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BIOLOGIC ORGANIC VALVULAR PROSTHESIS PORCINE

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Introduction

The diseases that affect cardiac valves cause major damage to health, compromising the circulatory system's activities, impairing the patient's quality of life. Among these illnesses is aortic stenosis, responsible for up to 60% of the deaths, mainly among elderly[(1)]. Aortic stenosis affects approximately 3% of the population above 70 years old.

The gold standard in the treatment is surgical intervention, with native valve replacement by a bioprosthesis, being classified as a high complexity procedure. Among the prosthesis available, there are mechanical valves, which require anticoagulant administration during the patient's entire life, and biological valves that, as a long-term problem (around 15 years average), shows a deterioration of their leaflets, with a new operation being required to replace the valve[(2)].

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The **BRAILE BIOMÉDICA BIOLOGIC PORCINE ORGANIC VALVULAR PROSTHESIS®** is one of the biological devices for aortic stenosis treatment. Several studies report the quality of this bioprosthesis, stressing the low calcification content, the resistance to mechanical fatigue, and dispensing anticoagulants. In addition, there is a very low incidence of thromboembolism and late mortality[3] found in the follow-up studies of patients submitted to treatment with this type of product.

According to Davila *et al*.(1978), the porcine valve is superior to the mechanical valvular prosthesis when in a mitral or tricuspid position, in addition to having high durability[3]. Maluf *et al*.(2000) affirmed that the porcine valve is efficient in the correction of Fallot tetralogy, having satisfactory results in the medium term[4].

Considering that one of the main causes of organic bioprosthesis deterioration is calcification, the **BRAILE BIOMÉDICA BIOLOGIC PORCINE ORGANIC VALVULAR PROSTHESIS®** is subjected to a specific treatment (see below) to reduce the incidence of such phenomenon, increasing its durability and reducing the need for new interventions.

Indication

BRAILE BIOMÉDICA'S BIOLOGIC PORCINE ORGANIC VALVULAR PROSTHESIS® (Figure 1) is indicated for replacing the mitral, aortic, tricuspid and pulmonary valves.

Manufacturing

They are made with a flexible polyacetal support, coated by a thin film of organic material, on which the cuspids are mounted. A stainless-steel ring 316, medical degree, inserted in the support base, reinforces its consistency and enables to identify the valve's position in the patient by a simple radiology exam.
They are provided in the diameters 19, 21, 23, 25, 27, 29, 31, 33 and 35 mm, in a formaldehyde 4% solution, non-pyrogenic, with sterility guaranteed by a validated procedure.

Figure 1. BRAILE BIOMÉDICA® BIOLOGIC PORCINE ORGANIC VALVULAR PROSTHESIS..

Anticalcifying Processing and Treatment

The manufacturing process of the **BIOLOGIC PORCINE ORGANIC VALVULAR PROSTHESIS®** is performed within the standards required by BPF-ANVISA and complies with ISO 13485, with quality control based on the evaluation of its physical properties and hystological integrity, from the collection of porcine valves to the end of its processing.

The porcine valve's cusps, after processing with glutaraldehyde (GA), are subjected to an oxidant treatment developed by Braile Biomédica® to reduce the GA's polymeric bindings and the free aldehyde groups present (Figure 2), which provenly contribute to the calcification of post-implant valvular bioprosthesis[5].

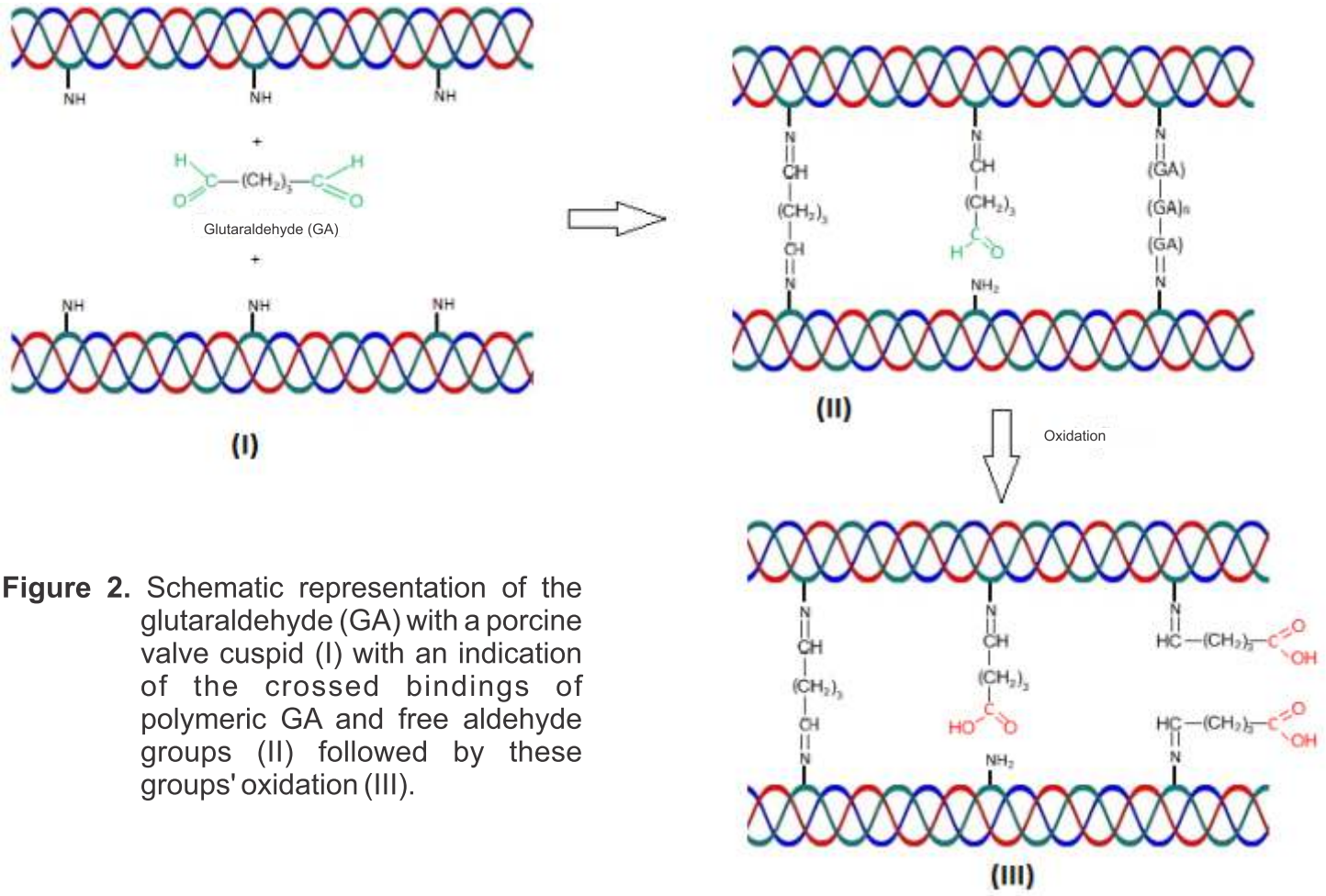

Figure 2. Schematic representation of the glutaraldehyde (GA) with a porcine valve cuspid (I) with an indication of the crossed bindings of polymeric GA and free aldehyde groups (II) followed by these groups' oxidation (III).

This treatment's effectiveness is confirmed by the significant reduction in calcification observed for the bovine pericardium (BP) submited to the same process, both in rats [6] and sheep's[7] subcutaneous. The calcification rates lower than 5 µg Ca/mg of dry tissue, being very favorably compared to other anticalcifying procedures described in literature and used in the fabrication of valves processed with GA[8-11]. In rats' subcutaneous, the calcification rates of bioprosthesis fabricated with porcine and BP valves treated only with GA without anticalcifying treatments are high and greater than 100 µg Ca/mg of dry tissue[12,13].

Hydrodynamic Performance

Hydrodinamic performance trials were performed in compliance to Technical Standard ISO 5840:2005/(R) 2010 - Cardiovascular Implants - Cardiac Valve Prostheses (Table 1) to evaluate the following parameters:

- Effective Orifice Area (EOA): internal valve area, in cm^2, which effectively opens during the cardiac cycle, under constant flow and pressure;
- Mean Pressure Gradient (Δ P): transvalvar pressure gradient, provided in mmHg;
- Regurgitation Fraction: volume, in percentage, which returns during valve closure (sum of the closure and leakage volumes), in regard to cardiac output.

Table 1. Hydrodynamic performance requirements of ISO 5840:2005/(R) 2010.

Parameter	Aortic / Mitral Position		
Valve Diameter (mm)	19	25	31
AEO (cm^2)	≥ 0.70	≥ 1.20	≥ 1.80
Fração de Regurgitação (%)	≤ 10	≤ 15	≤ 20

The results of these parameters' behavior for 19, 25 and 31 mm valves are illustrated in figures 3, 4 and 5.

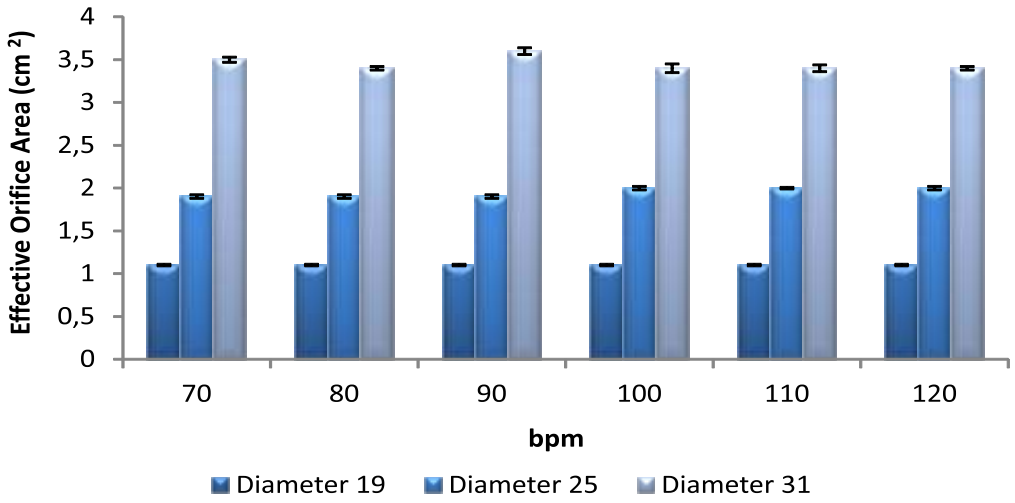

Figure 3. Effective orifice area (EOA) for the **BRAILE BIOMÉDICA BIOLOGIC PORCINE ORGANIC VALVULAR PROSTHESIS®** of 19, 25 and 31 mm diameter.

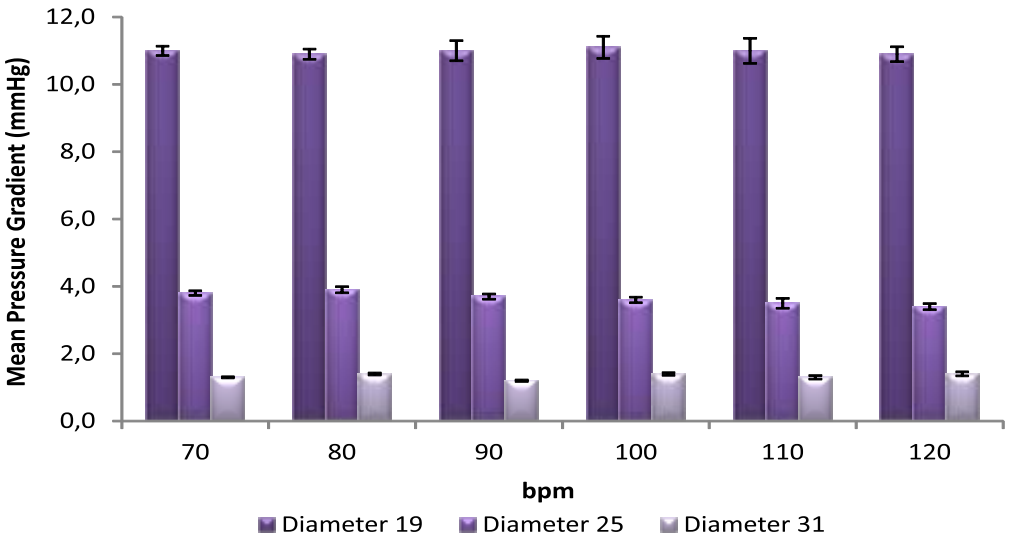

Figure 4. Mean pressure gradient (ΔP) for the **BRAILE BIOMÉDICA BIOLOGIC PORCINE ORGANIC VALVULAR PROSTHESIS®** of 19, 25 and 31 mm diameter.

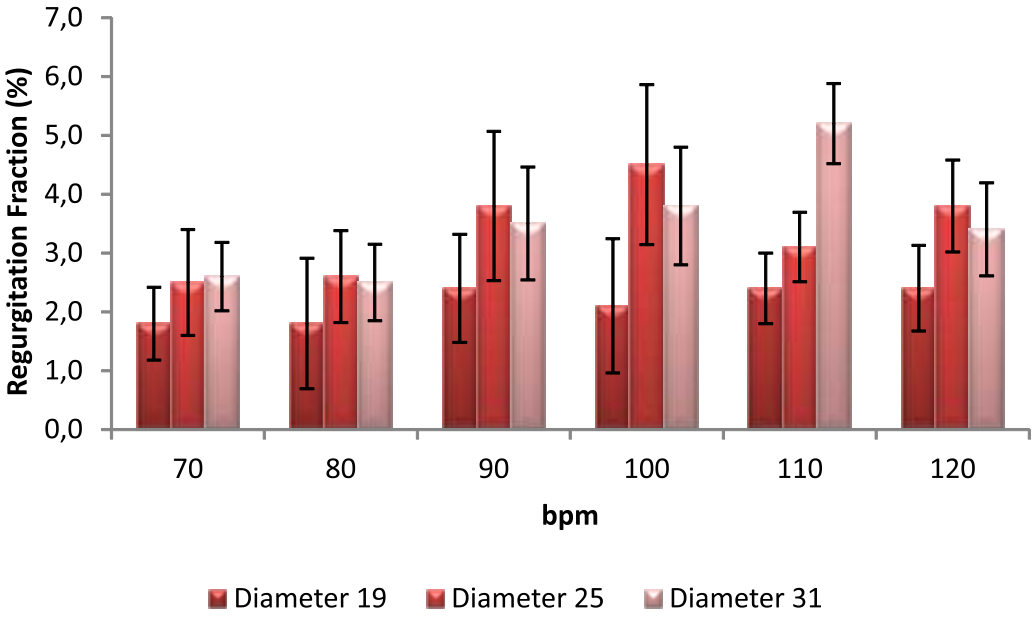

Figure 5. Regurgitation fraction for the **BRAILE BIOMÉDICA BIOLOGIC PORCINE ORGANIC VALVULAR PROSTHESIS®** of 19, 25 and 31 mm diameter.

These results are in agreement with the data previously obtained[14,15], according to the Technical Standard ANSI/AAMI/ISO 5840:1996 (ANS). The clinical use of **BRAILE BIOMÉDICA BIOLOGIC PORCINE ORGANIC VALVULAR PROSTHESIS®**, after the Health Department's approval for commercialization in Brazil, began in 1990, with over 50 thousand units produced within the quality standards that characterize Braile Biomédica's products®.

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