Propensity-matched 8-year outcomes following aortic valve replacement with novel versus contemporary tissue bioprostheses

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Disclosures

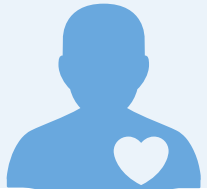
- **Advisory board member and consultant**
  Dr. Kaneko is on advisory boards for Edwards Lifesciences, Abbott Vascular, Johnson & Johnson, and serves as a consultant for Medtronic, Inc.

Background

- The selection of valve prosthesis depends on multiple factors including age, life expectancy, ability to tolerate anticoagulation, and patient preferences
- Durability of bioprostheses for surgical aortic valve replacement (SAVR) is an especially important consideration in patients with a longer life expectancy in terms of structural valve deterioration (SVD), reoperation risk, and survival
- Limited data has been published for long-term clinical outcomes of SAVR RESILIA tissue valves

RESILIA tissue is a bovine pericardial tissue incorporating a novel integrity preservation technology

- This tissue technology is incorporated in the INSPIRIS RESILIA aortic valve, KONECT RESILIA aortic valved conduit, MITRIS RESILIA mitral valve, and SAPIEN 3 Ultra RESILIA TAVR valve



Excellent outcomes for RESILIA tissue have been demonstrated through 7 years[1]

85.4%
Freedom from all-cause mortality at 7 years

99.3%
Freedom from structural valve deterioration (SVD) at 7 years

EARLY AND LATE CLINICAL EVENTS

Endpoint	**Early (≤30 POD) events (%)**	**Probability event-free at 7 years (%)** (95% CI)
All cause mortality	**8 (1.2%)**	**85.4 (82.2 – 88.7)**
Stroke	11 (1.6%)	94.0 (92.1 – 95.9)
Valve thrombosis	0 (0%)	99.4 (98.6 – 100.0)
Major bleeding	5 (0.7%)	90.9 (88.1 – 93.8)
Endocarditis	0 (0%)	97.3 (95.8 – 98.7)
Major PVL*	1 (0.1%)	99.5 (99.0 – 100.0)
NSVD *other than PVL*	0 (0%)	99.5 (98.6 – 100.0)
Structural Valve Deterioration	**0 (0%)**	**99.3 (98.3 – 100.0)**
Reoperation	1 (0.1%)	97.2 (95.5 – 99.0)

* Major paravalvular leak is paravalvular leak of any grade requiring surgical intervention or considered an SAE.
All event definitions per CW Akins et al. *J Thorac Cardiovasc Surg* 2008; 135:732-8

[1]Beaver T, Bavaria JE, Griffith B, et al. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. J Thorac Cardiovasc Surg. 2024;168(3):781-791. doi:10.1016/j.jtcvs.2023.09.047

Objective

SAVR outcomes through 7 years has been the **longest term** clinical data published on **RESILIA tissue** valves and **limited data** exist comparing this novel tissue to **contemporary** tissue valves

A **comparative 8-year analysis** has been undertaken that compares **SAVR clinical outcomes** of **RESILIA** and **Non-RESILIA** tissue valves

Today, we report 8-year comparative outcomes from this study

Methods and Study Design

OBJECTIVE

Compare outcomes of RESILIA tissue valves to Non-RESILIA tissue valves using propensity-score matching (inverse probability of treatment weighting)

ENDPOINTS

- All-cause mortality
- SVD
- Reoperation
- Reoperation due to SVD

STUDY COHORT

COMMENCE
n=689 Implanted Aortic patients

MAGNA EASE PAS
n=258 Implanted patients

Study Synopsis:

Device	RESILIA At 8 years	Non-RESILIA At 8 years
Study design	Multicenter	Multicenter
Comparator	Single-arm	Single-arm
Mean Age	66.9 years	68.5 years
Patients	689 (239 reconsented)	258
CEC	✓	✓
Core Lab	✓	✗
SVD definition*	Akins et al. (2008)	Akins et al. (2008)

Magna Ease + RESILIA vs. Magna Ease + TFX

*Standardized definition of SVD was utilized (Akins et. al 2008)

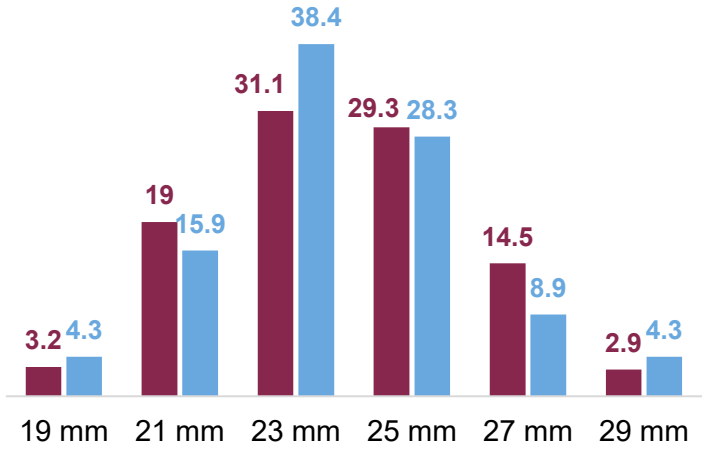
RESILIA

NON-RESILIA

Summary of baseline demographics

	RESILIA	NON-RESILIA
Age (years), Mean ± SD (n)	66.9 ± 11.61 (689)	68.5 ± 8.83 (258)
Male, % (n)	71.8 (495)	64.7 (167)
Baseline NYHA Class III/IV, % (n)	26.3 (181)	32.5 (82)

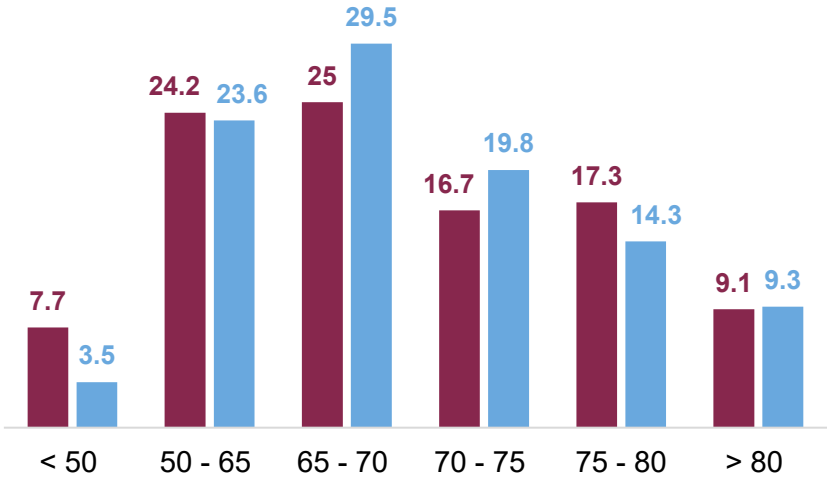
Valve Size Distribution



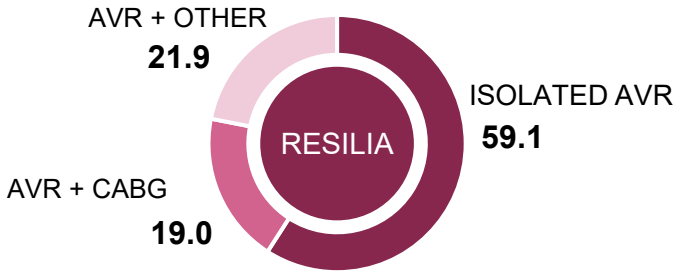
Etiology

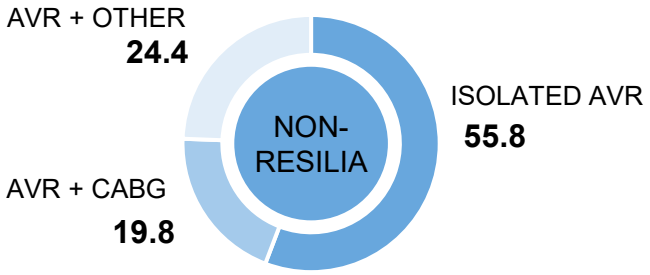
	RESILIA (N=689)	Non-RESILIA (N=258)
Aortic Stenosis %, (n)	50.9 (351)	70.9 (183)
Aortic Regurgitation %, (n)	7.0 (48)	9.7 (25)
Mixed Aortic Valve Disease, % (n)	38.8 (267)	18.6 (48)

Age Group, % (n)



Concomitant Procedure Group, % (n)





Cohorts were propensity score-matched according to pre-specified clinically relevant baseline variables

Age	Coronary artery disease	History of MI
Sex	Renal failure/insufficiency	COPD
BMI	Diabetes	Moderate/severe mitral regurgitation
NYHA class	Prior pacemaker implant	Aortic valve intervention
TIA/CVA	CABG	

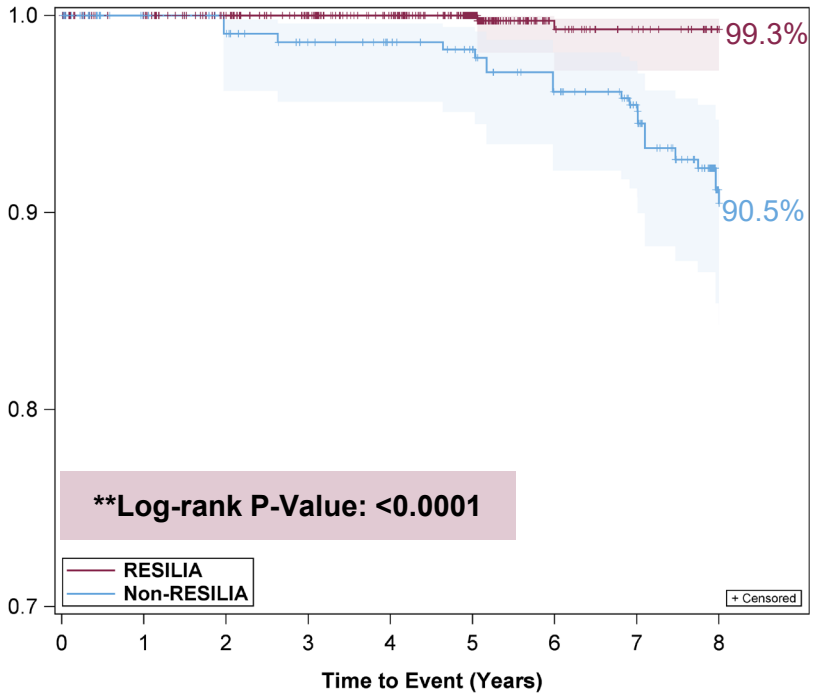
Baseline characteristics (after Propensity Score Adjustment)

*Variables**	**RESILIA** *(N=689)*	**Non-RESILIA** *(N=258)*	**Absolute Standardized Difference**
Age	67.4±11.4 (20.0, 90.0)	67.5±9.1 (36.1, 86.4)	0.0047
Sex - Female	30.2%	33.3%	0.0660
BMI	29.7±5.7 (16.3, 51.9)	29.8±6.0 (18.1, 50.8)	0.0167
Baseline NYHA Class III/IV	27.7%	28.9%	0.0282
Diabetes Mellitus	26.6%	25.4%	0.0275
Renal Failure/Insufficiency	6.9%	4.0%	0.1277
Coronary Artery Disease	51.8%	51.1%	0.0151
TIA/CVA	7.6%	5.8%	0.0737
History of Myocardial Infarction	7.0%	5.7%	0.0551
COPD	13.3%	13.8%	0.0147
Mitral Regurgitation - Moderate/Severe	2.7%	2.5%	0.0084
Prior Aortic Valve Intervention	3.3%	2.4%	0.0518
CABG	2.8%	1.3%	0.1115
Prior Pacemaker Implant	2.4%	2.7%	0.0195

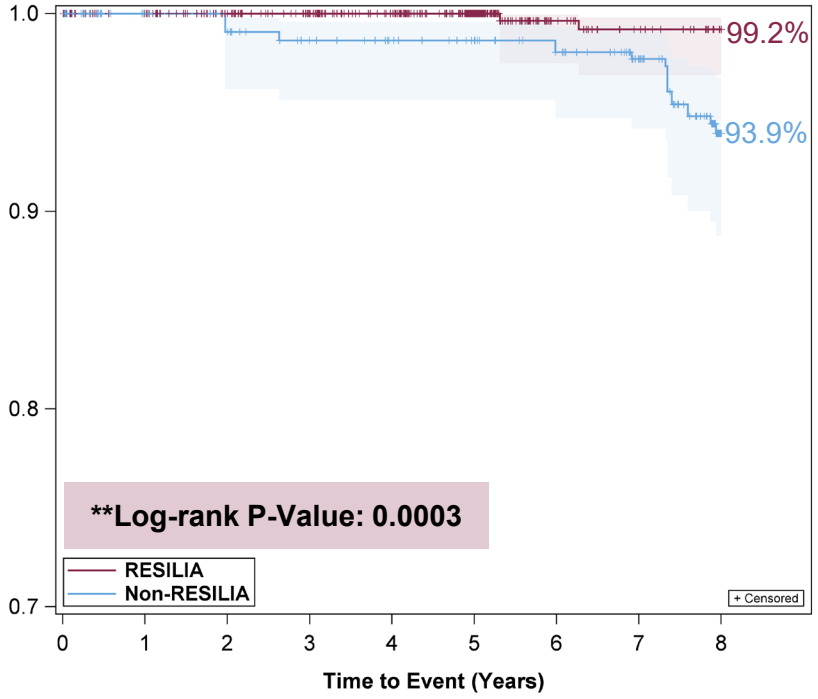
*No difference if the absolute standardized differences are <0.25

RESILIA tissue valves had significantly improved freedom from reoperation due to SVD compared to Non-RESILIA valves

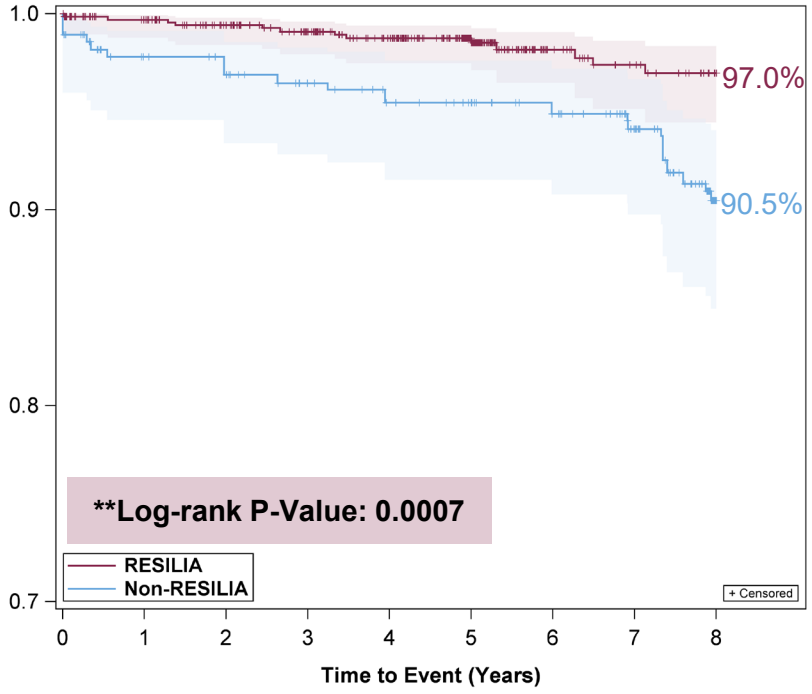
Freedom from SVD*



Freedom from Reoperation Due to SVD*



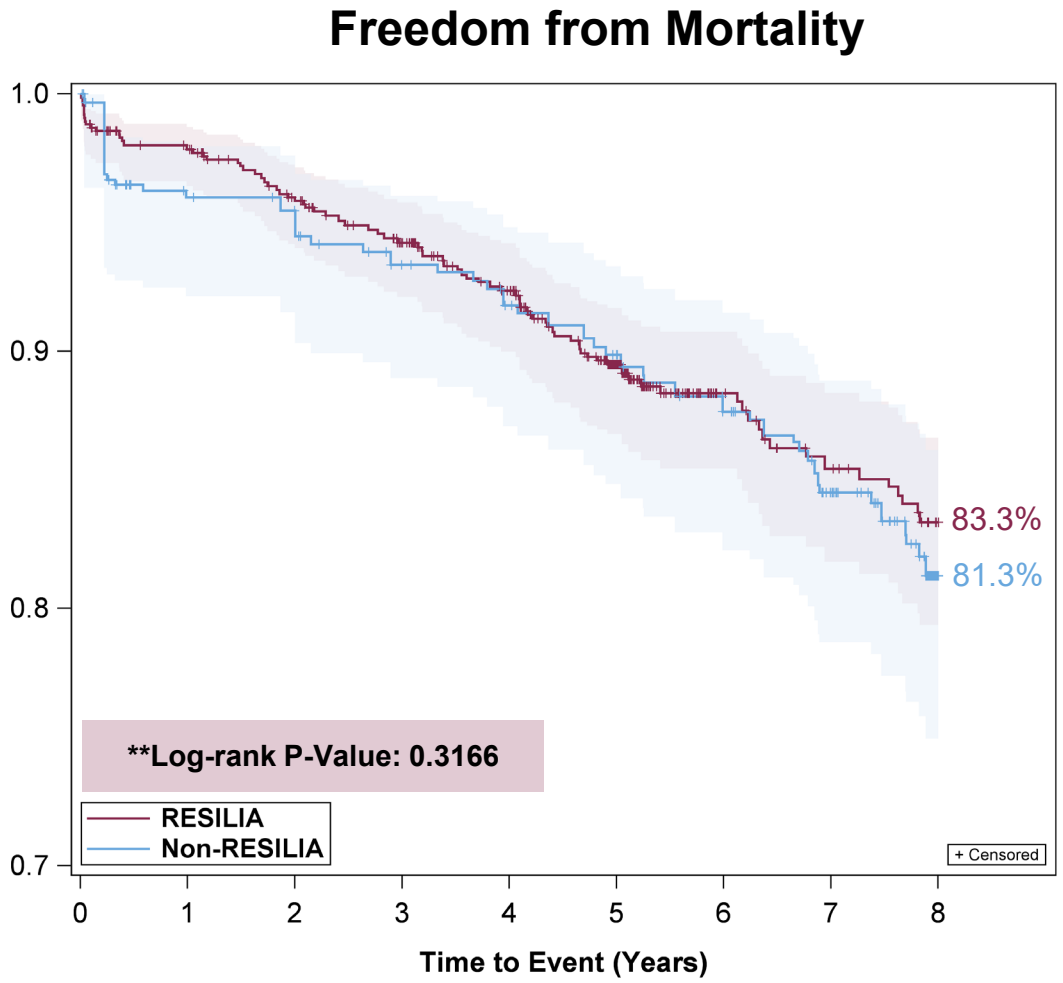
Freedom from Reoperation

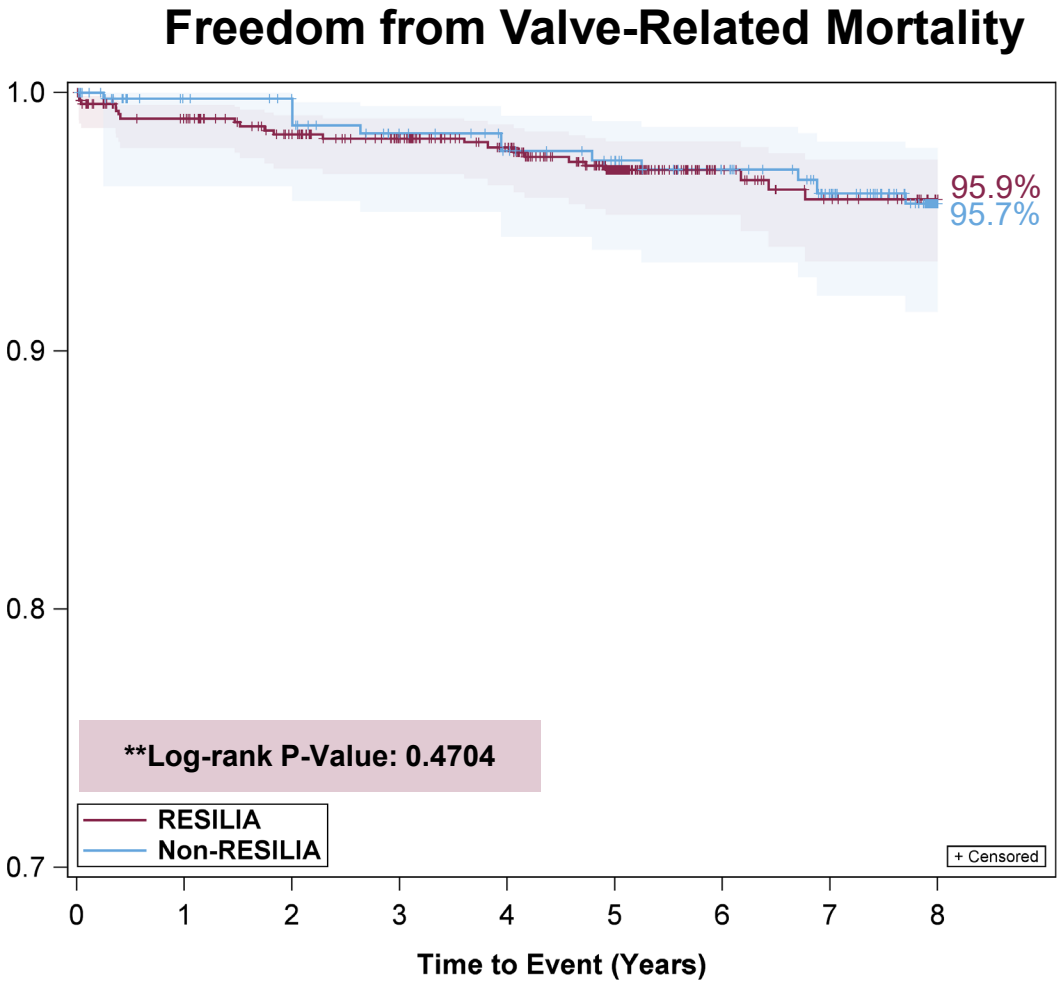


**Superiority Test Log-Rank P-Value

*Standardized definition of SVD was utilized (Akins et. al 2008)

Both groups demonstrated excellent freedom from mortality or valve-related mortality





**Superiority Test Log-Rank P-Value

Summary of 8-year safety events

After Propensity Score Adjustment

Safety Events	RESILIA *(N=689)*	Non-RESILIA *(N=258)*	Log-Rank P-value
All-Cause Mortality	83.3%	81.3%	0.6332
Valve Related Mortality	95.9%	95.7%	0.9409
Stroke	92.8%	93.2%	0.9020
Major Bleeding	**90.4%**	**85.3%**	**0.0177**
Structural Valve Deterioration	**99.3%**	**90.5%**	**<.0001**
Non-Structural Valve Deterioration	**99.1%**	**97.9%**	**0.0296**
Reoperation	**97.0%**	**90.5%**	**0.0014**
Reoperation Due To SVD	**99.2%**	**93.9%**	**0.0007**
Endocarditis	97.4%	97.0%	0.6906
Thromboembolism	88.5%	85.4%	0.2823

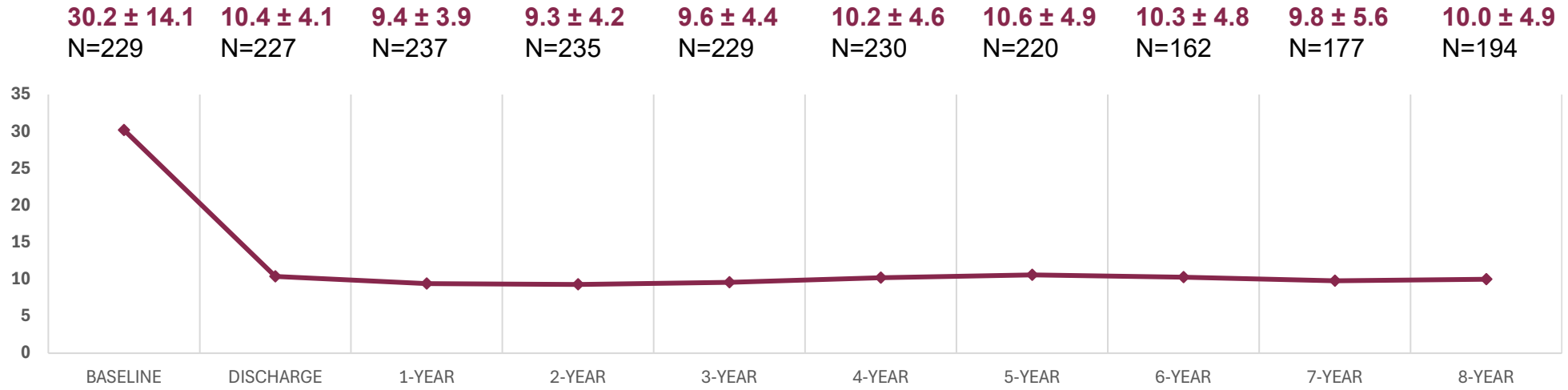
Cause of SVD*/Reintervention type

Group	*SVD type*	*Mode*	*Outcome*
RESILIA	Calcification	Stenosis	ViV
RESILIA	Restricted leaflet motion of uncertain etiology	Stenosis	Explant
Non-RESILIA	Calcification	Stenosis	Explant
Non-RESILIA	Stenosis	Stenosis	Explant
Non-RESILIA	Calcification	Stenosis	ViV
Non-RESILIA	Mild leaflet restriction	Regurgitation	ViV
Non-RESILIA	Stenosis	Stenosis	ViV
Non-RESILIA	Calcification	Stenosis	ViV
Non-RESILIA	Stenosis	Stenosis	Explant
Non-RESILIA	Severe AI/Regurgitation	Regurgitation	ViV
Non-RESILIA	Stenosis	Stenosis	ViV
Non-RESILIA	Stenosis and Insufficiency	Mixed	ViV
Non-RESILIA	Stenosis	Stenosis	ViV
Non-RESILIA	Stenosis	Stenosis	Not Re-Intervened
Non-RESILIA	Stenosis - Mild	Stenosis	Not Re-Intervened
Non-RESILIA	Stenosis	Stenosis	Not Re-Intervened
Non-RESILIA	Regurgitation	Regurgitation	Not Re-Intervened
Non-RESILIA	Stenosis	Stenosis	CHF/Death

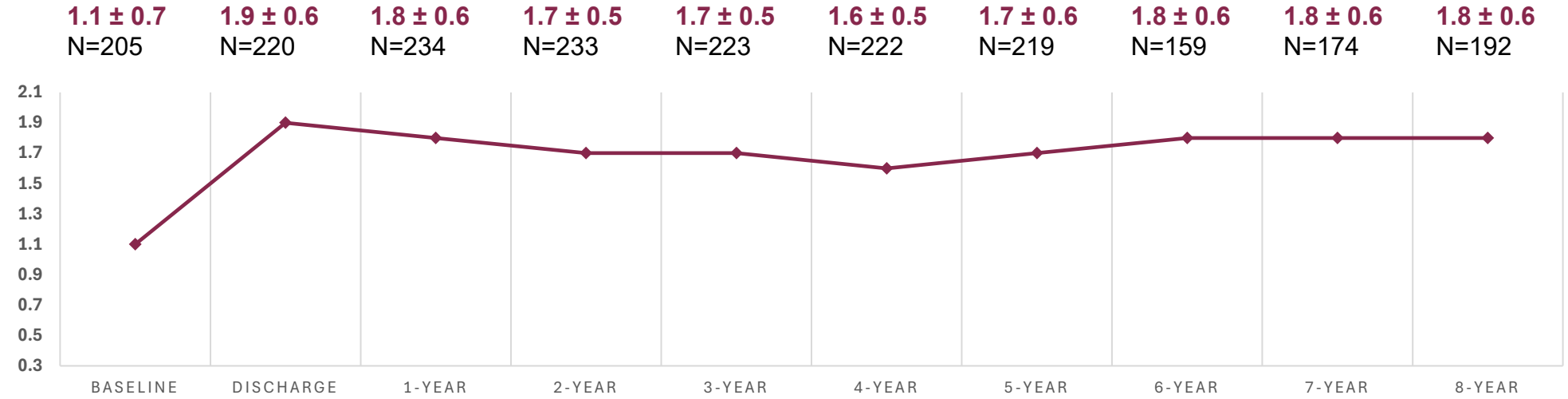
***Standardized definition of SVD was utilized (Akins et. al 2008)**

RESILIA valves demonstrated clinically stable hemodynamics through 8 years

Mean Gradient (mmHg)



EOA (cm^2)



Conclusions

In this propensity-score matched analysis:

- RESILIA tissue valves are proven to have better rates of SVD, reoperation due to SVD, and all-cause reoperation at 8 years than non-RESILIA tissue valves

- Clinically stable hemodynamics were observed in the RESILIA cohort, supporting excellent valve durability through 8 years

- These data support the choice of RESILIA tissue bioprosthesis for SAVR in patients aiming to maximize life expectancy while minimizing cumulative risk

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The present study represents the longest follow-up and first long-term propensity-matched analysis comparing outcomes from the novel calcification-resistant RESILIA tissue treatment versus a widely-used contemporary bioprosthesis