Acknowledgements to CNPq by support this work (project n° 520015/2000-1)

IRAP141 — OK

The importance of the cytotoxicity packaging examination for biological tissues before and after irradiation

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Biological materials which are stored in Tissue Banks must be conditioned in packaging that should physically protect the products during shelve life. Such packaging should also withstand handling, storage temperatures and eventually, complementary processing steps such as terminal sterilization. Nowadays packaging materials quite often include natural or synthetic derived plastics. In the scenario where the terminal sterilization process may involve the use of gamma rays, understanding the effects of ionizing radiation on these polymeric packaging materials that may lead to the formation of reactive intermediates, free radicals, ions and atoms in excited states. The degree of such response depends on the structure of the polymer and the irradiation conditions. The effect of ionizing radiation on polymeric materials has been found to manifest itself in two ways: one was the molecular weight increase (cross-linking), and the other, the molecular weight decrease (degradation). As a consequence, not only the expected protective barrier of the packaging may be destroyed, but cytotoxic products of this degradation can migrate into biological content and become impairment in the success of the transplantation process.

To establish the risk of ionizing irradiation and cytotoxicity , two different polymer packaging materials(A and B) currently employed for storage of biological tissues for transplantation , were irradiated at 25 kGy. The inherited cytotoxicity of the packaged tissue products pre and post irradiation was also assayed. Following the irradiation procedure, irradiated and none irradiated (control) pieces of A and B as well as fragments of respective tissue products were incubated for 48 h in culture medium RPMI 1640. Extract samples were submitted to five dilutions and incubated with CHO (Chinese Hamster Ovary) cells for 72 h at 37 °C. The cell viability was determined by the method of vital dye employing the MTS uptake method. The Cytotoxicity Index ($CI_{50\%}$) was estimated by curve interpolation, as the material extract concentration resulting in 50% inhibition of MTS uptake, after plotting the mean percentage of surviving cells against the concentration of the extract (%). A 0.3% phenol solution and alumina extract were used as positive and negative control, respectively.

As results, no cytotoxicity in non irradiated materials could be detected. However, comparative results of post irradiated material showed that whilst the irradiated polymer package A did not present cytotoxicity after irradiation, that was not true for the polymer B. The impact on the tissue products themselves of changes in irradiated packaging B was

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