Numerical simulation of a transcatheter aortic heart valve under application-related loading

Abstract: For the treatment of severe symptomatic aortic valve stenosis, minimally invasive heart valve prostheses have more recently become the lifesaving solution for elderly patients with high operational risk and thus, are often implanted in patients with challenging aortic root configuration. A correct prosthesis deployment and stent adaption to the target region is essential to ensure optimal leaflet performance and long-term prosthesis function. The objective of this study was the development of a suitable in silico setup for structural numerical simulation of a transcatheter aortic valve (TAV) in different cases of clinical relevance. A transcatheter valve prosthesis comprising an unpressurized trileaflet heart valve and an adapted stent configuration was designed. An aortic root (AR) model was developed, based on microcomputed tomography of a native healthy specimen. Using the finite-element analysis (FEA), various loading cases including prosthesis biomechanics with valve opening and closing under physiological pressure ratios throughout a cardiac cycle, prosthesis crimping as well as crimping and release into the developed AR model were simulated. Hyperelastic constitutive law for polymeric leaflet material and superelasticity of shape memory alloys for the self-expanding Nitinol stent structure were implemented into the FEA setup. Calculated performance of the valve including the stent structure demonstrated enhanced leaflet opening and closing as a result of stent deformation and redirected loading. Crimping and subsequent release into the AR model as well as the stent adaption to the target region after expansion proved the suitability of the TAV design for percutaneous application. FEA represented a useful tool for numerical simulation of an entire minimally invasive heart valve prosthesis in relevant clinical scenarios.

Keywords: Finite-element analysis, transcatheter aortic valve prosthesis, aortic root model.

1 Introduction

Since the first-in-man implantation in 2002, minimally invasive aortic valve prostheses are increasingly used in clinical practice. In particular, transcatheter aortic valve replacement (TAVR) became the treatment of choice in high-risk patients, who benefit from this therapy. Tendency to calcification and resulting durability issues are the major limitations of the current generation of devices. Additionally, transcatheter aortic valves (TAV) are often implanted in patients with challenging non-uniform shapes of the target regions.

Minimally invasive heart valve prostheses consist of valve leaflets mounted within a stent structure. In case of self-expandable devices the super-elastic Nitinol alloy is commonly used. During implantation expansion of the stent structure is subjected to the geometry of the aortic root. A correct prosthesis deployment and sufficient stent adaption to the target region are essential to ensure optimal leaflet performance and long-term prosthesis functionality.

Due to the heterogeneity of the material properties and the complexity of the geometries under physiological loading numerical simulations provide powerful tools for future heart valve development. Current research focuses on the investigation of minimally invasive heart valve prostheses implantation into physiological aortic root models and the analysis of the influence of the resultant stent deformations on device performance [1-4].

Within the current work, we used the Finite-element analysis (FEA) for numerical investigation of transcatheter valve prosthesis performance under physiological pressurization. Leaflet deformations during different load types as well as the prosthesis deployment as a function of the aortic root geometry were analyzed.
2 Materials and methods

2.1 The transcatheter heart valve

A transcatheter aortic valve including axially-symmetric trileaflet heart valve geometry and a closed-cell stent structure was developed, using computer-aided design (CAD) software package Creo Parametric 3.0 (Parametric Technology Corp., Needham, MA, USA). Modeling of the leaflet structure was based on design parameters of previously published literature [5]. The commissural line of the leaflet design was taken into account for the development of a stent structure. A sixth of a design of trapezoidal cells in a scattered arrangement was replicated to obtain the stent structure. While strut width was set to 300 µm, a strut thickness of 450 µm was chosen. A crown-like shape of the distal stent area facilitates an exact positioning within the ascending aorta. Interconnecting leaflet tissue with a skirt height of 11 mm was designed as the connecting part of developed leaflets and stent structure. Figure 1 (A-D) illustrates the design of the transcatheter heart valve prosthesis.

2.2 Aortic root model

In order to investigate the prosthesis deployment after crimping into a target region with non-uniform configuration, an aortic root (AR) model was considered. The AR used for numerical simulation consists of a reconstructed and simplified physiological AR model based on microcomputed tomography in vitro data of a native healthy specimen and is illustrated in Figure 1E. It includes the AR wall with a constant thickness, the left ventricular outflow tract (LVOT) as well as the first section of the ascending aorta (AA) and the sinuses of Valsalva.

Figure 1: Design of the transcatheter valve prosthesis and aortic root model: (A) leaflet design with interconnecting leaflet tissue and specific skirt height, (B) planar stent configuration with reported circumference and height: the dashed lines indicate the commissural line of aortic valve leaflets, (C) the planar stent geometry is wound up along a defined path to get the characteristic circular shape with crown-like distal stent part and indicated inner diameter, (D) developed transcatheter heart valve prosthesis, (E) aortic root model.

2.3 Numerical simulation

Abaqus/Explicit 2017 (Dassault Systèmes, Vélizy-Villacoublay, France) was used for FEA. Various loading cases were simulated, including prosthesis biomechanics with valve opening and closing under physiological pressure ratios throughout a cardiac cycle, prosthesis crimping as well as crimping and release into the AR model.

To implement both the crimping and the release loading step, a boundary condition was set to a cylindrical crimping tool wrapping the prosthesis. The tool is displaced in the radial direction with a velocity of $9.25 \text{ mm/s}$ for a time period of 2 seconds, while displacement of prosthesis inflow tract was constrained in tangential and sagittal direction. Applied boundary conditions for physiological pressurization of the leaflets were published previously [1].
Different contacts were defined between all models to enable the described loading cases. To create a glued bond between stent structure and the valve leaflets with its interconnecting leaflet tissue throughout the whole simulation, a tie-type constraint was used.

A hyperelastic constitutive law was used to describe the properties of polymeric leaflet material and interconnecting leaflet tissue [5]. Abaqus user material (UMAT) for superelasticity of shape memory alloys was used for the self-expanding superelastic Nitinol stent structure [6]. Elastic material for the AR was defined by a Young’s modulus of 250 MPa and Poisson’s ratio of 0.45.

The stent frame was modeled with 26,682 8-node hexahedral elements with reduced integration points. Meshing of the valve leaflets and interconnecting leaflet tissue was conducted, using a total of 15,882 8-node reduced-integration hexahedral elements. For the AR, the model was discretized by 4,816 4-node reduced-integration shell elements.

3 Results and discussion

3.1 Performance under compressive loading

Prosthesis performance under physiological pressurization was characterized by a leaflet deformation analysis yielding good agreement with previously published literature and is illustrated in Figure 2 [5]. Stent deformation has occurred as a result of redirected loading and led to an increased characteristic twisting of leaflets. Thus, enhanced leaflet closing and tightening was observed.

The results of previously published leaflet simulation and the computation of the entire prosthesis are compared in Table 1 [5]. Including the stent structure into the numerical simulation demonstrated a crucial influence and clarifies the necessity of structural simulation including both, the valve leaflets and the stent structure, for application-related loading.

Table 1: Maximum leaflet opening area (LOA) and maximum average coaptation surface area (CSA) under physiological pressurization of the entire TAV prosthesis and the leaflets.

<table>
<thead>
<tr>
<th>Model</th>
<th>Max. LOA [mm²]</th>
<th>Max. CSA [mm²]</th>
</tr>
</thead>
<tbody>
<tr>
<td>simulated TAV</td>
<td>435</td>
<td>65</td>
</tr>
<tr>
<td>valve leaflets [5]</td>
<td>360</td>
<td>41</td>
</tr>
</tbody>
</table>

3.2 Performance during crimping

Prosthesis deformation during a simulated process of crimping was characterized by even folding of the valve leaflets with consecutive stent crimping and is illustrated in Figure 3. Furthermore, prosthesis lengthening of approximately 13% was observed. Parts of the interconnecting leaflet tissue and cross-sectional conjunctions of the stent were identified to be the highest stressed regions during crimping. While the outer stent diameter before crimping was 26.9 mm, after crimping the stent diameter was finally reduced to 6 mm. Thus, the prosthesis design is suitable for percutaneous application.

Figure 2: Stress distribution of the prosthesis during valve opening and closing under physiological pressure ratios throughout a cardiac cycle.

Figure 3: Prosthesis crimping: (A) start position at outer stent diameter of 26.9 mm, (B) crimping at 1 s, (C) crimp end at outer stent diameter of 6 mm and TAV lengthening of ΔL, (D) leaflet folding.
3.3 Deployment into an aortic root

The deployment procedure of the prosthesis into the AR model with elliptical cross-section was characterized by an even expansion of the stent structure and is shown in Figure 4. Folding at the free edges of the leaflets can be observed at the end of release. Importance of the relative position of the prosthesis within the AR should be worked out in future investigations. Furthermore, it would be of great interest to consider the geometry of the native leaflets for the AR model, since it could be the main determinant for a better reproduction of the physiological situation. As a result of a non-uniform configuration caused by the native leaflets, a varying stent expansion might affect the stent symmetry and thus, the prosthesis performance.

In order to assess whether the AR geometry largely influences the transcatheter aortic valve performance, simulation of physiological pressurization should be repeated for the prosthesis after deployment into the AR model and subsequently compared to the results of this study.

Figure 4: FEA of the deployment procedure of the transcatheter aortic valve prosthesis into a CAD aortic root model based on microcomputed tomography in vitro data of a native healthy specimen.

4 Conclusion

Within the current study, we developed an in silico setup for structural numerical simulation of an entire transcatheter aortic valve prosthesis. Reproducing TAV performance under physiological pressurization enables application-related loading cases in comparison to computing the valve leaflets, solely. Suitability and performance of the stent structure can be assessed and additionally, future adaptations concerning the stent design can be provided with regard for the crimping process. The implemented process of TAV release into a physiological AR model enables a versatile assessment of the prosthesis function. However, a possible perspective might be the numerical simulation of physiological pressurization of the entire TAV after deployment into an enhanced AR model including native leaflets as well.

Subsequent to a validation of the numerical models by appropriate experimental setups, the FEA is a suitable tool for the assessment of the current generation of TAV prostheses with regard to optimized performance in target regions with uniform as well as non-uniform configurations. Furthermore, the implemented computational tools could be applied to different scenarios to investigate other relevant clinical aspects.

Author Statement

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References


