



## Guest Editor

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# In Search of the Ideal Heart Valve

Since the development of safe and dependable techniques for open heart surgery, surgeons have recognized the need for an ideal heart valve to substitute mainly for the mitral and aortic valves and less frequently for the pulmonic and tricuspid valves. After two decades and after many failures of prosthetic valves to perform satisfactorily in the human heart, the search continues. Much has been learned during this period but more remains to be elucidated and some widely held misconceptions about valve design must be discarded.

One of the misconceptions which confused early investigators was the belief that the prosthetic valve should resemble the normal human anatomy. Attempts to apply this concept in the early years of valve replacement met with limited success. The flexible leaflet valves of Hufnagel, McGoon, Bahnson and others usually came to a sad end when thrombosis, fracture and disruption occurred. During that period and around 1962 Albert Starr and Dwight Harken devised caged ball prostheses which aroused objections from advocates of the anatomic design concept. After all they implied, "If the Lord had thought the ball and cage principle was best, he would have made heart valves that way." One sage defendant of the caged ball design reminded us, however, that the wheel did not resemble the human leg but it had proved to be a mighty good substitute. And so it became a practical design and to this day the caged ball principle is widely used for valve prostheses. Yet certain disadvantages of this type of prosthesis are difficult to overcome. Because of the shape of the occluder or sphere a large high profile cage is necessary to permit adequate excursion of the poppet. In the open position the ball may impinge on surrounding tissues producing another critical obstruction to flow beyond the level of the valve annulus. The mitral caged ball prosthesis has caused serious arrhythmias because it irritated the ventricular septum. The aortic prosthesis may obstruct flow in a small ascending aorta. Moreover, the ball may displace considerable volume in the blood stream—a particularly undesirable feature in a small left ventricle after valve replacement for

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calcific mitral stenosis. Thus, it became obvious that the caged ball prosthesis would not be satisfactory for all situations and attention was turned to valves with low profile designs employing discs rather than spheres. These valves served well in the mitral annulus. Not until recently, however, has a streamlined double cone disc been introduced for the aortic prosthesis.

Selection and preparation of materials for the components of the valves did not seem difficult in those early years because inert, durable materials which caused minimal tissue irritation and blood damage were available. For example, testing in vitro revealed that valve occluders made of Silastic® would last almost indefinitely. However, because of a slight flaw in the curing and processing of Silastic, the occluders deteriorated when exposed to the enzymes and fatty acids in the blood. As a result swelling, fracture and occasional dislodgement and embolization of the poppet into the circulation occurred. Silastic was not the only material that failed. Teflon® occluders used in the Beall and Wada valves also deteriorated and sometimes caused fatal consequences. Obviously more durable materials were needed. Of course, some investigators have seized this opportunity to conclude that man could never improve nor even equal the Lord's work and, therefore, biological materials should be used. Indeed, homografts and heterografts after many early failures have recently shown real promise. At present the preserved porcine aortic valve of Hancock is enjoying considerable popularity but what about the future? Equally glowing reports indicate that valves fashioned from homograft dura mater will provide the answer. I believe using biological materials represents a retreat in our effort to develop a better valve substitute.

Two concepts which have crept into the designers' thinking should in my opinion be forgotten before the ideal synthetic valve can be produced. The first is that the surface of the valve and the cage must be covered with a fabric to promote endothelialization of the surfaces and thus prevent thrombosis and embolism by developing a living biological lining. Cloth-covered valves of various types have been introduced and the bad news is accumulating steadily. The major objections to cloth-covering are hemolysis which results and hemodynamic problems caused by the bulkiness of the cloth, leading to obstruction of the valve orifice.

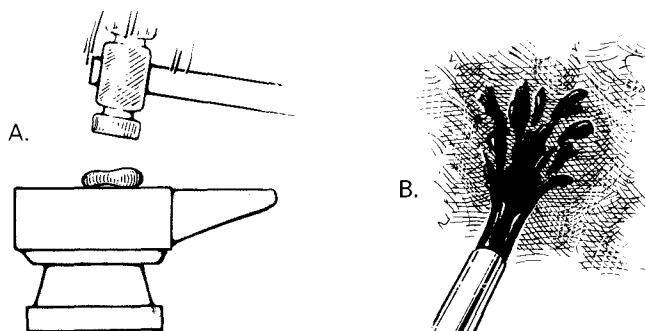


Fig. 1. Causes of hemolysis with synthetic valve prostheses. In (A) an erythrocyte is being crushed (hammer-and-anvil effect) and in (B) a jet stream of blood against a rough fabric causes disruption of the cell membrane (friction or abrasion effect).

Hemolysis is a well known complication of valve prostheses and is usually caused by two factors. One is the hammer-and-anvil effect—the erythrocytes and other cellular elements of blood are damaged or ruptured when the occluder closes on the metallic ring (Fig. 1A). This can be almost eliminated, or certainly reduced to an insignificant and easily tolerated degree, by having the occluder rest on small metallic struts. Thus the area where blood trauma occurs is reduced to a few square millimeters. The other factor is the abrasion or friction effect—the jet stream of blood against an irregular fabric surface damages the delicate cell membrane of the erythrocytes leading to hemolysis (Fig. 1B). Thus small-sized cloth-covered ball and seat aortic valves prostheses of standard design would almost uniformly lead to clinical hemolytic anemia. If the anemia is not evident by blood count in those patients, it can almost always be detected by studying the circulating enzymes (lactose dehydrogenase [LDH]). Several years ago we abandoned the fabric covered valves after a brief clinical trial because of such complications. Regardless of the design, however, all heart valves with a fabric sewing ring will cause hemolysis if a perivalvular leak develops since a jet of blood rushes over a rough cloth surface. Thus even an “ideal” valve must be sutured accurately and securely in the valve annulus.

The second concept which should be erased is the idea that the central flow principle is necessary in the design of a prosthetic valve (Fig. 2). Recently two ingenious prostheses known as the Bjork-Shiley and Lillehei-Kaster valves have been in widespread use. Both of these valves have a “hingeless” wafer which opens the central portion of the valve and virtually eliminates resistance to forward flow (Fig. 2B). While these valves function well in vitro in a pulse duplicator, I believe they invite thrombosis. Uneven flow around the periphery of the occluder inevitably produces areas of relative stasis on the lesser curvature of the annulus and at the fulcrum (Fig. 2B). Small deposits of fibrin at the pivot point can cause major interference with valve motion. When this begins, the ultimate thrombosis and fixation of the occluder is inevitable.

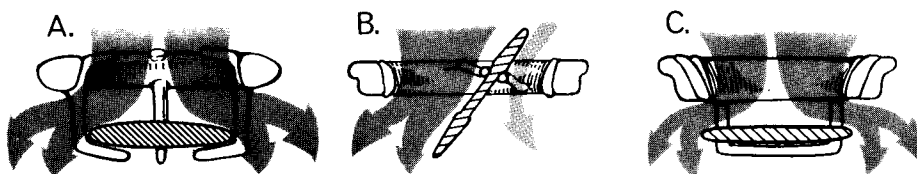


Fig. 2. Hemodynamic considerations in low profile valve design. Shown in (A) is the symmetrical peripheral flow of the double-caged full-orifice design (Cooley-Cutter valve), in (B) the tilting disc with unequal asymmetrical flow pattern (Bjork-Shiley) and in (C) the standard single-caged disc design revealing restriction of flow (Beall, Kay-Shiley and others).

The alternative to the central flow principle are valves with symmetrical flow such as the standard disc valve (Fig. 2C). The disc in most valves rests on the valve ring but this design tends to reduce diameter of the orifice and may also promote hemolysis by the hammer-and-anvil effect. With exception of the full-orifice principle introduced by Smeloff for a double cage ball valve, most valves have the occluder resting on and not in the valve ring (Fig. 2A). Advantages of the full orifice principle with a double caged design in reducing the flow pressure gradient are obvious, but the self-washing action is another distinct advantage. In the closed position the occluder rests upon struts rather than the ring and, therefore, a small margin of tolerance is necessary to provide free motion of the occluder. This margin between the occluder

and the ring produces a minute stream of regurgitation that washes away the fibrin and platelets which would tend to adhere to the upper and lower surfaces of the valve. The actual volume of the regurgitation is less than two percent of the total flow through the valve and, therefore, poses no physiological disadvantage.

With these concepts in mind and after more than 5,000 clinical valve implants we joined with engineers and design experts of the Cutter Laboratories in Berkeley, California to create a valve which met more nearly the characteristics of an "ideal" valve (Fig. 3).

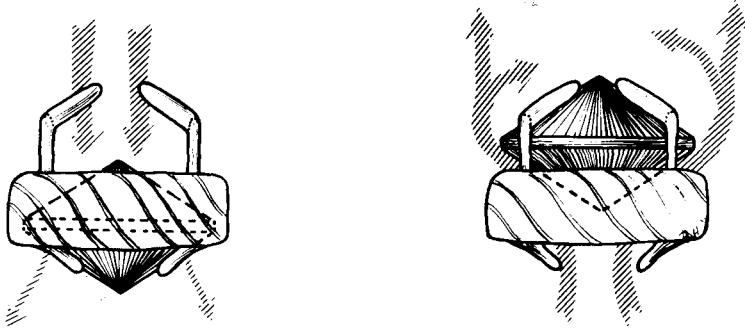


Fig. 3. Valve design of Cooley-Cutter aortic prosthesis showing streamlined double cone disc. The hollow disc is buoyant in the blood stream.

Our valve employed the full-orifice principle with a double open-caged design where the occluder rests inside the ring and closes only on struts. The ring is titanium milled from a solid metallic block. The mitral sewing ring is eccentric so the posterior part is larger than the anterior, placing the valve ring slightly forward and into the outflow tract of the left ventricle. This prevents impingement of the occluder on the left ventricular wall when it is in the open position. The occluder or poppet is made of an extremely hard and durable material known as Pyrolite Carbon®. The shape of the occluder for the mitral valve is discoid, but for the aortic valve a double cone disc was designed to fulfill the needs for the rapid jet stream at that point. Because of our favorable experience with the double cone disc, we anticipate in the future adopting this design for the mitral orifice. The double cone disc has a hollow center which increases the buoyancy and makes the valve highly responsive to minor changes in pressure and flow. An extensive clinical trial of this new valve in 1,200 implantations has convinced us that we have the best prostheses available today.

But can we claim to have found the ideal valve? Probably not. As we continue to make progress in surgery for valvular heart disease, better valves will likely be introduced. However, some of the knowledge and concepts learned the hard way by clinical experience during the past years should help us steer a more intelligent course in the future. Critical analysis of each valve in use today, applying some of the principles described herein, can be made of each type of valve that is presently available to the cardiac surgeon. Some are good, some are fair and others are so poor that they should be withdrawn from the market. We must be careful and critical shoppers and select only the valves which embody features which may be predicted to give superior results.