Reoperative Valve Replacement with the St. Jude Medical Valve Prosthesis: Long-Term Follow-Up

Robert W. Emery*, Kit V. Arom**, Christopher Krogh+, Lyle D. Joyce+, Ann Emery+, Demetre M. Nicoloff+

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OBJECTIVE: From 6/78 – 9/02, 448 redo open heart patients (following various primary cardiac operations) age range 18-91 years (average age 62 ± 14) underwent single-valve replacement with the St. Jude Medical (SJM) heart valve. Of 244 patients having aortic (AVR) and 204 patients having mitral valve replacements (MVR), 35% and 21% had concomitant coronary bypass respectively.

METHODS: Cardiac Surgical Associates has maintained an independent database of our patients 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: **Follow-up was 95% complete** for a total of **3,114 patient years (1,671 AVR; 1,443 MVR)**. Follow-up ranged from 0.1 to 24.3 years (average 7 ± 6 years). **Operative mortality was 9% (10% AVR, 8% MVR). Five deaths (13%) were valve related.** Freedom from all late mortality at 24 years was 64% (70% AVR, 56% MVR), and from valve-related mortality 83% (84% AVR, 82% MVR). Freedom from thromboembolic events was 85% (91% AVR, 82% MVR), from bleeding events 83% (83%AVR, 82% MVR), from endocarditis 97% (97% AVR, 97% MVR), from valve thrombosis 98% (99% AVR, 98% MVR), and from subsequent reoperation 94% (95% AVR, 94% MVR),. There were no structural failures.

CONCLUSION: Reoperative valve replacement carries a significant operative mortality, but long term results with the SJM valve show a low event rate, a durable prosthetic valve and excellent long-term patient survival.

INTRODUCTION

The St. Jude Mechanical (SJM) heart valve was the first FDA approved bileaflet prosthesis used for aortic and mitral valve replacement. It has subsequently become the most commonly implanted cardiac valve prosthesis worldwide. The World's first SJM valve was implanted on October 3, 1977 by one of the authors (DMN), since then over 1.25 million have been utilized. Cardiac Surgical Associates (CSA) surgeons have maintained a registry of all patients having valve replacement with the SJM valve and have reported outcomes at varying intervals. The current study reviews the outcomes of patients having reoperative open-heart (ROH) valve replacement (follow-up 95% complete) with the SJM valve following a variety of previous cardiac surgical procedures.

* 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

Patient Demographics

Aortic Valve

Gender	Number of Patients	Avg. Age at Time of Surgery
F	86	64 ± 15
M	158	63 ± 15

Longest Follow-Up	Total Follow-Up
24 years 101 Days	1,671 years

Operative Deaths
24

Mitral Valve

Gender	Number of Patients	Avg. Age at Time of Surgery
F	119	60 ± 12
M	84	62 ± 14

Longest Follow-Up	Total Follow-Up
23 years 315 Days	1,443 years

Operative Deaths
16

Table 1: Events cumulative incidence estimates for ***aortic*** patients by complication. (n = 244)

Event	YR	Cum Inc (%)	SE(Cum Inc)	95 % CL	# Left
TE	5	9.1	1.9	(5.4, 12.9)	104
	10	10.9	2.3	(6.4, 15.4)	38
	15	10.9	2.3	(6.4, 15.4)	10
	20	10.9	2.3	(6.4, 15.4)	3
Bleeding	5	15.0	2.4	(10.3, 19.7)	97
	10	20.1	2.9	(14.4, 25.9)	33
	15	22.0	3.4	(15.3, 28.7)	9
	20	22.0	3.4	(15.3, 28.7)	2
Thrombosis	5	.5	.5	(0, 1.5)	112
	10	1.6	1.2	(0, 4.0)	38
	15	1.6	1.2	(0, 4.0)	10
	20	1.6	1.2	(0, 4.0)	3
Endocarditis	5	2.1	.9	(.3, 4.0)	112
	10	3.9	1.5	(.9, 6.9)	39
	15	3.9	1.5	(.9, 6.9)	10
	20	3.9	1.5	(.9, 6.9)	3
Re-operation	5	3.8	1.3	(1.2, 6.4)	110
	10	5.5	1.8	(2.0, 9.0)	37
	15	5.5	1.8	(2.0, 9.0)	9
	20	5.5	1.8	(2.0, 9.0)	3

Table 2: Events cumulative incidence estimates for ***mitral*** patients by complication. (n = 204)

Event	YR	Cum Inc (%)	SE(Cum Inc)	95 % CL	# Left
TE	5	12.3	2.4	(7.7, 17.0)	100
	10	18.6	3.1	(12.5, 24.6)	41
	15	24.4	3.8	(17.0, 31.7)	20
	20	29.2	4.8	(19.9, 38.5)	5
Bleeding	5	12.6	2.4	(7.9, 17.2)	100
	10	17.6	2.9	(11.9, 23.3)	43
	15	22.1	3.5	(15.2, 28.9)	22
	20	24.9	3.9	(17.3, 32.4)	7
Thrombosis	5	1.5	.9	(0, 3.3)	110
	10	1.5	.9	(0, 3.3)	48
	15	3.1	1.8	(0, 6.6)	23
	20	3.1	1.8	(0, 6.6)	7
Endocarditis	5	2.0	1.0	(.1, 3.9)	108
	10	2.8	1.3	(.3, 5.4)	46
	15	2.8	1.3	(.3, 5.4)	23
	20	2.8	1.3	(.3, 5.4)	8
Re-operation	5	3.1	1.3	(.7, 5.6)	107
	10	4.0	1.5	(1.0, 7.0)	45
	15	4.0	1.5	(1.0, 7.0)	22
	20	6.9	3.2	(.7, 13.2)	7

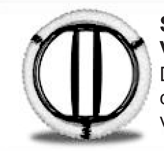
Table 3: Univariate analysis of **operative** mortality (n=24) for ***aortic*** patients (n=244).

Covariate	p-value	Association with greater op mort

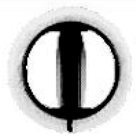
No significant variables resulted for this model

Table 4: Univariate analysis of **operative** mortality (n=16) for ***mitral*** patients (n=204).

Covariate	p-value	Association with greater op mort
Age (n=204)	.005	Older age



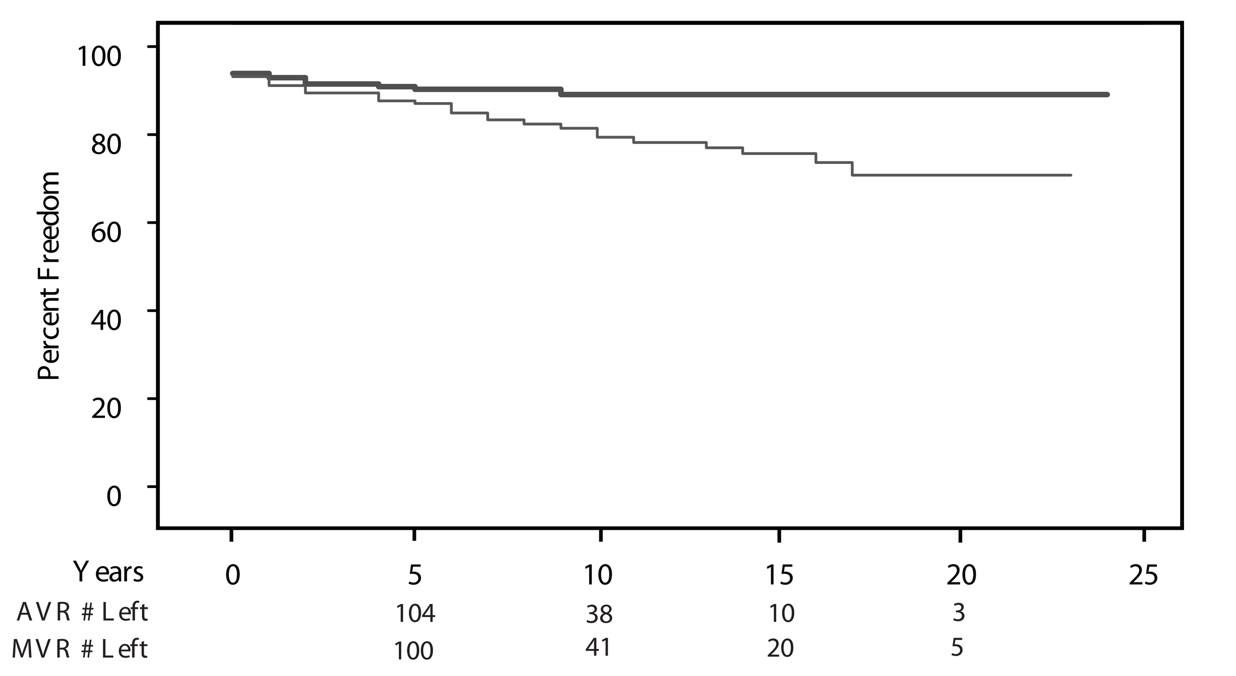
St. Jude Medical Mechanical Heart Valve
Designed and manufactured of pyrolytic carbon, this valve contains tungsten for easy visualization following implantation.

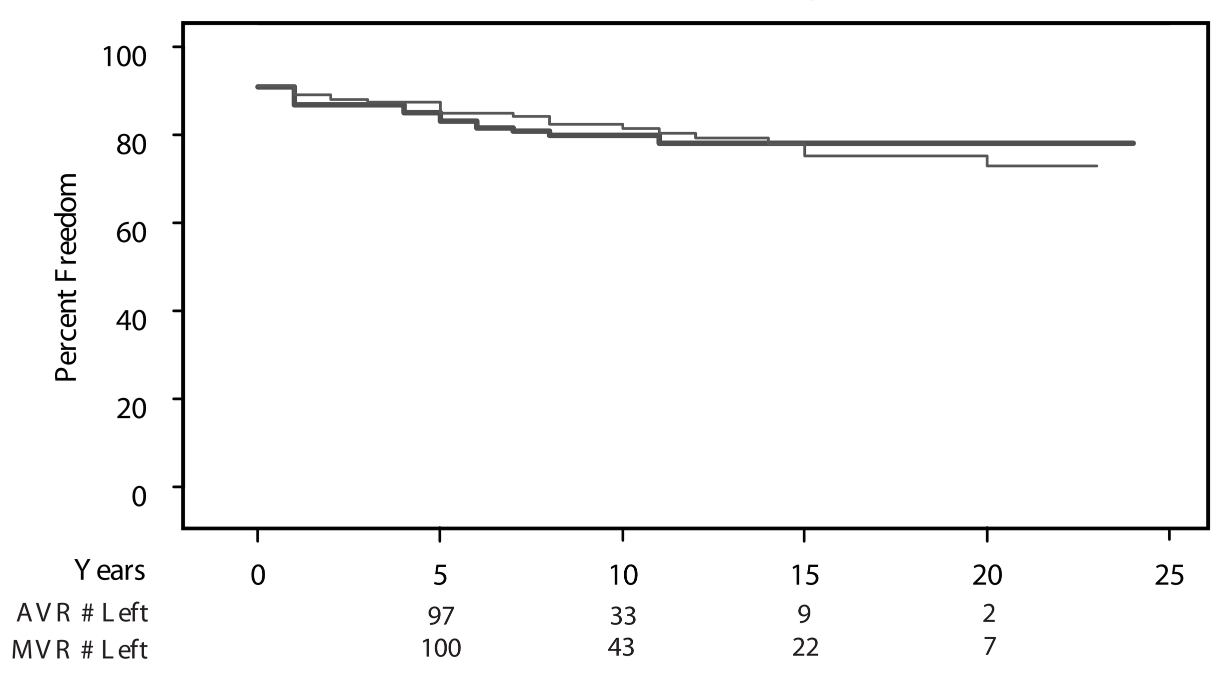


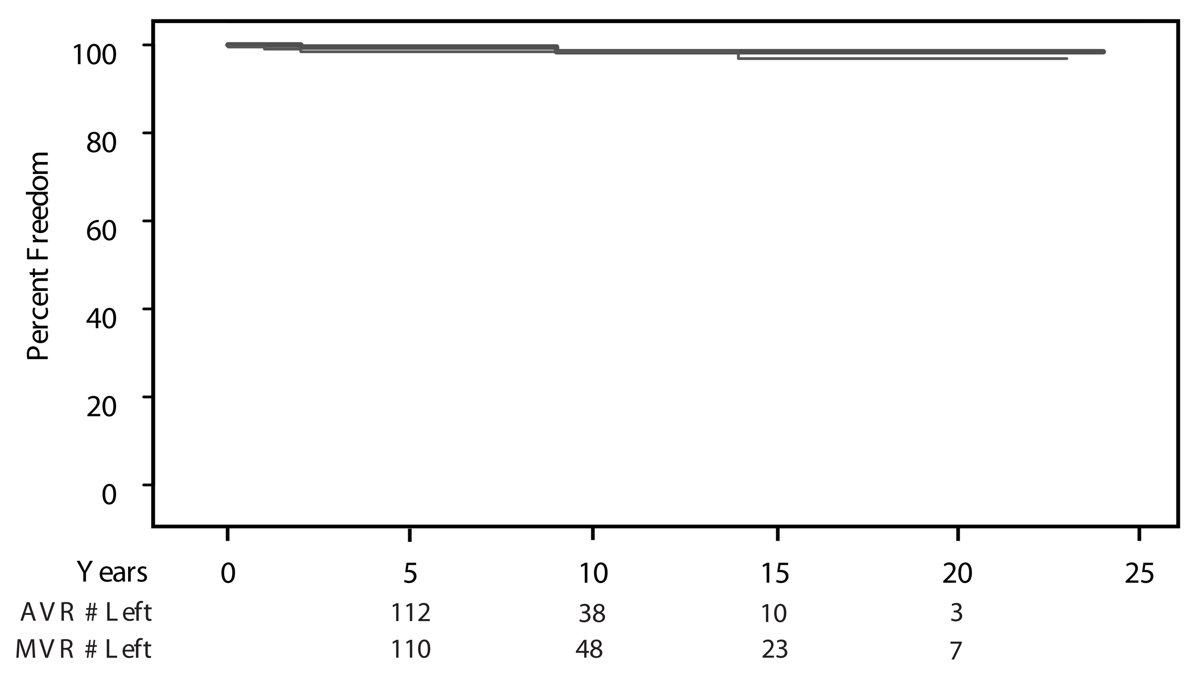
St. Jude Medical Mechanical Heart Valve Hemodynamic Plus (HP) Series
Designed to eliminate sewing cuff material from the valve annulus, allowing a greater flow area.

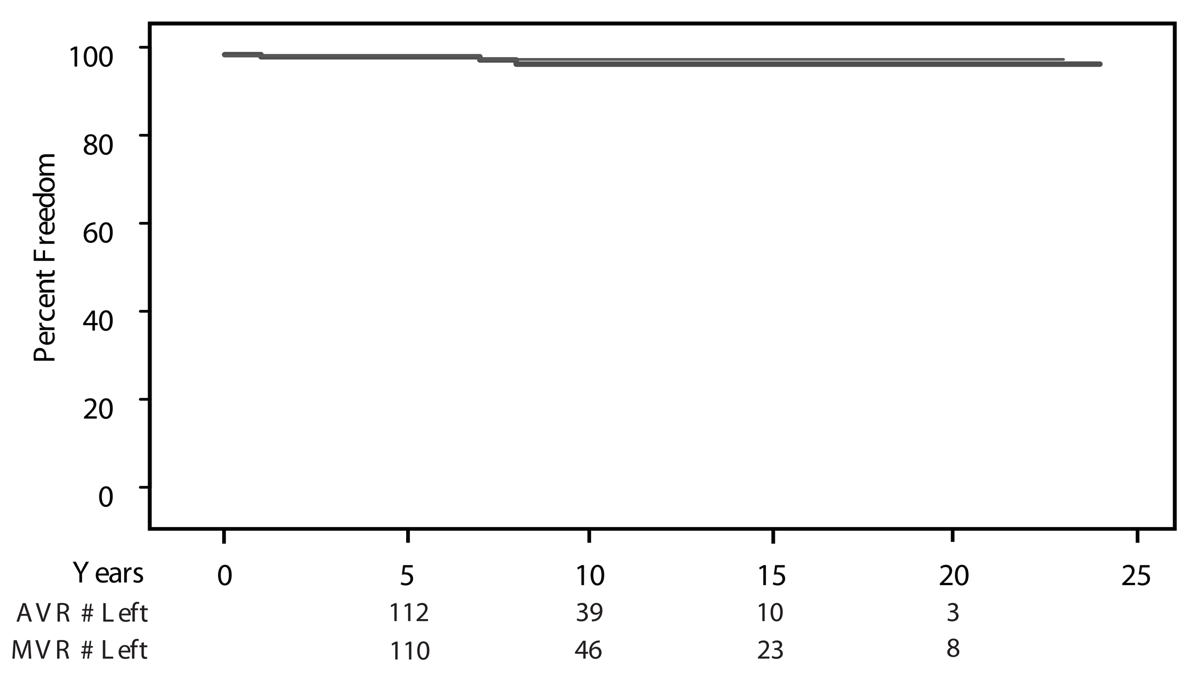
SJM Regent Valve
The SJM Regent valve provides better hemodynamic performance than you might have imagines possible with a mechanical heart valve.

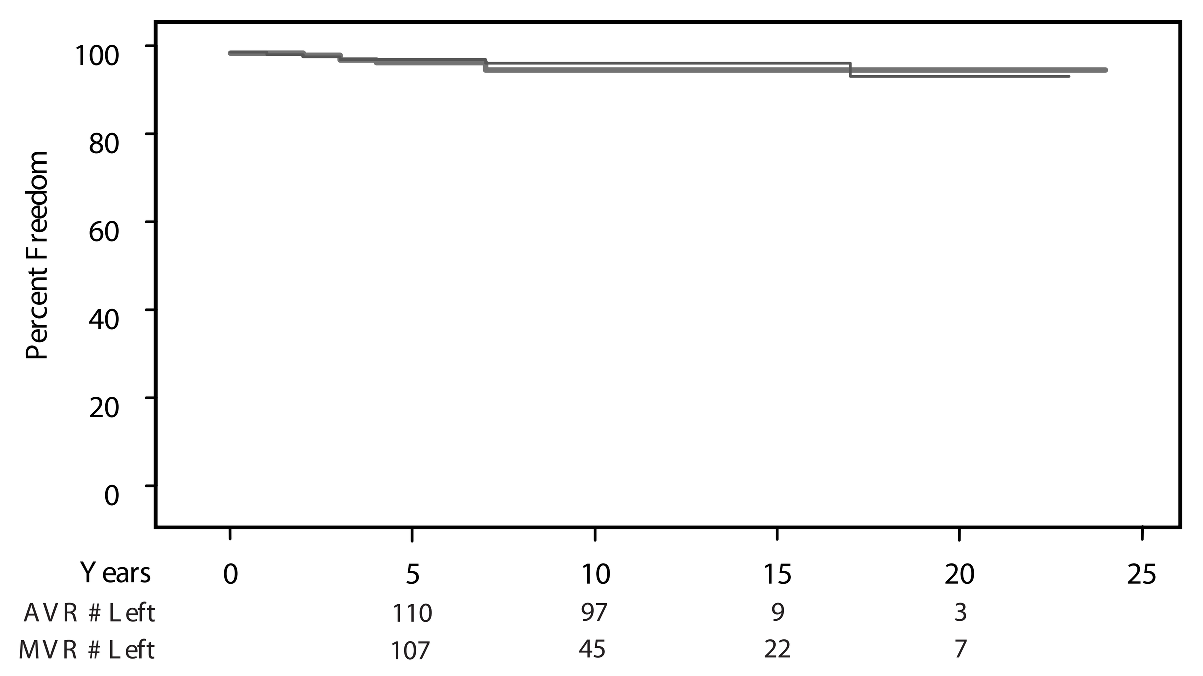
[1] Confidence limits (CL) in table 1 and 2











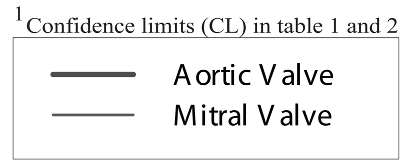


Table 5: Univariate analysis of **late** mortality (n=65) for ***aortic*** patients (n=244).

Covariate	**p-value**	**Associated with more late mort**
Age (n=244)	< .001	Older age
NYHA2 (n=159)	< .001	Class III and IV

Table 6: Univariate analysis of **late** mortality (n=82) for ***mitral*** patients (n=204).

Covariate	**p-value**	**Associated with more late mort**
Age (n=204)	< .001	Older age
BSA (n=202)	.026	Larger BSA
Gender (n=204)	.053	Female
NYHA2 (n=126)	< .001	Class III and IV

Table 7: Significant factors in the logistic regression of **operative** mortality (n=24) for ***aortic*** patients (n=244).

Variable	p-value	Odds ratio

Not significant variables resulted for this model

Table 8: Significant factors in the logistic regression of **operative** mortality (n=16) for ***mitral*** patients (n=204).

Variable	p-value	Risk ratio
Age (one year increase)	0.006	1.07

Table 9: Significant factors in the Cox regression of **late** mortality (n=65) for ***aortic*** patients (n=244).

Variable	p-value	Odds ratio
Age (one year increase)	<0.001	1.05

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

Table 10: Significant factors in the Cox regression of **late** mortality (n=82) for ***mitral*** patients (n=202).

Variable	p-value	Risk ratio
Age	<0.001	1.04
BSA	0.021	3.14

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

Table 11: Valve related **operative** mortality causes for ***aortic*** patients (n=5)

Valvular Cause of Mortality	Number of Patients
Bleeding Event-Other	1
Prosthetic Valve Endocarditis	2
Reoperation of Prosthetic Valve	2

Table 12: Valve related **operative** mortality causes for ***mitral*** patients (n=0)

No valve related operative mortalities

CONCLUSIONS

While carrying a higher operative mortality (9%) than primary valve replacement related to patient risk factors, long-term follow-up results show low event rates consistent with those seen in primary valve replacements. The SJM valve is durable over the long term and patient survival is excellent. Because of these factors, the SJM valve has become the mechanical prosthesis of choice for patients requiring reoperative cardiac valve replacement.