Contribution ID: **133** Type: **Poster**

Prediciting the Behavior of a Biomaterial as Bone Replacement

Thursday, 27 April 2017 14:15 (2 hours)

When an artificial material is implanted into the body, a fibrous capsule may appear separating the material and the tissue. But when the material is bioactive, this capsule doesn't appear, and the biomaterial conducts the formation of an interfacial bonding between the implantable device and living tissues, called apatite. The bioactivity is defined as the biologic positive answer in a determined biological environment (human body or a simulated human environment). When the feasibility of developing a new biomaterial is evaluated, it is important to know their bioactivity because this may predict the bone-forming ability of an implantable material for bone tissue replacement.
Another property that helps in this prediction is the bio-evaluation of these materials, where the initial evaluation involves the citotoxicity, among others. The citotoxicity determines the possible toxicity produced on cells by the device, and also considers the nature of body contact and duration of contact.

The objective of this study was to analyze the bioactivity and cytotoxicity of a biomaterial considered for bone replacement, consisting of high density polyethylene (HDPE) with a load of hydroxyapatite (HA).

Biomaterial samples were prepared by extrusion as flat and rectangular specimens composed of HDPE and different loads of HA (100:0; 90:10; 70:30; 50:50); and they were irradiated with different gamma radiation doses (15; 30 and 45 kGy). Radiation is used to promote crosslinking of the material, minimizing wear under physiological conditions, and also for sterilization.
To assess the bioactivity a blood similar solution was used (ISO 23317). The samples were incubated for 30 days. Their surfaces were analyzed by Scanning electron microscopy (SEM) and the cristallinity of the HA produced on the surface was determined by X-ray diffraction (XRD).
Citotoxicity was conducted using the MTT assay determining the cellular viability (ISO 10993-5).

The results obtained by XRD and SEM showed an homogeneous formation of HA crystals, without differences between compositions and irradiation doses. Only in the samples 100 % HDPE did not present apatite crystals on its surface.
All samples showed viability higher than 70%, indicating that no cytotoxicity was generated in any condition.

Based on the obtained results, the biomaterial samples composed of HDPE and HA were bioactive and non-cytotoxic. Therefore the biomaterial seems to be a good bone tissue implant.
These studies carried out, showed to be very useful, as a preliminary or screening step, before starting with the clinical trials. They can reduce costs, when the composition or the process has to be changed before going forward. On the other hand, when the results are satisfactory, they can predict that these materials will generate an appropriate beneficial cellular or tissue response in that specific situation. It has been demonstrated that materials that possess favourable hydroxiapatite layer formation integrate more successfully in the body.
Additional tests are underway on this biomaterial to define which the best composition is and which is the optimal radiation dose that generates a simil-bone biomaterial, with similar mechanical properties, and with minimal degradation debris.

Country/Organization invited to participate

Argentina

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Session Classification: P-A2

Track Classification: RADIATION SYNTHESIS AND MODIFICATION OF MATERIALS