PEEK-OPTIMA®

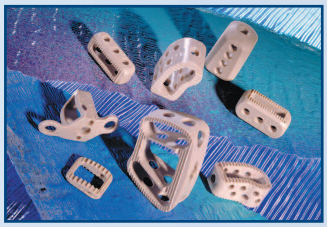
In Vivo Biostability Study on a Polyaryletheretherketone Biomaterial

by Dr. Stuart Green, Technical Manager, Invibio Ltd.

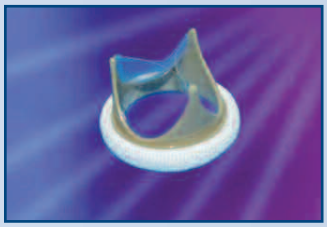
PEEK-OPTIMA® polymer is a biomaterial for long-term use in the human body. Radiolucency, excellent mechanical properties, relative ease of device fabrication by injection molding or machining and demonstrated biocompatibility have helped make this material become an important alternative to metals.

Available as natural polymer and fiber reinforced or radiopaque compounds, the mechanical and physical properties are wide ranging. Uses include spinal cages and spacers, developmental replacement heart valves, dental splines and healing caps, and other pins, screws and bone plate devices as shown in Figure 1.

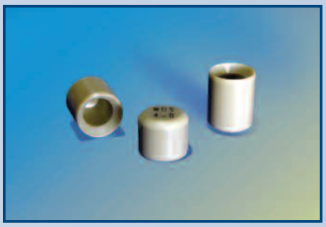
Figure 1



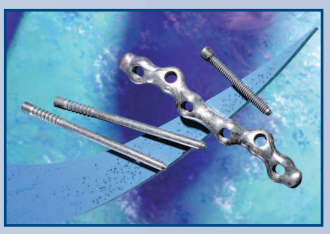
Spinal Cages



Heart Valve



Dental Healing Caps



Bone Plate and Screws

As previously reported[1], biocompatibility studies demonstrate that PEEK-OPTIMA® polymer is non-cytotoxic (ISO 10993-5) and chemical analysis (ISO 10993-18) records that there is no evidence that any harmful ingredients are contained that might be released during lifetime exposure.

Reported here are the results of a 1-year in vivo implantation study, including implant site histology and chemical analysis of the implanted material. The purpose was to investigate the tissue response and any changes in polymer composition or molecular weight.

Method

Samples of PEEK-OPTIMA® LT1 and LT3 polymers (standard and easy flow grades) were injection molded into 10mm thick plaques, nominally 150mm square under standard recommended conditions[2] and, from these, 25 rod samples for each grade, 3mm diameter and 10mm long, were prepared for implantation and chemical analysis. All rod samples were sterilized by gamma radiation (>73kGy) and incubated in physiological saline for 3 months at 90ºC to simulate 10 years real time ageing at 37ºC. Afterwards they were steam sterilized at 121ºC for 20 minutes. Rods from each material were implanted into the paravertabral muscles of 3 rabbits (between four and six per rabbit) according to ISO 10993-6. The implants remained in situ for a period of 1 year

Histopathology

After dehydration in alcohol and embedding in paraffin wax, sections were cut at approximately 5-micron thickness and stained with Haematoxylin and Eosin. Slide assessment of tissues was performed using light microscopy.

Chemical Analysis

Chemical analysis of samples removed from the implant sites was by gas chromatography using high temperature headspace (up to 320ºC) and solvent extraction methods (0.46g polymer, 1.0ml dichloromethane for 24hrs at 40ºC) to examine volatile and medium volatile substances. Infrared spectroscopy (FTIR) and Gel Permeation Chromatography (GPC) were used to further characterize the material. The results of these analyses were compared with non-implanted control specimens.

Results

A micro-section at an implant site is shown in Figure 2. The one shown is an implant site for PEEK-OPTIMA® LT3 polymer, the lowest molecular weight grade. It will be seen that the test material implanted for one year caused virtually no response-mild fibrosis, or in some cases a light fibrous capsule. There was no muscle degeneration, nor necrosis, nor any other significant change.

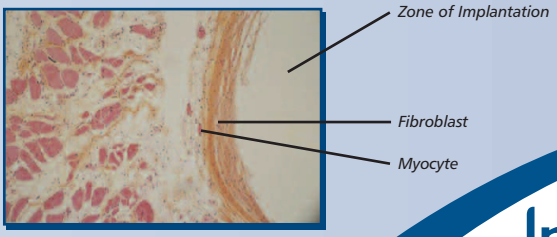


Figure 2
A micro-section of an implant site for PEEK-OPTIMA® LT3 polymer.

Invibio® biomaterial solutions

FTIR spectra from implanted and non-implanted material show no measurable differences (Figure 3) and the molecular weight distributions indicated by GPC are identical (Figure 4). Chemical analysis by headspace GC and GC of extracts from both implanted and non-implanted reference PEEK-OPTIMA® polymer show almost identical fingerprint patterns (Figures 5a-d), which are typical for PEEK-OPTIMA® polymer. The main detected compound was diphenyl sulphone at very low levels (<20ppm).

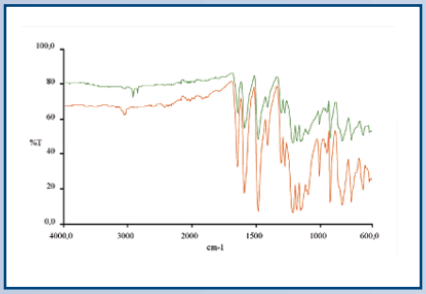


Figure 3
FTIR spectra for implanted (red) and non-implanted (reference) material.

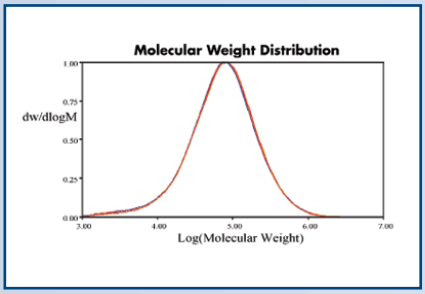


Figure 4
GPC data for implanted (blue) and non-implanted (reference) material.

Headspace Gas Chromatograms

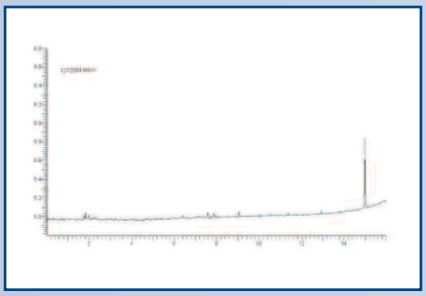


Figure 5a
PEEK-OPTIMA® LT3 polymer sterilized by gamma irradiation (dose 73.8kGy), accelerated aged (simulation of 10 years), implanted in rabbit (1 year).

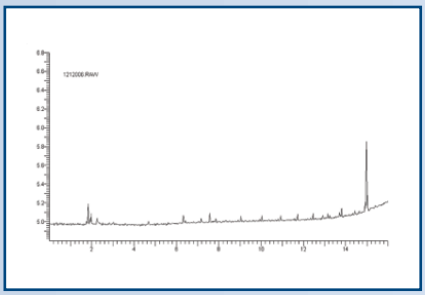


Figure 5b
Reference sample: PEEK-OPTIMA® LT3 polymer sterilized by gamma irradiation (dose 77.4 kGy).

Gas Chromatograms of Extracts

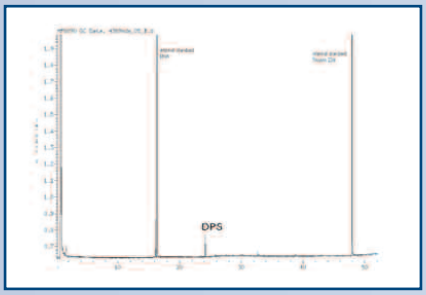


Figure 5c
PEEK-OPTIMA® LT3 polymer sterilized by gamma irradiation (dose 73.8kGy), accelerated aged (simulation of 10 years), implanted in rabbit (1 year).

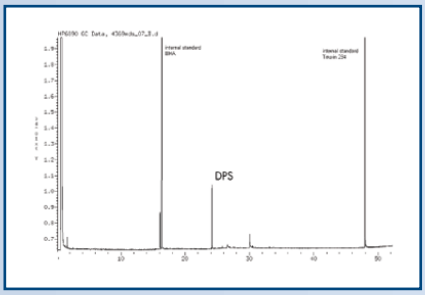


Figure 5d
Reference sample: PEEK-OPTIMA® polymer LT3 sterilized by gamma irradiation (dose 77.4 kGy).

Conclusion

PEEK-OPTIMA® polymer implanted in paravertabral rabbit muscle did not induce any adverse tissue reactions, only mild or moderate fibrosis. There was no necrosis or muscle degeneration. Chemical analysis indicates that the bulk material is apparently unaffected as a result of it being implanted in vivo. These data help support the use of PEEK-OPTIMA® polymer for medical implant devices.

References

1. Green S. Schlegel J., Polymers for the Medical Industry 2001, Conference Proceedings, Paper 2.

2. PEEK-OPTIMA® Polymer Processing Guide from Invibio.

The Author

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