

# Planning and working with S3ULTRA

Dr Karl Poon

St Andrew's War Memorial Hospital, Brisbane, Australia

The Prince Charles Hospital, Brisbane, Australia



# Disclosure

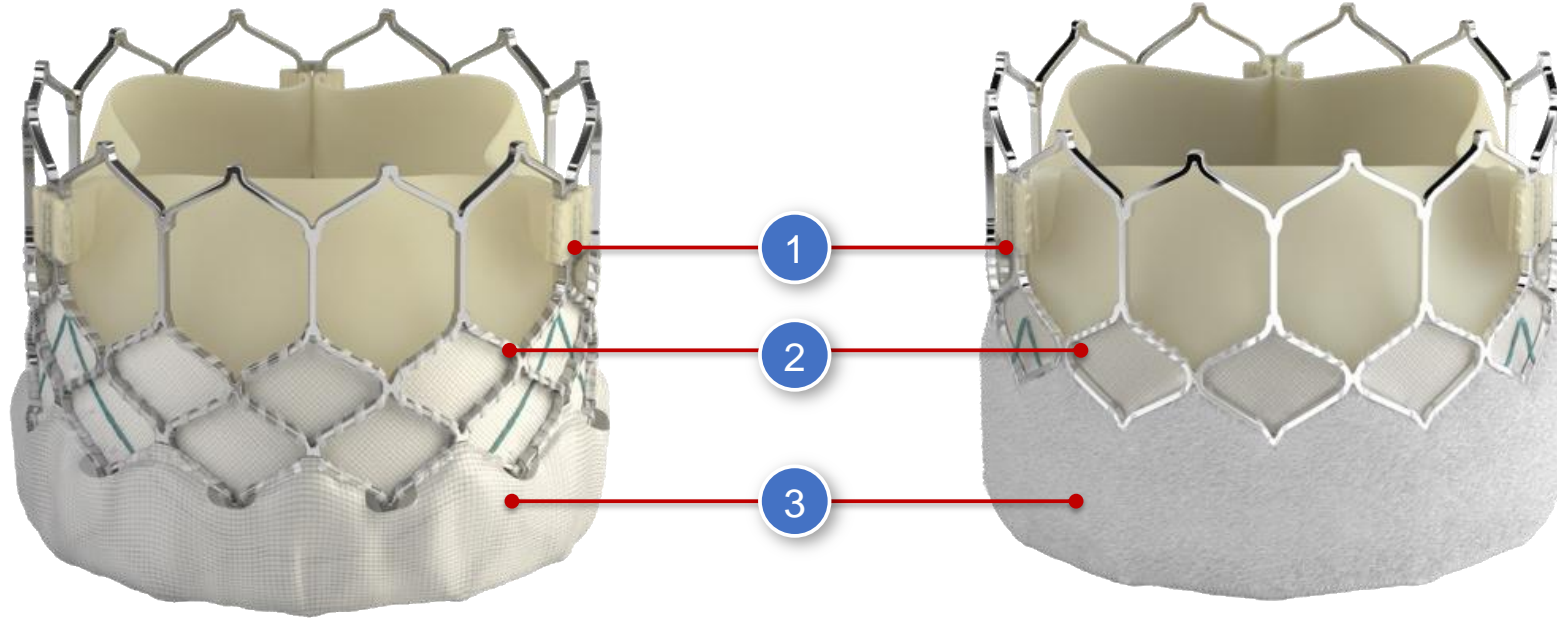
- In the past 12 months, I and/or my spouse, have received the following:

Nature of conflict relevant this presentation	Company
• Consulting fee/Proctoring fee	Edwards LifeSciences, Abbott Vascular
• Unrestricted institutional grant (QHI)	Edwards LifeSciences, Abbott Vascular

# S3 vs. S3ULTRA

## Edwards SAPIEN 3 Transcatheter Heart Valve

## Edwards SAPIEN 3 ULTRA Transcatheter Heart Valve



- 1 Bovine pericardial tissue**
- Scalloped leaflet shape
  - Utilizes the same bovine pericardial tissue and processes as Edwards surgical valves

- 2 Inner skirt**
- Polyethylene terephthalate (PET) material

- 3 Outer sealing skirt**
- PET outer sealing skirt designed to minimize paravalvular leak

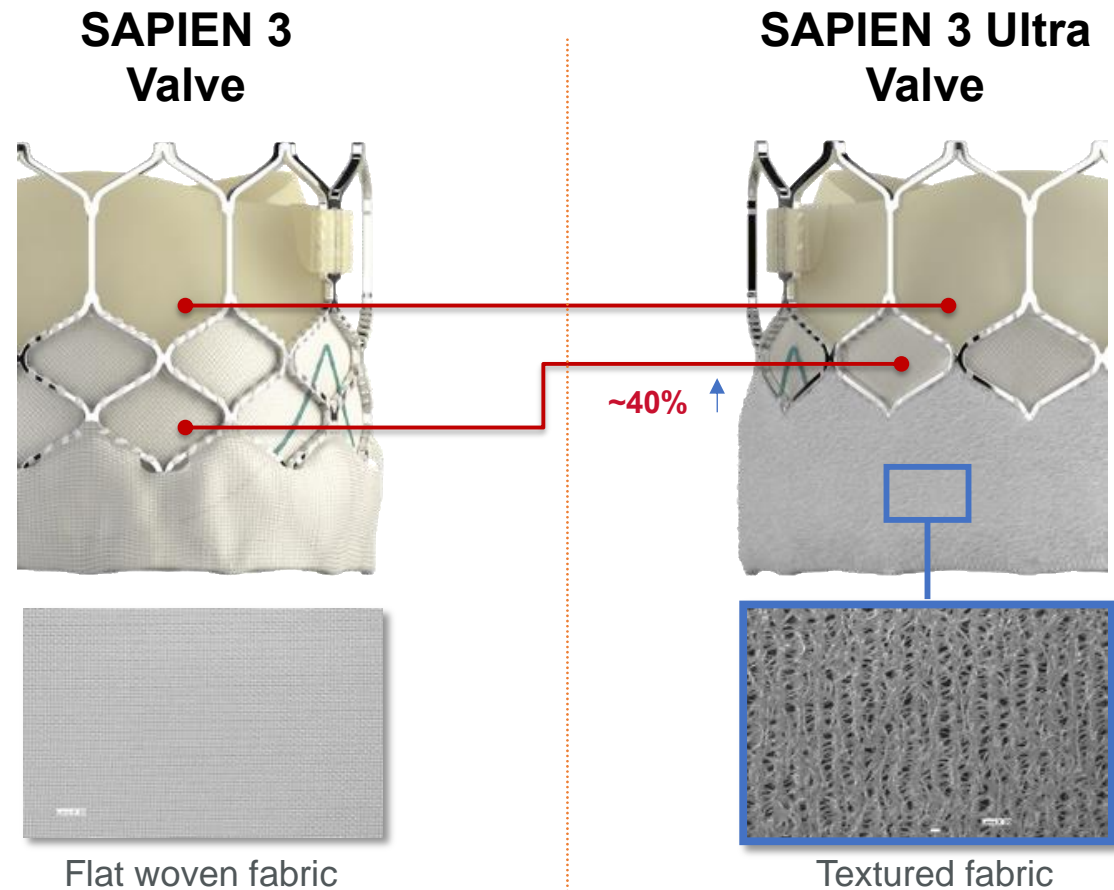
# Edwards SAPIEN 3 and ULTRA skirt comparison

## Outer skirt

- ~40% outer skirt height increase versus SAPIEN 3 valve (From ~1/3 to ~1/2 of valve height)
- Textured outer skirt material designed to aid in sealing
- Same biocompatible PET material as SAPIEN 3 valve outer skirt

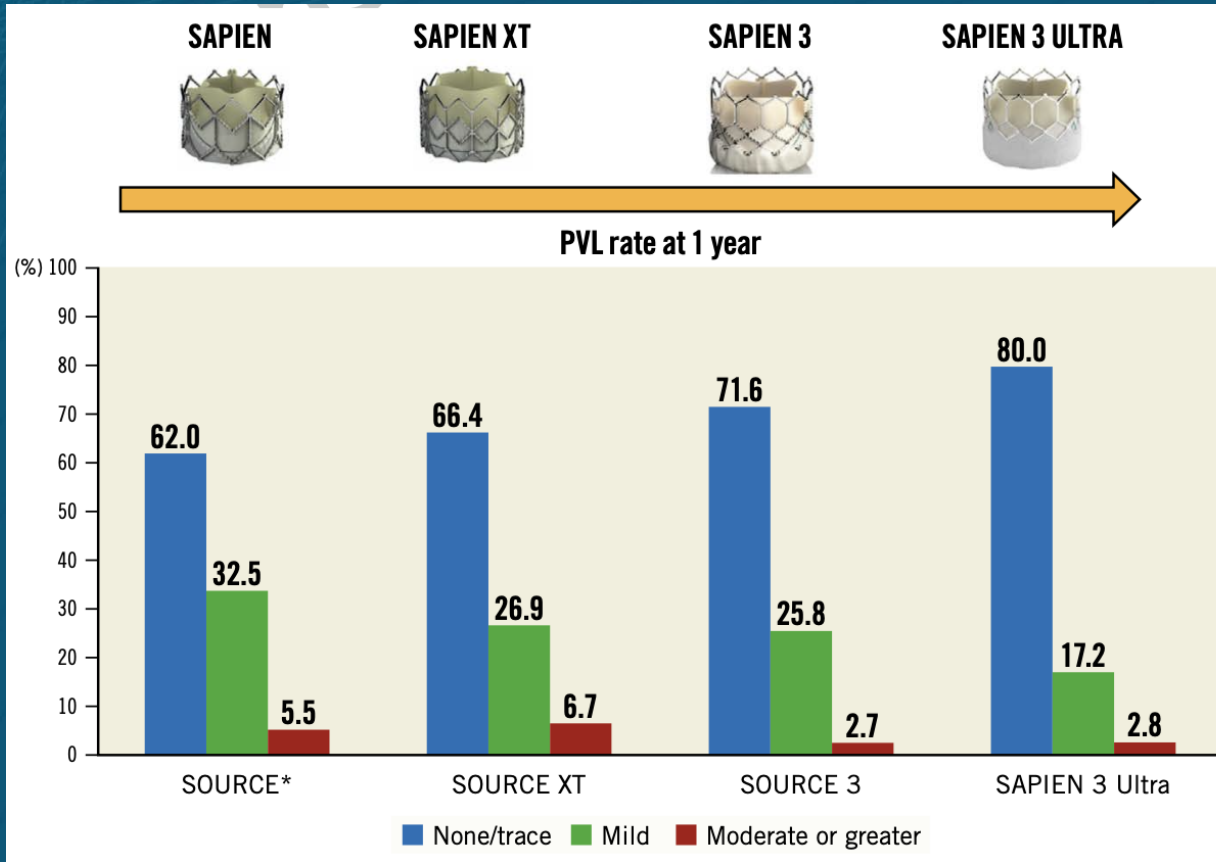
## Inner skirt

- Same inner skirt as SAPIEN 3 valve

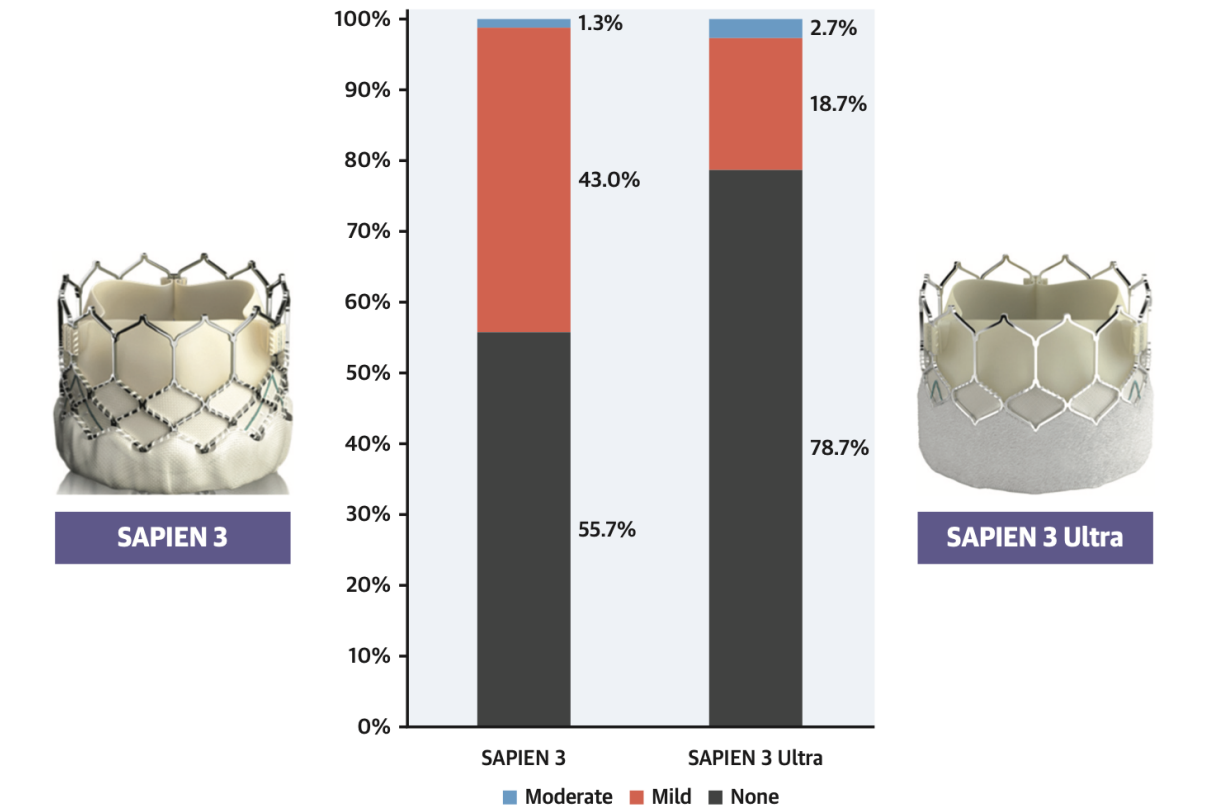


Same biocompatible PET material

# S3 vs. S3UTLRA clinical outcome – no PVL



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



Rheude, T. et al. J Am Coll Cardiol Intv. 2020; ■(■):■-■.

Reproduced with permission from Edwards Lifesciences.

Cannata, S, et al . Eurointervention 2023  
Rheude T, et al. Jacc Intv 2020



# Comparison between Edwards SAPIEN 3 and Edwards SAPIEN 3 ULTRA in Transcatheter Aortic Valve Implantation (TAVI): The First Australian Experience

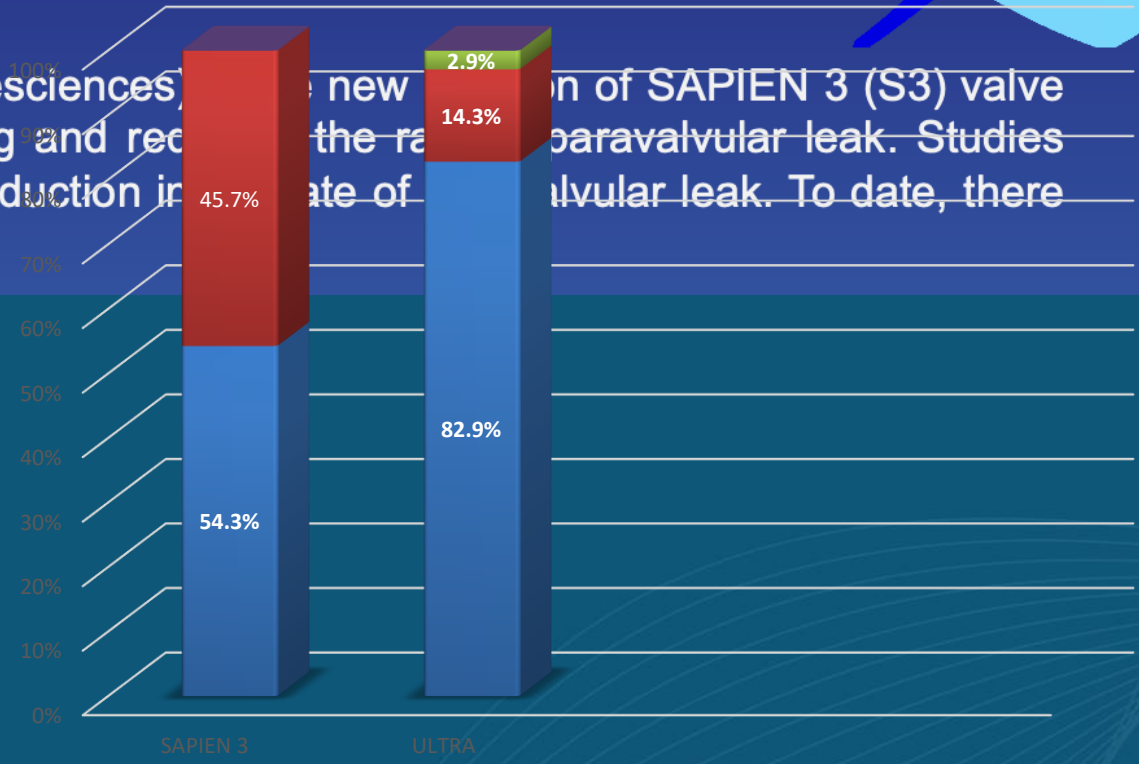
M Abdul Halim<sup>1,2</sup>; D Murdoch<sup>1,2</sup>; G Scalia<sup>1,2</sup>; K Poon<sup>1,2</sup>

<sup>1</sup> The Prince Charles Hospital, Brisbane, Queensland <sup>2</sup> University of Queensland



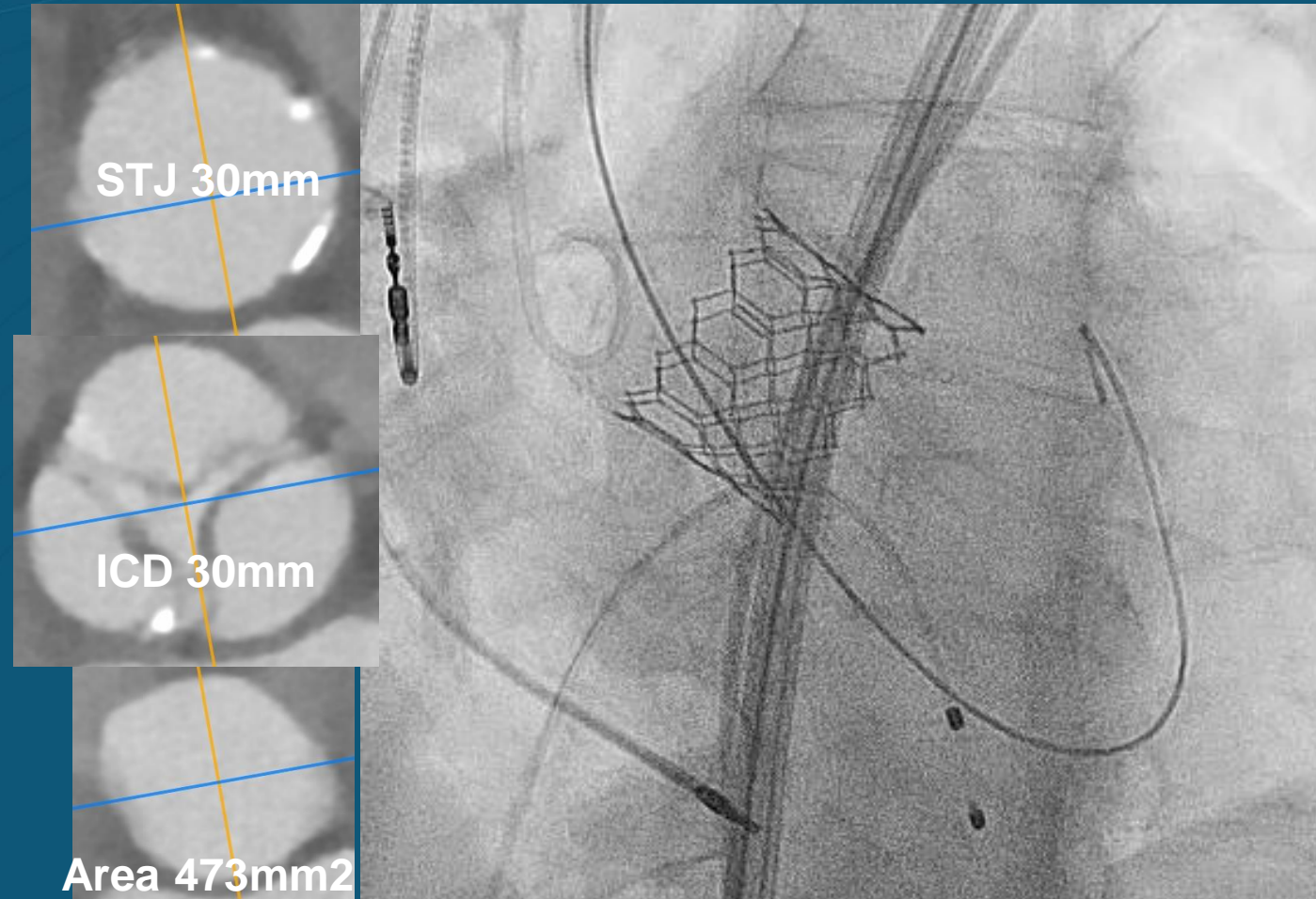
**BACKGROUND:** Edwards SAPIEN 3 ULTRA (Edwards Lifesciences), the new generation of SAPIEN 3 (S3) valve with an improved skirt, designed to improve annular sealing and reduce the rate of paravalvular leak. Studies from other centres outside Australia reported a significant reduction in the rate of paravalvular leak. To date, there is no

	SAPIEN 3 (n=35)	ULTRA (n=35)	p value
No	19 (54.3%)	29 (82.9%)	0.0009
Mild	16 (45.7%)	5 (14.3%)	0.0035
Moderate	0 (0%)	1 (2.9%)	0.3102
Severe	0 (0%)	0 (0%)	-



# Clinical case examples

# Trileaflet AS; Area 473mm<sup>2</sup>; no hostile features



## TAVI procedure

- local anaesthetic
- Direct implant
- 26mm S3ULTRA **nominal**
- **@ 6 atm**
- Rhythm unchanged
- No significant PVL

## TTE

- Mean 6 mmHg
- EOA 2.1cm<sup>2</sup>
- No PVL

**TAVI with no PVL/PPM and coronary clearance**



# Bicuspid Sievers I AS; Area 470mm<sup>2</sup>; non hostile



## TAVI procedure

- local anaesthetic
- Direct implant
- 26mm S3ULTRA **nominal**
- @ **6 atm**
- Rhythm unchanged
- No significant PVL

## TTE

- Mean 9 mmHg
- EOA 2.8cm<sup>2</sup>
- No PVL

Treating clean bicuspid with confidence

# Dealing with in between annular sizing

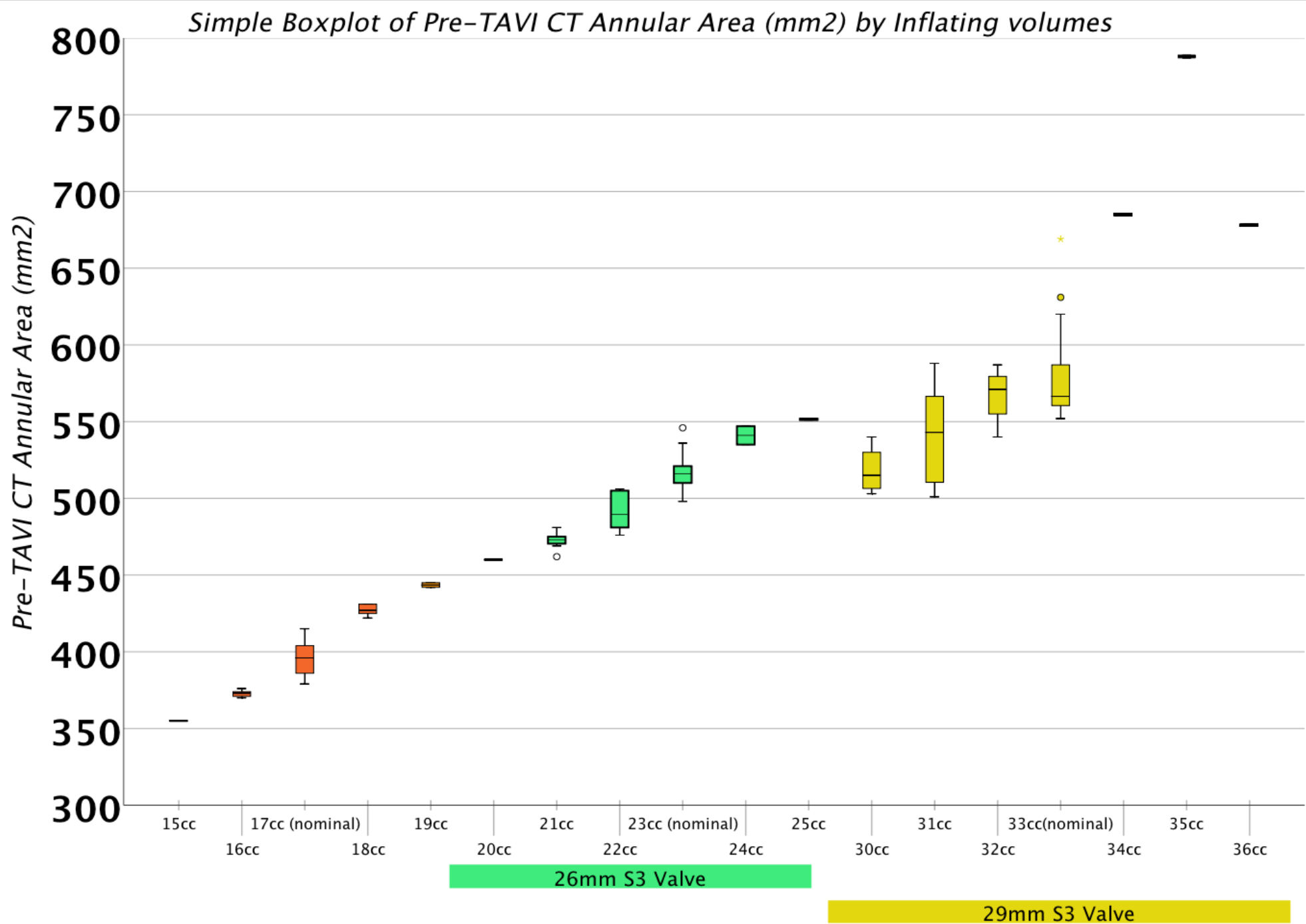
# Clinical and echocardiographic impact of *under* and *over* expansion of SAPIEN 3 transcatheter heart valves to tailor to aortic annular sizes

Srikantha Adusumalli MBBS<sup>1,2</sup>, Dale J Murdoch MBBS<sup>1,2</sup>, Karthik Gopal MBBS<sup>1,2</sup>, David Platts MBBS<sup>1,2</sup>, Karl K Poon MBBS<sup>1,2</sup>

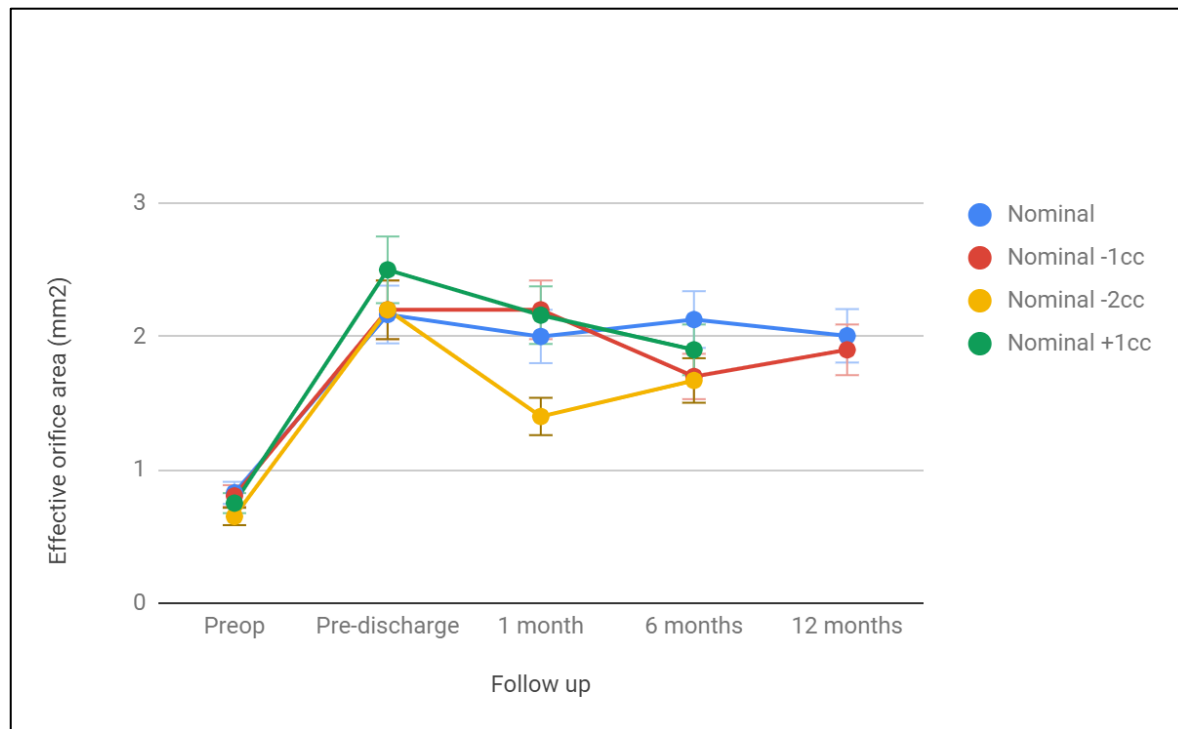
<sup>1</sup> Heart and Lung Institute, Dept of Cardiology, The Prince Charles Hospital, Brisbane, Australia

<sup>2</sup> School of Medicine, The University of Queensland, Brisbane, Australia

Figure demonstrates the balloon inflation volumes of 23mm, 26mm & 29mm S3 THV depending on the CT derived annular area.



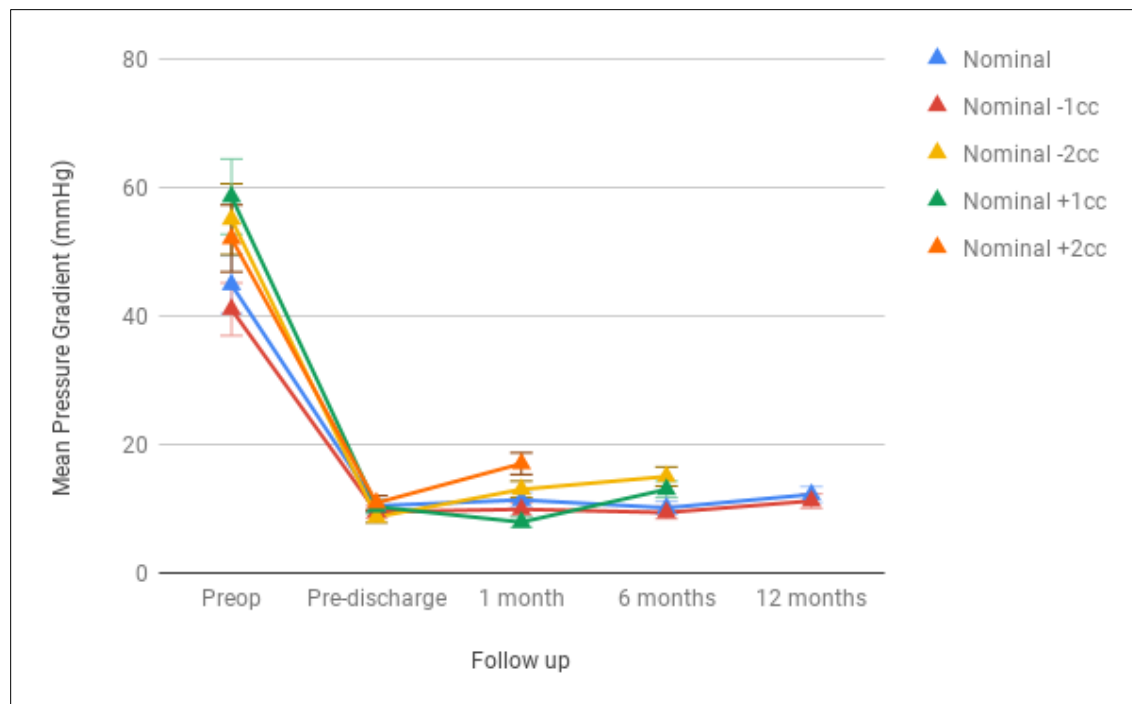
# Results- 26mm S3 valve- Effective orifice area (cm<sup>2</sup>)



26mm S3 (n=60)	Pre discharge EOA (cm <sup>2</sup> )	1M EOA (cm <sup>2</sup> )	6M EOA (cm <sup>2</sup> )	12m EOA (cm <sup>2</sup> )
		<i>p=0.07</i>		
Nominal -3ml (n=1)	2.49 (n=1)	1.9 (n=1)		
Nominal -2ml (n=8)	2.2+/-0.3 (n=8)	1.4+/-0.4 (n=7)	1.67+/-0.4 (n=3)	
Nominal -1ml (n=10)	2+/-0.5 (n=9)	2.2+/-0.5 (n=7)	1.7+/-0.3 (n=4)	1.9+/-0.3 (n=3)
Nominal (n=37)	2.23+/-0.48 (n=36)	1.9+/-0.4 (n=29)	2.1+/-0.56 (n=11)	2.02+/-0.37 (n=9)
Nominal +1ml (n=2)	2.5 (n=2)	2.16 (n=2)	1.71 (n=1)	
Nominal +2 (n=2)	1.95 (n=2)	2.16 (n=2)		

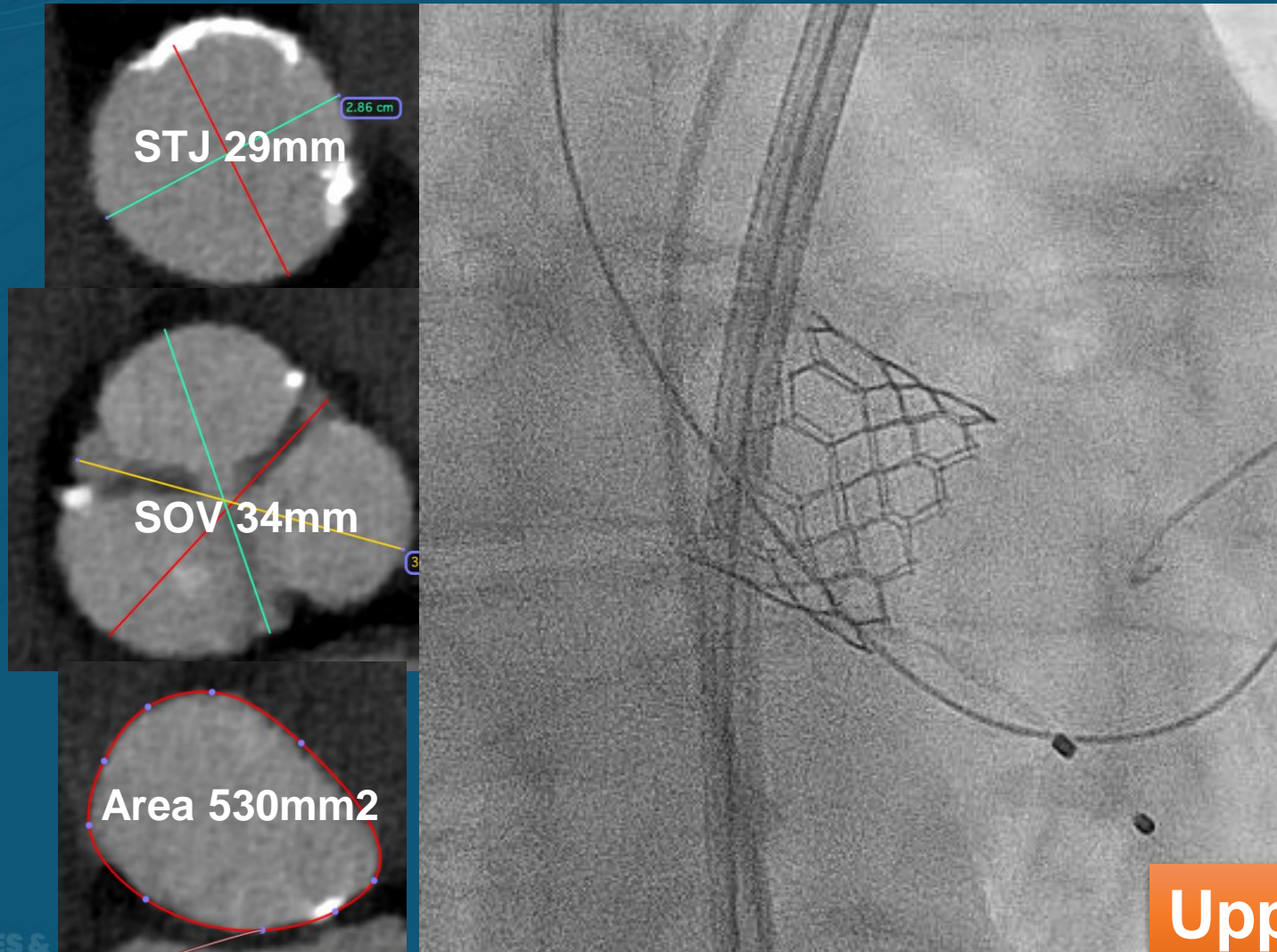
62% of 26mmS3 deployed at nominal volume

# Results- 26mm S3 valve- Mean pressure gradient (mmHg)



26mm S3 (n=60)	Pre discharge MPG (mmHg)	1M MPG (mmHg)	6M MPG (mmHg)	12m MPG (mmHg)
Nominal -3ml (n=1)	9.4 (n=1)	11 (n=1)		
Nominal -2ml (n=8)	8+/-3.6 (n=8)	15+/-6.8 (n=7)	12.2+/-5.8(n=3)	
Nominal -1ml (n=10)	8.59+/-3.3 (n=7)	9.85+/-1.1 (n=7)	9+/-2.1 (n=4)	11.5+/-1.4 (n=3)
Nominal (n=37)	9.43+/-3.8 (n=36)	9.7+/- 5.2 (n=29)	9.6+/-1.9 (n=11)	11.8+/-4.9 (n=9)
Nominal +1ml (n=2)	10.3 (n=2)	7.9 (n=2)	13 (n=1)	
Nominal +2 (n=2)	10 (n=2)	17 (n=1)		

# Trileaflet AS: Area **530mm<sup>2</sup>**; **Ca++ STJ**



## TAVI procedure

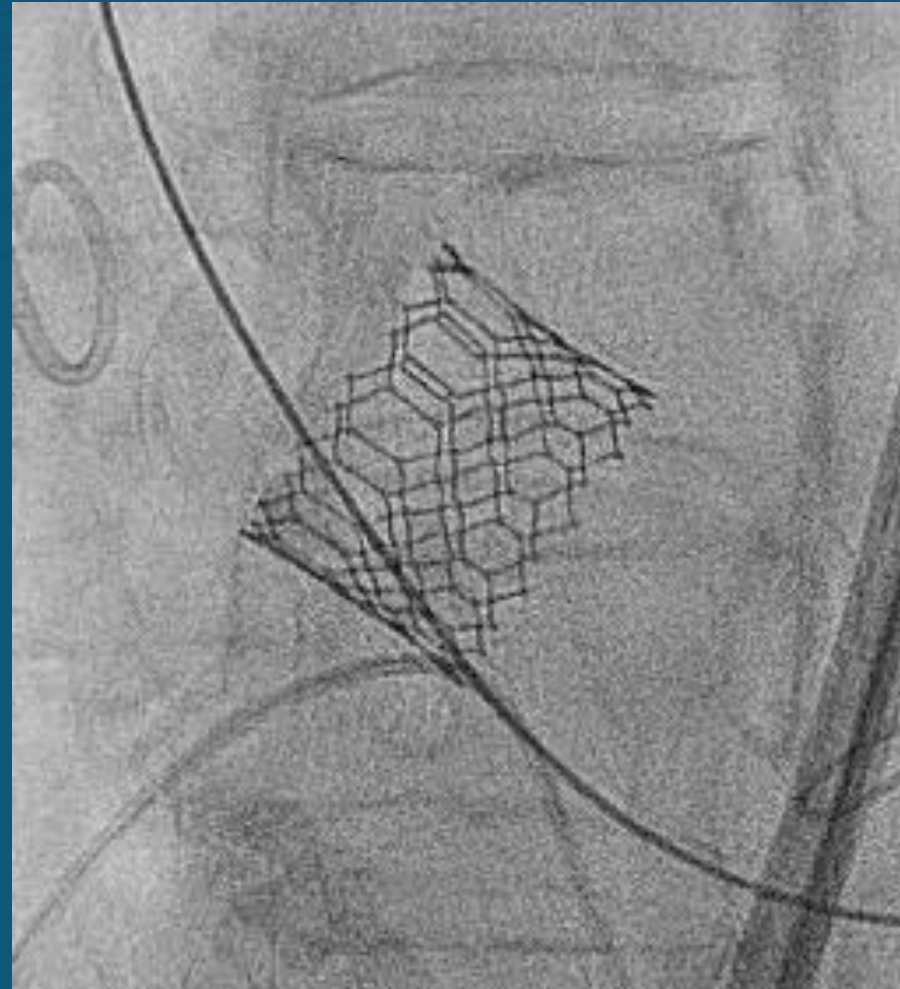
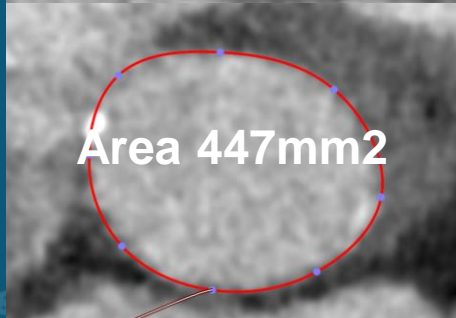
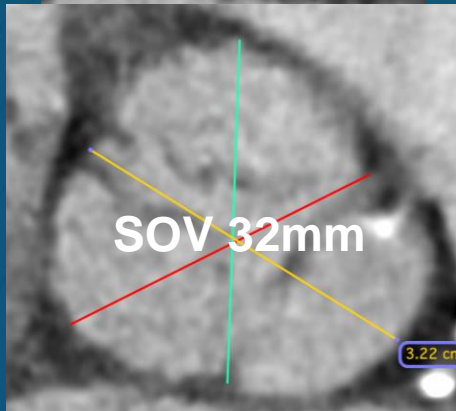
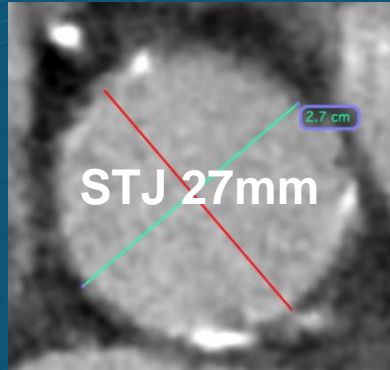
- local anaesthetic
- Direct implant
- 26mm S3ULTRA **nominal**
- @ **6 atm**
- Rhythm unchanged
- No significant PVL

## TTE

- Mean 9 mmHg
- EOA 2.8cm<sup>2</sup>
- No PVL

**Upper limit of sizing range**

# Trileaflet AS; Area **447mm<sup>2</sup>**; no hostile features



## TAVI procedure

- local anaesthetic
- Direct implant
- 23mm S3ULTRA + 2cc
- @ 8 atm
- Baseline LBBB unchanged
- No significant PVL

## TTE

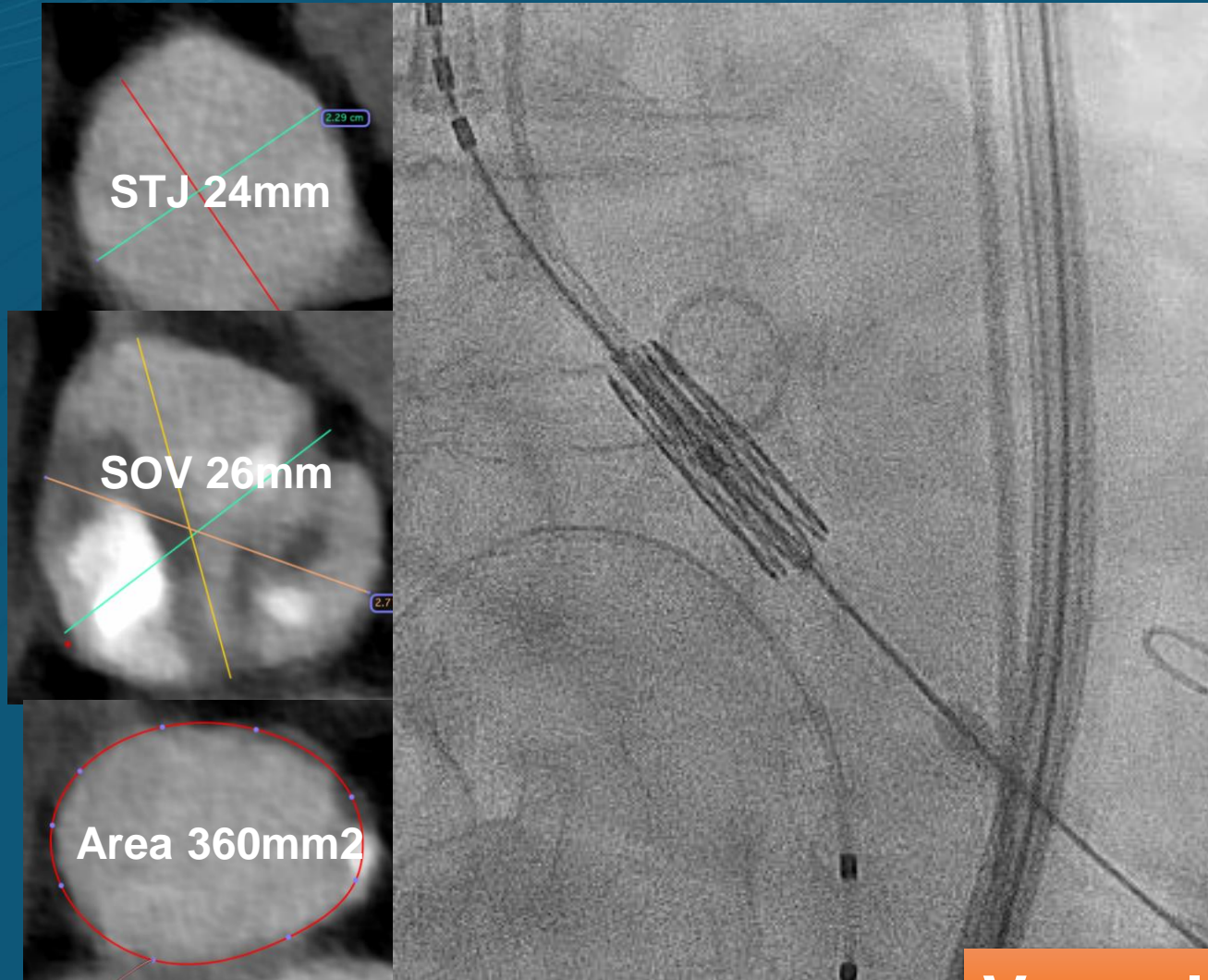
- Mean 8mmHg
- EOA 1.7cm<sup>2</sup>
- Trivial PVL

**Extreme “undersizing” of a 23mm S3U**



# Dealing with bulky leaflet

# Trileaflet AS; Area 360mm<sup>2</sup>; bulky NCC calcium



## TAVI procedure

- local anaesthetic (EF 15%)
- Direct implant
- 23mm S3ULTRA -1cc
- @ 6 atm
- Chest compression!
- No significant PVL
- Transient LBBB

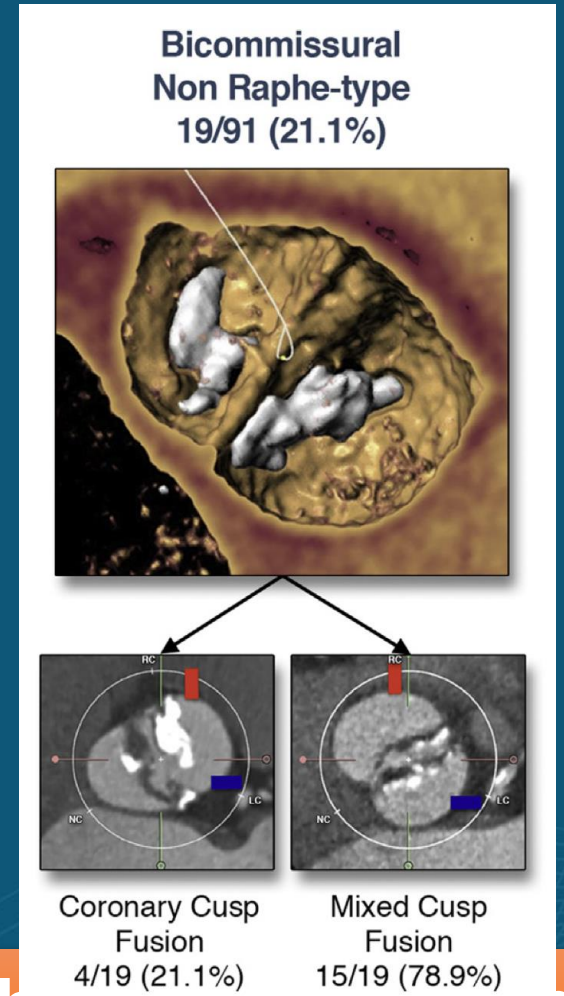
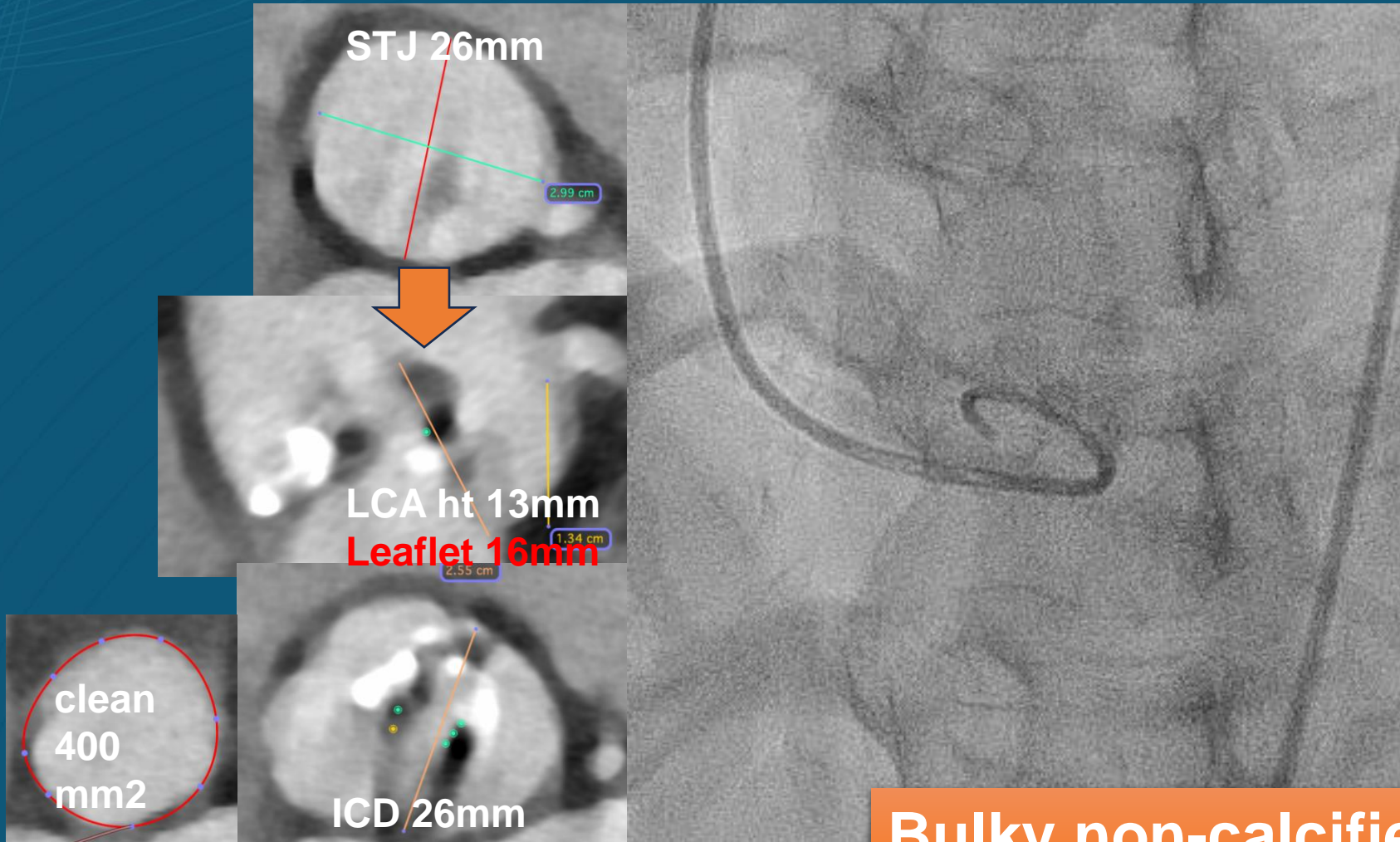
## TTE

- Mean 14 mmHg
- EOA 1.6 cm<sup>2</sup>
- No PVL (EF 38% 😊)

Very slow final phase of inflation

# Challenging bicuspid

# Bicuspid Type 0 AS; Area 400mm<sup>2</sup>; fibrous leaflet



**Bulky non-calcified/fibrous leaflet tip**  
**Left dominant CAD with small RCA**

# Bicuspid Type 0 AS; Area 400mm<sup>2</sup>; fibrous leaflet

## TAVI procedure

- general anaesthetic (53yo)
- Pre BAV 18mm – LM!!!
- 23mm S3ULTRA - 2cc
- @ 6 atm
- Gradient 5 to 8mmHg
- No significant PVL

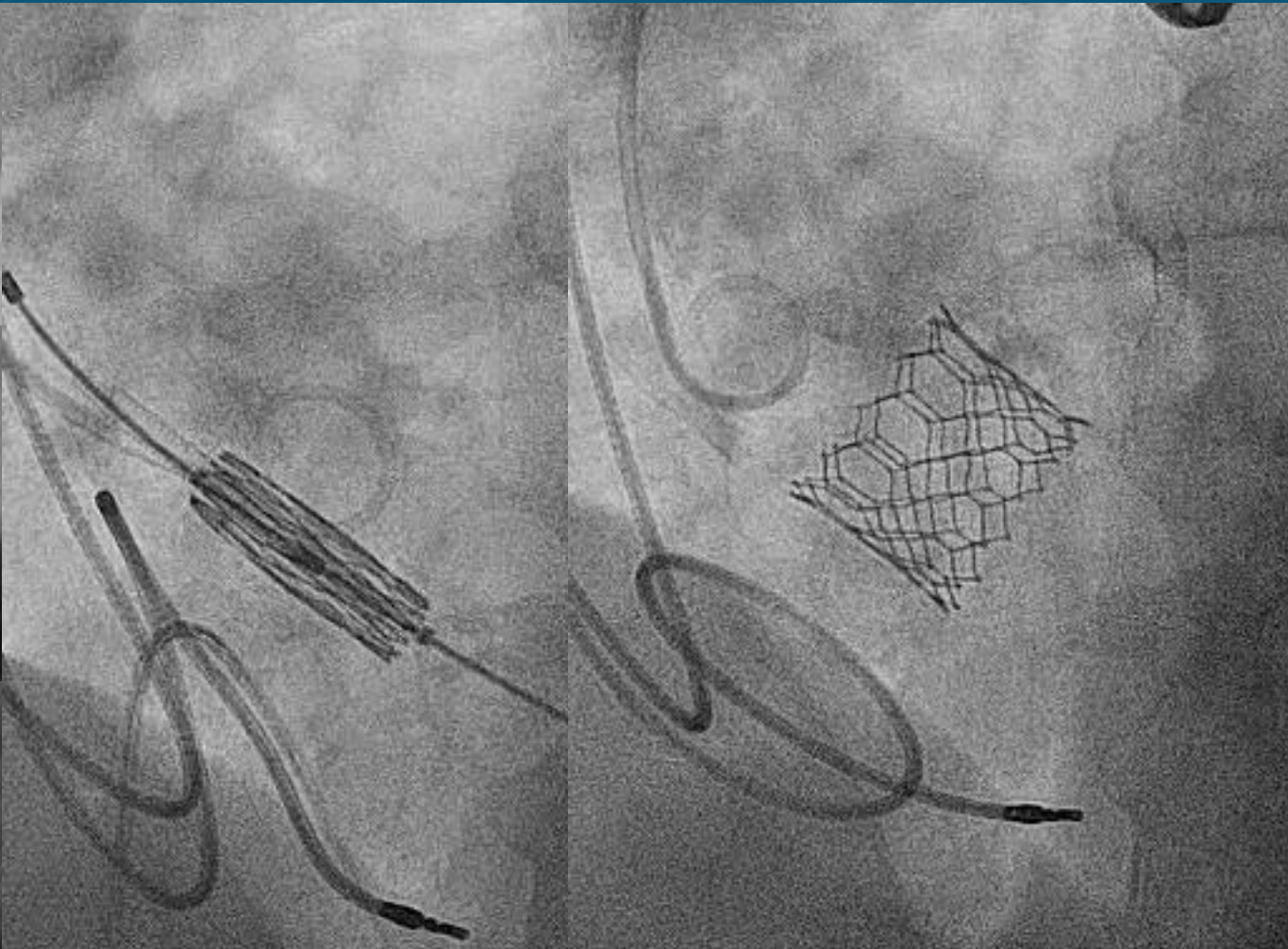
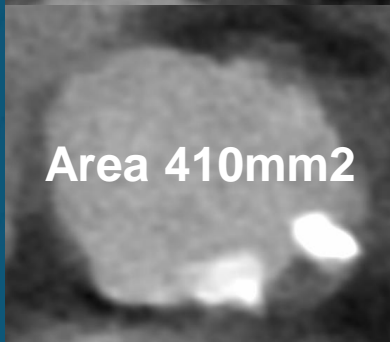
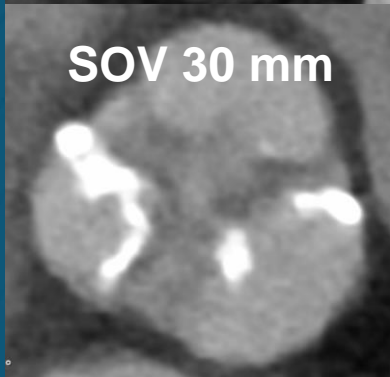
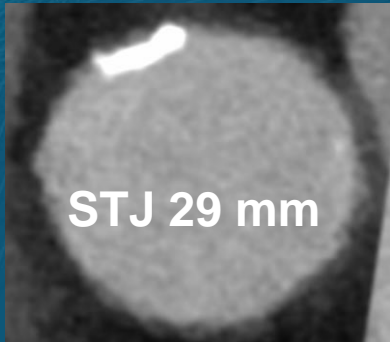
## TTE

- Mean 10 mmHg
- EOA 1.7cm<sup>2</sup>
- No PVL

RCC/NCC type BAV 0 – high risk LM occlusion

# Dealing with hostile annular calcification

# Trileaflet AS; 410mm<sup>2</sup>; Spotty hostile calcium



## TAVI procedure

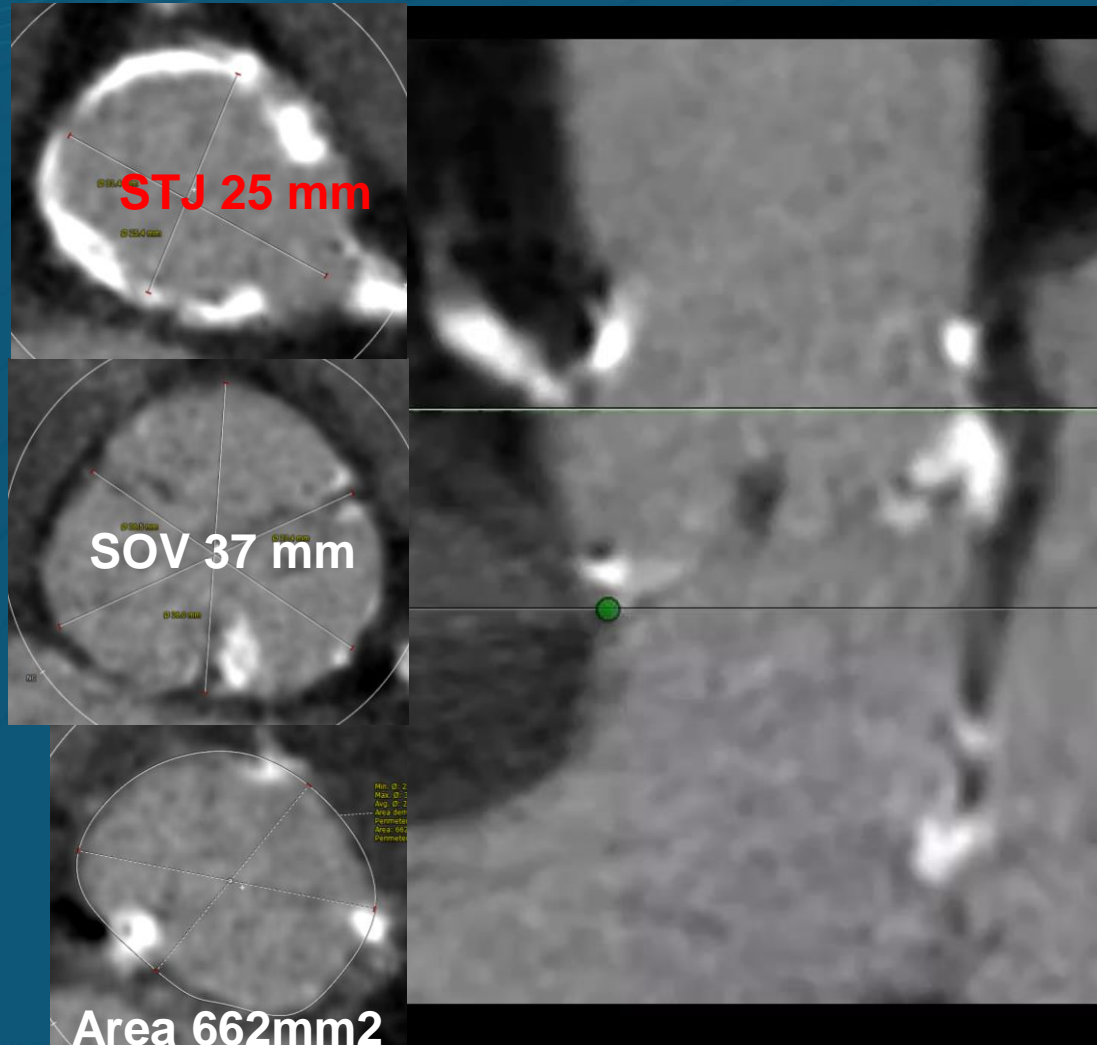
- general anaesthetic
- Direct implant
- 23mm S3U **nominal**
- @ **6 atm**
- Trivial PVL

## TTE

- Mean 8 mmHg
- EOA 1.8 cm<sup>2</sup>
- Trivial PVL

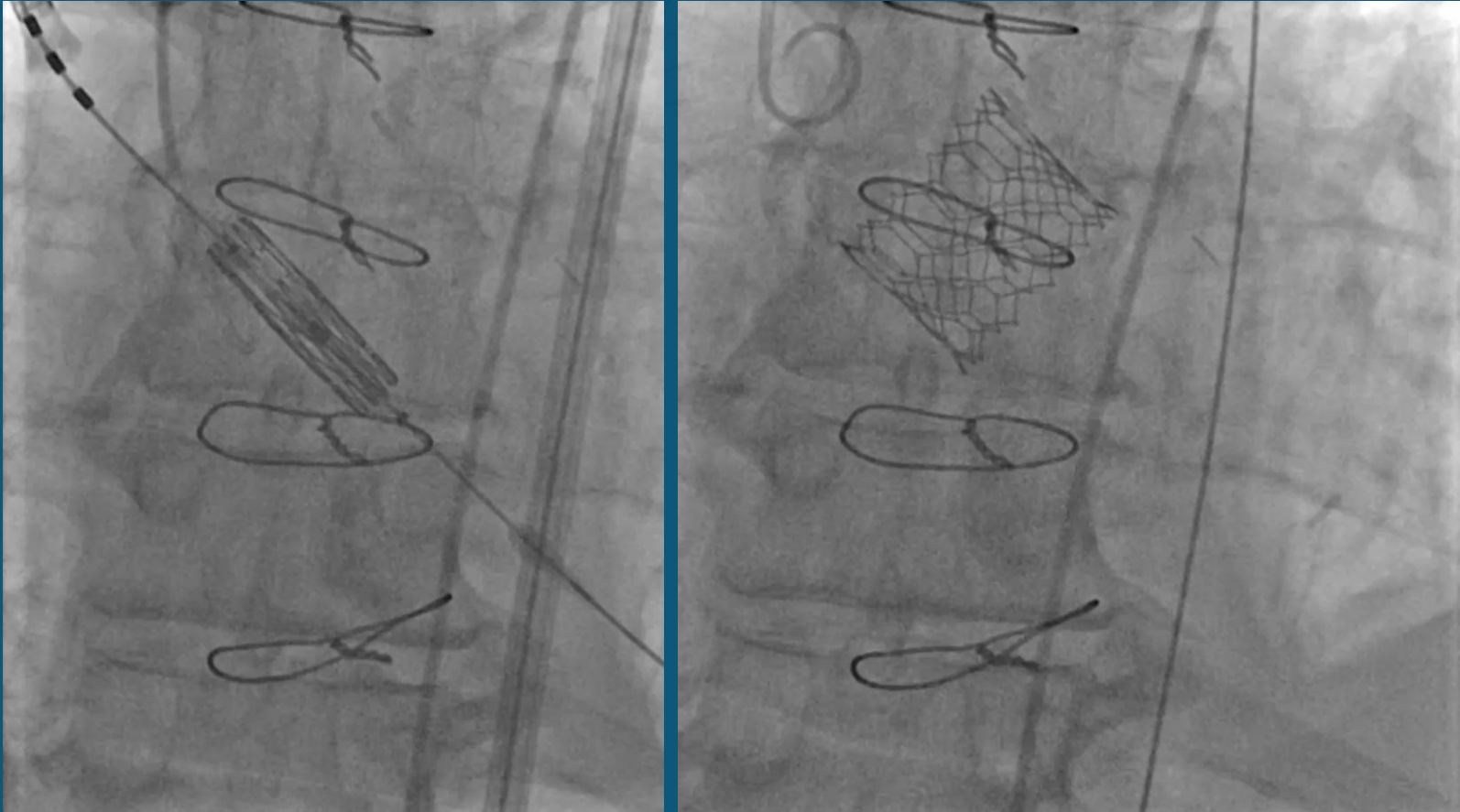
Capitalize on new sealing skirt to mitigate PVL

# Trileaflet AS; 662mm<sup>2</sup>; hostile STJ and annulus





# Trileaflet AS; 662mm<sup>2</sup>; hostile STJ and annulus



## TAVI procedure

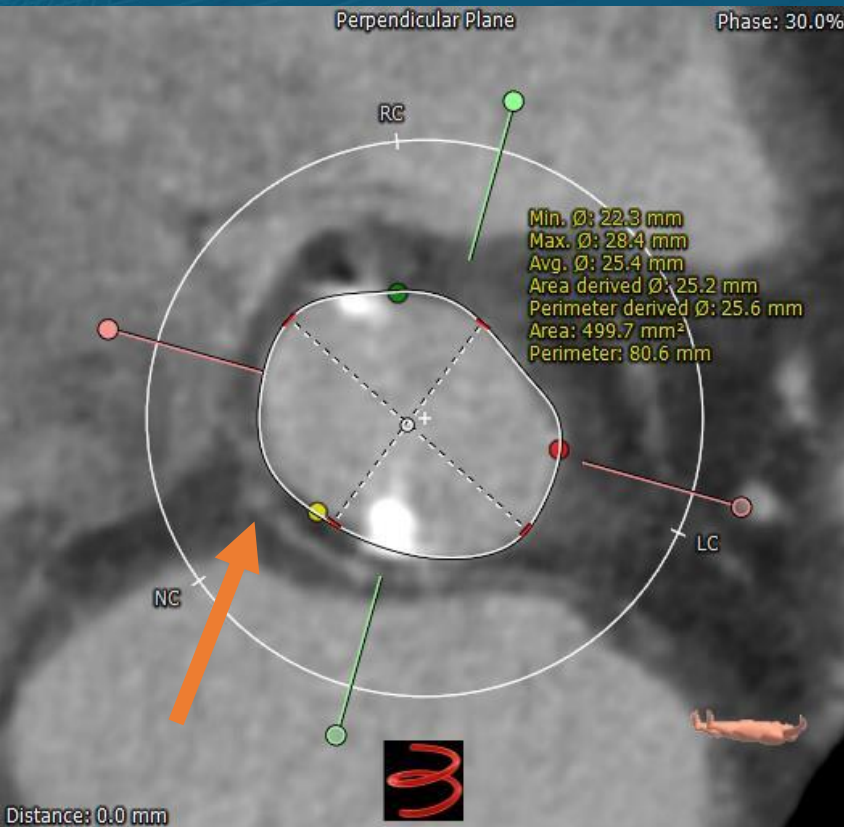
- general anaesthetic
- Direct implant
- 29mm S3 **nominal**
- **Underalignment**
- Trivial PVL

## TTE

- Mean 5 mmHg
- EOA 2.9 cm<sup>2</sup>
- Trivial PVL

**Underalignment of balloon to avoid STJ**

# RCC/LCC Bicuspid AS; 500mm<sup>2</sup>; hostile calcium

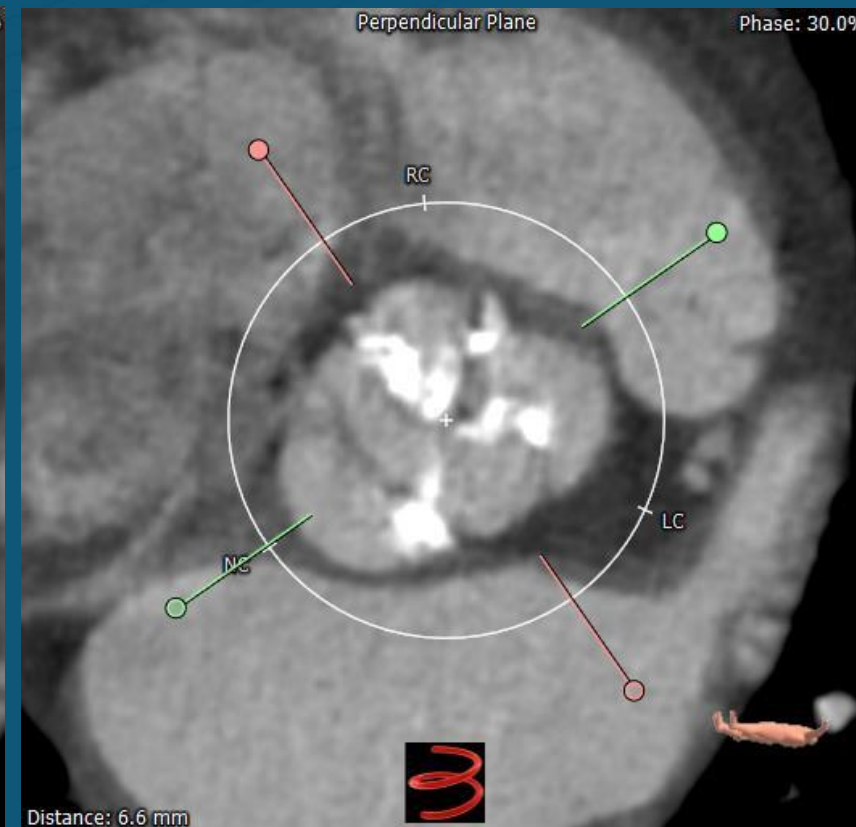


Area 500mm<sup>2</sup>

Perimeter 81mm

Max diameter 28mm

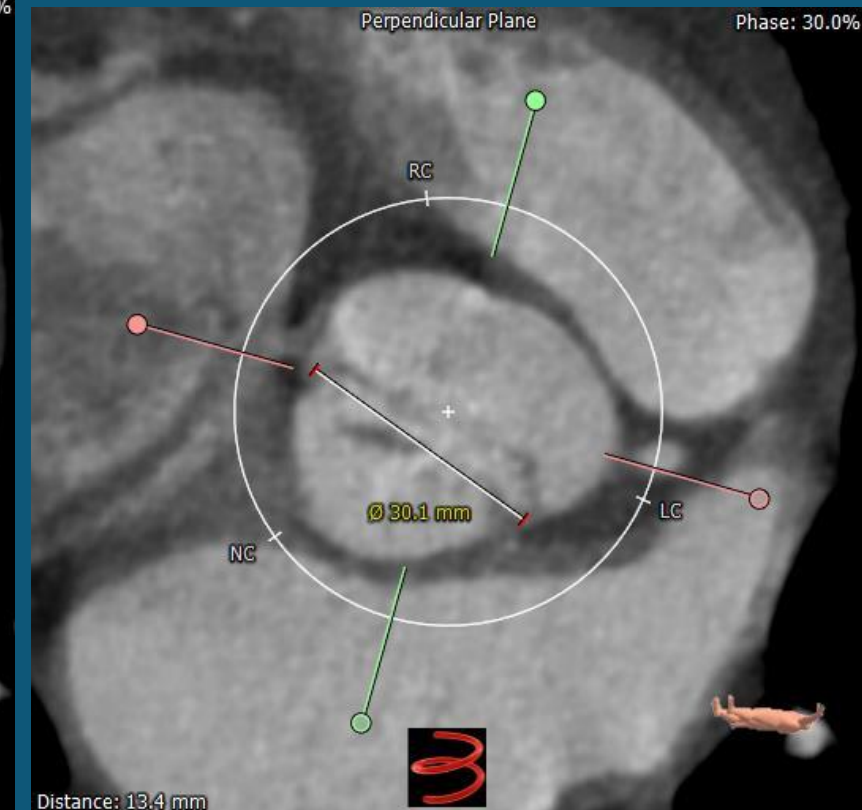
Min diameter 23mm



Calcium Score: 1500

Inter-commissural distance: 30mm

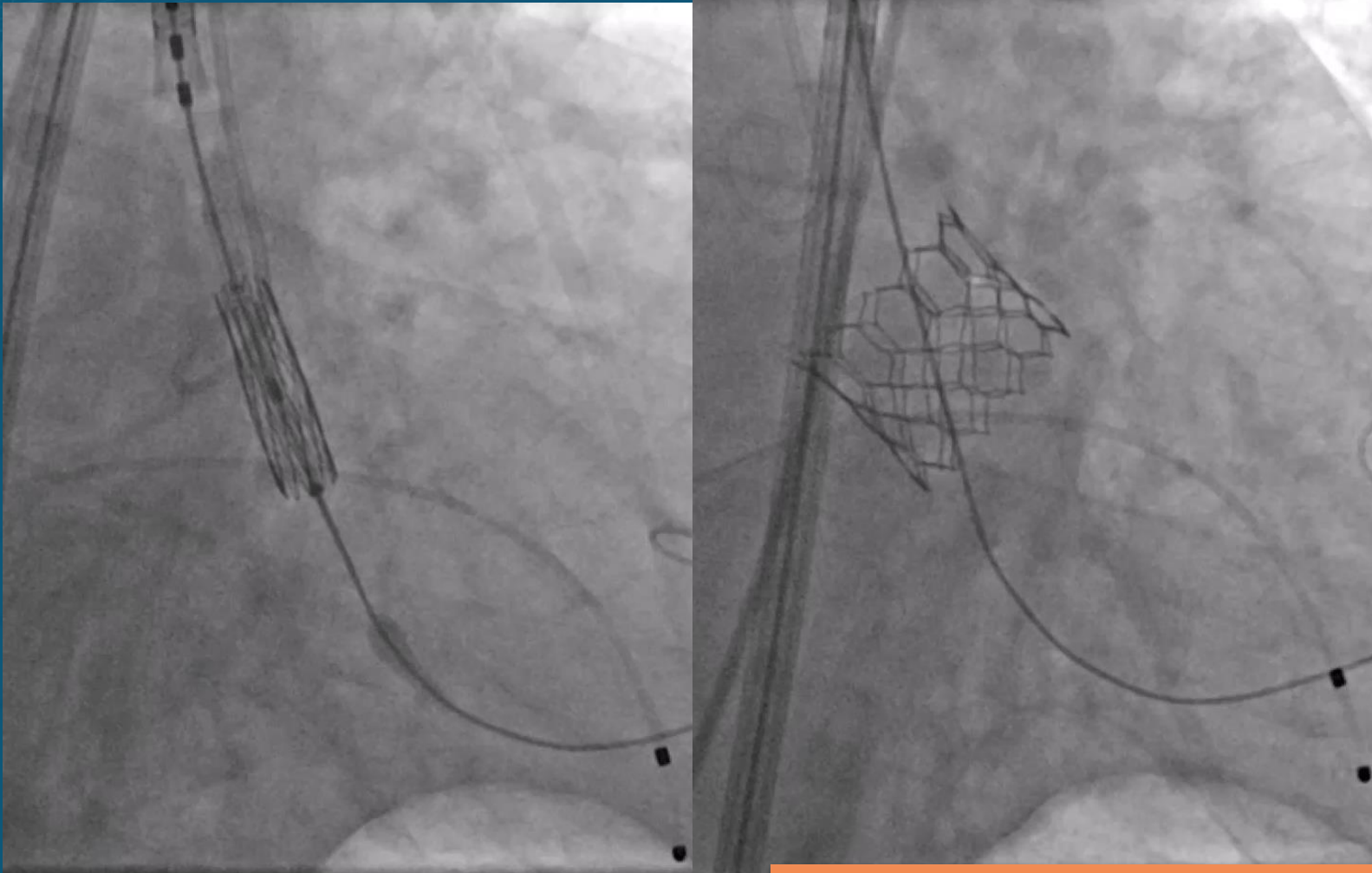
Large posterior calcium at annular level adjacent to **anomalous LCx**



Moderate calcium at raphe

Moderate calcium at leaflets

# Bicuspid AS; 500mm<sup>2</sup>; hostile calcium



## TAVI procedure

- general anaesthetic
- Direct implant
- 2 cusp view
- 26mm S3U nominal
- @ 9atm
- 100:0 placement
- Mild PVL

## TTE

- Mean 7 mmHg
- EOA 2.5 cm<sup>2</sup>
- Mild PVL

**100:0 placement to avoid annular calcium**

# S3ULTRA key tips

1. Absolutely mandatory to have a CT algorithm and CT interpretation expertise
2. Utilize the sealing mesh on S3ULTRA to aim for zero PVL.
3. Less oversizing of THV in relation to annulus (even zero oversizing).
4. NEVER oversize annulus by over 20%; NEVER with a calcified annulus by over 10%.
5. Longer skirt – can place deeper if desirable to preserve coronary access and future TAV-in-TAV possibility.

# S3ULTRA tips

- Further **improvisation** of S3ULTRA implant techniques could be considered (i.e. volume filling of THV and placement of THV).
- Rupture is exceedingly rare with S3 UTLRA now.

