

S3 in Transforming Patient Treatment Practice: Case Examples

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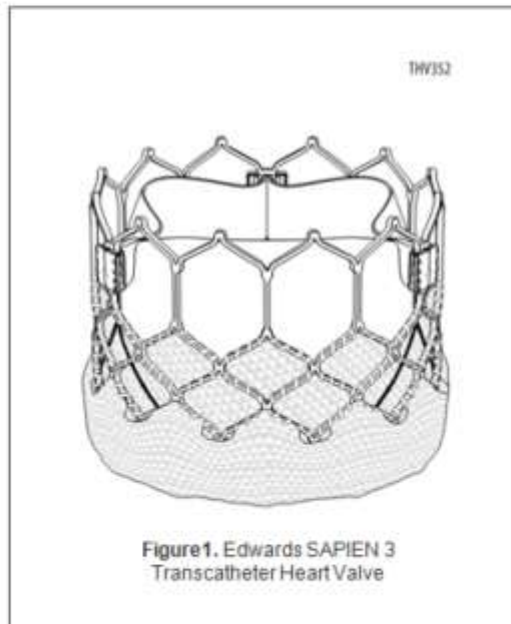
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Stephen Corday Chair in Interventional Cardiology

Sapien 3 FDA Instructions for Use



Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System



Sapien 3 FDA Instructions for Use

2.0 Indications

The Edwards SAPIEN 3 Transcatheter Heart Valve (THV), model 9600TFX, and accessories are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., Society of Thoracic Surgeons operative risk score $\geq 8\%$ or at a $\geq 15\%$ risk of mortality at 30 days).

“native calcific aortic stenosis”

Sapien 3 FDA Instructions for Use for Valve Sizing



Specifications		20 mm	23 mm	26 mm	29 mm
Native Valve Annulus Size (CT)	Area	273–345 mm ²	338–430 mm ²	430–546 mm ²	540–683 mm ²
	Area Derived Diameter	18.6–21 mm	20.7–23.4 mm	23.4–26.4 mm	26.2–29.5 mm

IFU: “safety and effectiveness not established”

- Safety and effectiveness have not been established for patients with the following characteristics/comorbidities:
 - Non-calcified aortic annulus
 - Severe ventricular dysfunction with ejection fraction < 20%
 - Congenital unicuspid or congenital bicuspid aortic valve
 - Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+)
 - Pre-existing prosthetic heart valve or prosthetic ring in any position
 - Severe mitral annular calcification (MAC), severe (> 3+) mitral insufficiency, or Gorlin syndrome
 - Blood dyscrasias defined as: leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy
 - Hypertrophic cardiomyopathy with or without obstruction (HOCM)
 - Echocardiographic evidence of intracardiac mass, thrombus, or vegetation
 - A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated
 - Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe “unfolding” and tortuosity of the thoracic aorta
 - Access characteristics that would preclude safe placement of 14F or 16F Edwards eSheath Introducer Set, such as severe obstructive calcification, severe tortuosity or diameter less than 5.5 mm or 6 mm, respectively
 - Bulky calcified aortic valve leaflets in close proximity to coronary ostia

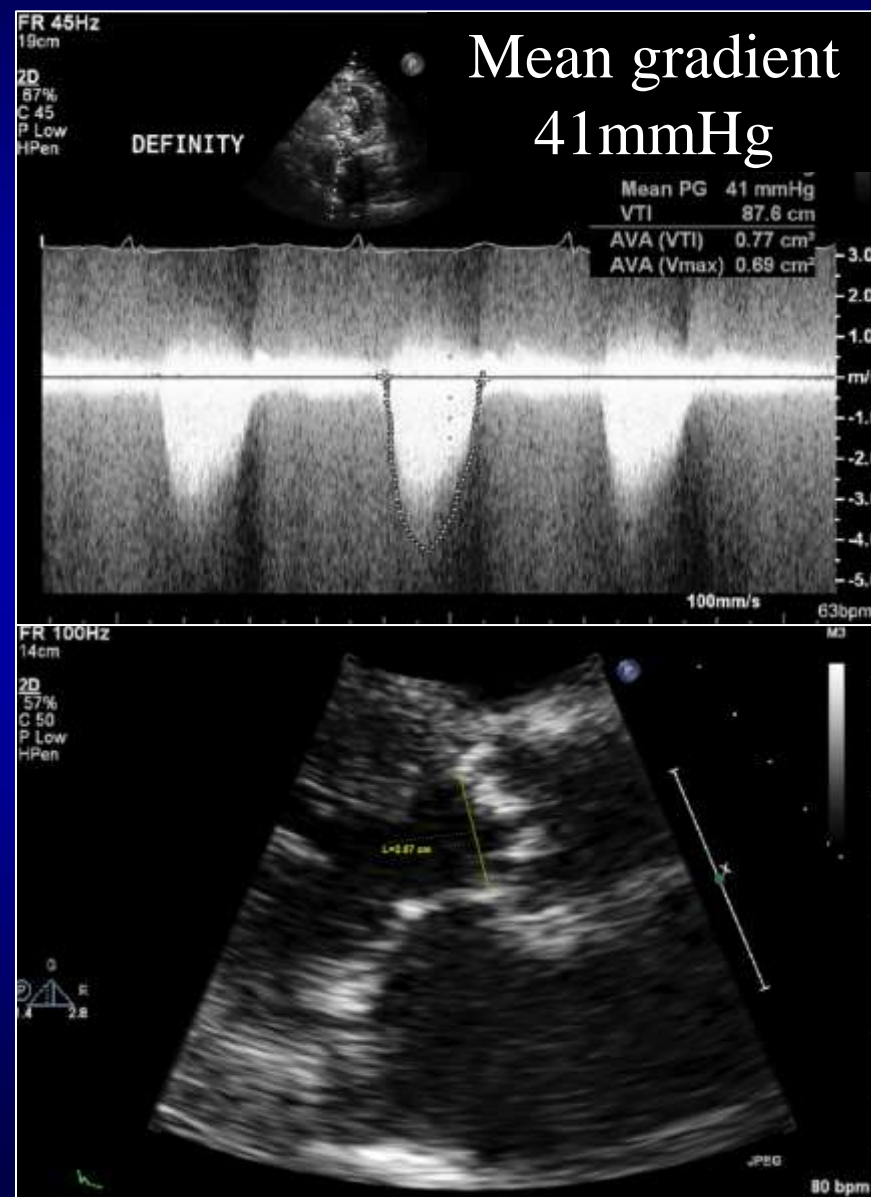
81 y/o female referred for TAVR

- WT 73.4kg, HT 165.1cm
- NYHA Class II, Creatinine 0.9
- CAD:
 - s/p CABG x4 (1997)
 - s/p PTCA & stenting of SVG-RCA (2013)
 - Angiogram: Patent grafts, patent stent
- HTN, hyperlipidemia
- A. Fib s/p watchman device
- s/p AAA repair
- CVA x2 (last in October 2012)
- h/o of breast cancer; s/p L mastectomy & chemo (1999)
- Bladder prolapse, hiatal hernia s/p repair, GERD
- STS 4.780%, EuroSCORE II 10.81%

Patient deemed high-risk for surgical aortic valve replacement

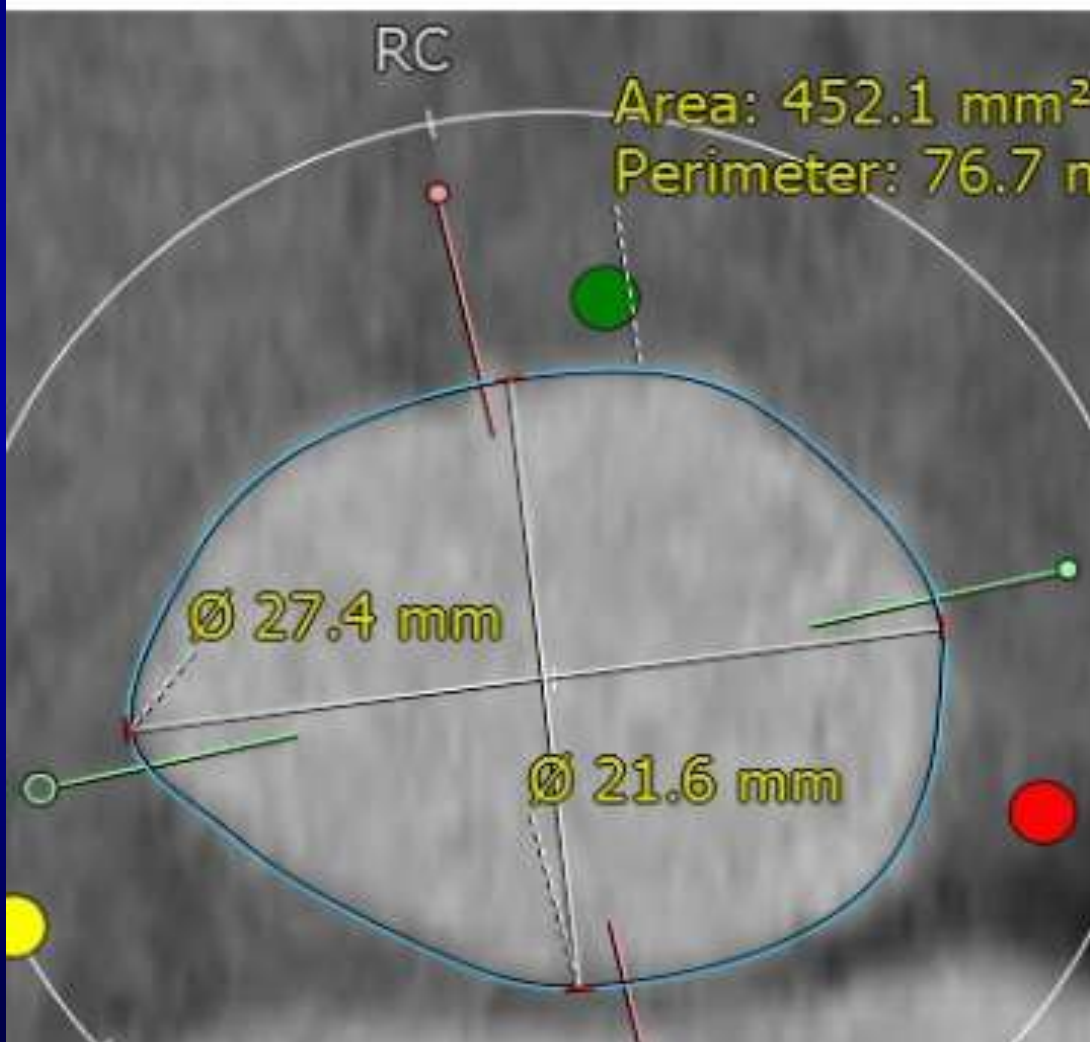
Severe aortic stenosis

Echo Variable (TTE)	Measure
Trileaflet valve	Y
Peak Transaortic Vel	428
Mean transaortic Grad	41
Calculated EOA	0.7
Calculated iEOA	
Severity of AR	Mild
Severity of MR	Trivial
Ejection Fraction	67%
TTE annulus diameter	20.7
Is echo within window?	Y
RV Pressures	42
Dobutamine	N
Resting EF	
Mcg used	
Peak Vel	
Mean Grad	



Annular Measurement Plan for 26mm Sapien3 valve

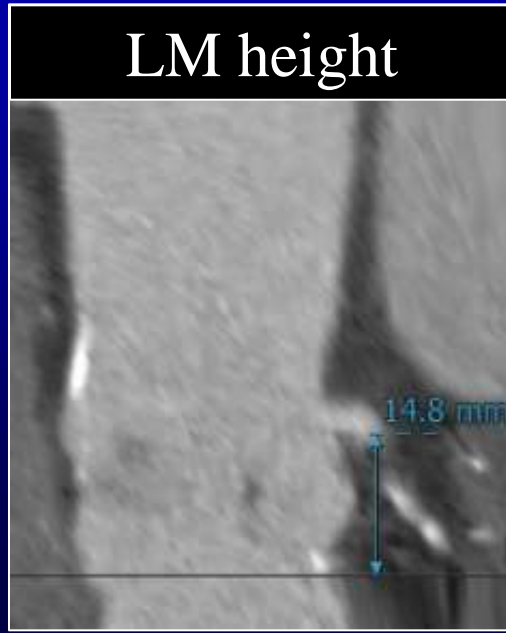
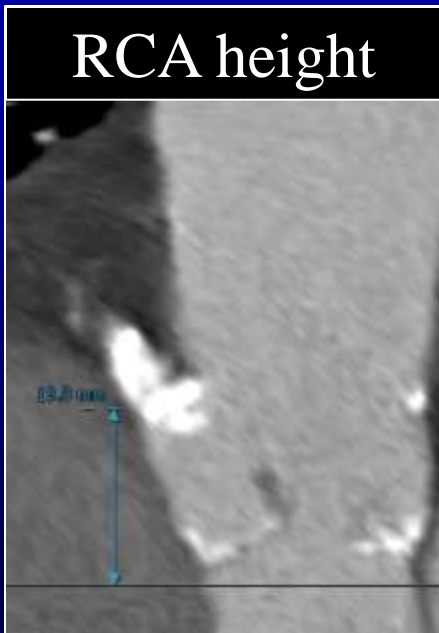
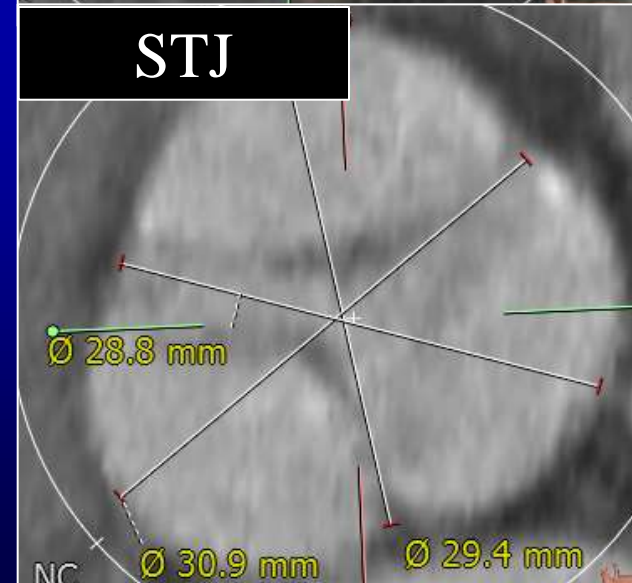
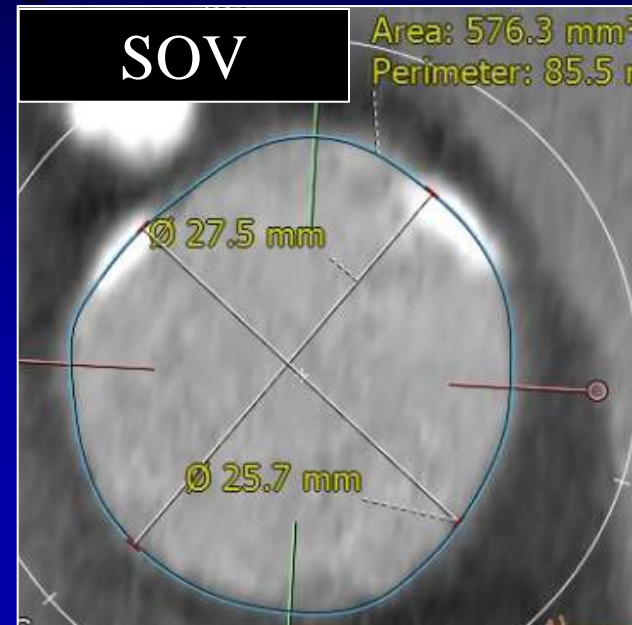
Dmean = 24.5 mm, Area = 452 mm², Peri = 76.7 mm



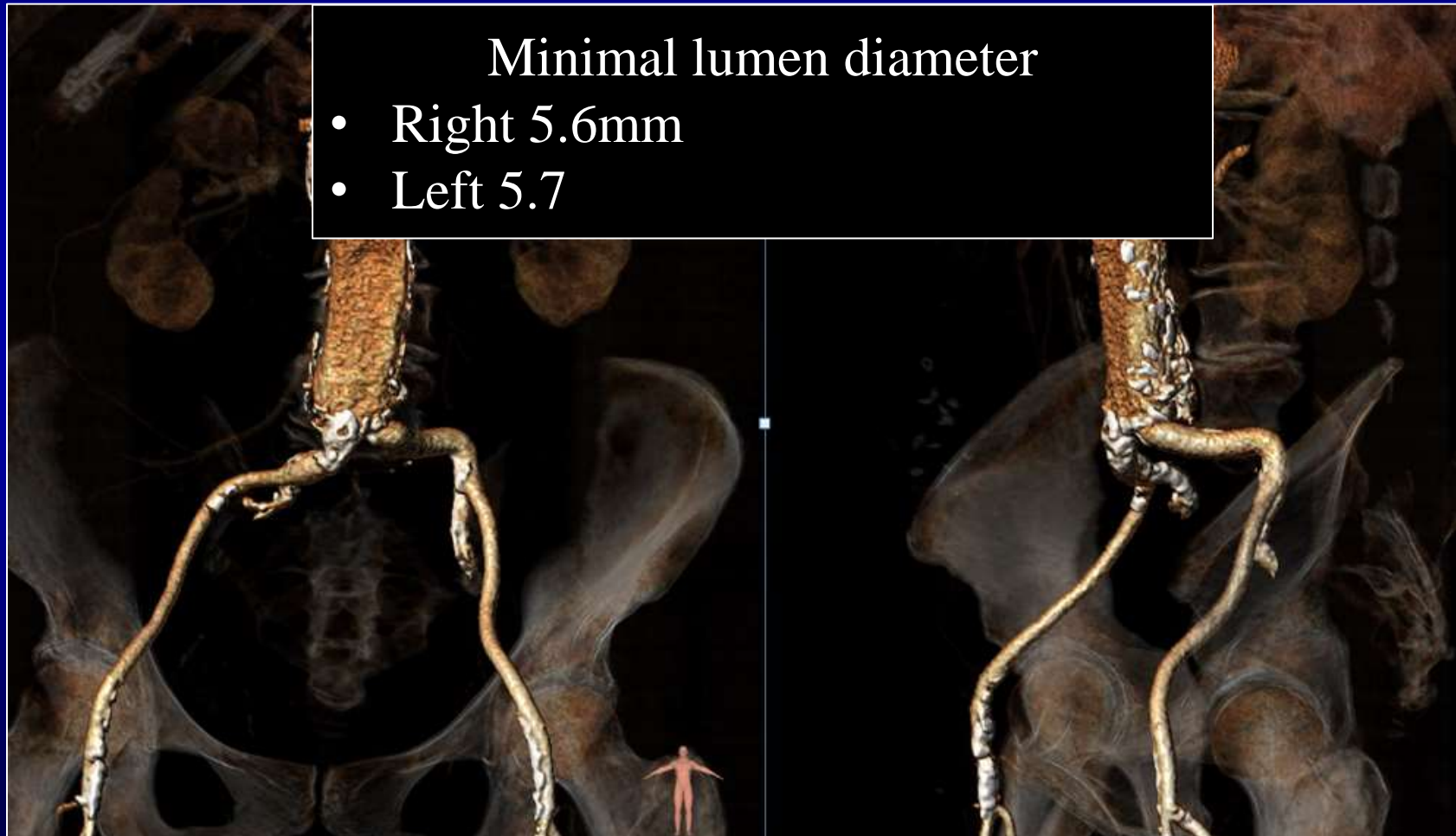
Annulus by CT	Measure
Short Annulus Diameter	21.6
Long Annulus Diameter	27.4
Annular Perimeter	76.7
Annular Area	452
% Area Oversizing	15.4%
Comment:	

Aortic Complex

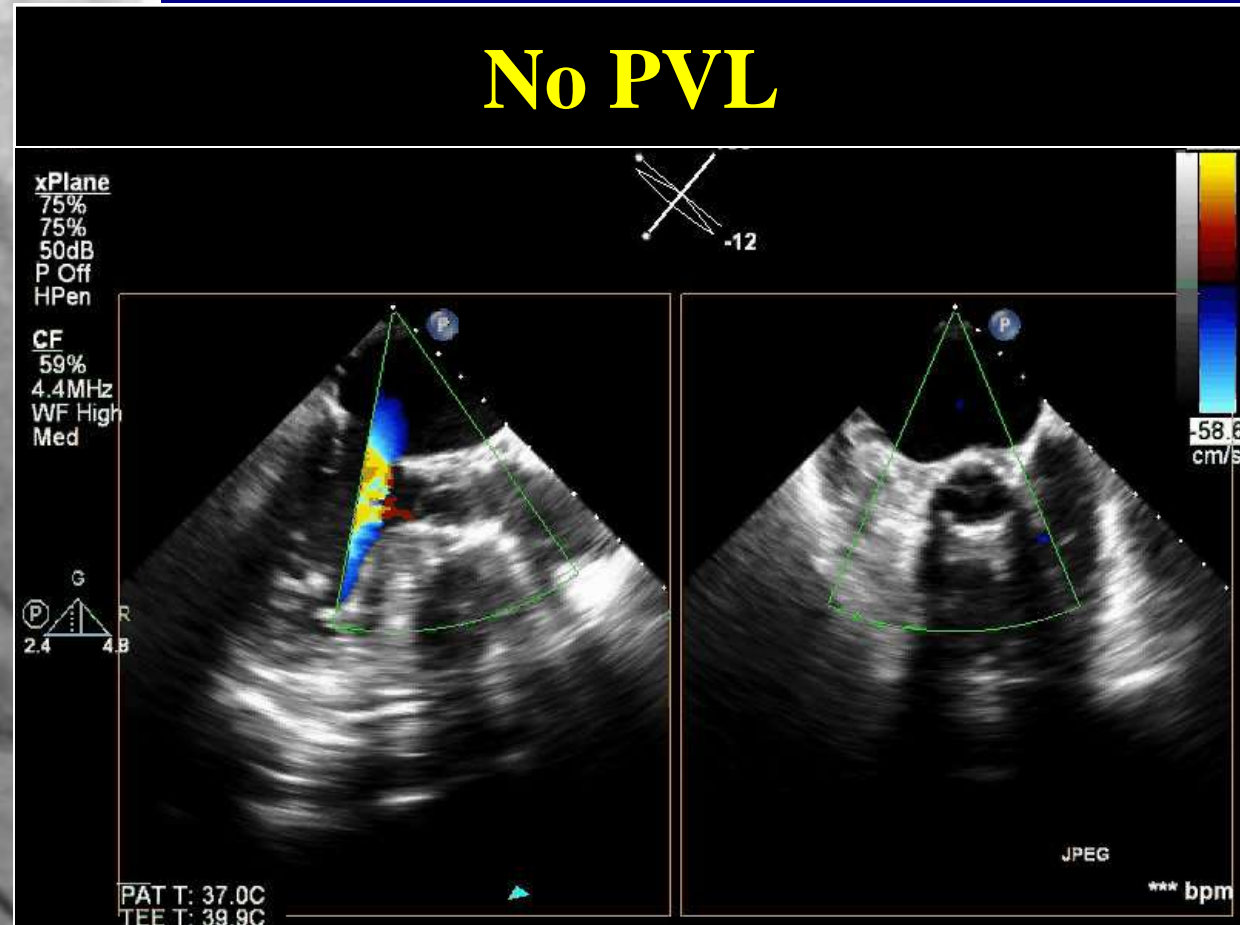
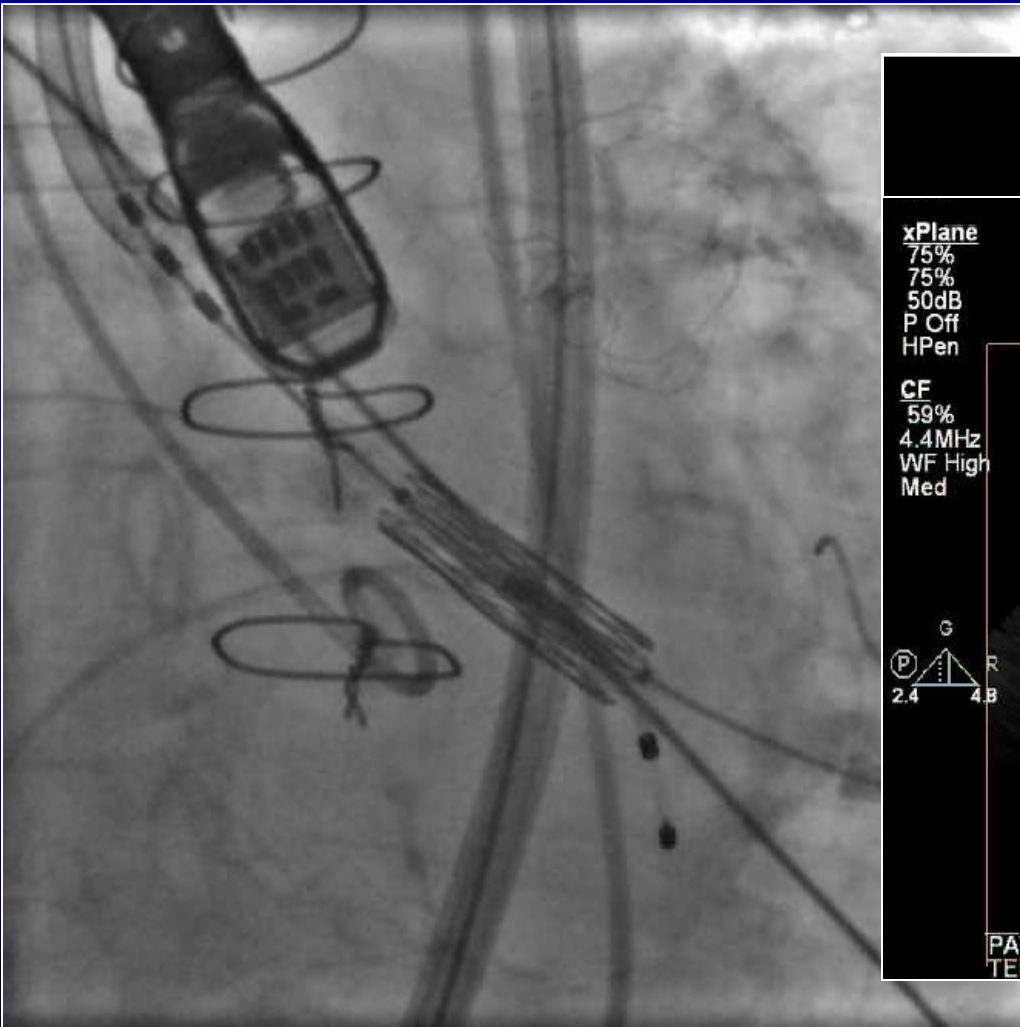
Aortic Root by CT	Measure
LVOT calcification	Trivial
Sinus of Valsalva Diameter	30
Sinotubular Junction Diameter	26.6
Left Coronary Height	14.8
Right Coronary Height	19.8



Iliofemoral vessels suitable for TF-TAVR with 26mm Sapien3 valve



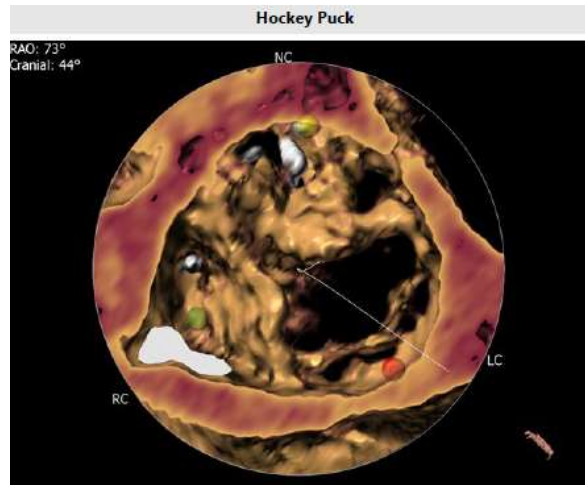
TAVR with 26mm Sapien3 performed



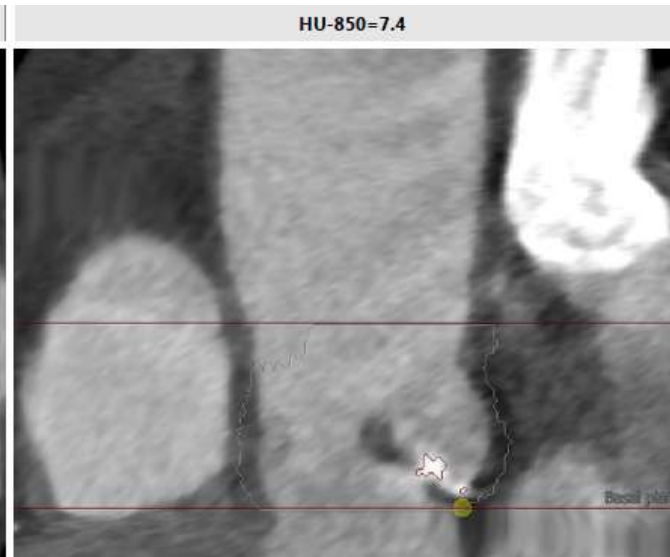
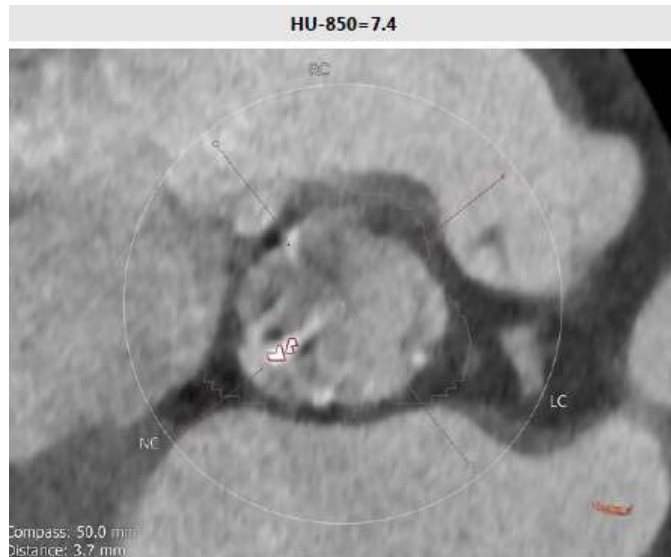
TAVR in minimal calcium

CT Analysis: extremely low AV calcification

Volume rendering

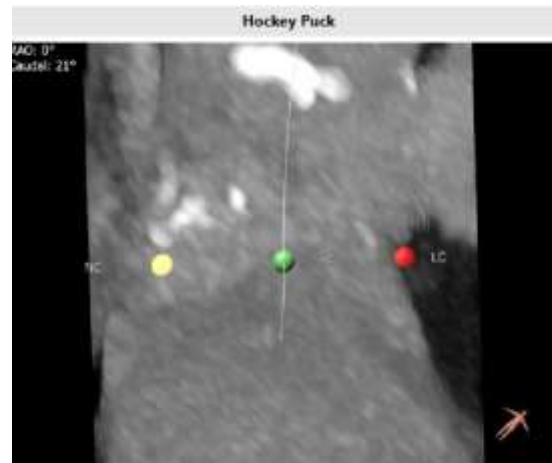


HU-850



CT Analysis: extremely low AV calcification

**maximal intensity
projection (MIP)**



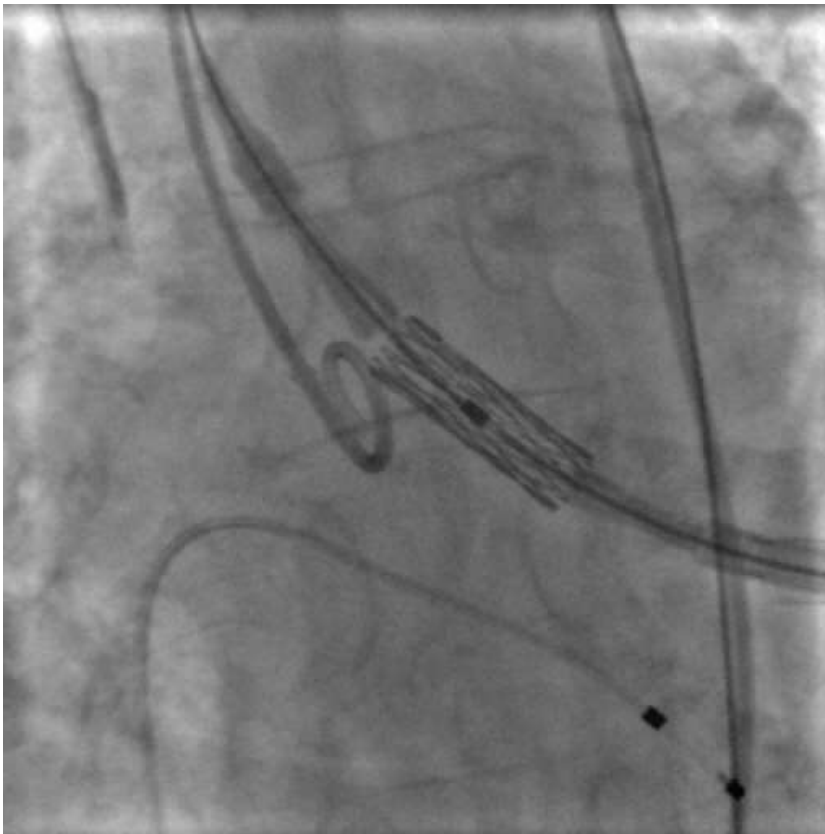
Agatston method in non-contrast CT: AV calcification score = 503 AU

CSMS mean value of AV calcification = 3474 AU

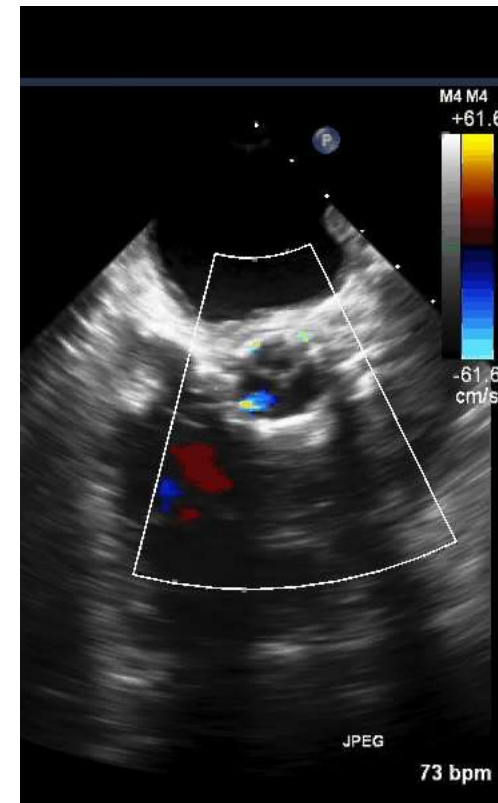
Only 1.3% below 600 AU

Intra-Procedural Images

**TA 23mm S3 valve
(deployment volume: 18cc)**



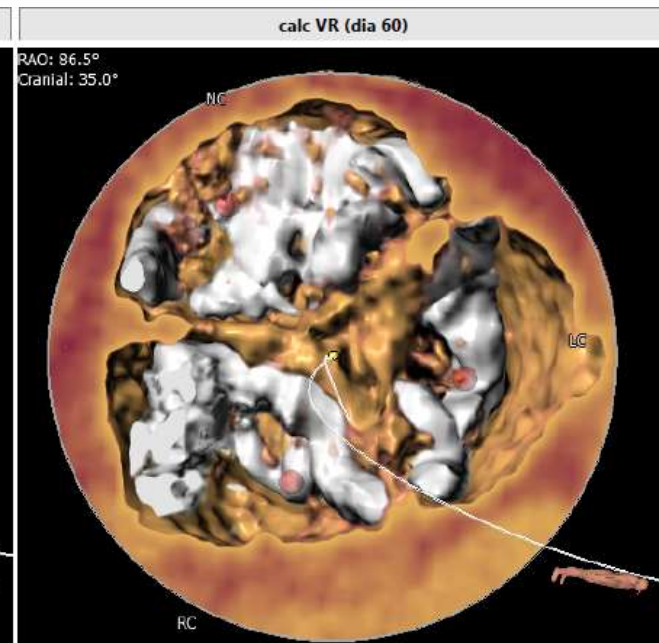
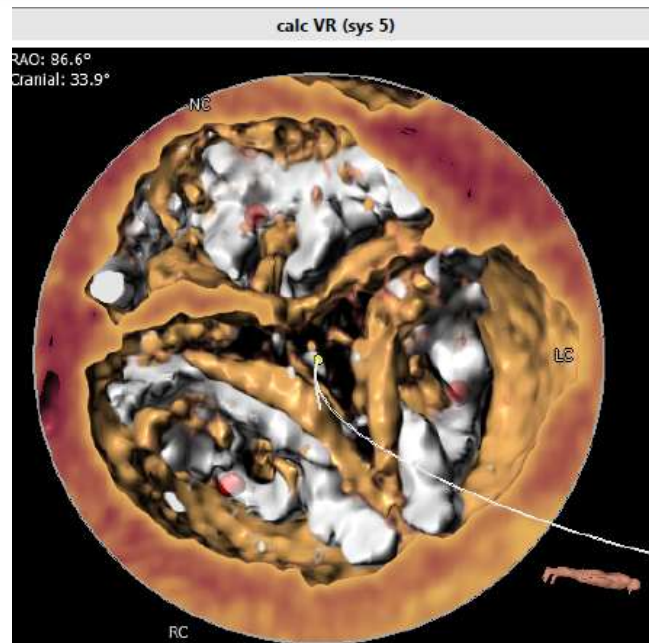
Trivial PVL



TAVR in Heavily calcified Valve

CT Analysis: extremely high AV calcification

Volume rendering

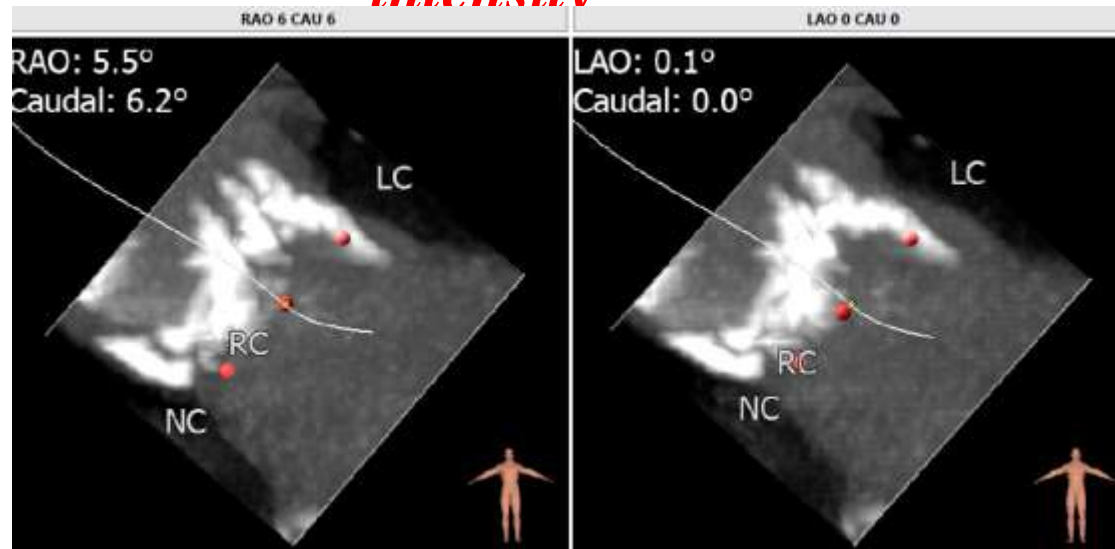


HU-850



CT Analysis: extremely high AV calcification

*maximal
intensity*



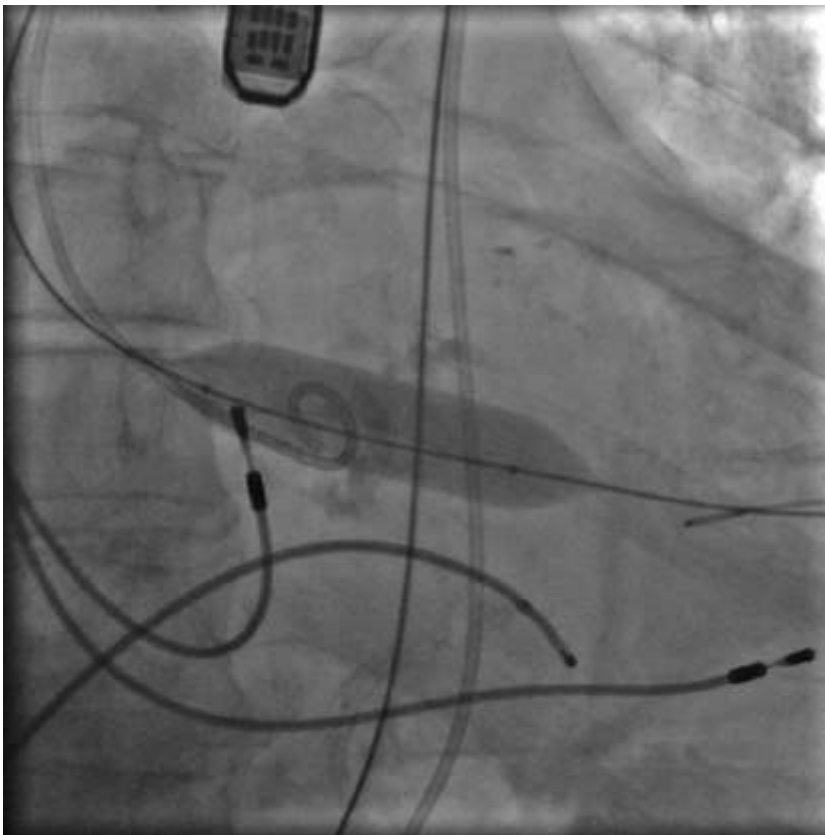
Agatston method in non-contrast CT: AV calcification score = 8563 Agatston Units (AU)

CSMS mean value of AV calcification = 3474 AU

Only 2.7% above 8500 AU

Intra-Procedural Images

**BAV with a 15mmX5cm
Z-med II balloon**

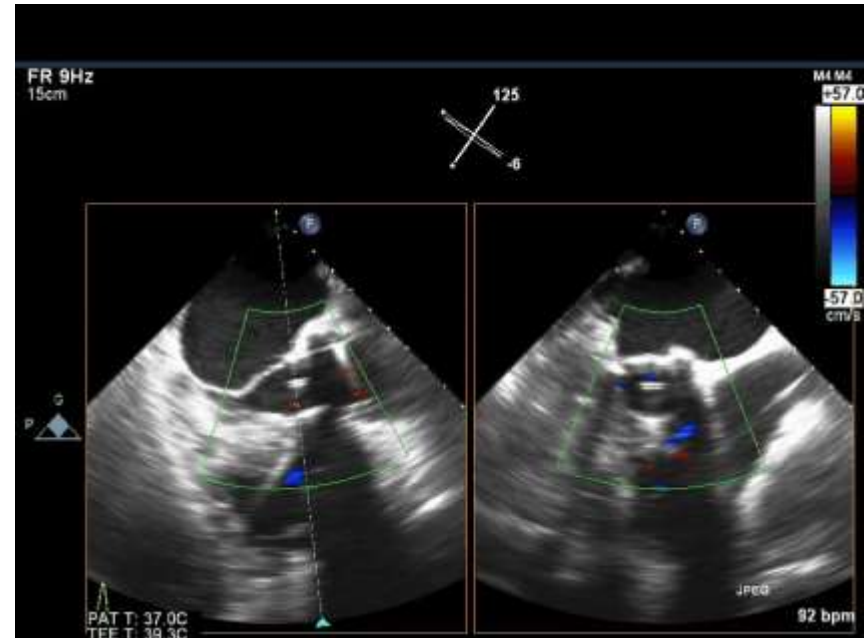
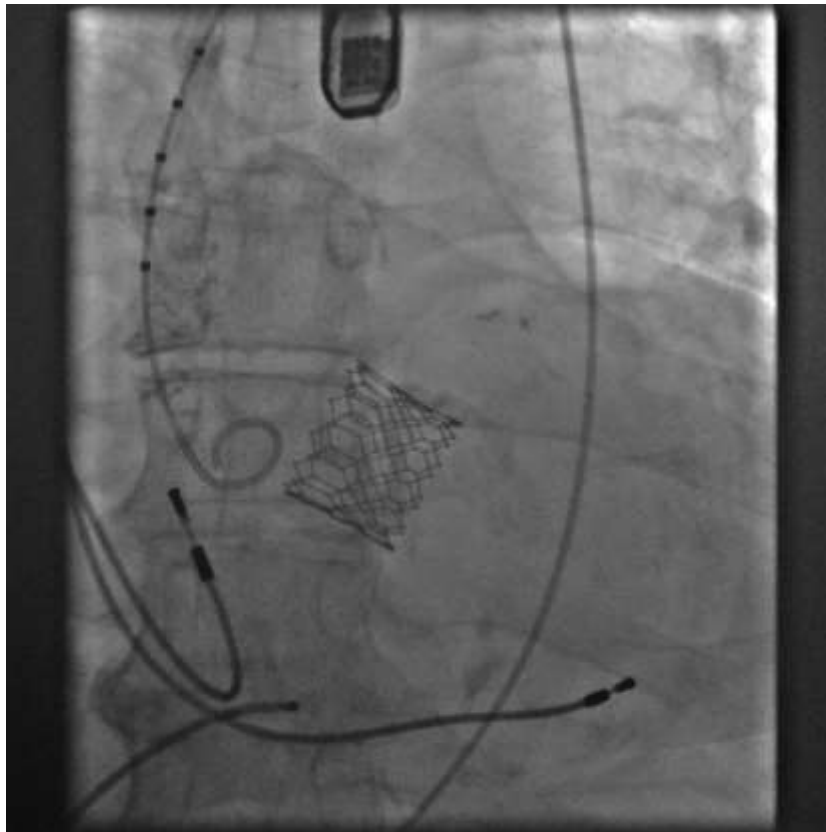


**TF 26mm S3 valve
(deployment volume: 23cc)**



Intra-Procedural Images

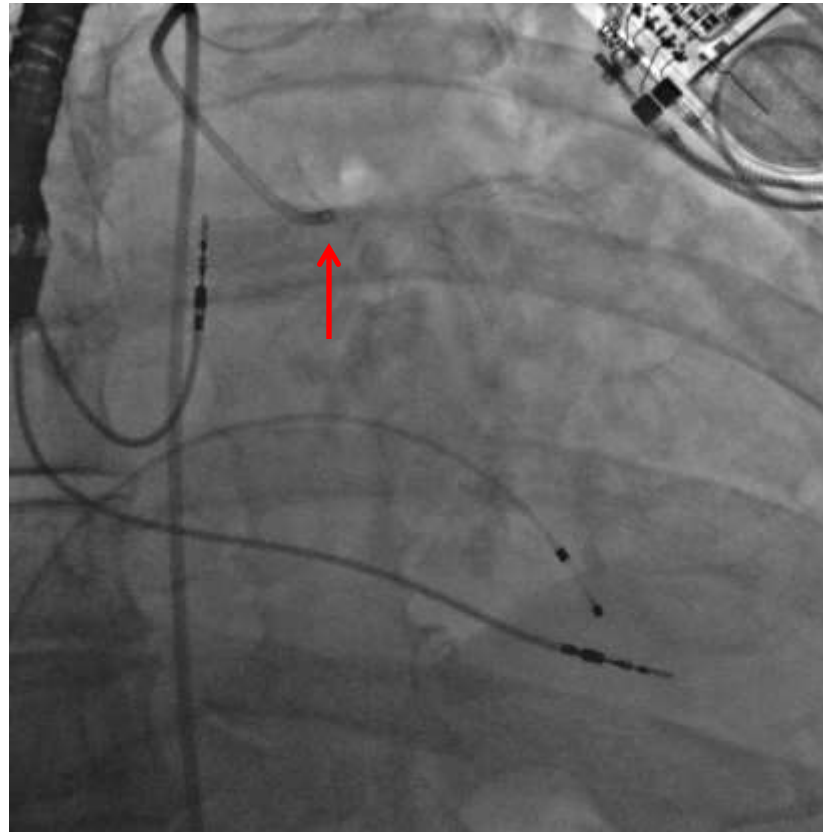
Trivial PVL



TAVR plus Left Main Stent

68 year old Male with h/o chest radiation for non-Hodgkins Lymphoma: AS+Left Main

50% LM stenosis

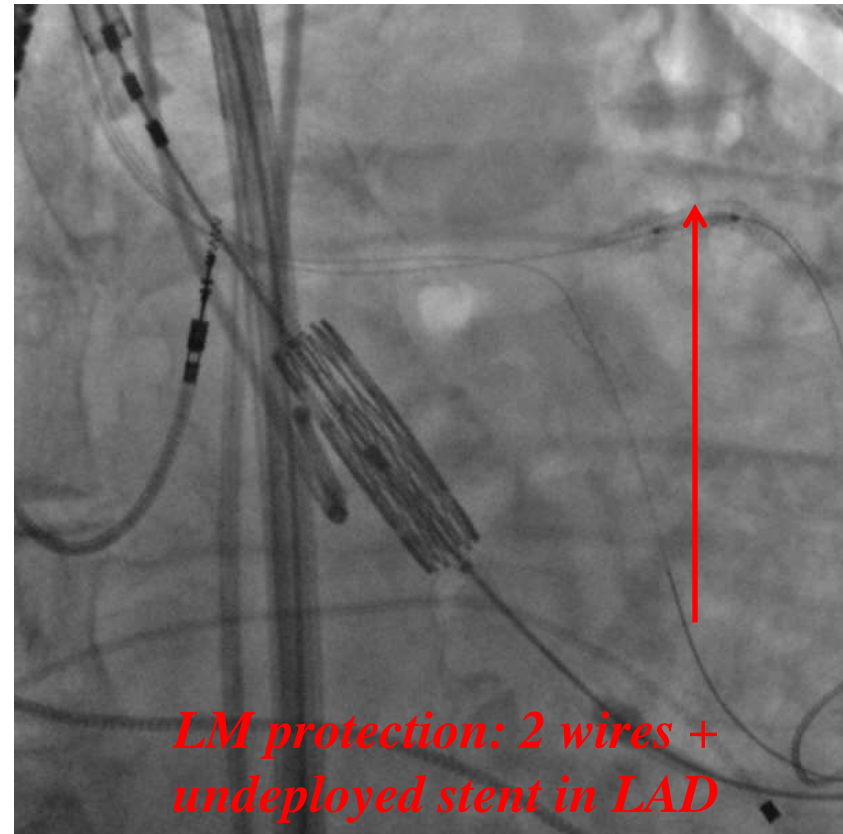


Intra-Procedural Images

BAV with 15mmX4cm Z-med II balloon

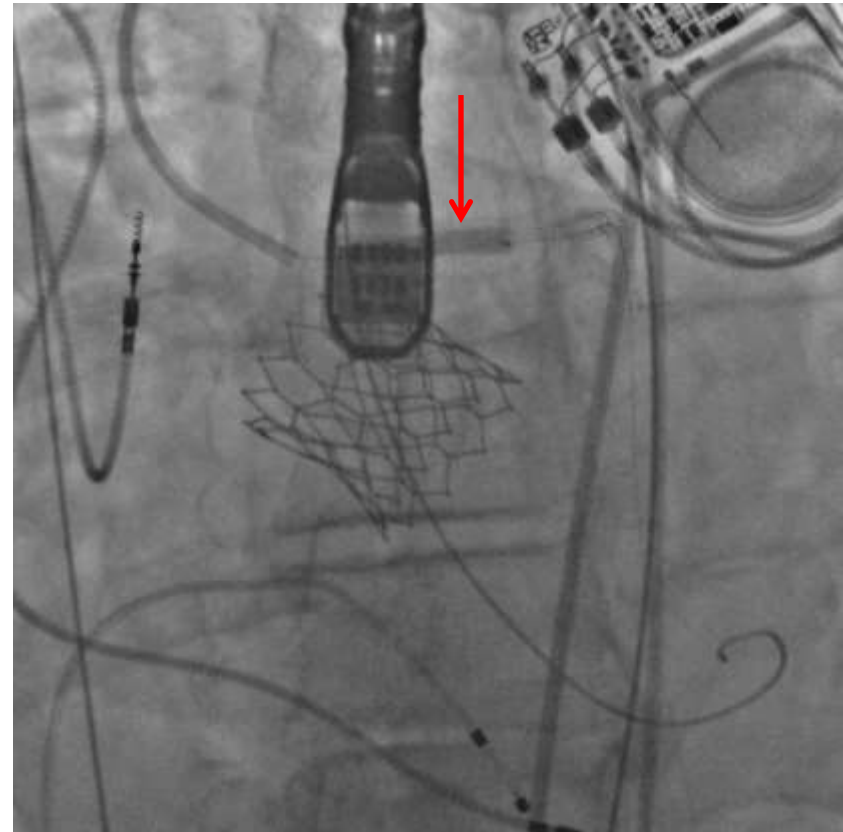
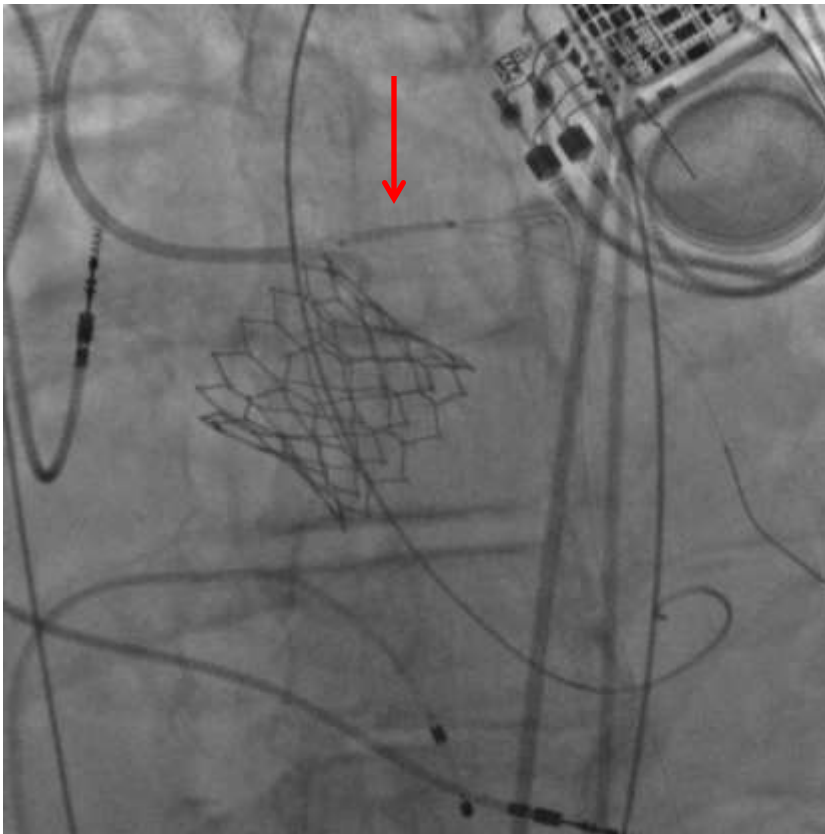


TF 26mm S3 valve



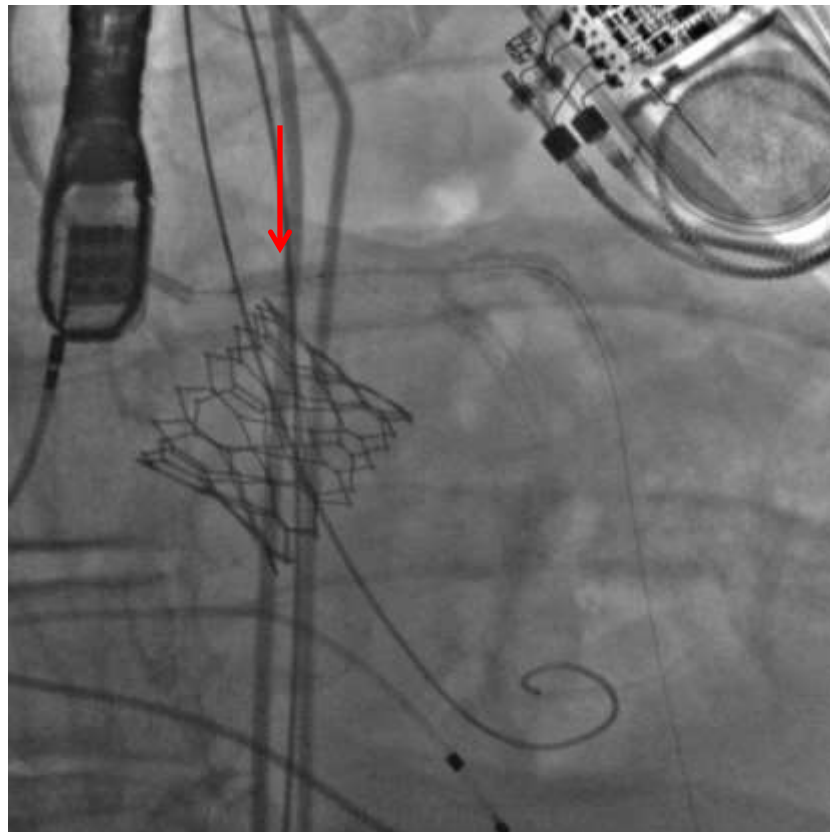
Intra-Procedural Images

3.5mmX15mm Xience DES in LM



Intra-Procedural Images

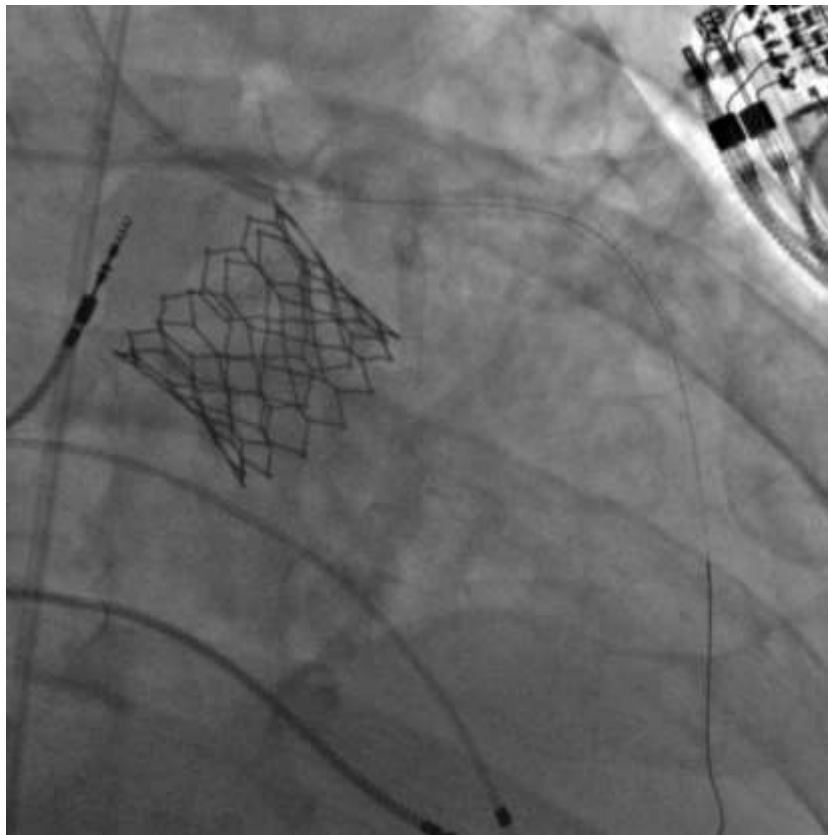
Postdilatation of LM stent and LM ostium



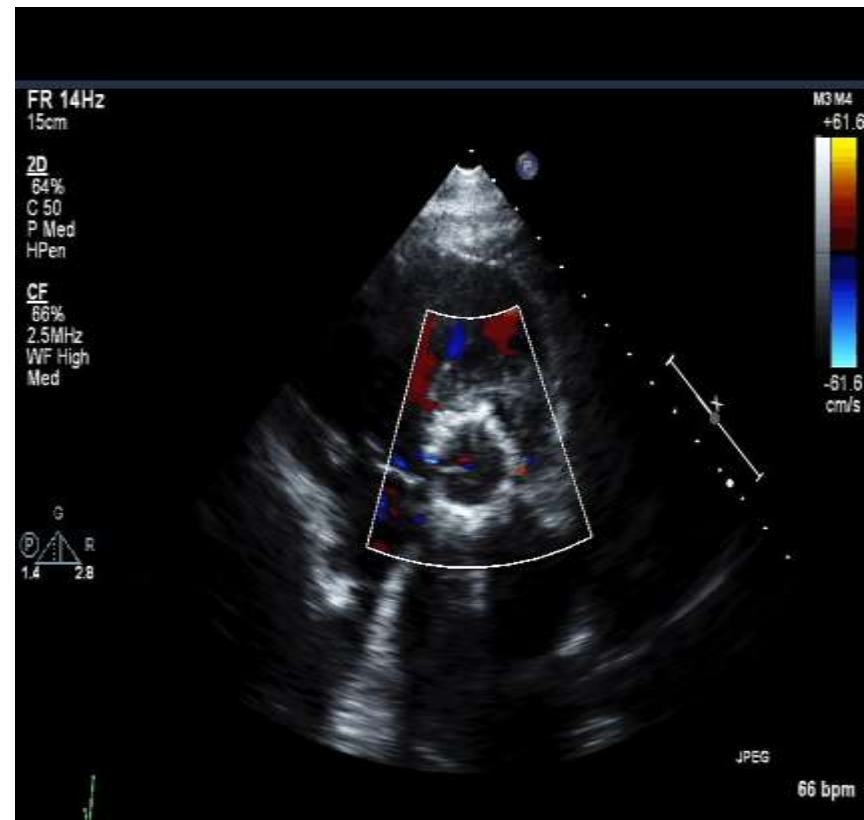
Intra-Procedural Images

Final result

Patent LM



Trivial PVL



TAVR in congenital bicuspid stenosis

60 y/o female undergoing TAVR

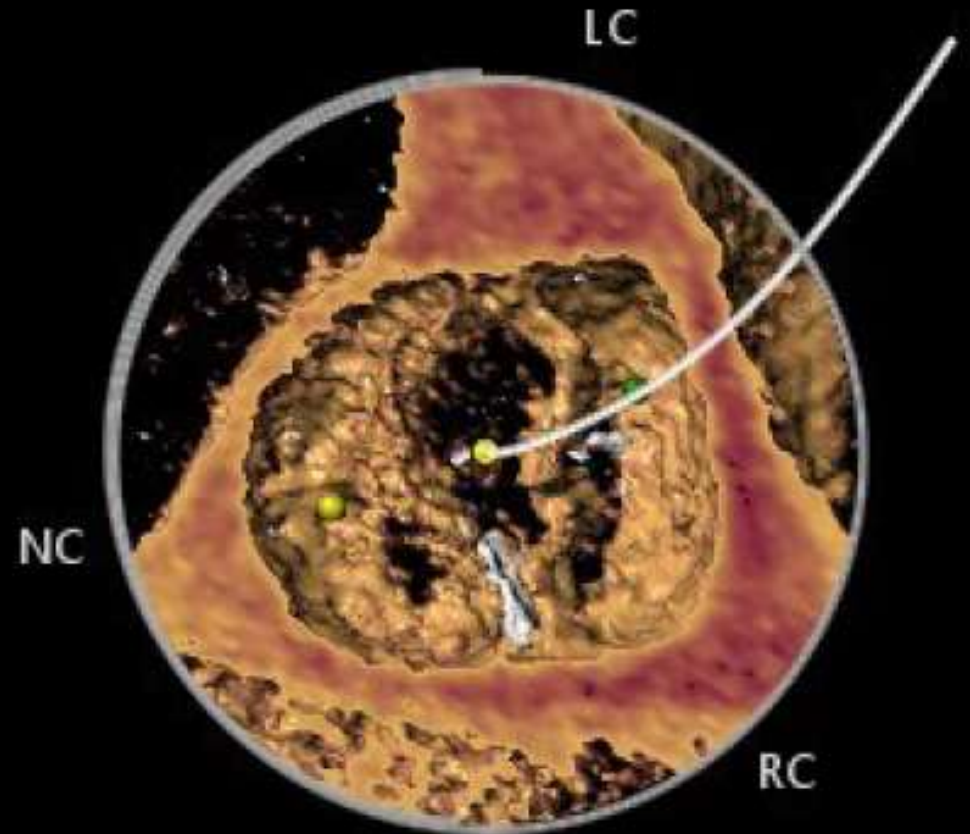
Annulus Area 356.2 mm²
Dmin 18.3, Dmax 24.8 mm

Area derived Ø: 21.3 mm_{RC}
Perimeter derived Ø: 21.8 mm
Area: 356.2 mm²
Perimeter: 68.4 mm

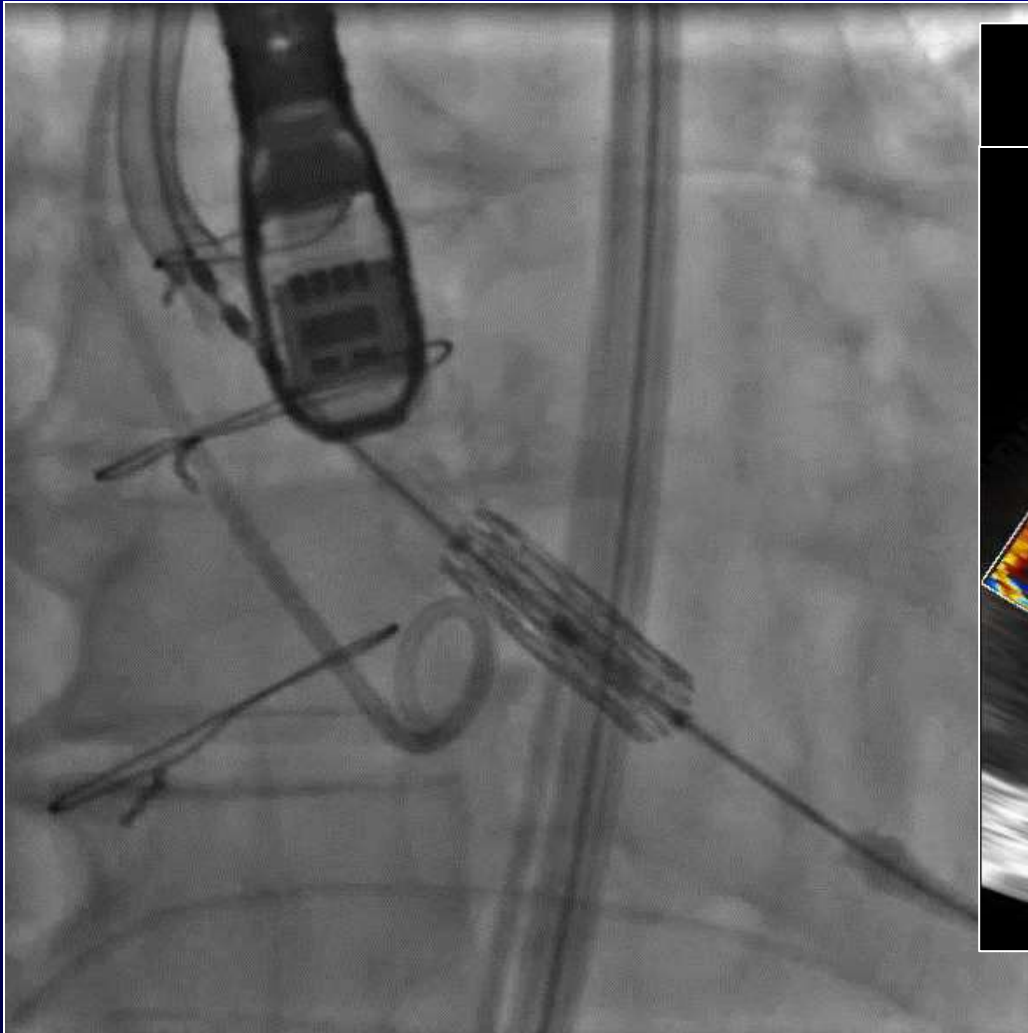


Compass: 50.0 mm
Distance: 0.0 mm

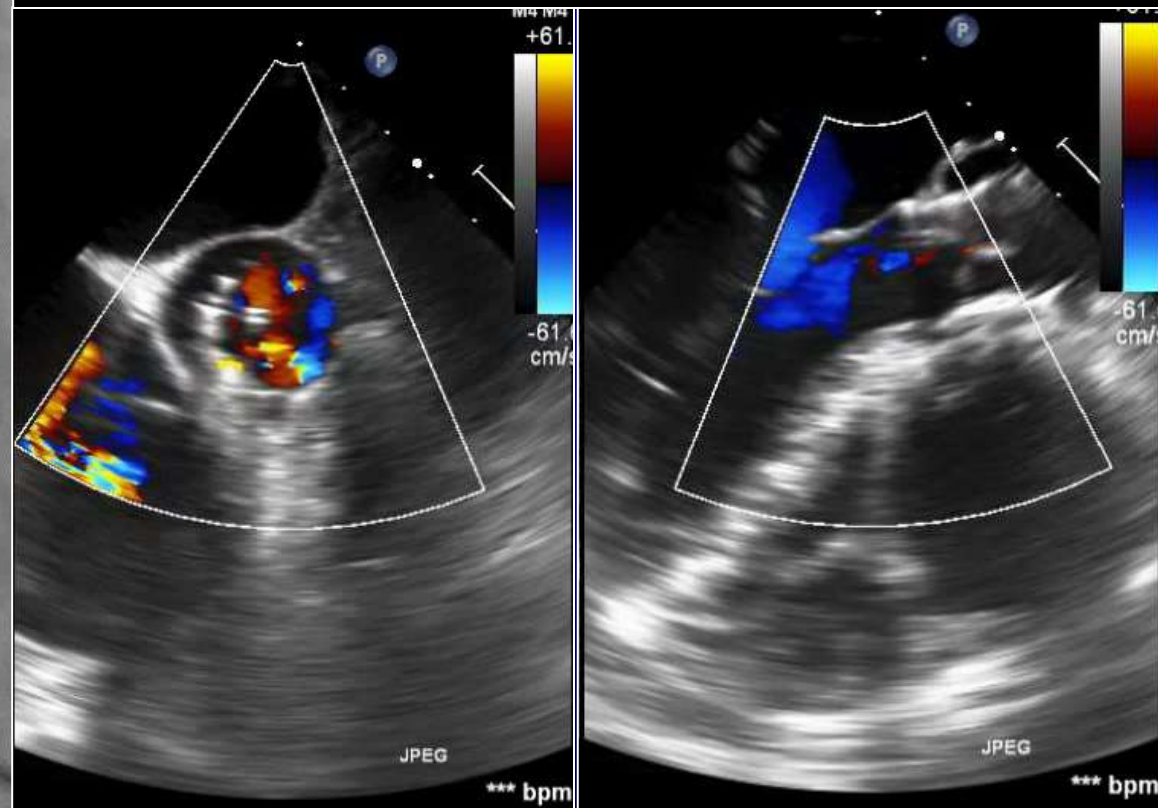
Congenital bicuspid aortic valve
Minimal calcification, with calcified raphe



TAVR with 23mm Sapien3 performed



Trace paravalvular AR



TAVR in functional bicuspid stenosis

88 y/o male undergoing TAVR

Bicuspid raphe type, heavily calcified
Fused left and right coronary cusps

Annulus Area 547.9 mm²

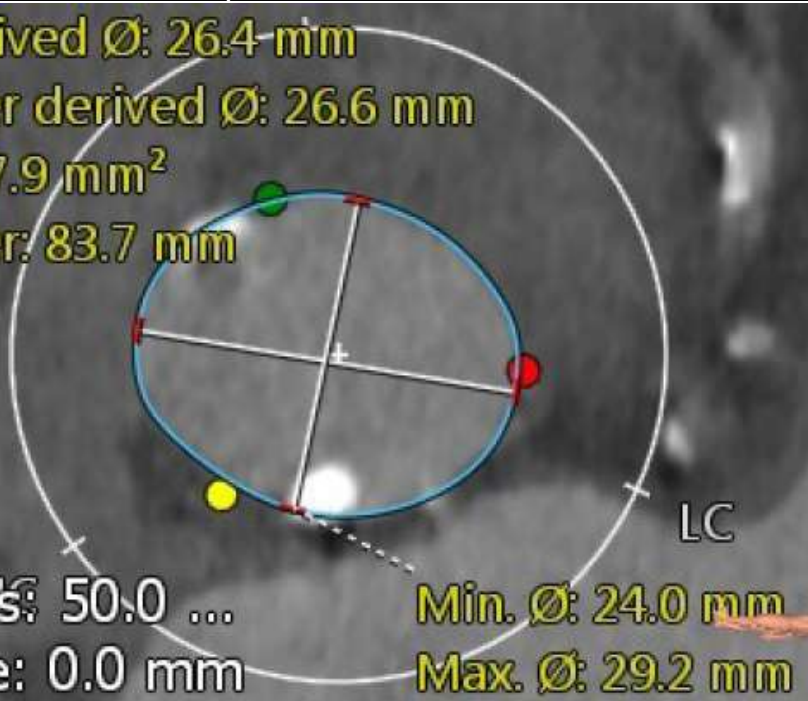
Dmin 24.0, Dmax 29.2 mm

Area derived Ø: 26.4 mm

Perimeter derived Ø: 26.6 mm

Area: 547.9 mm²

Perimeter: 83.7 mm

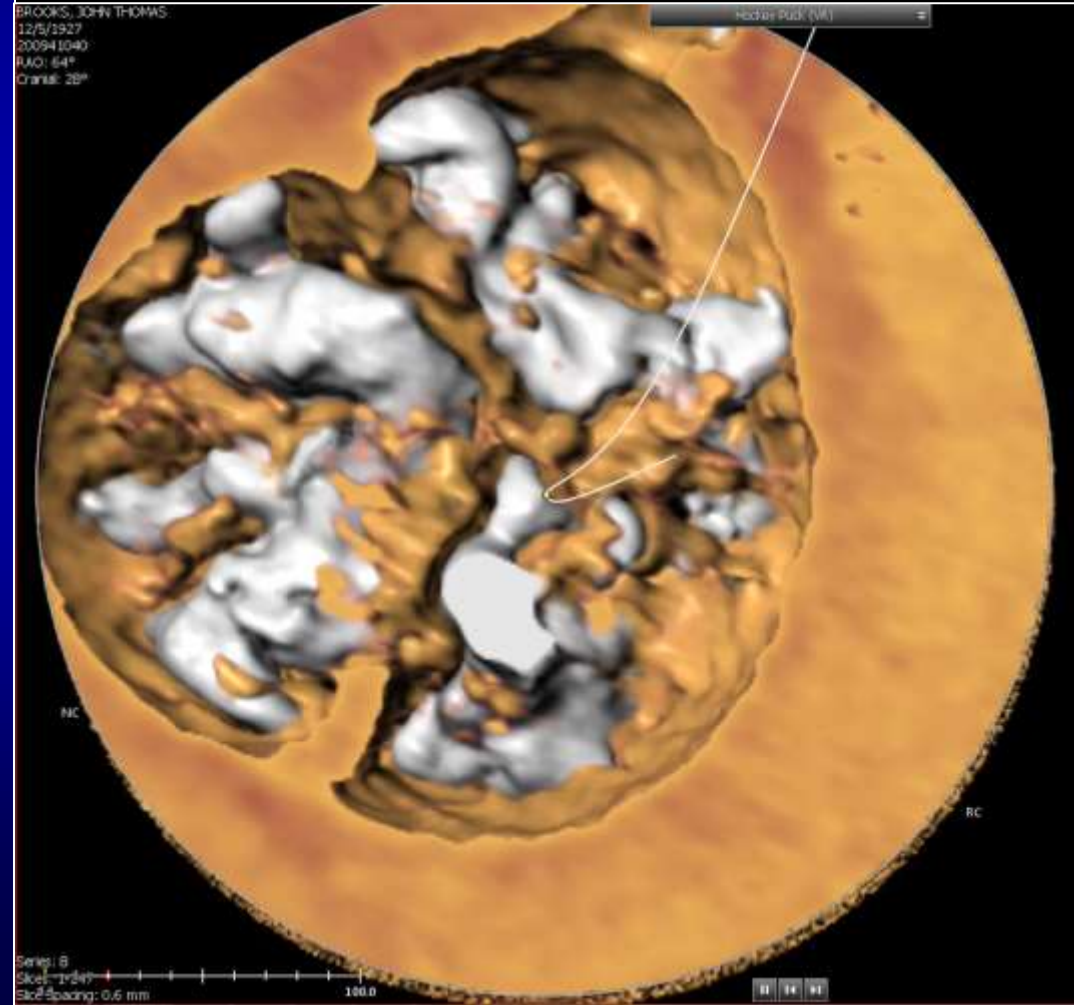


Compass: 50.0 ...

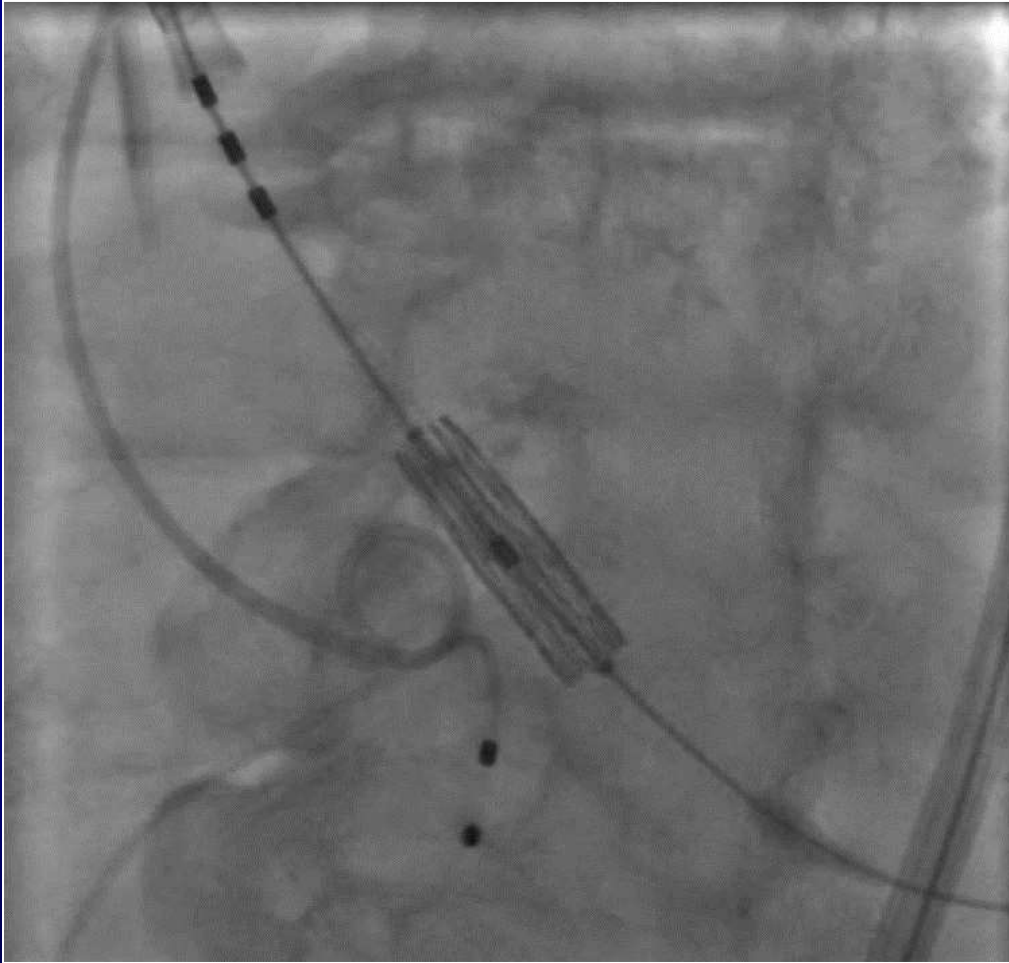
Distance: 0.0 mm

Min. Ø: 24.0 mm

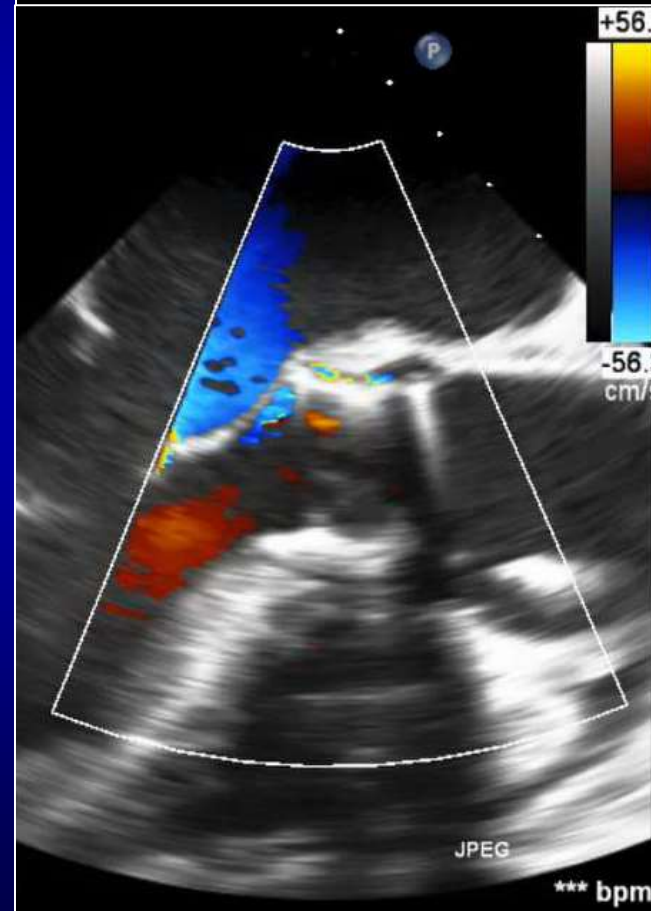
Max. Ø: 29.2 mm



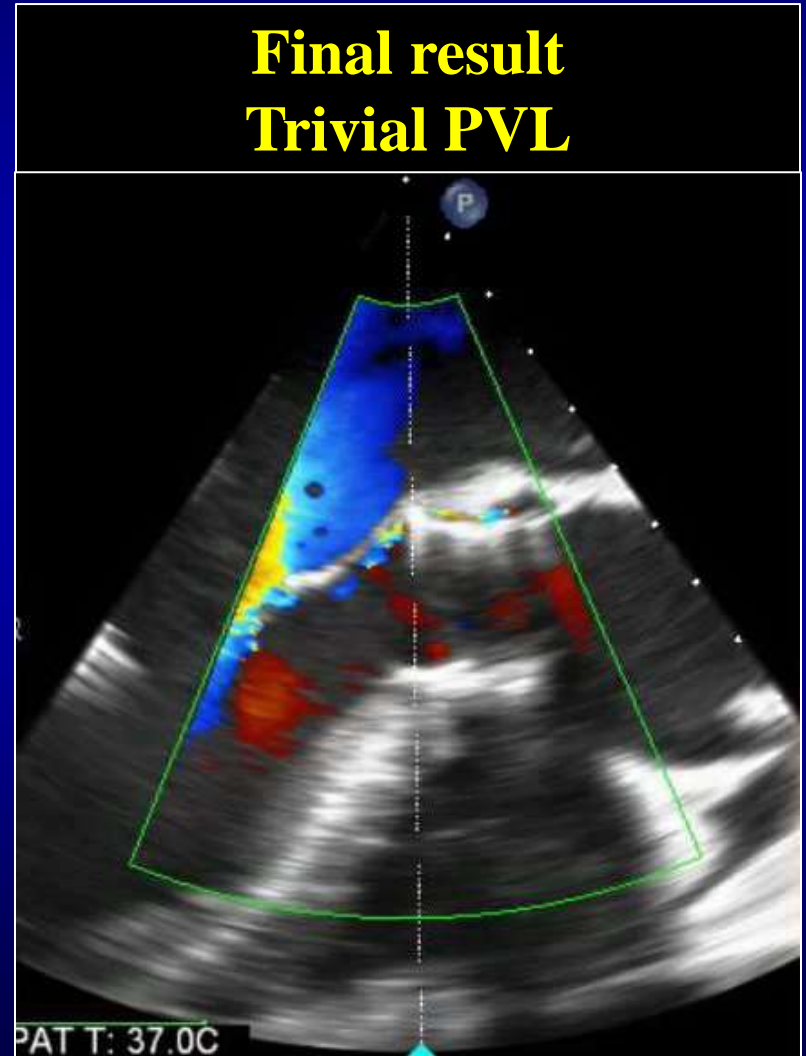
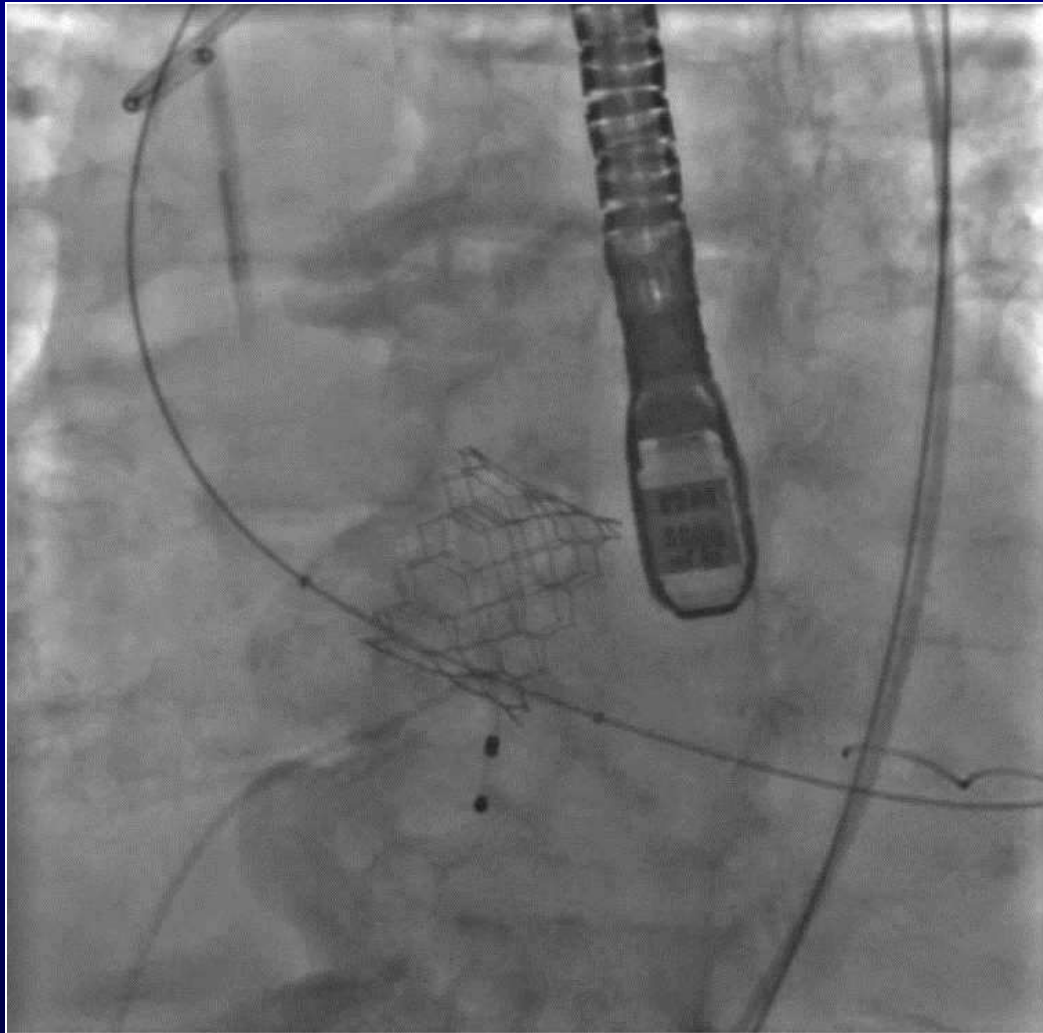
TAVR with 26mm Sapien3



**Moderate PVL after
valve deployment**



Post-dilation performed with a Z-Med II 26 x 4 cm Balloon



Large annulus (841 mm)

Sapien 3 FDA Instructions for Use for Valve Sizing



Specifications		20 mm	23 mm	26 mm	29 mm
Native Valve Annulus Size (CT)	Area	273–345 mm ²	338–430 mm ²	430–546 mm ²	540–683 mm ²
	Area Derived Diameter	18.6–21 mm	20.7–23.4 mm	23.4–26.4 mm	26.2–29.5 mm

65 y/o male undergoing TAVR

Annulus Area 841.4 mm²

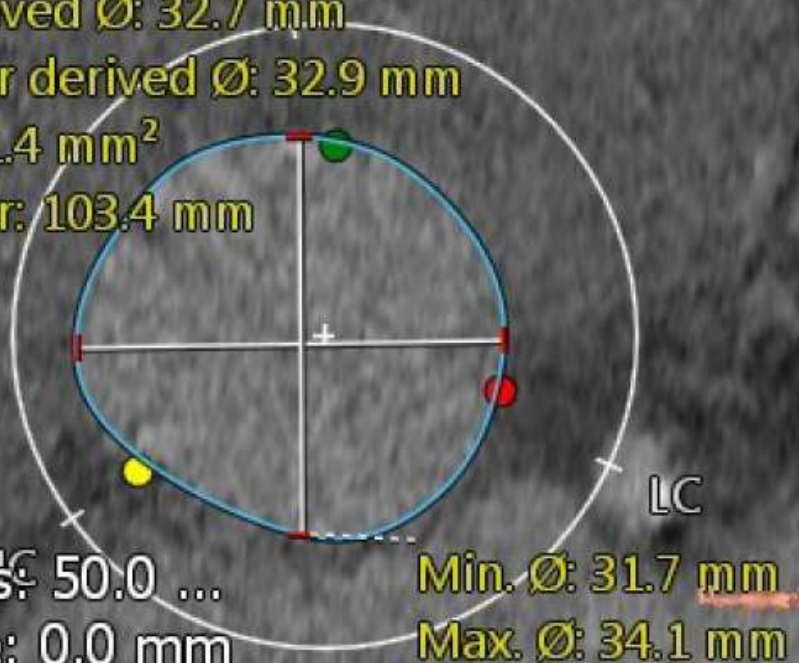
Dmin 31.7, Dmax 34.1 mm

Area derived \varnothing : 32.7 mm

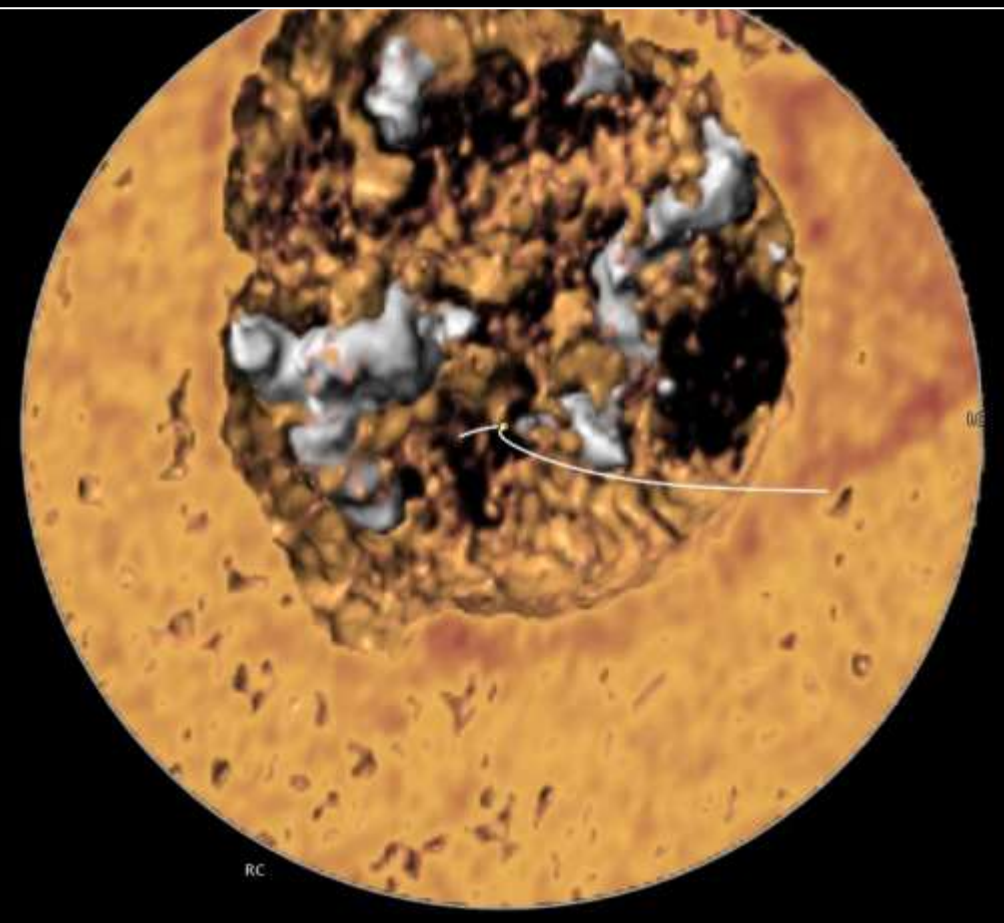
Perimeter derived \varnothing : 32.9 mm

Area: 841.4 mm²

Perimeter: 103.4 mm



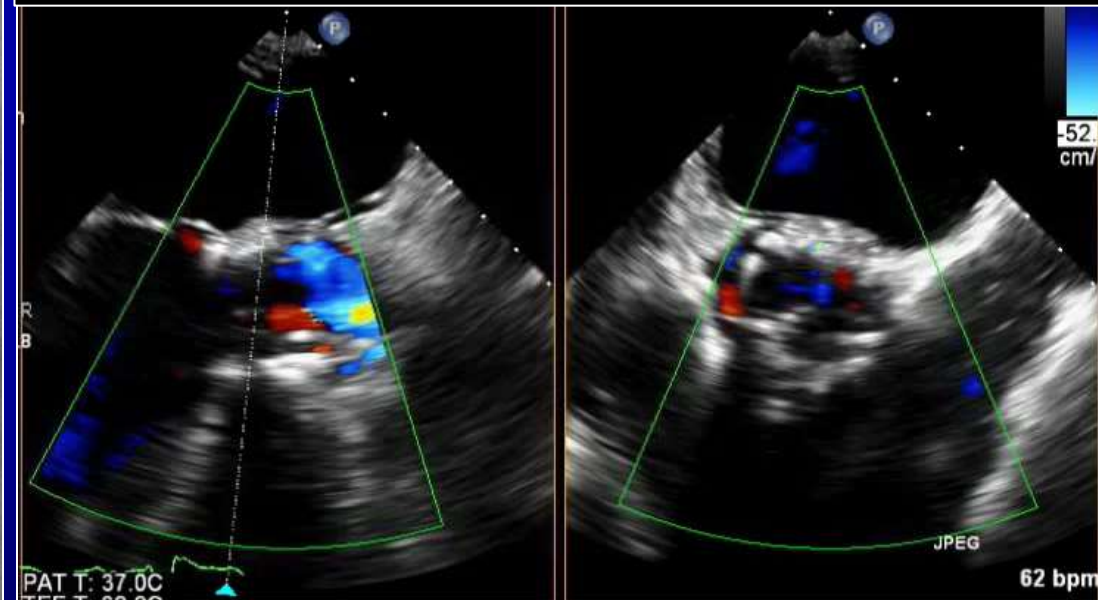
Bicuspid aortic valve
Fused left and right coronary cusps



TAVR with 29mm Sapien3 (+5cc)



Trace paravalvular AR



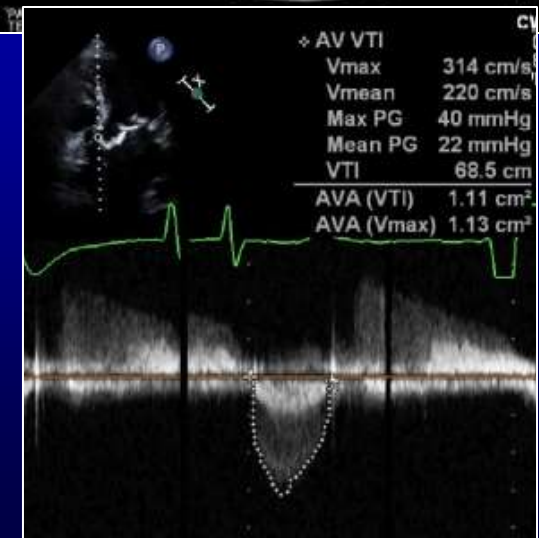
Transcatheter mitral and aortic ViV

72 y/o female presenting with NYHA III heart failure

Severe bioprosthetic mitral stenosis
29mm Bovine Edwards

Severe bioprosthetic aortic stenosis
23mm Bovine Edwards

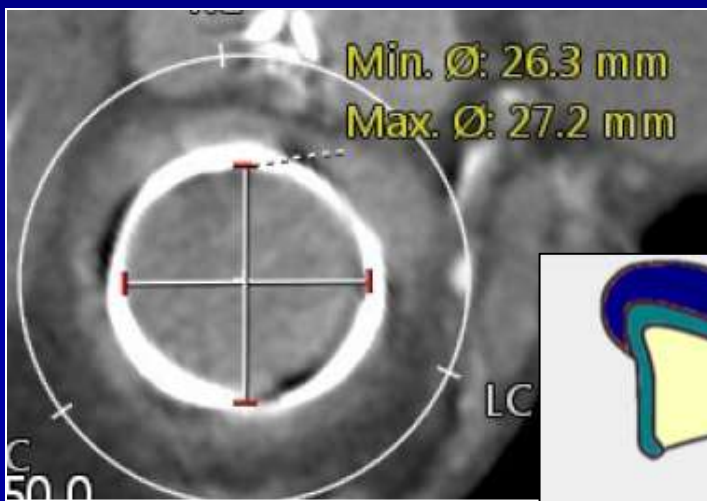
Deemed
inoperable due to
critical pulmonary
hypertension




Patient worked-up for transcatheter aortic and mitral ViV implantation

ViV implantation

Plan for 29mm Sapien 3 for mitral ViV



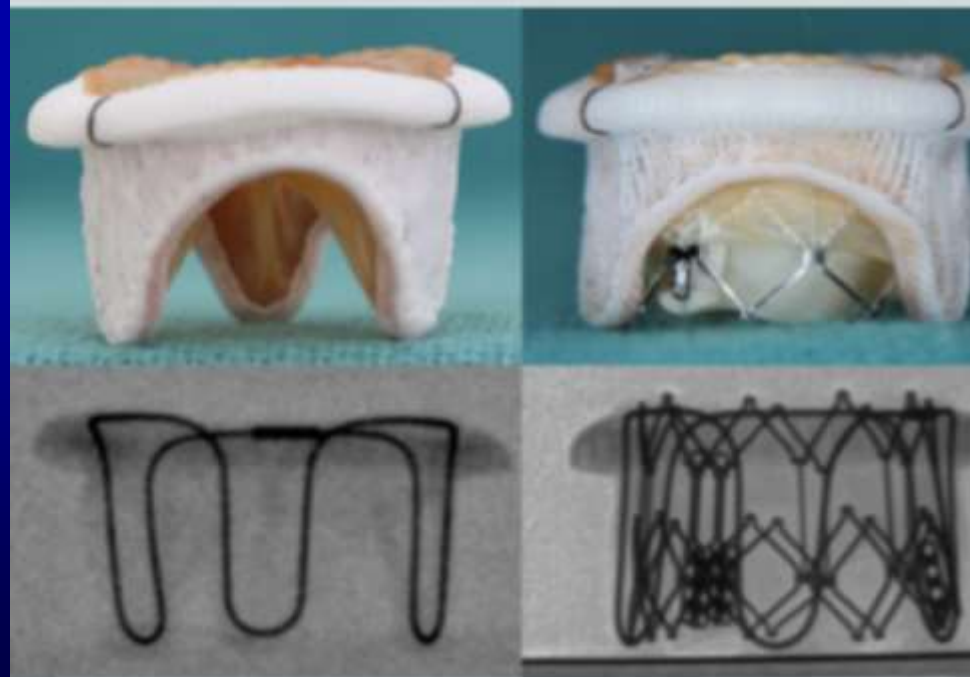
HT

Stent Internal Diameter	27
 True ID	25
Height	23
Suggested TAVI Valve Size	
Sapien Size	29

A cross-section diagram of a valve with a yellow leaflet and a blue stent. A vertical double-headed arrow on the right indicates the height (HT).

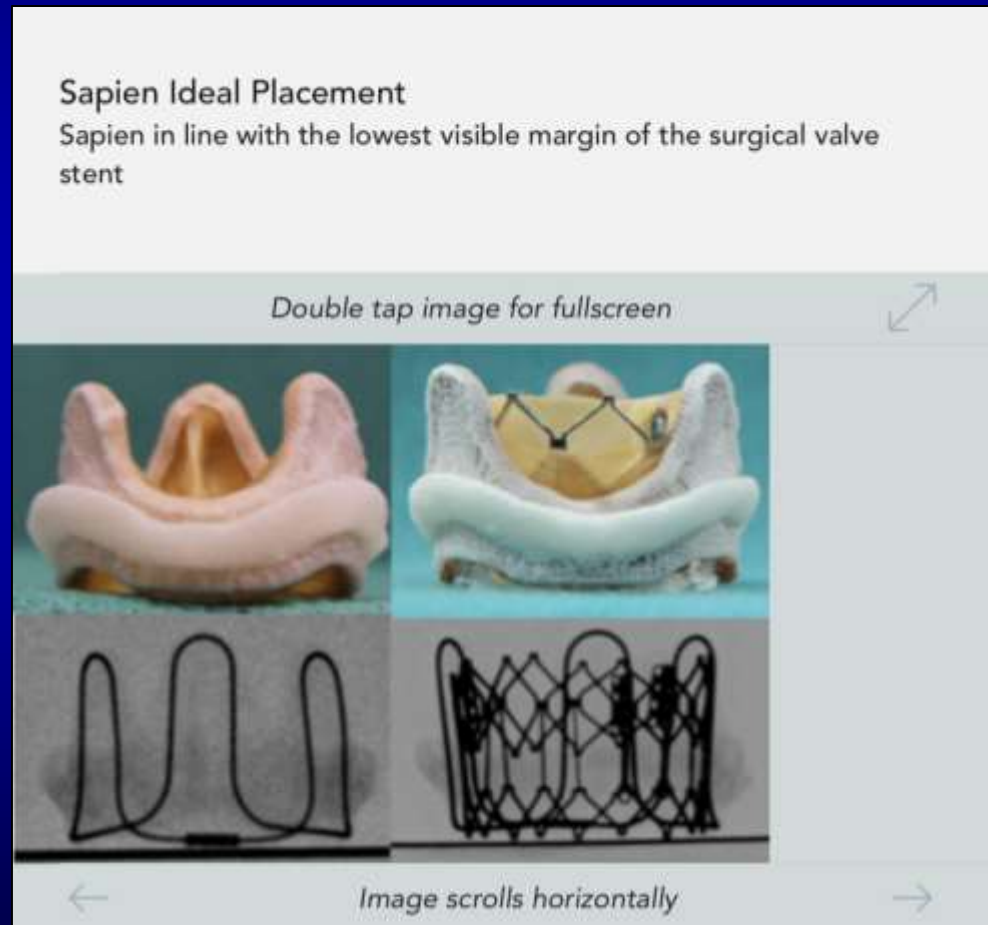
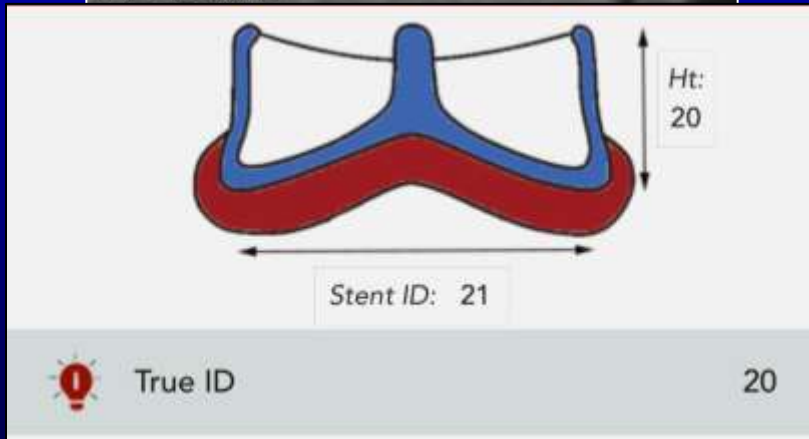
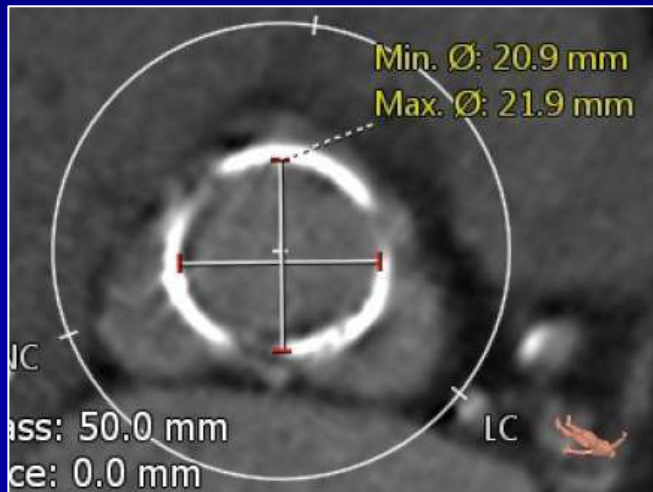
Sapien 10% higher than the 'atrial' end of the the fluoroscopic portion of the stent.
Achieve a 'conical' deployment.

Double tap image for fullscreen



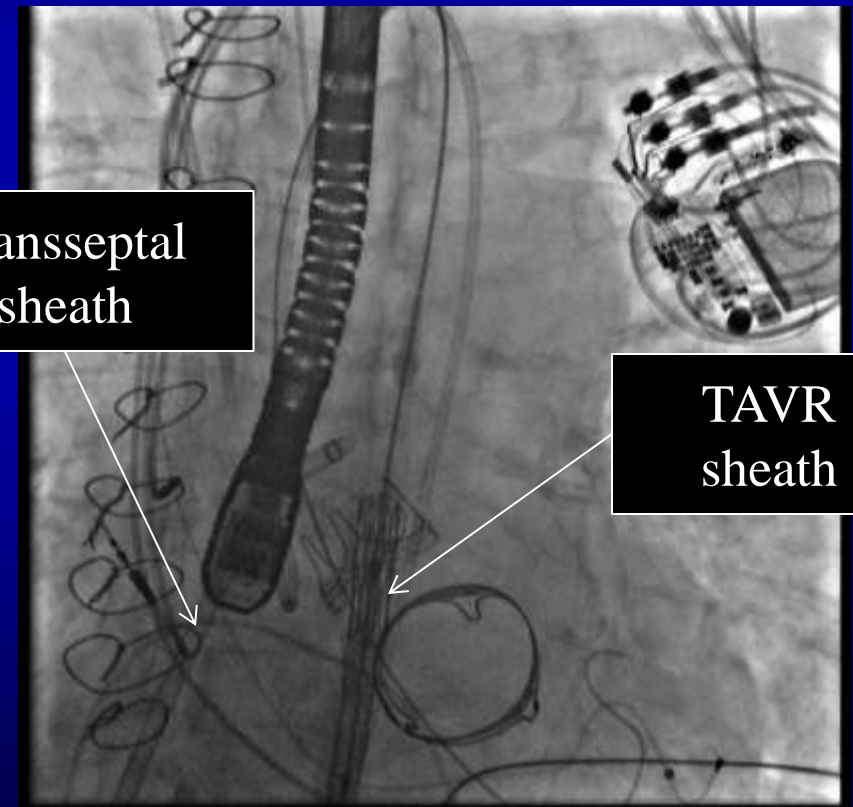
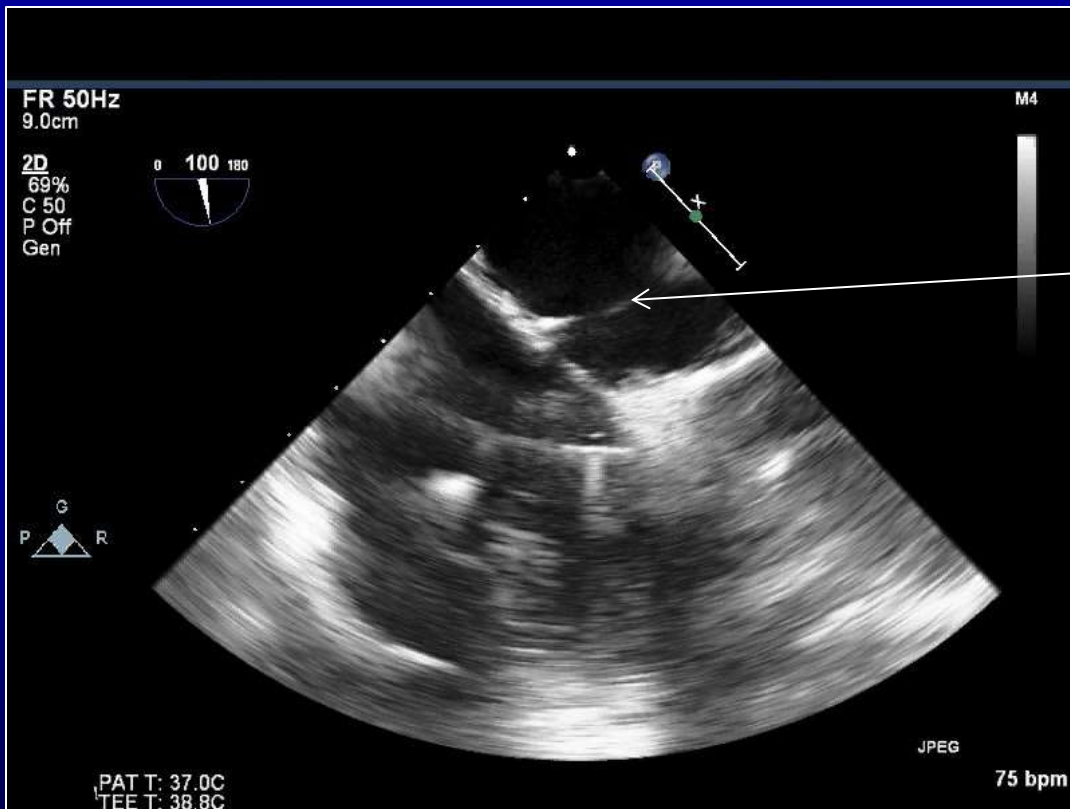
Patient worked-up for transcatheter aortic and mitral ViV implantation

Plan for 23mm Sapien 3 for aortic ViV

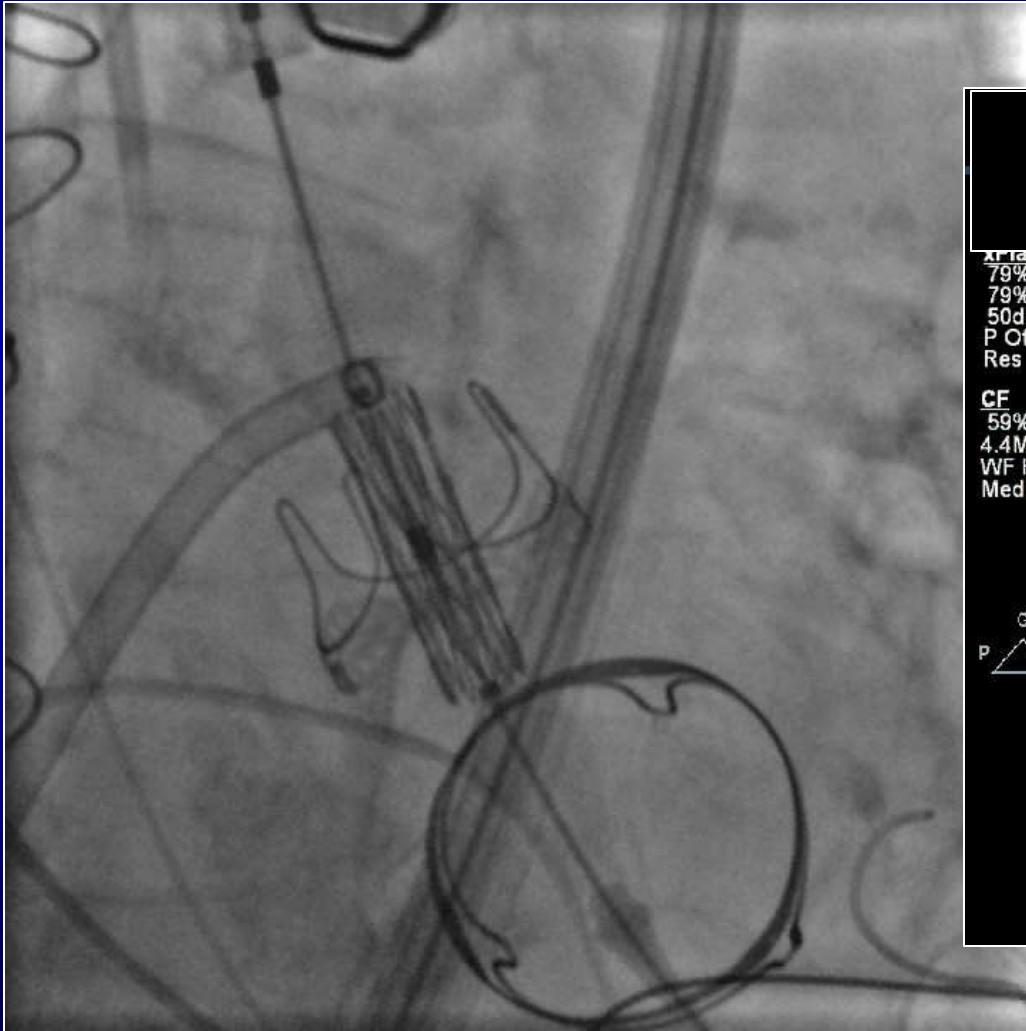


Patient brought to the cath lab for transcatheter aortic and mitral valve replacement

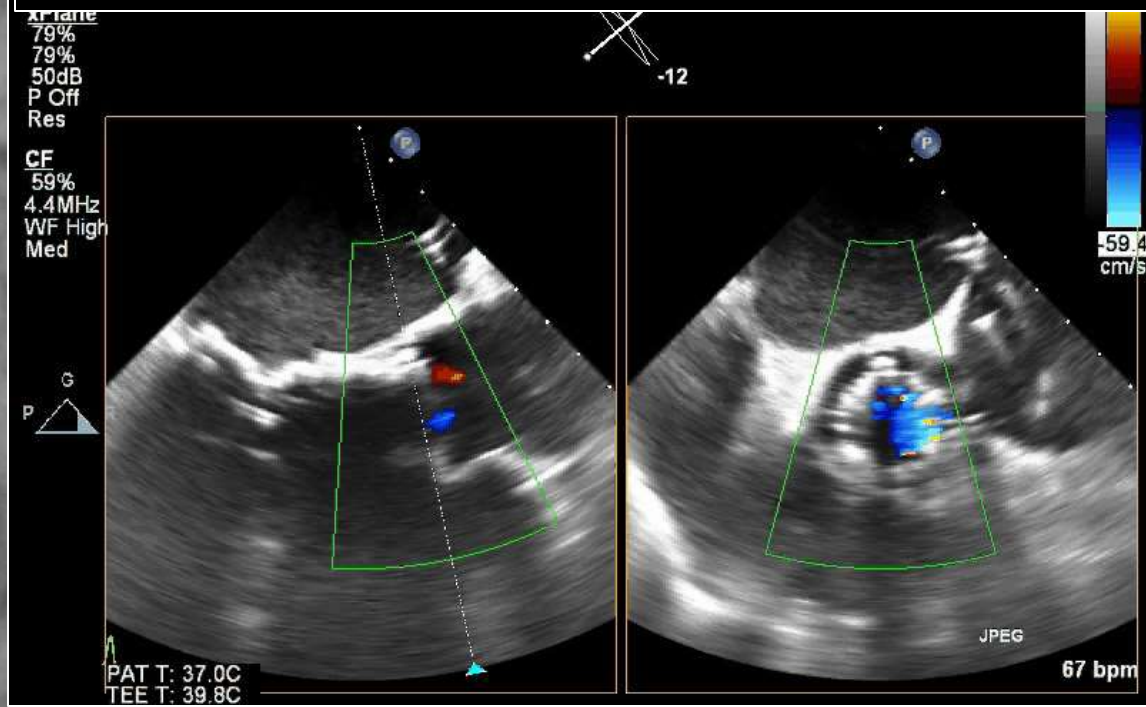
Trans-septal puncture for Transcatheter mitral ViV performed at the time of arterial access for Transcatheter aortic ViV



Transcatheter aortic ViV with 23mm Sapien 3 valve



No significant AR



AF rate
79%
79%
50dB
P Off
Res

CF
59%
4.4MHz
WF High
Med

G
P

-12

59.4
cm/s

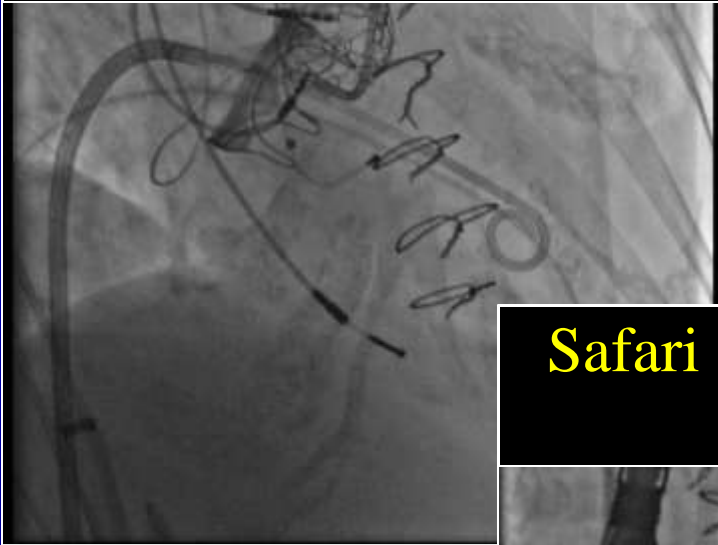
PAT T: 37.0C
TEE T: 39.8C

JPEG

67 bpm

Immediately after aortic ViV, Preparation for transcatheter mitral ViV

Pigtail across the mitral valve



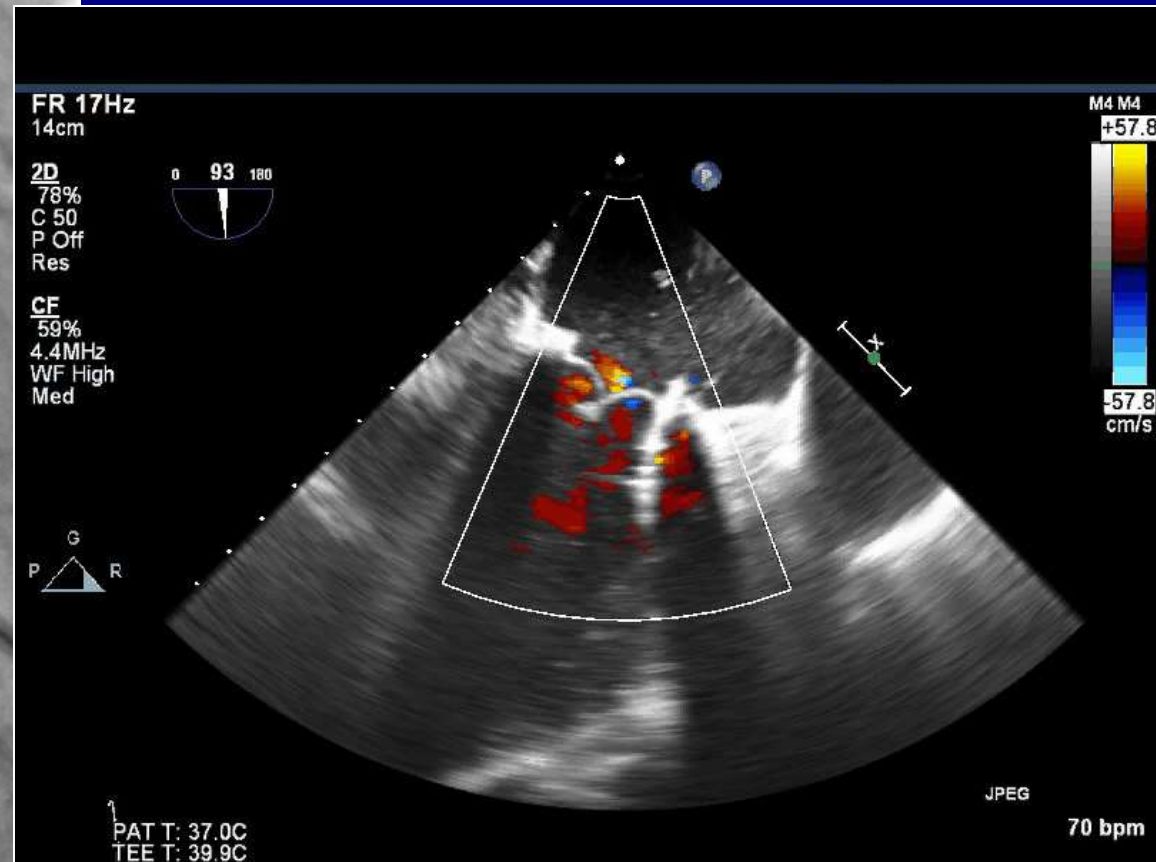
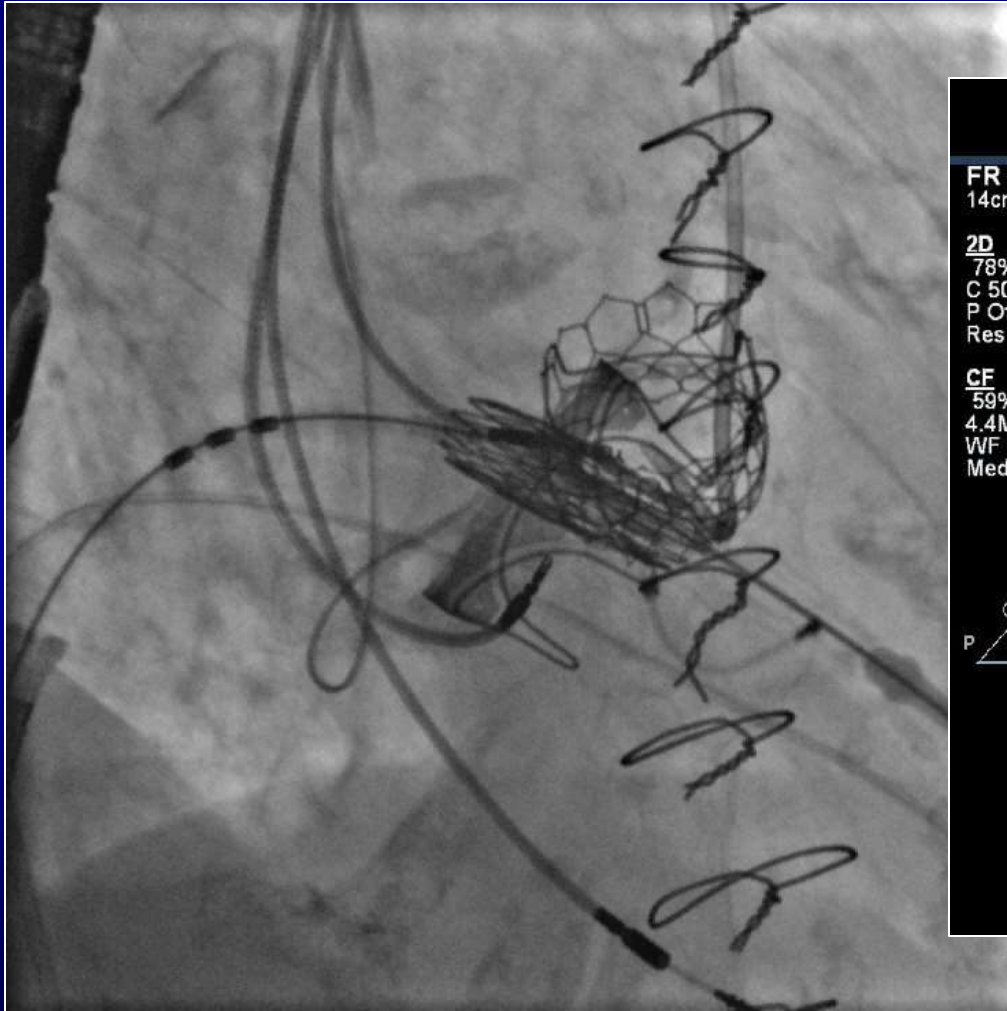
Safari across the mitral valve



Atrial septostomy with Z-med II
15 x 4 cm



Trans-septal transcatheter Mitral ViV implantation with a 29mm Sapien 3 valve

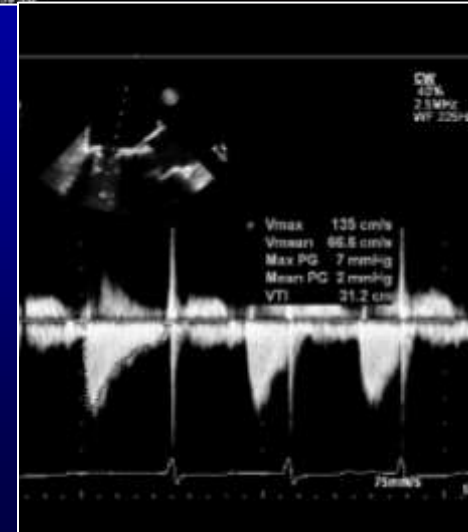
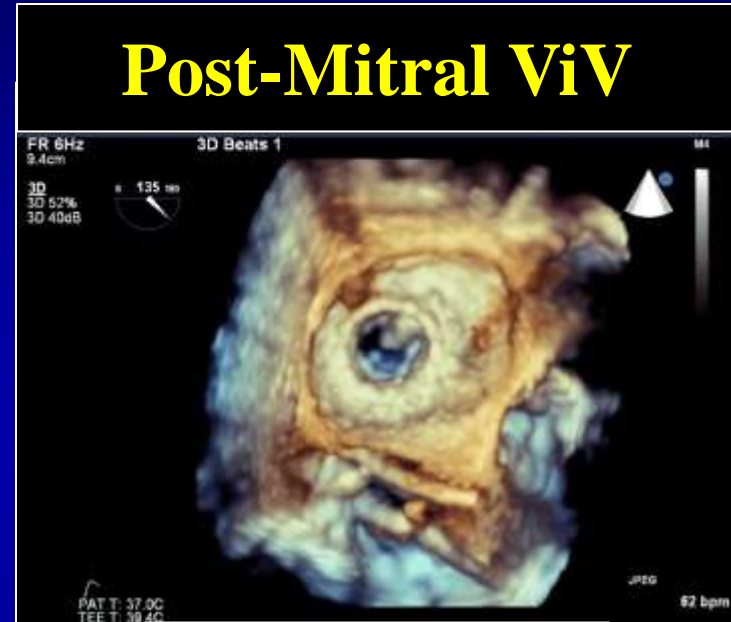


Final result s/p simultaneous transfemoral aortic and mitral ViV implantation

Pre-Mitral ViV

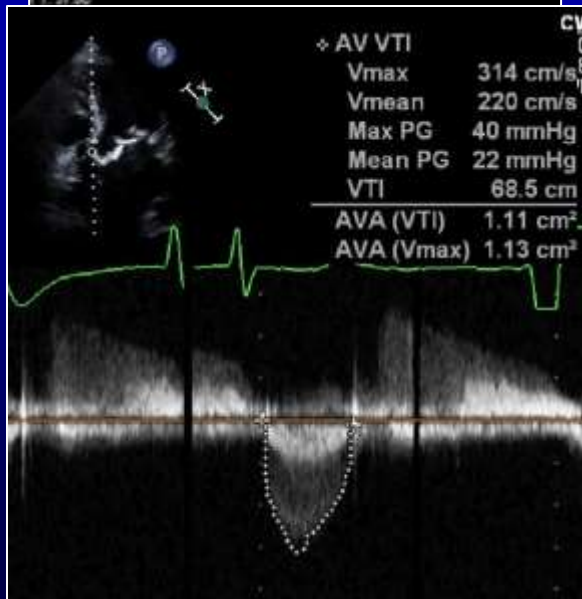


Post-Mitral ViV

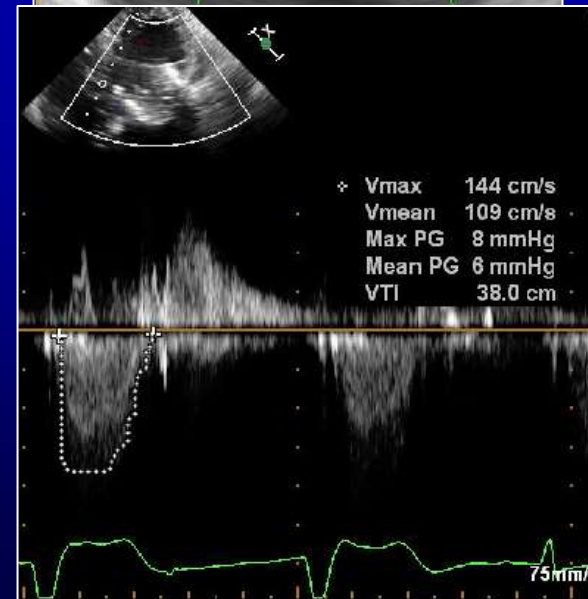


Final result s/p simultaneous transfemoral aortic and mitral ViV implantation

Pre-Aortic ViV



Post-Aortic ViV

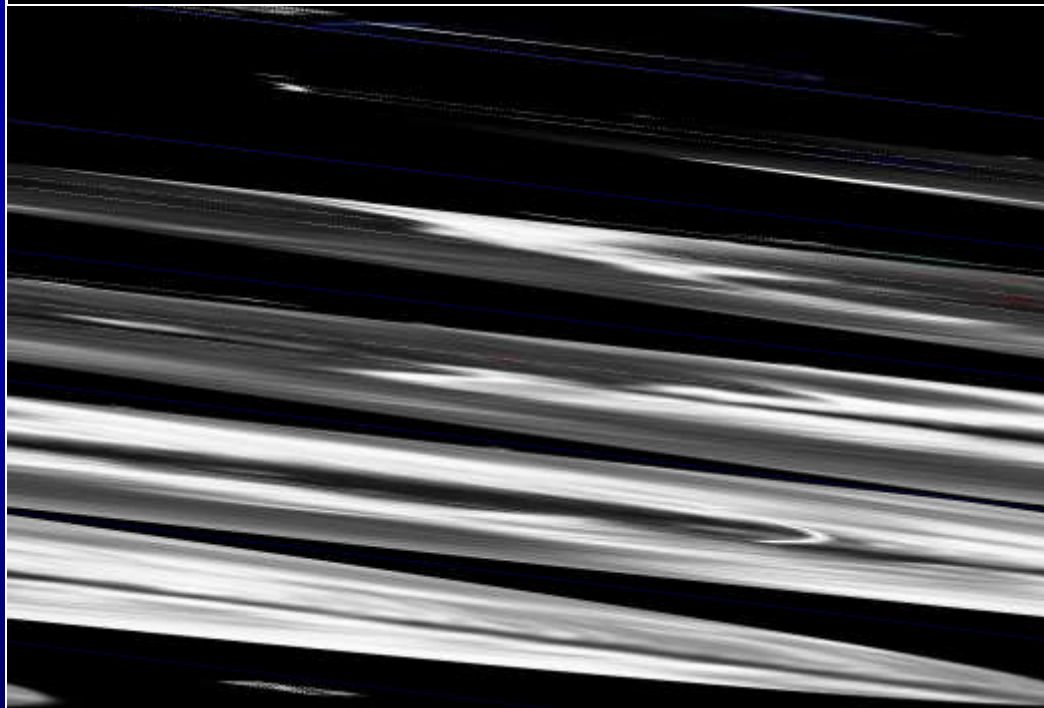


TAVR in Mitroflow with cracking of the Mitroflow valve ring

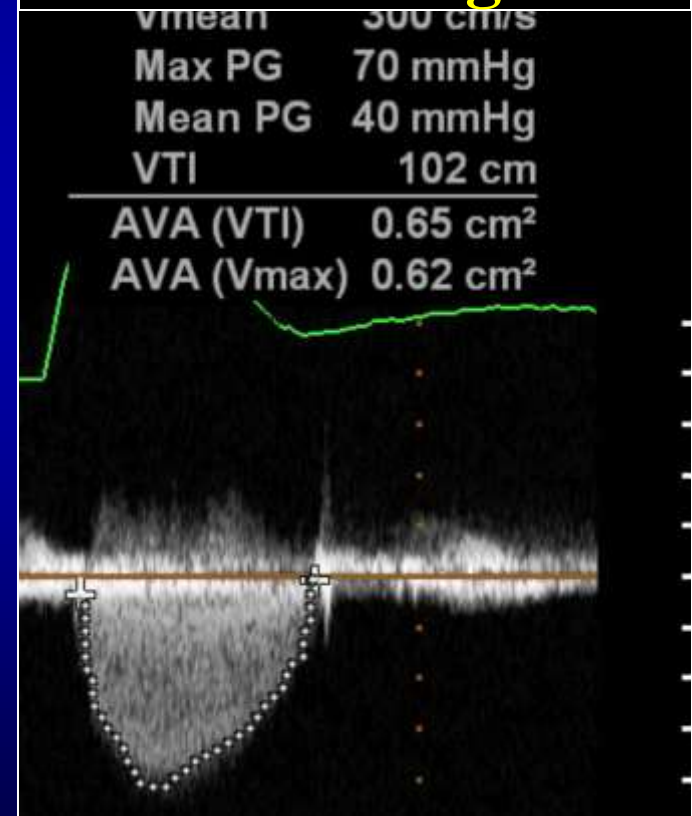
90 y/o female referred for transcatheter ViV

Deemed high-risk due to advanced age and comorbidities

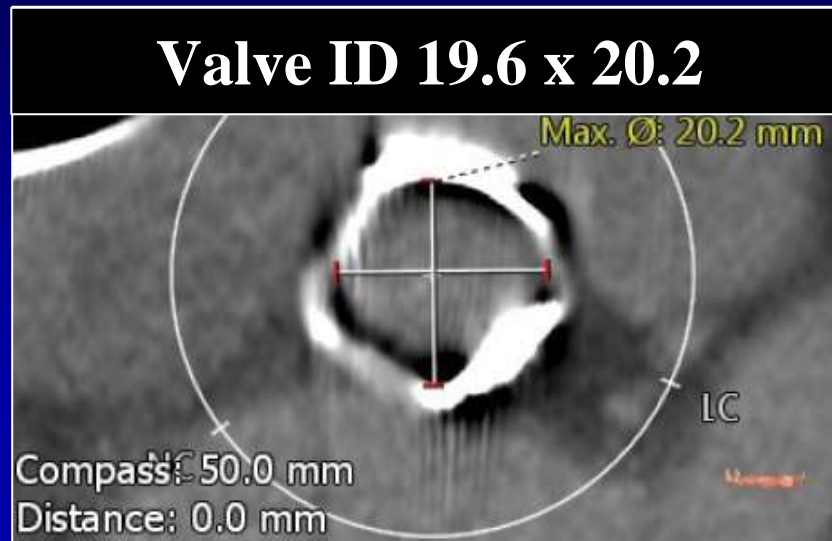
Severe aortic stenosis of #21 Mitroflow



Mean gradient 40mmHg



CT evaluation for TAVR



Low RCA height (5.5mm)



Low LM height (7.4mm)

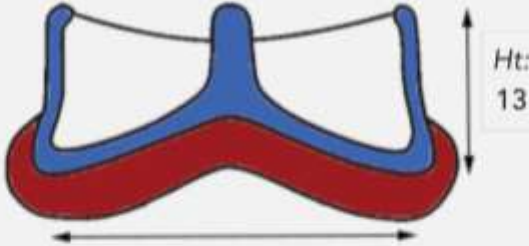


Plan for 20mm Sapien3 valve

Left and right coronary protection due to low coronary height

< Mitroflow Valve Size

Mitroflow, 21



Ht: 13

Stent ID: 17.3

! True ID 17

THV Selector

< Valve Size TAVI Choices

TAVI Valve Choices For:
Mitroflow, 21

Sapien 20	Core Valve Not Recommended
Portico Not Recommended	Jena Not Recommended
Lotus Not Recommended	S3 Not Recommended
Accurate TA Not Recommended	Accurate NEO Not Recommended

Home Stented Stentless Sutureless TAVI

Transcatheter ViV with a 20mm Sapien3

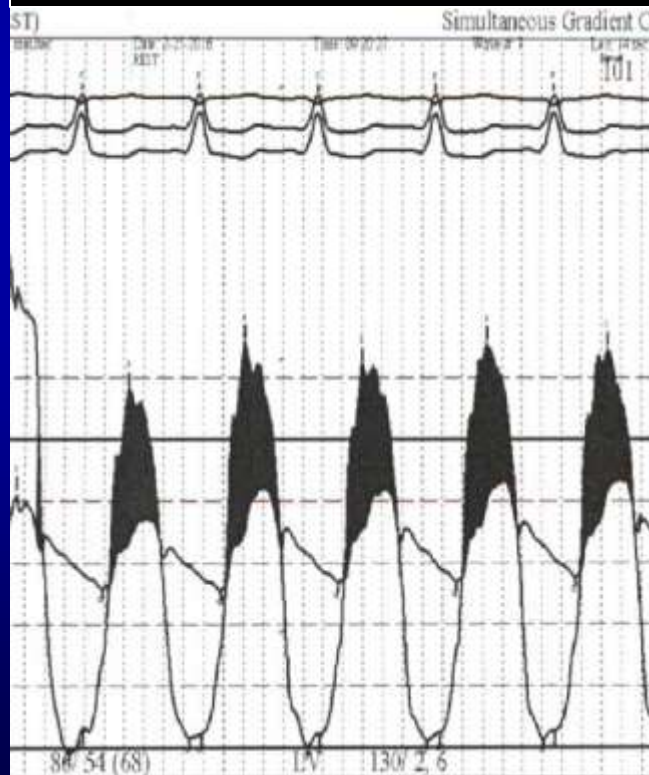
Coronary protection with 2 stents in LAD and LCx



Hemodynamics

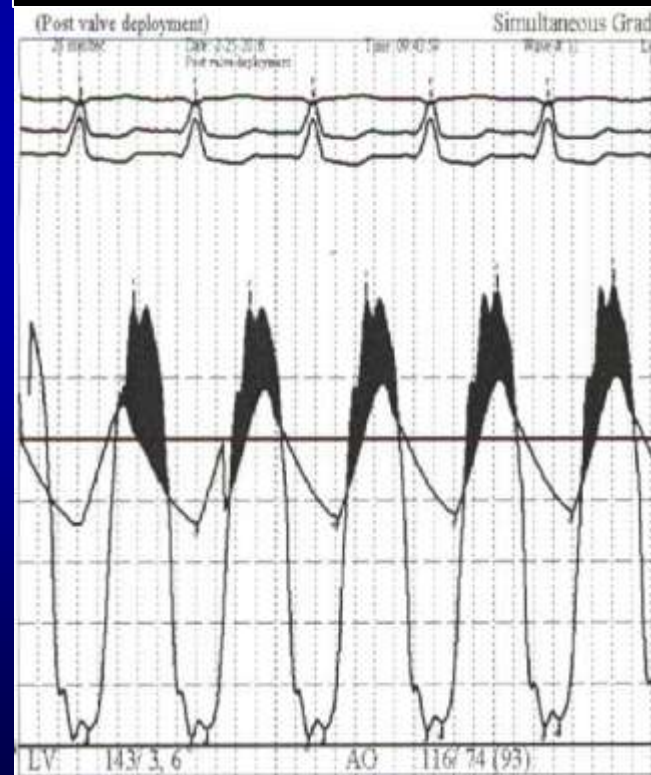
Baseline

Mean gradient 34.5mmHg



Post-valve deployment

Mean gradient 23.3mmHg



Post-dilation performed with a 22x4.5cm True Balloon



Reduction in gradients with post-dilation, but still high residual gradients

Post-valve deployment
Mean gradient 23.3mmHg

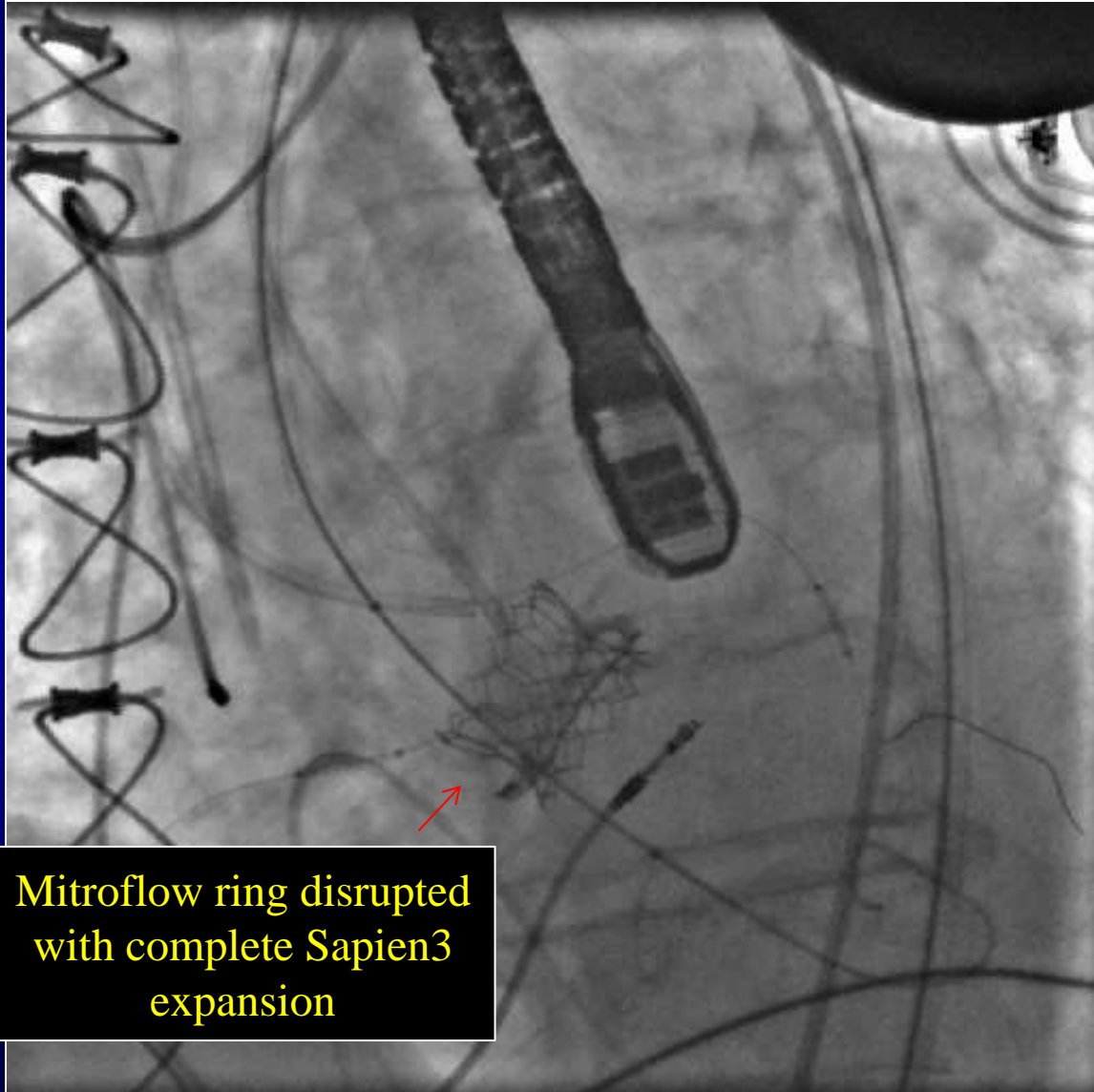


After 1st post-dilation
Mean gradient 12.5mmHg



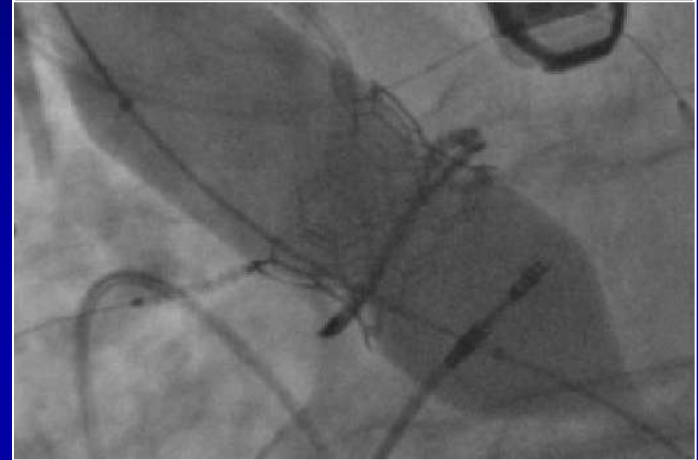
Post-dilation performed with a 22x4.5cm True Balloon

MitroFlow valve ring fractured



Mitroflow ring disrupted
with complete Sapien3
expansion

Before post-dilation



After post-dilation



Hemodynamics

Successful reduction in gradients with fracturing the Mitroflow ring

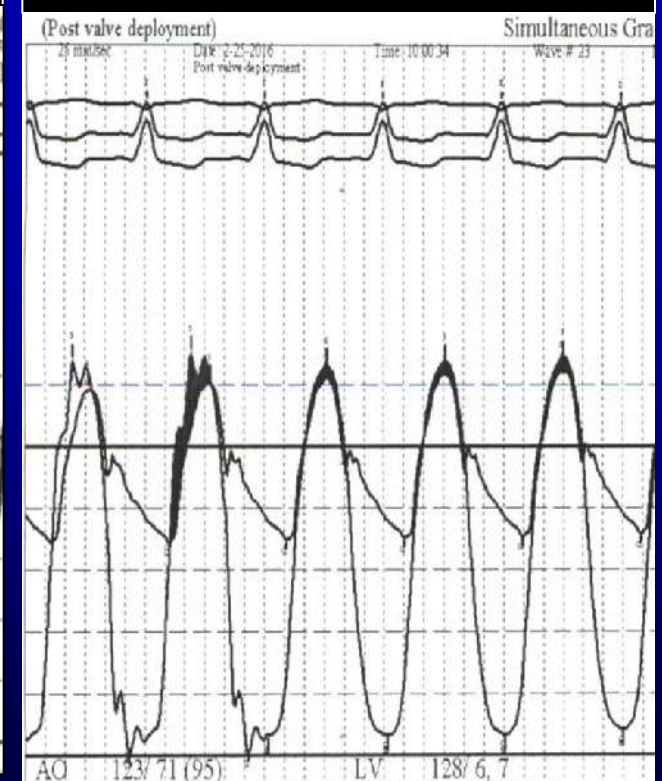
Post-valve deployment
Mean gradient 23.3mmHg



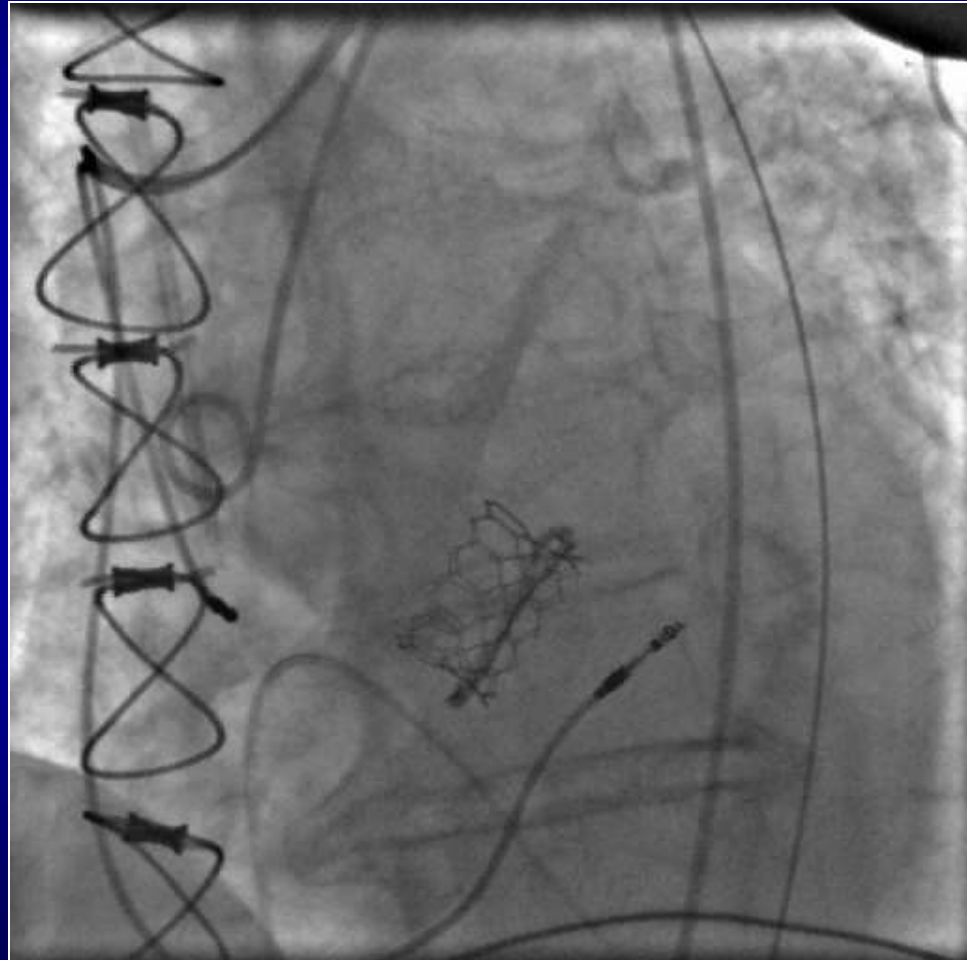
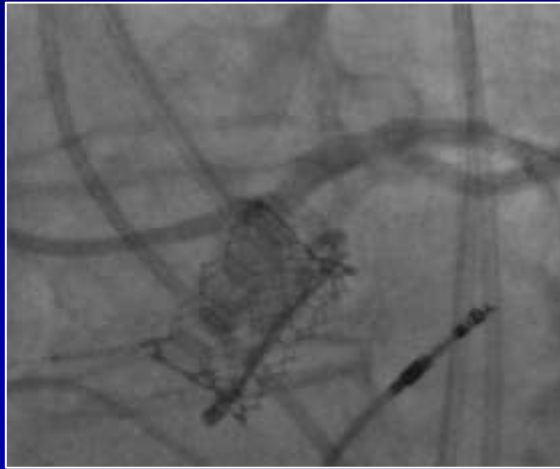
After 1st post-dilation
Mean gradient 12.5mmHg



After 2nd post-dilation with fracturing of the Mitroflow ring
Mean gradient 5.8mmHg



Ostial RCA and ostial LM stents deployed for coronary protection



TAVR in MAC for severe degenerative mitral stenosis

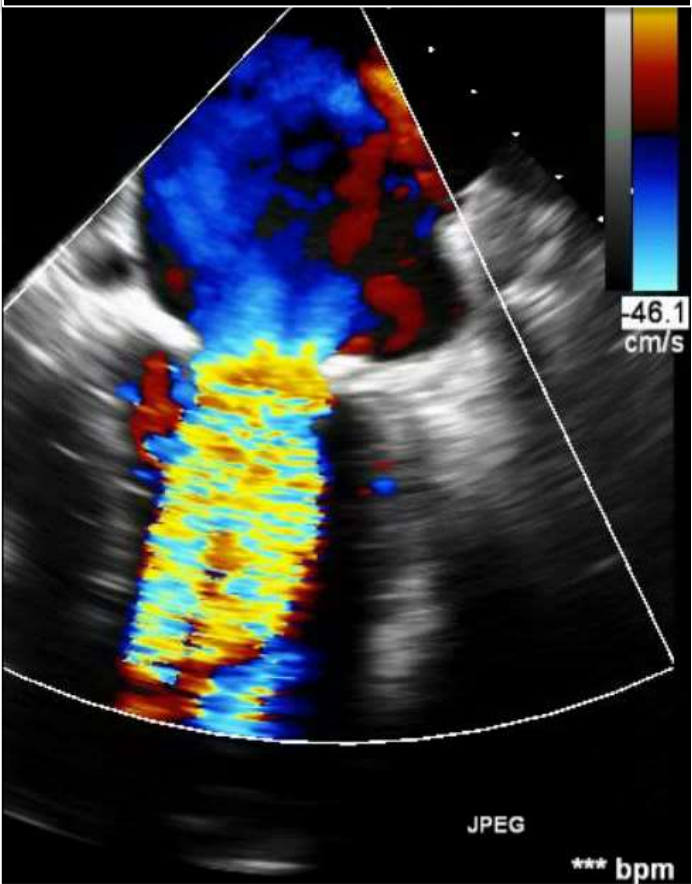
49 y/o female referred for percutaneous management of mitral and aortic valve disease

- Severe mitral stenosis and moderate-severe mitral regurgitation
- Diastolic congestive heart failure, NYHA III
- Severe pulmonary hypertension, on supplemental oxygen at night, 2 L
- End stage renal disease, on hemodialysis
- Thrombocytopenia (platelet count 80)
- Occluded SVC
- Central retinal occlusion
- Transient ischemic attack
- Diabetes mellitus
- Frequent pneumonias
- Frailty

**Patient deemed
inoperable for surgical
valve replacement**

Severe mitral stenosis and moderate mitral regurgitation

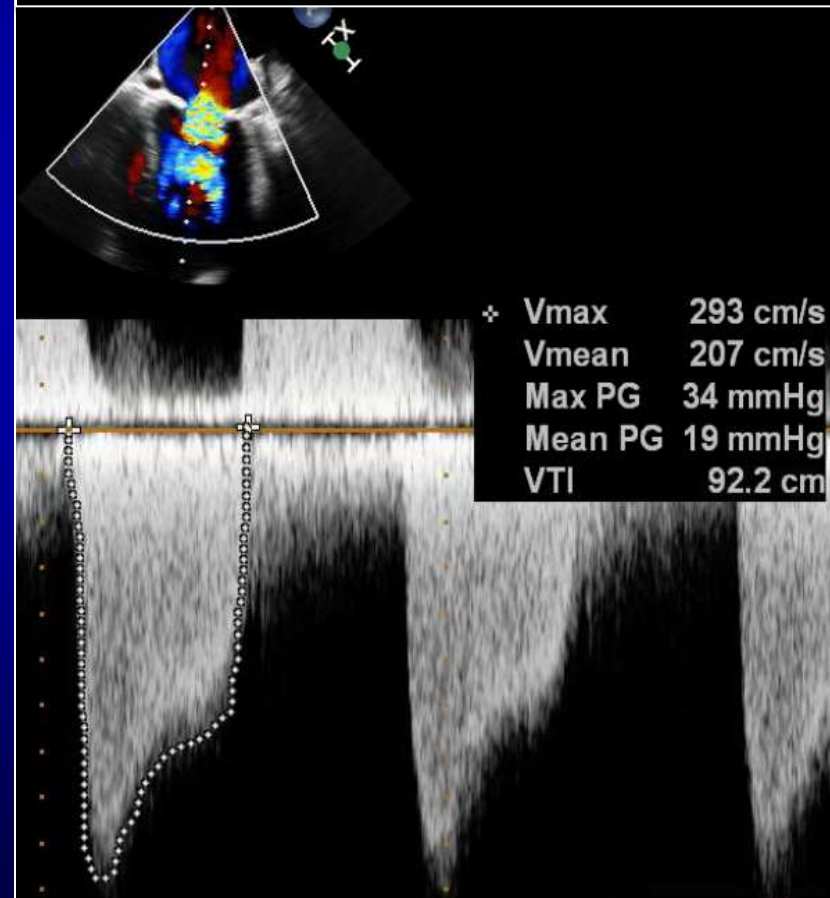
Moderate-severe MR



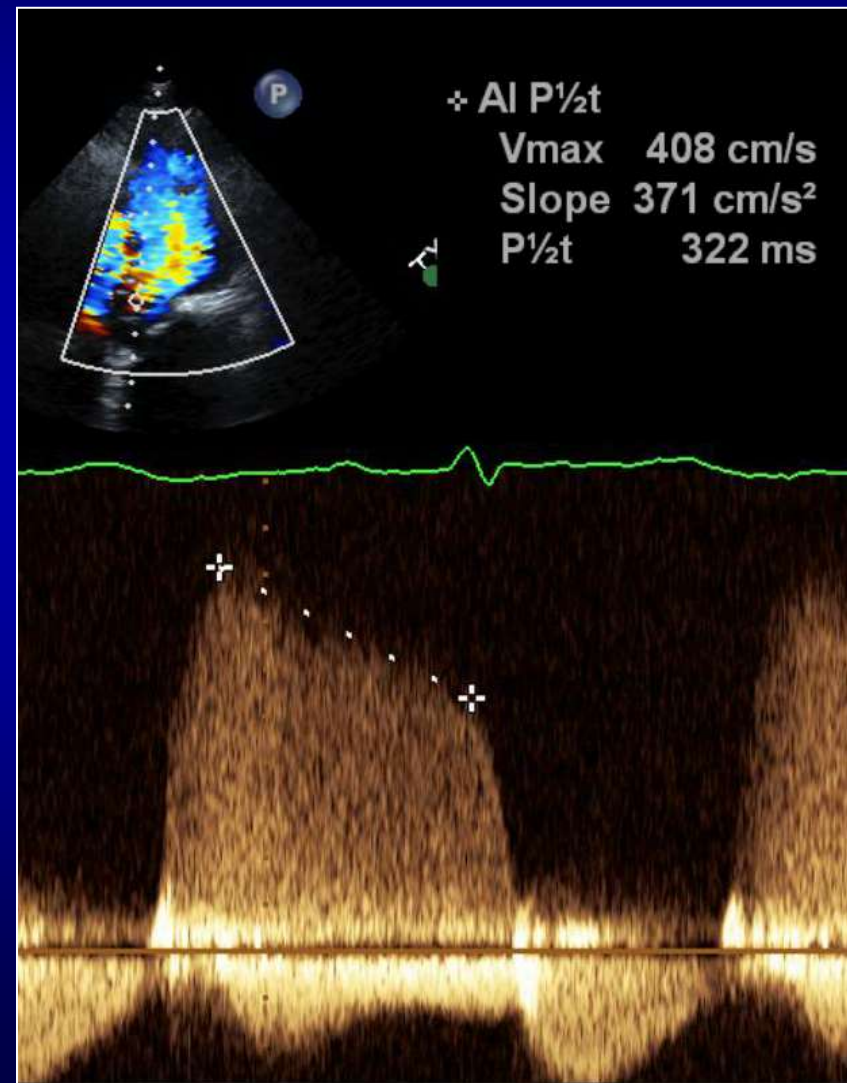
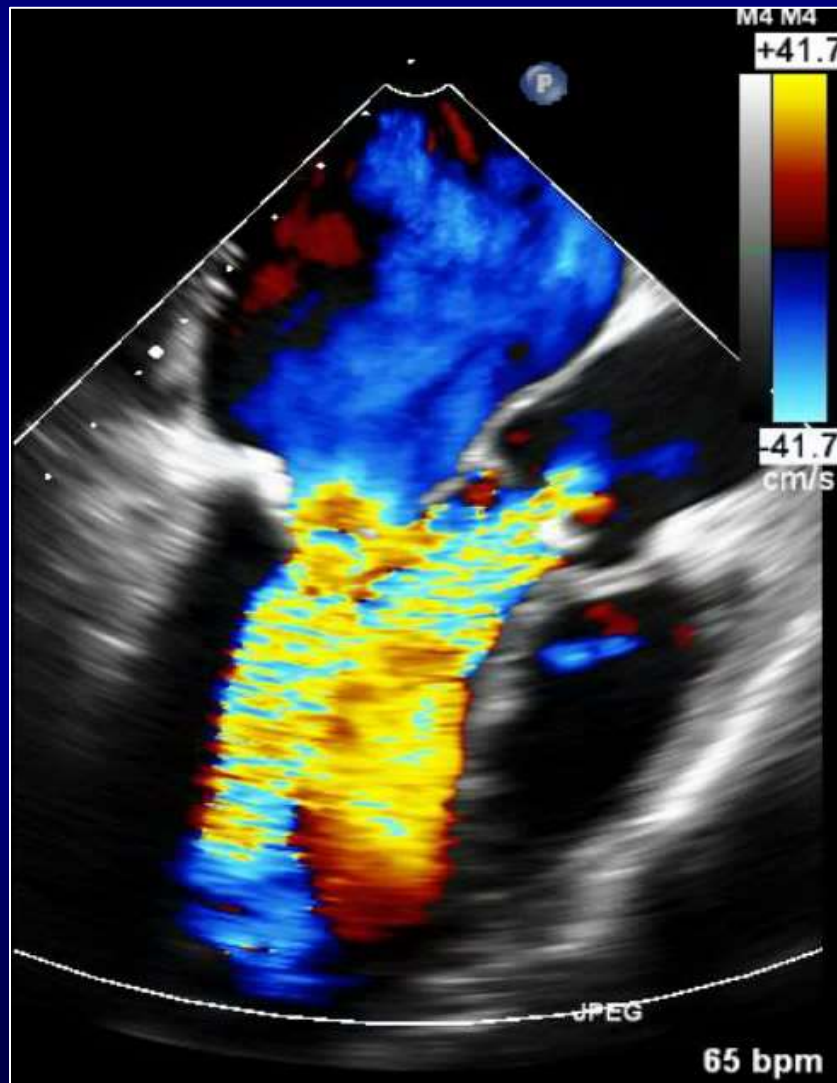
Severely restricted mitral valve leaflets with severe MAC



Severe mitral stenosis

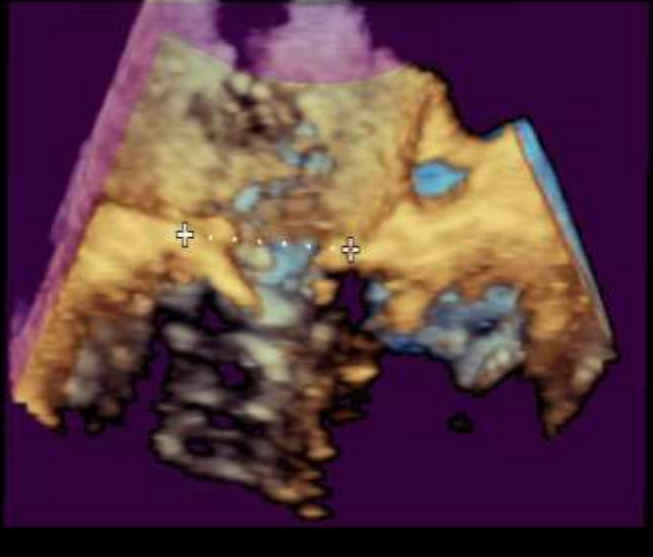


Coexisting moderate-severe AR

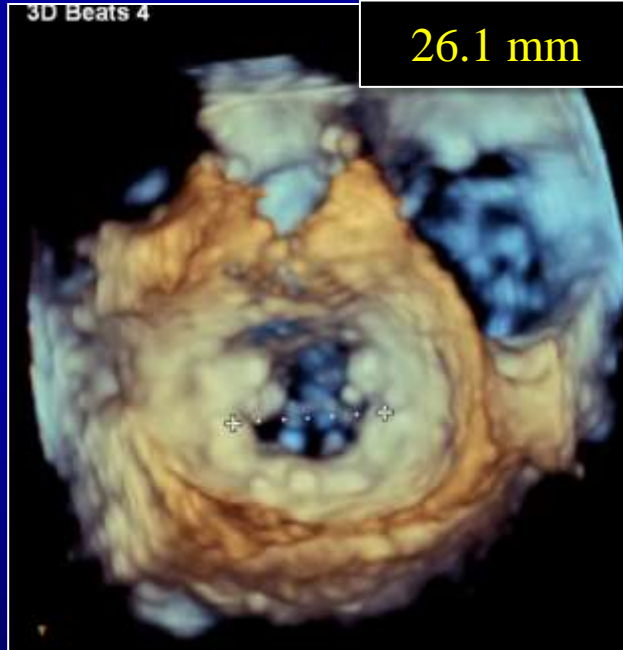


3D TEE based mitral annular dimensions

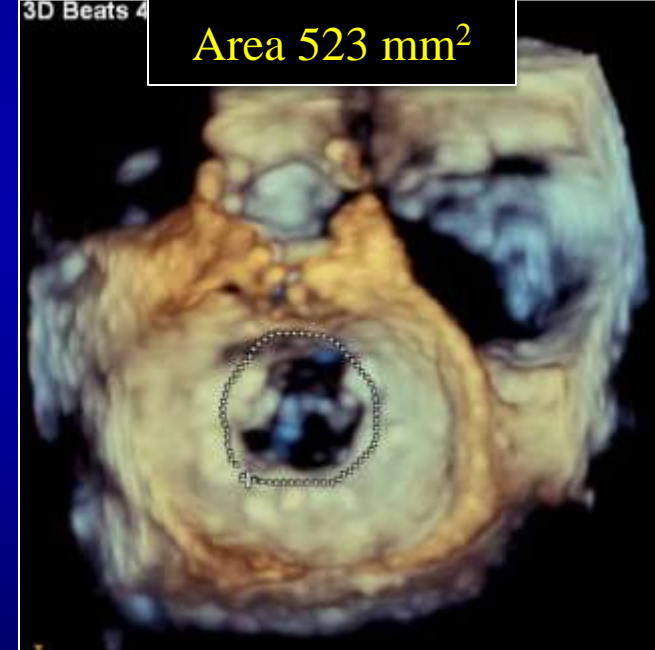
28.6 mm



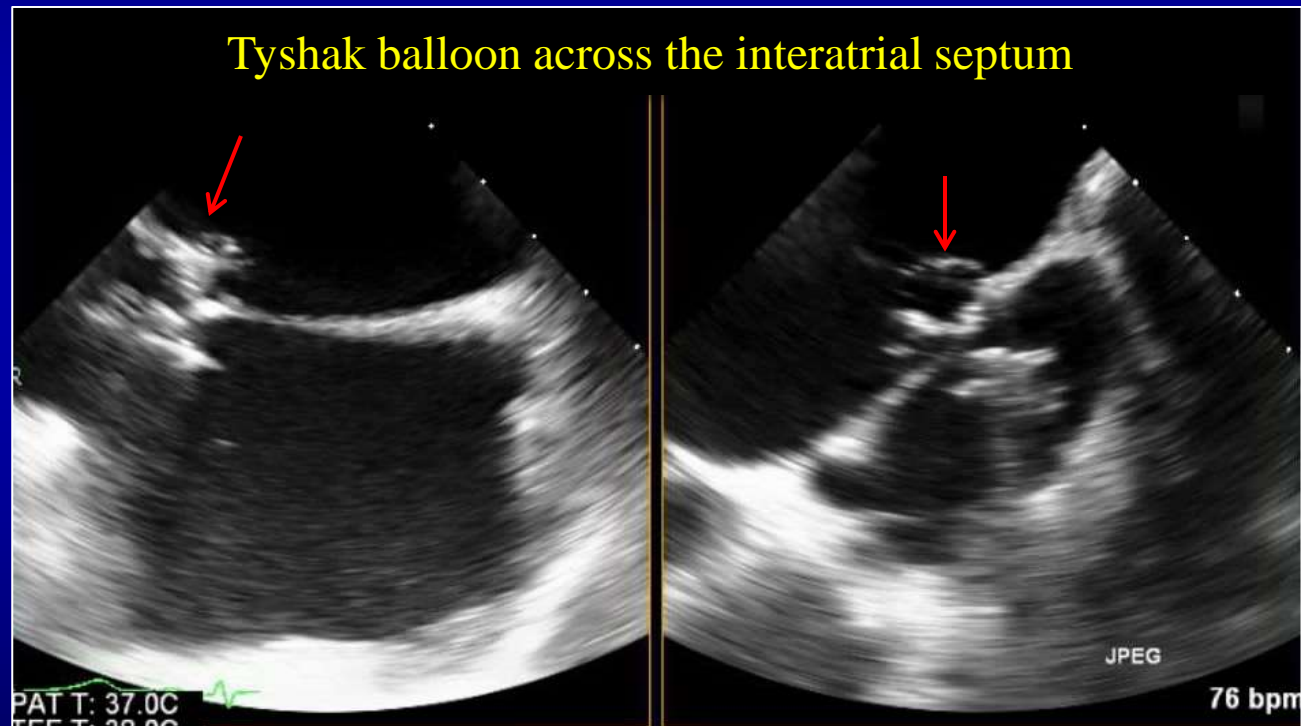
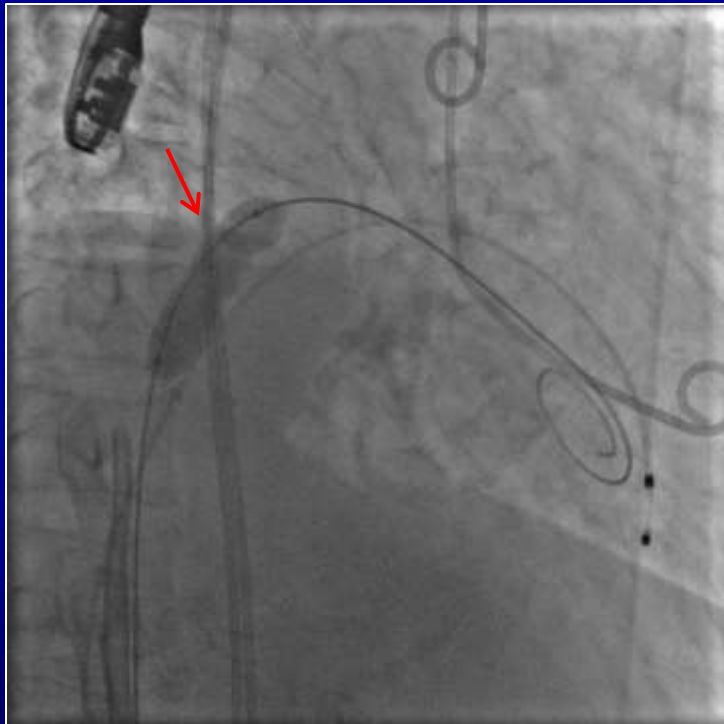
26.1 mm



Area 523 mm²



Balloon atrial septostomy performed with a 12 mm x 4 cm Tyshak II balloon



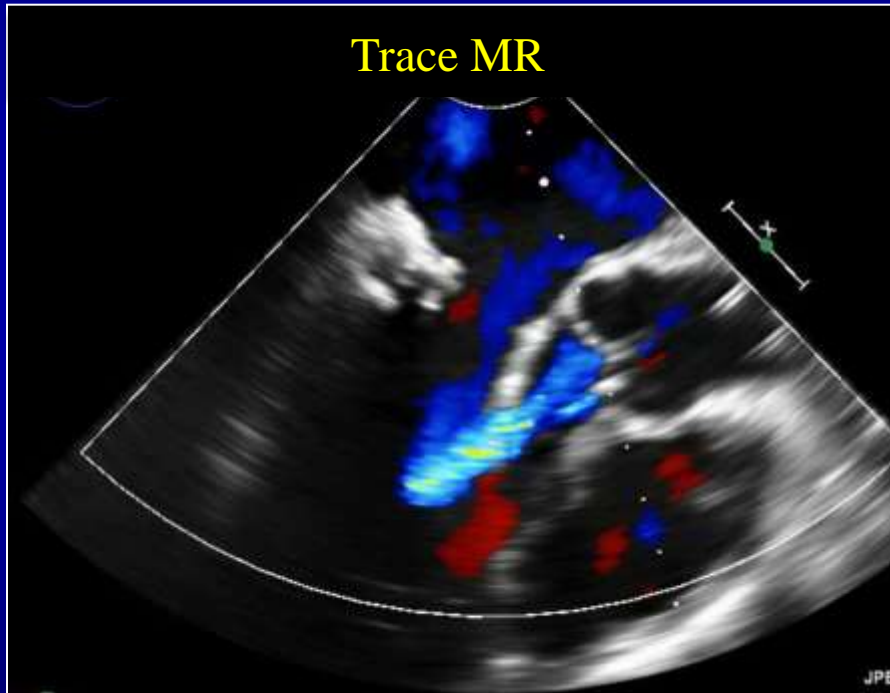
Transcatheter mitral valve replacement with a 29mm Sapien 3 valve

Rapid pacing at 180bpm



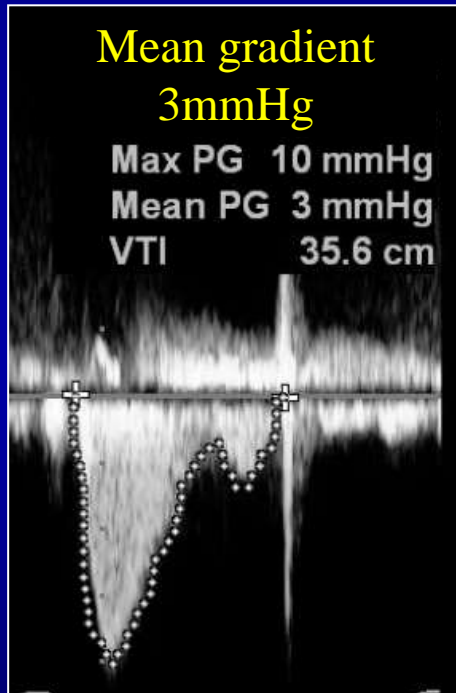
Final result

Trace MR



Mean gradient
3mmHg

Max PG 10 mmHg
Mean PG 3 mmHg
VTI 35.6 cm



Normal leaflet motion

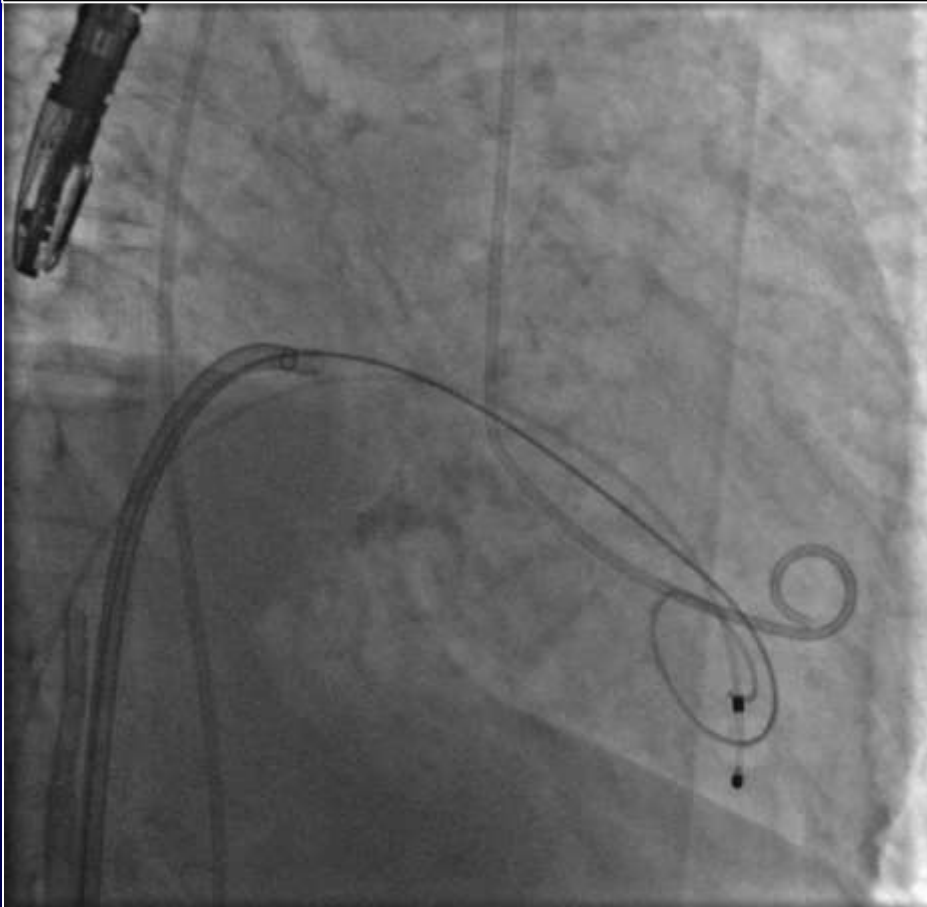


Left ventriculogram

No significant MR

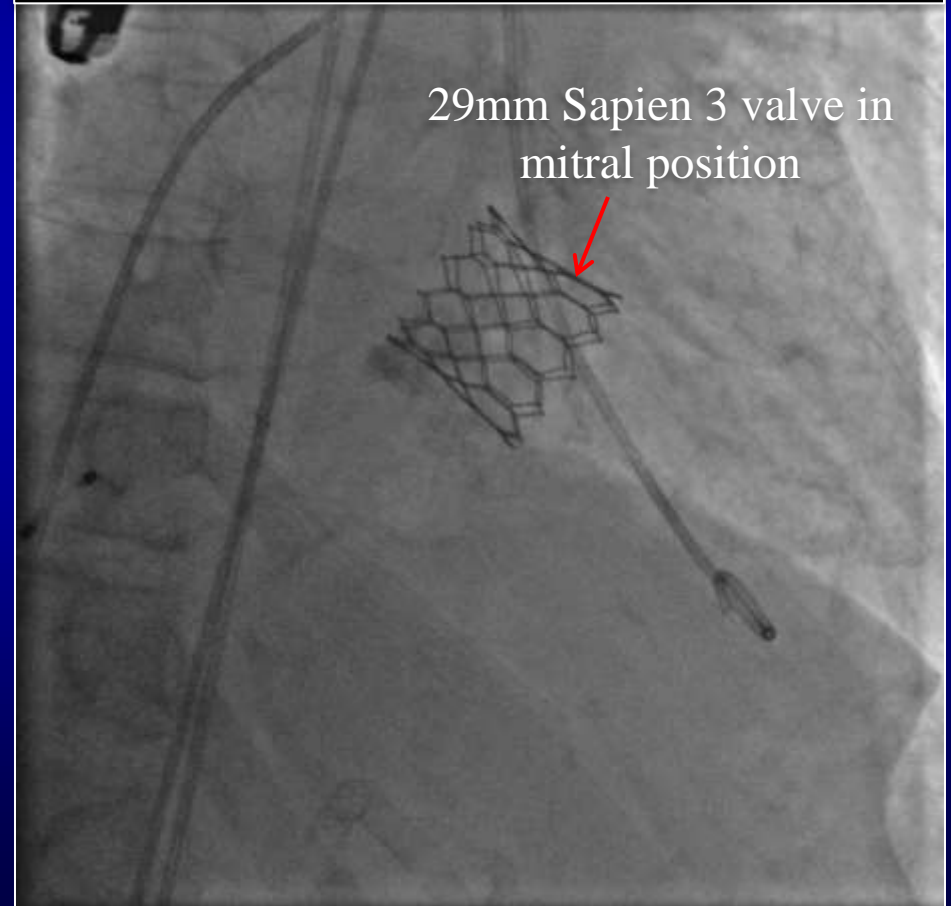
Baseline

Moderate-severe MR



Post-intervention

No significant MR



36 y/o female referred for transcatheter tricuspid ViV implantation

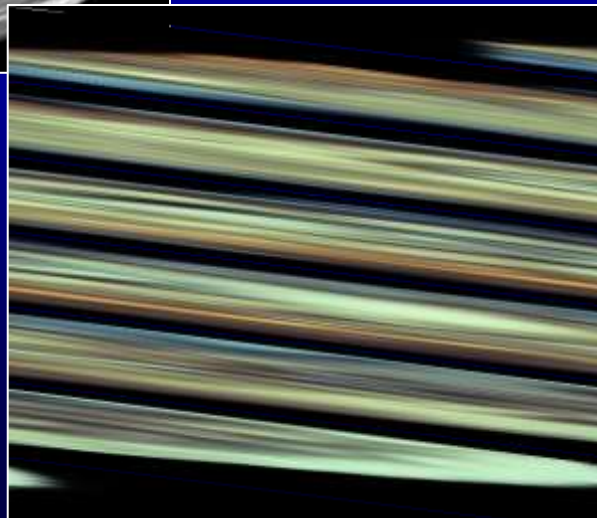
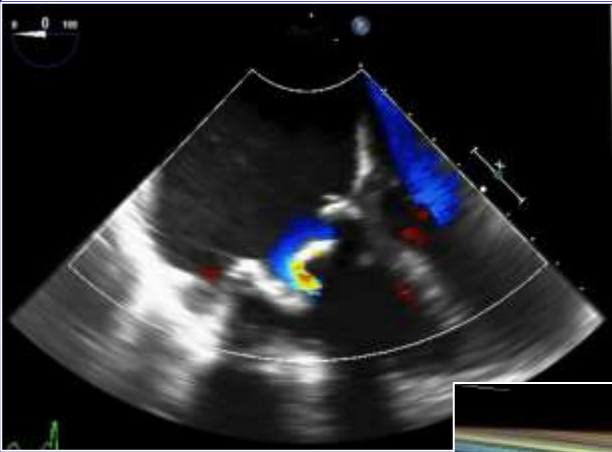
Severe tricuspid stenosis of bioprosthetic tricuspid valve

- Surgical tricuspid valve replacement with #31 Hancock bioprosthetic valve
- Severely depressed RV function
- Atrial fibrillation/flutter with RVR
- Recurrent pulmonary embolism

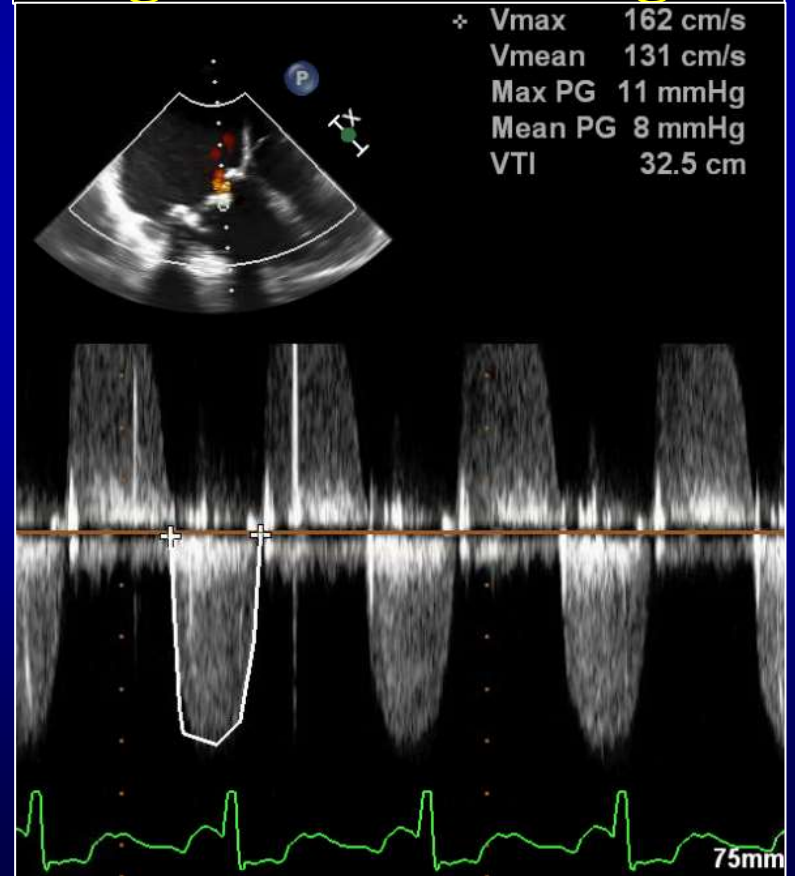
Patient initially worked-up for redo surgery; however after multidisciplinary team discussion, it was decided to proceed with transcatheter tricuspid ViV implantation

Severe degenerative #31 Hancock valve

Severe tricuspid stenosis



Mean tricuspid valve gradient 8mmHg



Plan for 29mm Sapien3 valve

True ID of Hancock II valve 26mm

Valve Size

Stent ID

HT

Stent Internal Diameter	28
True ID	26
Height	22

Suggested TAVI Valve Size

Sapien Size	29
-------------	----

Sapien Ideal Placement

Hancock II

10% above the fluoroscopic marker in the sewing ring.
Achieve a 'conical' deployment.

Double tap image for fullscreen

Image scrolls horizontally

Video Guidance

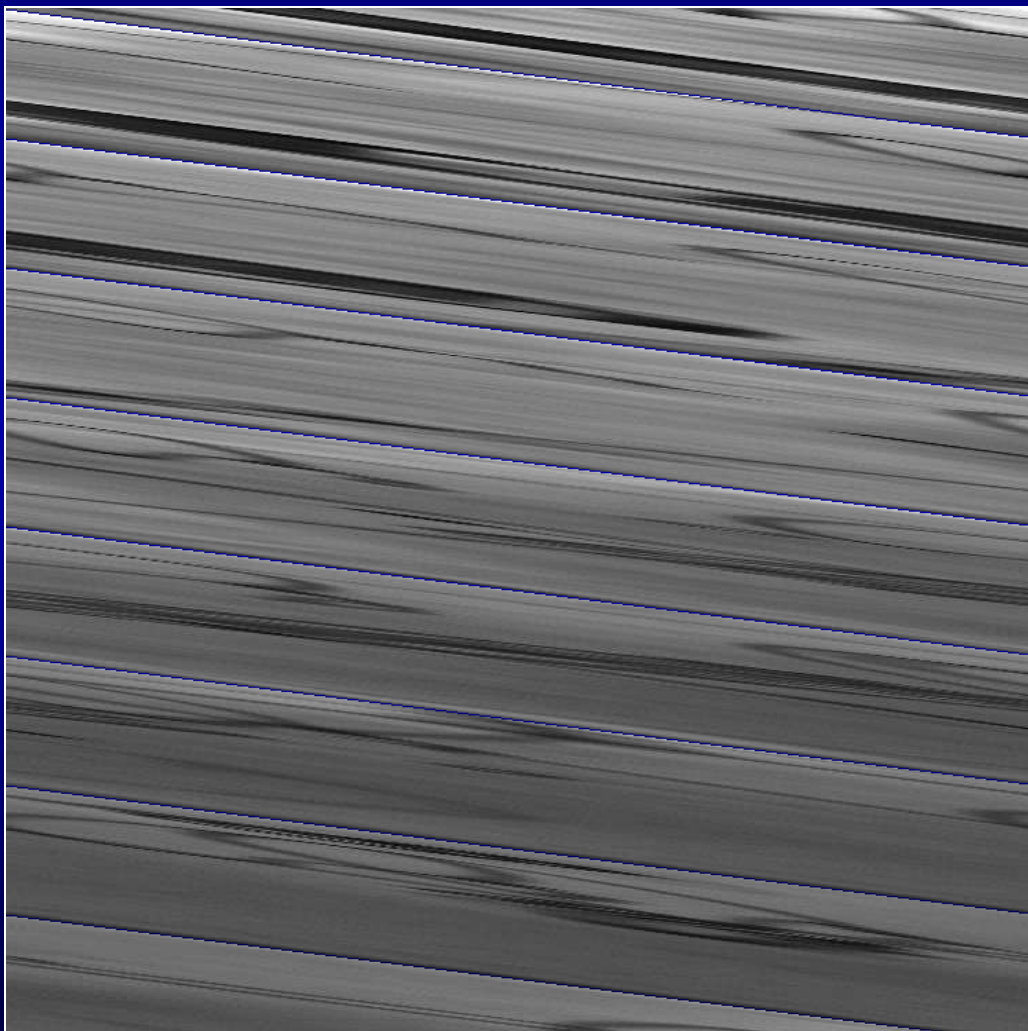
Home Valves Rings TAVI Valves Information

Tricuspid valve crossed with a JR4 catheter and 0.035 guidewire



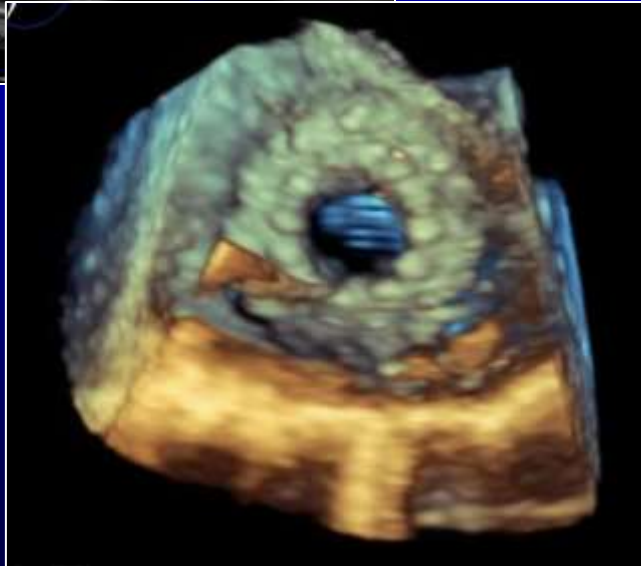
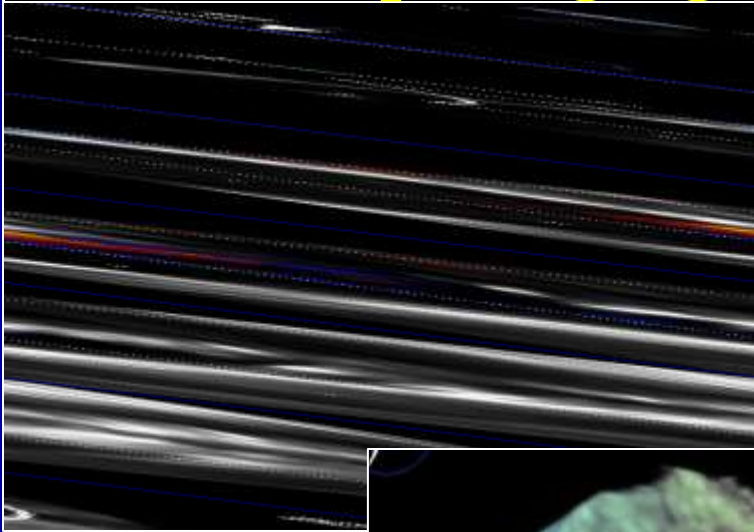
Tricuspid ViV with a 29mm Sapien3 valve

Rapid atrial pacing performed

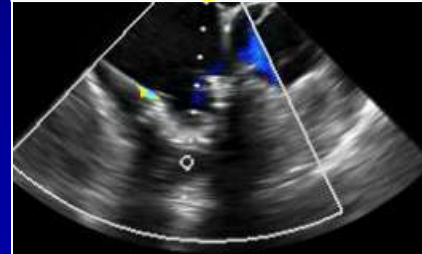


Final result

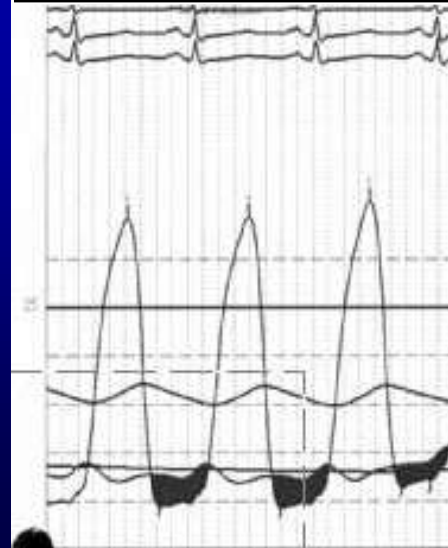
Normal leaflet motion
No tricuspid regurgitation



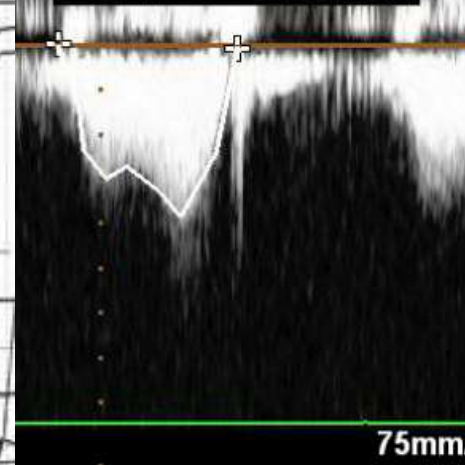
Mean tricuspid valve
gradient 1mmHg



Invasive gradient
2mmHg



÷ Vmax 76.6 cm/s
Vmean 49.8 cm/s
Max PG 2 mmHg
Mean PG 1 mmHg
VTI 20.1 cm



Hospital course

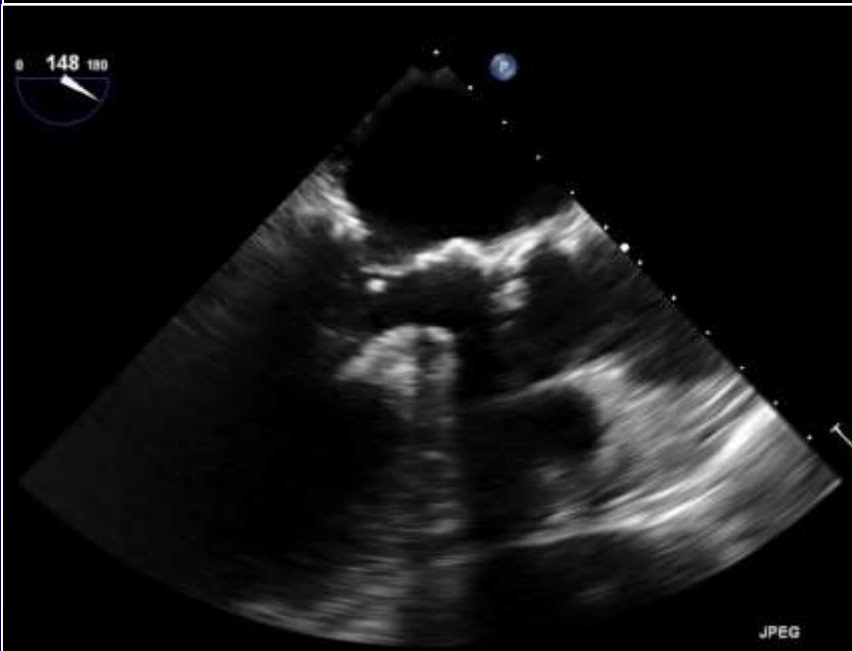
- Patient discharged on post-procedure Day 2
- Seen in clinic at 1 month, asymptomatic

Sapien in AS+MAC for severe MR

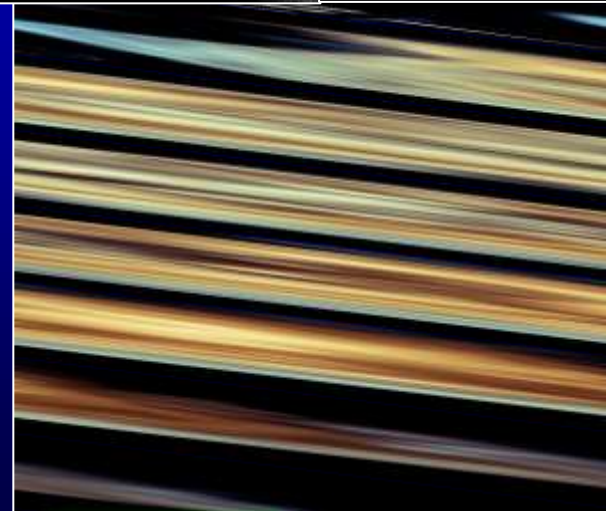
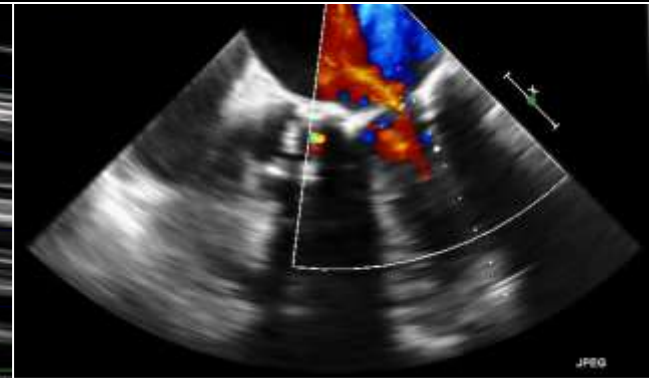
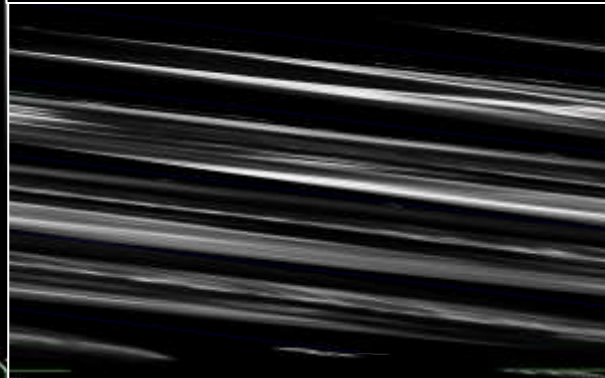
90 y/o female referred for TAVR

Deemed inoperable by 2 cardiothoracic surgeons

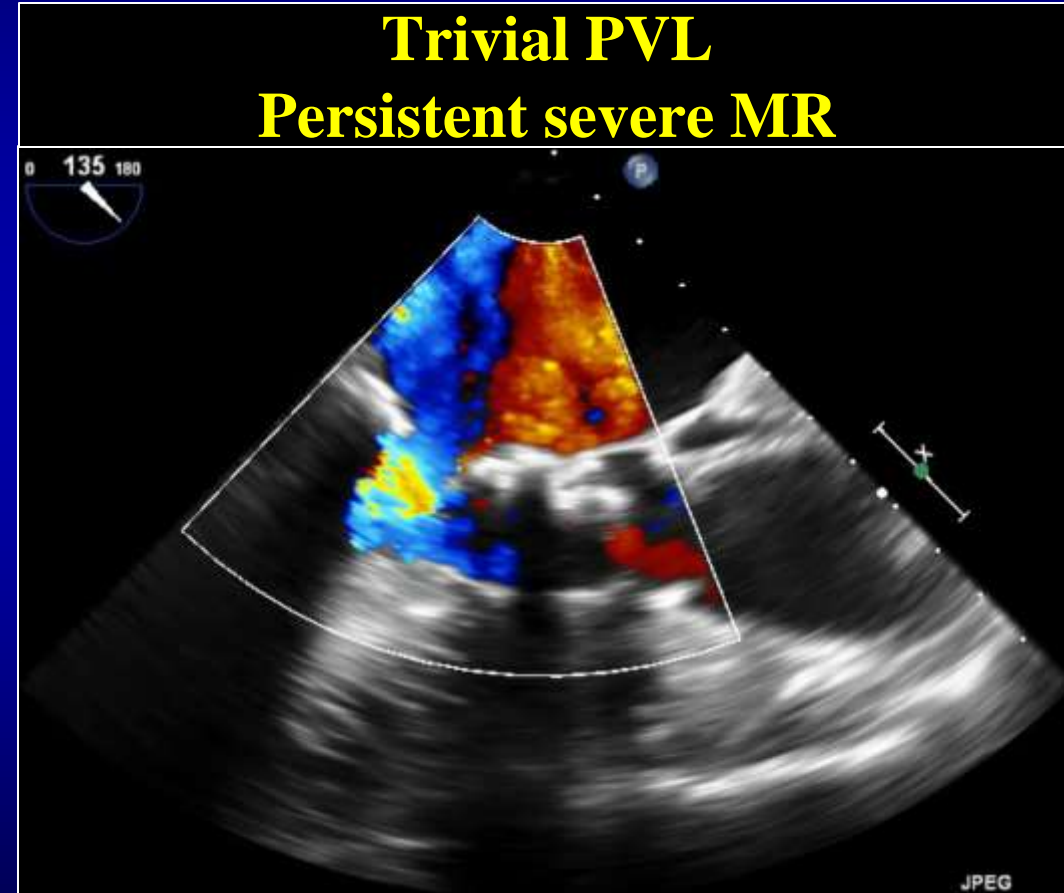
Severe aortic stenosis



Severe mitral regurgitation with flail P2 and severe mitral annular calcification

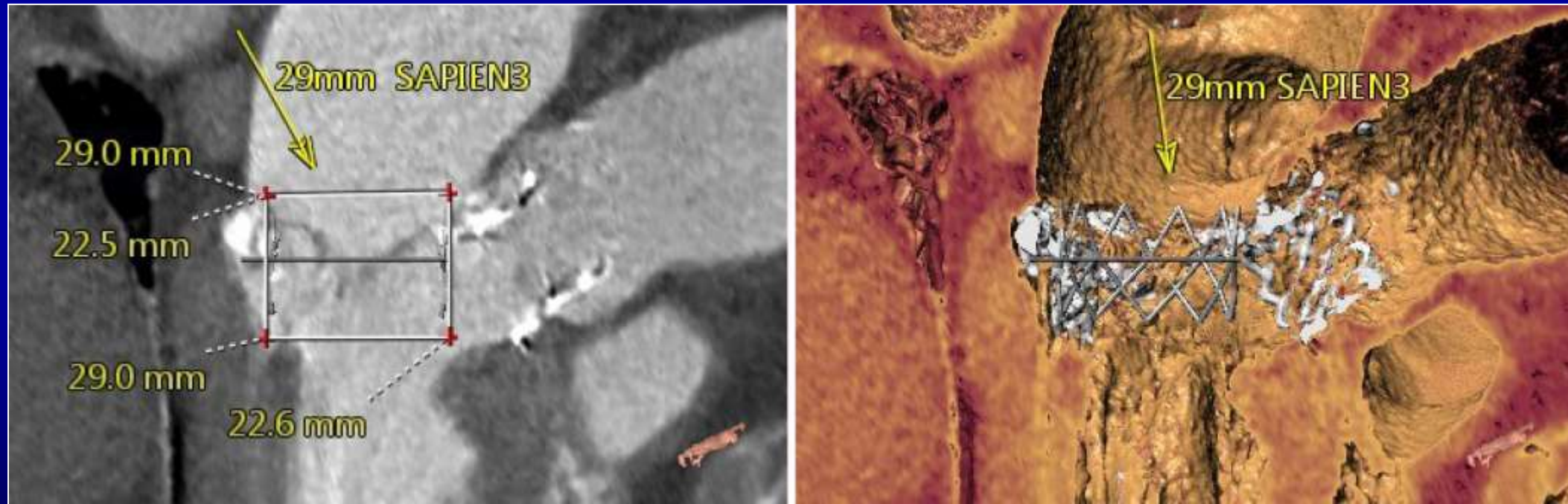


TAVR with 23mm Sapien 3



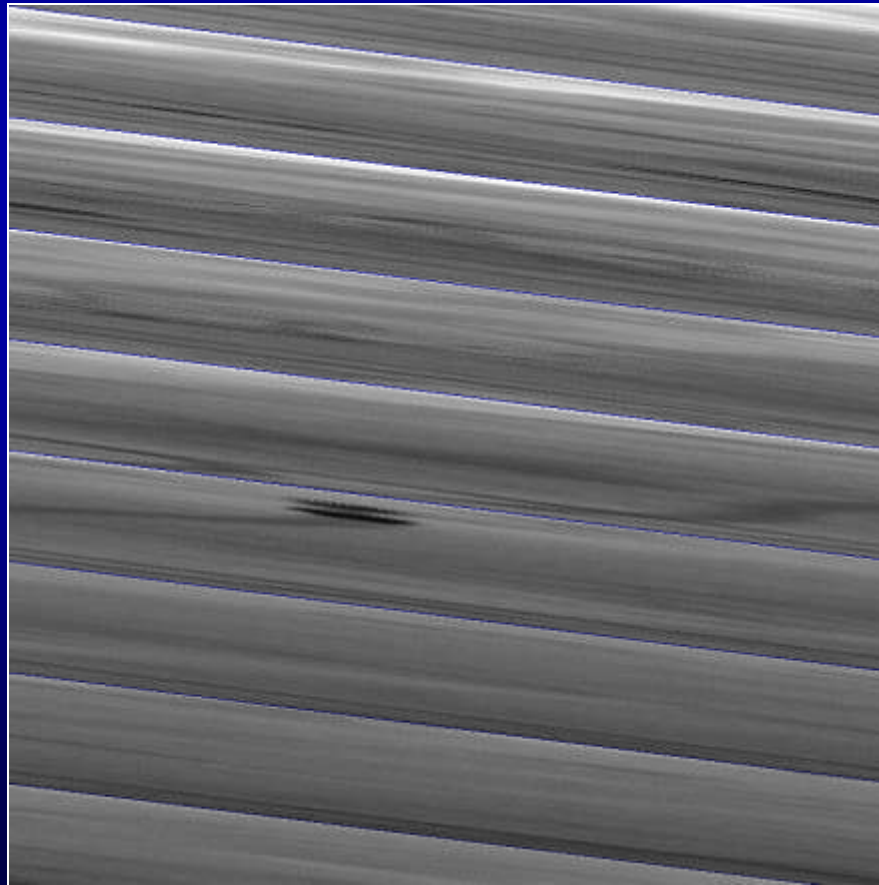
Patient readmitted 3 weeks later with decompensated, NYHA IV heart failure and failure to thrive

LV cavity and annular dimensions slightly more acceptable for Sapien in MAC

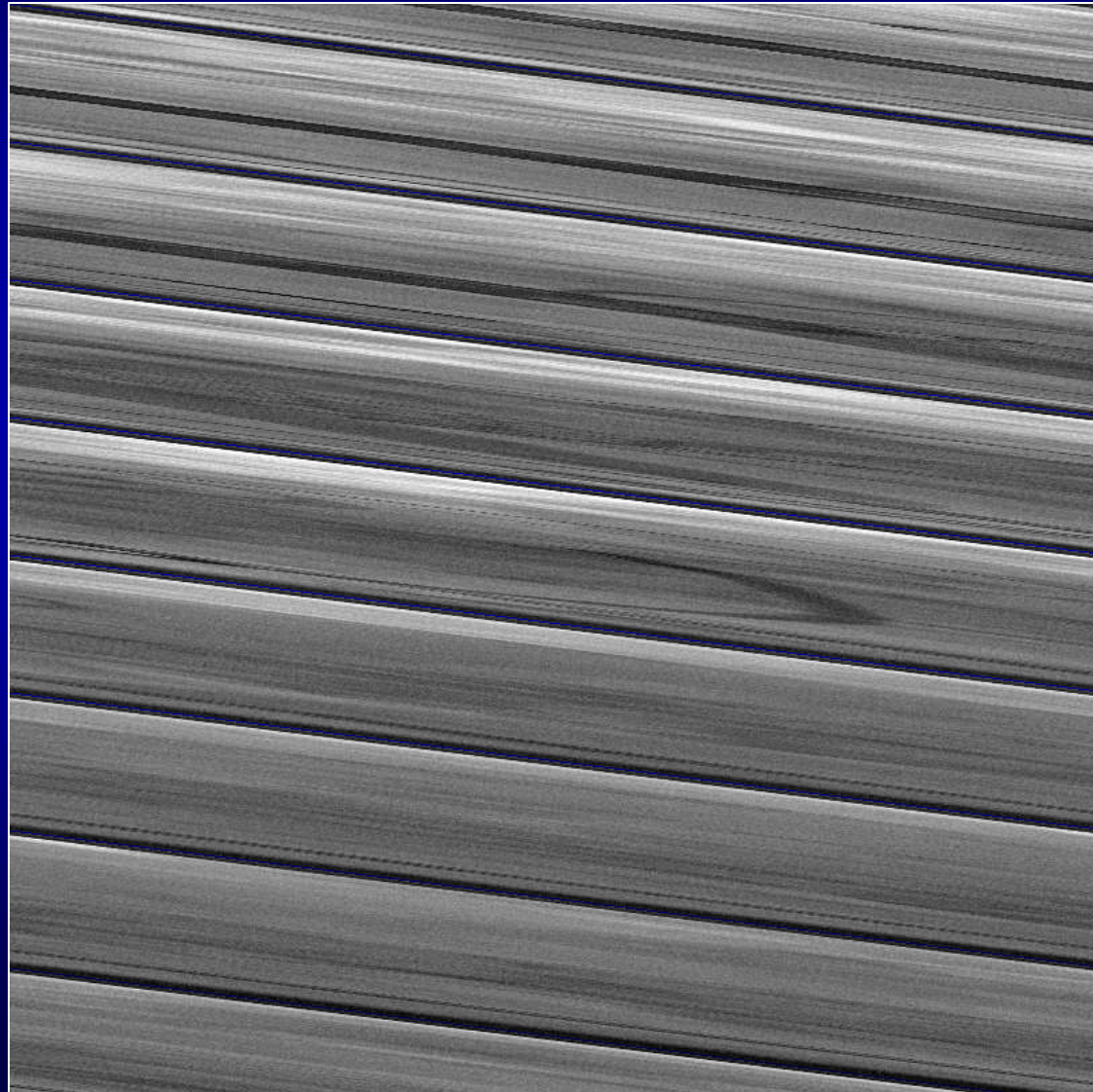


Decision made to proceed with TMVR after extensive discussion with the family

Prophylactic alcohol septal ablation performed with 2cc of alcohol to decrease the risk of LVOT obstruction

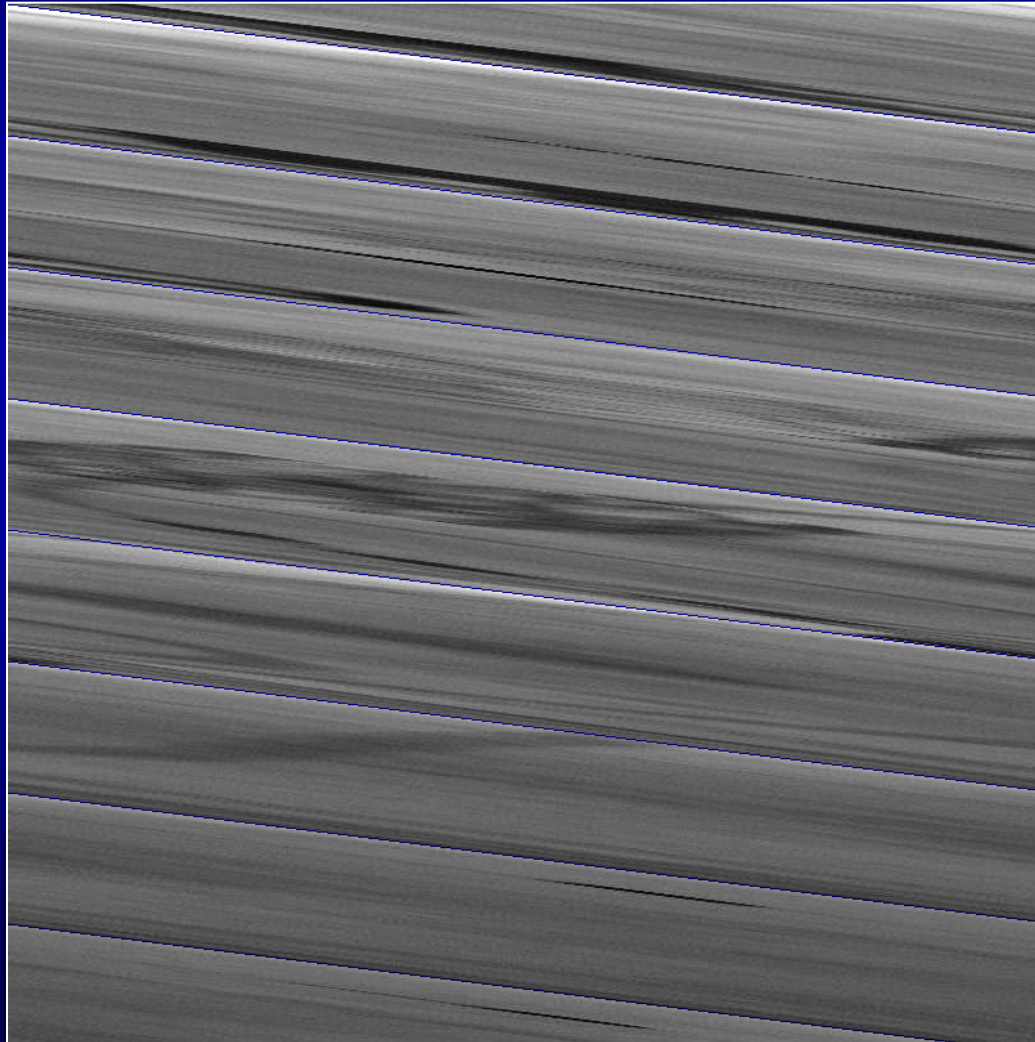


Balloon atrial septostomy performed with a 12 mm x 4 cm Tyshak II balloon

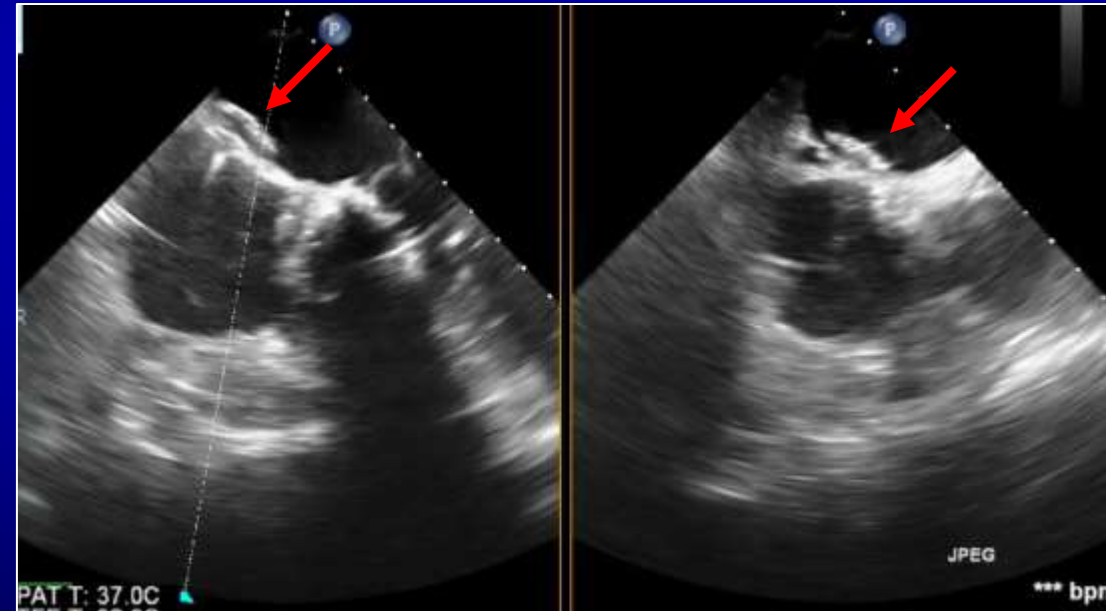
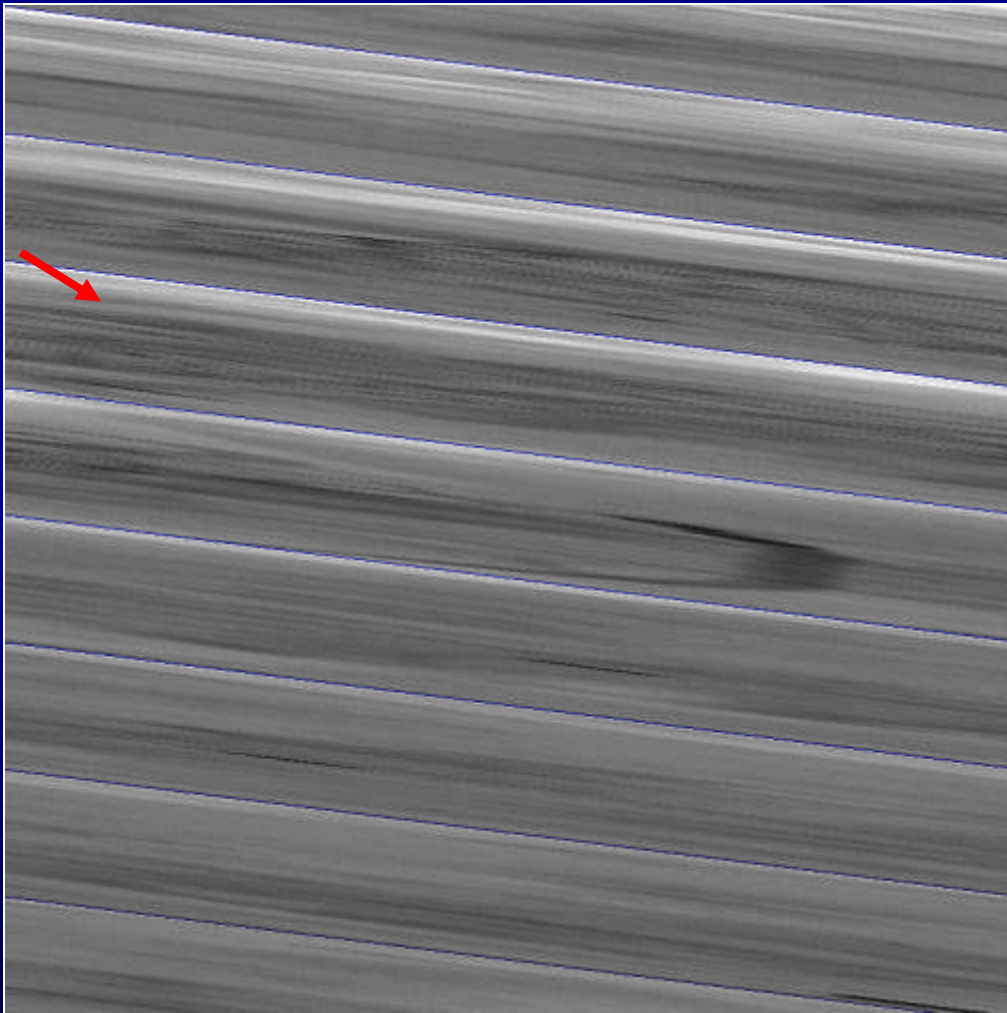


Transcatheter mitral valve replacement with a 29mm Sapien 3 valve

Rapid pacing at 180bpm



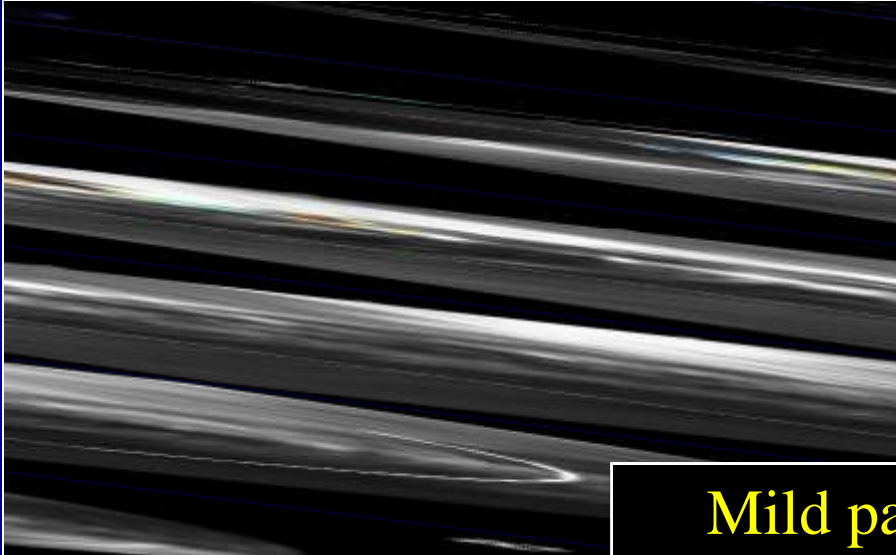
Due to persistent hypoxemia secondary to interatrial shunting, ASD closure performed
10mm Amplatzer Septal Occluder plug



Final result

Patient transferred out of the ICU on Day 2

Mild paravalvular MR



Normal leaflet motion



Mild paravalvular MR

