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ORIGINAL PAPER

Bovine xenograft locking Puddu plate versus tricalcium phosphate spacer non-locking Puddu plate in opening-wedge high tibial osteotomy: a prospective double-cohort study

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Abstract
Purpose The aim of the study was to compare clinical and radiographic outcomes of opening-wedge high tibial osteotomy (HTO) augmented with either xenograft or tricalcium phosphate spacer for the management of medial compartment osteoarthritis (OA) with genu varum.
Methods Between 2004 and 2007, we prospectively enrolled 52 patients with medial compartment knee OA who underwent opening-wedge HTO fixed with locking Puddu plate and xenograft (n=26) or non-locking Puddu plate and tricalcium phosphate spacer (n=26). The alignment of the lower limb was assessed by measuring the hip-knee-ankle (HKA) angle. Clinical outcomes were assessed with the Knee Society Score, Western Ontario and McMaster Universities Osteoarthritis Index, SF-36 and European Quality of Life-5 Dimensions scale. All patients were followed up at six weeks and at three, six, 12 and 24 months post-operatively. Clinical outcomes were assessed preoperatively and at 24 months post-operatively.
Results All clinical scores improved significantly in both groups after surgery, without any significant difference between the two groups. Immediately after surgery, the HKA angle went from 9.1±5.2° in varus to 3.1±4.8° in valgus (P=0.01) in the xenograft group, and from 8.5±5.9° in varus to 3.4±4.2° in valgus (P=0.01) in the tricalcium phosphate group. At the last follow-up, the tricalcium phosphate group showed a significant loss of correction (P=0.03).
Conclusions HTO performed with xenograft locking plate and tricalcium phosphate non-locking plate constructs showed good clinical outcomes. However, the xenograft locking plate construct is superior to the tricalcium phosphate spacer non-locking plate to prevent the loss of correction in the middle term.

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Introduction

High tibial osteotomy (HTO) is performed to manage osteoarthritis (OA) of the medial compartment of the knee in patients with genu varum [1]. A higher degree opening-wedge HTO may require the application of bone graft/substitute to fill the osteotomy gap. Moreover, it is associated with risk of non-union, collapse and loss of correction [2].

Although autologous bone graft is the “gold standard” to fill the bone deficit, it may produce donor site morbidity. Several strategies have been proposed as alternatives to autologous bone graft, including allograft [3–5], xenograft [6], hydroxyapatite [7–9], acrylic cement [10, 11] and calcium phosphate [12, 13] wedges.

We performed a prospective, double-cohort study to compare clinical and radiographic outcomes of opening-wedge

HTO, using either a bovine xenograft locking Puddu plate construct or a tricalcium phosphate spacer non-locking Puddu plate construct, for the management of medial compartment OA with genu varum.

Methods

Patient selection

Between 2004 and 2007, we prospectively enrolled 52 patients with painful medial compartment knee OA (Fig. 1). Inclusion and exclusion criteria are reported in Table 1.

Radiographic assessment

All patients had plain radiographs of the knee in weight-bearing anteroposterior, lateral at 30° of flexion, Rosenberg and axial at 30° of flexion views.

For each patient, two fully trained musculoskeletal radiologists measured the preoperative and post-operative hip-knee-ankle (HKA) angle (defined as the angle between the mechanical axis of the femur and the mechanical axis of the tibia, with both lines crossing at the central point between the tibial spines) with a full-length standing radiograph in the anteroposterior view on weight-bearing. Finally, the average value for each measurement was calculated for further analysis.

The degenerative changes to the medial compartment were scored using the Ahlbäck classification. The amount of correction was estimated preoperatively by the angle formed at the intersection between a line passing through the centre of the femoral head and another line passing through the centre of the tibiotalar joint to the tibial plateau at a point corresponding to 62.5 % of the distance from the medial to lateral side [14].

Clinical assessment

The functional outcome was assessed with self-administered rating systems such as the Knee Society Score (KSS) and Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index.

The KSS consists of two separate parts: the knee rating and the functional assessment. The former provides an objective assessment evaluating pain, knee stability and knee range of motion. The latter evaluates how the patient perceives his/her knee function. In both scores, the final score ranges from 0 to 100 points, with higher scores indicating a better function of the knee. The WOMAC Osteoarthritis Index is a disease-specific score, evaluating patients with OA of the hip and/or knee. The score assesses pain, stiffness and physical function. The final score ranges from 0 to 100, with a higher score indicating better physical functioning.

The generic health status was assessed with self-administered rating systems such as the SF-36 and European Quality of Life-5 Dimensions (EQ-5D) scale. Both questionnaires evaluate physical and mental functions and have a final score ranging from 0 to 100, with higher values indicating better health status.

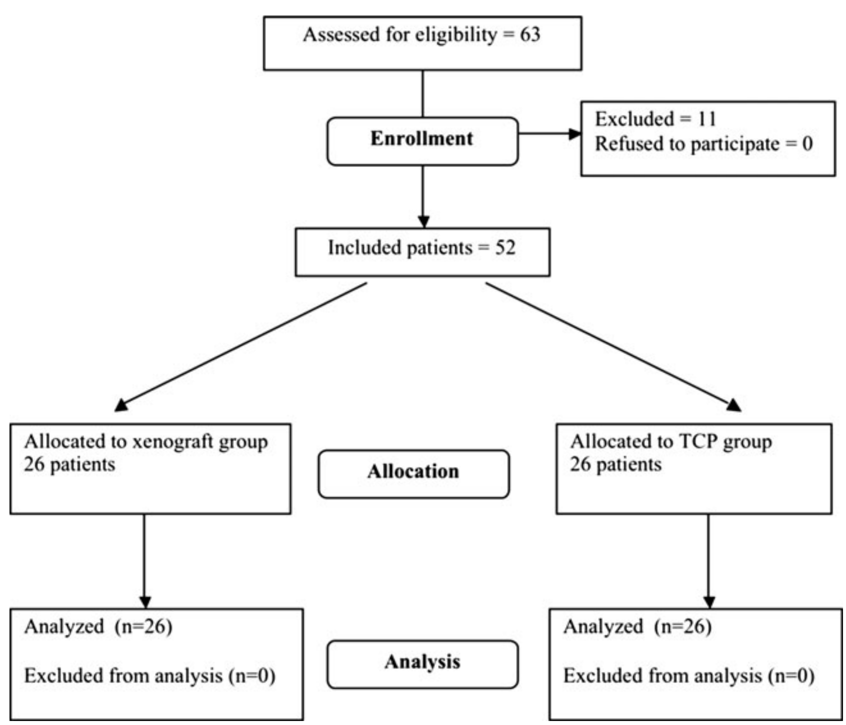

Fig. 1 Flow diagram of the enrolment procedure

Table 1 Inclusion and exclusion criteria of the study

Inclusion criteria	Exclusion criteria
• Age <70 years old	• Lateral compartment or tricompartmental OA
• Early-stage medial compartment OA (Ahlbäck grade 1 or 2)	• Femoropatellar OA
• Moderate to severe varus malalignment (5–15°)	• Range of motion <100°
• Medial joint pain refractory to conservative management (analgesics and/or painkillers and physiotherapy)	• Flexion contracture of >10°
	• Collateral ligament laxity
	• Anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) insufficiency
	• Previous ACL and/or PCL reconstruction
	• Previous femoral and/or tibial fractures
	• Joint infection
	• Rheumatoid arthritis

Surgical procedure

The procedure was performed under general anaesthesia. For prophylaxis 2 g of cefazolin was administered intravenously at induction. Patients were placed in the supine position.

All patients underwent routine diagnostic arthroscopy to ascertain the grade of degenerative joint disease in the medial, lateral and patellofemoral compartments. Patients with degenerative joint disease above grade 2 in the medial compartment or involvement of the lateral and/or patellofemoral compartments did not proceed to HTO. For this reason, 11 patients (four who would have received the xenograft) were excluded from the study.

A longitudinal skin incision about six centimetres long was made starting one centimetre below the level inferior to the knee joint, between the medial edge of the patellar tendon and the posterior border of the tibia. The medial part of the proximal tibia was exposed and the superficial portion of the medial collateral ligament (MCL) was visualised and reflected back. The tibial cutting guide was positioned at the medial aspect of the tibia, between the medial tibial plateau and the tibial tubercle, just above it. Two pins were inserted through the guide and were drilled towards the fibular head up to one centimetre from the lateral cortex. Subsequently, the osteotomy was performed with an oscillating saw along the guide wires and eventually completed with a scalpel. With appropriate instrumentation, the osteotomy was gradually opened producing a plastic deformation of the intact lateral bridge. The integrity of the lateral tibial cortex hinge was checked by fluoroscopy [15].

A calibrated trial wedge was inserted into the osteotomy, with each additional millimetre in wedge size representing an additional angle of correction along the weight-bearing axis, and the alignment of the extremity and the degree of correction were verified. Once the appropriate correction was made with the wedge, the Puddu plate with the appropriate spacer (Arthrex Inc., Naples, FL, USA) was applied and fixed in place with 6.5-mm cancellous screws proximally and 4.5-mm cortical screws distally. The screws were locking in the xenograft group and non-locking in the tricalcium phosphate group. After the fixation of the plate, the osteotomy was filled with graft material, including either bovine xenograft (Tutobone) or tricalcium phosphate (OSferion® B-TCP, Arthrex Inc., Naples, FL, USA) wedges.

Post-operative rehabilitation

In both cohorts of patients, knee movement and lower limb strengthening exercises were allowed starting from the first day after surgery. All patients were managed with a hinged knee brace. Full weight-bearing was allowed after six weeks. At this time, the brace was also removed.

Post-operative follow-up

All patients had a follow-up consultation at six weeks and at three, six, 12 and 24 months after surgery. All questionnaires were administered preoperatively and at the time of the last follow-up. All patients had control radiographs at each follow-up consultation (Figs. 2, 3 and 4). Any evidence of non-union, loss of correction, hardware failure and/or loss

Fig. 2 Preoperative radiograph (*anteroposterior view*) of a 50-year-old woman

Fig. 3 Post-operative radiograph (*left knee, anteroposterior view*) of a 50-year-old woman showing an opening-wedge osteotomy with xenograft and Puddu locking plate at 6 months

of fixation and lateral cortical breach was recorded. The following radiographic criteria were used to define the union of the osteotomy: absence of the line of condensation with continuity between the bone and the substitute for at least 75 % of bone-substitute interface on anteroposterior and lateral views and presence of a bone callus on the medial edge of the filled bone defect [12].

Sample size

We estimated that a sample size of 23 patients per group would provide an acceptable power of 0.85 with an alpha error probability of 0.05. To allow for attrition, we increased the sample by 10 % to 26 patients per group.

Fig. 4 Post-operative radiograph (*left knee, anteroposterior view*) of a 50-year-old woman showing an opening-wedge osteotomy with xenograft and Puddu locking plate at 12 months

Statistical analysis

All analyses were performed using SPSS for Mac (version 16.0). Descriptive statistics was calculated. The statistical significance of improvement of outcome measurements was assessed using the Wilcoxon signed rank test. Pearson's chi-square test with Yates' correction was performed to compare the frequencies of smokers and lateral cortical fracture between the two groups. Finally, we used the Wilcoxon-Mann–Whitney test to compare the two groups in terms of age, body mass index (BMI) and follow-up, and the measurements performed by two radiologists for each patient. A P value of <0.05 was considered significant.

Results

Demographics

Demographic data are reported in Table 2. There was no difference in terms of age, gender, BMI at the time of the index procedure, smoking rate and follow-up length between the two groups.

Radiographic outcomes

In both groups, there was a statistically significant improvement between preoperative and post-operative values of the HKA angle (Table 3). However, there was no statistically significant difference between preoperative and post-operative median values of the HKA angle ($P>0.05$) of the two groups.

At the time of the last follow-up, in the xenograft group there was no statistically significant difference between immediate post-operative and last follow-up values of the HKA angle ($P=0.06$). On the other hand, in the tricalcium phosphate group, the last follow-up values of the HKA angle were significantly lower than those recorded immediately after surgery ($P=0.03$). The tricalcium phosphate group showed a significantly greater loss of correction than the xenograft group ($P=0.02$), although no patient had reverted to a varus alignment in either group. The median opening of the osteotomy was 9.25 mm (range 7–15) in the xenograft group and 8.75 mm (range 7−15) in the tricalcium phosphate group ($P>0.05$). No patient experienced a non-union, and no cases of hardware failure and/or loss of fixation were recorded. Lateral cortical breach was found in three (11 %) of 26 knees with xenograft and 2 (8 %) of 26 knees with tricalcium phosphate. Finally, the comparison between the measurements performed by two radiologists showed no statistically significant difference.

Table 2 Demographic data of the enrolled patients

	Xenograft locking plate (n=26)	Tricalcium phosphate non-locking plate (n=26)	P value
Age, mean (range)	59.3 years (44–70)	58.2 years (42–69)	P>0.05
BMI, mean (range)	29.6 (24–31)	30.2 (25–32)	P>0.05
Male to female ratio	18:6 (69 %)	18:6 (69 %)	P>0.05
Smokers to non-smokers ratio	15:11 (58 %)	14:12 (54 %)	P>0.05
Follow-up, mean (range)	42 months (24–52)	40 months (24–49)	P>0.05

Clinical outcomes

In both groups, KSS knee and function scores, WOMAC, SF-36 and EQ-5D scores showed a statistically significant improvement after surgery (Table 4). However, none of the investigated clinical scores showed a statistically significant difference between the post-operative average values achieved in the two groups.

Complications

Wound infections occurred in one and two patients, respectively, in the xenograft and tricalcium phosphate groups, managed with oral antibiotics. No patient developed deep vein thrombosis.

In the xenograft group, there was one further operation for avulsion of the anterior tibial tuberosity in a patient who went dancing three weeks after the index procedure and fell (Fig. 5). Recovery was uneventful. In the tricalcium phosphate group, there was one further operation six months after the index procedure in a patient in whom the tricalcium phosphate protruded from the osteotomy site and produced local pain. Recovery was uneventful.

In the period of the study, no patient underwent Puddu plate removal or progressed to a joint arthroplasty.

Discussion

The most important finding of this study is that the xenograft locking Puddu plate is superior to the tricalcium phosphate spacer non-locking Puddu plate construct to prevent loss of correction in the middle term, while there is no difference in terms of clinical outcomes between the two groups.

Although we found a statistically significant improvement of the mechanical axes in both groups after surgery, the comparison between the immediate post-operative and the last follow-up values of the HKA angle showed a statistically significant loss of correction in the tricalcium phosphate group. The HKA angle value was preserved in the xenograft group, with adequate maintenance of the correction at the middle term follow-up. However, as the patients in the tricalcium phosphate group received a non-locking plate whereas patients in the xenograft group received a locking plate, we are not able to ascertain whether the loss of correction in the former group is related to the nature of the graft, the features of the plate system or a combination of both these factors.

Autologous bone graft is the “gold standard” for the augmentation, but due to donor site morbidity some concerns remain [2]. Several authors have reported good results with allograft [3–5], despite the fact that it is associated with a higher failure rate when compared to autograft [16]. The augmentation with calcium phosphate ceramics has been also investigated [12, 13], while the experience with xenograft is scanty [6].

Tricalcium phosphate can rapidly dissolve and be replaced with cancellous bone, providing weak mechanical properties and risk of post-operative compression [17, 18]. Because hydroxyapatite is more stable and dissolves slowly after implantation, the association with tricalcium phosphate aims to improve the mechanical strength of the spacer, maintaining a good biodegradability and macroporosity to

Table 3 HKA angle values in the xenograft locking plate and tricalcium phosphate non-locking plate groups

Groups		HKA angle Mean ± SD (range)	P value
Xenograft locking plate	Preoperative	9.1±5.2° (3–13°) in varus	Preop vs post-op P=0.01*
	Post-operative	3.1±4.8° (2–6°) in valgus	
	Last FU	2.8±3.8° (1.5–6°) in valgus	Post-op vs last FU P=0.06
Tricalcium phosphate non-locking plate	Preoperative	8.5±5.9° (3–13°) in varus	Preop vs post-op P=0.01*
	Post-operative	3.4±4.2° (2–6°) in valgus	
	Last FU	2.1±4.8° (1.2–5.6°) in valgus	Post-op vs last FU P=0.03*

FU follow-up

* Statistically significant

Table 4 Clinical questionnaire results in the xenograft locking plate and tricalcium phosphate non-locking plate groups

Groups	Scores	Preoperative Mean ± SD (range)	Last FU Mean ± SD (range)	*P* value
Xenograft locking plate	KSS knee score	42±19 (31–69)	73±22 (62–84)	*P*=0.001*
	KSS function score	42±16 (39–60)	81±12 (70–88)	*P*=0.01*
	WOMAC	45±17.3 (30–62)	74±25 (62–89)	*P*=0.001*
	SF-36	62.5±19.8 (52–92)	73.2±21 (65–81)	*P*=0.003*
	EQ-5D	59.3±22.1 (49–87)	75.1±22 (62–84)	*P*=0.001*
Tricalcium phosphate non-locking plate	KSS knee score	43±16 (33–67)	70±21 (62–80)	*P*=0.001*
	KSS function score	50±18 (38–60)	80±14 (72–86)	*P*=0.01*
	WOMAC	42±19.1 (30–65)	75.4±21.2 (60–90)	*P*=0.001*
	SF-36	60±21.3 (50–92)	74.1±15.2 (63–80)	*P*=0.003*
	EQ-5D	56.4±21.8 (46–87)	73.6±21 (60–84)	*P*=0.001*

FU follow-up

* Statistically significant

facilitate bone growth [12, 17]. However, the hydroxyapatite/beta-tricalcium phosphate spacer showed a statistically significant loss of correction when compared to autologous iliac crest bone graft fixed with locking plate (27 % vs 5 %) [12]. The loss of correction in the tricalcium phosphate spacer non-locking plate group could be at least in part related to the type of graft. Although some authors recommend that the gap be filled only in osteotomies greater than ten millimetres [17, 19], we prefer to use a filler bone graft regardless of the correction achieved to prevent complications with hardware failure.

The type of fixation is still a controversial topic [1]. The Puddu locking plate has been proposed in opening osteotomies less than 7.5 mm, non-overweight patients and absence of risk factors for bony healing like smoking [17], whereas a long rigid locking plate has been recommended in greater opening osteotomies, presence of lateral cortical fractures or risk factors for bony consolidation.

Although long locking plates showed better biomechanical properties when compared to short spacer plates [20, 21], their costs are higher, and hardware removal is required in a significant number of patients because of local discomfort [22]. On the other hand, the Puddu plate is a reliable implant associated with good clinical results [15, 23]. Moreover, the introduction of angle stable screws for the Puddu plate has improved its mechanical properties. A biomechanical comparison of short conventional plate and angle stable plate, with or without spacer, reported superior properties for spacer implants and showed that angle stable plates can prevent lateral cortical fractures [24]. The loss of correction in the tricalcium phosphate spacer non-locking plate group could be, at least in part, related to the type of fixation, and we suggest using the Puddu locking plate.

Fig. 5 Radiograph (*lateral view*) showing the avulsion of the anterior tibial tuberosity

Smoking and BMI can affect the bone healing and the post-operative alignment [17]. However, we did not find any difference in this respect between the two groups. Therefore, our results cannot be associated with these factors.

Finally, some authors have shown that the lateral cortical fracture at the osteotomy site increases the risk of the loss of correction [12, 16]. Although this event occurred in both groups (11 % in the xenograft and 8 % in the tricalcium phosphate groups), we found loss of correction with lateral cortical fracture only in the patients of the tricalcium phosphate group. Adequate strength of the construct can prevent the loss of correction, despite the onset of lateral cortical fracture [25].

In the literature, comparative studies investigating different grafts to fill the bony gap and different fixation systems are lacking. Only one prospective, controlled, randomised study has been performed to compare macroporous biphasic ceramic (hydroxyapatite/-beta-tricalcium phosphate) wedge and autologous iliac crest bone graft for augmentation of the opening-wedge HTO, fixed with plate and locked screws [12]. To our knowledge, this is the first comparative study comparing xenograft locking Puddu plate with tricalcium phosphate non-locking Puddu plate constructs.

The strength of the study consists in employing widely used and validated scoring systems to provide a quantitative assessment of clinical benefits related to the two procedures. A further strength of the study is that only one surgeon performed the operation in all patients included in the same cohort. Although the two groups underwent surgery by two different surgeons, we minimised this potential bias by inviting surgeons to perform exactly the same procedure.

One of the limitations of the study consists in its design, because two cohorts of prospectively enrolled patients were compared without any randomised allocation. Nevertheless, no statistically significant differences were found in terms of age, gender, BMI and smoking rate between the two groups. Although some authors propose the procedure in patients up to 60 years of age [1], we enrolled subjects up to 70 years of age, because old age should not be considered an absolute contraindication if the other inclusion criteria are satisfied and if the patients are physically active.

Another limitation consisted in comparing a locking plate and a non-locking plate. The different selection of the plate system reflects the clinical practice of the two surgeons involved in the study. For this reason, we are aware that no definitive conclusions can be drawn about the superiority of one graft over the other. In this study, we can only compare two different combinations, namely xenograft locking Puddu plate and tricalcium phosphate spacer non-locking Puddu plate, and further comparative studies, including all graft-plate combinations, should be performed to ascertain which of them provides better results.

In conclusion, high tibial opening-wedge osteotomy for the management of medial compartment OA performed with xenograft locking Puddu plate and tricalcium phosphate non-locking Puddu plate constructs showed good clinical outcomes. However, the xenograft locking Puddu plate is superior to the tricalcium phosphate spacer non-locking Puddu plate construct to prevent loss of correction in the middle term.

Conflict of interest The authors declare that they have no conflict of interest.

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