

The St. Jude Medical Biocor™ Bioprosthesis

Clinical Evidence of Long-term Durability

Long-term Biocor Experience
A Review and Comparative Assessment



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Long-term Biocor Stented Tissue Valve Studies

Twenty-year studies from two medical centers were recently published on the St. Jude Medical Biocor™ stented tissue valve.

Acquired Cardiovascular Disease Mykén and Bech-Hansen

A 20-year experience of 1712 patients with the Biocor porcine bioprosthesis

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Objective: The 20-year data from the ongoing long-term study of the St Jude Medical Biocor (St Jude Medical, St Paul, Minn) porcine bioprosthesis are reported. Earlier follow-ups have shown that the valve has excellent durability. After 20 years, will this continue to be true?

Methods: Data were obtained for 1712 patients who underwent valve replacement (1518 aortic valve replacements, 194 mitral valve replacements) with glutaraldehyde-preserved Biocor bioprostheses at Sahlgrenska University Hospital (Sweden) between 1983 and 2003. Follow-up after surgery was evaluated on alternate years using hospital records, interviews, and questionnaires.

Results: At 20 years, the cumulative follow-up was 8843 and 1195 patient-years for aortic valve replacement and mitral valve replacement, respectively. Survival after aortic valve replacement was $17.7\% \pm 3.3\%$, and survival after mitral valve replacement was $16.4\% \pm 4.7\%$. Actuarial freedom from reoperation because of structural valve deterioration was $61.1\% \pm 8.5\%$ and $79.3\% \pm 6.0\%$ after aortic valve replacement and mitral valve replacement, respectively. (The equivalent actual/cumulative values were $85.6\% \pm 2.2\%$ and $91.2\% \pm 2.6\%$, respectively.) In aortic valve recipients aged 65 years or less and more than 65 years, actuarial freedom from reoperation because of structural valve deterioration was $44.5\% \pm 9.2\%$ and $92.1\% \pm 3.9\%$, respectively. The equivalent values in mitral valve recipients were $75.2\% \pm 7.6\%$ and $88.0\% \pm 8.1\%$, respectively.

Conclusion: The 20-year data confirm the excellent valve durability reported at the 17-year follow-up after both aortic valve replacement and mitral valve replacement using the Biocor porcine bioprosthesis.

Close to 40 years after the introduction of bioprosthetic cardiac valves, prosthesis selection remains complex and must take into account each patient's individual needs. The first choice facing a cardiac surgeon is whether to use a mechanical valve—requiring the patient to undergo lifelong anticoagulant therapy with a subsequent risk of bleeding complications—or a bioprosthetic valve, with its potential risk of reoperation within 10 to 15 years because of tissue failure.¹ Patients aged more than 65 years have a relatively low risk of calcification and valve failure, which minimizes the risk of reoperation during their lifetime, and so are increasingly receiving bioprosthetic valves.² Mechanical valves are widely used for patients aged less than 65 years, although long-term anticoagulant use remains a concern.³ This has become enough of an issue in recent years that it is now more common to use bioprostheses in younger patients. It is impossible to predict whether this development will improve patient outcomes.

The choice of prosthesis is both supported, and further complicated, by emerging data from long-term studies of both porcine and pericardial valves.^{2,4} These studies are yielding much-needed information on valve durability, which should be the primary consideration for most patients.^{2,4} Previous publications on the Biocor porcine prosthesis (St Jude Medical, St Paul, Minn) have demonstrated that it performs well and has good durability for up to 17 years after implantation.⁵⁻¹⁰ This article reports outcomes at the 20-year follow-up from an ongoing long-term prospective study.^{5,8}

MATERIALS AND METHODS

The design and methods of this study have been outlined in previous publications.^{5,8}

Patients

This report includes data on consecutive patients who underwent either aortic valve replacement (AVR) (n = 1518) or mitral valve replacement (MVR) (n = 194) at Sahlgrenska University Hospital, Gothenburg, Sweden, between January of 1983 and January of 2003. Informed consent was obtained from each study participant. All patients in this study received a Biocor bioprosthesis preserved in glutaraldehyde at low pressure, some of which had been “Bio-React” treated. The Biocor valve was the only bioprosthesis used at the Sahlgrenska University Hospital during this period of time. Approximately 30% of our patients undergoing cardiac valve replacement received a bioprosthesis and 70% received mechanical valves during the study period. Baseline patient characteristics are shown in Table 1.

Surgical Procedures

Operative procedures, prophylactic antibiotic therapy, and anticoagulation were standardized as described previously.^{5,8} Patients received anticoagulation with warfarin for 3 months from the second day after surgery with

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Twenty-Year Experience With the St. Jude Medical Biocor Bioprosthesis in the Aortic Position

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Background: The purpose of this study was to evaluate the long-term performance of the St. Jude Medical Biocor stented porcine prosthesis in the aortic position.

Methods: From January 1985 to December 1996, 455 patients admitted for aortic valve replacement were consecutively enrolled in this study. The mean age was 72.5 ± 9 years, 18 patients (3.5%) had had previous cardiac surgery, and coronary artery bypass grafting was performed in 171 patients (37.6%). Follow-up was complete in 96.6%; up to 21 years were covered. Actuarial event-free rates are given as mean \pm standard error, and adverse events were classified according to the guidelines for reporting morbidity and mortality after cardiac valvular operations.

Results: Cumulative follow-up time was 3,321 patient-years with a mean follow-up of 8.2 years. The actuarial survival rate after 20 years was $9.4\% \pm 2.8\%$. The actuarial rate for freedom from structural valve deterioration was $49.1\% \pm 1.7\%$ at 10 years, $89.4\% \pm 3.5\%$ at 15 years, and $70.3\% \pm 10.9\%$ at 20 years. The actuarial rates for freedom from reoperation due to structural valve deterioration were $91.9\% \pm 1.6\%$ at 10 years, $90.6\% \pm 2.1\%$ at 15 years, and $86.5\% \pm 4.5\%$ at 20 years.

Conclusions: This study presents one of the largest series of St. Jude Medical Biocor aortic valves in the world. Results indicate an age-dependent risk of structural valve degeneration beginning as soon as 7 years postoperatively for patients below the age of 65 years, but show a low overall incidence of valve-related complications and excellent durability.

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Bioprostheses are prone to continuous degeneration and this may lead to structural valve deterioration (SVD) requiring reoperation [1-3]. Improvements in valve design and conservation methods have extended the lifetime of bioprostheses [4, 5]. Therefore, long-term data concerning valve dysfunction and the risk of reoperation are of particular interest.

The St. Jude Medical (SJM) Biocor valve (St. Jude Medical, Inc, St Paul, MN) is a triple composite porcine bioprosthesis that was first introduced in 1982 in Brazil [5]. The Biocor valve is prepared at low pressure in glutaraldehyde. During a 12-year period, from January 1985 to December 1996, the Biocor prosthesis was implanted in a series of 455 consecutive patients. This study aims to provide 21-year outcome data in patients who received a SJM Biocor bioprosthesis in the aortic position.

Material and Methods

Patients

This study includes data on all 455 patients who received a SJM Biocor bioprosthesis in the aortic position at our center between January 1985 and December 1996. This study was approved by the local Ethics Committee of the Technical University of Munich (number 1546/06). The

need for an individual consent for the study was waived by the Ethics Committee as in this retrospective study individual patients were not identified.

Follow-Up

The follow-up was conducted by questionnaires and telephone contacts with the patients in 2003 and 2006. The questionnaire was designed to answer the questions regarding clinical outcome [6]; telephone contact was made by two persons using standardized questions including a complete patient history. All possible valve-related complications were checked. Additionally, all available medical reports were obtained from the patients' cardiologists or home physicians. Causes of death were determined from hospital records and the governmental registration office. The latest follow-up was accomplished from January 2006 to July 2006.

Valve Selection

Patients older than 65 years received a bioprosthesis. The decision to implant a Biocor was made by the surgeon according to his (her) preferences. All implanted Biocor valves were standard Biocor tissue valves.

Operative Techniques

Operations were performed using standard cardiopulmonary bypass with moderate hypothermia. The valves were secured to the annulus with interrupted pledgeted

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Objectives

- The objectives of these studies were to evaluate the long-term performance of the Biocor stented tissue valve in durability, patient survival and adverse events.
 - The two studies were performed independently of each other and published in different major cardiac surgery journals within four months of each other.
 - Both centers consecutively enrolled patients.
 - Dr. Myken has reported her study results at 10, 15, 17, and now 20 years follow-up.

The Biocor Stented Tissue Valve Study Results: Aortic

Long-Term Biocor Study Results



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Demographics and Valve Size Distribution - Aortic

Age (mean)	72.5±9 years	
Gender	239 male 216 female	
NYHA (preop)	I	0 (0%)
	II	14 (3.0%)
	III	155 (34.0%)
	IV	49 (10.8%)
	unknown	237 (52.0%)
Concomitant Procedures	CABG	171 (37.6%)
	Other	26 (5.7%)
Valve Size	21mm	60 (13.2%)
	23mm	182 (40.0%)
	25mm	160 (35.2%)
	27mm	43 (9.5%)
	29mm	10 (2.2%)

Age (mean)	70.8±10.9 years	
Gender	964 male 554 female	
NYHA (preop)	I	122 (8.0%)
	II	381 (25.0%)
	III	855 (56.0%)
	IV	129 (8.4%)
	unknown	31 (2.0%)
Concomitant Procedures	CABG	632 (42%)
Valve Size*	21mm	113 (7%)
	23mm	623 (41%)
	25mm	489 (32%)
	27mm	219 (14%)
	29mm	57 (4%)
	31mm	13 (<1%)
	33mm	3 (<1%)

Eichinger W, 20-Year experience with the St. Jude Medical Biocor bioprosthesis in the aortic position. Ann Thorac Surg 2008;86 (4) 1204-11

- 455 consecutive patients were admitted for aortic valve replacement and enrolled from January 1985 to December 1996. Valve selection was physician preference. ¹

Myken P, A Twenty-Year experience of 1712 patients with the Biocor porcine bioprosthesis. J Thorac and Cardiovasc Surg 2009;137: 76-81

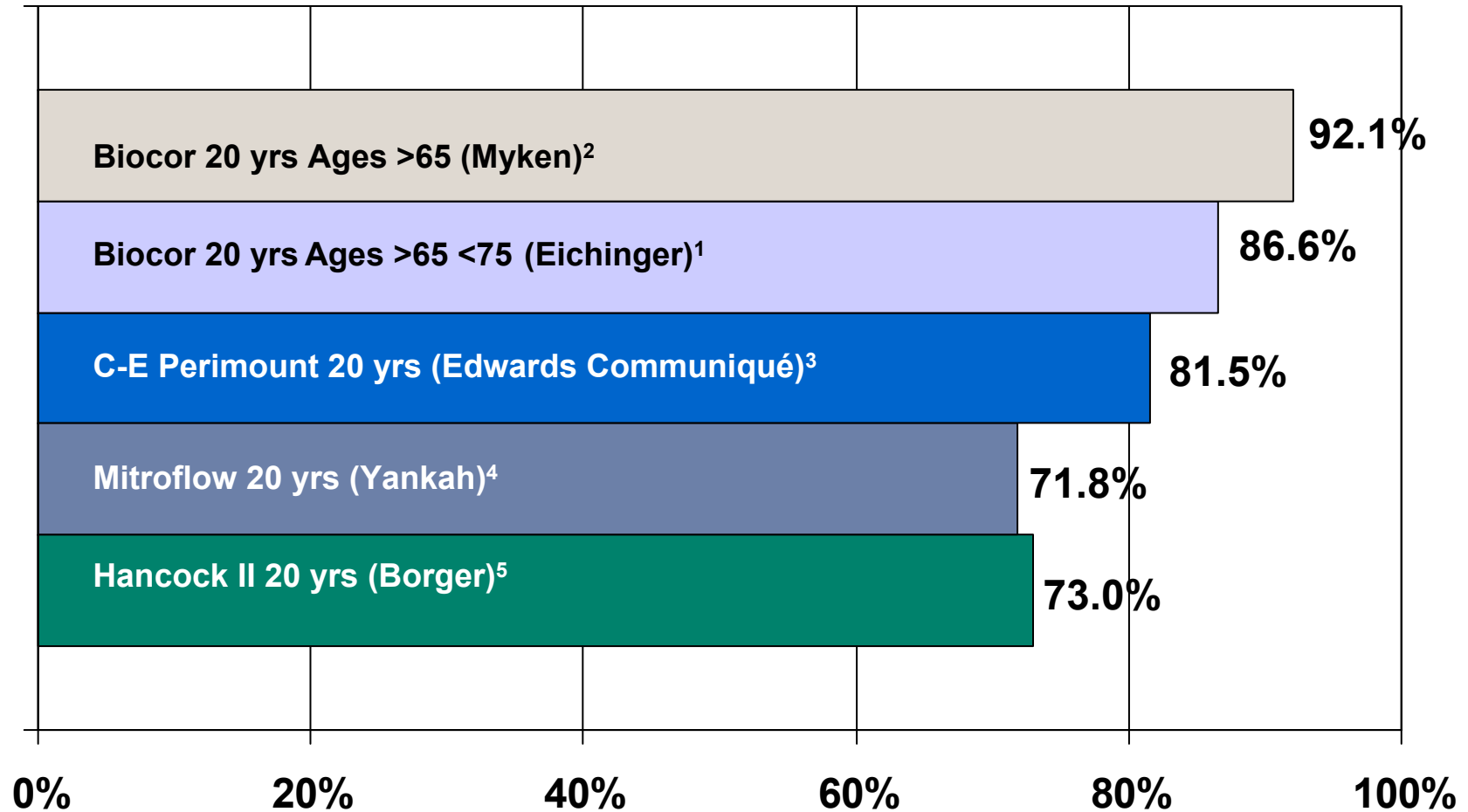
- 1518 consecutive aortic valve replacement patients were enrolled in this study between 1983 and 2003. ²

*Data missing for 1 patient

Results: Long-term Aortic Durability

Actuarial Freedom from Reoperation due to SVD

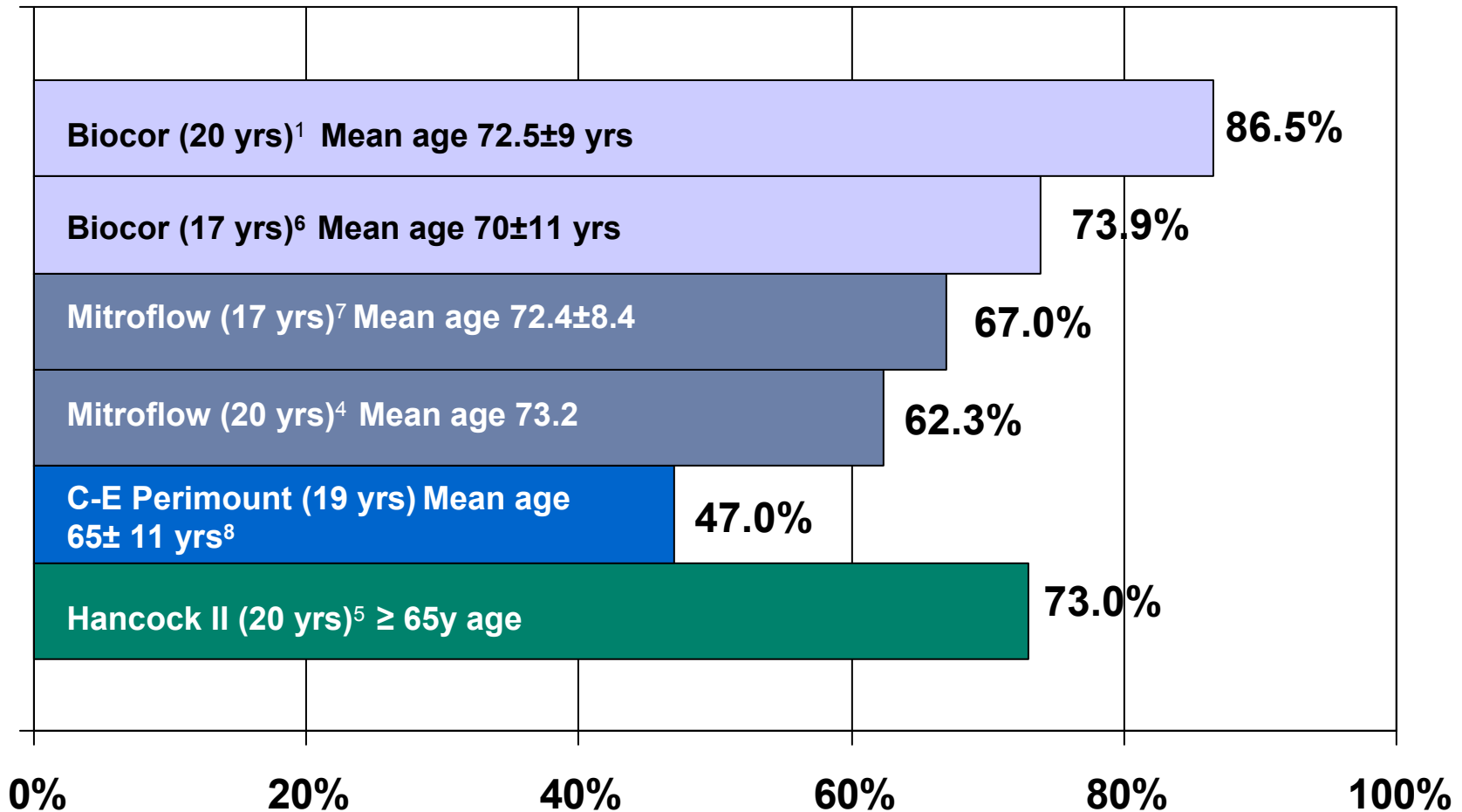
(Ages ≥ 65 unless specified)



Results: Long-term Aortic Durability

Actuarial Freedom from Reoperation due to SVD

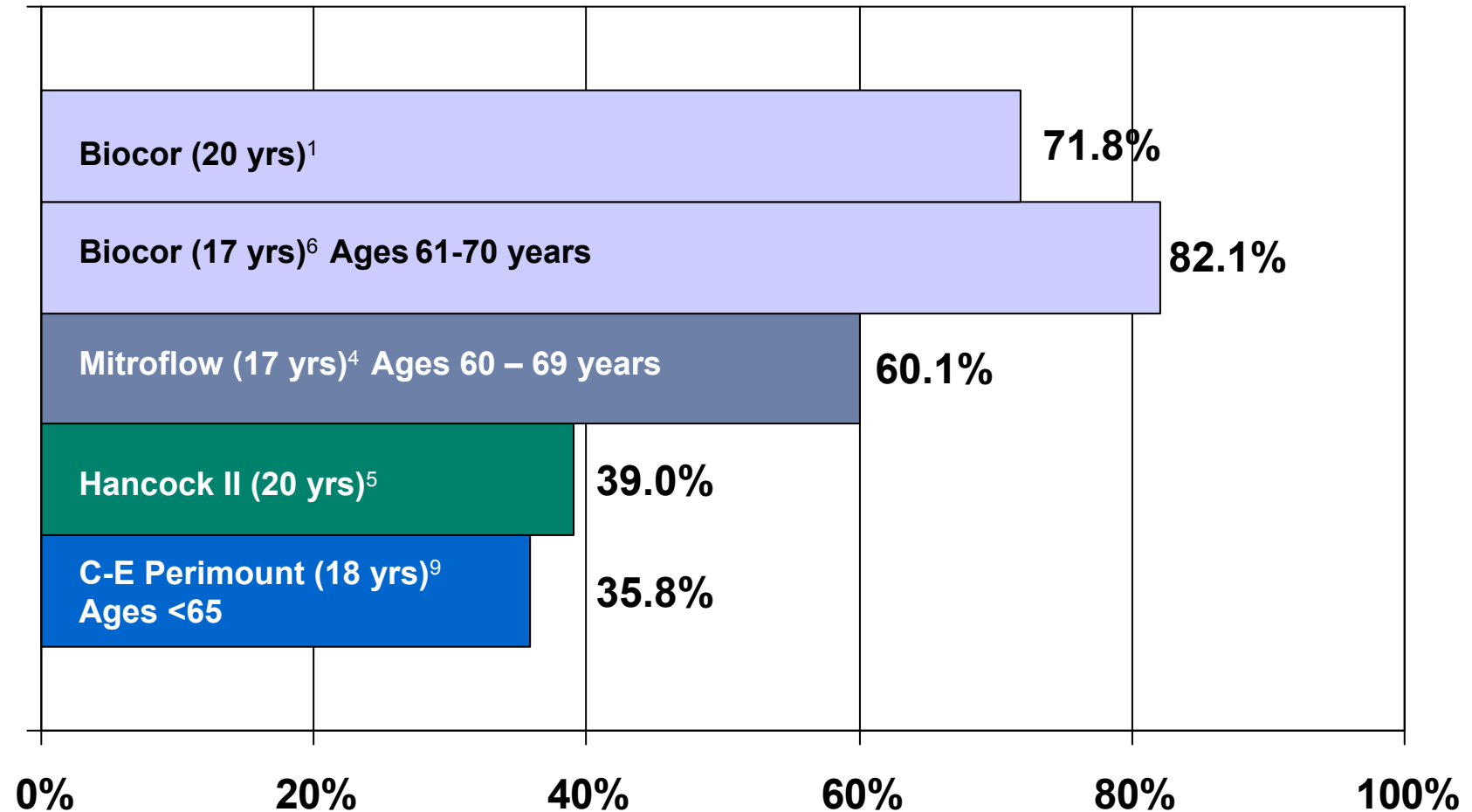
(All ages unless specified)



Results: Long-term Aortic Durability

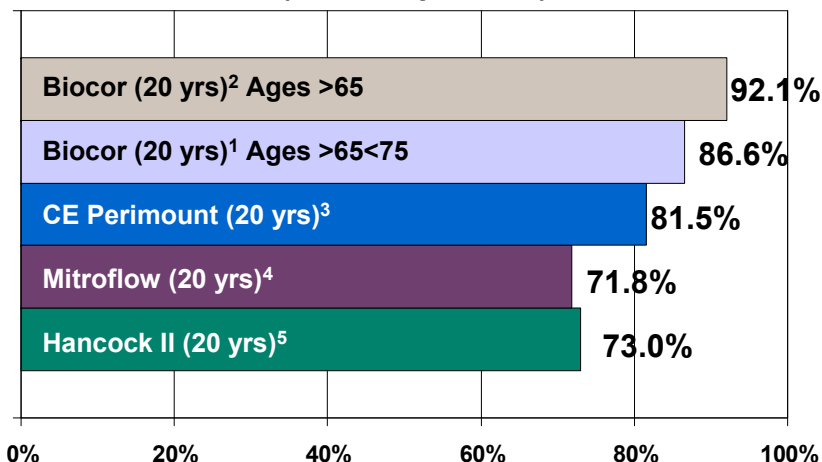
Actuarial Freedom from Reoperation due to SVD

(Ages ≤65 unless otherwise specified)

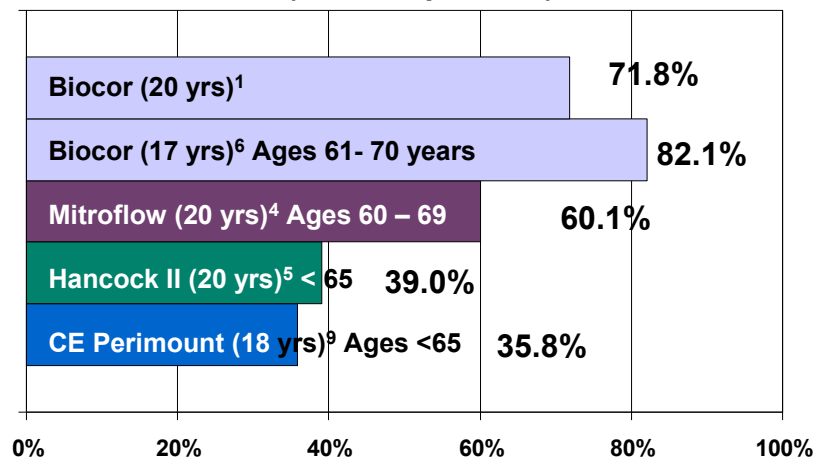


Results: Biocor Aortic Long-term Durability

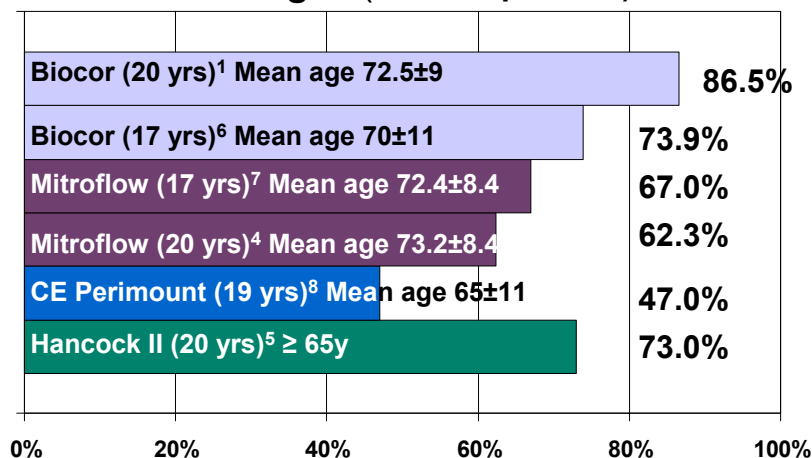
Patients ≥ 65 (unless specified)



Patients ≤ 65 (unless specified)



Patients All Ages (unless specified)



In long-term studies the Biocor aortic valve has demonstrated excellent durability in different patient age groups.

The Biocor Stented Tissue Valve Study Results: Mitral

Biocor Long-term Study Results



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Demographics and Valve Size Distribution - Mitral

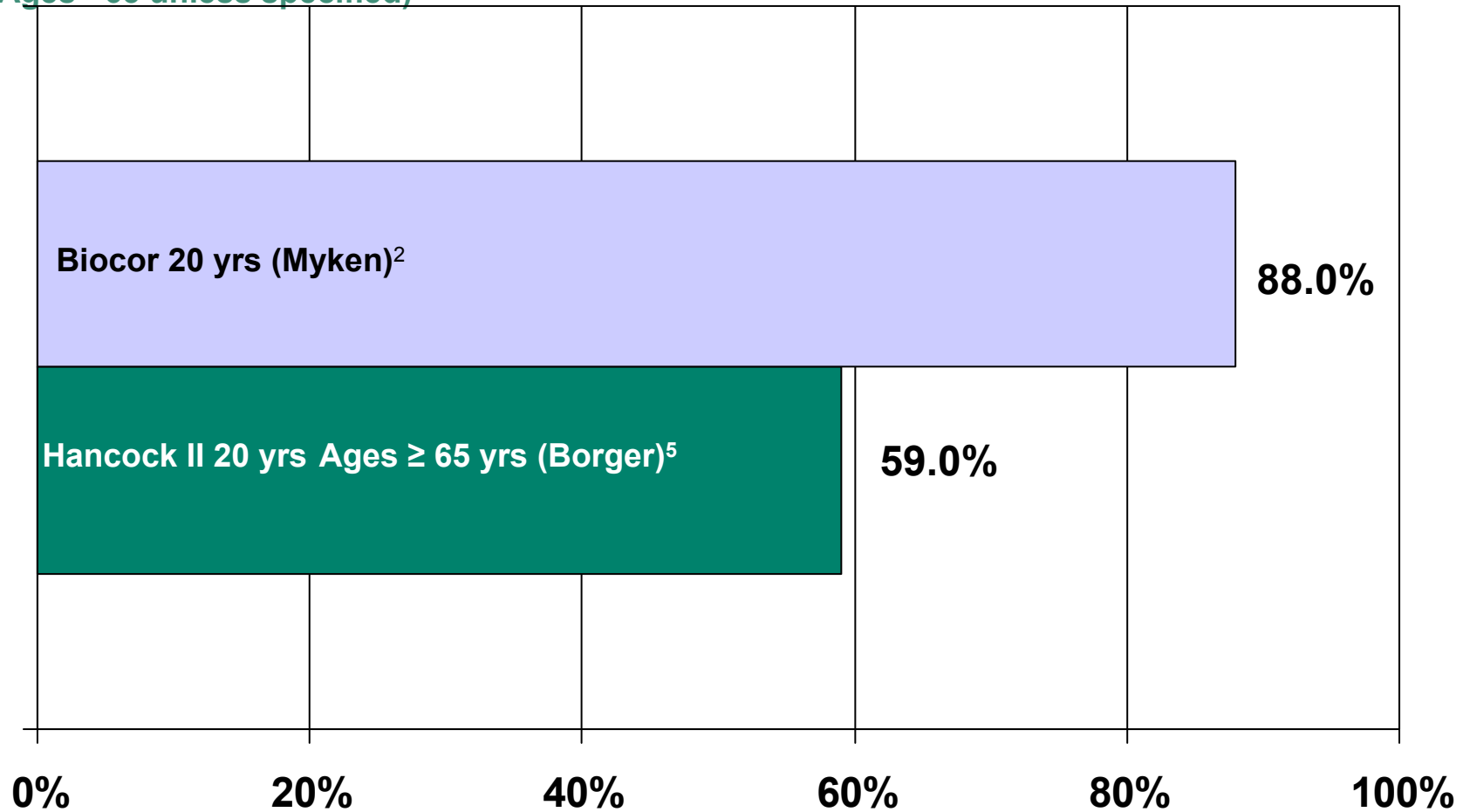
Age (mean)	64.9±12.3 years	
Gender	95 male 99 female	
NYHA (preop)	I	2 (1%)
	II	20 (10%)
	III	128 (65%)
	IV	44 (22%)
	unknown	0
Concomitant Procedure	CABG	65 (34%)
Valve Size	25mm	3 (1%)
	27mm	20 (10%)
	29mm	51 (26%)
	31mm	57 (29%)
	33mm	63 (32%)

- 194 consecutive patients were admitted for mitral valve replacement between 1983 and 2003.²
- The majority of patients were in NYHA class III (65%) preoperatively.
- 34% of the mitral patients also had a CABG procedure.

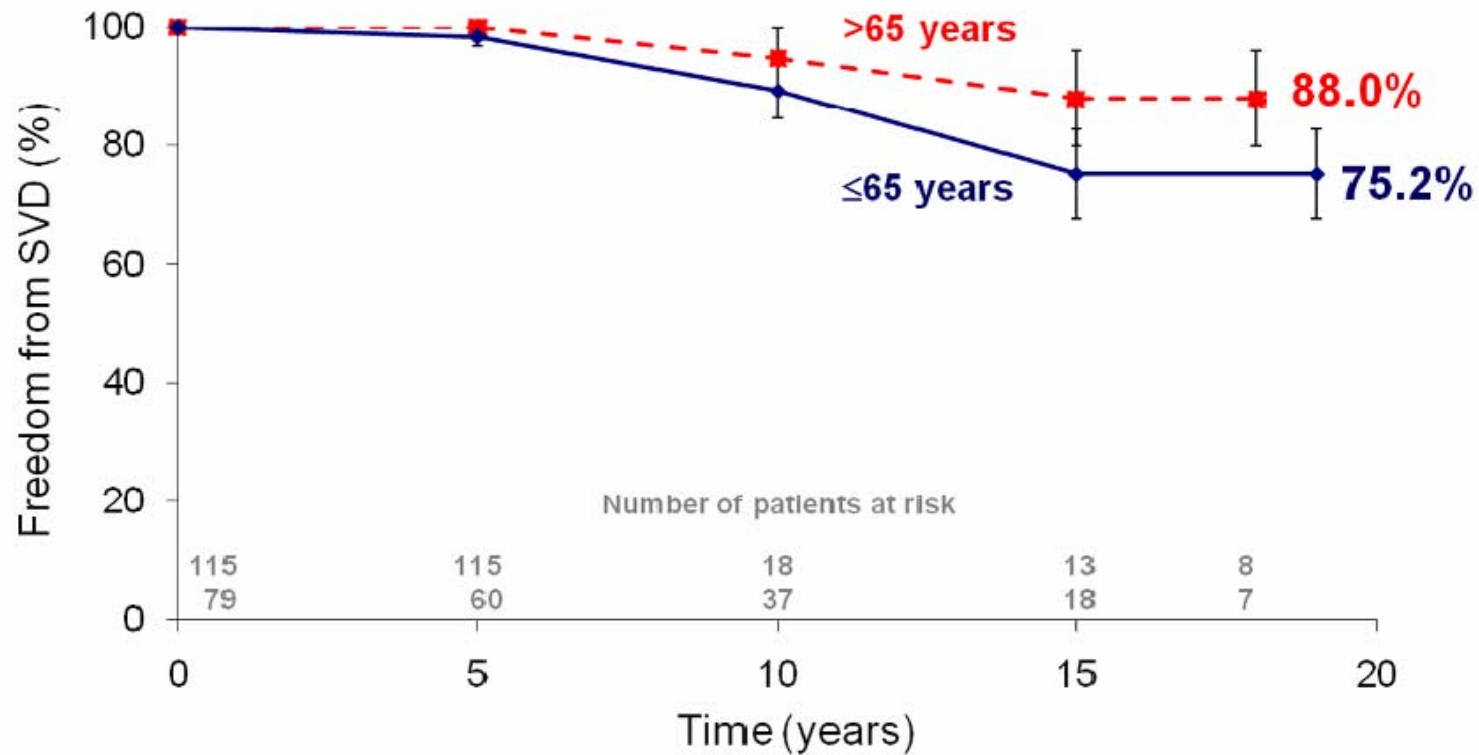
Myken P, A Twenty-Year experience of 1712 patients with the Biocor porcine bioprosthesis. J Thorac and Cardiovasc Surg 2009;137: 76-81

Results: Long-term Durability in the Mitral Position: Actuarial Freedom from Reoperation due to SVD

(Ages >65 unless specified)



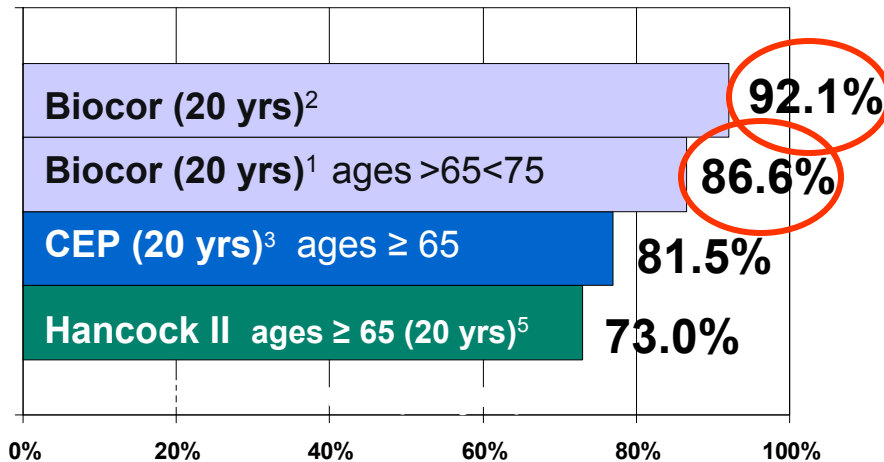
Actuarial freedom from reoperation due to SVD by age group: MVR²



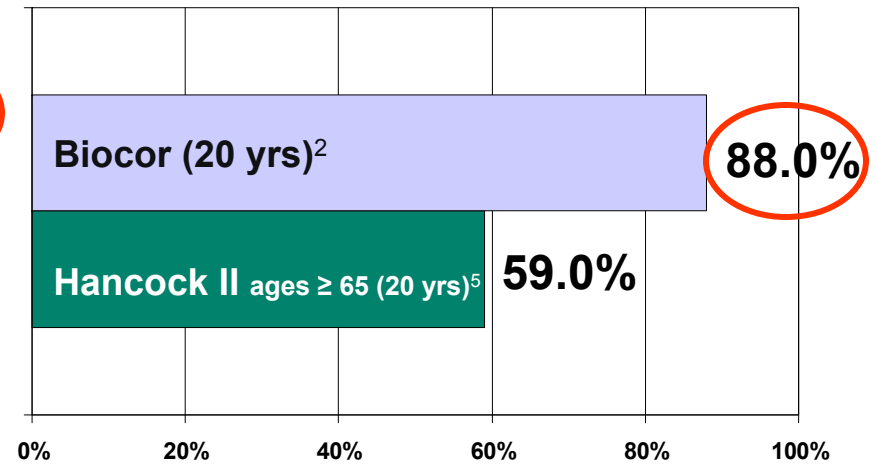
Clinical Evidence

Tissue Valve Leadership: Undeniable Proof Based on Decades of Experience

Long-term Durability in the *Aortic* Position:
Actuarial Freedom from Reoperation due to
SVD (ages >65 unless specified)



Long-term Durability in the *Mitral* Position:
Actuarial Freedom from Reoperation due to
SVD (ages >65 unless specified)



Conclusion

- Long-term durability is the most important parameter when evaluating bioprosthesis, and these results clearly demonstrate the excellent durability of the St. Jude Medical Biocor porcine bioprosthesis over twenty years in both aortic and mitral positions.²
- The long-term durability of the Biocor valve is excellent and confirms the results of other studies on this bioprosthesis. The Biocor porcine stented valve has lower structural valve deterioration and reoperation rates as compared to most other bioprostheses.¹

“These excellent long-term outcomes confirm the results of other Biocor studies with lower SVD and reoperation rates as compared to most other bioprostheses.”

Walter Eichinger, MD



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CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE ONLY BY OR ON THE ORDER OF A PHYSICIAN.

Brief Summary. St. Jude Medical Stented Tissue Valves are indicated for use as a replacement for malfunctioning native or prosthetic aortic and/or mitral valves. Adverse events potentially associated with the use of bioprosthetic heart valves include: angina, cardiac arrhythmia, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage (anticoagulant/anti-platelet-related), leak (transvalvular or paravalvular) myocardial infarction, nonstructural dysfunction (e.g. pannus, suture, inappropriate sizing, or other), prosthesis regurgitation, stroke, structural deterioration (e.g. calcification, leaflet tear, or other), thromboembolism and valve thrombosis. It is possible that these complications could lead to: reoperation, explantation, permanent disability, or death. Long-term anticoagulation and/or anti-platelet therapy should be considered in patients with dilated left atrium, a history of thrombotic events, or a cardiac rhythm of atrial fibrillation or flutter. Please see the Instructions for Use (IFU) for a full description of indications, contraindications, side effects, precautions, warnings, and Instructions for Use.

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