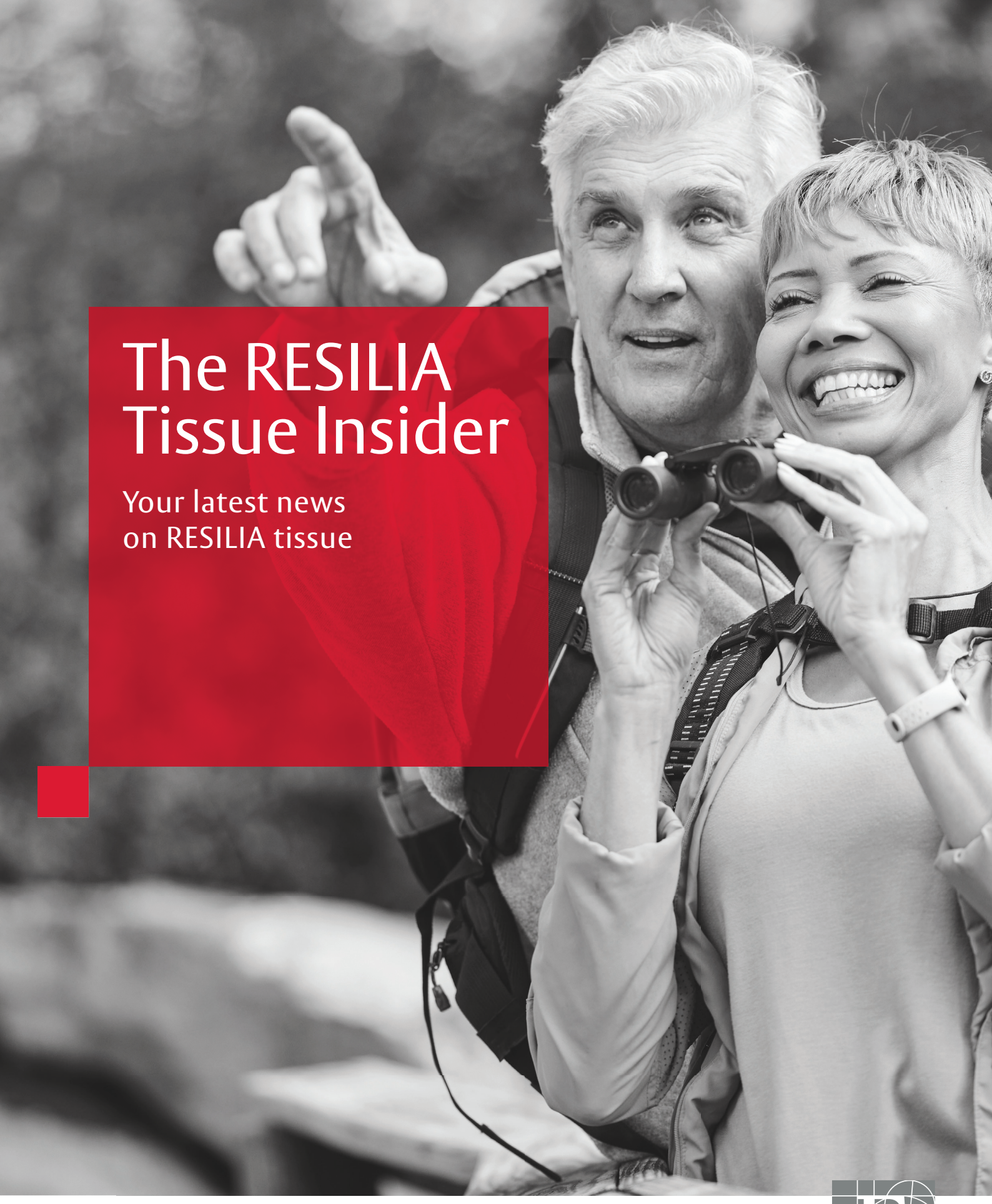


The RESILIA Tissue Insider

Your latest news on RESILIA tissue

Newsletter issue 11 – March 2025

Edwards

Over 330,000 patients have been treated with the INSPIRIS RESILIA valve globally

Celebrating a milestone in heart valve surgery

We are thrilled to share a remarkable milestone: the successful implantation of 330,000 INSPIRIS RESILIA valves! As the world's most implanted surgical tissue valve, the INSPIRIS RESILIA valve is leading the way in innovation. This achievement would not have been possible without the unwavering dedication and exceptional skill of the cardiac surgeon community. Together, we have made a significant impact on the health and well-being of patients around the world.

Our vision: Treating many more patients

At Edwards Lifesciences, we are driven by a passion to improve patient lives. As the leading global structural heart innovation company, we created the INSPIRIS RESILIA valve on that vision, innovating on a foundation of the Carpentier-Edwards PERIMOUNT valve design and the familiar procedural experience of the Carpentier-Edwards PERIMOUNT Magna Ease valve.

Commitment to clinical evidence

Our commitment to generating scientifically backed evidence continues to support the INSPIRIS RESILIA valve. RESILIA tissue has been extensively studied since 2011, with the first RESILIA tissue valve implanted in July 2011.[1] With now over **13 years of clinical experience**, RESILIA tissue has taken performance and durability to new heights, transforming the tissue valve landscape.

Learn more about the growing base of evidence backing up RESILIA tissue performance

Learn more about our RESILIA tissue valve portfolio and join us in celebrating this incredible achievement. Thank you for your dedication and partnership in advancing cardiac care. Together, we are making a difference, one heart at a time.

Testimonials from cardiac surgeons

Professor Olaf Wendler, consultant cardiothoracic surgeon at King's College Hospital, London, UK and Chair of the Heart, Vascular and Thoracic Institute at Cleveland Clinic London shares,

"The demonstrated long-term history of the Carpentier-Edwards PERIMOUNT valve, alongside the potential calcification delay of RESILIA tissue appeals to patients"

Professor Francesco Onorati, lead surgeon for the Heart Transplant and Mechanical Assisted Devices programmes at Verona University Hospital, Italy adds,

"We have built a European multicentre registry, retrospectively and prospectively collecting data for 1,871 patients, and the 6-year outcomes show low rates of structural valve deterioration with stable haemodynamics"

In this issue

FRONT COVER IMAGE: ISTOCK.COM/PEOPLEIMAGES

We hope you enjoy this issue of *The RESILIA Tissue Insider*.

Learn more about our growing RESILIA tissue valve portfolio: **Scan the QR code** to visit our website **www.edwards.com/gb/resilia**

Introduction

Welcome to the 11th edition of *The RESILIA Tissue Insider*, where we introduce our new series of *Feature* articles. These articles will celebrate the history of prosthetic heart valve innovation, from the first successful implantation of a mechanical artificial heart valve in 1960 all the way up to today, where over 330,000 INSPIRIS RESILIA bioprosthetic valves have been implanted worldwide, with 5-year real-world data now published.

We begin our journey in this issue with the special partnership between Dr Albert Starr and Miles 'Lowell' Edwards, who met in 1958 and developed the first artificial heart valve successfully implanted in humans. Turn to page 2 to discover their story.

We then present the latest data and research on RESILIA tissue valves, starting with the recently published 5-year real-world outcomes with the INSPIRIS RESILIA valve on page 7. *In vivo* results from a two-billion-cycle durability study of the INSPIRIS RESILIA valve can be found on page 8. A publication by Professor Thourani compares the performance of RESILIA tissue valves in patients with aortic stenosis against those with aortic regurgitation and mixed aortic disease – find out the results on page 9.

On page 10, we discuss a case where the INSPIRIS RESILIA valve was successfully used for redo surgical aortic valve replacement (SAVR).

RESILIA tissue valves have been discussed at recent congresses across the world. Early outcomes with the MITRIS RESILIA valve were reported at the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) Annual Meeting in 2024, turn to page 10 to see the results.

Key 3-year outcomes from the IMPACT registry, presented by Professor Bakhtiary at the 54th Annual Meeting of the German Society for Thoracic, Heart and Vascular Surgery (DGTHG) in February 2025, can be found on page 11. On page 12, we summarise the interesting discussions surrounding data on the MITRIS RESILIA valve from an Edwards symposium held in conjunction with the 61st Annual Meeting of The Society of Thoracic Surgeons (STS).

Finally, on page 13, we are excited to share an interview with Professor Stradiņš, who joined us to share his experiences with RESILIA tissue valves.

Enjoy reading!

Tirelessly pioneering cardiac surgical innovation

Since the development of the first successful artificial heart valve in 1958, Edwards Lifesciences have been partnering with cardiac surgeons worldwide to drive world-leading surgical innovations. These close collaborations have resulted in some of the biggest breakthroughs in cardiac surgery, including the development of RESILIA tissue valves.

In this issue of '*The RESILIA Tissue Insider*', we go back to where it all began and explore the beginning of this long journey – the partnership of Miles 'Lowell' Edwards and Dr Albert Starr.

65+ years of in-depth collaboration with surgeons worldwide

Miles 'Lowell' Edwards and Dr Albert Starr

Introduced the first successful artificial valve[a]

Dr Alain Carpentier

Developed the Carpentier-Edwards PERIMOUNT valve with bovine pericardial tissue

Professor Olaf Wendler

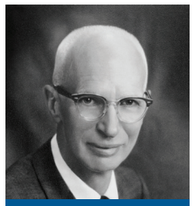
Implanted the first INSPIRIS RESILIA valve worldwide

Professor Jan Gummert

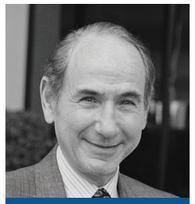
Implanted the first MITRIS RESILIA valve in Europe

[a]Device no longer on the market.

1958: The beginning of 65+ years of innovation



Miles 'Lowell' Edwards



Dr Albert Starr

Dr Albert Starr and Miles Lowell Edwards met in the spring of 1958, beginning the legacy of engineering and clinical partnerships that remain at the heart of Edwards Lifesciences. Dr Starr was working within the up-and-coming cardiac surgery field at the University of Oregon Medical School and had recently opened an animal laboratory to perform cardiopulmonary bypass studies. Edwards was a semi-retired hydraulic engineer who approached Dr Starr with an inspired and revolutionary idea: **to create an artificial heart**.[2,3]

They agreed to start the project by developing one valve at a time, starting with the mitral valve. The first valve design, a single-layer sewing ring of Dacron cloth attached between two Teflon rings bonded together, with two Silastic leaflets, was implanted in dogs on cardiopulmonary bypass. The operation was initially successful, with the native mitral valve apparatus fully replaced with the prosthetic valve and resulting good cardiac function. Unfortunately, thrombus formation quickly followed, resulting in mortality of all animal subjects.[3]

Undeterred, Dr Starr and Edwards set about improving their valve, eventually replacing the leaflets with a ball design to combat thrombus formation. It took three weeks from theoretical concept to the development of an open cage design with a solid Silastic ball. A Silastic shield that covered the implantation zone was later added, which vastly reduced thrombosis in animal studies.[3]

1960: The first implantation in humans

In 1960, Professor Herbert Griswold visited the laboratory and observed the successful mitral valve replacements in the dog test subjects. He had several patients with mitral valve disease who were in the terminal stages of heart failure and urged Edwards and Starr to precede with early human implantation.[3] This acceleration to human use prompted Lowell Edwards to form a new company, Edwards Laboratories, with the purpose of manufacturing artificial human heart valves – the first company of its kind in the world. This company would go on to become Edwards Lifesciences.[3]

Dr Starr and Edwards decided to start with the simpler, unshielded valve for the first human implantation in August 1960, to see if it would be successful, especially as anticoagulant treatment could be carefully controlled in humans.[3] In August, the first patient, a young woman with severe congestive heart failure and end-stage rheumatic mitral valve disease who had spent many months in an oxygen tent, received the first version of the Starr-Edwards mitral valve. The operation was successful but, unfortunately, the patient died of an air embolism 10 hours after the operation.[2–4]

The second patient, in September 1960, was Philip Admunson, a truck dispatcher from Washington, with calcific mitral stenosis. **This patient became the first survivor of an artificial heart valve**; he returned to work and lived for 15 more years before dying by falling from a ladder while painting his house.[2–4]

By February 1961, eight patients had undergone mitral valve replacement with the Starr-Edwards valve. Six patients survived with satisfactory haemodynamic results and a dramatic change in heart size and configuration.[4]

Dr Starr and Lowell Edwards wrote up their findings in *Annals of Surgery* in October 1961, showing that the use of a ball valve mitral prosthesis was justified in certain patients.[4]

As the years progressed, the valve design was further improved by introducing the process of heat curing the silicone balls to reduce variance.[5] Heart valve operations became commonplace, expanding quickly to fill aortic and tricuspid positions. By 1966, operative mortality with the mitral valve prosthesis had fallen from 50% (1960) to less than 5%.[3]

In 2003, a review reported that more than 250,000 Starr-Edwards valves had been implanted worldwide with virtually no ball valve malfunction.[5]

The Starr-Edwards mitral ball valve prosthesis used in the first implantations in humans is pictured below.

> *The artificial heart valve is definitely here to stay. We must think of it as an attempt to solve a clinical problem with wide ramifications. Our job is not to design a valve identical to nature's…but to overcome the clinical problem of the diseased heart valve.*
>
> **Dr Albert Starr[2]**

Looking to the future

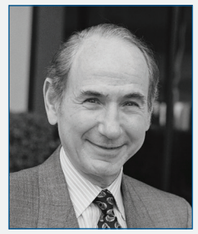
Mechanical heart valves were primarily used for the first 20 years. However, long-term anti-coagulation therapy is required for all patients with a mechanical valve to combat potential thrombosis.[3] To address this, a new innovation was on the horizon – a bioprosthetic heart valve with tissue leaflets. In the next edition of *The RESILIA Tissue Insider*, we will discuss why Edwards Lifesciences eventually exited the mechanical market to concentrate on creating durable bioprosthetic valves, leading the way in innovation with developing RESILIA tissue valves.

Nine commandments from Edwards Laboratories on the development of prosthetic heart valves (1968)[2]

- Embolism prevention
- Durability
- Ease and security of attachment
- Preservation of surrounding tissue function
- Reduction of turbulence
- Reduction of blood trauma
- Reduction of noise
- Use of materials compatible with blood and tissue
- Development of methods of storage and sterilisation

In memoriam: Dr Albert Starr (1926–2024)

Dr Albert Starr was an innovative surgeon whose work on prosthetic heart valves was a major breakthrough in cardiac surgery. He was born in 1926 and received his MD degree from Columbia's College of Physicians in 1949. In 1957, he moved to the University of Oregon Medical School to head a new heart surgery programme. Here, his drive for innovation led him to meet engineer Lowell Edwards and develop the Starr-Edwards heart valve – the first successful artificial heart valve used in humans, revolutionising cardiac surgery.



Throughout his life, Dr Starr continued to work on heart valve prostheses, pioneering the creation of a detailed registry of his patients with heart valves for careful lifetime monitoring. In 2007, he was a co-recipient of the Albert Lasker Award for Clinical Medical Research with Alain Carpentier for their development of prosthetic aortic and mitral valves. Dr Starr passed away on 12 December 2024, at the age of 98, leaving behind a valuable legacy in the field of cardiac surgery.

Real-world performance of the INSPIRIS RESILIA valve

Onorati F *et al*. *Ann Thorac Surg*. 2025; doi: 10.1016/j.athoracsurg.2023.02.015.6.[6]

The INSPIRIS RESILIA valve has the potential to reduce the risk of structural valve deterioration (SVD), as evidenced by the COMMENCE trial, which reported outcomes for a previous-generation valve with RESILIA tissue. The aim of this study was to report 5-year outcomes from an all-comer real-world European registry on SAVR with the INSPIRIS RESILIA valve.

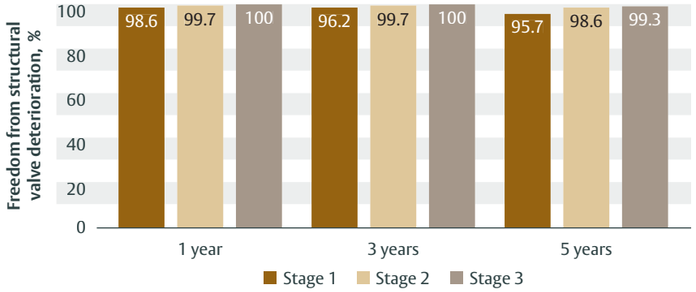
This large, prospective, multicentre registry included data from the first 498 consecutive patients who underwent SAVR with the INSPIRIS RESILIA valve across seven institutions since 2017. The primary endpoint was to evaluate the 5-year freedom from SVD according to Valve Academic Research Consortium 3 (VARC-3) criteria. Haemodynamic performance and freedom from all-cause and cardiovascular mortality, endocarditis, stroke and reintervention were also assessed.

Baseline characteristics

The mean (± SD) age was 60.1 ± 10.6 years, and 27.9% of patients were female. Mean (± SD) EuroSCORE II was 3.9 ± 6.5%, 53.8% of patients were in New York Heart Association (NYHA) Class III/IV, and 15.5% of patients had chronic kidney disease (CKD) stage ≥3.

Safety outcomes

The INSPIRIS RESILIA valve delivered high rates of freedom from SVD up to 5 years



The INPSIRIS RESILIA valve demonstrated favourable safety outcomes at 5 years

	Freedom from event at 5 years, % (95% CI)
All-cause mortality	93.2 (90.9–95.7)
Stroke	98.6 (97.4–100)
Endocarditis	98.1 (96.8–99.5)
NSVD	96.8 (94.7–98.9)
Moderate/severe PVL	97.3 (95.1–99.6)
Reintervention	98.2 (96.9–99.6)

CI: confidence interval; NSVD: non-structural valve deterioration; PVL: paravalvular leak.

Haemodynamics

Mean gradients remained stable over 5 years follow-up. At 5 years, the mean gradient for all valve sizes was 12.0 mmHg.

Conclusion

This study is the first to report real-world data from a relatively young patient population with risk factors for SVD such as advanced CKD, diabetes and morbid obesity. The INSPIRIS RESILIA valve demonstrated a favourable safety and durability profile, with stable haemodynamics and low SVD rates at 5-year follow-up, confirming data from the COMMENCE trial. In addition, low rates of endocarditis, non-structural valve deterioration and paravalvular leak contributed to a low rate of reintervention at 5 years.

Two billion cycles: INSPIRIS RESILIA valve demonstrates 50 years of mechanical durability

Bhat S *et al*. *Ann Thorac Surg Short Reports*. 2024; doi: 10.1016/j.atssr.2024.11.013.[7]

Evaluating the mechanical durability of a valve is essential to validate its use and observe any haemodynamic changes that may occur over time. The International Organisation for Standardisation (ISO) stipulates that all bioprosthetic heart valves should be tested for a minimum of 200 million cycles. The INSPIRIS RESILIA valve was previously tested to 1 billion cycles and showed good haemodynamic stability. This report investigates any further changes observed after 2 billion cardiac cycles, the equivalent to 50 years *in vivo*.

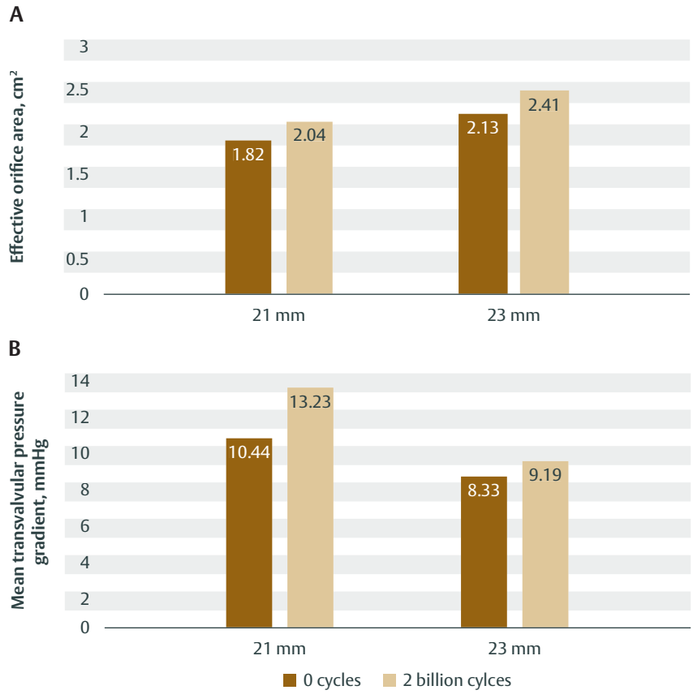
Haemodynamic and kinematic variables were measured for 21 mm (n=4) and 23 mm (n=4) INSPIRIS RESILA valves after testing (2 billion cycles, n=3 per valve size) and compared with control valves (0 cycles, n=1 per valve size). Valves were put through accelerated wear testing where saline was pumped through the valve to mimic *in vivo* conditions but at an accelerated frequency.

Kinematics and local flow

No tears or abrasions were noted for any control or tested valve. Systolic leaflet flutter was observed in all valves and velocity fields were consistent between control and test valves.

Haemodynamics

Both sizes of INSPIRIS RESILIA valves showed excellent effective orifice areas (EOA; A) and pressure gradients (B) after 2 billion cycles



Regurgitant fractions for both valve sizes were low and consistent with the control group (23 mm: control 2.8%; test 3.2%).

Conclusion

Accelerated wear testing cannot address all biologic phenomena that may affect valve performance in the body. However, this study demonstrates that the INSPIRIS RESILIA valve was durable for the equivalent of 50 years *in vivo* and the authors emphasise this excellent mechanical durability could provide long-term benefit to patients.

RESILIA tissue valves: Sustained excellent safety outcomes in patients with aortic stenosis, aortic regurgitation or mixed aortic valve disease

Thourani VH *et al*. *JTCVS Open*. 2024; **22:** 160–73.[8]

Aortic stenosis (AS) can be treated with either surgical or transcatheter aortic replacements, whereas aortic regurgitation (AR) is most commonly treated with surgery. In the case of mixed aortic valve disease (MAVD), treatment pathways can be unclear if there is no predominant lesion. This study compared 5-year clinical and echocardiographic outcomes in patients with pure AS *versus* pure AR and MAVD within the COMMENCE trial.

Haemodynamics

In terms of haemodynamics, both groups showed clinically stable gradients and EOAs across 5 years with no difference in rate of change for mean gradient (p=0.21) or EOA (p=0.10). Patients in the pure AR/MAVD group demonstrated a greater change in left ventricular mass reduction (p=0.03) when corrected for body surface area. Of the patients with data available, none had severe prosthesis-patient mismatch with elevated mean gradient (>20 mmHg) and valve dysfunction (Doppler velocity index <0.25).

Baseline characteristics

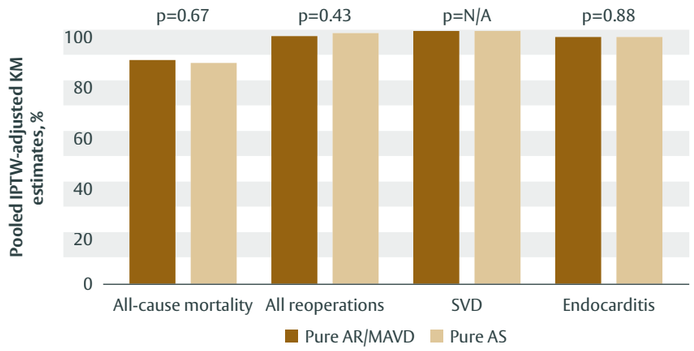
The mean (± standard deviation [SD]) follow-up duration was 5.3 ± 2.2 years. Baseline characteristics are shown below.

	Pure AR/MAVD (n=135)	Pure AS (n=323)	p value
Age, median (IQR), years,	65.0 (55.5–69.5)	69.0 (64.0–75.5)	<0.0001
Female, %	21.5	32.8	0.02
EuroSCORE II, median (IQR), %	1.5 (0.7–2.5)	1.6 (1.0–3.1)	0.02
Heart failure, %	23.0	21.7	0.76

AR: aortic regurgitation; AS: aortic stenosis; EuroSCORE: European System for Cardiac Operative Risk Evaluation; IQR: interquartile range; MAVD: mixed aortic valve disease.

Safety outcomes

Safety outcomes at 5 years were comparable for patients with pure AR/MAVD compared with pure AS



AR: aortic regurgitation; AS: aortic stenosis; IPTW: inverse probability of treatment weighting; KM: Kaplan–Meier; MAVD: mixed aortic valve disease.

Conclusion

The RESILIA tissue valve demonstrated excellent safety outcomes in patients with AS, AR, or MAVR, highlighting its benefits for patients, and may aid left ventricular reverse modelling in patients with AR.

Case report: Successful redo SAVR with an INSPIRIS RESILIA valve

Takemoto S *et al*. *Eur Heart J Case Rep*. 2024; **8:** ytae518.[9]

Takemoto and colleagues recently reported a case study of a patient who received a 19 mm Epic Supra aortic valve for severe AS at 81 years old. Two years after the initial procedure, transthoracic echocardiography (TTE) revealed progressive bioprosthetic valve dysfunction (peak velocity 4.7 m/s; mean gradient 54 mmHg). Another year later, the patient was readmitted with progressive exertional dyspnoea resulting from a pannus that had grown over the valve leaflets on the inflow surface, restricting leaflet mobility.

At 18-month follow-up:

- Functional improvement from **NYHA class III to class I**
- Excellent valve function **(peak velocity 2.3 m/s; mean gradient 9 mmHg)**
- **No signs of pannus formation**

Redo SAVR was performed with a 19 mm INSPIRIS RESILIA valve. The patient was eventually discharged from a rehabilitation hospital following a postoperative complete atrioventricular block requiring permanent pacemaker implantation. The authors highlight the importance of recognising pannus formation as a cause of early bioprosthetic valve dysfunction, despite its rare occurrence in elderly patients.

MITRIS RESILIA valve: Comparable outcomes to other mitral bioprostheses in an Australian single-centre cohort

Gilfillan M *et al*. Presented at ANZSCTS Annual Meeting, 7–9 November 2024, Sofitel Noosa, Queensland, Australia.[10]

At the ANZSCTS Annual Meeting 2024, Gilfillan and colleagues presented their retrospective study of patients undergoing bioprosthetic mitral valve replacement at Flinders Medical Centre, South Australia.

Postoperative outcomes were comparable between the MITRIS RESILIA valve and the other mitral valves with no statistically significant differences, except for a lower mean mitral valve gradient with the MITRIS RESILIA valve. However, there were numerically lower rates of stroke (0% *vs* 4%), acute kidney injury (7% *vs* 12%) and atrial fibrillation (28% *vs* 53%) in patients who received the MITRIS RESILIA valves compared with other valves. The mortality rate at 30 days was 1% for the MITRIS RESILIA valve and 2% for other valves.

Characteristic	MITRIS RESILIA valve (n=68)	Other valves (n=102)
Median age, years	48.3	55.5
Patients <65 years old, %	78	54
Postoperative echocardiography results		
Mean gradient, mmHg	4.3	5.9*
Mean LVEF, %	51	51
2-year follow-up echocardiography results		
Mean gradient, mmHg	4.5	5.9
Mean mitral valve area, cm^2	4.2	2.2
Mean LVEF, %	52	46
Freedom from valvular regurgitation	90	83

*p<0.001. LVEF: left ventricular ejection fraction.

The results from this centre show the MITRIS RESILIA valve is comparable to other mitral bioprostheses in the short-to-medium term, with potential haemodynamic advantages.

IMPACT registry: Favourable outcomes in young patients at 3-year follow-up

Bakhtiary F. Presented at DGTHG Annual Meeting, 15–17 February 2025, Hamberg, Germany.[11]

At the 54th Annual Meeting of the DGTHG, Professor Dr Farhad Bakhtiary presented the latest mid-term data from the IMPACT registry, focusing on mortality and haemodynamic performance.

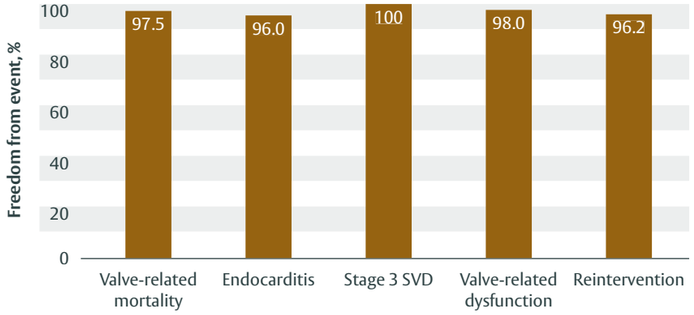
The IMPACT registry is an international multicentre registry assessing the impact of pre-existing comorbidities in a young population (n=556, mean age 63.4 ± 8.5 years) undergoing SAVR with the INSPIRIS RESILIA valve. The most common comorbidities in this cohort were hypertension (66.2%), coronary artery disease (29.0%) and diabetes (18.4%).

Transprosthetic regurgitation and paravalvular leak were stable across follow-up, with none/trace observed in 95.5% and 98.0% of patients, respectively, at 3-year follow-up.

Furthermore, left ventricular (LV) end-diastolic volume index and LV mass index significantly decreased and LV ejection fraction significantly increased at 3 years.

Clinical and functional outcomes

Clinical outcomes at 3 years show favourable valve-related mortality and dysfunction

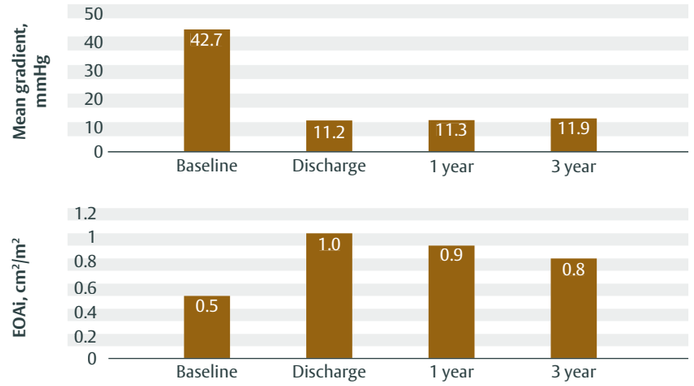


SVD: structural valve deterioration.

Functional outcomes also improved, with 5.7% of patients in NYHA class III/IV after 3 years compared with 41.2% at baseline.

Haemodynamics

Haemodynamic outcomes were improved at 3 years *versus* baseline



Median data presented. EOAi: indexed effective orifice area.

Conclusion

In a young population of patients with comorbidities, SAVR with the INSPIRIS RESILIA valve was associated with favourable clinical and haemodynamic outcomes at 3-year follow-up.

Mitral valve lifetime management: Breakfast symposium

Romano M, Acker M and Caranasos T. Presented at an Edwards Lifesciences sponsored symposium at the STS Annual Meeting, 24–26 January 2025, Los Angeles, California, USA.[12]

On 25 January 2025, Edwards hosted a symposium focused on mitral valve durability, haemodynamics and the MITRIS RESILIA valve.

Mitral valve replacement age guidelines

Professor Matthew A Romano began the symposium by presenting his recent publication questioning whether mitral valve replacement (MVR) age guidelines should be lowered.[13] In this study, patients who underwent MVR with a bovine pericardial prosthesis (2004–2020) were followed for a median of 75 months. The 30-day mortality rate was 5.4% and the late mitral valve mean gradient (mean ± SD) was 6.2 ± 3.5 mmHg. The cumulative incidence of SVD in this study was 6.2% at 10 years and 11.9% at 15 years, and the risk of mortality from re-do surgery was 5.6%. Importantly, this study showed that the incidence of mitral valve reintervention was not significantly different in patients aged 40–49, 50–59 and 60–69 years (p=0.1). Professor Romano concluded by stating that, as well as age, surgeons should also consider comorbidities, lifestyles and other upcoming surgeries when choosing a prosthetic valve for patients.

Preclinical mitral valve comparison

Next, Professor Caranasos presented a preclinical study comparing the MITRIS RESILA valve (25 mm) with the Epic valve and Mosaic valve (both 27 mm) in a porcine model.[14] Valve sizes with similar internal frame dimensions were selected.

	MITRIS RESILIA valve (25 mm)	Epic valve (27 mm)	Mosaic valve (27 mm)
Post implantation			
Mitral valve mean gradient, mmHg	2.6 ± 1.3	4.6 ± 1.9	3.9 ± 2.4
Surgical valve opening area, cm^2	2.4 ± 0.2	1.8 ± 0.3	2.0 ± 0.2
Post valve-in-valve implantation			
Mitral valve mean gradient, mmHg	2.2 ± 0.3	7.1 ± 1.1	5.3 ± 1.3

Data presented by Professor Caranasos revealed the strut and cuff design of the MITRIS RESILIA valve led to higher valve opening areas and lower LV outflow tract (LVOT) strut protrusion compared with the Epic and Mosaic valves. The MITRIS RESILIA valve was also the most fluoroscopically visible valve for valve-in-valve procedures and the SAPIEN 3 transcatheter valve (THV) within the MITRIS RESILIA valve had the lowest mean gradients, largest THV opening area and least LVOT protrusion.

MITRIS RESILIA valve implantability

Finally, Professor Michael Acker discussed the implantability of the MITRIS RESILIA valve. He described a recent 83-year-old female patient with mitral stenosis and mitral annular calcification (MAC). The patient had a small mitral valve annulus (21 mm), but a 25 mm MITRIS RESILIA valve was placed without difficulty. Professor Acker suggested that the MITRIS RESILIA valve's asymmetric design, saddle-shaped sewing cuff and foldable stents allow for easy placement, making it ideal for valves with MAC and small mitral valve annuli.

Pioneering technologies in RESILIA tissue valves: An interview with Professor Pēteris Stradiņš[a]

Professor Pēteris Stradiņš is a professor at Rīga Stradiņš University, Latvia. He is the head of the Cardiac Surgery Centre at Pauls Stradiņš Clinical University Hospital (PSCUS) and a member of PSCUS Medical Council. His expertise includes percutaneous valve replacement, aortic and mitral valve surgery, and hybrid procedures. He has contributed significantly to the field of cardiac surgery through his research, clinical work and educational initiatives.

Q. How long have you been partnering with Edwards Lifesciences?

A. Since we did our first transcatheter aortic valve implantation (TAVI) with the Edwards SAPIEN valve in 2008. At this time, TAVI was a totally novel approach for surgeons, and I appreciated the thorough training Edwards provided. In 2018, we started using the INSPIRIS RESILIA valve in surgical aortic valve replacements and we have now done about 630 procedures.

Q. Why do you think innovation is important in cardiac surgery?

A. Technologies are changing fast, and patients need and expect the latest developments. Therefore, companies who are innovating new devices and materials are very valuable. This is why I think Edwards is one of the major players in the field – their pioneering development of new technologies.

Q. How do features of the INSPIRIS RESILIA valve impact your recommendations for the lifetime management of your patients?

A. Traditionally, guidelines informed the choice between a mechanical or a bioprosthetic valve. Now, I think the question is – what type of bioprosthetic valve? We believe the two biggest advantages of the INSPIRIS RESILIA valve are the potential long-term durability of RESILIA tissue and VFit technology designed for potential future valve-in-valve procedures. These features offer potential long-term quality of life for our patients, free from anticoagulant therapy. At the moment, the INSPIRIS RESILIA valve is unique in this field, forming a new standard in the market.

Q. How has your practical experience been with INSPIRIS RESILIA valve implantation?

A. INSPIRIS RESILIA valves are stored under dry conditions, so you can have the prosthesis ready immediately without washing and changing water. This will be especially useful in the future when combining with aortic bioconduits. I also think the INSPIRIS RESILIA valve is good for minimally invasive techniques – we use the mini sternotomy and the 'Dresden approach' (transaxillary), and mostly direct vision with automatic suture devices.

Q. How has the experience been of launching the MITRIS RESILIA valve in your centre?

A. In April 2024, we did our first MITRIS RESILIA valve procedure on a 64-year-old woman with rheumatic disease, who wanted a biological valve. At 6-month follow-up, the results were very good. Mitral bioprosthetic valve degeneration is faster than in the aortic position, so for younger patients, the chance of repeat surgery is high. The potential for valve-in-valve surgery, not possible with other mitral bioprostheses, and potential long-term functionality of the MITRIS RESILIA valve, is a real opportunity.

Q. What are your thoughts on the implantability of the MITRIS RESILIA valve?

A. The sewing ring is soft and a joy to stitch. The stents fold down to the centre during implantation and can be expanded after. The valve is slightly asymmetrical – the struts near the outflow tract are shorter than the struts near the posterior commissural. I would say that this is one of the easiest mitral bioprostheses to implant.

> "Edwards is one of the major players in the field – their pioneering development of new technologies."

[a]Expert opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.

References:

1. Bartus K, Litwinowicz R, Bilewska A *et al*. Final 5-year outcomes following aortic valve replacement with a RESILIA tissue bioprosthesis. *Eur J Cardiothorac Surg*. 2021; **59:** 434–41.
2. Matthews AM. The development of the Starr-Edwards heart valve. *Tex Heart Inst J*. 1998; **25:** 282–93.
3. Starr A. Commentary: The artifical heart valve. *Nature Medicine*. 2007; **13:** 12–6.
4. Starr A, Edwards ML. Mitral replacement: Clinical experience with a ball-valve prosthesis. *Ann Surg*. 1961; **154:** 726–40.
5. Gott VL, Alejo DE, Cameron DE. Mechanical heart valves: 50 years of evolution. *Ann Thorac Surg*. 2003; **76:** S2230–9.
6. Onorati F, Geisler D, Theron A *et al*. Five-year results of aortic valve replacement with a novel bioprosthesis: Real-world data from a large multicenter registry. *Ann Thorac Surg*. 2025: doi: 10.1016/j.athoracsurg.2023.02.015.
7. Bhat S, Kim J, Karnik S *et al*. Long-term mechanical durability of INSPIRIS RESILIA surgical aortic valves. *Ann Thorac Surg Short Reports*. 2024; doi: 10.1016/j.atssr.2024.11.013.
8. Thourani VH, Puskas JD, Griffith B *et al*. Five-year comparison of clinical and echocardiographic outcomes of pure aortic stenosis with pure aortic regurgitation or mixed aortic valve disease in the COMMENCE trial. *JTCVS Open*. 2024; **22:** 160–73.
9. Takemoto S, Kumano H, Shimamura J *et al*. Pannus formation: A rare culprit of early bioprosthetic valve dysfunction-a case report. *Eur Heart J Case Rep*. 2024; **8:** ytae518.
10. Gilfillan M, Baker R, Hamson R *et al*. MITRIS RESILIA mitral valve replacement: A single centre's experience. ANZSCTS Annual Scientific Meeting, 2024, Queenland, Australia.
11. Bakhtiary F. Three years outcomes after surgical aortic valve replacement with a bioprosthetic valve from the multicentre IMPACT registy. German Society for Thoracic, Heart and Vascular Surgery, 2025, Hamberg, Germany.
12. Romano M, Acker M, Caranasos TG. What you need to know for mitral valve lifetime management. Durability, hemodynamics and the MITRIS RESILIA valve. In conjunction with STS Annual Meeting, 2025, Los Angeles, California.
13. Romano M, McCarthy PM, Baldridge AS *et al*. Should mitral valve replacement age guidelines be lowered due to better bioprosthetic mitral valve durability? *J Thorac Cardiovasc Surg*. 2024; **168:** 1448–58.
14. Wang DD, Caranasos TG, O'Neill BP *et al*. Comparison of a new bioprosthetic mitral valve to other commercially available devices under controlled conditions in a porcine model. *J Card Surg*. 2021; **36:** 4654–62.

Clinical data on valves with RESILIA tissue up to 7-year follow-up have been published, with additional follow-up to 10-years in progress.

Refer to device instructions for use for important warnings related to VFit technology. These features have not been observed in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedures. VFit technology is available on sizes 19–25 mm.

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).

Edwards Lifesciences Sàrl • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

Edwards