Percutaneous Aortic Valve Replacement In The Cath Lab

CoreValve ReValving™ System

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On behalf of the CoreValve Investigators:
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CoreValve *ReValving* System for PAVR Components

- S**elf-expanding multi-level** support frame
- Tri-leaflet **porcine pericardial** tissue valve
- Presently **18F catheter** delivery system

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Self-Expanding Multi-level Support Frame

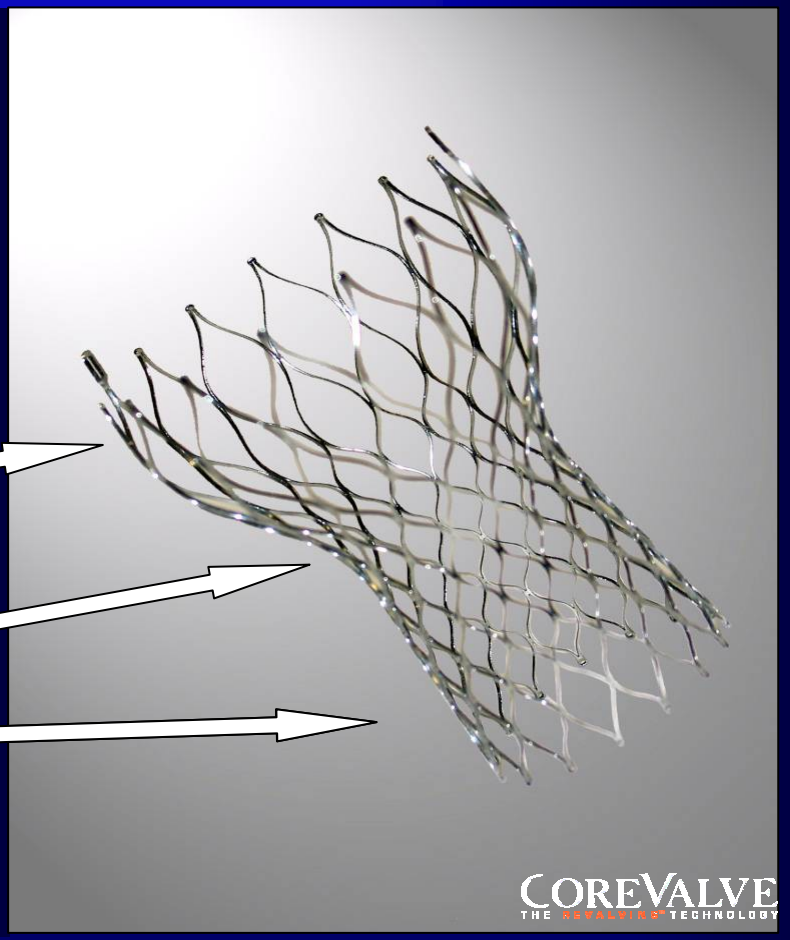
Diamond cell configuration

Nitinol: memory shaped/no recoil

Multi-level design incorporates three *different* areas of radial and hoop strength

- **Low radial force area** orients the system
- Constrained area **avoids coronaries** and features **supra-annular valve** leaflets
- **High radial force** provides secure anchoring and constant force mitigates paravalvular leak

Radiopaque



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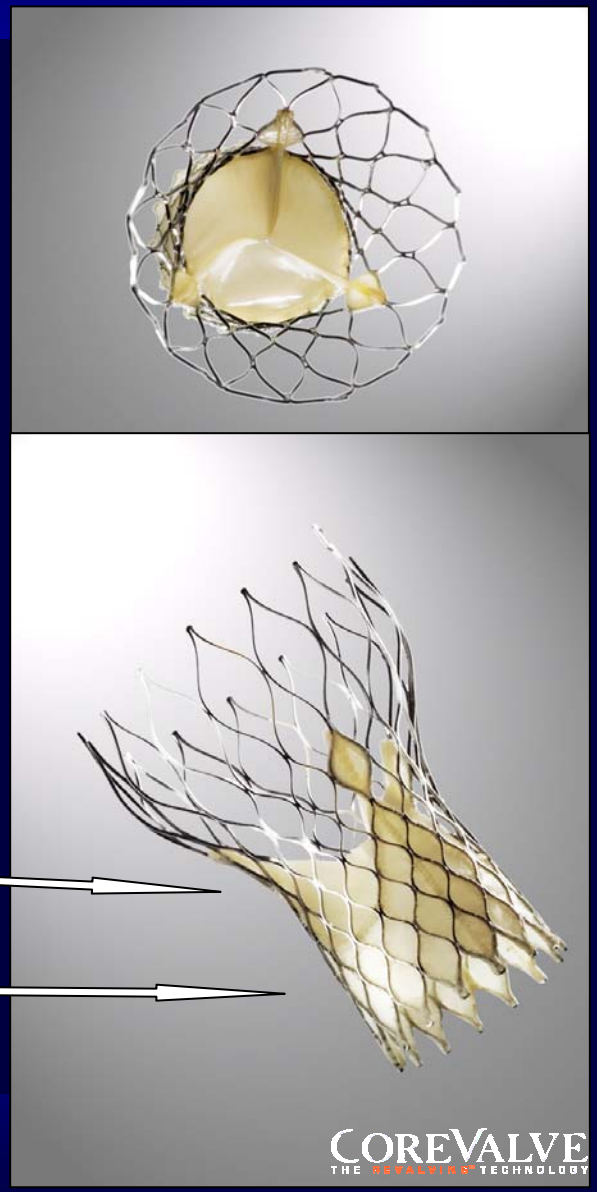
Porcine Pericardial Tissue Valve

- **Specifically designed for transcatheter delivery**
- **Single layer porcine pericardium**
- **Tri-leaflet configuration**
- **Tissue valve sutured to frame**
- **Standard tissue fixation techniques**
- **400M cycle AWT testing completed**
- **Supra-annular valve function**
- **Intra-annular implantation and sealing skirt**



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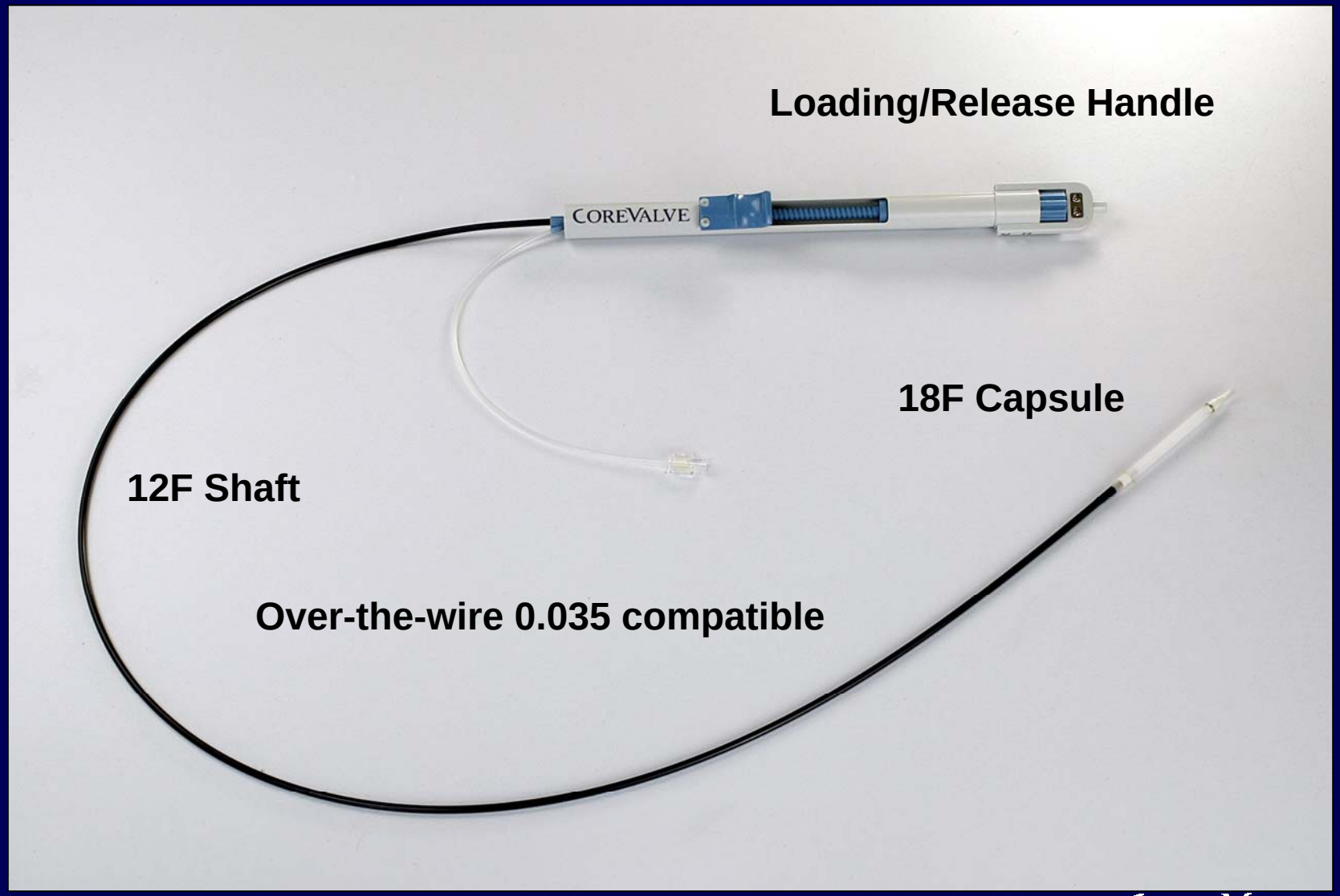
18F Delivery Catheter System



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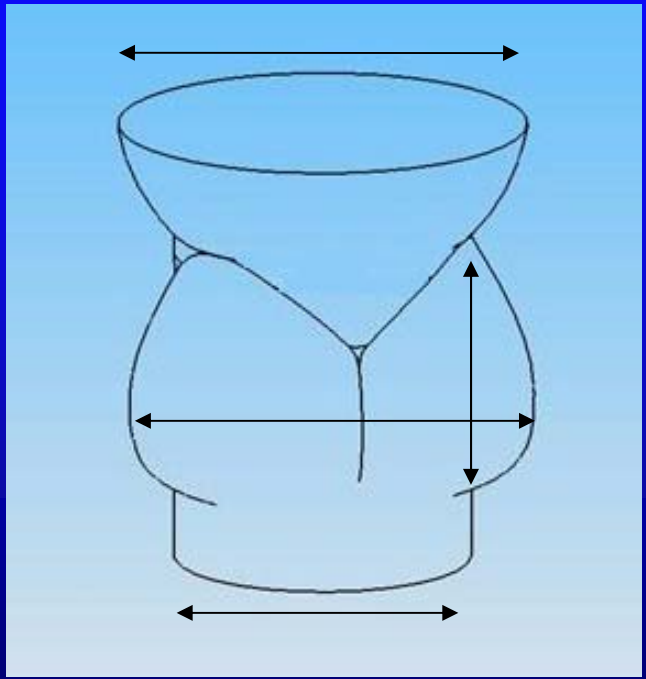
COREVALVE
THE REVALVING® TECHNOLOGY

Aortic Valve

Aorta ≤ 40 mm for 26 mm device

Aorta ≤ 43 mm for 29 mm device



Sinus of Valsalva:

≥ 15 mm height

≥ 30 mm width

Annulus: 20 – 23 mm for 26 mm device

Annulus: 24 – 27 mm for 29 mm device

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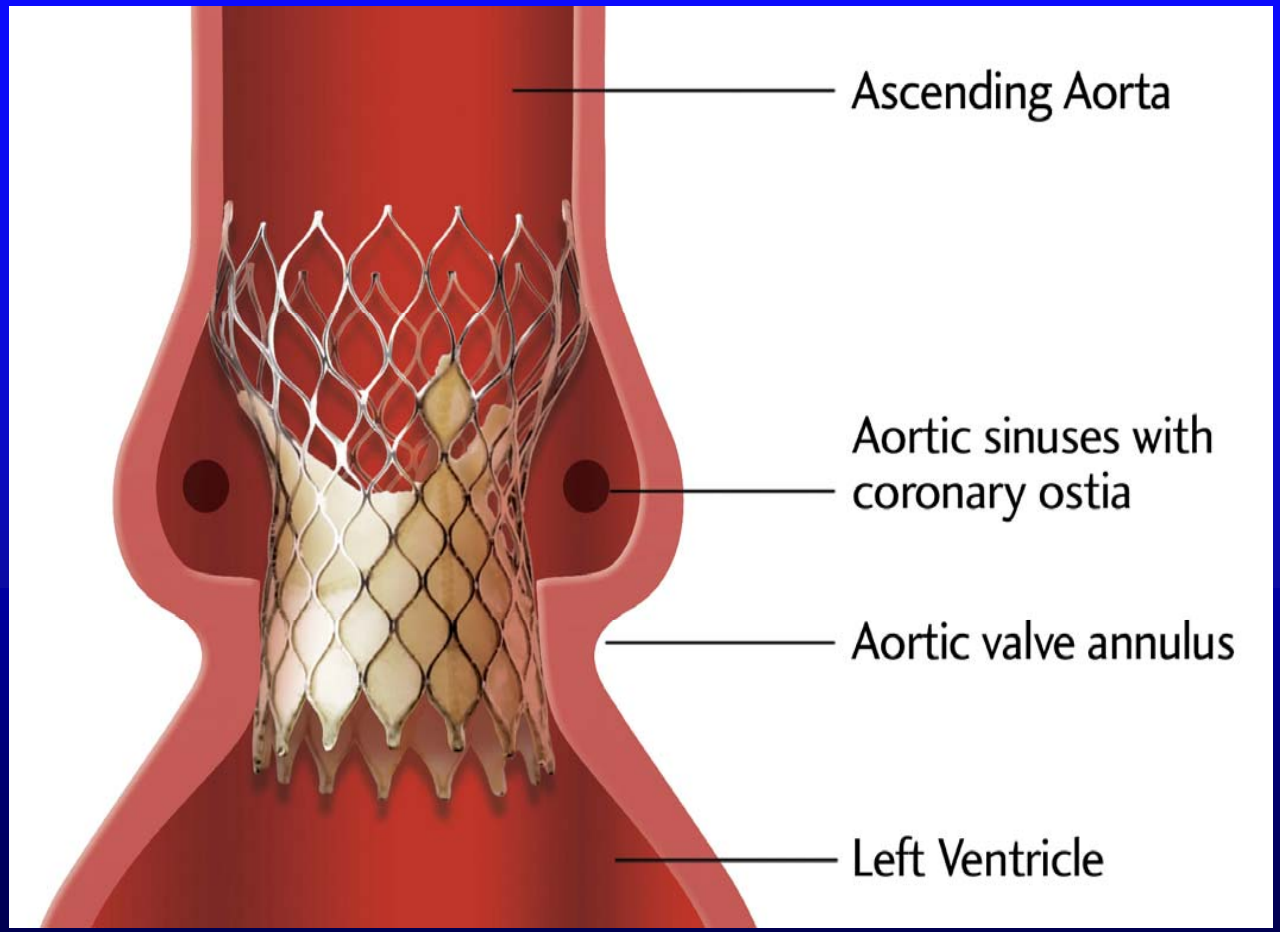
Optimal Implantation



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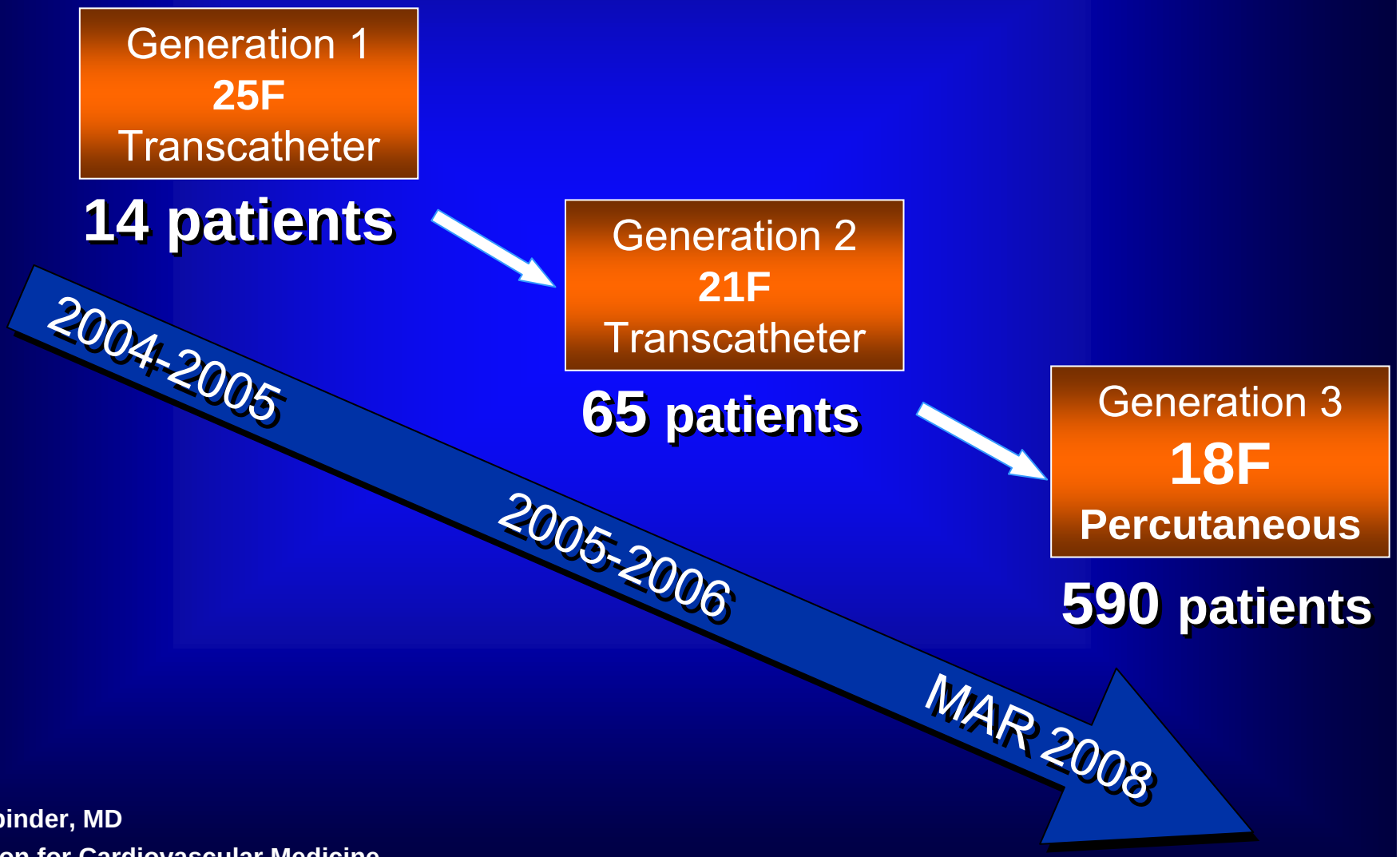
Catheter Size Reduction



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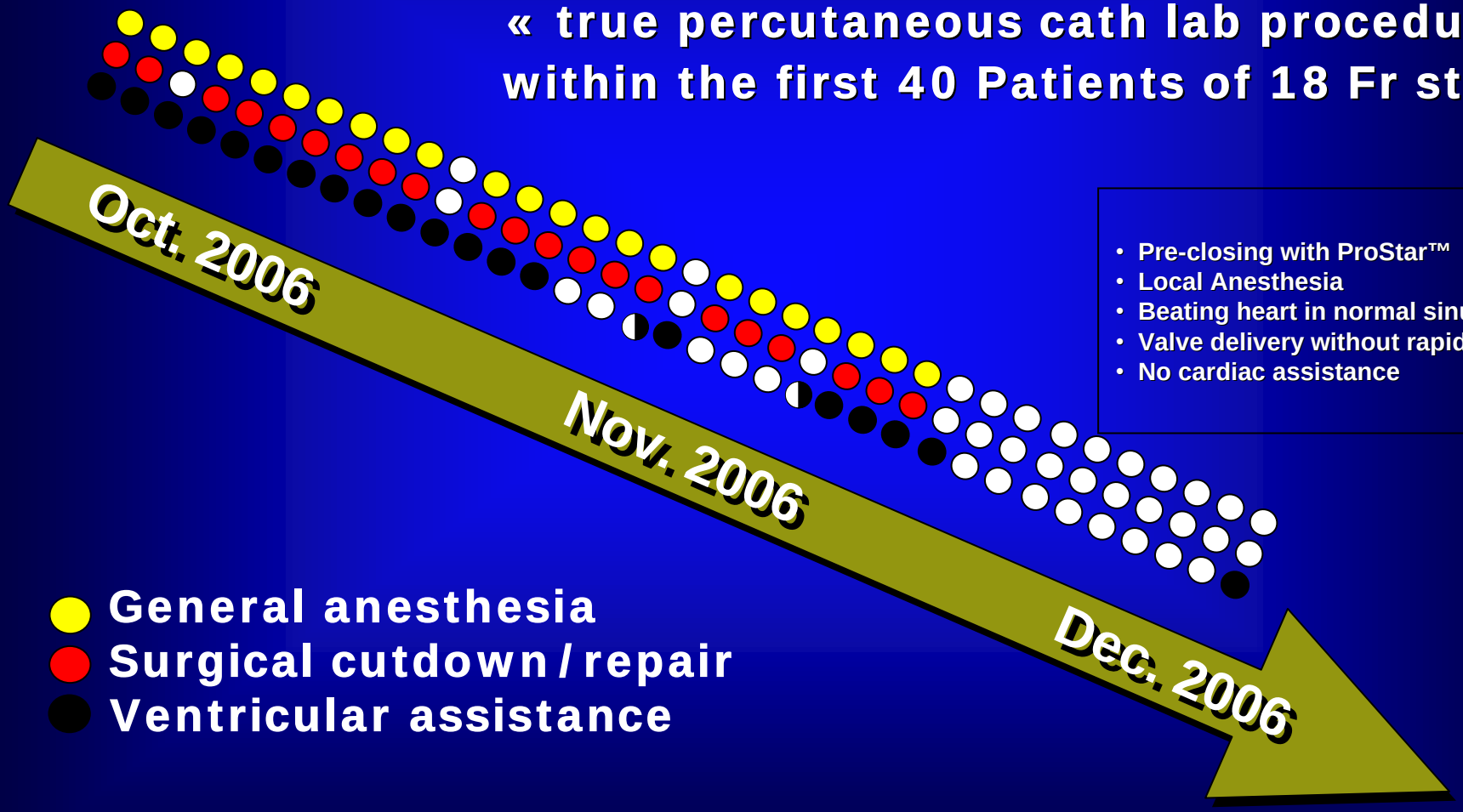
18 French System Procedural Progress

Evolution to a
« true percutaneous cath lab procedure »
within the first 40 Patients of 18 Fr study



- Pre-closing with ProStar™
- Local Anesthesia
- Beating heart in normal sinus rhythm
- Valve delivery without rapid pacing
- No cardiac assistance

- General anesthesia
- Surgical cutdown / repair
- Ventricular assistance

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Study Protocols

- Native Aortic Valve Disease
  - Severe AS: AVAI ≤0.6 cm^2/m^2
- 27mm ≥AV annulus ≥20mm
- Sino-tubular Junction ≤43mm

Age ≥80 y (21F)
≥75 y (18F)

Logistic EuroSCORE ≥20% (21F)
≥15% (18F)

Age ≥65 y

+1 or more

- Liver cirrhosis (Child A or B)
- Pulmonary insufficiency: FEV1<1L
- Previous cardiac surgery
- PHT (PAP>60mmHg)
- Recurrent P.E's
- RV failure
- Hostile thorax (radiation, burns,etc)
- Severe connective tissue disease
- Cachexia

Primary Endpoints:

- Procedural success
- 30-Day outcomes
- Long term outcomes

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CoreValve PAVR *ReValving* System
Total Experience

Time Period	Implant Phase	Device Used	Number of Patients
July 2004-July 2005	First in Man	25 French	14
May2005-August2006	21F Intl Trial Includes 2 ReDo	21 French	65
May 2006-Ongoing	18F Intl Trial	18 French	112
May 2007-Ongoing	Expanded Evaluation	CE 0050 18 French	598
Total Worldwide PAVR *ReValving* Patients Treated			**789**

Updated March 22, 2008

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Procedural and 30 Day Results

Reporting 18F safety & efficacy study results

Reporting post CE Mark 18F registry results

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Patient Demographics

	18F S&E (N=112)	18F Registry (N=478)
Age (years)	81.7 ±6.7 [58-92]	80.6 ±7.0 [46-95]
Female	62 (55%)	225 (54%)
Logistic EuroSCORE (%)	23.5 ±13.9 [3-69]	24.1 ±14.0 [3-85]
High Risk Co-morbidities		
Hypertension	78%	58%
Diabetes	26%	27%
CAD	61%	57%
Prior MI	19%	14%
Prior PCI	33%	31%
Prior CABG	28%	23%
AFib	41%	31%
Prior CVA	19%	8%
PVD	21%	26%

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Patient Demographics (continued)

Pre-procedure	18F S&E (N=112)	18F Registry (N=478)
AVA (cm^2)	0.59 ±0.18 [0.2-1.0]	0.64 ±0.20 [0.2-1.7]
Mean Gradient (mm Hg)	47.2 ±17.9 [15-97]	49.8 ±17.8 [15-114]
Peak Gradient (mm Hg)	71.5 ±27.0 [24-150]	78.3 ±26.8 [22-169]
% in NYHA Class III/IV	75%	86%
LVEF	51% ±15 [32-78]	51% ±14 [10-85]

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Procedural Results

	18 F S&E (N=112)	18F Registry (N=478)
Procedural Success	102 (91%)	465 (97%)
Mean Procedure Time	151 ±77 Min	130 ±49 Min
Discharged alive & well with CoreValve	96 (86%)	449 (94%)

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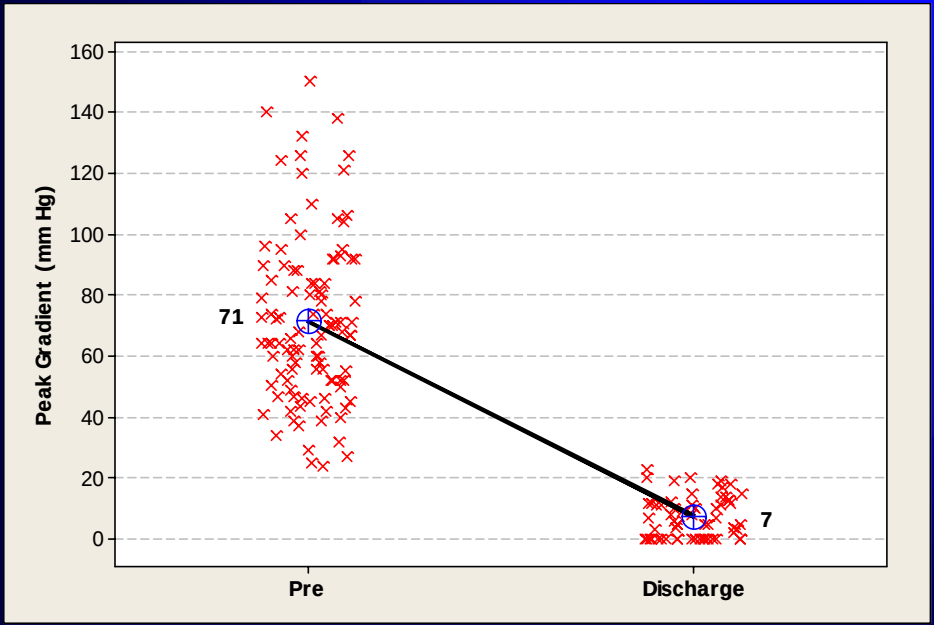
Procedural Results (continued)

Peak Gradient (mm Hg)

18F S&E
(N=112)

Pre: 71.46 ±27.03 [24-150]

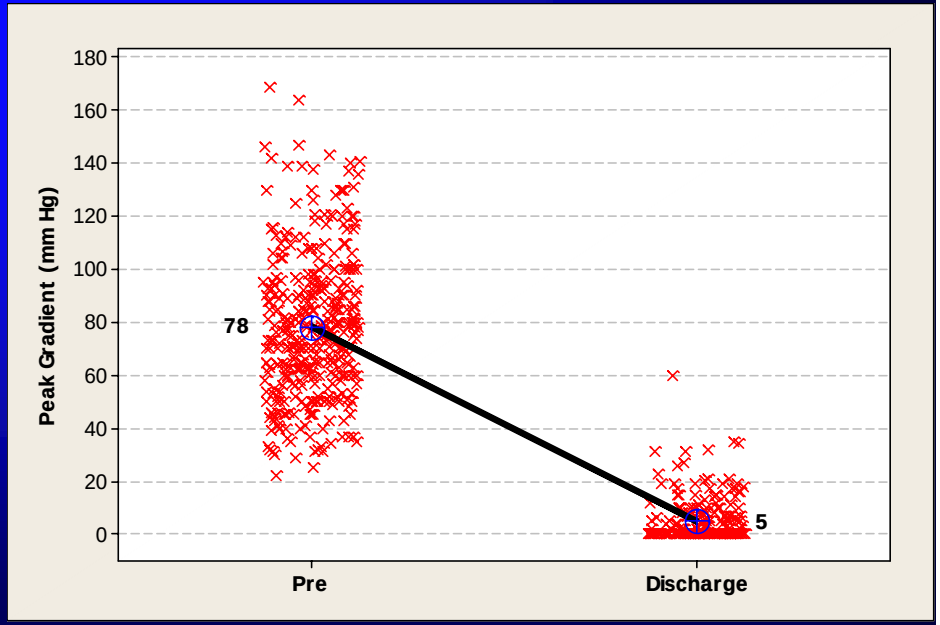
Discharge: 7.42 ±6.81 [0-23]



18F Registry
(N=478)

Pre: 78.27 ±26.77 [22-169]

Discharge: 4.79 ±8.31 [0-60]



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Procedural Results (continued)

	18F S&E (N=112)	18F Registry (N=478)
Procedural Failures	**10 (9%)**	**13 (3%)**
Inability to access vessel	0 (0%)	0 (0%)
Inability to navigate vasculature	0 (0%)	0 (0%)
Inability to cross native valve	0 (0%)	0 (0%)
Malplacement	6 (5%)	1 (<1%)
Aortic Root Perforation	1 (<1%)	2 (<1%)
Aortic Dissection	2 (2%)	1 (<1%)
Access Vessel Bleeding	4 (4%)	2 (<1%)
LV Perforation, guidewire	1 (<1%)	2 (<1%)
RV Perforation, temp pacemaker wire	0 (0%)	2 (<1%)
Difficulty with BAV	0 (0%)	1 (<1%)
Conversion to Surgery	4 (4%)	2 (<1%)

multiple events in same patients = data not cumulative

Procedural Results (continued)

Complications (0–30 Days)*	18F S&E (112)	18F Registry (478)
MI*	4 (4%)	3 (<1%)
Aortic dissection*	3 (3%)	2 (<1%)
Coronary impairment	2 (2%)	0 (0%)
Acute Vascular complications	4 (4%)	7 (2%)
Stroke/TIA*	6 (5%)	8 (2%)
Pacemaker	28 (25%) **	34 (7%)
Re-op for valve failure	0 (0%)	1 (<1%)

* multiple events in same patients = data not cumulative

** >1/3 prophylactic

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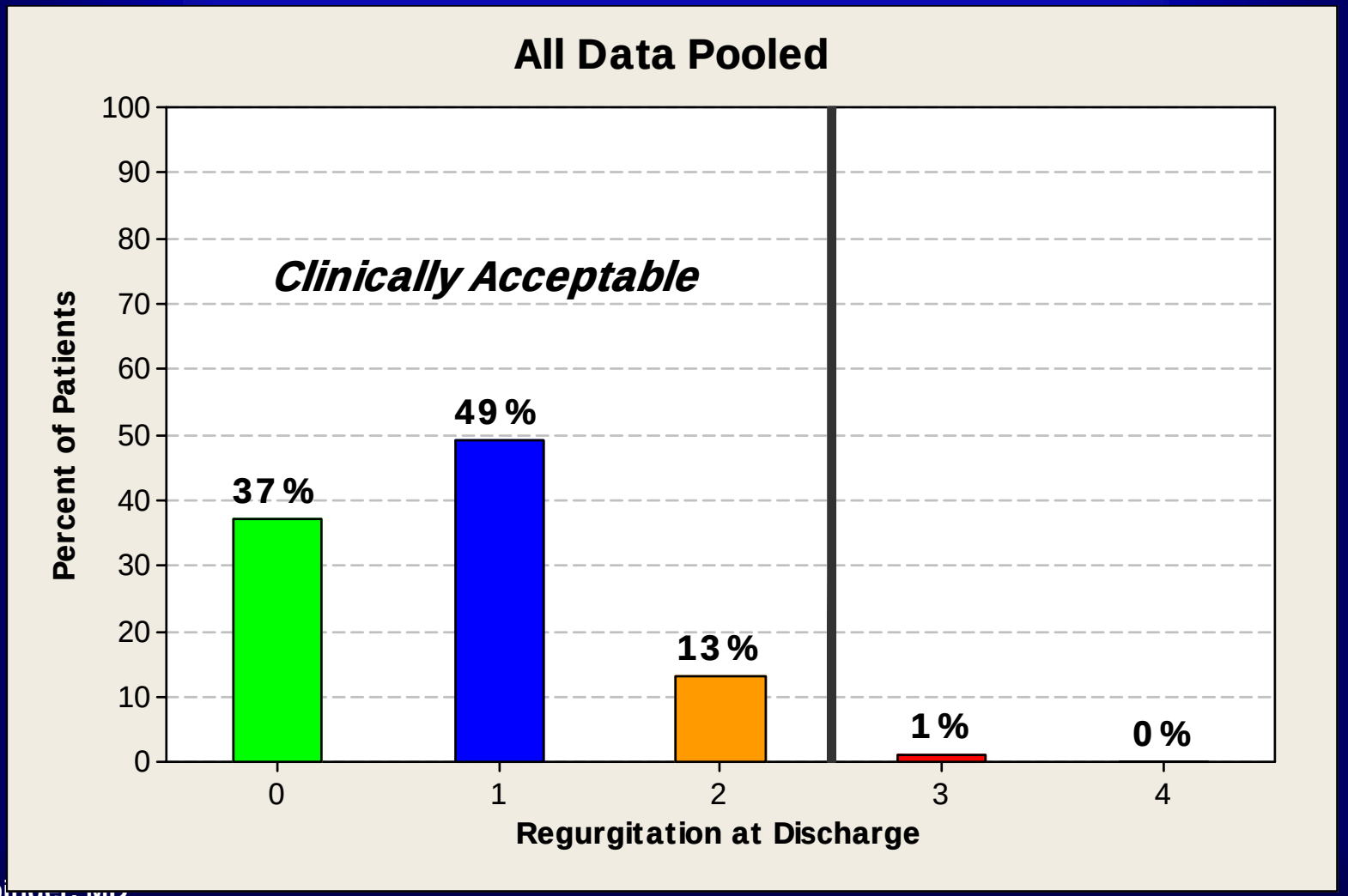
Procedural Results (continued)

Regurgitation at Discharge



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30 Day Outcomes

	18F S&E (N-112)	18F Registry (N=478)
Logistic EuroSCORE:	24%	25%
All cause 30-Day Mortality	15% (17)	8% (36)
Procedure Related	11 (10%)	15 (3%)
Non-Procedure/Non-valve Related	6 (5%)	18 (4%)
Unknown	0 (0%)	3 (<1%)

No valve dysfunction
No valve migration

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Medium Term Outcomes

Reporting 21F & 18F Safety & Efficacy Studies Follow-up

Note: Registry medium term follow-up not yet available

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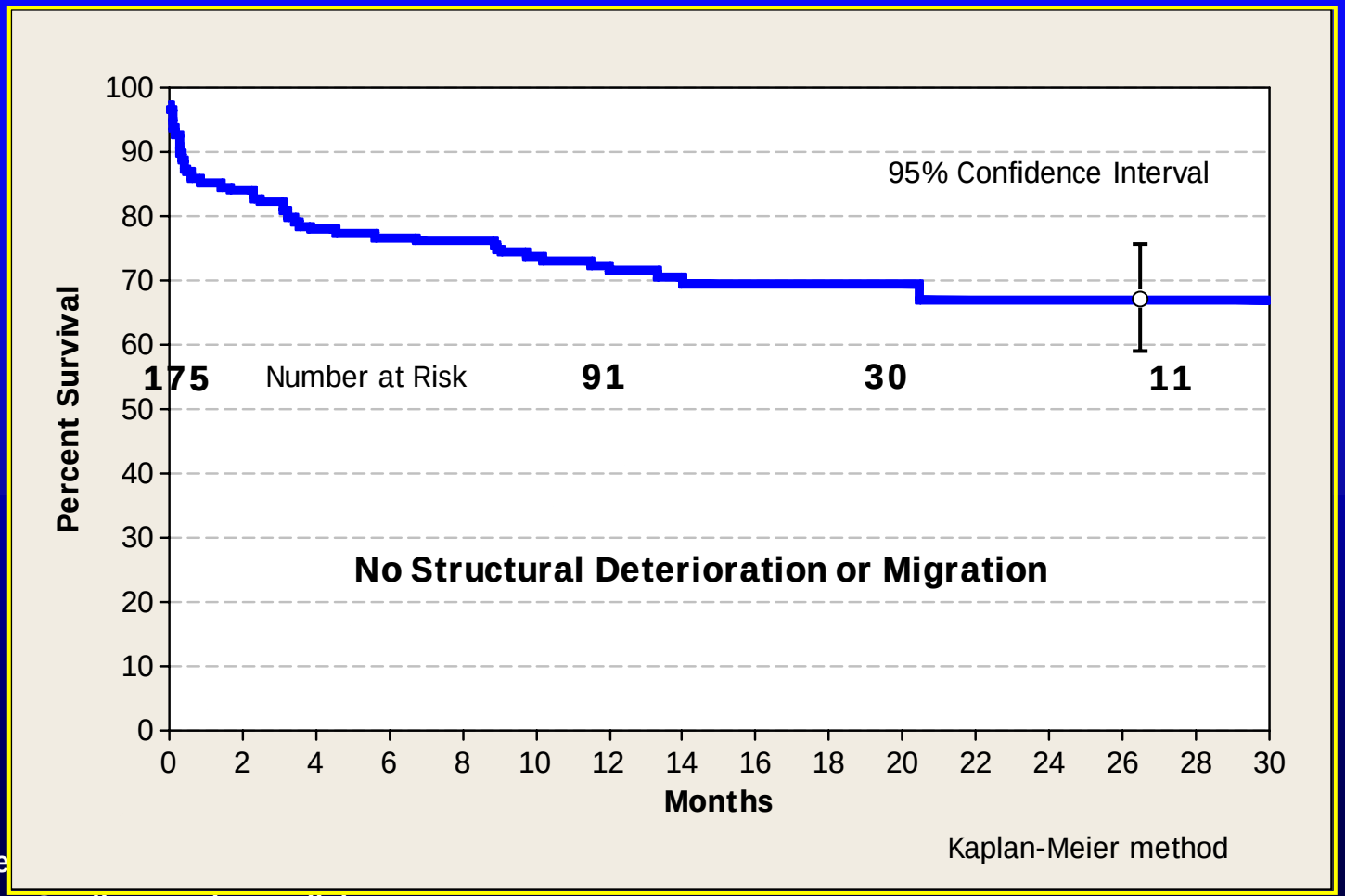
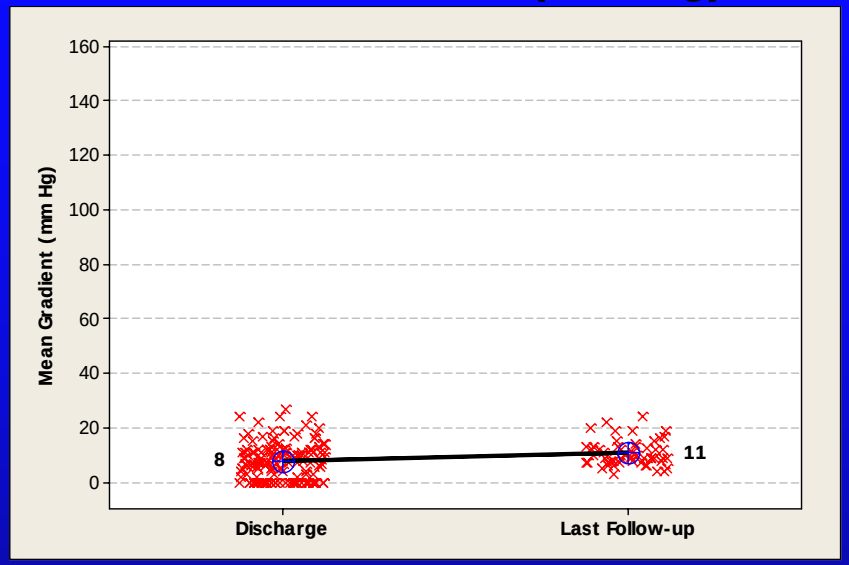
Medium term patient and valve follow-up
21F + 18F Safety Studies Pooled – N=175

Patient days with CoreValve: 368 ±256 [261-929]

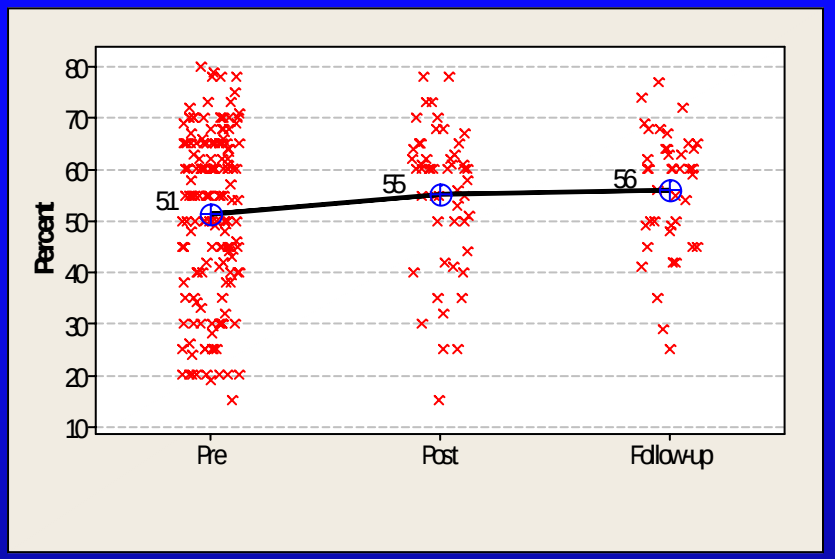


Quality of Life at Follow-up
21F + 18F Safety Studies Pooled – N=175

Mean Gradient (mm Hg)



Ejection Fraction (%)



Last Follow-up NYHA

I	42%
II	43%
III	14%
IV	1%

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Conclusions

Percutaneous Aortic Valve Replacement with the CoreValve System

- Is a relatively safe and effective procedure in high risk aortic stenosis patients.
- Has evolved as a true percutaneous procedure.
- As with many novel technologies PAVR has a definite learning curve which requires an in-depth understanding of patient selection and various anatomical criteria
- Long term efficacy and durability of PAVR in patients with aortic stenosis remains to be determined in future carefully conducted prospective trials .