12th AP VALVES & STRUCTURAL HEART
AUGUST 10-11 2023
GRAND WALKERHILL SEOUL, KOREA

Sharing Experiences on Why I Choose SAPIEN 3 for a Better Outcome

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I am proctors of Medtronic, Edwards, and Abbott TAVR devices and Boston Scientific cerebral protection device.

Understand the evolving patients' need for TAVI

Extreme High-Risk, inoperable patient

Low-risk, >75year-old patient

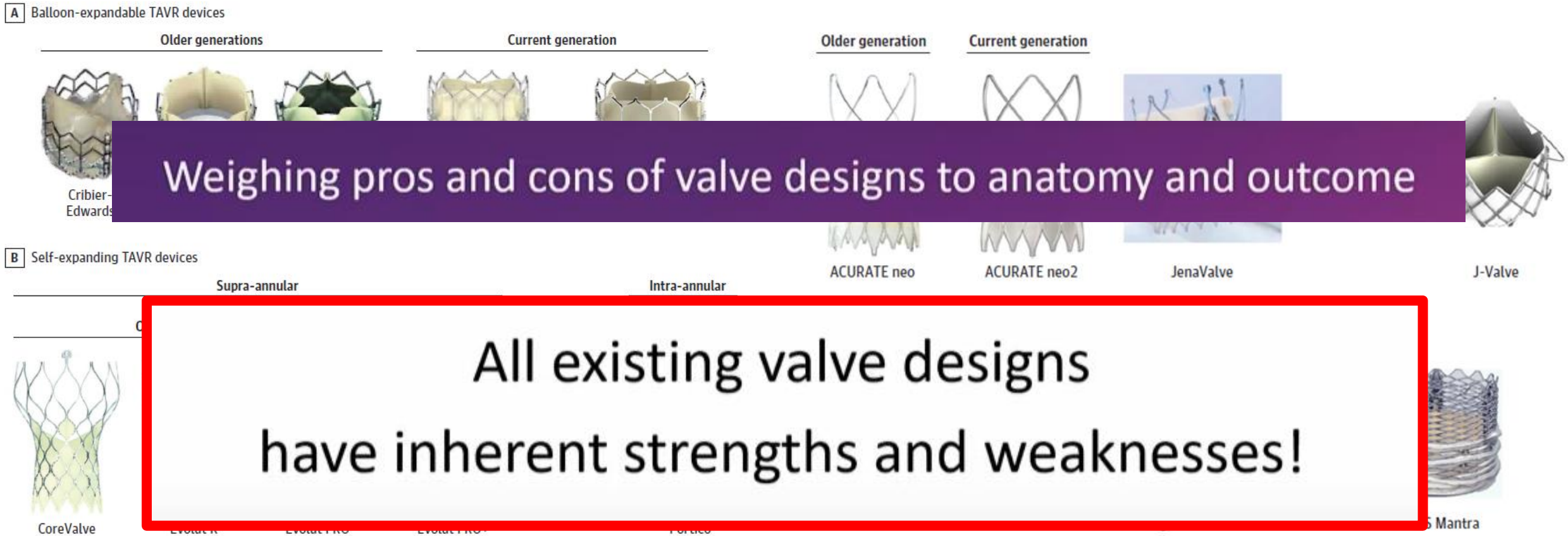
- Optimal results
- Coronary access/concomitant coronary disease
- Concomitant valve disease
- Durability
- Future treatment possibilities (TAV-in-TAV/SAVR after TAVR)

In 2023 we need to address not only procedural outcome but lifetime management of aortic valve disease including:

a. **Minimizing need for a 2nd valve i.e. low rate of SVD**

b. **Having a strategy for a 2nd valve procedure at the index procedure**

Currently available THVs on the market



Weighing pros and cons of valve designs to anatomy and outcome

All existing valve designs

have inherent strengths and weaknesses!

12th
AP VALVES & 2023
STRUCTURAL HEART

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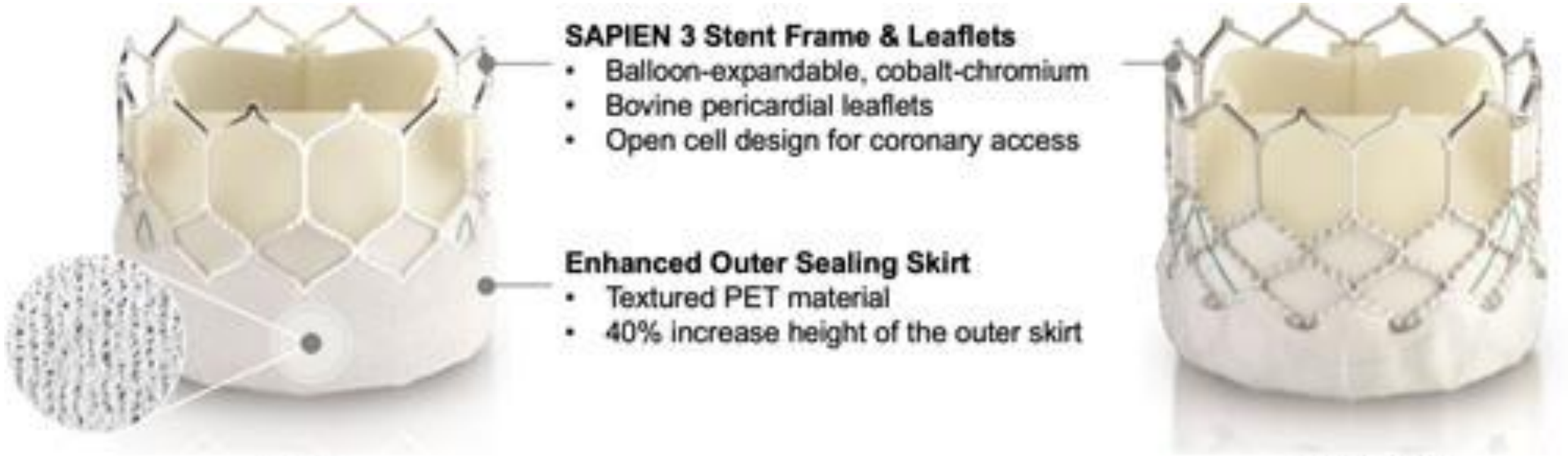
The Solution

HOW TO
OVERCOME CHALLENGES

In performing TAVR

Sapien 3 /Sapien 3 Ultra



PVL after TAVR is remarkably reduced by the S3 annular sealing skirt

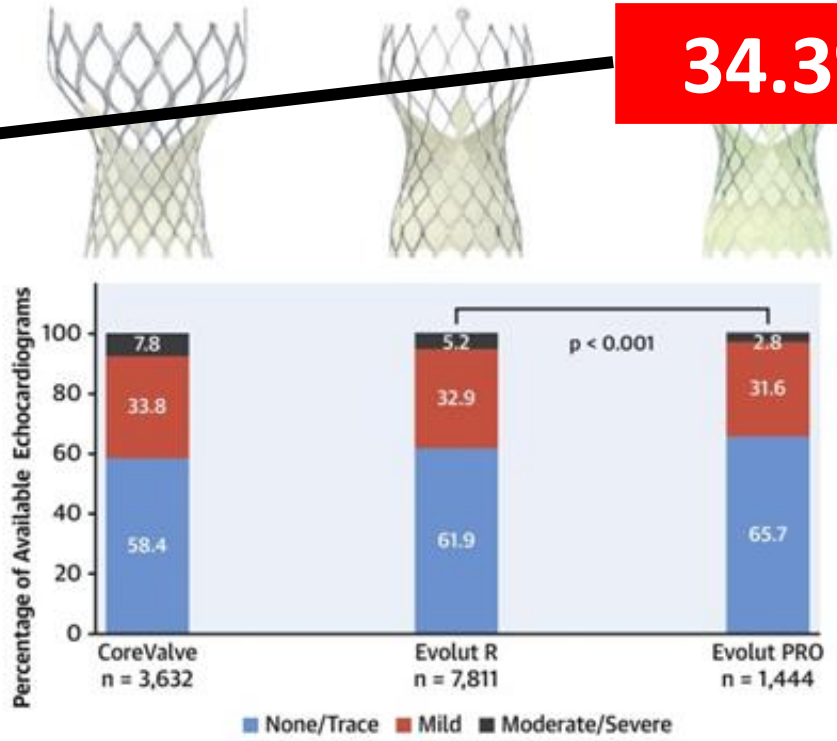
CENTRAL ILLUSTRATION: Paravalvular Leakage After Transcatheter Aortic Valve Replacement With SAPIEN 3 Versus SAPIEN 3 Ultra Transcatheter Heart Valve

20.3%

Rheude, T. et al. J Am Coll Cardiol Intv. 2020;13(22):2631-8.

CENTRAL ILLUSTRATION: Total Aortic Regurgitation at 30 Days With 3 Generations of Self-Expanding, Supra-Annular Transcatheter Valves

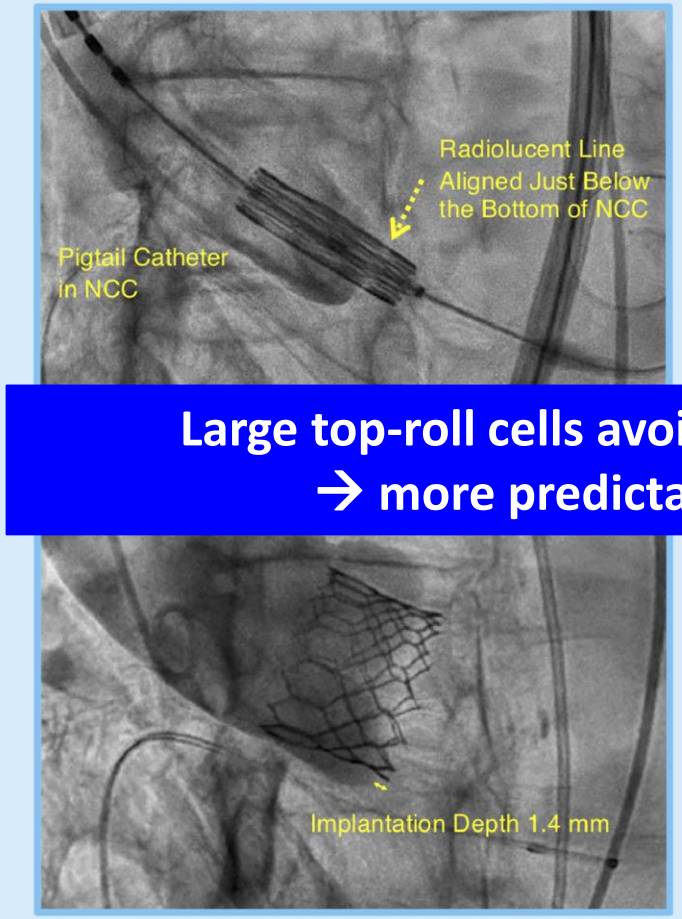
34.3%



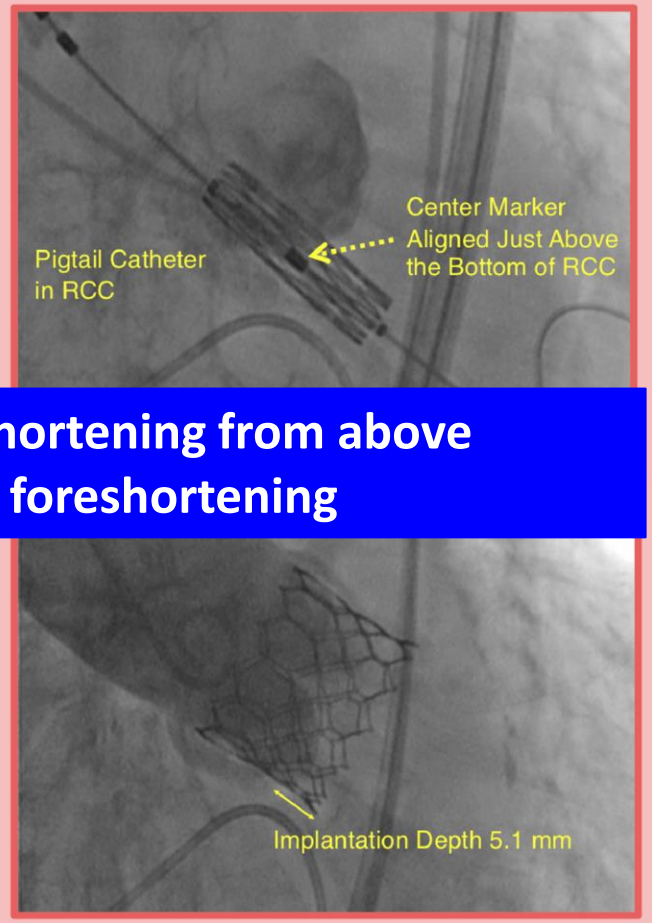
Forrest, J.K. et al. J Am Coll Cardiol Intv. 2020;13(2):170-9.

Aim high to avoid conduction disturbance w/ Sapien 3

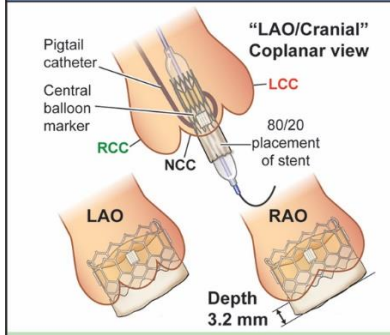
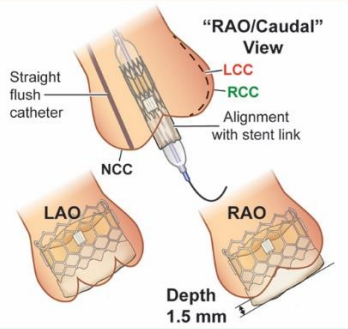
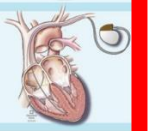
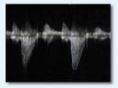
Radiolucent Line-guided Implantation



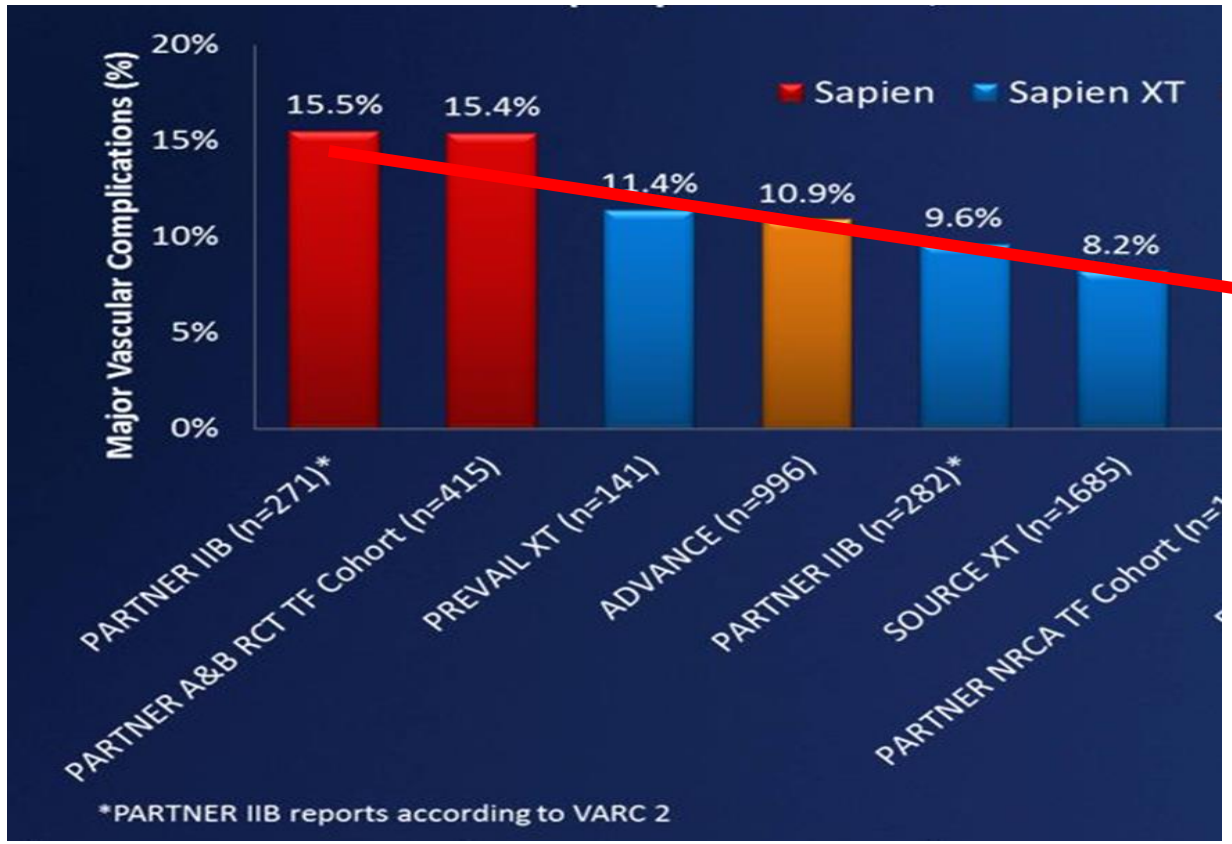
Center Marker-guided Implantation

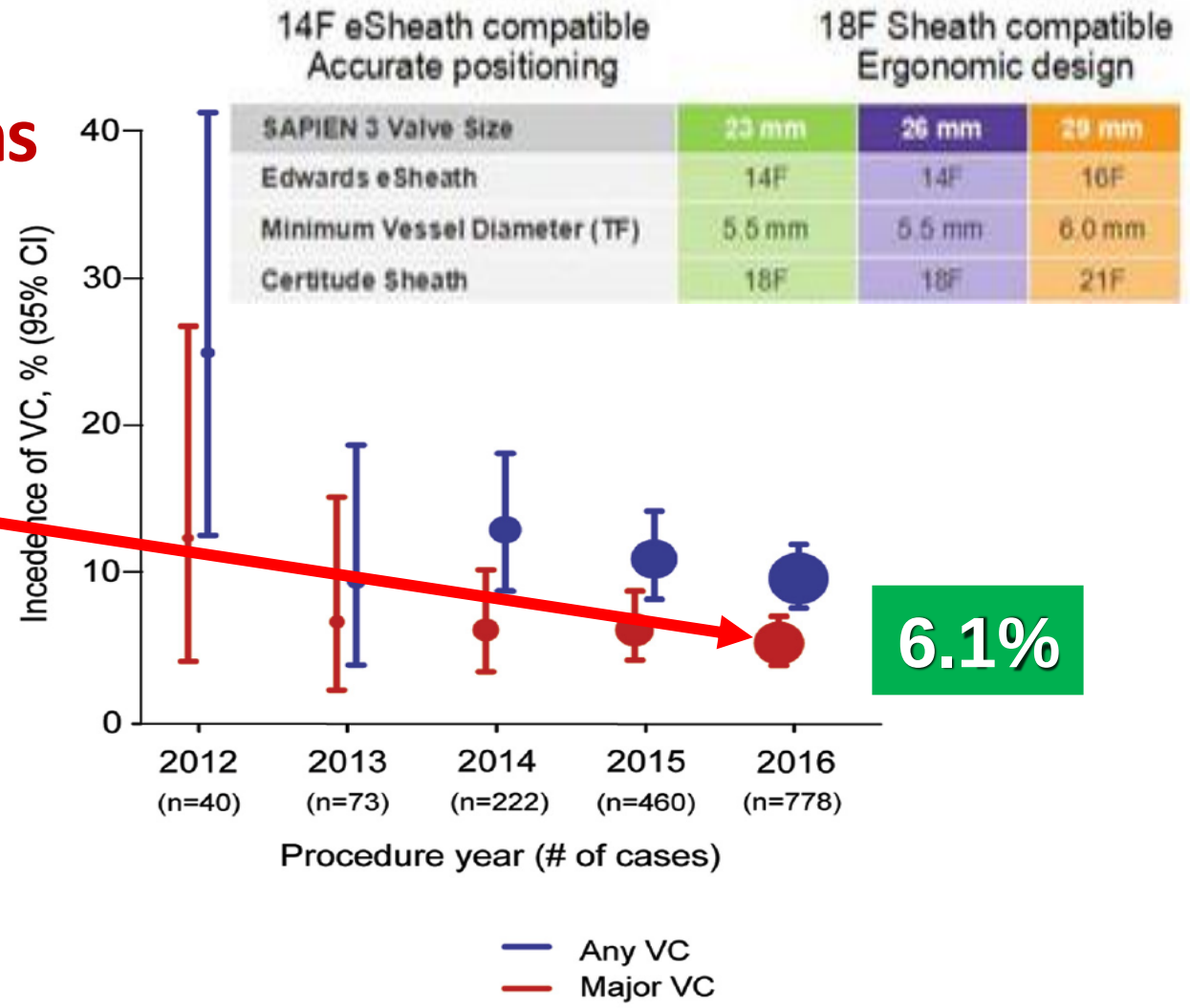


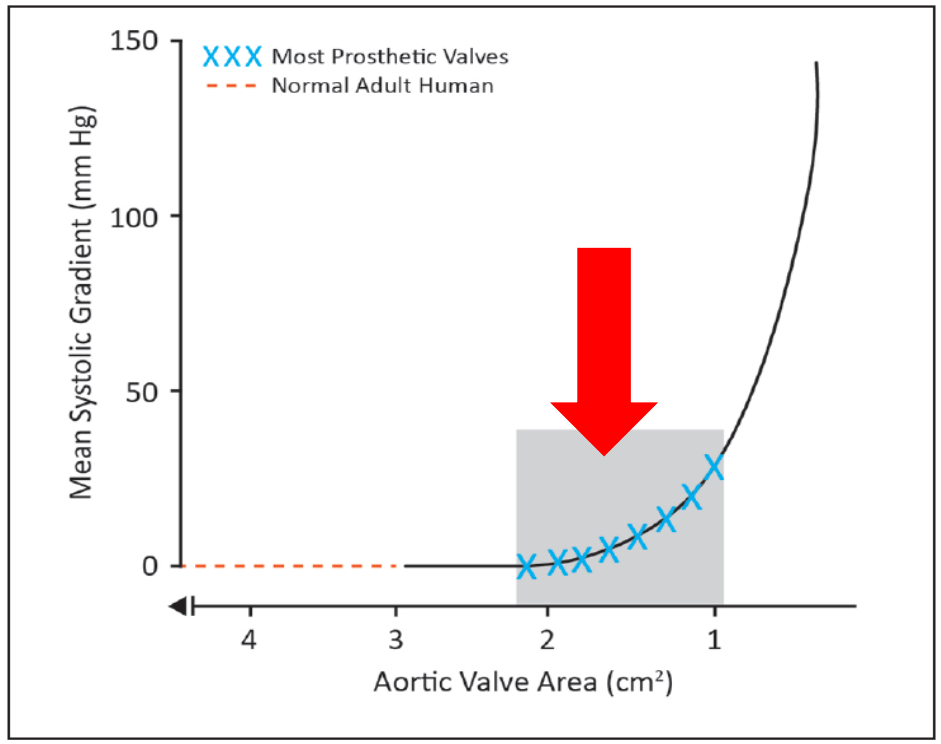
Large top-roll cells avoid shortening from above
→ more predictable foreshortening

	Conventional Deployment Technique		High Deployment Technique
			
Implantation Depth	3.2 ± 1.9 mm		1.5 ± 1.6 mm 
30-day Permanent Pacemaker Implantation	13.1%		5.5% 
New-onset Left Bundle Branch Block at Discharge	12.2%		5.3% 
1-year Aortic Regurgitation	15.9% 2.7%	Mild (≥1+ – <2+) Moderate-to-severe (≥2+)	16.5% 1% 
1-year Hemodynamic Performance	11.8 ± 4.9 mmHg 22.5 ± 9 mmHg 0.48 ± 0.13	Mean gradient Peak gradient Doppler velocity index	13.1 ± 6.5 mmHg 25 ± 11.9 mmHg 0.47 ± 0.15 

The lower delivery profile of S3 reduced major vascular complications

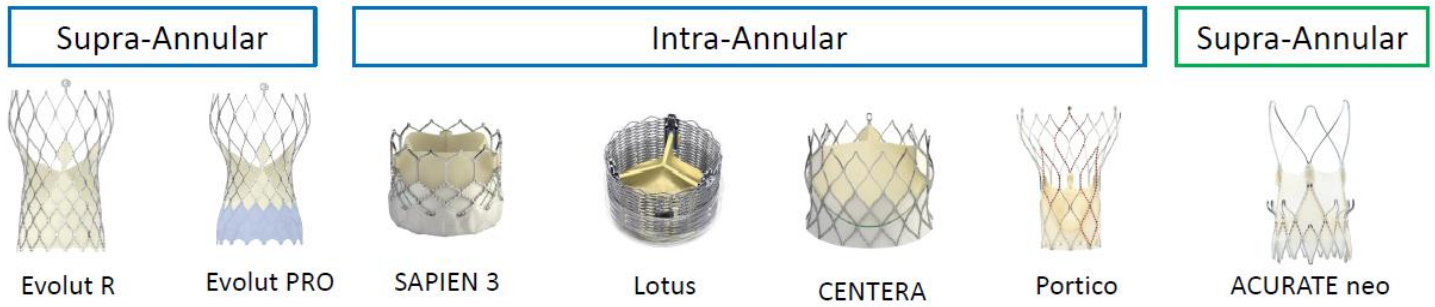


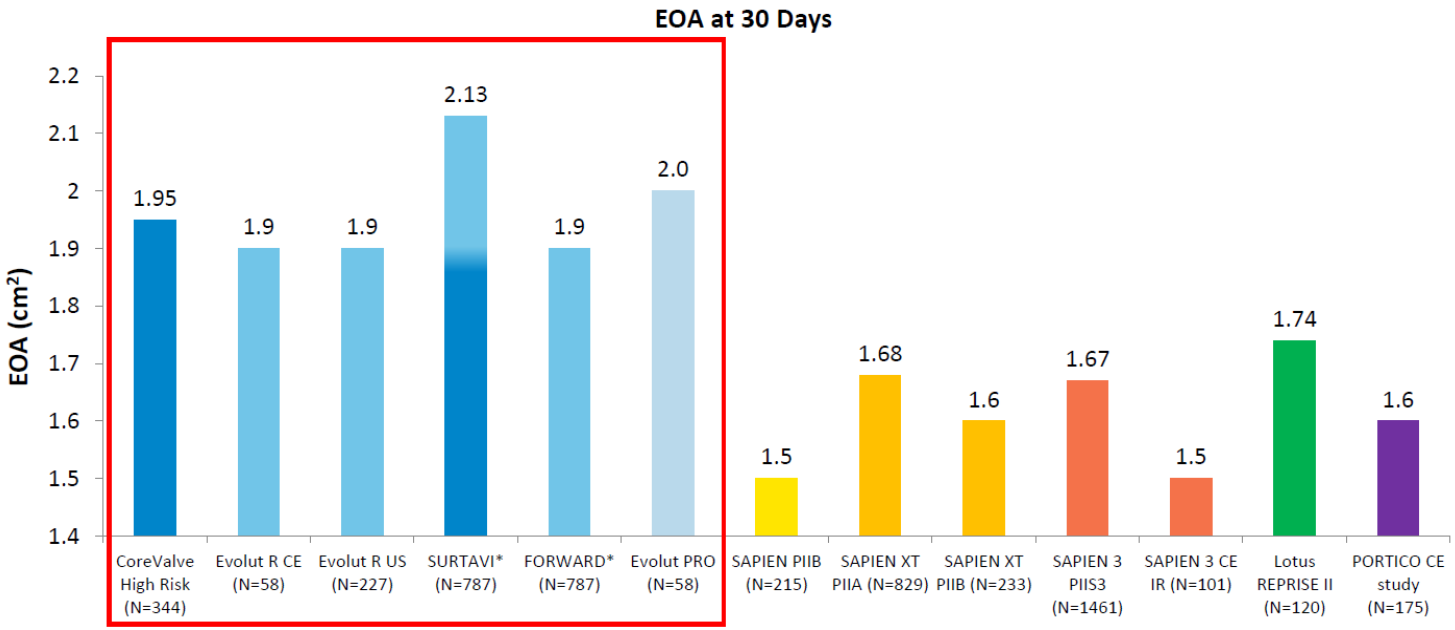




The gradient is proportional to the area available for flow, which is related to the square of the EOA radius.

The largest EOAs have been achieved with supra-annular self-expanding THVs!

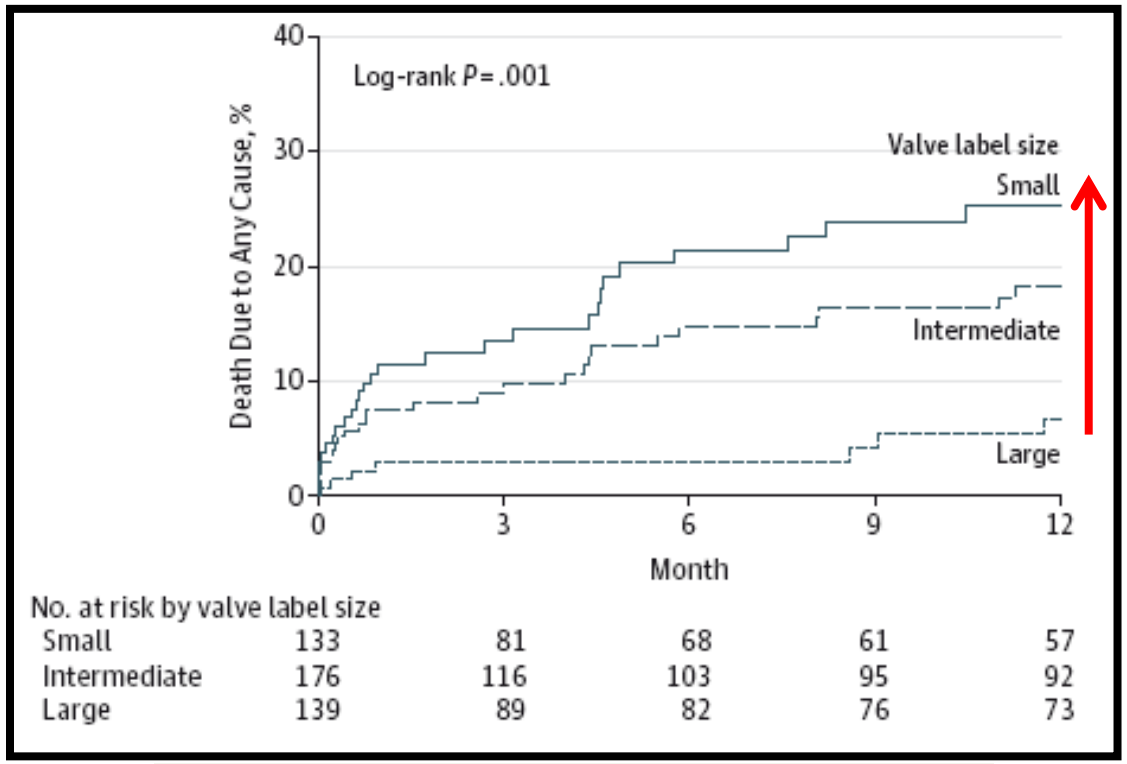




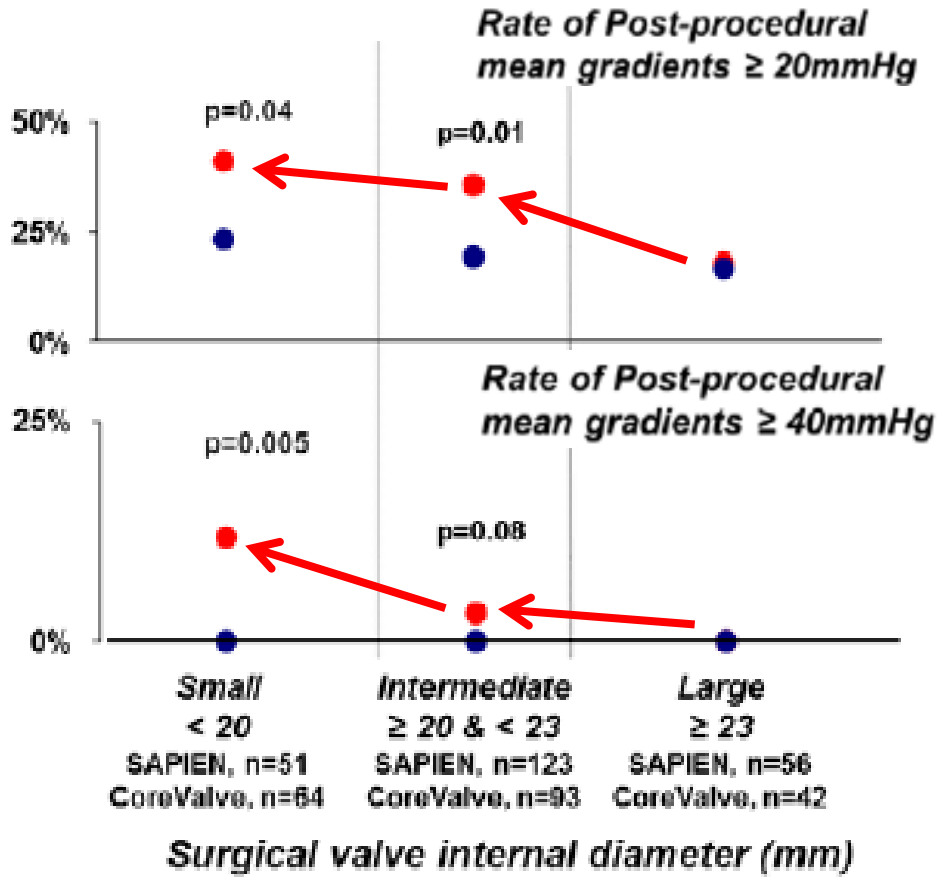
The device chosen matters in VIV TAVR for smaller surgical valves!

In the Edwards SAPIEN group, there was a negative trend between the bioprosthesis size and high post-procedural gradients rates

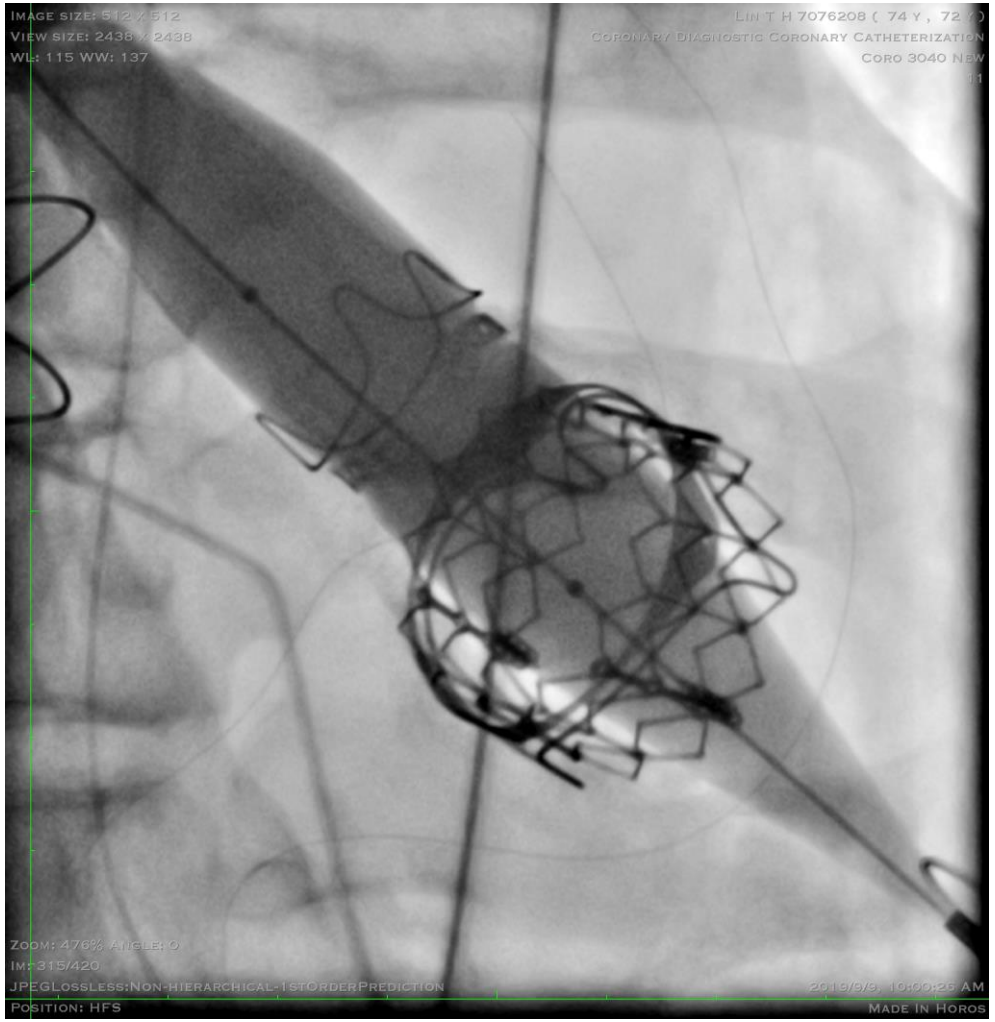
Surgical valve label size

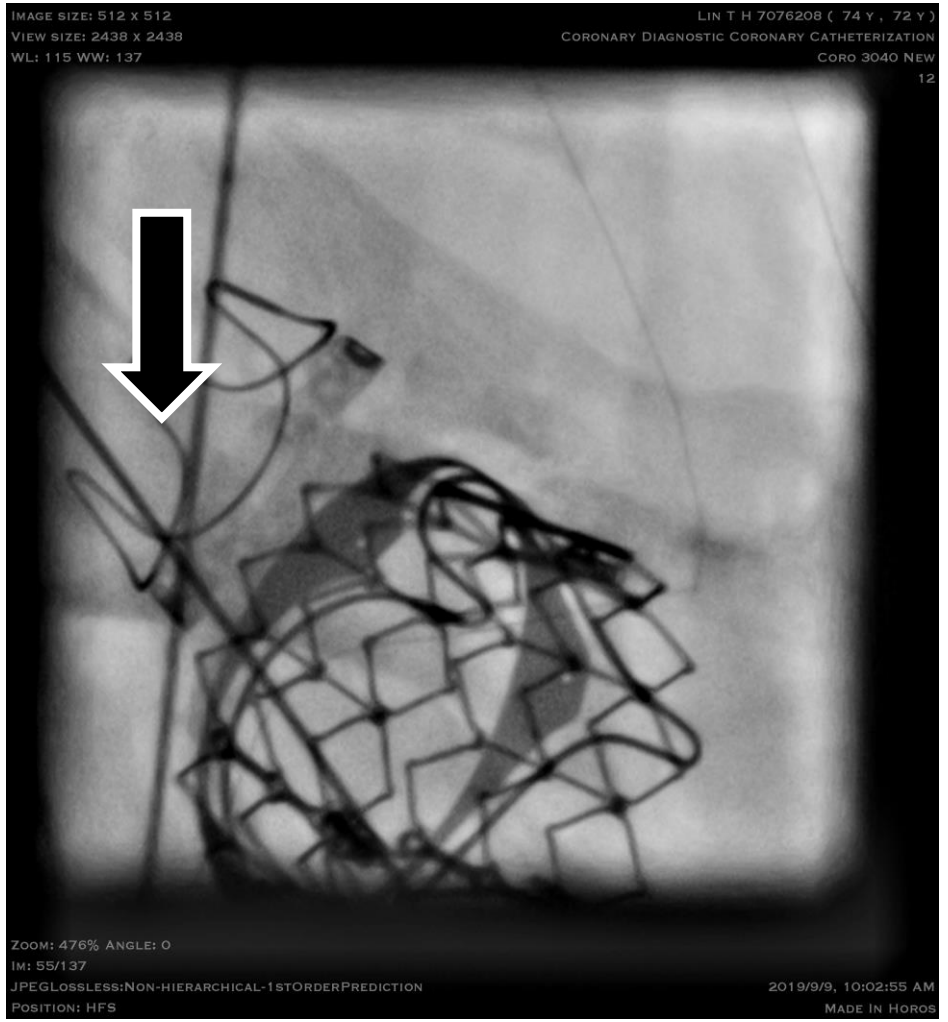


JAMA. 2014;312(2):162-170. doi:10.1001/jama.2014.7246



Bioprosthetic valve fracture

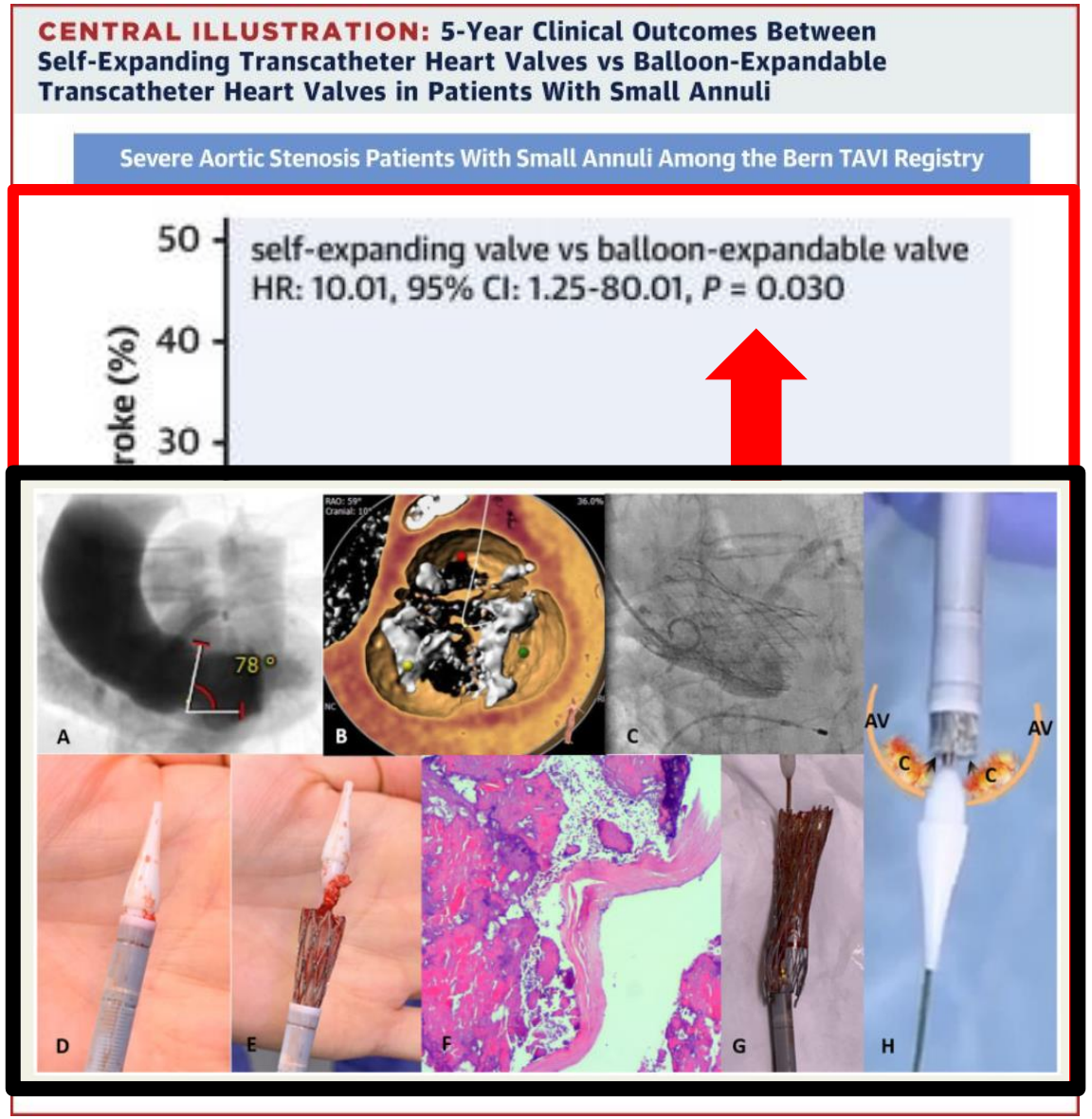




SEV vs. BEV in small annuli

- The echocardiographic hemodynamic advantage of self-expanding THVs **was not associated with better clinical outcomes** compared with balloon-expandable THVs up to 5 years in patients with small annuli.

- **Disabling stroke occurred more frequently in patients with a self-expanding THV** than those with a balloon-expandable THV (6.6% vs 0.6%; P = 0.030).



PCR online.com

PROTECTED TAVR: Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement

CRF TCT SEPTEMBER 16-19, 2022

Population

- 3,000 TAVR procedures from 51 sites
- Transfemoral TAVR with commercially available devices
- Baseline: 79y; ♀: 42% CEP group, 38% control group; mean STS: 3.4%

Interventic

Cerebral embolic pro
w/ Sentinel
(Boston Scientif

- Filter based (two
filters ➡ brachioc
and left common
artery)
- Placed via right ra

Severe AS patients undergoing transfemoral TAVR

TAVR w/

All stroke (1° EP)

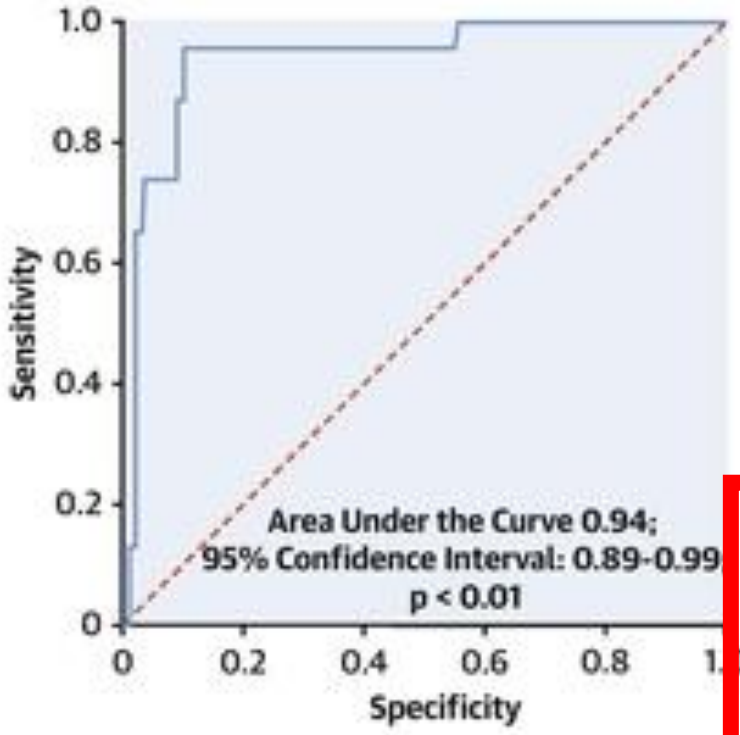
Disabling stroke (2° EP, not powered)

The primary endpoint of all stroke was not reduced when using CEP. However, given the significant reduction of disabling stroke (secondary EP) further investigation is warranted.

Cerebral protection device

Coronary reaccess after TAVR

CENTRAL ILLUSTRATION: Predictors of Unsuccessful Coronary Cannulation After Transcatheter Aortic Valve Replacement and Receiver-Operating Characteristic Curve Analysis Applied to Logistic Regression Model



Transcatheter Aortic Valve/
Sinuses of Valsalva Relation
Odds Ratio 1.1;
95% CI: 1.0-1.2; p < 0.01

Transcatheter Aortic Valve Implant Depth
Odds Ratio 1.7;
95% CI: 1.3-2.3; p < 0.01

Evolut Transcatheter Aortic Valve
Odds Ratio 29.6;
95% CI: 2.6-335.0; p < 0.01

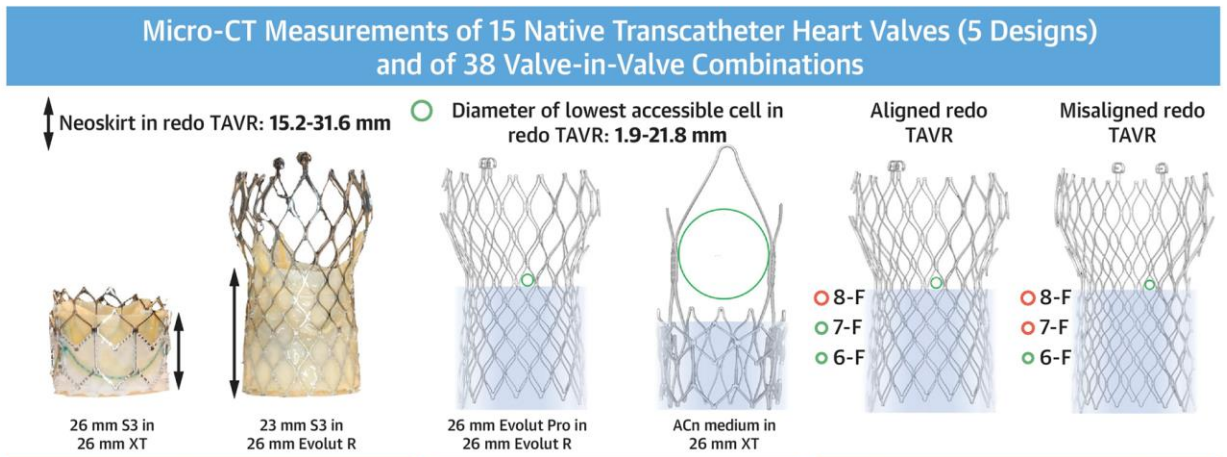
Barbanti, M. et al. J Am Coll Cardiol Intv. 2020;13(21):2542-55.

REACESS Trial

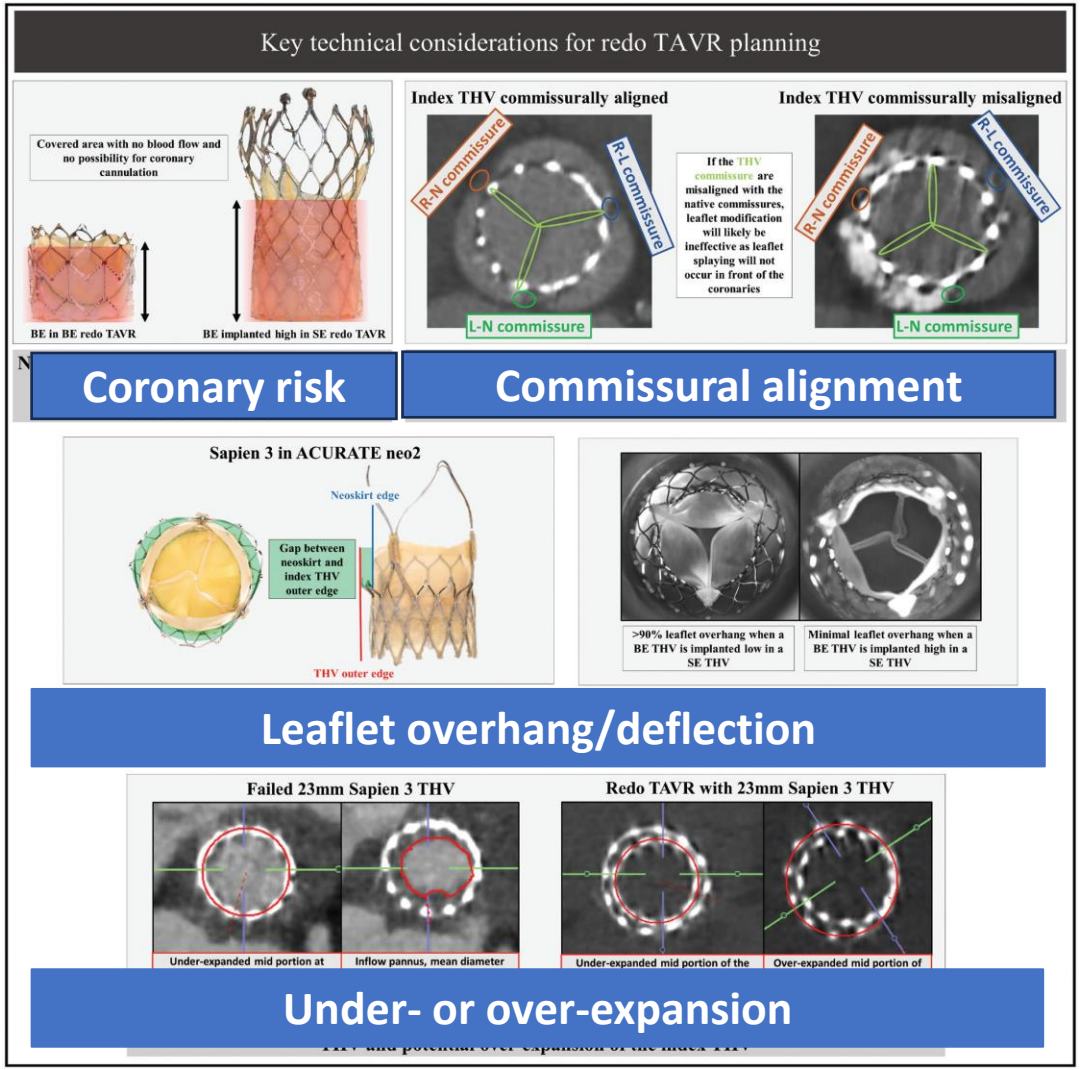
The near future will see an increase in redo-TAVR procedures

Coronary risk
Hemodynamics

CENTRAL ILLUSTRATION: The Impact of Transcatheter Heart Valve Design and Implant Characteristics for Coronary Access After Transcatheter Aortic Valve Replacement and Redo TAVR



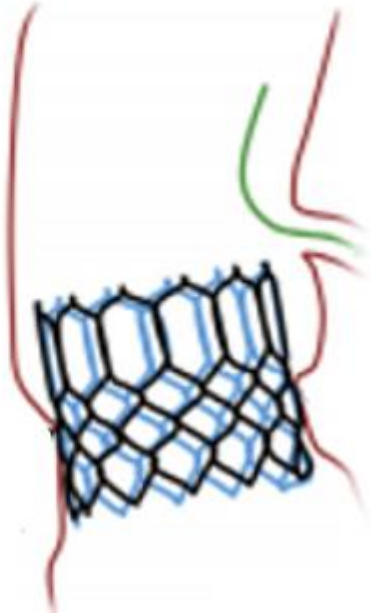
Meier D, et al. J Am Coll Cardiol Intv. 2022;15(15):1519-1531.



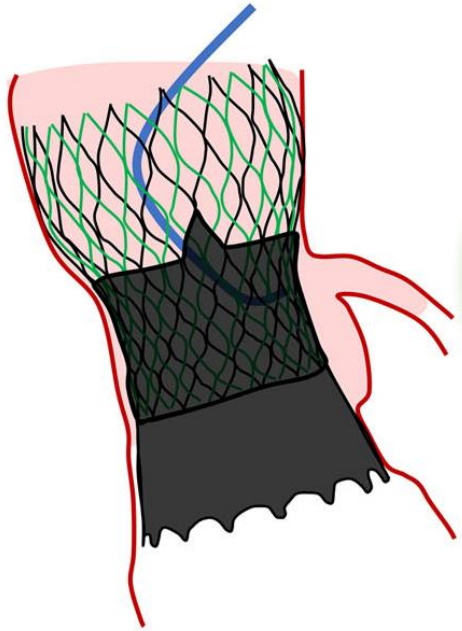
TAVI-in-TAVI and coronary access

Short valves with risk plane sub-coronaries allows for future coronary access

- Taller valves with risk plane above coronaries are theoretically feasible or even unfeasible based on the distance valve to aorta (VTA)



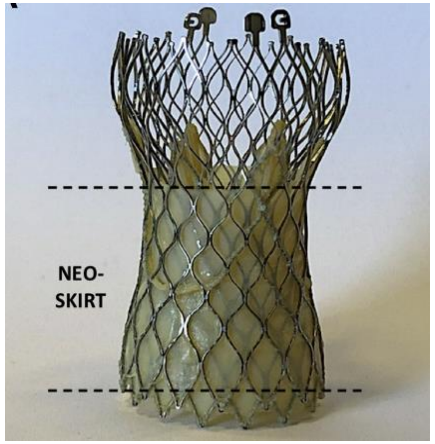
78.8% unobstructed access to coronaries[1] n=137



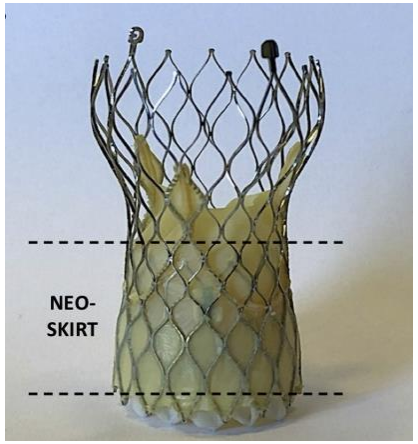
Up to **78%** inaccessible coronary arteries[2] n=81

1.Rogers T, Greenspun B, Weissman G, et al. Feasibility of Coronary Access and Aortic Valve Reintervention in Low-Risk TAVR Patients. JACC. 2020. VOL 13 (16).
2.Forrestal B, Case B, Yerasi C, et al. Risk of Coronary Obstruction and Feasibility of Coronary Access After Repeat Transcatheter Aortic Valve Replacement With the Self-Expanding Evolut Valve. Circulation. 2020. VOL 13 (12).

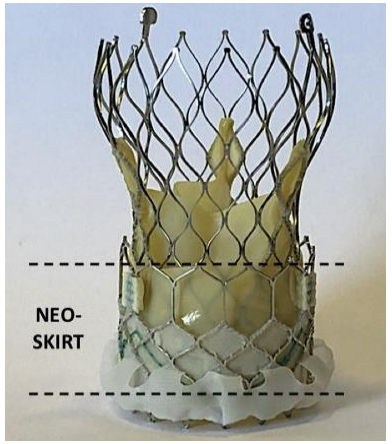
SAPIEN-first TAVI-in-TAVI has more favorable coronary access (BEV-in-BEV) and hemodynamics (SEV-in-BEV)



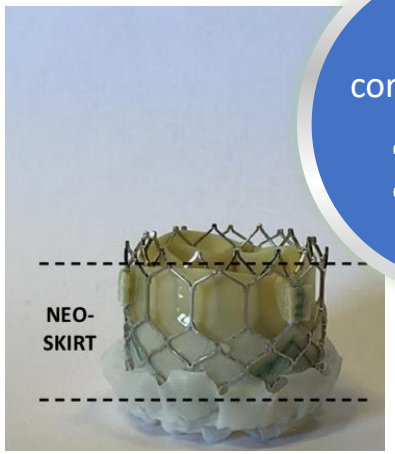
SEV-in-SEV



BEV-in-SEV



SEV-in-BEV



BEV-in-BEV

Limited coronary access **10%**

Valve choice today is also a valve choice for tomorrow

1. De Backer O, Landes Uri, Fuchs A, et al. Coronary access after TAVR-in-TAVR as evaluated by multidetector computed tomography. JACC: Cardiovascular Interventions. 2020;13(21).

TAVR for bicuspid AS

ORIGINAL ARTICLE

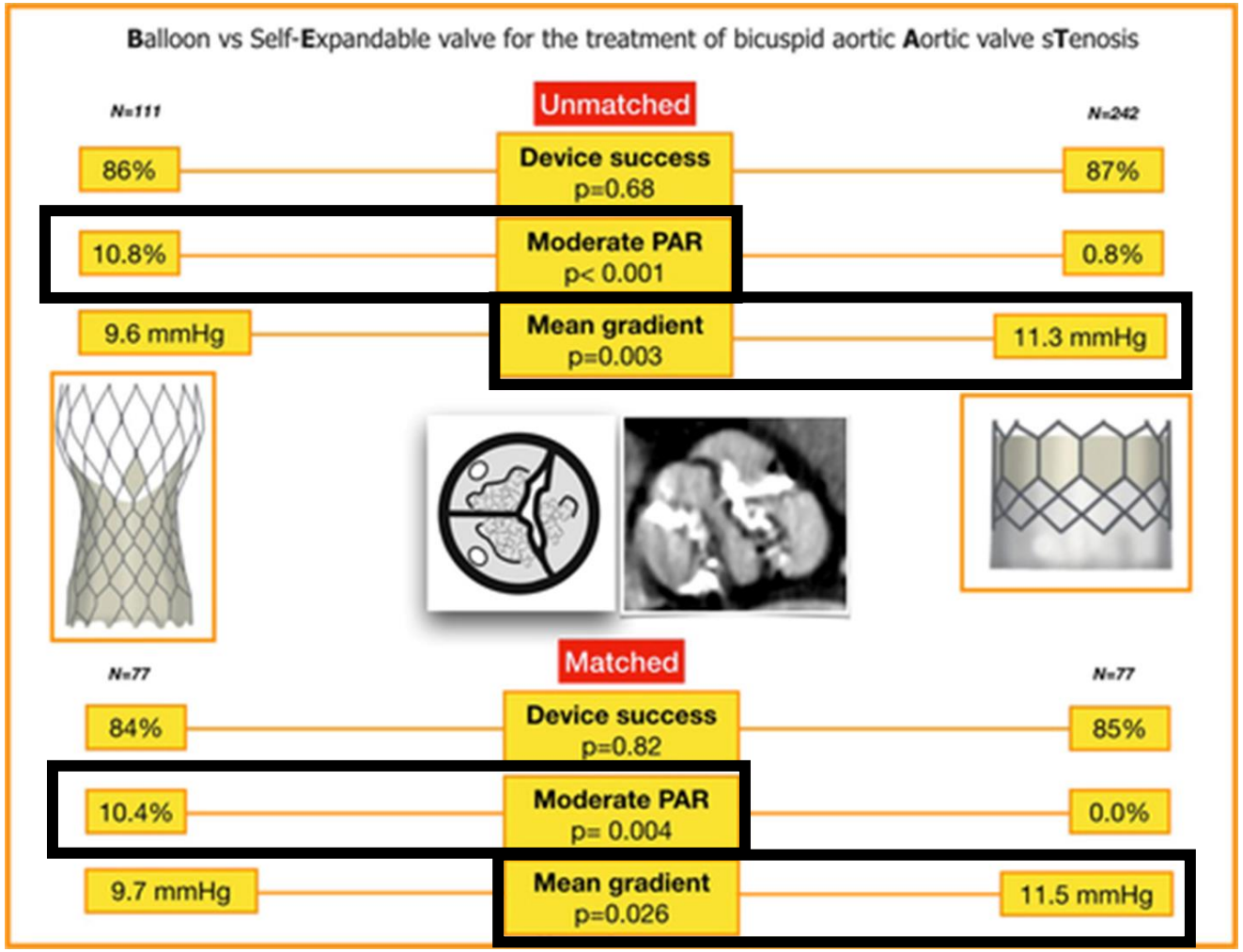
Balloon Versus Self-Expandable Valve for the Treatment of Bicuspid Aortic Valve Stenosis

Insights From the BEAT International Collaborative Registry

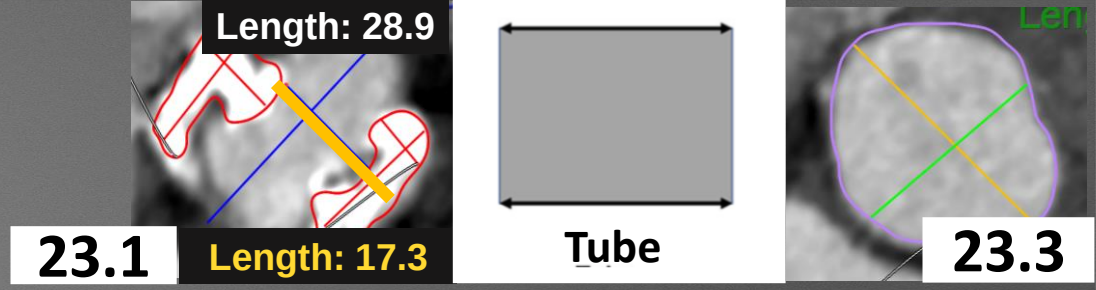
WHAT THE STUDY ADDS

- **Balloon-expandable** valves have **higher gradients** when used in bicuspid anatomies and **a trend toward a higher rate of annular ruptures**.
- **Self-expandable** valves have **higher rate of residual moderate-to-severe PVL**.

Mangieri et al. Circ Cardiovasc Interv. 2020;13:e008714.
DOI: 10.1161/CIRCINTERVENTIONS.119.008714



BEV in Bicuspid AS

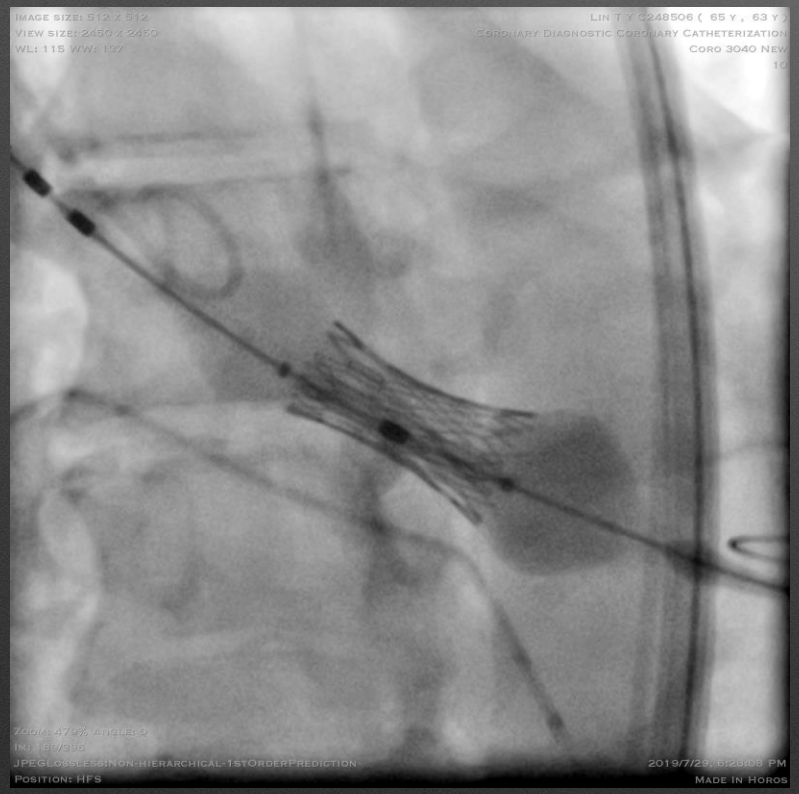


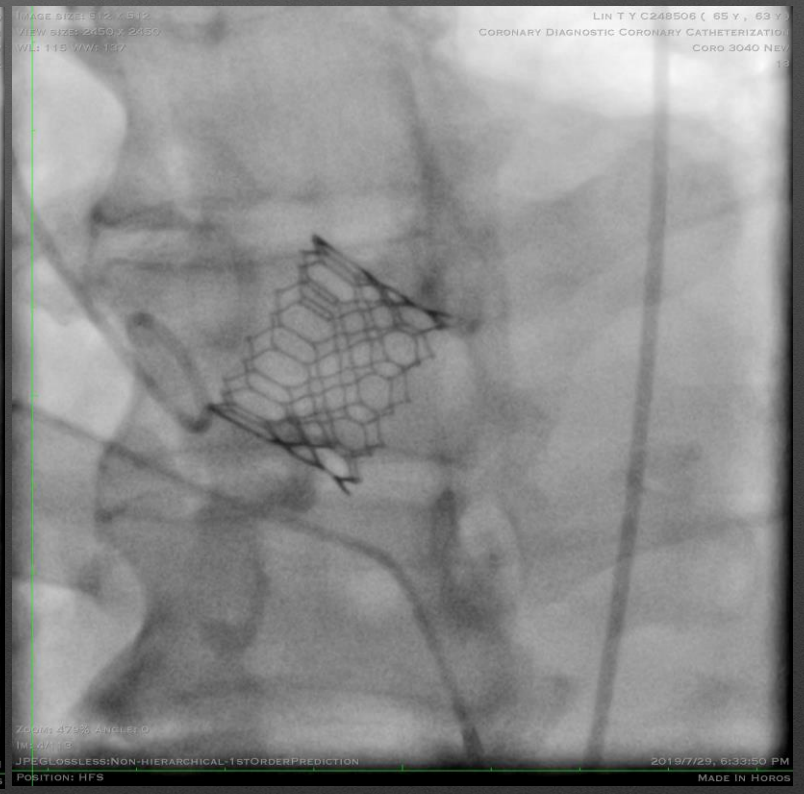
Stepwise deployment

23 mm S3 full volume without predilation

Post-dilation with full volume + 1 ml

Final angiography





Anchoring

Optimization

TAVR in patients w/ large annuli

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Transcatheter Aortic Valve Replacement in Large Annuli Valves With the Supra-Annular, Self-Expandable Evolut Platform in a Real-World Registry

Luis Augusto P. Dallan, MD, PhD; Gilbert Tang, MD; John K. Forrest, MD; Michael J. Reardon, MD; Wilson Y. Szeto, MD; Susheel K. Kodali, MD; Cristian Baeza, MD; Ruth Eisenberg, MS; Guilherme F. Attizzani, MD

WHAT IS KNOWN

- Symptomatic severe aortic stenosis patients with very large (≥30 mm) aortic annulus have limited transcatheter options.
- Understanding of the risk and benefits of treatment options is important for decision-making.

WHAT THE STUDY ADDS

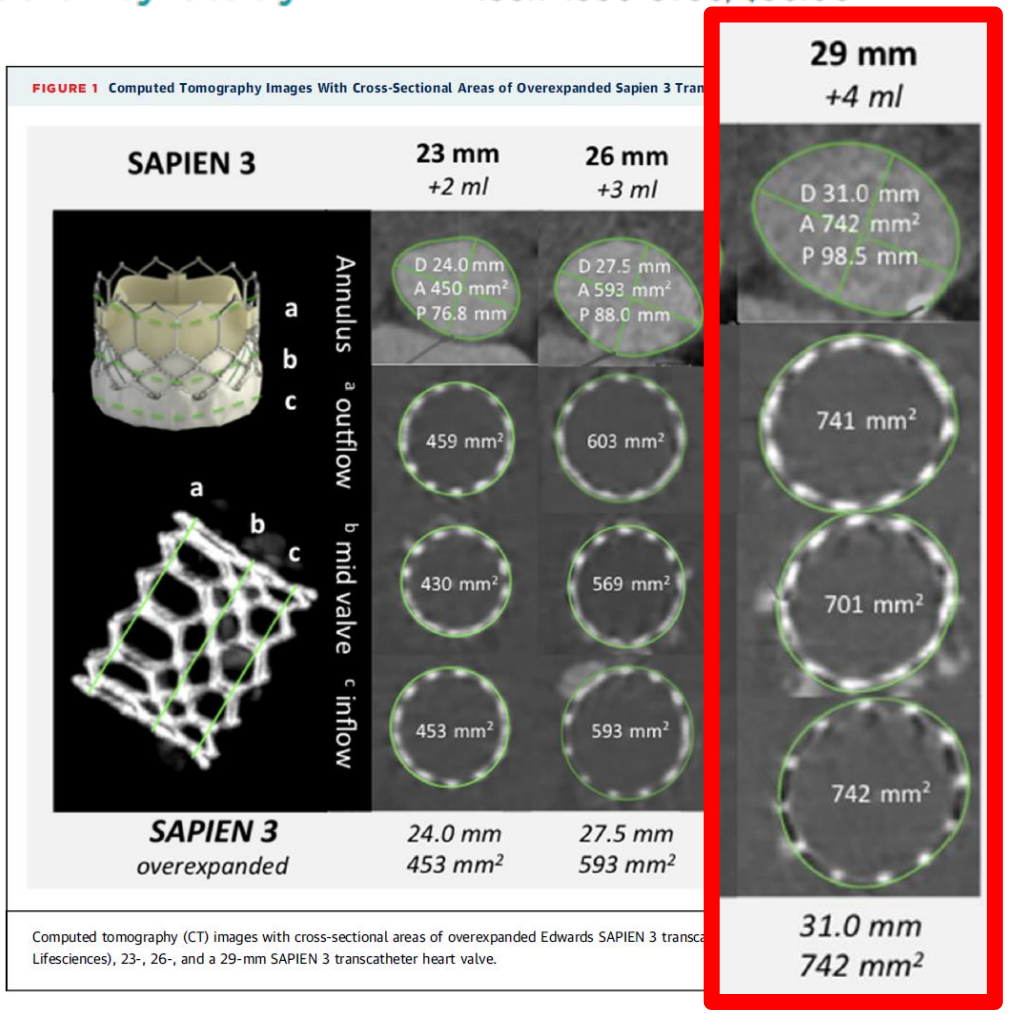
- In patients with annular diameters ≤30 mm, implan-

Below range (0%–12%) device oversizing in patients with annular diameters 30 to 34 mm is feasible but is at higher risk and warrants a detailed discussion of risk benefits, and alternative options

Overexpansion of the SAPIEN 3 Transcatheter Heart Valve

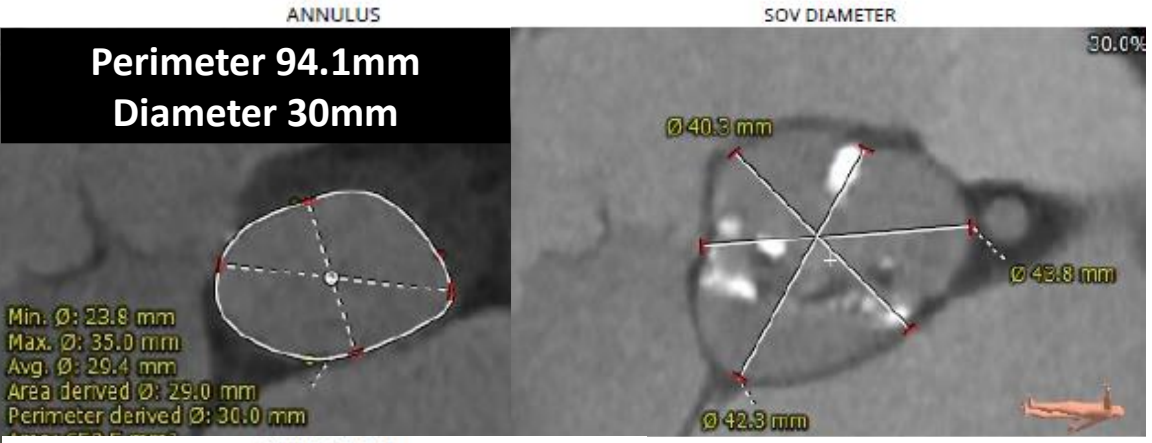
A Feasibility Study

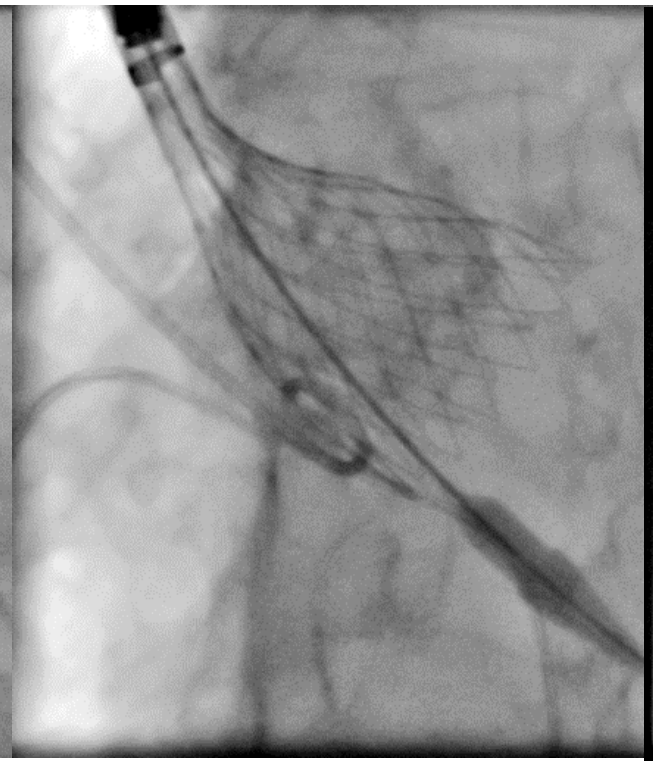
JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 8, NO. 15, 2015
ISSN 1936-8798/$36.00



Evolut R 34mm for large annuli

(re-sheathing 3 times)

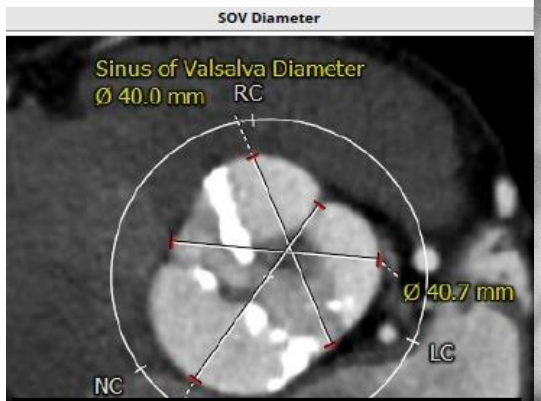




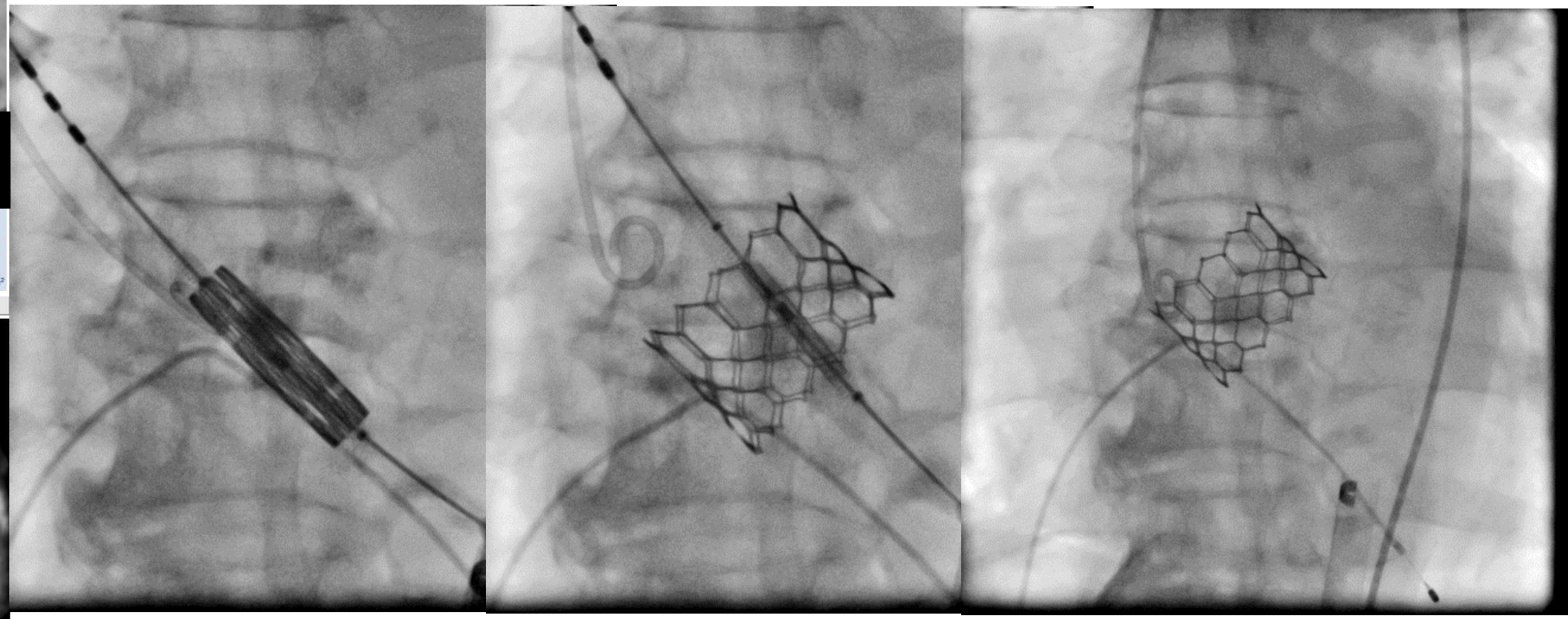
29mm Sapien 3 for large annuli
(overfilled 4cc)

Area 810 mm2
Diameter 32mm

Annulus Dimensions - Avg. Ø	31.9 mm
Annulus Dimensions - Area derived Ø	32.1 mm
Annulus Dimensions - Perimeter derived Ø	32.6 mm
Annulus Dimensions - Area	810.0 mm²



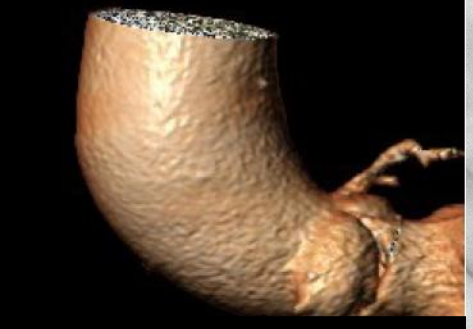
Type 1 bicuspid
Diameter 31mm (supra-A)



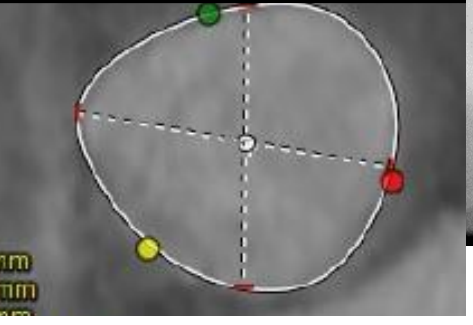
Evolut PRO 29mm for horizontal aorta

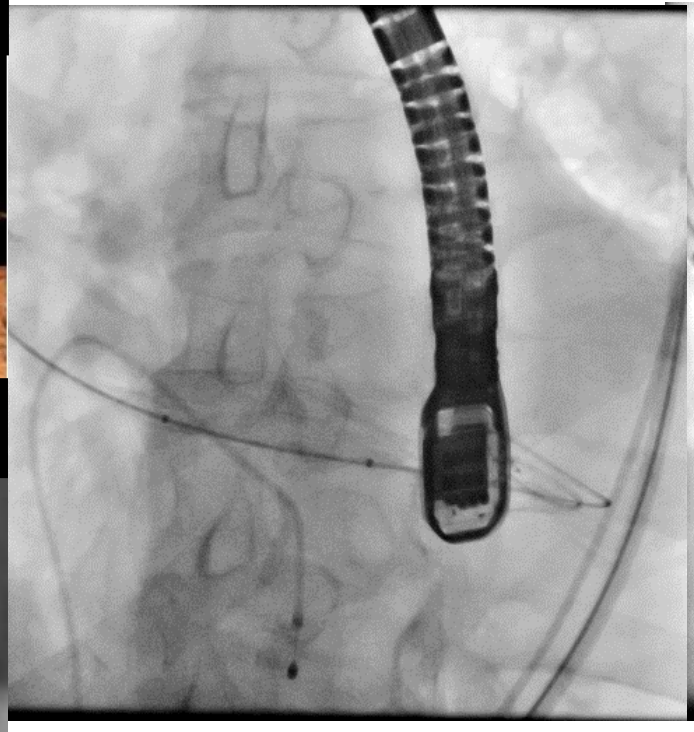
(re-sheathing 2 times; risk of aortic dissection)

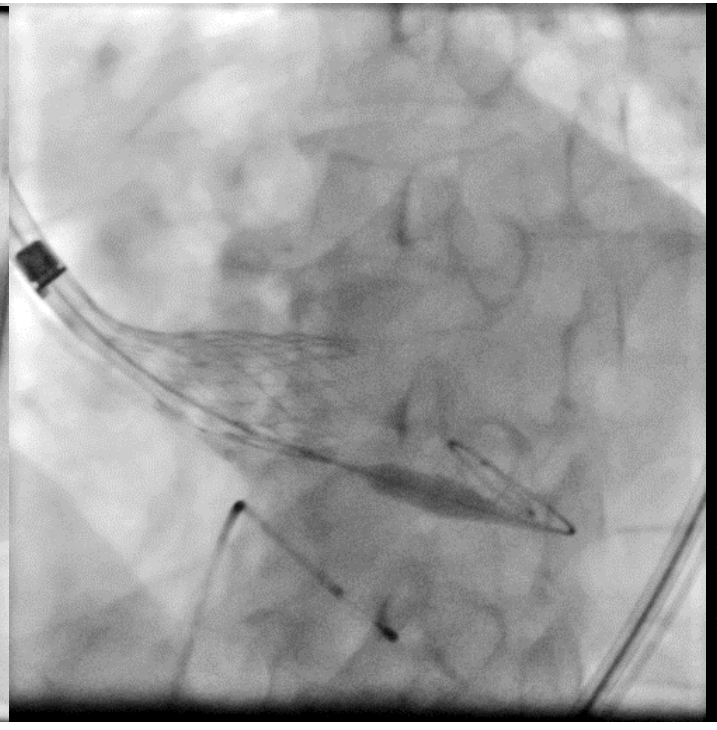
Aortic angle 72

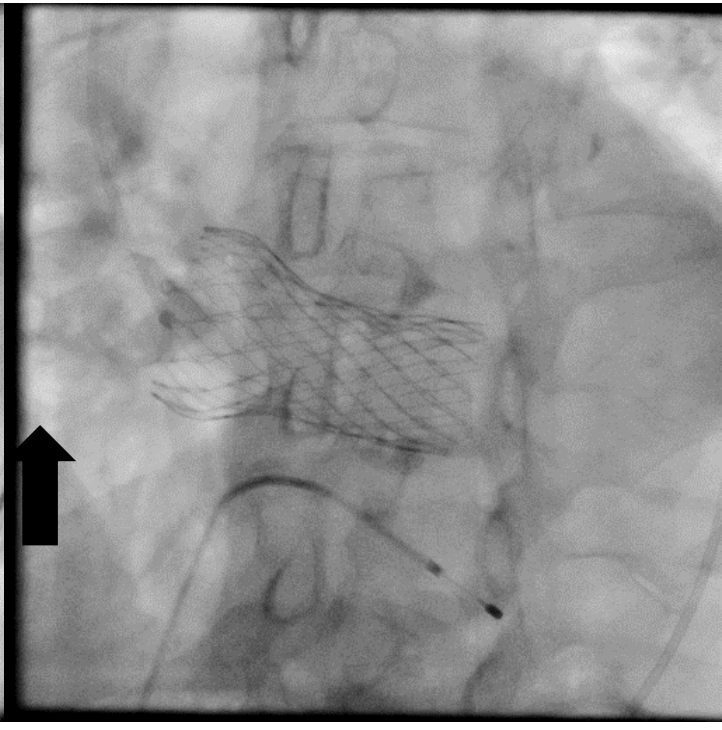


Annulus 22.6mm

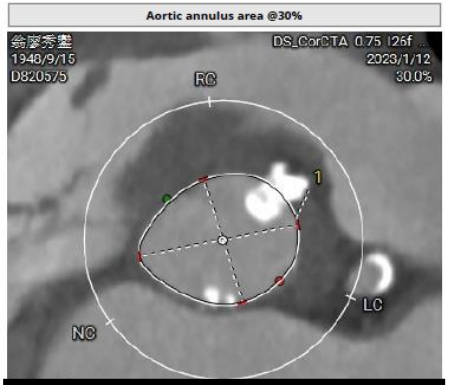




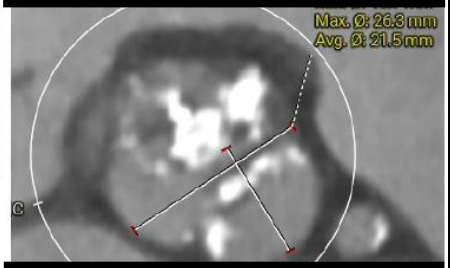




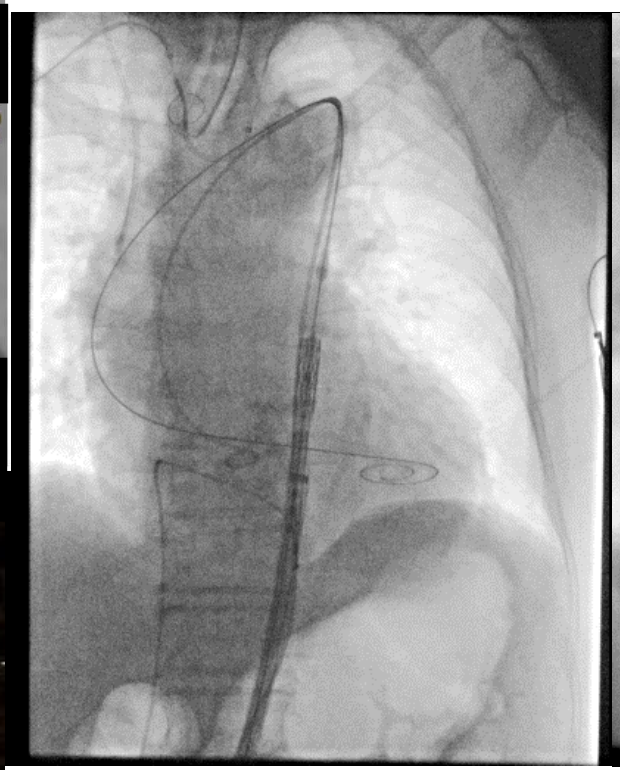
23mm Sapien 3 for horizontal aorta
(overfilled 1cc)

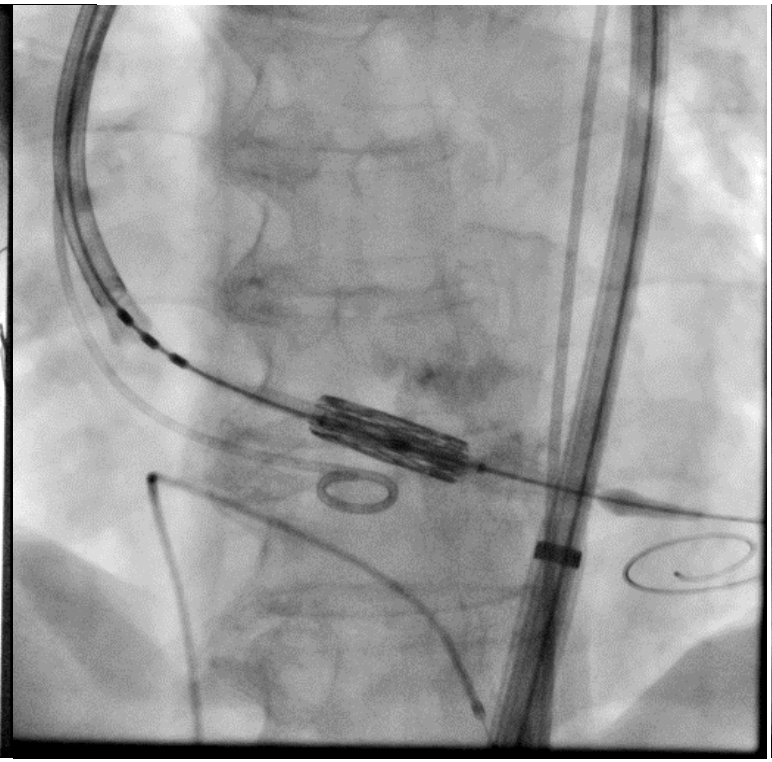


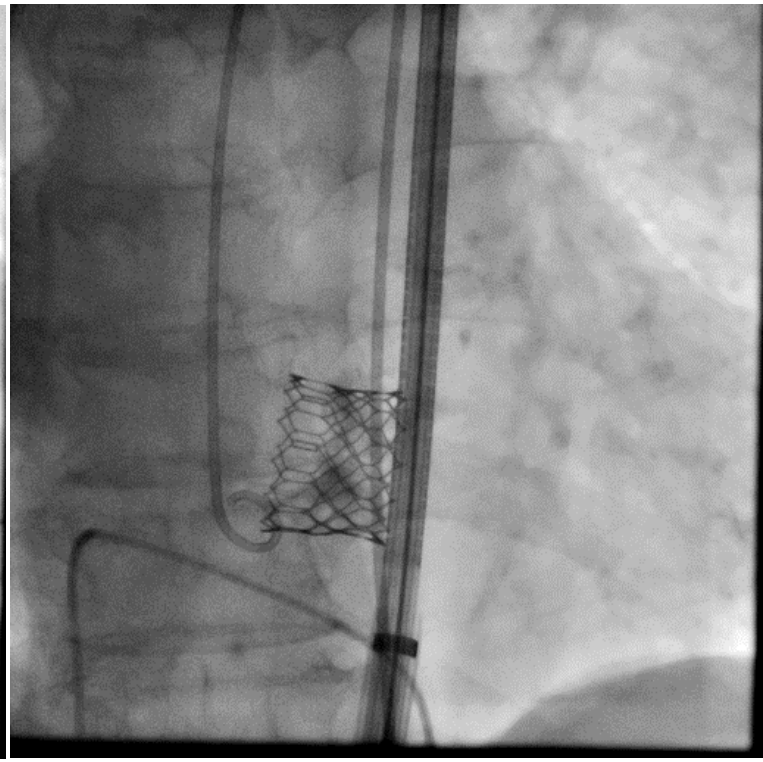
Aortic angle 74



Annulus 25.5mm
Supra-A 21.5mm

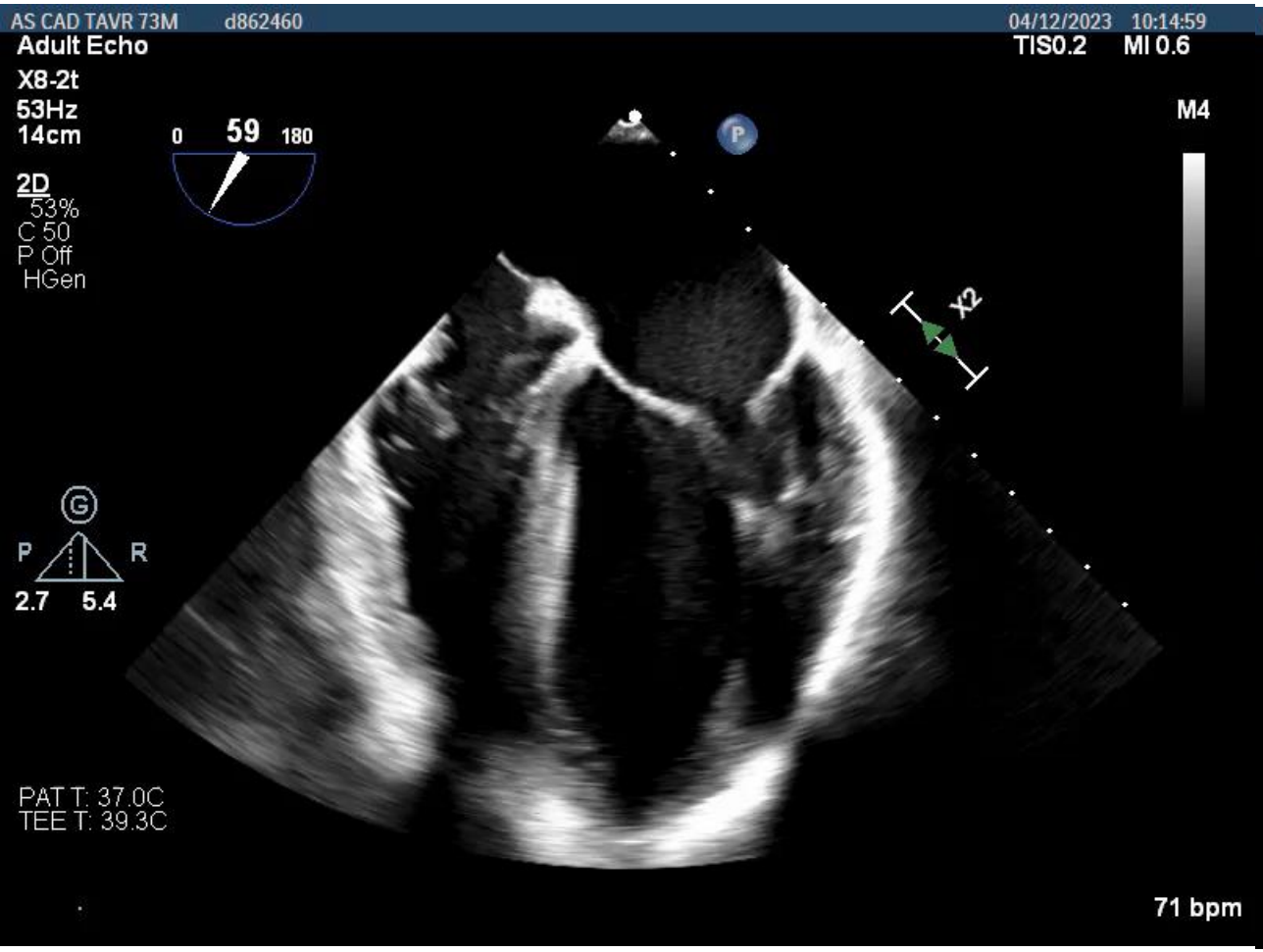




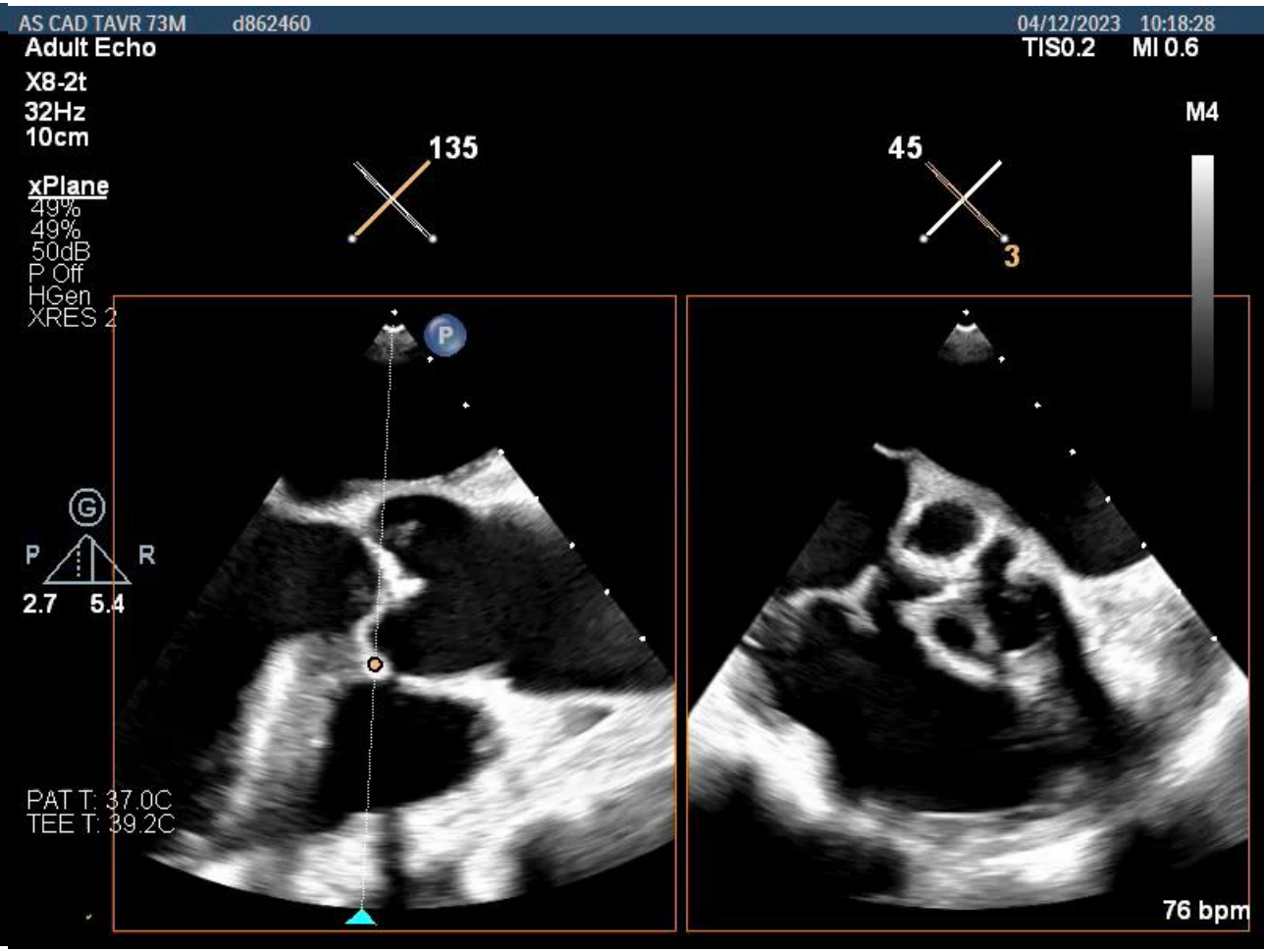


ECMO-assisted CHIP PCI and TAVR

F77, pulmonary edema & poor LV function



Pre-operative TEE before TAVR

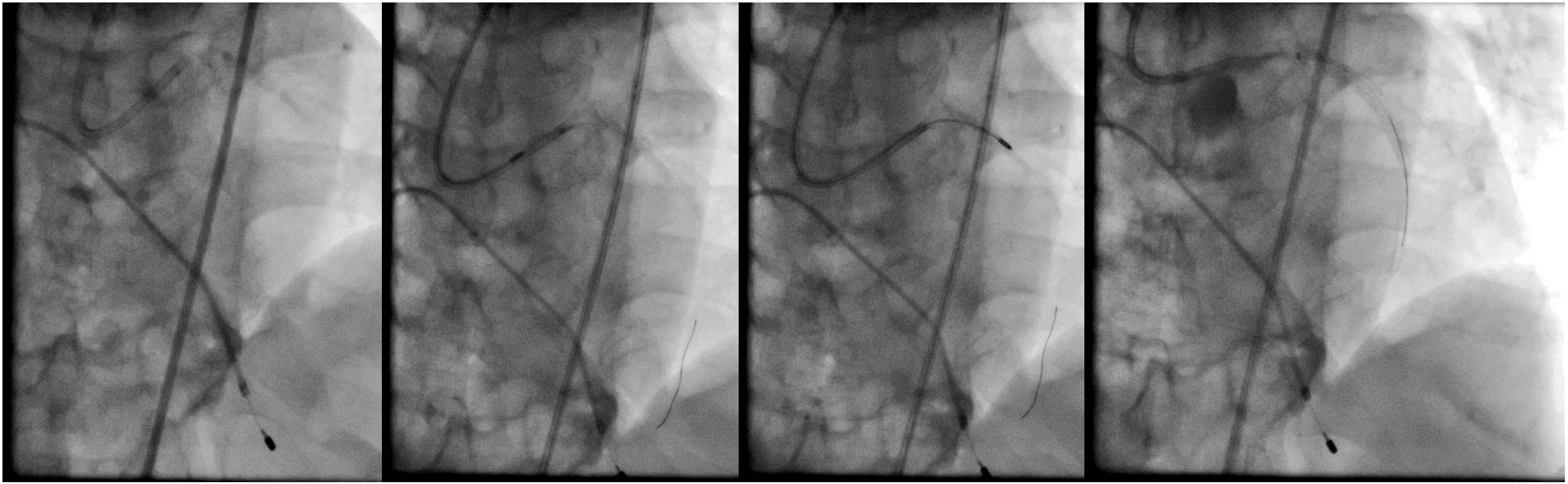


ECMO-assisted CHIP PCI and TAVR

Baseline CAG for LCA

ROTA with a 1.25 burr for LAD-P to M

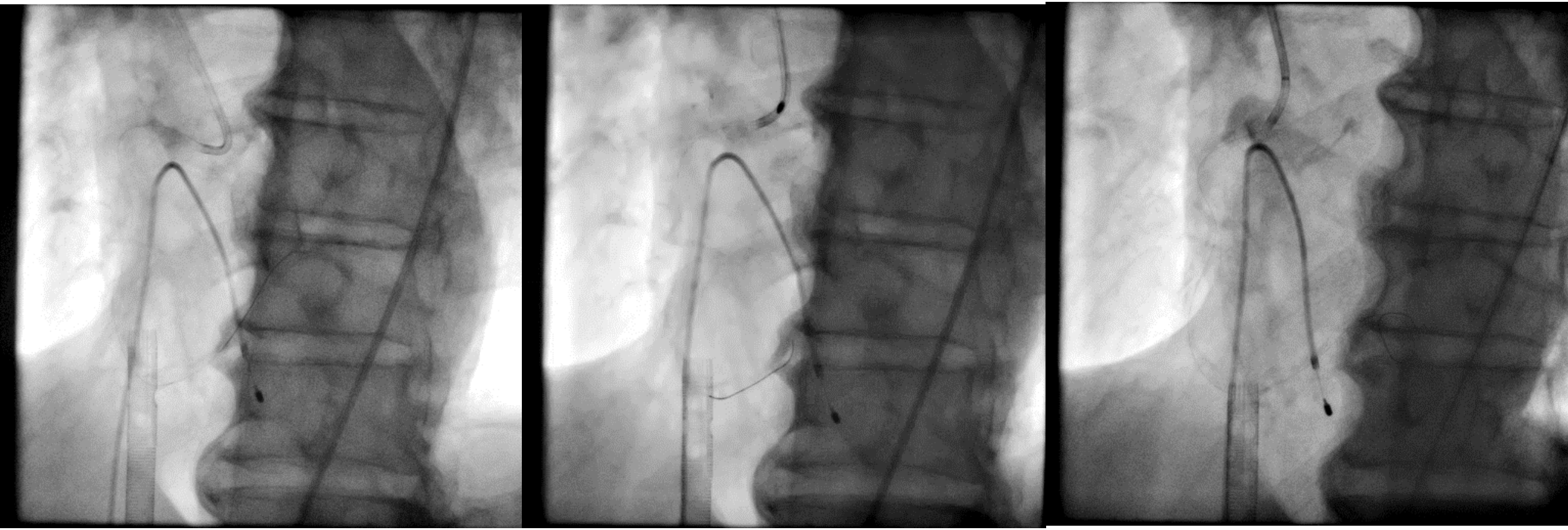
A 2.25 x 32mm and a
2.75 x 38mm DES for LM-LAD



ECMO-assisted CHIP PCI and TAVR

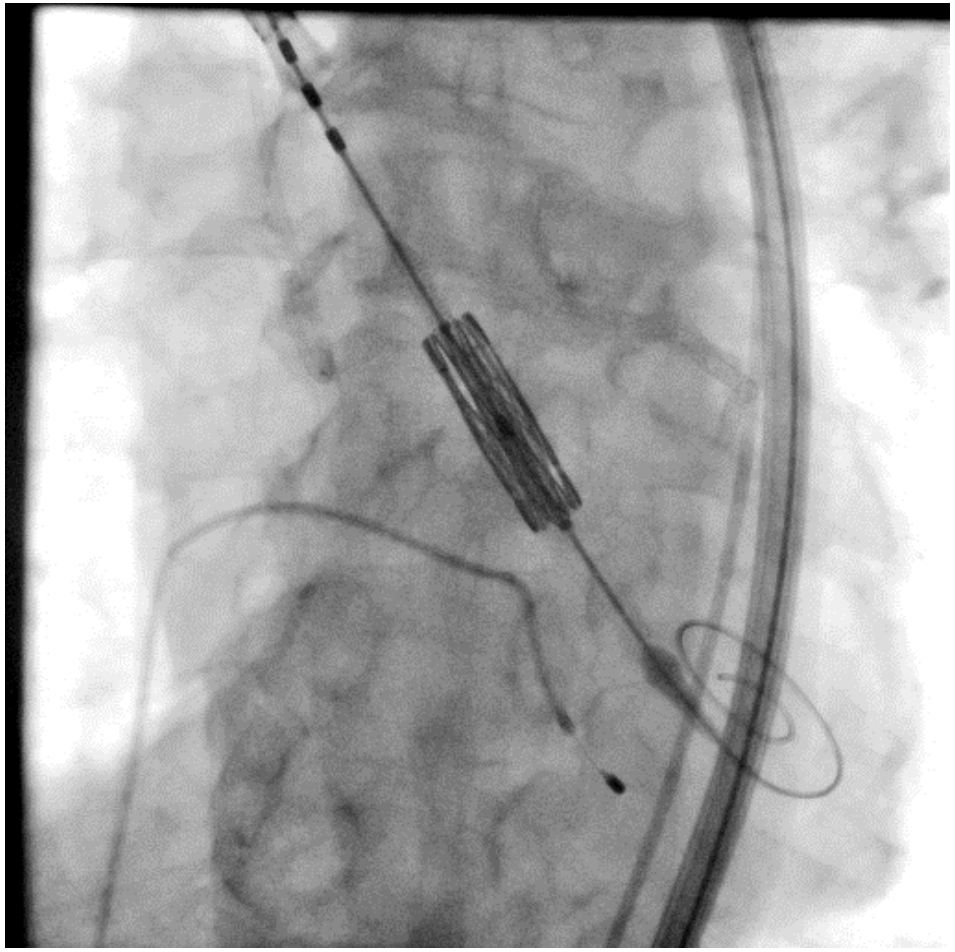
Baseline CAG for RCA

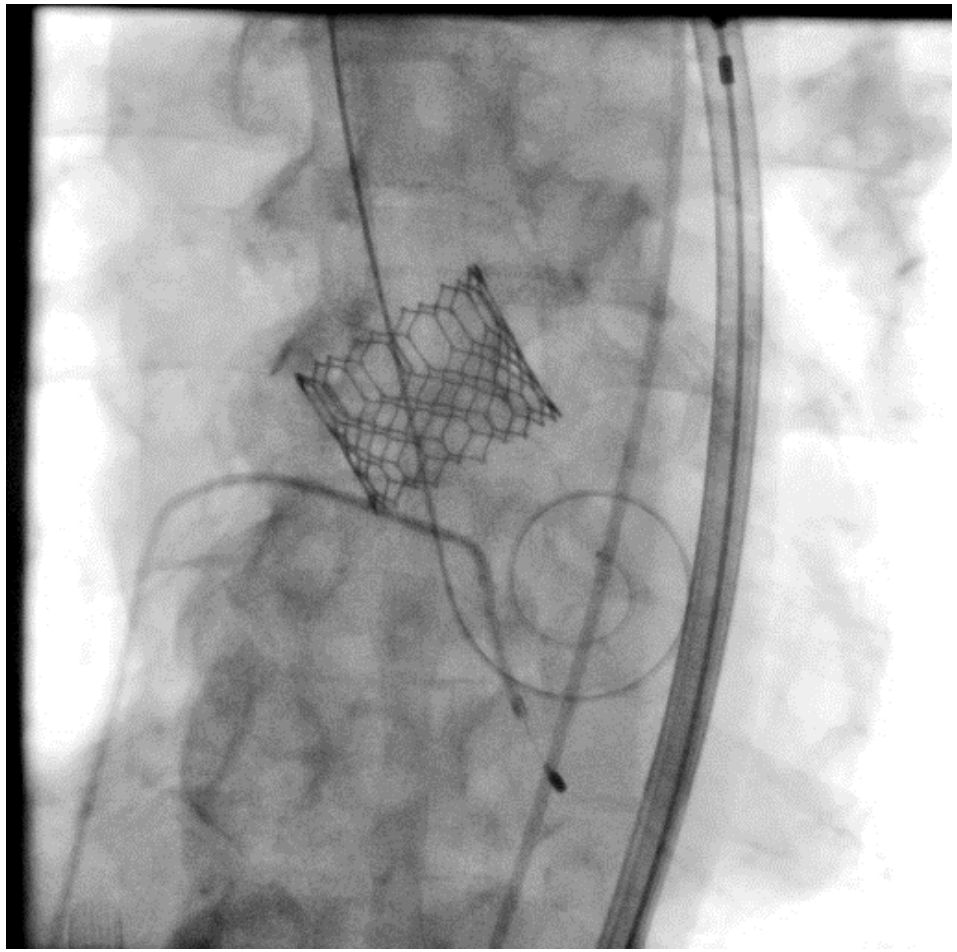
ROTA 1.25 burr and a 3.5 x 16mm DES for RCA-ostium to P



ECMO-assisted CHIP PCI and TAVR

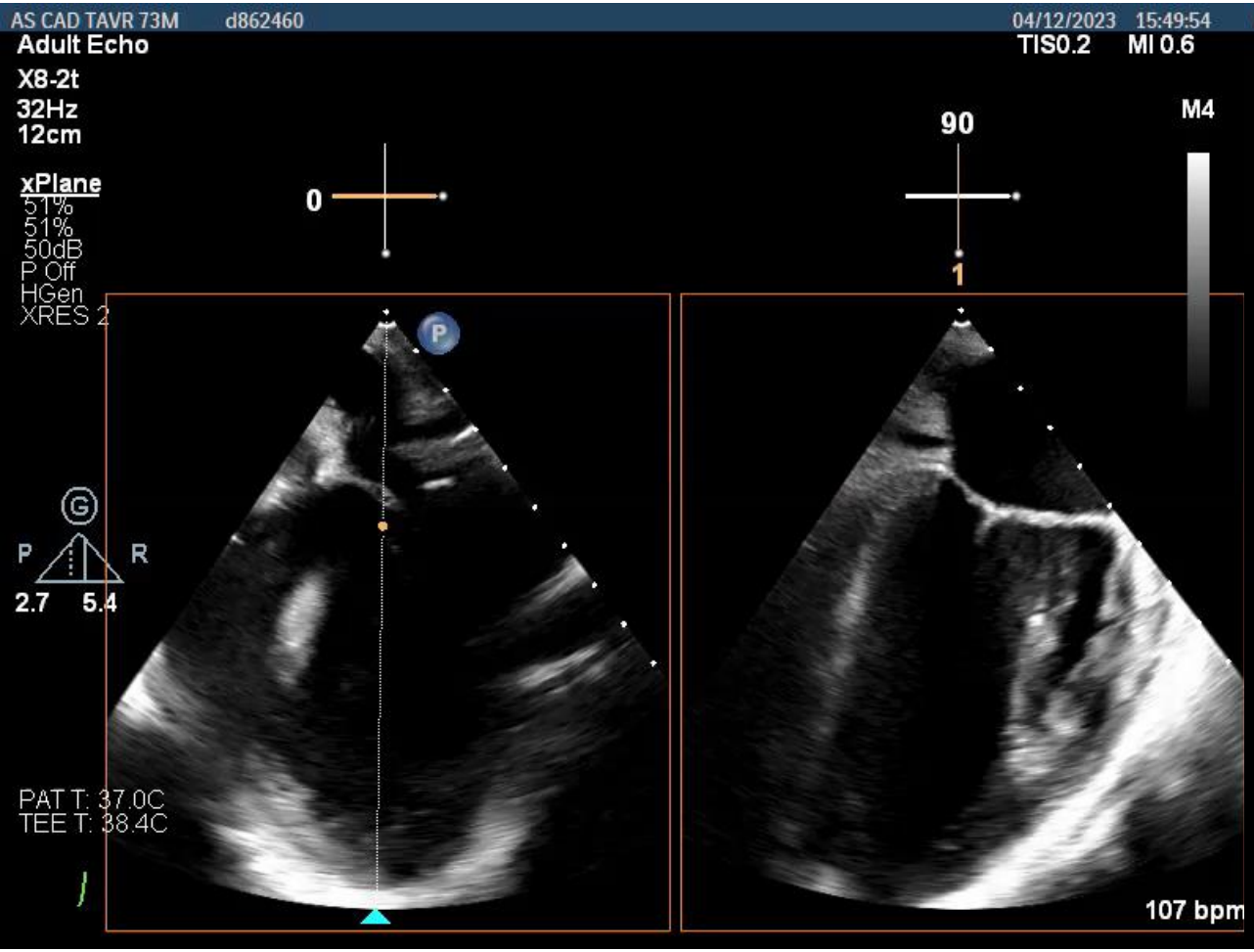
TAVR with a 26mm Sapien 3, full volume



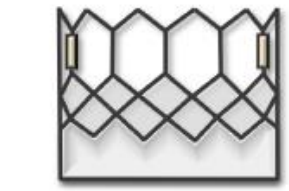


ECMO-assisted CHIP PCI and TAVR

Intra-operative TEE immediately after PCI &TAVR



Valve durability and long-term clinical outcomes

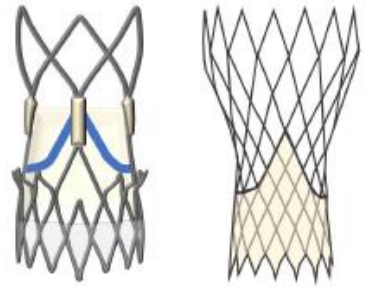


Intra-Annular TAVR

10 years after TAVR

≥5 year Follow-Up

604



Supra-Annular TAVR

Overall Survival			
15%	p = 0.21		11%
Hemodynamics			
↑↑ Higher	p < 0.05 (1m - 1y)	*Mean Gradient*	Lower ↓↓
Increase	p < 0.05	*Gradient Trend over Time*	p > 0.05 Stable
Severe HVD*			
5%	p = 0.05	*Overall*	1%
2%	p = 0.40	*Excluding IA TAVR ≤23mm*	1%
Bioprosthetic Valve Failure*			
8%	p = 0.02	*Overall*	1%
5%	p = 0.11	*Excluding IA TAVR ≤23mm*	1%

*VARC3

Limited to older generation Smaller Sapien XT

Sapien 3 is comparable to self-expanding valves

TAVR valve choice considerations

	Balloon-expandable valve	Self-expanding valve
Stroke	Need CEP	
Paravalvular leakage		
Permanent pacer implantation		
Coronary reaccess		
Patient-prosthesis mismatch (small annuli and TAVR-in-SAVR)		
Bicuspid aortic stenosis		
Extremely large annuli/horizontal aorta		
CHIP PCI + TAVR for cardiogenic shock		
Durability/Long-term clinical outcomes	Need RCT