

Biological Versus Mechanical Aortic Prosthesis? A Nineteen-year Comparison in a Propensity-matched Population

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Background and aim of the study: The choice of aortic valve substitutes remains controversial. Malfunction and systemic valve complications affect the results of mechanical and tissue valves. Two devices - the Sorin Monocast (tilting disk) valve and the Hancock Standard valve were compared, the study aim being to determine whether the valve model is a marker or a causal influence of poor outcome after aortic valve replacement (AVR).

Methods: Between January 1970 and January 1984, patients aged <70 years and operated on for aortic valve disease were selected. A total of 379 patients received either Sorin (group S) valves (n = 213; median age 51 years) or Hancock Standard (group HcK) valves (n = 192; median age 50 years) (p = NS). Total follow up was 2,471 patient-years (pt-yr) for group S and 2,368 pt-yr for group HcK. Follow up was 98% complete; median duration was 15 pt-yr for group S and 13.2 pt-yr for group HcK. Propensity matching for available patient intrinsic and operative risk factors was ultimately used to investigate whether biological or mechanical valve models impact upon outcome after aortic valve surgery. Patient survival was analyzed according to the 'intention to treat' principle.

Results: The 30-day mortality was 7.5% for group S and 10.9% for group HcK (p = NS). The 19-year Kaplan-Meier freedom from valve-related mortality

was 84% (group S) and 82% (group HcK) (p = NS), while overall survival was 42% (group S) and 35% (group HcK) (p = NS). Structural valve deterioration (SVD) was the major cause of reoperation in the HcK group. The 19-year freedom from all valve-related complications was 43% (group S) versus 19% (group HcK) (p = 0.0001). By propensity score, 61% of the valve replacements (247/405) were perfectly matched for available risk factors, with an equal distribution of risk covariates. When SVD and reoperation due to SVD were excluded, survival and freedom from all valve-related complications of the matched patients were identical between the prostheses under comparison.

Conclusion: In this relatively young population, the Sorin valve showed a significantly lower valve-related complication rate than the Hancock Standard valve. The latter valve showed a significantly increasing rate of reoperation due to SVD, and thereby a relative inadequacy for use in younger patients. When analyzed according to an 'intention to treat' principle, the 19-year survival and freedom from valve-related complications of patients with the same propensity score for selection of either valve type were similar.

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Despite biological (porcine) and mechanical prostheses having been available for use since the early 1960s, the ideal prosthesis is not yet available and prosthetic-valve related complications due to structural problems (1-5) and non-structural valve dysfunction have enforced the replacement of both types of prosthesis

(6,7). Today, studies comparing follow up data obtained from concurrent single biological or single mechanical valve over a very long term are few in number (8-12).

In the present study, the clinical performance and long-term complication rate were evaluated, prospectively, in two populations aged less than 70 years, who underwent aortic valve replacement (AVR) with either the Sorin tilting mechanical prosthesis or the Hancock Standard porcine bioprosthesis during the period between 1970 and 1984. The study aim was to determine, by using propensity score matching, whether the

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Table I: Continuous considered variables between matched patients.

Continuous variable	Matched Sorin patients		Matched Hancock patients		p-value
	Observations (n)	Mean ± SE	Observations (n)	Mean ± SE	
Age (years)	80	48.7 ± 1.4	167	48.2 ± 1.02	0.78
Age squared (years ²)	80	2,536 ± 127	167	2,501 ± 94	0.83
BSA (m ²)	80	1.7 ± 0.02	167	1.7 ± 0.01	0.93
Aortic valve size (mm)	80	25.6 ± 0.23	167	25.9 ± 0.12	0.15*
NYHA class	80	3.1 ± 0.06	167	3.1 ± 0.032	0.83
Cardiac index (l/min·m ²)	80	2.77 ± 0.17	167	2.62 ± 0.13	0.5
Mean PAP (mmHg)	80	22.7 ± 1.38	167	22.8 ± 1.74	0.65

*Kruskal-Wallis test.

BSA: Body surface area; PAP: Pulmonary artery pressure.

initial choice of mechanical or biological prosthesis, irrespective of their peculiar complications, affected the overall survival of patients with a similar risk profile.

Clinical material and methods

Patients

Between January 1970 and January 1984, a total of 379 patients aged <70 years and undergoing isolated AVR with the Sorin Monocast or Hancock Standard valve, were selected from the authors' cardiac prosthesis database. The Sorin Monocast (tilting disk) prosthesis was implanted in 213 patients (group S; median age at surgery 51 years; mean age 48.7 ± 12.4 years; range: 16.9 to 69.7 years). The Hancock Standard bioprosthesis was implanted in 192 patients (group HcK; median age at surgery 50 years; mean age 48.5 ± 13 years; range: 18 to 70 years). The age distribution of the two populations was similar, as confirmed by the Kolmogorov-Smirnov test (p = 0.20). Among group S patients, 23 (10.8%) underwent reoperation (21 first reoperation, two second reoperation), while six patients in group HcK (3%) underwent a first reoperation and had had previous cardiac surgery (p = 0.001). Myocardial revascularization was performed in 30 of 405 operations (7.4%); this included 17 patients in group S (8%) and 13 in group HcK (6.8%) (p = 0.6). Among the patients, 75% of group S patients (158/213) and 95% of group HcK patients (182/192) were in NYHA classes III-IV (p = 0.001). The prevalence of sinus rhythm was 95% in both groups.

In order to compare long-term survival, propensity scores were calculated. The 26 predictor variables collected for the analysis were continuous and categorical preoperative and operative variables (Tables I and II). According to these variables, the biological valve patients were matched with mechanical valve patients within quintiles of risk. Quintiles 3 to 5, with a total of

247 observations (61%), were satisfactorily matched (Table III).

Surgical technique

All surgical procedures were performed with patients under general anesthesia. Valves were implanted via a transaortic approach, using multiple interrupted sutures with 2-0 Ticron reinforced by Teflon pledgets. All group S patients were continuously anticoagulated. In accord with current policy and recommendations, anticoagulation in group HcK patients in sinus rhythm was restricted to the first three postoperative months. However, HcK patients in chronic atrial fibrillation, and with left atrial and left ventricular dilatation, were anticoagulated continuously.

Patient follow up

Follow up data were obtained via direct visits by the patients, by questionnaires or by telephone interviews. For this analysis, the follow up was closed at a common date in July 2001. The total follow up was 2,471 years in group S and 2,368 years in group HcK, and was 98% complete. The median duration of follow up was 15 pt-yr (maximum 24.7 pt-yr) in group S, and 13.2 pt-yr (maximum 27.13 pt-yr) in group HcK. The present analysis was limited to 19 years, with 17 patients at risk in group S and 60 at risk in group HcK. The number of Hancock S-Sorin crossovers was 16, whilst the number of Sorin-Hancock S crossovers was one.

Statistical analysis

Postoperative complications and prosthesis-related events (structural valve deterioration (SVD), thromboembolism, anticoagulant-related hemorrhage, endocarditis, paravalvular leak, reoperations and valve-related morbidity) were defined as previously published (13).

An estimate of age distribution of the two popula-

Table II: Categorical considered variables between matched patients.

Categorical variable	Matched Sorin patients		Matched Hancock patients		p-value
	Observations (n)	%	Observations (n)	%	
Clinical history					
Female sex	80	20	167	14	0.26
Atrial fibrillation	80	5	167	5.4	0.89
Previous cardiac surgery	80	1.25	167	0.6	0.59
Emergency	80	5	167	4.8	0.94
Preoperative pathology					
Aortic dissection	80	0	167	0.6	0.49
Ascending aorta aneurysm	80	3.75	167	1.2	0.18
Aortic valve regurgitation	80	41.25	167	38.9	0.72
Aortic valve stenosis	80	16.25	167	16.2	0.99
Etiology					
Rheumatic disease	80	63.7	167	69.5	0.37
Degenerative calcified valve	80	11.25	167	11.4	0.98
Degenerative non-calcified valve	80	10	167	7.8	0.56
Congenital disease	80	5	167	3	0.43
Active endocarditis	80	5	167	5.4	0.90
Non-active endocarditis	80	2.5	167	2.4	0.96
Prosthetic valve malfunction	80	11.25	167	6.9	0.15
Cardiac catheterization					
Left atrium enlargement	80	8.75	167	5.4	0.32
Coronary artery disease	80	7.5	167	14.9	0.099
Operative procedure					
Coronary artery bypass	80	5	167	7.2	0.51
Aortic annulus enlargement	80	1.25	167	1.2	0.97

tions was calculated using the Kolmogorov-Smirnov test.

Estimates of postoperative complications and prosthesis-related events were calculated using the Kaplan-Meier (K-M) method and expressed as percentage \pm SE or percentage \pm 95% confidence interval (CI). Statistical comparisons of the survival curves were made with the log-rank test.

Comparison of long-term surgical outcome was made after propensity matching for sex, age, age squared, body surface area, coronary artery disease, number of previous operations, emergency status, aortic valve size,

aortic dissection, ascending aorta aneurysm, aortic valve stenosis and/or incompetence, aortic annulus enlargement procedure (Manouguian), left atrium enlargement, atrial fibrillation, cardiac index, mean pulmonary pressure, NYHA class, rheumatic disease, degenerative calcified aortic stenosis, degenerative aortic valve incompetence, congenital aortic valve disease, active and/or not active endocarditis, prosthetic malfunction, and coronary artery bypass.

Sorin and Hancock prosthesis recipients with similar risk profile were identified by means of the P-score routine (Stata software: <http://www.stata->

Table III: P-score matching for the available risk factors.

P-score block	Sorin		Hancock Standard		p-value	Total observations
	Observations	Mean \pm SE	Observations	Mean \pm SE		
0	70	0.10 \pm 0.006	13	0.13 \pm 0.016	0.0424	83
0.2	63	0.28 \pm 0.006	12	0.34 \pm 0.018	0.0018	75
0.4	42	0.49 \pm 0.008	57	0.50 \pm 0.007	0.2072	99
0.6	33	0.69 \pm 0.01	68	0.70 \pm 0.007	0.5381	101
0.8	5	0.86 \pm 0.02	42	0.87 \pm 0.007	0.7502	47
Total no. of cases	213		192			405

journal.com/software/sj2-4/st0026.pkg). Groups 3 to 5, totaling 247 patients, were satisfactorily matched ($p = \text{NS}$).

A multivariate analysis of determinants of survival was performed by means of the semi-parametric Cox analysis with a backward elimination strategy. According to a loss in statistical power, due to separate analysis of the matched and unmatched groups, variables with a p -value < 0.1 (possibly significant) were retained in the model (Table IV).

Results

Early (30-day) mortality

A total of 37 patients (9.8%) died; among these, 16 were in group S (three reoperations) and 21 in group HcK (one reoperation). The overall 30-day mortality was 7.5% in group S and 10.9% in group HcK ($p = \text{NS}$). Functional NYHA class III-IV, low ejection fraction and urgent operation were identified as significant univariate risk factors ($p < 0.05$).

Late mortality

There were 114 late deaths in group S (53.5%), and 130 in group HcK (67.7%). The overall 19-year K-M survival was 42% in group S versus 35% in group HcK ($p = 0.1147$) (Fig. 1a). Among the late deaths, 17% were valve-related (19 in group S versus 23 in group HcK; $p = \text{NS}$). The 19-year KM freedom from valve-related mortality was 84% (CI 70-92) in group S versus 82% (CI 74-88 CI) in group HcK ($p = \text{NS}$) (Table V).

Long-term survival, including 30-day mortality, among the 247 propensity-matched patients was similar for the two groups (Fig. 1b) ($p = 0.68$). Among unmatched patients, group HcK had a higher 30-day mortality and a lower long-term survival ($p = 0.20$).

By multivariate analysis, a greater hazard of mortality was significantly related to older age (age squared), more severe NYHA class, increased mean pulmonary artery pressure, number of previous open-heart operations, use of an aortic root enlargement procedure and, in the propensity unmatched group, to hepatic failure. In the propensity unmatched group the hazard of NYHA class and of previous surgery was lower than in the matched group (Table V). The hazard risk of prosthesis type was 1 in matched patients, but 1.37 for the Hancock Standard prosthesis in unmatched patients ($p = 0.28$).

Thromboembolism

Twenty-six major thromboembolic events occurred in group S patients compared to 17 in group HcK ($p = \text{NS}$) (Table V). K-M freedoms from thromboembolism among propensity-matched patients were similar (Table VI).

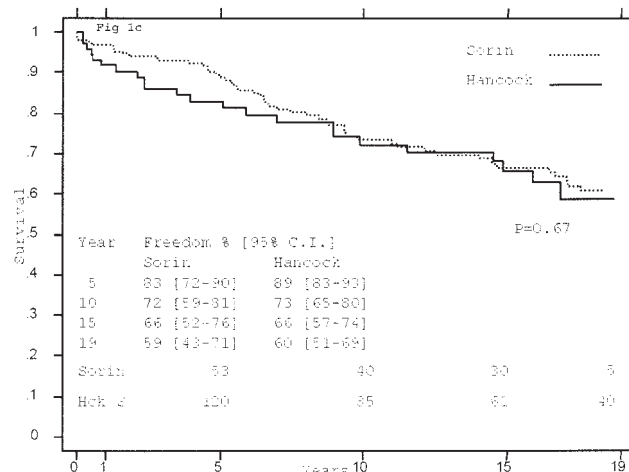
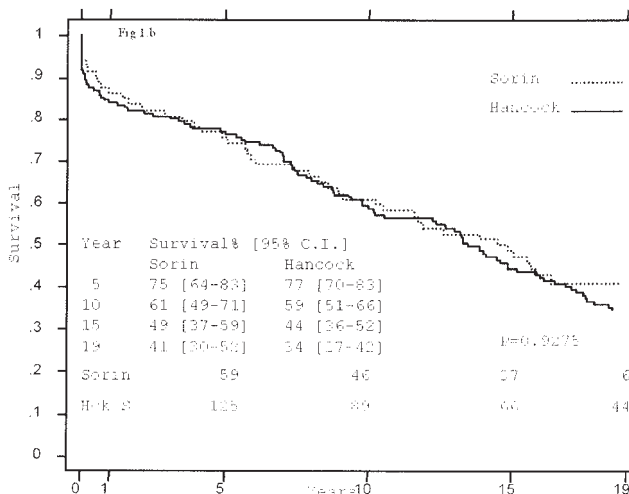
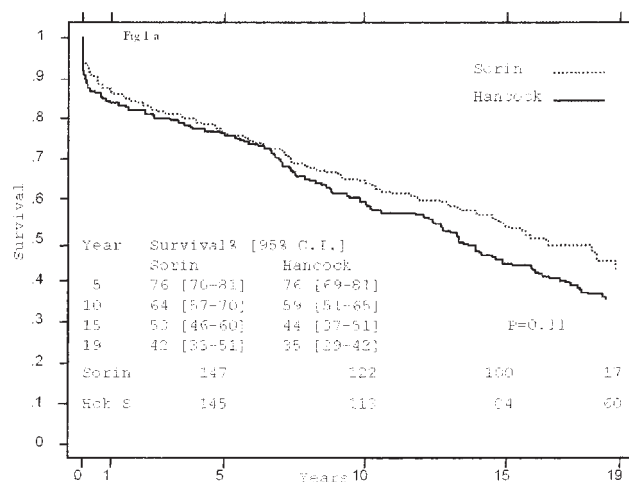


Figure 1: a) Kaplan-Meier survival of patients by prosthesis type after aortic valve replacement. b) Kaplan-Meier survival in propensity-matched patients. c) Freedom from valve-related mortality-morbidity in propensity-matched patients, excluding structural valve deterioration.

Table IV: Multivariate analysis of determinants of survival.

Parameter	Hazards ratio	SE	Z-value	P > z	95% CI
Previous surgery	8.1	6.14	2.78	0.005	1.86-35.71
NYHA class	1.9	0.25	4.57	0.000	1.42-2.43
Aortic root enlargement	2.4	1.09	1.91	0.056	0.97-5.86
Mean pulmonary pressure	1.015	0.0071	2.09	0.037	1.0009-1.028
Age squared	1.00025	0.00006	4.04	0.000	1.00013-1.00037
Hepatic failure*	3.1	1.71	2.02	0.044	1.032-9.15
Previous surgery*	0.16	0.13	-2.27	0.023	0.032-0.77
NYHA class*	0.92	0.046	-1.70	0.090	0.83-1.013

*Unmatched patients.
CI: Confidence interval.

Hemorrhagic events

Anticoagulation-related major hemorrhages occurred in 13 group S patients versus 16 group HcK patients (Table V). K-M freedoms from hemorrhage among propensity-matched patients were similar (Table VI).

Endocarditis

Twenty-three patients in group S developed endocarditis, compared to 11 in group HcK (Table V). K-M freedoms from endocarditis among propensity-matched patients were similar (Table VI).

Non-SVD and paravalvular leak

This event occurred in 33 patients in group S, and in 15 patients of group HcK (Table V). Paravalvular leak was observed in 25 patients of group S (seven reoperations) and in 12 of group HcK (one reoperation). When comparing patients of both groups with a single previous operation, the incidence of paravalvular leak was

not statistically different (18 group S patients versus 11 group HcK; $p = 0.12$). K-M freedoms among propensity-matched patients were similar (Table VI).

Structural valve deterioration

SVD was the major cause of reoperation in group HcK, with an exponential increase starting from five years after implantation. This event occurred in 81 patients in group S (Table V). After 19 years of function, the bioprosthesis showed a four-fold higher incidence of SVD-related failure when compared to the incidence at 10 years.

Reoperation

Reoperation was required in 39 group S patients compared to 96 group HcK patients (Table V). The overall freedoms from reoperation are listed in Table VI. K-M freedoms among propensity-matched patients are reported in Table VI.

Table V: Overall 5- to 19-years Kaplan-Meier freedom from valve-related events.

Kaplan-Meier freedom from:	Sorin			Hancock Standard			p-value at 19 years
	5 years	10 years	19 years	5 years	10 years	19 years	
Valve-related death	93 (89-96)	91 (86-95)	84 (70-92)	97 (92-99)	87 (80-92)	82 (74-88)	NS
Non-SVD and paravalvular leak	88 (83-92)	84 (78-89)	78 (70-85)	97 (94-99)	92 (87-96)	88 (80-92)	0.0153
Reoperation	88 (83-92)	84 (77-88)	75 (64-82)	89 (84-93)	57 (48-65)	15 (8-25)	0.00001
Thromboembolism	93 (88-95)	89 (83-93)	84 (76-89)	96 (91-98)	91 (85-95)	86 (78-91)	NS
Endocarditis	92 (87-95)	90 (85-94)	83 (73-89)	94 (90-97)	94 (89-97)	93 (88-96)	0.0443
Major bleeding	96 (92-98)	94 (89-97)	91 (85-95)	97 (92-98)	93 (87-96)	87 (80-92)	NS
Valve-related mortality and morbidity	78 (72-84)	69 (62-75)	43 (33-53)	84 (77-88)	49 (40-56)	17 (10-24)	0.00001
Valve-related mortality-, morbidity SVD-free	77 (70-82)	69 (61-75)	53 (43-62)	87 (80-91)	72 (64-78)	58 (49-66)	0.66

Values in parentheses are 95% confidence intervals.
NS: Not significant; SVD: Structural valve deterioration.

Table VI: Overall 5- to 19-years Kaplan-Meier freedom from valve-related events in propensity-matched patients.

Kaplan-Meier freedom from (events):	Sorin			Hancock Standard			p-value at 19 years
	5 years	10 years	19 years	5 years	10 years	19 years	
Valve-related death (%) (Sorin 5; HcK 21)	95.7 (87-99)	95.7 (87-99)	90.6 (78-96)	97.1 (92-99)	87.1 (80-92)	82.3 (74-88)	0.23
Non-SVD and paravalvular leak (%) (Sorin 9; HcK 10)	92.6 (83-97)	86.8 (75-93)	84.6 (72-92)	99.3 (95-99.9)	94.2 (88-97)	90.1 (82-95)	0.1
Reoperation (%) (Sorin 10; HcK 84)	92.8 (84-97)	86.7 (75-93)	82.4 (69-90)	90.7 (84-94)	61.2 (52-70)	16.6 (8-28)	0.00001
Thromboembolism (%) (Sorin 8; HcK 16)	95.6 (87-98)	91.6 (81-96)	80.1 (62-90)	96.2 (91-98)	91.1 (84-95)	84.9 (76-91)	0.71
Endocarditis (%) (Sorin 5; HcK 6)	95.7 (87-99)	93.7 (84-98)	91.1 (79-96)	96.5 (92-98)	96.5 (92-98)	95.5 (90-98)	0.36
Major bleeding (%) (Sorin 4; HcK 14)	96.8 (88-99)	95.1 (86-98)	92.5 (81-97)	96.4 (91-98)	91.8 (85-95)	88.3 (80-93)	0.71
Valve-related mortality-morbidity, SVD-free. (Sorin 23; HcK 48)	83 (72-90)	72 (59-81)	59 (43-71)	89 (83-93)	73 (65-80)	60 (51-69)	0.77

Valve-related complications

Hemorrhage, embolism, endocarditis, paravalvular leak, thrombosis and SVD were included among valve-related complications. Overall freedoms from valve-related complications are listed in Table V. K-M freedoms from valve-related complications (excluding SVD and reoperations due to SVD) among propensity-matched patients were similar (Table VI; Fig. 1c).

At the end of follow up, most patients in both groups were in NYHA functional classes I-II ($p = \text{NS}$) and in sinus rhythm ($p = \text{NS}$). All mechanical and all biological valve patients in atrial fibrillation, and 53% of the biological valve patients in sinus rhythm, were receiving oral anticoagulation (warfarin).

Discussion

When examining their valve database, the present authors extracted data from 379 patients aged less than 70 years who underwent isolated AVR with either a Sorin tilting disk mechanical valve or a Hancock Standard porcine valve between 1970 and 1984. During this era, mechanical and tissue valves were utilized indifferently across the entire spectrum of patient ages. The aim of the present study was to observe prospectively the survival of patients for up to 19 years postoperatively, and to identify - if possible - any long-term survival differences that might be attributable to valve type per se or to a higher prevalence of risk factors and postoperative complications related to a spe-

cific valve type. In order to minimize biases, a propensity scores analysis with a multivariable logistic model of a large number of variables that might affect the choice of prosthesis was utilized.

Several studies have - unconvincingly - compared prostheses produced by various manufacturers under the common headings of 'biological' or 'mechanical', even if patients were operated on during notably different surgical eras (9,14,15). In contrast, in the present study a large population of patients was analyzed who underwent AVR concurrently and with the exclusive use of two prosthesis models.

The favorable long-term outcome after prosthetic valve replacement is mostly related to the recovery of myocardial function and to operative timing (16), but it is also related to valve-related complications (17). Usually, there is consensus that the use of a bioprosthesis leads to low thrombogenicity and anticoagulant-related hemorrhage, but with limited durability; bioprostheses are therefore implanted in older patients, especially if their life expectancy is 10 years or less.

Bleeding complications were observed to be rare events for both types of valve. In the present series, freedom from bleeding was not significantly different between valve types, which was in contrast with the results of other authors, who found a significantly greater incidence of hemorrhage among recipients of mechanical prostheses (8-12,18,19).

Unlike Mykèn et al. (9), who compared St. Jude

Medical bileaflet valves with Biocor tissue valves, the mechanical valves used in the present series were Sorin tilting disk valves which, due to their flow profile, required a higher level of anticoagulation treatment than did the bileaflet valve. Nonetheless, Mykèn et al. reported an anticoagulant-related hemorrhage linearized ratio of 2.3% per pt-yr compared to an incidence of 0.5% per pt-yr in the current patients. These contrasting results might be explained by the fact that the authors' current mechanical population was younger than that of Mykèn et al., and therefore had a lower propensity towards hemorrhagic events (12). The difference in average age may also explain the different results observed in the Veterans Affairs randomized study (12,18), in which the patients were older than in the present investigation (mean age 59 versus 49 years).

The incidence of thromboembolism was also low for both devices. As expected (8-10), the rate of thromboembolism at both 10 years and 19 years of follow up was higher in the mechanical valve group, though the difference was not statistically significant.

Prosthetic valve endocarditis and paravalvular leak rates were seen to be significantly higher in patients with a mechanical valve. The higher incidence of paravalvular leak (as observed in the present series) among these patients is easily explained by the greater number of first and second reoperations in the Sorin group. In fact, several instances of paravalvular leak occurred in patients with previous aortic valve surgery who thereby were suffering from a frail and already surgically manipulated annulus. It is also noteworthy that the greater degree of softness of the Hancock Standard sewing ring cuff allowed an easier adaptability of the tissue valve to the annulus than did that of the Sorin valve, therefore limiting the leakage rate.

With regard to the incidence of SVD, an exponential increase in structural failure of the tissue valves starting five years after implant has been observed, and this was deemed responsible for a significantly lower freedom from reoperation in biological valve patients. The high SVD rate in the present study was related to the young age of the patients severely affecting the durability of this first-generation tissue valve when compared to other, more recent, models (9,20,21).

Survival of the present patients was comparable to that previously reported (8-12). Kassai et al. (19), in a meta-analysis of published randomized studies, failed to show any survival difference between mechanical and biological prostheses. The present data appeared to show a better survival for mechanical valve patients; however, when using an 'intention to treat' analysis while comparing long-term outcomes between propensity-matched patients, identical survival and freedom from valve-related complications (excluding

SVD) for biological and mechanical prostheses was observed, thus supporting the conclusion that the valve model was not a risk factor for long-term survival (8,10,11,18,19). Mykèn et al. (9) reported better survival with a tissue valve, but their duration of follow up was shorter than that of the present study, the sample size was smaller, no distinction was made between aortic and mitral patients, and they did not perform a propensity-matched analysis. More recently, in the final report of the Veterans Affairs randomized trial, Hammermeister et al. (12) observed better survival with a mechanical valve in the aortic position for patients aged <65 years. However, it must be stressed that the average operative age of these authors' biological valve patients was 59 years, compared to 49 years for the present patients and that, when dealing with long-term survival, a 10-year operative age difference renders comparison impossible.

Thus, it appears that the significant prevalence of reoperation in the biological valve group did not significantly modify the long-term survival of patients who initially received a tissue valve. To date, the present observational study is one of the largest to compare biological and mechanical prostheses in an isolated aortic position by using a propensity score analysis. The major points of this study were the number of patients at risk, the prolonged follow up and its validity, the same operative interval of prosthesis implantation, the similar follow up durations for the recipients of both types of prosthesis, and a propensity-matched patient population. Data derived from long-term follow ups are of the utmost importance when analyzing the results of 'intention to treat' choices, as shown by a recent randomized study in which the trend of results observed at 12 years were not confirmed at 20 years (11).

Study limitations

A possible criticism of the present study was the use of obsolete models of prostheses. Indeed, the first-generation Hancock Standard valve is no longer used due to an identified accelerated structural deterioration rate. In contrast, the Sorin tilting disk valve is largely used in developing countries, and demonstrates a performance that has a persistent clinical relevance. A second limitation of this non-randomized study was that unmeasured confounding variables may have been present that could have influenced any comparison between the matched patients.

In conclusion, the results of the present study suggest that, for implantation in the aortic position, prosthesis choice does not affect 19-year survival. The greater reoperation rate observed in the biological valve group does not imply a higher incidence of mortality.

However, based on the high reoperation rate for biological prostheses, the present authors' current policy, in accord with a general philosophy, is to use a tissue valve in patients aged >65 years, but to confine the use of mechanical valves to younger patients.

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