RESILIA Tissue Valves Seven-Year Outcomes

A summary of the results, patient demographics, study methods, and key points

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Clinical Summary:

Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis

Beaver T, Bavaria J, Griffith B, et al. Presented at the American Association for Thoracic Surgery Annual Meeting, May 2023.

Inspiring Results

Objective

The COMMENCE aortic trial is a FDA pivotal trial designed to evaluate the safety and effectiveness of a bioprosthetic valve with RESILIA tissue. As the follow up time in this study advances beyond the mid-term period, direct and indirect measures of durability of valves with RESILIA tissue will be highlighted.

Key Points

- As bioprosthetic aortic valve replacement (AVR) extends to younger cohorts, tissue durability is becoming of paramount importance. Data from this trial demonstrate excellent outcomes in a study of younger patients – 65.1 mean age
- The bioprosthetic valve with RESILIA tissue showed clinically stable gradients, high rates of freedom from mortality through 7 years, as well as high rates of freedom from reintervention and structural valve deterioration (SVD)
- Results of the COMMENCE aortic trial through 7 years indicate a favorable safety profile and strong hemodynamic performance of a bioprosthetic valve with RESILIA tissue

Methods

- A prospective, international IDE trial, now in its post-approval phase, is exploring the outcomes of AVR with a bioprosthesis utilizing RESILIA tissue
  - Study subjects were enrolled at 27 clinical sites in U.S. and Europe
  - At 5 years, patient re-consent was performed for extended follow-up (years 6-10) and was mandatory for the top 3 enrolling sites. If interested in extended follow-up participation, additional sites then offered all eligible patients to consent and participate
- Safety endpoints
  - All potential safety endpoints adjudicated by an independent Clinical Events Committee
  - SVD and other safety outcomes defined per "Guidelines for reporting mortality and morbidity after cardiac valve interventions" (Akins et al. 2008)
- Effectiveness endpoints
  - Hemodynamic performance evaluated by an independent echocardiographic core laboratory
  - New York Heart Association (NYHA) Class

Patient Demographics

Full Cohort

- Between January 2013 and March 2016, 689 patients underwent AVR with the Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue (model 11000A)
  - Mean age 66.9 ± 11.6 years
  - STS risk score 2.0 ± 1.8%
  - NYHA Class II and III were 50% and 24%, respectively
- A total of 512 patients completed 5-year follow up

Re-consented Cohort

- A total of 225 patients were re-consented for extended follow up
  - Mean age 65.1 ± 10.9 years
  - STS risk score 2.1 ± 2.1%
  - NYHA Class II and III were 43% and 19%, respectively
- A total of 195 patients completed 7-year follow up

Results

- Safety endpoints, probability event-free at 7 years (shown in Table 1):
  - Kaplan-Meier analyses showed freedom from all-cause mortality was 85.4% (95% CI: 82.2 – 88.7)
  - 99.3% (95% CI: 98.3 – 100.0) freedom from SVD
  - 97.2% (95% CI: 95.5 – 99.0) freedom from reoperation
  - Clinically stable hemodynamics out to 7 years:
    - Effective orifice area was 1.82 ± 0.57 cm^2
    - Mean gradient was 9.4 ± 4.5 mmHg
  - 99.5% (95% CI: 99.0-100) of patients had no major paravalvular regurgitation

Conclusions

- The 7-year data from the COMMENCE aortic trial represents the longest follow-up after AVR with RESILIA tissue in a large IDE trial utilizing an independent clinical events committee and an echocardiography core laboratory
- With excellent outcomes through 7 years, the COMMENCE trial demonstrates encouraging results for bioprostheses with RESILIA tissue
- Ongoing follow up out to 10 years will continue to evaluate the long-term safety and effectiveness of this bioprosthetic valve with RESILIA tissue

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Figure 1. Hemodynamic performance: Echo-derived mean gradients (mmHg)

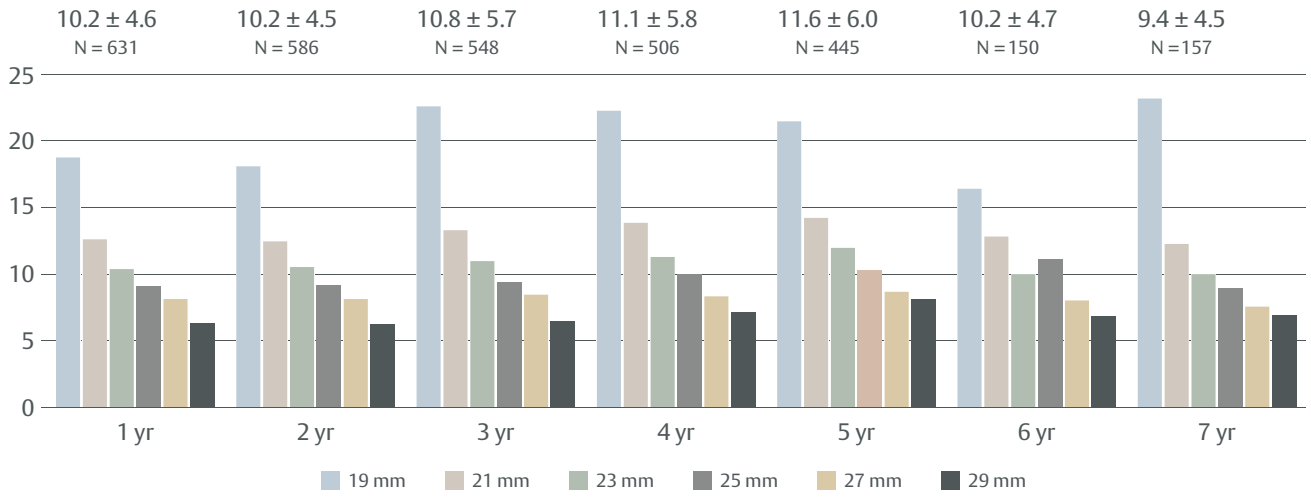

Table 1. Safety endpoints

Endpoint	Early (≤30 POD) events (%)	Cumulative events at 7 yrs	Probability event-free at 7 yrs (%) (95% CI)
All cause mortality	8 (1.2%)	78	85.4 (82.2 – 88.7)
Stroke	11 (1.6%)	37	94.0 (92.1 – 95.9)
Valve thrombosis	0 (0%)	2	99.4 (98.6 – 100.0)
Major bleeding	5 (0.7%)	45	90.9 (88.1 – 93.8)
Endocarditis	0 (0%)	15	97.3 (95.8 – 98.7)
Major PVL†	1 (0.1%)	3	99.5 (99.0 – 100.0)
NSVD *other than PVL*	0 (0%)	1	99.5 (98.6 – 100.0)
SVD	0 (0%)	2	99.3 (98.3 – 100.0)
Reoperation	1 (0.1%)	12	97.2 (95.5 – 99.0)

†Major paravalvular leak is paravalvular leak of any grade requiring surgical intervention or considered an SAE

All event definitions per CW Akins et al. *J Thorac Cardiovasc Surg* 2008; 135:732-8

Important Safety Information:

RESILIA Tissue Devices

Indications: INSPIRIS RESILIA Aortic Valve - For use in replacement of native or prosthetic aortic heart valves. **KONECT RESILIA Aortic Valved Conduit** - For use in replacement of native or prosthetic aortic heart valves and the associated repair or replacement of a damaged or diseased ascending aorta. **MITRIS RESILIA Mitral Valve** - For use in replacement of native or prosthetic mitral heart valves.

Contraindications: There are no known contraindications with the use of these RESILIA tissue heart valve devices.

Complications and Side Effects: INSPIRIS RESILIA Aortic Valve - 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. Additional adverse events potentially associated with the use of polyester vascular grafts in the **KONECT RESILIA AVC** include hemorrhage, thrombosis, graft infection, embolism, aneurysm, pseudoaneurysm, seroma, occlusion (anastomotic intimal hyperplasia), immunological reaction to collagen (shown to be a weak immunogen; infrequent, mild, localized and self-limiting), intimal peel formation, and conduit dilatation. **MITRIS RESILIA Mitral Valve** - Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability, and death.

Warnings: INSPIRIS RESILIA Aortic Valve - 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 (USA) law restricts these devices to sale by or on the order of a physician.
See instructions for use for full prescribing information.

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