

See the Clinical Evidence Behind RESILIA Tissue

COMMENCE aortic trial

The COMMENCE aortic clinical trial is a prospective, multicenter, single-arm IDE trial designed to demonstrate the clinical performance and durability of surgical valves with RESILIA tissue

Study design

Patient demographics represent the re-consented long-term cohort



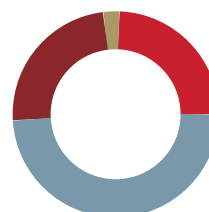
Mean age
 65.1 ± 10.9 years



Sex
76.9% male



Risk Score
 2.1 ± 2.1



- Class I: 36%
- Class II: 43%
- Class III: 19%
- Class IV: 2%

NYHA
Classification

Re-consented for
long-term follow up

$n = 225$



7yr

Completed 7-year follow up
 $n = 195$



COMMENCE aortic trial 7-year data^{*1}

99.3%

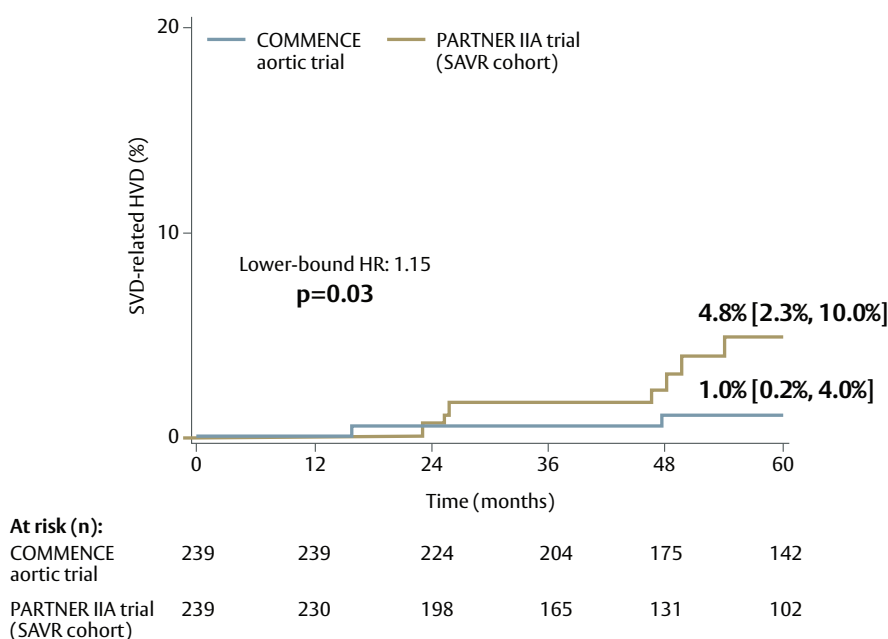
Freedom from structural
valve deterioration^{*1}

Outcome	Probability event-free at 7 years (%) (95% CI)
All-cause mortality	85.4% (82.2 - 88.7)

^{*1}SVD was adjudicated per Akins et al. 2008

5-year Analysis of the COMMENCE aortic trial and PARTNER IIA trial SAVR cohorts

SAVR with RESILIA tissue exhibited significantly reduced SVD related HVD compared with SAVR without RESILIA tissue²



Propensity matched, SVD analysis of the 5-year outcomes of subjects enrolled in the PARTNER IIA trial (SAVR cohort) and the COMMENCE aortic trial

SVD related hemodynamic valve dysfunction (HVD) of grade ≥ 2 according to VARC 3 definitions

Patients matched according to baseline characteristics reported to impact SVD

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

References:

1. Beaver T, Bavaria JE, Griffith B, et al. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. Presented at the 103rd Annual Meeting of the American Association for Thoracic Surgery, May 2023.
2. Bartus, K., Bavaria, J.E., Thourani, V. H., Xu, K., Keuffel, E.L., Structural hemodynamic valve deterioration durability of RESILIA-tissue versus contemporary aortic bioprostheses. J. Comp. Eff. Res. 2023;e220180.

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