Clinical Summary:

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

Johnston et al. AATS Conference Late Breaking Clinical Trial 2018

Objective

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

Key Points

- This premarket approval study demonstrated favorable safety profile and early effectiveness through 3 years of follow-up of a bioprosthesis with the novel RESILIA tissue for surgical AVR
- Absence of structural valve deterioration and valve thrombosis, stable transvalvular gradients, and freedom from transvalvular regurgitation were observed at 3 years

Methods

- Prospective, multinational, multicenter (n = 27), single-arm, FDA Investigational Device Exemption trial
- Data extract: April 6, 2017

Patient Demographics

- 689 patients underwent surgical AVR with the Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue (model 11000A)
  - 1384.3 late patient years (LPY)
  - Mean age 67.0 ± 11.6 years
  - 71.8% male
  - 26% NYHA Class III/IV
  - Mean STS PROM 2.0 ± 1.8 (0.3–17.5)
  - 59% isolated AVR

Results

- Late events (>30 post-operative days; Fig. 1):
  - No cases of SVD or valve thrombosis
  - All-cause mortality 2.1%/LPY
  - Major paravalvular leak was 0.1%/LPY
  - Endocarditis 0.6%/LPY
- At 3 years:
  - 97.1% of patients in NYHA I/II
  - 100% freedom from moderate or severe transvalvular regurgitation
- Improved hemodynamic performance compared to baseline was observed and sustained through 3 years:
  - Effective orifice area (aggregated all valve sizes) was 1.7 ± 0.3 cm² at 1 year, and 1.6 ± 0.5 cm² at 2 and 3 years
  - Mean gradient (aggregated all valve sizes) was 10.4 ± 4.9 at 1 year, 10.5 ± 4.5 at 2 years, and 10.3 ± 5.8 mmHg at 3 years (Fig. 2)

Fig 1. Safety Endpoints

Endpoint	Early (≤ 30 POD) Events (%)	Late (>30 POD) Events (%/LPY) LPY = 1384.3 years
Mortality	8 (1.2%)	29 (2.1%)
Thromboembolism	16 (2.3%)	36 (2.6%)
Valve thrombosis	0 (0%)	0 (0%)
Major bleeding	5 (0.7%)	14 (1.0%)
Endocarditis	0 (0%)	8 (0.6%)
Major paravalvular leak (PVL)†	1 (0.1%)	2 (0.1%)
Non-structural valve dysfunction (NSVD)‡	0 (0%)	1 (0.1%)
Structural valve deterioration (SVD)	0 (0%)	0 (0%)
Reoperation	1 (0.1%)	4 (0.3%)

† Major PVL is PVL of any grade resulting in intervention or considered a serious adverse event (SAE).

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

Conclusion

- Favorable safety profile and stable hemodynamic performance through 3 years of follow-up
- Stable transvalvular gradients, freedom from transvalvular regurgitation, and absence of explants for SVD support early durability

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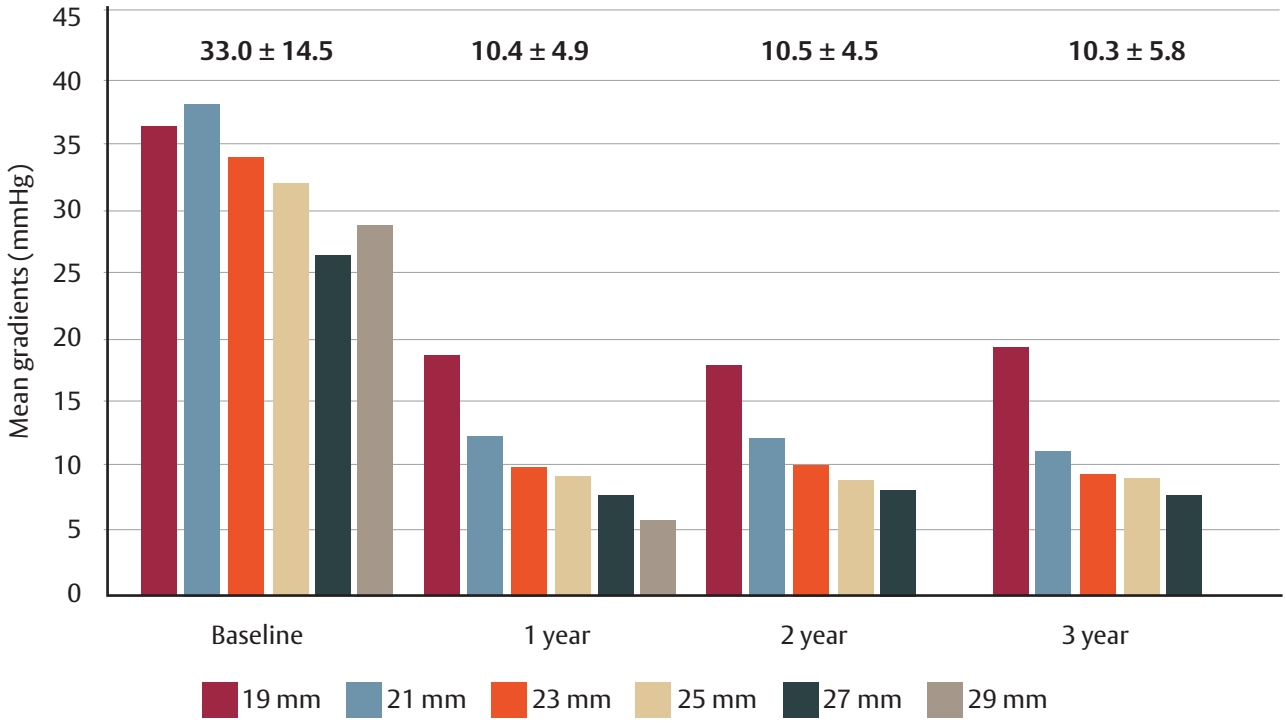
Fig 2. Hemodynamic Performance



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 procedures in an INSPIRIS valve should be performed according to the combinations in the SAPIEN XT valve IFU. Other combinations have not been evaluated and may result in the 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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