Anti-Rotational Plates with Intramedullary Nailing Stabilize Femoral Shaft Fracture Nonunion: A Biomechanical Study

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Abstract

Objectives: The purpose of this study was to determine the biomechanical effects of treating femoral shaft fracture nonunion with an anti-rotation plate (AP) in addition to intramedullary nailing (IM) to provide a theoretical basis for their clinical application.

Methods: Twenty-five synthetic bones were divided into the experimental (IM + AP, n = 20) and control (IM, n = 5) groups. The experimental group included four subgroups based on the number of screws and fixation method: IM + AP with two (C2 group) or three (C3 group) bicortical common screws and IM + AP with two (L2) or three (L3) unicortical locking screws. The experimental model was constructed in which their ends were embedded in the embedding apparatus. At last, the specimens were affixed to the mechanical testing system. Torsion testing was performed until each specimen's failure, while their torsional angle and torque values were recorded. All the data obtained have been analyzed by SPSS 10.0.

Results: 1. The mean value of the anti-torsional strength in the IM + AP group was greater than that in the IM group (0.01 < P < 0.05), which was statistically significant.

2. Based on the comparisons between the subgroups of IM+AP, the mean values of anti-torsional strength didn't show much difference. However, when the torsion angle turned to 25˚, the mean value in the C3 group was greater than the C2 group (0.01 < P < 0.05) which was statistically significant. When the torsion angle turned to 5˚, 10˚, 25˚, the mean value in the L3 group was greater than the L2 group (0.01 < P < 0.05) which was statistically significant. When the torsion angle turned to 20˚, 25˚, the mean value in the L3 group was greater than the C2 group (0.01 < P < 0.05) which was statistically significant.

Conclusions: 1. The anti-torsional strength in the IM + AP group was stronger than that in the IM group.

2. The anti-torsional strength of 3-screw groups (L3,P3) was stronger than the 2-screw groups (L2,P2). When the number of the screws was the same, there was no significant difference between unicortical locking screws groups and bicortical common screws groups.

3. Reserved IM + AP with three unicortical locking and bicortical conventional screws gave the strongest fixation, suggesting it should be used in the clinic for treating femoral shaft fracture nonunion.

Introduction

Intramedullary nailing (IM) is the primary method for treating nonunion of femoral shaft fractures [1]. However, with the advancement of IM technique and the increasing clinical indications, the incidence rate of femoral shaft fracture nonunion, according to the literature review, was 0.8% - 2% [2]. Regarding its treatment, exchanging intramedullary nailing is considered as the golden standard treatment for femoral shaft fracture nonunion, with a cure rate of up to 70-100% [1,3]. However, several reports have suggested that this method may increase the risk of future femoral shaft fracture nonunion [4,5]. Ueng et al. [6] firstly reported that reversed IM and additional plate fixation, with copious autologous bone grafting from the iliac crest, and is an effective and highly successful treatment with a union rate of up to 100%. Thus, this method has been extensively used by orthopedists and in clinical medicine generally. However, the biomechanical effects of the number and fixation methods of the screws used to secure the additional plate have not yet been described. Zhang et al. [7] stated that the main mechanical function of the additional plate is to provide rotational stability for the fracture site, which is called 'Anti-rotational plate' (AP).

The purpose of this study was to determine the biomechanical effects of treating femoral shaft fracture nonunion with an anti-rotation plate (AP) in addition to intramedullary nailing (IM) to provide a theoretical basis for their clinical application.

Materials and Methods

Materials and equipments

Artificial femurs (#3414, medium, left; Sawbones, USA), (Figure 1) AO intramedullary nails (Synthes Corporation, diameter: 10mm, length: 34 cm), and Anti-rotational plates (Synthes Corporation,7 hole narrow 4.5 series locking compression plate, 424.551/5 hole

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Figure 1: Artificial femur (sawbones3414, medium, left, USA)

Table 1: Groups of experiment

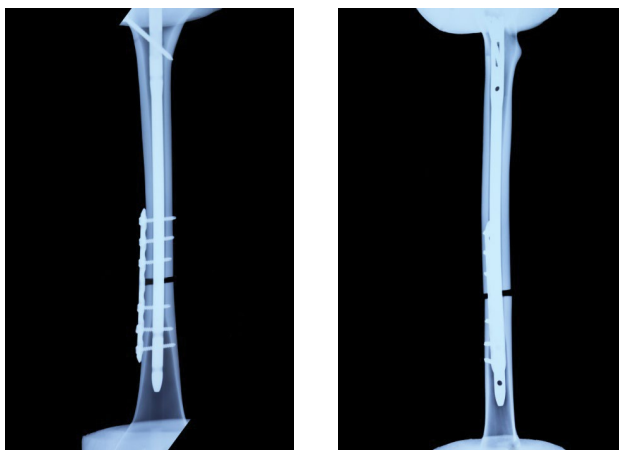|	IM	C2	C3	L2	L3
IM	+	+	+	+	+
plate	-	+	+	+	+
The type of screw	-	Bicortical - common screws	Bicortical - common screws	Unicortical - locking screws	Unicortical - locking screws
The number of screw	-	2	3	2	3

Figure 2: IM + plate + three bicortical common screws (C3 group)

Figure 3: IM + plate + three unicortical locking screws (L3 group)

Figure 4: The embedding apparatus

narrow 4.5 series locking compression plate, 424.571) were purchased. The embedding apparatus and mechanical testing system (MTS 858 MiniBionix testing machine; MTS Systems, Eden Prairie, MN, USA) were purchased.

Experimental groups

Twenty-five synthetic bones were divided into experimental group (IM + AP, n = 20) and control (IM, n = 5) groups. The experimental group was further divided into four subgroups based on the number of screws and fixation method: IM + AP with two (C2 group) or three (C3 group) bicortical common screws and IM + AP with two (L2) or three (L3) unicortical locking screws (Table 1).

Preparation of specimens

Based on the methods used in previously published studies [8], transverse osteotomies were performed on the model bones. Fractures were made 60% along the length of the femur, measured from the lesser trochanter to the adductor tubercle. After reducing the fracture, all specimens were reamed using the standard Kuntscher reamers, and up to a diameter of 11 mm. An AO intramedullary nail was inserted after reaming. One interlocking screw was fixed at the
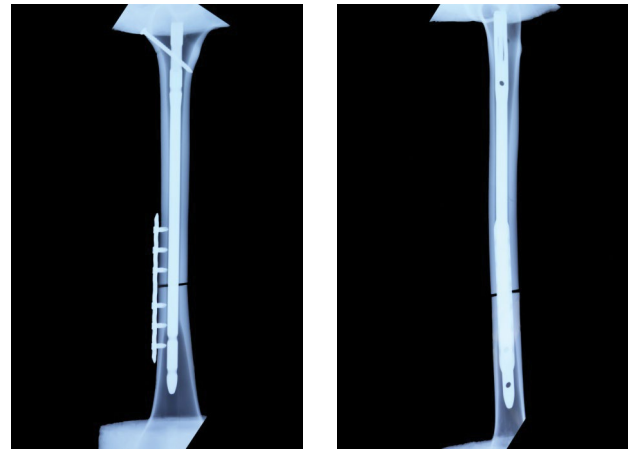
proximal portion and two screws were fixed at the distal portion. About IM+AP, firstly, according to the above method, IM was inserted and one interlocking screw was fixed at the proximal portion. But no screw in the distal portion was fixed in order to make the model of nonunion to maintain the rotational instability on the fracture site. In groups C3 and L3, an anti-rotational 7-hole plate was used to fix the fracture site, and the fracture of the proximal and distal parts were fixed with three bicortical common (C3) or three unicortical locking (L3) screws (Figure 2). In groups C2 and L2, an anti-rotational 5-hole plate was to fix the fracture site, and the fractures of the proximal and distal parts were fixed with two bicortical common (C2) or two unicortical locking (L2) screws (Figure 3).

Embedding the model femurs

Firstly, the specimens were placed in the embedding apparatus (Figure 4), ensuring that there was overlap between the longitudinal axis and the central red line of the scale. Then, polymethylmethacrylate (PMMA) was infused into the embedding apparatus. After embedding, the specimens were placed in the mechanical testing system (Figure 5).

Mechanical testing

Biomechanical testing was performed on an MTS 858 (Figure 6). The proximal portion of the specimen was fixed the fasten axis, while the distal portion was fixed the free-rotational axis on MTS 858. About the torsion direction of the specimen, its distal portion, relative

Figure 5: The specimens

Figure 6: The torsion test on an MTS 858

Figure 7: The comparison of the mean and standard deviation of torque values (Nm) in torsion angles (˚) and for each group

Figure 8: The comparison of the mean and standard deviation of torque values (Nm) in torsion angles (˚) and for each group

to its proximal portion, was external rotation. During the torsion test, each specimen was externally rotated through angles of 0-25˚ with no axial loading at a rate of 0.5˚/s, and the torsion-angle curves and torque values were recorded. (The most torsion angle which has been recorded was 25˚ in the experiment, because at current angle, mechanical failure of L2 group has been occurred).

Statistical analysis

Data collected from the synthetic femurs were analyzed using analysis of variance (ANOVA) followed by Tukey-Kramer *post-hoc* pairwise comparisons in SPSS 10.0 (IBM, Armonk, NY, USA). P-values less than 0.05 were considered as statistically-significant differences.

Results

The mean and standard deviation of the torque angles (˚) and torque values (Nm) for each group are shown in figure 7 and figure 8.

1. The mean value of the anti-torsional strength in the IM + AP group was greater than that in the IM group ($0.01 < P < 0.05$), which was statistically significant.
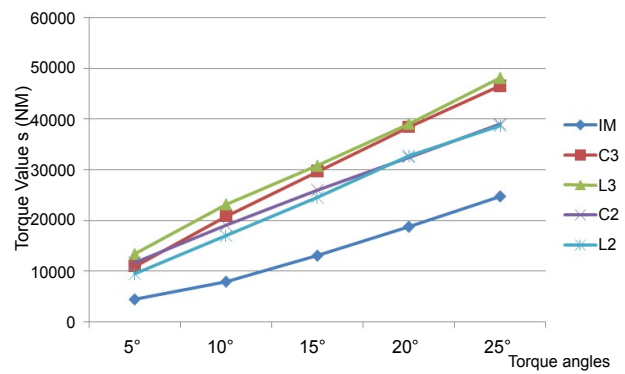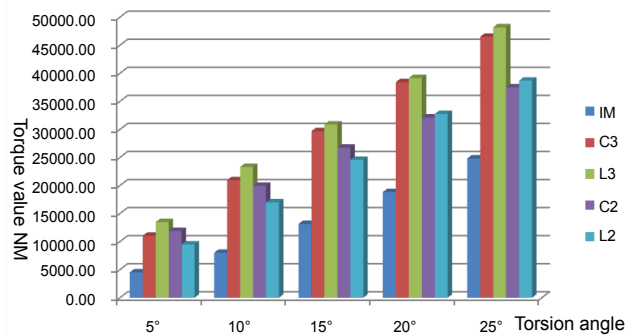
2. Based on the comparisons between the subgroups of IM + AP, the mean value of anti-torsional strength didn't show much difference. However, when the torsion angle turned to 25˚, the mean value in the C3 group was greater than the C2 group ($0.01 < P < 0.05$) which was statistically significant. When the torsion angle turned to 5˚, 10˚, 25˚, the mean values in the L3 group was greater than the L2 group ($0.01 < P < 0.05$), which was statistically significant. When the torsion angle turned to 20˚, 25˚, the mean value in the L3 group was greater than the C2 group ($0.01 < P < 0.05$), which was statistically significant (Table 2).

Discussion

The method of exchanging IM is considered as the golden standard treatment for femoral shaft fracture nonunion, with a cure rate of 72%-100% according to the literature [2,3]. However, Banaszkiewicz and Weresh et al. [4,5] reported high failure rates (73% and 58%) after treatment with this method. Park et al. [8,9] confirmed that the method of exchanging IM had higher failure rate for nonisthmal femoral nonunion, whose main reasons is its mechanical instability. In Ueng's study, it was discovered that IM was not able to provide enough rotational stability in nonisthmal femoral nonunion, rotational instability in fracture area is also observable during the operation.

Regarding the rotational instability of fracture site, Ueng [6] firstly proposed the method of retaining the original IM and plates with the autologous bone grafting treatment, which achieved the bone union in 17 patients. Soon afterwards, Park et al. also reported the same clinical efficacy. Zhang et al. [7] stated that the plate is mainly to improve the mechanical stability, as the mechanical instability is the main cause for the femoral shaft fracture nonunion. Retaining the original IM also guaranteed the axial stability and bending stability. Moreover, AP improved the rotational stability at the fracture ends, which provided the crucial mechanical elements for the local fiber cartilage calcification, and promoting callus preliminary connection.

Table 2: The pair wise comparisons between the subgroups of IM + AP

Torsion angle groups	5°	10°	15°	20°	25°
C3	11029 ± 2084	20936 ± 5235	2967 ± 7471	38426 ± 7933	46512 ± 6659
C2	11750 ± 2884	19145 ± 4007	2597 ± 4632	32496 ± 5648	39033 ± 8515
F	8.238	7.940	7.223	8.407	9.688
P-Value	0.122	0.718	0.394	0.095	0.034
L3	13479 ± 1680	23289 ± 3718	30878 ± 4432	39148 ± 5074	48194 ± 5343
L2	9500 ± 3616	16989 ± 5485	24579 ± 6275	32746 ± 6180	38687 ± 6559
F	8.238	7.940	7.223	8.407	9.688
P-Value	0.017	0.031	0.077	0.091	0.026
L3	13479 ± 1680	23289 ± 3718	30878 ± 4432	39148 ± 5074	48194 ± 5343
C2	11750 ± 2884	19145 ± 4007	25973 ± 4632	32496 ± 5648	39033 ± 8515
F	8.238	7.940	7.223	8.407	9.688
P-Value	0.133	0.232	0.235	0.065	0.014
L3	13479 ± 1680	23289 ± 3718	3087 ± 4432	39148 ± 5074	48194 ± 5343
C3	11029 ± 2084	20936 ± 5235	2967 ± 7471	38426 ± 7933	46512 ± 6659
F	8.238	7.940	7.223	8.407	9.688
P-Value	0.122	0.396	0.726	0.843	0.674
C2	11902 ± 2521	19944 ± 3902	26740 ± 4363	32105 ± 4969	37502 ± 8130
L2	9500 ± 3616	16989 ± 5485	24579 ± 6275	32746 ± 6180	38687 ± 6559
F	8.238	7.940	7.223	8.407	9.688
P-Value	0.129	0.289	0.529	0.860	0.767
C3	11029 ± 2084	20936 ± 5235	29679 ± 7471	38426 ± 7933	46512 ± 6659
L2	9500 ± 3616	16989 ± 5485	24579 ± 6275	32746 ± 618	38687 ± 6559
F	8.238	7.940	0.5291	8.407	9.688
P-Value	0.325	0.162	0.147	0.131	0.061

According to the study by Park et al., the torsional strength of retaining IM and plate group is 3.3 times stronger than the IM locking group. And in terms of bending strength, the former is 2.6 times stronger than the later one [9].

Based on the results from the present study, the torsional strength provided by 3-screw constructs (L3, P3) is stronger than that of 2-screw constructs (L2, P2). From the biomechanical study of Grawe B [10], it was proved that 3-screw non locking constructs is stronger than the 2-screw locking constructs. Stoffel et al. [11,12] found that the rotational stability mainly depends on the number of screws. They recommend using three screws on either side of the fracture for femoral and tibial fractures, which are mainly loaded in compression. At the same time, three or more screws are used for each main fragment, which didn't show much difference in its anti-torsional strength.

Nevertheless, when the same amount of screws is used, which one has stronger torsional strength, locking screws or non locking screws? According to the present study, two unicortical locking screw group has stronger torsional strength than the two bicortical common screw group; the three unicortical locking screw group also has stronger torsional strength than the two bicortical common screw group. But the two doesn't show any statistic significance; neither did previous literature reach a consensus conclusion. Verse et al. [13] reported that in 12 pairs of sheep tibia fractures fixed with either three locking or non-locking screws, there were no differences in four-point bending, torsion, or axial compression testing. However, these results were controversial. Fitzpatrick et al. [14] found that, in torsion and bending, the locked plating constructs provided a significantly lower stiffness and strength than the conventional constructs. They stated that the distance between the bone and locking plate eliminate their stability. Similarly, Stoffel et al. [15] reported that the locked constructs had a 26% lower torsional rigidity than the non-locked constructs, with no significant difference between the axial stiffness of the groups. On the other hand, Gardner et al. reported a subtle mechanical advantage of bicortical locked plating compared with conventional plating under torsional loading [16,17].

When choosing between using unicortical or bicortical screws in an anti-rotational plate for the fixation of the fracture site, we recommend using bicortical screws. The results of the present study suggest that unicortical screws may loosen more easily because of their weaker holding force to the bone, especially in patients with osteoporosis. Gautier et al. [18] realized that there must be sufficient cortical thickness when using unicortical locking screws to fix bone fragments to provide mechanical stability, especially in patients with osteoporosis. Roberts et al. [19] reported that unicortical locking screws were resulted in poor torsional stiffness, but an additional bicortical locking screw can increase the torsion stiffness by 58%.

According to the present study, the locking and non locking screws showed the different failure curves during mechanical testing. The rotation angle and torque at failure of the plate secured with non locking screws were less than those secured with locking screws. The torque curve increased steadily with the torsion angle in the locking group, but this trend was reversed in the non locking group, which may be explained by uneven loading at the interface between the plate and bone. The failure mechanism in the locking-screws group was due to the torsional stress that concentrated on the interfaces of both the screws and the bone with increasing torsion angle. Fracture occurred occasionally, but the screws often were unbroken. In the non locking constructs, there was often one or several loose screws at once, screw bending, or even screw rupture, with or without the fracture line.

This result of the study is significant in two perspectives. On the one hand, it proves the Anti-rotational plates provide not only the axial stability, but also anti-rotational stability on the fracture site. On the other hand, the reliable data contributes to the theoretical basis for the rational and standardized clinic use of anti-rotational plates, which provides clinicians with promising treatment options in the future.

There are some limitations in this mechanical experiment. Because this experiment was performed *in vitro* using model femurs, the conclusion may not be applicable to the human body. In addition, the small number of samples per group may have led

to errors in comparing the groups. Finally, because of the lack of certain corresponding instruments and some manual manufacturing variability, the model specimens in each groups had some differences. For example, the bicortical common screw was fixed by hands, which may cause the imbalance in either direction or strength.

Conclusions

1. The anti-torsional strength in the IM + AP group was stronger than that in the IM group.

2. The anti-torsional strength of 3-screw groups (L3, P3) was stronger than the 2-screw groups (L2, P2). When the number of the screws was the same, there was no significant difference between unicortical locking screws groups and bicortical common screws groups.

3. Reversed IM+AP with three unicortical locking and bicortical conventional screws gave the strongest fixation, suggesting it should be used in the clinic for treating femoral shaft fracture nonunion.

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