# Late failure of transcatheter heart valves:
# An open question

A comparison with surgically implanted bioprosthetic heart valves.

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# Conflict of Interest Statement

I do not have any
financial interest or affiliation to any
company that I mention their products or
name in this presentation.

**Alexis Carrell in:**

Carrell A: Results of transplantations of blood vessels, organs & limbs.

JAMA 1908; 51:1662

**A. Carpentier in:**

Biological factors affecting long term results of valvular hetrografts.

J. Thoracic Cardiovasc Surgery
1969:59:457

**A. Cribier in:**

Percutaneous transcatheter implantations of an aortic valve prosthesis for calcific aortic stenosis, 1st human case description.

Circulation 2002 Dec 10; 106:3006-8

# Surgery of the Aortic Valve & Root

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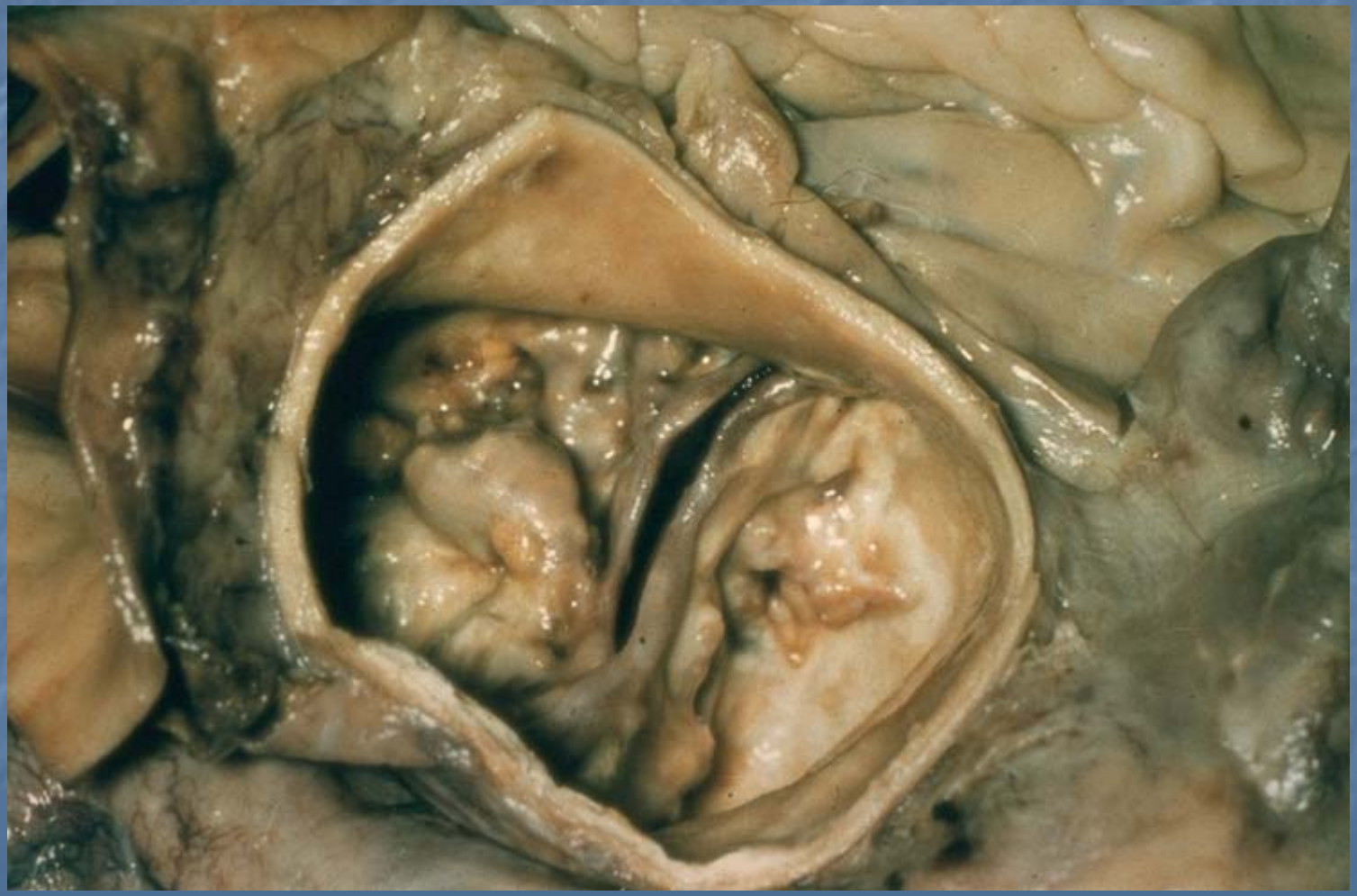
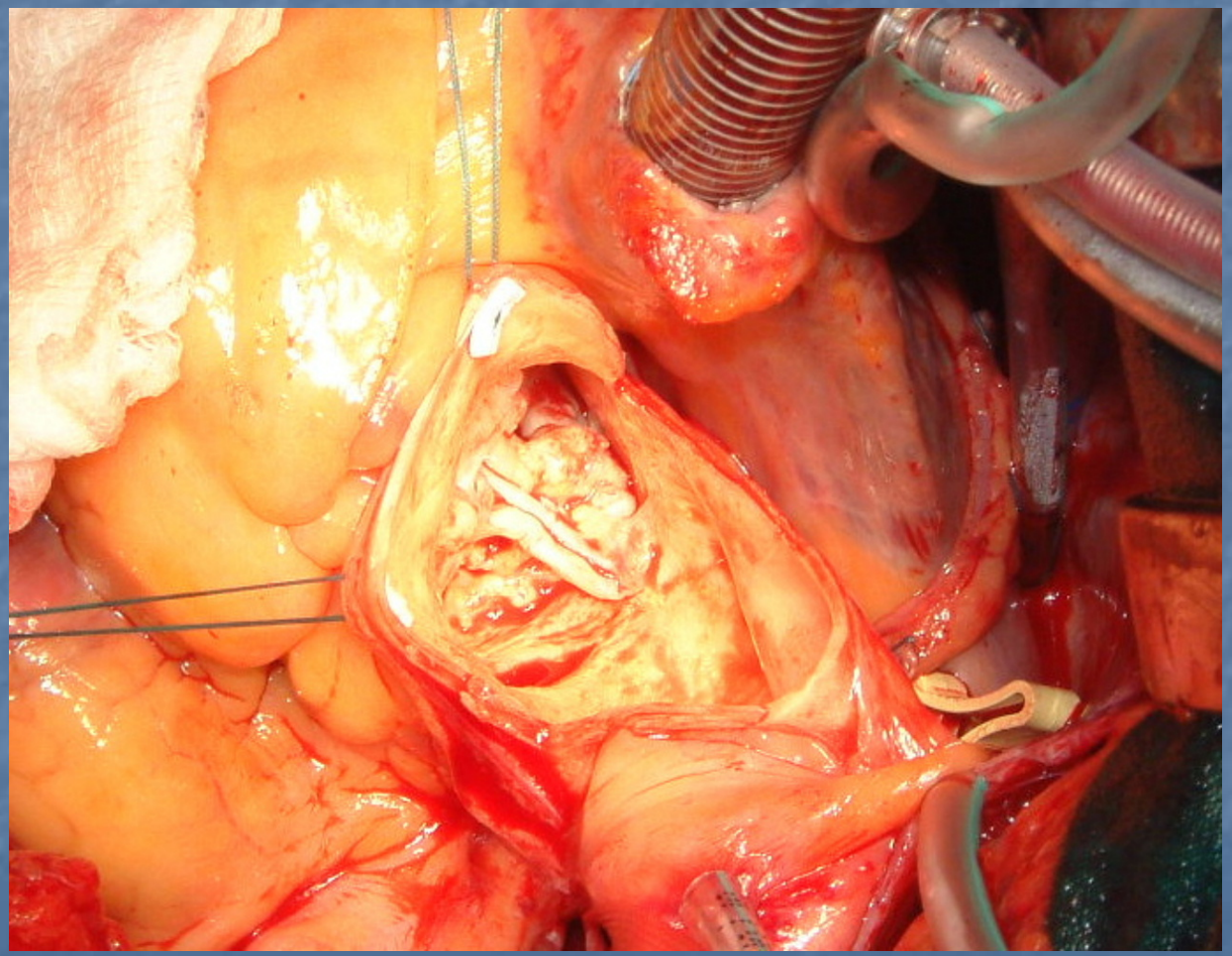


# Surgery of the Aortic Valve & Root



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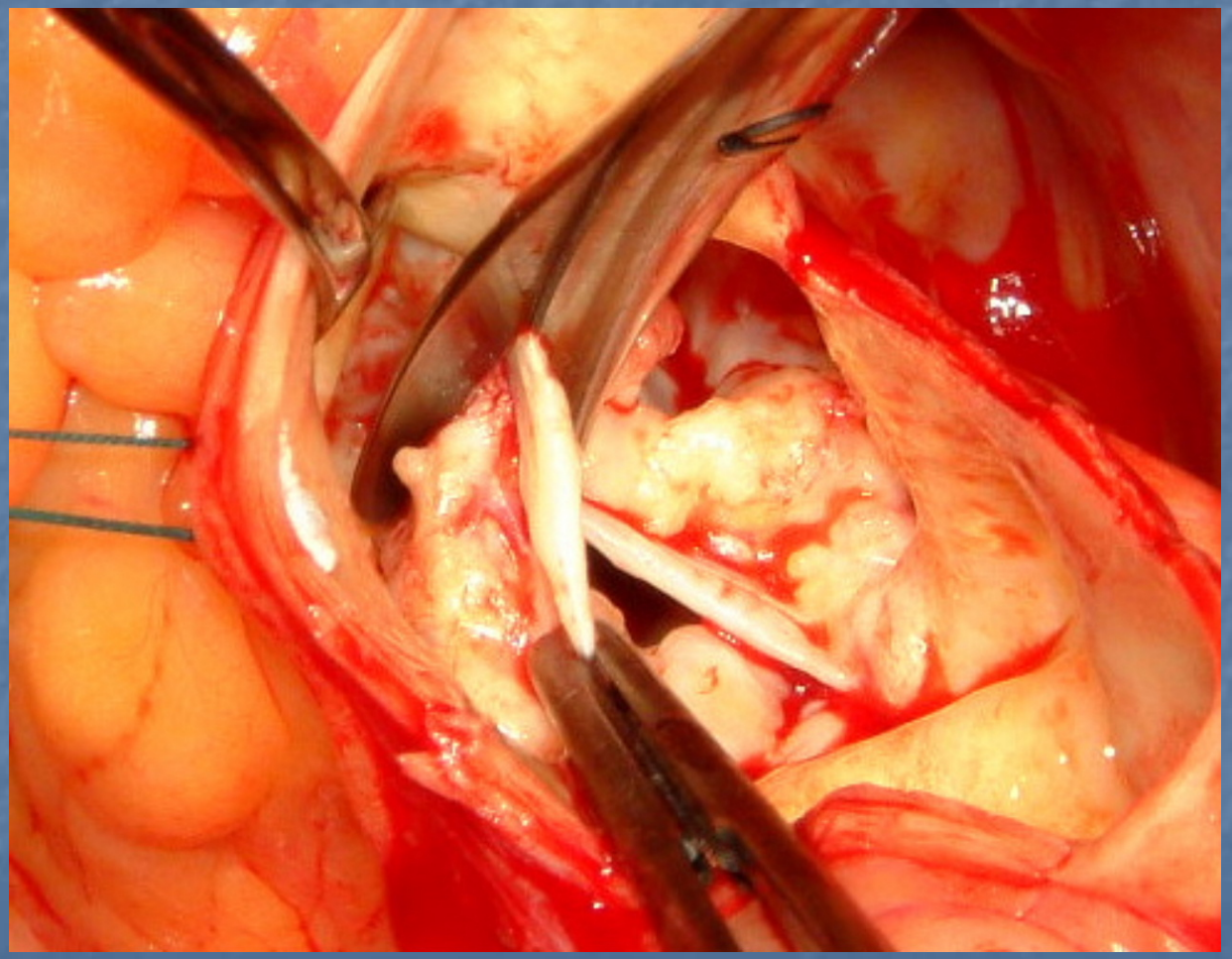
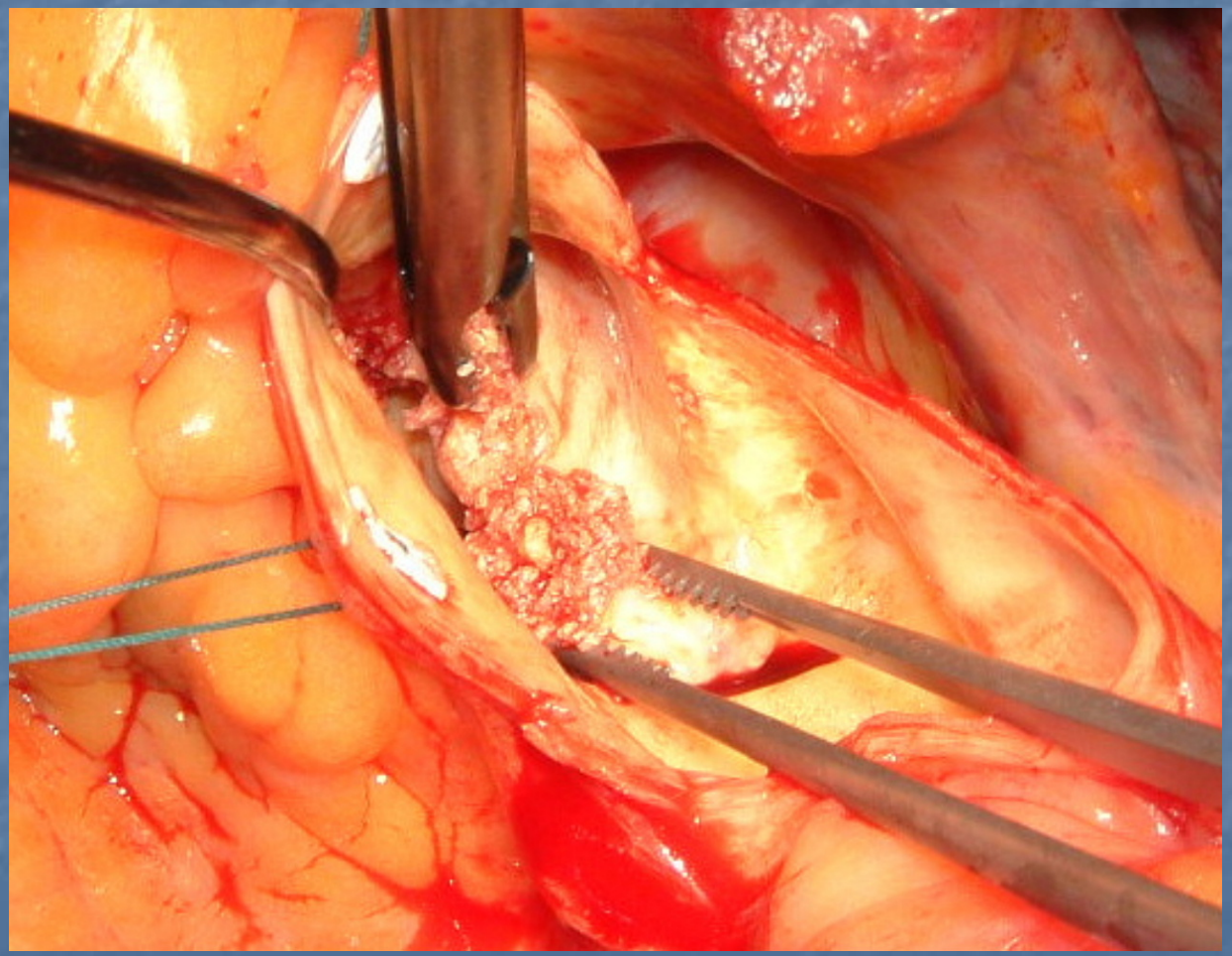
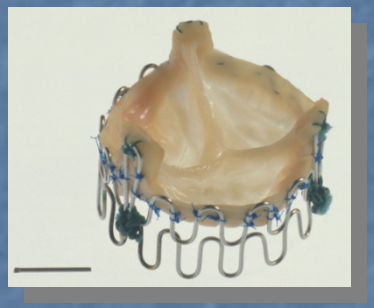


# Surgery of the Aortic Valve & Root



# Valve Evolution



Andersen Hand-made
Percutaneous Aortic Valve

Untreated
Equine Tissue

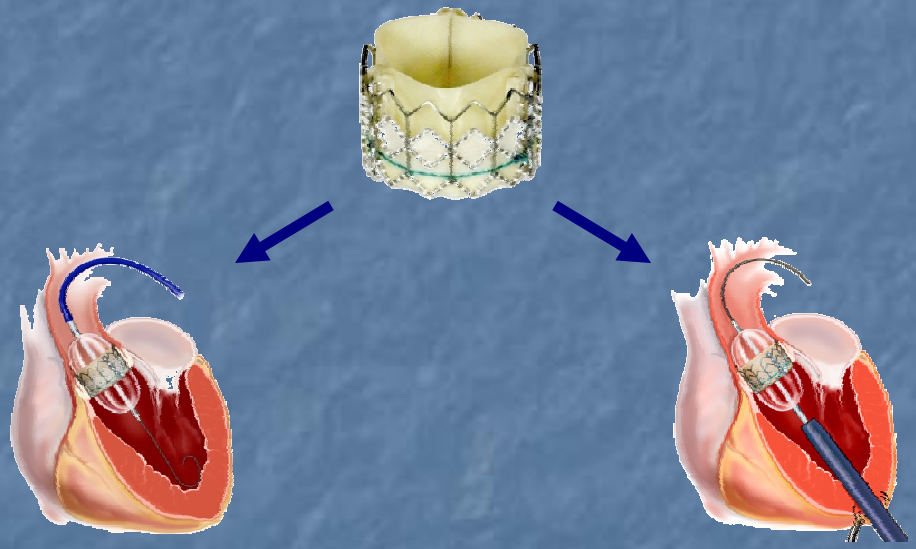
Cribier-Edwards™ THV
23mm

Treated
Bovine Tissue

Edwards SAPIEN™ THV
23mm, 26mm

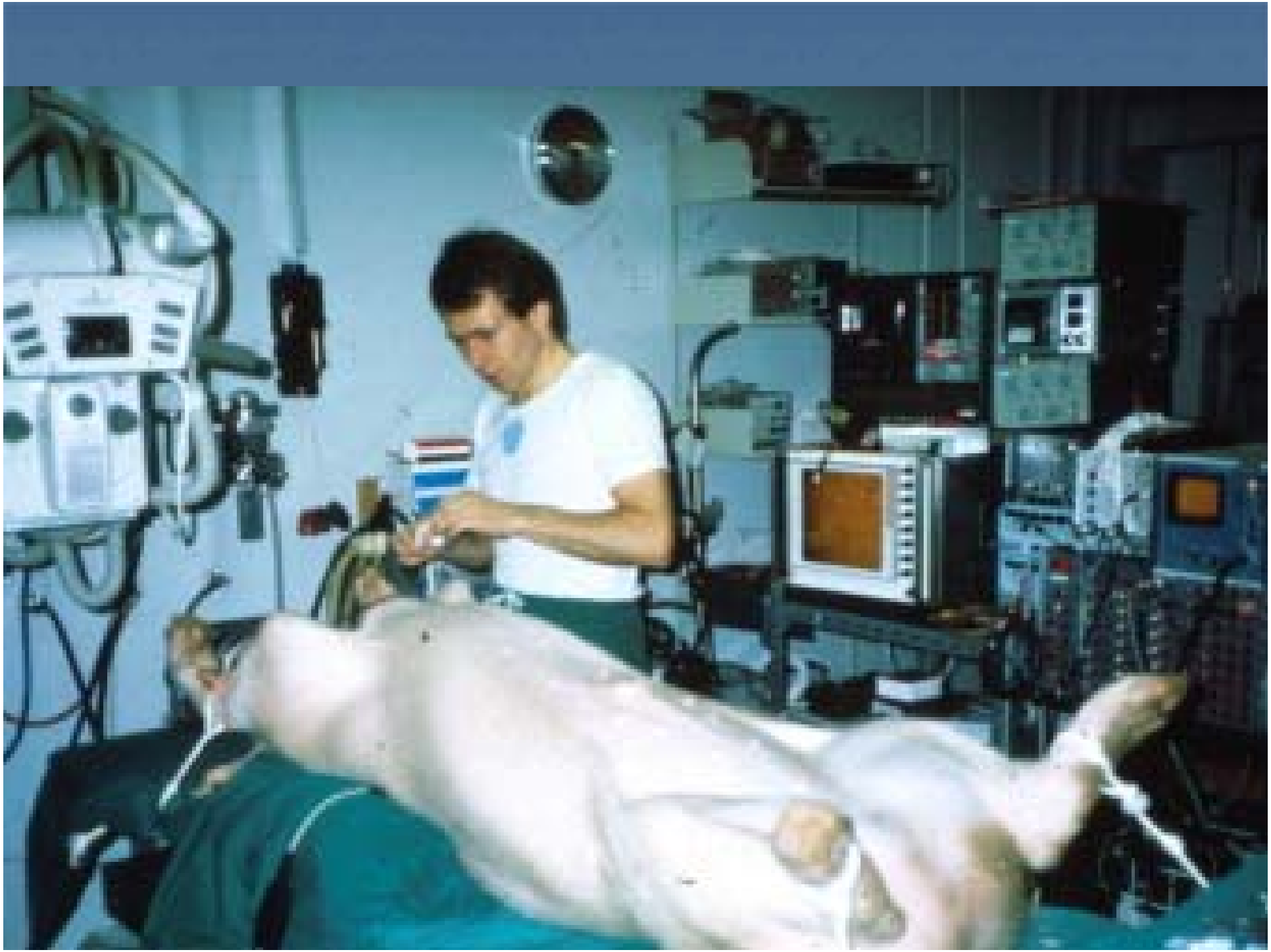
# Edwards SAPIEN™ THV

A single valve with 2 delivery options,
offers the versatility to treat
the widest range of high-risk AS patients.



Transfemoral
approach using the
RetroFlex™ Delivery System

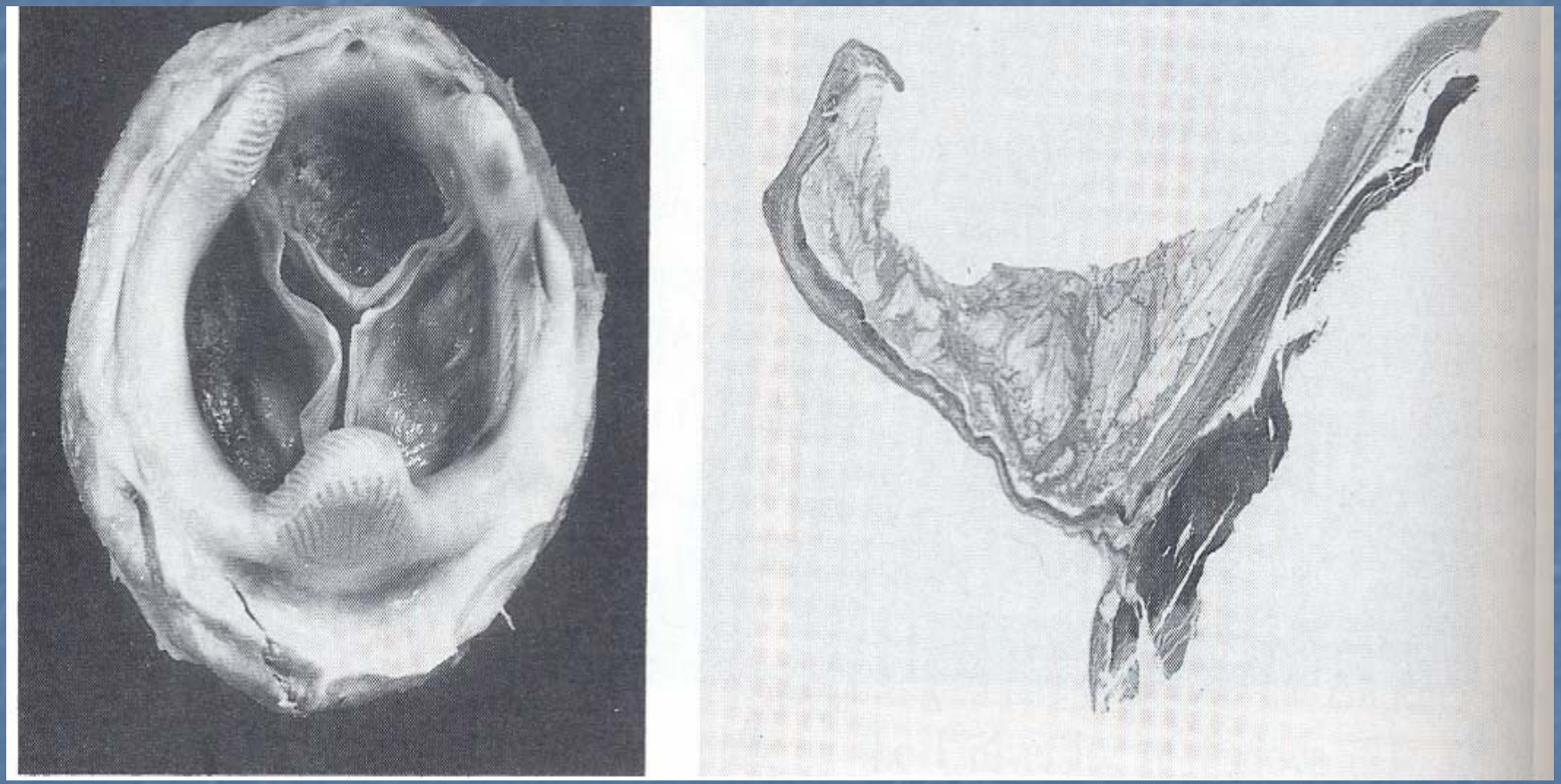
Transapical
approach using the
Ascendra™ Delivery System



# Modes of failure of tissue heart valves

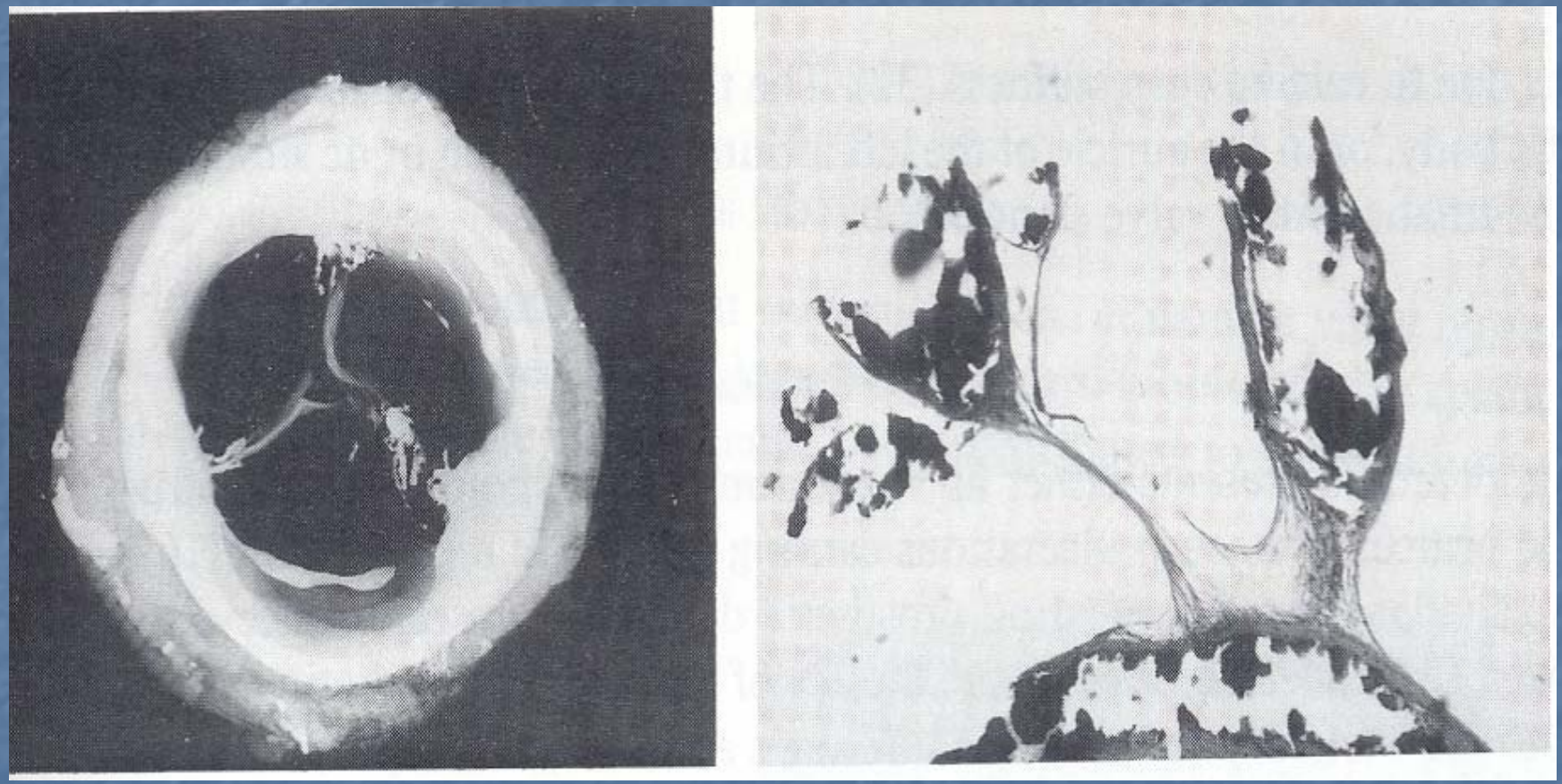
- Endocarditis
- Tissue overgrowth
- Degeneration
- Thrombosis

# Pathology



**Thrombus formation (Hancock standard)**

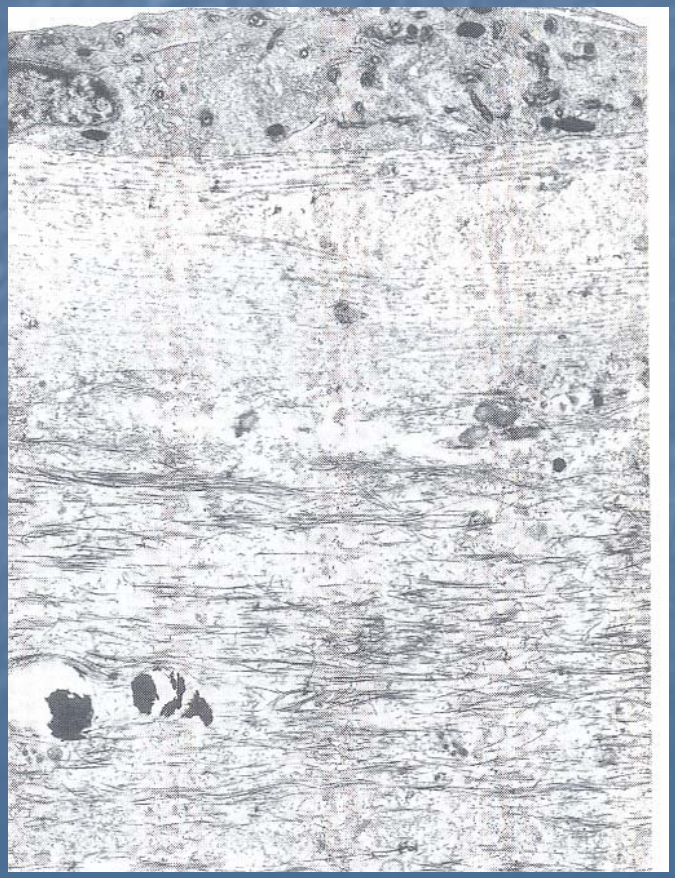
# Pathology



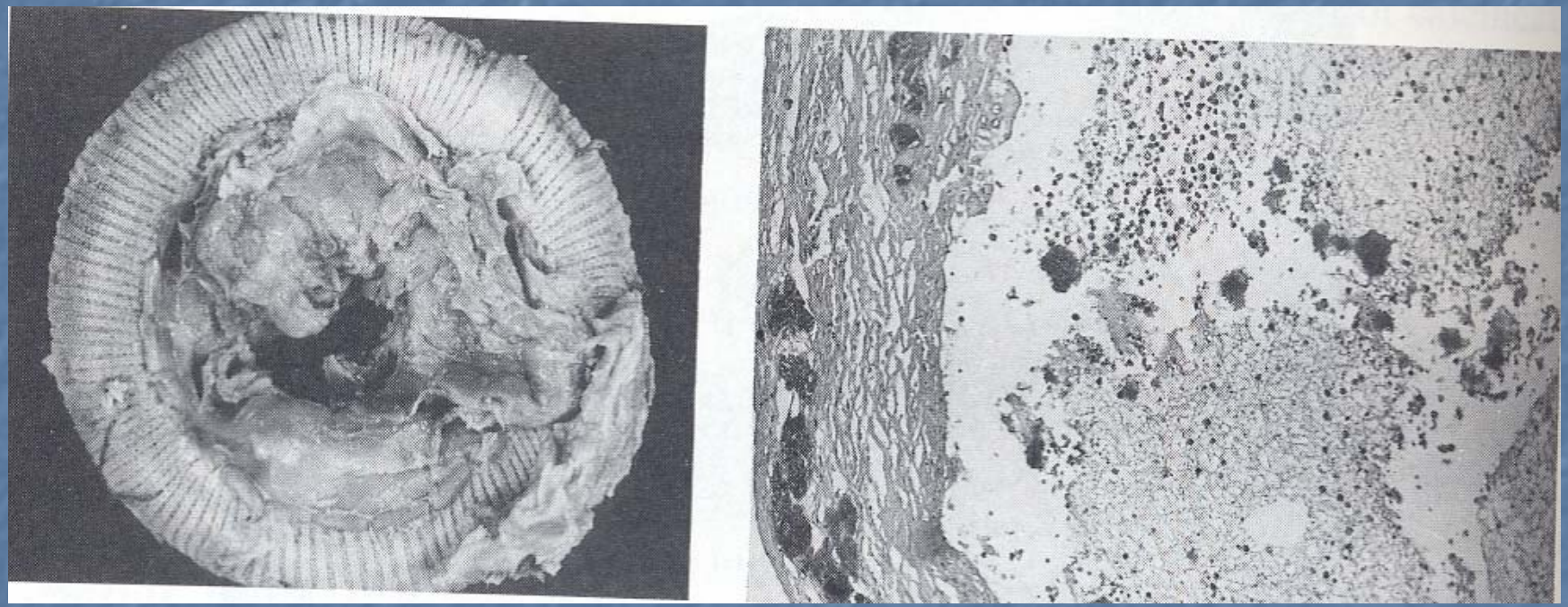
**Calcification, commissures.**
**(Hancock standard)**

Pathology, fibrous tissue overgrowth

Pathology, fibrous tissue overgrowth with calcification (Hancock Standard)

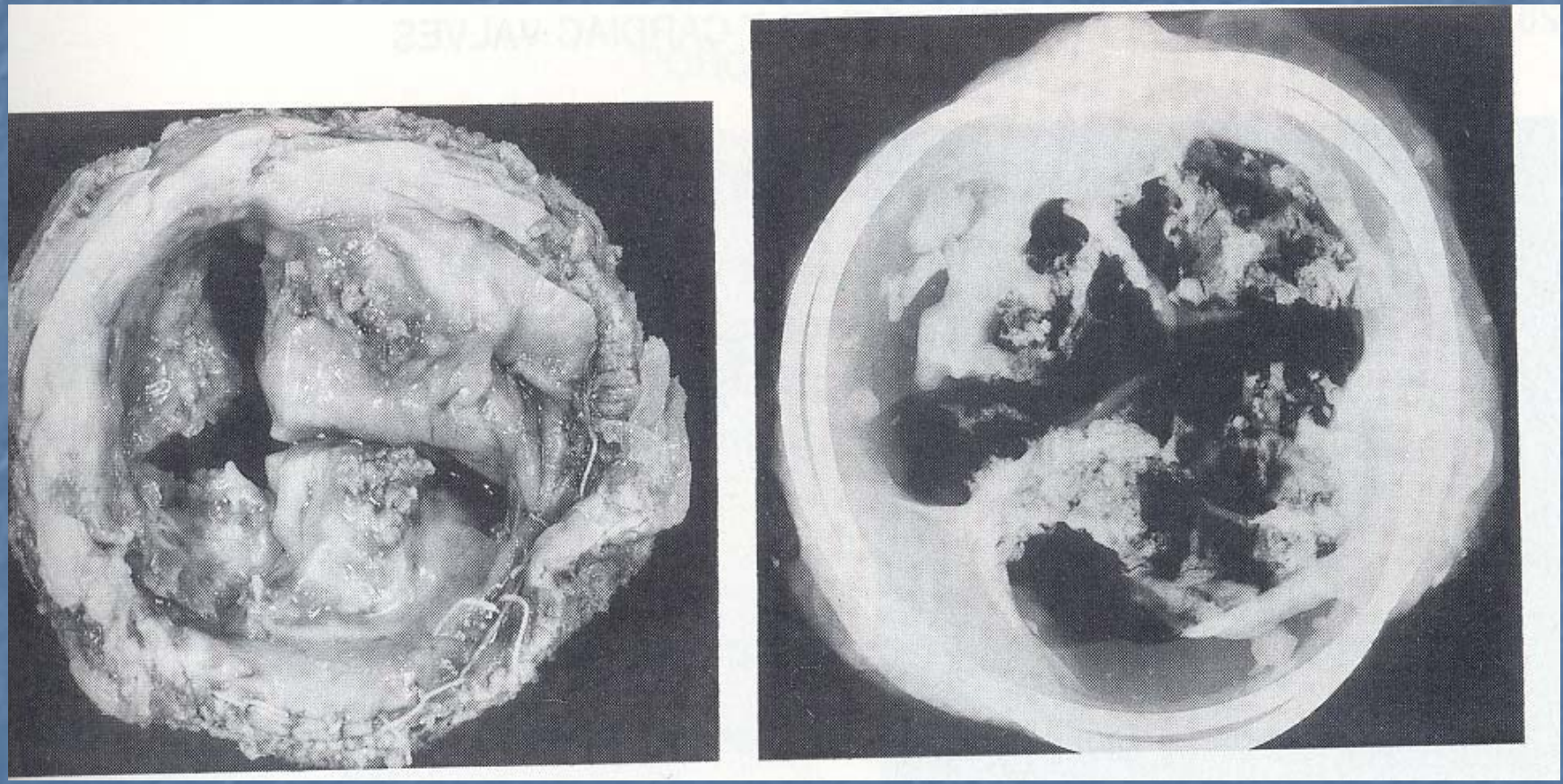


## Pathology



**Endocarditis**
**(Hancock standard)**

## Pathology



**Calcification, general. (Hancock standard).**

# Calcification

- Is one of the main factors influencing long term durability
- Progressive
- Time related phenomenons
- Involving all bioprostheses in place for more than 6 years

# Pathogenesis of calcium deposits.

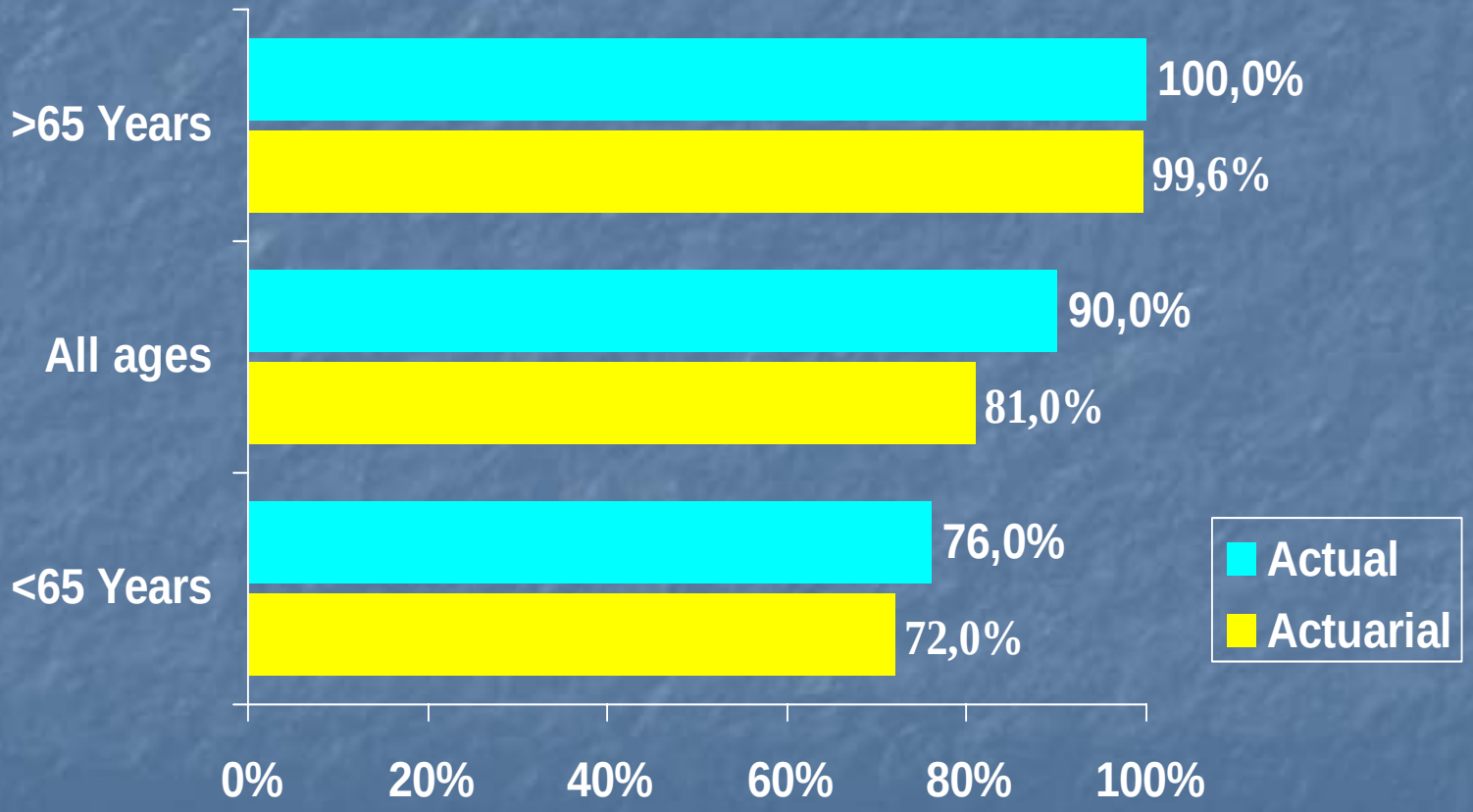
1. Metabolic factors
2. Tissue related factors
   - Pre-implantation treatment
   - Use of phosphates in the preparation solutions.
   - Loss of proteoglycans during this preparation.
   - Presence of calcium binding aminoacids in the tissues.
3. Calcium binding proteins derived from plasma and penetrate into biomaterial.

## Isihara types of anatomic degeneration of bioprosthetic valves (1982)

Type I – Tears involving the free edge of the cusps.
Type II – Linear perforation at the base of the cusps parallel to securing the ring.
Type III – Large perforation occupying the centre of the cusp.
Type IV – Small pin hole perforations in the central region of the cusp.

# Hancock II at 15 Years

## Freedom from SVD - Aortic Position




David et al. Late Results of Heart Valve Replacement with the Hancock II Bioprosthesis. J Thorac Cardiovasc Surg 2001;121;...

Cohen et al. Late Results of Heart Valve Replacement with the Hancock II Bioprosthesis. 80th Annual Meeting

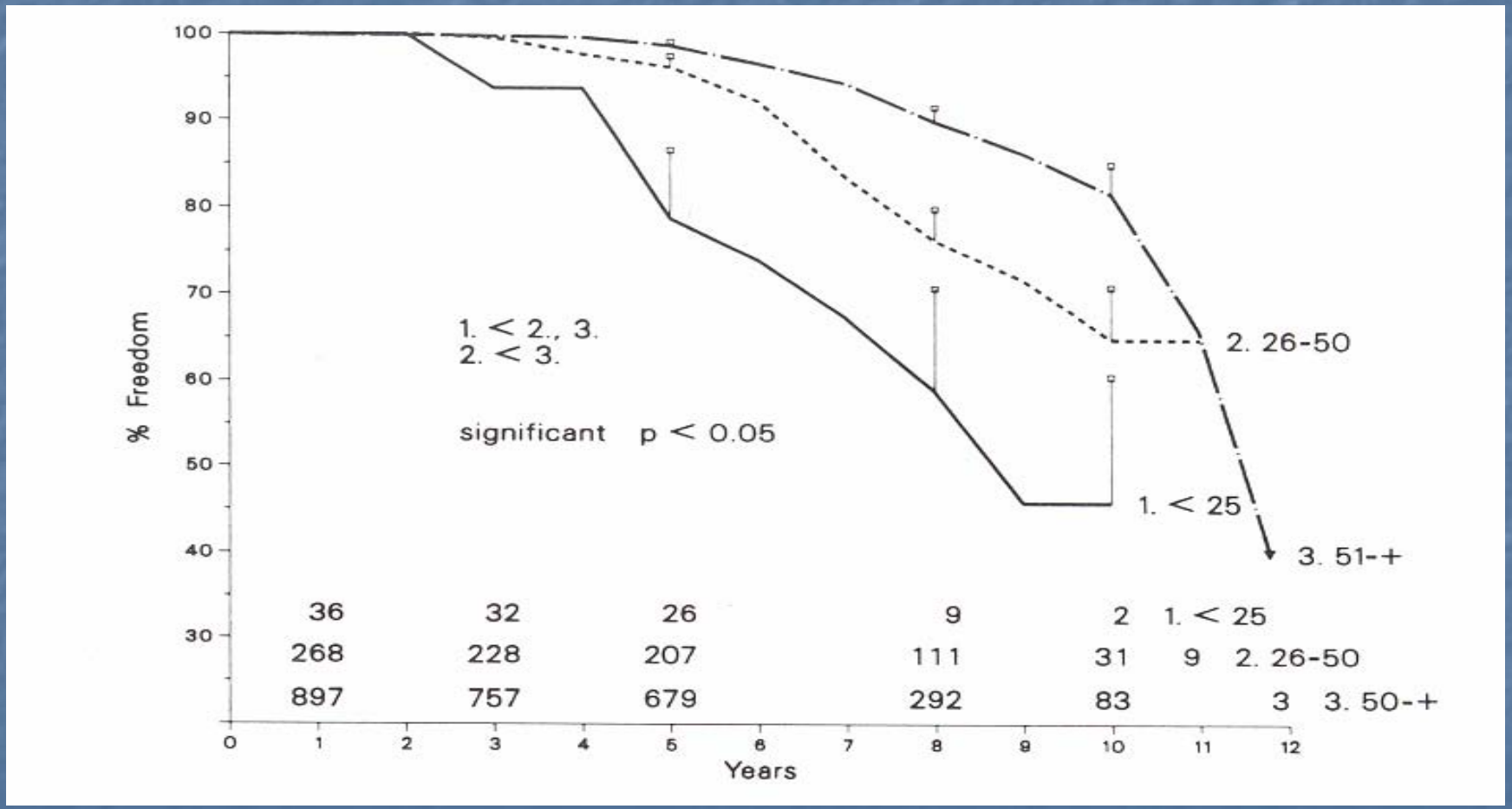
# ACTUARIAL FREEDOM SVD

- MVR 5YR 15YR

- ALL PTS 100% 70.8%
- >60YRS 100% 72%
- >65YRS 100% 75.6%

- JOURNAL OF HEART VALVE DISEASE 2006 ; 15 :49-56 GUILIO RIZZOLI PADUA TREVISO AND VENIZIA

# Structural valve deterioration (by age ranges overall)




Freedom from primary tissue failure (overall-age groups)
(University of British Columbia, Carpentier-Edwards standard).

# Modes of failure in tissue heart valves.

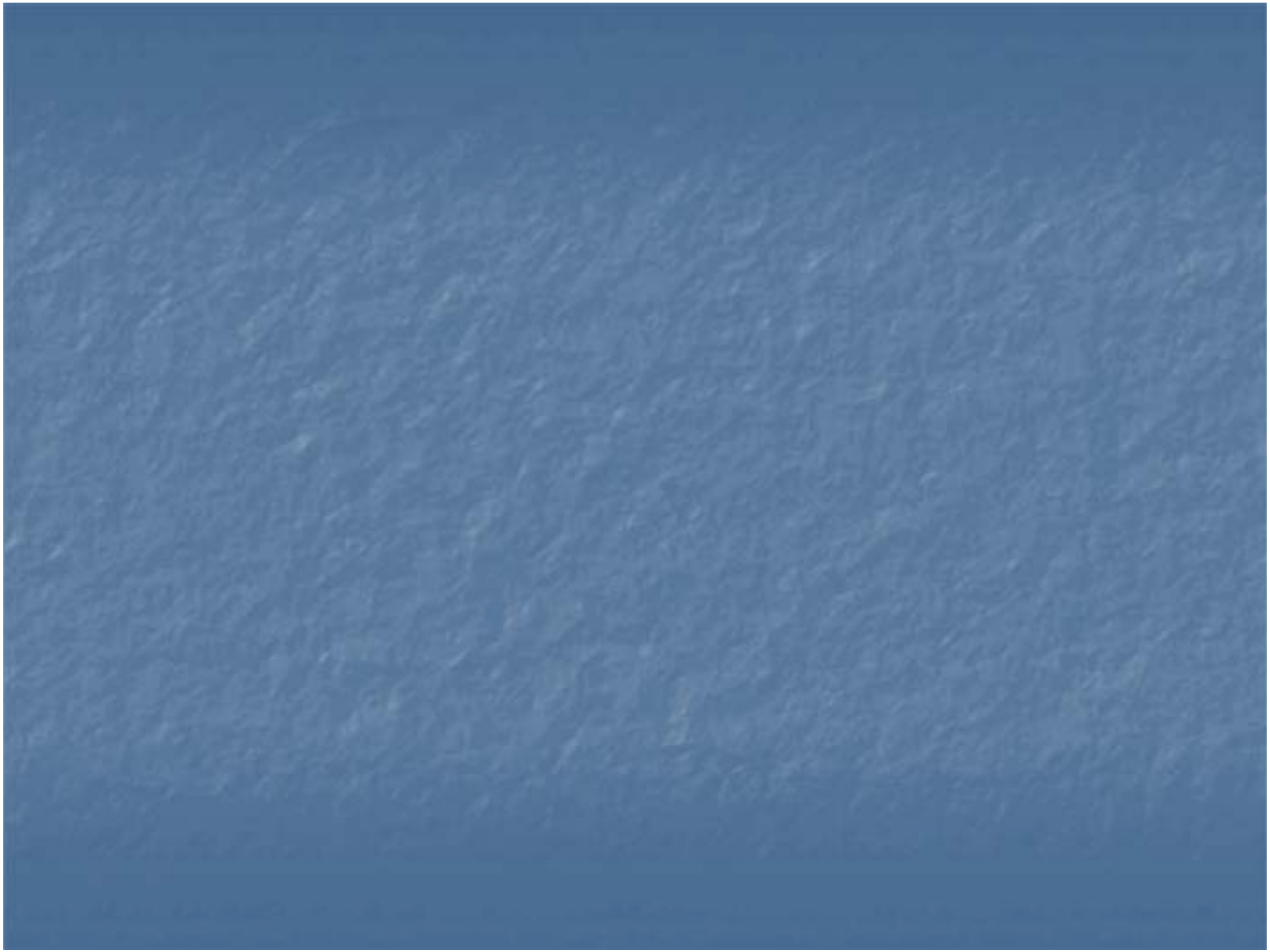
Long term results of successful valve replacement are determined by three factors:

1. Irreversible structural alterations in the heart and lungs secondary to valvular disease.
2. Occlusive coronary artery disease.
3. The mechanical reliability of the prosthesis and host tissue interactions.

# Conclusion

1. Transcatheter bioprosthetic heart valves may become ideal valves for the treatment of aortic valvular disease.

2. However because of similarity (of pre-implantation treatment, valve design, haemodynamic stress and prosthesis host tissue interaction and calcification) with surgically implanted bioprosthetic heart valves, similar late outcomes should be expected.



# Bioprosthetic Valves

Introduction of gluteraldehyde for the fixation of biological tissue by Carpentier in 1969 facilitated the use of bioprosthesis (porcine and bovine pericardium) as a satisfactory alternative to mechanical valves.

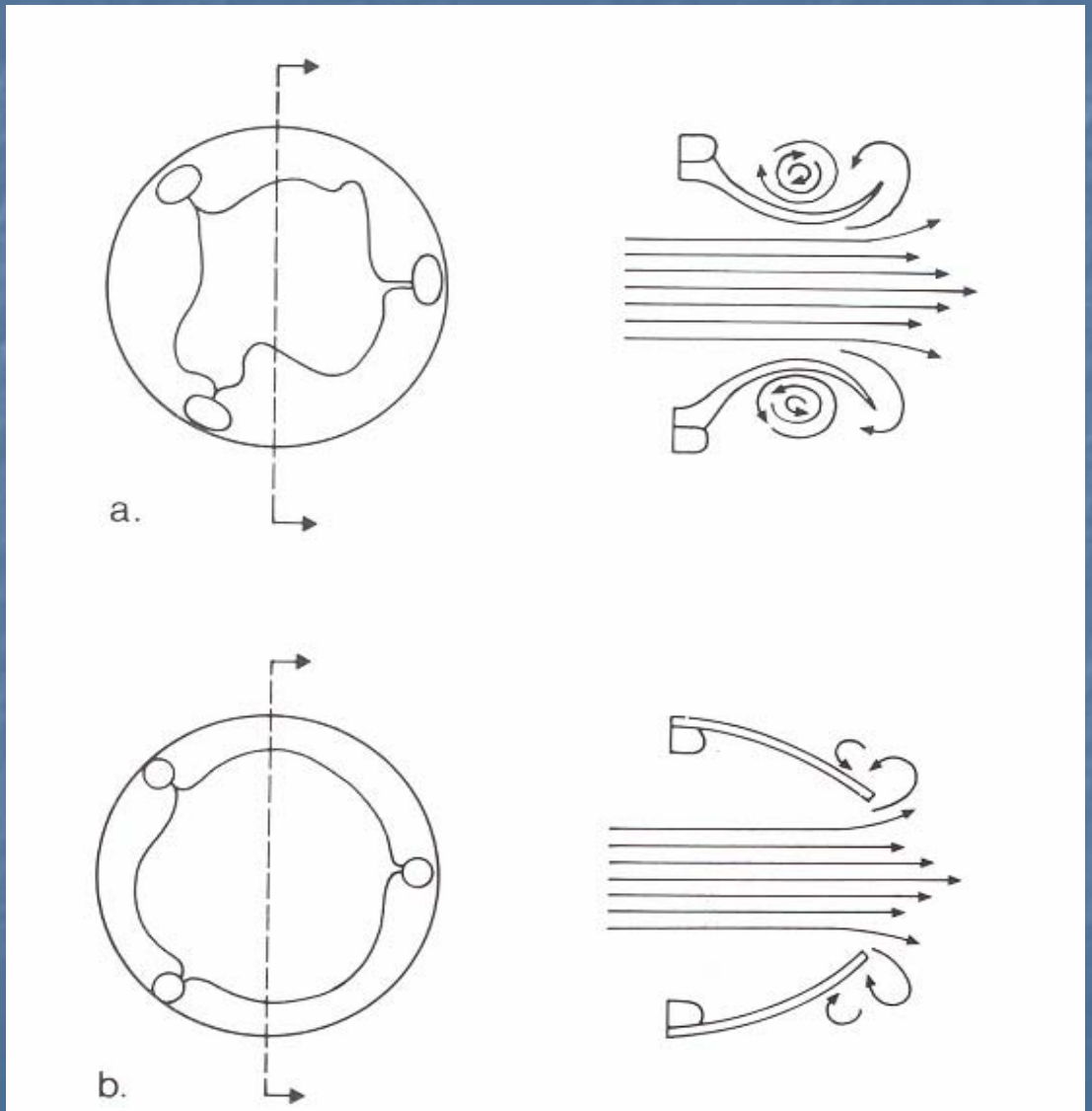
Clinical performance assessment usually considers:

- Patient survival
- Haemodynamics
- Thromboembolism
- Anticoagulant related haemorrhage.
- Valve endocarditis
- Re-operation
- Valve related mortality
- structural valve deterioration.

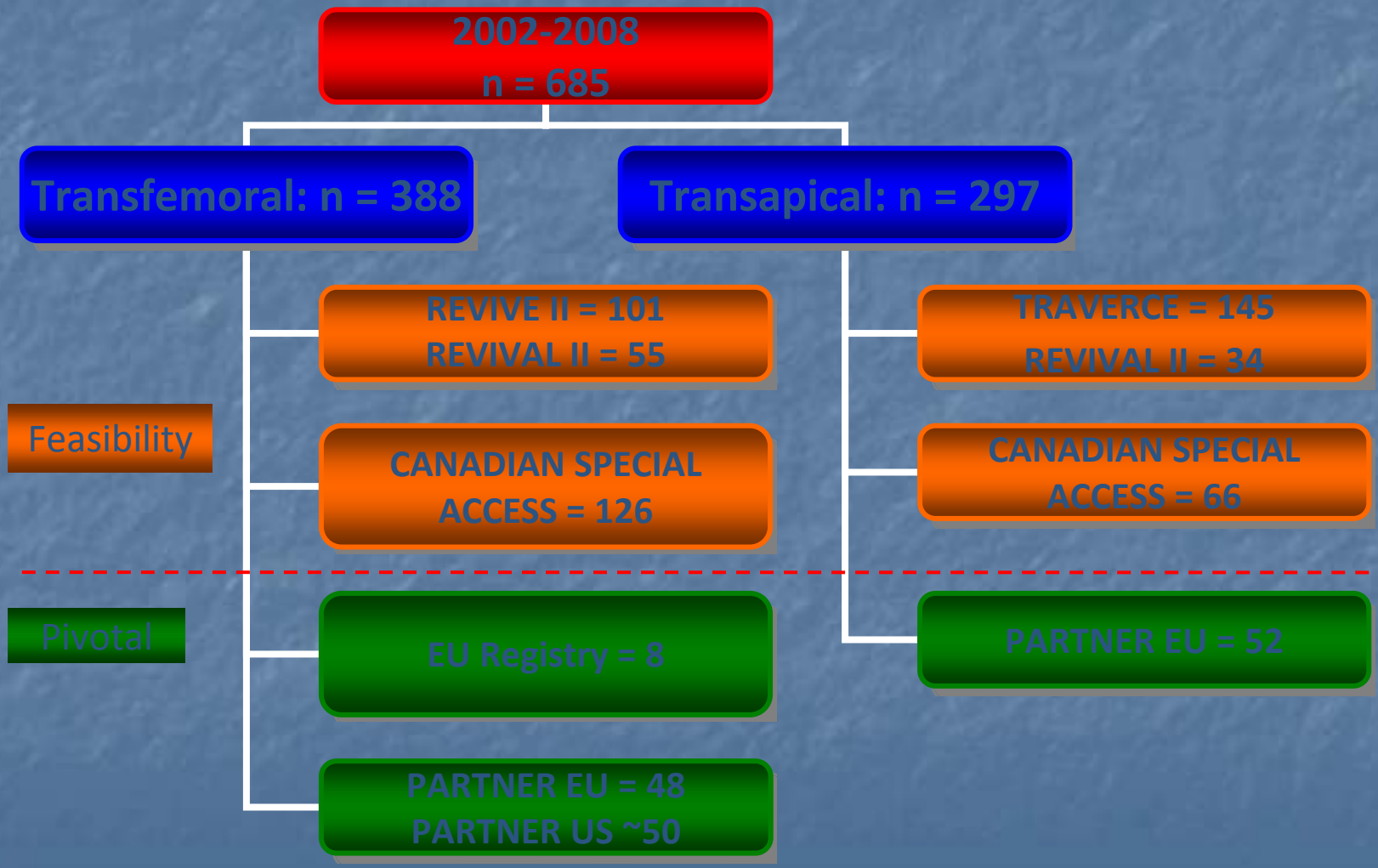
# Design & Flow Characteristics

a. **Porcine bioprosthesis**

b. **Pericardial bioprosthesis**



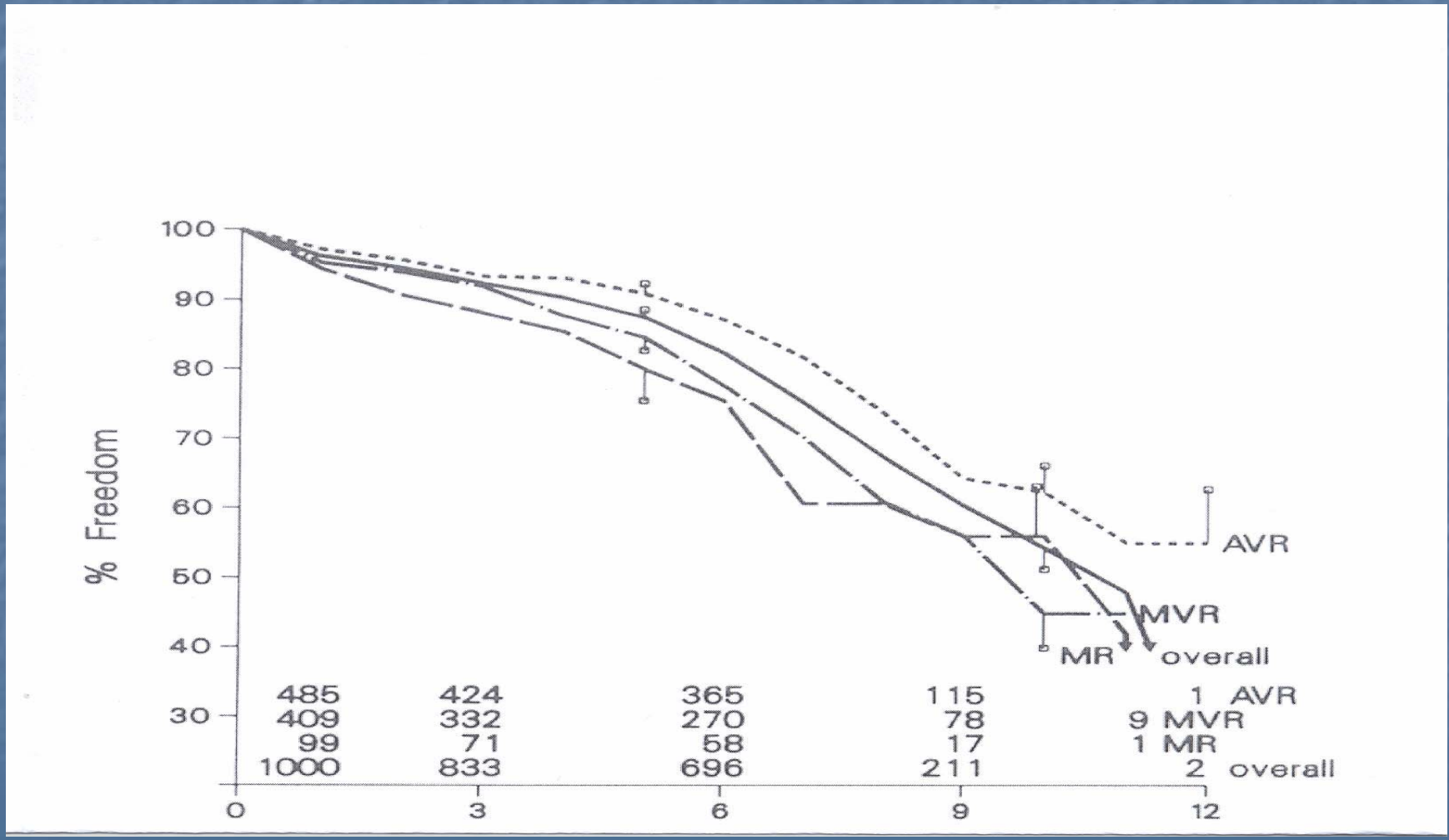
# Cribier-Edwards™ / Edwards SAPIEN™ THV*
# Aortic Implants - Transfemoral/Transapical



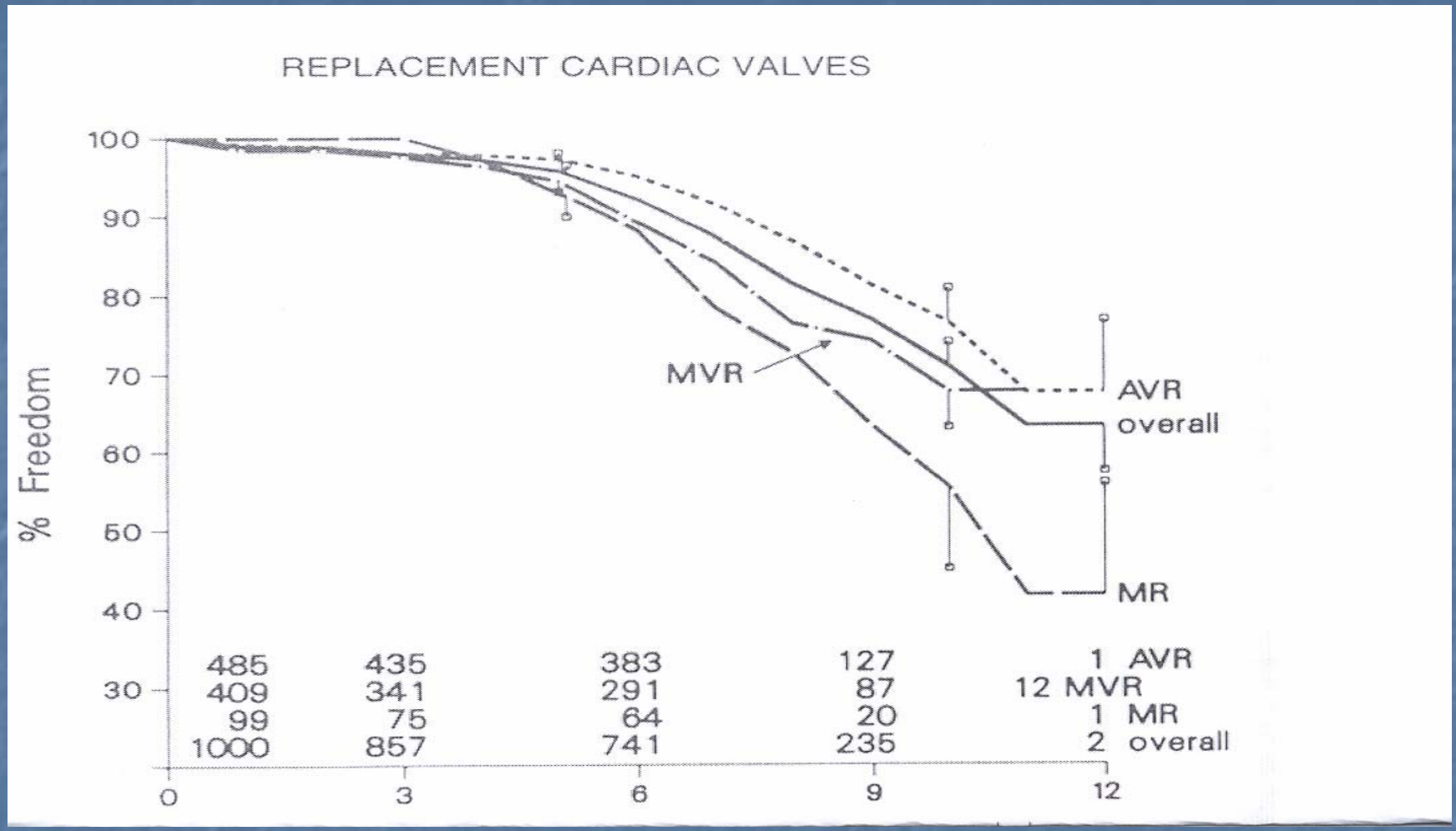

* The Edwards SAPIEN™ THV valve incorporates bovine pericardial tissue and TFX™ treatment

# Stentless Valve

# Freedom from primary tissue failure (overall) (University of British Columbia, Carpentier-Edwards standard).

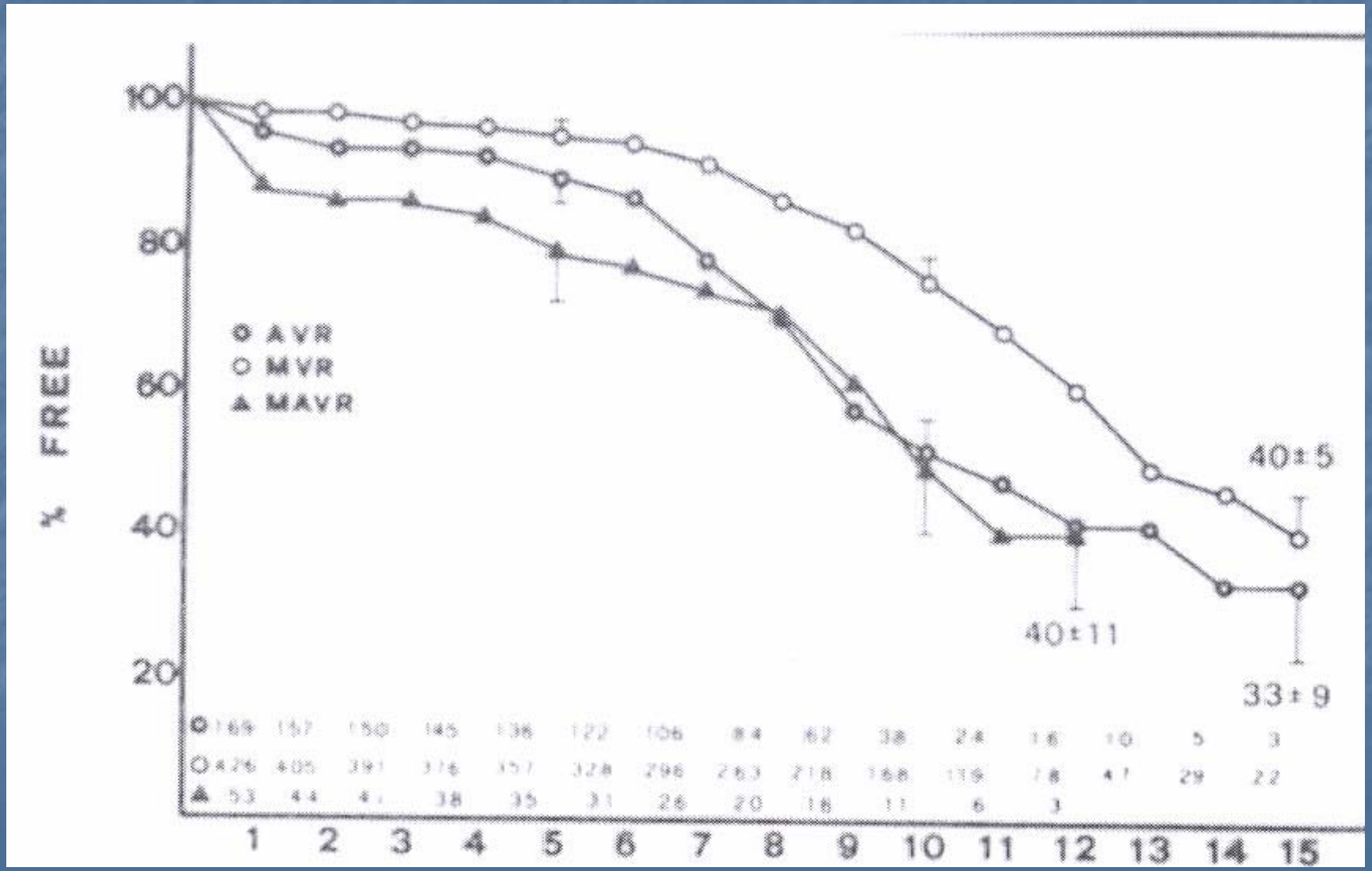


# Re-operation

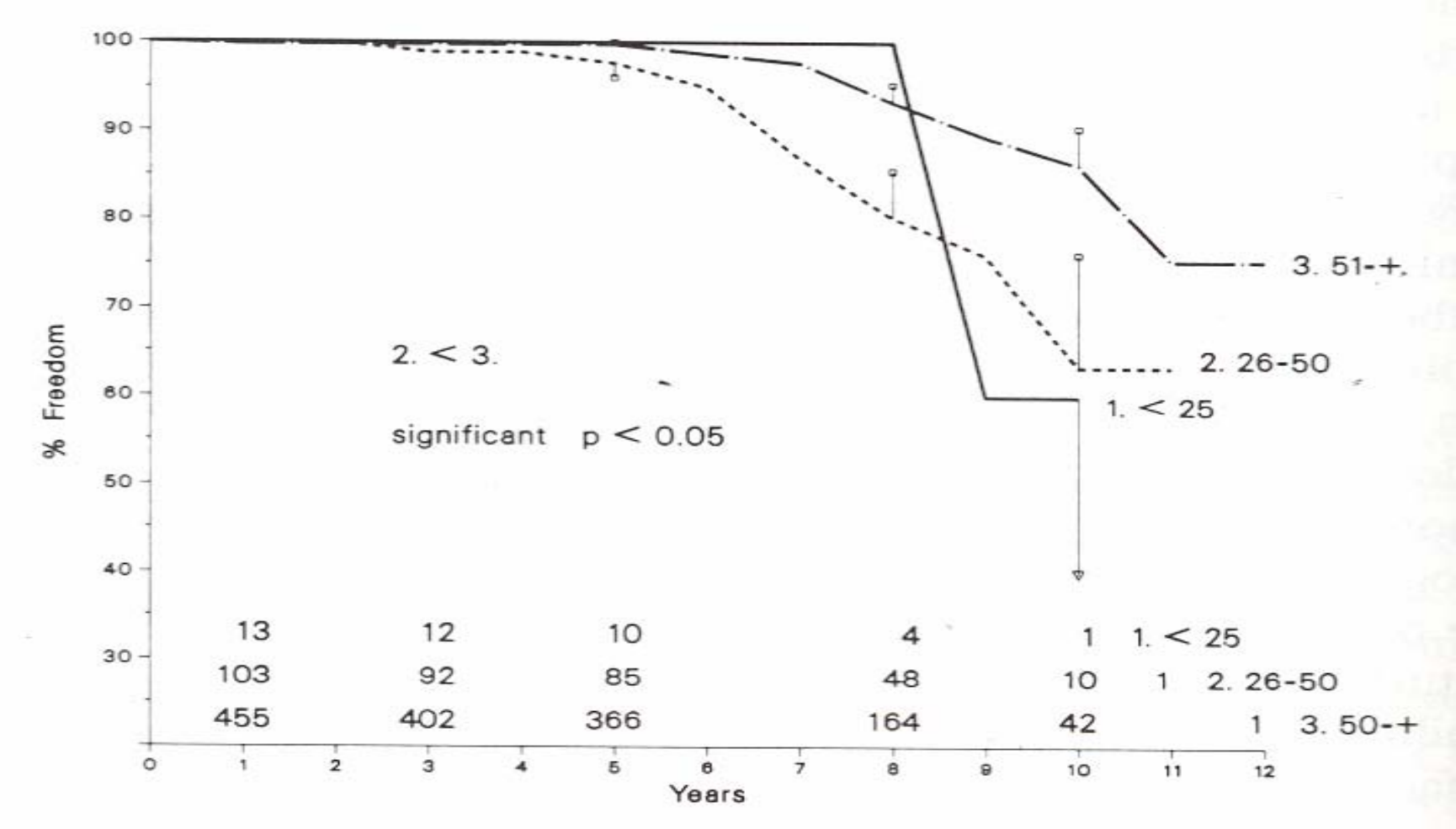



Freedom from valve-related re-operation
(University of Padova, Hancock standard).

## Freedom from valve-related (re-operation (University of British Columbia, Carpentier Edwards standard).

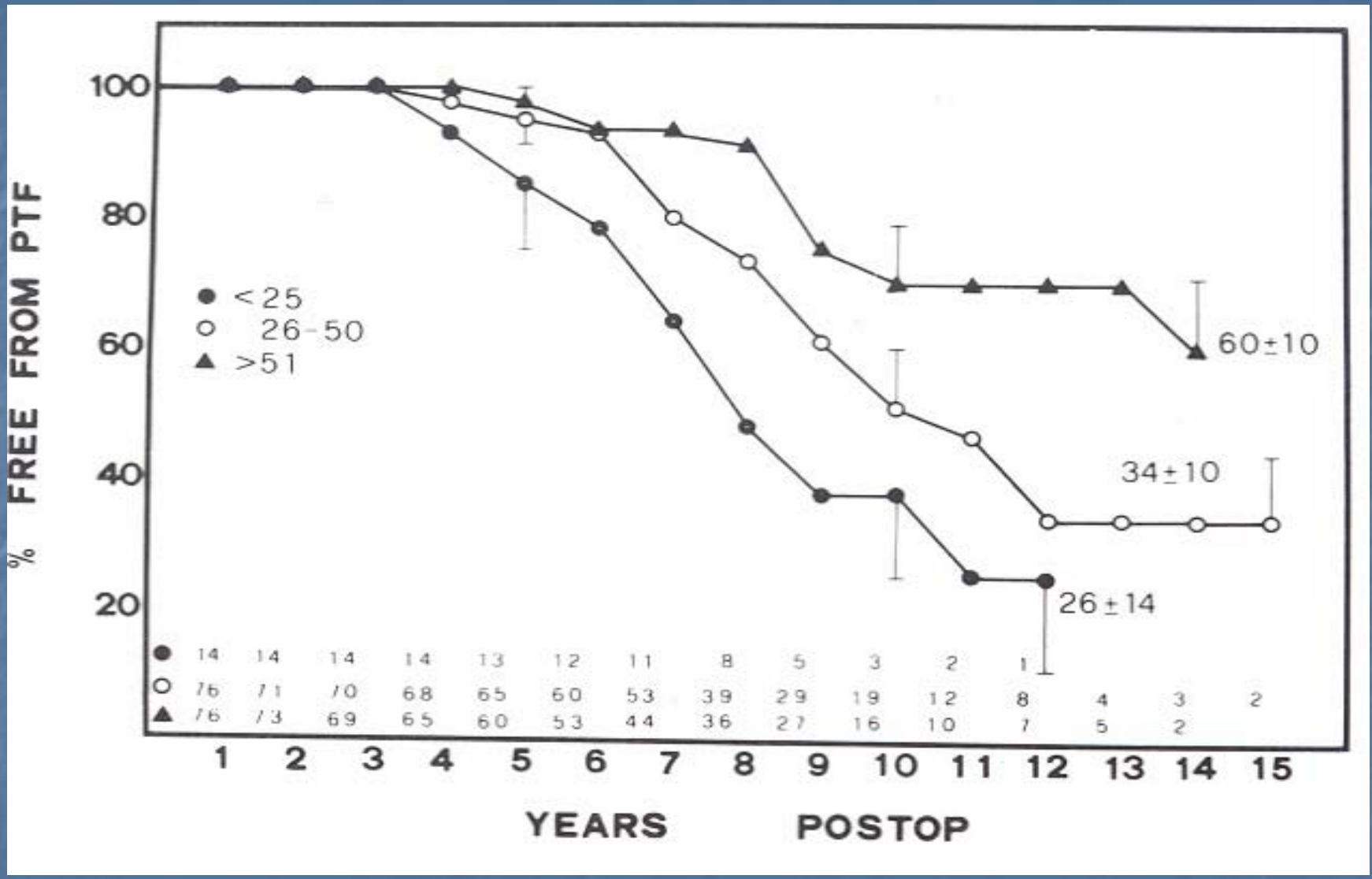


# Structural valve deterioration (by age ranges – AVR)



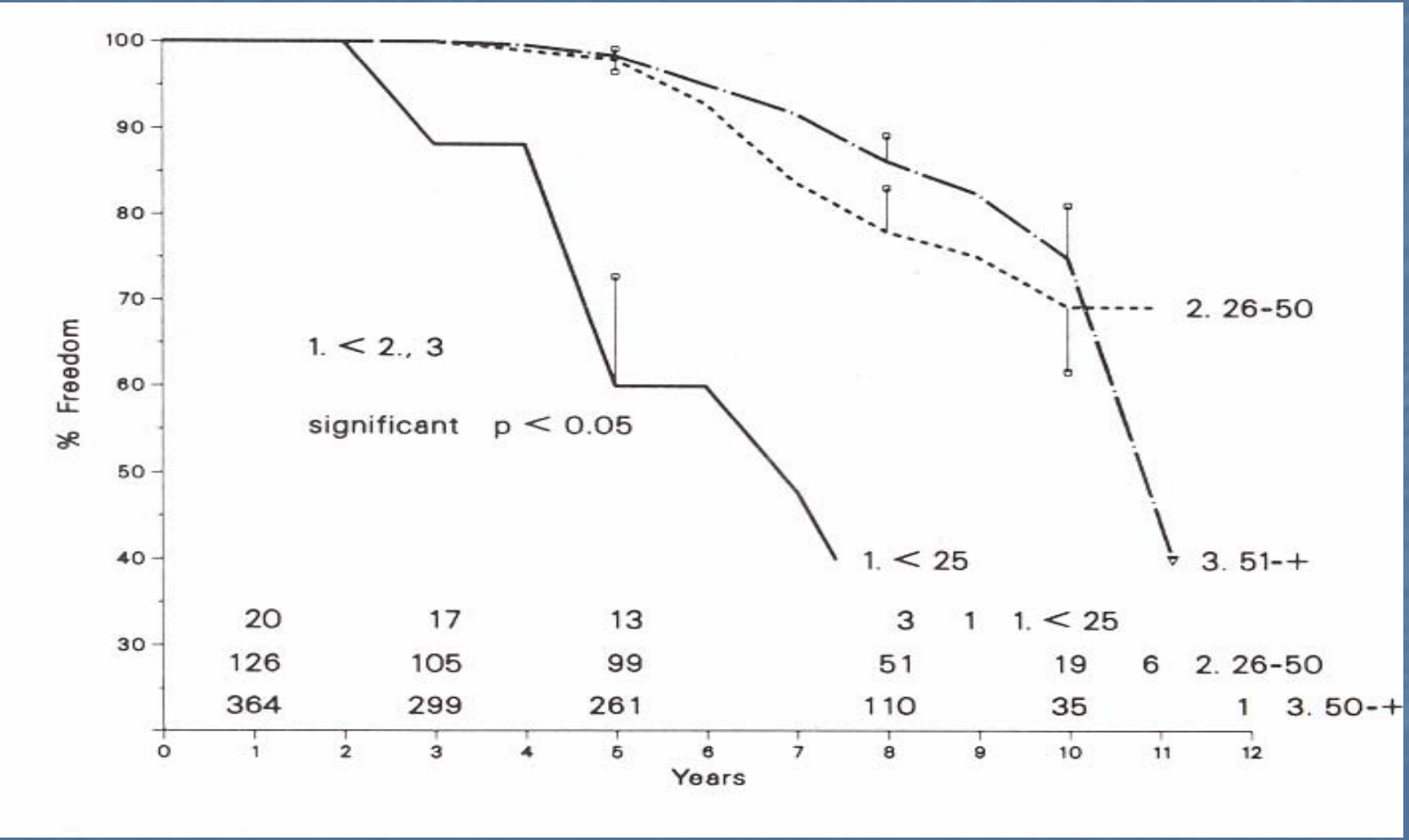

Freedom from primary tissue failure (aortic valve replacement –age groups) (University of British Columbia,Carpentier-Edwards standard).

## AVR

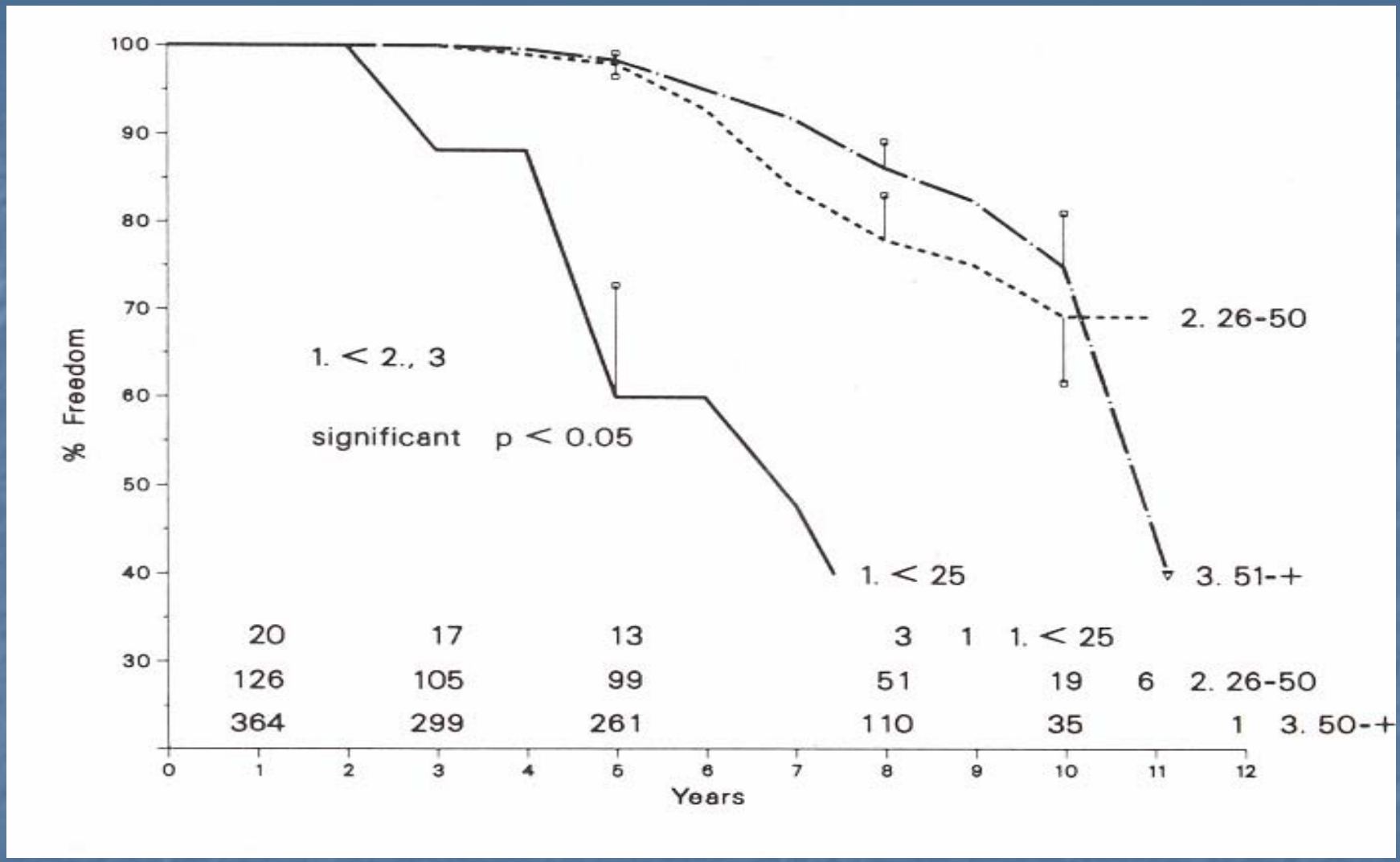



Freedom from primary tissue failure
(aortic valve replacement – age groups)
University of Padova, Hancock standard).

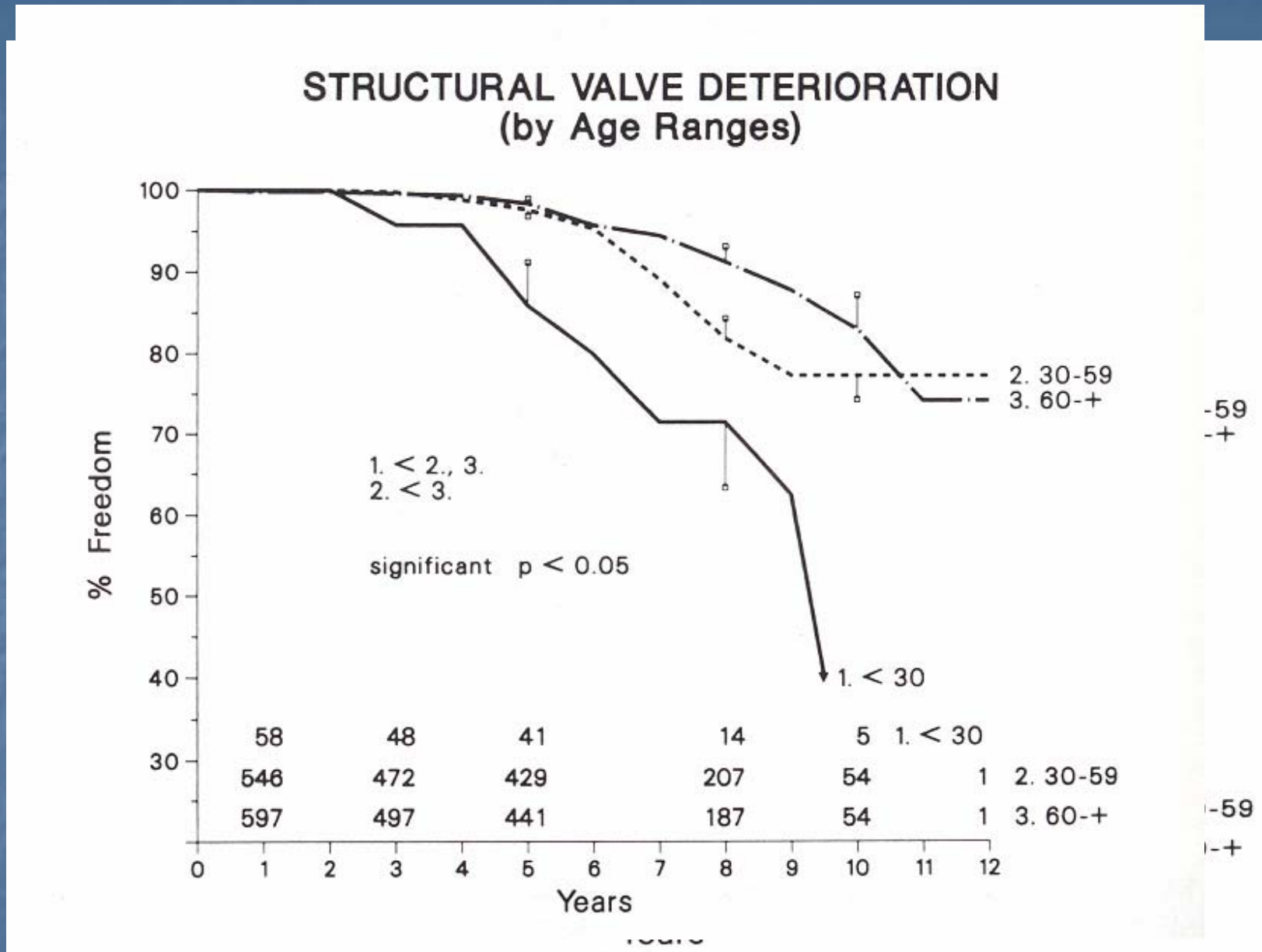
# Structural valve deterioration (by age ranges – MVR)




**Freedom from primary tissue failure (mitral valve replacement – age groups) (University of British Columbia, Carpentier-Edwards standard)**




**Freedom from primary tissue failure (mitral valve replacement-age groups) University of Padova, Hancock standard)**




**Freedom from primary tissue failure (overall-age groups)**
**University of British Columbia, Carpentier-Edwards standard)**

# Valve Related Complications and Survival Summary (% per patient per Patient Year)

| | AVR | | MVR | | Multiple | |
|---|---|---|---|---|---|---|
| | CE | H | CE | H | CE | H |
| Late mortality | 3.4 | 3.5 | 4.1 | 3.8 | 3.7 | 7.0 |
| Thromboembolism | 1.2 | 0.7 | 1.7 | 1.7 | 0.6. | 1.7 |
| fatal | 0.3 | 0.4 | 0.5 | 0.4 | 0.2. | 0.6 |
| Primary tissue failure | 1.0 | 3.9 | 1.9 | 2.6 | 3.3 | 4.1 |
| Re-operation | 1.6 | 4.9 | 2.7 | 3.0 | 3.8 | 6.1 |
| Complications (total) | 3.3 | 6.3 | 5.6 | 5.5 | 6.5 | 12.0 |

# Replacement of Cardiac Valves

Freedom from Valve-Related Complications
Mitral Valve Replacement (Carpentier-Edwards vs. Hancock).

| Complications | CE | H | |
|---|---|---|---|
| | 10 years (%) | 10 years (%) | 15 years (%) |
| Thromboembolism | 77.8 ± 5.2 | 83.5 ± 2.1 | 79.0 ± 3.4 |
| Primary tissue failure | 71.8 ± 4.9 | 78.8 ±2.6 | 41.0 ± 5.5 |
| Re-operation | 67.6 ± 4.6 | 75.7 ± 2.7 | 39.8 ± 5.4 |
| Mortality | 82.2. ± 4.3 | 90.1 ± 1.6 | 84.6 ± 4.1 |
| Complications (total) | 44.8 ± 5.0 | 56.0 ± 2.9 | 20.2 ± 4.1 |

## Freedom from Valve-Related Complications
## Multiple Valve Replacements
## (Carpentier-Edwards vs Hancock)

| | CE | H | |
|---|---|---|---|
| Complications | 10 years | 10 years (%) | 12 years (%) |
| Thromboembolism | 96.3 ± 2.1 | 87.2 ± 5.0 | 82.2 ± 5.0 |
| Primary tissue failure | 65.8 ± 7.9 | 59.5 ± 10.9 | 49.0 ± 13.0 |
| Re-operation (VR) | 55.3 ± 10.4 | 49.7 ± 10.2 | 40.7 ± 11.7 |
| Mortality (VR) | 87.8 ± 6.5 | 74.3 ± 6.7 | 74.3 ± 6.7 |
| Complications (total) | 55.9 ± 7.2 | 26.5 ± 7.8 | 18.9 ± 8.5 |

# ACTUARIAL FREEDOM SVD

| AORTIC | 5YR | 15YR |
|---|---|---|
| ALL PTS | 100% | 84.7% |
| >60YRS | 100% | 93.3% |
| >65YRS | 100% | 94.2% |

JOURNAL OF HEART VALVE DISEASE 2006 ; 15 :49-56 GUILIO RIZZOLI PADUA TREVISO AND VENIZIA

## Pathology of biological valve degeneration.

Degeneration of biological valves is related to:

1. Leaflet rupture.
2. Leaflet calcification.

- Mechanical stress plays an important role.
- Calcification starts at the commissures.
- Calcification has three characteristic features:
    1. Early intrinsic starts at the commissures.
    2. Intrinsic calcification involving the annulus of the three cusps.
    3. Extrinsic calcification (large calcium nodules) in the centre of leaflets.