

Cardiac valve replacement – An update

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Introduction

Even though artificial heart valve implants have a history of some 30 years, there is to this day no ideal valve substitute. Each of the categories of substitutes used has its own advantages as well as problems. Since my last review on the subject, that appeared in this journal, was some 13 years ago (Lim, 1977), it is perhaps appropriate to provide an update on the status of cardiac valve replacement for the general local readership.

General Comments

Artificial heart valve implants can be divided into two major categories.

- (i) Mechanical valve prostheses which imitate function but not much of form.
- (ii) Biological valve prostheses which not only imitate function but to some extent form as well.

Mechanical valve prostheses now come in three main designs viz. ball valves, disc valves and bileaflet valves. Biological valve prostheses on the other hand consist mainly of aortic valves from cadavers (homografts/allografts), porcine aortic valves and valves fashioned from bovine pericardium (xenografts/heterografts). In addition the patient's own pulmonic valves (autografts) as well as valves fashioned from human dura mater and fascia lata have also been tried.

Well manufactured mechanical valve prostheses are long lasting. Their durability usually exceeds the life expectancy of patients receiving them. Mechanical valve prostheses can be machined with high precision and identical valves can be repeatedly produced. As mechanical valve prostheses have been manufactured to mainly imitate function and not much of form, their use will result in a change of the usual hemodynamics of the heart. It is suspected that this as well as other factors have given rise to problems associated with their use. The major problem encountered is the occurrence of thrombosis and thromboembolism. Hemolysis, valve malfunction as well as the presence of metallic clicks are also some of the other problems encountered.

While the occurrence of thrombosis and thromboembolic episodes can be controlled with anti-coagulant therapy, this practice however can lead to problems of hemorrhage. Fortunately, hemorrhagic rates are usually not high and most hemorrhagic events such as hematuria, subcutaneous hematoma and epistaxis are not serious (Beaudet et al., 1987; Deviri et al., 1987). Even so, some cases that result in death have been reported (Czer et al., 1987). Since anti-coagulant therapy demands patient compliance, its control and regulation can at times be difficult. Problems of thromboembolism and bleedings associated with anticoagulant therapy represent roughly 75% of all mechanical valve related complications (Edmunds, 1987).

In the past, hemolysis was common mainly due to poor valve design and the use of unsuitable materials. This complication is now less common. Most prostheses now use highly polished surfaces that do not cause abrasion of erythrocytes. Red blood cell damage is caused chiefly by shear stresses in turbulent and rapid blood flows.

Malfunction of mechanical valve prostheses can be due to a variety of causes; chief of which are thrombosis, ingrowth of tissues, fault in manufacture, and wear of valve parts. Valve malfunction, if it occurs, can lead to sudden death. When valves malfunction, reoperation becomes mandatory.

One advantage of using biological valve prostheses is that no permanent anticoagulant therapy is needed as their use is generally not associated with the occurrence of thrombosis and thromboembolism. It is because of this reason that biological prostheses were developed and used. However the major problem encountered in the use of biological prostheses is their durability. The viability of tissues at the time of implant and thereafter is still controversial (Bodnar et al., 1989; Shumway, 1989; Brockbank, 1990). If cells that regenerate connective tissue that maintain tissue integrity do not continue to stay viable for long periods of time, elastin, collagen and mucopolysaccharide ground substance within the tissue will most likely degenerate as the tissue experiences fatigue and wear. This will then lead to eventual valve failure. Thus reoperation with its accompanying risks becomes a necessity.

Perivalvular dehiscence and infectious endocarditis have similar incidences for both categories of mechanical and biological prostheses. Some of these events may also require reoperation (Rabago, 1987). Infectious endocarditis is generally due to bacteremias, with the germs being attached to foreign materials in the blood stream.

A study of the Stanford group reported that the rate of reoperation in their tissue valve replacement series was not statistically different from the group receiving the ball or the disc valves (Shumway, 1987).

A 1985 survey showed that of the 99318 artificial valves sold worldwide, 57% were mechanical prostheses and 43% biological prostheses. Responses from centres performing heart valve implants also indicated a preference for mechanical prostheses over biological prostheses (Rabago, 1987). Even so, the general practice is not to use mechanical prostheses in patients who are unable to undergo anticoagulant therapy for medical or social reasons and in female patients desirous of pregnancy. Biological prostheses on the other hand, are not recommended for young patients as well as those suffering from chronic renal insufficiency as it has been found that the biological implants in these patients degenerated much more rapidly when compared to those in other categories (Deivri et al., 1987; Rabago et al., 1987).

Mechanical Valve Prostheses

Over the years many designs and models of mechanical heart valve prostheses have been produced and used in humans. Table 1 is a list of the major mechanical prostheses that are in use today while Table 2 lists some of the makes whose use has declined or totally discontinued, due principally to their poor performance record.

Table 1
Major mechanical valve prostheses in use today

Name	Type
St Jude (Medical)	bileaflet
Medtronic-Hall	tilting disc
Bjork-Shiley	tilting disc
Starr-Edwards	caged ball
Edwards-Duromedic	bileaflet
Sorin	tilting disc
Omniscience	tilting disc
Jatene-Macchi	tilting disc

Table 2
Some examples of mechanical valve prostheses where use has somewhat declined

Name	Type
Braunwald-Cutter	Cross-Jones
Smeloff-Cutter	Alvarez
Kay-Suzuki	UCT
Kay-Shiley	Hammersmith
Beall	Angell-Shiley
Wada-Cutter	DeBakey
Lillehei-Kaster	

Note: Materials such as metallic balls, silicone rubber ball, teflon disc, Delrin disc have also been tried.

Valve design and surface texture affect the thrombogenicity of mechanical valve prostheses. Valves with better hemodynamics appear to be associated with lower incidences of thromboembolism (Cohn, 1987). Ball valves in general have a slightly higher incidence of thromboembolic episodes when compared to either tilting disc or bileaflet valves (Akins et al., 1987; Cohn, 1987). Thromboembolic complications is still the major problem encountered in mechanical valve implants though valve designs have improved and new materials for valve construction introduced.

Improvements in valve design include a larger opening, lower profile, easy opening and closing of occluder, even wear, better and longer lasting materials with lower thrombogenicity and reduction of regurgitation to a small percentage of beat volume.

Valves with pyrolite carbon disc appear to be more resistant to thromboembolism and valves with highly polished titanium housing has resulted in a smooth surface being exposed to blood (Beauder et al., 1987).

Only endothelial cell-lined surfaces are non thrombogenic. Synthetic materials in contact with blood activate the coagulation system and result in thrombus formation. Thus when mechanical valve prostheses with synthetic materials are implanted, anticoagulant therapy becomes mandatory. Warfarin, dicumarol, acenocoumarol, heparin, dipyridamole and aspirin have all been used as anti-coagulant or antiplatelet agents. A recent report indicates that the administration of warfarin plus dipyridamole appears to be more beneficial than using warfarin alone and that antiplatelet agents alone without warfarin have not been shown to offer sufficient protection against thrombosis and thromboembolism (Stein and Kantrowitz, 1989).

With anticoagulant therapy the overall actuarial freedom from thromboembolic incidence for most mechanical valve prostheses currently in use is usually of the order of 90% at eight to 10 years of follow-up (Beauder et al., 1987; Czer et al, 1987; Arom et al. 1989). This represents a vast improvement from the early days of valve replacements. Even so many researchers and clinicians express concern that definitions of thromboembolic and anticoagulated bleeding events lack uniformity, thus making data comparison difficult though there are attempts at achieving uniform definition by many centres (Edmunds, 1987; Cohn, 1987).

In addition, certain studies (Cohn, 1987) indicate that factors such as chronic atrial fibrillation, enlarged heart size, type of initial valve lesions, age, previous heart operation, atrial thrombus and preoperative embolus appear to play an important role in determining post operative thromboembolic risk while others (Edmunds, 1987) do not appear to share the same view. At any rate it is generally accepted that thromboembolic risks are higher when mechanical valve prostheses are implanted in the mitral position when compared to their implantation in the aortic position (Cohn, 1987; Stein and Kantrowitz, 1989).

It thus appears that future efforts into mechanical prostheses research will be towards a design that will better simulate both function and form using materials that are less or nonthrombogenic. For this, coating of valve parts with nonthrombogenic material as well as inducing endothelialization seem to be the proper direction to pursue. One report mentioned that in a case where part of the mechanical valve sewing ring was covered by dura mater the area was found to be absolutely free of thrombus (Figuera and Montero, 1987). Since dura mater is an electronegative material the report also suggested the possibility of reducing valve thrombosis by totally covering the surface of the sewing ring (including the stitches) with a smooth layer of electronegative material (Figuera and Montero, 1987). Thus greater efforts in the study of blood surface interface are needed.

Biological Valve Prostheses

Except for homografts which are aortic valves harvested from cadavers, biological valve prostheses of porcine aortic and bovine pericardial tissues are fabricated and marketed under a variety of names. Table 3 is a list of such valves currently in use and the order reflects the frequency of use as reported by Rabagot (1987), with those most frequently used listed first.

Table 3
Biological valve prostheses

Carpentier-Edwards	Mitroflow
Ionescu-Shiley	Carpenter-Edwards Pericardial
Hancock	Biocor
Xenote	Gabbay
Wessex	Vascor
Liotta	Tascon
Xenomedia	Xymo

Homograft aortic valves are prepared for use in a variety of ways. For example Barratt-Boyes (1987) reported that valves are harvested from cadavers within 48 hours after death and are disinfected for seven days at 4°C in a nutrient medium containing antibiotics. The valves are then stored in the nutrient medium at 4°C until use. Most of their homografts are implanted within four weeks of collection and valves that are not used within three months are discarded. Hence the homograft aortic valves that they use are nonvital at the time of implant. Some centres use homograft aortic valves that are harvested under sterile conditions and preserved in Hanks solution with dilute antibiotics for a period of up to two weeks (Shumway, 1987), while others cryopreserve them after 24 hours of immersion in a weak antibiotic solution (Barratt-Boyes 1987). It should be realised that antibiotic solutions used can be different in different centers.

Porcine aortic heterografts on the other hand are generally prepared by sterilization and preservation in glutaraldehyde (Shumway, 1987), with some being fixed under pressure. Bovine pericardial tissue valves are both also generally preserved with glutaraldehyde. For both the porcine aortic and bovine pericardial valves, rigid as well as flexible stents have both been used. Flexible stents are made from materials such as polypropylene, Elgiloy (an alloy of cobalt and nickel) and an acetal resin (Delrin). Some stents are also covered with Dacron. More recently certain centres also use valves that have been treated with calcium retarding agents (Bortolotti et al., 1987; 1989).

Cardiac valve replacements using bioprostheses have early (within 30 days of operation) mortality rates that are generally less than 10% (Rabago et al., 1987; Odell et al., 1987; Barratt-Boyes, 1987; Bortolotti et al., 1987; Jamieson et al., 1987) with some centres reporting below 5% (Bircks, 1987). The actual patient survival after eight to 10 years generally varies from about 57% to about 70% (Rabago et al., 1987; Odell et al., 1987; Barratt-Boyes, 1987; Jamieson et al., 1987; Milano et al., 1988). Just as in mechanical prostheses, early mortality is a function of patient condition, surgical skill and post-operative care and facilities that are available. It is generally noted that biological valve prostheses implanted at the aortic position perform better than those placed in the mitral position in terms of durability as well as thromboembolic rates (Cohn, 1987; Jamieson et al., 1987). Even though thrombosis and thromboembolism do not present great problems with bioprosthetic implants, anticoagulants are usually administered, especially for those with mitral valve replacements, for from six weeks to six months post operatively with three months being the most common practice. However patients with a history of systemic embolism or have evidence of left atrial thrombus at surgery or who have atrial fibrillation, appear to suffer from a greater risk of thrombosis and thromboembolism. Thus for them, long term but lower dose anticoagulant therapy is recommended (Stein and Kantrowitz, 1989).

As mentioned, tissue failure is the greatest problem encountered when biological prostheses are used. Tissue failure can be manifested as cusp rupture or tears, cusp perforation, cusp thickening and stiffening, commissural rupture which then lead to stenosis or regurgitation. Tissue calcification, which can also lead to stenosis and regurgitation is also a common occurrence especially in xenografts. Incidences of calcification are generally found to be higher in younger patients, especially those with mitral valve replacements (Odell et al., 1987). It has also been suggested that calcification may be due to the glutaraldehyde preservation process (Odell et al., 1987).

Though initially bovine pericardial tissue valve prostheses are deemed to provide better hemodynamic performance when compared to porcine bioprostheses, recent reports seem to indicate that the incidence of tissue failure in pericardial tissue valves is higher than in porcine bioprostheses, especially those placed in the mitral position (Bortolotti et al., 1987; 1988). This therefore makes the use of pericardial tissue valves questionable and some centres have stopped using them.

Though in the majority of cases tissue failure are not catastrophic events (thus providing opportunities for successful reoperation on an elective or urgent basis), some instances of abrupt failure resulting in death have been documented (Magilligan, 1987).

Since tissue failure appears unavoidable at the present time, patients with biological valve prostheses will thus require reoperation at a rate of 20 to 30% within the first 10 years (Jamieson et al., 1987, Magilligan, 1987). Even so many proponents of biological valves are of the opinion that they provide better quality of life compared to patients receiving mechanical prostheses. The former are virtually free from thromboembolism, thus free from anticoagulant therapy and its related hemorrhagic complications. This view will become more widespread if reoperation risk can be reduced to its absolute minimum. Presently mortality rates at reoperation for both mechanical and bioprostheses

vary from 4–44% depending on the condition of the patient at the time of reoperation (Magilligan, 1987). It is found that patients in the higher NYHA functional class suffer from a higher rate of early mortality at reoperation (Magilligan 1987). As such some clinicians are inclined to recommend reoperation once signs of tissue failure are detected so as to prevent further deterioration of the heart.

Thus the future of biological valve prostheses can be bright if problems related to tissue durability can be solved. Currently many studies are being pursued in this direction and some examples are listed below.

- (i) problems related to viability or nonviability of tissues used.
- (ii) problems related to preservation and fixation techniques.
- (iii) problems related to physical, chemical and electrical properties of tissues.
- (iv) problems related to hemodynamics especially at the mitral position.
- (v) studies to designs that will reduce mechanical stress on the valve cusps. (In this Bortolotti suggested that excessive reduction of stent heights may lead to increases in mechanical stress on the cusps which will in turn affect valve durability (Bortolotti et al., 1988). Cusp tears at the commissures have been observed in Hancock pericardial and Inoescu-Shiley pericardial valve types. It is suspected that these are due to abrasion (by the stents) as well as fatigue.
- (vi) problems related to mechanical and fatigue properties of tissues used. (Included in this category are studies such as those of Radjeman and Lim (1985, 1985, 1986), Vesely et al. (1988, 1989, 1990), Broom (1978) and Schuster (1989)).
- (vii) problems related to more suitable materials for the stents.

In short all the above are attempts toward providing better hemodynamics, reducing mechanical stress on the valve cusps and therefore hopefully increase durability. It is envisaged that studies on synthetic materials for the valve cusps may not be fruitful as these will then introduce problems related to thrombosis and thromboembolism.

Concluding Remarks

The above short account indicates that an ideal cardiac valve substitute has not been found. To date, researchers have not been able to incorporate the advantages of both the bioprostheses and mechanical prostheses into one valve design/type and each recipient of an artificial heart valve is a potential candidate for reoperation. As far as patient survival is concerned the literature has not indicated any particular valve type as showing distinct superiority. The search therefore continues.

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