

## Six Year Clinical Study of Use of the Omniscience Valve Prosthesis in 219 Patients

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A 6 year experience of cardiac valve replacement with the Omniscience prosthesis is described. A total of 253 valves were inserted in 219 patients. The survivors were followed up for a total of 536 patient-years and for a mean of 2.8 years. The follow-up was 97.6% complete. Analyses were performed in accordance with recommended criteria regarding definitions of complications and grading thromboembolic events for severity and analysis of anticoagulant status. Results are described both in terms of actuarial and linearized rates.

For the patients at risk, actuarial survival at the end of 5 years was  $87.9 \pm 3.1\%$  overall,  $90.4 \pm 3.0\%$  for single valve (aortic  $88 \pm 5\%$ , mitral  $93.3 \pm 4\%$ ) replacement and  $71 \pm 11\%$  for multiple valve replace-

ment. The actuarial rates of freedom from complications were as follows: endocarditis  $95.7 \pm 1.8\%$  (aortic  $94 \pm 3.5\%$ , mitral 100%), periprosthetic leak  $98 \pm 1\%$  (aortic  $96.2 \pm 2.6\%$ , mitral 100%), thromboembolism  $95.2 \pm 2.3\%$  (aortic  $90.9 \pm 4.6\%$ , mitral  $96.7 \pm 3.3\%$ ), valve thrombosis  $98.7 \pm 0.9\%$  (aortic 100%, mitral 100%), anticoagulant-induced bleeding  $90.3 \pm 2.6\%$  and all valve-related complications  $79.4 \pm 3.6\%$  (aortic  $78.8 \pm 3.6\%$ , mitral  $85.9 \pm 4.5\%$ ). The functional improvement in patients was very satisfactory and the risk of reoperation was 1.1% per patient-year. Over a 6 year time frame, the Omniscience valve has given excellent clinical performance.

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The ideal valvular prosthesis has yet to be designed and consequently work is continuing to improve on the available substitutes. The Omniscience cardiac valve, which is derived from and superior to its predecessor, the Lillehei-Kaster valve, is a good example. Housed in a one piece titanium frame, it is a low profile central flow valve that has a free floating concave-convex pivoting ocular disc made of pyrolytic carbon. We found these features attractive and began implanting these valves in 1979. The first Canadian Omniscience valve implantation was performed in Edmonton. To this date the 73 year old recipient is doing well.

Data on the Omniscience valve (1-3) are scarce because in the United States only primary investigative centers had been to obtain the valve before it was given full approval by the Food and Drug Administration in May 1985. There have also been some published data generated outside the

United States. Therefore, stimulated by the few reports of poor results in England and in Spain, we decided to analyze our experience in a retrospective study based on the pooled data from two Canadian centers.

### Methods

**Patients.** Data from all patients receiving the Omniscience valve were compiled between November 1979 and June 1985 in two Canadian centers: The University of Alberta Hospital in Edmonton (194 patients) and the Victoria Hospital in London, Ontario (25 patients). These centers have a wide referral base and many patients go back to outlying areas that are without immediate access to specialist centers.

A total of 253 Omniscience valves were inserted in 219 patients: 190 received a single valve replacement, 26 double and 3 triple. The follow-up of current patients was done through office visits, telephone contact with the patients and their doctors and study of the hospitals' and the referring doctors' charts. All information was recorded at the University of Alberta Hospital and processed for actuarial analysis and linearized rates for complications using an IBM PCXT computer and Revelation System.

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**Follow-up.** Current follow-up was obtained for 192 patients at risk (97.6%); only 2 patients were unavailable for follow-up. Three patients (1.5%) were removed from the study; two of these underwent Omniscience valve explantation and subsequently received a biologic prosthesis because of valve thrombosis in one and valve obstruction due to pannus formation in the other; the third patient was removed from the study for an undetermined reason. The patients at risk were followed up for a total of 536.4 patient-years with a mean follow-up time of 2.8 years and (maximum 6).

**Operative techniques.** Valve replacement was carried out using cold cardioplegia and standard techniques; particular attention was paid to anular preparation, valve sizing and orientation. Interrupted Teflon buttressed mattress sutures were routinely used in valve insertion.

**Anticoagulation.** Anticoagulant therapy began when the patient was able to tolerate oral fluids, usually on the second or third day. When discharged the patients were advised to have their physician maintain their prothrombin times at 2 to 2½ times normal. One hundred eighty patients (92.8%) were receiving warfarin alone, two (1%) were receiving warfarin and dipyridamole (dipyridamole was added after the occurrence of a transient ischemic attack) and three (1.5%) were receiving aspirin alone (pediatric age group). Two patients (1%) were not taking any anticoagulant. Anticoagulant status could not be determined in seven patients (3.6%), including two patients (1%) who were lost to follow-up.

**Patient profile.** The mean age for the whole group was 50.2 ± 14.5 years; (range 2 months to 75 years) (Table 1). The distribution of patients according to implant site and sex is shown in Table 2. There was a preponderance of rheumatic valvular disease as an indication for surgery (68.9%) (Table 3). Previous prosthetic valve malfunction in other prostheses (10%) and endocarditis (9.1%) were major indications. A large number of patients had previous cardiac surgery (Table 4). Concomitant major operative procedures were commonly performed (Table 5).

*Valve size bears an important relation to the valve-related complication.* In our series the mean anular tissue

**Table 2.** Distribution of 219 Patients According to Implant Site and Sex

Implant Site	No. of Patients			% of Total
	Male	Female	Total	
AVR	60	16	76	34.7
MVR	41	61	102	46.6
TVR	3	9	12	5.5
Multiple	8	21	29	13.2
Total	112	107	219	100

AVR = aortic valve replacement; MVR = mitral valve replacement; TVR = tricuspid valve replacement.

diameter for the aortic valve was 24.0 ± 2.5 mm, and for the mitral valve 27.6 ± 2.1 mm.

## Results

**Mortality.** The 30 day hospital mortality for the whole group, irrespective of cause of death, was 11.4% (25 of 219 patients). Mortality breakdown according to implant site is as follows: aortic valve 11.8% (9 of 76); mitral valve 11.7% (12 of 102); tricuspid valve 8.3% (1 of 12); single valve replacement 11.6% (22 of 190) and multiple valve replacement 10.3% (3 of 29 patients). There were 17 late deaths (7.7%); 5 in the aortic valve group (6.5%) and 5 in the mitral valve group (4.9%).

**Survival data.** For the patients at risk (survivors), actuarial survival at the end of 5 years was 87.9 ± 3.1 for the whole group (aortic valve 88.2 ± 5.1, mitral valve 93.3 ± 3.7) (Fig. 1). As expected, the patient's preoperative New York Heart Association functional classification and age at surgery had a tremendous impact on outcome. Five year survival in patients in preoperative functional classes II, III and IV was 97.6 ± 22.4%, 89.3 ± 4.4% and 80.2 ± 6.3%, respectively. Similarly, 5 year survival in patient age groups 0 to 40, 41 to 50, 51 to 60 and 61 to 80 years was 97.2 ± 2.8%, 92.3 ± 7.4%, 84.9 ± 5.3% and 81.2 ± 7.3%, respectively. A gratifying improvement in the patients' postoperative status occurred (Fig. 2).

## Complications

These are considered in patients at risk; stringent criteria were used to define complications.

**Endocarditis (Fig. 3).** Infective endocarditis occurred in seven patients at an annual rate of 1.3% per patient-year; this includes all episodes, including those in patients in whom endocarditis occurred on a native valve or those who previously had prosthetic valve endocarditis. Four cases occurred after aortic valve replacement and two each after tricuspid valve and combined aortic and mitral valve replacement. In three patients, endocarditis occurred as a complication of surgery: one tricuspid, one aortic and one triple valve replacement. The remaining four patients had endo-

**Table 1.** Distribution of 219 Patients By Age

Age Group (yr)	Patients	
	No.	%
0 to 10	3	1.4
11 to 20	5	2.3
21 to 30	14	6.4
31 to 40	27	12.3
41 to 50	42	19.2
51 to 60	78	35.6
61 to 70	44	20.1
71 to 80	6	2.7

**Table 3.** Cause of Valvular Disease in 219 Patients Undergoing 253 Valve Replacements

	AVR	MVR	TVR	Mult.	Total*
Rheumatic	30	87	7	27	151 (68.9)
Congenital	11	4	4	—	19 (8.7)
Calcific aortic valve disease	30	—	—	—	30 (13.7)
Endocarditis	9	6	—	5	20 (9.1)
Previous prosthetic valve malfunction	3	12	3	4	22 (10)
Other†	3	16	1	3	23 (10.5)

\*Figures in parentheses indicate percentages; some patients have multiple causes; †Includes ischemic and degenerative causes; Mult. = multiple valve replacement. Other abbreviations as in Table 2.

carditis before the insertion of the Omniscience valve. Two of these died (0.34% per patient-year). Three patients were treated medically and the remainder came to surgery. One patient who had preoperative endocarditis died 9 days postoperatively; because this was an early death, he has been excluded from the analysis.

**Periprosthetic leak (Fig. 4).** This complication, excluding those due to active endocarditis, occurred in three patients (0.6 per patient-year); two in the aortic position and one in the mitral. One patient had aortic valve replacement for aortic regurgitation and 16 months later a leak developed. The second patient had previous mitral valve replacement with another mechanical prosthesis; the Omniscience valve was implanted because of prosthetic endocarditis. He developed a periprosthetic leak and came to surgery 1 year later. Both of these patients were treated by simple resuturing of the prosthesis to the valve anulus.

The third patient was a 70 year old man with previous native aortic valve endocarditis. At the original operation he had required aortic valve replacement, open mitral commissurotomy, coronary artery bypass grafting and circulatory assistance with the intraaortic balloon pump. Six months later he died, and autopsy showed periprosthetic valve dehiscence (fatal periprosthetic leak 0.2% per patient-year).

**Thromboembolism (Table 6, Fig. 5).** Thromboembolic episodes during active endocarditis are excluded. Eighteen of the 194 patients at risk had episodes of thromboembolism. Of these, 11 patients had transient ischemic attacks only (2 after aortic, 6 after mitral, and 1 after tricuspid valve replacement and 2 after multiple valve replacement). These patients were advised to exercise a tight prothrombin time

control of their warfarin dosage and some were also prescribed dipyridamole. Five patients had an embolic deficit (0.9% per patient-year), four after aortic and one after mitral valve replacement.

**Valve thrombosis (Fig. 6).** This occurred in three patients (0.6% per patient-year), one of whom died (fatal valve thrombosis 0.2% per patient-year) 7 months after a triple valve replacement. This patient died before surgery and the thrombosed valve was confirmed on autopsy. Of the nonfatal valve thromboses, one occurred in a 27 year old woman who at age 21 had had tricuspid valve replacement with a Beall prosthesis. Six years later it malfunctioned when she became pregnant and stopped taking warfarin. At the time of delivery she presented in extremis and required emergency tricuspid valve replacement with the Omniscience valve. One year later she again presented with a malfunctioning prosthesis and her Omniscience 31 valve was replaced with a smaller size and excellent results. The other patient was a 47 year old man who had a valve thrombosis 5½ years after mitral valve replacement, which was then replaced with a biologic prosthesis. At the time of the first operation, it was noticed that he had a giant left atrium with thrombus in it. Both of these patients are doing well. In the event free curve for valve thrombosis (Fig. 6) it should be noted that one patient had a valve thrombosis 5½ years after mitral valve replacement. Given the small number of patients with mitral valve replacement that have participated in this 6 year study we believe that no meaningful statistical percentage can be calculated for this event and hence it has been excluded from the event-free curve for mitral valve replacement.

**Table 4.** Previous Major Cardiac Operative Procedures in 219 Patients

Operative Procedure	AVR	MVR	TVR	Multiple	Overall
Coronary artery bypass grafting	2	1	—	2	5
Tricuspid annuloplasty	—	3	—	1	4
Mitral commissurotomy	3	17	2	4	26
Previous prosthetic valve	4	17	6	11	38
Other	2	5	3	—	10

Abbreviations as in Table 2.

**Table 5.** Concomitant Major Cardiac Operative Procedures in 219 Patients

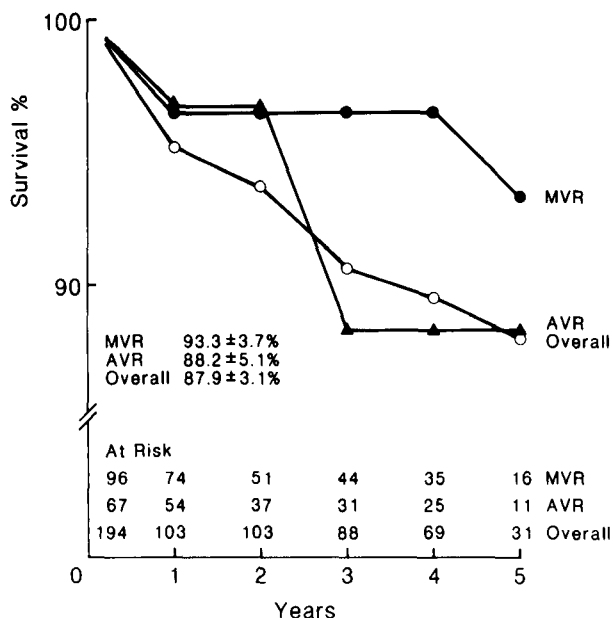
Operative Procedures	AVR	MVR	TVR	Multiple	Overall
Coronary artery bypass grafting	16	9	2	3	29
LV aneurysm repair	1	1	1	—	3
Ascending aortic graft	2	—	—	—	2
Tricuspid anuloplasty	—	6	—	3	9
Mitral anuloplasty	1	—	—	—	1
Mitral commissurotomy	2	—	1	—	3
Enlargement of narrow aortic root	2	—	—	—	2
Valve replacement other than omniscience	1	3	2	—	6
Total					55

Abbreviations as in Table 2.

**Pannus formation.** Reoperation demonstrated that one patient had valve dysfunction due to pannus formation (0.2% per patient-year). This occurred about 1 year after mitral valve replacement. At operation the Omniscience valve was replaced with a tissue valve. Percent freedom from valve obstruction due to pannus formation was  $98.7\% \pm 1.3$  for mitral valve replacement, 100% for aortic valve replacement and  $99.4\% \pm 0.6\%$  overall.

**Hemolysis.** This was noted in one patient (0.2% per patient-year), and was nonfatal. This patient showed evidence of hemolysis 4 months after aortic valve replacement and previously had the mitral valve replaced with another mechanical prosthesis. She later developed a periprosthetic leak. Freedom from hemolysis was 100% for mitral valve replacement,  $98.4\% \pm 1.6$  for aortic valve replacement and  $99.5\% \pm 0.5$  overall.

**Figure 1.** Five year actuarial survival for patients at risk. AVR = aortic valve replacement; MVR = mitral valve replacement.

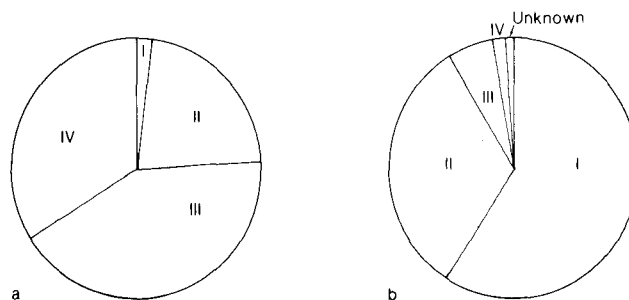


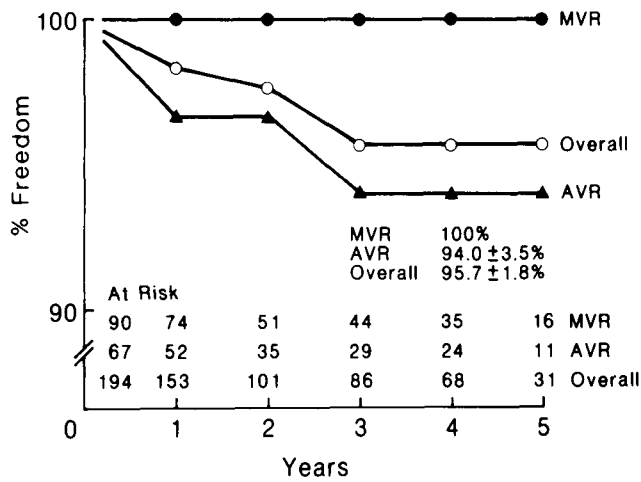
**Anticoagulant-induced hemorrhage (Fig. 7).** This does not include minor episodes such as epistaxis and cutaneous bleeding. A total of 14 patients had moderate to severe hemorrhage, which was fatal in none (2.6% per patient-year). The event-free curve in Figure 7 does not include three patients who had early hemorrhage: one cardiac tamponade 6 days postoperatively, one intracerebral hemorrhage 5 days postoperatively and one hematoma at a pacemaker site 12 days postoperatively. Although it is usual not to include early postoperative bleeding episodes, all of these patients were receiving warfarin and their prothrombin time was above therapeutic range; therefore, it seems unfair to us to exclude these patients from the analysis.

**Reoperation at site of valve prosthesis.** Eight patients underwent reoperation (1.5% per patient-year) for valvular complications. The indications were endocarditis in three, periprosthetic leak in two, obstruction due to pannus formation in one and valve thrombosis in two. Two patients with endocarditis died after reoperation. Note must also be made of two patients, one with valve thrombosis and one with a periprosthetic leak, who died before they could receive corrective surgery.

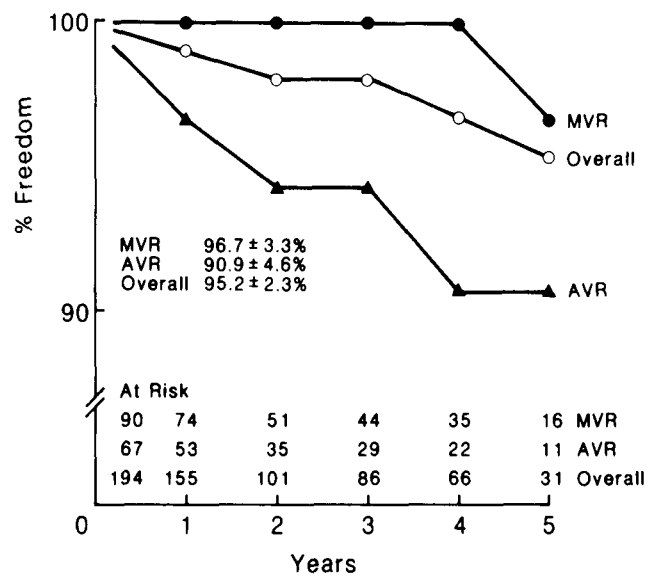
**Overall complications.** Figure 8 shows an event-free curve for freedom from all complications.

**Figure 2.** Patient improvement in terms of functional status (New York Heart Association functional classification). a, preoperative; b, postoperative.

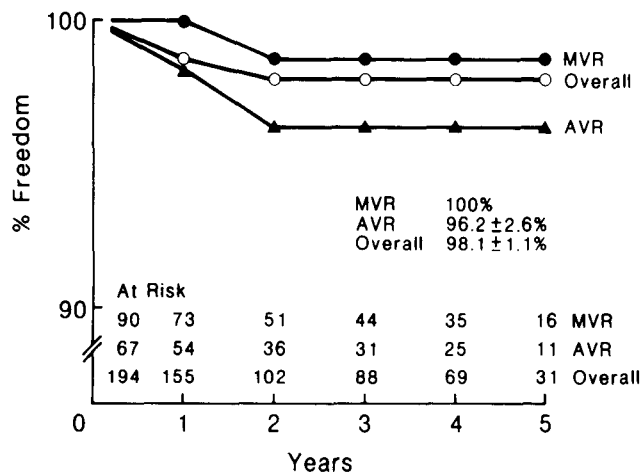




**Figure 3.** Five year actuarial rates for freedom from endocarditis. Abbreviation as in Figure 1.



**Figure 5.** Five year actuarial rates of freedom from thromboembolic complications. Abbreviation as in Figure 1.



**Figure 4.** Five year actuarial rates of freedom from periprosthetic leak. Abbreviation as in Figure 1.

**Discussion**

Since the 1960s, prosthetic replacement of acquired and congenital valvular lesions has been widely accepted and well established. During the last two decades a wide variety of prosthetic devices have been developed and continue to

be tested. The debate on the merits of mechanical versus biologic prostheses continues and the assessment of the long-term results of these valve replacements continues. The major areas of concern regarding prosthetic valves are hemodynamic performance, durability, thrombotic potential and risk of bleeding due to anticoagulant therapy.

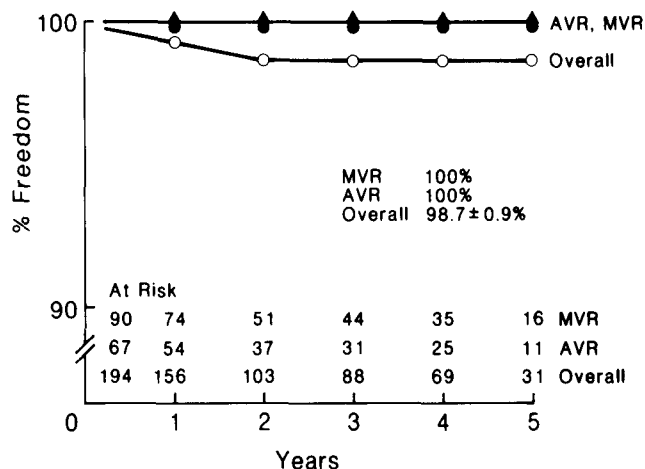
**Operative mortality.** Although there have been few reports on the Omniscience prosthesis, in vivo (4,5) and in vitro (6) data indicate excellent hemodynamic performance. Operative mortality is more in keeping with the patient's preoperative status and other surgical factors than with valve-related variables. In our series, no operative deaths were due to valve-related complications. The significance of late deaths is more complex especially when valve-related and unrelated variables are included as shown by our data on survival based on the patient's preoperative functional classification and age.

Our series has a high percentage of patients coming for reoperation (44 [20%] of 219) having valve malfunction of complicated origin such as endocarditis (20 [9.1%] of 219) and previous prosthetic valve malfunction (22 [10%] of

**Table 6.** Thromboembolic Complications in Patients at Risk

Thromboembolic Complication	No. of Patients	Linearized Rate (% per patient-yr.)	Site	No. of Patients
TIA only	11	2.1	Visual symptoms	7
			Vertigo/numbness	4
Embolism with recovery of deficit	1	0.2	Cerebral	1
Embolism with residual deficit	3	0.6	Cerebral	2
			Retinal artery	2
Fatal	1	0.2		1

TIA = transient ischemia attacks.



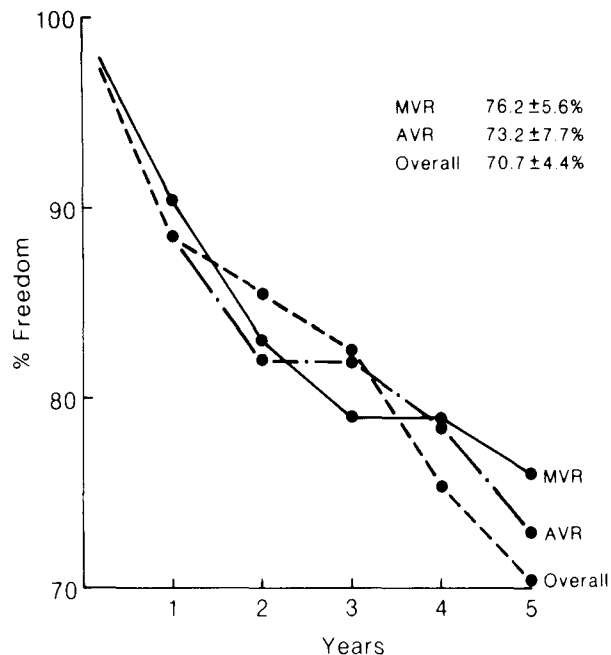
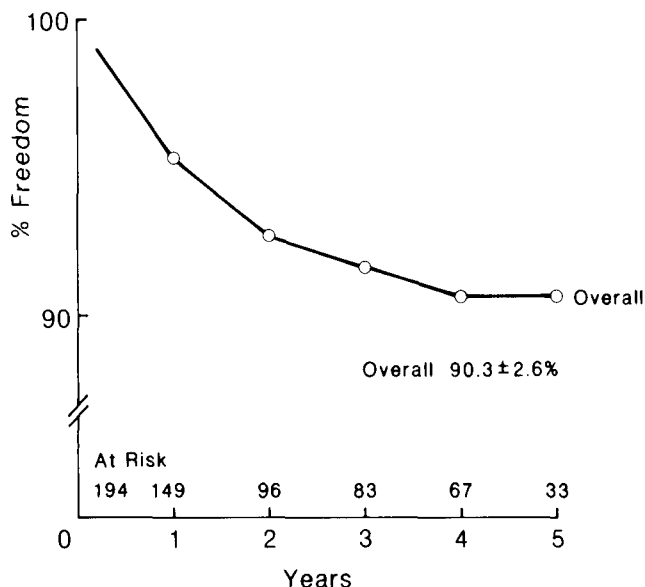
**Figure 6.** Five year actuarial rates of freedom from valve thrombosis. Abbreviation as in Figure 1.

219). This may have been responsible for our somewhat higher hospital mortality.

**Late mortality.** The overall actuarial survival in our group at the end of 5 years was  $87.9 \pm 3.1\%$ ; this compares favorably with that reported by others. The number of late deaths in the aortic valve replacement group are more than in the mitral valve replacement group, possibly because of the incidence of ischemic heart disease in the former. The risk of endocarditis seemed to abate after the third year; endocarditis was not seen in 86 patients at risk after the third year. However, the mortality for reoperation for endocarditis remains high.

**Complications (valve thrombosis and thromboembolism).** The difficulties regarding comparison among different reports on valvular prostheses are well described (7,8).

**Figure 7.** Five year actuarial rates of freedom from anticoagulant-induced hemorrhage.



**Figure 8.** Five year actuarial rates of freedom from all valve related complications. Abbreviation as in Figure 1.

However, we believe that our study of the complications in these 194 patients compares favorably with the studies (7,9-14) on patients with mechanical prostheses with respect to thrombotic complications and anticoagulant-induced hemorrhage. Our results are well within the respectable range (15). It has been well established that the risk of overall thrombotic complications appears, on the whole, to be linearly related for up to 5 years. Limitation of disc movement due to pannus formation can secondarily result in thrombosis, and we took particular care to ascertain the primary event as either valve thrombosis or disc obstruction.

*Thromboembolism is a linear related event* and it is probable that with additional follow-up more thromboembolic events will occur. Most of the thromboembolic events in our 6 year follow-up were of a minor nature (transient ischemic attacks). The ratio of valve thrombosis to total thromboembolic events was 15% (three valve thromboses in a total of 20 thrombotic events), which again compares well with data reported by others (16). We find that the thrombogenic properties of this valve are well within the accepted range. Although we have details of anticoagulant therapy (drug used, patient compliance, therapy interruption, usual prothrombin time ratio) in most patients, because of the small numbers involved we are unable to determine statistically their influence on thrombotic complications. However, it should be noted that one of our patients with Ebstein's anomaly and repeat tricuspid valve replacement for prosthetic valve thrombosis had a second thrombosis. We believe that this was caused by an oversized prosthesis, and since the insertion of a small prosthesis, she has been asymptomatic for the last 18 months. On the other hand,

there were two patients (one with tricuspid valve replacement who had not taken warfarin after surgery for 22 months and another who had aortic valve replacement who did not take warfarin for 9 months after surgery) who had apparent complications and remain well. The addition of dipyridamole to warfarin may significantly reduce thrombotic complications (17) in the future and we believe that this approach should be explored.

**Comparison with previous studies.** Our results for thrombotic complications are at marked variance with the experience with this prosthesis reported by others (1,2). Fananapazir et al. (2) observed thromboembolism in 14 of 96 patients (9.4% per patient-year), and Rabago et al. (1) observed it in 6 of 146 patients (2.6% per patient-year). Both series had a mean follow-up of only about 1.5 years compared with our 2.8 years. Despite our longer follow-up and larger number of patients our incidence of thromboembolism was only 0.6% per patient-year; one after mitral, one after tricuspid and one after triple valve replacement. As pointed out before, we believe that the patient with tricuspid valve replacement had an oversized prosthesis. We consider, as do others (3,18,19), that technical factors relating to the Omniscience prosthesis such as valve size, orientation (20) and compromise of anticoagulation are extremely important. Biologic abnormalities from stagnation (atrial fibrillation) and rheumatic etiology may have also played a role in the previous poor results with this valve (1,2).

**Other complications.** Our results for periprosthetic leakage (0.6% per patient-year) also contrast sharply with those of Fananapazir and Rabago and co-workers (1,2). Here again the roles of technical factors (21,22) and of nontechnical factors like endocarditis and myxoid degeneration have clearly been established. When the broad definition of "valve failure" is used (any complication resulting in death or reoperation including that for anticoagulant-induced hemorrhage), then a total of 18 patients can be classified in this group (endocarditis 4, pannus/tissue obstruction 1, valve thrombosis 3, thromboembolism 1, periprosthetic leak 3, and anticoagulant hemorrhage 7). This gives an annual rate of 3.4 per patient-year. We have further studies in progress on this prosthesis and preliminary data suggest that the results are even better.

**Conclusions.** The incidence of complications in our series equals or betters those previously reported (7). Hemorrhagic complications caused by anticoagulant agents seem to be to some extent unavoidable. On the other hand, the durability of the Omniscience valve has been unmarred by disruption or by structural failure. The quality of life after surgery has been satisfactory as shown by the marked improvement in functional status. Our data indicate that the Omniscience valve is safe, has a low incidence of complications and provides excellent performance.

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