EasyChair Preprint

№ 11517

A Polyaryletherketone Biomaterial for Use in Medical Implant Applications

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December 13, 2023

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Abstract- A polyaryletherketone biomaterial launched by Victrex and marketed as PEEK-OPTIMA, is suitable for medical implant use, enabling device manufacturers to make high performance implants with tailored properties that are compatible with modern medical imaging techniques. This family of products, manufactured under conditions of 'no change' has been achieved using enhanced manufacturing procedures, backed-up with extra physical, chemical or mechanical testing at key stages of manufacture. This paper describes aspects of PEEKOPTIMA manufacture, testing and application.

I. INTRODUCTION

1.1 PEEK BIOMATERIAL

PEEKis a polyaromatic semicrystalline thermoplastic (30-35% crystallinity typically) with a melting temperature of 343□C, a crystallisation peak of□160□C and a glass transition temperature of 145□C. It can be readily melt processed by injection moulding and extrusion using conventional methods. Three natural (unfilled) grades are available as high, medium and low viscosity variants. Natural PEEK is characterised by its high strength, its extreme resistance to hydrolysis and its resistance to the affects of ionising radiation. PEEK can be repeatedly sterilised using conventional steam, gamma and ethylene oxide without significant deterioration.

Surface treatment alone or in combination with surface coating can greatly improve the bioactivity of peek or reduces the wear and does not affect the internal structure.

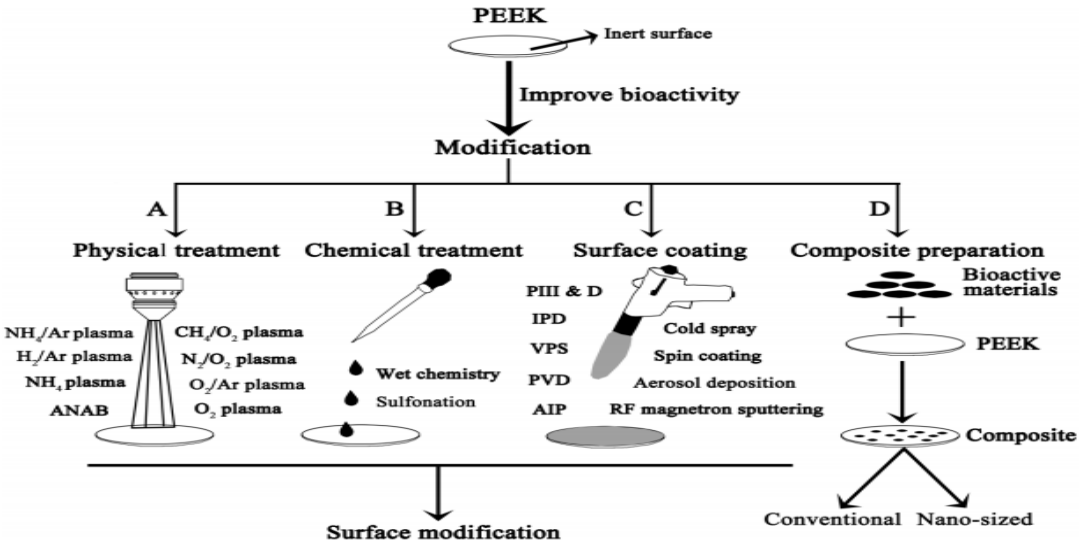

Fig 1. Scheme of current strategies to improve the bioactivity of PEEK

II. COMPOUNDS

Stiffness tailoring to bone is also possible with the judicious selection of fibres or other fillers at an appropriate concentration. Such bone modulus matching may be important in applications for which stress shielding should be minimised.

Figure 1 illustrates the stiffness of a range of implant materials, including short carbon fibre reinforced PEEK, compared with human femur.

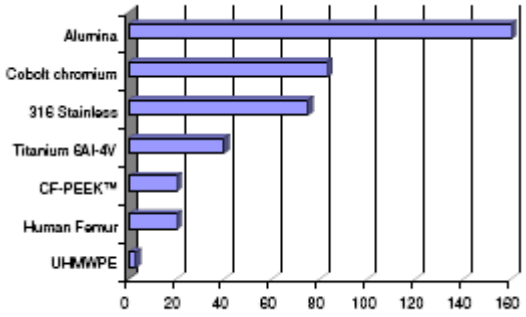

Fig 2. Implant material stiffness in comparison to human femur

With injection moulded carbon fibre reinforced PEEK at more conventional fibre concentrations promising results have been achieved as the bearing surface in an acetabular cup application with lower wear rates and lower maximum stress/yield stress ratio's reported compared with air-irradiated UHMWPE

Property	20%	25%	30%
Tensile Strength	200	209	228
Flexural Strength	288	290	324
Flexural Modulus	15	17	19
Notched Impact Strength	11	9	9.5

Considerably increased strength and stiffness is apparent as compared with natural unfilled material, as would be expected in common with other fibre/polymer systems.

III. PHYSICAL PROPROPTIES – RESISTANCE TO CHEMICAL ENVIRONMENT AND STERILIZATION

2.1 BASIC PROPERTIES

Some key basic mechanical properties for natural unfilled PEEK-OPTIMA LT are given in Table 2

Table 2.Basic Mechanical Properties of PEEK

Property	Test Method	Units	Value
Tensile Strength	ISO 527	MPa	97
Flexural Strength	ISO 178	MPa	170
Flexural Modulus	ISO 178	GPa	4.1

3.1 CYTOTOXICITY TESTING

PEEK-OPTIMA LT1 and LT2 test specimens were extracted (light protected) with dimethylsulfoxide (DMSO) in complete cell culture medium (DMEMFBS) for 7 days at 37ºC. A surface area to volume ratio of 9cm2/ml 1.5% DMSO in DMEM-FBS was used.

Control samples were prepared (7.5% v/v DMSO positive control and 1.5% DMSO in DMEM-FBS incubated at 37ºC for 7days negative control). Suspensions of L 929 mouse cells were then added to controls and different concentrations of extract and these were incubated for 72hrs at 37ºC. The protein content of each sample was measured using a colorimetric assay method. There was found to be no inhibition of L-929 cell proliferation. The results from this study indicate that there is no release of substances in cyotoxic concentrations from either sterilised or nonsterilised PEEK-OPTIMA and this is true for all of the sterilisation methods used.

Biostability has been investigated using similarly prepared specimens, sterilised with gamma radiation, co-incubated on a confluent L929 monolayer cell culture for 11 weeks before testing and afterwards examined for the release of cytotoxic substance in L-929 culture as described. Worst case conditions compared to actual standard requirements were used to characterise the material solubility and to ensure high sensitivity detection of toxic leachable substances on a cellular level. (Maximum dose 75,9kGy, 7 days extraction time, high surface area to volume ratio and organic solvent was added to extraction medium). No release of substances in cytotoxic concentrations was observed, confirming the stability of this material. Implantation tests to demonstrate long-term biostability with pre-aged PEEK-OPTIMA LT test specimens are ongoing. Interim 3-month implantation results indicate that the biological response is similar to implant grade UHMWPE.

Further biological effects, which depend on design, surface properties, material/tissue, and material/material interactions are not covered by this assessment and shall be evaluated by the manufacturer of the final device based on clinical application.

3.2 CHEMICAL ANALYSIS

The results of our chemical analysis, undertaken by a leading independent testing laboratory, confirm the inert properties of PEEK-OPTIMA™ LT. We can show using simulated-use extraction in ethanol-water 1:20 at 40ºC for 72hrs that the daily dose of leachable ingredients and leachable substances is below 0.1□g/g (detection limit of the analytical equipment used). An analysis of the total amount of *potentially* leachable substances, measured using gas chromatography of an organic solvent extract, obtained at high temperature, indicates there is no evidence that any harmful ingredients are contained in PEEK which may be released during lifetime exposure.

Sterilisation has no impact on the material solubility and the EtO residues are within the limits specified in ISO 10993-7, even following 3 times repeated sterilisation.

Victrex plc holds at the Food and Drug Administration (FDA) Drug and Device master-files (DMF) solely for PEEK polymer. These data are in addition to USP VI and toxicity reports of substances used in the manufacture contained in the drug and device masterfiles. Device manufacturers may consult the FDA with permission from Victrex plc to get access to these data.

MEDICAL APPLICATIONS

1. PEEK POTENTIAL
2. SPINE CAGE
3. BONE SCREWS AND PINS
4. HIP IMPLANTS
5. INTRACARDIAC PUMPS FOR MINIMAL INVASIVE SURGERY

IV. CONCLUSION

PEEK is biocompatible, chemically and physically stable, radiolucent and exhibits a similar elastic modulus to normal human bone, making it an attractive orthopedic implant material. However, PEEK is biologically inert, preventing good bonding with surrounding bone tissue when it is implanted in vivo. Surface modification and composite preparation are two main strategies to improve the bioactivity of PEEK. For surface modification, including surface chemical treatment, physical treatment, and surface coating, the stability of the modified surface will be the key issue requiring further investigation. For the preparation of bioactive PEEK composites, the main challenge is to keep the excellent mechanical properties of PEEK when impregnating bioactive materials. The development of PEEK composites containing nano-sized bioactive materials may provide an effective way to obtain both mechanical and biological benefits.

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