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STERILIZATION DECOMPOSITION EVALUATION OF COMPOSITE MATERIALS BASED ON CARBON FIBERS FOR USE IN MEDICINE

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Introduction

Radiolucent composite materials have superior properties to insufficiently radiolucent metal alloys and unreinforced polymers with poor mechanical properties. Their use as medical device materials requires an understanding of the micromechanical properties that provisionally define their behavior. Sterilization is a mandatory process for such materials used in a range of medical applications, e.g., intraoperative guides, screening equipment accessories and patient support systems. The steam or dry heat sterilization processes widely employed in medical practice can affect the micromechanical properties of polymeric composites, particularly in the interface region between the polymer matrix and the reinforcing fibers. However, the effect of sterilization processes on the properties of materials used in medical devices is often ignored [1]. The structural integrity and the overall performance of fiber reinforced polymer composites are strongly influenced by the stability of the fiber/polymer interfacial region. Absorption of moisture causes dilatational expansion and induces stresses associated with moisture-induced expansion, which degrade the structural stability [2-5]. This may induce plastic deformation by plasticization or differential strains [2]. These effects may greatly alter the physical, chemical and mechanical properties of the material at different scales [6]. This results in a significant mismatch in moisture-induced volumetric expansion between the matrix and the fibers, and leads to the evolution of localized stress and strain fields in fibrous composites [6]. Several variables affect the performance of composite materials, including matrix, reinforcement, manufacturing method and reinforcement orientation. It is necessary to investigate both microscopic and macroscopic changes in mechanical and structural properties due to the sterilization processes that are employed. The aim of this study was to prepare a composite material with suitable mechanical, structural and radiolucent properties after repeated sterilization by widely-used techniques.

Materials and methods

Composites based on carbon T300 fibers (plain weave fabrics, Toray, Japan) and/or polyetheretherketone (Porcher Industrie, France) and polyphenylenesulfide (TenCate, Holland) were prepared. T300/polyetheretherketone (PEEK) was cured under a pressure of 0.08 MPa at 395°C. T300/polyphenylene sulfide (PPS) was cured under a pressure of 1.0 MPa at 310°C. The mechanical properties were measured before sterilization (A), after 1 sterilization process period (B1), and after 30 (B30) sterilization process periods. An autoclave (Steridент, Prodenta, CZ) for steam sterilization (134°C, 304 kPa, 10 min) was used for this purpose. The ultimate strength in bending and the modulus of elasticity in bending in the direction of the fiber axis were determined with a four-point and three-point bending set-up using the Inspekt 100 HT material tester (Hagewald & Peschke, Germany), in accordance with ISO 14125.

Results

The flexural properties after multiple sterilizations were tested and compared with those of the corresponding unsterilized samples (FIGS. 1 and 2). The modulus of elasticity in bending is influenced by multiple sterilizations only in the case of T300/PEEK composite (PEEK). The inexpressive decrease in the modulus is equal to approx. 3-4% after 30 sterilization cycles. In the case of ultimate strength in bending, no decrease was observed. From this point of view, we can state that no weakening of the reinforcement-matrix bond occurred.

The influence of multiple sterilization processes on changes in the structural integrity of the composites was studied by an image analysis of cross sections. From the point of view of image analysis, we can state that no weakening of the reinforcement-matrix bond occurred (for illustration, see FIGs. 3 and 4).

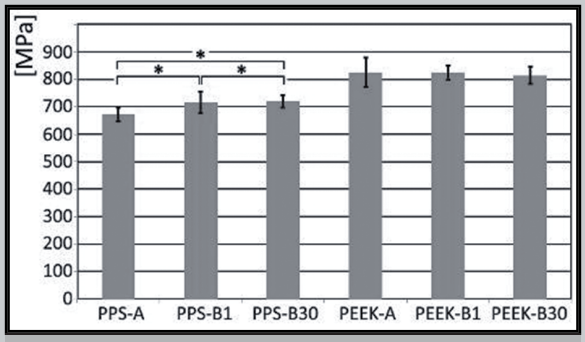

FIG. 1. The ultimate strength in bending (*denotes statistically significant differences, newman-keuls post-hoc test, α = 0.05).

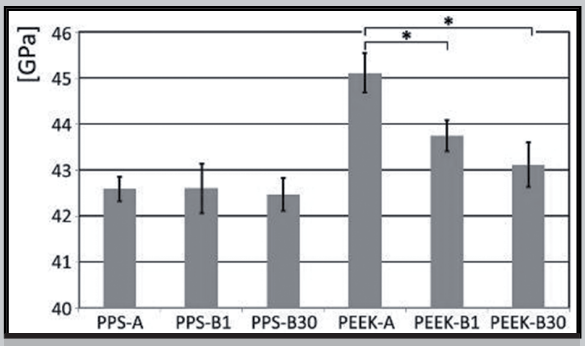

FIG. 2. The modulus of elasticity in bending (*denotes statistically significant differences, Mann-Whitney post-hoc test, α = 0.05).

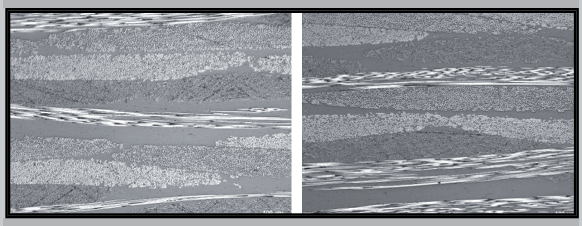

FIG. 3. Micrographs of polished sections of T300/PPS composites (from left: A and B30).

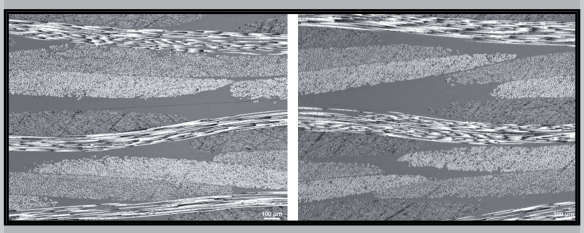

FIG. 4. Micrographs of polished sections of T300/PEEK composites (from left: A and B30).

Conclusions

On the basis of our analyses, we can state that both PEEK and PPS composites are good candidates for application as radiolucent materials providing resistance against sterilization decomposition. Presently, increased sterilization processes periods are applied and further analyses of physical properties are performed.

Acknowledgements

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ADHESION AND GROWTH OF HUMAN OSTEOBLAST-LIKE MG 63 CELLS ON TITANIUM AND STAINLESS STEEL SAMPLES DEVELOPED FOR CONSTRUCTING BONE IMPLANTS

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Titanium and stainless steel are strong, corrosion-resistant and biocompatible metals. Thanks to their remarkable properties, they have been in use for a long time in clinical medicine, mainly for constructing and replacing large joints, in particular the bone-anchoring parts, e.g. cups and stems, and also for fabricating orthopaedic screws and splints. In the Czech Republic, these devices are produced by Beznoska Ltd., and are clinically applied in the Orthopaedic Clinic, Bulovka Faculty Hospital in Prague.

This study has investigated the biocompatibility of samples made of pure titanium (according to quality standard ISO 5832-2) and corrosion-resistant steel (quality standards ISO 5832-1 and AISI 316L), obtained from Beznoska. In addition to Fe, the steel samples contained C (max. 0.025 wt.%), Si (0.6 wt.%), Mn (1.7 wt.%), P (max. 0.025 wt.%), S (max. 0.003 wt.%), Cr (17.5 wt.%), Ni (13.5 wt.%), Mo (2.8 wt.%), and Cu (max. 0.1 wt.%). The materials were used in the form of square samples (9x9 mm or 30x30 mm, thickness 1 mm). Both Ti and steel samples were grinded with SiO_2. The surface of the steel samples was then treated by polishing with Al_2O_3 paste (grain size up to 1 μm), while the surface of the Ti samples, i.e. a material not suitable for polishing, was finished by brushing using another type of Al_2O_3 paste with slightly larger grains. Thus, the surface of the steel samples was finally smoother and glossy, while the Ti surface was rougher and matted.

For the in vitro biocompatibility tests, human osteoblast-like MG 63 cells (European Collection of Cell Cultures, Salisbury, UK) were used. The smaller samples (9 x 9 mm) were inserted into polystyrene 24-well cell culture plates (TPP, Trasadingen, Switzerland; well diameter 1.5 cm). Each well contained 25 000 cells (approx. 14150 cells/cm^2) and 1.5 ml of Dulbecco's Modified Eagle Minimum Essential Medium (DMEM; Sigma, USA, Cat. No. 10270-106) supplemented with 10% foetal bovine serum (FBS; Gibco, Cat. No. 10270-106) and gentamicin (40 μg/ml, LEK, Slovenia). These samples were used for evaluating the size of the cell spreading area (day 1), and for evaluating cell shape and cell viability (days 1, 4 and 7 after seeding). The size of the cell spreading area was measured using Atlas Software (Tescan Ltd., Brno, Czech Republic). The viability of the cells was determined by the LIVE/DEAD viability/