POLITECNICO MILANO 1863

SCUOLA DI INGEGNERIA INDUSTRIALE E DELL'INFORMAZIONE

Executive Summary of the Thesis

Self-expandable transcatheter aortic valve finite-element models for patient-specific TAVI simulations

Laurea Magistrale in Biomedical Engineering - Ingegneria Biomedica

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Academic year: 2021-2022

1. Introduction

Calcific aortic stenosis (AS) is the most common pathology affecting the heart valves in the Western world. As highlighted by multiple studies [1], there is an incidence near to 2% in individual aged between 70 and 80 years, but this number increases with the age, reaching 3-9% after 80 years. AS is characterized by an obstruction of blood flow through the valve during the ventricular systole, causing an increase in the pressure that the left ventricle must win. This results in increased valve stiffness and in a progressive narrowing of the valve opening. The first solution was surgical aortic valve replacement (SAVR). The first successful open heart valve replacement took place in 1960, and since that time this operation saw a rapid increase inside the surgery rooms. The main problem of this approach is that one-third of the patients are not indicated for SAVR: according to Iung et al.[2] surgery in the first years of the century was denied in 33% of patients, due older age or left ventricular dysfunction. This can lead to an operative death risk during the operation as high as 10%, and there is another 10% of risk when the patient suffers from chronic renal disease. To solve this problem, a new operation had been implemented: the transcatheter aortic valve implantation (TAVI), a less invasive method to replace heart valves. In this way also high-risk patients can be treated. The aim is to reach the heart with an antegrade catheter with a valve over it, inserted inside the body from a low invasiveness spot (like the femoral artery for example).

One of the newest devices is Boston Scientific's ACURATE neo2 valve (Figure 1.a). It has been designed to reduce the post-TAVI complications and it presents three stabilization arches, that allow the axial self-alignment of valve within the native annulus. The valve is comprised of a self-expanding nitinol frame.

To understand this procedure and the associated biomechanics, computational simulations have become increasingly important. Those models allow to study complex problems and they can be applied to a wide variability of implant scenarios. *In silico* models can therefore speed up the introduction of new devices and procedures, reducing at the same time *in vivo* experimentation with all its limitations. However, computational methods are still less used due to the difficulty in the reproduction of a biological environment. The solution lies in the application

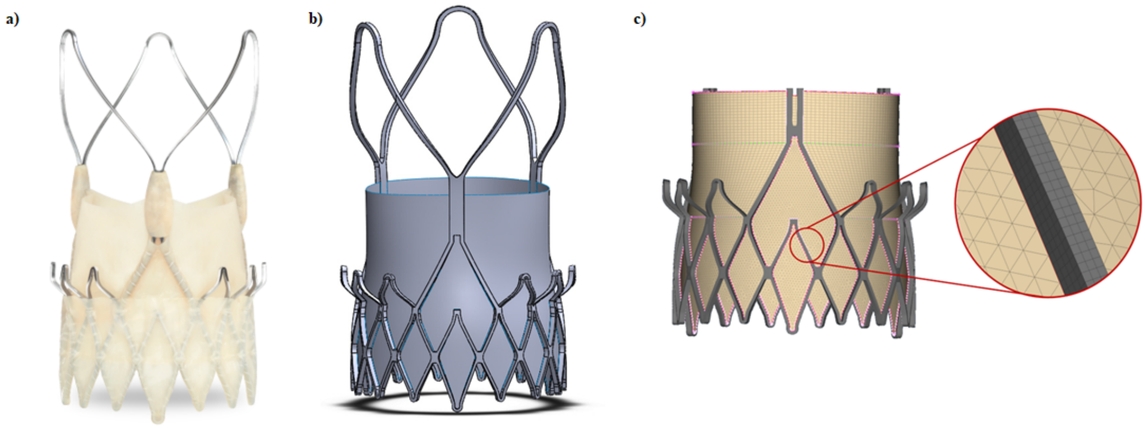

Figure 1: *a) Acurate neo2; b) Complete CAD model of the device; c) Mesh of the valve.*

of simplifications that are inevitably reflected in the results.

In the context of TAVI, different types of analyses can be conducted. The first is the structural one, based on the finite element method (FEM), in order to study mechanical quantities during the crimping and the deployment of the device. The FEM is based on the discretization of the domain into sub-volumes called finite elements, which define some specific points, called nodes, where the equations governing the system are solved. Usually, this method is used to find the displacements of the nodes under certain load and boundary conditions and to derive the deformations and the stresses. After FEM, the fluid dynamics can be evaluated by a computational fluid dynamic (CFD) analysis. This sequential approach is easy to implement and requires a limited computational time but CFD is based on the assumption that the structures are rigid.[3] An alternative to this sequential method is the fluid-structure one (fluid-structure interaction, FSI), in which the fluid model is coupled with the structural one. FSI simulations are more complex than CFD and FEM, but they are the most effective in reproducing TAVI.[4]

In literature, *in silico* models are used to assess all the complications associated with this procedure and to study TAVI applied in different pathologies, such as bicuspid aortic valve, mitral regurgitant, and in patients with previously implanted bioprosthetic valves.[3]

In this framework, this study aims to develop a structural computational model with the Acurate Neo2 device and the patient-specific anatomies of six patients who underwent TAVI surgery. The simulations should reproduce closely the actual positioning of the valve within the anatomies. From the results of these simulations, the main quantities of interest will then be highlighted, in order to better understand the procedure, the device and its interaction with six different anatomies.

2. Materials and methods

2.1. Prosthesis Model

A three-dimensional model of Acurate neo2 has been developed using SolidWorks (Dassault Systèmes SolidWorks Corporation, Waltham, Massachusetts, USA). Three sizes of the valve are available on the market: size medium has been reproduced in SolidWorks, while sizes small and large have been scaled in LS-DYNA. A constant-diameter metal frame was obtained by replicating some basic units. The real profile of the device was recreated deforming the latter. The skirt and the leaflets have been created as surfaces. In order to reproduce the actual geometry, the valve leaflets were then cut (Figure 1.b). The valve has been then discretized using ANSA Pre Processor v22.1.2 (BETA CAE Systems, Switzerland). The stent was meshed with 103908 hexahedrons with reduced integration and Puso hourglass control. The skirt was instead discretized with 16335 Belytschko-Tsay triangular membrane elements. Finally, the leaflets were meshed with 6486 fully integrated quadrilateral shell elements (Figure 1.c). The sewing sutures were not modeled, which is why the stent and the pericardium parts were fixed together with a node-to-node connection. The stent structure was considered as Nitinol, with the characteristics obtained according to Morganti et al.[5] The skirt and leaflets were instead modelled as linear elastic, with a Young's modulus E equal to 3.20 MPa, Poisson ratio μ equal to 0.30 and density ρ equal to 1100.00 $\frac{kg}{m^3}$.[6]

2.2. Patient-Specific Models

To develop patient-specific simulations, the aortic geometries of the six patients (including the native aortic valves and the calcifications) were segmented starting from pre-intervention contrast-enhanced CT images. All the components were then discretized in ANSA. With regard to the aorta, starting from a triangular shell mesh, three tetra layers were obtained with the ANSA Batch Mesh, a tool which performs automatic mesh generation on geometries through customizable meshing sessions.The formulation of the elements was chosen as tetrahedron with one integration point (Figure 2.a). The native aortic valves were created following reference points identified by the shape of the sinuses and they were discretized with triangular elements following the Belytschko-Tsay membrane's formulation. In order to obtain a more realistic geometry, the native valves obtained in ANSA were subjected to an initial computational simulation in LS-DYNA consisting of applying pressure to the leaflets, while the commissural edges were deprived of all degrees of freedom (Figure 2.b). The segmented calcifications were smoothed in ANSA and meshed using tetrahedron with one integration point (Figure 2.c). As for the materiales, the aorta was modelled as isotropic, incompressible, nonlinear hyperelastic, starting from a study by Azadani et al.[7] The values of the coefficients used in the simulations were chosen and applied to the Yeoh hyperelastic model:

$$W = C_{10}(I_1 - 3) + C_{20}(I_1 - 3)^2 + C_{30}(I_1 - 3)^3$$

where I_1 is the first invariant of the Left Cauchy-Green tensor and C_{10}, C_{20} and C_{30} are material model coefficients indicative of the mechanical properties. The value of the coefficients are shown in table 1.

Coefficient	*Value [MPa]*
C_{10}	0.0417
C_{20}	0.1186
C_{30}	0.4550

Table 1: *Values of the coefficient for the material of the aorta.*

The density ρ was set at 1060.00 $\frac{kg}{m^3}$ and Poisson ratio μ was equal to 0.48. The native valves were assumed to be linear elastic, with a low Young's modulus E, equal to 0.10 MPa. This assumption is reasonable because the interaction between the device and the native valve is always easily won by the metallic stent in reality. The density ρ was set at 1100.00 $\frac{kg}{m^3}$ and Poisson ratio μ was equal to 0.30.[6] For the calcifications, the material was modelled as linear elastic, with a density $\rho = 2000.00$ $\frac{kg}{m^3}$, Young's modulus E = 12.60 MPa, and Poisson ratio $\mu = 0.45$, according to Holzapfel et al.[8] The native valves and the aortas were fixed together with a node-to-node connection.

2.3. FE simulations

To reproduce accurately the real implant of the device, the simulations can be divided in two phases:

1. crimping phase;
2. deployment phase inside the aortic root.

The anatomies were imported and the right stent size was optimally placed for every patient. The correct orientation of the anatomies was obtained when the most distal points of the natural valve leaflets were aligned with the catheters needed for the deployment of the device. The implantation depth was reproduced thanks to the availability of the angiographies of the six patients, obtained during implantation. The crimping process was reproduced using 12 rigid concentric planes, placed outside the entire device. A prescribed radial displacement of 11.75 mm was imposed on these planes, in order to meet the valve and push it to close until it reaches the diameter of the catheters, which is approximately 12 mm. This first phase lasts 350 ms. At this stage, the contacts between the stent and the other components (calcifications, natural valve, aorta) are not activated. The subsequent deployment phase is modelled with the aid of two catheters, on which upward and downward translations are imposed, respectively. In

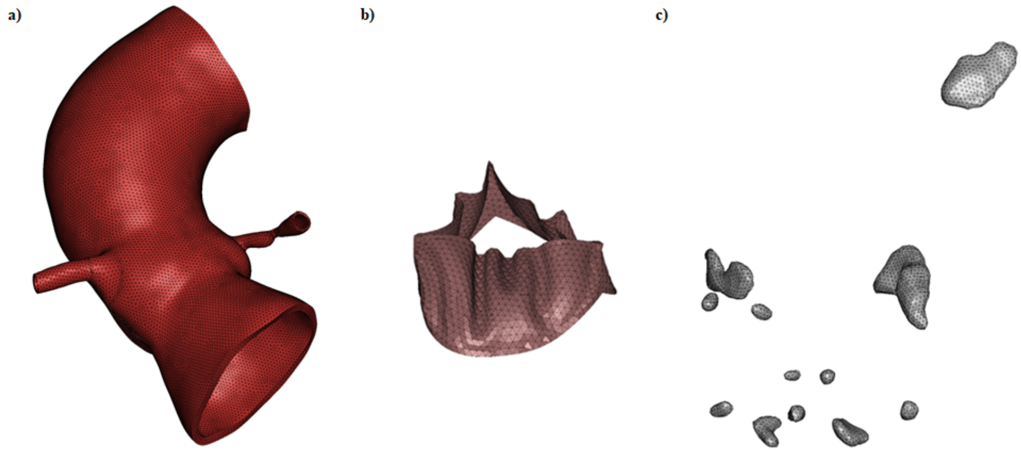

Figure 2: *Example of the anatomies' components: a) Aorta; b) Natural valve; c) Calcifications.*

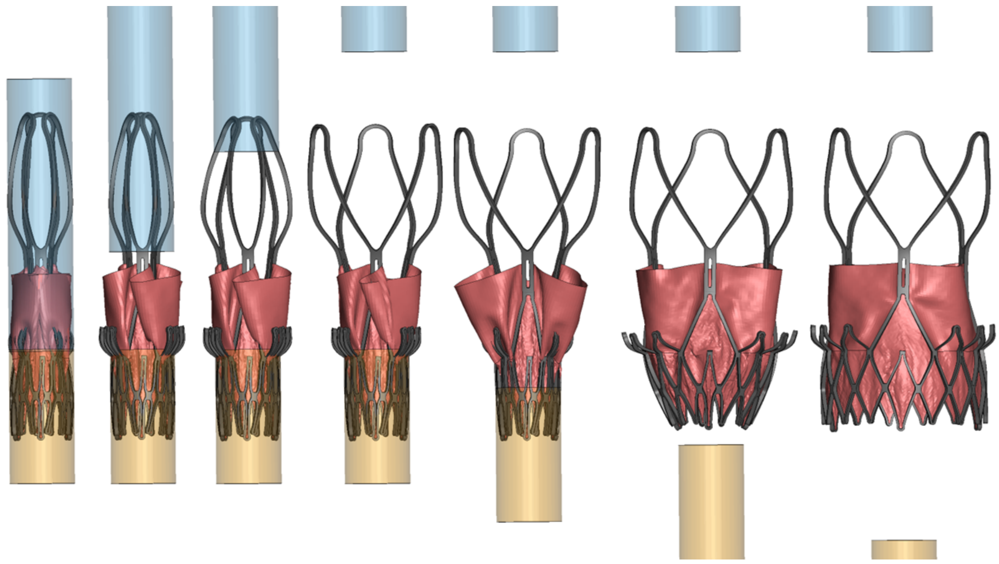

Figure 3: *Evolution of the deployment starting from the crimped configuration.*

this way, the device is released within the aortic root (Figure 3). In this second phase all contacts involving the patient's anatomy are activated.

3. Results

For all analysed quantities, their distribution was similar in all six patients, except for a few particularities, due to the different anatomical geometry of the various simulations. First, the first principal stresses on the aorta's wall have been analysed. It was possible to understand that the most stressed areas were the lower parts of the sinuses of Valsalva. This is due to their morphology and the fact that the lower cage of the stent, which is also the one with the most cells, adhered to the wall of the aorta precisely at this anatomical point. In one case the area involved was larger than the others, due to the presence of a calcification of considerable size. In the same patient, the highest value out of the six simulations of first principal stress was observed due to the compression of a portion of the aorta between two lateral hooks (Figure 4). Then the deformation of the aorta was analysed: it was established that the most deformed area is also in this case the lower sinuses area, due to the presence of the lower stent cage. A less intense, but larger area of deformation was also found in the upper part of the aorta due to the presence of the upper device's cage (Figure 5). The third analysis looked at the Von Mises stresses on the stent. It was possible to observe the presence of two great stress areas, i.e. the characteristic curvatures of some of the cells of the lower cage and the upper area of the lateral hooks. This

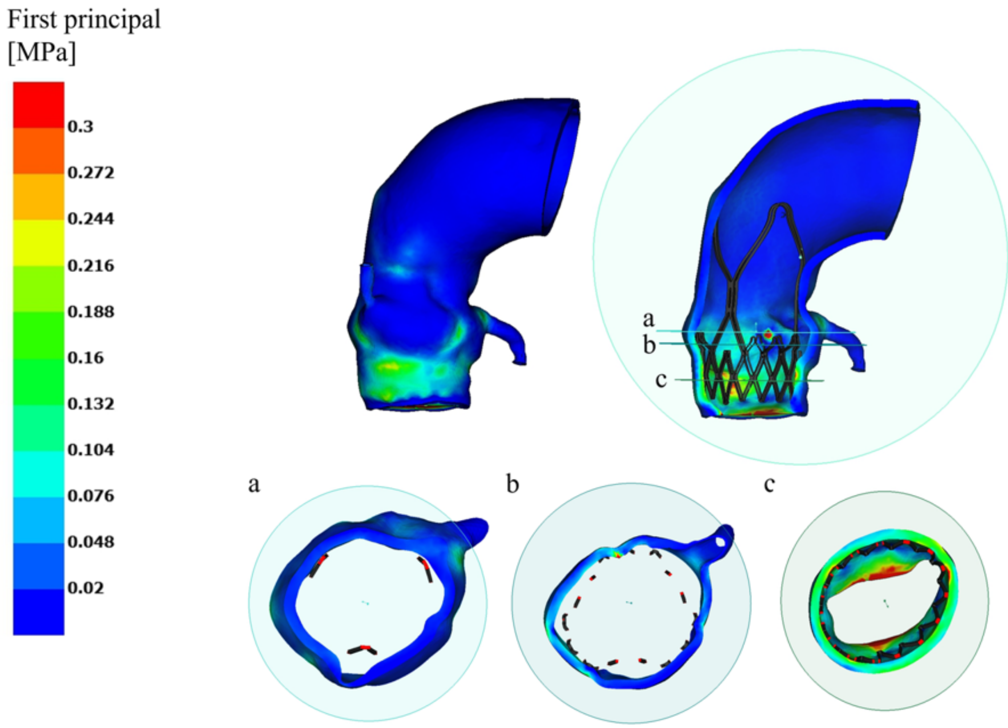

Figure 4: *First principal stress in one patient's aorta along 4 planes.*

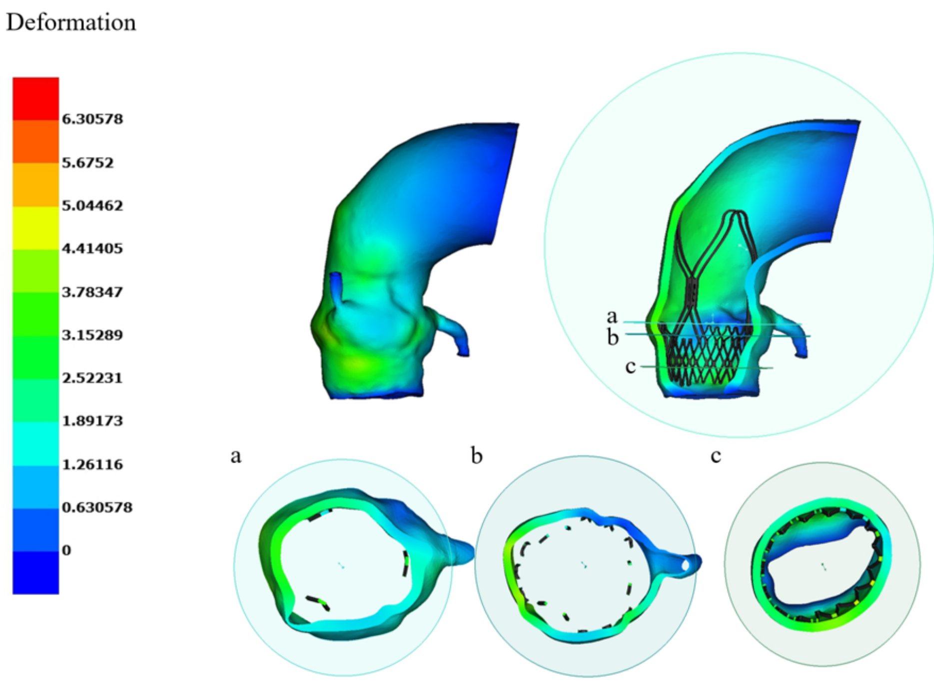

Figure 5: *Deformation of one patient's aorta along 4 planes.*

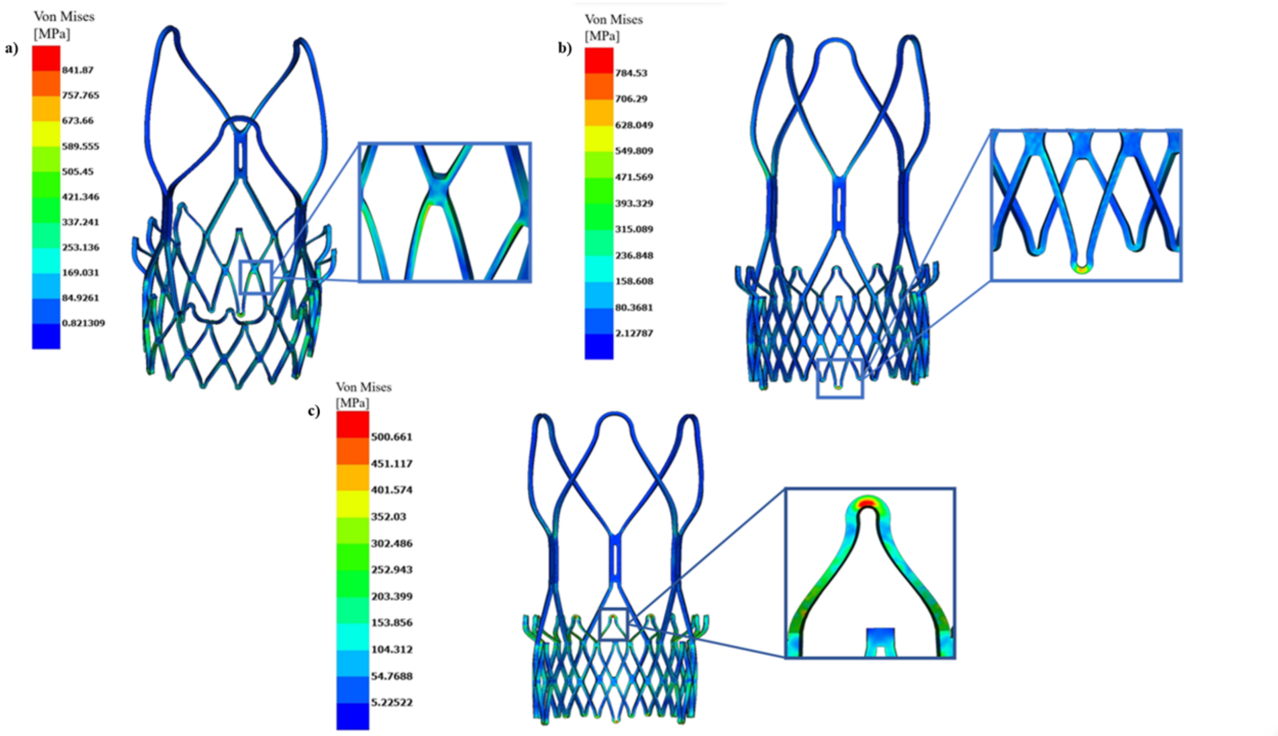

Figure 6: *Von Mises stress on three patients' stents.*

can be reconducted to the geometry of these two areas, which are very small and particular, and will therefore reasonably be subjected to very high stresses in order to ensure the correct opening and adhesion of the device within the aortic root (Figure 6 b,c). One patient, instead, suffered from the geometry of the aortic root. Due to the limited space available, the opening of the prosthetic valve was more difficult, which resulted in greater stresses at the lower cage, in correspondence of a connection between two cells, and in a slight distortion of the latter (Figure 6 a). Finally, the distance between the stent and the aorta was assessed. In all patients the lower part of the prosthesis is fully adhered to the wall of the patient's anatomy, while the upper part exhibits different behaviours according to specific anatomies. In some cases, in fact, the three upper crowns adhere almost perfectly to the curvature of the aorta, while in others the resulting distance is greater (Figure 7).

4. Conclusions

This thesis work showed the importance of accurately reproducing patient-specific geometries and the correct positioning of the device in order to obtain correct structural computational simulations of the TAVI procedure, as different geometries and placements are associated with different stress and deformation responses. Importance of carrying out patient-specific research was emphasised in the course of the work, so that the particularities of different anatomies can be understood more specifically, to achieve a more precise and safe result for every patient.

However, the work done is not without limitations. Most of the measurements of the actual device, the basis of CAD development, were made using a software and not on the actual valve. In the future, it might be interesting to develop a parametric model of this CAD.

In addition, the patients' natural valves were reconstructed following reference points on the aortas as they could not be obtained from CT images, thus being probably different from the real ones.

The positioning of the device inside the aortic root could also be inaccurate in some cases because some angiographies did not allow to obtain clear information.

Finally, the mechanical properties of some components could be improved by using more complex and accurate models, and data from pathological aortic roots.

The simulations developed in this thesis could

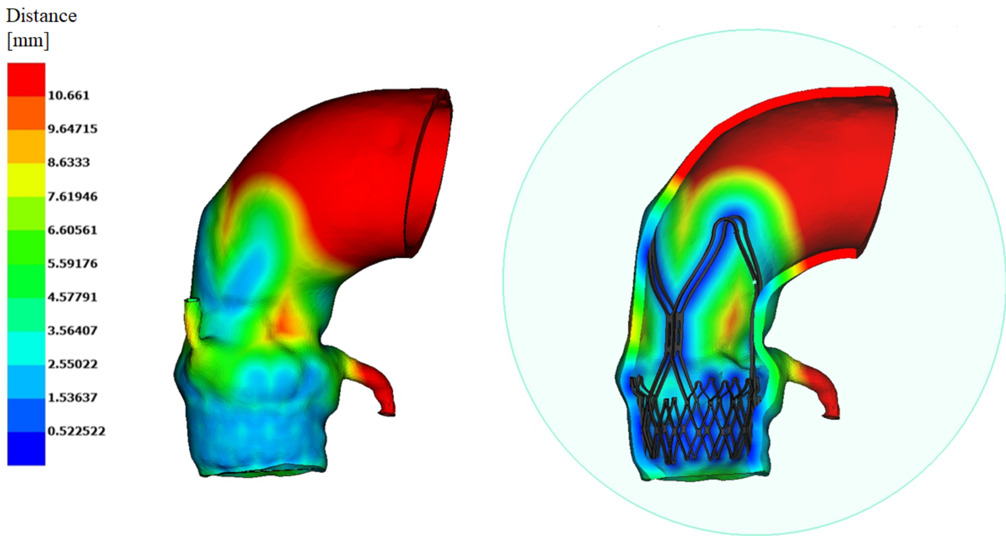

Figure 7: *Distances between the stent and the aorta for one patient.*

eventually be simplified by creating a one-dimensional model of the device, discretized with beam-type elements. This would also make possible the natural continuation of structural simulations, i.e. the development of fluid-structure models.

References

[1] B. Iung and A. Vahanian, "Epidemiology of valvular heart disease in the adult," *Nature Reviews Cardiology*, vol. 8, no. 3, pp. 162–172, 2011.

[2] B. Iung, A. Cachier, G. Baron, D. Messika-Zeitoun, F. Delahaye, P. Tornos, C. Gohlke-Barwolf, E. Boersma, P. Ravaud, and A. Vahanian, "Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery?," *European heart journal*, vol. 26, no. 24, pp. 2714–2720, 2005.

[3] G. Luraghi, J. F. Rodriguez Matas, and F. Migliavacca, "In silico approaches for transcatheter aortic valve replacement inspection," *Expert Review of Cardiovascular Therapy*, vol. 19, no. 1, pp. 61–70, 2021.

[4] M. Toma, S. Singh-Gryzbon, E. Frankini, Z. Wei, and A. P. Yoganathan, "Clinical impact of computational heart valve models," *Materials*, vol. 15, no. 9, p. 3302, 2022.

[5] S. Morganti, N. Brambilla, A. Petronio, A. Reali, F. Bedogni, and F. Auricchio, "Prediction of patient-specific post-operative outcomes of tavi procedure: The impact of the positioning strategy on valve performance," *Journal of biomechanics*, vol. 49, no. 12, pp. 2513–2519, 2016.

[6] F. Auricchio, S. Morganti, and D. Vella, "Transcatheter aortic valve implantation: from clinical data to finite element models,"

[7] A. N. Azadani, S. Chitsaz, P. B. Matthews, N. Jaussaud, J. Leung, T. Tsinman, L. Ge, and E. E. Tseng, "Comparison of mechanical properties of human ascending aorta and aortic sinuses," *The Annals of thoracic surgery*, vol. 93, no. 1, pp. 87–94, 2012.

[8] G. A. Holzapfel, G. Sommer, and P. Regitnig, "Anisotropic mechanical properties of tissue components in human atherosclerotic plaques," *Journal of biomechanical engineering*, vol. 126, no. 5, pp. 657–665, 2004.