THE DESIGN FEATURES AND THE DEVELOPMENT OF THE TOROIDAL PROSTHETIC HEART VALVE

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Some of the early developmental efforts of prosthetic cardiac valves resulted in failure while others realized marginal success. For the most part, the unavailability of satisfactory materials and/or the lack of design technology were the factors responsible for the deficient results of these early prostheses[1].

Valves constructed of rigid materials and having a caged or similarly constrained free-floating orifice occluder usually had better hemodynamic characteristics than flexible leaflet designs. Certain metals and plastics (Stellite 21, titanium, Silastic ®, polypropylene, polycarbonate, teflon, and dacron) have been successfully employed in free-floating occluder type prostheses. However, even with the more satisfactory functioning designs, there are occasions of adverse response of the circulatory system to the presence of the prosthesis. The prevalent reactions to the prostheses are increasing valvular stenosis, uncontrolled thrombus encapsulation, thromboembolism, and Silastic ® denaturization[2, 3]. These effects are in part a result of such valve characteristics as inadequate design, bulky mechanical structure, excessive resistance to opening under pressure, and obstruction to flow[4, 5]. Flexible leaflet valves, by design, have certain undesirable qualities such as areas of flow stasis dorsal to the open leaflet, resistance (stiffness) to opening, and in some cases leaflets that function asynchronously. The undesirable hematologic responses to the prosthesis and its structural limitation are being minimized, if not obviated, through improved designs, advances in fabrication and material technology, and meaningful methods of testing.

A titanium valve with a caged free-floating toroid type occluder was developed during the past 3 years (Figure 1). The principal features of the toroidal heart valve prosthesis are a reduction in occluder weight for a comparable size caged ball type valve, an open-end low profile cage, and a concentric lateral and central flow pattern. The flow pattern has a divergent circumferential lateral component and a convergent central component. The uniform lateral component thoroughly washes the prosthesis-annular tissue junction. In addition, the convergent flow through the center of the toroid relieves the lateral flow demand volume. These flow pattern components combine to increase total flow with a reduction in pressure gradient.

DESIGN

Valve housing. The valve housing is machined from pure commercial grade titanium. The 3 major components of this weldless unibody structure are an annular ring, an annular crossmember, and a 4-strut open-end cage (Figure 2). From inflow to outflow, the inside hydraulic surface of the annular ring is convex contoured overall. A structural enlargement of the annular bisecting crossmember (localized at the center of the orifice) seals off the toroid's central opening while the valve is closed. The crossmember lies in the annular region and subsequently reduces the hydraulic orifice area an average of 18% for all sizes. With an inflow hemispherical prominence followed by an outflow convex taper, the fixed occluder is structurally engineered to minimize turbulence and eddying, promoting streamline central flow. The open-end cage is formed by fixture-rolling the ends of the 4 struts to permanently capture the toroid occluder (Figure 3).

Toroid occluder. The solid titanium occluder has a convex inflow-outflow symmetry (Figure 2). Malfunctioning (wedging, sticking, or otherwise hanging-up) of the toroid in any position is eliminated by the use of convex surfaces throughout. Since the metallic occluder has a lens shaped cross section, sealing off all flow is achieved by the toroid engaging the appropriate valve body structure at its external and internal peripheral margins, respectively. This design characteristic minimizes the occluder size which reduces its planar obstruction to flow, particularly the lateral component. Titanium possesses the excellent qualities of structural longevity, light weight, ease of fabrication, and high resistance to biodegradation.

TESTING

Pulse duplicator. Since the pulse duplicator is a mechanical simulator, the test results of artificial valves studied therein can serve only as an indication of in vivo performance. Therefore, by testing the currently used clinical prostheses along with the new design, meaningful comparisons can be made and in some instances, conclusions drawn about the future in vivo potential use of the new valve. In addition to equivalent sized ball valve prostheses, 4 toroidal valves& (Table I) were tested in a left heart pulse duplicator (Figure 4) as both mitral and aortic replacements[6]. These studies were conducted under the following system conditions: Pulse rate = 60 beats/min., systolic period = 2/5 sec., diastolic period = 3/5 sec., arterial systemic resistance = 80 mm. Hg, left ventricular pressure range - 80 to 180 mm. Hg, (varied in 10 mm. Hg increments) and left atrial pressure -

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