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Research Article

The Effect of Nail Diameter in Reamed Intramedullary Exchange Nailing

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Abstract

Objectives: Treatment with exchange nailing is the most preferred treatment method in aseptic femoral and tibial diaphyseal non-unions without bone defect. In this study, patients treated with exchange nailing for femoral and tibial diaphyseal non-unions were evaluated clinically and radiologically. The aim of this study was to determine the factors effective in exchange nailing treatment and to evaluate the effect of changing diameter of the nail.

Methods: This single-center, retrospective study included 22 patients with femoral diaphyseal non-union and 13 patients with tibial diaphyseal non-union who underwent revision surgery with exchange nailing after diagnosis of non-union following operations of the femur or tibia with intramedullary nailing.

Results: Union and healing were determined in all the patients (100%). In the femoral non-union group, the most decisive factor on the time to union was the change in nail diameter. In the tibial non-union group, the most decisive factor on the time to union was comorbidity.

Conclusion: Exchange nailing treatment in aseptic femoral and tibial diaphyseal non-unions without bone defect, with fixation using stable locking reamed intramedullary nail is a treatment option with excellent results. The change of nail diameter, especially in femoral non-unions has a positive effect on the time to union.

Keywords: Femur, tibia, non-union, exchange nailing, nail diameter

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In femoral and tibial diaphyseal fractures, the union rates are extremely high with fixation with through reamed intramedullary nailing (IMN), and non-union is a rarely seen complication following this treatment.[1] Although rarely seen, non-union is a significant cause of morbidity.[2] Exchange nailing is the most preferred treatment method in aseptic femoral and tibial diaphyseal non-unions without bone defect.[3-6] Compared to other treatment methods, exchange nailing has biological (osteoinductive effect) and biomechanical advantages together with minimal blood loss, low surgical morbidity and shorter hospitalization.[7-9]

Successful results have been reported at 72%-100% with the exchange nailing procedure in femoral and tibial diaphyseal non-unions.[10-12] However, unsuccessful results have also been reported in patients who smoke or have avascular type non-unions.[6,13]

The aim of the study was to determine the factors effective in exchange nailing treatment and to evaluate in particular the effect of changing the diameter of the nail.

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Methods

This single-center, retrospective study included 22 patients with femoral diaphyseal non-union and 13 patients with tibial diaphyseal non-union who underwent revision surgery with exchange nailing after diagnosis of non-union following operations of the femur or tibia with intramedullary nailing between January 2012 and January 2016. The patients included had no clinical or laboratory findings of infection pre-treatment or during the treatment; patients with no preoperative elevation of sedimentation or CRP were included, intraoperative cultures were taken from these patients and there was no production in the cultures. Approval for the study was granted by the Local Ethics Committee.

Although there is no consensus on the definition for non-union, it is generally defined as fractured bone that has not completely healed within 9 months of injury and has not shown progression toward healing over 3 consecutive months on serial radiographs.[14] Non-union was confirmed by clinically and radiologically. The need to use walking stick, pain in the fracture site and deformity were used in clinical evaluation. Radiologically, nonunion formation was determined as lack of radiographic bridging of at least three out of four cortices assessed on two sided conventional radiologic views and CT scans.

Patients determined with pathological fracture and those who did not attend follow-up appointments were excluded from the study. Any patients determined with defective non-union or infective non-union were applied with a different treatment protocol and were not included in the study.

A record was made for each patient of age, gender, side, fracture classification, trauma type, soft tissue status at the time of the fracture (open or closed fracture), non-union classification, primary fixation material properties, secondary fixation material properties, whether or not dynamisation was applied during follow-up, risk factors in respect of non-union, comorbidities, time to union and complications (Tables 1, 2).

Table 1. Demographic and clinical characteristics of femur and tibia nonunions according to change in nail diameter

	(Group-2FEN)≥ 2 mm (n=12)	(Group-1FEN) 1 mm (n=10)	p	(Group-2TEN) ≥2 mm (n=7)	(Group-1TEN) 1 mm (n=6)	p
Age (year)	51.3±19.1	46.8±18.0	0.576†	46.7±15.9	51.3±21.1	0.661†
Gender			0.074‡			0.559‡
Female	2 (16.7%)	6 (60.0%)		1 (14.3%)	2 (33.3%)	
Male	10 (83.3%)	4 (40.0%)		6 (85.7%)	4 (66.7%)	
Side			0.691‡			0.266‡
Left	6 (50.0%)	4 (40.0%)		1 (14.3%)	3 (50.0%)	
Right	6 (50.0%)	6 (60.0%)		6 (85.7%)	3 (50.0%)	
AO classification						
A	8 (66.7%)	4 (40.0%)	0.391‡	4 (57.1%)	2 (33.3%)	0.592‡
B	3 (25.0%)	3 (30.0%)	>0.999‡	1 (14.3%)	1 (16.7%)	>0.999‡
C	1 (8.3%)	3 (30.0%)	0.293‡	2 (28.6%)	3 (50.0%)	0.592‡
Trauma			>0.999‡			0.559‡
Low energy (LE)	3 (25.0%)	3 (30.0%)		1 (14.3%)	2 (33.3%)	
High energy (HE)	9 (75.0%)	7 (70.0%)		6 (85.7%)	4 (66.7%)	
Open/closed			0.624‡			0.592‡
Open	2 (16.7%)	3 (30.0%)		5 (71.4%)	3 (50.0%)	
Closed	10 (83.3%)	7 (70.0%)		2 (28.6%)	3 (50.0%)	
Nonunion type			>0.999‡			0.266‡
Oligothrophic	4 (33.3%)	4 (40.0%)		6 (85.7%)	3 (50.0%)	
Hypertrophic	8 (66.7%)	6 (60.0%)		1 (14.3%)	3 (50.0%)	
Risk factor	9 (75.0%)	9 (90.0%)	0.594‡	5 (71.4%)	3 (50.0%)	0.592‡
Number of risk factors	1 (0-2)	1 (0-3)	0.346¶	1 (0-1)	0 (0-1)	0.534¶
Comorbidity	6 (50.0%)	5 (50.0%)	-	2 (28.6%)	4 (66.7%)	0.286‡
Number of comorbidities	1 (0-4)	1 (0-6)	0.923¶	0 (0-1)	1 (0-4)	0.181¶
Complications	5 (41.7%)	1 (10.0%)	0.162‡	0 (0.0%)	2 (33.3%)	0.192‡

† Student's t test; ‡ Fisher's exact result probability test; ¶ Mann Whitney U test.

Table 2. Union time according to demographic and clinical characteristics of cases in femur and tibia nonunions

	Femur		Tibia	
	Union time (month)	p	Union time (month)	p
Gender		0.178†		0.369†
Female	6.25±1.98		6.00±3.00	
Male	5.00±2.04		4.80±1.62	
Side		0.913†		0.621†
Left	5.40±2.07		5.50±2.65	
Right	5.50±2.15		4.89±1.69	
AO classification		0.215‡		0.785‡
A	4.75±1.36		5.00±2.28	
B	6.17±2.93		6.00±0.00	
C	6.50±2.08		4.80±2.05	
Trauma		0.951†		0.213†
LE	5.50±2.66		6.33±2.52	
HE	5.44±1.90		4.70±1.70	
Open/closed		0.681†		0.099†
Open	5.80±2.17		4.37±1.77	
Closed	5.25±2.09		6.20±1.79	
Nonunion type		0.235†		0.703†
Oligothrophic	4.75±1.39		5.22±2.17	
Hypertrophic	5.86±2.32		4.75±1.50	
Risk factors		0.572†		0.045†
+	6.00±2.94		6.40±2.19	
-	5.33±1.91		4.25±1.28	
Comorbidity		0.548†		<0.001†
-	5.18±2.18		3.57±0.79	
+	5.73±2.00		6.83±1.17	
Complications		0.540†		0.049†
-	5.62±1.82		4.64±1.63	
+	5.00±2.76		7.50±2.12	
Nail diameter change		<0.001†		0.205†
≥2 mm	4.08±1.08		4.43±1.62	
1 mm	7.10±1.73		5.83±2.14	

† Student's t test, ‡ One-Way ANOVA.

The patients were evaluated postoperatively at 6-week intervals. All patients were followed for at least one year. Union was evaluated clinically and radiologically. Union was accepted radiologically when the radiolucent line in the fracture region had disappeared and when callus bridging bone in at least 3 of the 4 cortices was visualised on two sided radiographs the non-union region.[11,15] Clinical healing was accepted when the fracture region was pain-free and when the patient achieved mobilization with full weight-bearing with or without a supportive device.[11,15]

In the follow-up of the patients in the femoral exchange nailing group (FEN) and those in the tibial exchange nailing group (TEN), the same postoperative follow-up and exercise programs were applied within their own groups.

The FEN and TEN groups were subdivided as groups applied with nail exchange of 1mm nail diameter and groups applied with nail exchange of 2mm or more nail diameter. The results were evaluated within FEN and TEN groups.

Surgical Technique

The operations were performed in all cases on a radiolucent table with the patient in the supine position. After removal of the previous IMN, a guide wire was placed in the medulla and the reaming procedure was applied. Reaming was made starting at 0.5mm larger than the extracted nail and was increased by 0.5mm stages until evident bone debris was observed. Then the new IMN of at least 1mm larger than the removed nail was applied. There is no patient whose nail diameter is not increased after exchange nailing.

The same surgical procedure was applied in all patients. The fracture site was not opened and the external bone graft was not applied to any patient. In all the patients diagnosed with femoral non-union, the first fixation was antegrade nailing and the exchange nailing was also applied antegrade.

For all patients, same brand titanium alloy femur and tibia nails were used. Proximally and distally at least two locking screws were used. In femoral nailing, 6.5 and 5.5 mm proximally and 4.5 mm distally locking screws were used. In tibial nailing 5,5 mm proximally and 4,5 mm distally locking screws used.

Statistical Analysis

The data obtained in the study were analyzed using IBM SPSS Statistics 17.0 software (IBM Corporation, Armonk, NY, USA). The conformity to a normal distribution of continuous numerical variables was assessed with the Shapiro-Wilk test and variance homogeneity with the Levene test. Descriptive statistics for continuous numerical variables were stated as the mean±standard deviation (SD) or median (minimum-maximum) values and categorical variables were stated as number (n) and percentage (%).

The significance of the difference of mean values between groups was evaluated with the Student's t-test for two independent groups and with One-Way Variance Analysis (ANOVA) for more than two independent groups. The significance of variables between groups not conforming to a normal distribution or not meeting the assumptions of variance homogeneity was examined with the Mann Whitney U-test. Categorical variables were evaluated with the Fisher's Exact test. Correlations between time to union and age, number of risk factors and number of comorbidities were examined with Spearman's Correlation test. The effects of all the risk factors together that were thought to have an effect on the time to union of the femoral and tibial fractures were investigated with Multiple Stepwise Regression Analysis. The regression coefficients, 95% confidence intervals, and t-statistics were calculated for each of the variables remaining in the final model as a result of the Multiple Stepwise Regression Analysis. A value of p<0.05 was accepted as statistically significant.

Results

Radiological union and clinical healing were determined in all the patients (n=100%). Average union time in FEN groups 5.45 months (Group 1FEN=7,1 mth, Group 2FEN=4,08 mth) and the union time of the TEN groups is 5,07 months (Group 1TEN=5,83 mth, Group 2TEN=4,42 mth).

When the femur and tibia non-unions were evaluated in their own groups, no statistically significant difference was observed in age, gender, side, AO classification, trauma, open/closed initial injury, non-union type, presence and number of risk factors, presence and number of comorbidities and complications (p>0.05) (Table 1). The patients did not have any complications except shortening and deep vein thromboembolism. None of the patients experienced implant related complications like screw breakage.

Within the FEN and TEN groups, no statistically significant effect on time to union was determined for gender, localization, AO classification, trauma type, open/closed fracture, non-union type, the presence of risk factors or presence of comorbidities (p>0.05).

In the FEN groups, there was no statistically significant difference in respect of time to union between those determined with complications and those without complications (p=0.540). The mean time to union was determined to be statistically significantly shorter in Group 2FEN with nail exchange applied at nail diameter ≥2mm, compared to Group 1FEN, where the nail exchange was of 1mm diameter (p<0.001) (Table 2). Between the union time and age, number of risk factors or number of comorbidities no statistically significant correlation was determined in FEN groups (p>0.05) (Table 2).

In the TEN group, compared to the group with no risk factors, the group with at least 1 risk factor, although not clinically significant, was determined with statistically significantly longer mean time to union (p=0.045). In the group with at least 1 comorbidity, the mean time to union was statistically significantly longer compared to the group with no comorbidities (p<0.001). (Risk factors: smoking, alcohol, substance use; Comorbidities: diabetes mellitus, hypertension, coronary artery disease, asthma or chronic obstructive pulmonary disease, hyperthyroidism/hypothyroidism). The mean time to union was determined as statistically significantly longer in the group determined with complications compared to those with no complications(p=0.049). The mean time to union was shorter in Group 2TEN compared to Group 1TEN, but the difference was not statistically significant (p=0.205) (Table 2).

The effects of all the risk factors together which were thought to have an effect on the time to union of the femoral and tibial non-unions were investigated with Multiple Stepwise Regression Analysis. As a result of the regression analysis of the femoral non-union group, the most decisive factor on the time to union was the change in nail diameter. Irrespective of other factors, in the group where nail exchange was applied with nail diameter of 2 mm or more, the mean time to union was 3.1 months shorter (95% CI, 2.0-4.2) than the group where nail exchange was applied with a nail of 1mm diameter (p<0.001). As a result of the regression analysis applied to the tibial non-union group, the most decisive factor on the time to union was comorbidity. Irrespective of other factors, the mean time to union of the group with at least one comorbidity was 3.3 months (95% CI, 2.1-4.5) longer than that of the group with no comorbidities (p<0.001) (Table 3).

Discussion

Fixation with IMN is the gold standard of treatment for femoral and tibial shaft fractures.[16,17] In addition, better union rates and shorter union time have been reported with the reamed locking IMN method compared to unreamed IMN in studies.[18,19] As in primary fracture treatment, extremely successful results have also been reported with the reamed locking IMN method in non-union cases.[11,15] In the current study, which included cases of femoral and tibial non-union, exchange nailing was applied to both groups and 100% union was obtained.

There are biological advantages of medullar reaming in

Table 3. The most determining factors on the change in union time (according to Multiple Stepwise Regression Analysis)

	B (%95 CI)	t	p
Femur			
Nail diameter change ≥2 mm	3.105 (1.960-4.250)	5.676	<0.001
Tibia	3.262	5.987	<0.001
Comorbidity	(2.063-4.461)		

B: Regression coefficient, CI: Confidence interval.

the exchange nailing procedure. These include preservation of periosteal blood circulation, providing autologous bone graft and activation of the inflammatory response and various growth factors.[11,20,21] Even if the opening of the fracture region is necessary during this procedure, soft tissue coverage must be applied first before the reaming procedure, reaming particles exposed with the re-reaming must remain in the non-union area and their strong osteoinductive effect of these must be protected.[9] Reaming also contributes to biomechanics in these cases. In brief, this is because a thicker IMN can be applied with intramedullary reaming and this increases the bone-implant interface. In our study, intramedullary reaming was applied without opening the fracture area and an IMN at least 1mm larger than the removed nail was applied in all cases.

In the reamed IMN method applied in primary surgery of femoral and tibial fractures, there are some important technical points related to non-union that require attention. In both fracture types, fixation must be made in the framework of biomechanical principles respecting soft tissue. Locking screws, nail length and especially IMN diameter are related to stability. While open fractures or open reduction are associated with avascular non-union, unstable fixation is related to hypertrophic non-union. When the intramedullary reaming procedure is applied with care, in addition to avoiding thermal necrosis caused by over-reaming and pulmonary complications, there are significant advantages in both primary fracture surgery and in non-union treatment.[22] In the exchange nailing procedure of the current study, reamed locking intramedullary nailing was applied which would create stable fixation, without opening the fracture site.

Various recommendations can be found in literature about the amount of reaming and the nail diameter for the application of the exchange nailing procedure. Some studies recommend increasing nail diameter by at least 1mm[11,23] while others advocate changing the nail diameter by 2mm or more.[11,15,24,25] In a study of femoral non-union cases, a comparison was made between groups applied with 1mm nail change and 2mm or more nail change and similar results were obtained in both groups. A union rate of 91.9% was obtained and in both groups, the union rates (91.2%, 92.5%) and time to union (4.4 months for both groups) were similar.[26] When the cases in our study were evaluated in respect of the change in nail diameter, a shorter time to union was obtained in the groups where nail exchange was made with a thicker diameter nail in both the femoral and tibial non-unions.

In a study of 50 cases applied with femoral exchange nailing, the time to union was reported as mean 7 months, and in another study of 46 cases applied with tibial exchange nailing, the union was obtained in mean 4.8 months.[11,15] In those two studies, dynamization was applied to 14 femoral non-union cases and to 3 tibial non-unions. In recent literature, the time to union has been reported varying from 4 months to 7.8 months in patients applied with exchange nailing for femoral and tibial non-union.[24-28] Although the mean time to union in our study was consistent with the literature and the above-mentioned studies, an even shorter time to union was obtained in cases where the nail diameter was increased by more than 2 mm.

There is no consensus in literature in respect of static locking or dynamic locking in the application of exchange nailing.[29] Dynamization is generally recommended in cases where healing is expected to be slow.[11] On the other hand, there are studies indicating dynamization is not necessary.[30,31] In cases applied with dynamization, even if the healing response is good immediately after the procedure, the expected union may not be obtained. There must also be an awareness that there could be the additional complication of shortness. A previous study compared static and dynamic locking in 52 cases of tibial non-union, and no significant difference was found.[28] In our study, static locking intramedullary nails were used for fixation and 100% union was obtained.

Limitations of this study can be said to be that it was retrospective and there was no control group. Nevertheless, in our study, which has the advantages of operating all cases in one center and by the same surgical team, valuable results were obtained in terms of nail diameter, stable fixation and union time.

There are different characteristics of femoral non-unions and tibial non-unions. Despite the good results obtained with the change in nail diameter in the FEN and TEN cases in the current study, the result was only statistically significant in the femoral group. In the TEN group, rather than the change in nail diameter, the presence of risk factors, comorbidities and complications were found to be more related to the time to union. In the regression analysis, the change in nail diameter was determined to have the most effect on time to union for the femur and the presence of comorbidities for the tibia. In the light of these data, it can be concluded that the local and systemic biological effect is lower in femoral non-union and when the operation is applied according to the appropriate technique, the union can be obtained in a short time. In tibial non-unions, however, local and systemic biological factors of the patient, in addition to the appropriate technique, have a greater effect on the success or failure of the non-union treatment.

Conclusion

In conclusion, exchange nailing treatment in aseptic femoral and tibial diaphyseal non-unions without defect, with fixation using static locking reamed intramedullary nails is a good treatment option with excellent results. In the current study, good outcomes were obtained without the need for dynamization or additional bone grafting. An increase of nail diameter of at least 2mm or more in hypertrophic and oligotrophic tibial non-unions and especially in femoral non-unions has a positive effect on the time to union.

Disclosures

Ethics Committee Approval: Approval for the study was granted by the Local Ethics Committee.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – Y.M.A.; Design – Y.M.A.; Supervision – Y.M.A.; Materials – C.K.; Data collection and/or processing – C.K.; Analysis and/or interpretation – C.K.; Literature search – Y.M.A., C.K.; Writing – Y.M.A.; Critical review – Y.M.A., C.K.

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