Clinical Summary:

Influence of tissue technology on pannus formation on bioprosthetic heart valves

TJ Tod et al. Cardiovasc Eng Technol 2021;12:418-25

Inspiring Results

Objective

To study the effect of RESILIA tissue on pannus formation

Key Points

- Bioprosthetic heart valves have several modes of failure. Tissue degeneration and calcification are the major modes of failure with the highest focus of attention; however pannus formation can also be problematic
- RESILIA tissue valves led to less pannus formation compared to control valves
- RESILIA tissue may beneficially influence both short- and long-term* valve behavior of bioprosthetic valves†

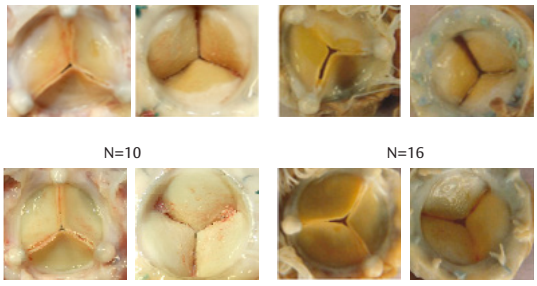
Methods

- This publication reports the outcomes of two independent studies using a juvenile sheep model of mitral valve replacement with bovine pericardial tissue
  - In an 8-month study, valves with RESILIA tissue were compared to control valves with XenoLogiX treatment (XLX)
  - In a 5-month study, valves with RESILIA tissue were compared to control valves treated with the ThermaFix process (TFX)
- Control valves were commercially available Carpentier-Edwards PERIMOUNT mitral valves, models 6900P, and 7000TFX. Test articles were the same models configured with RESILIA tissue (Edwards Lifesciences, Irvine, CA)
- Explanted valves were examined macroscopically and histologically. Histological observations were made by an independent pathologist, blinded to group identity
- Independent means of pannus quantification were employed in the two studies

Results

- In the 5-month study, pannus area measured over the whole RESILIA tissue valves was significantly lower than that of the control valves [p-value = 0.010; Table 1]
- For the 5-month study, a two sample t-test showed that the pannus on the atrial and ventricular side of each leaflet was significantly lower in test tissue samples (1.44 ± 1.52 mm2) compared to the controls (2.61 ± 2.15 mm2), with a p-value of 0.027
- For the 8-month study, pannus measured in RESILIA tissue (0.095 ± 0.049 mm^2) was significantly lower than control tissue (0.134 ± 0.066 mm^2), with a *p*-value of 0.002

Duration:	5 months	8 months
Purpose:	To evaluate safety and efficacy of RESILIA in a sheep model.	To evaluate calcification and hemodynamics in a long-term sheep model.
Control Valves	N=7	N=14
RESILIA Tissue Valves	N=10	N=16



The 5-month study on the left shows control valves treated with TFX. The 8-month study on the right shows control valves treated with XLX. RESILIA tissue valves led to less pannus formation compared to control valves.

Table 1. Summary data for the whole valve from the 5-month study

Treatment group	Pannus area over the whole valve area (in thousands of pixels)	T-test comparison
Control tissue (7 valves)	656.2 ± 385.43	*p*-value = 0.010
RESILIA tissue (10 valves)	234.4 ± 265.4	

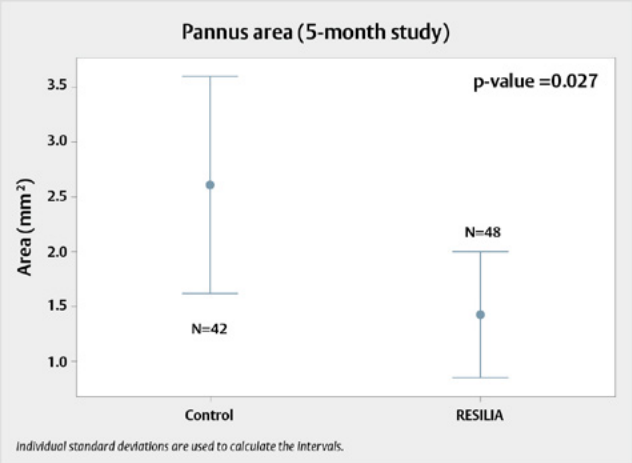
Conclusions

- RESILIA tissue valves were associated with reduced pannus formation when compared to control valves
- This technology has the potential to improve long term outcomes for patients

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.
†RESILIA tissue tested against tissue from commercially available bovine pericardial mitral valves from Edwards in a juvenile sheep model
Tod TJ, et al. Influence of Tissue Technology on Pannus Formation on Bioprosthetic Heart Valves. Cardiovasc Eng Technol 2021;12:418-25.

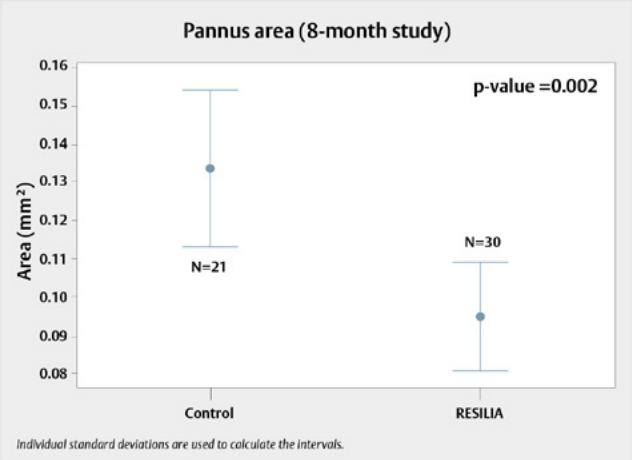
Edwards

Figure 1. Pannus growth on RESILIA tissue valves compared to control valves during the 5-month study



Tissue growth on RESILIA tissue valves compared to ThermaFix process control valves at 5 months.
N= number of leaflets.

Figure 2. Pannus growth on RESILIA tissue valves compared to control valves during the 8-month study



Tissue growth on RESILIA tissue valves compared to XenoLogiX treatment control valves at 8 months.
N= number of leaflets.

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.

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

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. 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.

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.

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

Edwards