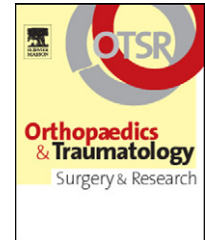




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ORIGINAL ARTICLE

Opening wedge high tibial osteotomy performed without filling the defect but with locking plate fixation (TomoFix™) and early weight-bearing: Prospective evaluation of bone union, precision and maintenance of correction in 51 cases

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KEYWORDS

High tibial osteotomy;
Medial opening;
Knee;
Knee osteoarthritis;
Bone union;
Locking plate

Summary

Introduction: A medial opening wedge high tibial osteotomy (HTO), where the osteotomy site is filled, is often preferred to a lateral closing osteotomy, but filling the defect can lead to certain complications.

Hypothesis: A medial opening HTO can be performed without filling the bone defect if fixation is carried out with a specially-designed stiff locking plate.

Patients and methods: Fifty-one patients, 37 to 72 years of age were followed prospectively and continuously from 2003 to 2006. A single surgical technique was used: medial opening HTO with locked plate fixation (TomoFix™, Synthes) but without filling the defect. The preoperative *genu varum* could not exceed 15°. The following were evaluated: time to return to weight-bearing, IKS functional score, long-leg standing film performed preoperative, postoperative and at follow-up to evaluate limb alignment and validate the precision of the correction and its stability over time. A measurement of the area of bone union in the osteotomy site was used to quantify the rate of union.

Results: Bone union occurred at 4.5 months on average; two cases of incomplete union (7%) were found and revised with an autograft at 7 and 9 months. Lower-limb alignment was 7.5°

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of varus on average before surgery (3° to 15° varus, $SD = 2.85$) and 1.2° of valgus on average after the surgery (4° varus to 5° valgus, $SD = 1.78$). The correction was maintained at 1 year post-surgery. The average IKS knee score went from 69 ± 15.5 (range 25 to 96) before surgery to 90 ± 7.4 (range 66 to 98) at follow-up ($P = 0.0001$). Full weight-bearing without assistance was possible after 3 months on average (range 1.5 to 8, $SD = 1.21$). Forty-seven patients (92%) were fully weight-bearing after 2 months. Forty-eight patients were able to return to work and sporting activities at the same or a higher level than before the procedure.

Discussion: Bone union seems to happen more slowly when the defect is filled; however, there are doubts about radiological evaluation of bone union in different published studies. When osteotomy defect was left unfilled in this study, union and filling of 4/5 of the osteotomy site was obtained in 4.2 months for 49 of the 51 cases. Fixation with the locking plate is reliable and provides stable correction and the option for early weight-bearing.

Level of proof: Level IV, prospective cohort study.

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Introduction

Surgical treatment of medial tibiofemoral osteoarthritis with opening wedge high tibial osteotomy is well-accepted [1–3]. Efficacy has been demonstrated in the short-, medium- and long term [4]. The goal of the surgery is to reduce, or even eliminate, the pain by unloading the medial compartment. Total or partial knee joint replacements are alternatives to this procedure. But an osteotomy is still indicated in young, active adults where the survival of a prosthesis could not be guaranteed.

Two osteotomy approaches are possible from a technical standpoint: lateral closing or medial opening [5]. The latter can sometimes result in the loss of correction when the fixation is light, notably when the defect is not filled with autologous bone [6–9]. Many materials are available to fill the osteotomy defect (acrylic cement, ceramic spacer, bone substitute, allograft or autograft) but each has their drawbacks: foreign body reaction, degree of resorption, degree of re-population, and donor site complications for the autograft. Although the gold standard is to use an autograft to ensure union, inert and/or resorbable materials are used more often; however, the latter requires use of stiffer fixation materials than the staples typically used with autologous bone [6–9]. Other methods where a specific osteotomy cut is made do not require the defect to be filled, but the complexity of this procedure makes them less desirable [10,11].

The availability of new internal fixation implants has made the medial opening wedge osteotomy even more reliable, to the point where some have proposed performing this procedure without filling the defect, letting the body (naturally) replace the lost bone material while a stiff material with locked screws protects the site [12]. We started using this technique in 2003, but were worried about the potential loss of correction and non-union problems inherent to this method. In this prospective study, the following hypotheses were tested: 1) leaving an opening wedge osteotomy defect unfilled but using a locking plate will not lead to delayed union; 2) this method provides a precise correction of the alignment and maintenance of the correction over time, with early full weight-bearing; 3) the defect can be completely filled in less than 2 years.

Patients and methods

Patients

This was a single-centre, continuous, prospective study of a 51-patient-cohort recruited from June 2003 to June 2005. Patients who met the following criteria were included in the study: 1) medial tibiofemoral osteoarthritis with or without associated early patellofemoral osteoarthritis (modest remodelling without joint space narrowing) with functional limitations in terms of pain and walking distance; 2) lower limb alignment with *genu varum* where the HKA angle is less than 180° on a single leg weight-bearing long-leg standing film; 3) the surgical technique used was the same – fixation with a TomoFix™ plate (High Medial Tibia, Synthes, Oberdorf, Switzerland) (Fig. 1), with the osteotomy site left unfilled. Patients were excluded if the *genu varum* was more than 15° (HKA angle under 165°), or if a surgical procedure was performed on the patellofemoral mechanism, or if a ligament repair procedure was planned for the same operative session.

There were 35 cases of primary knee osteoarthritis (OA), 13 cases of post-traumatic OA and three cases of secondary OA (two cases of osteochondritis and one case of

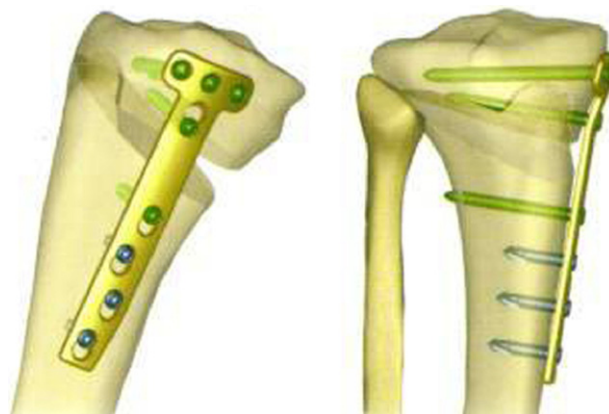


Figure 1 The TomoFix™ locking plate (Synthes, Oberdorf, Switzerland) implanted after high tibial opening wedge osteotomy with the defect left unfilled.

medial femoral condyle necrosis). In 10 of 51 cases, early patellofemoral OA was also present (without joint space narrowing).

A surgical procedure had previously been carried out on 25 of the 51 knees (49%): 21 cases of arthroscopic partial medial meniscus resection, one case of ACL ligament repair, two cases of lateral closing wedge osteotomy, and two cases of tibial tuberosity advancement. These procedures had been performed by different surgeons in our department.

Material and procedure

By allowing micromovements, the elasticity in the pure titanium TomoFix™ plate is supposed to facilitate union at the osteotomy site. The osteotomy is very well-stabilized through the use of locking screws, which act as an "internal fixator". Also, spacers place the plate 2 mm away from the bone, to preserve the periosteal vascularisation.

The procedure was performed with a tourniquet and under fluoroscopic control. The surgical technique was performed according to Staubli et al. [12]. Two small incisions were used: a medial horizontal one, 5 cm below the joint line and an opposing distal vertical incision at 1 cm from the distal part of the plate. Through the medial incision, the medial collateral ligament was removed from the posteromedial tibial cortex with a bone rasp and then a Hohmann retractor was inserted. The osteotomy was performed with an oscillating saw along a K-wire guide that is placed upward from medial to lateral and front to back from the medial tibial metaphysis curvature towards the upper tibiofibular joint. Opening was performed with a calibrated distractor according to the preoperative plan (single leg weight-bearing long-leg standing film); the target HKA angle was 183°, or 3° of valgus. Osteotomy fixation was performed using the TomoFix™ after preloading it, as indicated by its designer [12]. Fixation was ensured with three proximal locking screws and three unicortical locking screws and one bicortical screw distally. The plate was placed below the medial collateral ligament, which can be detached to get complete extension. A curette was used to disperse metaphyseal cancellous bone to both sides of the osteotomy site to facilitate union. The tourniquet was then released and superficial gauze-packing was performed for 8 minutes to allow for the formation of a blood clot at the osteotomy site. No drain was used and a light compressive bandage was placed over the osteotomy area.

Weight-bearing on the lower limb was allowed in the form of a "contact step" for the first 10 patients, then full weight-bearing for the following patients, as a function of the patient's pain.

Methods

Clinical and radiological data were collected prospectively with a computer (Sofia™ software, Pragmatik™) at the following intervals: preoperative consultation, after the surgery at 6 weeks, 3 months, 6 months, 1 year and then every year for the entire duration of the study. One of the authors (TB) analysed the radiological data at every follow-up. The clinical analysis consisted of the IKS score [13], with the knee and functional components quantified

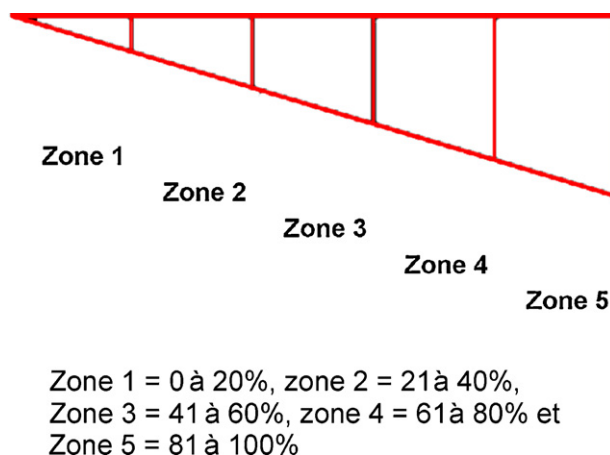


Figure 2 Osteotomy filling index with five identified zones.

during each visit. The correction of *genu varum* deformation was assessed by measuring the HKA angle on an A/P long-leg standing film with weight-bearing on the operated leg immediately after union occurred.

Bone union was assessed on A/P and lateral radiographs. Union at the osteotomy site follows the same process as normal bone healing [14,15]. Thus, on the lateral side of the osteotomy, the periosteal callus forms as a fibrous sleeve forms because the periosteum is continuous. The posterolateral callus was clearly visible on radiographs. On the medial side, healing occurs mainly through the medullary callus, due to the presence of an inter-fragment space. A radiological index to measure filling of the osteotomy was created (Fig. 2). A computerized tool was used to draw a triangle on digitized A/P radiographs, with the sides of the triangle being along the borders and corner of the osteotomy. This triangular surface was then divided into five zones of the same surface area on the pre- and postoperative radiographs (Fig. 3). These areas were numbered 1 to 5, starting from the lateral cortex. Each area corresponded to 20% of the osteotomy being filled. The



Figure 3 Application of the osteotomy filling index on a digitized radiograph.

amount of filling (disappearance then increase in density of the osteotomy) and its progression were assessed at each radiological session. The osteotomy was considered as being stable if the site was 40 to 60% filled (area 3) and if the patient no longer had pain over the tibial osteotomy site while weight-bearing on the operated leg. The tibial slope and its variations were measured according to Brazier et al. [16] and patella height and its variations were assessed with the Caton-Deschamps index [17].

The data were described using averages and standard deviations. Statistical analysis consisted of comparing averages using an Anova; continuous variables were compared using regression tests and discontinuous variables were evaluated with a Chi² test. The risk of a type I error was 5%.

Results

Postoperative complications

We observed five minor complications that did not require an additional procedure and resolved favourably: two cases of superficial haematoma, one case of superficial venous thrombosis, two cases of transient dysesthesia around the scar.

Three patients (6%) required a surgical revision: one for a deep infection, two for incomplete union.

A methicillin-resistant *Staphylococcus aureus* deep infection following a haematoma was treated with lavage and drainage for 6 weeks and appropriate antibiotic treatment for 2 months. The fixation material was removed at 6 months. The osteotomy was stable and this procedure did not result in loss of correction.

The two incomplete union cases occurred in 57- and 58-year-old women having a varus of 176° and 174° and resulting correction of 183° and 182°, respectively. In both cases, the osteotomy site did not continue to fill beyond zone 3, which was filled in the third month. Moderate pain persists beyond 6 months, which led to difficulty in returning to normal activity. A surgical revision was indicated at the 7th and 8th month after the first intervention. An autologous bone graft (iliac crest) was added, without changing the fixation. During the revision, we found that a natural, dense, bone callus had formed, without fibrosis. Good quality new bone was present but not in sufficient quantity to support the body weight. Patients were allowed immediate full weight-bearing after this revision and both patients showed bone union in less than 6 weeks with no more pain.

Clinical results

The patients were followed from February 2003 to March 2006. The average follow-up was 24 months (95% CI: 22 to 25 months). Fifty-one patients were included, 36 men and 15 women, with an average age of 53 ± 7.5 years (range 33–76). Body mass index (BMI) [18] showed that on average, both genders were overweight; 16 patients were overweight (M = 28.4, women = 29.6) and 16 were severely obese (maximum values: M = 35.6 and W = 37.2). Eighty-eight percent of patients were overweight or obese.

From the preoperative assessment to follow-up, the IKS knee score increased from 69 ± 15.5 (25 to 96) to 90 ± 7.4

(66 to 98) ($P=0.0001$) and the functional score increased 84 ± 15.5 (50 to 100) to 95 ± 8.9 (50 to 100) with 95% of patients scoring between 92 and 97 ($P=0.0001$). The average overall IKS score went from 154 ± 26.1 (104 to 196) to 185 ± 12.1 (144 to 198) ($P=0.0001$).

Weight-bearing was possible right away in 26 patients, in 3 to 5 weeks in eight patients, and in 6 weeks for 17 patients (including the first 10 patients included in the study, as a precaution taken by the surgical team).

Full weight-bearing without assistance was possible after 3 months on average. Forty-seven patients (92%) were fully weight-bearing after 2 months. Forty-eight patients were able to return to work and sporting activities at the same or a higher level than before the procedure. At the last follow-up, 33 patients (65%) were asymptomatic at the surgical site; seven were sensitive in the area over the fixation material (14%) and 11 had discomfort due to the plate (21.6%). The plate was removed in 12 of these 18 symptomatic patients, with relief achieved in 10 patients.

Radiological results

The tibial slope did not significantly change: 5.5° ± 3.37 before the surgery and 5.8° ± 2.87 after the surgery and at the (last) follow-up (NS). However, the patella was significantly lower: the Caton-Deschamps index went from 0.84 ± 0.12 before the surgery to 0.77 ± 0.12 on average ($P=0.0029$) at the last follow-up.

Before the surgery, the average varus was 172° ± 3.18 (165°–178°); after the surgery the HKA angle was 181° ± 1.18 (176°–185°) ($P=0.0001$). This correction was maintained at follow-up: the average HKA angle was 181° ± 1.60 (range 176°–185°) ($P=0.0001$). The HKA angle was between 180.69° and 181.71° in 95% of knees at follow-up (Fig. 4). There were no intraoperative lateral cortical hinge fractures.

There was a statistically significant under-correction of 1.98° between the correction planned (target correction of 183°) and correction carried out. The target correction of 183° was only achieved in five knees. Forty-two knees (82%) were under-corrected (< 3°); 25 knees were ± 1° of the target (HKA 182° to 184°). Taking into account a range between

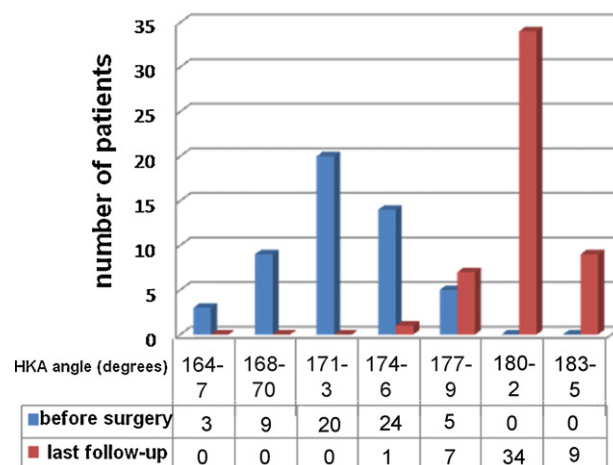


Figure 4 HKA before surgery and at the last follow-up.

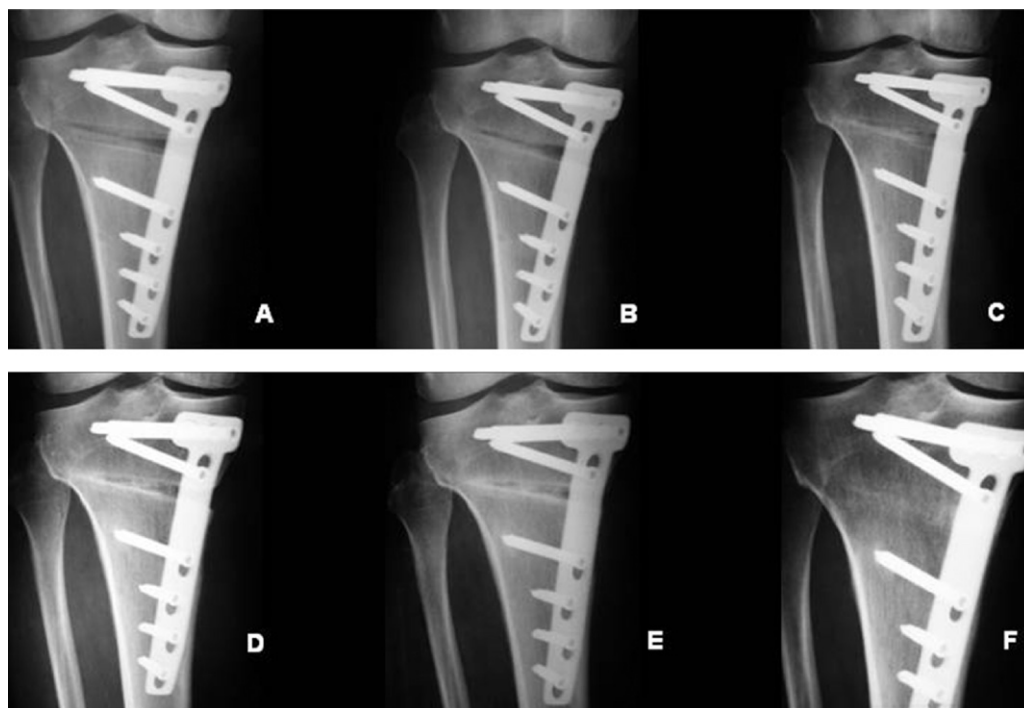


Figure 5 Radiographs showing union over time. A. Postoperative. B. Six weeks. C. Three months. D. Four months. E. Five months. F. One year.

180° and 183°, 37 knees (73%) were corrected into valgus, eight knees (15%) remained in varus and six knees (12%) were over-corrected (> 183°) without surpassing 186°. If the typical limits are considered (183° to 186°), there were nine knees within this range, but none beyond 186°.

Radiological union occurred on average after 4.5 months, with a minimum of 1.5 months and a maximum of 8. The time to union was the same for opening wedges of more than 10° (4.3 months ± 0.83) and opening wedges of 10° or less (4.7 months ± 1.5) ($P=0.2$). Union occurred between the 4th and 5th in 44 knees (86%). Two patients had incomplete union (union stopped in zone 3 with pain upon weight-bearing) and had to be operated on again (at month 7 and 8) to add bone; they are described below. There were no differences in the speed of union if patients were allowed immediate weight-bearing ($P=0.12$).

The progression in the bone callus size was linear over time for the first 4 months after the surgery. Forty-five knees were in zone 3 at the 3rd month and 40 were in zone 4 at the 4th month. At a follow-up of 2 years, 43 of 51 knees (84%) were in zone 5 and all the other knees were in zone 4 (the two patients who received a graft because of incomplete union at 7 and 8 months were at zone 4 at 2 years of follow-up) (Fig. 5).

Discussion

The series

Our study found that an opening wedge high tibial osteotomy can be performed without grafting and that early weight-bearing can occur without an elevated risk of non-union

or loss of secondary correction. The results of our series are comparable to published data in terms of functional results, since 92% of our patients were satisfied or very satisfied with the procedure. We are at the high end of good results expected in the first 5 years after a high tibial opening wedge osteotomy [4–9]. Similarly, the IKS knee functional score at follow-up (90 ± 7.4) was comparable to the series by Takeuchi et al. [19]. Pain and discomfort due to the plate was often felt by 18 patients (35%), but only 12 of them (23%) wanted the plate removed. Although it is larger, the Tomofix™ plate seems to be better tolerated than the Puddu™ plate (Arthrex) that had a 60% rate of removal because of pain or sensitivity on the medial side of the knee [20].

Angular correction

Our goal was a correction of 3° valgus to be consistent with published data [4,21,22] and a study of ranges by Thomine et al. [23]. These long-term data were validated during the 1991 SOFCOT symposium [24]. We were disappointed with the quality of the correction in this study. Based on postoperative angle measurements, nine knees were still in varus and 25 knees (49%) were within $\pm 1^\circ$ of the target. These results are probably related to insufficient precision in the instrumentation that measures the opening angle with the calibrated distractor. But this did not result in us questioning the advantages of this opening wedge osteotomy technique without grafting. Lootvoet et al. [25] also described an under-correction of 2.3°, which was greater than in our study. Our initial fixed target of 3° is also to blame; a range of 4° to 6° of angular correction could have helped to avoid this frequent under-correction. With an opening wedge

tibial osteotomy, Hernigou [4] reported that 25% of knees were outside the desired range of 3° to 6° of valgus.

Many aspects could have contributed to this correction error: 1) the radiographical analysis of *genu varum* could have been altered by a rotation of the lower limb or a flexion deformity; 2) the correction performed under the centre of the knee is typically under-estimated by 1.3° to 2.6° [2]; 3) the conversion of an angle into a distance such as the height of an osteotomy wedge is not easy to do, as shown by Hernigou et al. [26], who used a correction table to relate the angle and size of the tibial metaphysis; 4) potential rupture of the lateral cortical hinge which could result in the loss of secondary correction; 5) the saw cut line ended 5 to 10 mm from the lateral cortex to make sure not to fracture the lateral cortical hinge. The angle of the calibrated distractor was a set distance from the lateral side of the joint, which reduces the angle of the osteotomy. Other than the under-correction, the precision of the calibrated distractor was good, with a small standard deviation around the average axis (1.18°). The precision is similar to the variation reported by Saragaglia and Roberts [27] who verified 170 opening wedge tibial osteotomies by computer-assisted surgery.

Bone union

Primary bone union occurred in 49 of 51 knees (96%) in an average time of 4.5 months, similar to results reported by Brinkman et al. [28]. This time to union was longer than when a cement spacer was used medially, with a time to union of slightly more than 3 months reported [7]. Bonneville et al. [6] used a tricalcium phosphate macro-porous substitute to fill this opening; the average time to union of 3 months corresponded to the filling of the lateral metaphysis of the tibia. Koshino et al. [8] found a continuous network of bone in the osteotomy site after 4 months using porous hydroxyapatite as a filler (non-resorbable ceramic substitute) after a medial opening wedge osteotomy. Bove [29] used a porous inert alumina ceramic spacer to achieve union in an average of 3 months; a plate was used for fixation and there was no loss of correction in the 50 cases. However, a radiolucent margin was observed around this inert, non-resorbable spacer in one-quarter of the cases. Our technique without adding extraneous bone and without introducing an additional foreign body allows for union and filling of 4/5 of the osteotomy site in 96% of cases before the end of the first year.

Maintenance of correction

No loss of correction was found between the postoperative evaluation and the follow-up, even with early weight-bearing. This result follows the principles of the TomoFix™ locking screw plate, which protects the osteotomy site while allowing loading via the elasticity in the titanium [30].

Problems found and potential solutions

After this study, the average under-correction of 1.98° led us to systematically add 2° to the planned correction.

Similarly, the manufacturer modified the calibrated distractor to reduce the distance between the end of the wedge and articulation of the instrumentation from 1.0 to 0.5 cm.

The two cases of incomplete union (3.9% of patients) indicate that this technique is at the lower end for the risk of non-union after tibial osteotomy, independent of the technique used. Vainionpaa et al. [31] reported a 14% rate of non-union for infratubercle osteotomy and 3.6% for supratubercle osteotomy. These incomplete union cases were revised but we do not consider them severe failures because the addition of an iliac cortical-cancellous autograft without changing the fixation was sufficient for union to be achieved at the site in 6 weeks, without loss of correction.

Conclusion

A medial opening wedge HTO without grafting can be stabilized with a locking plate and used to treat medial tibiofemoral knee osteoarthritis in an active subject with *genu varum*. The reliability of the plate allows for a simpler postoperative recovery with early weight-bearing and primary union, which gets away from the risks related to filling the osteotomy site with bone or an inert substitute. The instrumentation to control the angle of correction must be used carefully to attain the desired angular correction. Conversely, spontaneous and total filling of the osteotomy site is usually achieved with this technique.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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