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Structural simulations of prosthetic tri-leaflet aortic heart valves

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Abstract

This study presents a combined computational and experimental approach for the nonlinear structural simulations of polymeric tri-leaflet aortic valves (PAVs). Nonlinear shell-based and quasi-static finite-element (FE) structural models are generated for a prosthetic valve geometry that includes the leaflets, stents and root materials, such as the bottom base and outside walls. The PAV structural model is subject to an ensemble averaged transvalvular pressure waveform measured from repeated *in vitro* tests conducted with a left heart simulator. High-resolution optical measurements are used to measure the *in vitro* kinematics of the leaflets and the stents. Qualitative and quantitative deformation measures are defined in order to compare the predicted kinematics from the PAV models with the *in vitro* measurements. Six new quantitative deformation metrics are introduced. They include three distances measuring the current PAV geometric center to the leaflet edges while additional three distances define the stent post-to-stent post (SPTSP) distances. The structural model is able to predict the kinematic deformation metrics with maximum errors around 10% especially in systole where the displacements are larger in magnitude. The combined structural modeling with experimental simulations along with the new proposed deformation metrics provide an effective way to study the PAV structural behavior and a path for improving the structural design of prosthetic valves.

Keywords: Heart valves; Polymeric aortic valves; Tri-leaflet; Structural FE simulation; *In vitro* testing; Nonlinear leaflet behavior

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1. Introduction

Computational mechanical models for the material and structural behavior of the aortic valve (AV) systems (both prosthetic and native) are important in order to better understand their response under normal and diseased states. Polymeric tri-leaflet aortic valve designs are currently advocated because they can provide a hemodyanmic performance comparable to bio-prosthesis and their durability seems to be comparable to current mechanical prosthesis. Like the bioprosthetic valves, their geometry also closely resembles the native AV and thus offers better flow profiles. Furthermore, since they are made of synthetic material, improved designs by introduction of new reinforced polymeric materials for the leaflets is possible. The main problem in new PAVs, however, is that data on long-term durability (service) of these new designs is still unavailable and many industrial studies are considered proprietary. In the absence of long-term data and experience with polymeric tri-leaflet valves, accurate structural simulations and modeling become an integral part in the assessment, design and future development. Current sophisticated computational mechanics tools have the potential to generate predictive AV models that help account for structural damage during service conditions, e.g. clotting, mineralization and material fatigue. This will ultimately lead to better and accelerated future designs.

Three-dimensional structural computational models of rubber or polymeric-based fiber reinforced AVs have been studied by De Hart et al. (1998) and Liu et al. (2007). The former examined the maximum principal stress in rubber fiber reinforced AVs and compared the results with unidirectional and sinusoidal oriented fiber models, while

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the latter studied the effect of different fiber orientations from 0° to 90° and number of composite plies on the stress reduction of a polymeric leaflet reinforced with polypropylene fibers. Stentless fiber reinforced AVs have also been proposed to reduce the large flexural stresses on the leaflet surfaces Cacciola et al. (2000). The latter studied the stentless AV structural behavior using 3D FE models. They showed that the maximum principal stress values are reduced compared to AV model with stent. Studies with biaxial stress–strain tests were also conducted to understand the mechanical tissue response under more realistic stress conditions (Sacks, 1999; Mayne et al., 1989). Several nonlinear constitutive models have been proposed using higher order strain-energy density function in terms of the strain (stretch) invariants. Uniaxial and biaxial test data were used to calibrate the anisotropic constitutive model with the goal to predict the behavior of general multi-axial states of deformations (Lanir, 1983; Sacks, 2000a,b; Sun et al., 2003). Kim et al. (2007) have provided a shell-based FE model for a bioprosthetic AV with bovine leaflets using the well-known FEAP (Taylor, 2007), nonlinear shell formulation. Their approach included using biaxial test stress–strain responses (in-plane stress) and three-point bending to calibrate the nonlinear stress-resultant behaviors of the FE shell cross-sections. The calibrated in-plane and three-point tests showed excellent agreement with their FE results for the stress paths provided by their fitted approach. However, it is not clear how their calibrated FE shell would have response for more general loading cases at the element level. The calibrated shell element was used to construct a full AV structural model that included the three leaflets without stents and showed only limited qualitative results for the leaflet configurations during systole. Bovine pericardial Bioprosthetic Heart Valve (BHV) was studied experimentally and simulated under quasi-static loading system (40, 80, and 120 mmHg) (Sun et al., 2005). Different degrees of anisotropy due to chemical treatments were considered in the simulations in order to examine their effect on the mechanical behavior of leaflets using the strain as a measure.

In this paper, we present a refined structural modeling approach to predict the mechanical behavior of stented tri-leaflet polymeric heart valves under physiological loading. Our approach is unique and novel compared to those mentioned above in the sense that the model uses the *in vitro* pressure measurements only as the loading on the valve. We hypothesize that 3D qua-sistatic structural models of polymeric AV systems, with applied transvalvular pressure, can predict the overall (structural level) temporal kinematic responses. Although, the valve system is truly a coupled fluid structures problem, we investigate the adequacy of the "first order" coupling where only the pressure field is used as the loading. As will be demonstrated in this paper, using only pressure as loading on the structural model gives excellent comparisons to *in vitro* measurements of the leaflet kinematics. In doing so, we also define new deformation measures of major points on the AV structure that can be used as metrics of structural performance. Detailed test result and comparison with experimental observations of leaflet and stent kinematics are presented and discussed.

2. Methods

2.1. Aortic valve system

Polymeric heart valves in an *in vitro* environment were chosen over tissue prostheses as a basis for code development and validation. A detailed fluid mechanical assessment of the polymeric valve used in this study has already been published by our laboratory (Leo et al., 2006). Therefore, this paper not only introduces a new structural simulation scheme but also builds on the existing biomechanical data available on polymeric valves by providing important structural mechanics information on these types of valves. The studied valve was a prototype design provided by AorTech Europe with leaflets manufactured from high silicone content polyurethane copolymers (Elast-EonTM) and the valve frame and stents were machined from PEEK (poly-etheretherketone). The valve is shown in Fig. 1. The valve is a 23 mm valve with the leaflets 80 μm thick and mounted onto flexible stents that lead to a circular orifice during forward flow. As can be seen in the Fig. 1, the leaflets had a semi-open position in the zero loaded state.

2.2. Proposed structural model

The nonlinear general purpose implicit finite-element (FE) (ABAQUS©) code was used in the structural modeling of the aortic valve system described above. Nonlinear material behavior is used for the polymeric leaflets in order to obtain accurate deformations and stress fields. Contact formulation was included in the models, which allow capturing the dynamic "bounding" effect between the leaflets at valve closure. The analyses generated were quasi static with a prescribed physiological transvalvular pressure measured from the *in vitro* experiments. Detailed formulation of the nonlinear FE can be found in several advanced FE and computational mechanics books (Bathe, 1996; Belytschko et al., 2000; Crisfield 1991; Simo and Hughes, 2001;Taylor, 2007).

The geometry of the FE model was generated following a typical natural valve geometry parameters (Thubrikar, 1990). Our polymeric aortic valve model is composed of a stent with diameter of 23 mm and

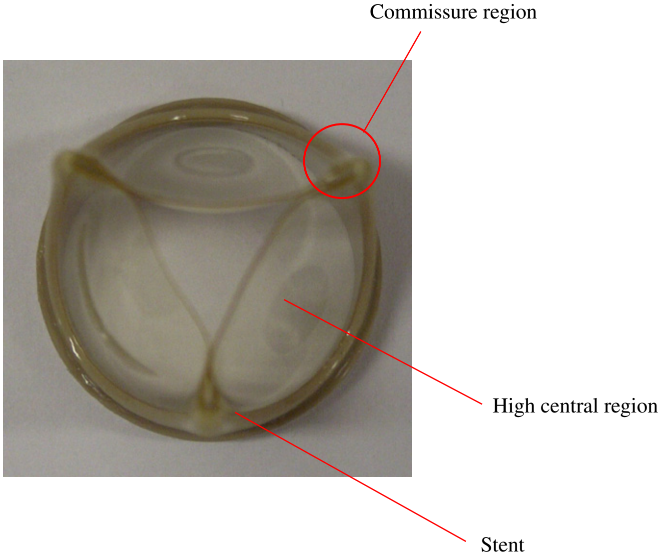

Fig. 1. Tri-leaflet polymeric aortic heart valve tested to verify the proposed modeling approach.