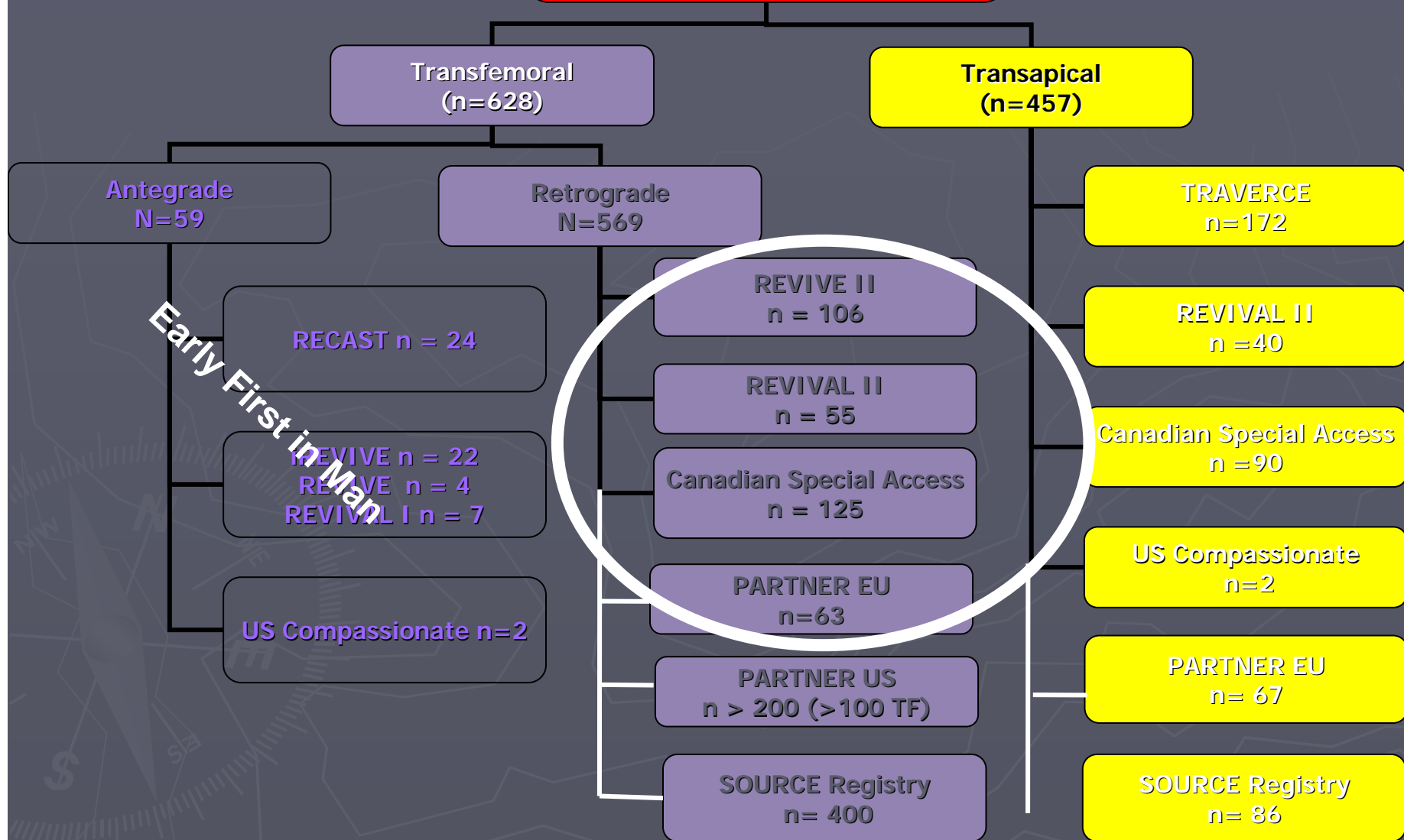


# > 1200 Patients 2002-2008



# Edwards THV Feasibility Clinical Trials Transfemoral

Columbia University (NY)

- REVIVE II
- REVIVAL II
- Canada Special Access

Aarhus  
(Andersen)

Essen  
(Sacks)

Frankfurt  
(Sievart)

Vancouver

Detroit (MI)

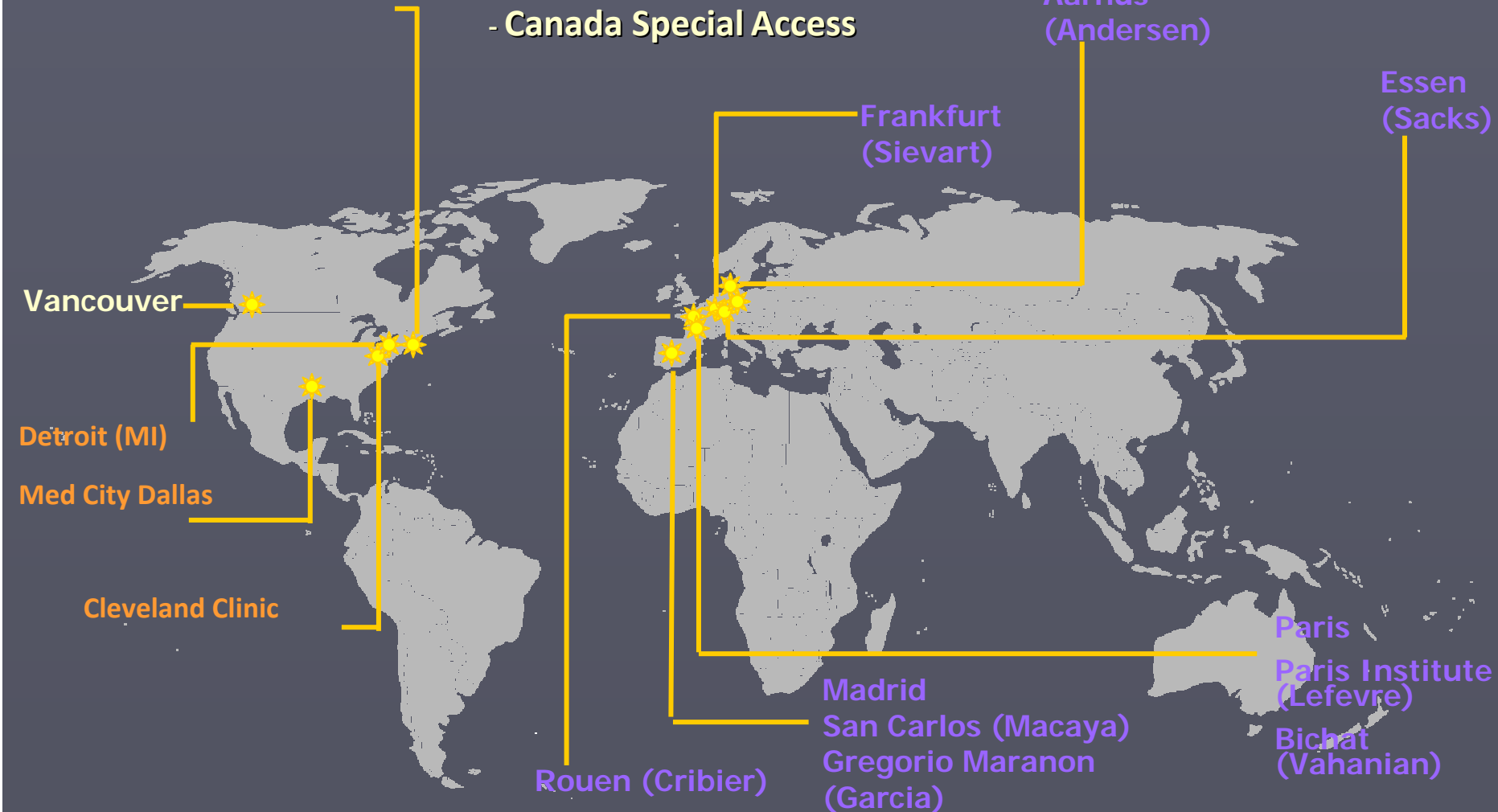
Med City Dallas

Cleveland Clinic

Paris  
Paris Institute  
(Lefevre)  
Bichat  
(Vahanian)

Madrid  
San Carlos (Macaya)  
Gregorio Maranon  
(Garcia)

Rouen (Cribier)



# REVIVE II (Europe)

Centers	n
Hôpital Charles Nicolle – Rouen- F	27
St. Paul's Hospital - Canada	13
Institut Jacques Cartier – Paris - F	13
Hôpital Bichat – Paris - F	12
Universitätsklinikum Essen - Allemagne	11
Skejby University Hospital -Danemark	9
Hospital Gregario Maranon - Espagne	8
Sankt Katharinen Hospital	8
Hospital Univer. San Carlos - Espagne	5
<b>REVIVE II -- TOTAL</b>	<b>106</b>

# REVIVE II & REVIVAL II TF Patient Demographics

	REVIVE II (n=106) Europe	REVIVAL II (n = 55) USA
<b>Age</b>		
Mean ± SD	83.9 ± 5.4	83.7 ± 5.2
<b>Gender</b>		
Female	54 (51.4%)	30 (54.6%)

# REVIVE II (Europe)

## Co-morbidities

Co-morbidities	%
Systemic hypertension	70.2
Angina	47.0
<b>Pulmonary disease</b>	<b>29.1</b>
Diabetes mellitus	23.8
<b>Chronic renal disease</b>	<b>24.0</b>
Peripheral vascular disease	17.6
<b>Congestive heart failure</b>	<b>84.5</b>
Myocardial infarction	15.6
Carotid disease	17.6
Prior PTCA/stent	18.4
<b>Prior CABG</b>	<b>22.9</b>
<b>Prior stroke</b>	<b>22.9</b>
<b>Prior aortic valvuloplasty</b>	<b>37.1</b>

# REVIVE II :

## Contra-indication to surgery

	REVIVE II (n=105)
Porcelain aorta	4 (3.8%)
Irradiated sternum	7 (6.6%)
Severe COPD	20 (18.9%)
Thorax distorsion	4 (3.8%)
Surgical refusal	31 (29.2%)

**Logistic Euroscore:  $29.9 \pm 13.2\%$  (16-43)**

REVIVE II

Procedural Success Rate

90.9%

# REVIVE II & REVIVAL II TF Procedure

Implantation Success	88 (88%)
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100% in the last 25 Pts (Webb et al)



# REVIVE II (Europe) 30-days follow-up

	REVIVE II (n=106)
Mortality	14 (13.2%)
AVR	1 (0.9%)

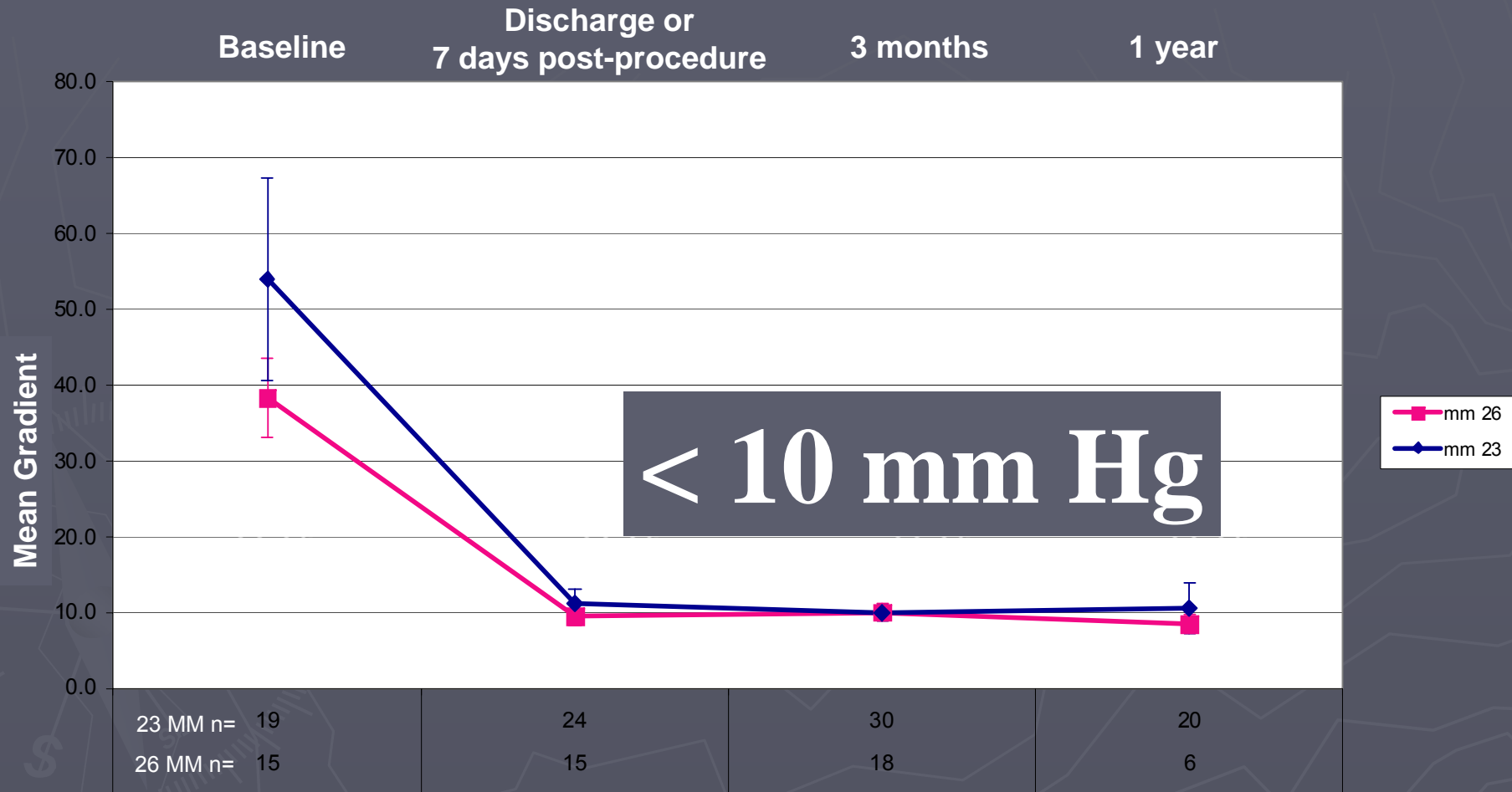
0% in the last 25 Pts (Webb et al)

Vascular complications or access problems	13 (12.3%)
Pacemaker	3 (2.8%)

+ MI defined as elevation of CK to more than 2 times normal with elevated CKMB. 7 of these 9 patients had had CK elevation without clinical of evidence.

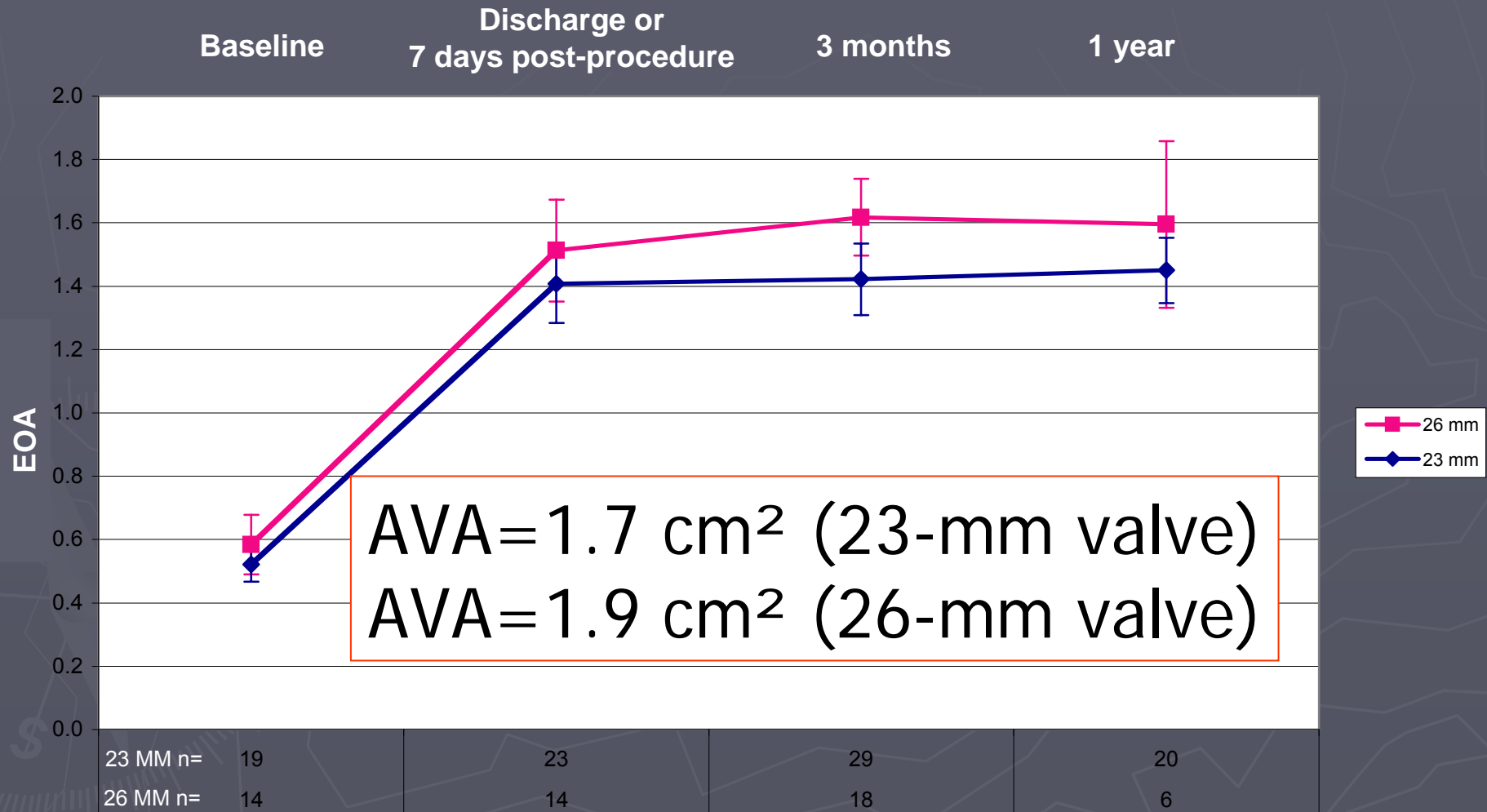
# REVIVE II

## Mean Gradient Progression<sup>†</sup>



<sup>†</sup> = Core Lab Analysis

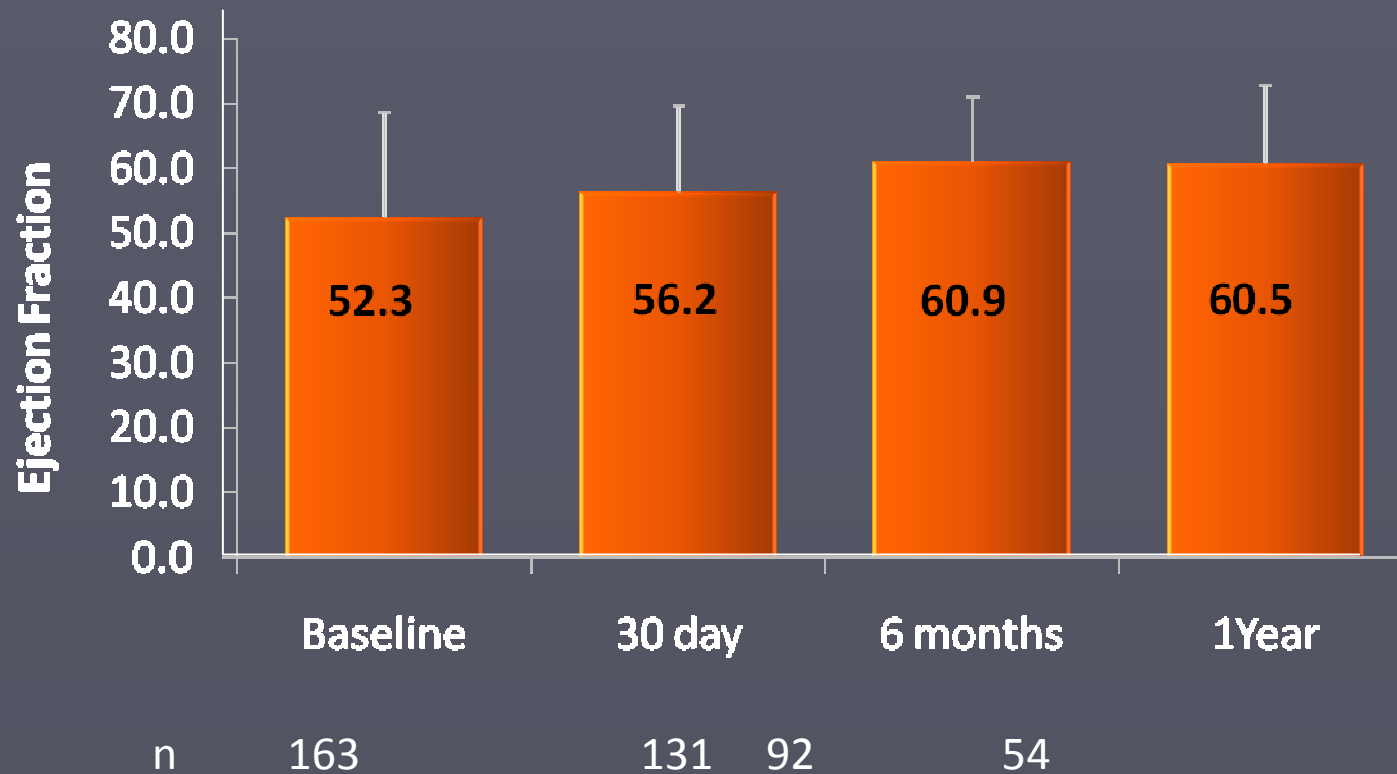
# REVIVE II : Aortic valve area<sup>†</sup>



† = Core Lab Analysis

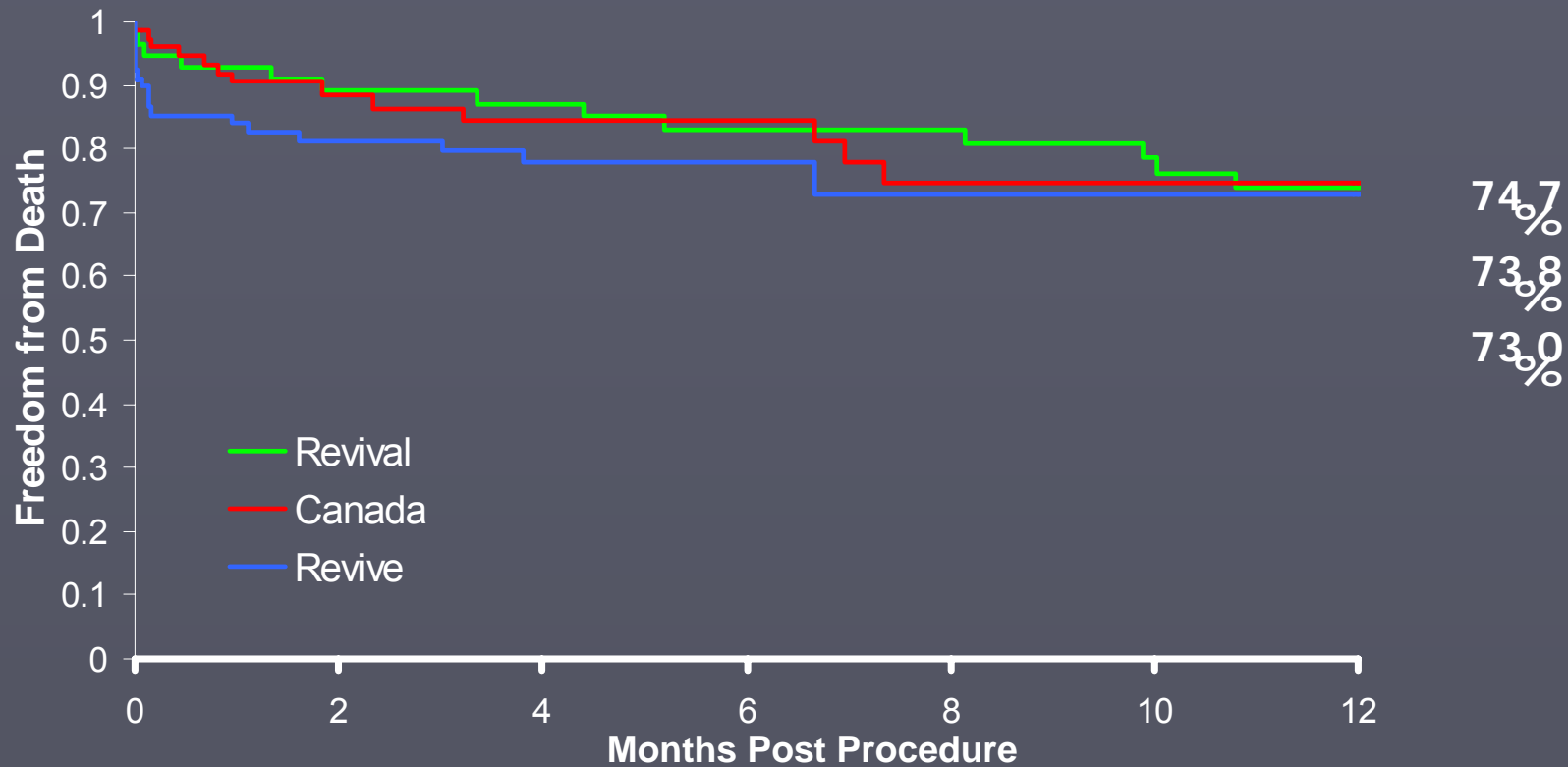
# REVIVE II, REVIVAL II, Canada

## LV Ejection Fraction



\* Assessed by Echo

# REVIVE, REVIVAL and Canada All cause Mortality



Number at Risk	0	2	4	6	8	10	12
Canada	73	42	32	26	23		
REVIVE	90	53	26	12			

# Randomized Study: PARTNER US

(1000 Pts, 15 Centers)

**High symptomatic patients  
with severe AS**

**Primary endpoint: Mortality at 1 year**

**NO**

**YES**

Medical Tt  
± BAV

THV  
TF ou TA

**RVA**

THV  
TF ou TA

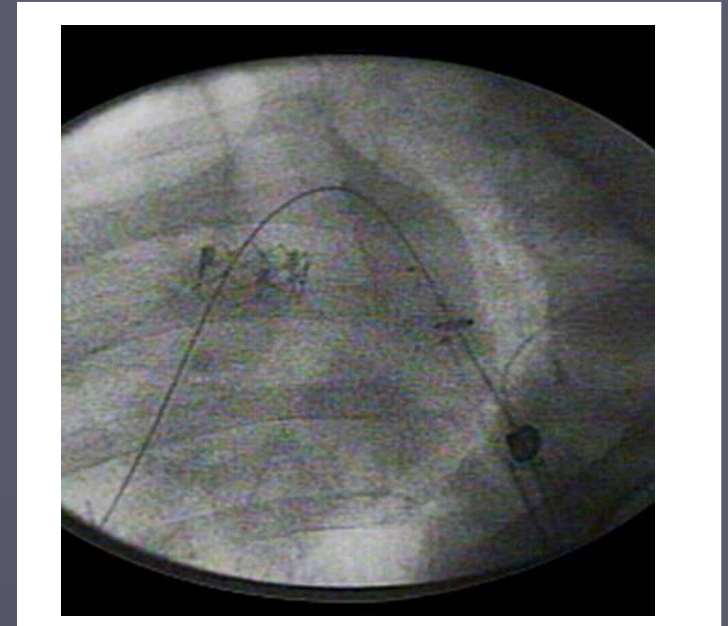
# New generation: Bioprosthesis

## ➤ Bioprosthesis:

- New stent (Cobalt-Chromium)  
Increased radial strength
- New valvular geometry for improved long-term function ( better stress distribution)
- Bovine pericardium treated with ThermaFix anti-calcification system

## ➤ New valve sizes:

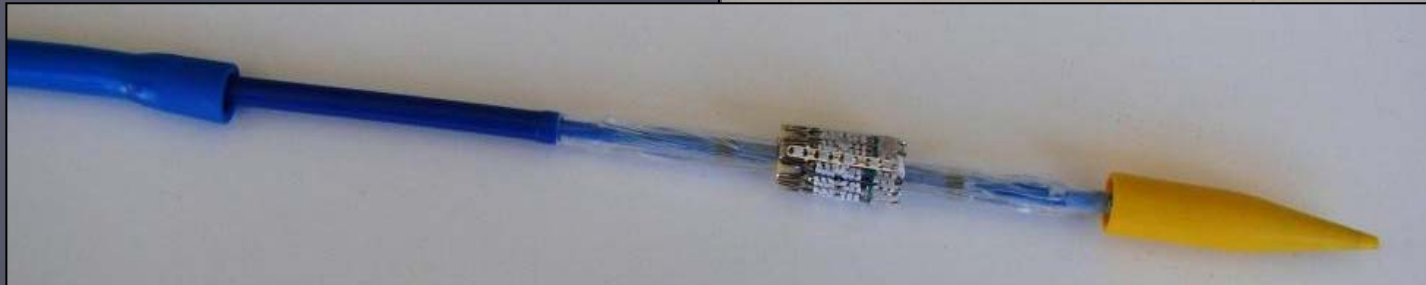
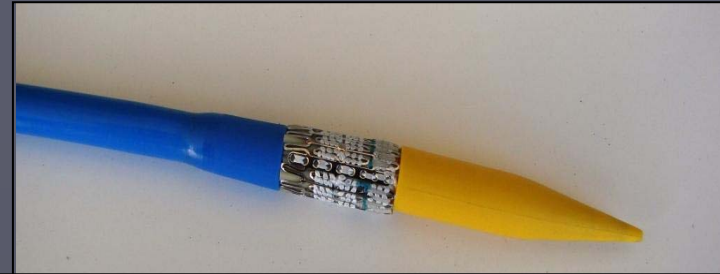
18, 23, 26 y 29 mm



**Laser mapping which assures uniform leaflet thickness and movement**

# New Generation: Delivery system

## 1. RetroFlex II Catheter



## 2. RetroFlex III: 3 a 5 F size reduction

*18F: 23 mm valve*

*19.5F: 26 mm valve*

*22F: 28 mm valve*



**FIM: Ist semester 2008**



# Conclusion

- ▶ Good acute results are observed in a high surgical risk population
- ▶ One year valve performance strong
- ▶ Up to 4.5 years follow-up with the Edwards bioprosthesis, with no sign of device deterioration
- ▶ Learning curve evident and vascular complications can be addressed with screening and product improvements