Original Article

Outcomes and Hemodynamics after Aortic Valve Replacement: A Comparison of Stentless versus Mechanical Valves

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Purpose: Some investigators suggest that hemodynamic outcomes may be superior with the stentless aortic bioprosthesis when compared with a mechanical valve. The goal of this study was to characterize outcomes and hemodynamic data associated with each type of valve.
Subjects and Methods: Patient outcomes and echocardiographic data were compared between 25 patients with stentless valves and 59 patients with mechanical valves.
Results: There were no significant differences in survival and freedom from cardiovascular adverse events between two groups. The duration of anticoagulation therapy was limited to 3 months in the stentless group. There was no significant difference in preoperative and postoperative New York Heart Association (NYHA) status when comparing the two groups, and NYHA status significantly improved in both groups (P<0.05). There was no significant difference in the echocardiographic data when comparing the two groups.
Conclusion: Aortic valve replacement using the stentless valve and the mechanical valve provided good clinical and hemodynamic outcomes. There was no significant difference in these parameters when comparing the two groups. There may be advantages in the limited required duration of anticoagulation therapy of the stentless valve , especially in elderly patients. However, longer follow-up is required before definitive conclusions regarding the benefits of the stentless valve relative to the mechanical valve can be determined. (Ann Thorac Cardiovasc Surg 2007; 13: 165–171)

Key words: aortic valve, stentless valve, mechanical valve, echocardiography, anticoagulation therapy

Introduction

Stentless aortic bioprostheses provide a large effective orifice area and are therefore postulated to yield good hemodynamic and clinical outcomes.[1)] However, recent studies have reported that there were no significant difference in peak velocity, effective orifice area,[2)] left ventricular mass (LVM) index (LVMI) regression or clinical outcomes[3)] when comparing the Freestyle valve (Medtronic Inc., Minneapolis, MN, USA) with other valves. We have used the Freestyle aortic root bioprosthesis instead of stented valves in elderly patients with aortic valve disease at our hospital since April 1998. The goal of the present study was to evaluate clinical and hemodynamic outcomes in patients receiving the Freestyle valve or the ATS open pivot heart valve (ATS Medical Inc., Minneapolis, MN, USA).

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Subjects and Methods

Patients

Between April 1998 and December 2004, 35 patients received the Freestyle aortic root bioprosthesis at our hospital. Of these patients, 28 patients underwent aortic valve replacement (AVR) using a subcoronary technique and 25 patients underwent isolated AVR or AVR with con-

comitant coronary artery bypass grafting (CABG). The present study examined these 20 patients and compared them with 59 patients who underwent AVR with the ATS valve during the same period.

Indication for the Freestyle valve

The Freestyle valve was initially implanted in all patients older than 70 years. After August 2000, all patients older than 65 years underwent AVR with the Freestyle valve at our hospital. Patients that did not meet these age/time-specific criteria underwent placement of the ATS valve.

Anticoagulation therapy

Anticoagulation therapy with warfarin was initiated and continued indefinitely in all patients in the ATS group. The patients would visit a hospital at least every 2 months. In the Freestyle group, anticoagulation therapy was initiated and continued for 3 months after discharge, followed by antiplatelet therapy using aspirin and the patients would visit a hospital every 3 months.

Outcomes and follow-up

Patient characteristics, clinical data, operative data, and echocardiographic data were compared between the Freestyle group and the ATS group. New York Heart Association (NYHA) class and outcome after hospital discharge was determined by telephone interview.

Echocardiography

Echocardiographic examination was performed before the operation, before discharge, and about 6 months to 1 year after discharge and then repeated on a yearly basis by experienced medical technologists. Measured parameters included peak aortic pressure gradient, degree of aortic regurgitation, ejection fraction (EF) and LVMI. The peak aortic pressure gradient was calculated using the modified Bernoulli equation. Aortic regurgitation was graded as absent, trace, grade 1, grade 2, grade 3, or grade 4. EF was calculated using Pombo's method. LVM was calculated using the following equation: $LVM = 1.04\times((IVS+LVDd+LVPW)^3-LVDd^3)-13.6$; where IVS is interventricular septal thickness (cm), LVDd is the left ventricular end-diastolic dimension (cm), and LVPW is the left ventricular posterior wall thickness (cm). LVMI was calculated from LVM divided by patient body surface area (m^2).

Statistical analysis

Numerical data are described as mean±standard (SD) deviation. Comparisons between the two groups were performed using the t-test for numerical data and with the Fisher's exact probability and Mann-Whitney's U tests for categorical data. Survival analyses using the Kaplan-Meier method were used to estimate survival and freedom from cardiovascular adverse events. A log-rank test was used to determine differences in survival and freedom from adverse events. Differences were considered significant at a value of $P<0.05$.

Results

Patient characteristics

Preoperative patient characteristics are shown in Table 1. Patient age was significantly higher in the Freestyle group (71.8±4.5 years) than in the ATS group (63.4±11.1 years) (P=0.0005) because of the different age indications for choice of specific valves. There were 11 males and 14 females in the Freestyle group and 32 males and 27 females in the ATS group. Diagnoses are summarized in Table 1. There was significant difference in diagnoses between two groups (P=0.01).

Operative data

Operative data is summarized in Table 1. There were no patient deaths within 30 days of the operation in the Freestyle group and one patient death in the ATS group. This patient had been on hemodialysis before the operation and died of multiple organ failure. There was no significant difference in operative mortality (P=0.69). There were no perioperative infarctions or cerebrovascular accidents in either group. Mean aortic cross-clamp time was significantly longer in the Freestyle group (170±33 min) than in the ATS group (118±37 min) (P=0.000000031). One patient in the Freestyle group and 9 patients in the ATS group underwent concomitant CABG. There was no significant difference in mean hospital stay when comparing the Freestyle group (20.3±17.6 days) and the ATS group (17.2±12.4 days) (P=0.35). There was a significant difference in valve size when comparing the two groups (P=0.042; Table 2).

Clinical outcomes

The mean follow-up period in the Freestyle group was 1,403 days (range: 140 to 2,535) and 1,159 days (range: 23 to 2,703) in the ATS group. Five patients died during follow-up (Freestyle group, n=3; ATS group, n=2). Of

Table 1. Patient characteristics and operative data

	Freestyle	ATS	P value
Number of patients	25	59	
Age at implant (years)	71.8±4.5	63.4±11.1	0.0005
Sex			0.27
Male	11	32	
Female	14	27	
Aortic lesion			0.01
Stenosis	20	29	
Regurgitation	1	20	
Mixed	4	10	
Operative mortality	0%	1 (1.7%)	0.69
Concomitant CABG	1 (4%)	9 (15.3%)	0.12
Cross-clamp time (min)	170±33	118±37	0.000000031
Hospital stay (day)	20.3±17.6	17.2±12.4	0.35

CABG, coronary artery bypass grafting; ATS, ATS group.

Table 2. Valve sizes

Freestyle		ATS		P value
Size	Number of the valves	Size	Number of the valves	
		16 AP	7	
		18 AP	17	
19	2	19	0	
		20 AP	4	
21	9	21	0	
		22 AP	14	
23	10	23	5	
25	4	25	8	
		27	4	
mean±SD	22.3±1.7	mean±SD	20.8±3.3	P=0.042

ATS, ATS group.

the three deaths in the Freestyle group, one patient died from gastric cancer 490 days after AVR and another patient died of unknown causes, while residing in an adult group home 487 days after AVR. The final patient had sick sinus syndrome and underwent pacemaker implantation after discharge but was later readmitted to our hospital because of loss of consciousness due to pacemaker failure. This patient died 140 days after AVR. One death in the ATS group was attributed to aplastic anemia 321 days after AVR. The other patient died of arrhythmia (ventricular fibrillation) 1,551 days after AVR (Table 3). Cardiovascular adverse events were observed in 6 patients (Freestyle group, n=2; ATS group, n=4). One patient was admitted because of heart failure and one patient in the Freestyle group underwent percutaneous coronary intervention . The lesion of this patient was segment 3 in the right coronary artery without ostium stenosis. One patient was admitted because of heart failure and the other 3 patients suffered from cerebral vascular accident in the ATS group (transient ischemic attack, n=1; cerebral infarction, n=2).

Table 3. Long-term mortality and cause of deaths

	Number	Postoperative days
Freestyle	3 (12%)	
Sick sinus syndrome	1	140
Unknown	1	487
Gastric cancer	1	490
ATS	2 (3.4%)	
Aplastic anemia	1	321
Ventricular Fibrillation	1	1,551

ATS, ATS group.

Actuarial survival and freedom from cardiovascular adverse events are shown in Figs. 1 and 2, respectively. There were no significant differences in survival and freedom from adverse events between the two groups (sur-

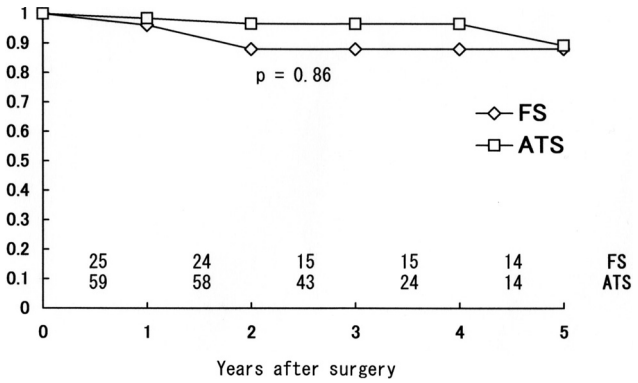

Fig. 1. Actuarial survival.
There were no differences between the Freestyle group and the ATS group in overall survival (P=0.86). Numbers below the graph represent patients at risk. FS, Freestyle group; ATS, ATS group.

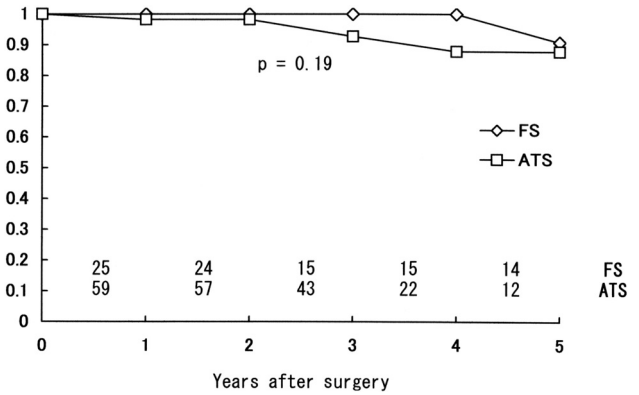

Fig. 2. Freedom from cardiovascular adverse events.
There were no differences between the Freestyle group and the ATS group (P=0.19). Numbers below the graph represent patients at risk. FS, Freestyle group; ATS, ATS group.

Table 4. NYHA classification

	Before operation		After operation	
	Freestyle	ATS	Freestyle	ATS
I	1	6	18	30
II	12	18	5	12
III	10	14	0	0
IV	0	4	0	0
P value	0.88		0.39	

ATS, ATS group.

Table 5. Postoperative aortic regurgitation

	Freestyle	ATS
Absent	17	4
Trace	6	43
Grade 1	2	7
Greater than grade 2	0	0

ATS, ATS group.

vival, P=0.86; freedom from adverse events, P=0.19). The 1-year, the 3-year, and the 5-year survival in the Freestyle group vs. in the ATS group were 96.0% (confidence interval (CI), 74.8 to 99.4) vs. 98.3% (CI, 88.6 to 99.8), 88.0% (CI, 67.3 to 96.0) vs. 96.6% (CI, 87.1 to 99.1), and 88.0% (CI, 67.3 to 96.0) vs. 89.2% (CI, 67.3 to 96.0), respectively. The 1-year, the 3-year and the 5-year freedom from cardiovascular adverse events in the Freestyle group vs. in the ATS group were 100% vs. 98.2% (CI, 88.2 to 99.8), 100% vs. 92.8 % (CI, 78.7 to 97.7), and 90.9% (CI, 50.8 to 98.7) vs. 87.9% (CI, 68.8 to 95.6), respectively. No adverse event was observed in the Freestyle group within 4 years after AVR.

Preoperative and postoperative NYHA class distribution in both groups is summarized in Table 4. Of the total study population, 23 patients in the Freestyle group and 42 patients in the ATS group were successfully contacted for evaluation of preoperative and postoperative NYHA class. There was no significant difference in preoperative NYHA status when comparing the Freestyle and the ATS groups (P=0.88), and NYHA status significantly improved in both groups after operation (P<0.0001 for both groups). There was also no significant difference in the postoperative NYHA class distribution when comparing the two groups (P=0.39).

Echocardiographic results

On postoperative echocardiography, absent, trace and grade 1 aortic regurgitation were observed as follows: 17, 6, and 2, respectively, in the Freestyle group; and 4, 43, and 7, respectively, in the ATS group. Severe regurgitation greater than grade 2 and perivalvular regurgitation was not detected in any of the patients (Table 5).

Table 6 summarizes echocardiographic results in the Freestyle group and the ATS group with the number of the patients whose data could be available. There was no difference in the mean postoperative peak aortic pressure gradient when comparing the Freestyle group and the ATS group before patient discharge, but at 1 year and 2 years after surgery, there were significant differences between two groups (1 year: P=0.0075, 2 years: P=0.038). There was no significant difference after that time point in the

Table 6. Echocardiographic data

	Pre-op (number)	Post-op (number)	1 year (number)	2 years (number)	3 years (number)	4 years (number)
Postoperative peak aortic gradient (mmHg)						
Freestyle		21.7±14.8 (25)	19.4± 9.9 (21)	22.3±10.7 (15)	21.4± 8.9 (12)	19.5± 5.9 (11)
ATS		25.3±12.2 (57)	28.2±12.1 (31)	31.2±13.6 (24)	25.4±14.9 (16)	21.3± 6.3 (12)
P value		0.26	0.0075	0.038	0.42	0.51
Postoperative ejection fraction (%)						
Freestyle	57.3±13.8 (18)	47.5±17.0 (10)	61.8±15.9 (16)	62.0±7.8 (12)	60.9±12.9 (10)	58.6± 9.3 (9)
ATS	59.3±14.7 (47)	48.5±22.0 (17)	56.8±22.4 (33)	65.2±13.6 (21)	61.5±15.7 (15)	61.6± 9.8 (10)
P value	0.63	0.9	0.44	0.46	0.88	0.74
LVMI measured in patients with aortic stenosis (g/m^2)						
Freestyle	186.4±52.1 (17)	146.7±46.5 (9)	123.0±50.5 (12)	135.9±48.9 (11)	132.7±41.2 (9)	117.6±52.3 (8)
ATS	201.1±68.8 (33)	140.8±45.3 (26)	134.7±44.3 (17)	127.1±32.9 (14)	148.8±47.3 (7)	122.3±41.9 (5)
P value	0.44	0.74	0.51	0.59	0.48	0.87

ATS, ATS group.

mean peak aortic pressure gradient. There were no differences in the mean EF when comparing the Freestyle group and the ATS group at each time point. On comparison of LVMI, patients in the each group were divided into subgroups according to the diagnosis (aortic regurgitation vs. aortic stenosis). The main lesion in all patients with mixed disease was aortic stenosis and they were included in the subgroups of stenosis. Comparison of LVMI between the Freestyle groups and the ATS group could be performed only on the subgroups of aortic stenosis, because LVMI could not be evaluated on the one patient with aortic regurgitation in the Freestyle group (Table 1). There were no differences in the mean LVMI when comparing the Freestyle group and the ATS group at each time point. LVMI significantly decreased before patient discharge in the ATS group (P=0.00030), and year one in both groups (Freestyle group: P=0.0030, ATS group: P=0.00075).

Discussion

The present study investigated clinical and hemodynamic outcomes following AVR with either a Freestyle valve or an ATS mechanical valve. There were no significant differences in operative deaths or duration of hospital stay when comparing the two groups. In both groups, NYHA status significantly improved after AVR, both types of valves provided good outcome, and there was no significant difference in NYHA status when comparing the two groups.

Previous studies by Florath et al. examined and compared mid-term outcomes for patients receiving stentless valves and mechanical valves. They reported that there was no significant difference between the stentless bioprosthesis and the mechanical valve in terms of operative and mid-term mortality, valve-related morbidity, duration of intensive care unit stay, and NYHA status. However, there were significant differences in terms of anticoagulation therapy when comparing the stentless bioprosthesis group and the mechanical valve groups. Specifically, patients requiring anticoagulation showed a decrease in quality of life when compared with those that did not require anticoagulation.[4)]

Although the effect of anticoagulation therapy on patient outcomes was not evaluated in the present study, our anecdotal experience suggests that outcomes for elderly patients on anticoagulation therapy are poor. The limited required duration of anticoagulation therapy may be advantages of the stentless valve especially in the elderly patients. There were no significant differences in survival and freedom from adverse events in the present study. However, no cerebrovascular accident was observed in the Freestyle group during the follow up period although the mean patient age was significantly higher. And no adverse event was observed in the Freestyle group within 4 years after AVR. Longer follow up should be needed for these issues.

The Freestyle stentless valve has a larger effective orifice area (EAO) when compared with a stented bioprosthesis or mechanical valve and may therefore offer greater hemodynamic advantages. While some studies report excellent 10-year outcomes with the use of the Freestyle valve,[1)] other studies yield conflicting information regarding the Freestyle valve and LVMI.[5–11)] For example, Perez de Arenaza et al. performed a large randomized trial comparing stentless versus stented valves and

reported a greater decrease in peak aortic gradient and a greater increase in indexed EAO showed a greater increase with the stentless valve when compared with the stented valve.[3] However, there was no significant difference in mean LVMI when comparing the two valves.[3] Furthermore, there was no significant difference in functional and clinical outcomes, such as NYHA class, 6-min walk test,[12] and quality of life measured by the SF-36 questionnaire,[13] when comparing the two groups. Left ventricular hypertrophy is associated with an increased risk of sudden death and congestive heart failure[14] and incomplete regression of left ventricular hypertrophy after AVR is indicative of impaired postoperative ventricular function and early and late mortality after valve replacement.[15] This data suggests that the decrease in LVMI is an important factor related to good outcomes after AVR. Therefore, the fact that Freestyle valve does not yield a favorable decrease in LVMI may account for the similar clinical outcomes with the use of the Freestyle and the ATS valves in the present study, despite the fact that the Freestyle may offer some hemodynamic advantages.

Although the patient numbers were relatively small and the comparison of LVMI was made only on the patients with aortic stenosis in the present study, there were no significant differences in hemodynamic data and LVMI when comparing the two groups at any time point, while significant differences were detected in the peak aortic gradient at 1 and 2 years after surgery. A LVMI decreased significantly after surgery in both groups. These results were compatible with those of the recent studies that reported hemodynamic status of the Freestyle valve. Hemodynamically good outcomes can be obtained by using both the Freestyle valve and the ATS valve. It could not be proven that the one valve is hemodynamically superior to the other valve in the present study.

There are some technical differences involved with the use of each valve-type that may affect clinical outcomes. For example, the complexity of implantation and the cross-clamp time is greater when using the Freestyle valve than when using the mechanical valve.[3] Indeed, Florath et al. reported an increased risk of stroke and longer stays in the intensive care unit in patients with NYHA class 4 disease who received the Freestyle valve when compared with those who received the mechanical valve.[4] However, even though implantation of the Freestyle valve required longer cross clamping time, the postoperative course was similar when comparing patients who received the Freestyle valve and those that received the ATS valve in the present study.

Previous studies have reported good long-term outcome and lower mortality associated with the use of the Freestyle valve.[1] Longer follow-up periods are necessary before definitive conclusions can be made regarding the benefits of either type of valve. Further, the present study was limited by changes in the indications for the difference valves, and additional investigation into the relationship between age, valve-type, and outcomes would be of benefit.

Conclusion

Aortic valve replacement using the stentless valve and the mechanical valve provided good clinical and hemodynamic outcomes, and there were no significant differences in these parameters when comparing the two groups. The limited required duration of anticoagulation therapy may be advantages of the stentless valve especially in elderly patients. Longer follow-up is required before definitive conclusions regarding the benefits of the stentless valve relative to the mechanical valve can be determined.

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