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ORIGINAL ARTICLE

The effect of X-ray beam distortion on the Edwards Sapien XT™ trans-catheter aortic valve replacement prosthesis

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Abstract

Introduction: Profiling the Aortic root perpendicular to the fluoroscopic image plane will achieve a more successful implant position for trans-catheter aortic valve replacement (TAVR). This study aimed to investigate whether the divergent nature of the X-ray beam from the C-arm altered the appearance of the TAVR device. **Methods:** Under bench-top testing, a 23, 26 and 29 mm Edwards Sapien XT valve was positioned coaxially at the bottom of a fluoroscopic image utilising 22 and 32 cm fields of view (FOV). The table was then moved so that the valve was positioned at the top of the image. The valve's appearance was scored using a previously published three tier classification tool (excellent, satisfactory and poor) and quantified with measurements. The number of degrees of C-arm rotation that were required to bring the valve back to a coaxial appearance was recorded. **Results:** When using the 32 cm FOV, the valve's appearance changes from excellent to satisfactory. When a 22 cm FOV was used, the change is less marked. More C-arm rotation is required to bring the appearance back to coaxial with the 32 cm FOV. **Conclusion:** Not maintaining the valve in the centre of the image can distort the valves appearance. This has the potential to affect the final implantation depth.

Introduction

Patients who present with severe aortic stenosis and who are deemed too high risk for conventional open heart surgery can now be offered aortic valve replacement percutaneously.[1,2] Trans-catheter aortic valve replacement (TAVR) is a relatively new procedure which utilises fluoroscopy to percutaneously implant a new aortic heart valve. This is performed without the requirement of open heart surgery and was first described in 2002.[3] Implantation of the Edwards Sapien (Edwards Lifesciences, Irvine, CA) trans-catheter aortic valve requires it to be accurately positioned in relation to the aortic valve annulus.[4] Inaccurate positioning can lead to paravalvular regurgitation post implant or even embolisation of the device into the left ventricular outflow tract or ascending aorta.[5] These complications can lead to a conversion into open heart surgery, with the associated negative impact on patient outcome.[6]

When implanting the TAVR device, a coaxial or perpendicular X-ray C-arm angle ensures that the three coronary sinuses are aligned in one plane under fluoroscopy and the depth of valve implantation in relation to the annulus can be accurately assessed (Fig. 1). Ideal positioning is one-third to one-half of the valve above the mid-level of the aortic annulus.[4] With a coaxial angle, the upper and lower stent struts of the implanted valve appear superimposed on the image post implant

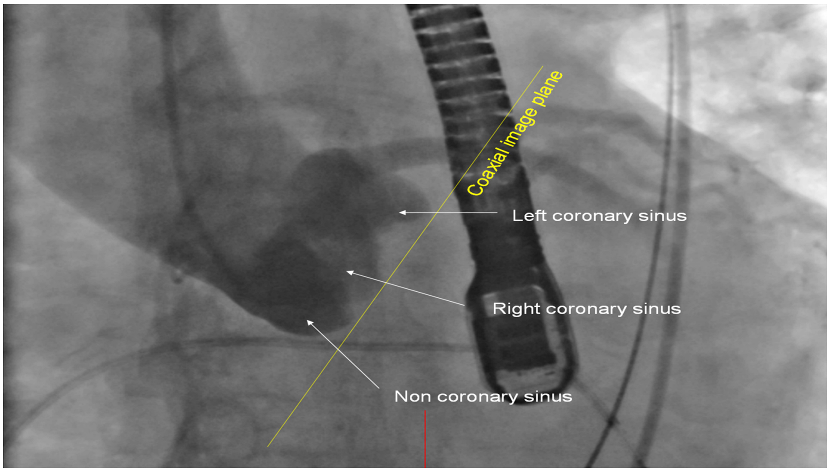

Figure 1. Pre-implant angiography of the aortic valve. This image demonstrates how the three sinuses of the aortic valve are aligned in one plane when the C-arm angle is optimal. The yellow line indicates the coaxial image plane and the level of the aortic annulus, which divides the aorta from the left ventricular outflow tract.

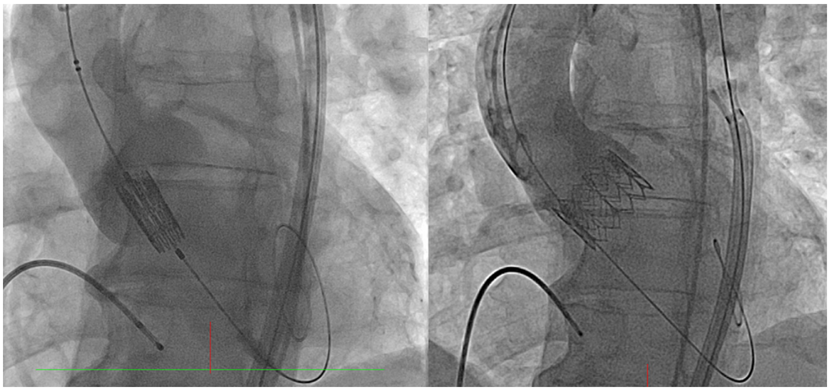

Figure 2. The trans-catheter aortic valve replacement (TAVR) device in the aortic annulus. This figure depicts the Edwards Sapien XT^{TM} TAVR device pre- and post-deployment. In this case the appearance of the deployed valve is termed excellent as the anterior and posterior stent struts are almost totally superimposed. It also highlights how good image quality and coaxial valve imaging is important pre deployment to achieve a good prosthesis position.

(Fig. 2). Previous studies have demonstrated the importance of coaxial imaging. Pre-operative multislice computed tomography (MSCT) or peri-operative cone beam computed tomography (also known as C-arm CT, angiographic CT and flat-panel CT[7] or three-dimensional (3D) angiography[8]) can accurately determine the best C-arm angle to achieve coaxial imaging.[8–10] Optimising coaxial imaging has also been linked to a decrease in paravalvular regurgitation.[9,11] X-ray equipment vendors have even released specialist software to aid the alignment of the valve sinuses, such is the importance of this phase of the procedure.[9]

The X-ray beam used in cardiovascular imaging systems, is emitted in a cone-shaped beam, determined by the small focal spot size and is described as a divergent beam. If an object is not placed in the centre of the image, distortion of the object on the image may occur. This is a well recognised phenomenon in all radiographic procedures[12] and it is most evident in radiographs using short object film distances and a large field of view (FOV). An example is the antero-posterior projection of the femur, where centring on the mid femur will mean that the knee joint is exposed to divergent rays and the joint space will appear distorted. In such cases, a second projection would be required to optimally visualise the joint.[13] Distortion is just as relevant during fluoroscopy procedures and in the case of TAVR procedures, which are performed under fluoroscopy, the appearance of the aortic valve could change due to distortion. The valve sinuses may not appear coaxial if the valve is not positioned in the centre of the image, even though the C-arm angle is optimal. This would make the aortic valve appear more oblique and therefore could affect the TAVR device's final implant position. The degree of distortion would be demonstrated by a change in the appearance of the TAVR prosthesis' framework post implant. This study aimed to investigate the effect of X-ray beam distortion on the TAVR prosthesis.

Methods

Equipment

Bench-top imaging was carried out on the three currently available *Edwards Sapien* XT™ Valve sizes: 23, 26 and 29 mm, using a modern, fluoroscopic system with a flat detector (Siemens Artis Zee; Siemens Healthcare, Erlangen, Germany). This X-ray system has annual compliance testing performed by a medical physicist to ensure X-ray beam quality. This is an advanced cardiovascular image system with 3D capability and as such, the manufacturer specifies that the accuracy of C-arm anglulations are within 0.1°.

Image capture

To investigate distortion, each valve was positioned towards the bottom third of the image field and the C-arm was moved to produce an image where the superior borders of the valve prosthesis frame are superimposed (Fig. 3A). The X-ray table was then moved or 'panned' to position the valve in the upper third of the image field (Fig. 3B). A calibrated sphere measuring exactly 30 mm was placed in the image field for measurement tool calibration purposes and an image was stored. The C-arm was then rotated with the valve in its new position to once again produce an image where the superior borders of the valve prosthesis frame are superimposed and the number of degrees that the C-arm rotated through to achieve this (as displayed on the X-ray systems data display) was recorded. This was performed to demonstrate the equivalent number of C-arm degrees that the distortion creates.

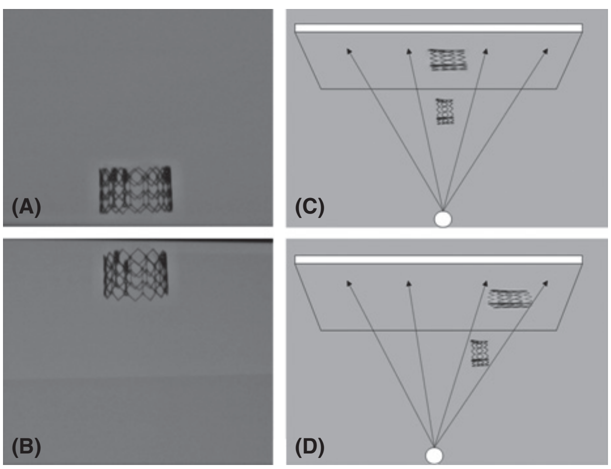

Figure 3. Change in appearance of the trans-catheter aortic valve replacement (TAVR) device as it is moved from the bottom to the top of the image. This figure demonstrates how the TAVR device can change in appearance as it is moved from the bottom of the image to the top. (A and B) In this case, a 29 mm valve in a 32 cm field of view (FOV) and its change from excellent in (A) to satisfactory in (B). (C and D) Describes how the TAVR device changes its appearance on the image due to the divergent nature of the X-ray beam and the resultant distortion.

Effect of magnification

In an effort to establish whether any change in appearance was affected by magnification, the above methodology was repeated with the X-ray table height lowered by three 10 cm increments from the isocentre (0, −10 and −20 cm) and also with the image detector raised in three 10 cm increments to change the source to image distance (SID) from 100 to 110 cm and then to 120 cm. The above methodology was performed at both a 22 cm FOV and a 32 cm FOV.

Image analysis

Using a previously published three tier classification tool, one can classify the success of the implant angle, using visual clues from the frame and struts of the newly implanted valve. *Excellent* refers to perfectly aligned superior struts, where the anterior strut is up to half the height of a cell different to the posterior struts. *Satisfactory* refers to where the superior struts are from half the height of a cell to a whole different cell. *Poor* refers to where the superior struts are more than a whole different cell.[10] These criteria were used to assess any change in the valve appearance due to distortion. Examples of the appearance in the clinical setting are demonstrated in Figure 4.

The change in appearance and the distance between the superior struts was assessed independently by two cardiac radiographers, with 7 and 19 years of experience respectively. These observers used the X-ray systems measurement tool to numerically quantify any change in appearance. Calibration of the measurement tool was performed against the 30 mm sphere. Correlation of the observers measurements were assessed using a Pearson's correlation coefficient. This study was a bench-top study and did not involve human subjects. Human research ethics approval was therefore not required.

Results

Overall, the distortion was not sufficient to change the appearance from excellent to satisfactory on any valve size

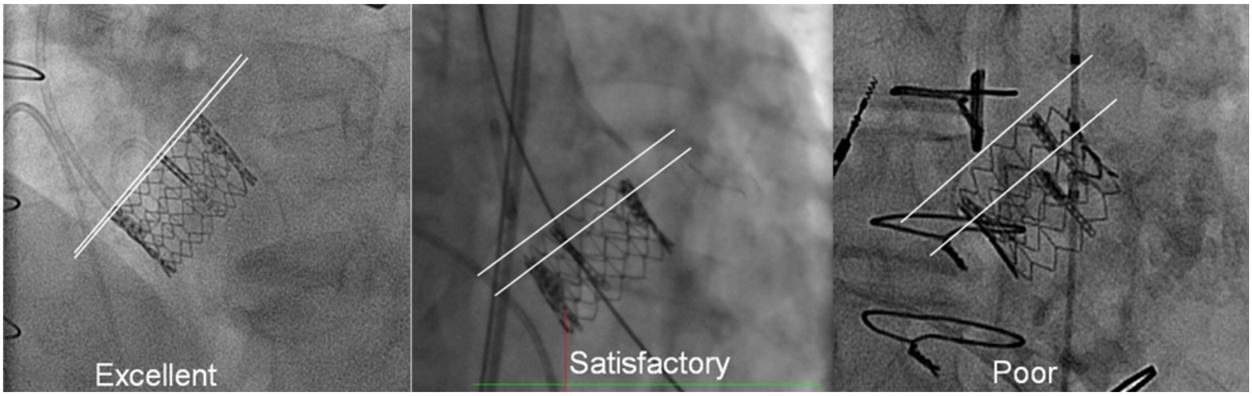

Figure 4. Clinical examples of the valves appearance using the 3 tier classification tool. This figure demonstrates examples of the appearance of the Edwards Sapien valve against the three criteria used in this and other studies. The white lines mark the anterior and posterior upper borders of the valve prosthesis.

at any magnification when using a 22 cm FOV. However, when a 32 cm FOV was used, the distortion was sufficient to change the appearance from excellent to satisfactory in certain conditions. The detail of the results of the bench-top testing is shown in Tables 1 and 2. The two observers scored the valve's appearance against the 3

Table 1. The results of bench-top testing with the Edwards Sapien XT valve imaged in a 32 cm field of view and the effect of distortion.

Valve size (mm)	FOV (cm)	SID (cm)	Table height (cm)	Distance table is moved to position valve from bottom to top of image (cm)	Appearance score	Mean distance between superior stent struts as measured on the image (mm)	Equivalent C-arm angulation (°)
29	32	100	0	16	Satisfactory	5.1	10
		100	−10	14	Satisfactory	5.4	10
		100	−20	11	Satisfactory	4.7	8
		110	0	14	Satisfactory	4.3	10
		110	−10	12	Satisfactory	4.4	9
		110	−20	10	Satisfactory	4.5	7
		120	0	14	Satisfactory	4.0	8
		120	−10	12	Satisfactory	4.4	9
		120	−20	9	Sat/Ex	3.4	6
26	32	100	0	15	Satisfactory	4.9	11
		100	−10	14	Satisfactory	5.1	10
		100	−20	11	Satisfactory	4.9	8
		110	0	13	Sat/Ex	4.1	9
		110	−10	11	Excellent	4.4	9
		110	−20	10	Excellent	4.2	8
		120	0	12	Sat/Ex	4.2	9
		120	−10	10	Excellent	4.3	8
		120	−20	9	Excellent	4.1	7
23	32	100	0	16	Satisfactory	4.1	10
		100	−10	14	Satisfactory	4.0	10
		100	−20	12	Satisfactory	3.8	9
		110	0	15	Sat/Ex	3.5	10
		110	−10	14	Excellent	4.0	10
		110	−20	11	Excellent	3.9	8
		120	0	14	Excellent	3.2	10
		120	−10	12	Excellent	3.3	9
		120	−20	10	Excellent	3.2	8

The table demonstrates how each of the three Edwards Sapien valves changes its appearance due to the image distortion created by the divergent beam in a 32 cm field of view. The distance between the anterior and posterior struts is quantified and the angulation required to bring the valve back to a coaxial angle is demonstrated. Disagreement in appearance score between the observers is demonstrated by a combined score (e.g. Sat/Ex). FOV, field of view; SID, source to image distance.

Table 2. The results of bench-top testing with the Edwards Sapien XT valve imaged in a 22 cm field of view and the effect of distortion.

Valve size (mm)	FOV (cm)	SID (cm)	Table height (cm)	Distance table is moved to position valve from bottom to top of image (cm)	Appearance score	Mean distance between superior stent struts as measured on the image (mm)	Equivalent C-arm angulation (°)
29	22	100	0	10	Excellent	3.7	7
		100	−10	9	Excellent	3.0	6
		100	−20	7	Excellent	3.1	5
		110	0	9	Excellent	2.4	4
		110	−10	8	Excellent	2.4	5
		110	−20	7	Excellent	2.5	6
		120	0	8	Excellent	2.3	4
		120	−10	7	Excellent	2.2	5
		120	−20	6	Excellent	2.8	5
26	22	100	0	9	Excellent	2.8	6
		100	−10	8	Excellent	2.5	6
		100	−20	6	Excellent	2.5	4
		110	0	9	Excellent	2.4	7
		110	−10	8	Excellent	2.4	5
		110	−20	6	Excellent	2.5	5
		120	0	7	Excellent	2.0	6
		120	−10	7	Excellent	2.2	5
		120	−20	6	Excellent	1.7	3
23	22	100	0	12	Excellent	2.7	8
		100	−10	10	Excellent	2.5	7
		100	−20	9	Excellent	2.3	6
		110	0	10	Excellent	2.4	7
		110	−10	8	Excellent	2.4	7
		110	−20	8	Excellent	2.3	7
		120	0	9	Excellent	2.5	7
		120	−10	7	Excellent	2.2	6
		120	−20	7	Excellent	2.2	5

The table demonstrates how each of the three Edwards Sapien valves changes its appearance due to the image distortion created by the divergent beam in a 22 cm field of view. The distance between the anterior and posterior struts is quantified and the angulation required to bring the valve back to a coaxial angle is demonstrated. FOV, field of view; SID, source to image distance.

tier classification tool with 92.3% agreement. The Pearson's correlation coefficient showed good agreement between the observers for the numerical measurement of the distorted prosthesis appearance: $r = 0.96$, $P < 0.001$.

Discussion

The effect of distortion from beam divergence is well understood in radiography and the principles are described in radiographic imaging technique text books.[12,13] Specific tools have even been designed to cater for the change in appearance of lateral lumbar spine radiographs due to distortion.[14] However, the effect of beam distortion has not been discussed before in relation to TAVR procedures. The effect may be most relevant during transaortic TAVR procedures, where the TAVR device is inserted through the superior aspect of the ascending aorta. During these procedures, visualisation of the insertion sheath under fluoroscopy is required to ensure that it is perpendicular to the valve's annular plane.[15] This scenario has the most potential to position the valve away from the centre of the image.

In this study, the greatest distortion of the valve is seen when the FOV is large (32 cm) and the magnification is low (detector low and table high). With this combination, the table can be moved further while still being able to visualise the valve in the image. This places the valve further from the photons that are travelling perpendicularly between the X-ray tube and detector, increasing the distorted appearance. With this scenario, the appearance of the valve changes to the equivalent of rotating the C-arm by up to 11°. The cut off for the valve changing from *excellent* to *satisfactory* appears to be between 10° and 6° of equivalent C-arm rotation, depending on the FOV used and the valve size.

The results also indicate that magnification does not greatly affect the degree of distortion visualised until the larger FOV is used. With this in mind, the 22 cm FOV is normally used for the set up aortogram and subsequent valve deployment. This configuration also electronically magnifies the image to better visualise the detail of the anatomy and prosthesis. However, it is noted from the results that under high geometric magnification, only small table movements or only a few degrees of C-arm angulation will distort the valve's appearance. This is problematic in clinical practice where a small deviation from the optimal C-arm angle or table position has a large effect on the appearance of the valve. Therefore, geometric magnification should be avoided or minimised. This issue may be highlighted again during procedures with trans aortic access, where there may be a tendency to increase the height of the detector away from the patient to enable better access and visualisation of the access site by the surgeon. This will increase magnification. The valve size is also shown here to influence the degree of distortion, with the 29-mm valve distorting more than the 23 mm, under the same beam geometry. This is due to the fact that with the larger valve, the distance between the upper and lower stent struts is greater and are therefore projected further apart onto the detector.

The appearance of implanted TAVR devices against the 3 tier classification tool used here was investigated in detail in the clinical setting in 2013. That study demonstrated that by using cone beam CT and specialist software to predict the best C-arm angle, an excellent appearance could be achieved in 84% of cases, compared to 42% without. It demonstrated that more aortograms and fluoroscopy were required to obtain the desired coaxial appearance in the group where cone beam CT was not used. The main finding in that study, however, was that with an *excellent* appearance, paravalvular regurgitation (leakage around the valve) from non-optimal TAVR device position was significantly lower.[9] This is clinically important as even mild paravalvular regurgitation has been associated with increased mortality at 2 years post procedure.[16] In another study, low positioning of the TAVR device has also been associated with a greater incidence of ECG rhythm disturbances, again highlighting the importance of accurate positioning.[17]

The results in this study demonstrate that, as expected, moving the TAVR device from the bottom to the top of the image distorts its appearance. The clinical application of these findings is that the set up angiogram, with a coaxial valve sinus appearance and the subsequent deployment of the valve must be performed with the valve positioned in the centre of the fluoroscopic image. Maintaining the native valve in the centre of the image as the prosthesis is positioned is of the utmost importance. Performing the initial aortogram with the valve positioned in one part of the image and deploying the valve in another could lead to inaccurate positioning from distortion. The team performing TAVR procedures should be aware of the existence of beam distortion and its potential to impact on final valve positioning. Practical ways to avoid prosthesis malposition from distortion are summarised in Table 3.

Table 3. Practical ways to avoid valve prosthesis malposition from distortion.

1	Ensure that the initial aortogram is performed with the native valve in the centre of the image.
2	Use pre-operative CT or peri procedural cone beam CT to predict the coaxial C-arm angle for better accuracy.
3	Use a small field of view.
4	Avoid excessive geometric magnification as small changes in C-arm/table movements will have a greater effect on distortion.
5	Ensure that the valve prosthesis is deployed in the centre of the image.

Limitations

This study was a bench-top study with a theoretical conclusion that the distorted appearance could lead to device malpositioning. Future studies could investigate the effect of distortion and its impact on deployment position of TAVR devices into 3D aortic models. Also, while this study concentrated on the Edwards valve prosthesis, it is likely that the other prosthesis types would demonstrate similar results.

Conclusion

Much effort is spent achieving coaxial imaging to ensure accurate TAVR position in relation to the aortic valve annulus. However, the basic radiographic effect of fluoroscopic beam distortion has the potential to affect coaxial imaging and the final TAVR device position.

Conflict of Interest

Dr Darren Walters is a proctor for Edwards Lifesciences and Primary investigator for the SOURCE registry and a consultant for Siemens. There is no other stock ownership, or other equity interests or patent-licensing arrangements within the article or conflicts of interest from any of the authors.

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