

Clinical Summary:

Four-year outcomes of aortic valve replacement with a bioprosthetic valve with a novel tissue

Griffith et al., American Association for Thoracic Surgery, 2019 Annual Meeting

Inspiring
Results

Objective

To evaluate the safety and effectiveness of a bioprosthetic valve with the novel RESILIA tissue.

Key Points

- This premarket approval study demonstrates a favorable safety profile and effectiveness through 4 years of follow-up of an aortic bioprosthesis with the novel RESILIA tissue
- Absence of structural valve deterioration and valve thrombosis, stable transvalvular gradients, and freedom from transvalvular regurgitation were observed at 4 years

Methods

- Prospective, multinational, multicenter (n = 27), single-arm, FDA Investigational Device Exemption trial
- Data extract: March 25, 2019

Patient Demographics

- 689 patients underwent surgical AVR with the Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue (model 11000A)
 - Mean age 67.0 ± 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
- 2,533 aggregate patient-years of follow up
 - Median follow up = 4 years

Results

- Safety events (shown in Fig. 1):
 - No cases of SVD or valve thrombosis
 - Late all-cause mortality 2.2%/late patient years (LPY)
 - Late major paravalvular leak was 0.1%/LPY
 - Late endocarditis 0.5%/LPY
- Improved hemodynamic performance compared to baseline was observed through 4 years:
 - Mean gradient was 10.2 ± 4.6 at 1 year, 10.2 ± 4.5 at 2 years, and 10.8 ± 6.0 at 3 years, and 11.0 ± 5.6 mmHg at 4 years (shown in Fig. 2)
- At 4 years:
 - 91.9% freedom from death
 - 98.6% freedom from re-operation

Fig 1. Safety Endpoints

Endpoint	Early (≤ 30 POD) Events (%)	Late (>30 POD) Events (%/LPY) LPY = 2476 patient-yr
All Cause Mortality	8 (1.2%)	54 (2.2%)
Thromboembolism	16 (2.3%)	42 (1.7%)
Valve thrombosis	0 (0%)	0 (0%)
Major bleeding	5 (0.7%)	29 (1.2%)
Endocarditis	0 (0%)	12 (0.5%)
Major paravalvular leak (PVL) [†]	1 (0.1%)	2 (0.1%)
Non-structural valve dysfunction (NSVD) [‡]	0 (0%)	0 (0%)
Structural valve deterioration (SVD)	0 (0%)	0 (0%)
Reoperation	1 (0.1%)	7 (0.3%)

[†] Major PVL is PVL of any grade requiring intervention or considered a serious adverse event (SAE).

[‡] Includes all other types of non-structural valve dysfunction (NSVD) besides paravalvular leak

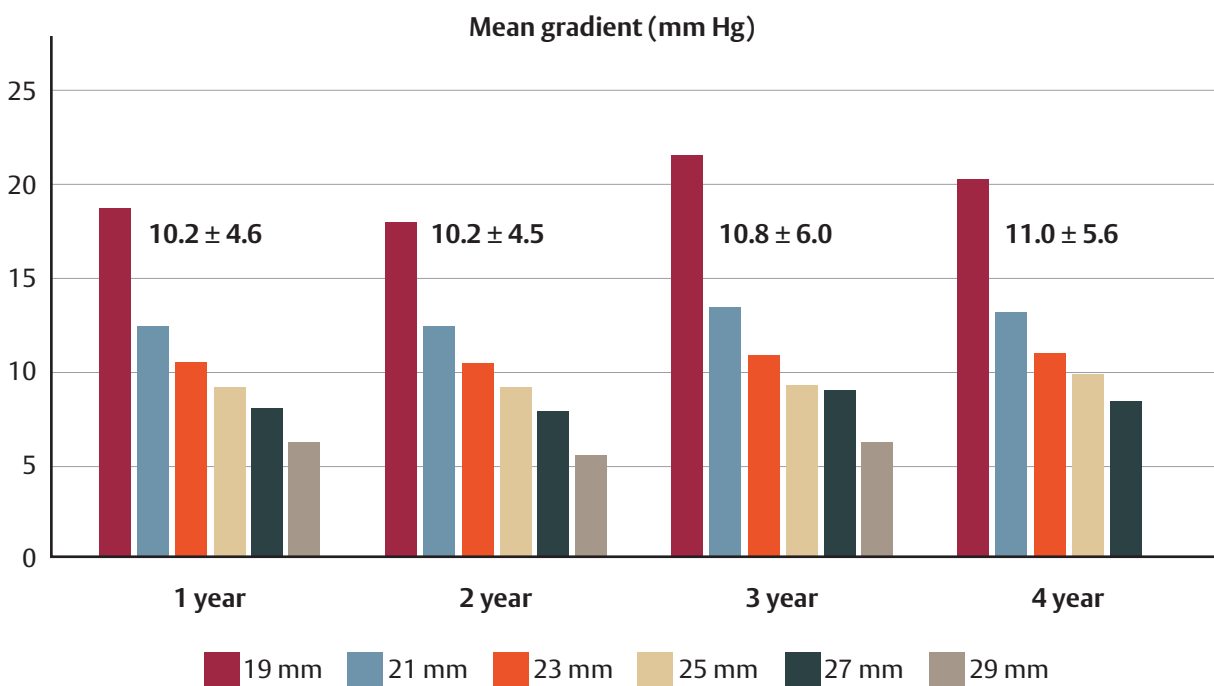
Conclusions

- Favorable safety profile and stable hemodynamics of RESILIA tissue in a bovine aortic valve
- Absence of SVD, increased gradients, and regurgitation support durability in comparison with contemporary tissue preservation methods
- Follow-up continues on the long-term safety and effectiveness of this new tissue



Edwards

Fig 2. Hemodynamic Performance



Important Safety Information: INSPIRIS RESILIA Aortic Valve

Indications: For use in replacement of native or prosthetic aortic heart valves. **Contraindications:** There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve. **Complications and Side Effects:** Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death. **Warnings:** DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO/OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19 – 25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-Valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves. Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

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