Национальный Медицинский Исследовательский Центр
имени академика Е.Н. Мешалкина
Министерства здравоохранения российской федерации

БИОЛОГИЧЕСКИЕ ПРОТЕЗЫ АОРТАЛЬНОГО КЛАПАНА

Богачев-Прокофьев А.В.

Новосибирск 2022

The Carpentier-Edwards aortic pericardial valve portfolio is built upon the PERIMOUNT bioprosthesis design

Carpentier-Edwards
PERIMOUNT
Pericardial Aortic Bioprosthesis

Model 2900

Features

Bioengineered
Flexible CoCr alloy stent
Pericardial leaflets

Carpentier-Edwards
Magna
Pericardial Aortic Bioprosthesis

Model 3000

Features

Supra-annular design
Upsize potential

Bioengineered
Flexible CoCr alloy stent
Pericardial leaflets

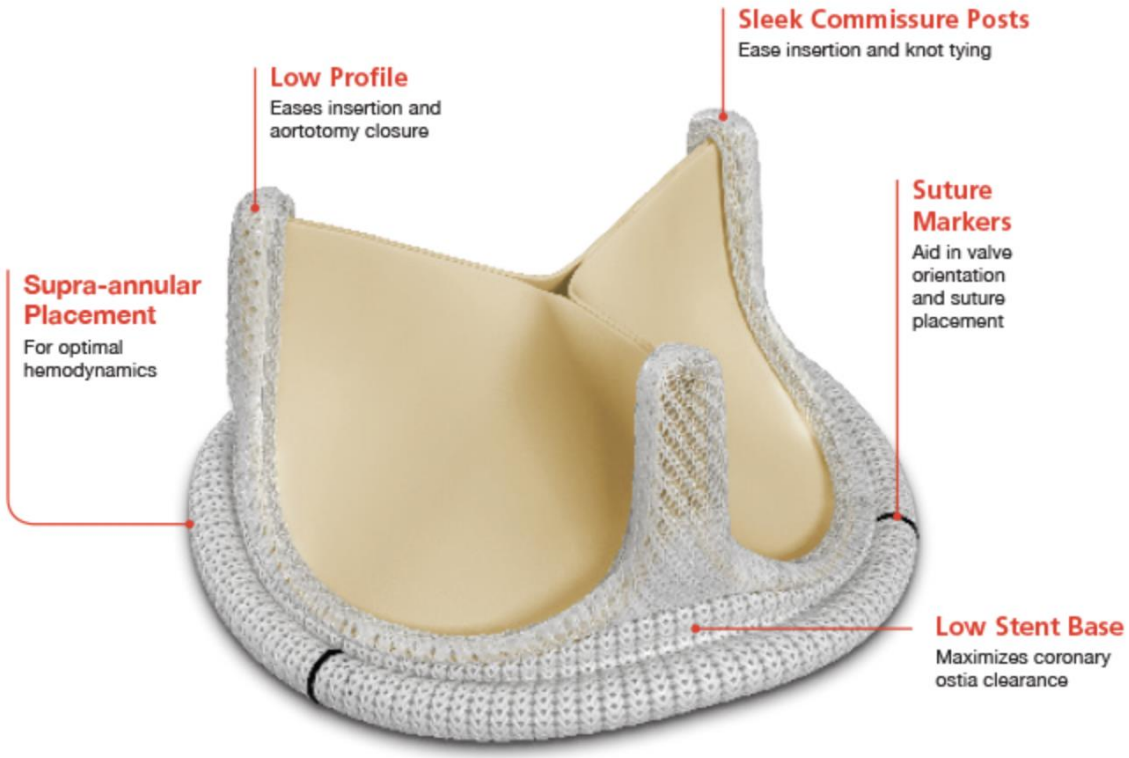
Carpentier-Edwards
Magna Ease
Pericardial Aortic Bioprosthesis

Model 3300TFX

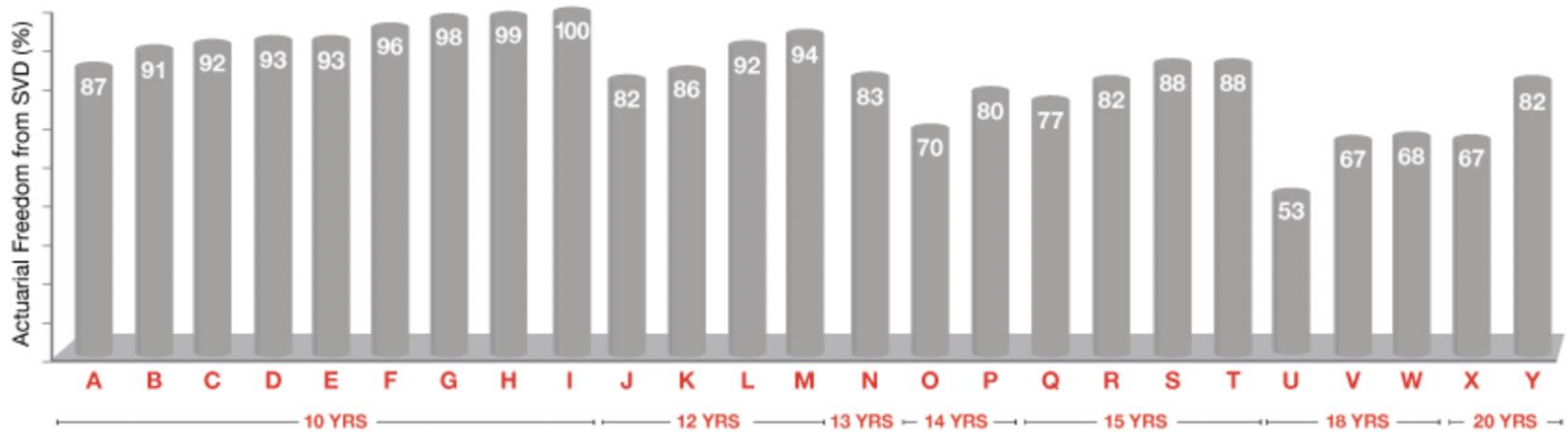
Features

Lower profile
Ease of Implant
Supra-annular design
Upsize potential

Bioengineered
Flexible Cocr alloy stent
Pericardial leaflets
ThermaFix process ‡



Actuarial Freedom from Structural Valve Deterioration – PERIMOUNT Aortic Bioprostheses



A Pelletier[5] (All Ages)
B Cosgrove[6*] (All Ages)
C Carrier[7] (All Ages)
D Murakami[8] (All Ages)
E Aupart[9] (All Ages)
F Aupart[10] (All Ages)
G Aupart[11] (All Ages)
H Gao[12*] (All Ages)
I Le Tourneau[13] (All Ages)
J Banbury[14] (All Ages)
K Dellgren[15] (All Ages)
L Nakajima[16] (All Ages)
M Neville[17] (All Ages)
N Pellerin[18] (All Ages)
O Frater[19] (All Ages)
P Poirier[20] (All Ages)
Q Banbury[21*] (All Ages)
R McClure[22] (All Ages)
S Minakata[23*] (All Ages)
T Jamieson[24] (All Ages)
U Biglioli[25*] (All Ages)
V Bergoënd[26] (All Ages)
W Aupart[27] (All Ages)
X Forcillo[28†] (All Ages)
Y 20 Year[29*] (≥65)

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

Ann Thorac Surg. 2015 Mar;99(3):831-7.
doi: 10.1016/j.athoracsur.2014.09.030.

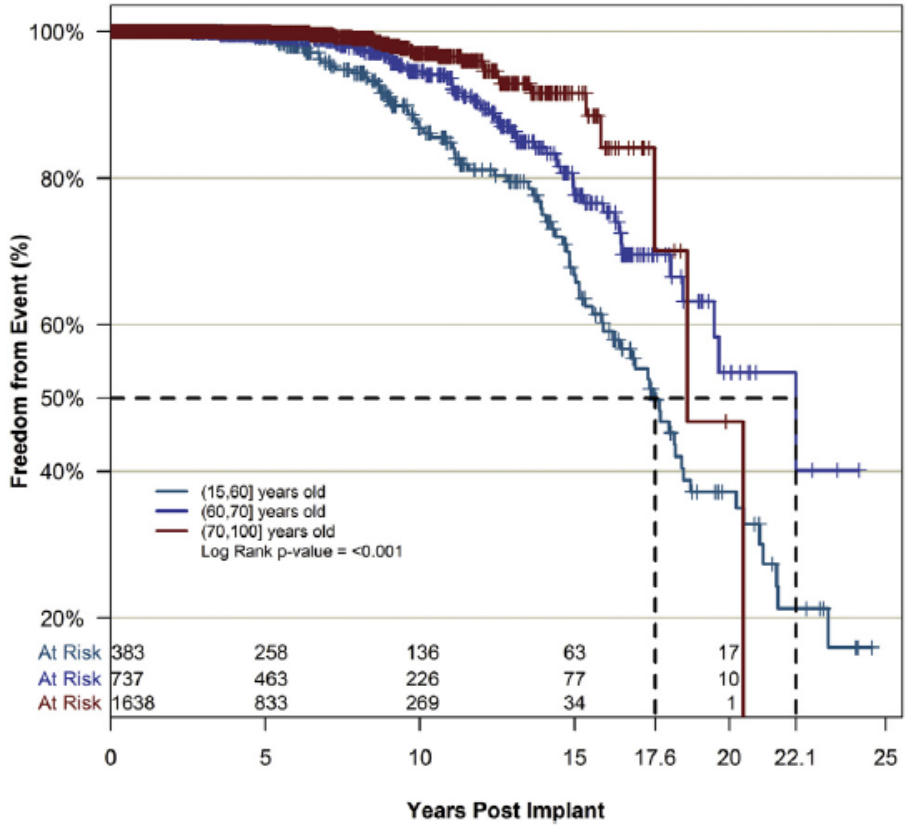
Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Candolfi, PhD, Alain Mirza, MD, Claudia Loardi, MD, Marc-Antoine May, MD, Rym El-Khoury, MD, Michel Marchand, MD, and Michel Aupart, MD

Department of Cardiac Surgery, Tours University Hospital, France; and Department of Biostatistics, Edwards Lifesciences, Nyon, Switzerland

From 1984 to 2008 at our center, **2,659 patients** (mean age, 70.7 ± 10.4 years) underwent aortic valve replacement using the Perimount pericardial bioprostheses.
Patients were prospectively followed on an annual basis (mean 6.7 ± 4.8 years, range 0 to 24.6 years) with an echocardiogram at the time of follow-up.

Age-stratified **freedom from reoperation due to structural valve deterioration** at **15** and 20 years was **70.8% ± 4.1%** and 38.1% ± 5.6%, respectively, for the group aged 60 years or less, **82.7% ± 2.9%** and 59.6% ± 7.6% for those 60 to 70 years, and **98.1% ± 0.8%** at 15 years and above for the oldest group.

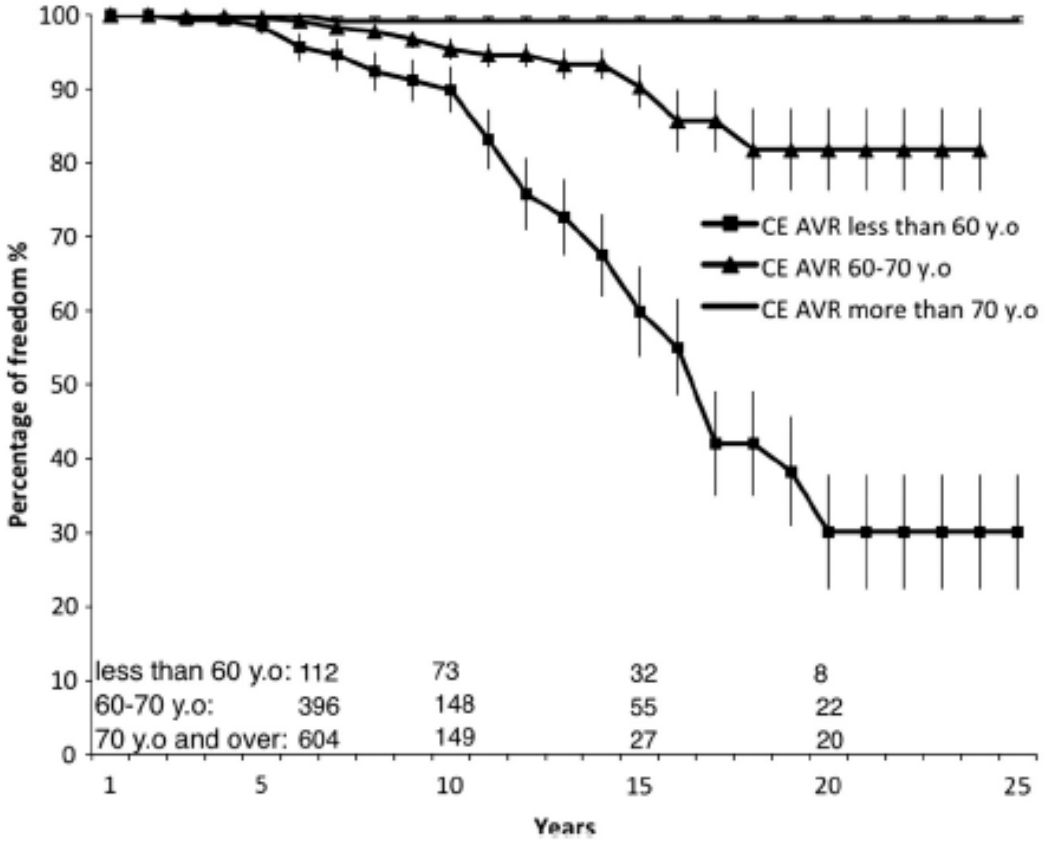
Expected valve durability is 19.7 years for the entire cohort.



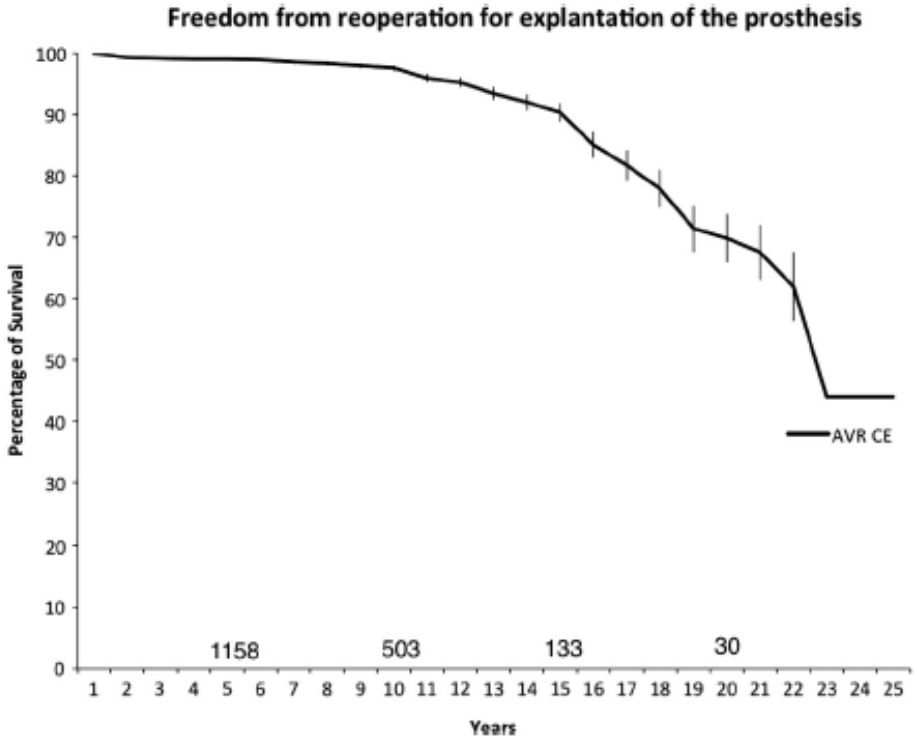
Carpentier-Edwards Pericardial Valve in the Aortic Position: 25-Years Experience

Jessica Forcillo, MD, MS, Michel Pellerin, MD, Louis P. Perrault, MD, PhD, Raymond Cartier, MD, Denis Bouchard, MD, MS, Philippe Demers, MD, MS, and Michel Carrier, MD, MBA

Department of Cardiac Surgery, Montreal Heart Institute and Université de Montréal, Montreal, Quebec, Canada



Freedom rate from re-exploration for prosthesis valve dysfunction by age groups



Retrospective cohort study of 2,405 patients from November 1981 to March 2011

The Trifecta GT valve further provides protection using Linx AC technology, a valve treatment that resists calcification[1,*] by:

- Reducing free aldehydes[2,3]
- Extracting lipids[4]
- Minimizing cholesterol uptake[5]
- Stabilizing leaflet collagen[5]

*No clinical data are currently available evaluating the long-term impact of anticalcification tissue treatment in humans.

REORDER NUMBER	TISSUE ANNULUS DIAMETER (MM)	CUFF OUTER DIAMETER (MM)
TFGT-19A	19	24
TFGT-21A	21	26
TFGT-23A	23	28
TFGT-25A	25	31
TFGT-27A	27	33
TFGT-29A	29	35

TITANIUM BAND

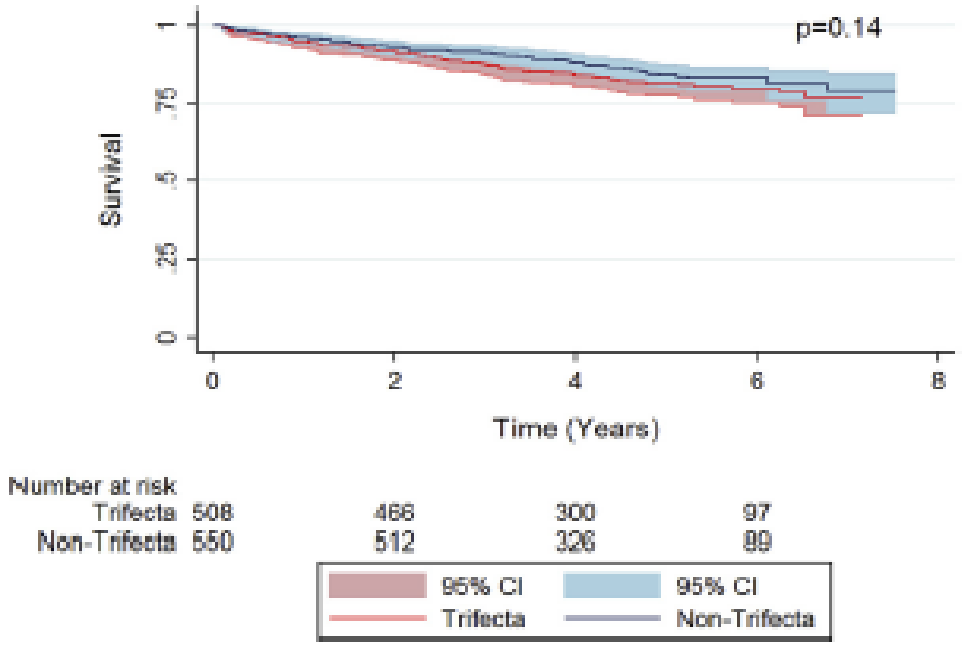
Enhances strength and improves visualization for future valve interventions

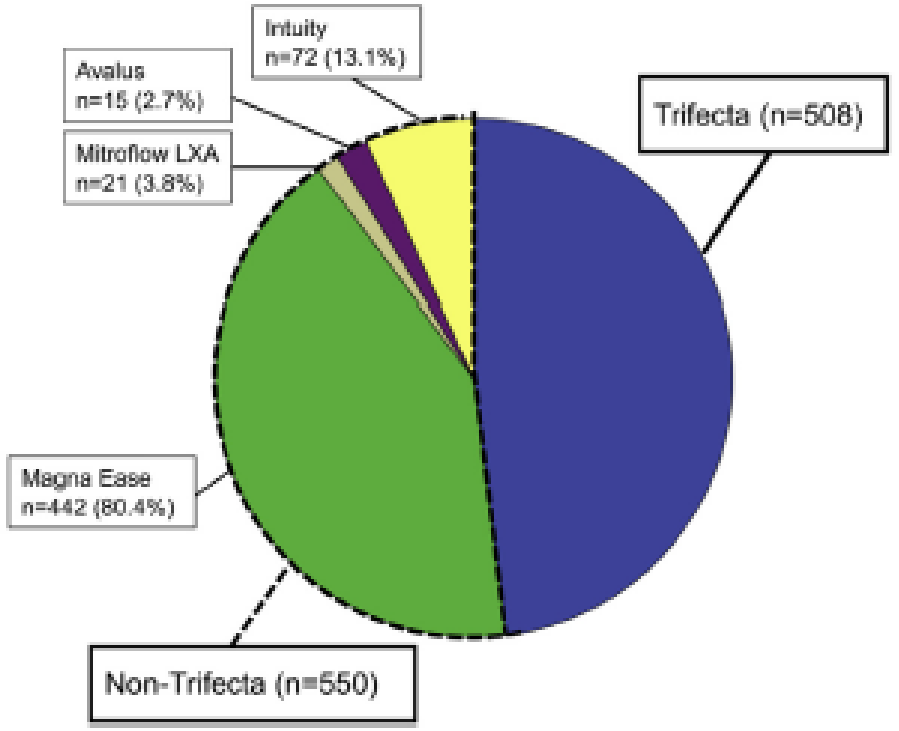
Early Structural Valve Degeneration of Trifecta Bioprosthesis

Ann Thorac Surg 2020 Mar;109(3):720-727.
doi: 10.1016/j.athoracsur.2019.06.032.

Shinichi Fukuhara, MD, Suzuna Shiomi, BS, Bo Yang, MD, PhD, Karen Kim, MD, MS, Steven F. Bolling, MD, Jonathan Haft, MD, Paul Tang, MD, Francis Pagani, MD, PhD, Richard L. Prager, MD, Stanley Chetcuti, MD, P. Michael Grossman, MD, Himanshu J. Patel, MD, and G. Michael Deeb, MD

Department of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan; and Division of Cardiovascular Medicine, University of Michigan, Ann Arbor, Michigan





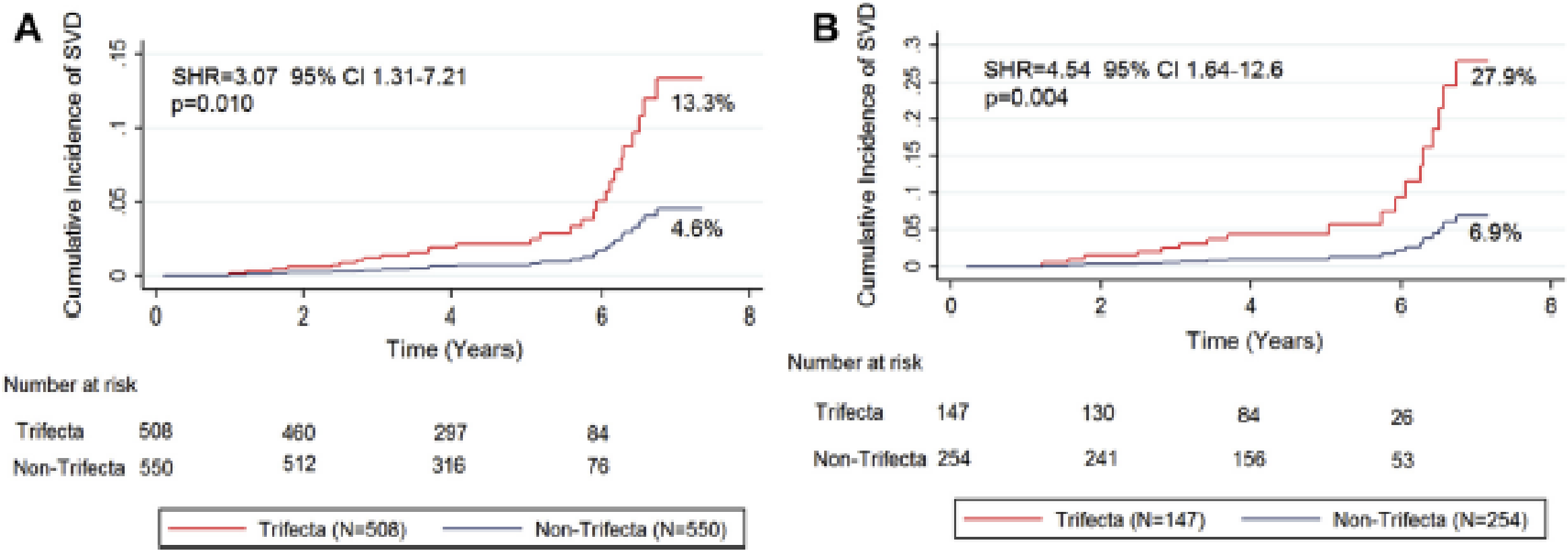


Figure 3. Cumulative incidence of structural valve degeneration: Trifecta (Abbott Vascular, Santa Clara, CA) vs non-Trifecta. Death and prosthetic valve endocarditis were considered as competing events. (A) Entire cohort. (B) Younger cohort (age ≤65 years). (CI, confidence interval; SHR, subdistribution hazard ratio; SVD, structural valve degeneration.)

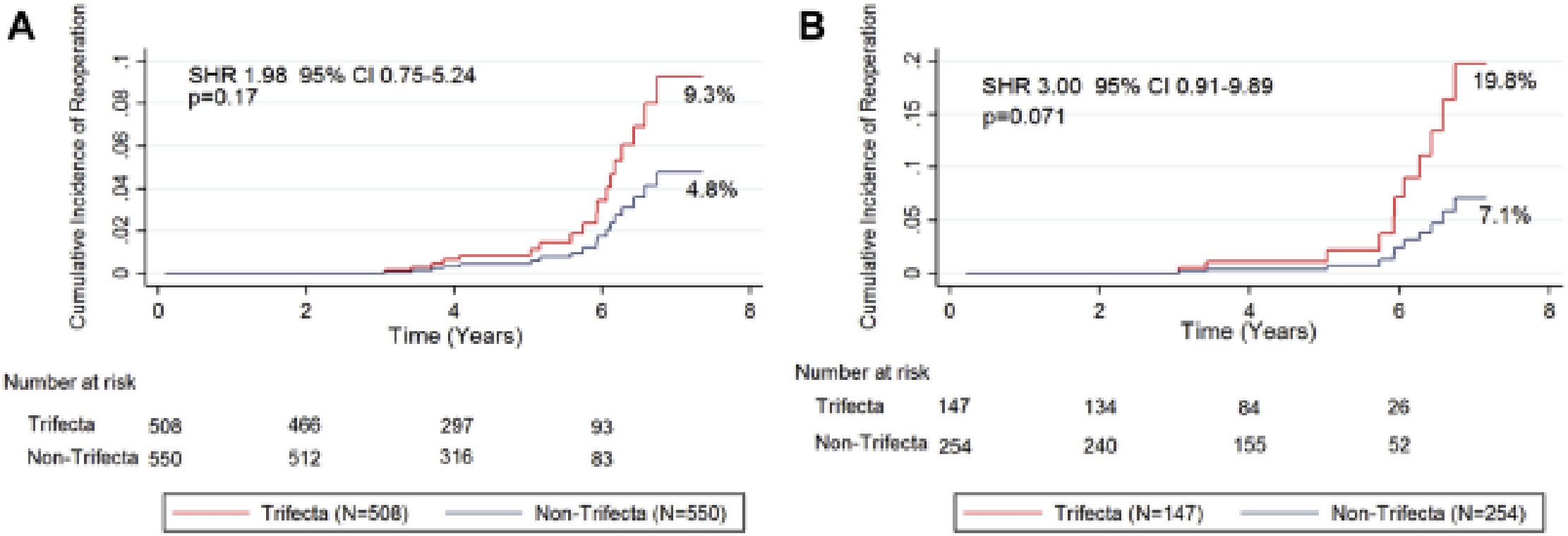
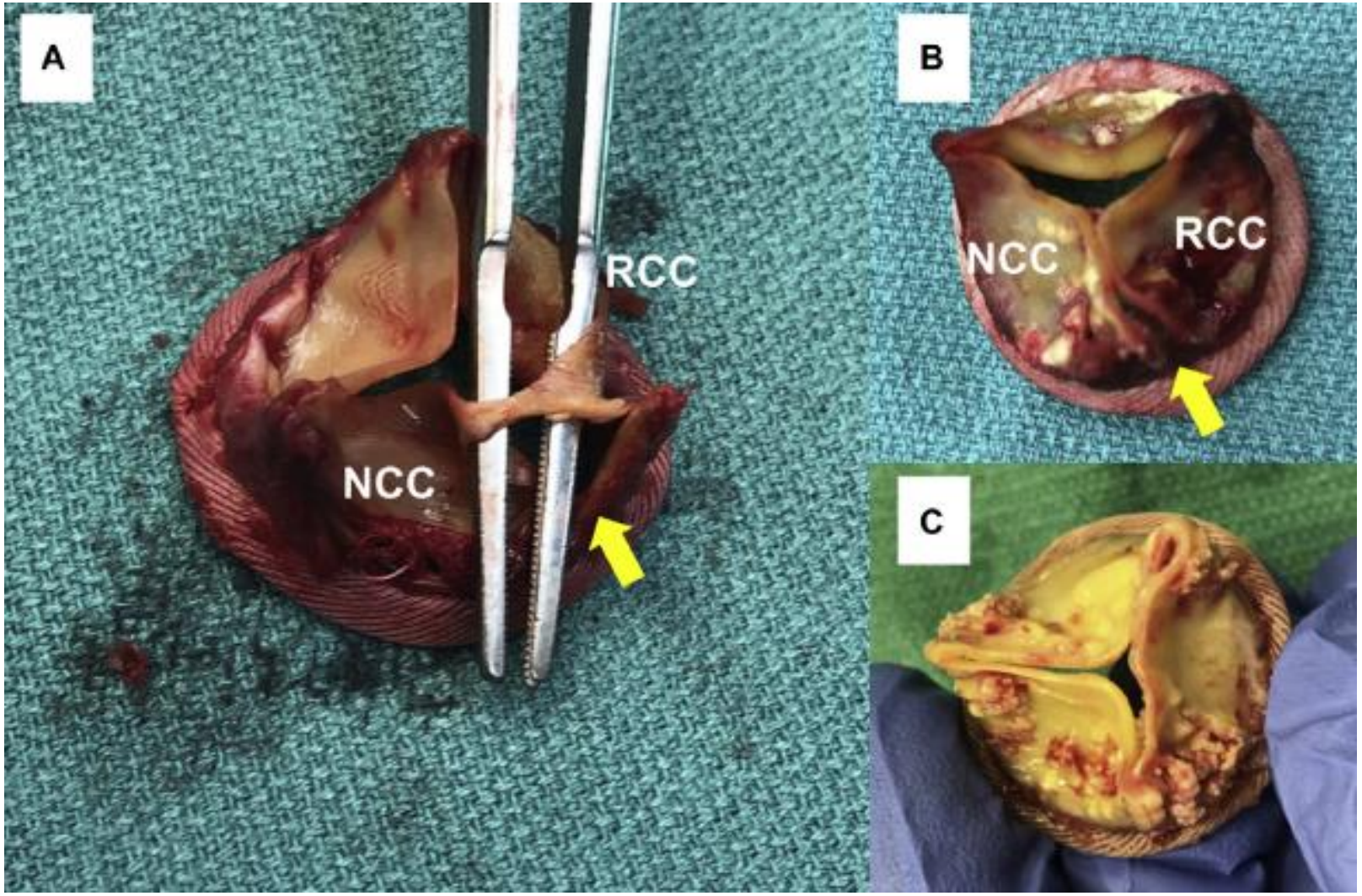


Figure 4. Cumulative incidence of reopenation (surgical or transcatheter aortic valve replacement): Trifecta (Abbott Vascular, Santa Clara, CA) vs non-Trifecta. (A) Entire cohort. (B) Younger cohort (age ≤65 years). (CI, confidence interval; SHR, subdistribution hazard ratio; SVD, structural valve degenenation.)



(A) A 4-year-old Trifecta (27-mm) valve with severe regurgitation that was explanted from a 70-year-old man. There was a detached cusp with a large tear (arrow) at the stent post between the noncoronary cusp (NCC) and the right coronary cusp (RCC).

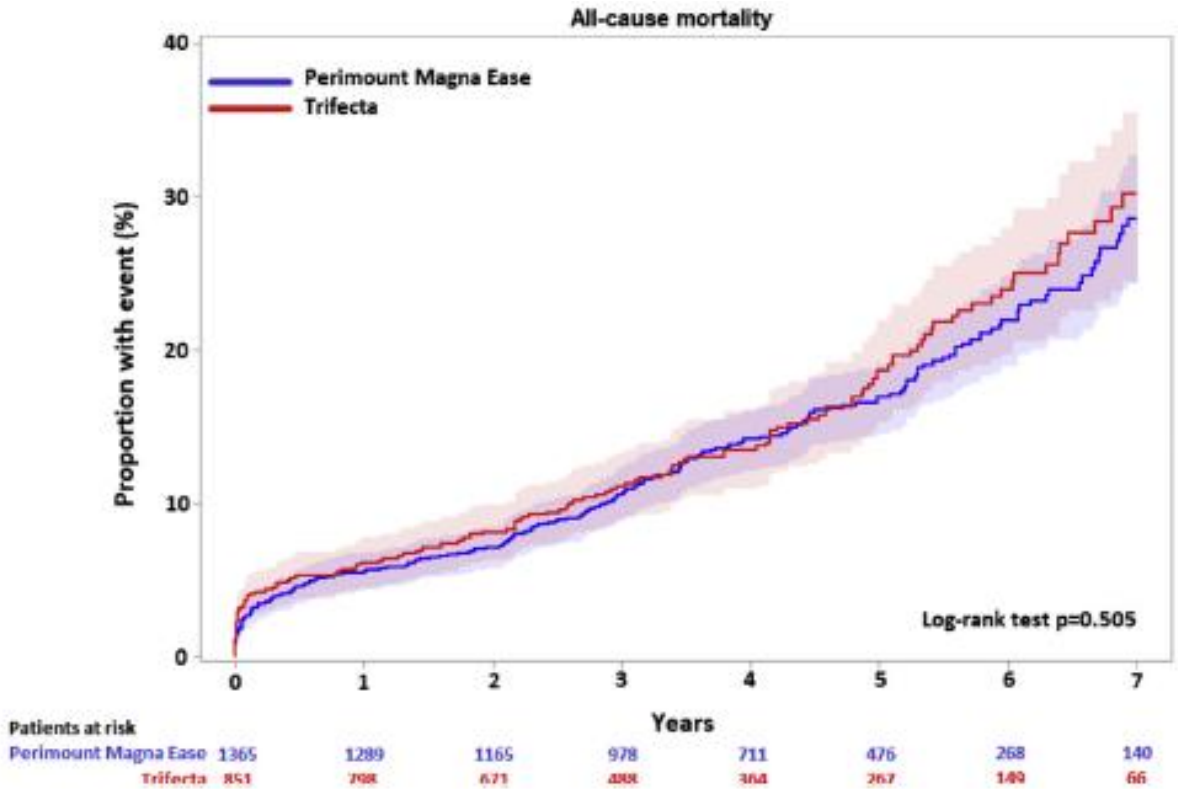
(B) A 51/2 -year-old Trifecta (21-mm) valve with mixed disease that was explanted from a 58-year-old woman. There was a longitudinal tear (arrow) between the noncoronary cusp and the right coronary cusp along with the diffuse cusp fibrosis. (C) A 6-year-old Trifecta (25-mm) valve with severe stenosis that was explanted from an 80-year-old woman.

Trifecta Versus Perimount Magna Ease Aortic Valve Prostheses

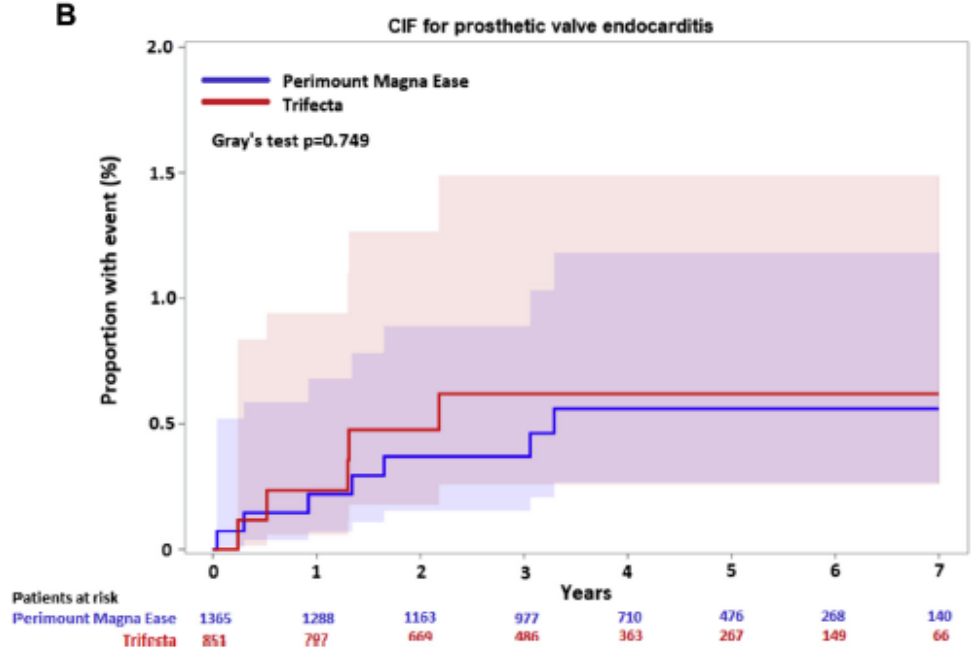
Fausto Biancari, MD, PhD, Antti Valtola, MD, Tatu Juvonen, MD, PhD, Annastiina Husso, MD, PhD, Sebastian Dahlbacka, MD, PhD, Teemu Laakso, MD, Maina P. Jalava, MD, Tuomas Tauriainen, MD, PhD, Tuomas Ahvenvaara, MD, Eeva-Maija Kinnunen, MD, PhD, Matti Niemelä, MD, PhD, Timo Mäkikallio, MD, PhD, Markku Eskola, MD, PhD, Marko P. O. Virtanen, MD, Pasi Maaranen, MD, Stefano Rosato, MSc, Vesa Anttila, MD, PhD, Antti Vento, MD, PhD, Juhani Airaksinen, MD, PhD, and Peter Raivio, MD, PhD

Heart Center, Turku University Hospital and Department of Surgery, University of Turku, Turku, Finland; Department of Surgery, Oulu University Hospital and Research Unit of Surgery, Anesthesia and Intensive Care, University of Oulu, Oulu, Finland; Heart Center, Kuopio University Hospital, Kuopio, Finland; Heart and Lung Center, Helsinki University Hospital, Helsinki, Finland; Department of Internal Medicine, Oulu University Hospital, Oulu, Finland; Heart Hospital, Tampere University Hospital, Faculty of Medicine and Health Technology, University of Tampere, Tampere, Finland; and Istituto Superiore di Sanità, Rome, Italy

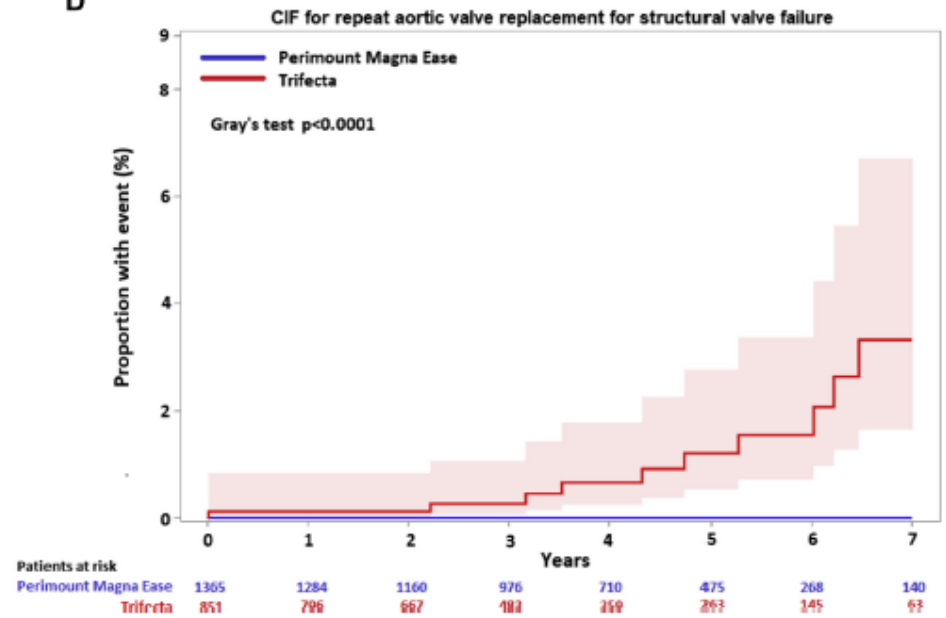
The FinnValve registry is a nationwide study (clinicaltrials.gov identifier: NCT03385915) that includes data of consecutive patients who underwent TAVR or SAVR for aortic stenosis between January 2008 and October 2017 at all Finnish University Hospitals (Helsinki, Kuopio, Oulu, Tampere, and Turku).


All-cause mortality
Perimount Magna Ease
Trifecta
Proportion with event (%)
40
30
20
10
0
Log-rank test p=0.505
0
1
2
3
4
5
6
7
Years
Patients at risk
Perimount Magna Ease 1365 1289 1165 978 711 476 268 140
Trifecta 851 298 671 488 364 267 149 66

B


CIF for prosthetic valve endocarditis
Perimount Magna Ease
Trifecta
Gray's test p=0.749
Proportion with event (%)
2.0
1.5
1.0
0.5
0
0
1
2
3
4
5
6
7
Years
Patients at risk
Perimount Magna Ease 1365 1288 1163 977 710 476 268 140
Trifecta 851 797 669 486 363 267 149 66

D

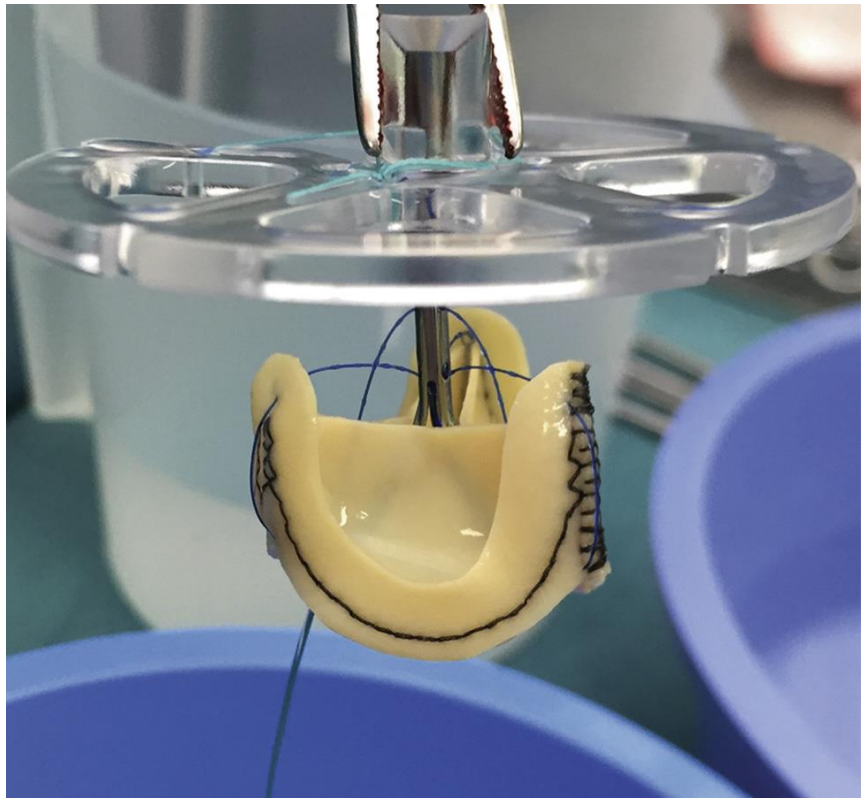

CIF for repeat aortic valve replacement for structural valve failure
Perimount Magna Ease
Trifecta
Gray's test p<0.0001
Proportion with event (%)
9
8
6
4
2
0
0
1
2
3
4
5
6
7
Years
Patients at risk
Perimount Magna Ease 1365 1284 1160 976 710 475 268 140
Trifecta 851 796 667 482 359 263 145 63

Aortic Valve Replacement With the Stentless Freedom SOLO Bioprosthesis: A Systematic Review

Laurens W. Wollersheim, MD, Wilson W. Li, MD, Berto J. Bouma, MD, PhD, Alberto Repossini, MD, Jan van der Meulen, MD, and Bas A. de Mol, MD, PhD

Departments of Cardiothoracic Surgery and Cardiology, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands; and Department of Cardiac Surgery, University of Brescia Medical School, Brescia, Italy

Ann Thorac Surg. 2015 Oct;100(4):1496-504.
doi: 10.1016/j.athoracsur.2015.06.048.



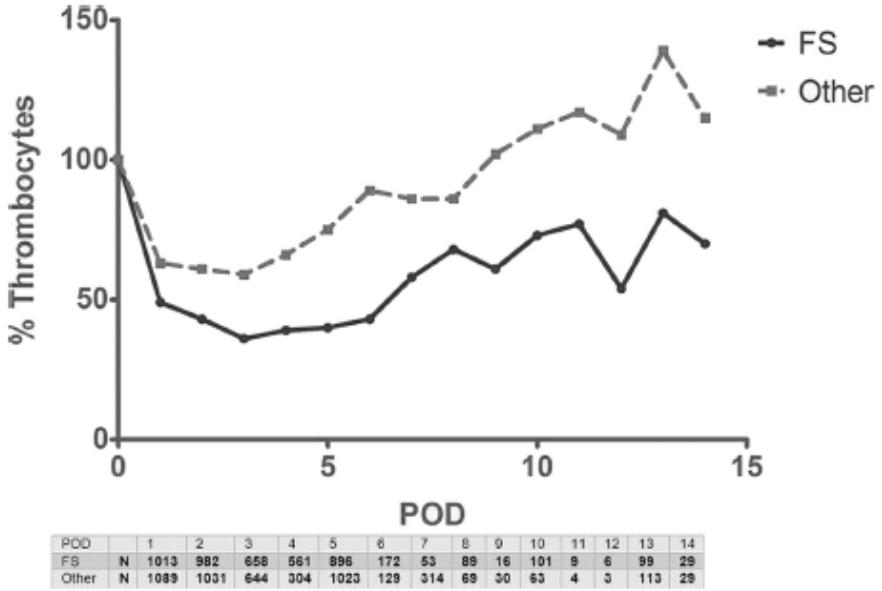
Clinical outcomes and follow-up of **2,185** patients with a Freedom SOLO.

AVR with the Freedom SOLO is safe and feasible, with good prosthesis performance after a mean follow-up of 22 months (maximum, 83 months).
Operative mortality of 3.5% and stroke rate of 1.1% (39% concomitant procedures) is comparable with other studies.
Data from The Society of Thoracic Surgeons National Database shows an observed mortality of 3.0% and stroke in 1.5% in 141,905 isolated AVRs

Learning curve

Two studies suggest that the Freedom SOLO has a short learning curve, which is illustrated by decreasing cross-clam times. Beholz and colleagues showed that after 10 cases, the mean cross-clamp time decreased from 46 minutes to 36 minutes for the next 38 cases. Thalmann and colleagues [20] showed a decreased cross-clamp time of 17% after the first 10 cases by each of 3 surgeons.

Incidence of thrombocytopenia



POD		1	2	3	4	5	6	7	8	9	10	11	12	13	14
FS	N	1013	982	658	561	896	172	53	89	16	101	9	6	99	29
Other	N	1089	1031	644	304	1023	129	314	69	30	63	4	3	113	29

Postoperative pacemaker implantation

Seven studies that included 702 patients with 49% concomitant procedures reported a pacemaker implantation rate of only 1.7%. In comparison, the reported incidence of pacemaker implantation after isolated AVR is 3.2% to 4% and is 6.6% to 7.2% in series with concomitant procedures.

The lower incidence in the Freedom SOLO is due to its supraannular implantation technique. The sutures are further away from the conduction system compared with stented prostheses, which necessitate sutures in the native aortic annulus.

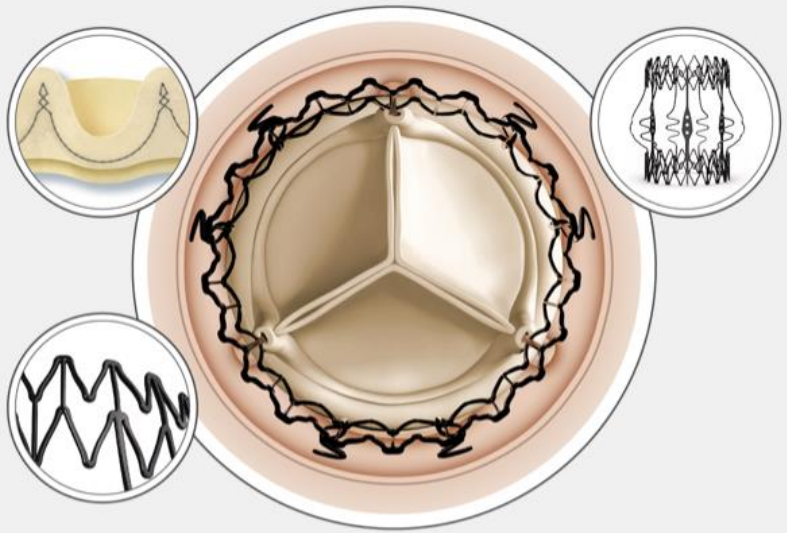
CORCYM
WE TAKE LIFE TO HEART

PERCEVAL™ PLUS

PERCEVAL HERITAGE

DOUBLE SHEET DESIGN
An outer sheet acts as a cushion to minimize the stress transferred to the leaflets

CARBOFILM™ COATING
Reduces inflammatory reaction favoring a gentle endothelialization[4]



SUPER ELASTIC STENT
Reduces the stress transferred to the leaflets[3]

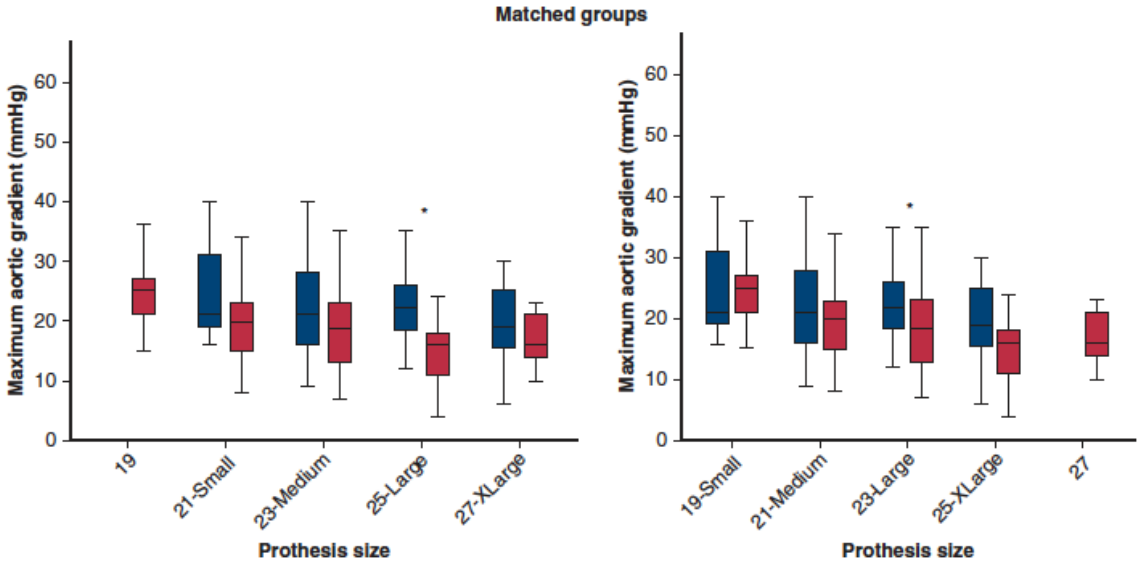
EXCLUSIVE TO PERCEVAL PLUS

REDUCED VALVE VENTRICULAR PROTRUSION
The reduction of the protrusion of the valve below the aortic annulus is expected to decrease the risk of impairment of the atrio-ventricular conduction system.

Surgical aortic valve replacement with new-generation bioprostheses: Sutureless versus rapid-deployment

J Thorac Cardiovasc Surg. 2020 Feb;159(2):432-442.e1.
doi: 10.1016/j.jtcvs.2019.02.135.

Augusto D'Onofrio, MD, PhD,[a] Stefano Salizzoni, MD,[b] Claudia Filippini, BSc,[c] Chiara Tessari, MD,[a] Lorenzo Bagozzi, MD,[a] Antonio Messina, MD,[d] Giovanni Troise, MD,[d] Margerita Dalla Tomba, MD,[d] Manfredo Rambaldini, MD,[e] Magnus Dalén, MD,[f] Francesco Alamanni, MD,[g] Massimo Massetti, MD,[h] Carmelo Mignosa, MD,[i] Claudio Russo, MD,[j] Loris Salvador, MD,[k] Roberto Di Bartolomeo, MD,[l] Daniele Maselli, MD,[m] Ruggero De Paulis, MD,[n] Ottavio Alfieri, MD,[o] Carlo Maria De Filippo, MD,[p] Michele Portoghese, MD,[q] Uberto Bortolotti, MD,[r] Mauro Rinaldi, MD,[b] and Gino Gerosa, MD[a]



Perceval-S valve implantation requires shorter cross-clamp and CPB times, whereas Intuity valve implantation provides lower transaortic peak and mean gradients.

March 2011 - May 2017
911 patients
18 Institutions

Intuity Rapid Deployment
562 patients

Perceval-S Sutureless
349 patients

Propensity score analysis

117 matched patients

Intuity n = 117	Variables	Perceval-S n = 117	*P* - value
4 (3,4%)	30-day VARC Mortality	2 (1,7%)	*P* = ,68
8 (6,8%)	Post-operative New implant of Pacemaker	7 (6%)	*P* = ,78
62 ± 24 min	Aortic Cross-Clamp Time	52 ± 14 min	*P* = ,001
19 ± 6,7 mmHg	Peak transaortic gradient	22,4 ± 8,1 mmHg	*P* = ,01
10,5 ± 3,9 mmHg	Mean transaortic gradient	11,8 ± 4,7 mmHg	*P* = ,0388

«ЮниЛайн»

Посадочный диаметр (размер), мм	Наружный диаметр, мм	Аортальный выступ, мм	Высота, мм
21±1	23±1	10,5±1,5	14,5±1,5
23±1	22±1	11,5±1,5	15,5±1,5
25±1	27±1	12,5±1,5	16,5±1,5

Гемодинамические характеристики аортальных биопротезов ЮниЛайн в зависимости от диаметра протеза

Показатель	Посадочный диаметр (размер), мм		
	21	23	25
ЭПО ($см^2$),	1,79±0,2	1,97±0,09	2,07±0,10
min-max	1,77-1,81	1,88-2,06	1,97-2,17
ΔP макс., мм рт.ст.,	18,1±5,3	17,9±5,0	18,4±6,2
min-max	8-31	9-33	6-32
ΔP сред., мм рт.ст.,	13,8±4,1	10,0±3,6	8,0±3,1
min-max	6-27	4,6-30	3,8-13

НЕПОСРЕДСТВЕННЫЕ И ОТДАЛЕННЫЕ РЕЗУЛЬТАТЫ ПРИМЕНЕНИЯ БИОПРОТЕЗОВ «ЮниЛайн» В АОРТАЛЬНОЙ ПОЗИЦИИ

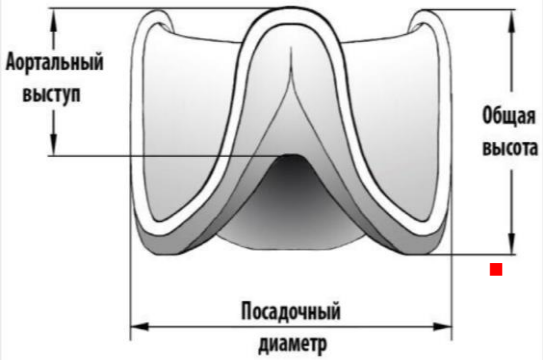
Козлов Б.Н.[1,2], Петлин К.А.[1], Пряхин А.С.[1], Середкина Е.Б.[1], Панфилов Д.С.[1], Шипулин В.М.[1,2]

[1] ФГБНУ «Томский национальный медицинский исследовательский центр» РАН, Научно-исследовательский институт кардиологии
[2] ФГБОУ ВО «Сибирский государственный медицинский университет» Минздрава России, Томск

За весь срок наблюдения (максимальное время наблюдения составило 5 лет) не было ни одного случая реоперации по поводу несостоятельности аортального биопротеза «ЮниЛайн».

Протез	Средний градиент, мм рт.ст. (*in vivo*)
ЮниЛайн	13,3
Carpentier-Edwards pericardial	16,3
Carpentier-Edwards porcine	17
Hancock II	11,7
St. Jude SPV	9,3

«ТиАра»



- Изначально возможна имплантации большего размера протеза (нет широкой манжетки, нативное кольцо аортального не является лимитирущим фактором)
- Тонкий проволочный каркас дает серьезное основание предполагать, что будет возможна транскатетрная имплантация по методике ViV с оптимальным диаметром и отсутствием необходимости сложных манипуляций по расширению или разрыву каркаса

Модель клапана	Посадочный диаметр (размер), мм	Высота, мм	Аортальный выступ, мм	Масса, г (не более)
«ТиАра» - TA19	19,0±1,0	16,6±1,5	10,1±1,0	2,1±0,5
«ТиАра» - TA21	21,0±1,0	17,8±1,5	10,1±1,0	2,3±0,5
«ТиАра» - TA23	23,0±1,0	19,0±1,5	10,1±1,0	2,5±0,5
«ТиАра» - TA25	25,0±1,0	20,2±1,5	10,1±1,0	2,6±0,5

Функциональные характеристики биопротезов ТиАра, полученные при стендовых испытаниях (данные производителя)

Показатель	Посадочный диаметр (размер), мм				Погрешность
	19	21	23	25	
Эффективная площадь отверстия, $см^2$	1,78-2,44	2,22-3,04	2,66-3,70	3,17-4,42	<0,05
ΔP сред., мм рт.ст., min-max	6,1-14,6	5,5-13,6	5,4-12,8	5,1-12,3	<0,05
Фракция регургитации, %	6,7-10,1	6,5-10,3	6,1-10,5	6,6-9,8	<0,05

ЭХОКГ результаты раннего послеоперационного периода

Размер клапана, мм	Средний градиент, мм рт ст	Пиковый градиент мм рт ст
21 (n 1)	12,0	20,0
23 (n 6)	12,6 ± 5,6	26,3 ± 10,5
25 (n 9)	11,1 ± 6,5	19,4 ± 10,9

Спасибо за внимание!