

# 8-year outcomes of aortic valve replacement with the Carpentier-Edwards PERIMOUNT Magna Ease valve

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## Abstract

**Introduction** The Carpentier-Edwards PERIMOUNT Magna Ease valve is a third-generation bioprosthesis for aortic valve replacement (AVR). This is a postapproval study reporting on its 8-year outcomes. **Methods** Adults undergoing AVR with the Magna Ease valve between October 2007 and December 2012 were enrolled for this prospective, nonrandomized, single-arm, multicenter study. Assessments occurred preoperatively, at hospital discharge, 6 months, 1 year, and annually thereafter up to 8 years. Outcomes included safety endpoints, hemodynamic performance, and New York Heart Association (NYHA) Functional Class. **Results** Of the 258 study patients, 67.5% were in NYHA Class I or II, and 32.5% were in NYHA Class III or IV at baseline. Concomitant procedures were performed in 44.2%. Total follow-up was 1,597.6 patient-years, median follow-up was 7 years (interquartile range: 5.5–8.0 years). Eight years following AVR, functional class remained improved from baseline with 93.9% in NYHA Class I/II and 6.1% in NYHA Class III; thirty-eight deaths had occurred, eight of which were valve related; freedom from all-cause mortality was 80.7% (95% confidence intervals 74.9, 86.4); freedom from valve-related mortality was 95.8% (92.8, 98.8); freedom from reintervention, explant, major bleeding events, and structural valve deterioration were 89.8% (85.1, 94.6), 94.8% (91.7, 97.9), 85.1% (80.0, 90.1), and 90.1% (84.7, 95.4), respectively; effective orifice area was  $1.5 \pm 0.5$  cm<sup>2</sup>, mean gradient was  $14.8 \pm 8.3$  mmHg, and 88.6% of patients had no or trivial aortic regurgitation. **Conclusions** This study demonstrated satisfactory safety and sustained hemodynamic and functional improvements at 8 years following AVR with the Magna Ease valve.

## Title

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## Authors

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## Data availability statement

All relevant site-specific data are maintained at the participating centers, and the relevant aggregated data are maintained at Edwards Lifesciences (Irvine, CA, USA). The data will not be made available to other researchers or organizations.

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## Conflict of interest disclosure

ST: financial support from British Standards Institute and 3R Life Sciences. MR: shareholder in Edwards Lifesciences. JA: honoraria for meetings from Edwards Lifesciences; owns stock in Kardium Inc. JS: no disclosures. AH: consulting fees from Edwards Lifesciences. JZ: financial support from Edwards Lifesciences, Medtronic, CryoLife Inc, Ethicon, Cambridge Medical Robotics, and LSI Solutions®. GS: no disclosures. GC: consulting fees from Edwards Lifesciences. MM: no disclosures. RL: financial support from Medtronic; owns stock in Highlife.

## Institutional Review Board approval or waiver

All study sites obtained Institutional Review Board approvals:

- \* UBC-Providence Health Care Research Institute, Vancouver, BC, #H11-00994, 06/24/11
- \* Providence Health and Services IRB, Portland, OR, #10-063B, 07/28/10
- \* Sunnybrook Health Sciences Centre REB, Toronto, ON, #382-2007, 02/21/08
- \* Dignity Health IRB, Sacramento, CA, #033588, 11/17/11

- \* Atlantic Health IRB, Morristown, NJ, #R09-12-004 (455058), 01/07/10
- \* The Cooper Health System IRB, Camden, NJ, #09-190EX, 02/05/10
- \* Mountain Star St. Mark's Hospital IRB, Salt Lake City, UT, #0221, 01/21/10
- \* MHH Ethics Committee 30623 Hannover, Germany, #5083, 08/22/08
- \* NHS National Research Ethics Committee, Papworth, Cambridge, UK, #08/H0304/34, 05/30/08
- \* NHS National Research Ethics Committee, Blackpool, Lancashire, UK, #08/H0304/34, 07/23/08
- \* Ethics Committee of the University Hospital Puerta de Hierro, Madrid, Spain, #892, 02/26/08
- \* Ethics Committee of the Faculty of Medicine of the Technical University of Munich, Munich, Germany, #1913/07, 12/04/07
- \* Ethics Committee of the Medical University Innsbruck A-6020, Innsbruck, Austria, #EK 1 25.09.07, 01/29/08
- \* Western IRB, Olympia, WA, (University of Arizona, Tucson, AZ), #20110574

### **Patient consent statement**

All study participants provided informed written consent.

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Not applicable.

### **Clinical Trial Registration**

ClinicalTrials.gov NCT01171625.

## **Structured abstract**

### **Introduction**

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### **Methods**

Adults undergoing AVR with the Magna Ease valve between October 2007 and December 2012 were enrolled for this prospective, nonrandomized, single-arm, multicenter study. Assessments occurred preoperatively, at hospital discharge, 6 months, 1 year, and annually thereafter up to 8 years. Outcomes included safety endpoints, hemodynamic performance, and New York Heart Association (NYHA) Functional Class.

### **Results**

Of the 258 study patients, 67.5% were in NYHA Class I or II, and 32.5% were in NYHA Class III or IV at baseline. Concomitant procedures were performed in 44.2%. Total follow-up was 1,597.6 patient-years, median follow-up was 7 years (interquartile range: 5.5–8.0 years). Eight years following AVR, functional class remained improved from baseline with 93.9% in NYHA Class I/II and 6.1% in NYHA Class III; thirty-eight deaths had occurred, eight of which were valve related; freedom from all-cause mortality was 80.7% (95% confidence intervals 74.9, 86.4); freedom from valve-related mortality was 95.8% (92.8, 98.8); freedom from reintervention, explant, major bleeding events, and structural valve deterioration were 89.8% (85.1, 94.6),

94.8% (91.7, 97.9), 85.1% (80.0, 90.1), and 90.1% (84.7, 95.4), respectively; effective orifice area was  $1.5 \pm 0.5$  cm<sup>2</sup>, mean gradient was  $14.8 \pm 8.3$  mmHg, and 88.6% of patients had no or trivial aortic regurgitation.

## Conclusions

This study demonstrated satisfactory safety and sustained hemodynamic and functional improvements at 8 years following AVR with the Magna Ease valve.

## Keywords

Aortic valve replacement; aortic stenosis; bioprosthetic valve; bioprosthesis

## Abbreviations

AVR: aortic valve replacement CEC: Clinical Events Committee CI: confidence interval EOA: effective orifice area NSVD: nonstructural valve dysfunction NYHA: New York Heart Association SVD: structural valve deterioration

## INTRODUCTION

Stenosis and regurgitation are common conditions affecting the aortic valve.[1] When severe and symptomatic, aortic valve replacement (AVR) is the guideline-recommended treatment.[2, 3] Over the last two decades, the proportion of AVR undertaken with bioprostheses has increased, substituting for mechanical valve prostheses.[4]

The effectiveness and durability of the Carpentier-Edwards PERIMOUNT valve (Edwards Lifesciences, Irvine, CA, USA), a stented bovine pericardial bioprosthesis, have been well described.[5-8] The Carpentier-Edwards PERIMOUNT Magna Ease aortic valve (model 3300TFX; Edwards Lifesciences) is an evolution of the original PERIMOUNT valve. The reduced profile was designed to facilitate supra-annular placement. It also incorporates a scalloped sewing ring to improve conformity with the native aortic leaflet attachment line. The Magna Ease valve was approved by the United States (US) Food and Drug Administration (FDA) in 2009. In a single-center study, it demonstrated excellent mid-term survival and good hemodynamics, but additional durability data are required.[11] This study was conducted to satisfy conditional FDA approval, evaluating the 8-year safety and effectiveness of the Magna Ease valve in patients undergoing AVR with or without concomitant procedures.

## METHODS

### Study design

This study was a prospective, nonrandomized, single-arm, postapproval, multicenter, 8-year study of the Magna Ease valve (ClinicalTrials.gov NCT01171625). The FDA required data from at least 101 patients over 8 years. The study protocol projected that at least 225 patients would need to be enrolled at the beginning to achieve the required number at 8-year follow-up and the study was terminated when this number was reached. The study protocol complied with ISO 14155:2011; European Medical Device Directive 2007/47/EC; and MedDev 2.12-1, 2.7.4, and 2.12.2. The ICH E6 GCP Good Clinical Practices was also used for guidance.

## Study cohort

Patients were enrolled between October 2007 and December 2012 at 14 investigational sites in Europe, Canada, and the US (Figure 1). Patients undergoing surgical replacement of their native or prosthetic aortic valve at participating centers were invited to participate. The inclusion criteria for this study were: requirement for a replacement aortic valve, as indicated in the preoperative evaluation; average or better operative risk; geographically stable and agreeable to attend follow-up assessments at the hospital of surgical services for at least 8 years; 18 years or older; signed and dated the subject informed consent form prior to surgery. The study's exclusion criteria were: any known non-cardiac life-threatening disease, which will limit the patient's life expectancy below 1 year; active endocarditis within the last 3 months; abnormal calcium metabolism (e.g., chronic renal failure, hyperparathyroidism); aneurismal aortic degenerative condition (e.g., cystic medial necrosis, Marfan's syndrome); pregnant or lactating; intravenous drug abuse; current prison inmate; current participant in a study of an investigational drug or device; requirement for replacement of a native or prosthetic mitral, tricuspid, or pulmonic valve; requirement for repair of the mitral or tricuspid valve with the use of an annuloplasty device; previous enrolment in the study; prior mitral, tricuspid, or pulmonic valve surgery, which included implantation of a bioprosthetic valve, mechanical valve, or annuloplasty ring that will remain in situ. The choice of surgical technique was left to surgeon discretion.

## Follow-up and endpoints

After implantation, patients were followed up at hospital discharge, 6 months, 1 year, and annually thereafter up to 8 years. This report includes data through to September 14, 2018 when the minimum requirement of 8-year follow-up for 101 patients had been achieved.

Safety endpoints included death, valve-related death, thromboembolism, hemorrhage, paravalvular leak, prosthetic valve endocarditis, valve thrombosis, hemolysis, structural valve deterioration (SVD), nonstructural valve dysfunction (NSVD), reintervention, and valve explant. All safety endpoints and serious adverse events were defined as per Akins *et al* .[12] and adjudicated by an independent Clinical Events Committee (CEC).

Effectiveness endpoints included the proportion of patients in New York Heart Association (NYHA) Functional Class I or II at 8 years, and hemodynamic performance as assessed by echocardiographic parameters: effective orifice area (EOA), mean gradient, and aortic regurgitation (combined paravalvular and central leak) severity. Hemodynamic data were collected and scored by the individual sites. Collection of these data at years 3 and 7 was not mandated and therefore not reported.

## Data management and statistical analyses

The investigational sites were responsible for accurate collection and recording of the clinical data. Edwards Lifesciences, the study sponsor, monitored and aggregated the clinical data, then analyzed them per the study protocol and statistical analysis plan. Summary statistics include absolute and proportional data for categorical variables and mean  $\pm$  standard deviation for continuous variables. Early safety events were defined as those occurring within 30 days of the index procedure and were reported as the number of patients with an event divided by the number of implanted patients. Late events represented those occurring beyond 30 days postoperatively and through 8 years (postoperative day 2,922). Actuarial Kaplan–Meier analyses were undertaken on each of the safety endpoints and reported with 95% confidence intervals (CI). SAS version 9.4 was used for all statistical analyses.

# RESULTS

## Baseline patient characteristics

A total of 283 patients across 14 investigational sites consented to participate. Of these, 258 patients met the eligibility criteria and received the Magna Ease valve, the outcomes of whom are reported here. Table 1 summarizes patient baseline characteristics. The average age was 68.5±8.8 years, and 167 (64.7%) were male. Aortic stenosis was the commonest indication for AVR (70.9%). Procedural data are summarized in Table 2. Most patients underwent isolated AVR (58.1%), while 41.9% underwent concomitant procedure(s). Implanted valve sizes were: 19 mm 4.3%, 21 mm 15.9%, 23 mm 38.4%, 25 mm 28.3%, 27 mm 8.9%, and 29 mm 4.3%.

## Patient follow-up

Overall, 258 patients underwent a total follow-up of 1,597.6 patient-years: median 7.0 years (5.5–8.0 years). At study closure, 103 patients (39.9%) had completed the 8-year follow-up and a further 67 patients (26.0%) were on-protocol with the study valve in place.

## Survival

One death (0.4%) occurred within the early postoperative period, and it was not valve related. Thirty-seven deaths occurred late, eight of which were adjudicated to be valve related: two endocarditis, one thromboembolism/stroke, and five other unknown causes. Figure 2 and Table 3 display the freedom from all-cause mortality.

## Safety

Safety endpoint events were experienced by 109 (42.2%) patients and are summarized in Table 3 as early event rates and actuarial freedom from safety endpoints based upon Kaplan–Meier analyses.

Study valve reinterventions were carried out in 18 patients, including 11 explants, six valve-in-valve insertions, and one repair procedure without explant. There were three early reinterventions, all explants that occurred during the index procedure due to complications during surgery not related to the study valve. The reasons for the 15 late reinterventions were endocarditis (n=4), SVD (n=9), NSVD (n=1), and major paravalvular leak (n=1). Freedom from study valve reintervention was 89.8% (95% CI 85.1, 94.6) at 8 years. Freedom from explant was 94.8% (95% CI 91.7, 97.9) at 8 years.

In the early period, 13 major bleeding events were reported in 12 patients and three minor bleeding events were reported in three patients. A further 19 major bleeding events and 14 minor bleeding events were reported in the late period through to 8 years. No bleeding events were adjudicated as study valve related. Six cases of prosthetic valve endocarditis were reported in six patients. Four of these resulted in study valve explant followed by one death, and one further case resulted in death, all of which were adjudicated to be study valve related. The remaining case had high grade lactobacillus bacteremia and was categorized as valve related. This patient proceeded to develop SVD and the study valve was explanted. Freedom from bleeding events was 78.0% (95% CI 72.2, 83.7) at 8 years; freedom from major bleeding events was 85.1% (95% CI 80.0, 90.1) at 8 years.

## Hemodynamics

Figure 3 and Table 4 show the hemodynamic performance for each study valve size; the performance stayed within expected levels over the observational period. Data on aortic regurgitation are shown in Table 5.

## Structural valve deterioration

Of the 14 patients with SVD, three underwent explant, seven had valve-in-valve procedures, and four cases were being monitored at study closure. Freedom from reintervention due to SVD was 93.6% (95% CI 89.3, 97.8) at 8 years.

## Functional outcomes

Figure 4 shows the proportion of patients in each NYHA Functional Class throughout follow-up. At baseline, 67.5% patients were in NYHA Class I/II, and 32.5% patients were in NYHA Class III/IV. By the 1-year follow-up, 98.3% were in Class I/II, with 74.8% patients reporting an improvement in functional class. This improvement persisted up to 8 years for 61.9% patients, with 93.9% of patients in NYHA Class I/II and 6.1% in NYHA Class III.

## DISCUSSION

This is the first prospective evaluation of the Magna Ease bioprosthesis for surgical AVR. These results demonstrate good safety and effectiveness, with functional and hemodynamic outcomes that remain consistent over the 8-year follow-up.

### Survival

Kaplan–Meier analyses showed freedom from all-cause and valve-related mortality at 8 years were 80.7% (95% CI 74.9, 86.4) and 95.8% (95% CI 92.8, 98.8), respectively. A recent retrospective study of AVR with the Magna Ease valve, with a median follow-up of 4.5 years, revealed overall survival at 12 years of 54% (95% CI 47.8, 62), albeit with limited numbers of patients. [13] Another retrospective, single-center study of the Magna Ease valve in 1,126 consecutive patients reported 78.2% survival probability at 9 years.[11] Studies of the Trifecta valve (Abbott Laboratories, IL, US) have shown comparable midterm all-cause and valve-related mortality.[14–16] The Freestyle valve (Medtronic, Dublin, Ireland) showed similar rates of 10-year survival to Magna Ease in a retrospective cohort analysis.[17, 18] In another multivariable retrospective analysis, the Mitroflow valve (LivaNova, London, UK) was associated with a higher risk of mortality compared with the Magna Ease valve at 5 years (hazard ratio 1.57 [95% CI 1.17, 2.11],  $p < 0.01$ ).[19]

### Thromboembolic events, bleeding, and endocarditis

Early and late complications in this study were consistent with others.[5, 14] Freedom from endocarditis, thromboembolism, and major bleeding at 8 years were 97.3% (95% CI 95.1, 99.5), 86.7% (95% CI 81.9, 91.5), and 85.1% (95% CI 80.0, 90.1), respectively. The reported rate of bleeding events does not pose an unexpected or additional risk to patients treated with the Magna Ease valve. Most of the bleeding events had no further clinical consequences, and those observed were typical for older patients following cardiac surgery.

### Hemodynamic performance

Mean gradient remained acceptable at 8 years: 14.8±8.3 mmHg compared with 12.2±5.0 mmHg at 1 year, and was consistent with findings of a recent study.[11] Although one meta-analysis concluded gradients were lower for the Trifecta valve than the Magna and Magna Ease valves at 6 months (mean difference 4.1 mmHg; 95% CI 3.5, 4.7;  $p < 0.0001$ ),[20] a recent large comparative analysis found a concerning decline in Trifecta hemodynamics over 5 years, with an increased rate of explant due to structural deterioration, compared with the original PERIMOUNT valve.[21]

The hemodynamic improvement seen in this study resulted in a sustained improvement in NYHA functional class for nearly two-thirds of patients.

## Valve durability

Freedom from SVD was 99.1% (95% CI 97.9, 100.0) at 5 years and 90.1% (95% CI 84.7, 95.4) at 8 years. The 8-year rate is slightly lower than the 10-year freedom from SVD rates with the Magna Ease valve reported by Bourguignon *et al.* (94.2%) and Forcillo *et al.* (98+/-0.2%), or the 12-year rates from Piperata *et al.* (93%). [5, 13, 22] However, comparing SVD rates from different studies is challenging because of differing SVD definitions and cohort ages. Freedom from SVD with the Trifecta valve was reported to be 98.7% and 93.3% at 5 and 8 years, respectively, [15] although a recent study demonstrated increased risk of valve failure in the Trifecta valve compared with the Magna Ease valve at 48 months. [18]

Freedom from reintervention due to SVD was 99.1% (95% CI 97.9, 100.0) at 5 years and 93.6% (95% CI 89.3, 97.8) at 8 years. Rates reported for the Trifecta valve were 97.3% (95% CI 94.7, 98.6) at 6 years. [14, 23] In a propensity score-matched analysis between the Trifecta valve and the Magna Ease valve, the Trifecta valve cohort had a significantly higher risk of repeat AVR for structural valve failure at 7 years (5.7% *vs* 0%,  $p=0.009$ ). [16] Another propensity score-matched analysis showed a significantly lower freedom from explant for the Trifecta valve compared with the PERIMOUNT valve at 5 years (95.9% *vs* 98.7%,  $p<0.001$ ). [21]

In an effort to reduce SVD and improve durability of bioprosthetic valves, Edwards Lifesciences has developed RESILIA tissue with advanced anticalcification technology, but durability data beyond 5 years with this tissue are still awaited. [24, 25]

## LIMITATIONS

This study has some limitations. While it includes outcomes from 14 centers and used an independent CEC to adjudicate safety events, an echo core lab was not used, potentially introducing variability, as echocardiographic data were collected and evaluated by individual centers. Secondly, this study did not include a comparator study arm to compare these Magna Ease valve outcomes to those of other contemporary valves.

## CONCLUSION

This is the first multicenter, prospective cohort study of the Magna Ease valve, with clinical events committee adjudication of all safety events. The Magna Ease valve demonstrated satisfactory freedom from mortality and valve-related complications requiring reintervention, and sustained improvement in hemodynamics at 8 years. These data support the continued use of this valve, adding to the growing body of evidence that the Magna Ease valve represents a standard of performance against which other surgical valves may be compared. [7, 11]

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Michael Moulton was an employee of University Medical Center, Tucson, AZ at the time of this research and is currently an employee of University of Nebraska Medical Center, Omaha, NE.

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