Aortic Valve Durability Improvement:
10-year Results from the COMMENCE Trial

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On Behalf of Commence Investigators

COMMENCE AORTIC

COI Relevant Disclosures

Within the past 36 months, I or my spouse/partner has had a financial interest/arrangement or affiliation with the organization(s) listed below.

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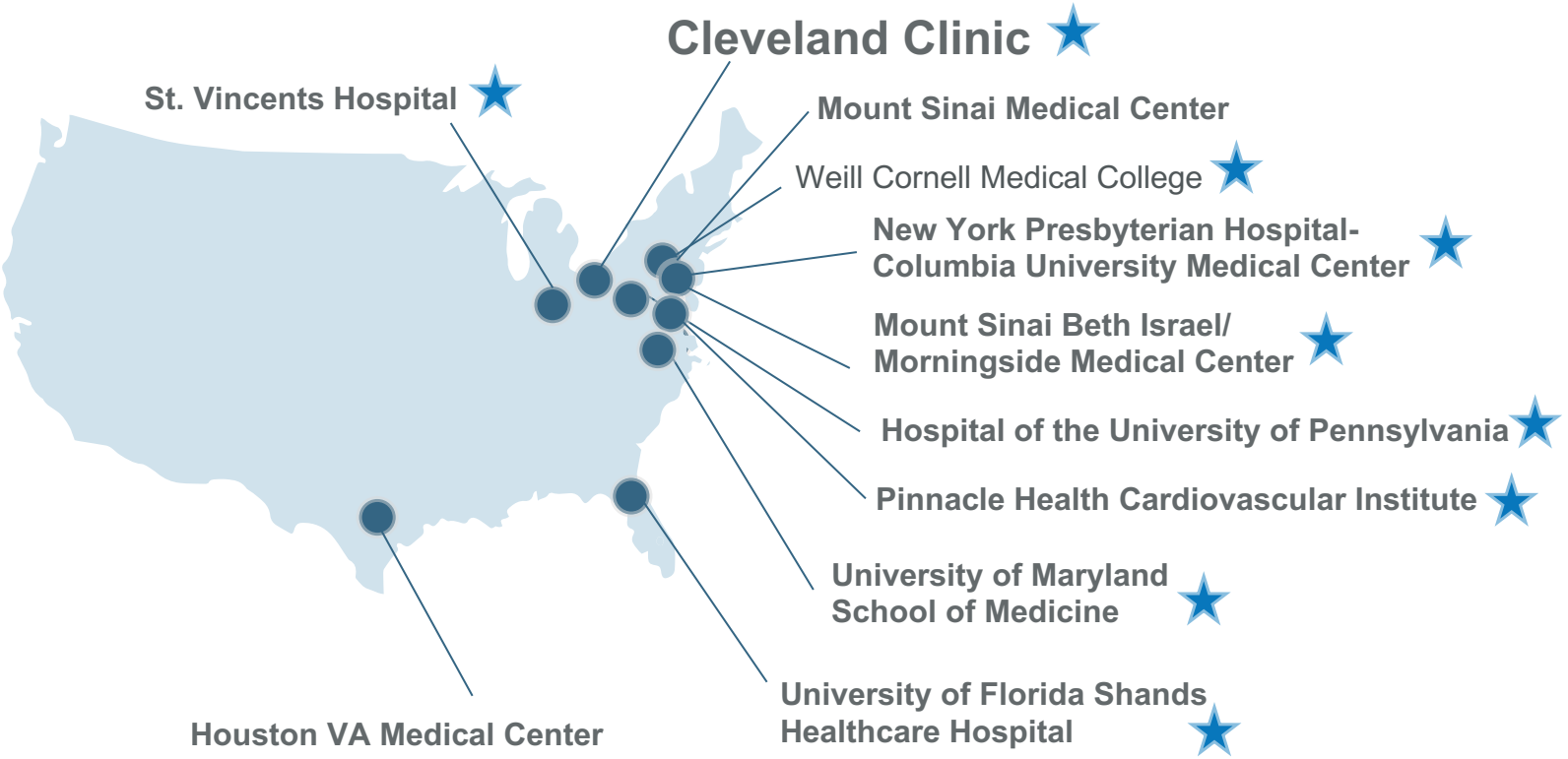
TOP 10 BASELINE & RECONSENTED Enrollment Sites

United States



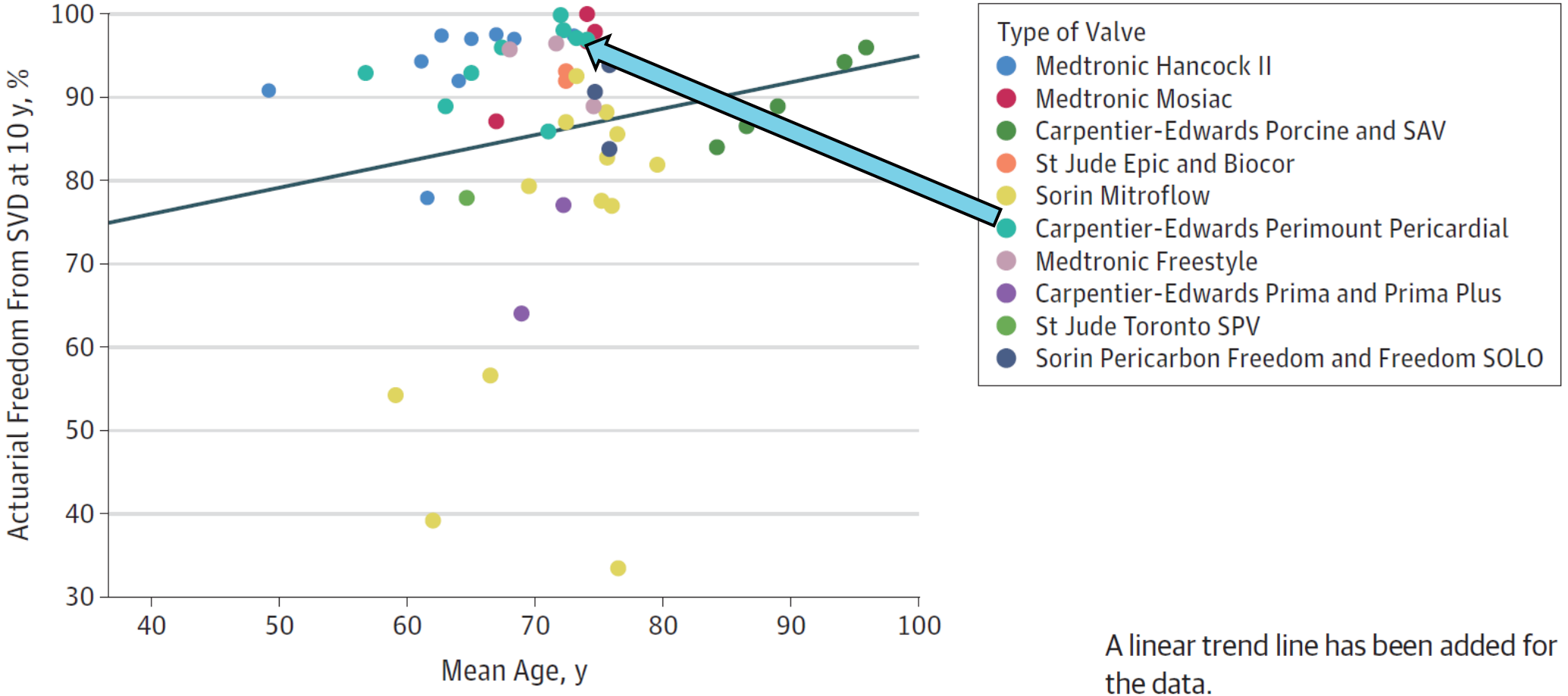
Poland

Top 10 baseline enrollment sites
Participated in 6–10-year follow-up

Background

- Early Research by Carpentier on Biological Valves 1980s
- Edwards CEPC 2700 Became Gold Standard
- Also 2700 Expandible for Larger TAVR Orifice

Scatterplot Reflecting Association of Mean Age With Actuarial Freedom From Structural Valve Deterioration (SVD) at 10 Years



A linear trend line has been added for the data.

Fatima et al, *JAMA Cardiology* January 2019 Volume 4, Number 1

10 – Year Freedom from Reoperation

Bloom JP et al J Am Heart J 2026;15:e044454

- Ross 84% - 92%
- Biological 55% - 70%
- Mechanical 85% - 94%
- TAVR 50% - 60%
  - 7-Yr (P3 = 92%, Evolut TAVR = 90.2%, AVR = 94%, p=.02)
- Aortic Repair 83% - 95% (15 – Yr)
  - COMMENCE Reop SVD 97%, All 94% (Abstract AATS)

Objective

- Evaluate a Novel Dry Storage, Bovine Pericardial RESILIA Treatment Technology, to Improve Durability for AVR on a MagnaEase Frame Model 11000A
- Use in Younger Patients
- Compare with Model 2700

Design

- Prospective, non-randomized multicenter, single-arm IDE Trial (NCT01757665)
- Annual follow-up to 5 years;
  - Subset reconsented 10-year follow-up
- Endpoints Adjudicated Independent Clinical Events Committee
- Valve Performance Core Echo Laboratory

Adult Population

Inclusion

- > 18 years
- Aortic Valve
- Include CABG, Asc Aorta, Myectomy, PVI/Maze
- 5 – Year Follow Up

Exclusion

- Emergency
- Endocarditis < 3 Months
- Other Procedures

Safety and Effectiveness

Clinical Events Committee

- SVD, NSVD
- Thrombosis, Bleeding, Thromboembolism
- Major Bleeding
- Endocarditis
- Valve Related Reoperation or Explant
- Paravalvular Leak
- All Cause Mortality
- Valve Related Mortality

Performance Echo Committee

- Mean and Peak Gradient
- Effective Orifice Area
- Valve Regurgitation
- NYHA Classification
- Quality of Life

Study Progress

694 patients enrolled

689 patients with study valve implanted

512 patients completed 5-year follow-up
Completion of IDE cohort follow-up

239 patients reconsented*
To 5-to-10-year follow-up

192 patients completed 10-year follow-up
Out of 194 eligible patients (99%)

Mean follow-up: **9.7 ± 1.0 years**

47/239 did not undergo 10-yr follow-up
- 44 exited study prior to 10-yr visit:
  - 26 deaths
  - 3 explants
  - 8 withdrew consent
  - 2 lost to follow-up
  - 5 ViV reintervention
- 2 missed 10-yr visit
- 1 10-yr visit pending

Interim data snapshot Feb 18, 2026; Includes monitored and unmonitored data. *Follow-up through 10 years was mandated for the top 3 enrolling sites and offered to all sites.
IDE, investigational device exemption; LTFU, long term follow-up; ViV, valve-in-valve

Patient Demographics and Baseline Characteristics

Characteristic	All implanted patients N=689	Reconsented cohort N=239
Age (years)	66.9±11.6 (689)	65.1±10.9 (239)
Age range (years)	20-90	23-86
Male†	71.8 (495/689)	76.6 (183/239)
NYHA classification†		
Class I	23.8 (164/689)	35.6 (85/239)
Class II	49.9 (344/689)	43.1 (103/239)
Class III	24.4 (168/689)	19.2 (46/239)
Class IV	1.9 (13/689)	2.1 (5/239)
STS PROM (%)*	2.0±1.8 (538)	1.7±1.5 (174)
Diabetes	28.4 (196/689)	23.4 (56/239)
Chronic obstructive pulmonary disease	14.2 (98/689)	11.7 (28/239)

Mean ± SD (n) or % (n/N). *STS scores only calculated for patients undergoing isolated aortic valve replacement (AVR) or AVR and coronary artery bypass graft.
†There were significant differences in sex (P=0.02) and NYHA class (P=0.0001) between reconsented and non-reconsented patients.
NYHA, New York Heart Association; STS PROM, Society of Thoracic Surgeons Predicted Risk of Mortality

Previous Cardiovascular Interventions: 5 – Year vs 10 - Year

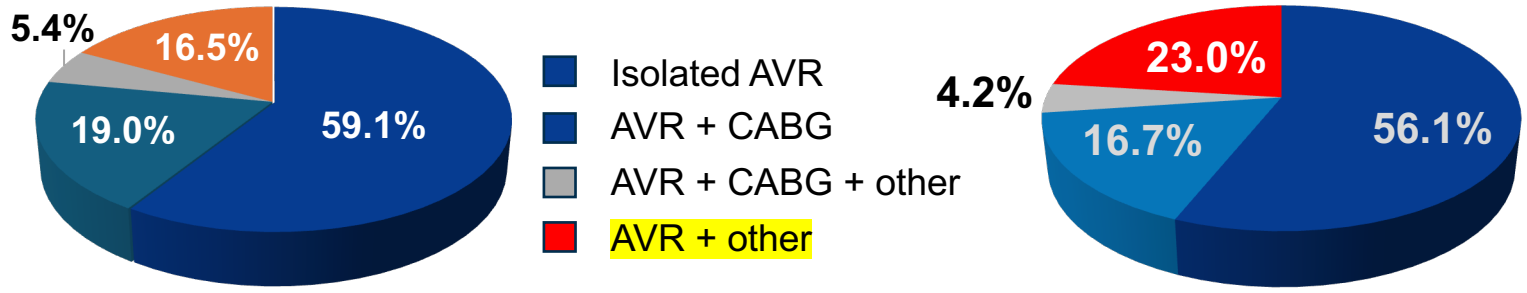
Coronary arteries	16.5% (114/689) vs 11.7% (28/239)
Prior cardiac surgery	7.1% (49/689) vs 7.9% (19/239)
Aortic valve Reops	4.2% (29/689) vs 5.4% (13/239)
Permanent PM or ICD	3.2% (22/689) vs 2.5% (6/239)

Procedural Data

Surgical Approach*

Implanted N=689 **Reconsented N=239**

Concomitant Procedures*



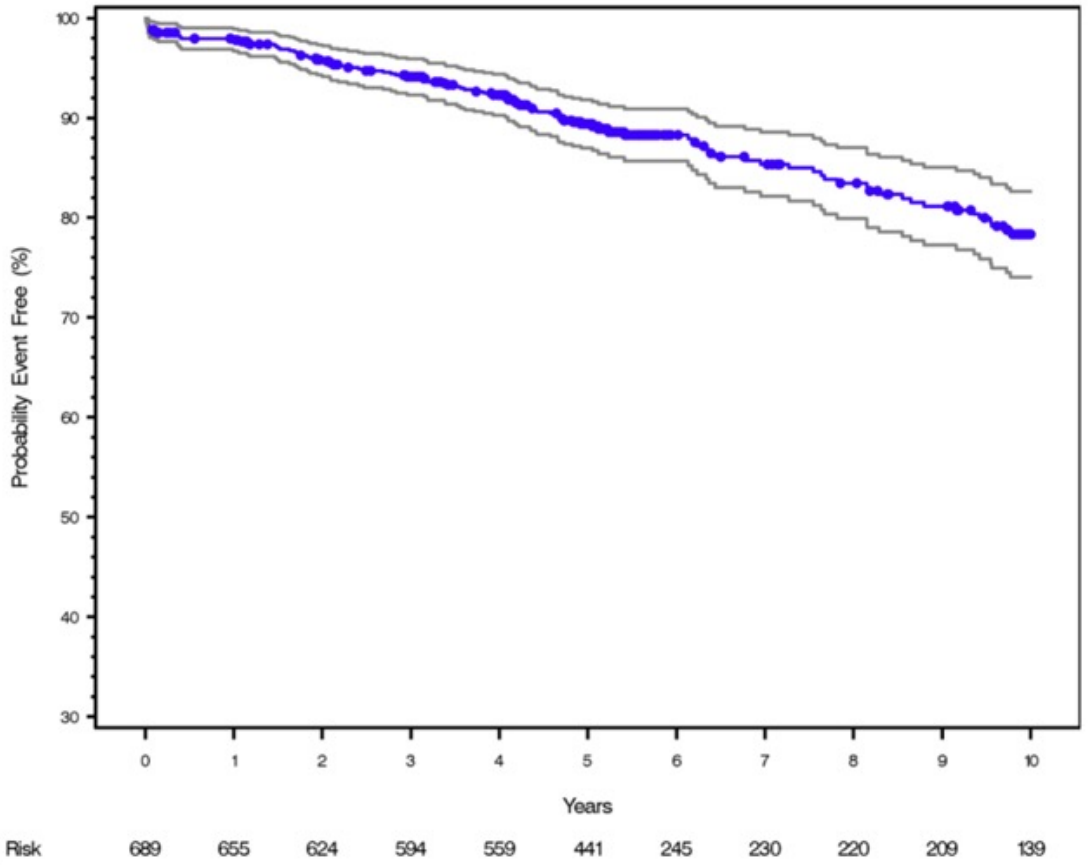
Implanted N=689 **Reconsented N=239**

Statistically significant differences in surgical approach (P=0.0005), concomitant procedures (P=0.005) and device size distribution (P<0.001) between reconsented and non-reconsented patients.
CABG, coronary artery bypass grafting; AVR, aortic valve replacement

Summary of Safety Events (through 10 years)

Endpoint	≤30 Days N=689	10-Year Kaplan-Meier Analysis (Cumulative N=689)		
	Patients with event n (%)	Patients with event (n)	Patients at risk (n)	Probability event-free % (95% CI)
SVD	0 (0%)	5	138	97.9% (96 - 99.8)
Reoperation	1 (0.1%)	18	138	94.5% (91.8 – 97.2)
Reoperation due to SVD	0 (0%)	5	138	97.8% (95.8 - 99.7)
Study valve explant	0 (0%)	10	139	97.5% (95.8 - 99.2)
All-cause mortality	8 (1.2%)	97	139	78.3% (74.1 – 82.6)
Valve-related mortality	3 (0.4%)	25	139	94.3% (91.8 - 96.8)
Cardiovascular mortality	6 (0.9%)	40	139	90.8% (87.7 – 93.8)
NSVD (other than PVL)	0 (0%)	3	139	98.6% (97 - 100)
Thromboembolism	16 (2.3%)	66	123	87.4% (84.2 - 90.6)
Stroke	11 (1.6%)	39	133	93.1% (90.9 - 95.4)
Valve thrombosis	0 (0%)	2	139	99.5% (98.7 - 100)
Major paravalvular leak*	1 (0.1%)	3	139	99.5% (99 - 100)
Major bleeding	5 (0.7%)	59	127	85.1% (81.2 - 89.1)
Endocarditis	0 (0%)	15	139	97.3% (95.9 - 98.7)

10-Year Survival



78.3%

10-year freedom from all-cause mortality: 78.3%

Implanted aortic population, N=689.

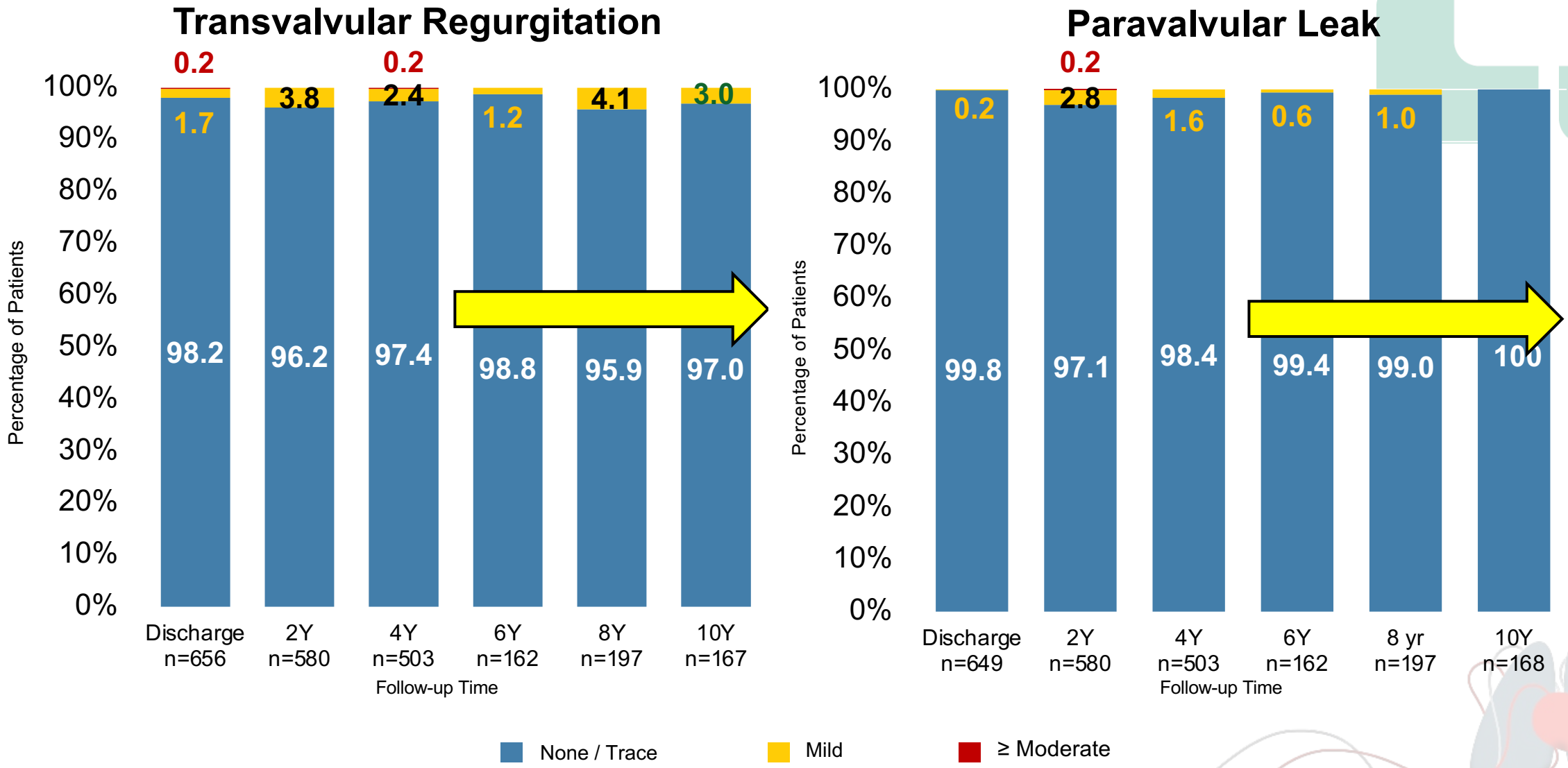
Re-operations / Re-interventions (N=18), All Survived

Days to re-op	Patient age* (years)	Valve size (mm)	Cause of re-op	Valve-related re-op?	Outcome – All Survived
6	74	21	NSVD - Paravalvular leak +4 Major	No	Surgical re-op to close the PVL
202	67	23	Endocarditis	Yes	Explant
471	49	25	Endocarditis	No	Explant
504	52	23	Endocarditis	Yes	Explant
893	67	23	Endocarditis	Yes	Explant
972	72	23	NSVD - Paravalvular leak +3 Major	Yes	Percutaneous vascular plug
1216	57	25	Endocarditis	No	Explant
1268	41	27	Endocarditis	Yes	Explant
1827	74	21	Endocarditis	Yes	Explant
1940	67	21	SVD – Study valve calcification	Yes	Percutaneous valve-in-valve
2290	71	25	SVD – Restricted leaflet motion of uncertain etiology	Yes	Explant
2371	60	29	Thoracic aneurysm	No	Explant
2604	72	21	NSVD- Study valve stenosis (severe)	Yes	Percutaneous valve-in-valve
3065	66	23	SVD – Study valve calcification	Yes	Percutaneous valve-in-valve
3345	66	21	NSVD – Study valve stenosis (severe)	Yes	Percutaneous valve-in-valve
3354	23	21	NSVD – Entrapment by pannus, tissue, or suture	Yes	Explant
3437	50	25	SVD- Study valve calcification	Yes	Percutaneous valve-in-valve
3552	65	23	SVD- Study valve calcification	Yes	Percutaneous valve-in-valve

5 - Year

Implanted aortic population, N=689. *Age at baseline. SVD, structural valve deterioration; NSVD, non-structural valve deterioration; PVL, paravalvular leak

Aortic Regurgitation

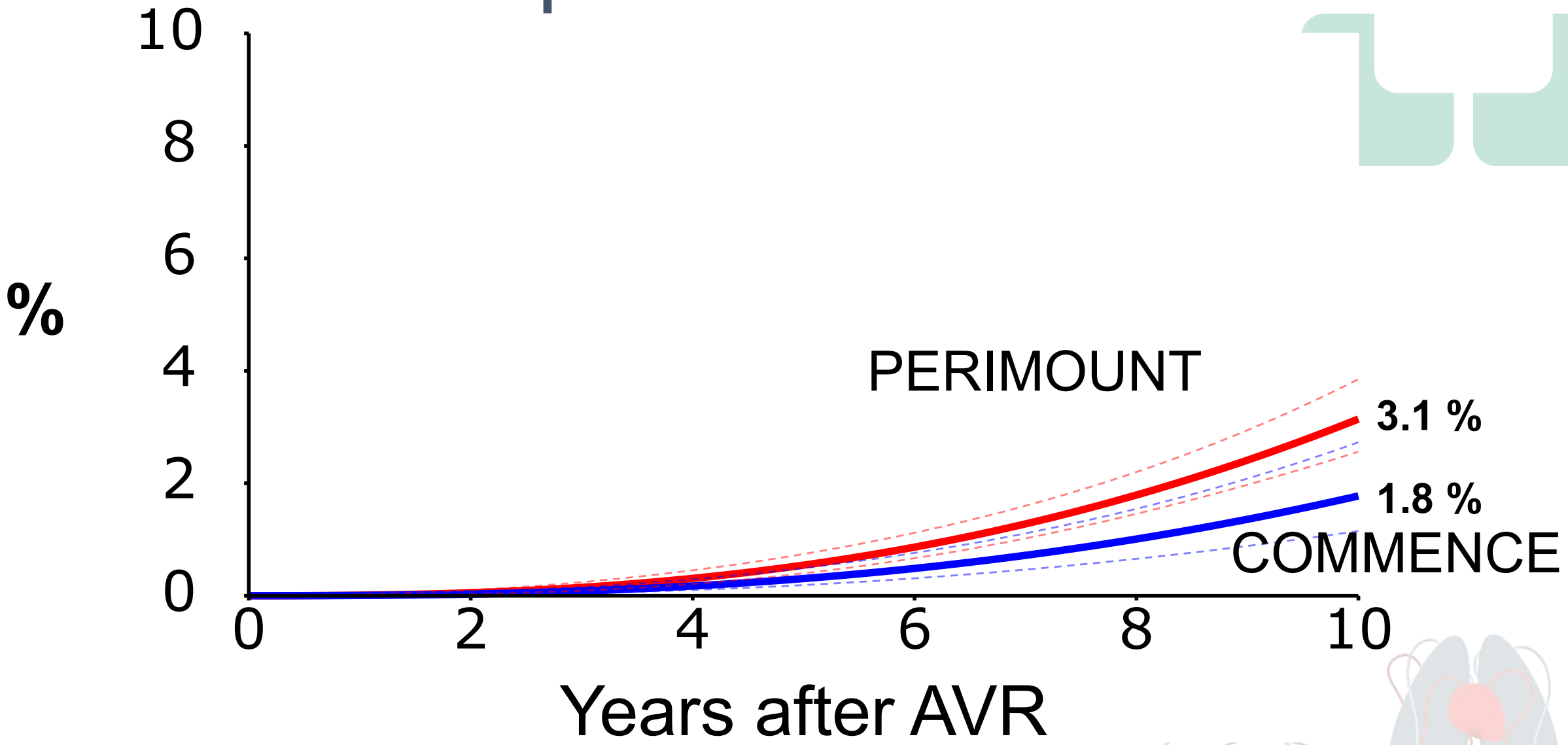


Implanted aortic population, N=689.

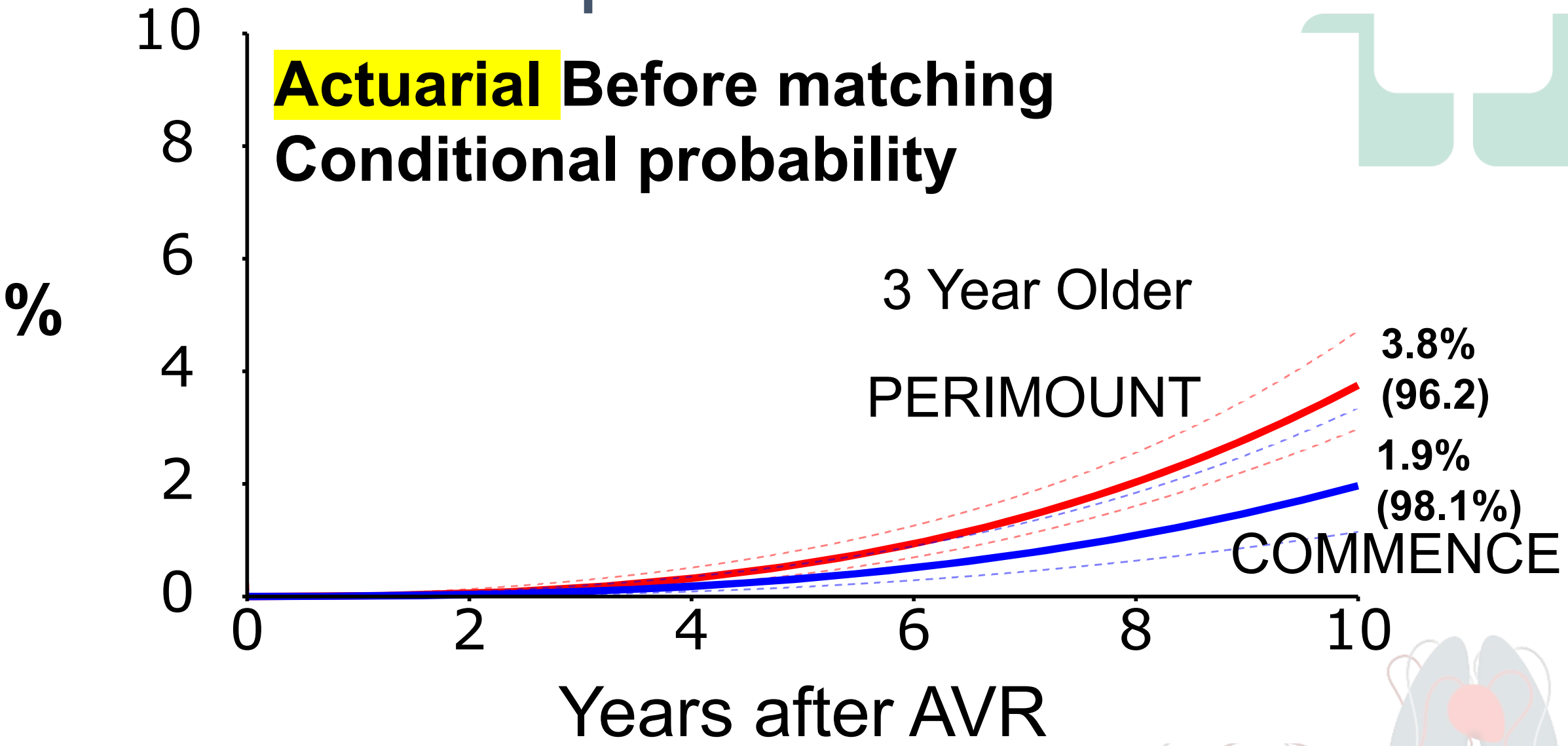
Statistical Propensity Matching

- Propensity Matching of Original All and Reconsented
- Propensity Matching of Propensity Matched Reconsented and Model 2700 (N = 1906)
- COMMENCE 10 – year N = 266 vs Model 2700 N = 257

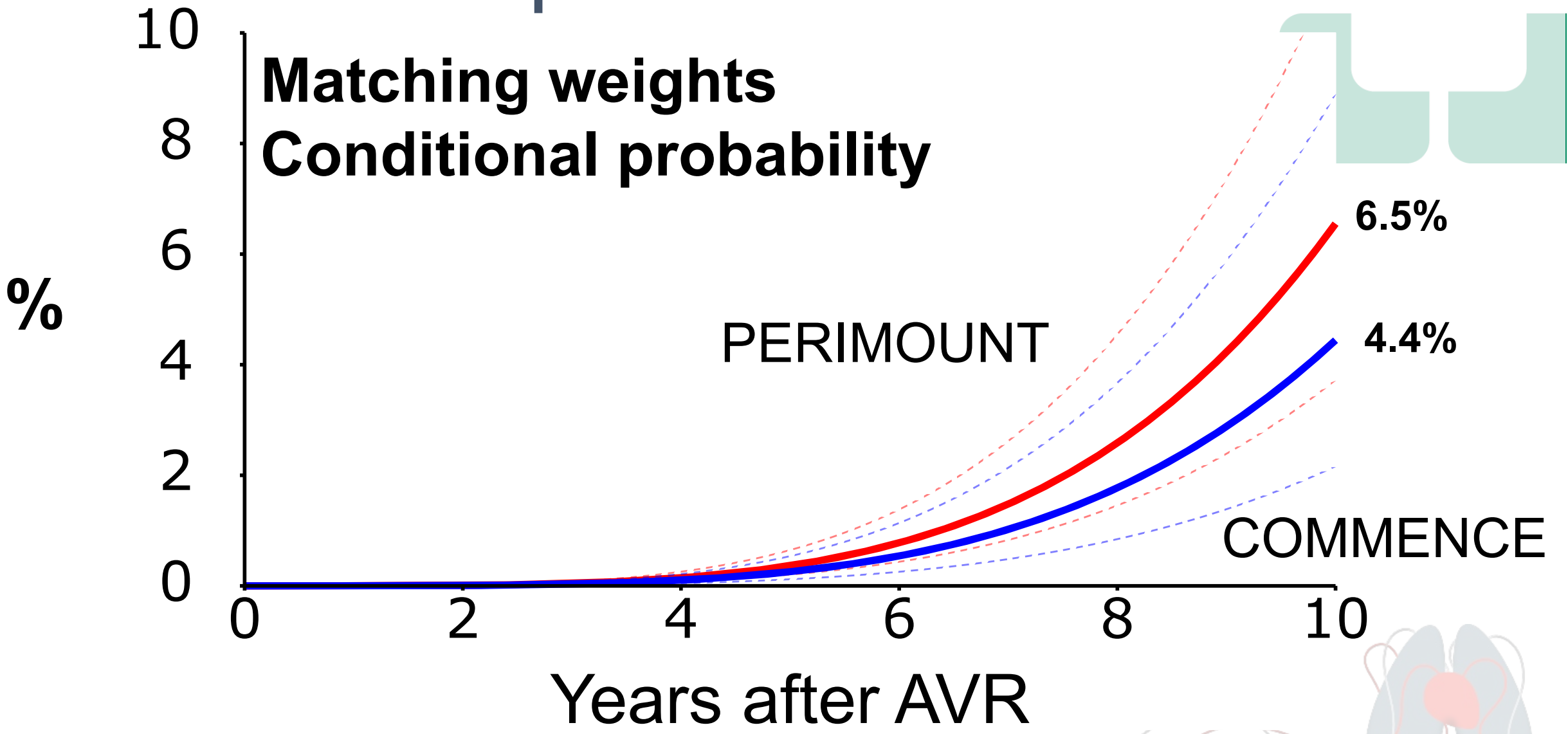
Reoperation for SVD



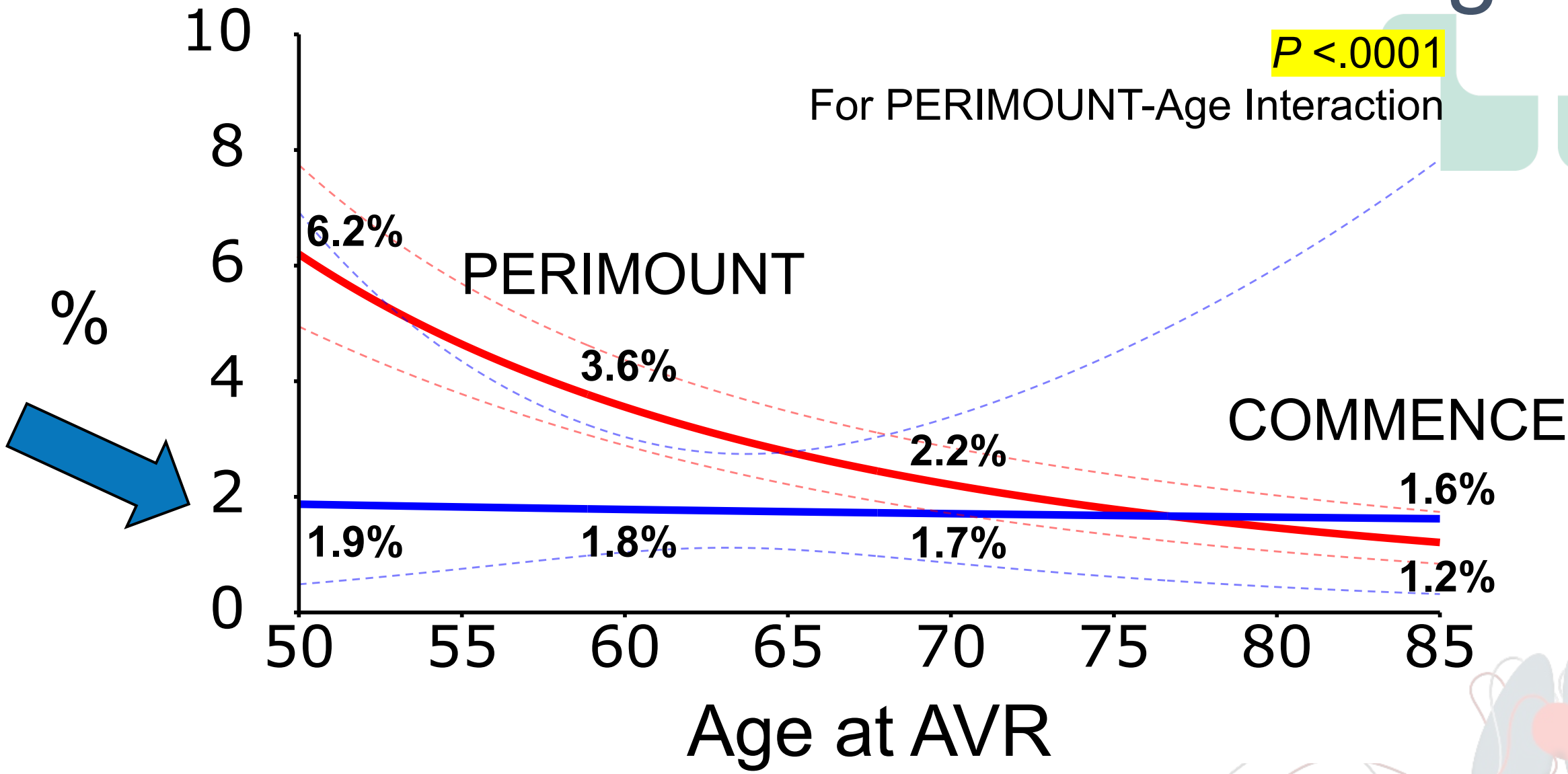
Reoperation for SVD



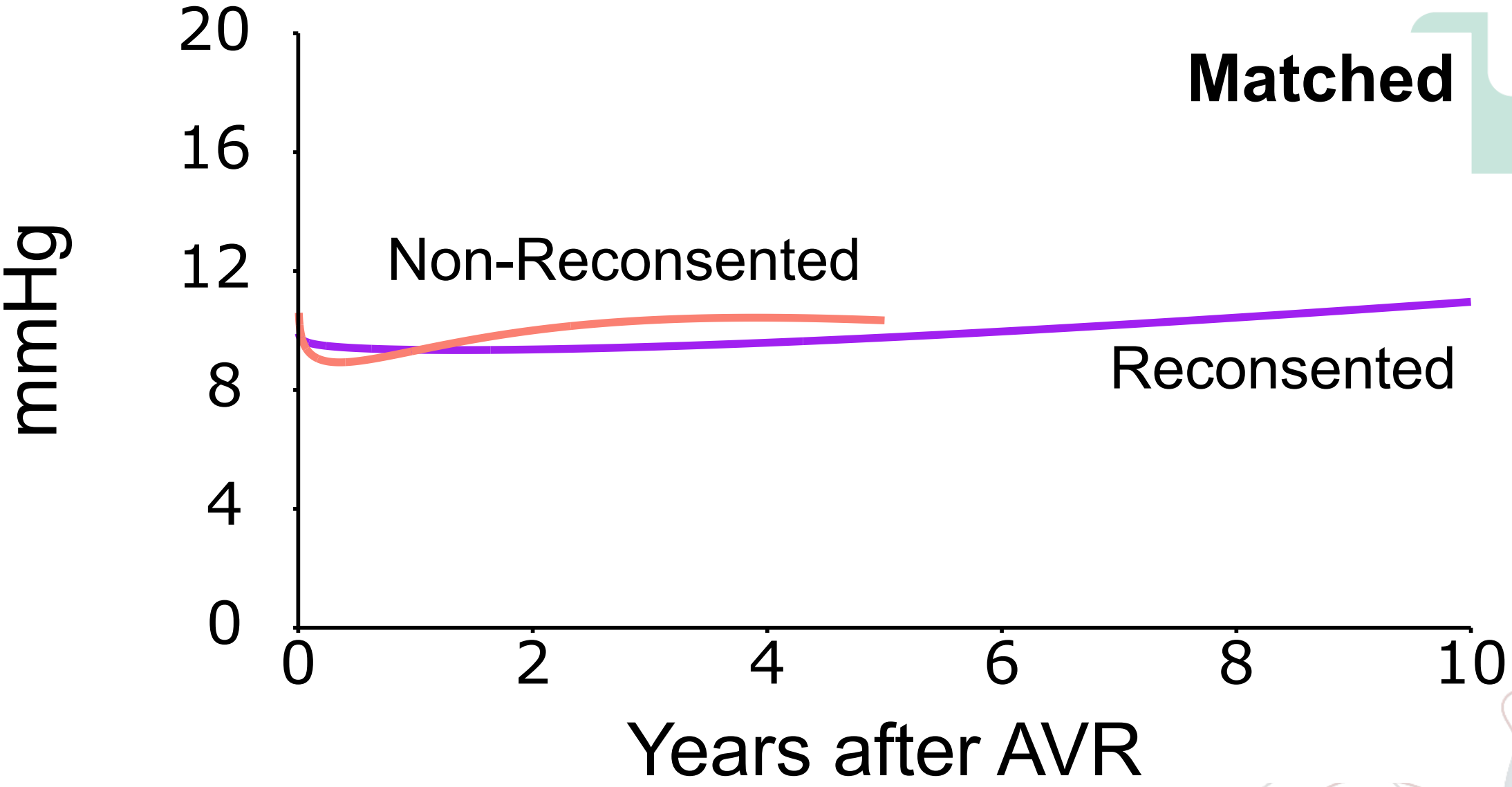
Reoperation for SVD



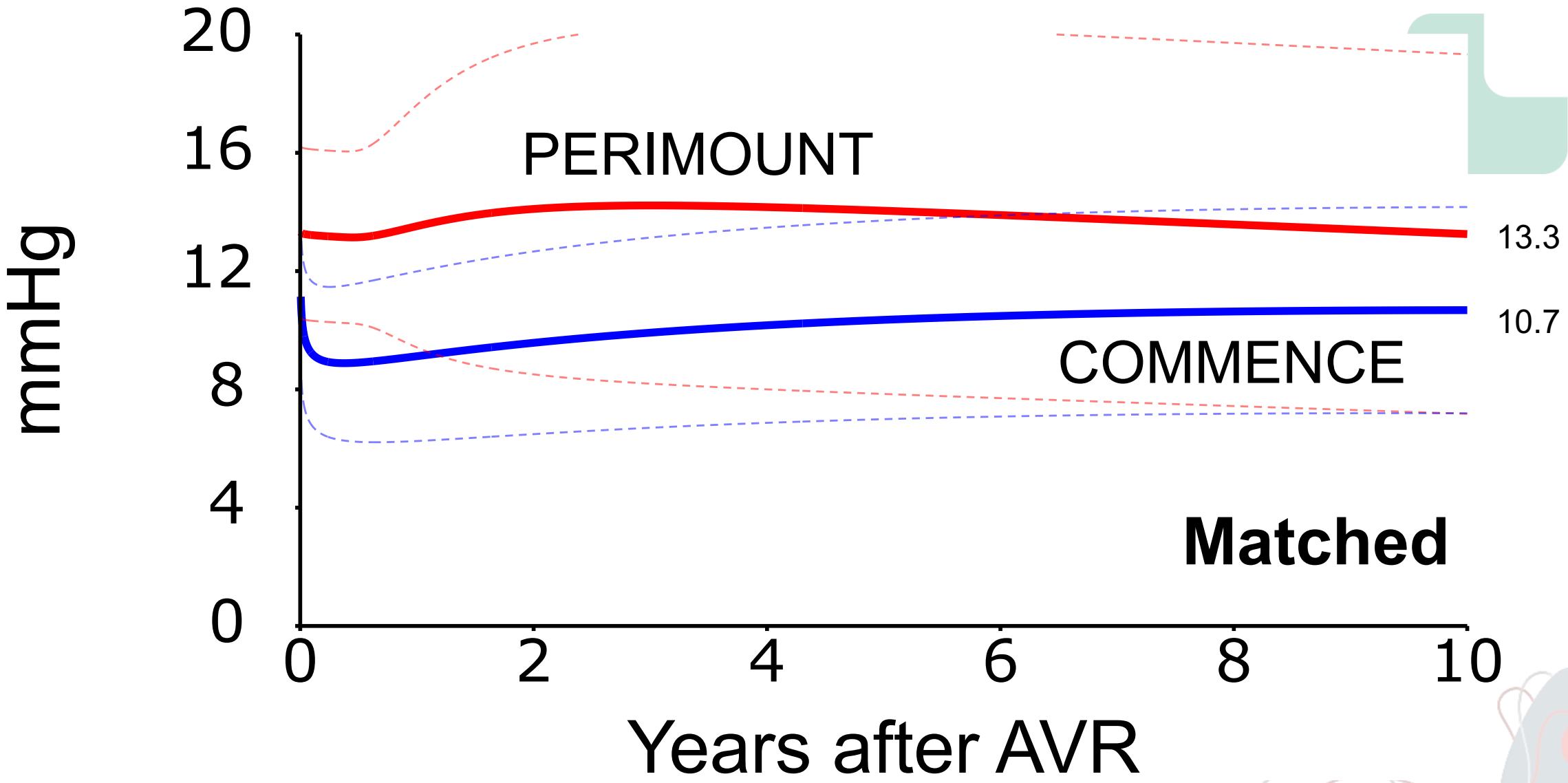
Predicted 10-Year SVD and Age



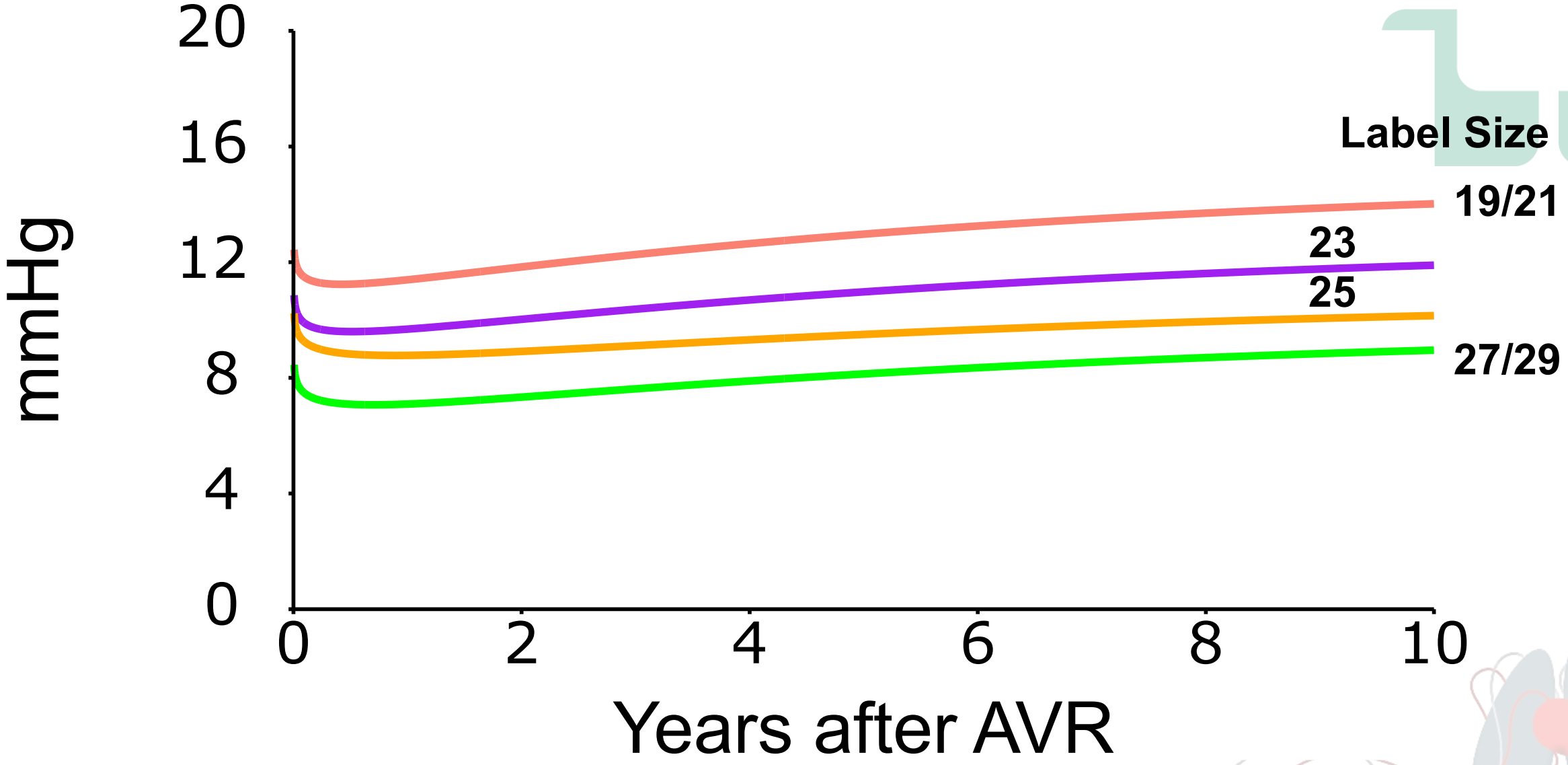
AV Mean Gradient: COMMENCE



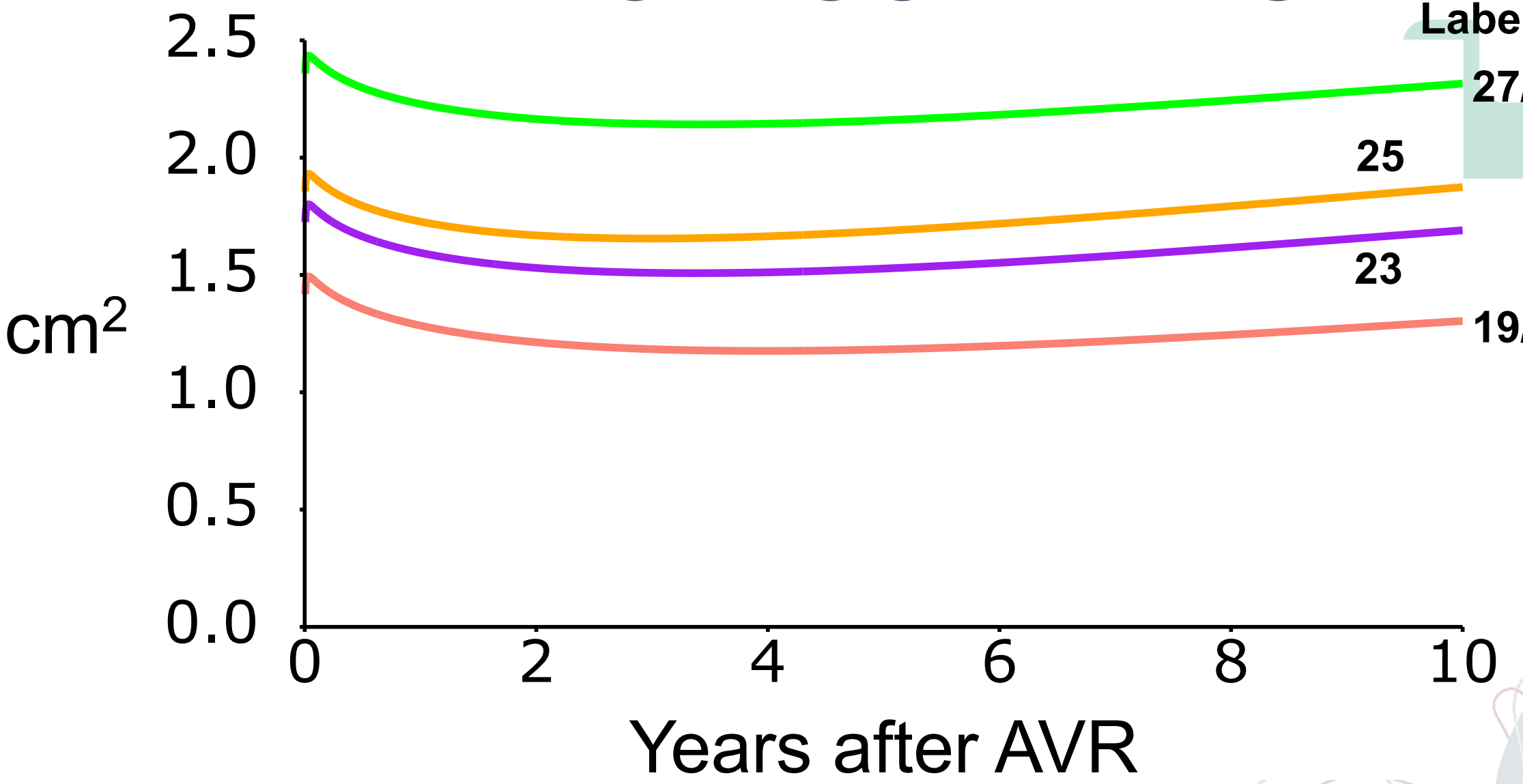
AV Mean Gradient



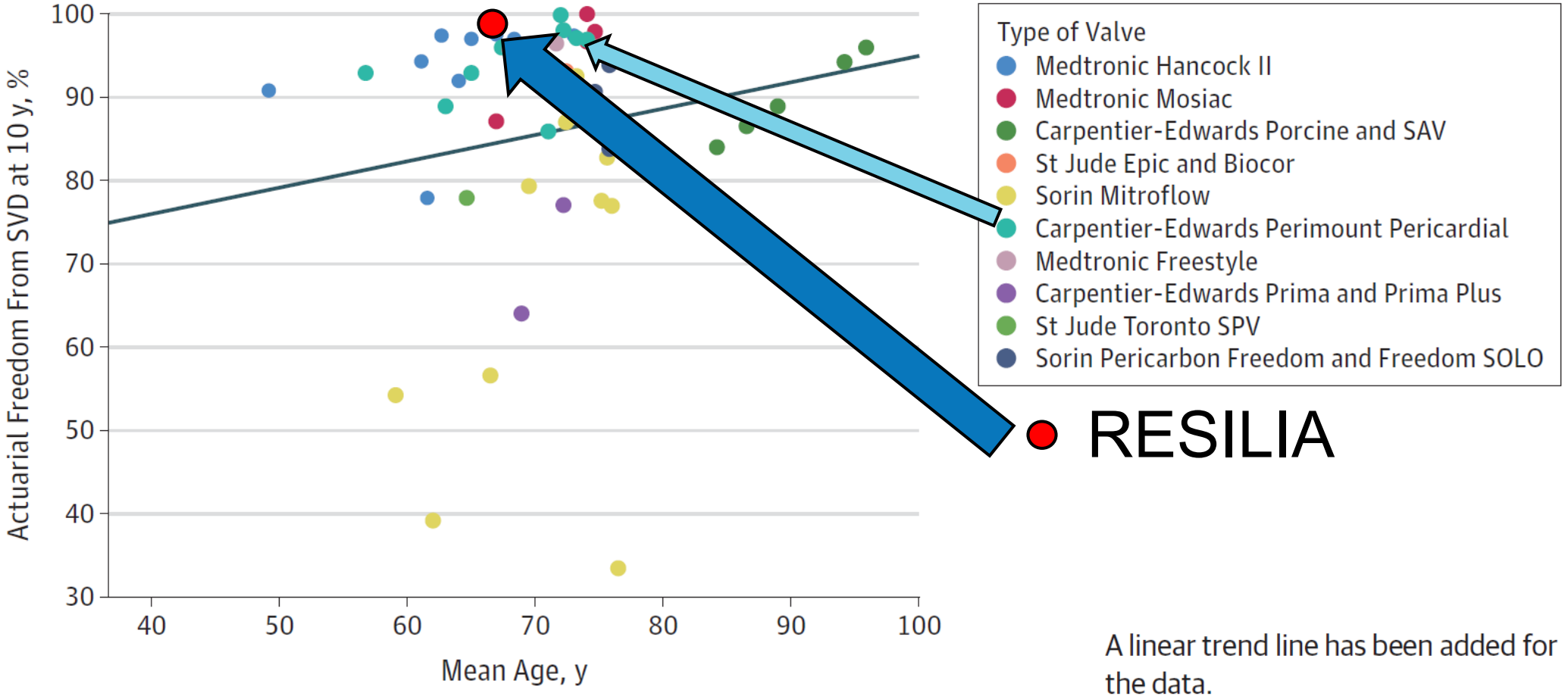
AV Mean Gradient: COMMENCE



AV EOA: COMMENCE



Scatterplot Reflecting Association of Mean Age With Actuarial Freedom From Structural Valve Deterioration (SVD) at 10 Years



A linear trend line has been added for the data.

Fatima et al, *JAMA Cardiology* January 2019 Volume 4, Number 1

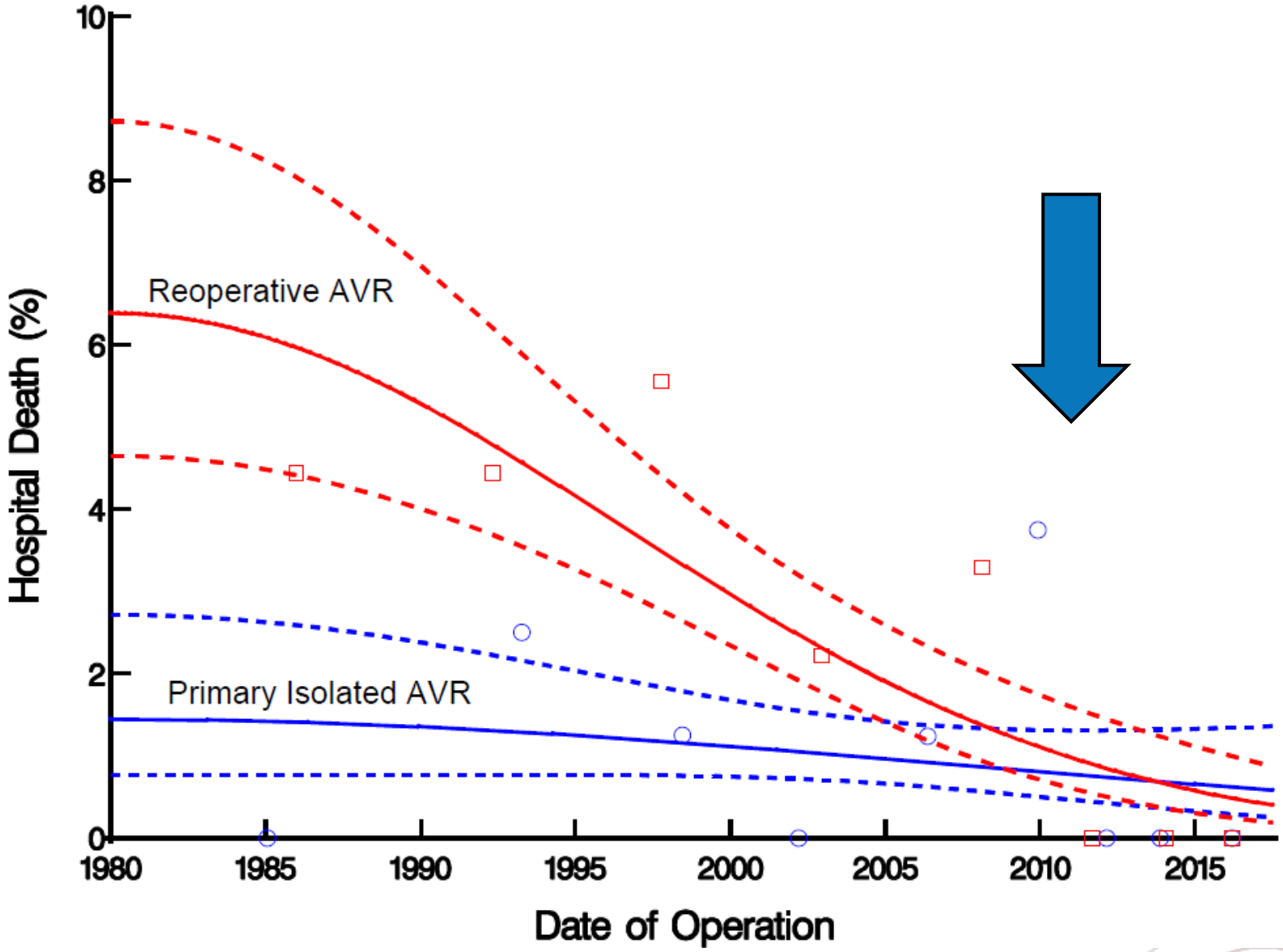
Conclusions

10 years of follow-up in the COMMENCE aortic trial showed:

- Favorable safety outcomes & sustained hemodynamic performance in patients ranging from ages 50 - 90 years
- 98.1% Actuarial and 95.9% Conditional Freedom, Irrespective of Age
- RESILIA on MagnaEase Frame Improved over Model 2700 valve
- 94.3% freedom from cardiovascular mortality (78.3% for All Cause)

Outcomes represent the longest prospective follow-up with RESILIA tissue

SVD, structural valve deterioration

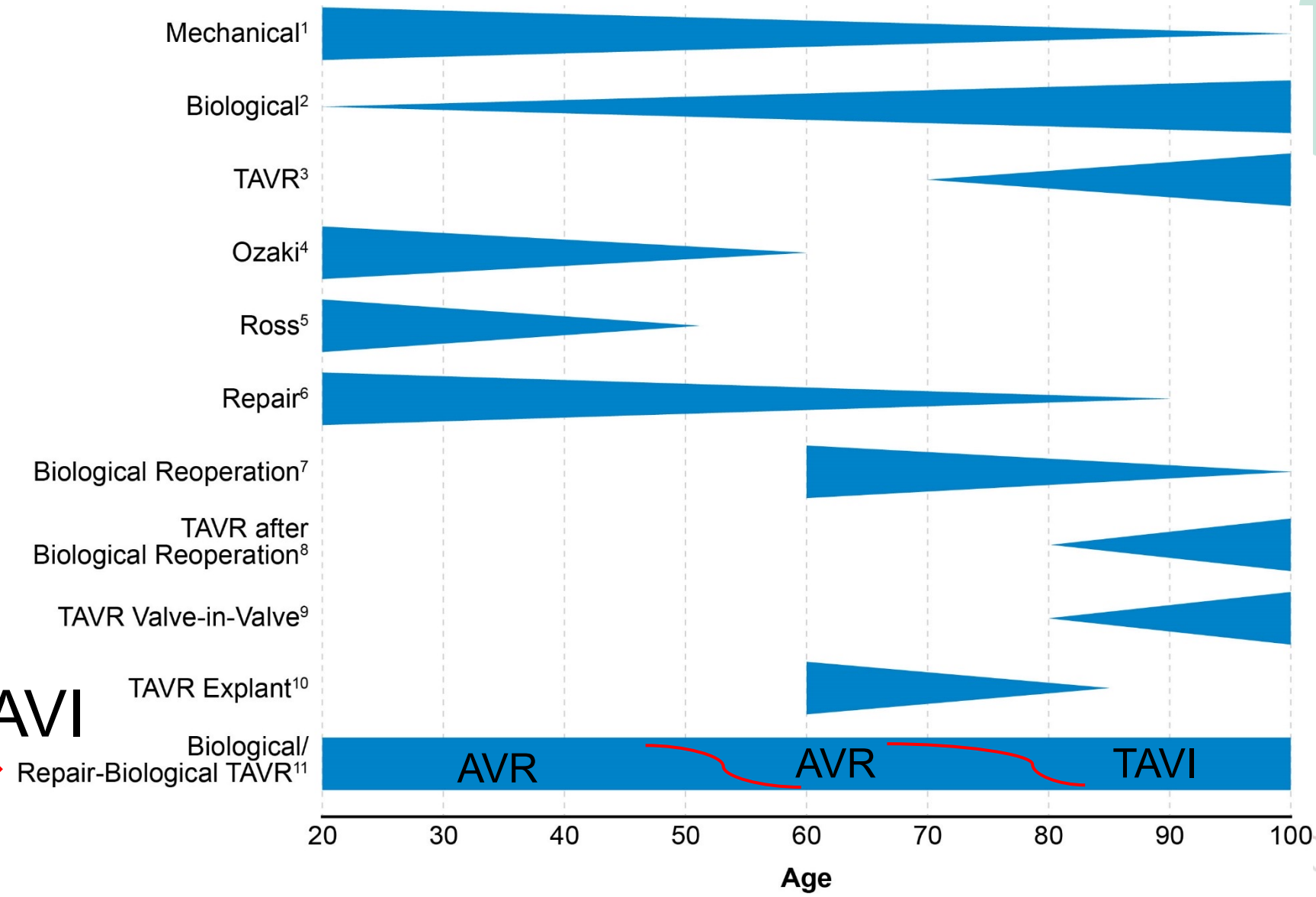

Hospital Death (%)
10
8
6
4
2
0
Reoperative AVR
Primary Isolated AVR
1980
1985
1990
1995
2000
2005
2010
2015
Date of Operation

Implications

- Better Performance in Young People
- Better Safety and Performance than Partner 3 or Evolut Trials (Despite approx. 8 years older)

Consideration of Bio AVR
Redo Bio AVR, and then TAVR?

Aortic Valve Management Pathways



2xAVR+TAVI

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Cleveland Clinic

Every life deserves world class care.

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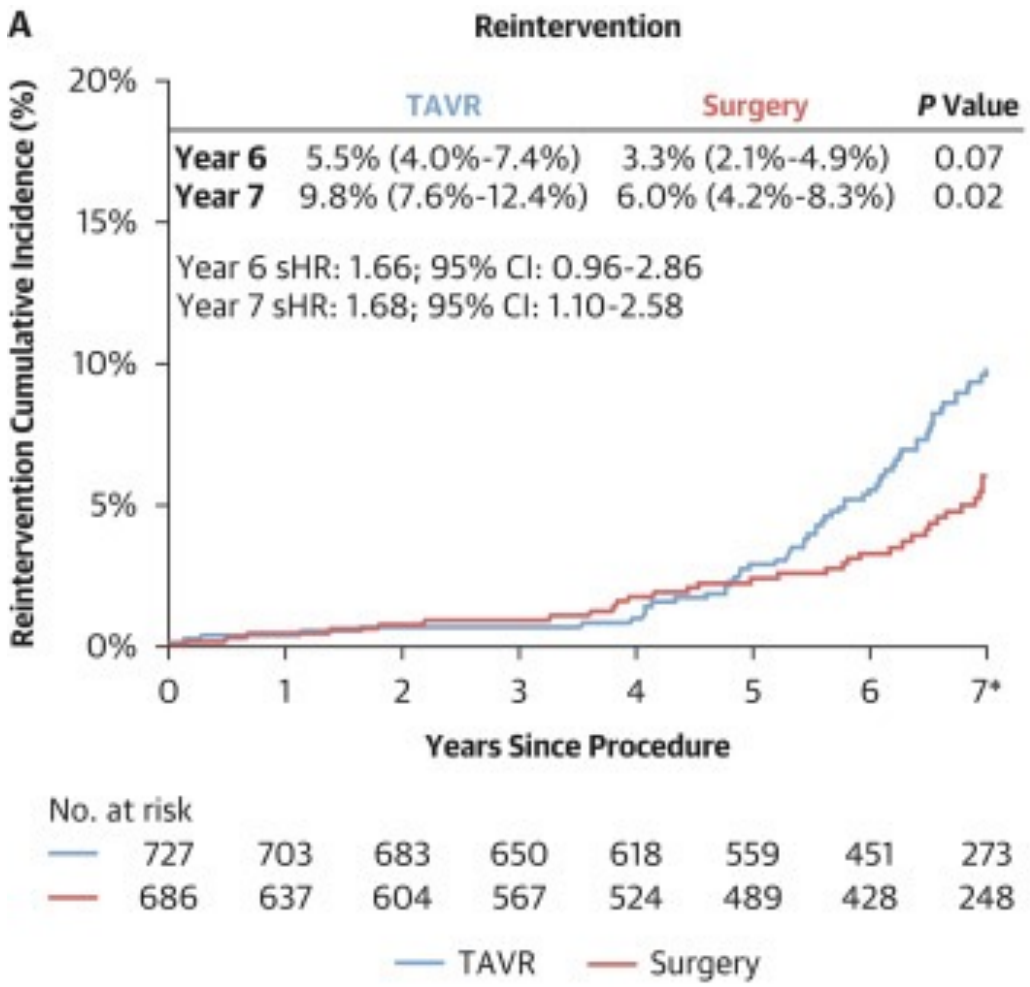
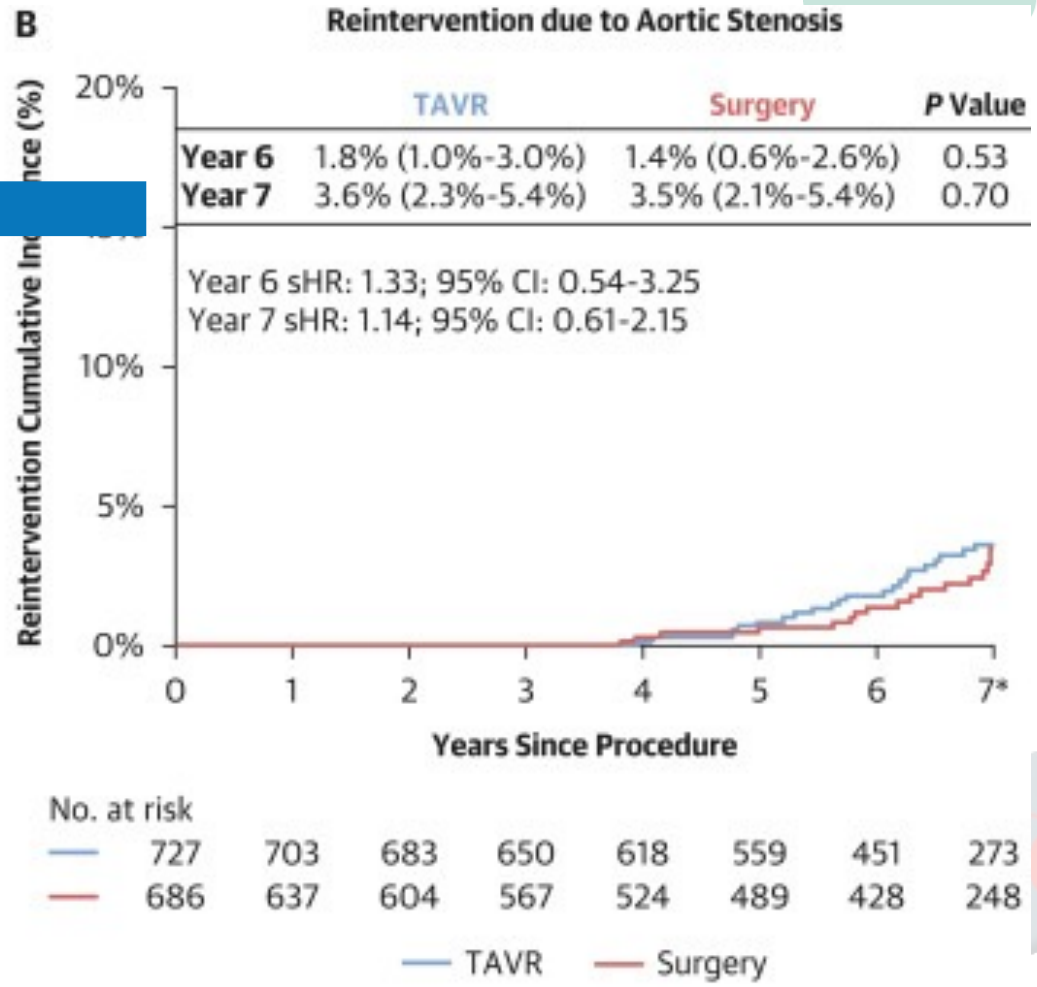
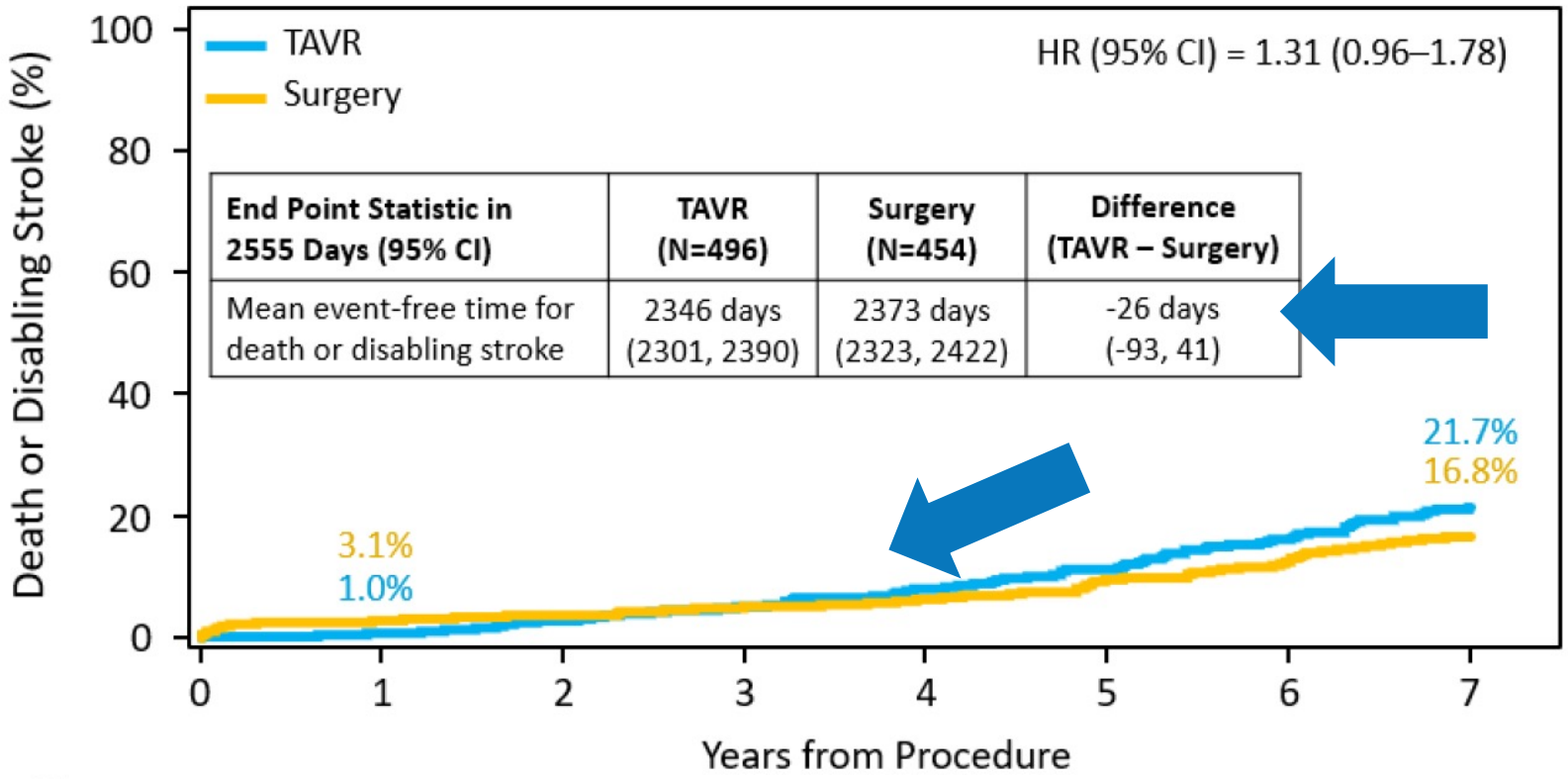
Evolut 7 – Years Freedom Re - Intervention





PARTNER Death or Disabling Stroke

A



End Point Statistic in 2555 Days (95% CI)	TAVR (N=496)	Surgery (N=454)	Difference (TAVR – Surgery)
Mean event-free time for death or disabling stroke	2346 days (2301, 2390)	2373 days (2323, 2422)	-26 days (-93, 41)

Number at risk:

TAVR	496	490	477	461	441	417	382	344
Surgery	454	425	408	392	379	357	339	306

Leon et al. Transcatheter or surgical aortic-valve replacement in low-risk patients at 7 Years. *N Engl J Med* 2026;394:773-83. DOI: 10.1056/NEJMoa2509766

Key Clinical End Points 5 to 7 Years

End point— no. of patients (Kaplan–Meier estimate)*	>5 - 7 Years		
	TAVR (N = 433)	Surgery (N = 390)	Hazard Ratio (95% CI)
Death or Stroke or Rehospitalization†‡	54 (15.3)	38 (13.6)	1.13 (0.75–1.72)
Death from any cause with vital status sweep	43 (10.1)	31 (8.0)	1.27 (0.80–2.02)
Death from any cause‡	42 (10.3)	26 (7.4)	1.42 (0.87–2.32)
Death from cardiovascular causes‡	19 (4.9)	10 (2.9)	1.67 (0.78–3.59)
Death from non-cardiovascular causes‡§	23 (5.7)	16 (4.6)	1.26 (0.67–2.39)
Stroke	10 (2.7)	6 (1.9)	1.45 (0.53–4.00)
Disabling Stroke	8 (2.1)	3 (0.9)	2.36 (0.63–8.90)
Non-Disabling Stroke	2 (0.5)	3 (0.9)	0.57 (0.10–3.44)
Death or Disabling Stroke‡	46 (11.4)	27 (7.8)	1.51 (0.94–2.43)
Rehospitalization†	28 (8.1)	20 (7.1)	1.14 (0.64–2.02)
Aortic valve reintervention§	15 (4.0)	10 (3.1)	1.32 (0.59–2.94)
Endocarditis	6 (1.6)	3 (0.9)	1.74 (0.44–6.96)
Clinical valve thrombosis¶	1 (0.2)	1 (0.3)	0.88 (0.06–14.14)
New left-bundle branch block§	1 (0.3)	1 (0.3)	0.99 (0.06–15.88)
New onset atrial fibrillation§	14 (4.8)	3 (1.8)	2.65 (0.76–9.21)
New permanent pacemaker§	13 (4.0)	8 (2.7)	1.47 (0.61–3.56)
Serious bleeding§	21 (5.9)	14 (4.7)	1.29 (0.65–2.53)
Myocardial infarction§	15 (4.0)	4 (1.2)	3.25 (1.08–9.80)
Revascularization§	14 (3.8)	5 (1.6)	2.45 (0.88–6.79)
Percutaneous coronary intervention	12 (3.3)	5 (1.6)	2.11 (0.74–5.99)
Coronary-artery bypass grafting	2 (0.5)	1 (0.3)	1.75 (0.16–19.24)

Leon et al. Transcatheter or surgical aortic-valve replacement in low-risk patients at 7 Years. *N Engl J Med* 2026;394:773-83. DOI: 10.1056/NEJMoa2509766

AV Reinterventions and Causes Through 7 Year

Endpoint*	0 – 5 Years		> 5 – 7 Years		0 – 7 Years	
	TAVR	Surgery	TAVR	Surgery	TAVR	Surgery
AV Reintervention — Kaplan-Meier% (no. of events/ no. of patients)	**2.6 (13/13)**	**3.0 (13/12)**	**4.0 (15/15)**	**3.1 (10/10)**	**6.7 (28/28)**	**6.0 (23/22)**
Redo Surgery — no.	**7**	**6**	**8**	**1**	**15**	**7**
≥ Moderate PVR	2	0	1	0	3	0
Stenosis	2	2	5	1	7	3
Endocarditis	1	4	2	0	3	4
Valve thrombosis	1	0	0	0	1	0
AR + MR	1	0	0	0	1	0
Valve-in-valve — no.	**3**	**4**	**7**	**9**	**10**	**13**
≥ Moderate PVR	1	0	0	0	1	0
Central AR	0	0	0	1	0	1
Stenosis	2	4	7	8	9§	12

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