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Progress in Cardiac Valve Replacement Clinical and Hemodynamic Results with the St. Jude Prosthesis

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Successful clinical introduction of extracorporeal circulation in the 1950's[1] opened an exciting and very productive era in the surgical therapy of virtually all kinds of heart disease-beginning with congenital, followed closely thereafter by acquired types.

The author and colleagues performed successful open heart operations by extracorporeal circulation on the mitral and aortic valves beginning in 1956.[2-4] However, the results of these early operations for acquired valvular disease (all reconstructive) were severely hampered by the advanced state of the pathology present. Fibrosis, distortion, tissue loss, and calcification frequently prevented satisfactory functional repairs.

Immediate intensive research efforts were begun to develop prosthetic substitutes for replacement of these severely diseased valves. The author achieved successful total aortic valve replacement in 1958 utilizing a silastic prosthesis.[5] Other early offorts utilized teflon or dacron leaflets. Initial results were encouraging; however, with the passage of relatively short periods of time, most of these prostheses either fatigue fractured or restenosed due to fibrous ingrowth.

The introduction of the caged-ball prosthesis in the subcoronary position in 1960[6] made heart valve replacement a more consistently successful operation.

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In the two decades that have passed, many significant improvements in preoperative diagnostic methods, operative techniques, perfusion physiology, patient monitoring, and prosthesis design have combined to make heart valve replacement a safe and effective procedure today.

In this report we wish to focus upon the progress that has been made in prosthetic valve performance with particular reference to the St. Jude Medical (SJM) heart valve (Figure 1). The latter is a rigid, bileaflet, central orifice, all-pyrolytic carbon device that has achieved widespread acceptance since its initial design description by Kalke and Lillehei[7-9] in the mid-60's, and its clinical introduction in 1977 by Nicoloff.[10,11]

On the basis of a number of early successful clinical and investigational reports[12-18] of superior hemodynamics, improved thromboresistance, and the promise of excellent durability, the SJM prosthesis has rapidly gained a worldwide clinical acceptance.[19]

Method of Study. All clinical data on SJM implantations have been collected in accordance with the Medical Devices Legislation of 1976 (U.S.A.) implemented under the guidelines and regulations formulated by the Federal Food and Drug Administration (FDA).

The provisions of this act provide for the establishment of clinical investigation centers where careful followup procedures must be followed with prompt reporting of all complications, suspected or actual, for analysis in return for continuing authorization to utilize the device.

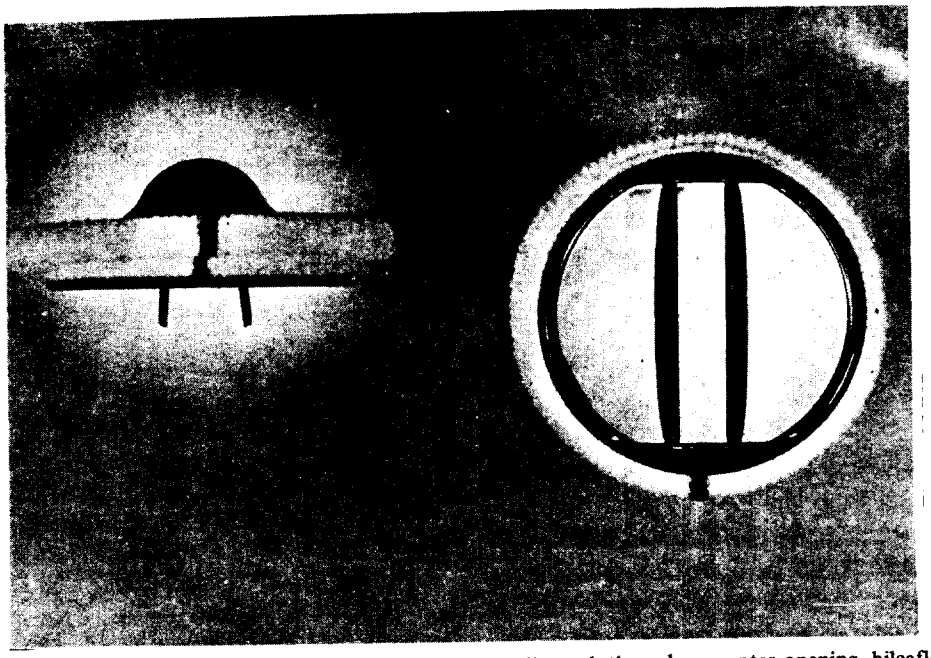

Figure 1. The St. Jude Medical Valve Prosthesis is an all pyrolytic carbon, center opening, bileaflet valve.

To the right: The two leaflets are viewed from the inflow side in the fully opened (to 85°) position. The large effective orifice area, free of any struts or other obstructions is seen. The sewing cuff is dacron velour.

To the left: The prosthesis, fully opened, is seen in profile with the inflow side on tope. The SJM prosthesis has the lowest profile in all of its sizes of any mechanical or bioprosthesis. The low profile improve flow performance, reduces blood stagnation, and lessens opportunities for entrapment.

Results. A total of 3,270 individuals have been followed for 1,305 patient years since the beginning of the current St. Jude Medical investigational trial in October 1980. The number of patient years of followup for isolated aortic, isolated mitral and other implants* are 683 years, 487 years, and 135 years respectively.

Table 1 represents time weighted (i.e., per patient year) complication rates for this patient group, reflecting data reported from 151 investigational centers throughout the United States.[20]

Hemodynamic Results. The in-vivo flow performances of the SJM prosthesis has been established through post-implant elective catheterization data. Of particular interest to clinicians has been the hemodynamic data for the small aortic sizes[20] (19, 21, and 23mm). The excellent flow performances for these small sized prostheses is detailed in Table 2.

In addition, one of the European investigational centers (University of Dusseldorf, W. Germany) has had the unique opportunity to study hemodynamics in a significant number of their patients comparing the results with six different types of prostheses all implanted and recatheterized at the same center. This data for their mitral valve replacements has been reported recently by Horstkotte, Loogen, and Bircks.[22] These results at rest (Table 3) and after exercise (Table 4) show consistently superior hemodynamic performance for the SJM prostheses under all conditions.

Thromboembolism. Thromboembolism and valve thrombosis (T.E.) have been one of the most dreaded complications associated with valve replacements of all types because of their propensity for sudden onset with a high incidence of fatal or severe disabilities in patients who up

Table 1. Complication rates[1] for 3270 patients receiving SJM prostheses at USA centers.

(Rates are Expressed as %/Patient Year)

Complication	Overall Rate	Aortic Rate	Aortic (+ S.E.[3])	Mitral Rate	Mitral (+ S.E.)	Other[2] Rate
Hemolytic Anemia[4]	0.2	–	–	0.2	(± 0.2)	0.7
Prosthetic Infection[5]	0.3	0.4	(± 0.3)	0.2	(± 0.2)	–
Valve Thrombosis[6]	0.5	0.2	(± 0.2)	1.0	(± 0.5)	–
Thromboembolism[7]	2.5	1.3	(± 0.4)	2.9	(± 0.8)	6.7
Prosthesis Failure[8]	0.1	0.2	(± 0.2)	–	–	–
Perivalvular Leak	2.2	1.8	(± 0.5)	3.1	(± 0.8)	0.7
Hemorrh. Complic. of Anticoagulation	2.4	2.8	(± 0.6)	2.1	(± 0.7)	1.5
Explant[9]	2.0	1.8	(± 0.5)	2.7	(± 0.7)	0.7
		(Rates are Expressed as %)				
Early Death (≤30 days)	8.4	5.9		10.9		11.8
		(Actuarial % Survival to One Year)				
Late Death	93.7	94.8	(± 0.9)	92.6	(± 1.2)	91.6

NOTE: The data reported here includes implants on or before 10/23/80 and reported by 9/01/82.

[1]Rates in this table are weighted by the duration of time patients were followed from implant (events/years of patient follow-up X100).

[2]The "OTHER" category includes tricuspid, pulmonic and multiple prosthetic implants.

[3]S.E. = Standard Error.

[4]To date, uncompensated hemolytic anemia has not been reported in absence of an underlying problem such as perivalve leak, infection, blood dyscrasia. Two cases of hemolytic anemia were included in this patient cohort. In one, the anemia was secondary to a perivalvular leak which was corrected by reoperation. In the second, the patient had aortic and mitral implants. The surgen indicated that irremovable calcification of the mitral annulus was a possible contributing factor.

[5]Of the 4 patients with prosthetic endocarditis, 3 were known to have a prior bacterial endocarditis.

[6]Of the 6 patients with thrombosed valves, all developed premonitory symtpoms prior to their diagnosis. This fact aided their therapeutic management. Three of the 6 patients were not on anticoagulants at the time of thrombosis. In three, the thrombosed valves were either explanted or reoperated to correct. Of the remaining 3, 2 patients expired during operative procedures and a third expired before a diagnosis was made.

[7]The Stanford definition of thromboembolic events (J. Thor. C.V. Surg. 78:343, '79) was used.

[8]The one possible structural failure reported for the entire series involved the onset of aortic regurgitation after 3 mo. of excellent function. At reoperation, the surgeon could not find any cause. The prosthesis was explanted, and appeared normal to the pathologist, but was then lost and could not be tested.

[9]All explants were performed for medical complications extrinsic to the prostheses, with the possible exception of one case (see #8 above).

to the time of the event were often living normal lives.

Continuing improvements in prostheses design, materials, flow characteristics, preservation methods and surgical techniques have progressively reduced the incidence of these complications in recent years for both mechanical and tissue types.

The overall incidence of these two complictions for the SJM prosthesis in a large group of patients from 151 centers in the U.S.A. is detailed in Table 1. A number of other reports have confirmed this low T.E. incidence with the SJM prostheses.[10-21,16,17,19,21]

Horstkotte and colleagues[23] have had the opportunity to compare thromboembolic com-

Table 2. St. Jude small-sized arotic replacement – recatheterization data[20]

Summary Statistics of Elective Resting Catheterization Values from Investigational Centers Taken at Least 30 Days Post-Implant by Valve Size

Aortic Position		19mm	21mm	23mm
Peak Press. N		8	11	15
Gradient (mmHg)	Mean	1.51	7.5	2.3
	Range	0 -25	0 -26	0 -7
Effective (1) Orifice Area (CM^2-Gorlin)	Mean	1.2	1.3	2.3
	Range	0.8-1.4	1.1-2.1	1.3-2.41
valve Area Index	Mean	0.9	0.7	1.4
Cardiac Index ($L./min./M^2$)	Mean	3.2	2.5	2.8
	Range	2.7-3.4	1.7-3.3	1.1-4.6

(1) In patients where no gradient was measureable, the geometric valve area was utilized for the effective orifice area. N=No. of patients studied.

plications with the SJM and Bjork-Shiley prostheses in a large number of implants followed a similar length of time in the same clinic and under the same environmental conditions and followup protocol. Their results show a very significant and consistent superiority of the SJM prosthesis over the Bork-Shiley implants in the occurrence of these serious complications of valve thrombosis and embolism in the aortic, mitral, and double valve positions (Table 5).

DISCUSSION

Those patients with severe aortic valve disease associated with a small aortic root, calcified, have been a source of increased morbidity and mortality due to the obstructive nature of all previously available mechanical and bioprostheses.

The recatheterization results from many investigative centers in the U.S.A., shown in Table 2, indicate the very significant improvement in the management of this vexing problem provided by the SJM prosthesis.

In recent reports, three other groups; Matloff et. al.[14], Wortham et. al.[15], and Nicoloff et. al.[17], have specifically studied postoperative hemodynamics in their patients and have fully confirmed the excellent flow characteristics through the small sized SJM prostheses.

The other studies listed herein have also documented the superior flow performance of the SJM prostheses in larger sizes and in the mitral position.

As might be anticipated, the better flow performance of the SJM valves has been associated with a low T.E. rate (Table 1). The many other reports confirming a low T.E. rate (Table 1). The many other reports confirming a low T.E. rate (Table 1). The many other reports confirming a low T.E. rate for the SJM patients maintained on anticoagulants have been enumerated above. In all comparative studies reported to date, the SJM prostheses have had lower T.E. rates than any other mechanical valve replacement. This substantial reduction in T.E. with the SJM prosthesis has significantly narrowed the gap in T.E. incidence that has existed between mechanical and tissue prostheses.

Especially noteworthy have been the studies from the Univ. of Dusseldorf Medical Center staff who have compared not only hemodynamics (Tables 3,4) but also thromboembolism (Table 5) in their patients with a number of different types of prostheses implanted and followed in the same center. In both categories, the SJM prostheses were superior generally by a wide margin.

Loop and associates[21] from the Cleveland Clinic have recently evaluated their clinical results with use of the SJM prosthesis in patients with particular reference to a small aortic root (sizes 19-23 inc.) and thromboembolism. They concluded their report as follows: "The excellent hemodynamic function of the St. Judge Medical aortic valve prosthesis, the consistent clinical success, and the low throboembolic rate are the reasons for continues use of this prosthesis in patients with small aortic root."

Table 3. Hemodynamic Comparisons at Rest of Six Different Mitral Valve Prostheses with Equal Tissue Annulus Diameters.

*From Horstkotte et. al.[22]

	BSM n=19	HKM n=5	ISM n=7	LKM n=12	SEM n=12	SJM n=20
ext. diameter	29mm	29mm	29mm	28.5mm	30mm	29mm
GOA	4.52cm²	4.52cm²	5.07cm²	3.80cm²	2.85 cm²	4.41cm²
dp (mm Hg)	4.5±1.6	5.2±3.3	5.3±1.6	7.1±1.3	6.3±2.0	2.3±0.6
Q (cm²)	2.2±0.5	1.9±0.5	1.9±0.8	1.7±0.3	1.8±0.4	3.1±0.8
eff./geom. OA	0.49	0.42	0.38	0.45	0.62	0.70

BSM = Bjork-Shiley; HKM = Hall-Kaster; ISM = Ionescu-Shiley; LKM = Lillehei-Kaster; SEM = Starr-Edwards; SJM = St. Jude. GOA = geometric orifice area of the prostheses, dp = diastolic pressue gradient, Q = effective orifice area, calculated using GORLIN formula. The effective to geometric valve orifice area ratios is given in the last line.

Table 4*. Calculations of Pressure Loss (dp) and Orifice Areas Under Light Bicycle Exercise. Abbreviations see Table 3.

*From Horstkotte et.al.[22]

	BSM n=19	HKM n=5	ISM n=7	LKM n=12	SEM n=12	SJM n=20
ext. diameter	29mm	29mm	29mm	28.5mm	30mm	29mm
GOA	4.52cm²	4.52cm²	5.07cm²	3.80cm²	2.85cm²	4.41cm²
dp (mm Hg)	9.4±2.8	16.5±1.7	11.2±2.3	15.2±4.0	11.9±3.6	6.4±3.0
Q (cm²)	2.8±0.6	2.3±0.6	2.1±0.9	2.2±0.4	2.0±0.4	3.4±0.7
eff./geom. OA	0.62	0.51	0.41	0.58	0.70	0.76

Table 5. Thromboembolic Complications*

Within a Comparable Follow-up Time (34 months) after Mitral (MVR), Aortic (AVR), and Double Valve Replacement (DVR) using Bjork-Shiley (BS) and St. Jude Medical (SJM) Prostheses

*From Horstkotte et. al.[23]

	MVR		AVR		DVP	
	BSM	SJM	BSA	SJA	BSM+BSA	SJM+SJA
n =	442	167	393	147	105	64
mean follow-up (months)	23.1±10.2	23.2±10.3	22.1±10.1	22.2±9.4	21.4±10.4	21.4±10.7
Cerebral	13(2)	2	6(1)	1	4(1)	
Peripheral	5	1	3		1	1
Abdominal, renal and others	3(2)		2(1)	1	1	
Valve thrombosis	3		3			
Σ	24(4)	3	14(2)	2	6(1)	1
TE/100 pat.-years	2.82 (0.47)	0.93	1.93 (0.28)	0.73	3.20 (0.53)	0.88

( ) fatal complications

CONCLUSIONS

(1) Durability of the St. Jude prosthesis to date, both on the basis of accelerated fatigue testing and clinical trials, has been excellent. (2) Hemolytic anemia has been absent. (3) Thromboembolism has had a very low incidence with anticoagulation therapy. (4) Hemodynamics have been consistently and significantly superior to all other prostheses studied.

The SJM prosthesis has been removed from investigational status by the FDA, and has been approved for worldwide distribution and clinical use.

REFERENCES

1. Warden, H.E., Cohen, M., Read, R.C., Lillehei, C.W. : *Controlled cross circulation for open intracardiac surgery. J Thorac Surg 28:331, 1954.*
2. Lillehei, C.W., DeWall, R.A., Gott, V.L., Varco, R.L. : *The direct vision of calcific aortic stenosis by means of a pump-oxygenator and retrograde coronary artery perfusion. Diseases of the Chest 30:123-132, 1956 (Aug.).*
3. Lillehei, C.W., Gott, V.L., DeWall, R.A., Varco, R.L. : *Surgical correction of pure mitral insufficiency by annuloplasty under direct vision. Journal Lancet 77:446-449, 1957 (Nov.).*
4. Lillehei, C.W., Gott, V.L., DeWall, R.A., Varco, R.L. : *The surgical treatment of stenotic or regurgitant lesions of the mitral and aortic valves by direct vision utilizing a pump oxygenator. J. Thorac Surg 35:154-191, 158 (Feb.).*
5. Long, D.M., Sterns, L.P., DeRiemer, R.H., Warden, H.E., Lillehei, C.W. : *Subtotal and total replacement of the aortic valve with plastic valve prostheses: experimental investigation and successful clinical application utilizing selective cardiac hypothermia. The Surgical Forum 10:660-665, 1960. American College of Surgeons, Chicago.*
6. Harken, D.E., et al. : *Partial and complete prostheses in aortic insufficiency. J. Thorac Cardiovas. Surg 40:774-762, 1960.*
7. Kalke, B.R., Mantini, E.L., Kaster, R.L., Carlson, R.G., Lillehei, C.W. : *Hemodynamic features of a double-leaflet prosthetic heart valve of new design. Transactions of the American Society for Artificial Internal Organs 13:105-110, 1967.*
8. Kalke, B.R., Carlson, R.G., Lillehei, C.W. : *Hingeless double-leaflet prosthetic heart valve for aortic, mitral or tricuspid positions: experimental study on replacement in the mitral position. Biomedical Sciences Instrumentation 4:190-196, 1968.*
9. Kalke, B.R., Lillehei, C.W., Kaster, R.L. : *Evaluation of a double-leaflet prosthetic heart valve of new design for clinical use. Prosthetic Heart Valves, 285-302, Brewer, L.A. III (Ed.) Charles C. Thomas, Springfield, Ill., 1969.*
10. Nicoloff, D.M., Emery, R.W. : *Current status of the St. Jude cardiac valve prosthesis. Contemporary Surgery 15:11-25, 1979.*
11. Emery, R.W., Anderson, R.W., Lindsay, W.G., Jorgensen, C.R., Wang, Y., Nicoloff, D.M. : *Clinical and hemodynamic results with the St. Jude Medical aortic valve prosthesis. Surgical Form 30:235-238, 1979.*
12. Emery, R.W., Mettler, E., Nicoloff, D.M. : *A new cardiac prosthesis: the St. Judge Medical cardiac valve: in vivo results. Circulation Part II 60:48-54, 1979.*
13. Gabbay, W., Yellin, L., Frishman, W.H., Frater, W.M. : *In vitro hydro-dynamic comparison of St. Jude, Bjork-Shiley and Hall-Kaster valves. ASAIO 16:231-235, 1980.*
14. Chaux, A., Gray, R.J., Matloff, J.M., Feldman, H., Sustaita, H. : *An appreciation of the new St. Jude valvular prosthesis. J. Thorac Cardiovasc Surg 81:202-211, 1981.*
15. Wortham, D.C., Tri, T.B., Bowen, T.E. : *Hemodynamic evaluation of the St. Jude Medical valve prosthesis in the small aortic anulus. J. Thorac Cardiovasc Surg 81:615-620, 1981.*
16. Horstkotte, D., Haerten, K., Herzer, J.A., Seipel, L., Bircks, W., Loogen, F. : *Preliminary results with mitral valve replacement with the St. Jude Medical prostheses: Comparison with the Bjork-Shiley valve. Circulation 64 (Suppl II):203-209, 1981.*
17. Nicoloff, D.M., Emery, R.W., Arom, K.V., Northrup,

W.F., Jorgensen, C.R., Wang, Y., Lindsay, W.G. : *Clinical and hemodynamic results with the St. Jude Medical cardiac valve prosthesis - A three year experience. J. Thorac Cardiovasc Surg 82: 674-684, 1981.*

18. Sutton, M.S.J., Roudaut, R., Oldershaw, P., Bricaud, H. : *Echocardiographic assessment of left ventricular filling characteristics after mitral valve replacement with the St. Jude prosthesis. Brit Ht J 45:365, 1981.*
19. Lillehei, C.W. : *Worldwide experience with the St. Jude Medical valve prosthesis: Clinical and hemodynamic results. Contemporary Surgery 20:17-31, January, 1982.*
20. Data from the St. Jude Medical Clinical Investigation submitted to the FDA as part of the Premarket Approval Application. Application approved December, 1982.
21. Gill, C.C., King, H.C., Lytle, B.W., Cosgrove, D.M., Golding, L.A.R., Loop, F.D. : *Early clinical evaluation after aortic replacement with the St. Jude Medical valve in patients with a small aortic root. Circulation 66 (Suppl I):I-147, 1982.*
22. Horstkotte, D., Haerten, K., Loogen, F., Schulte, H.D., Bircks, W., Budde, T. : *Rest and exercise hemodynamics after mitral valve replacement using diffeent prostheses. Circulation 66 (Part 2): 276, 1982.*
23. Horstkotte, D., Körfer, R., Seipel, L., Haerten, K., Loogen, F. : *Late complications following Bjork-Shiley and St. Judge Medical heart valve replacement. Circulation 66 (Part 2):313, 1982.*