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CLINICAL RESEARCH

Medial Open Wedge High Tibial Osteotomy: Can Delayed or Nonunion Be Predicted?

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Abstract

Background The opening wedge approach to high tibial osteotomy (HTO) is perceived to have some advantages relative to the closing wedge approach but it may be associated with delayed and nonunions. Because nonunions evolve over months, it would be advantageous to be able to identify risk factors for and early predictors of nonunion after medial opening wedge HTO.

Questions/purposes We sought to determine whether (1) preoperatively identifiable patient factors, including tobacco use, body mass index > 30 kg/m^2, and degree of correction, are associated with nonunion, and (2) a modified Radiographic Union Score for Tibial Fractures (RUST) score, taken at 6 weeks and 3 months, would be predictive for delayed or nonunion after medial opening wedge HTO.

Methods The medical records and radiographs of 185 patients, 21 bilateral cases, treated with a medial open wedge HTO using the TomoFix® device were retrospectively evaluated. For all patients, demographic data regarding risk factors were collected from their records. Diagnosis for delayed or nonunion was already done earlier for standard medical care by the orthopaedic surgeon based on clinical and radiographic grounds. For the retrospective radiographic evaluation, a modified RUST score was used in which each tibial cortex is scored by one observer. Logistic regression analysis was used to identify preoperative and postoperative predictive factors for developing delayed or nonunion. In the series, a total of 19 patients (9.2%) developed clinically delayed/nonunion of whom 10 patients (4.9%) developed a nonunion.

Results Smoking was identified as a risk factor for developing delayed/nonunion (19% for smokers versus 5.4% for nonsmokers; p = 0.005; odds ratio, 4.1; 95% confidence interval, 1.5–10.7). By contrast, body mass index, lateral cortical hinge fracture, age, infection, and degree of correction were not risk factors. Patients with

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Each author certifies that his or her institution approved or waived approval for the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.
All research in terms of data collection and analysis was performed at the Sint Maartenskliniek, Nijmegen, The Netherlands.

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delayed/nonunion had lower RUST scores at all time points when a radiograph was taken compared with the total study group.

Conclusions The RUST score at 6 weeks and 3 months after surgery and the use of tobacco were identified as predictive factors for development of delayed union and nonunion after open wedge HTO. Based on these results, we now actively try to stop patients from smoking and these data are helpful in doing that. The RUST score may be of use to identify which patients are at risk for developing a delayed union so that interventions may be offered earlier in the course of care.

Level of Evidence Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

The opening wedge approach to high tibial osteotomy (HTO) is perceived to have some advantages relative to the closing-wedge approach but it may be associated with delayed and nonunions. Earlier studies pointed to a concern about the risk of nonunion with this approach [20, 23], whereas some more recent work has suggested that the risk of nonunion for opening wedge HTO is not higher than that for the closed wedge technique [3, 6, 10].

Factors that can lead to problems in bone healing are loss of correction resulting from hardware failure [4, 16, 20] and lateral cortical hinge fracture [1, 19, 22]. In the past decade, new angle-stable fixation implants have made the medial open wedge HTO technique more popular as a result of the higher loading capacity and the high residual stability after failure of the lateral cortex [1]. Clinical results for the angle-stable implants have shown lower rates for loss of correction [8, 16, 17]. Besides mechanical factors, patient-related factors are of influence. Patient-related factors that could lead to nonunion are smoking, obesity, infection, advanced age, diabetes mellitus, and use of NSAIDs and/or corticosteroids [5, 10, 15]. Because nonunions evolve over months, it would be important to identify patients who are at risk for nonunion after HTO and perhaps even to identify patients before surgery whose risk is so severe that they should not undergo HTO.

We therefore sought to determine whether (1) preoperatively identifiable patient factors, including tobacco use, body mass index > 30 kg/m^2, and degree of correction, are associated with nonunion after medial opening wedge HTO; and (2) a modified Radiographic Union Score for Tibial Fractures (RUST) score, taken at 6 weeks and 3 months, would be predictive of the absence of union after medial opening wedge HTO.

Patients and Methods

Patients

We retrospectively reviewed a total of 206 medial open wedge HTOs in 185 patients (21 bilateral procedures) that were performed by different surgeons between January 2007 and December 2009. These patients were the ones whose charts and records offered sufficient followup on which to perform our analyses; these represented 100% of the HTOs performed during the period in question (we performed 206 HTOs between January 2007 and December 2009). Data collection was performed in 2012 and therefore surgery was at least 2 years before data collection. The study population consisted of 138 men and 47 women; mean age was 48 ± 9.7 years (range, 19–69 years) at the time of surgery; there were 115 left knees and 95 right knees. The average body mass index (BMI) was 28 ± 4 kg/m^2 (range, 18–43 kg/m^2).

Indications for open wedge HTO were varus malalignment with symptomatic osteoarthritic changes in the medial compartment (n = 183), congenital tibia vara (n = 12), and posttraumatic genu varum (n = 5). Four patients had in addition ligamentous instability with a varus thrust. One patient had osteonecrosis of the medial femoral condyle, and one patient had osteochondritis dissecans of the medial femoral condyle. At the time of this study, no closing wedge osteotomies were performed in our clinic.

Standard planning techniques for open wedge HTO included standing whole-leg radiographs to determine the amount of correction [11]. In most knees, the aim was overcorrection to achieve a mechanical axis of 3° valgus. In knees in which no overcorrection was intended, a mechanical axis of 0° was the aim.

Surgery

In all open wedge HTOs, medial plate fixation (TomoFix®; Synthes, Umkirch, Germany; FDA-approved) was used to stabilize the osteotomy. The surgical technique has previously been described by Staubli et al. [17]. In 80 cases, a modification of the biplanar osteotomy using a distal tuberosity osteotomy was performed to prevent lowering of the patella [7].

In 188 of the 206 procedures, no graft was used to fill the gap, whereas in 18 procedures, a graft, ie, autologous iliac crest, allograft, or tricalcium phosphate-ChronOS™ Beta-Tricalcium Phosphate (Synthes GmbH, Oberdorf, Switzerland), was used to fill the osteotomy gap; filling was mainly used when large corrections were required, as an earlier study of ours has suggested was reasonable [2]. In addition, in eight knees, a concurrent operative procedure was performed: an anterior cruciate ligament (ACL)

reconstruction in four knees, a tuberosity medialization in three knees (two patients) for symptomatic patellar instability, and a concomitant iliotibial band reconstruction in one patient. All patients received a single-dose antibiotic preoperatively and standard thromboembolic prophylaxis for 6 weeks.

Rehabilitation and Radiological Followup

Patients were mobilized on the first postoperative day. There was a 10- to 15-kg weightbearing protocol for the first 6 weeks; thereafter, full weightbearing was allowed [2, 9]. Patients who had concurrent ACL reconstruction received additional rehabilitation training. Each patient had clinical and conventional radiography performed directly postoperatively, before full weightbearing 6 weeks after the operation, and in most cases 3 months after the operation. On indication, a postoperative radiographic investigation at 6, 9, or 12 months was performed.

Primary Study Outcome: Delayed Union and Nonunion

The clinical characteristics of delayed and nonunion were defined as load-dependent pain at the osteotomy site and pain at the osteotomy site on physical examination in combination with absence of radiologic evidence of progressive bony healing. Delayed union was declared predominantly 6 months after surgery by the surgeon. When a surgeon defined it as a nonunion, it was, except for one case, at least 1 year after surgery. If a surgeon defined it as nonunion, it was based on lack of progression on open wedge bone healing on standard AP and lateral radiographs. No specific radiographic scores to determine delayed or nonunion were used by the surgeons. The medical charts were reviewed by one observer (AHvH).

Using Radiographs to Predict Delayed Union and Nonunion: The RUST Score

Cortical continuity is the best single predictor of bone healing on an radiograph [13]. To measure consolidation, a radiographic union scale based on the RUST score developed by Whelan et al. was used [24]. The RUST assigns a score to each tibial cortex: 1 point if a fracture line and no callus is visible; 2 points if a fracture line is visible and callus is visible; and 3 points if bridging callus and no evidence of a fracture line is visible. The scores for all cortices are summed for the total score. The minimum score of 4 indicates that the fracture is definitely not healed; the maximum score of 12 indicates that the fracture has healed. Because scoring the anterior cortex on the lateral radiograph is difficult for open wedge HTOs as a result of the fixation device's location, we altered the RUST by scoring the lateral and medial cortex on an AP radiograph and the posterior cortex on a lateral radiograph. The minimum score became 3 and the maximum 9 (Fig. 1A–D).

All available radiographs for each patient were retrospectively scored with the modified RUST by one independent author (AHvH). The RUST scores at 6 weeks and 3 months were used in comparison with the clinically ascertained delayed or nonunion to determine whether these early RUST scores could be useful to predict healing of the osteotomy.

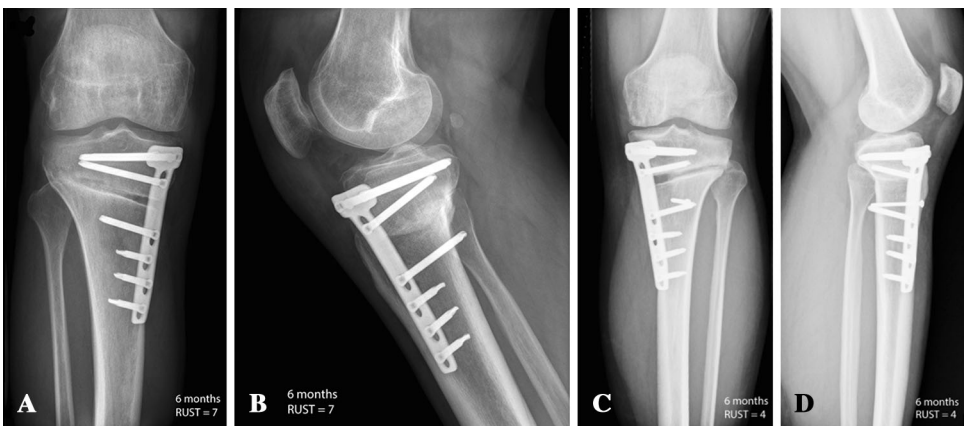

Fig. 1A–D (**A**) Normal union on AP radiograph 6 months postoperatively scored according to the modified RUST score. (**B**) Normal union on lateral radiograph 6 months postoperatively scored according to the modified RUST score. (**C**) Delayed/nonunion on AP radiograph 6 months postoperatively scored according to the modified RUST score. (**D**) Delayed/nonunion on a lateral radiograph 6 months postoperatively scored according to the modified RUST score.

Using Clinical Variables to Predict Delayed Union and Nonunion

The patients' medical reports and operative reports were collected and reviewed by one author (AHvH)

Potential risk factors gathered by chart and radiographic review included preoperative varus, degree of correction, patient's height, weight, age, concomitant diseases, tobacco use, corticosteroid use, and lateral cortical (hinge) fracture. Lateral cortex fracture was defined as less than 2 mm or greater than 2 mm [22].

Frequency of Radiographic Union in the Study Population

A total of 19 (9.2%) of 206 HTOs developed delayed union (nine patients [4.4%]) or nonunion (10 patients [4.9%]; Table 1). In the nine patients with delayed union, the clinical criteria for nonunion eventually diminished without surgical intervention. One patient after a deep infection developed nonunion; another who had intraoperative unstable osteosynthesis also developed nonunion.

Statistical Analysis

All potential risk factors and radiological scores were compared between these groups using crosstabulations with chi-square tests or independent t-tests. To identify predictive factors for delayed or nonunion, two logistic regression analyses were performed with delayed or nonunion as the dependent factor. The independent factors in the first model were all identified preoperative risk factors; in the second model, the postoperative RUST scores at 6 weeks and 3 months were used. Only factors with a Wald statistic < 0.05 were included in the model. An α level of 0.05 was considered statistically significant. The statistical analyses were performed using STATA 10.1 (STATA Corp, College Station, TX, USA).

Table 1. Demographic data and surgical factors for all patients undergoing open wedge high tibial osteotomy

Parameter	Total
Number of procedures	206
Number of patients (bilateral procedure)	185 (21 bilateral)
Male/female	138 male, 47 female
Left/right	115 left, 91 right
Age (years), mean (SD); range	48 (± 9.7); 19–69
Body mass index (kg/m^2), mean (SD); range	28 (± 4.1); 18–42
Preoperative varus (degrees), mean (SD); range	5.7 (± 3.1); −1 to 16
Correction (degrees), mean (SD); range	8.8 (± 3.1); 4–18
Number of lateral cortex (hinge) fractures < 2 mm	45
Number of lateral cortex (hinge) fractures > 2 mm	12

Results

Clinical Variables and the Likelihood of Delayed or Nonunion

Smokers were more likely to develop nonunion than were nonsmokers (Table 2). In the logistic regression model, smoking was the only significant predictive factor ($p = 0.005$); the odds of a smoker developing delayed or nonunion is four times higher than the odds of a nonsmoker (odds ratio, 4.1; 95% confidence interval [CI], 1.5–10.7). The estimated risk for developing a delayed/nonunion in our population was 5.4% for nonsmokers and 19.0% for smokers. By contrast, BMI was not a risk factor for delayed/nonunion in this study. Forty-five cases in the total study population had a lateral cortical hinge fracture < 2 mm. A lateral cortical hinge fracture of more than 2 mm was observed in 12 cases. The size of the lateral cortical hinge fracture did not lead to a higher incidence of delayed

Table 2. Demographic data and surgical factors in patients with a delayed or nonunion compared with patients with normal healing

Risk factor	Delayed or nonunion (n = 19)	Normal healing (n = 186)	p value
Smokers	11/19	47/185 (1 missing)	0.003
Body mass index > 30 kg/m^2	6/18 (1 missing)	47/183 (3 missing)	0.48
Degree of correction ≥ 10°	7	73	0.84
Auto/allograft/TCP	3	15	0.25
Lateral cortex (hinge) fracture < 2 mm	4	41	0.66*
Lateral cortex (hinge) fracture >2 mm	2	10	0.66*
Age > 60 years	2	16	0.78
Infection (deep)	1/18 (1 missing)	3/183 (3 missing)	0.52*
Infection (superficial)	1/18(1 missing)	10/183 (3 missing)	0.52*
Body mass index > 30 kg/m^2 combined with contralateral hinge fracture > 2 mm	3/18 (1 missing)	14/183 (3 missing)	0.19

* Tested in 3 × 2 table. One patient had too much missing data and was partly eligible for analysis; TCP = tricalcium phosphate.

union or nonunion. The amount of preoperative varus as measured on plain radiographs was not associated with delayed union or nonunion.

RUST Score and the Likelihood of Delayed Union or Nonunion

The modified RUST score at 6 weeks and 3 months was a strong predictor for delayed or nonunion ($p < 0.0001$ for the model and $p = 0.019$ and $p = 0.011$ for RUST score at 6 weeks and 3 months, respectively). For each 1-point increase on the modified RUST score at 6 weeks, there was a decrease in the odds for nonunion of 0.19 (95% CI, 0.045–0.76). At 3 months, each point higher was associated with a decrease in the odds of 0.20 (95% CI, 0.056–0.68; Table 3). At all postoperative periods, the modified RUST score appeared to be significantly lower for the delayed and nonunion group (all p values < 0.001; Fig. 2).

Discussion

The opening wedge technique for HTO is perceived to have some advantages relative to the closing wedge technique but it may be associated with a higher risk of delayed or nonunions. There are only few studies that evaluated the risk factors associated with delayed and nonunion in a large population of patients undergoing opening wedge HTO. Because nonunions evolve over months, it would be advantageous to be able to identify risk factors and early predictors for nonunion after medial opening wedge HTO. We found that smoking was an important risk factor for predicting delayed and nonunion, whereas degree of correction, BMI > 30 kg/m^2, and the presence of a lateral cortex hinge fracture were not. We also found that the modified RUST score at 6 weeks and 3 months after surgery was a good predictor of delayed union and nonunion.

This study had several limitations. Because of the retrospective character of this study, it is possible that patients who developed a nonunion sought treatment at another clinic. This could potentially lead to a higher rate of nonunion than reported. There was a minimum of 2 years between data collection and surgery; we think this should be sufficient to detect all nonunions, and insofar as the major purposes of our study were not to document the frequency of nonunion but rather risk factors for it, this would not be expected to influence this to a severe degree. Additionally, patients who did well clinically at the 3-month postoperative control were discharged from further followup. As a consequence, we had fewer radiographs in the group with normal consolidation. Theoretically, when a patient has no symptoms and on the radiograph the open wedge HTO appears to have consolidated, the RUST score would only increase. Therefore, the RUST score for the normal consolidation group could have been underestimated, resulting in an even greater difference between the groups. Finally, because this was a retrospective study, not all factors could be consistently identified in medical records, and so certain factors such as use of NSAIDs were not considered.

In terms of clinical risk factors for nonunion, we found that smoking tobacco was the only significant predictor, a finding that others also have identified [10, 12]. Some authors therefore do not advocate this surgical procedure in patients who use tobacco [8, 17]. The results of the present study support this and suggest a 13.6% lower risk (19% for smokers, 5.4% for nonsmokers) for developing delayed/nonunion when a patient stops smoking. Meidinger et al. [10] found a strong correlation between use of tobacco and fracture of the lateral cortical hinge and the occurrence of nonunion. By contrast, we found that the presence of a lateral cortical hinge fracture was not a risk factor for

Table 3. The risk of delayed or nonunion in relation to three possible scenarios

Patient	RUST (6 weeks)	RUST (3 months)	Risk of delayed or nonunion
A	3	4	40%
B	4	5	2.3%
C	5	6	0.087%

RUST = Radiographic Union Score for Tibial Fractures.

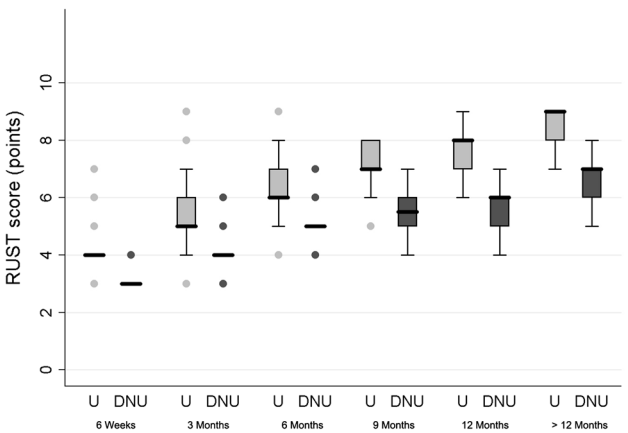

Fig. 2 Median RUST score for delayed or nonunion (DNU) and normal union (U) groups at all followup times. The lower median RUST score for the delayed or nonunion group was statistically significantly at all followup times. 6 weeks: N = 18 versus 150; 3 months: N = 15 versus 130; 6 months: N = 16 versus 92; 12 months: N = 12 versus 41; 24 months: N = 13 versus 50. The box shows the interquartile range (25–75) with median highlighted. Length of whiskers is at 1.5* interquartile range; outside values are represented by dots.

developing nonunion. Previous work reported that an intact lateral cortical hinge is important to provide stability and to prevent lateral displacement [22]. Furthermore, it has been suggested that instability resulting from a fracture of the lateral cortical hinge could lead to nonunion. Mechanical studies have shown that when the lateral tibial cortex is fractured, angle-stable implants provide superior stability compared with nonangle-stable implants, eg, the Puddu plate [1, 14, 19]. The present study shows that for open wedge HTO fixed using an angle-stable implant, fracture of the lateral cortical hinge is not a risk factor for developing nonunion. Therefore, based on our results, additional stabilization or bone grafting in case of a lateral cortical hinge fracture does not seem necessary. Surprisingly, the combination of a BMI > 30 kg/m^2 and disruption of the lateral cortical hinge > 2 mm was not a risk factor for delayed or nonunion. Previously, others have suggested using additional iliac crest bone grafting in these patients, whom they considered high risk [10]. Based on our results, we do not believe this is necessary.

We also found that patients who scored lower on a modified RUST score at 6 weeks and 3 months were more likely to develop delayed union or nonunion. Based on this finding, particularly where higher-risk patients are concerned (smokers, and perhaps patients with symptoms such as load-dependent pain and pain at the osteotomy site), a surgeon might decide to reoperate earlier. Although we did not validate the modified RUST score for open wedge HTO, this scoring instrument showed good interobserver and intraobserver variability for evaluating union in tibial fractures [24]. Previously, different radiographic evaluation systems for open wedge HTO have been developed [3, 18, 21]. These scores were either complex or could only be used in open wedge HTO with tricalcium phosphate [3, 18, 21]. A clear advantage of the modified RUST score compared with the previously discussed scoring systems is the scoring of each cortex on AP and lateral radiographs instead of only the AP radiographs. Besides, the scoring system can also be used in open wedge HTO with or without using a graft in the osteotomy.

In conclusion, we found that the use of tobacco was a major risk factor for development of nonunion in patients undergoing opening wedge HTO (odds ratio, 4.1; 95% CI, 1.5–10.7). We also found that the modified RUST score can help identify patients at high risk of developing delayed or nonunion. Based on these results, we now insist patients to stop smoking before we perform an open wedge HTO. We now routinely use the modified RUST to analyze patients with clinical and radiographic bone healing problems. Finally, we intervene early with bone grafting to promote bone healing in patients with load-dependent pain and a RUST score of 3 at 3 months after surgery.

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