Biocompatibility Data Supports Why PEEK-OPTIMA® Ultra Reinforced in Challenging Metals as a High Strength, High Performance Biomaterial for Trauma Applications

Mechanical Performance similar to metal but with the benefits of a polymer PEEK-OPTIMA Ultra Reinforced is a continuous carbon fibre-reinforced composite material manufactured from PEEK-OPTIMA polymer from Invibio Biomaterial Solutions that has very high strength and stiffness. This imparts very similar mechanical performance to that of metals typically used in the manufacture of medical devices, but without the weight, toxicity issues and imaging problems that can result from the use of these metals, which are becoming increasingly important areas of concern for surgeons. As a result, the PEEK-OPTIMA Ultra Reinforced grade is of great interest in medical device applications such as trauma plates and nails to replace the traditional metals currently in use such as Titanium, Cobalt Chrome and stainless steel.

PEEK-OPTIMA Reinforced with carbon has a successful clinical history of more than 10 years in spinal implants and its biocompatibility has been studied extensively\(^1\)\(^-\)\(^8\). However, with the use of a continuous fibre rather than a chopped fibre, it was important to assess the potential biological response to the material and to that end, many studies have already been performed, including a bone implant study\(^9\) per the ISO 10993-6 guideline.

ISO 10993-6: Bone Implantation Study

The purpose of the study was to evaluate the local effects of PEEK-OPTIMA Ultra Reinforced, when implanted in the femoral bone of rabbits for 26 weeks. In five male, New Zealand rabbits, the lateral mid-shafts of both femurs were surgically exposed and three unicortical circular defects were created in the mid-shaft of each femur. The defect holes were spaced at least approximately 1 cm apart. The test article was implanted in three sites in the right femur.

A control article, high density polyethylene, was implanted in three sites in the left femur of these same rabbits. At 26 weeks, the animals were sacrificed and the responses to the test article compared to the control article.
Study Provides Assurance of Biocompatibility

After 26 weeks of implantation in rabbit femurs, there were no adverse local effects observed for the test article and microscopically, the test article was considered a nonirritant to tissue as compared to the control. This result showing no adverse response to implanted PEEK-OPTIMA Ultra Reinforced material in bone tissue provides assurance that the material is biocompatible.

Along with the extensive biocompatibility testing already completed with the PEEK-OPTIMA Ultra Reinforced product, it’s exceptional mechanical performance ensures it is a good candidate for metal replacement in medical device applications such as trauma plates and nails.

NB: PEEK-OPTIMA Ultra Reinforced previously referred to as ENDOLIGN

References

9. Implantation Study of ENDOLIGN in the Femoral Bone of the Rabbit for 26 Weeks, Performed by: Namsa
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