Transcutaneous Aortic Valve Implantation (TAVI)

Percutaneous Aortic Valve Replacement (PAVR)

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on behalf of

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Neil Middleton, Nelis Kruger,

Auckland Heart Group, Mercy Angiography,

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Plan

1. Current treatment of Severe Calcific Aortic Stenosis

2. How CoreValve is works, and some patient presentations

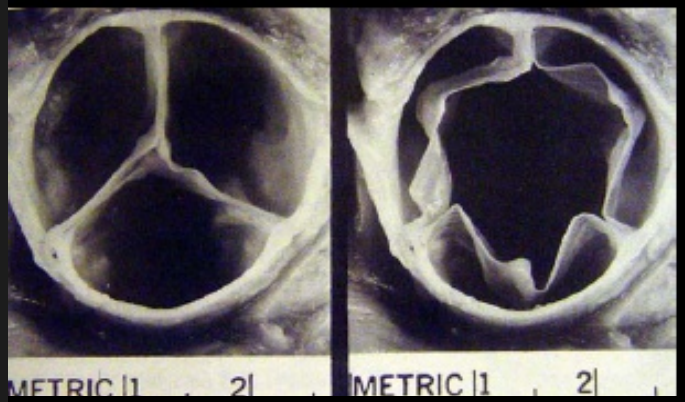
3. Mercy results for Core Valve TAVI in patients unsuitable for conventional surgery

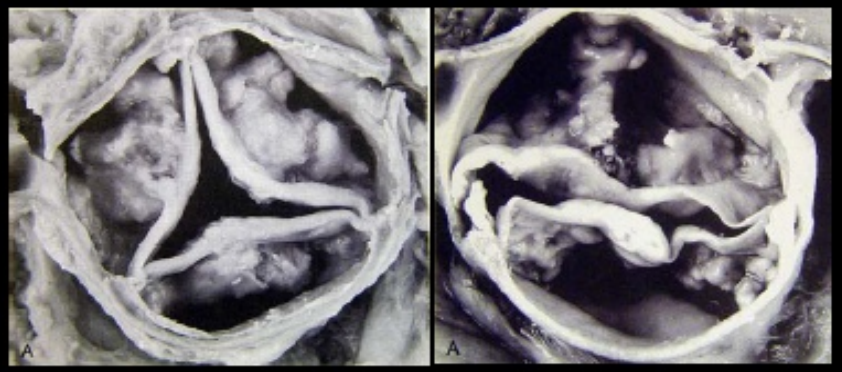
   37 cases no stroke and only one death by 30d
   Entirely percutaneous.
   First in Asia Pacific at Mercy

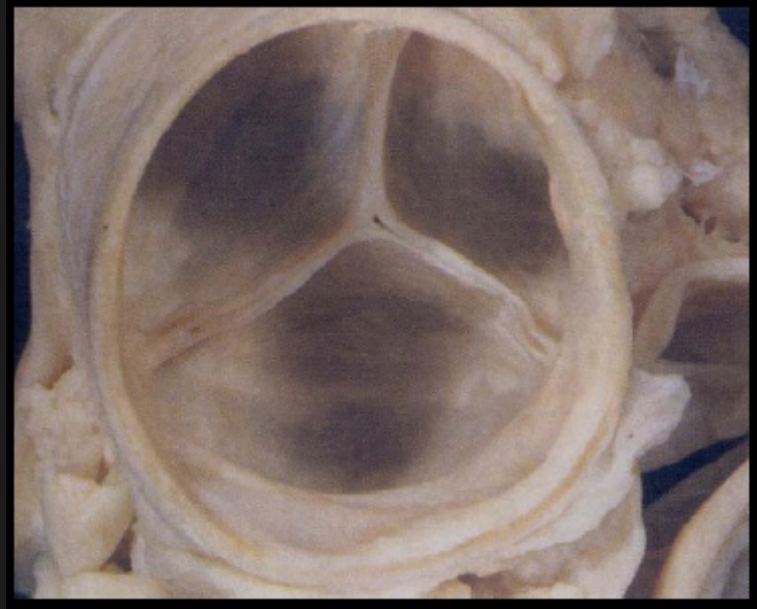
5. MitraClip- percutaneous treatment of Mitral Regurgitation- Efficacy is non-inferior to conventional surgery and Complications much fewer

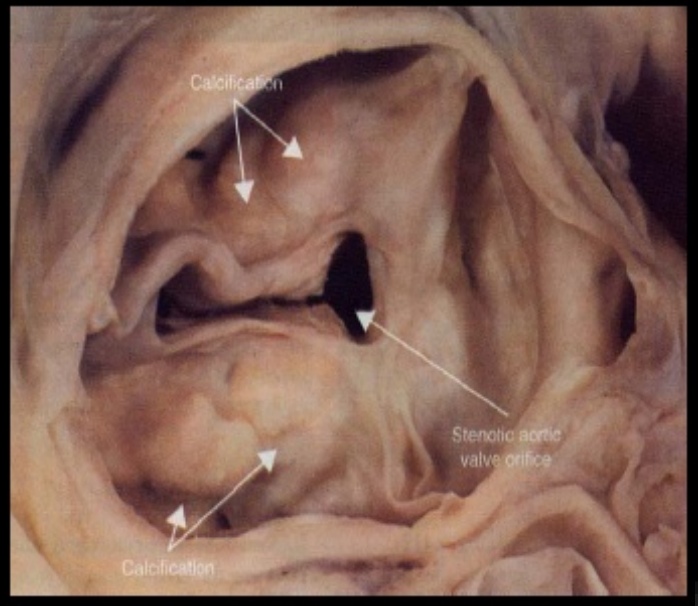
   Plan to be first in Asia Pacific

Normal and calcific aortic valves









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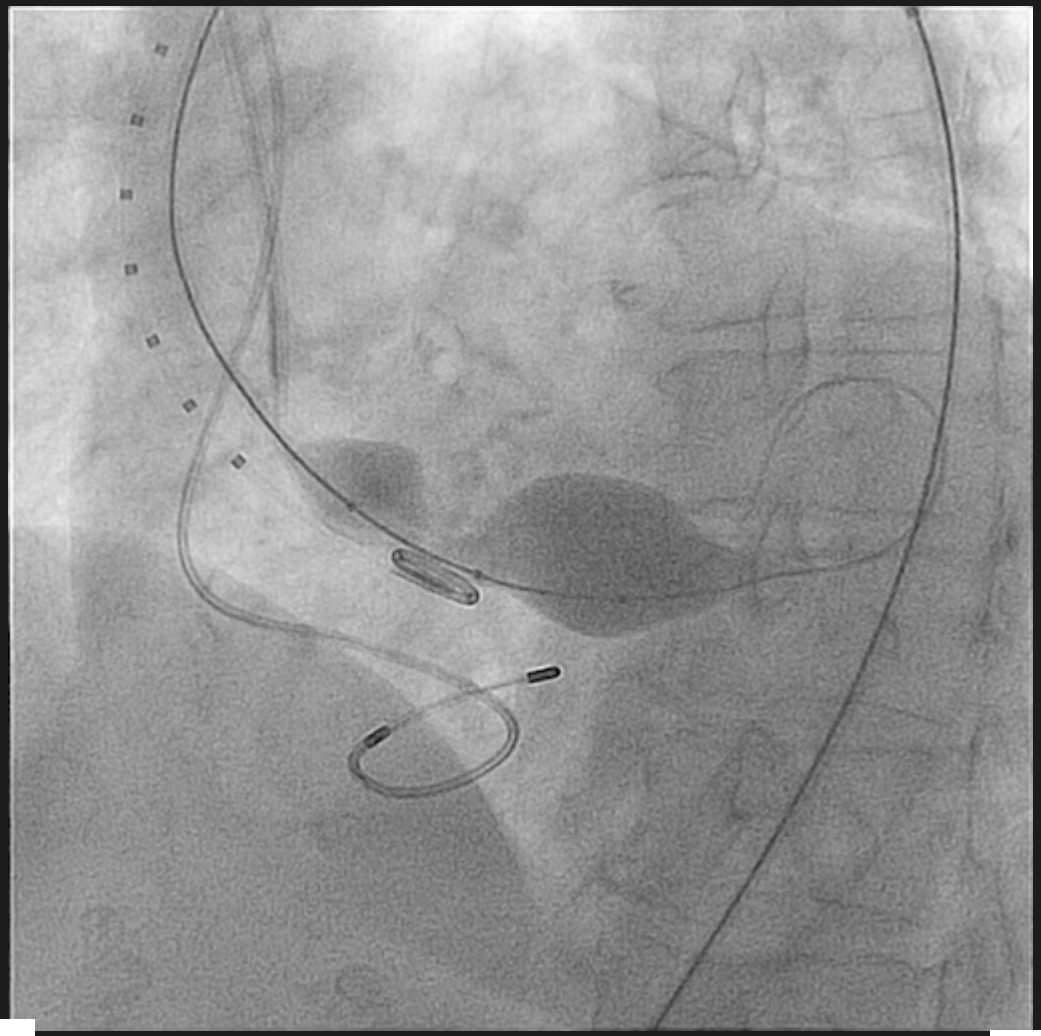
- Of patients with severe aortic stenosis who have symptoms, and who do not have valve replacement, between 50 and 80% will be dead in two years
- The standard of care for severe symptomatic aortic stenosis is surgical valve replacement
- There are many patients who are not suitable or are very high risk for surgical replacement because of comorbidities eg

  advanced age
  renal problems
  respiratory problems
  cerebrovascular disease
  LV dysfunction
  previous heart surgery

Patients who are high risk or unsuitable for Surgical Aortic Valve Replacement have been offered balloon aortic valvuloplasty (BAV) or managed medically

Balloon valvuloplasty



Balloon aortic valvuloplasty

- Can produce early symptomatic improvement
- Serious acute complications (10%)
- Restenosis and clinical deterioration occur in most patients within 6-12 months

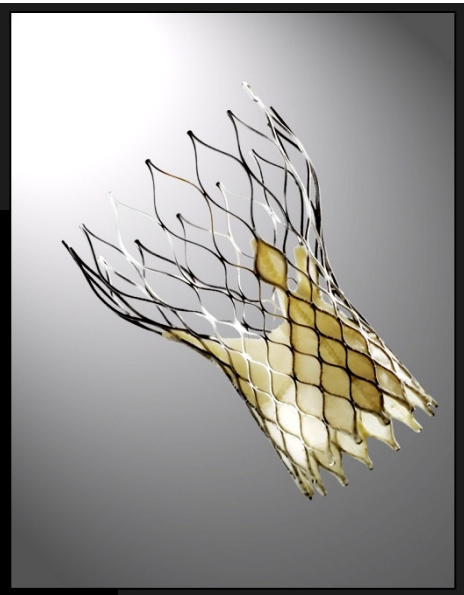
  1- yr survival in the order of 55%
  3- yr survival - 23%

  Otto et al, Circulation 1994;89:642

- There is no medical therapy that prolongs life and only limited medical therapies to alleviate symptoms

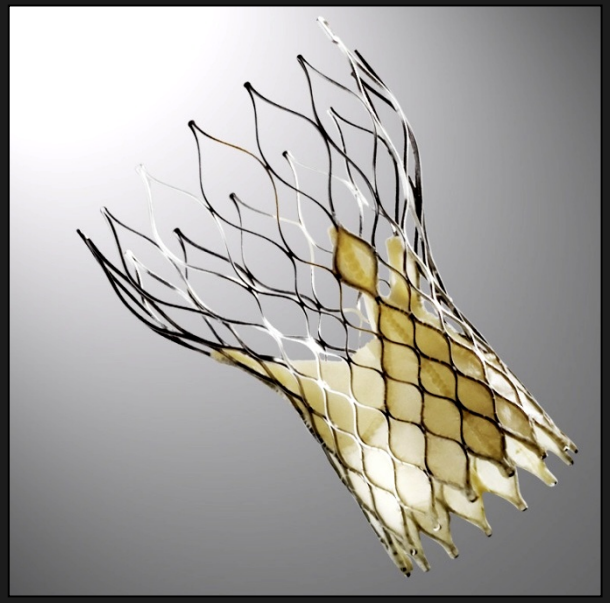
  Bonow et al. Circulation 2006;114:e84

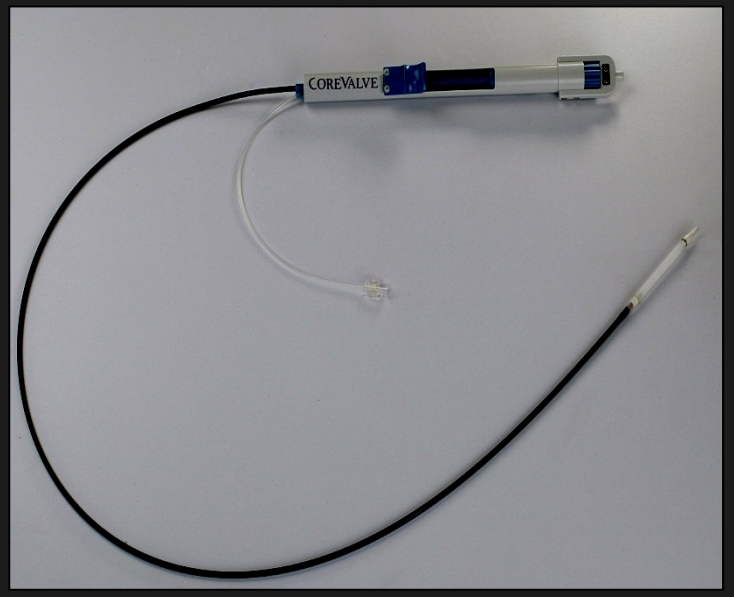
The Purpose of Percutaneous Aortic Valve Replacement



- Implant an aortic valve in patients at high risk or unsuitable for surgical aortic valve replacement (SAVR)
- Less invasive and recovery is more rapid than SAVR
- Aim is to relieve symptoms, to improve quality of life and improve duration of life.

CoreValve





Nitinol self expanding frame

Leaflets made from porcine pericardium

18F (6mm) delivery

Can be repositioned before final deployment

Percutaneous (unless cut down to eg subclavian)

Sapien Edwards percutaneous aortic valve

Stainless steel balloon expandable

Leaflets made from bovine pericardium

Rapid pacing needed during delivery

24F (8mm-becoming less)

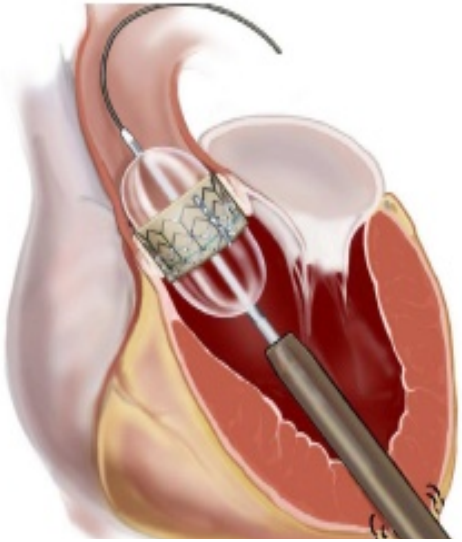
No repositioning during deployment

Cutdown usually – femoral or apical

Surgical closure usually

For those with Ilio-femoral artery disease---

1. Edwards- Trans-apical mini-thoracotomy for Edwards



2. CoreValve- Surgical cutdown to L subclavian artery

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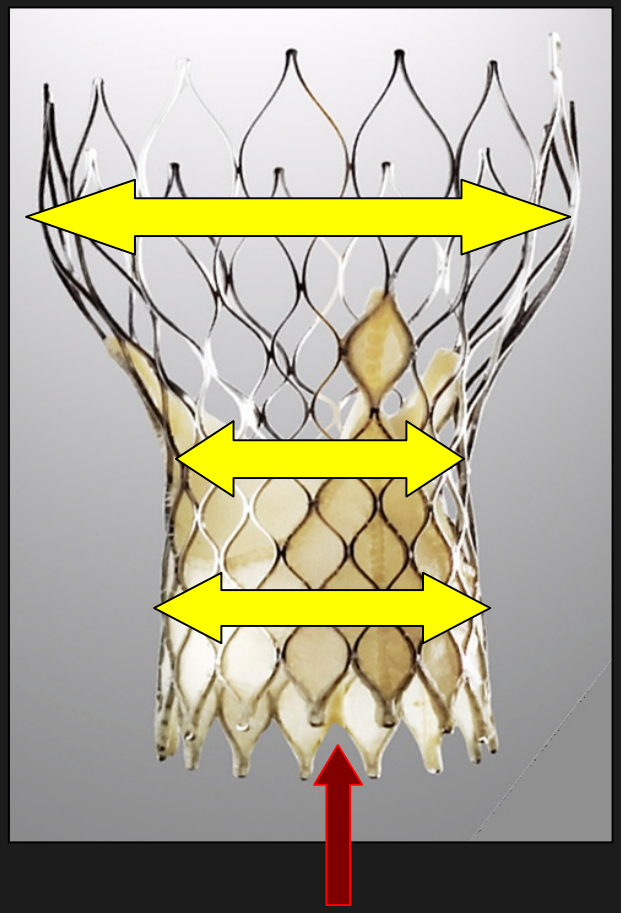
CoreValve-Self-Expanding Multi-Level Frame



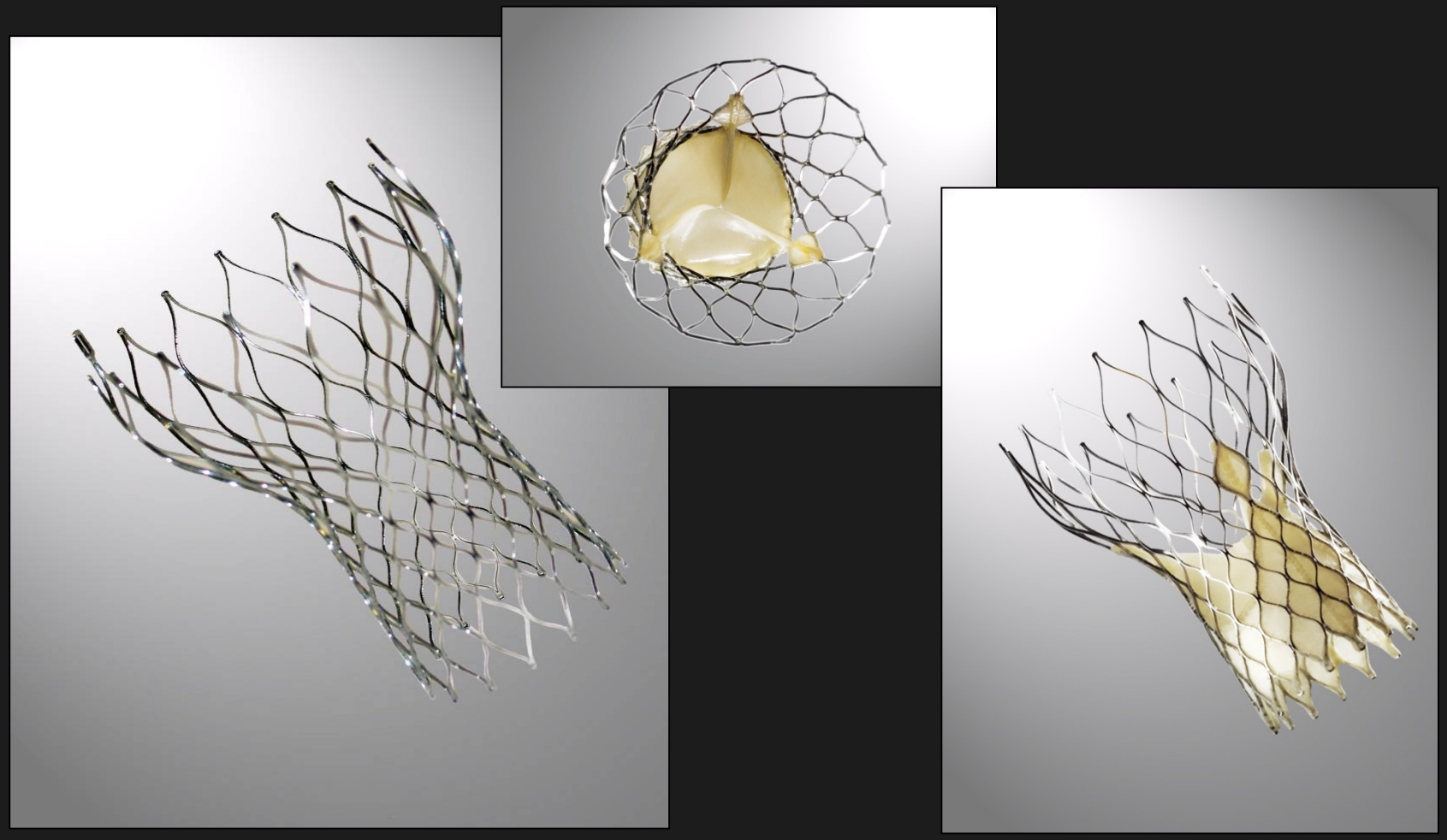
1. The downstream or ascending aortic zone orientates and secures the valve in the ascending aorta

2. The zone with the smallest dimension holds leaflets away from coronary arteries to preserve coronary blood flow. Coronary angiography and PCI are possible

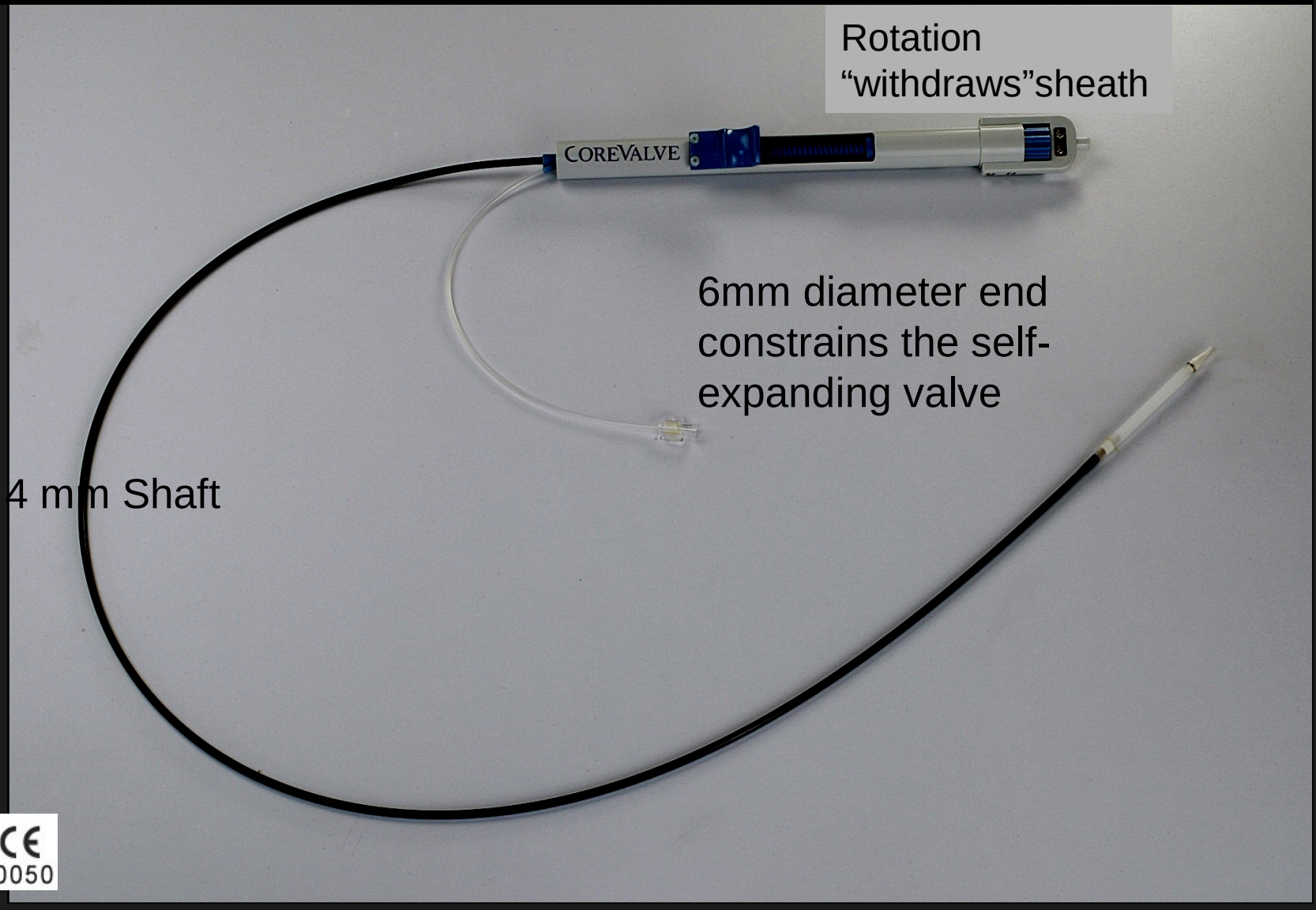
3. Flared intra-annular zone adapts to a range of annulus sizes preventing/limiting aortic regurgitation

CoreValve

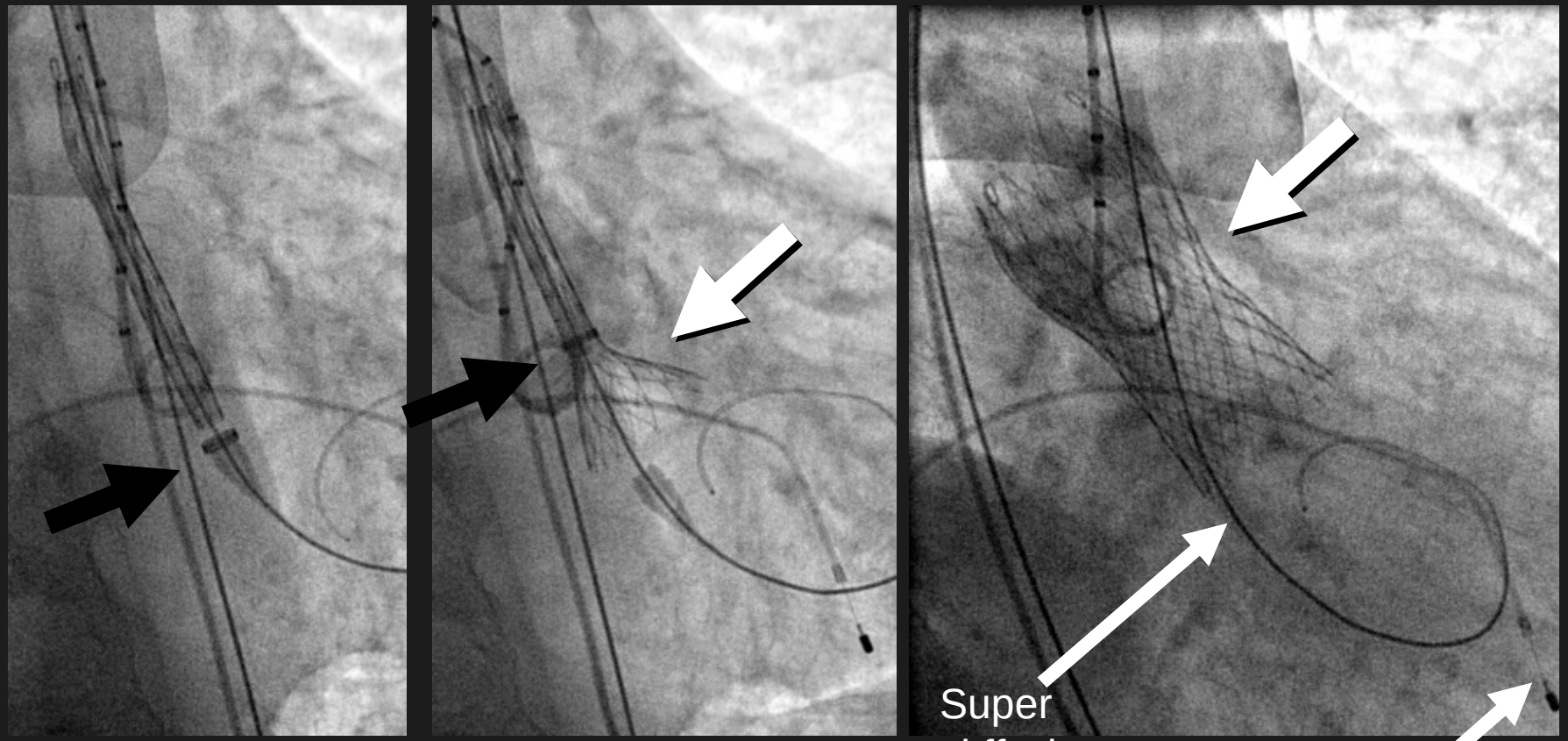
The leaflets are made from porcine pericardium



CoreValve percutaneous aortic valve delivery system



With the device across the diseased valve, the sheath is withdrawn (black arrow) so that the self-expanding frame is no longer constrained and can open up (white arrow)



CoreValve percutaneous aortic valve

As of May 2010 there have now been > 10,000 CoreValve Implants world wide !

When we began <2 yrs ago there had been 1500

Growth is exponential

FiCoreValve patients at Mercy Hospital

Supported by the Auckland Heart Group Charitable Trust

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Mercy Registry Cases – High risk or unsuitable for surgical AVR

► August 08- May 10,	35 patients (+2 not registry eligible)
► Mean age	85 years (44-96 yr)
► Symptomatic Class III/IV	33/35
► Mean Logistic Euroscore	23.46% (7.42-52.33)

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Mercy Experience- Echo Characteristics

- Severe AS –

peak aortic velocity	4.5 ± 1 m/s (3.8-5.5)
peak gradient	83 ± 49 mmHg (38-132)
mean gradient	51 ± 34mmHg (31-85)

- AVA — 0.6± 0.7 cm^2 (0.4-1.3)
- LV EF — 53% (range 30-75%)

Mercy Procedural Data

• Light General Anaesthesia	35/35
• Percutaneous closure	35/35
• Post-procedural gradient	trivial
• Post-procedural AR ≤ grade 2	23/35
• Procedure time, mins, mean (range)	80 (39-132)
• ICU	17hr (0-27)
• Post-procedural days in hospital	6.7 (4-12)

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Mercy Experience- Morbidity

► Transfusion	16/35(46%)
► Stroke/TIA	NIL
► Renal function deterioration	Nil
► Pacemaker after	9/35 (26%)

Mercy Experience Mortality

- Death by 30 days _____ 1/37
- Significant symptomatic improvement ___31/35
- Discharge medication includes
  - aspirin (and clopidogrel)
  - warfarin if in atrial fibrillation

Mrs JM 89 yo female First PAVR in Asia Pacific

Critical AS
Recent heart failure
Previous CVA
Not frail
Mild bilateral carotid stenoses
Did not want surgery.
Euroscore 32

Multidisciplinary meeting minutes

"JM 89 yo female
Recent heart failure, critical AS. Previous CVA. Mild bilateral carotid stenoses. Does not want surgery.
Euroscore 32
Unanimous agreement - percutaneous AVR appropriate"

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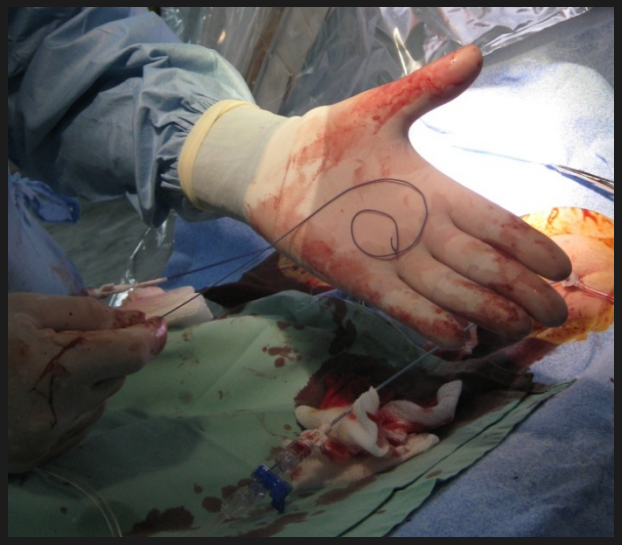
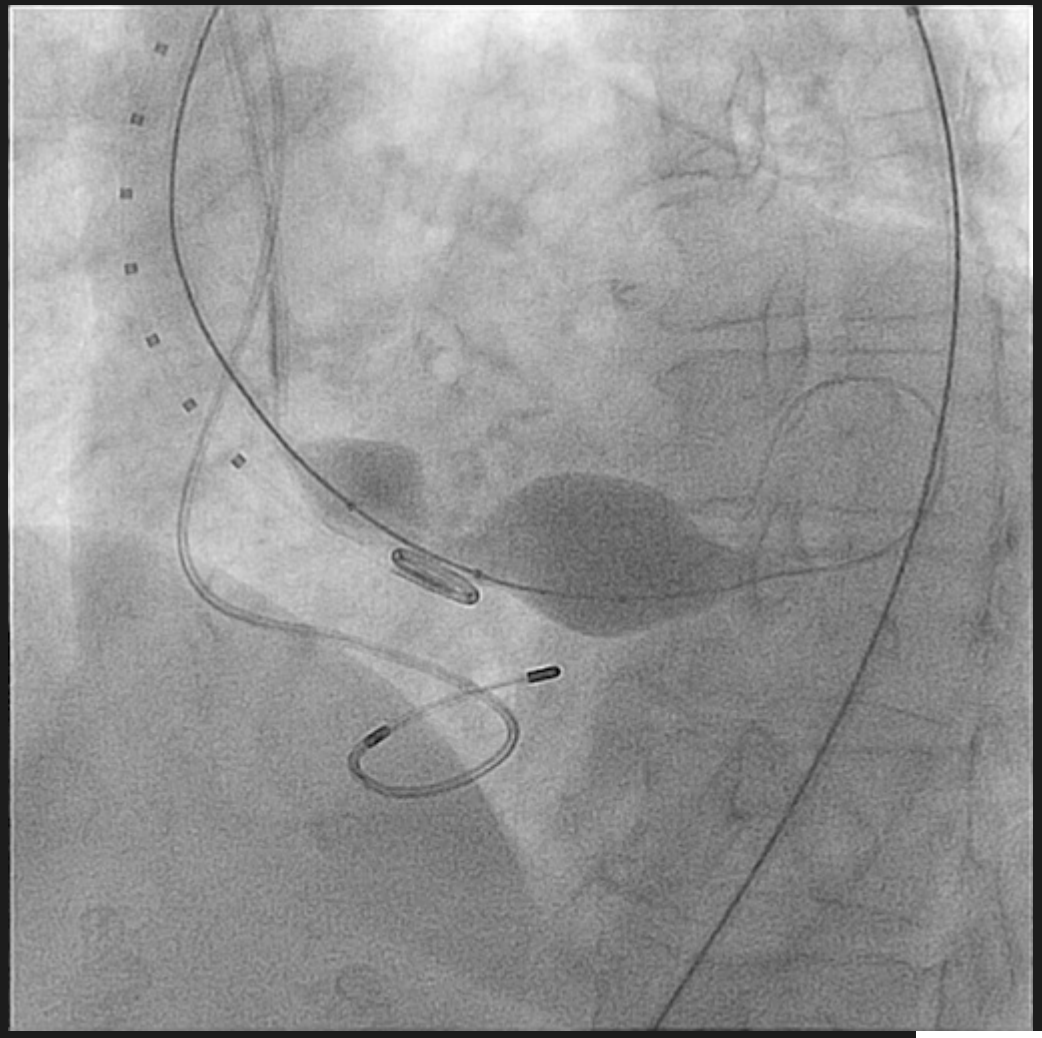


Balloon valvuloplasty before CoreValve insertion



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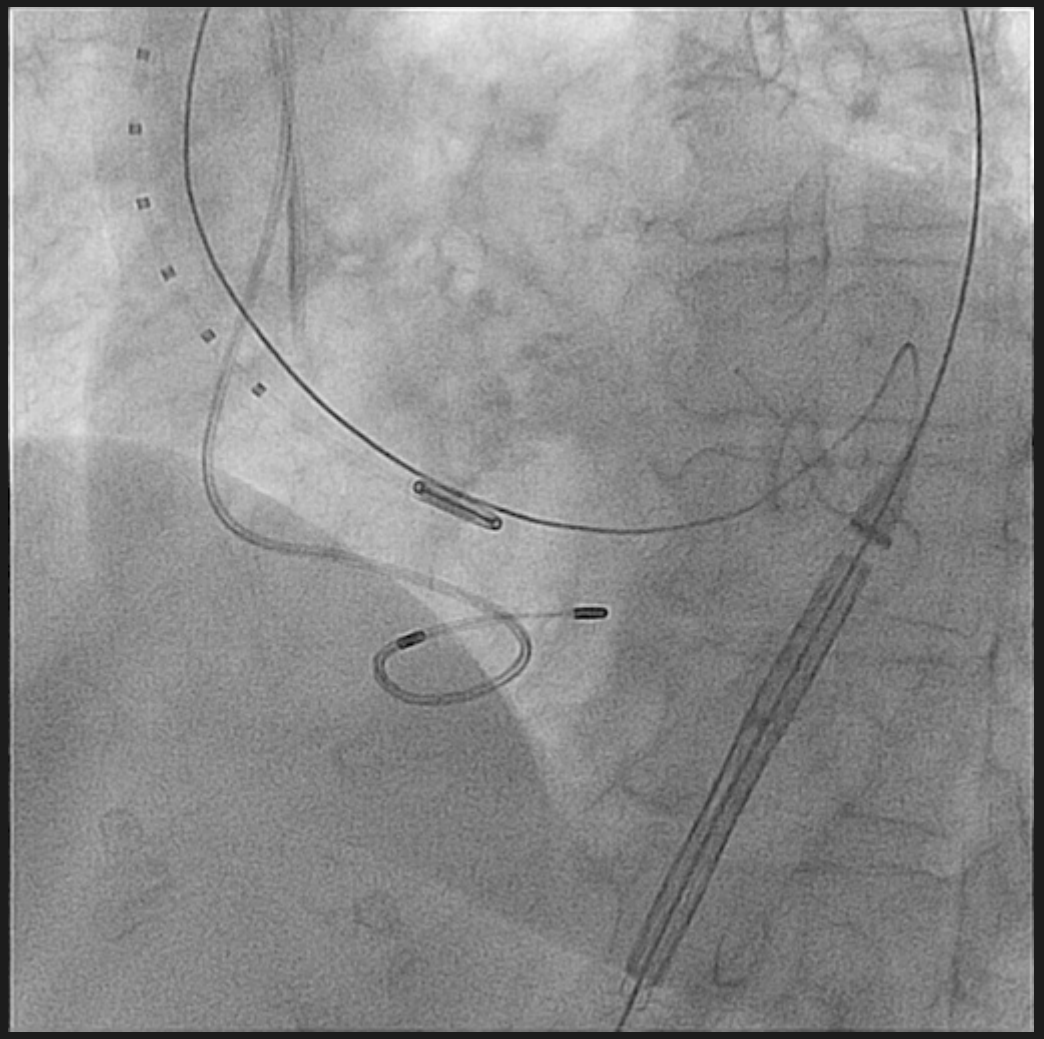
CoreValve advances up descending thoracic aorta



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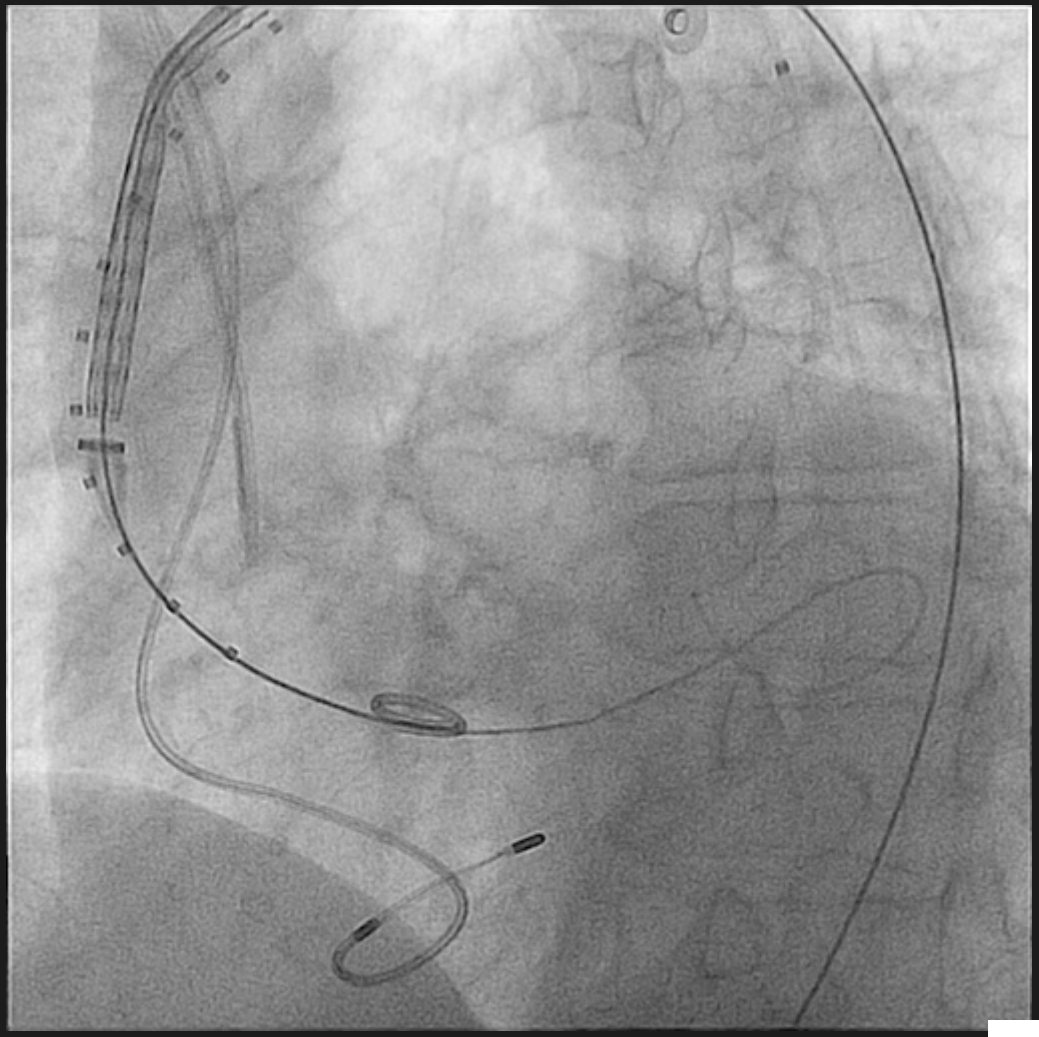
CoreValve advances across native aortic valve



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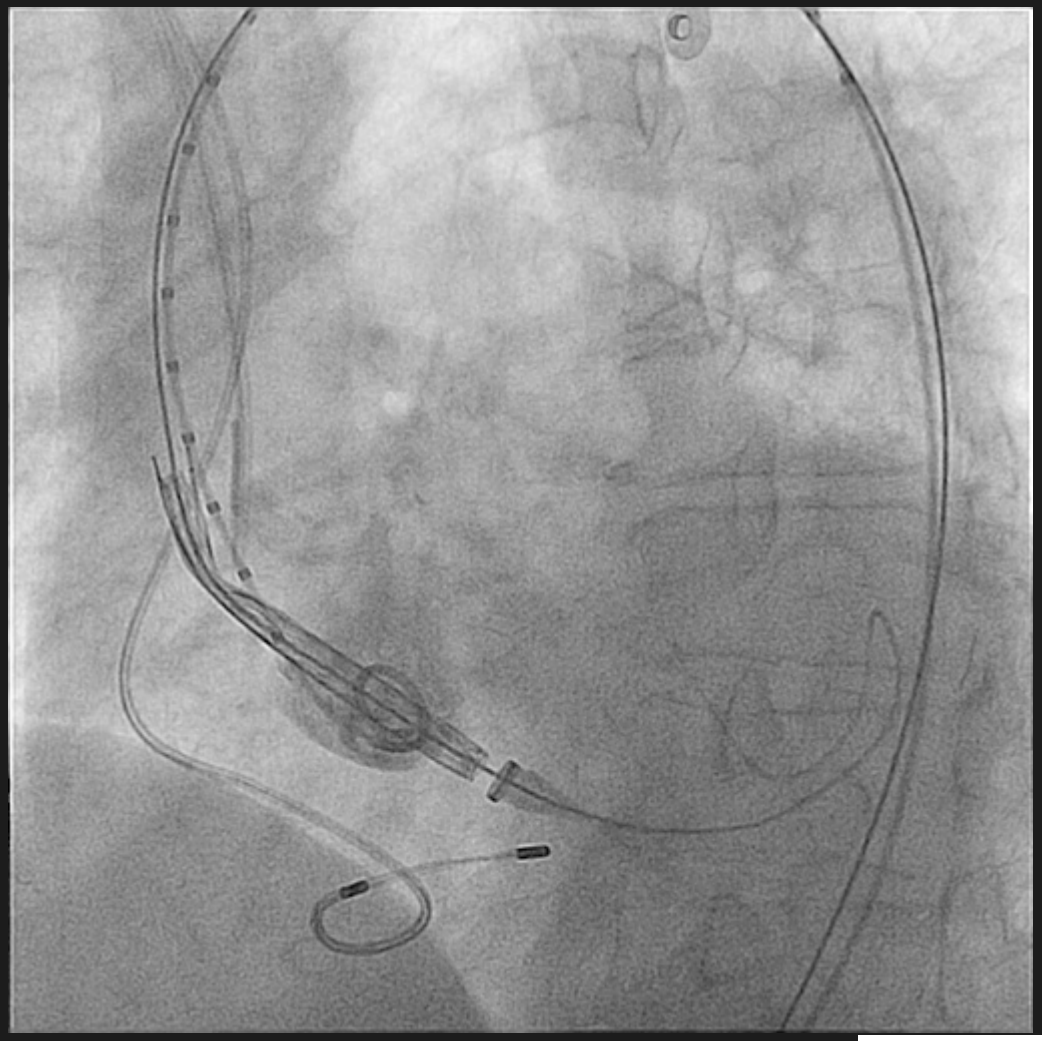
Aortogram to check position



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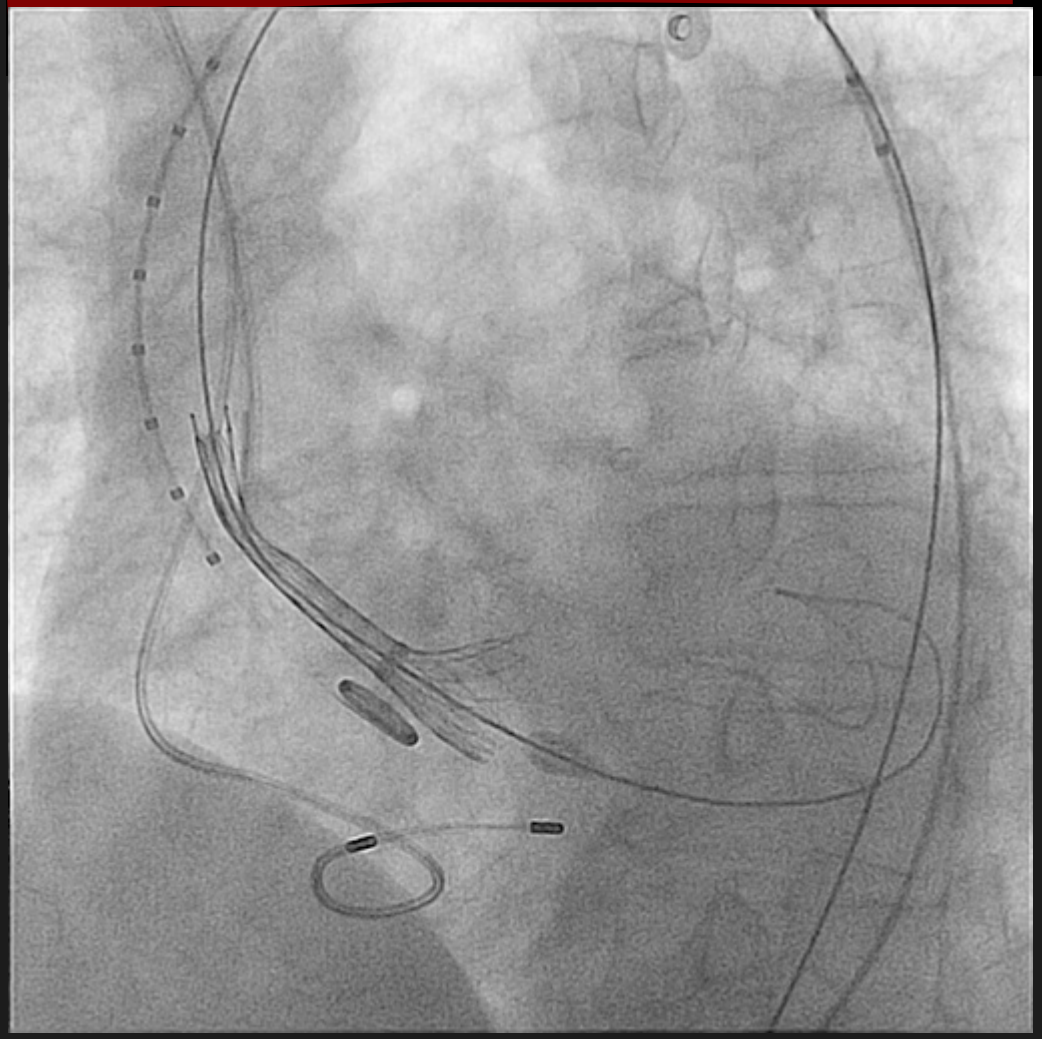
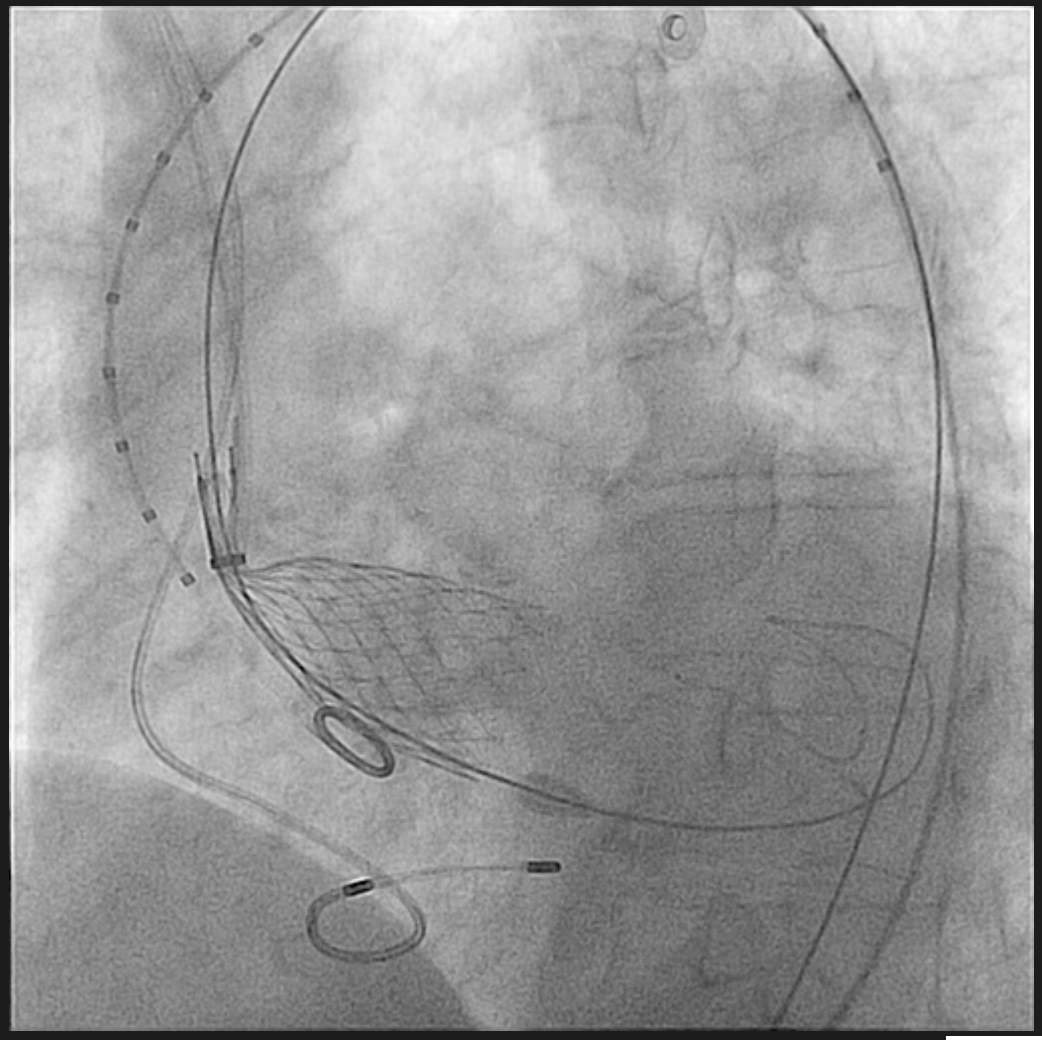
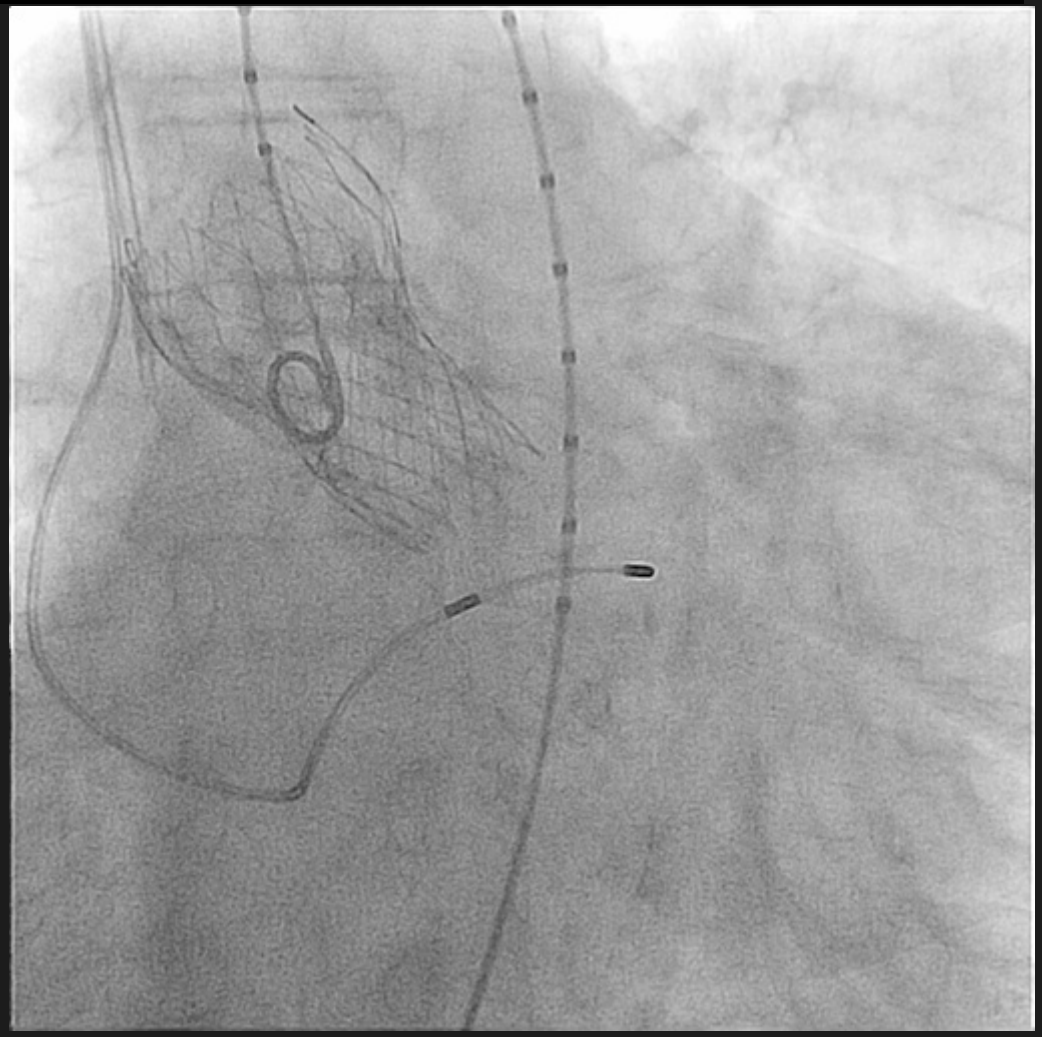
Sheath withdrawal begins and inflow portion of nitinol frame begins to expand



Further sheath withdrawal with further frame expansion



Aortogram after deployment



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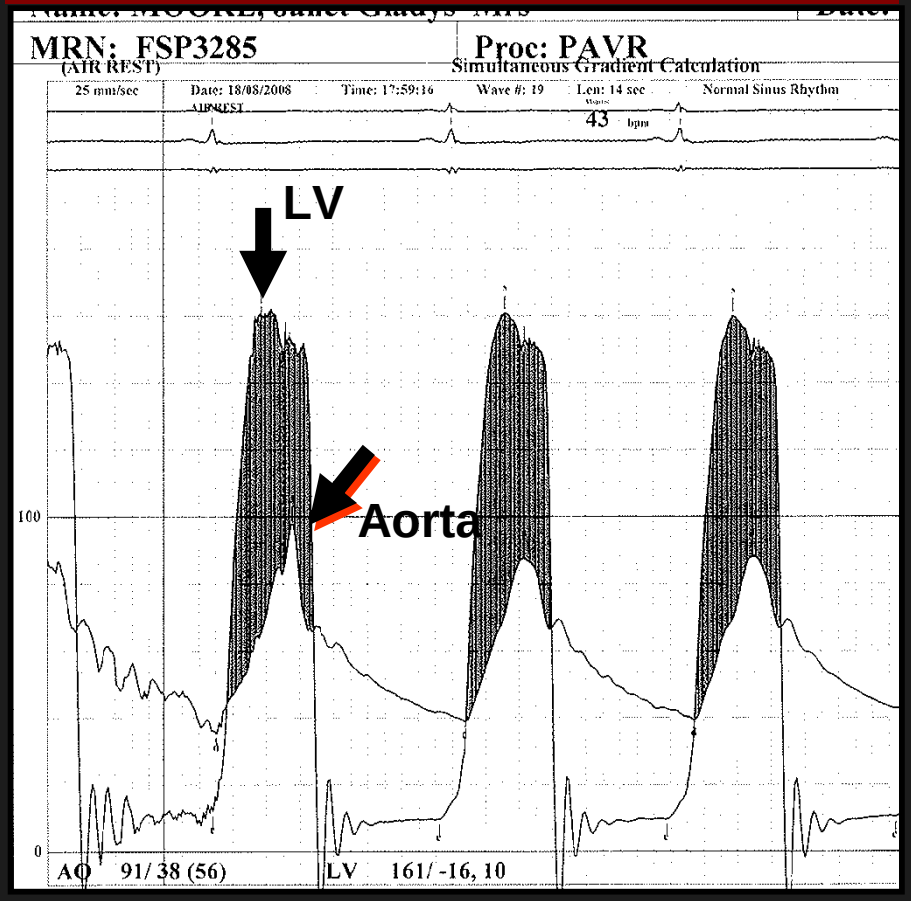
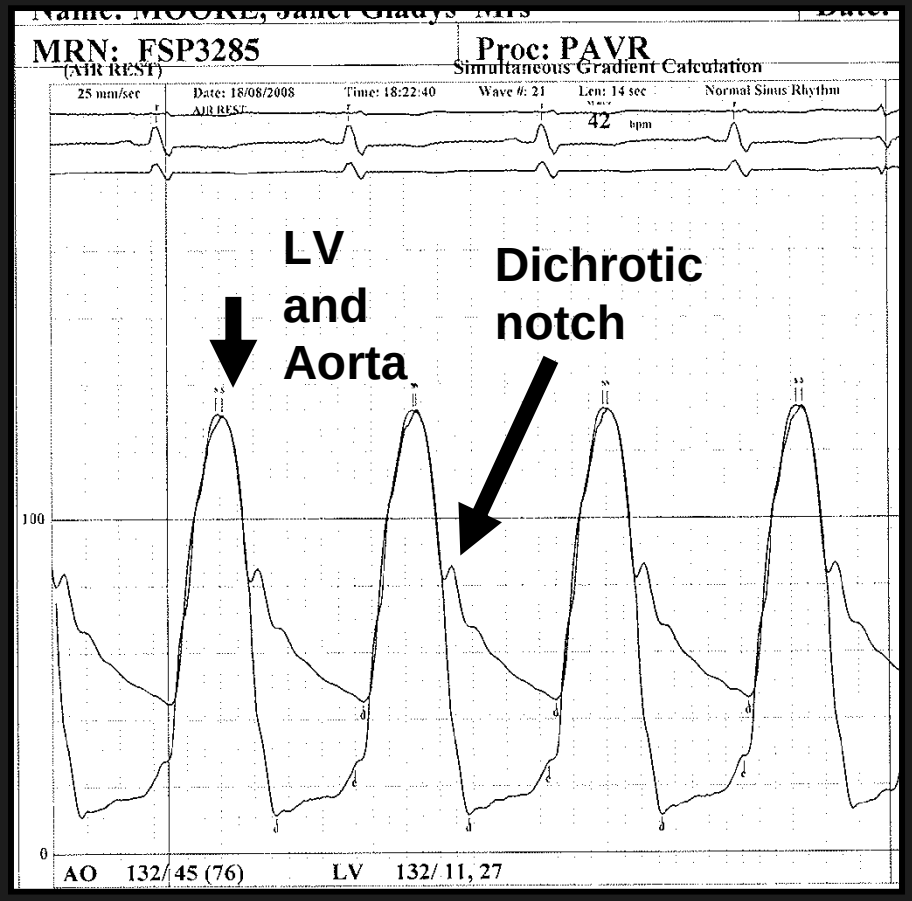
Gradient across the aortic valve before and after CoreValve implantation

Before P-P gradient 70 mm Hg



After P-P gradient 0mm Hg



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This patient was the first in Asia Pacific to have a percutaneous aortic valve replacement. She has had a dramatic improvement in symptoms

John Ormiston & partner

You are cordially invited to celebrate the

90th Birthday of

[redacted]

a musical evening with refreshments and a light meal provided

Date/Time
Saturday 10th January, 5pm

Venue
[redacted]
Sandringham, Auckland

RSVP
[redacted]st December
3909
[redacted]m@xtra.co.nz

Gifts are not necessary

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Ms O'C

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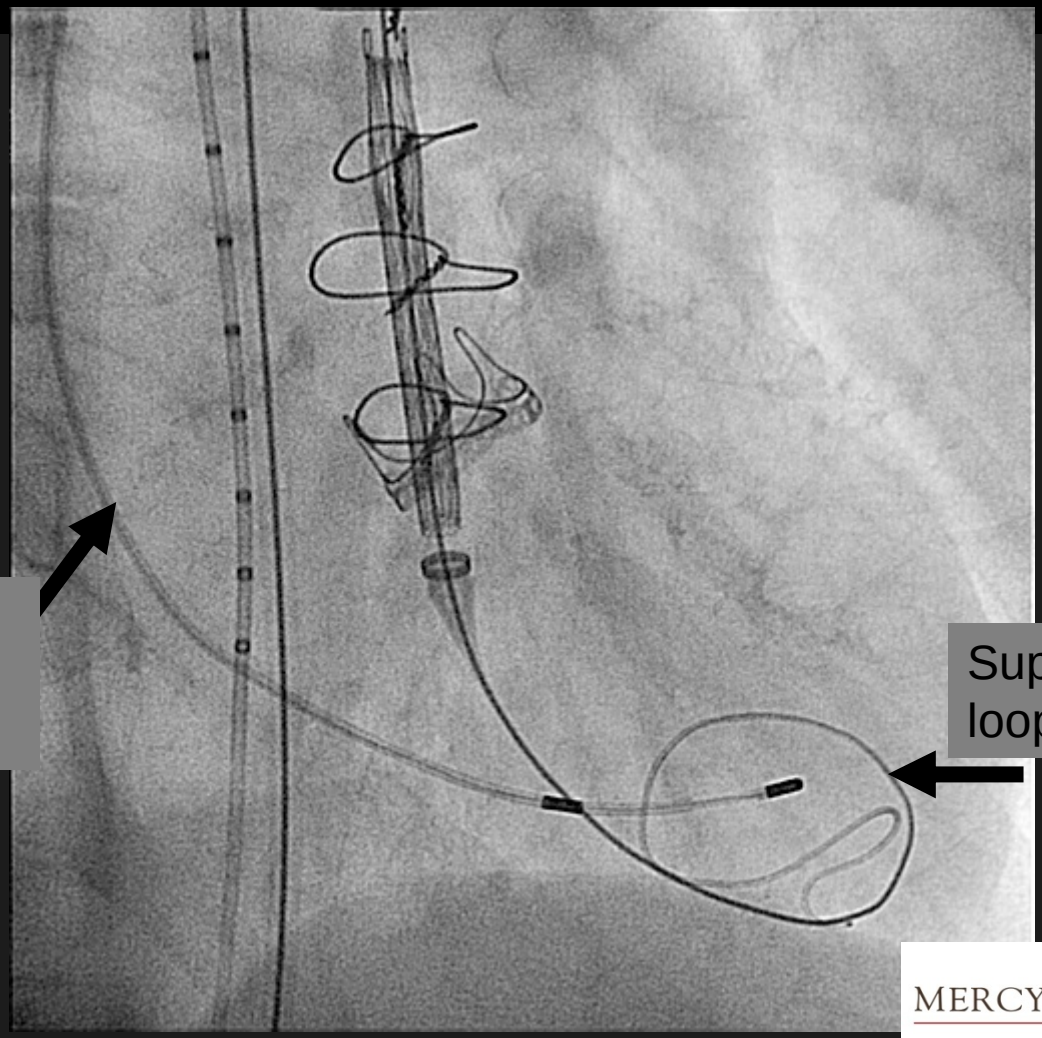
Ms O'C

- 76 yr old
- In 2000, she had surgical replacement of her calcified stenotic native aortic valve with a size 21 Carpentier Edwards bovine pericardial prosthesis
- Fragile aorta and pericardial patch to aortotomy site
- COPD FEV1/FVC 0.73/1.32
- 2008 progressively more breathless. NT-ProBNP 145mol/L (N <35)
- Serial echo increasing AS and AR – valve area 0.8 and mod AR
- EF fell from 53% to 38%
- Euroscore 31% and STS 40%

Ms O'C. CoreValve across failed Carpentier Edwards surgical valve



Flotation pacemaker from Jugular

Superstiff wire looped in LV

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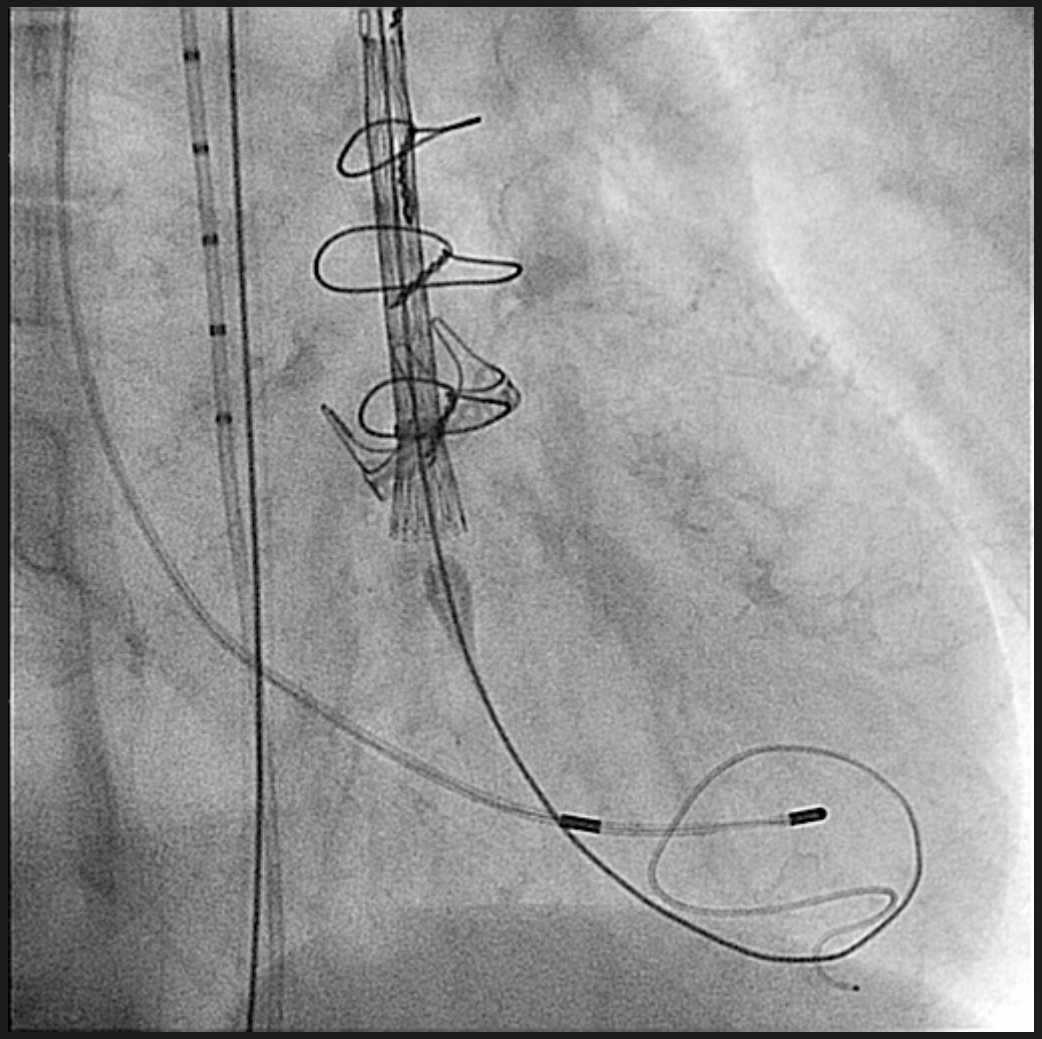

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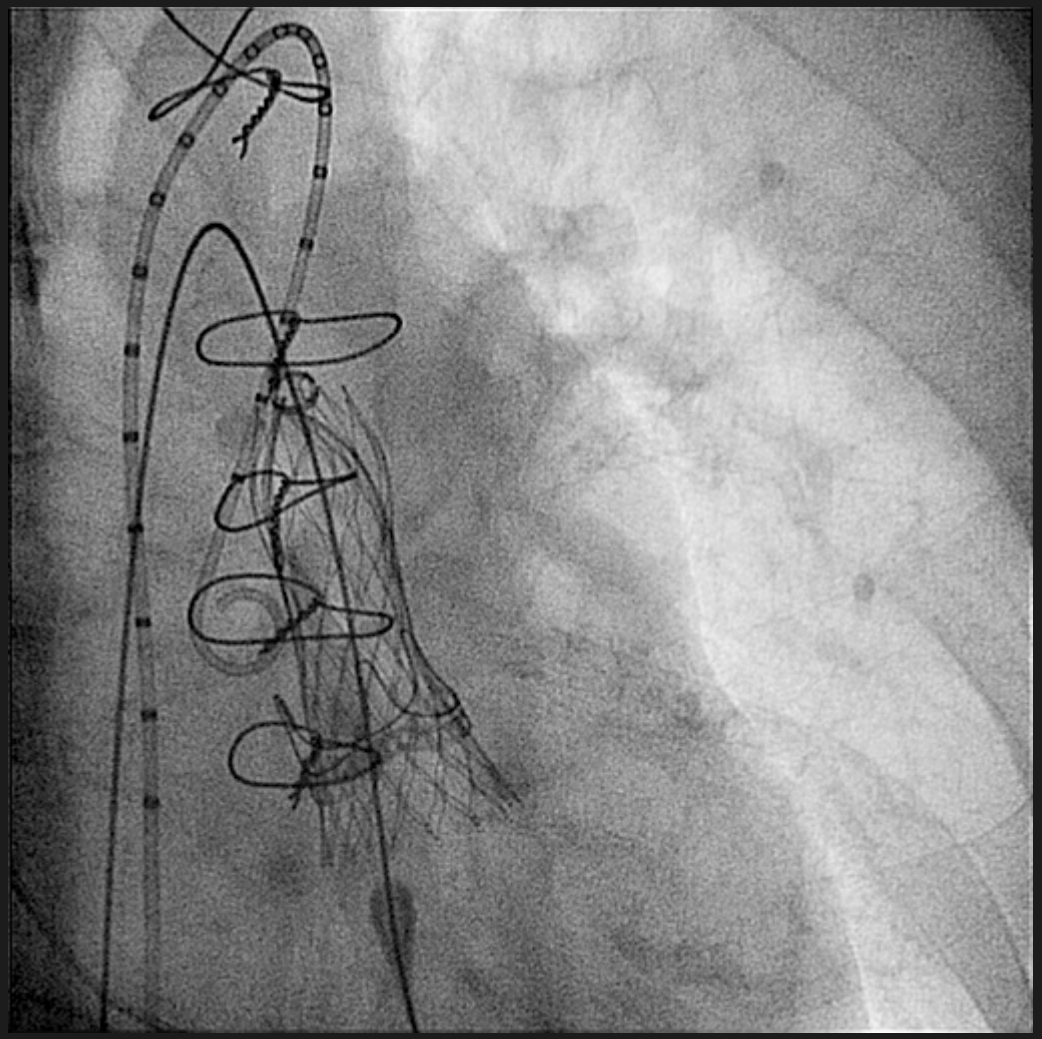
Not fully released



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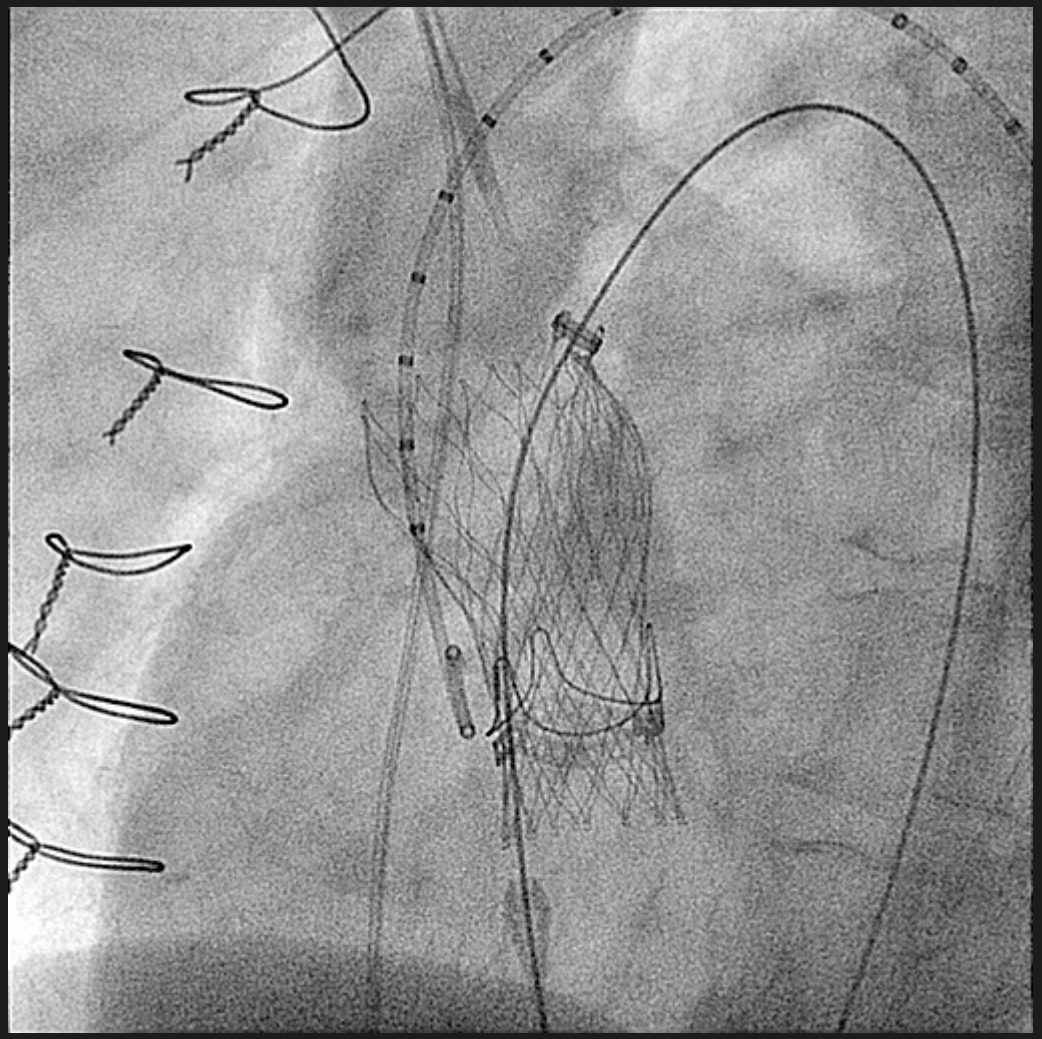

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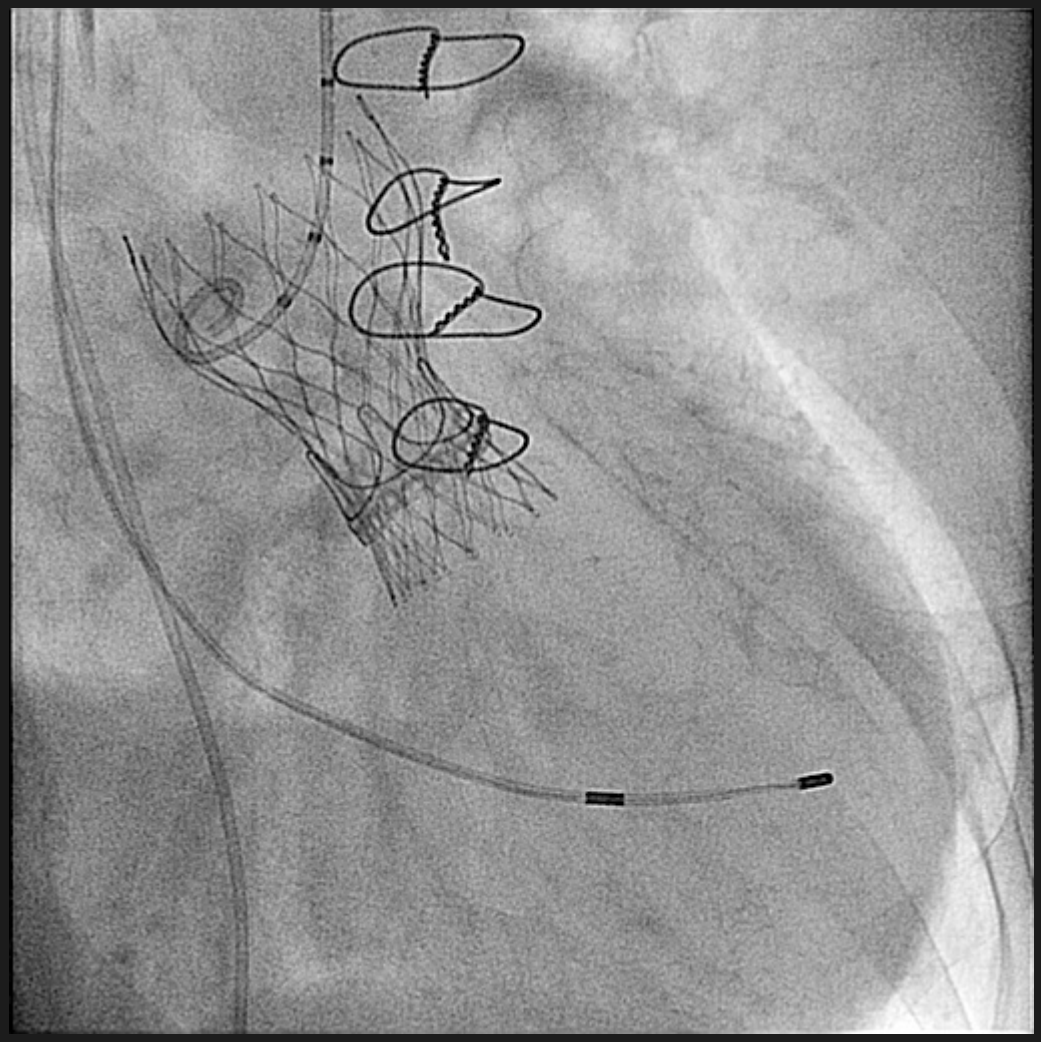
Trivial AR on final angio



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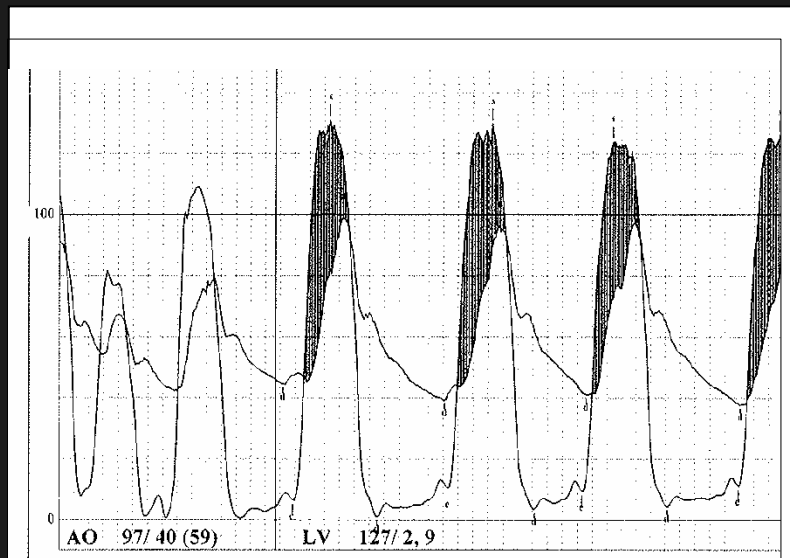
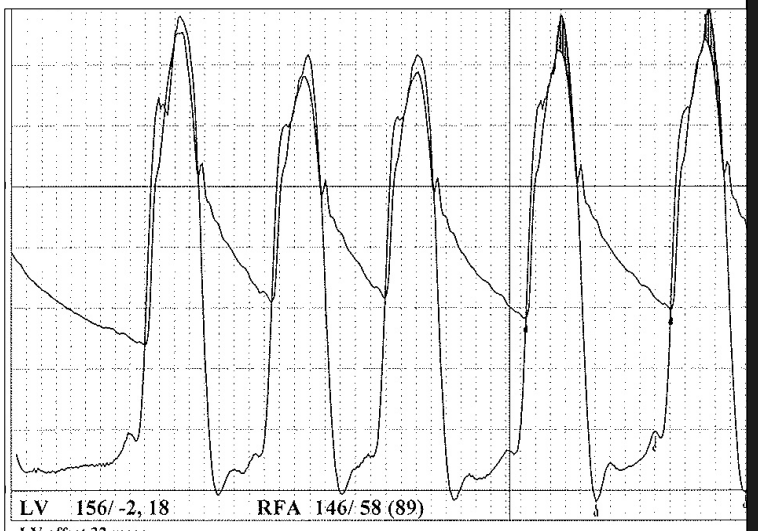
The gradient across the aortic valve is abolished



Calculations

AORTIC VALVE GRADIENT

	CO (l/m)	HR (bpm)	Mean (mmHg)	P-P (mmHg)	INS-PK (mmHg)	Perd (msec)
Fick		65	38.7	30.0	69.2	327



Calculations

AORTIC VALVE GRADIENT

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PAVR was successful in-

1. This was 76 yr old small woman with a deteriorating Carpentier-Edwards bovine pericardial prosthesis
2. The surgeon noted a fragile aorta that needed a pericardial patch to aortotomy site at the time of initial AVR
3. COPD FEV1/FVC 0.73/1.32
4. Euroscore 31% and STS
5.

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Choice of aortic valve prosthesis may change in the future

1. Currently mechanical surgical valves are chosen for younger patients because of the risk of leaflet deterioration in surgical bioprostheses

2. A disadvantage of mechanical valves is the need for warfarin

3. The potential for replacement of a surgical bioprostheses with transcutaneous valve means that some surgeons are selecting bioprostheses for younger patients when there are potential issues with eg warfarin therapy

Conclusion

- Percutaneous AVR has been introduced with good short term results in patients very high risk or unsuitable for surgery
- Only 1 death and no stroke by 30 days in 37 patients
- High incidence of pacemaker requirement
- No surgical scars, no cardiopulmonary bypass
- The procedure is expensive because valve costs nearly $40,000

Percutaneous treatment of mitral regurgitation

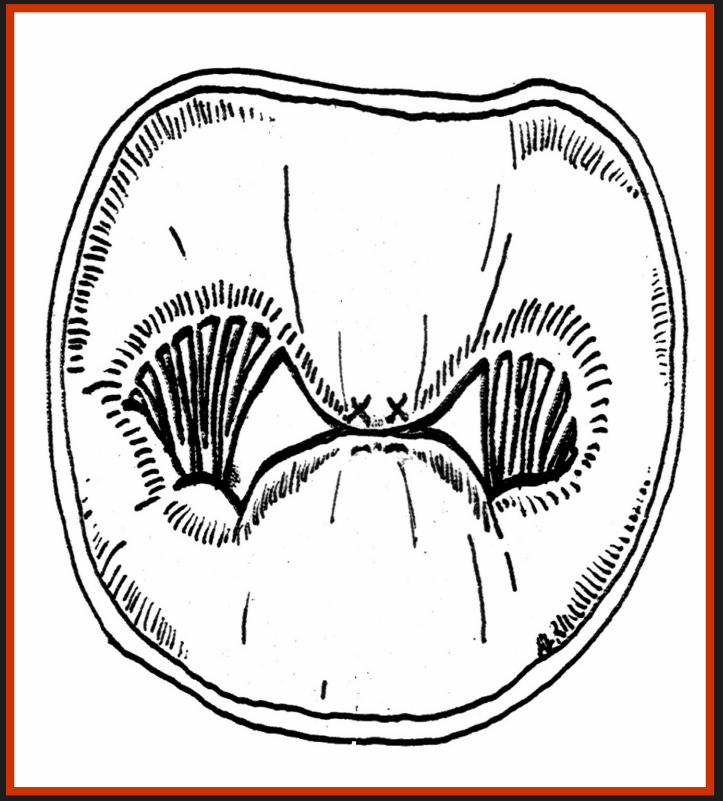
There is a current surgical edge-to-edge technique called the Alfieri stitch

Over 900 reported

Outcomes equivalent to standard of care surgical therapy

Applicable to both

- Structural (Degenerative) MR
- Functional MR



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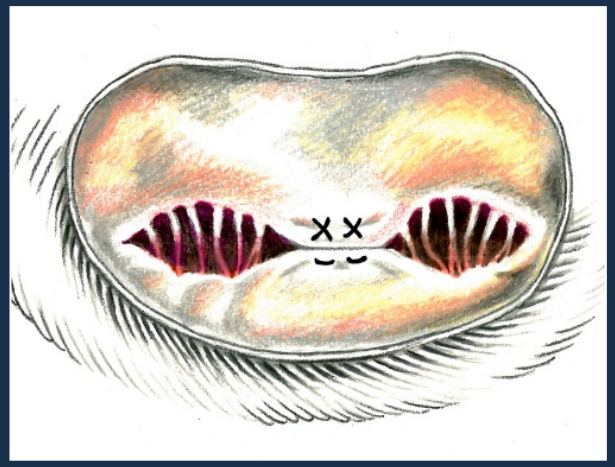
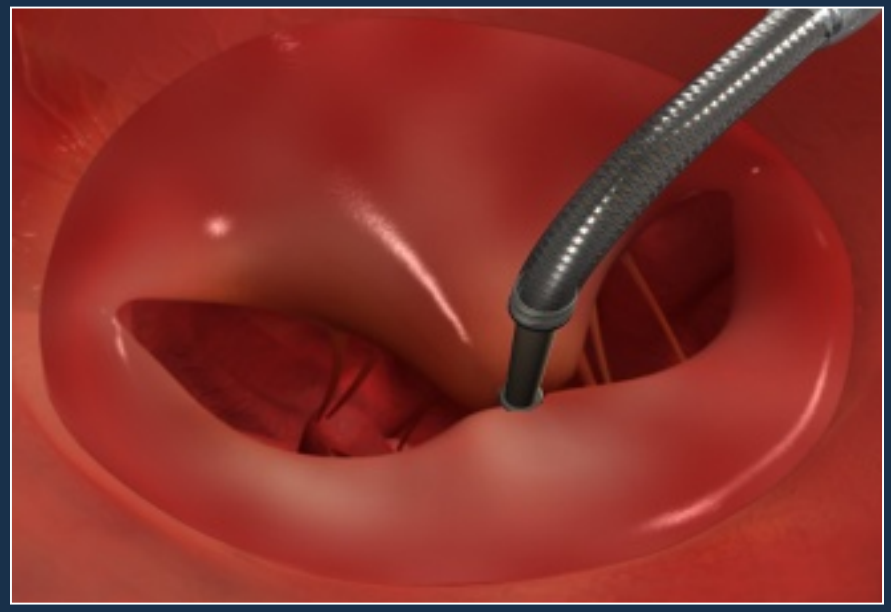
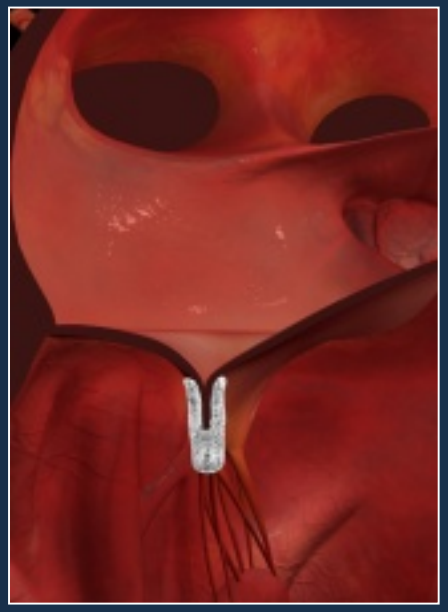
The anterior and posterior leaflets can be joined by a MitraClip mimicking the surgical suture

Catheter-Based Mitral Valve Repair

MitraClip® System







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Investigational device limited by Federal (U.S.) law to investigational use only. PML02827

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The Everest II randomized trial of surgery vs MitraClip for mitral regurgitation showed that the MitraClip was

1. Non-inferior for efficacy

2. Highly significant reduction in complications

Feldman ACC 2010

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We

The randomized trail results (Everest II) are very promising for MitraClip

We are working at Mercy this year toward the first MitraClip in Asia Pacific

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