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White Paper

In Vivo Biostability Study on a Polyaryletherketone Biomaterial

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Introduction:

A specific grade of polyetheretherketone (PEEK-OPTIMA® polymer) offers a high performance biomaterial solution for many bioengineering challenges[1]. Developed specifically for the implant market, the unfilled (natural) material is a high strength, chemically stable and biocompatible thermoplastic polymer offered as standard, medium and low viscosity grades. Additives may be incorporated to modify the mechanical properties, for example, to match the stiffness of bone or to modify the materials radiolucency. Two common device manufacturing methods include injection moulding and machining from blanks[2]. All grades can be sterilized by conventional methods including gamma radiation with substantially no effect on biocompatibility and mechanical properties. PEEK-OPTIMA polymer is already being used for implants in Europe and the US. This work was conducted in order to demonstrate the long-term (1-year) biostability of the polymer and report the local tissue response at the implant site.

Materials:

The material used in this study was machined injection moulded natural (unfilled) PEEK-OPTIMA of the highest and lowest molecular weight grades (LT1 and LT3). All implanted test samples were artificially aged to simulate 10-year real time and were gamma sterilized.

Method:

For each grade, a minimum of six PEEK-OPTIMA polymer samples, in the form of 10mm long, 3mm diameter rods (gamma sterilized and 10 year artificially aged), machined from injection moulded plaques were implanted into the paravertebral muscles of each of 3 rabbits (total of 18 implanted pieces) for a period of one year. Excised samples were then either fixed for histopathological examination or sterilized for chemical analysis. Chemical analysis of the excised material was by gas chromatography, using headspace and solvent extraction methods to examine volatile substances. Medium volatile substances were identified using GC with mass spectrometric coupling. In addition, FTIR and gel permeation chromatography (GPC) methods were used to investigate any changes in the composition and molecular weight of the polymer occurring as a result of the long-term in vivo implantation.

Results:

The reported response to the implanted material in all sites is of minimal, mild or moderate fibrosis degree. It is reported here that one animal responded with a mild ossification of the fibrosis, but there was no significant consistent response to the test material. There were no

muscle degradations, no necrosis, no marked inflammatory response or any other significant changes. The histopathological responses at the site of the implantation were very slight; fibrosis and in one animal osseous metaplasia of that fibrosis.

FTIR spectroscopy performed on implanted and non-implanted material showed no change in the position of the absorption peaks and GPC analysis showed that no measurable change in molecular weight occurred as a result of implantation.

Headspace GC/FID results using a Perkin Elmer HS40XL auto sampler showed that implanted material displayed the same fingerprint in the headspace gas as non-implanted reference material from the same batch. All gas fingerprints were normal for PEEK-OPTIMA polymer. Extraction with dichloromethane for 24hrs at 40°C and subsequent analysis of the extract shows good agreement between material tested at the end of the implantation period and the non-implanted material. As is normal for this material, a small amount of residual DPS (diphenylsulphone) process solvent was detected (at below 80ppm levels) in both cases.

Discussion:

The presence of DPS at these levels is not significant. Extraction experiments conducted under conditions that more closely resemble physiological conditions, as compared against dichloromethane extraction (1.5g polymer and 3ml of distilled water of 5% ethanol solution for 72 hours at 40°C) show that DPS is not removed in detectable quantities to a 0.1ppm detection limit.

Conclusion:

On the basis of these tests, it is concluded that PEEK-OPTIMA polymer shows no evidence of deterioration in vivo. There is no evidence of any change in polymer molecular composition or molecular weight occurring as a result of implantation. Muscle tissue responses are normal (no negative response to the implant). The results of these tests strongly support the use of this material for long-term implantation.

References:

1. Green S., Schlegel J., *Polymers for the Medical Industry 2001*, Conference Proceedings, Paper 2.
2. PEEK-OPTIMA® *Polymer Processing Guide* from Invibio.

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