Richard A. DeWall *

RECENT ADVANCES IN HEART VALVE SURGERY

Two major meetings occurred during 1982 relating the current thinking in valve surgery. These meetings were "The International Symposium on Cardiac Bioprosthesis" held in Rome during May 17-19, 1982 and the "International Symposium on the Mitral Valve" which met in San Diego, October 21-24, 1982. The proceedings of these meetings are to be published and have provided a compendium of recent information on valve surgery. Table I indicates the major prostheses in current use.

Table I

	Starr-Edwards ball valve
	Björk-Shiley tilting disc valve
	Lillehei-Kaster pivoting disc valve
	Porcine bioprosthesis
	Bovine pericardial bioprosthesis
	St. Jude bileaflet valve
	Hall Kaster
	Omniscience pivoting disc valve
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There are heart valves of other origins than the above, however they have had limited clinical use.

This report is not comprehensive, but represents general impressions from a survey of the information available. As the variables are great, it is impossible to present an analytical analysis comparing valves. Each sees a different type of patients, in different stages of illness, using dissimilar follow up methods.

STARR EDWARDS BALL VALVE

It is often said that the Starr Edwards Ball Valve is the benchmark valve against which all others must be measured. Several variations of the ball valve emerged through the Years, however none of the newer variations including cloth covered struts, cloth covered track strut valves, etc, have proven to be as successful as the earlier valve, the bare metal cage with the silastic ball occluder. This has been designated the Model 6120 which was first put to use in 1965. Starr¹ reported on his experience of the valve at the International Symposium of the Mitral Valve. He followed 237 patients with this valve for 999 patients years. Actuarial survival was 71% at five years, 56% at ten years and 39% at fifteen years. At fifteen years, 85% of the patients are free of a fatal valve failure and 74°, are free of any failure. The valve failure rates are lower than those reported for bioprosthesis, a difference which can be expected to increase in time¹. Thromboembolic events occurred at a rate of 3.9% per patient year since 1973. The embolic rate with the silastic ball valve compares favorably with that of bioprosthesis and other valves

Sala² reports survival for mitral valve replacements as 78% five years; 72% at ten years and 70% at thirteen years with thromboembolism. of 3.4% per patients years .

Macmanus³ reports for aortic Starr valves (Model 1200) bare strut, silastic ball a embolic rate of 5% per patient year for all emboli and 1.8% per patient years of fatal emboli. No structural failures were encountered. He observed one anticoagulant death in 1,698 patients years. Eight percent of the aortic valves required removal in eleven years.

BJÖRK-SHILEY TILTING DISC VALVE

The Björk-Shiley prosthesis has been in use in several configurations for thirteen years. The first version contained a Delrin disc opening to 50°. As the Delrin absorbed water and tended to swell causing acute lockup, pyrolite carbon was substituted to construct the disc. The disc in this design opened in the plane of the retaining ring which ment that the axis of pivoting was at the level of the ring. Clot formation occurred at the axis of pivoting in a small percentage of cases This observation lead to the development of the concave-convex disc, and a redesign which permitted the disc to move out to the axis of the retaining frame several millimeters and opened to 60°. The opening angle was later increased to permit the disc to open to 70°. These changes apparently created undue stress on the retaining struts as it was observed that the struts fractured in some patients neces-

^{*} Clinical Professor at Wright State University Medical School, Kattering Medical Center - Kettering, Ohio, USA.

sitating recalls. A new version has recently been introduced substituting a mono strut of heavier structure replacing the previous wire struts which tended to fracture⁴.

Björks⁵ using the flat disc version of the Björk-Shiley valve reports five year survival rates 82% for aortic valves, 66% for mitral valves and 66% for double valves. Systemic emboli occurred at 0.7% per patient year for aortics, 42% per patient year for mitral and 2,2% per patient year for A & M replacements Björk observes, however, that the embolism rate decreases from 4.2% per patient year to 1.2% per patient year using the concave-convex model.

Cheung⁶ reported on the experience of his group using the B-S prosthesis in the aortic position. They observed a five year survival rate of 70%. The risk of embolism was 12% patient year in anticoagulated patients. While that of hemorrhage was 1.2 per patient year. Valve malfunction occurred in 0.7% of their patient group. Their operative mortality (first thirty days) was 11,4% which would seem to be an average that is reported.

Long term mitral valve replacements with the Björk-Shiley prosthesis as reported by Kleimman⁷ incidence of bleeding and thromboembolic events was 0.98% and 2.12% per patient year. Two of 389 patients developed clotted valves, The ten year survival rate was 72,2%. The operative mortality was 3.9.% .

Only short term data is available for the use of the Björk-Shiley concave-convex prosthesis. The two year study by Marshall⁸ incorporating mitral, aortic and multiple valve patients, shows a survival rate of 76%. Six percent of their patients developed embolic problems in the two year period. Thirteen percent had anticoagulation problems within the two year period. No valve thrombosis was seen, but the time was short. The C-C Björk-Shiley valve from this study would not seem to be that much of an advantage over the flat disc B-S valve.

The comparative study of Gabbay⁹ found that the concave-convex Björk-Shiley valve to be less hemodynamically efficient than its preceding design, with the flat occluder.

Karp's¹⁰ experience with the Björk-Shiley valve found comparable long term survival results compared to the Hancock and the Starr Edwards bare strut valves. He observed a 2% year for adverse major anticoagulant events. Valve thrombosis occurred for aortic valves in 0.75% year and 3 .25% year for mitral and double valves.

A comparative study between Starr-Edwards and Björk-Shiley valves by Murphy¹¹ from Massachusetts General Hospital, shows no differences in any evaluation parameter between the two valves.

LILLEHEI-KASTER PIVOTING DISC PROSTHESIS

The Lillehei -Kaster Valve was clinically introduced in 1969. The L-K valve is still used in about 30 clinics around the world^{12,13} although it has not been as heavily merchandised as other valves.

Zwart et al.¹⁴ reported on their experience with this valve. For aortic valves the actuarial survival was 96% at five years and 87% at seven years. Thromboembolism, occurred 2 6% per patient year. With mitral valves, the actuarial survival was 81% at five years and 75% at seven years. Thromboembolism rate was 5% per patient year . The performance data, embolism rate, etc, of the L-K valve seem comparable to other valves. The L-K valve has never experienced a mechanical failure nor have there been any governmental recalls.

BIOPROSTHESIS

Bioprosthesis have been in popular use for over a decade. The clinical material and methods of management of bioprosthesis patients are variable from group to group making precise comparisons difficult. Broad impressions, however, are valid as this provides a norm for others to judge their work. Actuarial survival curves are useful in evaluating the expectations of patients with prosthetic valves, however, mortality is not a sole reflection of a given prosthesis. Teply¹⁵ notes that 52% of deaths are cardiac related while 13% are valve related in patients with the ball valve prosthesis. This must be true for all patients with prosthetic heart valves. Other nonheart factors also contribute to death.

	5 years	11 years
Aortic Valve	80%	78%
Mitral Valve	79%	74%
Double	45%	

A composite of actuarial survival curves for bioprostheses¹⁶ would appear to be as follows:

Thromboembolism rates with bioprostheses¹⁶ vary from 1.2% - 2.6% per patient year.

Primary operations for valve surgery have a mortality risk between 11% and 30% (Gallucci¹⁶) depending upon the severity of the disease and the number of valves and additional procedures. Reoperation death rates for replacing failing bloprostheses is reported between 10% and 15%. The risk of endocarditis with bioprostheses seems to be between 1% and 2% per patient year.

Figueroa¹⁶ reports that there is a time related hemodynamic deterioration of Porcine bioprosthesis suggesting a progressive stiffening of the leaflets. Pelletier¹⁶ found that smaller sized Carpentier-Edwards valves to be mildly stenotic. One would expect that with time the stenosis would increase. The functional area of the bioprosthesis is about 50% of the stent diameter (Stein¹⁶).

Progressive bioprosthesis dysfunction was demonstrated by Kirschbaum¹⁷. Right ventricular function improved immediately after mitral valve replacement, but progressively declined over one year in patients receiving Carpentier-Edwards bioprostheses indicating progressive deterioration of leaflet function. Patients receiving larger Carpentier prostheses had a greater degree of disfunction than patients receiving smaller Carpentier valves. Right ventricular improvement was sustained in patients with disc valves.

Bioprosthesis have fallen into disfavor for use in children generally due to progressive calcification (Odell-Villani¹⁶). Shore¹⁶ found no difference in the onset of degeneration in children between Porcine and Bovine pericardial grafts. Magilligan¹⁸ experienced a significantly greater incidence of bioprosthesis degeneration in patients under thirty-five. Block¹⁶ reserves the use of bioprostheses for patients over 65 years of age while Pupello ¹⁶ motes a lower rate of bioprosthesis failure in patients over the age of seventy. Arbustini¹⁹ observed that bioprosthesis can also be disrupted by massive lipid infiltration event in the elderly. This might suggest that bioprosthesis should not be used in hyperlipidemics.

In the failure mode, all types of bioprosthesis fail with calcifications in areas of greatest stress and flexion points of leaflets. (Deck¹⁶). Low atmospheric pressure (less than 1 mm Hg.) fixation in glutaraldehyde if thought by Broom and Wright¹⁶ to improve the wear resistance of bioprostheses, but this is unproven in vivo. Carpentier¹⁶ has investigated methods to reduce calcification. He concludes diet management has no effect. Incubation of the tissues in various amino acids along with mixed formalin glutaraldehyde preservation reduced calcification in animal subcutaneous implants. Perhaps the early calcification of bioprostheses in children is immunologically motivated^{20,21}. It is to be expected that further research will decrease the failure rate of bioprostheses.

The short term survival of patients (less than five years) is comparable with mechanical valves or bioprosthesis Schonbeck, Block and Thiene¹⁶ warn against prosthesis-heart annulus mismatch which is true for any valve. Excessively large valves cam lead to outflow obstruction, thrombosis, myocardial disruption, cardiac rupture, and mechanical interference with valve function.

One can conclude that bioprostheses, are to be avoided in young people less than 20 and probably less than 35 years of age. Anti-coagulation is used from six to three months post operatively and continuously in patients in chronic atrial fibrillation, and/or poor ventricular function. Bioprostheses do not improve patient survival. One must judge the risks in a mechanical valve of embolism problems and bleeding versus bioprosthesis and their incidence of embolism and mechanical failure, the off setting factors between the two types of valves are a trade off.

It is likely that as the time curve progresses the rate of bioprostheses failure accelerates as found by Borkon²². Bioprostheses failure rates occur as 1 % in five years, 4% at seven years, 30 % at nine years and 39% at ten years.

Al factors considered, there does not seem to be much difference between the clinical responses of the different types of bioprostheses except small gradient differences in smaller size valves of differing configurations.

ST. JUDE HINGED BILEAFLET VALVE

The St. Jude Hinged Bileaflet valve was introduced to clinical application about five years ago²³. Transvalvular pressure gradients an in the lower range of all valves available however. this may be offset by as high as 12% regurgitant flow for larger sizes²⁴. The significant leak rate may be due to the amount of clearance between the circumference of the leaflets relative to the housing and the split between the two leaflets. Presumably, this amount of clearance was designed to maximize the washing of the leaflets. Another factor contributing to regurgitant leakage is the observation of Chaux²⁵ that the leaflets may be subject to asynchronous closure Rainer²⁶ observed by high speed photography that one leaflet of the St. Jude valve will close under certain physiologic circumstances with delayed closure of the second leaflet.

As many patients needing valve replacements are in marginal states of cardiac compensation, a minimal amount of regurgitant leakage would be desired as they need all the forward output they can get.

Due to the recent introduction of the St. Jude prosthesis, there is no long term evaluation of survival curves.Nicoloff²⁴ report the incidence of thromboembolism (TE) for the St. Jude valve for an average of a one year follow up of 0.7% per patient year for aortic valve procedures and 3,6% per patient year for mitral valve replacements. A comparative study by Horkstkotte²⁷ between the Björk-Shiley and the St. Jude valve over a 34 month period indicated a lower TE rate for the St Jude valve.

	B-S	St. Jude
Aortic Valve	2.8% or 1%/Pt.Yr.	0.9% or 0.3%/Pt.Yr.
Mitral Valve	5.3% or 1.9%/Pt.Yr.	2.2% or 0.8%/Pt.Yr.

An additional study by Horstkotte and his group²⁸ observed an embolism rate of 12.5% in patients with a Björk-Shiley valve over one year but no TE in patients with St. Jude valves . In addition, they found with equal sized valves that the calculated functional orifice of the St. Jude valve was 1.35 cm^2 and for the Björk-Shiley was 0.53 cm^2 Both groups of patients were anticoagulated.

An overall incidence of thromboemnbolisn for the St. Jude valve was reported by $Chaux^{29}$ to be 1.6% per patient year for a men follow up of 21 months.

Due to the short term interval for clinical experience with the St. Jude valve, it is difficult to come to realistic comparative data of the incidence of thromboembolic episodes. Ant coagulation however, would seem to be indicated with all St. Jude implants²⁹⁻⁵³.

HALL-KASTER PIVOTING DISC PROSTHESIS

The Hall Kaster prosthetic heart valve is a pyrolyte flat disc, containing a central perforation. A curved guide rod fits through this perforation guiding the disc through its range of motion and preventing its escape. The first clinical application of this valve was in June of 1977. Nitter-Hauge36 and his group using the H-K valve experienced a late mortality of 4% in the aortic position, 11% in the mitral position, and 8 7% in the combined position. Thromboembolic events occurred in 1% of the aortic series, 2.5% in the mitral and 12% in the combined series. Pressure gradients of the H-K prostheses are better than either of the two Björk-Shiley prostheses but mot as optimal as the St. Jude. The H-K valve has a higher regurgitant flow than the St Jude⁹.

Antunes³⁷ believes that when the Hall-Kaster valve is oriented in the aorta in certain positions, the occluder will open beyond the axis of flow resulting in nonclosure during diastole.

There is not a sufficient level of experience with the Hall-Kaster valve reported to know the role this valve may have in clinical valve surgery.

Effler³⁸ experience an 8% (four out of fifty four patients) acute lock up with death with a short time post operatively in his patients with a Hall-Kaster Valve.

A valve is not a cork: In organizing this paper and having the opportunity to review valve data from many clinics around the world, one frequent misconception stands out. That is the understanding by some (fortunately not all) surgeons that in selecting a valve for implantation. - Larger Is Better. This is probably a hang over from many years ago when due to the poorer hydrolic efficiency of the ball and horizontal disc valves the larger prosthesis would (it was thought) permit greater blood flow with a lower pressure drop across the valve. The hydrolic efficiency of most of the currently used valves, pivoting disc, bileaflet, and bioprostheses, is good enough that increasing the size of the prosthesis (except for perhaps the smallest) will mot decrease the pressure drop by any significant physiologic degree nor will it increase the amount of blood flowing over the valve. The only amount of blood that can escape the heart is the volume of one stroke output. A larger valve will not increase the amount of blood flowing across it.

As most valve replacement is dome with cold cardioplegic arrest, the heart is in maximum diastolic relaxation. Generally excising a diseased valve removes fibrotic and calcific tissue and permits increased annular size, beyond physiologic needs or limits to see the ventricle as a bottle and feel the need to place the largest size cork (prosthesis) into that bottle (ventricle) makes no physiologic sense and is actually illogical.

Each prosthetic valve has its own characteristics however it is true for all the valves, oversizing has a great possibility of leading to disaster. Every heart with valve disease will decrease In size upon valve replacement (with the possible exception of pure mitral stenosis) and presents a real threat of impinging on the mechanics of that valve whether it be struts of a bioprosthesis or the discs of pivoting discs or leaflets with an over sized prosthesis. **Bigger is not necessarily better** in prosthetic valve replacement. Successful valve surgeons around the world generally downsize the valve prosthesis one to two sizes from the measured orifice. There is no problem in decreasing the annulus by appropriate suture technique to accommodate a smaller prosthesis as the annulus properly prepared is soft and pliable.

OMINSCIENCE PIVOTING DISC

The Omniscience is the prosthetic heart valve which I have had the most experience for over four years . The Omniscience is a second generation Lillehei-Kaster valve which is a central flow pivoting disc prosthesis. The changes included making the occluder disc concave-convex which produces a more laminar flow through the prosthesis minimizing pressure gradients. There are no retaining structures within the flow channel of the valve. The retaining mechanisms of the disc are small unobstrusive "ears", a modification of the L-K, located on the circumference of the valve and out of the central blood flow channel. There is no fixed hinge mechanism . The disc rotates with each cycle to equally distribute wear circumferentially around the disc.

The first patient receiving the Omniscience prosthesis had both aortic and mitral valves replaced in August of 1978. She has since done well. My total series with the Omniscience prosthesis as of this presentation are as follows:

	Number of patients	Follow up
Aortic Valve	75	149 Pt.yrs.
Mitral Valve	37	82 Pt.yrs.
A & M Valve	13	24 Pt.yrs.

Of the aortic valve patients 70 (93%) survived a mean time of two years (2-54 mo. range). The deaths were due to one clotted valve from sudden anticoagulation withdrawal for dental purposes and one death unidentified. That may or may mot have been valve related. Another death was due to cerebral hemorrhage apparently from poor anticoagulation control. The other two deaths were respectively from a pancreatic carcinoma and wound sepsis with congestive heart failure after eight months. He also had a metastatic broncogenic carcinoma.

Thirteen of the aortic valve patients also had concomitant coronary artery bypass surgery with one to four bypasses.

Of the thirty seven mitral patients 89% (33 of 37 patients) survived an average of 2 years (2-52 months range). Three of the patients died, possibly but not identified as valve related problems. Each had a larger size valve in place and probably should have had a smaller prosthesis. One patient died six months after surgery due to complications of diabetes mellitus. The second patient had a valve explanted due to pannus formation and survived with another Omniscience prosthesis. The third patient probably developed prosthetic dysfunction due to clot following acute reversal of coumadin levels because of bleeding hemor-

rhoids. A course of Streptokinase freed the valve with no subsequent problems.

Ten of these mitral valve patients had from one to four coronary artery bypass grafts.

Thirteen patients had both mitral and aortic valve replacements. Again these patients were followed from two to fifty two months with a mean time of 1 8 years. There were two late deaths in this group, one from Hodgkims and endocarditis. The other, age 74 probably died of complications of an infected prosthesis. Transient ischemic attacks occurred in one aortic and one double valve patient with no residual.

As mentioned above I believe sizing the prosthesis to the recipient annulus is of the most importance and down sizing is generally indicated. In my early experience with the Omniscience I probably used larger sizes of prosthesis than indicated. The following chart however indicates the sizes of Omniscience prostheses used in this series.

	19	20	23	25	27	29	31	
Aortic	4%	11%	19%	23%	33%	9%	1%	
Mitral	0%	0%	11%	24%	24%	16%	0%	

The acute anticoagulation reversal with Vitamim K is contraindicated inpatients with prosthetic heart valves. If necessary, their prothrombine time whould be allowed to drift toward normal. Inter-current operations can be done with prothrombine times 4-5 seconds above control.

Patients with the Omniscience prosthesis were kept anticoagulated with a control level of 10-11 seconds and a therapeutic level of 15-18 seconds.

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