CURRENT STATUS OF VALVE REPLACEMENT

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This paper presents a review of the experience in isolated valve replacement in the Open Heart Surgery Unit, University of Melbourne Hospitals from 1965 through to March 1972. In a total of 586 open valve procedures 414 isolated valve replacements have been carried out consisting of 264 aortic valve replacements and 150 mitral valve replacements. See Table I. Cases in which other procedures were combined with the isolated replacements have been excluded from the review. In this series Starr Edwards valves have been used in 306 cases. In the aortic replacements formalin preserved calf and pig heterografts have been used in 62 cases while the mitral series contains 12 cases in which a strut supported aortic heterograft has been inserted. See Table II.

An assessment of the overall risk involved in isolated valve replacements can be obtained by a study of the operative mortality. In the total of 414 cases there have been 41 operative deaths, an operative death being defined as a death due to any cause occurring within one month of the operation. This represents an overall mortality of 9.9%. See Table III.

Operative mortality must be viewed against the type of case subject to surgery. It is not intended in this communication to deal at length with indications for operation but in summary cases subject to surgery in this series were in either Grade III or Grade IV of the New York Heart Association classification of symptoms.

AORTIC VALVE REPLACEMENT

Aortic valve replacement has been carried out in 264 instances, in 62 cases using a heterograft and in 202 cases a Starr Edwards prosthesis. The overall mortality was 28 patients giving an operative mortality of 10.7%. See Table IV.

The causes of death are outlined in Table V. This table indicates that the major cause of death in the series was left ventricular failure in 8 cases. These were patients in whom the heart would not take over from the pump and comprised generally those with long standing severe aortic valve disease and considerable left ventricular hypertrophy. Recurrent arrhythmias accounted for three deaths, two of these patients had severe associated coronary artery disease. Cerebral complications accounted for three deaths. It is often difficult to be certain as to the cause of cerebral complications, air embolism being most commonly involved. The incidence of both fatal and non fatal cerebral complications occurring following open heart surgery would now seem to be significantly reduced by the inclusion in the pump circuit of Pall filters in both the venous and arterial lines suggesting that platelet macroaggregates may play a significant part in the production of cerebral complications.

Technical factors were responsible for death in four cases two of them being at reoperation. Other causes of death were renal failure, respiratory failure, cardiac failure, stuck ball, aortic dissection and infection. The low incidence of operative death due to infection in the month following surgery has been attributed to the careful preoperative screening of patients and staff and the prophylactic use of antibiotics.

AORTIC HETEROGRAFT REPLACEMENT

In an attempt to assess the value of tissue valve replacement a series of 62 cases had aortic valve replacements with formalin preserved calf or porcine valves. The operative mortality (14%) differed slightly from the Starr Edwards series (9%) but a major complication was the development of aortic incompetence.

This necessitated reoperation in 20 cases because of severe incompetence and left ventricular failure. The reoperation mortality was 15%. If reoperations for heterografts are excluded from the series the operative mortality for initial aortic valve replacement is 9.5%. This more clearly represents the true current mortality for aortic valve replacement as the practice of heterograft replacement has now been discontinued because of the high incidence of incompetence. The trial of heterografts has not been prejudicial to the overall survival of the patients as the survival curve for patients does not differ significantly from that of the Starr Edwards series being 70% at the five year period. See Figs. 1 and 2.

AORTIC REPLACEMENT FOLLOW UP

It has been possible to obtain follow up information on all but 2 of the patients who have gone on interstate. Details of the postoperative morbidity are contained in Table VI. Major embolism remains the commonest cause of death. In the first sixteen patients no anticoagulants were employed. There were 3 sudden deaths in this group due to embolism and accordingly all patients subsequently have been placed on anticoagulants. Of the nine deaths due to endocarditis six of them occurred within the first year of operation. This suggests that these infections may have been acquired during the operation or postoperative period and the low pathogenicity of the organisms is responsible for the failure to recognise them early and the difficulty of treatment once the endocarditis is established. There have been only three instances of fatal endocarditis in the patients surviving beyond the first year suggesting that late postoperatively acquired infection is at a low rate.

Coronary artery disease remains a major factor in determining postoperative mortality an inevitable association considering the average age at which aortic valve replacement is required. Reoperation for aortic incompetence accounted for five deaths. The majority of these were technical at the time of surgery. With increasing experience in the surgical problems posed by reoperation, this cause for mortality has been considerably lessened. In only one case has reoperation been required for perivalvular leak around a Starr prosthesis and as tissue valve usage has been abandonned the need for reoperation in the future is likely to be considerably lessened.

Left ventricular failure accounted for five deaths. This represents almost certainly the presence of irreversible changes in the left ventricle present at the time of surgery as in none of these cases were valve factors responsible for the persistent failure. This persistence of left ventricular problems might suggest the need for revision of the criteria for operation, now that the mortality has been reduced to an acceptable level.

Complications of the Starr Edwards prosthesis were responsible for sudden deaths in only two cases, one a prolapsed variant ball which embolised to the lower aorta and one a stuck ball in the silastic ball series occurring on the first postoperative day following reoperation for an incompetent heterograft. Now that the problem of ball variance has been overcome it is not likely that ball prolapse will remain a problem.

The remaining causes of death show a wide spectrum of causes none immediately related to valve failure apart from one case of aortic incompetence who died following a cardiac catheter to assess the degree of incompetence. In one case who had an aortic valve replacement and replacement of the ascending aorta for

Open Heart Surgery Unit, University of Melbourne Hospital.

TABLE I

OPEN HEART SURGERY UNIT
UNIVERSITY OF MELBOURNE HOSPITALS
ISOLATED VALVE REPLACEMENT

Total open valve Procedures	586
Aortic Valve Replacements	264
Mitral Valve Replacements	150
TOTAL REPLACEMENTS	414

TABLE II

OPEN HEART SURGERY UNIT
UNIVERSITY OF MELBOURNE HOSPITALS
TYPES OF VALVES USED

AORTIC REPLACEMENT	
Starr Edwards Prostheses	202
Heterograft Prostheses	62
MITRAL REPLACEMENT	
Starr Edwards Prostheses	138
Strut Supported Heterograft	12
TOTAL	414

TABLE III

ISOLATED VALVE REPLACEMENTS
OPERATIVE MORTALITY

Total Cases	414
Operative Deaths	41
MORTALITY	9·9%

TABLE IV

AORTIC VALVE REPLACEMENT
OPERATIVE MORTALITY

Total Cases	264
Operative Deaths	28
MORTALITY	10·7%

TABLE V

AORTIC VALVE REPLACEMENTS
CAUSES OF DEATH AT OPERATION

Left Ventricular Failure	9	Circulatory Failure	2
Technical	4	Respiratory Failure	1
Recurrent Arrythmias	3	Infection	1
Renal Failure	3	Stuck Ball	1
Cerebral Complications	3	Aortic Dissection	1

TABLE VI

AORTIC VALVE REPLACEMENT
LATE DEATHS

Embolism	10	Stuck Ball	1
Endocarditis	9	Prolapsed Ball	1
Coronary Artery Disease	5	Arrythmia	1
Reoperation	5	Catheter	1
Left Ventricular failure	4	Myopathy	1
Carcinoma	3	Aortic Rupture	1
Dissecting Aneurysm	2	Graft Rupture	1
Cerebral Complications	1		

TABLE VII

AORTIC VALVE REPLACEMENT
FOLLOW-UP MORBIDITY

REOPERATION			
Incompetence		Aortic Incompetence	15 (Starr 2)
Heterograft	17	Endocarditis	6
Starr	1	Minor	
Haemolysis	1	Embolism	3
		Major	
Ball Variance	3	Embolism	1
Stuck Ball	2	Haemolysis	1
TOTAL	24		

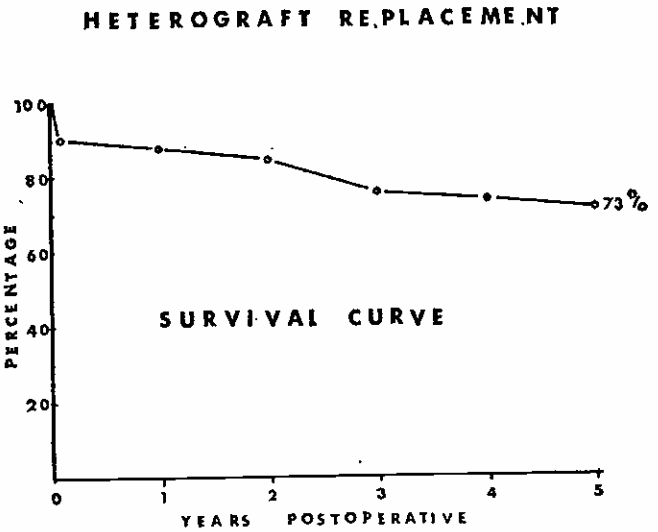

Fig. 1. Five-year survival for heterograft aortic valve replacement.

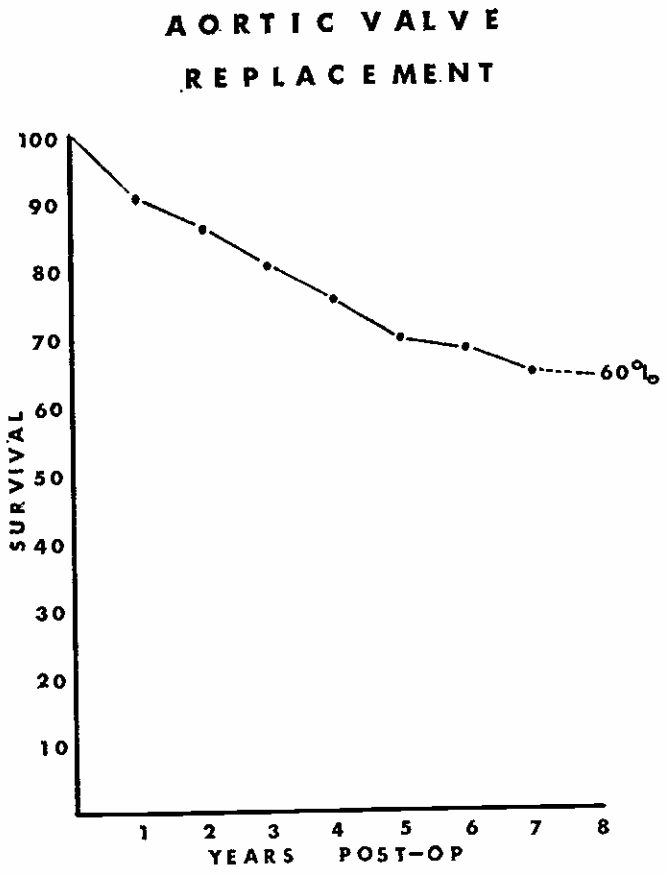

Fig. 2. Seven-year survival curve for aortic valve replacement.

cystic medial necrosis four years before redissection occurred at the junction of the graft and a cuff of aortic wall which had been left at the original operation. This suggests the need in operating for this condition to bring the graft right down to the aortic ring and to attach the coronary orifices to the graft. The remaining patients succumbed to arrhythmia, aortic rupture, cardiomyopathy, dissecting aneurysm and finally to carcinoma, two of the lung and one of the breast.

POSTOPERATIVE MORBIDITY

The major cause of morbidity in this series was the development of aortic incompetence. See table VII. This was severe enough to warrant reoperation in seventeen cases only one being apperivalvular leak around a Starr Edwards prostheses.

In five instances two being Starr replacements there is mild to moderate incompetence not causing sufficient hemodynamic disturbance to warrant further surgical procedures.

Six patients have developed late endocarditis which has been successfully treated the patients now being well. All of these late recoverable infections have occurred on Starr valves indicating that these days recovery from a late infection on a Starr valve can often be expected. As was indicated above there were nine late deaths from endocarditis. In none of these did the opportunity offer for a valve change over which should be the recommended policy for all patients who appear to be suffering from uncontrollable infection on any type of valve.

Embolism as a cause of major disability has not been prominent. Only one case has a persistent major disability following embolism while three patients have had recognisable neurological deficits following embolism from which they have made a complete recovery. A group of patients are seen however who complain of very transient impairment consciousness lasting only seconds in whom no neurological signs are ever detected. The explanation of this phenomenon may lie in platelet emboli which are unaffected by standard anticoagulant therapy and support is accruing for the combination of additional use of drugs such as asprin to diminish platelet adhesiveness. It is to be hoped however that the controlled trial being conducted by Starr may eventually indicate that anticoagulants with modern prostheses may be unnecessary.

Ball variance with the early Starr valve occurred in three instances when the series were being used. No cases have occurred with the later models.

In 1970 the Unit switched from the silastic model to the cloth covered metal ball series. Consequent upon the occurrence in two patients of intermittent sticking of the ball and in a further two patients of severe hemolysis, the cloth covered metal valve models series 2310 have been abandonned and a return to the series 1260 silastic ball has been made. Further evaluation of the last model Starr valve is thought to be required before final adoption of this type can be recommended as a result of our experience.

Patients have been followed now for a total of over seven years and Fig. 2 represents the calculated survival curve for each year. This curve shows a gradual drop off representing approximately 10% per year with a final survival figure of 60% at the six year plus mark. The number of cases entering the seven year plus group is too small at this stage to be considered accurate. This survival at 6 years represents a significant improvement on the survival curve for untreated aortic valve disease.

As far as work capacity and exercise tolerance is concerned, Table VIII illustrates that of the survivors 63% can be considered as belonging to Grade I of the New York Heart Association classification of heart disease i.e. having no symptoms and at work either in the home for female patients or at a gainful occupation, 27% are in Grade II with minor symptoms while only 10% have persistent troublesome cardiac symptoms only 2% in all having recognisable and severe cardiac failure.

MITRAL VALVE REPLACEMENT

One hundred and fifty patients have been subject to mitral valve replacement for chronic mitral valve disease. The indications for operation have been exercise intolerance of Grade III or IV or major embolism. A small number of patients who may have been considered as Grade II on symptoms have been found on catheter to have pulmonary hypertension approaching systematic levels and these have been subjected to operation.

The operation mortality is outlined in Table IX. Thirteen patients have died in the month following surgery. It is clear from analysis of the figures that increasing experience leads to a much improved mortality rate as there have been only four deaths in the last 119 patients operated upon.

Table X outlines the causes of operative deaths and as in most series the low output syndrome remains the commonest cause of death following replacement surgery. No exact idea of the cause of this syndrome has yet been established. Left ventricular failure which is multifactorial in origin is in our experience the likely cause and now that a policy of complete valve correction when other valves are diseased, early respiratory assistance by elective tracheotomy, monitoring left atrial pressure and the increased use of catecholamine drugs has been adopted a diminishing mortality from this cause can be expected. Only 3 patients in the last 100 operations have succumbed to this lesion.

Cerebral complications, probably air embolism have accounted for two deaths early in the series while technical factors, septicaemia, and cardiac failure have accounted for the remainder of operative deaths.

FOLLOW UP

The fall out following mitral replacement, see Table XI, has been particularly pleasing, there being only 12 deaths over the six years that the patients have been followed. Seven of these deaths occurred in the period up to the completion of the first postoperative year. The chances of survival following mitral replacement are therefore excellent and are shown in Fig. 3. From this survival curve it can be seen that in this series there is an 80% chance of survival beyond the fifth year. Figures for the six year survival are too small to be significant. The causes of late deaths are shown in Table XI. Cardiac failure is the commonest cause while major embolism has accounted for four deaths. All deaths which have been sudden when no postmortem has been obtained have been regarded as due to embolism unless some other cause has been established.

This to some extent probably makes the incidence of embolism slightly higher than is likely.

Two patients have died because of complications of their anticoagulant therapy while one patient has died of heart block.

As far as late morbidity is concerned the incidence and type of complication is shown in Table XII. Major embolism i.e. embolism leaving a neurological deficit has occurred in five patients while minor embolism leaving no residual deficit has occurred in 8 representating an overall incidence in the survivors of 3% and 5.8% over a period of six years postoperatively. 3 patients have been reoperated upon for mitral incompetence, two being incompetent heterografts and one being a perivalvular leak around a Starr prosthesis.

The activity of the patients in the follow up period is shown in Table XIII.

If graded according to the New York Heart Association classification 52% of patients are symptomless and working while 36.5% are in Grade II, the majority of which are working. A total of 88.5% of patients can therefore be said to be satisfactory or excellent.

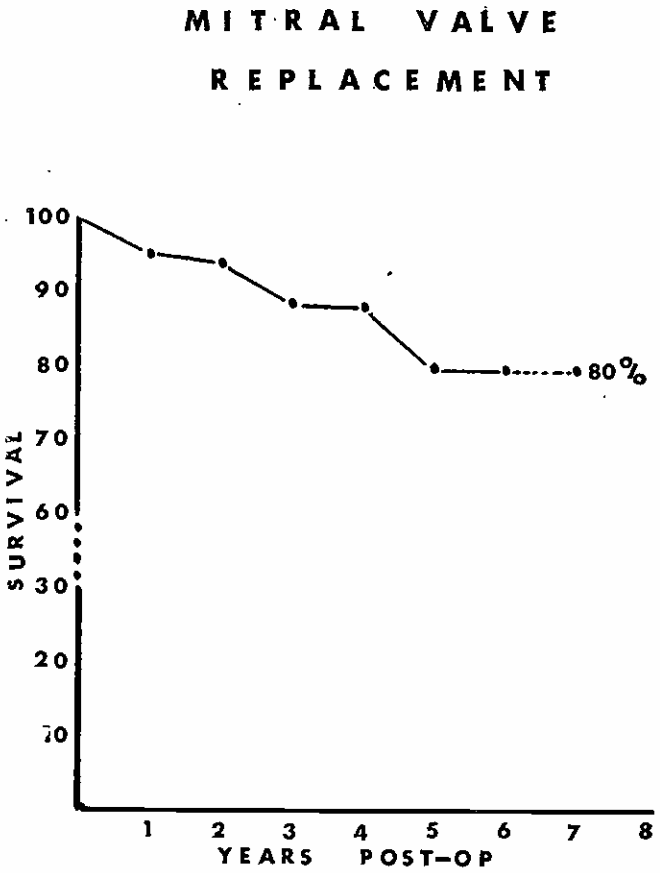

Fig. 3. Mitral valve replacement survival curve over 6 years.

11% of patients are in Grade III or IV only 1% of the total being in Grade VI.

ANTICOAGULANTS

Problems with anticoagulants have been strikingly small in these series of patients. Two deaths only have occurred from cerebral haemorrhage. Both of these occurred in the mitral group while no deaths have been recognised in the aortic group. This reflects the need as exists in this Unit for the establishment of an anticoagulant Clinic associated with the surgical unit.

EMBOLISM AND INFECTION

The incidence of overall embolism has been low. The overall incidence is 8.2% of which 5.3% can be regarded as major.

Postoperative endocarditis has occurred in 4.5% of the overall series. Only 2.4% of these patients succumbed. See Table XIV.

SUMMARY

The experience in this series of patients indicates that at the present time in patients requiring isolated valve replacement of the mitral or aortic valve this type of surgery can be accomplished with an overall mortality of under 10%, a mortality that is being reduced as experience accumulates and circulatory support methods improve. A patient's chance of surviving into the sixth year is 80% in the mitral series and 60% in the aortic series while of the survivors 88.5% of mitral patients and 90% of aortic patients can be classified as in satisfactory clinical condition.

From experience with tissue valves in this Unit a preference for the Starr Edwards valve as the prosthesis of choice for replacement has been established. Following a limited experience with the newer cloth covered mitral ball prosthesis the older silastic ball valve has been chosen for the moment. It seems very

TABLE VIII

AORTIC VALVE REPLACEMENT

FOLLOW-UP	ACTIVITY STATUS
A.H.A. Grade I	63%
Grade II	27%
Grade III	8%
Grade IV	2%

TABLE IX

MITRAL VALVE REPLACEMENT
OPERATIVE MORTALITY

TOTAL CASES	150	
Operative Deaths	13	
Overall Mortality		8·9%
Mortality Last 100 Cases		4·0%

TABLE X

MITRAL VALVE REPLACEMENT
CAUSES OF DEATH

Low Output Syndrome	7
Cerebral Complications	1
Ruptured Ventricle	2
Haemorrhage	1
Septicaemia	1
Cardiac Failure	1

TABLE XI

MITRAL VALVE REPLACEMENTS
LATE DEATHS

Embolism	4
Cardiac Failure	5
Anticoagulant Complications	2
Heart Block	1

TABLE XII

MITRAL VALVE REPLACEMENTS
MORBIDITY

Major Embolism	5
Minor Embolism	8
Infection	2
Perivalvular Leak	1
Reoperation for Incompetence	2

TABLE XIII

MITRAL VALVE REPLACEMENT
ACTIVITY STATUS

A.H.A Grade I	52%
Grade II	36·5%
Grade III	10·5%
Grade IV	1·0%

TABLE XIV

ISOLATED VALVE REPLACEMENT
TOTAL CASES 373

EMBOLISM			INFECTION		
Major	20	5·3%	Non-Fatal	8	2·1%
Minor	11	2·9%	Fatal	9	2·4%
TOTAL		8·2%	TOTAL		4·5%

likely however that future developments will render the totally cloth covered prosthesis safe. The return to the silastic ball valve and the routine use of anticoagulants has been encouraged by the low incidence of anticoagulant complications in this series. This latter low incidence has been produced because of close supervision of the cases in a specially run hospital anticoagulant clinic staffed by the members of the surgical unit.

Infection still remains a problem to be solved, the major incidence being in the first year and probably operatively determined. More careful attention to theatre design, personal staff prophylaxis, meticulous operative technique and postoperative isolated nursing away from infected cases are all factors which will lower incidence.

CONCLUSIONS

1. Study of a series of 414 operations for isolated valve replacements reveal that such procedures can be performed with a mortality of under 10%.

2. The problems of left ventricular failure still contributes significantly to the operative mortality in aortic valve replacement.

3. The low output syndrome is the commonest cause of death in mitral valve replacement.

4. Follow up survival reveals an 80% chance of survival into the 6th year for mitral valve replacement and 60% into the 7th year for aortic valve replacement.

5. Embolism and infection are the commonest causes of postoperative morbidity, 5.3% for embolism and 4.5% for endocarditis.

6. Careful control of anticoagulant therapy can reduce the incidence of anticoagulant deaths to 2 in 294 survivors with Starr valves in situ (6%).

7. Analysis of the exercise and work status of the survivors shows that 88.5% of the mitral series and 90% of the aortic series could be classed as satisfactory.