Aortic Valve Replacement: The Future is Tissue?

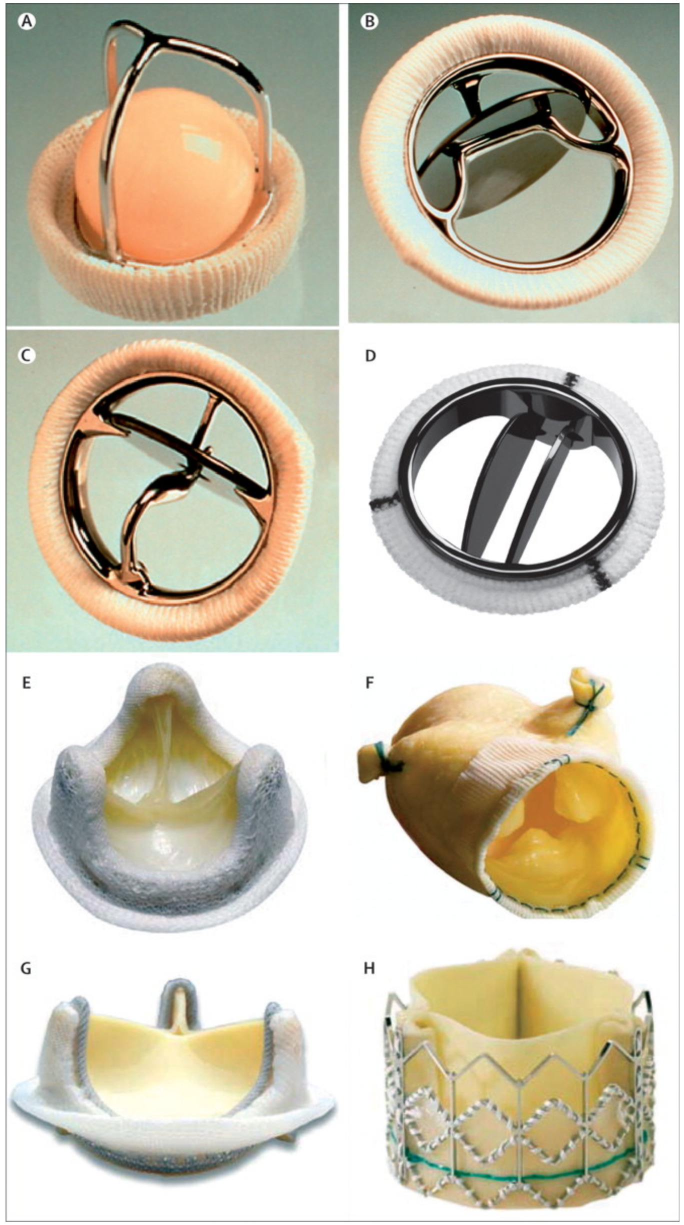
Dr Kenny Sin
National Heart Centre Singapore

70 years of Prosthetic Valves

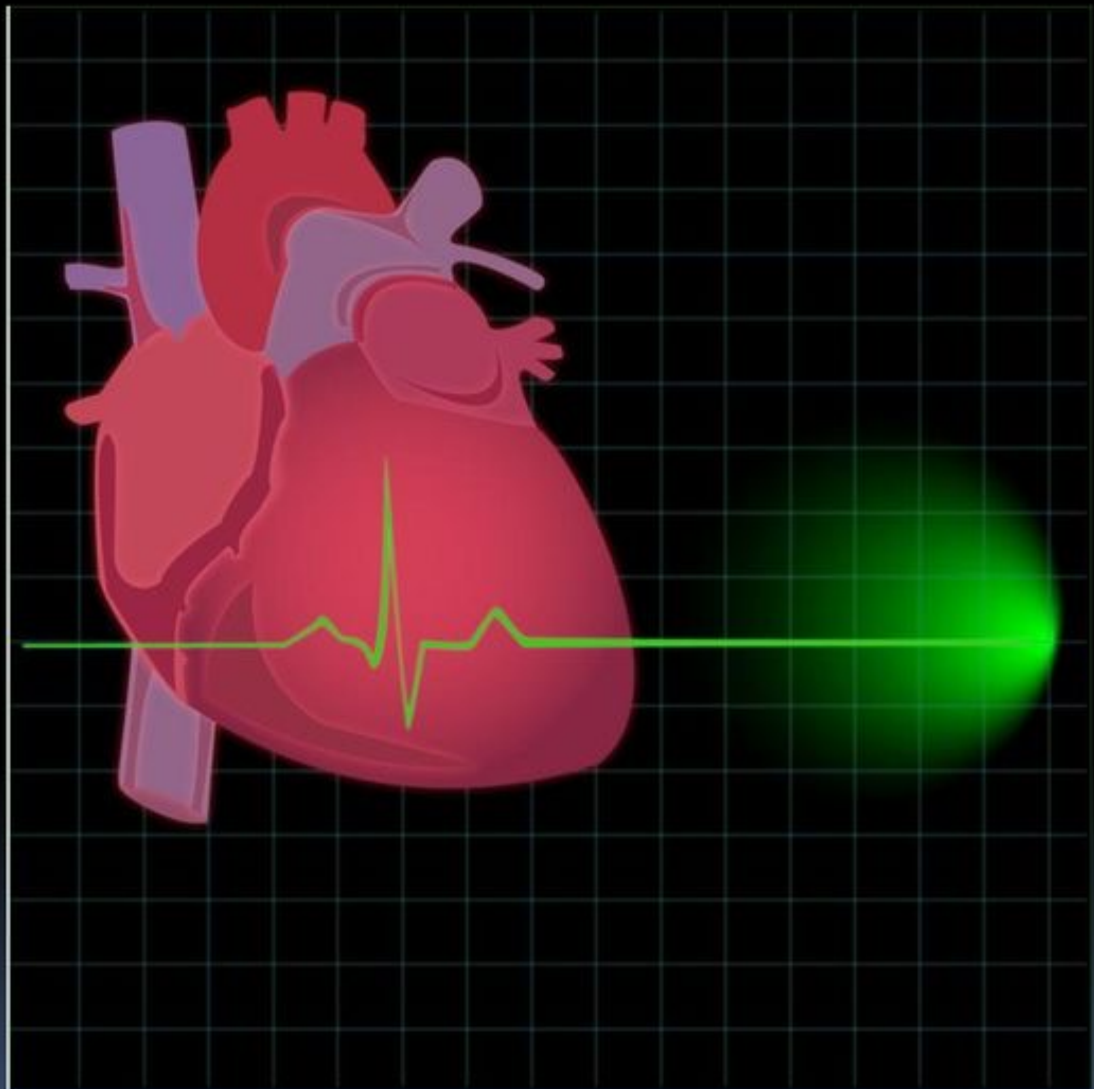
- 1952 Hufnagel

- 1959 Starr-Edwards Caged Ball
- 1969 Bjork-Shiley Tilting Disc
- 1977 St Jude Bileaflet

- 1966 Carpentier Porcine
- 1971 Ionescu-Shiley Bovine

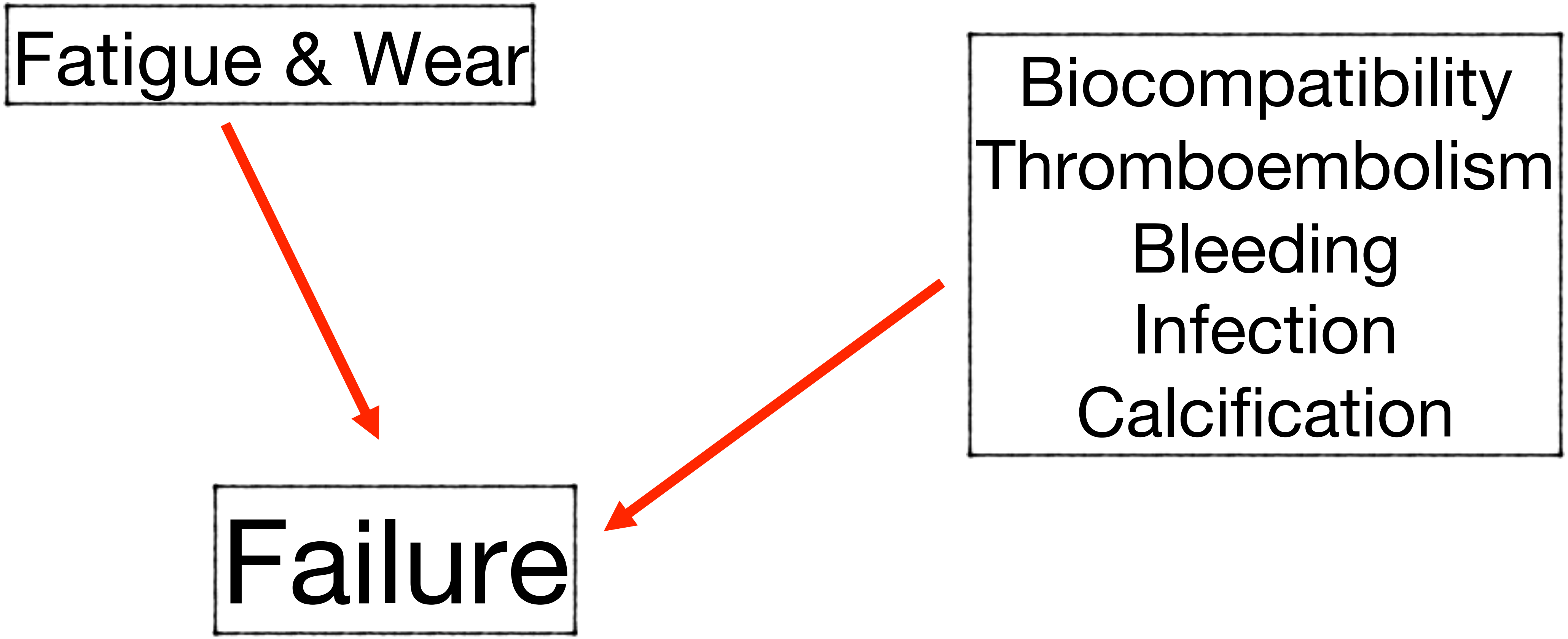


Mainstream Valve Substitutes



Human heart beats average of 75 times a minute = 40 million times a year or 2.5 billion times in a 70 year lifetime!

Durability


Fatigue & Wear
Biocompatibility
Thromboembolism
Bleeding
Infection
Calcification
Failure

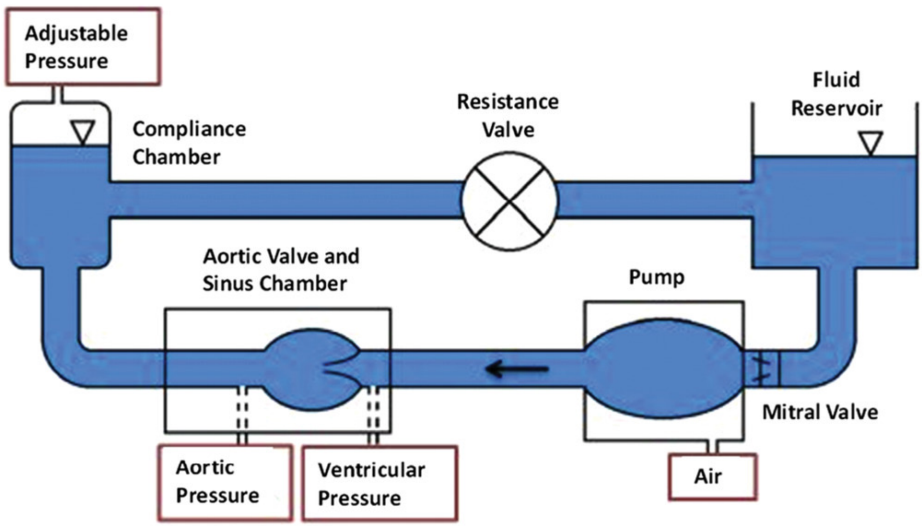
How to Assess Durability?

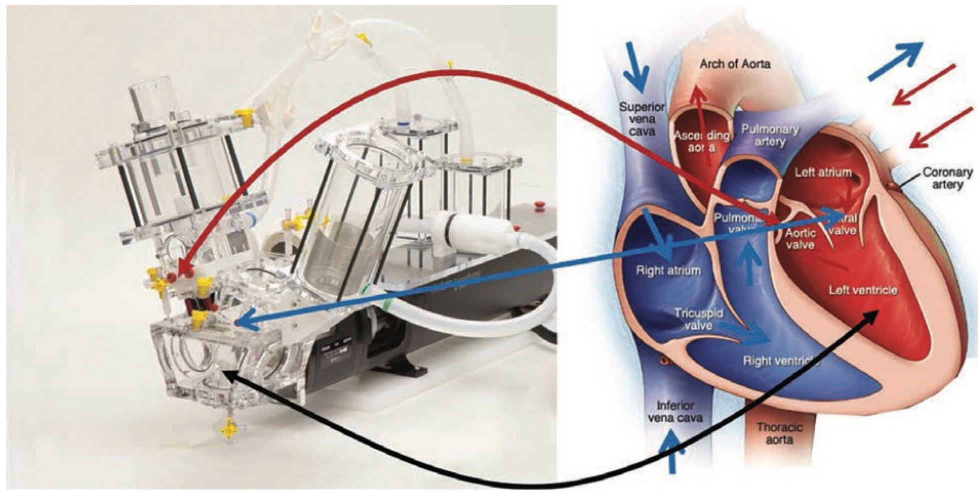
Bench Test

Animal Test

Clinical Results

Pulse Duplicator





1 billion cycles = 25 years

ELSEVIER

The Annals of Thoracic Surgery

Volume 26, Issue 4, October 1978, Pages 323-335

Durability of Prosthetic Heart Valves

Richard E. Clark M.D., W.M. Swanson Ph.D., John L. Kardos Ph.D., Ronald W. Hagen M.S., Richard A. Beauchamp B.S.

Lillehei-Kaster removed after 762 million cycles (19 years) without discernible wear.

Shiley Pyrolite disc	973 million cycles	24 years
Starr-Edwards 2320	150 million cycles	3.8 years
Björk-Shiley Delrin disc	140 million cycles	3.5 years
Hufnagel trileaflet	124 million cycles.	3.1 years
Shiley porcine pericardial	65 million cycles	1.6 years
Hancock porcine	62 million cycles	1.6 years
Edwards porcine	34 million cycles	0.9 years

J THORAC CARDIOVASC SURG 92:894-907, 1986

Mechanical failure of the Björk-Shiley valve

Incidence, clinical presentation, and management

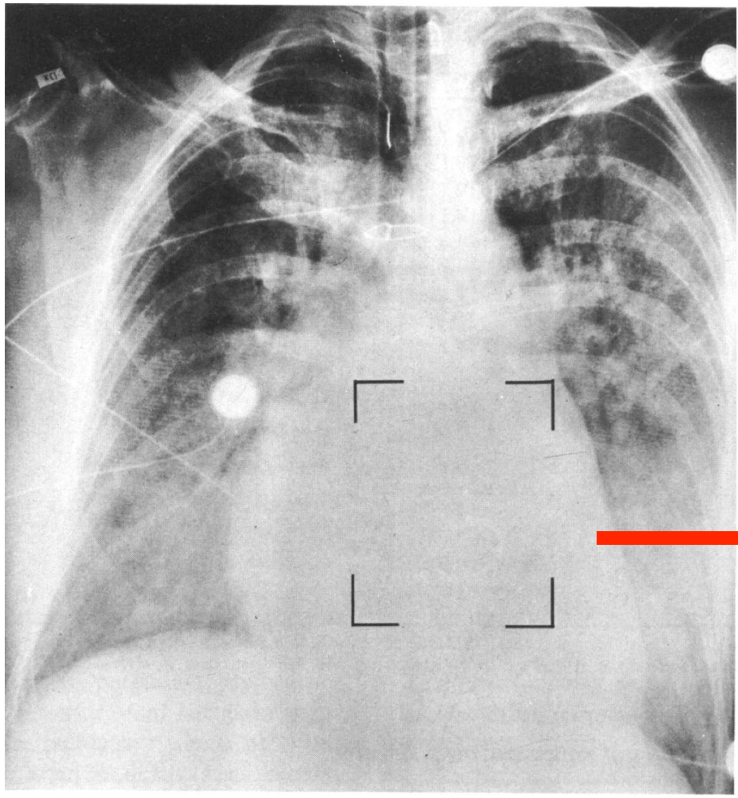
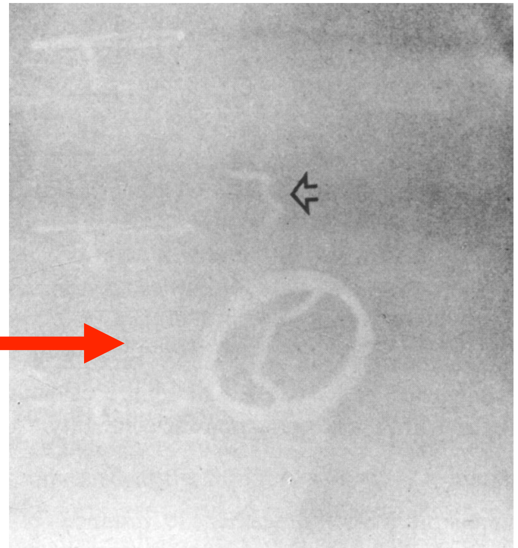
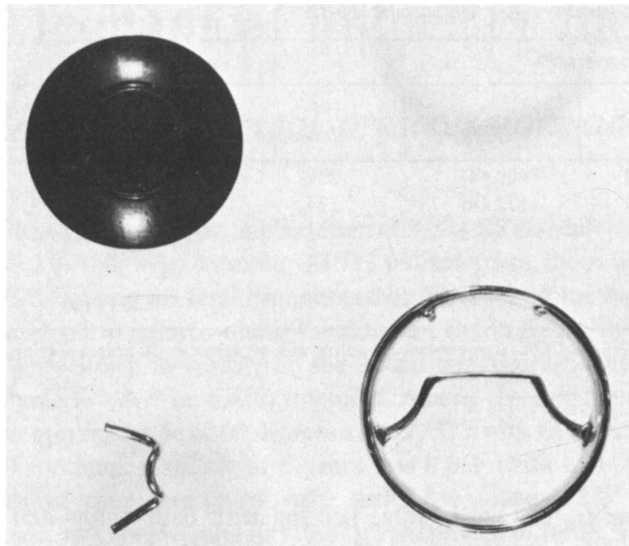


Fig. 2A. Chest x-ray film taken 24 hours before death (Patient 10, Table II). Severe pulmonary edema prevented the correct interpretation in time.

Outlet Strut Fracture



Autopsy



J THoRAc CARDIOVASC SURG 92:894-907, 1986

NATIONAL MUSEUM
OF AMERICAN HISTORY
BEHRING CENTER

Lillehei-Kaster OmniCarbon Heart Valve

This Lillehei-Kaster OmniCarbon pivoting-disc valve has a pyrolytic carbon and graphite ring and cage and a Dacron sewing ring. Lillehei-Kaster valve was in production 1970 and 1987. Tilting disc valves were first introduced by Lillehei-Kaster in 1969. These valves demonstrated high durability due to their pyrolyte composition and had "essentially no valve failures."

https://americanhistory.si.edu/collections/search/object/nmah_1726280

The Lillehei-Kaster aortic valve prosthesis

Long-term results in 273 patients with 1253 patient-years of follow-up

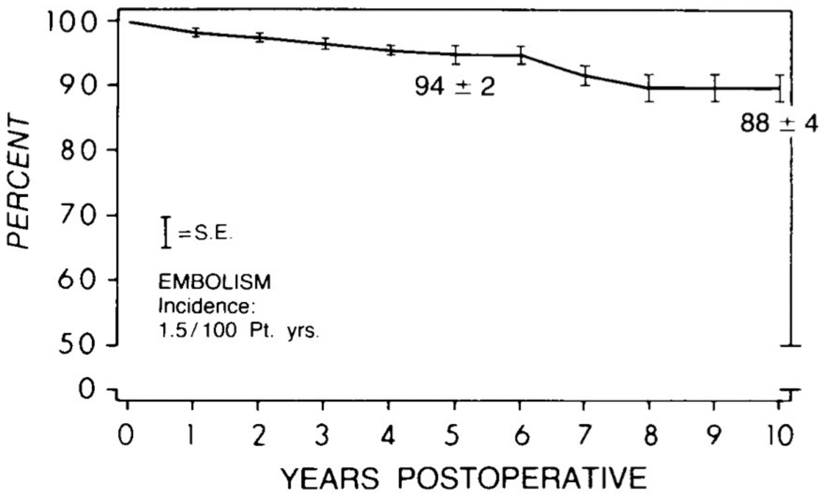


Fig. 3. Probability of freedom from systemic embolism.

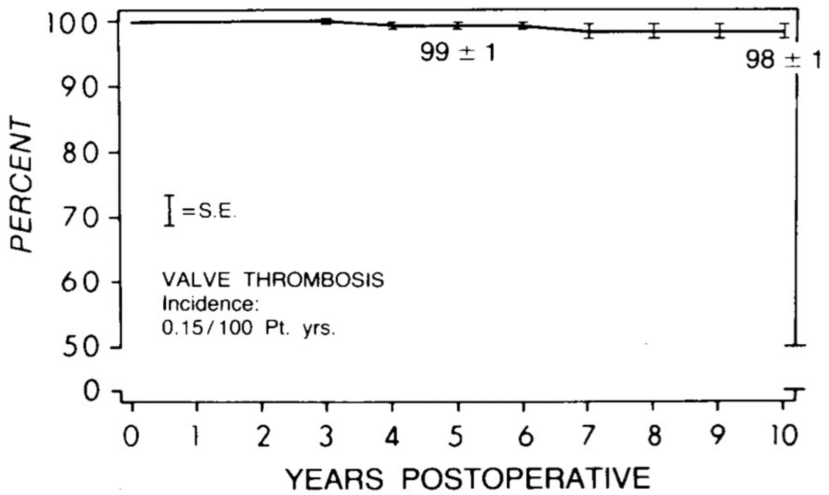


Fig. 4. Probability of freedom from valve thrombosis.

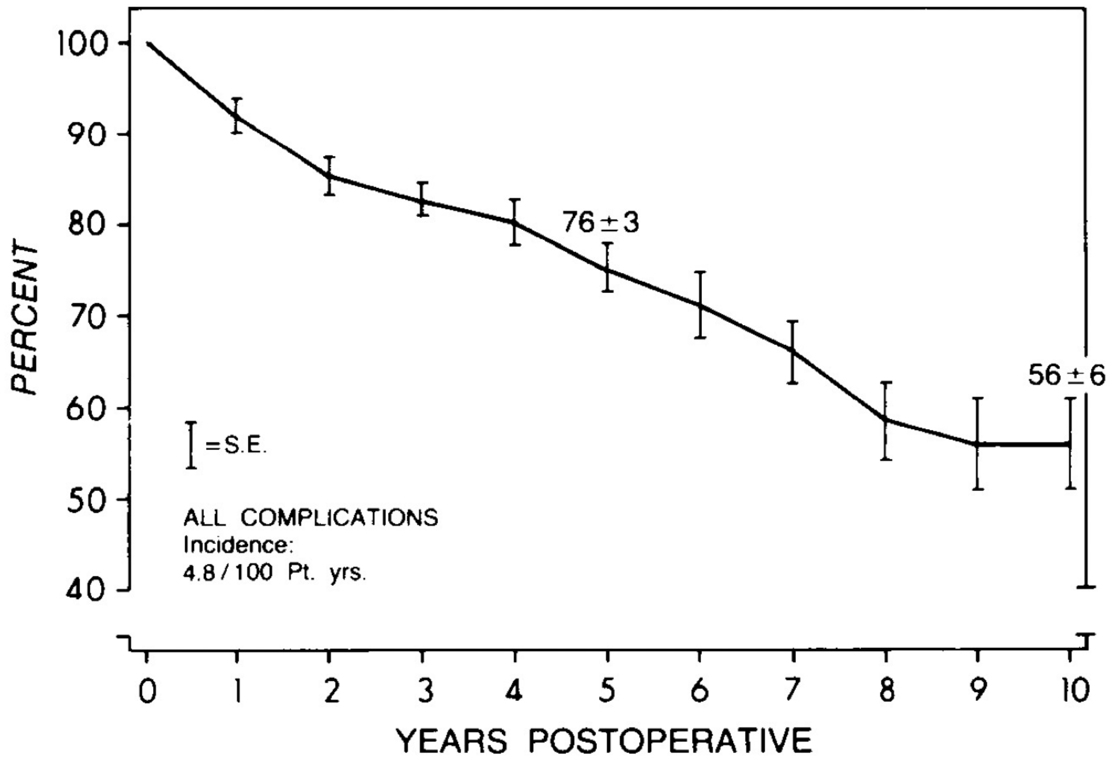
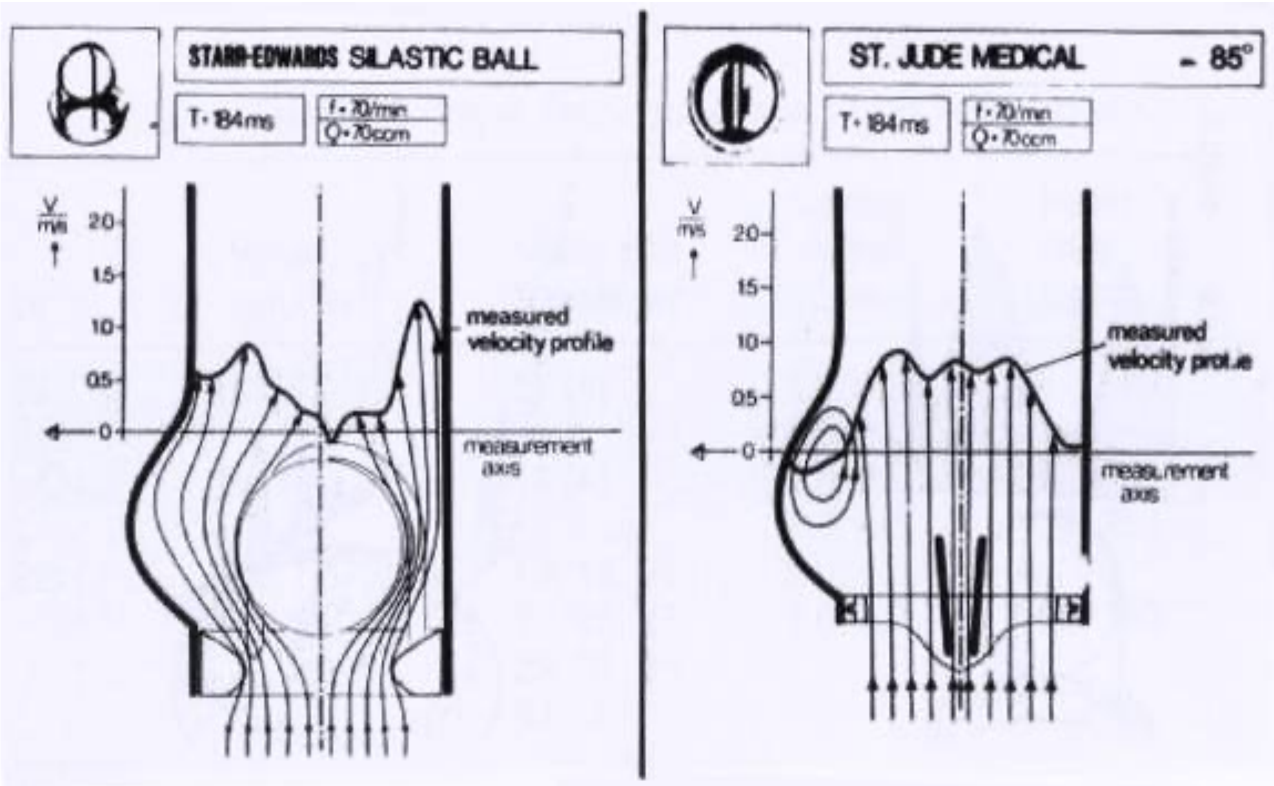
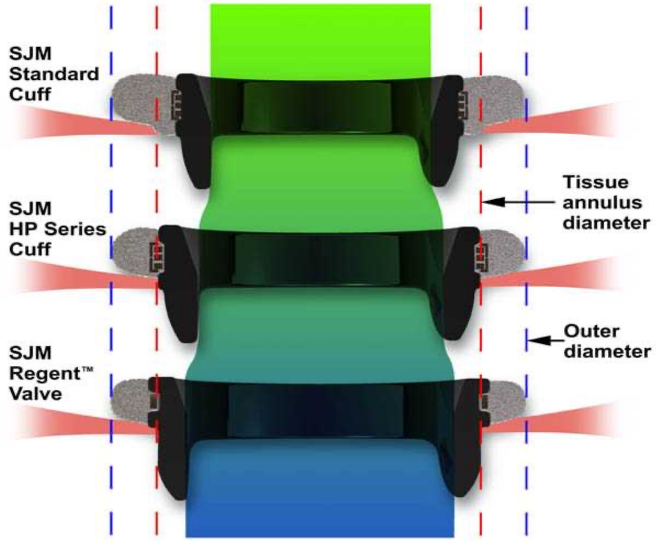


Fig. 9. Probability of freedom from all valve-related complications.

Improved Performance





Long-Term Experience With the St. Jude Medical Valve Prosthesis

James L. Zellner, MD, John M. Kratz, MD, Arthur J. Crumbley III, MD, Martha R. Stroud, MS, Scott M. Bradley, MD, Robert M. Sade, MD, and Fred A. Crawford, Jr, MD

Division of Cardiothoracic Surgery, Medical University of South Carolina, Charleston, South Carolina

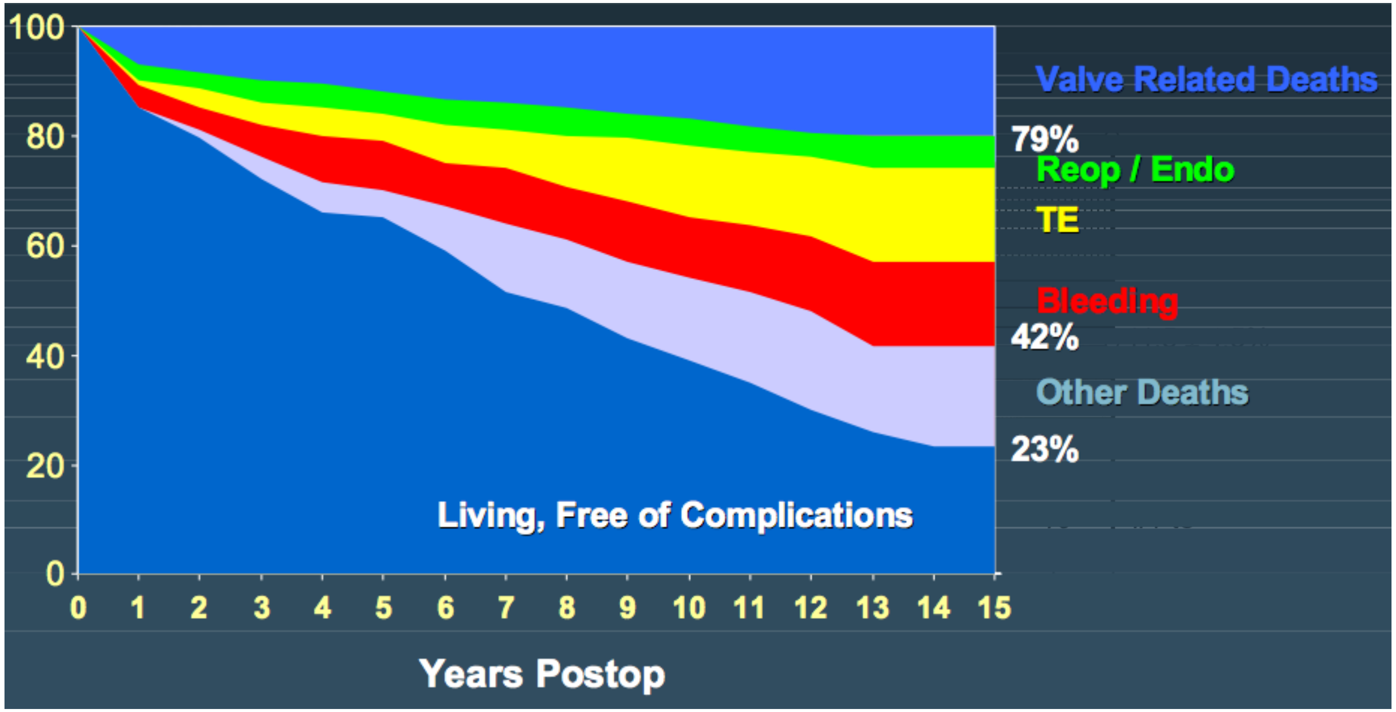
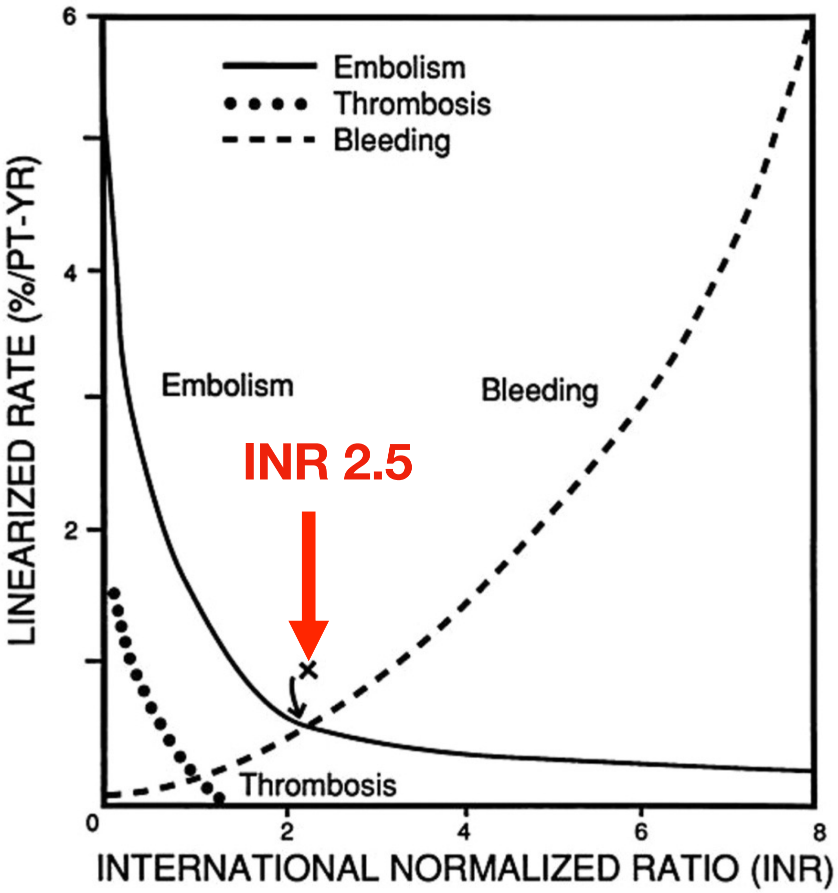


Fig 11. Freedom from all complication, combined, for AVR group patients. (Reop = *reoperation;* Endo = *endocarditis;* TE = *thromboembolism.)*

Ann Thorac Surg 1999;68:1210–8)

Evolution of INR



1995
Cannegieter et al INR 2.5-3.9

2017
AHA/ACC INR 2.5+ASA, 3.0 caged
ESC INR 2.5, 3.0 risk factors +0.5/+1.0/+ASA

PROACT Trial

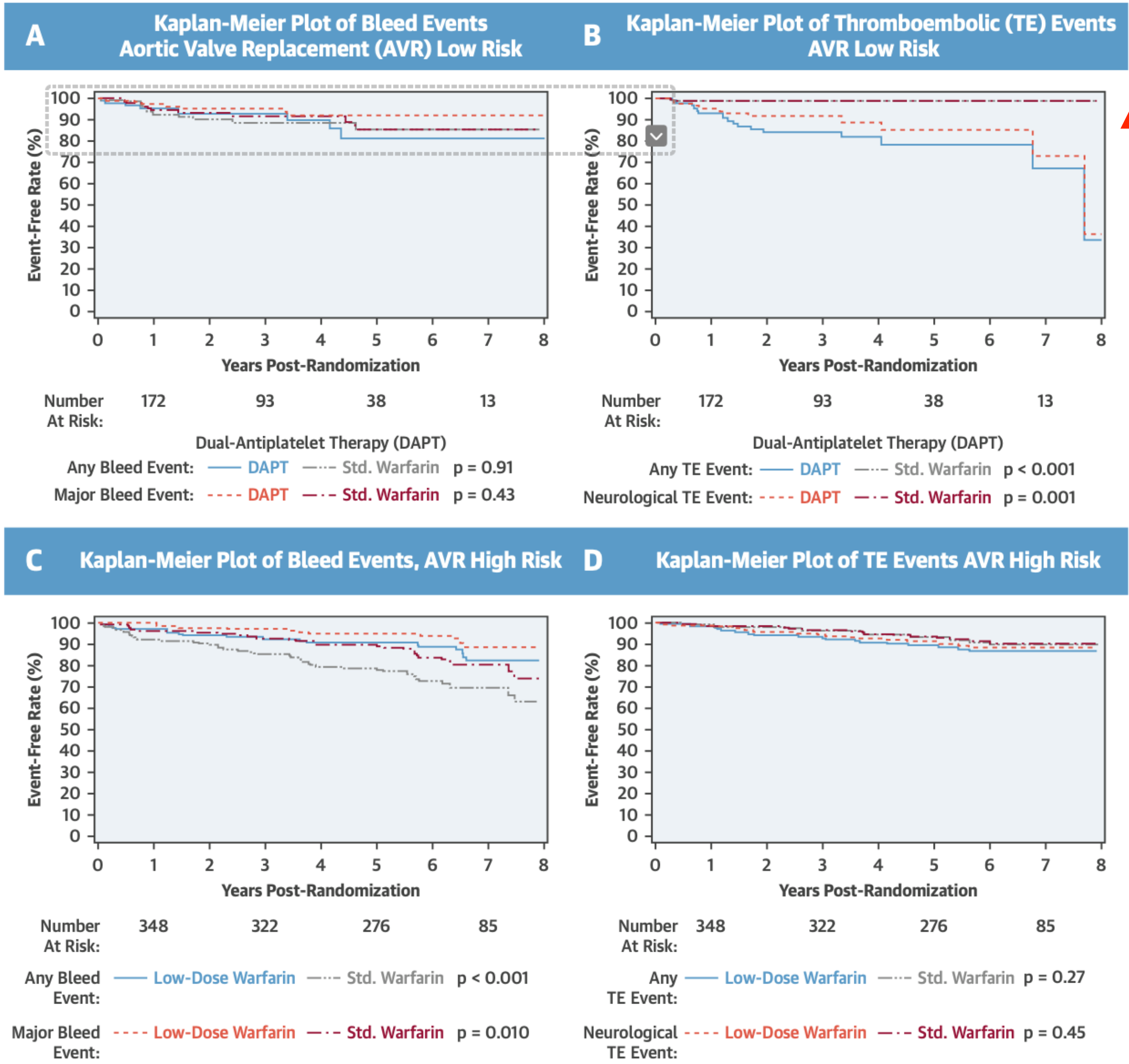
Anticoagulation and Antiplatelet Strategies After On-X Mechanical Aortic Valve Replacement

John D. Puskas, MD, MSc,[a] Marc Gerdisch, MD,[b] Dennis Nichols, MD,[c] Lilibeth Fermin, MD,[d] Birger Rhenman, MD,[d] Divya Kapoor, MD,[d] Jack Copeland, MD,[e] Reed Quinn, MD,[f] G. Chad Hughes, MD,[g] Hormoz Azar, MD,[h] Michael McGrath, MD,[h] Michael Wait, MD,[i] Bobby Kong, MD,[j] Tomas Martin, MD,[k] E. Charles Douville, MD,[l] Steven Meyer, MD, PhD,[m] Jian Ye, MD MSc,[n] W.R. Eric Jamieson, MD,[o] Lance Landvater, MD,[p] Robert Hagberg, MD,[q] Timothy Trotter, MD,[r] John Armitage, MD,[s] Jeffrey Askew, MD,[s] Kevin Accola, MD,[t] Paul Levy, MD,[u] David Duncan, MD,[v] Bobby Yanagawa, MD, PhD,[w] John Ely, MS,[x] Allen Graeve, MD,[c] for the PROACT Investigators*

Enrollment in the low-risk arm of the PROACT trial terminated because of increased cerebral TE events in the treatment group.

Puskas, J.D. et al. J Am Coll Cardiol. 2018;71(24):2717-26.

PROACT Trial



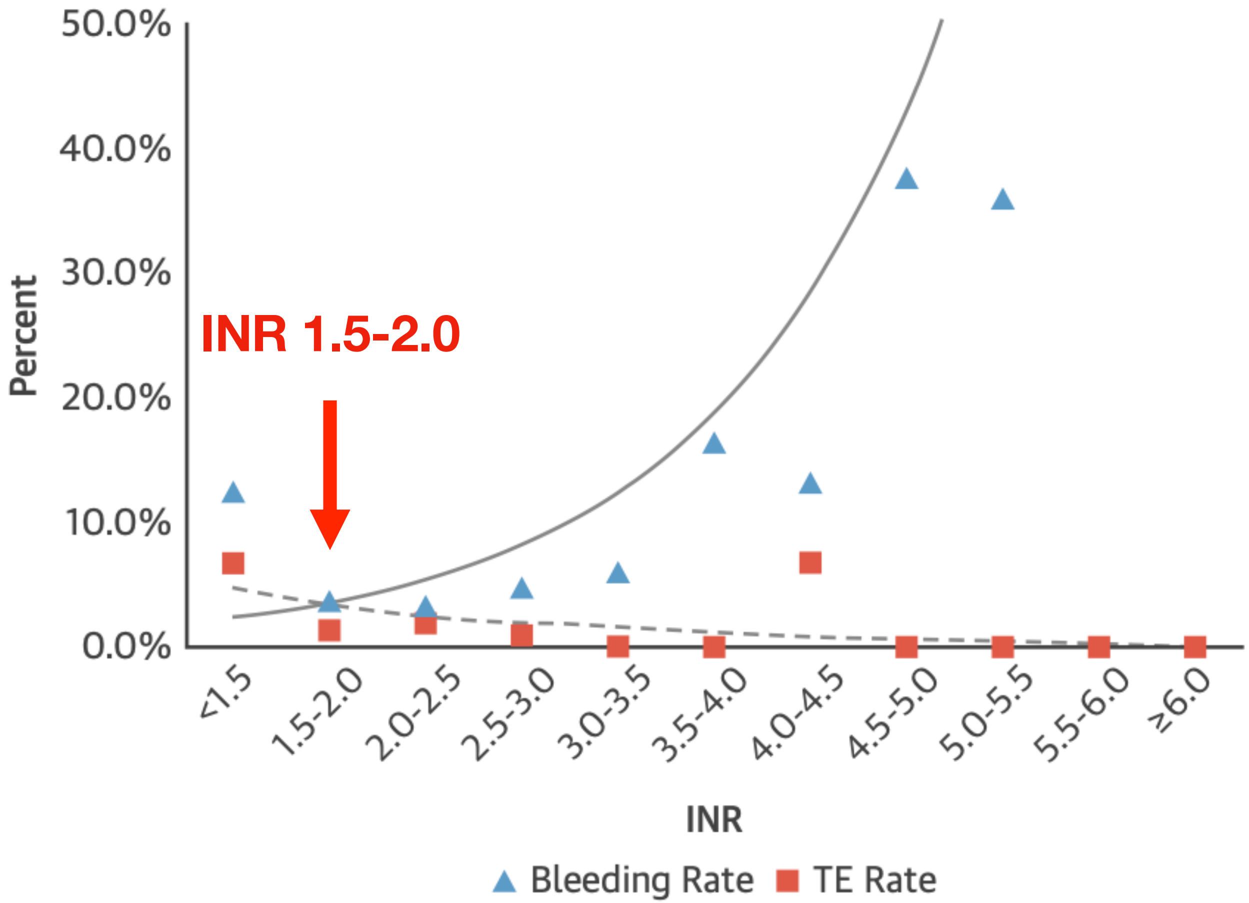
TE Event p < 0.001

Enrollment in the low-risk arm of the PROACT trial terminated Jan 2014 because of increased cerebral TE events in the treatment group.

Bleed p < 0.001

Puskas, J.D. et al. J Am Coll Cardiol. 2018;71(24):2717-26.

FIGURE 2 Relationship of International Normalized Ratio to Bleeding and Thromboembolic Rates in the High-Risk Arm



Puskas, J.D. et al. J Am Coll Cardiol. 2018;71(24):2717-26.

RE-ALIGN Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

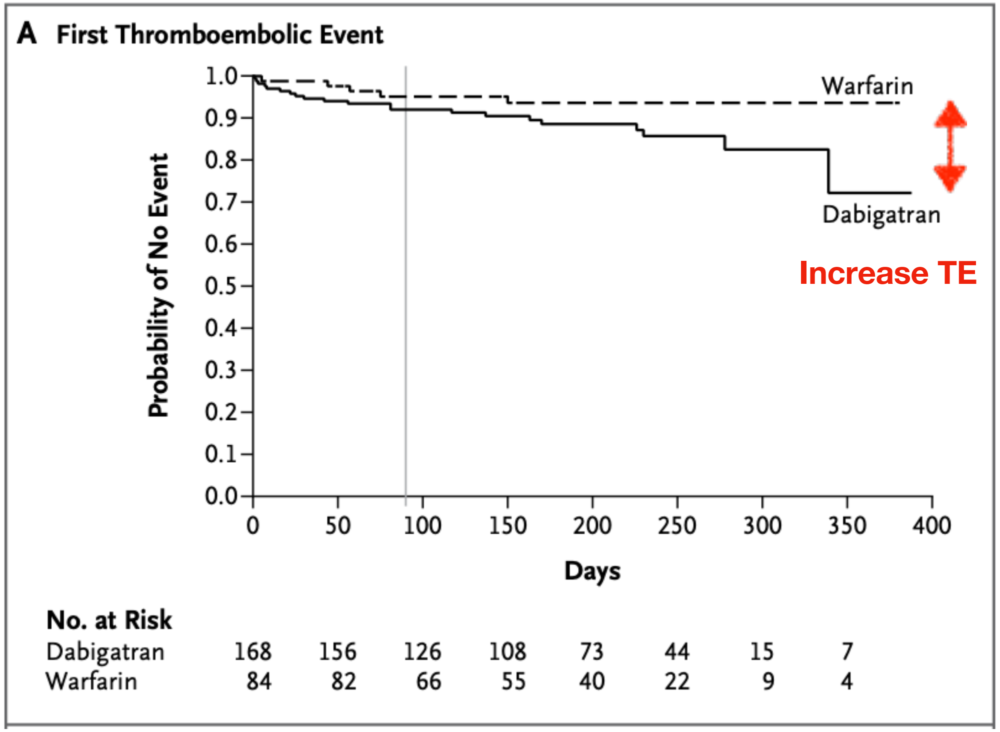
Dabigatran versus Warfarin in Patients with Mechanical Heart Valves

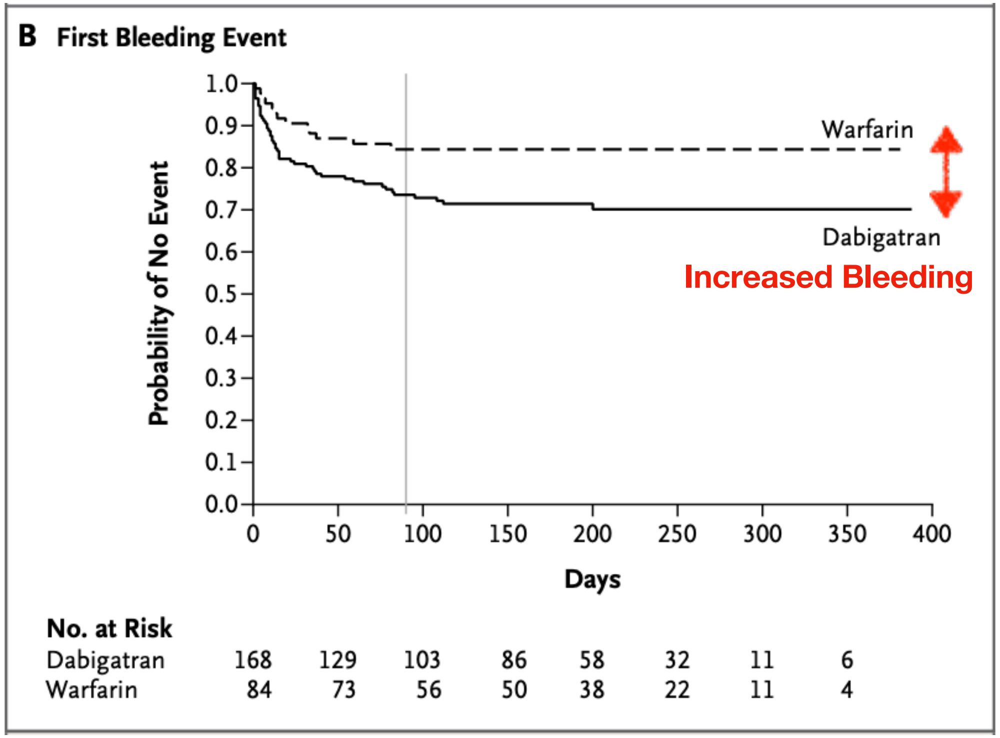
The trial was terminated prematurely after the enrollment of 252 patients because of an excess of thromboembolic and bleeding events among patients in the dabigatran group.

N Engl J Med 2013;369:1206-14.

RE-ALIGN Trial

Dabigatran versus Warfarin in Patients with Mechanical Heart Valves





These results might be explained by the relative inability of dabigatran to suppress activation of coagulation that occurs when blood is exposed to the artificial surfaces of the valve prosthesis. The use of dabigatran has no positive value and

N Engl J Med 2013;369:1206-14.

PROACT Xa

Rationale and design of PROACT Xa: A randomized, multicenter, open-label, clinical trial to evaluate the efficacy and safety of apixaban versus warfarin in patients with a mechanical On-X Aortic Heart Valve☆

Oliver K. Jawitz, MD MHS, [a,b] Tracy Y. Wang, MD MHS MSc, [a] Renato D. Lopes, MD PhD, [a] Alma Chavez, BSN, [a] Brittanny Boyer, BS CCRP, [c] Hwasoon Kim, PhD, [a] Kevin J. Anstrom, PhD, [a] Richard C. Becker, MD, [d] Eugene Blackstone, MD, [e] Marc Ruel, MD MPH, [f] Vinod H. Thourani, MD, [g] John D. Puskas, MD, [h] Marc W. Gerdisch, MD, [i] Douglas Johnston, MD, [e] Scott Capps, MS, [c] John H. Alexander, MD MHS, [a] and Lars G. Svensson, MD PhD [e]

NEWS • Daily News

Another DOAC Fails in the Setting of Mechanical Heart Valves

The PROACT Xa trial of apixaban has been stopped due to an excess risk of blood clots compared with warfarin.

by Todd Neale | SEPTEMBER 28, 2022

RESULTS

The trial was stopped after 863 participants were enrolled owing to an excess of thromboembolic events in the apixaban group.

Mechanical vs Tissue Survival

Mechanical Versus Bioprosthetic Aortic Valve Replacement in Middle-Aged Adults: A Systematic Review and Meta-Analysis

Dong Fang Zhao, BA, Michael Seco, BMedSc, MBBS, James J. Wu, BMusStudies, James B. Edelman, MBBS(Hons), PhD, Michael K. Wilson, MBBS, Michael P. Vallely, MBBS, PhD, Michael J. Byrom, MBChB, PhD, and Paul G. Bannon, MBBS, PhD

Sydney Medical School, University of Sydney, Sydney; Baird Institute of Applied Heart and Lung Surgical Research, Sydney; Cardiothoracic Surgery Unit and Institute of Academic Surgery, Royal Prince Alfred Hospital, Sydney; and Australian School of Advanced Medicine, Macquarie University, Sydney, Australia

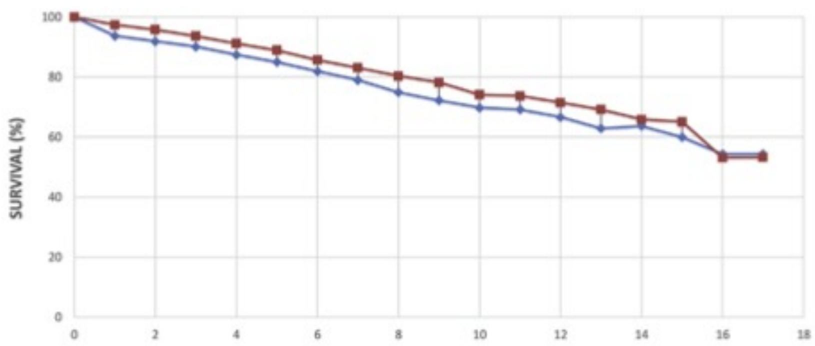
No difference in survival

BV lower risk of bleeding and thromboembolism, but higher risk re-operation

The choice of a bioprosthetic valve (BV) or mechanical valve (MV) in middle-aged adults undergoing aortic [illegible] systematic review and meta-analysis was performed to compare long-term survival, major adverse prosthesis-related events, anticoagulant-related events, major [illegible] Results from patients aged less than 70 years undergoing [illegible] with a BV or MV were included. There were 12 studies involving 8,661 patients. Baseline characteristics were similar. There was no significant **difference in long-term survival among patients aged 50 to 70 or 60 to 70 years. Compared with MVs, BVs had significantly fewer long-term anticoagulant-related** events (hazard ratio [HR] 0.54, $p = 0.006$) and bleeding (HR 0.48, $p < 0.00001$) but significantly greater major adverse prosthesis-related events (HR 1.82, $p = 0.02$), including reoperation (HR 2.19, $p < 0.00001$). The present meta-analysis found no significant difference in survival between BVs and MVs in patients aged 50 to 70 or 60 to 70 years. Compared with MVs, BVs have [illegible] of major bleeding and anticoagulant-related [illegible] increased risk of structural valve degeneration and reoperation. However, the mortality conse- [illegible] lower than that of major bleeding, and recent advances may further lower the reoperation rate for BV. Therefore, this review supports the current trend of using BVs in patients more than 60 years of age.

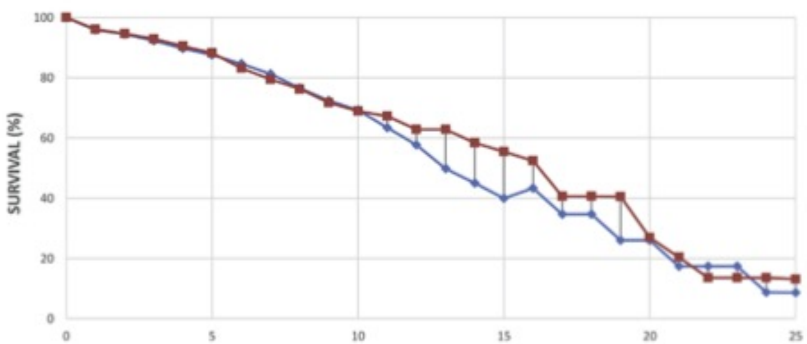
(Ann Thorac Surg 2016;102:315–27)

A



HR 1.13
(95% CI 0.89-1.45)
P=0.32

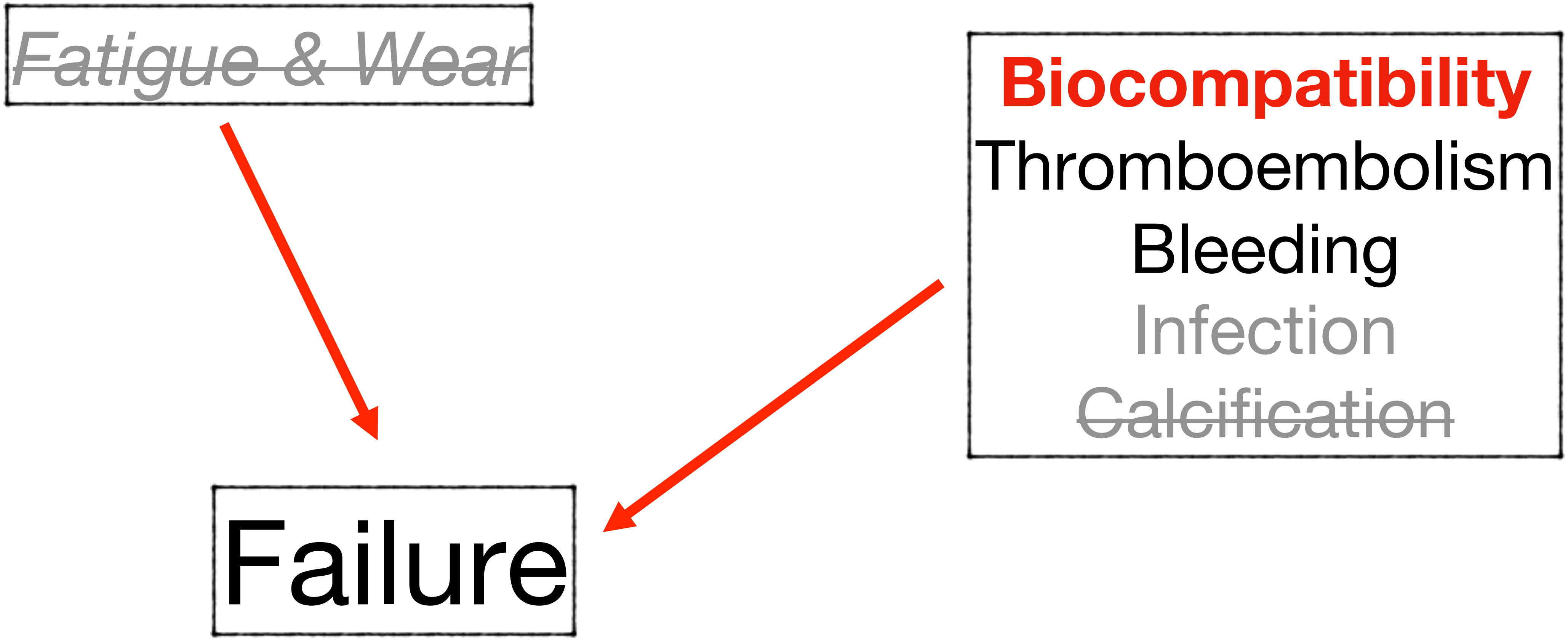
B



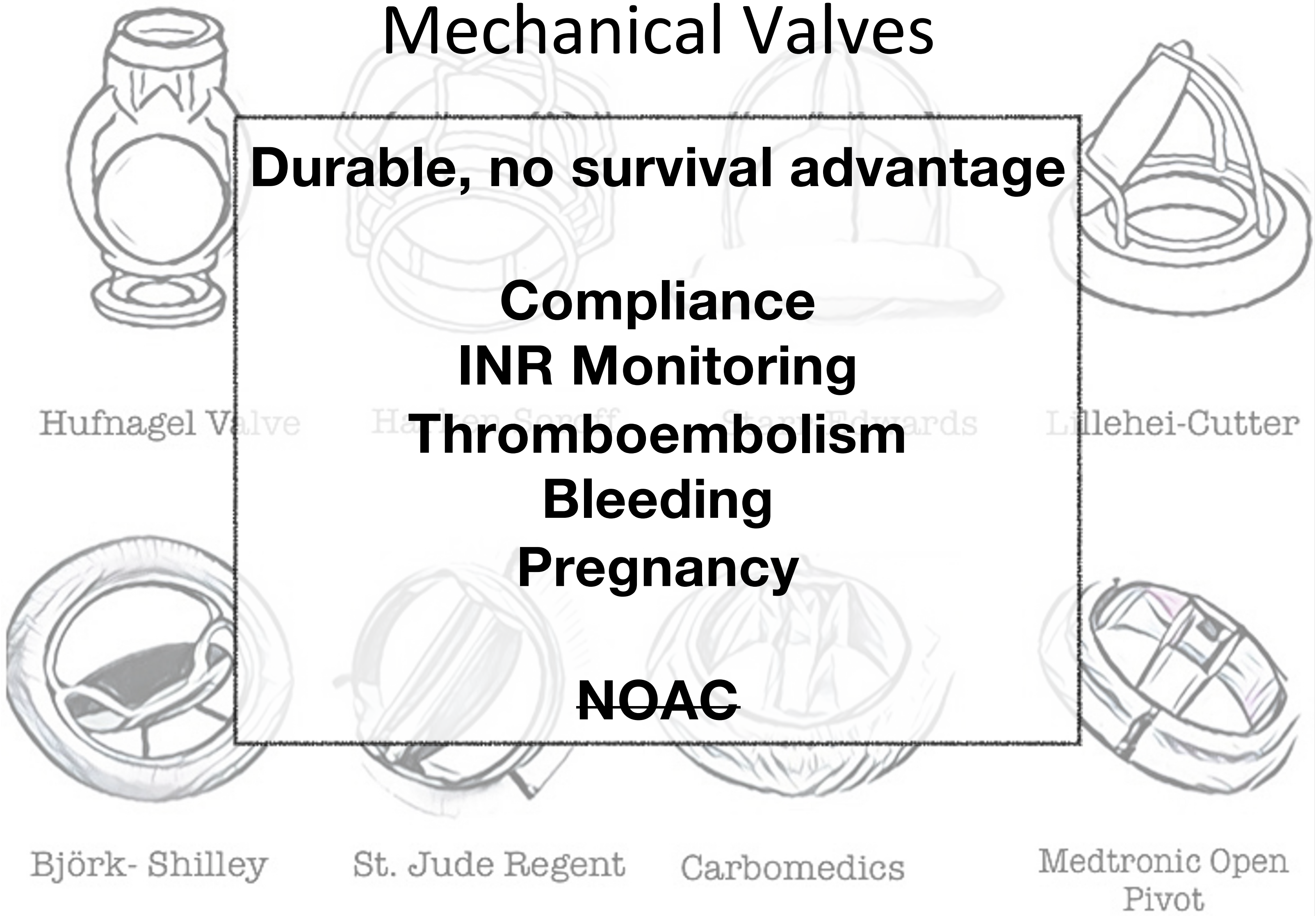
HR 0.87
(95% CI 0.66-1.15)
P=0.32

Ann Thorac Surg 2016;102:315–27

Mechanical Valve Failure



Mechanical Valves

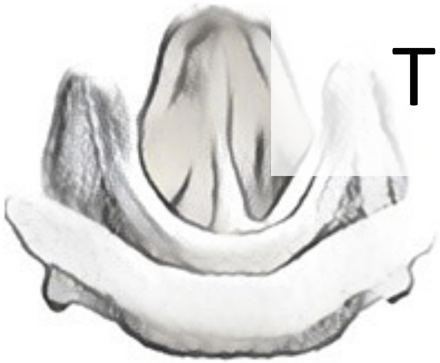


Durable, no survival advantage

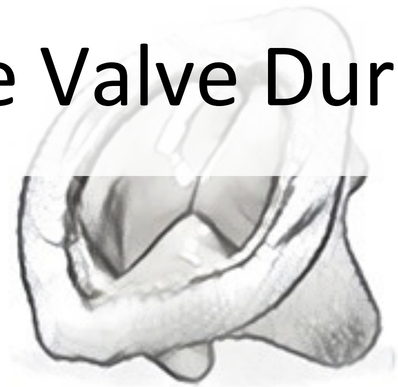
Compliance
INR Monitoring
Thromboembolism
Bleeding
Pregnancy

~~NOAC~~

Tissue Valve Durability



Carpentier Edwards
Porcine MItral



Medtronic Hancock
II

St. Jude Epic

Livanova Mitroflow

Carpentier- Edwards
Perimount Magna Ease

St. Jude Trifecta

Cardiovascular Diseases, Bulletin of the Texas Heart Institute
Volume 7 Number 2 June 1980

Ionescu-Shiley pericardial xenograft valve: Hemodynamic evaluation and early clinical follow-up of 326 patients

David A. Ott, M.D., Aldemire T. Coelho, M.D.,
Denton A. Cooley, M.D., and George J. Reul, Jr., M.D.

Dissatisfaction with the hemodynamic characteristics of available porcine valves prompted a clinical trial of the Ionescu-Shiley percardial xenograft (ISPX) valve. Three hundred fifty-six ISPX valves were implanted consecutively in 326 patients. Operative mortality was 2.6% (2/75) for aortic valve replacement alone and 7.7% (12/155) for aortic valve replacements that included reoperations and combined procedures such as mitral commissurotomy, annuloplasty, and coronary artery bypass. Operative mortality for all patients who underwent mitral valve replacement was 9.5% (14/147). The mean peak systolic gradient pressure in the aortic position was 5.4 mm Hg overall and 4.27 mm Hg with the size 19 mm valve. There were no embolic episodes in patients who received the ISPX valve in the aortic position. The available data indicate that the rate of peripheral embolism with the ISPX valve compares favorably with that of porcine valves. Considering its hemodynamic advantage, if the long-

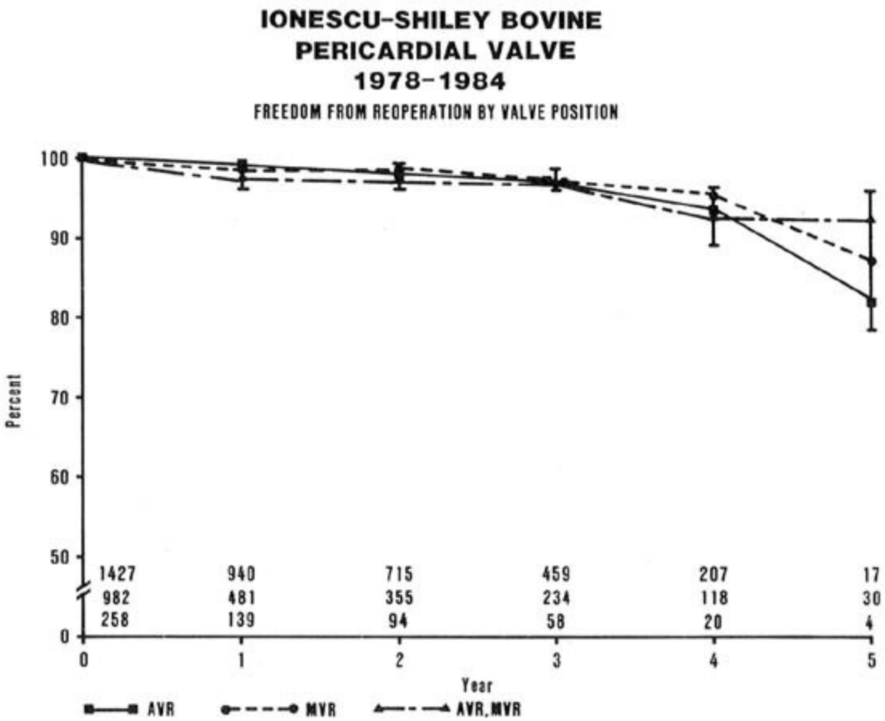
1980:

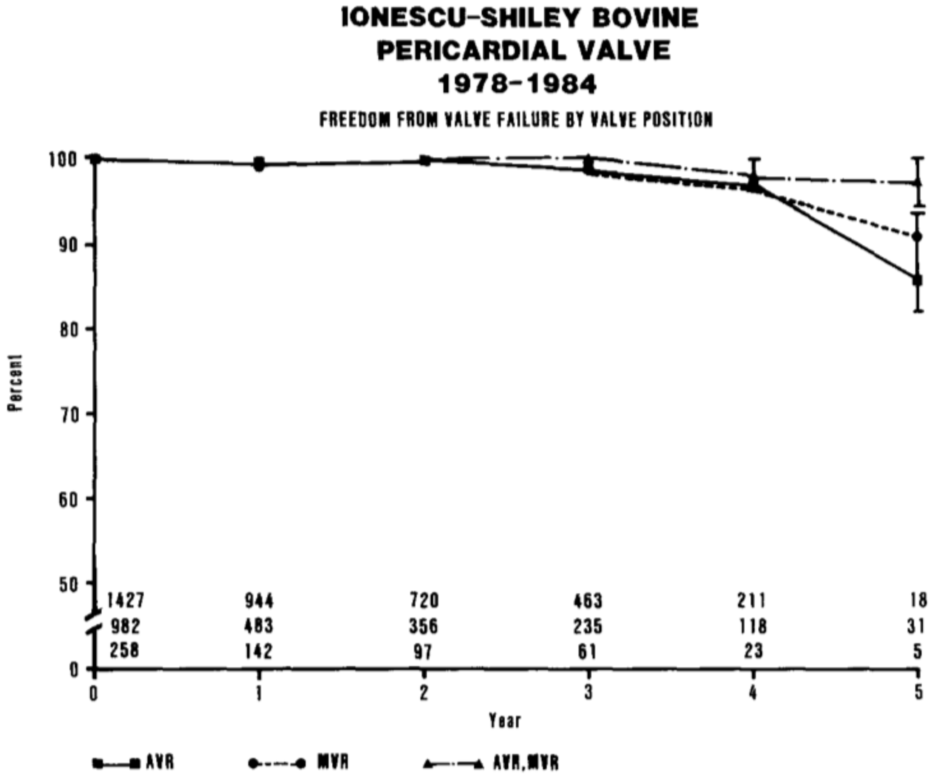
"Considering its hemodynamic advantage, if the longterm durability of the full-orifice Ionescu-Shiley pericardial xenograft valve continues to be confirmed by follow-up studies, it is our opinion that it is the biologic valve of choice."

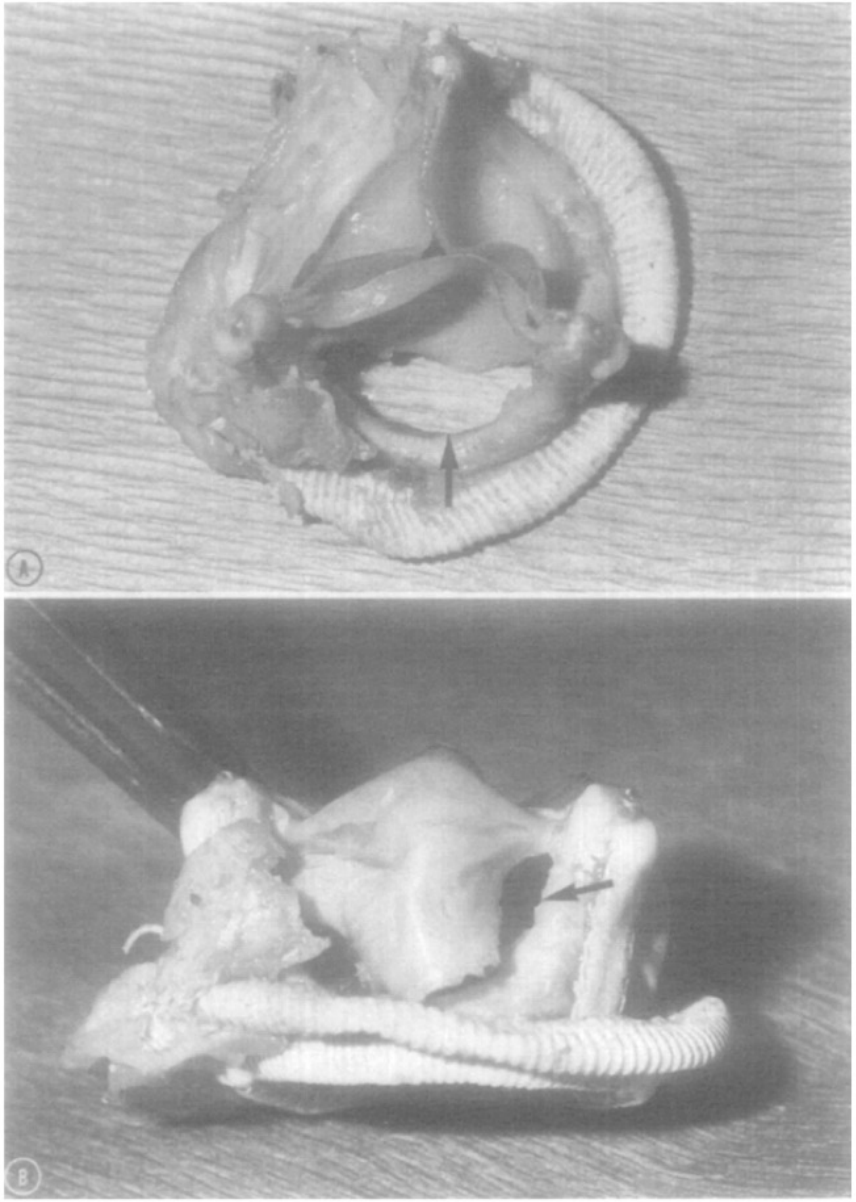
J Vasc Surg 1985; 2:192-204.

Valve failure with the Ionescu-Shiley bovine pericardial bioprosthesis: Analysis of 2680 patients

George J. Reul, Jr., M.D., Denton A. Cooley, M.D., J. Michael Duncan, M.D.,
O. H. Frazier, M.D., Grady L. Hallman, M.D., James J. Livesay, M.D.,
David A. Ott, M.D., and William E. Walker, M.D







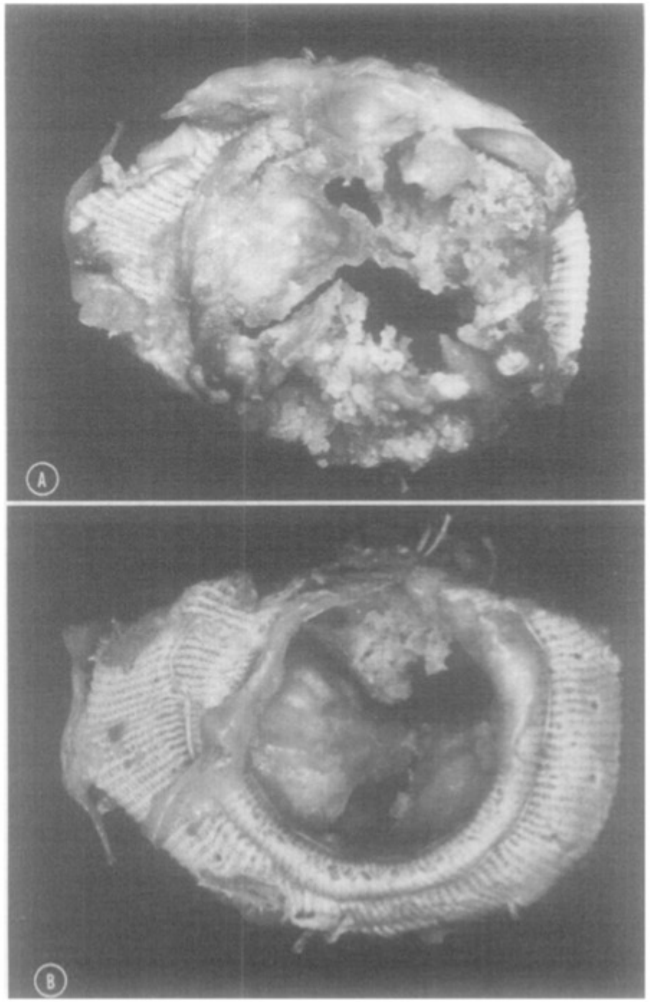
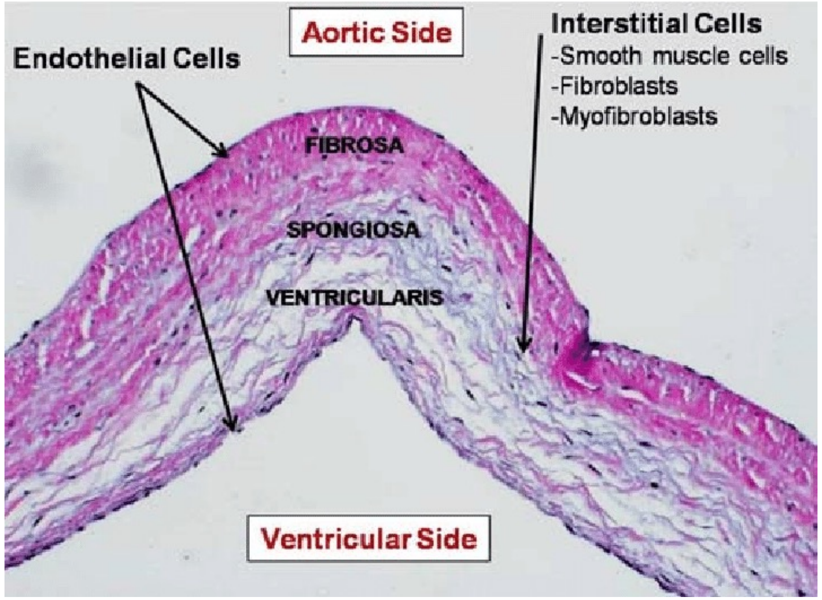
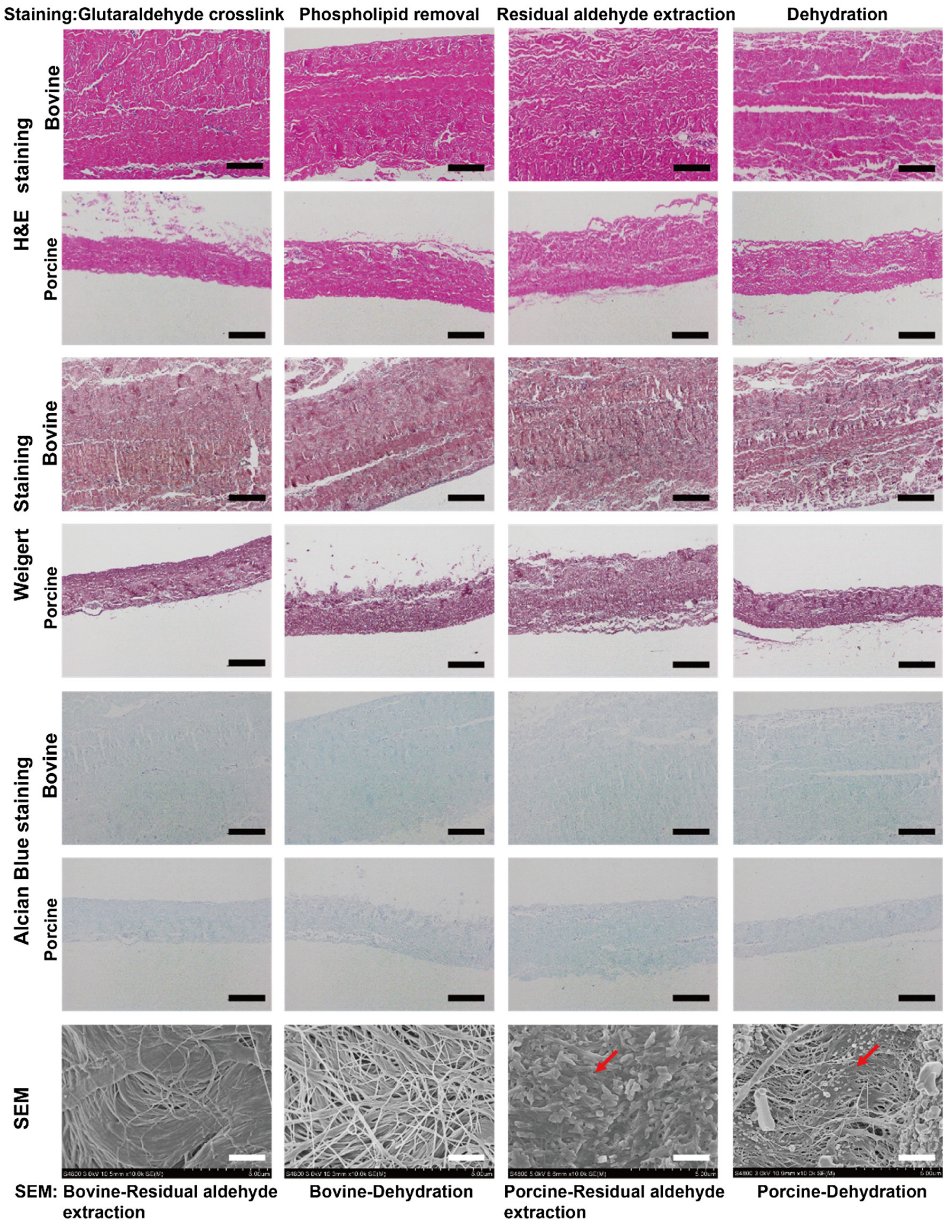


Fig. 4. Severe calcification in aortic valve removed 30 months postoperatively from patient who was 15 years old at time of implantation. Patient had marked obstruction to left ventricular outflow with all of the signs and symptoms of critical aortic stenosis. Note massive amount of calcification on aortic surface of valve.

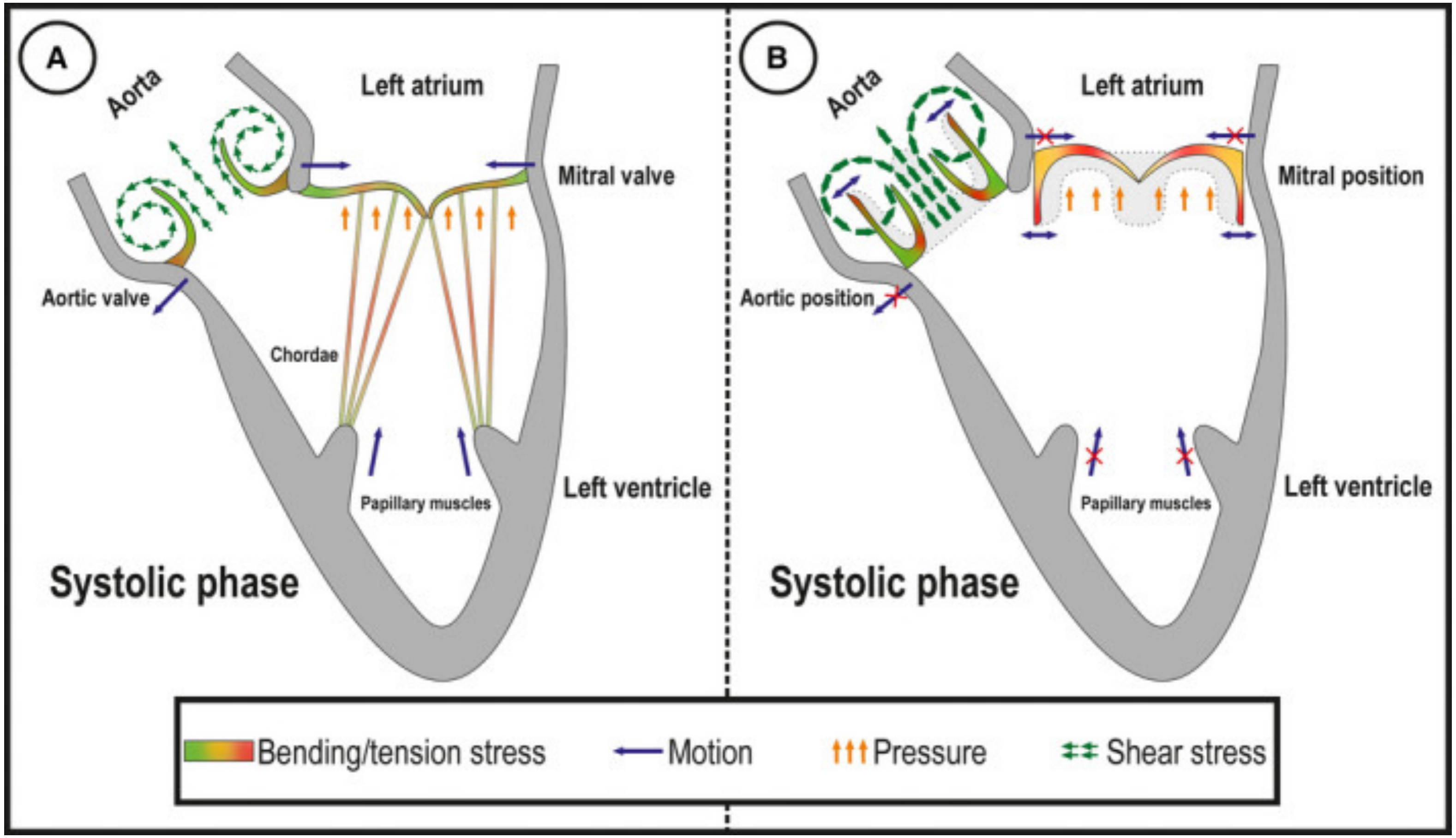
Native vs Fixed Valve



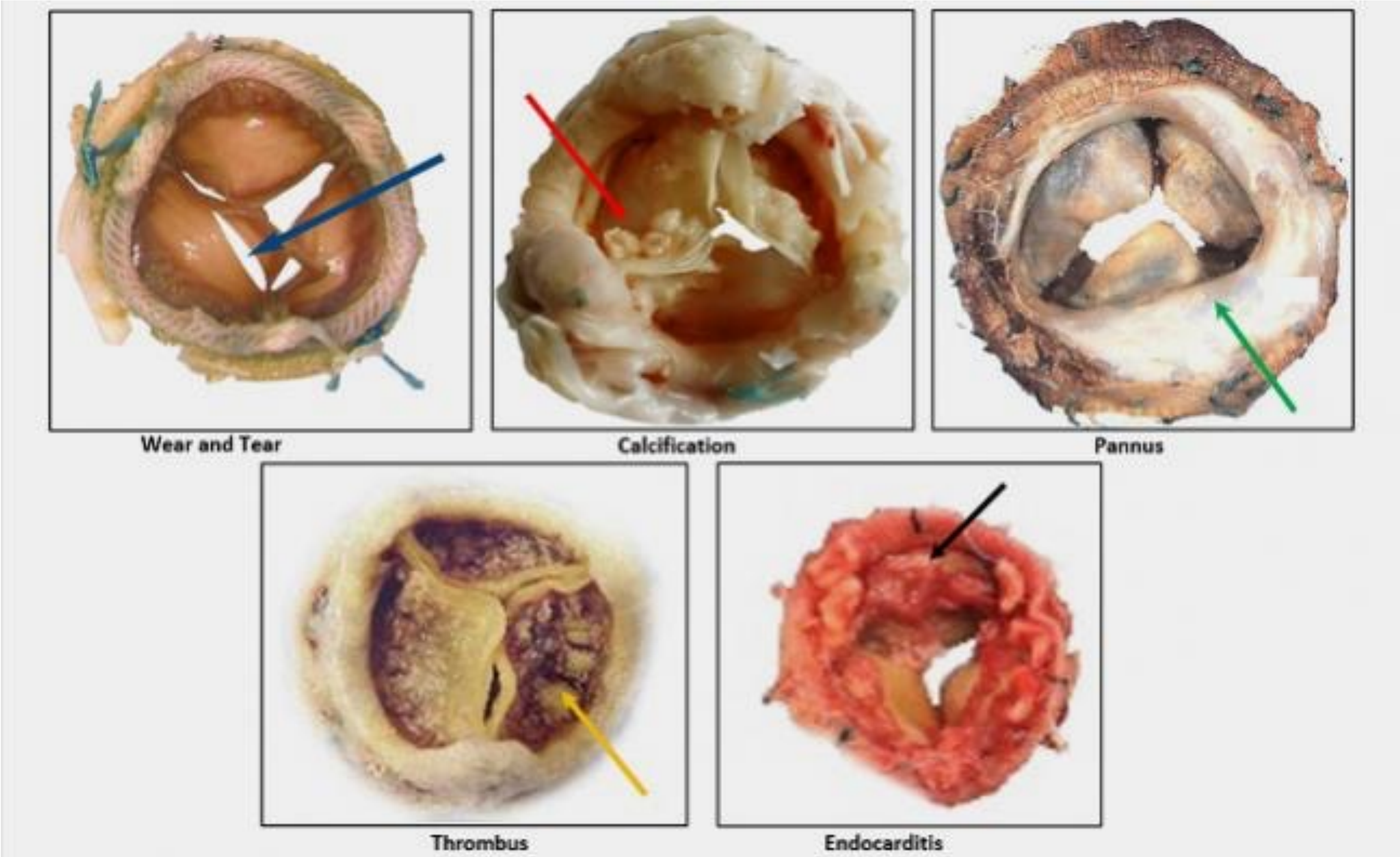
Native aortic valves and BHVs have major structural differences. Leaflets of the native aortic valve consist of 3 ECM layers: *fibrosa*, *spongiosa*, and *ventricularis*, all having different mechanical properties that enable load damping, have high elasticity, and provide the nonlinear response to stress.



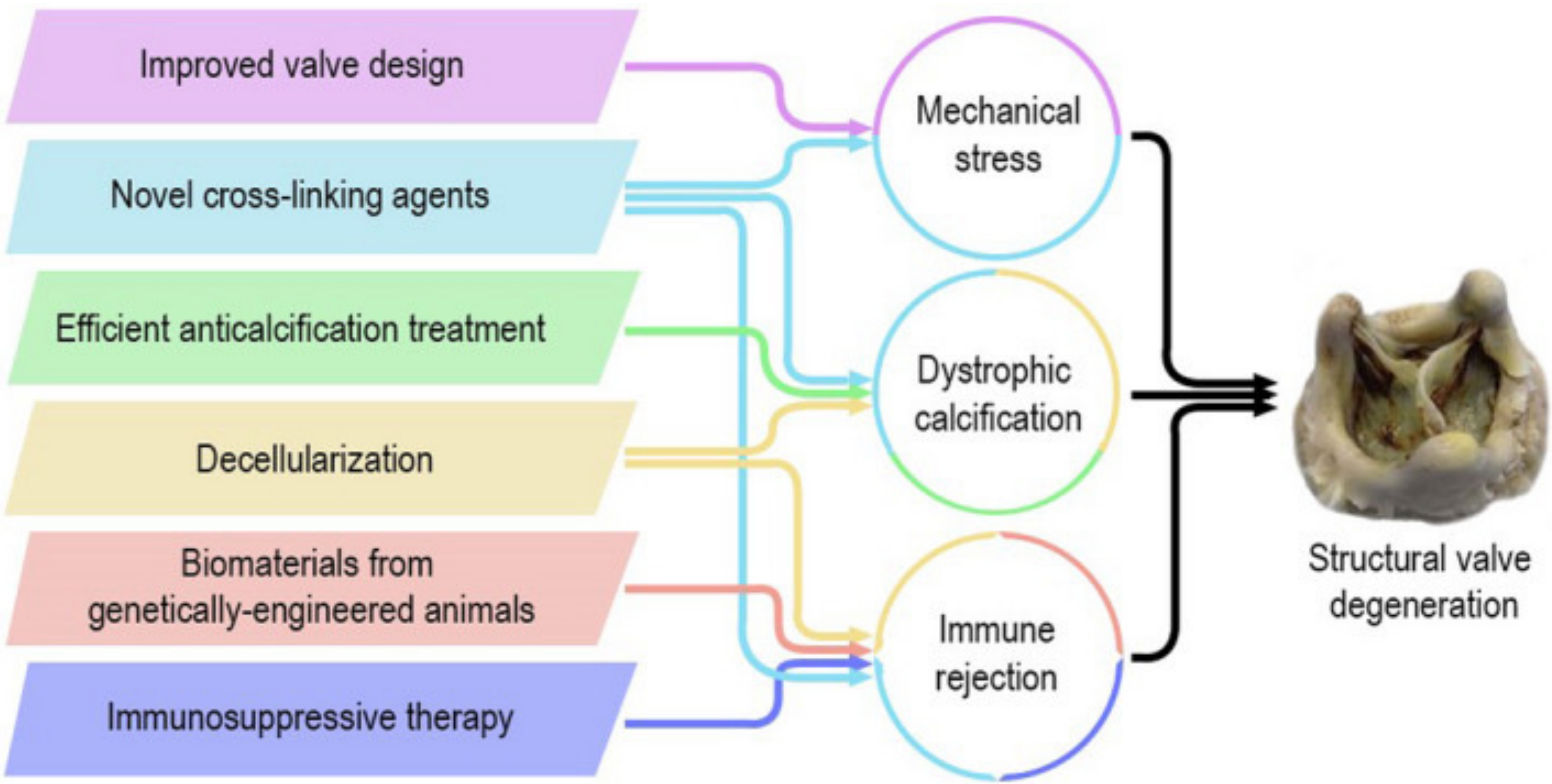
Mechanical stress and structural valve degeneration.



Mechanism of Failure



Key factors of structural valve degeneration (SVD) development and strategies to retard SVD.



Long-Term Durability of Carpentier-Edwards Magna Ease Valve: A One Billion Cycle In Vitro Study

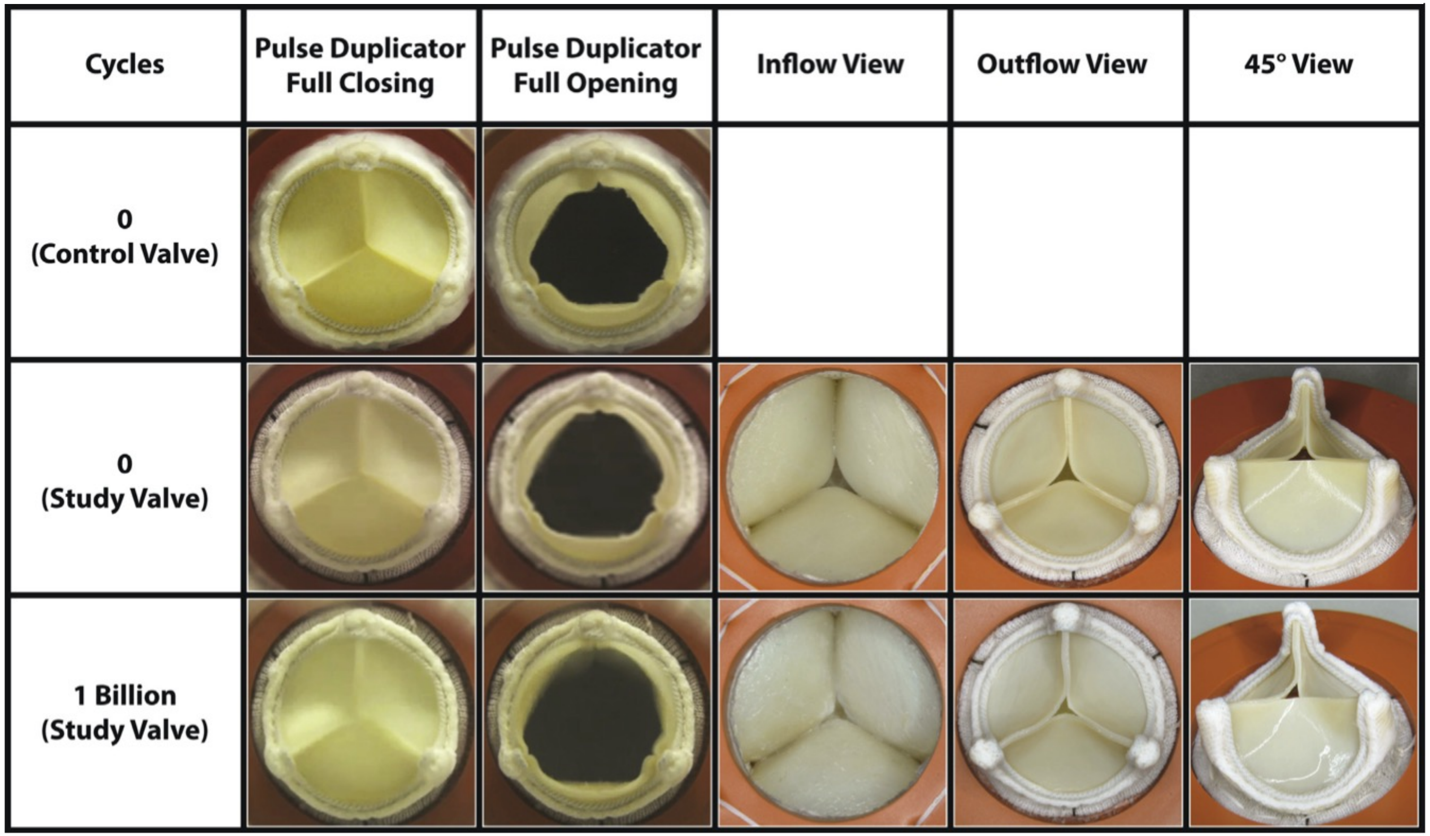


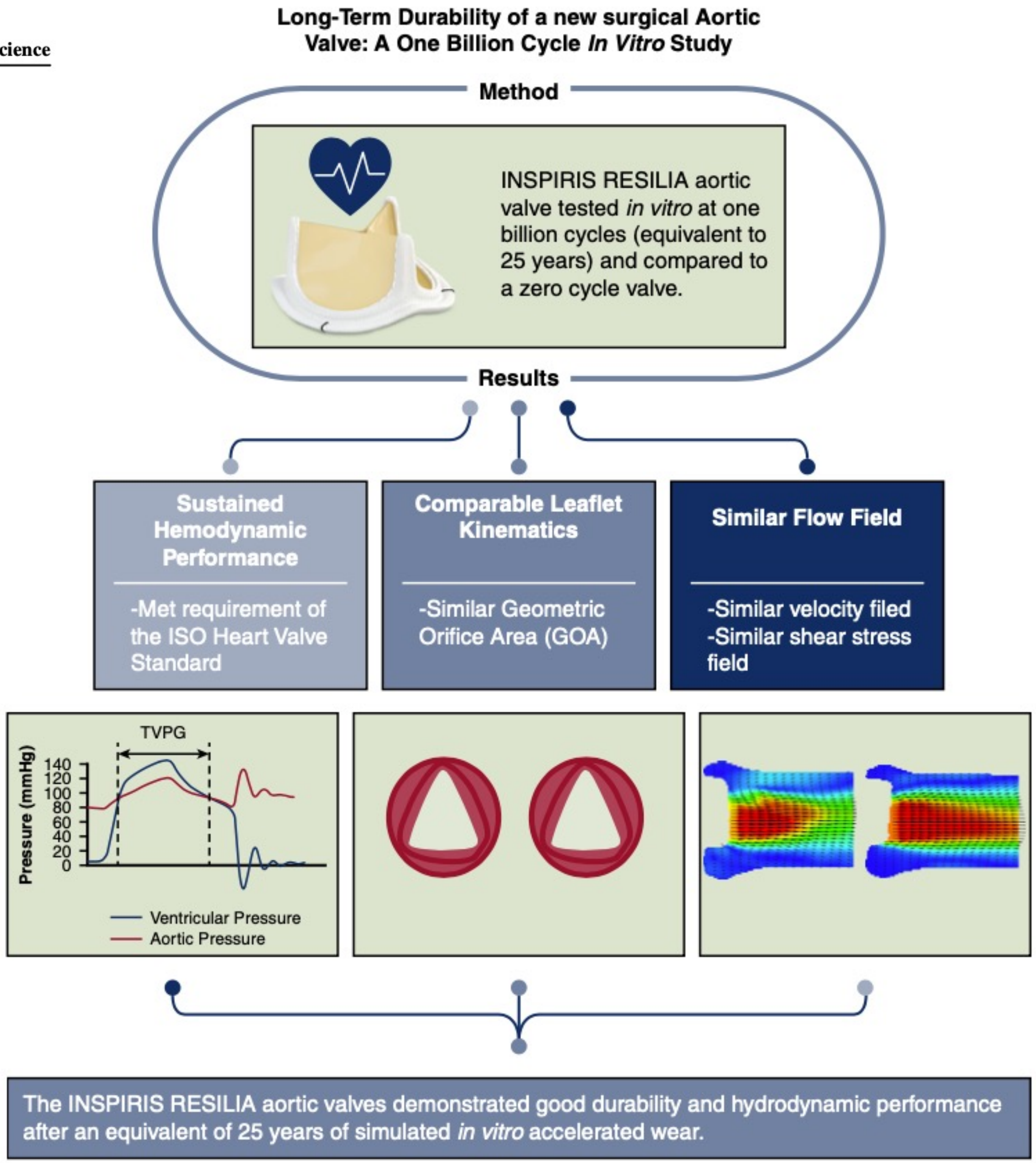
Fig 2. Representative 23 mm control and study valves opening and closing in the pulsatile tester, and photo inspection of 23 mm study valve at time 0 and at 1 billion cycles.

[Ann Thorac Surg 2016;101:1759–67

Long-term durability of a new surgical aortic valve: A 1 billion cycle in vitro study

Vahid Sadri, PhD,[a] Phillip M. Trusty, PhD,[a] Immanuel David Madukauwa-David, PhD,[b] and Ajit P. Yoganathan, PhD[a]

(JTCVS Open 2021;■:1-11)

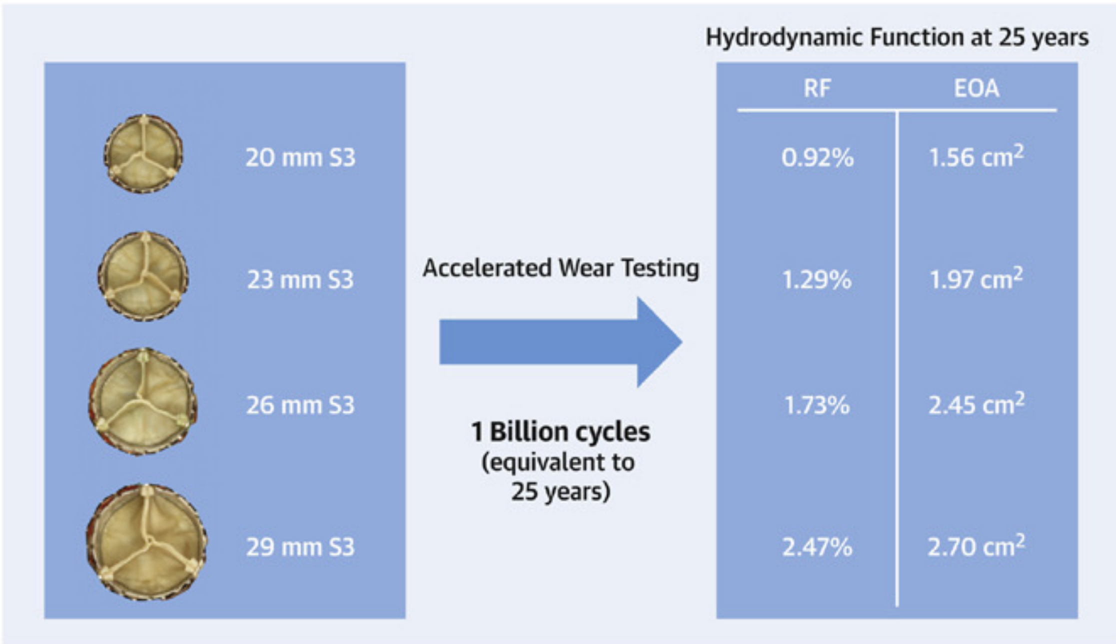


Long-Term Durability of Transcatheter Heart Valves

Insights From Bench Testing to 25 Years

Janarthanan Sathananthan, MBChB, MPH,[a] Mark Hensey, MB BCh BAO,[a] Uri Landes, MD,[a] Abdullah Alkhodair, MD,[a] Adeeb Saiduddin, BSc,[b] Stephanie Sellers, PhD,[c] Anson Cheung, MD,[a] Sandra Lauck, PhD,[a] Philipp Blanke, MD,[a] Jonathon Leipsic, MD,[a] Jian Ye, MD,[a] David A. Wood, MD,[a] John G. Webb, MD[a]

CENTRAL ILLUSTRATION: Bench Test of Transcatheter Heart Valve Durability to 25 Years

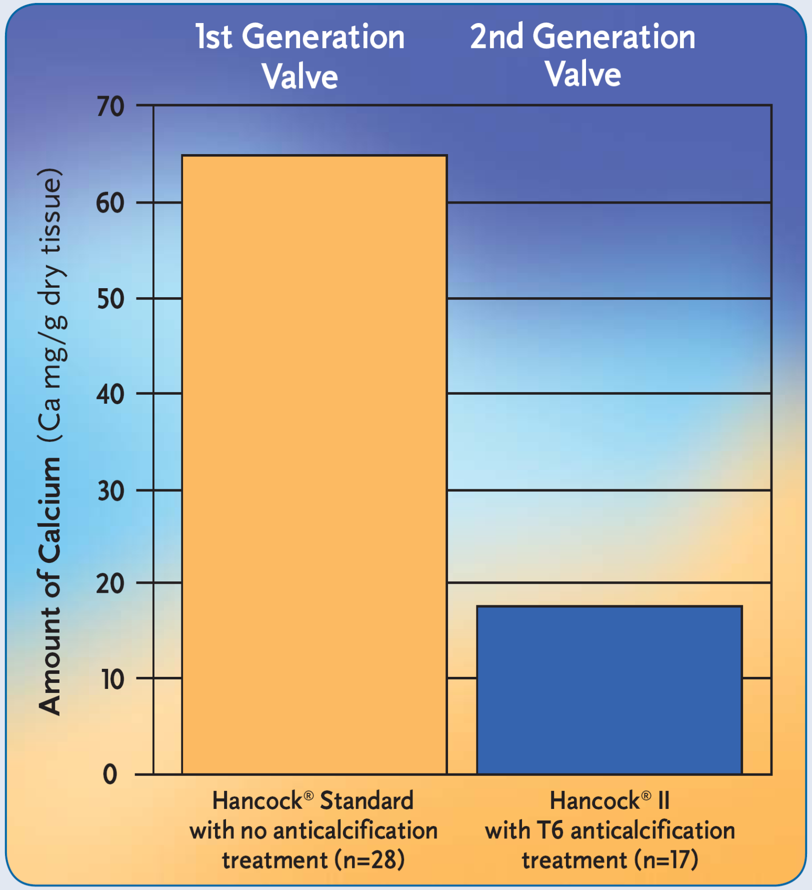


Sathananthan, J. et al. J Am Coll Cardiol Intv. 2020;13(2):235-49.

J Am Coll Cardiol Intv. 2020 Jan, 13 (2) 235–249

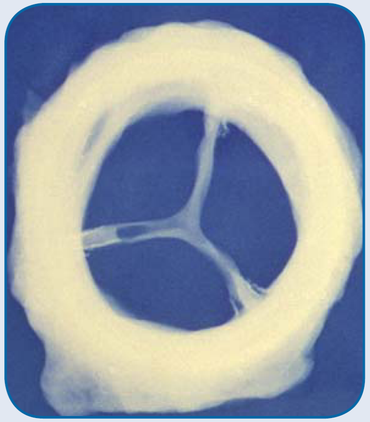
From 1st To 2nd Generation Valves:
ANTICALCIFICATION TREATMENT MAKES A DIFFERENCE

After 20 Weeks In Juvenile Sheep.[1]



After 16 Weeks In Juvenile Calves.[2]

Hancock® Standard
with no anticalcification
treatment



Hancock® II
with T6 anticalcification
treatment

REFERENCES

1. Jones M, Eidbo E, Hilbert S, Ferrans V, Clark R. Anticalcification Treatments of Bioprosthetic Heart Valves: In Vivo Studies in Sheep. *Journal of Cardiac Surgery* 4:69-73, March 1989.
2. Lentz D et al. Inhibition of Mineralization of Glutaraldehyde-Fixed Hancock Bioprosthetic Heart Valves. In: Cohn LH, Galucci V (ed) Cardiac Bioprostheses, Proceedings of the 2nd Int'l Symp. York Med Books, NY 1982:306-19.

A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model

Willem Flameng, MD, PhD, Hadewich Hermans, MD, Erik Verbeken, MD, PhD, and Bart Meuris, MD, PhD

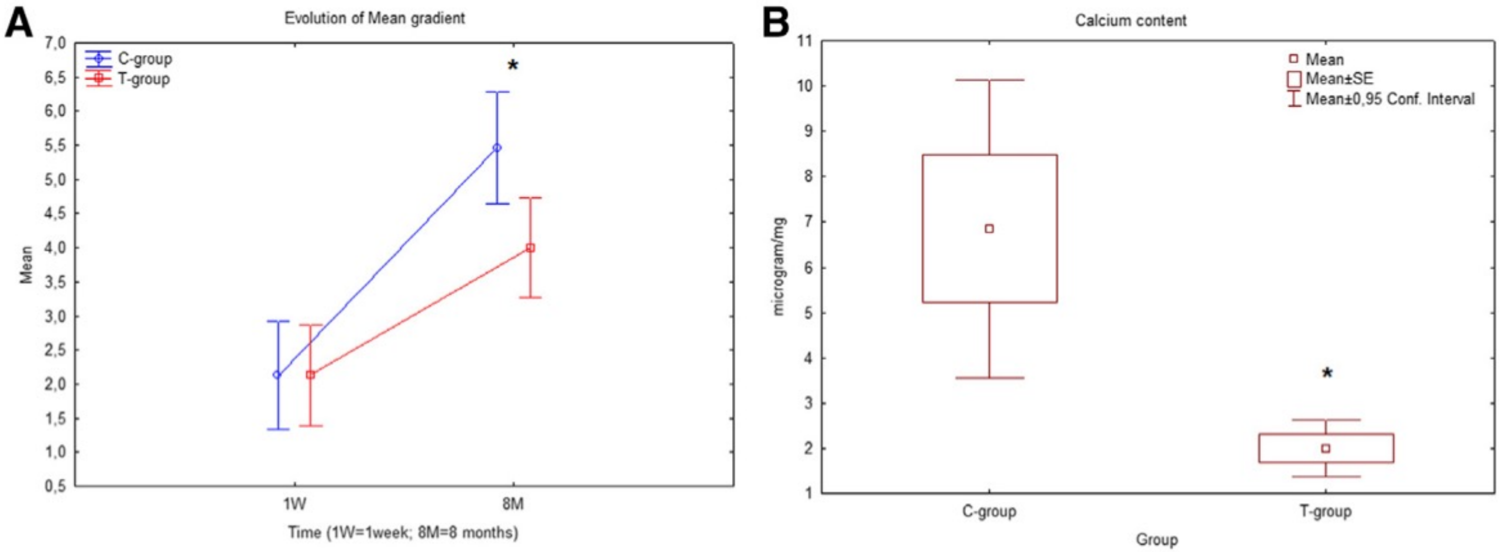
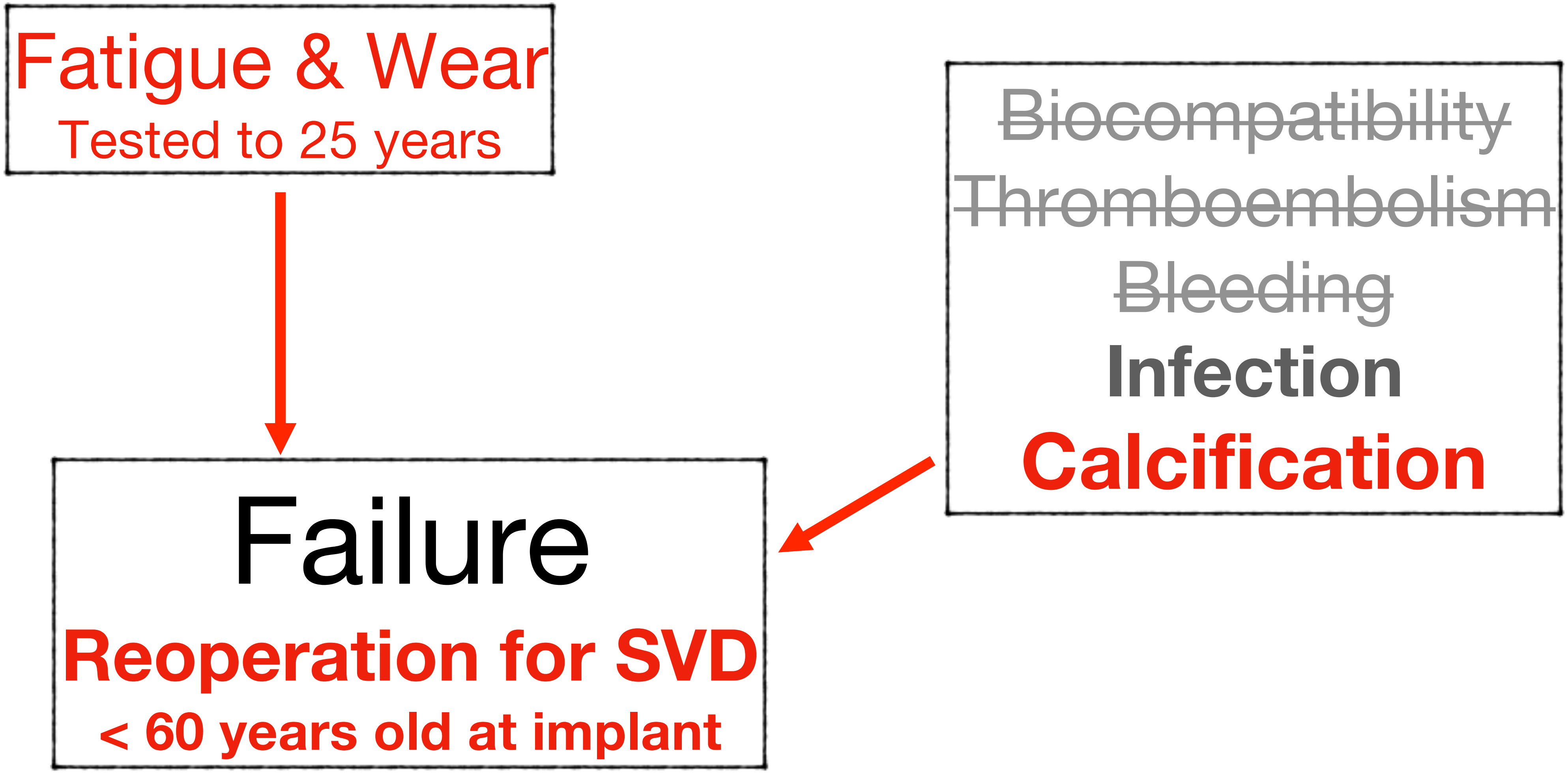


FIGURE 2. A, Evolution in mean transvalvular gradients (mean ± standard error of the mean) from 1 week to 8 months in both groups (*$P = .03$ at 8 months). B, Final calcium content of both valve types (*$P = .002$). *SE*, Standard error.

J Thorac Cardiovasc Surg 2015;149:340-5

Mechanism of Tissue Failure



Carpentier-Edwards Pericardial Valve in the Aortic Position: 25-Years Experience

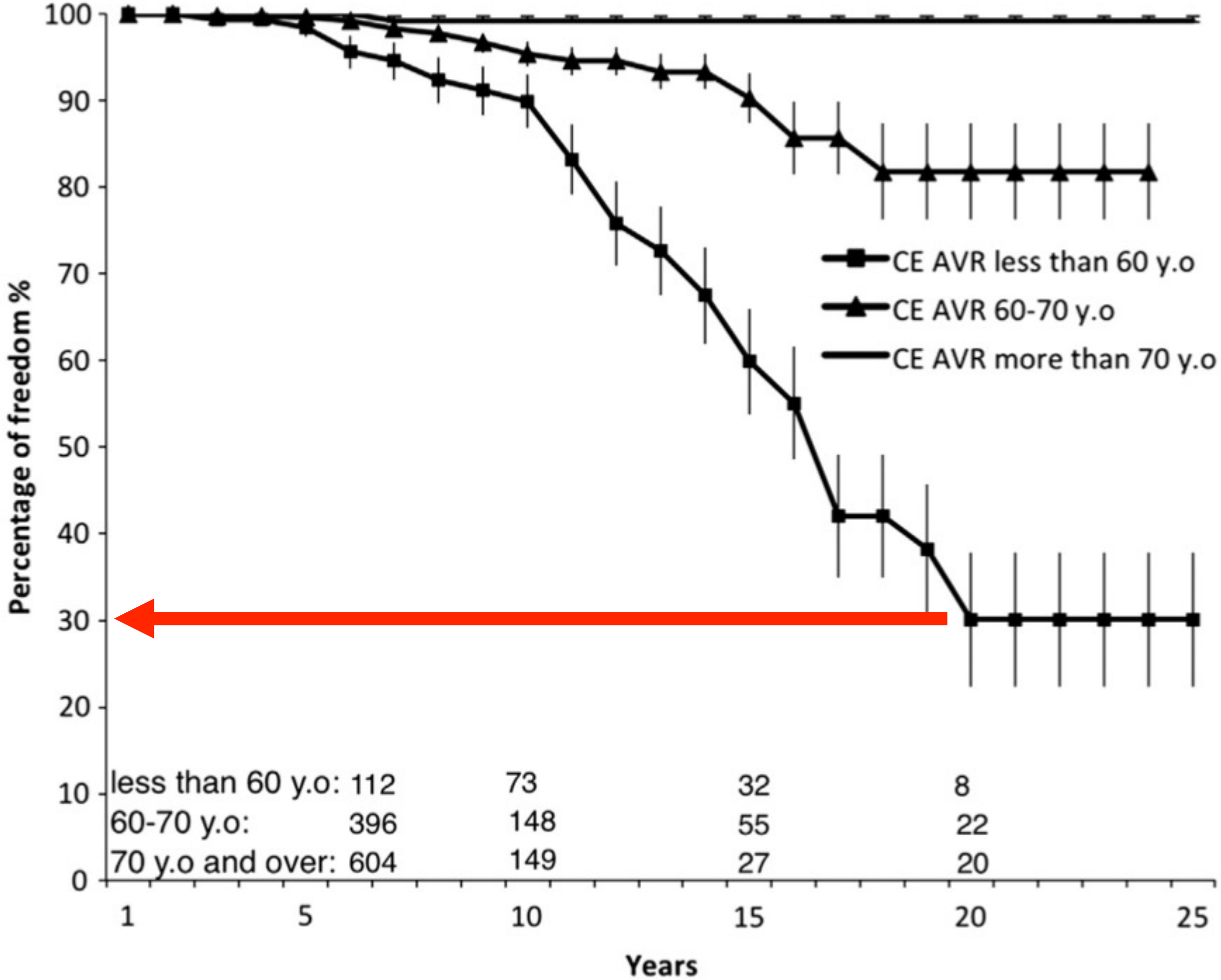


Fig 5. Freedom rate from reexploration for prosthesis valve dysfunction by age groups (excluding endocarditis) (log-rank: p = 0.001); mean ± standard error. (■ = Carpentier-Edwards [CE] aortic valve replacement [AVR] < 60 years old [y.o.]; ▲ = CE AVR 60 to 70 y.o.; — = CE AVR > 70 y.o.)

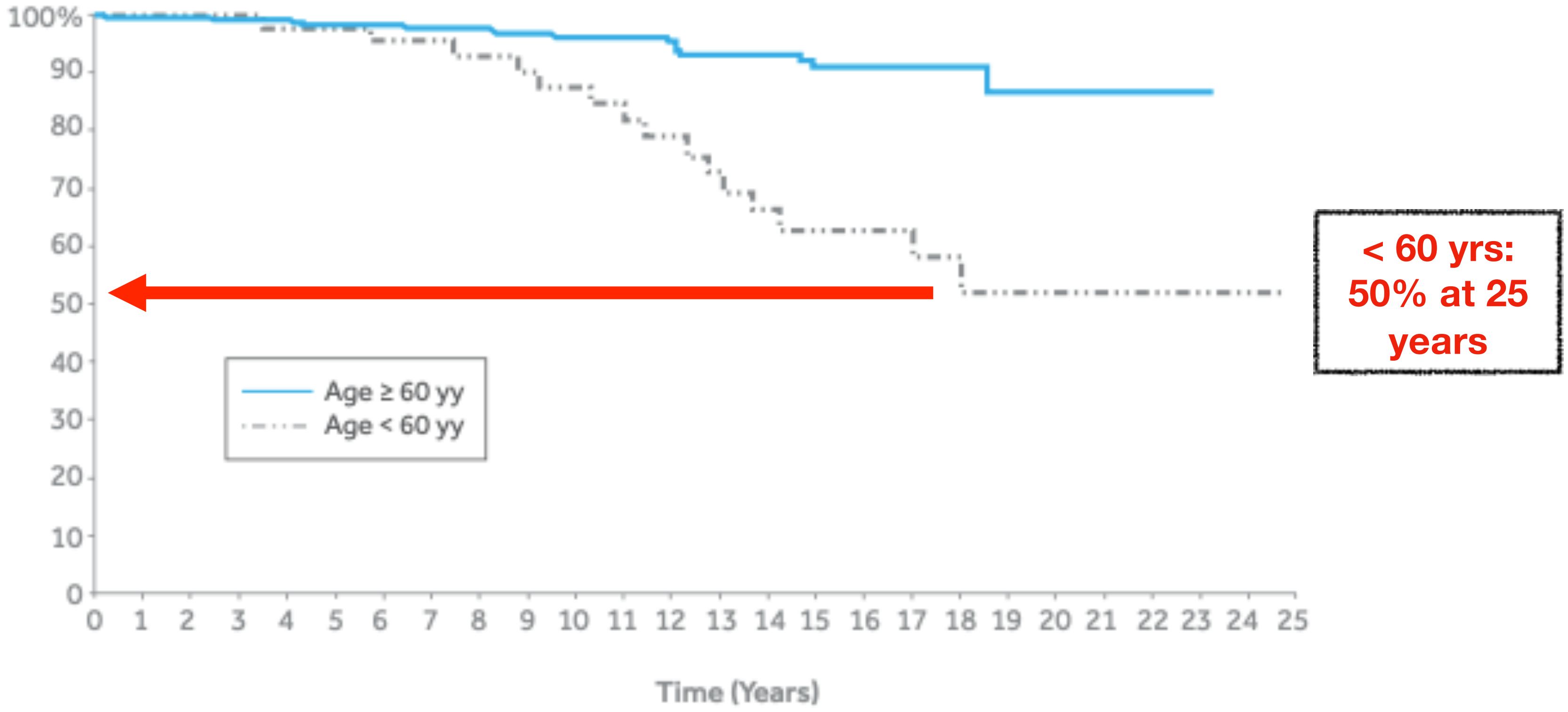
< 60 yrs: 30% at 25 years

Ann Thorac Surg 2013;96:486–93

The Fate of Hancock II Porcine Valve Recipients
25 Years After Implant

Valfré C, Ius P, Minniti G, et al. *Eur J Cardiothorac Surg*. August 2010;38(2):141-146.

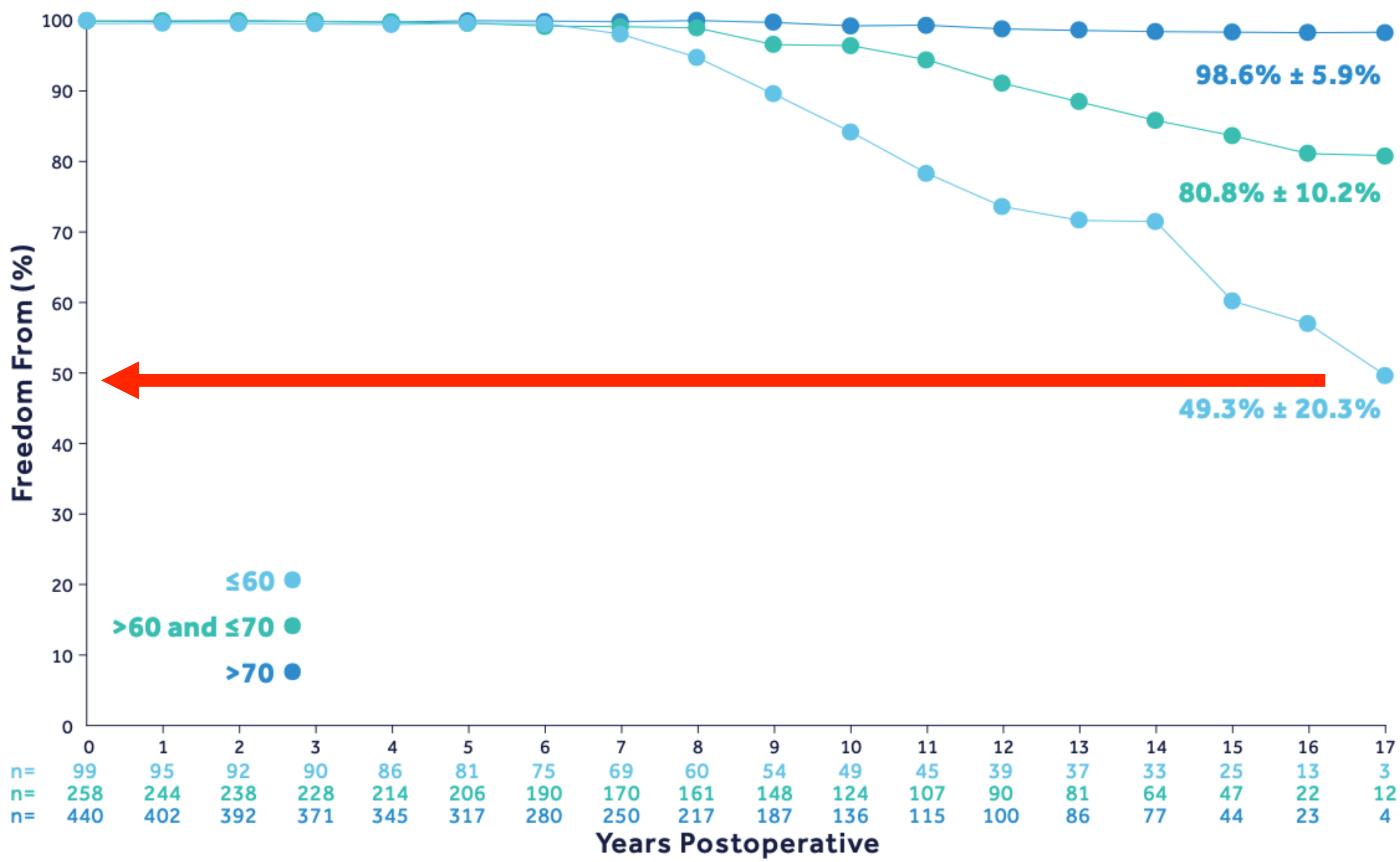
Freedom from Reoperation — Aortic Patients Stratified by Age



< 60 yrs	50	42	33	23	6	2
≥ 60 yrs	252	212	163	85	12	2

MOSAIC® AORTIC BIOPROSTHESIS | 17-YEAR CLINICAL COMPENDIUM

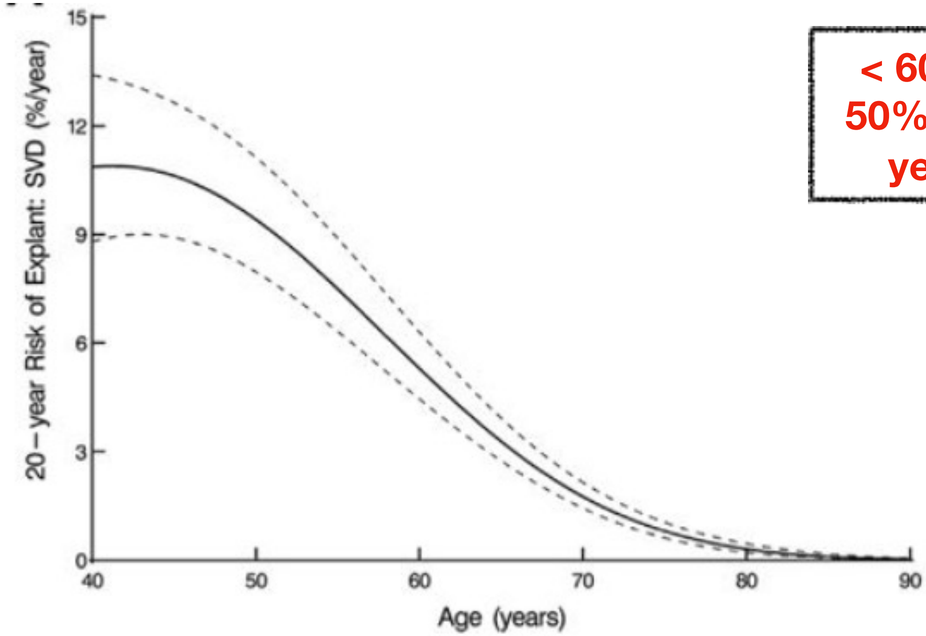
Figure 7. Freedom from Explant due to SVD by Patient's Age at Implant

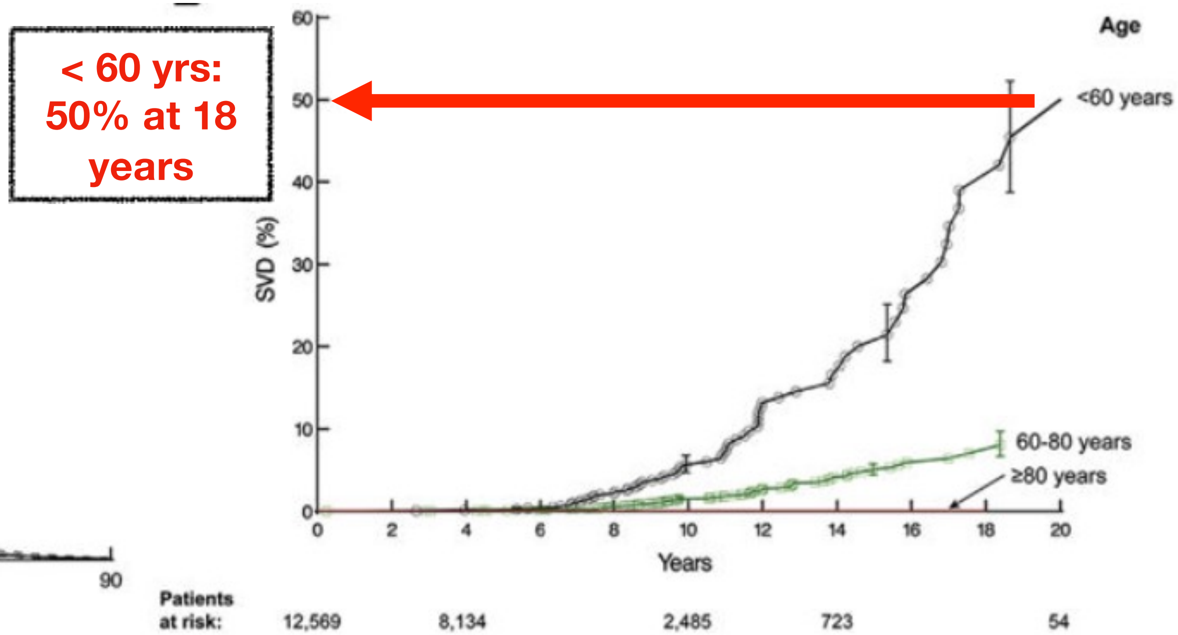


< 60 yrs: 50% at 17 years

Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

Douglas R. Johnston, MD, **Edward G. Soltesz, MD**, **Nakul Vakil, MD**, **Jeevanantham Rajeswaran, PhD**, **Eric E. Roselli, MD**, **Joseph F. Sabik III, MD**, **Nicholas G. Smedira, MD**, **Lars G. Svensson, MD, PhD**, **Bruce W. Lytle, MD**, and **Eugene H. Blackstone, MD**





Ann Thorac Surg. 2015 April ; 99(4): 1239–1247

Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

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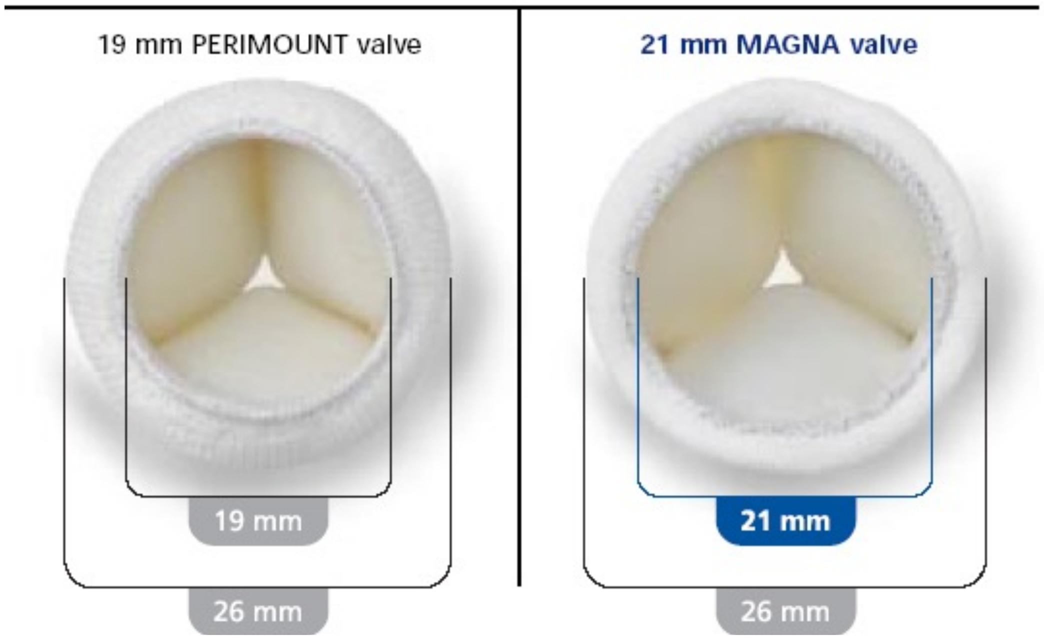
Conclusions:

Durability of the Carpentier-Edwards PERIMOUNT aortic valve is excellent even in younger patients.

Explant for SVD is related to gradient at implantation, especially in younger patients. Strategies to reduce early postoperative AV gradients, such as root enlargement or more efficient prostheses, should be considered.

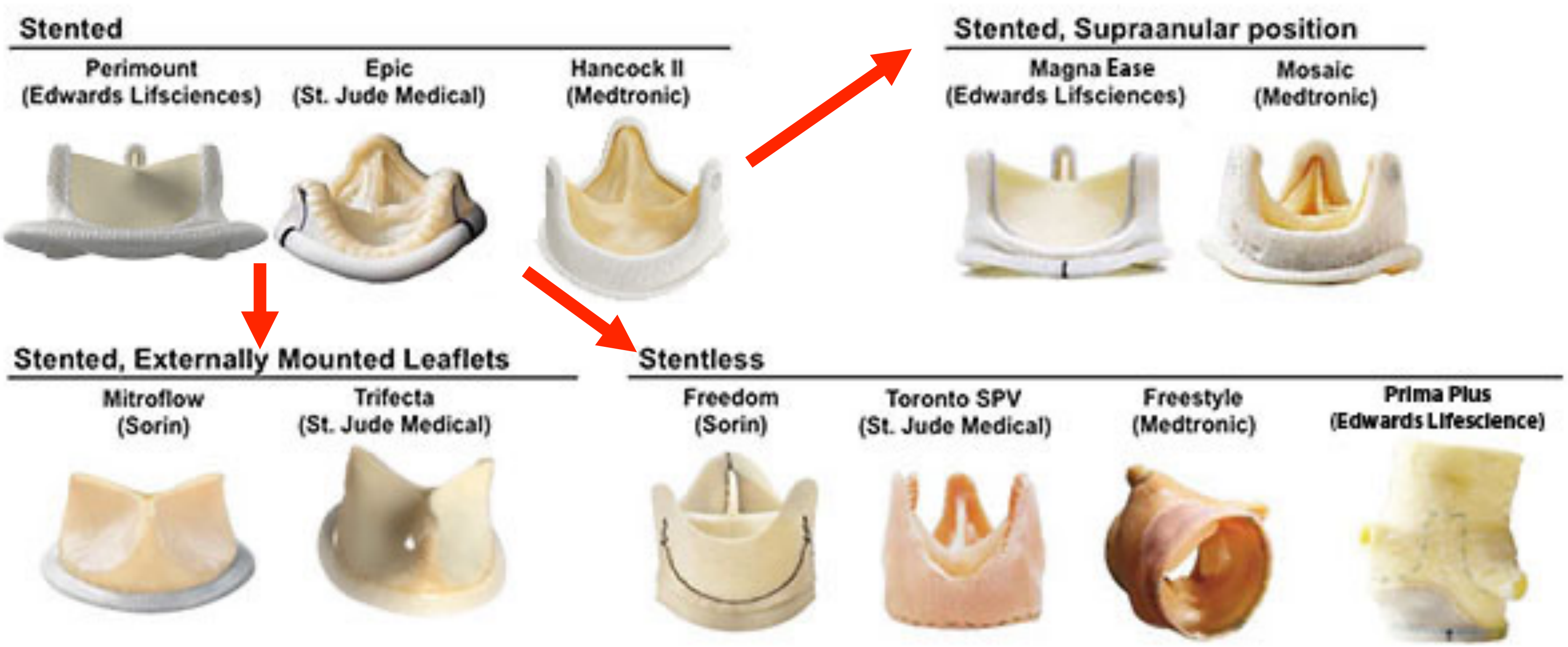
Ann Thorac Surg. 2015 April ; 99(4): 1239–1247.

EOA: Valve Design



- supra-annular design, smaller and scalloped sewing ring
- 24% greater EOA through upsizing

EOA: Valve Design



Early First-Generation Trifecta Valve Failure: A Case Series and a Review of the Literature

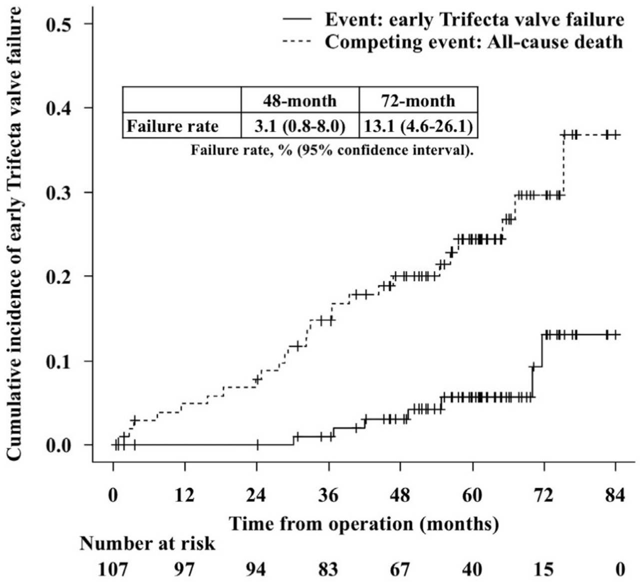
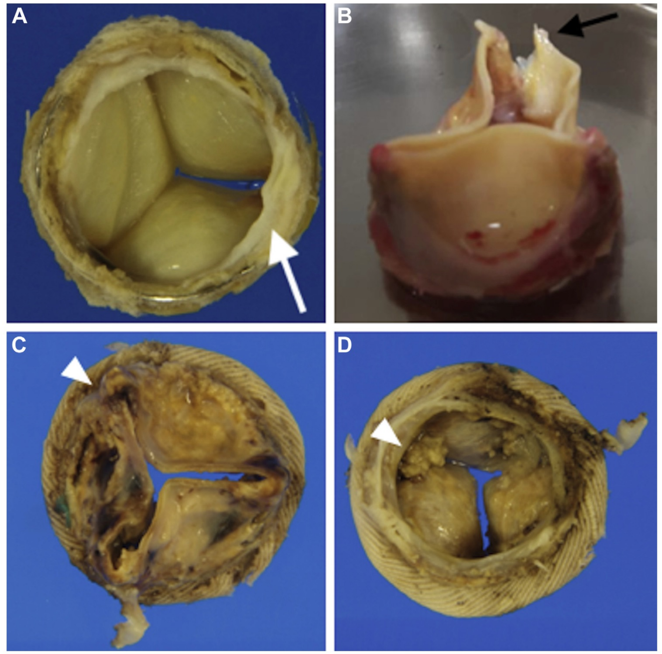


Figure 2. Cumulative incidence of early Trifecta valve failure. The competing event was death by all causes.



Conclusions: In our experience, early Trifecta valve failure was caused by cusp tears or leaflet calcification. Patients with end-renal stage disease and prosthesis–patient mismatch should be closely followed. Some patients with cusp tears may require urgent surgery.

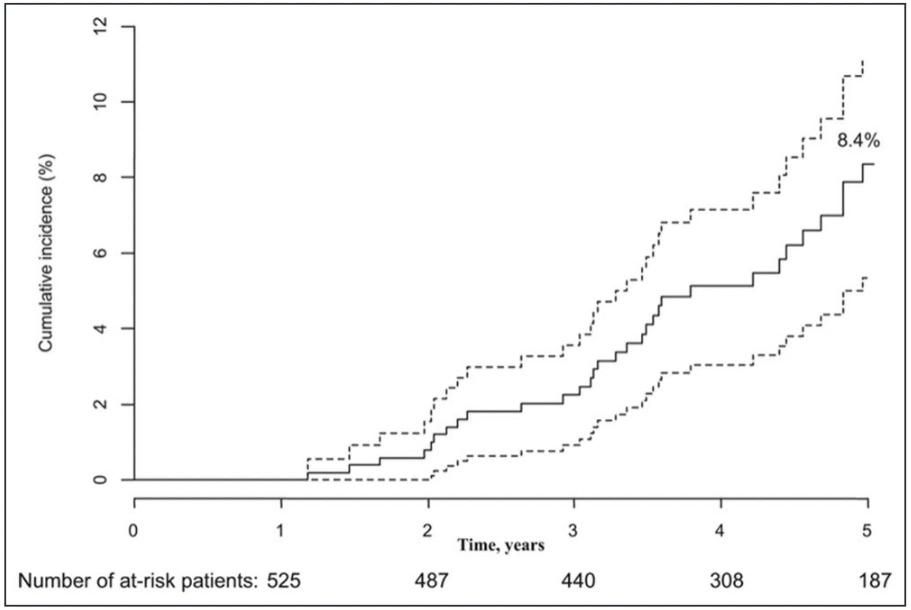
Ann Thorac Surg 2020;109:86-93

Circulation
Volume 130, Issue 23, 2 December 2014; Pages 2012-2020
https://doi.org/10.1161/CIRCULATIONAHA.114.010400
American Heart Association

ORIGINAL ARTICLE

Early Structural Valve Deterioration of Mitroflow Aortic Bioprosthesis

Mode, Incidence, and Impact on Outcome in a Large Cohort of Patients



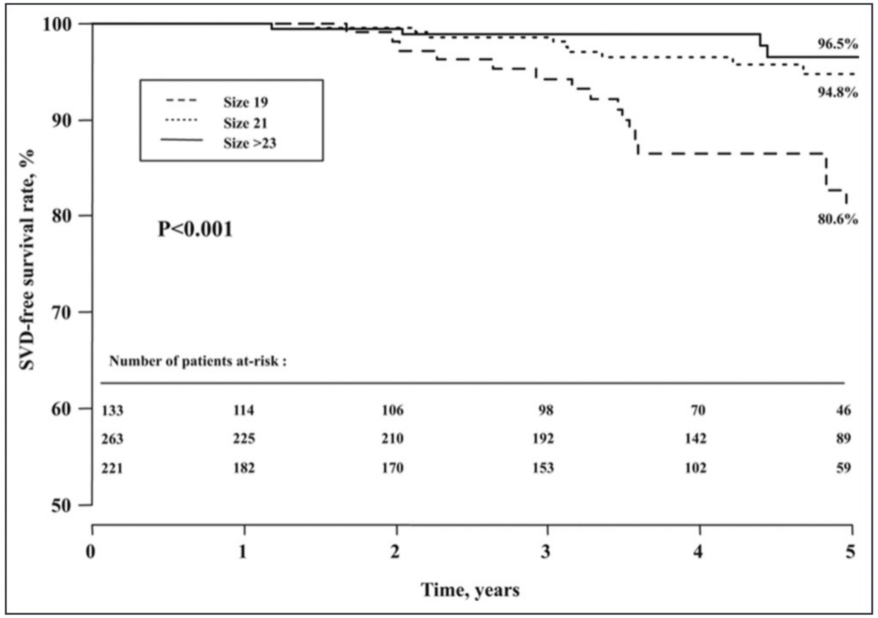
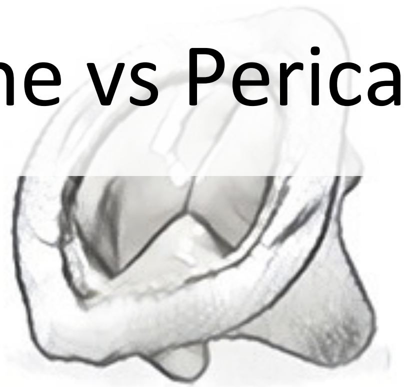


Figure 3. Cumulative incidence of structural valve deterioration (Kaplan–Meier method). Note the early occurrence of structural valve deterioration from 1 year after surgery and the high 5-year rate of structural valve deterioration.

Porcine vs Pericardial?

Carpentier Edwards
Porcine MItral



Medtronic Hancock
II

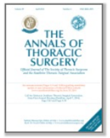
St. Jude Epic

Livanova Mitroflow

Carpentier- Edwards
Perimount Magna Ease

St. Jude Trifecta

The Annals of Thoracic Surgery
Volume 97, Issue 4, April 2014, Pages 1314-1320



Original article
Adult cardiac

Late Survival After Aortic Valve Replacement With the Perimount Versus the Mosaic Bioprosthesis

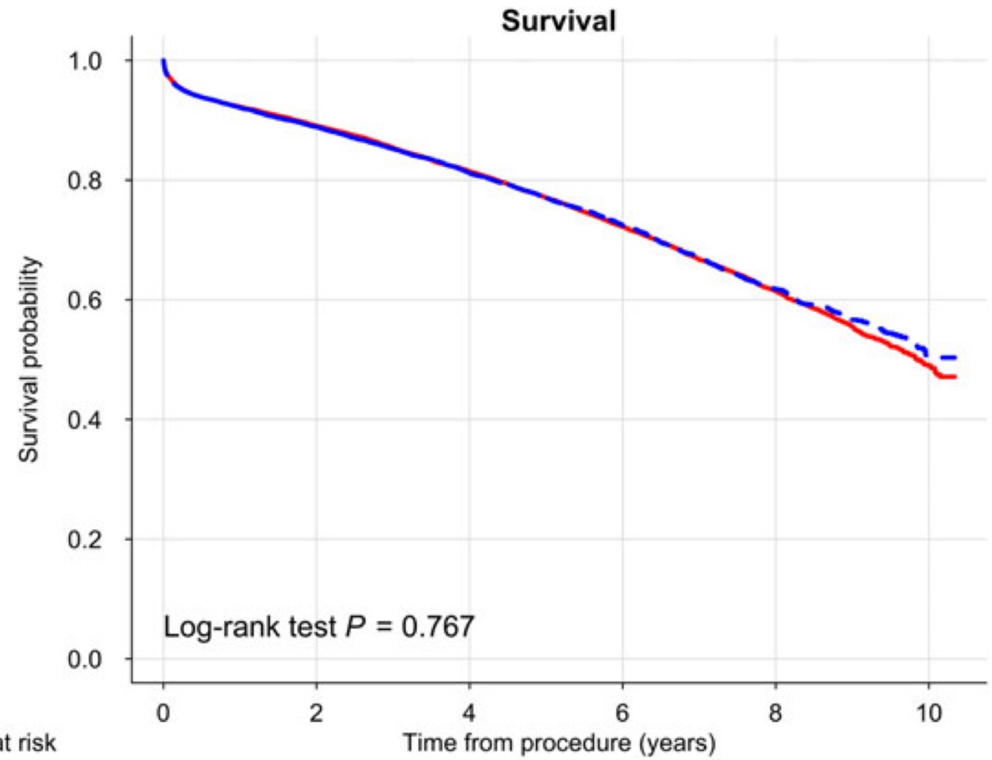
Comment

- We found no significant difference in late survival after AVR with a Perimount bioprosthesis compared with a Mosaic bioprosthesis after 8 years of follow-up.
- The freedom from aortic valve reoperations was also similar between the groups.
- Even though severe PPM was almost 3 times more common in the Mosaic group, it did not affect late survival or the frequency of reoperation.

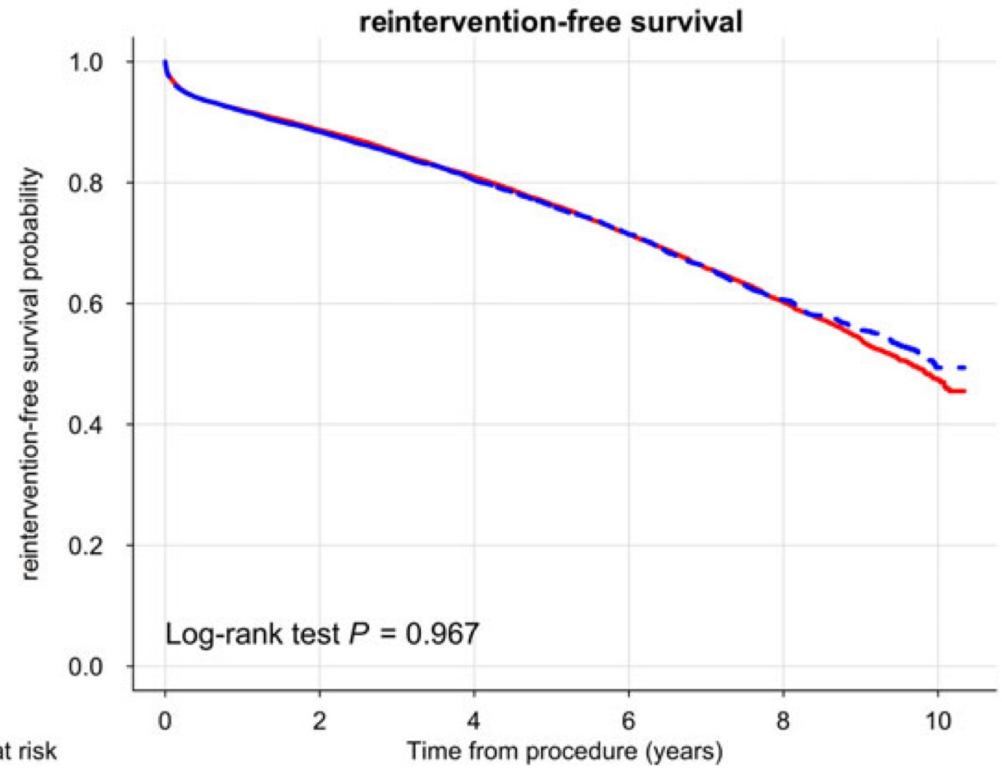
The Annals of Thoracic Surgery Volume 97, Issue 4, April 2014, Pages 1314-1320

A comparison of outcomes between bovine pericardial and porcine valves in 38 040 patients in England and Wales over 10 years

Graeme L. Hickey[a,b], Stuart W. Grant[b,c], Ben Bridgewater[a,b,c], Simon Kendall[d], Alan J. Bryan[e], James Kuo[f] and Joel Dunning[d,*]



No. at risk	0	2	4	6	8	10
Bovine	24695	16588	10814	5981	2645	256
Porcine	13345	9781	6479	3147	1057	114



No. at risk	0	2	4	6	8	10
Bovine	24695	16520	10748	5917	2589	243
Porcine	13345	9734	6422	3104	1039	111

European Journal of Cardio-Thoracic Surgery 47 (2015) 1067–1074

Failure Mode: Porcine vs Bovine?

Carpentier Edwards
Porcine MItral

Medtronic Hancock
II

St. Jude Epic

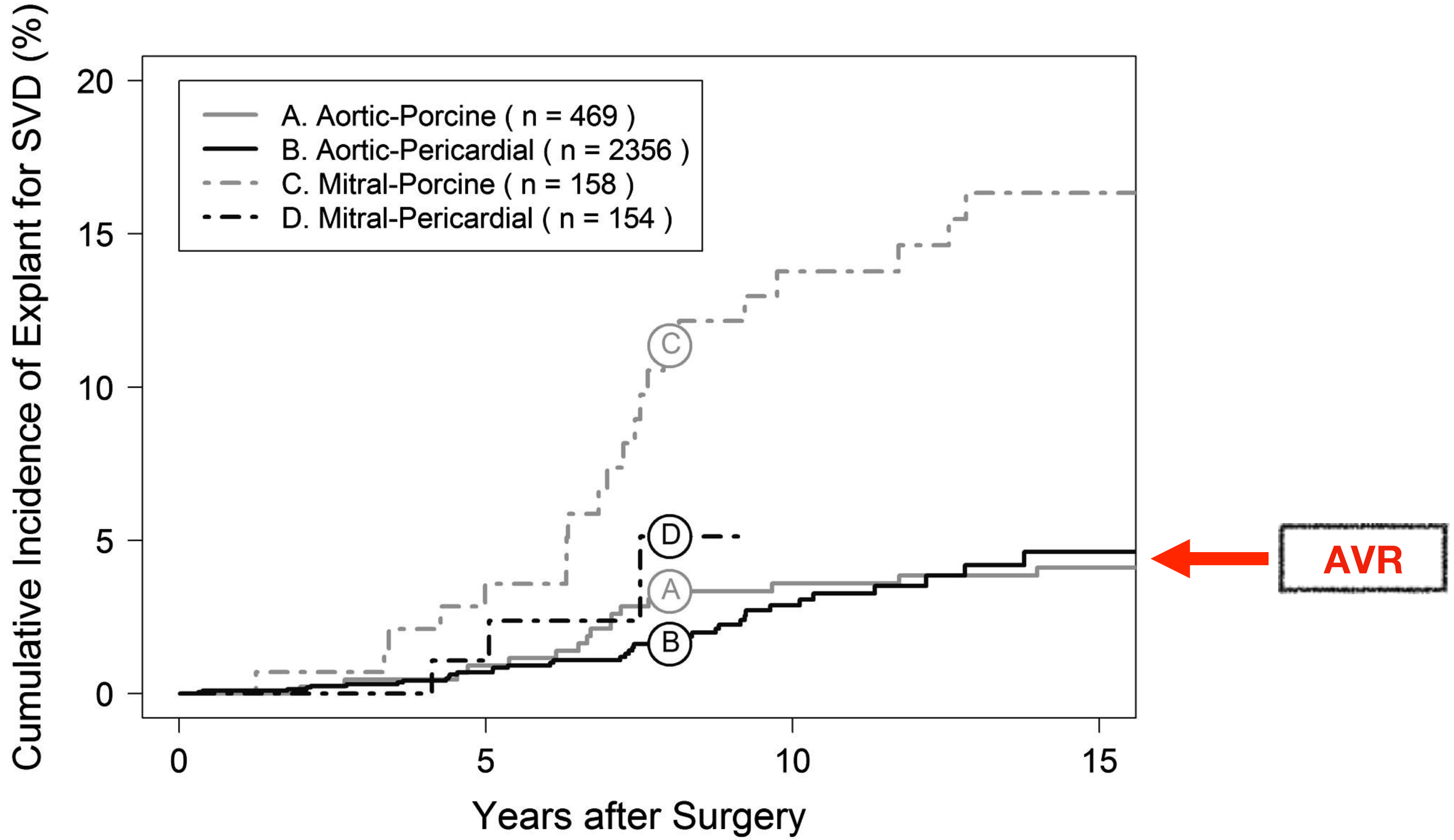
Livanova Mitroflow

Carpentier- Edwards
Perimount Magna Ease

St. Jude Trifecta

Durability of pericardial versus porcine bioprosthetic heart valves

Gary L. Grunkemeier, PhD,[a] Anthony P. Furnary, MD,[b] YingXing Wu, MD, MS,[a] Lian Wang, MS,[a] and Albert Starr, MD[c]



J Thorac Cardiovasc Surg 2012;144:1381-6

Failure Mode

	Leaflet Tears	Fibrosis/Calcification
Porcine	61%	39%
Pericardium	46%	54%

Conclusions: ……The mode of structural valve deterioration was predominantly leaflet tear for porcine valves and fibrosis/ calcification for pericardial valves.

J Thorac Cardiovasc Surg 2012;144:1381-6

JAMA Network Open

Original Investigation | Cardiology

Comparison of Long-term Performance of Bioprosthetic Aortic Valves in Sweden From 2003 to 2018

Michael Persson, MD; Natalie Glaser, MD, PhD; Johan Nilsson, MD, PhD; Örjan Friberg, MD, PhD; Anders Franco-Cereceda, MD, PhD; Ulrik Sartipy, MD, PhD

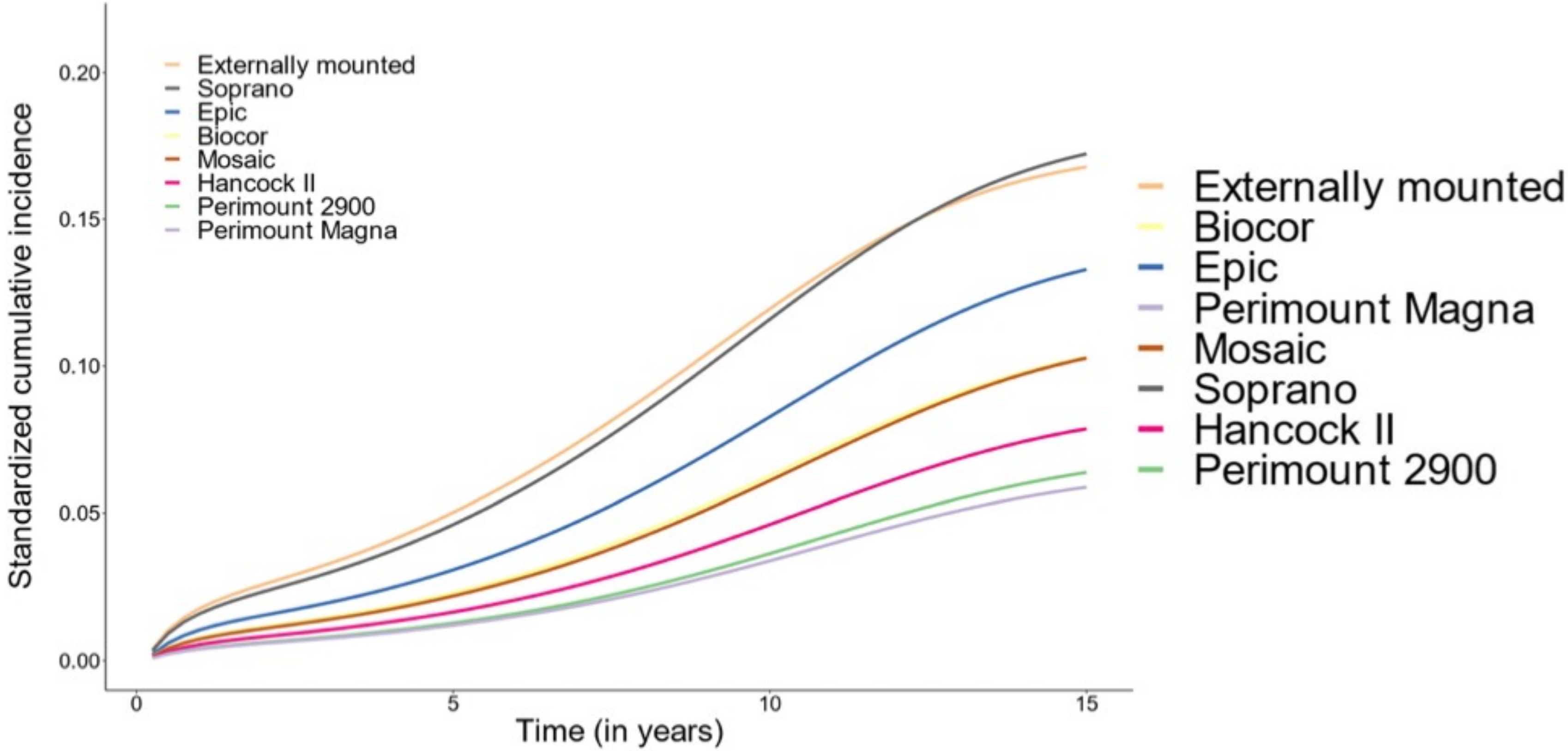
OBJECTIVE To analyze the long-term rates of reintervention, all-cause mortality, and heart failure hospitalization associated with commonly used bioprosthetic aortic valves and to identify valve model groups with deviation in clinical performance.

DESIGN, SETTING, AND PARTICIPANTS This population-based, nationwide cohort study included all adult patients who underwent surgical aortic valve replacement (with or without concomitant coronary artery bypass surgery or ascending aortic surgery) in Sweden between January 1, 2003, and December 31, 2018. Patients were identified from the SWEDEHEART (Swedish Web-System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies) registry. Patients with concomitant valve surgery, previous cardiac surgery, and previous transcatheter valve replacement were excluded. Follow-up was complete for all participants. Data were analyzed from March 9, 2020, to October 12, 2021.

EXPOSURES Primary surgical aortic valve replacement with the Perimount, Mosaic/Hancock, Biocor/Epic, Mitroflow/Crown, Soprano, and Trifecta valve models.

JAMA Network Open. 2022;5(3):e220962.

eFigure 9. Regression Standardized Cumulative Incidence of Reintervention, Accounting for the Competing Risk of Death, All Models



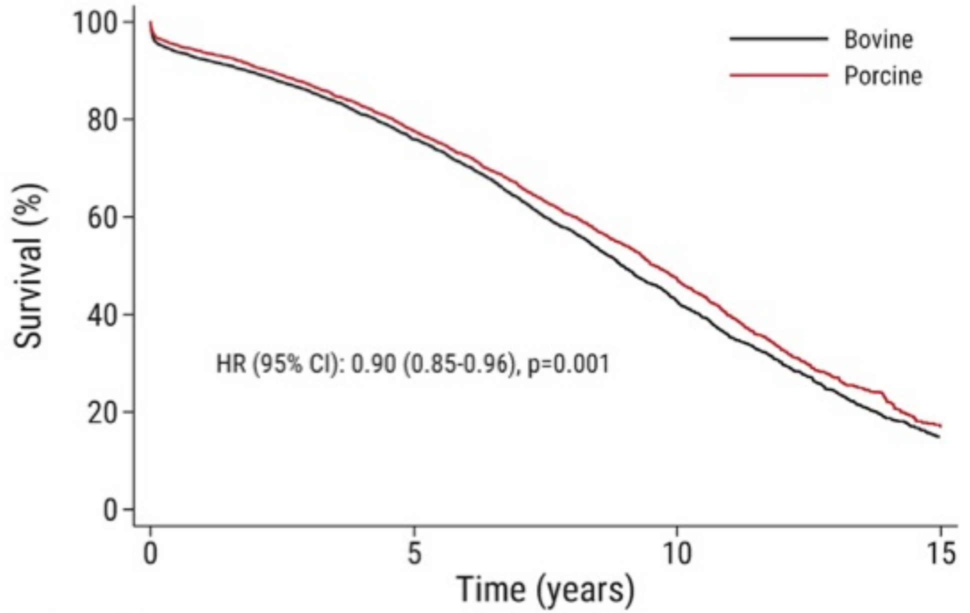
The curves represent the expected outcome if the entire population receives each respective valve group (e.g., if the entire population receives a Perimount valve, 3.6% of the population is expected to have had a reintervention at 10 years).

Open. 2022;5(3):e220962.

Porcine vs Bovine Bioprosthetic Aortic Valves: Long-Term Clinical Results

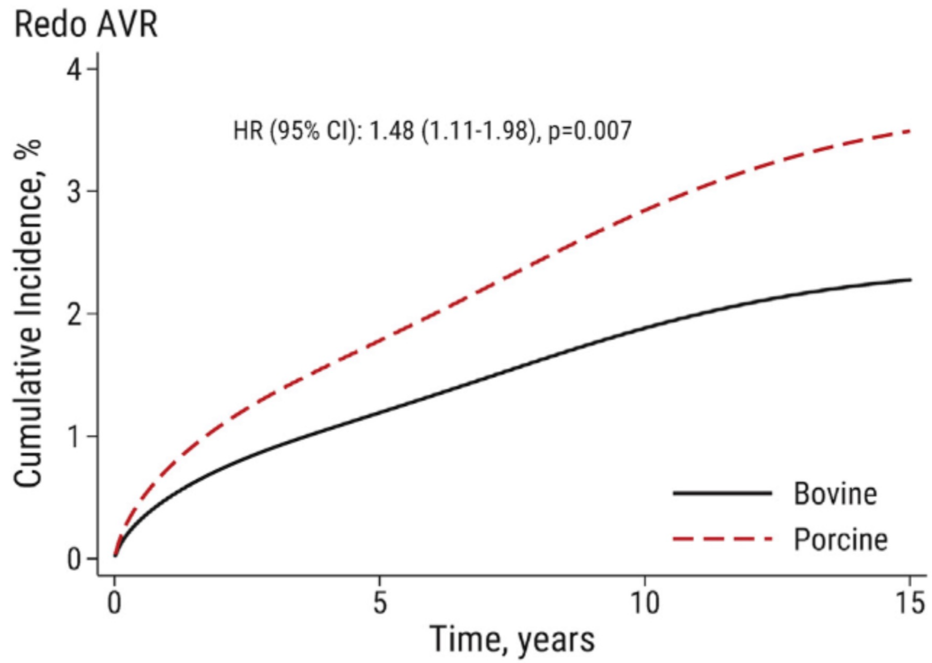
Michael Persson, MD, Natalie Glaser, MD, PhD, Anders Franco-Cereceda, MD, PhD, Johan Nilsson, MD, PhD, Martin J. Holzmann, MD, PhD, and Ulrik Sartipy, MD, PhD

SWEDEHEART (Swedish Web-System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies) Registry



Number at risk

	0	5	10	15
Bovine	12506.2	6073.6	1398.1	188.1
Porcine	12072.0	6237.0	1870.0	200.2



Ann Thorac Surg 2021;111:529-36)

Porcine vs Bovine Bioprosthetic Aortic Valves: Long-Term Clinical Results

Check for updates

Michael Persson, MD, Natalie Glaser, MD, PhD, Anders Franco-Cereceda, MD, PhD, Johan Nilsson, MD, PhD, Martin J. Holzmann, MD, PhD, and Ulrik Sartipy, MD, PhD

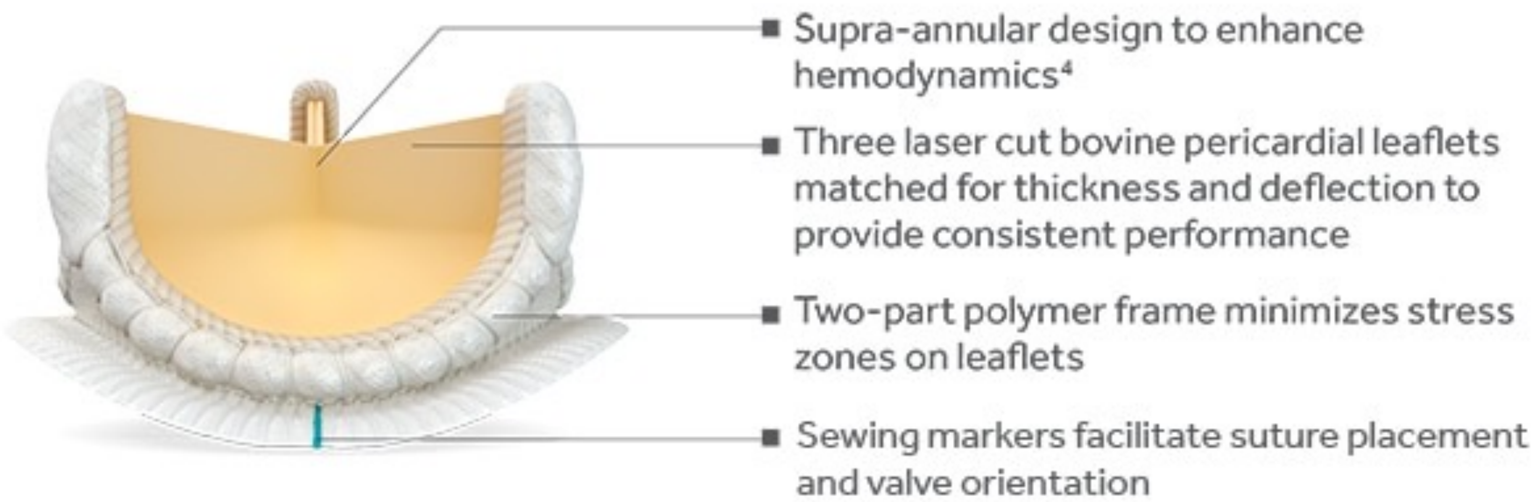
SWEDEHEART (Swedish Web-System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies) Registry

Conclusions:

- **Patients receiving porcine prostheses had a higher rate of reoperation**
- **Porcine prostheses were associated with improved long-term survival compared with bovine**
- **The use of bioprosthetic aortic valves has excellent long-term outcomes, regardless of the xenograft material used.**

Ann Thorac Surg 2021;111:529-36)

Next Generation Valves

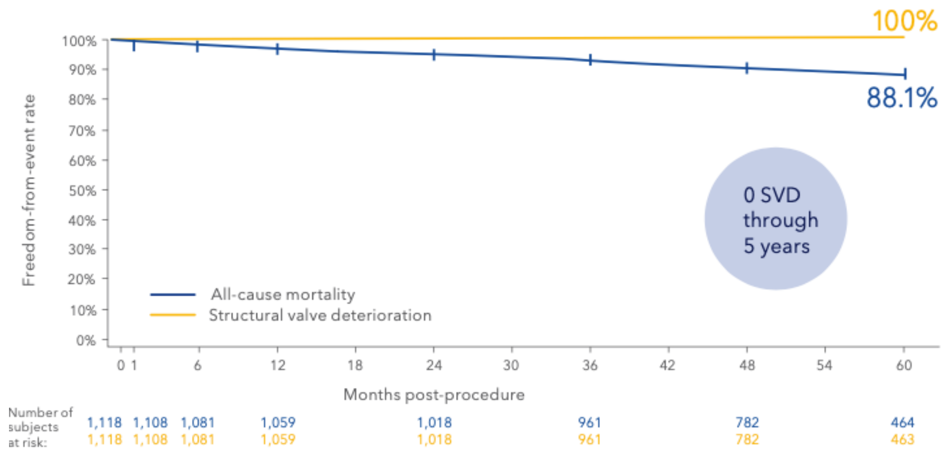


Avalus™

PERIGON Pivotal Trial 5-year clinical update

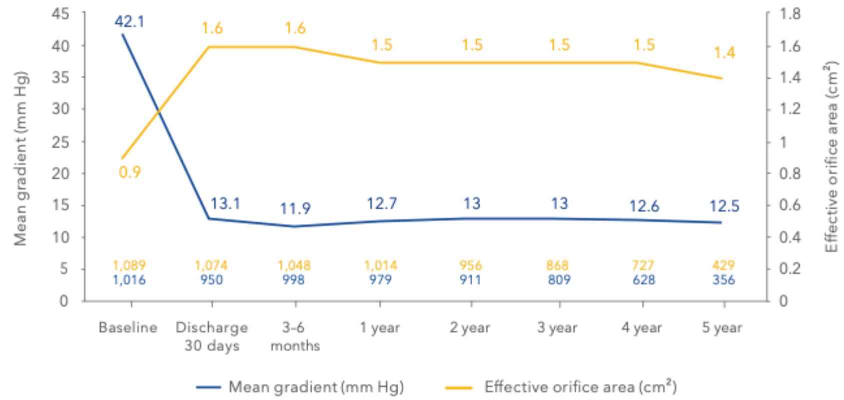
Kaplan-Meier survival analysis

Freedom-from-event rate for all-cause mortality and structural valve deterioration



Echocardiographic findings

All valve sizes[†]



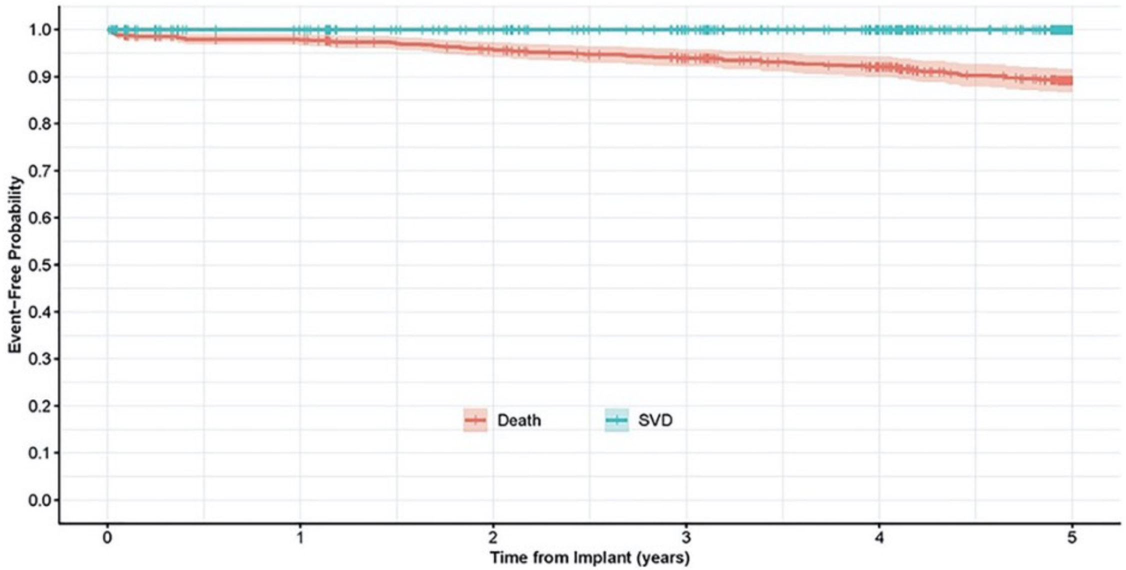
[†]Data are not paired.

Published by Elsevier Inc.
0003-4975/$36.00

https://doi.org/10.1016/j.athoracsur.2021.12.058

Five-year Outcomes of the COMMENCE Trial Investigating Aortic Valve Replacement with RESILIA Tissue

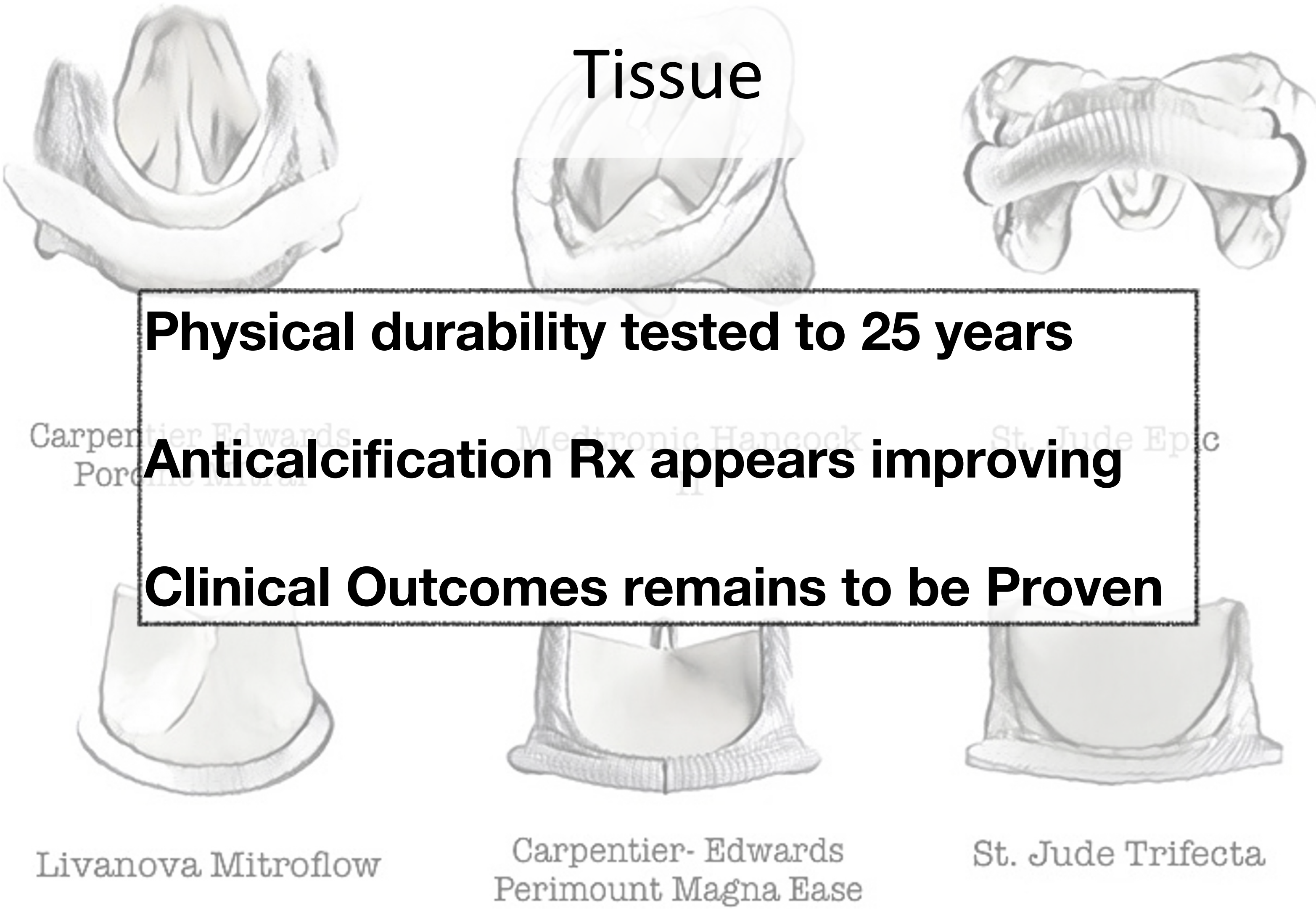
Joseph E. Bavaria, MD, Bartley Griffith, MD, David A. Heimansohn, MD, Jacek Rozanski, MD, Douglas R. Johnston, MD, Krzysztof Bartus, MD, PhD, Leonard N. Girardi, MD, Thomas Beaver, MD, MPH, Hiroo Takayama, MD, PhD, Mubashir A. Mumtaz, MD, Todd K. Rosengart, MD, Vaughn Starnes, MD, Tomasz A. Timek, MD, Percy Boateng, MD, William Ryan, MD, Lorraine D. Cornwell, MD, Eugene H. Blackstone, MD, Michael A. Borger, MD, PhD, Philippe Pibarot, DVM, PhD, Vinod H. Thourani, MD, Lars G. Svensson, MD, PhD, and John D. Puskas, MD, for the COMMENCE Trial Investigators



	0	1	2	3	4	5
No. of Subjects at Risk						
Death	689	655	624	592	540	342
SVD	689	655	624	593	541	342
Cumulative No. of Events						
Death	0	15	29	40	51	67
SVD	0	0	0	0	0	0
Event−free Probability (95% CI)						
Death	1.00 (1.00,1.00)	1.00 (1.00,1.00)	1.00 (1.00,1.00)	1.00 (1.00,1.00)	1.00 (1.00,1.00)	1.00 (1.00,1.00)
SVD	1.00 (1.00,1.00)	0.98 (0.97,0.99)	0.96 (0.94,0.97)	0.94 (0.92,0.96)	0.92 (0.90,0.94)	0.89 (0.87,0.92)

FIGURE 2 Kaplan-Meier curves of freedom from all-cause mortality and structural valve deterioration. (CI, confidence interval; SVD, structural valve deterioration.)

Tissue

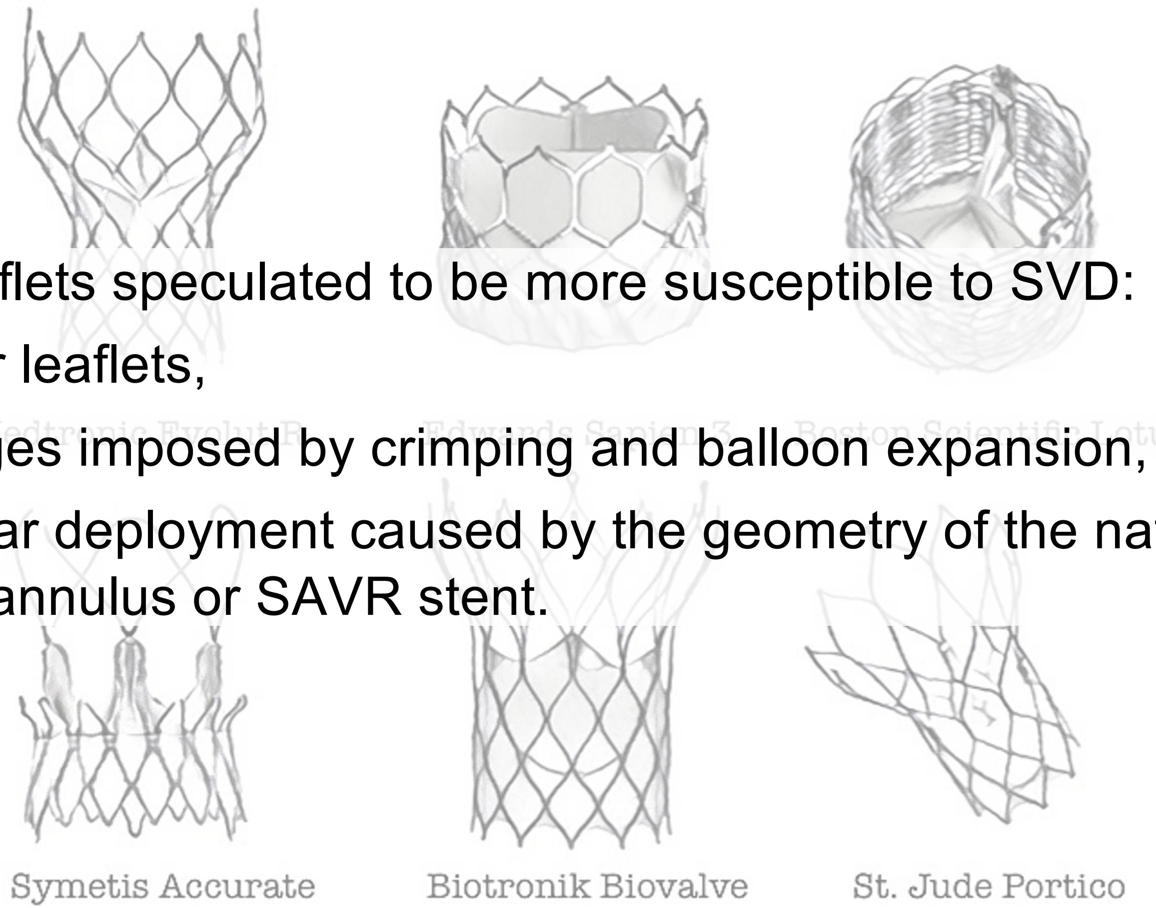


Physical durability tested to 25 years

Anticalcification Rx appears improving

Clinical Outcomes remains to be Proven

TAVR Durability



TAVR leaflets speculated to be more susceptible to SVD:

(1) thinner leaflets,

(2) damages imposed by crimping and balloon expansion, and

(3) irregular deployment caused by the geometry of the native aortic annulus or SAVR stent.

Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement

Troels Højsgaard Jørgensen[1]*†, Hans Gustav Hørsted Thyregod[2†], Nikolaj Ihlemann[3], Henrik Nissen[3], Petur Petursson[4], Bo Juel Kjeldsen[5], Daniel Andreas Steinbrüchel[6], Peter Skov Olsen[2], and Lars Søndergaard[1]

Aims The aims of the study were to compare clinical outcomes and valve durability after 8 years of follow-up in patients with symptomatic severe aortic valve stenosis at low surgical risk treated with either transcatheter aortic valve implantation (TAVI) or surgical aortic valve replacement (SAVR).

Methods and results In the NOTION trial, patients with symptomatic severe aortic valve stenosis were randomized to TAVI or SAVR. Clinical status, echocardiography, structural valve deterioration, and failure were assessed using standardized definitions. In total, 280 patients were randomized to TAVI ($n = 145$) or SAVR ($n = 135$). Baseline characteristics were similar, including mean age of 79.1 ± 4.8 years and a mean STS score of 3.0 ± 1.7%. At 8-year follow-up, the estimated risk of the composite outcome of all-cause mortality, stroke, or myocardial infarction was 54.5% after TAVI and 54.8% after SAVR ($P = 0.94$). The estimated risks for all-cause mortality (51.8% vs. 52.6%; $P = 0.90$), stroke (8.3% vs. 9.1%; $P = 0.90$), or myocardial infarction (6.2% vs. 3.8%; $P = 0.33$) were similar after TAVI and SAVR. The risk of structural valve deterioration was lower after TAVI than after SAVR (13.9% vs. 28.3%; $P = 0.0017$), whereas the risk of bioprosthetic valve failure was similar (8.7% vs. 10.5%; $P = 0.61$).

Conclusions In patients with severe aortic valve stenosis at low surgical risk randomized to TAVI or SAVR, there were no significant differences in the risk for all-cause mortality, stroke, or myocardial infarction, as well as the risk of bioprosthetic valve failure after 8 years of follow-up.

European Heart Journal (2021) 42, 2912–2919

Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement

Troels Højsgaard Jørgensen[1*†], Hans Gustav Hørsted Thyregod[2†], Nikolaj Ihlemann[3], Henrik Nissen[3], Petur Petursson[4], Bo Juel Kjeldsen[5], Daniel Andreas Steinbrüchel[6], Peter Skov Olsen[2], and Lars Søndergaard[1]

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European Heart Journal (2021) 42, 2912–2919

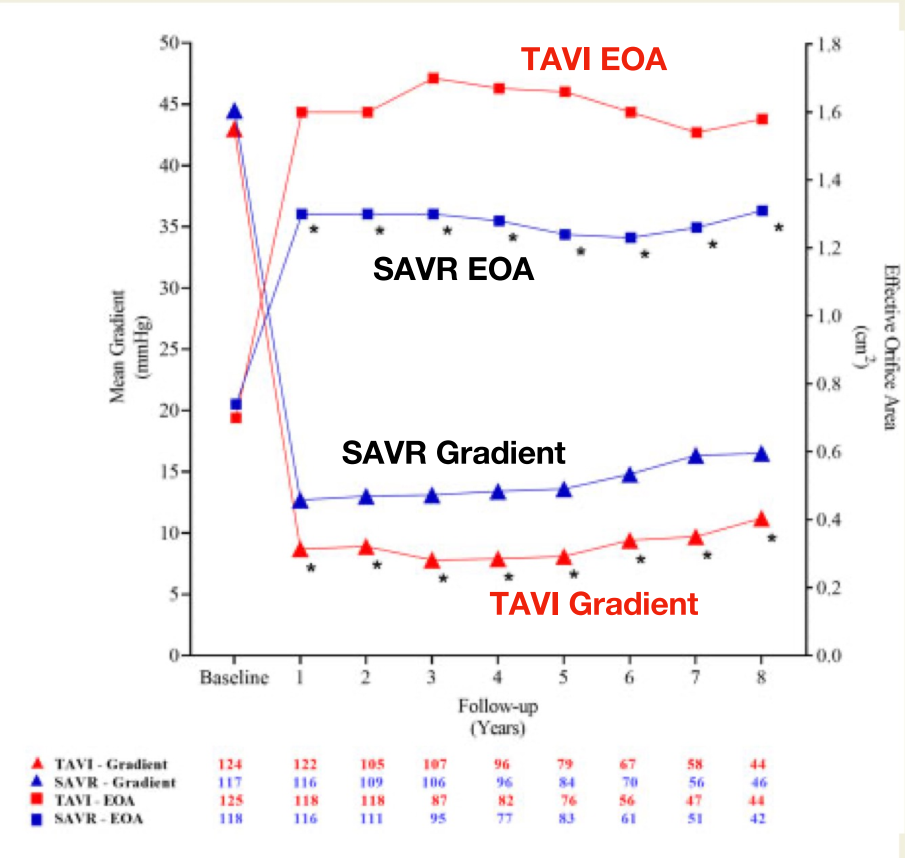


Figure 3 Mean gradient and effective orifice area during follow-up. EOA, effective orifice area; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation. *$P < 0.05$.

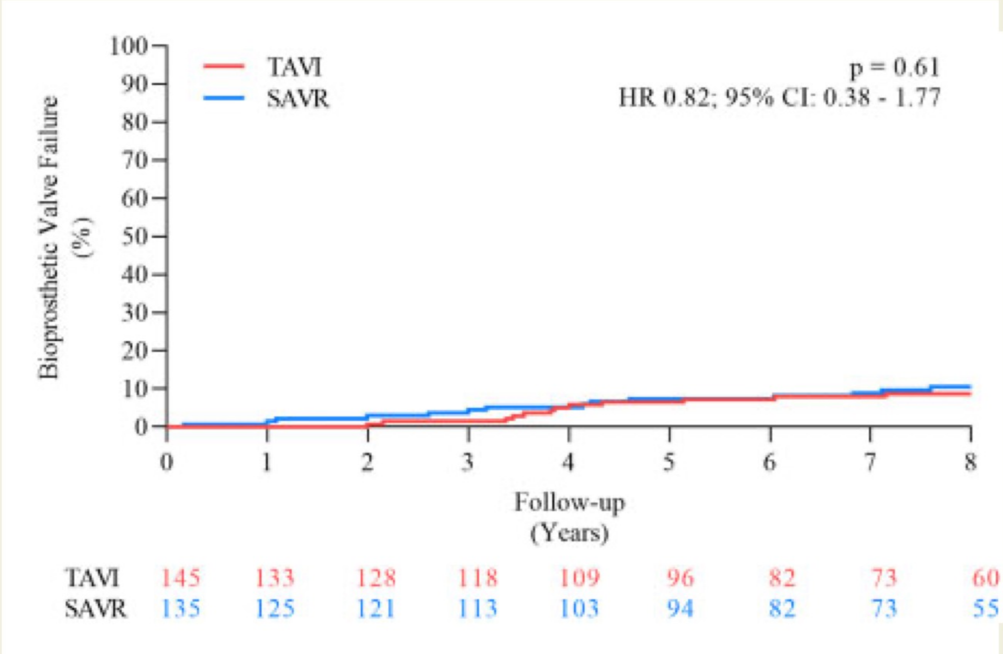


Figure 5 Bioprosthetic valve failure. CI, confidence interval; HR, hazard ratio; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

European Heart Journal (2021) 42, 2912–2919

Ler et al. Journal of Cardiothoracic Surgery (2020) 15:127
https://doi.org/10.1186/s13019-020-01170-7

Journal of Cardiothoracic Surgery

RESEARCH ARTICLE Open Access

Structural durability of early-generation Transcatheter aortic valve replacement valves compared with surgical aortic valve replacement valves in heart valve surgery: a systematic review and meta-analysis

Ashlynn Ler[1,2], Yeo Jie Ying[1,3], Faizus Sazzad[1,4,6], Andrew M. T. L. Choong[1,4,5,6] and Theo Kofidis[1,4,5,6*]

Abstract

Background: The current treatment for aortic stenosis includes open surgical aortic valve replacement (SAVR) as well as endovascular transcatheter aortic valve replacement (TAVR). This study aims to compare the 1-year, 2–3 year and 5-year structural durability of TAVR valves with that of SAVR valves.

Method: A systematic literature search was conducted in July 2019 on Medline (via PubMed), Embase and Cochrane electronic databases according to the PRISMA guidelines.

Results: Thirteen randomized controlled trials were included. From the meta-analysis, we observed higher rates of 1-year (OR: 7.65, CI: 4.57 to 12.79, $p < 0.00001$), 2–3-year (OR: 13.49, CI: 5.66 to 32.16, $p < 0.00001$) and 5-year paravalvular regurgitation (OR: 14.51, CI: 4.47 to 47.09, $p < 0.00001$) associated with the TAVR valves than the SAVR valves. There were also higher rates of 1-year (OR: 5.00, CI: 3.27 to 7.67, $p < 0.00001$), 2–3-year (OR: 8.14, CI: 3.58 to 18.50, $p < 0.00001$) and 5-year moderate or severe aortic regurgitation (MD: 14.65, CI: 4.55 to 47.19, $p < 0.00001$), and higher rates of 1-year (OR: 3.55, CI: 1.86 to 6.77, $p = 0.0001$), 2–3-year (OR: 3.55, CI: 1.86 to 6.77, $p = 0.0001$) and 5-year reintervention (OR: 3.55, CI: 1.22 to 10.38, $p = 0.02$) in the TAVR valves as compared to SAVR valves.

Conclusion: TAVR valves appear to be more susceptible to structural valve deterioration and thus potentially less structurally durable than SAVR valves, given that they may be associated with higher rates of moderate or severe aortic regurgitation, paravalvular regurgitation and reintervention in the 1-year-, 2–3 year, and 5-year period.

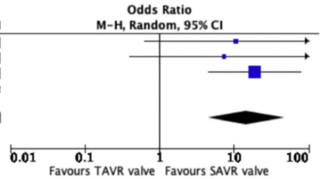
Keywords: SAVR valves, TAVR valves, Structural durability

MOD-SEVERE AR

Study or Subgroup	TAVR valve Events	TAVR valve Total	SAVR valve Events	SAVR valve Total	Weight	Odds Ratio M-H, Random, 95% CI
Douglas 2017	44	387	0	40	17.4%	10.49 [0.63, 173.65]
Gleason 2018	4	112	0	88	15.9%	7.34 [0.39, 138.20]
Mack 2015	40	280	2	228	66.7%	18.83 [4.50, 78.83]
Søndergaard 2019	0	139	0	135		Not estimable
Total (95% CI)		918		491	100.0%	14.65 [4.55, 47.19]
Total events	88		2			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.39$, $df = 2$ ($P = 0.82$); $I^2 = 0\%$

Test for overall effect: $Z = 4.50$ ($P < 0.00001$)

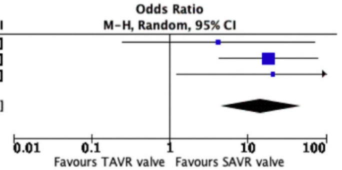


PARAVALVULAR LEAK

Study or Subgroup	TAVR valve Events	TAVR valve Total	SAVR valve Events	SAVR valve Total	Weight	Odds Ratio M-H, Random, 95% CI
Douglas 2017	19	395	0	40	17.3%	4.20 [0.25, 70.79]
Søndergaard 2019	30	139	2	135	65.6%	18.30 [4.28, 78.31]
Thyregod 2019	10	145	0	135	17.1%	21.00 [1.22, 361.96]
Total (95% CI)		679		310	100.0%	14.51 [4.47, 47.09]
Total events	59		2			

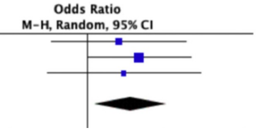
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.90$, $df = 2$ ($P = 0.64$); $I^2 = 0\%$

Test for overall effect: $Z = 4.45$ ($P < 0.00001$)



REINTERVENTION

Study or Subgroup	TAVR valve Events	TAVR valve Total	SAVR valve Events	SAVR valve Total	Weight	Odds Ratio M-H, Random, 95% CI
Douglas 2017	20	2482	1	313	28.4%	2.53 [0.34, 18.95]
Gleason 2018	10	391	2	359	49.4%	4.69 [1.02, 21.53]
Søndergaard 2019	3	139	1	135	22.2%	2.96 [0.30, 28.78]
Total (95% CI)		3012		807	100.0%	3.55 [1.22, 10.38]
Total events	33		4			



Conclusion

TAVR valves may be associated with higher rates of 1-year, 2–3 year and 5-year moderate or severe aortic regurgitation, paravalvular leak and reintervention than SAVR valves. This could be indicative of TAVR valves being more susceptible to SVD and hence potentially less durable in the long term than SAVR valves.

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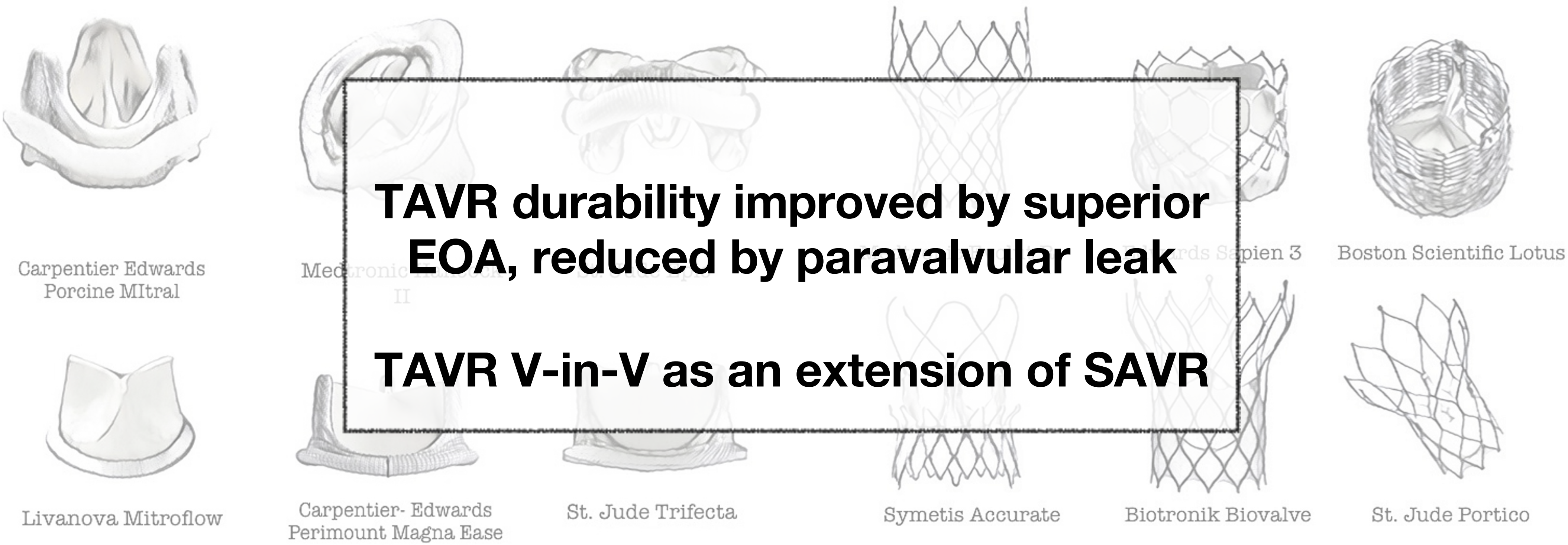
Tissue + TAVR

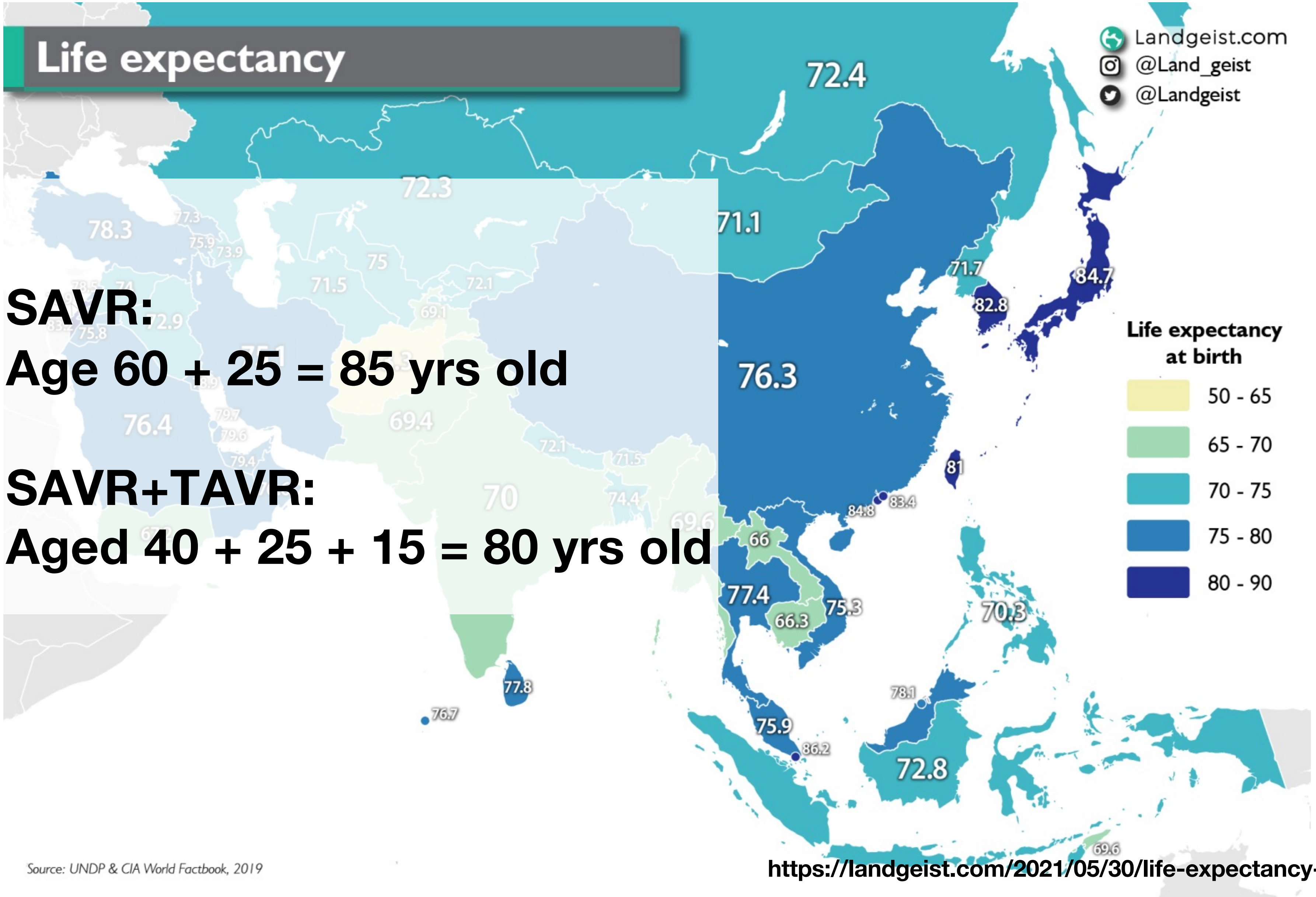


TAVR durability improved by superior EOA, reduced by paravalvular leak

TAVR V-in-V as an extension of SAVR

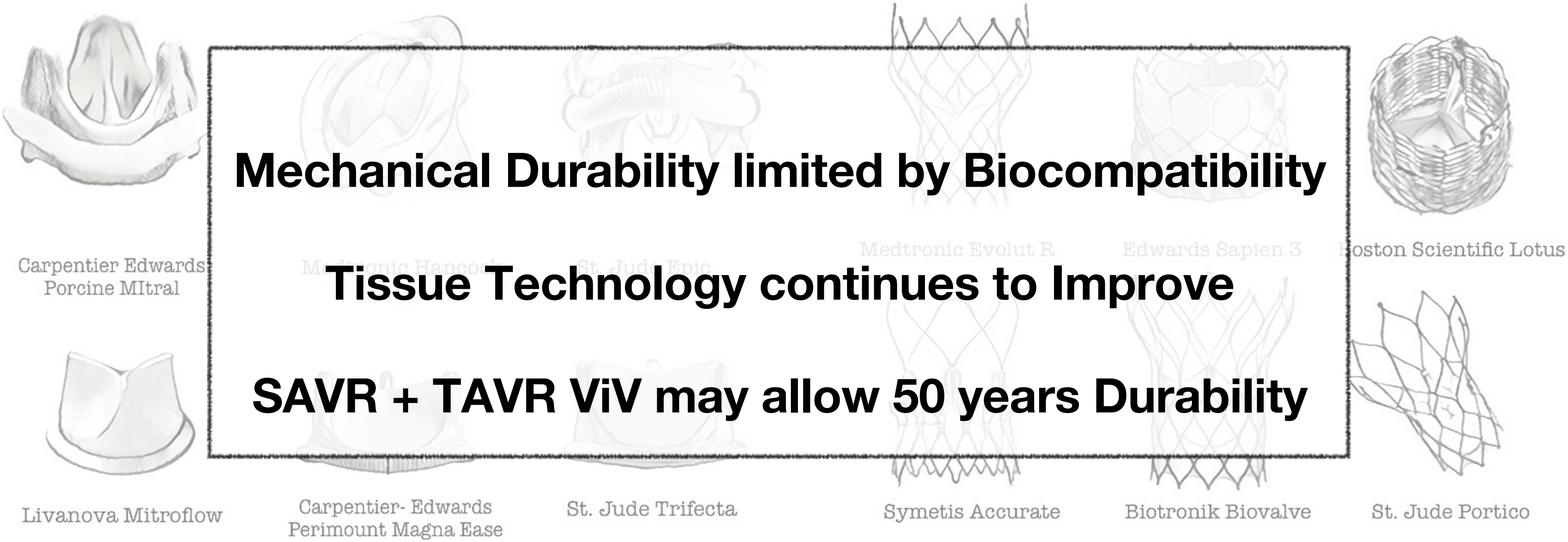
SAVR:
Age 60 + 25 = 85 yrs old

SAVR+TAVR:
Aged 40 + 25 + 15 = 80 yrs old



https://landgeist.com/2021/05/30/life-expectancy-in-asia/

Conclusion



Mechanical Durability limited by Biocompatibility

Tissue Technology continues to Improve

SAVR + TAVR ViV may allow 50 years Durability