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Validation of 3D-reconstructed computed tomography images using OsiriX® software for pre-transcatheter aortic valve implantation aortic annulus sizing

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Abstract

OBJECTIVES: We report validation of OsiriX® —an image processing freeware—to measure multi-slice computed tomography-derived annulus diameters for preprocedural transcatheter aortic valve implantation planning.

METHODS: A total of 137 patients (82 ± 6.5 years, 42.3% male, logistic EuroSCORE 24.1 ± 14.2%) with severe aortic stenosis at high surgical risk underwent transcatheter aortic valve implantation assessment: transoesophageal echocardiography, angiography and multi-slice computed tomography. Retrospectively, 3D multi-slice computed tomography reconstructions were generated using OsiriX and the reliability evaluated regarding inter- and intraobserver variability, intermodality correlation and estimation of the clinical impact on transcatheter aortic valve implantation sizing.

RESULTS: Reliability of the novel OsiriX software was high with an interobserver mean difference of 0.6 ± 1.4 mm and intraclass correlation of absolute agreement of 0.84 (95% confidence interval 0.74–0.90). The intermodality accuracy between OsiriX measurements and conventional 2D computed tomography reconstructions, transoesophageal echocardiography and angiography revealed significantly larger sizing with OsiriX, with a mean difference to 2D computed tomography of 0.4 ± 2.2 mm, which would have changed valve sizing in 38% of patients. In 28%, a larger size would have been chosen, and this correlated highly with the occurrence of postoperative severe aortic regurgitation ($P < 0.001$).

CONCLUSIONS: While OsiriX measurements are an accurate and reproducible assessment of the aortic annulus, there are distinct and clinically relevant differences in aortic annulus dimensions between OsiriX measurements and previously standard imaging modalities. Sizing with OsiriX resulted in a larger perimeter compared with conventional 2D imaging. Careful assessment of valve size will take into account multiple imaging modalities.

Keywords: TAVI prosthesis sizing • Aortic annulus dimensions • 3D imaging

INTRODUCTION

Aortic valve stenosis represents the most common structural heart disease in the Western world [1]. Aortic valve replacement is the only effective therapy, but patients are frequently above 70 years of age, have left ventricular dysfunction or severe comorbidities. It was estimated that more than 30% are either not referred or rejected for surgery, as their surgical risk is deemed too high [2]. Transcatheter aortic valve implantation (TAVI) has emerged as a minimally invasive therapy and has quickly become the standard choice of treatment for patients with high surgical risk [3].

For TAVI, preoperative imaging plays a crucial role for patient evaluation, aortic annulus sizing and procedural planning. Inaccurate sizing bears the risk of severe complications, such as paravalvular leak, prosthesis dislocation or annular disruption due to size mismatch of the prosthesis [4].

The different imaging modalities used in the current clinical practice are transthoracic echocardiography and transoesophageal echocardiography (TEE) as well as angiography and computed tomography. Since a major advantage of 3D imaging is a more complete depiction of the complex, often oval shape of the aortic annulus, widely available 3D multi-slice computed tomography (MSCT) has been firmly established for prostheses sizing in TAVI.

The aim of this study was to validate OsiriX (Pixmeo, Geneva, Switzerland)—a 3D MSCT-based image processing application—for preprocedural TAVI evaluation. Thus, we examined accuracy and reproducibility of OsiriX measurements and compared it with 3mensio (3mensio Medical Imaging BV, Bilthoven, Netherlands), a different 3D MSCT reconstruction tool specifically designed and already validated [5] for TAVI screening. Furthermore, we assessed the intermodality agreement among former standard imaging modalities to 3D MSCT OsiriX measurements alike.

Further, we compared the different commonly used imaging modalities: TEE, angiography and conventional 2D MSCT, to 3D MSCT for preoperative aortic annulus sizing in patients undergoing TAVI in order to establish a clinical impact of imaging modality on TAVI sizing on procedural outcome.

METHODS

Study population and patient evaluation

We retrospectively analysed 137 consecutive patients with TAVI at our institution between October 2007 and March 2012 who underwent preprocedural assessment including left and right heart catheterization, TEE, angiography and MSCT. All patients had severe aortic stenosis and were adjudicated by a multidisciplinary heart team at increased risk for surgical aortic valve replacement due to their general condition, medical history or significant comorbidities. All patients provided written informed consent for data collection and analysis. This study was mandated by our institutional review board.

Aortic valve implantation

All patients received either the Edwards SAPIEN XT transcatheter heart valve (Edwards Lifesciences, Irvine, CA, USA) or the Medtronic CoreValve (Medtronic Inc, Minneapolis, MN, USA) prosthesis. The available prosthesis sizes were 23, 26 and 29 mm for Edwards SAPIEN XT prosthesis and 23, 26, 29 and 31 mm for Medtronic CoreValve prosthesis (Table 2).

Multi-slice computed tomography (MSCT) imaging

Patients received 80 to 120 ml contrast medium at a flow rate of 5 ml/s. The scan was performed during a mid-inspiratory breath hold and was timed using an automated peak enhancement detection in the descending aorta. Either a Siemens Somatom Sensation Cardiac 64 scanner or a Siemens Somatom Definition Flash Dual-Source scanner (Siemens Medical Solutions, Inc., Forchheim, Germany) with slice collimation of 1.5 mm or 0.6 mm and tube voltage of 100 or 120 kV, respectively, and tube current according to patient size were used. The images were acquired either electrocardiographically-triggered or retrospectively electrocardiographically-gated and reconstructed in the diastolic phase at 60% of the RR interval.

Image analysis

- 2D MSCT reconstruction: For conventional reconstructions, standard axial and sagittal views were used for initial orientation, coronal and a single oblique sagittal view perpendicular to the aortic valve plane were reconstructed. On these 2D views, the cross-sectional diameter was measured as a line connecting both sides of the annulus ($MSCT_{cor}$ and $MSCT_{sag}$, respectively) and its mean was calculated $(MSCT_{mean} = MSCT_{cor} + MSCT_{sag}/2)$.
- 3D MSCT reconstruction: 3D MSCT reconstructions were done applying 2 different softwares, OsiriX and 3mensio. Using 3D multiplanar reconstruction tools allowed the representation of the aortic annular plane defined by its anatomic landmarks; it is declared as the plane intersecting the nadirs of the 3 semilunar aortic valve leaflets [6].
- With OsiriX, the aortic plane is reconstructed manually by identifying the annular plane in a 3D multiplanar reconstruction mode. Starting with standard orthogonal multiplanar reconstruction slices in coronal, sagittal and transverse orientation, the planes were rotated with focus along the left ventricular outflow tract to identify the annular plane in a double-oblique transverse view. Then, a polygonal ring surrounding the annulus was traced manually for automatic perimeter and area determination, from which the perimeter-derived diameter $(\text{pdD} = \text{perimeter}/\pi; \text{OsiriX}_{pdD})$ and the area-derived diameter $(\text{adD}=2 \times \sqrt{[\text{area}/\pi]}; \text{OsiriX}_{adD})$ were calculated (Fig. 1A).
- 3mensio encodes an automated reconstruction and segmentation of the aortic root, wherein the annular plane was then manually identified in a perpendicular short-axis view. Similarly, manual polygonal border tracing allows automatic determination of the annular perimeter and area, and again, perimeter- ($3mensio_{pdD}$) and area-derived diameter ($3mensio_{adD}$) were calculated (Fig. 1B).

Transoesophageal echocardiography

TEE-based aortic annulus diameter measurements were obtained in zoom mode in the 110° to 140° mid-oesophageal long-axis view. In this so-called 3-chamber view, the diameter was measured between the nadirs of the right and the non-coronary leaflet during diastole.

Angiography

Aortic root angiography was performed in 0°–20° left anterior oblique projection, aiming at an alignment of all 3 aortic cusps. Then, 25–30 ml of contrast medium were injected into the aortic root at a rate of 15 ml/s using a marked pigtail catheter, and the diameter was measured in a coronal direction from the nadir of the left coronary to the one of the non-coronary cusp.

Evaluation approach and statistical analysis

Inter- and intraobserver variability: 3D MSCT-based aortic annulus sizing was independently performed by 2 observers. Twenty-five randomly selected patients were analysed twice by one observer with an interval between measurements to determine intraobserver agreement. Observers were blinded to data from each other, other imaging techniques or previous measurements and clinical data. Interrater and intrarater agreement, as well as

Table 1: Baseline clinical characteristics

Age (years)	82.2 (±6.5)
Height (cm)	165 (±8.2)
Body surface area (m^2)	1.80 (±0.2)
Body mass index (kg/m^2)	26 (±5.08)
Cardiovascular risk factors	
Hypertension	97 (70.8%)
Diabetes mellitus	37 (27%)
Hypercholesterolaemia	80 (58.4%)
Current smoker	22 (16.1%)
Past medical history	
Atrial fibrillation	33 (24.1%)
Coronary artery disease	85 (62%)
Myocardial infarction	17 (12.4%)
Coronary artery bypass graft	29 (21.2%)
Percutaneous coronary intervention	27 (19.7%)
Pacemaker	11 (8%)
Peripheral vascular disease	22 (16.1%)
Stroke	13 (9.5%)
Chronic obstructive pulmonary disease	25 (18.2%)
Systolic pulmonary artery pressure (mmHg)	53.1 (±17.4)
Pulmonary artery hypertension (>60 mmHg)	43 (31.4%)
Renal failure (eGFR rate <60 ml/min/1.73 m^2)	89 (65%)
Clinical status	
NYHA III–IV	56 (77%)
Aortic valve area (cm^2)	0.6 ± 0.2
Mean transvalvular aortic gradient (mmHg)	43.5 ± 16.2
LVEF (%)	51.1 ± 15.6
Risk assessment	
Logistic EuroSCORE (%)	24.1 (±14.2)
STS score (%)	6.1 (±4.2)

eGFR: estimated glomerular filtration rate; NYHA: New York Heart Association; LVEF: left ventricular ejection fraction; STS: Society of Thoracic Surgeons.

Table 2: Periprocedural data

Access site	Total	Trans-femoral	Trans-apical	Trans-subclavian
CoreValve	90	88		2
Prosthesis size (mm)				
23	33	33		
26	57	55		2
29				
31				
Sapien XT	47	21	26	
Prosthesis size (mm)				
23	11	7	4	
26	36	14	22	
29				
Outcome				
AR Grade 0–I	91 (66%)			
AR Grade ≥ 2	45 (33%)			
Aortic valve area (cm^2)	1.9 ± 0.7			
Mean gradient (mmHg)	7 ± 3.5			

agreement of OsiriX and 3mensio, were assessed by calculating intraclass correlation coefficients (ICC). We constructed correlation plots and Bland–Altman plots and used paired *t*-tests to assess systematic differences. Fisher's exact test was used to address correlation between OsiriX-based prosthesis sizing and resulting aortic regurgitation (AR). Continuous measures are presented as means ± standard deviation; categorical variables are presented as frequencies and percentages. A *P*-value of <0.05 was considered statistically significant, tests were two-sided, and all analyses were performed using Stata 12 (StataCorp LP, TX, USA).

RESULTS

Baseline clinical characteristics

The baseline clinical characteristics of the 137 patients included in this study are displayed in Tables 1 and 2.

High inter- and intraobserver reliability for OsiriX-based 3D imaging

The mean interobserver difference of annular dimensions using OsiriX software was 0.6 ± 0.12 mm [95% confidence interval (CI): 0.38–0.86, P <0.001] for OsiriX_{pdD} and 0.61 ± 0.12 mm (95% CI 0.35–0.84, P < 0.001) for OsiriX_{adD}, and ICC for absolute agreement was 0.84 for both (Fig. 2A, Table 3). The corresponding high agreement and correlation are illustrated in Bland–Altman and Scatter plots in Fig. 2.

The intraobserver comparison revealed no significant differences (Fig. 2B) between repeated measurements: -0.1 ± 1.6 mm for OsiriX_{pdD} (95% CI: -0.80 to 0.55, P = 0.71) and -0.2 ± 1.8 mm for OsiriX_{adD} and a slightly lower ICC of 0.77 and 0.74, respectively. MSCT_{pdD} resulted in constantly larger diameters with a mean difference of 0.6 ± 0.31 mm to adD (95% CI: 0.55–0.65, P < 0.001), indicating that annuli were not perfectly round.

OsiriX-based sizing closely resembles validated method

Comparing the two 3D MSCT-derived diameters, pdD and adD, measured with 2 different imaging post-processing softwares, OsiriX and 3mensio, revealed a strong 'inter-software' correlation (r = 0.84). The measurements differed only slightly between 0.3 ± 1.5 mm (95% CI: -0.56 to -0.04, P = 0.025) for pdD and 0.8 ± 1.5 mm (95% CI: -1.07 to -0.55, P < 0.0001) for adD. The agreement is displayed in the Bland–Altman plots in Fig. 3.

Annular diameters appear larger when measured with 3D MSCT

In the second part of this study, we assessed the agreement of 3D MSCT-based aortic annulus sizing with standard 2D imaging techniques, as well as the resulting change in valve size selection, and evaluated the clinical outcome of patients receiving TAVI.

We compared mean aortic annulus diameters among the different imaging or software modalities (Fig. 4): by 3D MSCT, the annular diameter was measured larger than with 2D $\text{MSCT}_{sag\ view}$ and TEE (mean difference of 2.24 ± 2.38 mm (95% CI: 1.83–2.65, P < 0.001) and 2.24 ± 2.33 mm (95% CI: 1.84–2.65, P < 0.001), but this did not reach statistical significance in comparison with 2D $\text{MSCT}_{cor\ view}$ and angiography (mean 3D MSCT pdD was 23.8 ± 2.6 mm vs 2D $\text{MSCT}_{sag\ view}$ 21.6 ± 1.8 mm). The agreement between OsiriX_{pdD} and angiography or MSCT_{cor} reached only modest values for correlation (r = 0.59 and 0.62, respectively). TEE

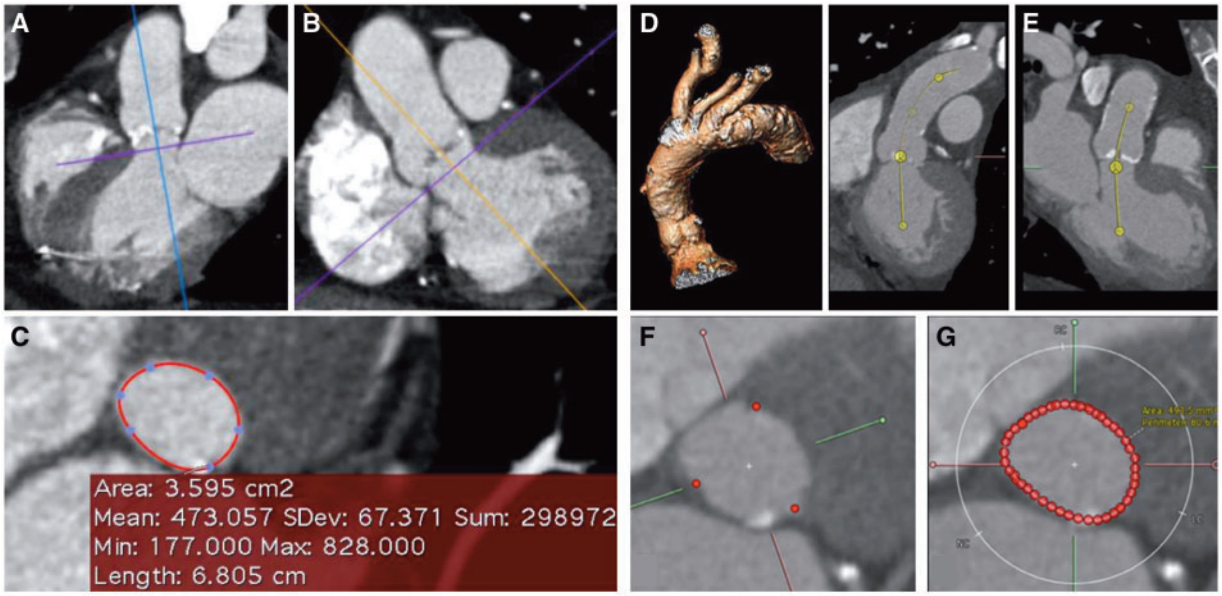

Figure 1: **A-C** displays the aortic annular reconstruction using OsiriX post-processing software and **D-G** using 3mensio MSCT processing software. Both illustrate the identification of the aortic annular plane in double-oblique sagittal and coronal views. (**C**) shows the annular plane in a double-oblique transverse view with 3mensio manual traced annulus and, among others, automatically calculated perimeter and area. (**D**) shows the automated reconstruction of the aortic root and arch; (**E**) displays the identification of the annular plane in double-oblique coronal and sagittal views. In (**F**), the aortic annular plane is seen in a short-axis view intersecting the 3 lowest valvular insertion points. (**G**) illustrates the manual tracing of the annular border, likewise with automatically determined perimeter and area.

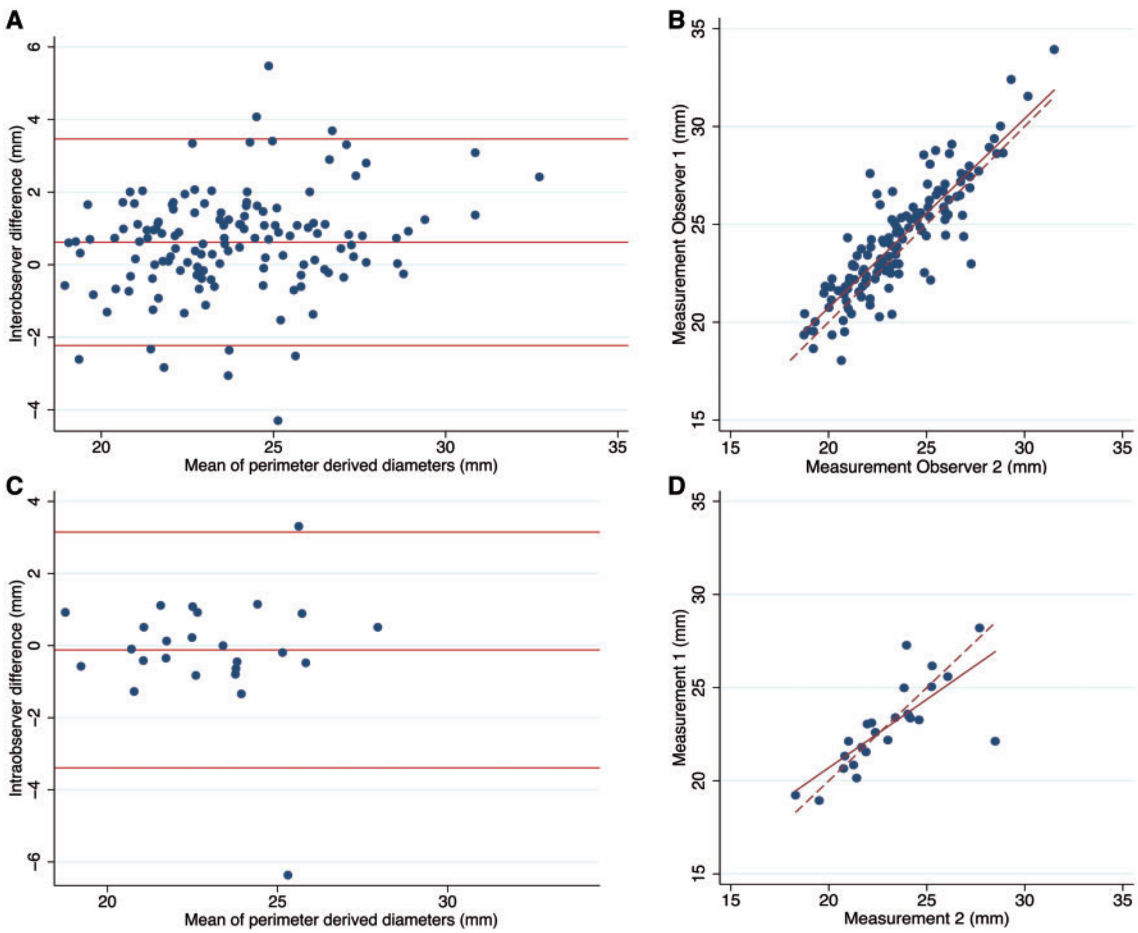

Figure 2: Reliability and correlation of OsiriX_{pdD} measurements illustrated in Bland–Altman and Scatter plots: (**A**) and (**B**) depict interobserver variability and agreement and (**C**) and (**D**) show intraobserver variation and agreement. In Bland–Altman plot, the middle line represents the mean difference and upper and lower lines the limits of agreement (LOA = mean difference ± 1.96 × SD of the difference). The dashed line in the correlation plot depicts the diagonale that represents perfect agreement.

Table 3: Intra-class correlation coefficients

	n	Difference ± SE	ICC	CCC
Inter-rater, $OsiriX_{pdD}$	136	-0.61 ± 0.12	0.84 (0.74–0.90)	0.86 (0.82–0.90)
Inter-rater, $OsiriX_{adD}$	136	-0.60 ± 0.12	0.84 (0.74–0.89)	0.86 (0.81–0.90)
Intra-rater, $OsiriX_{pdD}$	25	0.01 ± 0.31	0.77 (0.54–0.89)	0.76 (0.53–0.89)
Intra-rater, $OsiriX_{adD}$	25	0.10 ± 0.34	0.74 (0.49–0.87)	0.73 (0.48–0.87)
$3mensio_{pdD}$ vs $OsiriX_{pdD}$	126	0.30 ± 0.13	0.82 (0.75–0.87)	0.83 (0.76–0.87)
$3mensio_{adD}$ vs $OsiriX_{adD}$	126	0.20 ± 0.13	0.82 (0.75–0.87)	0.82 (0.76–0.87)

SE: standard error; ICC: intraclass correlation coefficient; CCC: concordance correlation coefficient; pdD: perimeter-derived diameter; adD: area-derived diameter.

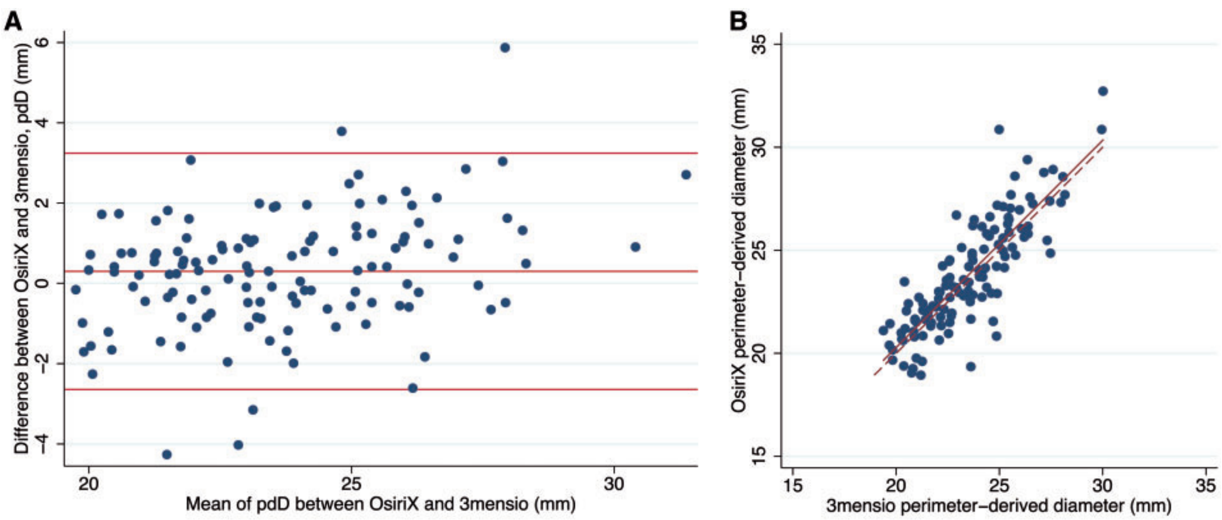

Figure 3: Correlation and Bland–Altman plots describing the agreement of the two 3D MSCT post-processing softwares OsiriX and 3mensio for pdD (**A**) and adD (**B**).

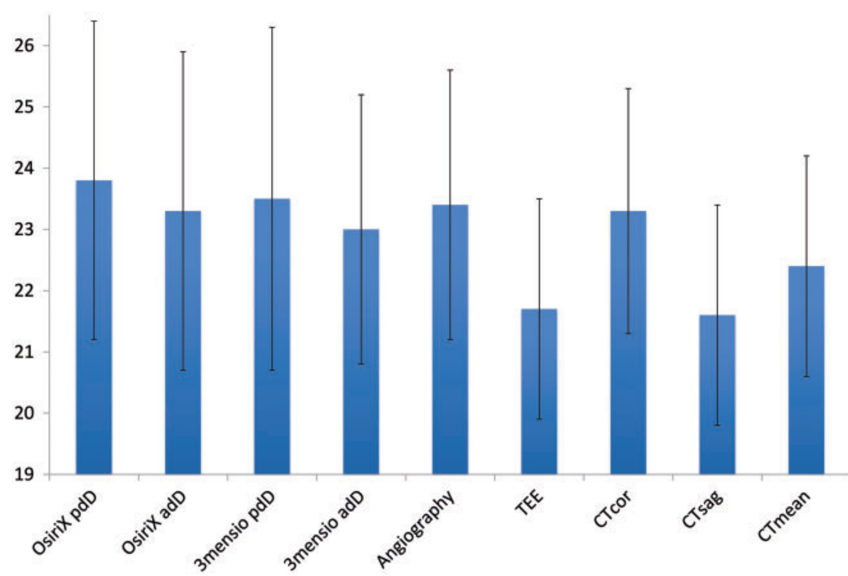

Figure 4: Mean aortic annulus diameters among different imaging or software modalities are displayed (mean ± SD). Largest diameter was seen by 3D $MSCT_{pdD}$ measurements, smallest diameter by CT_{sag} and TEE.

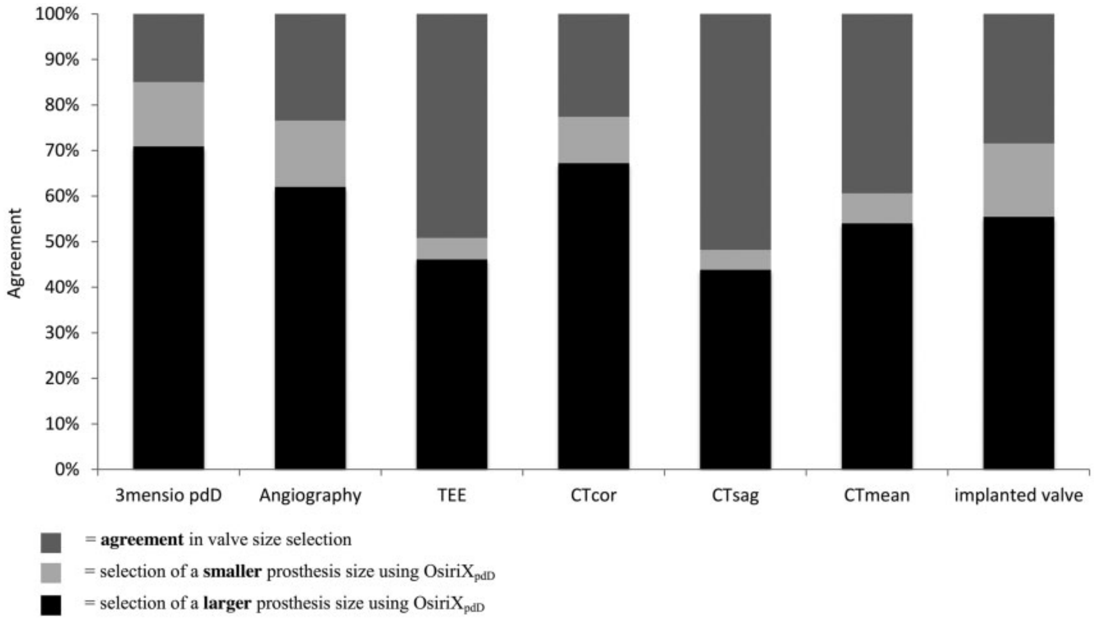

Figure 5: Effect on valve size selection. Changes in valve size selection using different imaging modalities compared with 3D MSCT OsiriX$_{pdD}$-based sizing. The green bar indicates conformity in valve size selection, while the blue colour indicates disagreement: with light blue OsiriX$_{pdD}$-based sizing would have resulted in the choice of a smaller valve device and with deep blue a larger one would have been chosen.

and MSCT$_{sag}$, which underestimated the annular diameter to a greater extent, showed even lower correlation coefficients of 0.51 and 0.48, respectively.

Putative effect on valve size selection and clinical outcome

To put the observed sizing differences into clinical context, we evaluated the effect of sizing modality on prosthesis size selection (Fig. 5). When taking into account TEE and MSCT$_{sag\ view}$, which agreed least with Osirix $_{pdD}$ measurements, the resulting effect on the selected prosthesis size would have been a change in more than half of the patients (54% and 56%, respectively). Mostly, a smaller valve prosthesis size would have been chosen (Fig. 5).

The retrospective analysis showed that, based on the analysis of the 3D-reconstructed images with the OsiriX software, a larger prosthesis size would have been chosen in 17% of patients. Furthermore, of the 45 patients with a post-interventional aortic regurgitation of Grade 2 and higher (Table 2), a majority of 29 (64%) would have received a larger prosthesis according to OsiriX-based sizing ($P = 0.001$). This finding would point towards the potential clinical impact of the measurements based on the 3D reconstruction freeware, whose reliability was validated in this study.

DISCUSSION

The OsiriX software renders valid assessment for preoperative TAVI sizing, and it allows accurate and reproducible observer and examination conditions for independent assessment of the aortic annulus dimensions. It proved to produce highly correlating diameter determinations with only slight inter- and intra-rater variations. Further, the high agreement of OsiriX measurements with those of a different software used for TAVI sizing [5] proved that 3D MSCT-based software was accurate in aortic annulus sizing in general, and OsiriX sizing software in particular.

The clinical significance of the observed slight inter- and intra-rater variations was low with a high agreement in prosthesis size selection in 83–93%, comparable or even superior to those published in other trials [7–9]: Schuhbaeck *et al.* [7] reported the highest reliability for MSCT$_{pdD}$ with a change in prosthesis size in 11% for inter- and 19% for intraobserver evaluation, followed by MSCT$_{adD}$ with a change in 20% and 25%, respectively [7].

Comparison of different 3D MSCT reconstruction softwares revealed that prosthesis selection would have differed in around 30%, depending on which software is used for 3D MSCT-based sizing. Given the small annular diameter range that lies between 2 prosthesis sizes of about 3 mm, even slight sizing differences would potentially already provoke a change towards a larger or smaller prosthesis size, especially when annular dimensions lie close to a cut-off. Accordingly, there is an absolute need for a highly reproducible and accurate TAVI sizing technique to prevent potential adverse effects from missizing. Our data could also be interpreted as pointing towards a need for standardized annular dimension assessment that is observer independent [10].

Previous studies compared sizing with 3D MSCT adD and pdD to TEE, as the basic and initially predominantly used aortic annulus imaging method, and found a change in device size selection in around 40% of cases [8, 10–12], while MSCT single-diameter measurements modified the choice even more often [10, 13]. Schultz *et al.* [10] found a change in TAVI strategy in 40% comparing MSCT$_{pdD}$ with TEE-based sizing.

The main reason for the existing sizing differences is inaccurate sizing due to the fact that the aortic annulus is mostly oval in shape [14, 15], with larger dimensions in coronal and smaller ones in sagittal direction [9, 10, 14–18]. Since standard 2D imaging modalities generally measure 1 single-plane diameter in a longitudinal axis through the aortic annulus, under the assumption of a circular geometry, this clearly induces some sizing error. Echocardiographic measurements, as well as $MSCT_{sag}$, are done in a sagittal direction depicting the smallest diameter, likely resulting in an underestimation of true annular dimensions. Angiographic and coronal MSCT measurements, on the other hand, display the coronal and therefore largest annular diameter. This explains why $MSCT_{cor}$ and angiography, as well as $MSCT_{sag}$ and TEE have the best intermodality agreement. However, the degree of ovality varies, provoking a variable shift in measured annular dimensions compared with other diameters.

The aortic annulus is not only oval but has a complex 3D structure, which is also composed of the crown-like attachment of the 3 semilunar cusps onto the aortic root. This represents the surgical definition of the annulus, and so the prosthetic device is sewn onto this crown-shaped annulus, whereas for TAVI, the aortic annulus is defined as the virtual ring connecting all 3 lowest valve hinge points, since this represents the tightest part of the aortic root and the anchoring point for the prosthetic valve [6]. Three-dimensional reconstruction tools enable an exact anatomic identification of the annular plane and a free in-space reconstruction of the annulus in a double-oblique plane. This accounts, on the one hand, for an increase in reliability and, on the other hand, for more precise sizing, closer to real annular dimensions. Indeed, we found highly reproducible 3D MSCT pdD and adD determinations and various works verified this increase in reliability too: highest and actually excellent reproducibility for aortic annulus evaluation was seen using 3D $MSCT_{pdD}$ and $MSCT_{adD}$ [7–9, 19, 20], higher than for 2D MSCT, TEE, transthoracic echocardiography or angiographic measures [8, 13, 16, 18].

Overall, $MSCT_{pdD}$ theoretically corresponds most precisely to true annular dimensions, as the annular perimeter of the aortic wall represents the most consistent value of the aortic annulus [20]. The annular shape changes throughout the cardiac cycle as well as after valve implantation by being shaped into a more circular geometry [9, 21, 22], thus both the annular diameter and the area increase.

The most common, and therefore mainly evaluated adverse effect of undersizing, is paravalvular regurgitation [9, 12, 13, 15, 19, 23, 24]. It was demonstrated that a device chosen upon TEE-based diameters was often too small and that, a higher rate of paravalvular regurgitation occurred [9, 12, 13, 19, 24]. It was shown that the amount of oversizing when applying $MSCT_{pdD}$- or $MSCT_{adD}$-based sizing was strongly associated with the severity of paravalvular regurgitation [19, 24]. Thus, 3D MSCT seems to predict the amount of oversizing needed most precisely.

CONCLUSION

The OsiriX 3D reconstruction software tool renders valid depiction of the aortic anatomy and serves as a suitable tool for reliable annular measurements for use in TAVI sizing. The benefit of including 3D MSCT aortic annular dimension assessment is evident and 3D MSCT-guided TAVI sizing potentially improves clinical outcome.

Conflict of interest: Christoph Huber is a proctor for Edwards Lifesciences and Consultant for Medtronic. Lutz Buellesfeld is consultant for Medtronic and Edwards Lifesciences. All the other authors have no conflicts of interest to declare.

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