Phospholipid Coatings on PEEK For Enhanced Osseointegration

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Statement of Purpose: Spinal fusion devices are used in over 330,000 patients in the US annually to treat spinal disorders. Since the late 1990s, PEEK (polyether ether ketone) has emerged as one of the leading choices of surgeons for their spinal fusion procedures, due to its optimal biomechanical properties, resistance to degradation, biocompatibility and radiolucency. Numerous attempts have been made to improve osseointegration on PEEK, such as controlling surface texture and porosity, and applying osseointegrative coatings such as hydroxyapatite to PEEK fusion cages. However, none of these efforts has succeeded to date in bringing a coated PEEK cage to market. Prior work has shown that the phospholipid phosphatidylserine (PS) can improve new bone mineralization and osseointegration [1]. This work inspired the development of an aerosol spraying approach for applying thin, uniform, consistent PS coatings on titanium implants [2], to aid in osseointegration. The study reported here uses this method for applying thin PS coatings on PEEK.

Methods: Our study was completed in two parts: (1) establish the best parameters for coating uniformity and conformity; and (2) use these parameters to evaluate coating adhesion on cylindrical PEEK implant test devices in ovine cadaver vertebrae. In part one, PEEK (Invibio Optima LT1) plates (8mm x 8mm x 2mm thick) were fabricated using an Exact saw. Aerosol spray parameters were varied to identify the best coating characteristics, as judged by coating uniformity and conformity observed by SEM/EDS. Coating composition was analyzed using XPS. Static water contact angles were measured to evaluate hydrophilicity.

In part two, cylindrical PEEK samples (6 mm diameter x 14 mm length) were machined by Lanx Inc., then PS-coated using the spray parameters discovered in part 1. Adhesion was tested in sheep cadaver vertebrae (L3, L4 or L5) obtained from the CSU Veterinary Hospital. Briefly, a 14mm deep cylindrical defect was created in the lamina portion of vertebral bodies using a standard 5.95mm drill bit with a stop on the end allowing 14mm of depth. A PL-coated implant was imaged with SEM then inserted into a drill hole, fitting tight and flush, using an inserter tool supplied by Lanx. After 30 minutes, the devices were removed using the same tool, and imaged again using SEM/EDS.

Results: PS coatings on PEEK were uniform and conformal, as shown in the following SEM images.

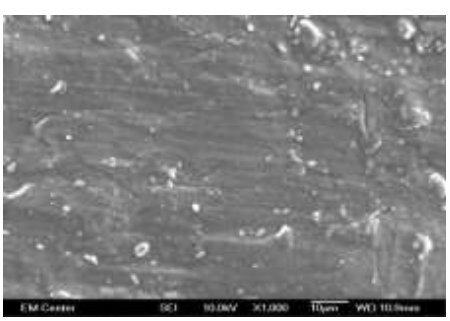

Figure 1: uncoated cylindrical PEEK implant test sample

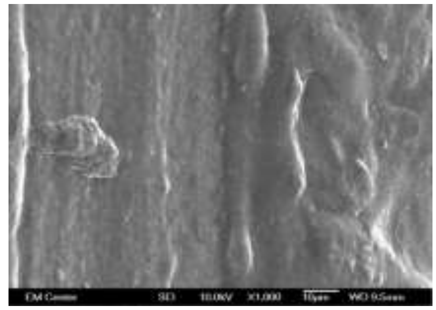

Figure 2: SEM image of PS-coated cylindrical PEEK implant test sample shows conformal nature of coatings on curved surface

The following EDS results confirm the presence of PS on the cylindrical PEEK implant test devices.

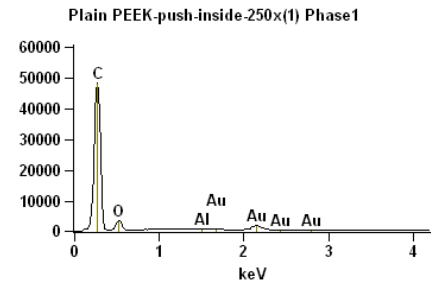

Figure 3: EDS of uncoated cylindrical PEEK implant test device

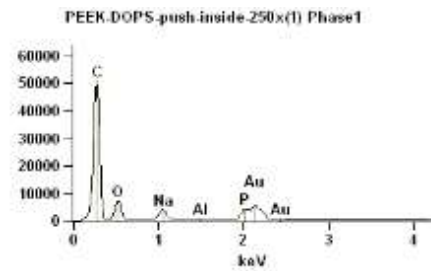

Figure 4: EDS of PS-coated cylindrical PEEK implant test device. Note peaks "P" and "Na".

The presence of phosphate and sodium peaks indicate phospholipid coating is present on these test devices.
PS coatings on cylindrical PEEK implant test devices (part 2 in methods) were not notably damaged by the shear forces associated with insertion and removal from cadaver ovine vertebrae.

Conclusions: Phosphatidylserine can improve osseointegration. Coating techniques have been developed for applying thin, uniform coatings of PS onto titanium. PEEK implants could benefit from similar techniques. We have demonstrated that a simple aerosol spraying method can apply a uniform, conformal, sufficiently durable PS coating on PEEK, which can withstand the shear forces of surgical application. We subsequently implanted similar PS-coated PEEK devices in an *in-vivo* ovine spinal vertebral model and await results.

References:

1. Santin, M., R. Soc. Interface, 2005. **3**: p. 277-281.
2. Rodgers, W. CSU Ph.D. dissertation, 2013.

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