Micro-and Nano-scale Surface Topographic Characterization of a Novel PEEK Titanium Structural Composite

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Statement of Purpose: The synthetic thermoplastic Polyetheretherketone (PEEK) has been widely utilized for orthopedic devices, particularly in the arena of spinal implants [1]. However, its practical use suffers from its own limitations. Although PEEK is biocompatible, chemically stable, radiolucent and has an elastic modulus similar to that of normal human bone, it is biologically inert, limiting its long term integration with adjacent bone tissues. In efforts to improve the bioactivity of PEEK, a novel PEEK titanium structural composite was developed by combining bioactive porous titanium end plates and a radiolucent PEEK core. As shown in Figure 1, this novel PEEK titanium structural composite is a multilayer structure with porous titanium endplates (50% porosity with 400μm average pores) opposing adjacent bone tissues for osteo-integration and a radiolucent PEEK core for post-operative imaging evaluation. The proprietary design creates a PEEK titanium inter-digitation layer that ensures an integrated and secure mechanical bond between the titanium plate and the PEEK core.

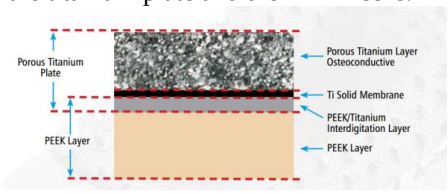

Figure 1. Schematic of the PEEK titanium structural composite

The porous titanium plates are manufactured using a 3-dimentional metal printing technology, direct metal laser sintering (DMLS). In addition, the plates also went through a proprietary acid etching process, generating a micro- and nano-scale surface texture that may create a positive microenvironment for bone cells. An ovine study has shown that animals implanted with the PEEK titanium composite device (Fig. 2) have significantly higher fusion scores and significantly more bone present in the graft window compared to a traditional PEEK device [2]. However, the surface topography of the PEEK titanium composite on the micro- and nano-scale has not been studied. The purpose of this study was to characterize (1) the micro-roughness of a typical single strut of the porous titanium plate, (2) the topography of PEEK titanium inter-digitation layer and (3) the presence of nano-scale structures in the PEEK titanium structural composite.

Methods: One sample of a lumbar interbody spacer made of the PEEK titanium structural composite (Forza™ spacer from Orthofix Inc.) was used in this study.

Figure 2. PEEK Titanium Composite Implant

The surface morphology and the micro-roughness of one typical strut of porous titanium layer of the sample were investigated using a Park XE 70 atomic force microscopy (AFM) system in a contact mode. Micro-surface roughness measurements such as peak to valley roughness (R_{pv}) and root mean square roughness (R_q) were obtained from various locations. The surface topographic images and the interface between the PEEK core and the titanium plate at the inter-digitation layer were characterized using a Hitachi S-3000N variable pressure scanning electron microscope (SEM). The nanostructure on the surface of one typical strut of porous titanium was investigated using a high-resolution SEM in a Hitachi S-4800 field-emission SEM.

Results: Figure 3 shows typical results for the micro-roughness of a single strut. The results show that the measured average peak to valley roughness (R_{pv}) is 7.82 μm and the average root mean square roughness (R_q) is 1.76 μm.

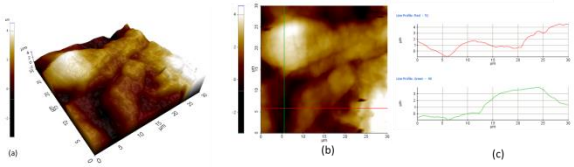

Figure 3. Typical AFM images and measurement of micro-roughness

Figure 4 shows typical SEM images of the PEEK titanium inter-digitation layer. A well jointed interface between the titanium plate and the PEEK core was observed.

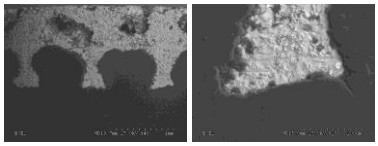

Figure 4. SEM images of PEEK titanium inter-digitation layer

Figure 5 shows that two types of nano-structures were presented on the sample. Nano particles/features with a size of ~40 nm were observed in the rough regions of the surface, while nano pores with a size <10 nm observed in the flat regions.

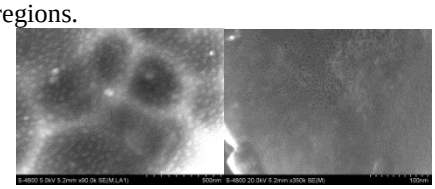

Figure 5. SEM images of nano-structure

Conclusions: Using AFM, the measured micro-roughness ranges from 1.76μm to 7.82μm depending on the parameters. SEM images have shown two types of nano-structures were presented in the sample. In addition, SEM images of the PEEK Titanium composite also show a solid joint of the PEEK core and the titanium plate at the inter-digitation layer.

References: [1]Kurtz S, Biomaterials, 2007; 32:4845-4869. [2] Waldorff EI, NASS, 2016, Boston, MA