



## THE BIOSAFETY STUDIES OF ORTHOPAEDIC MEDICAL IMPLANT COATED WITH SILVER: THE IN-VITRO AND IN-VIVO STUDIES

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### SUMMARY

The prevalence of orthopaedic implant-associated infections remains high. Bacterial colonization and biofilm adhesion on implant can cause infection at underlying bone and surrounding tissues. The management of this incidence poses major challenges in orthopaedics. Several conventional strategies were taken to control the incidence. The application of orthopaedic metallic implant coated with silver composite (OMICS) has been suggested as an alternative treatment of implant-associated infection. This study aimed to evaluate the biological safety assessment of OMICS through in vitro and in vivo experimental settings. Other than bench works, this study also explores the bioethical aspect on the usage of animal model from an Islamic perspective. A silver release study was conducted to determine the optimum time for the OMICS to show its antibacterial effect against, *Staphylococcus aureus* (ATCC 25923). As for biosafety of the product, the extraction OMICS were performed to access its cytotoxicity, genotoxicity, dermal skin sensitization, pyrogenicity, acute systemic toxicity and irritation potentials respectively in cells, bacteria and animals model. As for results, the L929 cell monolayer showed no cell lysis at the highest concentration of 200mg/ml of OMICS extract. The OMICS extract was neither corrosive nor irritant as observed in the primary skin irritation test. This product did not induce rising in the body temperature of the tested rabbit in the pyrogen test, with no indication in the induction of skin sensitization. The overall findings of this present study have indicated that OMICS as medical device presents has no toxicity effect to cells and animals and it is safe to use. Our outcome represents an important step toward the detailed investigation of OMICS prior to their widespread clinical usage.