

40 Years Experience in Mitral Valve Replacement Using Starr-Edwards, St. Jude Medical and ATS Valves

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Background: We have used the Starr-Edwards ball (S-E) valve since 1963, the St. Jude Medical (SJM) valve since 1978, and the ATS valve, since 1993 as the first choice of mechanical valve. In this study, the results with each valve during the 40 years were investigated in single mitral valve replacement (MVR) cases.

Patients and Methods: The mean age for S-E valves was 32.8 ± 11.1 years old (y.o.), for SJM it was 47.2 ± 12.6 y.o. and for ATS it was 56.3 ± 11.4 y.o., indicating the aging of patients over time. The operative mortality decreased over the same time from 10.3% to 5.2% then 1.4% respectively. A significant difference was observed among the 3 groups with regards to the valve-related complication-free rate and cardiac event-free rate. However, there was no significant difference among the 3 groups with the other complications.

Conclusion: Although there are many cases of valve-related complications with S-E valves, they have a role as an initial stage mechanical valve. In view of the long-term results extending over 20 years, the SJM valves is considered as the most reliable valve. The ATS valve is expected to achieve favorable results in the future because it may improve the quality of life (QOL) of patients and produce fewer valve-related complications. (*Ann Thorac Cardiovasc Surg* 2006; 12: 249–56)

Key words: mitral valve, mitral valve replacement, quality of life, valvular disease

Introduction

Mitral valve replacement (MVR) using the Starr-Edwards ball (S-E) valve, was first performed by Starr and Edwards, in 1960.¹⁾ Various mechanical valves have been developed during the subsequent 40 years.^{2,3)} This is not only due to the development of prosthetic valves, but also to progress in extracorporeal circulation methods, myocardial protection and postoperative controls. The surgical treatment of valvular disease has improved and

consistent follow-up results have been achieved through the maintenance of anticoagulation and antiplatelet therapy. However, an ideal mechanical valve has yet to be developed because various problems still occur during long-term follow-up. Recently, hemodynamic improvements in biological valves have been acknowledged and favorable reports have been published, suggesting improved durability in comparison with the past biological valves. The market share of biological valves has reached close to 60% in the USA. Although mechanical valves accounted for 90% of market share in the past, the biological valves is currently encroaching upon the mechanical valves market gradually in Japan.²⁾ However, the global market share of mechanical valves is still 50% or more and this trend is not expected to change in the future.

We have been using the S-E valves since 1963, the St.

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Table 1. Patient's background

	S-E	SJM	ATS	<i>p</i> value
Number	58	135	71	
Age (y.o.)	32.8±11.1	47.2±12.6	56.3±11.4	<0.001
Gender (male:female)	27:31	69:66	33:38	ns
Diagnosis				
MS	13	35	18	
MR	25	55	37	ns
MSR	16	30	11	
Reoperation	4	15	5	
Lost follow-up	15.5%	1.5%	0%	
Mean follow-up (years)	16.9	11.5	3.6	
Maximum follow-up (years)	36.4	21.7	10.5	
Cumulative follow-up (years)	940.9	1,564.1	257.9	

S-E, Starr-Edwards ball valve; SJM, St. Jude Medical valve; ATS, ATS valve; y.o., years old; MS, mitral stenosis; MR, mitral regurgitation; MSR, mitral stenosis and regurgitation; ns, not significant.

Jude Medical (SJM) valves (St. Jude Medical Inc., St. Paul, MN, USA) since 1978 (the first case in Japan), and the ATS valves (ATS Medical Inc., Minneapolis, MN, USA) since 1993, which is our preferred choice of mechanical valves. In this regard, the changes and results achieved with each valve during the 40 years as well as the future prospects were investigated in single MVR cases.

Patients and Methods

Patient population

A total of 264 patients received single MVR using mechanical valves at Itabashi Hospital of Nihon University School of Medicine from November 1963 to March 2004. S-E, SJM and ATS valves were used in 58, 135 and 71 cases respectively. The mean age of the S-E valve cases was 32.8±11.1 years old (y.o.) (10–58 y.o.), that of the SJM valve cases was 47.2±12.6 y.o. (11–71 y.o.) and that of the ATS valve cases was 56.3±11.4 y.o. (24–72 y.o.), indicating the aging of patients along with the lapse of time. A significant difference was observed among the valves ($p<0.001$). By gender, 27 males and 31 females used the S-E valves, 69 and 66 used the SJM valves, and 33 and 38 used the ATS valves. In preoperative diagnosis there were 13 patients for mitral stenosis (MS), 25 for mitral regurgitation (MR) and 16 for MS and regurgitation (MSR). In the S-E valve group, there was 1 after MVR using a SAM valve, 1 after closed mitral commissurotomy (CMC) and 2 after open mitral commissurotomy (OMC) operation. There were 35 MS, 55 MR and 30 MSR patients as well as 4 after MVR operation (S-E valve: 2, Carpentier-Edwards valve: 2), 3 after CMC and

8 after OMC operation in the SJM valve group. There were 18 MS, 37 MR and 11 MSR patients as well as 4 after MVR operation (S-E valve: 2, SJM valve: 2) and 1 after OMC operation in the ATS valve group (Table 1).

Follow-up

The postoperative course of patients was observed by the heart surgeons and cardiologists at the outpatient ward of this hospital as well as by general practitioners. The postoperative events were assessed according to the guideline for postoperative assessment of valvular diseases established by The Society of Thoracic Surgeons/The American Association for Thoracic Surgery (STS/AATS).⁴⁾

Assessment of prosthetic valve noise

Beyond 1 year following operation, patients were interviewed to investigate the prosthetic valve noise. The noise index proposed by us in the past was used to assess the stress imposed by prosthetic valve noise. The noise index indicates the stress of prosthetic valve noise in a value from zero (0, no stress) to 10 (maximum stress).⁵⁾

Anticoagulant therapy

In our institution, the following anticoagulation therapy and antiplatelet therapy has been performed since 1988: warfarin plus ticlopidine (Panaldine, 200 mg/day, Daiichi Pharmaceutical Co., Ltd., Tokyo, Japan) or dipyridamole (Persantin, 300 mg/day, Nippon Boehringer Ingelheim Co., Ltd., Hyogo, Japan). Bucolome (Paramidin, 300 mg/day, Takeda Pharmaceutical Co., Ltd., Osaka, Japan and Grelan Pharmaceutical Co., Ltd., Tokyo, Japan) was ad-

ditionally administered to control the patients requiring 4 mg or more of warfarin. Only warfarin was administered to these patients from 1963 to 1987. The international normalization ratio (INR) was 1.8–2.0. In this regard, patients complicated with atrial fibrillation and those with a left atrial diameter of 50 mm or more were controlled at the level of 2.0–2.5.

Statistical analysis

The actuarial survival rate and the postoperative event-free rate of complications were evaluated with the Kaplan-Meier method. Logrank analysis was employed for the statistical process. The remaining statistical processing was done by analysis of variance (ANOVA) or χ^2 test. The values were indicated in mean \pm standard deviation (SD) with $p < 0.05$ as a significant difference.

Results

Follow-up

The subsequent course of patients was investigated by this hospital or by the attending physicians of these patients at the follow-up hospitals. The follow-up rates of the S-E valve group was 84.5%, SJM valve group 98.5% and ATS valve group 100%. The mean numbers of follow-up years were 16.9 years (0–36.4 years), 11.5 years ($p = 21.7$ years) and 3.6 years (0.3–10.5 years). The cumulative numbers of follow-up years were 940.9 years, 1,564.1 years and 257.9 years respectively (Table 1).

Operative and late mortality

The operative death (in-hospital death) occurred in 6 (10.3%) for the S-E valve group, 7 (5.2%) for the SJM valve group and 1 (1.4%) for the ATS valve group. The causes of deaths in the S-E valve group were 4 by low output syndrome (LOS), 1 by left ventricular rupture and 1 by acute renal failure. In the SJM valve group, 5 by LOS, 1 by acute renal failure and 1 by left ventricular rupture and in the ATS valve group, 1 by acute renal failure. The late deaths occurred in 22 for the S-E valve group, 26 for the SJM valve group and 3 for the ATS valve group. The causes of deaths were 9 by heart failure, 3 by cerebral infarction, 3 by malignant tumor, 2 by arrhythmia, 1 each by pneumonia, periventricular leukomalacia (PVL), cerebral hemorrhage and sudden death in addition to 2 deaths by unknown cause in the S-E valve group, 8 by heart failure, 3 by arrhythmia, 3 by hemorrhage (2 by gastrointestinal hemorrhage, 1 by cerebral hemorrhage), 2 each by acute renal failure, dyspnea and malignant tu-

mor, 1 each by acute myocardial infarction, fulminant hepatitis and cerebral infarction and 2 by sudden death in addition to 1 death by an unknown cause in the SJM valve group, and 2 by heart failure and 1 by millary tuberculosis in the ATS valve group. There was no significant difference among the 3 groups in the actuarial survival rate of 9.6 years ($p = 0.11$) (Fig. 1). Cardiac complications occurred in 29 (3.55%/patient-year) in the S-E valve group, 34 (2.35%/patient-year) in the SJM valve group and 3 (1.19%/patient-year) in the ATS valve group. A significant difference among the 3 groups was observed in the cardiac event-free rates within the duration of 9.6 years ($p = 0.04$) (Fig. 2).

Valve-related complications

Valve-related complications occurred in 23 (2.99%/patient-year) in the S-E valve group, 25 (1.81%/patient-year) in the SJM valve group and 2 (0.77%/patient-year) in the ATS valve group. A significant difference among the 3 groups was observed within the duration of 9.3 years ($p = 0.04$) (Fig. 3).

Thromboembolism

Thromboembolism occurred in 7 (0.85%/patient-year) in the S-E valve group, 12 (0.83%/patient-year) in the SJM valve group and 1 (0.39%/patient-year) in the ATS valve group. No significant difference was observed among the 3 groups (Fig. 4).

Anticoagulant-related hemorrhage

Anticoagulant-related hemorrhage occurred in 1 (0.11%/patient-year) in the S-E valve group, 6 (0.39%/patient-year) in the SJM valve group and 0 (0%/patient-year) in the ATS valve group. No significant difference was observed among the 3 groups.

Valve thrombosis

Valve thrombosis occurred in 5 (0.57%/patient-year) in the S-E valve group, 4 (0.26%/patient-year) in the SJM valve group and 0 (0%/patient-year) in the ATS valve group. No significant difference was observed among the 3 groups.

Prosthetic valve endocarditis

Prosthetic valve endocarditis occurred in 1 (0.12%/patient-year) in the S-E valve group, 0 (0%/patient-year) in the SJM valve group and 0 (0%/patient-year) in the ATS valve group. No significant difference was observed among the 3 groups.

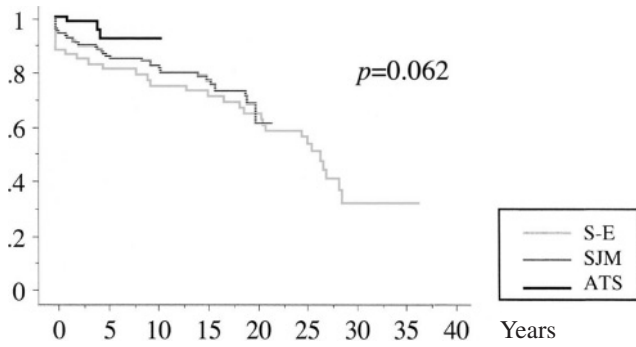


Fig. 1. Actuarial survival rate after mitral valve replacement. S-E, Starr-Edwards ball valve; SJM, St. Jude Medical valve; ATS, ATS valve.

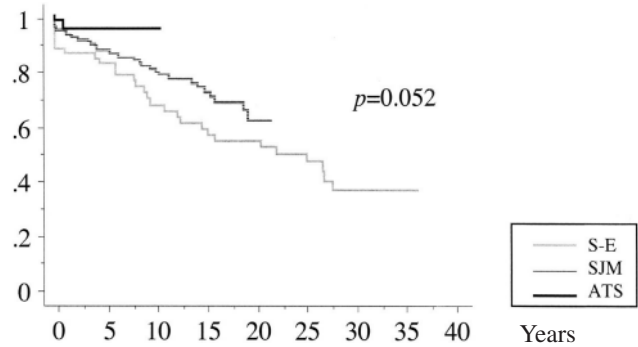


Fig. 2. Cardiac event-free rate after mitral valve replacement. S-E, Starr-Edwards ball valve; SJM, St. Jude Medical valve; ATS, ATS valve.

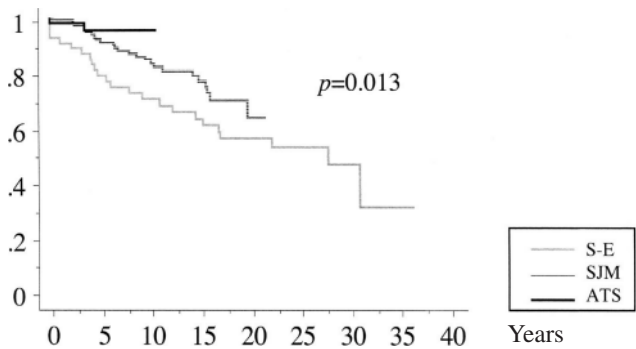


Fig. 3. Valve-related complication-free rate after mitral valve replacement. S-E, Starr-Edwards ball valve; SJM, St. Jude Medical valve; ATS, ATS valve.

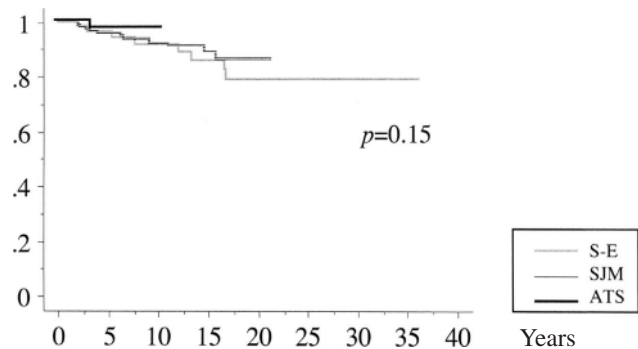


Fig. 4. Thromboembolic event-free rate after mitral valve replacement. S-E, Starr-Edwards ball valve; SJM, St. Jude Medical valve; ATS, ATS valve.

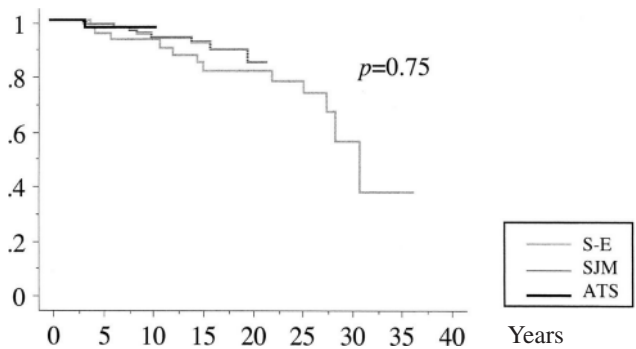


Fig. 5. Reoperation free rate after mitral valve replacement. S-E, Starr-Edwards ball valve; SJM, St. Jude Medical valve; ATS, ATS valve.

Reoperation

Reoperation was necessary in 12 (1.38%/patient-year) in the S-E valve group, 9 (0.61%/patient-year) in the SJM valve group and 1 (0.39%/patient-year) in the ATS valve

group. No significant difference was observed among the 3 groups (Fig. 5).

Structural dysfunction

Structural dysfunction occurred in 3 (0.34%/patient-year) in the S-E valve group, 3 (0.24%/patient-year) in the SJM valve group and 0 (0%/patient-year) in the ATS valve group. No significant difference was observed among the 3 groups.

Non-structural dysfunction

Non-structural dysfunction occurred in 1 (0.11%/patient-year) in the S-E valve group, 1 (0.06%/patient-year) in the SJM valve group and 0 (0%/patient-year) in the ATS valve group. No significant difference was observed among the 3 groups.

Questionnaire survey on prosthetic valve noise

The patients in the S-E valve group were all (100%) aware

of the noise of the prosthetic valve, while 72.6% in the SJM valve group and 13.0% in the ATS valve group were aware, indicating a significantly lower rate in the ATS valve group than the remaining 2 valve groups. The noise indices were 3.3 ± 3.2 , 1.8 ± 1.5 and 0.2 ± 0.6 points in the S-E, SJM and ATS valve groups respectively, indicating a significant difference among the 3 groups ($p < 0.001$). As for the reoperation cases, there were 4 patients who required another valve replacement (from S-E to SJM), 2 from S-E to ATS, 1 from SJM to ATS and 1 from Björk-Shiley valve (the valve replacement was performed at another hospital) to ATS. Compared with the former mechanical valves, all the patients became aware of the decrease in noise and this improved their quality of life (QOL).

Comment

Currently, more elderly patients are undergoing surgery and mortality is low. This could be due to the progress in cardiopulmonary bypass, cardioplegia and postoperative management that has made it possible for elderly patients to undergo surgery. Since MVR was performed for the first time in 1960 by Starr et al., the operative results of valvular diseases have drastically improved. According to a report made by Gao et al. on the results achieved in 40 years at Starr's institution, the 10-, 20- and 30-year mitral valve survival rates were 51%, 23% and 8% respectively.⁶⁾ Godje et al. reported that the 10-year, 20-year and 30-year mitral valve-related complication-free rates (operative mortality excluded) were 73.4%, 35.4% and 14.3% respectively and the 20-year and 30-year survival rates were 36.5% and 22.6% respectively.⁷⁾ At our institution, the 20-, 30- and 35-year cumulative mitral valve survival rates were 61%, 33% and 25% respectively (Fig. 3), indicating favorable results in comparison with the above mentioned 2 institutions. The reason why is unknown but the difference occurred partly because of the younger age of our patients (32.8 ± 11.1 y.o.) in comparison with theirs (55.5 ± 13.0 y.o.) in the report by Gao et al., and 40.1 ± 10.1 y.o. in the report by Godje et al. (including aortic valve replacement cases). Cloth wear is a serious complication attributable to some prosthetic valves. The incidence of cloth wear was reported to be 0.4–2.6%/patient-year on the basis of autopsy and reoperation result investigation.^{8–10)}

Regarding the indication of reoperation, although a preventive reoperation example of a ball valve from our experience in the durability of the ball valve is included

in this study, the indication of reoperation has been studied basically for the case that showed a valve related complication. As was reported in the past, reoperation of the S-E valve became necessary in 12 patients among those treated in our institution, and cloth wear or pannus was observed in all of them.¹¹⁾ Accordingly, we have been performing prophylactic reoperation since 2000 in our institutions even in the patients without heart failure symptoms or with mild heart failure symptoms not requiring reoperation, provided that the informed consent is obtained. The reoperation in this regard has been performed in 4 patients to date and all of them were discharged without complication. All of the extracted S-E valves demonstrated cloth wear. Marked thrombi attachment to the valve seat was observed in one of them, indicating that the prophylactic reoperation of the S-E valve was valid.

As mechanical valves have been studied and developed, non-tilting disc valves, tilting disc valves and bileaflet valves have followed S-E valves. The development progress of medical materials such as pyrolytic carbon has also contributed to the device development. Bileaflet valves with the central flow and better hemodynamic pattern improve both the surgical and late results, and have been used globally for nearly 30 years. The Gott-Daggett valves were the first bileaflet valves clinically used. The first implant of the SJM valves was performed in 1977 and about 1.5 million valves worldwide have been implanted. It also has been reported of long-term results in 20-year excess, the SJM valves become the most highly reliable valve. The first SJM valve in Japan was implanted in 1978 at our institution and favorable long-term results have been obtained.^{12,13)} However, antithrombotic performance still needs some improvement and the problems including hemorrhage related to anticoagulation therapy have yet to be solved. During an observation period of 10 years or more, the incidence of thromboembolism was 0.20–3.5%/patient-year, valve thrombosis was 0.06–0.12%/patient-year and hemorrhage related to anticoagulation therapy was 0.14–3.5%/patient-year.^{14–18)} The SJM valves release modified valves such as HP and Regent® series, and are currently the largest in global market share for aortic position.

The ATS valves are bileaflet valves developed by Villafana who also developed the SJM valve. It is said that its open pivot structure has superior functions in antithrombotic features and hemolysis to the conventional mechanical valves. We were the first institution to use the ATS valves in Japan in 1993, and they have become the first choice of mechanical valves.¹⁹⁾ After approval by

the Ministry of Health, Welfare & Labor in 1996, general use of the valves has become possible. Reports including the one made by our institution indicate the efficacy of the valves on the basis of their antithrombotic features, hemolysis and prosthetic valve noise.^{5,20–24)} Fewer valve-related complications were noted in the patients implanted with the ATS valves, indicating favorable results. Though it is just early stage results in the literature, Westaby et al. investigated 200 patients during the mean 20 months (maximum 3 years) of follow-up, and reported 2 cases of paravalvular leakage, 1 case of each thromboembolism and valve thrombosis of tricuspid valves.²²⁾ Shiono et al. conducted a 15-month follow-up in 77 patients to investigate the clinical trial results of these valves at 4 institutions in Japan, and reported that thromboembolism, TIA and paravalvular leakage occurred in 1, 3 and 1 patients. Concerning postoperative hemolysis measured by LDH, Shiono et al. reported that a decrease was observed earlier with the ATS valves than with the SJM valves, and that normalization was observed in the single valve cases.²⁰⁾ Westaby et al. also reported that the LDH value was 500 IU or less (normal range: 230–460 IU) in all cases with the ATS valve.²²⁾

Many of the patients who received valve replacement using mechanical valves complained of the noise of the prosthetic valve in addition to prosthetic valve-related complications including hemolysis and thromboembolism, etc. Even though this noise problem is very important in the QOL for the patient, not much research has been made in this direction. The authors interviewed the patients and assessed the noise of the prosthetic valve. The noise index proposed by the authors is “an index to express the degree of a patient’s complaint against prosthetic valve noise”.⁵⁾ This index was employed in the present study as a method to assess the patient’s complaint as well as the QOL. There was only small number of cases in the corresponding observation period, so was not possible to sufficiently investigate the S-E valve cases. However, changes requiring reoperation were made from the S-E valves to the SJM valves in 2 cases and to the ATS valves in 1 case, from the SJM valves to the ATS valves in 1 case, and from the Björk-Shiley valves (the valve replacement was performed at another hospital) to the ATS valves in 1 case. Compared with their former mechanical valves, all of the patients became aware of the decrease in noise and this improved their QOL. Compared with the 2 other valves, the noise index of the ATS valve was significantly lower and the QOL of the patients in regard to the noise was improved after the change. The

reason why the noise of the ATS valve is lower is unknown. In this regard, the authors made a report on the frequency characteristic of the valve in the past. It was clarified in the report that the sound pressure of the ATS valve is less than that of the SJM valve in the frequency range of 2–5 kHz to which the human is highly sensitive. Although this is still in the range of conjecture, reports have been made on the favorable results of the ATS valves attributable to the material used, the smaller stress at the time of leaflet collision and the flow dependent opening angle,^{25,26)} indicating that these factors are also involved in the lower noise of the ATS valves. At present, research is ongoing to determine why the noise of the ATS valves is lower by investigating the physique, age, blood pressure and pulse rate of patients, prosthetic valve function by ultrasonography of the heart, valve opening angle by cinefluoroscopy, bone density, bone conduction sound, etc.

The differences among these valves were observed in this study in the cardiac event onset, valve-related complications, age at the time of operation, presence or absence of awareness of prosthetic valve noise and noise index. Compared with the status at present, the heart failure therapy and anticoagulation therapy, etc. had not been established in the era of the S-E valves. In this regard, it is of interest to find out what long-term results could be obtained if the S-E valves were used now. However, considering the problems of the S-E valves including cloth wear and prosthetic valve noise as described in the foregoing, the superiority of current mechanical valves is not deniable even though the S-E valves are considered to have fulfilled their role as the initial stage mechanical valves. Few reports have been made on the comparison of various mechanical valves at the same institution. There are still few reports comparing the S-E valves and the SJM valves that are frequently used worldwide. Murday et al. conducted a prospective controlled trial in this regard using the S-E valves and the SJM valves. Excluding that prosthetic endocarditis occurred in the aortic position more frequently with the S-E valves in comparison with the SJM valves, they reported that hardly any difference was noted between the 2 valves in the operative mortality and thromboembolism, etc.²⁷⁾ Their result is considered as a very valuable research result. On the other hand, there is another report on the inferiority of the S-E valves to the SJM valves in the prosthetic valve functions regarding thromboembolism, pressure difference in the prosthetic valves, etc. In other words, the opinions are divided as to the assessment of these valves.^{28,29)} The re-

port made by Murday et al. was on the 10-year results but our results obtained from the S-E valve cases after 20 years from operation indicated pannus formation and cloth wear.²⁷⁾ Accordingly, there is much interest in future results. At present, the only available data on comparison of the ATS valves with other mechanical valves are the research on prosthetic valve noise and the comparison of valve function by ultrasonography of heart; both of which were conducted by us in the past.^{5,21)} It is only 10 years since the clinical application of the ATS valves started and reports of long-term results are anticipated. Because of the lower incidence of prosthetic valve-related complications and lower noise, the ATS valves are considered as the most reliable mechanical valve and it is consistently used as the first choice mechanical valve at our institution. Since this valve was concluded to be reliable in long-term follow-up results and QOL of the patients including artificial valve sound as well.

As for anticoagulation therapy, in the case of Japanese patients, there is a problem of bleeding when INR is controlled near 2.5. Therefore the case with INR control range of 2.0–2.5 has been managed and limited to the case of an atrial fibrillation with the left atria diameter of over 50 mm. No problem has been recognized so far, in those cases.

The result of this study indicated the aging of patients but the operative mortality has gone down in the lapse of time. The progress in extracorporeal circulation methods, myocardial protection and postoperative control are considered to have contributed more to the decrease in mortality rather than the improvement of the prosthetic valve itself. However, in view of the QOL of patients, the anticoagulation therapy is the most serious problem after replacement with mechanical valves. The development of superior mechanical valves with antithrombotic features is expected to further improve the QOL of patients.

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