**Porous Titanium Particles in Cemented Impaction Grafting Hip Revision Arthroplasty: Pre-Clinical Results**

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**Introduction:** Bone impaction grafting (BIG) is a surgical technique for the restoration of bone stock loss in revision total hip arthroplasty (tTHA) by impaction of allograft bone particles (BoP) into the bony defect. BoP are considered to be the gold standard, although many alternative materials have been developed, most of them being ceramic based. Important properties of these synthetic materials are surgical handling characteristics (impactability) and primary stability of the reconstruction. Furthermore, optimal porosity of reconstructive materials should combine limited cement penetration with long term stabilization by ingrowth of bone tissue. Previous studies showed that porous biphasic bioceramic particles (CeP) have to be mixed with bone grafts to limit cement penetration and to prevent pulverization during impaction. In order to create a full bone graft substitute for impaction grafting, a more deformable material was chosen to overcome the mechanical limitations of CeP. The goal of a series of *in-vitro* experiments was to assess the suitability of porous titanium particles (TiP) for application as a full bone graft substitute to be used in tTHA.

**Methods:** *In-vitro:* Impactability and graft layer elastic properties after standardized impaction (density of impacted TiP: 1.1 g/ml; Fondel Medical BV, Rotterdam, The Netherlands), CeP and BoP. Realistic cemented *in-vitro* acetabular reconstructions (n=8) (Sawbones Europe, Malmö, Sweden; AAOSS type 2 defects 60 mm; Exeter Contemporary cup, Stryker Orthopaedics, Exeter, UK) were made with TiP and with BoP to evaluate handling and cement penetration and to measure initial migration, rotation, and shear force resistance with a servo-hydraulic MTS machine and radiostereometric analysis (RSA).

Realistic *in-vitro* femoral TiP reconstructions (n=7) (Sawbones Europe, Malmö, Sweden) were used to evaluate the applicability in the femur. Subsidence was measured during prolonged cyclic loading (300,000 loading cycles) and potential micro-particles that were released from the graft layer due to impaction or loading were analyzed using laser diffraction techniques (Malvern Mastersizer® 2000, Malvern Instruments Ltd, Malvern, UK).

*In-vivo:* Mature Dutch milk goats (Capra Hircus Sanus) with a mean body weight of 55 kg were used for all *in-vivo* experiments and all procedures were approved by the Animal Ethics Committee of the University of Nijmegen, The Netherlands. TiP (with or without a bioceramic coating) were tested under unloaded conditions in a femoral condyl study (n=12) and compared with BoP. To test TiP under realistic and loaded *in-vivo* conditions, acetabular defects (AAOSS type 3 defect, 60 mm; Exeter Contempory cup, Stryker Benoist, Girard, France). Blood samples were taken throughout the experiment to assess the release of Ti-ions into the blood. Goats were killed after fifteen weeks for histological analysis.

**Results:** *In-vitro:* The confined compression chamber test showed that TiP were more deformable than BoP. TiP created an entangled graft layer and did not fracture whereas CeP were pulverized during impaction. The elastic modulus of the graft was lower in TiP specimens than in CeP specimens but higher than in BoP specimens. Acetabular *in-vitro* testing showed that TiP stick together well during impaction (density of impacted TiP: 1.1 g/ml). Bone cement intrusion was found about 1.0 mm deeper in BoP graft layers than in TiP graft layers (p<0.02). TiP reconstructions showed better primary stability. Cup migration and rotation were about three times larger in BoP reconstructions than in TiP reconstructions (p<0.01) and shear force resistance was about four times larger in TiP reconstructions compared to BoP reconstructions (lever-out moment 12±4 Nm respectively 56±12 Nm, p<0.001). Good primary stability and limited cement penetration were reproduced in realistic *in-vitro* femoral reconstructions (density of impacted TiP: 1.1 g/ml). Average subsidence rates of the stem relative to the bone were low and reproducible (0.59 mm ± 0.41 mm after 300,000 loading cycles) and much smaller than subsidence seen in femoral bone impaction grafting [1]. Impaction generated 1.3 mg titanium particles per gram TiP, with a particle diameter range of 0.7-2000 µm and a trimodal size distribution (particle diameter at peak volume: 11 µm respectively 33 µm respectively 380 µm). The amount of particles collected at the end of loading was too small for analysis by laser diffraction.

*In-vivo:* a thin bioceramic coating (10-40 µm) increased osteo-conduction of impacted TiP. Bone ingrowth speed and distance were comparable between coated TiP and BoP. Cemented acetabular revision arthroplasty in goats (with 5-10g TiP) reproduced the findings of *in-vitro* and *in-vivo* studies: despite the limited penetration depth of the cement (408±309 µm) reconstructions were stable both at the cement-TiP interface and at the TiP-bone interface (Fig. 1). Two failures occurred at the cup-cement interface without affecting the TiP layer or gait of the goats. As a result these failures were unnoticed until post-mortem retrieval. Reconstructive layers of TiP had a mean thickness of 4479±566 µm (Fig. 1). Bone ingrowth occurred early (within four weeks) and was also present in very small TiP pores (Fig. 2, pink staining). Mean bone ingrowth distance after fifteen weeks was 282±438 µm. A thin fibrous tissue interface with a mean thickness of 91±110 µm separated the cement from the TiP. After reconstructions with BoP in the same model this interface is ca 1 mm thick. Serum titanium concentrations increased gradually on a logarithmic scale from 0.60 ± 0.28 parts per billion (ppb) before operation to 1.06 ± 0.70 ppb at the end of the study (p=0.18).

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**References:**