Durability of THV and Management of Failed THV

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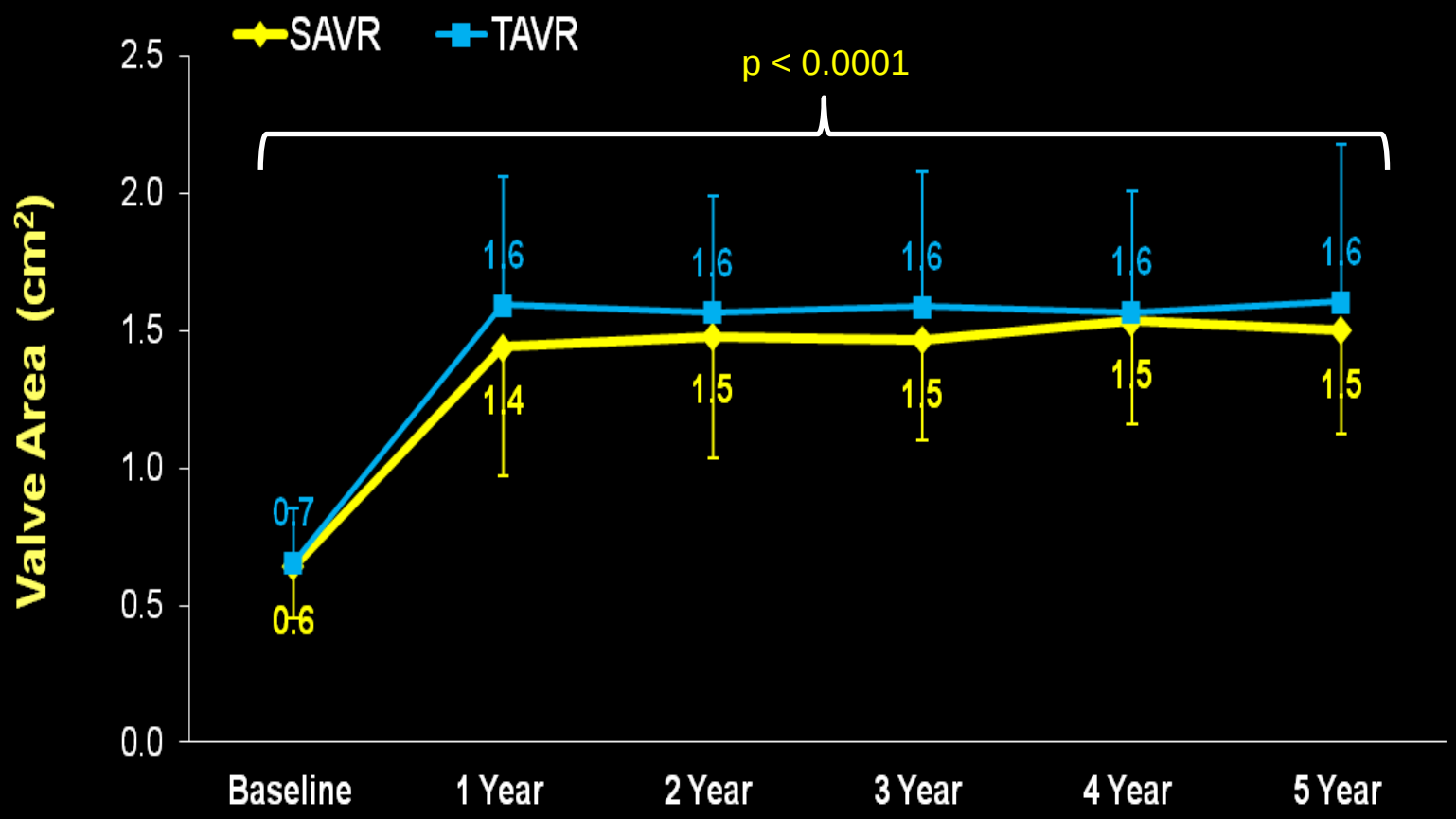
St. Paul's Hospital, Vancouver

Consultant:

- Abbott
- Edwards Lifesciences
- Gore
- Medtronic
- Mitralign
- Orford
- St Jude Medical
- Transverse Medical
- Siemens
- Valtech
- Vivitro

Durability at 5 years:
similar for transcatheter and surgical surgical valves



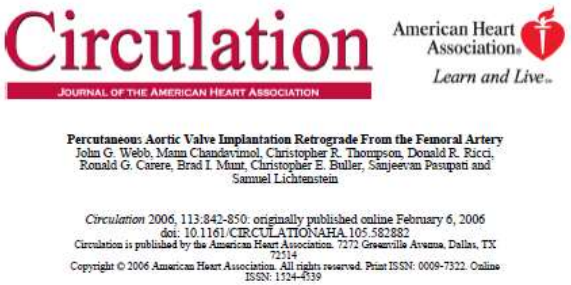
The NEW ENGLAND JOURNAL of MEDICINE

PARTNER 1A

Background

- Transcatheter heart valve (THV) durability has only been documented up to 3-5 years

- We aimed to evaluate the long-term durability of TAVI from the Vancouver first-in-human transarterial and transapical experience


Circulation
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Percutaneous Aortic Valve Implantation Retrograde From the Femoral Artery

John G. Webb, Manu Chandavimol, Christopher R. Thompson, Donald R. Ricci, Ronald G. Carere, Brad I. Munt, Christopher E. Buller, Sanjeevan Pasupati and Samuel Lichtenstein

Circulation 2006, 113:842-850: originally published online February 6, 2006
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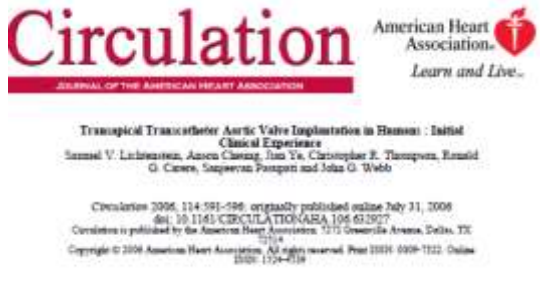
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Transapical Transcatheter Aortic Valve Implantation in Humans : Initial Clinical Experience

Samuel V. Lichtenstein, Anson Cheung, Jian Ye, Christopher R. Thompson, Ronald G. Carere, Sanjeevan Pasupati and John G. Webb

Circulation 2006, 114:591-596: originally published online July 31, 2006
doi: 10.1161/CIRCULATIONAHA.106.632927
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Methods

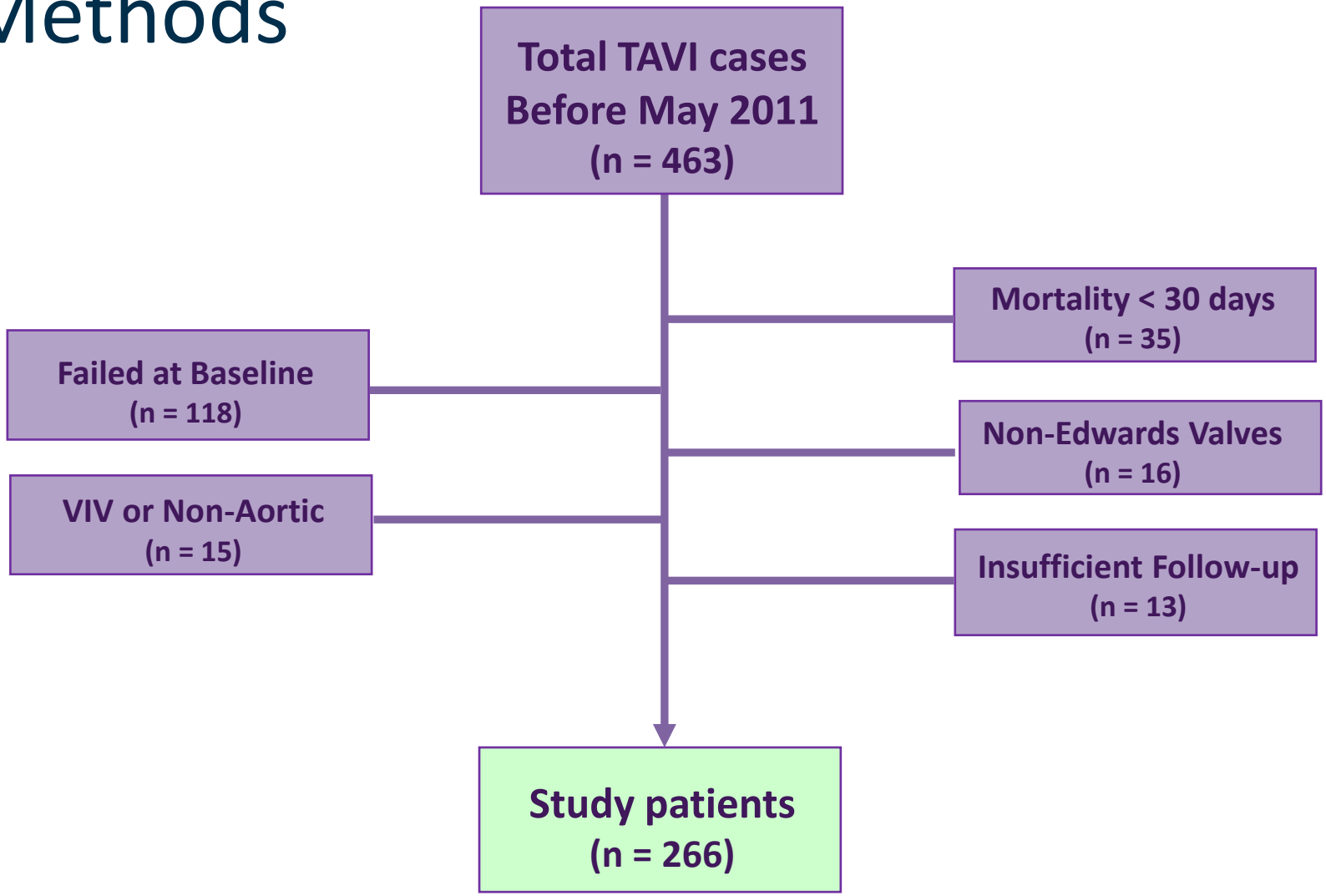
- **Inclusion Criteria:**
  - Patients that underwent TAVI **more than 5 years** ago
  - January 2005 - May 2011, **range 5-11 years**
  - St. Paul's Hospital, **Vancouver**, Canada
  - **Balloon-expandable** transcatheter heart valves

- **Exclusion criteria:**
  - More than one THV implanted in the aortic position
  - THV used to treat a failed surgical valve (valve-in-valve)
  - Device failure ≤ 30 days after TAVI (≥ moderate stenosis OR regurgitation)
  - Patient mortality within ≤ 30 days after TAVI
  - Infective endocarditis in the aortic position after TAVI
  - Non balloon-expandable THV devices
  - Insufficient echocardiographic follow-up (≤ 90 days after TAVI)

Methods

- Patients were followed in a database initiated in 2005
- Echocardiographic exams were adjudicated by an experienced echocardiographer
- Long-term echocardiographic exams performed during house visits
- Informed consents were obtained for photographs

Methods



Survival time- median 35 months (IQR 12-66months).

Patient characteristics at TAVI (n=266)

Baseline characteristics	
Age (years)	82.6 ± 7.7
Gender (female)	50.8%
Diabetes mellitus	27.8%
Peripheral vasc disease	32.1%
Renal failure (GFR<60cc/min)	30.1%
Previous MI	41.7%
Chronic AF	41.1%
Previous Stroke	17.3%
Chronic lung disease	26.7%
Coronary artery disease	77.7%
Previous bypass surgery	32.8%

Calculated risk scores	
EuroScore II	4.4 ± 4.1
STS PROM (%)	8.9 ± 5.2

Echo parameters	
Aortic area (cm^2)	0.65 ± 0.18
Aortic mean gradient (mmHg)	42.2 ± 16.2
LVEF (%)	55 ± 13.6
Aortic regurgitation	
None/Mild	70.3%
Moderate	26.3%
Moderately Severe	2.7%
Severe	0.8%

Procedural characteristics and early outcomes (n=266)

Procedural characteristics	
Transcatheter heart valve	
Cribier-Edwards (28)	**10.5%**
Edwards SAPIEN (142)	**53.4%**
SAPIEN XT (96)	**36.1%**
Device diameter (mm)	**25.2 ± 1.5**
Access	
Transfemoral	**62.4%**
Transapical	**37.6%**

30-day outcomes (VARC II)	
Major Vascular Complication	**7.9%**
Major / Life-threatening bleed	**10.9%**
Major stroke	**1.5%**
Need for pacemaker	**9%**
Warfarin at discharge	**35.6%**
Aortic valve area (cm2)	**1.54 ± 0.37**
Aortic mean gradient (mmHg)	**10.3 ± 3.6**
LVEF (%)	**57 ± 12.4**
Valvular AR >mild	**0%**

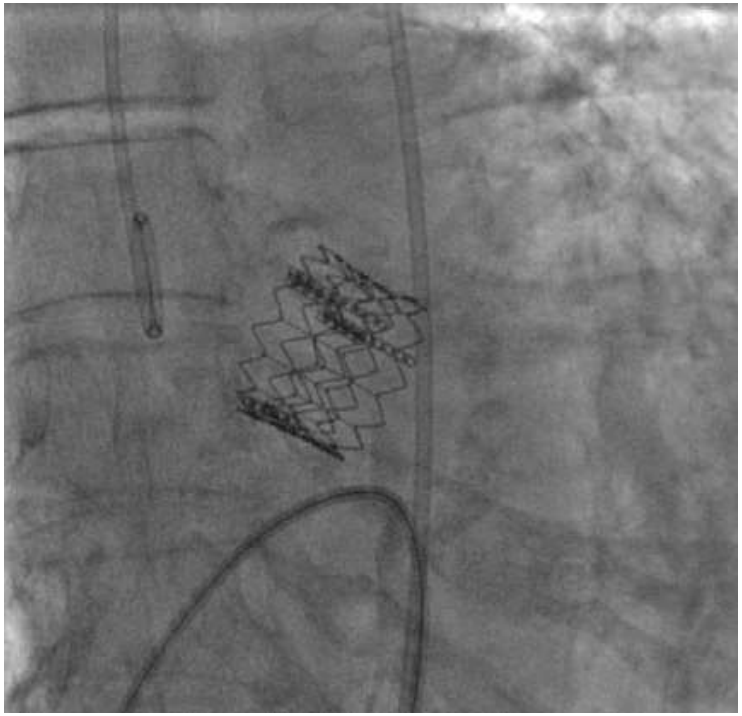
Structural Valve Degeneration (5 of 266 cases)

SVD definition	# of cases	% of cases
Severe Stenosis and/or Regurgitation[1,]	5	1.9%
Re-intervention (SAVR or TAVR) [3]	3	1.1%
Severe AS, severe AR, or Re-intervention	5	1.9%

1. predominantly: stenosis in 3, regurgitation in
2. EOA <0.8cm^2 or indexed EOA <-0.5cm^{2}A<0.5cm2/
3. SAVR in 3 patients, 2 of whom died peri-operatively

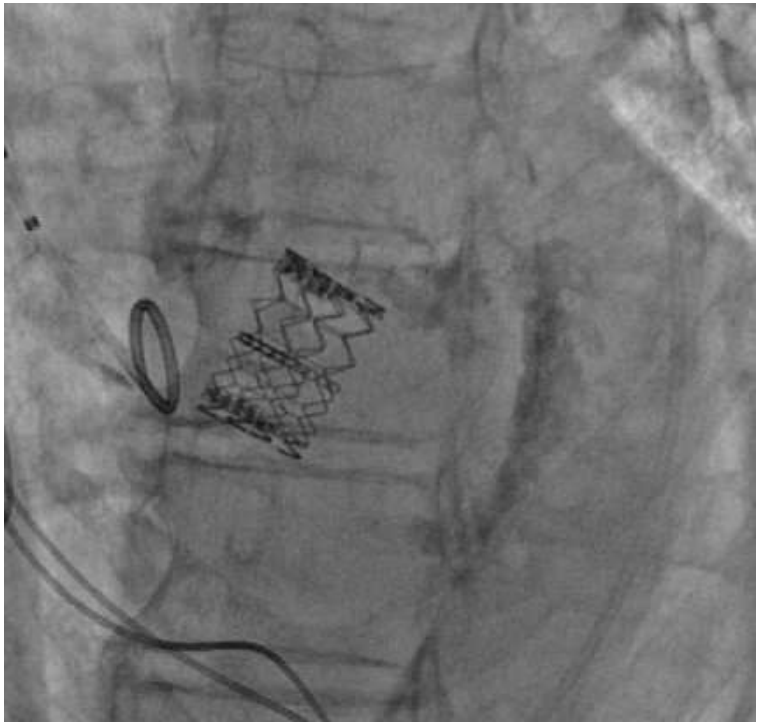
Case 1 of 5

2006: age 88 female



TF Cribier-Edwards, 23mm

2013: age 95, 7 year follow-up



Severe stenosis, moderate AR

Case 1

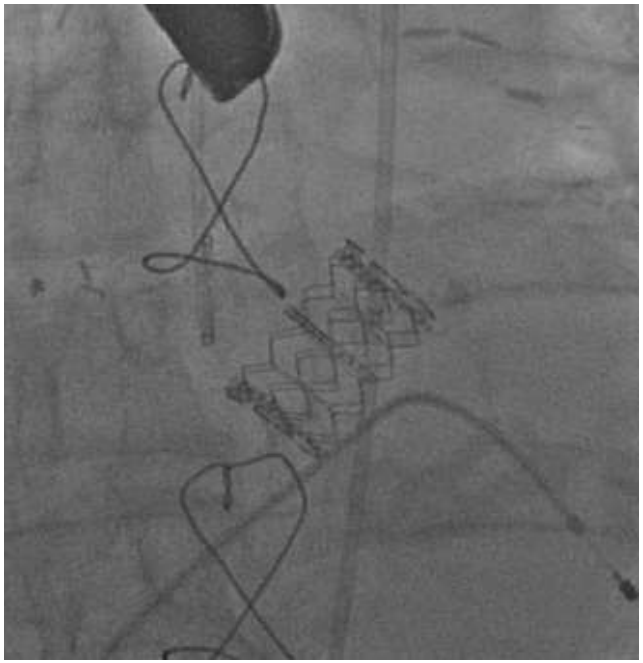
Death due to CHF, age 95, 7 years after TAVI

Outflow

Inflow

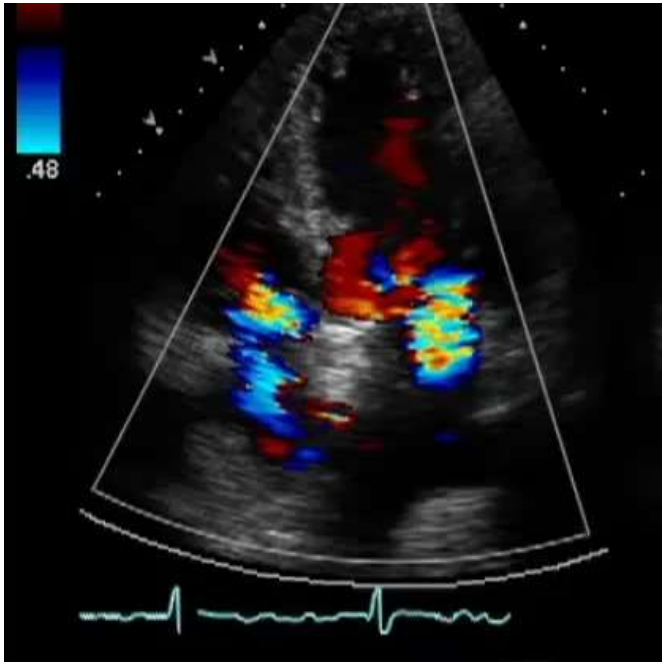
Case 2 of 5

2006: age 81, male



Edwards SAPIEN, 26mm, TF

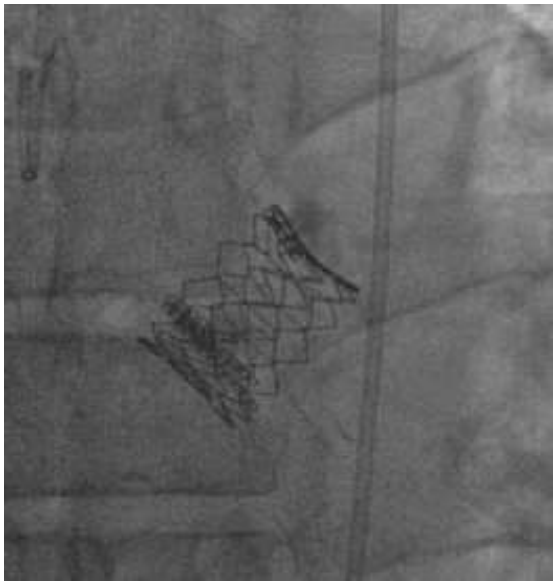
2012: age 87,palliation, death due to CHF



Severe AR, Moderate AS

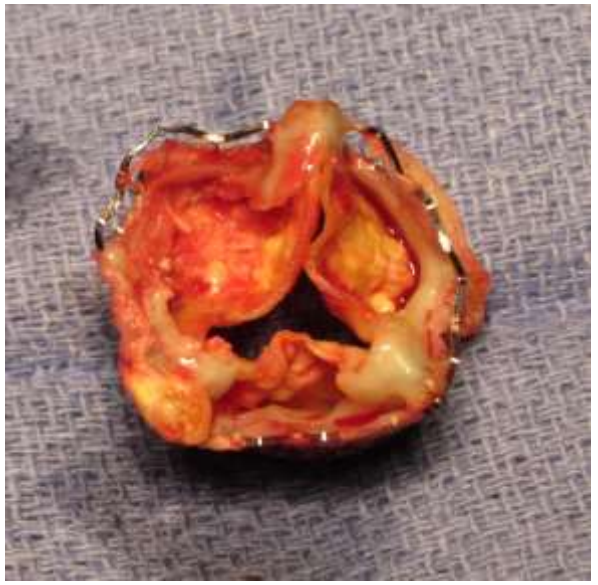
Case 3 of 5

2007: age 50, male,
severe liver cirrhosis



Edwards SAPIEN, 26mm, TF

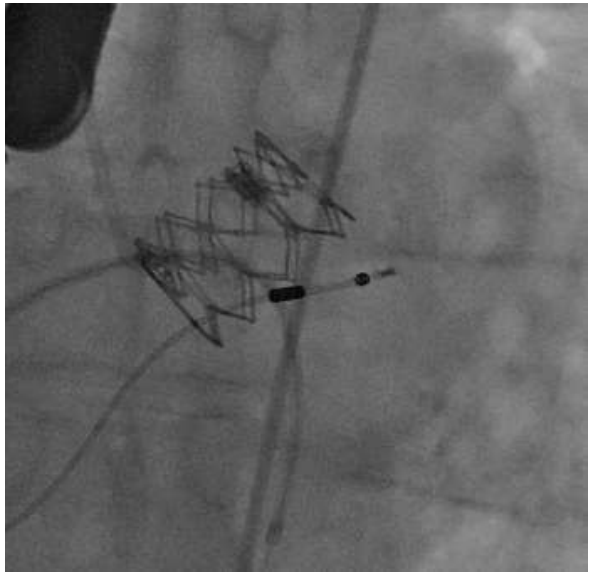
2011: 4 years later, severe stenosis,
cirrhosis improved



Surgical AVR, did well

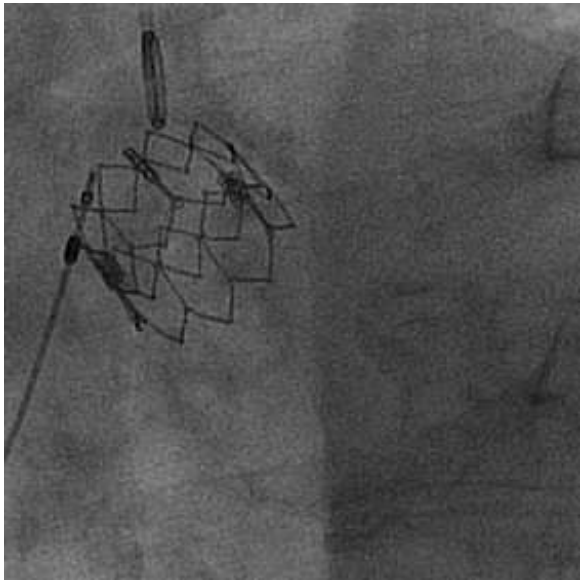
Case 4 of 5

2010: Age 53, female, morbidly obese



SAPIEN XT, 23mm, TF

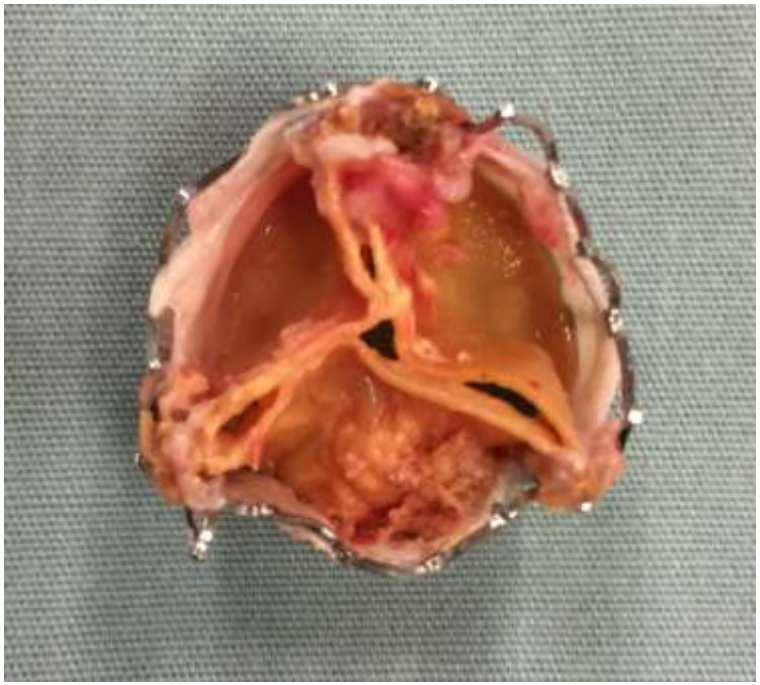
2014: 4 years later, severe AR and AS



Surgical AVR resulted in death

Case 4

Reintervention: surgical AVR complicated due to obesity. Died of operative complications.



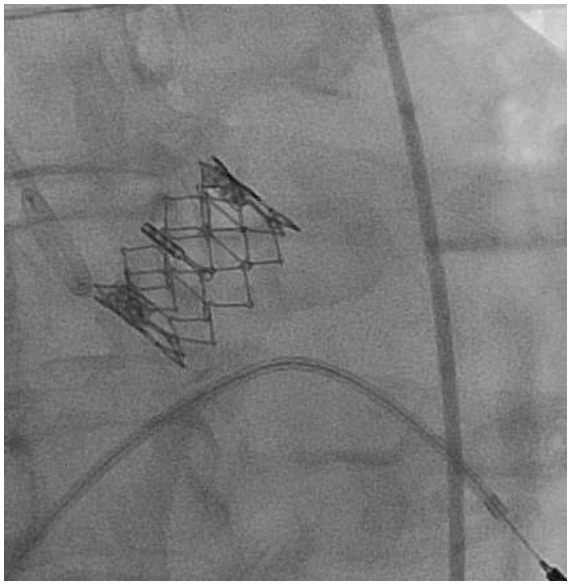
Outflow

Inflow

Asymmetric degeneration

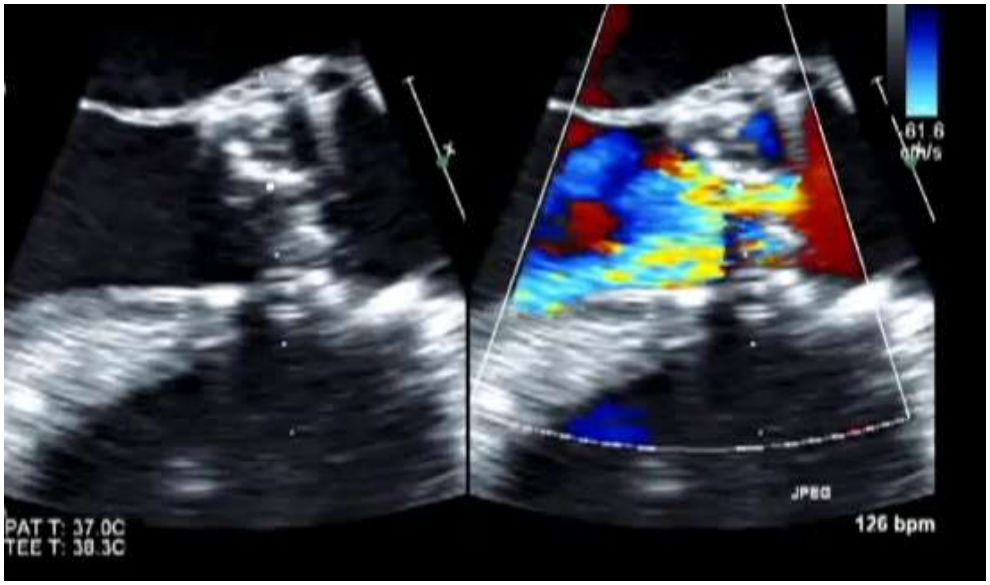
Case 5 of 5

2011: 69, female, obese, Jehovah's Witness



SAPIEN XT, 23mm, TF

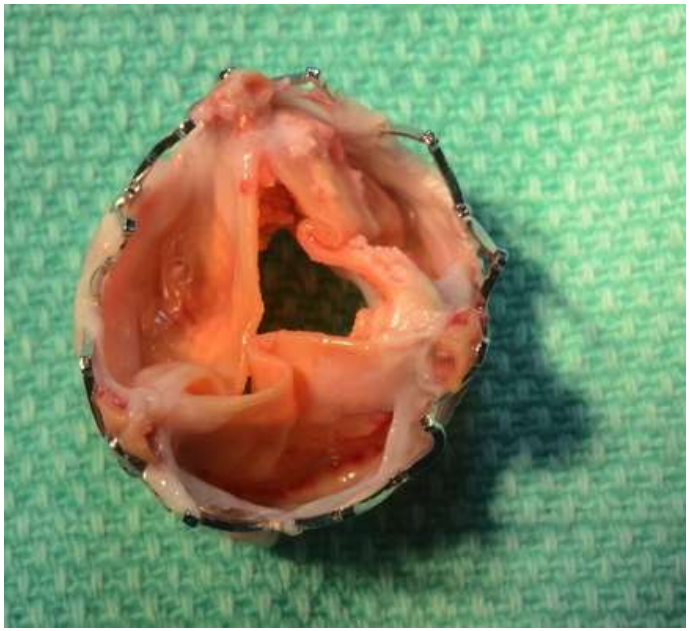
3 years later



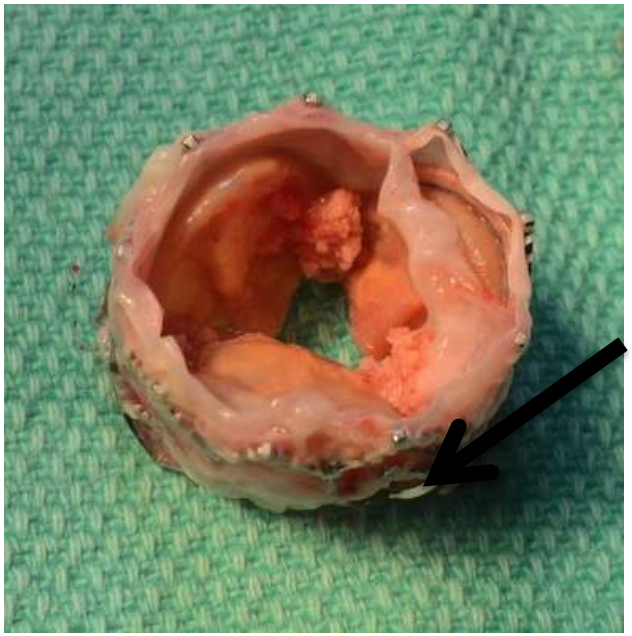
Severe AR/S

Case 5: M.D.

Reintervention: Surgical AVR complicated due to obesity and bleeding. Died of operative complications.



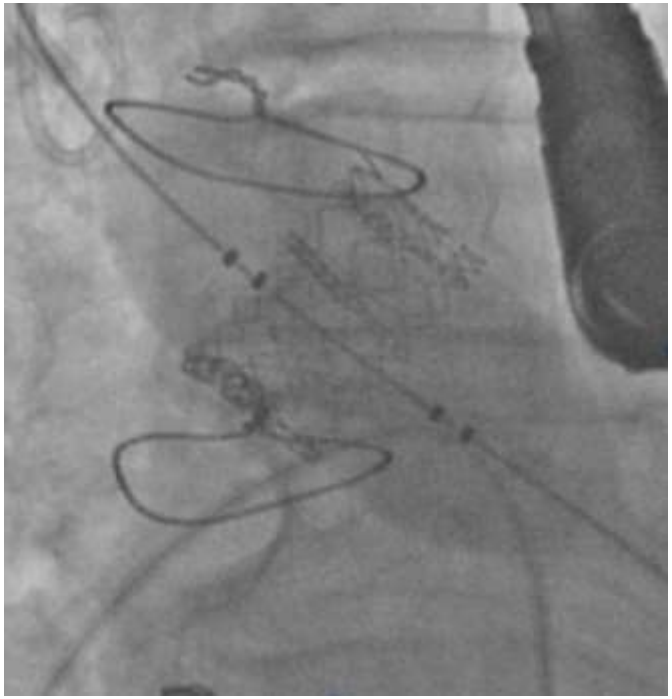
Outflow



Inflow

However, structural valve degeneration was rare (5 of 266)

Example of a non-degenerated THV at 7 years

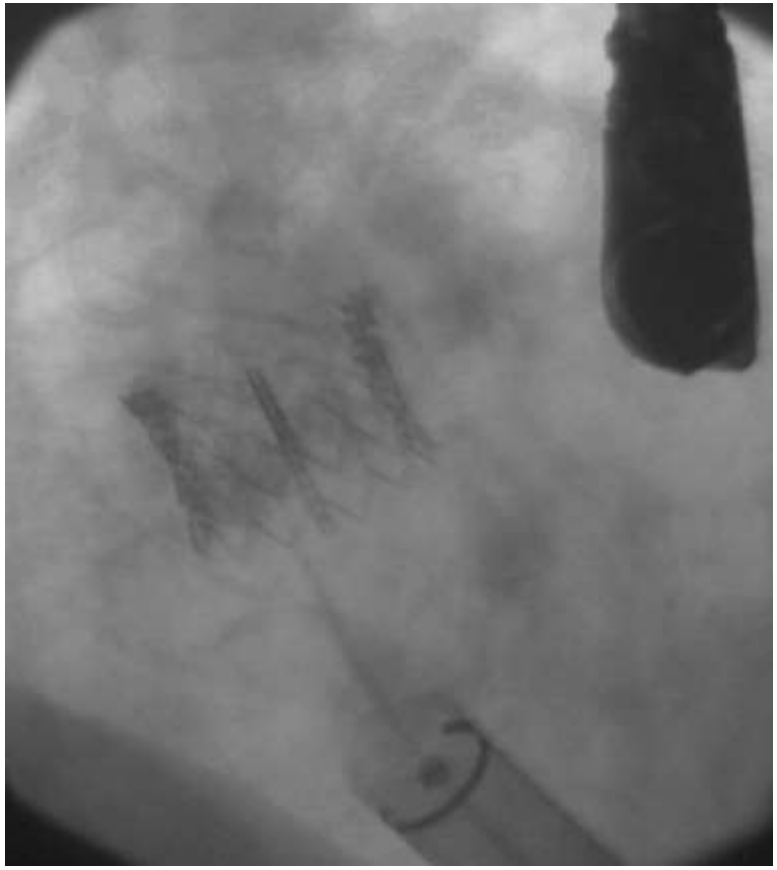


2006: TF Edwards SAPIEN 26mm

2013: Age 89, non-cardiac death
Minimal deterioration
Normal leaflet thickness

Ten years after TAVI: example 1

2006: age 87

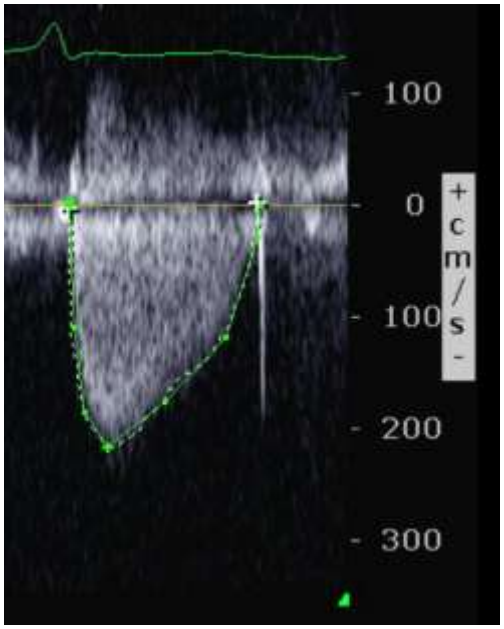


TA Cribier-Edwards, 23mm

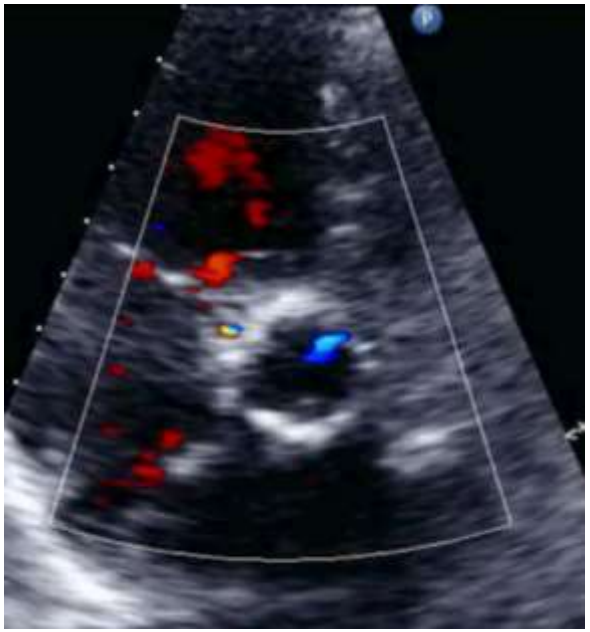
2016: age 97

Well

Ten years after TAVI: example 1



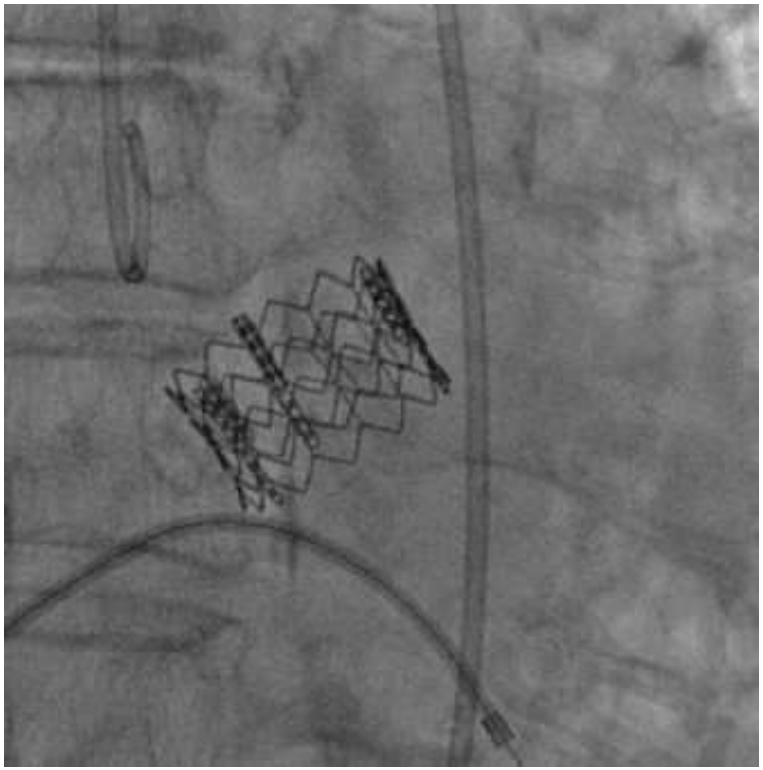
Mean gradient
11 mmHg



Mild AR

Ten years after TAVI: example 2

2006: age 86



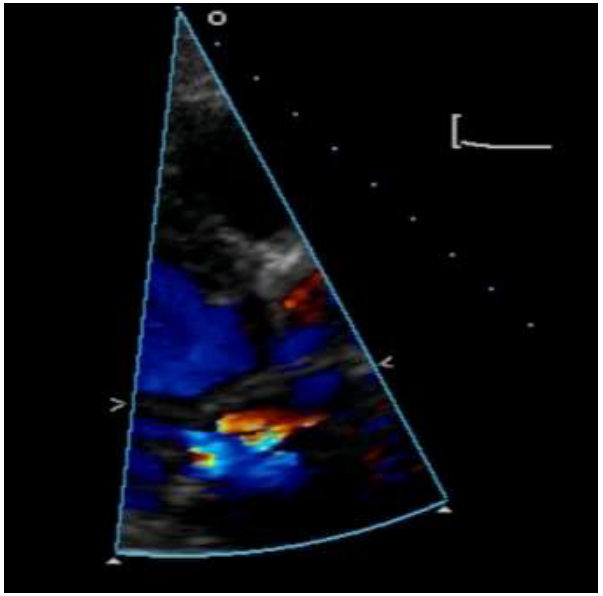
TF Cribier-Edwards, 23mm

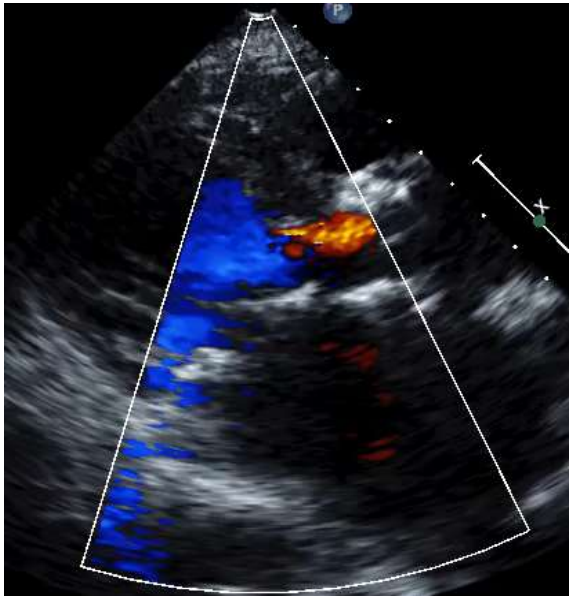
2016: age 96

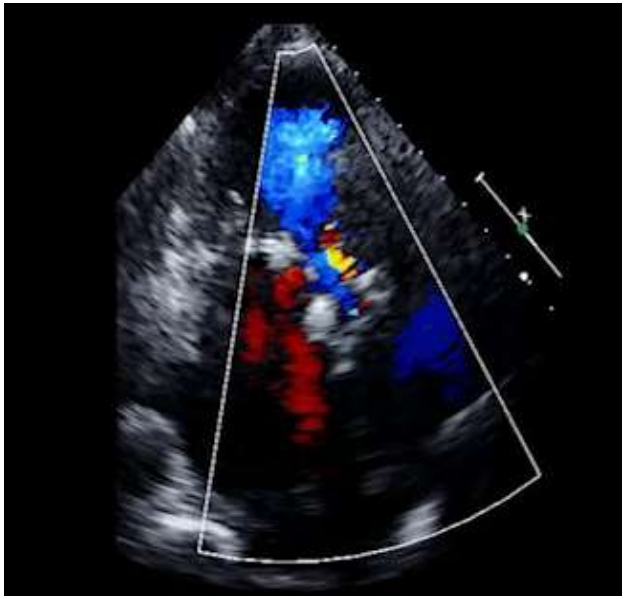
Well

Ten years after TAVI: example 2

1 year post TAVI **6 years** **10 years**







Trivial AR

Mild AR

Moderate AR
MG 13mmHg
LVEF 50%

Very late outcomes for mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 25-year follow-up of 450 implantations

Thierry Bourguignon, MD,[a] Anne-Lorraine Bouquiaux-Stablo, MD,[a] Claudia Loardi, MD,[a] Alain Mirza, MD,[a] Pascal Candolfi, PhD,[b] Michel Marchand, MD,[a] and Michel R. Aupart, MD[a]

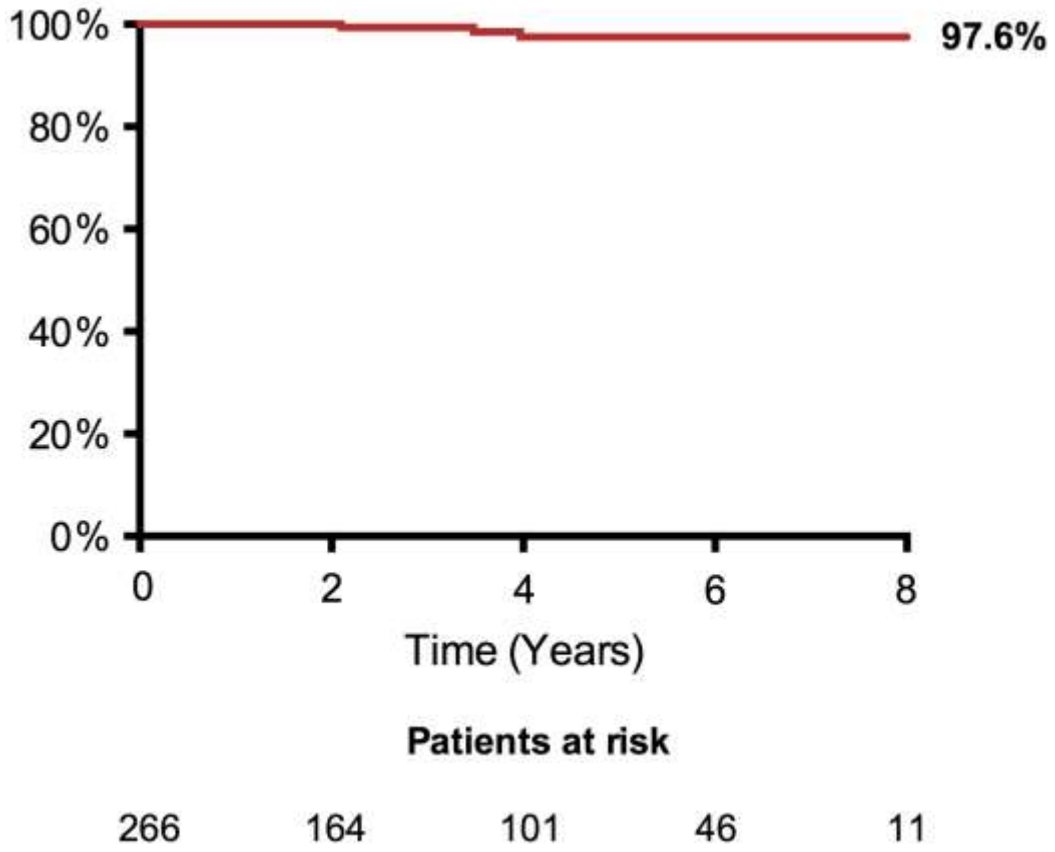
Objective: The aim of the present study was to evaluate the very-long-term results of the Carpentier-Edwards pericardial bioprosthesis in the mitral position.

Methods: From 1984 to 2011, 450 Carpentier-Edwards PERIMOUNT pericardial mitral bioprostheses were implanted in 404 consecutive patients (mean age, 68 years; 53% female). Patients undergoing multiple valve replacements were excluded. The clinical, operative, and follow-up data were prospectively recorded. The mean follow-up was 7.2 ± 5.1 years, for a total of 3258 valve-years. The follow-up data were 97.8% complete.

Results: The operative mortality rate was 3.3%. A total of 188 late deaths occurred, for a linearized rate of 5.8%/valve-year. At 20 years, the overall actuarial survival rate was 16.9% ± 3.9%. Age at implantation, preoperative New York Heart Association class III or IV, and redo procedure were significant risk factors affecting late survival. The actuarial freedom from complications at 20 years was thromboembolism, 83.9% ± 7.6%; hemorrhage, 80.2% ± 10.8%; endocarditis, 94.8% ± 1.4%; structural valve deterioration, 23.7% ± 6.9%; and explantation owing to structural valve deterioration, 40.5% ± 8.0%. The competing risk analysis demonstrated an actual risk of explantation owing to structural valve deterioration at 20 years of 25.5% ± 2.9%. The expected valve durability was 16.6 years for the entire cohort (11.4, 16.6, and 19.4 years for patients aged <60, 60 to 70, and >70 years, respectively).

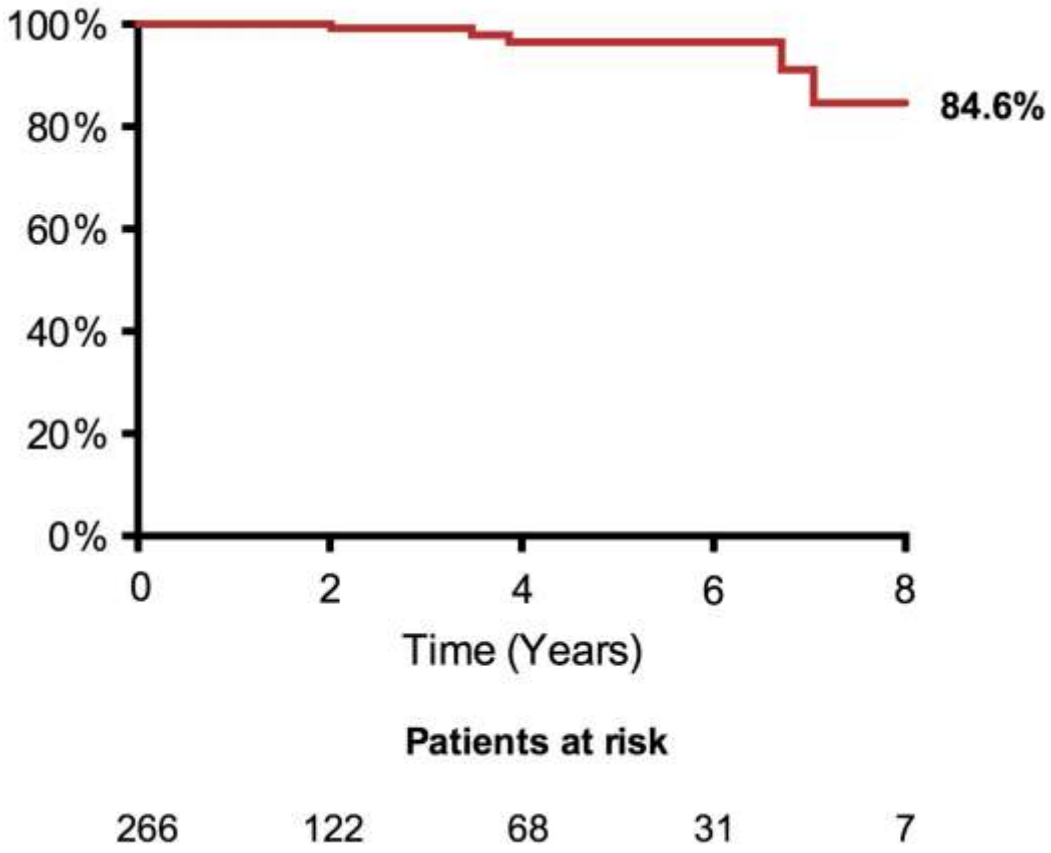
Conclusions: With a low rate of valve-related events at 20 years and, in particular, a low rate of structural valve deterioration, the Carpentier-Edwards PERIMOUNT pericardial bioprosthesis remains a reliable choice for a mitral tissue valve, especially in patients >60 years old. (J Thorac Cardiovasc Surg 2014;■:1-8)

Vancouver Freedom from Re-intervention



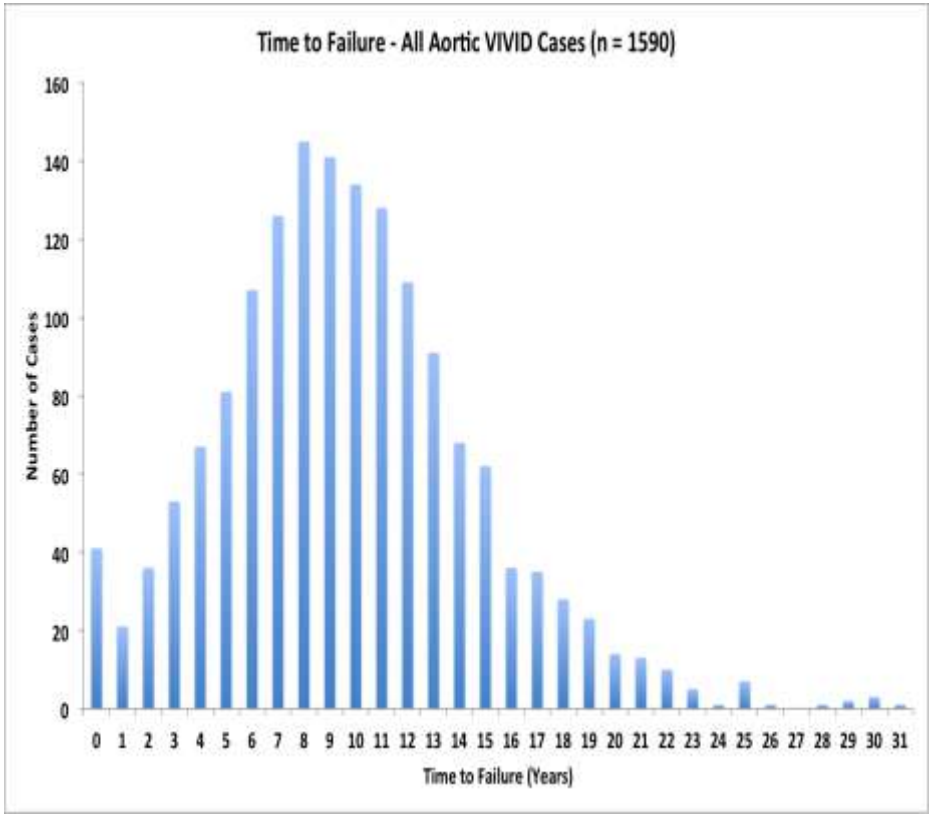
KM estimate of reintervention included censoring of patients at their mortality date or event

Freedom from severe stenosis or severe regurgitation, or re-intervention (TAVI or SAVR)



THV severe failure was defined severe AS AND/OR severe AR. KM estimate of THV degeneration included censoring of patients at their date of last known THV functioning well without evidence for failure per study definition.

When do surgical valves present for VIV TAVI?



Predictors of early tissue valve failure

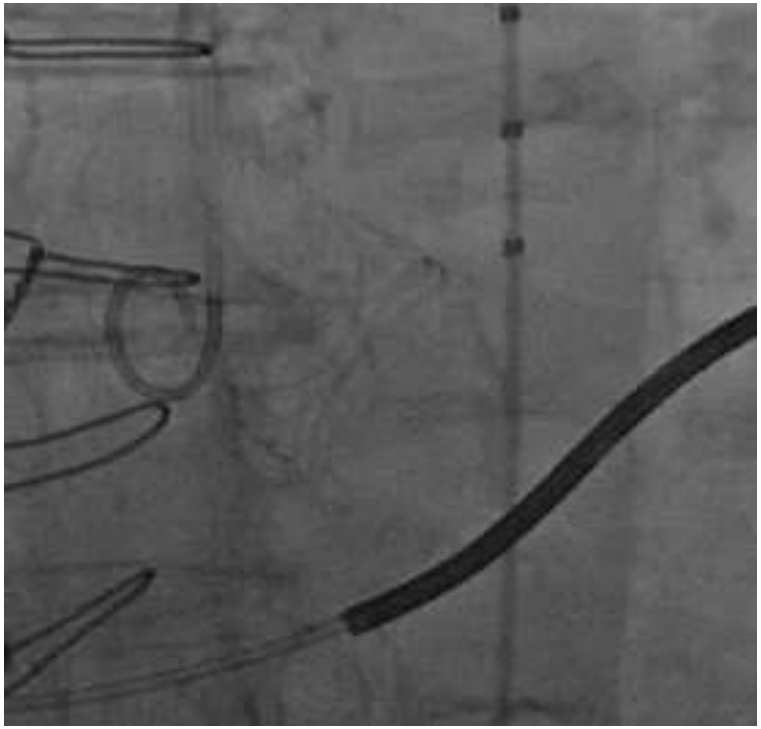
- Low age
- Renal failure
- Valve type

A mean of 9 years

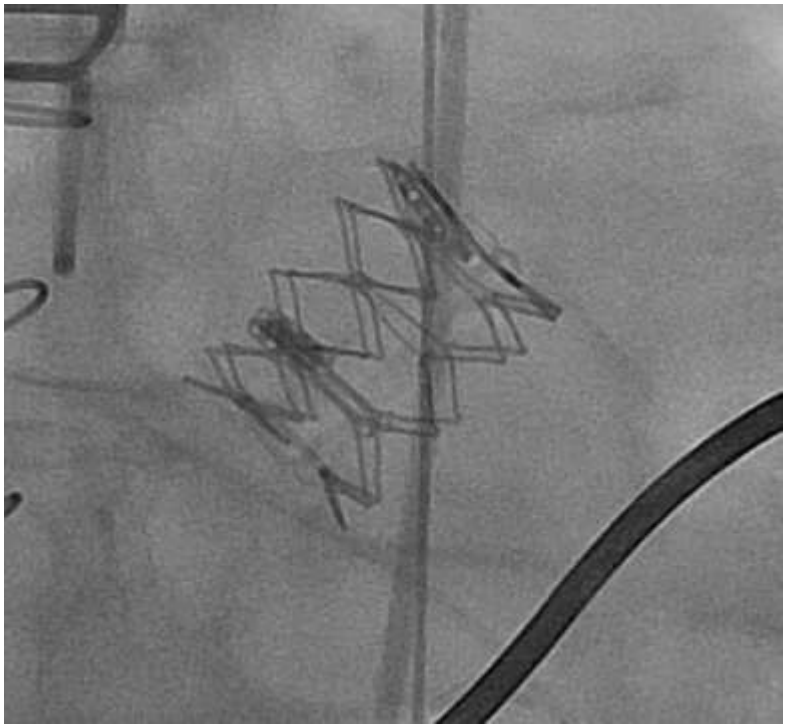
VIVID Registry

Some surgical valves fail early

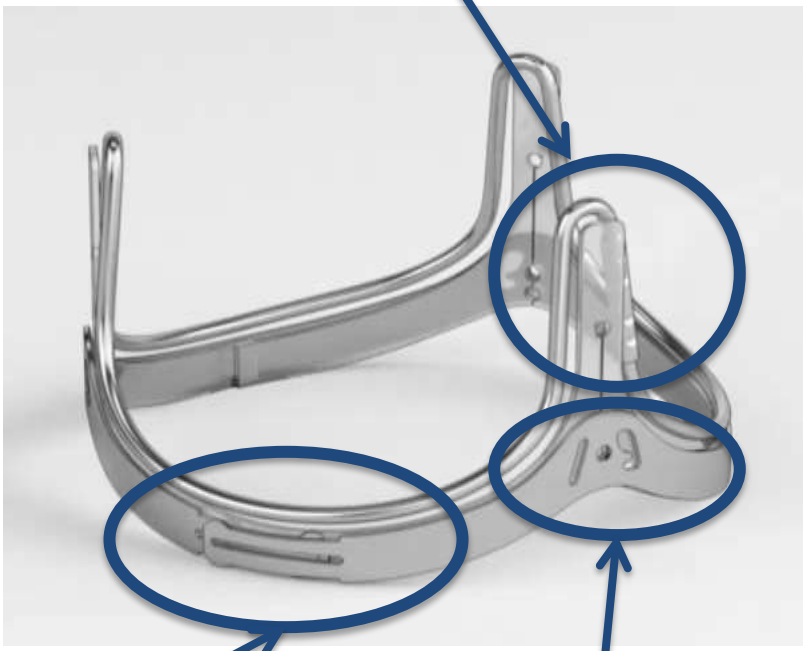
Failed Trifecta surgical valve at 2 years



Sapien XT transcatheter valve implanted In the surgical valve



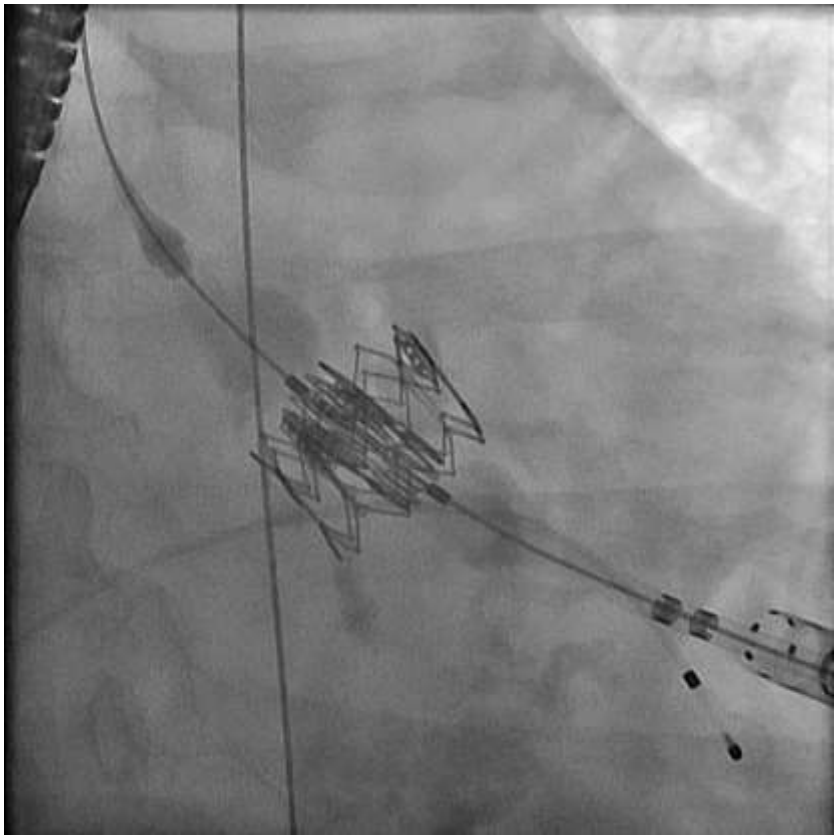
Bioprosthesis will be optimized for valve-in-valve



Some transcatheter valves will fail early too.

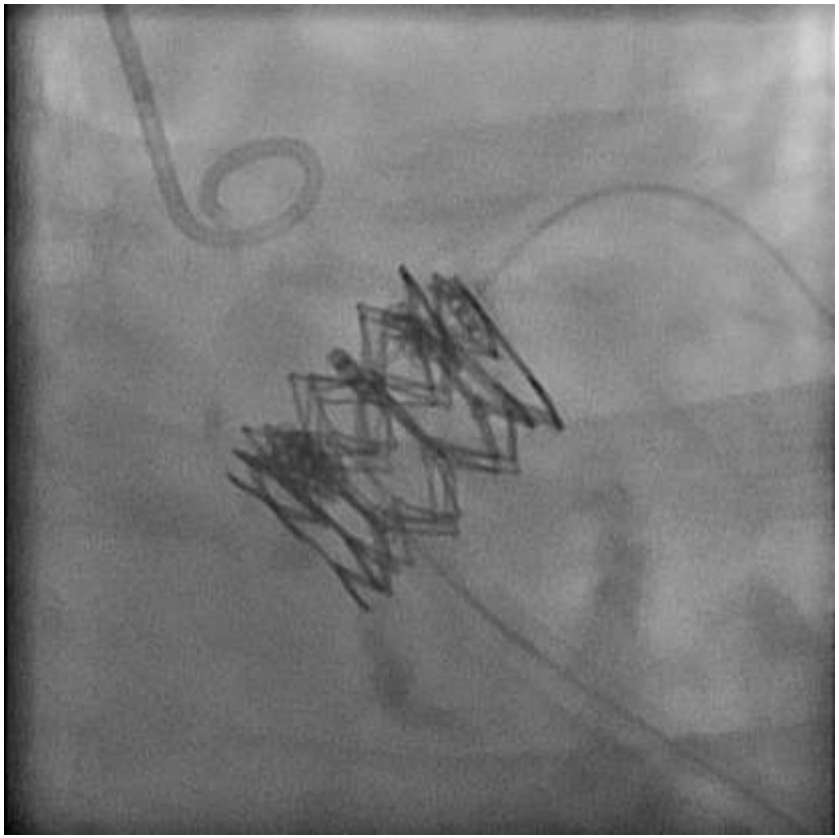
56 y/o obese with COPD.

Stenosis at 4 years



SXT 26 in SXT 26.

MG <10 mmHg, no AR



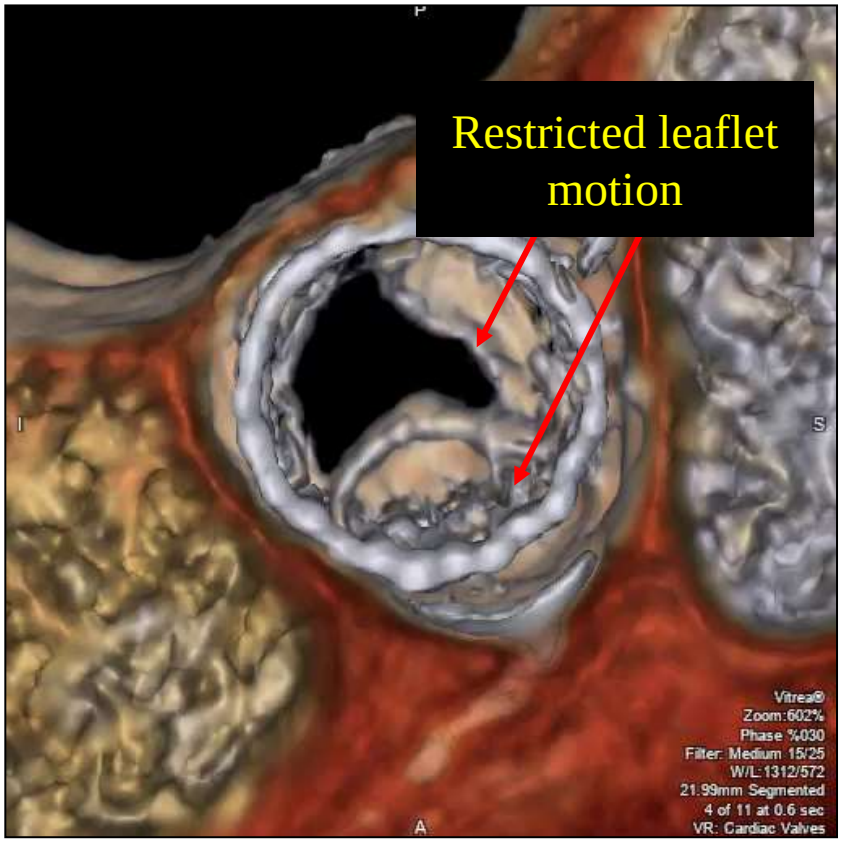
Subsequent to the 5-11 year study

Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

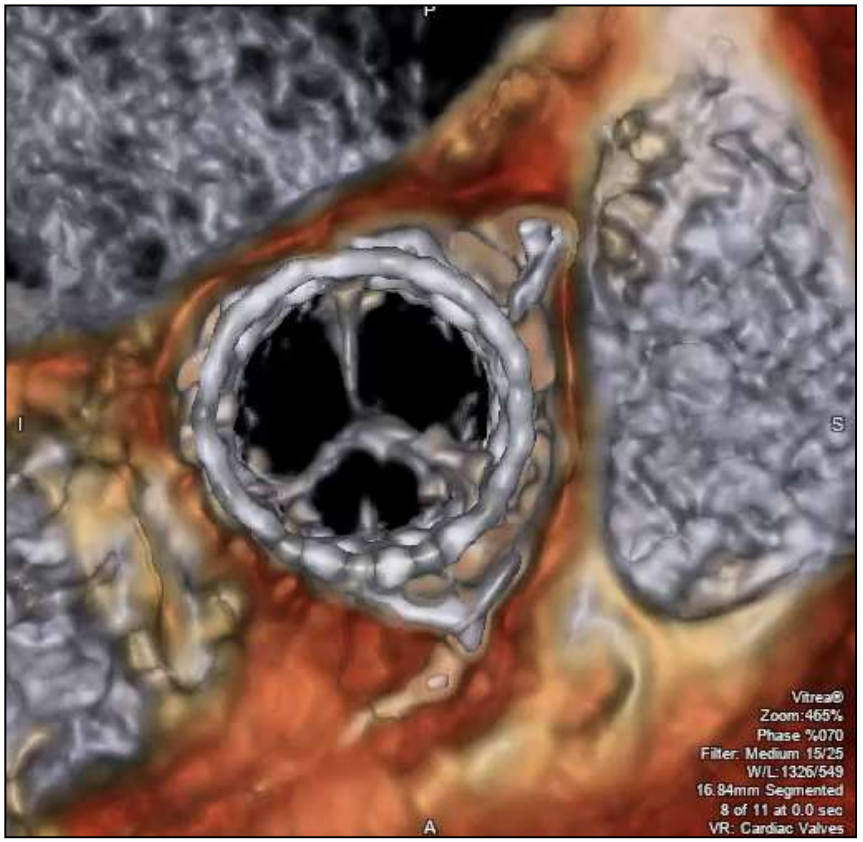
End

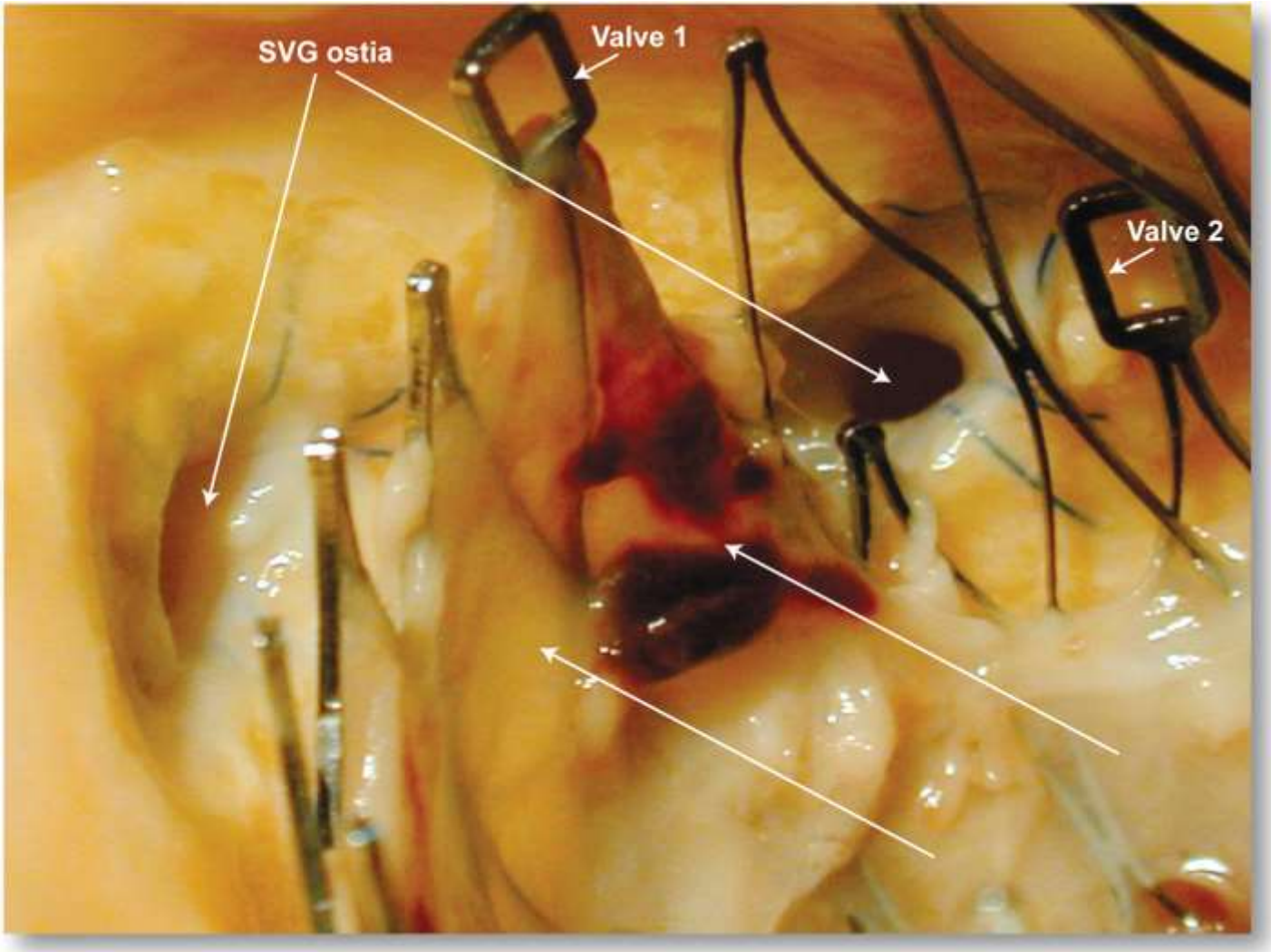
Leaflet thickening

4 months post-TAVR
MG increased 10-23mmHg



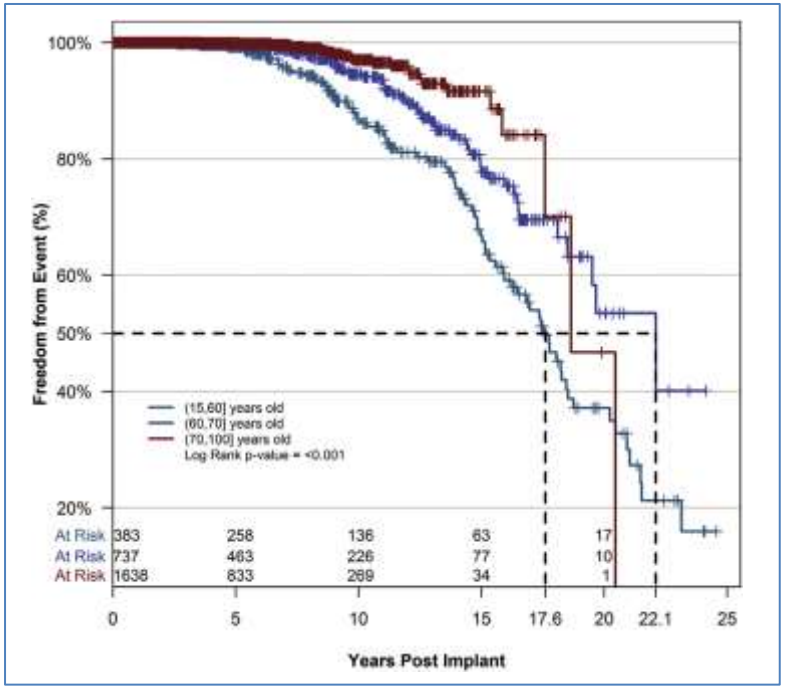
3 after warfarin begun
Normal leaflet motion




SVG ostia
Valve 1
Valve 2

How durable are surgical valves?

Kaplan-Meier freedom from Structural Valve Deterioration



Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position

Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Candolfi, PhD, Alain Mirza, MD, Claudia Loardi, MD, Marc-Antoine May, MD, Rym El-Khoury, MD, Michel Marchand, MD, and Michel Aupart, MD

Department of Cardiac Surgery, Tours University Hospital, France; and Department of Biostatistics, Edwards Lifesciences, Nyon, Switzerland

Ann Thorac Surg 2015

Freedom from Structural Valve Deterioration
= freedom from Severe AS/AR or Redo surgery

Expected valve Durability
= median survival time without SVD