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Total prosthetic replacement of atrioventricular valves in the dog

Part I. Development of a free-floating cone valve for the right atrioventricular ostium

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A free-floating cone valve to be used as a prosthesis for the tricuspid valve of the heart is described. It consists of a stainless steel flat cage with a Lucite cone inside. The experience and reasoning that led to its construction are presented and the results obtained with it in a series of 32 dogs are given.

During the last decade much research has been done on total prosthetic replacement of the intracardiac valves (Dreyer, Akutsu, and Kolff, 1959; Merendino, 1961). This has resulted in the development of three fundamentally different types.

The cusp or leaflet valve (Akutsu, Dreyer, and Kolff, 1959; Akutsu, Mirkovitch, Seidel, and Kolff, 1961; Braunwald, Cooper, and Morrow, 1960; Roe, Kelly, and Myers, 1965) resembles the natural one as closely as possible and is often derived from a mould or a cast of the actual valve. It is made of a pliable material and may be equipped with artificial chordae. It has the advantage of complying with the rapidly changing shape of the atrioventricular ring during the cardiac cycle, it provides an ample outflow with minimal obstruction, and it offers laminar flow of the blood. It is, however, difficult to make in numbers; it often tears loose and, since up till now no pliable fabric has been found that can endure the forces subjected to it inside a performing heart without changes in its structure and qualities, it often shrinks or disintegrates.

The hinged-leaflet, trap-door, or butterfly-wing valve (Gott, Daggett, Whiffen, Koepke, Rowe, and Young, 1964; Gott, Rowe, Daggett, Whiffen, Koepke, and Young, 1965; Young, Gott, and Rowe, 1965) is made from a strong and rigid material but is prone to blocking or breaking, since any hingeing device will wear down sooner or later.

The cage-valve consists of a rigid cage with an opening and closing device inside it. The cage and ball valve (Starr, 1960; Starr and Edwards, 1961; Starr, Herr, Wood, Edwards, and Griswold, 1965; Starr, Herr, and Wood, 1966) has gained a great and well-deserved reputation in human surgery. It has, however, the disadvantage of its large volume; moreover, the height of its cage is directly related to the diameter of the ostium into which it is inserted, so that when it is used as an atrioventricular prosthesis it protrudes into the ventricle, obstructs its outflow, and diminishes the filling volume of the ventricle during diastole. Therefore in recent years several investigators have advocated a flat cage and disc valve which may have a much smaller volume (Cross and Jones, 1965), although, according to Beeson, West, and Burns (1965), its efficiency is less than that of the ball valve, mainly because of the turbulence it causes in the bloodstream.

Since 1960 we have been interested in making a prosthetic atrioventricular valve of the flat cage type, suited for long-term use inside the heart of the dog. We felt that such a prosthesis should be as light and small as possible, allow for a maximum flow during the ventricle's diastole, yet close rapidly and completely during its systole; it should not interfere with the diastolic filling volume of the ventricle nor obstruct its outflow tract; any moving part should have a specific gravity comparable with that of the blood, so that it might float and promptly follow the changes in

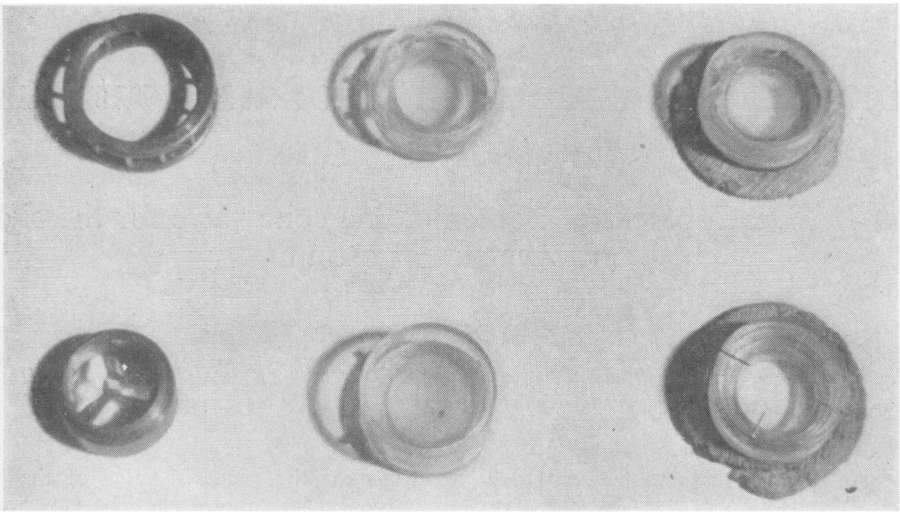

FIG. 1. *Some early specimens of free-floating disc prostheses.*

the direction of the intracardiac circulation; it should not contain any hingeing, interlocking, or plying parts, since this inevitably means wear and tear, deformation, and blocking.

These demands led us primarily to the construction[1] of several valves consisting of a freely floating disc of Lucite inside a rigid, flat, circular cage of stainless steel, Teflon, or Lucite, and, although many different types of these free-floating disc prostheses performed satisfactorily in a mock-circulation, they failed under actual working conditions when we inserted them into the right atrioventricular ostium.[2]

Dogs pose special problems, since their hearts are normal and have never developed any compensating mechanism to valvular stenosis or incompetence, so that if one of these or both occur during the experiment, circulatory trouble may rapidly ensue. As will be shown later, tricuspid insufficiency affords an exception to this rule. Another factor in normal hearts is the absence of dilatation of the ventricles and widening or circular deformation of the atrioventricular ring, and experience has taught us that any cage-type valve will perform best if these two conditions are present.

Since it is known that clotting of blood and fibrin deposits are the main cause of failure in experimental prosthetic valve replacement, all animals were put on intensive anticoagulant medication with phenprocoumon (Marcoumar), starting on the day of operation. In spite of this most of our initial failures were caused by fibrin deposits inside the prosthesis, blocking the free movement of its disc. In some cases mechanical defects enhanced clinical failure. Some of the prostheses that did not function satisfactorily in the right atrioventricular ostium are shown in Figure 1. The type shown in Fig. 2, which is similar to the now commercially available Cross-Jones (Cross and Jones, 1965) lenticular prosthesis, was discarded mainly because the myocardium of the right ventricle impaled itself on the legs that retain the disc, causing deformation and breaking of the legs and dislocation of the disc from the cage (Fig. 3). Making the ends of the legs club-like did not prevent their intrusion into the myocardium. The valve shown in Fig. 4 performed best of all, although clot formation occurred sooner or later in every case, despite anticoagulant treatment. The figure shows a simple and effective way of inserting a prosthesis by using a double ring on its atrial side: the upper one may hold interrupted or continuous sutures; the lower one supports the disc when the valve is closed. In between these two the atrioventricular ring fits snugly. One may also use these two rings to anchor a Teflon fixation rim in place, as shown in some later types.

Why do these disc valves promote clotting and fibrin deposition even during anticoagulant treatment? A small series of experiments showed us that it is not just the foreign material or the

[1]All valves shown in this report were manufactured by Mr. R. P. de Graaf and Mr. A. Kroon, of the Laboratory of Physiology of the State University at Leyden

[2]The preliminary valves were demonstrated at the XXII International Congress of Physiological Sciences held at Leyden (den Otter, 1963)

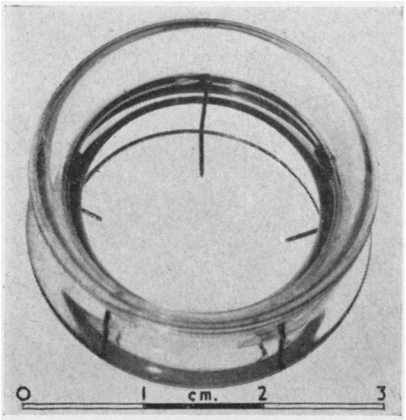

FIG. 2. *Free-floating disc prosthesis.*

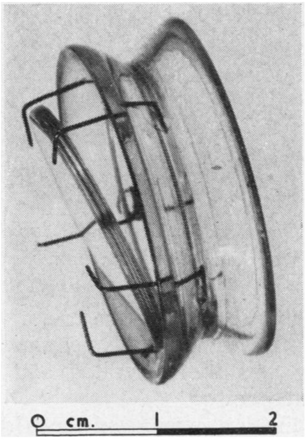

FIG. 3. *The same as shown in Fig. 2, but damaged by impalement of the myocardium on the legs of the prosthesis.*

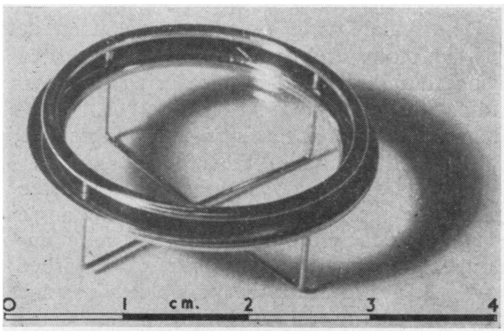

FIG. 4. *Flat disc prosthesis yields good early results but ultimately becomes obstructed by clots.*

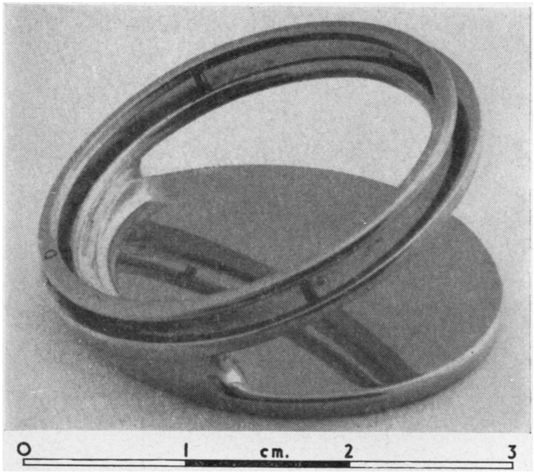

FIG. 5. *Stainless steel plate. See text.*

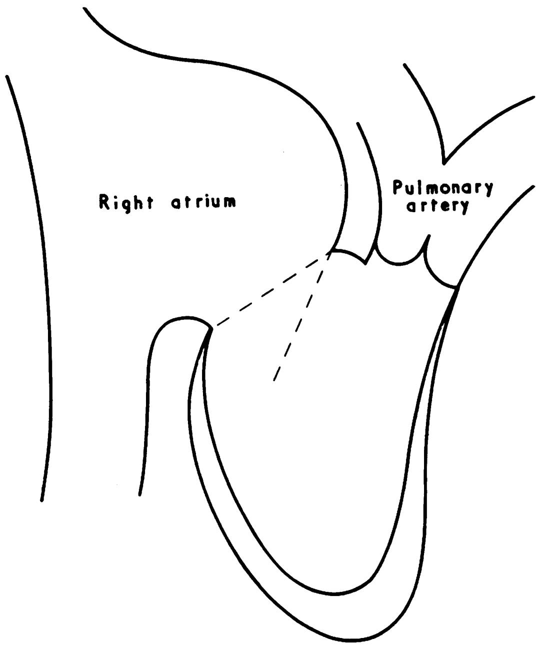

FIG. 6. *Position of plate in the heart.*

diversion of the blood flow that are not tolerated. Figure 5 shows a stainless steel circular plate rigidly fixed to the double insertion ring we described above. No movement between the two parts of the device is possible. The angle between them is 33°. It was mounted in the right atrioventricular ostium after excision of the tricuspid valve, so that the free rim of the plate was directed

FIG. 7. *Stainless steel plate in the heart after 1½ years, as seen from the right ventricle.*

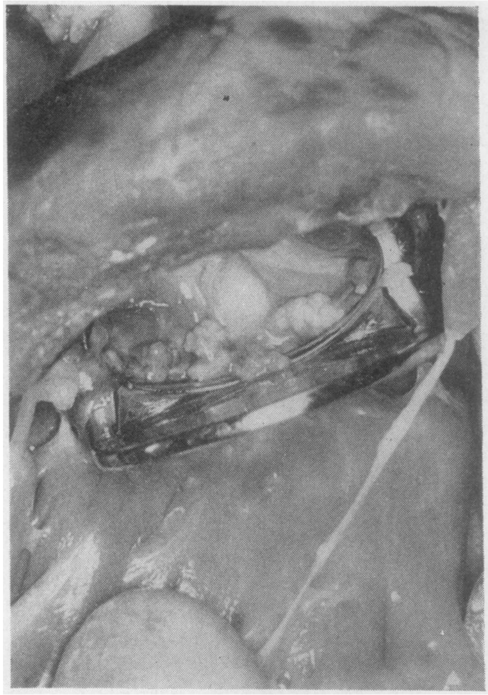

FIG. 8. *The same as in Fig. 7, looking from the right ventricle into the atrium.*

towards the lateral wall of the right ventricle, without touching its endocardium, and protruded into the ventricle (Fig. 6). It diverted the bloodstream but formed no square obstruction to it, as did the orginal discs. It is remarkable that this device was well tolerated for one and a half years; the animals were then sacrificed and, although no anticoagulants had been given, there was no trace of clotting. Figures 7 and 8 show such an oblique plate in situ after one and a half years: there is fibrous reaction around its insertion and a fibrin strand inside the ventricle, but no clots or fibrin deposits inside the 'outflow tract' of the device. Therefore it seems likely that the main cause of clotting in our flat disc prosthesis is the perpendicular obstruction they present to the blood which causes severe turbulence and probably damage to the corpuscular elements and the blood proteins. These experiments supplied more valuable information. We expected that the contraction of the right ventricle, given an optimum diameter of the oblique plate, would close the gap between it and the ventricular wall, thus forming an ideal valve without any moving parts. However, this non-moving valve never became competent even though the ventricular wall was distinctly hypertrophied at the end of the experimental term. Nevertheless this permanent tricuspid insufficiency was well tolerated and caused no clinical symptoms.

In two animals we removed the tricuspid valve without supplying any substitute, and both remained in excellent health, being active and lively for about two years, when ascites and oedema developed. This shows that after tricuspid valve replacement one should be careful when evaluating the results. Incompetence of right atrioventricular valve prostheses does not cause early symptoms and can only be demonstrated by angiocardiography and by measuring the pressure gradient through the valve.

Since we found that a flat disc provokes clotting but that a diversion of the blood stream of 33° is well tolerated, it was only a logical step to replace the disc by a cone with a top angle of 114°. To reduce the mass of the cone an air chamber was made in its centre. We wished to know whether it would be possible to use a cone without a cage around it. Figure 9 shows a series of cones with a ring rigidly fixed at their tops. Using a corresponding probe, a cone was selected that could be inserted through the atrioventricular

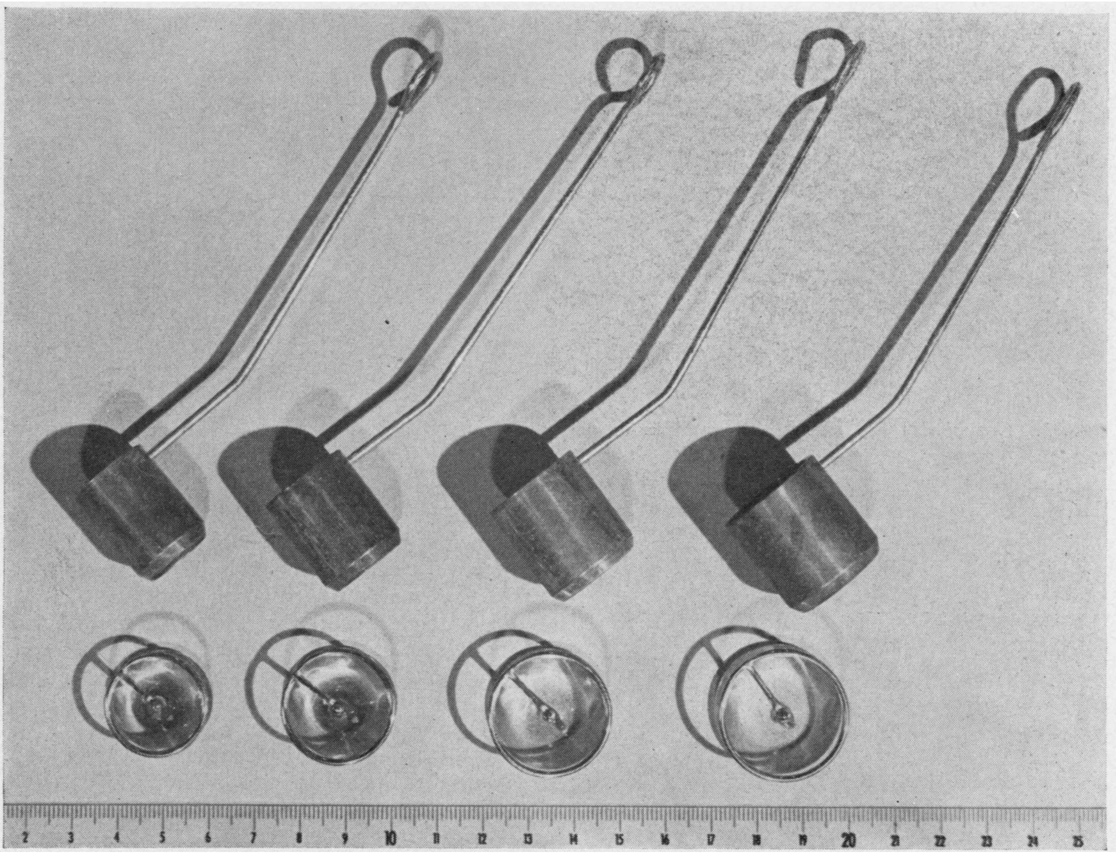

FIG. 9. *Cones without cages and corresponding probes.*

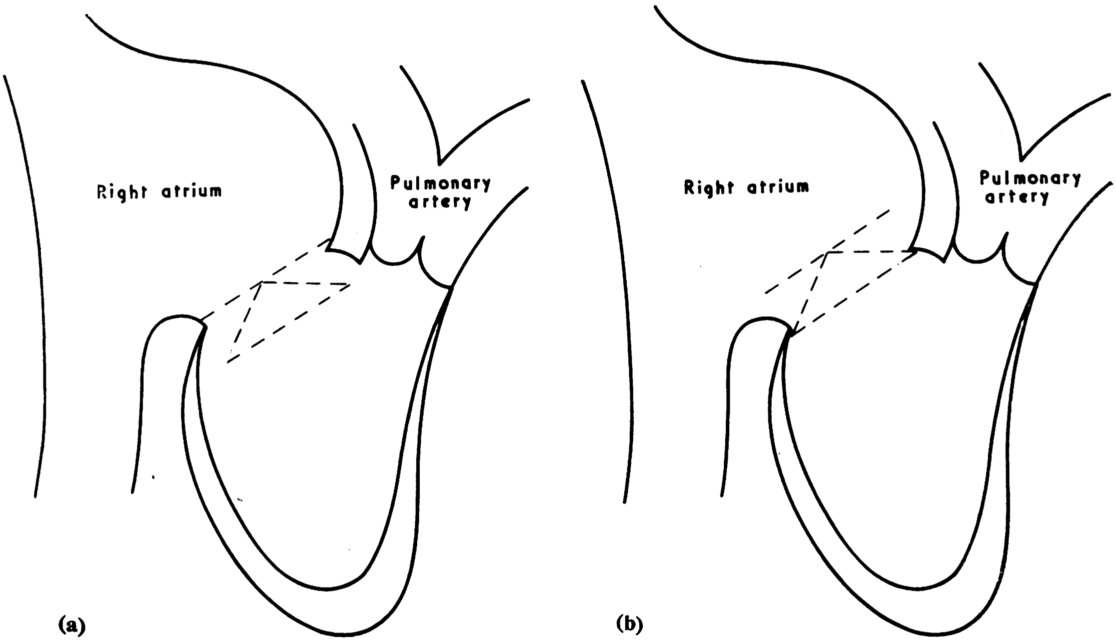

FIG. 10. (a) *A cageless cone in the right atrioventricular ostium during the atrium's systole.* (b) *The same during the ventricle's systole.*

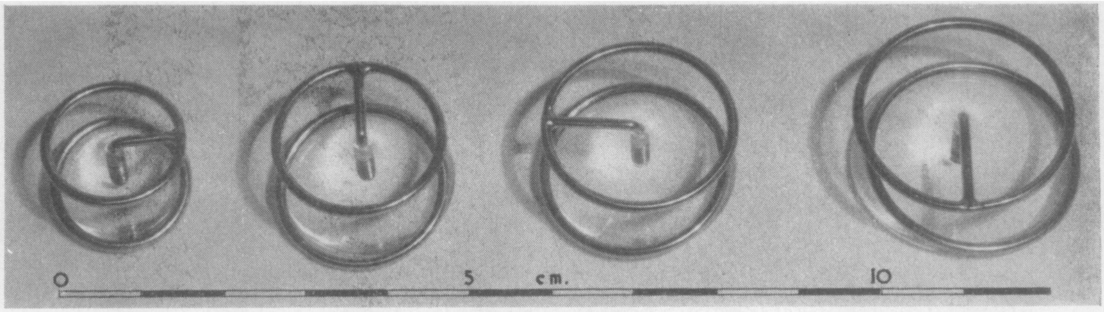

FIG. 11. *Cones without cages but equipped with an insertion ring.*

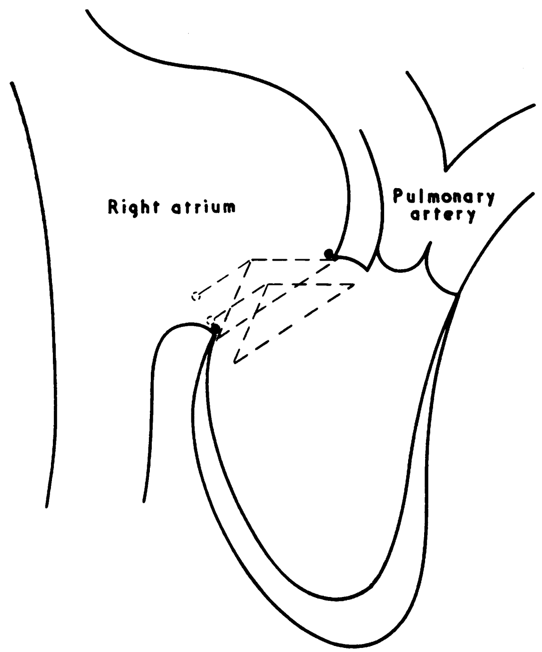

FIG. 12. *Behaviour during the cardiac cycle of the cones shown in Figure 11.*

ostium so that the steel ring stayed inside the atrium and rested on the atrioventricular ring during the atrium's systole, thus opening the valve. The cone was arrested by the atrioventricular ring during the ventricle's systole (Figs 10a and b). Some of these cones performed well for several hours; but eventually all were extruded by the ventricle into the atrium.

Figures 11 and 12 show other types of cones and ways of insertion into the atrioventricular ostium. They failed because the cones tipped over or became eccentric to the ostium. The type shown in Fig. 13, a double insertion ring and a cone with a slit in it, became rapidly stenotic because of fibrin deposited in the slit.

It seems that a real cage is necessary to keep the cone in its track. Figure 14 shows the ultimate valve: a free-floating Lucite cone inside a flat stainless steel cage to be used as a replacement of the tricuspid valve in the dog. Figure 15 shows its behaviour during cardiac action. Several sizes have been produced. The one shown in Fig. 14 has the following parameters:

Internal diameter on atrial side	24 mm.
External diameter on atrial side	30·5 mm.
Internal diameter on ventricular side	24 mm.
Surface of inflow plane	4·5 cm.^{2}
Surface of outflow plane	4·5 cm.^{2}
Height of cage (external)	8·0 mm.
Height of cone	7·6 mm.
Angle at top of cone	114°
Diameter of cone	26·8 mm.
Weight of cone	1·35 g.
Total weight of prosthesis	6·4 g.

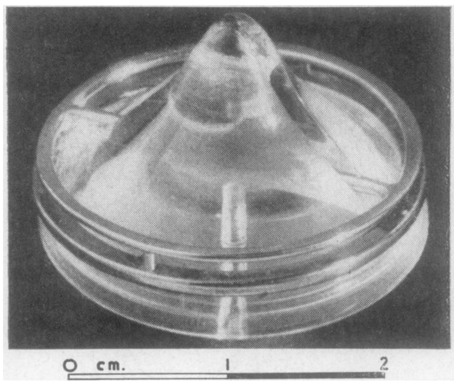

FIG. 13. *Cone without cage, fixed by a bar through a slit. Double insertion ring.*

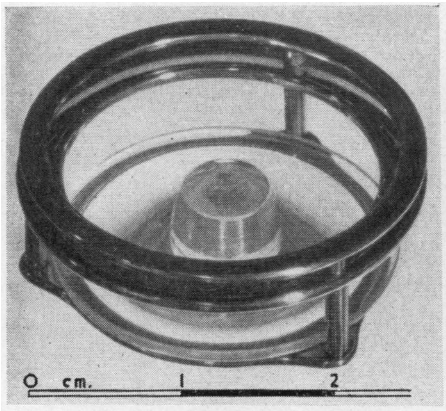

FIG. 14. *Free-floating cone atrioventricular valve prosthesis, size 24.*

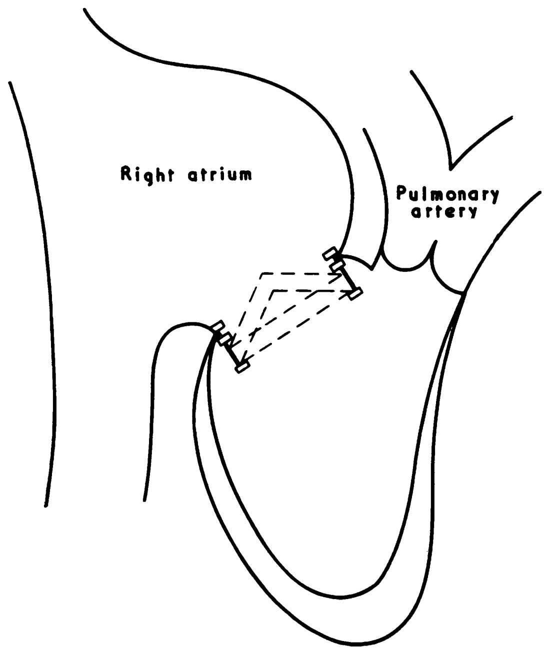

FIG. 15. *Behaviour of the prosthesis (Fig. 14) during the cardiac cycle.*

We inserted this valve in the right ventricular ostium of 32 adult mongrel dogs, weighing between 18 and 23 kg. They were anaesthetized with intravenous thiopentone sodium, intubated with a cuffed endotracheal tube, and placed on assisted or controlled respiration using oxygen, nitrous oxide, and halothane. Succinylcholine was used as a muscle relaxant. Body temperature was lowered to 30° C. (oesophageal) by immersion in cold water. The right chest was entered through the fourth intercostal space. The pericardium was opened anteriorly in order that the right atrium could be readily exposed. The azygos and caval veins and the pulmonary artery were occluded, and a right atriotomy was performed. The tricuspid valve and its chordae were excised and replaced by the prosthesis, which was sutured in place by 10 to 12 interrupted 3–0 atraumatic silk sutures. Care was taken to prevent damage to the conducting system of the heart and to the coronary sinus. After fixation of the prosthesis the atriotomy was closed with a running 5–0 atraumatic silk suture. The total time of circulatory arrest was 7 to 10 minutes and this was tolerated well, although in 12 cases ventricular fibrillation occurred, requiring defibrillation and massage of the heart. Anticoagulant treatment was started on the day of the operation and continued until the death of the animal.

Six of these animals did not survive for more than 36 hours due to excessive post-operative

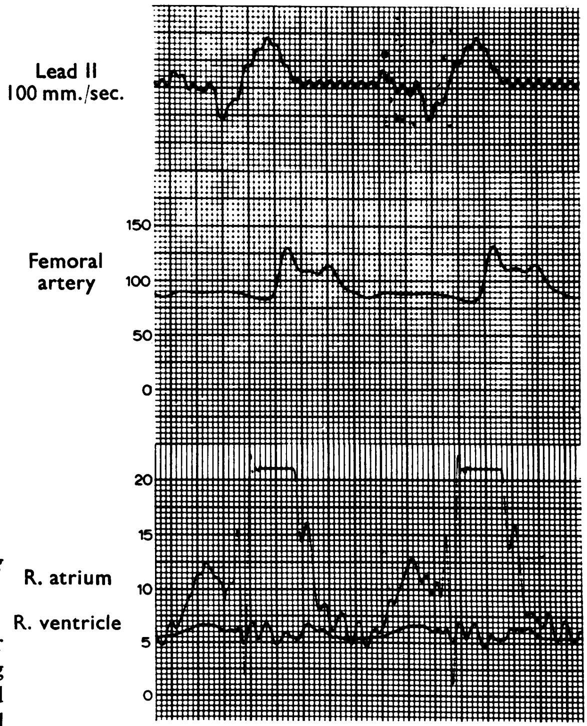

FIG. 16. *Electrocardiogram lead II, blood pressure in right femoral artery and pressure curves in right atrium and right ventricle one year after insertion of a free-floating cone prosthesis in the right atrioventricular ostium.*

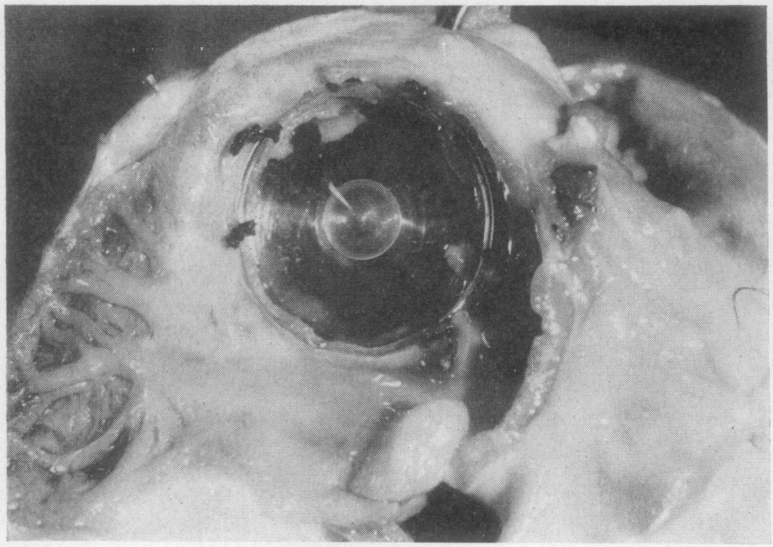

FIG. 17. *Free-floating cone tricuspid prosthesis after 14 months' functioning as seen from the right atrium.*

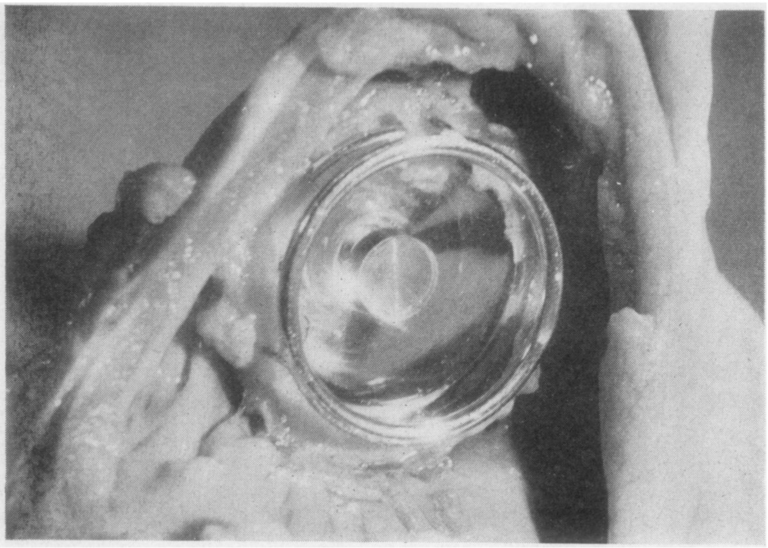

FIG. 18. *The same as in Fig. 17, as seen from the right ventricle.*

bleeding from the whole wound area and into the right pleural space. The others did well and, although long-term survival was not the main object of these experiments and several dogs were sacrificed, eight lived for over one year with a well-functioning prosthesis. A typical example of the pressure curves obtained after one year is shown in Figure 16.

Figures 17 and 18 show a prosthesis after 14 months. There is no clotting inside the cage and most of the sutures are covered by reactive endothelial tissue, which also fills the space between the two rings on the atrial side, holding the prosthesis in its place without intruding into the cage. Occasionally, however, the reactive tissue did invade the cage itself, in some cases causing incompetence, sometimes combined with stenosis. Since tricuspid incompetence is well tolerated clinically, as has been shown previously, the ultimate results will have to be critically evaluated. These will be published in a separate paper, as will the local tissue reactions we found in and under the endocardium.

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