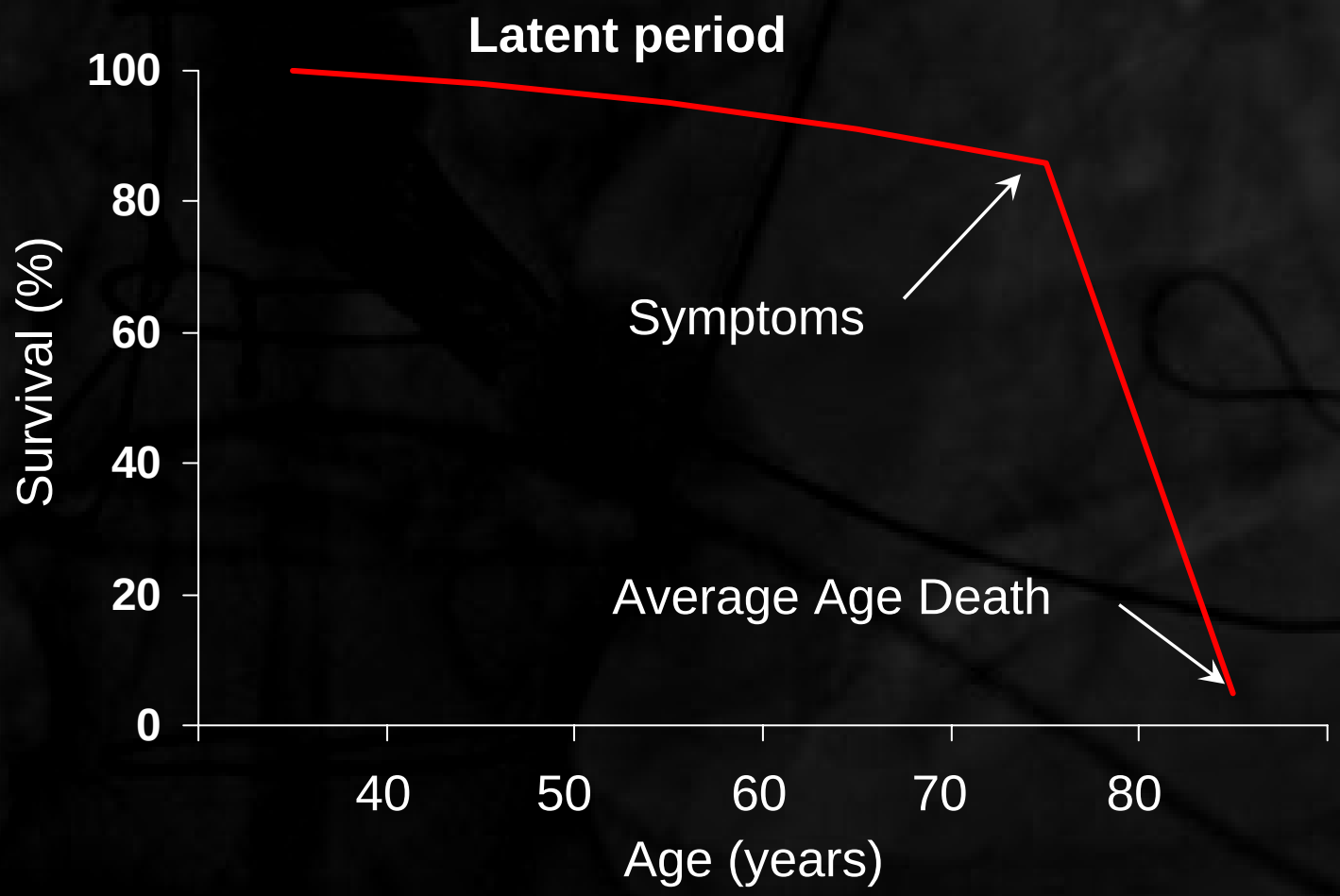
13th Annual
Angioplasty Summit TCT Asia Pacific
3rd APSIC Fellowship Convocation

Percutaneous Aortic Valve Implantation. Core-Valve and Cribier-Edwards Update

T. Lefèvre

Institut Cardiovasculaire Paris Sud

Natural History of Aortic Stenosois



From Ross and Brauwald, Circulation 1968

European Heart Journal (2005) **26**, 2714–2720
doi:10.1093/eurheartj/ehi471

EUROPEAN SOCIETY OF CARDIOLOGY®

Clinical research

Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery?

Euroheart Survey
5001 Patients, April–July 2001
32% NYHA class ≥ 3
had no surgery.

Table 3 Factors associated with a decision not to operate

	P-value	Odds ratio	95% CI
LV ejection fraction	0.004		
>50%		1	
30–50%		2.66	1.57–4.64
≤30%		7.09	2.42–20.82
Age (years)	0.005		
75–80		1	
80–85		1.90	1.22–2.99
≥85		3.60	1.47–8.82
Neurological dysfunction	0.02	3.82	1.23–12.27

Multivariable analysis including separate comorbidities. Hosmer–Lemeshow goodness-of-fit $\chi^2 = 5.48$ (df = 4), $P = 0.24$, *c*-index 0.73.

Bernard Iung et al. EHJ. 2005; 26: 2714-20

Many Patients Considered too High Risk

Patient factors		Φ	βi	Xi
Age	87yr	6	0,0666354	29
Sex	☑ femelle	1	0,3304052	VRAI
Pulmonary disease	☐ Oui	1	0,4931341	FAUX
Peripheral vascular disease	☐ Oui	2	0,6558917	FAUX
Neurologic disorder	☐ Oui	2	0,841626	FAUX
Previous cardiac surgery	☐ Oui	3	1,002625	FAUX
Creatinine pre surgery > 200 µmol/ L	☐ Oui	2	0,6521653	FAUX
Endocarditis	☐ Oui	3	1,101265	FAUX
Critical status pre surgery	☐ Oui	3	0,9058132	FAUX
Cardiac factors				
Unstable angina	☐ Oui	2	0,5677075	FAUX
Ejection fraction 30-50%	☐ 30-50%	1	0,4191643	FAUX
Ejection fraction <30	☐ <30%	3	1,094443	FAUX
Recent MI	☐ Oui	2	0,5460218	FAUX
sPAP > 60 mmHg	☐ Oui	2	0,7676924	FAUX
Surgical factors				
Emergency	☐ Oui	2	0,7127953	FAUX
Associated cardiac surgery	☐ Oui	2	0,5420364	FAUX
Associated thoracic aorta surgery	☐ Oui	3	1,159787	FAUX
Associated septal rupture treatment	☐ Oui	4	1,462009	FAUX

Additive EuroSCORE	7
Mortality	7,40%

Additive euroSCORE = $\Sigma\Phi$

Logistic euroSCORE =

$$e^{(-4.789594 + \Sigma\beta i\, Xi)} / 1 + e^{(-4.789594 + \Sigma\beta i\, Xi)}$$

For the latest information on EuroSCORE visit http://www.euroscore.org

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Additive EuroSCORE	12
Mortality	31,51%

Additive euroSCORE = $\Sigma\Phi$

Logistic euroSCORE =

$$e^{(-4.789594 + \Sigma(\beta i\, Xi))} / 1 + e^{(-4.789594 + \Sigma(\beta i\, Xi))}$$

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Balloon Aortic Dilatation

Popularized in the '80s

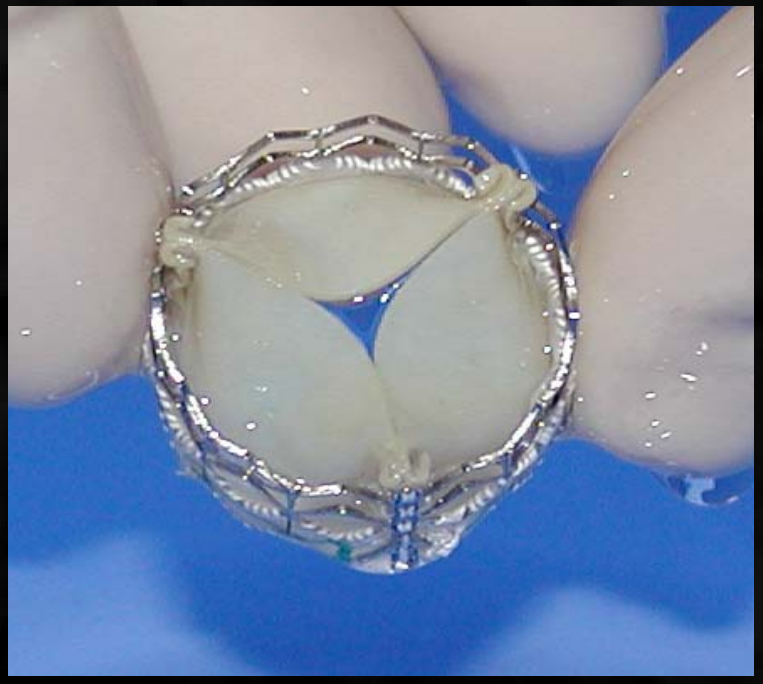
- ✓ Good acute results
- ✓ Low risk of complication
- ✓ Poor mid-term results

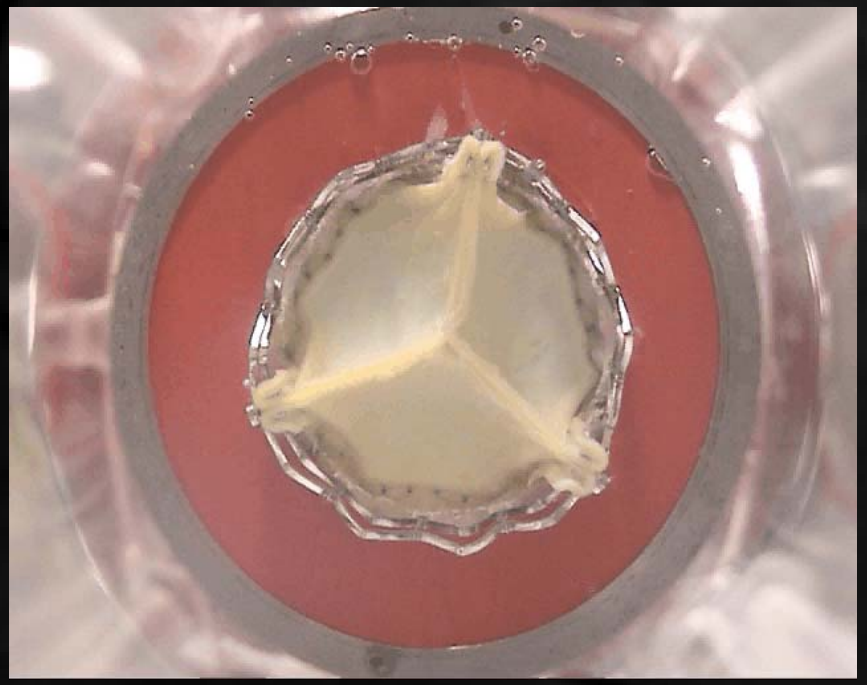
Still used in some centers

- « Bridge » to surgery
- Palliative treatment
- Before non cardiac urgent surgery

Cribier-Edwards Valve

- ✓ Tricuspid Equine Pericardial valve
- ✓ Balloon expandable Stainless steel bioprothesis (23mm)
- ✓ Durability in vitro > 10 years





I-REVIVE / RECAST

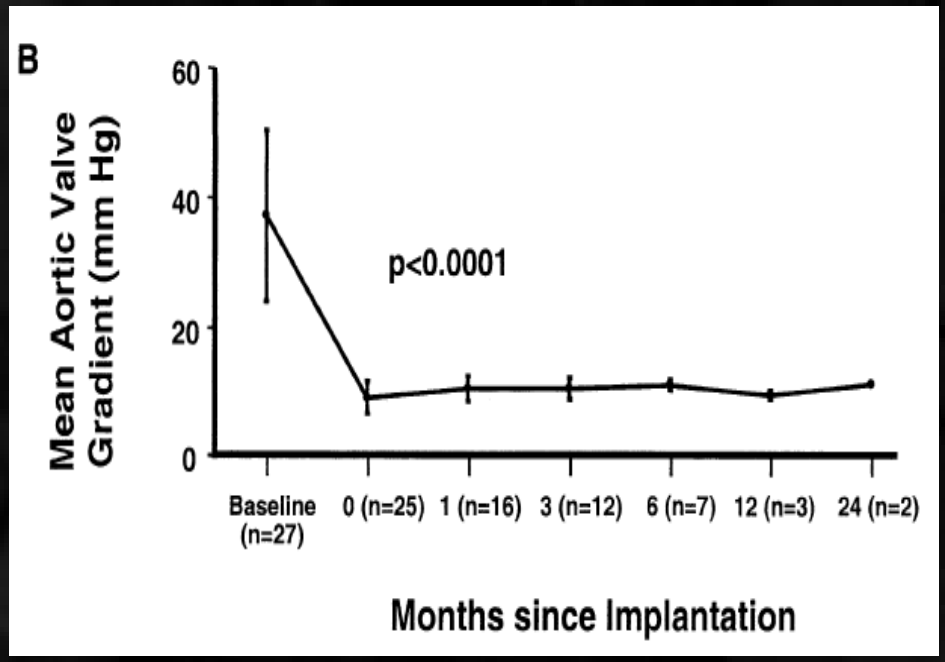
Feasibility study

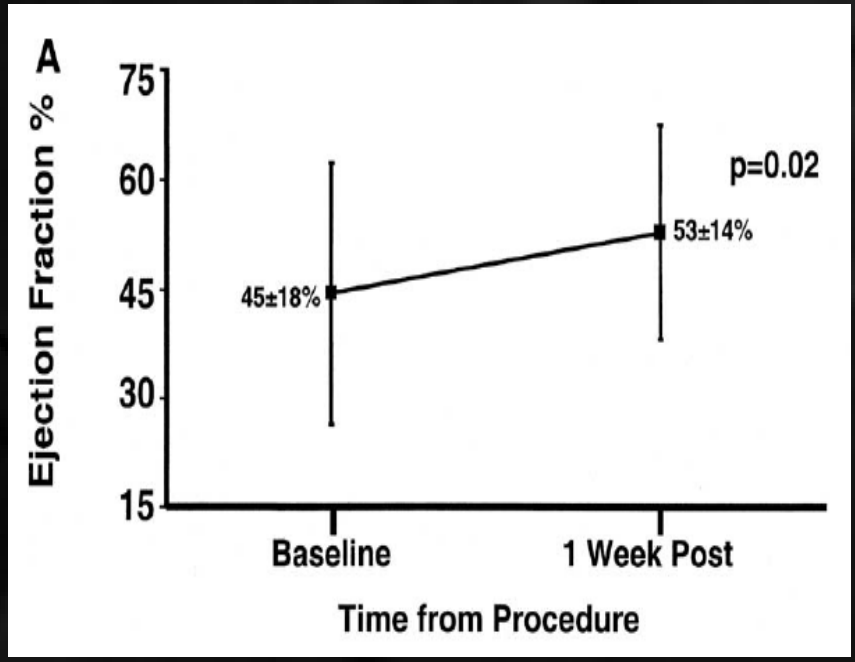
Patients included (n)	36
Procedure performed (n)	33
Implantation success (%)	82
Death 1 month (%)	25
Death 6 months (%)	53
Emergency surgery (%)	0
Valve dysfunction (%)	0

Cribier et al. JACC 2006; 47: 1214-23

I-REVIVE / RECAST

Hemodynamic results





Cribier et al. JACC 2006; 47: 1214-23

Retrograde approach, Vancouver registry

Retro FLEX Catheter

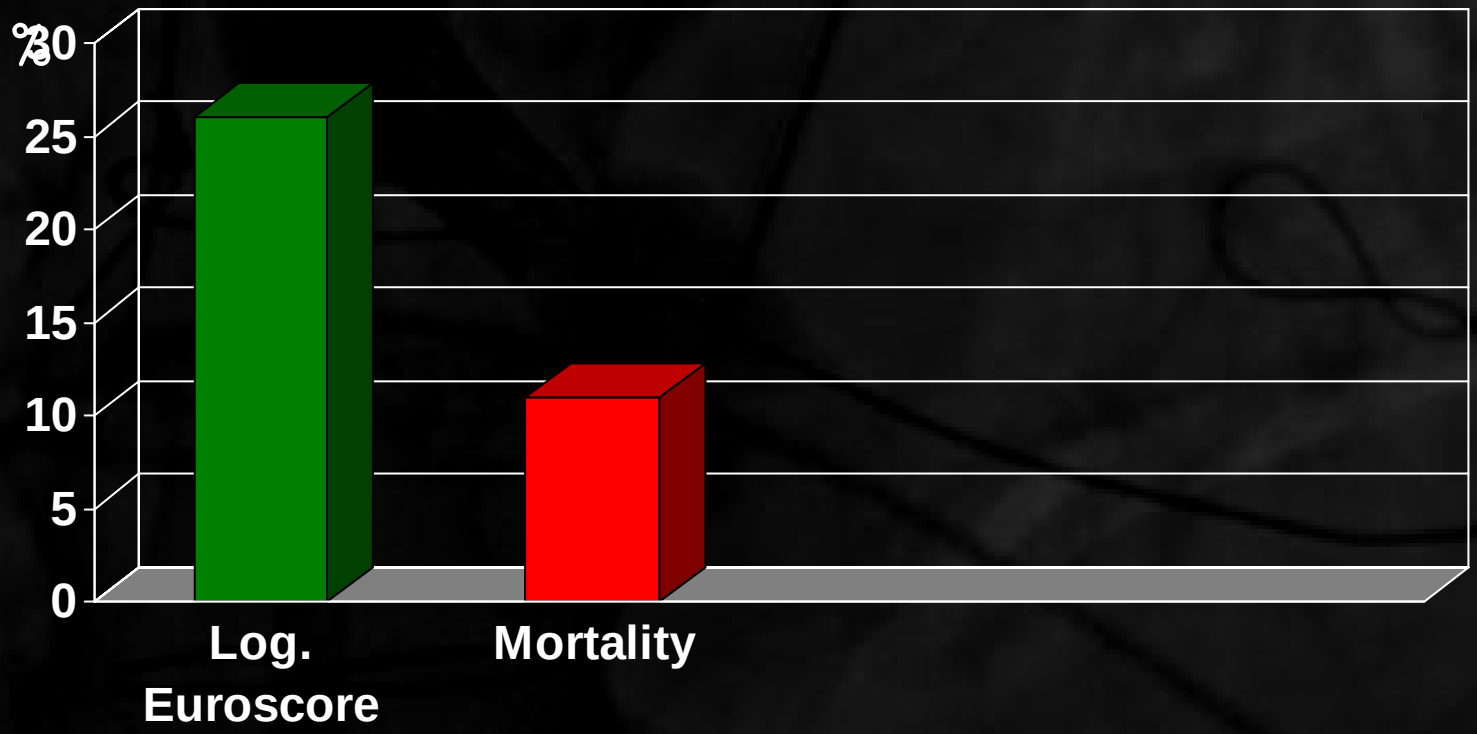
Retrograde approach, Vancouver registry

30 day mortality

John Webb et al. ACC 2006

Retrograde approach, Vancouver registry

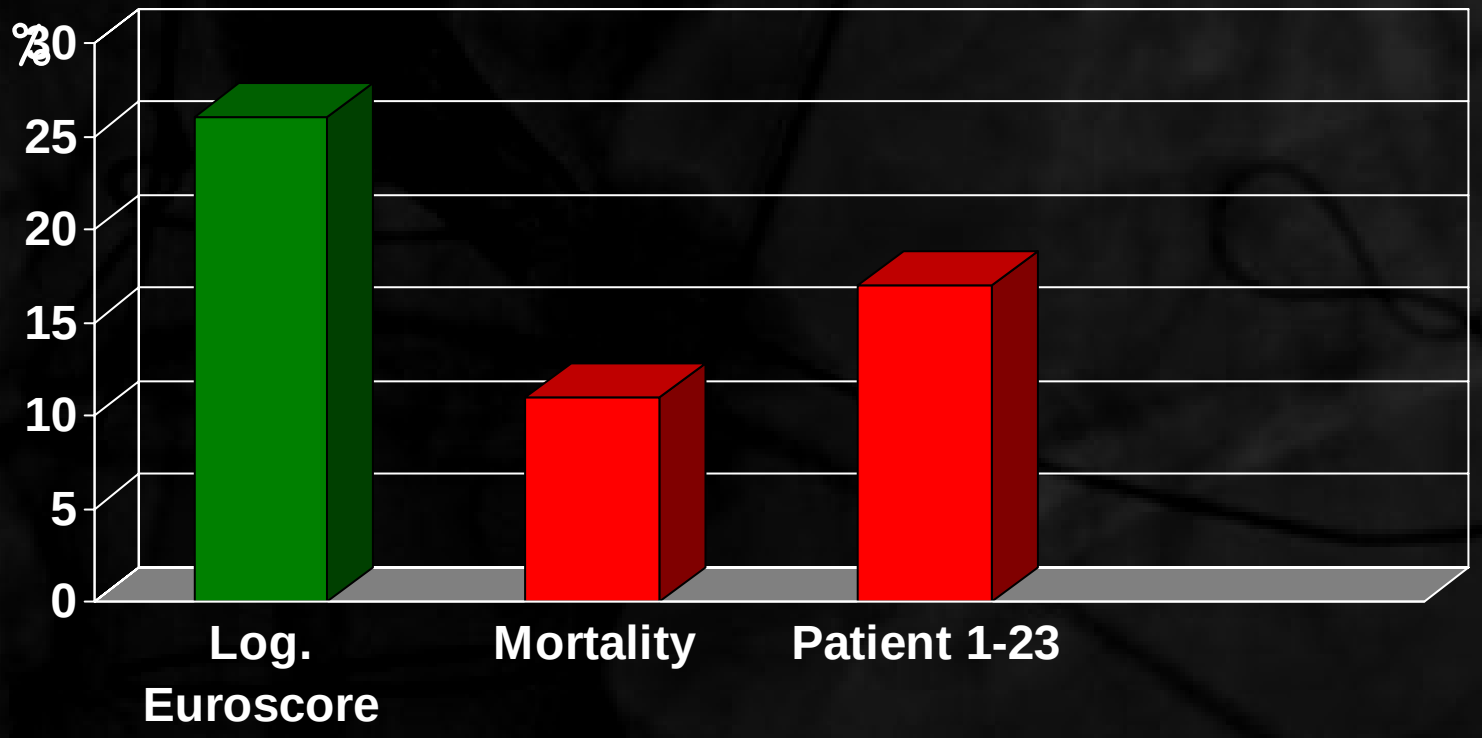
30 day mortality



John Webb et al. ACC 2006

Retrograde approach, Vancouver registry

30 day mortality



John Webb et al. ACC 2006

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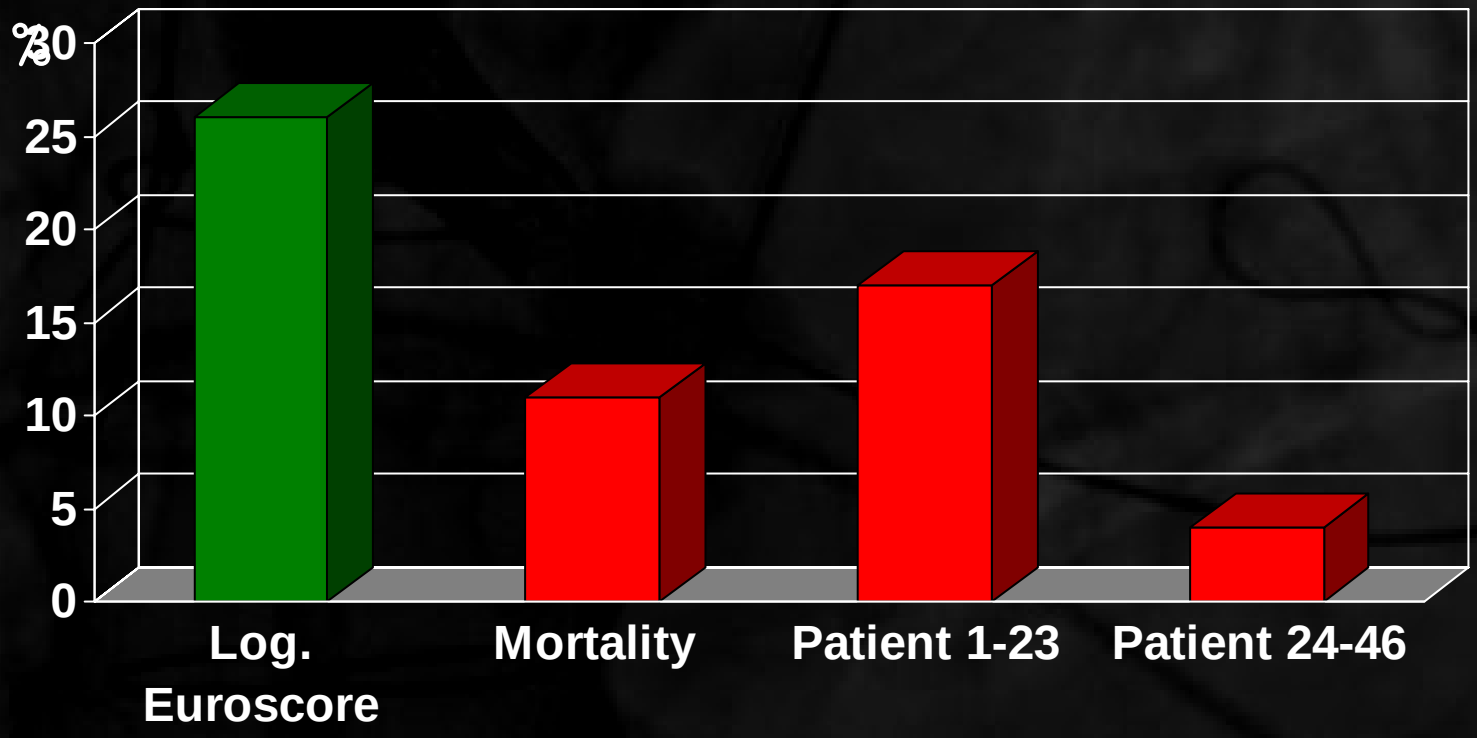
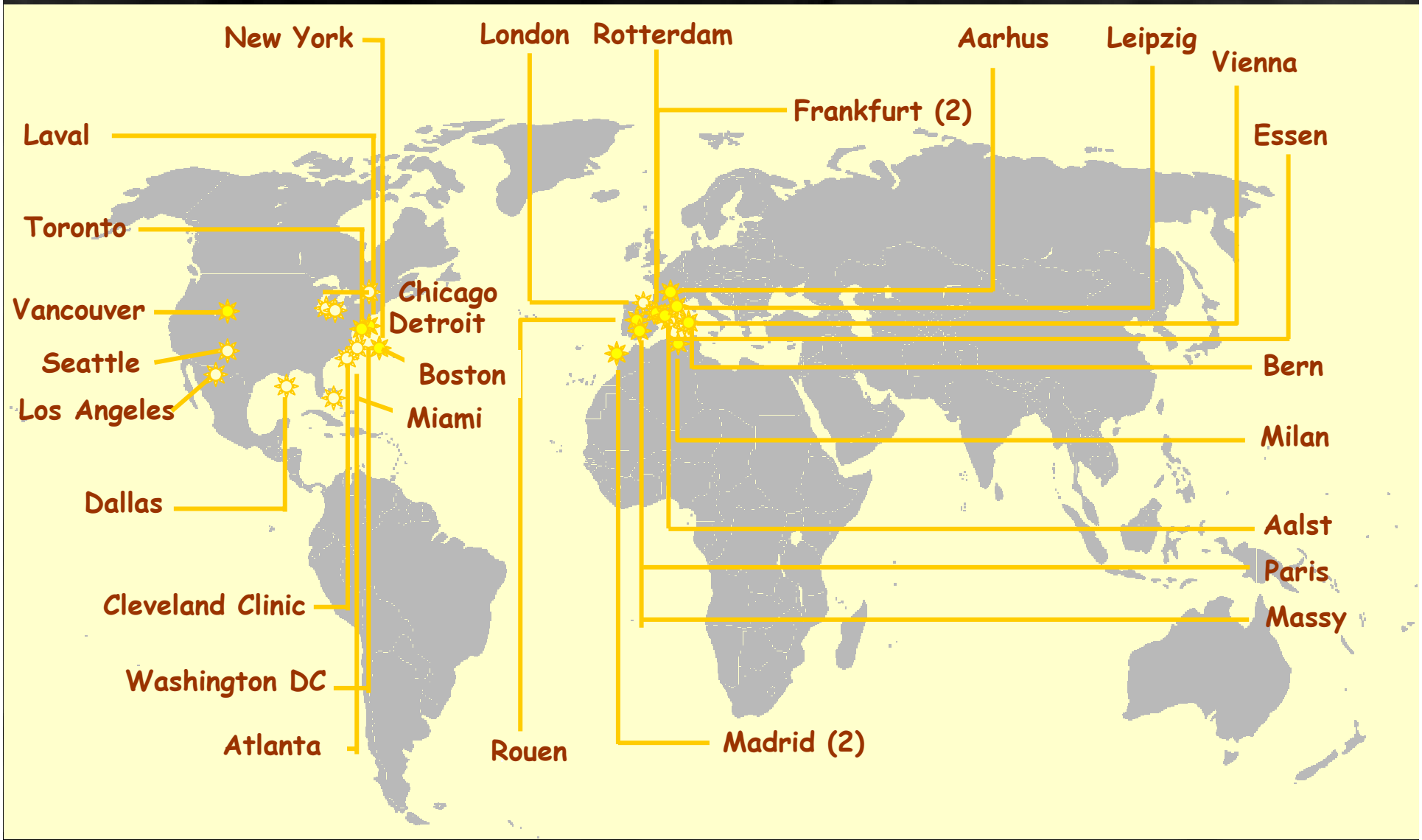


John Webb et al. ACC 2006

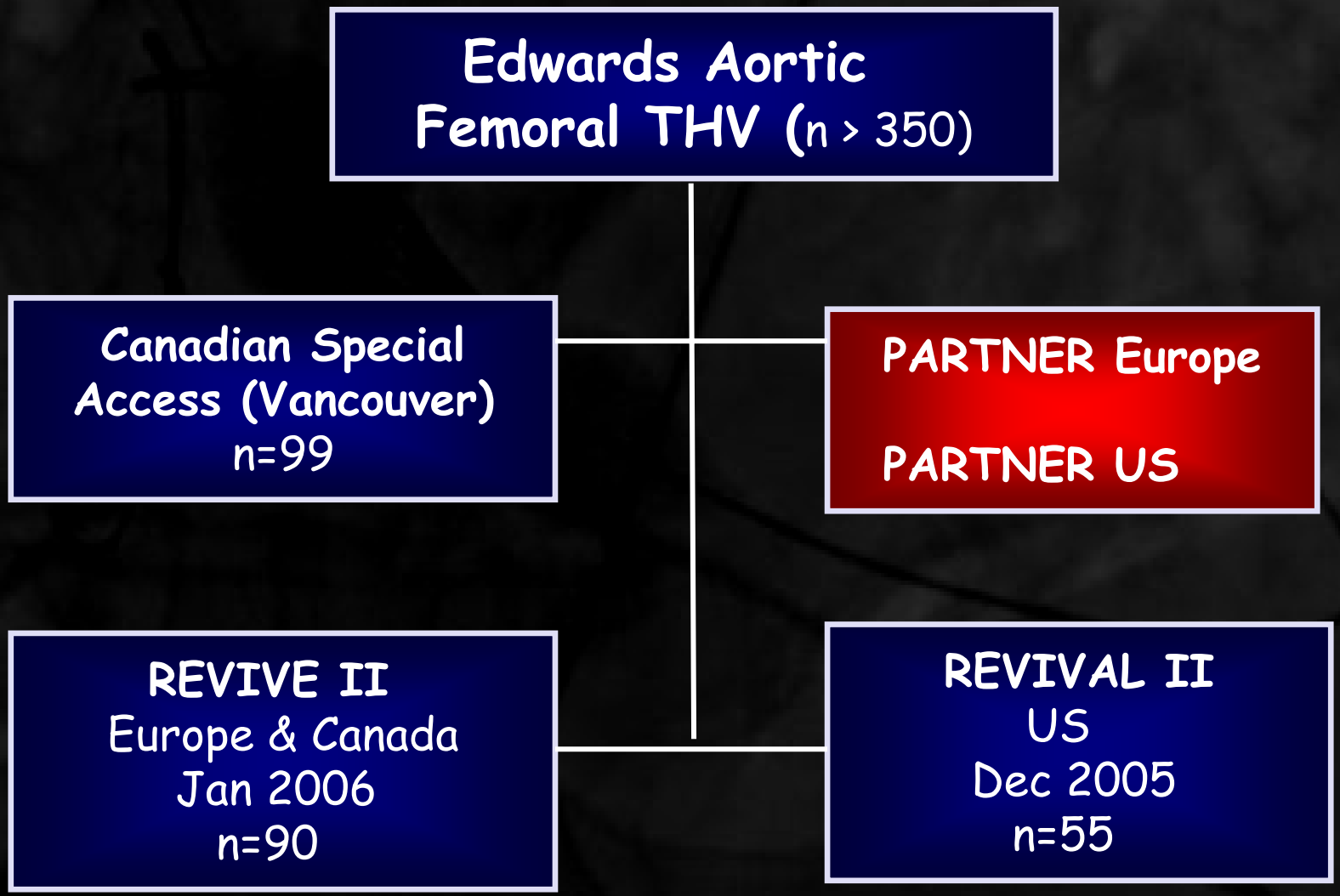
Edwards THV Clinical Trial Sites Worldwide



Two bioprosthesis sizes: 23 and 26-mm

Bovine pericardium

Edwards THV Worldwide (Transfemoral)



REVIVE II: EU Feasibility Trial

Multicentre European Study

May 2005 - October 2007

N=30 Roll-in patients

N=90 Trial patients

REVIVE II: Inclusion Criteria

- ✓ Symptomatic AS, AVA < 0.7 cm^2
- ✓ Age >70 yrs old
- ✓ Logistic EuroSCORE > 20% or surgical contra-Indication

REVIVE II: Patient Characteristics

Patients (n)	89
Age (years)	83.9 ± 5.1
Female gender (%)	47
EuroSCORE (%)	28.7± 13.8
Ejection Fraction (%)	52.8 ± 16.9
AVA baseline (cm^2)	0.58 ± 0.14
Mean gradient (mmHg)	45.6 ± 20.6

REVIVE II: Access site Complications

Jan 06 – May 06:

5 complications/20 patients

= 25%

↓

Vascular screening + User training

↓

Aug 06 – Aug 07:

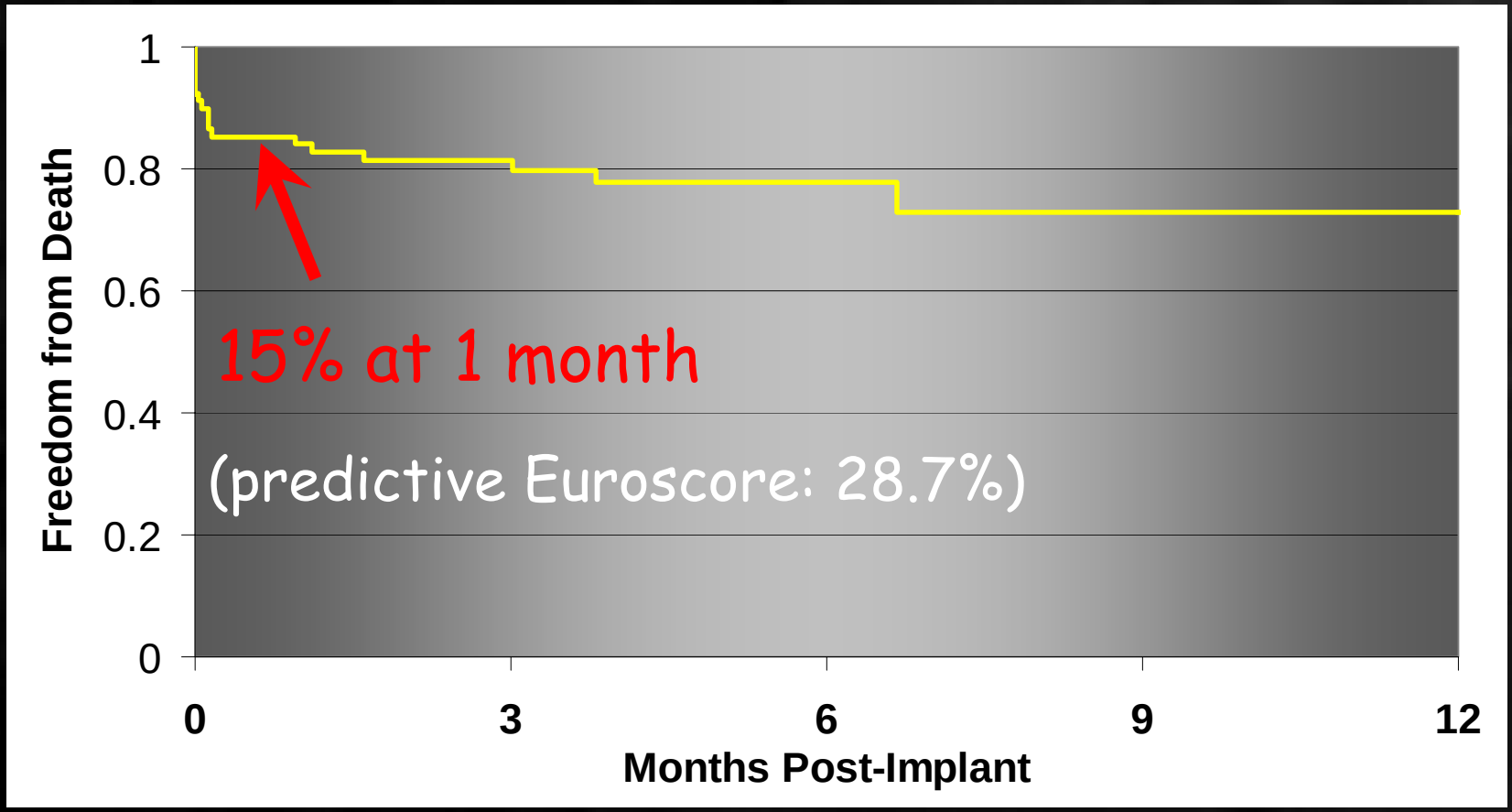
5 complications/67 patients

= 7.5%

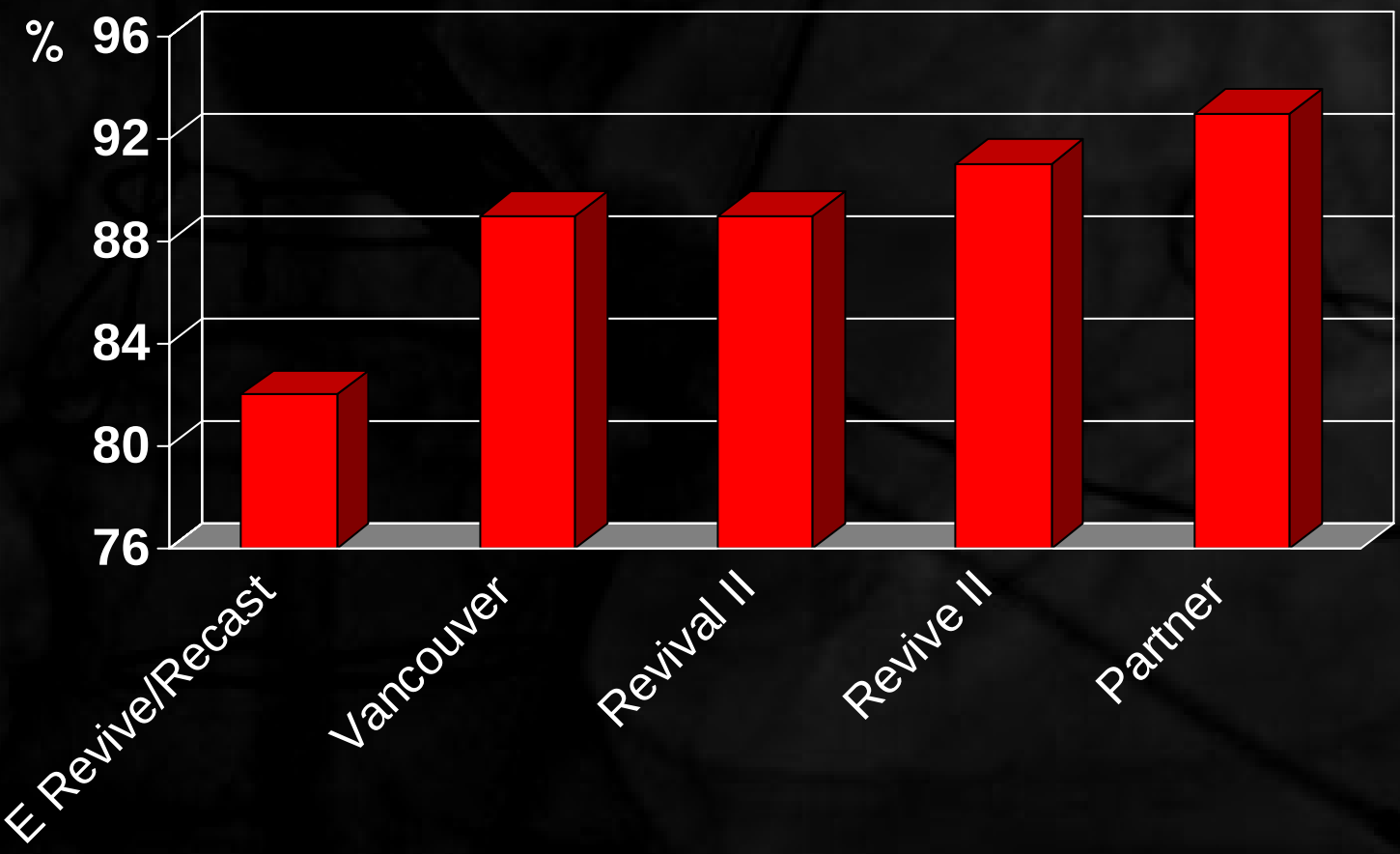
REVIVE II: Procedural Complications

Coronary occlusion	1.1%
Stroke	1.1%
Pacemaker	3.4%

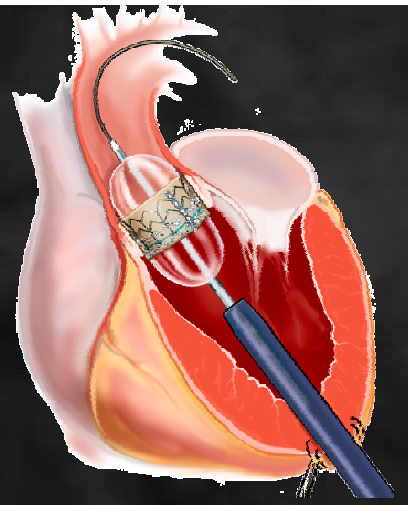
REVIVE II: All Cause Mortality



Implantation Success Rate



Edwards THV Worldwide (All Transapical)



Edwards Aortic THV
n > 270

Canadian Special Access (Vancouver)
n=44

PARTNER Europe

PARTNER US

TRAVERCE
Europe
n=125

REVIVAL II
US
n=22

TRAVERCE Trial (N=125 Pts)

Age (years)	81.7 ± 5.0
Female Gender (%)	78.4
Logistic Euroscore (%)	26.7 ± 13.1
Ejection fraction (%)	49.6 ± 16.2
AVA pre-intervention (%)	0.55 ± 0.22
26 mm valve (%)	69.6

TRAVERCE: Procedure Outcomes

Patients (n)	125
BAV to Valve deployment (min.)	8.3 ± 5.3
Total procedure Time (min.)	128 ± 81
Off pump (%)	71.2
Correct positioning (%)	92.8
Conversion (%)	8.8

TRAVERCE: Mortality

125 Patients

Procedure Related
- Sudden death
- Multi-organ failure
- Cardiac failure
- Stroke

Late Deaths (>30 days) N=18 (14.4%)

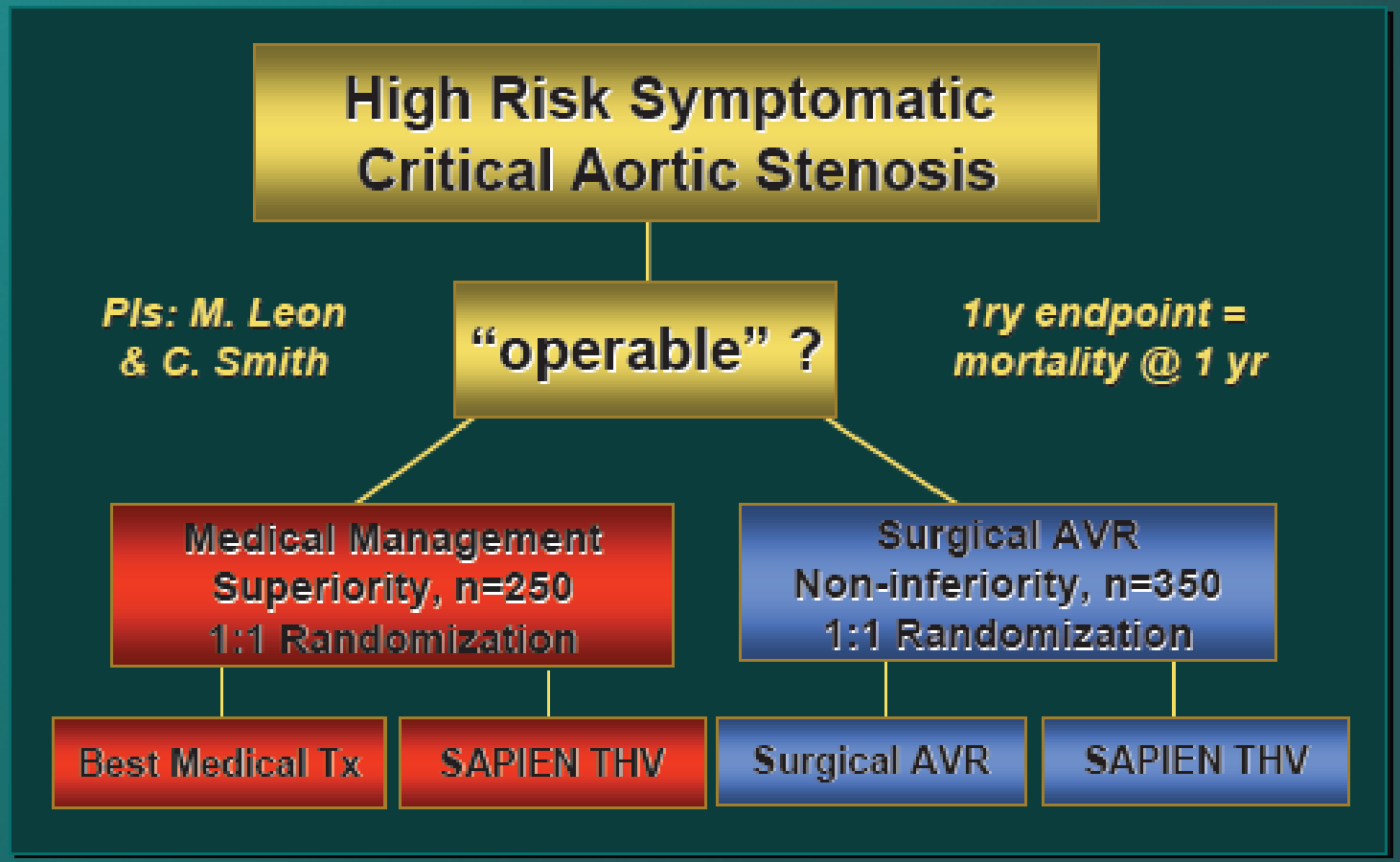
Early Deaths (<30 days) N=15 (12%)

Procedure Related
-Sudden death
-Multi-organ failure
-Cardiac failure
-Stroke

14 Non procedural
- GI comp.
- Stroke
- Sepsis
- MI

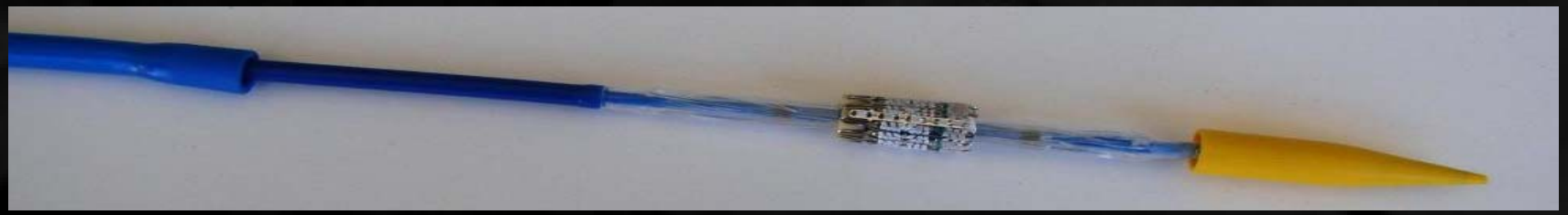
11 Non Procedural
- Cardiac failure
- Arrhythmia
- Bleeding
- Multi-organ failure
- Leg ischemia
- GI comp.
- Embolic event

PARTNER US, Randomized Trials
Total = 600 Patients



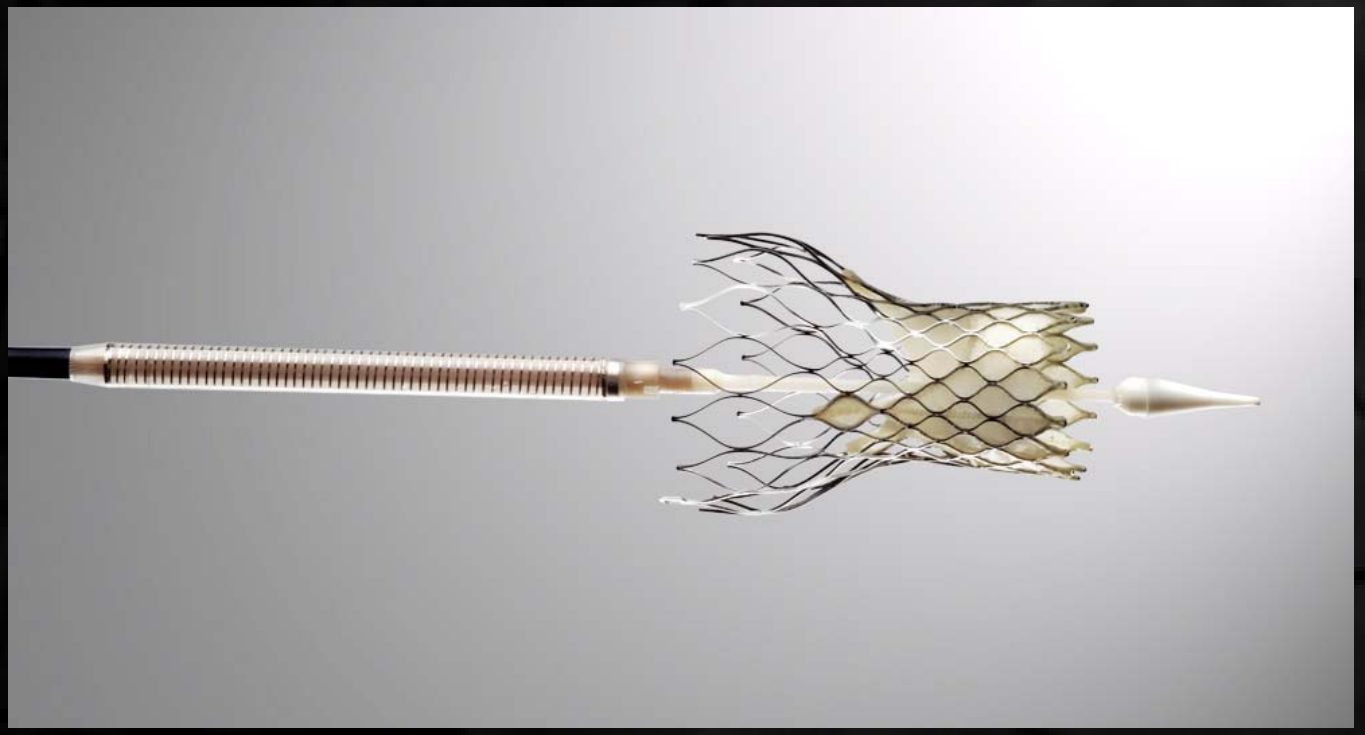
Next Generation Transcatheter Valve

- ✓ Refined balloon expandable valve frame and delivery system (overall size reduced by 3-5Fr)
- ✓ Refined leaflet geometry
- ✓ The RetroFlex II delivery catheter



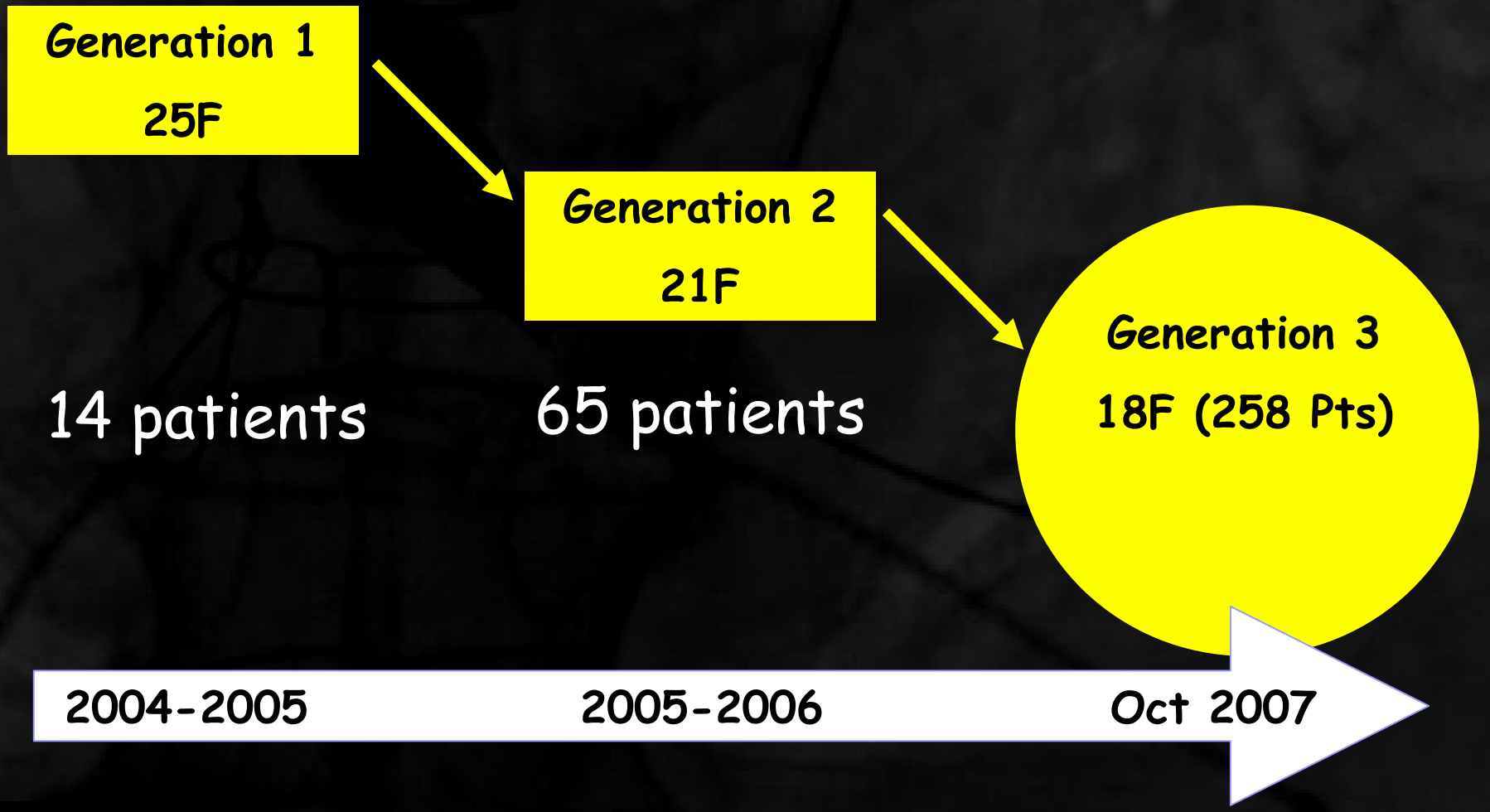
CoreValve ReValving™ System

18 Fr Delivery System



Self-expanding nitinol frame, porcine pericardial valve, and 18 Fr sheathed delivery system

CoreValve Self-Expanding Bioprosthesis Clinical Experience: 337 Patients



CoreValve : Patients Demographics

	21F (n=63)	18F (n=112)
Age (years)	81 ± 6	82 ± 7
Female gender (%)	68	55
Logistic EuroSCORE (%)	26 ± 15	24 ± 14
CAD (%)	60	61
Prior MI (%)	19	19
Prior PCI (%)	35	33
Prior CABG (%)	23	28

CoreValve : Patients Demographics

	21F (n=63)	18F (n=112)
Procedural Success (%)	92	92
Procedure Time (min)	204±62	151±77

CoreValve : Complications 0-30 days

	21F (n=63)	18F (n=112)
Conversion to surgery (%)	3	4
AMI (%)	2	1
Aortic dissection (%)	3	2
Coronary impairment (%)	2	1
Vascular complications (%)	10	1
Stroke/TIA (%)	5	7
Pacemaker (%)	16	24

Non Hierarchical events

CoreValve : 30-day Mortality

	21F (n=63)	18F (n=112)
Logistic EuroSCORE (%)	26	24
30-Day Mortality	14	15

Percutaneous Aortic Valve Implantation

In 2008

Surgery

150 000 Pts / year

> 40 years' experience

Percutaneous

> 1000 Pts

> 600 Pts

> 400 Pts

Conclusion

- ✓ Feasibility and efficacy of percutaneous aortic valve implantation in patients at very high risk or with contra-indications to surgery is now clearly demonstrated.
- ✓ Hemodynamic performance and mid-term durability of the valve are excellent.

Conclusion

- ✓ The main limitation of the retrograde approach is optimal screening for femoral approach and learning phase of the Team in managing difficulties and complications.
- ✓ When the femoral access is contra-indicated, the trans-apical approach seems to be a good alternative.

Conclusion

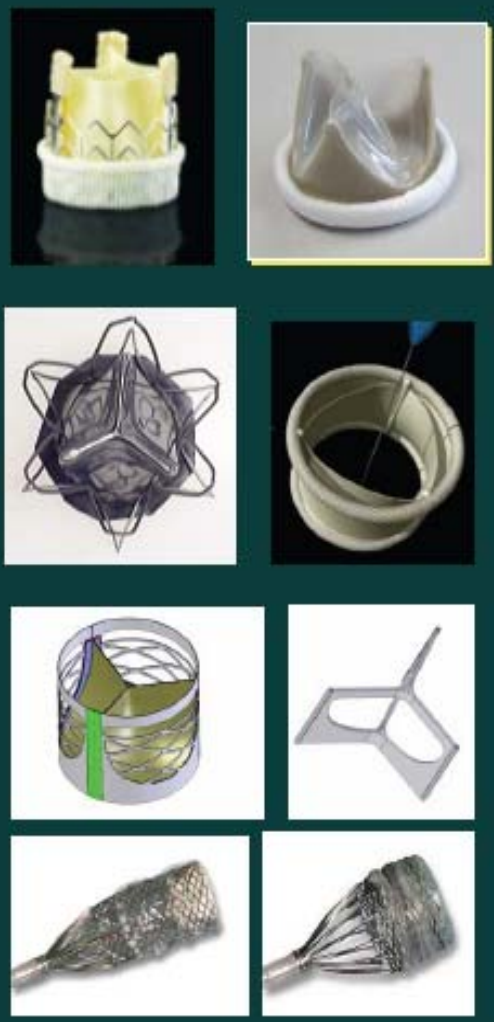
- ✓ Finally, this technique opens a new field in which more patients with symptomatic aortic stenosis will have access to treatment (percutaneous or conventional).

The first Human Heart Transplant

Percutaneous Aortic Valve Implantation

Future Aortic Valve Concepts

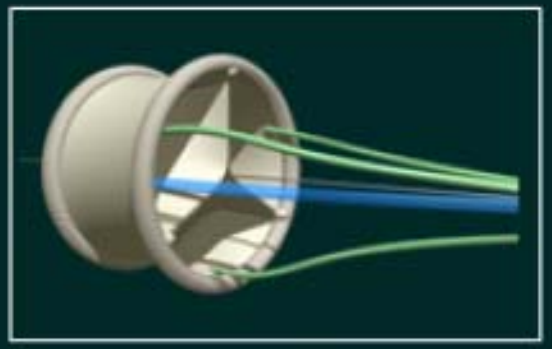
- **Other stent-valve designs**
  - Bonhoeffer (bovine jugular vein)
  - AorTech
  - Paniagua (EndoTech)
  - 3F (apical)
  - Palmaz-Bailey (nanotech-nitinol)
  - Direct Flow
  - AorTx
  - Sadra Lotus valve



Next Generation Devices

Lower profile, repositionable, less pAR

AorTx



DirectFlow

Sadra