

Transcatheter Aortic Valve Implantation

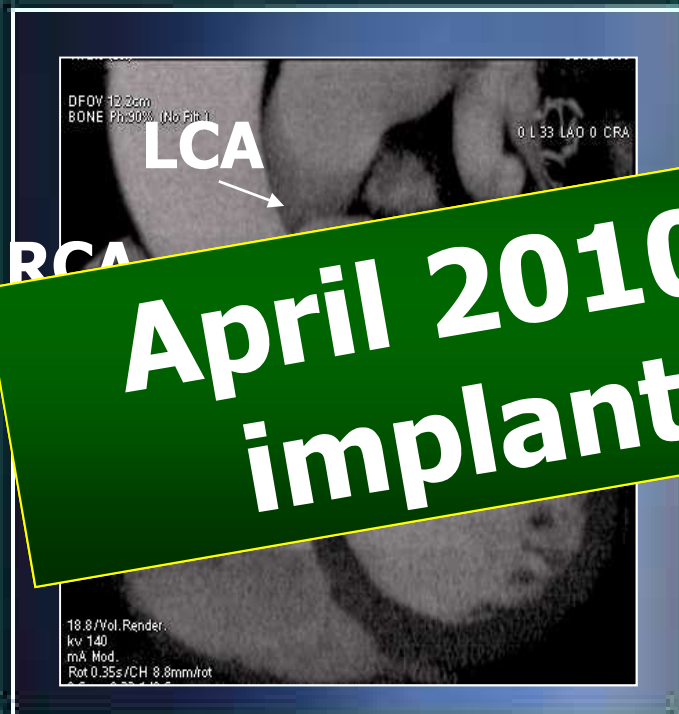
Present Status and Perspectives

Angioplasty Summit TCTAP 2010

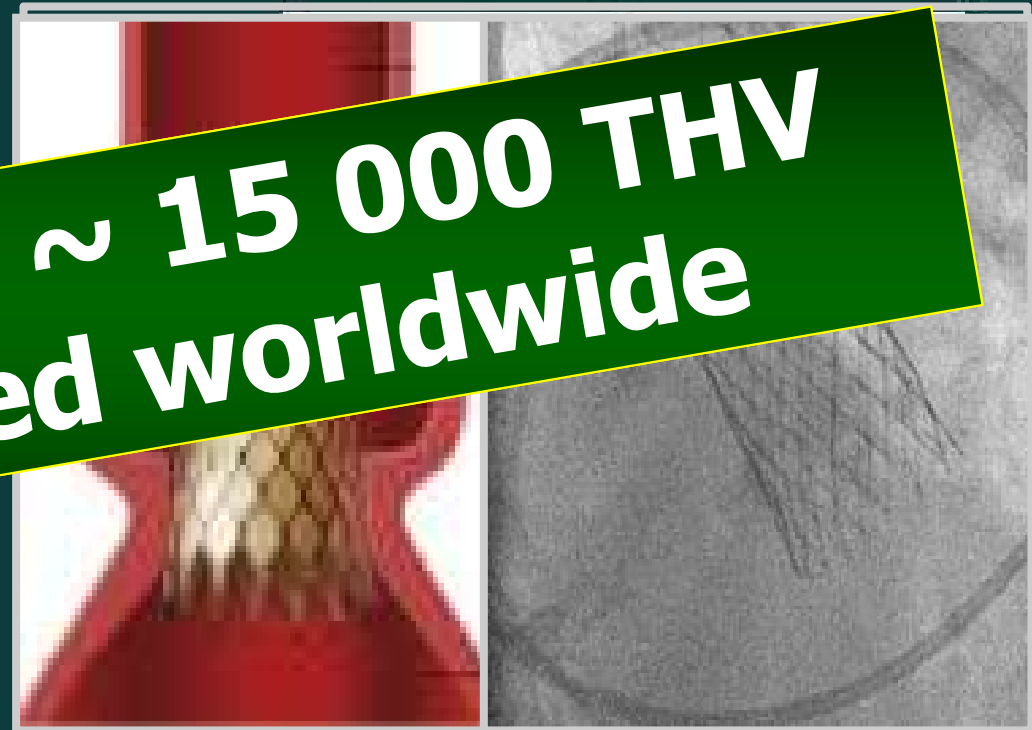


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Transcatheter Aortic Valve Implantation has entered the real world and is here to stay



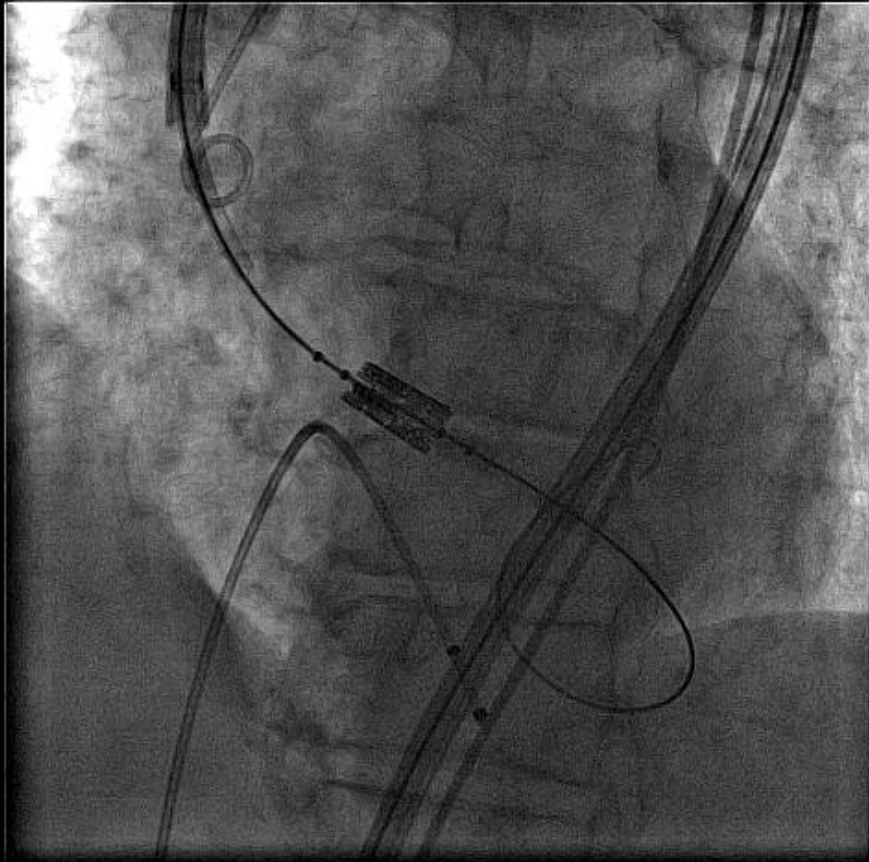
Edwards-Sapien
Balloon-Expandable Valve



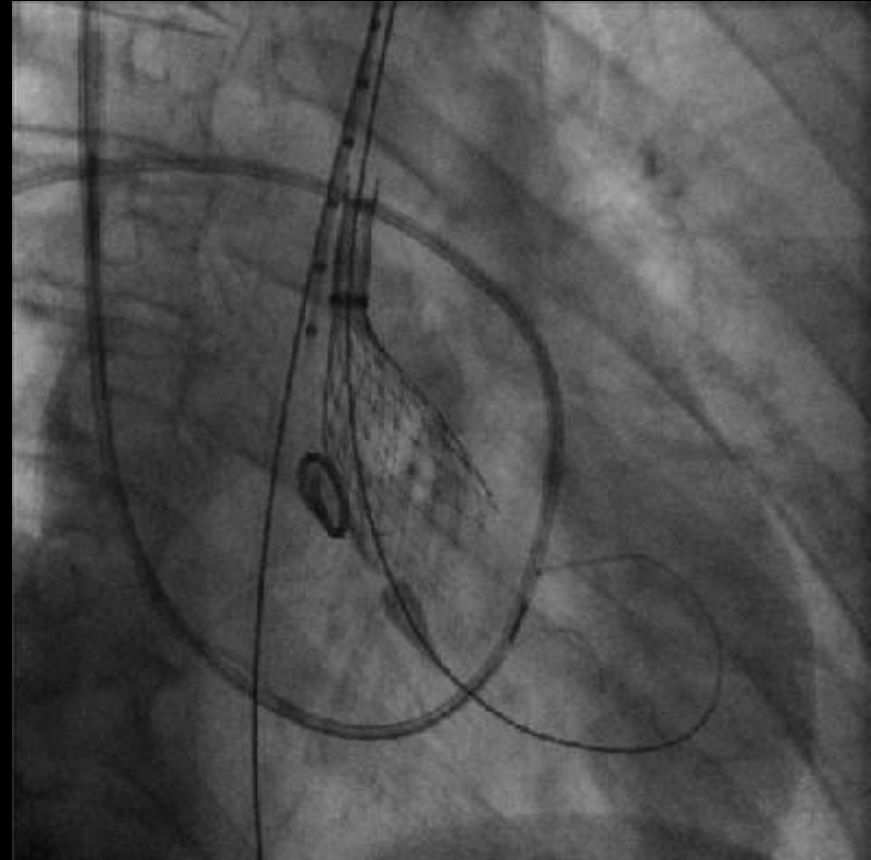
CoreValve
Self-Expandable Valve

April 2010 ~ 15 000 THV
implanted worldwide

Valve delivery



Edwards-Sapien
Balloon-Expandable Valve



CoreValve
Self-Expandable Valve

TAVI

What is known in 2009

- **Early prosthetic valve performance similar to surgical valve replacement**

Current indications

- **Decreased mortality**
- **Combination of transcatheter and surgical procedures**
- **Imaging**
- **Severe degenerative / calcific AS**
- **Highly symptomatic patients**
- **High surgical risk or non operable at mid-term**
- **Still some device related complications (vascular events, complete AV block)**

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 Equine pericardium Treated bovine pericardium

Stainl. steel frame Stainl. steel frame Stainl. steel frame

23mm

23mm

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

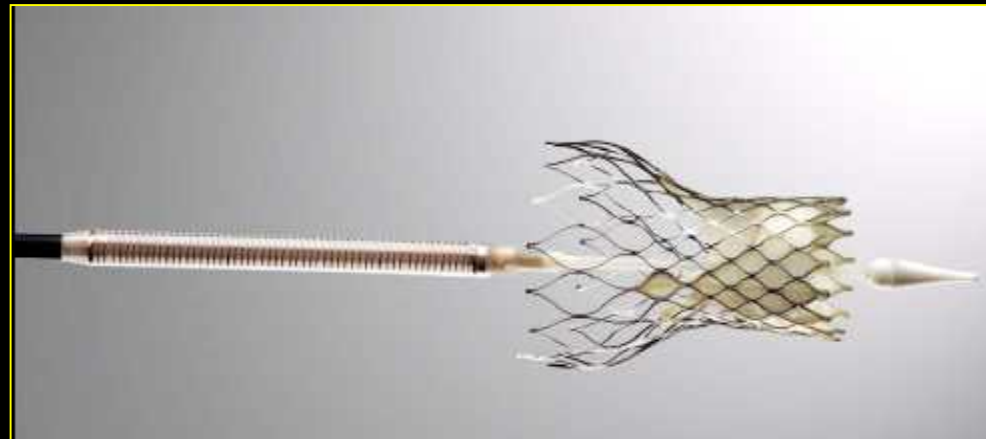
Generation 3
18F

Generation 4
18F

2004-2005

From 2006

2010

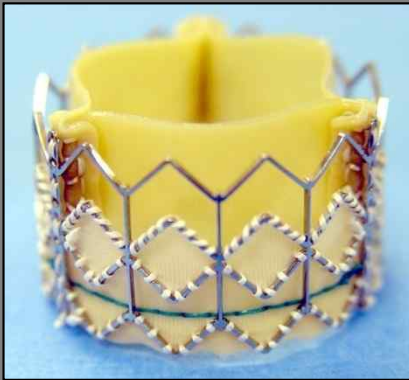


Porcine pericardium valve
Nitinol stent

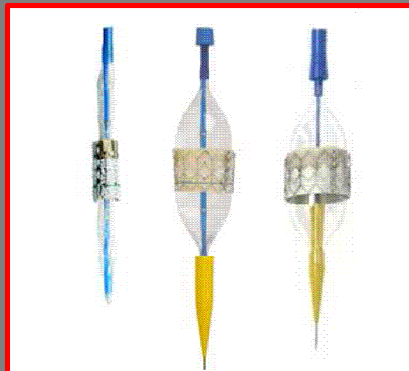
Improved
delivery ?

Improved valve designed and delivery systems

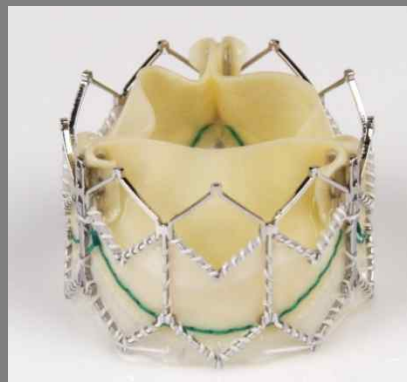
Reduction of sheath sizes



Edwards Sapien
(22F & 24F)



New: NovaFlex



Edwards Sapien XT
(18F & 19F)

Medtronic CoreValve

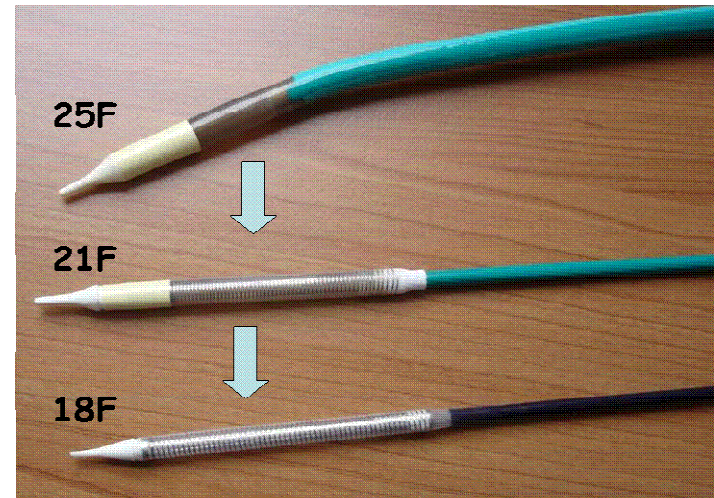
2004



2005

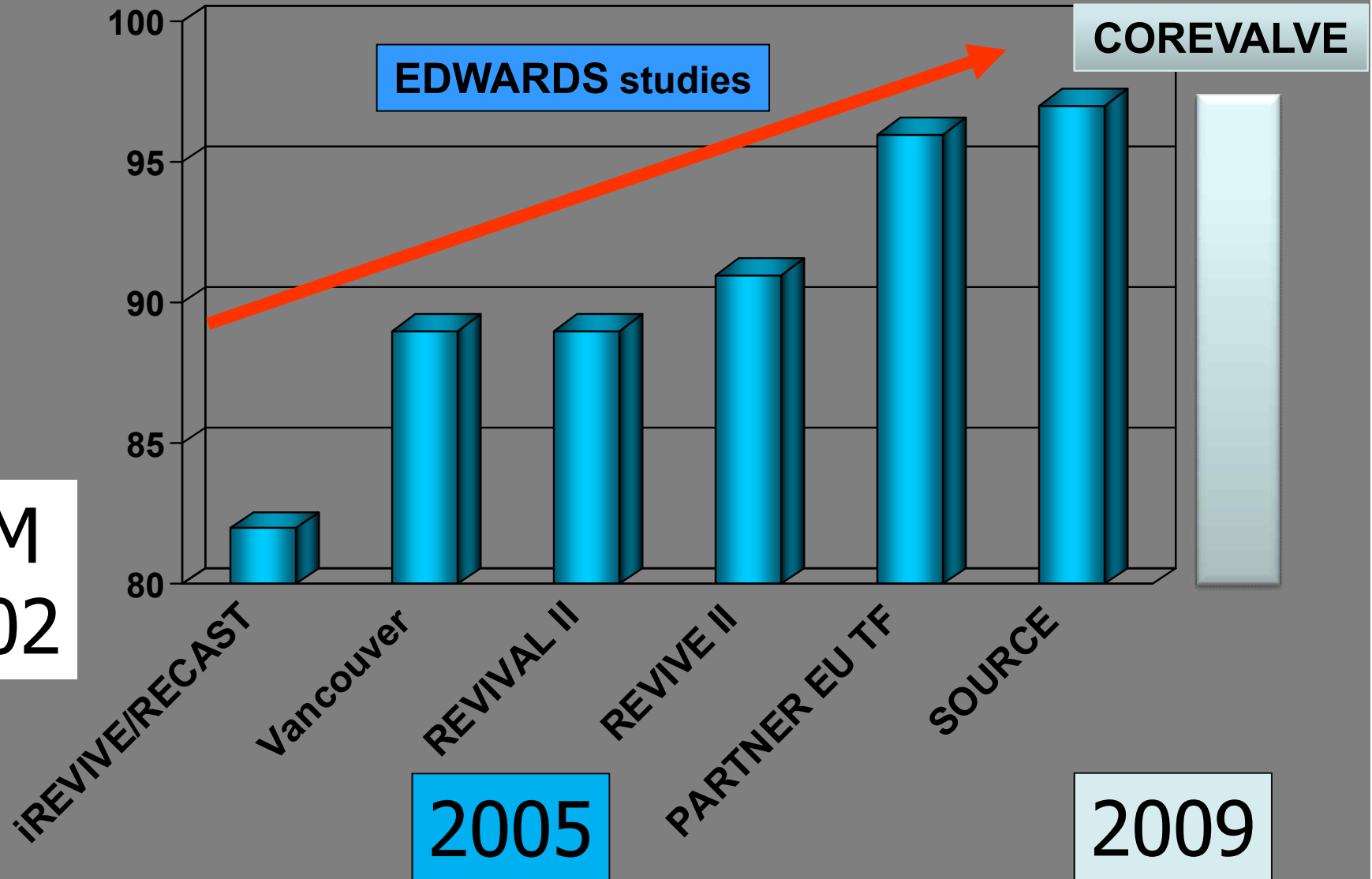


2006



Device success rate

FIM
2002

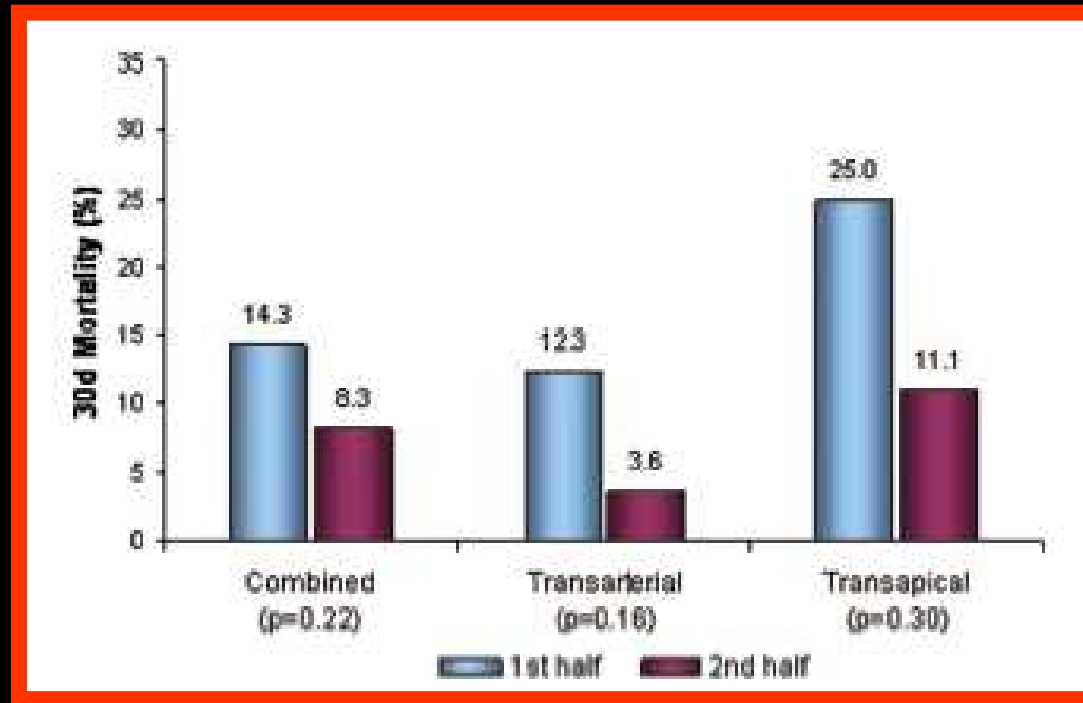


30-day mortality and complications

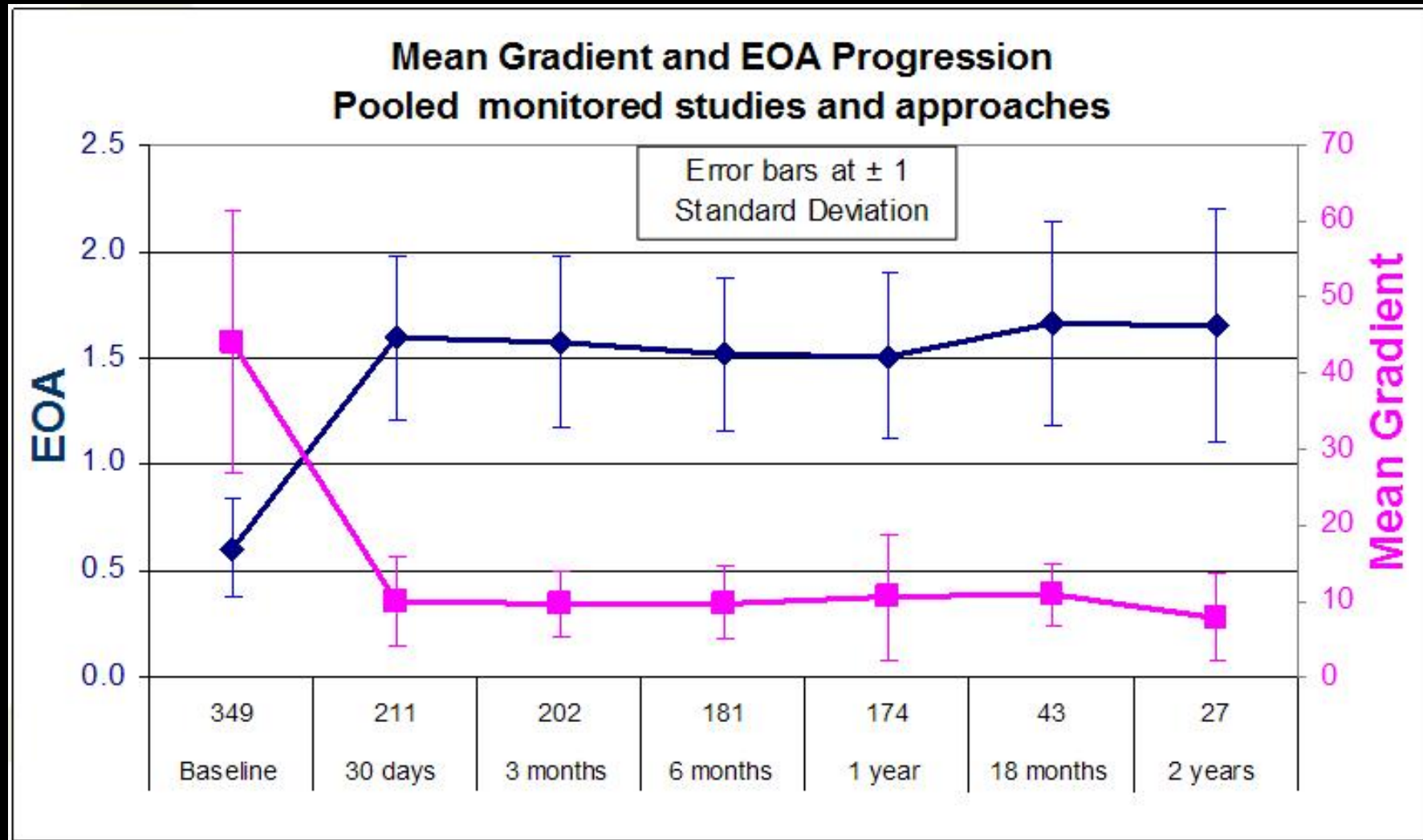
Edwards	PARTNER N=130	SOURCE N=1038	Webb N=168	FRANCE N=166	CoreValve
Mortality					
TF	8.1%	6.3%	8.0%	8.4%	10.3%
TA	18.8%	10.3%	18.2%	16.9%	
Stroke	3.0%	2.5%	4.2%	3.6%	2.2%
Pacemaker	3.0%	7.0%	5.4%	5.4%	25%
Major Vascular	10.0%	7.0%	6.6%	6.0%	7%

Learning curve is evident

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

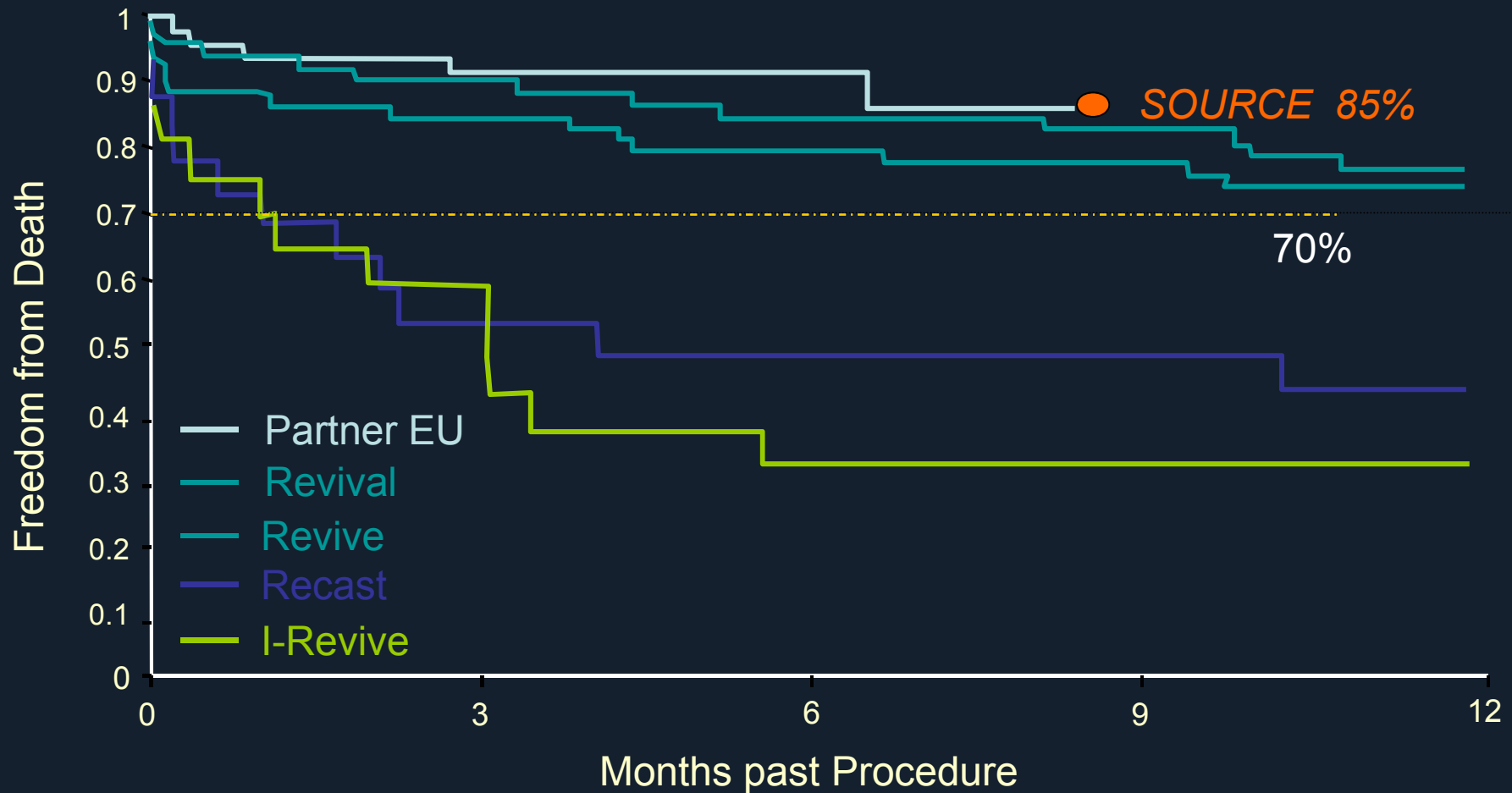


No change in EOA and gradient over time



Edwards pooled monitored studies

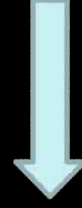
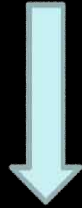
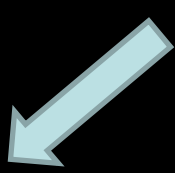
All Cause Mortality Transfemoral and Early Studies



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

PERSPECTIVES

Where do we go?



Improved
THV
and delivery
systems

Upcoming
controlled trials
in specific
subsets of pts

Assessment of
Valve +
Platform
durability

THV and
procedural
cost /
reimbursement



Expanded clinical indications ?

Valve + Platform durability is a crucial issue

Little is known on valve durability
and follow-up beyond 2 years

- No case of valvular dysfunction reported so far
(*unchanged E.O.A. and gradient*)

Survival ~ 60% at 2 years
(whatever the valve used)

Longest reported clinical follow-up (Rouen)

Mrs S..., 90 y-old: > **6.5 years** with THV



Normal life

No valve dysfunction

AVA: 1.68 cm², mean gradient: 12 mmHg

TAVI: need for additional registries and controlled trials

- **Registries should report 100% in data base (SOURCE, FRANCE)**
 - **Controlled trials vs surgery in specific subsets of patients**

**Very old patients (> 80 years) at lower risk??
Any low risk patients ???**

PERSPECTIVES ON ACCESS

Angiography + CT Scan

Diameter
Tortuosities Calcification

Trans -
apical

Transfemoral
Retrograde
Approach

Edwards-SAPIEN

2011

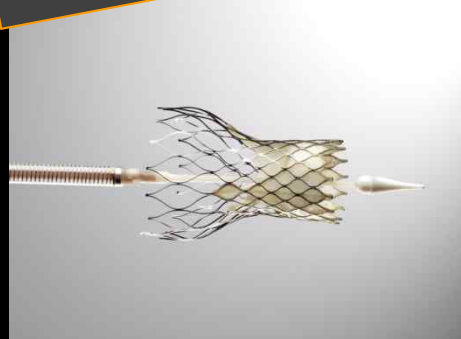
> 70% Transfemoral
Local anesthesia
Preclose technique

STENT LIKE PROCEDURES

Subclavian

≈ 70%

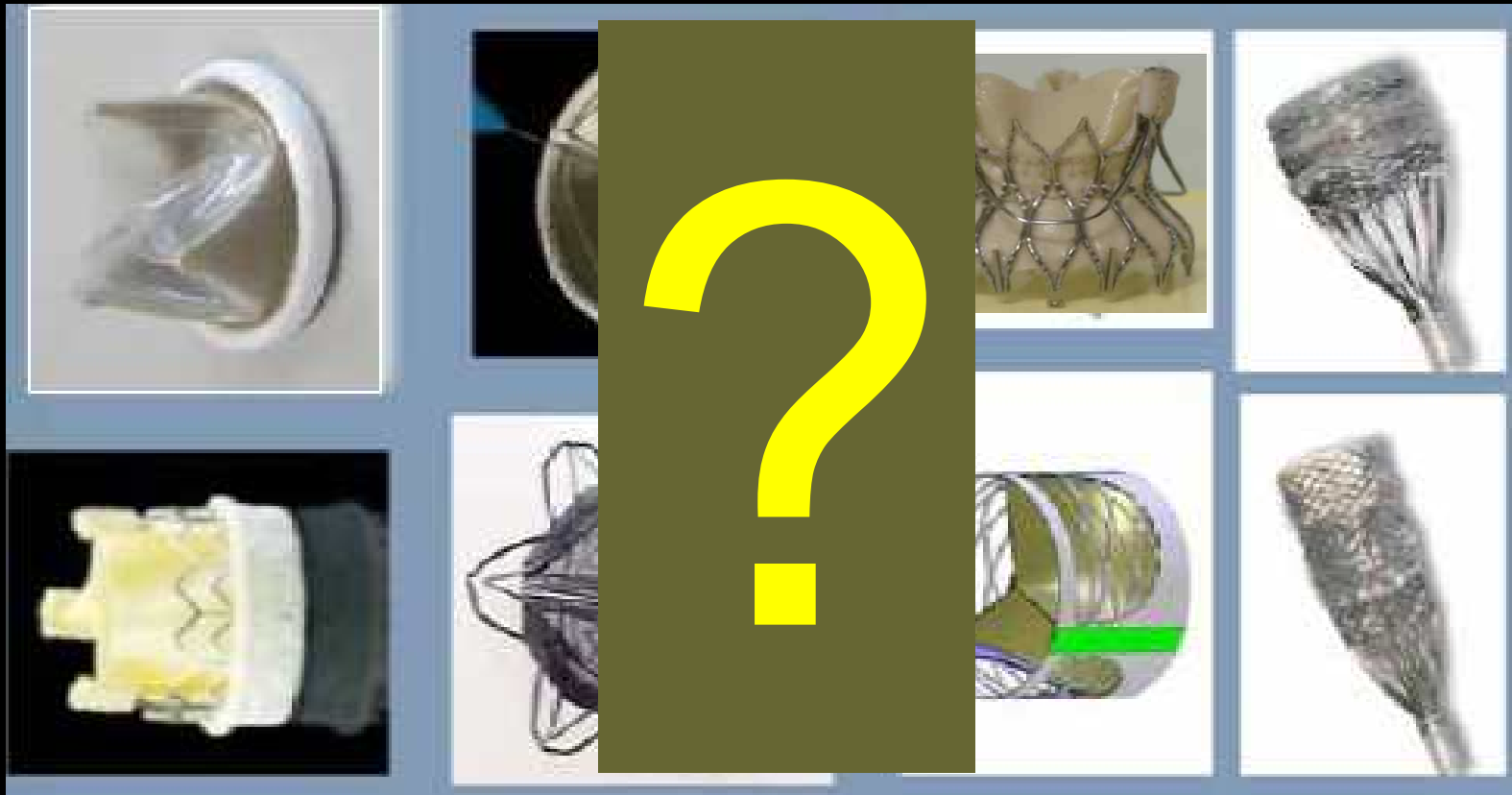
THV 26mm:
19F: FA > 7 mm



THV 26mm / 29mm
18F: FA > 6 mm

≈ 70%

Technology advancements Future directions



TAVI

Interventional issues

- **Importance of physician and staff training**
validating training and proctoring programs
- **Dedicated cath-labs and / or hybrid OR**
with optimal imaging capabilities
- **Interventional vs surgical operators**
no competition, no fight, optimal partnership
- **Team work for screening and procedures**

Conclusions

Perspectives of TAVI: my predictions

- TAVI has generated an enthusiastic response of interventionists and surgeons. **In 2010**, with technological advancements and optimal training, the number of centers and procedures should continue to expand in high surgical risk patients.
- **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 this subset of high risk patients. A stent like procedure might be used in about 70% of cases.

Conclusions

Perspectives of TAVI: my predictions

- Within 5 years, expansion of indications to less severely ill patients can be expected. More indication concerning valve+platform durability (4 to 5 years) from previous trials and registries should be obtained before starting randomized trials in younger and otherwise healthy patients with the current devices

Conclusions

Perspectives of TAVI: my predictions

- **Within 10 years**, with further improvement of the devices and procedures, and depending on the long term results of upcoming controlled trials in a broad population, TAVI may become the treatment of choice in a majority of patients with degenerative AS.