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Degradation Kinetics of Cardiovascular Implants Employing Full Blood and Extra-Corporeal Circulation Principles: Mimicking the Human Circulation In vitro

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Abstract : Tissue engineered (TE) heart valves based on degradable electrospun fiber scaffold represent a promising approach to overcome the known limitations of mechanical or biological prostheses. But the mechanical stress in the high-pressure system of the human circulation is a severe challenge for the delicate materials. Hence, the prediction of the scaffolds` in vivo degradation kinetics must be as accurate as possible to prevent fatal events in future animal or even clinical trials. Therefore, this study investigates whether long-term testing in full blood provides more meaningful results regarding the degradation behavior than conventional tests in simulated body fluids (SBF) or Phosphate Buffered Saline (PBS). Fiber mats were produced from a polycaprolactone (PCL)/tetrafluoroethylene solution by electrospinning. The morphology of the fiber mats was characterized via scanning electron microscopy (SEM). A maximum physiological degradation environment utilizing a test set-up with porcine full blood was established. The set-up consists of a reaction vessel, an oxygenator unit, and a roller pump. The blood parameters (pO2, pCO2, temperature, and pH) were monitored with an online test system. All tests were also carried out in the test circuit with SBF and PBS to compare conventional degradation media with the novel full blood setting. The polymer's degradation is quantified by SEM picture analysis, differential scanning calorimetry (DSC), and Raman spectroscopy. Tensile and cyclic loading tests were performed to evaluate the mechanical integrity of the scaffold. Preliminary results indicate that PCL degraded slower in full blood than in SBF and PBS. The uptake of water is more pronounced in the full blood group. Also, PCL preserved its mechanical integrity longer when degraded in full blood. Protein absorption increased during the degradation process. Red blood cells, platelets, and their aggregates adhered on the PCL. Presumably, the degradation led to a more hydrophilic polymeric surface which promoted the protein adsorption and the blood cell adhesion. Testing degradable implants in full blood allows for developing more reliable scaffold materials in the future. Material tests in small and large animal trials thereby can be focused on testing candidates that have proven to function well in an in-vivo-like setting.

Keywords : Electrospun scaffold, full blood degradation test, long-term polymer degradation, tissue engineered aortic heart valve
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