

Aortic annulus anatomy and measurement and its relevance to successful transcatheter aortic valve replacement

Proposed new gold standard

Introduction

The aortic surgical annulus is a complex three-dimensional crown shaped structure. The diameter at the base of the aortic root, the basal ring, is also called the “aortic annulus,” specifically during surgical aortic valve sizing. The basal ring is not a true anatomical entity but is defined as a virtual ring with three anchors at the nadir of each of the attachments of the aortic cusps. The basal ring is non-circular and may have an oval or elliptical shape, and calcification makes its shape non-homogenous.

During surgical AVR, the native aortic leaflets are cut out along the line of the surgical annulus, but the sizing of the “annulus” is done under direct vision by selecting an aortic valve sizer that best fits the size of the basal ring after the native aortic leaflets are removed. The sizers are unique to the type of prostheses used and are not interchangeable. The surgically implanted prosthesis is then sewn into place and this is one of the biggest differences between a surgically implanted aortic

valve and an aortic valve implanted using transcatheter techniques. The surgically implanted prosthesis is sewn into place at the level of the surgical annulus between the basal ring and the sino-tubular junction. The transcatheter aortic valve is anchored at the basal ring calcification without any sutures.

Multimodality imaging is usually recommended for patient selection and sizing prior to selecting a transcatheter aortic valve. Methods include transthoracic echocardiography (TTE); transesophageal echocardiography (TEE) – two-dimensional and three-dimensional; multislice CT (MSCT) and contrast angiography.¹ Emerging data has clearly identified the limitations of using two-dimensional imaging to accurately size a complex three-dimensional structure like the aortic root.

This article aims to highlight these limitations and propose a new gold standard in annular sizing using 3D TEE. Using a method that reliably and consistently can identify the nadir of the leaflets and



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use that as a reference point much like in MSCT, reconstruction of the annular diameter is possible mathematically. Potential advantages over MSCT would be the better spatial resolution of ultrasound over CT, the lack of need for radiographic contrast media to obtain this measurement and the reproducibility in the CathLab or OR.

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Clinical relevance

Proper sizing of the aortic annulus is crucial to the TAVR procedure. The following two scenarios may arise from improper annular assessment each with immense clinical significance:

- Denial of therapy or inappropriate approval for TAVR when the image-measured annulus size is on either end of the spectrum (18 mm or 25 mm). This has particular relevance in market places like in the US where the technology is still in its infancy with limited choices of FDA approved valve sizes (23 mm and 26 mm).
- Improper valve selection impacting valve function with risk of either paravalvular regurgitation or annular rupture with under or over sizing of the device. Valve undersizing can lead to aortic insufficiency. Over-dilation by the TAVR balloon can rupture the aortic root.

Paravalvular leak (PVL) is common post TAVR and is known to occur in 22 – 40% of patients.^{2,3} Aortic insufficiency (AI), when more than just trace, has been shown to be a predictor of both in-hospital and long-term mortality. One of the important predictors of PVL and post procedure AI is prosthesis-annular mismatch. Prosthesis device sizing for the Edwards Sapien Balloon Expandable Transcatheter aortic valve, the only FDA approved device available in the US as of this writing, is based on two-dimensional echocardiographic criteria. The 23 mm device is selected for aortic annulus measurements of 18 – 21 mm and the 26 mm device is selected for diameters between 22 – 25 mm.

Table 1.

| Sapien valve | Aortic annulus |
|--------------|----------------|
| 23 mm | 18 – 21 mm |
| 26 mm | 22 – 25 mm |

When compared to 3D TEE and MSCT, 2D echocardiography may underestimate or sometimes overestimate the size of the aortic annulus. The reason for this is that the coronet-shape basal attachments of the leaflets, which is the site of measurement of aortic annulus size by 2D TTE or TEE, does not transect the full diameter of the left ventricular outflow tract (LVOT). Instead it makes a tangential cut across the aortic root, and the leaflet attachments shown are along the surgical annulus above the basal ring level. By definition, this can result in inaccurate estimation of the basal ring diameter (Figures 5, 6, 7).

Another major limitation of 2D TTE or TEE is the vast inter-observer and intra-observer variability because of uncertainty about where in the dense calcium to place the cursor and also the frequent need for guessing where the leaflet hinge point is. The question then becomes:

- What is the ideal imaging modality for the pre-procedure and intra-procedure planning?
- What is appropriate patient selection?
- How can clinicians maximize procedural safety?
- How does appropriate sizing contribute to proper device function and long-term durability of the transcatheter valve?

Case selection and annular sizing

A current industry standard for percutaneous aortic valve selection is based on using 2D echocardiographic and 3D CT imaging. The use of 2D echocardiographic measurement is based on the presumption that the annulus is circular in shape. The annulus is known, however, to be an irregularly shaped oval or ellipse and hence the circular measurement is potentially fraught with error. Using CT measurements, we recognize that in the

majority of patients the sagittal diameter is the minimum and the coronal diameter is the maximum diameter of the annulus.⁴ However in a third of the patients the true minimum and maximum diameter will be at oblique angles and not in the true coronal and sagittal plane respectively. The investigators at the Thoraxcenter in Rotterdam recommend using the mean of the minimum and maximum diameter as a pragmatic way of sizing the annulus. This may also be an imperfect and imprecise measurement in up to 33% of the patients.

Two-dimensional echocardiography

The current standard of care measurement of aortic annulus by two-dimensional echocardiography is shown in Figure 1. A zoomed aortic long-axis view with the largest internal diameter possible is obtained to get the best visual identification of the hinge points, where two leaflets are attached to the wall of the aortic root. Two cursors are placed to mark the two hinge points, and then the two cursors are connected with a straight line. The distance measured is called the aortic annulus diameter. Different methods are proposed where to place the two cursors in a heavily calcified annulus, where these hinge points are not as clear and obvious.

Contrary of this current standard of care of measuring the aortic annulus by two-dimensional echocardiography, we report that a two-dimensional echocardiography plane of the long-axis view of the aortic root may not identify the basal ring. Failing to identify the basal ring means that measurements taken by two-dimensional echocardiography can be unreliable.

Aortic root anatomy

The aortic root anatomy is described in Figure 2. The aortic root is comprised of three main components: the sinotubular junction, the aortic sinus (containing the sinuses of Valsalva, the leaflets of the aortic valve and the coronet-shaped surgical annulus) and the basal ring (where the aortic root joins the left ventricle). The aortic root is connected to one end at the sinotubular junction to the aorta, and at the other end to the left ventricular outflow tract. The aortic root extends from the sinotubular junction to the basal ring.

A colored illustration of the aortic root and its components is displayed in Figures 3A and 3B. As it is shown, the surgical aortic annulus is a coronet-shaped anatomical structure where the aortic leaflets are attached to the wall of the aortic sinus. The lowest parts of this coronet-shaped surgical annulus are the nadirs of the sinuses of Valsalva, the highest parts are the commissures. An imaginary or virtual circle, formed by joining the nadirs, defines the virtual basal ring. The surgical annulus, which is the base of the aortic leaflets where the leaflets attach to the wall of the aortic sinus, is a coronet-shaped three-dimensional structure. The surgical annulus straddles the entire aortic root lengthwise between the basal ring and the sinotubular junction. These two separate anatomical structures are perpendicular to each other and are touching each other at the three nadirs. With recent catheter based aortic valve implantation procedures (TAVR) the basal ring is the most relevant anatomical structure of the aortic root for proper sizing of the transcatheter aortic valves, and this imaginary and virtual line is the very part of the aortic root which is not seen and identified by two-dimensional echocardiography.

The three-dimensional coronet-shape annulus' nadirs and commissures are illustrated in Figure 4, when viewing a two-dimensional aortic valve short-axis image.

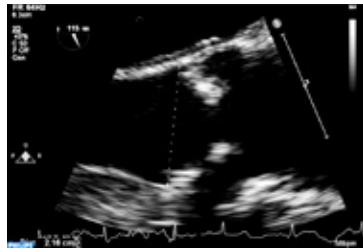


Figure 1. Two-dimensional zoomed aortic long-axis view measurement of aortic annulus by current standard of care

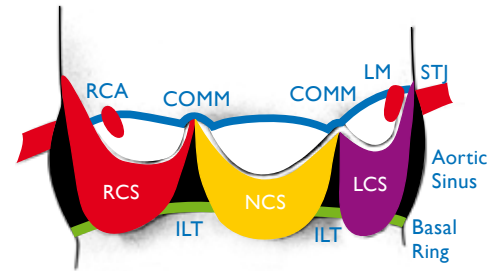


Figure 2. Aortic root (RCA-right coronary artery, RCS-right coronary sinus, NCS-Non-coronary sinus, LCS-Left coronary sinus, ILT-Interleaflet triangle, COMM-Commissure, LM-Left main, STJ-Sinotubular junction)

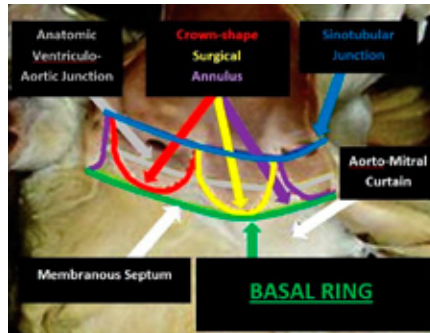


Figure 3A. Anatomical components of the aortic root

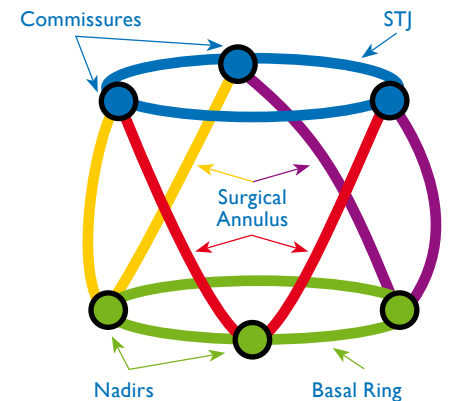


Figure 3B. Coronet-shaped surgical annulus, virtual ring/true aortic annulus, sinotubular junction, nadirs, commissures

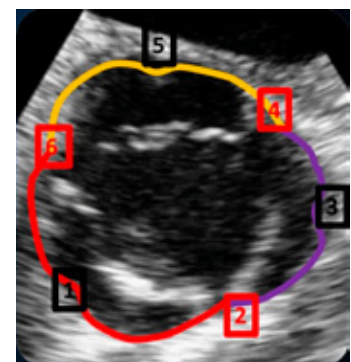
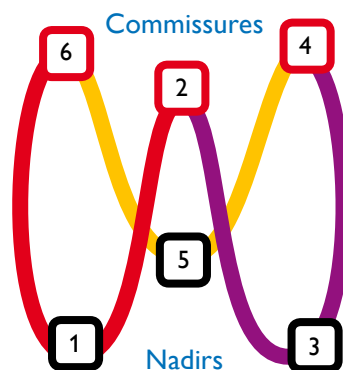
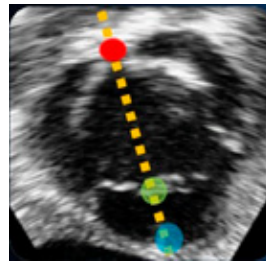


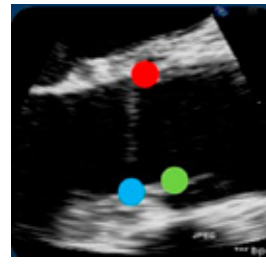
Figure 4. Surgical annulus orientation as seen on two-dimensional aortic short-axis view; Red – right coronary cusp surgical annulus; Purple – left coronary cusp surgical annulus; Yellow – Non-coronary cusp surgical annulus; 1 – 3 – 5 Nadirs, 2 – 4 – 6 Commissures

Inapplicability of two-dimensional echocardiography

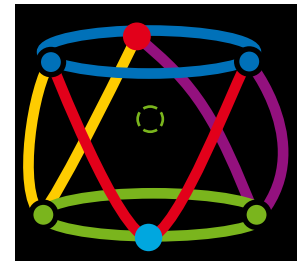
In two-dimensional echocardiography as used in the prior art, the long-axis aortic valve view is used to identify and measure the aortic annulus dimension. The two-dimensional echocardiographic image of the long-axis view of the aortic valve can only show the coronet-shaped surgical annulus within the sinus as the hinge points of the visible leaflets (Figures 5 – 6), giving the clinician the potentially false impression of having identified and visualized relevant annulus measurements, when in fact the basal ring, the anatomical structure to be identified, remains entirely unrevealed. Thus, two-dimensional echocardiography, either single plane or xPlane, is not suitable to identify and measure the basal annular ring.



5A



5B

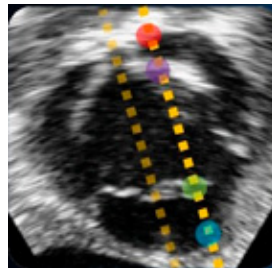


5C

Figure 5A. The two-dimensional aortic long-axis plane is positioned between the left and non-coronary cusps posteriorly and in the middle of the right coronary cusp anteriorly. The markers are points of intersections with anatomical structures within the aortic root.

Figure 5B. Two-dimensional aortic long-axis view obtained in A with correlating markers.

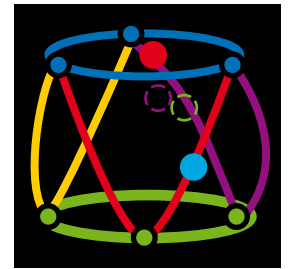
Figure 5C. Surgical annulus and basal ring with correlating markers. Make note of the blue and red markers spatial relationship to the basal ring (green ring).



6A



6B



6C

Figure 6A. The two-dimensional aortic long-axis plane is positioned to the left from its position in Figure 5. The plane now intersects the left coronary cusp posteriorly and the right coronary cusp anteriorly. The markers are points of intersections with anatomical structures within the aortic root.

Figure 6B. Two-dimensional aortic long-axis view obtained in A with correlating markers.

Figure 6C. Surgical annulus and basal ring with correlating markers. Make note of the blue and red markers position in relation to the basal ring (green ring). The blue and red markers are the hinge points on the surgical annulus, and would be considered the "annulus" by the traditional two-dimensional aortic long-axis view measurement in B.

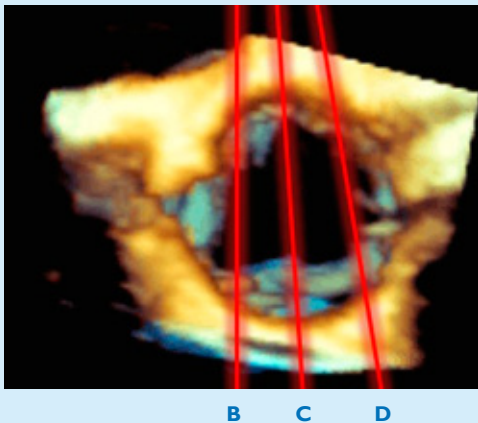


Figure 7A. Three two-dimensional aortic long-axis planes (red lines #B – C – D) within the aortic root. All three planes intersect the right coronary cusp anteriorly; all three planes intersect different structures posteriorly.

Inapplicability of xPlane

xPlane, a modality of current three-dimensional echocardiographic technology, also can fall short of identifying the basal ring. While xPlane technology is able to provide two separate two-dimensional images simultaneously, the annulus measurements are still performed on the two-dimensional aortic long-axis view, providing the visible hinge-points located along the surgical annulus, without any relevant information about the basal ring.

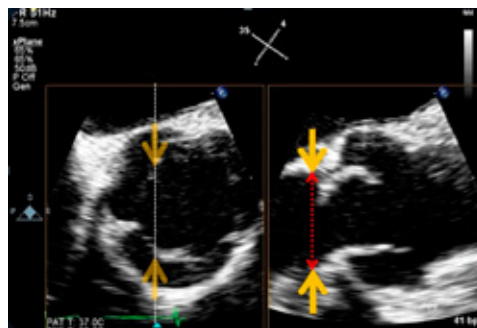


Figure 7B. Plane #B intersects the non-coronary cusp posteriorly

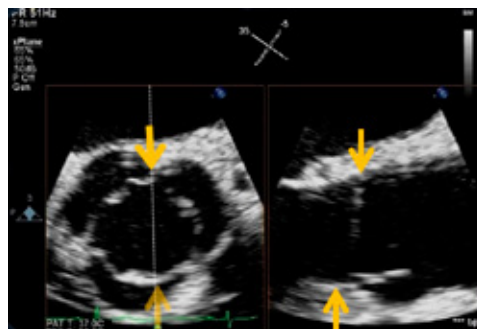


Figure 7C. Plane #C intersects no cusp at all posteriorly, only the commissure and the interleaflet triangle between the non- and left coronary cusps

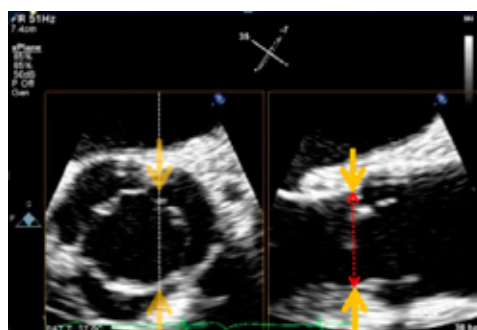


Figure 7D. Plane #D intersects the left coronary cusp posteriorly

Three-dimensional echocardiography, a new paradigm

In contrast, based on our experience, three-dimensional echocardiography and a specific methodology can identify the basal ring with certainty and with precision:

1. Collect a high-quality three-dimensional data set of the aortic root (Philips iE33 Live 3D TEE X7-2t transducer, iE33 xMATRIX system).
2. Activate the 3D quantification program (Philips QLAB 3DQ quantification tool)
3. Align the three multiplanar reconstruction planes, MPRs (the aortic short-axis, long-axis, and coronal MPR planes) during systole to obtain simultaneously the three nadir points of the sinuses of Valsalva in the short-axis MPR. (Figure 8A.)
4. Trace the true aortic annulus defined by the blood-tissue interface in the aortic short-axis MPR (Figure 8B.)

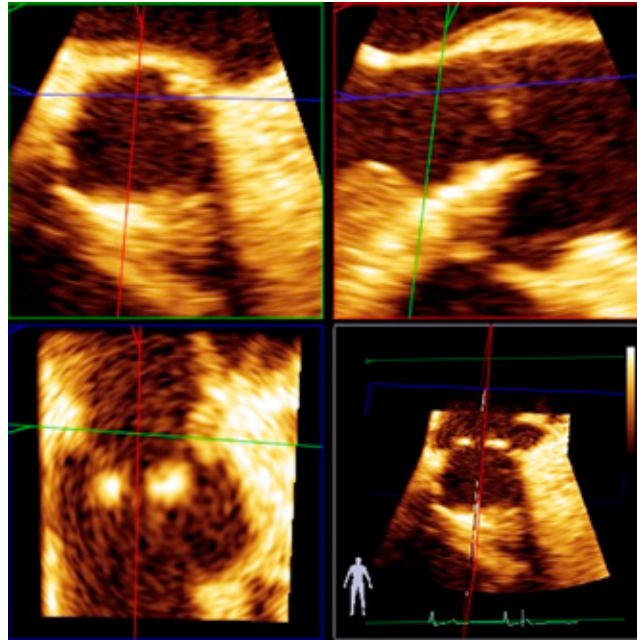


Figure 8A. Alignment of the three MPR planes to obtain the true aortic annulus in the short-axis view (left upper corner)

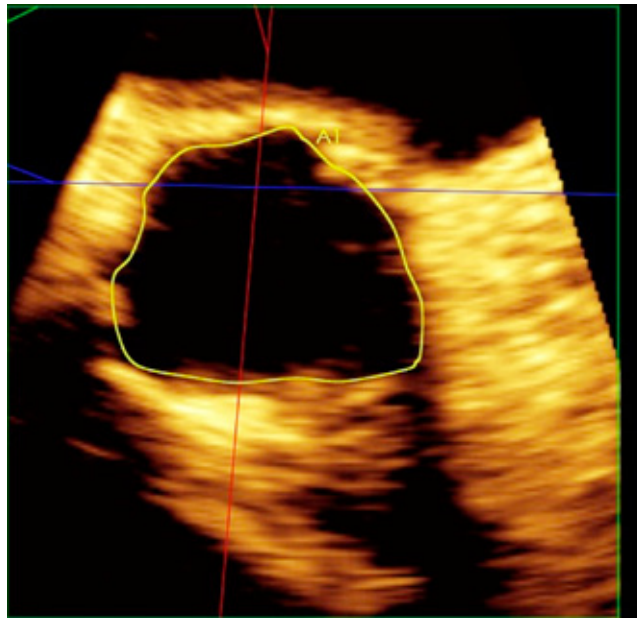


Figure 8B. Tracing of the basal ring and obtaining the area under the traced area.

Methodology of basal ring measurements

The shape of the basal ring (and LVOT) is not circular, but oval. In our experience the shape of the basal ring is a highly irregular oval shape. We found that using the minimal and maximal internal diameters of the basal ring to determine an average diameter for valve sizing, a frequently applied method by MSCT, can be unreliable and inaccurate due to this irregularity of the shape of the basal ring.

The commercially available Edwards Sapien Valve resumes a circular shape after deployment within the aortic root including the basal ring.

Our method is that first we obtain the area ("A") of the basal ring by using planimetry. Then we use the formula $A = \pi r^2$ to calculate "r" where "A" is the obtained traced area and " π " equals 3.14. Next we multiply "r" by 2 to obtain the diameter ("D"), which is the diameter of a perfectly round circle. This circle has the same area as the irregular shape true aortic annulus, obtained by the planimetry tracing. This circle's diameter ("D") determines the diameter of the circular shape prosthesis to be deployed in the available space and area of the basal ring.

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