SURGICAL TECHNIQUE

ELECTION OF CARDIAC VALVULAR PROSTHESIS FOR CARDIAC SURGERY

ABSTRACT

The objective of this paper is to describe cardiac valvular prosthesis, focused on performance and indications. Cardiac structural's diseases are main concern in the world because of people´s longevity and medical advances. The age alone is not a contraindication for surgical approach; therefore a good prosthesis is needed. The main characteristics are exposing: single implantation technique, flow, structural stability, immunogenicity, coagulation tendency and noise. Division between biological and mechanical type is just one issue. The design characteristic is important for make a correct decision. Nowadays, TAVI procedures comes to changes the future and that kind of prosthesis are describe.

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INTRODUCTION

Many years have passed since the implant of the first cardiac valvular prosthesis. This technique has allowed for the survival of countless patients. The cleverness of experts and the development of science have turned this into a routine procedure in all surgical centers worldwide[1]. Different valvular prosthesis models appeared sequentially, from the ball valve to the handmade designs created during the very procedure. Today, knowledge has set proposals and there is an agreement on the type and/or model to be used. The European and the American consensuses propose a use grounded on basic criteria, such as the age of patients, to advise on the use of two opposite aspects of cardiac valvular prostheses – biological or mechanical – without making too many contributions on the subgroups established within them[2-3]. Below, we will elaborate on the apparently simple but actually very complex issue of the surgeon's selection of the prosthesis to be implanted. The participation of

the patient and the intervening cardiologist in the selection is not discussed here, since the professional performing the implantation is the one who is usually familiar with the specific advances of the industry[4].

IDEAL VALVULAR PROSTHESIS

Today, there is not an ideal cardiac valvular prosthesis. If that were the case, we would not need to choose every time a valvular replacement were contemplated, whatever the valve involved. The following items are preconditions for optimal development.

1- EASE OF IMPLANTATION
2- HEMODYNAMIC PERFORMANCE
3- STRUCTURAL STABILITY
4- NON-THROMBOGENIC
5- NON-IMMNUNOGENIC
6- QUIET

EASE OF IMPLANTATION

In order to achieve universal utility, surgical techniques must comply with the requirement of reproducibility by the average ductility of surgeons. A technique that may be performed only by a person with special skills will not provide significant improvement to the large population suffering such pathologies. There is also a logical self-regulation that prevents its broad use. A great number of brilliant ideas could not be explained due to such limitation. It is absolutely natural that the surgeon chooses the simplest techniques with the best results[5] *(Figure 1)*.

HEMODYNAMIC PERFORMANC

At the initial stage of this kind of valvular prostheses, this issue was not so important. Valvular failures were so serious that having some mechanism available to solve the hemodynamic failure was considered sufficient. This explains the creation of so inefficient valves such as the Starr Edwards or the disc valve parallel to the valve plane[6]. The prosthesis must replace a valve with hydrodynamic function. It consists of a geometric area determined by the valvular ring and is calculated taking into account the surface of the circle. This already causes divergence between anatomy and theory, since current CAT studies confirm the ovoid shape of the aorta and the non-circular shape of the mitral plane already known. As it may be deduced, implanting a valve designed perfectly circular in shape implies divergence from the very beginning and usually makes it difficult to determine the number of valves to be implanted. Nowadays, the cardiac Doppler ultrasound test[7] is the best method for the hemodynamic evaluation of valvular prosthesis performance. In the future, the contribution of magnetic resonance will surely allow for a full analysis of cardiac flows. In addition to the geometric area, the effective orifice, which is the measure derived from quantifying the blood flow rate, can also be estimated. This allowed for the progress and improvement of valvular substitute designs. The proper size allows to avoid the difference between the orifice of the prosthesis and that needed

by the patient. When it is not the appropriate one according to body surface area and weight, there is a mismatch. The first mechanical valves were ball valves enclosed in a metallic cage (Starr). This kind of valves obstructed the flow deviating it to the peripheral prosthetic area. As the metallic cage had a great tendency to form blood clots, nowadays they are not used. The next step was to build a valve with metallic circular structure and a tilting disc on a stud that opens and closes with each pressure cycle. Opening angles varied according to each trademark. They offered good flow in large diameters but high gradients in small sizes. Therefore, they have been discontinued. There is a number of individuals bearing this kind of valves with very good distant survival in those without mismatch. The current state of mechanical prostheses is the division of the mono-disc in two semi-discs[8] that, when opened, do not obstruct the effective orifice, achieving significant hemodynamic improvement. The natural limit is the reduced development of the anatomic orifice of valves, which prevents the placement of larger valves. This has two solutions: one consists of enlarging the anatomic ring using prosthetic material, and the other consists of obtaining a different design of the prosthesis in which the suture ring is implanted over it and it is called supra-annular. This allows for a larger geometric orifice. Examples of these include the Carbomedics Top Hat valve, the St Jude Medical Regent valve and the Medtronic AP360 valve, even numbers *(Figure 2)*.

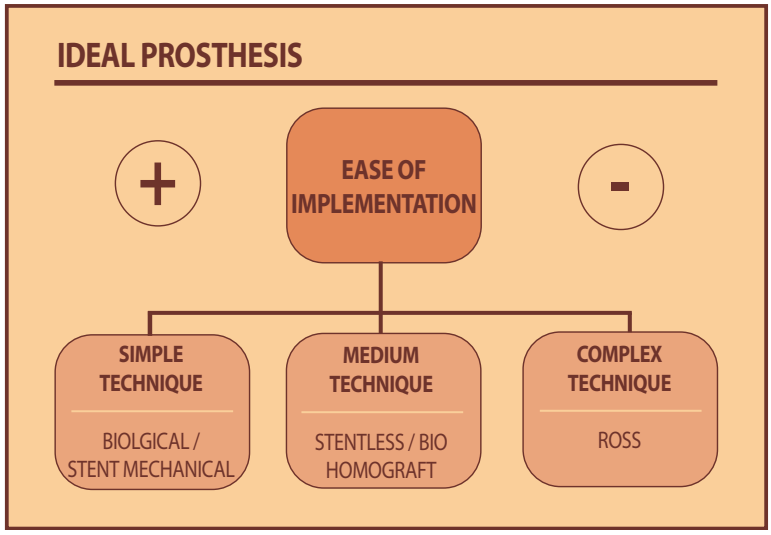

Figure 1. The simplest technique is for mechanical and biological prostheses with *stent*.

STRUCTURAL STABILITY

This concept means that the natural form and conditions of the valve at the time of implantation must not be altered over time. As expected, mechanical valves are the most stable, but initially several alterations, such as the breaking of the stud with embolization of the disc or discs, were informed. This may be tested by a piece of equipment called flow duplicator, in which the prosthesis is subject to mechanical stress situations, such as repeated opening and closing under high pressure and with high frequency. This allows in the laboratory to exceed the demand to which it will be subject to in the patient[9]. Current mechanical bileaflet prostheses have an almost

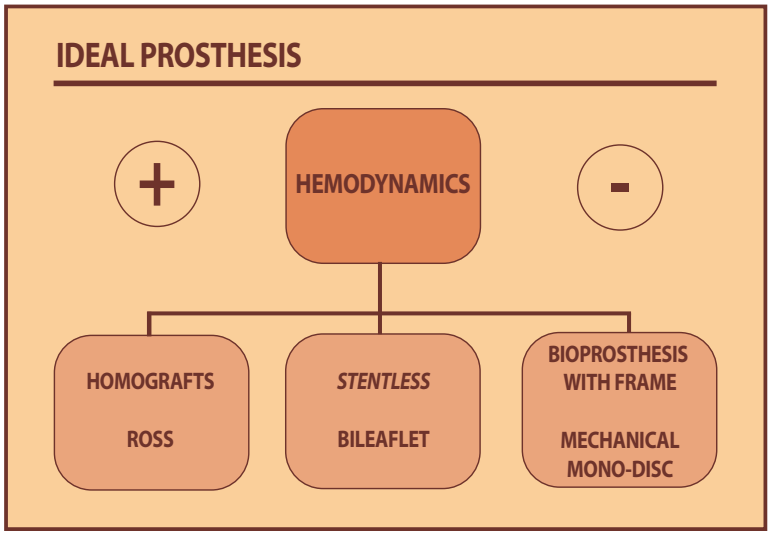

Figure 2. Homografts and the Ross procedure have the best hemodynamic performance, while stented bio-prostheses are the least efficient.

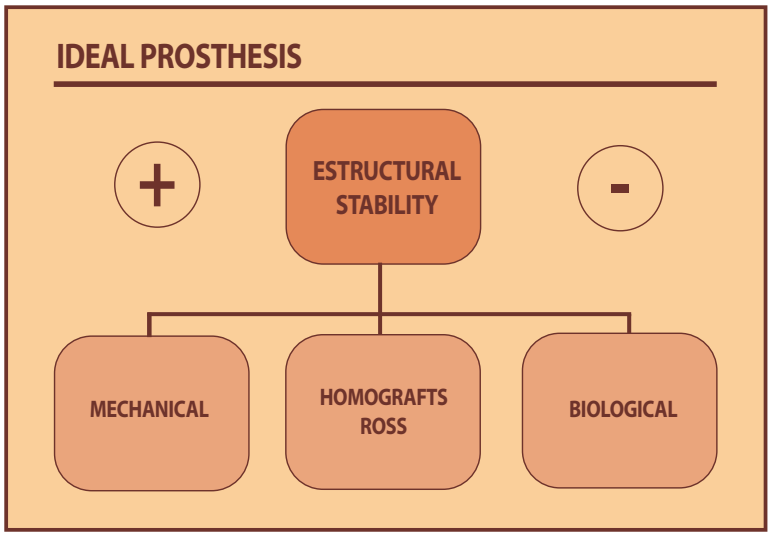

Figure 3. Mechanical valves are the most effective and the structure of biological valves is compromised over time.

optimal structural stability, since the annular frame and the disc socket are made from a solid metallic block, thus avoiding welds with failures. In biological prostheses, structural stability is seriously compromised due to the use of animal material, such as porcine or bovine, or human material. This causes a foreign body situation and an attack to it with fibrosis, retraction, calcification and even valve tearing, being more evident in younger patients [10]. Regarding the prosthetic design, they use complete porcine valves sutured over a rigid or flexible stent, such as the St Jude Medical Biocor valve or the Medtronic Hankok valve[11-12]. In some cases, such as Medtronic, even the complete porcine aortic root is used. Also, these valves are built using porcine pericardium, which is trimmed and sutured producing the valve shape. The use of the stent implies using part of the geometric ring, thus reducing the effective area. This led to the creation of valves with reduced stent or even without it. While it improves the flow, its implantation requires a very hard technique. A current alternative consists of recoating the outer part of the stent with the pericardium constituting the neo-valves, linked to a supra-annular ring, as in the case of the St Jude Medical Trifecta valve[13]. The homograft taken from human hearts has very good initial performance but suffers degradation for the same immunological reasons mentioned above and calcification usually occurs over the years[14] *(Figure 3)*.

NON-THROMBOGENIC

This characteristic prevents the use of anticoagulants for life with the risk of hemorrhage in the digestive tract, the central nervous system or the retroperitoneal system[15]. The possibility of embolisms is another serious associated complication, as well as the valvular prosthetic thrombosis. From the theoretical point of view, biological prostheses are close to the ideal valve, since they cause fewer embolisms due to the type of material. Instead, mechanical valves require the compulsory administration of dicumarin for life, with the strict control of the anticoagulation level by blood tests. There has been an attempt to experiment without oral anticoagulants in prostheses in aortic position with evidence of a low incidence of thromboembolism, but only one level below the international normalized ratio (INR) for anticoagulation was authorized. For biological valves, the current recommendation is initial anticoagulation for three months until the endothelialization of the ring and valvular sutures. However, in old patients with increased risk of anticoagulation, single anti-aggregation seems to be a good alternative. It should be mentioned that, in special situations, anticoagulation is

mandatory regardless of the valvular prosthesis used. Such situations are dilated left atrium associated or not with atrial fibrillation, ventricular malfunction and/or ventricular aneurysm. In mitral position, there is higher risk of thromboembolism in general and it deserves special consideration *(Figure 4)*.

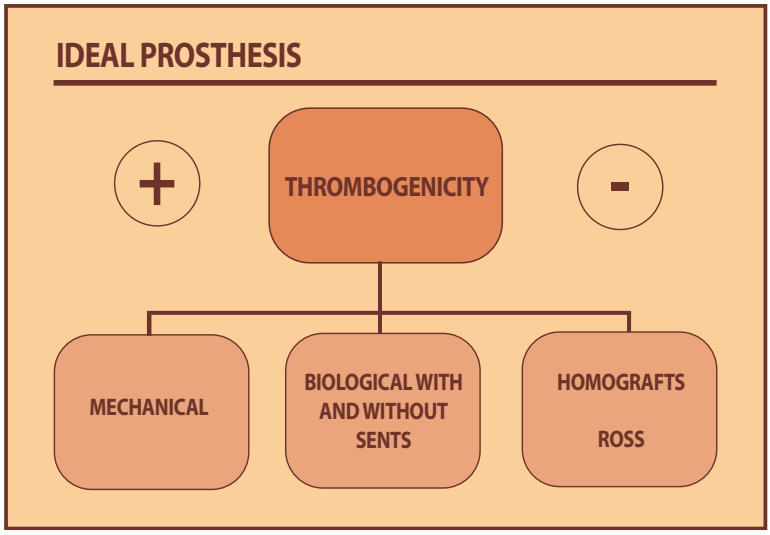

Figure 4. Mechanical valves are the most thrombogenic, thus requiring anticoagulation.

NON-IMMUNOGENIC

This is a requirement related to the structural resistance of prostheses [16]. Mechanical valves are made with components with adequate biotolerance, such as light ring alloys covered with dacron for suture or pyrolytic coal for discs. The latter is coal with a special treatment called pyrolyzation, which gives it diamond-like hardness and a surface with little platelet aggregation. It is high-tech material used in aerospace and missile elements. This is why mechanical prostheses do not cause known immunogenic reaction as biological valves do. These were created to be implanted in all patients but in young patients showed very marked early deterioration, with severe malfunction leading to a new surgery for the replacement of the affected valve. Immunodepressant therapy is not used to preserve prostheses, since it increases the probability of generalized infections, prosthetic endocarditis and neoplasms *(Figure 5)*.

QUIET

Today, this characteristic is not so important. Biological prostheses as well as mechanical bileaflet valves do not produce any special noise. In the first mono-disc designs, especially in the largest ones, the closing caused significant sound waves that were noticeable in some thoraces of special structure that acted as voice boxes. This caused the use of discs of plastic material like Delrin, which made them more quiet. However, the deterioration of this material caused its discontinuation[17]. There are still some patients with mono-disc prostheses whose heart beats are perfectly audible in a quiet environment, such as a doctor's office, a few meters away *(Figure 6)*.

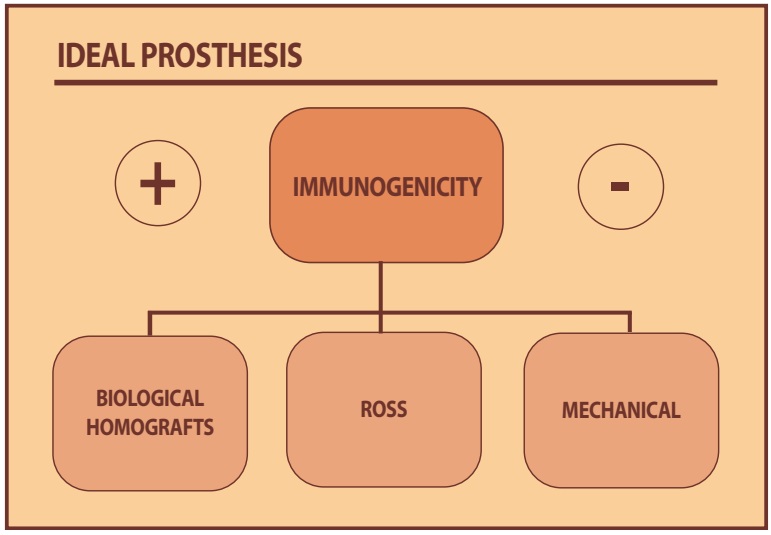

Figure 5. Biological xenografts cause great immunological reaction.

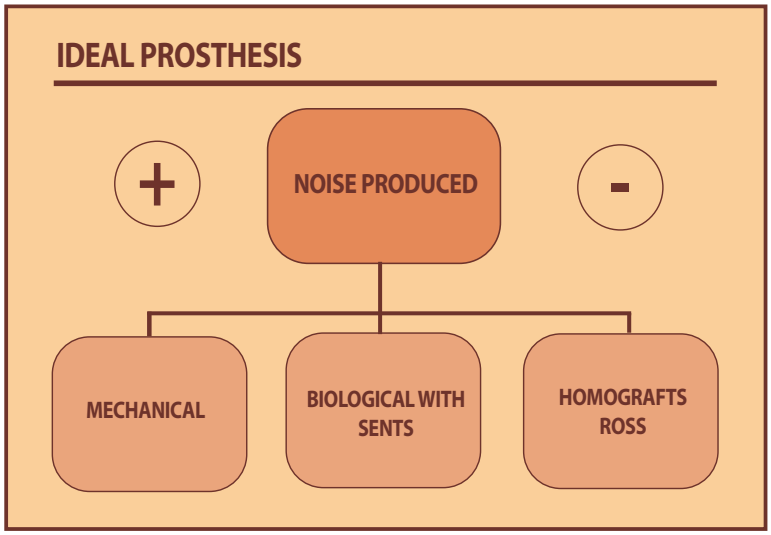

Figure 6. Mechanical valves are noisier.

SPECIAL CONSIDERATIONS TO CHOOSE THE SIZE OF A VALVULAR PROSTHESIS

The prosthesis must perform the function of the native valve replaced. This means that it should not have central or perivalvular failure. In addition, it must have an appropriate functional orifice. The functional orifice of a valve must relate to the body surface area, which depends on the height and weight of each individual. There are quick reference tables to determine them and establish a proportional rate per square meter[18]. The effective orifice is determined by Doppler ultrasound test and is a function that depends on the transvalvular flow rate and the orifice diameter[19]. The effective orifice in aortic valves ranges between 0.75 – 0.85 cm/m. The effective orifice in mitral valves must be higher than 1.2 cm/m. An orifice with a lower value establishes a mismatch, which must be avoided regardless of the existence of a divergence from long-term functional results. Medical literature provides tables to obtain the effective orifice of each valvular prosthesis. Special attention must be paid to the prosthesis numbering established by each manufacturer, since identical label numbers may correspond to different sizes of native rings required for implantation.

INSTRUCTIONS FOR BIOLOGICAL PROSTHETIC VALVE REPLACEMENT

There is general agreement, reached by consensus, on the implantation of biological valves for: patients older than 70 years, younger than 70 years with impossibility of permanent anticoagulation, limited life expectancy due to terminal disease. It should be taken into account that new European guides recommend to consider the age of 65 as cut-off point, due to good distant results with biological prostheses.

SELECTION OF THE TYPE OF BIOLOGICAL PROSTHESIS

• AORTIC HOMOGRAFT

CLASS I: endocarditis with destruction of aortic valvular ring.
Not recommended as aortic valvular substitute in other situations in young patients because of its high tendency to calcification and valvular malfunction.

• ROSS PROCEDURE

Great complexity and distant failure of lung homograft.
Specially recommended in young high-performance athletes and women expecting to get pregnant.

• BIOPROSTHESIS WITH CONVENTIONAL *STENT*
Patients with large valvular ring.

• BIOPROSTHESIS WITH VALVE SUTURED OUTSIDE THE *STENT*
Patients with small valvular ring.

• BIOPROSTHESIS WITHOUT *STENT*
Patients with small valvular ring and when the aortic root needs to be replaced. In the pre-implantation analysis, it should be evaluated particularly if it is a valvular design for intra-annular or supra-annular suture, as the techniques differ.

VALVULAR PROSTHESES WITH EXTRACORPOREAL CIRCULATION IMPLANT (TAVI)

This is the latest design of valvular prostheses. Conceptually, it is a stent with a biological valve sutured. The great advantage is that it is implanted with the thorax closed, through an arterial line of appropriate diameter – usually femoral, axillary or trans-aortic. Another advantage is that it causes less damage and, because of its structural design, can leave a very low residual gradient. The great disadvantage is that it leaves the ill native valve in situ and this may cause perivalvular leaks. A variation of this kind of valves is the valve created to be inserted through the left ventricle end, called transapical. As an advantage, it can avoid vascular tree difficulties for anatomy or pathology reasons. In addition, the proximity of the implantation area facilitates handling and implantation *(Figure 7)*.

TAVI INSTRUCTIONS

Given its biological condition, it falls within the general rules for this kind of procedure. Its use is recommended for those patients for whom surgery poses high risk. Usually, the high risk is conditioned by chronic pulmonary disease, previous heart surgery with permeable bypass, general fragility, and any other condition that may turn conventional surgery with extracorporeal circulation unfeasible.

SELECTION OF THE TYPE OF MECHANICAL PROSTHESIS *(Figures 8 and 9)*

• MECHANICAL BILEAFLET: currently, all valves comply with this requirement.

• INTRA-ANNULAR SUTURE RING: more frequently used; almost all brands have these designs.

Figure 7. Biological prostheses. From left to right: TAVI for aortic valve replacement (A), TAVI for pulmonary implantation (B), sutureless valve for conventional implantation (C), and valve without frame (D).

E F G H

Figure 8. Biological prostheses. From left to right: porcine root for replacement of aorta + valve (E), (F), two biological valves (G), and mechanical bileaflet valve at the right end (H).

• **SUPRA-ANNULAR SUTURE RING:** it allows implanting valves with larger effective orifice for the same ring diameter. Example: the Carbomedics Top Hat valve, the St Jude Medical Regent valve and the Medtronic AP360 valve. ■

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A B

Figure 9. Mechanical valve with intra-annular suture ring (A) and supra-valvular ring (B).

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