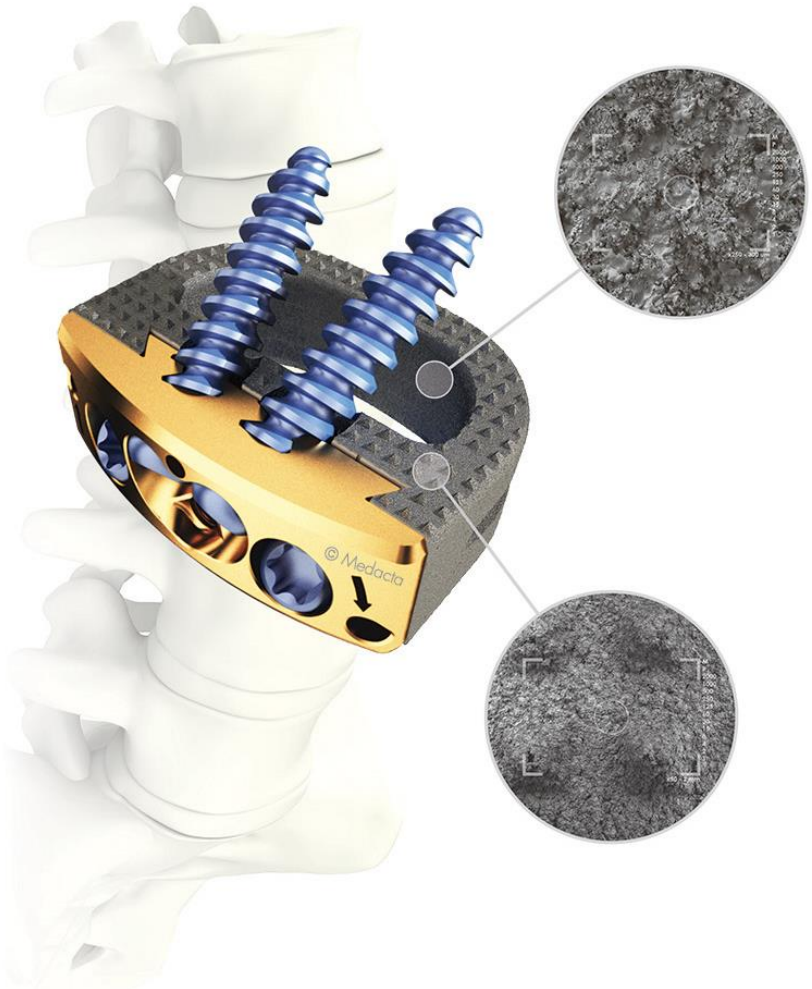
Bioactivity of Titanium coated PEEK cages : early in vitro results of the TiPEEK interbody fusion devices

[based on the report study from W.R Walsh et al. named “Bioactivation of titanium coatings on PEEK”. Available on internal files]



MectaLIF TIPEEK

TI-COATED INTERBODY FUSION DEVICE

Introduction

Artificial materials implanted into bone are generally encapsulated by fibrous tissue, which isolates them from surrounding bone, and consequently they do not bond to living bone. This is a normal protective reaction of the living body against foreign materials and a common- well known response of PEEK to interbody cages.

Bioactive materials, such as titanium metals, **allow the living bone** to **bond spontaneously to the metal** without the formation of surrounding fibrous tissue. A **calcium phosphate layer** (CaP) is forming on their surfaces in the living body: this amorphous calcium phosphate **eventually transforms into bone-like apatite**. By this process the **surrounding living bone can soon tightly bond** to these materials through the bone-like apatite layer[1].

The apatite formation can be reproduced in vitro in an acellular simulated body fluid (SBF) with ion concentrations nearly equal to those of human blood plasma. It is thus useful to examine apatite-forming ability on a material's surfaces in SBF to predict the bone-bonding ability of a material as a preliminary to animal experiments [2].

Goal of the study

This study was conducted in order to evaluate the **bioactivity**, defined as the ability of the material to form an **in-vitro apatite-like layer**[2], of the Titanium coated PEEK cages {TiPEEK} when assessed by SEM and/or SEM+EDX compared to the PEEK.

Materials and methods

To evaluate the bioactivity of the PEEK and TiPEEK cages, the formation behavior of the apatite layer on the samples was examined by immersing them in Simulated Body Fluid (**SBF**) **for up to 7 days**. The current study chose to evaluate actual devices rather than "test" parts to examine the surfaces of "real" implants.

The surface morphology of the samples was observed by Scanning electron Microscopy (SEM) and SEM+EDX (Energy Dispersive X-ray Spectrum) after incubation in SBF.

Macroscopic images, Environmental SEM (eSEM) and SEM+EDX were performed at day 0, 1 and 7.
PEEK and TiPEEK cages were also examined at day 0 in order to assess surface roughness at 3 locations (ISO Standard 97).

Results

Macroscopic images showed a small amount of translucent material located on the endplate of TiPEEK cage and a **large amount of white material suggestive of apatite** visible under Stereo-Zoom imaging at day 7 after incubation in TES-10 solution (Fig. 1).

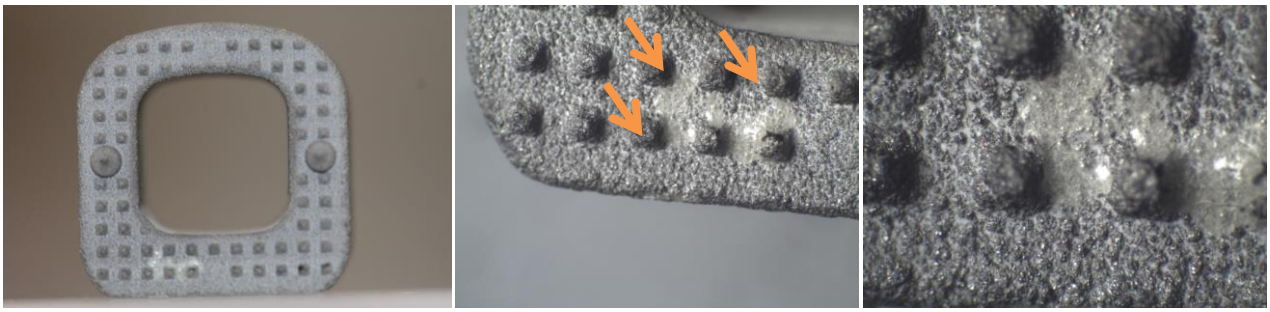


Fig 1. Day 7 Ti-PEEK Photographs TES-10: There is a deposit on this sample that is clear in color and the entire endplate surface showed signs of white accumulation.

eSEM analysis showed some **small globular masses** that may indicate **early bioactivity and CaP formation** at day 1 in SBF (Fig. 2a). Extensive structures indicating CaP formation on TiPEEK cage were seen at day 7 (Fig. 2a-b).

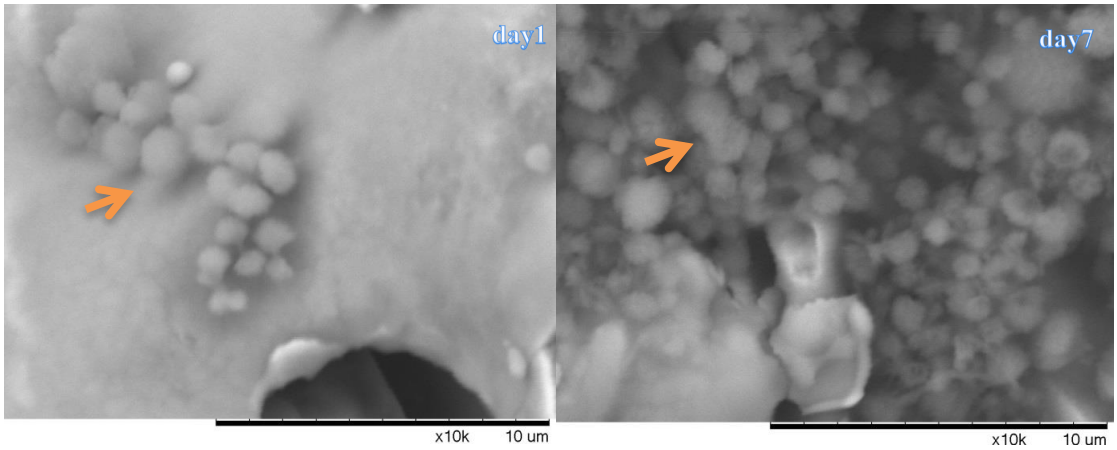


Fig 2a. Day 1 and Day 7 TiPEEK eSEM images. Arrows indicate CaP structure

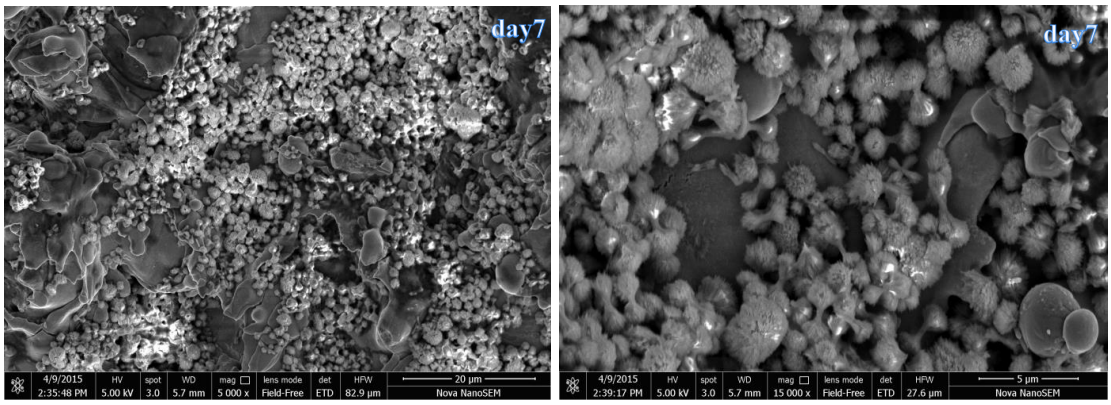


Fig 2b. Day 7 TiPEEK eSEM images. Arrows indicate CaP structure

The indication of CaP formation was confirmed by SEM+EDX analysis at day 7 (Fig. 3). Day 1 glomerular formation seen with eSEM was not further investigated by EDX because of study design.

No deposition of CaP was seen in the PEEK samples at the analyzed time points.

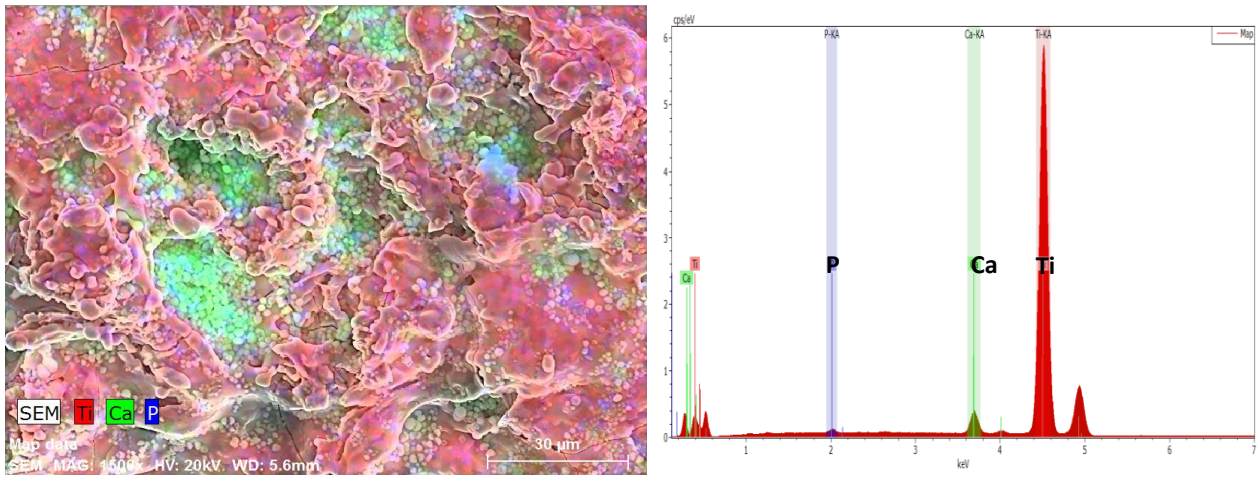


Fig. 3. Day 7 Ti-PEEK SEM+EDX TES-10: The image shows the location of the CaP on the Ti substrate. The resulting spectrum shows the color coded ranges used to separate peaks of P and Ca

Surface roughness analysis on PEEK and TiPEEK cages revealed micro-roughness texture (Fig.4) with the following reported values:

ROUGHNESS	Mean (µm)
PEEK	1.5
TiPEEK	10.5

Table 1. Mean surface roughness

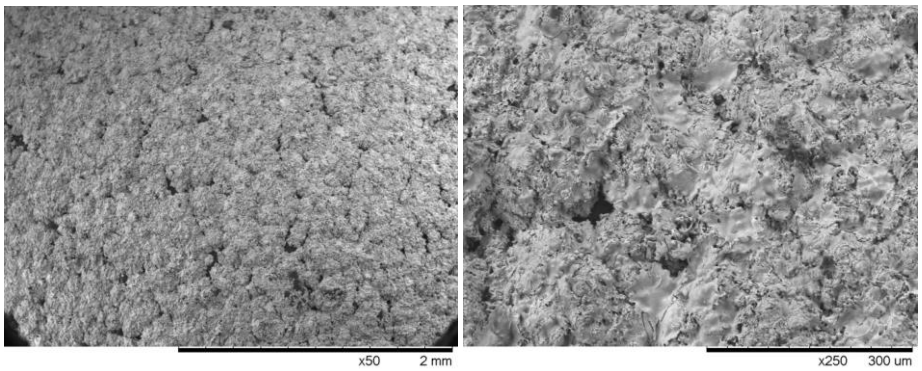


Fig.4 Macro and micro magnification of the Titanium layer roughness

Discussion

Morphological characteristics of particles seen with eSEM on the **TiPEEK** sample soaked in SBF from day 1can be considered **signs of bioactivity**. This however could not be verified with EDX due to the small number of particles that were present at this early time point. At day 7 eSEM revealed a large number of globule shaped particles on the surface. Areas of a white colored coating were also visible with stereo zoom and photographic methods. EDX verified the presence of CaP on the surface, confirming bioactivity for the TiPEEK coated samples.

Microroughness has been well established in the literature to have a **beneficial effect on osseointegration of implants**, directly affecting early cell behavior of osteoblasts and long-term osseointegration[3]. It was demonstrated that calcification and expression of Type I collagen, alkaline phosphatase and osteocalcin message levels were increased on the rough titanium surface compared to smooth surface[4]. We can therefore conclude that elevate **roughness of TiPEEK cages allows** to form CaP that potentially participate on the **bone formation** (in vitro data). The presence of the titanium coating on the whole surface of the cage can give further potential advantages in this process.

Conclusion

The results of the current study demonstrate a **bioactive surface of TiPEEK cages**. This findings associated with the **elevate roughness** of the implant coating suggest that the use of **TiPEEK can potentially facilitate bone formation** at the implant/vertebra interface.

References

1. Kokubo T, Kim HM, Kawashita M, Nakamura T J, Bioactive metals: preparation and properties. Mater Sci Mater Med. 2004 Feb;15(2):99-107
2. Kokubo T1, Takadama H, How useful is SBF in predicting in vivo bone bioactivity? Biomaterials. 2006 May;27(15):2907-15. Epub 2006 Jan 31.
3. Gittens RA, Olivares-Navarrete R, Schwartz Z, Boyan BD, Implant osseointegration and the role of microroughness and nanostructures: lessons for spine implants. Acta Biomater. 2014 Aug;10(8):3363-71.
4. Karen B. Sagomonyants, Marcus L. Jarman-Smith, John N. Devine, Michael S. Aronow , Gloria A. Gronowicz, The in vitro response of human osteoblasts to polyetheretherketone (PEEK) substrates compared to commercially pure titanium, Biomaterials (2007), doi:10.1016/j.biomaterials.2007.12.001

Paper Analysis in Pills

1. Goal of this study is to evaluate the **bioactivity** of the Titanium coating of the Medacta TiPEEK cages intended as **the ability of the material to form a CaP layer** (and compare it to the PEEK cages bioactivity)
2. CaP layer eventually transforms into bone-like apatite by allowing surrounding living bone to directly tightly bond onto the TiPEEK cages
3. The formation behavior of the apatite layer on the cages was examined by immersion in SBF for up to 7days.
4. Globular masses indicating **early bioactivity and CaP formation was noticed at day 1 on TiPEEK** targets and an increasing formation of extensive CaP structures was seen at day 7
5. No deposition of CaP was seen in the PEEK samples at the analyzed time points
6. Surface analysis revealed a micrometric roughness of TiPeek layer potentially representing a beneficial factor to drive bone formation rather than smooth surfaces can do (like PEEK cages), as based on literature data
7. The results of **the current study demonstrate the bioactive nature of the TiPEEK** cages. This findings associated with the elevate roughness of the implant coating suggest that the use of TiPEEK can potentially facilitate bone formation at the implant/vertebra interface