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ORIGINAL ARTICLE

Evaluation of the effect of eccentric nailing on femoral diaphyseal union delay

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ABSTRACT

Objectives: In this study, we aimed to investigate whether there was a relationship between deformity at the fracture line/eccentric placement of the nail, and union time (UT) in isthmal diaphyseal femoral fractures treated with intramedullary nails.

Patients and methods: Between September 2017 and December 2020, a total of 61 patients (38 males, 23 females; median age: 47 years; range, 23 to 62 years) with closed femoral shaft fractures who underwent antegrade nailing were retrospectively analyzed. The following parameters were examined: *(i)* amount of angulation in the fracture line (AFL), *(ii)* varus/valgus of the fracture line (VAFL), *(iii)* amount of deviation of the distal tip of the nail from the femoral notch (DDT), *(iv)* medial lateral orientation of the distal nail relative to the notch (MLON), *(v)* number of fracture parts (NFP), and *(vi)* UT.

Results: The causes of injury were high-velocity traffic accidents in 42 patients and falls in 19 patients. The median surgical delay was 4.5 (range, 2 to 8 days). The median follow-up time was 37 (range, 12 to 57) months. There was a moderate, statistically significant and positive correlation between UT and AFL, DDT, and NFP (r=0.486, p<0.001). The difference in UT according to MLON (p=0.002) was statistically significant.

Conclusion: Our study results suggest that impaired weight-bearing force and translational force may cause impaired healing. Thus, angulation of the fracture line and eccentric nail placement may delay fracture union. We recommend using bold screws to ensure that there is no deformity in the fracture line and to fully center the nail inside the distal bone.

Keywords: Bone and bones, femur, femoral fixtion, femoral fracture, injuries.

Femoral nail fixation is the preferred method by which to reconstruct isthmal diaphyseal femoral fractures.[1] It is important to center the guidewire to prevent eccentric reaming and subsequent nail malpositioning and malalignment. If the nail is eccentrically located or there is angulation in the fracture line (AFL), the weight bearing force is divided into force vectors based on load bearing. Eccentric reaming can also weaken the adjacent cortex, which can inhibit healing and cause a fatigue fracture; however, if the distal femur is not drilled properly toward the notch, it would be difficult to distally lock the nail due to the oblique placement of the holes. If the nail tip is oriented medially, fluoroscopy should be angled craniocaudally; if nail tip is oriented laterally, fluoroscopy should be angled caudocranially (Figure 2). It is difficult to prevent eccentric reaming and deformity and achieve fracture reduction due to the enlargement in the distal femoral segment which causes lack of cortical

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contact.[2] A bold screw technique was developed to overcome this problem. Blocking screws reduce the metaphyseal intramedullary space and support the nail as a cortical wall.[3] Research has shown that persistent deformity can lead to delayed union, nonunion, or malunion.[2] The relationship between weight bearing and union time (UT) has not been established; however, it has been observed that delays in weight bearing are independently associated with UT in tibial fractures.[4] Persistent deformity and/or eccentric ingrained nail may cause insufficient weight bearing and axial loading on the fracture line due to an altered anatomical axis. In the present study, we aimed to investigate whether there was a relationship between deformity at the fracture line/eccentric placement of the nail, and UT in isthmal diaphyseal femoral fractures treated with intramedullary nails.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at Haydarpasa Numune Training and Research Hospital, Department of Orthopedics and Traumatology between September 2017 and December 2020. Initially, a total of 112 patients with femoral fractures underwent antegrade nailing in our center. Exclusion criteria were as follows: incomplete radiographic and/or clinical data (n=6); open fractures, distal or proximal 1/3 fractures (only included middle third of the femoral shaft), comminuted fractures with more than four pieces (n=21); metabolic, pathological, and insufficiency fractures (n=7); accompanying injuries (n=9); bisphosphonate-related atypical fractures (n=4); and adolescent patients (n=4). The remaining 61 patients (38 males, 23 females; median age: 47 years; range, 23 to 62 years) who met the inclusion criteria were recruited. Fractures were classified according to AO classification. According to AO classification, multifragmentary fractures and segmental fractures were also excluded. Written informed consent was obtained from each patient. The study protocol was approved by the Haydarpasa Numune Training and Research Hospital Ethics Committee (Date: 27.05.2024, No: HNEAH-KAEK/KK/2024/83). The study was conducted in accordance with the principles of the Declaration of Helsinki. All methods were conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

Antegrade nails were inserted with the patient in the supine position on a fracture table using traction. A titanium femoral TRIGEN TAN nail (Smith & Nephew, Memphis, TN, USA) was used. Reduction was made using a mini-open technique in all patients. The bone was reamed in all cases and the thickest nail was placed. Statical distal locking was performed in all patients. The union was assessed using radiographs of two orthogonal planes, commonly the anteroposterior (AP) and lateral views. The union was scored, when three out of four cortices demonstrated cortical bridging or complete disappearance of fracture lines. The radiographic union scale in tibial fractures (RUST) score was used to evaluate this. The RUST score is a radiological tool that was developed to standardize the union assessment of tibial fractures. This score focuses on cortical bridging. Cortical bridging and biomechanical strength relation were also shown *in vivo* models in the original paper. Authors found a good agreement among five observers. The RUST score is calculated separately for each cortex (Table I). The scores of all cortices are added together and a minimum score of 4 (definitely not healed) and a maximum of 12 (completely healed) are found.[5] This union was also defined as the ability to bear full weight

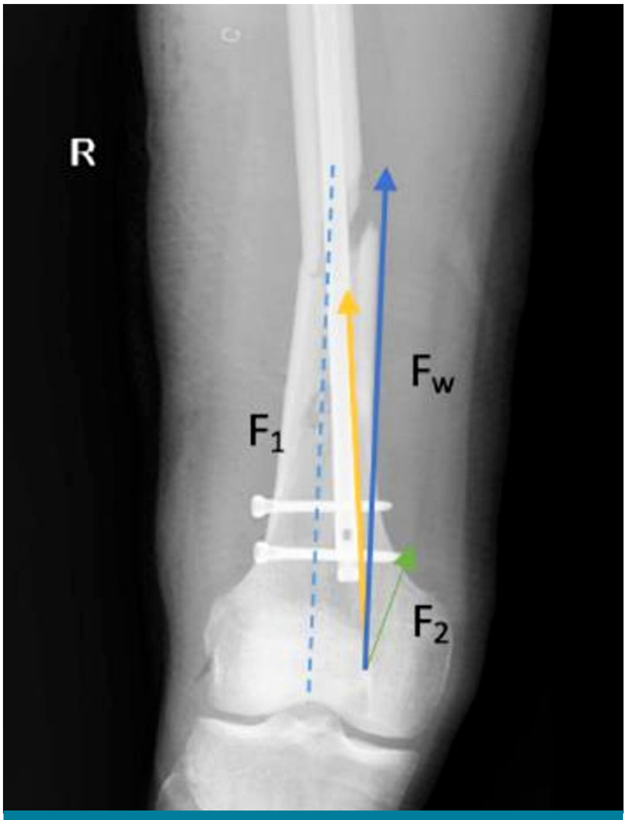

FIGURE 1. Divided force vectors.
Fw: weight-bearing force; F1: force component reflected from the nail to the fracture linee; F2: translationally reflected force component.

TABLE I
Radiographic union scale in tibial fracture (RUST)

Score per cortex	Callus	Fracture line
1	Absent	Visible
2	Present	Visible
3	Present	Invisible

without pain. Malunion was defined as more than a 5° angulation on radiographs (Figure 1).[1] The body mass index (BMI), smoking, non-steroidal anti-inflammatory drug (NSAID) use, or steroid use were also recorded. Partial weight bearing started immediately after surgery in all patients. After one day after surgery, radiographic imaging was taken, and monthly clinical and radiological (AP and lateral X-rays) follow-ups were made until the radiological union was seen. The minimum follow-up period was determined as 12 months. Three investigators (trauma surgeons) made the decision of union. Investigators were blind to the theory of this study. The parameters investigated in this study were as follows: *(i)* amount of AFL, *(ii)* varus/valgus angulation of fracture line (VAFL), *(iii)* deviation distance of the distal tip of the nail from the femoral notch (deviation of distal tip [DDT]), *(iv)* medial/lateral orientation of the distal nail relative to the notch (medial/lateral orientation of nail [MLON]) (Figures 2, 3), *(v)* number of fracture parts (NFP), and *(vi)* UT. The effects of these parameters on UT were investigated.

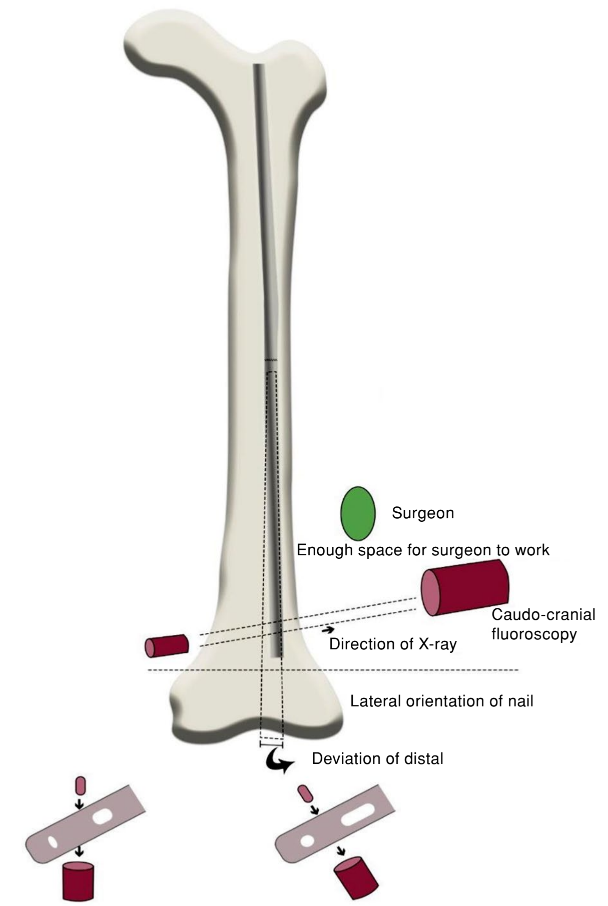

FIGURE 2. Deviation of distal and medial/lateral orientation of nail. With deviation of the nail, the distal screw holes become oblique. Thus, fluoros-copy settlement must also be oblique. X-ray tube must be on the opposite side and should be clos-est to the leg to see the widest holes. At the same time, there should be a large area in which the surgeon can comfortably work.

Notes: Deviation of distal, deviation of distal tip; medial/lateral orientation of nail, medial lateral orientation of the distal nail relative to the notch.

Statistical analysis

Statistical analysis was performed using the MedCalc version 12.7.7 (MedCalc Software Ltd., Ostend, Belgium). Continuous data were expressed in mean ± standard deviation (SD) or median (min-max), while categorical data were expressed in number

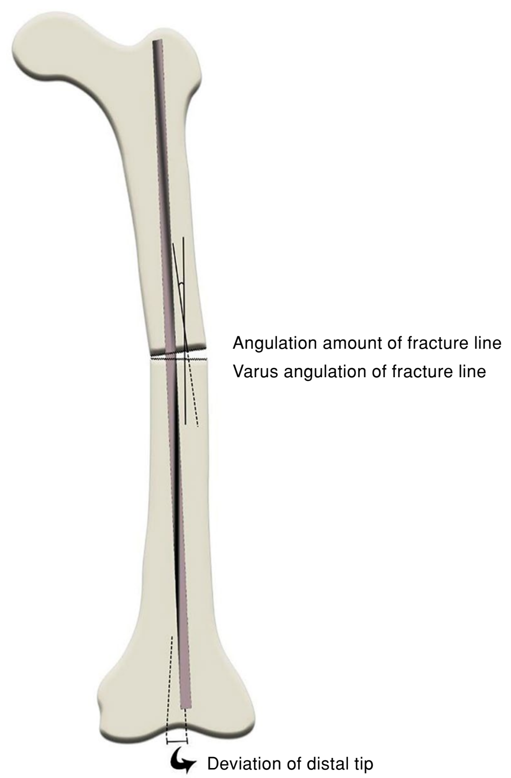

FIGURE 3. Angulation of fracture line and varus/valgus angulation of fracture line.

TABLE II
Demographics and classification

High-velocity traffic accidents		Fall from a height		Simple, oblique, middle third fractures AO32A2(b)		Simple, transverse, middle third fractures AO32A3(b)		Simple, spiral, middle third fractures AO32A1(b)		Wedge, fragmentary, middle third fractures AO32B3 (b)		Smoking		Regular alcohol use		Metabolic disorders (diabetes, osteoporosis)	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
42	69	19	31	36	59	15	25	6	10	4	7	16	26	9	15	8	13

AO: Arbeitsgemeinschaft für osteosynthesefragen.

and frequency. The Kruskal-Wallis test was used to compare independent and more than two variables that did not conform to normal distribution. The Mann-Whitney U test was used to compare two independent and non-normally-distributed variables. The Spearman's rho correlation analysis was conducted to correlate two continuous variables that did not conform to the normal distribution. Linear regression analysis was used to examine the effect of independent variables on the continuous dependent variables. A p value of <0.05 was considered statistically significant.

RESULTS

The causes of injury were high-velocity traffic accidents in 42 patients and falls in 19 patients. The median surgical delay was 4.5 (range, 2 to 8) days. Demographics and fracture types are summarized in Table II. The median follow-up time was 37 (range, 12 to 57) months.

To evaluate the relationship between DDT and AFL measurements, a Spearman's rank-order correlation was conducted, revealing a moderate and statistically significant association ($\varrho=0.494$, $p<0.001$). A post-hoc power analysis was performed to assess the adequacy of the sample size using the observed effect size ($r=0.494$), significance level ($\alpha=0.05$), and sample size ($n=61$). To evaluate whether the sample size was sufficient to detect this observed effect, a post-hoc power analysis was performed using Cohen's z transformation for correlation and approximated with the normal approximation method in the statsmodels library (version 0.14.0, Python 3.11). The analysis indicated an achieved statistical power of 0.85, suggesting that the study had an 85% probability of detecting a true effect of this magnitude.

There was a moderate and positive relationship between DDT and AFL ($r=0.494$, $p<0.001$). A Fleiss' multi-rater kappa value of 0.246 revealed fair agreement among the three raters. While statistically significant, the kappa value suggested that agreement could be improved.

Using an intraclass correlation coefficient (ICC) of 0.592, there was a moderate level of absolute agreement between raters based on a two-way model ($p<0.001$). Accordingly, there was a reasonable, but not excellent, degree of consistency in the raters' numeric evaluations. The AFL was 0° in 52 (85%), VAFL was 0° in 44 (72%) patients, but valgus was found in eight (16%) and varus in nine (5%) patients. The DDT was 0 mm in 37 (61%) patients.

In the remaining patients, the mean DDT was 8.41±2.69 mm. The MLON was neutral in 38 (62%), medial in 15 (25%), and lateral in eight (13%) patients. The mean NFP was 2.35±1.35 (Table III). There was no relationship between UT and BMI, smoking, and NSAID and steroid use ($p<0.138$). However, there was a moderate, statistically significant, and positive correlation among UT and AFL, DDT, and NFP ($r=0.486$, $p=0.00044$). There was also a statistically significant difference in terms of UT according to MLON ($p=0.0003$) (Table IV). According to the post-hoc pairwise comparison results, the mean of the neutral group was lower than that of lateral and medial ($p=0.008$). There was a moderate, statistically significant, and positive correlation between DDT and AFL ($r=0.382$, $p=0.0005$). There was no multicollinearity problem, as the variance inflation factor (VIF) value was <10 in the backward variable selection model. The model was statistically significant ($p=0.001$). A 1° increase in AFL increased UT by 0.373 month. In addition, a 1-mm increase in DDT increased UT by 0.278 month. Figure 4 provides illustrations of UT-AFL, DDT, NFP, AFL-DDT, and Figure 5 provides an illustration of DDT-MLON. We found no significant correlation among BMI, smoking, NSAID use, steroid use, and UT. There were seven (11%) superficial wound infections which healed with oral antibiotics. No deep infections were observed. Only one patient had deep vein thrombosis detected by computed tomography angiography and treated with anticoagulants. No other complications were observed in any of the patients.

TABLE III

Distribution of the study parameters

Parameters	n	%	Mean±SD	Median	Min-Max
Angulation in fracture line (°)			1.43±1.13	0	0-9
Deviation of distal tip (mm)			3.87±4.94	0	0-15
Number of fracture parts			2.35±1.35	3	2-4
Union time (month)			3.71±2.4	3	2-12
VAFL					
Neutral	45	73.7			
Valgus	8	13.1			
Varus	9	14.75			
MLON					
Lateral	11	18.3			
Medial	20	32.7			
Neutral	38	62.2			

SD: Standard deviation; VAFL: Varus/valgus angulation of fracture line; MLON: Medial/lateral orientation of nail.

TABLE IV

Relationship among varus/valgus angulation of fracture, medial/lateral orientation of nail distal tip, and union time

Parameters	Median±SD	Median	Min-Max	*p*
VAFL				
Neutral (month)	3.09±1.34	3	2-6	
Valgus (month)	7±4.69	6.5	3-12	0.087
Varus (month)		4	UT	
MLON				
Lateral (month)		4[a]		
Medial (month)	6±3.5[b]	5.5	2-12	**0.0003**
Neutral (month)	2.5±0.5[a,b]	2.5	2-3	

SD: Standard deviation; VAFL: Varus/valgus angulation of fracture line; UT: Union time; MLON: Medial/lateral orientation of nail. Notes: Kruskal-Wallis test, Mann-Whitney U test: post hoc pairwise comparisons, there is a statistically significant difference between the mean values of the groups with common lowercase letters.

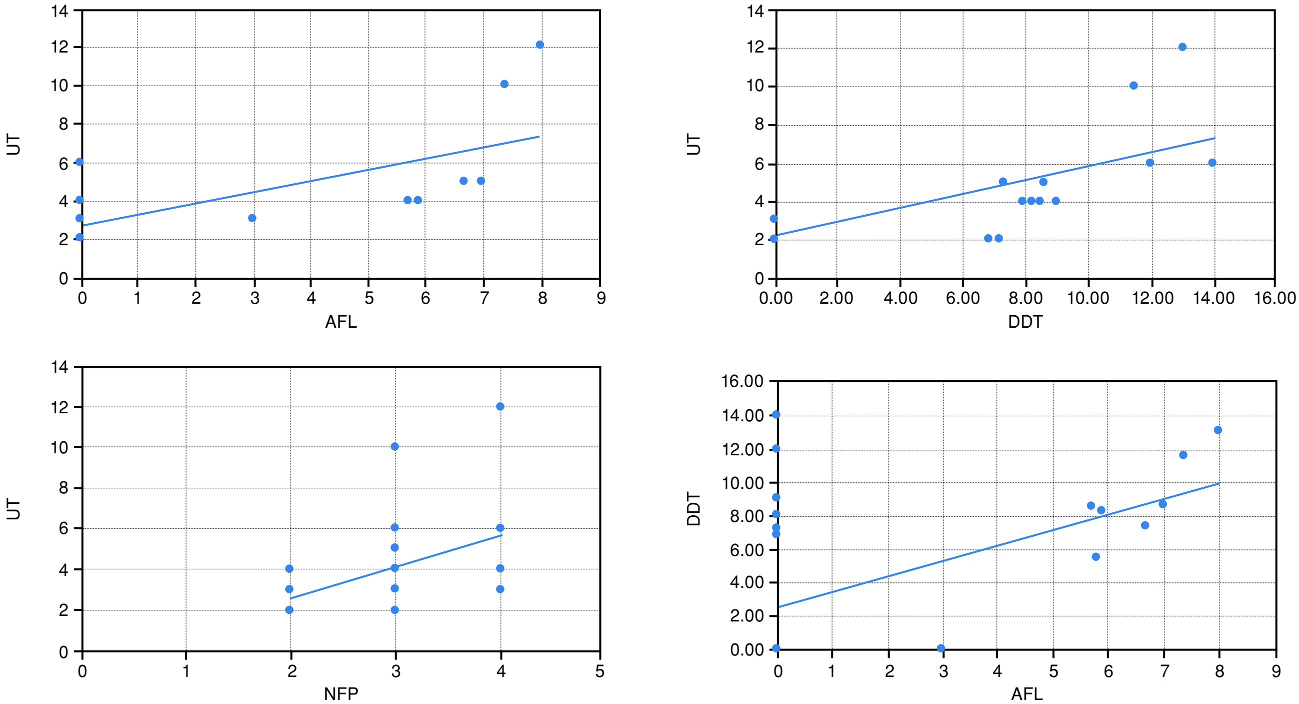

FIGURE 4. Correlation graphics of parameters.
UT: Union time; AFL: Angulation of fracture line; DDT: Deviation of distal tip; NFP: Number of fracture parts.

DISCUSSION

The reported risk of nonunion after femur nailing in isthmal fractures is 0.5 to 12.5% in the literature.[6-8] Many factors, including biological and mechanical, have been identified as causing a nonunion. Some of these are the fracture type, displaced third or fourth parts, unreaming, and delayed weight bearing;[1] however, there has been no study examining AFL and eccentric nail placement and problems with UT. Persistent deformity in the femur fracture line or eccentric nail settlement may cause UT problems.[2] One of the most common definitions of angular malalignment used in the literature is a >5° deformity in the coronal or sagittal plane.[2] Another study concluded that the frequency of malalignment greater than 5° observed on postoperative radiographs was 10%; and malalignment greater than 10° occurred in 1.6% of the femurs treated with nail. Proximal and distal diaphysis fractures was strongly correlated with risk of malalignment.[9] Patients with fractures of the middle third of the femoral shaft had low rates of malreduction regardless of the degree of comminution; therefore, we believe that malreduction in middle third of the femoral shaft does not attract enough attention, due to its low incidence rate, although this may cause a delayed UT or nonunion. Since the metaphysis of the distal femur is wide, the aforementioned authors suggested using bold screws to decrease the diameter of the canal. Blocking screws have been used with femoral nailing and provide coronal and sagittal alignment, as they act like a sham cortex and increase stability.[10,11] Krettek et al.[3] concluded that UT was one week shorter in the bold screw group than in the nail-only group. Stedtfeld et al.[12] reported that the addition of blocking screws could prevent the possible deformity up to 57% in the tibia. In another recent review, the authors suggested intramedullary nailing with poller screws had lower rates of nonunion and coronal malalignment compared to nailing

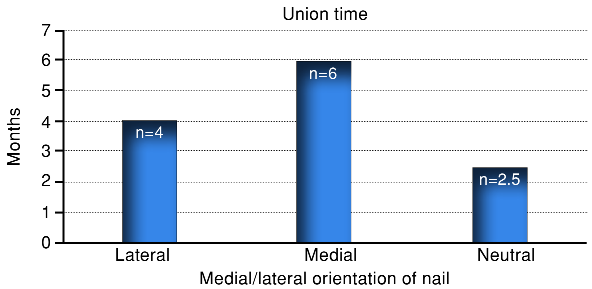

FIGURE 5. Deviation of distal tip-medial lateral orientation of the distal nail relative to the notch.

alone.[13] Our results are compatible with this study. In this study, our results showed that coronal malalignment was a reason and nonunion was the result. The positive effect of weight bearing after surgery on UT has been demonstrated in several studies.[14,15] Houben et al.[4] showed that late weight bearing was an independent risk factor of impaired healing. Today's nails are resistant to full weight bearing, and it has been shown that loading 50% of the other extremity in the first post-surgery week does not cause implant failure;[4,16,17] however, if the nail is eccentrically located or there is AFL, the weight bearing force is divided into force vectors based on load bearing. According to the results of the present study, we believe that this problem increased the risk of delayed UT and some may speculate that the diameter of the nail can change UT; however, in their study of 287 patients, Yoon et al.[18] concluded that the use of 10-mm nails had no significant effect on UT rates or healing times; however, we believe that a thin nail might increase AFL and the risk of distal eccentric placement and union delay as well.

Nonetheless, the present study has several limitations. First, only a small number of patients were included, and second, this was a retrospective study. Further large-scale, prospective studies are needed to confirm these findings. Third, different surgeons performed the operations, and fourth, other factors which may be correlated with nonunion, such as sagittal deformity, nail and medullary diameters, surgery duration, and blood loss, were unable to be examined. In the current study, we only examined coronal-angular deformities. Rotational and length deformities were not examined, due to the need for additional X-rays. Fifth, this study focused on the relationship between the deformity or eccentric nail settlement and UT. Since the possibility of deformity or eccentric nail settlement with nail is less common in diaphyseal fractures, the number of patients was low, thereby reducing the specificity of the study group. Thus, patients with other factors that may delay the union such as open reduction and comorbidities (i.e., diabetes, osteoporosis, smoking, alcohol use) were not excluded. Future studies with more specific groups would provide more robust data on this subject.

In conclusion, our study results suggest that impaired weight-bearing force and translational force may cause impaired healing. Thus, angulation of the fracture line and eccentric nail placement may delay fracture union. We recommend using bold screws to ensure that there is no deformity in the fracture line and to fully center the nail inside the distal bone. However, these findings should be examined in larger studies.

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

Author Contributions: Idea/concept, design, writing the article, materials: O.E.; Control/supervision: H.S.Y.; Data collection and/or processing: M.K.; Analysis and/or interpretation: L.A.; Literature review: E.K. MM.; Critical review: İ.E.K.; References and fundings: S.T.

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