Inspire

Your latest news on RESILIA tissue

Newsletter #6 – November 2023

Life^{R}

Life to the power of RESILIA

A promise of freedom. That's the power of RESILIA tissue.

Edwards

MITRIS RESILIA Mitral Valve

Now CE Marked in Europe

In this issue

We hope you enjoy this issue of Inspire. Learn more about what the MITRIS valve can do for your patients: scan the QR code to visit our website.

FRONT COVER IMAGE: ISTOCK.COM/MONKEYBUSINESSIMAGES

Introduction

We are delighted to announce that we have received CE mark approval for our MITRIS RESILIA mitral valve. Built on the trusted Carpentier-Edwards PERIMOUNT valve platform, and made with RESILIA tissue for decreased calcification, we are proud to provide the MITRIS RESILIA valve to your patients, with potential improved durability.[1,2*] Find out more about the features and benefits of MITRIS RESILIA valve on page 3.

The launch of the MITRIS RESILIA valve is backed by a strong and growing body of clinical evidence supporting RESILIA tissue's durability and haemodynamic performance.[2–4] This includes the encouraging 5-year data from the COMMENCE Mitral clinical trial.[2] Turn to page 5 to read a summary of these data.

Exciting data on RESILIA tissue in the aortic position were presented at the European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting in Vienna in October. Researchers from five European centres joined forces to assess the 5-year clinical and echocardiographic results of the INSPIRIS RESILIA valve in real-world patients.[5] Turn to page 7 for a summary of their results. Additionally, Andrea Zierer at Linz University Hospital and colleagues aimed to address what difference – if any – a patient's sex makes to outcomes of surgical aortic valve replacement (SAVR) using INSPIRIS RESILIA valve data from the IMPACT and INDURE registries.[6] Check out their findings on page 8.

Finally, we summarise recent publications on the INSPIRIS RESILIA valve (pages 9–12) and discuss the value of clinical research with Professor Francesco Onorati (page 13).

Enjoy reading!

MITRIS RESILIA Mitral Valve

Designed to handle the pressure of the mitral position

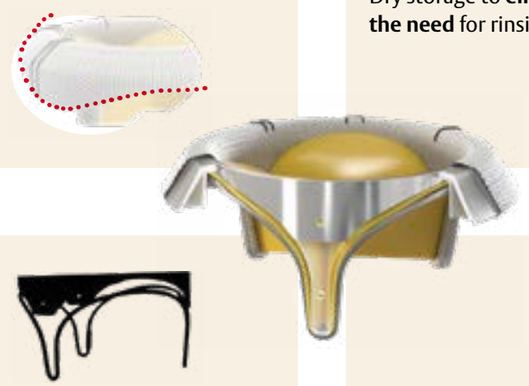
*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

MITRIS RESILIA mitral valve: Specifically designed for the mitral position

When your patient's disease may be too complex, and mitral valve repair is not feasible, replacement is likely the best choice.[7]

The MITRIS RESILIA valve is designed to handle the pressure of the mitral position.[1]

A **saddle-shaped** sewing cuff that mimics the native mitral annulus. This asymmetrical design is specifically tailored to the contours of the native annulus.



RESILIA tissue* is designed to offer enhanced tissue anticalcification technology that will potentially allow the valve to last longer.

Dry storage to **eliminate the need** for rinsing.

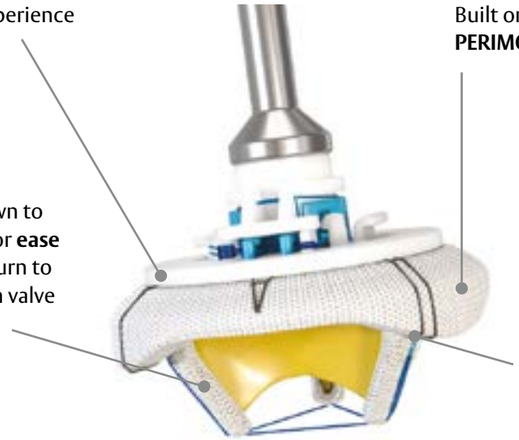
Good visibility under fluoroscopy for easy identification of the landing zone for potential future transcatheter interventions.

Low anterior profile stents do not obstruct blood flow through the left ventricular outflow tract.

Additional features to enhance the delivery experience include folding nitinol stents for ease of implant and commissure markers to aid correct positioning of the valve.[1]

Enhanced delivery experience

Nitinol stents fold down to 55 degrees allowing for **ease of implant; stents** return to original position when valve is implanted



Built on the **Carpentier-Edwards PERIMOUNT valve platform**

A posteromedial commissure mark (single black line), an anterolateral commissure mark (double black line), and an anterior segment mark ("A" mark). The black commissure markers **facilitate the orientation of the valve** and help avoid obstruction of the left ventricular outflow tract by stent posts

RESILIA tissue is backed by a strong and growing base of clinical evidence, including clinically stable haemodynamics throughout 7 years' follow-up and very low rates of structural valve deterioration (SVD).[2–4]

Actuarial freedom from SVD

COMMENCE Mitral clinical trial[2]
98.7%
throughout 5 years

COMMENCE Aortic clinical trial[3]
99.3%
throughout 7 years

Turn to page 5 to read more about the 5-year results from the COMMENCE Mitral clinical trial.

The MITRIS RESILIA valve can help you meet the specialised needs of your patients.
Visit info.Edwards.com/inspire to find out more.

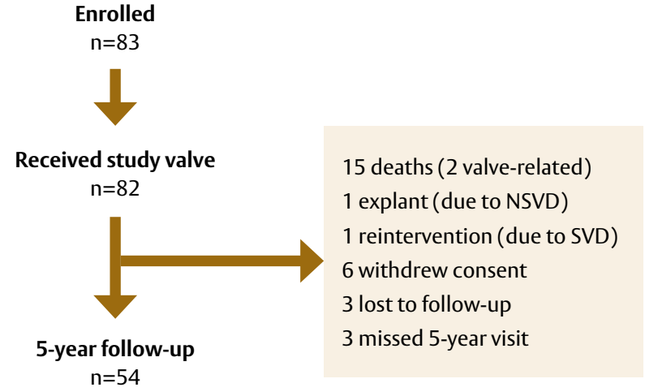
*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

Good mid-term outcomes and promising durability from the COMMENCE Mitral clinical trial at 5 years

Heimansohn DA *et al*. *J Thorac Cardiovasc Surg*. 2023; **15:** 151–63.[2]

Following promising 7-year results from the COMMENCE Aortic clinical trial,[3] Heimansohn and colleagues report encouraging mid-term outcomes from the mitral arm of the COMMENCE trial in the September issue of the *Journal of Thoracic and Cardiovascular Surgery*.

The COMMENCE Mitral trial is an ongoing, prospective, single-arm FDA Investigational Device Exemption trial evaluating the performance of RESILIA tissue for mitral valve replacement. The trial enrolled 83 patients from 17 study sites across the USA and Canada. Median (interquartile range [IQR]) follow-up was 5.1 (1.4) years with 5-year outcome data available for 54 patients.



NSVD: non-structural valve deterioration; SVD: structural valve deterioration

Baseline patient demographics	
Age, median (IQR), years	70 (13)
NYHA III/IV, %	59
Female, %	58.5

IQR: interquartile range; NYHA: New York Heart Association

An independent clinical events committee adjudicated all safety endpoints, which were as defined by Akins *et al*.[8] An independent core laboratory evaluated haemodynamic performance.

Safety outcomes at 5 years

79.9%
Freedom from all-cause mortality
(95% CI 70.8–89.1%)

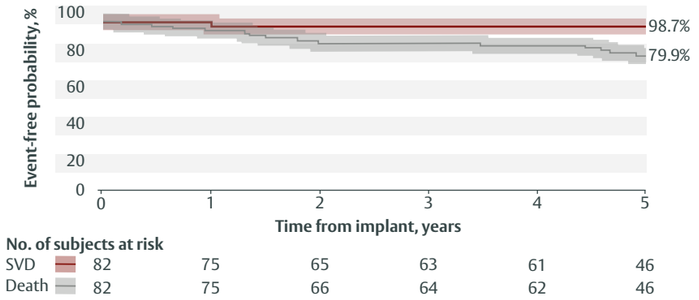
98.7%
Freedom from SVD
(95% CI 96.1–100%)

97.1%
Freedom from reoperation
(95% CI 93.1–100%)

100%
Freedom from major paravalvular regurgitation

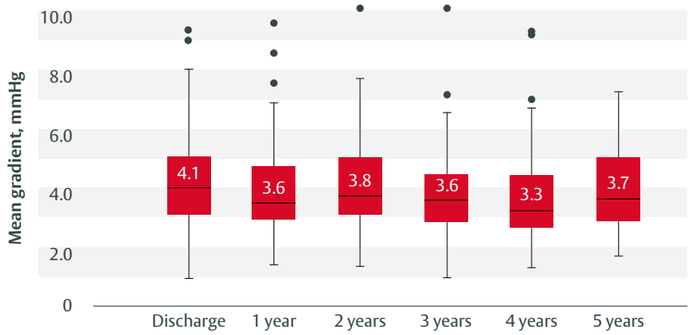
SVD: structural valve deterioration

The risk of death exceeded that of SVD throughout the follow-up period



SVD: structural valve deterioration

Mean mitral pressure gradients remained stable throughout 5 years of follow-up



Box plot showing median (horizontal black line), interquartile range (red box), minimum and maximum (vertical black line) and outliers (black dots)

RESILIA tissue in a mitral bioprosthetic valve displays a favourable safety profile and clinically stable haemodynamics at mid-term follow-up, consistent with results from the aortic arm of the COMMENCE trial.[9]

The COMMENCE Mitral trial is one of only a few mitral valve replacement clinical trials in the last 25 years, and the first to report on the use of RESILIA tissue in a bioprosthetic mitral valve. The results so far are encouraging for the durability of RESILIA tissue in the mitral position. The trial is ongoing, and follow-up will continue through to 10 years to evaluate the long-term safety and effectiveness of the tissue.

Fresh from EACTS: longest real-world follow-up to date

Francica A. Presented at the 38th EACTS Annual Meeting, 4–7 October 2023, Vienna, Austria.[5]

Although the mid-term safety and efficacy of the INSPIRIS RESILIA valve have been well demonstrated in industry-driven trials, at the EACTS 2023 conference, Dr Francica presented 5-year clinical and echocardiographic results from a young patient population in a multicentre study, representing the largest and longest follow-up for INSPIRIS RESILIA valve in the real world.

Since 2017, data from all-comer patients receiving the INSPIRIS RESILIA valve in the aortic position were collected at five European cardiac surgery centres (Verona, Wien, Marseille, London and Bologna). Patients with 4–5 years of follow-up were included in this analysis.

Key patient demographics at baseline

N	486
Male, %	72.8
Age, mean ± SD, years	56 ± 10.7
Follow-up, mean ± SD, months	49.8 ± 0.75
EuroSCORE II, % ± SD	3.7 ± 6.2
NYHA III/IV, %	46.9

EuroSCORE: European System for Cardiac Operative Risk Evaluation; NYHA: New York Heart Association; SD: standard deviation

Key results at 5-year follow-up

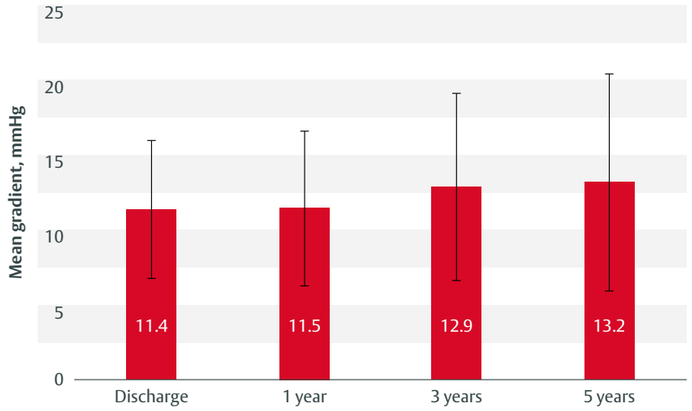
95.7% Survival

↓84% NYHA III/IV*

2 SVD

* reduction from baseline
SVD: structural valve deterioration

Mean gradients remained stable throughout 5 years of follow-up



Error bars represent standard deviation

The INSPIRIS RESILIA valve demonstrated good clinical results with stable haemodynamic performance at 5 years for each valve size in a young population of patients.

The 5-year freedom from reoperation was excellent and only two patients had SVD. The main cause of reintervention was infective endocarditis.

These real-world results from a multicentre study, with a young patient cohort, confirm the positive mid-term results of the INSPIRIS RESILIA valve reported by the industry-driven trials.

Does a patient's sex affect clinical outcomes and safety of surgical aortic valve replacement?

Zierer A. Presented at the 38th EACTS Annual Meeting, 4–7 October 2023, Vienna, Austria.[6]

According to current scientific literature, fewer women undergo SAVR compared with men. SAVR is associated with worse short-term outcomes, and 30-day mortality is higher in women. At the EACTS 2023 conference, Dr Zierer presented the results of a multicentre, prospective study that merged the prospective, observational data from the INDURE and IMPACT registries. Sex-specific differences, outcomes, and valve performance up to 2 years' follow-up were analysed in a young (mean age 59 years) patient population.

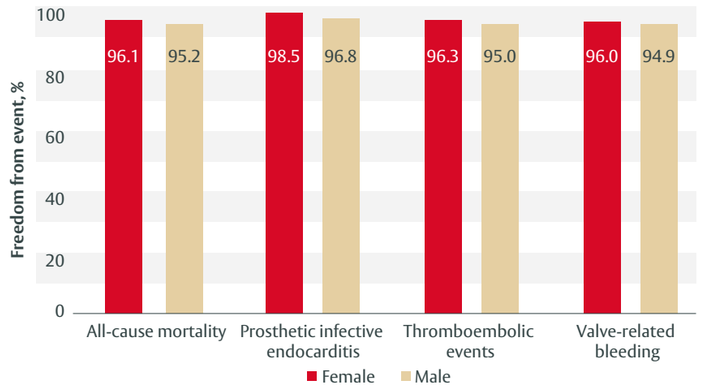
Female patients have a lower functional status and greater preoperative risk profile

	Female	Male	p value
NYHA III/IV, %	47.1	29.7	<0.001
EuroSCORE II, %	2.3	1.8	0.025

EuroSCORE: European System for Cardiac Operative Risk Evaluation; NYHA: New York Heart Association

Young female patients had a smaller valve anatomy, therefore they received smaller valves during SAVR, and were more likely to undergo minimally invasive surgery. The 30-day mortality (1.2%) did not differ significantly between sexes, and the difference in overall, cardiovascular and valve-related mortality remained non-significant up to 2 years. The rates of adverse events were not significantly different between males and females, except for life-threatening bleeding following isolated aortic valve replacement (AVR), which was lower in females.

No significant difference in clinical outcomes in female *versus* male patients at 2 years



In conclusion, despite female patients being referred for SAVR with a lower functional status and greater preoperative risk profile compared with males, 30-day mortality and mortality up to 2 years were not significantly different.

INSPIRIS RESILIA valve demonstrates excellent 1-year haemodynamic performance in young patients

Porto A *et al*. *Front Cardiovasc Med*. 2023; **10:** 1196447.[10]

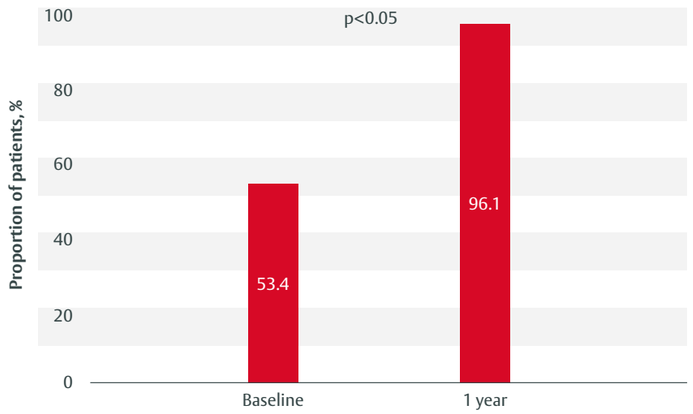
A prospective, single-centre study from La Timone Hospital in Marseille, France demonstrated excellent 1-year haemodynamic performance and safety outcomes with the INSPIRIS RESILIA valve in young patients who underwent AVR.

Porto and colleagues included 487 consecutive patients (mean [± standard deviation (SD)] age 58.2 ± 11.5 years; EuroSCORE II 4.8 ± 7.9%) who underwent AVR with the INSPIRIS RESILIA valve between June 2017 and July 2021. Early outcomes were good, with a mortality rate of 1.6% and a stroke rate of 0.8% at 30 days; pacemaker implantation rate at discharge was 4.7%.

At 1-year follow-up, the Kaplan–Meier survival rate was 96.4 ± 0.9%, with a freedom from major adverse cardiac events of 96.7 ± 0.8%.

NYHA functional status was significantly improved at 1-year follow-up (see figure below).

More patients were in NYHA class I/II at 1-year follow-up



In summary, these data show excellent haemodynamic performance and good safety outcomes for the INSPIRIS RESILIA valve in young patients, although further studies are needed to assess long-term durability.

Haemodynamic performance

Moderate and severe patient–prosthesis mismatch (PPM) were seen in 6.2% and 1.4% of patients at 30-day follow-up, and in 10.5% and 1.2% at 1 year. No SVD or valve failure requiring redo surgery were reported during the 1-year follow-up.

Indexed effective orifice area increased from 0.4 cm^2/m^2 at baseline to 1.0 cm^2/m^2 at 1 year, with no difference seen when patients were grouped by age. Mean gradient was also unaffected by the age of the patient.[10]

Potential cost savings associated with INSPIRIS RESILIA valve *versus* mechanical valves

Malcolm R *et al*. *Expert Rev Pharmacoecon Outcomes Res*. 2023; **23:** 1087–99.[11]

INSPIRIS RESILIA valve could be a cost-effective intervention for people in the UK over 55 years old requiring SAVR, according to the authors of a recent study.

Bioprosthetic valves are the standard of care for older patients, but their durability is a concern for younger patients, who often receive mechanical valves instead. As the INSPIRIS RESILIA valve is designed to offer enhanced anticalcification technology that will potentially allow the valve to last longer,[12] understanding its cost-effectiveness *versus* a mechanical valve is important.

The authors developed a model using data from published clinical studies, including the COMMENCE trial. Inputs into the model included mortality, adverse events, NYHA classification, health-related quality of life and a variety of costs, including procedure costs, anticoagulation-related costs and medication. Primary outcomes generated from the cost-effectiveness model included incremental costs.

The analysis showed a potential cost saving for UK patients with aortic stenosis aged 55 and over with the INSPIRIS RESILIA valve compared with generic mechanical valves.

Potential cost savings over the lifetime of the patient with INSPIRIS RESILIA valve

Age 55–64 years

£408

per patient

Age ≥64 years

£53

per patient

Reoperation rates had a considerable impact on the model results. In fact, the analysis indicated that a reduction in reoperation rates by 30% in patients aged 55-64 years with the INSPIRIS RESILIA valve could improve savings up to around **£800** per patient.

The collection of evidence on the INSPIRIS RESILIA valve is ongoing and could be used to improve the robustness of this model in the future.

INDURE registry – excellent haemodynamic performance of INSPIRIS RESILIA valve at 1 year

Meuris B *et al*. *Interdiscip Cardiovasc Thorac Surg*. 2023; **37:** ivad115.[13]

Mean gradient

11.7 mmHg
Discharge

12.6 mmHg
1 year

Effective orifice area

2.1 cm²
Discharge

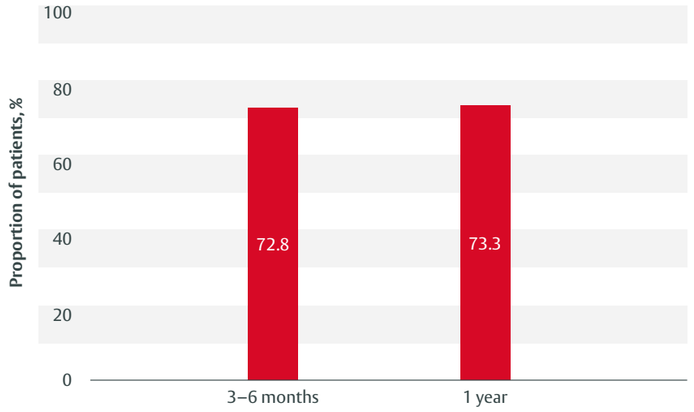
1.9 cm²
1 year

Recently published 1-year follow-up data from the INDURE registry show excellent haemodynamic performance for the INSPIRIS RESILIA valve, with good safety outcomes and an early improvement in quality of life.

The INDURE registry enrolled 421 patients with a mean (± SD) age of 53.5 ± 6.9 years undergoing AVR with an INSPIRIS RESILIA valve from 21 sites across Europe and Canada. Of these patients, 308 (73.2%) had bicuspid aortic valve.

Early (≤30 days) outcomes were good, with a mortality rate of 0.7%, thromboembolic event rate of 1.7% and pacemaker implantation rate of 3.8%. Freedom from all-cause mortality at 1 year was 98.3%, with no valve-related deaths, and freedom from valve-related dysfunction was 98.7% with no stage 3 SVD.

Patients reporting an improvement in quality of life



In this cohort of young patients with a high rate of bicuspid aortic valve morphology, the INSPIRIS RESILIA valve demonstrated good safety and excellent haemodynamic outcomes with a corresponding improvement in patient quality of life.[13]

Favourable mid-term haemodynamic performance of INSPIRIS RESILIA valve after 2 years

Bernard J *et al*. *Interdiscip Cardiovasc Thorac Surg*. 2023; **37:** ivad117.[14]

In this retrospective single-centre study, Bernard *et al*. compared mid-term data for the INSPIRIS RESILIA valve with the Carpentier-Edwards PERIMOUNT Magna Ease valve.

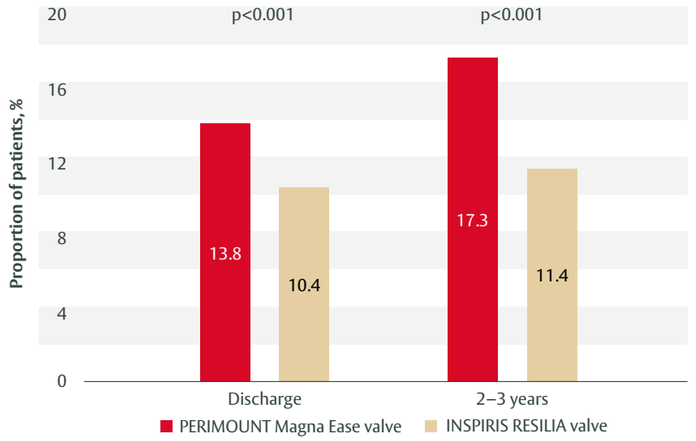
The study included patients who underwent SAVR with the INSPIRIS RESILIA or PERIMOUNT Magna Ease valves between January 2018 and July 2021. Patients were propensity score matched into two groups of 217 patients who received either the INSPIRIS RESILIA valve or PERIMOUNT Magna Ease valve. The mean (± SD) age of patients was 70 ± 7 years for the PERIMOUNT Magna Ease valve group and 69 ± 7 years for the INSPIRIS RESILIA valve group.

Early (30-day) outcomes were similar between the two groups, with in-hospital mortality rates of 1.6% and 0% for isolated AVR with the PERIMOUNT Magna Ease and INSPIRIS RESILIA valves and no incidence of stroke reported for either group.

Survival at 30 months was 91% for the PERIMOUNT Magna Ease valve group and 94% for the INSPIRIS RESILIA valve group. Freedom from readmission for the PERIMOUNT Magna Ease valve group was 87% at 12 months and 86% at 30 months; for the INSPIRIS RESILIA valve group, it was 94% at both timepoints. Subsequent multivariate analysis confirmed that the PERIMOUNT Magna Ease valve was independently associated with an increased risk of readmission.

In the matched cohort, the INSPIRIS RESILIA valve demonstrated superior haemodynamics to the PERIMOUNT Magna Ease valve, with significantly lower mean gradients at discharge and 2–3 years' follow-up.

Mean gradients were lower with the INSPIRIS RESILIA valve



There were two cases of moderate SVD in the INSPIRIS RESILIA valve group and none in the PERIMOUNT Magna Ease valve group. Moderate PPM occurred in 31% of each group, and severe PPM occurred in 16% of the PERIMOUNT Magna Ease valve group and 7% of the INSPIRIS RESILIA valve group.

These data demonstrate comparable safety outcomes with the PERIMOUNT Magna Ease and INSPIRIS RESILIA valves, and improved haemodynamic performance for the INSPIRIS RESILIA valve.

INSPIRIS RESILIA valve: Learnings from clinical practice

Professor Francesco Onorati is lead surgeon in the Heart Transplant and Mechanical Assisted Devices programmes at Verona University Hospital. The hospital was one of the first institutions to investigate the haemodynamics of the PERIMOUNT Magna Ease and INSPIRIS RESILIA valves. We caught up with him at the EACTS Annual Meeting to discuss his experience with these valves.

Q. Here at the EACTS Annual Meeting, you presented your propensity-matched durability and haemodynamic data for the PERIMOUNT Magna Ease and INSPIRIS RESILIA valves. Please can you describe the main findings?

A. We started implanting the INSPIRIS RESILIA valve when it came on the market in 2017. Given that we have a huge database on PERIMOUNT Magna Ease valve performance, we decided to compare the clinical and echocardiographic data for the two valves up to 3 years' follow-up. A propensity score-matched analysis gave us 122 pairs of patients. From these, we were able to demonstrate that clinical results after 3 years in a young population of patients were excellent. No operative or cardiovascular-related deaths were reported, and only one patient required further surgery, because of endocarditis. Turning to durability, no patient in the INSPIRIS RESILIA valve cohort developed SVD within 3 years of implantation, according to VARC-3 criteria; however, four patients in the PERIMOUNT Magna Ease valve cohort developed SVD within this timeframe. The difference was not statistically significant in this small study.

Q. In this study, you also assessed left ventricular remodelling. Why was it important to assess remodelling compared with traditional measures, such as valvular gradients and PPM?

A. Pressure gradients relate to valve function, but, from a clinical standpoint, reverse remodelling of the heart is more important. Even if you have excellent valve function, without reverse remodelling the patient is likely to die from cardiovascular causes, such as fibrosis, arrhythmia or diastolic heart failure.

We found that almost all patients experienced significant reverse remodelling. This was stable for up to 10 years for the PERIMOUNT Magna Ease valve and up to 3 years for the INSPIRIS RESILIA valve, which was the extent of echocardiographic data available at the time.

Q. Your colleague, Dr Francica, presented some durability data for the INSPIRIS RESILIA valve from a multicentre registry. Can you please tell us about it?

A. I am proud to be collaborating with colleagues from five centres – Verona, Bologna, Marseilles, Vienna and St Thomas' Hospital in London – on this multicentre, independent registry searching for mid- and long-term results for the INSPIRIS RESILIA valve. We reported preliminary 5-year outcomes, showing that results remain excellent, with a very low rate of SVD. (Read more on page 7)

Q. How relevant are data from real-world registries for the field of cardiac surgery research?

A. Real-world data are always important, because they describe real clinical practice by different surgeons in different centres, with different surgical techniques and postoperative care. Connecting efforts from different centres results in large patient numbers and provides strong evidence, be that positive or negative.

"The surgical community trusts the INSPIRIS RESILIA valve."

Professor Francesco Onorati

Q. How do you see clinical research evolving in cardiac surgery now compared with the past?

A. We need medicine based on clinical evidence, rather than expert opinions, hence the interest in cardiac surgery research and multicentre studies. In the last few years, we have also seen major randomised controlled trials, which were lacking before 2010. We are being encouraged to be more scientific and rely less on subjective opinions.

Q. What further research would you like to see on the INSPIRIS RESILIA valve?

A. Aside from the ongoing COMMENCE trial, the longest follow-up available, we need more independent data about the real incidence of SVD in clinical practice, for different age groups. Younger patients are asking for bioprostheses, so we need more data in patients aged 55 and younger. We also need to understand how RESILIA tissue behaves in patients with chronic kidney disease and other comorbidities linked to early SVD.

Q. Over 200,000 patients have now received the INSPIRIS RESILIA valve. What does that mean to you?

A. It shows that the surgical community trusts the INSPIRIS RESILIA valve because of the strength of Edwards products over the last two decades. They are excellent products, and we put a lot of hope into new products from the Edwards portfolio.

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No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

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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