ACTA MED PORT, Suppl I: 95, 1980

VALVE SUBSTITUTES IN CARDIAC SURGERY

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Since 1955, with the progress of safer methods of extra corporeal circulation, open heart surgery started to go through great advancements. As far as the treatment of valve disease is concerned those improvements made it possible to think about replacing the diseased heart valves with prostheses.

Even before the era of open heart surgery, correction of aortic insufficiency had been clinically experimented placing in the descending thoracic aorta either a rigid prosthesis — Hufnagel valve — or one homologous graft (Lam and Murray).

Some of the details of the Hufnagel valve were actually adapted to the project of the first rigid prosthesis placed in subcoronary position, to replace a diseased aortic valve, and Dwight Harken was responsible for this work in 1960. This was very similar to the pioneer work done, almost simultaneously, by Albert Starr. Since that period multiple types of mechanical valve prosthesis have been described, and this shows a constant effort oriented to find a valve substitute that would function as nearly as possible to the normal valve.

The characteristics, mentioned by Harken, which the ideal substitute should follow, have been used in the background af all those works and experiments and they were the following: durability, adequate haemodynamic performance — with acceptable transvalve gradients and non significant regurgitation — and, finally, without haemolysis and without the risk of thromboembolism.

With the finality of producing a valve that could really follow the above cited principles, various concepts and ideas were described. One of the first, which was later recognized as mistaken, was that the artificial valves should be anatomically as similar as possible to the normal human valves. Valves of flexible synthetic material (like Teflon), described by Bahnson, Kay, Morrow and Mc Goon, were very early discarded as the risks were too high of deterioration, disinsertion, infection and thrombosis.

A totally different concept, initially received with skepticism, but readily accepted as really valid, was thereafter introduced by Harken and Starr: the concept of a prosthesis using a poppet as occluder.

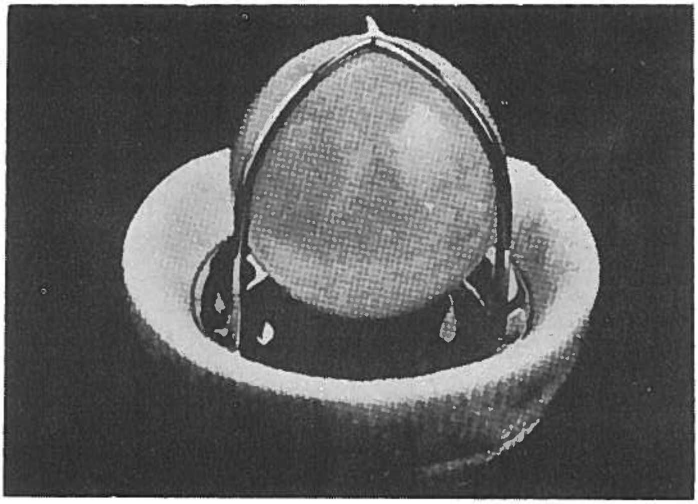

Fig. 1 — *Starr aortic valve*

The Starr valve, as one of the most widely used since the beginning of valve replacement, is already well known about its advantages and limitations. This valve has the following characteristics: high profile due to the ball occluder, symmetrical peripheral flow as the poppet avoids central flow, and an occlusive mechanism which adapts itself to the prosthetic ring at the moment of closing.

The criticism of the importance attributed to each of those characteristics, the value accorded to lining the metallic struts for prevention of thromboembolism and the choice of the prosthetic materials constitute the variables on which depend the design and engineering of valve prostheses (Table 1). We are going to try and analyze them successively.

Table 1

Mechanical Valve Prosthesis
Variables of Design and Engineering

Type of Profile	High (Poppet as Occluder) Low (Disc as Occluder)
Type of Flow	Peripheral and Symmetrical Central and Laminar
Mechanism of Occlusion	Overlapping the valve ring Setting in instead of Overlapping the valve ring
Covering of Metallic Structures	
Type of Materials	

The type of profile (high or low) is defined depending on the type of closing mechanism. In high profile prosthesis this mechanism is a poppet locked up in a cage; in low profile valves the occluder is a disc.

Amongst the ball prostheses and besides the Starr valve, we wish to mention the Magovern-Cromie aortic valve, the Smellof-Cutter and the Braunwald-Cutter prostheses. Amongst the disc valves the examples are the Bjork-Shiley, Cooley-Cutter, Lillehei--Kaster, Beall-Surgitool, Kay-Shiley, Hall-Kaster and St. Jude.

In patients with a small left ventricle mitral valve replacement whith disc valves seems to be advantageous as they do not protrude into the left ventricular cavity. In fact the latter can be the cause of arrhythmias, as the valve may impinge on the ventricular septum, and could also result in left ventricle out-flow obstruction.

In cases of aortic valve replacement with a narrow aorta and in cases of tricuspid valve replacement many surgeons also prefer a mechanical disc valve as the high profile valve is not very adaptable to the mentioned anatomical details (Table 2).

Table 2

Mechanical Valve Prosthesis
Variables of Design and Engineering
Type of Profile

Advantages of low profile prosthesis (Disc Valves)
— Mitral valve replacement in cases of tight stenosis with small left ventricle
— Aortic valve replacement with narrow ring
— Tricuspid valve replacement

The type of flow observed in mechanical valves depends entirely on the closing system being central or with a tilting disc.

Center occluding systems prevent, obviously, a central flow and this happens in all types of ball prostheses and in many prostheses with a disc like the Cooley-Cutter, the Beall and the Kay-Shiley; they all have a peripheral symmetrical flow. One of the first examples of the use of a tilting disc was in the valve of Wada-Cutter which was abandoned for the very important reason of late dysfunction related to deterioration of the Teflon disc. But, even before that, the Hammersmith mitral prostheses (Alvarez--Melrose) had been used and discarded for high thrombogenicity.

The same principle was, however, reutilized with success in the Bjork-Shiley, the Lillehei-Kaster and in the Hall-Kaster prostheses.Nowadays a pyrolytic carbon disc is used in all of them. The opening angle in the Björk-Shiley valve is 60°, in the Lillehei--Kaster 80° and in the Hall-Kaster 75°. But the increase of the opening angle above 60°, according to Björk, does not reduce the gradient across the prostheses. Some more details will be mentioned later.

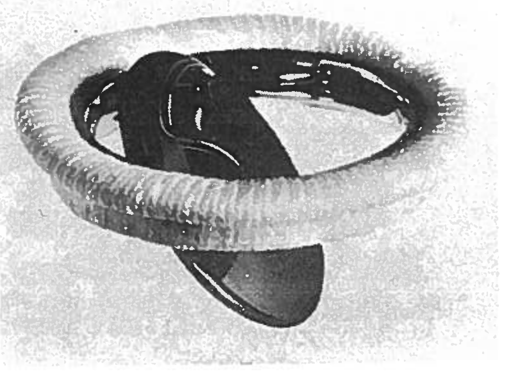

Fig. 2 — *Björk-Shiley mitral valve*

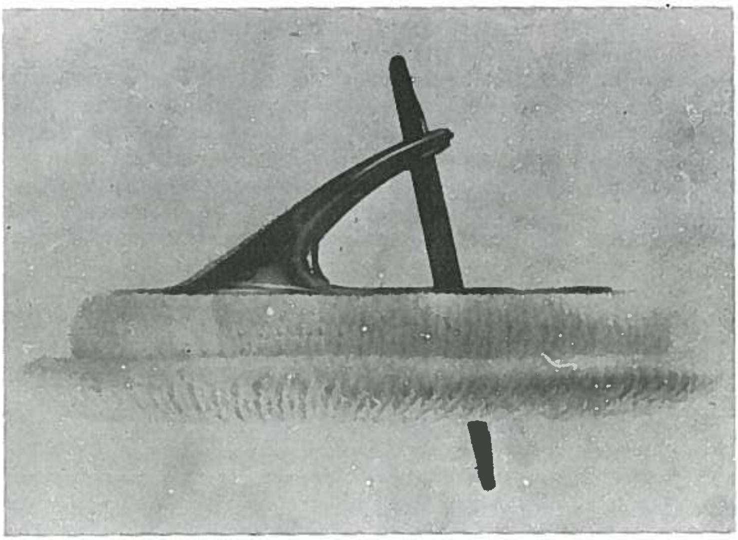

Fig. 3 — *Lillehei-Kaster valve*

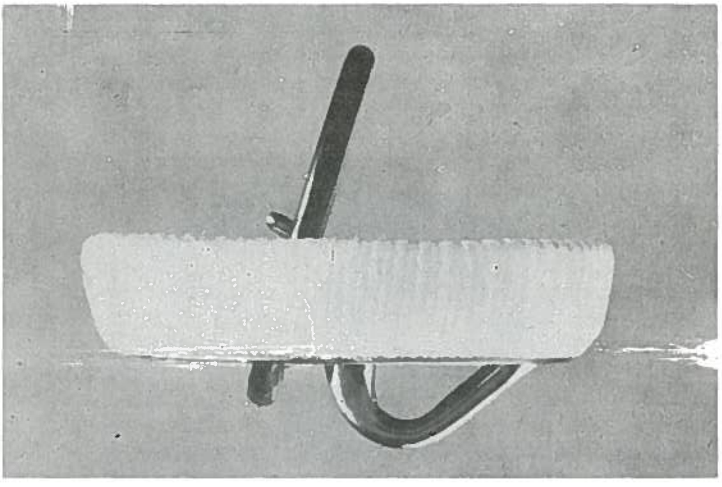

Fig. 4 — *Hall-Kaster aortic valve*

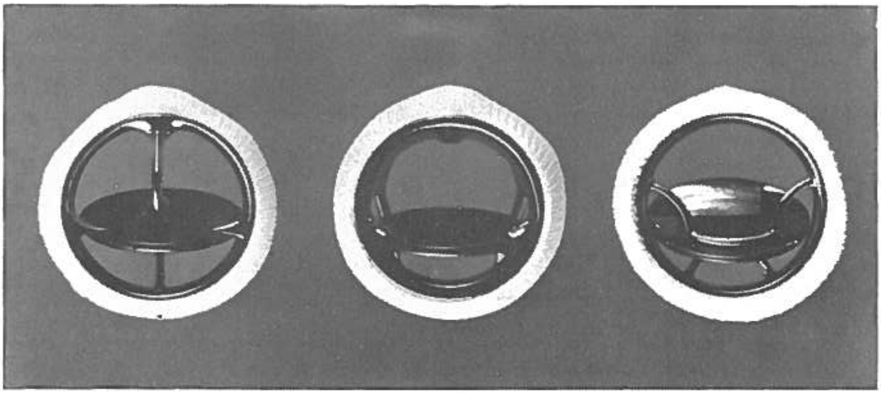

Fig. 5 — *Comparison of the inflow view of aortic valves: Hall-Kaster (left), Lillehei-Kaster (middle) and Björk-Shiley (right)*

The occluding system of the tilting disc allows a central and almost laminar flow and this has been considered as a significant progress in the design of mechanical valves (Table 3).

Table 3

Mechanical Valve Prosthesis
Variables of Design and Engineering
Type of Flow

Advantages of prosthesis with tilting disc as occluding system:
— Better haemodynamic performance, with central and almost laminar flow.

Whatever the profile and the characteristics of the flow, mechanical prostheses may present two types of occluding mechanism: either the disc is above the valve ring at the moment of closing or it actually sits inside the valve ring. In the first, the closing system overlaps the prosthetic ring in each diastole and this happens in the Starr valve with a poppet or in the Lillehei-Kaster with a tilting disc. The second hypothesis in which the occluder sits inside the ring instead of overlapping it, happens in the Björk--Shiley valve, in the Cooley-Cutter valve and also with the ball of the Smellof-Cutter valve. In these last examples of occlusion there is a higher ratio between the intern diameter of the prosthesis and the valve orifice and this is why the transvalve gradients are lower compared to other valves with identical diameter. This is particularly useful in situations of narrow aortic ring. As an additional advantage of this second type of occluding mechanism one should mention the lesser erythrocyte destruction with consequent reduction of haemolysis, as compared with a probably higher trauma of red cells verified in prosthesis with overlapping occluders (Table 4).

Table 4

Mechanical Valve Prosthesis
Variables of Condiction Design and Engineering
Mechanical Occluder

Advantages of the prosthesis in which the ocllulder sits inside the ring:
— Lower transvalvar gradients
— Lesser degree of traumatism to the erythrocytes

In relation to the characteristics analized above, it seems that the Björk-Shiley valve associates the advantages of low profile, of pratically central flow and lower transvalvar gradients in prosthesis of small diameter, this being due to the fact that the occluding tilting disc fits inside the ring at the moment of closing.

The newest Björk-Shiley valve with a convexo concave tilting disc is less thrombogenic and produces even lower gradients. This is due to the fact that the smaller opening, when the disc is tilted, has been increased by 40%. Therefore the lower flow area behind the disc is diminished and the rinsing with high velocity blood flow becomes much more effective. A paper by Björk about his new prosthesis is included in this same Supplement of Acta Médica Portuguesa and it is, therefore, unnecessary to give any more details about it.

There are some characteristcs of the Lillehei-Kaster prosthesis that are essentially different from the Björk-Shiley valve. Their authors claim that the design have such feactures as low profile housing, central flow pattern, easier opening, rapid closing, limited peripheral back leakage when closed, minimal obstruction to flow, reduced flow turbulence and a true free floating, unpinned disc.

The Hall-Kaster prostheses have been used in varios centers in increasing numbers. In various publications the authors mention that this valve has been improved in various ways. One of them is that the disc, when in the open position divides the orifice into two very similar appertures. From the closed to the open position the disc pivots to a maximum of 75°. Throught its entire peformance the disc is free to rotate about its central axis and also about the guiding strut. In the closed position the peripheral edge of the disc, like the Björk-Shiley prosthesis, fits into the internal orifice of the ring.

The newest mechanical valve prosthesis is the St. Jude. Its clinical use is not yet very widespresad but there seems so be general acceptance as to its functioning system. It consists of one double leaflet disc divided in its middle. The leaflets open to the sides as the wings of a butterfly. The main characteristic is a very free flow with minimal gradient or turbulence (Fig. 6).

Fig. 6 — *St. Jude Valve in the opening position*

The different degrees of durability, of improvement of haemodynamic characteristics and of complications, which intervene in the comparison of mechanical valve prostheses should be attributed to various structural types and various techniques that are used in the several types or models of these prostheses.

In the already well established models of mechanical valve prostheses the durability and an adequate haemodynamic behaviour are already proven by long periods of follow-up. However, whatever their type may be, mechanical prostheses involve risks of thromboembolism. The thrombogenicity of these valves is fundamentally related to the presence of metallic surfaces hardly mobile and directky exposed to the blood flow. Thrombosis starts in the transition of the exposed metal structure and the place where the same is lined with any sort of foreign tissue. It has been interpreted as a reaction to encapsulation which exists in the interface between metal and tissue (Table 5).

Table 5

Mechanical Valve Prosthesis
Variables of Design and Engineering
Lining of Metallic Strutures

Finality: Thrombogenicity related to the existence of immobile-metallic surfaces directly exposed to blood flow.
Site of thrombus formation: Transition between exposed metal and covered housing (metallic, tissular interface).

Between this basic thrombogenic mechanism and the hydraulic characteristics of the prosthesis an important interrelation has been established as this is probably the clue to lessen thrombus formation even in areas where metal is directly exposed to the blood stream. Although this is not completely agreed upon, thromboembolic phenomena are less frequent in the prostheses with a pivoting disc and central flow than in the ball valves without any lining: it is as though an equilibrium has been obtained between better haemodynamic conditions and the process developed against encapsulation. It should be stressed, however, that even prostheses which have better flow and lesser gradient are not free from thrombosis wihch may be started by inadequate anticoagulation or increased local turbulence.

Correct anticoagulation is, in fact, the major determinant factor for survival in patients with mechanical valve prosthesis. Nevertheless, anticoagulation needs continuous laboratorial checking; moreover, the need for anticoagulation may produce lack of attention from the patients but, on the other hand, may create an attitude of dependency which is quite often made worse by difficulties in getting correct laboratorial control.

The risks of thromboembolism and the ones related to excessive anticoagulation, and these are the main opposition to the utilization of mechanical valves, led the way to various laboratorial and clinical works in order to replace these mechanical prostheses with others that would not involve the above cited risks. And this was, in actual fact, the start of biological valves.

As it had happened with mechanical valve prostheses in relation to the Hufnagel valve, replacement with biological valves stemmed from investigations connected to the study of the evolution of the homologous aortic valves implanted in the descending aorta.

After various studies about implantation of the homologous aortic valve in the subcoronary position, or, in other words, in the aortic ring, various surgeons like Sir Brian Barratt-Boyes and Donald Ross started to use them almost as routine.

The first aortic homografts implanted in subcoronary position were fresh valves. But after a limited experience and due to logistic problems, those homografts started to be sterilized, by chemical means or by irradiation, and stored at low temperatures. Sterilization and preservation of the homografts with these methods have impaired viability with the disappearance of all cellular elements. It was admitted, however, that the implanted valve would end up with formation of new cusps of autologous tissue using the implant as a ***skeleton***. In a very high percentage of patients these facts were not to be verified and alterations of the biological valves became so important that surgical replacement was required. These alterations were attributed not only to mechanical effort and biochemical phenomena created by the receptor, but mainly to the agents utilized for sterilization and tissue preservation.

Since 1969 it was recognized that the highest probabilities of surival of homografts without late degenerative changes were obtained with the implant of fresh and viable aortic valves whose cellular components (fibroblasts) not only survive «in vitro» but are revitalized with the transplantation, as is proved by the obvious process of cellular division. The existence of cellular viability has become a fundamental condition and, in order to preserve it, the sterilization and conservation of homografts was obtained by the use of antibiotic solutions.

The hopes derived from the good results of viable and fresh aortic homografts became less enthousiastic with the passing of time. And various good reasons could be invoked to explain the pathological alterations and haemodinamic disfunctions observed in these grafts. Therefore, in spite of the obvious advantages that their advocates started by claiming. and they were essentially the utilization of valves with excellent hydrodynamic behaviour and minimization of thromboembolism, risks-of--anticoagulation, haemolytic anemia and sudden valve dysfunction, the facts prove that the late analysis of the post-operative results did not demonstrate, in more than a few centers, that aortic homografts, even fresh, posessed a high degree of biostability. And this was the reason why they became less popular.

In 1969 when presenting the conclusions of the 1st International Conference on biological valves, Dwight Mc Goon, expressed the idea, which was not confirmed later, that valves of autologous tissue, offering more certainty in the point of view of immunology, presented a better perspective, followed by homografts.

Limitations to the aortic homografts have already been presented. But even more spectacular was the fairly rapid pessimism that involved the utilization of autologous valves.

The use of these valves had already been mentioned, experimentally, by Murray and by Templeton who, respectively, used veins and autologous pericardium. Van der Spuy, in 1964, and Fadai and Geha, in 1970, again described their use and called the attention to the possibility of utilization of pericardium, peritoneum and tissues otained from reaction to silicon. However. it was Senning who proposed, in 1962, the use of autologous valves namely of fascia lata. In the mitral and tricuspid position fascia lata valves were used mounted in rigid frames; in the aortic position, either in rigid frames or as free grafts. Whatever the way or site of implantation, it was soon realized that these valve substitutes were a failure mainly because of the high occurence of endocarditis or valve insufficiency due to late degenerative changes. Fascia lata, in fact, suffers the process of fragmentation of collagen fibers and reduction of cellular viability, with valvar shortening, thickness of the free edge and deposition of fibrin on its surface. For these reasons, fascia lata could not be recommended as a valve substitute and the position of the ones who defended autografts suffered a notorious setback.

About the same subject one has to mention, as an exception, the operation proposed by Ross of switching the pulmonary valve in cases of aortic valve disease. The graft of the pulmonary valve, in the terms of durability and viability may be, indeed, one of the best substitutes of the aortic valve. In fact, no degenerative signs have been found and its normal architecture seems to withstand the switch witout alterations. The operation proposed, which can only be used in patients whose dimensions of the root of the aorta are appropriate, and which involves also the implantation of some other valve in the pulmonary position, is not technically easy and probably involves a higher mortality. It has been, therefore, restricted to fairly young patients whose operative risk is not high.

The idea of utilizing valve heterografts, in the beginning considered as less promising for immunological reasons, revealed itself, with accumulated experience, highly advantageous. The reasons that led investigators to orient their views to the field of heterografts were actually due, fundamentally, to difficulties in the obtention of aortic homografts. The positive results obtained by this work, together with the possibility of commercial production, with assured standardization, are basically the reasons of sucess of heterografts as cardiac valve substitutes.

The early investigation, realized by Durand, and the first clinical implant by Binet in 1965 were not, however, immediately followed by sucess. In fact, a very high percentage of valve failures, after implantation of freeze dried porcine aortic valves, was described. The same happned when the first stabilizing agents were used with the purpose of obtaining a valve which could last. After this lack of success, it was only after 1968, when Carpentier introduced glutaraldehyde in the preparation of heterologous valves, that the interest for heterografts became alive again. The action of glutaraldehyde results from its stabilizing properties, producing irreversible cross-links with protein molecules in a complex process of intra and inter molecular aggregation which involves the formation of secondary amines and pyridinium salts. In the irreversibility of these cross-links lies the advantage of glutaraldehyde over any other stabylizing agents used beforehand (dialdehyde, mercurial salts and formaldehyde). The blockage exerted at the level of the free and reactive prosthetic groups of the collagen molecular bodies and of glicoproteins reduces the antigenicity of the heterologous tissues to be implanted.

The alterations induced by the treatment with glutaraldehyde are so deep and important, stable and long lasting, that biological valves mounted in frames and prepared according to modern chemical processes have been designated as bioprosthesis. Thus, a very clear distinction is established between biological valves not treated chemically, whose duration is related only to the presevation of cellular viability, and bioprosthesis, whose durability is based on the stability of the biological material.

In the commercial production of valve heterografts treated with glutaraldehyde two types of tissue have been used: the porcine aortic valve (in xenografts of Carpentier-Edwards, Hancock and Angell-Shiley) and the heterologous pericardium (in the Ionescu-Shiley xenograft) (Fig. 7 and 8).

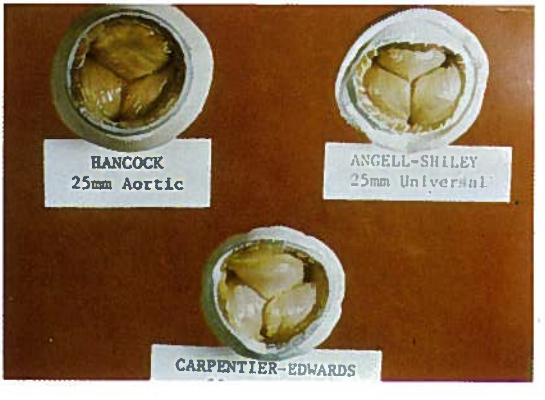

Fig. 7 — *Three glutaraldehyde preserved porcine valves; Hancock, Angell-Shiley and Carpentier-Edwards*

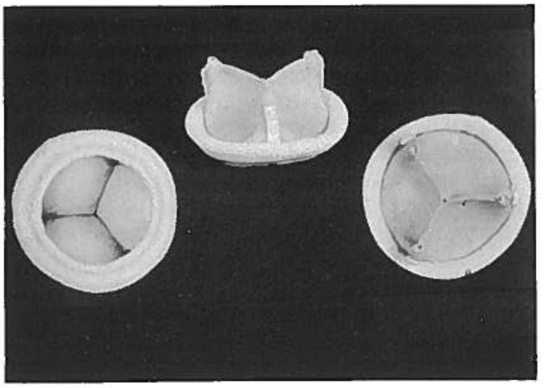

Fig. 8 — *Ionescu-Shiley heterologous pericardium xenograft*

Besides the significant and important differences connected to the way how the chemical treatment by glutaraldehyde is processed, the above cited xenografts also present some differences related to the technique of making them. Such differences do not mean that durability is not known particularly with porcine xenografts. Indeed, the analysis of these valves, recuperated after various lapses of time after implantation, demonstrates that, even realizing that most of them show signs of some degradation of the ulterstructure of the collagen and of the net of elastine, and some also definite calcification, the degree of which can not be related to the lapse of time after implantation, it is rare that these changes are of great importance or are deep seated. The valve degradation of the porcine xenografts treated by glutaraldehyde is characterized by the fact that it is processed in a very discrete manner, less frequently and more slowly than the one observed with other methods of tissular preservation. Hence the generalized interest and acceptation of these valve substitutes.

Once recognized the long-term tissular stabilization obtained by glutaraldehyde, Ionescu started trying to obtain, with bovine pericardiun xenograft treated in the same manner, a valve substitute which could present a superior haemodynamic performance, as compared to the porcine xenografts, although maintaining all the fundamental aspects of the investigation which ended up by the development of bioprosthesis — acceptable durability and disappearance of the risks of thromboembolism without anticoagulation.

In the Ionescu-Shiley xenograft the technique of mounting, using just one piece of pericardium and maintaining totally free the central opening of the valve, the thinness of the heterologous tissue and the geometry of the bioprosthesis, and of its suture ring, made it possible that the ratio between the areas of the orifice and the diameter of the valve was excellent. This is the explanation for the minimal transvalve gradients of these prostheses even in the smallest xenografts. «In vitro» studies using constant flows and comparing the relative merit of the various valve substitutes, as far as their hydraulic characteristics are concerned, and which, of course, may relate to the respective behaviour in vivo, indicate that the Ionescu-Shiley valve has better haemodynamic characteristics than the porcine heterografts already mentioned. The utilization of the Ionescu-Shiley bioprosthesis seems to be particularly indicated in cases of small aortic root and, possibly, also in valve replacement in children.

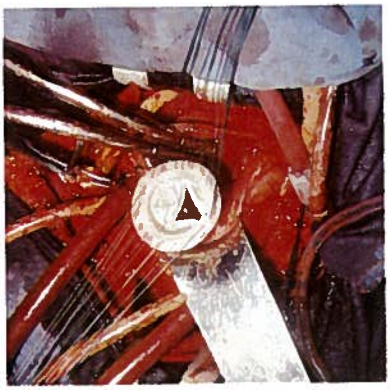

Fig. 9 — *Dura-mater valve being implanted in a case of Ebstein disease*

Amongst the modern cardiac bioprothesis we can not forget another type of valve substitute: the valve of homologous dura mater developed by Puig and Zerbini in São Paulo, Brazil. The utilization of this tissue, removed from the temporal region, is based on the fact that its structural characteristics are considered as specially indicated. Its conservation and sterilization is maintained, although with chemical mechanisms not entirely clarified, by the action of glycerol at 98% during a period not less than 12 days.

The follow-up studies which confirm, after eight years, the satisfactory clinical and laboratorial results, the pathological examination carried out in valves (removed for other reasons) showing that there was preservation of the valvular architecture, and, over and above, economical reasons, connected to the low cost of its production, amply justify the maintenance of the dura mater valve as one of the bioprosthesis to be used.

In the way of summary, the following table (Table 6) describes the various types of biological valves.

Table 6

Biological Valves
Summary

Aortic Homografts		
Autologous Tissue Valves	Fascia Lata	
	Pulmonary Autografts	
Bioprosthesis	Heterografts treated with glutaraldehyde	
	Aortic Porcine Xenografts	Carpentier-Edwards
		Hancock
		Angell-Shiley
	Bovine Pericardiun Xenografts	Ionescu-Shiley
	Homologous Dura Mater teated with Glycerol	

In this paper we have tried to express, in a very condensed way, the definite progresses which have been gradually obtained in the design and preparation both of mechanical valves and bioprosthesis. The ideal valve, however, has not yet been discovered and if biological valves definitely constitute an answer to the risks of thromboembolism and to the ones connected to excessive anticoagulation, the truth is that the fundamental characteristic of mechanical valves, i.e., durability, is not at all guaranteed.

Weighing the risk of choosing mechanical valves or bioprosthesis, the surgeon still has to make a fundamental option between these types of valve substitutes.

In the Department of Cardio-Thoracic Surgery of the «Hospitais Civis de Lisboa», «Hospital de Santa Marta», and until the 31st of July 1979, 336 operations for valve replacement have been carried out. We do not wish to mention morbility and mortality and the following two tables (Table 7 and Table 8), refer only to the valve substitutes which have been used.

Table 7

Department of Cardio-Thoracic Surgery
Hospital de Santa Marta
Operations for valve replacement until 31st of July 1979

Mitral Valve Replacement	192
Aortic Valve Replacement	64
Tricuspid Valve Replacement	1
Multiple Replacements	79
Total	336

Table 8

Hospitais Civis de Lisboa
Department of Cardio-Thoracic Surgery
Hospital de Santa Marta

Operations for valve replacement until 31st of July 1979

	Starr Valve	Bjork-Shiley Val.	Alvarez & Starr Val.	Starr & Bjork Val.	Dura-Mater Val.	Hancock Valves	Ionescu-Shiley Val.
Mitral Valve Replacement	21	147				4	20
Aortic Valve Replacement	12	43					9
Tricuspid Valve Replacement					1		
Multiple Replacements		76	1	1			1
	33	266	1	1	1	4	30
					Total		336

The attitude of our Department, in the choice of valve substitute, taking in consideration all the theoretical advantages or disadvantages and the limitations of our Country, which made us avoid more risky options, consisted in the choice of commercialized valves having had a very wide experience throughout the world. As far as mechanical valves, our Department started with the Starr valve and for the past few years has preferred the Bjork-Shiley valve. We are going to start in 1980 to use the convexo concave Bjork-Shiley valve which, so far, has not been obtainable in this Country. We are also going to use the Lillehei-Kaster valve and start with the more recent Hall-Kaster valve. As our Department has, nowadays, a fairly high output we are going to use a number of these valves and compare, in a short time, the results with the ones previously implanted.

We have only recently started the use of bioprosthesis and as indicated in Table 8 we have given preference to the Ionescu-Shiley valve.

Considering the guarantee of duration of the present day bioprosthesis, we have, in fact, been recently using a practical criterion in order to choose the valve more adaptable to the particular details of each case.

Hence, although we continue to use generally the Bjork-Shiley valve, we have considered the implantation of bioprosthesis in cases where one or more of the three following possibilities may occur:

— If anticoagulation is contraindicated as in patients with haemorrhagic disease, old patients, young women who want to have children.
— If anticoagulation is difficult to maintain as is the case in children or because there are some limitations of social or geographical order.
— If there are special conditions particularly favourable to thromboembolic complications as in patients with a history of reccurent embolism, patients with very large or thrombosed left atrium; in these cases we would associate, possibly only temporarily, a treatment with anticoagulants.

RESUMO

SUBSTITUTOS VALVULARES EM CIRURGIA CARDÍACA

Após uma breve história da evolução da *Substituição Valvular em Cirurgia Cardíaca,* descrevem-se, em primeiro lugar, os vários tipos de válvulas mecânicas cuja utilização se iniciou em 1960. Estabelecem-se as diferenças entre os vários modelos fazendo-se referência mais detalhada às próteses com oclusor de bola e, especialmente, àquelas em que o oclusor é de disco basculante.

Relaciona-se o fluxo e a turbulência com as complicações observadas neste tipo de válvulas em que a anticoagulação é obrigatória.

Em seguida descrevem-se as válvulas biológicas que também passaram por diversas fases de progresso, principalmente relacionadas com a preservação do tecido utilizado. A maior parte das actuais biopróteses é construída com válvulas aórticas de porco mas também, numa delas, se utiliza o pericárdio de vitela. Realça-se o papel do glutaraldeido como meio estabilizador a que se deve o progresso e durabilidade das biopróteses em que os anticoagulantes são habitualmente dispensados.

Finalmente menciona-se a estatística do Serviço de Cirurgia Cardio-Torácica dos Hospitais Civis de Lisboa estabelecendo-sae as razões da preferência pelo tipo de válvulas mais frequentemente usado.

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