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Fixation of a double-coated titanium-hydroxyapatite focal knee resurfacing implant
A 12-month study in sheep

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SUMMARY

Objective: Focal cartilage lesions according to International Cartilage Repair Society (ICRS) grade 3–4 in the medial femoral condyle may progress to osteoarthritis. When treating such focal lesions with metallic implants a sound fixation to the underlying bone is mandatory. We developed a monobloc unipolar cobalt-chrome (Co-Cr) implant with a double coating; first a layer of commercially pure titanium (c.p.Ti) on top of which a layer of hydroxyapatite (HA) was applied. We hypothesised that such a double coating would provide long-lasting and adequate osseointegration.

Design (materials and methods): Unilateral medial femoral condyles of 10 sheep were operated. The implants were inserted in the weight-bearing surface and immediate weight-bearing was allowed. Euthanasia was performed at 6 (three animals) or 12 months (six animals). Osseointegration was analysed with micro-computer tomography (CT), light microscopy and histomorphometric analyses using backscatter scanning electron microscopy (B-SEM) technique.

Results: At 6 months one specimen out of three showed small osteolytic areas at the hat and at 12 months two specimens out of six showed small osteolytic areas at the hat, no osteolytical areas were seen around the peg at any time point. At both time points, a high total bone-to-implant contact was measured with a mean (95% confidence interval – CI) of 90.6 (79–102) at 6 months and 92.3 (89–95) at 12 months, respectively.

Conclusions: A double coating (Ti + HA) of a focal knee resurfacing Co-Cr implant was presented in a sheep animal model. A firm and consistent bond to bone under weight-bearing conditions was shown up to 1 year.

Introduction

Full thickness cartilage injuries beyond a certain rather small size (4–7 mm in sheep) do not heal instead they may develop to osteoarthritis[1–4]. Hence, treatment is warranted but is still controversial and remains an unsolved clinical challenge[5]. The treatment of cartilage injuries evolves along two dichotomously differing approaches. On one side there are attempts at biological healing by means of cell stimulation of different kinds (autogenous chondrocyte implantation – ACI, mosaicplasty or simple microfracturing). As of yet there is insufficient evidence to state which of these methods is superior[6–9]. The alternative approach is to resurface the cartilage defect with a metallic implant[10–13]. If the latter is chosen, sound fixation to the underlying bone is mandatory. Focal cartilage injuries are being treated more frequently with metallic resurfacing implants in human joints although data on osseointegration are still scarce and only a few animal studies present promising but varying results[11,14,15]. In this report we describe the osseointegration process up to 1 year postoperatively in a sheep animal model.

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When fixating a small unipolar (articulating against opposing cartilage) focal knee resurfacing (FKR) implant distinct challenges are encountered. First, in this middle-aged patient group bone should be spared, should future intervention be needed. Existing FKR implants use large penetrating anchoring screws fixating to metaphyseal condylar bone, potentially creating large defects upon removal and hence augmenting complexity of revision surgery[16]. For the same reason polymethylmethacrylate (PMMA) cement is generally avoided in the younger patient (<50 years)[17]. Secondly, a firm fixation warrants a tight sealing between the implant and surrounding tissue, as penetration of joint fluid into the implant–bone interface is prone to induce osteolysis and subsequently implant loosening[11]. Additionally, previous studies have shown that FKR implants should not protrude but rather be recessed in relation to surrounding cartilage level, in order not to damage the opposing tibial cartilage[11,13,18]. Thus, a secure yet highly accurate fixation method and instrumentation is demanded.

We developed a slender monobloc implant with a double coating on a cobalt-chrome (Co-Cr) core for non-cemented fixation. First a coating of commercially pure titanium (c.p.Ti) was used, on top of which a superficial layer of hydroxyapatite (HA) was applied. In this first report we introduce the double coating for FKR fixation, and hypothesised that this method should provide a long-lasting secure fixation of the implant to the bone. Such a durable bond would be created first by ongrowth of bone to the HA layer and secondly, should the HA dissolve, by the establishment of a permanent bone-titanium bond.

Materials and methods

Animals

Ten healthy female sheep (Swedish landrace) from the same breeder were operated and housed at the Department of Clinical Sciences, Swedish University of Agriculture Sciences (SLU) in Uppsala, Sweden. One animal was euthanized 2 months postoperatively and data are reported from the remaining nine animals. The mean age and weight of sheep was 4 years (range 2–6) and 74.4 kg (range 62–90), respectively. The animals were kept indoors in stables in groups of three. Food was given twice a day and water was freely available. Well-known personnel monitored the animals daily for general condition, signs of pain and lameness (where grade 0 was normal gait and 1–4 was mild, moderate, major and severe lameness respectively). Euthanasia was performed after 6 months in three animals, and six animals were euthanized after 12 months. Animal Ethics Committee, Uppsala, Sweden, approved the protocol.

Implant

The implants (diameter 7.5 mm) had a double-curved (radii 19 and 12 mm) articulating surface, modelled after computer tomography (CT) scans of a standard sheep knee and manufactured from implant-grade Co-Cr by computer aided design and manufacturing (CAD/CAM) process. The implants were coated with commercially pure titanium (60 μm) on which a layer of HA (60 μm) was plasma-sprayed (Plasma Biotal Ltd., Buxton, GBR). A 10 mm peg (diameter 2 mm) was introduced into an undersized (diameter 1.8 mm) drill hole in the bone for primary interference fit. The implants were manufactured and provided by Episurf AB, Stockholm, Sweden.

Anaesthesia

The animals were anaesthetized by an intravenous (IV) injection in the jugular vein of xylazine (Rompun® vet, Bayer Animal Health, Lyngby, Denmark) 0.11 mg/kg and ketamine (Ketaminol® vet, Intervet, Stockholm, Sweden) 2.2 mg/kg after which they were intubated. The anaesthesia was maintained with isoflurane (IsoFlo® vet, Orion Pharma Animal Health, Stockholm, Sweden) 1.5–3% in 100% oxygen. All animals breathed spontaneously. After anesthetization, blood samples were taken from the cephalic vein. The animals were given antibiotics, cefuroxime (Cefuroxim, Farmaplus, Oslo, Norway) 22 mg/kg IV and analgesic, carprofen (Rimadyl® vet, Orion Pharma Animal Health, Stockholm, Sweden) 4 mg/kg subcutaneously (SC), buprenorphine (Temgesic®, Schering-Plough, Stockholm, Sweden) 0.01 mg/kg intramuscularly (IM), glykopyrrolate (Robinul®, Meda, Solna, Sweden) 0.25 ml/10 kg SC. The animals were operated in dorsal recumbency and the surgical field was aseptically prepared.

Surgery

Surgery was performed on one knee; randomly prepared closed envelope determined the side. All operations were carried out under aseptic conditions by the same surgeons (HNS, NMC and LR). The medial femoral condyle was exposed through a medial parapatellar 5–6 cm incision through skin and subcutaneous tissue. After inspecting the knee the operation was carried out using a set of specially designed instruments: First, a centralising aiming guide with a built-in guiding tube, adapted to the contour of the posterior weight-bearing condylar surface was applied and fixed to the condyle by means of three pins engaging the metaphysis outside the articulating cartilage. Through the guiding tube, positioned perpendicular to the articulating surface, a specially designed drill was used to cut the cartilage and the underlying bone in a way to exactly correspond to the shape of the implant. According to previous studies[13], we aimed to position the implant at a level 0.5 mm recessed below the surrounding cartilage. A slightly smaller testing device with identical articulating contour as the final implant was subsequently used to control the position in height relative to the surrounding cartilage before finally inserting the implant. Finally, the joint capsule was sutured in a continuous pattern using polydioxanone (PDS®, Ethicon) and the subcutaneous tissue and skin were closed in a similar pattern using polyglicaprone 25 (Monocryl®, Ethicon). No surgical complications occurred during the operations. The sheep were extubated in their stables and under continuous observation and regained consciousness within 1-h postsurgery. The animals were randomly sacrificed at 6 months (three animals) or after 12 months (six animals) using an overdose pentobarbital (100 mg/ml) after securing blood samples. The knees were removed from the body and the joint was inspected macroscopically, according to ICRS (0–4) and a modified O'Driscoll score (0–6 points instead of 0–10) as the parameter restoration of contour and cartilage erosion of the graft was not possible to evaluate[14,19,20]. Also, imaging and histological assessments were performed.

Micro-CT

The specimens were scanned using a high-resolution micro-CT system (μCT 40, Scanco Medical, Switzerland) in multislice mode. Each image data set consisted of approximately 600 horizontal micro-CT slice images perpendicular to the long axis of the peg. The specimens were scanned in high-resolution mode with an *x*-, *y*-, *z*-resolution of 16 μm. The image data sets were used to produce 3D views of the specimens using a software program (Scanco Medical, Switzerland).

Light microscopy

The specimens were prepared for light microscopy according to the ground sectioning technique by Donath and Breuner[21]. In short, the specimens were dehydrated in a graded series of ethanol: 60%,

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