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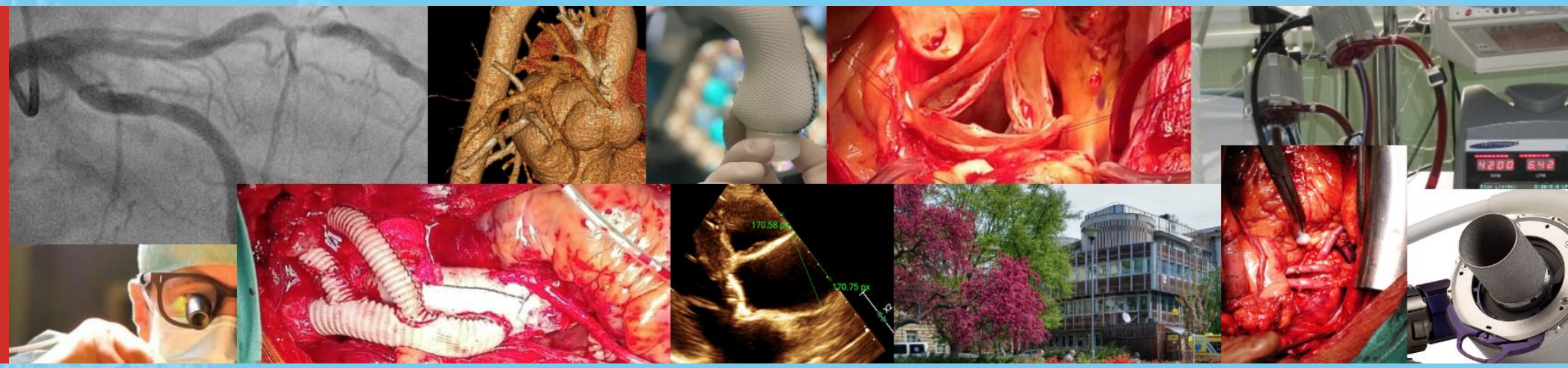


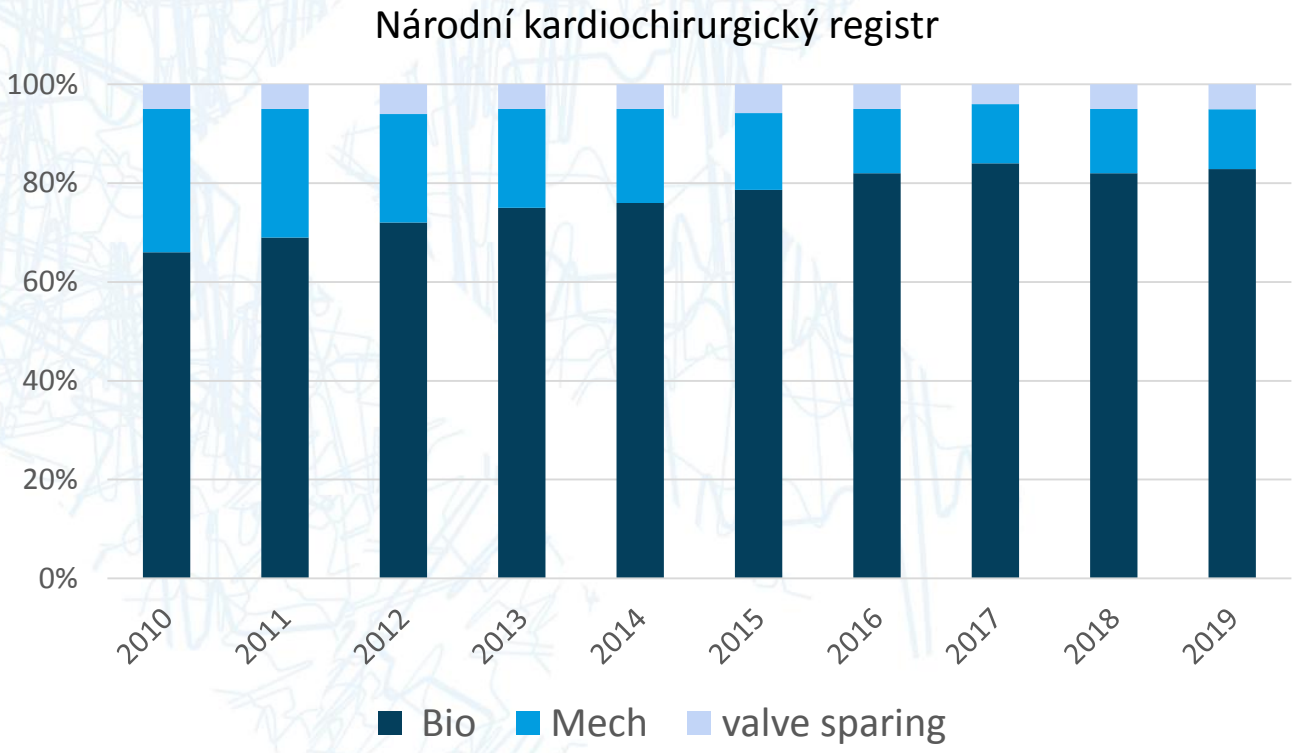
AORTÁLNÍ BIOPROTÉZA V MLADŠÍM VĚKU
- trvanlivost, nebo i něco více?

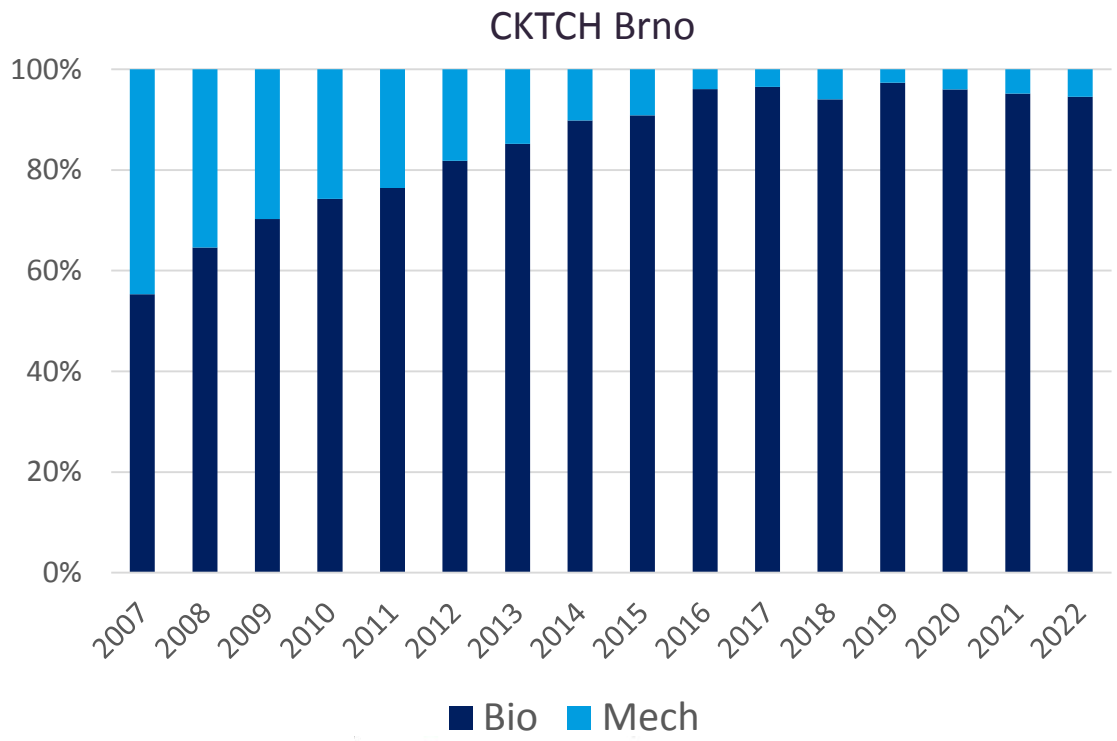
Petr Fila

Aortální bioprotéza

výrazný nárůst v poslední dekádě

- 80% (EU, US)
- 82% Česká republika, 93% CKTCH Brno (2022)





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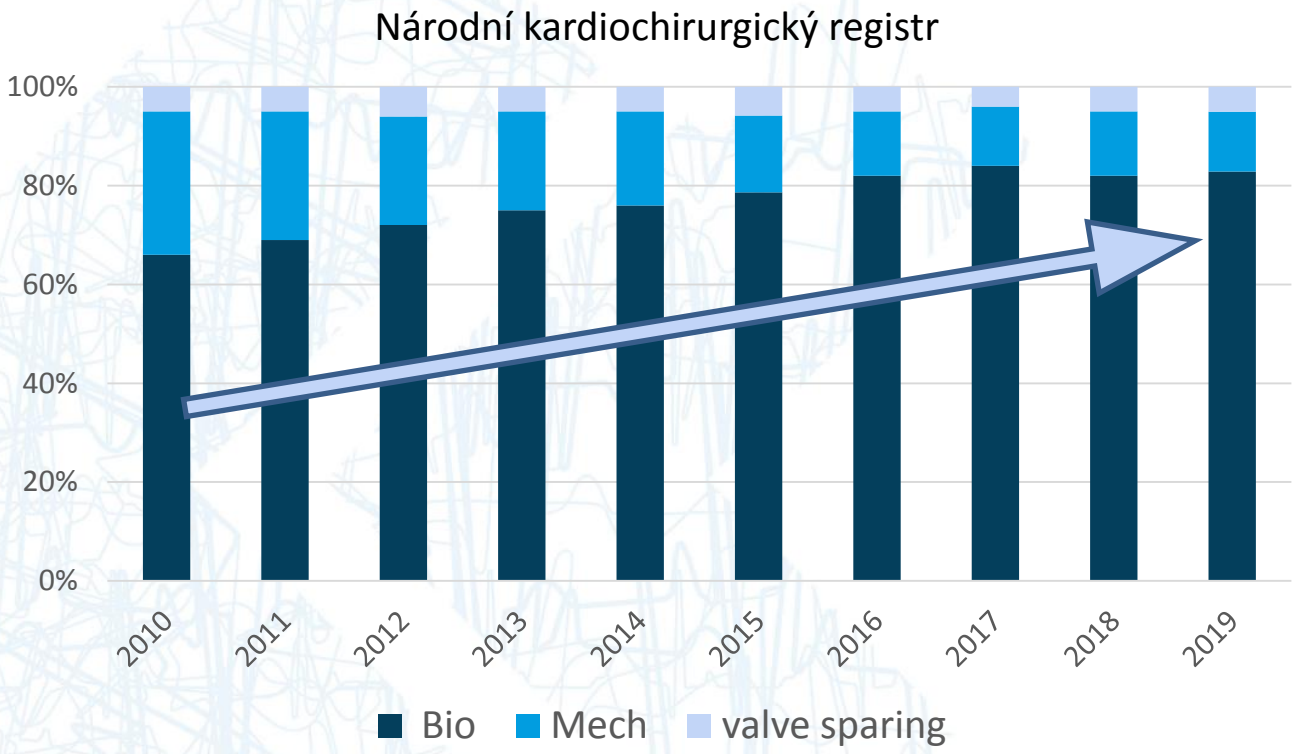
Co stojí za tímto posunem?



- **trend „ANTI“ antikoagulační terapie**
- odmítání dlouhodobé AKT u mladých
- předpoklad, že nové generace biochlopní poskytnou delší čas bez reoperace
- reoperace - nízká morbidita a mortalita
- možnost ViV

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Aortální bioprotéza v mladším věku

A bioprosthesis should be considered in patients aged >65 years for a prosthesis in the aortic position or aged >70 years in a mitral position.	IIa	C

Beyersdorf, 2021 ESC/EACTS Guidelines for the management of valvular heart disease. EJCTS, 2021, 60.4: 727-800.

2a	B-NR

4. For patients 50 to 65 years of age who require AVR and who do not have a contraindication to anti-coagulation, it is reasonable to individualize the choice of either a mechanical or bioprosthetic AVR with consideration of individual patient factors and after informed shared decision-making. (1-10)

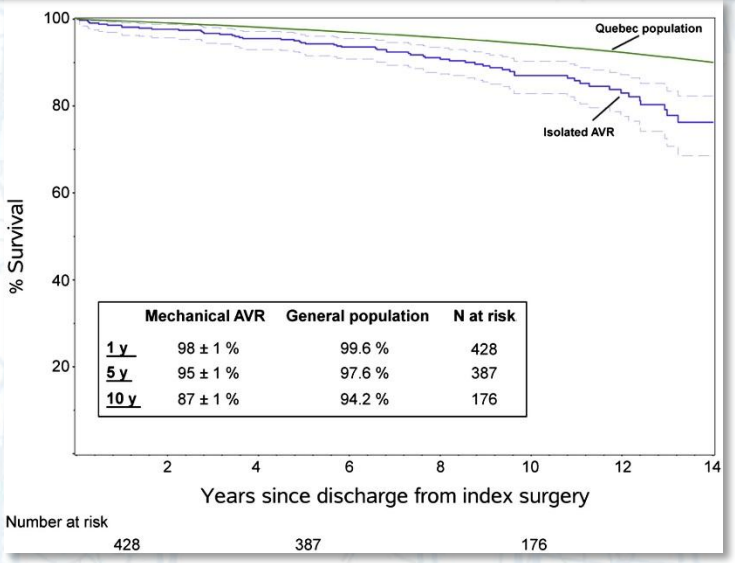
perhaps a decrease in survival rate (6,25-27). There are several other factors to consider in the choice of type of valve prosthesis (see Section 11.1). Ultimately, the choice of mechanical versus bioprosthetic valve replacement for all patients, but especially for those between 50 and 65 years of age, is a shared decision-making process that must account for the trade-offs between durability (and the need for reintervention), bleeding, and thromboembolism (1).

Otto, CM. 2020 ACC/AHA guideline for the management of patients with valvular heart disease. JACC, 77(4), e25-e197.

Přežívání po mAVR

Long-term outcomes after elective isolated mechanical aortic valve replacement in young adults

Ismail Bouhout, MSc,[a] Louis-Mathieu Stevens, MD, PhD,[b] Amine Mazine, MSc,[a] Nancy Poirier, MD,[a] Raymond Cartier, MD,[a] Philippe Demers, MD,[a] and Ismail El-Hamamsy, MD, PhD[a]



	Mechanical AVR	General population	N at risk
1 y	98 ± 1 %	99.6 %	428
5 y	95 ± 1 %	97.6 %	387
10 y	87 ± 1 %	94.2 %	176

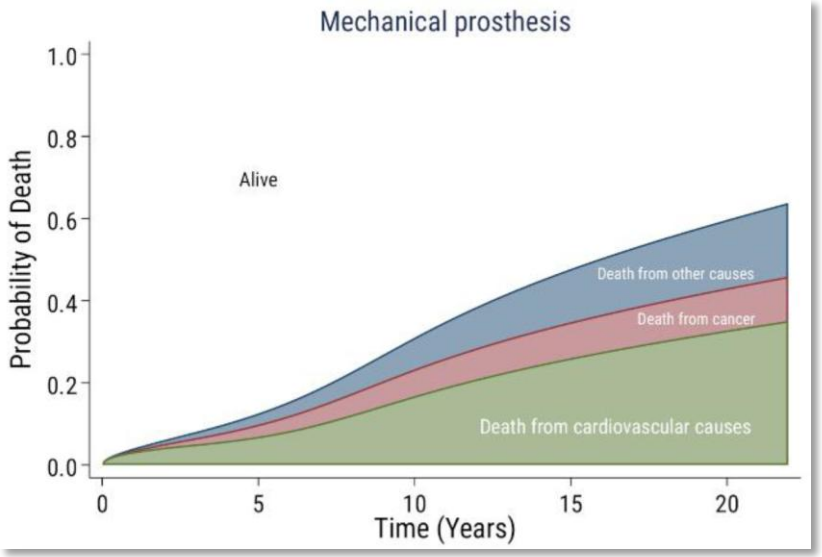
N = 455, mAVR, věk <65 let

- elektivní, izolovaná mAVR - **suboptimální přežívání** ve srovnání s běžnou populace (vztažené k věku a pohlaví)

ORIGINAL RESEARCH

Cause of Death After Surgical Aortic Valve Replacement: SWEDEHEART Observational Study

Natalie Glaser, MD, PhD; Michael Persson, MD; Anders Franco-Cereceda, MD, PhD; Ulrik Sartipy, MD, PhD



N = 33 018

- horší přežívání po AVR – vyšší riziko KV smrti
- KV riziko smrti **vyšší u pacientů s mAVR** ve srovnání s biochlopněmi

Bouhout I, J. Thorac. Cardiovasc. Surg. , 2014, 148.4: 1341-1346. e1.
Glaser N, J Am Heart Assoc. 2021 Nov 16;10(22):e022627.

Trvanlivost biochlopní

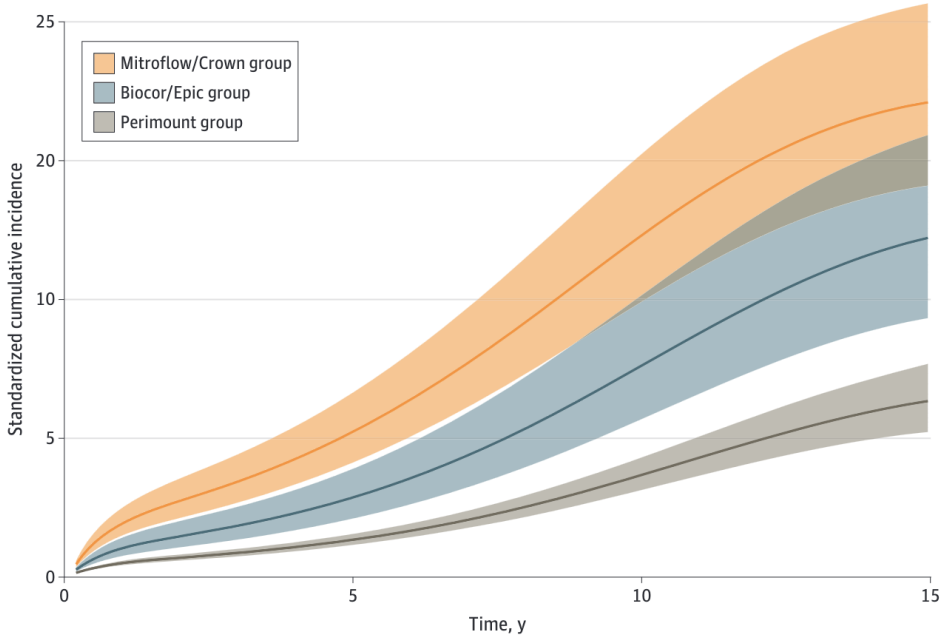
Original Investigation | Cardiology

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

SWEDEHEART
2003-2018,
16 983 pts AVR bio
věk 72.6 ± 8.5

chlopeň Perimount
- **3.6% reintervence po 10 letch**
- **6,1% reintervence po 15 letech**



Persson, Comparison of long-term performance of bioprosthetic aortic valves in Sweden from 2003 to 2018. JAMA Network Open, 2022, 5.3: e220962-e220962.

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Mechanické vs. biochlopně

Journal of Clinical Medicine

MDPI

Article

Surgical Aortic Valve Replacement—Age-Dependent Choice of Prosthesis Type

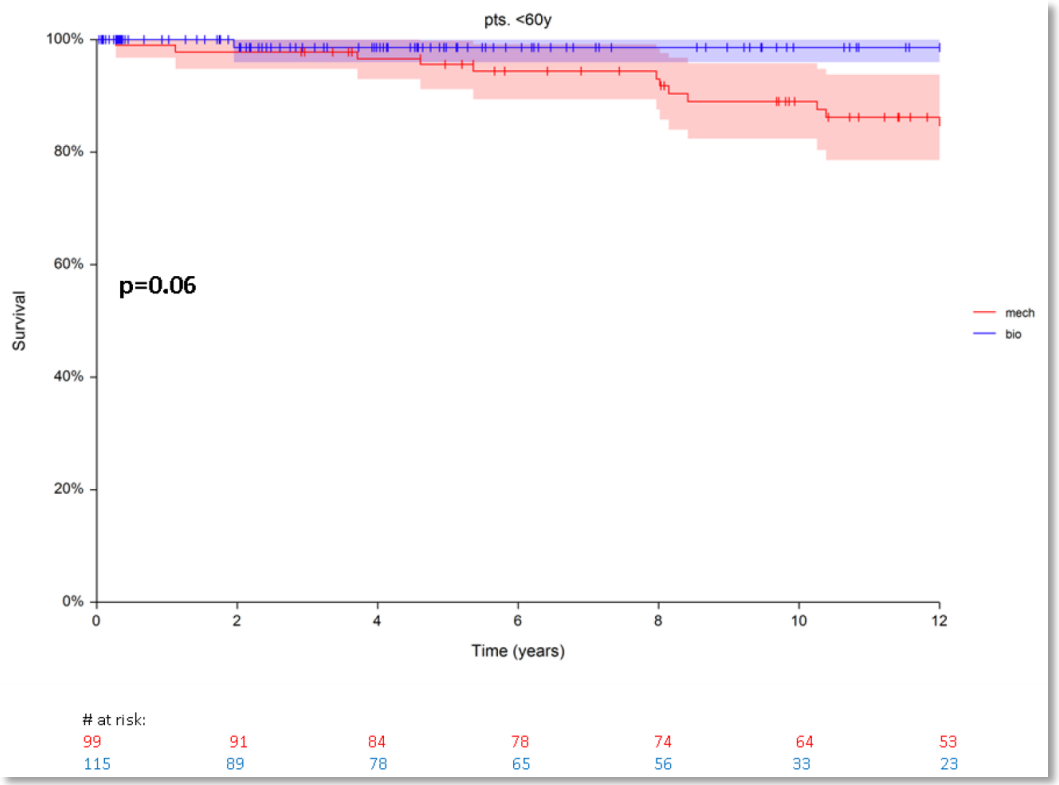
Keti Vitanova [1,2,*,†], Felix Wirth [1,2,†], Johannes Boehm [1,2], Melchior Burri [1,2], Rüdiger Lange [1,2,3] and Markus Krane [1,2,3,4]

n = 2172

PSM - 214 mech. vs. 214 bio

věk <60 let

- smrt, stroke, velké krvácení, reoperace – **žádný rozdíl mezi mech and bio**
- 10 leté přežívání **97% bio vs. 89% mech (p = 0,06)**



Vitanova, Journal of Clinical Medicine, 2021, 10.23: 5554.

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Mechanické vs. biochlopně

Similar long-term survival after isolated bioprosthetic versus mechanical aortic valve replacement: A propensity-matched analysis

Tamer Attia, MD, PhD,[a] Yanzhi Yang, BS,[b] Lars G. Svensson, MD, PhD,[a] Andrew J. Toth, MS,[c] Jeevanantham Rajeswaran, PhD,[c] Eugene H. Blackstone, MD,[a,c] and Douglas R. Johnston, MD,[a] and Members of the Cleveland Clinic Aortic Valve Center

n = 6143 pts
(mAVR 637, bioAVR 5506)
PSM - 527 párů

- **hospitalizační mortalita - 0,38% vs 0,57%**
- **stroke - 1,7% vs. 1,5%**
- **PVL žádný/trace – 98% vs 91%**

Outcome	Biological n = 527		Mechanical n = 527		*P*
	n*	No. (%) or 15th/50th/85th percentiles	n*	No. (%) or 15th/50th/85th percentiles	
Hospital death	527	2 (0.38)	527	3 (0.57)	>.9
Operative death	527	3 (0.57)	527	4 (0.76)	>.9
Stroke	527	9 (1.7)	527	8 (1.5)	.8
Deep sternal wound infection	527	1 (0.19)	527	6 (1.1)	.12
Septicemia	527	3 (0.57)	526	5 (0.95)	.5
Reoperation for bleeding or tamponade	526	3 (0.57)	527	3 (0.57)	>.9
New requirement for dialysis	520	1 (0.19)	523	0 (0)	>.9
Prolonged ventilation >24 h	524	12 (2.3)	525	11 (2.1)	.8
New postoperative atrial fibrillation	458	119 (25)	443	118 (27)	.8
New heart block	422	10 (2.4)	399	10 (2.5)	.9
Intensive care unit length of stay (h)	527	23/25/62	527	24/25/68	.2
Postoperative length of stay (d)	527	4/6/9	527	5/7/10	<.0001
Postoperative mean transvalvular gradient (mm Hg)	326	16 ± 5.9	297	16 ± 7.6	>.9
Postoperative regurgitation (grade)	253		244		.0003
None/trace		247 (98)		238 (91)	
Mild		4 (1.6)		24 (9.2)	
Mild to moderate		2 (0.79)		0 (0)	

Attia, Similar long-term survival after isolated bioprosthetic versus mechanical aortic valve replacement. Journal of Thoracic and Cardiovascular Surgery, 2022, 164.5: 1444-1455. e4.

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Chirurgická náhrada chlopně

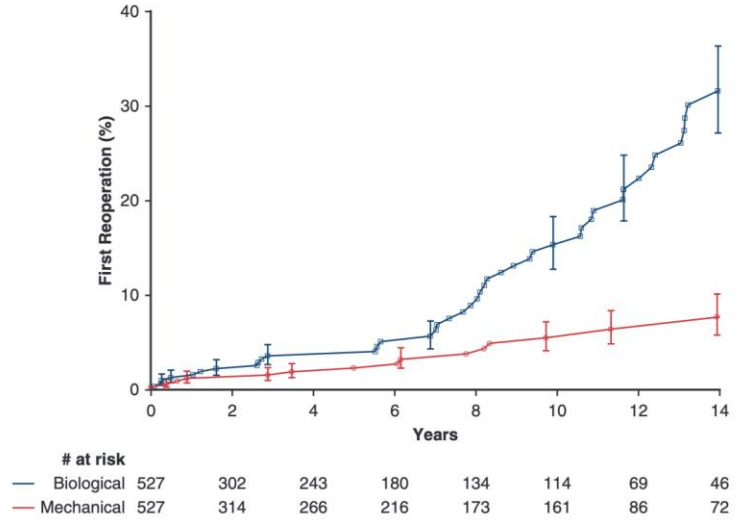
Similar long-term survival after isolated bioprosthetic versus mechanical aortic valve replacement: A propensity-matched analysis

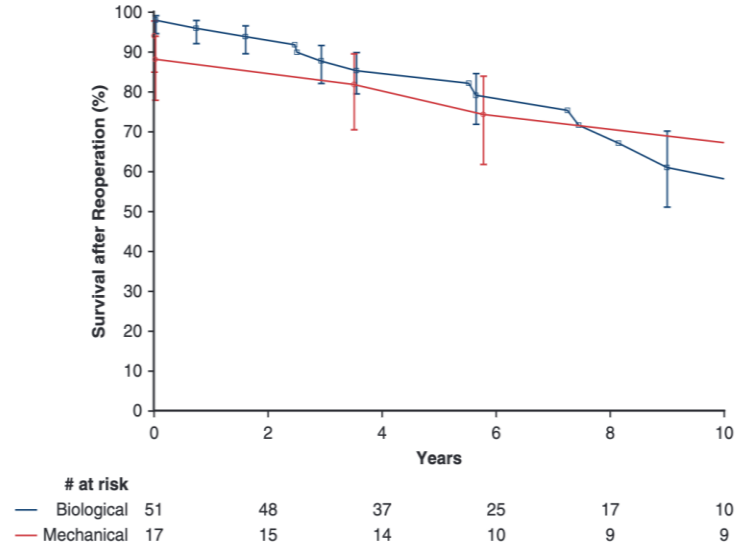
Tamer Attia, MD, PhD,[a] Yanzhi Yang, BS,[b] Lars G. Svensson, MD, PhD,[a] Andrew J. Toth, MS,[c] Jeevanantham Rajeswaran, PhD,[c] Eugene H. Blackstone, MD,[a,c] and Douglas R. Johnston, MD,[a] and Members of the Cleveland Clinic Aortic Valve Center

n = 6143 pts
(mAVR 637, bioAVR 5506)
PSM - 527 párů

- hospitalizační mortalita - 0,38 vs 0,57%
- stroke - 1,7 vs. 1,5%
- PVL žádný/trace – 98 vs 91%

- **větší počet reoperací u bioAVR**
- **bez ovlivnění přežívání**



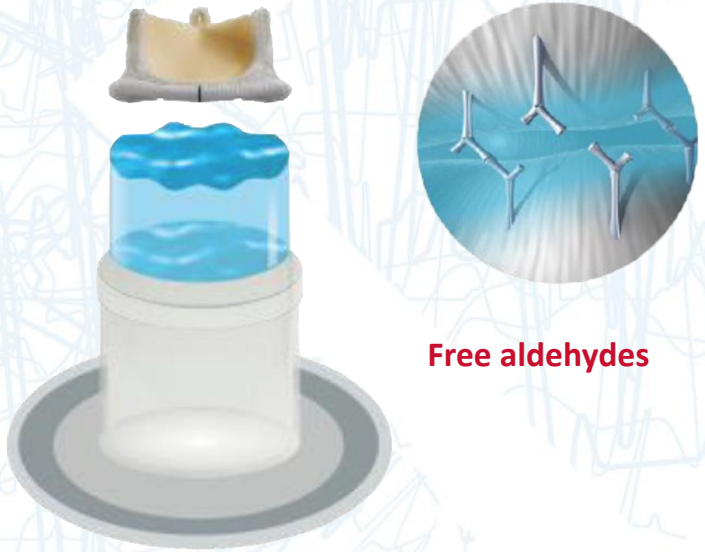
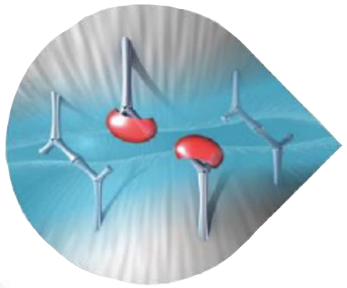
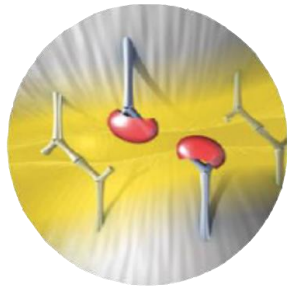
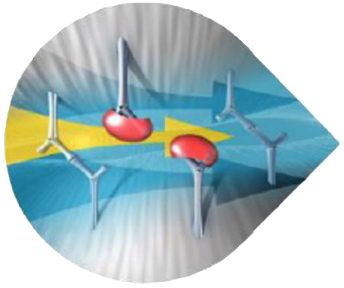


Attia, Similar long-term survival after isolated bioprosthetic versus mechanical aortic valve replacement. Journal of Thoracic and Cardiovascular Surgery, 2022, 164.5: 1444-1455. e4.

Prevence SVD - tkáňové inženýrství

- **RESILIA tissue** – blokování volných aldehydů – klíčový faktor pro kalcifikace

-> redukce kalcifikací - chlopeň odolnější degeneracím

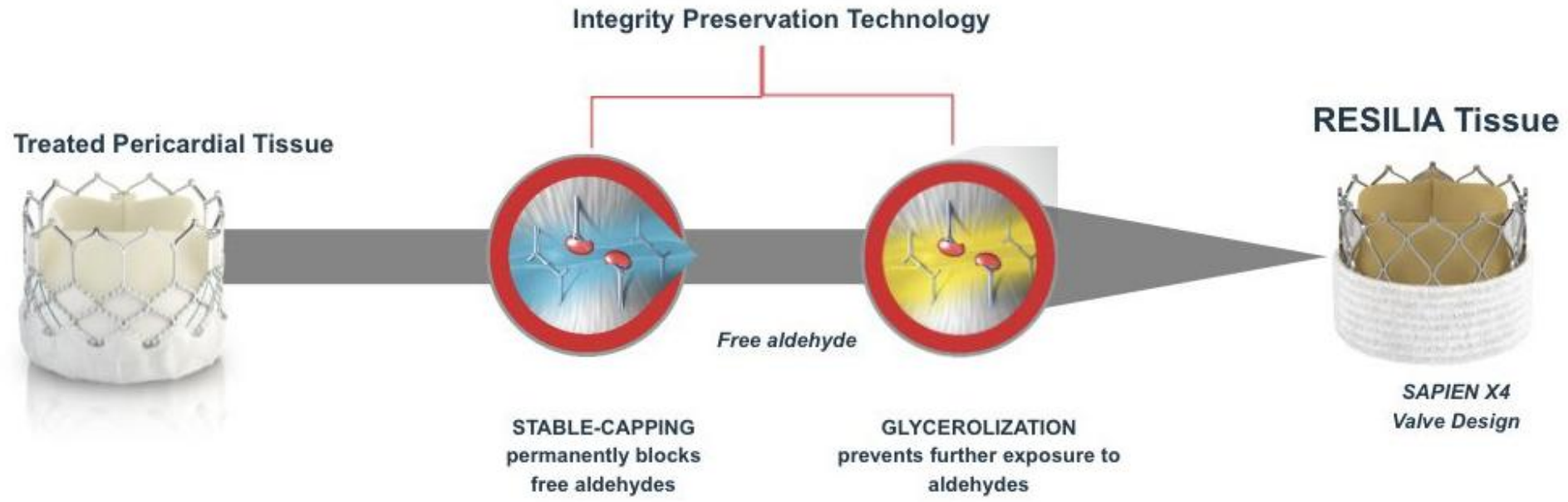
Glutaraldehyde stabilisation	Integrity preservation technology	RESILIA tissue
 Free aldehydes	 **Stable capping** Anticalcification process to block free aldehydes and reduce calcium binding[1,2]	 Glycerolised tissue
	 **Glycerolisation** Removes the need to store in glutaraldehyde and eradicates exposure to unbound aldehyde groups[1]	 **Stable dry storage** Removes the need for rinsing before implantation[1]

Edwards Lifesciences INSPIRIS RESILIA aortic valve. Model 11500a. Instructions for Use. 2020; Tod TJ, Dove JS. J Mater Sci. 2016

Prevence SVD u THV - tkáňové inženýrství

- **RESILIA tissue** – blokování volných aldehydů – klíčový faktor pro kalcifikace

-> redukce kalcifikací - chlopeň odolnější degeneracím

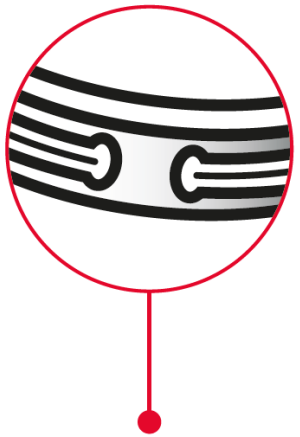


Edwards Lifesciences INSPIRIS RESILIA aortic valve. Model 11500a. Instructions for Use. 2020; Tod TJ, Dove JS. J Mater Sci. 2016

Bioprotéza Inspiris Resilia

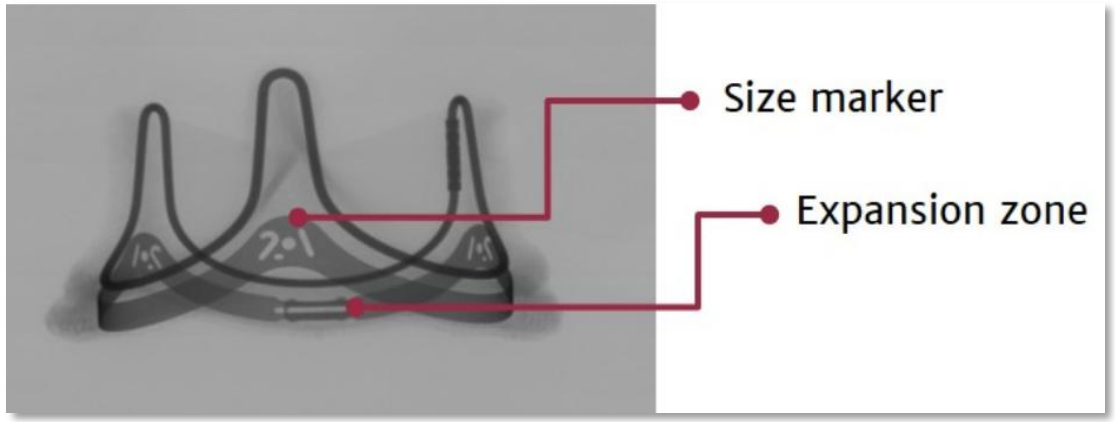
- glycerolizovaná tkáň (**Integrity technology**) – uchovávání v suchu
- nízký profil, flexibilní, expandibilní

  - pro usnadnění případné ViV v budoucnosti



Fluoroscopically visible size markers

Expandable cobalt–chromium alloy band

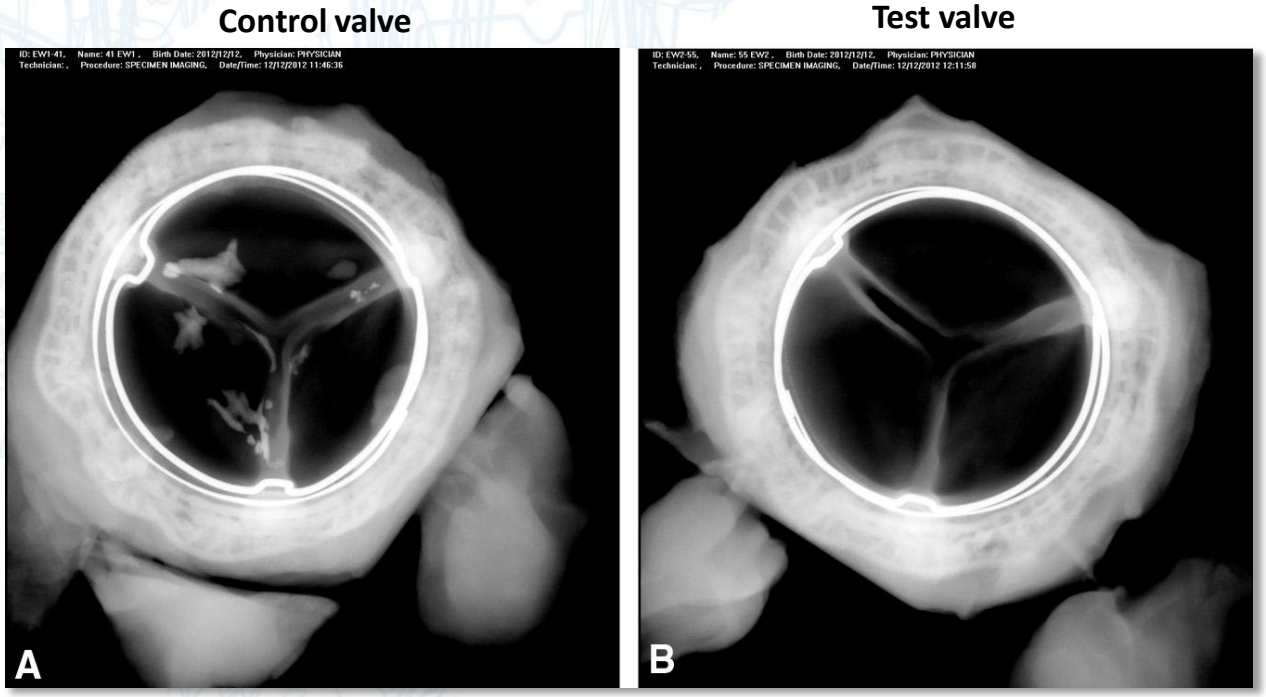


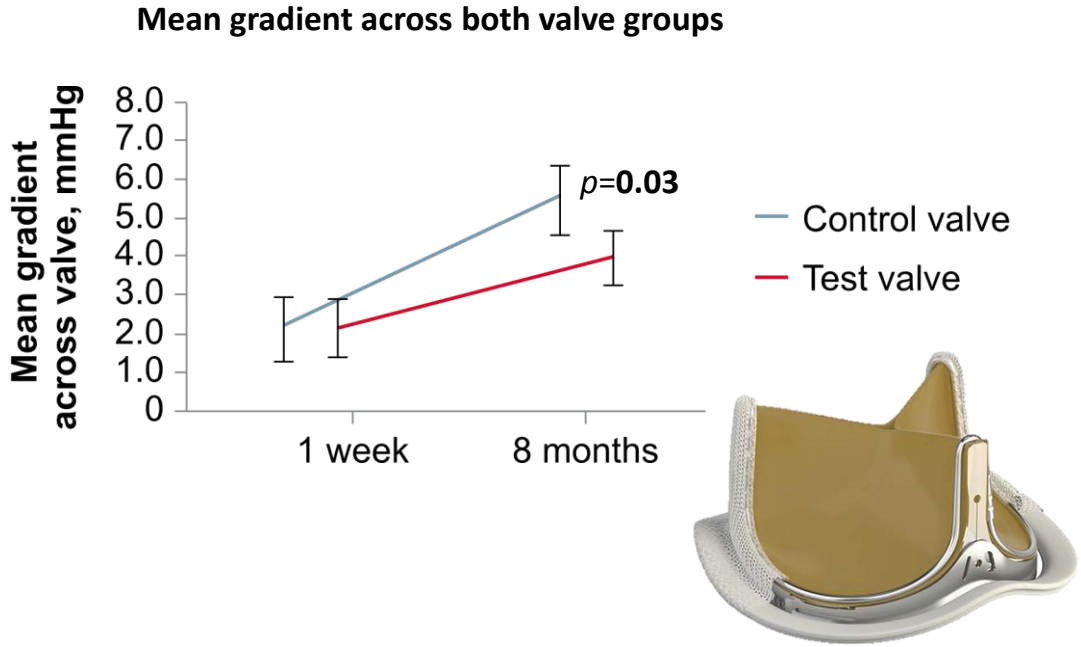
Bioprotéza Inspiris Resilia

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

ovčí model
- po 8 měsících
- testovaná chlopeň obsahovala o 72% méně kalcia než kontrolní





Flameng W, et al. J ThoracCardiovasc Surg. 2015;149:340–5.

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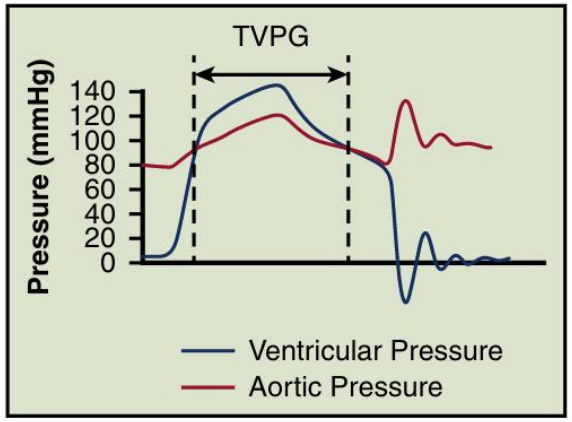
Bioprotéza Inspiris Resilia - in vitro studie

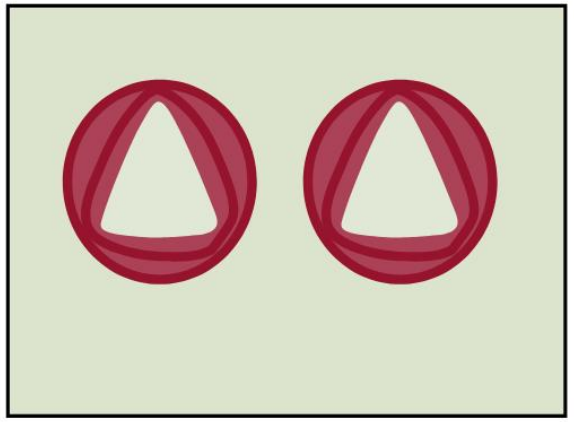
Long-term durability of a new surgical aortic valve: A 1 billion cycle in vitro study

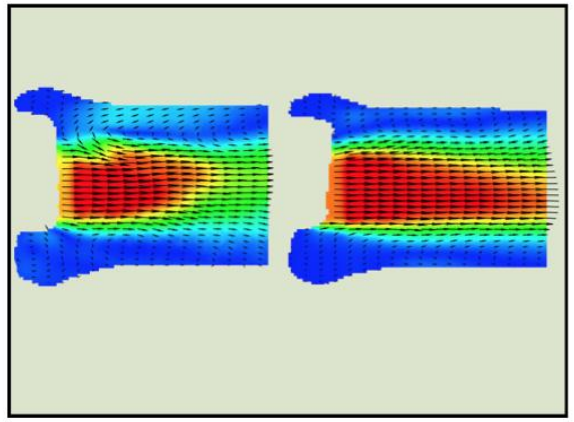
Vahid Sadri, PhD,[a] Phillip M. Trusty, PhD,[a] Immanuel David Madukauwa-David, PhD,[b] and Ajit P. Yoganathan, PhD[a]

1 billion cyklů (ekvivalent 25 rokům)
- strukturální komponty **intaktní**
- hemodynamické parametery – **funkčně srovnatelné** s úvodními hodnotami

Sustained Hemodynamic Performance	Comparable Leaflet Kinematics	Similar Flow Field
-Met requirement of the ISO Heart Valve Standard	-Similar Geometric Orifice Area (GOA)	-Similar velocity filed -Similar shear stress field







Sadri, et al. JTCVS Open, 2022, 9: 59-69

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Bioprotéza Inspiris Resilia

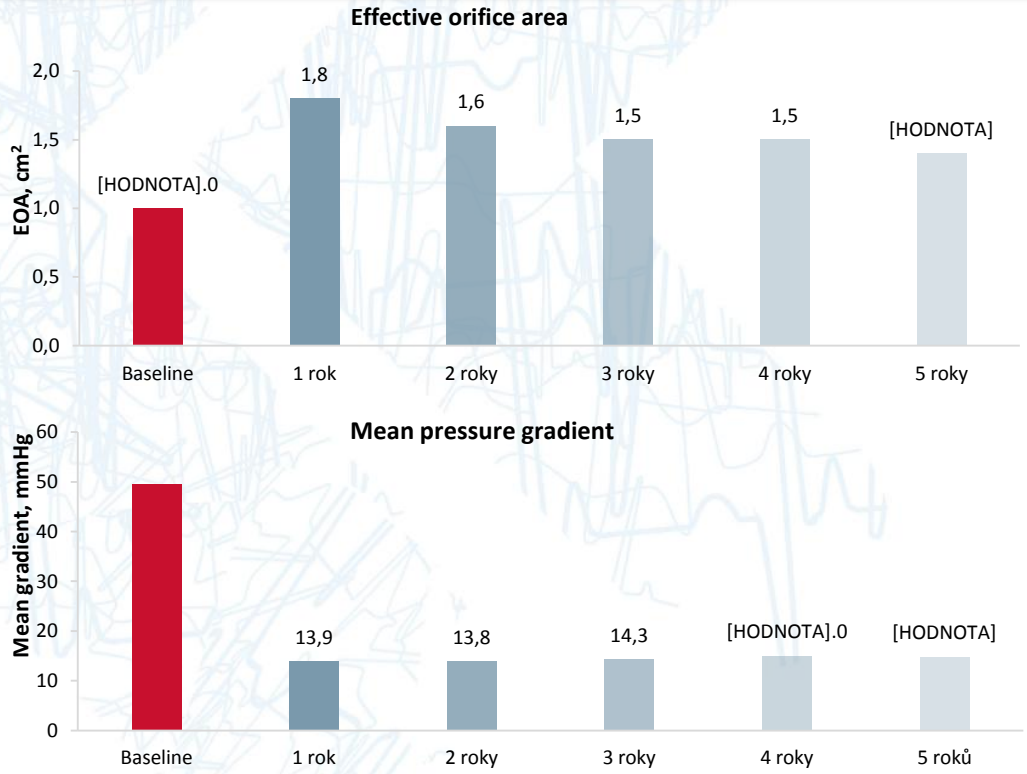
European Journal of Cardio-Thoracic Surgery 59 (2021) 434–441
doi:10.1093/ejcts/ezaa311 Advance Access publication 3 November 2020

ORIGINAL ARTICLE

Cite this article as: Bartus K, Litwinowicz R, Bilewska A, Stapor M, Bochenek M, Rozanski J *et al.* Final 5-year outcomes following aortic valve replacement with a RESILIA™ tissue bioprosthesis. Eur J Cardiothorac Surg 2021;59:434–41.

Final 5-year outcomes following aortic valve replacement with a RESILIA™ tissue bioprosthesis

Krzysztof Bartus[a,b], Radoslaw Litwinowicz [a,b,*], Agata Bilewska[c], Maciej Stapor[a], Maciej Bochenek [a,b,d], Jacek Rozanski[c], Jerzy Sadowski[a,b], Grzegorz Filip[a,b], Mariusz Kusmierczyk[c] and Boguslaw Kapelak[a,b]



N=133, Ø věk 65,3 ± 13,5; (25,6% ≤ 60 roků)

FU 4,2 ± 1,5 roků

meanG 14,8 ± 7,6mmHg, EOA 1,4 ± 0,5 cm2

Safety event	Early events (≤30 days), % (N=133)	Late events (>30 days), %	Probability event free at 5 years, % (95% CI)
Mortality	2.3	3.2	83.4 (76.8–89.9)
Reoperation	0	0.2	99.2 (97.7–100)
Explan	0	0.2	99.2 (97.7–100)
Thromboembolism	2.3	0.4	95.9 (92.3–99.5)
Valve thrombosis	0	0.2	99.2 (97.6–100)
All bleeding	8.3	0.4	89.8 (84.5–95.1)
Major bleeding	6.8	0.4	91.3 (86.4–96.3)
Major PVL	0	0	100 (100–100)
Endocarditis	0	0.2	99.2 (97.7–100)
Non-SVD	0	0.2	99.1 (97.4–100)
SVD	**0**	**0**	**100 (100–100)**

Bartus, et al. EJCTS, 2021, 59.2: 434-441.

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Inspiris Resilia - COMMENCE trial vs. PARTNER 2A

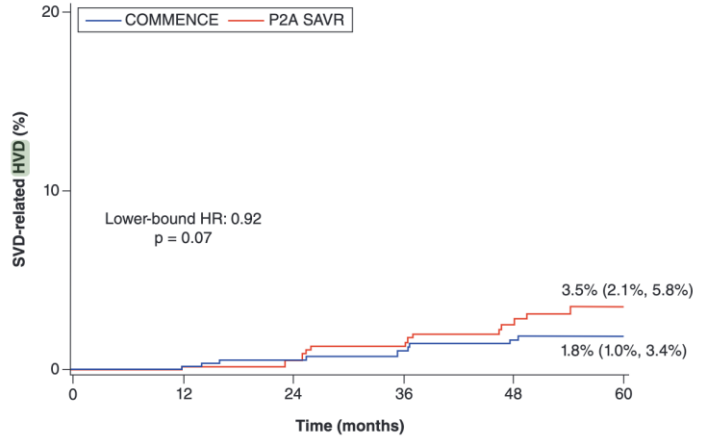
Structural hemodynamic valve deterioration durability of RESILIA-tissue versus contemporary aortic bioprostheses

Journal of Comparative Effectiveness Research

Krzysztof Bartus*,[1], Joseph E Bavaria[2], Vinod H Thourani[3], Ke Xu[4] & Eric L Keuffel[5]
[1]Department of Cardiovascular Surgery & Transplantology, Jagiellonian University Medical College, Institute of Cardiology, John Paul II Hospital, Krakow, Poland
[2]Department of Cardiovascular Surgery, Hospital of the University of Pennsylvania, Philadelphia, PA, USA
[3]Department of Cardiovascular Surgery, Marcus Valve Center, Piedmont Heart Institute, Atlanta, GA, USA
[4]Edwards Lifesciences, Irvine, CA, USA
[5]Health Finance & Access Initiative, Ardmore, PA, USA
*Author for correspondence: krzysztofbartus@gmail.com

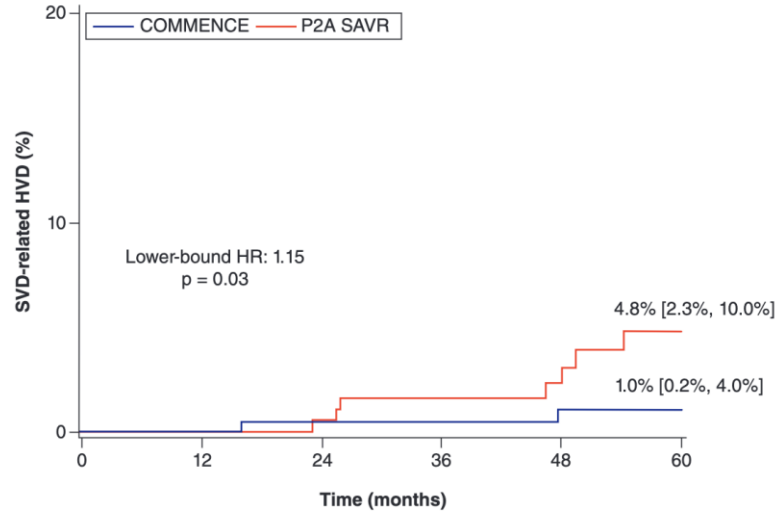
COMMENCE trial (n = 689) vs PARTNER 2A
AVR arm (n = 936)
Ø věk: 66,9 ± 11,6let vs 81,7 ± 6,7let
SVD 1,8% vs. 3,5%

PSM (n=239 párů)
SVD 1,0% vs. 4,8%



At risk (n):

COMMENCE	620	619	587	547	478	397
P2A SAVR	664	625	538	449	346	265



At risk (n):

COMMENCE	239	239	224	204	175	142
P2A SAVR	239	230	198	165	131	102

Bartus, Structural hemodynamic valve deterioration durability of RESILIA-tissue versus contemporary aortic bioprostheses. Journal of Comparative Effectiveness Research, 2023, 0: e220180.

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Inspiris Resilia - INDURE registr

INDURE registr - 21 center (EU, CAN), 2018 - 2021
N = 421, věk < 60 years
Ø věk: 53 let

Outcomes, n/N (%)	Discharge	1-year FU
All-cause mortality	**1/421 (0.2)**	**7/354 (2.0)**
Valve-related mortality:		
Valve-related	0/421 (0.0)	1/354 (0.3)
Not valve-related	1/421 (0.2)	3/354 (0.8)
Unknown	0/421 (0.0)	3/354 (0.8)
Repeated procedure	**0/421 (0.0)**	**1/349 (0.3)**
Stroke	2/421 (0.5)	2/349 (0.6)
Life-threatening bleeding	16/421 (3.8)	16/351 (4.6)
Pacemaker implantation	16/421 (3.8)	19/350 (5.4)
Endocarditis	**0/421 (0.0)**	**1/348 (0.3)**
Sub-clinical valve thrombosis	0/421 (0.0)	6/348 (1.7)
SVD stage 3†	**N/A**	**0/301 (0.0)**

Hemodynamic	Discharge	1-year FU
	mean ± SD	mean ± SD
MPGs, mmHg	11.7 ± 4.3	12.8 ± 5.4
PPGs, mmHg	20.9 ± 7.7	22.7 ± 9.0
EOA, cm^2	2.1 ± 0.6	1.9 ± 0.6

Mean valve size: 24.4 ± 2.3

Meuris B, et al. Presented at the EACTS meeting, Milano, October 2022

Inspiris Resilia - minitorakotomie

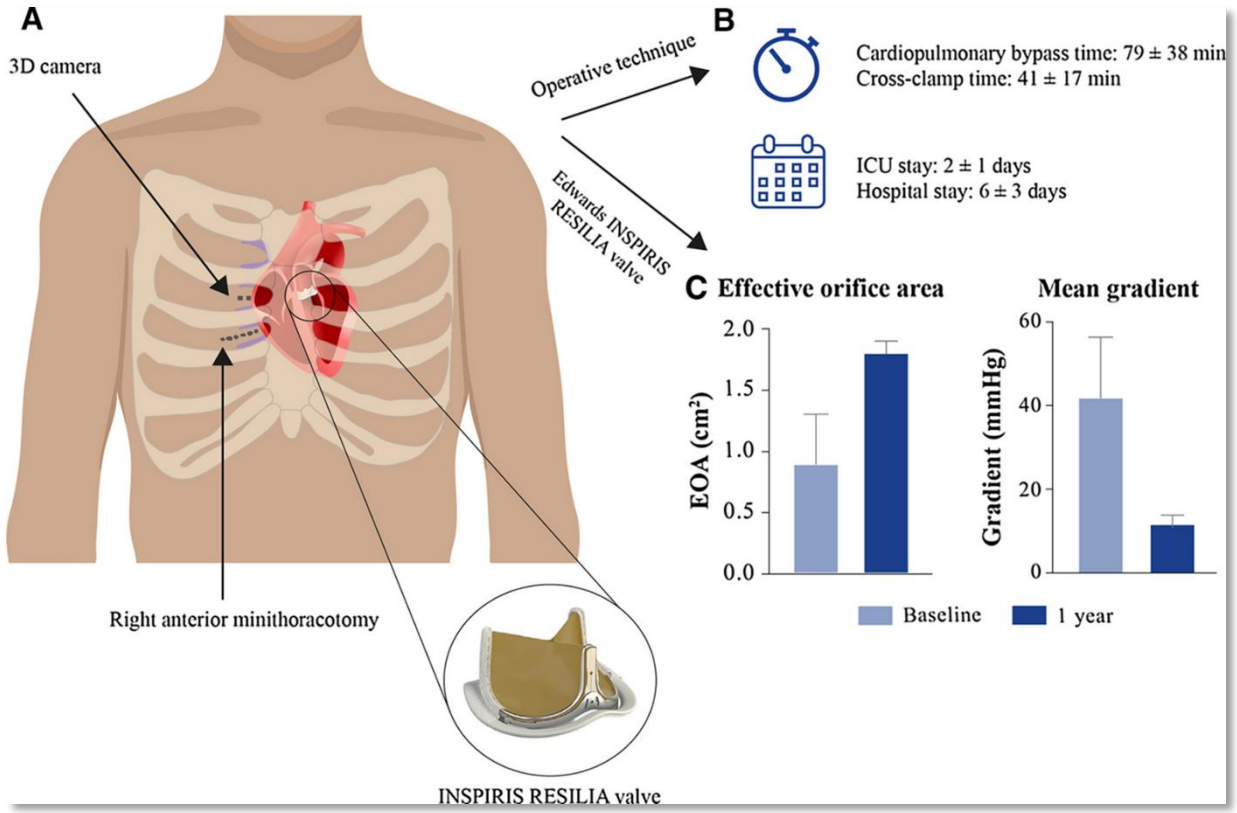
Adv Ther (2021) 38:2435–2446
https://doi.org/10.1007/s12325-021-01705-x

ORIGINAL RESEARCH

The First 100 Cases of Two Innovations Combined: Video-Assisted Minimally Invasive Aortic Valve Replacement Through Right Anterior Mini-Thoracotomy Using a Novel Aortic Prosthesis

N=100, Ø věk 56±9
video-assistovaná mini-thorakotomie
30-denní mortalita 0%, CMP 0%

EOA after 1y: 1.8 ± 0.1 cm²
mean gradient: 11.5 ± 2.3 mmHg
BEZ - SVD, PVL, IE, trombózy



El-Sayed, et al.. Advances in Therapy, 2021, 38.5: 2435-2446.

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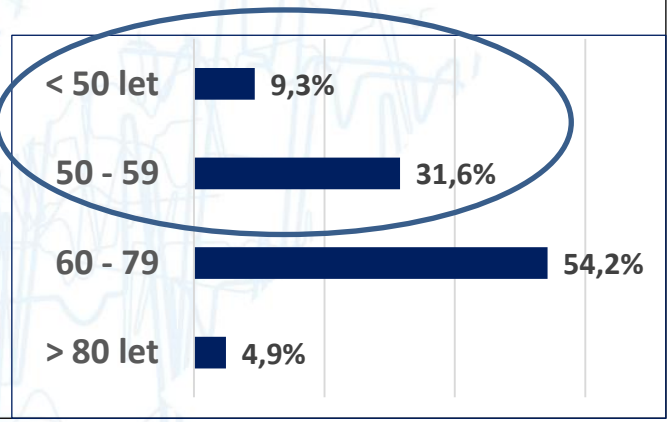
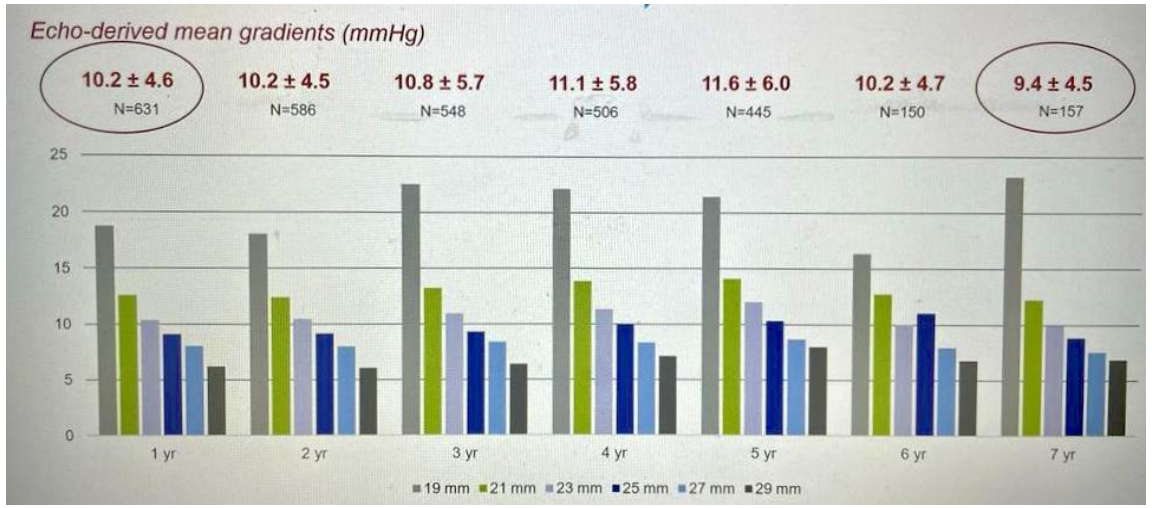
COMMENCE trial - 7 let

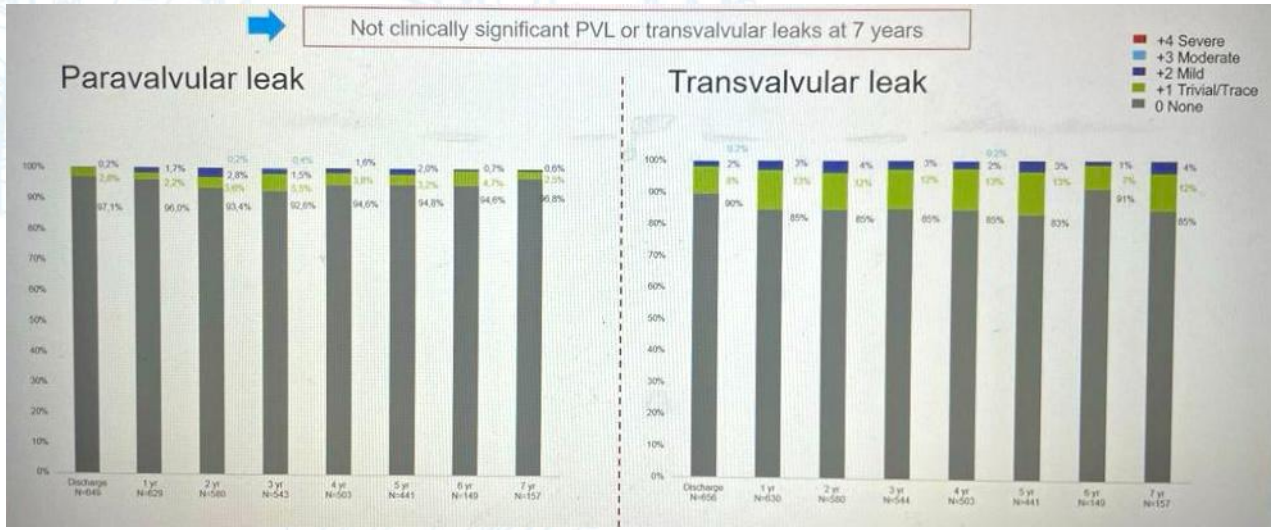
COMMENCE trial
N=225
Ø věk: 65,1 ± 10,9
20-90 let

FU 7,7 ± 0,7 let

2x SVD (67,71 let)







Beaver T, Bavaria J, Griffith B, Presented at the 103nd Annual Meeting of the AATS, May, 2023

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Závěr