Novel Unidirectional Porous Hydroxyapatite used as a Bone Substitute for Tibial Wedge Osteotomy in Canines

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A microstructure of unidirectional porous hydroxyapatite (UDPHAp) has a diameter of 100-300 µm, which penetrates through the material. In addition, it has a porosity of 75% and initial compression strength of approximately 14 MPa. The objective of the present study was to investigate the feasibility of UDPHAp for the tibial wedge osteotomy in canines. We performed the operation on the right tibia of the dogs, and a wedge-shaped UDPHAp was implanted in the gap after the osteotomy. At 6 and 12 weeks after the operation, the specimens were solid and bony union could be macroscopically observed. Radiological examination revealed that complete consolidation between the osteotomy site and the UDPHAp was established at 12 weeks. Histological evaluation revealed fibrous tissues between the host bone and the UDPHAp at 6 weeks, although new bone formation was observed at the edges of the material. At 12 weeks, direct bonding and bone ingrowth was observed. This study indicates that UDPHAp has great potential for use as a bone substitute for open-wedge high tibial osteotomy in clinical condition.

Key words: unidirectional porous hydroxyapatite (UDPHAp), high tibial osteotomy (HTO), bone substitute, tibial wedge osteotomy model

Introduction

Open-wedge high tibial osteotomy (HTO) is one of the treatment options for knee osteoarthritis. In recent years, synthetic augmentation material has been used as a bone substitute instead of autogenous bone grafts for HTO.¹,²,³ Previously, we reported that a novel unidirectional porous hydroxyapatite (UDPHAp) whose microstructure consists of cross-sectional oval pores (diameter, 100-300 µm) that penetrate through the material; UDPHAp has a porosity of 75% and the initial compression strength of approximately 14 MPa, parallel to the unidirectional pores (Figure 1). Furthermore, it possesses good osteoconductivity, as shown by its implantation in the femoral intramedullary cavity and in the tibial cortical defect in a rabbit.⁴,⁵ The objective of the present study was to investigate the feasibility of UDPHAp for the tibial wedge osteotomy in canines. We hypothesized that UDPHAp is useful in open-wedge high tibial osteotomy since it has good biocompatibility, osteoconductivity, and initial compression strength.

Materials and Methods

We used 7 female dogs (body weight, approximately 10 kg) as a tibial wedge osteotomy model. A special saw guide was designed to achieve an exact osteotomy. A wedge-shaped bone defect (height, 6.5 mm) was made on the proximal part of the right tibia, and a wedge-shaped UDPHAp (Figure 2) obtained from Kuraray Co., Ltd. was implanted. The direction...
of the unidirectional pore was parallel to the tibial bone axis. An L-shaped locking plate (locking distal radius system 2.4; SYNTHES®) was fixed on the medial aspect of the tibia with screws (Figure 3). Cast immobilization was performed to prevent the dogs from using the surgically operated limb. After 3 weeks, the cast was removed, and full weight-bearing was allowed. The dogs were euthanized at 6 weeks (n=3) and 12 weeks (n=4) after the operation. In the 12-weeks group, a fluorochrome label, calcine (Wako, Osaka, Japan; 20 mg/kg body weight) was injected subcutaneously 2 and 1 weeks before euthanization. The proximal part of the tibia was harvested and evaluated macroscopically. X-ray computed tomography (CT) was performed on a LaTheta LCT-100 (Aloka, Tokyo, Japan) to radiologically evaluate the tissue samples. The decalcified slice was histologically examined using hematoxylin and eosin (HE) staining, while the undecalcified ground section was examined using Villanueva Goldner (VG) staining, and toluidine blue staining.

**Results**

Of the 7 dogs, one showed a plate breakage and a tibial fracture at each time point; therefore, we excluded these 2 dogs from the analyses. At 6 and 12 weeks after the operation, all specimens were solid, and bony union could be macroscopically observed (Figure 4). X-ray CT showed that the consolidation between the osteotomy site and the UDPHAp implant was incomplete at 6 weeks after the operation; complete consolidation was observed at 12 weeks (Figure 5).

Figure 6 shows the histological findings at 6 and 12 weeks after implantation; the decalcified slice was stained using HE stain, while the undecalcified ground section was stained using VG stain, and toluidine blue staining. At 6 weeks, fibrous tissue was mostly detected between the host bone and the UDPHAp implant; however, osteogenesis had occurred on the upper margin of the material and inside it. At 12 weeks after implantation, new bone formation was observed to a greater extent.
extent, and a direct bonding was detected between the host bone and the new bone inside the pores. Moreover, newly formed bones were observed as green lines in dark view; these were observed along the walls of the HA pores.

**Discussion**

Previously, we reported good osteogenesis after implantation of UDPHAp in a tibial cortical bone defect of a rabbit. In the results section, we speculated whether UDPHAp would be suitable for the treatment of a cortical bone defect under weight-bearing conditions. In the present study, a tibial wedge osteotomy was performed in canines to simulate the open-wedge HTO in a clinical condition. On radiological and histological examination at 12 weeks, the wedge-shaped UDPHAp showed bony consolidation and direct bonding with the osteotomy site. However, 2 dogs showed a plate breakage and a tibial fracture. The hardware failure and the fracture may have occurred because of a lack of controlled postoperative weight-bearing and also because the plate which is used for a human forearm fracture, was not strong enough for weight-bearing in our experimental settings.

At 6 weeks, we detected new bone formation in the region of the UDPHAp implant in the wedge-shaped gap. Further, the formation of new bone was confirmed using the dark view, and the bone formation was seen to a greater extent at 12 weeks than at 6 weeks by using VG staining. These findings may indicate that bone remodeling and subsequent osteogenesis had occurred.

**Conclusion**

This study suggests that with a sufficient biomechanical support and an appropriate postoperative rehabilitation, UDPHAp has great potential for use as a bone substitute for open-wedge HTO.

**References**

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