

**Stanford University**  
**Drs. Alan Yeung/William Fearon**  
**SAPIEN 3 Cohort: Intermediate**

# Disclosure Statement of Financial Interest

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

## **Affiliation/Financial Relationship**

- Grant/Research Support
- Grant/Scientific Advisory Board
- Executive Physician Council

## **Company**

- Edwards Lifesciences
- Medtronic
- Boston Scientific Corp



# Stanford TAVR Experience

Sapien	TA	80	306
	TF	193	
	TAO	33	
Sapien - XT	TA	5	49
	TF	42	
	TAO	2	
Sapien 3	TA	3	51
	TF	44	
	TAO	4	
Total		406 TAVR cases	

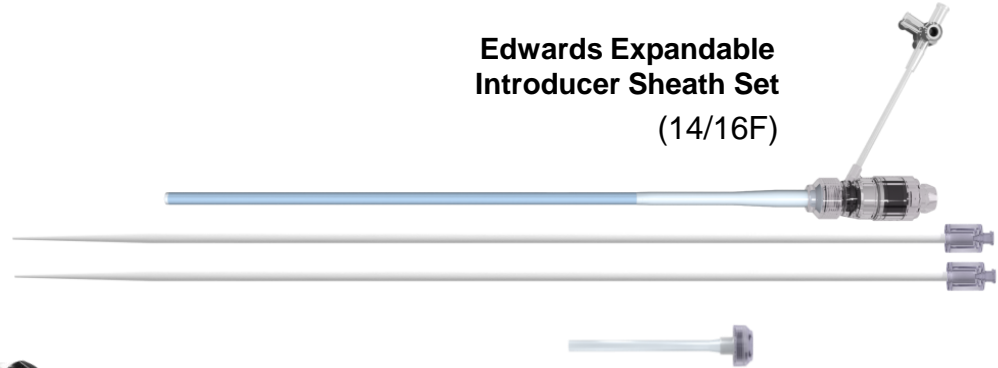


# Edwards SAPIEN 3 Transfemoral System

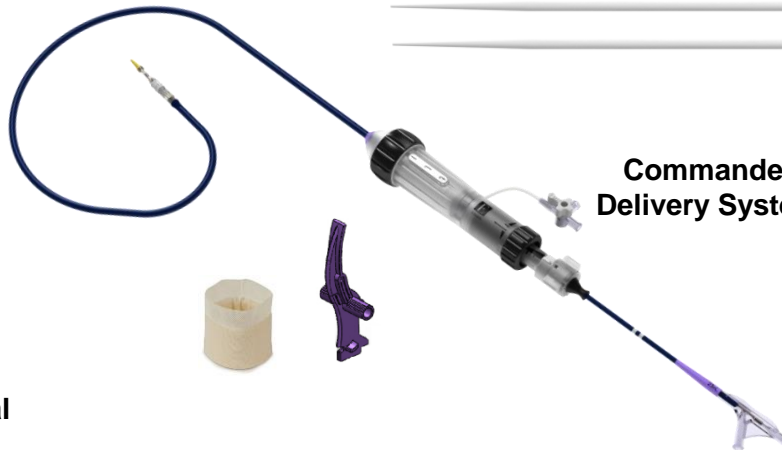
**Edwards SAPIEN 3  
Transcatheter Heart Valve  
(THV)**



**Edwards Expandable  
Introducer Sheath Set  
(14/16F)**



**Commander  
Delivery System**



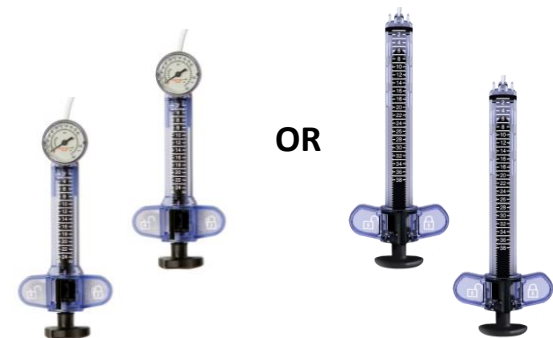
**Edwards Transfemoral  
Balloon Catheter**



**Crimper**



**Atrion Devices**



## Relevant history

- 89 year old male WWII veteran with history of HLD, CVD, CAD, and severe symptomatic aortic stenosis
- History of TIA followed by carotid endarterectomy in 2008
- Currently symptomatic of dizziness with pre-syncopal “near death” experience

## STS score: 4.1%

Age 89, male, Caucasian, 62.1 kg, 167.6 cm (BSA 1.7),  
Cr 1.0, CVD, 3V CAD, NYHA Class II, EF 60%, AS, trace AI,  
MR, trace TR, first op, elective

Site surgeon: Michael Fischbein

### Calculations

Procedure Name	Isolated AVRepl
Risk of Mortality	4.091%
Morbidity or Mortality	21.247%
Long Length of Stay	8.968%
Short Length of Stay	20.717%
Permanent Stroke	2.359%
Prolonged Ventilation	12.531%
DSW Infection	0.207%
Renal Failure	5.737%
Reoperation	9.950%

# Intermediate Risk Profile

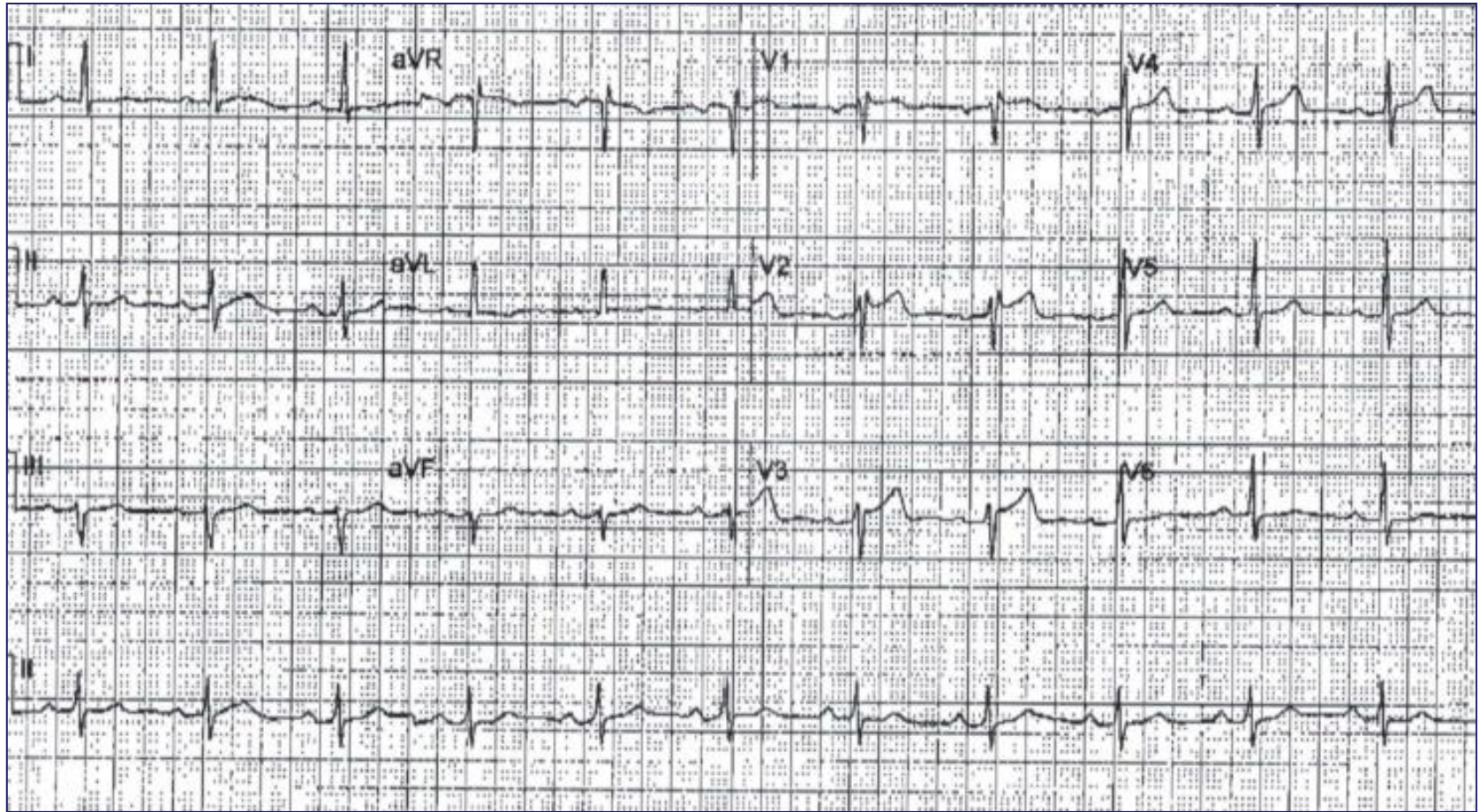
Intermediate risk justification: STS of 4.1%

## Frailty data

Frailty index	Frail?
ADLs	No (6/6)
Grip	Yes (20 kg)
5MWT	Yes 7.5 sec)
Albumin	Yes (3.4 g/dl)
# Met	3

PFTs (July 2014): FEV1 = 2.1 L (92%); DLCO 16 ml (61%)

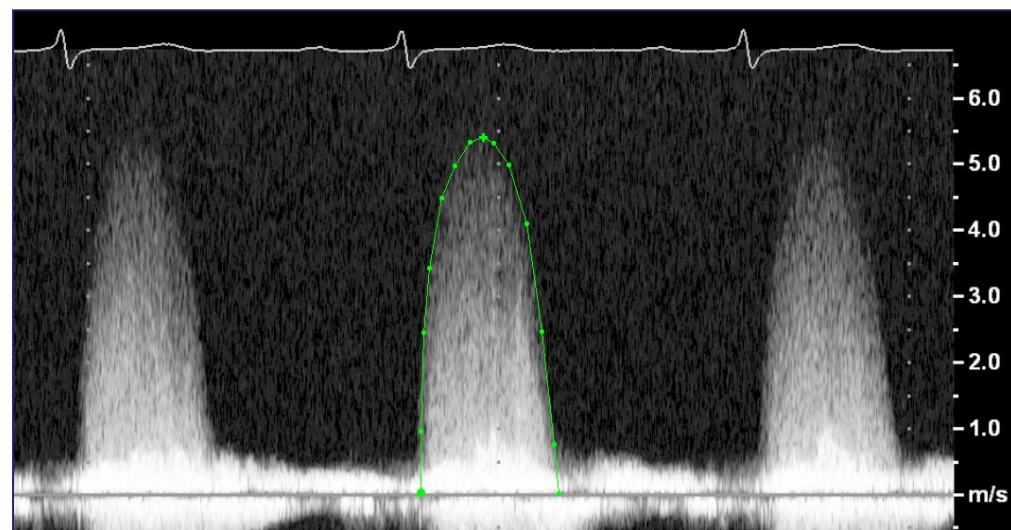
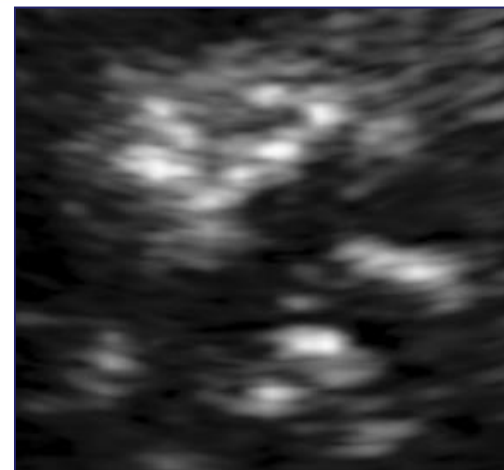
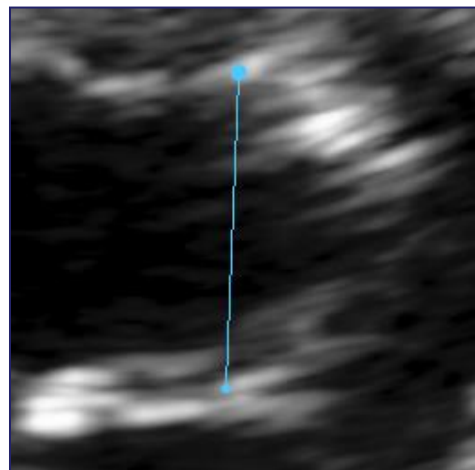
# Conduction History 3/24/14





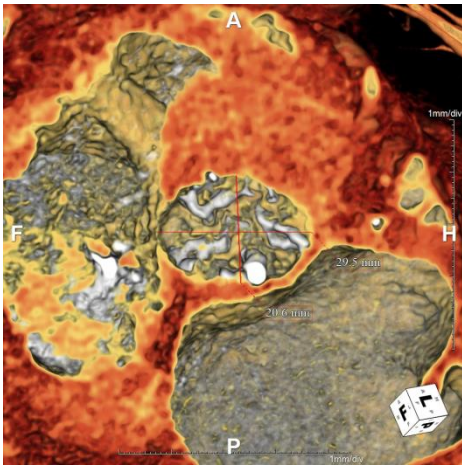
# AS Assessment: 7/15/14

Echo Variable (TTE)	Measure
Trileaflet valve	Yes
Peak Velocity	5.4 m/sec
Mean Gradient	76 mmHg
Calculated AVA	0.41 cm <sup>2</sup>
Calculated AVA index	0.24 cm <sup>2</sup> /m <sup>2</sup>
Severity of AR	Trace
Severity of MR	Trace
Ejection Fraction	60%
TTE/TEE annulus diameter	22
Is echo within window?	Yes
If OOW, date will be repeated	
RV Pressures	NA
Dobutamine	No
Resting EF	
Mcg used	
Peak Velocity	
Mean Gradient	





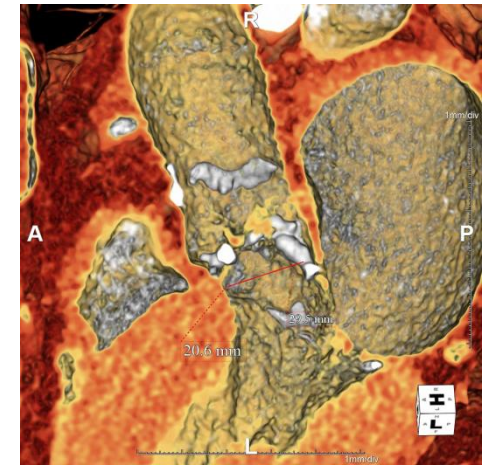
# CT Analysis (Site)



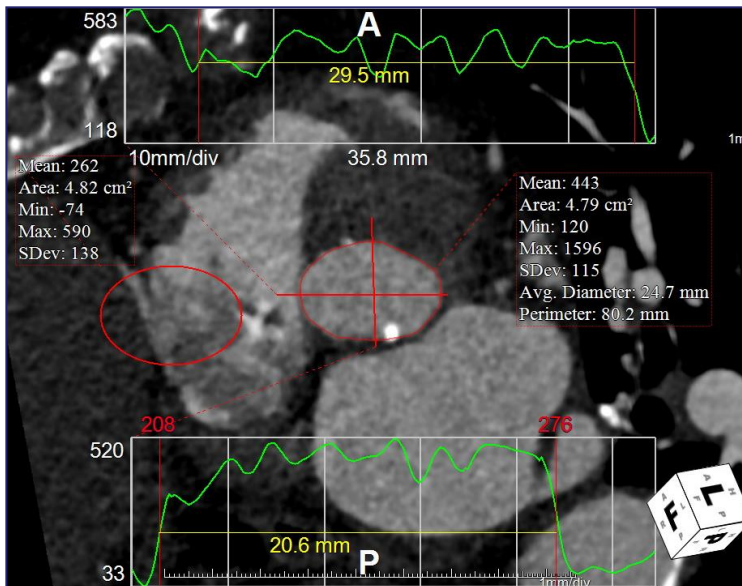
Axial



Coronal



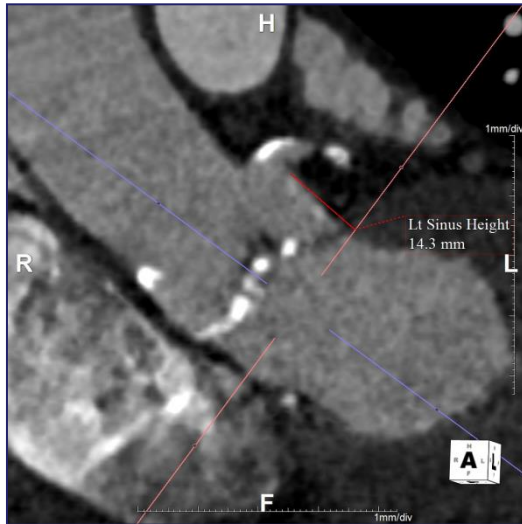
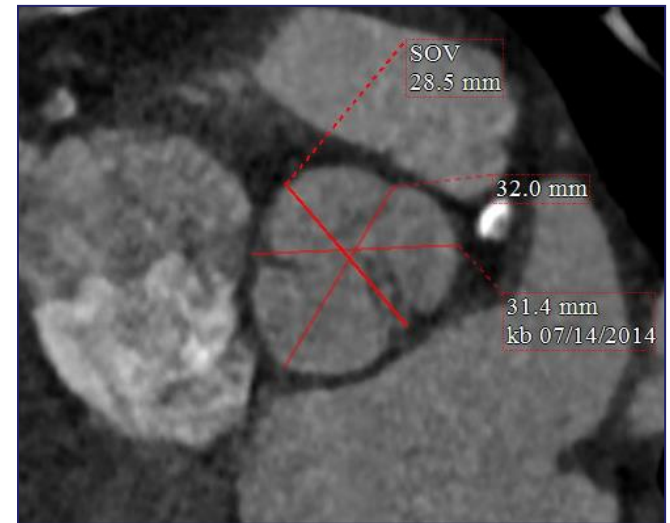
Sagittal



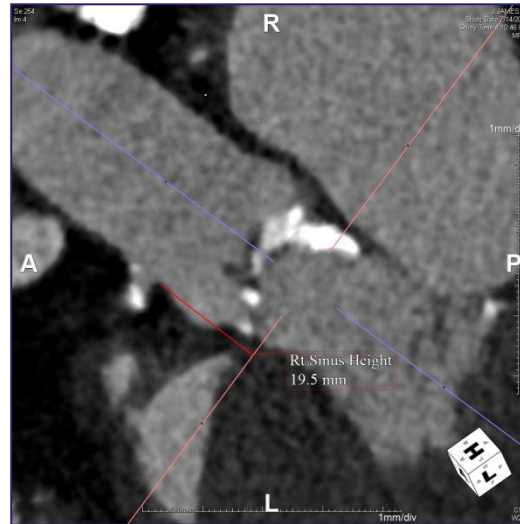
Annulus by CT (7/14/14)	Measure
Short Annulus Diameter	20.6 mm
Long Annulus Diameter	29.5 mm
Annular Perimeter	80.2 mm
Annular Area	479 mm²
% Area Oversizing	8.1%
Planned Valve Size mm	26 mm

# CT Analysis (Site)

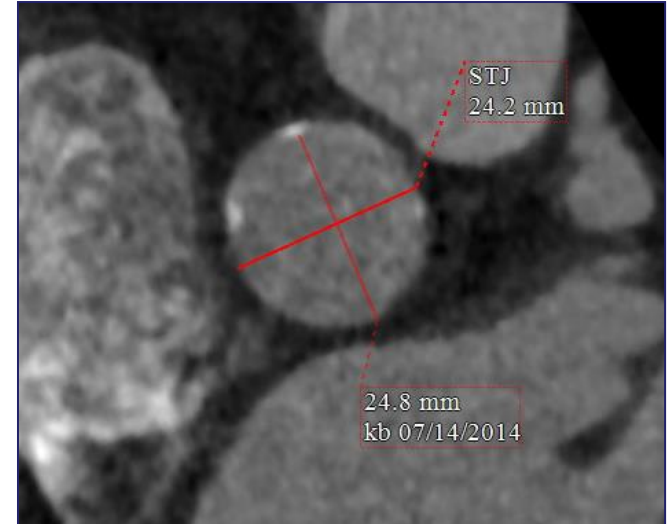
Aortic Root by CT (7/14/14)	Measure
LVOT calcification	none
Sinus of Valsalva Diameter	32.0 x 28.5 mm
Sinotubular Junction Diameter	24.8 x 24.2 mm
Left Coronary Height	14.3 mm
Right Coronary Height	19.5 mm



Left Coronary



Right Coronary



# Coronary Evaluation: 7/21/14

Revascularization Planned	Yes
Same setting as TAVR/Staged - If staged, before/after TAVR	Same setting as TAVR

Syntax score	20
Planned PCI Date	7/29/2014



	% stenosis	Location (prox/mid/distal)	Graft SVG/IMA	% graft stenosis	Revasc (Y/N)
LM	20%	distal			
LAD	40/90%	Prox/mid			
LCx	70%	ostial			
RCA	80%	ostial			

# PCI Plan

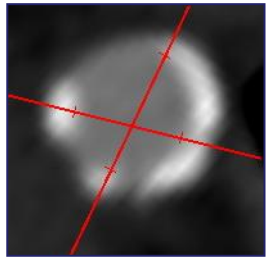
Plan for PCI of focal, ostial RCA lesion and focal, mid LAD lesion.

Proximal LAD is moderate and plan is to treat medically and follow.

Circumflex system is quite small (vessels <2 mm diameter) and disease is unlikely to cause issues at time of TAVR.



# Access: CT 7/14/14



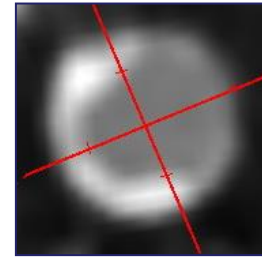
RCIA



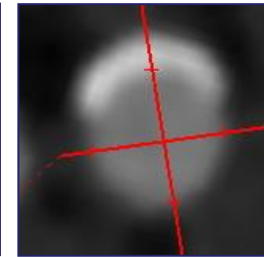
REIA



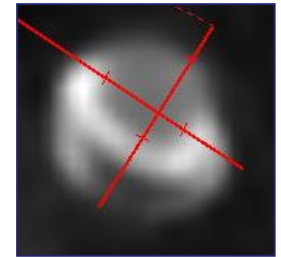
RCFA



LCIA



LEIA



LCFA

	Min Diameter	Max Diameter	Significant Calcium (Y/N)	Significant Tortuosity (Y/N)
RCIA	6.8	7.8	No	No
REIA	8.1	8.2		
RCFA	6.8	7.9		
LCIA	5.9	8.1		
LEIA	6.8	6.9		
LCFA	5.0	5.0		



# Summary – JMJ

STS: 4.1%

SAPIEN 3 Cohort: Intermediate

Key Risk Contributors: Age

Access: Transfemoral, Right side

Echocardiography:

- Peak Velocity: 5.4 m/sec
- Mean Gradient: 76 mmHg
- AVA: 0.41 cm<sup>2</sup>
- AVA index: 0.24 cm<sup>2</sup>/m<sup>2</sup>

Planned Valve Size: 26 mm

Date Procedure Planned: July 29, 2014

CT Annular Measurements (Site):

- Area: 479 mm<sup>2</sup>
- Diameters: 29.5 x 20.6 mm
- % Oversizing: 8.1%
- Valve Size: 26 mm

CT Annular Measurements (Core Lab):

- Area: 482 mm<sup>2</sup>
- Diameters: 28.0 x 22.2 mm
- % Oversizing: 8.1%
- Valve Size: 26 mm