

Complication Prediction and Management

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Disclosure Statement of Financial Interest

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

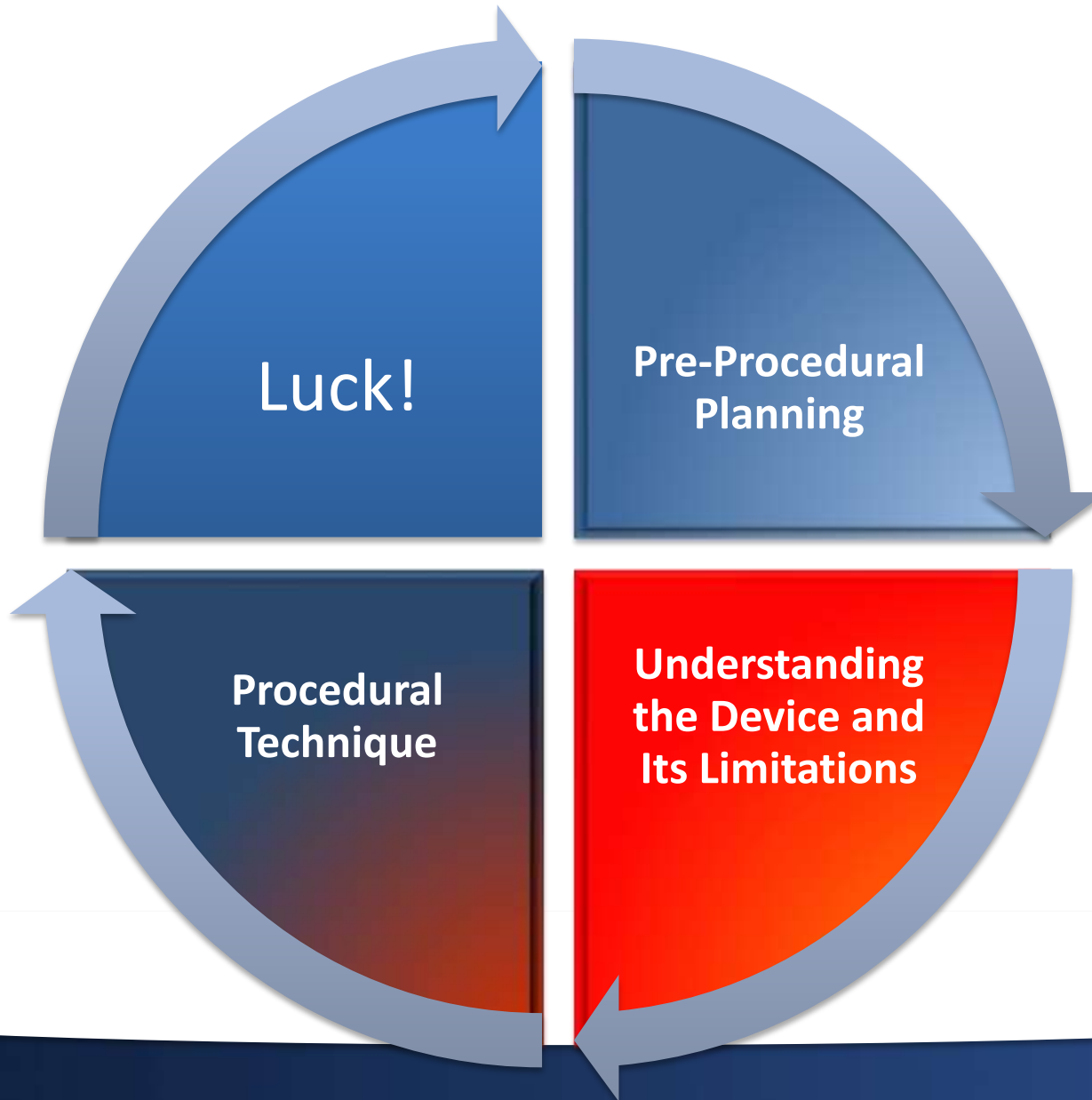
Affiliation/Financial Relationship

- Honoraria
- Steering Committee
- SAB

Company

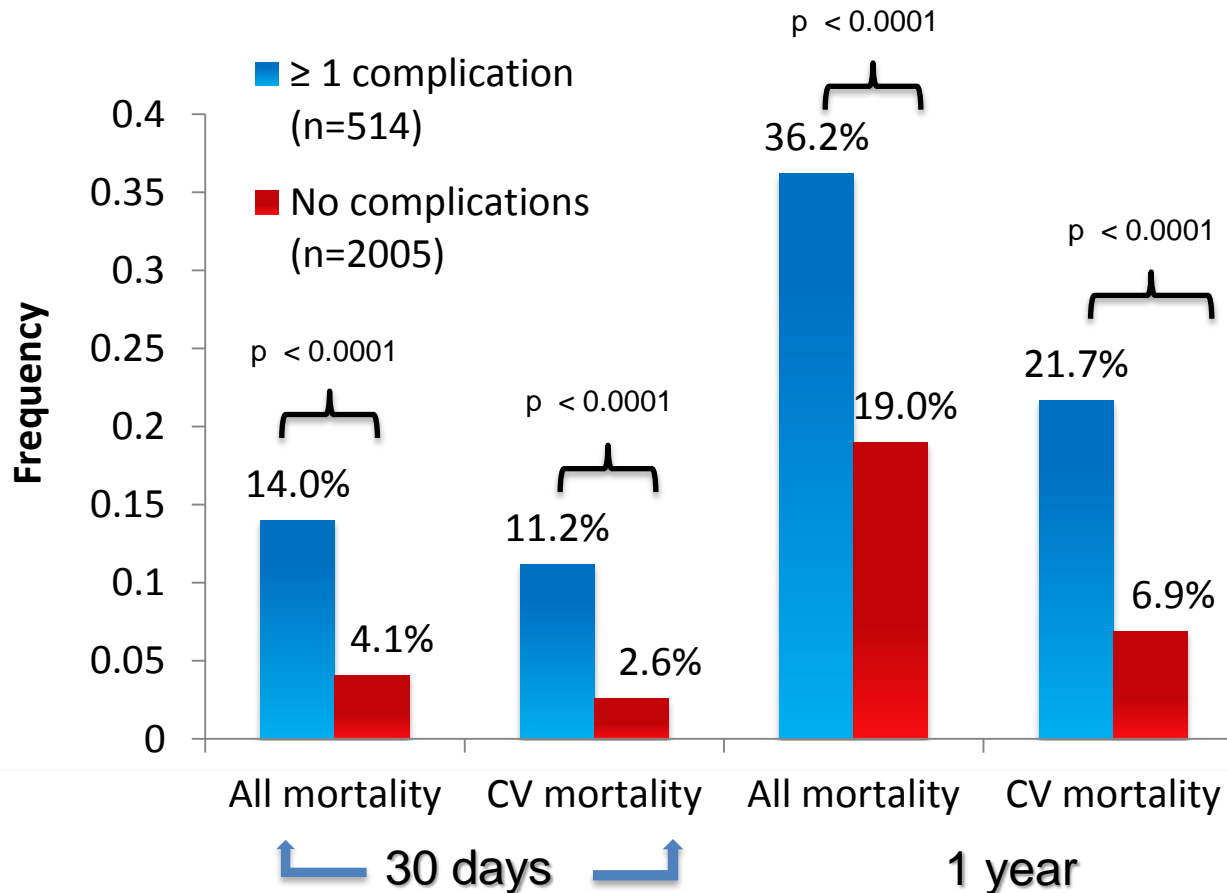
- St. Jude Medical, Claret Medical
- Edwards Lifesciences, Claret Medical
- Thubrikar Aortic Valve, Inc, Dura Biotech, VS Medtech

Keys to a Successful Procedure



Complications Impact Outcomes

PARTNER Trial



TAVI ADVERSE EVENTS

■ Clinical Adverse Events:

- Coronary artery obstruction
- Paravalvular leakage
- Device migration
- Aortic dissection/rupture
- Stroke

Biomechanical Events:

- ⇒ Stent displaces native leaflet
- ⇒ Stent underexpansion
- ⇒ Low stent expansion force
- ⇒ High stent expansion force
- ⇒ Calcium thromboembolism



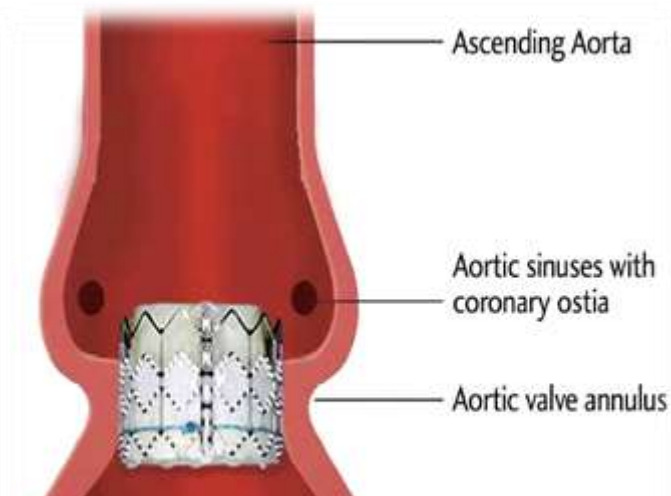
Aortic root-TAV stent mechanical interaction

Coronary Artery Occlusion

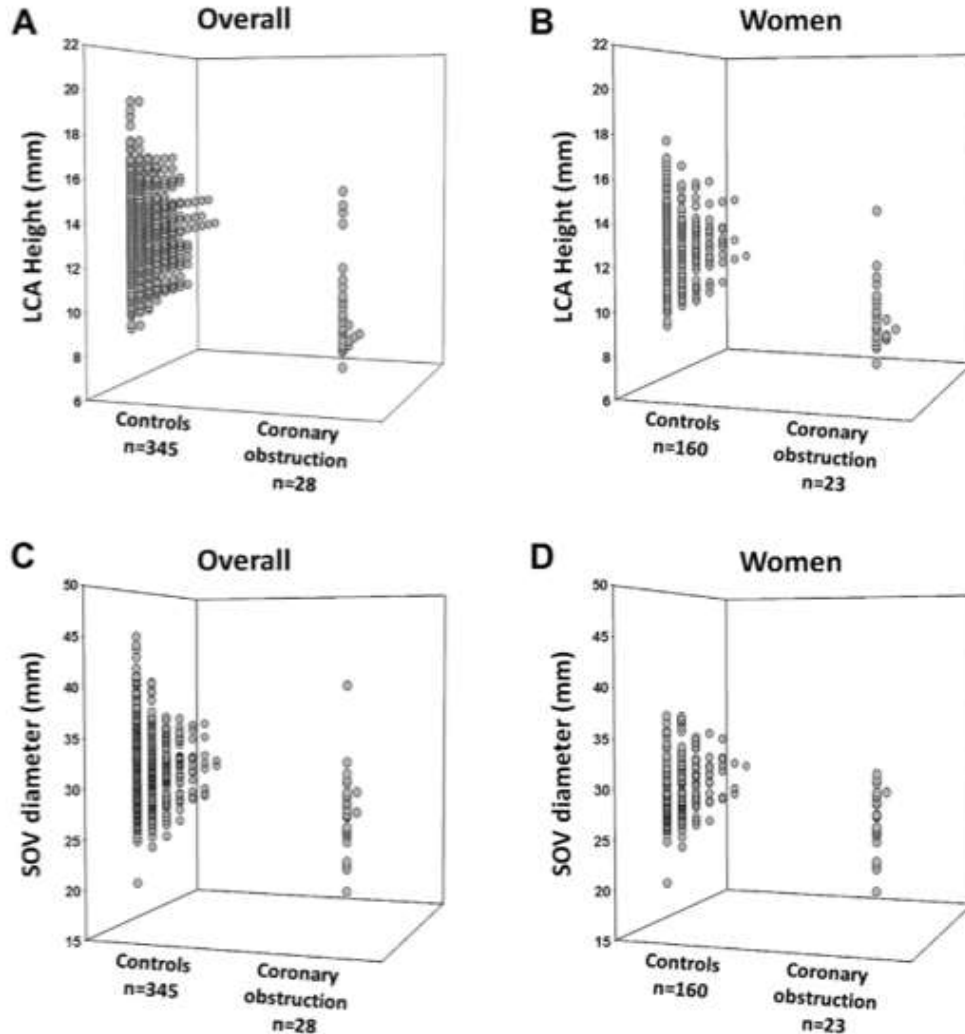
Why does it occur?

Anatomical considerations

- Severely calcified aortic root
 - root angiogram, CT
- Bulky leaflets
 - root angiogram, echo
- Shallow sinuses of Valsalva
 - root angiogram, CT dimensions
- Low coronary ostia and annulus
 - angiogram, CT annulus-ostia distance <12mm

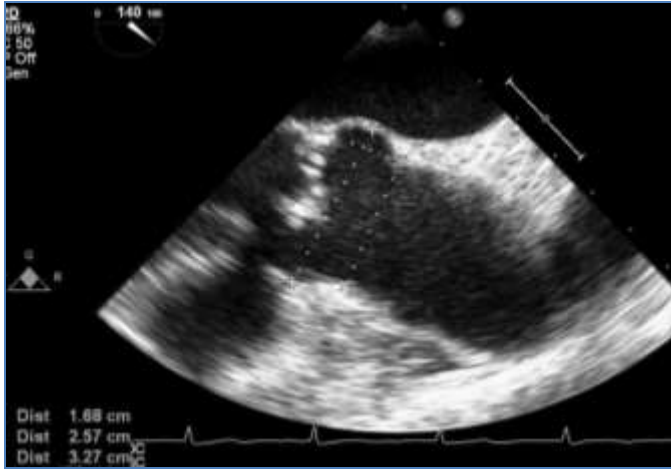


Coronary Occlusion during TAVR



Sinus width < 30mm and LCA height < 12mm was associated with coronary occlusion

Risk of Coronary Occlusion

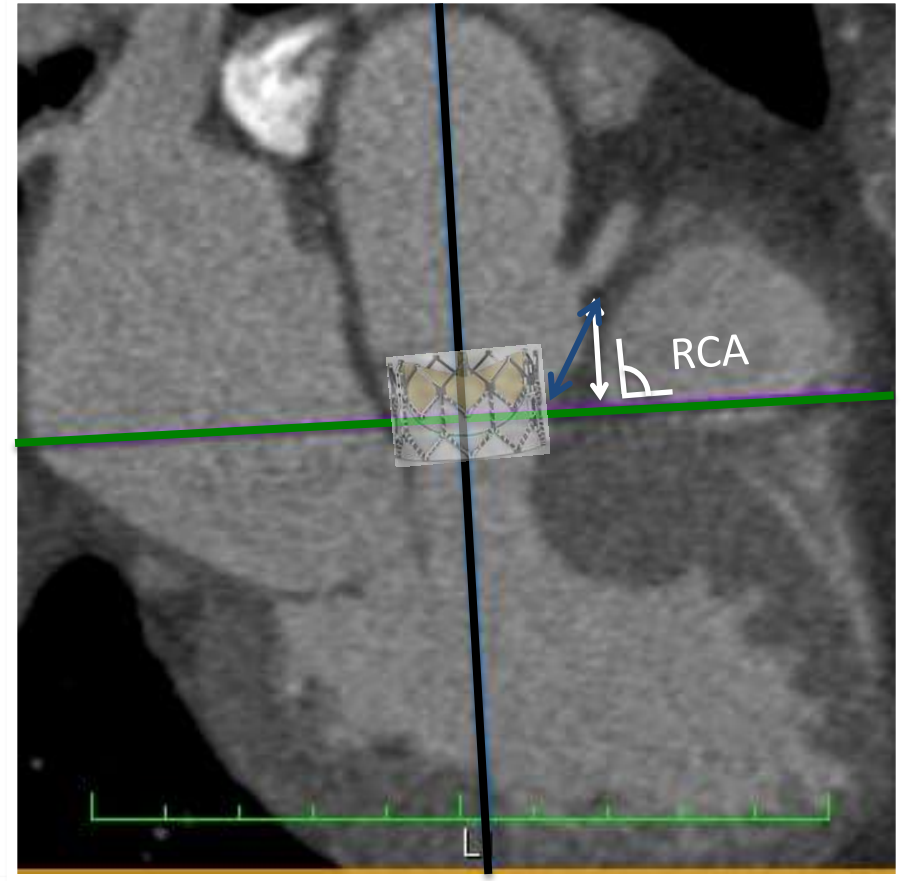
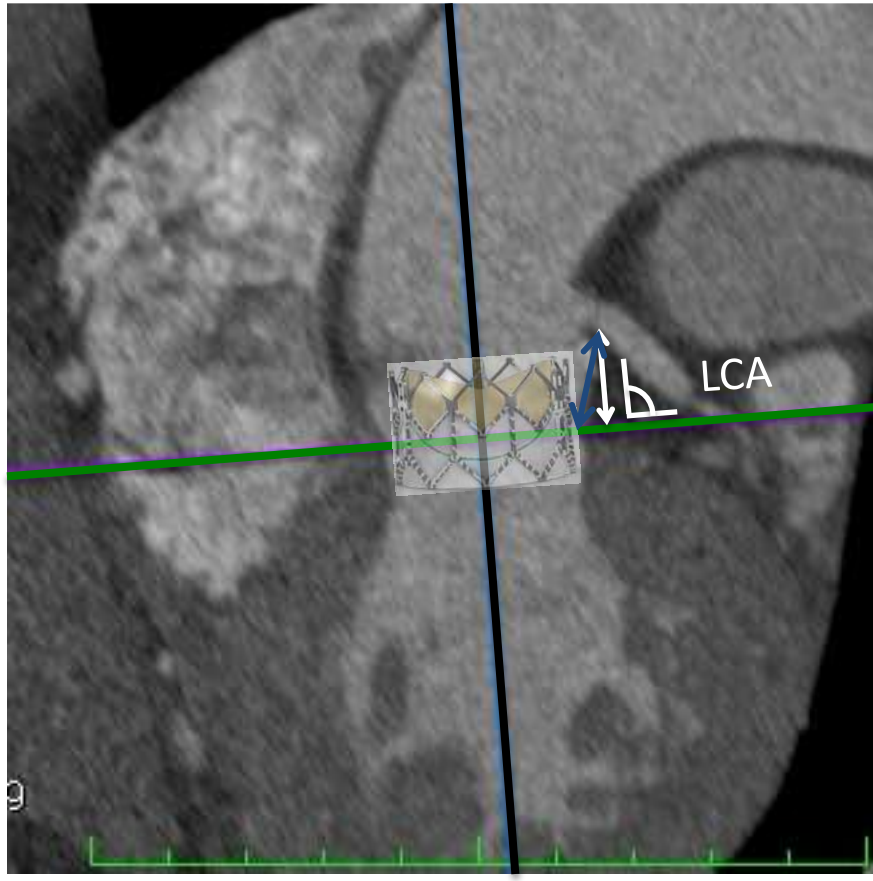


- Important Aortic Root Measurements:
 - Height of the Sinuses
 - Different valve sizes have different heights
 - Width of the Sinuses
 - Diameter and calcification of the sino-tubular junction (STJ)
 - Annulus → LM length
 - Length of the LCC



Must define the anatomy of the ENTIRE LANDING ZONE AND ADJACENT STRUCTURES

Coronary Heights



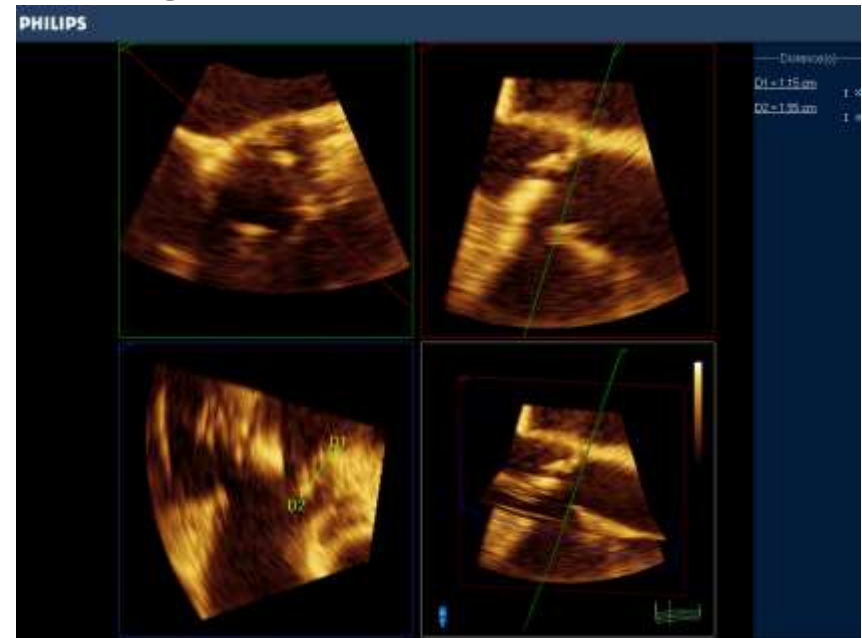
Preventing and Managing Coronary Occlusion

Effaced sinuses
STJ Diameter 2.56 cm
Aortic root diameter 2.83 cm



Effacement = Difference < 6 mm

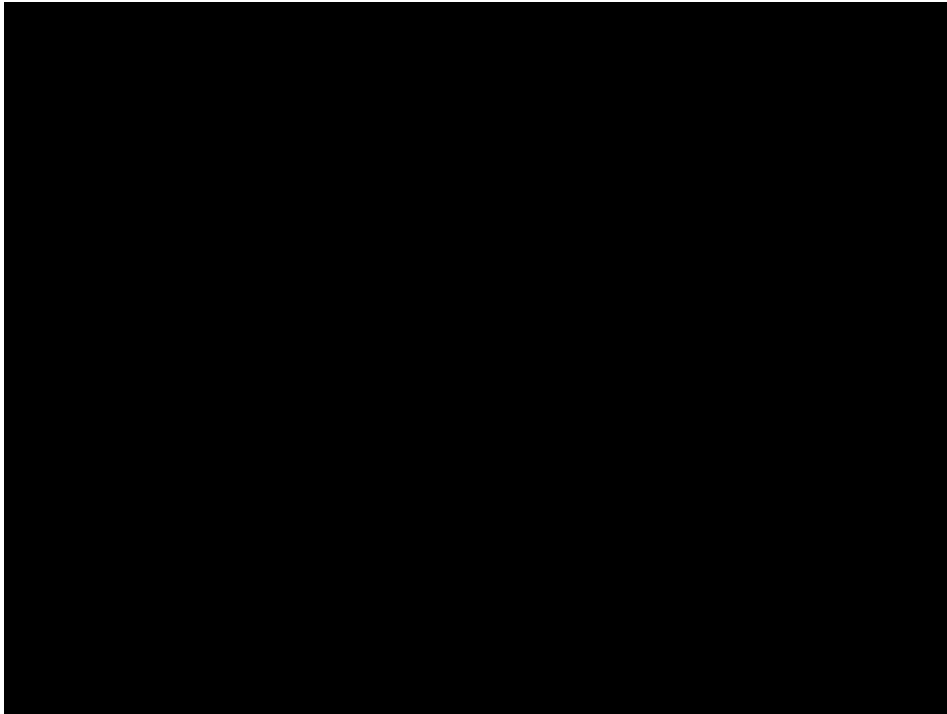
Short annulus to LM distance
Annulus to LM = 1.15 cm
Length of valve leaflet = 1.55 cm



Desirable annulus to LM distance:

- >10 mm for 23 mm valve
- >11mm for 26 mm valve

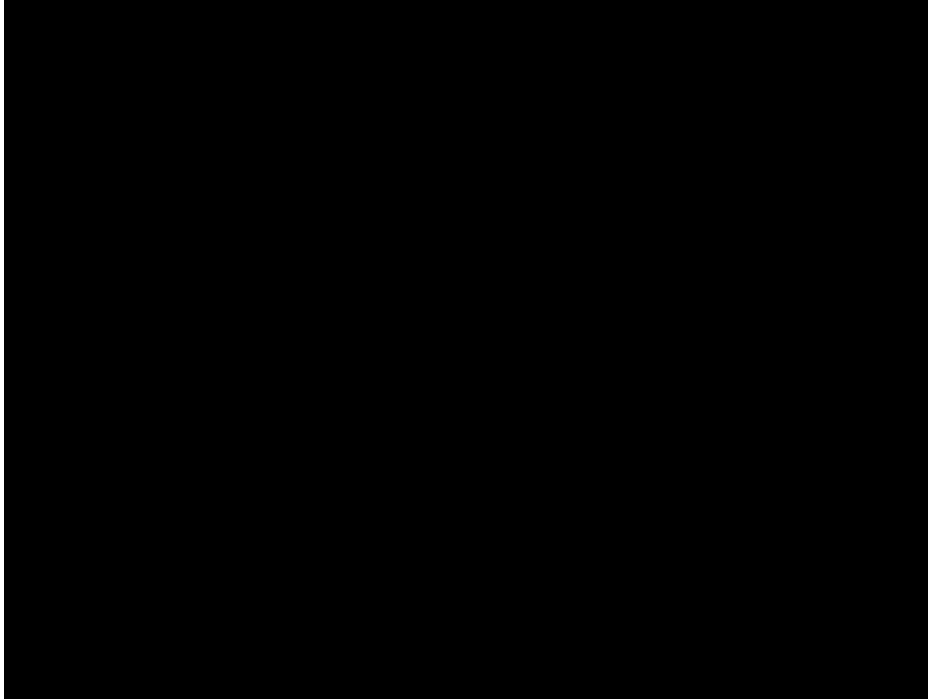
Movement of Calcified Leaflet Towards LM Ostium During BAV



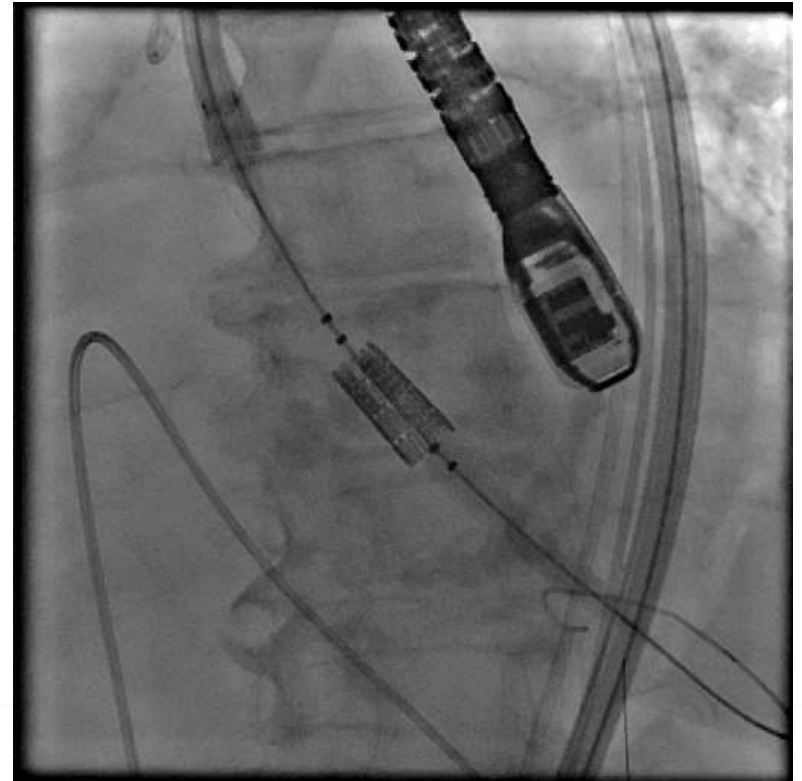
Remained hemodynamically stable



Valve Deployment



SBP dropped to 30 mm Hg, pressors started



LM Stenting

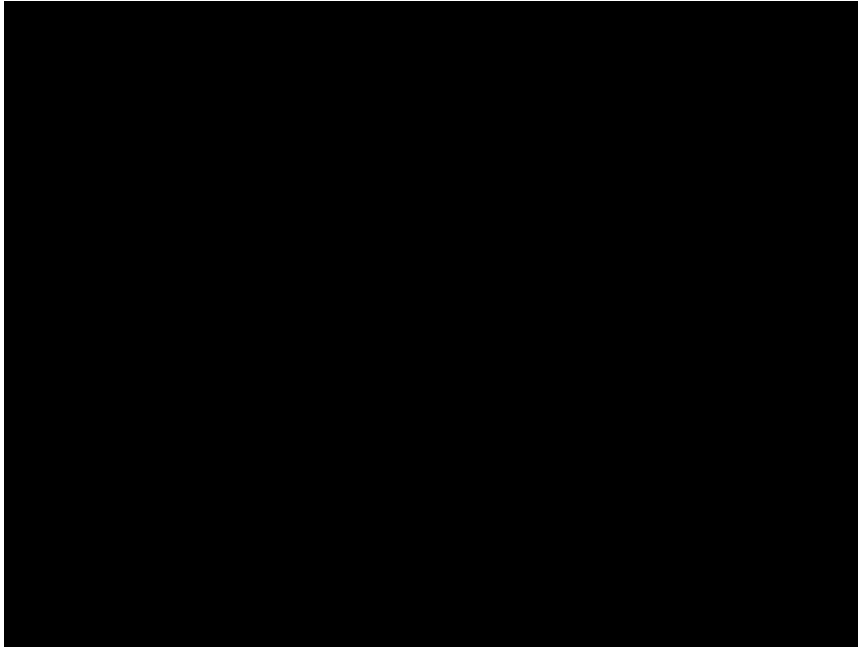


Significant difficulty noted during advancement of stent

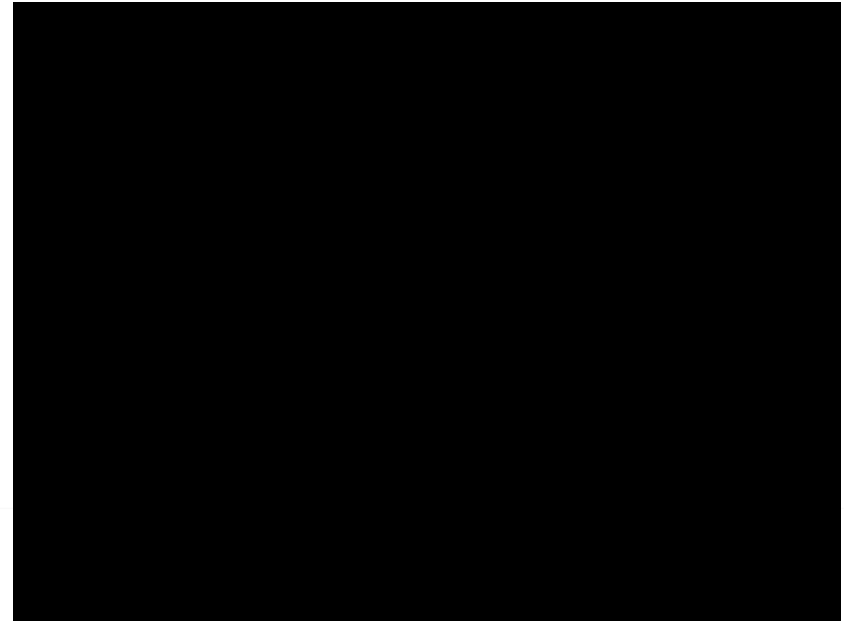
After post-dilatation



LV function improved significantly



Valve function good with minimal PVL



Annular Rupture

Is it still an issue?

- PARTNER Cohort A/B
 - Annular 0.5%
 - LVOT 0.6%
- CoreValve Pivotal 1.3% (LV perf)
- GARY Registry 0.4%
- PARTNER IIA 0.3%
- S3 30 d 0.3%

Overall incidence ~ 0.3-.5%

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MAY 26, 2015:2173-80

N Engl J Med 2011;364:2187-98.

N ENGL J MED 370;19 NEJM.ORG MAY 8, 2014

Valvular Heart Disease

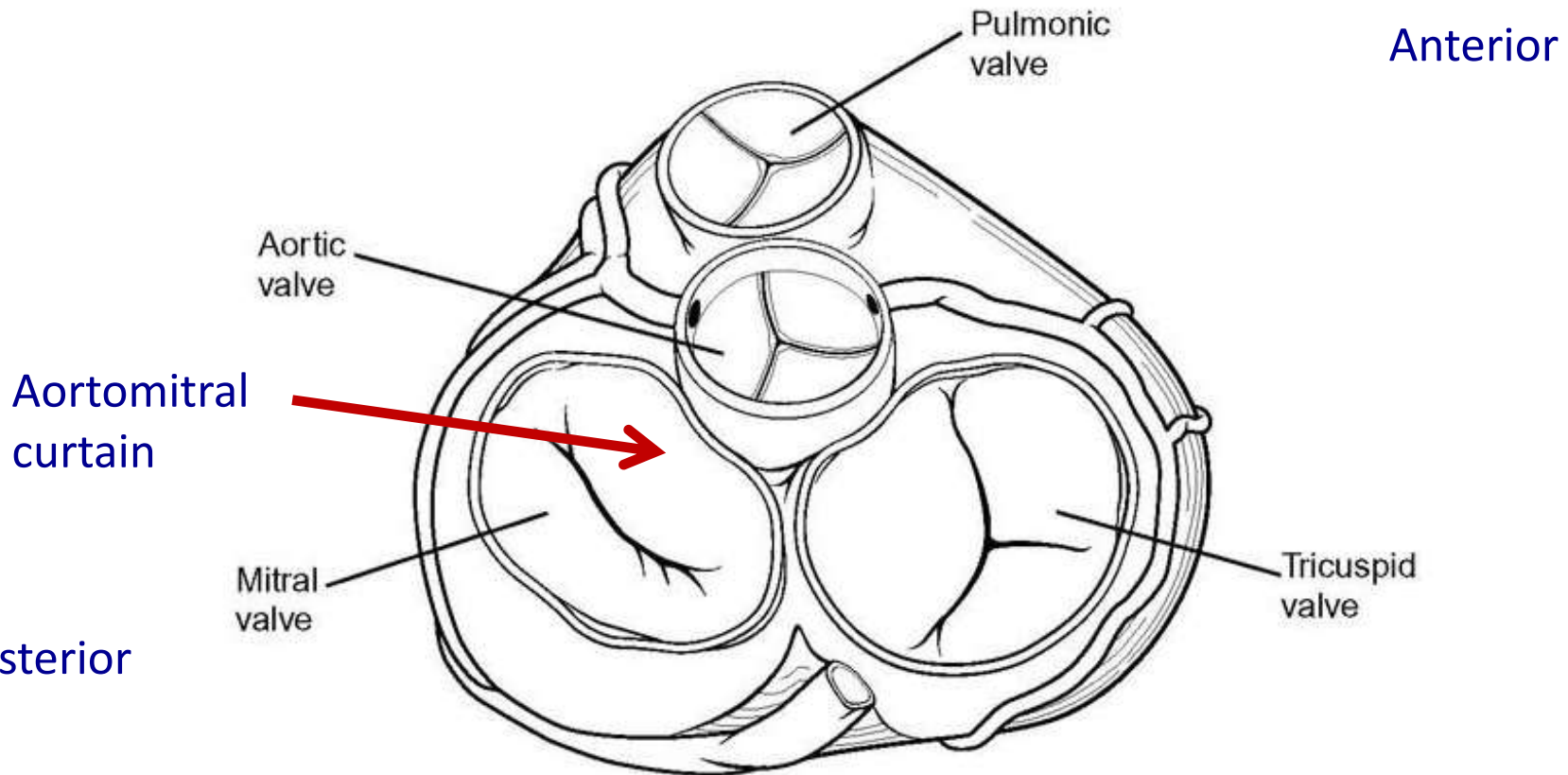
Anatomical and Procedural Features Associated With Aortic Root Rupture During Balloon-Expandable Transcatheter Aortic Valve Replacement

Marco Barbanti, MD; Tae-Hyun Yang, MD, Josep Rodès Cabau, MD; Corrado Tamburino, MD; David A. Wood, MD; Hasan Jilaihawi, MD; Phillip Blanke, MD; Raj R. Makkar, MD; Azeem Latib, MD; Antonio Colombo, MD; Giuseppe Tarantini, MD; Rekha Raju, MD; Ronald K. Binder, MD; Giang Nguyen, MD; Melanie Freeman, MD; Henrique B. Ribeiro, MD; Samir Kapadia, MD; James Min, MD; Gudrun Feuchtner, MD; Ronen Gurtvich, MD; Faisal Alqoofi, MD; Marc Pelletier, MD; Gian Paolo Ussia, MD; Massimo Napodano, MD; Fabio Sandoli de Brito, Jr, MD; Susheel Kodali, MD; Bjarne L. Norgaard, MD; Nicolaj C. Hansson, MD; Gregor Pache, MD; Sergio J. Canovas, MD; Hongbin Zhang, PhD; Martin B. Leon, MD; John G. Webb, MD; Jonathon Leipsic, MD

- Higher calcium in the R coronary LVOI
- No difference if small or large valve
- No difference if sinus large vs effaced
- No difference if annulus eccentric
- **Annular oversizing (>20%) (OR – 8.38)**
- Post-dilation (same size, 1-2 mm larger)

(*Circulation*. 2013;128:244-253.)

It's all about the anatomy

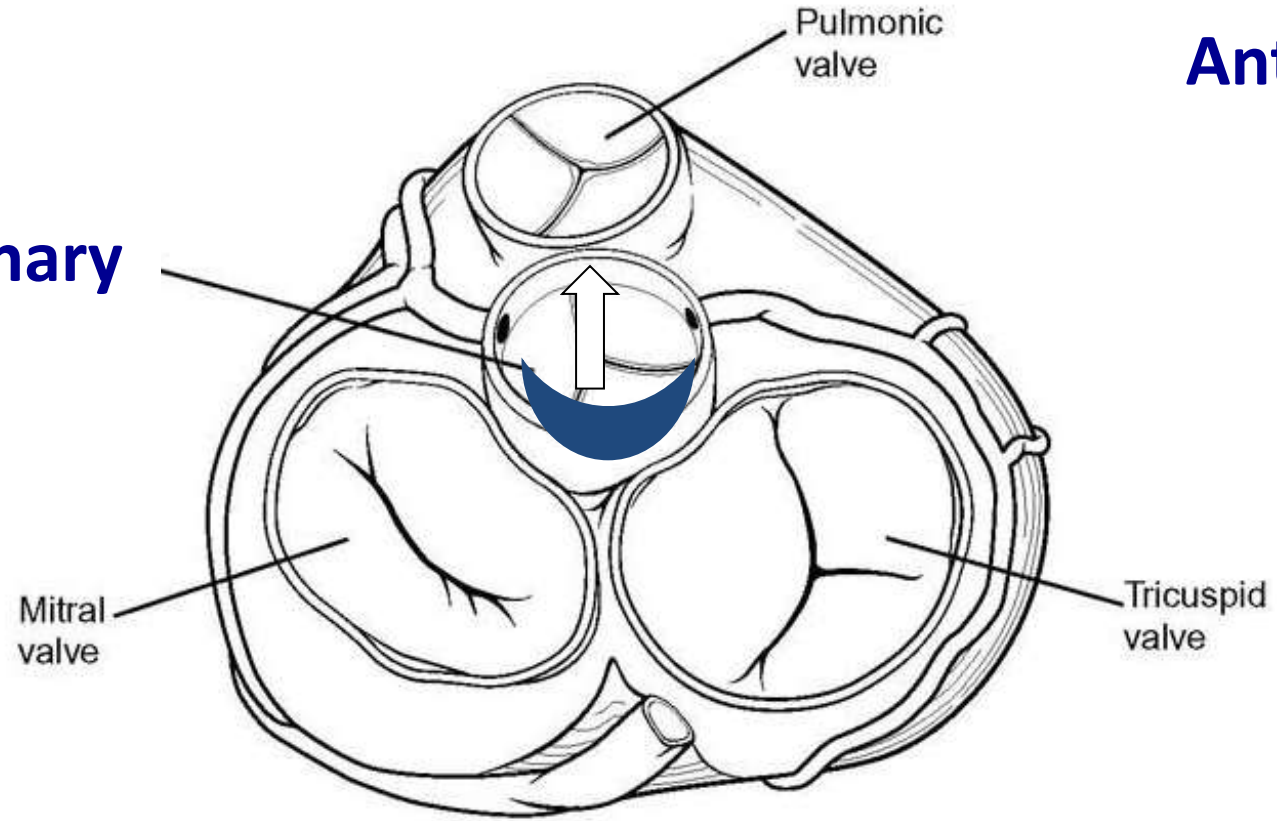


1. Annular calcium doesn't move
2. If calcium doesn't move, the area opposite the calcium moves

Non coronary Ca^{+2} = IVS rupture

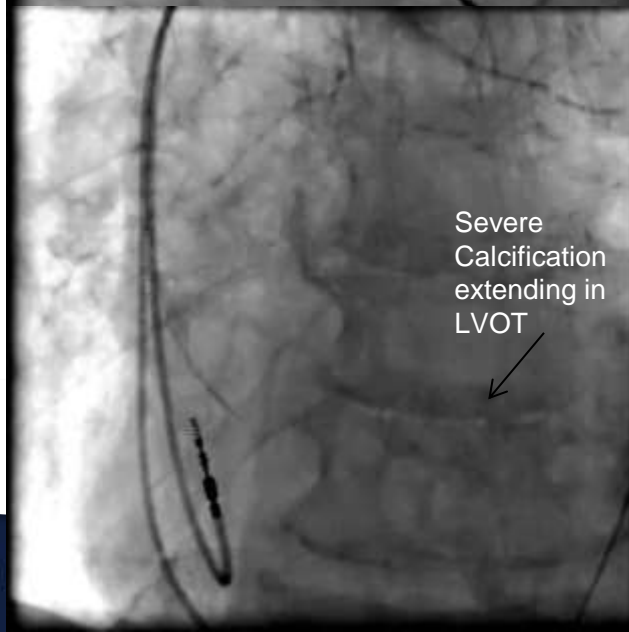
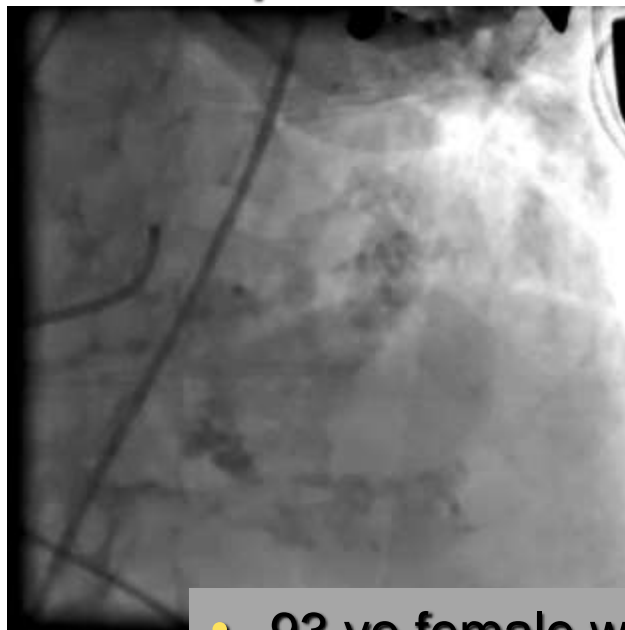
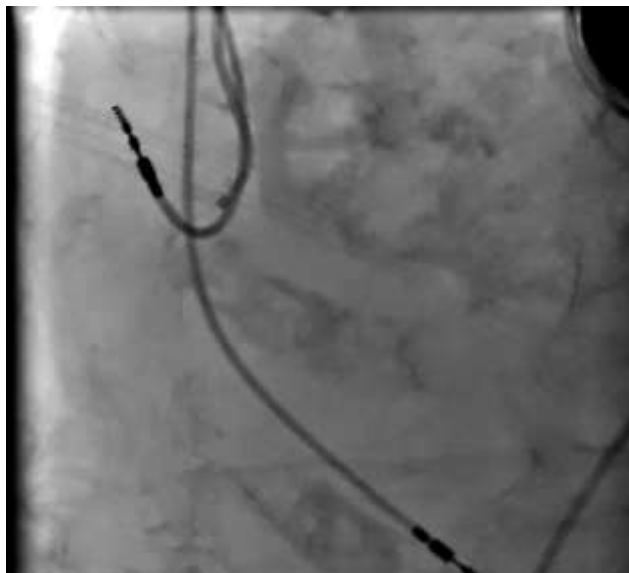
Anterior

Left coronary



Aortic Root Rupture

Case Example



- 93 yo female with severe aortic stenosis and NYHA III CHF
- Echo: EF 55%, AVA 0.8 cm²
- STS score 8.4%, inoperable due to porcelain aorta

Aortic Root Rupture

Case Example



**Aortic Annulus by
3D TEE 478 mm²**

Aortic Root Rupture

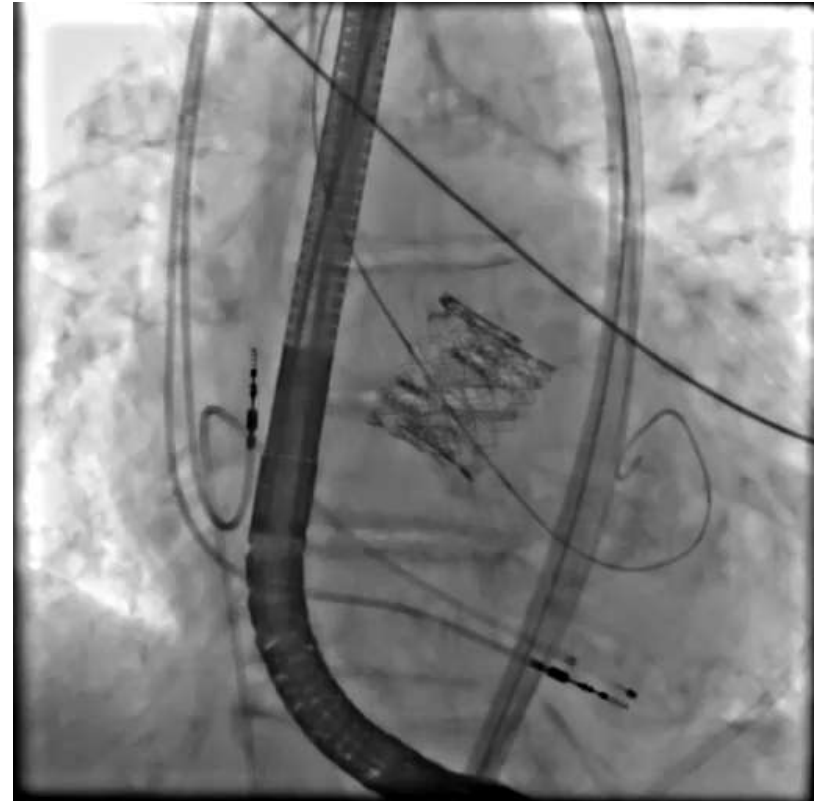
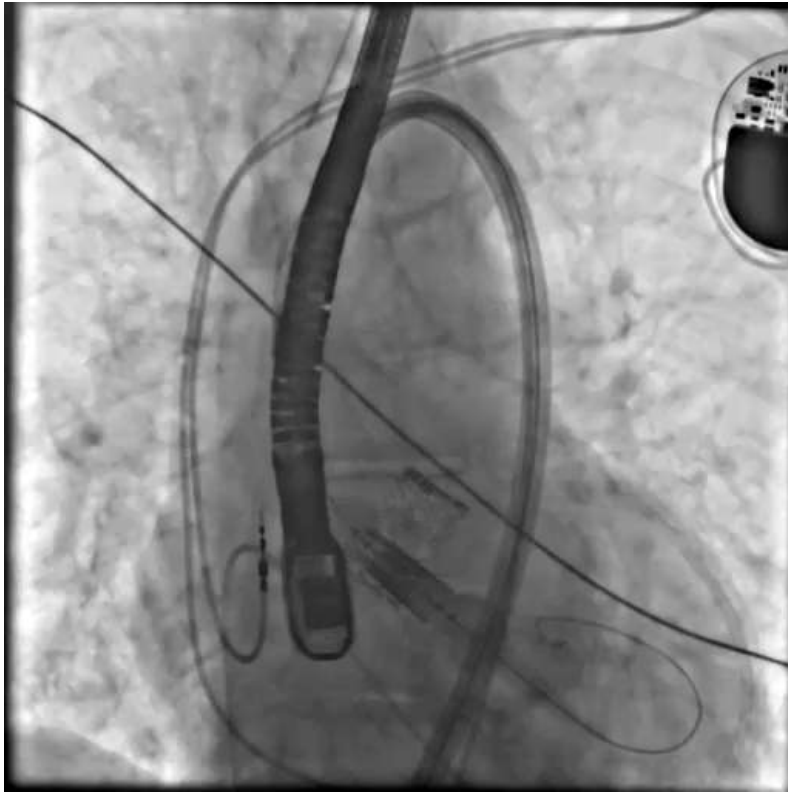
Case Example



Acute Hypotension Immediately
Post Valve Deployment

Aortic Root Rupture

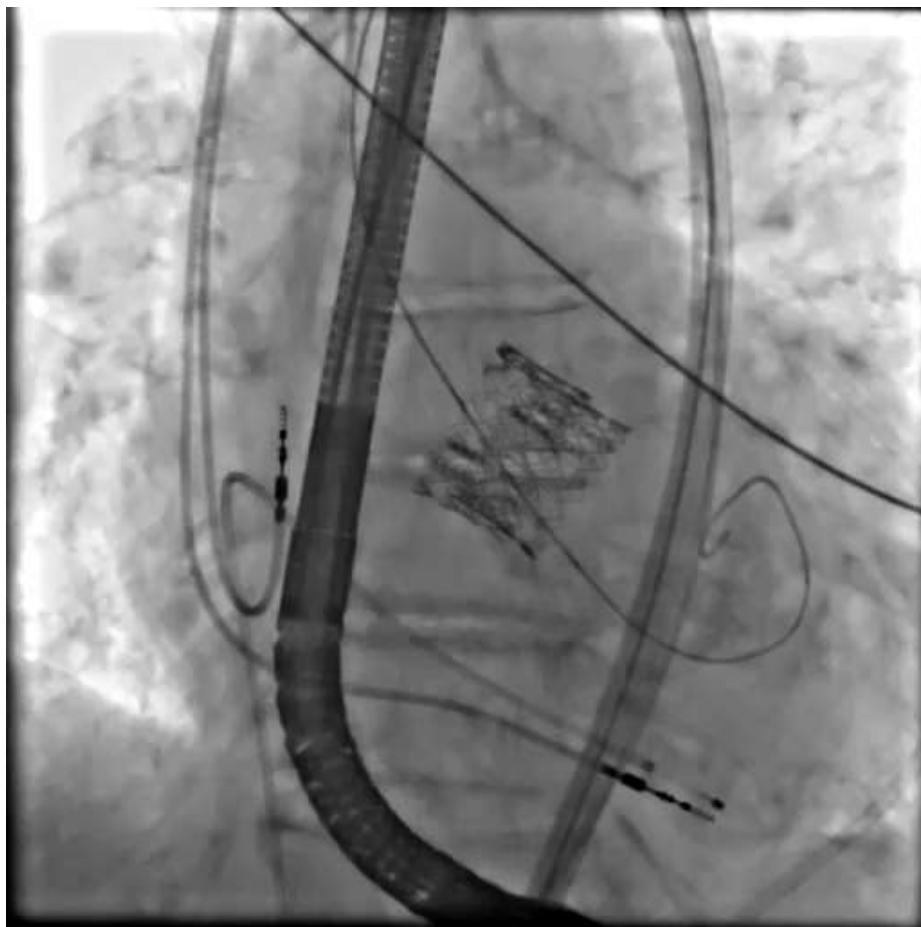
Case Example



Emergent pericardiocentesis performed and a 2nd
26 mm Sapien THV placed to seal the annular rupture

Aortic Root Rupture

Case Example

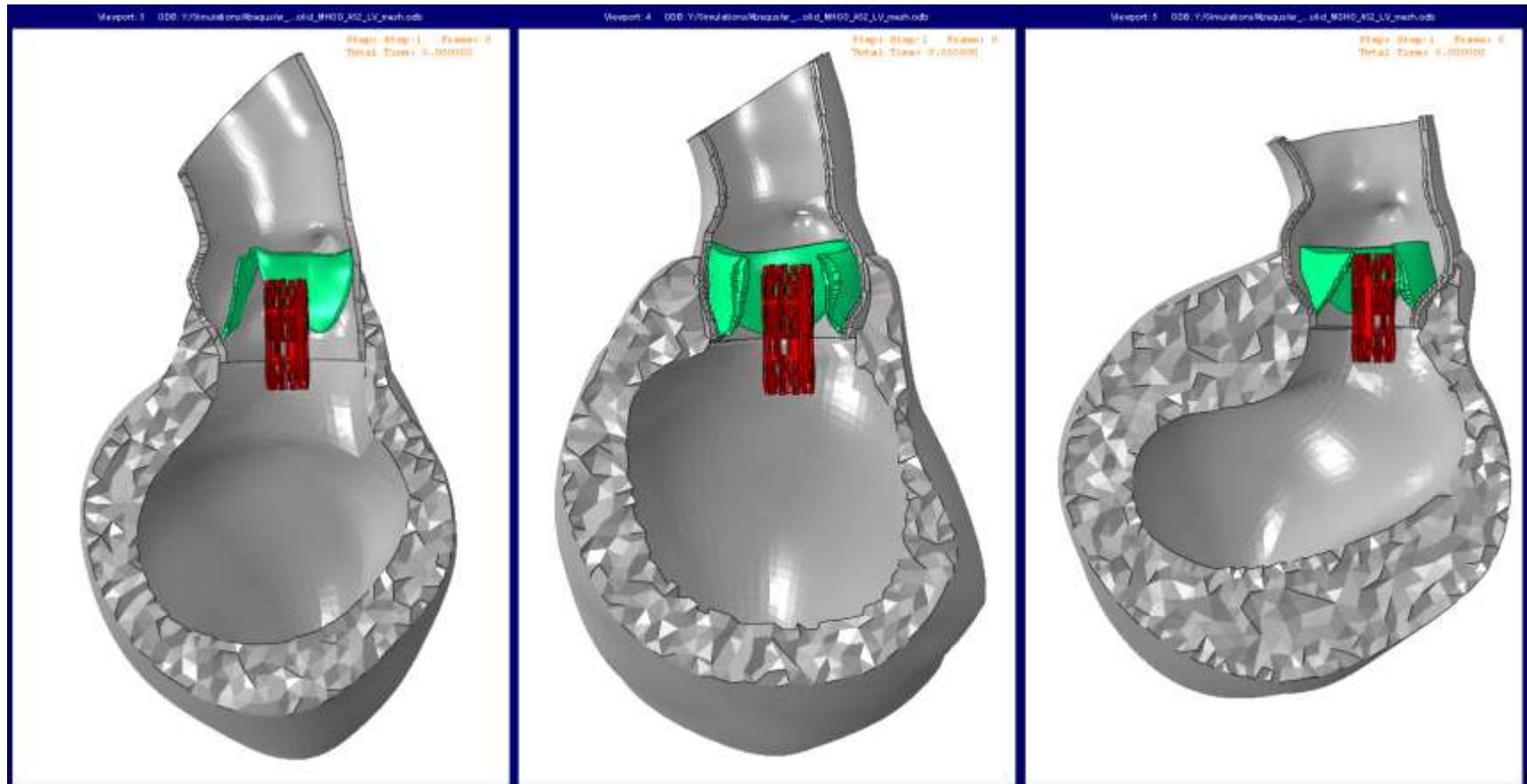


Aortogram And Echo After
Pericardiocentesis And Second Valve
Deployment

*In retrospect, could I have predicted all
of these complications?*

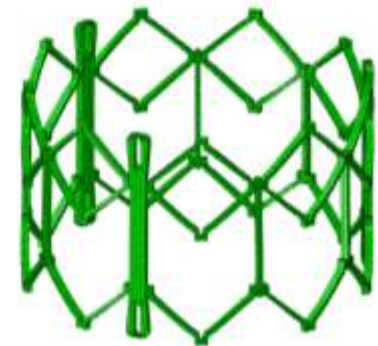
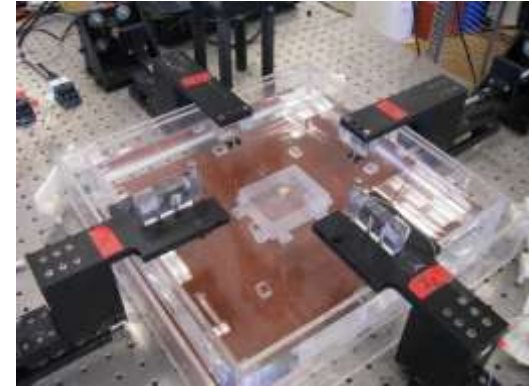
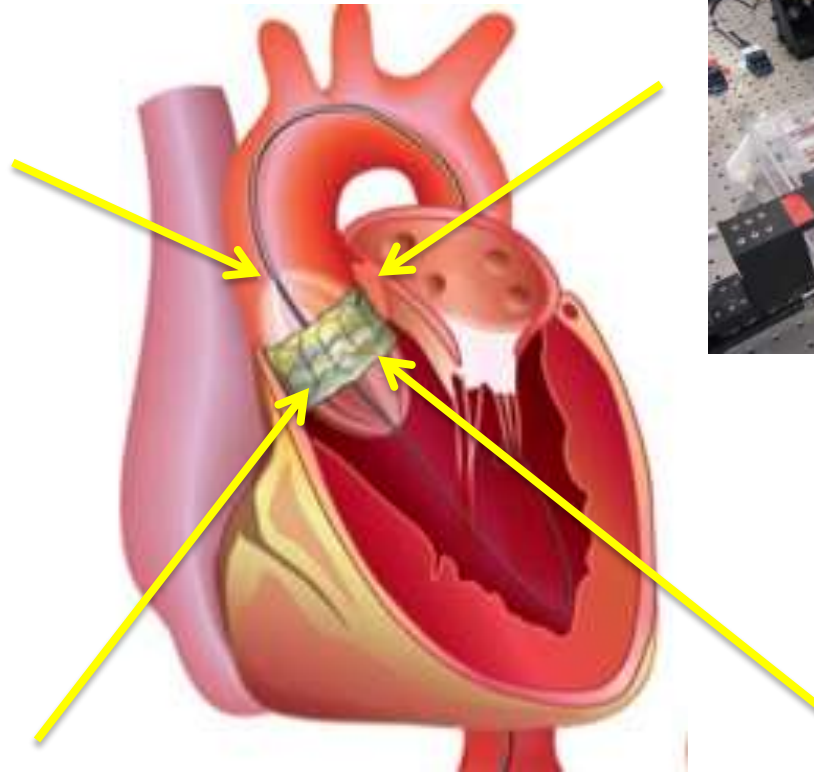
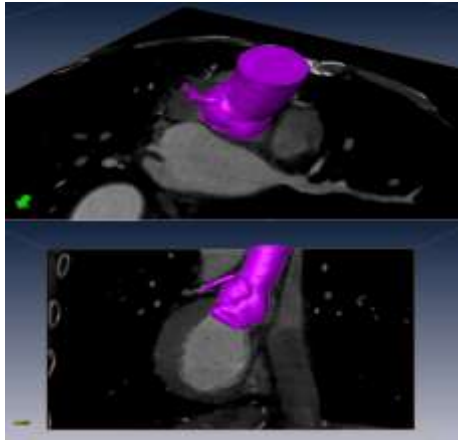
YES

Can we model patient specific results using a CT scan?



* Courtesy Wei Sun

What It Requires?

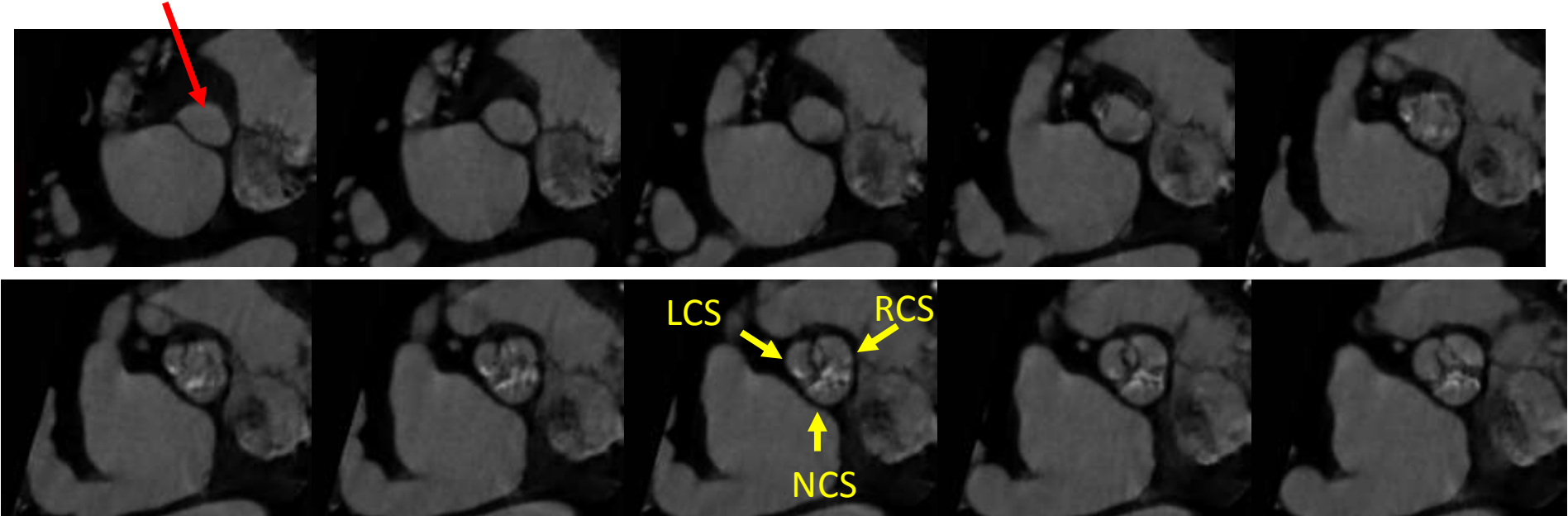


Objective:

Aortic root and
Stent interaction

CASE 1: ANNULUS RUPTURE

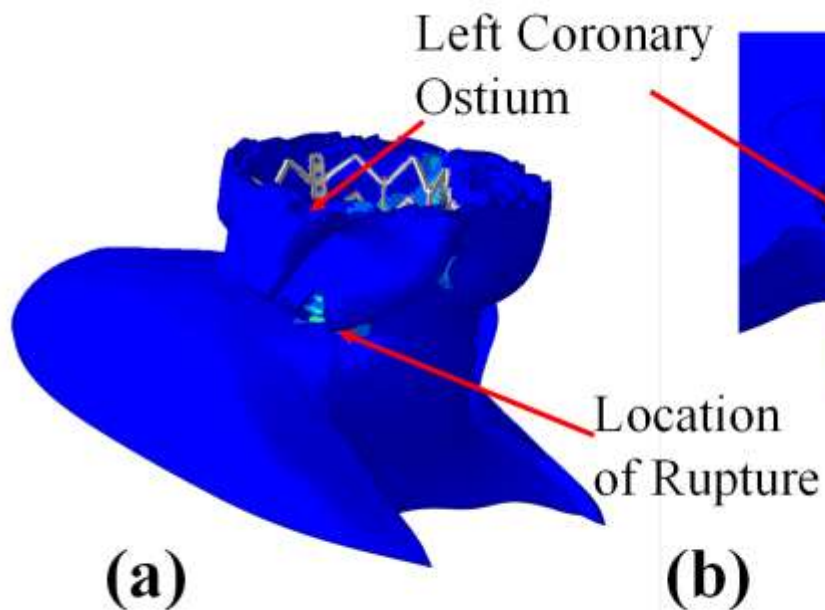
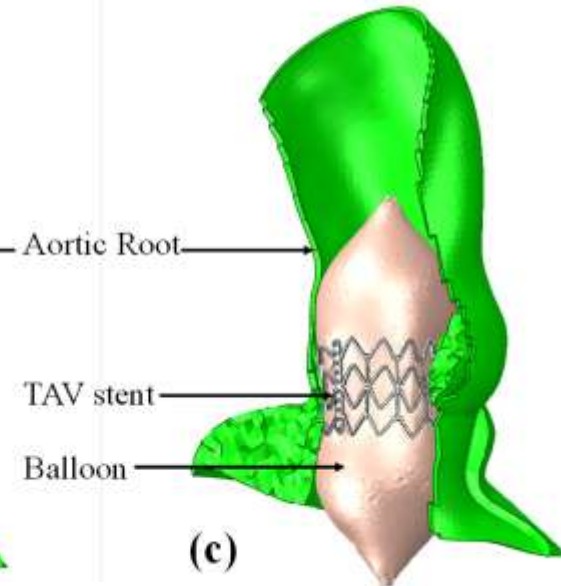
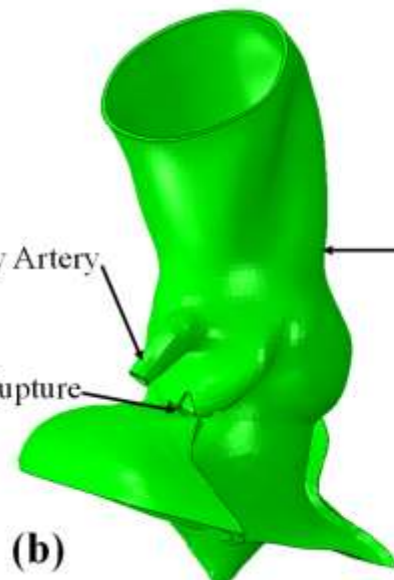
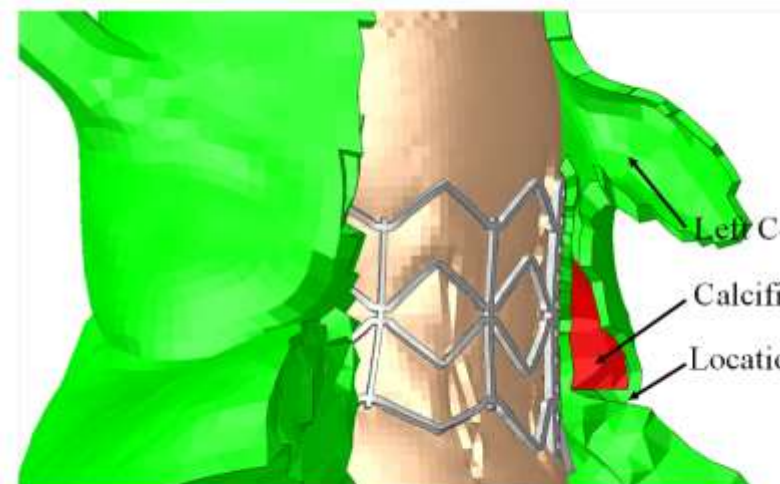
Aortic annulus



Patient Information and Clinical Observations

- 94-yo female with annulus size of 19.6mm
- Only the left coronary leaflet opens
- Calcification concentrates in the non-coronary leaflet

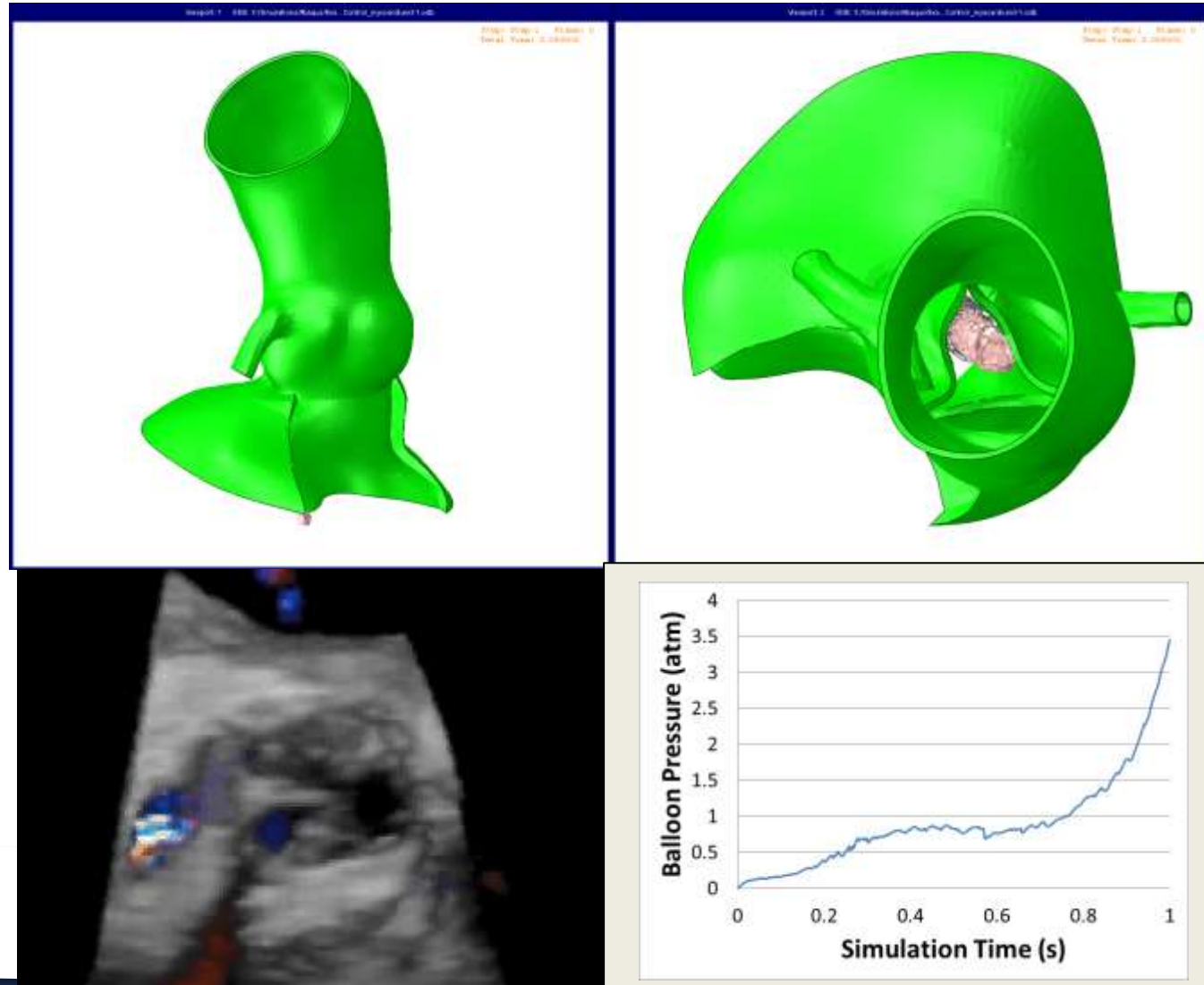
Case Simulation Results



* Courtesy Wei Sun

Case Simulation Results

- Annulus rupture occurs under left main which correlates with findings on echo and at surgery
- Rupture occurs at a pressure of ~ 3.5 atm
- Typical deployment pressure of Edwards Sapien Valve – 2-4 atm
- Rated burst pressure of deployment balloon is 7 atm



* Courtesy Wei Sun

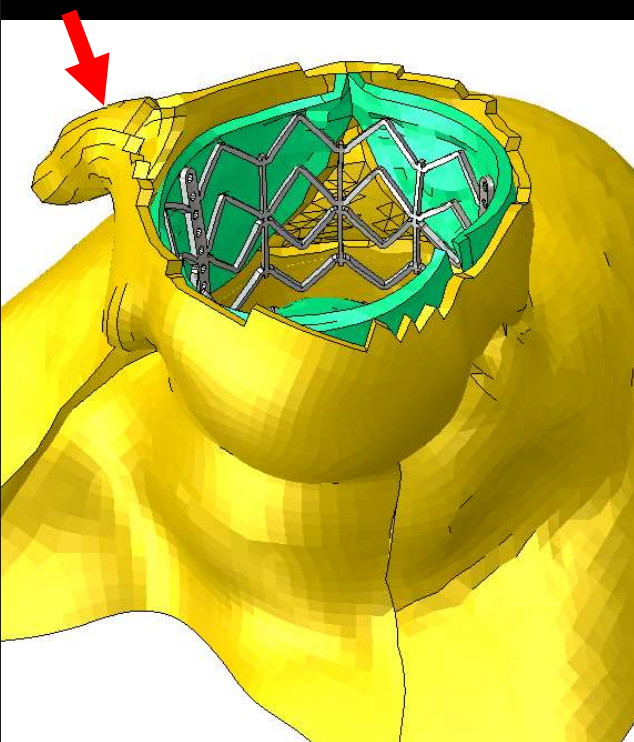
Deployed Aortic Valve

Case 1

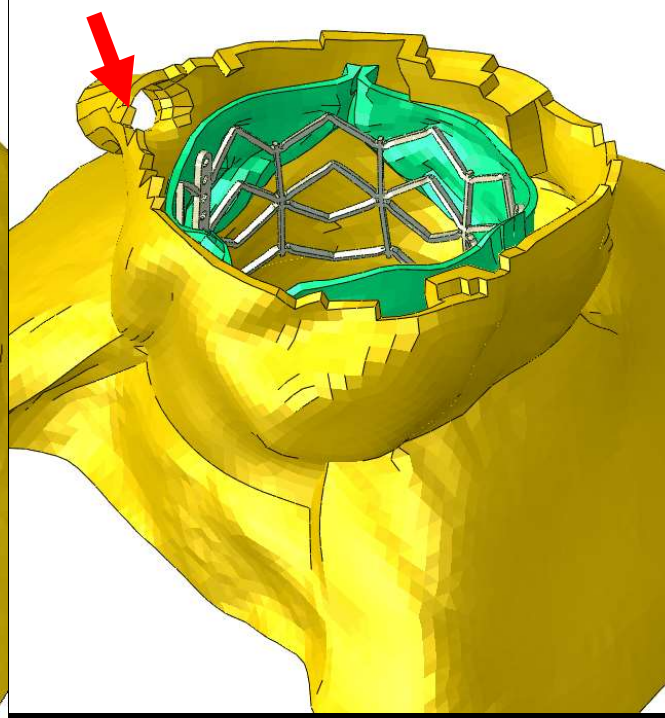
Case 2

Case 3

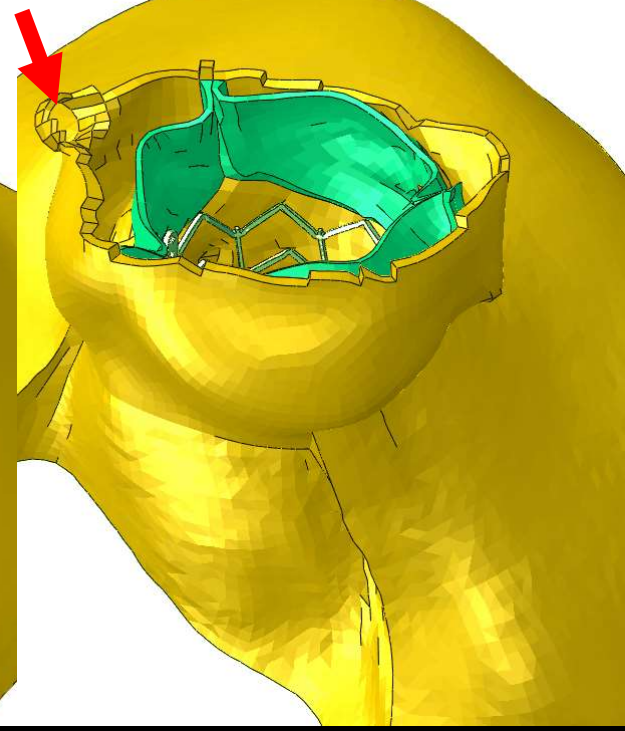
Left CO



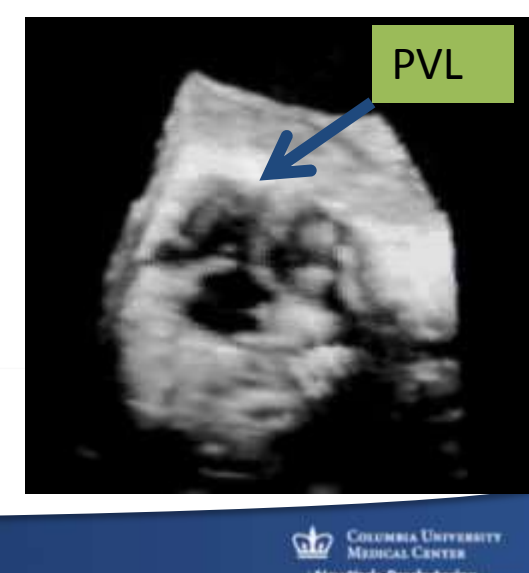
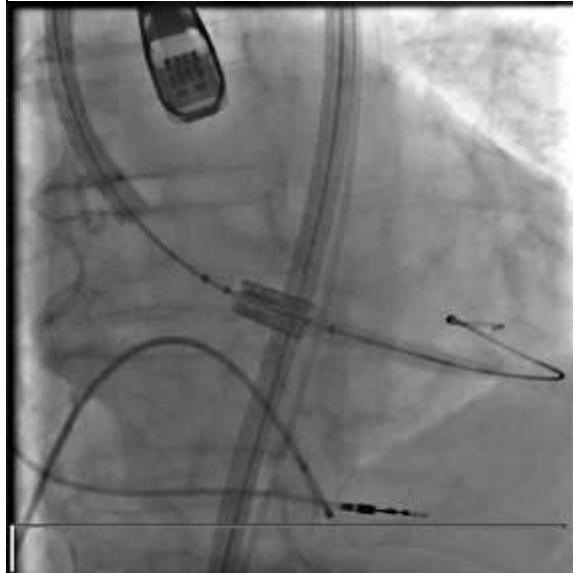
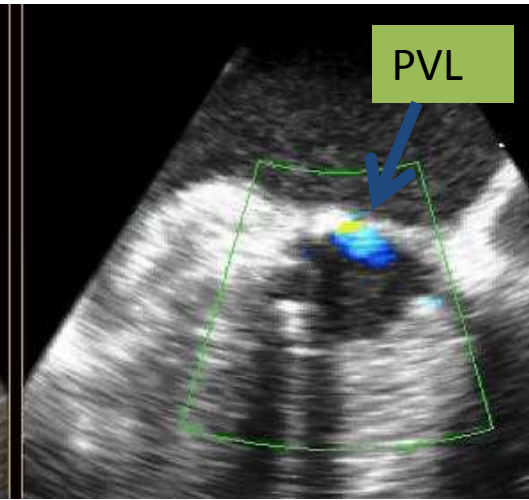
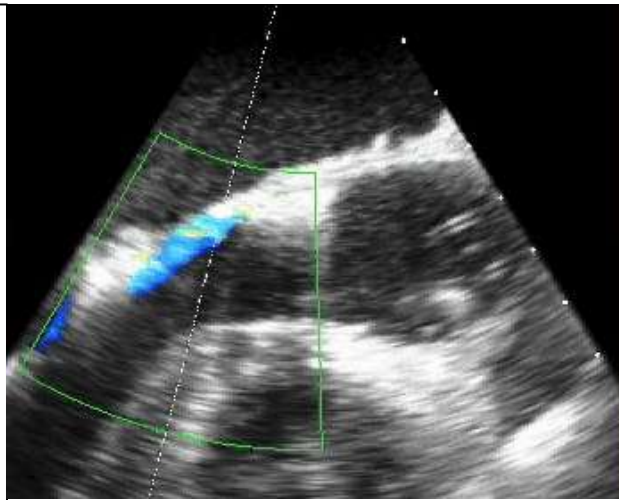
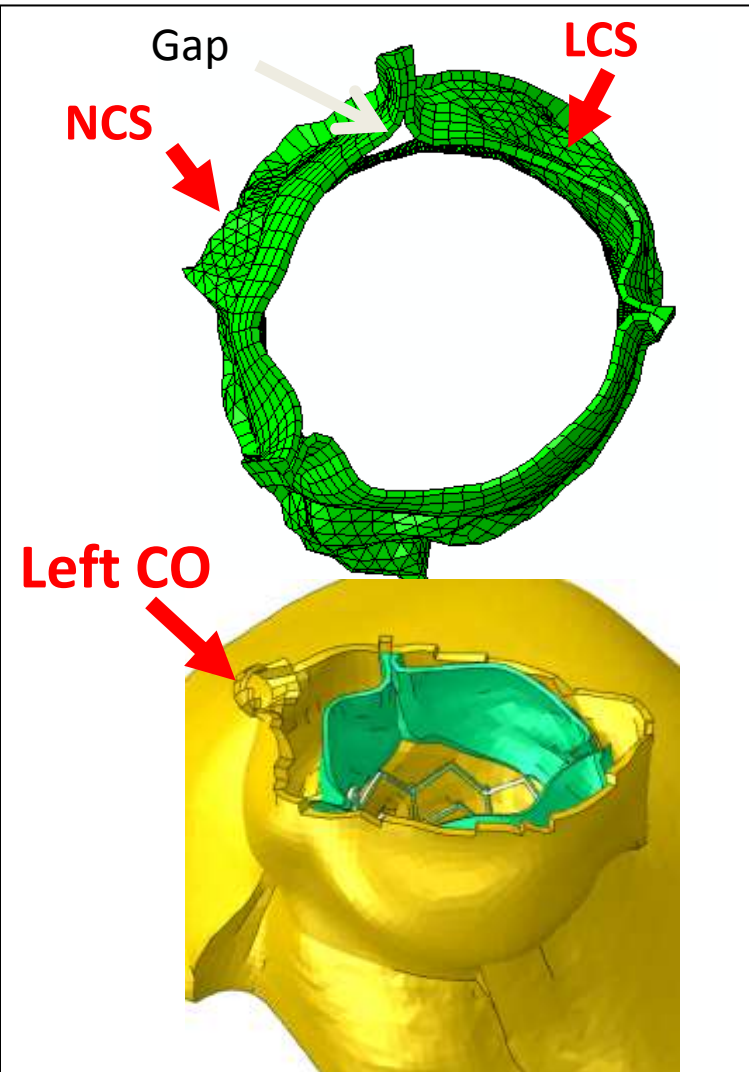
Left CO



Left CO



Predicting Valve Deployment



Final Thoughts

- Complications following TAVR have decreased with improved procedural screening and technique – MDCT essential in every case
- Modeling using FEA of pre-operative CT scans may be a method to identify not only patients at high risk for catastrophic complications but potentially which valve may be better suited for an individual patient
- However, further validation of this technique needs to be performed