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Joint European Congress of the ECVP and ESVP

Bologna, 7 to 10 September, 2016

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BIOCOMPATIBILITY STUDIES OF LOCAL ANTIBIOTIC-ELUTING DEVICES FOR ORTHOPEDICS APLICATIONS

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Introduction: Efficient local antibiotic-eluting devices could be an alternative to deliver locally therapeutic antibiotics at target tissues, avoiding bacterial contamination on implanted materials and minimizing side effects. A proper assessment of biocompatibility of the biomaterials used is of utmost importance to guarantee their safety after implantation. We present cytotoxicological studies and implantation tests results to evaluate the biocompatibility of two drug-eluting systems with potential use in orthopedic implants.

Materials and Methods Cytotoxicological studies were carried out by evaluating the *in-vitro* dose-dependent effect of cefazolin and linezolid in fibroblasts, keratinocytes (HaCaT), macrophages (THP1) and osteoblasts. Cells were incubated with antibiotic concentrations ranging from 0.25 to 1.5 mg/ml. Cellular viability was assessed by using the Alamar Blue test. Cell cycle and apoptosis were measured by flow cytometry. Short-term implantation tests were performed in an ovine model to assess the device's local pathological effects. Two hollow antibiotic-loaded implants were used, (A) macroporous stainless steel reservoir loaded with linezolid and (B) stainless steel pins with orifices drilled in the reservoir wall loaded with cefazolin. Implants were placed in the sheep's tibia. Tissues were studied by pathological means, focusing on determining the local effect and tissue response under the presence of the implanted device.

Results: Cytotoxic effects of cefazolin and linezolid were only found for the highest concentrations tested (1.5 mg/mL) on keratinocytes and osteoblasts, respectively.. There were no significant changes on cell cycle and apoptosis at the dose studied (1.0mg/mL). Sheep with both A and B antibiotic-loaded implants did not show any evidence of local or systemic adverse effects.

Conclusions: These results showed no potential toxic effects for the designed devices. However, the antibiotic local concentration should not exceed 1.0 mg/mL.