Clinical Summary:

Five-year outcomes of the COMMENCE trial investigating aortic valve replacement with a novel tissue bioprosthesis

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Inspiring Results

Objective

The COMMENCE trial is an FDA pivotal trial designed to evaluate the safety and effectiveness of a bioprosthetic valve with the novel RESILIA tissue. In particular, as the follow up time in this study advances beyond the early period, direct and indirect measures of RESILIA durability will be highlighted.

Key Points

- Through a median follow up of 5 years, results of the COMMENCE aortic trial indicate a favorable safety profile and stable hemodynamic performance of a bioprosthetic valve with RESILIA tissue
- No SVD through 5 years, stable gradients, and freedom from regurgitation all support durability over the observational period*

Methods

- Prospective, non-randomized, multicenter, single-arm Investigational Device Exemption (IDE) Trial
  - Study subjects were enrolled at 27 clinical sites in U.S. and Europe
  - All patients undergo annual follow up through 5 years; a subset will be followed through 10 years
- Safety endpoints
  - All potential safety endpoints adjudicated by an independent Clinical Events Committee
  - Structural valve deterioration (SVD) and other safety outcomes defined per "Guidelines for reporting morbidity and mortality after cardiac valve interventions" (Akins et al. 2008)
- Effectiveness endpoints
  - Hemodynamic performance evaluated by an Independent Echocardiographic Core Laboratory
  - NYHA Functional Class

Patient Demographics

- 689 patients underwent surgical AVR with the Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue (model 11000A)
  - Mean age 66.9 ± 11.6 years, with 140 patients (21%) under 60 years
  - 71.8% male
  - 26% NYHA Class III/IV
  - Mean STS PROM 2.0 ± 1.8%
  - 59% isolated AVR
- 2989 aggregate patient-years of follow up
  - Follow up: 4.3 ± 1.4 yrs

Results

- Safety endpoints, probability event-free at 5 years (shown in Fig. 1):
  - All-cause mortality, 89.2%
  - Major paravalvular leak, 99.5%
  - Endocarditis, 97.8%
- Improved hemodynamic performance compared to baseline was observed through 5 years
  - Mean gradient was 10.2 ± 4.6 at 1 year, 10.2 ± 4.5 at 2 years, and 10.8 ± 5.7 at 3 years, 11.1 ± 5.7 mmHg at 4 years, and 11.5 ± 6.0 at 5 years (shown in Fig. 2)

Fig 1. Safety endpoints

Endpoint	Early (≤ 30 POD) events (%)	Kaplan-Meier probability event-free at 5 yrs (%) (95% CI)
All-cause mortality	8 (1.2%)	89.2 (86.7 – 91.6)
Stroke	11 (1.6%)	94.5 (92.7 – 96.3)
Valve thrombosis	0 (0%)	100.0 (100.0 – 100.0)
Major bleeding	5 (0.7%)	94.3 (92.4 – 96.1)
Endocarditis	0 (0%)	97.8 (96.6 – 99.0)
Major PVL†	1 (0.1%)	99.5 (99.0 – 100.0)
NSVD (other than PVL)	0 (0%)	100.0 (100.0 – 100.0)
SVD*	0 (0%)	100.0 (100.0 – 100.0)
Reoperation	1 (0.1%)	98.7 (97.8 – 99.6)

†Major PVL is PVL of any grade requiring surgical intervention or considered an SAE.

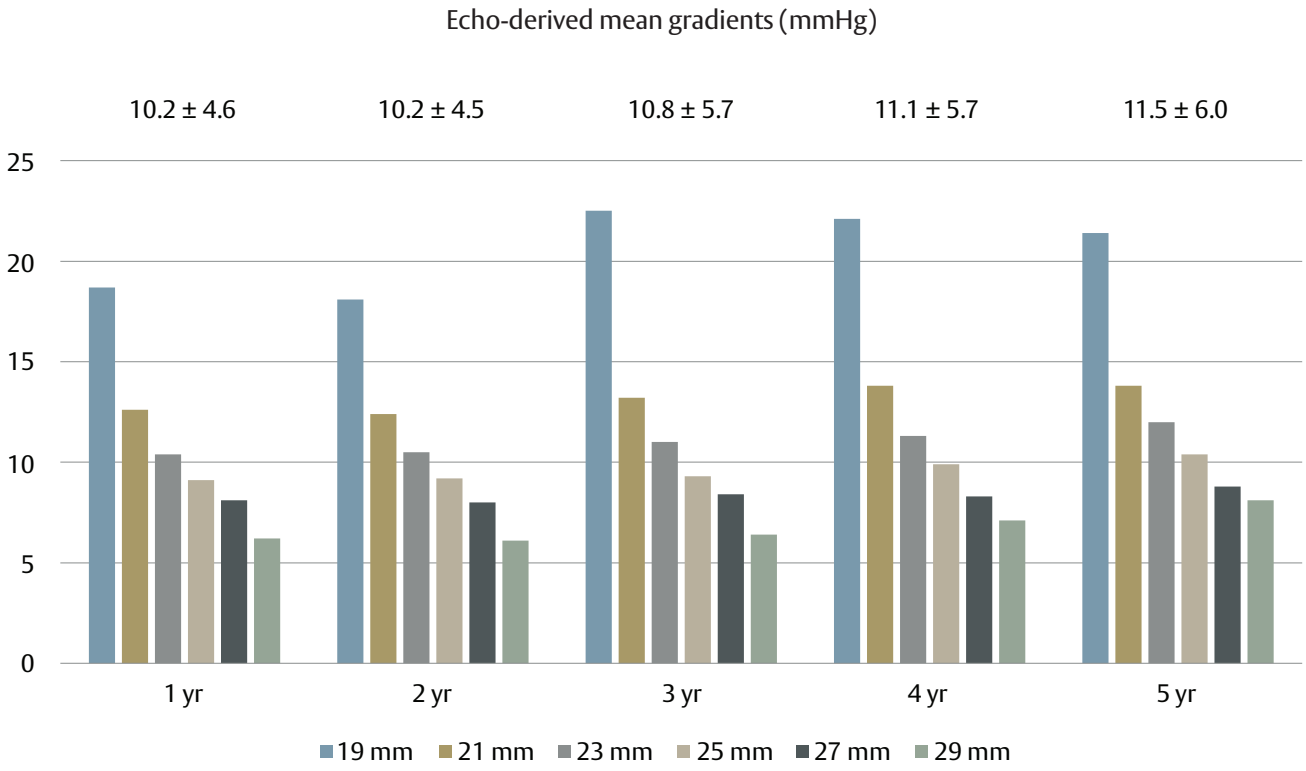
*1 SVD diagnosed at POD 1848.

Conclusions

- Favorable safety profile and stable hemodynamic performance of a bioprosthetic valve with RESILIA tissue
- No SVD through 5 years*, stable gradients, and freedom from regurgitation all support durability over the observational period
- Ongoing follow-up continues to evaluate the long-term safety and effectiveness of this new tissue
  - Data from 10-year follow up in extended follow-up cohort and RESILIENCE trial with 11-year follow-up forthcoming

Edwards

Fig 2. Hemodynamic performance



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