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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).