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Developments in mechanical heart valve prosthesis

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Abstract. Artificial heart valves are engineered devices used for replacing diseased or damaged natural valves of the heart. Most commonly used for replacement are mechanical heart valves and biological valves. This paper briefly outlines the evolution, designs employed, materials being used,. and important factors that affect the performance of mechanical heart valves. The clinical performance of mechanical heart valves is also addressed. Efforts made in India in the development of mechanical heart valves are also discussed.

Keywords. Mechanical heart valves; biological valves; valve design; valve performance.

1. Introduction

The human heart can be considered a twin positive displacement pump working in tandem for supporting the systemic and pulmonary circulation of blood. Each pump comprises of a receiving chamber called atrium and a pumping chamber called ventricle. Each ventricle has two valves, one each at the inlet and outlet to ensure the unidirectional flow of blood. Artificial heart valves are engineered devices used for replacing the diseased or damaged natural valves of the heart. Two types of artificial heart valves are mainly used today: (1) mechanical heart valves and (2) biological valves. Mechanical heart valves are made from materials of synthetic origin like metals, ceramics and polymers, whereas the biological valves may employ in addition to synthetic materials, materials of biological origin after proper modification using physico-chemical treatments.

Biological tissue valves are made from porcine aortic valves or fabricated using bovine pericardial tissue and suitably treated with gluteraldehyde to preserve them and to remove antigenic proteins. Clinical experiences with different tissue valve designs have increasingly indicated time-dependent (5 to 7 year) structural changes such as calcification and leaflet wear, leading to valve failure. Therefore tissue valves are rarely used in children and young adults at present. On the other hand, mechanical valves made with high strength biocompatible material are durable and have long-term functional capability. However, mechanical valves are subject to thrombus deposition and subsequent complications resulting from emboli, and so patients with implanted mechanical valves need to be on long-term anticoagulant therapy. Currently, mechanical valves are preferred except in elderly patients or those who cannot be put under anticoagulant therapy, like women who may still wish to bear children, or hemolytic patients.

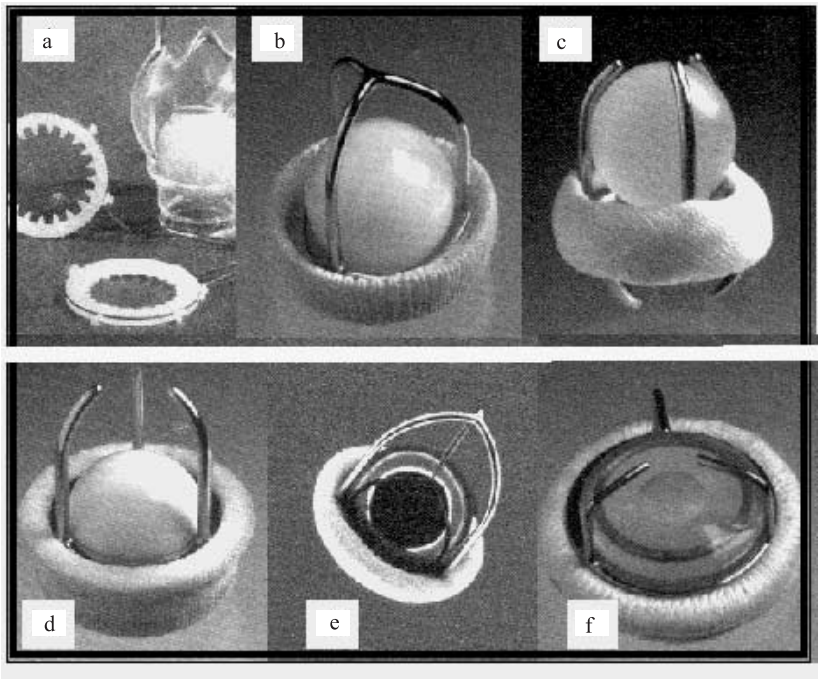

Figure 1. Caged ball valves. **(a)** Hufnagel–Lucite valve, **(b)** Starr–Edwards, **(c)** Smeloff–Cutter, **(d)** McGovern–Cronie, **(e)** DeBakey–Surgitool and **(f)** Cross–Jones.

2. History of mechanical valve

The pioneering efforts of Dr. Charles Hufnagel, who made the first successful placement of a totally mechanical valvular prosthesis, started the era of artificial heart valves [1,2]*. Hufnagel achieved this feat in 1952, by inserting a Plexiglas cage containing a ball occluder into the descending thoracic aorta. The first implant of a mitral valve replacement in its anatomic position took place in 1960, when the Starr-Edwards prosthesis was put the clinical use [3]. A number of similar caged ball designs appeared subsequently; like the Magovern–Cromie, DeBakey–Surgitool, Smeloff–Cutter prostheses (see figure 1).

Even though caged ball valves have proven to be durable, their centrally occluding design results in a larger pressure drop across the valve and higher turbulent stresses, distal to the valve. Their relatively large profile increases the possibility of interference with anatomical structures after implantation. This led to the development of low-profile caged disc valves in the mid-1960s. The Cross–Jones, Kay–Shiley and Beall caged-disc designs were introduced during 1965 to 1967 [4]. These valves were used exclusively in the atrio-ventricular position. However, because of high complication rates, this model soon fell into disuse.

The next significant development was the introduction of tilting disc valves by Bjork–Shiley in 1967 [4]. The design concept of this valve involves a free-floating disc, which in the open position tilts to an angle depending on the design of the disc-retaining struts. In the open position it acts like an aerofoil, with the blood flowing over and around it, thus minimising the flow disturbance. The original Bjork–Shiley prosthesis employed a Delrin

*References in this paper are not in journal format

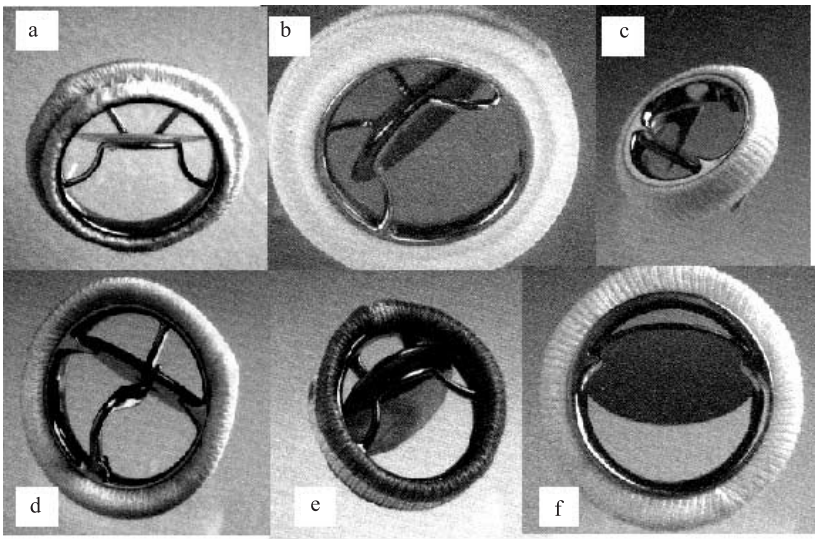

Figure 2. Tilting disc valves of the 1970s. **(a)** Bjork–Shiley Delrin valve, **(b)** Bjork–Shiley standard, **(c)** Lillehei–Kaster, **(d)** Medtronic–Hall, **(e)** Zorin and **(f)** Omniscience.

(polyacetal) occluder, which was later replaced by pyrolitic carbon. The Medtronic–Hall prosthesis was introduced in 1977 [5]. Figure 2 gives different models of tilting disc valves that were introduced in the market during the 1970s.

Due to the high prevalence of rheumatic valvular disease in the country, a programme for the development of a Indian valve was initiated in the late seventies by the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum. The Chitra Valve design was chosen to be of tilting disc type with a metallic cage, disc occluder and a sewing ring made of knitted polyester fabric [22]. During the decade of development, four models incorporating different materials were evaluated to various stages. The fourth model incorporating the Haynes-25 alloy cage, ultra high molecular weight polyethylene occluder and polyester sewing ring was introduced into clinical use in 1990 (see figure 3).

The first bileaflet valve was introduced by St. Jude Medical Inc. in 1978 [4]. This design incorporates two semicircular-hinged pyrolitic carbon occluders (leaflets), which in the open position are intended to provide minimum disturbance to flow. During the last two decades, many new designs of bileaflet valves have been introduced by various manufacturers [6] (see figure 4)

During the last fifty years, many valve designs have been tried in laboratories. Few of them have gone through extensive stages of evaluations and reached clinical use. Of these few only three variants are currently in clinical use; viz. the caged ball, tilting disc and the bileaflet designs.

3. Materials in mechanical heart valves

The development of heart valves has been related to a great extent to the identification and proper utilization of suitable materials, which are biocompatible and blood compatible. During

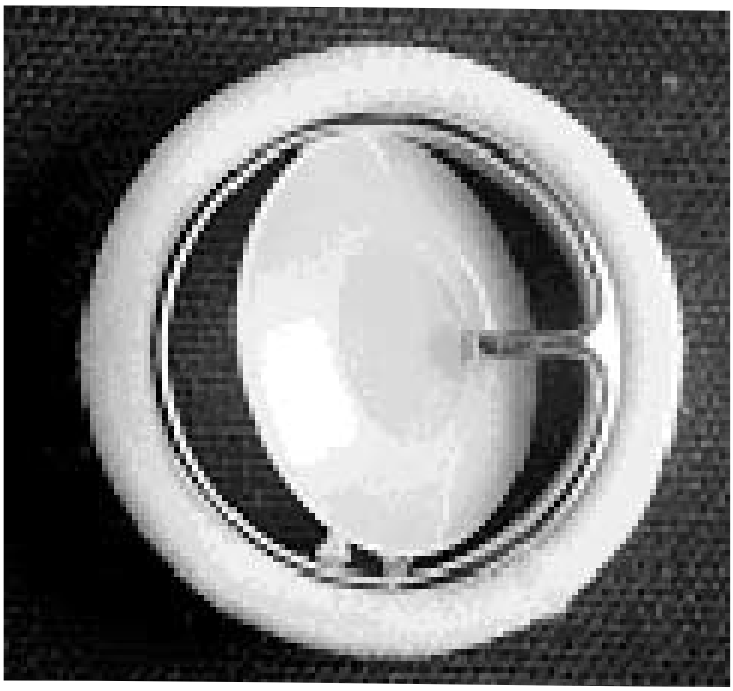

Figure 3. Chitra heart valve.

the last fifty years of development, a set of material requirements for valves have evolved which can be summarised as [7] below.

- Cause minimal trauma to blood elements and the endothelial tissue of the cardiovascular structure surrounding the valve.
- Show good resistance to mechanical and structural wear.
- Minimise chances for platelet and thrombus deposition.
- Be non-degradable in the physiological environment.
- Neither absorb blood constituents nor release foreign substances into the blood.
- Have good processibility (especially suitable for sterilization of the device by appropriate means) and take good surface finish.

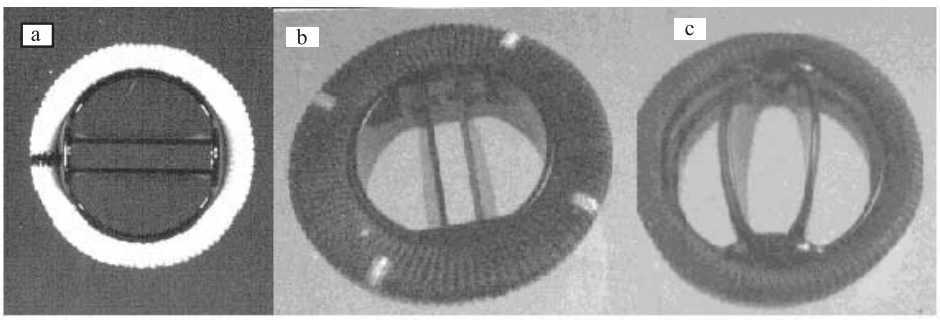

Figure 4. Bileaflet valve models. **(a)** St. Jude Medical, **(b)** Carbomedics and **(c)** Duramedics.

Table 1. Biomaterials used in different valve modules.

Component	Biomaterials used
Cage, housing or hinge design	Commercially pure titanium or titanium alloys (Ti6Al4V) Cobalt-based alloys (Stellite-21, Haynes-25) Pyrolytic carbon (LTI carbon)
Occluder, disc, leaflet or ball	Pyrolytic carbon (LTI carbon) Silicone rubber Polyacetals (Delrin) Polyolefins (ultra high molecular weight polyethylene)
Sewing ring	Polypropylene Polytetra fluoroethylene (Teflon) Polyethylene terephthalate – PET (Dacron)

Because of these inherent limitations, very few engineering materials are suitable for mechanical valve designs. Table 1 below describes the various materials used for the components of mechanical heart valves.

The choice of materials is closely related to structural factors, since fatigue and wear resistance of a valve depend not only on its configuration and loading but on its material properties and combinations as well. Materials that exhibit good biocompatibility may have inferior durability and vice versa. For many patients, the implanted prosthetic valve should last through their life, and in the case of young patients this amounts to over fifty or sixty years. In most patients in developing countries the requirement for valve replacement arises out of rheumatic heart disease in the early ages; whereas in developed countries the need arises out of the pathological changes due to aging.

The first caged ball valve used an acrylic housing and silicon rubber ball. The early Starr–Edwards (S–E) valves consisted of a stainless steel four-strut cage, housing a silicon rubber ball. Subsequently, the cage material was changed to Stellite 21, which is an alloy of cobalt (61–63%), chromium (25·5–29%), molybdenum (5–6%), and nickel (1·75–3·75%). The silicon rubber composition was modified by adding barium sulphate to make it radio opaque. The valve sewing rings used a silicone rubber insert under a knitted composite polytetrafluroethylene (PTFE – Teflon) and polypropylene cloth. The most well-known material-related problem was described as *ball variance of the silicon-rubber balls*. This was due to the infiltration of body fluids, especially lipids, into the material, resulting in swelling and cracking of the balls. The problem was later solved by modifying the processing of silicon rubber to improve its post curing characteristics [8].

The initial designs of Bjork–Shiley tilting disc valve consisted of a Stellite-21 cage, polyacetal (Delrin) disc and a PTFE (Teflon) sewing ring. Delrin is a thermoplastic polymer manufactured by the polymerization of formaldehyde. Teflon and delrin were tested as candidate materials for disc fabrication and it was found that teflon wore out much faster than delrin [9]. Although teflon exhibits a low coefficient of friction and a low surface energy, its lack of resistance to abrasive wear was the reason for this behaviour. However, there have been other problems with Delrin. It absorbs moisture during steam sterilization and deforms causing obstruction to proper functioning of the valve.

Failure of polymeric occluders, led to the development of LTI carbon (pyrolytic carbon) components in later versions of the Bjork–Shiley valve and has remained the most preferred biomaterial for heart valves thereafter. LTI carbon is deposited on to preformed high-density

graphite substrates at temperatures around 1200° C (low temperature isotropic pyrolytic carbon, LTI pyrolite). In order to increase strength and wear resistance silicon (up to 8% by weight) is co-deposited to form silicon carbides. The LTI carbon exhibit excellent blood compatibility, biocompatibility as well as wear and fatigue resistance.

Of all wear couples so far considered for heart valve applications, the one giving the best wear resistance uses LTI carbon–LTI carbon. The first valve to use the LTI carbon–LTI carbon combination with fixed pivots and focussed wear was the St. Jude medical prosthesis. The leaflets and the housing of the bileaflet valves are made of LTI carbon, and these valves show improved hemodynamic characteristics, especially in smaller sizes when compared to tilting disc valves. The only major cause of failure is mistreatment during assembly of the valve itself or insertion of the valve in the housing. Being a ceramic material, LTI carbon is inherently brittle and can crack when subject to delayed fracture failure mode due to high stress concentrations.

4. Mechanical heart valve designs

Table 2 enumerates the primary characteristics of the caged ball, tilting disc and bileaflet designs and their design related drawbacks.

4.1 *Caged ball valves*

There is little question that introduction of caged ball valves was a major advance in the treatment of patients with valvular heart disease. The place of caged ball valves in history remains undisturbed as they continue to serve as a bench mark against which the newer designs of tilting disc and bileaflet valves are evaluated. It is also clear from literature that these seemingly indestructible mechanical valves carry an array of associated complications, the majority of which are related to higher pressure drops and poor fluid flow patterns across these devices.

Table 2. Characteristics of most popular valve designs.

Valve design	Design characteristics	Design related drawbacks
Caged ball	Time tested Structurally sound – built in redundancy in the strut design Low levels of regurgitation in the closed phase	Relatively large valve height Flow separation downstream of the valve, which might lead to thrombus formation
Tilting disc	Better hemodynamic characteristics than the caged ball design Lower valve height and hence suitable for all anatomical locations Maximum number of valves used till date is of the tilting disc design	Lower levels of redundancy in the cage strut structure Lower minor orifice flow can lead to tissue over growth and thrombosis Strut fracture and related complications have occurred in certain models
Bileaflet	Uniform flow profiles Lower levels of structural complications	Hinge design prone to thrombus formation and valve failure Leaflet escapement reported in certain models

4.2 *Tilting disc valves*

The concept of the tilting disc valve arose out of the recognition that caged-ball valves were bulky and that their hemodynamic characteristics were less than optimal. In an attempt to reduce the profile of such valves, a flat disc, instead of a ball, was used as an occluder in caged-disc valves. These were of a lower profile than caged-ball valves, but still suffered from the hemodynamic problem of having an occluder that remained relatively obstructive in the open position. Thus the concept of a disc that tilted within the valve ring, causing minimal obstruction to blood flow in the open position, was especially attractive. The earliest examples of the tilting disc concept were flap valves. These had a ring with a straight segment along which a disc was hinged, much like the lid of a toilet seat. Blood flowed entirely along the inflow surface of the disc, and the stasis on the outflow side resulted in thrombus formation that obstructed disc movement.

In 1964, Melrose and colleagues introduced a valve in which a free-floating polypropylene disc was equipped with integral blocks that retained it within the valve ring and limited its travel [5]. In clinical application, however, severe wear of the polypropylene hooks occurred within 2 yeas of implantation, with subsequent valve malfunction. In 1969 Bjork and Shiley collaborated to produce a valve in which the free-floating disc restrained by two low profile M shaped struts [9]. These allowed the disc to pivot to an opening angle of 60 degrees. In 1978 the struts were modified to allow the disc to move downstream as it tilted, and the disc profile was changed from plano convex to convexo concave [10]. During the next one decade, a large number of implantations were carried out all over the world with this convex-concave design. But during the later half of the 80s, it was observed that this design had a basic flaw and many larger size valves started failing due to structural dysfunction. This led to the withdrawal of this design followed by the introduction of an all integral monostrut valve by Bjork–Shiley.

The Lillehei–Kaster valve was introduced clinically in 1978 [11]. Its thin flat pyrolytic carbon disc fits between four angled projections, or guide lugs, arising eccentrically from the valve ring. The ring and the guide lugs are machined from a single block of titanium. The valve can be rotated within its knitted polyester sewing ring. The disc opens to an opening angle of 80°. The disc does not move downstream on opening but is in permanent contact with part of the ring throughout the cardiac cycle. Its regurgitant flow in the closed position is significantly smaller than that of the other tilting disc prosthesis. In 1984 a new development of this prosthesis was introduced as the omniscience valve. It has similar design, but the entire valve mechanism is made of LTI carbon, and early models also have a carbon-covered sewing ring.

The Medtronic–Hall tilting disc valve prosthesis was introduced into clinical practice in 1977[12]. The valve was designed to offer an improved ratio of effective orifice to external diameter with the minor section of the orifice as large as possible. It has a thin and flat pyrolytic carbon disc that is guided by a sigmoid strut that passes through a hole in the centre of the disc and is restrained by another strut and two guide lugs projecting from the ring. The opening angle if 75° for aortic prosthesis and 70° for mitral prosthesis.

In 1990, the Chitra heart valve was introduced into clinical use [13]. The disc had a plano-convex shape with opening angle of 70°. The free-floating disc was able to rotate on its centre to avoid the problem of thrombosis around the hinge as well as to distribute the wear over its surface. The plano convex shape of the disc with inlet side flat, increases the inflow into the minor orifice. This shape also makes the fabrication of the cage and disc easier.

4.3 *Bileaflet valves*

The bileaflet principle, a hinge mechanism, and a low profile are basic to the design features of bileaflet heart valve prosthesis. They have two semicircular leaflets retained within the ring by hinges. The potential for impeded leaflet movement due to interference with cardiac structures is slim, as the open leaflets are positioned in the middle of the blood stream and enclosed within the ring in the closed position. Bileaflet valves are the most protected as the leaflets hardly protrude from the valve ring, even during maximum opening.

The large effective orifice area of the bileaflet valves, contributes to creating a flat, nearly normal flow profile with far less obstruction and turbulence, as compared with earlier generations of replacement valves. However, data on the rate of thromboembolism, with and without anticoagulation, have made it clear that this valve is not exempt from the pitfalls of mechanical prosthesis in general; lifelong anticoagulation is necessary, just as with any other mechanical valve [14].

5. Failure modes in mechanical valve

Problems that interfere with the successful performance of valves can be grouped as [15] below.

- Degradation of valve components
- Structural failure
- Clinical complications associated with the valve.

Clinically, valve failure has been considered to be present if any of the following events require reoperation and/or cause death:

- Anticoagulant-related hemorrhage (ACH),
- Prosthetic valve occlusion (thrombosis or tissue growth),
- Thromboembolism
- Prosthetic valve endocarditis (PVE),
- Hemodynamic prosthetic dysfunction, including structural failure of prosthetic components (strut failure, poppet escape, ball variance),
- Reoperation for any other reason (e.g.; hemolysis, noise, incidental) etc.

The performance of mechanical valves is in several ways related to valve design and structural mechanics. The design configuration affects the load distribution and dynamics of the valve components, which in conjunction with the material properties determine the durability and successful performance of the valve. The flow engendered by the geometry of the components determines the extent of flow separation and high shear regions. The hinges in the bileaflet and tilting disc valves can produce regions of flow stagnation, which may cause localised thrombosis, which may in turn restrict occluder movement.

Biochemical degradation and mechanical wear is often inter-related, since degradation accelerates material removal from surface due to wear, which in turn accelerates the rate of the biochemical reaction by continually exposing new surface to the corroding media. The use of large surface areas of exposed metal in valves is often quoted as leading to thromboembolic complications [16]. A cloth covering on the metal can sharply reduce these complications, but other problems associated with fabric wear or uncontrollable tissue proliferation that restricts flow can arise. The degradation of the silicon-rubber balls used in ball valves provides a good

example of deterioration caused by biochemical incompatibility and also leads to mechanical failure.

Under the conditions used, namely high flow rate, all of the materials are reasonably non-thrombogenic. Very small surface cracks have been demonstrated to initiate thrombus formation, presumably due to a small volume of stagnant flow. In spite of desirable characteristics of the biomaterials used in the heart valves prosthesis, problems of thromboembolic complications continue to occur at the rate of 1 to 3% per patient year in these valves. The mechanical stresses induced by the flow of blood across the valve prosthesis have been linked to blood damage and activation of formed elements (red blood cells, white blood cells and platelets) resulting in the deposition of thrombi in regions of relative stasis in the vicinity of the valve.

Reports of strut failure, material erosion, and leaflet escape as well as pitting and erosion of valve leaflets and housing have resulted in numerous investigations of the closing dynamics of mechanical valves. The dynamics of the leaflet motion and its impact with the valve housing or seat stop is very complex, and a number of experimental and numerical studies have appeared recently. As the leaflet impacts against the seat stop and comes to rest instantaneously, a water hammer effect results. High positive and negative pressure transients present on the outflow and inflow side of the occluder respectively are generated at the instant when the leaflet impacts against the seat stop or the guiding strut. The negative pressure transients have been shown to reach magnitudes below the liquid vapor pressure and have been demonstrated to be a function of the loading rate on the leaflet inducing the valve closure. As the magnitudes of negative pressure transients go below the liquid vapor pressure, cavitation bubbles are initiated, and the subsequent collapse of the cavitation bubbles can be a factor in the lysis of red blood cells, platelets, and valvular structures.

The pressure distribution on the leaflets, and impact forces between the leaflets and guiding struts are also being experimentally measured in order to understand the causes of strut failure. The flow through the clearance between the leaflet and the housing at the instant of the valve closure and in the fully closed position, and the resulting wall shear stresses within the clearance are also suggested as being responsible for clinically significant hemolysis and thrombus initiation. Further improvements in the design of the valves based on the closing dynamics as well as improvements in material may result in minimizing thromboembolic complications as well as occasional structural failure with implanted mechanical valves.

6. Soft occluder and its effect on valve closing dynamics

The occluder of a mechanical valve moves towards the closing position due to the pressure reversal during the valve-closing phase. Most of the currently available tilting and bileaflet valves have relatively rigid pyrolytic carbon occluders. At the instant of the closing impact of the occluder on its seating, the occluder comes to a sudden stop, resulting in water hammer effect. Large positive pressure transients are induced near the occluder tip close to the downstream side of the valve. Similarly large negative pressure transients have been noticed on the upstream side of the valve. These large pressure gradients induced across the valve, even though for a very small fraction of a second, can force blood through the clearance between the occluder and the valve housing. This can be the source of several fluid dynamically induced stresses that can initiate haemolysis as well as platelet activation [17].

Another phenomenon which may give rise to local disturbances and blood cell damage is the formation and collapse of cavitation bubbles. Cavitation is the rapid formation and collapse of vapor filled bubbles caused by a transient reduction in local pressure below the

Table 3. Threshold loading rate for initiation of cavitation and the occluder design/material for different valves.

Valve model	Design type and occluder material	Threshold loading rate dp/dt (mm Hg/s)
Medtronic–Hall	Tilting disc Pyrolytic carbon on graphite	300
Bjork–Shiley Standard	Tilting disc Pyrolytic carbon on graphite	1500
Jomed Implantate	Tilting disc Carbon/Delrin composite	200
Edwards Duramedics	Bileaflet Pyrolytic carbon on graphite	200
Carbomedics	Bileaflet Pyrolytic carbon on graphite	750
Chitra	Tilting disc UHMW-PE	> 3000

vapor pressure of blood. The implosion of these bubbles can damage the blood cells in the vicinity as well as activate platelets [18].

Studies of these cavitation bubbles and the possibility of generation of large negative pressure transients both in vitro and in vivo conditions have been studied by many investigators. A series of studies conducted at the University of Iowa, USA [22] with different types of mechanical valves have revealed certain relation between the type of material used for disc fabrication and the potential of the valve to generate cavitation damages on the formed elements of blood. As such a rigid valve disc impacts against the seat stop at the instant of valve closure, the water hammer effect results, since the disc material does not yield significantly to the impact nor absorb part of the impact energy. On the other hand, polymeric valve discs (like UHMW-PE) absorbs a portion of the impact energy and hence the negative pressure transients will be significantly smaller. The threshold-loading rate for cavitation initiation for different valves is given in table 3 [19].

7. Clinical performance of mechanical heart vlaves

The use of mechanical heart valves has been associated with certain incidence of embolism, anticoagulant complications, perivalvular leak, endocarditis, thrombosis and structural failure. These complications may be patient related, surgery related or valve related to varying degrees. The occurrence of perivalvular leak is related to the surgical technique and the quality of host annulus. Anticoagulant related hemorrhage is common in noncompliant patients or who abuse alcohol. However, some complications such as thrombotic obstruction and structural failure are clearly related to the valve design and choice of material.

Comprehensive reviews on the clinical performance of the mechanical heart valves have shown that the complication rates are comparable amongst tilting disc and bileaflet valves [5]. A comparison of the valve related clinical complications during mitral valve replacement is given in table 4 [20, 21].

Many features of the bileaflet design should be considered as an advance compared with those of the caged-ball and tilting disc prosthesis. The majority of the available data demon-

Table 4. Comparison of valve related complications in studies on MVR.

Valve model	Valve type	Incidence (%/patient-years)					
		Thrombosis	Embolism	Bleeding	Infective endocarditis	Paravalvular leak	Total
Bjork–Shiley	Tilting disc	0·6 ± 0·1	1·7	1·2 ± 0·2	0·1	0·7 ± 0·1	4·3
Medtronic–Hall	Tilting disc	1·1 ± 0·3	3·1 ± 0·5	0·5 ± 0·2	NA	0·7 ± 0·2	5·4
Chitra	Tilting disc	1·6 ± 0·5	2·4 ± 0·6	0·4 ± 0·2	0·5 ± ·3	0	4·9
St. Jude Medical	Bileaflet	0	3·4	1·6	0·3	NA	5·3
Carbomedics	Bileaflet	0·4	0·9	2·4	0·5	0·9	5·1

strates that clinical and hemodynamic results are at least good as those obtained with tilting "mono"-disk valves. An overall superiority of the bileaflet valves, however, has not been established yet. There is no scientifically sound evidence in terms of controlled studies to decide if there is any difference in clinical performance and hemodynamic functions among these mechanical valves.

8. Conclusions

There has been considerable improvement in the durability and functional efficiency of mechanical heart valves. These improvements have been by gradual incremental improvements coupled with a few revolutionary advances like the introduction of tilting disc/bileaflet valves. Despite all these improvements, complications (though their rates are very low) continue to be associated with their use. All current models of mechanical heart valves need anti coagulation therapy to minimise the risk of thrombosis and embolism. Management of anticoagulation levels and bleeding are other concerns.

The over all complication rates in different valve models of tilting disc and bileaflet valves are comparable. Marginal differences seen could be attributed to the patient population, surgical and post operative management and follow up data collection.

Recent trends in the choice of materials indicate a preference towards soft occluder materials. One team in Germany is working towards bileaflet valves with soft occluders. Medtronic–Hall also had announced that they will be looking for a valve with soft occluder in the near future. The advantages of using soft occluder material are many. They absorb the impact forces generated during valve closure, there by reducing the chance of suture dehiscence. The reduction in the impact forces also reduces the load that needs to be transferred to the surrounding tissues through the suture ring, reducing the irritation caused by the continuous movement at the cloth–metal interface. Another improvement caused by the soft occluder is the reduction in the probability of occurrence of cavitation and cavitation damage. This has been reasonably established by various studies conducted on Chitra heart valve, which showed that even at very high loading rates, the chance for cavitation in valves with soft occluders is minimum.

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