Abbott

CLINICAL INSIGHTS

EPIC™ MITRAL STENTED TISSUE VALVE WITH LINX™ AC TECHNOLOGY

Reported 15-Year Data: The Epic™ Mitral and the Magna Mitral Ease‡ Platforms[1,2]

Epic Mitral valve delivers excellent durability for patients of different age groups in long-term study.

REVIEW OF LONGEST PUBLISHED DURABILITY DATA

The studies with the longest-known published follow-up for the Biocor™ (Mykén et al. 2009) and Perimount‡ (Bourguignon et al. 2014) mitral valves had initial implants performed in the early 1980s. Both of these studies provide reliable data out to 15 years where approximately 10% or more of the initial patient cohort was available for follow-up. Since the Biocor and Perimount mitral valves are the predecessors of the Epic™ Mitral and Magna Mitral Ease‡ valves, respectively, the long-term clinical outcomes from these two studies provide valuable information regarding the expected durability and performance for the latest generation devices.

EXCELLENT DURABILITY ACROSS AGE GROUPS

Mykén and colleagues reported excellent actuarial freedom from reoperation due to structural valve deterioration (SVD) after 15 years (see Figure 1A)[1].

- 79.3% overall freedom from reoperation due to SVD
- 75.2% freedom from reoperation due to SVD in patients 65 and under

In a separate study by Bourguignon et al., Perimount valve exhibited lower durability figures than those in Myken's groups.[2] Though not directly comparable, there were large differences in the overall actuarial freedom from reoperation due to SVD as well as in patients under 65 (see Figure 1B).*

Bioprostheses have traditionally been used more frequently in older patients, but avoidance of life-long anticoagulation therapy is desirable for many younger patients. Therefore, long-term performance in this younger group remains critical.

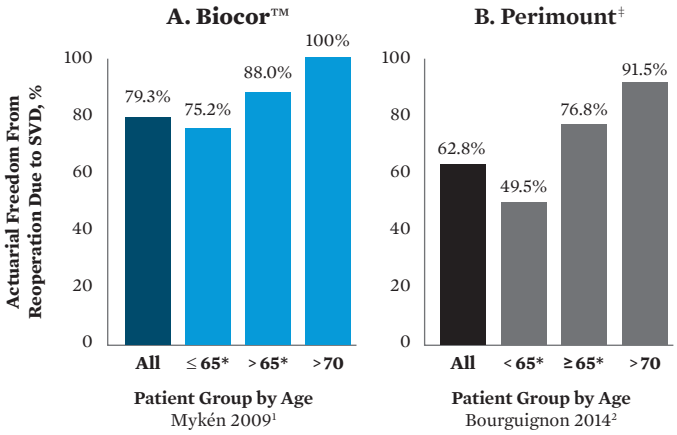

Figure 1. Actuarial freedom from reoperation due to SVD at 15-year follow-up for A) Biocor and B) Perimount valves when used in MVR procedures.

TABLE 1. STUDY OVERVIEW

Publication	Mykén 2009[1†]	Bourguignon 2014[2]
Valve	Biocor™ (porcine)	Perimount‡ (bovine pericardial)
Implant years	1983-2003	1984-2011
MVR patients, n	194	450
Mean age, years	64.9 ± 12.3	68 ± 10.4
Patients at 15-year follow-up, n (%)	23 (11.9)	36 (8.0)
Maximum follow-up, years	20	25
Total follow-up (patient-years)	1,195	3,258

n, number of study participants; MVR, mitral valve replacement

*Mykén et al. include 65-year-old patients in their younger group; Bourguignon and colleagues in their older group.

† Study of structurally-identical Biocor valve in mitral position.

NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

See Important Safety Information within.

ALL VALVES ARE NOT SIZED EQUALLY

The Importance of True-Size Labeling when Individualizing Care

When comparing the hemodynamic performance of various devices, a key consideration is the actual dimensions of a given valve, which may not be the same as the labeled size. In the case of Epic™ Mitral, the tissue annulus diameter is reflected on the product and sizer set. In contrast, the Magna Mitral Ease‡ uses the diameter of the valve stent. As such, Perimount Magna Mitral Ease's small size, "25" requires 28 mm of clearance in the annulus. The ability to properly size the replacement valve is critical in order to maximize hemodynamics and minimize patient-prosthesis mismatch. Epic Mitral's excellent hemodynamic profile across all valve sizes can be especially useful for smaller patients.

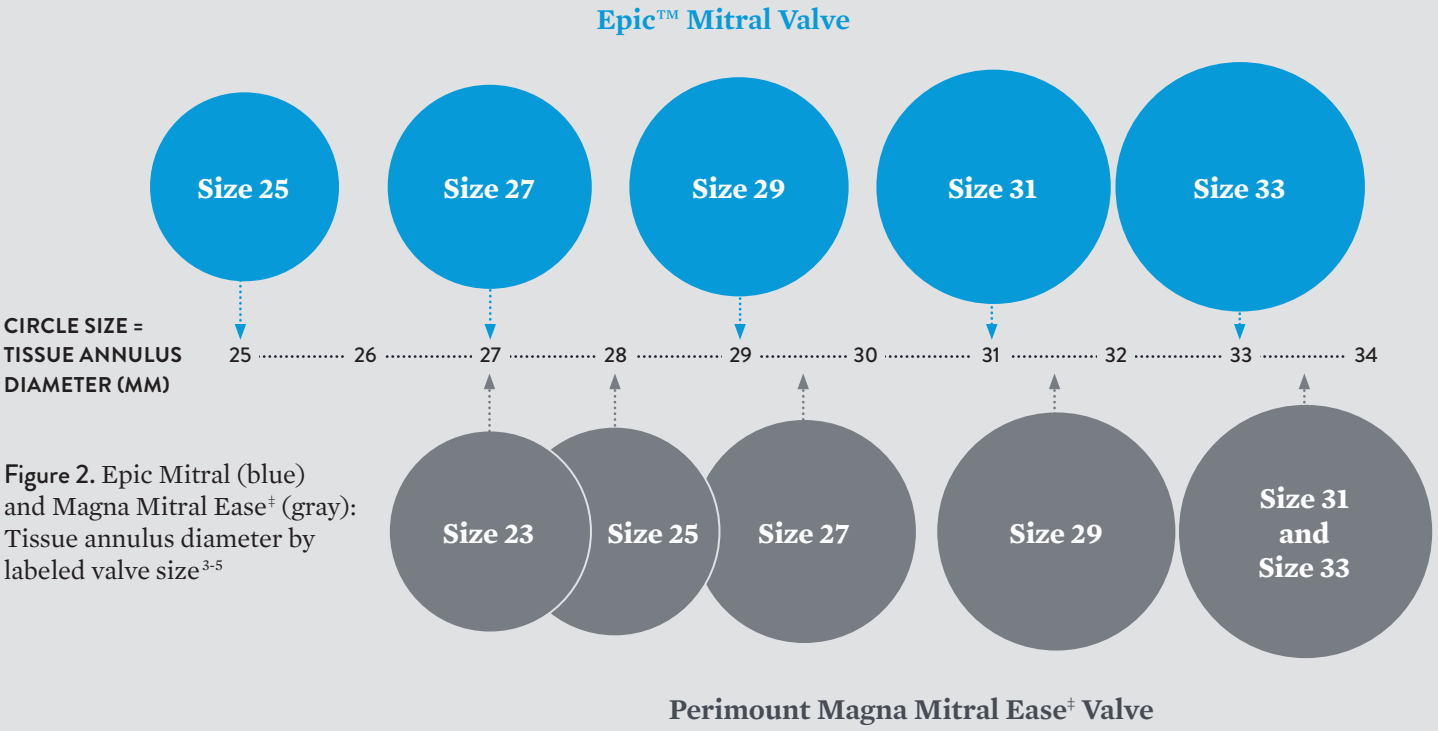

Figure 2. Epic Mitral (blue) and Magna Mitral Ease‡ (gray): Tissue annulus diameter by labeled valve size[3-5]

THE IMPORTANCE OF LEAFLET BEHAVIOR

Epic Mitral's porcine leaflets do not stand tall to form a "curtain" between stent posts resulting in greater neo-left ventricular outflow tract (LVOT) area.[6] Bapat and colleagues however, observed that the pericardial leaflets of other valves that did not crumple in bench testing may have the potential to increase LVOT obstruction in patients undergoing MVR.[7]

MAKING THE BEST CHOICE FOR EACH PATIENT

There are a number of factors to consider when selecting a replacement valve for patients undergoing MVR. However, the need for proper sizing, long-term durability,[1] and excellent hemodynamics are universal.

Mykén and colleagues data confirms the long-term durability of the Epic Mitral platform.[1,8,9]

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℞ ONLY IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE

The Epic valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve. The Epic Supra valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

CONTRAINDICATIONS

None known.

WARNINGS

- Valve size selection is based on the size of the recipient annulus, and for supra-annular aortic placement, the anatomy of the sinotubular space. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the St. Jude Medical™ Bioprosthetic Heart Valve Sizer Set Model B1000 with the Epic and Epic Supra valves.
- Accelerated deterioration due to calcific degeneration of the Epic and Epic Supra valve may occur in:
  - children, adolescents, or young adults;
  - patients with altered calcium metabolism (e.g., patients with hyperparathyroidism or chronic renal failure); or
  - individuals requiring hemodialysis.
- For single use only. Do not reuse or resterilize. Attempts to resterilize the valve may result in valve malfunction, inadequate sterilization, or patient harm.
- Passage of a catheter or transvenous pacing lead through any bioprosthesis may damage the valve and is therefore not recommended.
- Do not use if:
  - the valve has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration;
  - the expiration date has elapsed;
  - the tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging; or
  - the storage solution does not completely cover the valve.

PRECAUTIONS

- The safety and effectiveness of the Epic™ and Epic™ Supra valves has not been established for the following specific populations:
  - patients who are pregnant
  - nursing mothers
  - patients with chronic renal failure
  - patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, Marfan's syndrome)
  - patients with chronic endocarditis
  - patients requiring pulmonic or tricuspid valve replacement
  - children, adolescents, or young adults
- Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, deformed, or damaged sizer set components.
- Do not pass the flanged portion of the valve replica sizing tool through the annulus.
- Do not place the non-sterile exterior of the valve container in the sterile field.
- Do not expose the valve to solutions other than the formaldehyde valve storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline solution used to irrigate the valve.
- Do not add antibiotics to either the formaldehyde valve storage solution or the rinse solution.
- Do not apply antibiotics to the valve.
- Do not allow the valve tissue to dry. Place the valve in sterile isotonic saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- Do not use the valve if shipping temperature indicators on the product carton have turned red, or if the valve has been improperly stored in temperature conditions outside of the 5 °C to 25 °C range.
- Do not implant the valve without thoroughly rinsing as directed.
- Do not lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced.
- Do not attempt to repair a valve. Damaged valves must not be used.
- Do not use cutting edge needles, unprotected forceps, or sharp instruments as they may cause structural damage to valve.
- Never handle the leaflet tissue.
- Position the mitral valve in a manner to avoid commissure obstruction of the left ventricular outflow tract, and minimize any potential of commissure contact with the ventricular wall.
- Position the aortic valve so that the stent posts do not obstruct the coronary ostia.
- Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.

ADVERSE EVENTS

The clinical investigation of the Epic valve supports the safety and effectiveness of the Epic valve and the Epic Supra valve. Between January 2003 and March 2006, seven-hundred and sixty-two (762) subjects were implanted with 791 Epic Valve(s) at 19 investigational sites in the United States (U.S.), and three sites in Canada. Five-hundred and fifty-seven (557) subjects received isolated aortic replacement, 176 received isolated mitral replacement, and 29 received replacement of both the aortic and mitral valves. The cumulative follow-up for all subjects was 773.51 patient-years with a mean follow-up of 1.02 patient-years (s.d. = 0.71 patient-years, range 0 – 3.10 patient-years).

POTENTIAL ADVERSE EVENTS

Adverse events potentially associated with the use of bioprosthesis heart valves (in alphabetical order) include: angina; cardiac arrhythmias; endocarditis; heart failure; hemolysis; hemolytic anemia; hemorrhage, anticoagulant/antiplatelet-related; leak, transvalvular or paravalvular; myocardial infarction; nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other); prosthesis regurgitation; stroke; structural deterioration (calcification, leaflet tear, or other); thromboembolism; valve thrombosis. It is possible that these complications could lead to: reoperation; explantation; permanent disability; death

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