TCT Asia 2006

Percutaneous Aortic Valve Implantation

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Siegburg - Stanford

Optimal therapy for valve disease…

It doesn’t take a genius to realize that we need better therapy solutions for elderly patients with end-stage aortic stenosis!!!

Outcome of AVR in High Risk Patients with severe AS

Study	# pts	High risk features	In-Hosp mortality	Late mortality
Brogan (1993)	18	↓ LVEF + ↓ gradient	33%	na
Powell (2000)	55	LVEF ≤ 30%	18%	na
Jegaden (1986)	71	LVEF ≤ 40%	10%	5yr – 28%
Connolly (2000)	52	LVEF ≤ 35% + ↓ gradient	21%	3yr – 29%
Pereira (2002)	68	LVEF ≤ 35% + ↓ gradient	8%	1yr – 18%
Sundt (2000)	133	≥ 80 yo	11%	1yr – 20%
Mortasawi (2000)	105	≥ 80 yo	9%	1yr – 10%
Kohl (2001)	83	≥ 80 yo	13%	1yr – 14%
Bloomstein (2001)	180	≥ 70 yo	17%	na
Bernard (1992)	23	> 75 yo	9%	17%

Surgical AVR - Mortality

Overall Operative Mortality (1994-2004)*

Isolated AVR	**4.0%**
AVR + CABG	**6.8%**

***Society of Thoracic Surgeons National Cardiac Database**

EuroSCORE and long-term survival**

	5ys	10ys
Lowest risk quartile (<5)	90%	78%
Highest risk quartile (>11)	55%	35%

****Toumpoulis et al**

Surgical AVR - Mortality

EuroSCORE - Example

76 y/o, female

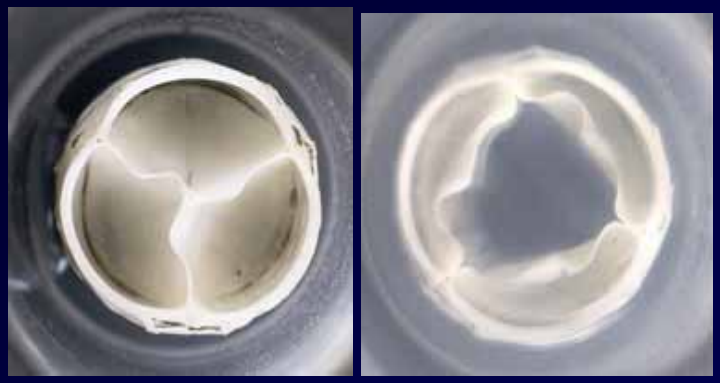
Previous CABG

LVEF 38%

Predicted operative mortality: 12,41%
(Logistic EuroSCORE)

Balloon expandable AV Prosthesis

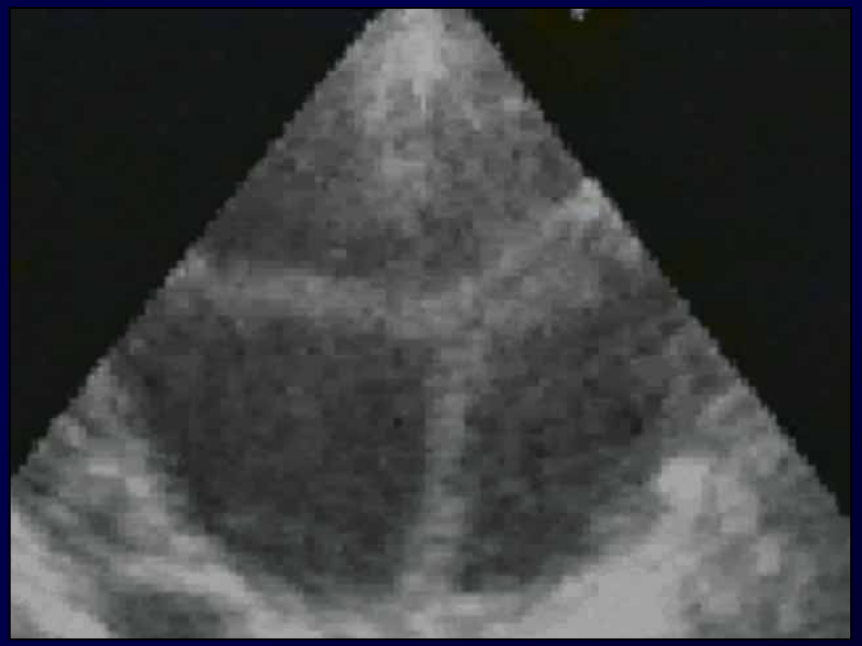
Percutaneous Valve Technologies, NJ – USA



First generation – polyurethane

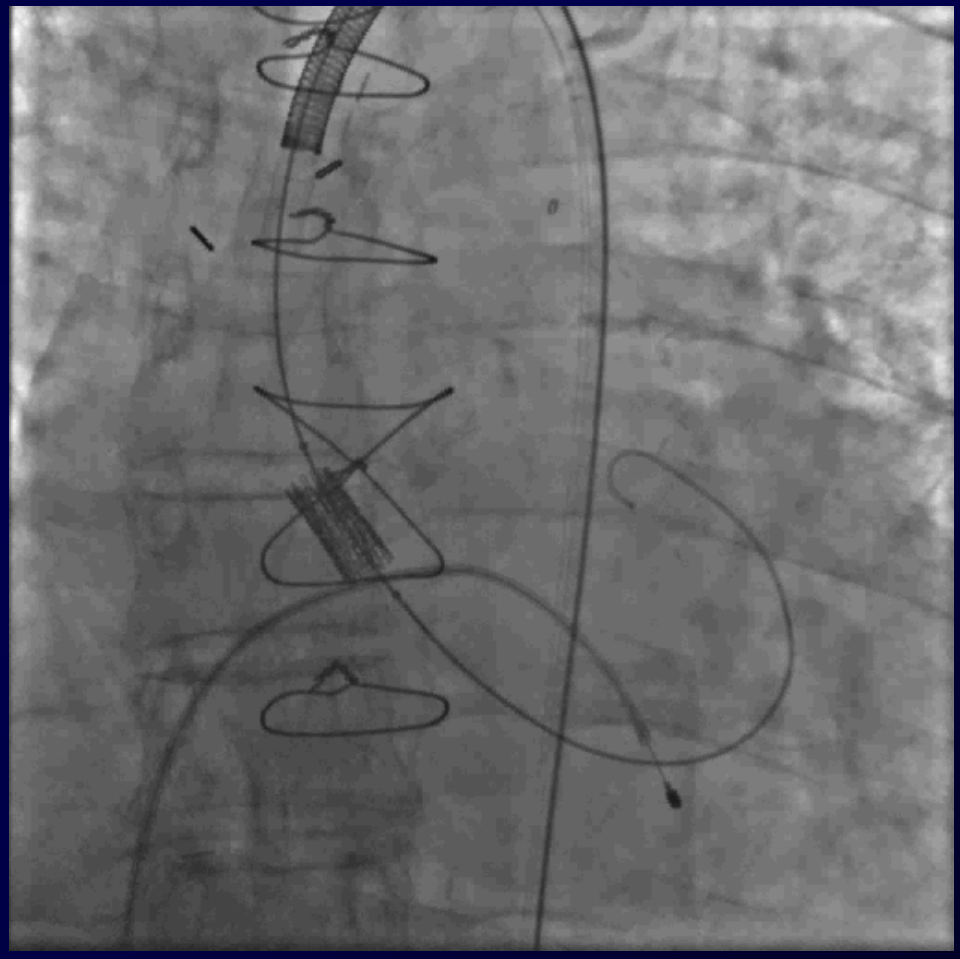
Second generation – Bovine pericardium

Animal Implants



AVA
1.7 cm²

Cribier-Edwards Aortic Bioprosthesis



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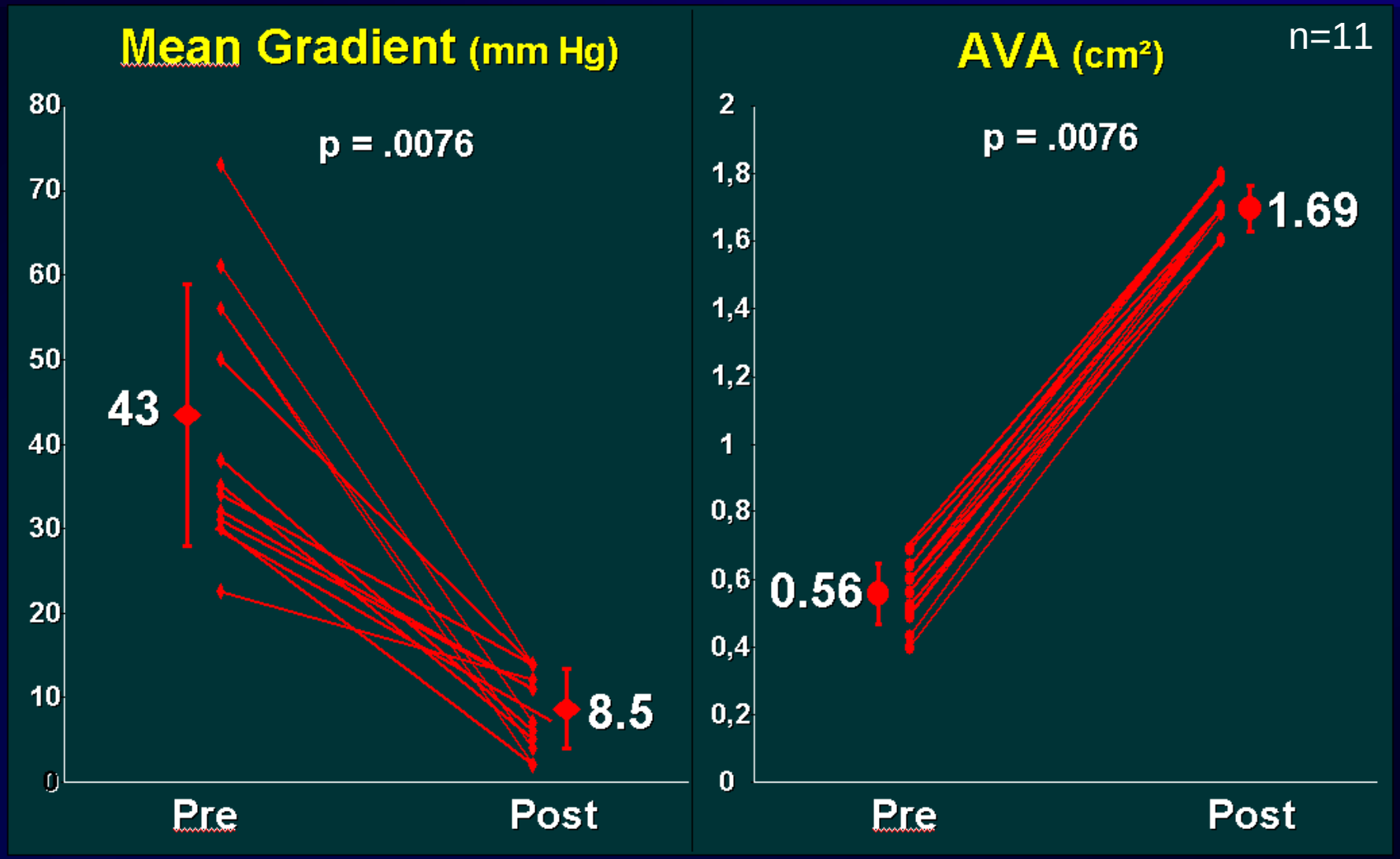
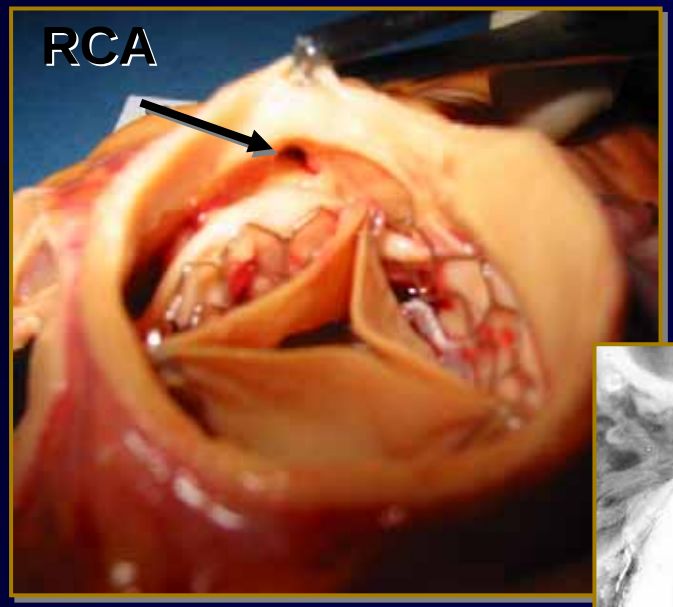
Balloon expandable AV Prosthesis

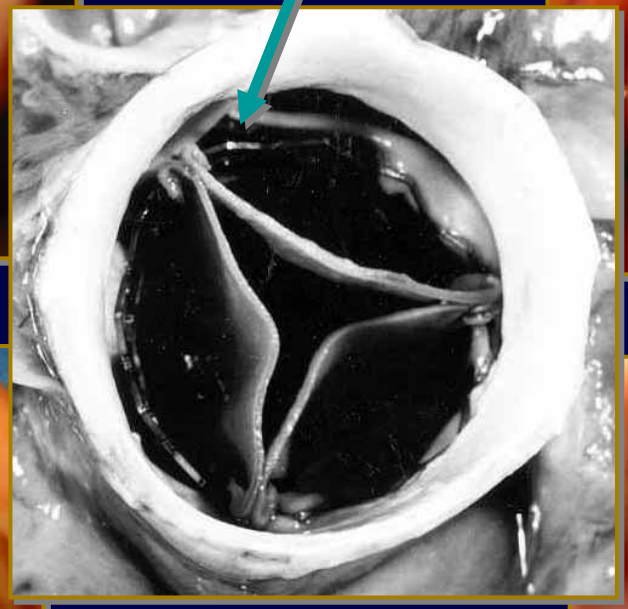
Percutaneous Valve Technologies, NJ – USA

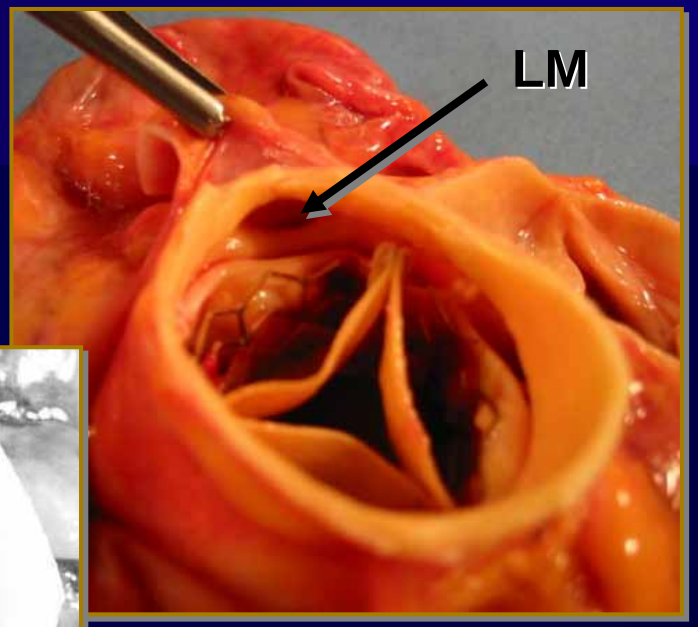


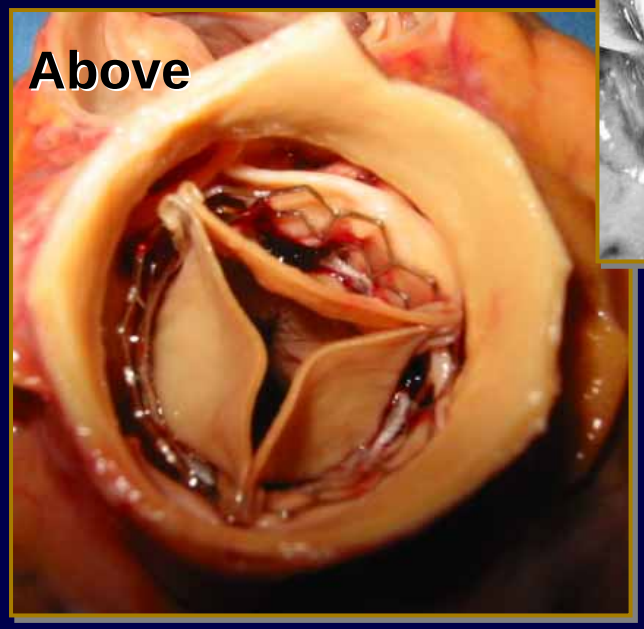
Cribier et al.

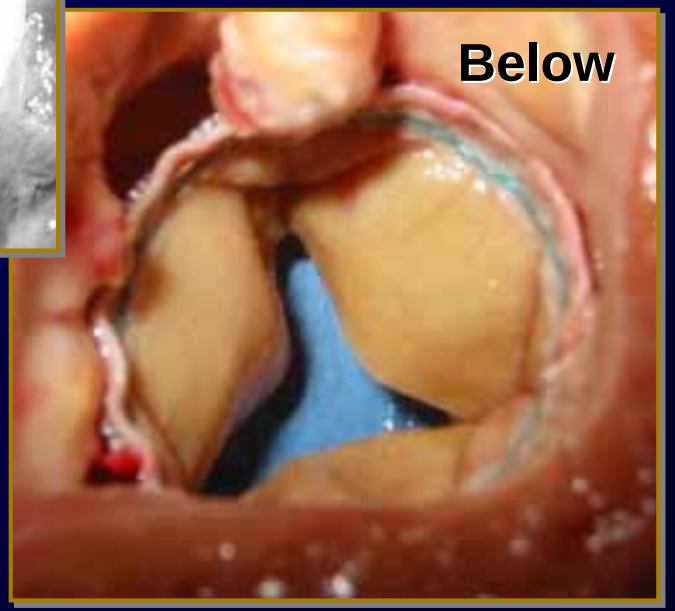


Paravalvular leak









Patient n° 3

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Postprocedural Outcome PVT (n=18 pts) (Follow-Up of 75 +/- 55 Days, range 4–179 Days)

Death, 30 days	2 (11.1)
Alive at follow-up	16 (88.9)
Thromboembolism	0 (0)
Disabling stroke	0 (0)
Hemolysis	0 (0)
Endocarditis	0 (0)
Heart block	0 (0)
Hospital readmission	2 (11.1)
Repeat valve procedure*	1 (5.5)
NYHA failure class, median (range)	2 (1–3)

NYHA indicates New York Heart Association.
n=18. Values are n (%) unless otherwise stated.
*Elective surgical aortic valve implantation as described in text.

Webb et al. Circulation 2006;113:842-850

Echocardiographic Outcome PVT (n=18 pts)

Characteristic	Baseline (n=18)	Postprocedure (n=13*)	One Month (n=9†)
Gradient, mm Hg, mean±SD	50±12	13±6	14±4
Valve area, cm^2‡, mean±SD	0.6±0.2	1.6±0.4	1.5±0.3
Calcification, grade	2 (n=5)	N/A	N/A
Annulus diameter, mm, mean±SD	23.0±1.5	N/A	N/A
Ejection fraction, %, mean±SD	56±14	58±12	60±12
Mitral insufficiency, grade (range)	2+ (0–4+)	1+ (0–4+)	3+ (0–4+)
Prosthetic-mitral valve contact	N/A	0	0
Mitral injury	N/A	0	0
Aortic valvular insufficiency, grade (range)	2+ (1–2+)	0	0
Aortic paravalvular insufficiency, grade (range)	0	2+ (0–3+)	2+ (0–3+)
Valve failure	N/A	0	0

N/A indicates not applicable.
*Does not include 4 patients in whom valve implantation was unsuccessful.
†Does not include 4 patients who had not yet reached 1-month follow-up.
‡Derived from continuity equation.

Webb et al. Circulation 2006;113:842-850

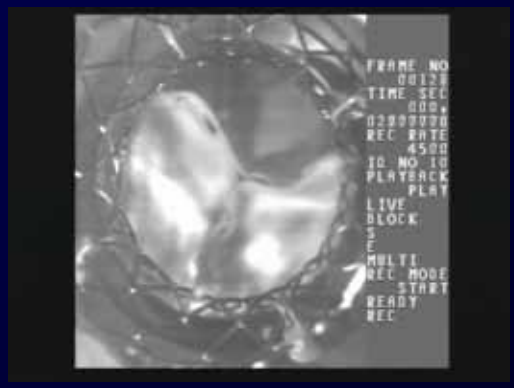
Selfexpanding AV Prosthesis

CoreValve

1. Generation

2. Generation

- A pericardium tissue valve
- Fixed to the frame in a surgical manner
- With PTFE sutures



AVA 1.7 cm^2

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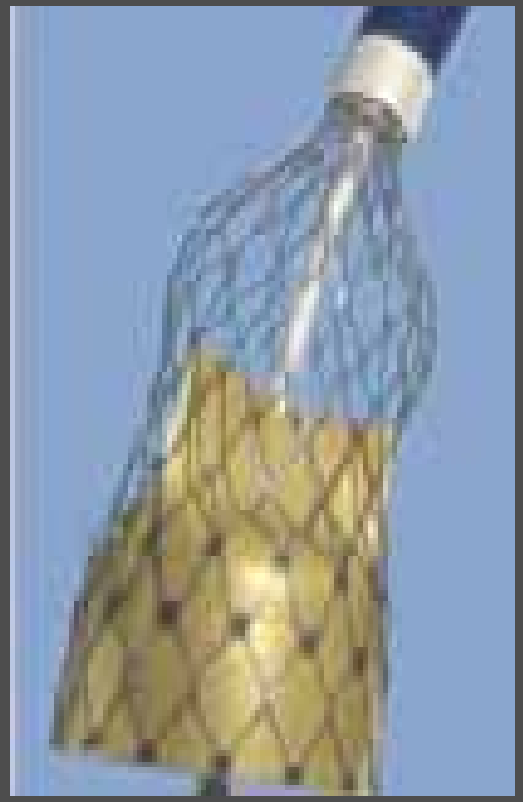
Selfexpanding AV Prosthesis

CoreValve

- **HIGHER PART** : increases quality of fixation and axes the system
- **MIDDLE PART :** is constrained to avoid coronaries (no rotational positioning) and carries the valve
- **LOWER PART:** High radial force of the frame pushes aside the calcified leaflets and avoids recoil = no paravalvular leaks

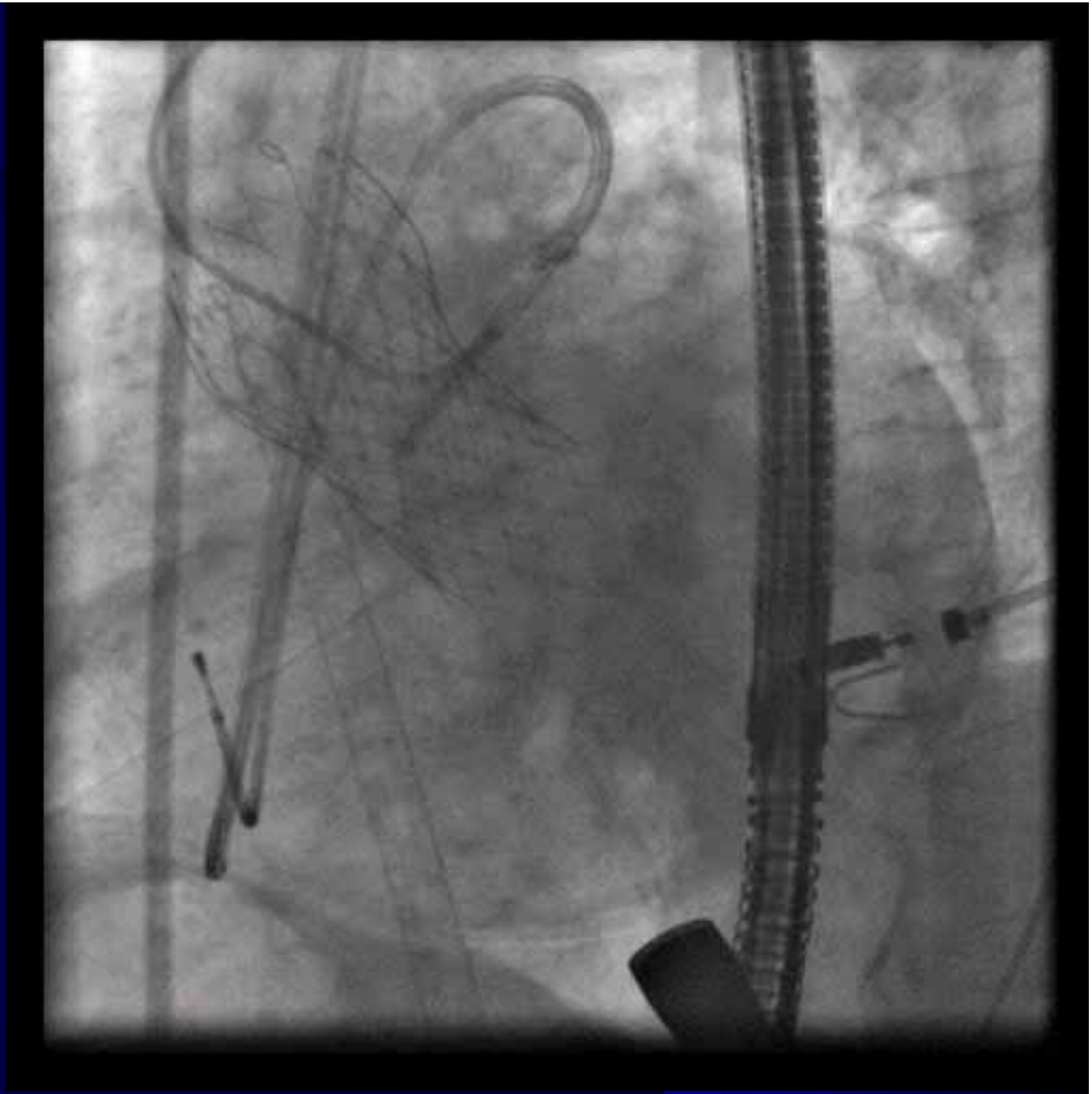
Selfexpanding AV Prosthesis

CoreValve



CoreValve
Case Example

Visualization of coronary access



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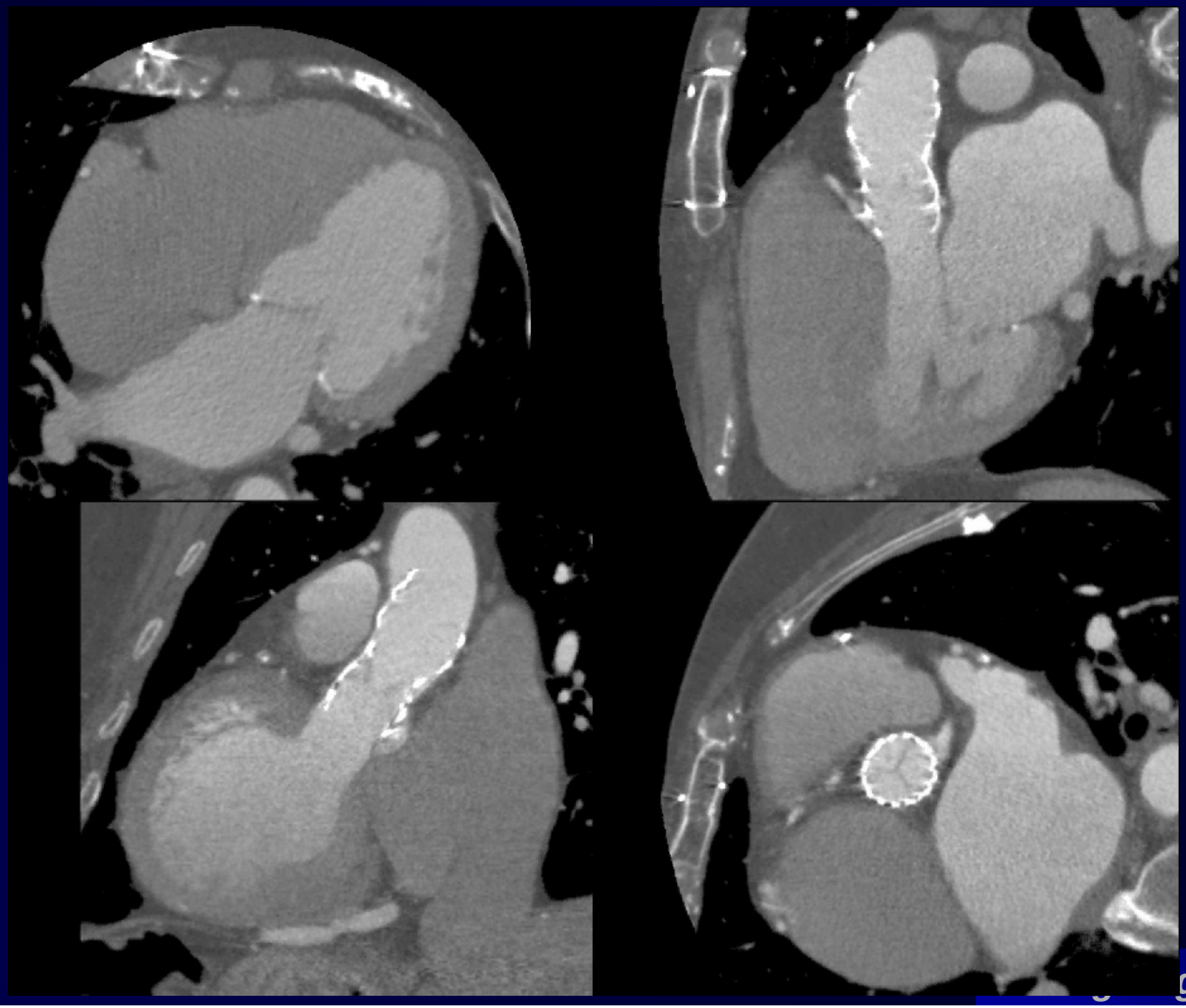
CoreValve Follow-up

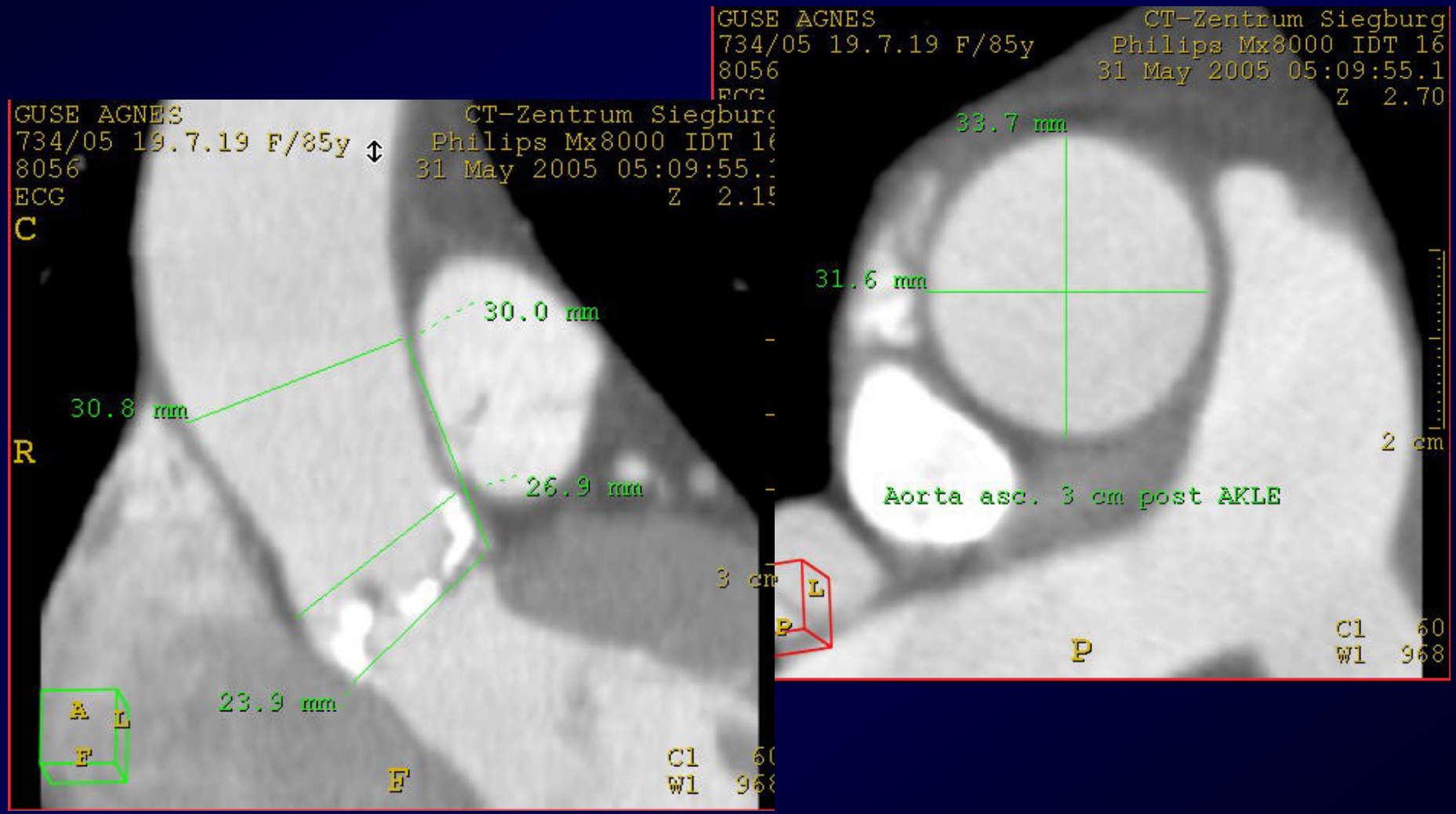
Post-Implant Morphological Assessment by CT-scan



CoreValve Screening

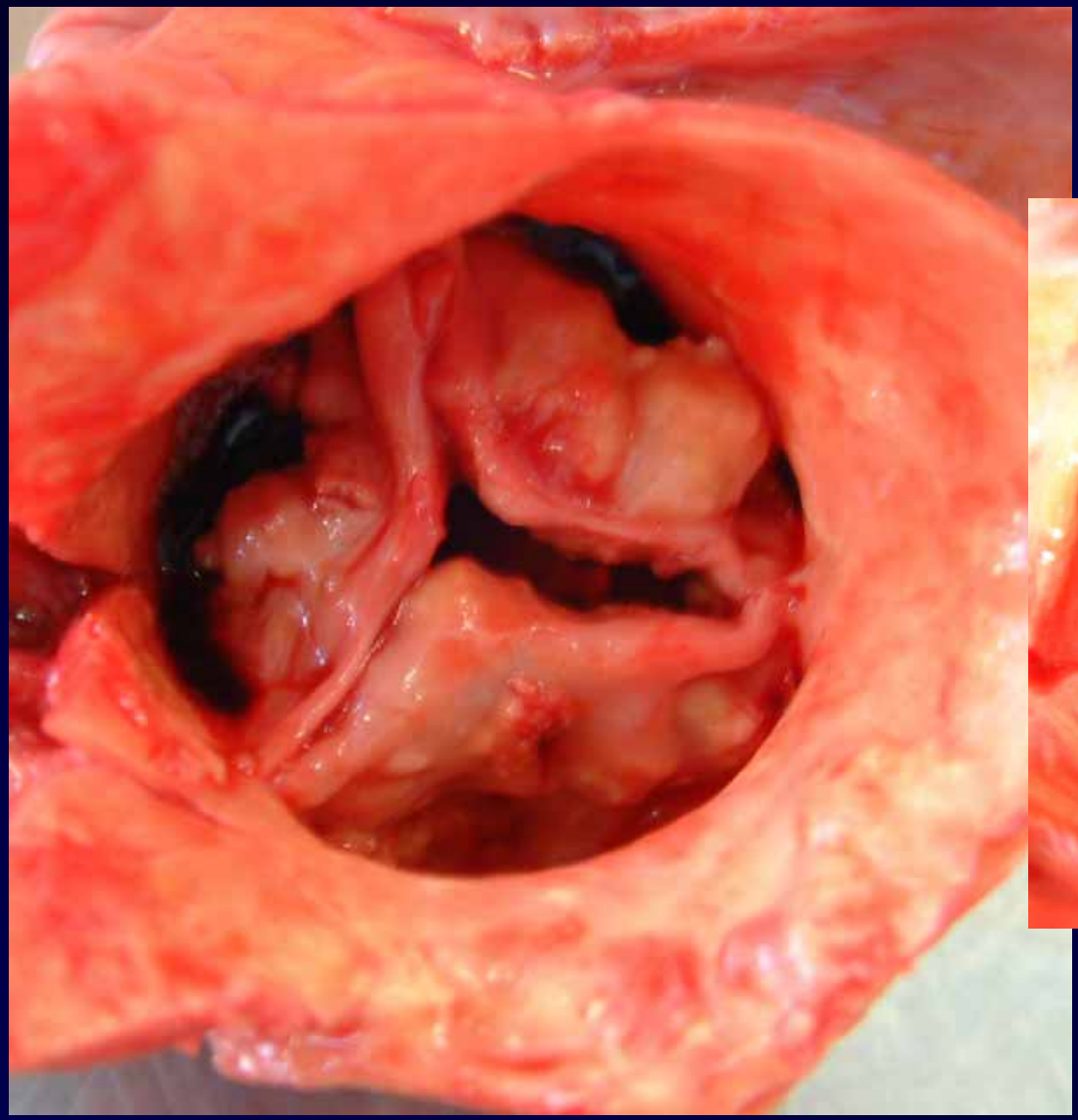
CoreValve

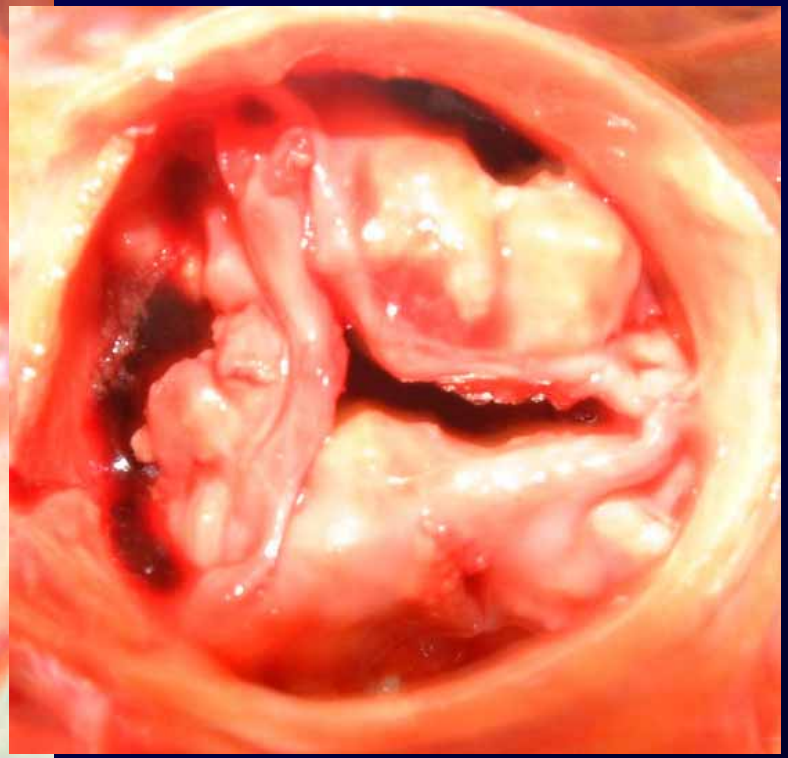
Morphological Quantification



CoreValve – The Unsuitable Patient

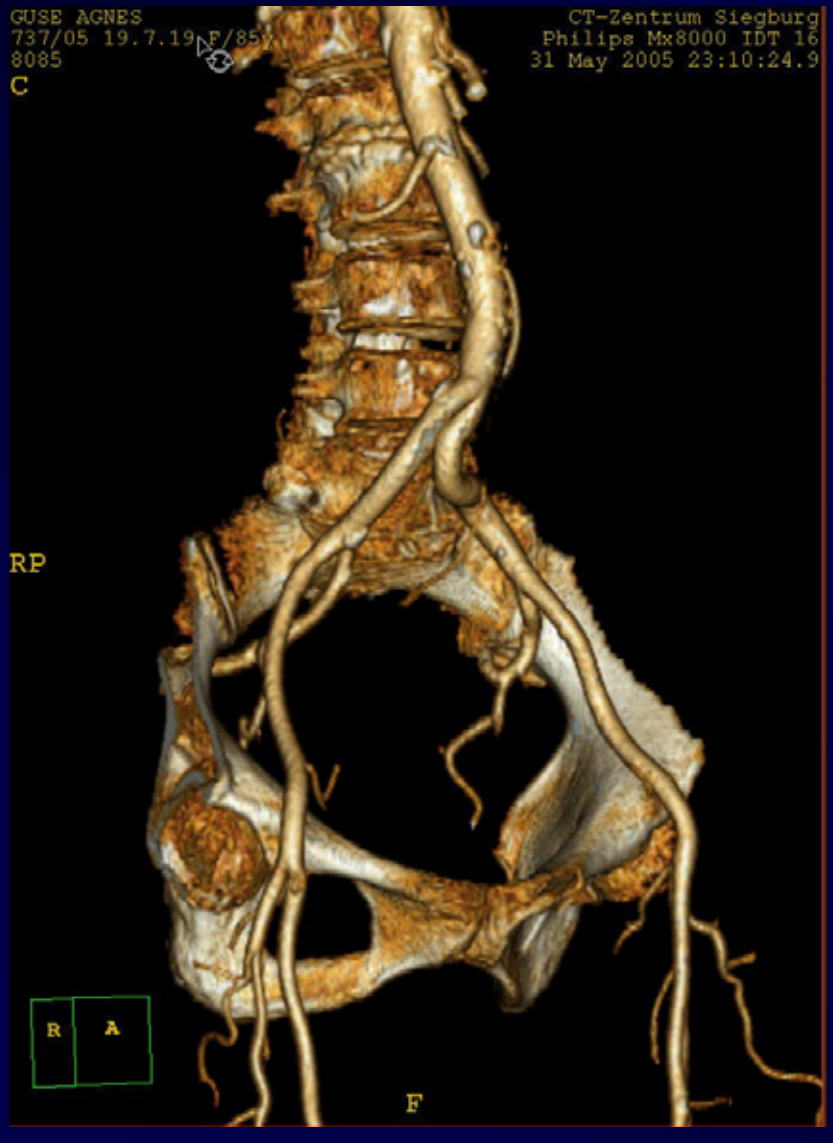
Severe Calcifications of the Native Valve

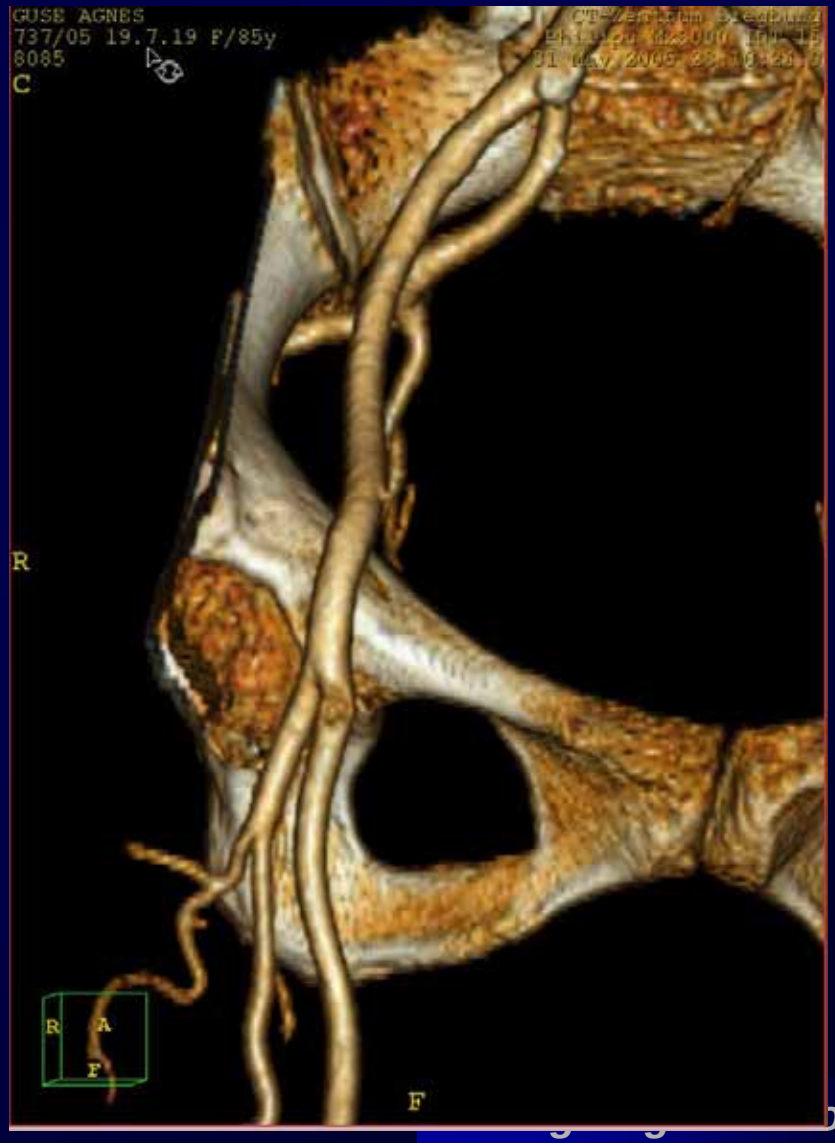




CoreValve

Access Site Assessment





CoreValve Results

CoreValve FIM

Phase 1: First Generation Device (24 F)
India, South America, Siegburg; 14 patients

Phase 2: *Second Generation Device* (21 F)
Siegburg; 18 patients

CoreValve Study

Inclusion criteria

- symptomatic AS, valve area < 1.0 cm^2
- Age >80J

or

- Logistic EuroSCORE ≥ 20%

or

- Age >65 yrs plus 1 or 2 of the following criteria:

  Cirrhosis of liver, pulmonary insufficiency, previous cardiac surgery, pulmonary hypertension (>60mmHg), recurrent pulmonary embolus, right ventricular insufficiency, history of mediastinum radiotherapy, severe connective tissue disease

- Aorta-Annulus ≥ 20mm and ≤ 27mm
- Diameter ascending aorta ≤ 45mm

CoreValve Study
Patient Charakteristics

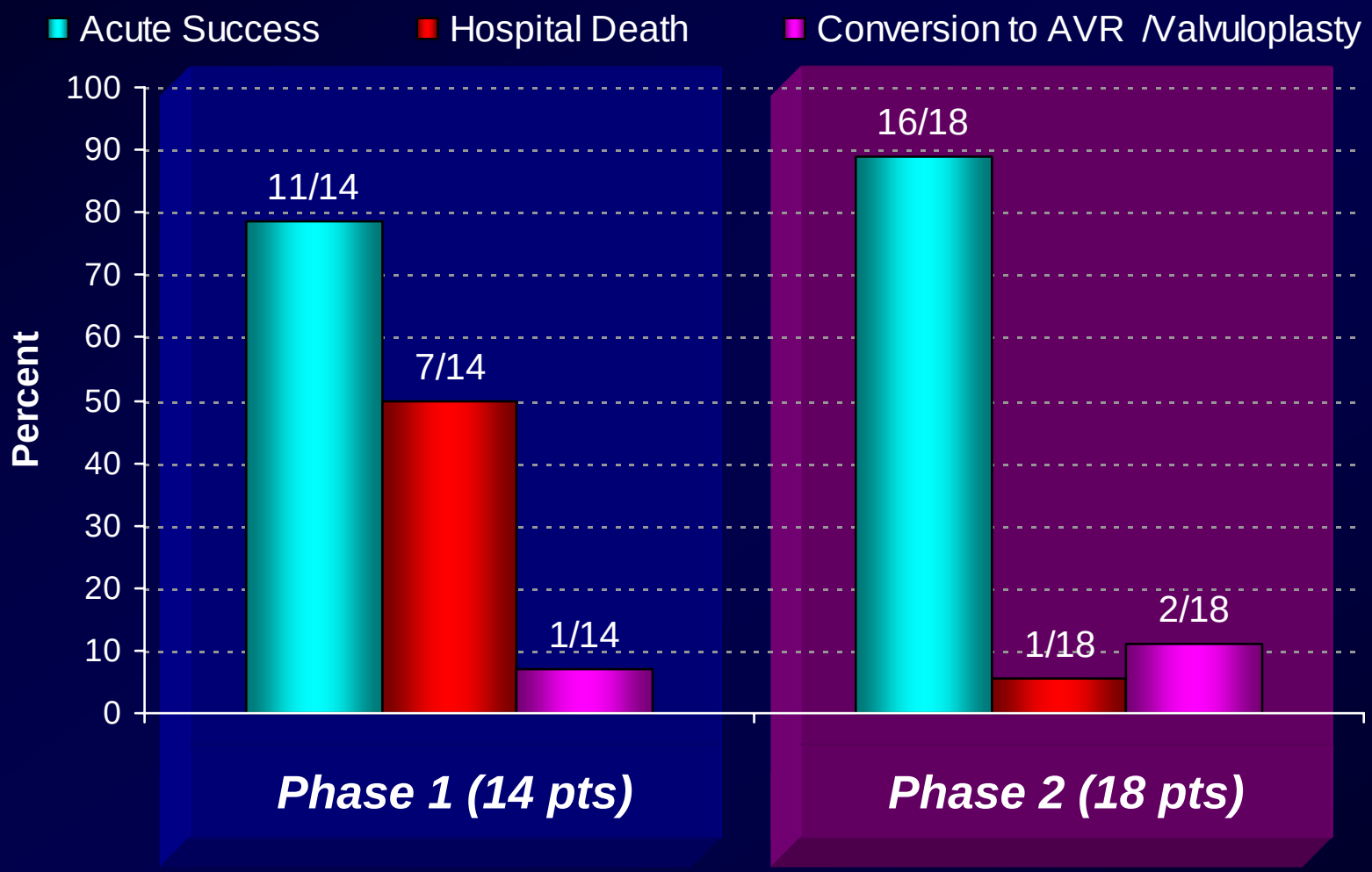
	Phase 1 India, S. America, Siegburg Gen 1	Phase 2 Siegburg Gen 2
Number of patients (n)	14	18
Indication (n)		
Aortic valve stenosis	6	13
Aortic valve regurgitation	2	1
Combined	6	4
Peak gradient (mmHg)	76.2 +/- 30.6	63.6 +/- 20.3
LV-EF (%)	53.8 +/- 9.6	55.9 +/- 18.9
Logistic EuroSCORE (%)	14.6 +/- 5.2*	22.0 +/- 17.4

*Only Siegburg patients

CoreValve Study Results

	Phase 1 India, S. America, Siegburg Gen 1	Phase 2 Siegburg Gen 2
Acute Procedural Success	11/14	16/18
Peak Gradient (mmHg)	17.5 +/- 9.6	20.5 +/- 9.2
Conversion to Surgery	1/14	1/18
Conversion to Valvuloplasty	0	1/18
In-hospital Mortality	7/14	1/18
Out-of-hospital Mortality	0/14	0/18

CoreValve Study Results



CoreValve Study Results

Phase 1

1 procedural death

wire perforation (1)	day 0

6 postprocedural deaths

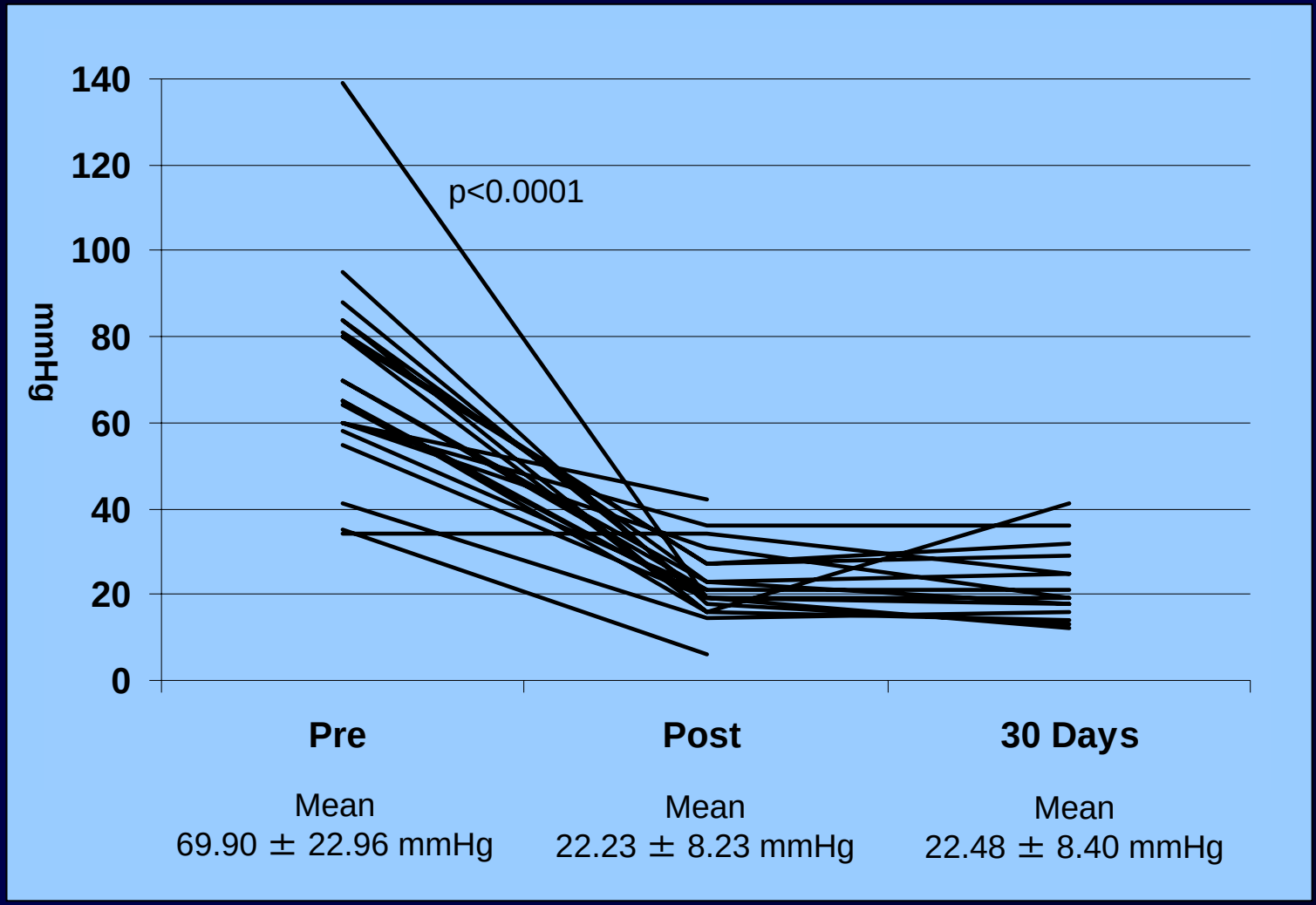
pericardial tamponade (1) (due to delayed wire perforation)	day 2
pulmonary insufficiency (1) (lung cancer)	day 7
DIC (1)	day 15
compartment syndrome (1)	day 2
multi-organ failure (1)	day 13
hemodynamic failure (1)	day 9

Phase 2

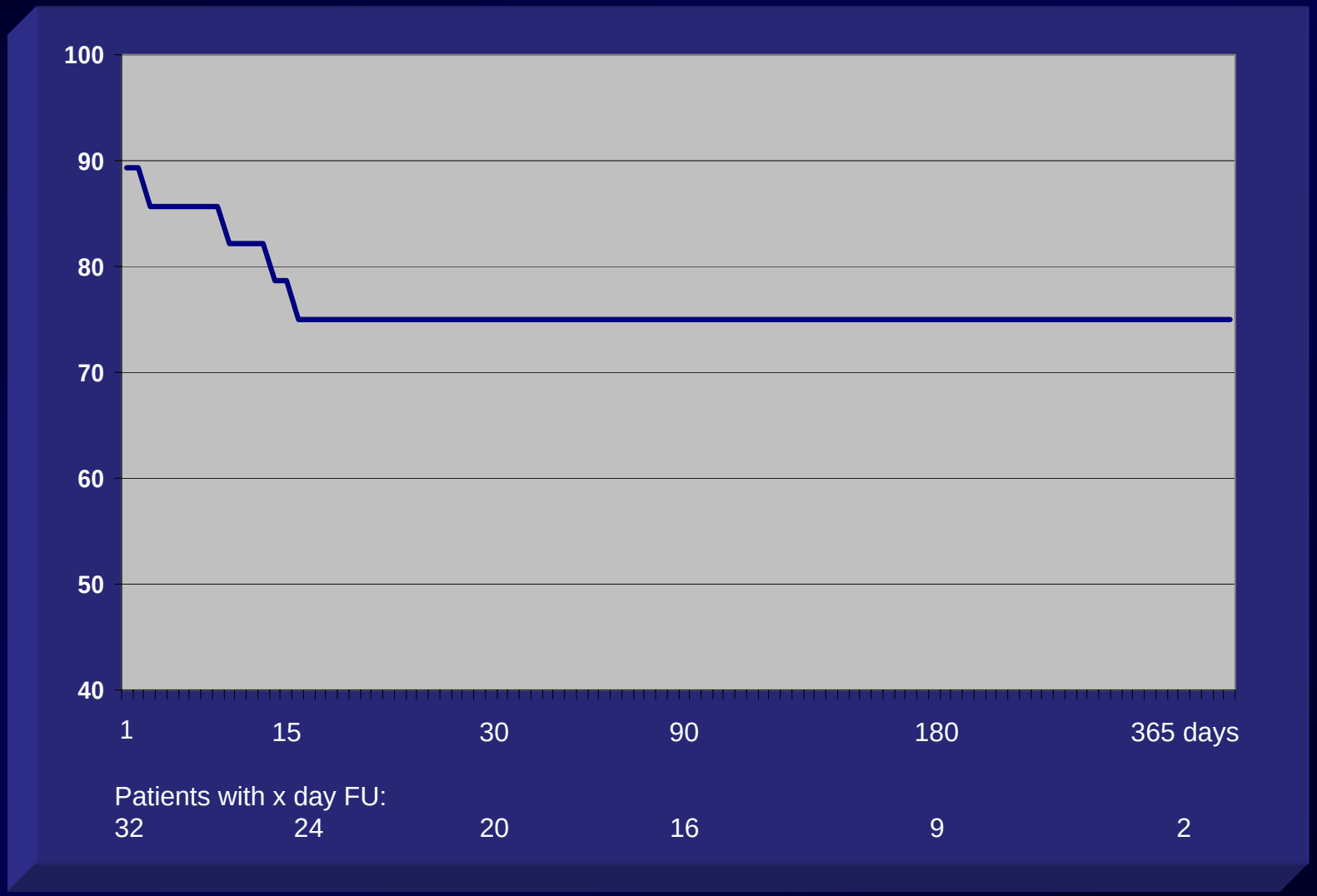
1 postprocedural death

hemodynamic failure (1) (after conversion to valvuloplasty)	day 1

CoreValve Study
Peak Pressure Gradients



CoreValve Studie
Event-free survival (MACE-free)



CoreValve Study
Follow-up

Clinical Follow-up (NYHA); n=22

Clinical Status	Pre	30 day FU
NYHA IV	2 (9.1%)	0
NYHA III	19 (86.4%)	0
NYHA II	1 (4.5%)	17 (77.3%)
NYHA I	0	5 (22.7%)

CoreValve Feasibility Study
(on going)

CoreValve Study

- Prospective, multi-center (≤ 7 Centers)
- Single arm
- n ≤ 35

Objective

Evaluation of feasibility and safety of the CoreValve Prosthesis

Study Centers

EUROPE

- Siegburg Heart Center, Germany, Prof Grube (PI)
- Leipzig, Germany, Prof Schuller
- Erasmus, Rotterdam, Holland, Prof Serruys
- Amphia, Breda, Holland, Dr den Haiyer
- University Hospital, Antwerp, Belgium, Dr Bosmans
- Heart Center, Hasselt, Belgium, Dr Benit

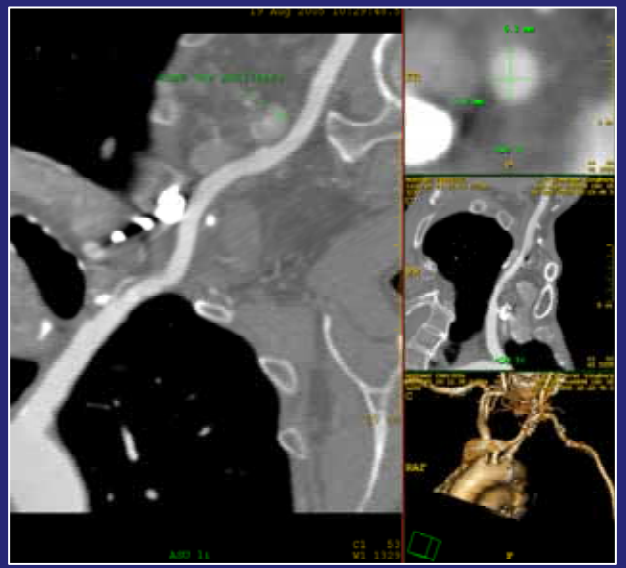
NORTH AMERICA

- Montreal Heart Center, Montreal, Canada, Dr. Bonan

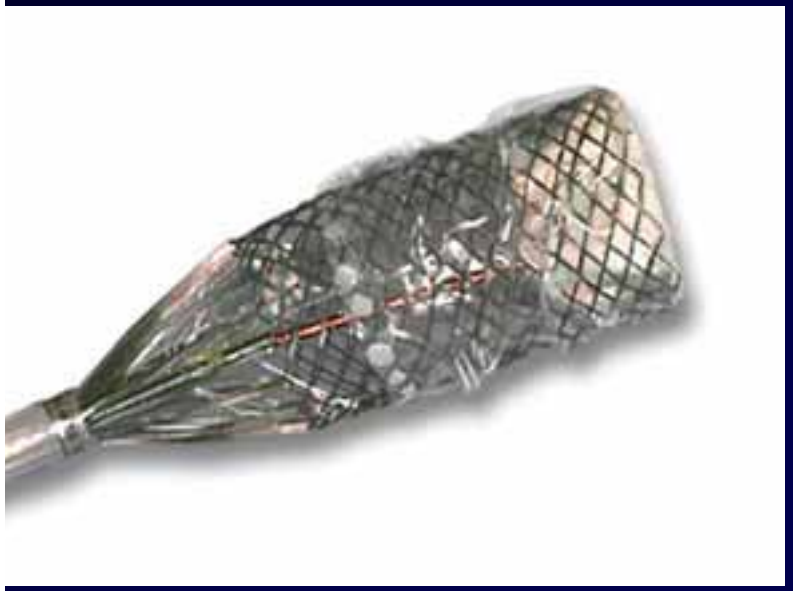
Benefits of 2./3. Generation Device

Subinguinal access side with surgical cut-down (common femoral art. 7,5 – 8mm) possible

18 F Device 4.06 planned
(subclavian access possible)

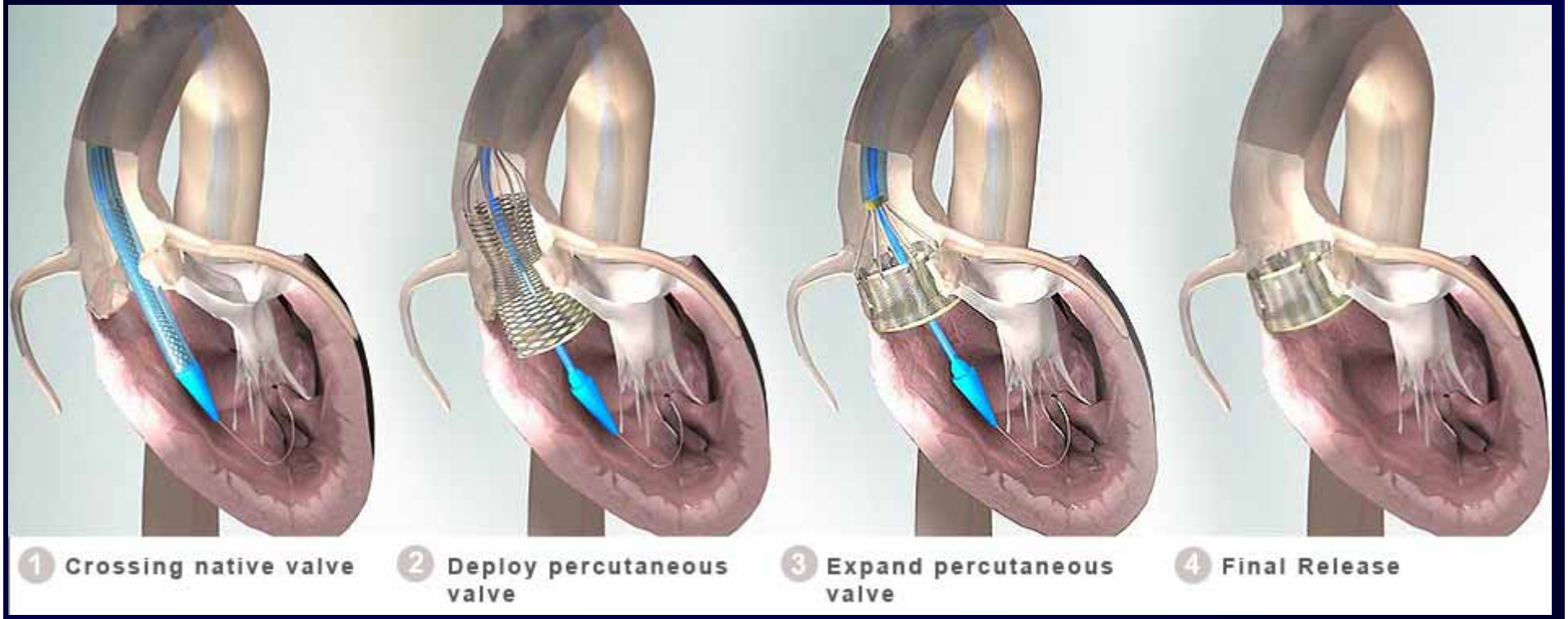


Phoenix Valve



- Percutaneous retrograde delivery
- Accurate positioning/ repositioning
- Unique valve function during deployment
- Outer Adaptive™ Seal to minimize peri-prosthetic regurgitation

Phoenix Valve



At this point the device can be fully retracted, back to step 1, and repositioned

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Conclusion

First experience using a self-expanding aortic valve prosthesis for percutaneous treatment of AS

Demonstration of feasibility, safety and efficacy of this new technique with immediate improvement of the hemodynamic status and promising out-of-hospital outcome

Further studies are currently ongoing

Vielen Dank

Phoenix Valve

Unique Valve Properties

- Un-interrupted valve function and visualization throughout the procedure
- Novel membrane is designed to seal against irregular surface of native anatomy
- Valve is pre-assembled on delivery system