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Comparative Study of Radiation Process from Gamma and Electron Beam Sources in Blood Bags at Sterilization Dose Range

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1. Introduction

Polyvinyl chloride (PVC) as blood storage bags began to be used in the mid-20th century because they are lightweight, resistant, transparen and malleable, characteristics guaranteed by the use of plasticizing additives that increase the polymer's flexibility [1]. In Brazil, in 2024 alone, more than 3.3 million donations were registered [2], with a corresponding number of bags for their storage. The most common sterilization method is that using ethylene oxide (EtO), which is effective, but has disadvantages such as the generation of waste in the material and risks to the health of workers [3].

Sterilization using ionizing radiation (gamma, electron beam, or X-rays) is a widely used technique for medical devices, representing approximately 45% of global demand. This process offers high efficiency, speed, and the ability to sterilize packaged products. However, its application to polymers, especially polyvinyl chloride (PVC), presents significant challenges due to their sensitivity to radiation.

In this study, blood bags were subjected to irradiation using both gamma radiation source and an electron accelerator at doses close to the sterilization dose of materials (10 kGy to 30 kGy). The effects of the process on this material were evaluated in mechanical terms (tensile tests) and by its yellowing index in post-irradiation periods from 1 day to 635 days. Mechanical tests assess the resistance of the polymeric material based on its viscoelastic behavior and the yellowing index evaluates the degradation of the material due to dehydrochlorination (loss of HCl) in response to ionizing radiation, the objective of this work. The results were presented and discussed, providing novel information on the behavior of this polymer constituent of the medical device in question, especially in the initial stages of its natural aging.

2. Methodology

In this study, blood bags were subjected to gamma irradiation using a ^{60}Co source (BRIT – India) and to electron beam radiation from a 1.5 MeV Dynamitron model Job188 electron accelerator (DC1500/25/4), at doses close to sterilization (10 kGy to 30 kGy). All dosimetry of the irradiation process in each source was performed from readings of red perspex dosimeters placed throughout the area of interest (flat region of the device – approximately 9 dosimeters per irradiated bag), excluding tubular and other parts with specific geometry.

After the irradiation process, the blood bags were exposed to the conditions of a climate-controlled room (temperature of 23°C ± 1°C and relative humidity of 40% to 60%), and were characterized at intervals of 1 day, 15 days, 35 days, 210 days and up to 635 days (evaluated only for blood bags processed by electron beam). The characterization of the effects of radiation on the aged material under these conditions was carried out using mechanical tests and yellowing index.

Mechanical tensile tests were performed on an Instron model 5567H universal testing machine, using dumbbell-shaped specimens cut from the medical device in question using a cutting template based on the ISO527-1B standard; a 1000 N load cell and a displacement rate of 20 $mm.min^{-1}$ were used. Stress-strain curves were obtained from 5 specimens from each irradiated blood bag at each aging period studied, and the following parameters were calculated: modulus of elasticity (Young's modulus) and tensile strength..

Yellowing index measurements were obtained using a BYK Spectro-Guide 45/0 Gloss colorimeter. The CIELab methodology was used, where the *b* parameter was used to evaluate the degree of yellowing of the samples. For each irradiated blood bag in each aging period studied, a series of measurements was obtained, resulting from 5 readings: one at each upper end (right and left), one in the center, and one at each lower end. Before each series of measurements, the equipment was calibrated with its factory standards (light trap, white color and glossy black).

All tests were performed at room temperature (23 °C ± 2 °C). The final value of each parameter measured for each irradiated blood bag in each aging period studied was the arithmetic mean of each series of measurements with its respective standard deviation.

3. Results and Discussion

Figure 1 shows the stress-strain curve for the PVC samples that make up the blood bags, where up to 40% strain the stress is directly proportional to the strain, which corresponds to the elastic behavior region of the polymer. Above this value, the material assumes a plastic behavior. From these curves, the mechanical parameters for each sample and at each storage period were calculated and shown below.

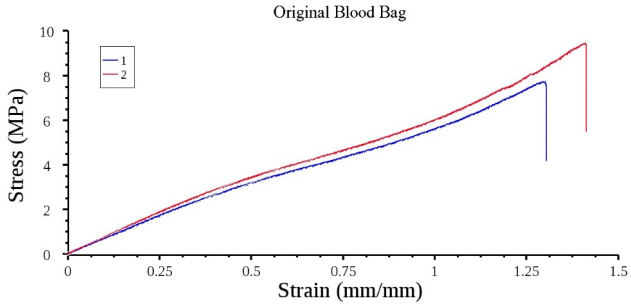

Figure 1: Stress-strain curve of samples from the original blood bag.

Figure 2 shows the behavior of the modulus of elasticity (or Young's modulus) as a function of storage time, a parameter that assesses the stiffness of the material. These results show that, in samples irradiated with both types of source, this parameter presents higher values than the original sample in the first days after irradiation; maximum values are reached within 15 days of storage. After this period, the parameter reaches a minimum value (at 30 days) and then increases again, reaching constant values at longer storage times, indicating that the material becomes stiffer and consequently deforms less intensely, which may be an advantage of the methodology if this medical material needs to be stacked.

The tensile strength limit as a function of storage time is shown in Fig. 3. This behavior is also similar in samples irradiated with both sources used. In periods from 1 to 15 days after irradiation, the values of this parameter are high; however, they reach their lowest values at 30 days, and may even fall below that of the original sample depending on the irradiation source/dose, indicating the prevalence of the scission mechanism of the constituent molecules of the polymer; the values after this period increase above the value of the original sample until reaching constant values, indicating that in this post-irradiation period, polymer crosslinking is predominant.

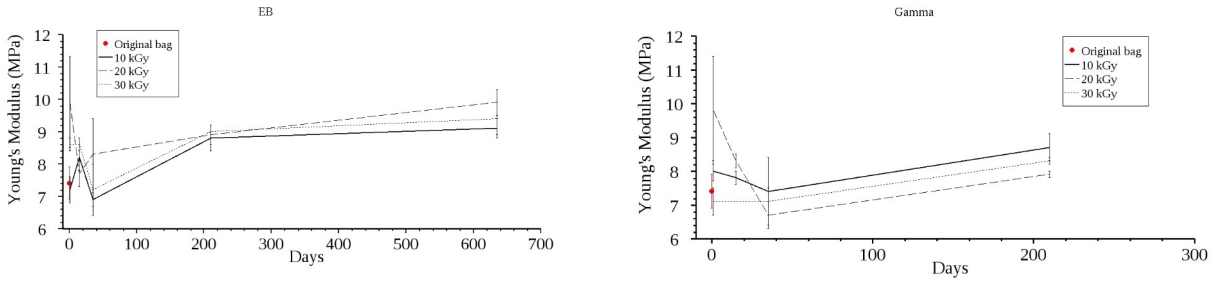

Figure 2: Young's modulus in irradiated samples from EB and gamma sources at different doses as a function of storage time.

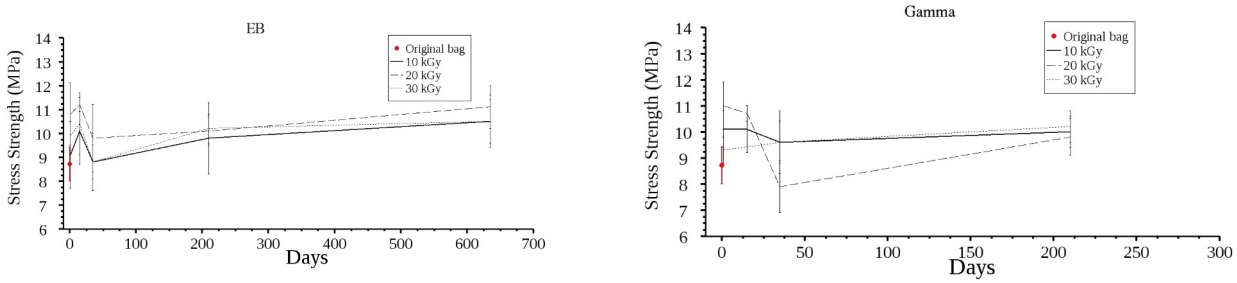

Figure 3: Tensile strength of irradiated blood bags from EB and gamma sources.at different doses as a function of storage time.

The yellowing index (YI) as a function of post-irradiation time is shown in Fig. 4. The yellowing index is an indicator of polymer degradation; in PVC, this degradation occurs both through chain scission and C-Cl bond breakage [4]. The results obtained show that the behavior of this parameter is distinct in the samples irradiated with each type of source: In electron beam irradiation, on the first day post-irradiation, the YI has higher values than naturally found in the original sample; with increasing storage time, these values also increase until they reach constant values, always above the value of the original sample.

Conversely, when polymer samples are irradiated with a gamma source, the first day after irradiation shows the highest values in the series of measurements, values that are above those of the original sample; over the days following irradiation, these values decrease and, depending on the dose, may reach values lower than those presented by the original sample. These results suggest that electron beam irradiation induces an autocatalytic mechanism for breaking C-Cl bonds, which reach a steady state at long storage times; in the case of gamma irradiation, the C-Cl bond cleavage initially occurs on a large scale, but decays over the storage time.

a) b)

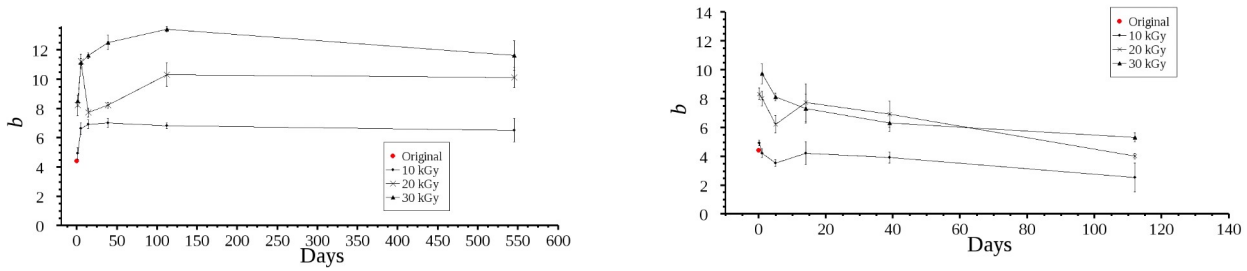

Figure 4: Yellowness index at original and irradiated blood bags samples from: a) EB and b) gamma sources.

4. Conclusions

PVC of blood bags shows minimal quantitative and qualitative differences in mechanical parameters in the post-irradiation period using both electron beam and gamma sources, which shows convergence in both used ionizing irradiation methods. Also, mechanical behavior in function of storage time suggest that the simultaneous mechanisms of degradation and crosslinking are distinct and one prevails over the other depending of the post-irradiation time, specially in the first 35 days of storage. However, PVC chains degradation is accompanied by the breaking of the C-Cl bond and this mechanism is distinct in both radiation sources, showing a specific kinetic mechanism.

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