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ACREDITADO EXCELÊNCIA
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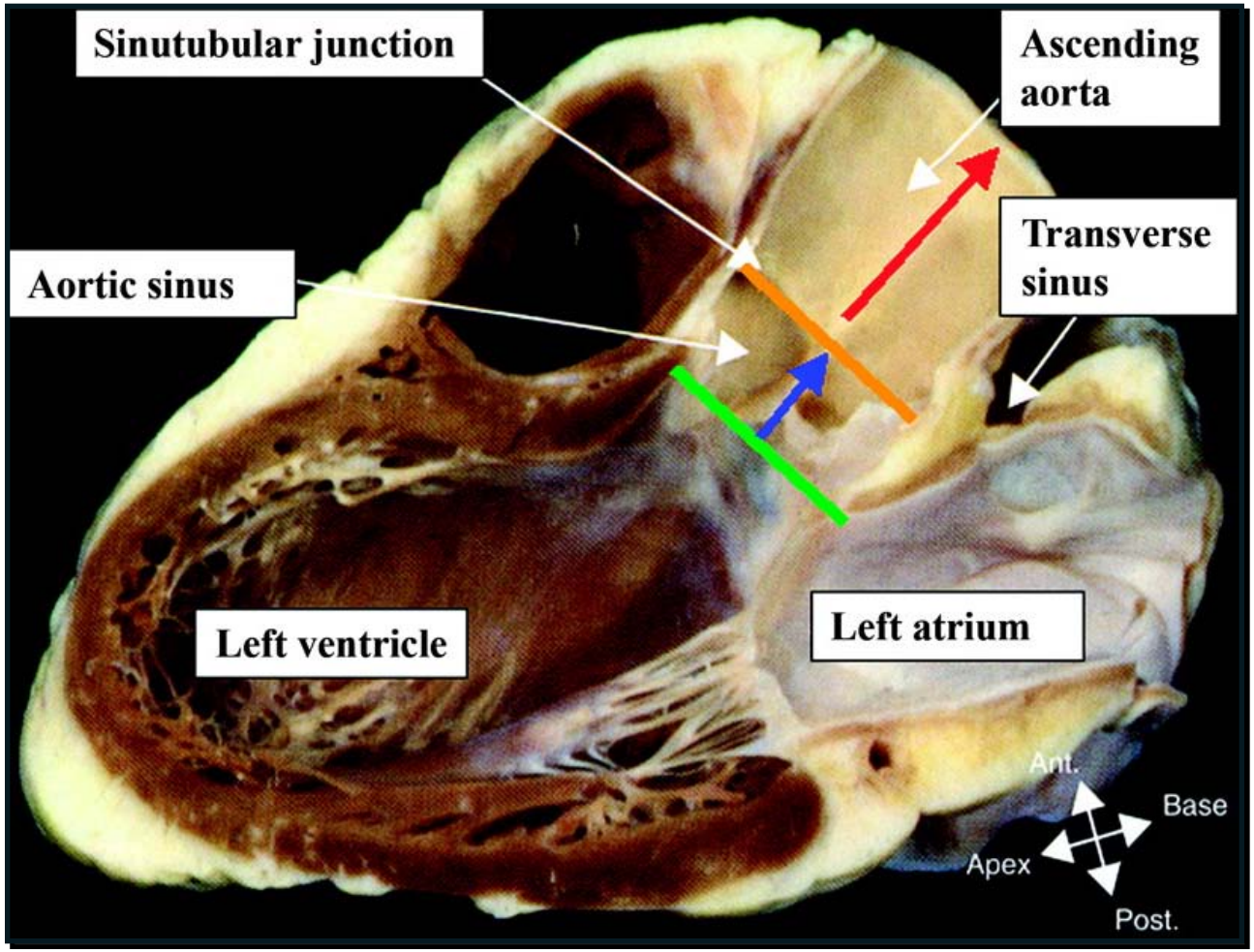
CoreValve
Celebrating 1000 implants

Sizing the Annulus: Understanding the new challenges for optimal result

Luiz Antonio Carvalho

Aortic Root Anatomic Overview



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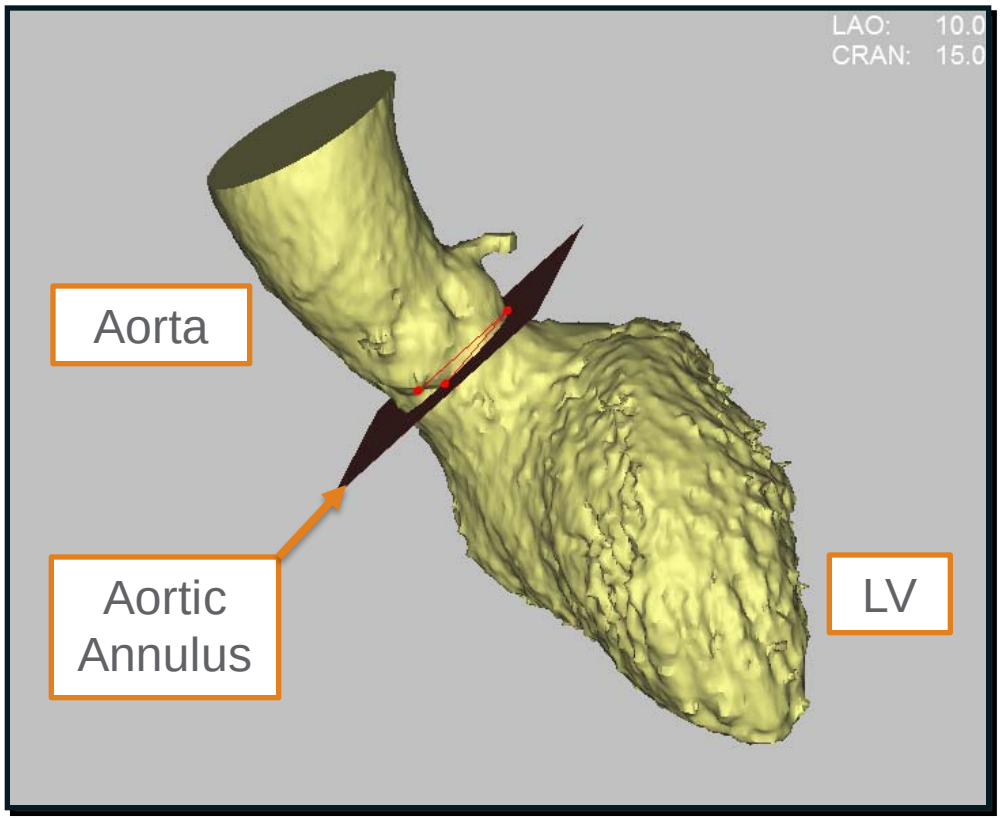
The Aortic Annulus

- Virtual plane defined by the most basal point of each of the three leaflets of the aortic valve
- Also known as:
  - Basal plane
  - Basal ring
  - Annulus plane
- Primary location measured for choosing prosthesis size



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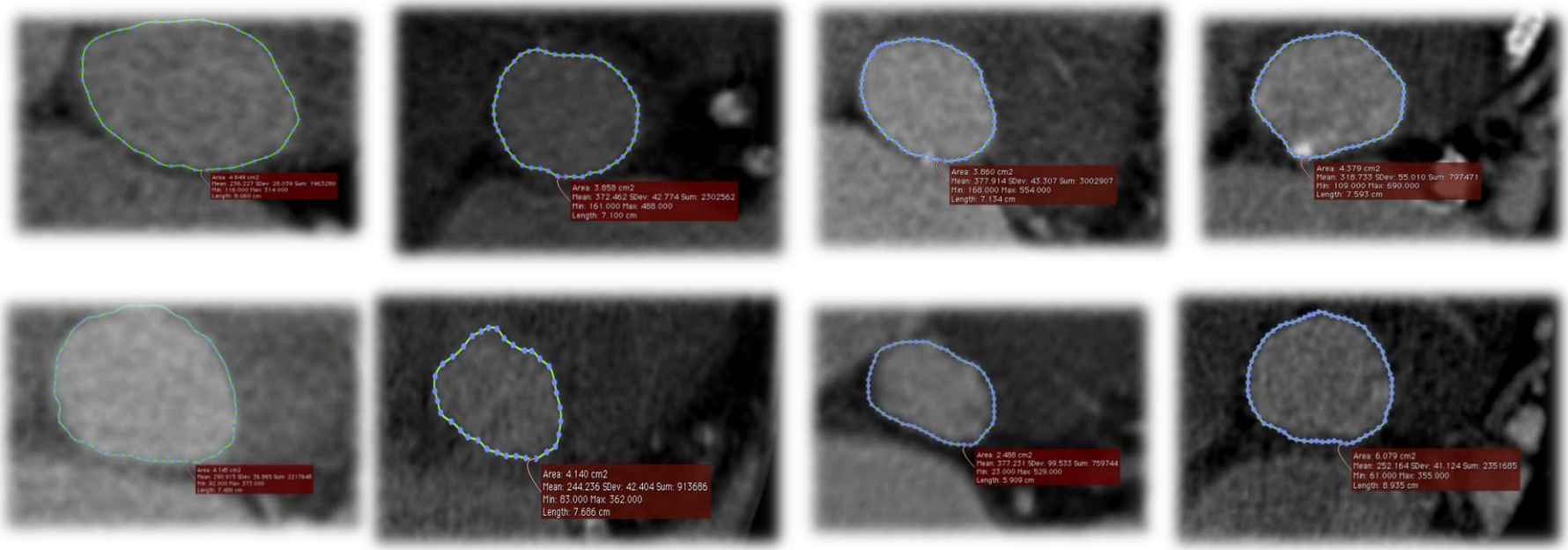
The Aortic Annulus

The aortic annulus is typically non-circular



Double-oblique axial images at the aortic annular plane

Courtesy of Dr. Piazza and Prof. Lange, German Heart Center, Munich Germany

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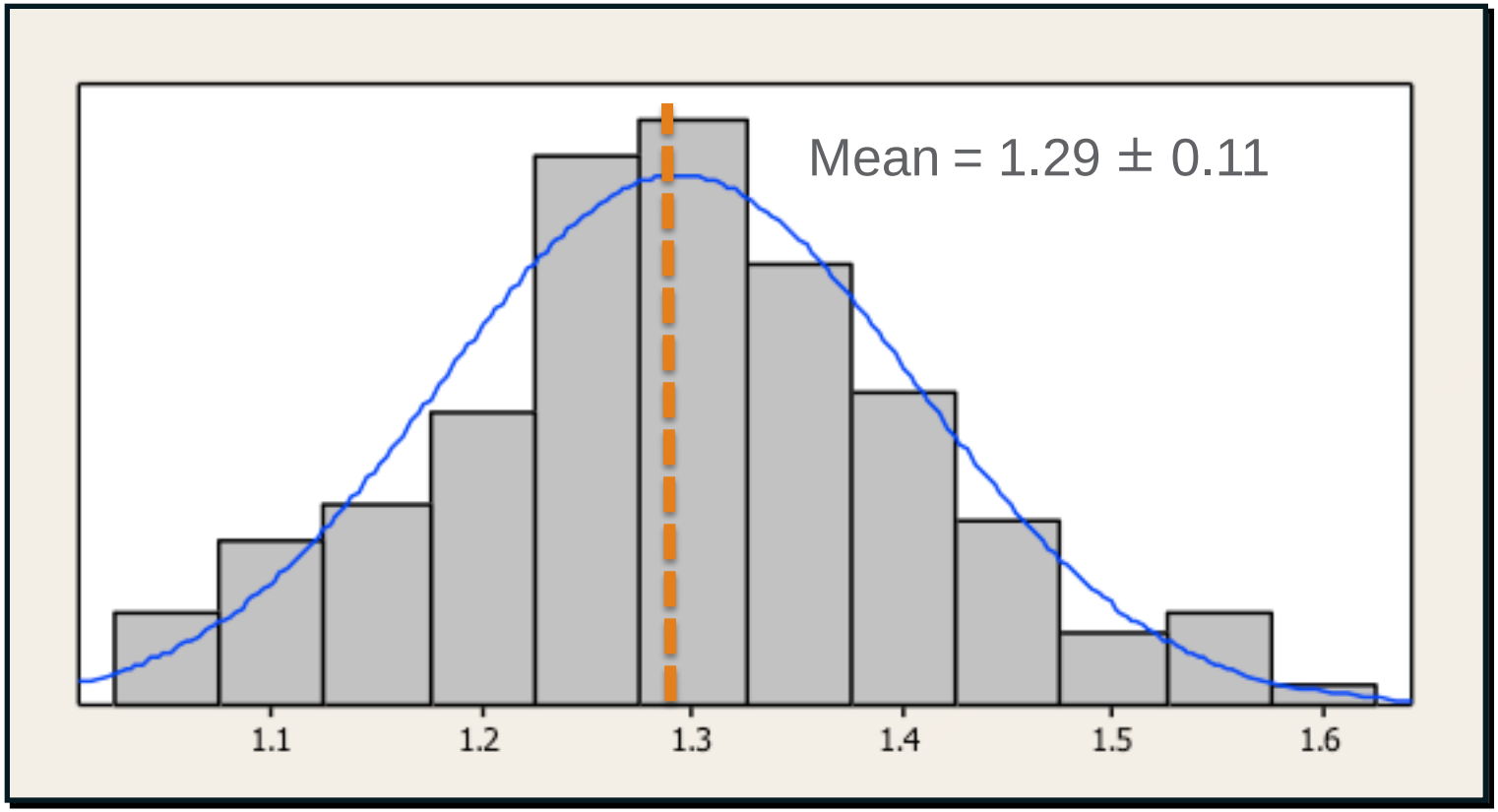
The Aortic Annulus



Distribution of D_{max}/D_{min} from 164 TAVI patients

Courtesy of Dr. Piazza and Prof. Lange, German Heart Center, Munich Germany

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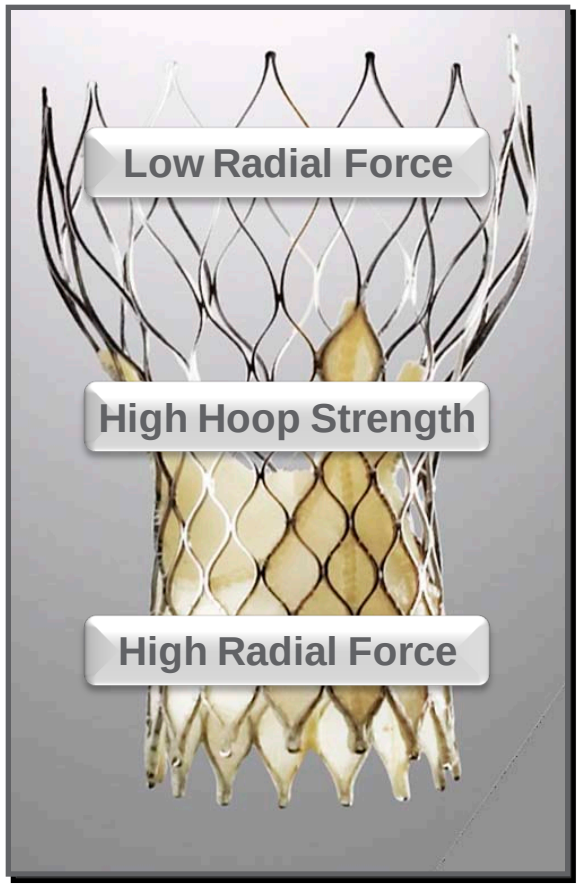
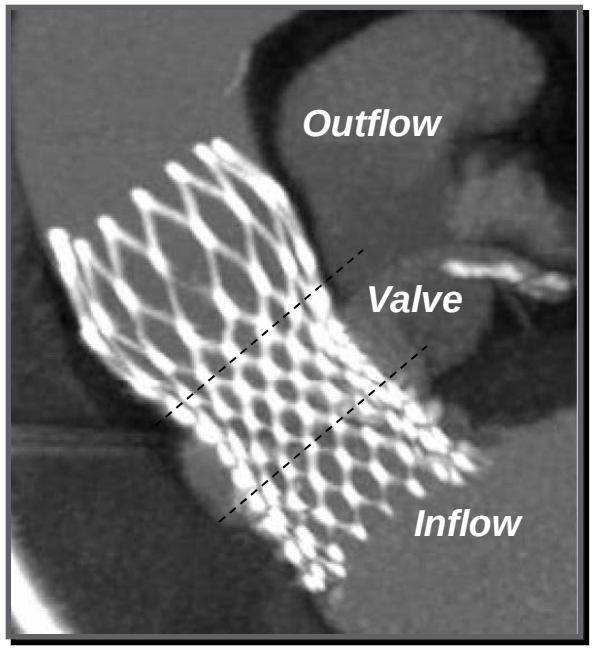
Designed to Conform to Anatomy

Outflow
Orientation

Constrained Portion
Supra-annular Valve
Function

Inflow Portion
Anchors Device
Promotes Sealing
Conforms to Anatomy





Photograph provided by Piazza, Serruys, and DeJaegere

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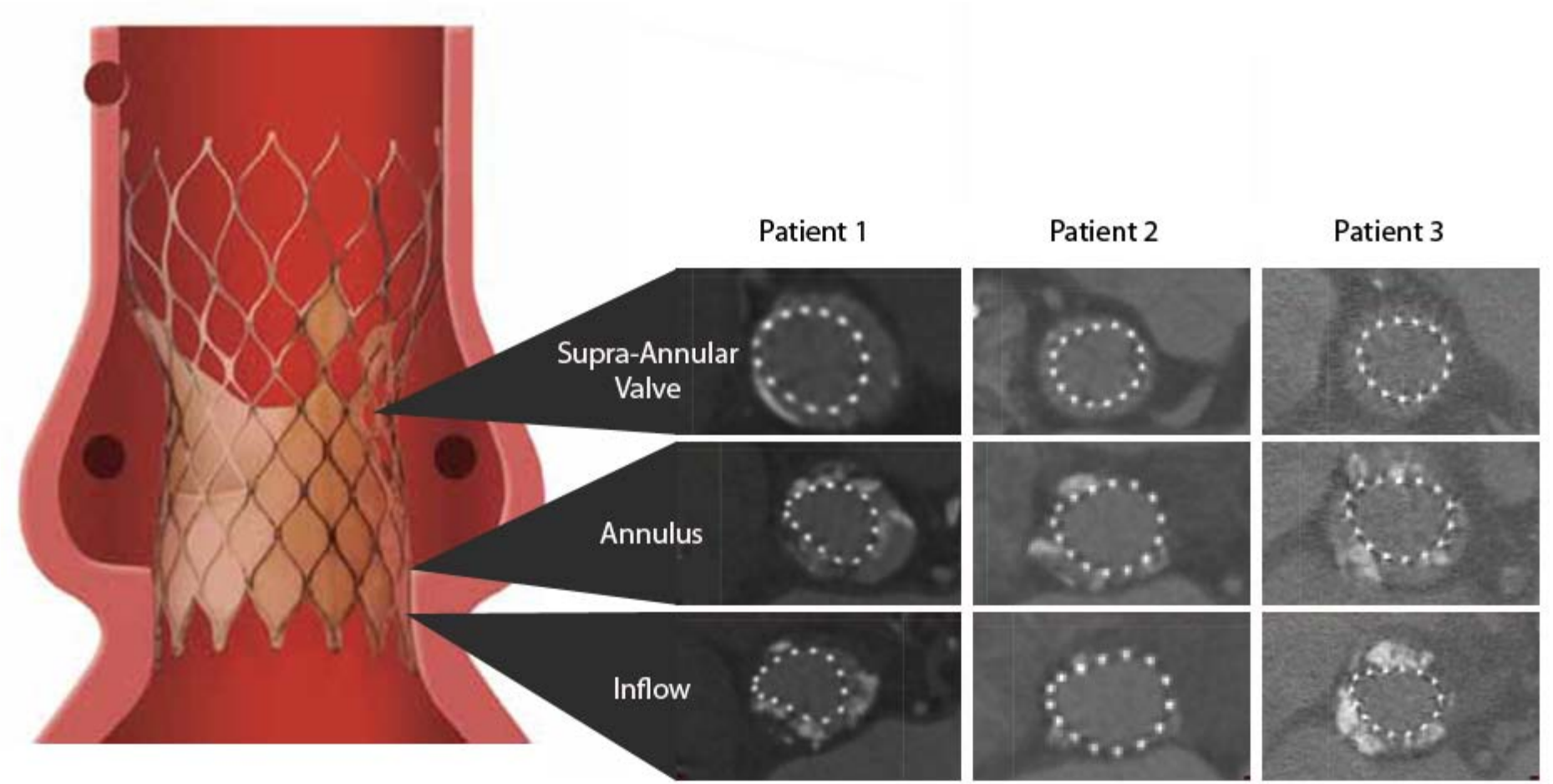
Examples of Conformability



Courtesy of Drs. de Jaegere and Schultz, Erasmus MC, Rotterdam, The Netherlands

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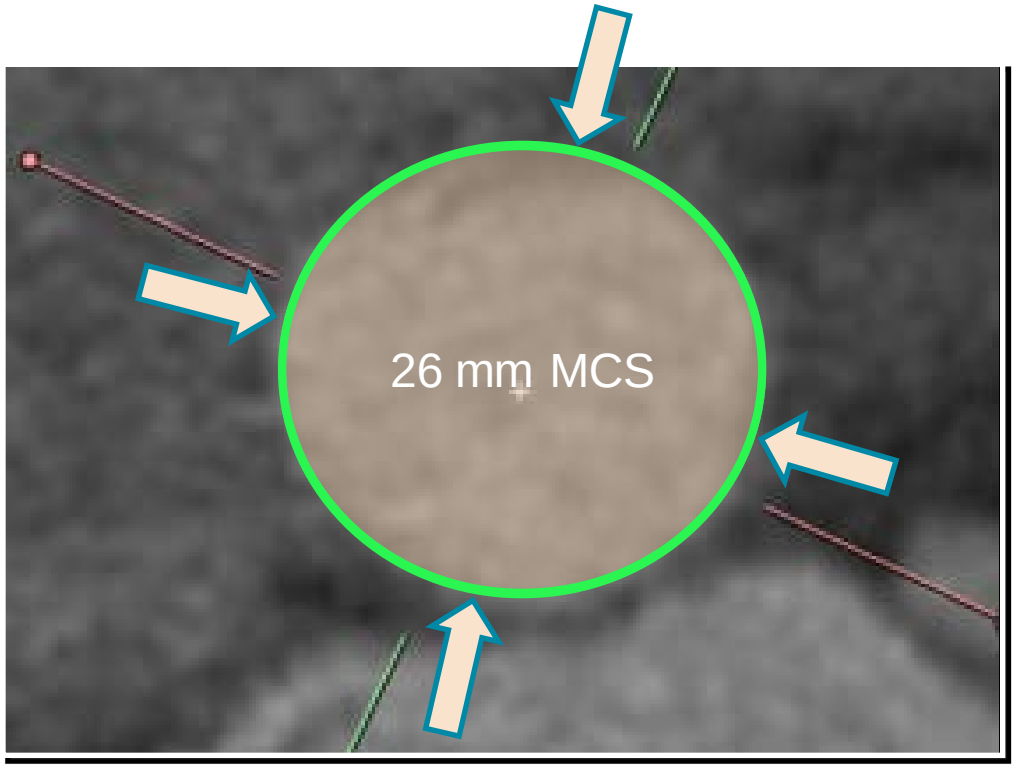
Anatomic Implications for TAVI Imaging

- The aortic annulus is clearly a complex structure and requires imaging that can take into account its elliptical and irregular shape
- Single diameter sizing methods can provide misleading results
- 3D imaging can provide a more accurate representation of the aortic annulus

Circular Example



2D Sizing

1. If the annulus is a circle, the device **will have** uniform inflow interference.
2. Imaging modality **not critical** - a diameter is a diameter is a diameter

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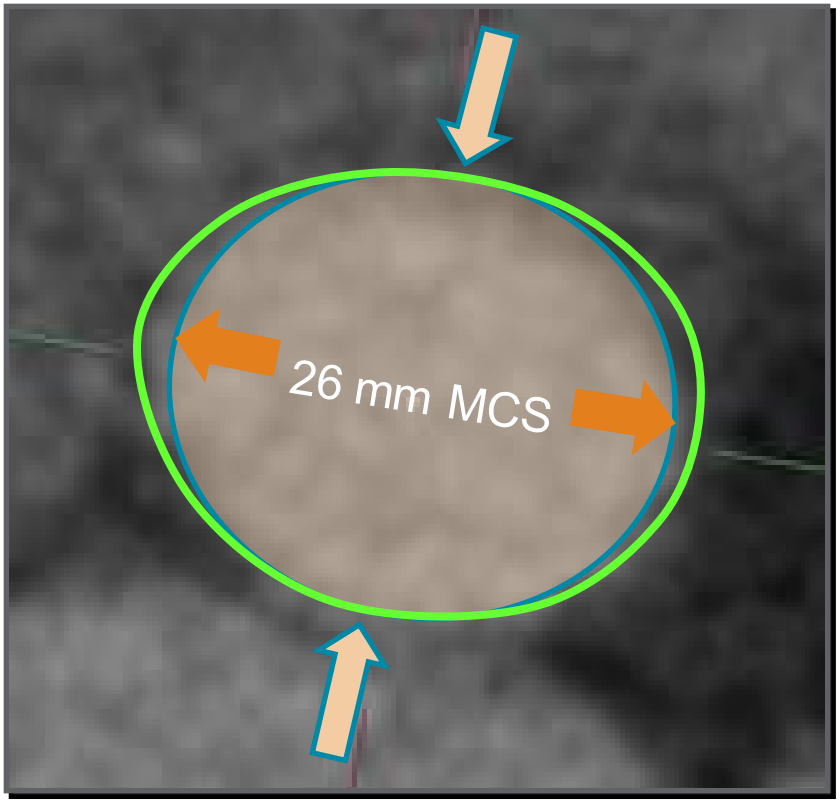
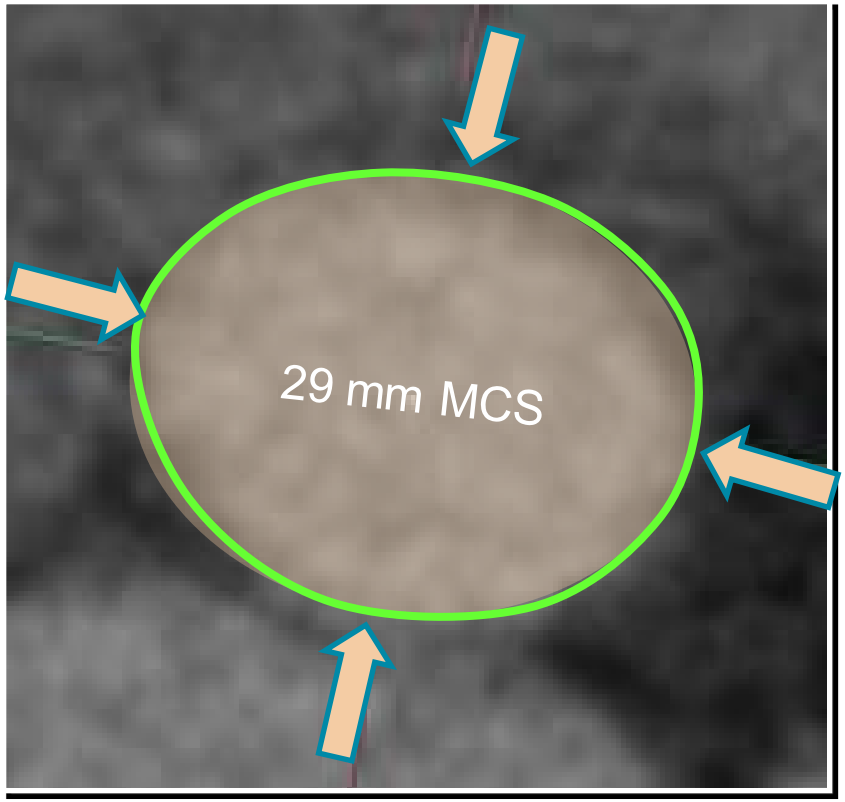
Non-Circular Example



2D Sizing



3D Sizing

1. If the annulus is non-circular, the device can still have the intended inflow interference.
2. Imaging modality important – 3D will provide better sizing insight than 2D

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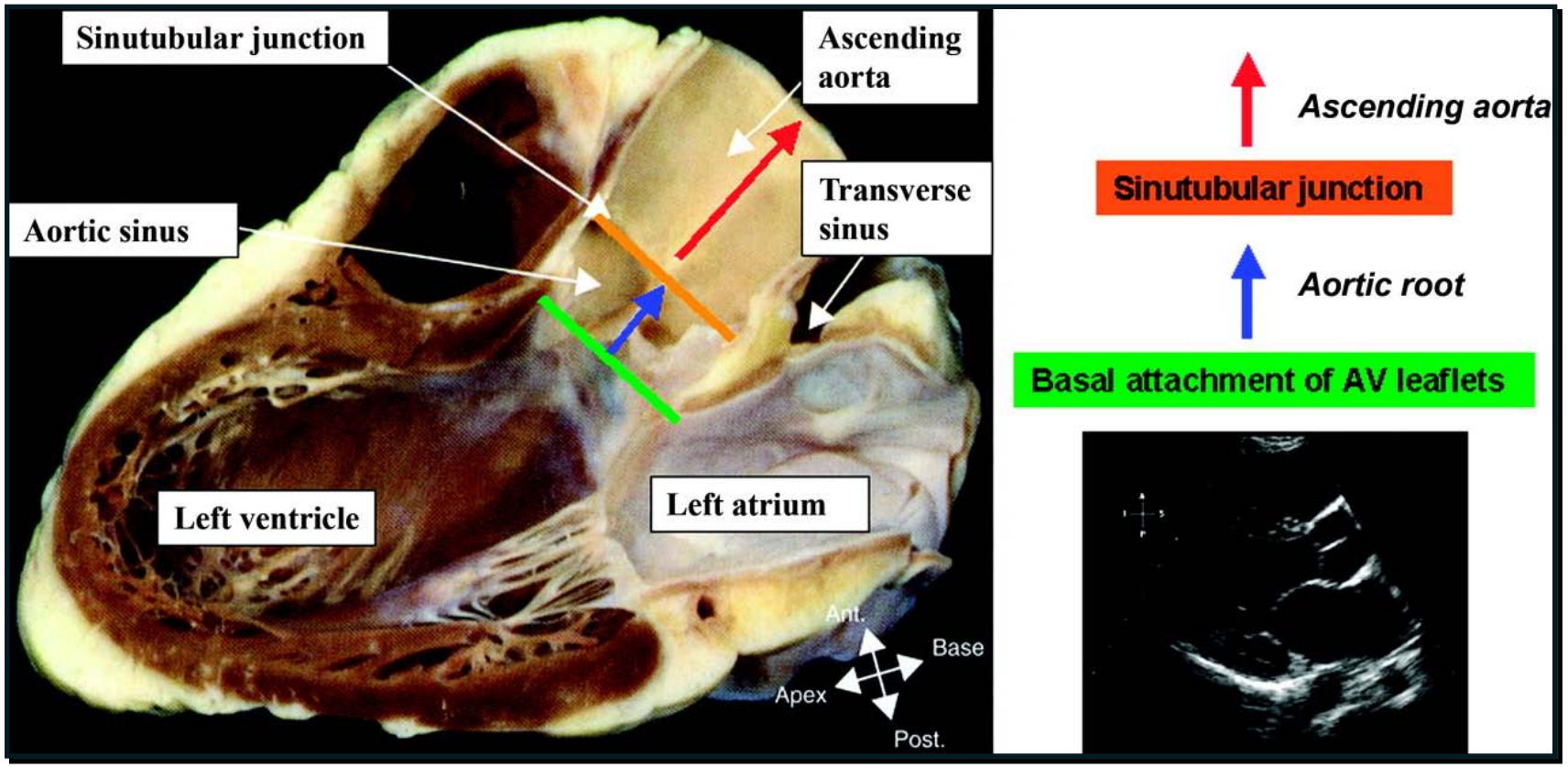
Sizing Imaging Comparison

- 2D echocardiography has been historically used for TAVI sizing
  - Availability for use before, during and after procedure
  - Primary modality used for hemodynamic evaluation
- 3D MSCT offers the following advantages
  - Multiple measurements (area, perimeter, diameters)
  - High reproducibility and spatial resolution
  - Calcification can be assessed
  - The rest of the device landing zone can be similarly analyzed
  - Peripheral assessment

Aortic Root Anatomy on Echo



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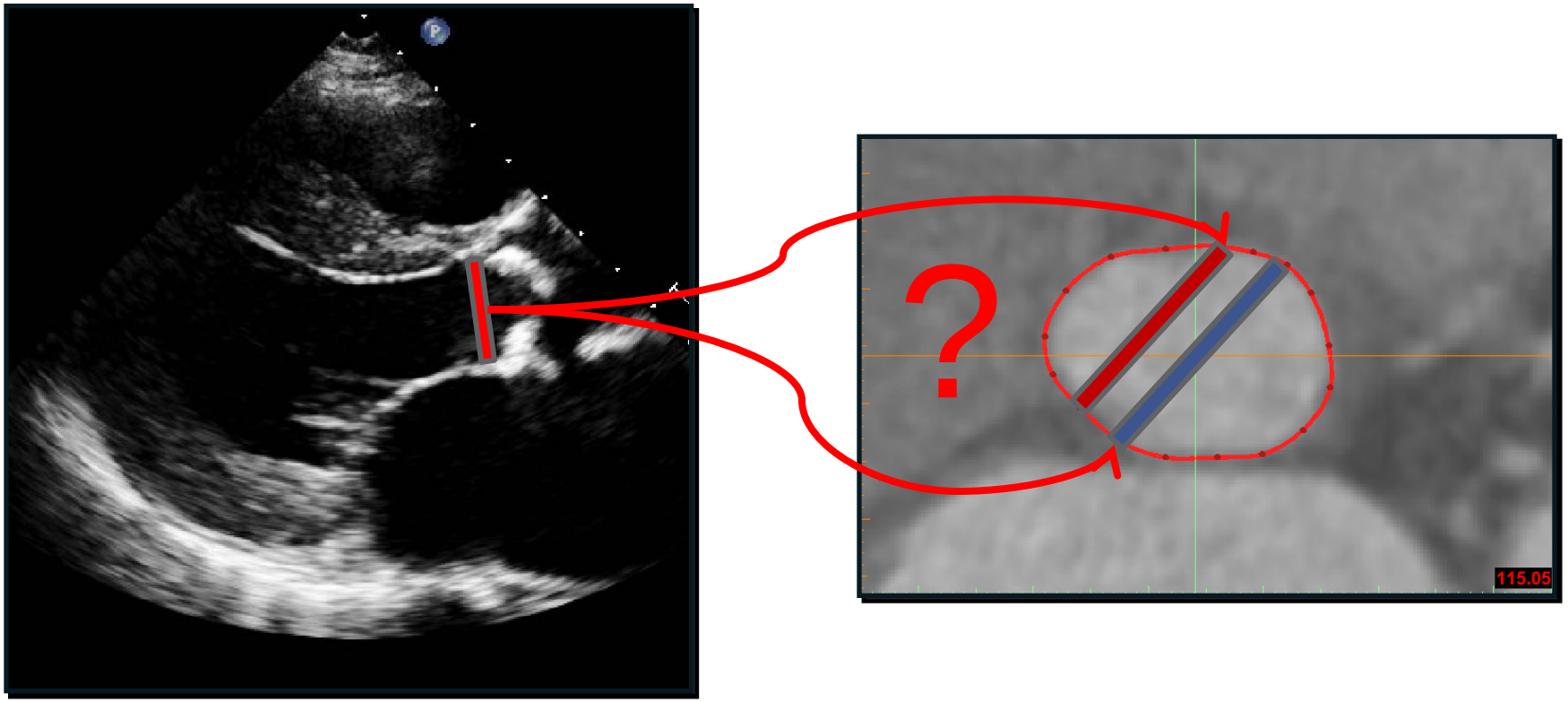
A Limitation of Echo



It is possible a true diameter is not measured due to the imaging plane acquired

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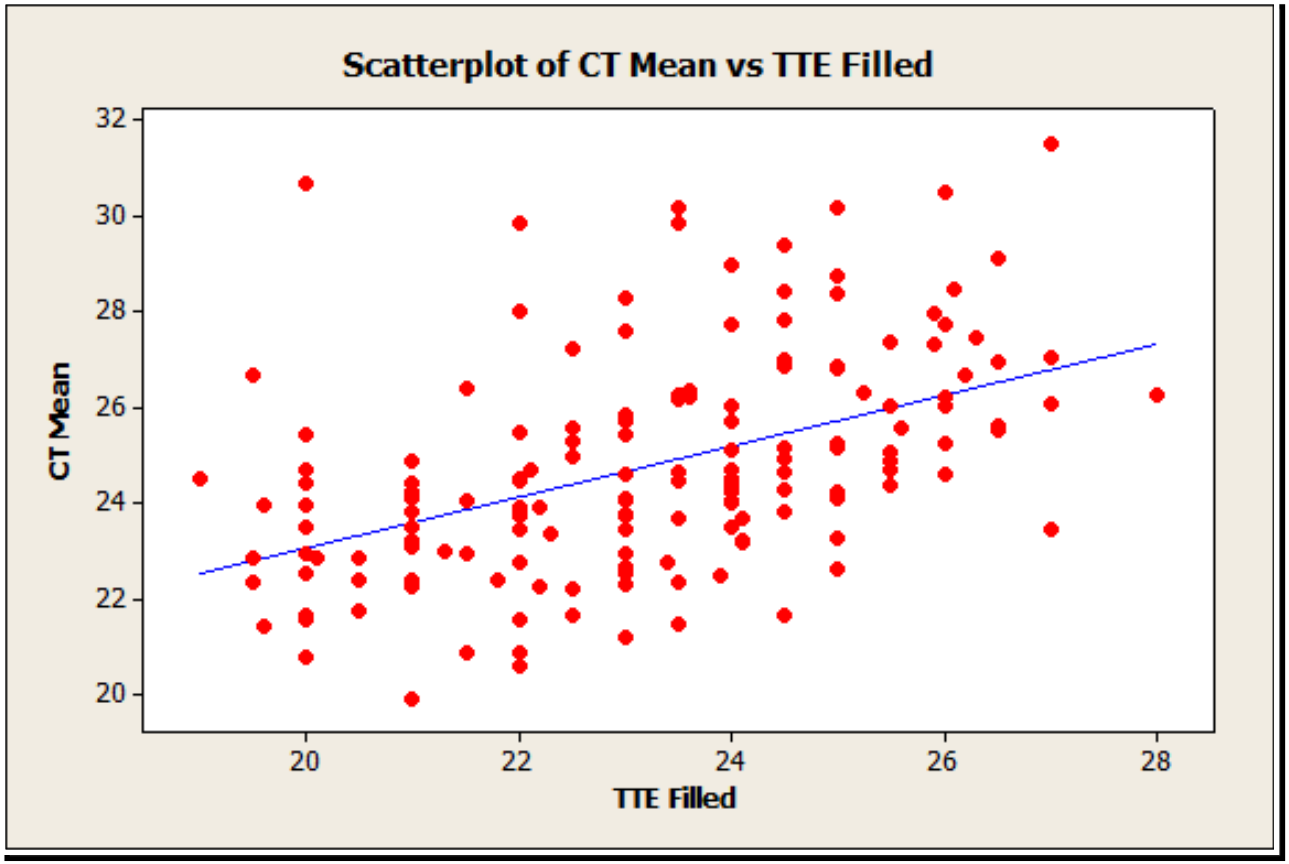
Low Correlation Between Echo and CT

MEAN DIAMETER



162 patients → Low correlation between echo diameter and all CT derived measurements (major, minor, & mean diameters, perimeter, and area)

Courtesy of Dr. Piazza and Prof. Lange, German Heart Center, Munich Germany

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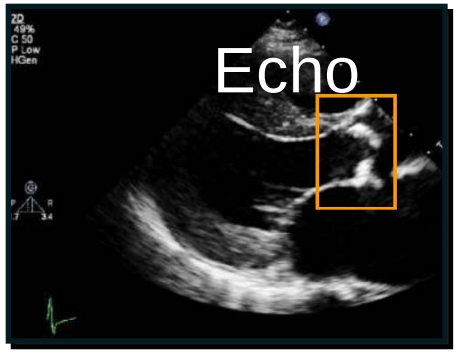
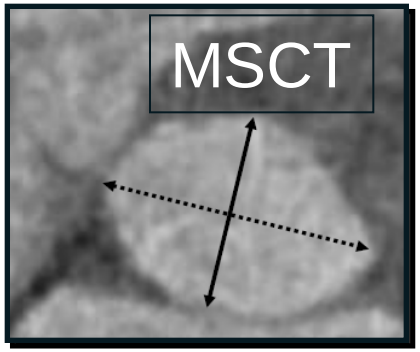
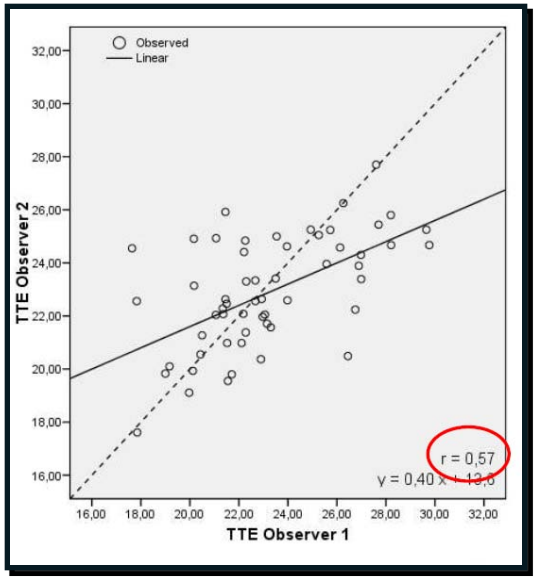
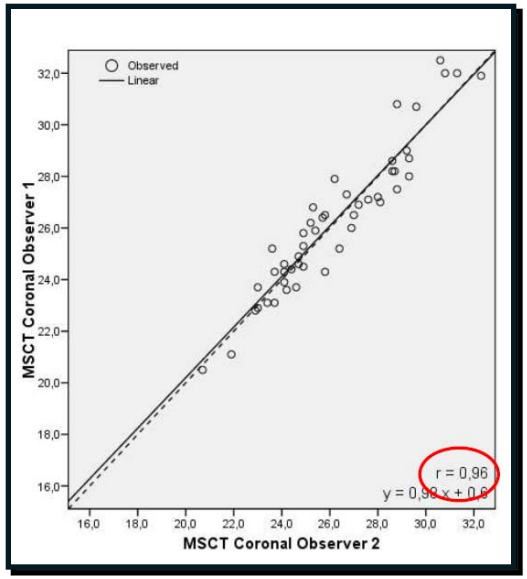
MSCT is Highly Reproducible Compared to Echo









1. Tzikas A, et al. *Catheter Cardiovasc Intervent*. 2011;77(6):868-75. Reprinted with the permission of John Wiley and Sons.

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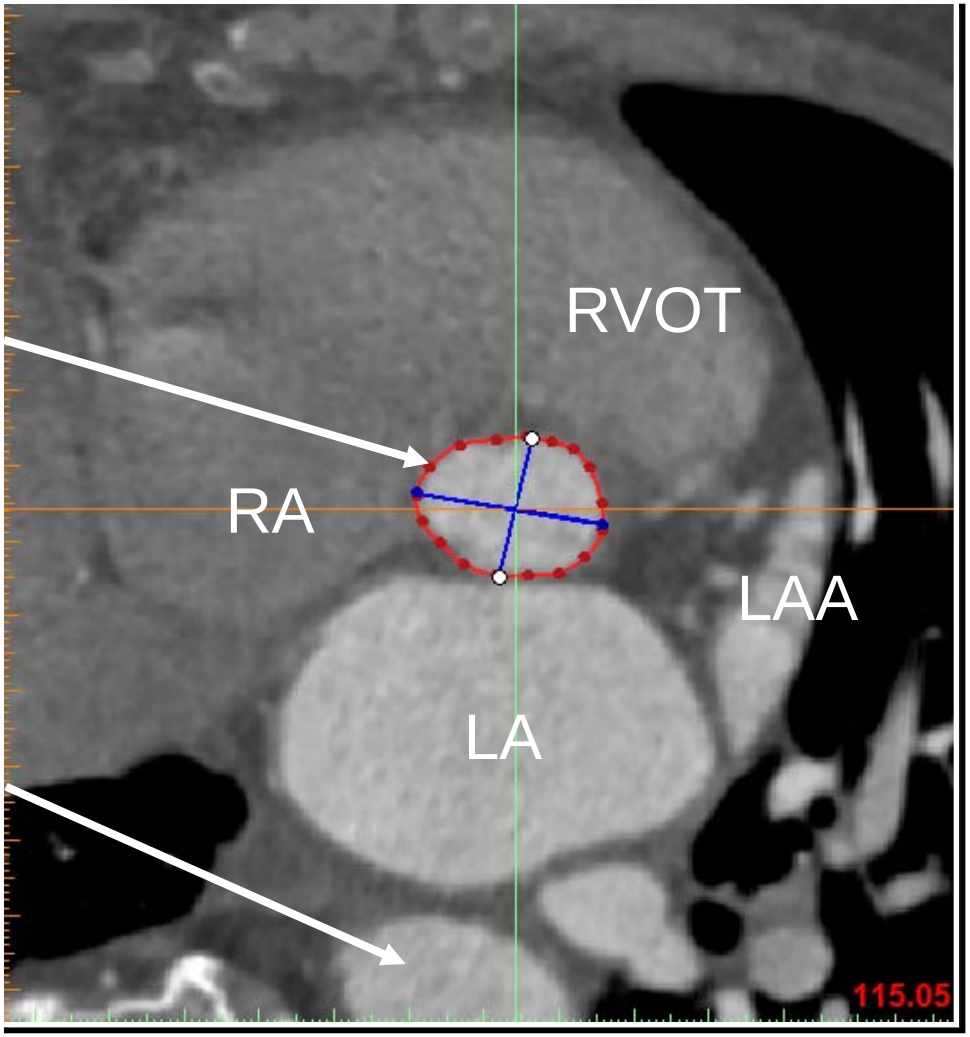
MSCT Basics for TAVI

- The aortic annulus is not co-planar with the traditional planes of the body (axial, sagittal, coronal)
- Because MSCT is a 3D (and 4D) imaging modality, it allows for reformatting of the 3D images
- This technique is called multi-planar reformatting (MPR)
- To properly assess the aortic annulus using MSCT, MPR is used to reformat the images such that the original axial image is now co-planar with the annular plane
  - It is commonly referred to as the double oblique axial image
  - The coronal and sagittal images are also reformatted into oblique coronal and oblique sagittal

The Aortic Annulus on MSCT

Aortic Annulus

Descending Aorta



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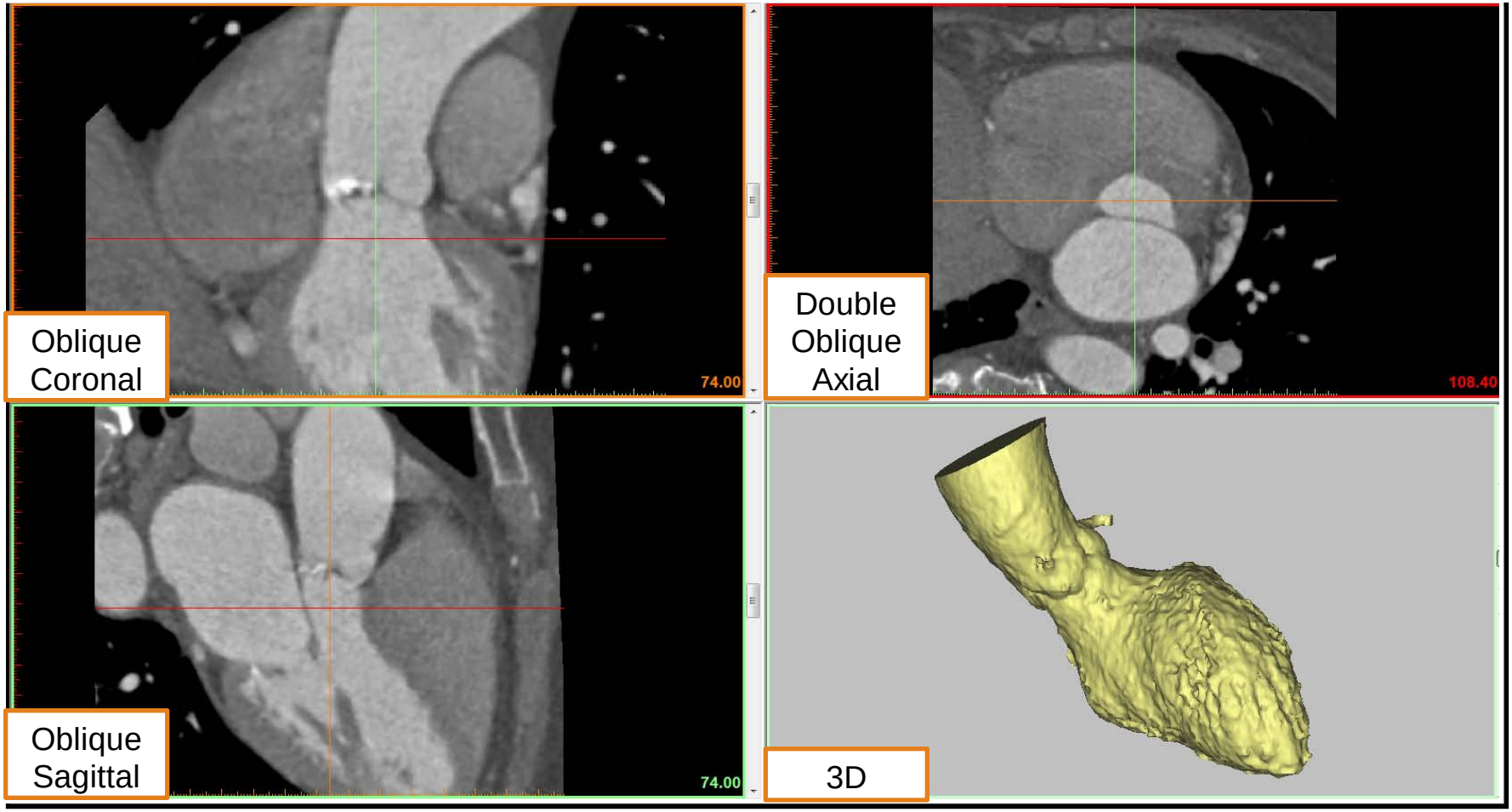
Example of Incorrect Plane – Too Low



Example images of reformatted oblique coronal (upper left), oblique sagittal (lower left), double oblique (upper right) and 3D reconstruction lower right. The double oblique axial image is located approximately 10 mm into the LVOT.

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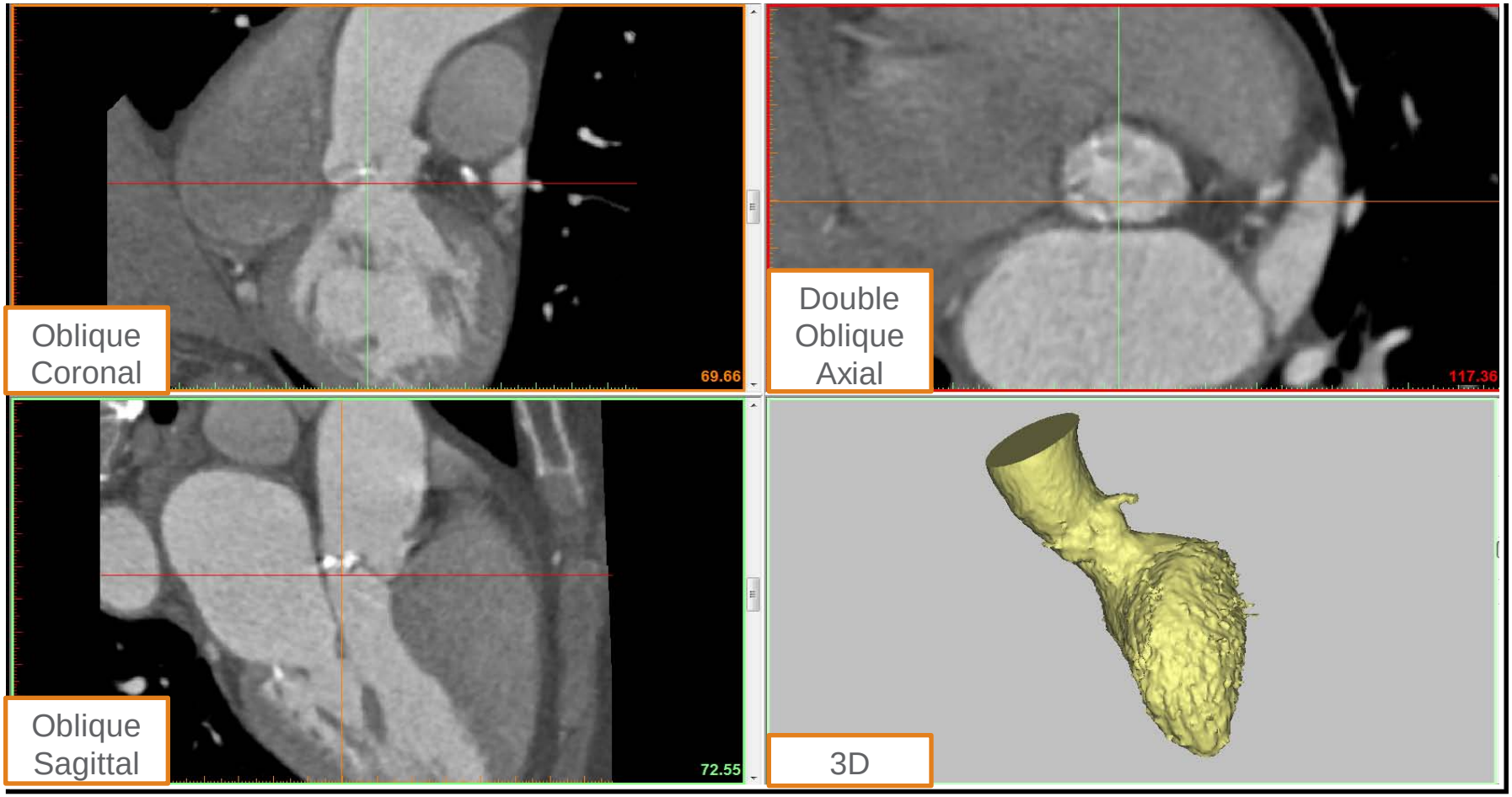
Example of Incorrect Plane – Too High



Example images of reformatted oblique coronal (upper left), oblique sagittal (lower left), double oblique (upper right) and 3D reconstruction lower right. The double oblique axial image is located a few mm into the aortic root and the leaflets are visible.

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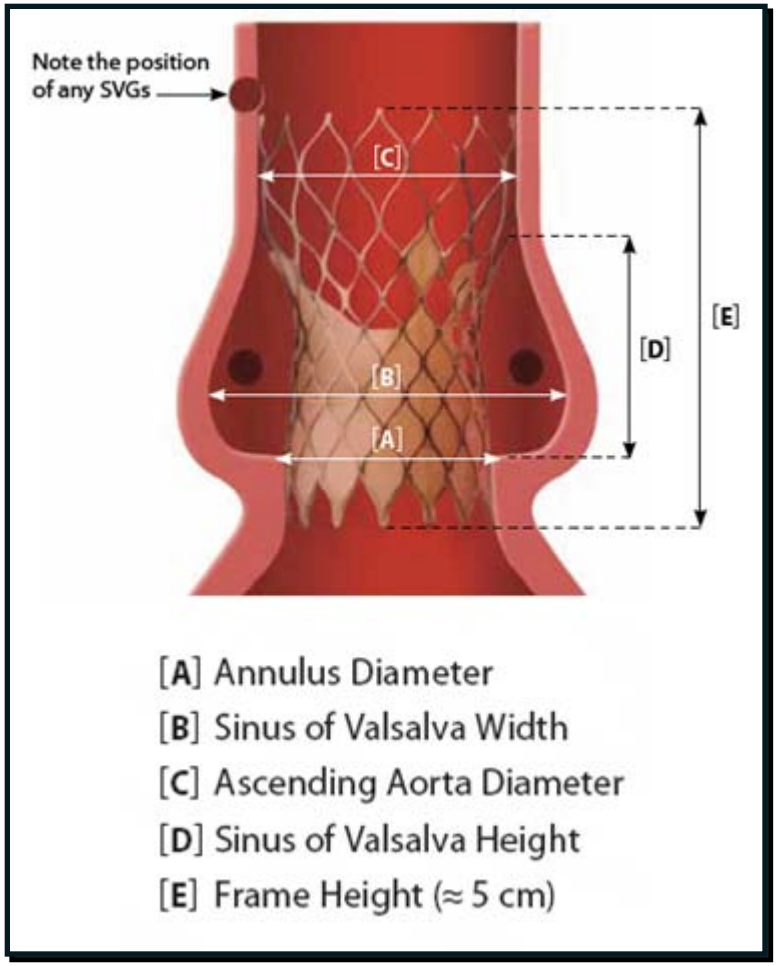
Device Sizing Can Impact Procedural Outcomes

- Significant variation exists in TAVI device selection
  - Imaging modality differences
  - Definition of aortic annulus
  - Industry differences
  - Physician preference and experience
- The aortic annulus is a non-circular structure and proper imaging is important[1-6]
- Several publications have demonstrated a correlation between sizing and clinical outcomes[7-14]

See slide 34 for references.

Anatomic Features Important for TAVI Sizing

- Primary features:
  - The aortic annulus
  - The sinuses of Valsalva
  - The ascending aorta
- Secondary features:
  - Coronary artery ostiums
  - Left ventricular outflow tract (LVOT)



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Aortic Root Measurements

- Aortic annulus measurements
  - Annulus perimeter.
  - Annulus area.
  - Major aortic annulus diameter.
  - Orthogonal minor aortic annulus diameter.
- Additional aortic root measurements
  - Sinus of Valsalva diameters.
  - Sinus of Valsalva heights.
  - Maximum ascending aorta diameter at 40mm above annulus.

→ Measured on ECG-gated images of the chest

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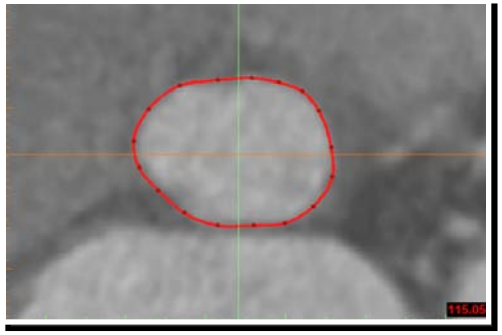
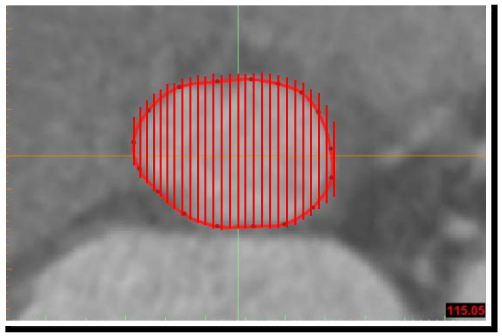
Step 1: Aortic Annulus Measurements

Perimeter: linear distance of tracing around the aortic annulus

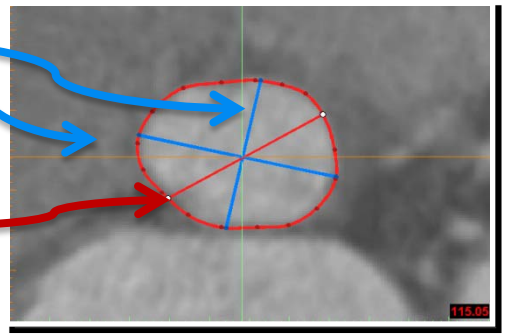


Area: area contained within tracing around the aortic annulus



Major & Orthogonal Minor Diameters: linear distances through the center of the aortic annulus

Mean Diameter: Calculated mean of major and minor diameters



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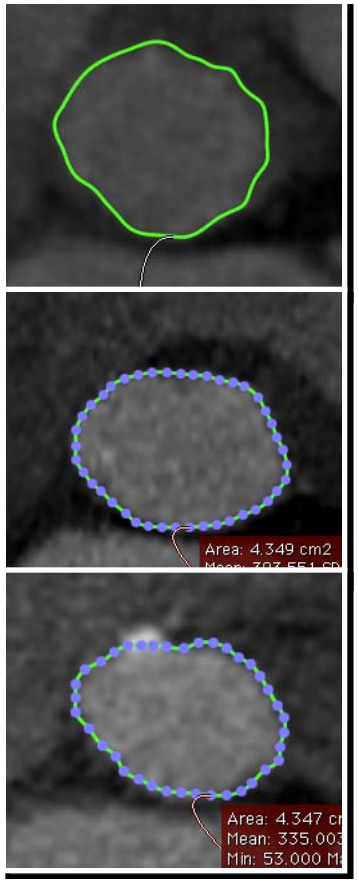
The Aortic Annulus – A Critical & Measurable Parameter for Device Selection

- The annulus is easily definable and measurable.
- It represents the constriction between LVOT and aortic root – a major anchoring point for the inflow of the CoreValve frame
- It has a multitude of shapes:
  - Non-circular and non-elliptical (most common)
  - Elliptical
  - Circular (rare)



Any single diameter may not necessarily approximate the annulus "size" appropriately due to ellipticity or irregularity in shape.

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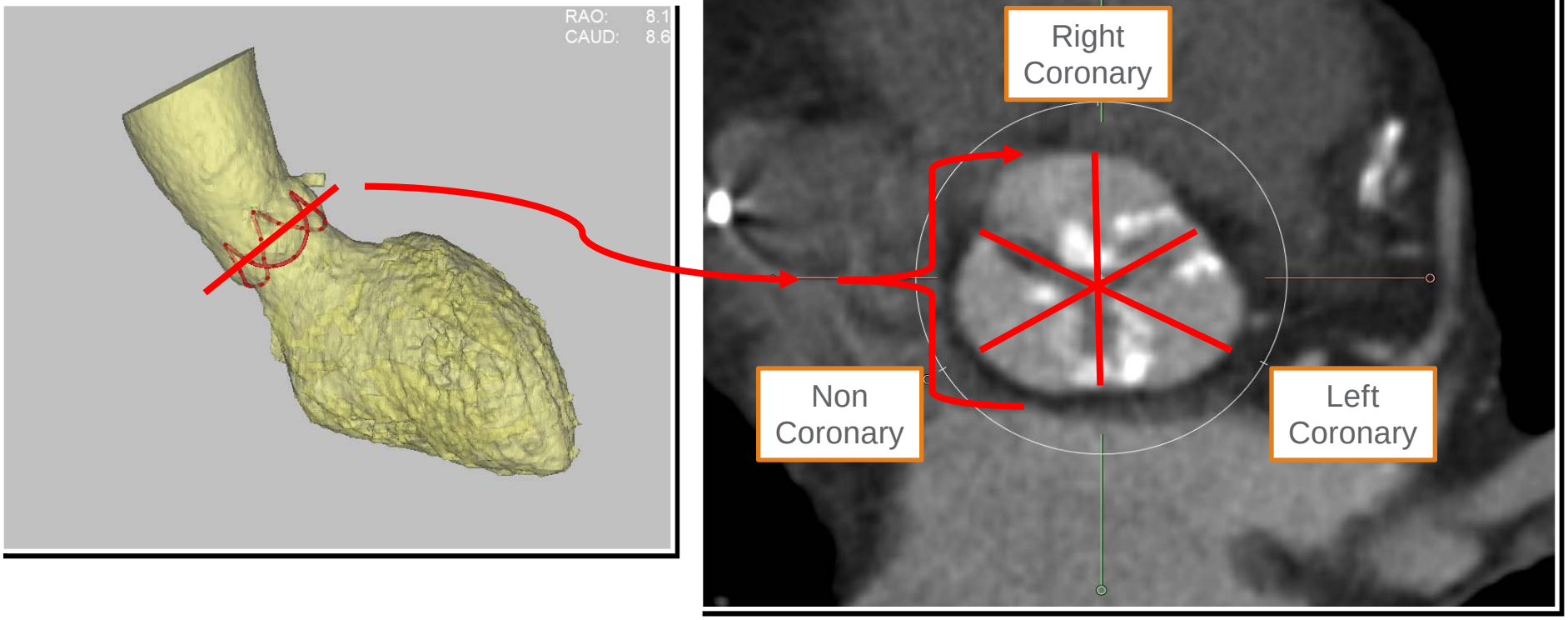
Step 2: Sinus of Valsalva Diameters



Scroll to the widest portion of the sinus in the reformatted double oblique axial images. Measure from commissure through center to opposite sinus. Complete for all three sinuses.

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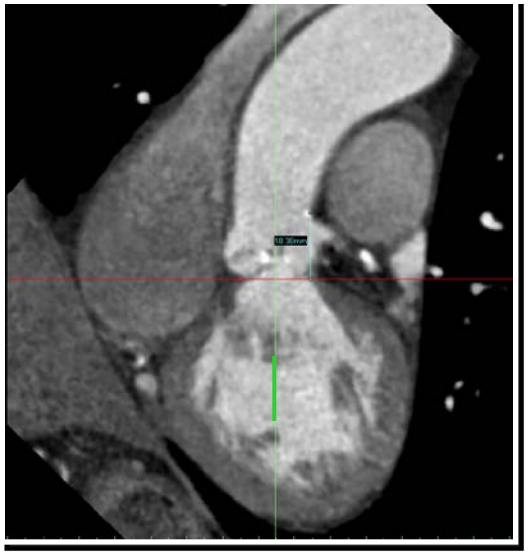
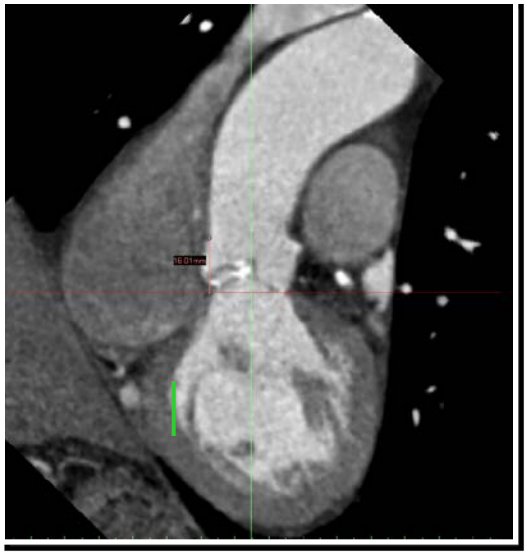
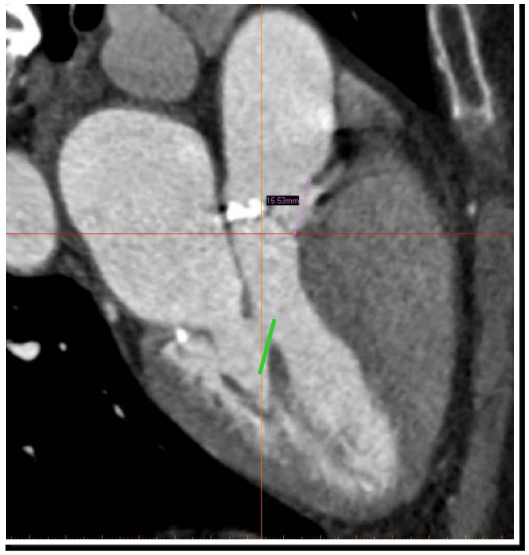
Step 3: Sinus of Valsalva Heights



Left coronary sinus height



Non coronary sinus height



Right coronary sinus height

Measurements should be completed on the oblique coronal and sagittal images and taken from the aortic annulus (shown as the red line) to the highest point of the sinus, along the direction of the sinus.

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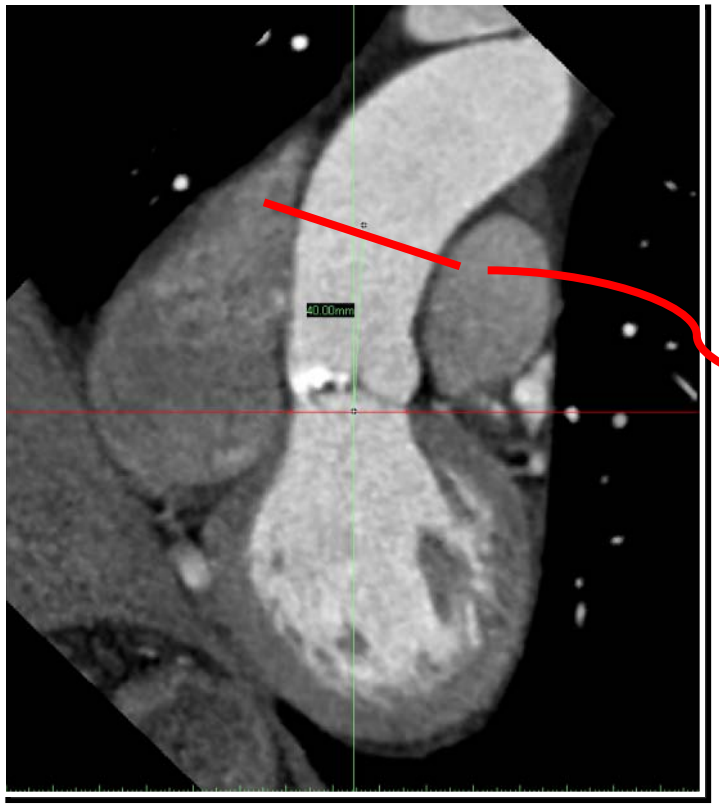
Step 4: Maximum Ascending Aorta Diameter



On oblique coronal measure 30 or 40mm from aortic annulus along root.

Measure maximum and orthogonal ascending aorta diameters on orthogonal image at 30 or 40mm above annulus.

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Step 5: Device Size Selection
Sinus of Valsalva and Ascending Aorta Ranges

	Sinus of Valsalva Diameter (mm)	Sinus of Valsalva Height (mm)	Ascending Aorta Maximum Diameter (mm)
23	≥ 25	≥ 15	≤ 34
26	≥ 27	≥ 15	≤ 40
29	≥ 29	≥ 15	≤ 43
31	≥ 29	≥ 15	≤ 43

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Step 5: Device Size Selection
Aortic Annulus Ranges

	Diameter Range (mm)	Perimeter Range (mm)	Area Range (mm^2)
23	18 - 20	56.5 - 62.8	254.5 - 314.2
26	20 - 23	62.8 - 72.3	314.2 - 415.5
29	23 - 27	72.3 - 84.8	415.5 - 572.6
31	26 - 29	81.7 - 91.1	530.9 – 660.5

Recent evidence supports perimeter as the recommended method for TAVI sizing

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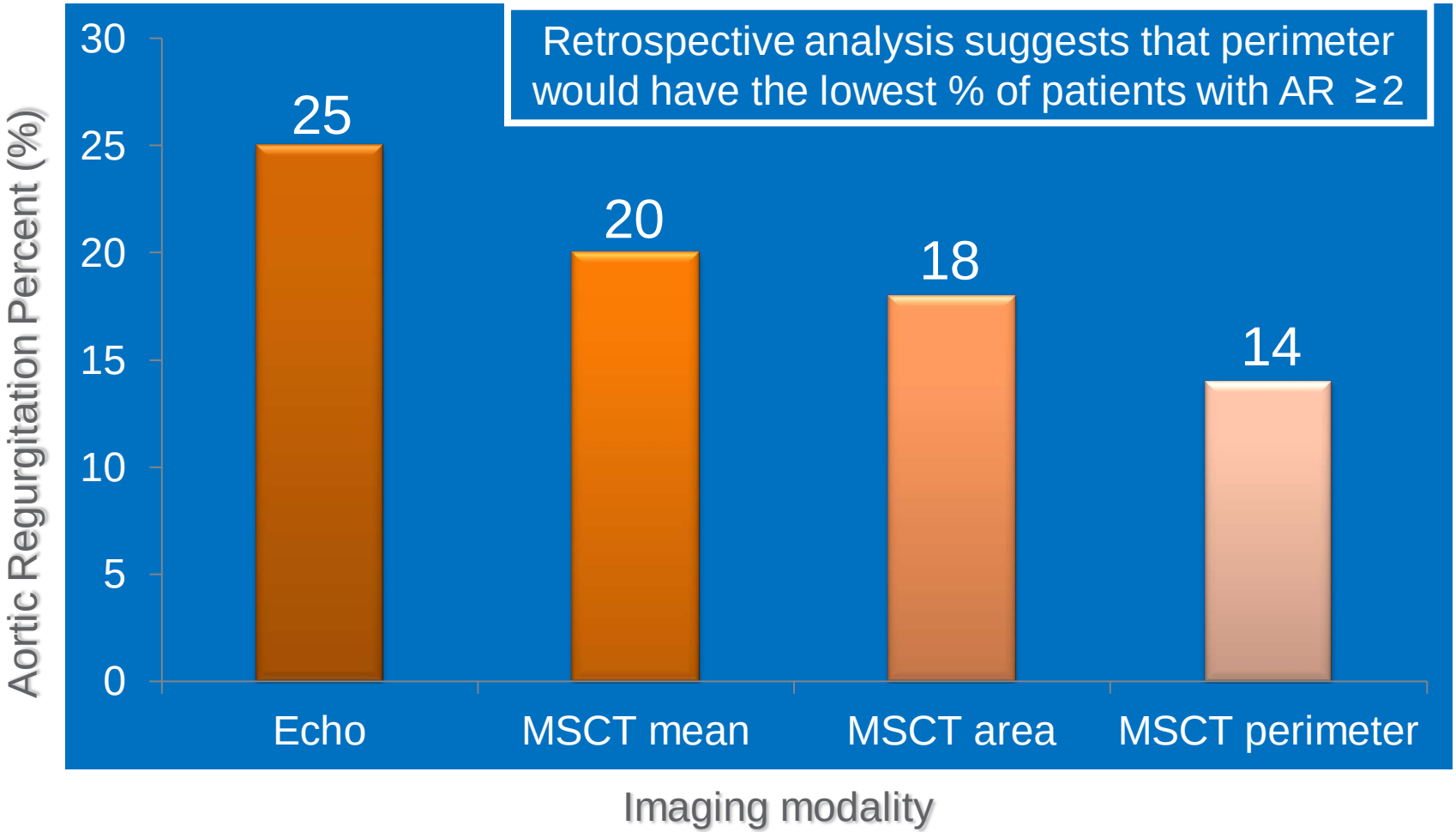
Comparison of MSCT Annulus Measurements



Retrospective analysis. Courtesy of Dr. Piazza and Prof. Lange, German Heart Center, Munich Germany

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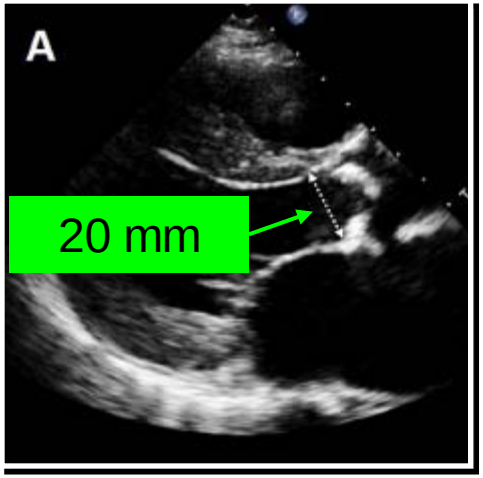
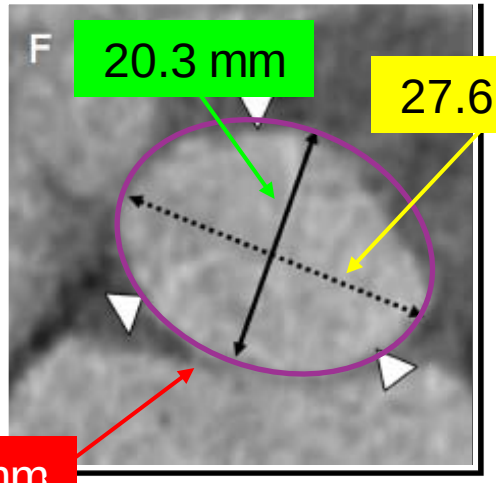
Hypothetical Sizing Example #1





Modality	Device Size
Echo	26 mm
CT Minor Diameter	26 mm
CT Major Diameter	31 mm
CT Perimeter	***29 mm***
CT Area	***29 mm***
CT Mean	***29 mm***

1. Tzikas A, et al. *Catheter Cardiovasc Intervent*. 2011;77(6):868-75. Reprinted with the permission of John Wiley and Sons.

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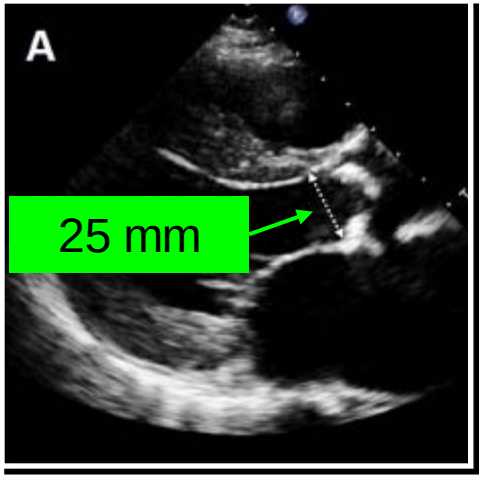
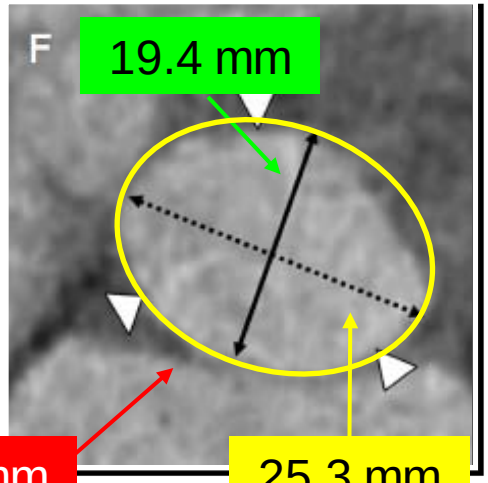
Hypothetical Sizing Example #2





Modality	Device Size
Echo	29 mm
CT Minor Diameter	23 mm
CT Major Diameter	29 mm
CT Perimeter	***26 mm***
CT Area	***26 mm***
CT Mean	***26 mm***

1. Tzikas A, et al. *Catheter Cardiovasc Intervent*. 2011;77(6):868-75. Reprinted with the permission of John Wiley and Sons.

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Clinical Implications: Paravalvular Leak

Transcatheter aortic valve implantation: role of multi-detector row computed tomography to evaluate prosthesis positioning and deployment in relation to valve function

Victoria Delgado[1], Arnold C.T. Ng[1], Nico R. van de Veire[1], Frank van der Kley[1], Joanne D. Schuijf[1], Laurens F. Tops[1], Arend de Weger[1], Giuseppe Tavilla[1], Albert de Roos[2], Lucia J. Kroft[2], Martin J. Schalij[1], and Jeroen J. Bax[1]*

CLINICAL RESEARCH

Correlation of Device Landing Zone Calcification and Acute Procedural Success in Patients Undergoing Transcatheter Aortic Valve Implantations With the Self-Expanding CoreValve Prosthesis

Daniel John, MD, Lutz Buellesfeld, MD, Seyrani Yuecel, MD, Ralf Mueller, MD, Georg Latsios, MD, Harald Beucher, MD, Ulrich Gerckens, MD, Eberhard Grube, MD

Association of aortic valve calcification severity with the degree of aortic regurgitation after transcatheter aortic valve implantation

Kathrin Brehmer [a], Rolf W. Günther [b],

Determinants of Significant Paravalvular Regu… Transcatheter Aor…

Impact of Device and Annulu…

Delphine Détaint, MD, Laurent …

Multimodality Imaging in Trans… Implantation and Post-Procedu…

Comparison Among Cardiovascular Mag… Cardiac Computed Tomography, and …

Andrew Jabbour, MBBS, PhD,*† Tevfik F. Ismail… Ankur Gulati, MBBCh,*† Isabelle Roussin, MBB… Bradley Park, MSc,* Francois Okoroafor,* Anita … Sanjay K. Prasad, MD,*† Michael Rubens, MBBS…

London, United Kingdom

EXPEDITED PUBLICATION

Cross-Sectional Computed Tomographic Assessment Improves Accuracy of Aortic Annular Sizing for Transcatheter Aortic Valve Replacement and Reduces the Incidence of Paravalvular Aortic Regurgitation

Hasan Jilaihawi, BSc (Hons), MBChB,* Mohammad Kashif, MD,* Gregory Fontana, MD,† Azusa Furugen, MD, PhD,* Takahiro Shiota, MD,* Gerald Friede, BS, MS,* Rakhee Makhija, MD,* Niraj Doctor, MBBS,* Martin B. Leon, MD,‡ Raj R. Makkar, MD*

Los Angeles, California; and New York, New York

…rasse 30, 52074 Aachen, Germany …Pauwelsstrasse 30, 52074 Aachen, Germany …elsstrasse 30, 52074 Aachen, Germany

…r Aortic Regurgitation …nplantation Using the …Prosthesis

… Adriaan Moelker,[2] MD, PhD, …el M. Geleijnse,[1] MD, PhD, …, PhD, Pim de Feyter,[1,2] MD, PhD, … de Jaegere,[1] MD, PhD

…t by …edicts Moderate or Severe Paravalvular Regurgitation After Transcatheter Aortic Valve Replacement

A Multicenter Retrospective Analysis

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Sizing and calcification are being investigated as major determinants of TAVI outcomes, for both Medtronic CoreValve® & Edwards Sapien®

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MSCT – Complete Pre-Implant TAVI Planning Tool

- 3D
- Multiple measurements possible (area, perimeter, diameters)
- Assessment of calcification
- Assessment of entire device landing zone
- Assessment of peripheral access routes
- High reproducibility and spatial resolution

MSCT is Recommended

- The aortic annulus is non-circular and exhibits variability in shape across the patient population
- MSCT sizing has been linked to a reduction in paravalvular leakage
- Calcification location and burden have been linked to paravalvular leakage – MSCT is the only method available to properly assess calcification
- MSCT allows for complete patient assessment in one exam

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