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Simulation of Transcatheter Aortic Valve Implantation under Consideration of Leaflet Calcification

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Abstract— **Transcatheter aortic valve implantation (TAVI) is a minimally invasive off-pump procedure to replace diseased aortic heart valves. Known complications include paravalvular leaks, atrioventricular blocks, coronary obstruction and annular rupture. Careful procedure planning including appropriate stent selection and sizing are crucial. Few patient-specific geometric parameters, like annular diameters, annular perimeter and measurement of the distance to the coronary ostia, are currently used within this process. Biomechanical simulation allows the consideration of extracted anatomy and material parameters for the intervention, which may improve planning and execution phases. We present a simulation workflow using a fully segmented aortic root anatomy, which was extracted from pre-operative CT-scan data and apply individual material models and parameters to predict the procedure outcome. Our results indicate the high relevance of calcification location and size for intervention planning, which are not sufficiently considered at this time. Our analysis can further provide guidance for accurate, patient-specific device positioning and future adaptations to stent design.**

I. INTRODUCTION

Cardiovascular diseases are considered the largest cause of human deaths worldwide as reported by the World Heath Organization [1]. Detection of these diseases often occur at a late stage as early signs are ignored or not recognized. Aortic valve stenosis is the most common heart valve disease and leads to a decrease of blood output. Congestive heart failure and hypertrophy of the ventricle are resulting. The therapy of choice today for patients with severe aortic valve stenosis (AVS) is the surgical replacement.

Transcatheter aortic valve implantation (TAVI) is a minimally invasive off-pump procedure with a comparatively low recovery time, often used in elderly patients that are considered having a higher risk for open-heart surgery. A heart valve prosthesis inside a stent is delivered directly into its proposed location under direct image-guidance (angiography). The stent is crimped before insertion through a catheter and guided along a wire. Preoperative selection of the optimal valve type and size and determination of the optimal position of placement for the selected device are crucial to minimize the onset of complications such as paravalvular leaks, atrioventricular blocks, coronary obstruction, tissue rupture and valve embolization.

With regards to the wide variety of patient-specific anatomy, several stent models and sizes are available to physicians. For procedure planning, only basic geometric measurements such as the cross-sectional area of the aortic annulus or its diameter and distance to the coronary ostia are currently taken into account in preoperative planning. Biomedical simulation on the other hand allows the use of material models and detailed geometric surfaces for patient-specific intervention planning and analysis as discussed previously in [2]. In the presented work we compare the impact of valve calcification on stent expansion, by taking in consideration different geometric features and material complexity.

Experiments related to mechanical simulation of stent expansion can be found in a number of articles in the literature ([3], [4], [5]) and is considered an active research field. Deployment of self-expanding or balloon-inflatable stents have been analyzed by [6], [7], [8]. They commonly are based on direct wall-stent contact interactions and optimization problems, but neglect the inclusion of valve leaflets into the analysis. [9] among others, simulates implanted aortic valve leaflets separately, but does not review the implications of a dynamic interaction with an implanted stent for TAVI. This work will therefore focus on stent-valve interaction under consideration of leaflet calcification, which has not received sufficient attention.

II. METHODS

For the purpose of assisting the planning stage of TAVI interventions through biomedical simulation of stent expansion inside the aortic root, patient-specific artery models are required. The generation of surface meshes for finite element analysis (FEA) and definition of material parameters for various tissue types and sections is essential to achieve reasonable simulation results. Abaqus/Explicit[1] is used as a numerical solver due to its extensive support for nonlinear FEA and contact problems involving large deformations.

A. Geometric and Material Modeling

The geometry used in this study is based on a preoperative CT-scan of an 96 year old female patient, performed at the UniversityHospital Zurich, Switzerland using a Somatom Definition Flash[2] CT-scanner. The following surfaces are

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extracted using the Philips Heart Navigator [10] as shown in Fig. 1:

- left ventricle (LV) and left ventricle outflow tract (LVOT),
- aortic valve (AV), consisting of three aortic leaflets (AL),
- vascular calcification (VC) found in close proximity to the aortic root (AR),
- ascending aorta (AA) containing coronary artery (CA) attachments.

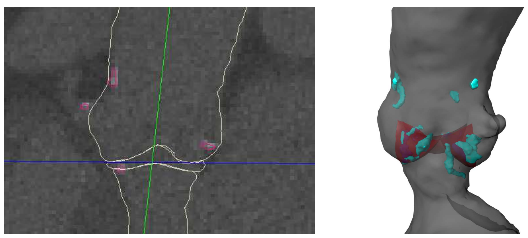

Fig. 1. *Left:* Segmentation of aortic root, valve, LVOT and plaque. *Right:* Extracted surfaces showing left ventricle (grey), valvular leaflets (red), calcification (turquoise) and part of the ascending aorta (grey).

The extracted regions are further processed as parametric surfaces to generate continuous transitions and define relevant surface interaction sections. Aorta, leaflets, LVOT and ventricle surfaces are considered as thin structures, for which bending stress is negligible within the frames of this simulation. Therefore, these structures are modeled with two dimensional membrane elements. An intensity based approach is used for segmentation of calcifications using 650 Hounsfield units (HU). The surface is retrieved by the marching cubes algorithm [11] on voxel regions expanded from individual seed-points. The extracted meshes are considered volumetric objects and shall consists of tetrahedral and hexahedral elements for FEA. Element generation is performed using ICEM CFD[3].

Material models for individual sections of the model are required. The shell-based sections, representing soft tissue, are assigned rigid, linear, nonlinear and hyper-elastic material models for individual experiments using $19,776$ *M3D3* membrane elements and $9,860$ nodes. The density of soft tissue is set to $1.0\,g/cm^3$ with a variable material thickness (LV: $6.0\,mm$, AA: $2.5\,mm$, AL: $0.7\,mm$). VC are modeled with a linear-elastic, isotropic material model, using *C3D4* and *C3D8* volumetric elements at a density of $1.2\,g/cm^3$.

A beam-element based model of the self-expanding CoreValve®[4] stent, presented by [12], resembles the stent geometry as measured from micro-CT scan data. A linear nitinol material model was shown to sufficiently follow stent deformations with an elastic modulus of $58\,MPa$ and a density of $6.45\,g/cm^3$. The actual valve prosthesis inside the stent is not included as its effect on mechanical dynamics of the stent are considered negligible with an elastic modulus and density values several orders of magnitude below nitinol.

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[4]Medtronic, Inc., Minneapolis, MN, USA

B. Calcification and Surface Interactions

Surface nodes of the defined AV calcification are projected onto close LVOT, AL and AA surface elements depending on their proximity. A tie constraint is used to combine the individually meshed parts and allow continuous deformation propagation between different materials. General contact between all elements is enforced, using hard contact along the normal direction. Damping is enabled with a coefficient of 0.1. The effect of friction was analyzed experimentally comparing frictionless contact with a penalty-based method (friction coefficient: $0.2\,\mu$).

III. EXPERIMENT SETUP

A. Stent Configuration

To analyze the effects of vascular calcification on stent expansions inside the AR, the stent is initially aligned with the AR geometry and centered between the aortic leaflets. The narrow end is constrained to remain leveled with the LVOT, while the opposite end is stretched into the AA. This step leads to the initial stent deformation, which is motivated by the crimping procedure to reduce the stents diameter before insertion. Contact conditions are disabled in this step. To release the stent structure, the displaced nodes at the wider stent opening are continuously moved in the opposite direction (towards the LVOT), which establishes initial contact with AL surfaces. In the following simulation step those nodes are released, allowing the stent to open. Experiments are performed using a $29\,mm$ diameter stent model.

During an actual intervention, the device expands at the bottom level first, but is constrained by a tube-shaped stent catheter, which is removed continuously. Comparable experimental procedures to our simulation setup have been described in similar studies [13] and allow to balance control over stent constraints and degrees of freedom during device expansion.

B. Leaflet, Aorta and Ventricle Model

A low amount of pressure is applied on the leaflets as shown in Fig. 2 to simulate a slight opening of the AL as found in systolic movement. This step is required to avoid pre-existing contact between the compressed stent and leaflet geometry. The leaflet elements are connected directly to the aorta elements and share equivalent nodes. Leaflets function primarily as connective tissue for calcification in our experiment and will be analyzed using linear-elastic and hyper-elastic materials. The aorta and ventricle are constrained in position at each opposing end.

IV. PERFORMED SIMULATIONS

The aorta and ventricle elements are simulated in three different configurations, which shall allow individual analysis of leaflet deformation and aorta-leaflet-stent interaction:

- static, rigid-body element configuration,
- linear-elastic, isotropic membrane,
- hyper-elastic (Neo-Hooke), isotropic membrane.

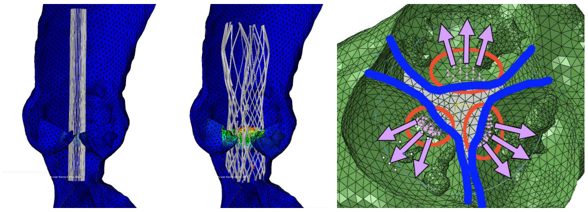

Fig. 2. *Left:* Expansion of CoreValve® (after initial crimping) shows contact with leaflets. *Right:* Low pressure (arrows) is applied to each leaflet (blue outline) to avoid pre-conditioned contact between surfaces.

For each of these simulation options, the calcification have initially been removed. They were added in a secondary simulation for comparison. As contact and surface interaction can be considered as major factor for the described simulation setup, friction might impact the results. As outlined by [14], insufficient knowledge about friction between these surfaces is available. The effect of friction was therefore experimentally verified, using a proposed frictionless contact [13] and a friction coefficient of $0.2\,\mu$ [15].

V. RESULTS AND DISCUSSION

The focus of this study is set on stent deformation and interaction with leaflet calcification. As a ground truth the patient's implanted core valve has been extracted from post-operative CT data, using a technique described in [16]. The resulting deformed stent models are compared by circumference with this ground truth. Numerical calculations were performed on a heterogeneous cluster utilizing 16 processors and 16 GB RAM for each experiment, requiring an average time-interval below four hours.

Every experiment has been performed with two different friction configurations (frictionless, friction coefficient: $0.2\,\mu$). Performance was slightly decreased with active friction, while accuracy was improved $28\,\%$ on average (circumference-based stent comparison). For further results, we will therefore make it the superior choice in our simulation environment.

TABLE I

COMPARISON OF CIRCUMFERENTIAL ERROR AFTER STENT EXPANSION

Aorta Deformation Material Model	Without Calcification Deformation Error	With Calcification Deformation Error
Rigid (full)	6.7 %	7.4 %
Rigid (half)	5.6 %	6.0 %
Linear-Elastic (full)	5.9 %	5.8 %
Linear-Elastic (half)	4.6 %	4.0 %
Hyper-Elastic (full)	6.0 %	5.5 %
Hyper-Elastic (half)	5.2 %	4.2 %

To allow direct comparison of leaflet deformation without the influence of deformable aortic tissue, the elements related to AA, LVOT and LV have initially been defined as rigid. Fig. 3 visualizes the resulting AL location without and with plaque. Not including the calcification allows the stent to deform leaflets freely, whereas plaque connected to AL can substantially influence the prosthesis shape. As the aorta is not deformable, the stent takes a less realistic final configuration in the latter case, as the device is compressed by surrounding calcification, which otherwise would be absorbed further by aortic tissue. This experiment results in the highest circumferential error, shown in Table I, which compares the global error (*full*) with an error only computed for the more relevant lower half of the stent (*half*), which is colliding with the leaflets.

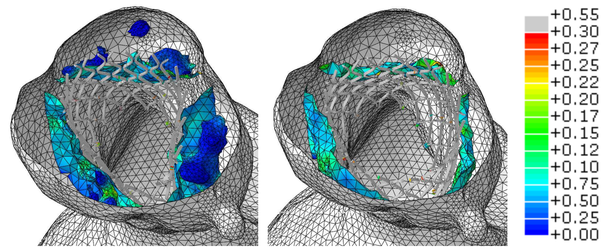

Fig. 3. Aorta, LVOT and LV defined as rigid structures for interaction analysis between stent, leaflet and plaque. *Left:* Stent expansion obstructed by plaque. *Right:* Fully relaxed stent not including plaque (color scale shows AL stress in MPa).

A. Linear- and Hyper-Elastic Material Simulation

As shown by [17] hyper-elastic material models can improve simulation accuracy, particularly under high stress and strain situations. Stent dynamics under consideration of deformable AA, LVOT and LV in our experiments generally decreases the resulting stenting error as shown in Table I. A critical step during simulation can be seen in Fig. 4, where the plaque heavily influences the stents shape, before it deforms the AR surface. This shows how calcifications actually increase strain on aortic tissue. This simulation can help to predict potential areas of paravalvular leak, where stent and AR surface are not aligned accurately.

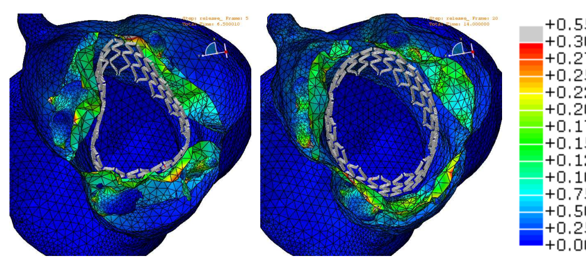

Fig. 4. *Left:* Dynamic stent expansion showing large stent deformation dependent on plaque location initially. *Right:* The completely expanded stent is shown at the end of the simulation (color scale shows stress in MPa).

Fig. 5 compares final configuration under rigid, linear elastic and hyper-elastic material modeling. It provides further clues to choosing an optimal height during procedure planning within the AR on expansion as potential areas prone to result in paravalvular leaks or coronary obstruction can be studied prior to the intervention. In each experiment the stent expands with a final average circumferential error below $8\,\%$, with generally improved results in the linear- and hyper-elastic case. When including plaques into fully dynamic simulations, a clear tendency to improved simulation accuracy can be seen. Note, that the rigid case shows an increased error when adding calcification as a result of increased stiffness of the surrounding AR surface.

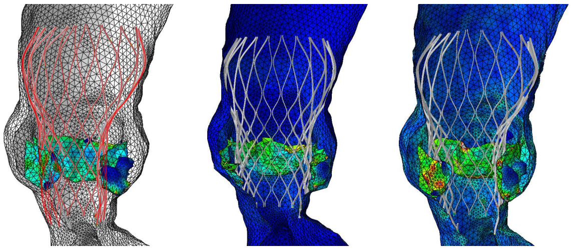

Fig. 5. *Left:* Result of simulation using rigid AA, LVOT, LV. The stent is highlighted (red) for visibility. *Center:* Linear-elastic aorta and leaflets. *Right:* Hyper-elastic material model used for computations.

Our results indicate that the inclusion of the formation and location of calcification at the aortic annulus and leaflets into TAVI simulations is important, because they effect the dynamics of stent expansion and tissue interaction in the model. In particular the quantitative stress and strain implications for tissues surrounding the plaque are relevant when considering atrioventricular blocks or annular rupture.

B. Future Work

The presented experiments focus on the simulation of self-expanding stents. Balloon dilatation previous or after implantation to improve device positioning was not performed as part of this study. Aortic leaflets and calcification are modeled without tearing effects. Anisotropic hyperelastic material models based on multiple tissue fibre directions (e.g. [18]) will be investigated in the future towards their influence on simulation results. We will also test our method on a greater variety of patient datasets using additional stent models for more conclusive results.

Another restricting factor of the simulation is the positioning constraint applied to the stent. More rotational degrees of freedom through constraints within a global cylindrical coordinate system are expected to improve the results further.

VI. CONCLUSION

In this study TAVI simulation under consideration of leaflet calcification has been performed to analyze its implications on overall aortic root and stent deformation. Additionally, the added value for preoperative treatment planning was investigated. Our results indicate a substantial effect of plaque location and size on the dynamics of stent deformation as well as stress and strain distribution on surrounding tissue. The presented experimental simulation setup allows more accurate procedure planning and prediction of potential paravalvular leaks, atrioventricular blocks, coronary obstruction and annular rupture.

We present a suitable FEA setup for TAVI simulation that allows predictive analysis for procedure planning for self-expandable heart valve prostheses in relation to leaflet calcification. Potential improvements will focus on stent constraints and additional workflow pattern like balloon dilatation or other commonly used stent models.

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