The Impact of Size and Position of a Mechanical Expandable Transcatheter Aortic Valve: Novel Insights Through Computational Modelling and Simulation

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ORIGINAL ARTICLE

The Impact of Size and Position of a Mechanical Expandable Transcatheter Aortic Valve: Novel Insights Through Computational Modelling and Simulation

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Abstract

Transcatheter aortic valve implantation has become an established procedure to treat severe aortic stenosis. Correct device sizing/positioning is crucial for optimal outcome. Lotus valve sizing is based upon multiple aortic root dimensions. Hence, it often occurs that two valve sizes can be selected. In this study, patient-specific computer simulation is adopted to evaluate the influence of Lotus size/position on paravalvular aortic regurgitation (AR) and conduction abnormalities, in patients with equivocal aortic root dimensions. First, simulation was performed in 62 patients to validate the model in terms of predicted AR and conduction abnormalities using postoperative echocardiographic, angiographic and ECG-based data. Then, two Lotus sizes were simulated at two positions in patients with equivocal aortic root dimensions. Large valve size and deep position were associated with higher contact pressure, while only large size, not position, significantly reduced the predicted AR. Despite general trends, simulations revealed that optimal device size/position is patient-specific.

Keywords Aortic regurgitation · Equivocal aortic root dimensions · Computer simulations · Conduction abnormalities · TAVI

Abbreviations

AR	Aortic regurgitation
LCC	Left coronary cusp
LVOT	Left ventricular outflow tract
MSCT	Multi-slice computed tomography
NCC	Noncoronary cusp
NPV	Negative predicted value
PPV	Positive predicted value
RCC	Right coronary cusp
TAVI	Transcatheter aortic valve implantation
THV	Transcatheter heart valve

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Introduction

Transcatheter aortic valve implantation (TAVI) is a widely accepted minimally invasive treatment for patients suffering from severe aortic stenosis [1–3]. Over the last decade, it has become clear that selection of the appropriate transcatheter heart valve (THV) size is of critical importance for the success of the procedure. A too small device size might result in valve migration or paravalvular regurgitation, while oversizing can cause new conduction abnormalities [4, 5], annular rupture, or coronary obstruction [6, 7]. Similarly, the final position of the THV within the aortic root strongly influences procedural outcome. Too low/high positioning is in many cases associated with paravalvular aortic regurgitation (AR) [8], while

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several studies demonstrated that low THV implantation increases the risk of TAVI-induced conduction abnormalities [8, 9].

The mechanically expandable Lotus valve (Boston Scientific, MA, USA) is a repositionable second generation THV which allows for great control over the deployment and precise positioning. On the other side, the selection of the appropriate device size remains challenging. According to the current recommendations, the selection of the Lotus valve size is based upon aortic root measurements (aortic annulus and left ventricular outflow tract (LVOT)), preferably assessed by multi-slice computed tomography (MSCT) [10]. Hence, in clinical practice, it often occurs that the sizing matrix offers the possibility to select two valve sizes for a specific patient. In those cases, industry guidelines do not provide detailed indications, and device size selection strongly relies on individual experience. Therefore, in patients with equivocal aortic root dimensions, a patient-specific computational model that allows virtual implantation of multiple device sizes at several implantation depths could provide useful additional insights facilitating decision-making.

Patient-specific computational modelling has previously been used to investigate the effect of the THV positioning on the stress distribution on the aortic root [11, 12]. Others focused on the effect of THV positioning on the THV leaflet performance in terms of coaptation area and stress distribution [13, 14]. Bianchi et al. [15] explored whether THV positioning influences device anchoring and therefore impacts the risk on device migration. However, these studies were based on a single patient-specific model and, as such, the specific results cannot be assumed to represent the entire population. A more extensive study, based on 112 patients, recently demonstrated that patient-specific computational modelling and simulation can accurately predict the occurrence of new conduction abnormalities [16]. This study quantified the pressure induced by the self-expandable CoreValve/Evolut R (Medtronic, MN, USA) frame on the aortic root, in the region of the atrioventricular conduction pathway. Furthermore, few patient-specific studies demonstrated that finite-element simulations can accurately predict the paravalvular AR after implantation of a self-expandable [17–19] or balloon-expandable device [20]. However, its accuracy for mechanically expandable remains unclear.

The aim of this paper is twofold. First, we verified the predictive power of computer simulations for post-TAVI complications in patients who received a mechanically expandable Lotus device. Second, we evaluated to what extent different device sizes and different valve positions in patients with equivocal aortic root measurements influence the predicted pressure generated on the atrioventricular conduction pathway and the paravalvular regurgitation.

Materials and Methods

Population

The study population consists of 62 patients with severe aortic valve stenosis who underwent TAVI with a Lotus valve at four European centres (San Raffaele Hospital, Milan, Italy; Rigshospitalet, Copenhagen, Denmark; St Antonius, Nieuwegein and the Erasmus Medical Center, Rotterdam, the Netherlands). All patients had undergone preoperative MSCT for sizing, and MSCT quality was sufficient to allow computer simulation as previously described [16, 18, 21]. The cardiac region of interest (i.e. aortic root) was fully visible in the MSCT set and filled with contrast. No motion artefacts or noise due to the presence of other implanted devices affected the cardiac region of interest. MSCT in-plane and through-plane resolution ranged from 0.31 to 0.93 mm/pixel, slice increment from 0.25 to 0.7 mm, and slice thickness from 0.5 to 1.5 mm. Pre- and postoperative electrocardiograms were recorded for all patients. Postoperative echocardiography and angiography were available respectively for 42 and 58 patients. In 13 patients, postoperative MSCT was also available. At the participating hospital, all patients were informed about the procedure and provided written informed consent for the anonymous use of their data for scientific research.

Computer Modelling

Anatomical Reconstruction Patient-specific 3D models of the native aortic root including the LVOT, the calcified native leaflets and the ascending aorta, were reconstructed from preoperative MSCT using image segmentation techniques (Mimics v18.0, Materialise, Leuven, Belgium). An *in-house* software (TAVIguide, FEops, Gent, Belgium) was used to generate high-quality meshes of the native leaflets, by fitting a template mesh to the output of the segmentation step.

The material properties assigned to each anatomical region were previously calibrated through an iterative back-calculation method using both pre- and postoperative MSCT [21]. The aortic tissue was modelled with elastic material properties ($E = 2$ MPa, $\nu = 0.45$) [22, 23] and spring elements were added at each node of the aortic wall to incorporate the impact of surrounding structures. The leaflets were assumed to be linear elastic ($E = 0.6$ MPa, $\nu = 0.3$), while calcifications were modelled using a stiffer elastic material with perfect plasticity ($E = 4$ MPa, $\nu = 0.3$, yield stress = 0.6 MPa). A constant thickness of 2 mm and 1.5 mm was assumed for the aortic wall and the leaflets, respectively [21].

Preoperative MSCT was also used to identify the inferior border of the membranous septum as landmark for the region (of interest) of the LVOT where the atrioventricular conduction system is located (Fig. 1b). Starting from this inferior border of the membranous septum, the region of interest was

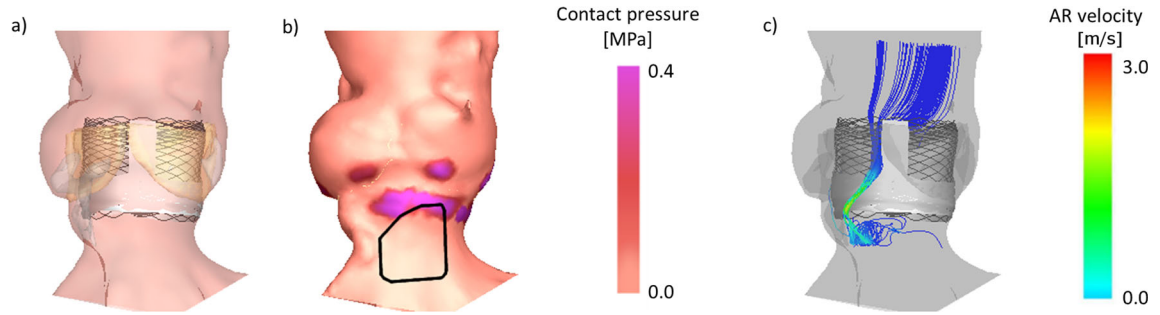

Fig. 1 Computer modeling workflow. **a** Lotus valve 25 mm virtually implanted in a patient-specific aortic root 3D model reconstructed from preoperative MSCT images. **b** Contact pressure exerted on the aortic root surface and selection of the region where the AV conduction system is located (selected region border in black) (maximum contact pressure = 0.47 MPa, contact pressure index = 9%). **c** Predicted aortic regurgitation channel (predicted AR = 6.6 ml/s). AR aortic regurgitation. MSCT multislice computed tomography

extended towards the right coronary cusp (RCC) and up to 15 mm below the annular plane, to ensure the inclusion of the left bundle branch [16].

Finite-Element Computer Simulations Implantation of the Lotus valve in each patient's aortic root model was retrospectively simulated using finite element computer modelling (Abaqus/Explicit v6.12, Dassault Systèmes, Paris, France). The aortic root wall was modelled with triangular elements, whereas prism elements were adopted for the native valve tissue and the calcifications.

Accurate device models of all Lotus valve sizes were generated based on information provided by the device manufacturer. Device models included the braided Nitinol stent and the external skirt. Device leaflets were not included in the model because they are assumed to fully coapt in the diastolic phase. Furthermore, previous studies have reported that detailed device leaflets have a negligible effect on the paravalvular AR [19] as well as on the postdeployment deformation of the fame [15, 22]. General contact with finite sliding between all the surfaces was applied with hard contact properties to prevent penetrations along the normal direction. A friction coefficient of 0.7 was used to model the interaction between the frame and the aortic model.

To validate the computer model, the implanted device size was respected. Device repositioning and retrieval attempts were not integrated in the model, but the final depth of implantation at the noncoronary and left coronary cusp (NCC and LCC, respectively) was matched with the actual position derived from contrast angiography performed immediately after the final deployment ('matched' simulation). Alternatively, the simulated position was matched with the implanted device reconstructed from postoperative MSCT, when available.

For the purpose of this study (i.e. assessment of the impact of device size and position on AR and contact pressure in patients with equivocal aortic root dimensions), a smaller cohort of patients with annular and LVOT dimensions (diameters, perimeter, area) leading to equivocal THV sizes was selected. The LVOT dimensions were assessed at 4 mm below the annular plane. For each of those patients, four additional simulations were performed: two different Lotus valve sizes were implanted in a high and low position, respectively at 0–3 mm and 3–6 mm below the annular plane.

From each simulation (matched + four additional ones), the pressure exerted on the selected region of interest of the LVOT was extracted. In particular, the maximum contact pressure within that region and the contact pressure index (i.e. relative area of contact within the selected region) were evaluated (Fig. 1b).

Prediction of Aortic Regurgitation Subsequently, AR following each virtual Lotus implantation was quantified by modelling blood flow during diastole using computational fluid dynamics (OpenFOAM v2.1.1, OpenCFD Ltd., Bracknell, UK). The ico-FOAM solver available within OpenFOAM was adopted. The extended flow domain was discretized using hexahedral elements and refined within the region of interest (i.e. the lumen within the rigid aortic root wall). The blood was modelled as incompressible fluid with constant density of 1060 kg/m^3 and a viscosity of 0.0035 Pa s. The flow was assumed to be laminar. No slip condition was assumed at the aortic wall. A fixed pressure difference of 32 mmHg was applied over the valve (Fig. 1c). The imposed pressure is the average of the postoperative diastolic transaortic pressure difference retrospectively observed in a sample of 20 patients in a previous study [18]. This value is in line with the end-diastolic gradient observed by Sinning et al. in a cohort of 146 patients [24].

Data Analysis

AR Evaluation Post-TAVI AR was predicted by the matched simulation for all patients (cohort A) and compared to the grade of clinically assessed postoperative AR based on echocardiography and angiography [25, 26]. The degree of AR was dichotomized in 'none or trace' and 'mild or more.'

Predicted Conduction Abnormalities In 52 patients (cohort B), the contact pressure exerted on the region of the LVOT where the atrioventricular conduction system is located was measured and compared in patients with and without new conduction abnormalities (left bundle branch block or high-degree atrioventricular block) that emerged after postoperative ECG evaluation. Patients with a previously implanted pacemaker (four patients) and with the inferior border of the membranous septum not clearly visible on preoperative MSCT (six patients) were excluded from this analysis.

Device Size and Position in Patients with Equivocal Aortic Root Dimensions Impact of implantation depth and device size on postoperative predicted AR, and contact pressure was investigated in 12 patients with equivocal aortic annular measurements (cohort C).

Statistical Analysis

Data are presented as mean ± standard deviation (SD) or median [Q1-Q3] and tested with Student's *t* test or Mann–Whitney *U* test, depending on the distribution. Effects of device size and position on predicted AR and conduction abnormalities were tested with the nonparametric Wilcoxon paired test. Statistical significance was set at $p < 0.05$. Cut-off values to distinguish between patients with and without postoperative AR or new conduction abnormalities were identified using the Youden criterion [27]. The statistical analysis was performed in SPSS version 22.0 (IBM Corporation, NY, USA).

Results

Sixty-two patients (cohort A) were used to verify the predictive power of computer simulations for postoperative AR and 52 patients (cohort B) for postoperative conduction abnormalities. Twelve patients with equivocal aortic root dimensions (cohort C) were used to evaluate the impact of valve size and position on the predicted postoperative TAVI complications.

Postoperative AR Angiography and/or echocardiography showed postoperative AR in 19 patients. Mean Lotus implantation depth was comparable in patients with and without postoperative AR (4.9 ± 1.0 vs 4.9 ± 1.9 mm).

Patient-specific simulations predicted significantly higher AR in patients with postoperative 'mild or more AR' compared to patients with none or trace AR, respectively 9.6 [2.3–41.2] ml/s vs 3.7 [0.5–11.3] ml/s ($p < 0.05$) (Fig. 2a). Predicted AR of 13.5 ml/s was used as cut-off value to differentiate between patients with and without postoperative AR with an accuracy of 71%. Resulting sensitivity, specificity, positive predicted value (PPV) and negative predicted value (NPV) are reported in Table 1.

Postoperative Conduction Abnormalities Sixty-nine percent of the patients (36/52) experienced left bundle branch block or total atrioventricular block post-TAVI. Measured maximum contact pressure and contact pressure index in those patients were about twice the value observed in patients without new conduction abnormalities (Fig. 2b, c). Maximum contact pressure in patients with and without new conduction abnormalities was respectively 0.57 [0.29–0.80] MPa and 0.30 [0.00–0.36] MPa ($p = 0.005$), while the contact pressure index was respectively 13 [8–25] % and 6 [0–13] % ($p = 0.016$). The selected cut-off value was respectively 0.36 MPa for maximum contact pressure and 9% for contact pressure index, which respectively resulted in an accuracy of 75% and 71%. Obtained sensitivity, specificity, PPV and NPV are reported in Table 1. Moreover, the accuracy of the prediction further increases when combining the two contact pressure parameters (Fig. 3).

Analysis of Patients with Equivocal Aortic Root Dimensions Aortic annulus and LVOT dimensions led to unequivocal THV size in 20 patients. In another group of 20 patients, equivocal annulus or LVOT dimensions led to the selection of two valve sizes, with one common size that was selected in clinical practice (i.e. annulus −> 23-mm and 25-mm Lotus; LVOT −> 25-mm Lotus). Twelve patients with equivocal aortic root measurements were considered suitable for two different device sizes (i.e. patients with annulus measurements suggesting a 23-mm Lotus and with LVOT measurements a 25-mm Lotus, or patients with annulus and LVOT measurements suggesting both a 23-mm and a 25-mm Lotus). In three patients, simulations were performed with a 23- and 25-mm Lotus, and in nine patients with a 25- and 27-mm Lotus.

Personalized simulations revealed an increase of maximum contact pressure and contact pressure index when a large THV size is implanted or when the THV position is deeper ($p < 0.001$) (Fig. 4). Figure 5 shows the observed general trend of predicted contact pressure with respect to device size and position with a representative case.

With regard to the predicted AR, the device size plays a more crucial role as compared to depth of implantation. Modelling results showed a reduction of predicted AR in case the larger device was selected, regardless the valve position within the aortic root ($p < 0.001$) (Fig. 4).

Besides the general impact of device size and position on predicted outcomes, personalized simulations showed that optimal device size and position differ from one patient to another. In 25% of the cases, the smaller device showed to limit the contact pressure on the atrioventricular conduction system as well as postoperative AR (Fig. 6, left panel). However, in some other cases (21%), the smaller device generated already significant contact pressure on the region of the atrioventricular conduction system, and was also associated with higher postoperative AR. Therefore, for those patients, the larger

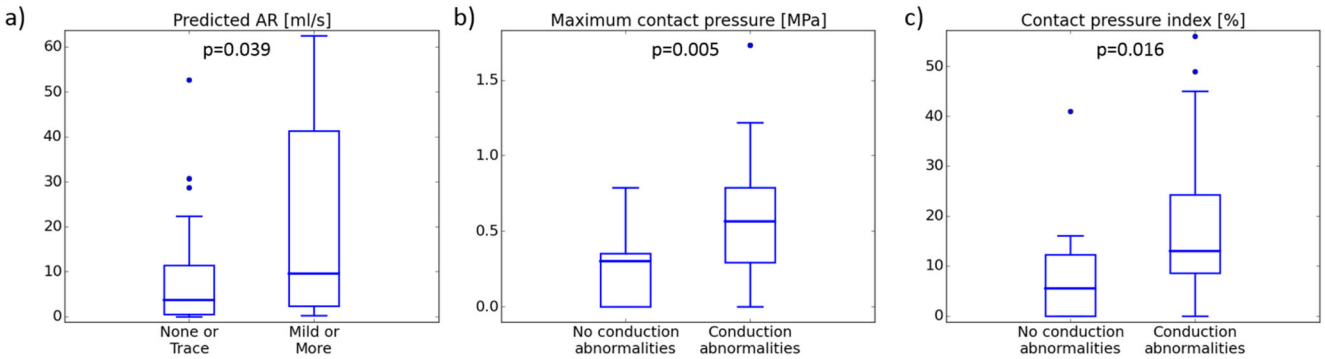

Fig. 2 Box plot graphs of predicted AR, maximum contact pressure and contact pressure index. AR aortic regurgitation

device would be the preferable choice to significantly reduce the postoperative AR while inducing comparable contact pressure on the atrioventricular conduction system (Fig. 6, right panel).

Discussion

This study showed that patient-specific computational modelling and simulation can accurately predict postoperative AR and conduction abnormalities in patients treated with a mechanically expandable Lotus valve. Second, we used computational modelling and simulation to better understand the impact of device size and position in patients with equivocal aortic root dimensions. The obtained results show trends that are in line with previous clinical studies, but also reveal that optimal size and position are patient-specific.

Patient-specific computer simulation which integrates MSCT-derived patient-specific geometry and the mechanical properties of the valve accurately predicts the occurrence of AR after the implantation of a Lotus device: the selected cut-off value ensured to differentiate patients with none or trace and 'mild or more' AR with good accuracy (71%). Using the same strategy, de Jaegere et al. reached an accuracy of 73% to predict the severity of AR following TAVI with a self-expandable valve ('none-to-mild' and 'moderate-to-severe')

Table 1 Sensitivity, specificity, and positive and negative predicted values and accuracy for computer simulations predicted outcomes. AR aortic regurgitation

	Predicted AR (%)	Predicted maximum contact pressure (%)	Predicted contact pressure index (%)
Sensitivity	47	72	75
Specificity	81	81	63
PPV	53	90	82
NPV	78	57	52
Accuracy	71	75	71

[18]. It has to be noted that the two studies adopted different dichotomization of the degree of postoperative AR.

Next to postoperative AR, we derived from the patient-specific computer simulations the contact pressure exerted by the device on the atrioventricular conduction system. In particular, we assessed the maximum contact pressure and contact pressure index parameters, which recently have been associated with new left bundle branch block or total atrioventricular block after TAVI [16]. The results of this study agreed with previous findings. The cut-off value for the maximum contact pressure that best identifies patients with new conduction abnormalities after implantation of Lotus valve (0.36 MPa) was comparable to what found after implantation of the CoreValve System (0.39 MPa). Also, the accuracy of the prediction was comparable between the two studies (75% for the Lotus and 76% for the CoreValve). A slightly lower Lotus-related cut-off was identified for the contact pressure index (9% for the Lotus vs 14% for the CoreValve). As this parameter represents the area of contact within the selected atrioventricular conduction region, higher implantation depth of the Lotus device might explain the lower contact pressure index associated with that valve. In fact, in this study, the Lotus valve was implanted on average at 4.8 ± 1.7 mm below the annular plane, while Rocatello et al. reported the CoreValve System to be implanted at about 7.2 ± 3.5 mm below the annular plane. The contact pressure index showed a slightly higher accuracy of prediction for new conduction abnormalities after CoreValve implantation (77% vs 71%). However, combining both maximum contact pressure and contact pressure index enhances the prediction of new conduction abnormalities after Lotus valve implantation. When both parameters are above the cut-off value, 24/26 patients (92.3%) with new conduction abnormalities were correctly identified (Fig. 3).

Besides the verification of the model accuracy, we evaluated the influence of device size and position on the predicted outcomes in patients with equivocal aortic root dimensions. This revealed trends that are in line with previous clinical findings: selecting the larger device limits the predicted AR, while lower implantation and more aggressive device

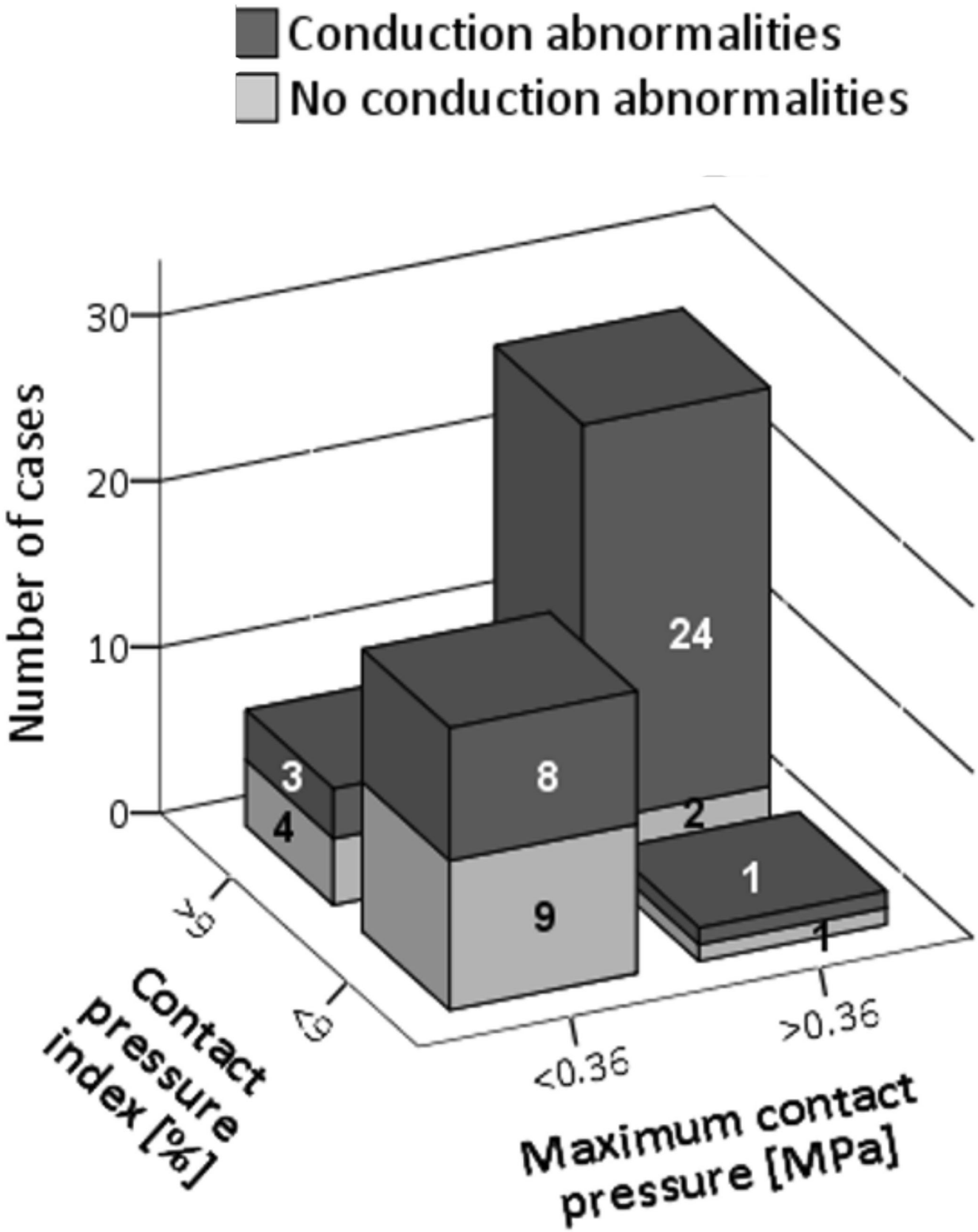

Fig. 3 Prediction of conduction abnormalities according to the maximum contact pressure and contact pressure index based on the chosen cut-off values (0.36 MPa and 9%, respectively)

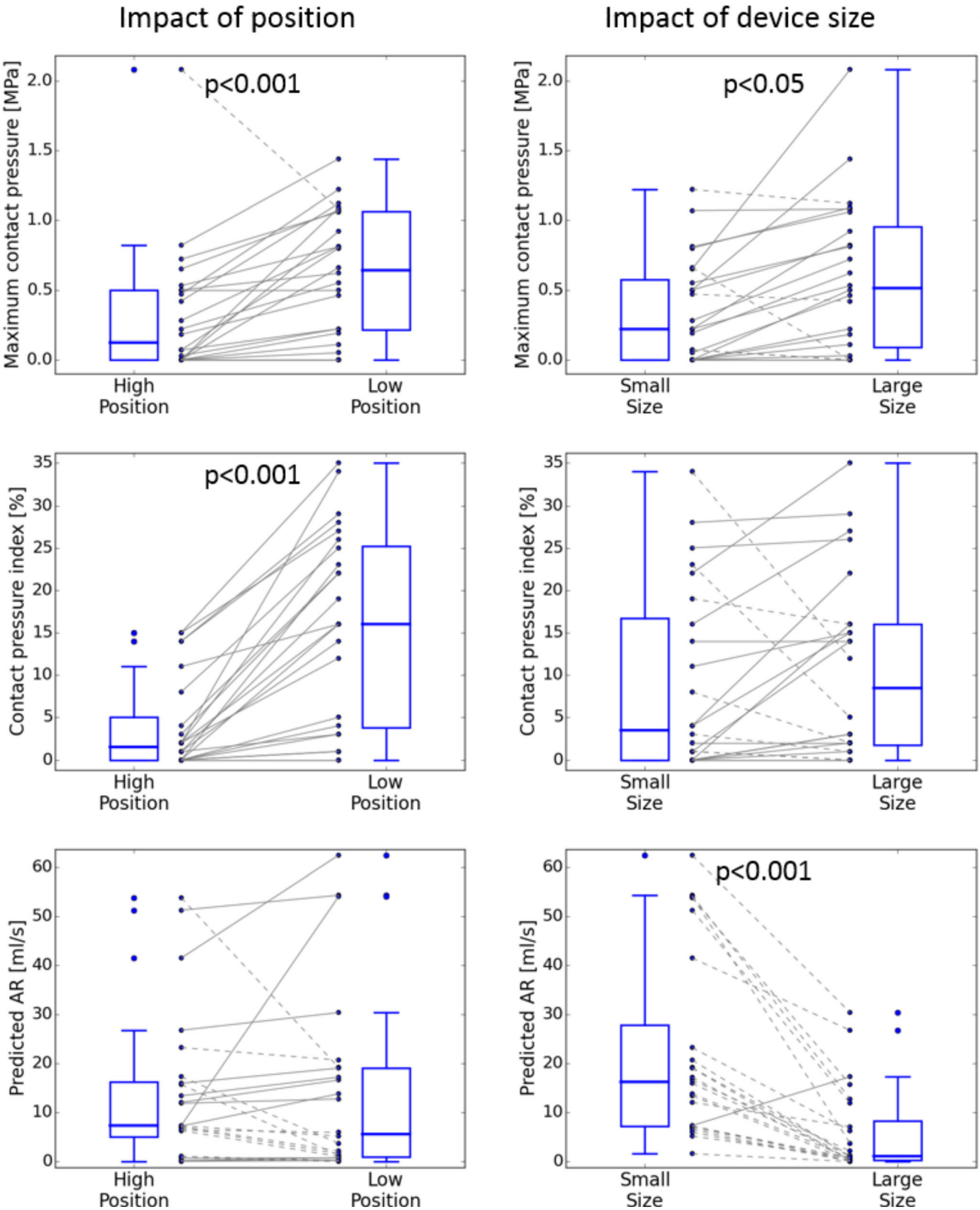

Fig. 4 Predicted AR, maximum contact pressure and contact pressure index distribution in case of high/low implantation depth or large/small valve size. AR aortic regurgitation

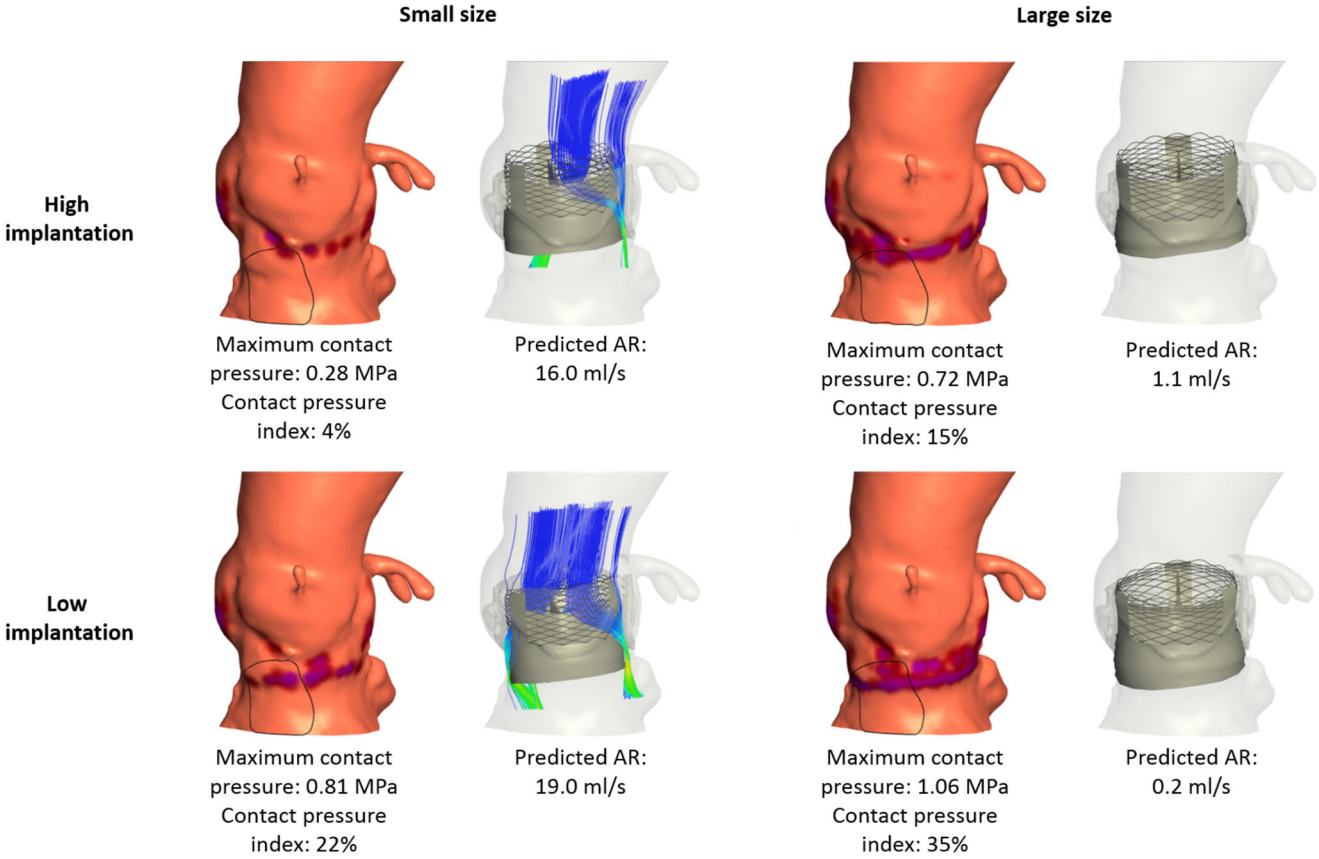

Fig. 5 Predicted AR and contact pressure-related parameters according to a different depth of implantation and device size. AR aortic regurgitation

oversizing increase the contact pressure on the region of interest (and thus the risk on TAVI-induced conduction abnormalities).

Some studies have associated a high THV position with increased rate of postoperative AR [8, 19, 28]. Using patient-specific computer simulation in a single patient, Mao et al. [19] observed that high implantation of a CoreValve device exhibits much larger regurgitant jets than lower positioning. This observation corresponds with the finding of Sherif et al. (2010) [8] who reported that a low implantation depth (about 10 mm below the aortic annulus) of a CoreValve device minimizes the AR degree. On the contrary, Bianchi et al. [20] observed that high implantation of the CoreValve (about 3 mm below the annular plane) favoured AR reduction in one patient. In the same study, the authors also observed that a Sapien valve implanted in high position increased regurgitation jets in two patients, suggesting that the effect of positioning on postoperative AR is device-related.

Blackman et al. reported that patients with Lotus valve implanted less deep than 4.7 mm are more likely to develop postoperative AR [28]. However, this observation contrasts with our findings. In fact, among all patients enrolled in our study, no difference in implantation depth was observed between those with and without postoperative AR. Also, for patients with aortic root dimensions in the equivocal range, the device size seems to play a more relevant role, compared to the implantation depth, in preventing postoperative AR. Similarly, Bianchi et al. [20] observed that paravalvular AR is highly dependent on the patient-specific anatomy and calcification distribution more than depth of implantation.

Despite the general observation that a low implantation depth and larger THV are associated with a higher maximum contact pressure and contact pressure index, analysis of the individual cases shows that this strongly depends on the patient-specific anatomy (i.e. location and amount of calcifications, location of the atrioventricular conduction system). We observed that in patients with a not very calcified aortic valve, the smaller THV reached a good apposition preventing residual AR and maintaining the contact pressure on the atrioventricular conduction system low. Whereas, bulky leaflets and sub-annular calcifications prevented the smaller THV from an optimal sealing against AR. Also, in some patients, calcium nodules that accumulated mainly on the LCC or towards the commissure between the NCC and LCC, not only obstructed the good apposition of the valve, but also pushed the valve towards the opposite side (NCC/RCC), increasing the contact pressure on the atrioventricular conduction system, which is in line with previous findings [29]. In such cases, the larger THV showed better performance: at comparable maximum contact pressure it reduced the postoperative AR.

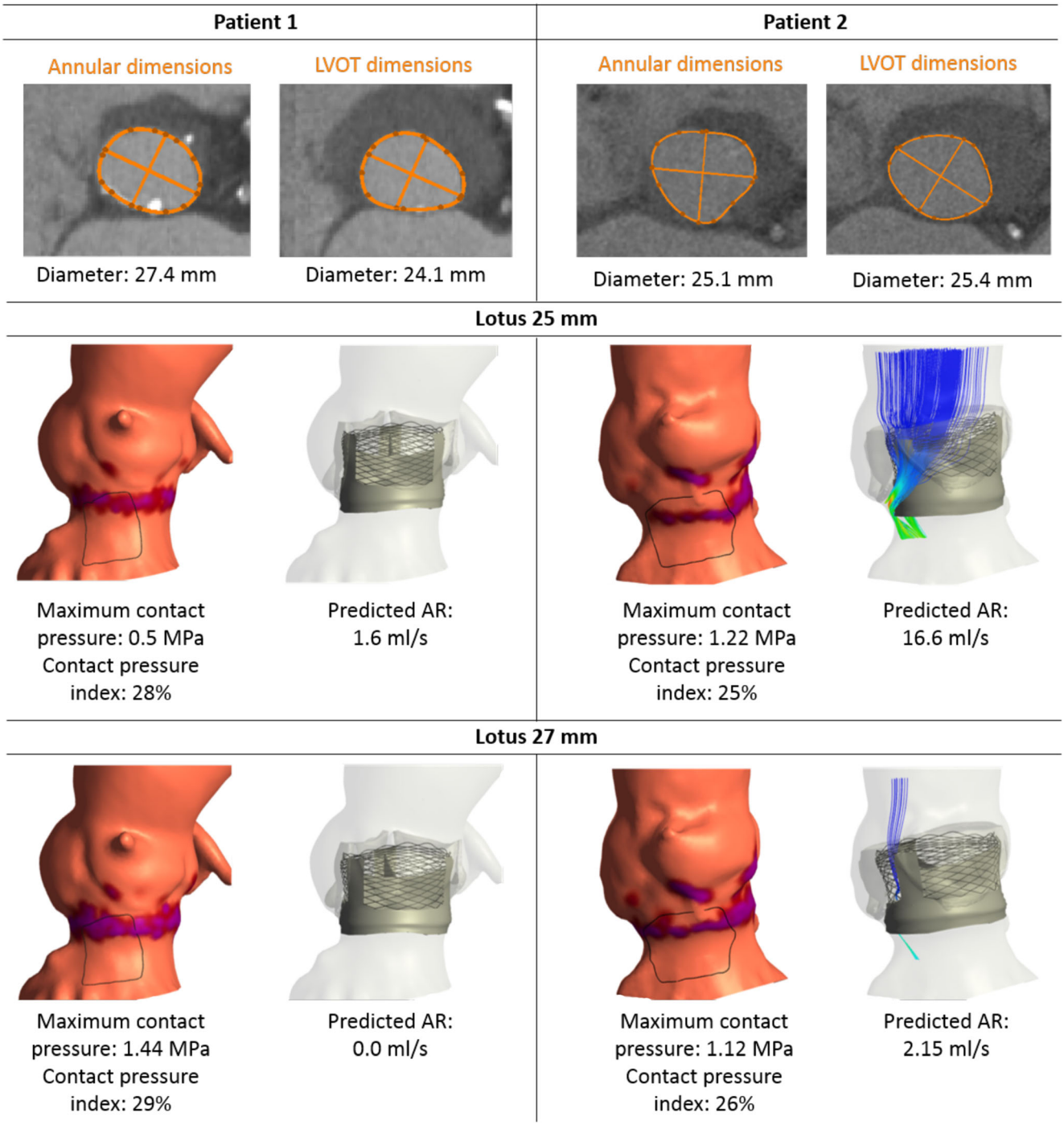

Fig. 6 Predicted AR and contact pressure after implantation of the Lotus device (smaller (high panel) vs larger (low panel)). A representative example where the smaller valve (left panel) and larger valve (right panel) represents the optimal choice. AR aortic regurgitation

However, this was observed only in few patients, and therefore further investigation is required.

Our findings confirmed also that a deep valve implantation is generally associated with new conduction abnormalities, as reported in several clinical studies [9]. Similarly, McGee et al. observed that a deep THV position increases the mechanical stresses on the bundle of His, under the assumption that the stress distribution in this region might contribute to new conduction abnormalities [12]. However, this observation is based on a single patient-specific model and, therefore, it cannot be assumed to represent the entire population. Furthermore, they limited the location of the bundle of His to the interleaflet triangle between the NCC and RCC. However, the atrioventricular conduction system is typically located near the inferior

border of the membranous septum, which is subjected to interpatient variability. Some patients have the membranous septum located in a high position (i.e. closer to the annular plane) [16, 30, 31]. Therefore, for those patients, a high valve implantation would not avoid the THV to exert pressure on the atrioventricular conduction system, resulting in a quite high predicted contact pressure and a relatively extended region of contact (Fig. 5). Therefore, a high THV implantation seems not always advisable.

Another aspect that may influence device positioning is the coronary height and the sinotubular junction size. In a number of patients, the simulated high implantation showed that the deployed braid was adjacent to the coronary ostia and might therefore limit the access to the coronary for future percutaneous coronary intervention. In such cases, a very high valve implantation should probably be avoided.

These findings indicate that, despite certain general trends, optimal THV size selection and positioning in patients with equivocal annulus dimension is complex. However, the selection of the valve size that best fits the individual patient, and its optimal position, is mandatory to ensure maximum safety and efficacy. Personalized computer simulation that can accurately predict post-TAVI AR and conduction abnormalities may offer additional support during decision making.

Study Limitations

The number of patients included in this study was not based on a power analysis, but on the amount of data received from the participating hospitals. Also, the impact of device size and position on predicted AR and contact pressure in patients with equivocal aortic root dimensions was investigated in a limited cohort of patients. In future, a large sample size should be studied to confirm our findings.

Elastic material properties were used to model the aortic tissue. Although the hyperelastic model may better reflect the actual tissue mechanical behaviour, previous studies have reported that the accuracy of the predicted frame deformation using a simple linear elastic material or a more complex hyperelastic material is comparable. Therefore, linearization of the material property seems viable [23, 32]. Similarly, there are many other modelling simplifications and assumptions and it is challenging to assess the impact of the modelling results for all simplifications and assumption. However, based on the amount of validation that is available we believe that those are justified [16, 18, 21].

In this study, the contact pressure on the atrioventricular conduction system was evaluated after full device deployment. However, an analysis over the entire positioning and deployment phase might offer a more complete understanding in the mechanisms of the development of new conduction abnormalities, as high contact pressure might occur periprocedurally.

Same boundary conditions were adopted to predict paravalvular AR in each patient although the postoperative end-diastolic pressure varies from patient to patient. However, a population averaged value needs to be employed when the aim is to develop a predictive model.

Finally, as we were interested in the paravalvular AR, only the diastolic phase was simulated and the valve was assumed to be fully closed (i.e. full leaflet coaptation). Therefore, the central regurgitation was not considered in this study.

Conclusions

Patient-specific computer simulations can accurately predict AR, maximum contact pressure and contact pressure index after implantation of the mechanically expandable Lotus valve. Also, they offer insight on patients with equivocal aortic root dimensions and provide additional information related to optimal THV size and position.

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Compliance with Ethical Standards

Conflict of Interest Matthieu De Beule and Peter Mortier are shareholders of FEops. Ole De Backer has been consultant for Abbott and Boston Scientific. Azeem Latib is a consultant and on the Advisory Board of Medtronic and Abbott. All other coauthors declare that they have no conflict of interest.

Ethical Approval For this retrospective study, formal consent is not required. This article does not contain any studies with animals performed by any of the authors. Informed consent was obtained from all individual participants included in the study.

Clinical Relevance In TAVI, choosing the appropriate size of the Lotus device remains challenging. As Lotus sizing is based on anatomical aortic root dimensions, often two valve sizes might be selected for the same patient. Patient-specific computer simulations have shown to accurately assess postoperative aortic regurgitation and the risk of new conduction abnormalities. Therefore, it can offer insight on patients with equivocal aortic root dimensions and provide additional information related to optimal device size and position.

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