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High resolution three-dimensional strain mapping of bioprosthetic heart valves using digital image correlation

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ABSTRACT

Transcatheter aortic valve replacement (TAVR) is a safe and effective treatment option for patients deemed at high and intermediate risk for surgical aortic valve replacement. Similar to surgical aortic valves (SAVs), transcatheter aortic valves (TAVs) undergo calcification and mechanical wear over time. However, to date, there have been limited publications on the long-term durability of TAV devices. To assess longevity and mechanical strength of TAVs in comparison to surgical bioprosthetic valves, three-dimensional deformation analysis and strain measurement of the leaflets become an inevitable part of the evaluation. The goal of this study was to measure and compare leaflet displacement and strain of two commonly used TAVs in a side-by-side comparison with a commonly used SAV using a high-resolution digital image correlation (DIC) system. 26-mm Edwards SAPIEN 3, 26-mm Medtronic CoreValve, and 25-mm Carpentier-Edwards PERIMOUNT Magna surgical bioprosthesis were examined in a custom-made valve testing apparatus. A time-varying, spatially uniform pressure was applied to the leaflets at different loading rates. GOM ARAMIS[®] software was used to map leaflet displacement and strain fields during loading and unloading. High displacement regions were found to be at the leaflet belly region of the three bioprosthetic valves. In addition, the frame of the surgical bioprosthesis was found to be remarkably flexible, in contrary to CoreValve and SAPIEN 3 in which the stent was nearly rigid under a similar loading condition. The experimental DIC measurements can be used to characterize the anisotropic material behavior of the bioprosthetic heart valve leaflets and validate heart valve computational simulations.

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1. Introduction

Transcatheter aortic valve replacement (TAVR) is an alternative therapy for patients with severe aortic stenosis deemed at high- and intermediate-risk for surgical aortic valve replacement (SAVR) (Adams et al., 2014; Leon et al., 2010; Smith et al., 2011). TAVR has been widely used worldwide since 2002, and to date more than 200,000 patients have undergone this minimally invasive and life-saving procedure (Seidler et al., 2017). TAVR has the potential to change the paradigm from SAVR to TAVR in low-risk younger patients with aortic valve stenosis. However, there are currently limited clinical data available regarding the long-term durability of the commercially available transcatheter aortic valves (TAVs) (Dvir et al., 2016). Furthermore, unlike surgical bioprostheses, the

primary failure mechanism of TAV is not known and should therefore be investigated. In surgical bioprosthetic heart valves, leaflets degenerate through two distinct but potentially synergistic mechanisms: (i) calcification and (ii) fatigue-induced structural deterioration (Schoen et al., 1985; Schoen, 2012). It has been demonstrated that high stress regions in stented surgical bioprostheses correlate with regions of mechanical deterioration and calcification (Ferrans et al., 1978; Sacks and Schoen, 2002). Since the commercially available TAV leaflets are made from chemically treated bovine or porcine pericardium tissue, it can be postulated that the structural deterioration of TAVs occurs via the two failure mechanisms.

To assess longevity of the currently available TAVs and develop the next generation of heart valve prostheses, in-depth comparison and assessment of strain and stress of the leaflets is essential. Numerous computational models have been developed to determine stress and strain distribution of the bioprosthetic heart valve leaflets under physiological loading conditions (Abbasi et al., 2016; Gunning et al., 2014; Hsu et al., 2015; Martin and Sun, 2015). In the

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computational simulations, considering robust and accurate constitutive models for the leaflets is of the utmost importance (Holzapfel and Ogden, 2009; Humphrey, 2003). As a result, experimental validation of the computational models should be an indispensable step to confirm the accuracy and reliability of the simulations (Abbasi et al., 2016). Due to the limited temporal and spatial resolution of the currently available imaging modalities in real-world in vivo clinical cases as applied to bioprosthetic heart valves, in vitro experimental testing of the bioprostheses provides a viable alternative to characterize soft tissue mechanical properties and validate the computational simulations. High-resolution optical measurements can be regarded as an appropriate non-invasive in vitro measurement technique to assess the deformation of the leaflets and determine the strain field. A suitable and accurate optical measurement technique is three-dimensional digital image correlation (DIC) technique which becomes more readily available and more widely used in experimental mechanics (Chu et al., 1985; Luyckx et al., 2014; Palanca et al., 2015; Rogge et al., 2005; Sun et al., 2005). The DIC technique is particularly suited for determination of TAV leaflet deformation due to its high temporal and spatial resolution (Heide-Jørgensen et al., 2016). The goal of this study was to perform a side-by-side comparison of leaflet displacement and strain fields of three commonly used bioprosthetic heart valves: (i) Carpentier-Edwards PERIMOUNT Magna surgical bioprosthesis, (ii) Medtronic CoreValve, and (iii) Edwards SAPIEN 3 using a high-resolution DIC system. The obtained results can be used to characterize the anisotropic material behavior of the leaflets and validate computational models of the commercially available bioprosthetic valves.

2. Materials and methods

In this study, three different bioprosthetic heart valves with comparable size were investigated (Fig. 1). The first bioprosthetic

valve was a 25-mm Carpentier-Edwards (CE) PERIMOUNT Magna aortic heart valve (Edwards Lifesciences, CA, USA). The surgical bioprosthetic valve consists of bovine pericardium leaflets mounted on an Elgiloy frame. The internal diameter of the frame is 24 mm. The second bioprosthesis was a self-expanding 26-mm Medtronic CoreValve (Medtronic, Minneapolis, MN, USA), constructed from porcine pericardial leaflets mounted on a self-expanding Nitinol stent. The third bioprosthetic valve examined in this study was a 26-mm Edwards SAPIEN 3 (Edwards Lifesciences, Irvine, CA, USA). The TAV is made from bovine pericardial leaflets mounted on a balloon-expandable cobalt-chromium stent. The thicknesses of the bioprosthetic heart valve leaflets were measured using a Mitutoyo Digital caliper. The average thickness of the leaflets of the PERIMOUNT Magna, Medtronic CoreValve, and Edwards SAPIEN 3 bioprostheses was 0.56 mm, 0.43 mm, and 0.32 mm, respectively.

For DIC measurements, graphite (synthetic powder, <20 μm , Sigma-Aldrich, St. Louis, MO) was applied to the top side of the leaflets to achieve a speckled pattern (Fig. 2). Graphite was used due to its negligible effect on the mechanical properties of soft tissue as compared to ink dyes, verified by planar biaxial testing of bovine pericardial patch. To create a suitable stochastic pattern, graphite was applied multiple times to the top side of the leaflets. Subsequently, the valves were stored in normal saline solution at the room temperature prior to the DIC measurements. All the DIC measurements were conducted in an in vitro test setup comprised of an optically clear acrylic chamber, peristaltic pump, pressure transducer, and data acquisition system (Fig. 3A). The valves were mounted inside the chamber using a silicone washer on a custom-made fixture fabricated by U-Print SE Plus 3D printer (Stratasys Ltd., MN, USA). A Masterflex peristaltic pump (Cole Parmer Instrument Co., Chicago, IL, USA) was used to fill the valve housing and apply uniform pressure within the chamber. The bioprosthetic valves were submerged fully in the chamber and care was taken to make sure no air bubbles remain in the chamber.



Fig. 1. (Left) 25-mm surgical Carpentier-Edwards PERIMOUNT Magna Pericardial bioprosthetic aortic valve. (Center) 26-mm self-expanding Medtronic CoreValve. (Right) 26-mm ballooned expandable Edward SAPIEN 3 transcatheter heart valve.

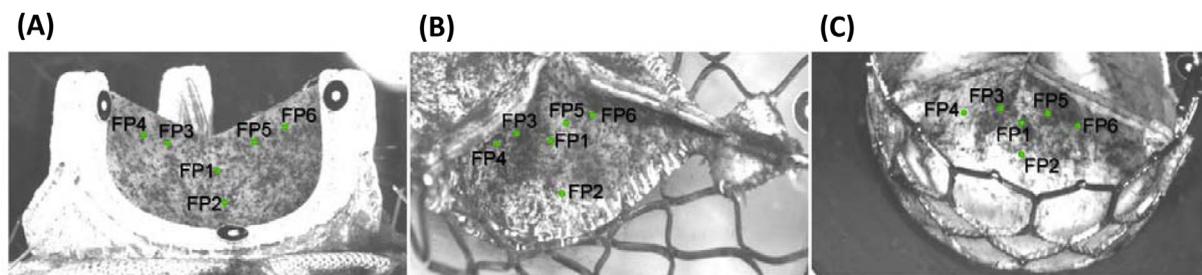


Fig. 2. Example of speckled pattern and facets points that were used for post processing of the experimental data. (A) 25-mm surgical Carpentier-Edwards PERIMOUNT, (B) 26-mm Medtronic CoreValve, and (C) 26-mm Edward SAPIEN 3.

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