Interfacial Shear Strength of Bioactive Coated Carbon Fiber Reinforced Polyetheretherketone After In Vivo Implantation

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Introduction:

Carbon-fiber-reinforced polyetheretherketone (CFR/PEEK) has been attractive for use as orthopaedic implants, due to material characteristics such as high fatigue strength, easy modification of mechanical properties, including strength, toughness, and stiffness by the arrangement of reinforcing fiber volume and orientation, no metal ion release, and excellent biocompatibility. These characteristics are expected to provide CFR/PEEK cementless hip prostheses with greater longevity than traditional metal joint prostheses [1,2].

Despite of the mechanical characteristics suitable for cementless hip prostheses, achieving a stable bone-implant interface by osseointegration has been a longstanding problem associated with CFR/PEEK, which is considered to be bio-inert but not bio-active. On polymer devices, as well as metal devices, bioactive material coatings have been attempted to improve osseointegration [3], however, mechanical strength of fixation at the bone-implant interface has not yet been adequately investigated. In addition, sufficient interfacial shear strength between the coating layer and the main structure is also of equal importance for a stable bone-implant interface.

We developed a new method of HA coating of CFR/PEEK in order to achieve tight interlock at the HA-implant interface. To evaluate the effect of the HA-coating on the interfacial shear strength between the bone and the implant quantitatively, we conducted mechanical tests after in vivo implantation in a rabbit femur-implant pull-out test model.

Materials and Methods:

All test pieces were cylindrical with a threaded hole at one edge of cylinder to enable connection with a mechanical testing machine. Test implants constructed from CFR/PEEK were HA-coated (HA-coated CFR/PEEK) as follows. HA granules were embedded in the polymer by heat pressing, and the surface was blasted to expose the HA granules. The surface was then treated with nitrogen (N2) plasma to improve the hydrophilic properties. The implant was then dipped in α-tricalcium phosphate (α-TCP) solution and subsequently treated with vapor at 100°C. Using this method, the α-TCP transformed into HA. Componental analysis revealed that 80% of the coating was transformed into HA at an average coating thickness of 20 µm. As control implants, the CFR/PEEK cylinder without any surface treatment (uncoated CFR/PEEK), titanium alloy (Ti6Al4V) cylinder, the surface of which was blasted with aluminum beads (R=3µm) (uncoated Ti), and HA-coated blasted Ti6Al4V cylinder (HA-coated Ti) were used. The HA was coated onto the blasted titanium alloy by a plasma spray technique at a thickness of 20 µm (Fig. 1).

Japanese white rabbits weighing 3 to 3.5 kg were used as a model in the present study. Under general anesthesia, the implants were inserted into drilled femoral cortex in a line-to-line fashion. The femora were retrieved at 6 or 12 weeks postoperatively and were scanned by micro-computed tomography (µCT) to measure the contacted cortical thickness for the evaluation of the interfacial shear strength (MPa). The specimen was attached to a universal testing machine (Model 4303, Instron Corp) and the pull-out tests were performed under a controlled condition at a displacement of 1 mm/minute. The maximum load (N) was obtained for each specimen by examining load-displacement plots. Then, the interfacial shear strength (MPa) values were calculated by dividing the maximum load by the contacted cortical area. The topography of the surface of the retrieved implant was analyzed by macrograph, SEM, and energy dispersive X-ray (EDX).

Two samples from each group at each time period were processed for histologic examination of the bone-implant interfacial regions.

Results:

At 6 weeks, 12 HA-coated CFR/PEEK, 10 uncoated CFR/PEEK, 12 uncoated Ti, and 12 HA-coated Ti implants were obtained for the mechanical test. At 12 weeks, 12, 10, 8, and 8 were obtained, respectively. The interfacial maximum shear-strength in each implant is shown in Fig. 2.

The macro- and SEM-findings of the removed HA-coated CFR/PEEK implants and HA-coated titanium alloy implants revealed that the HA layer partially disappeared and substrate material appeared in both the 6- and 12-week samples. In the EDX analysis of both the HA-coated implants, the area in which HA was detached macroscopically showed lower spectra of calcium and phosphorous compared to the area in which HA remained adherent. However, the spectra of calcium and phosphorous remained.

In both the 6- and 12-week histology from the HA-coated CFR/PEEK implants, new bone formed from the original cortex was growing directly on the implant surface and completely bridged the original cortex and the implants.

Discussion:

The present results clearly indicated that the bioactive treatment onto CFR/PEEK is an efficient method by which to enhance the interfacial shear strength between CFR/PEEK and bone. Due to the effect of acceleration of osseointegration by HA coating, the HA-coated CFR/PEEK implants achieved the ultimate interfacial shear strength in an earlier stage and subsequently plateaued as well as the HA-coated titanium alloy implants.

The surface analysis after the pull-out tests revealed that fixation of the HA-coated implants was lost mainly at the coating-implant interface or within the coating for both the CFR/PEEK and titanium alloy substrates. This means that loss of fixation was dependent on the adhesive strength of the coating layer. The results that the achieved interfacial shear strength of the HA-coated CFR/PEEK implant was similar to that of grit-blasted titanium alloy implant with HA coating, which is one of the surface treatment of clinically successful implants, suggests that sufficiently tight adhesion of the HA coating layer for clinical use could be demonstrated on the CFR/PEEK device.

In conclusion, the proposed method of coating HA onto CFR/PEEK significantly increased the interfacial shear strength between bone and CFR/PEEK. The achieved interfacial shear strength of the HA-coated CFR/PEEK implant was similar to that of grit-blasted titanium alloy with HA coating.

Significance: It is essential for CFR/PEEK cementless hip prostheses to create a stable bone-implant interface by osseointegration after in vivo implantation. By the novel HA-coating onto CFR/PEEK, mechanically stable interface between bone and CFR/PEEK could be demonstrated.

References:

Acknowledgement: This work was supported by a grant from the New Energy and Industrial Technology Development Organization.