PERFORMANCE OF MATERIALS IN VASCULAR PROSTHETIC DEVICES: HEART VALVES*

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DURING the first few years that prosthetic replacement of a heart valve was carried out, the flexible variety of artificial valve leaflets made of Teflon fabric were used almost exclusively. Although the design and hemodynamic function of these valves was satisfactory, the material from which the leaflets were constructed was not durable enough and, in time, they demonstrated excessive wear as manifested by tears in the leaflet substance, especially at the flexion creases. Surgeons then turned their attention toward the rigid artificial prosthetic valve, and this is the type most frequently used clinically for the replacement of a valve at the present time.

The rigid prosthetic valve presently employed for replacement of a valve is usually of the ball-valve or low-profile design. It is made of materials demonstrated to be biologically compatible in the bloodstream. The sewing ring is usually of a fabric: Teflon, Dacron, or polypropylene; the cage is of metal: Stellite 21, a chromium-molybdenum alloy, or of titanium, a pure noncorrosive material, being most commonly used. A number of substances have been used for the moving poppet, including Stellite 21, Teflon, and polypropylene. Two different prosthetic models are commonly available from each valve manufacturer in a range of sizes—one for the aortic valve and another for the mitral or tricuspid position.

Most of the rigid valves have fabric fixation sewing rings and require the placement of multiple sutures to hold them in place. This is a time-consuming and tedious process. In order to avoid this, one type

*Presented as part of a Symposium on Problems in Evaluating the Blood Compatibility of Biomaterials held by the Section on Basic Medical Sciences and the Section on Biomedical Engineering of the New York Academy of Medicine February 18 and 19, 1971.
of ball-valve prosthesis, the McGovern valve, has been designed with multiple pin fixation instead of the standard sewing ring to secure it to the heart. With the use of an inserter tool, a series of metal pins are ejected from a plastic housing and seat themselves in the tissue of the valve annulus.

In deciding on the materials to be employed for the fabrication of a prosthetic valve, certain factors must be taken into consideration. An artificial valve must be able to withstand the stress of prolonged wear opening more than 40 million times a year under a pressure of 2 to 6 psi. The materials from which the valve is fabricated must be biologically compatible in the bloodstream. They must not be unduly thrombogenic. The valve must be designed so that it does not damage the blood elements and must offer little resistance at physiologic flows.

Originally silicone rubber (a polysiloxane polymer), plus a vulcanizing agent (dichlorobenzoperoxide), to which a small amount of silicone dioxide was added for reinforcement, was selected by valve designers as a material of choice for fabrication of the moving ball. However, degenerative changes in the silicone balls were described in a significant number of patients in whom some of the earlier models of rigid prosthetic heart valves were implanted. The average implant time before onset of this complication was found to be about two years and the degenerative changes observed included discoloration, softening, and splitting of the ball. The problem, when it first became evident, was thought to be due in part to some ill-defined relation between physical stress on the ball and lipid absorption by the silicone rubber in the high pressure aortic area. It was often noted to be associated with some malposition of the valve, an unusually tight fit of the prosthesis, a paravalvular leak, or an accumulation of thrombotic deposit on the frame that limited normal ball motion in the cage. While this was seen fairly frequently following aortic valve prosthesis implantation, it was a rare occurrence following mitral valve replacement. Interestingly enough, in some patients in whom both the aortic and mitral valves had been replaced and who subsequently died, the ball variance was noticed in the aortic prosthesis but not in the mitral prosthesis at the time of postmortem examination. The concern for this particular problem led some valve manufacturers to search for other materials to be used as substitutes for the fabrication of the moving poppets. Those explored included the pure metals such as titanium, metal alloys such as
Stellite, and polymer plastics, including Teflon and polypropylene.

Poppet wear has also been a factor in the late failure of low-profile prostheses. The earliest lenses used in valves implanted in patients were made of silastic and showed some problems of wear. In a search for a more durable material the possibility of using lens poppets made of polypropylene suggested itself and was explored in our laboratory. Polypropylene is a durable, stable hydrocarbon polymer that stimulates little tissue reaction. Polypropylene discs, identical in size to silicone rubber prototypes used in commercially available models of valves, were fabricated to fit the Cross-Jones low-profile valve. The results of studies following implantation of low-profile valves in a series of calves indicated that the amount of lens wear seen in the experimental animals in which polypropylene lenses were used in combination with fabric-covered frames was significantly less than that seen in the surviving control animals having silastic discs. The moving poppet used in the low-profile valve in general is subjected to greater stress than the moving poppet used in a prosthesis of the ball-valve design. A spinning ball made of a relatively soft elastomer material tends to bounce off the struts with less friction as it moves up and down in the cage, thus producing less frictional wear. A moving lens has a definite tendency to move up and down in a more fixed locus, thus placing more abrasion stress on the contacting moving parts.

At the same time that it became apparent that wear of the moving parts of prosthetic heart valves was going to be a problem, a new concept relating to the prevention of thromboembolic complications associated with the use of artificial valves also appeared. It was noted that prostheses having frames entirely covered with cloth were less prone to incur thrombosis than those with the conventional bare metal frames. It was appreciated that cloth would also act to cushion the impact of the poppet as it struck the frame and simultaneously decrease the noise level if a metal poppet was used in a metal frame. Therefore when the first ball-valve prostheses with metal poppets became commercially available, they were combined with entirely cloth-covered frames.

As has been previously mentioned, in the initial clinical experience with rigid prosthetic heart valves, silicone rubber was selected as the material of choice for fabrication of the moving poppet. With the appearance of significant incidence of ball variance in the earliest clinical
models of the Starr-Edwards aortic valve prosthesis, a search was initiated by several investigators for a more durable material to substitute for fabrication of the valve poppets. Most of these were materials considerably harder than silicone rubber. However, pulse duplicator studies, animal implantation, and clinical experience with fabric-covered valves in our laboratory consistently demonstrated a specific disadvantage associated with the use of poppets made of hard material. The harder the ball, the greater the degree of fabric wear ultimately seen on the contact surface of the fabric-covered struts of the valve seat. Use of a metallic poppet requires a heavier multilayered fabric to provide maximum wear resistance and this objective was achieved at the cost of increased stenosis in the earliest models of these commercially available valves. Catheterization studies carried out in patients following valve replacement with many of the better designed models of the rigid prostheses have demonstrated improved hemodynamic performance when compared with the patient's preoperative status. However, in general these types of valves demonstrate some tendency toward stenosis, especially at the higher cardiac outputs associated with exercise. Therefore rigid valves of the cage design cannot tolerate any further reduction in their effective orifices without becoming unacceptably stenotic. In spite of the use of heavier fabric layers on the struts, the development of fabric wear at the friction points was not an uncommon event when fabric-covered cages were used in combination with metal poppets. On the other hand, fabric wear was never seen experimentally when silicone poppets were used, even up to three years postoperatively. Silicone rubber is a resilient, relatively soft elastomer and imposes little abrasion wear on fabrics.

In the interim since the first ball-valve prosthesis was developed, valve manufacturers have significantly improved the formulations of silicone rubber, as well as the modeling techniques used to make silastic poppets. These improvements have been associated with a significant decrease in the incidence of silicone ball degeneration noted recently when compared to previous clinical experience with the earlier models of caged valves. Experience, now exceeding five years with the Smeloff-Cutter prosthesis demonstrated a significant reduction of the frequency of ball variance after a change to a "modified cure" silicone rubber poppet. Thus the experience to date suggests that perhaps silicone rubber was abandoned prematurely by some valve manufacturers when
in fact it was their curing and fabrication techniques which were at fault. Edwards Laboratories recently reported that over a 66-month observation period there have been virtually no variances in the silicone balls with the 6,120 series mitral prosthesis; and over 57 months only six variant balls with the 1,200 series aortic prostheses—a significant reduction from the 75% incidence noted in the earlier 1,000 series aortic valve. Therefore, for the present, the potential problems relating to the use of poppets made of hard materials such as metal appear to outweigh any theoretical advantages. In fact the evidence suggests that at the present time the improved cure silicone rubber remains the material of choice for fabrication of the poppet used in rigid prosthetic heart valves.

Continued advancement in plastic and metal technology in the future, as well as in bioengineering knowledgeability, will undoubtedly lead to continued improvement in the design and fabrication of artificial heart valves. The ultimate goal—a valve which will outlast the life span of any patient in whom it is implanted—will undoubtedly be achieved one day.