Cases with the Masters

A Primer on Prevention, Recognition and Management of Aortic PVL

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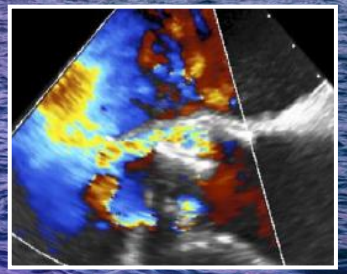
CRF®

TCT® TRANSCATHETER CARDIOVASCULAR THERAPEUTICS®



Cedars Sinai

Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Pi-Cardia
Consultant Fees/Honoraria	Edwards Lifesciences, Medtronic
Individual Stock(s)/Stock Options	DASI simulations
Scientific Advisory Board	DASI simulations, Pi-Cardia

All Relevant Financial Relationships have been mitigated.
Faculty disclosure information can be found on the app

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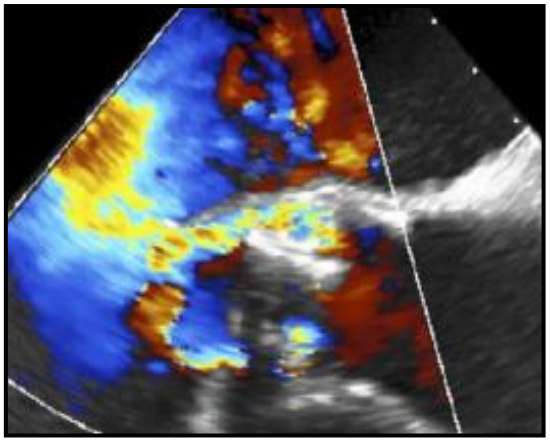
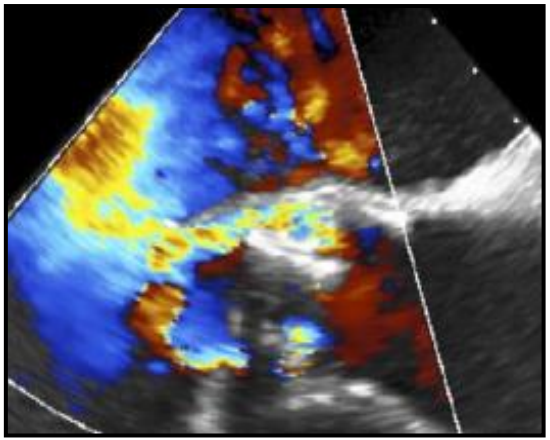
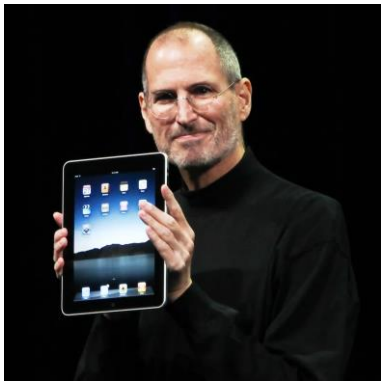


Prevention of Aortic PVL

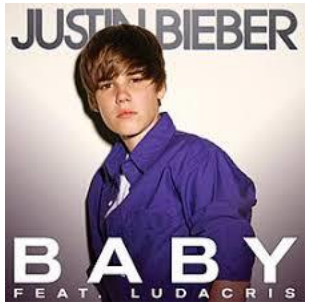


First, a History lesson!
It is the year **2010**.....

Instagram is launched
Facebook surpasses 500m Users



Apple releases the first iPad



Justin Bieber explodes to fame with "Bieber Fever"

.....and aortic paravalvular leak (PVL) is a **major** and relatively **common** predictor of mortality after TAVR

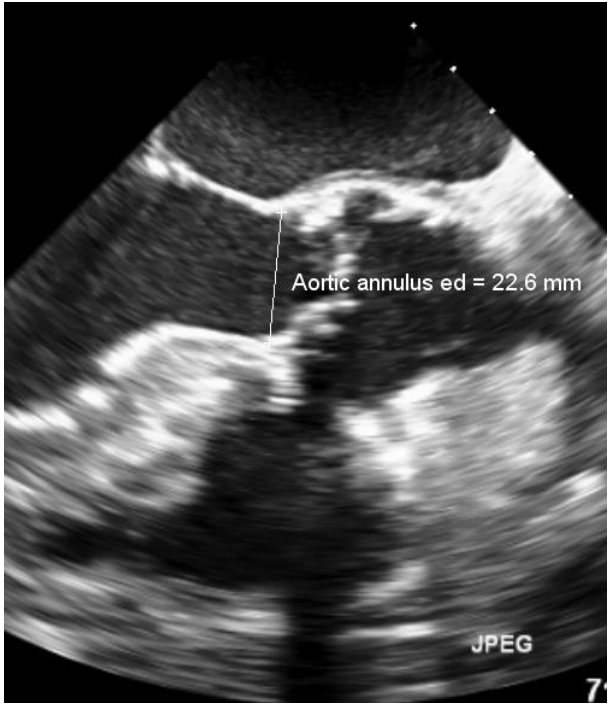
Study	No. of patients	Significant PV AR, n (%)	Follow-up	HR (95% CI) (multivariable)
Sinning et al	146	22 (15.0)	Up to 1 year	**2.4 (1.0–5.4)**
Tamburino et al	663	139 (21.0)	Median 18 months	**3.79 (1.57-9.10)**
Moat et al	877	115/849 (13.6)	> 11 months	**1.66 (1.10–2.51)**
Gilard et al	3195	316/1915 (16.5)	Median 114 days	**2.49 (1.91-3.25)**
Abdel-Wahab	690	119 (17.2)	In-hospital	**2.43 (1.22-4.85)**
Vasa-Nicotera et al	122	20 (16.3)	1-year	**4.19 (2.05-8.59)**

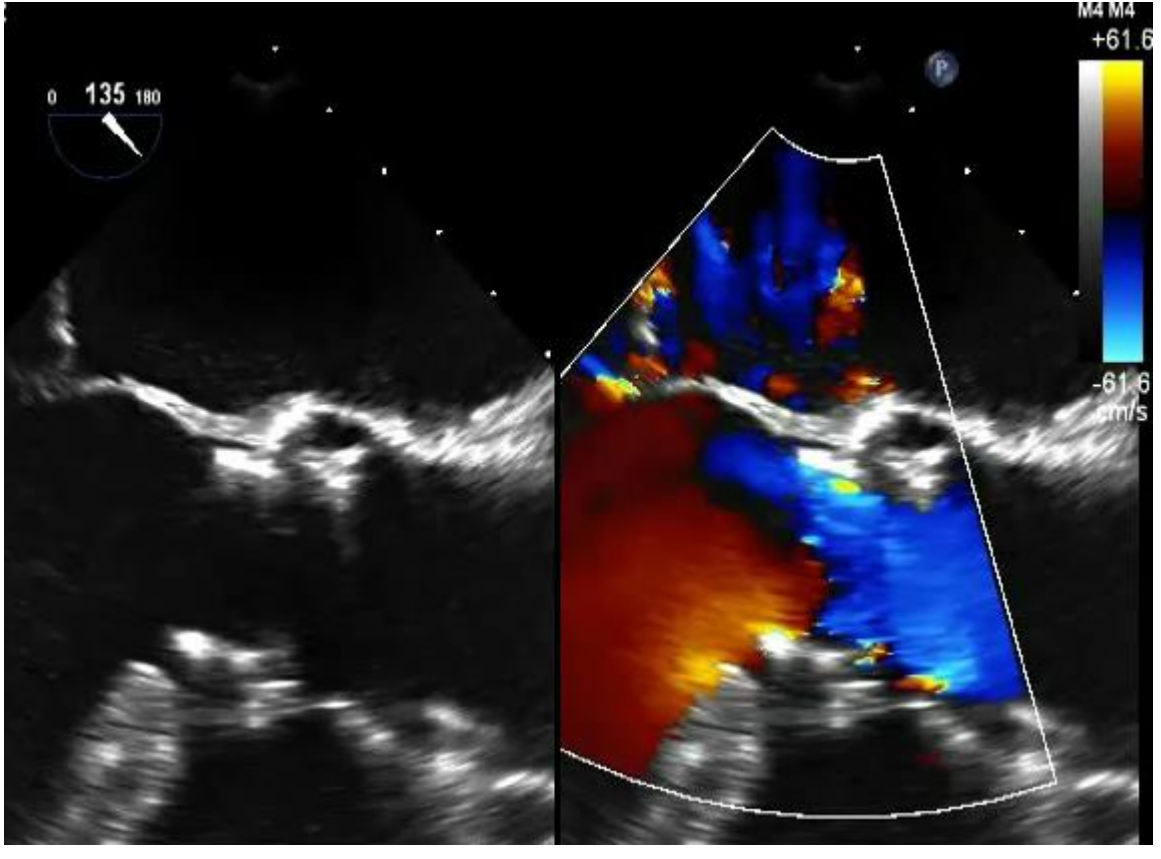
Sinning et al. JACC 2012; Tamburino et al. Circulation 2011; Moat et al. JACC 2011; Gilard et al. NEJM 2012; Abdel-Wahab et al. Heart 2011

AND 3D measurements are not used for TAVR in the PARTNER trial!

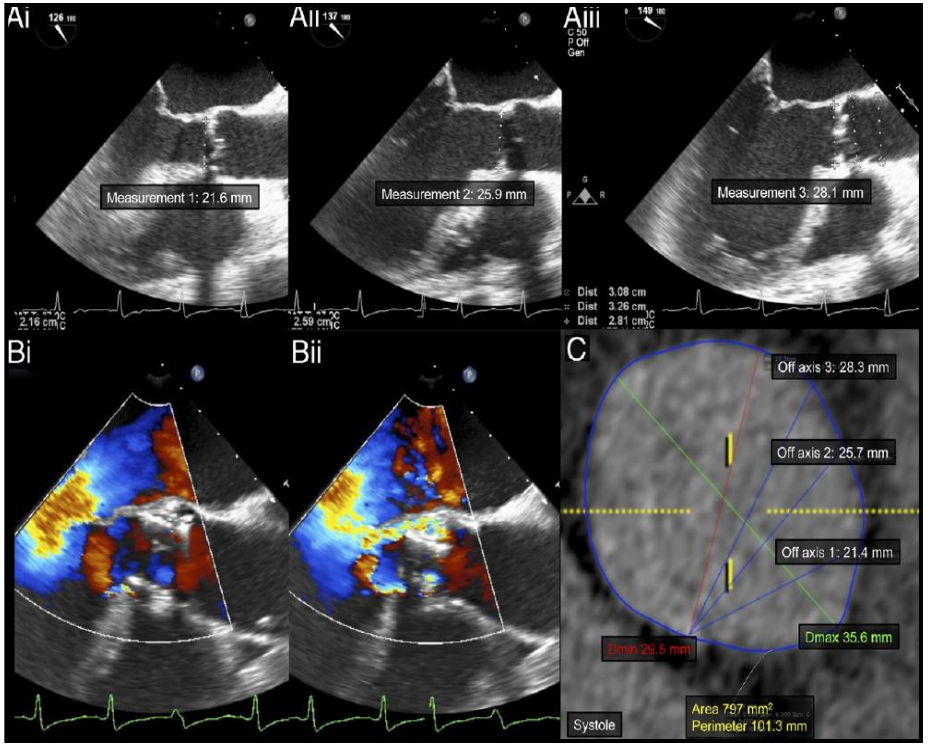
26 mm Edwards SAPIEN

Severe, dynamic **fatal PVL** with a rocking valve





Cross-sectional CT is a better measure of annular size than 2D TEE

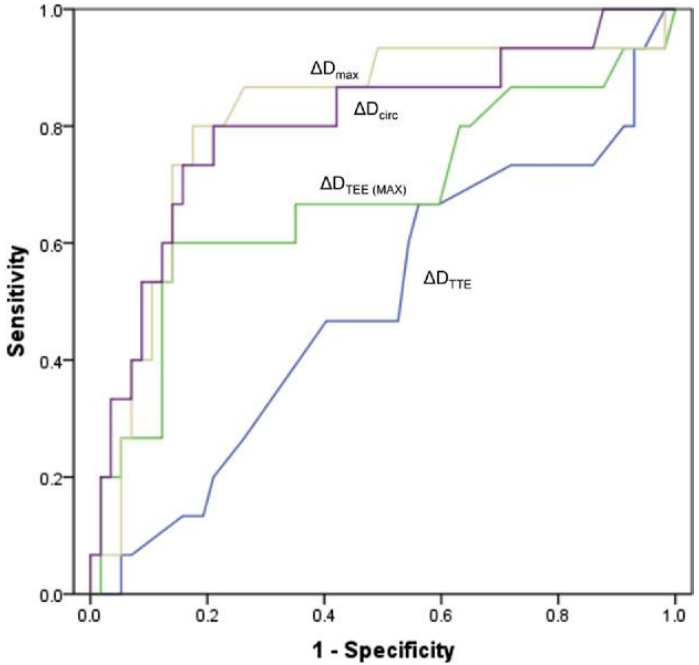


Smallest 2D TEE measurement used for annular sizing: 21.6 mm
Retrospective measurement of annular area: 797mm^2

Gross undersizing resulted in severe AR and a rocking valve

Jilaihawi et al, JACC 2012

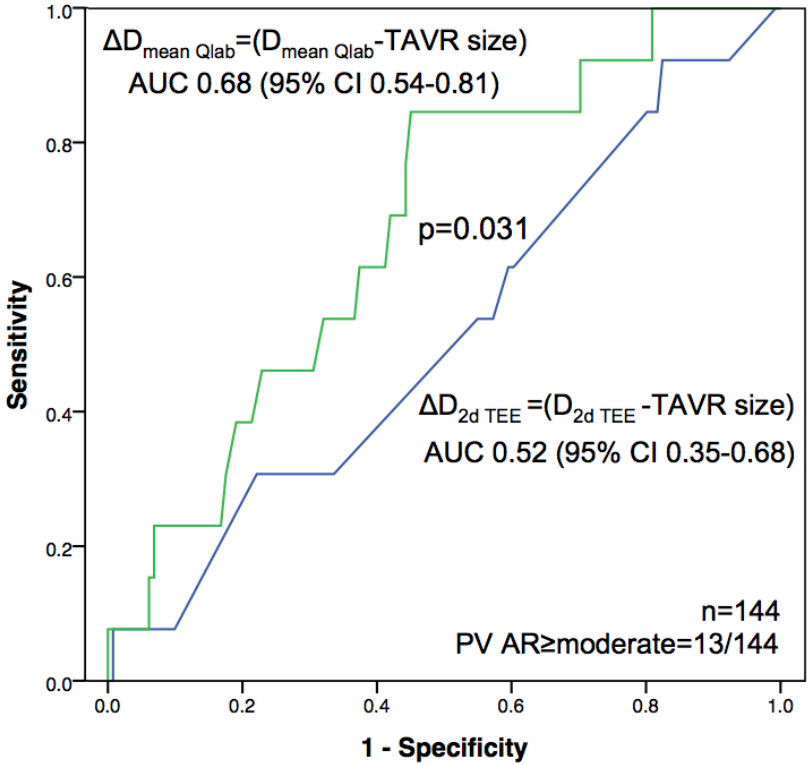
Cedars-Sinai data:
Cross-sectional CT vs 2D TEE



Cross-sectional CT measures have greater discriminatory value for PVL than largest 2D TEE measurement

Jilaihawi et al, JACC 2012

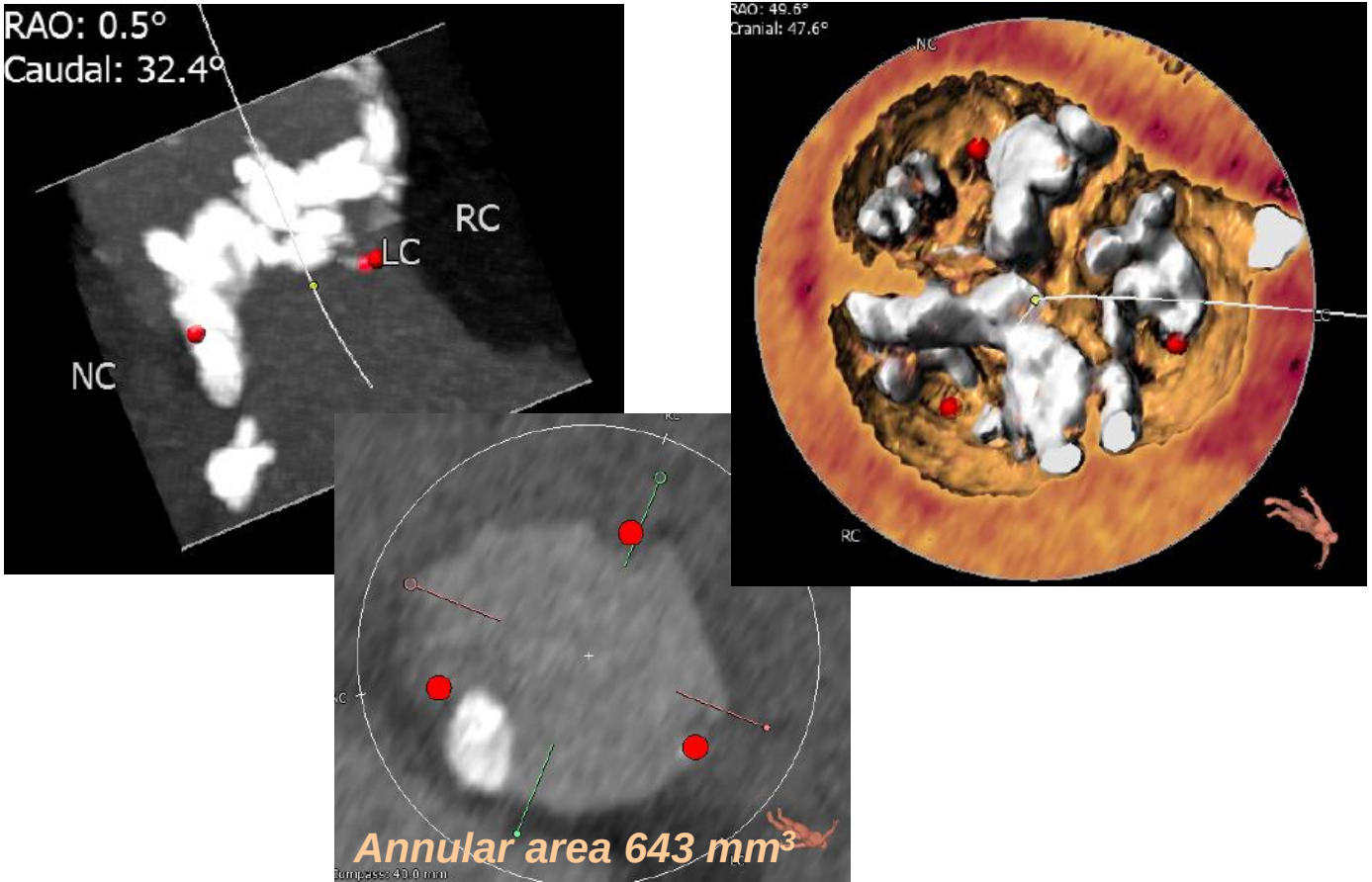
Evidence for 3D TEE?
3D TEE (Qlab) vs 2D TEE



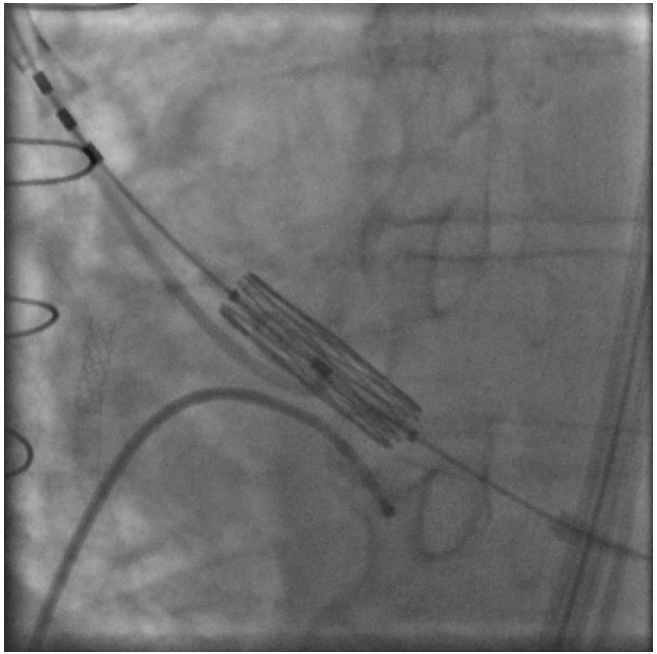
Cross-sectional 3D TEE measures have greater discriminatory value for PVL than largest 2D TEE meaurement

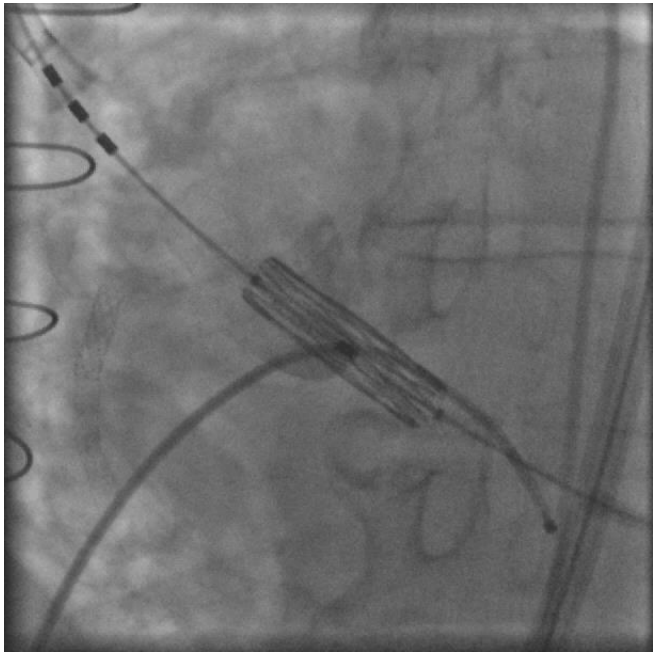
Jilaihawi et al, JACC 2013

Not only 3D sizing but also device iterations mitigate PVL
Heavily calcified AS with LVOT calcium



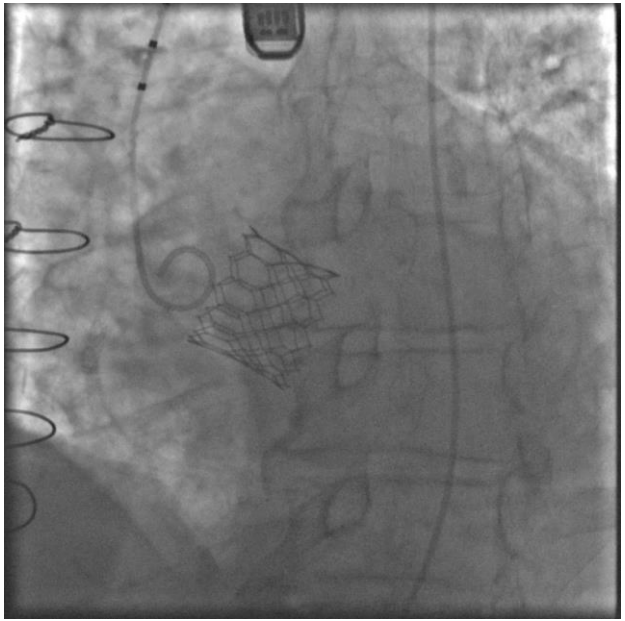
29 S3 in heavily calcified AS with LVOT calcium

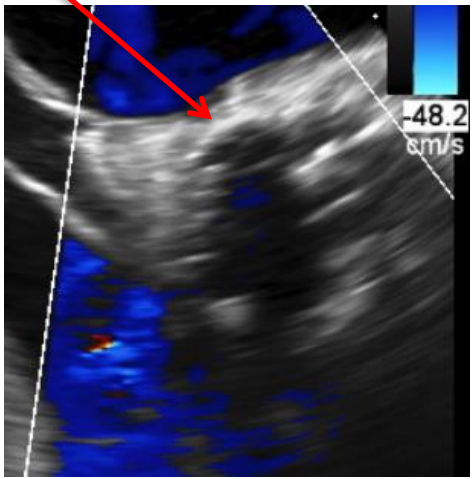




Sealing skirt mitigates PVL with severe LVOT calcium
Now improved further with S3UR

Nodule of calcium prevents full expansion
<u>BUT</u> Zero PVL=no malapposition





Several other platforms also incorporate the benefit of the sealing skirt

Bicuspid Mega-annulus

Cedars Sinai
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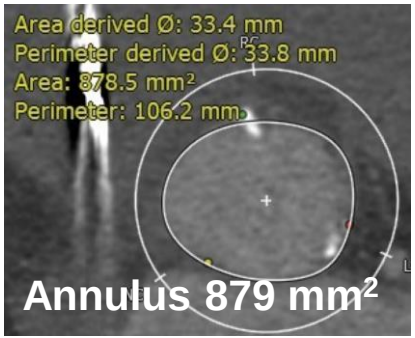
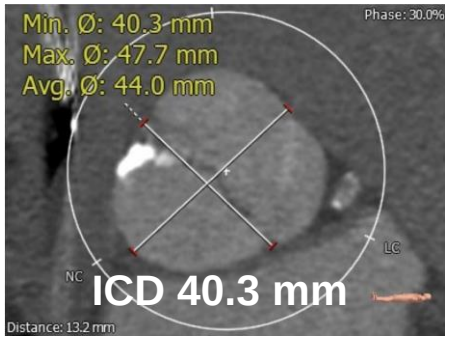
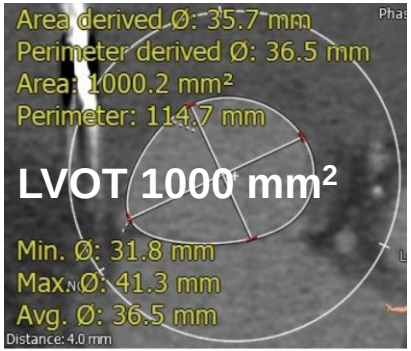
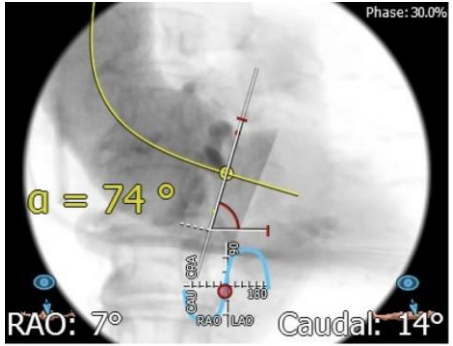
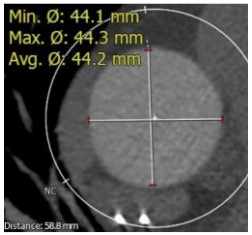
75 yo male
Non-ischemic cardiomyopathy; ICD; LFLG AS
EF 27%; DI 0.2; AVA 0.5; Mean PG 14 mmHg

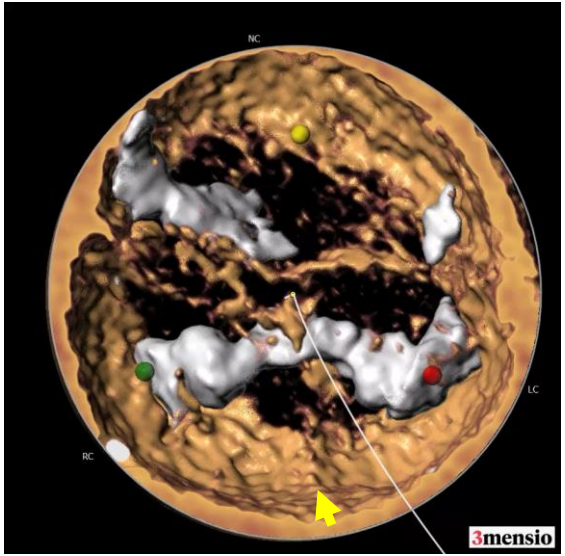












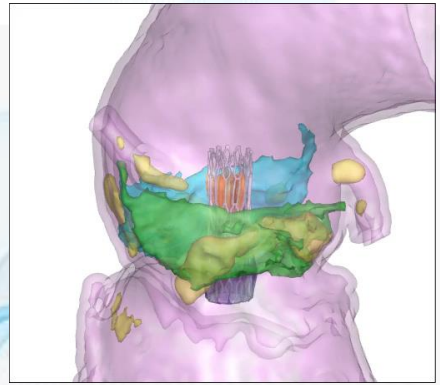
Type 1 LR
Non-calcified raphe;
AoMAX 44 mm

What are the concerns?

- **Embolization / Migration**
- **Paravalvular leak**

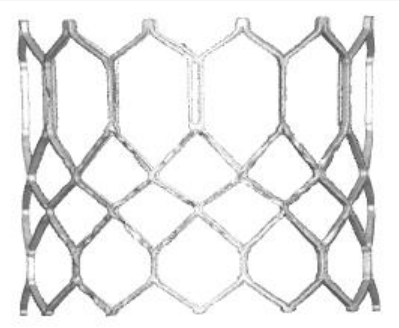
DASI Simulation: ROM (Reduced Order Modeling)

Min(mm)/Max(mm)	BE 29 Nominal	+3cc	+5cc
Inflow	26.8/27.4	27.7/28.1	28.8/28.9
Waist	24.8/25.2	27.0/27.1	28.5/28.9
Outflow	27.4/27.8	28.3/28.5	29.2/29.4

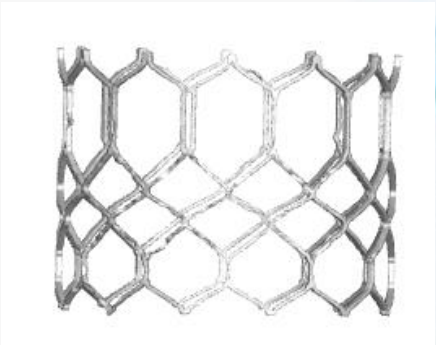


Waist at nominal deployment implies device stability

BE 29 Nominal



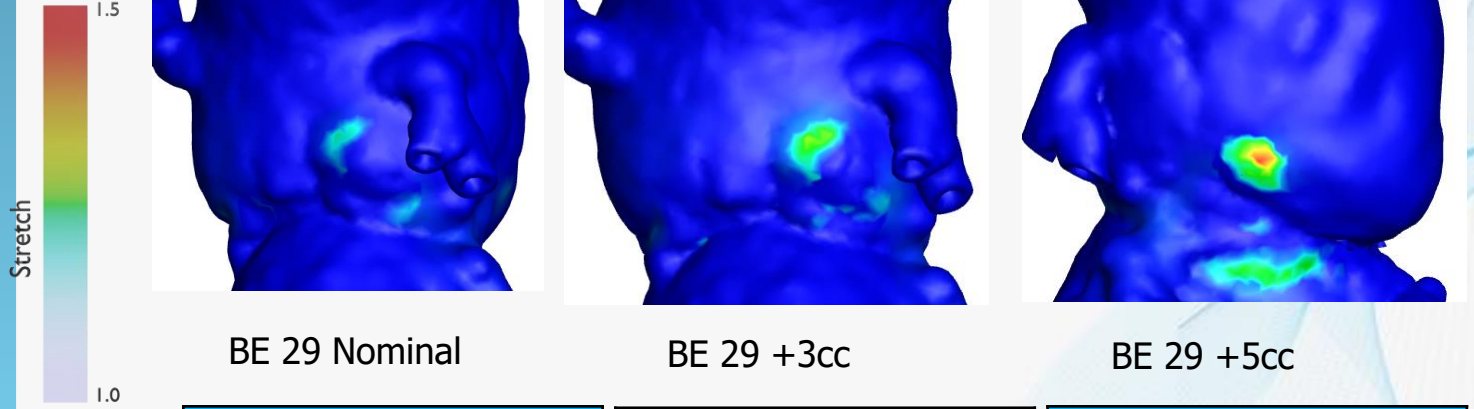
BE 29 +3cc



BE 29 +5cc

Simulation: 29 S3 Root Rupture Risk

Left-Right Cusp
Non-Coronary Cusp



BE 29 Nominal

BE 29 +3cc

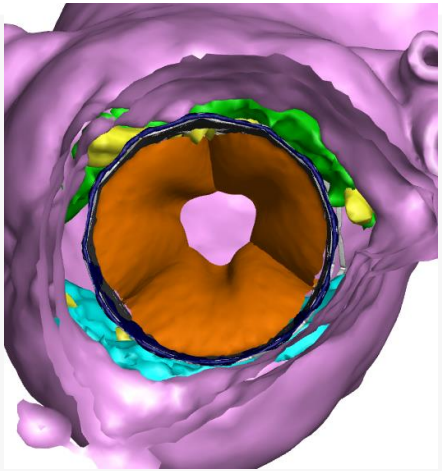
BE 29 +5cc

Stretch Magnitude	Stretch Magnitude	Stretch Magnitude
Max stretch of 1.2	Max stretch of 1.4	Max stretch of 1.5

Stretch≥1.6 may = ↑ root injury

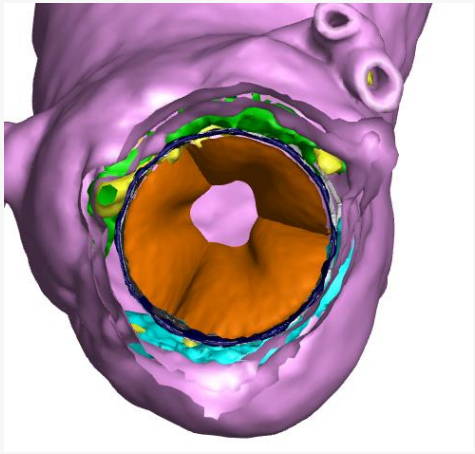
Balloon-Expandable 29 Nominal PVL Risk

Left-Right Cusp
Non-Coronary Cusp



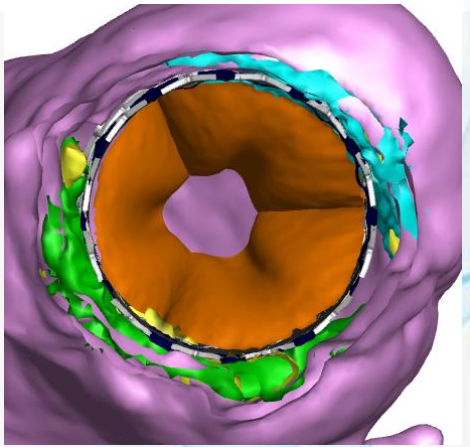
BE 29 Nominal

	BE 29 Nominal
Gap distance	1.0mm; 1.9mm



BE 29 +3cc

	BE 29 +3cc
Gap distance	0.9mm; 1.7mm



BE 29 +5cc

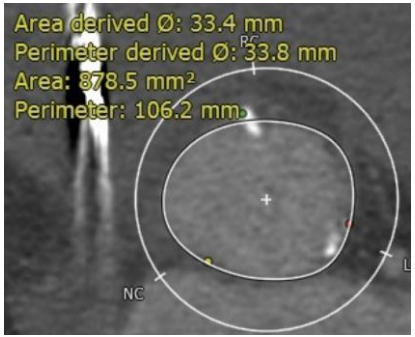
	BE 29 +5cc
Gap distance	0.7mm; 1.4mm

Gaps ≥2 mm may = ↑ PVL (S3U)

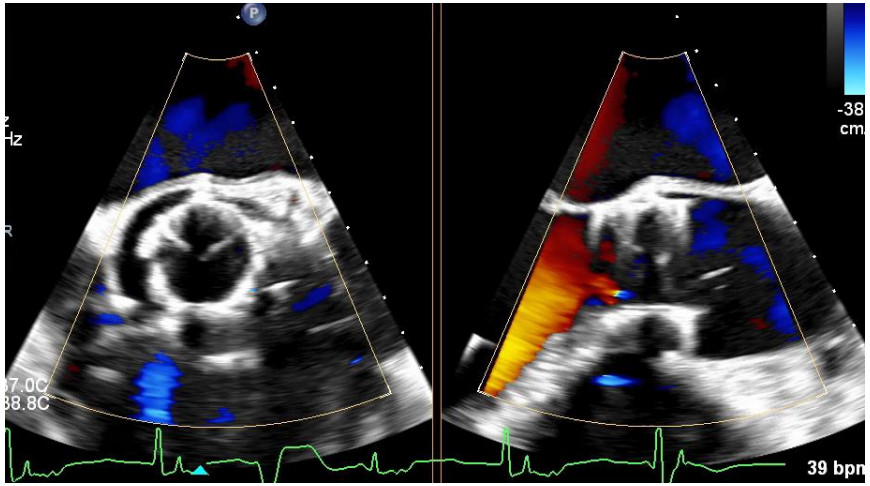
Gaps<2 mm Implies no significant PVL

*Threshold is yet to be determined. Please use clinical judgement.

Bicuspid Mega-annulus

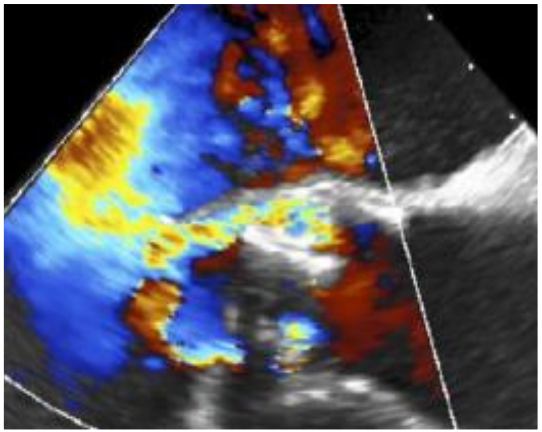


29 S3U Deployed @ Nominal with post-dil x1



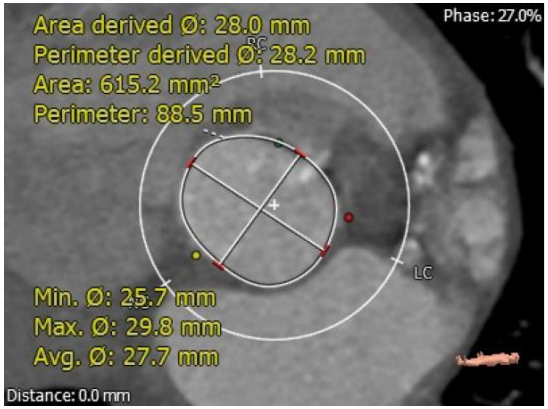
No PVL Mean AV gradient 4 mmHg EF ↑ to 34%

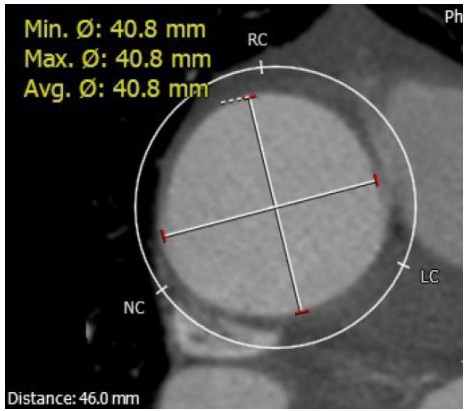
Recognition of Aortic PVL

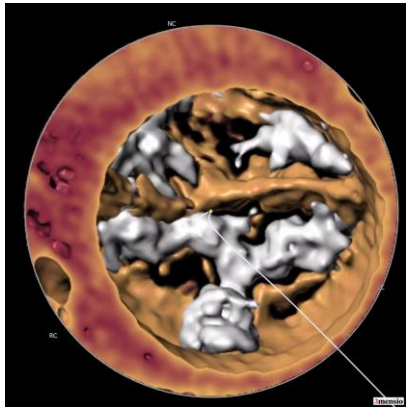


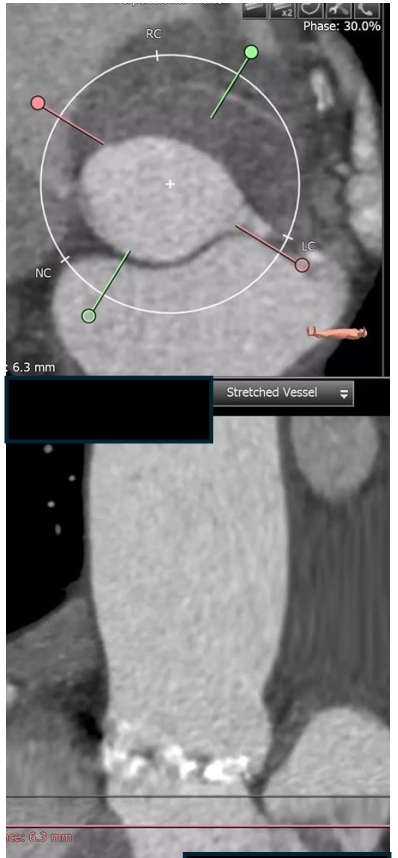
Know which anatomies to have a high expectation for PVL!

Risk phenotype-
73-year-old male with Type 1 L-R fusion and calcified raphe

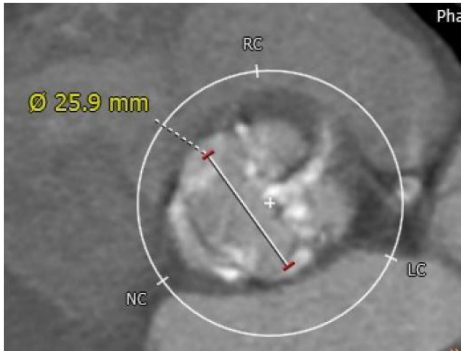






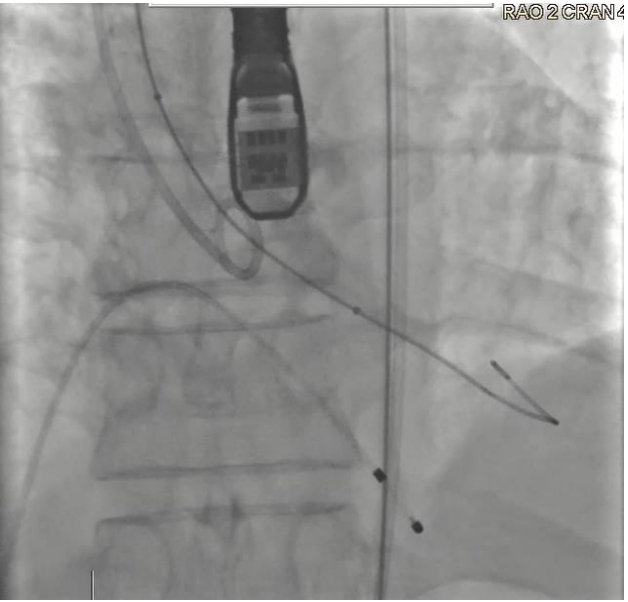


CT risk phenotype: High
Plan: 29 mm S3 – Double tap

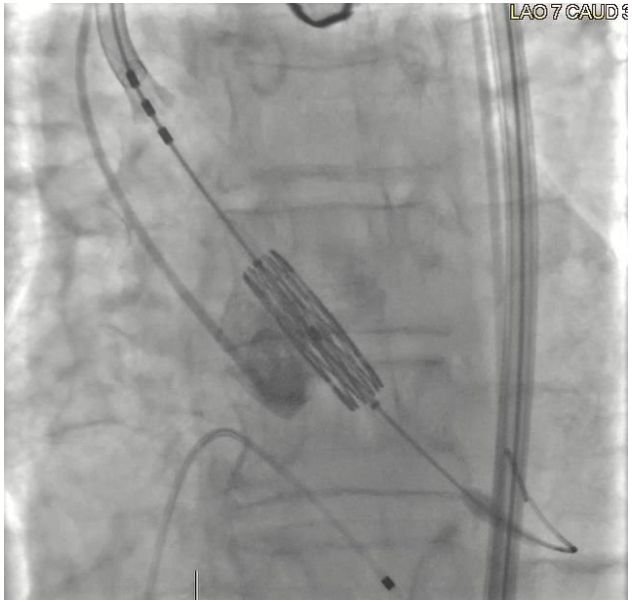


- PROCEDURE
- Cerebral protection using Sentinel device
- Transcatheter Aortic Valve Implantation using 29 mm Sapien 3 Ultra Resilia

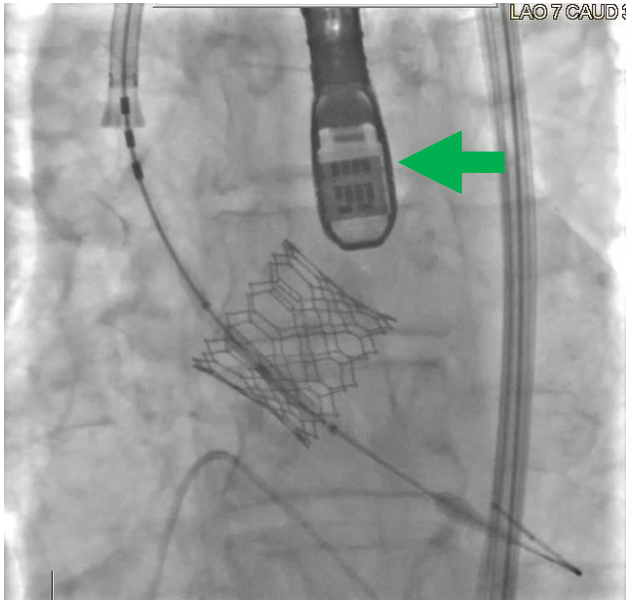
#MAXIMALIST!



Pre-dilatation with 22mm Z MED II

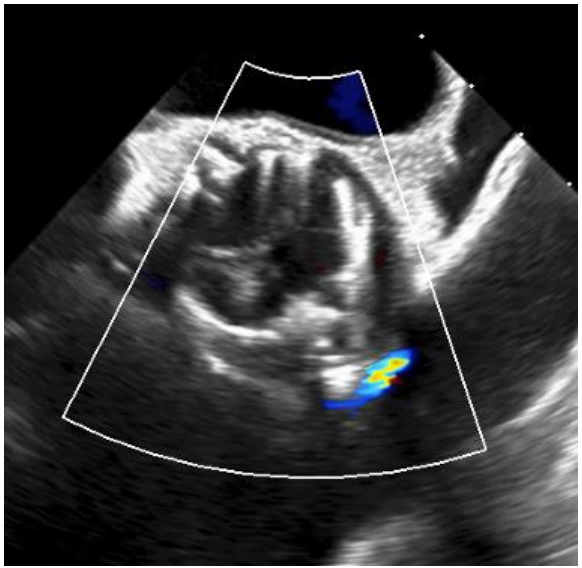


Initial deployment with -4 cc

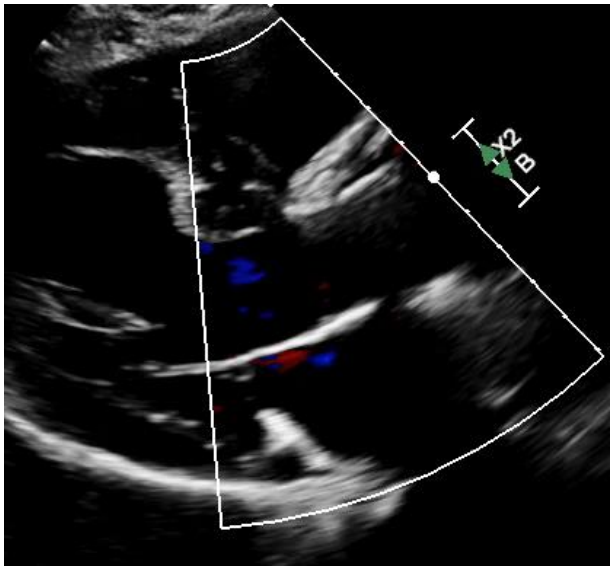


Post dilatation with -2 cc

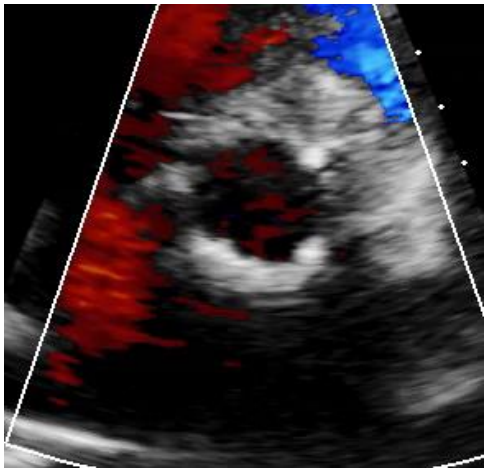
Final result

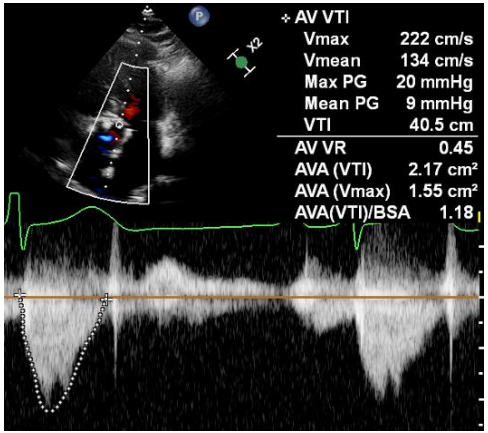


Intra-procedure TEE



Discharge TTE

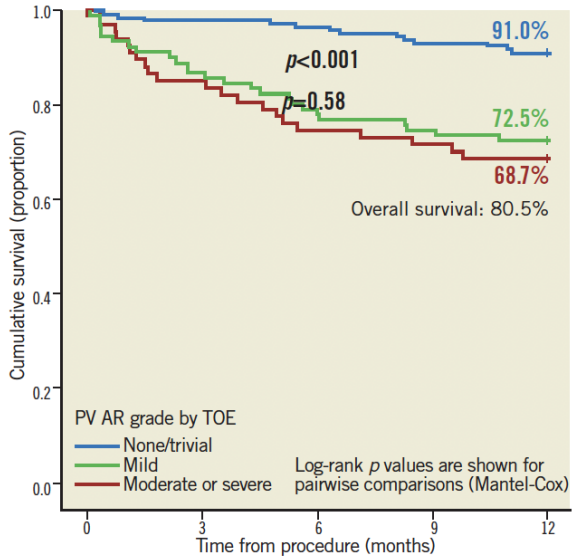




Circular deployment – good hemodynamics

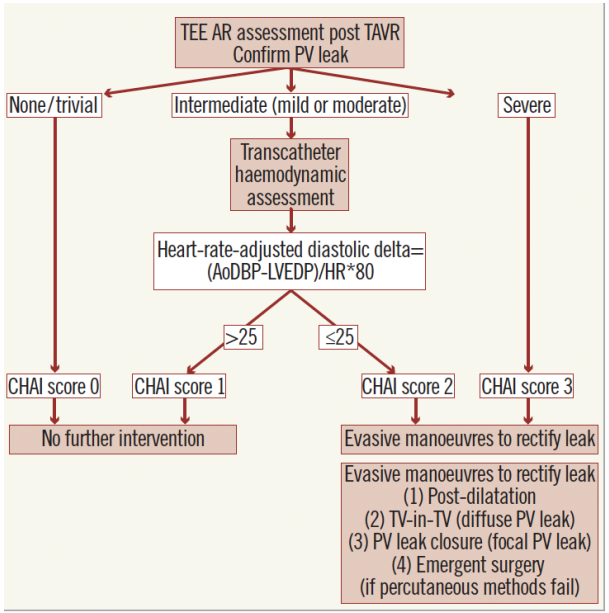
Elucidated definitively on TEE

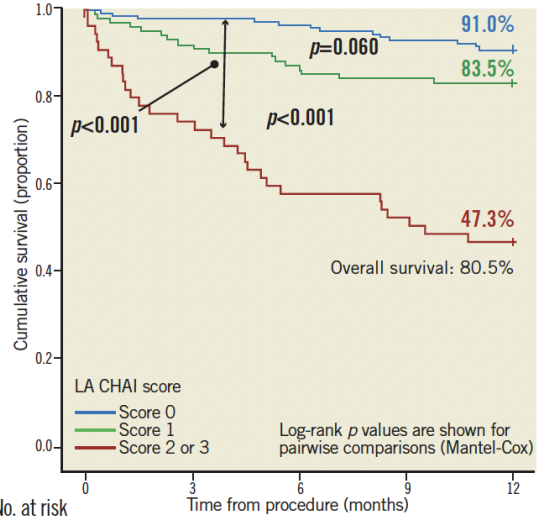
Transcatheter hemodynamics can help evaluate *prognostically significant* aortic PVL



No. at risk

None/trivial	145	139	131
Mild	91	71	65
Moderate or severe	67	49	45



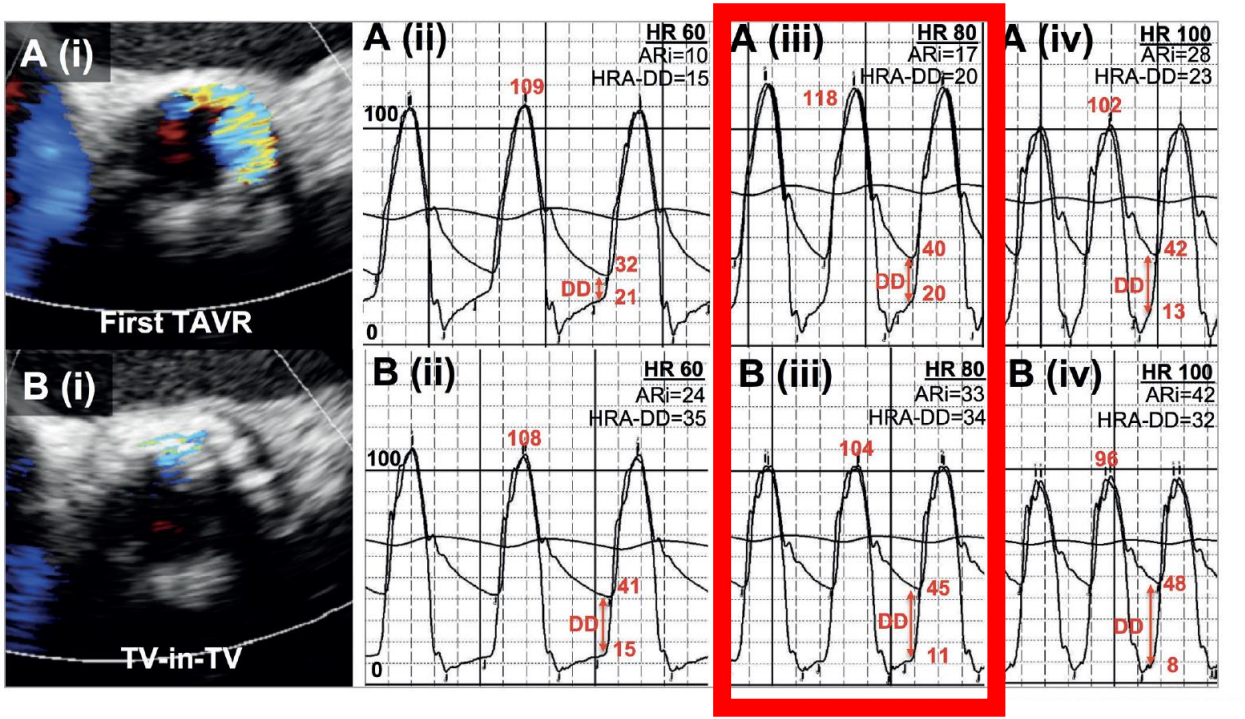


No. at risk

CHAI 0	145	139	131
CHAI 1	103	89	85
CHAI 2/3	55	31	25

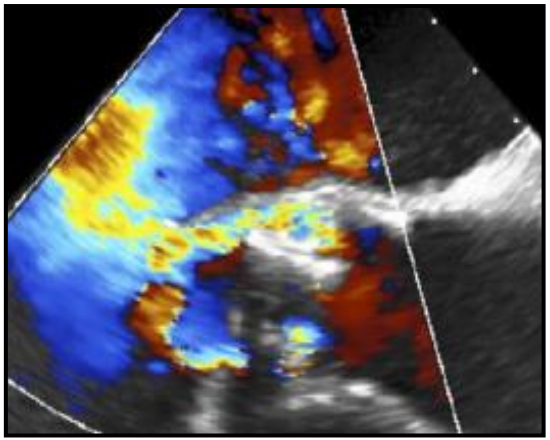
Jilaihawi et al, EuroIntervention 2015;11:456-464

Transcatheter hemodynamics can help evaluate *prognostically significant* aortic PVL

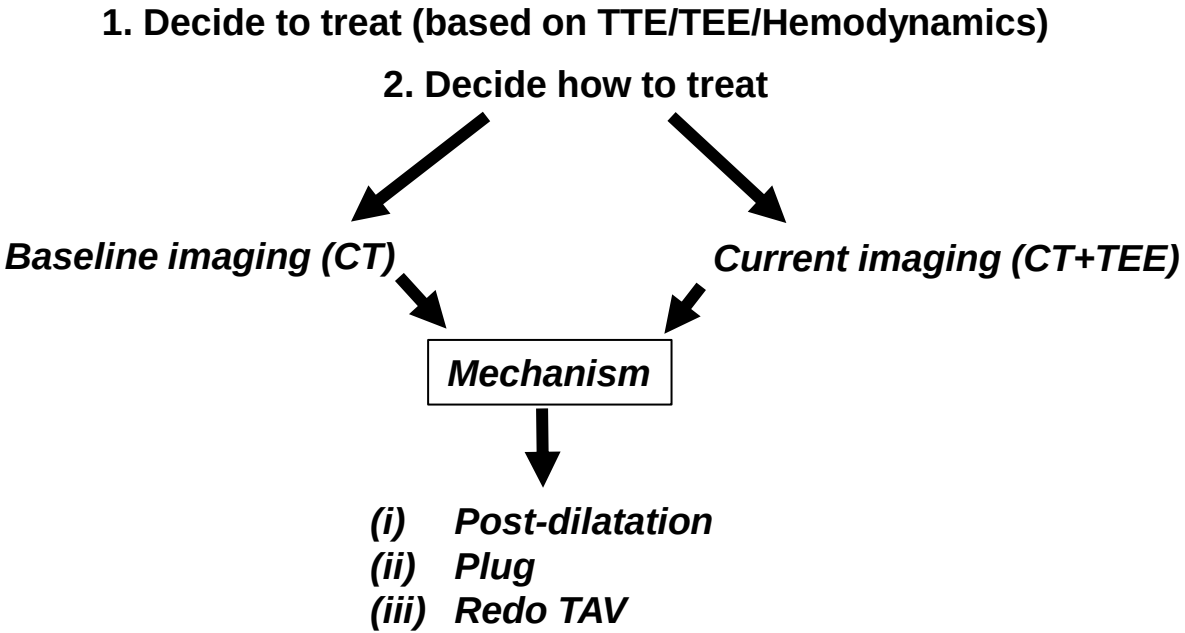


Jilaihawi et al, EuroIntervention 2015;11:456-464

Management of Aortic PVL

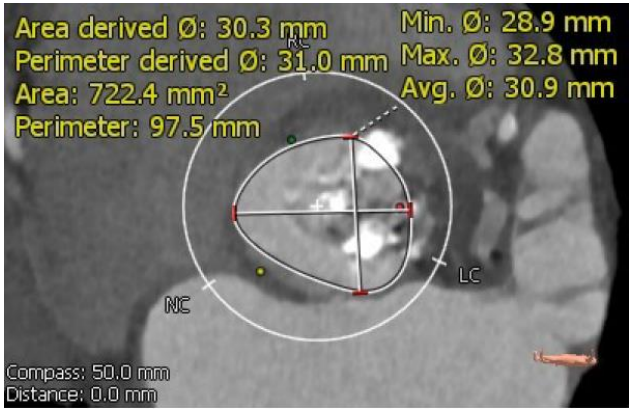


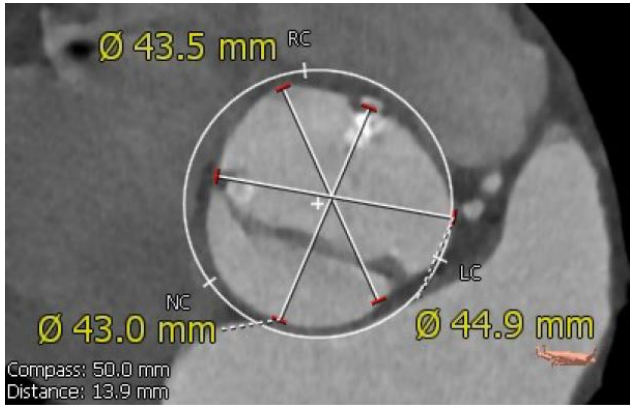
Management of Aortic PVL – decision making

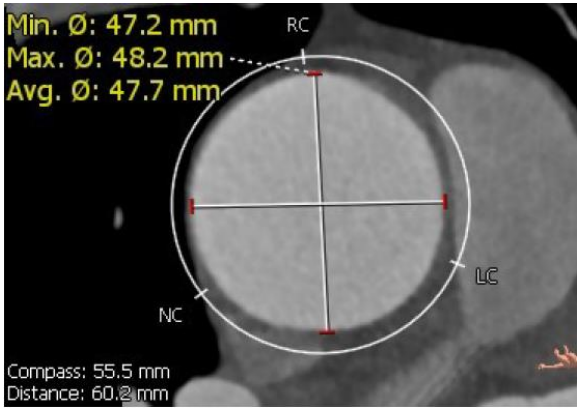


88-year-old male with Type 1 L-R fusion

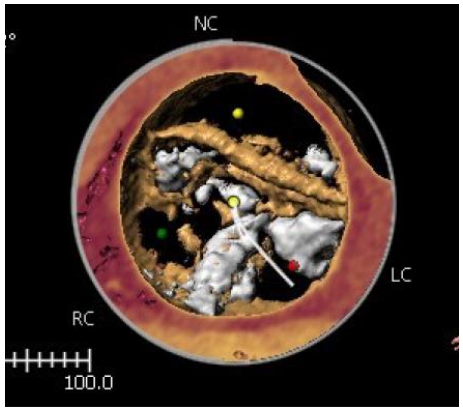
CT risk phenotype: High

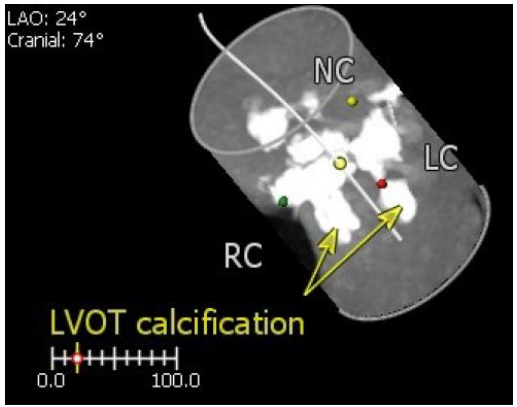




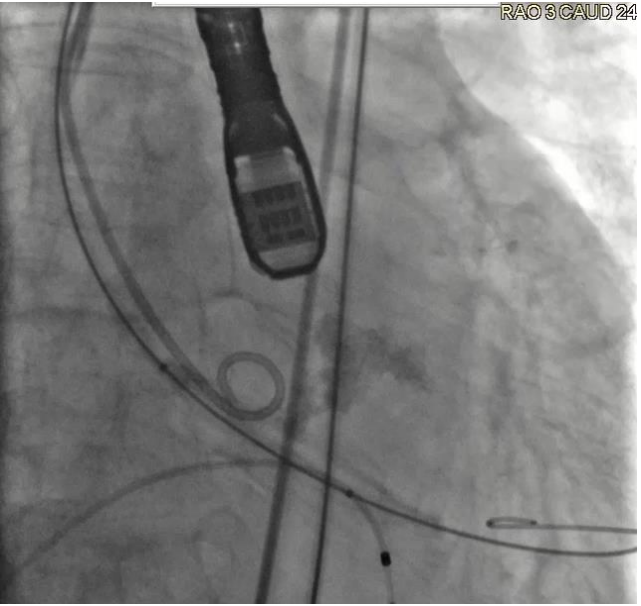


SOV	Area:	1568	Peri:	142
LVOT	Area:	694.3	Peri:	95.4
Coronary Height	RCA:	14.8	LCA:	16.4

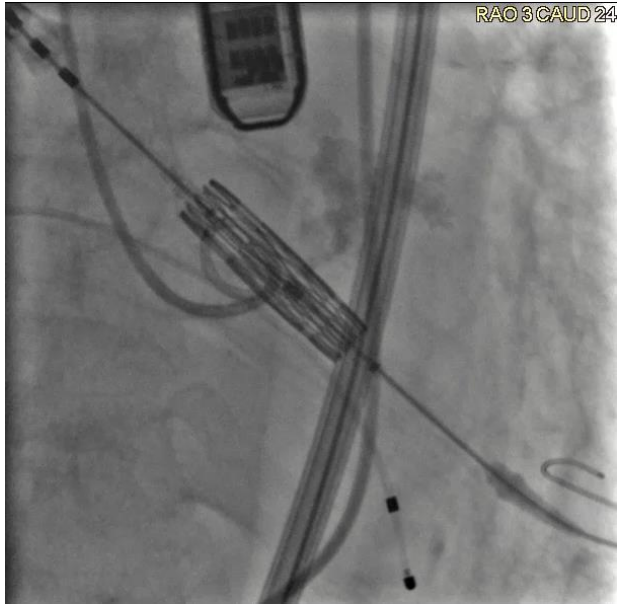




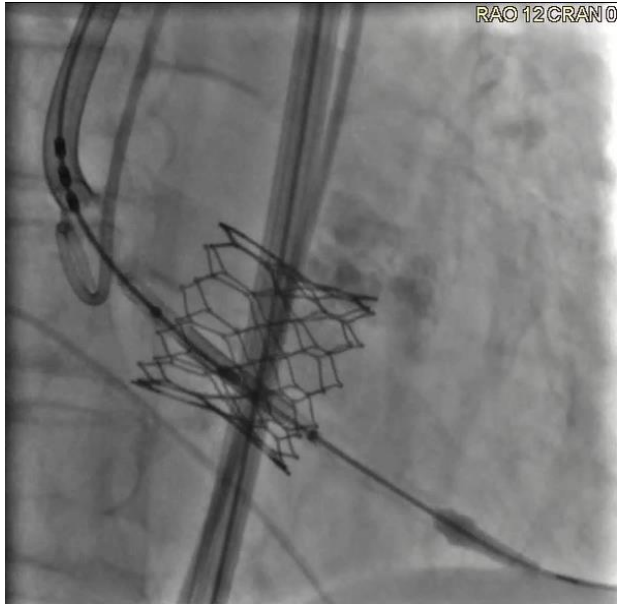
- PROCEDURE
- Cerebral protection using Sentinel device
- Transcatheter Aortic Valve Implantation using 29 mm Sapien 3



Pre-dilatation with 20mm Z MED II

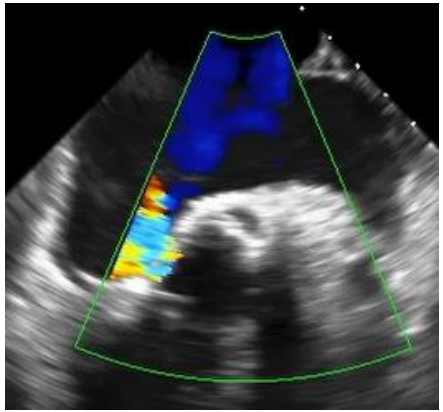


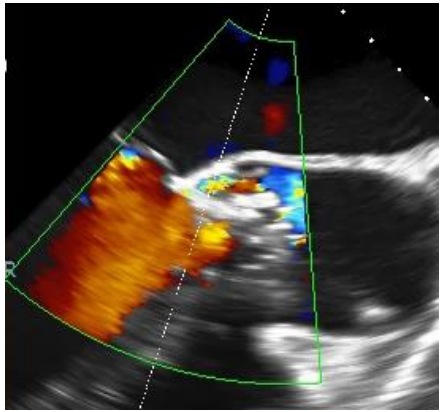
Initial deployment with nominal volume

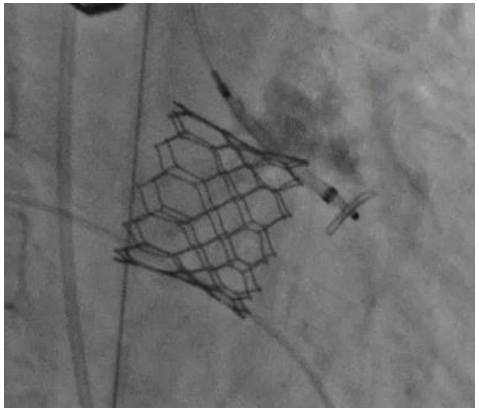


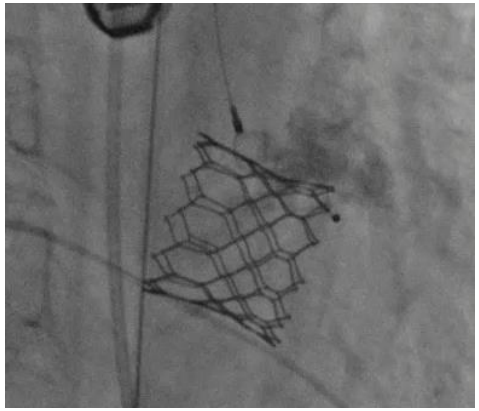
Post-dilatation with nominal volume

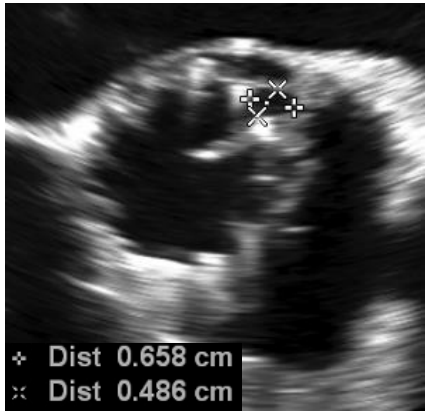
Persistent PVL due to calcium



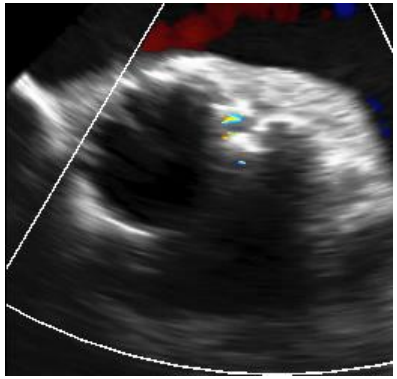


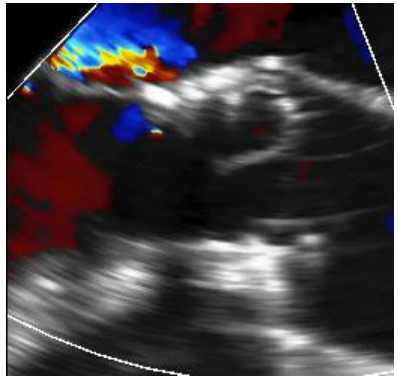




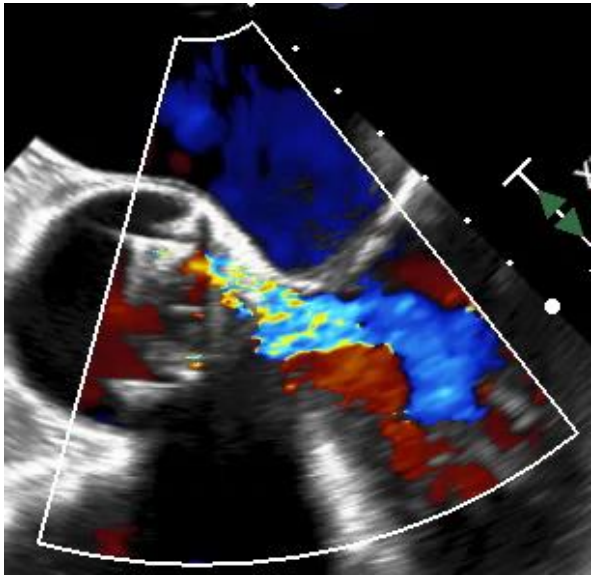


12mm AVP II Plug

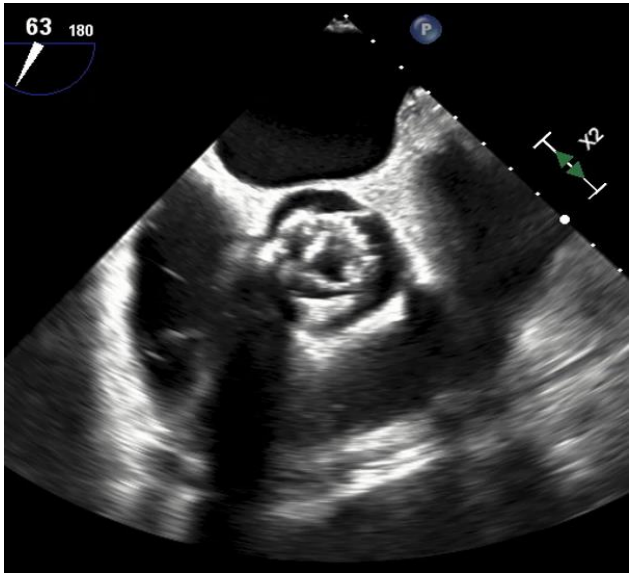




Patient presents to CSMC with BVD (PVL+AS) in 2024 (26 S3 outside institution in 2022)



Significant paravalvular leak

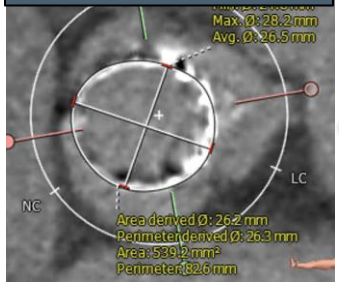


Restricted bioprosthetic leaflet motion

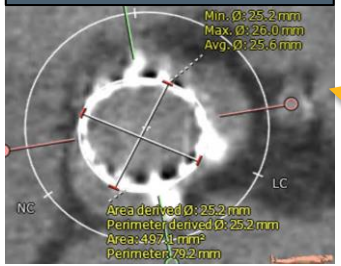
Transesophageal Echocardiogram

CT shows in vitro sizing for 26 S3 but with large LVOT

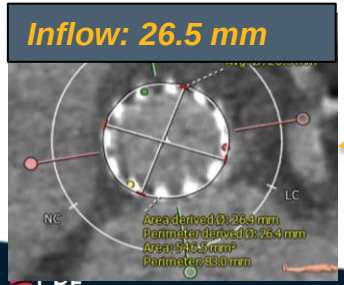
Outflow: 26.5 mm

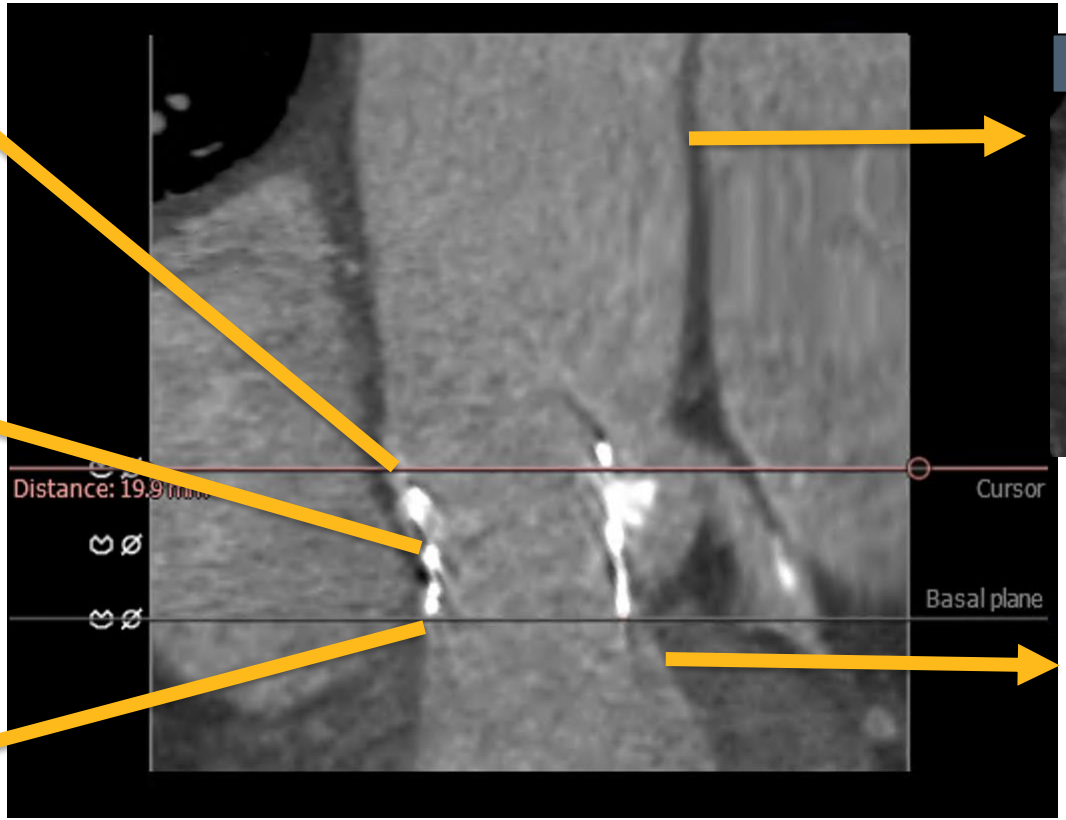


Mild: 25.6 mm

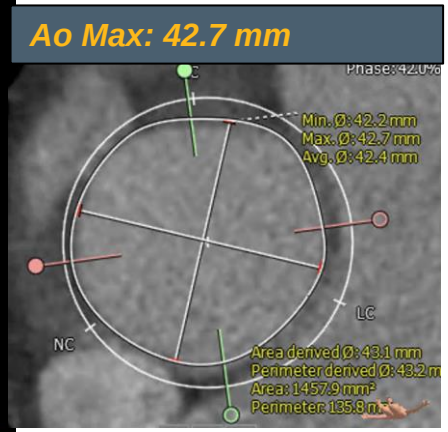


Inflow: 26.5 mm



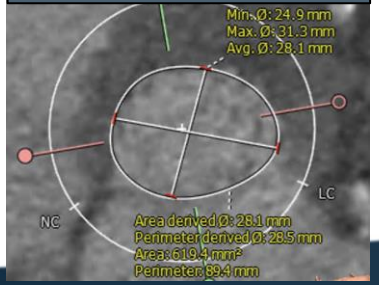


Ao Max: 42.7 mm



Larger LVOT

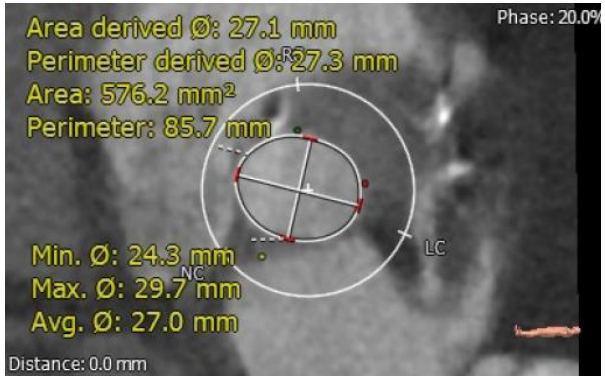
LVOT: A619



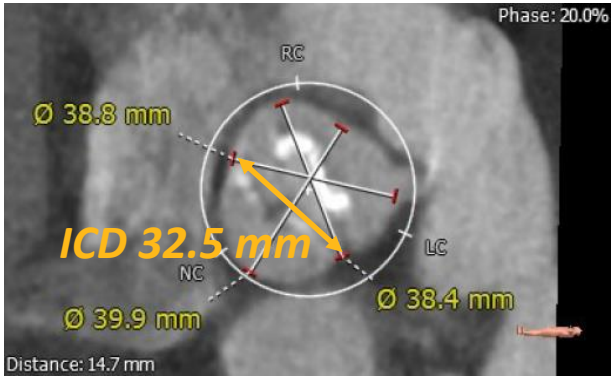
Commissurally aligned; Calcified Leaflets; Minimal waist

Pre-index TAVR CT, prior to index TAVR in 2022
Type 1 LR bicuspid non-calcified raphe

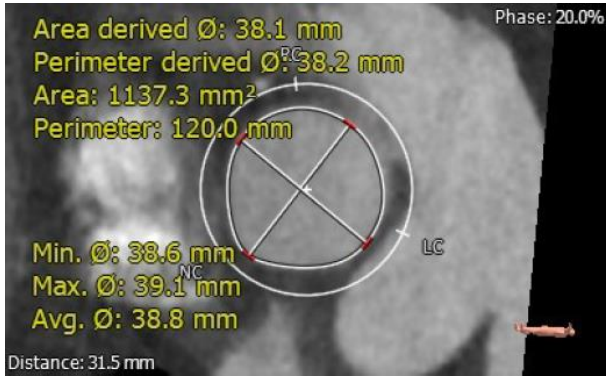
Annulus: 576 mm²

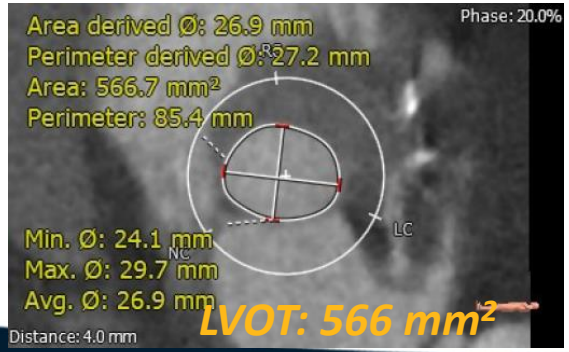


SOV: 38.8 x 39.9 x 38.4 mm

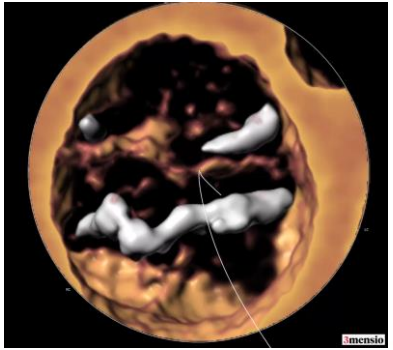


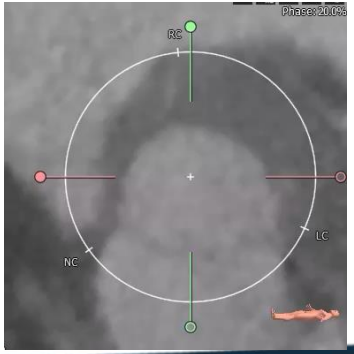
STJ 38.6 x 39.1 mm





LVOT: 566 mm²

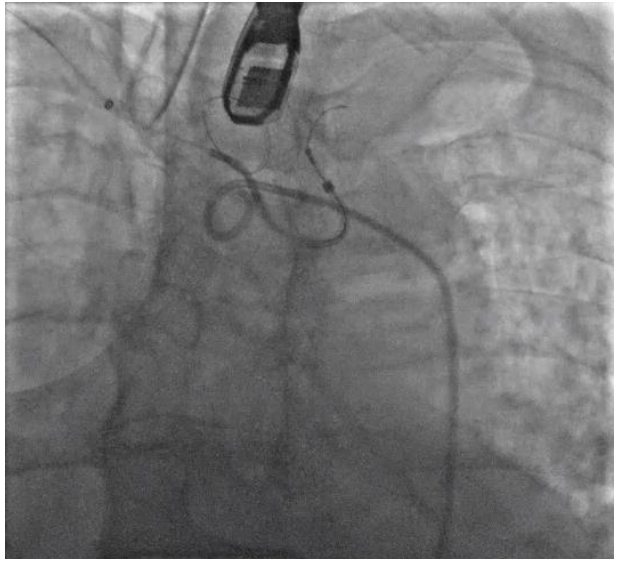




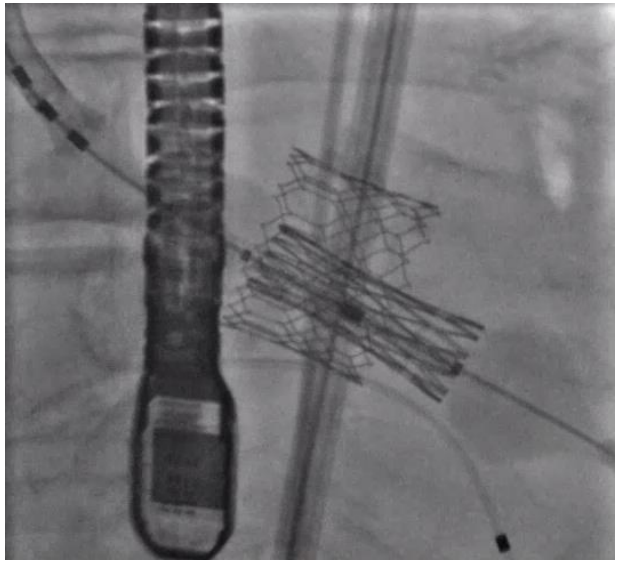
CRF® TCT®

Annular and supra-annular dimensions support sizing for 29 S3

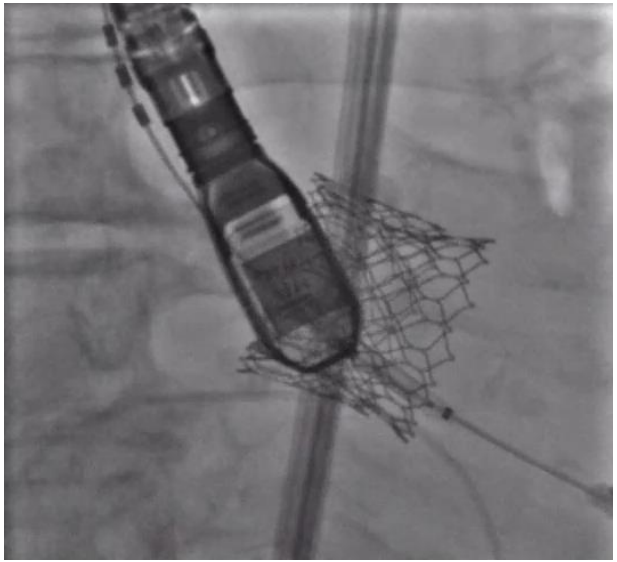
Redo TAV: 29 S3UR



Cerebral Embolic Protection using Sentinel

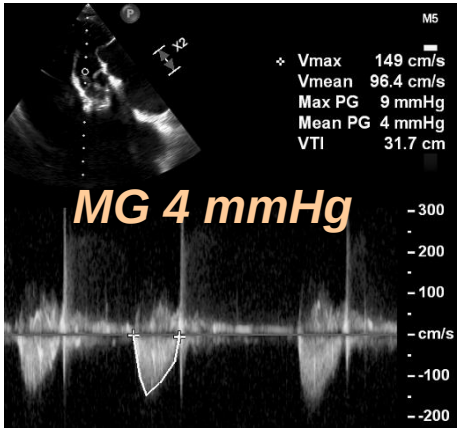


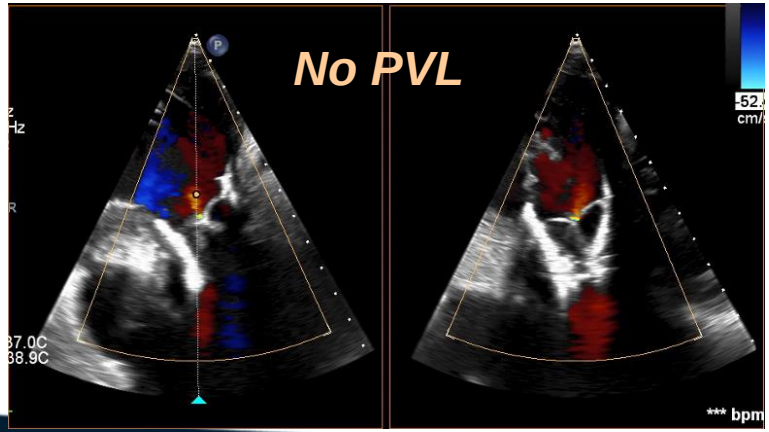
Deployment of 29mm Sapien 3 Ultra Resilia at nominal volume



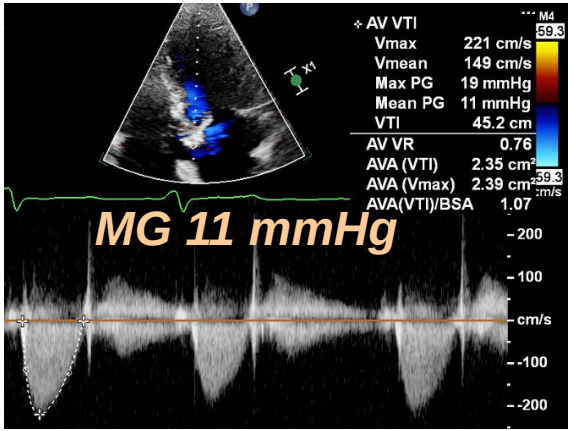
Post-dilatation with the Commander balloon at nominal volume

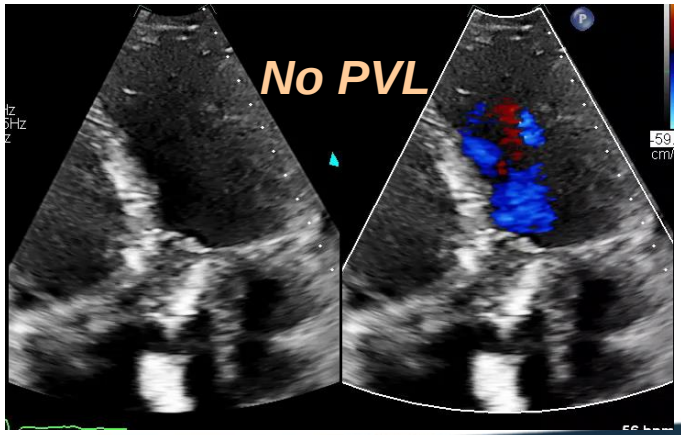
Final Result





Discharge





A Primer on Prevention, Recognition and Management of Aortic PVL

- All 3 are heavily dependent on imaging:
- Prevention:
  - Size optimally using 3D imaging, consider simulation
  - Optimize procedurally- predil/postdil
- Recognition:
  - Underestimated by TTE, take clinical cues to have low threshold for TEE
  - Hemodynamics can prognosticate
- Management:
  - Understand the mechanism to best guide safe and effective management