Factors Impacting Leaflet Coaptation and Durability in Prosthetic Heart Valves

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Abstract

The treatment of Aortic regurgitation using TAVR has not met with excellent outcomes that TAVR did with Aortic stenosis treatment due to differences in patient anatomies, and manifestation of the disease at the native valve annulus. With exception of JenaValve device which relies on proprietary clipping mechanism to anchor the valve, off-label use of TAVR devices that are otherwise indicated for use only to treat AS disease, relied on valve-in-valve for anchoring to prevent paravalvular leakage and valve embolization. The under-expansion of the inside valve due to stiffness and geometry of the outside valve has an impact on leaflet coaptation leading to additional stresses on the leaflets and decreased durability. This article explores the stent frame and leaflet design considerations and their impact on valve durability in AR patient anatomies that rely predominantly on valve-in-valve configuration for anchoring.

Introduction

Aortic regurgitation (AR) disease is prevalent in 4.9% of the population which is primarily caused by the malfunction of valve leaflets, by aortic root dilation or a combination of these factors[1]. Although Transcatheter aortic valve replacement (TAVR) has demonstrated excellent outcomes in patients with Aortic stenosis (AS), this cannot be directly translated to TAVR in AR[2]–[4]. This is primarily because of differences in patient anatomies between AS and AR, and also the lack of rigid anchoring zone for valve deployment in AR[5]. While there are a few TAVR devices like JenaValve that are indicated to specifically treat AR patients[6], handful of TAVR devices are used off-label to treat AR. The off-label devices had varying degrees of success in treating patients with AR due to lack of rigid frame of calcium at the annulus that is commonly seen in AS for valve anchoring. Predominantly, the off-label use of several devices has been in the application of implanting them in valve-in-valve (ViV) configuration[7]. However, the cons of using TAVR valve in ViV configuration is inadequate expansion of the newly implanted valve due to the stiffness and geometrical constraints of the outside prosthetic valve. The physicians sometimes also rely on oversizing the TAVR devices to overcome inadequate expansion with mixed outcomes, however there is no specific recommendation on oversizing from the manufacturers to treat AR[5]. Also, another unintended impact of ViV is lack of adequate leaflet coaptation leading to pinwheeling effect where the leaflets overhang on each other causing additional leaflet stresses and strains which could impact its durability[7]. In this article we focus on exploring the impact of stent frame design on leaflet coaptability and its implications on valve durability. A case study to explore the aspect...
of leaflet coaptability in two (2) novel designs for the stent frame with constant oversizing of 10% is presented to illustrate the impact of stent frame design on leaflet coaptability. Furthermore, leaflet design changes that improve the leaflet coaptability to address pinwheeling effect and to reduce stresses in the chosen stent frame design are also discussed.

Materials and Methods

CAD and material models

Nitinol Stent

The stent frame designs used for the analysis presented in this paper is based on the design discussed in detail in this article[8]. The stent frame design 1 is unchanged from the previous article, while stent frame design 2 excludes the open cells between valve commissures. Design 2 was perceived to allow for easy coronary access and optimized radial stiffness to minimize the stresses on the aortic root (See Figure 1). The referenced article [8] has further details on the geometrical parameters of the stent frame and the uniaxial properties of the Nitinol (Ni50.8 Ti49.2) material used.

Leaflets

The geometry of the leaflets used is same as the one reported in the referenced article[8]. Both stent frame designs 1 and 2 used the same initial leaflet design (Figure 2) which was perceived to being able to optimally conform to transvalvular hemodynamics with minimal stresses during different cardiac phases. Besides leaflets, both designs also included tissue covering the diamonds between the leaflets and the annulus section referred to as inner skirt (Figure 3). The mechanical properties, fixation method used for the porcine pericardium used for the leaflets, and the inner skirt is detailed in the referenced article[8].

Aortic root model

For this analysis, an aneurysmal aorta with root dilatation as reported in Morganti et.al article [9], with ventricular-aortic junction diameter (Da) of 30 mm was chosen. Further details on the anatomical parameters used for the aortic root’s CAD model are discussed in detail in the referenced article[8]. This model chosen was only used as representative geometry for the aortic root in contact with the stent near the basal plane, and the analysis of the aortic root is not included in the scope of the study reported in this article.

Finite Element modeling and Loading

The element type used for meshing of each of the components, and the boundary conditions to fully define the assembly is identical to those of the referenced article[8]. Also, for the loading conditions, 10% oversizing for anchoring in the native annulus, pressure gradients experienced by the valve during systolic/diastolic phases of the cardiac cycle, and distention radial displacement to represent reduction in annual diameter between systolic to diastolic phases of the heart were used identical to those detailed in the reference article[8].

Figure 1: Stent Frame-Design 1 and Design 2

Figure 2: Leaflet Geometric Profile

Figure 3: THV assembly (Stent frame with leaflet and skirt)
Results and Discussion

Figure 5 illustrates the radial displacement in leaflets in stent frame designs 1 and 2 during the diastolic cardiac phase. The radial displacements are higher in design 2 compared to that of design 1, due to lower stent frame stiffness causing it to deform more which results in higher displacements in the leaflets as well. Figure 5 also illustrates the contact opening (COPEN), also referred to as coaptation depth, between the leaflets in the 2 designs during the diastolic cardiac phase. This COPEN value measures the clearance between the leaflet contacts which is shown to be higher in design 2 compared to design 1. The higher leaflet coaptation depth in design 2 increases the radial displacements leading to improper leaflet coaptation causing phenomenon referred to as leaflet “pinwheeling” effect. The pinwheeling effect is described as a situation in which leaflets twist and overhang over each other during valve closure. This effect is associated with higher stresses in the leaflets leading to their early degeneration[7], [10].

Other effects of leaflet pinwheeling include durability, transvalvular leakage, and a higher degree of stresses on the leaflets which affects its fatigue life. To address the issue of pinwheeling observed in stent frame design 2, the case study was extended to identify leaflet modifications that could minimize the effect of this phenomenon. Several experimental runs were conducted in Finite Element Analysis (FEA) to identify a leaflet configuration in combination with stent frame design 2 to minimize the pinwheeling effect. Figure 7 illustrates the new leaflet design and its visual comparison when used with stent frame design 2.

After subjecting the new valve design (new leaflets with stent frame design 2) to identical loading conditions as with the previous iterations of valve designs, the resultant leaflet coaptation profile (Figure 8) is shown to have reduced the pinwheeling effect. Leaflet coaptation depth measurement also indicated that the coaptation depth reduced by 78% indicating the reduction in the extent of leaflet overhang on each other. Figure 9 also indicates that when the leaflet free margin length is reduced in the modified design by 4%, the maximum stress on the leaflets is reduced by 18% indicating potential for longer durability of modified leaflet with stent frame design 2 compared to that of previous leaflet design. However, further design optimization is needed to prevent any potential transvalvular leakage across the valve. This analysis was executed with an underlying oversizing of 10% with respect to native annulus perimeter, and the impact of
oversizing on the pinwheeling effect is outside the scope of this investigation.

Figure 8: Modified Leaflet vs Current Leaflet comparison

Figure 9: Von-mises stress comparison of leaflet designs

Conclusion

The off-label use of TAVR valves in ViV configuration results in inadequate expansion of the inside prosthetic valve due to stiffness and geometry of the outside valve. Although this configuration addresses the problem of valve embolization in AR patients with no calcification of leaflets for anchoring, under-expansion causes the TAVR device to have improper coaptation of leaflets due to increase in their free margin. The case study presented in this article explores the impact of 2 stent frame designs at constant oversizing of 10% on leaflet coaptation and pinwheeling effect. The stent frame design 2 with lesser radial stiffness, and higher accessibility for future coronary intervention is shown to have greater pinwheeling effect and corollary effect of reduced leaflet durability in the valves. However, design modification to decrease leaflet margin by 4% has minimized the bending stresses in the leaflets by 18% reducing the impact of pinwheeling and improving valve durability. Therefore, TAVR valve design for specifically treating AR disease condition also needs to focus on the impact of stent frame design and leaflet design on overall durability of the leaflets in the aortic valves.

Conflict of Interests

The authors declare no conflict of interest.

References