Current Options for Replacing the Aortic Valve in Adults

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There are myriad options today for prosthetic aortic valve replacement (AVR), with even more on the horizon. A variety of single tilting disc and bileaflet design mechanical valves are available in the United States, and several more bileaflet designs are in various stages of clinical trials. There has been even more activity recently in the development of new tissue valve prostheses including modifications in the tissue fixation processing of stented xenografts aimed at retarding calcification and improving leaflet durability, bioengineering of stented bovine and porcine valves to improve hemodynamics and the introduction of stentless xenografts and the popularization of the pulmonary autograft, an operation introduced decades ago by Donald Ross. The issues that enter into the decision to proceed with AVR are well known. What may be less well understood are the elements that enter into the individual surgeon's choice of prosthesis. Our purpose here will be to highlight the surgeons' perspective on the selection of a valve substitute.

Mechanical Prostheses

The single floating disc and the bileaflet designs dominate the mechanical valve marketplace in the United States today (Figure 1). There are likely few substantial differences in performance among these valves with respect to hemodynamics and risk of thromboembolism (Table 1). An exception is the plastic ball-and-cage design that is seldom used today because of poor flow characteristics. The single floating disc design has some theoretical appeal, as there are no hinge points at which there could be repetitive wear. Similarly, there are no blind pockets at the hinge points that could promote thrombus formation. It has been suggested that the single floating disk valve is, therefore, a better choice for patients at higher risk of non-compliance with anticoagulation, however this has not been sufficient to move the marketplace away from the bileaflet design. Floating disc valves have a higher profile than bileaflet designs, meaning that the occluder's range of excursion above and below the sewing ring is greater and, from a practical standpoint, that greater care must be taken at implant to ensure that no extraneous tissue is within the outflow tract that could impinge upon leaflet mobility. This is seldom a problem, but when it occurs, the prosthesis may have to be removed entirely and reimplanted. Single-disc prostheses also tend to be somewhat noisier. For these reasons, bileaflet designs have become increasingly popular among surgeons. The issues related to repetitive wear and thromboembolism due to the hinge mechanisms among bileaflet prostheses have proven uncommon.

Both bileaflet and single-disc valves are fundamentally non-physiologic in design as the valve mechanism itself resides in the middle of the outflow tract, unlike the native valve leaflets that completely clear the outflow tract during systole. Among the bileaflet valves there are some differences in the opening angle of the occluders and, accordingly, their obstruction to flow. There have also been some efforts to modify leaflet design to maximize the flow via the central orifice in the interest of maximizing laminar flow. Perhaps the most popular design modification to optimize hemodynamics, however, has been in the structure of the sewing ring to afford a supra-annular implant location.

Traditionally the most common valve implant technique entailed securing the entire valve mechanism (occluder, housing and sewing ring) within the surgical annulus roughly in the same plane as the aorto-ventricular junction. This minimized the risk of interference with leaflet excursion by fragments of native leaflet of other debris. It also maximized obstruction to flow. Newer designs have incorporated changes in the valve housing and sewing ring to permit placement of the prosthesis on top of the surgical annulus rather than within it. Such prostheses, called "supra-annular," are gaining popularity.

Other modifications in sewing rings are marketed with the hope of attracting the interest of surgeons; some are softer or more pliable, which manufacturers argue will conform more readily to an irregular annulus potentially decreasing the risk of perivalvular leak. A recent attempt to improve on sewing ring design to make them less susceptible to infection has entailed the introduction of silver impregnated fabric into the sewing ring. An additional theoretical advantage of this technique was reduced tissue ingrowth and perhaps reduced risk of late valve obstruction by pannus. Unfortunately it appears that the rate of perivalvular leak might be increased, not decreased, perhaps because of reduced tissue ingrowth.

Tissue Prostheses

The principle alternatives to mechanical prostheses are biological tissue valves (Figure 2). Although differences exist, all tissue valves share the positive aspect of freedom from long-term anticoagulation at the cost of limited durability. It is perhaps a bit curious that although surgeons perform more reoperations for structural deterioration of tissue valves than for mechanical valve thrombosis, and in most instances surgeons are not responsible for long-term anticoagulation management, the current trend among most cardiac surgeons is increasingly to favor tissue valves over mechanical prostheses. The current belief is that the risk of valve reoperation, particularly in the presence of well-preserved left ventricular function, is lower than pre-

Published by Elsevier Science Inc.

1062-1458/02/$22.00
PII S1062-1458(01)00528-1

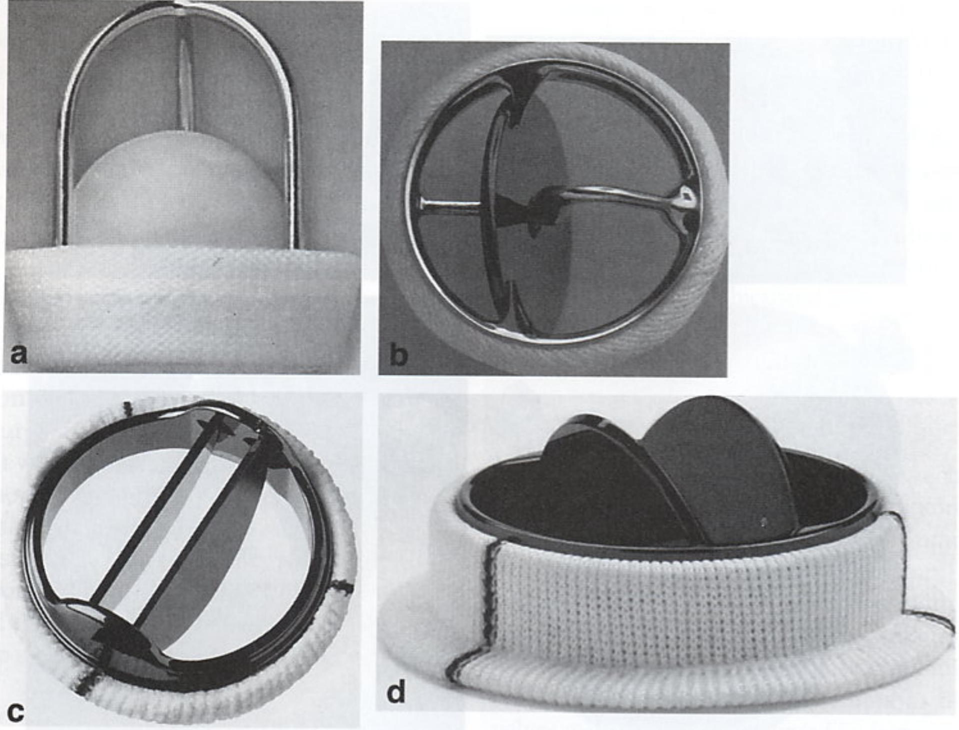

Figure 1. Mechanical prostheses: A) The Starr-Edwards ball-in-cage prosthesis was popular for many years and demonstrated excellent durability (photo courtesy of Edwards Lifesciences, LLC); B) The Hall-Medtronic single tilting disc prosthesis is the dominant single-disc valve in the United States (photo courtesy of Medtronic Corporation); C) The St. Jude bileaflet design is the most popular mechanical prosthesis in this country at the current time (image is provided courtesy of St. Jude Medical, Inc. All rights reserved.); D) The Carbomedics "top-hat" bileaflet design is designed to permit supra-annular implantation (photo courtesy of Carbomedics, Inc).

viously thought. This bias reflects an impression that the currently available prostheses will likely demonstrate at least some incremental improvement in durability.

The principle differences, real or hypothesized, among tissue prostheses revolve around durability and hemodynamics. Each option—stented xenograft, stentless xenograft, allograft or "homograft" and pulmonary autograft—has its own set of loyal advocates. Yet, as is the case with mechanical prostheses, there is no universally accepted front-runner.

Stented Xenografts

Of the biological valves currently being implanted, the vast majority are stented xenografts. These valves were developed in the 1960s with the aim of simplifying and standardizing implantation techniques to provide reproducible results. They have certainly succeeded in this effort. The valve itself consists of a metal or plastic frame on which glutaraldehyde-fixed biological leaflets are mounted. A flat or slightly crown shaped fabric sewing ring or skirt is arranged at the inflow for suture placement. The leaflets themselves are most often harvested from a porcine aortic valve, although new designs utilize bovine pericardium as an alternative.

Unfortunately, all stented xenograft valves appear to deteriorate with time. Significant advances have been made, however, in the design of these prostheses to improve their durability. Changes in the technique of tissue treatment, such as the ambient pressure during fixation and the addition of substances to retard calcification, appear to have resulted in an improvement in durability for "third generation" valves as shown in Table 2. It should also be noted that the risk of structural valve deterioration is dependent in part on the age of the patient. Not only is the risk of deterioration advertised over a shorter period of time in the elderly who have a shorter life expectancy than younger patients, but the actual rate of deterioration appears age dependent, with tissue valves lasting longer in older patients. This observation has encouraged more aggressive tissue prosthesis use in patients over the age of 65 years.

In addition to limited durability, the principle disadvantage of the stentless xenograft valves is due to a relatively poor hemodynamic profile because of the bulky frame that

Table 1. Mechanical Prostheses Actuarial Estimates of Freedom From all Valve-Related Complications

Aortic Mechanical Prostheses*	5-Year Freedom From Events	10-Year Freedom From Events	15-Year Freedom From Events
Medtronic Hall	87.2%	72%	60%
St. Jude Medical	70%	58%	41.5%
Star Edwards Silastic Ball Valve	80%	70%	51%
Carbomedics	79.3%		

* The mechanical valves listed show 100% freedom from SVD.

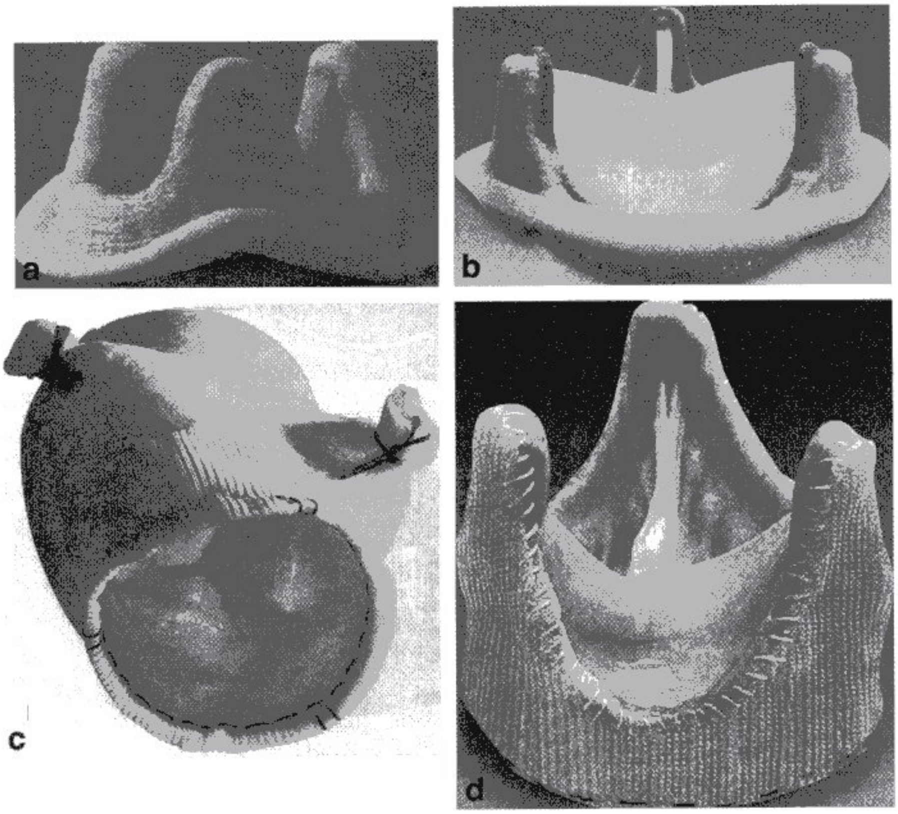

Figure 2. Xenograft tissue valves: A) The Medtronic Hancock Bioprosthesis is constructed from a porcine aortic valve (photo courtesy of Medtronic Corporation); B) The Baxter Perimount (Registered trademark, Edwards LLC) valve was engineered to optimize hemodynamics and durability with leaflets made from bovine pericardium (photo courtesy of Edwards LLC); C) The Medtronic Freestyle stentless xenograft may be implanted as a free-standing root replacement or using a subcoronary technique (photo courtesy of Medtronic Corporation); D) The St. Jude Toronto SPV (registered trademark of St. Jude Medical, Inc.) stentless xenograft must be implanted using the subcoronary technique (photo courtesy of St. Jude Medical Inc).

is particularly evident in small valve sizes. There have been efforts in the design to improve hemodynamic performance, either via modification of the natural porcine valve as in the case of the Medtronic Hancock MO (modified orifice) or complete engineering of a synthetic valve as in the Edwards Perimount pericardial valve. It should also be noted that a variety of surgical techniques exist for enlargement of the aortic root whether mechanical or tissue valves are inserted.

Table 2. Bioprostheses: Actuarial Estimates of Freedom From Structural Valve Deterioration (SVD)

Aortic Bioprostheses	5-Year Freedom From SVD	10-Year Freedom From SVD	15-Year Freedom From SVD
Hancock Standard	98%	78% ± 2	49% ± 4
Age >70	98% ± 1	91% ± 3	89% ± 3
Hancock MO	99% ± 1	79% ± 3	57% ± 4
Ages >70	100% ± 0.03	96% ± 2	87% ± 5
CE porcine		85.5% ± 1.8	41%
Age >70		96%	82%
CE pericardial*	100%	87.3%	68.8% ± 4.1
Age >70		95.3% ± 3	
Hancock II*	100%	97% ± 1	90% ± 3
Age >65	100%	100%	100%
Mosaic*	100% (4 yrs)		
Freestyle†	100%	99.5% (7 yrs)	
St. Jude Toronto†	100%		
Prima†	97.9%		
Allograft	97%	87%	65% (12 yrs)

* "Third generation" stented xenografts; † stentless xenografts.

Stentless Xenografts

Several manufacturers have introduced stentless xenografts into clinical practice over the last decade. They were designed to improve hemodynamics by elimination of the bulky stent and sewing ring with hopes of approximating the excellent hemodynamics of the human homograft. While it appears that the stentless xenografts have accomplished their hemodynamic aim, the degree to which this translates into improved long-term survival and left ventricular mass regression remains uncertain. There was also hope of improved durability because of more physiological stress distribution along the leaflets themselves. Currently it is unclear whether the durability of stentless valves is or will be superior to that of stented valves. Their implantation is, however, more complex than stented valves.

Stentless valves, depending on the design of the specific prosthesis, may be implanted either as a full root replacement with reimplantation of the coronary arteries similar to a composite root replacement (or Bentall Procedure) or may be implanted using the subcoronary technique. The latter involves two suture lines with a circular inflow suture line at the aorto-ventricular junction and a scalloped outflow suture line following the base of the leaflet below the coronary arteries and deep into the noncoronary cusp. While the root technique offers optimal hemodynamics since it places the entire valve above the aorto-ventricular junction, it is a bit more complex, especially if there is significant calcification of the coronary ostia. It is also likely that a reoperation to replace this type of prosthesis will be more complex than replacement of a stented valve or a subcoronary stentless valve. Conversely, the subcoronary technique has the potential disadvantages of predisposing to aortic regurgitation secondary to misalignment of the commissural posts or as a result of dilatation of the sinotubular ridge resulting in central aortic regurgitation. Historians of homograft aortic valve replacement will note that, in general, the "free hand" subcoronary homograft technique has given way to the free standing root replacement technique in most centers because of a demonstrable reduction in early aortic regurgitation with the root technique. Perhaps because of these complexities, and the as yet unproven advantage, stentless valves continue to search for their appropriate place in our armamentarium.

Allografts or Homografts

The earliest tissue valve substitute introduced was the allograft or homograft as it is colloquially called in the surgical literature. Currently, the most commonly used homografts are cryopreserved. Accordingly the tissue is soft, supple, and they offer ideal hemodynamics. Their use, however, is hindered in part by their limited availability and the necessity for liquid nitrogen storage facilities. Their implantation is also more complex than that for a stented xenograft, similar to stentless xenografts. Homografts are also of limited durability although they may have better long-term performance than stented xenografts. Still, in a young patient, they are almost certainly not a permanent substitute.

The principle advantage of a homograft valve is its remarkable flexibility. The prosthesis itself can accommodate nicely to complex root pathology. It is therefore an ideal substitute for the multiple redo replacements or the complicated case of aortic valve endocarditis. These tissue valves may also be more resistant to recurrent infection after endocarditis. Complex endocarditis is one of the most common indications today for their use.

Pulmonary Autograft

Closely related to the aortic homograft operation is the pulmonary autograft or Ross Procedure. It was introduced by Donald Ross (who also, simultaneously with Sir Brian Baratt-Boyes, introduced the aortic homograft) and in the last decade has become increasingly popular. It entails moving the autologous pulmonary valve to the aortic position and implanting a pulmonary homograft. As the autograft is viable, the hope is that it will be more durable and, in the case of children, will be able to grow.

Although the pulmonary autograft is a promising alternative, it has not been universally embraced. Critics point out that although the patient starts the operation with pathology involving only one valve, he or she leaves the operating room with two abnormal valves. As a homograft is still used in the procedure, the late performance of the pulmonary reconstruction is still an uncertainty in the minds of many surgeons. In addition, there is some concern about late dilatation of the pulmonary autograft itself, especially in patients with bicuspid aortic valves. Still the potential for growth appears to have been born out, and this may be the best choice for children.

Reparative Techniques

Finally a few words about reparative techniques seem in order. Techniques for leaflet repair in aortic regurgitation have been around for many years. Some of these early approaches included annular reduction, leaflet plication and leaflet extension or replacement with pericardium or dura mater. Durability of these techniques proved limited however, and with leaflet extension techniques, thromboembolism was a problem. Attempts to decalcify stenotic valves were universally plagued by late regurgitation due to retraction of the leaflets. The excellent performance of prosthetic valves overshadowed reparative techniques in the 70s and 80s. Recently, perhaps in part because of the remarkable success of mitral valve repair, interest in aortic repair has resurged. There has been particular interest in reapplication of techniques for leaflet prolapses such as free-edge plication and plication at the commissures. Unfortunately, the late results of repair, even in the current era, are likely significantly inferior to the results observed with mitral valve repair.

Another type of reconstructive technique that has become popular over the last decade is root remodeling. Both Sir Magdi Yacoub and Dr. Tirone David have described techniques to accomplish replacement of the aortic sinuses and ascending aorta with Dacron grafts while preserving the native aortic valve leaflets. The two techniques differ somewhat with respect to the manner in which the sinuses are created and with respect to annular reinforcement. There are no clear data yet supporting one technique over the other, however. As of this writing, these techniques appear to be indicated in the presence of normal aortic valve leaflets and a dilated aortic wall. As such, they are an exciting possibility for treating patients with Marfan syndrome, although histologic abnormality of the leaflets themselves in Marfan syndrome has been documented. The long-term performance of such reconstructions will be a matter of great interest.

Summary

A wide variety of options are currently available for aortic valve replacement. Now as before, none of the options is ideal. This challenges the physician to tailor the valve choices to the patient's age, pathology and lifestyle. This makes the choice of aortic valve prosthesis an important area for truly patient-centered decision making.

Questions and Answers

1. What is the best choice for AVR in an active individual in his mid-50s?

The choice among prosthetic valves for a particular patient should be dictated by age, associated cardiac conditions (e.g., presence of coronary disease, ventricular function or atrial fibrillation) and associated medical conditions as well as lifestyle. Clearly the patient himself should play an active role in the decision. All options have risks and benefits, and it is the patient that bears those risks. Individuals in their third, fourth and fifth decades of life are at low risk for anticoagulation in general and with a biological valve can look forward to more than one repeat valve replacement if biological valves are used. This tips the balance in the minds of most patients and physicians toward a mechanical prosthesis. Individuals in their eighth decade, however, are unlikely to come to repeat valve surgery with a biological valve, tipping the balance the other direction.

Perhaps the most challenging decision is for patients in their 50s and 60s. Newer generation biological valves offer the hope of extended freedom from structural valve deterioration, making it possible that repeat valve replacement may not be necessary. Certainly the biological valve manufacturers promote this view. On this basis, a growing number of patients and physicians are opting for xenografts in this age group. The risk of valve deterioration is not constant over time; however, making actuarial predictions based on large numbers of patients still relatively early in the survival period is hazardous. Ultimately only time will tell the true risk of repeat operation among this population.

Mechanical valves have certainly been the most popular choice for patients in their 50s and 60s over the past decade, as the prospect of repeat surgery is unappealing to most patients. The presence of coronary artery disease favors this choice as well, since the risk of repeat surgery is likely elevated somewhat by the presence of bypass grafts. Anticoagulation is generally well tolerated among these individuals as well. Ultimately, there is no single answer to this question. Ideally, appropriately educated patients should make this decision for themselves.

2. Would you choose a mechanical or tissue valve for an elderly person in atrial fibrillation?

The presence of atrial fibrillation is cited by many as an indication for a mechanical valve, as the former mandates anticoagulation. While this would certainly sway one toward a mechanical prosthesis in younger patients, those in their 80s and 90s, who represent a growing part of our practice, may tolerate full anticoagulation poorly due to gastrointestinal bleeding or risk of cerebral hemorrhage associated with a fall. The use of a biological prosthesis leaves the option of low-level anticoagulation open. It also simplifies perioperative management should other non-cardiac procedures be required.

3. Are tissue valves more resistant to infection than mechanical valves?

There is a substantial body of literature supporting the resistance of human allograft valves to infection, and many surgeons use these valves in the setting of valve replacement in the presence of active infection. The notion that stented xenografts are more resistant to infection than mechanical valves is likely fallacious, however, as prosthetic infection occurs most often in the sewing ring, a structure present in both mechanical and tissue valves.

4. Are small valves bad in small people?

Although it is intuitive that patients will ultimately do better with less residual outflow tract gradient, it has been difficult to prove that small valves are bad in small patients. Clearly a 19- or 21-mm valve is inadequate for an active individual with a body surface area over 2.0 m^2. But what about a frail 80-year-old who is relatively inactive? And everyone in between? Despite intense interest on the part of a subgroup of academic surgeons and a growing body of evidence in the surgical literature on both sides of the question, it has proven difficult to demonstrate a clear impact of prosthesis size on survival. Annular enlargement can be accomplished with little additional risk by surgeons familiar with the techniques, however, particularly among younger patients. These are in fact the patients most likely to present with a disproportionately small annulus, often associated with a bicuspid or unicuspid valve. Among older patients, in whom the risks associated with extensive manipulations of what may be a calcified root are higher, the benefits of implanting a slightly larger valve are likely less. From a practical standpoint, therefore, an aggressive approach to annular enlargement in young patients seems appropriate, while a more conservative approach may be advisable in the elderly.

5. Should the moderately stenotic aortic valve be replaced at the time of coronary artery bypass?

Aortic valve replacement after prior coronary artery bypass is a challenging operation, particularly in the presence of patent bypass grafts. Several early studies demonstrated a mortality rate of 15–20% for this procedure and argued on that basis for a more aggressive approach to replacement of moderately stenotic valves at the time of coronary bypass. More recently, we and others have demonstrated a similar risk for primary AVR/CAB and redo AVR/CAB, weakening this argument somewhat. Clearly the issue at hand is the increase in operative risk imposed by the addition of AVR vs. the likelihood of progression of aortic stenosis. In younger patients for whom the additional risk is less and the life expectancy is greater, most surgeons would favor valve replacement (with a mechanical valve in most instances). The more difficult, and more common, problem is the elderly patient with senile aortic sclerosis. As of yet, there are no good predictors of progression of the valvular lesion. Accordingly, the decision can only be made on an individual basis, with the intraoperative transesophageal echo playing a major role in demonstrating both the degree of calcification and leaflet mobility.

Suggested Reading

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