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Introduction: Bone prostheses constructed with more flexible non-metallic composite materials have been the subject of many studies due to their expected capacity to reduce bone loss that is attributed to stress shielding. However, their limited success has essentially been attributed to early failures as a result of poor design or reliability and early implant loosening caused by the low stiffness of the material at the bone-implant interface. Recently, a hybrid design that averages the stiffness from a Co-Cr stem overmolded with a PEAK (polyaryletherketone) layer and coated with a porous Ti has attracted attention[1,2]. Clinical studies confirmed the expected reduced bone loss, as well as stable initial and mid-term bone fixation. This suggests that a femoral stem with bone-matching stiffness (BMS) would increase the effectiveness in preventing bone loss. The objective here is to demonstrate the *in vitro* and *in vivo* response to polymer composite BMS femoral rods.

Materials and Methods: The composite material was fabricated from polyamide12 and carbon fibers. Ethylene oxide (EtO) sterilized samples of plasma-sprayed HA (hydroxyapatite) coated and non-coated composite were placed in tissue culture plates (TCP) containing MG63 osteoblast-like cell cultures for 14 days. Plain TCP and medical grade Ti was used as control. Alkaline phosphatase (ALP) and osteocalcin (OC) content were monitored as two important osteoblast differentiation markers for early and late mineralization respectively. The ALP and OC levels released in the medium were determined spectrophotometrically using commercial kits. Results are normalized to the total protein content in the medium and cell lysates. *In vivo* osteointegration potential was evaluated by composite or Ti rod insertions in both femurs of six New Zealand white rabbits (craniocaudal skin incision at the level of the patella, the lateral joint capsule was cut open, the epiphysis of the distal femur was exposed and the medullary canal was accessed via retrograde hand-drilling starting at the middle and distal extent of the femoral trochlea). Rabbits were allowed to bear full weight immediately after surgery. Rabbits with Ti and composite rods equally recovered normally from surgery after 1 week (no statistical difference from T-test). Results shown are bone apposition fraction (%) obtained from backscattering scanning electron microscopy (SEM) image analysis of at least 5 polished 100 μm thick sections of bone-embedded rods. All rods had the same surface roughness (R_a = 6.3 μm).

Results and Discussion: The ALP and OC levels released by MG63 cells on the 4 materials are shown in Fig. 1. By day 7 and especially by day 14, increasingly more ALP had been secreted by the cells on the HA-coated composites than from those on the non-coated composite and the Ti and TCP controls. By day 3, there was no significant difference between the OC levels released from cells on the HA-coated composite and non-coated composites or controls. But by day 7, the cells on both coated and non-coated composites had released significantly more OC that the cells on the controls. By day 14, these levels had dropped to the day-3 values.

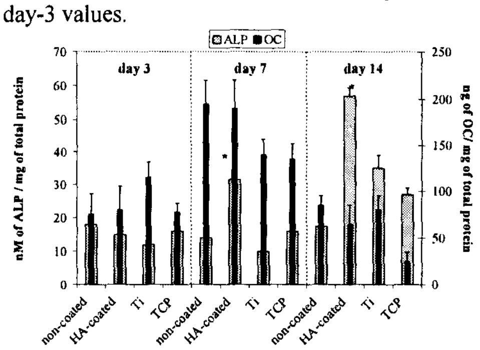

Fig. 1 Normalized ALP and OC levels in medium after 3, 7 and 14 days (values are the mean ± std dev. of 3 cultures; * $p < 0.05$ composite *vs* TCP).

Fig. 2 SEM of BMS composite femoral implant.

Osteointegration was evaluated with bone apposition measurements on femoral Ti or HA-coated composite rods: it was significantly ($p < 0.01$, t-test) higher for composite (34.1±15.0%) than for Ti rods (22.4±14.2%). SEM of sections in Fig. 2 show the extensive adherence to and penetration into the HA-coated surface of the BMS composite rods by the trabecular bone around the implant (a) and the bone apposition on and extensive penetration of bone into this composite rod (b).

Conclusions: The very high ALP plus the high OC levels released from HA-coated composites together indicate promotion of osteoblastic differentiation on HA-coated BMS composites. Rods made of the latter and implanted in rabbit femurs induced higher bone apposition and penetration than did Ti rods. This was expected since HA coatings are commercially used to improve bone-system bioactivity. These results confirm the value of HA coatings and carbon fiber composites for bone implants since strong osteointegration promoters are needed for durable hip arthroplasty.

References: 1. Kärrholm, J et al, JBoneJointSurg Am 84, 1651, 2002. 2. Akhavan, S et al, *ibid.*, 88, 1308, 2006.