Microporous Pure β–Tricalcium Phosphate Implants for Press-Fit Fixation of Anterior Cruciate Ligament Grafts: Strength and Healing in a Sheep Model

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Purpose: A sheep study was conducted to test a press-fit technique using microporous pure β–tricalcium phosphate (β-TCP) dowels for fixation of the anterior cruciate ligament (ACL) graft. **Methods:** Microporous (5 μm) cylindrical plugs of β-TCP (diameter, 7 mm; length, 25 mm) with interconnecting pores were used. The material featured a novel configuration of structure and surface geometry. Implants were tested by use of press-fit fixation of ACL grafts with and without bone blocks in 42 sheep over a period of 24 weeks. Biomechanical, radiologic, histologic, and immunohistochemical evaluations were performed. **Results:** In load-to-failure tests at 6, 12, and 24 weeks after surgery, the intra-articular graft always failed, not the fixation. Grafts showed bony fixation in the tunnel at 6 weeks and primary healing at the junction of the tunnel and joint after 24 weeks. Tricalcium phosphate was resorbed and simultaneously replaced by bone. Remodeling was still incomplete at 24 weeks. **Conclusions:** In the sheep model microporous β-TCP implants used with press-fit fixation of ACL grafts permit early functional rehabilitation. After 6 weeks, the graft is fixed by woven bone or bony integration. Implanted microporous tricalcium phosphate is resorbed and replaced by bone. **Clinical Relevance:** In a sheep model we showed that primary healing of ACL grafts with resorption and bony replacement of the fixating implant can be achieved by means of press-fit fixation with pure β-TCP. **Key Words:** ACL reconstruction—Press-fit fixation—Tricalcium phosphate—Sheep model—Biomechanics—Histology.

Screws made of bioinert materials such as titanium or resorbable screws are often used in patellar tendon reconstruction, with the advantage that they guarantee a high load-bearing ability.[1-3] In addition, for hamstrings, interference screw anchoring is a suitable method of fixation.[4] Metal screws may hamper a second operation on the bone. Reduced strength of fixation during healing, bone resorption, and inflammatory reactions have been described in some cases after the use of resorbable screws.[1] Bony remodeling of the resorbable screws is not guaranteed.[4] Systems involving anchoring distant from the joint line are clinically well proven. However, they may result in micromovements in the bony tunnel.[2,3] Fixation close to the joint line involving transcondylar pins results in increased stiffness. Furthermore, breakage of a pin sometimes leads to increased laxity.[5] For press-fit anchoring with autologous bone blocks, no additional fixation material is necessary[6]; however, primary stability has been described as being lower than that achieved with interference screw fixation.[7] Because

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these established methods of fixation have some disadvantages, we set out to find an osteoconductive anchoring system that resorbs to be replaced by bone, permits secure implantation close to the joint, provides pullout strength comparable to that of interference screw fixation, and does not limit the ability to perform future interventions.

The purpose of this study was to examine the biomechanical, radiologic, and histologic properties of anterior cruciate ligament (ACL) reconstructions during the healing process in a sheep model using microporous β–tricalcium phosphate (β-TCP) dowels for press-fit fixation. The hypothesis was that stable primary tendon healing of the ACL graft is achieved and β-TCP is replaced by bone.

METHODS

Study Design

Forty-two sheep were used to test 2 methods of ACL repair. Half of the animals (n = 21) were submitted to ACL reconstruction of the left knee joint by use of the middle third of the ipsilateral patellar tendon with proximal and distal bone blocks. The remaining 21 sheep underwent ACL graft placement in the left knee joint by use of the ipsilateral flexor digitorum superficialis tendon without bone blocks.[8] This was designed to simulate hamstring reconstruction in humans, because the semitendinosus tendon in sheep is fascial in nature. In both types of ligament repair we used press-fit fixation with microporous β-TCP implants in the tibia and femur. The animals were randomly assigned to the 2 groups by use of closed envelopes. At 6, 12, and 24 weeks after surgery, we subjected the excised joints to radiologic and biomechanical investigation. The healing processes were examined by histology, histomorphometry, and immunohistochemistry. The right knee joints served as controls.

The present in vivo animal study was approved by the state authorities of Germany/Saschsen-Anhalt (reference 203.6.1-42502/2-687) on January 18, 2005.

Fixation Implant

We used pure β-TCP ceramic cylinders (diameter, 7 mm; total length, 25 mm; cylindrical portion, 21.5 mm) with a mean pore size of 5 μm, porosity of approximately 40% volume, and interconnecting pores for press-fit fixation of the tendon grafts. The cylinders' maximally tolerated axial force was 7616 $\pm$ 1312 N/cm^2 (Fig 1).

ACL Reconstruction Anchored With Tricalcium Phosphate Implant

For one group (21 sheep), the middle third of the ipsilateral patellar tendon with proximal and distal bone blocks, each of which was 7 mm wide and 20 mm long, was harvested. For the other group (21 sheep), the ipsilateral flexor digitorum superficialis tendon, with a diameter of 6 to 7 mm, was taken by splitting the Achilles tendon.

The knee joint was opened by a medial parapatellar approach. Removal of the ACL was followed by a lateral notchplasty of 1 to 2 mm. From within the joint, a 7-mm-wide hole was drilled through the site of origin of the ACL at the dorsal margin of the intercondylar notch. A second hole of the same diameter, perpendicular to the joint surface, was drilled from inside the joint into the head of the tibia through the insertion site. After placement of the graft, a tensiometer was used to pre-tension the reconstruction to 90 N during 25 alternations between full extension and flexion. This was followed by impaction of the bony bed with 5-, 6-, and 7-mm dilators and press-fit fixation close to the joint line by use of tricalcium phosphate (TCP) cylinders introduced over a 0.2-mm oversized sleeve from inside the joint. The cylinders were

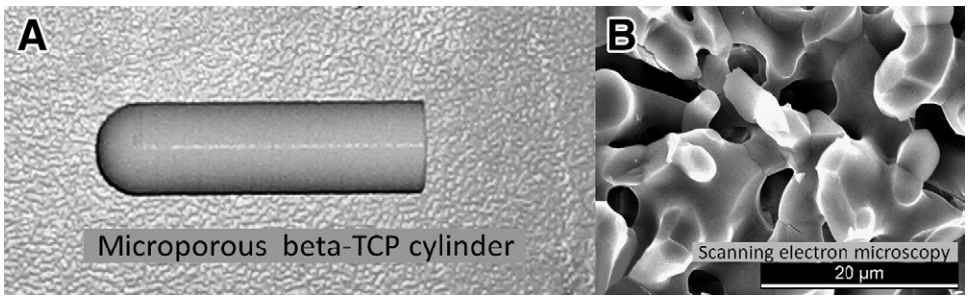

FIGURE 1. (A) Microporous β-TCP cylinder: pore diameter, 5 μm; overall size, 7 $\times$ 25 mm. (B) Scanning electron microscopy shows the interconnecting structure of the pores.