

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



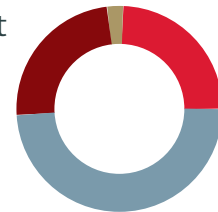
Mean age
65.1 ± 10.9 years



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)

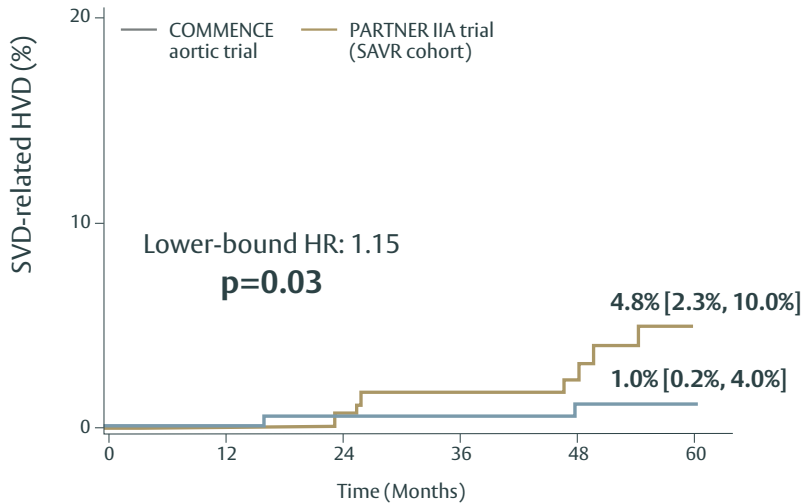
All-cause mortality

85.4% (82.2 - 88.7)

*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 IA 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

At risk (n):	0	12	24	36	48	60
COMMENCE aortic trial	239	239	224	204	175	142
PARTNER IIA trial (SAVR cohort)	239	230	198	165	131	102



Discover how to take your patients farther.
Learn more about SAPIEN 3 Ultra RESILIA valve and our tissue technology at www.heartvalves.com/ca

¹No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients

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;220180.

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