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Numerical investigation of the effects of pre-dilatation on paravalvular leakage during transcatheter aortic valve implantation

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Abstract: Due to promising results, the patient cohort for transcather aortic valve replacement (TAVR) has been extended in recent years to include patients with a bicuspid aortic valve (BAV). There are different types of BAV. One variant is the tricommisural bicuspid aortic valve (TBAV). BAV have an increased risk of post-TAVR complications such as paravalvular leakage. In the case of paravalvular leakage, blood flows past the prosthesis back into the ventricle during diastole. Clinically, patients with BAV are often pre-dilated.

For this reason, we want to investigate how pre-dilatation of BAV can affect the leakage rate. A simplified model is used for pre-dilatation, where the calcification nodule is cut along the free edge of the leaflets before the deployment.

In order to evaluate the effects of this method, a deployment simulation was carried out for both geometries using an explicit calculation. A flow simulation was then performed to determine the paravalvular leakage.

The pre-dilatation allows the leaflets to move independently of each other. Without pre-dilatation, the TAVR cannot fully expanded. The leakage rate is higher for the BAV than for the pre-dilated geometry ($53.1\,\mathrm{mL\,s^{-1}}$ vs. $19.4\,\mathrm{mL\,s^{-1}}$).

In this model, we have shown the effect of pre-dilatation on implantation results.

Keywords: transcatheter aortic valve replacement, bicuspid aoritc valve, paravalvular leakage, numerical simulations

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1 Introduction

Transcatheter aortic valve implantation (TAVI) is an established, minimally invasive procedure for treating severe aortic valve stenosis. One of the most common and partly fatal complication after TAVI is the occurrence of paravalvular leakage (PVL), where blood flows back past the transcatheter aortic valve replacement (TAVR) into the left ventricle. For this reason, the optimization of TAVR to reduce PVL is still an ongoing research topic.

In this context, numerical simulations are increasingly used for design optimization [1]. In particular, the use of patient-specific geometries and the investigation of multiple patients to evaluate the safety and efficacy of TAVR has become more common in recent years.

In addition to clinical data, synthetically generated data are used to model patient-specific geometries, which represent the anatomical and pathological characteristics of the TAVR patient cohort. An important pathology in TAVR patients is the calcification of native leaflets, causing the stenosis of the aortic valve.

Besides patients with a obviously tricuspid aortic valve (TAV), patients with tricommissural bicuspid aortic valve (TBAV) can be detected in clinical [2] and synthetic data. BAV occurs in $2\,\%$ of population and in up to $50\,\%$ of patients with aortic stenosis [3]. According to Jilaihawi et al., there are different calcification morpholgical of BAV [2].

In clinical context, these patients are undergoing pre-dilatation. The fusion of the two leaflets by calcification is separated accordingly.

Complex fracture models are one approach to approximate calcified TBAV in numerical simulations. Yeats et al. presented a method in which elements of calcification that have exceeded a stress threshold are no longer taken into account in the simulation [4]. They conclude that the calcification fractures have no significant influence on the deformed TAVR geometry. Another approach of mimicking balloon valvuloplasty is by choosing a plastic material model for the calcification [5].

We want to present a simplified framework where no further simulation steps are necessary. Therefore, we created two cases featuring the same virtual patient. In one case calcification led to tricommissural bicuspid configuration and in the second case the same calcification was divided resulting in a tricuspid configuration, see Fig. 1.

2 Materials and methods

2.1 Deployment simulation

The geometry of the aortic root was created using the virtual cohort generator developed by Verstraeten et al. [6]. The shape is characterized by an annulus diameter of $25.09\,\mathrm{mm}$, a diameter at the sinutubular junction of $30.03\,\mathrm{mm}$ and a sinus height of $26.5\,\mathrm{mm}$.

Patient-specific calcifications were added to the synthetic geometry. The creation of the calcification is based on post-TAVI computed tomography (CT) data and was built using a shape model. Synthetic patient data combining both the virtual aortic geometry and the calcification shape model. For this analysis, a synthetic patient geometry was selected that exhibited TBAV, see Fig. 1 A. For the second model, the calcium nodule of the TBAV, which initially extended over two leaflets, was divided mimicking the pre-dilatation (see fig. 1 B). The separation was defined along the free edge of the two leaflets.

The TAVR model was reconstructed using μCT scans (resolution of $16\,\mu\mathrm{m}$ per pixel) of the commercial TAVR (Medtronic Evolut R 29). The patient would be treated with this stent size according to the instructions for use.

For simplification, a beam model with a circular cross-section was used. This assumption has already been confirmed as valid in earlier studies [7]. The diameter of the beam elements was calculated to achieve the same area moments of inertia of the rectangular shape of the real stent struts. Superelastic material properties of the TAVR stent were adopted from Finotello et al. [8].

A linear-elastic material model of the aortic root and the native leaflets was assumed. The parameters used, including the thicknesses, were taken from [5].

For calcification, a linear elastic material behavior with a Young's modulus of $10\,\mathrm{MPa}$, a Poisson's ratio of 0.35 and a density of $2000\,\mathrm{kg\,m^{-3}}$ was used [9].

The deployment simulation consists of two steps. In the first step, the TAVR was crimped to a diameter of $6\,\mathrm{mm}$. The crimping process took place via radial displacement of twelve circumferentially arranged plates. In the second step, the TAVR was deployed by opening the crimping tool and release the TAVR into the calcified aortic root model.

In both steps, the aortic root was fixed in axial direction on the ventricular side and in all spatial directions on the aortic side. The TAVR stent was fixed axially and tangentially on the ventricular side. The stent was implanted approximately half a cell height below the annulus area. It was positioned centrally between the leaflets and coaxially to the aortic root. The calcification was attached to the leaflets with a tie constraint.

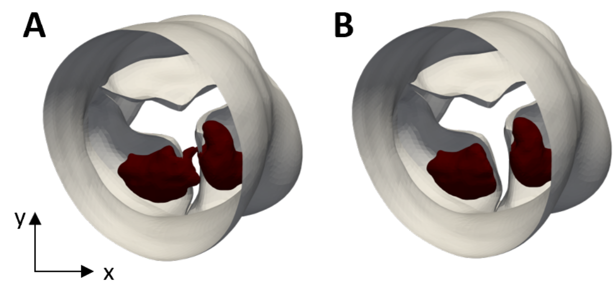

Fig. 1: Patient-specific aortic root geometry **A** tricommisural bicuspid aortic valve (TABV) and **B** tricuspid aortic valve.

The calculation was carried out using Abaqus/Explicit 2023 (Dassault Systèmes, Vélizy-Villacoublay, France). Mass scaling was selected to assure that the kinetic energy corresponds to less than $5\,\%$ of the internal energy at any time during the simulation.

2.2 Leakage simulation

The fluid domain was derived on the internal lumen of the deformed geometry. A solid body was modeled to mimic the closed valves and the skirt. The height of the solid body was $13\,\mathrm{mm}$, which corresponds to the skirt height of the real prosthesis [10]. The blood was assumed to be an incompressible Newtonian fluid with a representative dynamic viscosity of $0.0035\,\mathrm{Pa\,s}$ [11] and a density of $1060\,\mathrm{kg\,m^{-3}}$ [12]. A pressure of $90.39\,\mathrm{mmHg}$ on the aortic side was specified as the boundary condition. The pressure in the ventricular side was set to $0\,\mathrm{mmHg}$. A no-slip boundary condition was applied to the vessel wall and the solid body. The flow was additionally assumed to be steady-state. Due to the near-wall jet, the k-ω-SST turbulence model was used. The leakage rate was determined as the product of the area-averaged velocity in z-direction at the outlet and the outlet area. The flow simulations were performed with openFOAM v2012 (OpenCFD Ltd., UK) using the simpleFOAM solver algorithm.

3 Results and discussion

Fig. 2 shows the results of the TAVR deployment simulation. In the case of TAV, the TAVR is able to displace the calcified valves more effectively, see Fig. 2, B. The stent follows the internal surface of the aortic wall. In contrast, the stent deployed in the TBAV is obstructed by the calcification, resulting in a more elliptical shape, see Fig. 2 A.

The resulting flow fields of the simulated leakage flow are shown in Fig. 3. The leakage rate is $19.4\,\mathrm{mL\,s^{-1}}$ for TAV and $53.1\,\mathrm{mL\,s^{-1}}$ for TBAV. The maximum velocities are similar for both geometries ($5.67\,\mathrm{m\,s^{-1}}$ and $5.71\,\mathrm{m\,s^{-1}}$, respectively). The leakage channel is larger in the TBAV without pre-dilatation (see Fig. 3). This results in a significantly wider jet.

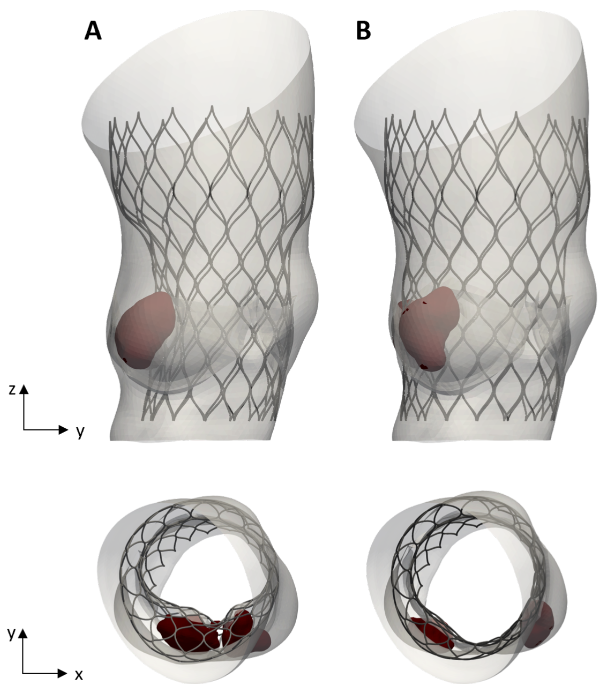

Fig. 2: Results of the TAVR deployment simulations for the **A** calcified TBAV and **B** TAV geometry.

As the TAVR in the pre-dilated geometry between the calcification nodules fits closely to the aortic wall, the jet between the calcification nodules is less pronounced. The TAVR in calcified TBAV is unable to fully expanded, which leads to higher leakage.

The maximum velocities are comparable to values reported in other numerical studies on PVL [1]. The deformation of the TAVR is also significantly better deployed in TBAV compared to studies involving TAV [13, 14].

In contrast to [5], the pre-dilatation is not modeled by the plastic deformation of the calcium nodule, but by a specific removal of the material. Due to the plastic behavior, calcifications not extending over two leaflets are also deformed. In our

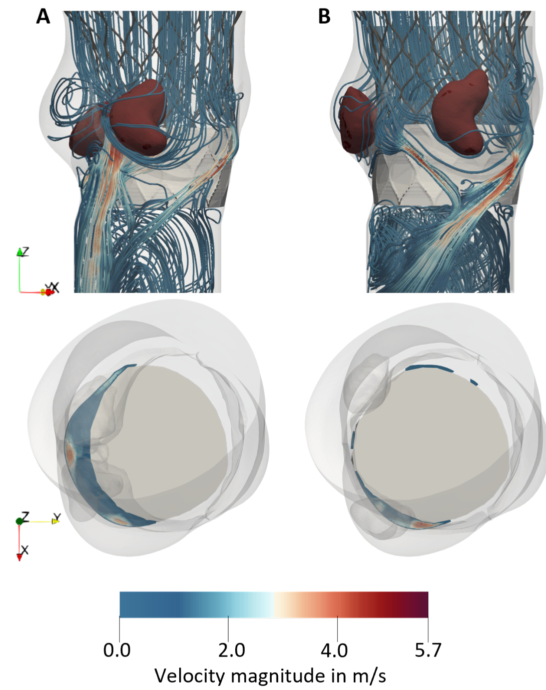

Fig. 3: Flow field results of the leakage simulations for the **A** calfified TBAV and the **B** TAV.

method described, only the calcification between two leaflets is removed. This is similar to the method presented in [4], in which calcification elements are removed that have exceeded a threshold stress.

To summarize, it could be shown that the pre-dilatation of self-expandable TAVR has an influence on the implantation result. Using the example shown, it was demonstrated that the PVL could be significantly reduced by the method used. In addition, the TAVR stent deployed significantly better with the pre-dilated geometry.

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