Mechanical heart valves: Are two leaflets better than one?

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Objective: We sought to compare the long-term clinical outcomes of patients who underwent isolated aortic valve replacement with single-disc and bileaflet mechanical heart valves.

Methods: From May 1975 through October 2001, 590 single-disc valves (7 models) were used for isolated valve replacement, and from November 1980 through July 2002, 1283 bileaflet valves (10 models) were used for isolated valve replacement. Detailed follow-up was performed to a maximum of 27.4 and 21.9 years with a total of 6872 and 5811 patient-years for single-disc valves and bileaflet valves, respectively. Survival and valve-related events were analyzed.

Results: Single-disc valves were mainly implanted from 1975 through 1995, whereas bileaflet valves were mainly implanted from 1987 through 2002; thus the years of concurrent use were 1987 through 1995. The bileaflet valve had a significantly lower explantation rate, whereas the single-disc valve had a significantly lower thromboembolism rate. No significant differences were detected in early mortality, long-term survival, and other valve-related complications. When limiting the comparison to the concurrent period of 1987 through 1995, no significant difference was detected in survival or in any valve-related complication.

Conclusion: Single-disc and bileaflet valves provide similar clinical performance. The predominant use of bileaflet valves is not based on clinical outcomes.

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The first successful mechanical heart valves, beginning in the early 1960s, were of the caged-ball design.¹ Then came the low-profile single-leaflet disc (L1) valves during the 1970s,² followed by bileaflet (L2) valves since the early 1980s.³ L1 valves have a housing with a single free-floating circular disc. L2 valves have 2 semicircular leaflets that are mounted on hinges within a housing that open and close simultaneously. Nowadays, most mechanical valves being implanted are L2 valves. It is generally perceived that, being more “modern,” L2 valves must be more advanced. However, the question of which one has better long-term performance remains unanswered.

Materials and Methods

Patients

From May 1975 through October 2001, 590 L1 valves and 1283 L2 valves were implanted in 1873 consecutive patients undergoing isolated aortic valve replacement at the Department of Cardiothoracic and Respiratory Sciences, Second University of Naples, V Monaldi Hospital. There were 7 models of L1 valves and 10 models of L2 valves. These 17 models were divided into 10 subgroups on the basis of similarity of design and manufacturer (Table 1). The choice of prosthesis was according to surgeon preference, and no overt selection criteria were used. The use of valve types over time is shown in Figure 1. L1 valves were

TABLE 1. Valve groups with 2-letter abbreviations (in parentheses) used to label Figures 4 to 7

Valve model (abbreviations)	No. of valves	Mean follow-up (y)
Single disc (L1)		
Bjork Shiley (BS)	80	12
Medtronic Hall (MH)	36	8
Medical CV (MC)		
Lillehei-Kaster	6	8
Omnicarbon	8	6
Sorin Monodisc (SM)		
Sorin (standard model)	290	13
Sorin Allcarbon	59	9
Sorin Carbocast	111	12
Bileaflet (L2)		
ATS-Medical (AM)	51	4
Edwards MIRA (EM)	266	3
Sorin Bicarbon (SB)	253	4
Carbomedics (CM)		
Carbomedics (standard model)	90	8
Carbomedics HP	202	8
Edwards Lifescience (EL)		
Duromedics	17	12
TEKNA	13	4
St. Jude Medical (SJ)		
St. Jude (standard model)	335	4
St. Jude HP	52	4
St. Jude Regent	4	1

mainly used from 1975 through 1995, and L2 valves were mainly used from 1987 through 2002, with concurrent use of both types from 1987 through 1995 (Figure 1, shaded area). The percentage use ratio of L1:L2 valves was 97%:3% from 1975 through 1986 and 2%:98% from 1996 through 2002. From 1987 through 1995, the use ratio was 49%:51%. Because the 2 types of valves were implanted in different eras, many improvements over time could make the results favor the recent valve type. Thus the analyses of the patients operated on from 1987 through 1995, when the 2 types of valve were used concurrently, are considered as the primary analyses, although results are also given for the entire series of valves.

Surgical Technique

Valve replacement was performed by the same group of surgeons, and the surgical technique remained substantially the same over the years. Standard cardiopulmonary bypass was performed in all cases. Bubble oxygenators were used until January 1990, and since then, hollow-fiber membrane oxygenators were used routinely. Myocardial protection was achieved with mild systemic hypothermia (26°C), antegrade crystalloid cardioplegia, and topical cooling with the Shumway technique. Kirsh cardioplegia was used until March 1981, and since then, St Thomas 1 solution has been used in all cases. Cardioplegia has been infused through the aortic root in patients with predominant aortic stenosis; in patients with valve regurgitation, cardioplegia was delivered through direct cannulation of the coronary ostia.

All prostheses were inserted in the intra-annular position by using unplicated, interrupted, simple Tevdek 2-0 stitches. Single-

disc valves were oriented with the main orifice toward the non-coronary sinus and bileaflet valves with their axis perpendicular to the septum. Leaflet mobility was always evaluated at the end of the procedure.

Anticoagulation Methods

Anticoagulation with warfarin was begun on the second postoperative day for all patients. The criterion for an adequate anticoagulation state was a prothrombin activity of $28\% \pm 8\%$, which in our laboratory equals an international normalized ratio of 2.8 ± 0.8 . International normalized ratio assay was performed at least once a month. Data concerning anticoagulation status for each patient were recorded. New hospital admissions either for cardiac or noncardiac causes were recorded as well.

Follow-up

Our follow-up methodology was about 60% prospective and 40% retrospective.

Our collection of follow-up data has high accuracy because our referrals are very restricted, and only a small percentage of patients come to us from other centers. Almost all patients visit our outpatient clinic almost yearly. Nearly 70% of our population is followed in our anticoagulation clinic by one of us every day. About 20% of patients are managed in 2 other satellite anticoagulation clinics and followed up by their own physicians, who are well informed and aware of our anticoagulation policy recommendations. Patients who are not followed up at our clinic or by their general practitioner are contacted by telephone or by mail to assess their healthy status. Such work is periodically done by our students doing medical theses. We record any event that occurred since the operation into a dedicated follow-up database. When we decided to begin this project, we initially checked our database, collecting the most recent follow-up data for 56% of the patients. For patients lost at our follow-up clinic or with their most recent examination more than 6 months old, we checked their status by telephone calls to the patient or his or physician. For patients who did not reply to our telephone call or letter, an official letter was sent to the Polls Department of City Office to assess whether the patient was dead or alive or had moved to another city, and in such cases recontact was made by means of telephone or mail to the latest address. For patients who died during the follow-up period, we interviewed the closest relative.

Statistics

Data are presented in accordance with the Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Operations.⁴ Early events, including death, are defined as occurring before hospital discharge or within 30 days after the operation, whichever is longer. Late events were all other events. Comparison between the preoperative characteristics of the 2 valve groups was made by using the χ^2 test for discrete variables and the Student *t* test for continuous variables. Univariate comparison of operative mortality was also made by using the χ^2 test. Actuarial survival curves and event-free curves were produced by using the Kaplan-Meier method, with the log-rank test for comparison. Cox regression was used to estimate the effect of risk factors on survival and explanation. Linearized rates, calculated as the number of late events divided by total late follow-up years and then multiplied by 100 to

Figure 1. The use of L1 and L2 valves over time. The shaded area indicates the time period when the use of the 2 valve types overlapped.

TABLE 2. Clinical material for patients undergoing aortic valve replacement by 3 time frames

	1975-1986	1987-1995 (Concurrent)			1996-2002
	Single disc (L1)	Single disc (L1)	Bileaflet (L2)	P value	Bileaflet (L2)
No. of patients	249	326	337		938
Age, y	44 ± 13	53 ± 14	54 ± 14	.9	60 ± 14
Female sex	54 (22)	71 (22)	129 (38)	<.001	393 (42)
Valve pathology				.01	
Stenosis	55 (22)	93 (29)	126 (37)		482 (51)
Regurgitation	113 (45)	121 (37)	99 (29)		257 (27)
Combined	74 (30)	102 (31)	92 (27)		181 (19)
Prosthetic dysfunction	7 (3)	10 (3)	20 (6)		18 (2)
Valve size (mm)	23 ± 2	23 ± 2	22 ± 2	<.001	22 ± 2
Previous AVR	7 (3)	10 (3)	20 (6)	.08	18 (2)
Follow-up, y					
Mean	15.2 ± 7.4	9.4 ± 4.5	8.6 ± 3.7	.02	3.0 ± 2.0
Maximum	27.4	15.6	15.5		6.8
Total	3777	3062	2910		2768
Postoperative NYHA class				.6	
I	126 (75)	200 (81)	217 (83)		742 (88)
II	34 (20)	40 (16)	42 (16)		92 (11)
III	5 (3)	5 (2)	3 (1)		5 (1)
IV	3 (2)	1 (0)	0 (0)		4 (1)

AVR, Aortic valve replacement; NYHA, New York Heart Association.

convert to the percentage per patient-year, were used to describe late valve-related complications. The 95% confidence intervals (CIs) for individual linearized rates were calculated with a method suggested by Cox.⁵ The Cochran test⁶ was used to test the heterogeneity of the linearized rates within each group. Because no significant heterogeneity was found among valves of the same type, likelihood ratio tests were used to compare the weighted mean linearized rates between the 2 valve groups. Statistical anal-

ysis was done with SPSS10 (SPSS Inc, Chicago, Ill) and S-PLUS 2000 (Insightful Corp, Seattle, Wash) software.

Results

The patients receiving L1 and L2 implants during the concurrent era had similar clinical profiles (Table 2). Because there were very few cases of L2 valves from 1975 through

Figure 2. Actuarial overall survival after valve replacement for patients operated on from 1987 through 1995 (shaded area in Figure 1). Numbers above the horizontal axis indicate the number of patients at risk.

TABLE 3. Cause of death: All time frames

Cause of death	Single disc (L1)		Bileaflet (L2)	
	Early	Late	Early	Late
Cardiac death				
Valve related				
Stroke	—	—	—	3
Hemorrhage	—	1	—	1
Endocarditis	—	1	—	2
Leak	—	6	—	—
Fibrous tissue overgrowth	—	1	—	1
Sudden death	—	20	—	13
Nonvalve related				
Acute myocardial infarction	3	11	10	7
Rupture of aorta, dissection	2	3	1	1
Arrhythmia	5	—	6	—
Congestive heart failure	—	9	1	9
Low output syndrome	15	—	14	—
Mitral valve disease	—	1	—	—
Multiple organ failure	6	2	9	1
Noncardiac death	12	64	30	56
Total	43	119	71	94

TABLE 4. Cause of explantation: All time frames

	Single disc (L1)	Bileaflet (L2)
Endocarditis	7 (1)	6 (2)
Thrombosis	2	—
Perivalvular leak	21 (5)	4
Fibrous tissue overgrowth	1 (1)	1 (1)
Aortic dissection	—	1
Ascending aorta aneurysm	1 (1)	—
Total	32 (8)	12 (3)

Numbers in parentheses indicate fatal explantation.

1986 and very few cases of L1 valves from 1996 through 2002, these were omitted from Table 2.

Follow-up

The closing date of this study was October 2002. For the L1 valve group, there were 6872 cumulative patient-years of follow-up, with a mean of 11.6 years and a maximum of 27.4 years. For the L2 valve group, there were 5810 cumu-

lative patient-years of follow-up, with a mean of 4.5 years and a maximum of 21.9 years. The follow-up was 100% complete for both groups. For the concurrent subset of patients from 1987 through 1995, the total follow-up was 3062 patient-years (mean, 9.4; maximum, 15.6) for L1 valves and 2910 patient-years (mean, 8.6; maximum, 15.5) for L2 valves.

Patient Survival

Early mortality was 7.3% (43/590) for L1 recipients versus 5.5% (71/1283) for L2 recipients ($P = .140$). For the concurrent subset, early mortality was 7.4% (24/326) for L1 recipients versus 6.5% (22/337) for L2 recipients ($P = .673$). For the entire series, overall survival was 79% (95% CI, 76%-82%) versus 79% (95% CI, 75%-83%) at 10 years and 68% (95% CI, 63%-72%) versus 75% (95% CI, 70%-80%) at 20 years ($P = .359$) for L1 and L2 valves, respectively. For the concurrent subset, the overall survival was similar between patients receiving L1 and L2 valves: 70%

Figure 3. Freedom from explantation after valve replacement for patients operated on from 1987 through 1995 (shaded area in Figure 1). Numbers above the horizontal axis indicate the number of patients at risk.

TABLE 5. Comparisons of linearized event rates within and between valve groups: All time frames

Events	Single disc (L1)		Bileaflet (L2)		Likelihood ratio P value†
	Linearized rate (95% CI)	Cochran P value*	Linearized rate (95% CI)	Cochran P value*	
Thromboembolism	0.059 (0.020-0.14)	.9	0.26 (0.15-0.42)	.7	.003
Hemorrhage	0.073 (0.028-0.16)	.3	0.070 (0.024-0.17)	.2	.9
Leak	0.38 (0.25-0.55)	.7	0.28 (0.17-0.44)	.2	.3
Endocarditis	0.16 (0.086-0.28)	.2	0.16 (0.078-0.29)	.8	1
Thrombosis	0.029 (0.0061-0.094)	.9	0.018 (0.0019-0.082)	.9	.7
Explantation	0.45 (0.31-0.64)	.6	0.21 (0.11-0.36)	.8	.02
Death	1.7 (1.5-2.1)	.4	1.7 (1.3-2.0)	.1	.7

CI, Confidence interval.

*Cochran tests of differences within valve models in each group.

†Likelihood ratio tests of differences between valve group.

(95% CI, 63%-77%) versus 73% (95% CI, 68%-79%) at 15 years ($P = .758$, Figure 2). In the Cox regression for this subset, age and previous aortic valve replacement were found to be significant risk factors, but valve type was not ($P = .718$). Causes of death for the entire series are given in Table 3.

Reoperation

In the entire series 44 L1 recipients required reoperation: 32 resulted in valve explantation, and 8 were fatal (Table 4). Two thirds of explantations were caused by perivalvular leak. One explantation in this group happened within the 30-day postoperative period. Twenty-one L2 recipients required reoperation: 12 resulted in valve explantation, and 3 were fatal. In the entire series the L2 group had a higher freedom from explantation than the L1 group, with 98%

(95% CI, 96%-99%) versus 95% (95% CI, 92%-96%) at 10 years and 93% (95% CI, 84%-97%) versus 91% (95% CI, 86%-94%) at 20 years ($P = .012$). For the concurrent subset of patients, the L2 valve group had a higher, although not significant, result: 95% (95% CI, 89%-98%) versus 95% (95% CI, 91%-97%; $P = .146$) at 15 years (Figure 3). Cox regression with the concurrent subset found previous aortic valve replacement ($P = .001$) to be a significant risk factor, but valve type was not ($P = .101$).

Valve-related Complications

Death and the valve-related complications of explantation, thromboembolism, hemorrhage, perivalvular leak, endocarditis, and prosthesis valve thrombosis were summarized as linearized rates for the entire series of 4 L1 subgroups and 6 L2 subgroups (Table 5). The complication rates varied

Figure 4. Thromboembolism rates for L1 and L2 valves (all time frames). *Circles* indicate L1 valves, and *paired semicircles* indicate L2 valves. *Dashed horizontal lines* indicate weighted mean rates for each valve group. *Two-letter valve-model abbreviations* are specified in Table 1. Numbers at the bottom of the graph show the number of events (*Events*) and total late follow-up years (*Pt-yr*s) for each valve model. For statistical comparisons between L1 and L2 valves during the concurrent era only, see Table 6. For model abbreviations, see Table 1.

Figure 5. Hemorrhage rates for L1 and L2 valves. See legend to Figure 4.

between and within the L1 and L2 subgroups (Figures 4-7).

To properly compare the pooled complication rates between L1 and L2 valves, we needed to test the assumption that the complication rates of all the subgroups within the same group were homogeneous.⁷ For death and all valve-related complications, the Cochran test did not show signif-

icant heterogeneity within either valve group. Therefore weighted mean linearized rates were compared between the L1 and L2 groups (Table 5). The L2 group had a lower explantation rate, whereas the L1 group had a lower thromboembolism rate. The 2 groups had very similar linearized rates for hemorrhage, endocarditis, leak, thrombosis, and

Figure 6. Leak rates for L1 and L2 valves. See legend to Figure 4.

Figure 7. Endocarditis rates for L1 and L2 valves. See legend to Figure 4.

late mortality. Very few valve thromboses were observed in either group.

Separating all the valves by the 3 time periods created 4 well-balanced groups (Table 6). L1 and L2 valves showed consistent complication rates over the different time periods. When the comparison between L1 and L2 is limited to 1987 through 1995, the period of concurrent use, no significant difference was detected for any complications.

Discussion

There is a common perception that L2 valves, being a later generation of mechanical valves, must be superior to L1 valves with regard to both hemodynamic performance and clinical outcomes. However, some in vitro and in vivo studies have demonstrated that an L1 valve can offer better hemodynamic performance than an L2 valve with both valves implanted in their optimum orientation in the aortic

TABLE 6. Comparison of the complication rates between valve groups during the 1987 through 1995 period of concurrent use (middle section of table)

	1975-1986	1987-1995 (concurrent)			1996-2002
	Single disc (L1)	Single disc (L1)	Bileaflet (L2)	P value*	Bileaflet (L2)
Late follow-up, y	3757	3036	2883		2693
Thromboembolism	0.027	0.10	0.21	.3	0.33
Hemorrhage	0.53	0.10	0.035	.3	0.13
Leak	0.40	0.36	0.35	.9	0.15
Endocarditis	0.13	0.17	0.24	.5	0.074
Thrombosis	0	0.066	0.035	.6	0
Explantation	0.43	0.46	0.28	.2	0.074
Death	1.7	1.8	1.9	.9	1.5

Rates for the remaining valves are given in the outside columns for reference.

*Likelihood ratio tests of differences between valve groups.

position.⁸⁻¹⁰ This is because the L1 valve's asymmetric design matches the natural eccentric flow profile of the aortic root. However, whether the specific hemodynamic advantages can be translated into better clinical outcome is not clear. The preference for the L2 valves could also be due to less noise or a perception of more safety as a result of the redundancy of the 2-leaflet design.

Several studies have compared the clinical outcomes of these 2 types of valves on the basis of their experience on 2 or 3 specific valve models.¹¹⁻¹⁴ A comparison of many published reports found similar event rates between L1 and L2 valves.¹⁵ In fact, even the earliest caged-ball Starr-Edwards valve, for which the design has not been changed since 1966, offers very good performance.¹⁶ Therefore we summarized our experience of the performance of 590 L1 valves and 1283 L2 valves. We hoped this study could provide some information about the long-term performance of these 2 main types of mechanical valves or, if not, to at least open to question the issue of bileaflet valve superiority. Even though we gradually switched from L1 to L2 valves from 1987 through 1995 (Figure 1), looking back now at our 28 years of experience, it seems that this switchover was not evidence based.

There was no significant difference in overall long-term survival for L1 and L2 valves (Figure 3). When the entire series was used, L1 valves had a lower thromboembolism rate but a higher explantation rate, which was primarily because of perivalvular leak. The diagnosis of perivalvular leak was always based on echocardiography. For perivalvular leak, surgeons were more likely to replace the old L1 valve with the newer L2 device but to repair a sterile, leaking L2 valve. When limiting the comparison to the concurrent patients operated on from 1987 through 1995, however, no significant difference was detected in any valve-related complications. The complication rates were low in our study, which could be due to our relatively young

patient age; many complications, such as death and thromboembolism, are related to patient age.

The study was a mixture of prospective and retrospective follow-up, and only a limited number of patient characteristics were available for risk adjustment. There are large numbers of valves of both types and long-term follow-up but a small number of valves for some valve models. Moreover, there are few events that could affect the detection of heterogeneity. It is a statistical challenge to compare 2 nonrandomized clinical series. If they are concurrent, there are unknown patient selection factors. If they are consecutive, there are changes over time, which can improve the more recent results. This study included 3 eras: an early one in which L1 valves were used almost exclusively, a recent one in which L2 valves were used almost exclusively, and a middle one in which both were used concurrently and in almost equal numbers. We were thus able to compare the overall results, which included periods of unselected (almost consecutive) use, and the concurrent results, which matched for time frame of surgical intervention.

The results of the present study show that L1 and L2 valves offer similar good clinical performance. The predominant use of L2 valves has not been scientifically justified on the basis of clinical outcomes.

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