The St. Jude Medical Biocor™ Bioprosthesis
Clinical Evidence of Long-term Durability

Long-term Biocor Experience
A Review and Comparative Assessment
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.

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

Mubin and Beth-Elman

Objective: The 20-year data from ongoing long-term study of the St. Jude Medical Biocor Stentless Valve-20, which provides long-term follow-up, are presented. This unique study shows that the valve has excellent durability. After 20 years, will the valve continue to be used?

Methods: Data were obtained for 1712 patients, who underwent 1937 valve replacements (938 aortic valve replacements, 995 mitral valve replacements, 87 tricuspid valve replacements, and 9 double valve replacements). The study was performed at two medical centers, the University of Illinois at Chicago and Loyola University Medical Center.

Results: Data were analyzed for 20 years for aortic valve replacement, 27 years for mitral valve replacement, and 22 years for tricuspid valve replacement. The primary endpoint was valve-related death, defined as death from any cause within 30 days of surgery or 1 year postoperatively. Valve-related death occurred in 20 patients (1.0%), 23 patients (0.5%), and 22 patients (0.6%) in the aortic, mitral, and tricuspid groups, respectively.

Conclusions: The Biocor valve continues to show excellent valve durability at 20 years after follow-up on both aortic and mitral valve replacement using the Biocor porcine bioprosthesis.

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

Valve B. R. Kilgore, MD, Rea H. M. Kiesbich, MD, Daniel J. Reckles, MD, Eleanor Harper, MD, Caitlin Schaffer, Sabine Blaschitz, MD, and Rodrigo Lara, MD

Department of Cardiovascular Surgery, University of California, San Francisco, San Francisco, California

Background: The purpose of this study was to examine the outcomes of the St. Jude Medical Biocor bioprosthesis in the aortic position.

Methods: From January 1983 to December 2003, 1,148 patients underwent valve replacement using the Biocor prosthesis in the aortic position. The study population included four medical centers: the University of California, San Francisco, the University of Illinois, Loyola University, and the Cleveland Clinic.

Results: There were 1,148 patients who underwent valve replacement using the Biocor prosthesis in the aortic position. The hospital mortality rate was 2.3%. At 5 years, 10 years, and 15 years, the estimated freedom from reoperation was 92%, 90%, and 88%, respectively. At 5 years, 10 years, and 15 years, the estimated freedom from severe aortic valve stenosis was 95%, 95%, and 91%, respectively. At 5 years, 10 years, and 15 years, the estimated freedom from severe aortic valve regurgitation was 95%, 98%, and 98%, respectively.

Conclusions: The Biocor bioprosthesis continues to provide excellent valve durability at 20 years after follow-up. The study provides new data to extend the follow-up period to 20 years and shows a lower incidence of reoperation and aortic valve stenosis.
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
Demographics and Valve Size Distribution - Aortic

<table>
<thead>
<tr>
<th>Age (mean)</th>
<th>72.5±9 years</th>
</tr>
</thead>
</table>
| 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%) |

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

<table>
<thead>
<tr>
<th>Age (mean)</th>
<th>70.8±10.9 years</th>
</tr>
</thead>
</table>
| 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%) |
|            | Other  |
| Valve Size* | 21mm  113 (7%) |
|            | 23mm  623 (41%) |
|            | 25mm  489 (32%) |
|            | 27mm  219 (14%) |
|            | 29mm  57 (4%) |
|            | 31mm  13 (<1%) |
|            | 33mm  3 (<1%) |

- 1518 consecutive aortic valve replacement patients were enrolled in this study between 1983 and 2003.²
*Data missing for 1 patient

¹
²
Results: Long-term Aortic Durability
Actuarial Freedom from Reoperation due to SVD
(Ages ≥65 unless specified)

- Biocor 20 yrs Ages >65 (Myken)^2: 92.1%
- Biocor 20 yrs Ages >65 <75 (Eichinger)^1: 86.6%
- C-E Perimount 20 yrs (Edwards Communiqué)^3: 81.5%
- Mitroflow 20 yrs (Yankah)^4: 71.8%
- Hancock II 20 yrs (Borger)^5: 73.0%
Results: Long-term Aortic Durability
Actuarial Freedom from Reoperation due to SVD
(All ages unless specified)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Mean Age</th>
<th>Actuarial Freedom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biocor (20 yrs)</td>
<td>72.5±9 yrs</td>
<td>86.5%</td>
</tr>
<tr>
<td>Biocor (17 yrs)</td>
<td>70±11 yrs</td>
<td>73.9%</td>
</tr>
<tr>
<td>Mitroflow (17 yrs)</td>
<td>72.4±8.4 yrs</td>
<td>67.0%</td>
</tr>
<tr>
<td>Mitroflow (20 yrs)</td>
<td>73.2 yrs</td>
<td>62.3%</td>
</tr>
<tr>
<td>C-E Perimount (19 yrs)</td>
<td>65±11 yrs</td>
<td>47.0%</td>
</tr>
<tr>
<td>Hancock II (20 yrs)</td>
<td>≥65 yrs</td>
<td>73.0%</td>
</tr>
</tbody>
</table>
Results: Long-term Aortic Durability Actuarial Freedom from Reoperation due to SVD
(Ages ≤65 unless otherwise specified)

- **Mitroflow (17 yrs)**
  - Ages 60 – 69 years: 39.0%

- **C-E Perimount (18 yrs)**
  - Ages <65: 35.8%

- **Biocor (17 yrs)**
  - Ages 61-70 years: 60.1%

- **Biocor (20 yrs)**
  - Ages 60 – 69 years: 71.8%

- **Hancock II (20 yrs)**
  - Ages 60 – 69 years: 82.1%
Results: Biocor Aortic Long-term Durability

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
Demographics and Valve Size Distribution - Mitral

- 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.

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

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

- Biocor 20 yrs (Myken)\(^2\)
  - 88.0%

- Hancock II 20 yrs Ages ≥ 65 yrs (Borger)\(^5\)
  - 59.0%
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)

- Biocor (20 yrs)$^2$ 92.1%
- Biocor (20 yrs)$^1$ ages >65<75 86.6%
- CEP (20 yrs)$^3$ ages ≥ 65 81.5%
- Hancock II ages ≥ 65 (20 yrs)$^5$ 73.0%

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

- Biocor (20 yrs)$^2$ 88.0%
- Hancock II ages ≥ 65 (20 yrs)$^5$ 59.0%

Clinical Evidence
Tissue Valve Leadership: Undeniable Proof Based on Decades of Experience

- Biocor (20 yrs)$^2$
- Biocor (20 yrs)$^1$ ages >65<75
- CEP (20 yrs)$^3$ ages ≥ 65
- Hancock II ages ≥ 65 (20 yrs)$^5$

St. Jude Medical
More control. Less risk.
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
References


**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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