

## PROSTHETIC VALVE REPLACEMENT

*J. R. Pluth*

Mayo Clinic Foundation. Rochester. Minnesota. U.S.A.

I find it somewhat surprising that after twenty years of valve replacement the subject is still a topic for discussion at major cardiac surgical meetings. This undoubtedly reflects the status of valves today since there still remains no ideal valve substitute. In fact in recent years there appears to be a general trend toward trying to preserve the patient's own natural valve by rather extensive reconstruction rather than resorting to valve replacement. Unfortunately, at the time of surgery, relatively few valves lend themselves to reconstructive procedures so that a valve substitute is necessary and the question then becomes as to what valve to employ. If I were to be asked what valves we are currently using at the Mayo Clinic, I would have to say nearly all valve models. This is due not only to the diversity of opinion among the surgeons, but also because the choice of the valve should vary according to the physiological and anatomical factors noted at the time of surgery.

A few years ago Dr. McGoon and I extended Dr. Harken's criteria upon which valves should be assessed. These criteria were durability, hemodynamic characteristics, thromboembolism, assurance of function, availability and choice of size, ease of insertion, and record of survival. These criteria still seem valid today, although available size and ease of insertion are virtually equally achieved by all valve models; however, among the other criteria all valves currently fall short in one or more areas. Therefore the choice today is not which valve is the best, but which valve compromises the patient the least. As a result, we are still not in a position to be offering valve replacement in the earliest phases of valvular heart disease but must wait until a degree of myocardial decompensation occurs that will justify inserting a less than ideal valve substitute. As the complication rate and mortality remains higher for mitral valve replacement, we feel that functional limitation equivalent to nearly Class III New York Heart Association limitation be achieved before we replace a mitral valve while Class II disability for aortic valve replacement seems indicated. Certainly awaiting this degree of decompensation takes its toll in myocardial reserve and the ultimate improvement of the patient is undoubtedly compromised. Alternatively, however, even a normally functioning prosthetic valve is equivalent to moderate valvular dysfunction and although the patient's status may be temporarily stabilized by valve replacement, further deterioration as a result of this dysfunction may ultimately arise.

Before proceeding with the choice of a prosthetic valve, it might be well to briefly review the current valve models and to note some of their advantages and liabilities.

### *The Starr-Edward ball valve*

Undoubtedly the Starr-Edward ball and cage valve has had the longest track record of any currently employed valve model since it was introduced in 1960. This valve still forms a standard against which other valve substitutes are compared, although other valve models have currently surpassed it in popularity. Over the years

the valve has undergone many evolutions having begun with the pre-1000 and pre-6000 aortic and mitral valve prosthesis respectively in 1960 to the 1260 and 6120 valve models introduced in 1965. This latter valve, which employs a silastic poppet with a stellite cage, is still rather widely used today. In the larger sizes, that is over 25-27 mm in diameter, this valve has excellent hemodynamic qualities at least in the aortic position with gradients rarely exceeding 10-15 mm. Hg. In the mitral position gradients from the normally functioning ball valve can reach as high as 9-11 mm. Hg. so that it is mild to moderately stenotic in this position. Regurgitant flow with this valve is approximately 6-9%. The disadvantage of the 1260 and 6120 valve is mainly its thromboembolic potential. In our experience this risk in the aortic position was slightly less than 5% at five years, but in the mitral area that risk was 25% in the same time period. As a result of some experimental work by Bonchek and Braunwald (1966) in 1967 which indicated that cloth covering of the valve could reduce the incidence of thromboembolism, a new generation of Starr-Edward valves was created. The first model was the 2300-6300 series which was never widely employed due to the poor hydraulic performance. In 1968 the 2310 and 6310 series was released and this was called the close-tolerance Starr-Edward valve because of the reduced distance between ball and cage. Unfortunately the results from this valve were disastrous and in 1970 we reported the occurrence of sticking of the ball within the cage and at that time estimated that 35% of our patients in whom this valve model was inserted succumbed from this complication (Arrigoni et al 1972). This model was withdrawn from the market in 1970 and subsequently replaced with a 2320, 6320, series in which the tolerance of the cage was increased and in addition a layer of polypropylene mesh was added to the covering of the struts in order to reduce cloth wear. Even with this modification the change was inadequate to prevent this occurrence so that hemolysis, noise, and even strut fracture occurred. The hydraulic characteristics, however, were excellent and were comparable to the original 1260, 6120 valve. The most recent modification was produced in 1974 and was called the track valve. This valve employs a metal strip within the strut to guard against cloth wear while still combining the features of cloth covering. Hydraulics are again equivalent to the original 1260 and 6120 models and in Dr. Starr's hands thromboembolic rates appear low, although this same experience is not reported by others.

If we, therefore, summarize the features of the Starr-Edward valve, we would have to say that of the models presently available, hydraulic characteristics are satisfactory at least in the larger sizes in the aortic position, although still producing relative stenosis in the mitral position. Thromboembolism is acceptable for aortic valve replacement, but unacceptably high thromboembolic rates are present in the mitral position.

The Smelhoff-Cutter valve is similar in principle to the Starr-Edward 1260 and 6120 series although its design allows slightly more regurgitant flow. The valve does have somewhat improved hemodynamic characteristics of the small valve sizes as compared to the Starr-Edward valve and its durability is virtually identical. Thromboembolic rates with this valve appear to vary markedly and are extremely low in Dr. Smelhoff's hands, but virtually identical thromboembolic rates to the Starr valve have been reported by others (Duvoisin et al 1968).

### *Disc Valve Prosthesis*

The true disc valve, as represented by Starr, Beall, or Cooley, has virtually given away to the near central orifice tilting disc valve in which the lens of the valve opens toward the direction of blood flow. The original disc valve which opened perpendicular to blood flow was associated with the highest gradients of any prosthetic valve especially in the mitral position with end diastolic gradients of 11-14 being recorded for a normally functioning valve. In modifying the orientation of the lens opening in the

current generation of tilting disc valves, these gradients have been markedly reduced so that hydraulically the near central flow valves have now one of the most favourable hemodynamic ratios. In part this is also related to the removal of the cage which has thereby allowed a decrease in the diameter of the sewing ring so that the central orifice as compared to the total valve diameter is very favourable. As a result, the effective orifice of the disc valve is hemodynamically equivalent to a ball valve two sizes larger and this is an important consideration in the smaller valve sizes. However, as the orientation of the disc has become more parallel to the blood flow, regurgitant fractions have necessarily increased. In general regurgitation fraction with these valves varies between 6 to 11%.

Generally two valve models are commonly employed — the Bjork-Shiley valve and the Lillihei-Kaster valve. The characteristic that distinguish these two valves from each other is that the Lillihei-Kaster valve opens to 80° from horizontal while in the closed position rests at 15° from the horizontal. Its effective opening of 65° is virtually identical to the Bjork-Shiley valve. Despite its greater orientation to the direction of blood flow, the Lillihei-Kaster valve appears to be associated with slightly higher gradients; however, pulse duplicator studies appear to favor the mechanical properties of the Lillihei-Kaster valve and a longevity of greater than 25 years as anticipated. Clinically these valves have been employed for about eleven years, although the current ferro-pyrolite disc was introduced around eight years ago. Both of these valves have undergone a modification in the past year in which a curvilinear disc is now employed in an attempt to reduce gradients and provide better flow characteristics. Regurgitant fraction does not appear to be greatly changed and may be reduced as a result of these changes.

Thromboembolic rates with the Bjork-Shiley tilting disc valve have been as high or perhaps even higher than with the ball valve series. This has been especially true in the early postoperative period and in our own experience has been 2-3 times higher in the first two months. Some authors have reported a 5% incidence of valve thrombosis and obstruction when this valve has been employed in the aortic or mitral position. In our experience this complication rarely develops in the presence of adequate anticoagulation and is probably more related to poor anticoagulant control than to valve design. In the mitral position valve gradients of approximately 4-7 mm Hg across the valve are not unusual even with a normally functioning prosthesis.

Currently a new prosthetic valve has been introduced which truly provides central blood flow. This valve consists of two leaflets that are parallel to the flow of blood while retaining the favorable effective orifice to total diameter of the valve. The reported hydraulic performance of this St. Jude valve is excellent with gradients of only 1-3 mm Hg across the aortic valve even in the smaller valve sizes. Our experience with this valve has indeed been very limited with only three valves thus far having been inserted. In one adult a 19 mm valve was inserted into a small aortic root and no gradient was noted; however, in the second patient a 21 mm valve was employed and a gradient of 30 mm Hg was encountered. In the mitral position low end diastolic gradients have also been noted.

This valve has now been in clinical use for approximately two years and the thromboembolic incidence appears very low. In fact over a hundred patients are now being followed without anticoagulation and thus far only one instance of thromboembolism has been reported. Personally I do not believe that the mechanical design of the valve is sufficiently different from the mechanical design of the valve is sufficiently different from the Bjork or Lillihei-Kaster valve to justify not recommending anticoagulation therapy. Although the stenotic gradient across the valve is extremely low with this valve model, regurgitant fraction has been high in the range of 6-14% at pulsing rates of 120 beats per minute or greater. With a normal heart rate the regurgitant

fraction would undoubtedly be still higher. Although this valve does appear to have potential, the total period of observation thus far appears inadequate to strongly endorse the wide spread utilization of this valve model.

The final group of valves that we would consider are the porcine heterograft valves. Foremost among these are the Hancock, Angell-Shiley, and the Carpentier-Edward valve. There appears to be little at this time to distinguish them. The Carpentier valve has a flexible stent and the actual valve size seems to be somewhat better matched to the mounting stent. Yet that valve appears to have slightly higher gradients than the Hancock valve and certainly higher than the modified Hancock valve. There are to be sure differences in the method of fixation or sterilization among the models, but these differences have not as yet been related to factors of durability. In contrast to the mechanical valves, longevity with the heterograft has yet to be determined. Certainly with pulse duplicator studies their longevity is but a few weeks, although they undoubtedly act as a bioprosthesis and therefore this type of evaluation has little value. Yet the manufacturers of both valves admit that they consider them a ten or at best a twelve year valve. Carpentier has recently in his own series passed the ten year mark on one of his valves, but this does not establish longevity. Failures with the heterograft have been reported including incompetence and calcification. The latter problem seems particularly prone to occur in children and in patients with renal failure. These factors should be weighed in the decision of whether to use the valve in those situations. Failure rates at present appear to be still less than 1%, but I believe we are just reaching the period when failures will start to be reported. With the lack of knowledge regarding durability I find it somewhat surprising why there remains this current enthusiasm for the heterograft. In regard to hydraulic characteristics they rank third to the tilting disc or to the central orifice disc especially in sizes less than 25 mm. In the small sizes gradients of 25-40 mm Hg are not uncommon and gradients of 6-9 mm Hg across the mitral valve are usually found even with normally functioning prostheses. The regurgitant fraction varies between 3-6% and is only slightly above the regurgitant fraction of a normal valve; however, the one very favorable feature of the porcine valve that distinguishes it from all mechanical prostheses is the low thromboembolic rate. Generally for the aortic position this is 2.5% while for the mitral position it appears to be 4.5% without anticoagulant therapy. However, as the majority of patients requiring mitral valve replacement are usually in atrial fibrillation anticoagulants are required on that indication alone. Whether it is worthwhile to employ a heterograft in order to reduce the risk of thromboembolism in the presence of limited durability is a choice that the surgeon and the patient must make.

For the purposes of discussion I believe we should also include in this category the Ionescu bovine pericardial heterograft valve. Fashioned from a single sheet of pericardium this valve has the lowest gradient of any prosthesis today. Regurgitant flow is higher than with heterograft valves due to loss of some of the concavity of the cusps, but the degree of regurgitation has not been reported. Unfortunately the durability of this valve still remains in great question. Ionescu has employed the valve for approximately eight years, but they have been commercially available for distribution only for approximately three years. Failure rates from this valve are similar to that of other heterografts with both insufficiency and calcification being noted. Valve failures are running approximately 2% in Ionescu's series.

Having touched briefly on the most popular current valves how does one decide on which valve to employ. Certainly there appears to be differences regarding the hemodynamic characteristics of these valves so should this be our guidelines? In actual fact there is little that hydraulically distinguishes one valve from another. Too often surgeons are preoccupied with the gradient produced by the prosthesis but fail to consider the total left ventricular work that the left ventricle views. In this regard regurgitant fraction must be included and in the aortic position it is a more important

factor than the gradient. With regurgitation the left ventricle is faced with increased volume of blood to eject past the stenotic valve and the left ventricular dimension of the ventricle increases to that based on La Place's Law the left ventricular work increases. To quantify regurgitant work in terms of stenotic gradient a factor of three must be multiplied by the regurgitant fraction (Sauvage et al 1972). When this is done, it is obvious that there is little that differentiates the valves as regard to hydraulic performance. Clinically this is borne out since longevity does not appear to be influenced by the valve model except where a valve has had an inherent mechanical defect such as in the close-tolerance 2310 Starr-Edward aortic valve series or the Braunwald-Cutter aortic valve prosthesis.

So if we again refer back to the criteria of comparing substitute valves are there factors that should help us in deciding on the proper valve to employ? Durability at present seems to be directly related to thromboembolism; that is, valves with the greatest durability also seem to have the highest thromboembolic rates. Therefore the decision favoring one of these criteria automatically affects the other. Hydraulic characteristics, as previously mentioned, seem to be relatively unimportant as all valves appear equally damaging to the myocardium; however, in the smaller sizes the tilting disc or central orifice disc do provide the lowest gradients. Although regurgitant fractions are higher with the tilting disc valves, the amount of regurgitation is less in the smaller valve sizes. The decision therefore does not rest as much in the criteria of comparison of valves as in the physiological and anatomical conditions at the time of surgery. Prime among these is the consideration of age. In infants and children where growth is anticipated it would appear reasonable to employ the best hemodynamic valve in relationship to size that is possible in order to delay and minimize the need for reoperation; however, once ultimate cardiac size has been achieved other considerations seem more significant. In the child bearing female the use of a valve with a low risk of thromboembolism seems warranted if other valve models have an inherently high risk of thromboembolism from the discontinuation of anticoagulants. In an active male patient or in a patient who lives in an area where control of anticoagulation is difficult, the same consideration is necessary; however, in a young adult with good anticoagulant supervision a valve of proven durability might be more appropriate to employ to minimize the need for reoperation. In the elderly patient the choice again changes. For here when life expectancy is limited one might choose a valve with low thromboembolic characteristic and be willing to forego the longevity features.

Anatomic conditions also bias the decision for valve replacement. In a patient with a small aortic root one may favor the choice of a hemodynamically superior valve rather than to prolong an operation and increase the risk from root enlarging procedures. Alternately in the presence of ascending aortic aneurysm a low profile valve should be considered when re-implantation of the coronaries into the conduit is necessary. In the mitral position the presence of a large left atrium seems related to a high incidence of thromboembolism so that a valve with lower thromboembolic potential, such as a heterograft, may be indicated. Tricuspid valve replacement similarly has its uniqueness. Inasmuch as there is a greater potential for thrombotic occlusion of mechanical valves in this position, a biological valve appears more rational on the right side of the heart where pressures and rate of flow is reduced. In general these are the guidelines which I find influence me at the time of surgery favoring one or another valve model.

Recently there has been a report indicating that heterografts are more resistant to infection than the prosthetic valves and their use in infective endocarditis has been recommended. This has not been our experience and both mechanical and biological valves seem equally susceptible. Fortunately the risk of infection is low with an incidence of early valve infection of 0.35% and a late risk of 0.62% for a total incidence of just under 1%.

Postoperatively we believe that all models of mechanical prosthetic valves should be placed on anticoagulant therapy indefinitely and even patients with heterograft replacement are anticoagulated indefinitely if they are in atrial fibrillation. In addition, I have added dipyridamole to this program for a period of 6-9 months postoperatively and this is employed even for a heterograft replacement. This time period was selected on the basis of platelet survival studies on patients have prosthetic vascular grafts

Table 1

*Aortic valve*

Aortic Valve	Author	N <sup>o</sup> Implanted	A C Status	Follow-up (mos.)	% in incidence T. E.	T. E. Episodes 100 pt. years
Starr-Edwards						
1260	Shumway	455	+	96	6%/yr.	6.0*
2300	Stanford	72	0	22	12.5	9
2300	Isom	128	+ 0	30	3%/yr.	4.7*
Lillehei-						
Kaster	Forman	65	+ 0	29	9%	3.7
	Dale	85	+	23	11.8	8.5
Bjork-						
Shiley	Dale	81	+	24	11.1	7.9
St. Jude	Co.	404	+	18	—	—
Hancock	Shumway	251	0	12	2.6/yr.	2.5*
Ionescu	Ionescu	216	0	30	1.5	0.48

\* Calculated from information presented in article

Table 2

*Mitral valve*

Mitral Valve	Author	N <sup>o</sup> Implanted	A C Status	Follow-up (mos.)	% in incidence T. E.	T. E. Episodes 100 pt. years
Starr-Edwards						
6120	Shumway	515	+	96	10.9/yr.	40.9*
(6300-	Isom	323	+	30	4%/yr.	1*
6310-6400)	Forman	332	+	60	7%/yr.	
Lillehei-						
Kaster	Forman	55	+	29	13%	5.1*
Bjork-						
Shiley	Ionescu	12	+	—	—	4.7
St. Jude	Co.	318	+	<18	0	
		11	0	<18	9%	
Hancock	Shumway	338	0	12	1.5/yr.	4.6*
	Edmiston	22	+	16	23	
Ionescu	Ionescu	150	0	26.1	1.5	1.22

\* Calculated from information presented in article

which demonstrated normal platelet survival at the end of that time. Currently we are undergoing a prospective series comparing aspirin with dipyridamole in combination with Coumadin anticoagulation.

Thromboembolism continues to be a major consideration of prosthetic valve replacement though more of a concern in the mitral position than the aortic where velocity of blood flow seems to decrease the likelihood of thrombus formation. A recent review of the literature comparing thromboembolic complication is compiled on Table 1 and 2.

We should probably not end this discussion on such a pessimistic note and therefore I feel it is justified to portray longevity data on patients with prosthetic valves. As stated previously, there appears to be no significant difference between valve models so that longevity should be roughly comparable to any valve type. For aortic valve replacement surgical risk remains low at approximately 3-4% and 80% of the patients are alive at five years. In the mitral valve patients operative mortality is a bit higher and currently appears to be running approximately 5-6%. Survivorship at seven years is 70%.

In conclusion I think that we must still await the ideal prosthetic valve. All valves are at least moderately damaging to the myocardium and none are totally free of complications. Durability seems adequate for mechanical prosthesis, but the price of durability is a higher incidence of thromboembolism. Contrariwise bioprosthetics appear to have an acceptable risk of thromboembolic complications but in terms of present knowledge can only be considered a temporary valve replacement.

## RESUMO

### *PRÓTESES VALVULARES CARDÍACAS*

Parece extraordinário que após vinte anos de experiência de substituições valvulares este assunto ainda seja um dos que se discute nos congressos de Cirurgia Cardíaca. Sem dúvida isto deve-se ao facto de ainda se não ter encontrado o substituto valvular cardíaco ideal e, nos últimos anos, tem-se desenvolvido a tendência para plastias em vez de substituições valvulares. Mas a verdade é que, quando os doentes chegam a ser operados já as válvulas ultrapassaram a fase de poderem ser reconstruídas e têm de ser substituídas.

Na Mayo Clinic usam-se praticamente todos os modelos de próteses valvulares e isto depende não só da tendência dos vários cirurgiões mas também dos factores fisiopatológicos e anatómicos de cada caso operado.

Descrevem-se em seguida as várias próteses mecânicas mais utilizadas, com suas vantagens e inconvenientes, nomeadamente as válvulas de oclisor de bola (Starr-Edwards e Smelhoff-Cutter) e as de disco (Björk-Shiley e Lillehei-Kaster).

Finalmente faz-se ampla referência aos heteroenxertos de válvula aórtica de porco, como as de Hancock, de Angell-Shiley e de Carpentier-Edwards.

Em seguida faz-se a discussão dos vários factores que podem prevalecer na escolha dos vários tipos de próteses valvulares concluindo-se que ainda se aguarda o aparecimento da prótese ideal. Todas as válvulas são, pelo menos moderadamente nocivas ao miocárdio e nenhuma é verdadeiramente livre de complicações. A durabilidade parece adequada no que se refere às próteses mecânicas, mas o preço desta durabilidade é um maior risco de tromboembolismo. Pelo contrário as biopróteses têm um risco aceitável de tromboembolismo mas deve-se reconhecer que terão de ser consideradas como substitutos valvulares temporários.

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Address for reprints: *J. R. Pluth*  
*Mayo Clinic/Foundation*  
*Rochester, Minnesota 55901*  
*U.S.A.*