Publication Summary:
Long run savings associated with surgical aortic valve replacement using a RESILIA tissue bioprosthetic valve versus a mechanical valve

Keuffel EL, Reifenberger M, Marfo G, et al. Long run savings associated with surgical aortic valve replacement using a RESILIA tissue bioprosthetic valve versus a mechanical valve. J Med Econ. 2023;26(1):120-127

Objective

- This economic evaluation quantified the expected 15-year run savings when using a RESILIA tissue valve relative to a mechanical valve for surgical aortic valve replacement (SAVR) given the 5-year results of the COMMENCE trial and expected performance through year 15

Key points

- SAVR with RESILIA tissue valves may further reduce future health system expenditures relative to mechanical valves due to potential lower rate of reoperation than legacy tissue technology
- By year 5, the discounted cumulative savings for RESILIA tissue are $8,872 and are expected to increase to $20,498 projecting to year 15
- RESILIA tissue valves accrue approximately 30-50% larger savings than anticipated for using legacy tissue valves

Methods

- Two SAVR cohort models (tissue vs. mechanical) of 10,000 patients were used to estimate disease progression over a 15-year period
- The first 5-years for RESILIA tissue data relied on incidence data on events from the results of the COMMENCE trial and the next 10-years relied on weighted data from 3 primary legacy long-term tissue valve studies
- The models estimated sequelae after the initial SAVR and accounts for mortality, endocarditis, bleeding or hemorrhagic event, thrombosis, reoperation, and anti-coagulant monitoring (ACM)
- Sensitivity and scenario analyses were conducted to highlight the key determinants that drive our central outcome
- Deterministic model and Monte Carlo simulation were used to calculate the average expected savings incorporating both the mean and the distribution

Results

- Median net discounted savings for SAVR with RESILIA tissue is $9,093 ($6,589–$12,048) by year 5 and $20,755 ($15,780–$26,636) by year 15 (See table 1)
- Cumulative net savings drop to $15,697 for RESILIA tissue relative to mechanical when reoperation relative risk increases from 1.1 to 2.2 upon year 5 (See figure 1)
- ACM cost is the central driver of savings, however, savings would still accrue for RESILIA tissue patients if ACM cost was excluded but levels will be substantially lower ($1,727 by year 5 and $1,481 by year 15)

Limitations & Conclusion

- Recent advances in technology with RESILIA tissue given the 5-year clinical data have potentially expanded the economic benefit relative to mechanical valves beyond what they were previously estimated with legacy tissue valves
- Additional data is required to precisely inform the long-term benefit of RESILIA tissue as reoperations do occur over extended periods
- This evaluation suggests that tissue valves confer long-run economic benefit relative to mechanical valves at the payer, insurer, and patient level

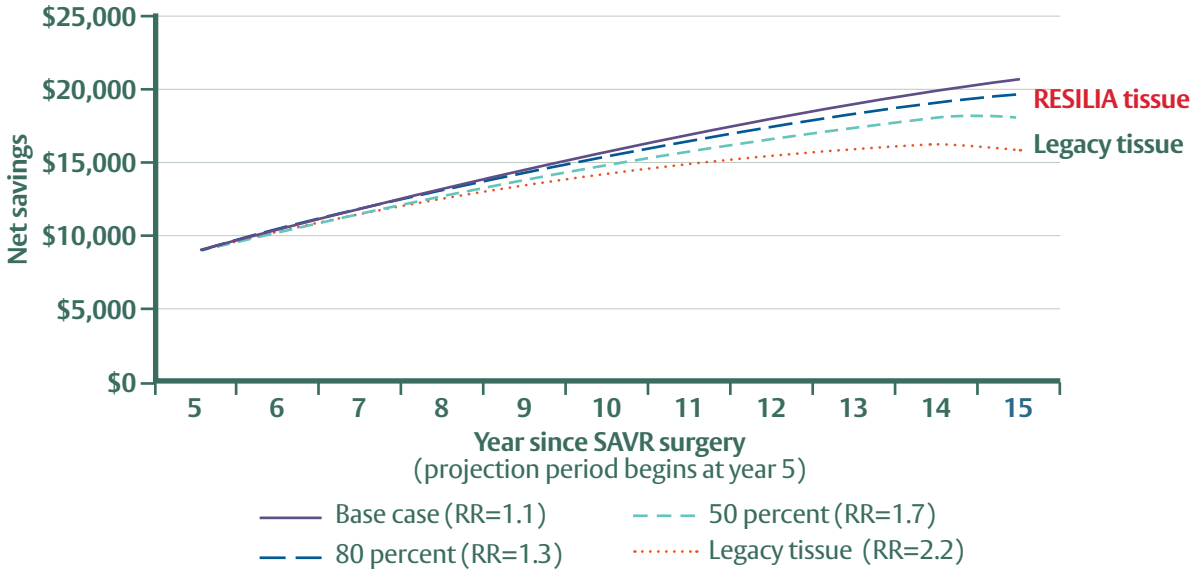
Edwards

Table 1: Cumulative net discounted savings per initial SAVR surgery associated with the novel tissue vs. mechanical valves ($US 2020) base case model

Time Since Initial SAVR	Overall Savings (Deterministic Model)	Simulation Model Median (95% CI)	Share of Simulations with Savings
30 days	$478	$506 (–$1,542 to $2,604)	69.00%
1 year	$1,550	$1,622 (–$469 to $3,809)	93.84%
5 years	$8,872	$9,093 ($6,589 to $12,048)	99.89%*
10 years	$15,622	$15,864 ($12,816 to $19,605)	99.94%*
15 years	$20,498	$20,755 ($15,780 to $26,636)	99.94%*

* Statistically significant at 99% level (99% of estimates exceed $0)

Figure 1: Cumulative net discounted savings over time per initial SAVR surgery associated with novel tissue vs. mechanical valves ($US 2020), by reoperation relative risk estimate (projection period)



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 (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.com

Edwards