

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†

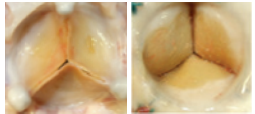
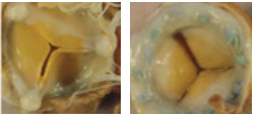
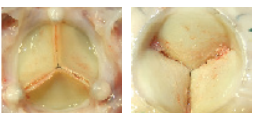
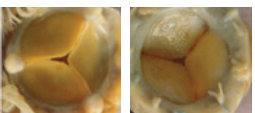
Methods

- 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 ThermoFix 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 ($1.44 \pm 1.52 \text{ mm}^2$) compared to the controls ($2.61 \pm 2.15 \text{ mm}^2$), with a p-value of 0.027

- For the 8-month study, pannus measured in RESILIA tissue ($0.095 \pm 0.049 \text{ mm}^2$) was significantly lower than control tissue ($0.134 \pm 0.066 \text{ mm}^2$) 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.	
	N=7	N=14	
Control Valves			
	N=10	N=16	
RESILIA Tissue Valves			

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

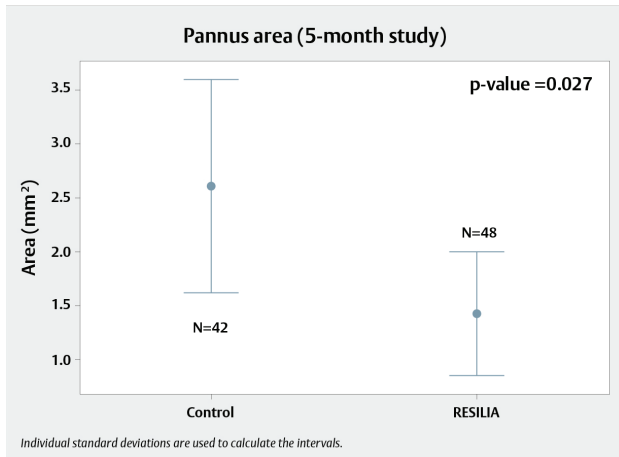
*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

†RESILIA tissue tested against tissue from commercially available bovine pericardial mitral valves from Edwards in a juvenile sheep model



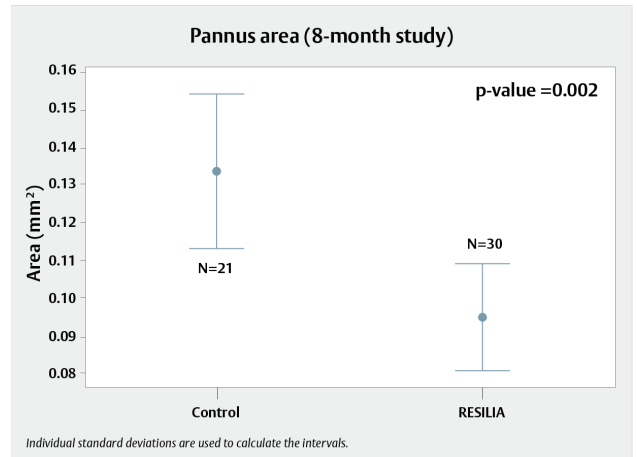
Edwards

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 ThermoFix 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.

Reference:

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Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the instructions for use (consult eifu.edwards.com where applicable)

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