

Clinical Summary:

Final 5-year outcomes following aortic valve replacement with a RESILIA tissue bioprosthesis

Bartus et al., European Journal of Cardio-Thoracic Surgery, 2020;
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Inspiring
Results

Objective

Report the outcomes through 5 year follow-up of the EU feasibility study, investigating the safety and performance in AVR patients of a bioprosthesis with the novel RESILIA tissue.

Key Points

- These findings represent the longest follow up of AVR patients with RESILIA tissue, and demonstrate excellent hemodynamic performance and safety outcomes at the final five year follow up.
- Absence of structural valve deterioration (SVD) and stable transvalvular gradients were observed through 5 years.

Methods

- Prospective, multicenter, single-arm, trial conducted at two sites
- 133 patients underwent surgical AVR with an Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue
 - 19 or 21 mm valve implanted in 43.6% of patients
 - Mean age 65.3 ± 13.5 years, with (26%) ≤ 60 years
- Mean follow up = 4.2 ± 1.5 years

Results

- Safety events at 5 years (shown in Fig. 1 and 2):
 - 100% freedom from SVD or major paravalvular leak
 - 83.4% freedom from all cause mortality
 - 99.2% freedom from valve thrombosis
 - 99.2% freedom from endocarditis
- Stable hemodynamic performance observed at 5 years
 - Mean gradient was 14.8 ± 7.6 mmHg (shown in Fig. 3)
 - Average EOA was 1.4 ± 0.5 cm²

Conclusions

Through 5 years of follow-up, an aortic valve with RESILIA tissue exhibited good hemodynamics and zero SVD events.

Fig 1. Kaplan-Meier survival rates at 5 years of various safety events

	Patients at risk at 5 years	Cumulative events	Probability event free (95% CI)
Mortality	65	21	83.4% (76.8–89.9%)
Reoperation on study valve	65	1	99.2% (97.7–100%)
Explant	65	1	99.2% (97.7–100%)
Thromboembolism	65	5	95.9% (92.3–99.5%)
Valve thrombosis	65	1	99.2% (97.6–100%)
Major paravalvular leak	65	0	100% (100–100%)
Endocarditis	65	1	99.2% (97.7–100%)
Haemolysis	65	0	100% (100–100%)
Non-structural valve dysfunction	64	1	99.1% (97.4–100%)
Structural valve deterioration	65	0	100% (100–100%)

CI: confidence interval



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Fig 2. Kaplan-Meier curve

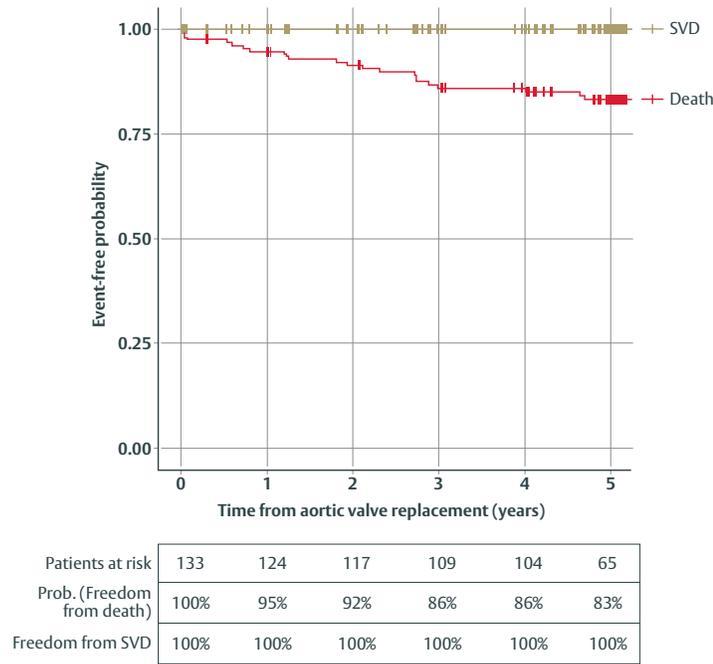
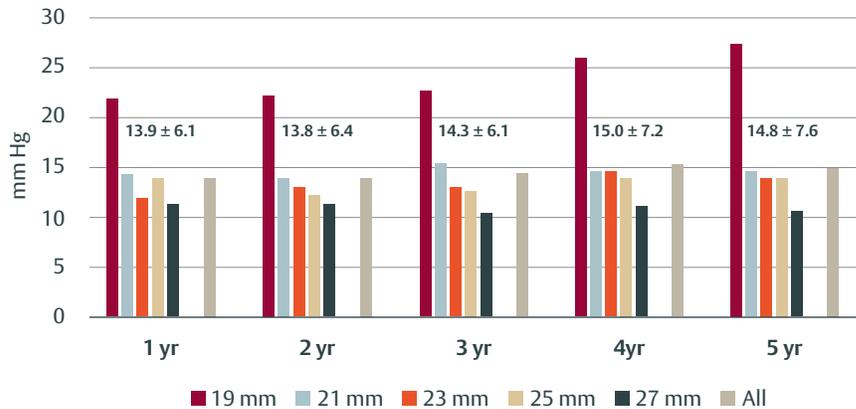


Fig 3. Mean gradient



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