

COMMENCE Aortic Trial 10-Year Outcomes

Study Introduction¹

The COMMENCE aortic trial was an FDA-approved pivotal trial designed to evaluate the safety and effectiveness of a bioprosthesis with RESILIA tissue used in surgical aortic valve replacement (SAVR). As the follow-up time in this study has reached the 10-year mark, direct and indirect measures of valve durability with RESILIA tissue will be highlighted.

Durability Highlights¹



Ten-year milestone for RESILIA tissue valves

The innovation that advanced the tissue valve landscape continues to demonstrate favorable safety outcomes and durable performance at 10 years



Tissue designed to last: Promising durability through 10 years

- The first reported long-term data demonstrating excellent results through 10 years with RESILIA tissue valves
- High rates of freedom from reintervention and structural valve deterioration (SVD)

At 10 years, RESILIA tissue demonstrated:¹

97.9%
Freedom from SVD

97.8%
Freedom from reoperation due to SVD

94.3%
Freedom from valve-related mortality

Study Methods & Patient Demographics¹

Methods



Trial methodology

- Between January 2013 and March 2016, 689 patients in the full cohort underwent SAVR with the Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue (model 11000A)
- A large, prospective, non-randomized multicenter, single-arm Investigational Device Exemption (IDE) trial exploring the outcomes of SAVR with a bioprosthesis utilizing RESILIA tissue
- Study subjects were initially enrolled at 27 clinical sites in the US and Europe
- At 5 years, patient re-consent was performed across 10 centers for longer-term follow-up to 10 years



Safety endpoints

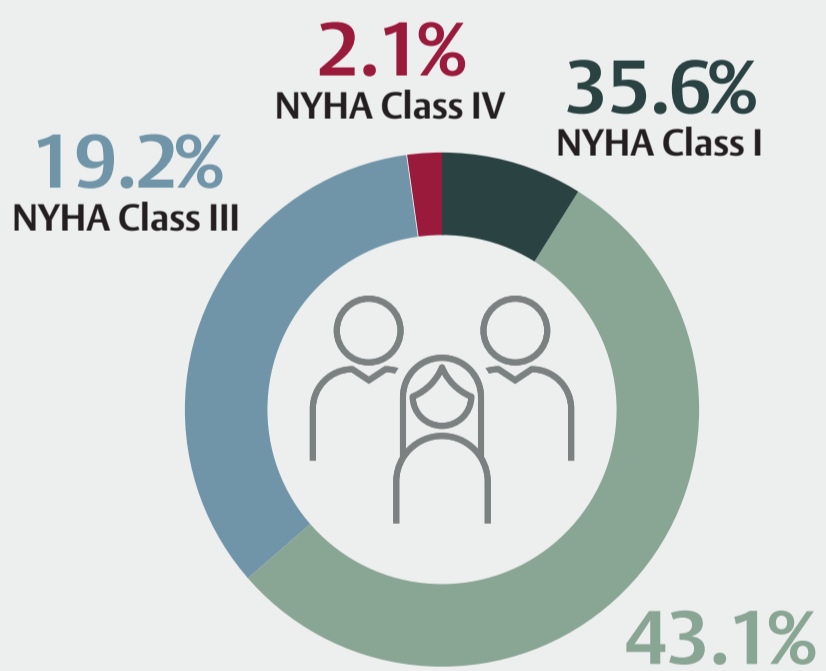
- The first reported long-term data demonstrating excellent results through 10 years with RESILIA tissue valves
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Patient demographics of the re-consented cohort at 10 years

192
patients completed
10-year visits

65.1 ± 10.9
years mean age

1.7 ± 1.5%
mean STS risk score*



*STS scores only calculated for patients undergoing isolated aortic valve replacement (AVR) or AVR and coronary artery bypass graft.

†There were significant differences in sex (P=0.02) and NYHA class (P=0.0001) between re-consented and non-re-consented patients.

Summary of Safety Events^{1,2,3}

Endpoint	Cumulative events at 10 years	Freedom from events, (%) (95% CI)		
		At 5 years	At 7 years	At 10 years
SVD	5	100.0 (100.0–100.0)	99.3 (98.3–100.0)	97.9 (96.0–99.8)
Valve-related mortality	25	96.8 (95.4–98.2)	N/A	94.3 (91.8–96.8)
Reoperation	18	98.7 (97.8–99.6)	97.2 (95.5–99.0)	94.5 (91.8–97.2)
Reoperation due to SVD	5	N/A	N/A	97.8 (95.8–99.7)
Study valve explant	10	99.0 (98.2–99.8)	N/A	97.5 (95.8–99.2)
Stroke	39	94.5 (92.7–96.3)	94.0 (92.1–95.9)	93.1 (90.9–95.4)
Valve thrombosis	2	100.0 (100.0–100.0)	99.4 (98.6–100.0)	99.5 (98.7–100.0)
Endocarditis	15	97.8 (96.6–99.0)	97.3 (95.8–98.7)	97.3 (95.9–98.7)
All-cause mortality	97	89.2 (86.1–91.6)	85.4 (82.2–88.7)	78.3 (74.1–82.6)

Implanted aortic population, N=689.

Freedom from event: Survival estimate (lower confidence limit, upper confidence limit). Event counts, survival estimates, and CI based on Kaplan-Meier analysis of time to first occurrence (early or late).

N/A, not applicable.

RESILIA tissue:¹



Ten years of data

The 10-year data from the COMMENCE aortic trial represents the longest follow-up after SAVR with RESILIA tissue



Stable, durable performance

The low incidence of SVD and valve-related reintervention at 10 years demonstrate sustained long-term durability

References:

1. Svensson L, Blackstone E, Bavaria JE, et al. Long-term outcomes following aortic valve replacement with a novel tissue bioprosthesis: 10-year results from the COMMENCE trial. Presented at the American Association for Thoracic Surgery, May 2026.
2. Bavaria JE, Griffith B, Heimansohn DA, et al. Five-year outcomes of the COMMENCE trial investigating aortic valve replacement with RESILIA tissue. *Ann Thorac Surg.* 2023;115(6):1429-1436. doi:10.1016/j.athoracsur.2021.12.05
3. 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

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 progress³.

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