

Evolution of transcatheter hearts valves and results

Angioplasty Summit TCTAP 2010



Alain Cribier
University of Rouen, France

CoreValve



CE Mark

2007

CE mark commercialization

2005-07

International TF and TA Feasibility Studies

FIM

2004

Edwards Lifesciences Technological improvements

2002-03

2002

April 2010 ~ 15 000 THV implanted worldwide

Implantation (sheep)

« Percutaneous Valve Technology » (prototypes)

1987

Post-mortem studies of intra-valvular stenting

1985

Concept of « stented valve »,

F.I.M. Balloon Aortic Valvuloplasty

From PVT to Edwards balloon expandable Valves

Edwards Valves

2000: **PVT Valve**

2003-2004

2005-2009

2009

Percutaneous Heart Valve

Cribier Edwards

Edwards Sapien

Edwards Sapien XT



Bovine pericardium
Stainl. steel frame
23mm

Equine pericardium
Stainl. steel frame
23mm

Treated bovine pericardium
Stainl. steel frame .
23 and 26mm

Next to come
20mm / 29mm

Next generation

24F

22F

22F, 24F

18F, 19F

TF sheath sizes

Self expandable Medtronic CoreValve

Generation 1
25F

Generation 2
21F

Generation 3
18F

Generation 4
18F

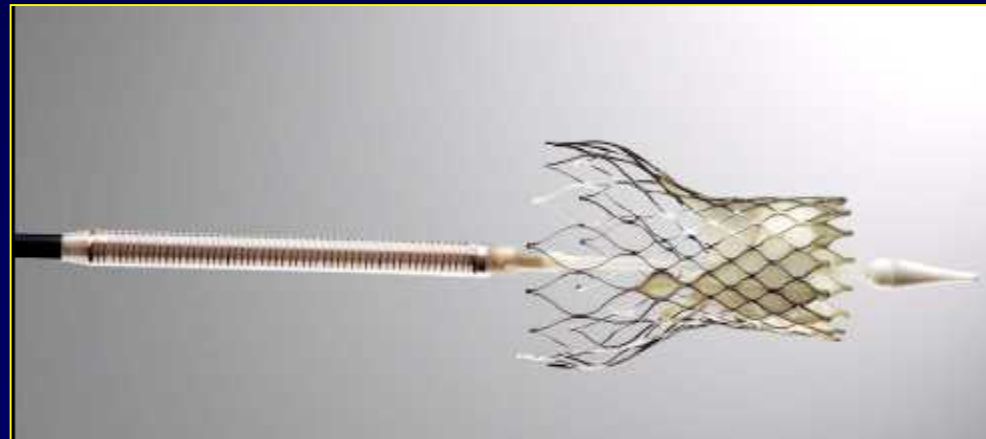
2004-2005

From 2006

2010



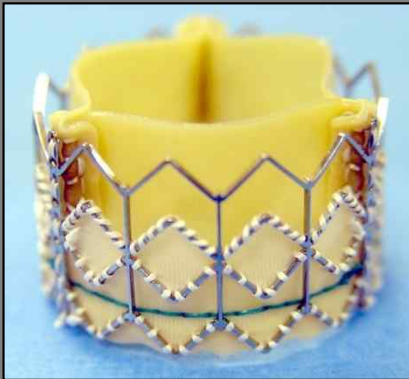
Porcine pericardium valve
Nitinol stent



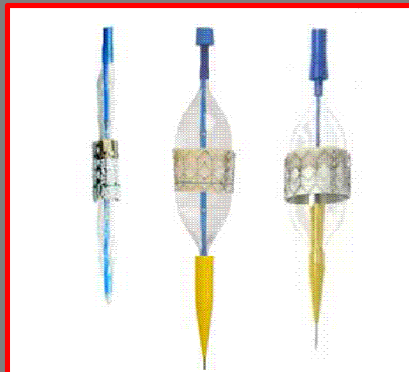
Improved
delivery ?

Improved valve designed and delivery systems

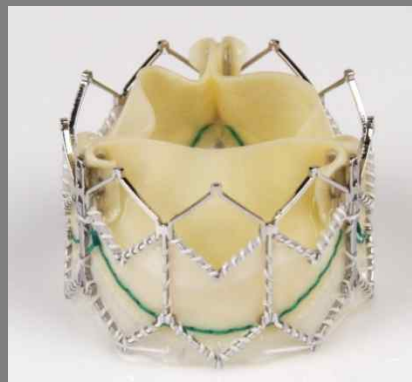
Reduction of sheath sizes



Edwards Sapien
(22F & 24F)



New: NovaFlex



**Edwards Sapien
XT**
(18F & 19F)

Medtronic CoreValve

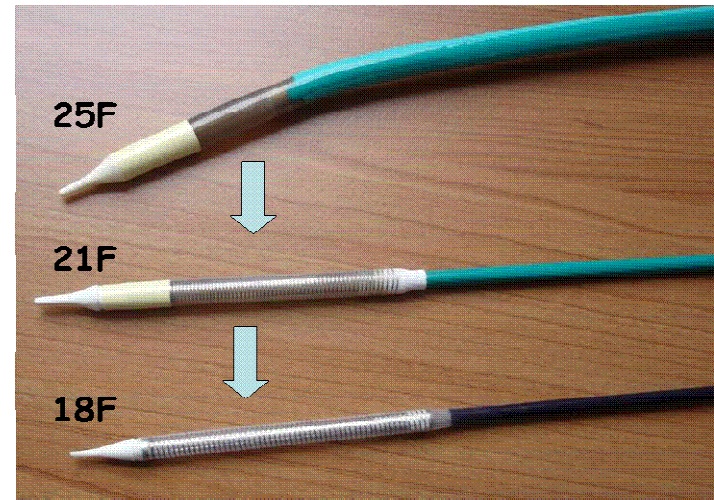
2004



2005



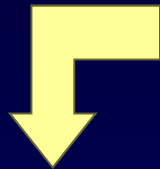
2006



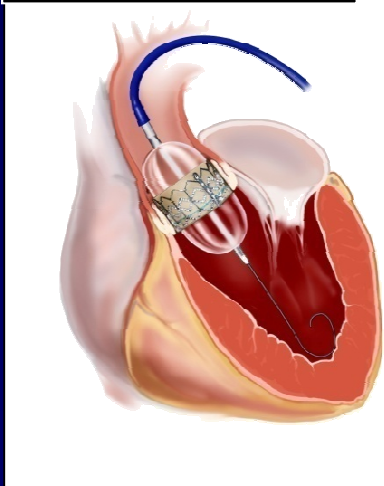
Approaches used for valve implantation



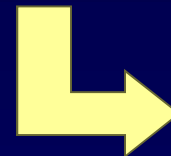
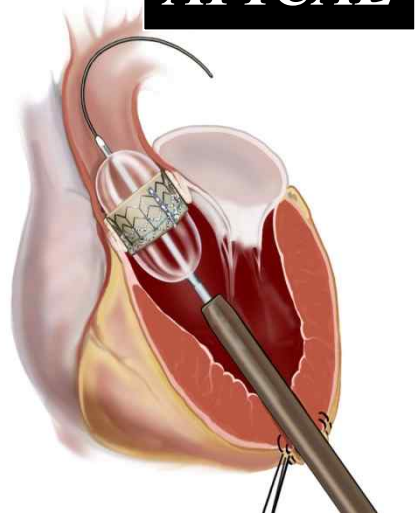
SUB-CLAVIAN



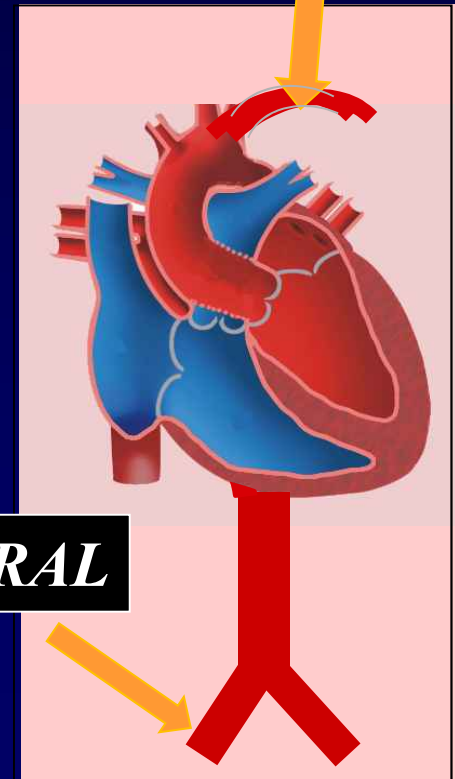
FEMORAL



APICAL



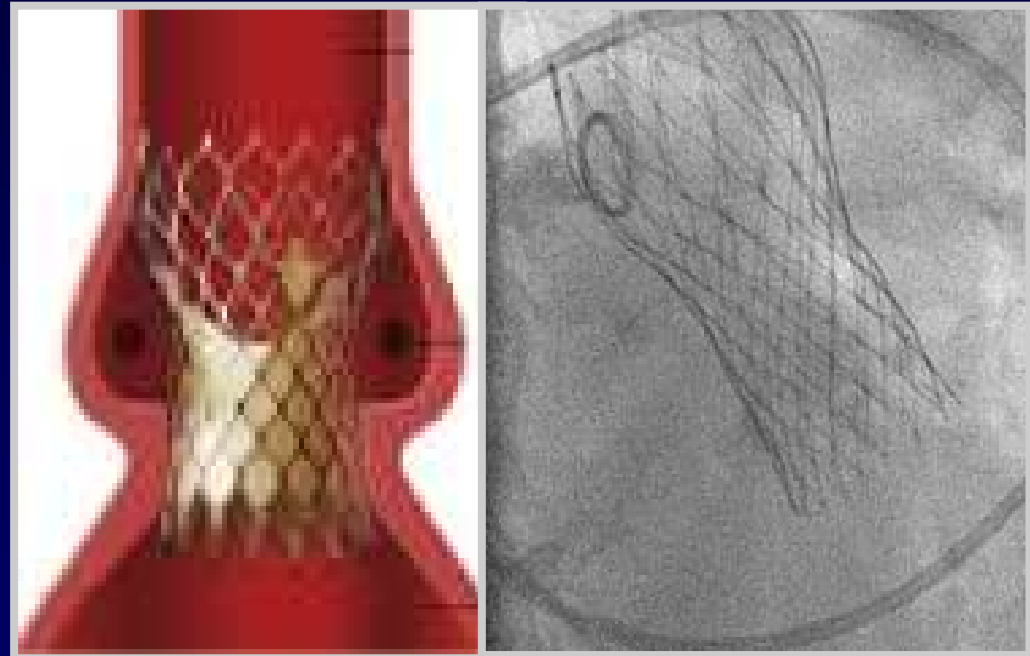
FEMORAL



Valve positioning



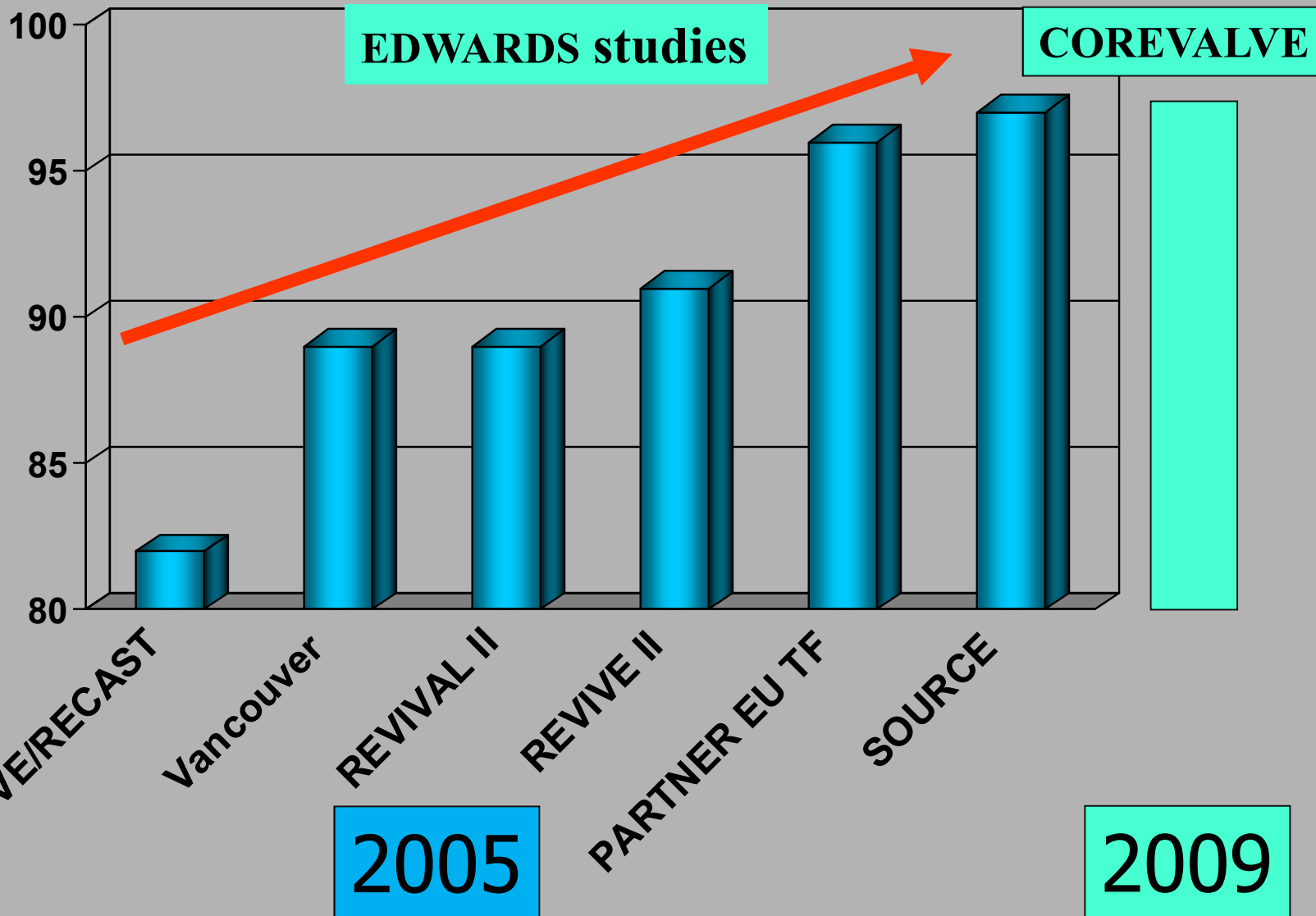
**Intra-annulus
Sub-coronary**



**Intra-annulus
Aorta, supra-coronary**

Device success rate

FIM
2002



30-day mortality and complications

Edwards	PARTNER N=130	SOURCE N=1038	Webb et al N=168	FRANCE N=166	CoreValve
Mortality					
TF	8.1%	6.3%	8.0%	8.4%	10.3%
TA	18.8%	10.3%	18.2%	16.9%	
Stroke	3.0%	2.5%	4.2%	3.6%	2.2%
Pacemaker	3.0%	7.0%	5.4%	5.4%	25%
Major Vascular	10.0%	7.0%	6.6%	6.0%	7%

PARTNER: PCR 2009

SOURCE: PCR 2009

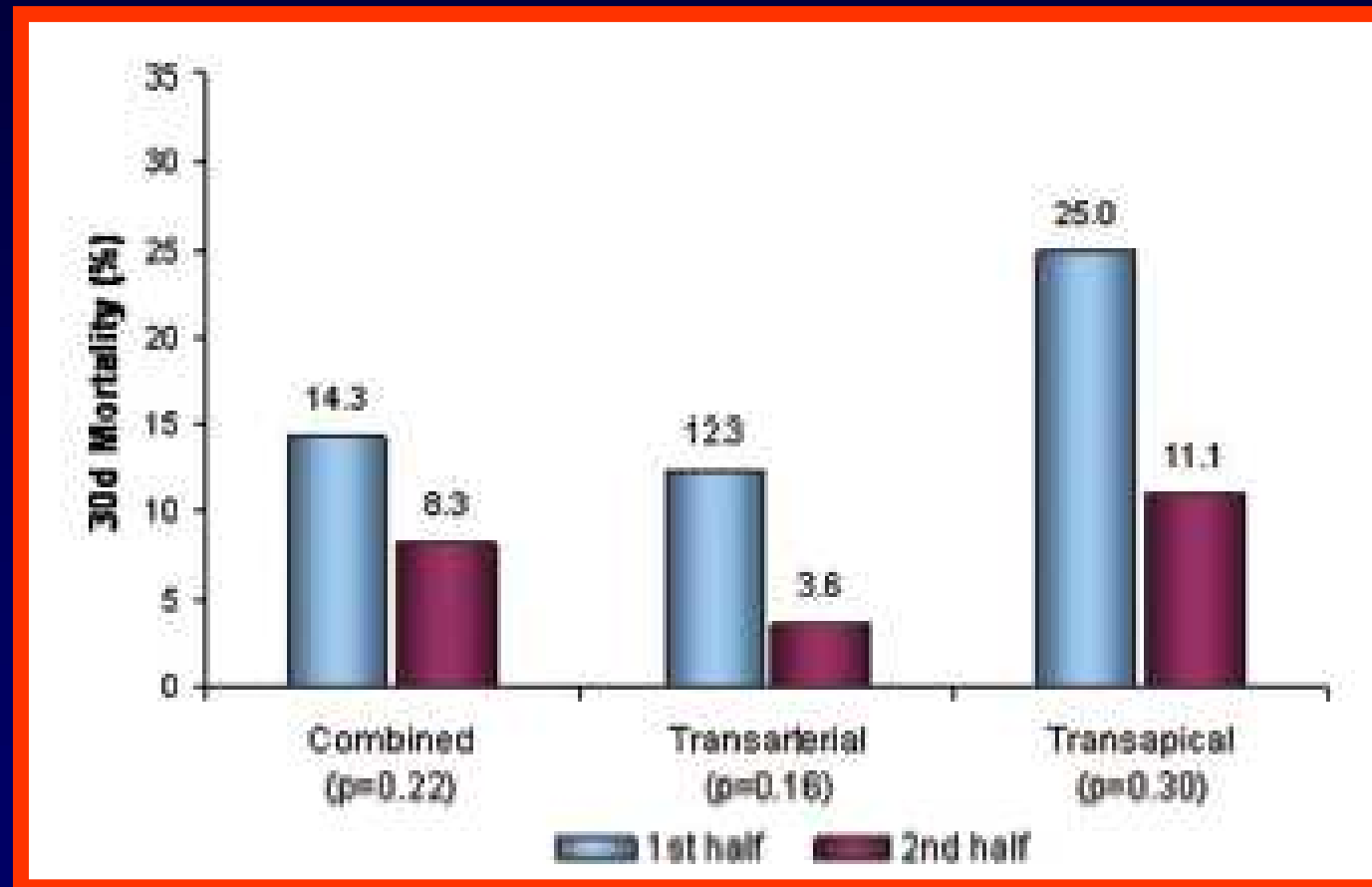
Webb et al: Circulation 2009

France: AHA 2009

PCR 2009

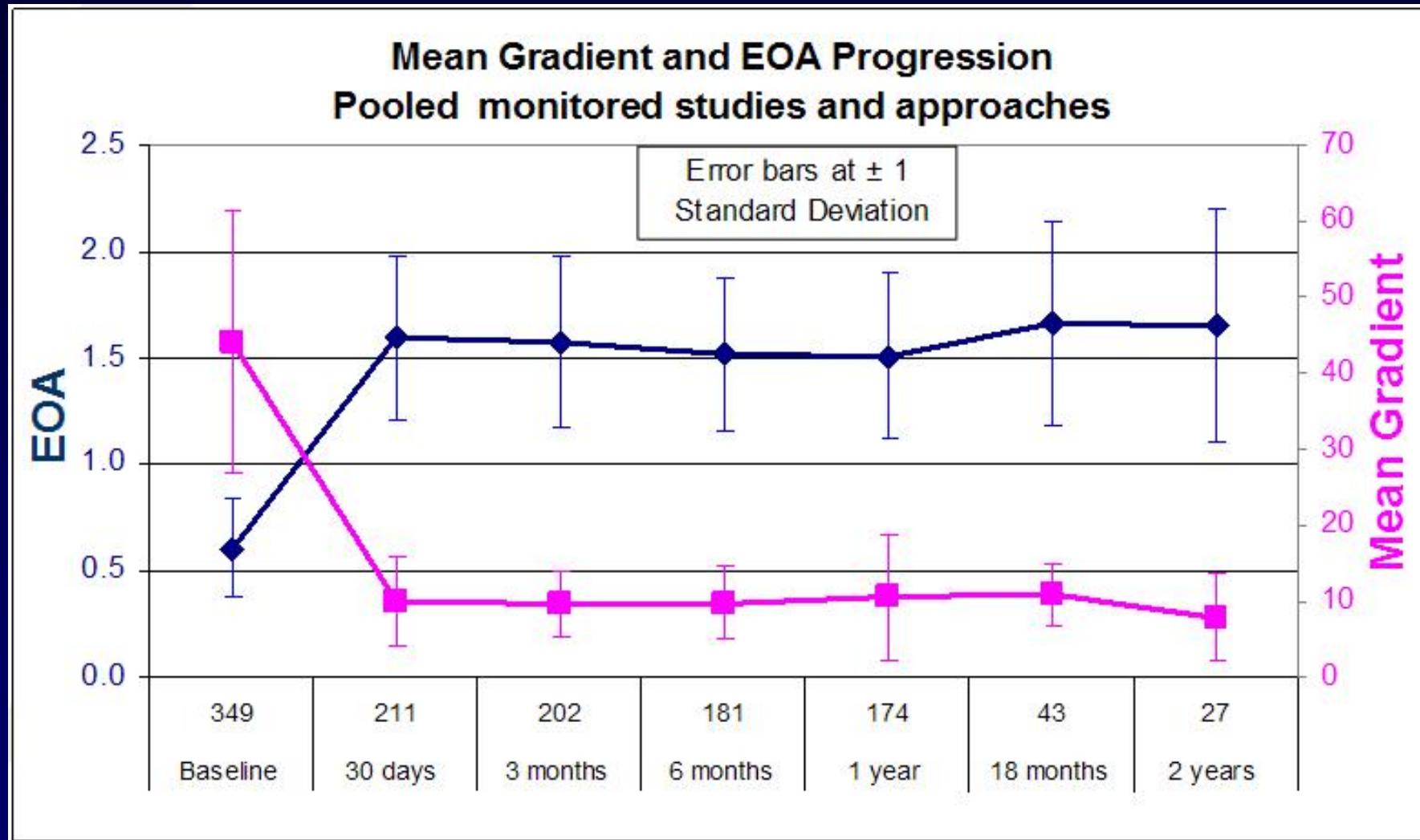
Learning curve is evident

J. WEBB et al, Circulation 2009; 119: 3009-16

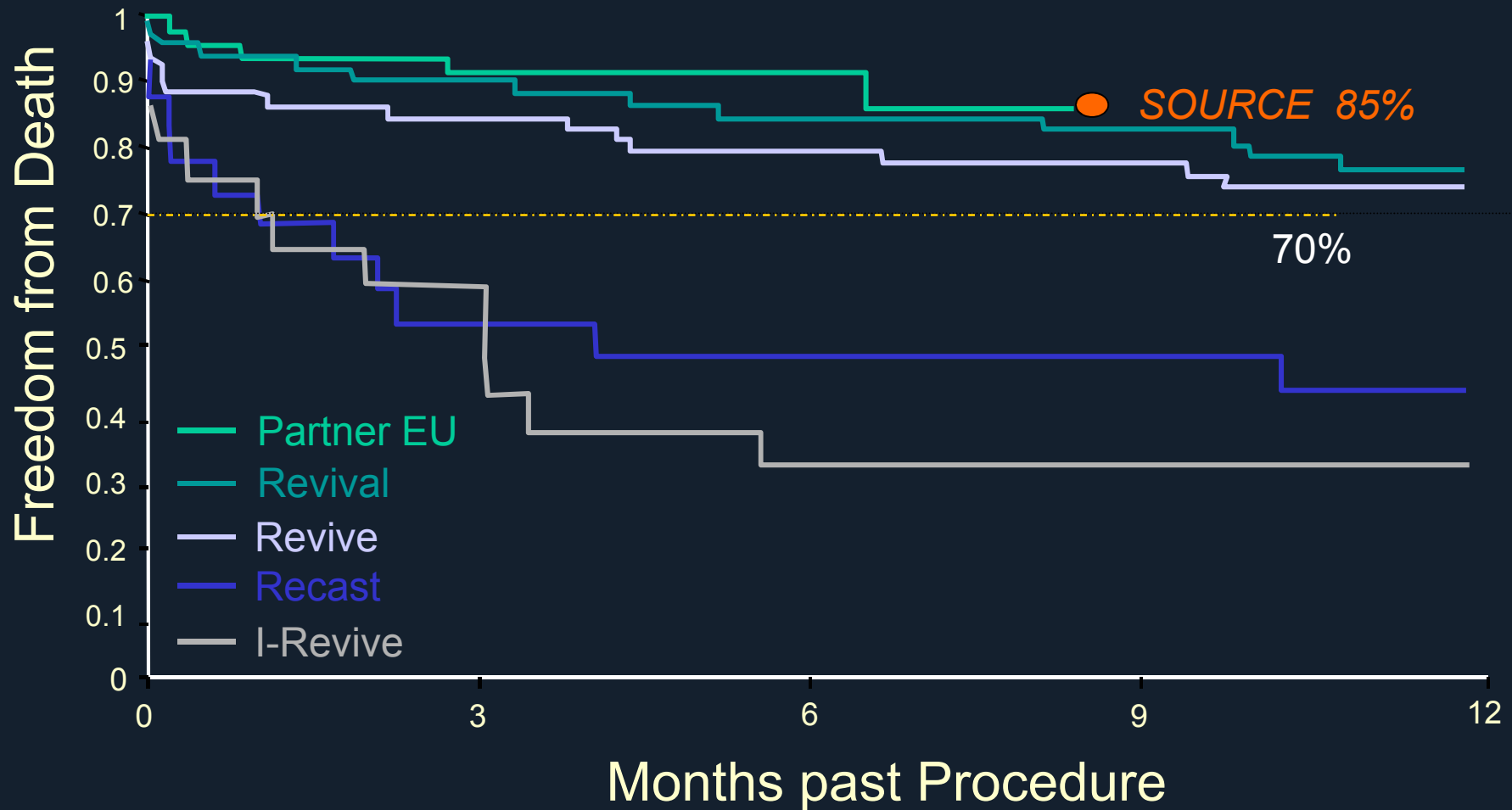


Pooled Monitored Studies and Approaches

No change in EOA and gradient over time



All Cause Mortality Transfemoral and Early Studies



No change in E.O.A. and transvalvular gradient

PARTNER U.S. Pivotal Trial

YES

OPERABLE
ASSESSMENT

NO

Inclusions completed: August 2009

24 centers, 1040 pts

Results expected: 2011

TF
THV

VS

Surg.
AVR

TA
THV

VS

Surg.
AVR

TF
THV

VS

Medical
management

NON INFERIORITY

SUPERIORITY

Many other valves under investigation



Perspectives and Conclusions

The perspectives of TAVI are wide and the future looks bright!

- Over the last 5 years, the devices and procedures have rapidly evolved making TAVI simpler, faster, safer and more efficient
- The number of centers and well trained interventionists will continue to expand worldwide for the treatment of high surgical risk patients
- With the improved devices profile, TAVI will be soon performed in the vast majority of patients as a stent-like procedure
- **In 2011/2012**, depending on the results of PARTNER-US and in the event of FDA approval, TAVI might explode in USA and worldwide in the subset of high risk patients.

Perspectives and Conclusions

The perspectives of TAVI are wide and the future looks bright!

- The issue of valve+platform durability remains unsolved and should be better assessed before expanding the indications to younger patients with less surgical risks
- **Within 10 years**, and depending on the *long term results* of upcoming controlled trials in a broad population, TAVI might become the treatment of choice in a majority of patients with degenerative AS.