Clinical Summary:

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

Kaneko, T, Johnston D, Bavaria JE, et al. Propensity-matched 8-year outcomes following aortic valve replacement with novel versus contemporary bioprostheses. Presented at the Heart Valve Society Annual Scientific Meeting, April 2025.

Objective

This study aimed to compare outcomes of RESILIA tissue valves to non-RESILIA tissue valves using propensity-score matching.

Key Points

- The 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.
- This study supports the choice of RESILIA tissue valves over non-RESILIA tissue valves for SAVR in patients aiming to maximize life expectancy while minimizing cumulative risk.

Study Cohort

- The RESILIA tissue valve cohort consisted of patients from the COMMENCE aortic trial (n=689).
- The non-RESILIA tissue valve cohort originated from the Carpentier-Edwards PERIMOUNT Magna Ease post-approval study (n=258).

Table 1. Study synopses

Device	RESILIA tissue valves at 8 years	Non-RESILIA tissue valves at 8 years
Study Design	Multicenter	Multicenter
Study Cohort	COMMENCE Aortic	Magna Ease PAS
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)

End Points

- All-cause mortality, structural valve deterioration (SVD), reoperation, reoperation due to SVD.

Propensity Matching

- Cohorts were propensity score-matched according to pre-specified clinically relevant baseline variables including age, sex, BMI, NYHA class, TIA/CVA, coronary artery disease, renal failure/insufficiency, diabetes, prior pacemaker implant, CABG, history of MI, chronic obstructive pulmonary disease, moderate/severe mitral regurgitation, and aortic valve intervention.

Results

- RESILIA tissue valves demonstrated significantly improved freedom from SVD [Figure 1], reoperation due to SVD [Figure 2], and reoperation compared to the non-RESILIA tissue valves. [Table 2 for key endpoints].
- RESILIA tissue valves demonstrated clinically stable hemodynamics through 8 years. [Figure 3].

Table 2. Key Endpoints

Endpoint (Freedom From)	RESILIA tissue valves	Non-RESILIA tissue valves	Log-Rank P-Value
All-cause mortality	83.3%	81.3%	0.6332
SVD	99.3%	90.5%	<.0001
Reoperation	97.0%	90.5%	0.0014
Reoperation due to SVD	99.2%	93.9%	0.0007

Conclusions

- 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 tissue valve cohort, supporting excellent valve durability through 8 years.

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RESILIA tissue valves demonstrated significantly improved freedom from SVD and reoperation due to SVD compared to the non-RESILIA tissue valves.

Figure 1.

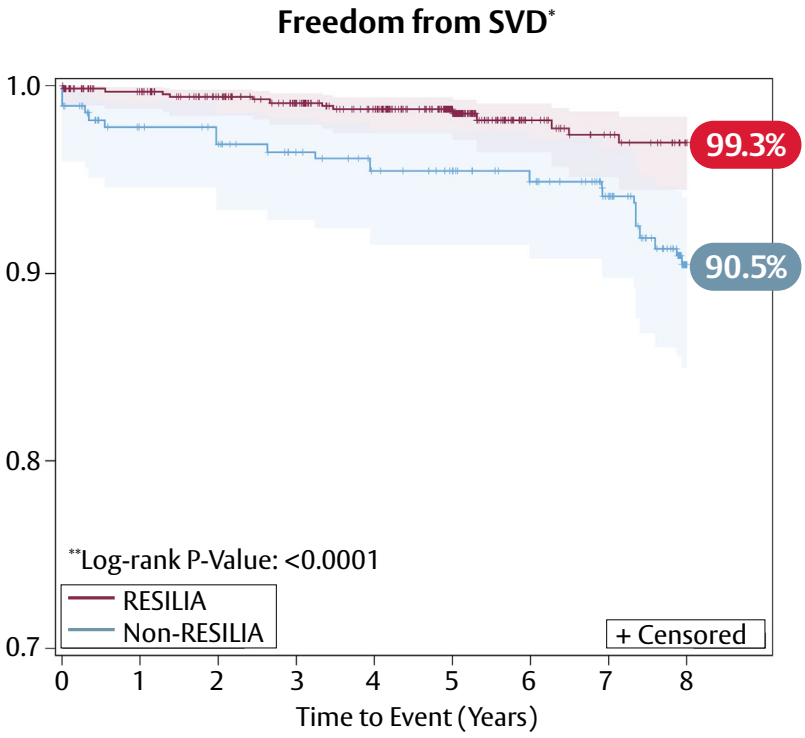
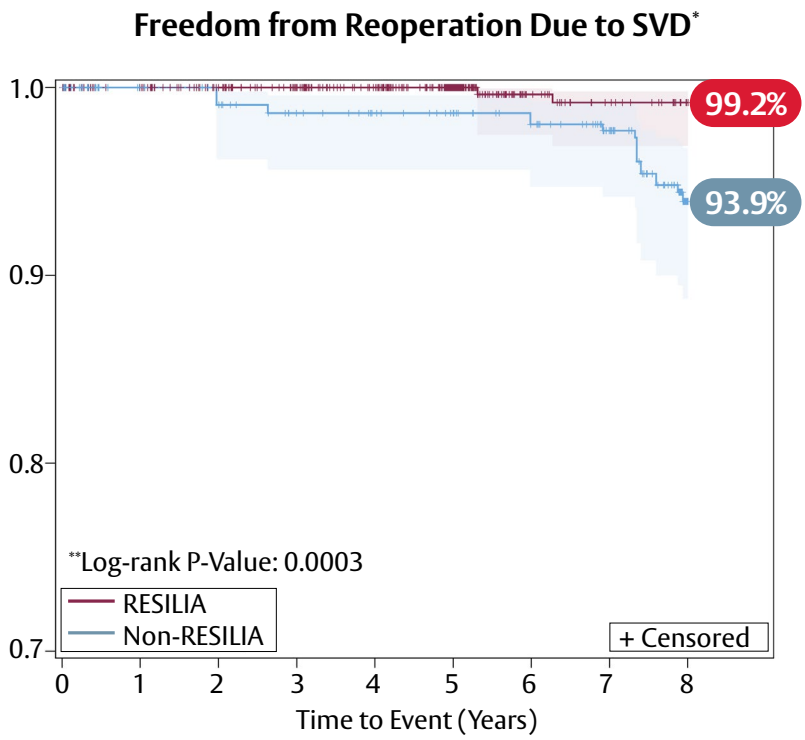


Figure 2.



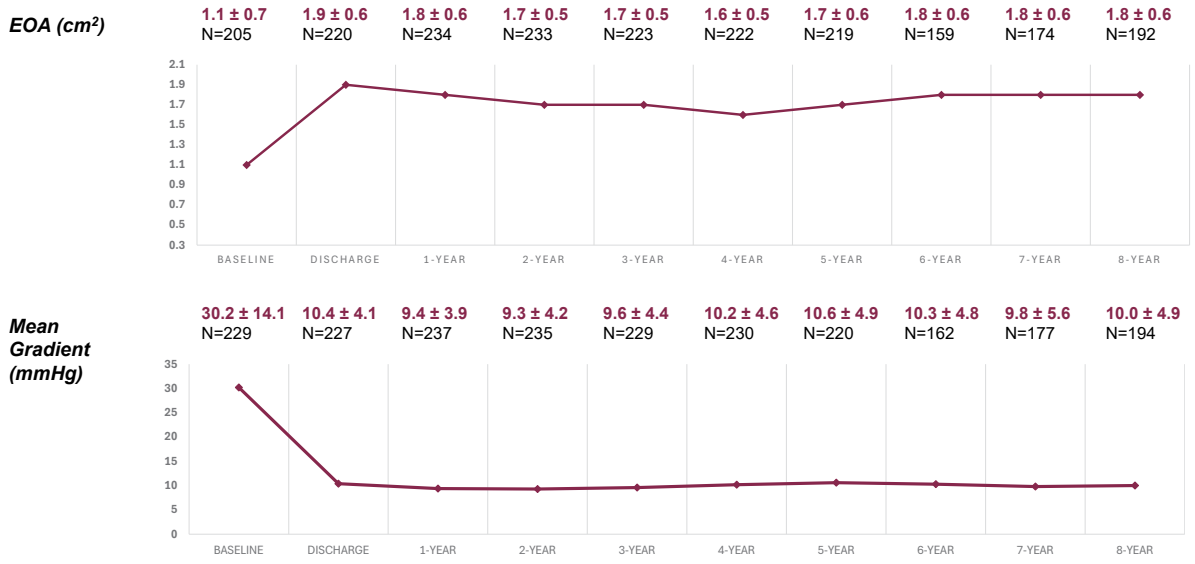
*Standardized definition of SVD was utilized (Akins et. al 2008)

**Superiority Test Log-Rank P-Value

Table 3. Summary of 8-year safety events, after propensity score adjustment

Safety Events	RESILIA tissue valves (N=689)	Non-RESILIA tissue valves (N=258)	Log-Rank P-Value
All-Cause Mortality	83.3%	81.3%	0.6332
Valve Related Death	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

Figure 3. RESILIA tissue valve only hemodynamics through 8 years



Clinical data on surgical valves with RESILIA tissue up to 7-year follow-up have been published, with additional follow-up to 10-years in progress.[2]

Reference:

1. Kaneko T, Johnston D, Bavaria J, et al. Propensity-matched 8-year outcomes following aortic valve replacement with novel versus contemporary tissue bioprostheses Presented at HVS 2025.
2. 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 Sep;168(3):781-791.

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