

# PATIENT SELECTION DEVICE SELECTION VALVE SIZE SELECTION

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TAVI Summit 7<sup>th</sup> September 2012

# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial Interest /arrangement or affiliation with the organization(s) listed below

## Affiliation/Financial Relationship

## Company

**Grant/ Research Support:**

**Consulting Fees/Honoraria:**

**Edwards Lifesciences  
(consultant & proctor)**

**Major Stock Shareholder/Equity Interest:**

**Royalty Income:**

**Ownership/Founder:**

**Salary:**

**Intellectual Property Rights:**

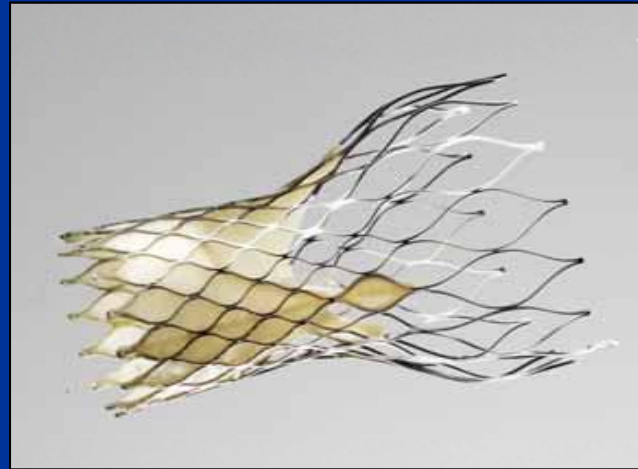
**Other Financial Benefit:**

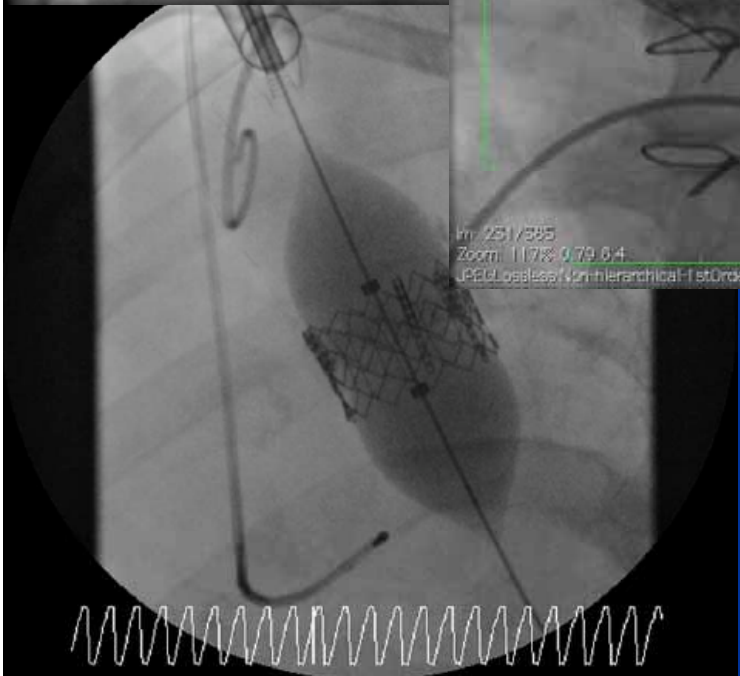
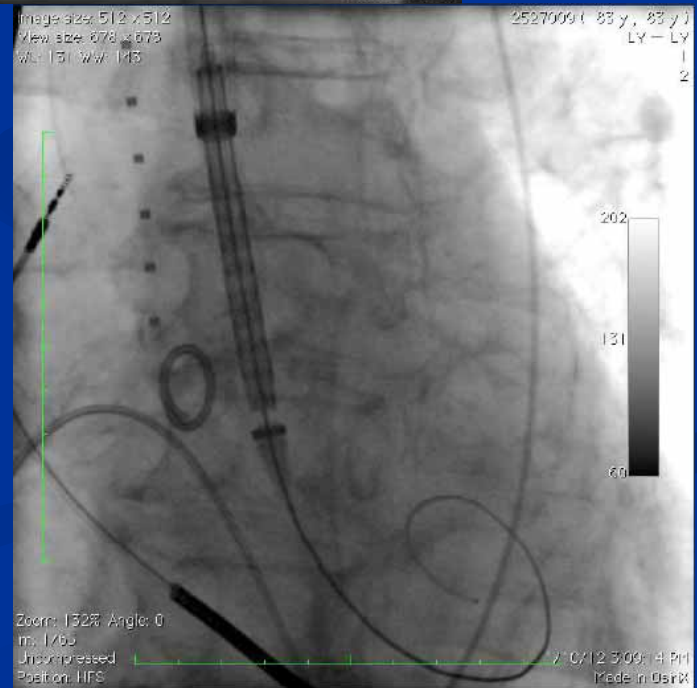
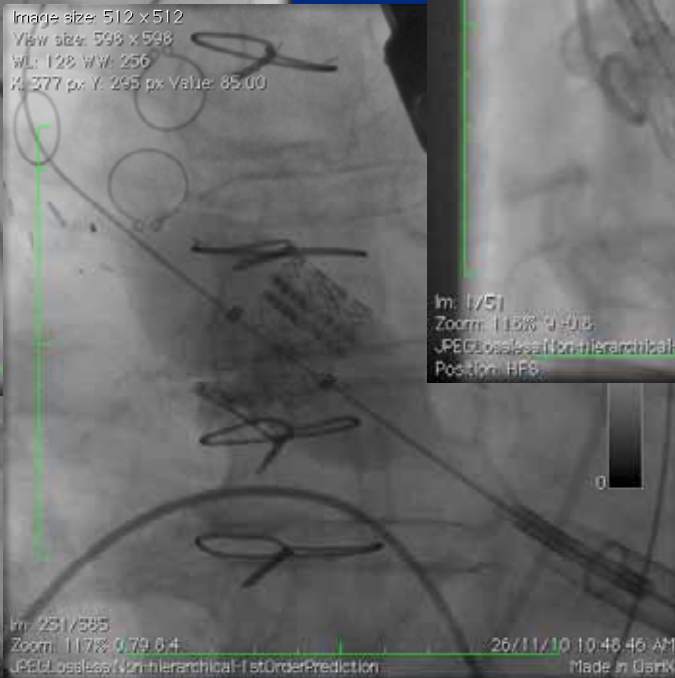
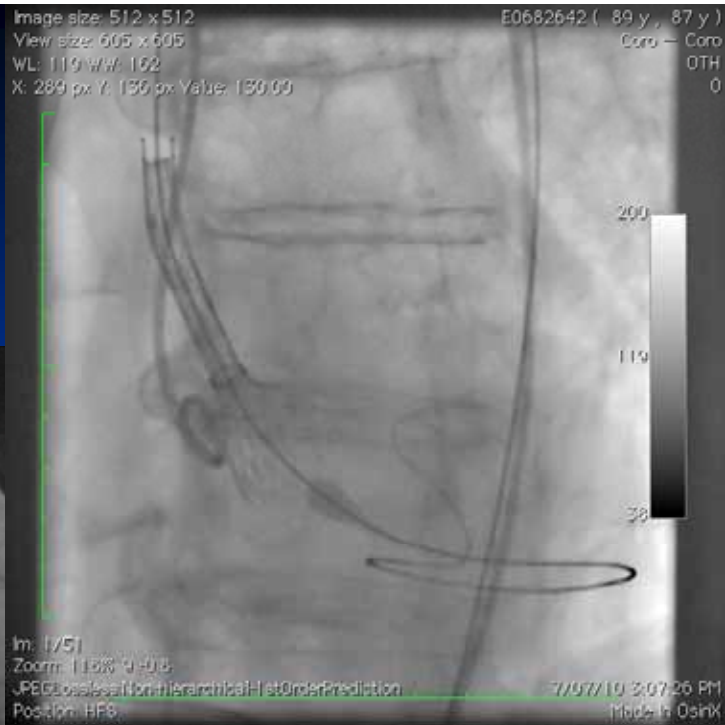
# Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

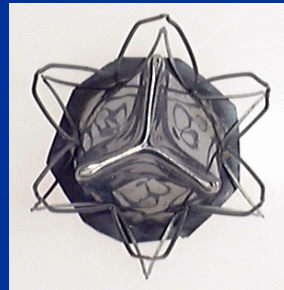
## First Human Case Description

Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD









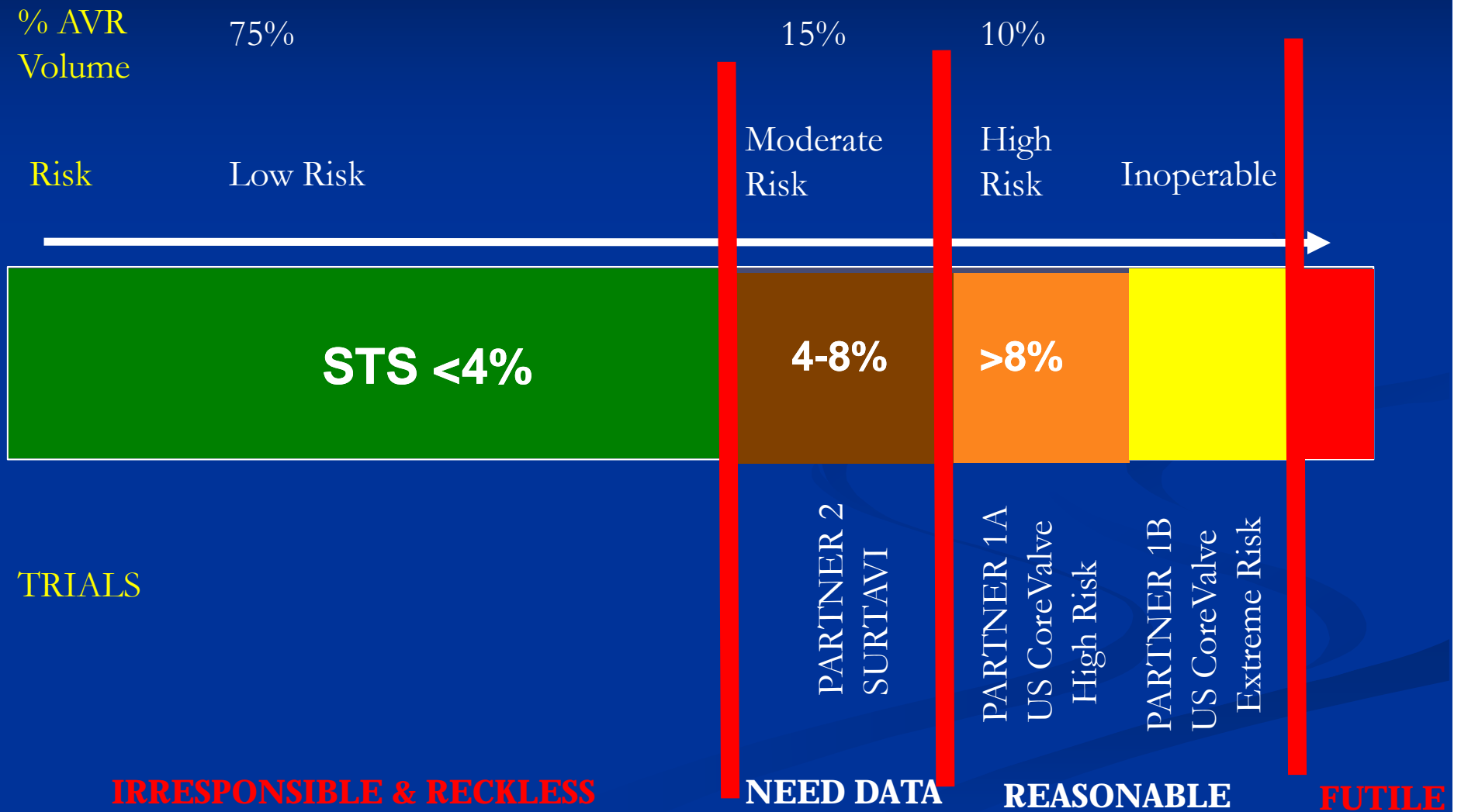
# PATIENT SELECTION

# PATIENT SELECTION

- Indication
  - Symptomatic severe aortic stenosis
  - High risk for surgical AVR
- Suitable anatomy
- Other high risk clinical features to be aware
  - Severe MR
  - Severe LVF
  - Irrevascularised CAD
  - Pulmonary hypertension



# Current TAVR Eligibility According to Operative Risk



## Other high risk features not included in Surgical Risk Scores

- Porcelain aorta
- Chest deformity
- Chest irradiation
- Degenerative neurocognitive function
- Cirrhosis
  
- FRAILTY INDICES



# Frailty

Syndrome of multisystem impairment associated with aging that results in decreased physiologic reserve and increased vulnerability to stressors.

# Frailty

- 5m walk
- “Get up and Go” test
- Wt loss
- Grip strength
- Dependency on ADL score – Katz
- Serum albumin
- Serum hematocrit

# The IDEAL TAVR Patient....



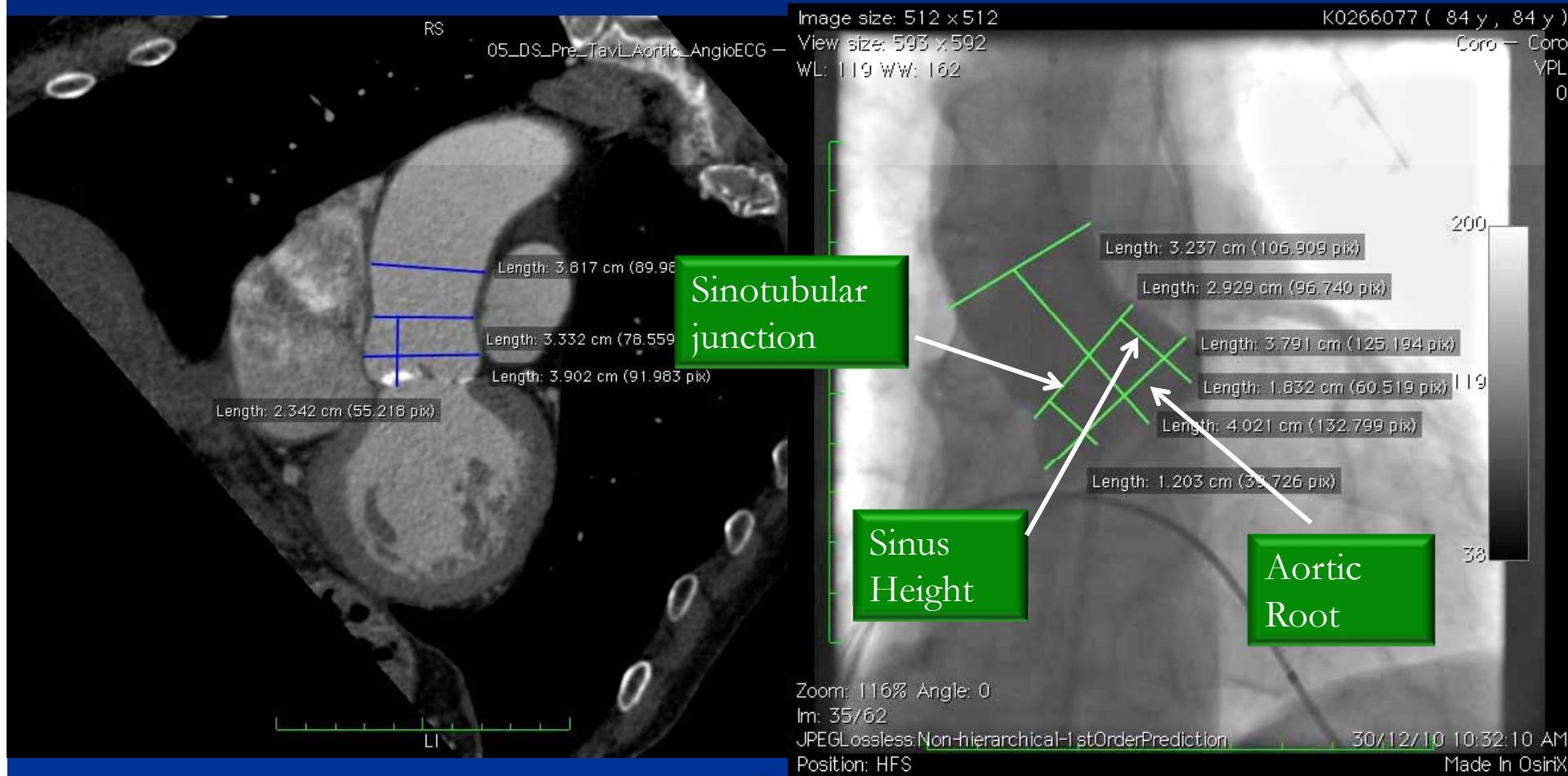
# **ANATOMY ASSESSMENT**

# Aortic Root Measurement

- Angiography with marker pigtail
- CT
  
- Caution if
  - Small aortic root (<30mm)
  - Short sinus height or distance to coronaries (<11mm)
  - Small STJ

# Aortogram

## With Marker Pigtail for calibration



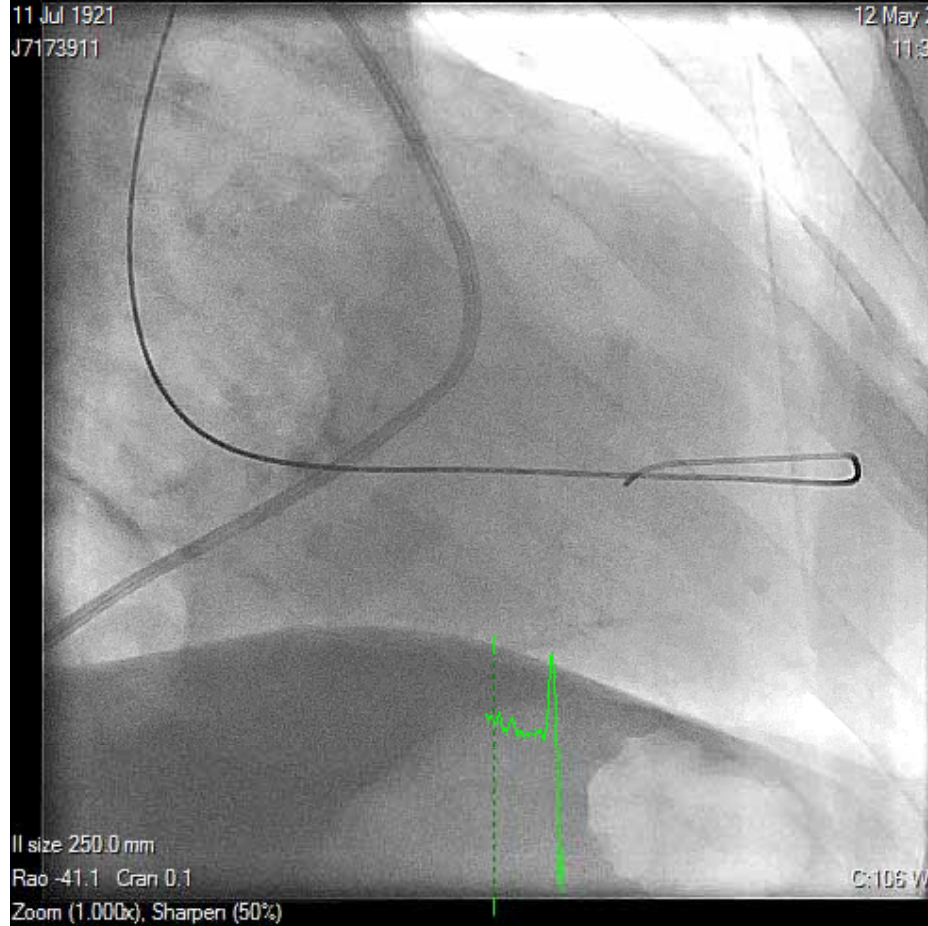


# Other Aortogram Issues...

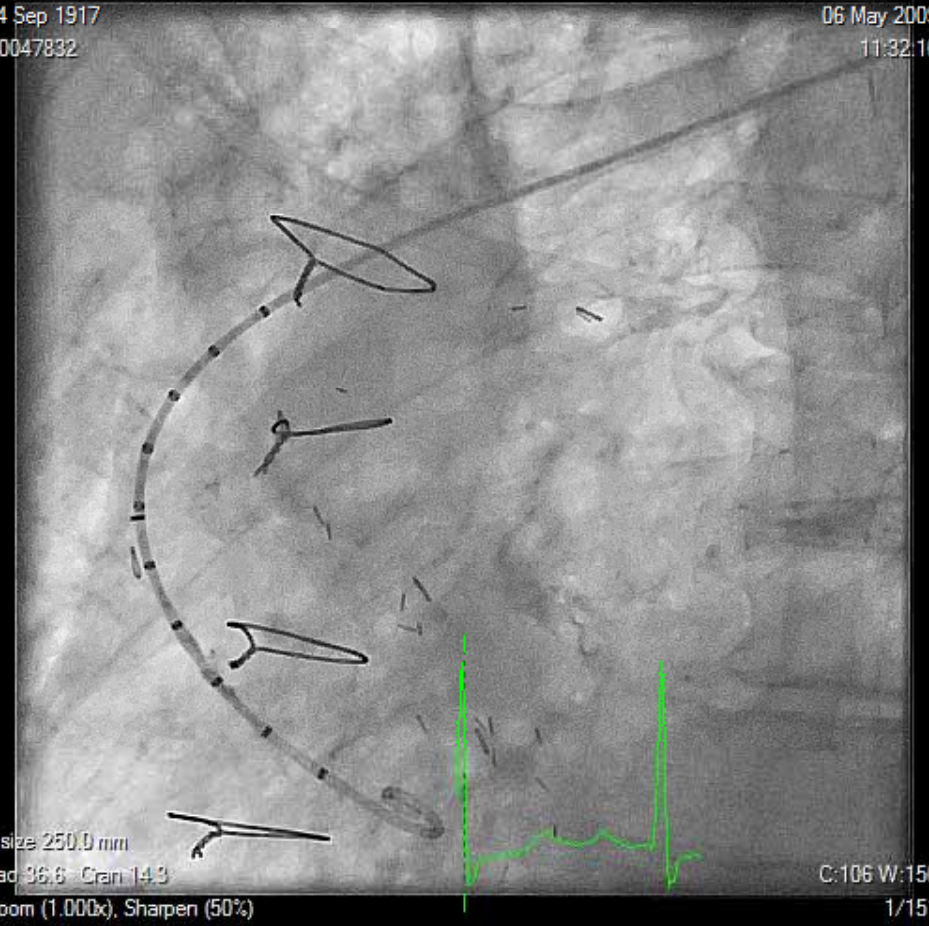
Melvin Kleinig  
11 Jul 1921  
J7173911

Royal Perth Hospital Ben Chandler  
12 May 2009 14 Sep 1917  
11:34:35 E0047832

Royal Perth Hospital  
06 May 2009  
11:32:10

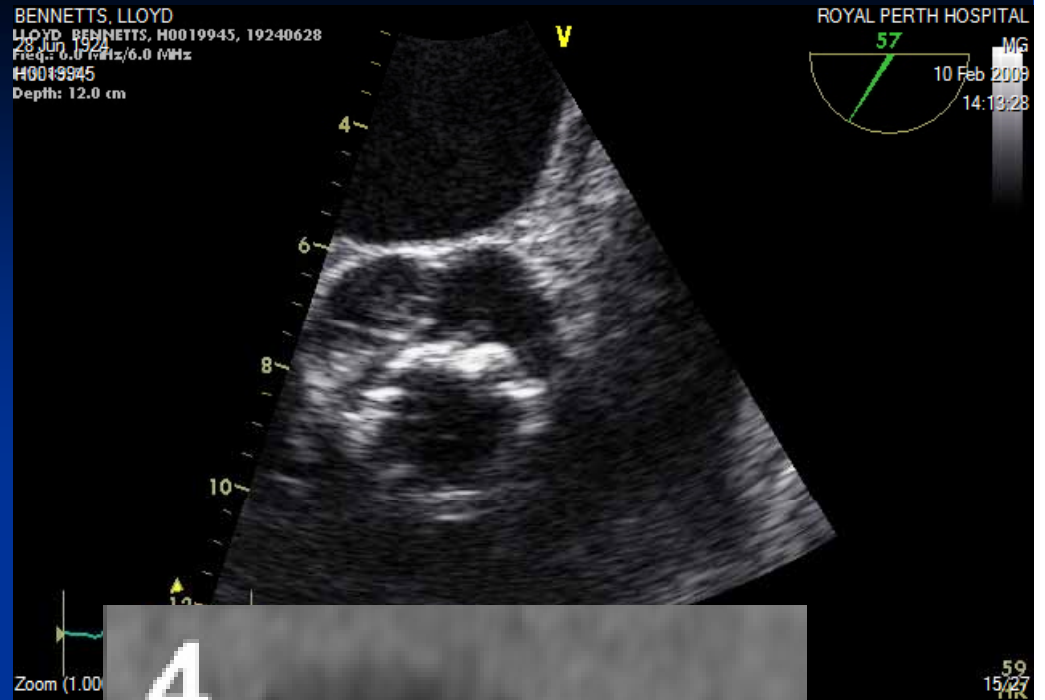
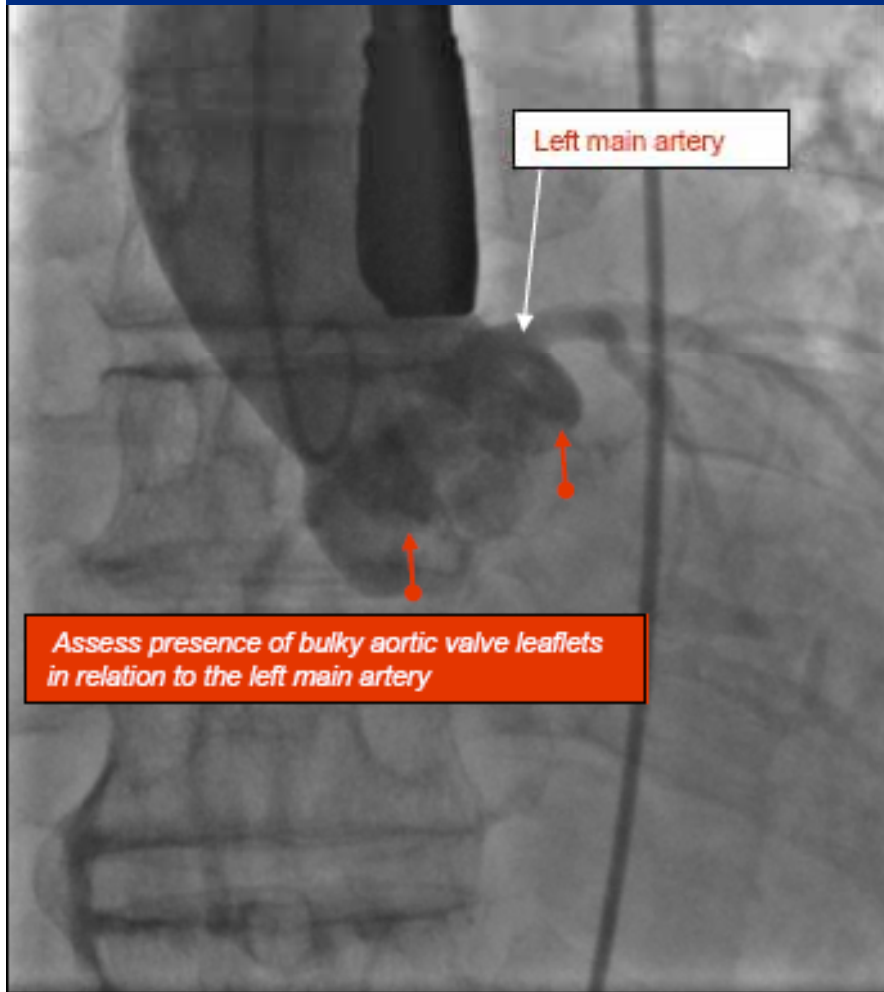


**Vertical valve plane**



**Unfolded aorta**

# Bulky Calcium in Aortic Valve



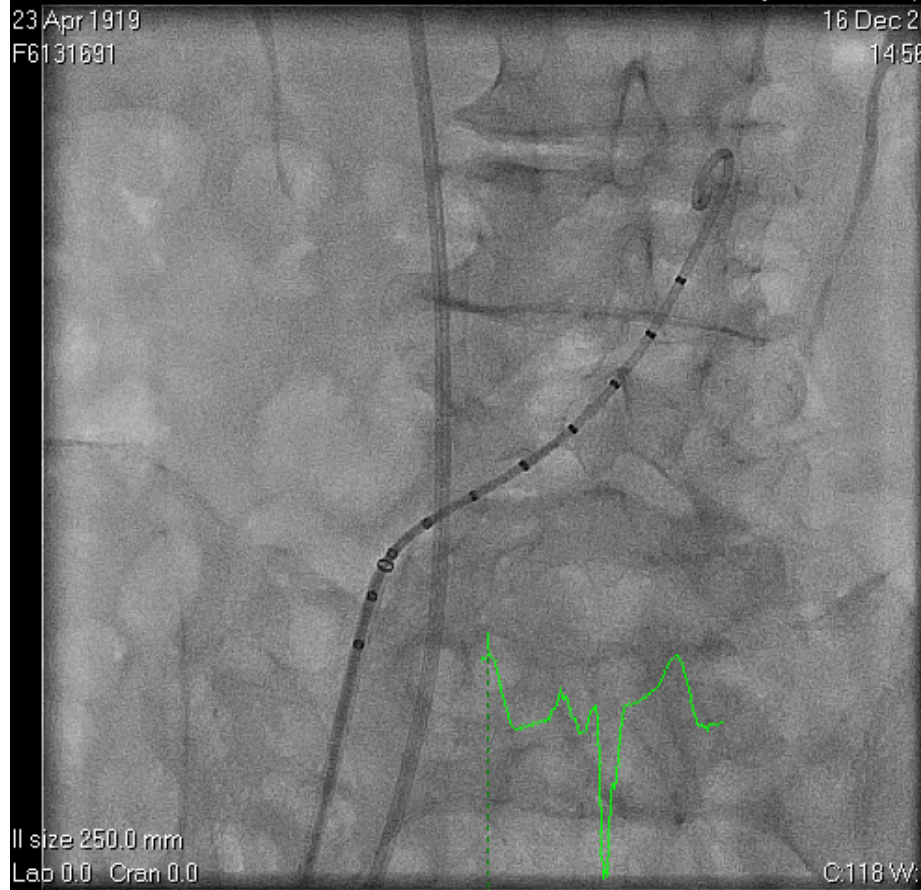
# Peripheral Vessel Assessment

Laurence Rollond  
23 Apr 1919  
F6131691

Royal Perth Hospital  
16 Dec 2009  
14:56:47

Image size: 512 x 512  
View size: 605 x 605  
WL: 127 WW: 255

BDC641Z ( 89 y , 89 y )  
05\_DS\_Pre\_TavLAortic\_AngioECG - VR Rotation Abdo Aorta  
CT  
346



Il size 250.0 mm  
Lab 0.0 Cran 0.0  
Zoom (1.000x), Sharpen (50%)

C:118 W:162  
1/146

Im: 1/22  
Zoom: 118% --  
Uncompressed  
Position: FFS



24/08/12 11:47:41 AM  
Made with...

# DEVICE SELECTION



**EDWARDS**

**COREVALVE**

## TAVR – Contemporary Results from Clinical Trials and Registries

	<b>PARTNER B</b>	<b>PARTNER A</b>	<b>SOURCE</b>	<b>Canadian</b>	<b>SOURCE XT</b>	<b>FRANCE 2</b>	<b>ADVANCE</b>	<b>CoreValve Meta-analysis</b>
<b>N &amp; Valve type</b>	Edwards 179 TF	Edwards 244 TF 104 TA	Edwards 920 TF 1387 TA	Edwards 162 TF 177 TA	Edwards XT valve 2600	Edwards - 2017 CoreValve - 1043	CoreValve 1015	CoreValve 2156
<b>Age</b>	83.1	83.6	80.1	81.8	81.2	82.7	81	81.6
<b>Logistic EuroScore</b>	26.4%	29.3%	26.1%	N/A	20.3%	21.9%	19.2	21.3%
<b>30 day Mortality</b>	5.0%	3.4%	9.5%	10.4%	6.2%	9.7%	4.5	6.6%
<b>30 day Stroke</b>	6.7%	5.5%	2.9%	2.3%	2.2%	4.1%	2.9	2.8%
<b>1 year Mortality</b>	30.7%	24.2%	23.5%	24%	N/A	24.0%	N/A	17.1%

Kodali, et al., *NEJM*; 2012;366:1686-95 ; Makkar, et al., *NEJM*, 2012;366:1696-704 ; Thomas, et al., *Circulation*, 2011;124:425-33 ; Rodes-Cabau, et al., *JACC*, 2010;55:1080-90 ; Gilard, et al., *NEJM*, 2012;366:1705-15 ; Wendler *EuroPCR* 2012 ; Ruiz *EuroPCR* 2011

## TAVR – Contemporary Results from Clinical Trials and Registries

	<b>PARTNER B</b>	<b>PARTNER A</b>	<b>SOURCE</b>	<b>Canadian</b>	<b>SOURCE XT</b>	<b>FRANCE 2</b>	<b>ADVANCE</b>	<b>CoreValve Meta-analysis</b>
<b>N &amp; Valve type</b>	Edwards 179 TF	Edwards 244 TF 104 TA	Edwards 920 TF 1387 TA	Edwards 162 TF 177 TA	Edwards XT valve 2600	Edwards - 1145 CoreValve - 540	CoreValve 1015	CoreValve 2156
<b>Major Vascular Cx</b>	16.8%	11.0%	5.7%	13.0%	5.2%	12.5%	10.7%	4.2%
<b>Bleeding</b>	16.2%	9.3%	3.3%	N/A		18.4%	9.7%	N/A
<b>PPM</b>	3.4%	3.8%	6.9%	4.9%	9.1%	12.4%	26.3%	28.7%

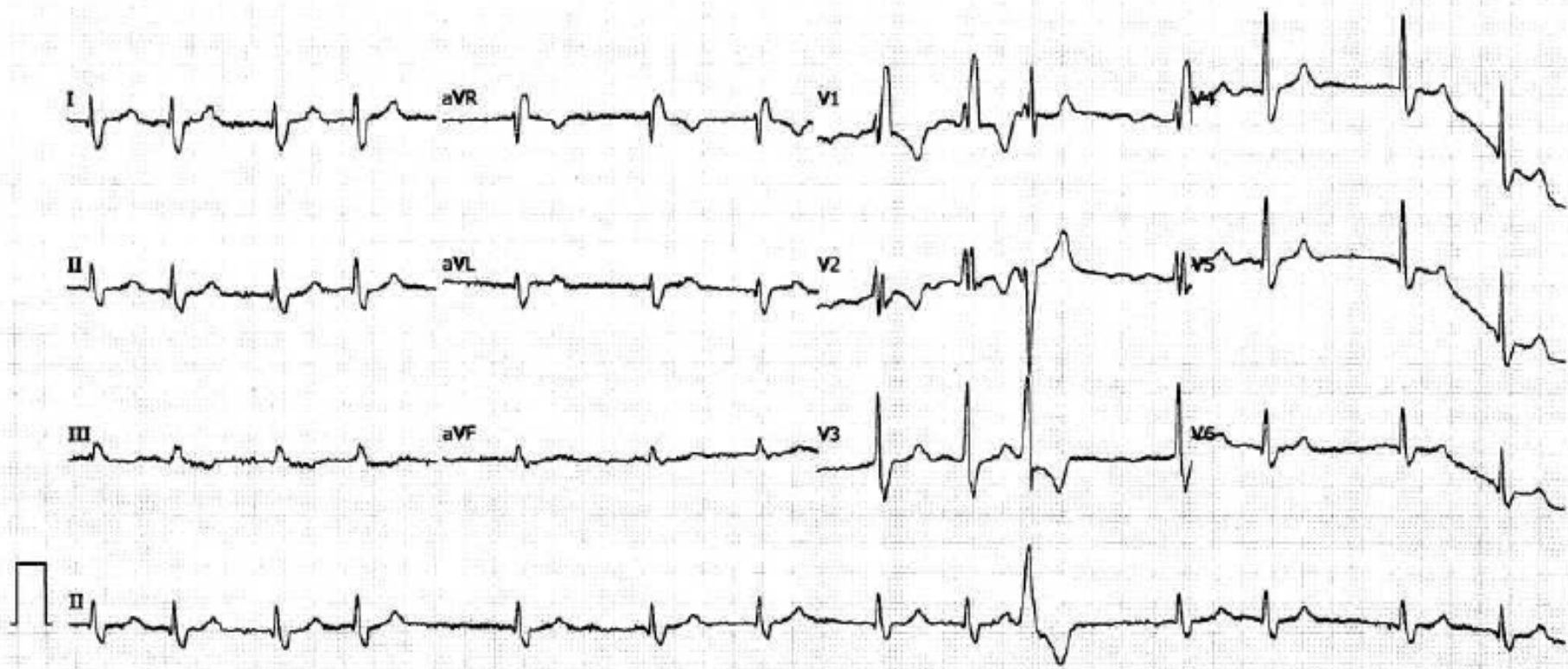
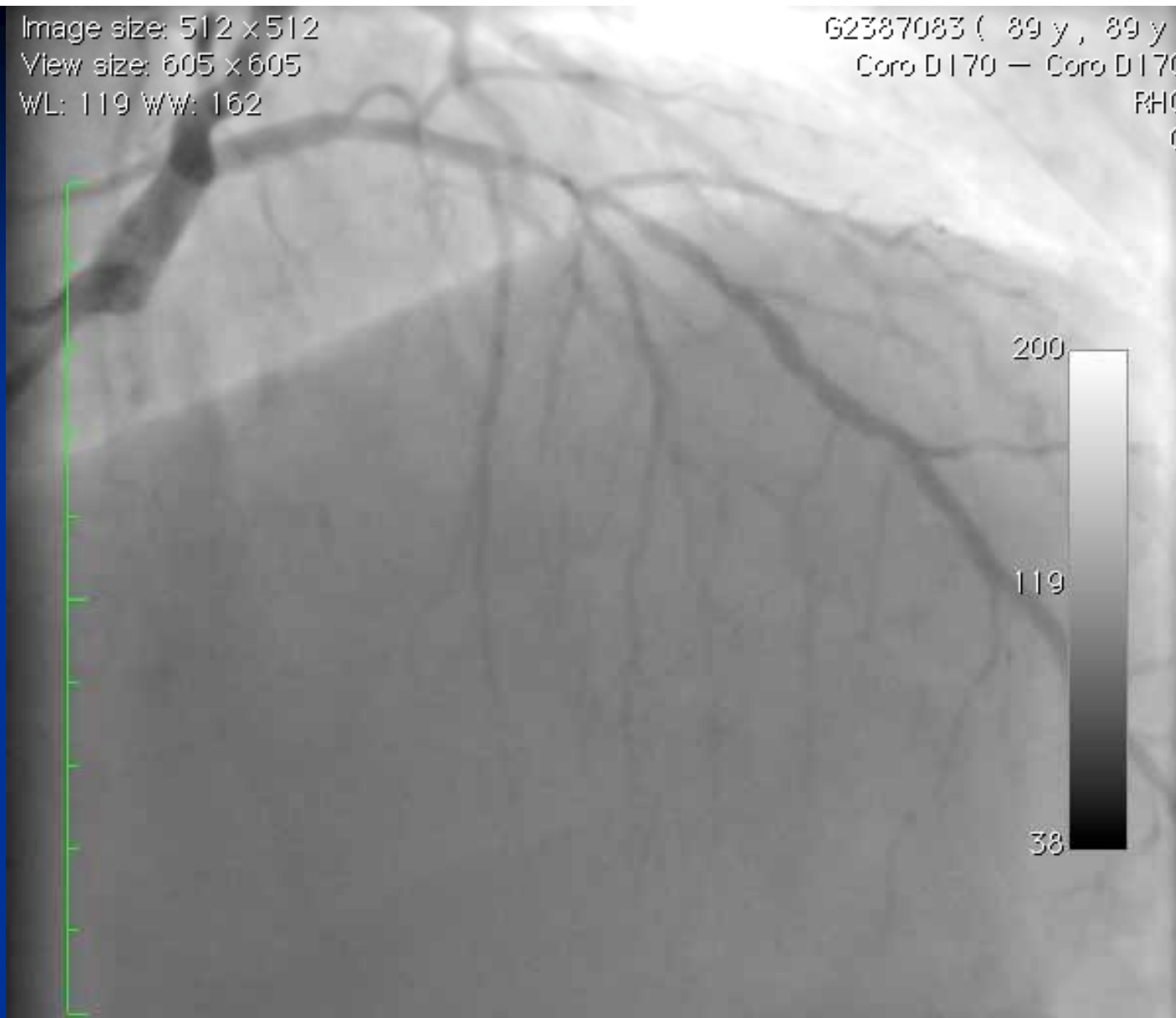




Image size: 512 x 512  
View size: 605 x 605  
WL: 119 WW: 162

G2387083 ( 89 y , 89 y )  
Coro D170 - Coro D170  
RHC  
0



Im: 26/53  
Zoom: 118% -33.7 39

JPEGLossless:Non-hierarchicalHistOrderPrediction

Position: HFS

6/07/12 1:21:20 PM

Made In OsirX

PHILIPS

TIS0.1 MI 0.5

X7-2t/TOE

FR 50Hz  
11cm

M5

2D  
69%  
C 50  
P Off  
Gen

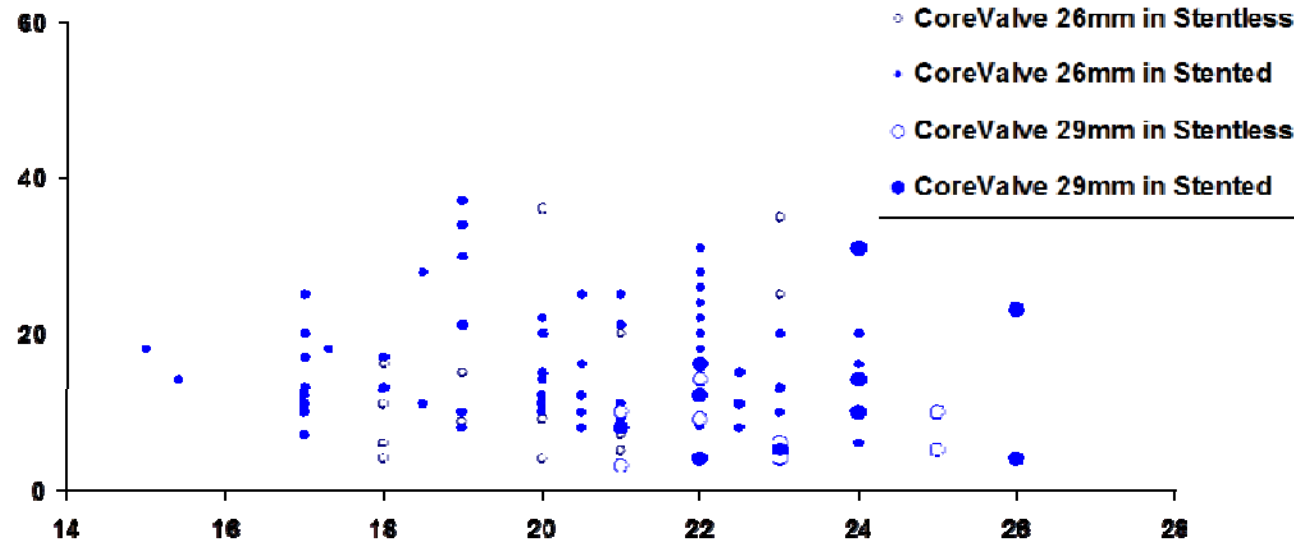
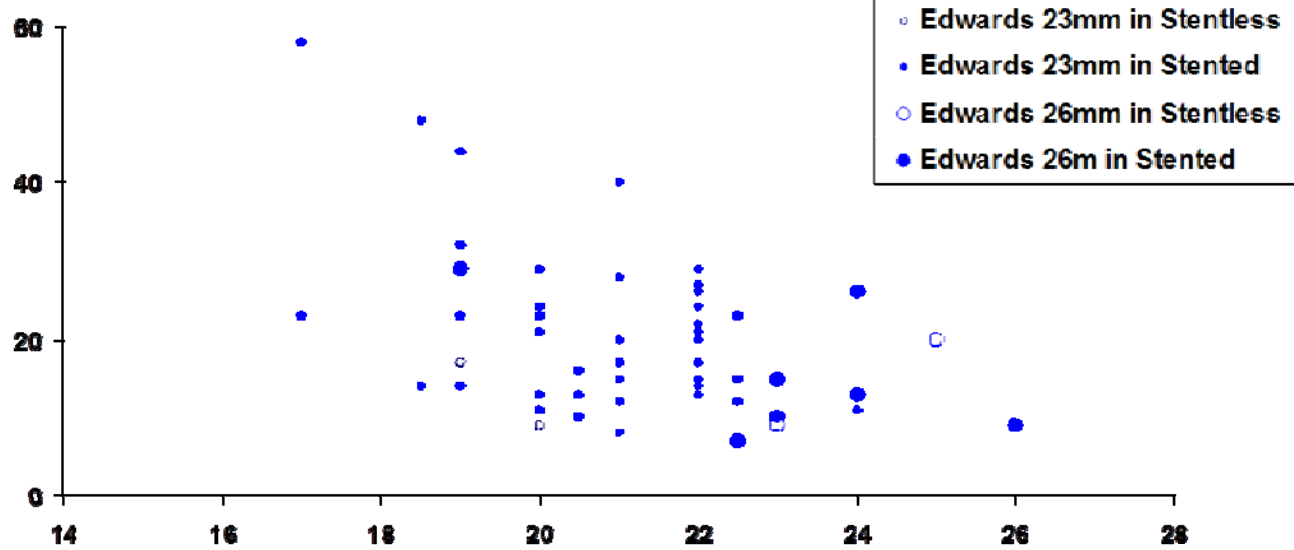


JPEG

PAT T: 37.0C  
TEE T: 39.3C

62 bpm

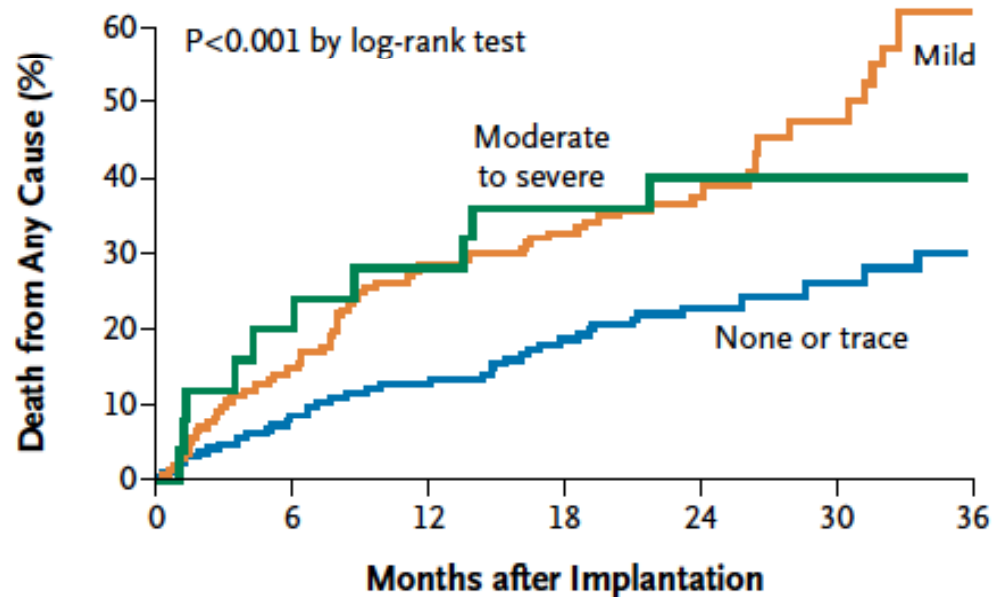
# Valve in Valve



# DEVICE SIZING

## Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

**B** Severity of Paravalvular Leak: None or Trace, Mild, or Moderate to Severe



### No. at Risk

None or trace	158	142	134	121	84	39	15
Mild	136	115	95	86	51	21	10
Moderate to severe	24	19	17	15	13	5	2

# PVL after

# mortality

Author (journal)	Predicts mortality
Abdel-Wahab (Heart 2011)	in-hospital mortality
Tamburino (Circulation 2011)	in-hospital mortality – 1 year
Gotzman (AHJ 2011)	in-hospital mortality 6 mos
Moat (JACC 2011)	in-hospital mortality 1 year



# Predictors of Paravalvular Leak

- Malposition of valve
- Degree and asymmetry of valve Ca
- Undersizing of valve

Detaint et al. JACC Interv 2009;2:82107

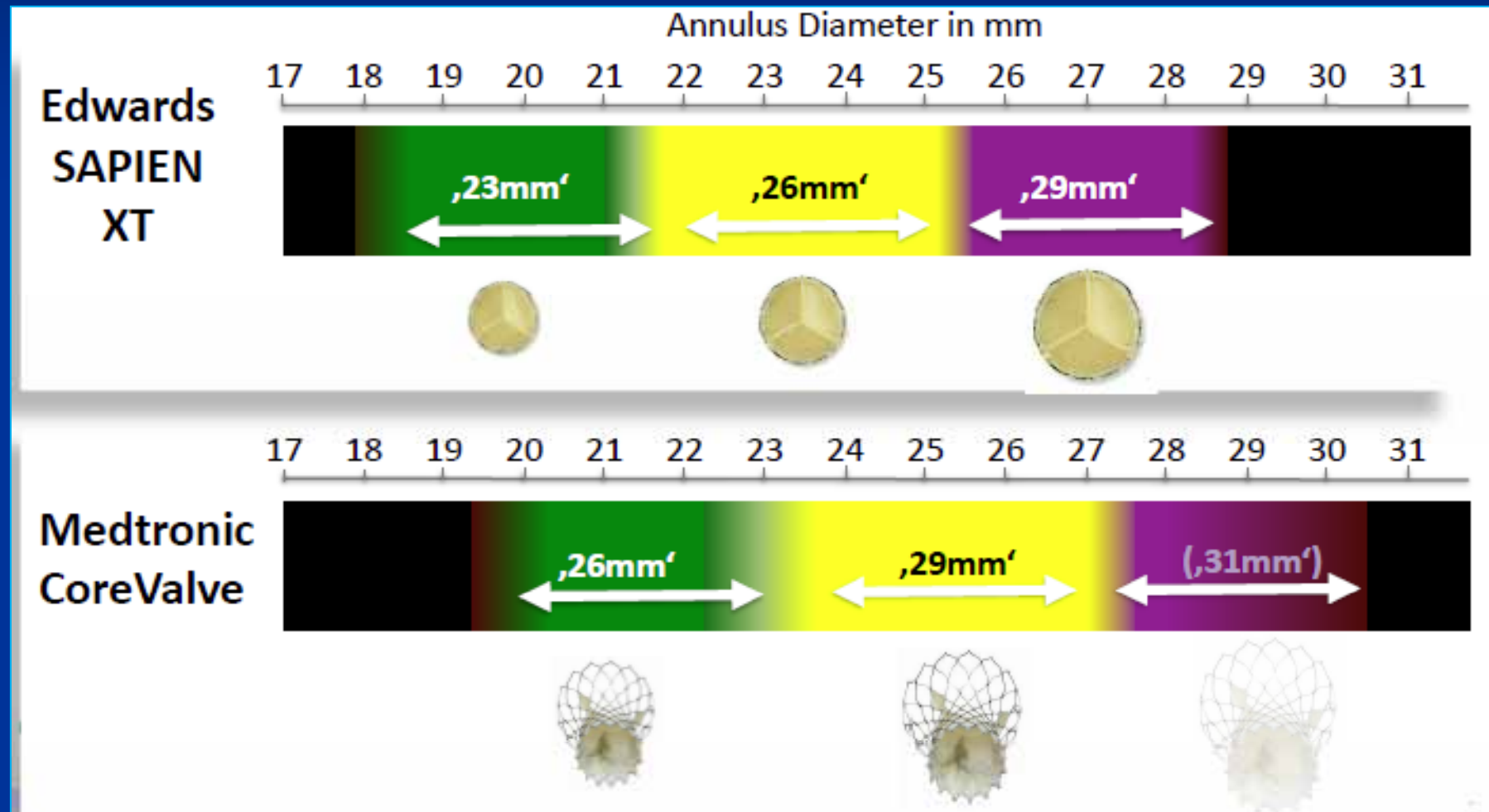
Coli et al. Circulation 2009;120:S982

Delgado et al. Circulation 2009;120:S957

Willson, et al., JACC, 2012;59:1287-94

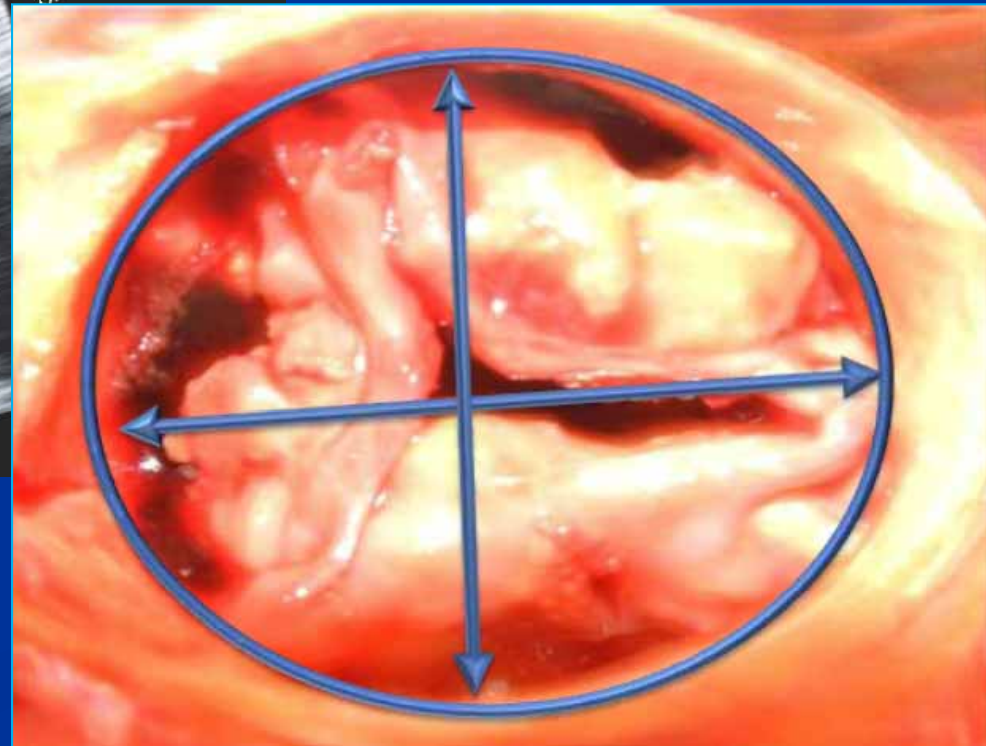
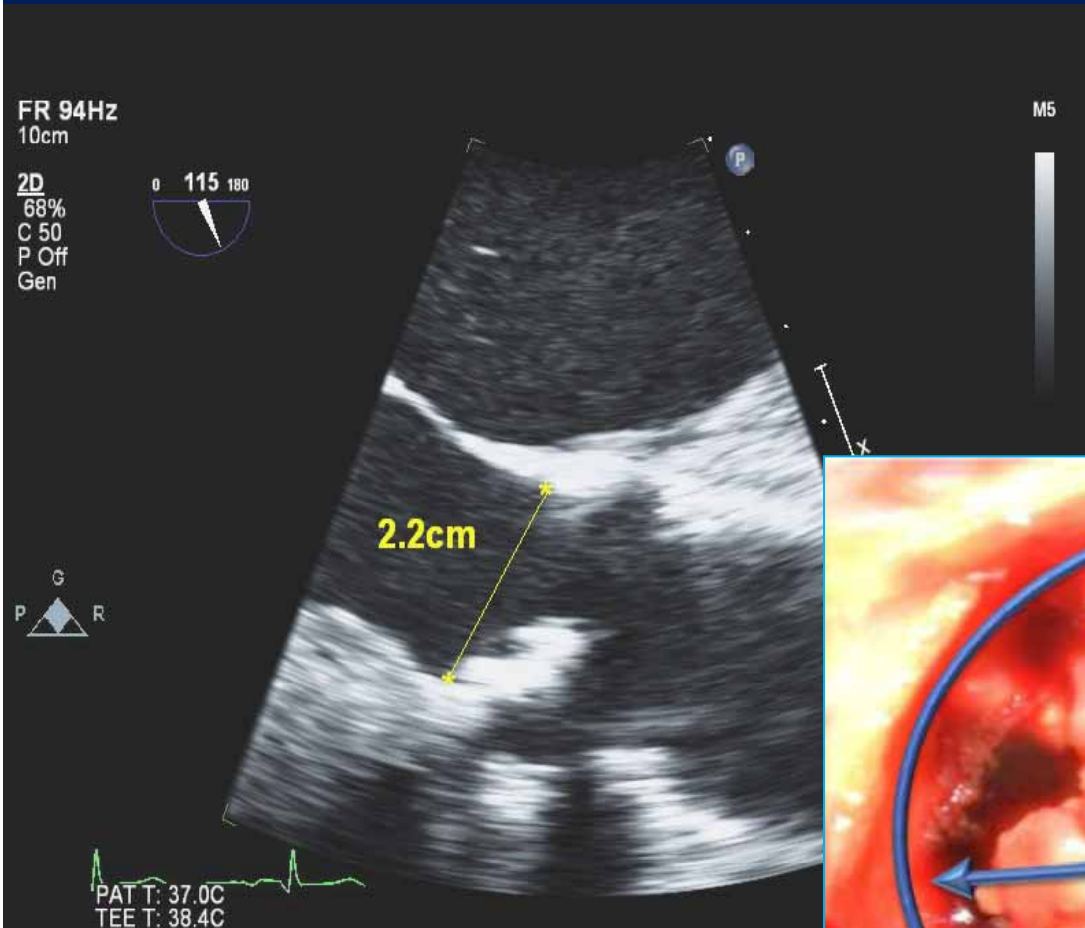
Jilaihawi, et al., JACC, 2012;59:1275-86

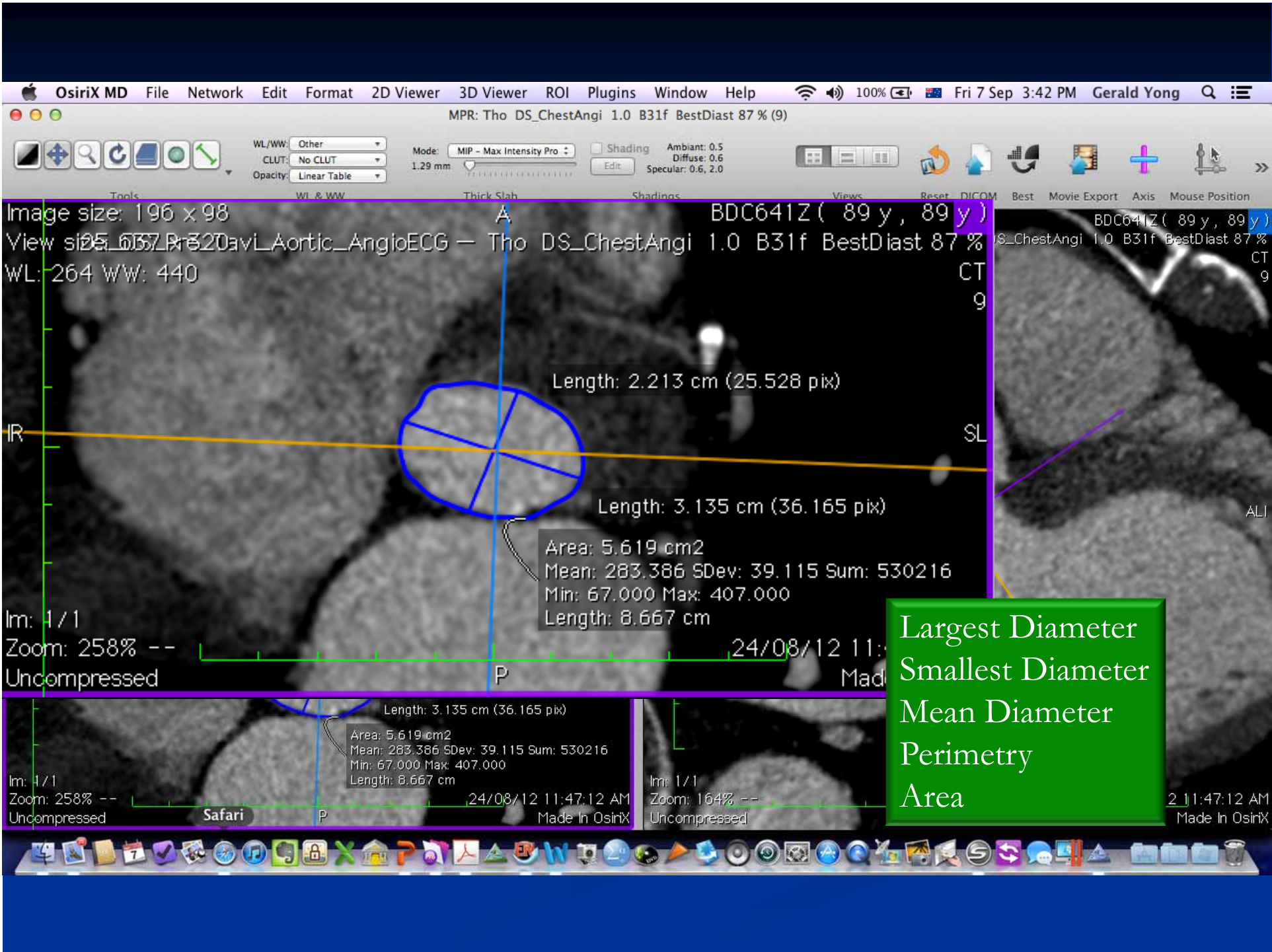
# Valve Sizing Dependent On Annulus Measure





# Traditional Imaging for Annulus Sizing

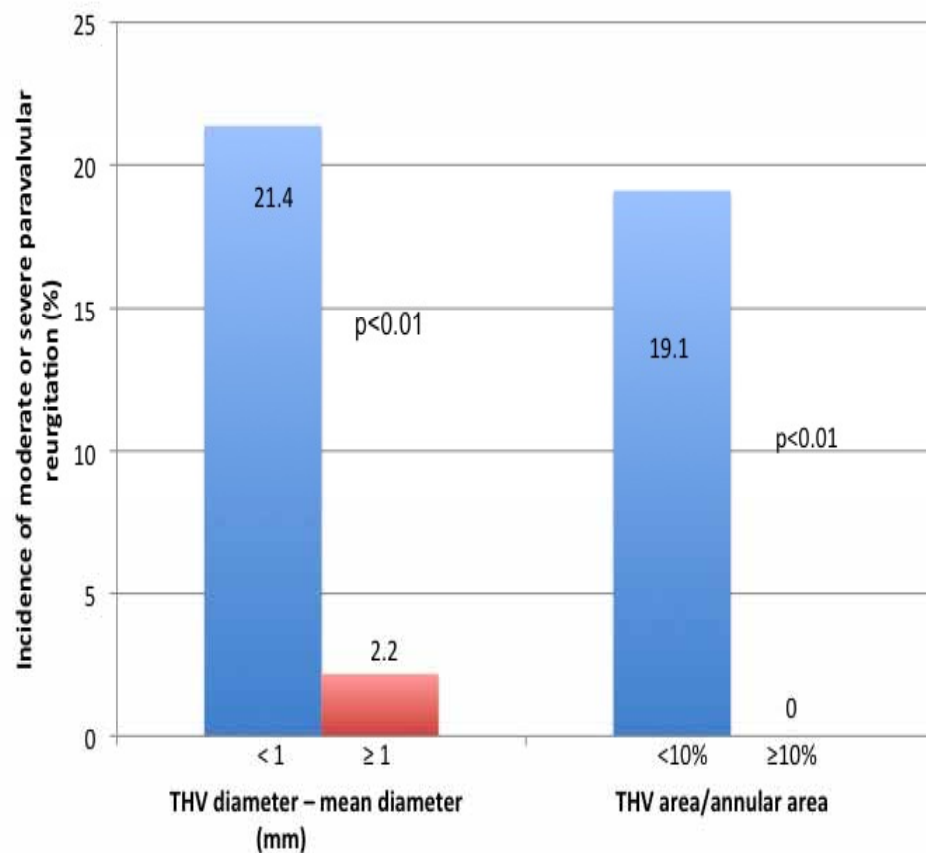




# 3-Dimensional Aortic Annular Assessment by Multidetector Computed Tomography Predicts Moderate or Severe Paravalvular Regurgitation After Transcatheter Aortic Valve Replacement

A Multicenter Retrospective Analysis

Alexander B. Willson, MBBS, MPH,\* John G. Webb, MD,\* Troy M. LaBounty, MD,†

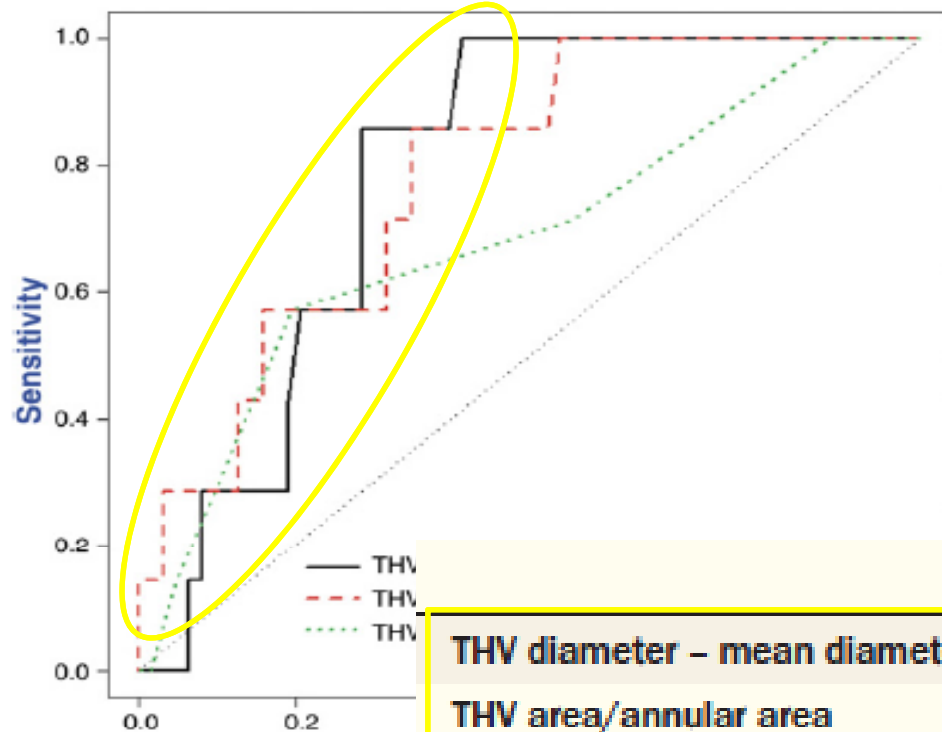


109 patients underwent TAVI using Edwards SAPIEN valve

Valve size determination multifactorial

Retrospective analysis of MSCT and TOE assessment of annulus size

# Predictor of PVL

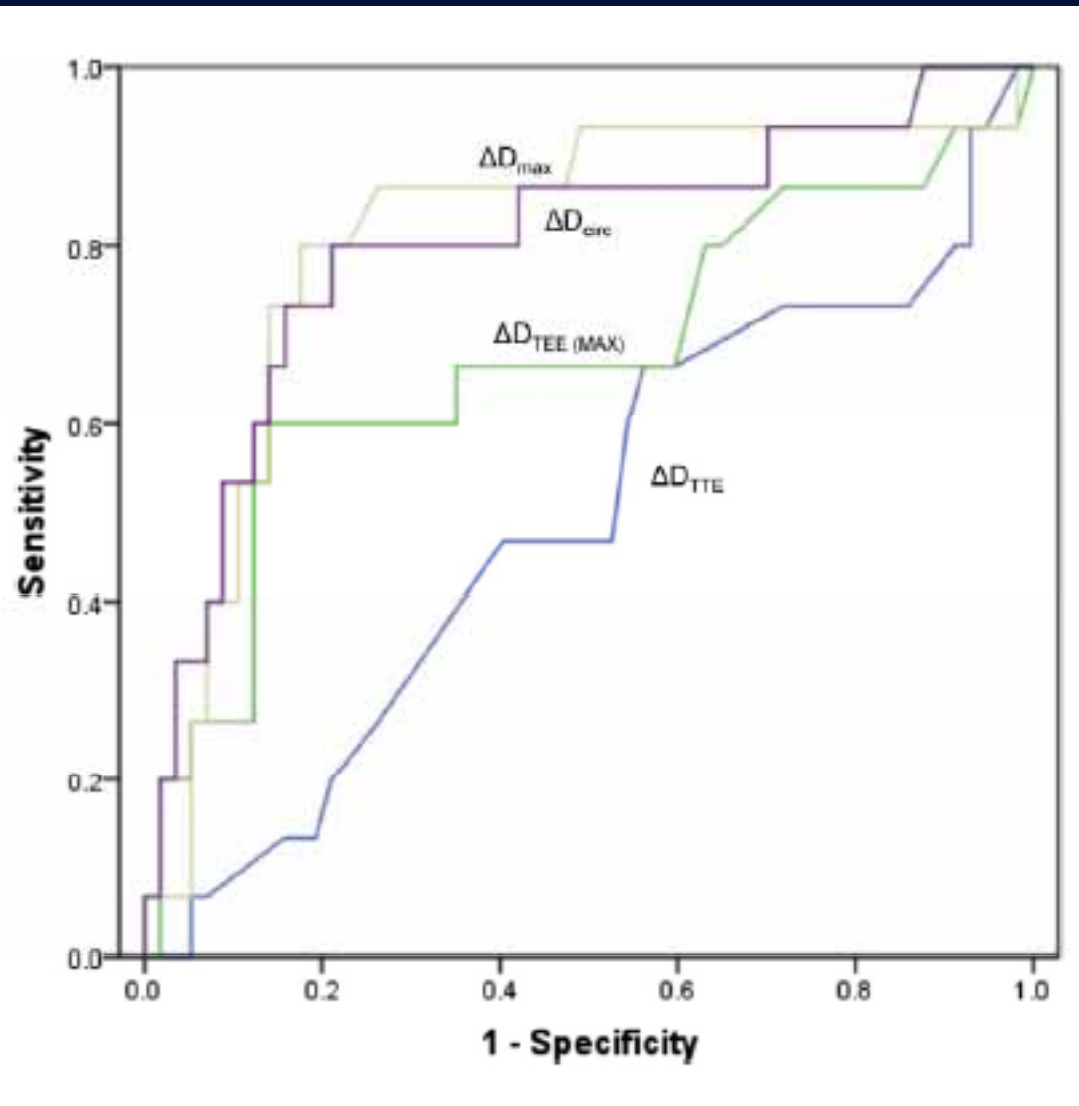


**Figure 3**

**Area Under the Curves for Pred**

MDCT mean diameter (0.81, 95% area (0.80, 95% CI: 0.65 to 0.90) (TEE) diameter (0.70, 95% CI: 0.5 tation; other abbreviations as in Fi

	<b>AUC</b>	<b>95% CI</b>
<b>THV diameter - mean diameter</b>	<b>0.81</b>	<b>0.68-0.88</b>
<b>THV area/annular area</b>	<b>0.80</b>	<b>0.65-0.90</b>
<b>THV circumference/annular circumference</b>	<b>0.76</b>	<b>0.59-0.91</b>
<b>THV diameter - TEE annulus diameter</b>	<b>0.70</b>	<b>0.51-0.88</b>
<b>Female</b>	<b>0.62</b>	<b>0.50-0.77</b>
<b>Age, yrs</b>	<b>0.59</b>	<b>0.50-0.72</b>
<b>Annular eccentricity</b>	<b>0.58</b>	<b>0.46-0.75</b>






**Figure 4**

Superimposed ROC Curves Evaluating Predictive Value of Cross-Sectional CT and Standard Echocardiographic Measurements for Post-TAVR Paravalvular Regurgitation (> M1d)

# Valve Sizing by CT – Edwards Valve

## The “St Paul’s CT Sizing Scale”

Annular Area (mm <sup>2</sup> )	THV size (mm)	
<p data-bbox="517 528 658 568">23mm</p>  <p data-bbox="517 1129 703 1182">4.15cm<sup>2</sup></p>	<p data-bbox="987 528 1128 568">26mm</p>  <p data-bbox="987 1129 1173 1182">5.31cm<sup>2</sup></p>	<p data-bbox="1525 528 1666 568">29mm</p>  <p data-bbox="1525 1129 1711 1182">6.61cm<sup>2</sup></p>
<b>&gt;660</b>	Risk of leak/embolisation with 29	

## Step 5: Device Size Selection

### Aortic Annulus Ranges

	Diameter Range (mm)	Perimeter Range (mm)	Area Range (mm <sup>2</sup> )
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

# Conclusion

- Proper patient selection and assessment is important to optimise outcome post TAVI
- No significant difference in outcomes between the commonly used valves in current registries
- Device sizing critically important. Improved device sizing, potentially by improved imaging modality, may reduce paravalvular leak and improve outcome and