Title: Experimental design approach for engineering biomimetic osteochondral device

Name: Elisa Figallo, Lucia Forte
Affiliation: Fin-ceramica Spa

Suitable materials that induce and restore biological functions together with the right mechanical properties are particularly needed for the regeneration of osteochondral lesions. An effective way to address these requirements is through the creation of a stable composite multi-phase implant, designed for the regeneration in a single step of both cartilage and bone. The biomaterial consists of three layers: the lower one, mimicking bone tissue, is formed by 70/30 wt% Mg-HA/collagen. The intermediate layer, mimicking the tidemark, is formed by 40/60 wt% Mg-HA/ collagen and the upper layer, mimicking the cartilaginous layer, is made of 100 wt% equine type I collagen. Biomineralization of collagen fibers is achieved by nucleation and growth of Mg-HA nanocrystals on the self-assembling collagen template. Mimicking the composition, structure and morphology of human osteochondral tissues, the devices is rapidly populated in vivo by the host cells, which specific drive tissue growth, without eliciting any inflammatory or adverse reaction. In order to slow down the degradation kinetics in a physiological environment, BDDGE (1,4 Butanedioldiglycidyl ether), was added as a chemical stabiliser.
However, it must be considered that all production processes have a certain variability due to various factors, which can be linked to process parameters or raw materials. Design of Experiments (DOE) is a statistical design technique, useful for maximizing information derived from experimental data. Here DoE was used to evaluate which process parameters (BDDGE concentration, reaction temperature and pH) significantly affect the final product physico-chemical/mechanical characteristics. Statistical analysis highlighted the critical process parameters for product quality.