

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;
DOI: 10.1093/ejcts/ezaa311

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 good 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



Edwards

Fig 2. Kaplan–Meier curve showing freedom from allcause mortality and structural valve deterioration

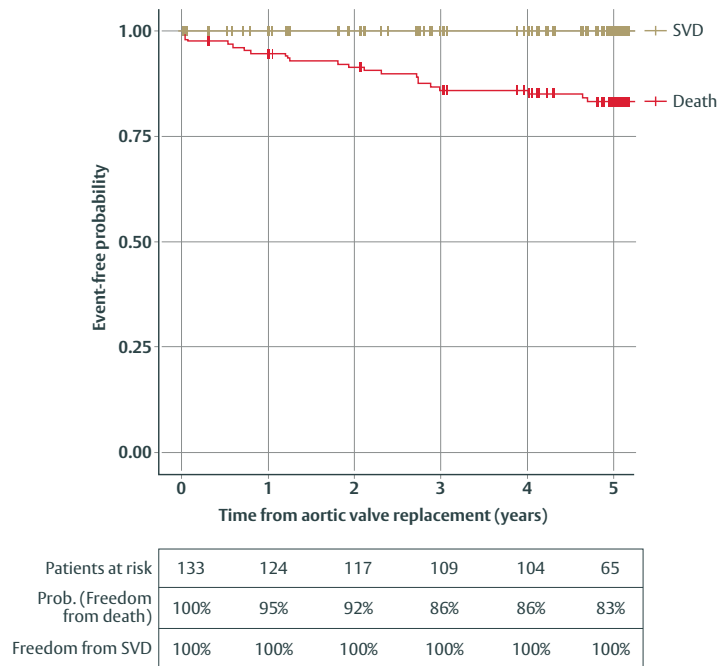
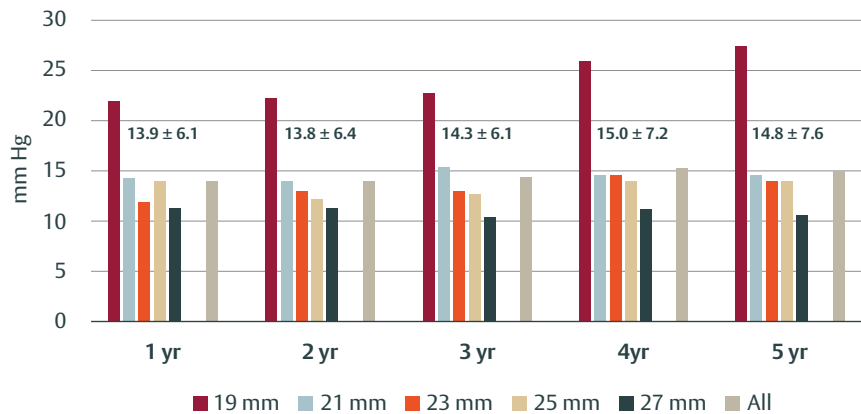


Fig 3. Mean gradient



For more information, contact your Edwards sales representative or visit www.edwards.com/gb

