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Chapter 1

New Polyurethane Prostheses for Substitution of Cardiac Valve Disease and Remodeling of the Right Ventricle in Congenital Heart Malformations

Miguel A. Maluf, Hector A. Barone and
Fabricio Sena

Additional information is available at the end of the chapter

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1. Introduction

The presence of an obstruction in the outflow tract of the right ventricle (RV) consists of a relatively common defect, present in 20% to 30% of cyanotic congenital heart diseases. The extreme degree of pulmonary obstruction is pulmonary atresia (anatomical discontinuity between RV - Pulmonary Artery), present in approximately 5% of patients with heart defects. In these situations, surgical treatment may require the use of a prosthesis or implantation of a valved conduit to reconstruct the pulmonary valve and outflow tract of the RV. Different valve replacements have been proposed, including the fresh aortic homografts, pulmonary heterografts, pig or bovine pericardial prostheses. Amongst the valved conduits we have: bovine pericardial grafts, porcine pulmonary graft, bovine jugular containing Dacron prostheses, aortic homograft, or more recently, pulmonary homografts. Mechanical prostheses were virtually abandoned. Whichever type of replacement valve used, many studies have reported calcification or tissue degeneration associated to pseudo-intimal proliferation and progressive obstruction of the conduit [1], [2], [3], [4], [5] with the need for reoperation, the incidence of which may vary between 14% and 30% at 5 years and 32% to 100% at 10 years. [4], [5], [6], [7], [8] In 1991, we began a new experience in the Cardiovascular Division of the Federal University of São Paulo (Unifesp), using 2 models of biological prostheses: heterografts (swine) treated with glutaraldehyde and formaldehyde [9], adding in recent years other 2 models. These 4 different prostheses were implanted in 203 children with heart defects that required reconstruction of the pulmonary valve and right ventricular outflow tract. [10] The late outcome of these patients is represented by actuarial Kaplan & Meier curve: The survival of these patients

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was 86.6% operated and free reoperations in 68.3% of cases, in 180 months of median rate of follow-up. (Figure 1) The most frequent cause of reoperations was calcification, tissue degeneration and loss of function due to growth of the patient.

The implantation of a bioprosthetic porcine valve in a patient, is considered as a form of living tissue transplantation. Xenotransplantation, which usually has a very aggressive form of rejection by the immune system of the patient. Aiming to reduce this type of immunogenicity, bioprostheses are fixed in glutaraldehyde solution, with the intention of transforming the tissue graft immunologically inert.

However, bioprostheses that were fixed in glutaraldehyde also have the propensity to calcify. This calcification is a major contributor for dysfunction of cardiac bioprostheses due to the pre-treatment of biological tissue with glutaraldehyde to devitalize the cells ceasing residual cells that become the primary sites for deposition of calcium phosphate. The reaction of calcium with the extracellular fluid associated with the reactions of phosphorus to the cell membrane causes pathological calcification of bioprostheses.

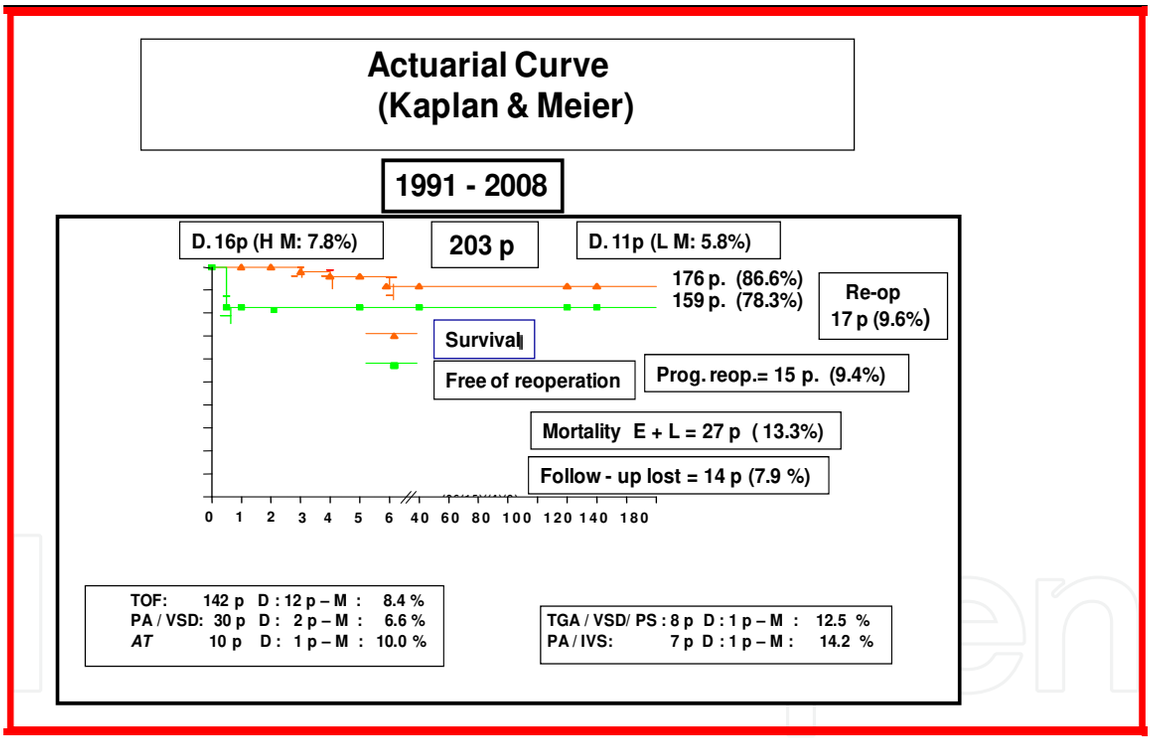

Figure 1. Actuarial curve of patients undergoing reconstruction of the pulmonary valve and outflow tract of the right ventricle with pulmonary heterograft. (Miguel Maluf, *The Heart Surgery Forum 2011; 14 (1): E40-50.*

Despite the deterioration of the heterograft keeps the order of 35% to 45% in 15 and 20 years, respectively. There are always isolated cases with long postoperative course, without compromising tissue or calcification of porcine bioprostheses. [11].

During the last decade there was an excellent immediate biocompatibility of *polycarbonourethane* valves *(PCU)* used in temporary ventricular assistance. [12] Although the follow-up in

this group of patients is quite short, low rates of thromboembolic complications and no failures or calcification have been documented. Such valves were implanted experimentally, replacing heart valves and satisfactory results in long-term left ventricular assistance devices in between the apex of the left ventricle and the aorta. [13] Furthermore, the replacement valve is used in a next generation of total artificial heart implants. [14] However, the intermediate result of such artificial valves, when the prosthesis is implanted on the right side of the heart, exposed to low pressure and low levels of oxygen saturation, the prosthesis would have increased durability. The *segmented polyurethanes (SPUs*) are a class of versatile material possessing various controllable properties. This unique feature can make them advantageous for use as biomaterials, structural materials and other applications.

More than 50 years of research has been devoted to this area, which led to an understanding of the synthesis, structure and properties of these fascinating materials. In general, the *SPUs* have a structure comprising a *macrodiol* "soft" segment (SS) and *urethane* "hard" segment (SH), each segment has an incompatible composition with the separation of different phase driving nanoscale domains which control properties of *SPUs*. It is believed that HSS, glassy or crystalline, has the melting temperature (Tm) above room temperature. Forman domains are on the order of a few tens of nanometers. These domains SSs, are difficult to separate and are generally formed at low temperature to the glass transition (Tg) of amorphous to crystalline.

2. Objectives of research

The objectives of this study are:

To build a heart prosthesis of *segmented polyurethane (SPU)*

2.1. Methods

a. Drawing in 3D of a human aortic valve, obtained from an examination of Angio-Computerized Tomography (Angio-CT)

b. Matrix of the prosthesis.

c. Prepare of segmented polyurethane (SPU).

d. Manufacture of prosthesis by injection of SPU in the matrix.

2.2. Building a model of segmented *Polyurethane (SPU)* prosthesis

a. Design of the prosthesis in 3 D and Manufacturing of Moulds:

The 3-D drawing for manufacturing of the *polyurethane* was based on anatomical characteristics of Angio-CT of the human aortic and pulmonary valve.

We considered internal and external diameter, shape of the ring and stem where they operate the valve leaflets.

The valve leaflets were preserved, an angle of 120° from the place of central coaptation to the base of the valve ring deployment. Each leaflet has a thickness in the central region of the free edge of 0.2 mm and 0.5 mm in the rest of the extension. The program to be used for the design of this prosthesis is generated by Solid Works software, the computer program generates mesh and solid parametric.

Figure 2. Angio Computerized Tomography (Angio-TC) of a human Aortic Valve

- Modeling of the Ring and Membrane

From pre-established dimensions by Angio-CT, the software was modeled using the ring and the membranes of the 3 cusps. figures 2,3,4

- Drawing of the Ring

Figure 3. Drawing of a prosthetic ring

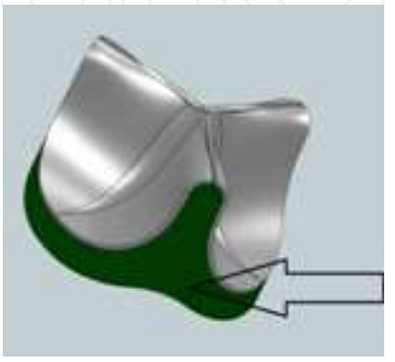

Figure 4. Drawing of three leaflets of the membrane, with the prosthetic ring

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b. Making the Matrix

The array was fabricated on a machine called "Vertical Machining Center". It is nothing more than a machine tool with computer numerical control. Utilizing cutting tool, and stainless steel plant directly. Figures: 5,6,7

Figure 5. Matrix made of stainless steel

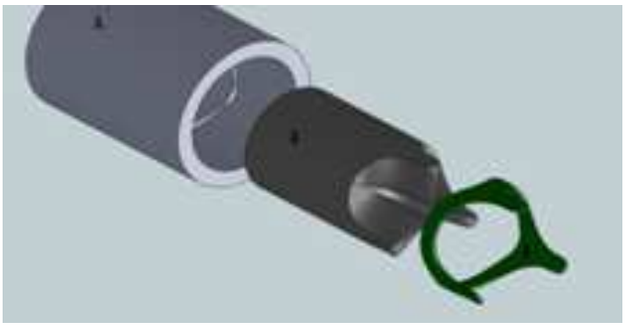

Figure 6. Coupling ring in the matrix and stainless steel support

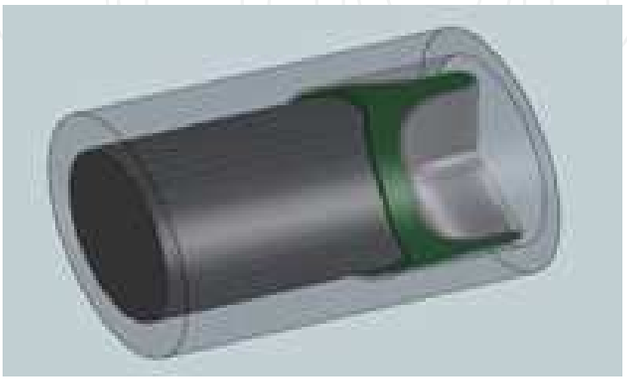

Figure 7. Coupling of the matrix to the ring and support for the filling with *segmented polyurethane (SPU)*

c. Manufacturing segmented polyurethane prostheses

Among the polymeric materials used in clinical practice, *polyurethanes* have paved their place in the market and are the best choice for application in the field of medical implants. Present biostability, biocompatibility, high lubricity, strength, abrasion resistance and fatigue is also easy to use, presenting flexibility and resistance to thromboembolism. These are some of the reasons why *polyurethanes* are used for a variety of medical devices. To develop a prosthetic heart it will be necessary to use a polymer that has the characteristics described above, it is necessary hemodynamic and biophysical testing to rate the quality of the material.

- Polyurethanes

Thermoplastic *polyurethanes* exhibit a wide range of technological applications due to the versatility of the chemical structure and properties that can be achieved from various commercially available *diisocyanates* and *alkanediols*. Additionally, the physical properties achievable in these materials can be enlarged by the relative concentrations of the raw materials capable of producing polymers.

The *polyurethanes* exhibit microphase separated structure comprising soft segments and hard segments. The flexible segments are formed usually from oligomers with long segments such as *methylene*, *oxy-alkylene*, or other *aliphatic* sequence, while the hard segment is formed by *urethanic* segments resulting from the reaction of short chain *alkanediols* and *diisocyanates*. The highly polar nature of the urethane linkages is responsible for the thermodynamics of phase separation micro-heterogeneous, which together with the possibility of formation of crystalline phase in the hard and soft phases, make complex relations between these various domains and the physical and mechanical behavior observed. Additionally, it is noted that the formation of these domains in *polyurethanes* is also a function of its processing, since, in general, the thermodynamic equilibrium is not achieved in these materials during their transformation process. In order to ensure consistent performance of the product it is essential that its microstructure does not change significantly with time. Thus, for applications with high demands is the use of appropriate heat treatment, annealing, and the environmental application similar to the use of the product, where in contact with blood, subjected to cyclic strain. It is noteworthy that the use of dynamic mechanical thermal analysis allows detailed tracking of transformations undergone by the product according to the process of thermal annealing and contact with fluid.

d. Manufacturing prostheses by injection of PCU matrix

In this design, it is intended to prepare *polyurethane* membranes from different sources using the techniques of hot pressing and evaporation of the solution. Prepare membranes with different thicknesses in the range of 50 to 200 *um*. These membranes are subjected to thermal annealing treatments in idealized fluids simulating blood.

The membranes obtained under different conditions are identified, using the techniques of X-ray diffractometry, differential scanning calorimetry and dynamic mechanical thermal analysis, among others. Additionally, ultrasound technique allows the analysis for the

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presence of defects in 100% of the membranes to be employed in the construction of prosthetic heart *polyurethane*. Figure 8.

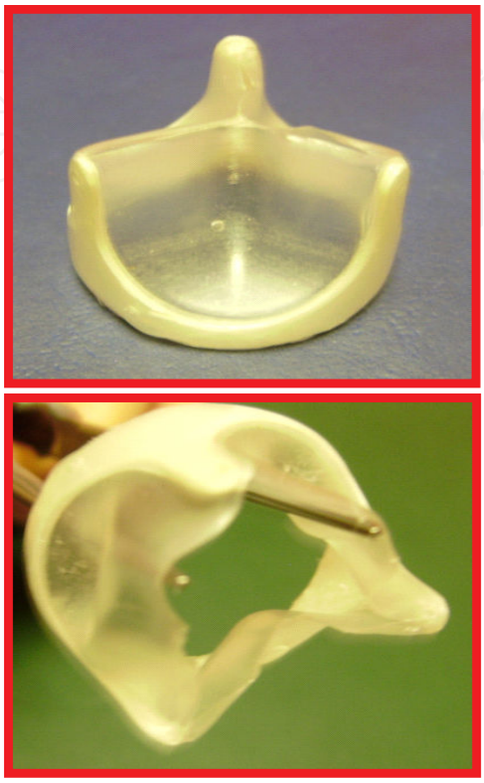

Figure 8. Prototype of *Segmented Polyurethane(SPU)* prosthesis.

3. Discussion

3.1. Durability of *polyurethane* prosthesis tested "*in vitro*"

The *SPU* prostheses have shown a useful life of over 130 million cycles in real time and 420 million cycles at accelerated conditions without failure of the *SPU* [13]. *In vivo* conditions, the longest period after implantation was 399 days, performing euthanasia due to the excessive growth of the animal. [13] In summary, these data demonstrate the good hemodynamic performance behavior of the implanted SPU prosthesis right side of the heart, in particular lack of a significant pressure gradient after 1 year of implantation. This study confirms the good biocompatibility of *SPU* (low thrombogenicity in animals without anticoagulant therapy) and short-term durability of such compounds without the use of anti-calcification in a model of accelerated mineralization.

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