Artificial aortic valves tested by simultaneous recording of aortic and ventricular pressures

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REPLACEMENT of a diseased aortic valve with a valve prosthesis is now considered a standard cardiosurgical procedure.[1, 2] Clinical results from the use of the currently available artificial valves are satisfactory, yet the valves are not ideal and new valves are being developed and tested.[3-5] Although clinical success is the final proof of the competence of artificial valves, careful in vitro testing can help us to evaluate and to compare them better.

The various testing devices are used primarily for the testing of reliability and durability.[6, 7] Most experimental setups are not so similar as to make comparison of results between different laboratories valid. We have used methods common in cardiac catheterization of patients with valvular heart disease,[8-10] and have tried to evaluate whether or not these methods can be used in a simulated circulatory system for valve testing. Our goal was to define the constant characteristics needed for hemodynamic comparison of various artificial heart valves in a mock circulation. An additional stimulus for the study was the need for competent valves in the artificial hearts.

MATERIAL AND METHODS

The six types of artificial aortic valves (*Fig. 1*) that have been evaluated are the *Gott leaflet valve,* the *teardrop discoid valve,* the *Starr-Edwards ball valve,* the *polyurethane leaflet valve,* the *pin teardrop valve,* and the *heavy Teflon discoid valve.* The mock circulation used for valve testing was that designed by Dreyer, Akutsu, and Kolff.[7] It consists of a pump driven by compressed air and a simulated circulatory system able to maintain a stable filling pressure of from 5 to 10 cm of water, and a peripheral resistance represented by a hydrostatic diastolic pressure of 125 cm of water. The pump intermittently compresses a Tygon tube (artificial ventricle) and pumps fluid through the aortic testing chamber into the simulated circulatory system. The valves were put into the testing chamber in aortic position. We

This study was sponsored by Dr. Willem J. Kolff, Head, Department of Artificial Organs, and was supported by Grant HE 4448-08 from the United States Public Health Service for the Artificial Heart Inside the Chest.

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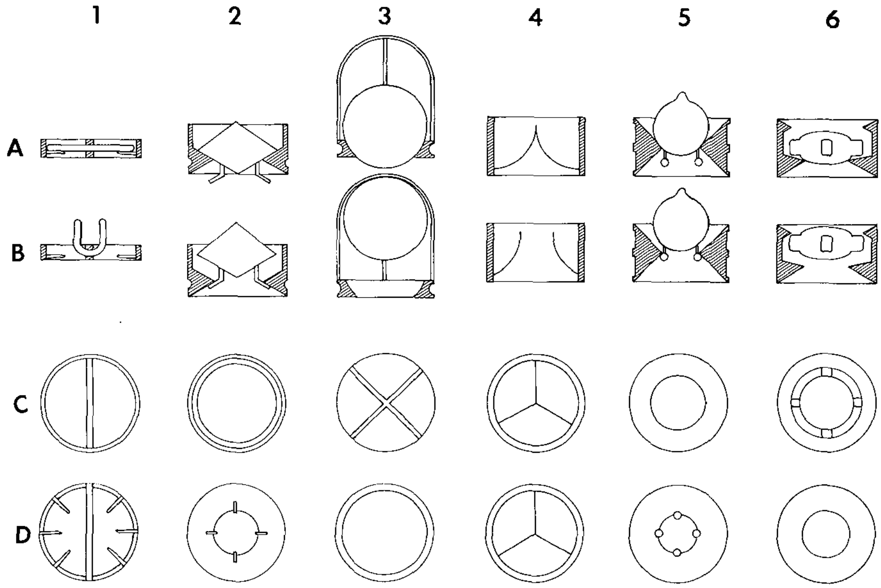

Fig. 1. Types of artificial aortic valves: (1) Gott leaflet, (2) teardrop discoid, (3) Starr-Edwards ball, (4) polyurethane leaflet, (5) pin teardrop, and (6) heavy Teflon discoid.
Row A: cross sections of closed valves;
row B: cross sections of opened valves;
row C: top views of closed valves;
row D: bottom views of closed valves.

have simultaneously measured pressures in front of and behind the valve, that is, in the ventricle, and in the aorta. A Honeywell photographic recorder was used, which recorded pressures either on the same baseline, or else the differential pressures that resulted from transmission. The curves were recorded at a paper speed of 100 mm per second, and were analyzed according to the constants shown in *Figure 2*. The mean leak constituted the amount of fluid that flowed back through a closed valve in the testing chamber under the hydrostatic pressure in the range of 125 to 130 cm of water.

RESULTS (FIG. 3[11, 12])

The best aortic *valve areas* were obtained with the Gott leaflet and the teardrop discoid valves (*Table 1*). Although the Starr-Edwards ball valve has a large orifice, the greater opening inertia raises *the mean ejection gradient* and thereby lessens *the aortic valve area.*

In evaluating the closing of aortic valves, the best results were obtained with the Starr-Edwards ball and the teardrop discoid valves. The Gott leaflet valve has the advantage of a quick closing, but it has a greater leakage than that of the others.

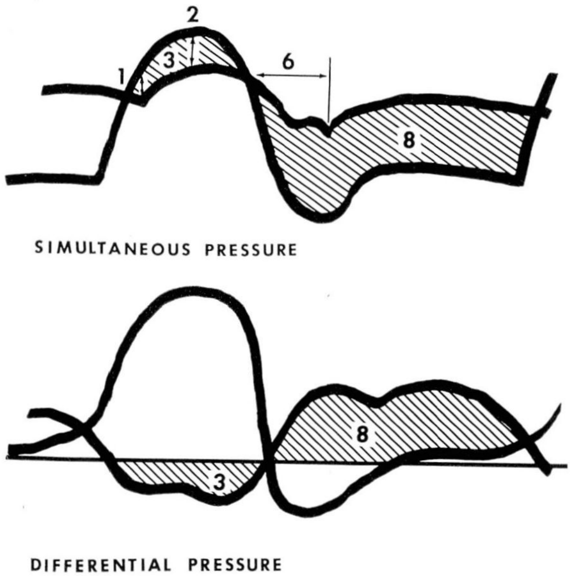

Fig. 2. Aortic valve constants for simultaneous measurements of differential pressures of the various types of valves. **Opening:** (1) *Opening resistance:* Pressure gradient between ventricular pressure and aortic pressure at time of opening of aortic valve (in mm Hg). (2) *Peak ejection gradient:* Maximal systolic pressure gradient across the valve (in mm Hg). (3) *Mean ejection gradient:* Mean systolic pressure gradient across the valve (in mm Hg). (4) *Stenosis index:* Square root of mean systolic pressure gradient. (5) *Aortic valve area* (AVA):

$$\text{AVA} = \frac{\text{Aortic valve flow, ml/systolic second}}{44.5\sqrt{\text{mean systolic pressure gradient}}}.$$

Closing: (6) *Closing delay*: Delay of aortic valve closure from decrease of pressure in the ventricle under the aortic pressure to the closing notch (in msec). (7) *Mean leak:* Milliliters of backflow of a closed valve under hydrostatic pressure of from 125 to 130 cm of water. (8) *Mean diastolic pressure gradient:* Gradient between mean diastolic aortic and ventricular pressures (indirectly proportional to the amount of regurgitation) (in mm Hg or relative planimetric units).

Discussion

The function of a cardiac valve is twofold: the opening and the closing of the valve (*Fig. 4*). The opening of the aortic valve can best be expressed by the *valve area* calculated according to Gorlin and Gorlin.[13] It is expressed in square centimeters and does not indicate the actual orifice; however, it allows comparison of various valves tested even at different flow rates and different periods of systole. The opening is influenced by two factors: the opening resistance and the orifice stenosis. The *opening resistance* represents the inertia of the moving parts and is reflected by the opening pressure

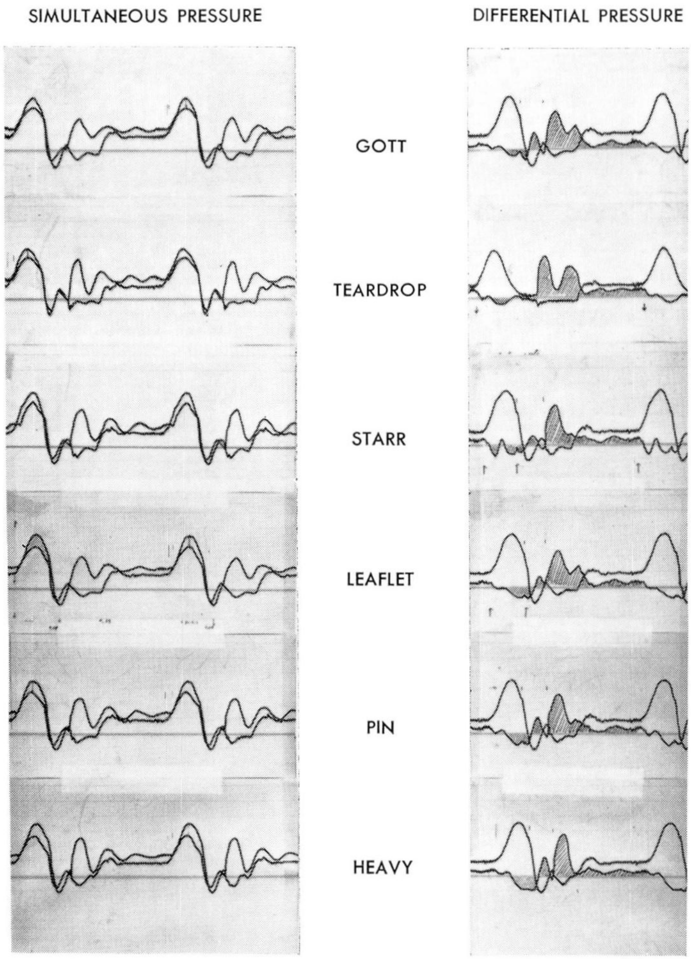

Fig. 3. Aortic valve pressure tracings. (Courtesy of Klain, M.; Leitz, K. H.; Phillips, P. M., and Kolff, W. J.: Functional evaluation of artificial heart valves. Proceedings of Symposium on Biomedical Engineering at Marquette University, Milwaukee, Wisconsin, June 1966, Section **12:** 283–286, 1966. Also, Klain, M.: Discussion, p. 310–311, *in* Nosé, Y.; Sarin, L.; Klain, M.; Leitz, K. H.; Tesny, T. J.; Phillips, P. M.; Rose, F. L., and Kolff, W. J.: Elimination of some problems encountered in total replacement of the heart with an intrathoracic mechanical pump: venous return. Tr. Am. Soc. Artif. Int. Organs **12:** 301–309, 1966.)

gradient. Unfortunately, a valve itself may cause *opening resistance* because it sticks. The size of orifice and its stenosis is expressed by the *peak ejection gradient* and represents the stenosis of the fully opened valve. The *mean ejection gradient* is a combination of both of these factors; the square root of it is the *stenosis index,* and, from the formula of Gorlin and Gorlin,[13]

Table 1.—*Artificial valves tested in the aortic position*

Constants	Artificial valve						
	(Ideal)	Gott leaflet	Tear-drop discoid	Pin tear-drop	Starr-Edwards ball	Poly-urethane leaflet	Heavy Teflon discoid
Opening resistance, mm Hg	(0)	0	12	0	42	0	48
Peak ejection gradient, mm Hg	(0)	36	36	48	36	42	48
Mean ejection gradient, mm Hg	(0)	13.5	15.7	19.5	22.2	24.3	26
Stenosis index	(0)	3.68	3.96	4.42	4.72	4.93	5.10
Aortic valve area, cm²	(3 to 4)	1.45	1.33	1.18	1.11	1.07	1.03
Closing delay, msec	(0)	15	18	17	18	14	16
Mean leak, ml/min	(0)	78	45	4	5	58	10
Mean diastolic gradient, planimetric units		80	94	78	83	78	75

* All values were measured at a flow of 213.5 ml per systolic second with a heart rate of 57 and a systolic period of 0.23 sec.

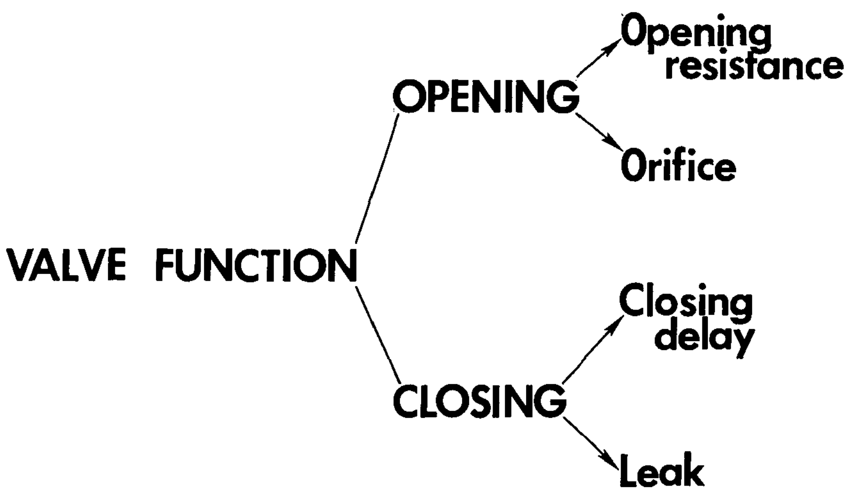

Fig. 4. Schema of aortic valve function.

which takes into consideration flow and duration of systole, the *valve area* is obtained. All of these constants, common in cardiology, may be used easily in functional evaluation of artificial heart valves in a mock circulation.

The results indicate that most of our present artificial valves do not have sufficiently large orifices compared to those of the natural valves. The best *valve areas* were obtained with the Gott leaflet and the teardrop discoid valves. Although, as stated before, the Starr-Edwards ball valve has the same orifice as the Gott leaflet and teardrop discoid valves, the greater opening inertia raises the *mean ejection gradient* and therefore the *aortic valve area* is less.

The overall closing defects are expressed by the difference between the aortic and the left ventricular mean diastolic pressures. The more the valve leaks, the more the aortic pressure decreases and the ventricular pressure increases during diastole, and the differential pressure between them decreases. So the *mean diastolic pressure gradient* is indirectly proportional to the amount of regurgitation.

The closing of the artificial aortic valves is also influenced by two factors: the closing resistance, and the amount of leakage. The valve does not close immediately after decrease of ventricular pressure, and during this *closing delay* some regurgitation takes place. The valve actually needs a little backflow to be closed. The rest of the regurgitation is from the leakage of the closed valve. To distinguish between these two factors, we used *mean leak* as a constant for leakage of the closed valve under pressure, and were able to eliminate some artifacts created in pressure tracings by pulsatile flow in rigid tubings in the mock circulation.

Most of the artificial valves have greater leakage than we would expect. The closing resistance was best in the valves with tiny leaflets, namely the Gott leaflet valve or the polyurethane leaflet valve. The *mean leak* was least, and therefore best, in the Starr-Edwards ball and the teardrop valves. As mentioned, the Gott leaflet valve has the advantage of a quick closing, but it has a considerable leakage. The aortic valve is closed throughout the entire diastole, so the leakage more than the closing delay influences the resulting overall regurgitation. For that reason, the best results were obtained with the Starr-Edwards ball and the teardrop discoid valves.

Every valve has its advantages and disadvantages. This must be taken into consideration in regard to the proposed use of the valve. The natural, normal aortic valve is closed twice as long as it is open, consequently regurgitation is particularly damaging. Moreover, regurgitation of the aortic valve also prevents sufficient filling of the ventricle from the inflow side. Some stenosis is less serious than regurgitation for a valve in the aortic position. Of the artificial valves tested, the most suitable for the aortic position was the Starr-Edwards ball valve, and the pin teardrop valve. They are not the best in terms of opening, but they have the least amount of regurgitation that we consider to be an important drawback.*

** Recently, a Hammersmith discoid valve was tested. It has a large orifice, but it closes slower and has a greater leakage than other valves previously tested. In preliminary tests it seems to be more suitable for the mitral than for the aortic position.*

Functional evaluation and comparison of artificial heart valves under standard experimental conditions in a mock circulation may indicate the direction of improvement of design for new valves. For example, the weight of moving parts and their shapes can be correlated to the speed of closing. Soft compressible materials in firm seats give better results in regard to the leakage than hard material on both sides, but soft material may stick. The constants that were used and are suggested for testing of artificial valves will help in the further development of artificial valves.

SUMMARY

By simultaneous recording of aortic and ventricular pressures of each of six types of artificial heart valves, each in the aortic position in a mock circulation under standard conditions, we compared the measurements of valvular function. The comparative efficiencies are expressed in mathematical values in standardized constants. From the valves tested the most suitable for aortic replacement were found to be the Starr-Edwards ball valve and the teardrop discoid valve.

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