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Abstract

Effects of additive manufacturing and sterilization on a medical grade biodegradable polymer

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Although 3D printing has become of increasing interest in the medical field and the demand for biodegradable polymers has rapidly developed, there are only a few additively manufactured, biodegradable implants on the market. Due to the thermosensitive behavior of such polymers, processing and sterilization of biodegradable implants and the side effects on their degradation have still not been sufficiently studied.

The effects of fused filament fabrication (FFF) as well as low-temperature sterilization (H_2O_2 plasma and gamma radiation) on poly(p-dioxanone) (PPDO) and its degradation behavior were assessed. To quantify PPDO *in vitro* degradation the differently sterilized samples and a non-sterilized control group were immersed in phosphate buffered solution (PBS) over 4 weeks. Surface morphology, thermal and mechanical properties and molecular weight change were investigated directly after processing and at regular time intervals of immersion.

Within this work, printability of thermosensitive PPDO via FFF was successfully demonstrated. Thermal characteristics, molecular weight (M_w) and inherent viscosity (IV) were not significantly affected by the printing process. Further, the investigation of the different sterilization methods presented that H_2O_2 plasma did not significantly harm the thermosensitive polymer whereas gamma radiation lowered M_w and IV statistically significant ($p < 0.001$).

After being immersed in PBS, non-sterilized samples did not show any change of surface morphology, plasma-sterilized samples revealed small microcracks after two weeks while gamma-sterilized samples had already shown small microcracks directly after being radiated which further deteriorated over immersion duration. M_w and yield strength decreased for all samples. However, gamma-sterilized samples were affected the most. In addition, cell proliferation tests proved the cytocompatibility of degraded PPDO independently of the sterilization method.

To conclude, we demonstrated that FFF and H_2O_2 plasma sterilization are well suited for processing thermosensitive, biodegradable PPDO. This research is meant to support the establishment of adequate production and sterilization methods for biodegradable implants.

AUTHOR'S STATEMENT

Conflict of interest: The content of this paper has been prepared solely and independently by the listed authors. The corresponding author Stefanie Ficht has compiled all the contents of this publication within the framework of her PhD during her employment as a research scientist at the Chair of Medical Materials and Implants at Technical University of Munich. From 15.08.2022 on she will be employed by Kumovis GmbH (Munich, Germany).
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