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Open-wedge high tibial osteotomy: incidence of lateral cortex fractures and influence of fixation device on osteotomy healing

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Abstract
Purpose Open-wedge high tibial osteotomy (HTO) is an established treatment for young and middle-aged patients with medial compartment knee osteoarthritis and varus malalignment. Although not intended, a lateral cortex fracture might occur during this procedure. Different fixation devices are available to repair such fractures. This study was performed to evaluate osteotomy healing after fixation with two different locking plates.
Methods Sixty-nine medial open-wedge HTO without bone grafting were followed until osteotomy healing.
Results In patients with an intact lateral hinge, no problems were noted with either locking plate. A fracture of the lateral cortex occurred in 21 patients (30.4 %). In ten patients, the fracture was not recognized during surgery but was visible on the radiographs at the 6-week follow-up. Lateral cortex fracture resulted in non-union with the need for surgical treatment in three out of eight (37.5 %) patients using the newly introduced locking plate (Position HTO Maxi Plate), while this did not occur with a well-established locking plate (TomoFix) (0 out of 13, $p = 0.023$).
Conclusion With regard to other adverse events, no differences between both implants were observed. In cases of lateral cortex fracture, fixation with a smaller locking plate resulted in a relevant number of non-unions. Therefore, it is recommended that bone grafting, another fixation system, or an additional lateral fixation should be used in cases with lateral cortex fracture.
Level of evidence III.

Keywords High tibial osteotomy · Results · Complications · TomoFix · Position HTO Maxi Plate

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Introduction

Open-wedge high tibial osteotomy (HTO) is an established treatment for young and middle-aged patients with medial compartment knee osteoarthritis (OA) and varus malalignment [4, 6, 11, 31]. HTO is a realignment procedure which redistributes the weight-bearing load from the damaged medial compartment to the relatively unaffected lateral compartment of the knee [25].

Various surgical techniques can be used for HTO. These include the medial opening wedge HTO with or without interposition of bone graft, the lateral closed wedge technique, and dome osteotomy. The medial open-wedge osteotomy is preferred by many surgeons because it avoids an osteotomy of the fibula, it avoids compromising the peroneal nerve, and it allows subtle adjustment in the sagittal and coronal plane [11, 14, 16]. Medial opening wedge HTO is used more frequently since special fixation devices have been developed for this procedure that do not need bone grafting of the osteotomy gap and the surgical technique has been improved [11, 15, 32]. The efficacy of this procedure has been shown in various studies for short-, medium- and long-term follow-up [7, 8, 11, 27].

Ideally, the osteotomy is performed incompletely, leaving the lateral cortex intact and creating a posterolateral fulcrum. However, lateral cortex fractures are reported in the literature with frequencies ranging from 0.3 to 34.0 %

[2, 12, 22, 30, 34, 36]. In these fracture cases, sufficient fixation is necessary to maintain alignment and to promote bone healing. Different implants are available for use as fixation devices after medial open-wedge HTO, including locking plates [1, 2, 30, 32]. However, there are few in vitro studies comparing different fixation devices with regard to fixation strength [1, 5, 13, 24, 28]. Axial load and displacement were measured by Agneskirchner et al. [1] who investigated four different fixation devices (short spacer plate, short spacer plate with locking bolts, long spacer plate with multi-directional locking bolts, and a long spacer plate with locking bolts). Less displacement was seen with rigid long medial tibial plate fixators with locking bolts compared to short spacer plates. In cadaveric bone exposed to axial loads, Pape et al. [24] reported a constant increase in creep failure at the opposite cortex and a constant increase in the plastic deformity after open-wedge HTO with the short spacer Puddu plate. Most of the bone constructs repaired with that fixation device failed at 1600 N. In contrast, the internal TomoFix fixator had elastic deformity until 2000 N and no failure of fixation device or construct [28]. Use of a bone graft or bone substitute has been suggested to avoid complications with plate failure in constructs repaired with short spacer plates.

The purpose of this study was to evaluate osteotomy healing after fixation with two different locking plates.

Materials and methods

Between 2003 and 2012, a total of 69 medial open-wedge HTO were performed in the authors' department. Those patients were sent a questionnaire and invited to a follow-up visit including clinical and radiographic evaluation.

The following data were recorded from the individual patient records: age, sex, date of surgery, radiographic evaluation pre- and postoperatively (osteoarthritis grade, alignment, degree of correction), results from arthroscopic cartilage evaluation, knee range of motion (ROM), evidence of lateral cortex fractures during surgery and at the 6-week follow-up, complications, and time of bone healing of the osteotomy.

Surgical technique

Arthroscopy was performed within 3 months or immediately prior to HTO to assess the lateral compartment cartilage and to evaluate and treat intra-articular lesions. Additional surgery was performed in 34 patients (49.3 %): two autologous chondrocyte implantation (MACI); 16 microfracturing; and 22 partial meniscectomies.

Leg axis correction was aimed to an overcorrection as described by Fujisawa [6]. Alignment planning was based on full-weight-bearing long-leg standing anteroposterior radiographs and accomplished using dedicated software (MediCad, Hectec, Niederviehbach, Germany). The degree and the width of the planned osteotomy gap were measured and recorded.

Using an oblique incision, a biplanar osteotomy was performed in all patients, as described by Stäubli et al. [32], aiming lateral to the upper third of the proximal tibiofibular joint. The posterior osteotomy was stopped 10.0 mm before the lateral cortex, creating a fulcrum when the osteotomy was opened. After reaching the designated osteotomy depth, chisels were inserted and the gap was slowly opened until the planned distance was reached and the leg axis correction was achieved. The opening was performed slowly to allow a plastic deformation of the lateral cortex and to prevent a fracture which would destabilize the osteotomy. Correction of the leg axis was controlled by measuring the osteotomy gap size [20] and fluoroscopy.

After achieving the preoperatively designated leg axis correction, the osteotomy was fixed with an internal plate fixator with locking screws, either the TomoFix (Synthes, Oberdorf, Switzerland) implant from April 2003 until September 2009 or the Position HTO Maxi Plate (Aesculap, Tuttlingen, Germany) from July 2009 until December 2012. In case of the TomoFix implant, the lateral hinge compression screw manoeuvre had been used: After proximal fixation of the plate, the plate was pretensioned by inserting a temporary lag screw distal to the osteotomy. The manoeuvre approximated the distal fragment to the plate and induced compression on the lateral cortical hinge [29]. The lag screw was replaced by a locking head screw at the end. No bone grafting was performed in any knee. Finally, the osteotomy and implant position were checked with fluoroscopy in both planes.

Postoperatively patients were allowed 20 kg partial weight bearing for 6 weeks and then full weight bearing. A standardized rehabilitation programme was performed. Perioperative complications occurred in one patient (infection, 1.5 %). There were no instances of nerve palsy or postoperative haematoma.

Follow-up and radiographic evaluation

Clinical and radiographic follow-up visits took place at 6 weeks, 3 month, and 1 year after surgery. Radiographs acquired intraoperatively, at hospital discharge, and at each follow-up were reviewed for lateral hinge fracture and osteotomy healing. All medical records were reviewed by one observer (JD). A non-union was defined as load-dependent pain at the osteotomy site in combination with absence of radiologic healing. Radiographic evidence of non-union was characterized by missing bony consolidation in conventional radiographs, as well as the appearance of defects

Table 1 Baseline characteristics of patients given as mean (SD; range) or absolute and relative frequencies

	TomoFix $N = 49$ (71.1 %)	Position HTO Maxi Plate $N = 20$ (28.9 %)	p value
Age at surgery (years)	44 (8.4;17.0–61.7)	44 (11.9; 18.4–60.2)	n.s.
Gender			
Male	34 (69.4 %)	17 (85.0 %)	n.s.
Female	15 (30.6 %)	3 (15.0 %)	
Side			
Right	18 (36.7 %)	11 (55.0 %)	n.s.
Left	31 (63.3 %)	9 (45.0 %)	
BMI (kg/m^2)	28.6 (5.1; 18.8–42.6)	27.6 (8.4; 21.3–34.6)	n.s.
Smoker	14 (28.6 %)	4 (20.0 %)	n.s.
Follow-up (years)	6.3 (1.8; 3.7–9.4)	2.3 (0.8; 0.9–3.4)	<0.001
Osteotomy opening (°)	9.4 (2.2; 5.8–11.8)	10.1 (2.4; 5.4–14.5)	n.s.
ASA			
1	21 (42.9 %)	7 (35.0 %)	n.s.
2	23 (46.9 %)	12 (60.0 %)	
3	5 (10.2 %)	1 (5.0 %)	
Cut–sew time (min.)	89.7 (18.8; 53.0–153.0)	81.0 (14.8; 63.0–123.0)	n.s.

and sclerosis at the bony osteotomy boundaries in a follow-up CT scan [26]. In case of delayed bone healing at the 3-month follow-up, there were additional clinical visits until osteotomy healing.

After approval of the Institutional Review Board of the medical faculty of the University of Dresden, patients' records were reviewed and medial open-wedge HTO identified.

Statistical analysis

Data description was based on means and standard deviation (SD) for continuous values and absolute and relative frequencies for categorical values. Comparisons between groups were accomplished using t tests for continuous values and Chi-square tests for categorical values. A multivariate logistic regression analysis was performed to investigate the influence of risk factors on implant survival. Significance level was set at $p < 0.05$. Sample size calculation was not performed prior to commencing data collection. All analyses have been performed with SPSS® software (release 22.0 for Windows®).

Results

A total of 69 medial open-wedge HTO were performed over a 9-year period. Forty-nine (71.1 %) patients were operated with the TomoFix system and 20 (28.9 %) with the Position HTO Maxi Plate system. The groups were comparable for demographic baseline characteristics, with the exception of significantly longer follow-up interval for the TomoFix group (Table 1).

Table 2 Comparison of adverse events between the groups

	TomoFix	Position HTO Maxi Plate	p value
Non-union needing surgical treatment	0 (0.0 %)	3 (15.0 %)	0.02
Lateral cortex fracture			
Recognized at surgery	7 (14.6 %)	4 (20.0 %)	n.s.
6-week follow-up	6 (12.5 %)	4 (20.0 %)	
Infection	1 (2.0 %)	0 (0.0 %)	n.s.
Screw loosening	2 (4.1 %)	1 (5.0 %)	n.s.

In four patients (5.8 %), symptoms persisted after union of the HTO and total knee arthroplasty (TKA) was performed between 15 and 103 months after surgery. Adverse events are presented in Table 2.

Osteotomy healing

Lateral cortex fracture was recognized during surgery in 11 patients. At the 6-week follow-up, it was diagnosed in additional ten patients (Table 2). Three of these patients went on to have non-union that needed further surgical treatment, all in the Position HTO Maxi Plate group (3/8) and none in the TomoFix group (0/13).

In multivariate logistic regression analyses, the fixation device type ($p = 0.008$) and the occurrence of a lateral cortex fracture ($p = 0.006$) were the only independent factors associated with non-union. Neither patient-specific parameters nor the correction angle had significant association. In all patients of non-union, iliac bone graft was used at reoperation, and in two patients change of the fixation device was necessary (Fig. 1).

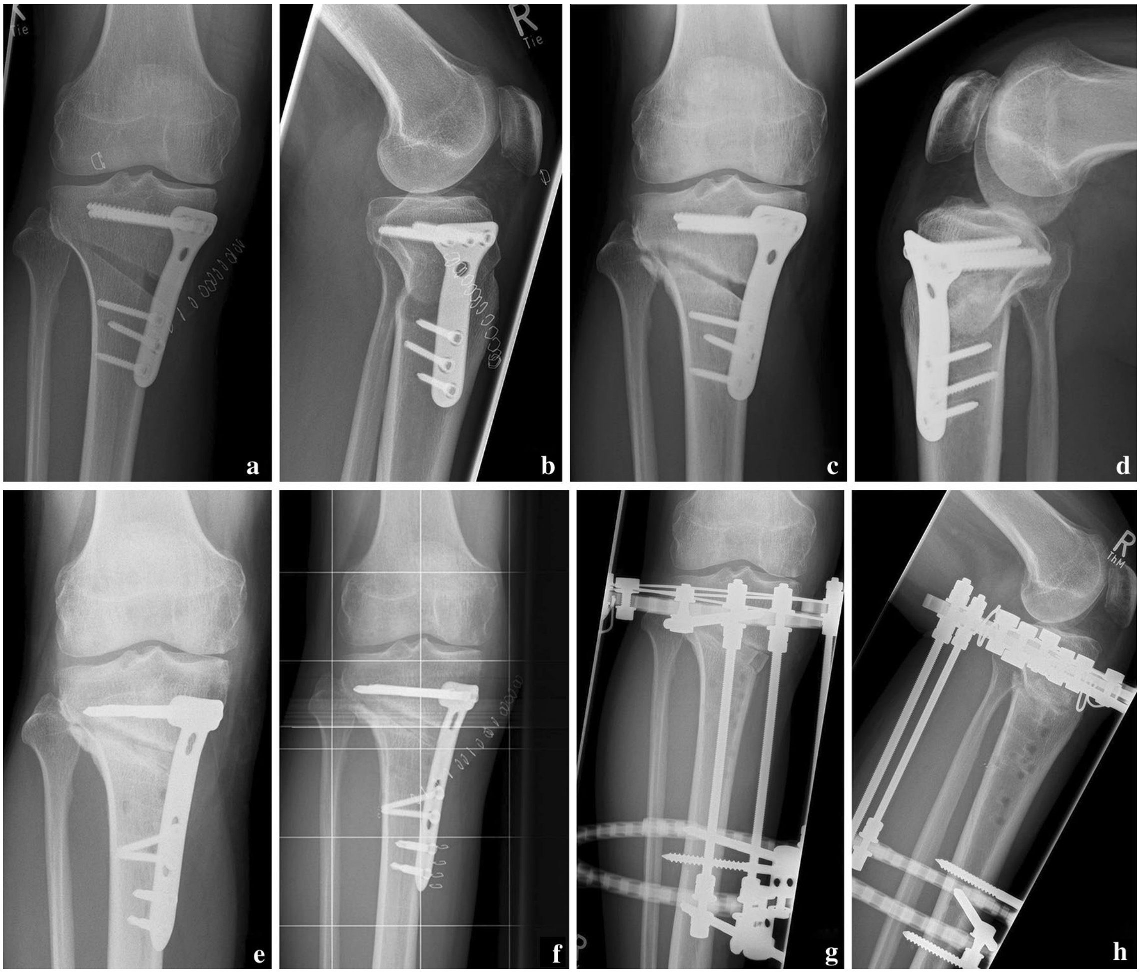

Fig. 1 51-year-old men with initially regular HTO (**a**, **b**), a secondary lateral cortex fracture and resulting non-union 6 months after surgery (**c**, **d**), iliac crest bone grafting and change of the fixation system (**e**, **f**). Another revision with external fixation after deep infection was necessary (**g**, **h**) and finally bone healing occurred

Discussion

The most important finding in the current study was that fracture of the lateral cortex occurred frequently in both groups. These fractures resulted in a non-union using a newly introduced locking plate in three out of eight patients (37.5 %), while this did not occur with a well-established locking plate (0 out of 13 patients). Fracture of the lateral cortical hinge occurred in 21 patients (30.4 %) in the entire patient cohort. Eleven (16.0 %) were recognized during HTO surgery, and an additional ten (14.4 %) were recognized at the 6-week follow-up. In previous studies, fracture of the lateral cortical hinge was reported in 0.3–34 % after open-wedge HTO [2, 12, 22, 30, 34, 36].

In most studies, only the fractures which were recognized during surgery have been reported. A description of a cortical hinge fracture after 6 weeks (postsurgical lateral cortical fracture) is rare. Jung et al. [13] reported lateral cortex fractures in 7.5 % of patients during surgery and an additional 8 % in the postsurgical interval. Schröter et al. [28] reported lateral cortex fractures in 3 % of patients during surgery and an additional 6 % at follow-up. A possible mechanism was mentioned by Schröter et al. [28] who assumed that the apex of the locking screw generates a new hinge point, with a maximum load on the apex. This may lead to a fracture of the tibia during the time of partial weight bearing.

The lateral hinge seems to be important for primary stability [17]. Fracture of the lateral cortex results in a considerable reduction in axial and rotational stiffness, as well as an increase in micromotion at the osteotomy site [18]. This may lead to a loss of angular correction, a delayed union, or even non-union of the osteotomy [19]. It has been suggested that enlarging the osteotomy gap slowly and carefully can help avoid a fracture of the lateral cortex [15, 18, 30]. The size of the osteotomy gap also has been reported to influence the incidence of lateral cortex fractures [19, 21, 30]. However, in the current study, the gap size had no influence on the occurrence of a lateral cortex fracture. This might be due to relatively small range of osteotomy gap sizes in our patients, consistent with the results of other studies [10, 21].

The stability and healing of an open-wedge osteotomy is determined by the fixation device type used for fixation. Various studies have reported the biomechanical properties of several types of HTO fixation devices [1, 5, 9, 24]. Less displacement occurs with rigid long medial tibial plates with locking bolts compared to short spacer plates [1]. van Houten [35] presented a non-union rate of 4.9 % in 206 HTO's using the TomoFix system. The only risk factor he could identify was smoking; a lateral cortical hinge fracture was not associated with a higher rate of delayed or non-union. Stoffel et al. [33] concluded that in case of a lateral hinge fracture, the TomoFix plate creates immediate stability, whereas a small spacer plate (Puddu plate, Arthrex Inc., Naples, FL, USA) requires additional lateral fixation or bone grafting of the osteotomy gap.

The Position HTO Maxi Plate has been introduced as a smaller-sized alternative to well-established system. The authors' department started using this device in 2009 and recognized three patients with non-unions which needed surgical treatment and therefore initiated this study. In patients with an intact lateral hinge, no bone healing problems occurred with either locking plate. However, in cases of lateral hinge fracture, non-union occurred in 37.5 % with the Position HTO Maxi Plate, while this did not occur with the TomoFix device. This suggests that in case of lateral cortex fracture, the Position HTO Maxi Plate does not provide sufficient stability. In case of a lateral cortex fracture, the authors suggest additional bone grafting, additional lateral fixation, or the use of a more stable fixation system.

The lag screw compression mechanism, as described by Staubli et al. [32], was used only in tandem with the TomoFix plate. The HTO Maxi Plate was used without this procedure. This difference might be another reason for the higher rate of lateral cortex fractures in the HTO Maxi Plate group. The rate of non-union in the current study was 4.4 %, which is consistent with rates of 4.9–5.4 % reported in other published studies after medial open-wedge HTO without bone grafting [17, 35]. Known risk factors for non-union after medial open-wedge HTO are obesity, smoking, and the fracture of the lateral hinge [17, 23]. In the current study, patient-specific parameters or correction angle did not significantly influence bone healing. However, one patient suffered from Takayasu disease which is a chronic inflammation of the large blood vessels that distribute blood from the heart. The blood supply in the lower extremity might have been disturbed. The treatment of Takayasu disease involves suppressing the inflammation with cortisone medication, which may have led to an unrecognized osteopenia in the proximal tibia. In the cases of lateral cortex fracture, additional bone grafting, use of another fixation system, or additional lateral fixation has been recommended. This is complicated by the fact that lateral cortex fractures are not always recognized during surgery, with only 52 % noted intraoperatively and 48 % presenting at follow-up. Further adverse events were consistent with published studies and not different between the groups. Infections after open-wedge HTO have been reported in 2.3–33.6 % [2, 3, 11, 12, 29].

This study has some limitations. Although data were recorded prospectively, it is a retrospective evaluation. The fixation devices were used consecutively, and there were more patients in the TomoFix group. Therefore, the follow-up time for this group is longer and the conversion rate to TKA higher. The number of the patients in the HTO Maxi Plate group was only 20 because the authors stopped using this system after identifying three non-unions. Lateral cortex fractures were more frequent in the HTO Maxi Plate group than in the peer group, which might be an additional reason for the findings of the study. However, the groups were not different for baseline characteristics and known risk factors for delayed bone healing.

Conclusion

This study demonstrated that lateral cortex fracture is frequent in medial opening wedge HTO, and a considerable number are not recognized during surgery. In such cases, fixation with a HTO Maxi Plate resulted in a relevant number of non-unions. Therefore, it is recommended that bone grafting, use of another fixation system, or an additional lateral fixation should be used in cases with lateral cortex fracture.

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