Discussion

Dr. Frank C. Spencer (New York, New York): Dr. Becker, gentlemen, ladies: My comments will be brief as the hour is late.

The development of the porcine valve is certainly one of the most exciting areas of investigation in the field of valve prostheses. Last September, about three months ago, I had the opportunity to visit the Hancock Laboratories at Los Angeles. They are currently processing 30,000 pigs a month, a third of 1,000,000 a year! About 90% are discarded because of anatomical defects, but, nonetheless, the production capacity is about 3,000 usable valves a month. This well indicates the widespread activity in this field.

The data presented by Dr. Bryant clearly show the phenomenal influence of the type of preservative used. This unusual factor has confounded all predictions about the durability of all the porcine prostheses, for all previous types of heterograft prostheses failed quickly, almost always within one year.

Dr. Bryant also well emphasized that there is no ideal valve available for every patient. The best valve for a particular patient will vary with the disease, and the specific circumstances, such as age, concomitant disease, feasibility of long-term anticoagulation therapy, and other considerations.

As Dr. Bryant has stated, any new prosthetic valve should be considered experimental for at least five years, since history of cardiac surgery is replete with enthusiasm for new concepts, soon followed by a series of preliminary papers and then discarding the entire concept within one to two years. Hyperbaric oxygenation, for example, is familiar to everyone. Hence, all new concepts should be considered tentative for a minimum of five years.

I thought it would be of interest to comment briefly about the Starr-Edwards cloth-covered steel ball valve, a prosthesis, which we have regularly used for about 9 years. We have no particular interest in the valve except the crucial fact that we get our best results with it. It is currently used in about 80% of patients, while 10% have disc valves, and 10% porcine valves.

In the last 9 years, 1456 of these ball valves have been implanted, with a 98% follow-up completed about two months ago. We did a careful, precise, follow-up evaluation because of the curious number of dismal reports about cloth wear and other complications. Our data include about 490 aortic replacements, 400 mitral replacements, 150 combined procedures and various miscellaneous combinations.

The actuarial survival curves following aortic valve replacements are 74% at five years decreasing to 58% at 8 years. Corresponding data following mitral valve replacement are 68% five year survival, 64% at 8 years.

Regarding complications, the most serious one is thromboembolism. Among 1251 patients surviving operation, 87% of the group, nine out of 10, have never had an embolus. A fatal embolus occurred in less than 1%, and a similar number, 0.8% died from complications of anticoagulant therapy.

To emphasize my earlier comments about selecting a prosthesis, a crucial consideration is whether a patient can safely maintain anticoagulant therapy over a long period of time. It is clearly foolhardy to insert a valve requiring anticoagulant therapy in someone who cannot be well supervised.

Two per cent of our group of 1251 surviving patients developed endocarditis, one-fourth of whom required reoperation. Cloth wear, which has been widely discussed as a serious handicap, has been of minimal significance. Among the total group, clinically significant cloth wear was recognized in only 0.5%. It undoubtedly has occurred in many other patients, but has not been of clinical significance. We remain puzzled about why our results are far better than those reported by many others. Whether this will be true with porcine valves remains to be seen.

In closing, and complimenting Dr. Bryant again on his careful analysis, I would like to ask him the impossible question that everyone around the world would like to see answered: How long will these valves last? Seven years? Ten years? Twelve years? And, how long would be satisfactory?

Data from clinical results with several types of prostheses indicate that the failure rate may not be linear. With the aortic homographs [sic] results were excellent for about four years, but the failure rate became prohibitive in most groups within the next two years. Whether this will be true with the porcine valves or not is a crucial question.

Dr. Ellis L. Jones (Atlanta, Georgia): At Emory University Hospital in the last 28 months we have used the heterograft porcine valve in over 250 patients, in both the aortic and mitral position. We have been very pleased with this valve, as long as certain guidelines have been observed.

(Slide) In 101 consecutive isolated aortic valve replacements there was a mortality of just udner 3%.

(Slide) Twenty-three of the 101 patients having aortic valve replacement were recatheterized, trying to delineate the hemodynamic function of the valve. We found some interesting data, in that these twenty-three patients had a resting mean left ventricular-aortic pressure gradient of 21 mm Hg, rising to 35 mm Hg during exercise.

(Slide) Certain conclusions were drawn from the hemodynamic data and follow-up: There has been a very low thromboembolic rate in these patients, none of whom were on coumadin anticoagulation. Unlike Dr. Spencer, we have had problems in following patients on anticoagulants. The embolus rate has been about 1–2% following aortic or mitral valve replacement.

We have felt that in this short time frame, and we would agree with Dr. Spencer that the whole story is not yet in, there has been no evidence of leaflet wear or valve dysfunction. There are certain important aspects of using the small bioprosthesis. We feel that one should avoid the small size (19 mm) prosthesis in the adult patient. It has an unacceptable left ventricular-aortic pressure gradient. The 21 mm valve has been used satisfactorily in the patients that we have elected to use it, and these have been very small females, with a small body surface area and reduced cardiac output. In these patients there has been a very acceptable left ventricular-aortic pressure gradient.

However, we feel the 23 mm, 25 mm, and larger prostheses are very satisfactory for large adult males. If it is necessary to avoid the small sizes—that is, the 19 and 21 mm in an adult male patient—we have gone to either the Bjork-Shiley tilting disc valve, or we have enlarged the aortic root, by one of two methods.

The first is the least extensive, and involved extending the aortotomy down into the noncoronary sinus, just through the mitral annulus, and then sewing a Dacron patch into this area, thus allowing the Dacron patch to become the new aortic annulus. Usually this will allow an increase of one prosthetic size.

If a more extensive annulus enlarging procedure is required, as in children, we have divided through the left portion of the ventricular septum. A Dacron patch is then sewn to the ventricular septum and becomes the new aortic annulus. This procedure is more extensive, but works very nicely in the small child, or infant.

Dr. Robert Wallace (Rochester, Minnesota): The impetus for my discussing the paper comes primarily from the last sentence in the abstract, which reads "The continuing long-term results indicate that the porcine xenograft is the valve of choice for cardiac valve replacement." My skepticism concerning this conclusion is that the glutaraldehyde porcine valve has not yet shown durability by long experience. All experience with tissue valves, whether autogenous tissue, heterografts, or homografts, although initially enthusiastically accepted, with longer follow-up have fallen into disrepute.

Our own experience with the preserved aortic valve homograft substantiates this. Between May, 1965 and October of 1972, 231 patients underwent aortic valve replacement with a preserved aortic valve homograft. The operative mortality for aortic valve replacement was 4% in this group of patients, and thus 220 patients survived

the first 30 days following operation. There have been 27 late deaths in this series, with the homograft still in place. Thus 193 patients have remained at risk for valve dysfunction. Of these 193 patients, 80 patients have required reoperation. Of these 80 patients, there was one operative death, and there have been 7 subsequent late deaths in this group.

Thus, from 4 to 10½ years following insertion of the valve, 83% of the total group of patients remain alive. However, 80 have required reoperation.

Early reoperation was due primarily to technical difficulties. These were unstented, freehand inserted valves. Our enthusiasm with patients who did not develop incompetence in the first 12 months following operation was great; however, as Dr. Spencer indicated, although our results at three and four years looked very good, our actuarial curves relating to reoperation at five years showed progressive increase in the incidence of reoperation and this has continued. I now feel that every patient who lives long enough will develop dysfunction of his homograft valve. The fate of fresh homografts appears to be the same as reported by Angel in 1972 and Stinson in 1975.

From a clinical standpoint, the xenograft is comparable to the mechanical prosthesis in terms of endocarditis, the incidence of perivalvular leaks, hemolysis, and hemodynamic function, except perhaps in the small-size xenografts, where a prohibitive gradient might exist. The singular advantage of the xenograft is the low incidence of thromboembolic complications.

For these reasons, I think the conclusions reached by Dr. Bryant and associates is not substantiated. Perhaps there is a place for this valve, when its durability has been established, for use in patients whose natural life expectancy is less than the proven length of durability of the xenograft; also in certain patients where the risk of thromboembolic complications or anticoagulation exceeds the risk of reoperation.

DR. C. J. LAMBERT (Dallas, Texas): Our group has accumulated experience with tissue valves dating back to the late 1960's. The initial experience was gained with hand fabricated valves and paraformaldehyde fixation whereas the subsequent and predominant experience has been with the glutaraldehyde valve of the commercial variety. From that experience, I would like to relate to you some thoughts which we have formulated.

These valves, as is now known, are not viable although we had initially thought that they might constitute a matrix into which viable tissue in-growth would occur.

Tissue valves on the other hand, are not subject to rejection, do not require anticoagulation and are not subject to catastrophic deterioration as has been so with the prosthetic valves. Even if they do undergo degeneration and a large number of the formalin treated valves did degenerate, catastrophe was never noted and an elective replacement was possible with a 0 mortality. The essentiality of that knowledge is that one can very safely reoperate in a situation wherein myocardial deterioration is not allowed to occur, and thus it is that I would question whether it still would not be better.

The essential chemistry difference between formalin fixation and glutaraldehyde fixation is that there is a single cross-link bonding with formalin and a double cross-link protein bonding with glutaraldehyde. As a consequence, "wash-out" does not occur as was so with formalin fixation techniques. Nevertheless, the accuracy and deliberateness with which the valve is sculptured, mounted and equalized in terms of selection and geometric design, make a tremendous difference. Of the five five-year formalin fixed valves, the most interesting aspect upon review was that all of these valves had been prepared in a manner of harvesting, formalin fixation and subsequent mounting. As such, it must be acknowledged that formalin as a method of fixation and preservation is not a total determinant under these conditions.

Since 1970, we have utilized some 285 glutaraldehyde valves predominantly of the Hancock design. 138 of these valves were used in the aortic position; 147 in the mitral position. Anticoagulants have not been utilized at any time during their period of hospitalization nor subsequent to discharge. Embolization has been noted in only one instance, that being earlier manifested by transient dysphagia only and responded to no specific treatment. Endocarditis has been observed in only two instances, and in only one instance did it necessitate reoperation. No glutaraldehyde valve followed to date has required reoperation because of tissue failure. No valve has shown x-ray evidence of calcification and the valves available for study either at reoperation for unrelated conditions or at subsequent autopsy examination, have revealed complete endothelialization, the absence of clot formation and fibrin deposition and excellent leaflet pliability. Shrink temperature, employed by Mr. Hancock, continues relatively normal thereby suggesting that longevity is, and can be, expected from this type of valve.

At the present time there are two types of commercial valves available. To help accommodate the small aortic annulus, Edwards Laboratories has introduced a valve with a smaller sewing ring. This has improved the situation in those patients with annuli requiring valves smaller than a 21 mm, thereby lessening the residual gradient. The Edwards solution is somewhat stronger and different in chemistry than has been the solution relating to the Hancock valve being discussed this morning. Whether this strength difference will make any chemical difference in the long run I do not believe we can say at this time. On the other hand, the Edwards glutaraldehyde solution is bactericidal, whereas the Hancock solution is said to be only bacteriostatic. Even so, no valve is released for use until a three-week quarantine culture period has been observed at the point of fabrication.

DR. LESTER R. BRYANT (Closing Discussion): Dr. Spencer's group have had such superior results with prosthetic valves over such a long period of time that they have clearly become the benchmark against which other groups may measure their own results. This particularly applies to the problems of thromboembolism.

I think Dr. Spencer's group is to be congratulated because of their ability to resist the tide of enthusiasm to switch to each new valve that comes along. Thus, over a long peiod of time we are able to hear results from the Starr-Edwards valve, for example, that probably are not available from many other groups.

To Dr. Jones I'd like to offer thanks for the data which he has given us in terms of the postoperative catheterizations in their patients with porcine valves. Although a number of papers are now being published about the porcine valve, we are still collecting data in terms of their behavior hemodynamically, and I believe that the results that he mentioned are very similar to what we have found.

Dr. Wallace's disagreement with our conclusion about the porcine valve being the valve of choice is taken well. We do feel, however, that the ability to discontinue anticoagulants and the freedom from worries about embolic complications, particularly in the type of patients that we see in Veterans Administration hospitals and in charity hospitals, has to make us stick to our feeling that the porcine valve is the one that should be used by first priority in these patients.

Finally, Dr. Lambert's point about the fact that the tissue valves are not subject to catastrophic failure is a very good one, and it is mentioned in our text. All of the patients who have developed valve failure have done it in a slow and gradual fashion that has allowed us to bring the patients in, have them studied, and reoperate upon them without the need for urgent procedures. All of us are aware of the catastrophic complications that can occur with prosthetic valves, although that is getting to be less frequent.