O-11 - STERILIZATION BY SCCO2 TECHNOLOGY: CAN WE DESTROY BACTERIAL SPORES WHILE BEING GENTLE TO ABSORBABLE BIOMATERIALS?

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Background

The development of biomaterials represents a challenge to existing medical sterilization technologies, since they are often sensitive to high temperatures. Supercritical CO_2 ($scCO_2$) has recently been identified as an effective technique for the sterilization of thermally and hydrolytically sensitive polymers [1]. $scCO_2$ sterilization can be achieved at low temperature and presents several advantages such as inertness, non-toxicity, high penetration ability and non-flammability [1]. According to EN 556–1, a guaranteed sterility assurance level (SAL) is required, or a one in a million chance of a contaminated item [2]. It has been demonstrated that $scCO_2$ combined with low molecular volatile additives can markedly improve bacterial endospores inactivation to reach the required SAL [3]. Although progress has been done in this field demonstrating the efficacy of $scCO_2$ sterilization of several absorbable polymers, many are still to be studied. In this work, $scCO_2$ was used for sterilizing 3D printed polylactic acid (PLA) and PLA/graphene composites, presently under development as surgical instruments and for other potential biomedical applications.

Method

$scCO_2$ sterilization process was conducted at different conditions of time, pressure and temperature using hydrogen peroxide as residual co-solvent. Stirring was set to 600 rpm during the process. Three types of pore strips, were used as biological indicators, containing more than 10^6 spores of the species: *Bacillus stearothermophilus*, *Bacillus pumilus* and *Bacillus atrophaeus*. Characterisation of biomaterials before/after $scCO_2$ sterilization, was performed by Scanning Electron Microscopy (SEM), Differential Scanning Calorimetry (DSC) and Fourier Transformed Infrared (FTIR).

Results & Conclusions

The different parameters of the sterilization process such as time, pressure, temperature and the amount of co-solvent have been optimized in order to ensure sterilization efficiency while minimizing its effect on the studied materials. Confirmation of sterility was assured by placing the different spore strips in the reactor and further demonstration of the achievement of SAL level. FTIR and DSC results did not present any detectable modification to the chemical structure nor to the thermal behaviour of the materials after sterilization. Studies are on-going to access the stability of the materials in physiological conditions.

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