

An Evaluation Study on the Quietness of the ATS Valve

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Background: The closure sound of the ATS bileaflet mechanical valve is said to be quieter than that of the other mechanical valves. However, the reasons for this are still unknown. In this study, we investigated the reasons for the quietness of the ATS valve closure sound.

Patients and Methods: The valve closure sound was evaluated in 70 patients and in another 70 patients in whom the SJM valve had been used for single valve replacement, based on frequency analysis of the closure sound, measurement of the opening angle of the valve, cardiac function, and patient interviews.

Results: In the valve closure sound analysis, the mean peak frequency of the valve closure sound was 1.02 kHz for the ATS valve, and the mean pressure was 22.8 ± 4.04 dB. The mean peak frequency of the closure sound of the SJM valve was 1.02 kHz, with another intermittent peak at 3 to 9 kHz in the human audibility range. The mean sound pressure was 25.0 ± 3.20 dB. The noise classification score was 2.07 ± 1.95 points for the SJM valve, significantly higher as compared with that for the ATS valve which was 0.36 ± 0.95 points. Multilateral examinations showed a significant difference in the mean opening angle between the ATS and the SJM valves: the angle was 76.6 ± 4.67 degrees for the ATS valve and 82.3 ± 2.05 degrees for the SJM valve.

Conclusion: In view of the lower sound pressure in the human audibility range and lower patient awareness of the valve closure sound, the ATS valve would appear to be a superior mechanical valve when compared to the SJM valve from the point of view of the quality of life of the patients. The significant difference in the opening angle in patients with the ATS valve between those who were aware of the valve closure sound and those who were not suggested a possible association between the opening angle and the patient awareness of the valve closure sound. (*Ann Thorac Cardiovasc Surg* 2007; 13: 172–177)

Key words: ATS valve, bileaflet valve, prosthetic valve, mechanical valve

Introduction

The first mechanical heart valve replacement was performed by Hufnagel et al. in 1952; a ball valve was transplanted into the descending aorta.¹⁾ In 1960, mitral valve replacement with a ball valve was performed by Starr et al.²⁾ Since then, a variety of mechanical valves, including disc valves, tilting valves, and bileaflet valves have been

developed through various modifications and become available, to yield superior antithrombogenicity, hemodynamics, and durability. The ATS valve (ATS Medical, Inc., Minneapolis, MN, USA) is a bileaflet valve developed by Villafana et al., one of the members who developed the SJM valve (St. Jude Medical Inc., St. Paul, MN, USA). As compared with the conventional bileaflet valves, the ATS valve is unique on account of its Open Pivot™ hinge design (Fig. 1), which yields superior antithrombogenicity and hemodynamics. The quieter valve closure as compared with that of the conventional valves appears to be associated with an improved quality of life of the patients.^{3,4)} Since its first use in a patient by Sadeghi et al. in Switzerland in May 1992, the ATS valve has been used in more than 10,000 patients in the EU and

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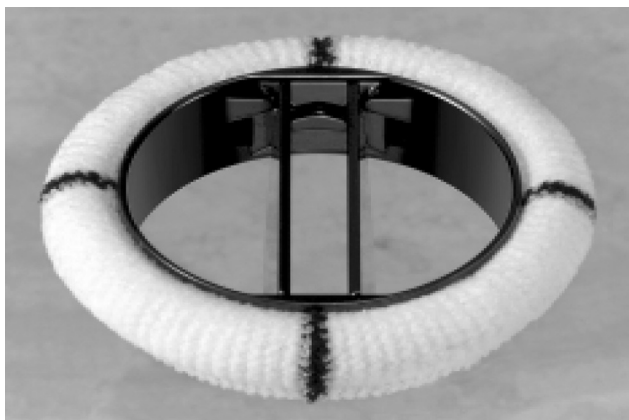


Fig. 1. Open pivot™ structure of the ATS valve.

other countries.⁵⁻⁷⁾ In Japan, the first ATS valve replacement was conducted in a patient with mitral stenosis at Nihon University in September 1993.^{8,9)}

One of the major post-valve replacement problems with mechanical valves has been the metallic sound generated by the closure of the valves. While the problem has been evaluated for various mechanical valves in previous studies, there are few reports of investigation of the quietness of the ATS valve. We conducted a multilateral evaluation to compare the ATS valve with the St. Jude Medical valve in relation to the relatively quieter closure sound of the former (SJM valve).

Patients and Methods

Between September 1993 and June 2005, 200 patients underwent heart valve replacement with the ATS valve at the Department of Cardiovascular Surgery, Itabashi Hospital, Nihon University School of Medicine. Seventy of these patients who underwent single valve replacement were included in the current study. Patients with severe hearing impairment (>90 dB loss at >2,000 Hz) were excluded from the study. A control group of patients who had undergone valve replacement with the SJM valve around the same time period was established for comparison.

The ATS group consisted of 31 patients with aortic valve replacement and 39 with mitral valve replacement (39 males and 31 females). The patients ranged in age from 22 to 82 years (mean, 59.7±12.8 years). The SJM group consisted of 36 patients with aortic valve replacement and 34 with mitral valve replacement (36 male and 34 female). These patients ranged in ages from 33 to 87 years (mean, 61.5±10.4 years) (Table 1). No significant

Table 1. Patient data

	ATS	SJM
Patients	70	70
Age (years)	59.7±12.8	61.5±10.4
Gender (male/female)	39:31	36:34
Aortic position	31	36
Mitral position	39	34

differences in the sex distribution or age of the patients were noted between the two groups.

Six months post-surgery, the patients were asked the following: (i) your valve sound is audible to yourself; (ii) your valve sound is audible to others; when audible; (iii) you sometimes feel uneasy about the valve sound; (iv) the valve sound disturbs you during the daytime; (v) the valve sound disturbs your sleep; (vi) you want to replace it with a quieter valve if possible; and (vii) to score themselves on a noise classification scale [The original scoring method used at our institute for stress associated with the valve closure sound, referred to as the “noise index” in our previous report.³⁾ Stress is evaluated on a scale of 0 (no stress) to 10 (maximum stress)].

The frequency of the mechanical valve closure sound was analyzed in every patient 6 months post-surgery. The patients were bare from the waist up lying in the supine position. The room was a soundproofed room while the valve sound was analyzed. A highly sensitive microphone (TS-32235, Nihon Kohden Corp., Tokyo, Japan) was placed in the second intercostal space at the right sternal border in patients with an mechanical aortic valve or the sixth intercostal space in the midclavicular line in those with an mechanical mitral valve. A bone conductal ear microphone (Y’S GEAR Co., Ltd., Tokyo, Japan) was set on their left ears. The heart rate and rhythm were recorded in an electrocardiogram (CARDIO-PRO, FX-3111, Fukuda Denshi, Co., Ltd., Tokyo, Japan). The sound frequency was analyzed by Super Scope II and Sound Scope (GW Instrument Inc, Boston, USA). The maximum sound frequency and sound pressure were measured, the characteristics of the waveform were observed, and the correlation between the sound pressure and the noise classification was evaluated using a Macintosh computer (PowerBook G3, Apple Computer Inc, Cupertino, CA, USA).

The opening angle of the mechanical valves was measured by cinefluorography. The cardiac function [ejection fraction (EF), maximum velocity and pressure gradient in mechanical valve] was evaluated by echocardiography

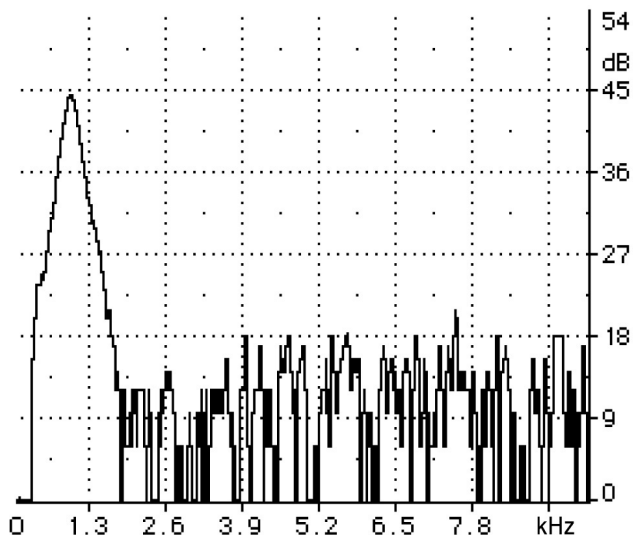


Fig. 2. Sound frequency analysis of the ATS valve.

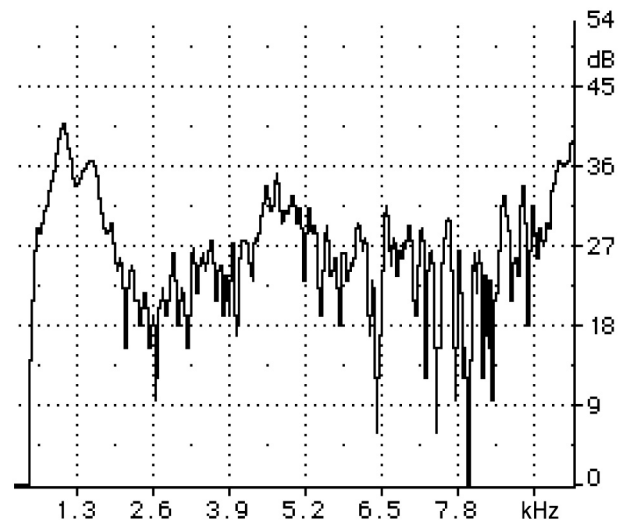


Fig. 3. Sound frequency analysis of the SJM valve.

(VIVID 7, GE Yokokawa Medical Systems Co., Hino, Japan). Bone quantity was measured using the digital image processing (DIP) method. The heart rate and rhythm, systolic and diastolic blood pressure, height, weight, and body surface area were measured in all the patients. The body fat ratio was measured with a body fat scale (Inner Scan BC-522-DB, Tanita Corp., Tokyo, Japan).

The statistical data were expressed as the mean±standard deviation. Mann-Whitney's U test was used for the analysis of the peak frequency and sound pressure. Significant difference was defined at P-value of less than 0.05.

Results

Hemodynamics

Mean systolic blood pressure was not significantly different between the two valve groups: 121.5 ± 8.16 mmHg in the ATS group vs. 124.5 ± 10.4 mmHg in the SJM group. No significant difference was seen in the pulse rate (72.2 ± 10.1 bpm in the ATS group vs. 69.4 ± 9.51 bpm in the SJM group) or ejection fraction ($59.8 \pm 11.4\%$ in the ATS group vs. $60.4 \pm 10.6\%$ in the SJM group) either between the two groups. The maximum velocity was 2.13 ± 0.80 m/s in the patients with aortic valve replacement and 1.61 ± 0.96 m/s in those with mitral valve replacement in the ATS group, while the corresponding values were 2.30 ± 0.92 m/s and 1.64 ± 0.31 m/s in the SJM group, the difference not being significant in either of the valve groups. The maximum pressure gradient was

23.5 ± 8.82 mmHg in the patients with aortic valve replacement and 7.68 ± 4.23 mmHg in those with mitral valve replacement in the ATS group, and the corresponding values were 26.1 ± 9.62 mmHg and 9.21 ± 5.66 mmHg in the SJM group, the difference not being significant in either of the valve groups.

Physical constitution

There was no significant difference in the body surface area (1.54 ± 0.16 m² in the ATS group vs. 1.48 ± 0.16 m² in the SJM group) or body fat ratio ($24.6 \pm 5.51\%$ in the ATS group vs. $26.5 \pm 3.94\%$ in the SJM group) between the two valve groups.

Sound frequency and sound pressure analysis

In the frequency analysis of the valve closure sound through the chest wall, the mean peak frequency of closure of the ATS valve was 1.02 kHz, with a mean dB of 22.8 ± 4.04 dB (Fig. 2). For the case of the SJM valve, the peak frequency was around 1.02 kHz, with another intermittent peak with a sound pressure of 20 dB or higher in the human audibility range of 3 to 9 kHz (Fig. 3). The mean dB was 25.0 ± 3.20 dB. The maximum sound pressure was significantly higher in the SJM group, regardless of whether the mitral or aortic valve was replaced.

Opening angle

The maximum opening angle of both the ATS and SJM valves has been reported to be 85 degrees based on their structure. However, cinefluorographic measurement of the

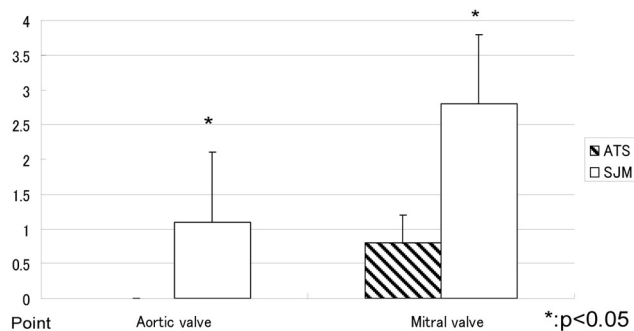


Fig. 4. Comparison of the voice classification score between the ATS and SJM valves.

opening angle revealed a mean opening angle of $76.6 \pm 4.67^\circ$ (range, 68° to 85°) for the ATS valve: $78.59 \pm 4.38^\circ$ in those with mitral valve replacement and $74.0 \pm 3.72^\circ$ in those with aortic valve replacement. The mean opening angle of the SJM valve was $82.3 \pm 2.05^\circ$ (range, 80° to 85°): $81.38 \pm 2.15^\circ$ in those with mitral valve replacement and $83.11 \pm 2.15^\circ$ in those with aortic valve replacement. There were significant differences in the opening angles between the mechanical valves.

Interview

The patients were interviewed to seek their answers to the 6 questions mentioned above. Fifty-six of all the patients (80%) with the ATS valve were not aware of the valve sound, and most of the remaining 14 patients who were aware of the sound only heard it when they were in a quiet place. Only one patient of all the patients said that the valve sound was audible to others and that it caused discomfort. On the other hand, 62 of all the patients (88%) with the SJM valve reported being aware of the valve sound. When the ear was pressed against the chest wall, the closure sound of the SJM valve was apparently louder than that of the ATS valve. However, none of the patients complained about daily life or sleep disturbance by the valve closure sound or demanded replacement of the current valve with another type. A significant difference in the noise classification score was observed between the two valve groups: the mean score was 0.36 ± 0.95 (range, 0 to 4) in the ATS group and 2.07 ± 1.95 points (range, 0 to 9) in the SJM group. When analyzed in further detail, the score was 0 in the ATS group and 1.12 ± 0.83 in the SJM group in the patients undergoing aortic valve replacement. On the other hand, in the patients undergoing mitral valve replacement, the score was 0.82 ± 0.43 in the ATS group and 2.52 ± 1.63 in the SJM group. The noise classification scores stratified according to the replaced

Table 2. Comparison of the ATS and SJM valves

	ATS	SJM	P value
Opening angle ($^\circ$)	76.6 ± 4.67	82.3 ± 2.05	0.0161*
Ejection fraction (%)	59.8 ± 11.4	60.4 ± 10.6	0.8547
Heart rate (bpm)	72.2 ± 10.1	69.4 ± 9.51	0.1515
Blood pressure (mmHg)	121.5 ± 8.16	124.5 ± 10.4	0.1515
V_{max} (m/s)	1.83 ± 0.92	1.98 ± 0.85	0.4046
Body surface area (m^2)	1.54 ± 0.16	1.48 ± 0.16	0.1543
Body fat ratio (%)	24.6 ± 5.51	26.5 ± 3.94	0.1375
Bone quantity (mmAl)	2.70 ± 0.49	2.50 ± 0.51	0.1451

*, $P < 0.05$.

Table 3. Comparison of the ATS valve sound

	Noise (+)	Noise (-)	P value
Opening angle ($^\circ$)	80.2 ± 4.38	75.2 ± 3.67	0.0061*
EF (%)	60.3 ± 9.74	58.3 ± 12.2	0.604
Heart rate (bpm)	77.6 ± 11.1	70.9 ± 9.00	0.0096*
Fat ratio (%)	23.7 ± 5.78	24.7 ± 6.26	0.6166
Body surface area (m^2)	1.55 ± 0.15	1.56 ± 0.15	0.8328
Bone quantity (mmAl)	2.74 ± 0.44	2.67 ± 0.53	0.8634

*, $P < 0.05$; EF, ejection fraction.

valve were significantly different between the two valve groups (Fig. 4).

While a significant difference was observed in the opening angles, there were no significant differences in the EF, maximum velocity, pressure gradient, body surface area, body fat percentage, or bone mass between the two valve groups (Table 2). Bone conduction analysis was abandoned since no credible data could be obtained. Comparison of the patients with the ATS valve who were aware of the valve closure sound with those who were not revealed significant differences in the opening angle and pulse rate between the two groups (Table 3). Some patients had atrial fibrillation; however, no significant differences in any of the measured parameters were observed between the patients with atrial fibrillation and those without.

Comment

In the current study, we evaluated the possible factors influencing the valve closure sound of the ATS valve, which has been reported to be quieter than that of other mechanical valves. The ATS valve is a bileaflet mechanical heart valve that allows excellent hemodynamics, antithrombogenicity and valve functions to be achieved. A post-surgical follow-up of patients who had undergone

valve replacement with the ATS valve revealed that the valve closure sound of the ATS valve was quieter as compared with that of other mechanical valves. The volume of the valve closure sound can seriously affect a patient's quality of life; however, few studies have been conducted to investigate this issue. The focus of our current study was the "sound" generated by mechanical heart valves. No clinical reports have been published on the quietness of the valve closure sound of the ATS valve, which is one of the major advantages of this type of valve.

According to the evaluation criteria of the International Standards Recommendations (ISR), the human audibility range is between 20 Hz and 20 kHz. While the human sensitivity to sound is unstable, we are generally more sensitive to sounds in the frequency range of 2 to 5 kHz. According to the sound frequency pattern analysis, the peak frequency of the valve closure sound in patients with the ATS valve was 1.02 kHz. On the other hand, two peaks were observed in the patients with the SJM valve: 1.02 kHz and 3 to 9 kHz; the second peak fell in the human audibility range.

Johansen et al. demonstrated no significant differences in the sound pressure level among the bileaflet heart valves [SJM, CarboMedics (CM) (CarboMedics, Inc., Burnaby, Canada), and ATS] evaluated by them. Their study results also suggested that the sound pressure level at the time of the valve closure showed slight association with the left ventricular function.¹⁰⁾ However, our current study showed a significant difference in the opening angle between the ATS and SJM valves, but no difference in the cardiac function between patients undergoing valve replacement with the ATS and SJM valves. According to a study by Aoyagi et al., the mean opening angle in people with aortic valve replacement was 71.2°, while that in patients with mitral valve replacement was 75.15°: the full opening angle of 85° was not achieved in either case.^{11,12)} However, the association of the opening angle with the valve closure sound was not examined.

Moritz et al. conducted a clinical survey on the sound volume level of artificial heart valves of Duromedics Edwards (DE), CM, Bjork-Shiley Monostrut (BS), and SJM, and reported substantially higher sound pressure of the BS valve (31 dB) and DE valve (33.5 dB) as compared with that of the CM valve (25 dB) and SJM valve (24 dB).¹³⁾ Patients with BS or DE valves were rather dissatisfied with the valve closure sound as compared with the patients with the other two valves. Younger patients and patients with abnormal sinus rhythm appeared to be more aware of the valve closure sound. The study results

suggested that the valve size and patient's weight may affect the level of awareness of the valve closure sound. However, these factors did not seem to have any significant influence in the current study. The basic study conducted by Thulin et al. established that different mechanical valves (Omniscience, Hall-Kaster, BS, DE, SJM, Starr-Edwards, and Carpentier-Edwards) produce different closure sound volumes, suggesting that the sound volume may be affected by the rhythm, the systolic blood pressure, the replaced valve, i.e., whether mitral or aortic, and the valve size.^{14,15)} Moritz et al. reported that differences in design, such as the leaflet thickness, rather than a difference in the closing force, affected the generation of the valve closure sound. The SJM valve produced the lowest sound pressure in that study. However, the ATS valve was shown to produce quieter valve closure in the current study. Blome-Eberwein et al. examined six kinds of prosthetic valves (DE valve, BS valve, SJM valve, Medtronic valve, CM valve, and Omicarbon valve) at a point 10 cm from the chest wall. They reported that the valve sounds of the DE valve (84.2 dB) and SJM valve (73.5 dB) were the highest and lowest among them, respectively, and that the complaints about the valve sound were not related to age, gender, type of valve, position, or heart rhythm, and that audition of the patient was a determination factor.¹⁶⁾ Koertke et al. reported that women under the age of 60 years were more likely to feel uncomfortable with the mechanical valve closure sound. However, in the current study, no significant difference related to the age or sex of the patients was observed in relation to awareness of the valve closure sound.¹⁷⁾ Fritzsche et al. reported that even slight changes in the function of artificial heart valves could be detected by ambulatory monitoring with a sound pressure measurement system with a digital frequency analysis feature. The current study focused on the characteristic quietness of closure of the ATS valve. Use of the aforementioned device described in the study of Fritzsche et al. may be expected to lead to early detection of cardiac abnormalities and improvement of the QOL of the patients.¹⁸⁾ The current study results suggested that the reason for the superior quietness of closure of the ATS valve was related to its opening angle. Valve sound occurs when a leaflet touches the orifice. If opening angle is small, the development of energy is small and valve sounds is more quiet. However, the small opening angle also seemed to pose no clinical problem. The valve opening may be associated with biocompatibility. Therefore, the valve opening angle, valve function, and cardiac function must be

investigated in further detail in the future.

Conclusion

We compared the valve closure sound between the ATS and SJM valves in patients who had undergone heart valve replacement, by analyzing the frequencies of the valve closure sound and interviewing the patients. A significant difference was seen in the opening angle between the two valve types. Patients with the ATS valve could be divided into two groups according to their awareness of the valve closure sound to identify the cause. Frequency analysis of the valve closure sound revealed that the ATS valve closure was relatively quieter; however, evaluation of the hemodynamics and physical constitution of the patients suggested that the valve opening angle may greatly affect the quietness of the valve closure.

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