

Clinical Summary:

Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis

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Objective

The COMMENCE aortic trial is an FDA pivotal trial designed to evaluate the safety and effectiveness of a bioprosthetic valve with RESILIA tissue. As the follow up time in this study advances beyond the mid-term period, direct and indirect measures of durability of valves with RESILIA tissue will be highlighted.

Key Points

- As bioprosthetic aortic valve replacement (AVR) extends to younger cohorts, tissue durability is becoming of paramount importance. Data from the COMMENCE 7-year aortic trial demonstrate excellent outcomes and the longest follow-up in a study of younger patients – 65.1 mean age
- The bioprosthetic valve with RESILIA tissue showed high rates of freedom from mortality, structural valve deterioration (SVD) and reintervention, including no major paravalvular regurgitation plus clinically stable gradients
- Results of the trial indicate a favorable safety profile and strong hemodynamic performance of a bioprosthetic valve with RESILIA tissue

Methods

- A prospective, international IDE trial, now in its post-approval phase, is exploring the outcomes of AVR with a bioprosthesis utilizing RESILIA tissue
 - Study subjects were enrolled at 27 clinical sites in U.S. and Europe
 - At 5 years, patient re-consent was performed for extended follow-up (years 6-10) and was mandatory for the top 3 enrolling sites. If interested in extended follow-up participation, additional sites then offered all eligible patients to consent and participate
- Safety endpoints
 - All potential safety endpoints adjudicated by an independent Clinical Events Committee
 - SVD and other safety outcomes defined per “Guidelines for reporting mortality and morbidity after cardiac valve interventions” (Akins et al. 2008)
- Effectiveness endpoints
 - Hemodynamic performance evaluated by an independent echocardiographic core laboratory
 - New York Heart Association (NYHA) Class

Patient Demographics

Full Cohort

- Between January 2013 and March 2016, 689 patients underwent AVR with the Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue (model 11000A)
 - Mean age 66.9 ± 11.6 years
 - STS risk score $2.0 \pm 1.8\%$
 - NYHA Class II and III were 50% and 24%, respectively
- A total of 512 patients completed 5-year follow up

Re-consented Cohort

- A total of 225 patients were re-consented for extended follow up
 - Mean age 65.1 ± 10.9 years
 - STS risk score $2.1 \pm 2.1\%$
 - NYHA Class II and III were 43% and 19%, respectively
- A total of 195 patients completed 7-year follow up

Results

- Safety endpoints, probability event-free at 7 years (shown in Table 1):
 - Kaplan-Meier analyses showed freedom from all-cause mortality was 85.4% (95% CI: 82.2 – 88.7)
 - 99.3% (95% CI: 98.3 – 100.0) freedom from SVD
 - 97.2% (95% CI: 95.5 – 99.0) freedom from reoperation
 - 99.5% (95% CI: 99.0-100) of patients had no major paravalvular regurgitation
 - Clinically stable hemodynamics out to 7 years:
 - Effective orifice area was 1.82 ± 0.57 cm²
 - Mean gradient was 9.4 ± 4.5 mmHg

Conclusions

- The 7-year data from the COMMENCE aortic trial represents the longest follow-up after AVR with RESILIA tissue in a large IDE trial utilizing an independent clinical events committee and an echocardiography core laboratory
- With excellent outcomes through 7 years, the COMMENCE trial demonstrates encouraging results for bioprostheses with RESILIA tissue
- Ongoing follow up out to 10 years will continue to evaluate the long-term safety and effectiveness of this bioprosthetic valve with RESILIA tissue



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Figure 1. Hemodynamic performance: Echo-derived mean gradients (mmHg)

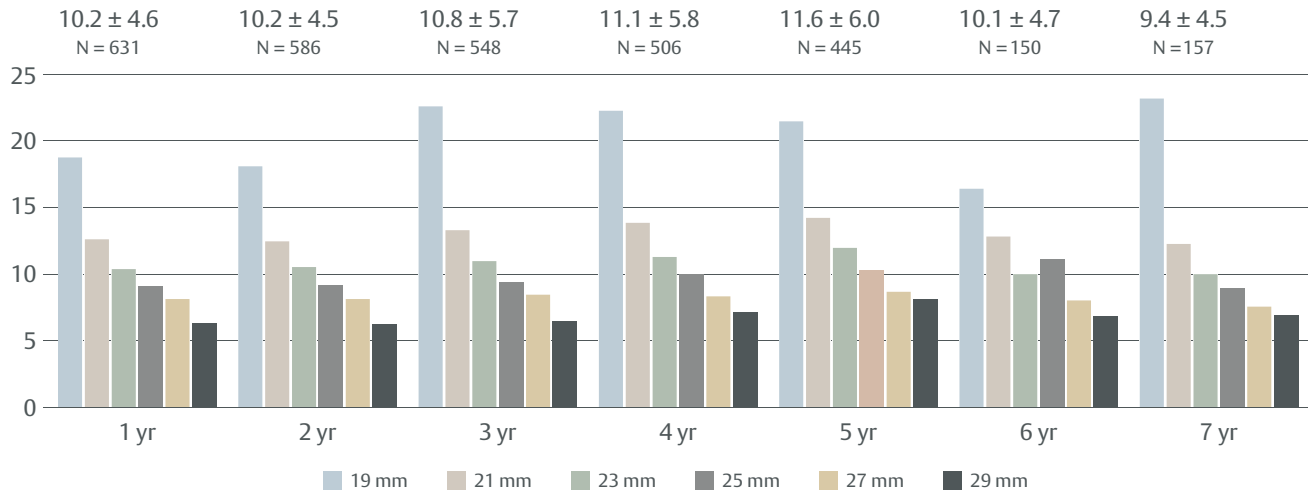


Table 1. Safety endpoints

Endpoint	Early (≤30 POD) events (%)	Cumulative events at 7 yrs	Probability event-free at 7 yrs (%) (95% CI)
All cause mortality	8 (1.2%)	78	85.4 (82.2 – 88.7)
Stroke	11 (1.6%)	37	94.0 (92.1 – 95.9)
Valve thrombosis	0 (0%)	2	99.4 (98.6 – 100.0)
Major bleeding	5 (0.7%)	45	90.9 (88.1 – 93.8)
Endocarditis	0 (0%)	15	97.3 (95.8 – 98.7)
Major PVL [†]	1 (0.1%)	3	99.5 (99.0 – 100.0)
NSVD other than PVL	0 (0%)	1	99.5 (98.6 – 100.0)
SVD	0 (0%)	2	99.3 (98.3 – 100.0)
Reoperation	1 (0.1%)	12	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

No clinical data are available to evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

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