Long-Term Results with the St. Jude Medical Aortic Valve: A 25-Year Experience.
Robert W. Emery, Kit V. Arom, Christopher Krogh, Lyle D. Joyce, Ann Emery, Demetre M. Nicoloff

**BACKGROUND:** From 10/77 – 10/02, 2982 patients (age range 17-94 years, average age 65 ± 13) underwent aortic valve replacement (AVR) with the St. Jude Medical (SJM) heart valve. Concomitant coronary bypass was performed in 1239 (42%) patients.

**METHODS:** Cardiac Surgical Associates has maintained an independent database of our patients having valve replacement with the SJM prosthesis since the world's first implant in 10/77. Patients were contacted by questionnaire and/or phone from 11/02 through 6/03. Hospital course and valve-related events were verified by patient chart review and/or physician contact.

**RESULTS: Operative mortality was 4%** (AVR 3%; AVR/CAB 6%) of which 15 (12%) were valve related. **Total follow-up (94%) was 21,742 patient years** (range 1 month to 24.8 years, average 7 ± 5 years). At 25 years, overall patient freedom from late mortality was 61% and from late valve-related mortality 93%. Freedom from thromboembolic events was 86%; from bleeding events 81%; from endocarditis: 98%, and from valve thrombosis 99%; and from reoperation 99%. Reoperation was carried out in 51 patients (2%) for suture closure of paravalvular leak (n=4), valve replacement (34) and debridement of valve (13). There were no structural failures.

**CONCLUSION:** The SJM valve has proven to be an effective and durable heart valve prosthesis with a low event rate over the long term.

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* The following relationship(s) exist: St. Jude Medical: Grant, Stock, Presenter

** The following relationship(s) exist: St. Jude Medical: Consulting fee

+ No relationship(s) to disclose

## Introduction

The St. Jude Medical (SJM) heart valve was the first bileaflet prosthetic valve to be approved by the FDA. Since one of the authors (DMN) implanted the world's first SJM valve on October 3, 1977, it has become the most commonly used cardiac valve prosthesis the world over. Cardiac Surgical Associates has maintained a research database of all SJM valves implanted by our surgeons for the past 25 years. The longest patient follow-up is 24.8 years. The current study reviews the outcomes of patients having single aortic valve replacement over a 25-year period (follow-up 94% complete).

## Patient Demographics

| Total Years of Follow-Up | Longest Follow-Up |
|---|---|
| 21,742 | 24 Years 202 Days |

| Operative Category | Number of Patients |
|---|---|
| CAB+Valve | 1201 |
| CAB+Valve+Other | 38 |
| Valve | 1696 |
| Valve+Other | 60 |

| Age at Time of Surgery | Number of Patients |
|---|---|
| Younger than 50 | 397 |
| 50-60 | 470 |
| 60-70 | 902 |
| 70-80 | 970 |
| Older than 80 | 243 |

| Gender | Number of Patients |
|---|---|
| F | 1112 |
| M | 1870 |

| Youngest at Time of Surgery | Oldest at Time of Surgery |
|---|---|
| 17 | 94 |

| Operative Deaths |
|---|
| 125 |

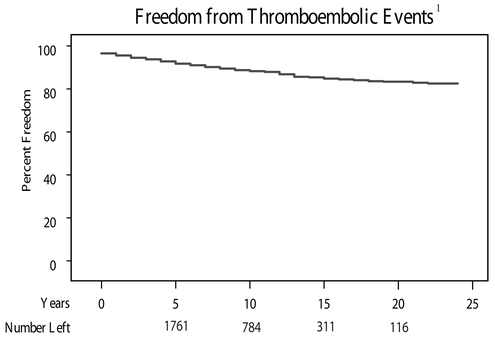
**St. Jude Medical Mechanical Heart Valve**
Designed and manufactured of pyrolytic carbon, this valve contains tungsten for easy visualization following implantation.

**St. Jude Medical Mechanical Heart Valve Hemodynamic Plus (HP) Series**
Designed to eliminate sewing cuff material from the valve annulus, allowing a greater flow area.

**SJM Regent Valve**
The SJM Regent valve provides better hemodynamic performance than you might have imagines possible with a mechanical heart valve.

[1] Confidence limits (CL) in table

Aortic Valve



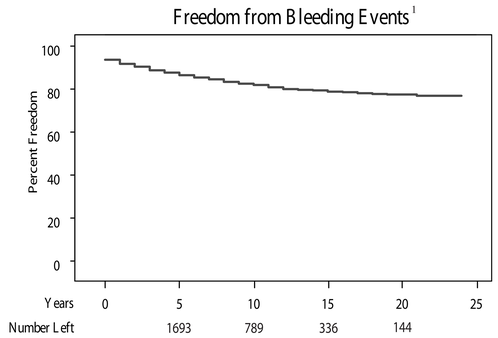
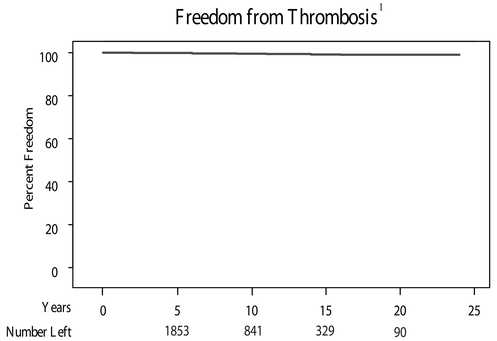
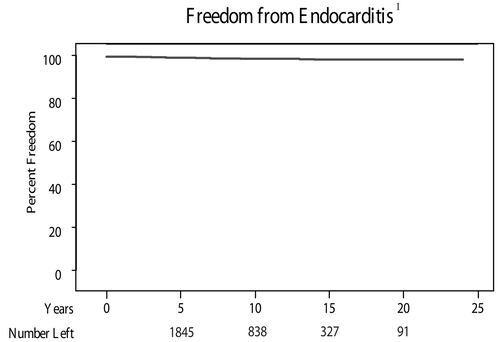




**Table 1**: Event cumulative incidence estimates by complication (n = 2982).

| Event | YR | Cum Inc(%) | SE(Cum Inc) | 95 % CL | # Left |
|---|---|---|---|---|---|
| TE | 5 | 7.2 | .5 | (6.2, 8.2) | 1761 |
| | 10 | 11.3 | .6 | (10.0, 12.6) | 784 |
| | 15 | 14.7 | .8 | (13.1, 16.3) | 311 |
| | 20 | 16.6 | 1.0 | (14.7, 18.5) | 116 |
| Bleeding | 5 | 12.4 | .6 | (11.2, 13.6) | 1693 |
| | 10 | 17.5 | .8 | (16.0, 19.0) | 789 |
| | 15 | 20.7 | .9 | (18.9, 22.4) | 336 |
| | 20 | 22.5 | 1.0 | (20.6, 24.5) | 144 |
| Thrombosis | 5 | .1 | .1 | (0, .3) | 1853 |
| | 10 | .5 | .2 | (.2, .8) | 841 |
| | 15 | .8 | .2 | (.4, 1.3) | 329 |
| | 20 | 1.0 | .3 | (.4, 1.6) | 90 |
| Endocarditis | 5 | 1.2 | .2 | (.8, 1.6) | 1845 |
| | 10 | 1.7 | .3 | (1.1, 2.2) | 838 |
| | 15 | 2.0 | .3 | (1.4, 2.6) | 327 |
| | 20 | 2.0 | .3 | (1.4, 2.6) | 91 |
| Re-operation | 5 | 1.0 | .2 | (.6, 1.4) | 1844 |
| | 10 | 1.4 | .2 | (.9, 1.8) | 838 |
| | 15 | 1.6 | .3 | (1.1, 2.2) | 328 |
| | 20 | 1.9 | .3 | (1.2, 2.6) | 89 |



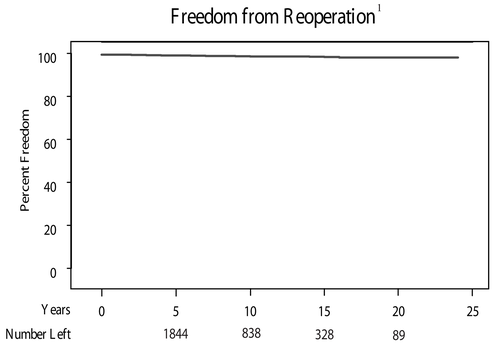




**Table 2**: Univariate analysis of **operative** mortality (n=127) for ***aortic*** patients (n=2982).

| Covariate | p-value | Association with greater op mort |
|---|---|---|
| Age (n=2982) | < .001 | Older age |
| Valve size (n=2982) | .009 | Smaller sizes |
| BSA (n=2915) | < .001 | Smaller BSA |
| Gender (n=2982) | .290 | ---- |
| Re-operation (n=2982) | < .001 | Reop = yes |
| NYHA2 (n=1810) | Insufficient data | ---- |
| CVA (n=2979) | .193 | ---- |

**Table 3**: Univariate analysis of **late** mortality (n=1100) for ***aortic*** patients (n=2982).

| Covariate | p-value | Associated with more late mort |
|---|---|---|
| Age (n=2982) | < .001 | Older age |
| Valve size (n=2982) | < .001 | Smaller size |
| BSA (n=2915) | < .001 | Smaller BSA |
| Gender (n=2982) | .980 | ---- |
| Re-operation (n=2982) | .449 | ---- |
| NYHA2 (n=1810) | < .001 | Class III and IV |
| CVA (n=2979) | .002 | CVA = yes |

**Table 4**: Significant factors in the logistic regression of **operative** mortality (n=125) for ***aortic*** patients (n=2915).

| Variable | p-value | Odds ratio |
|---|---|---|
| Age) | <0.001 | 1.05 |
| BSA | 0.013 | 0.37 |
| Reoperation | <0.001 | 3.12 |

**Table 5**: Significant factors in the Cox regression of **late** mortality (n=1098) for ***aortic*** patients (n=2979).

| Variable | p-value | Odds ratio |
|---|---|---|
| Age | <0.001 | 1.07 |
| CVA | <0.001 | 1.70 |

Note: NYHA2 was not included in the above model because of missing values

Table 6: Valve related operative mortality in **aortic** patients (n=15)

| Valvular Cause of Mortality | Number of patients |
|---|---|
| Bleeding Event-Neuro | 2 |
| Bleeding Event-Other | 1 |
| Embolic-Neuro | 2 |
| Embolic-Peripheral | 1 |
| Prosthetic Valve Endocarditis | 3 |
| Reoperation of Prosthetic Valve | 3 |
| Sudden Unexplained, Unknown | 3 |

## Conclusion

The SJM aortic valve is a safe and effective cardiac valve prosthesis. Redesign of the sewing ring and leaflet housing over this quarter century has allowed the current device to be highly effective hemodynamically. The mechanical prosthesis carries low event rates, can be managed with low levels of chronic anticoagulation, and can be expected to last the life of the patient.