ORIGINAL ARTICLE

Open wedge high tibial osteotomies: Calcium-phosphate ceramic spacer versus autologous bonegraft

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KEYWORDS
Opening wedge; High tibial osteotomy; Bone substitute spacers; Calcium-phosphates

Summary
Introduction: Valgus tibial osteotomy (VTO) is a well-known procedure for the treatment of medial compartment femoro-tibial osteoarthritis. Good and very good results have been reported with calcium phosphate wedges, which avoid the inconveniences of autologous grafts use. The hypothesis of this study is that with equivalent results in the treatment of osteoarthritis of the knee, the use of calcium phosphate wedges (BMCaPh) to fill the bone defect created by osteotomy would result in fewer specific complications and less pain associated with autologous grafts (AUTO) harvesting.

Patients and methods: This prospective, controlled, randomised study included one arm that received a macroporous, biphasic calcium phosphate wedge (BMCaPh group) and one arm that received an autologous tricortical graft (AUTO group) for filling. The same plate with locked screws was used for fixation in all cases. All patients underwent at least two years of clinical and radiographic post-operative follow-up.

Results: Forty patients were included. Loss of correction occurred in six of the twenty-two patients in the BMCaPh group (27%), resulting in three early surgical revisions, compared to one loss of correction in the AUTO group. Lateral cortical hinge tears were a risk factor for loss of correction for the entire cohort and in the BMCaPh group. (relative risk 13.3 [1.9—92]. Moreover, union took significantly longer and pain lasted significantly longer in the BMCaPh group, although results were comparable at 6 months.

Discussion: A significant number of undesirable events (loss of correction) occurred in this study, limiting the number of included patients. Nevertheless, the results show that although there
Introduction

Valgus tibial osteotomy is a well-known treatment for certain forms of femorotibial osteoarthritides of the medial compartment. The risk of valgus proximal closing wedge osteotomy is injuring the fibular nerve and less precise correction, prompting certain authors to use valgus medial opening wedge osteotomy [1,2]: this technique has the advantages of being a single osteotomy (no fibular osteotomy), of providing more precise correction of varus angle, and of being less difficult if total knee arthroplasty must be performed [2,3,4].

Except for Lobenhoffer and Agneskirchner [5] who feel that it is not necessary to fill the bone defect created by osteotomy and that a plate is sufficient if there are no biological bone anomalies, other groups have used several types of bone substitutes. Although autologous grafts are the reference technique [6], xenografts [7], acrylic cement [8] and ceramic wedges [9] have all been used, and each has specific inconveniences.

To our knowledge, there are no controlled studies comparing the results of autologous graft and calcium phosphate ceramics as bone substitutes in valgus tibial osteotomy. Two studies have been published in the Anglo Saxon literature [10,11]. The first reports very good clinical and radiographic results after 6.6 years of follow-up with a hydroxyapatite wedge associated with a fibular autologous bone graft (wedge). The second reports radiographic results of filling with tricalcium phosphate granules. Three retrospective studies have been published in the French literature with excellent radiographic and clinical results and no specific complications [12,13,14].

We have been using macroporous calcium phosphate ceramics for more than 10 years in our department with satisfactory clinical results [15,16,17]. The hypothesis of this study was that short term clinical and radiographic results would be similar with macroporous biphasic calcium phosphate ceramic wedges and autologous grafts for the treatment of femoro-tibial osteoarthritis, while specific complications and post-operative pain would be more frequent with autologous grafts.

Patients and methods

Patients

From September 1999 to March 2003, 40 patients (40 knees) were treated with a valgus proximal opening wedge tibial osteotomy (VTO) and included in this prospective randomized study. The average follow-up was 45 ± 21 months (range 24–66 months), and none of the patients were lost to follow-up.

Patients between 18–75 years old, with an indication for VTO (medial single compartment osteoarthritis, lateral instability of the knee, post-traumatic genu varum) were enrolled in this study and included after providing informed consent. This study was approved by the CPP Ouest IV (Committee for the Protection of Persons) and the office for clinical research at our university hospital facility. Patients presenting with a history of infection, radiation therapy or femoropatellar osteoarthritides were excluded from the study.

Pre-operative evaluation and planning

Pain was evaluated with a visual analogic scale (VAS pain, no pain = 0, the most intense imaginable pain = 10). Functional difficulties were evaluated with a VAS of 100 mm. The clinical evaluation was based on the Knee Society score (IKS) [18]. All patients had frontal and profile plain X-rays, 30° tangential views and stress X-rays. The extent of radiographic osteoarthritis was evaluated with the Ahlback [19] classification. Frontal weight-bearing X-rays (Schuss view) completed the analysis of osteoarthritis. The mechanical HKA angle of the legs was measured on standing leg X-rays.

The aim of surgery was to obtain an HKA angle of between 182–186° (post-operative valgus 2–6°). The height of the opening was calculated by the Slocum, Larson and James [20] graphic method and Hernigou and Goutallier [21] tables.

Randomization/surgery

Randomization was performed in the operating room after the osteotomy had been performed and was determined by random allotment to the autologous graft (AUTO) or ceramic wedge (BMCaPh) groups. The osteotomy opening in the patients in the AUTO group was filled with a tricortical graft harvested from the homolateral iliac crest. The osteotomy opening in the patients in the BMCaPh group was filled with a ceramic wedge mixed with 2 ml of autologous bone marrow harvested percutaneously from the homolateral iliac crest. The macroporous biphasic ceramic wedges (BMCaPh) were composed of 60% pure synthetic hydroxyapatite Ca10(PO4)6(OH)2 and 40% pure beta tricalcium phosphate Ca3(PO4)2 (Fournitures hospitalières industrie, Heimsbrunn, France) sintered at 1200° C. The implants were formed into wedges with four dimensions: 40 mm long, 3 mm thick ends, 20–30 mm wide and wedge heights of, 6, 8, 10 and 12 mm. (Non-commercial wedges specially designed for this study). Macroporosity was 75–80% and pore diameter was 300–500 μm. Resistance to pressure was 1–5 Mpa.
All osteotomies were fixed with the same plate with locked screws (Surfix®).

Post-operative follow-up

Knee movement and muscular exercises began on the second day after surgery. Weight was applied depending on the amount of post-operative pain and left up to the discretion of the surgeon for the first 6 weeks. It was complete by D45.

Post-operative follow-up

All patients were seen for a follow-up consultation at 6 weeks and 3, 6, 12 and 24 months after surgery, and examined at the last follow-up visit by an examiner who was not the operating surgeon. Pre- and post-operative pain was evaluated on the VAS. All incidents and complications were recorded. The duration of surgery and hospitalization were noted, and the IKS score and functional VAS were calculated at each follow-up consultation.

All patients had control X-rays at each follow-up consultation. A loss of correction was defined as displacement of the osteotomy before union or if the HKA angle decreased by 3° or more on standing leg X-rays.

Bone consolidation, remodelling, and incorporation of the ceramic bone substitute were evaluated according to GESTO criteria [22] by two independent surgeons.

The osteotomy was considered to be solid when the following criteria were fulfilled:

- disappearance of the line of condensation on the edge of the substitute material with continuity between the bone and the substitute (along more than 75% of the frontal and profile interface);
- development of a bone callus on the medial edge of the filled bone defect.

Statistical analysis

The quantitative data were compared with the Student t test, the qualitative data with the Chi² test modified by the Fischer test. The influence of the type of bone substitute (AUTO or BMCaPh) was studied for each of the post-operative parameters. A difference of p > 0.05 was considered to be significant. A provisional inclusion of 40 patients in each arm was decided based on similar results for osteotomy in terms of union and correction, but with a reduction in pain and complications link to harvesting of the graft to reach a power of 80% (Beta risk 0.2). The statistical tests were performed with JMP® 7.01 software.

Results

The results are summarized in Table 1.

Patients included in the study

Forty patients were included in this study: 22 (15 men and seven women) received BMCaPh as a bone substitute and 18 AUTO (11 men and seven women). Because of the unexpectedly high incidence of patients with loss of correction (cf. infra), the study was discontinued after 40 inclusions (more than 80 had been initially planned). The mean age was 51 years old (10—75 years old), the mean body mass index was 29.5 including 50% with moderate, severe or morbid obesity. Fifty two percent of the patients had a physical job or practiced sports regularly. Fifty percent of patients had undergone a homolateral meniscectomy, 32% had no history of knee surgery and 25% presented with osteoarthritis of the contralateral knee. There was no difference between the two groups.

Surgical indication

In the AUTO group, 15 out of 18 patients presented with medial femorotibial osteoarthritis on varus knee, one patient presented with a varus malformation on proximal tibial fracture malunion and two patients presented with chronic knee instability.

In the BMCaPh group, 20 out of 22 patients presented with medial osteoarthritis of the knee, one patient with chronic instability and one patient presented with sequel from osteochondritis dissecans for which mosaicplasty had failed. There was no difference between the two groups.

Surgical procedure

The mean opening was 10 mm in the two groups (6—15 mm). The mean duration of surgery was 49.3 min in the BMCaPh group and 53. 5 min in the AUTO group with no significant difference between the groups.

Clinical results

Knee pain

Between the pre-operative evaluation and the final follow-up, knee pain had improved and decreased by a mean 3.3 and three points on the VAS in the BMCaPh and AUTO groups respectively. The patients in the BMCaPh group had significantly more pain 3 months (p = 0.04) after surgery; this difference had disappeared at 6 months (Fig. 1).
Table 1  Local progression of Hip Knee Ankle (HKA) angle and surgical revisions according to type of substitute use.

<table>
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BMCaPh W = filling with biphasic macroporous calcium phosphate ceramic wedge, AUTO = filling by tricortical autologous graft, D = day, M = month.

Knee function
At the last follow-up knee function on the VAS had improved by a mean 3.5 and 2.5 points in the BMCaPh and AUTO groups respectively. This difference was not significant (Fig. 2).

Knee Society score
The mean improvement in IKS knee scores and IKS function was respectively 20.3 and 14.6 points for the BMCaPh group and 21.2 and 18.3 points for the AUTO group. IKS func-
Calcium-phosphate ceramic spacer versus autologous bonegraft

Subjective Knee Function (Visual analog scale)

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Figure 2  Evaluation of knee function by VAS at different post-operative follow-up visits. No difference between the two groups.

IKS knee score at the different post-operative follow-up visits. No significant difference between the two groups.

Figure 3  IKS knee score at the different post-operative follow-up visits. No significant difference between the two groups.

Function IKS

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Figure 4  IKS function score at different post-operative follow-up visits. This score was significantly lower in the calcium phosphate wedges group at 3 months. * (p = 0.017).

Iliac crest pain

This pain disappeared rapidly. At the last follow up one patient presented with a pain level of 4 on the VAS, and three patients had a pain level of 1 on the VAS (Fig. 5).

Subjective results

At the last follow-up, 80% of the patients were satisfied or very satisfied with surgery and there was no significant difference between the two groups. At the last follow-up, the subjective results were correlated with knee function and knee pain on the VAS (p = 0.036 and p < 0.01).

Radiographic results

Loss of correction and the lateral cortical hinge tears six out of 22 patients (27%) in the BMCaPh group had a loss of

Iliac Crest Pain (Visual Analogue Scale)

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Figure 5  Iliac crest pain at different post-operative follow-up visits.

Figure 6  a: post-operative X-rays of a proximal opening tibial osteotomy filled with a biphasic macroporous calcium phosphate ceramic wedge; b: painful knee with loss of correction at 3 months associated with a lateral cortical hinge tear.
correction ($\geq 3^\circ$) requiring surgical revision in three cases (by autologous graft) (Fig. 6). All of these complications occurred within 6 months after surgery. One patient who presented with persistent pain on the medial side of the knee had the plate removed at 6 months. Loss of correction developed after this procedure, showing that the osteotomy had not healed. In the AUTO group, loss of correction occurred in one patient. This difference was not significant, but there was a strong tendency towards loss of correction in the BMCaPh group ($p = 0.1$).

In the BMCaPh group a lateral cortical hinge tear occurred in six out of 22 patients (27%) resulting in five cases of loss of correction, while the lateral hinge was torn in four out of 18 cases in the AUTO group (22%) resulting in one case of loss of correction.

In the BMCaPh group a lateral cortical hinge tear was a significant risk factor ($p = 0.001$) for loss of correction (relative risk 13.3 [1.9—92]). A lateral cortical hinge tear occurred in a total of 10 patients and six of them presented with a loss of correction, while in the 30 patients without a lateral cortical hinge tear, loss of correction only developed in one. A lateral cortical hinge tear was significantly associated with a loss of correction ($p = 0.0003$) relative risk 43.5 [4.1—461]).

No difference was found between pre- and post-operative tibial slope measurements in any of the groups.

Bone union
Union occurred in all patients except for the three cases of revision surgery for loss of correction, whatever the bone substitute. When an autologous graft was used to fill the bone defect created by osteotomy, union occurred within a mean 2.6 months (45 days—6 months). When the BMCaPh ceramic was used union occurred within a mean 5.8 months (45 days—16 months) ($p = 0.001$) (Fig. 7).

Incorporation of calcium phosphate wedges bone substitute
X-rays performed during the final follow-up showed only partial incorporation of the BMCaPh wedge. Even 5 years later the material was still visible on the AP X-rays.

Complications
All complications, even minor (Fig. 8) were recorded. Thus, one patient who presented with a hematoma, loss of correction and who underwent revision surgery was recorded three times, as ‘‘complications linked to bone substitute’’, ‘‘loss of correction’’ and ‘‘revision’’.

There was no significant difference between the two groups for complications.

Finally in the BMCaPh group, five patients underwent revision surgery, three for loss of correction and two for an infection. Three patients underwent revision surgery in the AUTO group: one for a painful calcification of the iliac crest, one for an infection of the crest and one for a tibial infection. There was no significant difference in the number of surgical revisions between the two groups.

Discussion
This study is based on the short-term results of proximal opening tibial osteotomy and comparing filling of the bone defect with a biphasic macroporous ceramic wedge (BMCaPh) and an autologous tricortical graft (AUTO). Loss of
correction was more frequent in the (BMCaPh) group than in the (AUTO) group. The presence of lateral cortical hinge tears significantly increased the risk of loss of correction in the entire series and in the BMCaPh group (but not in the AUTO group). The functional IKS score was significantly lower and there was significantly more pain 3 months after surgery in the BMCaPh group, but not in the later follow-up period, while time to union was significantly longer with BMCaPh as a bone substitute. However, after 2 years of follow-up, the rate of complications and revision surgery was not different between the groups.

Randomized controlled studies on synthetic bone substitutes are rare, and to our knowledge, there are no studies on VTO. This study has several limitations: the number of cases is limited and the group is smaller than was initially planned due to the number of patients with loss of correction in the BMCaPh group. This reduced the statistical power of the study. Most of the patients included in the study were treated in a university hospital department and the reproducibility of the surgical technique is probably less good than if only one surgeon had performed the operations for the study. Moreover, the delay until full weight was placed on the knee varied during the first year of inclusion. These two factors undoubtedly influenced the comparative results of these two types of bone substitute for osteotomy. Despite this, there were significant differences between the BMCaPh and the AUTO control groups. The follow-up is short but since the initial hypothesis was that the use of autologous grafts would result in more pain and complications from the harvesting than BMCaPh for the same local results in the knee, a follow-up of two years was enough to measure these elements. Indeed, long-term results of VTO in the treatment of femorotibial osteoarthritides of the knee have been well documented in the literature [1,18,23,24,25], thus only short-term follow-up was necessary to reach the goal of the study.

This study used a wedge shaped macroporous biphasic ceramic (hydroxapatite/β tricalcium phosphate). These wedges have been shown to be feasible as a bone substitute in previous studies [15,16]. These two compounds, (hydroxapatite and β tricalcium phosphate) are bioactive ceramics that bond to bone with no interposition of tissue. β tricalcium phosphate dissolves rapidly after implantation and cancellous bone replaces the material. In vivo hydroxapatite is more stable in the long term and dissolves much more slowly; it bonds to bone by apatitic chemical bridges [26]. The interest of these biphasic compounds is to provide the reactivity of the first and the stability of the second in appropriate proportions. The high macroporosity of this compound (100–400 μ) is also an important parameter to facilitate bone growth [27,28]. On the other hand, this type of compound has low mechanical strength. However in an animal model of implantation Trécant et al. [29] showed that 3 weeks after implantation bone growth improves the mechanical characteristics of this compound, increasing compressive strength by 2.5 times. For this reason, we used a metal plate with locked screws for maximum rigidity of the osteotomy and to prevent post-operative compression. Despite this type of fixation, six patients (22%) in the BMCaPh group had an angular loss of correction compared to one patient in the AUTO group. These results are different from most studies in the literature, although numerous parameters make comparison difficult [10,11,12,13,14,30]. Lavalle et al. [14] used a technique which was very similar to ours with a metal plate and locked screws and a similar type of macroporous biphasic substitute; only one post-operative loss of correction was reported in the 24 cases in that retrospective study. However the difference may be explained by two elements: although the same type of wedge was used, it did not have the same shape—the width of the wedges in our study was narrower and thus filled less than those used by Lavalle et al. In the Lavalle study radiological evaluation of loss of correction was based on standard knee X-rays, while standing leg X-rays were used in our study. Moreover three of their 24 patients were lost to follow-up. Koshino et al. [10] also used a macroporous substitute for the filling of osteotomies, and no varus revision surgery was necessary in this retrospective study of 21 patients. Fixation with two plates was used in that study as well as a ceramic wedge for filling associated with ceramic granules, fibular autologous grafts and “chips”. The results of Bonneville et al. [12] and Dehoux et al. [13] in two retrospective studies using “light” osteosynthesis were contradictory: both studies used microporous β tricalcium phosphate ceramic wedges which are more easily incorporated than hydroxapatite but which limit bone growth due to their microporosity. On the other hand, these wedges have better mechanical characteristics than macroporous ceramics, theoretically limiting the risk of compression. Moreover Dehoux et al. [13] associated the ceramic wedges with ceramic granules and autologous “chips”. Nevertheless a high rate of loss of correction (43%) of an average of 3° was reported in this study requiring revision surgery in one patient: finally 8% of the patients had a valgus correction of between 3 and 6° and the authors recommend more rigid fixation. Bonneville et al. [12] only reported a loss of correction in one out of 55 patients and two fractures on staple fixations. Finally except for Lavalle et al. [14] all of these authors recommend delaying weight bearing. For Lobenhoffer et al. [5], delaying weight bearing and rigid fixation results in a low rate of loss of correction (two out of 92), even without a bone substitute for filling.

Our results for loss of correction are poor compared to those in the literature. The post-operative mechanical conditions probably favoured these complications. Filling of the bone defect caused by osteotomy was less effective in our study (due to narrow wedge corners) than in other studies except for that of Lobenhoffer et al. [5], and more than the type of bone substitute (BMCaPh versus AUTO), a lateral cortical hinge tear was a significant risk factor for these failures, despite fixation with a rigid plate. This risk factor was also significant in the BMCaPh group, indicating that there is less tolerance to this material than to AUTO in the presence of unfavorable mechanical conditions. Although placing weight on the knee too early may also have been an aggravating mechanical factor, the methodology of our study makes it impossible to reach this conclusion. We recommend being careful when indicating this type of ceramic filling in patients who will not be compliant to weight bearing recommendations.

This procedure has been shown to successfully treat medial femorotibial osteoarthritis, with pain on the VAS decreasing from 5.7 pre-operatively to 2.5 post-operatively and functional IKS knee scores increasing from 62.4–70
pre-operatively, 82–86 post-operatively with no difference between the BMCaPh and AUTO groups. However clinical results and radiological union occurred significantly later in the BMCaPh group than in the AUTO group. To our knowledge, there are no other controlled studies confirming these results, although this tendency has been suggested in different bone substitute studies [10,11,12,13,14,31].

The lack of clinical difference 6 months after surgery suggests that BMCaPh successfully bonds into a mechanically adapted bone-material composite; however this study does not respond to uncertainty about long term results and the stability of correction after plate removal: only three plates were removed before 12 months with one case of loss of correction in the BMCaPh group. The only long-term study in the literature is the report by Koshino et al. [10], in which the ceramic substitute was combined with an autologous cortical graft; there were no reported cases of loss of correction after 78.6 ± 22 months of follow-up. Long-term clinical and radiographic studies are needed to confirm the stability of these results over time.

Conclusion

This randomised study compared macroporous biphasic ceramic wedges and autologous grafts, the reference procedure, as bone substitutes for defects caused by tibial osteotomy. Loss of correction was more frequent in the BMCaPh group (27 versus 5%). The presence of lateral cortical hinge tears significantly increased the risk of loss of correction in the BMCaPh group suggesting that this material was less tolerant to high mechanical restraints. Moreover, union took significantly longer and the clinical results occurred significantly later in the BMCaPh group although results for all parameters were the same at 6 months in the two groups. Although the results with this bone substitute were the same as with autologous grafts, care should be taken with indications, because of problems with mechanical tolerance in the post-operative period, especially in case of lateral cortical hinge tears, and in patients who will not comply to weight-bearing recommendations.

Conflict of interest

None.

References


