Optimising the future of aortic valve therapy: Prosthesis choice in the under 60s

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Disclosure

Proctor for Corcym and Artivion

Speaker for Edwards

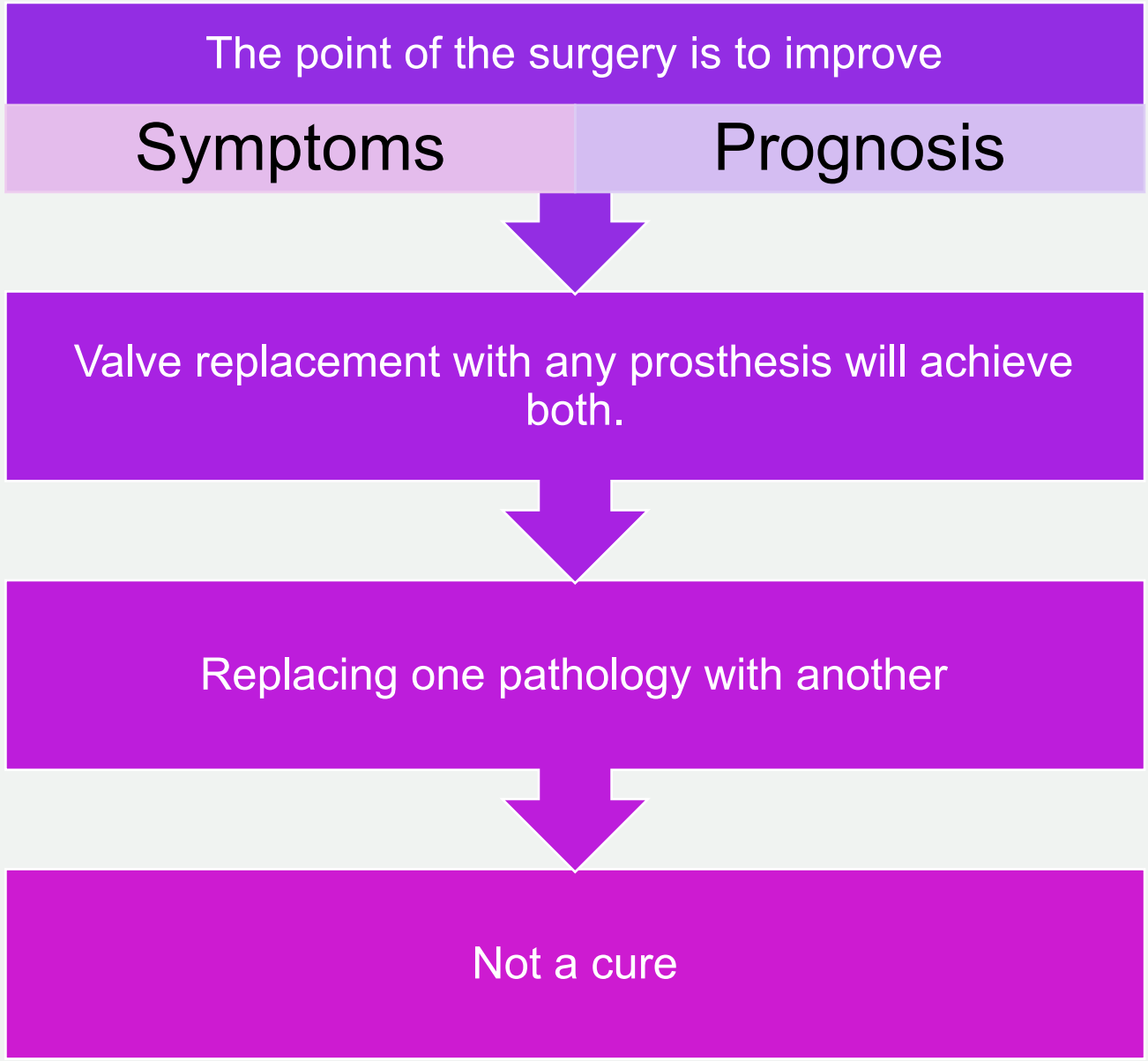
Aortic Valve Procedures

>300,000 procedures worldwide/year

In UK there are

- 8,000 surgical AVRs
- >6,000 TAVIs

Surgical Valve Procedure



Ideal Prosthesis

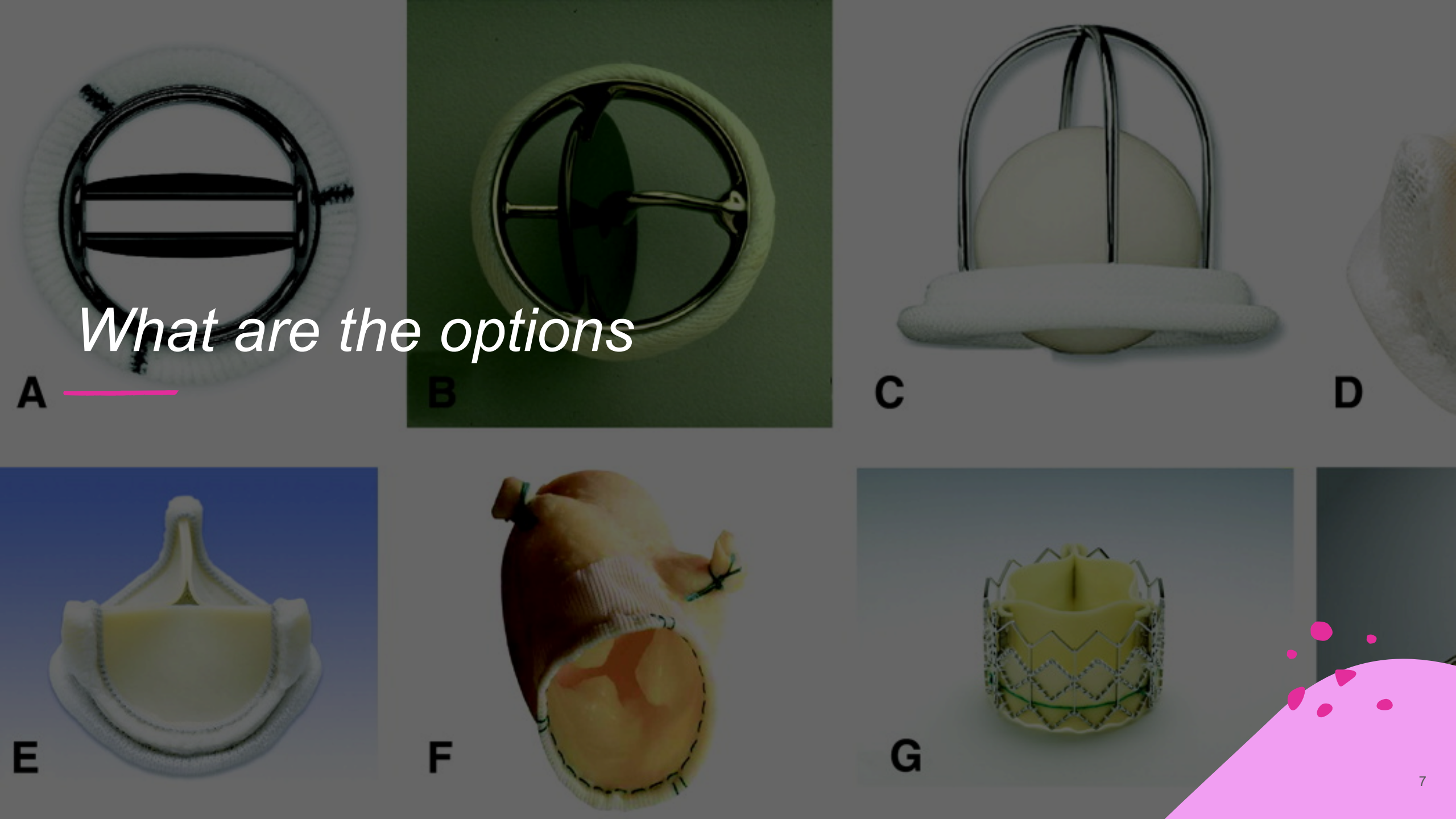
- Good haemodynamics
- Durable
- Low thrombogenicity
- No anticoagulation needed
- Low rate of endocarditis
- Low rate of PPM
- Does not exist

Role of the Surgeon

Educate and guide the patient through the choosing process

- Provide all options
- Refer to guidelines for reassurance
- Consider patient factors
  - Age
  - Life expectancy / comorbidities
  - Anticoagulation
- Finally accept patient preference

What are the options



Guidelines

- Repair or replace
- Biological Vs Mechanical
- Anticoagulation Vs Biological prosthesis degeneration
- Age Vs Lifestyle

Guidelines - Mechanical

Choice of the aortic/mitral prosthesis in favour of a mechanical prosthesis; the decision is based on the integration of several of the following factors

Recommendations	Class[a]	Level[b]
A mechanical prosthesis is recommended according to the desire of the informed patient and if there are no contraindications to long-term anticoagulation.[c]	I	C
A mechanical prosthesis is recommended in patients at risk of accelerated structural valve deterioration.[d]	I	C
A mechanical prosthesis should be considered in patients already on anticoagulation because of a mechanical prosthesis in another valve position.	IIa	C
A mechanical prosthesis should be considered in patients <60 years of age for prostheses in the aortic position and <65 years of age for prostheses in the mitral position.[e]	IIa	C
A mechanical prosthesis should be considered in patients with a reasonable life expectancy[f] for whom future redo valve surgery would be at high risk.	IIa	C
A mechanical prosthesis may be considered in patients already on long-term anticoagulation due to the high risk for thromboembolism.[g]	IIb	C

Or TAVI if appropriate

Guidelines - biological

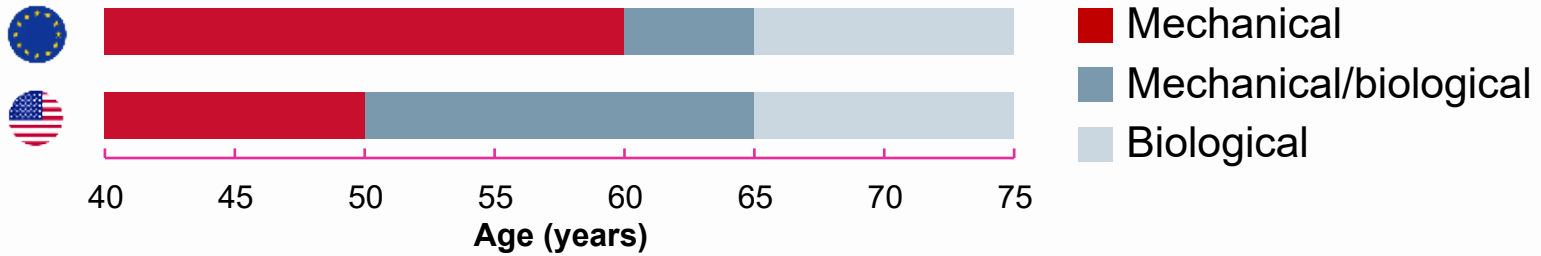
Choice of the aortic/mitral prosthesis in favour of a bioprosthesis; the decision is based on the integration of several of the following factors

Recommendations	Class[a]	Level[b]
A bioprosthesis is recommended according to the desire of the informed patient.	I	C
A bioprosthesis is recommended when good-quality anticoagulation is unlikely (compliance problems, not readily available) or contraindicated because of high bleeding risk (previous major bleed, comorbidities, unwillingness, compliance problems, lifestyle, occupation).	I	C
A bioprosthesis is recommended for reoperation for mechanical valve thrombosis despite good long-term anticoagulant control.	I	C
A bioprosthesis should be considered in patients for whom there is a low likelihood and/or a low operative risk of future redo valve surgery.	IIa	C
A bioprosthesis should be considered in young women contemplating pregnancy.	IIa	C
A bioprosthesis should be considered in patients >65 years of age for a prosthesis in the aortic position or > 70 years of age in a mitral position or those with a life expectancy[c] lower than the presumed durability of the bioprosthesis.[d]	IIa	C

A bioprosthesis may be considered in patients already on long-term NOACs due to the high risk for thromboembolism.[466–469 f]	IIb	B

Guideline recommendations for the treatment of valvular heart disease

Age recommendations based on the 2020 ACC/AHA and 2021 ESC/EACTS guidelines[1,2]



2020 ACC/AHA and 2021 ESC/EACTS guidelines[1,2]

- **Class I recommendation:** prosthetic valve choice should be based on shared decision-making
- Patient values and preferences must be taken into account

2020 ACC/AHA guidelines[1]

- **Class IIa recommendation:** for patients aged 50–65 years, individual factors should be considered alongside informed shared decision-making

2021 ESC/EACTS guidelines[2]

- **Class IIa recommendation:** for patients 60–65 years, both mechanical and biological valves are acceptable. The decision should be based on factors other than age

1. Otto CM *et al. J Am Coll Cardiol.* 2021; 2. Vahanian A *et al. Eur Heart J.* 2022

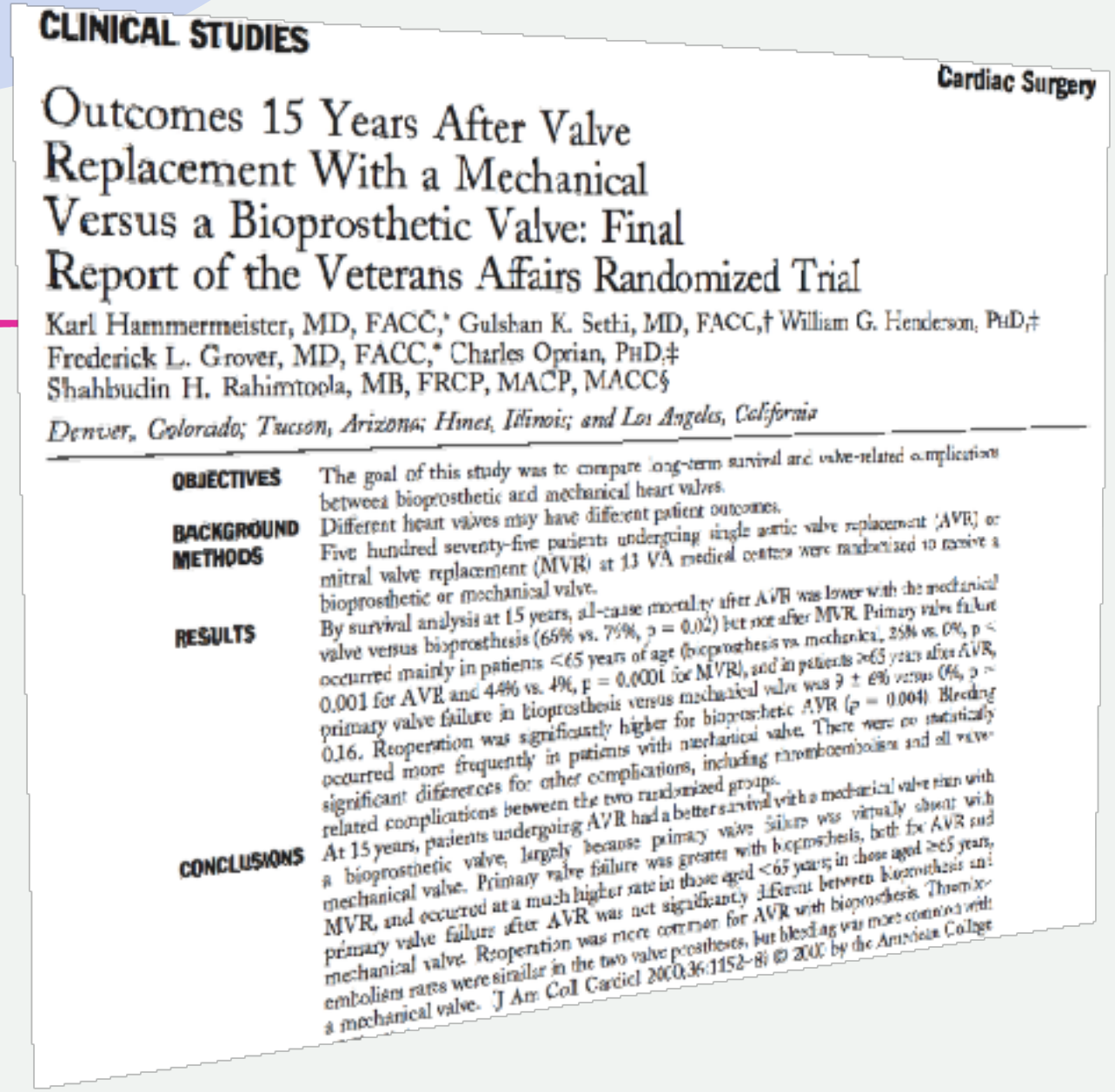
Hospital	Valve type (%), 2016/19 (aggregate data)	
	Mechanical	Biological
UK	17.3	82.5
King's College Hospital	5.9	94.1
London Bridge Hospital (PP)	7	93

Table 27: *Proportion of prosthesis types (%) used for isolated Aortic Valve Replacement in the UK over the last 3 years categorised by age of patient (<60; 60-69; >70 years)*

	Valve type by age group (%), 2016/19 (aggregate data)					
	<60		60-69		≥70	
Nation	Mechanical	Biological	Mechanical	Biological	Mechanical	Biological
UK	60.1	39.9	18.3	81.7	1.8	98.2
England	59.3	40.7	18.6	81.4	1.8	98.2
Northern Ireland	71.3	28.7	12.1	87.9	0.3	99.7
Scotland	78.1	21.9	13.6	86.4	1.0	99.0
Wales	59.5	40.5	18.7	81.3	2.1	97.9

Hospital	<60		60-69		≥70	
	Mech	Biol	Mech	Biol	Mech	Biol
UK	60.1	39.9	18.3	81.7	1.8	98.2
King's College Hospital	26.0	74.0	0	100.0	0	100
Royal Brompton Hospital	27.9	72.1	4.0	96.0	0	100
Southampton General hospital	30.8	69.2	6.3	93.8	9.5	90.5
Manchester Royal infirmary	31.3	68.8	6.7	93.3	4.7	95.3
St Thomas Hospital	37.5	62.5	5.0	95.0	1.2	98.8
Harefield Hospital	40.0	60.0	12.4	87.6	0	100
Glenfield Hospital	43.6	56.4	14.1	85.9	0.8	99.2
Golden Jubilee Hospital	48.1	51.9	18.2	81.8	3.7	96.3
Basildon Hospital	52.5	47.5	5.2	94.8	0	100
Hammersmith Hospital	53.6	46.4	5.6	94.4	0	100
Royal Infirmary of Edinburgh	53.7	46.3	12.6	87.4	7.3	92.7
Freeman Hospital	53.7	46.3	18.1	81.9	1.4	98.6
Blackpool Victoria Hospital	54.3	45.7	12.5	87.5	1.1	98.9
Nottingham City Hospital	54.5	45.5	37.4	62.6	5.6	94.4

Derriford Hospital	54.9	45.1	12.7	87.3	0.6	99.4
Bristol Royal Infirmary	56.6	43.4	12.8	87.2	2.6	97.4
Royal Sussex County Hospital	60.0	40.0	3.7	96.3	0	100
Liverpool Heart and Chest Hospital	62.8	37.2	14.0	86.0	0.8	99.2
Aberdeen Royal Infirmary	63.2	36.8	14.8	85.2	0	100
Papworth Hospital	64.7	35.3	8.7	91.3	0.5	99.5
St George's Hospital	66.7	33.3	30.8	69.2	2.9	97.1
James Cook University Hospital	66.7	33.3	27.5	72.5	1.3	98.7
Morriston Hospital	68.3	31.7	14.0	86.0	1.1	98.9
John Radcliffe Hospital	69.1	30.9	5.6	94.4	1.3	98.7
Queen Elizabeth Hospital, Edgbaston	70.9	29.1	8.7	91.3	0.8	99.2
Royal Victoria Hospital	71.3	28.7	12.1	87.9	0.3	99.7
Leeds General Infirmary	76.8	23.2	45.8	54.2	9.8	90.2
Barts and the London	77.1	22.9	33.7	66.3	4.6	95.4
Wythenshawe Hospital	77.1	22.9	20.7	79.3	1.0	99.0
University Hospital Coventry	78.3	21.7	11.7	88.3	0	100
University Hospital of North Staffordshire	81.4	18.6	32.9	67.1	0.8	99.2
New Cross Hospital	83.9	16.1	21.3	78.7	1.6	98.4
Castle Hill Hospital	84.8	15.2	36.5	63.5	2.8	97.2
Northern General Hospital	85.1	14.9	51.7	48.3	2.6	97.4



CLINICAL STUDIES

Cardiac Surgery

Outcomes 15 Years After Valve Replacement With a Mechanical Versus a Bioprosthetic Valve: Final Report of the Veterans Affairs Randomized Trial

Karl Hammermeister, MD, FACC,* Gulshan K. Sethi, MD, FACC,† William G. Henderson, PhD,‡
Frederick L. Grover, MD, FACC,* Charles Oprian, PhD,‡
Shahbudin H. Rahimtoola, MB, FRCP, MACP, MACC§

Denver, Colorado; Tucson, Arizona; Hines, Illinois; and Los Angeles, California

OBJECTIVES The goal of this study was to compare long-term survival and valve-related complications between bioprosthetic and mechanical heart valves.

BACKGROUND Different heart valves may have different patient outcomes.

METHODS Five hundred seventy-five patients undergoing single aortic valve replacement (AVR) or mitral valve replacement (MVR) at 13 VA medical centers were randomized to receive a bioprosthetic or mechanical valve.

RESULTS By survival analysis at 15 years, all-cause mortality after AVR was lower with the mechanical valve versus bioprosthesis (66% vs. 79%, p = 0.02) but not after MVR. Primary valve failure occurred mainly in patients <65 years of age (bioprosthesis vs. mechanical, 25% vs. 0%, p < 0.001 for AVR and 44% vs. 4%, p = 0.0001 for MVR), and in patients ≥65 years after AVR, primary valve failure in bioprosthesis versus mechanical valve was 9 ± 6% versus 0%, p = 0.16. Reoperation was significantly higher for bioprosthetic AVR (p = 0.004). Bleeding occurred more frequently in patients with mechanical valve. There were no statistically significant differences for other complications, including thromboembolism and all valve-related complications between the two randomized groups.

CONCLUSIONS At 15 years, patients undergoing AVR had a better survival with a mechanical valve than with a bioprosthetic valve, largely because primary valve failure was virtually absent with mechanical valve. Primary valve failure was greater with bioprosthesis, both for AVR and MVR, and occurred at a much higher rate in those aged <65 years; in those aged ≥65 years, primary valve failure after AVR was not significantly different between bioprosthesis and mechanical valve. Reoperation was more common for AVR with bioprosthesis. Thromboembolism rates were similar in the two valve prostheses, but bleeding was more common with a mechanical valve. J Am Coll Cardiol 2000;36:1152–8) © 2000 by the American College

The VA Trial

575 patients

- AVR 394
- MVR 181

Outcomes:

- Death
- VR complications

The VA Trial
AVR primary valve failure

At 15 years, patients undergoing AVR had better survival with a mechanical valve

Primary valve failure was greater with bioprosthesis especially <65 years

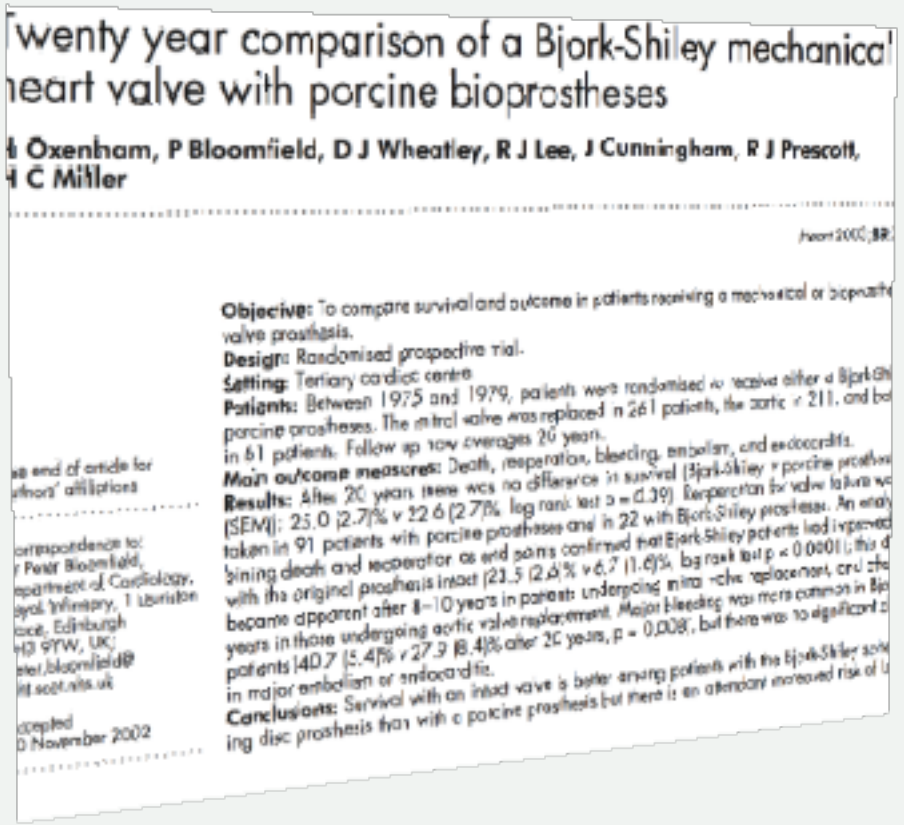
>65 years: primary valve failure after AVR not significantly different

Reoperation was more common for AVR with bioprosthesis

Thromboembolism rates were similar with the two prostheses

Bleeding was more common with a mechanical valve

The Edinburgh Trial



wenty year comparison of a Bjork-Shiley mechanica
heart valve with porcine bioprostheses

Oxenham, P Bloomfield, D J Wheatley, R J Lee, J Cunningham, R J Prescott,
C Miller

Objective: To compare survival and outcome in patients receiving a mechanical or biopros
valve prosthesis.
Design: Randomised prospective trial.
Setting: Tertiary cardiac centre
Patients: Between 1975 and 1979, patients were randomised to receive either a Bjork-Shi
porcine prostheses. The mitral valve was replaced in 261 patients, the aortic in 211, and bo
in 61 patients. Follow up now averages 20 years.
Main outcome measures: Death, reoperation, bleeding, embolism, and endocarditis.
Results: After 20 years there was no difference in survival (Bjork-Shiley v porcine prosthe
(SEM)): 25.0 (2.7)% v 22.6 (2.7)% log rank test p = 0.39). Reoperation for valve failure wa
taken in 91 patients with porcine prostheses and in 22 with Bjork-Shiley prostheses. An early
joining death and reoperation as end points confirmed that Bjork-Shiley patients had improved
with the original prosthesis intact (23.5 (2.6)% v 6.7 (1.6)%, log rank test p < 0.0001); this d
became apparent after 8–10 years in patients undergoing mitral valve replacement, and the
years in those undergoing aortic valve replacement. Major bleeding was more common in Bjo
patients (40.7 (5.4)% v 27.9 (8.4)% after 20 years, p = 0.008), but there was no significant d
in major embolism or endocarditis.
Conclusions: Survival with an intact valve is better among patients with the Bjork-Shiley scho
ing disc prosthesis than with a porcine prosthesis but there is an attendant increased risk of

end of article for
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cepted
0 November 2002

- 533 patients
  - AVR 211
  - MVR 261
  - AVR+MVR 61
- Outcomes:
  - Death
  - VR complications

The Edinburgh Trial

There was no difference in survival between the two groups with regards to aortic valve replacement

No significant difference in rates of valve thrombosis and thromboembolism

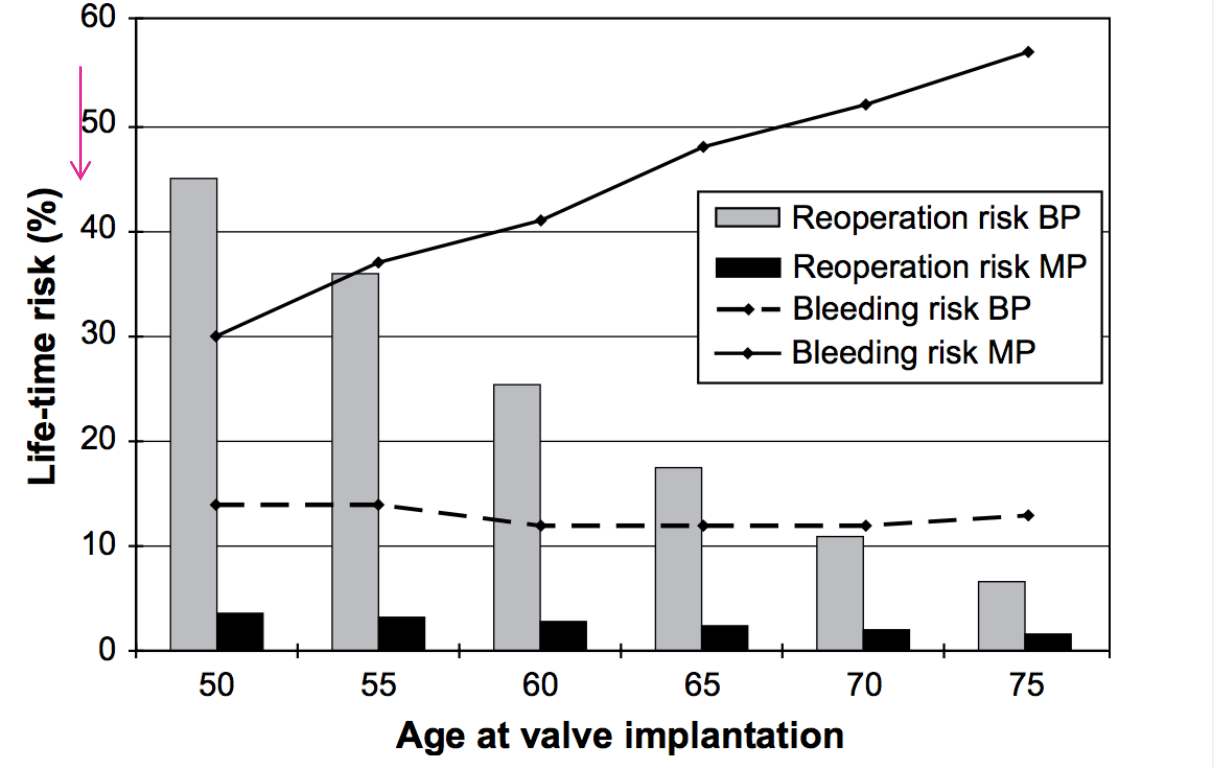
Higher rates of bleeding with mechanical prostheses

Higher rates of re-intervention with bioprostheses

Patient outcome after aortic valve replacement with a mechanical or biological prosthesis: Weighing lifetime anticoagulant-related event risk against reoperation risk

Martijn W. A. van Geldorp, MD, MSc,[a] W. R. Eric Jamieson, MD,[c] A. Pieter Kappetein, MD, PhD,[a] Jian Ye, MD,[c] Guy J. Fradet, MD,[c] Marinus J. C. Eijkemans, PhD,[b] Gary L. Grunkemeier, PhD,[d] Ad J. J. C. Bogers, MD, PhD,[a] and Johanna J. M. Takkenberg, MD, PhD[a]

The Journal of Thoracic and Cardiovascular Surgery • Volume 137, Number 4 2009

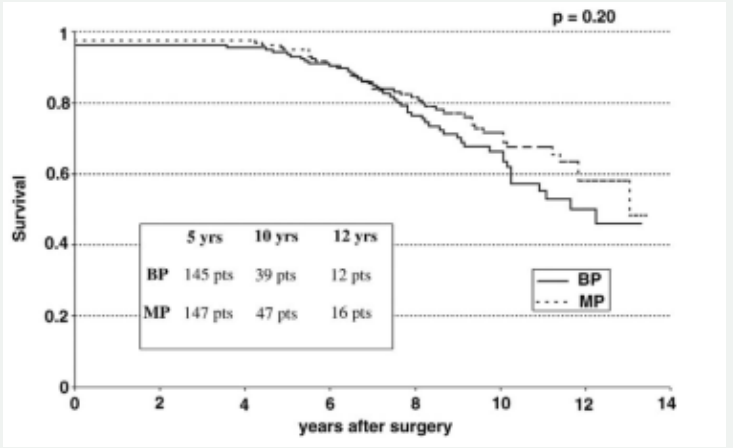


JACC Vol. 54, No. 20, 2009

Similar survival rate

Similar rate of occurrence of:

- thromboembolism
- bleeding
- endocarditis
- adverse prosthesis-related events



Patients who had aortic valve bioprosthesis had a significantly higher risk of valve failure and reoperation

Aortic Valve Replacement

A Prospective Randomized Evaluation of Mechanical Versus Biological Valves in Patients Ages 55 to 70 Years

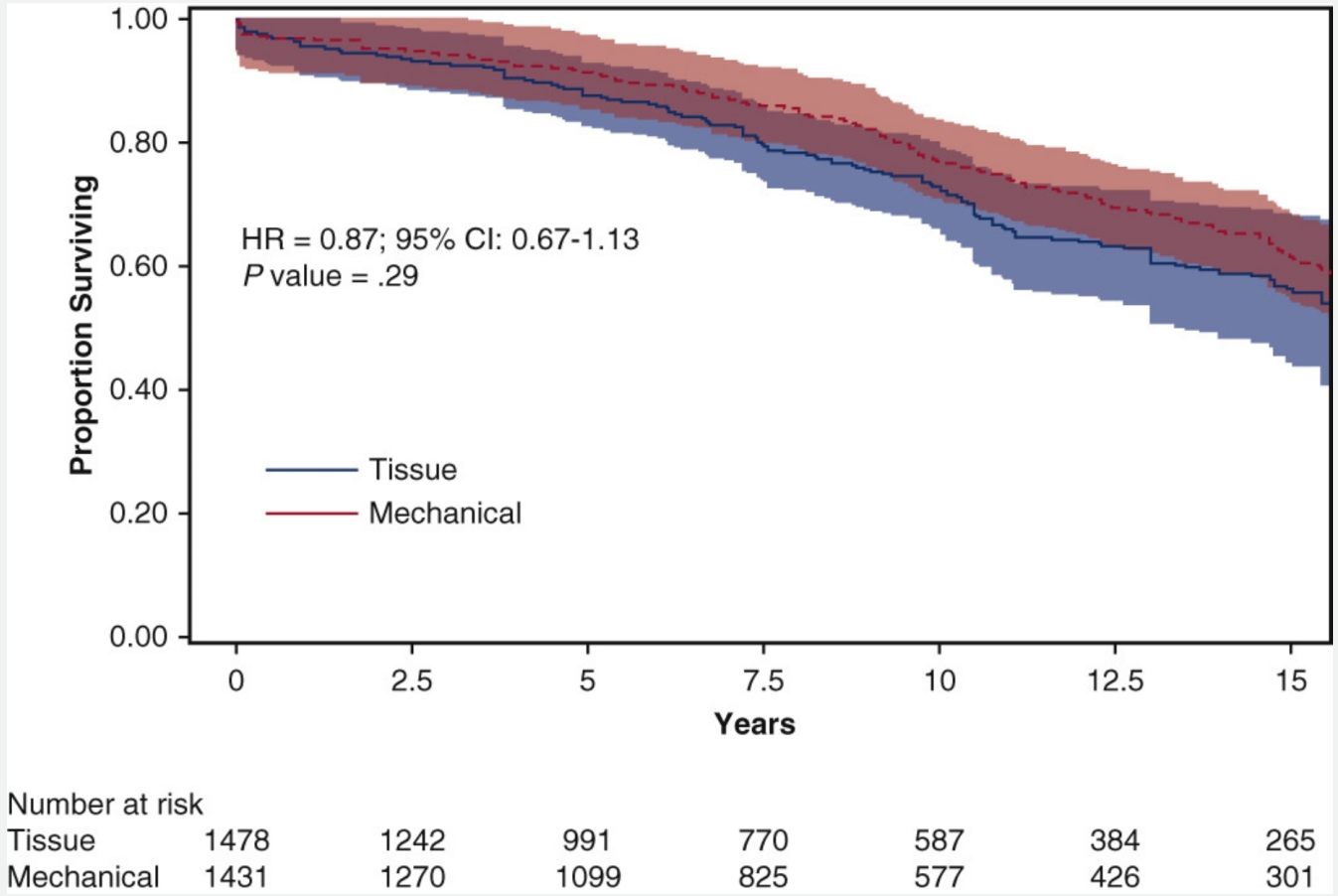
Paolo Stassano, MD,* Luigi Di Tommaso, MD,* Mario Monaco, MD,† Francesco Iorio, MD,* Paolo Pepino, MD,† Nicola Spampinato, MD,* Carlo Vosa, MD*

Tissue versus mechanical aortic valve replacement in younger patients: A multicenter analysis

Alexander Iribarne, MD, MS,[a] Bruce J. Leavitt, MD,[b] Michael P. Robich, MD,[c] Gerald L. Sardella, MD,[d] Daniel J. Gelb, MD, MS,[e] Yvon R. Baribeau, MD,[f] Jock N. McCullough, MD,[a] Paul W. Weldner, MD,[g] Robert A. Clough, MD,[h] Cathy S. Ross, MS,[e] David J. Malenka, MD,[e] and Anthony W. DiScipio, MD,[a] for the Northern New England Cardiovascular Disease Study Group

Multicenter, retrospective analysis of isolated AVRs
9388 Patients aged 50 to 65 years

No difference in adjusted long-term survival according to prosthesis type, but tissue valves were associated with a higher risk of reoperation.



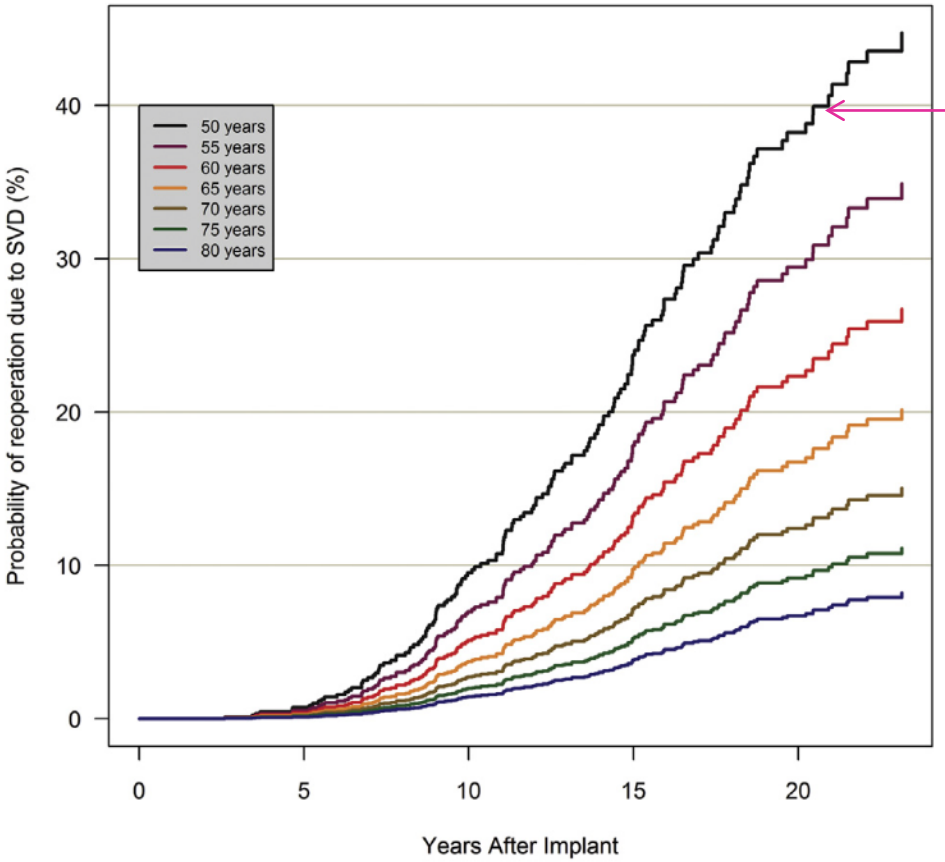
The Journal of Thoracic and Cardiovascular Surgery 2019 1581529-1538.e2DOI: (10.1016/j.jtcvs.2019.02.076)

Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position

Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Candolfi, PhD, Alain Mirza, MD, Claudia Loardi, MD, Marc-Antoine May, MD, Rym El-Khoury, MD, Michel Marchand, MD, and Michel Aupart, MD

Department of Cardiac Surgery, Tours University Hospital, France; and Department of Biostatistic
Switzerland

Reoperation for SVD at 20 years **40%**



(Ann Thorac Surg 2015;99:831–7)

Special circumstances

Pregnancy

Endocarditis

Very young

Renal disease

Lifetime management of 40-60 yr olds

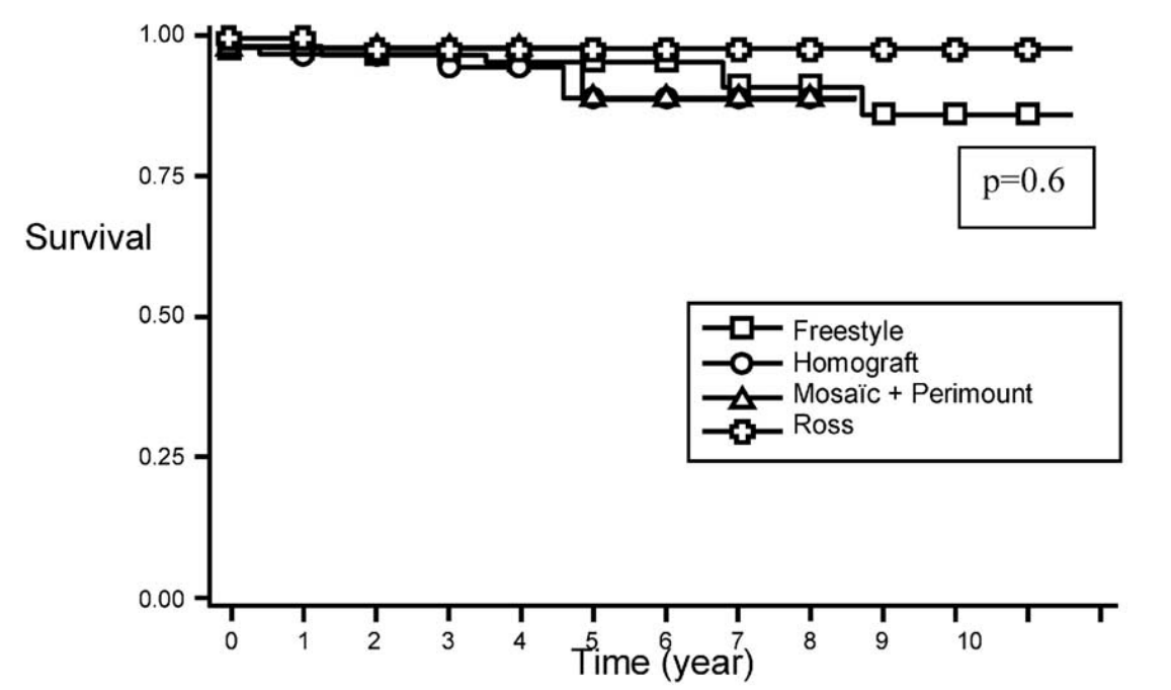
- Mechanical
- SAVR with/without ARE >> ViV >> ViV/Redo SAVR
- TAVI >> ViV >> SAVR

What about homograft, stentless, Ross…

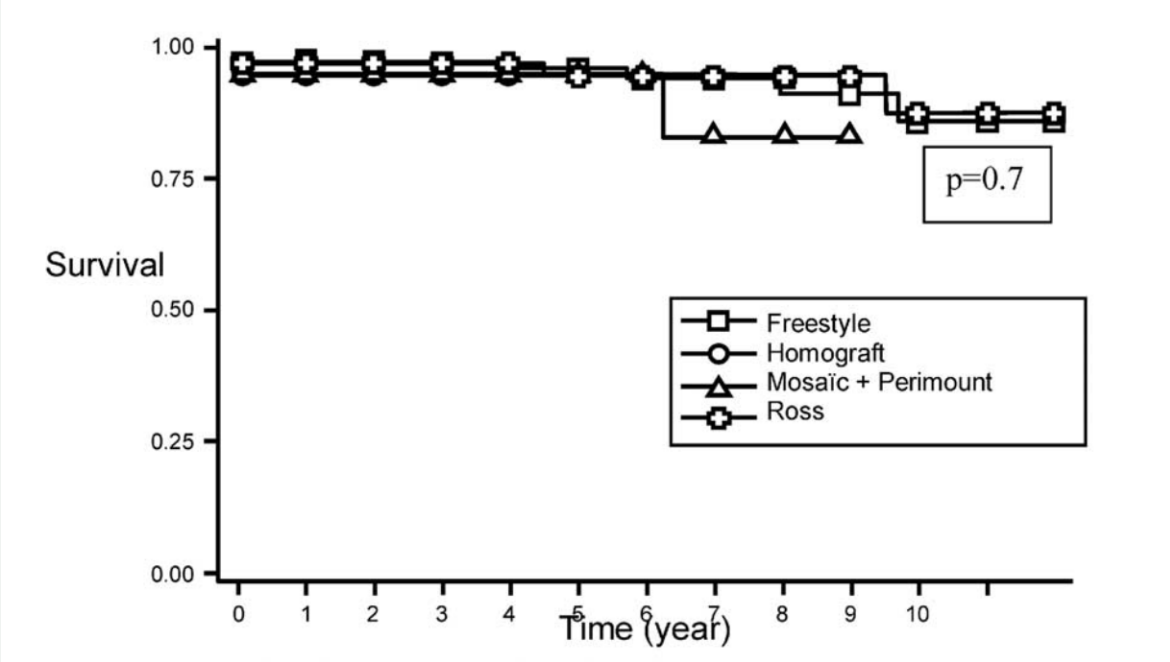
Which biologic valve should we select for the 45- to 65-year-old age group requiring aortic valve replacement?

F. Dagenais, MD, P. Cartier, MD,† P. Voisine, MD, D. Desaulniers, MD, J. Perron, MD, R. Baillot, MD, G. Raymond, MD, J. Métras, MD, D. Doyle, MD, and P. Mathieu, MD

Freedom from reoperation



Freedom from cardiac death



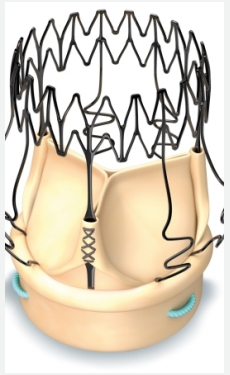
New options

TAVI

Minimal access surgery with sutureless valves

Valve in valve

Ozaki procedure

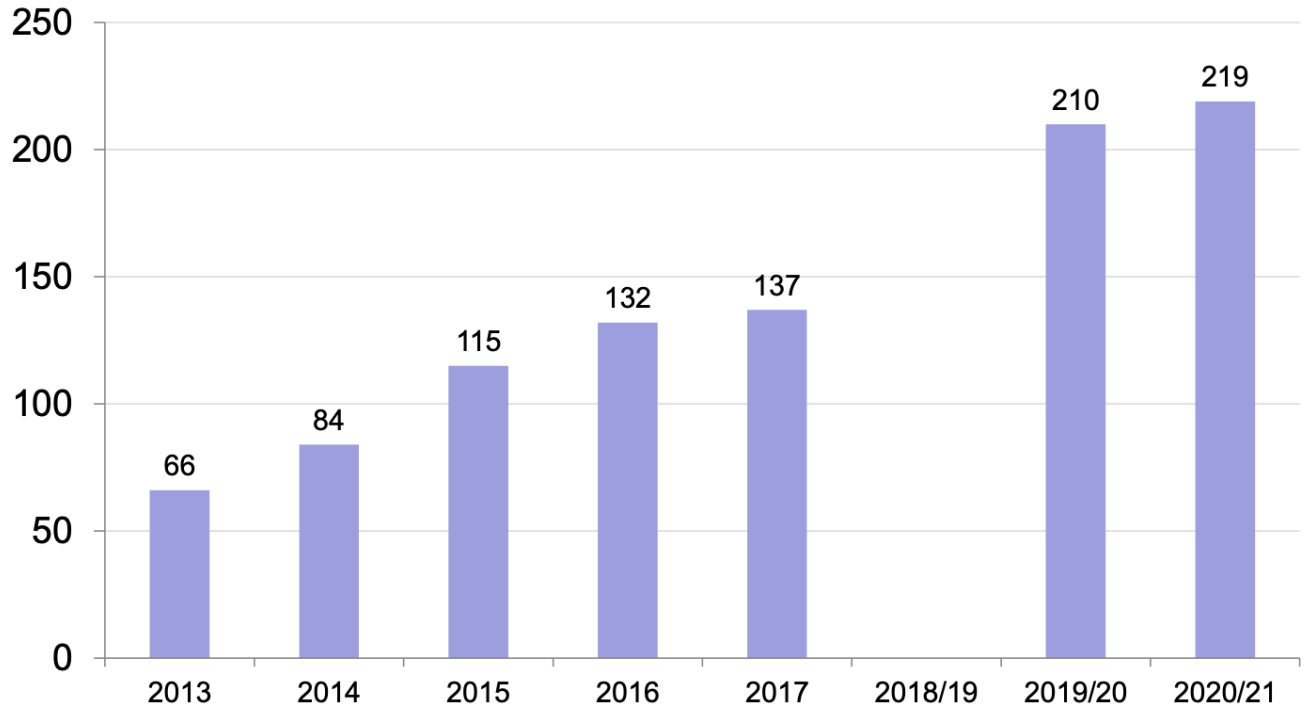


NICOR

TAVI Extract
25-10-2021

BCIS
2020-21 data

TAVI for Aortic Bioprosthetic Valve Failure



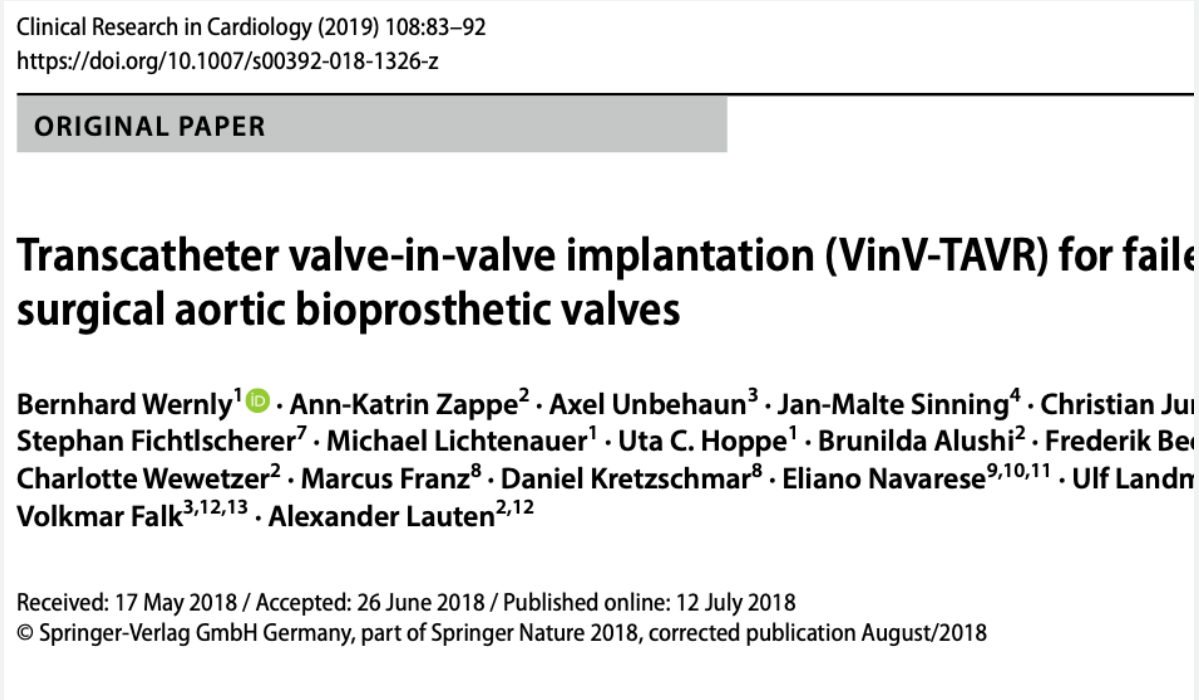
To Contents

Valve in valve

Conclusion

Safe procedure resulting in hemodynamic improvement in the majority of patients.

Residual stenosis is a common finding which can be observed in 25%



Clinical Research in Cardiology (2019) 108:83–92
https://doi.org/10.1007/s00392-018-1326-z

ORIGINAL PAPER

Transcatheter valve-in-valve implantation (VinV-TAVR) for faile surgical aortic bioprosthetic valves

Bernhard Wernly[1] · Ann-Katrin Zappe[2] · Axel Unbehaun[3] · Jan-Malte Sinning[4] · Christian Ju
Stephan Fichtlscherer[7] · Michael Lichtenauer[1] · Uta C. Hoppe[1] · Brunilda Alushi[2] · Frederik Be
Charlotte Wewetzer[2] · Marcus Franz[8] · Daniel Kretzschmar[8] · Eliano Navarese[9,10,11] · Ulf Landm
Volkmar Falk[3,12,13] · Alexander Lauten[2,12]

Received: 17 May 2018 / Accepted: 26 June 2018 / Published online: 12 July 2018

Valve-in-valve TAVI is an important component of this lifetime planning

"Valve-in-Valve TAVI may be the preferred approach for the treatment of failed biological prostheses"[1]

Matched 30-day outcomes (n=131 pairs)[1]

30-day Mortality	New Pacemaker	Blood Transfusion	30-day Readmission
-7.5% absolute	-9.8% absolute	-63.1% absolute	-3.1% absolute
vs redo surgery	vs redo surgery	vs redo surgery	vs redo surgery

Adapted from the original article.

1. Tam DY, Dharma C, Rocha RV, et al. Transcatheter ViV Versus Redo Surgical AVR for the Management of degenerated Biological Prosthesis: Early and Late Outcomes in a Propensity-Matched Cohort. JACC Cardiovasc Interv. 2020;13(6):765-774.

*Despite being a relatively uncommon procedure, early aortic THV-in-THV outcomes are encouraging**

“In the future, redo-TAVI may play a key role in treating patients whose life expectancy exceeds valve durability”[1]

0,2% Incidence of redo TAVI 1-year or later after the first TAVI

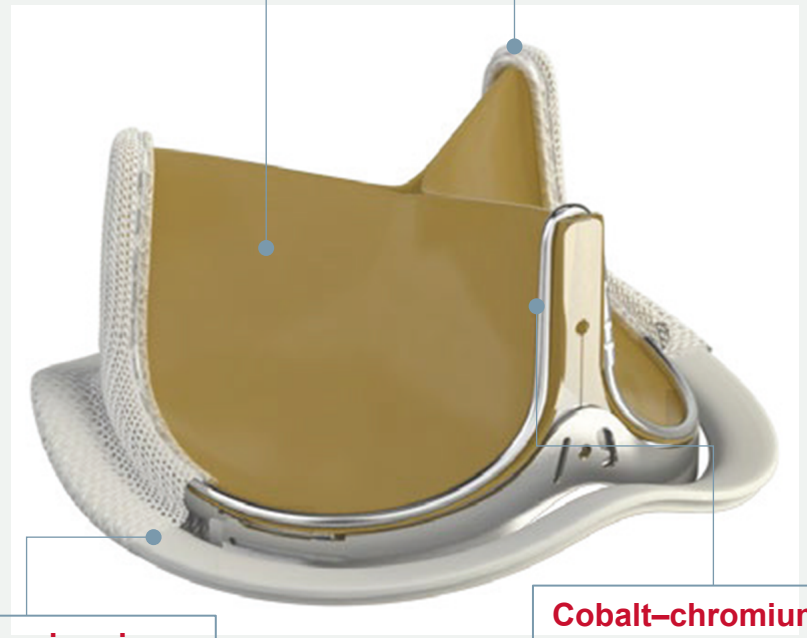
30-day outcomes redo TAVI 1 year or later after the first TAVI (n=138)[1]

1,4%	All cause mortality
0,7%	All Stroke
14,3%	High residual gradient ≥ 20 mmHg
0,7%	Coronary obstruction

* Aortic THV-in-THV

1. Landes U, Webb JG, De Backer O, et al. Repeat Transcatheter Aortic Valve Replacement for Transcatheter Prosthesis Dysfunction. J Am Coll Cardiol. 2020;75(16):1882-1893.

INSPIRIS RESILIA aortic valve (model 11500A)



Design characteristics

- Low profile for patients with a small aortic root
- Flexible, cobalt–chromium alloy wireform
  - Corrosion resistant
  - Good spring efficiency and fatigue resistance
  - Covered with a polyester fabric
- Scalloped silicone sewing ring
  - Conforms to the natural aortic annulus and fits against an irregular or calcified tissue bed
  - Has three equally spaced suture markers to help valve orientation and suture placement
- Integrated valve holder facilitates valve handling and suturing during implantations, and is detached by the surgeon

1. Edwards Lifesciences INSPIRIS RESILIA aortic valve. Model 11500a. Instructions for Use. 2020

RESILIA tissue out-performs standard PERIMOUNT valve in juvenile sheep study

Flameng W *et al. J Thorac Cardiovasc Surg.* 2015; 149: 340–5

Aim

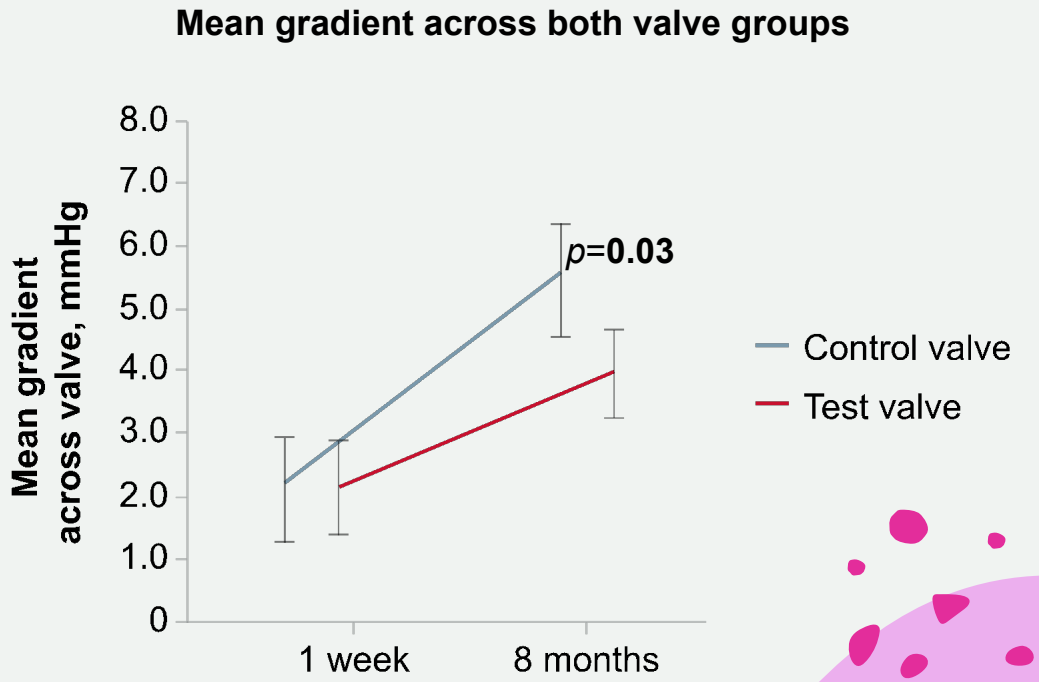
To assess the effects of a novel advanced tissue preservation technology on valve function and durability in a juvenile sheep model

Methods

- 45 juvenile sheep received either a standard PERIMOUNT mitral valve (control group) or a PERIMOUNT mitral valve incorporating RESILIA tissue (test group)
- TTE was performed at 1 week and 8 months post-operatively
- The animals were killed and the valves were examined radiographically, histologically and chemically

Results

- Both groups showed normal valve function at 1 week
- At 8-month follow-up, 31 sheep were in perfect condition
- 64% of valves in the control group developed moderate-to-severe turbulence *vs* 6% in the test group (*p*=**0.0008**)
- Cardiac output increased to the same extent in both groups (*vs* baseline, *p*<**0.01**)



INSPIRIS RESILIA valve registry for young patients demonstrates excellent haemodynamics and good safety up to 1 year

1. Meuris B *et al. J Cardiothorac Surg*. 2020; 15: 119;

2. De Paulis R *et al.* Presented at the European Association for Cardio-Thoracic Surgery annual meeting, 2021

Results

Patient characteristics	Age ≤50 years (n=103)	Age 51–60 years (n=332)	*p* value
Age, years ± SD	43.5 ± 7.7	56.6 ± 2.7	N/A
Female, %	25.2	22.0	0.491
EuroSCORE II, % ± SD	1.7 ± 1.7	1.5 ± 1.6	0.347
NYHA class III or IV, %	30.1	25.4	0.344
Dominating aortic valve: Stenosis, % Regurgitation, % Severe AR without/trace stenosis, %	 61.8 33.3 19.6	 74.7 20.8 11.4	 **0.011** **0.009** **0.034**
Bicuspid aortic valve, %	82.5	70.5	**0.016**
CAD, %	17.6	25.1	0.121
Diabetes mellitus II, %	6.8	15.4	**0.025**
Hypertension, %	31.1	55.7	**<0.001**

	Median (IQR)	Min–max
Cross-clamp time, min	70 (56–89)	29–169
CPB time, min	89 (73–117)	33–222
Operation time, min	187 (156–233)	64–438
Length of stay: Hospital, days ICU, hours	 7.0 (6–10) 29.5 (22–56)	 1–33 0–582

Younger patients (≤50 years) were more likely to have bicuspid valves or AR at baseline

Older patients (51–60 years) were more likely to have aortic stenosis, hypertension or diabetes at baseline

1. Durability of bioprosthetic aortic valves in patients under the age of 60 years – rationale and design of the international INDURE registry ;
2. Surgical aortic valve replacement in patients under 60 years old: A prospective, multicentre real-world registry in Europe and Canada

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Outcomes, n/N (%)*	30 days	3–6 months	1 year
All-cause mortality	4/434 (0.9)	3/392 (0.8)	1/196 (0.5)
Valve-relatedness of mortality			
Valve-related	0/434 (0.0)	0/392 (0.0)	0/196 (0.0)
Not valve-related	2/434 (0.5)	2/392 (0.5)	0/196 (0.0)
Unknown	2/434 (0.5)	1/392 (0.3)	1/196 (0.5)
Repeated procedure	0/434 (0.0)	2/381 (0.5)	1/189 (0.5)
Stroke	2/425 (0.5)	1/382 (0.3)	0/190 (0.0)
Life-threatening bleeding	16/434 (3.7)	0/382 (0.0)	0/197 (0.0)
Pacemaker implantation	17/434 (3.9)	2/381 (0.5)	0/196 (0.0)
Endocarditis	0/434 (0.0)	2/377 (0.5)	0/189 (0.0)
Valve thrombosis	0/434 (0.0)	3/379 (0.8)	1/191 (0.5)
SVD stage 3†			
New/worsening of transprosthesis regurgitation ≥2 grades	0/434 (0.0)	N/A	0/160 (0.0)
Worsening of mean PG ≥20 mmHg + EOA ≥0.6 cm^2 + DVI ≥0.2	0/409 (0.0)	N/A	0/157 (0.0)

Low rates of all-cause mortality and endocarditis

No stage 3 SVD

Conclusion

INDURE registry data indicate excellent haemodynamic outcomes. Preliminary safety outcomes up to 1 year show low all-cause mortality and endocarditis rates, and no stage 3 SVD

*Follow-up data for each time point represent additional new events; †As defined by Salaun E *et al. Heart*. 2018; **104:** 1323–32

1. Durability of bioprosthetic aortic valves in patients under the age of 60 years – rationale and design of the international INDURE registry ;
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Large multicentre study of RESILIA tissue valve shows favourable outcomes through 5 years

COMMENCE AORTIC

Bavaria J *et al. Ann Thorac Surg.* 2022; doi: 10.1016/j.athoracsur.2021.12.058

Aim

To present 5-year results from the COMMENCE trial, evaluating safety and effectiveness after AVR with the RESILIA tissue valve

Methods & patient population

- Prospective, multicentre single-arm trial
- 689 patients (mean age 66.9 ± 11.6 years) with symptomatic AV disease who underwent SAVR
  - Model 11000: tri-leaflet valve identical to the PERIMOUNT Magna Ease valve except for RESILIA tissue leaflets

Results

- Mean gradient at 5 years: 11.5 ± 6.0 mmHg
- Mean EOA at 5 years: 1.6 ± 0.5 cm^2
- PVL: 97.8% none/trace
- Transvalvular regurgitation: 96.3% none/trace
- Results support durability over the observational period

Limitations

- Longer-term follow-up required and ongoing

Endpoint	Early (≤30 days) events, n (%)	**Probability event free at 5 years, % (95% CI)**
All-cause mortality	8 (1.2)	89.2 (86.7–91.6)
Stroke	11 (1.6)	94.5 (92.7–96.3)
Valve thrombosis	0 (0)	100 (100–100)
Major bleeding	5 (0.7)	94.3 (92.4–96.1)
Endocarditis	0 (0)	97.8 (96.6–99.0)
Major PVL	1 (0.1)	99.5 (99.0–100)
Non-SVD	0 (0)	100 (100–100)
SVD	0 (0)	100 (100–100)
Reoperation	1 (0.1)	98.7 (97.8–99.6)

Conclusion

Five-year results from the COMMENCE trial indicate that the RESILIA tissue valve has a favourable safety profile and stable haemodynamic performance, with no SVD up to 5 years

*One SVD event reported at Post-operative Day 1,848

INSPIRIS RESILIA valve performs well in young patients to 3 years

Francica A *et al.* Presented at the Heart Valve Society Annual Meeting, 2022

Aim

To assess short- and mid-term clinical and haemodynamic outcomes of the INSPIRIS RESILIA valve in young patients

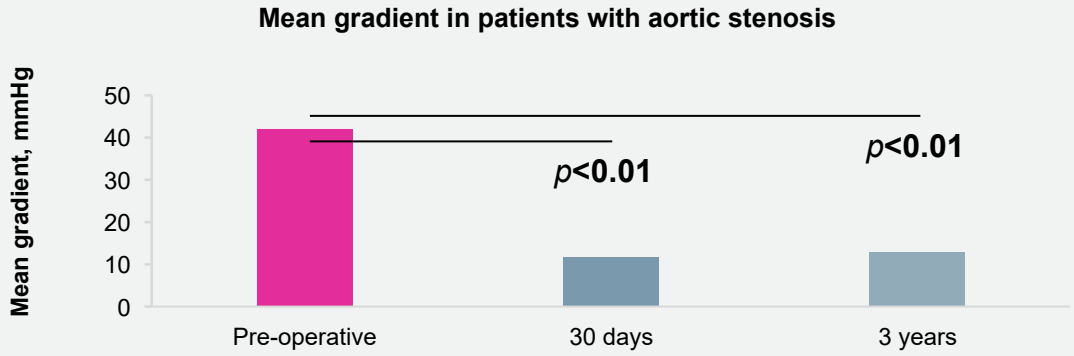
Methods & patient population

- Single-centre study of 161 adults (mean age 56.8 ± 10.0 years) who underwent SAVR with an INSPIRIS RESILIA valve between 2017 and 2021
- Kaplan–Meier curves used to assess survival, and freedom from reoperation, SVD, endocarditis and rehospitalisation
- Short- and mid-term echocardiographic data assessed

Results

- Overall survival: 99.4% at 30 days; 93.8% at 3 years
- Freedom from cardiovascular death and from SVD: 100%
- 1 patient (0.6%) underwent reoperation for endocarditis
- 2 patients (1.2%) required pacemaker implantation

- Patients who had SAVR for AR showed LV reverse remodelling (LVEDV: 123.8 ± 32.5 mL at 3 years *vs* 238.5 ± 131.04 mL pre-operatively, ***p*<0.01**)



Conclusion

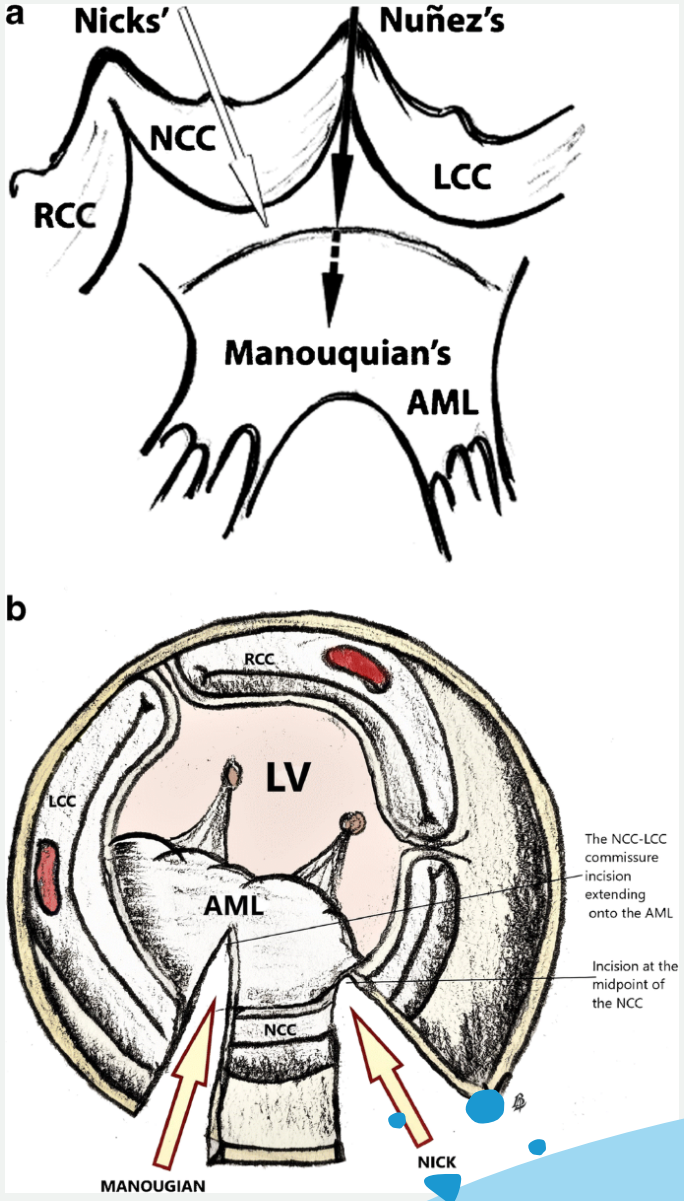
The INSPIRIS RESILIA valve is effective in young patients, with good safety outcomes and excellent short- and mid-term haemodynamic performance

Edwards INSPIRIS RESILIA® prosthesis for aortic valve replacement in young adults: Short-term and mid-term clinical outcome and haemodynamic performances

Root enlargement

Types:

- Nicks
- Manouguian
- Nunez (modified Manouguian)
- Kanno-Rastan procedures



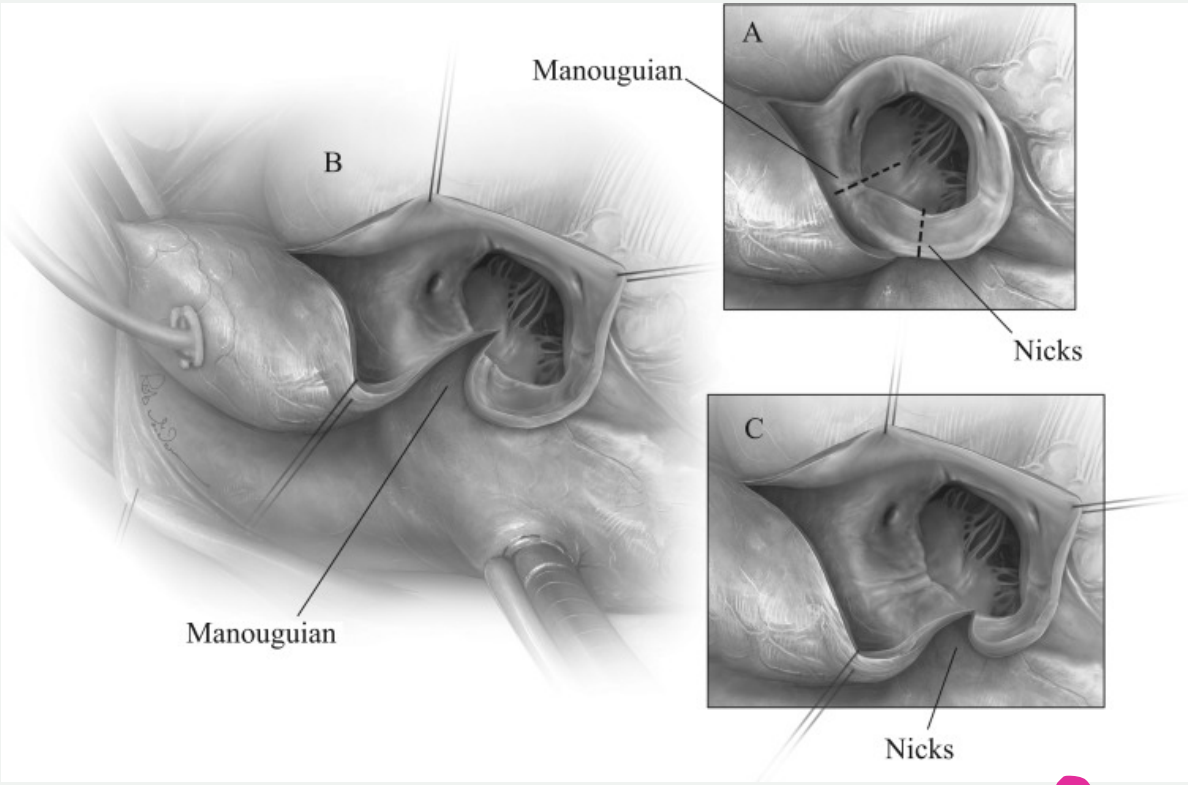
Root enlargement

Larger prosthesis

Lower incidence of PPM

Lower incidence of Pacemaker

No significant increase in risk



Massias SA, Pittams A, Mohamed M, Ahmed S, Younas H, Harky A. Aortic root enlargement: When and how. J Card Surg. 2021 Jan;36(1):229-235. doi: 10.1111/jocs.15175. Epub 2020 Oct 30. PMID: 33124077.

Over to John

Thank you

What is your choice?

1. Mechanical
2. SAVR with/without ARE >> ViV >> ViV/Redo SAVR
3. TAVI >> ViV >> SAVR