0003-4975
https://doi.org/10.1016/j.athoracsur.2025.03.015



Valve: Research

# Five-Year Results of Aortic Valve Replacement With a Novel Bioprosthesis: Real-World Data From a Large Multicenter Registry

Francesco Onorati, MD, PhD,[1] Daniela Geisler, MD,[2] Alexis Theron, MD,[3] Alessandra Francica, MD,[1] Vincenzo Caruso, MD,[4] Carlo Mariani, MD,[5] Antonio Fiore, MD,[6] Romy Hegeman, MD,[7] Alizee Porto, MD,[3] Thierry Folliguet, MD,[6] Gianluca Lucchese, MD,[4] Patrick Klein, MD,[7] Davide Pacini, MD,[5] Martin Grabenwöger, MD,[2] and Giovanni Battista Luciani, MD[1]

## ABSTRACT

**BACKGROUND** The clinical performance and safety of a glutaraldehyde-free bioprosthetic valve using a novel tissue treatment in a large real-world patient population have not previously been reported.

**METHODS** This is a prospective, multicenter, real-world registry of all patients undergoing surgical aortic valve replacement with a novel bioprosthesis at 7 European cardiac surgery centers. The primary end point was the 5-year freedom from structural valve deterioration per Valve Academic Research Consortium 3 criteria. Secondary end points included hemodynamic performance of the bioprosthesis and freedom from all-cause and cardiovascular mortality, prosthetic endocarditis, stroke, and reintervention at 5 years.

**RESULTS** A total of 498 patients were included in the analysis; the mean age was 60.1 years, with a mean EuroSCORE II of 3.9% and 27.9% being female. The median follow-up was 4.8 years. Five-year freedom from structural valve deterioration stages 1, 2, and 3 was 95.7%, 98.6%, and 99.3%, respectively. The estimated 5-year overall survival was 93.2%; freedom from cardiovascular mortality was 97.2%. Event-free probabilities at 5 years for endocarditis, stroke, and reintervention were 98.6%, 98.1%, and 98.2%, respectively. Moderate-severe paravalvular leakage was infrequent (97.3% event-free probability at 5 years), and mean aortic valve pressure gradient was stable compared with discharge (median, 11.0 mm Hg at discharge vs 12.0 mm Hg at 5 years).

**CONCLUSIONS** These real-world clinical data of a novel aortic bioprosthesis demonstrated good 5-year results for both durability and safety outcomes as well as stable hemodynamic valve performance.

(Ann Thorac Surg 2025;■:■-■)



Aortic stenosis is a highly prevalent valvular disease in Western countries and will continue to rise with the growing life expectancy. Aortic regurgitation has been reported to affect nearly 5% of the population, with 0.5%

The Supplemental Material can be viewed in the online version of this article [https://doi.org/10.1016/j.athoracsur.2025.03.015] on http://www.annalsthoracicsurgery.org.

Accepted for publication Mar 10, 2025.

[1]Division of Cardiac Surgery, University of Verona Medical School, Verona, Italy; [2]Department of Cardiovascular Surgery, Clinic Floridsdorf, Vienna, Austria; [3]Département de Chirurgie Cardiaque, AP-HM, CHU Timone, Marseille, France; [4]Department of Cardiac Surgery, St Thomas Hospital, London, United Kingdom; [5]Division of Cardiac Surgery, S. Orsola University Hospital, IRCCS, Bologna, Italy; [6]Department of Cardiac Surgery, Hôpitaux Universitaires Henri Mondor, Assistance Publique-Hôpitaux de Paris, Creteil, France; and [7]Division of Cardiac Surgery, Amsterdam UMC, Amsterdam, The Netherlands

Address correspondence to Dr Francesco Onorati, Division of Cardiac Surgery, University of Verona Medical School, Piazzale Aristide Stefani 1, 37126 Verona, Italy; email: francesco.onorati@univr.it.

of the population displaying moderate or severe aortic regurgitation.[1,2]

Aortic valve replacement, performed through either open heart surgery (surgical aortic valve replacement [SAVR]) or a transcatheter approach (transcatheter aortic valve replacement), is the only effective treatment option for managing severe aortic stenosis. SAVR is considered the most standardized treatment of aortic regurgitation.[3]

Although current European guidelines (class IIa) recommend a bioprosthesis for patients older than 65 years[4] and the American guidelines accept an age threshold of 50 years,[5,6] the use of biologic prostheses is expanding worldwide to younger patients,[7] primarily because of the perceived risks of lifelong anticoagulation therapy required by mechanical valves.[8] Nonetheless, long-term durability remains a challenge for bioprostheses, especially when they are implanted in younger decades of life, with structural valve deterioration (SVD) being the major cause of bioprosthetic valve failure requiring reintervention.[8,9] Of note, several risk factors associated with accelerated (<5 years) valve deterioration have been identified to date, with young age (<60 years) at surgery being one of the most relevant ones.[5,6]

The recently developed INSPIRIS RESILIA (IR) aortic valve (Edwards Lifesciences) has been launched on the market with the promise of reducing the risk for accelerated cusp degeneration, thanks to its novel tissue integrity preservation technology free of glutaraldehyde.[10-13] At this time, however, midterm data on this valve are lacking in the literature. Indeed, preclinical studies have demonstrated excellent valve performance and durability.[14,15] Clinical results, reported up to 5 and 7 years after aortic valve replacement, were part of the industry-driven prospective multicenter COMMENCE trial, which had specific inclusion and exclusion criteria (like any safety trial), and the study valve was not the IR valve itself but a previous generation valve with RESILIA tissue.[16,17] Therefore, this study aimed to report the 5-year real-world clinical and echocardiographic results coming from a multicenter European registry on SAVR with the IR bioprosthesis.

## PATIENTS AND METHODS

This is a large, prospective, multicenter, real-world registry including data from all patients who underwent isolated or combined SAVR with the IR valve across 7 European cardiac surgery institutions since 2017. No specific exclusion criteria were considered. The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the institutional review board of the Division of Cardiac Surgery, University of Verona (BB-CCH847CESC201). Study approval was also obtained from the ethics committee responsible for each participating center, and formal written informed consent was obtained from every patient at enrollment.

**PATIENT POPULATION.** The registry included to date 1871 consecutive patients undergoing SAVR with the IR valve. For the purpose of this analysis, data from the first 498 consecutive patients aged ≥18 years undergoing SAVR with the IR valve, as either an isolated or a combined procedure, and who completed the fourth or fifth year of follow-up since surgery were analyzed. Supplemental Figure S1 depicts the flowchart of the population enrolled in this study.

Perioperative and postoperative care was left to institutional discretion and followed individual institution-specific guidelines. The choice to implant an IR valve was left to surgeons, given that different types of prostheses were also implanted in other patients at these institutions during the same study period.

**DATA DOCUMENTATION.** All data were prospectively collected at each institution. The local cardiac surgical team at each center enrolled patients in the study after written informed consent and collected baseline parameters and surgical variables as well as perioperative, postoperative, and follow-up patient-specific data. Postoperative follow-up clinical and echocardiographic data were collected at 5 time windows (1-3 months, 6 months, 1 year, then yearly thereafter up to the fifth postoperative year) by examination of the patients at the participating cardiac surgical centers. In cases in which that was impossible, clinical and echocardiographic data were obtained either by querying the electronic clinical chart of each patient (retrieving data from the Regional Health Database) or by interviewing the patient by phone. Missing echocardiographic data were retrieved from the institutional databases of cardiologic referring hospitals, which were all accredited to European standards of echocardiography. All patient data were anonymized and captured by a specifically designed electronic case report form.

**OBJECTIVES.** The primary end point was the 5-year freedom from SVD staged according to the Valve Academic Research Consortium 3 (VARC-3) criteria.[18] Briefly, VARC-3 defines SVD as any intrinsic permanent change to the prosthetic

valve (eg, wear and tear, leaflet disruption, flail leaflet, leaflet fibrosis or calcification, or strut fracture or deformation) and recognizes 3 stages:

- Stage 1: SVD with no significant hemodynamic impairment
- Stage 2: SVD with moderate hemodynamic impairment (ie, increase in mean transvalvular gradient ≥10 mm Hg resulting in mean gradient ≥20 mm Hg, with concomitant decrease in effective orifice area ≥0.3 $cm^2$ or ≥25% or decrease in Doppler velocity index ≥0.1 or ≥20% compared with echocardiographic assessment performed 1 to 3 months after the procedure, *or* new occurrence or increase of ≥1 grade of intraprosthetic aortic regurgitation resulting in ≥ moderate aortic regurgitation)
- Stage 3: SVD with severe hemodynamic impairment (ie, increase in mean transvalvular gradient ≥20 mm Hg resulting in mean gradient ≥30 mm Hg with concomitant decrease in effective orifice area ≥0.6 $cm^2$ or ≥50% or decrease in Doppler velocity index ≥0.2 or ≥40% compared with echocardiographic assessment performed 1 to 3 months after the procedure, *or* new occurrence or increase of ≥2 grades of intraprosthetic aortic regurgitation resulting in severe aortic regurgitation)[18]

The secondary end point was the echocardiographic hemodynamic performance of the IR bioprosthesis since surgery to the end of the 4- or 5-year follow-up. Other clinical outcomes of interest were hospital outcome; all-cause and cardiovascular mortality at follow-up; and incidence of prosthetic endocarditis, stroke, and reintervention since surgery to the end of follow-up.

**STATISTICAL ANALYSIS.** Data were analyzed by descriptive statistics, with categorical variables presented as absolute values and frequencies and continuous variables presented as means (SD) and median (interquartile range [IQR]). Testing for normal distribution was carried out by Kolmogorov-Smirnov test. Kaplan-Meier survival analyses were conducted to estimate survival probabilities over time as well as the cumulative probabilities of other events, such as endocarditis, stroke, and SVD. A survival curve was generated to illustrate the cumulative proportion of survival across the study period. A $P$ value of $< .05$ was considered statistically significant. Statistical analysis was performed with R statistical software (https://www.R-project.org/), with the survival curves fitted using the survfit package and visualized using the ggsurvplot package.

## RESULTS

**PATIENT CHARACTERISTICS.** All baseline clinical and echocardiographic characteristics of the total study population (N = 498) are shown in Supplemental Table S1. In brief, patients had a mean age of 60.1 ± 10.6 years (median, 61.0 years; IQR, 54.0-67.0 years) and were primarily male (72.1%). Mean European System for Cardiac Operative Risk Estimation II (EuroSCORE II) was 3.9% ± 6.5% (median, 1.9%; IQR, 1.0%-3.7%), and 53.8% were classified as New York Heart Association class III/IV. History of chronic kidney disease (CKD) stage ≥3 was documented in 15.5% of patients, 1.8% of whom were on chronic dialysis. A total of 9.5% of patients had previous cardiac surgery. Preoperative mean aortic valve pressure gradients were 47.3 ± 18.7 mm Hg (median, 49.0 mm Hg; IQR, 38.0-60.0 mm Hg).

**PROCEDURAL DETAILS.** All procedural details are reported in Supplemental Table S2. Briefly, most patients (91.8%) were operated on with full sternotomy. Isolated aortic valve replacement was performed in 222 (44.6%) patients. The median cardiopulmonary bypass time was 103 minutes, and the median aortic cross-clamping time was 76 minutes. The median diameter of the implanted valve was 23 mm. Valve size distribution is reported in Supplemental Figure S2. One case (0.2%) of intraoperative mortality was reported.

**IN-HOSPITAL AND DISCHARGE OUTCOMES.** In-hospital complications and discharge data are reported in Supplemental Table S3. In brief, the most common perioperative complications were new-onset atrial fibrillation (19.1%), transient conduction disturbances (6.6%), and pneumonia (3.0%). The mean duration of hospital stay from implantation to discharge was 12.5 ± 10 days (median, 10 days), with a median of 22 hours spent in the intensive care unit. Prolonged mechanical ventilation (>3 days) was required in 25 (5.0%) patients.

Discharge echocardiographic data reported peak and mean aortic valve pressure gradients of 21.9 ± 8.0 mm Hg (median, 20.0 mm Hg) and 11.8 ± 4.8 mm Hg (median, 11.0 mm Hg), respectively. Moderate or severe prosthesis-patient mismatch was documented in 5 (1.0%) patients. Five (1.0%) patients received a permanent pacemaker. Nine patients (1.8%) died during hospitalization for the index procedure or within 30 days from discharge.

**PRIMARY END POINT: SVD.** The mean duration of follow-up was 4.7 ± 1.1 years (median, 4.8 years; IQR, 4.3-5.2 years), including 2322.6 patient-

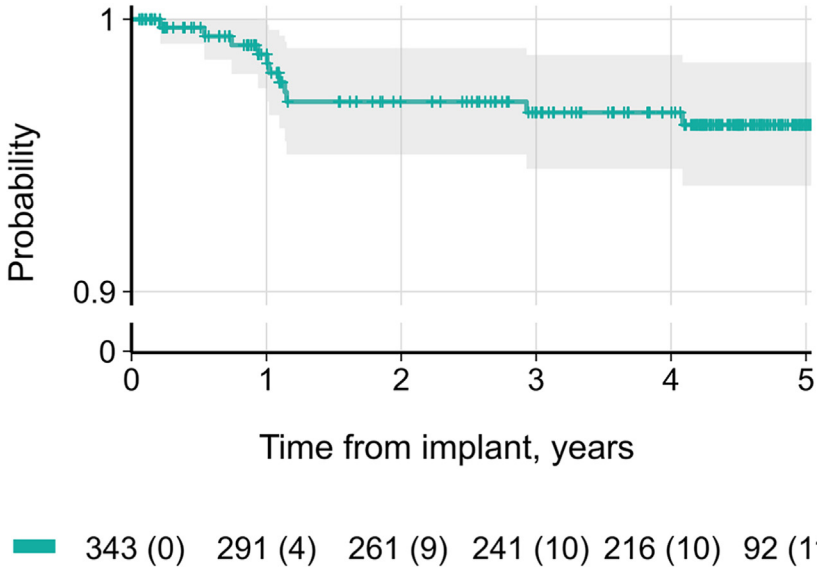


**FIGURE 1** Kaplan–Meier freedom from structural valve deterioration stage 1.

years. Freedom from SVD at 1 year, 3 years, and 5 years, respectively, was as follows: 98.6%, 96.2%, and 95.7% for stage 1; 99.7%, 99.7%, and 98.6% for stage 2; and 100.0%, 100.0%, and 99.3% for stage 3 (Figures 1-3; Table). Four cases of SVD stage 2 were caused by moderate-severe intraprosthetic stenosis (n = 1 preoperative endocarditis with no relapse), whereas in 1 more case the cause was mixed disease (moderate stenosis and moderate regurgitation). The rates of intraprosthetic regurgitation are shown in Figure 4. Furthermore, mean gradients were also reported according to valve size categories (small, 19 mm and 21 mm; medium, 23 mm and 25 mm; large, 27 mm and 29 mm), showing progressively lower mean gradients moving from small to medium to large prosthetic sizes (Supplemental Figure S3).

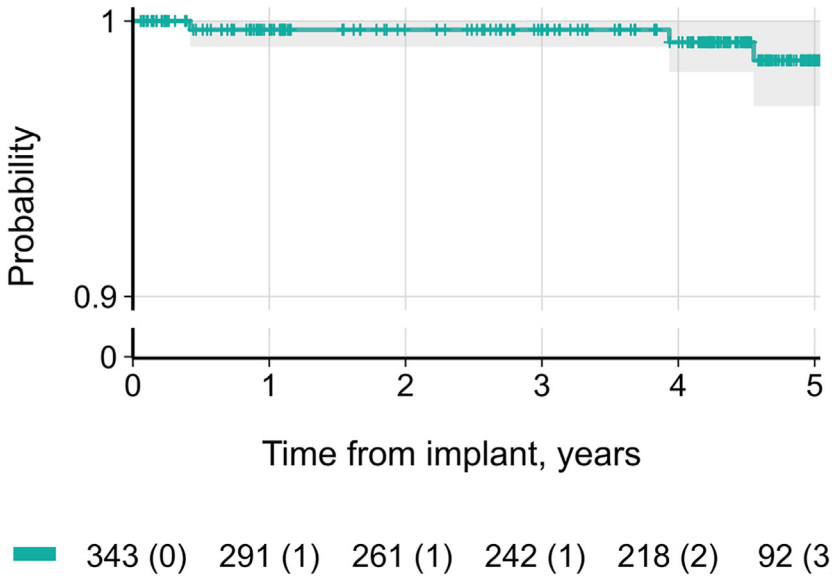


**FIGURE 2** Kaplan–Meier freedom from structural valve deterioration stage 2.

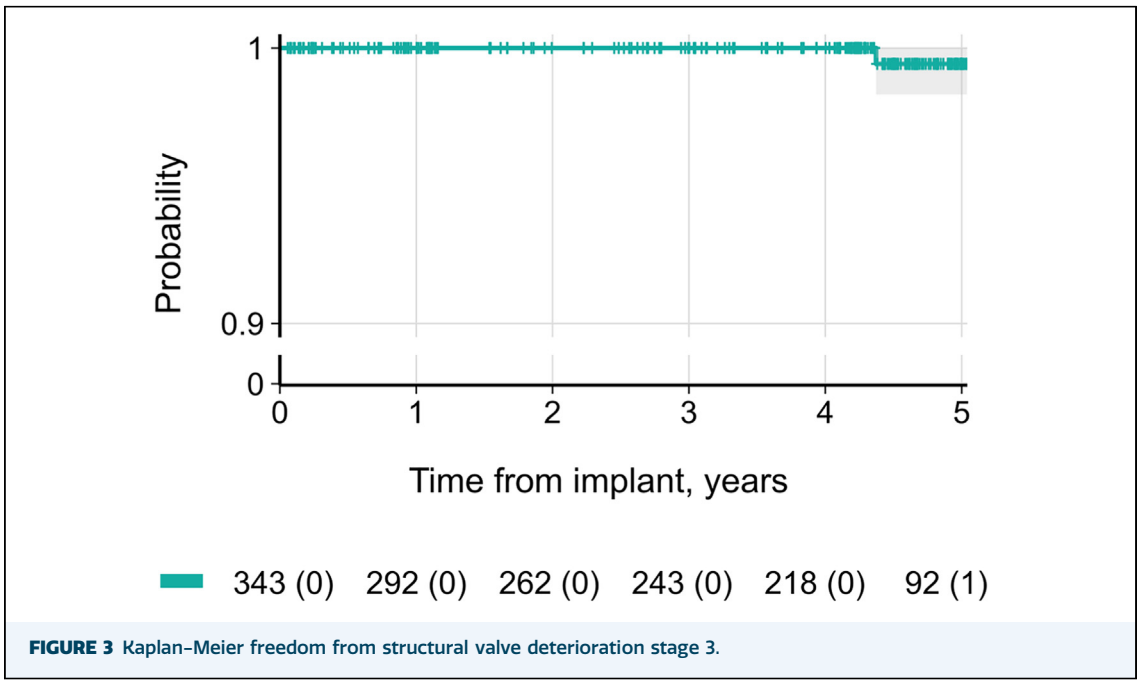


**FIGURE 3** Kaplan–Meier freedom from structural valve deterioration stage 3.

**SECONDARY END POINTS: SAFETY OUTCOMES AND VALVE PERFORMANCE.** The estimated survival rates at 1 year, 3 years, and 5 years were 97.0%, 95.0%, and 93.2%, respectively; and freedom from cardiovascular mortality was 97.6%, 97.2%, and 97.2%, respectively (Figure 5; Table). Kaplan-Meier estimates for freedom from endocarditis (Supplemental Figure S4) and stroke (Supplemental Figure S5) at 1 year, 3 years,

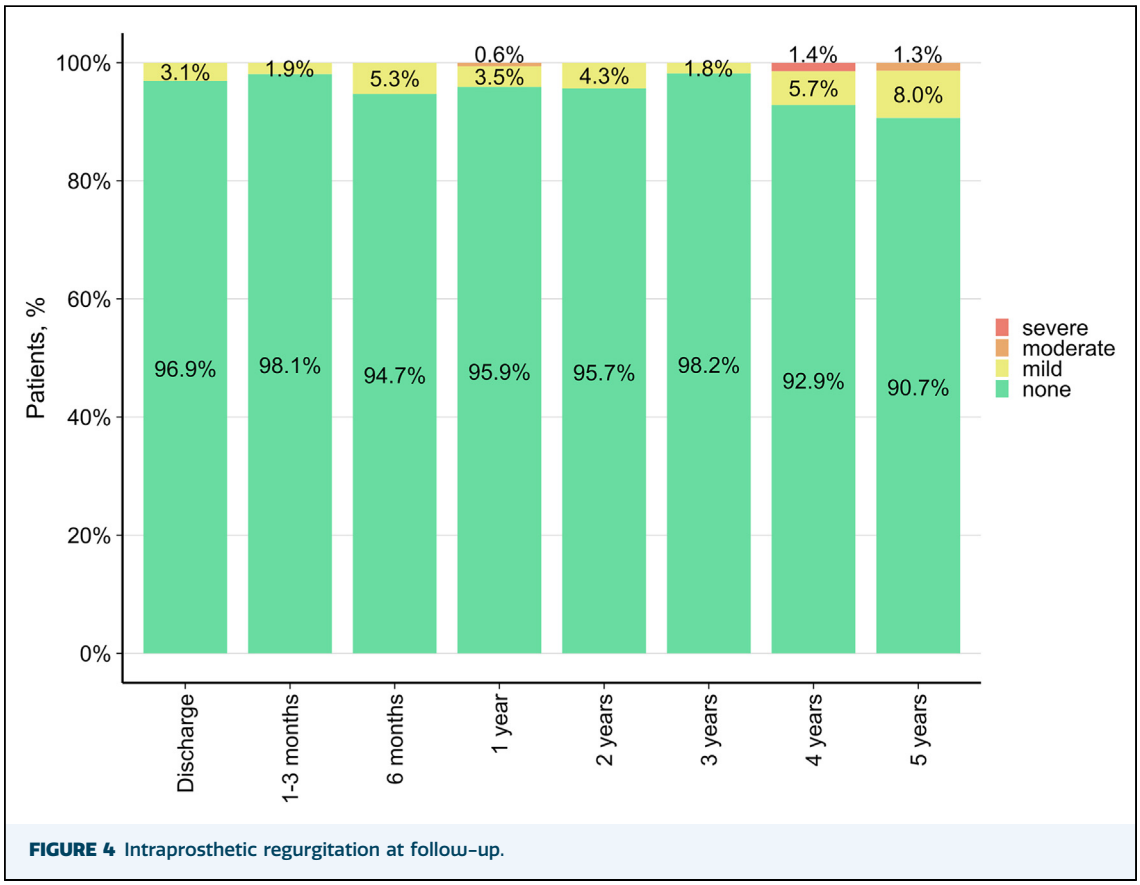


**FIGURE 4** Intraprosthetic regurgitation at follow-up.

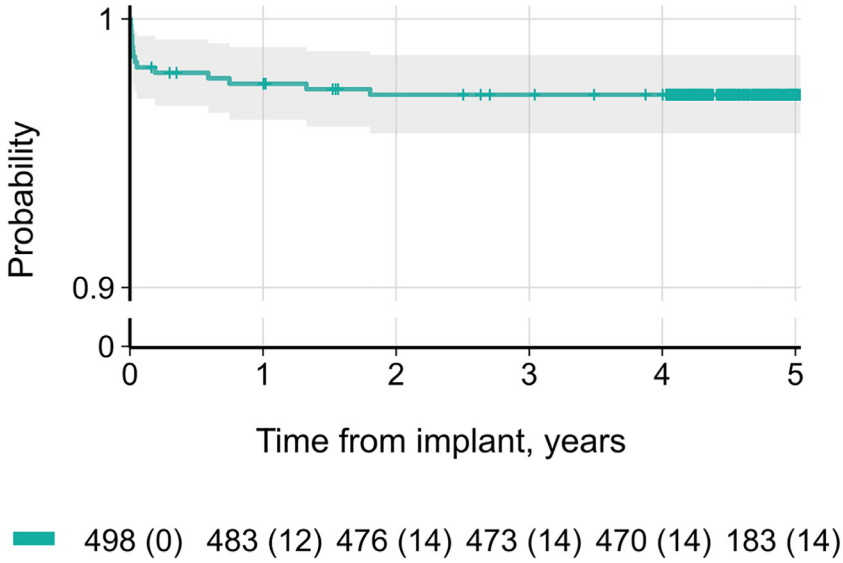


**FIGURE 5** Kaplan-Meier freedom from cardiovascular mortality.

and 5 years were 99.2%, 98.8%, and 98.1% and 99.6%, 99.4%, and 98.6%, respectively. Freedom from non-SVD was 97.6% at 1 year and 96.8% at both 3 and 5 years. Reintervention was reported in a total of 7 patients up to 5 years (98.2% freedom from event) due to endocarditis (n = 5) and SVD (n = 2). The event-free probability from moderate-severe paravalvular leakage (PVL) was 98.6% at 1 year and 3 years and 97.3% at 5 years. In 3 of 6 PVL cases, preoperative endocarditis was present. Stable mean aortic valve pressure gradient was observed from discharge (median, 11.0 mm Hg) to 5 years (median, 12.0 mm Hg; Figure 6).

## COMMENT

This analysis demonstrates satisfactory valve hemodynamics and safety outcomes at 5 years after SAVR with use of the IR bioprosthetic valve in a real-world setting. In particular, the key finding of this study was that a population of young patients (mean age, 60.1 years) from a multicenter real-

**TABLE Safety End Points at 1 Year, 3 Years, and 5 Years**

| End Point | 1 Year, N | 3 Years, N | 5 Years, N | Cumulative at 5 Years, N (%/valve-years[a]) | Freedom From Event, % (95% CI) | | |
|---|---|---|---|---|---|---|---|
| | | | | | 1 Year | 3 Years | 5 Years |
| SVD (VARC-3) | | | | | | | |
| Stage 1 | 9 | 2 | 0 | 11 (0.5) | 98.6 (97.2-100.0) | 96.2 (93.9-98.5) | 95.7 (93.2-98.2) |
| Stage 2 | 1 | 1 | 3 | 5 (0.2) | 99.7 (99.1-100.0) | 99.7 (99.1-100.0) | 98.6 (96.9-100.0) |
| Stage 2S | 1 | 1 | 2 | 4 (0.2) | | | |
| Stage 2R | 0 | 0 | 0 | 0 (0.0) | 100.0 | 100.0 | 100.0 |
| Stage 2RS | 0 | 0 | 1 | 1 (0.0) | 100.0 | 100.0 | 99.5 (98.5-100.0) |
| Stage 3 | 0 | 0 | 2 | 2 (0.1) | 100.0 | 100.0 | 99.3 (98.0-100.0) |
| All-cause mortality | 15 | 10 | 6 | 31 (1.3) | 97.0 (95.5-98.5) | 95.0 (93.1-96.9) | 93.2 (90.9-95.7) |
| Cardiovascular mortality | 12 | 2 | 0 | 14 (0.6) | 97.6 (96.2-98.9) | 97.2 (95.7-98.6) | 97.2 (95.7-98.6) |
| Stroke | 2 | 1 | 2 | 5 (0.2) | 99.6 (99.0-100.0) | 99.4 (98.7-100.0) | 98.6 (97.4-100.0) |
| Prosthetic valve endocarditis | 4 | 2 | 2 | 8 (0.3) | 99.2 (98.4-100.0) | 98.8 (97.8-99.8) | 98.1 (96.8-99.5) |
| Prosthetic reintervention | 3 | 1 | 3 | 7 (0.3) | 99.4 (98.7-100.0) | 99.2 (98.4-100.0) | 98.2 (96.9-99.6) |
| Non-SVD | 9 | 1 | 1 | 11 (0.5) | 97.6 (95.8-99.4) | 96.8 (94.7-98.9) | 96.8 (94.7-98.9) |
| PVL (moderate-severe) | 4 | 1 | 1 | 6 (0.3) | 98.6 (97.2-100.0) | 98.6 (97.2-100.0) | 97.3 (95.1-99.6) |

[a]Total valve-years: 2322.6 years. PVL, paravalvular leakage; SVD, structural valve deterioration; VARC-3, Valve Academic Research Consortium 3.

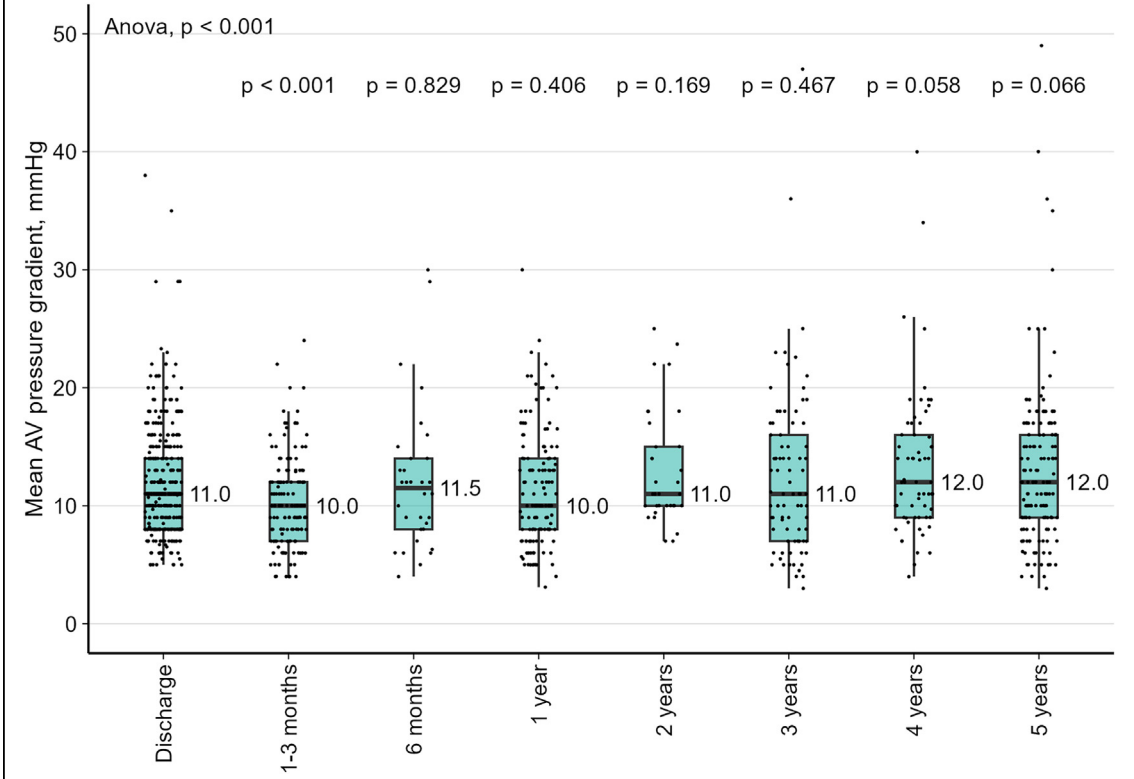


**FIGURE 6** Mean aortic valve (AV) gradient at follow-up. *P* values refer to the comparison against discharge. (Anova, analysis of variance.)

world registry showed high (99.3%) 5-year actuarial freedom from severe SVD (stage 3) together with a high (96.8%) 5-year freedom from non-SVD (with low rate of moderate-severe PVL, given the 97.3% 5-year freedom from moderate-severe PVL), thus accounting for a low rate of reintervention on the aortic valve (98.2% freedom from reintervention at 5 years).

Our results confirm the reported 5-year safety outcomes for RESILIA tissue observed in the COMMENCE trial,[17] in which Bavaria and colleagues reported 89.2% freedom from all-cause mortality at 5 years; freedom from SVD was 100%. Although their results are in accordance with our findings, the population of patients in the COMMENCE trial was older (mean age, 66.9 years), and the trial had important inclusion and exclusion criteria; this study included relatively young patients with a more severe preoperative risk profile, as in any real-world setting (eg, patients with advanced stages of CKD, decompensated diabetes mellitus, and morbid obesity anticipating prosthesis-patient mismatch, all well-known factors associated with a higher risk of SVD). Of note, patients with advanced stages of CKD and those requiring surgery for endocarditis as the primary indication, root surgery, or a redo procedure are typically excluded from trials such as COMMENCE. Furthermore, the definition of SVD in the COMMENCE trial was initially based on the detection of dysfunction or deterioration involving the valve operated on (exclusive of infection or thrombosis), as determined by reoperation, autopsy, or clinical investigation,[17] which differs from the most up to date VARC-3 definition. However, the COMMENCE investigators also recently reported SVD rates according to VARC-3, confirming a low rate of stage $\geq$2 also compared with other contemporary valves.[19] Another safety trial has reported a variable rate of SVD for a different bioprosthesis type in older patients (mean age, 70.2 $\pm$ 9.0 years) at 5-year follow-up, and the investigators questioned the current definitions of SVD purely based on echocardiographic data, suggesting a risk of underestimating or overestimating the phenomenon.[20,21] Nevertheless, our study is mainly based on serial echocardiographic assessments and provides granular information on SVD rates. In the future, perhaps more accurate

results could be reported if clinical symptoms or ventricular remodeling parameters consequent to high gradients would also be incorporated in definitions of SVD.

Furthermore, IR has been launched on the market as a potential long-lasting bioprosthesis, promising better results compared with previous bioprosthetic platforms. Despite that we did not have a direct comparison with other valves, we detected only 1 patient showing SVD stage 3 at 5 years (1.4%). So far, similar durability results with the IR valve were reported in other single-arm registries, mainly in young patients, but with a much shorter follow-up.[22] Of note, Thorp and coworkers[23] reported an overall SVD rate of any grade of 28.7% at 9 years, which is as high as >20% at 5 years, for the Perimount Magna Ease (PME) valve, although the SVD definition in that study was purely based on echocardiographic low cutoff values, possibly leading to an overestimation of SVD rates.[24] In fact, that is likely the case, as other authors reported an SVD rate ranging from only 1.3% to 3.1% at 5 years for PME.[25-27] To date, the only available direct comparisons between IR and PME belong to propensity score-matched studies; 1 study showed comparable mean gradients across the valves, limited to 3 years of follow-up,[28] whereas the other study found a significantly higher mean gradient in PME after 2 years,[29] thus collectively suggesting a potential advantage of a lower SVD rate with the IR valves.

Whereas a younger age at implantation is probably the strongest risk factor for subsequent SVD because of the high likelihood for long-term survival, the rates of SVD in our cohort were favorably low, offering promise for continued durability in this population of patients. In this light, our data—coming from a population with a mean age of 60 years—might be helpful also in clinical decision-making, given that European guidelines recommend bioprostheses for patients older than 65 years, whereas US guidelines are more permissive, allowing bioprostheses also in the age range of 50 to 65 years.[4-6] Although it has previously been demonstrated that the risk of SVD significantly increases beyond 5 years,[30] the 5-year time point is still considered to represent a meaningful milestone by which contemporary valves begin to fail, especially in younger patients and others at risk.[19] It is well known, for example, that the Trifecta valve showed early degeneration with a cumulative incidence of severe SVD of 2.1% at 5 years in the overall population, which increases to 4.2% in patients younger than 65 years; these data further increase to 13.3% and 27.9% in the overall population and in patients <65 years of age, respectively, at 7 years.[31] Another study clearly highlighted how Trifecta valves tended to be replaced at a mean of 4.5 years after index surgery, further underscoring the importance of continued surveillance at 5 years for newly developed valves or tissues.[32] Another pathology study demonstrated a mean time to severe SVD of 10 ± 5 years for the Hancock II bioprosthesis in the aortic position, further underscoring that a significant number of patients may already have severe SVD at 5 years.[33] In contrast, the only available data on RESILIA tissue at 7 years comes from the COMMENCE trial, showing a 99.3% freedom from SVD.[16] We reported a 1.3% "moderate" intraprosthetic regurgitation (which proved to be almost always a central regurgitant jet in large valve sizes) at 5 years, without echocardiographic evidence for intrinsic changes to the involved valve prostheses, thus not fulfilling the current definition of SVD. Certainly, our extended follow-up might contribute further to this knowledge in the future. The relatively young age of our population deserves long-term surveillance on the risk for prosthetic endocarditis, being to date extremely low, given the long-term exposure to several endocarditis-related risk factors.

**LIMITATIONS.** Several limitations need to be acknowledged. This is a single-arm study with no comparative groups, which limits the judgment against other valves and tissues. In addition, the study reports midterm outcomes, and it is generally accepted by cardiac surgeons that SVD rates are often expected to increase after 5 years and further after 10 years. Therefore, it is mandatory to understand whether these findings are maintained beyond 5 years and reach the 10-year follow-up for conclusive data. Nevertheless, these limitations are largely unavoidable in real-world circumstances within the given timeline, and the data presented here offer encouraging results for patients with aortic stenosis requiring valve replacement who choose to opt for biologic solutions with modern prostheses. Finally, no subanalysis has been done in patients receiving an IR valve in a redo aortic valve scenario, given the limited number of redo cases (n = 37) and the case mix of this subset of patients.

**CONCLUSION.** This study in a real-world setting of a relatively young population undergoing SAVR with the IR valve confirms data from the COMMENCE trial showing a favorable safety and durability profile, stable hemodynamic performances, and a low rate of SVD at 5 years of follow-up.

The authors wish to thank Violetta Hachaturyan and Nataliya Trushina from IPPMed GmbH, Cloppenburg, Germany; Dr Vincenzo Grimaudo, Cecile Amanatiou, ARC, and Marie Lebosse, ARC, Département de Chirurgie Cardiaque, CHU Timone, Marseille, France.

## FUNDING SOURCES

The study was supported by an Institutional Grant from Edwards Lifesciences (SURG-122-292). Francesco Onorati reports financial support was provided by Edwards Lifesciences Corporation.

## DISCLOSURES

Francesco Onorati reports a relationship with Edwards Lifesciences Corporation that includes: consulting or advisory and funding grants; and received speaker fees from Abbott Italy. Alexis Theron reports a relationship with Edwards Lifesciences Corporation and Medtronic that includes: consulting or advisory and funding grants; and with Edwards Lifesciences Corporation that includes: consulting or advisory and funding grants. Thierry Folliguet reports a relationship with Edwards Lifesciences Corporation that includes: consulting or advisory and funding grants. Gianluca Lucchese reports a relationship with Edwards Lifesciences Corporation and Bard/BD that includes: consulting or advisory and funding grants. Patrick Klein reports a relationship with Edwards Lifesciences Corporation and Medtronic that includes: consulting or advisory and funding grants. Davide Pacini reports a relationship with Artivion, Terumo Aortic, Peters, and Corcym that includes: consulting or advisory and funding grants; and received speaker fees from Corcym. Martin Grabenwöger reports a relationship with Artivion that includes: consulting or advisory and funding grants. All other authors have no conflicts of interest to declare.

## REFERENCES

**1.** Singh JP, Evans JC, Levy D, et al. Prevalence and clinical determinants of mitral, tricuspid, and aortic regurgitation (the Framingham Heart Study). *Am J Cardiol*. 1999;83:897–902.

**2.** Iung B, Vahanian A. Epidemiology of valvular heart disease in the adult. *Nat Rev Cardiol*. 2011;8:162–172.

**3.** Spadaccio C, Alkhamees K, Al-Attar N. Recent advances in aortic valve replacement. *F1000Res*. 2019;8:F1000 Faculty Rev-1159.

**4.** Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J*. 2022;43:561–632.

**5.** Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2017;135:e1159–e1195.

**6.** Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2021;77:e25–e197.

**7.** Meuris B, Roussel JC, Borger MA, et al. Durability of bioprosthetic aortic valve replacement in patients under the age of 60 years—1-year follow-up from the prospective INDURE registry. *Interdiscip Cardiovasc Thorac Surg*. 2023;37:ivad115.

**8.** Stocco F, Fabozzo A, Bagozzi L, et al. Biological versus mechanical aortic valve replacement in non-elderly patients: a single-centre analysis of clinical outcomes and quality of life. *Interact Cardiovasc Thorac Surg*. 2020;32:515–521.

**9.** Balmforth D, Dimagli A, Benedetto U, Uppal R. Fifty years of the pericardial valve: long-term results in the aortic position. *J Cardiac Surg*. 2021;36:2865–2875.

**10.** Johnston DR, Griffith BP, Puskas JD, Bavaria JE, Svensson LG; COMMENCE Trial Investigators. Intermediate-term outcomes of aortic valve replacement using a bioprosthesis with a novel tissue. *J Thorac Cardiovasc Surg*. 2021;162:1478–1485.

**11.** 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;59:434–441.

**12.** Sadowski J, Bartuś K, Kapelak B, Chung A, Stąpor M, Bochenek M. Aortic valve replacement with a novel anti-calcification technology platform. *Kardiol Pol*. 2015;73:317–322.

**13.** Puskas JD, Bavaria JE, Svensson LG, et al. The COMMENCE trial: 2-year outcomes with an aortic bioprosthesis with RESILIA tissue. *Eur J Cardiothorac Surg*. 2017;52:432–439.

**14.** Flameng W, Hermans H, Verbeken E, Meuris B. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg*. 2015;149:340–345.

**15.** Sadri V, Trusty PM, Madukauwa-David ID, Yoganathan AP. Long-term durability of a new surgical aortic valve: a 1 billion cycle in vitro study. *JTCVS Open*. 2022;9:59–69.

**16.** Beaver T, Bavaria JE, Griffith B, et al. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. *J Thorac Cardiovasc Surg*. 2024;168:781–791.

**17.** Bavaria JE, Griffith B, Heimansohn DA, et al. Five-year outcomes of the COMMENCE trial investigating aortic valve replacement with RESILIA tissue. *Ann Thorac Surg*. 2023;115:1429–1436.

**18.** Généreux P, Piazza N, Alu MC, et al. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. *J Am Coll Cardiol*. 2021;77:2717–2746.

**19.** Bartus K, Bavaria JE, Thourani VH, Xu K, Keuffel EL. Structural hemodynamic valve deterioration durability of RESILIA-tissue versus contemporary aortic bioprostheses. *J Comp Eff Res*. 2023;12:e220180.

**20.** Velders BJ, Vriesendorp MD, Asch FM, et al. Current definitions of hemodynamic structural valve deterioration after bioprosthetic aortic valve replacement lack consistency. *JTCVS Open*. 2024;19:68–90.

**21.** Klautz RJ, Dagenais F, Reardon MJ, et al. Surgical aortic valve replacement with a stented pericardial bioprosthesis: 5-year outcomes. *Eur J Cardiothorac Surg*. 2022;62:ezac374.

**22.** Sef D, Thet MS, Klokocovnik T, Luthra S. Early and mid-term outcomes after aortic valve replacement using a novel tissue bioprosthesis: a systematic review. *Eur J Cardiothorac Surg*. 2024;65:ezae045.

**23.** Thorp SD, Khazaal J, Yu G, Parker JL, Timek TA. Magna ease bioprosthetic aortic valve: mid-term haemodynamic outcomes in 1126 patients. *Interact Cardiovasc Thorac Surg*. 2021;32:839–845.

**24.** Anselmi A, Aymami M, Tomasi J, et al. Late clinical and echocardiographic results with the Magna Ease pericardial aortic bioprosthesis. *Eur J Cardiothorac Surg*. 2024;65:ezad351.

**25.** Francica A, Benvegnu L, San Biagio L, et al. Ten-year clinical and echocardiographic follow-up of third-generation biological prostheses in the aortic position. *J Thorac Cardiovasc Surg*. 2024;167:1705–1713.e8.

**26.** Kermen S, Strella J, Aupart A, et al. Durability of a bovine pericardial aortic bioprosthesis based on Valve Academic Research Consortium-3 echocardiographic criteria. *JTCVS Open*. 2022;11:72–80.

**27.** Mayr B, Burri M, Vitanova K, et al. Serial echocardiographic evaluation of the Perimount Magna Ease prosthesis. *J Thorac Dis*. 2021;13:4104–4113.

**28.** Francica A, Tonelli F, Rossetti C, et al. Perimount MAGNA Ease vs. INSPIRIS Resilia valve: a PS-Matched analysis of the hemodynamic performances in patients below 70 years of age. *J Clin Med*. 2023;12:2077.

**29.** Bernard J, Georges G, Hecht S, et al. Mid-term clinical and echocardiographic results of the INSPIRIS RESILIA aortic valve: a retrospective comparison to the Magna Ease. *Interdiscip Cardiovasc Thorac Surg*. 2023;37:ivad117.

**30.** Johnston DR, Soltesz EG, Vakil N, et al. Long-term durability of bioprosthetic aortic valves: implications from 12,569 implants. *Ann Thorac Surg*. 2015;99:1239-1247.

**31.** Fukuhara S, Shiomi S, Yang B, et al. Early structural valve degeneration of Trifecta bioprosthesis. *Ann Thorac Surg*. 2020;109:720-727.

**32.** Abbas AE, Madanat L, Khalili H, et al. Aortic regurgitation, time to aortic valve reintervention, and mortality in degenerated Trifecta versus non-Trifecta bioprosthesis. *Am J Cardiol*. 2024;220:49-55.

**33.** Butany J, Leong SW, Cunningham KS, Cruz GD, Cramichael K, Yau TM. A 10-year comparison of explanted Hancock-II and Carpentier-Edwards supraannular bioprostheses. *Cardiovasc Pathol*. 2007;16:4-13.