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Original article

Opening-wedge high tibial osteotomy with a secure bone allograft (Osteopure™) and locked plate fixation: Retrospective clinical and radiological evaluation of 69 knees after 7.5 years follow-up

G. Villatte[a], R. Erivan[a], P.-L. Fournier[a], B. Pereira[c], M. Galvin[a], S. Descamps[a,b], S. Boisgard[a,*]

[a] Service d'orthopédie-traumatologie, CHU Montpied, 58, rue Montalembert, 63000 Clermont-Ferrand, France
[b] Laboratoire C-Biosenss, EA 4676, Université d'Auvergne 1, 63000 Clermont-Ferrand, France
[c] Service Biostatistique, CHU de Clermont-Ferrand, 58, rue Montalembert, 63000 Clermont-Ferrand, France

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ABSTRACT

Background: Medial opening-wedge high tibial osteotomy (OWHTO) provides reliable and long-lasting benefits, despite the wide range of wedge-filling and internal-fixation techniques used. The purpose of this work was to assess the clinical and radiological outcomes in a case-series of OWHTO performed using a secure bone allograft and locked plate fixation.
Hypothesis: The clinical and radiological outcomes of OWHTO with a high-safety bone allograft and locked plate fixation are similar to those reported in previous case-series studies.
Materials and methods: A single-centre retrospective design was used to study 69 knees in 64 patients with a mean age of 51.8 years (31–53 years) and a preoperative hip-knee-ankle (HKA) angle of 173° (165°–180°). The wedge was filled with secure Osteopure™ bone allograft and fixation was achieved using an Integra Surfix® locked plate. Mean follow-up was 7.5 years (5–9.3 years). Clinical and functional outcomes were assessed by determining the IKS and KOOS-PS scores and recording complications related or unrelated to the allograft. The main criterion for assessing OWHTO survival was the time to revision surgery for symptom recurrence. Radiological assessment criteria were the HKA angle, tibial slope, patellar height, and osteoarthritis grade. GESTO criteria were used to evaluate the behaviour of the allograft.
Results: Of the 69 knees, 64 (92.8%) were re-evaluated. The survival rate after 9.3 years was 95% ± 2.7% (3 failures managed with arthroplasty). The functional IKS score improved significantly, by 20 points ($P < 0.001$). Mean increases of 7.8° for the HKA angle and 3.5° for tibial slope were recorded. Bone healing without radiological abnormalities was consistently achieved within 6 months. There were no complications related to the allograft (infections, allergies; local or systemic toxicity).
Discussion: The clinical, radiological, and safety outcomes documented in our study were similar to those reported in earlier work.
Level of evidence: IV, retrospective case-series study.

1. Introduction

The use of surgery to treat knee osteoarthritis is expanding [1], and the target population is composed of increasingly young patients with long life expectancies. Knee osteoarthritis affects the medial tibiofemoral compartment in 70% of cases, usually in knees with varus malalignment.

Medial opening-wedge high tibial osteotomy (OWHTO) is a rational and validated procedure that provides lasting benefits, with good results in 85% of cases after 10 years [2,3]. The tibial wedge is usually filled. Autografts can be used but are associated with donor-site morbidity [4–8]. Consequently, researchers have developed a number of other options such as allografts, acrylic cement, and bone substitutes [9]. Filling materials must be biologically safe and capable of osteo-integration and healing. A specific locked plate designed to ensure rigid internal fixation used without filling the wedge has produced satisfactory outcomes [10,11].

The objective of this study was to assess outcomes in consecutive patients at a mean of 7.5 years after medial OWHTO with

* Corresponding author.
E-mail addresses: sboisgard@chu-clermontferrand.fr, stephane.boisgard@wanadoo.fr (S. Boisgard).

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implantation of the secure bone allograft Osteopure™ and locked plate fixation. The working hypotheses were that clinical and radiological outcomes with this technique were at least as good as those reported with other methods and that Osteopure™ was not associated with any specific complications.

2. Materials and methods

2.1. Study design

A retrospective single-centre design was used to study consecutive patients in whom medial OWHTO was carried out in our department between January 2004 and December 2007. After a mean of 7.5 years (5.2–9.4 years), patients underwent a clinical and radiological assessment performed by an independent observer.

The study protocol was approved by the ethics committee of the Clinical Investigations Centre (CECIC) of the Rhône-Alpes/Auvergne inter-region (IRB 00005921). Patients were informed about the study.

2.2. Study population

The study included 69 knees in 64 patients, 43 males and 21 females with a mean age of 51.8 years (range, 31–74 years). Mean preoperative body mass index (BMI) was $27.2 \pm 6.4\,kg/m^2$. The diagnosis was degenerative joint disease in all 69 knees. Radiological osteoarthritis severity according to the Ahlbäck system [12] was as follows: grade 1, 32%; grade 2, 53.5%; grade 3, 14.5%; and grade 4, 0%. Mean varus deformity was 173° (range, 165°–180°). The mean Caton-Deschamps index of patellar height [13] was 0.90 (range, 0.5–1.25) and the mean tibial slope was 5.3° (range, 0°–16°).

2.3. Operative technique

Osteopure™ was distributed by Ostéobanque d'Auvergne (Clermont Ferrand, France) as wedges (height, 10 or 15 mm; and slope, 6° or 10°) specifically designed for filling the defects created during OWHTO. The allogeneic bone was harvested during primary total hip arthroplasty procedures. Virus inactivation and sterilisation was achieved using a urea-based procedure and beta radiation carried out by OST Développement (Clermont Ferrand, France). This procedure was previously validated by the microbiology safety task force of the French Drug and Healthcare Safety Agency (AFSSAPS, accreditation # 99-08802B02), and bone allografts treated with this procedure were first used in humans in 1999.

Internal fixation was with the Surfix® locked plate (Integra, Saint Priest, France). Surfix® is a thick L-shaped plate specifically designed to ensure stability in all three planes after OWHTO. Threaded holes lock the screws into the plate.

The amount of correction needed was determined based on a weight-bearing evaluation of lower limb alignment. The target HKA angle was 183° (±3°).

No immobilisation was used after surgery. A non-weightbearing rehabilitation programme was followed for 45 days. Prophylactic anticoagulant therapy was given for 2 months.

2.4. Assessment methods

Patients were required to have two clinical and radiological evaluations, one performed preoperatively and the other done at last follow-up by an independent observer. Revision surgery consisting in total knee arthroplasty (TKA) was the endpoint used to assess OWHTO survival. Functional outcomes were assessed by determining the Charnley functional class and IKS score preoperatively and at last follow-up, as well as the KOOS-PS (knee-related quality of life) at last follow-up. All complications were recorded, including general complications (e.g., infection, intraoperative fracture, thrombo-embolism) and adverse events directly related to the bone allograft (contamination with infectious agents, allergy, acute or chronic toxicity).

Table 1
GESTO criteria for evaluating bone graft appearance [15].

Evaluation of the host bone: no change, sclerosis, lysis
Evaluation of the host bone/graft interface: surrounding line absent or present (size < 25%, 25–50%, 50–75%, > 75%, 100%; and thickness in millimetres)
Evaluation of the graft: sclerosis, fragmentation, migration, resorption (none, < 25%, 25–50%, 50–75%, > 75%, 100%)

Standard radiographs (weight-bearing anteroposterior and lateral views and skyline view with the knee flexed at 30°) and an assessment of lower-limb alignment were used to determine the following: tibiofemoral osteoarthritis grade in the Ahlbäck classification system, mechanical axis of the knee (HKA angle), tibial slope according to Dejour[14], Caton-Deschamps index of patellar height, and degree of bone healing. The appearance of the graft was assessed based on criteria developed by the Greffes Et Substituts Tissulaires en Orthopédie (GESTO) [15] (Table 1).

2.5. Statistical tests

Paired data (preoperative vs. postoperative values) were compared using Student's or Wilcoxon's test. Categorical variables in independent groups were compared by applying the chi-squared test or Fisher's exact test. Associations (multivariate analysis) between quantitative variables were assessed by computing Pearson's or Spearman's correlation coefficients. The Kaplan-Meier method was applied to assess data that were considered censored, namely, survival and revision surgery. Values of $P < 0.05$ were considered significant. All analyses were performed for a two-sided Type I risk of 5% using STATA V12 software (StataCorp, College Station, TX, USA).

3. Results

3.1. General results

After a mean follow-up of 7.5 years, 64 knees in 59 patients were assessed based on an in-person visit (91%) or on information from a telephone call and imaging studies (9%). Data were not available for 3 (4.7%) patients who were lost to follow-up and 2 (3.1%) who died.

OWHTO failed in 3 knees, after a mean of 5.25 ± 0.86 years. In all 3 cases, TKA was performed because of symptom recurrence and radiological osteoarthritis progression (HKA angle values at revision surgery: 179°, 189°, and 184°, respectively).

The Kaplan-Meier analysis showed a survival rate of $95\% \pm 2.7\%$ after 7.5 years (Fig. 1).

3.2. Complications

Intraoperative fracture of the lateral tibial plateau occurred in 3 (5.1%) cases and consistently healed within 3 months. This complication had no impact on the HKA angle at last follow-up (180°, 183°, and 184°, respectively). Deep vein thrombosis developed in 2 (3.4%) patients, both of whom achieved a full recovery with curative-dose anticoagulant therapy. No blood vessel or nerve injuries were recorded, and none of the patients experienced non-union.

There were no complications specifically related to the bone allograft (infection, allergy, local or systemic toxicity).

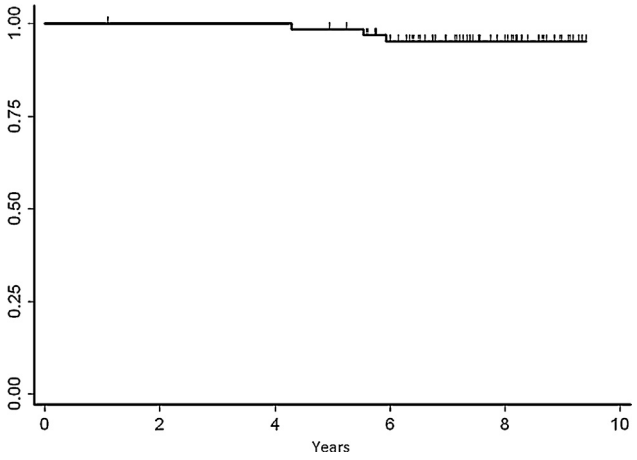

Fig. 1. Survival curve (revision with TKA as the endpoint).

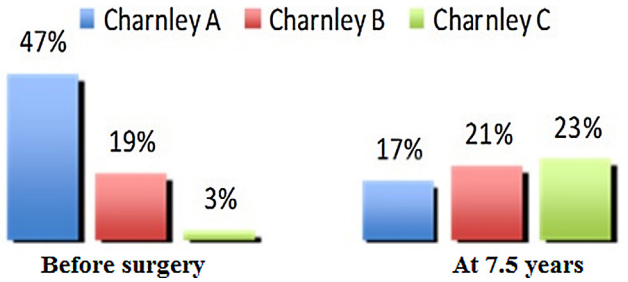

Fig. 2. Changes over time in the distribution of patients according to Charnley class.

3.3. Clinical outcomes

At last follow-up, significant worsening ($P < 0.001$) of the Charnley class was noted, with a shift towards class C (Fig. 2). The total IKS score improved significantly ($P < 0.001$), from 132 (95% confidence interval [95%CI], 127–136) preoperatively to 151 (95%CI, 142–159) at last follow-up. The same significant differences were noted for the clinical and functional components of the score.

The mean KOOS-PS score at last follow-up was 38.8/100. The score result was considered good in 45% of cases, fair in 49%, and poor in 6%.

3.4. Radiological outcomes

The HKA angle target of 183°±3° was achieved in nearly 70% of cases (mean HKA angle, 180.9° [176°–189°]). Tibial slope increased significantly, by a mean of 3.5° ($P < 0.001$). The patellar index decreased significantly, by 0.19 ($P = 0.001$) (Table 2).

The osteoarthritis severity grade worsened in both the tibiofemoral and patellofemoral compartments (Fig. 3).

No evidence of allograft fragmentation was seen 6 months after surgery, when the density of the implant was either equal (82%) or higher (18%) than that of the surrounding bone. Evaluation of the GESTO criteria did not show any lines at the host bone-allograft interface or changes in the host bone in contact with the implant. Finally, healing was achieved in all cases (Fig. 4).

Table 2
Changes in mean values of radiological variables during the study.

	Preoperative values	After 7.5 years	*p* value
HKA angle (°)	173.1	180.9	< 0.001
Tibial slope (°)	5.3	8.8	< 0.001
Patellar index	0.90	0.71	= 0.001

HKA: mechanical axis of the lower limb.

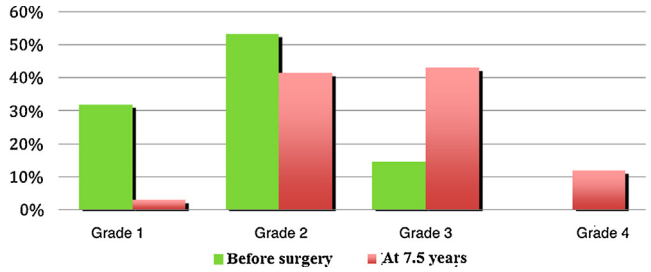

Fig. 3. Changes over time in tibio-femoral osteoarthritis severity (Ahlbäck grade).

3.5. Multivariate analysis

None of the clinical or radiological variables (including age, BMI, and HKA angle at last follow-up) correlated significantly with failure of the OWHTO procedure. The only significant association found was between worsening of tibiofemoral osteoarthritis severity and the clinical/functional IKS score at last follow-up ($P < 0.05$).

4. Discussion

This retrospective study of 64 knees managed consecutively with OWHTO then re-evaluated after a mean of 7.5 years shows that filling the wedge with bone allograft and using locked plate fixation produces similar outcomes to those reported previously [2,3,11,16–28] (Table 3).

The mean follow-up of 7.5 years in our population may seem too short, given that OWHTO outcomes are known to deteriorate over time, particularly after 10 to 15 years [2]. Furthermore, the loss of HKA angle correction over time (difference between the early postoperative value and the value at last follow-up) was not assessed, a fact that limits the validity of the analysis of the correction achieved.

4.1. Clinical and radiological outcomes

Medial OWHTO is a safe technique associated with fewer complications than lateral closing-wedge HTO. In particular, the frequency of nerve injury is low (0–8.3%) [2,29–32]. The data from our case-series confirm the low adverse event rate by documenting the absence of complications having noticeable effects on the patients.

The radiological outcomes were satisfactory at last follow-up. Overall, the HKA angle was returned to the normal range (mean, 181°) and was within the predefined target of 183°± 3° in 70% of patients. This slight undercorrection is probably ascribable to loss of correction over time (about 3° over 10 years on average) [2,33,34], although we did not evaluate this point. Another hypothesis is insufficient initial correction during surgery. Given this possibility, and in agreement with the conclusions of the 2008 SOFCOT symposium [2], we now target an HKA angle of 183° to 186° in the coronal plane.

In contrast to most of the previous studies [2,4,33,35], this tendency towards undercorrection (mean HKA angle, 181°) was not correlated with OWHTO survival (95% after 7.5 years), which was similar to that reported in recent work [2,3,11,16–28]. This apparent contradiction may be ascribable in part to the short follow-up. Similarly, the HKA angle did not correlate with the IKS score, which improved by 20 points.

Tibial slope increased by 3.5° and the patellar index decreased by 0.21 in our study, in keeping with previously reported radiological changes induced by OWHTO [2,36,37,38,39,40,41]. These changes

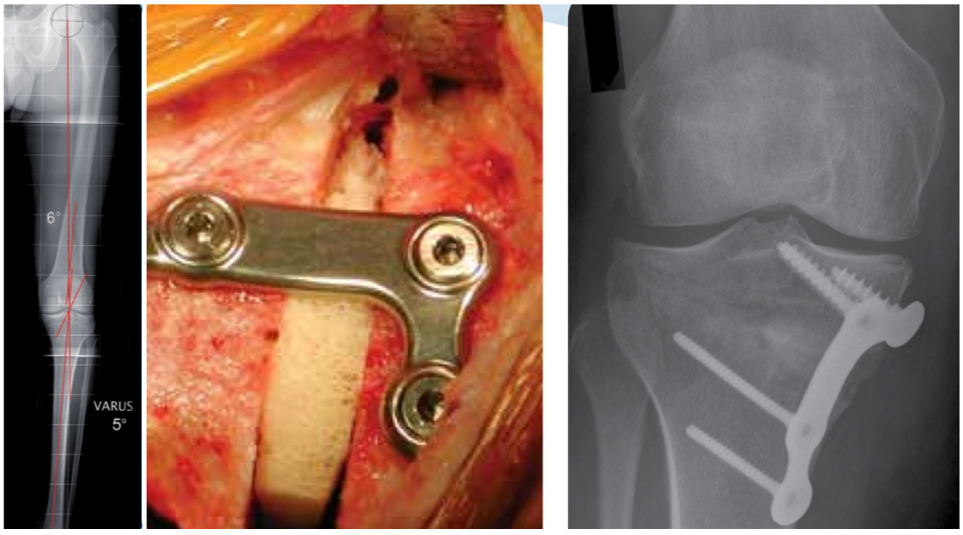

Fig. 4. Pre-operative long-leg radiograph showing 5° of varus. Intraoperative photograph of the Osteopure™ graft and locked plate fixation. Radiograph at last follow-up after 7.5 years.

Table 3
Survival rates of opening-wedge high tibial osteotomy in recent case-series studies.

Study	Year	Number of patients	Techniques	Follow-up (years)	Survival rate (%)
Dubrana et Sofcot [2]	2008	164	Opening/Subtraction	11	85
Hernigou et al. [25]	2010	53	Opening + β Tricalcium Phosphate wedges	10	88.7
DeMeo et al. [18]	2010	20	Opening	8	70
Saragaglia et al. [23]	2011	124	Opening + β Tricalcium Phosphate wedges	5	88.8
				10	74
Shallberger et al. [26]	2011	71	Opening/Subtraction	10	92
				15	71
Niinimäki et al. [27] (meta-analysis)	2012	3195	Opening/Subtraction	5	89
				10	73
Bode et al. [28]	2013	51	Opening without filling	5	96
Harris et al. [20] (meta-analysis)	2013	4557	Opening/Subtraction	5	92.4
				10	84.5
				20	72.3
Bonasia et al. [17]	2014	99	Opening	7.5	75.9
Duivenvoorden et al. [19]	2014	92	Opening/Subtraction	6	85
Our study	2015	75	Opening	7.5	95

occurred despite the special attention given to the posterior positioning of the plate and allograft.

4.2. *Wedge filling using Osteopure™ bone allograft*

Different schools of practice exist regarding the need for filling the opening wedge. Nevertheless, filling seems to improve the quality and speed of healing [11], irrespective of the type of fixation plate [42].

Several materials can be used to fill the wedge. Autografting is the reference standard [42–44] based on good healing potential and low risk of infection. However, non-negligible donor site morbidity occurs (10–25% of complications) [4–8]. Many synthetic bone substitutes are available (e.g., calcium phosphate ceramics and calcium phosphate cements) [9]. They produce good healing rates [23,42,45,46], although residual traces of substitute often persist in the long term.

Secure bone allografts combine the theoretical advantages of the various materials (no donor-site morbidity, biological safety, good-quality healing, and restoration of the normal bone stock). The evaluation of GESTO criteria in this case-series confirmed these advantages: the healing and resorption rates were similar to those seen with autografts, with no allograft-related morbidity or specific complications (in particular, no infections). These findings are in accordance with earlier reports [42–44,47–50].

Finally, the use of this high-safety bone allograft ensures the availability of a good bone stock in the event of subsequent revision surgery for TKA.

5. Conclusion

Medial OWHTO with a high-safety bone allograft and locking plate fixation is a safe and reproducible technique that produces similar outcomes to those of other procedures for managing knee osteoarthritis with varus malalignment in younger patients.

Disclosure of interest

S.B. and S.D. are members of the scientific committee of Ostéobanque d'Auvergne.

The other authors declare that they have no competing interest.

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