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Case report

Use of unidirectional and spherical porous β-tricalcium phosphate in opening-wedge high tibial osteotomy: a case series

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Abstract

Introduction: Unidirectional porous β-tricalcium phosphate (UDPTCP) consists of a novel porous artificial bone that is structurally different from conventional artificial bone comprised of spherical porous β-tricalcium phosphate (SPTCP).
Case presentation: We present our first four clinical cases of opening-wedge high tibial osteotomy (OWHTO) using UDPTCP and SPTCP together. The patients' mean age was 54.5 ± 5.9 years, and the mean observation period was 20.8 ± 2.8 months. In OWHTO, two wedge shaped pieces of UDPTCP and SPTCP were cut to fit the gap and implanted parallel to each other in the anterior and posterior parts, respectively. We evaluated the correction loss and bone remodeling for UDPTCP and SPTCP over time using radiography and computed tomography, and evaluated the clinical outcomes.
Conclusion: There was no correction loss reported in any case, and early bone remodeling was observed with UDPTCP. All patients achieved satisfactory clinical results with no adverse events.

Key words: unidirectional porous β-tricalcium phosphate, spherical porous β-tricalcium phosphate, opening-wedge high tibial osteotomy

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Introduction

Opening-wedge high tibial osteotomy (OWHTO) has been an effective surgical option for treating osteoarthritis and osteonecrosis of the knee[1, 2]. OWHTO has the disadvantage of a large vacant space being left in the proximal tibia after surgery[3]; therefore, wedge-shaped synthetic bones are often used to fill this vacant space. It is necessary for the OWHTO spacer to demonstrate sufficient strength as well as early bone remodeling. Previously, hydroxyapatite showing sufficient stability was used. However, with the development of beta-tricalcium phosphate (β-TCP), which has excellent stability and bone remodeling, spherical porous β-TCP (SPTCP) is frequently used[4, 5].

Affinos® (Kuraray Co., Tokyo, Japan) is a unidirectional porous β-tricalcium phosphate (UDPTCP), consisting of a novel porous artificial bone with a porosity of 57 ± 5%. The unidirectional porous structure of UDPTCP is achieved by promoting and freeze drying the material in ice columns. Oval pores of 25–300 µm in diameter penetrate through the material. The initial compression strength of UDPTCP is >14 MPa when parallel to the direction of pores and >2 MPa when perpendicular to the pores. It is characterized by balanced artificial bone resorption and replacement of autologous bone[6].

Use of UDPTCP in calcaneal fracture, benign bone tumors of the hand, lumbar interbody fusion, and early bone remodeling has been reported[7–9], but there is no report of UDPTCP use in OWHTO. We used UDPTCP and SPTCP in OWHTO with stable clinical results, and reported the radiological and clinical results of four cases. We hypothesized that there was no correction loss, and early bone remodeling was observed with UDPTCP due to the difference in pore structure. Moreover, the clinical outcomes were good.

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Case presentation

Four patients (2 males and 2 females, aged 50–63 years), who underwent OWHTO between January and June 2017 and followed up for 20.8 ± 2.8 (mean ± standard deviation) months, were retrospectively evaluated. The average body mass index was 26.0 ± 5.2 kg/m^2. All patients had osteoarthritis of the medial compartment, and the preoperative radiographic parameters are shown in Table 1.

The proximal tibia was exposed through a 7-cm medial longitudinal incision. Osteotomy was performed from the medial side of the proximal tibia laterally and proximally toward the head of the fibula. Biplanar osteotomy of the tibia was performed, which consisted of an oblique high tibial osteotomy and a frontal plane osteotomy behind the tibial tubercle, using a micro bone saw. The distraction was performed gradually at the most posterior gap until the target mechanical axis was obtained. Typically, the target point was around 62.5% of the weight-bearing line[10].

After osteotomy, two wedge-shaped β-TCPs were cut to fit the gap and placed with the pores parallel to the tibial axis. UDPTCP (Affinos®, Kuraray Co., Tokyo, Japan) and SPTCP (Osferion 60®, Olympus Terumo Biomaterials Co., Tokyo, Japan) were implanted parallel to each other in the anterior and posterior parts of the opening, respectively. We then fixed the tibia with a locking compression plate (TriS Medial HTO Plate System®, Olympus Terumo Biomaterials Co., Tokyo, Japan). The loading conditions on the two artificial bone spacers differ depending on whether they are placed anteriorly or posteriorly in the OWHTO gap. Hence, SPTCP, which has been reported to have good results, was implanted in the posterior part. Partial weight bearing was started after 1 week of no weight bearing, and full-body weight bearing was allowed at 4 weeks.

Radiography was performed 1 week and 12 months postoperatively to assess the correction loss, and computed tomography (CT) was performed 1 week and 6 months postoperatively to assess the bone remodeling. Correction loss was calculated as change in the medial proximal tibial angle (MPTA) and posterior tibial slope (PTS) on the radiographs. Using the method by Tanaka *et al.*[11], CT images parallel to the osteotomy plane were captured, and images at the center were used to evaluate the β-TCP resorption and bone formation. The CT image data were divided into two areas (UDPTCP and SPTCP), and the CT attenuation values (Hounsfield units: HU) of each area were analyzed using the imaging software Osirix® (Pixmeo, Geneva, Switzerland) (Figure 1). The patients were evaluated using the scoring system by the Japanese Orthopaedic Association (JOA)[12]. The clinical evaluations were carried out twice, preoperatively and 1 year postoperatively. We used a paired t-test to compare the CT values of each β-TCP implanted area. A *P*-

Table 1 Demographic data and preoperative radiographic data of each case

Case	Age (yr)	Sex	Body mass index (kg/m^2)	FTA (°)	MPTA (°)	PTS (°)
1	51	M	27.0	181.9	81.7	4.0
2	63	F	33.4	180.4	83.0	9.1
3	50	F	18.8	183.1	80.7	6.7
4	54	M	24.9	182.8	80.1	4.7

M: Male; F: Female.

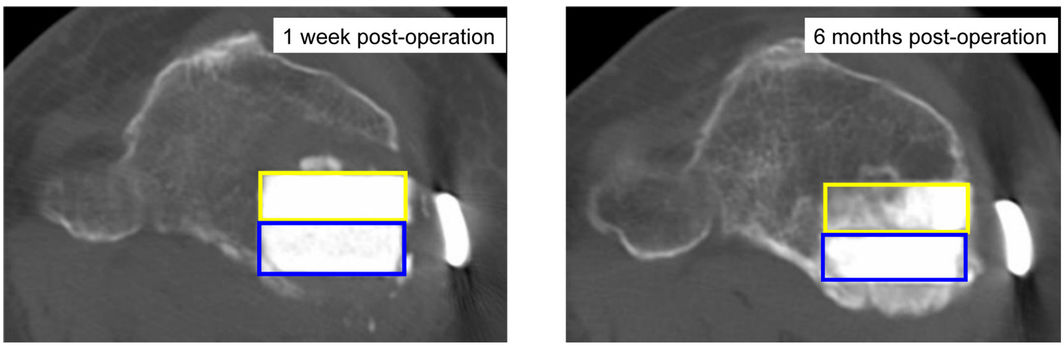

Figure 1 Computed tomography (CT) images showing the center of the osteotomy plane.
The mean CT values (Hounsfield units [HU]) of the areas implanted with unidirectional porous β-tricalcium phosphate (UDPTCP; yellow rectangle) and spherical porous β-tricalcium phosphate (SPTCP; blue rectangle) are shown here.

value <0.05 was considered statistically significant.

The postoperative radiographic parameters are shown in Table 2. The mean MPTA values at 1 week and 12 months were 92.6 ± 0.6° and 92.3 ± 0.6°, respectively. The mean PTS values at 1 week and 12 months were 7.4 ± 2.2° and 7.6 ± 2.0°, respectively. The loss of correction angle of the MPTA and PTS was 0.3 ± 0.4° and 0.3 ± 0.2°, respectively (Table 3). The mean CT values of the area implanted with SPTCP at 1 week and 6 months were 1,327 ± 115 HU and 1,229 ± 158 HU, respectively. The mean CT values of the area implanted with UDPTCP at 1 week and 6 months were 1,510 ± 191 HU and 1,021 ± 201 HU, respectively. There was a statistical difference between the CT values of UDPTCP at 1 week and 6 months (Figure 2).

The JOA scores improved from 76.2 ± 4.8 (range 70–90) preoperatively to 96.2 ± 4.8 (range 90–100) postoperatively. All the patients underwent a second surgery for the removal of the fixation plate, and there were no intra- and postoperative complications reported.

Written informed consent was obtained from all patients for the publication of this paper and any accompanying images.

Discussion

In OWHTO using both UDPTCP and SPTCP, no correction loss was reported, and the CT values decreased with UDPTCP, suggesting rapid remodeling. Furthermore, the JOA scores were good.

UDPTCP and SPTCP are both β-TCPs. The initial

Table 2 Postoperative radiographic parameters of each case

Case	FTA (°) 1 year post-operation	MPTA (°) 1 week post-operation	MPTA (°) 1 year post-operation	PTS (°) 1 week post-operation	PTS (°) 1 year post-operation
1	171.5	92.1	92.0	5.9	5.3
2	172.1	93.3	93.2	10.5	10.4
3	172.3	92.9	92.1	7.6	7.4
4	172.6	92.3	92.1	6.7	6.5

Table 3 Change in the medial proximal tibial angle (MPTA) and posterior tibial slope (PTS)

	1 week post-operation	1 year post-operation	Correction loss
MPTA (°)	92.6 ± 0.6	92.3 ± 0.6	0.3 ± 0.4
PTS (°)	7.4 ± 2.2	7.6 ± 2.0	0.3 ± 0.2

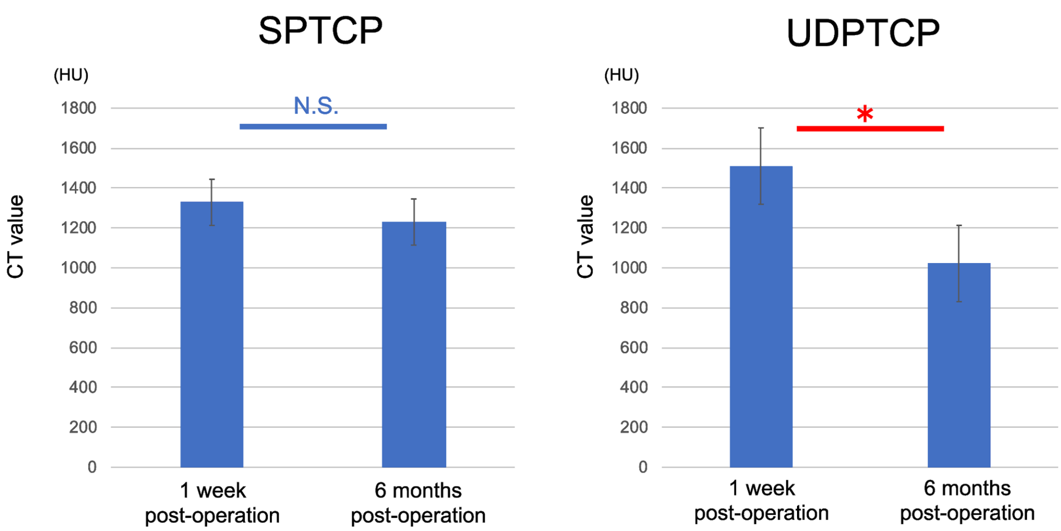

Figure 2 Computed tomography (CT) values of each β-tricalcium phosphate (β-TCP) material at 1 week and 6 months postoperatively.
There was a statistical difference between the CT values of UDPTCP at 1week and 6 months postoperatively.

strength of UDPTCP is reported to be ≥14 MPa in the long axial direction, while that of SPTCP is reported to be 20 MPa. The load on the plate was decreased when SPTCP was used[13], and locking plate and SPTCP enabled early full weight-bearing exercise[5]. There was no correction loss in the two radiographical assessment parameters of this study combining UDPTCP and SPTCP. This stabilizes the post-HTO clinical outcomes and suggests the effectiveness of UDPTCP in securing initial strength.

The porosity of UDPTCP and SPTCP are 57% and 60%, respectively, as they have different pore structures. The CT value of UDPTCP reached that of cancellous bone (100–200 HU) earlier than SPTCP did, suggesting that it promoted faster remodeling. In a non-comparative animal study, UDPTCP used on a rabbit tibial defect model allowed histological remodeling in 6 weeks[6].

The postoperative JOA scores were good, with a mean score of 96.2. Onodera *et al.* reported a JOA score was 93.5 when SPTCP was used to fill the gap[14]. Although they cannot be compared directly as the patient backgrounds were not controlled, the clinical outcomes of OWHTO using UDPTCP and SPTCP were comparable.

In this study, UDPTCP was used in the anterior opening, while SPTCP was used in the posterior opening of the OWHTO. The limitation of this study was that the difference in load depending on the position was not considered. Future studies should be conducted to evaluate OWHTO with UDPTCP in the posterior site and SPTCP in the anterior site.

Conclusion

We performed OWHTO surgery using UDPTCP and SPTCP. Correction loss did not occur in any case, early bone remodeling was observed with UDPTCP, and the clinical outcomes were favorable.

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