PEEK-OPTIMA®

Effects of Gamma Sterilisation on Implant Grade Polyetheretherketone

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PEEK-OPTIMA® Polymer, Polyetheretherketone, is rapidly becoming increasingly significant in the biomedical sector as an implantable polymer. The work described here was undertaken to demonstrate that PEEK-OPTIMA polymer is highly resistant to gamma radiation in terms of its physical properties and biocompatibility.

Methods

Specimen preparation

PEEK-OPTIMA polymer grade LT1 from Invibio® was injection molded into tensile, flexural and impact test pieces in accordance with ISO test requirements under standard processing conditions. The batch of molded parts was arbitrarily divided into two. One half was used as the control, the other half was treated with gamma radiation.

Gamma Sterilisation

Treatment consisted of a gamma dose of approximately 75kGy, representing approximately three times the usual dose for a single sterilisation cycle. The process was completed by GAMMASTER® in Germany with certification evidence of dosage.

Mechanical and Physical Testing

For both the gamma irradiated and as received samples, an Instron test machine was used to measure tensile strength and elongation and, flexural strength and modulus, in accordance with ISO 527 and ISO 178 test methods. Izod notched impact strength was measured using a Zwick machine fitted with a 1 J hammer. Other measurements included density, thermal transitions by differential scanning calorimetry (DSC) and molecular weight by gel permeation chromatography (GPC). The material was further characterised by infrared spectroscopy (FTIR).

Biocompatibility Testing

Both gamma treated and as received materials were tested according to ISO10993 for biocompatibility. In particular, the samples were evaluated according to ISO 10993-5 cytotoxicity and ISO 10993-18 chemical analysis by headspace GC and GC of extracts.

A 1-year implantation study in rabbit paravertebral muscle was also completed using material subjected to approximately 75kGy and artificially aged to simulate 10 years real time ageing.

Results

Test	Test Method	Control	After 75kGy Gamma
Tensile Strength	ISO 527	100 MPa	100 MPa
Tensile Elongation	ISO 527	32%	34%
Flexural Strength	ISO 178	164 MPa	164 MPa
Flexural Modulus	ISO 178	4 GPa	4 GPa
Impact Strength	ISO 180	7 kJ/m^2	7 kJ/m^2
Density	ASTM D792	1.30 g/cc	1.30 g/cc
Tg	DSC	146.8	144.3
Tm	DSC	341.3	339.5
Tc	DSC	289.8	290.3

Table 1 identifies the mechanical properties, density and thermal transition results.

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The GPC results are shown in Figure 1. Mw increased by approximately 4.8% and polydispersity increased from approximately 3.0 to approximately 3.7 in the worst case as a result of gamma sterilisation. FTIR spectra appeared identical for control and irradiated samples as shown in Figures 2 and 3.

Biocompatibility testing to ISO 10993-5 showed that no substances were released in cytotoxic concentrations following irradiation treatment and chemical analysis to ISO 10993-18 showed a substantially identical composition in both cases. Implantation of irradiated PEEK-OPTIMA polymer into rabbit paravertebral muscle showed a normal response, with only mild fibrosis evident around the implanted material.

Discussion

The mechanical properties of the irradiated and control specimens are almost identical. The small differences in tensile elongation are not considered significant. Biocompatibility testing confirms that PEEK-OPTIMA polymer exceeds the requirements for an implant grade. Long-term implantation shows no unusual response for an acceptable implant material.

Conclusions

It can be concluded that PEEK-OPTIMA polymer, irradiated to high levels of gamma radiation (at least 3 times that used for normal sterilisation) does not change in terms of physical properties or chemical make-up. There may be small changes in the molecular weight distribution, as recorded by GPC, but these do not apparently affect the mechanical performance of the material. Irradiated material continues to meet the specified parameters for PEEK-OPTIMA LT1.

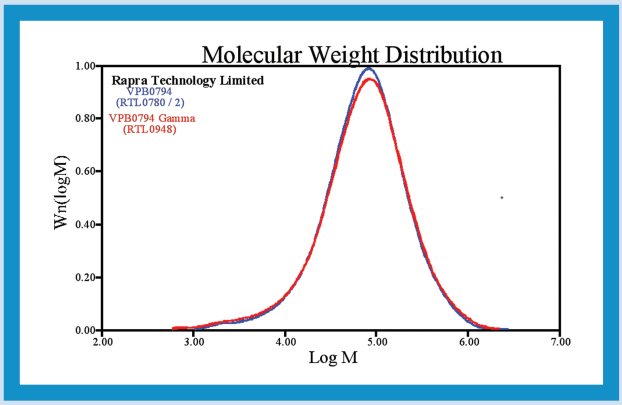

Figure 1
GPC Results for PEEK-OPTIMA polymer Control and Gamma Sterilised

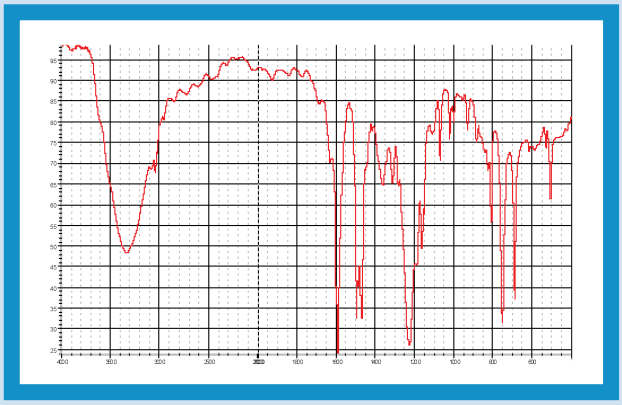

Figure 2
Pyrolysate IR Spectrum of PEEK-OPTIMA polymer LT1 Control

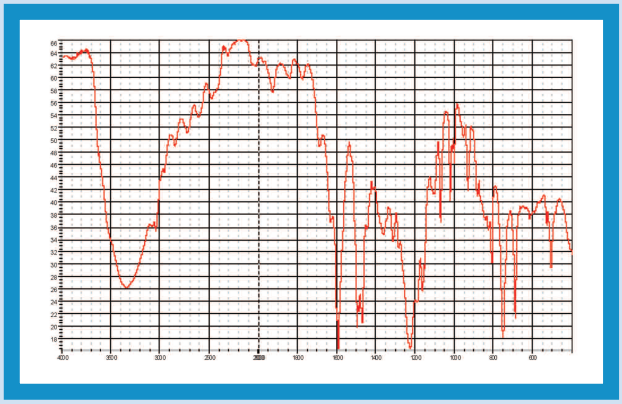

Figure 3
Pyrolysate IR Spectrum of PEEK-OPTIMA polymer LT1 Gamma irradiated

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