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Tricalcium phosphate granules or rigid wedge preforms in open wedge high tibial osteotomy: a radiological study with a new evaluation system

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Abstract

The capacity of two forms of porous beta-tricalcium phosphate bone substitutes (TCP) to promote bone healing in open wedge high tibial osteotomy (OWHTO) was studied. We reviewed the X-rays of 27 osteotomies, with either TCP wedges or TCP granules as filling material, to compare the bone healing rates and bone remodelling, at specific postoperative intervals. A new radiologic rating system for OWHTO was created and tested for clinical applicability. All osteotomies healed uneventfully and complete resorption of TCP was demonstrated at 1 year postoperative in 85% (n=23) of the procedures. In 44% (n=10) of these 23 procedures, the osteotomy site was no longer visible. No difference in bone healing rate and bone remodelling was found when comparing the use of granules to a wedge, and no adverse effects of TCP were observed. The good inter- (k=0.7) and intraobserver (k=0.6) reliability of the new radiologic rating system enables clinical use.

Good bone healing was found in OWHTO with both wedges and granules of TCP.

Keywords: Tricalcium phosphate; Wedges; Granules; Osteotomies

1. Introduction

Patients with medial compartment osteoarthritis and a varus leg axis can be successfully treated with a valgus high tibial osteotomy [4,10]. In recent years, the medial opening wedge technique has been favoured over the lateral closing wedge osteotomy to avoid co-morbidity associated with the fibular osteotomy from the latter procedure [8]. In the open wedge high tibial osteotomy (OWHTO), a medially based gap is created in the tibial metaphysis that many surgeons prefer to fill with bone or ceramic materials. Various arguments have been used such as decrease of local blood loss, increase of mechanical stability, or increase of bone healing.

The introduced filling material may cause specific changes in bone healing and bone remodelling. Fracture treatment of proximal tibial fractures has provided insight into bone healing [7,16] and radiological phases of bone remodelling in the proximal tibia [22]. Bone healing in open wedge osteotomies differs from that in fractures because of the bone distraction in the opened wedge and introduced filling materials. Therefore a specific radiographic rating system is needed. As yet, no radiologic rating system to monitor bone healing in OWHTO is available.

Autologous bone is often used to fill bone defects. These graft materials however have become less popular due to co-morbidity at the donor site, increase of operation time and risks of disease transmission [6,8,20]. Hence, bone substitutes, e.g. acrylic bone cement [9], hydroxyapatite [11] and tricalcium phosphate [18], have become more popular. In OWHTO, these bone substitutes are used

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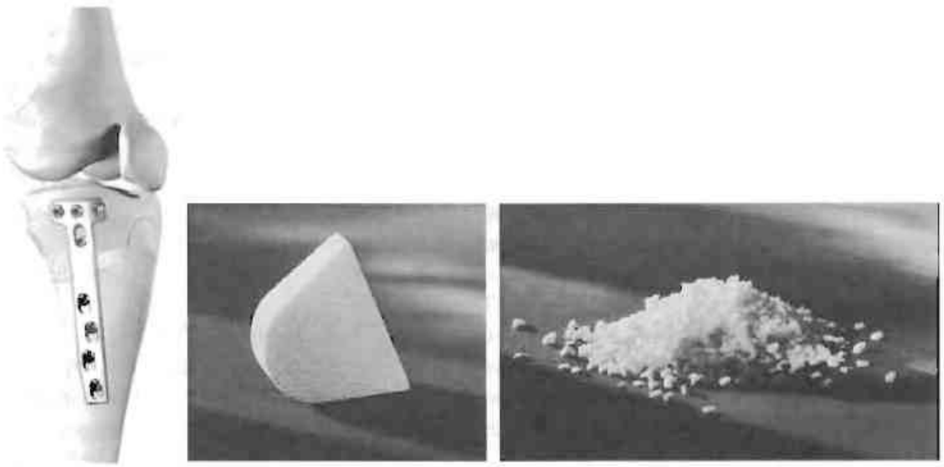

Fig. 1. OWHTO with Tomofix™ (left), chronOS™ wedge (middle) and granules (right).

by surgeons who assume that they enhance initial mechanical stability and that they shorten bone healing time, which enables early full weight bearing. This thereby shortens the time until fixation material removal.

Porous beta-tricalcium phosphate (TCP), when used as a bone substitute in orthopaedic surgery, has been shown to be osteoconductive and resorbable [21]. TCP granules and TCP wedges are available to fill the OWHTO bone gap (Fig. 1). The granules cover a large area of cancellous bone in the open wedge gap and provide a loose matrix for bone ingrowth. The bone wedges might add some mechanical stability but cover only part of the bone gap. However, by closing the wedge, they may prevent haematoma leakage, a mechanism proposed to enhance bone healing. Furthermore, bone ingrowth into the open porous, but densely structured wedges may be more difficult. Therefore, it remains uncertain whether bone healing and bone remodelling will be retarded if a rigid TCP wedge is used as OWHTO filling material instead of loose TCP granules.

The objective of this study was to compare bone healing and bone remodelling in OWHTO patients with bone gaps filled with TCP granules to that of patients treated with TCP wedges as well as to assess the clinical use of TCP in OWHTO. To monitor fracture healing, a new radiological rating system was designed and tested for inter- and intraobserver reliability to verify its clinical applicability.

2. Patients and methods

The X-rays of 27 patients who underwent an open wedge high tibial osteotomy for medial osteoarthritis of the knee between January 2000 and May 2001 were reviewed. In all cases, the open wedge gap was filled with TCP preforms (chronOS™—Synthes, Switzerland): in 16 patients in granular form and in 11 patients with rigid wedges. The mean age at surgery was 43 years (S.D. of the mean 10.5). None of the patients suffered from diseases disturbing bone healing and only three patients were regular tobacco smokers at the time of operation.

All OWHTO's were performed by one surgeon (AW) using a medial plate fixation (TomoFix™—Synthes) to stabilize the osteotomy. Pre-operative varus alignment ranged from 4° to 11° and correction of leg axis was aimed at 3° valgus in all patients. Immediately before plate fixation, the opened wedge gap was filled with TCP. Both the granules and the rigid wedges were impregnated with patient's own blood before insertion. The surgeon was asked which of the two types of TCP was easier to handle during surgery. The postoperative rehabilitation protocol consisted of 10–15 kg weight bearing for 6 weeks, after which full weight bearing was allowed as tolerated.

Conventional AP and lateral X-rays were acquired immediately after surgery and at 6 weeks, 3, 6, and 12 months, postoperatively. For each radiograph, the bone remodelling phase was determined independently by two investigators using the new rating system (Table 1). Bone

Table 1
Phases of remodelling

	Phase in article	McKibbin	Explanation
0	Direct postoperative	Inflammation	Haematoma
1	Vascular phase	Soft callus	Osteopenic bone, rounded osteotomy sites, clear distinction between TCP and bone
2	Calcification phase	Soft and Hard callus	Whitening of sites and blurred distinction between TCP and bone
3	Osteoblastic phase	Hard callus, remodelling	Distinction between TCP and bone slightly visible, though healed osteotomy
4	Consolidation phase	Hard callus and remodelling	Full reformation, though osteotomy recognizable, no TCP
5	Full reformation	Remodelling	No sign of osteotomy

union was defined as grade 4 or above. Complete reformation is defined as the diminishing of the osteotomy gap with the full resorption of the TCP. The time to full remodelling was noted. A chi-square analysis was used to evaluate differences in bone healing between the two different types of TCP implants at the various time intervals. Alpha was set at 0.05.

2.1. Tricalcium phosphate

Tricalcium phosphate (chronOS™—Synthes) is a synthetic and phase pure porous beta-tricalcium phosphate ceramic. β-TCP is resorbed in vivo by osteoclasts [13]. Its interconnecting pore structure with 70% total open porosity and a pore size ranging from 100 to 500 μm is in a range which allows vascularisation [15] and bone ingrowth [3]. The smaller pores in the range of 1–10 μm are more suitable for fluid flow and diffusion to improve the metabolic environment [22].

2.2. The radiologic rating system

The rating system to monitor bone healing was modified from an existing fracture healing system described by McKibbin [11]. It consists of five stages (Table 1). The vascular phase typically has osteopenic bone and sharpened to rounded osteotomy sites, and with the bone filler used in this study the TCP can be easily differentiated from the bone (Fig. 2). In the calcification phase, callus formation and calcium deposition causes whitening of the edges of the osteotomy and the edges of the filling material become blurred as a first sign of resorption. Typical for the osteoblastic phase is the cloudy bone formation above the whitened osteotomy sites and the decrease of visibility of the TCP. In the consolidation phase, the bone is healed; however, the osteotomy site is still recognizable as the TCP filling material has not yet full been resorbed. Full reformation is reached when the filling material is not visible anymore and the osteotomy is hardly visible as a sign of radiological full resorption.

2.3. Reproducibility of the radiologic rating system

The radiographs were classified by two investigators (WH and KW) at three different times. The first round was used to practice with the new rating system. During this round, the sequence of the radiographs was known to the investigators. The second round was performed 1 month later and at that time each investigator was blinded to the patient's name as well as to the sequence of the radiographs. The same protocol was used for the third round which was held 2 weeks later. These scores for each radiograph provided the basis for inter- and intraobserver reliability. Interobserver reliability was determined for each follow-up interval of every patient as well as the agreement whether in a follow-up sequence the next radiograph showed a similar bone healing phase or advancement when compared to the previous.

Interobserver variability as well as the intraobserver variability during the first, second and third rounds was determined using Cohen's kappa. Interpretation of these values was according to the guidelines described by Landis and Koch [12]: A kappa value between 0.21 and 0.4 corresponds to a fair agreement. A value between 0.41 and 0.6 represents moderate agreement and values between 0.61 and 0.8 indicate substantial agreement. A value above 0.81 is considered to be almost perfect.

3. Results

The radiographs of 16 osteotomies using TCP granules as a bone substitute and those of 11 osteotomies using a TCP wedge could be evaluated. All 27 procedures were performed without any complications during or after the operation. The performing surgeon preferred a wedge type of TCP if he was able to choose, due to difficulties in properly positioning the granules in the gap created by the opened wedge. At clinical evaluation, there were no wound healing problems, no non-unions, no loss of corrections, and no infections. Specific properties of the two groups are

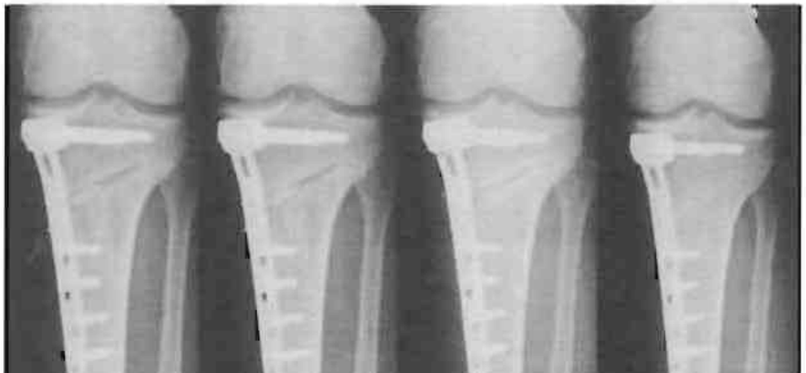

Fig. 2. Radiologic follow-up of OWHTO with TCP at 6 weeks, 3, 6 and 12 months intervals.

Table 2
Specific properties of TCP groups

Group	Sex	Resorption of TCP	Mean age	Size of osteotomy
TCP solid wedge (n=11)	Male 55% (n=6)	82%	43	91% >5 mm
	Female 45% (n=5)			
TCP granules (n=16)	Male 69% (n=11) Female 31% (n=5)	87%	42	87% >5 mm
Overall (n=27)	Male 63% (n=17) Female 37% (n=10)	85.2% (n=23)	43	89% >5 mm

presented in Table 2; sex, age and size of the osteotomy are similar for the two groups.

During the first round of evaluations of all radiographs, almost perfect agreement was reached (k=0.8) whereas the investigators reached substantial agreement both during the second (k=0.6) and third rounds (k=0.7). The intraobserver reliability for the two investigators is presented in Table 3.

As shown in Table 4, after 12 months the TCP was no longer visible in 85% (n=23) of the patients X-rays. In 44 (n=10) of the 23 osteotomies, no sign of the osteotomy was visible (Fig. 2). As shown in Fig. 3 and Table 5, the bone union rate in both groups progressed gradually. Union of OWHTO's filled with TCP did not depend on sex, age or the size of the osteotomy. Also, no retarded bone healing was found in the three patients who smoked. No significant difference in union between the osteotomies with wedges and the osteotomies with granules could be demonstrated (p=0.164).

4. Discussion

All of the performed osteotomies with stable fixation and filling of the osteotomy gap with porous tricalcium phosphate healed without complications, (i.e., infection or non-union) within 12 months of the operation. In 85% of the osteotomies, the TCP preforms were not visible on the radiographs at 12 months. They could thus be considered to be remodelled. No difference in osteotomy healing or TCP remodelling was found between the group of granules and the group of solid wedges: however, pre-shaped wedges improved the ease of handling.

Table 3
Kappa scores for intra-observer reliability

Rounds compared	1st investigator	2nd investigator
First and second	0.53	0.6
First and third	0.53	0.57
Second and third	0.62	0.59

Table 4
Progress of union of TCP treated osteotomies

Grade	6 weeks	3 months	6 months	12 months
1	48% (n=13)	none	none	none
2	52% (n=14)	56% (n=15)	none	none
3	none	41% (n=11)	52% (n=14)	15% (n=4)
4	none	3% (n=1)	44% (n=12)	48% (n=13)
5	none	none	4% (n=1)	37% (n=10)

To our knowledge, no radiologic rating system to monitor bone healing in open wedge osteomies has been reported. For this study, such a system was developed for radiological evaluation of bone healing. The process of bone healing, which in fact is continuous, was divided into five phases according to the system used by McKibbin [16] to enable postoperative monitoring at the intervals used in clinical practice. A rating system based on standard AP and lateral radiographs enables universal application and comparison between studies. However, the system is not designed to correlate specific phases to stability of bone union as this was found to be unreliable for fracture healing classification with AP and lateral radiographs [7]. The descriptions of the distinct phases which would be clear to both clinicians and radiologists was chosen to improve interobserver agreement.

Observer agreement of radiologic measurements may be unreliable which has been reported in different papers [1,2,19]. Whelan et al. [22], however, measured substantial inter- and intraobserver agreement in a study on radiological assessment of the bone healing in tibial fractures. On two separate occasions 8 weeks apart, they independently assessed the radiographs of 30 patients with tibial shaft fractures that had been treated by intramedullary fixation. The interobserver agreement was expressed by Cohens kappa, and ranged from 0.57 to 0.89. Among the variables examined, the number of cortices bridged by bone appeared to be a reliable and easily measured radiological variable. For the radiologic rating of the osteotomy gaps created during OWHTO, rating in specific phases of bone healing proved to be clinically applicable according to guidelines

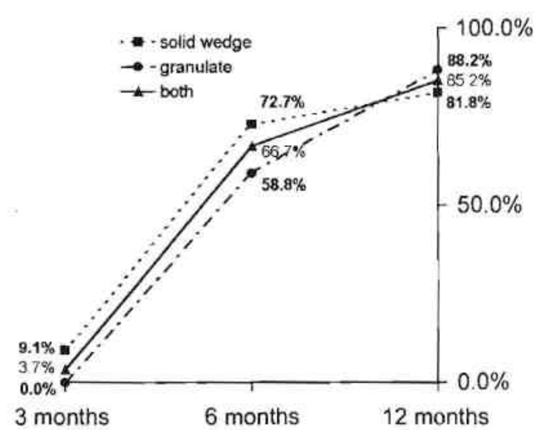

Fig. 3. Difference of union rate between TCP granules and wedges.

Table 5
Progress in radiological bone healing phases in time (in percentage per group)

Grade	6 weeks		3 months		6 months		12 months	
	Granules	Wedge	Granules	Wedge	Granules	Wedge	Granules	Wedge
1	44% (n=7)	55% (n=6)						
2	56% (n=9)	45% (n=5)	56% (n=9)	55% (n=6)				
3			44% (n=7)	36% (n=4)	56% (n=9)	45% (n=5)	12% (n=2)	18% (n=2)
4				9% (n=1)	38% (n=6)	55% (n=6)	50% (n=8)	45% (n=5)
5					6% (n=1)		38% (n=6)	36% (n=4)

described by Landis and Koch [12]. The results of inter- and intraobserver agreement found in the present study are satisfying, since the observers reached substantial agreement both during the second (k=0.6) and third rounds (k=0.7).

The good resorption and remodelling of the TCP that was used in the present study has been previously reported. In an in vivo study in a non-human primate evaluating the safety and efficacy of a novel local bone harvesting technique in the spine, Steffen et al. [21] demonstrated the complete integration of TCP cylinders with newly formed bone and resorption in 80% of the study population after 6 months. In a clinical study, Muschik et al. [17] used the same TCP granules as those inserted in the granules group of patients to achieve dorsal spondylodesis in adolescent idiopathic scoliosis and observed complete remodelling of TCP based on X-ray and CT measurements after 8 months. This is consistent with the results of the patients in the granules group (Fig. 3). Resorption and remodelling of the TCP wedges has not been evaluated previously in a biomechanical or clinical study. In the present study, no difference in resorption or remodelling capacity for the solid wedge preform was found as compared to the granules.

The resorption and remodelling properties are attributed to the chemical composition and the interconnecting pore structure and pore size of the TCP used in this study. In another study, significant bone formation was seen as early as 3 weeks and bone ingrowth paralleled tricalcium phosphate resorption [5]. The authors found that after 1 year, the new bone and the tricalcium phosphate were remodelled into a bone tissue that was indistinguishable from the normal bone on radiological and histological examination [5]. These results are confirmed in our study by the disappearance of 85% of the tricalcium phosphate, on studied radiographs from both implant groups after 1 year.

The use of different bone substitutes in OWHTO has been previously described. However, these studies lack a standardized radiological follow-up as well as details regarding bone healing at different intervals. In a clinical study using acrylic bone cement as bone substitute, Hernigou et al. [9] reported good results in a large series of 245 valgus producing osteotomies. A 5-year survival of 94% of the performed OWHTO's is reported. A disadvantage of the use of the acrylic bone cement, which is mainly used to provide initial stability, is the exothermic setting reaction which might harm the living bone tissue and both the missing porosity and lack of resorption. Recently, Koshino et al. [11] reported on the use of porous hydroxyapatite in OWHTO for 21 cases. The use of this non-resorbable ceramic bone substitute resulted in excellent 7-year follow-up results. At 12–16 weeks, trabecular continuity was observed at the osteotomy site on radiographs. We believe that the synthetic, osteoconductive and resorbable bone substitute used in this study provides an excellent alternative to other methods described above. Furthermore, the use of autologous bone graft from the iliac crest which is often accompanied with serious co-morbidity issues involving pain and risk of infection [6,8,20] is prevented.

It is important to note that tricalcium phosphate, whether using granules or a wedge, is not intended for load bearing and therefore an OWHTO should always be supported by an internal or external fixation method. For optimal results, an implant with angle stable screws should be used to bridge the osteotomy gap [14]. TCP must be used in a mechanically stable environment otherwise it cannot remodel into bone.

Lobenhoffer et al. [14] used in their study no filling material and radiographic full consolidation was also observed in corrections up to 12°. This raises the question whether a bone substitute is necessary. Prospective randomized studies should be preformed to compare the use of TCP and leaving the gap open. The maximum wedge size that can heal with TCP is not yet defined. As the used TCP wedges are currently only available for up to 13°, we use bone grafts for corrections exceeding this amount.

In conclusion, TCP implants such as the chronOS™ wedges and granules can be successfully used as bone substitutes in open wedge high tibial osteotomies with a plate with angle stable screws. Our hypothesis that TCP granules offer a larger contact area for newly formed bone and could stimulate a faster vascularisation, remodelling and consolidating of the osteotomy was not confirmed by our results. There was no significant difference in healing time between the TCP granules or wedge preforms. The new classification for healing of the open wedge osteotomies of the tibia was reliable for comparison of the results of the two bone substitutes.

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