Forty-Year Survival with the Starr-Edwards Heart Valve Prosthesis

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Background and aim of the study: **The study aim was to update an analysis of the long-term survival of heart valve replacement using the Starr-Edwards prosthesis.**

Methods: **Cases of isolated aortic (AVR, n = 2,247) and mitral (MVR, n = 1,406) valve replacement with Starr-Edwards prostheses implanted between 1960 and 1997, with follow up to 2003, were reviewed. Introduced in 1965, the Models A1200/1260, M6120 are still in use (Current), while other models have been discontinued (Discontinued). For AVR, 938 valves were Discontinued, with a total follow up of 8,506 patient-years (pt-yr) and a maximum of 41 years; by comparison, 1,309 valves were Current, with a total follow up of 11,586 pt-yr and a maximum of 36.1 years. For MVR, 635 valves were Discontinued, with a total follow up of 6,454 pt-yr and maximum of 37.2 years; and 771 valves were Current, with a total follow up of 6,211 pt-yr and maximum of 37.0 years.**

Results: **Kaplan-Meier (KM) survival at 10 years was 53% for AVR and 51% for MVR; KM survival at 20 years was 23% for both AVR and MVR; KM survival at 30 years was 8% for both AVR and MVR; KM survival at 40 years was 4% for AVR. The standard error for all KM percentages was 1%. Four patients are currently alive with their original valves, more than 40 years after implantation.**

Conclusion: **This series of patients, who underwent valve replacement with the Starr-Edwards valve, now have a follow up extending beyond 40 years, thereby confirming the excellent durability of this valve.**

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More than 40 years have passed since Starr and Edwards described the first successful prosthetic valve replacement (1). The Starr-Edwards (S-E) valve is a caged-ball prosthesis which was first used clinically in the early 1960s. The original S-E valve was composed of a silastic ball which was seated in the sewing ring when closed, and moved forward into the cage when opened. Between 1960 and 1964, some engineering alterations were made to enhance hemodynamic performance and fixation. This entire early group of prostheses was called the Model 6000 (Mitral; Fig. 1, left) and Model 1000 (Aortic). From 1965 to 1968, several other modifications were made. The fabric margin was extended to the inflow orifice to eliminate the larger bare metal surface in the original model, the intention being to reduce thromboembolism (2). This group of prostheses was called the 'extended-cloth prosthesis', and included Model 6120 (Mitral) and Model 1200/1260 (Aortic; Fig. 1, right); they have been used continuously since that time. Encouraged by the substantial decrease in the incidence of postoperative emboli noted in the 'extended-cloth valve', total cloth covering of the cage arose, which resulted in a new group of S-E prostheses - called 'cloth-covered valves' - and culminated in the 'track valve'. These models were later discontinued in favor of the original bare strut design when it became evident that the initially observed improvement was a function of the time frame of implantation and that the cloth covering offered no overall advantage with regard to reduced thromboembolism (3). Later on, a beaded metal model was developed, but subsequently discontinued.

Since its introduction, more than 200,000 S-E valves have been implanted worldwide. Some patients who underwent valve replacement with the S-E valves in the 1960s are still alive. Since the time of their first

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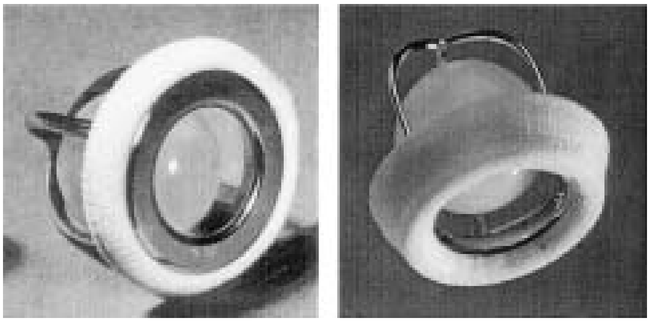

Figure 1: Starr-Edwards valves. Left: The original mitral valve (Model 6000); Right: The current aortic valve (Model 1260).

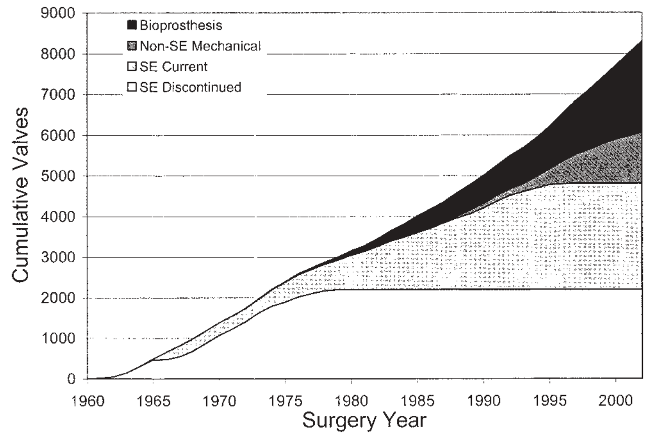

Figure 2: Cumulative valve usage by year at the authors' institution. The total valves used from 1960 to 2002 were 2,198 S-E Discontinued (26%), 2,616 S-E Current (32%), 1,247 Non-S-E Mechanical (15%), and 2,239 Bioprosthesis (27%).

heart valve replacement, the present authors have provided a prospective lifetime follow up service for all patients, contacting them at least annually to determine survivorship and heart valve complications. Previously, the authors' experience has been reported at three months (1), six years (2), 15 years (4) and 25 years (5). The present report summarizes the 40-year experience, and comprises a consecutive series of patients who have undergone valve replacement with the S-E valve. The report considered only those patients who underwent isolated aortic (AVR) or isolated mitral (MVR) valve replacement; those patients undergoing multiple valve replacement and tricuspid valve replacement were excluded.

Clinical material and methods

Patients

Between 1960 and 2002, a total of 8,300 heart valve prostheses was implanted in the aortic or mitral position at the authors' institution. Of these prostheses, 4,814 (58%) were S-E valves, 1,247 (15%) were other mechanical valves, and 2,239 (27%) were tissue valves. The cumulative prosthesis usage by year for S-E Models 6120 and 1200/1260 ('Current'), all other S-E models ('Discontinued'), other mechanical valves, and tissue valves is illustrated in Figure 2.

Since 1960, totals of 2,247 isolated S-E AVR and isolated 1,406 S-E MVR have been carried out. The preoperative clinical profiles of each group are summarized in Table I. For AVR, the mean patient age was 57.6 ± 13.4 years (range: 9 to 88 years), and for MVR was 55.8

Table I: Clinical profiles of patients.

Parameter	AVR		MVR	
	Current	Discontinued	Current	Discontinued
Valves implanted (n)	1309	938	771	635
Age (years)*	60.6 ± 12.9	53.5 ± 12.9	59.7 ± 12.7	51.1 ± 11.8
Sex ratio (M:F)	941:368	734:204	301:470	252:383
Valve size (mm)				
19	4	6	1	-
21	89	105	3	-
23	426	214	1	2
25	616	469	18	26
27	101	100	129	166
29	40	29	410	303
31	27	3	235	138
Associated CABG	338 (26)	131 (14)	159 (21)	52(8)
Re-replacement	73 (6)	80 (9)	54 (7)	26 (4)

*Values are mean ± SD.
Values in parentheses are percentages.
CABG: Coronary artery bypass grafting.

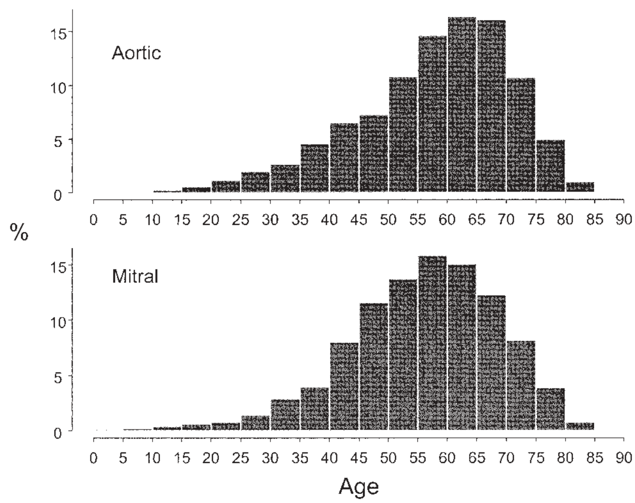

Figure 3: Age distribution of MVR and AVR with S-E valves.

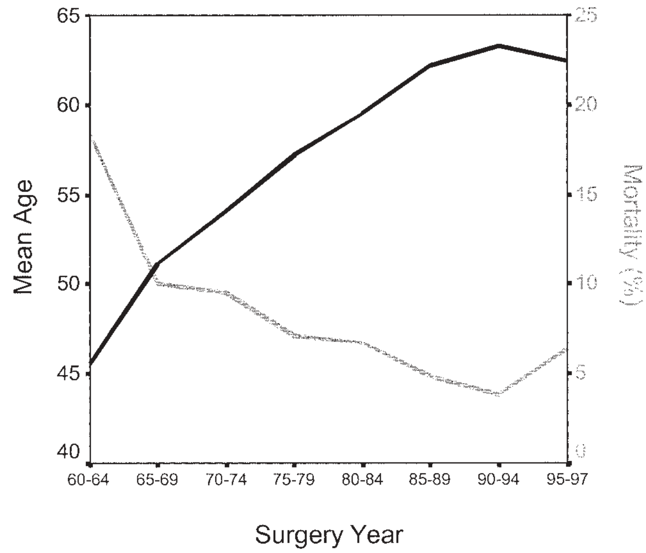

Figure 4: Average patient age and overall operative mortality by year. Black curve: Mean age trend with its unit on left-side vertical axis. Gray curve: Operative mortality trend with units on right-side vertical axis.

± 13.0 years (range: 1 to 84 years). The age distribution for each group is illustrated in Figure 3.

Follow up

Beginning with the first valve patient, a prospective lifetime follow up service was implemented. All patients undergoing valve replacement are followed up at annual intervals, using a combination of mailed questionnaire and telephone interview. The total and maximum follow up years by position and valve model group are summarized in Table II. For AVR, 938 valves were Discontinued, with a total follow up of 8,506 patient-years (pt-yr) and a maximum of 41.0 years; and 1,309 valves were Current, with a total follow up of 11,586 pt-yr and a maximum of 36.1 years. For MVR, 635 valves were Discontinued, with a total follow up of 6,454 pt-yr and a maximum of 37.2 years; and 771 valves were Current, with a total follow up of 6,211 pt-yr and a maximum of 37.0 years.

Valve-related deaths and complications were defined following the *Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Operations* (6). The primary outcome of interest in this analysis was long-term survival. Cause of death was established from hospital records or autopsy reports when available. Operative death was defined as any death occurring in the hospital or after discharge, but within 30 days of operation.

Statistical analyses

Continuous data were presented as mean ± SD, and

Table II: All models of Starr-Edwards (S-E) valve and their years of follow up.

Model (implant period)	AV			MVR		
	Valves (n)	Follow up		Valves (n)	Follow-up	
		Total (pt-yr)	Max. (years)		Total (pt-yr)	Max. (years)
Discontinued S-E	938	8,506	41.0	635	6,454	37.2
Original (1960-1966)	186	1,669	41.0	111	1,058	37.2
Cloth-covered (1967-1975)	438	3,687	33.5	291	2,953	34.1
Track (1972-1980)	297	2,960	30.0	225	2,357	30.0
Beaded metal (1974-1979)	17	190	24.0	8	87	25.0
Current S-E (1965-1997)*	1,309	11,586	36.1	771	6,211	37.0

*Mitral Model: 1200/1260; Aortic Model: 6120.

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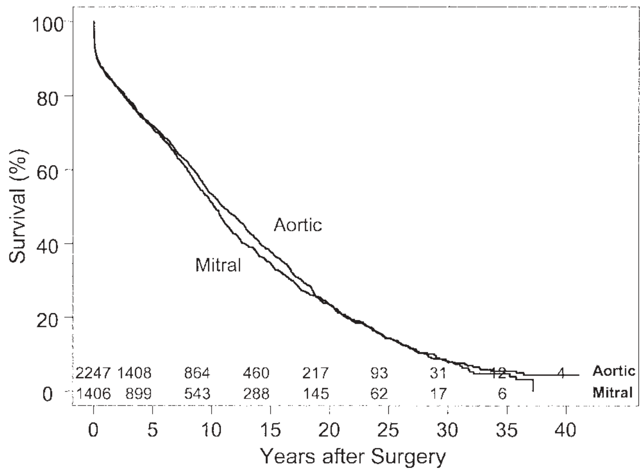

Figure 5: Actuarial survival curve of AVR and MVR with all models of S-E valve.

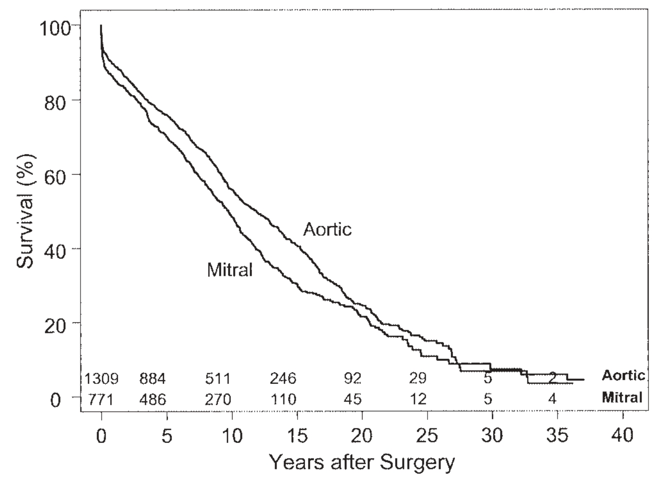

Figure 6: Actuarial survival curve of AVR and MVR with the Current S-E valve.

actuarial probabilities and linearized rates as means with 95% confidence limits of the mean. Linearized rates were the number of events per 100 pt-yr (%/year) of follow up. Survival curves were obtained using the Kaplan-Meier (KM) method and compared by log-rank test; only the first event for each patient was used. Thromboembolism (TE)-free curves were obtained by using both the KM method and actual (cumulative incidence) method (7). Statistical analysis was carried out using SPSS 10 (SPSS Inc., Chicago, IL, USA) and S-PLUS 2000 (Insightful Corp, Seattle, WA, USA).

Results

Operative mortality

During the postoperative period, 167 of 2,247 patients died after AVR (operative mortality 7.8%), and 112 of 1,406 patients after MVR (operative mortality 8.0%). Overall operative mortality for both AVR and MVR has decreased over the years (Fig. 4) yet, during the same time, the mean age of patients has risen from 45 to 60 years. During the past decade, operative mortality has decreased to 4.2%.

Late mortality

For all valve models, there have been 1,243 late AVR deaths (6.2%/year) and 828 late MVR deaths (6.6%/year). Actuarial survival by valve implant position is illustrated in Figure 5. Kaplan-Meier survival at 10 years was 53% for AVR and 51% for MVR; KM survival at 20 years was 23% for both AVR and MVR; KM survival at 30 years was 8% for both AVR and MVR; KM survival at 40 years was 4% for AVR. The standard error for all KM percentages was 1%. Four patients are still alive at 40 years after valve implantation (Table III).

For the Current valves, actuarial survival for AVR at 10, 20 and 30 years was 55.9 ± 1.5%, 24.5 ± 1.8% and 6.8 ± 2.0%, respectively; and for MVR was 48.5 ± 2.0%, 21.5 ± 2.1% and 8.7 ± 2.3%, respectively (Fig. 6). Causes of late death for the Current group are shown in Table IV. There have been no deaths among patients with the Current S-E valve which have resulted valve from structural dysfunction.

Thromboembolism

In the Current group, 291 late TE events occurred after AVR, and 306 late TE events after MVR. Actuarial freedom from TE at 35 years was 59% with AVR and 50% with MVR. However, actual freedom from TE at 35 years was 77% and 66%, respectively (Fig. 7).

Table III: Clinical profile of patients currently alive.

Case	Age (years)	Gender	Operation (date)	Valve model	Valve-related events
1	59	M	AVR (5/9/1962)	1000	Leak and repair in 1963; peripheral embolus in 1965
2	89	M	AVR (10/31/1962)	1000	Stroke in 2000
3	90	M	AVR (5/15/1963)	1000	Repair (ball change) in 1967; transient ischemic attack in 1966
4	67	F	AVR (6/19/1963)	1000	Repair (ball change) in 1983; MVR added in 2001

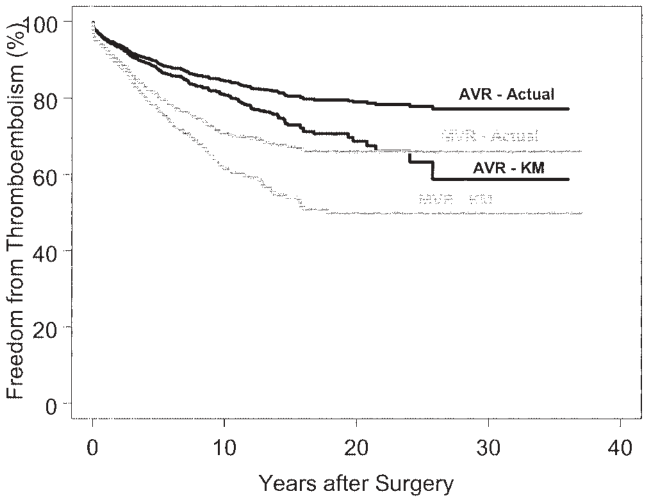

Figure 7: Actuarial and actual freedom from thromboembolism (TE) of AVR and MVR with the Current S-E valve.

Discussion

In the aortic series, the maximal follow up was 41 years, and the KM estimate at 40 years 4% (Fig. 5). In fact, as of June 1, 2003, there were four AVR patients who have documented follow up beyond 40 years, and these are believed to be the longest heart valve prosthesis survivors in the world (8-12). What makes the S-E valve so remarkable is its intrinsically durable design: a cage, a ball, and a sewing ring. The alloy cage is made from a single cast without welds, bends or hinges. This design provides it with integrity and structural strength that compares favorably with other heart valve prostheses. Ball variance may occur, but is neither critical nor fatal. If it does occur with a valve in the aortic position, the ball can be replaced without intervention with the sewing ring and cage.

Thromboembolism is the most disturbing complication, but there is marked variation from one reported S-E series to another (13). This variability may result from discrepancies in the patient population, anticoagulation therapy, or follow up frequency. It has been reported that TE is more related to the patient than to the valve itself (14). In the present series, for the Current group, the KM curves for TE were not promising, with freedom from TE values of 59% (AVR) and 50% (MVR) at 35 years. However, the actual method of analysis showed 77% of patients TE-free with AVR and 66% TE-free with MVR at 35 years. In fact, at present, 83% (1,085/1,309) of AVR patients and 71% (544/711) of MVR patients are still alive or have died without suffering a thromboembolic event.

One advantage of the S-E valve is that of less prosthetic thrombosis. As the poppet does not continually contact with the orifice during each cardiac cycle - where thrombosis is prone to generate - it reduces the risk of prosthetic thrombosis. Furthermore, even if this complication does occur, the ball motion is not immediately restricted. Thus, a clinical deterioration will develop, whereas with disc valves disc motion can stop suddenly and the patient will collapse (15).

The S-E valve is a remarkably durable prosthesis, though its hemodynamic performance in the smaller aortic sizes, and its perceived incidence of valve-related complications make it less competitive than newer disc prostheses. This may be mostly age discrimination, as though it must be too old to be taken seriously. However, it is arguably equivalent in clinical performance to the newer, most popular valves (16,17). Despite advances in valve design, the present authors' interest in the Current model of S-E valve remains strong for its historical significance, as well as for the ongoing care of those patients who continue to rely on this prosthesis. The present report represents the longest follow up available on any heart valve prosthesis, and provides a

Table IV: Causes of late death for the Current valve group.

Cause of death	AVR	MVR
Cardiac	454 (68)	303 (72)
Valve-related	258 (39)	176 (42)
Thromboemboli	36 (5)	37 (9)
Hemorrhage	27 (4)	22 (5)
Endocarditis	11 (2)	10 (2)
Valve thrombosis	3 (0.4)	3 (0.7)
Periprosthetic leak	5 (0.6)	2 (0.5)
Structural failure	0	0
Sudden death/Unknown	176 (27)	102 (24)
Non-valve-related	196 (29)	127 (30)
Non-cardiac	211 (32)	118 (28)
Total	665	421

Values in parentheses are percentages.

baseline on which subsequent new heart valve prostheses might be judged. In any event, this valve herewith presents 40-year survival results, which the more recently introduced models may be challenged to match.

In conclusion, this series of patients who have undergone AVR or MVR with the S-E valve, now have a follow up extending beyond 40 years, thereby confirming the excellent, long-term durability of this valve and setting the mark to be exceeded by newer valves.

References

1. Starr A, Edwards ML. Clinical experience with a ball valve prosthesis. Ann Thorac Surg 1961;154:726-740
2. Starr A, Herr RH, Wood JA. Mitral replacement. Review of six years' experience. J Thorac Cardiovasc Surg 1967;54:333-358
3. Macmanus Q, Grunkemeier GL, Lambert LE, Teply JF, Harlan BJ, Starr A. Year of operation as a risk factor in the late results of valve replacement. J Thorac Cardiovasc Surg 1980;80:834-841
4. Macmanus Q, Grunkemeier G, Thomas D, Lambert LE, Starr A. The Starr-Edwards model 6000 valve. A fifteen-year follow-up of the first successful mitral prosthesis. Circulation 1977;56(4 Pt.1):623-625
5. Grunkemeier GL, Starr A. Twenty-five year experience with Starr-Edwards heart valves: Follow-up methods and results. Can J Cardiol 1988;4:381-385
6. Edmunds LH, Jr., Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. The American Association for Thoracic Surgery, Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity. Ann Thorac Surg 1996;62:932-935
7. Grunkemeier GL, Anderson RP, Miller DC, Starr A. Time-related analysis of nonfatal heart valve complications: Cumulative incidence (actual) versus Kaplan-Meier (actuarial). Circulation 1997;96(suppl.):II-70-II-74
8. Godje O, Brenner P, Fischlein T, Reichart B. Thirty years survival after double valve replacement with Starr-Edwards prostheses in aortic and mitral position. Eur J Cardiothorac Surg 1997;11:391-393
9. John S, Rao C. Prosthetic valve replacement in Ebstein's malformation: 30-year follow-up. Ann Thorac Surg 1999;68:556-557
10. Kucukaksu DS, Akgul A, Uzun A, et al. Thirty years survival without anticoagulation after aortic valve replacement with a Björk-Shiley prosthesis. J Heart Valve Dis 2001;10:548-549
11. O'Brien MF, Harrocks S, Stafford EG, et al. The homograft aortic valve: A 29-year, 99.3% follow up of 1,022 valve replacements. J Heart Valve Dis 2001;10:334-344
12. Grunkemeier GL, Li HH, Starr A. Heart valve replacement: A statistical review of 35 years' results. J Heart Valve Dis 1999;8:466-470; discussion 470-471
13. Grunkemeier GL, Li HH, Naftel DC, Starr A, Rahimtoola SH. Long-term performance of heart valve prostheses. Curr Probl Cardiol 2000;25:73-154
14. Butchart EG, Lewis PA, Kulatilake EN, Breckenridge IM. Anticoagulation variability between centres: Implications for comparative prosthetic valve assessment. Eur J Cardiothorac Surg 1988;2:72-81
15. Metzdorff MT, Grunkemeier GL, Pinson CW, Starr A. Thrombosis of mechanical cardiac valves: A qualitative comparison of the silastic ball valve and the tilting disc valve. J Am Coll Cardiol 1984;4:50-53
16. Akins CW. Mechanical cardiac valvular prostheses. Ann Thorac Surg 1991;52:161-172
17. Akins CW. Results with mechanical cardiac valvular prostheses. Ann Thorac Surg 1995;60:1836-1844

Meeting discussion

DR. K. ZEHR (Rochester, MN, United States): Certainly Dr. Starr has contributed greatly to heart valve replacement, and this is shown to be a durable prosthesis. One thing that would be helpful would be to examine survival curves related to an age-matched population in patients without the disease. That would indicate if these patients are indeed put back on a survival curve - which would be equivalent if they did not have aortic or mitral valve disease.

DR. A. P. FURNARY (Portland, OR, USA): I would agree with you. This study began just as a valve centric study, to see how the prosthesis would last over time. As I became involved, I realized that there is probably a need for an operation centric study to investigate aortic and mitral valve replacement - and how that does or does not improve survival as compared with the normal curve.

DR. ZEHR: This study is also valuable in the sense that we often look at Kaplan-Meier curves in order to sense what will happen over 20-25 years compared with the current situation. In fact, the actual freedom from thromboembolism is a more important value than the Kaplan-Meier values, as here we are seeing it for such a long follow up.

DR. FURNARY: For such a long follow up I was quite surprised to see how high the actual freedom from thromboembolism was 77% in aortic valves, which is not bad after 30 years. The original patients had no other option and were going to die - yet these are the patients who are now at 30 and 40 years follow up.