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A New Full Orifice Disc Valve for Mitral Replacement

Experimental Evaluation

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Because of dissatisfaction with certain features of the currently available ball and disc valve prostheses when implanted in patients with mitral stenosis and a small volume left ventricle, a full orifice discoid valve has been designed which avoids many of these shortcomings. The valve has been tested mechanically in a pulse duplicator and compared to existing prostheses. High speed cine studies were used to evaluate turbulence. Implantation was carried out in animals. Evaluation by these various methods indicates that the valve is satisfactory for human implantation and may have significant advantages over other artificial valves when used in patients with mitral stenosis and small left ventricles.

An acceptably low operative mortality has been obtained with several of the currently available cardiac valve prostheses.[1] However, the limited postoperative studies[2,3] which have been reported indicate that many of the surviving patients have continued cardio-pulmonary disability and a limited exercise tolerance. Unless other causes for these difficulties are demonstrated (such as perivalvular leaks, malfunction of the valve due to ball variance, or myocardial diseases), suboptimal hemodynamic characteristics of the prosthesis itself must be suspected as the source. Our interest in designing an improved prosthesis for mitral replacement resulted from dissatisfaction with certain features of the available caged ball and disc type valves when used in patients with mitral stenosis. In our experience, this group is particularly prone to increased morbidity and mortality from impaired cardiac output in the postoperative period. Besides intraoperative causes of myocardial dysfunction, such as coronary air emboli and anoxic myocardial damage, the impaired output in some of these patients may result from the use of a ball type prosthesis in the presence of a left ventricle with small volume. There are at least three possible mechanisms by which a ball type prosthesis may interfere with cardiac output in the patient with mitral stenosis and a small volume ventricle: 1) impairment of ventricular filling (stenosis effect) by a valve occluder occupying a large space in the small volume ventricle; 2) encroachment on the left ventricular outflow tract, or 3) a stenotic "second orifice effect" due to obstruction of the outflow between the occluder and the encircling ventricular myocardium (Fig 1). The "second orifice effect" may also occur with currently available disc valves, since these discs are of large diameter and may, therefore, significantly reduce the flow-through space between the occluder and adjacent myocardium. In the late postoperative period, lesser degrees of impaired ventricular filling may pro-

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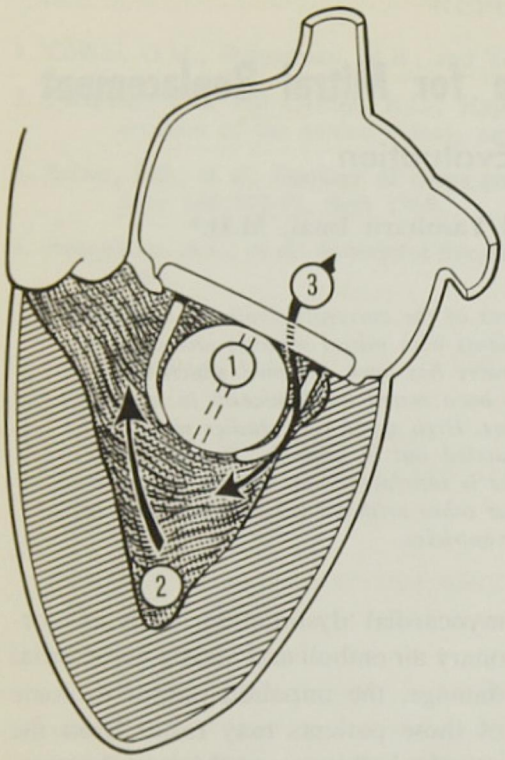


Figure 1

Three mechanisms by which ventricular filling and cardiac output may be impaired when a ball-type prosthetic valve is implanted in patients with mitral stenosis and a small left ventricle: 1) large space occupying occluder, 2) encroachment on left ventricular outflow tract, and 3) "second orifice" obstruction between edge of occluder and adjacent ventricle.

duce cardiopulmonary disability during exercise, when the heart is unable to increase cardiac output to meet physiologic demands. This may be the cause of the considerable elevation of pulmonary artery and left atrial pressures noted during exercise at the time of postoperative catheterization[2] of some of these patients.

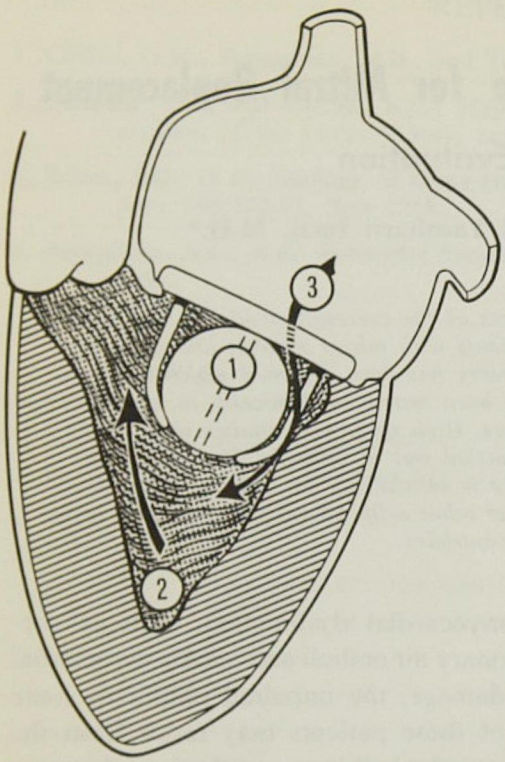
This presentation describes the development and testing of a full orifice discoid valve which avoids many of the shortcomings present in currently available valve prostheses when used in patients with mitral stenosis and a small volume left ventricle.

Valve Design

Besides those design features which minimize wear of moving parts, thrombogenesis and turbulence, the most important consideration in a prosthetic *mitral* valve relates to the hydrodynamic characteristics of the opening phase of valve function. An effective valve orifice is also an important component of the opening characteristics of a prosthetic mitral valve, since flow through the valve depends on a pressure differential, which is little more than that of gravity filling, in the presence of atrial fibrillation. Since peak pressures are low and of short duration in the mitral position, forward flow will be significantly affected by limited orifice size, excess inertia, or sticking of the prosthetic valve occluder in the valve seat.

The full orifice discoid valve * was designed to minimize the causes of impaired ventricular filling which may exist when using current mitral prostheses in the presence of a small volume left ventricle (Fig 2). The full orifice principle of the Smeloff-Cutter valve was employed, since the larger orifice area, which this design permits, is a major advantage. The full orifice principle allows a 30% to 50% greater orifice area as compared to other ball and disc type prostheses with the same outer diameter which close by means of a larger occluder overlapping the valve seat (Fig 3). This larger orifice is particularly desirable in the design of a mitral valve since the

* Manufactured by Cutter Laboratories, Berkley, California.



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struts and the valve seat, so cocking is impossible. Clearance between the occluder and the inside of the valve seat is .003 to .005 inches measured at 37°C and regurgitation through this space is estimated at 3-5 cc/stroke. The thinner titanium cage and struts which may be used with the light weight disc valve construction permits a 10% to 34% larger orifice area (depending on valve size) than the Smeloff-Cutter ball valve with the same tissue annulus. This increased orifice area is 50% to 60% larger than current disc valves which occlude on the valve seat (Fig 3).

The discoid occluder is composed of molded silastic. The edges are thicker than in other disc or lens-type occluders to minimize wear and provide less turbulent flow. The disc volume is 1.6 cc compared to a comparable ball of a Smeloff-Cutter valve which has a volume of 5.87 cc. The volume of the ball in a valve seat occluding prosthesis, such as a Starr-Edwards valve of similar outer diameter, is 6.20 cc.

Wear Evaluation

The silastic, Teflon fabric and titanium cage components used in the full orifice disc valve are undergoing testing in an accelerated fatigue testing apparatus. The valve is subjected to 900 cycles per minute at a flow rate of 11 liters per minute. At this writing, there has been no detectable wear after six months of accelerated wear testing.

Variance—the adsorption of blood lipid fractions after implantation [6,7] — has been an occasional source of mechanical dysfunction or failure in all valve prostheses utilizing silastic occluders. A prolonged period of clinical testing will be required to evaluate this potential source of trouble. Pulse duplicator and animal implantation studies do not furnish the answer to this question. Sticking of a silastic occluder in the valve orifice, due to swelling of the elastomer, is a theoretical source of dysfunction with valves of the full orifice design which cannot be evaluated without clinical experience. The rarity of this complication in an extensive

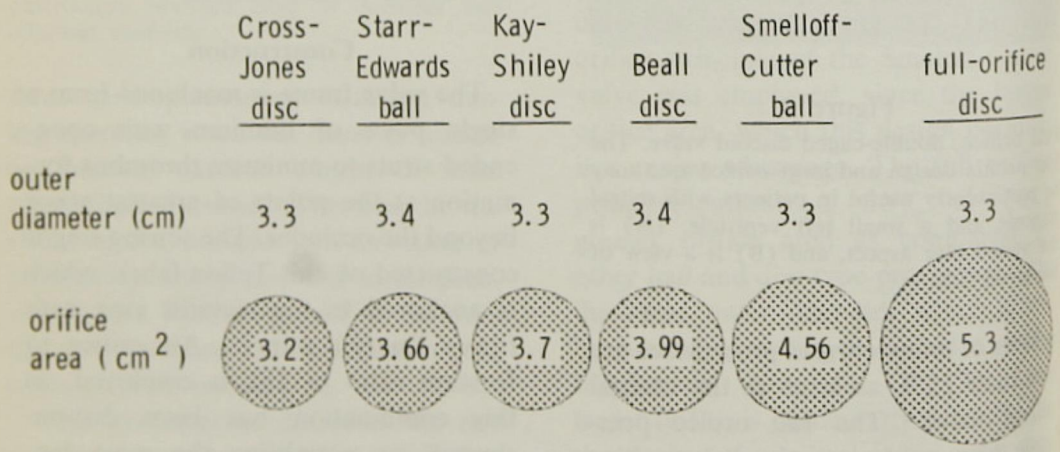

Figure 3

Comparative valve orifice sizes of frequently used mitral valve prostheses and the full orifice discoid valve. The normal mitral valve area is approximately 4 to 5 sq cm.

clinical experience[7] with the Smeloff-Cutter ball valve, however, would suggest that this is quite unlikely.

Pulse Duplicator Testing

The full orifice discoid valve has been extensively evaluated by pulse duplicator testing. A blood analogue was employed consisting of 37% glycerine by weight, to approximate the specific gravity of blood, and the fluid was maintained at 35°C during testing. Flow rates of 2500 and 5000 cc/min were used and pressures on each side of the valve were measured with physiological transducers and recorded on a multi-channel polygraph. A controlled (atrial) filling pressure of 5-10 cm of water and outflow resistance of 110 cm Hg were maintained throughout the experiments. The test chamber was constructed to allow downstream clearance around the valve occluder, simulating that in normal adult hearts. High speed cine (400 frames/sec) evaluation in the pulse duplicator was performed using aluminum filings in the fluid with high intensity illumination to identify areas of turbulence and cavitation.

Comparative flow and pressure measurements were performed on the Starr - Edwards (silastic ball - model 6120), Smeloff-Cutter, Kay-Shiley, and the full orifice discoid valve, each with approximately comparable annulus diameters (32 to 34 mm). All prostheses performed satisfactorily with pulsatile flow rates of 5000 cc/min. There was an insignificant diastolic filling gradient at these flow rates and regurgitation was not evident as manifested by "V" waves (Fig 4). We did not expect these relatively low flow rates, which were comparable to resting adult cardiac output, would demonstrate significant pressure gradients with these prostheses in a pulse duplicator. Other flow studies are in progress to demonstrate the importance of valve orifice size. In these, greater flow rates (simulating exercise and peak flows) are being used to compare the efficiency of various valve designs. The cine studies showed that there was no tendency for the discoid valve to cock in the open position. However, the ball of the Starr-Edwards valve did show a tendency to stick in the valve seat before opening. The latter characteristic may be artifactual in a pulse duplicator setting; however, it was repeatedly observed in the high speed cine studies. Turbulence as noted in the cine evaluation was greater around the less streamlined disc than the ball type occluder, but it was minimal with flow rates as high as 5000 cc/min.

Animal Implantation

The full orifice discoid valve has been used for mitral replacement in the calf and in dogs. A special 19 mm size with a Teflon occluder was used in 10 to 15 kg dogs and a valve with a 34 mm tissue annulus in the calf. Immediately after implantation, pressure gradients across the prosthesis and the left atrial pressures were within normal limits, as would be expected in these resting animals with normal left ventricles.

Now that experimental and hydrodynamic testing of the full orifice discoid valve have been completed, the prosthesis is considered to be ready for implantation in properly selected patients. The valve will probably have its greatest usefulness in those patients with mitral stenosis and a small left

ventricle. Postoperative physiologic studies in these patients will be needed to demonstrate the value of this prosthesis over those in current use.

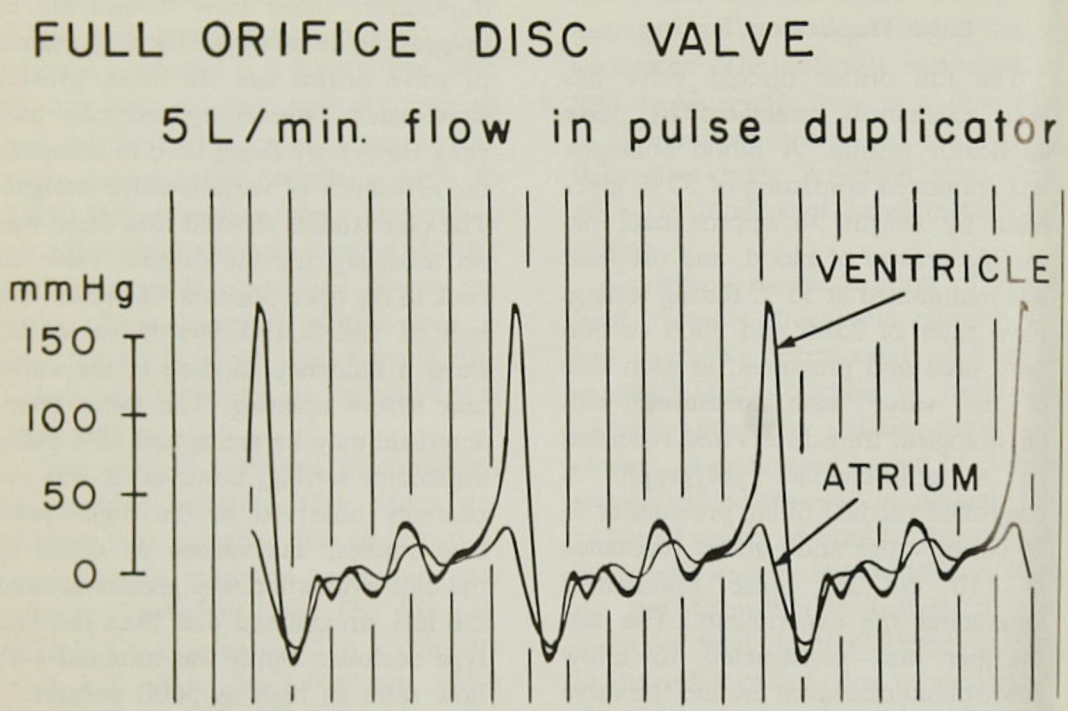

Figure 4

Pulse duplicator tracing of full orifice discoid valve with a flow of 5000 cc/min. There is little, if any, measurable diastolic filling gradient at this flow rate.

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