EFFECT OF THE STERILIZATION PROCESS ON PHYSICAL AND MECHANICAL PROPERTIES OF THE BONACRYL BONE CEMENT

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***Abstract*– The use of bone cements of poly(methyl methacrylate) (PMMA) to fix artificial prosthesis to the human body is a habitual method in orthopedic surgery. The hip and the knee joints have a very complex biomechanics and support high loads, for these reasons, acrylic bone cements have to comply with international standards in order to secure the biofuncionality and durability of the implant.**

In this work we report the effect of sterilization by ethylene oxide or gamma radiation on the BONACRYL Cuban cement. We determined how sterilization methods affect the molecular weight of the polymer as well as its quasi-static mechanical properties. The results demonstrated that the gamma radiation modifies the molecular weight of the PMMA although the compression and bending strength were not affected by the sterilization process applied.

***Keywords*— bone cements, poly(methylmethacrylate), sterilization, mechanical properties**

I. INTRODUCTION

Acrylic bone cements are widely used in orthopedic surgery to fix artificial prostheses in the body osseous structure (Charnley, 1970). The success of a hip arthroplasty depends on a great number of factors. Statistical data show that the cemented prostheses fail due to septic processes, the mechanical breakage of the acrylic cement or prostheses, or the loosening of bone/cement and cement/prostheses interfaces (Horowitz *et al.*, 1993). Bone cement failure through crack initiation, propagation and fracture may be a critical factor in the process of failure of the implant. Since in most of the cases the cement contributes to the failure of the implant, it is necessary for the cement to have the adequate properties to guarantee implants durability (Horowitz *et al.*, 1993; Willert *et al.*,1990).

The acrylic bone cement is composed of a solid and a liquid part. The solid part consists of PMMA beads, barium sulfate as a radiopaque material, and benzoyl peroxide as the initiator. The liquid part is usually formulated by using methyl methacrylate as the monomer, hydroquinone, which prevents earlier polymerization and N,N-dimethyl-p-toluidine, which accelerates initiator decomposition. Cement setting takes from 5 to 15 minutes which permits a firm and immediate anchorage of the implant to the body structure. Cement setting takes place as a result of radical polymerization. Because of the complexity of the biomechanics of the hip joint and the high loads that they have to support some static mechanical properties have to comply with international standards in order to secure the biofuncionality and durability of the implant (ISO 5833, 2002).

In this work we report the effect of the sterilization by ethylene oxide and gamma radiation on the Bonacryl Cuban cement on molecular weight of the polymer beads and in some quasi-static mechanical properties of the bone cement.

II. METHODS

A. Bone Cement

The liquid part of the Bonacryl bone cement is composed by 97.3% vol. methyl methacrylate, 2.7% vol. N,N-dimethyl-p-toluidine and 80 ppm of hydroquinone. The solid part of the Bonacryl cement consists on 90% wt. of a mixture of two types of PMMA beads (A and B) and 10% wt. of barium sulfate from Fluka. The bead mixture was prepared by mixing A and B beads (Table 1) in a ball mill in a proportion of 80/20 wt. By means of Iodinemetry it was found that the PMMA beads had a 2.63 ± 0.02% of residual peroxide, which is in the range of the amount required for the polymerization of the Bonacryl, so more peroxide was not added to the solid formulation. A 2/1 solid/liquid ratio was used for all formulations

To determine the effect of sterilization, 25 samples consisting each one in 1.0 g of the solid part were sterilized with ethylene oxide using a ED-100 Sakura equipment. Samples were wrapped with paper and introduced into the sterilization camera containing 20% ethylene oxide and 80% carbon dioxide, where they were maintained at 60 °C for 6 hours. Then the samples were desgasificated for 8 hours. Also, other 25 samples consisting each one in 1.0 g of the solid part were sterilized by gamma radiation using an laboratory blinded irradiator (PXM-Gamma 30, Russian made) using a Co^{60} source at a dose of 25 kGy.

B. Beads characterization

The molecular weight of polymeric beads, before and after sterilization, were determined by viscosimetry at 23.0 ± 0.1°C using an Oswald viscosimeter. The beads