Simulation of transcatheter aortic valve implantation through patient-specific finite element analysis: Two clinical cases

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A B S T R A C T

Transcatheter aortic valve implantation (TAVI) is a minimally invasive procedure introduced to treat aortic valve stenosis in elder patients. Its clinical outcomes are strictly related to patient selection, operator skills, and dedicated pre-procedural planning based on accurate medical imaging analysis. The goal of this work is to define a finite element framework to realistically reproduce TAVI and evaluate the impact of aortic root anatomy on procedure outcomes starting from two real patient datasets. Patient-specific aortic root models including native leaflets, calcific plaques extracted from medical images, and an accurate stent geometry based on micro-tomography reconstruction are key aspects included in the present study. Through the proposed simulation strategy we observe that, in both patients, stent apposition significantly induces anatomical configuration changes, while it leads to different stress distributions on the aortic wall. Moreover, for one patient, a possible risk of paravalvular leakage has been found while an asymmetric coaptation occurs in both investigated cases. Post-operative clinical data, that have been analyzed to prove reliability of the performed simulations, show a good agreement with analysis results. The proposed work thus represents a further step towards the use of realistic computer-based simulations of TAVI procedures, aiming at improving the efficacy of the operation technique and supporting device optimization.

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1. Introduction

The first percutaneous transcatheter implantation of an aortic valve prosthesis in humans was described more than 10 years ago, in 2002, by Cribier et al. (2002). Since then, such a minimally invasive procedure to restore valve functionality in case of calcific stenosis has become a routine approach for high-risk or even inoperable patients (Smith et al., 2011).

Many papers collecting the results of transcatheter aortic valve implantation (TAVI) demonstrate that, with respect to standard therapy, rates of death from any cause are reduced (Leon et al., 2010). Mid-term follow-up has shown no evidence of restenosis or prosthetic dysfunction (Zajarias and Cribier, 2013). Incomplete prosthesis apposition due to calcifications or annular eccentricity (Blanke et al., 2010), undersizing of the device, and malpositioning of the valve (Détaint et al., 2009) are the most common determinants of paravalvular leakage. As a direct consequence, an appropriate annular measurement, a correct evaluation of calcifications, and an appropriate sizing of the prosthetic valve are “of utmost importance” (Gurvitch et al., 2011; Delgado et al., 2010; Détaint et al., 2009).

Given such considerations, advanced computational tools integrating patient-specific information and accurate device modeling can be used to support pre-operative planning. In the literature, several studies addressing computer-based simulations of TAVI through finite element analysis (FEA) are already available. Specifically, Smuts et al. (2011) have developed new concepts for different percutaneous aortic leaflet geometries while Wang et al. (2012) and Sun et al. (2010) have investigated the post-operative TAVI mechanics and hemodynamics, respectively. Moreover, Capelli et al. (2012) have virtually evaluated the feasibility of TAVI

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in morphologies which are currently borderline cases for a percutaneous approach (e.g., failed bioprosthetic aortic valves). More recently, Auricchio et al. (2012a) have proposed a patient-specific FEA-based simulation accounting for all the procedural steps able to reproduce the prosthesis post-operative performance through the inclusion in the analysis of the biological valve sewn into the metallic frame. However, to the authors' knowledge, a comparison with postoperative medical data has not been addressed yet.

In this context, the present work proposes a systematic approach to realistically simulate TAVI, tailored to the clinical practice; in particular, we propose a study, based on the analysis of pre-operative medical images of two real patients who underwent TAVI, with the final ambitious goal of predicting the post-operative performance of the prosthesis with respect to the specific anatomical features. The present work includes different issues which make it an original contribution, presenting the capabilities of an advanced tool for clinical support and, in particular: (i) the aortic valve model is complete of both the aortic sinuses and the native valve leaflets and the considered material model is calibrated on human data, (ii) the calcific plaque is included within the model on the basis of imaging records, (iii) the geometry of the prosthetic stent is very accurate, being obtained from micro-tomography (micro-CT) reconstruction.

Last but not least, post-operative data collected by physicians for patients' follow-up are used for comparison with numerical results with the aim of assessing the capabilities of the proposed simulations to predict the procedural outcomes. Validation of TAVI simulation is a critical issue since it is usually difficult to obtain good quality post-operative data and images from standard post-operative procedures. Additionally, postoperative CT is not included in the routine protocol of transcatheter aortic valve implantation either to not overload renal activity of often already critical patients with the use of a contrast die, or to avoid high radiation doses for the patient. Instead, the operation outcome is generally evaluated by intraoperative angiography as well as by follow-up ultrasound. In the present paper, on the basis of such routinely obtained data, we try to address a comparison between the real procedure outcomes and the simulation results.

2. Materials and methods

Two patients that underwent TAVI have been included in the present study, both with severe symptomatic aortic stenosis: Patient-1 is a 83 year-old male subject, while Patient-2 is a 84 year-old male subject; both patients underwent TAVI through transapical access. In both cases, the preoperative planning started from a CT examination, which, at present, represents the standard methodology for the optimal device for implantation. In both cases, the implantation was performed successfully, that is, without procedural mortality as well as without embolization (i.e., migration of the implanted valve either into the left ventricle or into the aorta).

The adopted computational framework to simulate transcatheter aortic valve implantation can be roughly divided into four main steps:

- Step 1: Processing of medical images.
- Step 2: Creation of analysis-suitable models.
- Step 3: Performance of all the required analyses to reproduce the entire clinical procedure.
- Step 4: Post-processing of the simulation results and comparison with follow-up data.

As described in Table 1, the four main stages of the developed workflow account for different sub-steps, which are detailed in the following:

<table>
<thead>
<tr>
<th>Table 1</th>
<th>The four blocks of the developed modeling strategy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step-1</td>
<td>Medical images</td>
</tr>
<tr>
<td>Step-2</td>
<td>Analysis-suitable models</td>
</tr>
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<td>Step-3</td>
<td>Analysis</td>
</tr>
<tr>
<td>Step-4</td>
<td>Post-processing</td>
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<tr>
<th>Ct data</th>
<th>Aortic sinuses native leaflets calcifications prosthetic device</th>
<th>Stent crimping stent expansion valve mapping valve closure</th>
<th>Simulation output follow-up data</th>
</tr>
</thead>
</table>

**Fig. 1.** Through image processing procedures the aortic lumen (red) and the calcium deposits (yellow) can be isolated and extracted from CT data of the whole body. (For interpretation of the references to color in this figure caption, the reader is referred to the web version of this article.)

2.1. Medical image processing

Preoperative CT examinations were performed at IRCCS Policlinico San Matteo (Pavia, Italy) using a dual-source computed tomography scanner (Somatom Definition, Siemens Healthcare, Forchheim, Germany). To obtain contrast-enhanced images a iodinated contrast agent was injected. Scan main parameters for cardiac CT were as follows: scan direction, cranio-caudal; slice thickness, 0.6 mm; spiral pitch factor, 0.2; tube voltage, 120 kV.

The CT data sets are processed using ITK-Snap v2.4 (Yushkevich et al., 2006). In particular, a confined region of interest (i.e., the aortic root from the left ventricular outflow to the sinotubular junction) is extracted from the whole reconstructed body exploiting the contrast enhancement, cropping, and segmentation capabilities of the software.

Using different Hounsfield unit thresholds, it is possible to discern the calcific component from the surrounding healthy tissue and evaluate it in terms of both location and dimension. Once the segmented region is extracted, we export the aortic lumen as well as the calcium deposits as stereolithographic (STL) files, represented in Fig. 1.

2.2. Analysis-suitable models

In this section, we describe the procedure to obtain analysis-suitable models of both the native aortic valve including calcifications and prosthetic device.

**Native aortic valve model**: The obtained STL file of the aortic root is processed implementing in MatLab (The Mathworks Inc., Natick, MA, USA) a procedure able to define a set of splines, resembling the cross sectional contours of the aortic lumen. These curves are used to automatically generate a volume model of the aortic root wall, which is finally imported in Abaqus CAE software (Simulia, Dassault Systems, Providence, RI, USA) for the finite element analysis set-up.

The geometrical model of the aortic root obtained by processing the STL file thus represents the starting point of the finite element analysis of TAVI. It is worth noting that we generate not only the aortic wall but also the native valve leaflets in order to get a complete and realistic model for the simulations. In particular, to include the native leaflets geometry, the first step consists in the identification of nine reference

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1 For technical details refer to Lichtenstein et al. (2006).
points: six of them refer to the commissural extremes (A, A’, B, B’, C, C in Fig. 2a) while the others correspond to the center of the basal leaflet attachment (N1, N2, N3 in Fig. 2a).

Such reference points are used for the definition of proper planes which drive the partition of the whole aortic root model aimed at extracting the leaflet commissures and attachment lines (light blue lines in Fig. 2). The free margin is simply defined as a circular arc whose length can be measured by ultrasound. Once the perimeter of all the leaflets is identified, it is possible to reconstruct the leaflet surface in the open configuration.

The aortic wall model of Patient-1 is meshed using 265,976 tetrahedral elements for the healthy region and 2936 for the calcific part while the leaflets are discretized using 3212 shell elements with reduced integration for the healthy tissue and 427 for the calcific tissue. The healthy tissue of the leaflets is discretized using 3258 shell elements with reduced integration for the healthy tissue and 427 for the calcific tissue.

Fig. 3 shows the resulting aortic root model in the case of Patient-1: the model is composed of the vessel wall, the native leaflets and calcific plaque. The superimposition of the model on the 3D reconstructions derived from medical images shows a good correspondence; in particular, in Fig. 3b,c the closed model of the native aortic valve, obtained through a simulation of valve closure, highlights a good agreement between the real patient’s plaques and the position of calcific shell elements.

Material models: For the sake of simplicity, the material for the native aortic tissues is assumed to be isotropic and homogenous, as already assumed in Goyanesbwar et al. (2002) and Capelli et al. (2012). In particular, the nearly incompressible reduced polynomial form is used to reproduce material behavior (Selvadurai, 2006; Yeoh, 1993). The form of the reduced polynomial strain energy potential is

$$\Psi = \sum_{i=1}^{3} C_i (\lambda_i - 3)^i,$$

where $N$ and $C_i$ are material parameters, $\lambda_i$ is the first deviatoric strain invariant defined as

$$\lambda_i = \lambda_{i1} + \lambda_{i2} + \lambda_{i3},$$

where the deviatoric stretches $\lambda_{i} = J^{-1/3} \lambda_i$ being $J$ the total volume ratio and $\lambda_i$ the principal stretches. After choosing a sixth-order polynomial form ($N=6$), we find the unknown material constants $C_i$ by fitting experimental data obtained from human samples for each single leaflet and sinus (Martin et al., 2011; Stradins et al., 2004). In particular, in Table 2 we report the constant values resulting from the implemented fitting procedure described in Auricchio et al. (2012c):

In Fig. 4, the results of the fitting procedure are shown for the Left-Coronary sinus. Both circumferential and axial behavior are well-captured by the considered model.

**Table 2.** Yeoh parameters [kPa] obtained from model calibration on human aortic data.

<table>
<thead>
<tr>
<th>Anatomical region</th>
<th>$C_{10}$</th>
<th>$C_{20}$</th>
<th>$C_{30}$</th>
<th>$C_{40}$</th>
<th>$C_{50}$</th>
<th>$C_{60}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left-coronary</td>
<td>23.29</td>
<td>624.4</td>
<td>1.98e3</td>
<td>201.5</td>
<td>22.15</td>
<td>29.11</td>
</tr>
<tr>
<td>Non-coronary</td>
<td>18.35</td>
<td>190.9</td>
<td>1.22e3</td>
<td>629.7</td>
<td>1.58e3</td>
<td></td>
</tr>
<tr>
<td>Right-coronary</td>
<td>22.44</td>
<td>959.9</td>
<td>2.58e3</td>
<td>1.36e3</td>
<td>205.3</td>
<td></td>
</tr>
<tr>
<td>Left-coronary</td>
<td>23.46</td>
<td>1.01e3</td>
<td>2.11e3</td>
<td>607.8</td>
<td>674.3</td>
<td>679.9</td>
</tr>
<tr>
<td>Non-coronary</td>
<td>18.01</td>
<td>1.69e3</td>
<td>1.95e3</td>
<td>994.1</td>
<td>1.49e3</td>
<td>301.5</td>
</tr>
<tr>
<td>Right-coronary</td>
<td>0.11</td>
<td>758.2</td>
<td>941</td>
<td>895.7</td>
<td>1.04e3</td>
<td>752.8</td>
</tr>
</tbody>
</table>

Prosthesis model: Although several devices for TAVI have been proposed over the last decade (Padala et al., 2010), only two of them are very frequently used in clinical practice: the Medtronic CoreValve and the Edwards Lifesciences SAPIEN. While the CoreValve is self-expandable, the Edwards SAPIEN valve is basically composed of three flexible biological leaflets sutured into a balloon-expandable stent. In the present study, we focus on the SAPIEN XT prostheses moving from medical images regarding two real patients who underwent TAVI as discussed in the following.

Both patients were treated with an Edwards Lifesciences SAPIEN XT size 26. A faithful geometrical model of such a device is based on a high-resolution micro-CT scan (SkyScan 1172 with a resolution of 0.17 micron) of a real device sample. The obtained stent model is meshed using 84,435 solid elements with reduced integration.

**Fig. 2.** From 3D reconstructions of the aortic lumen it is possible to identify reference points for modeling native valve leafllet: (a) the commissures and basal leaflet attachment lines are highlighted on a rendering of the aortic lumen; (b) reference points extracted from the aortic root reconstruction are used to generate leaflet surface. (For interpretation of the references to color in this figure caption, the reader is referred to the web version of this article.)

**Fig. 3.** Rendering of the STL file vs aortic model created for simulations: (a) the real aortic root lumen (red) and calcifications (yellow) are overlapped to the aortic wall model (gray); (b) the closed native leaflets (blue mesh) of our model are perfectly matching with real calcifications obtained by processing CT images; (c) top view is shown. (For interpretation of the references to color in this figure caption, the reader is referred to the web version of this article.)
Aortic wall and native valve leaflets are assumed to have a uniform thickness of 2.5 and 0.5 mm, respectively (Auricchio et al., 2012a). Following Capelli et al. (2012), calcified tissue is assumed to be characterized by an elastic modulus of 10 MPa, a Poisson ratio of 0.35, a density of 2000 kg/m³, while the thickness of calcific shell elements is chosen equal to 1.4 mm.

A Von Mises plasticity model with an isotropic hardening is adopted for the stent which is made of a cobalt–chromium alloy. In particular the following parameters are used: 233 GPA, 0.35, 414 MPa, 933 MPa and 44.5% in terms of Young modulus, Poisson coefficient, yield stress, ultimate stress and deformation at break, respectively (Morlacchi et al., 2013).

Finally, regarding the prosthetic valve leaflets, there are different beliefs concerning the constitutive characteristics of bovine pericardium after the fixation process. In the present work, we model the leaflets as an isotropic material (Hanlon et al., 1999; Lee et al., 1989; Trowbridge et al., 2011) and, in particular, an elastic modulus of 8 MPa, a Poisson coefficient of 0.45, and a density of 1100 kg/m³ are used following Xiong et al. (2010). The prosthetic valve is meshed with 6000 quadrilateral shell elements, while a uniform thickness of 0.4 mm is considered.

### 2.3. Finite-element analyses

The TAVI procedure is a complex intervention composed by several steps; to realistically reproduce the whole procedure, we set-up a simulation strategy consisting in the following two main stages:

a. Stent crimping and deployment: In this step, the prosthetic stent model is crimped to achieve the catheter diameter which, for a transapical approach, is usually 24 French (8 mm); then, the prosthetic stent is expanded within the patient-specific aortic root to reproduce the implantation due to balloon expansion.

b. Valve mapping and closure: The prosthetic leaflets are mapped onto the implanted stent and a physiological pressure is applied to virtually recreate the diastolic behavior of the SAPIEN device.

All the numerical analyses are non-linear problems involving large deformation and contact. For this reason, Abaqus Explicit solver v6.10 is used to perform large deformation analyses; in particular, quasi-static procedures are used again assuming that inertia forces do not change the solution. Kinetic energy is monitored to ensure that the ratio of kinetic energy to internal energy remains less than 10%.

**Fig. 5.** Procedural steps of TAVI reproduced through a computer-based simulation strategy: (a) the crimped stent is properly placed inside the aortic root model; (b) the stent is expanded within the patient-specific aortic root; (c) prosthetic leaflet closure is reproduced to evaluate postoperative performance.

<table>
<thead>
<tr>
<th>Strain [-]</th>
<th>Circumferential [kPa]</th>
<th>Axial [kPa]</th>
<th>Model [kPa]</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>70</td>
<td>60</td>
<td>50</td>
</tr>
<tr>
<td>0.01</td>
<td>60</td>
<td>50</td>
<td>40</td>
</tr>
<tr>
<td>0.02</td>
<td>50</td>
<td>40</td>
<td>30</td>
</tr>
<tr>
<td>0.03</td>
<td>40</td>
<td>30</td>
<td>20</td>
</tr>
<tr>
<td>0.04</td>
<td>30</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>0.05</td>
<td>20</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>0.06</td>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>0.07</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Fig. 4.** Fitting results on the experimental data (dots) of the human aortic left-coronary sinus (Martin et al., 2010) by using a reduced-polynomial form of the strain energy function.
obtained holes, again at the annulus level. Finally, the coaptation area is defined as the total area of the prosthetic leaflet elements in contact with each other at the end of diastole.

3. Results

The obtained results can be classified into two main groups: (i) from the simulation of stent expansion we can evaluate the impact of the metallic frame of the stent on the native calcified aortic root wall; (ii) from the simulation of valve closure, we can predict the post-operative device performance.

In Fig. 6a von Mises aortic wall stresses induced by stent expansion are shown from two different views for the two considered patients.

Such a distribution should be ideally uniform, resembling an homogeneous interaction of the stent prosthesis with the aortic root base. Our results suggest instead that the stresses are not uniformly distributed. In particular, in both cases, spots of concentrated stresses are visible in correspondence with the adhesion between the inner aortic wall and the metallic frame of the stent.

In Fig. 7a, a contour map representing the point-wise distance between the basal stent crown of the expanded stent and the inner aortic wall is shown.

Higher values (up to 2 mm) are obtained for Patient-2 while a good and uniform degree of adherence is achieved after stent expansion in Patient-1. Such results are also confirmed by Fig. 7b where two proximal cross-sections of the implanted device are represented. Greater holes (for a total area of 36.9 mm²) between the stent and the aortic wall are found for Patient-2 than for Patient-1 whose area associated to paravalvular leakage is negligible being equal to 4.1 mm².

The native morphology of the aortic root and, in particular, the quantity and position of calcifications may induce a non-circular shape to the implanted device. In both cases, an elliptical shape of the device is obtained, as highlighted in Fig. 8a. Regarding stent eccentricity, the sides of the obtained post-implant triangle (red dotted lines in Fig. 8a) measure: $a=22.2$ mm, $b=23.1$ mm, $c=21.8$ for Patient-1; $a=23.4$ mm, $b=23.3$ mm, $c=21.3$ for Patient-2.

The ratio between the minor and major elliptical axes (blue dotted lines in Fig. 8a) is: $e=0.91$ for Patient-1 and $e=0.75$ for Patient-2.

Finally, simulation of valve closure (see valve top-view of Fig. 8b) allows the quantification of coaptation area which results equal to 207.3 mm² for Patient-1 and 164.8 mm² for Patient-2.

Table 3 summarizes all the obtained results for the two specific patients.

4. Discussion

It is well-known and extensively reported in the literature that the selection of prosthetic device size and type is very important to avoid (or, at least, reduce) aortic regurgitation and/or other TAVI complications (Generaux et al., 2013; Delgado et al., 2010; Détaint et al., 2009). Such a critical choice not only depends on annular dimensions but also on the complex native aortic root morphology as well as on position and dimensions of calcifications (Feuchtner et al., 2013).

Computational analyses, which take into account both the patient-specific structure of the native aortic valve and an accurate evaluation of calcifications, can be used to predict several parameters which, being of clinical interest, can support and guide device selection. In the present work, a complete framework to reproduce transcatheter aortic valve implantation has been developed and applied to two real clinical cases.

Stress distribution is characterized by concentrated spots of higher stress values induced by the contact between the stent and the aortic wall (see Fig. 6). Additionally, in agreement with Wang et al. (2012), high values of the maximum principal stress are obtained in the aortic regions closed to calcifications. On one side, higher stress values can be related to higher force of adherence between stent and aortic wall; on the other side, high stress patterns concentrated in the annular region can indicate a major risk of aortic rupture (Eker et al., 2012) which is a possible TAVI complication leading to cardiac tamponade and subsequent fatal events.

![Fig. 6](image-url) Impact of the prosthesis implant on the aortic root: von Mises stress [MPa] distribution along the vessel is reported to evaluate the interaction between the prosthetic stent and the aortic root wall; a huge difference in terms of maximum stress values is observable. This is attributable to the position and extension of calcifications of the aortic root as well as to the preoperative configuration of the aortic annulus: for Patient-2 a very irregular and elliptic shape has been extracted from CT images.
If aortic rupture is quite unusual, paravalvular leak is one of the most frequent complications which may occur after TAVI due to incomplete adherence of the prosthetic stent to the aortic wall. For both considered patients, we can quantitatively evaluate the area of the perivalvular holes, which can be assumed to be proportional to the amount of retrograde perivalvular blood flow (i.e., perivalvular leakage). Interestingly, the obtained results are in agreement with postoperative medical data.

Indeed, as reported in Fig. 9, quantitative postoperative Doppler Echocardiography has recorded a significantly higher regurgitant flow for Patient-2, whose maximum retrograde jet velocity was measured equal to 3.86 m/s, while the maximum velocity for Patient-1 was 1.70 m/s. Also angiographic movies (attached as supplementary material) are in agreement with our results since the postoperative retrograde flow, highlighted by a contrast agent, is qualitatively much more visible in Patient-2 than in Patient-1.

Finally, the measured eccentricity of the implanted stent shows that for both patients the positioned stent assumes a non-circular shape. For Patient-2 a slightly worst scenario has been predicted by our analyses (see Fig. 8a). Eccentricity of the implanted stent directly influences valve closure and, in particular, coaptation. In fact, the non-symmetric closure highlighted in Fig. 8b is attributed to the elliptical stent configuration, in agreement with results by Auricchio et al. (2011) and Auricchio et al. (2011) showing that one leaflet closes below the other two producing a small central gap responsible of a regurgitant flow. Even though we think that the geometrical asymmetry of the stent is the main determinant of the central gap obtained during diastole, it is worth highlighting that the choice of the leaflet material model, which has been proven to have a strong impact on coaptation values (Auricchio et al., 2012b), may alter the obtained results. However, the resulting intravalvular gap is in agreement with follow-up evaluations which, in both patients, have highlighted a central “mild intra-prothesic leak” (extraction from postoperative medical records of both Patient-1 and Patient-2).

5. Limitations

Even though the present work represents a clear improvement with respect to the current state of the art due to the previously

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**Fig. 7.** Evaluation of the degree of apposition between the prosthesis stent and the patient-specific root anatomy: (a) the reconstructed model of the aortic root is represented in light-gray, while the stent is shown in dark-gray; on the basal crown of the stent, which, at the end of implantation, should completely adhere with the aortic annulus, a contour-map of the radial distance [mm] between the inner aortic wall and the outer surface of the implanted stent is represented; (b) for both patients a cross-section at the proximal side of the implanted device allows to highlight the holes between the stent and the aortic root wall, responsible of paravalvular leakage.
Fig. 8. Prosthesis configuration after implantation: (a) An evaluation of the non-circularity of the implanted stent is proposed as the measure of the three distances between the points at the top of the three supporting bars; minor and major axes of the originated ellipse are also highlighted for Patient-1 and Patient-2. (b) Due to stent non-circularity, the top-view of the closed prosthetic valves shows a non-physiological closure in both cases. Even though no insufficiency is evident from this view, a central gap due to asymmetric closure may occur. (For interpretation of the references to color in this figure caption, the reader is referred to the web version of this article.)

Table 3
Analysis results from simulation of TAVI in the two considered patients. VMS stands for Von Mises Stress; MPS stands for Maximum Principal Stress.

<table>
<thead>
<tr>
<th>Anatomical region</th>
<th>Peak VMS (MPa)</th>
<th>Peak MPS (MPa)</th>
<th>Distance stent-wall (mm)</th>
<th>Perivalvular holes (mm²)</th>
<th>Eccentricity (–)</th>
<th>Coaptation area (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient-1</td>
<td>3.41</td>
<td>7.09</td>
<td>0.71</td>
<td>4.1</td>
<td>0.91</td>
<td>207.3</td>
</tr>
<tr>
<td>Patient-2</td>
<td>12.2</td>
<td>20.1</td>
<td>2.01</td>
<td>36.9</td>
<td>0.75</td>
<td>164.8</td>
</tr>
</tbody>
</table>

Fig. 9. Postoperative Doppler Echocardiography records show a lower retrograde blood flow for Patient-1 (a) than for Patient-2 (b).
highlighted key aspects, it still presents some limitations. Material modeling has been simplified: homogeneous isotropic properties have been assigned to all the involved materials, even though calibrated on human experimental data. Our findings indicate a different level of post-implant solicitation of the root tissue. Such results call for further developments in two directions: investigation of the constitutive modeling influence on the simulation outcomes, i.e., stress of the root wall after the implant; study extension to a higher number of cases in order to evaluate the statistical relevance of the simulation findings. Further developments of the study will be also devoted to the evaluation of the influence of ecographic resolution of the performed leaflet measurements and on the final simulation outcomes. In dealing with the simulation strategy, we expand the metallic frame of the prosthesis using a cylindrical surface while in the real procedure a balloon is used. Future developments of the work will enhance the realism of the proposed approach.

Finally, postoperative CT data can be used to perform a detailed comparison between the resulting configuration of the implanted device, outcome of the analysis, and the real scenario. However, postoperative CT is not usually included within the TAVI protocol, and we believe that also a comparison with commonly performed examinations (angiography and ultrasound) represents an interesting added value of the present work.

6. Conclusions

Two clinical cases of transcatheter aortic valve implantation have been investigated through structural finite element analysis. In particular, the impact of patient-specific anatomical features of the native aortic valve on the postoperative performance of the balloon-expandable Edwards Sapien XT device has been analyzed. Stress distributions, geometrical changes, coaptation values, and risk of paravalvular leakage have been computed and evaluated for both patients. Comparison between the obtained numerical results and in-vivo postoperative measurements shows a good agreement, demonstrating that the proposed simulation strategy can offer a reliable and useful tool to evaluate several clinically relevant aspects of TAVI. Although limited to only two patients, this study represents a further step towards the use of realistic computer-based simulations for virtual planning of TAVI procedures, aiming at improving the efficacy of the operation technique and supporting device optimization.

Conflict of interest

The authors report no conflicts of interest.

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Appendix A. Supplementary material

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.jbiomech.2014.06.007.

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