

A new biocompatible biomaterial : PEEK / β -TCP / TiO₂

Introduction : Polyetheretherketone (PEEK) is an aromatic, rigid semi-crystalline thermoplastic with excellent mechanical properties and bone-like stiffness, and good biocompatibility. Moreover for biomedical applications, particularly in the area of load-bearing orthopaedic applications, PEEK is able to be repeatedly sterilized, and shaped by machining or injection moulding. Devices utilising PEEK's unique combination of properties have found considerable success in spine, cardiovascular and dental applications. PEEK composites were developed such as fiber reinforced PEEK composites for bone plates, or PEEK-HA composites as a possible bone analogue substitute for load-bearing functions; or as scaffold for bone tissue engineering. An innovant PEEK based composite has been produced consisting of a dispersion of β -tricalcium phosphate (β -TCP) (10 % w/v) and Titanium oxide (anatase) (10 % w/v) throughout a PEEK matrix. The PEEK/ β -TCP/TiO₂ demonstrated excellent mechanical properties, with elastic modulus comparable to that of natural cortical bone : tensile strength of 98 MPa, flexural modulus of 4.7 GPa and a flexural strength of 16MPa. Moreover based on the recommendations of ISO 10993 "Biological evaluation of medical devices" (2004) cytotoxicity, acute systemic toxicity, irritation, sensitization, mutagenicity (Ames test, chromosome aberrations using human lymphocytes, sister chromatid exchange) were performed and demonstrated composite biocompatibility.

Cell attachment and proliferation : SEM assessment shows that HOB are able to attach, adhere and proliferate on the composite. Figure 1a shows the surface state of the composite. Figure 1b and 1c show the cell layer at day 3 and day 27 respectively : In this study we have investigated the cytocompatibility and bioactive nature of the material using human osteoblasts. HOB are very well spread at day 3 on the test material, and constitute a multilayer at day 27.

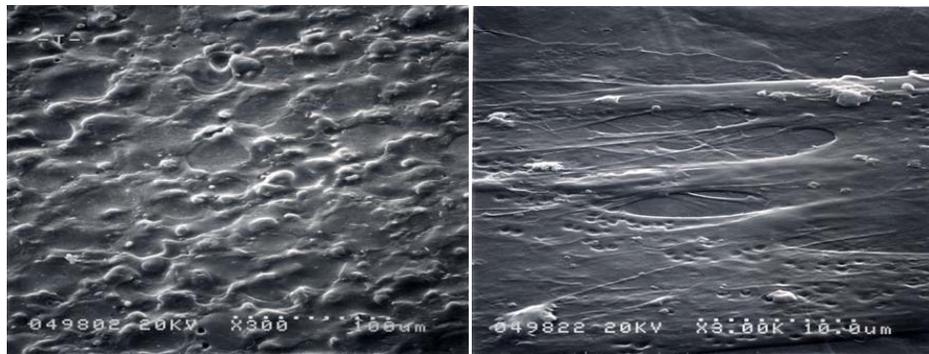


Fig.1a : surface of PEEK-implant under microscope

Fig.1b : cell layer after 3 days on implant PEEK

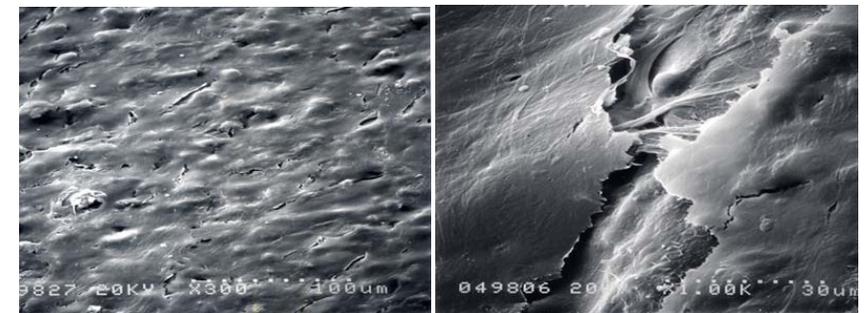


Fig.1c : cell layer after 27 days

Fig.1d : same layer magnified

Figure 1d shows a detail of the multilayer at higher magnification. A slight increase in cell attachment kinetics (Figure 2) is observed for the composite with regard to negative control : + 12 %, $P < 0.05$ at 3 h. HOB proliferated better on the compound than on the negative control. At 27 days cell density was 17 % ($P < 0.02$) higher than on the negative control.

This is the consequence of a lower HOB doubling time : for the control T112 (1st exponential phase of growth) is 5.5 days and T2 112 (2nd exponential phase of growth) is 23.5 days, whereas for the test material T1 112 and T2 112 are 5 days and 18.5 days respectively.

ALP activity : Figure 3 shows the amount of ALP activity (nMPI/min/106 cells) after 3, 15 and 27 days of culture. HOB exhibited an increase in ALP activity over time on both negative control and test material. ALP activity, an early marker of HOB differentiation, was significantly higher on the test material as soon as day 3.

At day 27, ALP activity is increased by 21 % ($P < 0.01$) on the PEEK composite. In conclusion, the results obtained in this study justify further investigation, specially the level of osteoblast adhesion into the use of this new composite PEEK/ β -TCP/TiO₂ in dental and orthopaedic applications : the composite demonstrates excellent mechanical properties, can be considered biocompatible in the framework of ISO 10993 "Biological evaluation of Medical devices". It supports human osteoblasts adhesion, proliferation and differentiation suggesting bioactivity and osteointegration potential through osteoconduction.

This was confirmed by clinical results. CE mark was obtained for a dental implant made of PEEK/ β -TCP/ TiO₂ : 4000 cylindrical implants have been implanted over a 10 year period, 50 % as immediate implants after extraction and 50 % after socket bone healing, with 96 % success.



Fig.11 PEEK-Implant IOTA

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