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Evaluating of bone healing around porous coated titanium implant and potential systematic bias on the traditional sampling method

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ABSTRACT

Introduction: The mechanical properties of bone can largely be explained by bone density and the anisotropic orientation of the trabecular bone. The type of trabecular structure plays an important role in determining the mechanical properties of cancellous bone. Gap-healing and implant fixation could be affected by the various quality and quantity of bone in the local environment. Thus, implant fixation in one part might differ from the other part of the implant. This study aimed to investigate the influence of the sampling method on data evaluation.

Material and methods: Titanium alloy implants (Biomet Inc.) of 10 mm in length and 6 mm in diameter were inserted bilaterally into the proximal humerus of 8 skeletally mature sheep. Thus two implants with a concentric gap of 2 mm were implanted in each sheep. The gap was filled with allograft. Standardised surgical procedure was used. At sacrifice, 6 weeks after surgery, both proximal humeri were harvested. The specimens were randomized to superficial or profound groups. In the superficial group, mechanical testing or histological analysis was carried out on the superficial part of the implant. In the profound group, the mechanical testing or histological analysis was performed on the profound part of the implant.

Result: The mechanical fixation, bone volume and bone ongrowth showed no statistically significant differences. Mechanical test demonstrated a slight tendency to increased strength and failure energy were observed in the superficial group. Histomorphomety revealed bone ongrowth was slightly increased and volume fraction was decreased in the profound group.

Conclusion: Histological analysis and mechanical testing can be applied to the superficial or profound part of the implant.

1. Introduction

Gap healing and implant fixation are mainly influenced by surface design and texture, biological response and biomechanical factors such as micromotion in addition to host factors. Surface texture of titanium implants is known to play a role in implant anchorage (Overgaard et al., 1997b). Tissue response in the peri-implant gap depends on the quality and quantity of the host bone. The type of trabecular structure is known to determine the mechanical properties of cancellous bone (Ding et al., 2002). The mechanical properties of bone can largely be explained by bone density and the anisotropic orientation of the trabecular bone (Goldstein et al., 1993; Kabel et al., 1999). By inserting a loaded implant such as non-cemented femoral stem, an adaptive remodeling of the surrounding bone could occur (van Rietbergen et al., 1993; Kerner et al., 1999). On implants without direct load, the mechanical stimulus signal is largely missing – Stress shielding – thus, bone loose can occur (Brunski, 1999; van Rietbergen et al., 1993). Many factors that influence the peri-implant bone healing are known, but still several aspects have to be investigated. Little is known about the healing pattern of peri-implant tissue in different site of the same implant with the same topography. Moreover, the mechanical properties of the interface may differ significantly in the same gap. By estimation of bone volume and bone ongrowth in a peri-implant gap, the sampling method could influence the data evaluating. Unbiased systematic sampling is therefore important to ensure sufficient data evaluation.

This study investigates the risk of systematic bias by applying the sampling method, which includes the evaluation of mechanical fixation by using the superficial part and the histological analysis by using the profoud part of the implant. We hypothesized that this sampling method had an effect on data evaluation and that the mechanical testing and histological analysis will result in better mechanical fixation and more bone ongrowth in

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the profound part of the implant. We believe that the study is of importance in order to know whether we introduce bias, as experimental implant research by tradition, always have sampled the most superficial part of the implant for mechanical testing and the most profound for histology.

2. Materials and methods

Eight skeletally mature female sheep with a mean age of 5.7 years (5–8) and body weight of 72.2 kg (51.5–86) were included in the study. The sheep were treated in compliance with Danish laws for the use of experimental animal. This study was approved by the Danish Animal Experiments Inspectorate.

2.1. Study design

The gap-model has been described in detail in previous studies (Overgaard et al., 1997b; Babiker et al., 2012). The implant is cylindrical in shape and has a plasma-sprayed porous-coating made of titanium alloy implants (Ti–6A1–4V) (6% aluminium, 4% vanadium and 90% titanium) (Biomet Inc., Warsaw IN). The implant is 10 mm in length and 6 mm in diameter, and has a footplate and a top washer of 10 mm in diameter. This gives a circumferential gap around the cylinder of 2 mm, which has a volume of 0.5 ml. The implant size was chosen according to the anatomy at the implantation site of the sheep in the proximal humerus in trabecular bone. The implants were inserted bilaterally, extra-articularly and transversely into the proximal humerus. Thus, two implants were inserted in each sheep. The gap was filled with allograft.

For preparation of the specimens for mechanical and histological analysis, two different sampling methods were used. The right and the left implants in each animal were randomly allocated either to perform:

(I.) The mechanical testing from the superficial part and the histological analysis from the profound part of the implant; or
(II.) The mechanical testing from the profound part and the histological analysis from the superficial part of the implant (Fig. 1). By choosing this design, we were able to evaluate the differences between the superficial part and the profound part with regard to histology and implant fixation, but on different limbs.

2.2. Bone allograft

Allograft bone was harvested from the femoral head and femoral condyles of a donor sheep. The preparation was performed under sterile conditions. The soft tissue and cartilage were removed completely from the bone. The bone was milled in a bone mill (Ossano Scandinavia ApS, Stokholm, Sweden). The morselized bone was placed into small sterile glass tubes and stored at −80 °C until transplantation.

2.3. Surgery

The surgical procedures were performed under general anaesthesia. The animals were premedicated with Rompun (xylacinhydrochlorid, 20 mg/ml, Bayer animal health GmbH, Germany) 0.2 mg/kg and the anaesthesia was induced by Rapinovent (propofol 10 mg/ml, Shering-Plough animal health GmbH, Germany) 3 mg/kg and maintained by 2% isoflurane in 40% oxygen and 60% atmospheric air in automatic-assisted ventilation.

Under sterile conditions, a 7 cm skin incision was made above the proximal humerus. The bone was gently exposed at the implantation site, and the periosteum was retracted. A guide Kirschner wire was inserted approximately 15 mm into the bone perpendicular to the bone surface using a levelled drill. A 12 mm deep cylindrical cavity was then drilled with a 10 mm drill. Low speed was used to avoid thermal injury to the surrounding bone. The bottom was levelled with a flat drill. The cavity was cleaned from bone parts and rinsed with saline-water. The implant was inserted in the hole and the circumferential gap was filled with allograft. The hole was closed with the top-washer. The wound was closed in layers. The sheep were allowed free activity after surgery. Postoperative analgesia was achieved with Temgesic (buprenorphinum, 0.3 mg/ml, Shering-plough animal health GmbH, Germany) 0.01 mg/kg for 3 days. Prophylactic Ampivent (ampicillin 810 mg/g, Boehringer Ingelheim, Denmark A/S.) 0.2 mg/kg was administrated before and after surgery for a period of 5 days. The observation period was 6 weeks. The sheep were euthanized with an overdose of pentobarbital (200 mg/ml). Both humeri were harvested and kept frozen at −20 °C until preparation.

2.4. Sample preparation

Bone-implant specimens (approximately 20 mm in diameter and 10 mm in length) were cut orthogonally along the long axis into two parts with water cooled diamond band saw (EXAKT-Cutting Grinding System, Germany). The specimens were randomized into two groups. In the first group, a 3.5 mm thick implant-bone sample was taken from the superficial part of the specimens and kept at −20° until mechanical testing. The other sample of 6.5 mm in thickness was dehydrated in graded ethanol 70–100% containing 0.4% basic fuchsine, and embedded in methyl methacrylate (Technovit® 9100 NEW, Heraeus Klzer GmbH, Wehrheim, Germany) for histological sectioning. In the second group, the superficial part of the specimens of 6.5 mm was served for histological sectioning and the profound part of 3.5 mm was served for mechanical testing (Fig. 1).

2.5. Mechanical testing

The implant-bone interface was tested to failure by a destructive push-out test on a 858 Bionix MTS hydraulic material testing machine (MTS system cooperation,

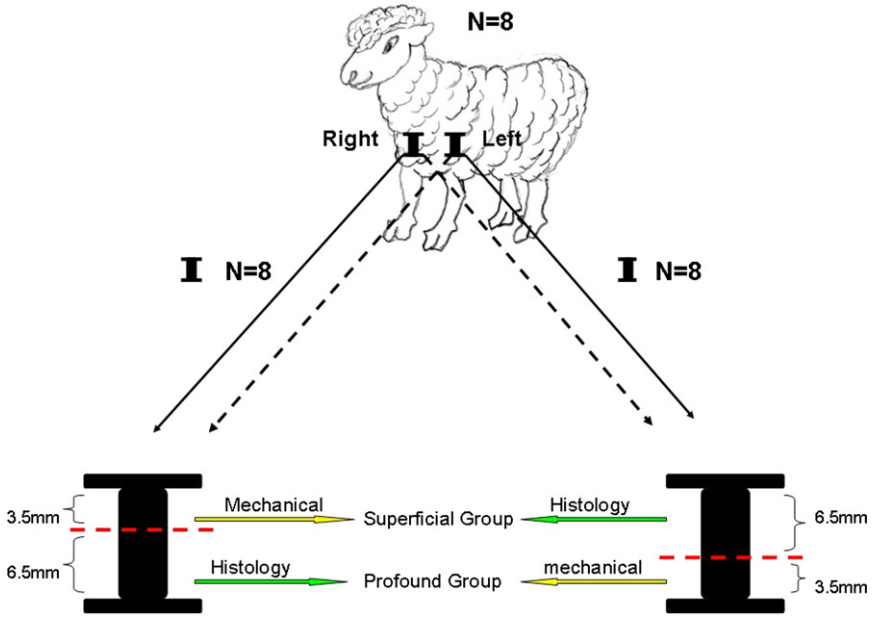

Fig. 1. Sketch showing design of study III. During preparation, the right and left implants from each animal were randomly allocated either to perform the mechanical testing from the superficial part and the histological analysis from the profound part, or to perform the mechanical testing from the profound part and the histological analysis from the superficial part of the implant.