Joint Diseases and Related Surgery

Jt Dis Relat Surg
2024;35(3):546-553

ORIGINAL ARTICLE

Risk factors for delayed bone union in opening wedge high tibial osteotomy

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ABSTRACT

Objectives: The purpose of this study was to investigate the relationship between patient demographics and potential intraoperative factors and delayed bone union in opening wedge high tibial osteotomy (OWHTO).

Patients and methods: A retrospective review of 65 patients (37 females, 28 males; mean age: 60.1±10.1 years; range, 44 to 77 years) who underwent OWHTO using an angle-stable implant with beta-tricalcium phosphate gap filling between September 2016 and October 2019 was conducted. The osteotomy site was divided into five zones from the lateral hinge on anteroposterior radiographs, and we defined the zone in which bone healing was observed. The bone union area was assessed according to this definition at three, six, nine, and 12 months after surgery, and bone union was defined as union at the fourth zone or greater. A generalized estimating equations approach was employed to investigate longitudinal data pertaining to bone union area as a dependent variable. In addition, the association of bone union at six months postoperatively and predictors were evaluated using cross-sectional statistical methods. The categorical predictors included in the models were smoking, diabetes, hinge fracture, and autologous osteophyte grafting. The continuous variables included in the models were age, body mass index, opening gap width, and plate position.

Results: Smoking (odds ratio [OR]=0.478, $p<0.01$), large opening gap width (OR=0.941, $p=0.014$), and anterior plate placement (OR=0.971, $p<0.01$) were significantly associated with decreased bone union area. Union rate at six months in smokers was significantly lower compared to nonsmokers (16.6% and 67.8%, respectively; OR=0.10, $p=0.023$). Area under the curve in the receiver operating characteristic analysis for bone union at six months was 0.60 for gap width and 0.63 for plate placement.

Conclusion: Smoking, large opening gap width, and anterior plate placement are risk factors for delayed bone union after OWHTO. Surgeons should avoid anterior placement of the plate and carefully consider other options for smokers and those who require a large correction.

Keywords: Bone union, opening wedge high tibial osteotomy, plate position, risk factors.

Opening wedge high tibial osteotomy (OWHTO) has been favored for patients with medial compartment osteoarthritis and a varus deformity leg. However, severe complications following OWHTO, including delayed union and nonunion, have been reported.[1-3] Delayed union was defined as the absence of radiographic evidence of bone healing or a combination of osteotomy site pain and radiographic findings at three to six months postoperatively in previous studies.[4,5] Delayed union relates to persistent osteotomy site pain with failure to achieve clinical recovery. Importantly, the rate of delayed union is reported to range from 0 to 12%.[1,6]

Smoking, obesity, large opening gaps, and unstable hinge fractures have been reported as risk factors for delayed union and nonunion after

Received: January 23, 2024
Accepted: June 24, 2024
Published online: August 14, 2024

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Doi: 10.52312/jdrs.2024.1636

Citation: Araya N, Koga H, Nakagawa Y, Shioda M, Ozeki N, Kohno Y, et al. Risk factors for delayed bone union in opening wedge high tibial osteotomy. Jt Dis Relat Surg 2024;35(3):546-553. doi: 10.52312/jdrs.2024.1636.

OWHTO.[4,5,7-10] To the best of our knowledge, few studies have focused on the effect of plate position on delayed union in OWHTO. Biomechanical tests and a numerical model based on the finite element method have demonstrated that plate location affects the resistance to applied mechanical loads, potentially leading to nonunion.[11-13] However, the relationship between plate position and delayed union remains to be elucidated in clinical settings. A factor hindering this elucidation has been that the number of events in delayed union subgroups in previous studies is too low to enable confident multivariate analysis.[1] For this and other reasons, ongoing debates persist regarding the factors leading to delayed union.

The purpose of this study was to use generalized estimating equations (GEEs), incorporating data from all time points, and examine a range of patient characteristics and intraoperative factors previously proposed as risk factors for delayed bone union in OWHTO. The underlying hypothesis for this study was that smoking, large opening gap width, and a more anterior plate placement would be detected as risk factors for delayed bone union after OWHTO.

PATIENTS AND METHODS

Eighty-three patients who underwent primary OWHTO performed at the Department of Orthopaedic Surgery, Tokyo Medical and Dental University Hospital between September 2016 and October 2019 were retrospectively reviewed. Study exclusion criteria were as follows: *(i)* patients with early plate removal prior to 12 months; *(ii)* patients who were lost to follow-up prior to one year; *(iii)* lack of radiographic data at measurement points (3, 6, 9, and 12 months). After excluding 18 knee joints from a total of 83 based on the exclusion criteria,

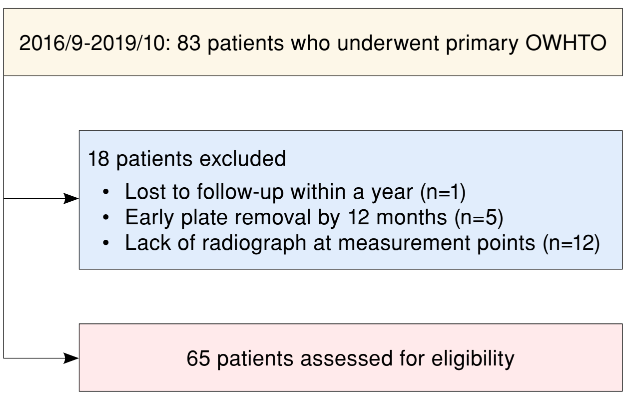

FIGURE 1. Flowchart of patients' selection.
OWHTO: Opening wedge high tibial osteotomy.

65 knee joints (37 females, 28 males; mean age: 60.1±10.1 years; range, 44 to 77 years) were eligible for inclusion (Figure 1). Demographic data, including age, sex, height, weight, and body mass index (BMI), were recorded preoperatively.

All surgeries were performed by or under the supervision of two senior surgeons. A standard arthroscopic evaluation was performed before OWHTO. Any unstable meniscal tears were repaired using the "all-inside" or the "inside-out" suture techniques if possible[14,15] or were resected. The OWHTO procedure followed the method proposed by Staubli et al.[16] In brief, the preoperative plan involved shifting the mechanical axis to a point 57% lateral on the transverse diameter of the tibial plateau. The correction angle and opening width were then measured, and the osteotomy site was opened to the preoperatively planned width while limb alignment was simultaneously monitored using fluoroscopy to determine the position of the alignment rod at the knee. A beta-tricalcium phosphate wedge (Osferion 60; Olympus Terumo Biomaterials, Tokyo, Japan) was inserted into the opened osteotomy site. The osteotomy site was fixed with a tris medial high tibial osteotomy plate system (Olympus Terumo Biomaterials, Tokyo, Japan) placed on the medial side of the tibia under fluoroscopic control and fastened with locking screws.

Postoperative rehabilitation began with range of motion and quadriceps setting exercises one day after surgery. One-third, two-thirds, and full weight-bearing with crutches were initiated three, 10, and 14 days after surgery, respectively. Patients were allowed to commence running exercises at three months if bone union was considered sufficient. Patients progressed to full activity six months postoperatively.

The bone union area in the osteotomy site was assessed on postoperative anteroposterior radiographs at 3, 6, 9, and 12 months by a physician who had not performed any surgeries in this series. A triangle was drawn with the sides of the triangle converging from the opening at the medial tibial cortex along the borders of the osteotomy to form an apex at the lateral cortex. The triangular area was then divided into five numbered zones starting from the lateral cortex utilizing Brosset et al.'s[17] osteotomy filling index (Figure 2). The bone remodeling phase was determined using van Hemert et al.'s[18] criteria, the most medial zone showing the consolidation phase was recorded, and bone union was defined as consolidation at fourth zone or greater.[19]

The plate position was evaluated on postoperative radiographs as shown in Figure 3. From all postoperative lateral radiographs available for each patient, the truest possible lateral radiographs were chosen, based on alignment of the visible posterior outlines of the femoral condyles. The maximum anteroposterior diameter of the proximal tibial bone (referred to as value A) and the distance from the insertion site of the proximal posterior screw to the tibial posterior margin (referred to as value B) were measured along a line perpendicular to the tibial axis. The plate position was calculated as value B divided by value A such that values closer to one indicate more anterior placement. Intra- and interobserver reliability for plate position measurements were assessed using intraclass correlation coefficients. For intraobserver reliability, an interval of >4 weeks was maintained between the first and second assessments, and the observer was blinded to previous results. Once intraobserver reliability had been calculated, interobserver reliability was checked by having another observer additionally assess the plate position for randomly selected patients using the same lateral radiographs previously used to assess each patient.

Statistical analysis

Statistical analyses were performed using IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Data were expressed as mean ± standard deviation or frequency and percentage. Generalized estimating equations with a ranking data logistic and type 3 Wald statistical tests were employed to investigate longitudinal data related to bone union area at 3, 6, 9, and 12 months after surgery as a dependent variable. The odds ratio (OR) in GEEs indicated the predicted change in odds for a unit increase in the predictor. When the OR was <1, increasing values of the variable correspond to decreasing odds of the progression of bone union area. The association of bone union (union area achieved in zones 4 or 5) at six months postoperatively and the risk factors identified by GEEs were evaluated using the chi-square test for categorical variables and a receiver operating characteristic (ROC) curve analysis for continuous variables. Categorical predictors that were included in the models were smoking, diabetes, hinge fracture, and autologous osteophyte grafting. The continuous variables included in the

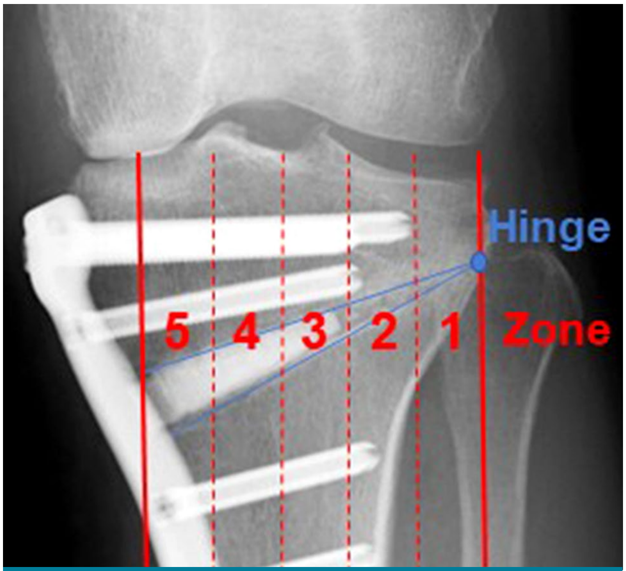

FIGURE 2. Application of the Brosset's osteotomy filling index on a digitized radiograph. The osteotomy site of anteroposterior radiographs was divided into five zones using a radiological index.

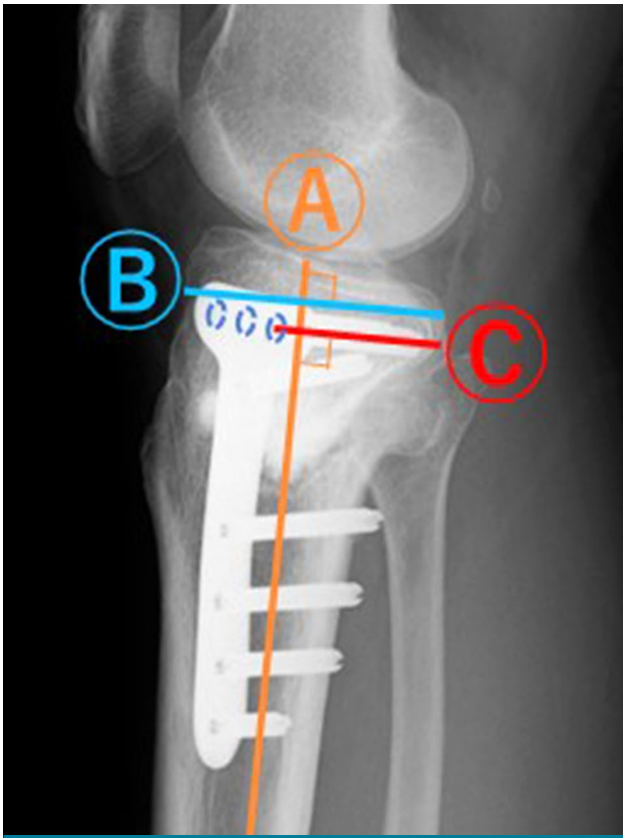

FIGURE 3. Application of the plate anterior- posterior position calculation on a digitized radiograph. (Line A) Tibial axis. (Line B) The maximum anterior-posterior diameter of the proximal tibial bone on the perpendicular line to the reference line. (Line C) The distance from insertion site of proximal posterior screw to tibial posterior margin on the perpendicular line to the reference line.

TABLE I Participant characteristics (n=65)				
	n	%	Mean±SD	Range
Age (year)			60.1±10.1	
Sex				
Male	28	43		
Female	37	57		
Body mass index (kg/m^2)			24.3±3.2	
Smoker	6	9		
Diabetes		5		
Autograft osteophyte grafting	27	42		
Opening gap width (mm)			10.2±2.6	5.5-15.5
Plate position			0.68±0.11	0.41-0.94
Hinge fracture	6	9		

SD: Standard deviation.

models were age, BMI, opening gap width, and plate position. Repeated measures ANOVA (analysis of variance) with Greenhouse-Geisser and Tukey's post hoc correction were employed to analyze differences in bone union area between time points. A p-values <0.05 was considered statistically significant.

RESULTS

Patient characteristics are shown in Table I. No patients suffered nonunion requiring reoperation. All cases of hinge fracture were type 1 according to the Takeuchi classification.[20] Repeated measures ANOVA determined that the bone union area significantly differed between time points (F (2.42, 155)=345, p<0.05). The radiological bone union area increased in a time-dependent manner

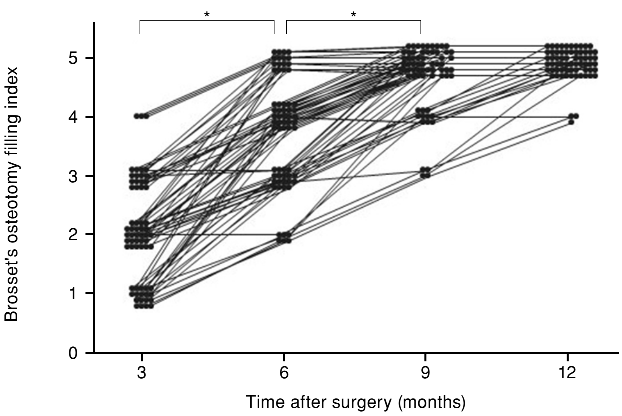

FIGURE 4. Line graph of Bone union progression.
* There was significant difference of Brosset's osteotomy filling index between two measurement points.

(Figure 4). Representative radiographs of a moderate bone union case are presented in Figure 5. Bone union in the fourth zone was accomplished in 5%, 63%, 94%, and 100% of current cases at 3, 6, 9, and 12 months after OWHTO, respectively. Smoking (OR=0.478, p<0.01), large opening gap (OR=0.941, p=0.014), and anterior plate placement (OR=0.971, p<0.01) were statistically associated with decreased bone union area after surgery (Table II). Union rate at six months in smokers was significantly lower compared to nonsmokers (16.6% and 67.8%, respectively; OR=0.10, p=0.023). Area under the ROC curves for bone union at sine months were 0.60 for opening gap width (cut-off value=10.5 mm, sensitivity=61.0%, specificity=62.5%) and 0.63 for plate placement (cut-off value=0.74, sensitivity=50.0%, specificity=78.0%). The bone union progression for each risk factor is shown in Figure 6. The intra- and interobserver intraclass correlation coefficients for plate position assessment were 0.86 and 0.72, respectively. These reliability ratings were considered excellent.[21]

DISCUSSION

The most important findings of the present study were that smoking, a large opening gap width, and a more anterior plate placement emerged as risk factors for delayed bone union after OWHTO using beta-tricalcium phosphate bone-substitute wedges.[22] Delayed bone union should be avoided since it leads to pain and requires extended nonoperative treatment, such as partial weight-bearing.[1,10]

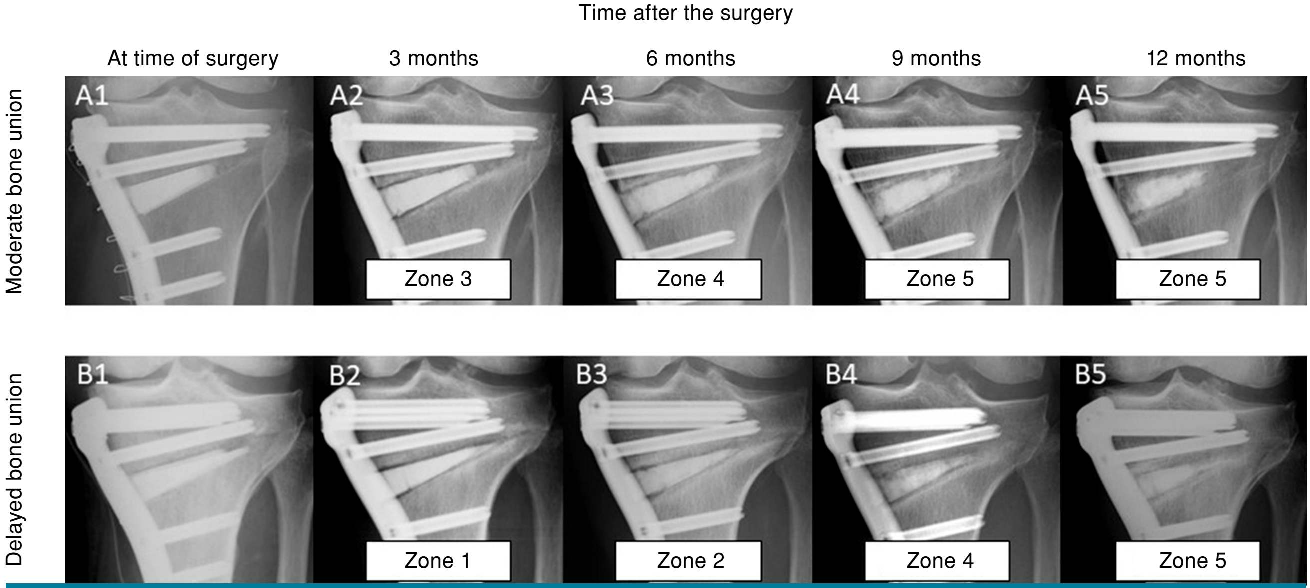

FIGURE 5. Representative radiographs of a moderate bone union case **(A1-A5)** and a delayed bone union case **(B1-B5)**.

TABLE II
Logistic regression model of risk factor effects on bone union time with generalized estimating equation

	OR	95% CI	*p*
Age (year)	0.999	0.982-1.016	0.891
Sex			
Female, (Male as reference)	0.883	0.681-1.145	0.347
Body mass index (kg/m^2)	0.978	0.931-1.027	0.368
Smoking (nonsmoker as reference)	0.478	0.314-0.726	0.001
Diabetes (no diabetes as reference)	0.688	0.413-1.146	0.151
Autologous osteophyte grafting (no osteophyte grafting as reference)	0.875	0.633-1.208	0.417
Opening gap width (mm)	0.941	0.896-0.988	0.014
Plate position	0.970	0.959-0.981	<0.001
Hinge fracture (no hinge fracture as reference)	1.508	0.896-2.583	0.122

OR: Odds ratio; CI: Confidence interval.

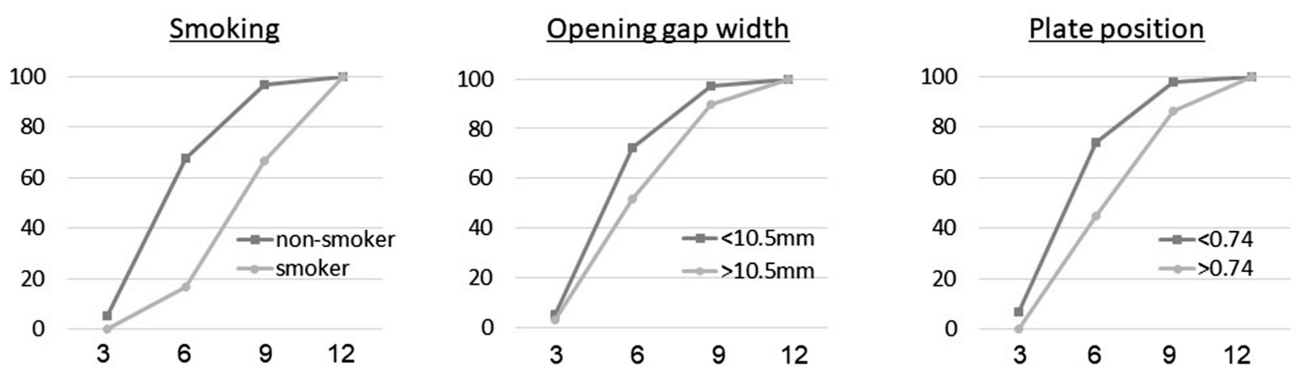

FIGURE 6. Line graph of bone union progression. The horizontal axis represents time after the surgery (months) and the vertical axis represents bone union rate (%).

Previous studies across a spectrum of techniques have found a large opening gap to be a risk factor for delayed bone union after OWHTO. In 2010, Jung et al.[23] reported that at three months, the degree of bone union was confirmed in 91.3% of patients with a 7-mm opening gap, while it was achieved in only 52.6% of those with a gap >13 mm. A systematic review by Slevin et al.[2] in 2016, designed primarily to compare bone void filler options, also provided substantial evidence regarding the impact of opening gap width on osteotomy healing. Another study by Goshima et al.[5] in 2019, using no graft material, reported that an opening gap >13.0 mm significantly delayed bone formation (OR=1.61) after OWHTO. Similarly, our current analysis using GEEs demonstrated that a large opening gap width was a risk factor for delayed bone union after OWHTO.

It is well-established that cigarette smoke inhalation impairs biological bone healing processes and delays fracture union in general.[24,25] However, specifically for OWHTO, the effect of smoking on delayed union has been subject to debate, with at least one study concluding that smoking has no significant impact on functional outcomes.[26] On the other hand, Meidinger et al.[7] noted in 2011 that 50% of nonunion OWHTO recipients were smokers, while only 23% of unproblematic patients were smokers. They concluded that for OWHTO, the risk of nonunion must be discussed with patients who smoke. Another study identified smoking as a risk factor for developing delayed union or nonunion in OWHTO with an OR of 4.[4] Furthermore, a tendency toward delayed gap filling over the entire follow-up period (12 weeks, 6 months, 12 months, and 18 months after surgery) was reported in a group of smokers.[27] Our study provides additional evidence that smoking is associated with delayed bone union after OWHTO.

Computational simulation studies and biomechanical tests indicate that plate location changes the resistance to applied mechanical loads.[11-13] A numerical model based on the finite element method previously demonstrated that an anteriorly placed plate results in increased stress at the tip of the osteotomy gap and increases micromotions in the osteotomy gap by up to 3.5-fold compared to a medially placed plate.[11] Biomechanical studies have indicated that anteromedial plate placement withstands lower loads with more displacement compared to medially placed plates and concluded that anterior placement is biomechanically inferior to posteromedial plate placement.[12,13] However, the relationship between plate position and delayed union has not been elucidated in clinical settings. In our patient population, a more anterior plate placement was associated with delayed bone union after surgery.

A biomechanical study of OWHTO demonstrated superior primary stability of the angle-stable implant (Tomofix plate; DePuy Synthes, Pennsylvania, USA) compared to other less rigid plates in the presence of lateral hinge fractures.[28] Furthermore, angle-stable implants with allograft or bone substitute gap filling have a higher loading capacity and reduced rate of nonunion and delayed union.[17,29] In this study, we used an angle-stable implant and bone substitute for these reasons. However, our findings may have been influenced by the use of angle-stable implants and bone substitute gap filling, potentially explaining why we did not observe a significant correlation between hinge fracture and delayed bone union.

Bone union progresses from the lateral hinge towards the medial side, with the bone union area increasing over time after surgery.[30] It is thought that although placing bone substitute into the site opening improves mechanical stability, the bone remodeling phase takes longer when using bone substitute. A previous study reported that bone union at the third zone was accomplished in only 25% of all patients six months after OWHTO using angle-stable implants with bone substitute.[31] In the current study, bone union in the third zone was accomplished in only 29% of current cases three months after OWHTO. In all cases, the current technique resulted in bone union in the fourth zone, which indicated thorough stability, before the end of the first year.

There were certain limitations to the present study. First, although three risk factors for delayed bone union after OWHTO were detected, the present study involved a relatively small number of participants. Additional studies with a larger number of participants are required to draw a robust conclusion. Second, this study was retrospective in nature, thus potentially introducing selection bias. In this patient population, the mean BMI was 24.3±3.2, and only six patients were >30. Our study involved only three patients with diabetes. The observed low mean BMI and small proportion of patients with diabetes potentially affected our results. Third, although two senior surgeons participated in each other's surgeries to unify surgical methods, several other surgeons performed surgeries under their supervision, resulting in variations in surgical techniques based on the attending surgeon. Fourth, the bone union areas at all time points for any given patient were evaluated by one observer who was aware of the assessment results (i.e, nonblinded) from all previous time points, if any, for the patient being assessed. This could introduce a potential observer bias in assessments over the time course of bone union.

In conclusion, smoking, large opening gap width, and anterior placement of plates emerged as the main risk factors for delayed bone union after OWHTO. Surgeons should avoid anterior placement of plates and carefully consider other options for smokers and those who require major correction to mitigate the risk of delayed bone union. Further studies with greater numbers of participants are required to draw robust conclusions.

Ethics Committee Approval: The study protocol was approved by the Tokyo Medical and Dental University Ethics Committee (date: April 03, 2015, no: M2000-2054-01). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Analyzed the data and drafted the manuscript: N.A.; Designed the initial plan, conducted the study and edited the manuscript: H.K.; Designed the initial plan: Y.N., M.S.; Collected the data: T.O., N.O., Y.K., T.N., I.S.; Designed the initial plan, conducted the study and completed the final manuscript: H.K. All authors read and approved the final manuscript.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding: The authors received no financial support for the research and/or authorship of this article.

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