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Radial force and expansion behavior of an elliptical transcatheter aortic valve replacement in a bicuspid aortic valve

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Abstract: Transcatheter Aortic Valve Replacement (TAVR) is a widely used treatment for severe aortic stenosis, particularly in patients with a high surgical risk. Although initially designed for tricuspid aortic valves (TAV), its use in bicuspid aortic valves (BAV) presents unique challenges due to anatomical variations and extensive calcifications, which can hinder optimal stent expansion.

In this study, a prototype of an elliptical TAVR stent was produced. Radial force measurements were carried out to calibrate the simulation model. In addition, the deployment behaviour of this elliptical TAVR stent was investigated in a patient-specific bicuspid aortic valve geometry with severe calcification. Finite Element (FE) simulations were conducted to analyze the crimping and expansion process of an elliptical TAVR stent. Expansion behavior and radial force behavior were compared with a conventional circular stent design. The simulation results demonstrate that both stents exhibit elliptical deformation due to calcification-induced constraints. However, the elliptical stent experiences less deformation in the narrowest regions, potentially reducing leaflet stress and improving valve function. The elliptical design may enhance the long-term durability of the artificial valve.

The findings highlight the potential benefits of elliptical TAVR stents for bicuspid anatomies. Further investigations, including large-scale *in silico* studies are necessary to optimize stent design and improve clinical outcomes for bicuspid valve patients.

Keywords: TAVI, Finite Element Analysis, Bicuspid Aortic Valve, Radial Force

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1 Introduction

Transcatheter Aortic Valve Replacement (TAVR) has become an established procedure for treating severe aortic valve stenosis, particularly in patients with a high surgical risk. While originally developed for patients with a tricuspid aortic valve (TAV), TAVR has also been used in selected bicuspid aortic valve (BAV) patients in recent years, although surgical intervention remains the recommended treatment. Despite the challenges associated with BAV in TAVR procedures, initial studies have shown promising results [1]. However, further optimization of TAVR stents is necessary, particularly for bicuspid patients.

One major challenge is that conventional TAVR prostheses often exhibit incomplete expansion in BAV cases, as demonstrated both clinically and numerically [2]. This incomplete expansion can impact not only the long-term durability of the valve but also leads to pathophysiological flow conditions [3]. To address this issue, Helbock et al. proposed eccentric leaflet designs for BAV treatment [4]. Their numerical study demonstrated that the new leaflet design improved both the geometric and effective orifice area while also reducing leaflet loading. Beyond leaflet modifications alternative stent geometries have also been explored. Shen et al. introduced a TAVR system with an elliptical cross-section instead of a conventional circular one [5]. Their study employed numerical simulations to evaluate the implantation of an elliptical TAVR prosthesis in a bicuspid aortic root. Bicuspid aortic valves exhibit different morphological subtypes. According to Sievers et al., these subtypes are classified based on the number of raphes present: Type 1 BAVs have a single raphe, while Type 2 BAVs have two rahpes [6]. The BAV studied in Shen et al. had only two leaflets and no raphe, classifying it as a Type 0 BAV. Their findings showed that reducing the stent's ellipticity relative to the annulus improved implantation outcomes by minimizing paravalvular leakage, reducing wall stress, and enhancing post-TAVR stent shape.

Building on these findings, the current study investigates the expansion behavior of an elliptical TAVR stent in a calcified patient-specific BAV geometry. Unlike Shen et al. [5], the present study focuses on a tricommissural bicuspid aortic root with extensive calcifications on two leaflets, significantly restricting their mobility. An elliptical TAVR stent prototype was produced and radial force measurements were used to calibrate the material model.

2 Materials and methods

2.1 Prototype manufacturing and testing

A TAVR stent prototype with an elliptical shape (semi-major axis a = $14\,\mathrm{mm}$ and semi-minor axis b = $10.5\,\mathrm{mm}$) was produced for the investigations, see Figure 1, **A** and **B**. This corresponds to an eccentricity of 0.25 and a hydraulic circular diameter of $23.9\,\mathrm{mm}$. The stent was cut with a fs-laser system

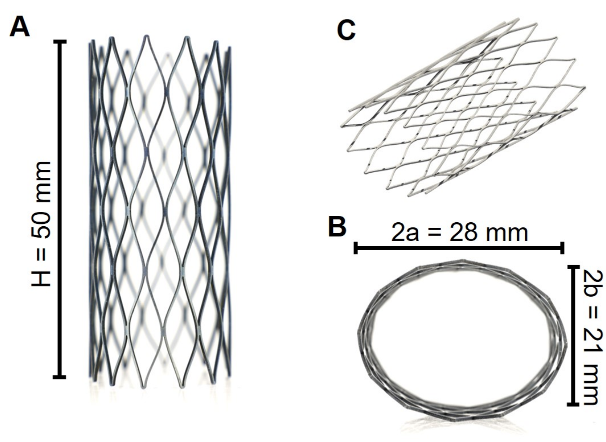

Fig. 1: Prototype of the elliptical TAVR stent (**A** and **B**) and reconstructed 3D model (**C**)

(StarCut Tube, Coherent, Inc., Santa Clara, California, USA) utilizing a Nitinol-tube (diameter: $7\,\mathrm{mm}$ and wall thickness: $500\,\mathrm{\mu m}$) and then annealed in three steps. The first two annealing tool had a circular cross-section, while only the final annealing step shaped the stent into its elliptical form. This stent was scanned using micro computed tomography (Skyscan1273, Bruker Corporation, Billerica, Massachusetts, USA) at a resolution of $15\,\mathrm{\mu m}$ to obtain the final 3D geoemtry, see Figure 1, **B**. A line body model was generated from the strut centers, serving as the basis for the Finite Element (FE) simulations.

Radial force testing of the prototype was conducted at $37\,^{\circ}\mathrm{C}$ using a radial force tester with an iris diaphragm (TTR 2 and Large-Twin Cam Station RLU248, Blockwise Engineering LLC, USA) and a testing speed of $0.1\,\mathrm{mm\,s^{-1}}$. Radial force measurements were performed over three cycles, during which the TAVR stent was crimped to a diameter of $14\,\mathrm{mm}$ and subsequently expanded. A final single cycle involved crimping the stent to a diameter of $6\,\mathrm{mm}$.

2.2 Deployment Simulation

A FE simulation of the crimping and expansion process was conducted to determine the material parameters of Nitinol, according to Finotello et al. [7]. In accordance with the radial force measurements, the stent was crimped by a radial displacement of ten plates and then released. The stent was centrally positioned between the plates, consistent with the experimental measurements. To reduce computation time, beam elements were used in the calculations. A circular cross-section was assumed, with a moment of inertia equivalent to that of the actual rectangular strut. This assumption has already been confirmed in earlier studies [8]. To prevent rigid body movement, the TAVR stent was blocked at one node in the axial and tangential direction.

The experimentally measured force-diameter curves were compared with the simulation results, and the material parameters were iteratively adjusted until a good match was achieved.

Subsequently, the TAVR stent model was deployed in a synthetic bicuspid patient to analyze its expansion behavior. For comparability with a conventional circular stent, analog simulations were performed for a circular stent with a diameter of $26\,\mathrm{mm}$. The deployment simulation followed the methodology established in our previous work [9, 10]. In brief, the TAVR stent was crimped by a radial displacement of twelve circumferentially arranged plates and then released in the aortic root. Both stents were implanted approximately half a cell height below the annulus level. The elliptical stent was aligned to ensure that the semi-major axis was parallel to the calcified and connected leaflets. The aortic root geometry was created with a virtual cohort generator [11] and extended by a patient-specific calcification [12]. The material properties for the aortic root and leaflets were taken from Bosi et al. [13], while the values for calcification were obtained from Morganti et al. [14]. The simulations were carried out using Abaqus/Explicit 2023 (Dassault Systèmes, Vélizy-Villacoublay, France).

For comparability of the implantation results, the eccentricity was calculated using the formula:

[1 - (semi-minor axis / semi-major axis)] [5].

In addition, the changes in length of the connections between the three attachment points AP1 to 3 were also calculated. The distance between AP 1 and 2 is designated as L12, and analogously for the other attachment points. Since we only performed a stent simulation, this metric will allow us to predict the possible post-TAVR leaflet deformation.

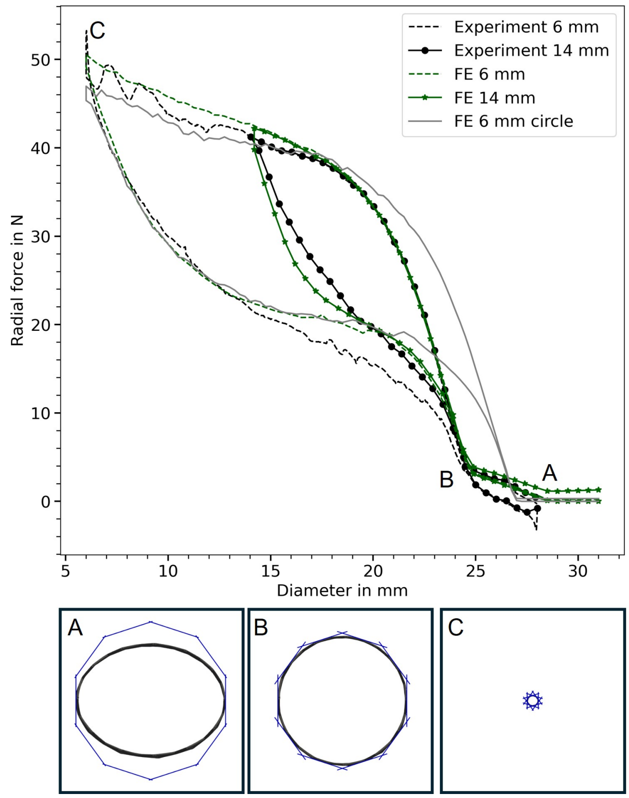

Fig. 2: Experimentally and numerically obtained radial force of the elliptical TAVR stent compared to a circular stent.

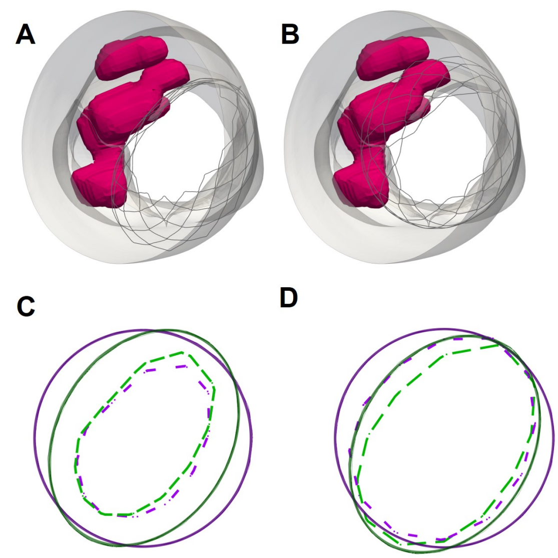

Fig. 3: Implantation result in a calcified (pink) bicuspid, synthetic patient of the elliptical stent **A** and circular stent **B**. Cross-sections of the expanded elliptical (green) and circular (purple) stents at the narrowest point **C** and at the level of the possible attachments **D**.

3 Results and discussion

The results of the radial force measurement and the FE simulation are shown in Figure 2. Initially, the force increases only slightly until the elliptical stent adopts a circular shape (see Figure 2, **B**) and comes into full contact at a diameter of $24.7\,\mathrm{mm}$, after which the force rises significantly. This characteristic is observed for the two crimp diameters $14\,\mathrm{mm}$ and $6\,\mathrm{mm}$. In comparison, the circular TAVR stent is in full contact from the beginning, leading to an immediate increase in force. The larger diameter of the circular TAVR stent displays in the force increase at approximately $26\,\mathrm{mm}$ in diameter.

The results of the deployment simulation are shown in Figure 3. The deformed geometry in the annulus region and around the calcified native leaflets is very similar for both stent designs (see Figure 3, **C**). In both cases, complete expansion is hindered by severe calcification, leading to an elliptical expansion. The eccentricities at the narrowest point are 0.41 for the elliptical and 0.34 for the circular TAVR. At the level of possible attachements, the eccentricity is higher for the elliptical stent (0.36) than for the circular stent (0.21). The displacements of the attachment points in relation to each other are shown in Figure 4. The greatest changes in length occur between attachment point AP1 and AP2. The length L12 reduced by $16\,\%$ for the circular stent, and by $11\,\%$ for the elliptical stent. The length L31 is reduced by only $2\,\%$ in both cases. L23 is shortened by $6\,\%$ for the elliptical stent and $11\,\%$ for the circular stent. The elliptical stent therefore deforms less than the circular stent compared to the initial position. Since the circular stent is larger, it expands further above the valve level (see Figure 3, **D**). The radial forces of commercial TAVR stents extend over a wider range. The TAVR used here has a lower radial force than the Corevavle Evolut 26 (Medronic plc, Dublin, Ireland) ($35.4\,\mathrm{N}$ vs.$75.2\,\mathrm{N}$ at a diameter of $20\,\mathrm{mm}$), but comparable to the Symetis Acurate Neo size Small (Boston Scientific Corporation, Marlborough, Massachusetts, USA) ($35.7\,\mathrm{N}$ at a diameter of $20\,\mathrm{mm}$) and Portico size 25 (Abbott Laboratories, North Chicago, Illinois, USA) ($32.7\,\mathrm{N}$ at a diameter of $20\,\mathrm{mm}$)[7]. Due to the initial eccentricity of 0.25, the elliptical stent experiences less deformation at the narrowest regions compared to the circular stent. Even if the eccentricity increases with both stents, the change is less pronounced with the elliptical stent. As a result, leaflet stress could be reduced, potentially improving the opening and closing behavior of the valve. It has already been shown in several studies that the ellipticity of the stent and the resulting deformation of the leaflets increases the stresses within the leaflets [3, 15]. Helbock et al. was able to show that asymmetric leaflets in a circular TAVR after implantation in a bicuspid patient can be beneficial in terms of stresses within the leaflets [4]. The elliptical expansion allows the leaflets to unfold better in the prede-

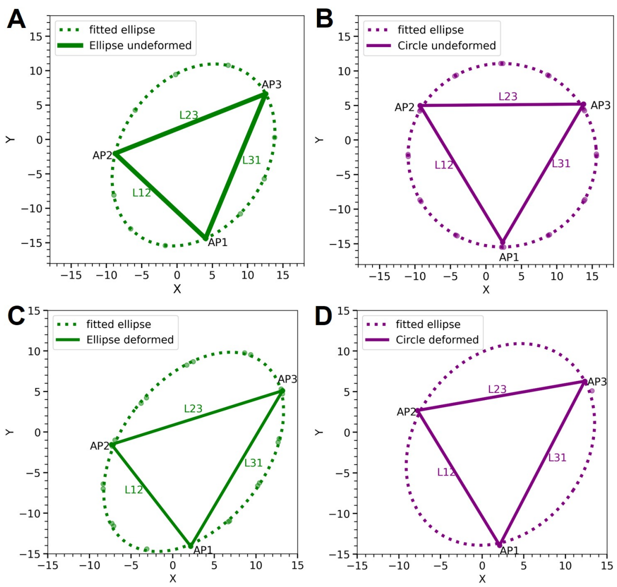

Fig. 4: Potential leaflet deformation of the possible attachment points (AP 1 to 3) for the elliptical stent (**A**,**C**) and the circular stent (**B**, **D**). The lines (L12, L23, L31) describe the direct connetction between the attachment points.

fined, asymmetrical manner. We expect a similar behavior in our approach, since the leaflets would also be arranged asymmetrically in the elliptical stent and the deformations would be smaller than in the circular stent. In contrast to the results of [5], no reduction in the ellipticity of the deformed stent was observed by using an elliptical stent.

To summarize, an elliptical TAVR stent prototype was successfully manufactured and transferred to a FE model. The elliptical stent showed comparable crimping and expansion behavior to the circular stent. In addition, the elliptical stent deforms less than the circular stent, which is why the associated deformation of the leaflets should be less pronounced. This in turn could lead to an increase in durability. In future studies, the deformations of the artificial leaflets should be investigated in detail in subsequent studies. In addition, the investigations should be applied to a larger cohort so that statistical statements can be made about the functionality of such a bicuspid valve replacement.

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