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Comparison of two biological aortic valve prostheses inside patient-specific aorta model by bi-directional fluid-structure interaction

Abstract: In Germany in 2016 17,085 patients received TAVI operations and 9,579 had conventional aortic valve surgery. The ‘Heart Team’ uses established scoring systems (EuroSCORE, STS, German AV Score) to evaluate operation risks and which technique to use. However, such risk grading fails to consider patient morphology and possible long-term behavior of the replacement valve chosen. Therefore, pre-operative simulation of the dynamic loading on the valve leaflets after TAVR provides information vital for the selection of the appropriate aortic valve therapy – interventional versus conventional.

Individual aorta used in this study was captured by MRI. Segmentation and data processing were done with Mimic In-ovation Suite. The available biological aortic valves prostheses were reverse engineered to create a 3D CAD model. Simulations combined bi-directional fluid structure interaction (FSI) with a first order Ogden model of the hyperelastic behavior of aortic leaflets from bovine pericardium.

Movements induced by flow and the resultant tension on the biological leaflets were computed with developed simulation model. Stress analyses of the leaflets showed behavior attributable to their particular structure. Both valves showed two stress peaks within the initial 0.3 s. Maximum stress occurred, however, at other time points. Furthermore, the initial increase in stress showed a delayed onset. The patterns of movement were also significantly different. So, at opening of the valve, the freely perfused area of the valve, the freedom of leaflet movement and symmetry at closure were different in the two valves.

Simulated movement of valve leaflets corresponds well with reality. The estimated stresses clearly lie below thresholds published in the literature for bovine pericardium. It is planned to further develop the current workflow to increase stability and optimize processing time, with the intention of providing the ‘Heart Team’ with a tool for incorporating individual anatomy when selecting the aortic valves.

Keywords: Risk stratification; decision support tool, patient-specific; pre-operative; prosthetic aortic valve, Fluid-Structure-Interaction

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1 Introduction

After arterial hypertension and coronary heart disease, the aortic stenosis is the third most common cardiovascular disease with a prevalence of 2 – 5% for over 65-year-olds. If complaints such as dyspnea, syncope and angina occur, the natural course of this flap error is extremely unfavorable, so a quick flap replacement operation is indicated. The prevalence of this valve disease increases to 5-10% for patients over 80 years of age.

In 2014 for the first time more TAVI procedures than conventional aortic valve replacement operations were carried out in Germany with more than 10,000 transcatheter valves [1]. Used primarily for the treatment of aortic valve stenosis in high-risk and inoperable patients, this increase is due to the extension of the indication to medium and low risk
patient groups. This approach is based on the good study results from large randomized studies such as the partner trial or the COREVALVE US Pivotal Trial. [2, 3] Furthermore, published data from the PARTNER II trial do not show any disadvantages of TAVI therapy if compared to the conventional aortic valve replacement with regard to a combined end point of mortality and stroke rate after a period of 2 years in a patient population with medium risk (mean STS score 5.8 ± 2.1). [4]

Despite these excellent study results, there are a number of TAVI-specific complications that have an impact on the overall prognosis. These include: para-valvular leakage, pacemaker implant, incomplete unfolding of the stent due to pronounced calcification, rupture of the aortic root, severe bleeding, premature valve degeneration, coronary obstruction [5, 6, 7]. Even premature valve degenerations due to the dynamic, mechanical stresses (periodic stress states) of the valve leaflet will increase because of the constantly increasing time of use. An important factor in the occurrence of these complications is the interaction between the implant valve device and the patient. These interactions are clinically difficult to predict due to a multitude of different geometries and dimensions of aortic root as well as different calcific load and calcific distribution pattern. There are different workflows that focus on individual aspects of the transcatheter valves or stent grafts such as development (design) or use (selection, sizing, positioning) [8, 9, 10, 11].

The main focus of this study is the investigation of the dynamic loads of the sails of two biological valve prostheses. It is another building block in the development of a surgical decision support tool for the selection of the optimal valve therapy (interventional vs conventional) based on numerical simulations with the individual morphological criteria as well as the resulting mechanical permanent load of the valve type to implant.

## 2 Materials and methods

To investigate the behavior of the biological transcatheter valves boundary conditions as realistic as possible were demanded. This requires an appropriate mapping of the anatomical conditions. Therefore the material behavior, the geometry of the aorta and the valve as well as the physiological boundary conditions are to be modeled as precisely as possible.

For this purpose, an individual aorta was transferred from a patient to a 3D model using MRI. For use in the simulation software, these data were segmented with the help of the software Mimics Innovation Suite by Materialise© (Materialise HQ, Technologielaan 15, 3001 Leuven, Belgium) and converted into a fully editable 3D CAD model. The geometry includes the aortic bulbus, the subclavian, carotid and brachiocephalic artery, and a part of the descending aorta. Using this method, patient specific aortic geometries can be prepared for numerical simulation.

The examined biological replacement valves, including the frame geometry, were transferred to a 3D model by means of reverse engineering. For the study of the 2-way fluid-structure interaction, the valve and the aortic arch were merged with the help of CAD tools. To ensure a realistic behavior of the aortic wall and the valve sails, these were applied with a hyperelastic material model. The hyperelasticity of the valve sails was illustrated by an Ogden model of first order based on investigations of the elastic behavior of bovine pericardium.

Using this method, patient specific aortic geometries can be prepared with different valve geometries for numerical simulation. Individual adjustments of the valves to the respective aorta are also conceivable. Furthermore the positioning of the valves can be analyzed.

For the simulation of fluid behavior, the non-Newtonian behavior of blood was considered. Blood flow was transferred to the simulation using patient specific measured data. The natural resistance of the subsequent vascular system was also observed for the outlet boundary conditions. The expansion of the aortic wall as well as the freedom of movement of the valve sails were also taken into account in order to allow a realistic simulation.

## 3 Results

The simulation of a transient 2-way fluid-structure interaction allows the evaluation of the valve sails and the vessel wall of the aortic arch in relation to the movement behavior, the forces acting there as well as the flow behavior in the examined part of the aorta within one or more heart cycles.

In the study, two biological replacement valve models were used under identical boundary conditions with the segmented aortic scan for comparison. The evaluation shows a different movement behavior of the valve sails, which is explained by the specific sail geometries (thickness, curvature, arrangement of the sails). The sails of the two models are initially delayed due to their different stiffness and show a different overall opening behavior. The maximum opening of the two models also shows differences. The closing of the two valves is slightly asymmetrical, as the valve sails are reopened shortly after the inlet speed has
4 Conclusion

This study by means of a 2-way FSI in combination with the creation of geometry using MRI and reversed engineering shows that the preoperative examination of various replacement valves is possible. The workflow developed in this way allows the exchange of the valve and the aortic geometry. In order to increase the efficiency of the investigation by means of numerical simulation, the workflow is to be further developed. The stability of the calculation and the calculation duration should be further reduced. This is planned to be the way to develop a tool that will help the 'Heart Team' to choose a suitable replacement valve for each patient. In addition, the stress analysis of different valve models is possible, which can contribute to the further development of such models.

Author Statement

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References


