*Case Report*

# A Case of Aortic Valve Replacement with St. Jude Medical Regent Valve (First Implant in Japan)

Akira Sezai, MD,[1] Motomi Shiono, MD,[1] Kenji Akiyama, MD,[1] Yukihiko Orime, MD,[1] Mitsumasa Hata, MD,[1] Mitsuru Iida, MD,[1] Isamu Yoshitake, MD,[1] Shinji Wakui, MD,[1] Makoto Taoka, MD,[1] Tomofumi Umeda, MD,[1] Nanao Negishi, MD,[1] Yukiyasu Sezai, MD,[1] and Yuji Kasamaki, MD[2]

**The St. Jude Medical (SJM) Regent® valve was developed as a new mechanical valve by improving the conventional SJM valve. The effective orifice area is wider than that of Hemodynamic Plus (HP) series. The efficacy of the new valve has been reported in Europe and the United States. On October 26, 2004, we first performed aortic valve replacement (AVR) with the SJM Regent® valve for aortic valve stenosis in Japan.**

**A 64-year-old female was admitted to our hospital with dyspnea on exertion. She was diagnosed with aortic valve stenosis. She underwent AVR with a 17 mm SJM Regent® valve. According to the results of echocardiography conducted two months postoperatively, the peak pressure gradient of the prosthetic valve was 32.0 mmHg, the mean pressure gradient was 13.2 mmHg, and the effective orifice area index (EOAI) was 0.92 $cm^2/m^2$. Cinefluoroscopy showed the valve opening angle of 85 degrees indicating full opening. She was discharged 15 days after surgery without complications.**

**As demonstrated by the present case, implantation of a 17 mm SJM Regent® valve produced a satisfactory result reflected by lower pressure gradient and absence of patient-prosthetic mismatch. In the future, the new valve is expected to be the optimum mechanical valve for a narrow annulus. (Ann Thorac Cardiovasc Surg 2005; 11: 329–34)**

**Key words:** prosthetic valve, valve replacement, St. Jude Medical valve

## Introduction

In 1952, Hufnagel et al. implanted a plastic ball valve in the descending aorta,[1)] and in 1960, Starr et al. used a ball valve for valve replacement.[2)] Since then, prosthetic valve replacement was rapidly introduced in many countries. Currently, the bileaflet valve has been used as an international standard valve because of its advantages in several aspects such as hemodynamics, antithrom-bogenicity and hemolysis. The St. Jude Medical (SJM; St. Jude Medical, Inc., St. Paul, MN, USA) valve was first clinically used in 1977. Its advantages in durability, antithrombogenicity and hemolysis have been reported in many institutes. The excellent long-term results of SJM demonstrated its efficacy and it has been positioned as the most widely used mechanical valve in the world.[3-6)] In our institute, we started to use the mechanical valve in July 1978 as the first case in Japan and it has shown good results.[3,7,8)] Recently, mechanical valves with wide effective orifice areas have been developed for a narrow annulus. These prosthetic valves have enabled valve replacement without annular enlargement.[9-11)] However, the problem of patient-prosthesis mismatch has not yet been solved[12)] and development of prosthetic valves with wider effective orifice areas is expected.

We were the first to perform aortic valve replacement (AVR) with a SJM Regent® valve in Japan, which was

*From Departments of [1]Cardiovascular Surgery and [2]Cardiology, Nihon University School of Medicine, Tokyo, Japan*

Received February 22, 2005; accepted for publication March 31, 2005.

Address reprint requests to Akira Sezai, MD: Department of Cardiovascular Surgery, Nihon University School of Medicine, 30-1 Oyaguchi-kamimachi, Itabashi-ku, Tokyo 173-8610, Japan.

**Fig. 1.** SJM Regent® valve.

said to have a wider effective orifice area than conventional prosthetic valves,[13,14] and report the clinical result along with the characteristics of this new valve (Fig. 1).

## Case Report

The patient was a 64-year-old female who was admitted to our hospital with dyspnea on exertion. Arrhythmia, hypertension and cardiac murmur, had been recognized seven years before, but were left untreated. She noticed shortness of breath five years ago and dyspnea on exertion six months ago. She was seen in the department of cardiology at our hospital, and was admitted for an examination. She was diagnosed with aortic valve stenosis by echocardiography. During the hospital stay, she suffered an attack of cholelithiasis. Cholecystectomy was carried out at our hospital. After surgery, she was diagnosed with aortic valve stenosis requiring surgical treatment by cardiac catheterization. Then, she was referred to our department. She was 158 cm in height and 56 kg in weight and her body surface area was 1.56 $cm^2$. Blood pressure was 110/70 mmHg and her pulse was 70 per minute. Chest X-ray showed cardiac enlargement (cardiothoracic ratio 60%) although there was no increase in pulmonary vascular shadow. The peak pressure gradient across the aortic valve was 141.9 mmHg and the effective orifice area was 0.45 $cm^2$ by transthoracic echocardiography (TTE) The ejection fraction (69.2%) and %FS (38.6%) demonstrated normal cardiac functions. A chest CT scan showed neither enlargement nor calcification of the ascending aorta although calcification of the aortic cusp and annulus was recognized. The cardiac catheterization showed the left ventricular end-diastolic pressure of 18 mmHg, the peak pressure gradient across the aortic valve of 101 mmHg, the mean pressure gradient of 89.0 mmHg and the effective orifice area of 0.52 $cm^2$. The cardiac function was normal because the cardiac index was 3.58 l/mim/$m^2$ and the left ventricular ejection fraction was 71%. She underwent AVR under cardiopulmonary bypass on October 26, 2004. The aortic valve was a bicuspid valve with marked calcification. AVR was undertaken in a supraannular position with a 17 mm SJM Regent® valve, using a noneverting suture 2-0 Ethibond (Ethicon, Inc., Somerville, NJ, USA). In the process of suturing the valve, pushing the threaded needle in and out of the sewing ring was smoothly completed and excellent fixation to the aortic valve ring was achieved. After implantation of the prosthetic valve, the orifice was rotated without difficulty. The postoperative course was uneventful and administration of heparin (10,000 U/day) was started from the day after surgery and continued for three days until warfarin control became effective. She was given warfarin and ticlopidine (200 mg/day, Panaldine; Daiichi Pharmaceutical Co., Ltd., Tokyo, Japan) from the day after surgery with international normalized ratio of prothrombin time (PT-INR) level controlled at approximately 1.8. The serum lactate dehydrogenase (LDH) was 355 IU/l, serum free hemosiderin, haptoglobinm, urine-hemosiderin were normal values 14 days after the surgery. The results of resting TTE and dobutamine stress echocardiography (DSE) conducted on 14 days after the surgery were satisfactory (Table 1). BNP decreased after the surgery: 148 pg/ml before the surgery, 120 pg/ml two weeks after the surgery, 78 pg/ml one month later and 70 pg/ml two months later. Cinefluo-roscopy showed a valve opening angle of 85 degrees indicating full opening. The mechanical valve noise was analyzed by using the high sensitivity microphone (TS-32235, NIHON KODEN CORP., Tokyo, Japan) and Sound Scope (GW Instruments Inc., Boston, Mass, USA)[15] and the peak sound pressure was 46 Hz. The patient was discharged 15 days after the surgery and returned to normal life. The results of TTE conducted after discharge were satisfactory as demonstrated by reduction of the left ventricular mass index (LVMI), peak pressure gradient and mean pressure gradient and increase in effective orifice area index (EOAI) (Table 1).

**Table 1. Transthoracic echocardiographic data**

| | Pre | 2W | 1M | 2M |
|---|---|---|---|---|
| LVDd (mm) | 46.1 | 41.5 | 48.5 | 45.8 |
| LVDs (mm) | 27.1 | 21.0 | 22.0 | 24.8 |
| EF (%) | 69.2 | 81.2 | 85.2 | 77.4 |
| %FS (%) | 38.6 | 49.5 | 54.5 | 45.9 |
| LVMI g/m$^2$ | 197.8 | 190.9 | 183.9 | 145.5 |
| Peak PG (mmHg) | 141.9 | 57.0 | 35.6 | 32.0 |
| Mean PG (mmHg) | - | 23.8 | 18.4 | 13.2 |
| EOAI (cm$^2$/m$^2$) | - | 0.64 | 0.88 | 0.92 |
| Regaigitation | mild | trivial | trivial | trivial |

LVDd, left ventricular diastolic diameter; LVDs, left ventricular systolic diameter; EF, ejection fraction; FS, fraction shorting; LVMI, left ventricular muscle index; PG, pressure gradient; EOAI, effective orifice area index

## Discussion

The first implantation of a SJM valve was performed in 1977. More than 1.5 million cases of its implantation have been reported all over the world to date. The long-term results of the SJM valve have been reported and it has been regarded as the most reliable mechanical valve in the world. In 1978, the first implantation of the SJM valve was carried out at our hospital and the long-term results were excellent.[3,7,8] Recently, in order to acquire a wider effective orifice area without annular enlargement for narrow annulus cases, a new series of mechanical valves have been developed for clinical application, such as Hemodynamic Plus (HP) series in SJM valve,[9] Advanced Performance (AP) series in ATS valve (ATS Med. Inc., MN, USA)[10] and TopHat series in CarboMedics valve (Sulzer Carbomedics Inc, Austin, TX, USA).[11] However, several cases of patient-prosthesis mismatch have been reported[12] and development of mechanical valves with wider effective orifice areas has been expected. The SJM Regent® valve has a modified external profile that achieves a larger geometric orifice area without changing the existing design of the pivot mechanism or blood-contact surface areas. This SJM Regent® valve has the horizontally extended sewing cuff, which can be securely fitted to various forms of annuluses (flex cuff).

Walker et al. evaluated a comparison of 19 mm valves in vitro. According to their data, the effective orifice area of the SJM Regent® valve was wider than that of the standard SJM valve by 46% and that of SJM HP valve by 16%. The Regent valve was advantageous from the hemodynamic data as demonstrated by the comparison of mean pressure gradients: 17 mm HP (18.93 mmHg), 17 mm Regent (11.99 mmHg); 19 mm standard (18.93 mmHg), 19 mm HP (10.49 mmHg), 19 mm Regent (6.69 mmHg); 21 mm standard (10.49 mmHg), 21 HP (5.68 mmHg), 21 Regent (3.45 mmHg).[13] 361 patients were implanted with a SJM Regent® valve in 17 institutes in North America and Europe and their clinical outcomes were reported (maximum follow-up period 2.7 years, mean follow-up period 0.8±0.7 years). Of 361 patients who underwent AVR, 17 patients (4.1%) died and 6 patients (1.7%) were lost to follow-up. Two patients experienced a valve-related death (stroke, hemorrhage). The in-

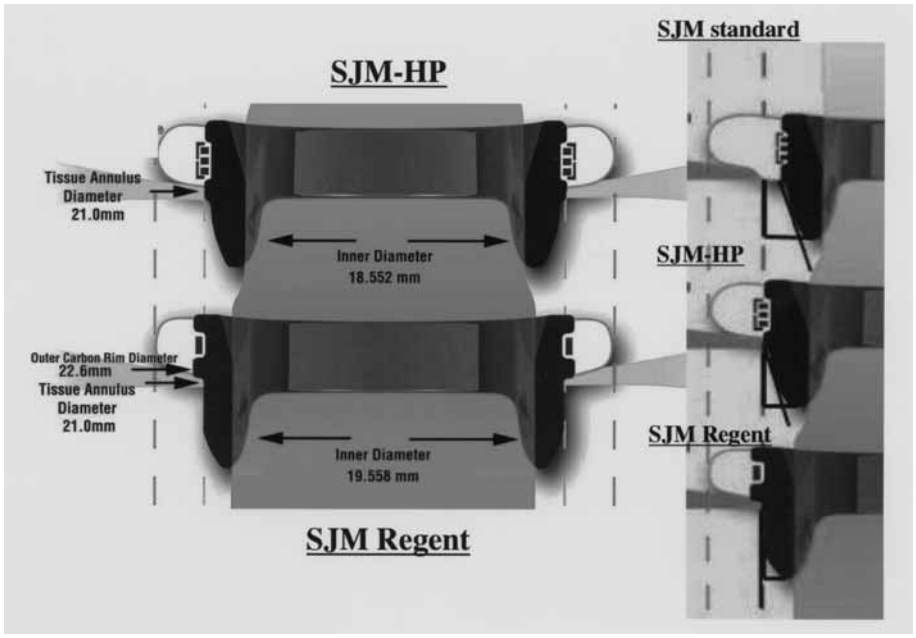


**Fig. 2.** Comparison of SJM standard, Hemodynamic Plus (HP) and Regent® valve.

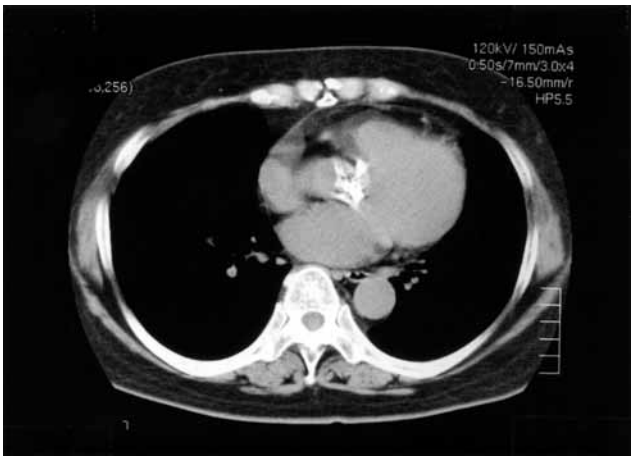


**Fig. 3.** Chest CT before the surgery.

cidence of thromboembolic event was 1.5%/patient-year, that of paravalvular leakage was 1.1%/patient-year, that of bleeding was 1.8%/patient-year and that of reoperation was 0.4%/patient-year. Function of prosthetic valves was evaluated by TTE six months after the surgery. The peak pressure gradients by size were as follows: 20.6 mmHg (19 mm), 15.7 mmHg (21 mm), 13.2 mmHg (23 mm), 12.0 mmHg (25 mm), 8.6 mmHg (27 mm), 9.2 mmHg (29 mm). The mean pressure gradients by size were as follows: 9.7 mmHg (19 mm), 7.6 mmHg (21 mm), 6.3 mmHg (23 mm), 5.8 mmHg (25 mm), 4.0 mmHg (27 mm), 4.5 mmHg (29 mm). The mean pressure gradients of all the sizes over 19 mm were below 10 mmHg and EOAI exceeded 1.0 $cm^2/m^2$. Compared with the LVMI in the early stage after surgery, the index obtained six months after surgery showed a significant decrease.[16] Although we selected the 17 mm valve for the present case, only a few cases of its clinical application have been reported. In Italy, Gelsomino et al. implanted 17 mm SJM Regent® valves in four cases. In TTE data, although the peak pressure gradients were not reported, the mean pressure gradients at the time of discharge and six months after the surgery were 18.5 mmHg and 17.1 mmHg respectively. EOAIs at the time of discharge and six months after the surgery were 0.71 $cm^2/m^2$ and 0.91 $cm^2/m^2$ respectively. LVMI was decreased after the surgery.[17,18] According to our data, the peak pressure gradient and mean pressure gradient two weeks after the surgery seemed to be slightly high, 57.0 mmHg and 23.8 mmHg respectively. EOAI was 0.64 $cm^2/m^2$. These results suggested the possibility of patient-prosthesis mismatch. However, one month after the surgery, the peak pressure gradient was 35.6 mmHg, the mean pressure gradient was 18.4 mmHg, and EOAI was 0.88 $cm^2/m^2$. Two months later, the peak pressure gradient was 32.0 mmHg, the mean pressure gradient was 13.2 mmHg, and EOAI was 0.92 $cm^2/m^2$. This data including EOAI exceeding 0.85 $cm^2/m^2$ shows contradicts, the possibility of patient-prosthesis mismatch. Gelsomino et al. studied a total of 40 cases including those of 17 mm valve and reported that patient-prosthesis mismatch was recognized in 27.5% of them at time of discharge. However, all the cases showed levels exceeding 0.85 $cm^2/m^2$ one year after the surgery. Because of marked calcification of the bicuspid valve, implantation of the 17

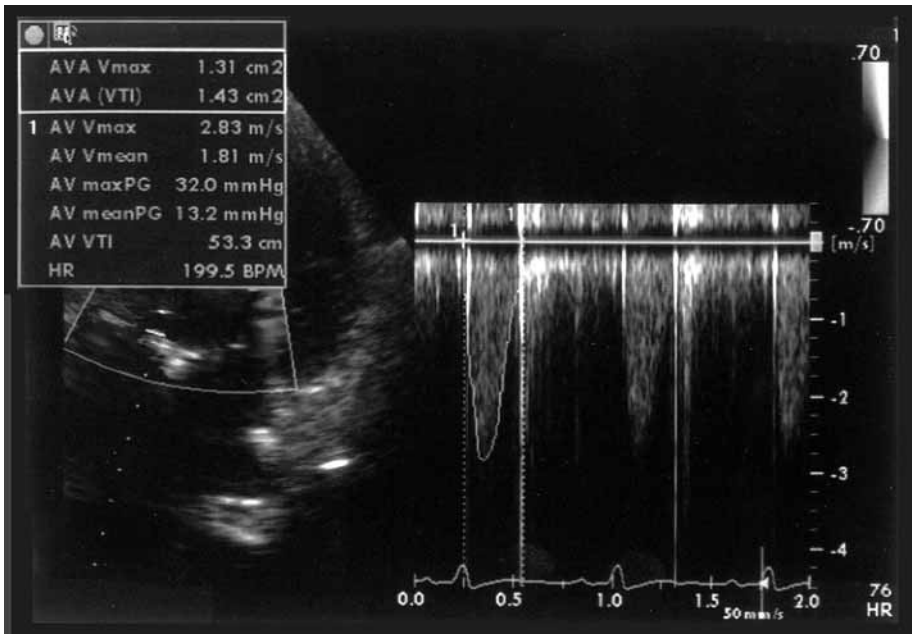


**Fig. 4.** Transthoracic echocardiography two months after the surgery.

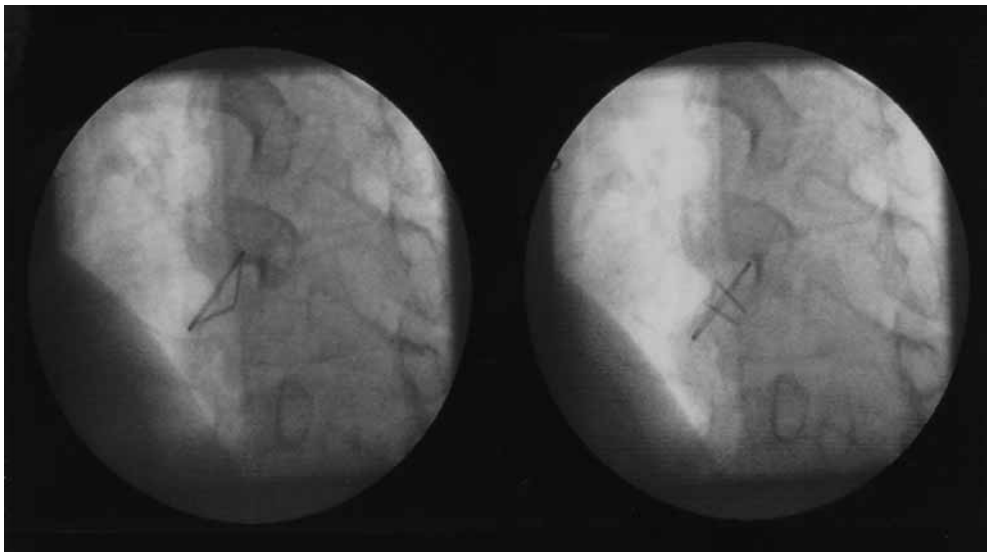

**Fig. 5.** Cinefluoroscopy after the surgery.

mm SJM Regent® valve without annular enlargement resulted in a better outcome in the present case. Although Gelsomino et al. did not mention DSE, we performed DSE to evaluate this valve. In our case, the maximum dose was evaluated to 40 μg/kg/min and the following results were obtained: peak pressure gradient 72.0 mmHg, mean pressure gradient 30.0 mmHg, EOAI 0.64 $cm^2/m^2$. These data were obtained two weeks after the surgery and their re-measurement should be performed in the stable period.

The patients who undergo implantation of mechanical valves may complain of the noise produced by prosthetic valves. We reported that ATS valves produced less noise than SJM standard valve. In that report, we proposed use of the noise index to evaluate the prosthetic valve noise and demonstrated that ATS valve produced significantly less noise than SJM standard valve.[15] In this case, the patient did not notice the prosthetic valve noise and the noise index was zero. The peak sound pressure was 46 Hz. From the aspect of patient's quality of life, this prosthetic valve proved to be excellent. Cardiac cinefluoroscopy showed the valve opening angle of 85 degrees indicating full opening. Consequently, this prosthetic valve was regarded as a reliable valve from the hydrodynamic aspect.

Because the incidence of narrow annulus is higher in Japan than in Europe and the US, clinical application of this valve may contribute to the reduction of the cases of patient-prosthesis mismatch.

The selection criteria of prosthetic valves in our institute are bioprosthesis for 70 years or older, and mechanical valves for those younger than 70 years old. However, with availability of this valve, enlargement of mechanical valve application is expected, even for those 70 years or older, since it seems that the one with 17 mm that was used in this case may be necessary for a narrow annulus case where valve replacement with a bioprosthesis is impossible.

We report AVR with a SJM Regent® valve. We have not obtained data suggesting complications such as hemolysis and thromboembolism to date. During the operation, the valve was handled without difficulty and the results of echocardiography demonstrated satisfactory function of the prosthetic valve. We can expect its widespread use in the future. More cases of AVR with SJM Regent valve should be accumulated to clarify and evaluate its characteristics.

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