• Equine Bone Matrix Protein Lyophilisate augments Fixation and Osseointegration of HA-coated Ti Implants

INTRODUCTION:

Joint replacements should be firmly anchored in vital bone to avoid early implant subsidence and late aseptic loosening. Much effort is put into adjuvant therapy approaches for augmenting implant fixation, especially within the bone growth factors of the TGF-β superfamily.

This experiment addresses the question whether the mechanical fixation of orthopedic implants can be improved by adding an osteoinductive extract of equine cortical bone, Colloss E (Ossacur AG, Germany), between the implant and the surrounding bone.

METHODS:

Colloss E is a lyophilized complex of the extracellular matrix proteins of equine bone, and has no mechanical strength by itself. It is FDA-approved and used clinically as an osteoinductive bone void filler and to augment fracture healing. In canine experiments, the Colloss E device has proven useful in augmenting implants grafted with allograft and ceramic bone graft substitutes1, 2.

We used cylindrical non weight-bearing HA-coated plasma-spray Ti implants (length 10 mm, diameter 6 mm) (Biomet Inc.). Washers of 10 mm diameter were fitted on both ends of the implant, providing a 2.0 mm defect around the implant.

Following approval from the local Animal Care and Use Committee, two implants were inserted into Ø10 mm drill holes in the proximal tibia of each of 9 American Hounds with a mean body weight of 24.2 kg. The intervention implant was treated with 20 mg Colloss E in the gap around the implant. The implant in the contra-lateral tibia was not treated and served as control. The observation time was 4 weeks.

Implant fixation was evaluated blinded by mechanical push-out test and stereological histomorphometry on vertical sections. Neither mechanical nor histological data followed normal distribution, and were evaluated non-parametrically with Wilcoxon signed rank test. Group differences were considered significant for p<0.05.

RESULTS:

The Colloss E treated implants had better mechanical fixation than the untreated implants in the parameters Strength and Energy (Table 1).

By histomorphometry, the Colloss E treated implants had increased new bone formation on the implant surface as well as in the defect around the implants, and the presence of fibrous tissue was eliminated (Figure 2 A and B).

DISCUSSION:

Topical application of the Colloss E device around the HA-coated implants increased the mechanical fixation compared to the untreated control implants. The treated implants were better osseointegrated and fibrous tissue was eliminated.

Previous experiments on this device have also shown good bone regenerating properties in areas varying from augmenting the bioactivity of bone grafts1 and bone graft substitutes2 in canines, bone defect healing in sheep3 to spinal fusion models in pigs4. One ovine study similar to the present study showed a reduced implant fixation with the use of Colloss E5.

The encouraging results may be attributed to its range of osteogenic growth factors (BMP-2, BMP-7, TGFβ1, and IGF-1) in low concentrations and with a delayed release from the Collagen I matrix proteins4. This distinguishes the device from the human recombinant growth factors available as mono-therapy. There has, however, been some concern about foreign-body host response to the xenograft nature of the device.

The results suggest that Colloss E may augment early implant fixation and thereby reduce the risk of long-term failure. This may in particular be useful in revision arthroplasty with bone loss. Some caution should be taken due to its xenograft nature and adverse results in one preclinical experiment5. Human use of the device with load-bearing implants should be documented in protocolled clinical studies initially.

REFERENCES:

2) Baas et al. ORS Trans. Vol.31, Chicago, IL, 2006 paper 1743