Edwards

Proof that Ignites Progress

COMMENCE Aortic Trial
10-Year Outcomes

Study Introduction & Key Points[1]

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.

Key points[1]

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

Sustained hemodynamic performance

- Clinically stable hemodynamic performance through 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)

Results[1]

Outcomes @ 10 years

97.9% Freedom from SVD

97.8% Freedom from reoperation due to SVD

94.3% Freedom from valve-related mortality

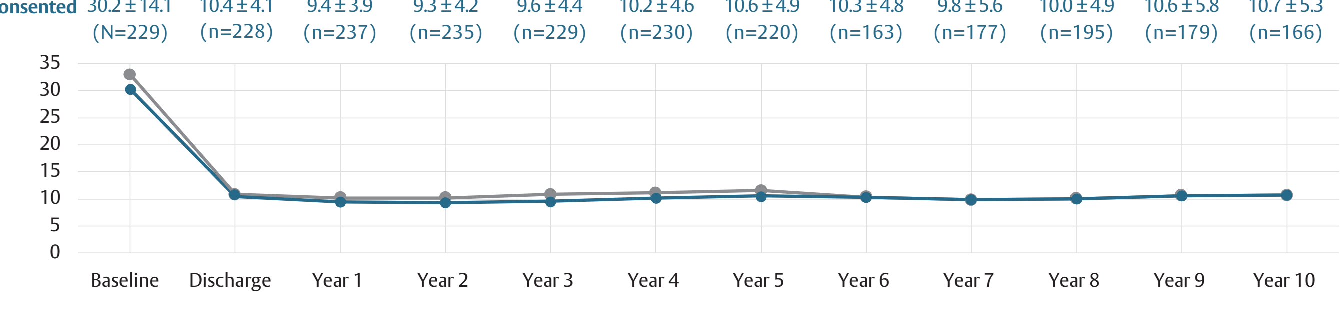
98.6% Freedom from non-structural valve dysfunction (other than paravalvular leak)

Clinically stable hemodynamics through 10 years*

1.8 ± 0.7 cm²
Mean effective orifice area

Mean gradient (mmHg)

	Baseline	Discharge	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Implanted	33.0 ± 14.5 (N=665)	10.8 ± 4.8 (n=655)	10.2 ± 4.6 (n=631)	10.2 ± 4.5 (n=586)	10.8 ± 5.7 (n=548)	11.1 ± 5.8 (n=506)	11.5 ± 6.0 (n=446)					
Reconsented	30.2 ± 14.1 (N=229)	10.4 ± 4.1 (n=228)	9.4 ± 3.9 (n=237)	9.3 ± 4.2 (n=235)	9.6 ± 4.4 (n=229)	10.2 ± 4.6 (n=230)	10.6 ± 4.9 (n=220)	10.3 ± 4.8 (n=163)	9.8 ± 5.6 (n=177)	10.0 ± 4.9 (n=195)	10.6 ± 5.8 (n=179)	10.7 ± 5.3 (n=166)



*Publication details to come.

Favorable safety outcomes and sustained hemodynamic performance at 10 years

Study Methods & Patient Demographics[1]

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, IDE trial exploring the outcomes of SAVR with a bioprothesis 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

- All potential safety endpoints were adjudicated by an independent Clinical Events Committee
- SVD and other safety outcomes were defined per Akins et al. 2008[2]

Key primary effectiveness endpoints

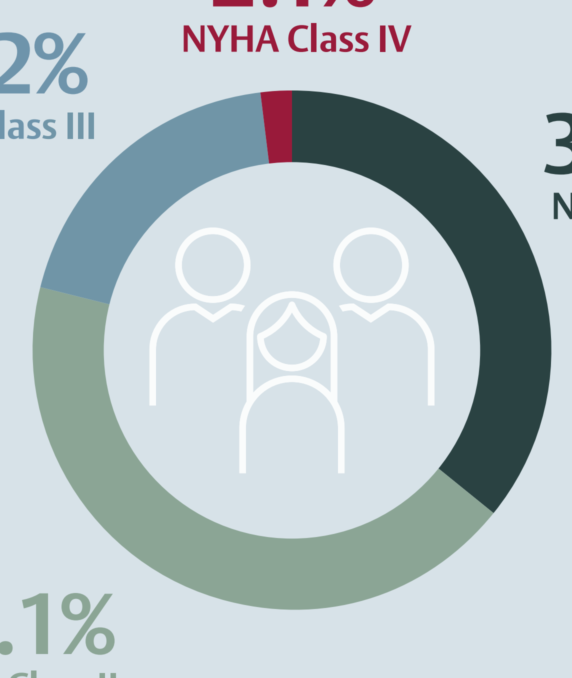
- Hemodynamic performance was evaluated by an independent echocardiographic core laboratory
- NYHA Class improvement

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



Summary of Key Safety Events[1,3,4]

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 (86.7–91.6)	85.4 (82.2–88.7)	78.3 (74.1–82.6)

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.

Conclusions[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**

Important Safety Information: RESILIA Tissue Devices

Indications: INSPIRIS RESILIA Aortic Valve - For use in replacement of native or prosthetic aortic heart valves. **KONECT RESILIA Aortic Valved Conduit** - For use in replacement of native or prosthetic aortic heart valves and the associated repair or replacement of a damaged or diseased ascending aorta. **MITRIS RESILIA Mitral Valve** - For use in replacement of native or prosthetic mitral heart valves.

Contraindications: There are no known contraindications with the use of these RESILIA tissue heart valve devices.

Complications and Side Effects: INSPIRIS RESILIA Aortic Valve - Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death. Additional adverse events potentially associated with the use of polyester vascular grafts in the **KONECT RESILIA AVC** include hemorrhage, thrombosis, graft infection, embolism, aneurysm, pseudoaneurysm, seroma, occlusion (anastomotic intimal hyperplasia), immunological reaction to collagen (shown to be a weak immunogen; infrequent, mild, localized and self-limiting), intimal peel formation, and conduit dilatation. **MITRIS RESILIA Mitral Valve** - Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability, and death.

Warnings: INSPIRIS RESILIA Aortic Valve - DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19 – 25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves. Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

CAUTION: US law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information.

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**. Akins CW, Miller DC, Turina MI, et al. Guidelines for reporting mortality and morbidity after cardiac valve interventions. *Ann Thorac Surg*. 2008;85(4):1490-1495. doi:10.1016/j.athoracsur.2007.12.082 **3**. 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 **4**. 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

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