateral sides of the leaflets were sutured together and then the leaflets were sutured at the base to a Dacron Sheet. A cylindrical stainless steel stent (height 14 mm and thickness 0.34 mm) was dilated to an external diameter of 23 mm to hold the Dacron sheet and leaflets. The 23 mm TAV was crimped and balloon-expanded to diameters ranging from 18 to 23 mm in 1 mm increments. A pre-drilled acrylic template was used to precisely expand the valve to the desired diameters (Fig. 2). TAV leaflet geometry was then obtained using NextEngine 3D Laser Scanner. Subsequently, surface reconstruction was performed using RapidWorks and SOLIDWORKS packages.

2.2. Biaxial testing system

A planar biaxial stretching system (CellScale, Waterloo, Canada) was used to determine mechanical properties of the bovine pericardium patch (Fig. 3). Three square samples were cut from the pericardium patch. Sample orientation was aligned such that the circumferential edge of the square samples was parallel to the free edge of the TAV leaflets. The circumferential and longitudinal directions were considered as x and y directions, respectively. Specimen dimensions and thicknesses were measured using Mitutoyo Digital caliper, and were stored in normal saline solution.

To obtain mechanical properties, the specimens were mounted on the biaxial system using a set of four CellScale BioRakes. The biaxial system equipped with two Honeywell 1000 g load cells located on two orthogonal arms. The load cells were zeroed after mounting the specimen. A temperature-controlled normal saline bath heated to 37 °C provided a physiological environment. The top sides of tissue samples were sprinkled with graphite to create a textured surface for strain measurements. Real-time displacement of the graphite markers was obtained at a rate of 15 Hz using a camera placed over the top surface. Specimens were examined using the following equibiaxial displacement controlled protocol. First, 10 preconditioning cycles of 10% true strain were applied on both axes at 0.5 Hz. Subsequently, each specimen was stretched to 100% strain on both axes with a 5 s stretch and a 5 s recovery. Furthermore, CellScale LabJoy image tracking software was used to obtain strain maps of the samples.

2.3. Constitutive modeling

Soft tissues are mostly comprised of water (Fung, 1993); therefore, the pericardium samples were considered to be incompressible. Planar forces (F_{xx}, F_{yy}) measured by the two load cells were used to calculate Cauchy stresses (T_{xx}, T_{yy}) in the circumferential and longitudinal directions.

$$T_{xx} = \lambda_x \frac{F_{xx}}{t_0 l_{x0}} \tag{1a}$$

$$T_{yy} = \lambda_y \frac{F_{yy}}{t_0 l_{y0}} \tag{1b}$$

where t_0 is tissue thickness in the zero stress state, and $\lambda = l/l_0$ is stretch ratio which represents the ratio of deformed tissue length (l) to resting length (l_0). Components of Green strain (E) were calculated using the following equations:

$$E_{xx} = \frac{1}{2}(\lambda_x^2 - 1) \tag{2a}$$

$$E_{yy} = \frac{1}{2}(\lambda_y^2 - 1) \tag{2b}$$

A four parameter Fung's exponential strain energy function was fitted to the stress–strain data (Fung et al., 1979).

$$W = \frac{C}{2}\left(e^Q - 1\right), \quad Q = c_{xx}E_{xx}^2 + 2c_{xy}E_{xx}E_{yy} + c_{yy}E_{yy}^2 \tag{3}$$

where E_x and E_y are the Green strains in x and y directions, respectively. c_{xx}, c_{yy}, c_{xy}, and c are the material constants. Cauchy stresses can be obtained by the following equations:

$$T_{xx} = \lambda_x^2 (c_{xx}E_{xx} + c_{xy}E_{yy}) C \exp(Q) \tag{4a}$$

Fig. 1. (Left) Edwards SAPIEN XT valve. (Center and right) Side and top view of homemade 23 mm transcatheter aprotic valve; leaflet geometry was based on the SAPIEN XT valve design.