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

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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

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Abstract

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.

Introduction

Drs Emery and Arom disclose that they have a financial relationship with St. Jude Medical, Inc.

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 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].

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.

| View this table: 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 |
| [in this window] | [in a new window] |

| View this table: Table 2. Demographics and Operative Procedures for Patients Having Aortic or Mitral Valve Replacement With the St. Jude Medical Cardiac Valve Prosthesis Over 25 Years |
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**Patient Survival**

The total operative mortality was 6% (n = 256), and 19 of these (7.4% of deaths; 0.4% of patient population) were determined to be valve-related deaths. During the 25-year follow-up, an additional 1,650 (37%) patients died, and of these, 341 (21% of deaths, 7.6% of patient population) were valve-related. Valve-related causes of mortality are shown in Table 3. Actuarial freedom from death and from valve-related death for AVR and MVR are shown in Figures 1 and 2, respectively.

| View this table: Table 3. Causes of Valve-Related Mortality for Patients Having Aortic or Mitral Valve Replacement With the St. Jude Medical Cardiac Valve Prosthesis Over 25 Years |
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Valve-Related Events

Valve-related events are discussed in the following subsections. The data for 5-year time frames including cumulative incidence and 95% confidence limits are shown in Table 4 and 5 for aortic and mitral valves, respectively. Note that confidence limits are not shown in the graphic representatives as the incidence with time was low enough not to be clearly visible.

**REOPERATION**

During 25 years, 71 patients (1.6%) required reoperative replacement or repair of their SJM valve. Causes included valve thrombosis (incidence, 0.2% AVR; 0.5% MVR), prosthetic valve endocarditis (PVE;
incidence, 0.4% AVR; 0.2% MVR), paravalvular leak (incidence, 0.4% AVR, 1.0% MVR), and entrapment or pannus formation (incidence, 0.1% AVR, 0% MVR). The cause of one reoperation is unknown. There was one structural failure early in our experience as a result of embolization of one leaflet. Patient mortality for reoperation was 10%. The cumulative freedom from reoperation at 10 and 20 years from AVR was 98% ± 0.15% and 97% ± 0.35% and for MVR was 97% ± 0.25% and 96% ± 0.5%, respectively. Freedom from reoperation is shown in Figure 3.

Fig 3. Freedom from reoperation in patients having valve replacement with the St. Jude Medical valve prosthesis more than 25 years. (AVR = aortic valve replacement; MVR = mitral valve replacement.)

ANTICOAGULANT-RELATED HEMORRHAGE
Anticoagulant-related hemorrhage (ARH) was the most common event, occurring in 589 AVR and 285 MVR patients. In patients having AVR, 4% (n = 122) had a major bleeding event before hospital discharge and 16% (n = 467) in subsequent follow-up. Mortality related to bleeding events was 2.5% (n = 3) and 13.0% (n = 60) of patient deaths, respectively. In the MVR group, 5% (n = 74) had events before discharge and 16% (n = 211) in follow-up. Mortality related to these events was 1.4% (n = 1) and 9.8% (n = 20) of patient deaths, respectively. The overall incidence of events was 2.7%/pt-y for AVR and 2.7%/pt-y for MVR. Freedom from ARH is shown in Figure 4.

Fig 4. Freedom from anticoagulant related hemorrhage in patients having valve replacement with the St. Jude Medical valve prosthesis more than 25 years. (AVR = aortic valve replacement; MVR = mitral valve replacement.)

THROMBOEMBOLIC EVENTS
A total of 421 thromboembolic events (TE) events occurred in the AVR group and 293 events in the MVR group. In the AVR group before discharge, transient ischemic attacks occurred in 42 patients, permanent strokes in 42 patients, and peripheral events in 15 patients, a total of 3% of patients. After discharge, 153 transient ischemic attacks, 139 permanent strokes, and 30 peripheral events occurred in the follow-up period.
for a total of 11% incidence. Mortality related to these events (n = 421) was 0.7% (n = 3) early and 14% (n = 58) late. The incidence of TE after AVR was 1.9%/pt-y.

With MVR, 23 patients had transient ischemic attacks, 30 permanent strokes, and 9 peripheral events before discharge. After discharge, 116 transient ischemic attacks, 92 permanent strokes, and 23 peripheral events occurred (15% incidence). Mortality related to these events (n = 293) was 0.7% (n = 2) early and 15% (n = 43) late. The incidence of TE after MVR was 2.8%/pt-y. Freedom from TE during the 25-year follow-up period is shown in Figure 5.

**Fig 5. Freedom from thromboembolism in patients having valve replacement with the St. Jude Medical valve prosthesis more than 25 years. (AVR = aortic valve replacement; MVR = mitral valve replacement.)**

**PROSTHETIC VALVE ENDOCARDITIS**
A total of 71 patients had PVE events. Eleven of these were in the operative period (5 AVR, 0.2%; 6 MVR, 0.4%). After discharge, 60 cases of PVE developed, 39 AVR (1%) and 21 MVR (2%). Fifteen of these patients required reoperation. Overall mortality related to PVE was 0.5%. The overall incidence of PVE was 0.2%/pt-y for AVR and 0.3%/pt-y for MVR.

**VALVE THROMBOSIS**
Thrombosis of the prosthetic valve occurred in 34 patients, 15 AVR (0.5%) and 19 MVR (2.0%). Reoperation was reported in 13 patients. The incidence of valve thrombosis is 0.06%/pt-y AVR and 0.18%/pt-y MVR. Patient mortality related to valve thrombosis was 0.07% AVR and 0.3% MVR.

**STRUCTURAL FAILURE**
One patient had early structural failure. Embolization of one leaflet was the result of a manufacturing flaw, not prosthetic material wear. Reoperation was required. Overall freedom from structural failure was 100% for AVR and 99.9% for MVR.

**Comment**
This retrospective study represents the longest, largest, and most complete report on a bileaflet prosthetic valve. Grunkemeier and associates [18] reported on a 35-year experience with aortic and mitral replacement; however, multiple valve models were reported. As opposed to their results, during the current study period, AVR mortality remained consistent in spite of a prospectively older patient population, whereas MVR mortality decreased, likely related to changes in
replacement techniques (preservation of the posterior leaflet chord) and improved myocardial protection.

Excellent hemodynamic performance was the initial benefit of the SJM valve compared with the other clinically available mechanical valve prostheses. There were still, however, hemodynamic gradients in the smaller sizes [19, 20]. This led to the change in the sewing ring configuration (SJM HP) and ultimately to the valve housing itself (SJM Regent), further improving hemodynamics and becoming the first mechanical valve to demonstrate improved left ventricular mass regression [6].

Because of the long time frame, enough stress cannot be placed on the efforts made to capture VREs. All living patients who reported events were further contacted. Hospital records of deceased and living patients were reviewed, and their primary attending physician was contacted. Official causes of death were ascertained from hospital records or by contact with the county or state clerk of records in 10 states. Only 44 of 1,906 patient deaths (7%) did not have a cause of death identified. The role of valve-related mortality, which is quite low during the long time frame, is overstated, as sudden or unexplained patient death was the most common cause of valve-related mortality. In this study 28% of patients followed up were older than 80 years of age. This cohort of patients had their prosthetic valve for 5 ± 3 years. As in other studies, the long-term patient mortality in this series is caused much more commonly by patient-related factors than by the presence of a prosthetic valve [4, 21].

The need for reoperation owing to structural valve failure was nearly nonexistent (1 of 4,480). There were no valve failures as a result of prosthetic material wear. Reoperation for other reasons was also rare, encompassing 1.9% of the entire study.

Patients having valve replacement surgery do not survive in parallel to the normal population [4]. This has been attributed to patient-related factors rather than the prostheses itself. The longevity of the prostheses is its most notable component.

Chronic anticoagulation remains the major cause of VREs in patients with mechanical prostheses. Butchart and coworkers [22] suggested that patient-related factors may be more important than the presence of a prosthetic valve per se. We concur. In young patients with limited risk factors, it was demonstrated that VREs were exceedingly low [23]. With this information, we have revised our recommendations for target INR based on patient risk, comparable to that of Butchart and associates [22].

Consistent management of INR minimizes VRE during the long term. Koertke and colleagues [24] recently reported that early INR home management enables patients to lower target anticoagulation levels. Home monitoring was not used on our patients. Patients are at greatest risk for events the more time spent out of the target INR range [25]. Horstkotte and associates [26] noted that VREs occurred during fluctuation in anticoagulant levels, later reflected in the findings of Koertke and coworkers [24]. Unfortunately, we were unable to verify this as anticoagulant levels were not consistently available at the actual time of events in the majority of patients.

Consistent with Ikonomidis and colleagues [4], we found ARH most commonly occurred early with nearly half of all events occurring in the first year post-operative (Fig 4). We agree with recommendations to slowly bring the patient to therapeutic anticoagulant range in the early postoperative period as the risk of ARH is greater than TE. After 5 years there were very few bleeding events in the AVR population, whereas in the MVR population ARH occurs on a more consistent basis (Fig 4). This is likely related to the higher
recommended target INR. The INR is a more precise measurement of anticoagulation than the less reliable prothrombin time. Importantly, alternative thrombin inhibitors are being researched, and their application will change the landscape for mechanical valve therapy [27].

Thromboembolism, on the other hand, appears to occur more commonly after the operative period and remains a continued risk throughout the patient's life. This is somewhat counterintuitive, as one would expect increased TE risk early in the face of a newly implanted valve sewing ring. As patients age, risk factors for TE increase and the patients may be at risk to have an increasing number of events [22]. Although TE events between AVR and MVR groups are equal for the first 10 years, the incidence separates at 10 years, likely because of the increased incidence of atrial fibrillation in MVR patients (Fig 5). The TE rates of biologic valves without anticoagulation are equivalent to those of mechanical prostheses with anticoagulants, underlining the importance of patient risk factors [3]. The TE rate reported is similar to that of Khan and associates [3] and Ikonomides and colleagues [4].

Analogous to the recent experience of Ikonomidis and coworkers [4], our use of biologic prostheses has increased owing to the greater number of elderly patients and the increased life expectancy of modern biologic valves. Yet in making this decision, one has to take into account that reoperation is not without risk, 10% mortality in this study, whereas the repeat reoperative mortality rate is even higher. Up to one third of patients with biologic valves are placed on chronic anticoagulation for the long term, negating the advantage [28]. As the incidence of ARH does not differ between patients older or younger than 65 years of age, age in and of itself is not a contraindication to mechanical valve replacement [29–31]. Mechanical valves are optimal for patients who already require chronic anticoagulation and those at risk for future anticoagulant therapy. The need for chronic anticoagulation can be predicted by using a table of patient risk factors and should be considered in discussions with patients [22]. Patients are living longer after valve replacement because of the availability of more reliable prosthetic valves and more accurate anticoagulant management. This likely accounts for the fact that greater than one fourth of our follow-up patients were older than 80 years, most having valve replacement before age 75.

Current recommendations to our patients include the use of a mechanical valve in the aortic position if the patient is younger than 70 years of age, and in the mitral if younger than 75 years. In the more elderly and those who are already taking or are at high risk for being placed on anticoagulation, a mechanical valve is recommended. Because there is risk of bioprosthetic valve loss as early as 6 to 8 years after implant, mean time to biologic repeat replacement may be short. Thus, we recommend mechanical valve replacement for reoperative patients, regardless of the reason for reoperation [3, 28].

Finally, mention should be made regarding the Silzone sewing ring. Forty-three patients had AVR with this modified sewing ring and 17 in the MVR group. There were no reoperations for PVE or for perivalvular leak. This differs from the multicenter AVERT trial [32]. The number is small, but may reflect our group's effort at extensive annular decalcification at the time of surgery and the use of closely placed pledgeted mattress sutures.

In summary, this extensive experience demonstrates excellent function of the SJM valve in the mitral or aortic position. Valve-related events were low, most commonly caused by patient-related factors as opposed to the presence of a prosthetic valve. Valve-related mortality was low, and there have been no reoperations as a result of valve wear. The SJM valve can be recommended to patients as a prosthesis that will last their lifetime.
Footnotes


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