The St. Jude Medical Cardiac Valve Prosthesis: A 25-Year Experience With Single Valve Replacement

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Background. **From October 1977 to October 2002, 4,480 patients (age range, 17 to 94 years; average, 64 ± 13 years) underwent single valve replacement with the St. Jude Medical heart valve. Of 2,982 aortic (AVR) and 1,498 mitral valve replacements (MVR), concomitant coronary artery bypass grafting was performed on 42% and 33%, respectively.**

Methods. **Cardiac Surgical Associates has maintained an independent database of patients having valve replacement with the St. Jude Medical prosthesis since the world's first implant. Patients were contacted by questionnaire or phone from November 2002 through June 2003. Hospital course and valve-related events were verified by patient chart review or physician contact.**

Results. **Follow-up was 95% complete. Operative mortality was 4% with AVR and 9% with MVR. Total follow-up was 32,190 patient-years (range, 1 month to 24.8 years; average, 7 ± 5 years). During the study period, patient freedom from late mortality was 61% (AVR, 61%; MVR, 63%), and from valve-related mortality 92% (AVR, 93%; MVR, 91%). Freedom from thromboembolic events was 85% (86% AVR, 81% MVR), from bleeding events, 81% (81% AVR, 81% MVR), from reoperation, 98% (99% AVR, 97% MVR), from endocarditis, 98% (99% AVR, 98% MVR), and from valve thrombosis, 99% (99% AVR, 98% MVR). There was one MVR structural failure (0.06%).**

Conclusions. **The St. Jude Medical valve has proven to be an effective and durable valve prosthesis with a low event rate during the long term.**

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On October 3, 1977, the first St. Jude Medical (SJM) valve was implanted by Dr. Demetre M. Nicoloff. This prosthesis represented a significant advance in clinically available mechanical valve prostheses. In vitro and in vivo data indicated excellent hemodynamics, resistance to wear, and flow patterns predictive of a low incidence of valve-related events (VRE) [1, 2]. Two long-term reports have demonstrated continued attributes [3, 4] of this prosthesis, recording more than 1,300,000 implants. Of the more than 70 mechanical valves that have been introduced clinically, the SJM has been the most successful [5].

To continue documentation of the results for the long term, this report represents an analysis of patient outcomes after single valve implantation with the SJM prosthesis in the aortic (AVR) and the mitral (MVR) position during a 25-year experience.

During this time three models of the SJM valve have been used in the aortic position, and the single model of the mitral has remained unchanged since introduction. The aortic valve modifications include a change in the sewing ring from the original design renamed the SJM HP (high performance) in which the bulk of the sewing ring was reduced. A larger effective orifice area by approximately one size could be implanted.

The latest model, the Regent valve, has a modified external profile that achieves a larger geometric orifice area without changing the existing design of the pivot mechanism or blood-contact surface areas. This allows implant of an even larger device, approximately 1.5 sizes larger than the original design, resulting in excellent hemodynamics [6].

Material and Methods

Pertinent demographic data on patients older than 17 years of age having SJM valve implantation by Cardiac Surgical Associates surgeons were maintained in an independent database in the Cardiac Surgical Research Foundation. This database has been continuously updated from the first implant in October 1977 through October 2002 for all patients having valve implantation with the SJM valve, and interim reports were issued [7–12].

Clinical charts were reviewed to assure postoperative events and complications through the original operative

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Abbreviations and Acronyms

ARH = anticoagulation-related hemorrhage.
AVR = aortic valve replacement
INR = international normalized ratio
MVR = mitral valve replacement
PVE = prosthetic valve endocarditis
TE = thromboembolism
SJM = St. Jude Medical
VRE = valve-related events

period were captured. To assure that the SJM valve itself was evaluated, patients maintained in our database who had other model valves in addition to the SJM prosthesis and all patients with composite graft replacements were eliminated from this study. The primary objective was to document patient survival and VREs in up to a 25-year experience.

Follow-up was conducted by questionnaire and telephone contact with the patient, and if warranted or valve-related complications occurred, the primary physician or the patient's hospital records were accessed. Owing to the extended time frame of the study to assure that all events were captured, clinical study documents obtained in prior studies were crosschecked [10, 12]. Causes of patient deaths were determined from hospital records and government-authorized death certification. All sudden or unknown causes of death were considered valve-related [13].

Operative data were entered into a database upgraded from the Society for Thoracic Surgeons model to meet Cardiac Surgical Research Foundation requirements. For consistency with earlier recorded VREs, data were collected in accordance with standards described by Edmunds and colleagues [13] and the US Food and Drug Administration document *Replacement of Heart Valve Guidance, 1996* [14].

The surgical techniques were consistent during the 25 years of this study and have been previously reported [8], with only changes in individual techniques of myocardial preservation.

Anticoagulation

Chronic warfarin sodium (Coumadin) anticoagulation has been recommended in all patients with the exception of some pediatric patients who are not included in the current review [15]. In the first 15 years of this study, prothrombin time was used to monitor anticoagulation (target range equals 1.5 times control), between years 15 and 20 a transition occurred from prothrombin time to international normalized ratio (INR), and in the last 5 years INR has been recommended exclusively for anticoagulation follow-up. The target INR is 1.8 to 2.5 for AVR, 2.0 to 3.0 for MVR, and if atrial fibrillation is present the target INR is 2.5 to 3.5. Low-dose aspirin was also added in the latter portion of the study [16].

Table 1. Distribution of Valve Types Implanted for Patients Having Aortic or Mitral Valve Replacement With the St. Jude Medical Cardiac Valve Prosthesis Over 25 Years

Valve Size (mm)	Aortic			Mitral
	Standard	HP	Regent	Standard
17	0	15	0	0
19	129	140	3	0
21	395	303	9	2
23	645	182	11	7
25	678	92	8	76
26	5	0	0	0
27	321	1	3	348
29	55	0	0	631
31	0	0	0	319
33	0	0	0	128
Total	2,228	733	34	1,511

HP = high performance.

Statistical Analysis

Continuous variables were reported as mean ± standard deviation. Actuarial rates were calculated using nonparametric actuarial Kaplan-Meier calculations. Linearized event rates were expressed in percentage per patient-year (%/pt-y). This analyses as well as statistical variables were contracted independently outside of the Cardiac Surgical Research Foundation. Actuarial analysis offers a different estimate of the nonfatal end points, therefore actual curves are included in the graphs for the most common VREs (reoperation, anticoagulation-related hemorrhage, and thromboembolism) to be consistent with other reports [4, 17]. In graphic representations, the number of patients at risk for each time interval is shown at the base of the graph.

Results

From October 3, 1977, through October 3, 2002, 6,470 SJM prostheses were implanted; of these, 2 were triple-valve replacement, 343 were double-valve replacement, 3 were pulmonary valve replacement, and 10 were tricuspid valve replacement. These patients were eliminated. Owing to the additional exclusion criteria mentioned previously, this study includes 4,480 patients with a total of 4,508 valves.

The patient population consists of 2,982 single aortic (AVR) and 1,498 mitral (MVR) valve replacements; of these 28 had repeat single AVR or MVR. Distribution of valve type and size is shown in Table 1. The mean age was 64 ± 13 years (range, 17 to 94 years), and the mean follow-up was 7 ± 5 years. The longest patient follow-up was 24.8 years, and the oldest patient, 102 years of age, had the SJM valve for nearly 8 years. Follow-up was 95% complete, and the total follow-up was 32,190 patient-years. Patient demographics and operative procedures are shown in Table 2.

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