Experiences with New Types of Aortic Valvular Prostheses *

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SURGICAL correction of cardiac valvular lesions has made great progress in the past ten years. Among these, aortic insufficiency has been studied extensively. In spite of vastly increased knowledge of the process and its mechanisms it has continued to present great problems. During an intensive study of this type of disease we have found a wide variety of etiologic agents to be responsible for the production of the anatomic problem. It is worthwhile to differentiate these various forms of aortic insufficiency since there is frequently a direct relationship between the origin of the lesion and the type of anatomic situation which it presents. In this respect knowledge of the etiology may be of value in selection of the proper method of treatment. It is of further importance to distinguish between those types which are of acute origin and those which occur more slowly. The acute production of aortic insufficiency is associated with a rapid clinical deterioration, and the hemodynamics of this lesion are poorly tolerated. Therefore, it is imperative that in such instances early operation be advised. Unless this is done the disease may progress to produce irreversible changes. In the chronic varieties a wide variation in the course which is pursued is found. This depends upon the type of lesion, the amount of insufficiency which results and the degree to which the myocardium itself is involved by the disease process. Tables 1 and 2 outline the types of origin of the lesion which we have encountered in patients who have had operation.

The original efforts directed toward the correction of aortic insufficiency were highly varied. As early as 1946, we experimentally employed a ball valve type prosthesis, and in 1952 first applied this work clinically. This valve has been modified in several respects since its first use. The important features of this type of valve are outlined here. The currently used prosthesis employs a special type Plexiglas housing with a silicone rubber ball (Fig. 1). This silicone rubber is molded over a hollow Nylon center and the ball is of a critical weight so that it will be activated by minimal changes in pressure. The use of this silicone covered ball has greatly reduced the sound of opening and closing of the valve so that it is no longer audible. This is in contrast to the early valves which made a distinct clicking noise with each opening and closing. While the sound was well-tolerated by the patients, the elimination of this feature extends the usefulness of the prosthesis to earlier cases.

The valve is held in place in the descending aorta by fixation rings, employing the principle which we have termed "multiple point fixation." It is only through the use of multiple point fixation that one can successfully and uniformly implant a prosthesis into the major arterial tree without producing necrosis. Figure 2 shows the presently employed position of the valvular prosthesis. Here the ball is in the open position

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TABLE 1. *Types of Origin of Aortic Insufficiency*

A—Acute

1. Traumatic
2. Luetic
3. Acute endocarditis
4. Sub-acute bacterial endocarditis
   C̄ Major deformity of cusp
5. Aneurysm of sinus of Valsalva
   a) Ruptured

B—Chronic

1. Rheumatic
2. Congenital
   a) Bicuspid valve
      —Uncomplicated
      —C̄ Rheumatic valvulitis
      —C̄ Endocarditis
      —C̄ Coarctation
   b) Marfan's
3. Sub-acute bacterial endocarditis
   C̄ Moderate to minor deformity
4. Aneurysm of sinus of Valsalva
   a) Unruptured
5. Dissecting aneurysm of aortic root
6. Luetic (chronically progressive)

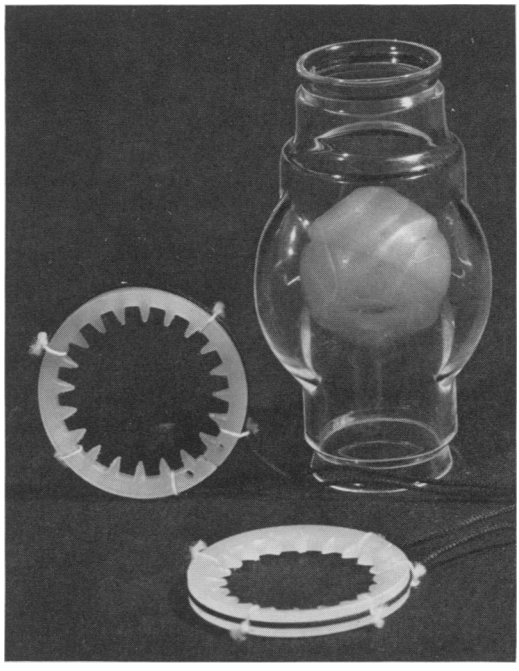

FIG. 1. Quiet type of aortic ball valve.

where blood can pass freely around it; when reflux begins the ball seats at the proximal end and prevents any return of blood in a backward direction. The chambers of the valve are sufficiently large to permit a free flow of blood around the ball. In order to accomplish this it is necessary to have these chambers larger than the diameter of the normal aorta, and the body of the valve cannot be contained within the aortic lumen.

The principle of multiple point fixation can best be illustrated by the following figures. Figure 3 shows a cross section through the prosthesis at a point where one of the teeth of the fixation ring is present. This illustrates how the aorta is compressed in the groove near the end of the valve. The distance from the fixation point to the inner end of the valve is extremely short and the inner diameter of the ring is less than the outer diameter of the end of the valve. The aorta is held firmly in this way and displacement is not possible. Figure 3 also illustrates that the aorta is compressed beneath the ring but that the ring point does not penetrate fully through the aortic wall. Figure 4 shows a section through the end of the valve at which the fixation ring is in place. The teeth of the fixation ring compress the aorta beneath them, but do not penetrate the aortic wall completely. The teeth distribute the force of compression of the aorta to prevent leakage of blood between them. The aortic wall itself does not touch the body of the ring. It is essential that the aorta be compressed only at these points in order to maintain the blood supply between them and to avoid the necrosis which would occur if complete circumferential pressure were exerted. In these interstices between the teeth the blood supply of the aorta is maintained to permit the distal portion of the cut end of the aorta to remain viable.

When multiple point fixation was first used, the valve was merely inserted into the aorta and the fixation ring applied. If the prosthesis did not fit the aorta extremely accurately, and the valve was slightly

smaller than the systolic diameter of the aorta, the aortic wall moved away from the valve when the systolic expansion of the aorta occurred as one sees in Figure 5A. In diastole the aortic wall again came back into contact with the intra-vascular portion of the prosthesis (Fig. 5B), but over a period of time it was possible in some instances to build up clot between the prosthesis and the aortic wall in this potential cul-de-sac which was present (Fig. 5C). In order to eliminate this possibility the aorta has been wrapped with a semi-elastic Orlon mesh which fits snugly up to the point of fixation and compresses the aorta firmly against the intravascular part of the prosthesis. This prevents the systolic expansion and also eliminates the possibility of the aorta striking the body of the fixation ring (Fig. 5D). This wrapping procedure minimizes the possibility of two early complications of insertion of rigid plastic prostheses. These were: (1) erosion of the aorta when striking a fixed point and (2) the cul-de-sac with its potential thrombus and subsequent embolization. In our early experience embolism occurred in approximately 10 per cent of the cases. By this method we have essentially been able to eliminate embolization in the cases in which this method has been applied. In order to discuss several new types of aortic valvular prostheses other ramifications of the clinical aspects of the treatment of aortic insufficiency will be omitted except to summarize briefly our experience in operating on a very large group of patients. To date insertion of the ball valve prosthesis has been the primary method which we have used to treat this lesion. There have been observed striking results in terms of improvement of the patient following operation in properly selected cases. The valve placed in the descending arch does not control all of the insufficiency but it prevents approximately 70 per cent of the reflux. With a better understanding of the disease process and the methods of treatment the mortality rates have steadily fallen. In the last forty patients using this type of valvular prosthesis with the technic already described there have been no operative deaths and only two late deaths. This group includes a large per-

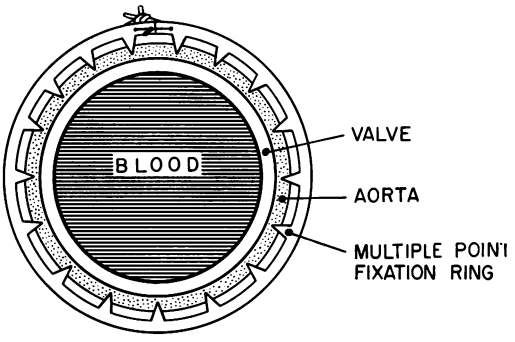

FIG. 3. The aortic wall is held in the groove of the valve by "multiple point" fixation. Note that the aorta does not contact the body of the ring.

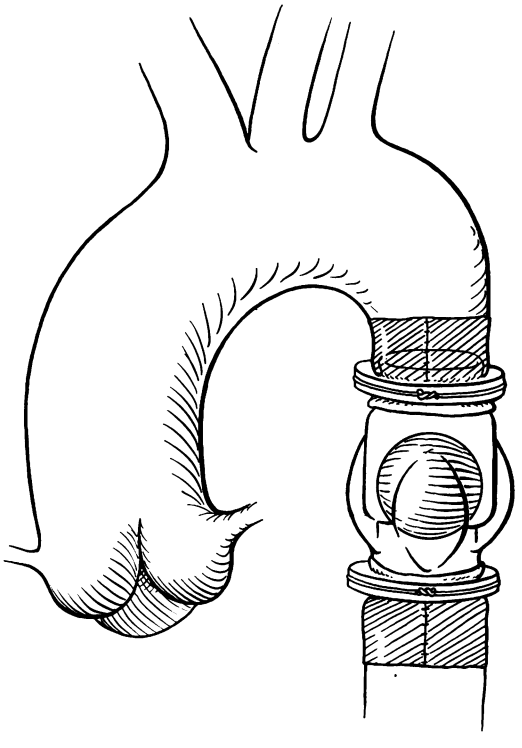

FIG. 2. Ball valve in descending aorta. The proximal and distal ends of the valve are opposed to the aorta by Orlon cloth.

centage of patients who were far advanced in their disease.

In patients in whom clamping of the aorta even for a short period of time is undesirable two methods have been devised. The first of these involves the use of a simple bypass between the subclavian artery and the aorta distal to the point of insertion of the valve. In some instances it is simpler to bypass from the subclavian to the femoral artery. This provides for distal blood flow during the period of aortic occlusion, but does not prevent an increased work load for the ventricle unless one interposes a pump in the bypass system. The second method which uses the method of providing a permanent bypass has been evolved and is illustrated in Figure 6. Short sleeves of Dacron or Dacron-Teflon tubing are attached to these standard valvular prostheses. With the aorta partially clamped an end-to-side anastomosis is made to the flexible portion of the prosthesis. The proximal partial occlusion clamp is slowly removed to allow the bypass to fill with blood, and when the suture lines have been demonstrated to be secure both clamps are removed. In this way the major aortic circulation is not interrupted during the placing of the valve. When the flow is maintained satisfactorily through the prosthesis, the aorta is clamped and the intervening portion excised. The aortic ends are then closed with sutures. The retraction of the aortic ends causes the prosthesis to assume an essentially linear direction.

We have well recognized that an aortic valve placed in the descending aorta offers great advantages in terms of safety. In this location, however, it does not attain the ideal of control of all the insufficiency. Work in the laboratory has continued to seek experimental methods whereby a prosthetic valve could be placed in the normal aortic position, which would have application both in cases of aortic stenosis and insufficiency.

One of the methods which we have used

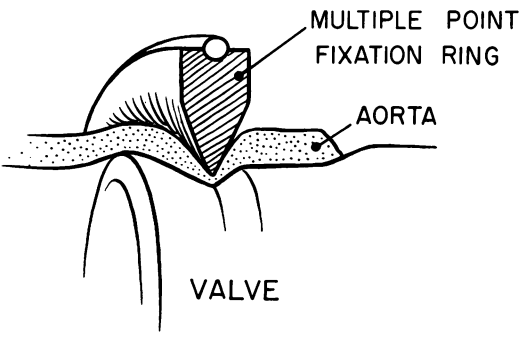

FIG. 4. The aorta wall is compressed by the teeth of the fixation ring but is not completely penetrated.

extensively experimentally has been a modification of the ball valve prosthesis which is fixed below the coronary orifice such as shown in Figure 7. After a sub-coronary dissection is carried out a wide cloth ribbon is placed around the aortic base below the coronaries which fixes the lower portion of the valve. This prosthesis is similar to the original ball valve type but with the walls of the chamber removed to permit reflux into the coronary vessels and which can be placed through a slit in the aorta and fixed distally with multiple point fixation, and proximally with a broad ligature which is approximated only tight enough to approximate the wall to the prosthesis. Three openings are present—one for each of the cusps so that this valve can be placed into the orifices rather simply. This has shown promising results experimentally, but we have felt that the size of the ball which is necessary to give complete occlusion without narrowing of the aortic outlet is sufficiently large that it offers some real increased resistance to flow even though the aorta widens normally just above the valvular insertion and one has an increased aortic diameter with which to work. However, this is not always adequate to permit flow without considerable restriction imposed by the presence of the ball.

During the last three years we have attempted to develop a cusp type of valve which follows the general configuration of

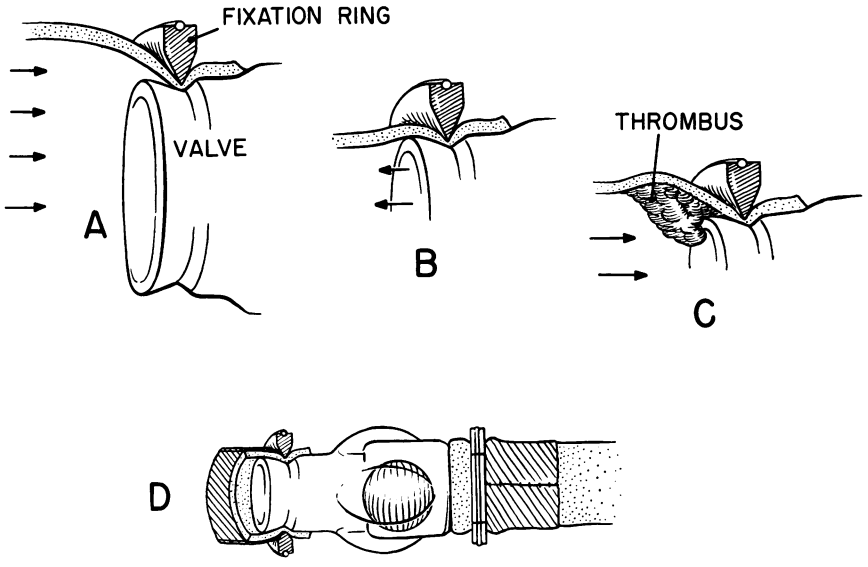

FIG. 5. A. The aorta wall is elevated from the end of the prosthesis by systolic expansion. B. In diastole the aorta again controls the end of the valve but may leave a small amount of blood cul-de-sac. C. Thrombus formation may extend over edge of valve. D. The aortic wall is compressed against the prosthesis by wrapping with Orlon mesh. This eliminates the potential cul-de-sac and subsequent thrombus formation.

the normal aortic valve. Figure 8 shows one of the early models of such a cusp valve. These have been constructed of a variety of materials; currently, silicone rubber of a special formulation, is being used which gives great promise of standing up very well after long-term implantation. A further development of the previous valve is shown in Figure 9. This model has the cusps held together only by a central ring and these cusps are flared in a fashion to approximate a normal aortic contour. This has the great advantage of being able to be seated into the normal curve of the scalloped aortic valvular ring. An important principle of the construction of sub-coronary type of valvular prosthesis is embodied in following this contour of the normal aortic cusp insertion. This greatly increases the feasibility and simplicity of placing the prosthesis. This prosthesis is extremely thin-walled and flexible, but very strong. It has been utilized experimentally over a period of six months without embolization or failure to operate. Figure 9 also illustrates the valve in systole and diastole and the manner in which it approximates the normal configuration of the aortic valve. The spring which is contained within the edges of the leaflet exerts a slight uniform outward pressure to seat the base of the valve against the aortic wall in the remnants of the valvular cusps, providing a seal at the base of the valve. This provides for continuous contact at the base of the cusp at the aortic wall. Fixation of the valve at the top can be accomplished either by suture or by multiple point fixation.

A new type of valvular prosthesis which departs from the classical approach is shown in Figure 10. This is a helical coil spring which opens by elongation and closes by shortening. The spring is constructed so that blood striking the upper surface will maintain the closure of the valve. The closed position is the normal position, so that it tends to resume this

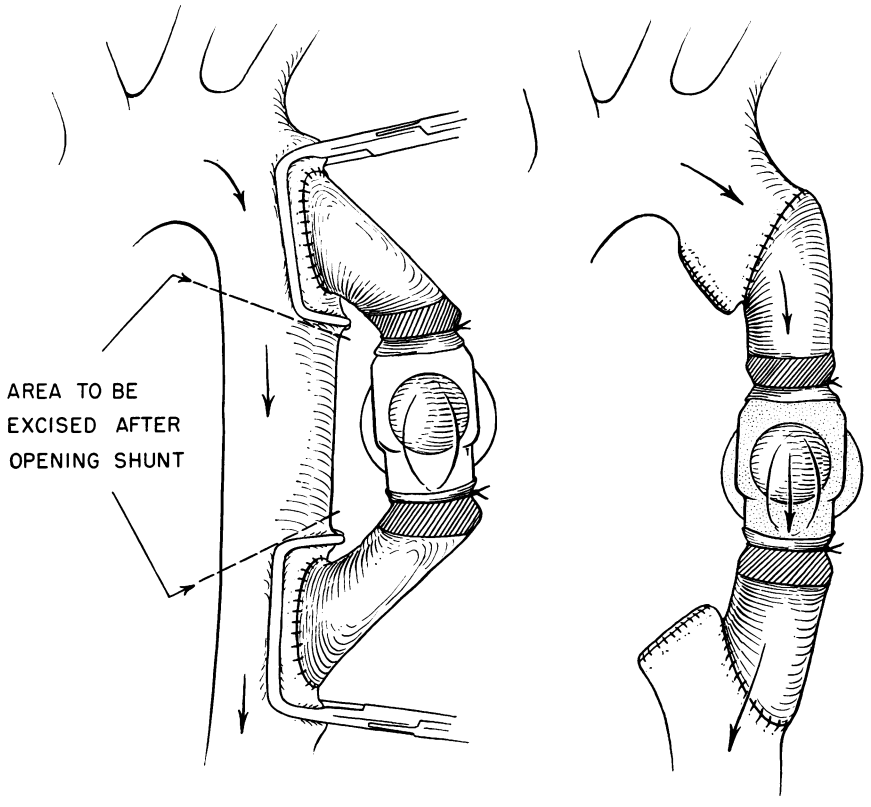

FIG. 6. A ball valve with short lengths of flexible cloth prosthesis attached to the ends is shown being sutured to the aorta. Partial occlusion clamps permit uninterrupted aortic flow. After establishment of flow through the valve, the area of the aorta between the end-to-side anastomosis is resected.

position as soon as systolic flow ceases and pressure is reduced. The open position offers extremely little resistance to flow at any one point in the diameter of the outflow tract of the aorta. The resistance of the spring to the opening pressure is extremely light, so that the valve opens fully at the first major differential in pressure.

Since it assumes a spiral shape only the cross-sectional area of any one part of the spring offers resistance to outflow at any given point in the diameter. The spring is so constructed that the terminal portion is lighter than the base. In this way it opens equally along its length since the ability to elongate decreases with the decreasing radius, if the spring is of equal temper throughout. The valve shown here is made of Teflon. Figure 11 shows such a valve in a sub-coronary position. The three posts occupying the positions of the commissures which insures that the aortic wall cannot impinge to the area which is normally occupied by the spring. The two methods of fixation of this type of prosthesis are: 1) the suture method with open operation; 2) multiple point fixation. The use of the three supporting columns is primarily to maintain the valve in a position normal to the aortic wall. It is necessary for a prosthesis of this type to have a length which is greater than the diameter of the aortic wall at the point at which it is inserted or it will tend to assume a tilted position. Prostheses of this type have been used successfully in experimental animals over the last

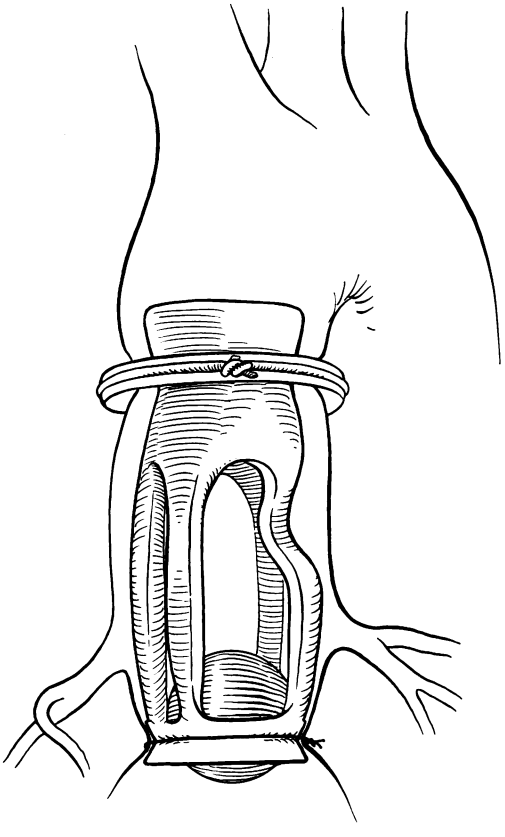

FIG. 7. Ball valve prosthesis with open chamber to permit coronary flow.

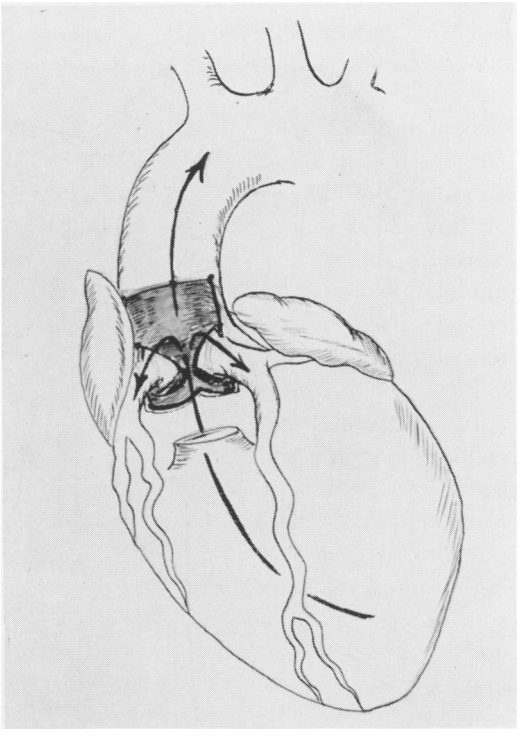

FIG. 8. A tricuspid valve implanted in the normal aortic valve position. The opening in the side permits coronary filling. Note that the base of the valve follows the contour of the base of the cusps.

three months and have been constructed of Teflon and steel.

It would seem that this type of valve would offer considerable promise in its lack of resistance to flow and the simplicity of its operation. It is necessary to observe these experimental models for long periods of time before it can be ascertained with

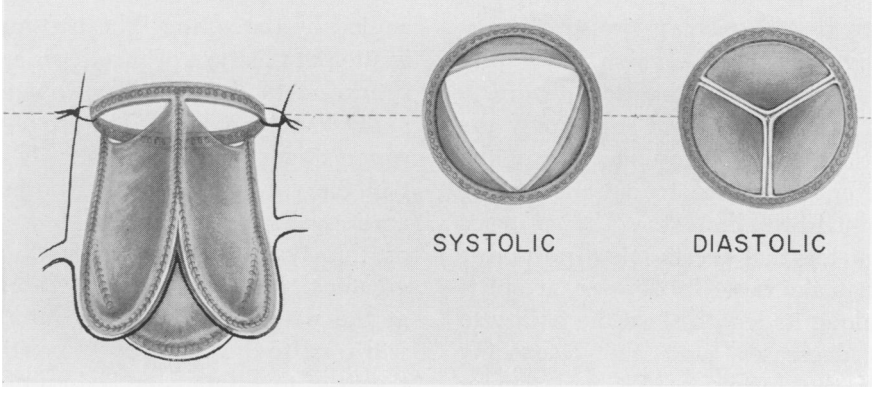

FIG. 9. Tricuspid leaflet type of subcoronary valvular prosthesis.

certainty that deformation with failure to function or clotting will not impair their action. However, after short periods of observation of up to three months, with the Teflon or the Teflon coated materials this did not appear to be a problem. It is anticipated that a special alloy steel spring of this character would maintain its intrinsic qualities for at least fifty years. This model early in its development will require considerable investigation, but which offers a new approach which is extremely helpful.

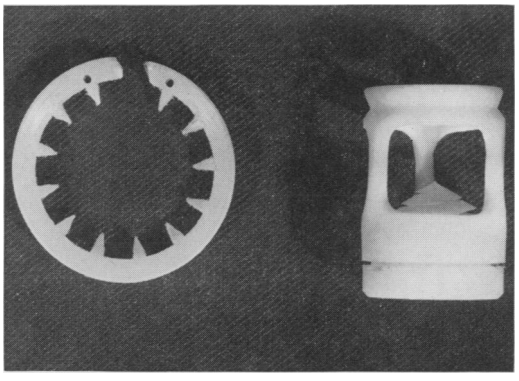

FIG. 10. Helical spring type valve. The length of the prosthesis can be altered as desired by increasing the length of the housing which acts only as an aid to fixation.

In an effort to avoid the use of an artificial implant in certain types of aortic insufficiency a reconstructive procedure has also been devised. This procedure is applicable in most cases in which there is dilatation of the ring or shrinkage of a cusp so that there is an excessive diameter of the aortic valvular ring. It is apparent that if one can reduce the diameter of the valvular ring and maintain the size of the cusp, that the cusp will be allowed to protrude further forward and effect closure. This procedure illustrated in Figure 12 utilizes the non-coronary bearing cusp. It is best accomplished under direct vision so that the valve leaflet can be retracted anteriorly and the initial stitch is placed at the base of the cusp in such a way to approximate the aortic wall, narrowing the area between the commissures of the posterior cusp. A line of similar sutures is then placed up-

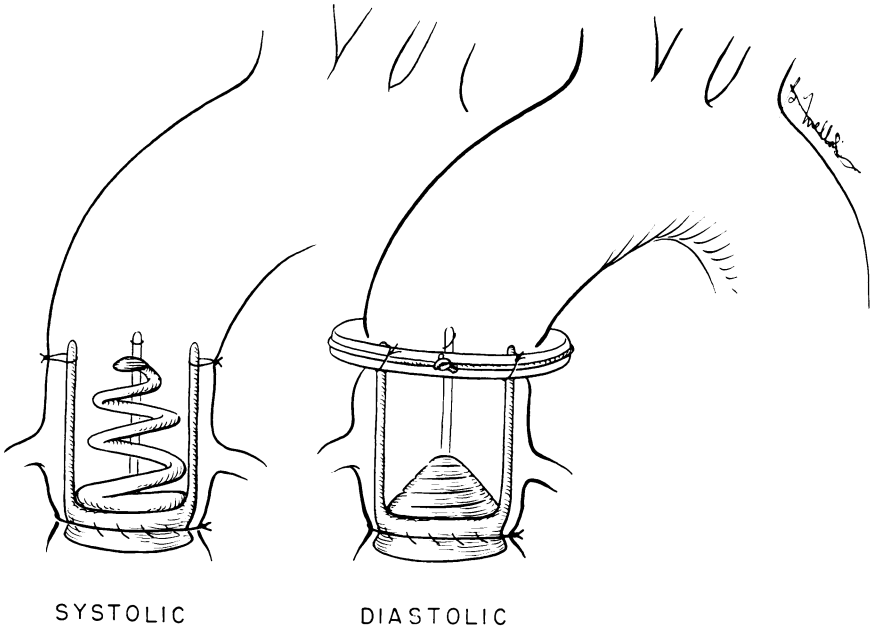

FIG. 11. New helical spring type of valvular prosthesis showing two methods of fixation.

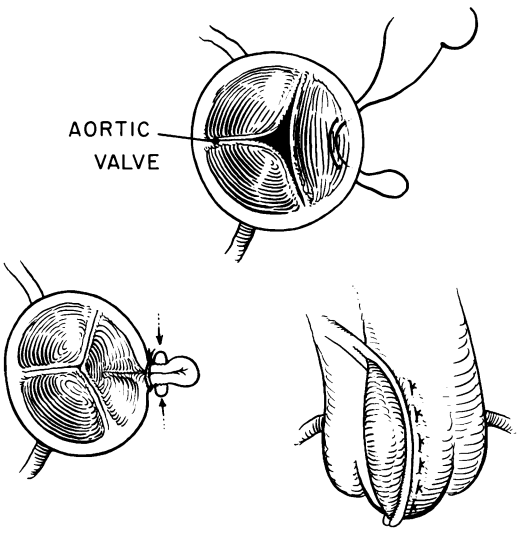

FIG. 12. Plastic reconstruction of aortic valve used when valve itself is relatively normal but the valve ring is dilated. Decreasing the circumference at the level of the cusp of the non-coronary sinus permits the leaflet to close by decreasing cross-sectional area at valve level.

ward to above the level of the top of the insertion of the cusps. This plication type of procedure will allow the posterior leaflet to move forward and effectively increase its closure by approximating it with the other two cusps.

The clinical modification of the ball valve prosthesis has led to decreased risk of operation and increased applicability to a wider variety of patients. The over-all results from the application of this are such that it must be demonstrated that the methods which are being sought by placing the valve in the normal position will significantly improve these results. We have summarized some of the recent work which has given promise experimentally, making it possible to place a prosthetic valve in the normal aortic position. It has been demonstrated that these can function successfully in dogs for periods up to six months, and that these valves are capable of maintaining normal hemodynamic relationships after destruction of the normal aortic valve and offer promise for the treatment of both luetic stenosis and insufficiency.

DISCUSSION

DR. H. WILLIAM SCOTT, JR.: I know that I can speak for this audience in expressing my own and its admiration for Dr. Hufnagel's fantastic ingenuity. He is to be warmly congratulated on his persistent efforts and contributions to the therapy of aortic insufficiency.

There is one aspect of the problem about which I would like to speak: the ideal position of the valve, as Dr. Hufnagel has pointed out, may compromise the origins of the coronary arteries. He has devised several very ingenious mechanical methods of getting around this problem. One other way would be to shift, by arterial grafting, the origins of the coronaries to a position higher up on the aortic arch. This has been done experimentally by Dr. Adams and Dr. Lance who are working on this problem in our laboratory with the pump oxygenator. By shifting the origin of the coronaries to the aortic arch one might then insert a prosthetic valve securely into the base of the aorta without having to worry about closing off the coronary ostia.

The second point I would like to comment on is the problem of cross-clamping the aorta when inserting the Hufnagel valve in its originally described position in the descending aorta. Many of us are not quite so dexterous as Dr. Hufnagel, and he has pointed out that the safe period for occlusion of the aorta and insertion of the valve is a matter of about 3 to 5 minutes. He can do this within this short period of time, but certainly few others of us can. We have lost patients because of cardiac dilatation and ventricular fibrillation and cerebral hypertension during brief periods of aortic occlusion for insertion of a valve. Dr. Walter Gobbel in our institution has recently worked on this problem and has investigated the possibility of simultaneous occlusion of the inferior vena cava as a means of preventing cerebral hypertension and cardiac dilatation while the descending aorta is occluded for the insertion of the valve.

(Slide) This shows the abrupt elevation in carotid pressure in the dog when the descending aorta is occluded and the absence of this elevation when the inferior cava is occluded just above the diaphragm simultaneously with the aortic clamping.

(Slide) This principle can be applied clinically by the insertion of a balloon catheter through the saphenous vein into the atrial opening of the in-