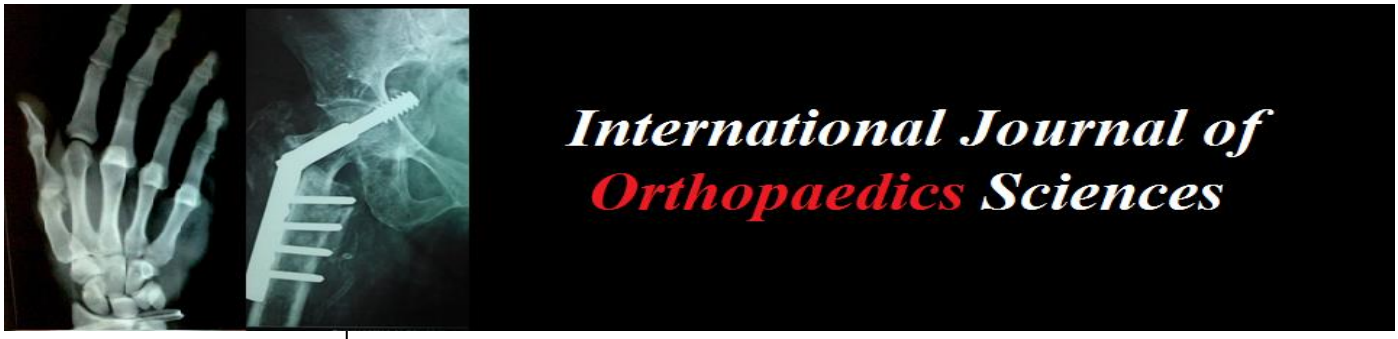

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Study of nonunion fracture shaft femur in cases treated by intramedullary nailing in adults

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Abstract
Background: For many kinds of fractures of femoral shaft, interlocking intramedullary nailing (IMN) is regarded as the most effective definitive therapy. The aim of this work was to study and evaluate the factors that lead to nonunion fracture shaft femur in adults treated by IMN.
Methods: The prospective and retrospective randomized study that carried out by 150 patients, with criteria of diaphyseal fractures shaft femur and closed fractures shaft femur. Antegrade nailing positioning the patient supine on a fracture table, skin traction was applied to the foot, that was put in a boot, the non-injured leg was positioned in hemi-lithotomy manner, abducted and flexed widely. Retrograde nailing: patient was put in supine position on fracture table with roll beneath the thigh to set the knee in a 30° flexed position, disinfect from above the iliac crest to the foot.
Results: 11 cases had nonunion (7.33%), and 139 cases achieved successful union (92.67%). There was statistically significant relation between nonunion and BMI (P = 0.004), Diabetes Mellitus (DM) (P = 0.003), using Non-steroidal Anti-inflammatory Drugs (NSAIDs) (P = 0.008), there was statistically significant relation between nonunion type of fracture, nail size (reamed vs unreamed) and delayed weight bearing (p<0.0001).
Conclusions: Nonunion occurred in 7.33% of ILN for fracture shaft femur. Overweight, DM, NSAIDs, type of fractures, nail insertion without reaming and delayed weight bearing had a statistically significant relation with nonunion of femoral shaft fractures that were treated by IMN.

Keywords: nonunion fracture, shaft femur, intramedullary nailing

Introduction
Fractures of femoral shaft are less common than other fractures of long bones. Many femoral shaft fractures are closed fractures, however open fractures of the shaft femur accounted for 23.2% of all fractures of the shaft femur that occurred in adults [1].
Causes of fracture shaft femur are mostly high velocity traffic accidents, falls from height, crushing and running over mechanisms [2]. These fractures lead to permanent and severe disabilities, such as rotational deformity, and limb shortening of the affected limb. In addition, other common complications include residual pain, infection, nonunion and delayed union [3].
Nowadays, the preferred method for treating fractures of the femoral shaft is intramedullary nailing (IMN) [4].
For the majority of femoral shaft fracture types, IMN is thought to be the most effective form of the ultimate treatment. As the rate of healed fractures is favorable with nailing, it offers robust fixation, rotational stability, and quickest return to functional condition [5]. Atrophic non-union is sometimes caused by avascular alterations at the site of fracture as a consequence of open fractures or open reductions, while hypertrophic non-union is caused by unstable fixation [6]. Although IMN is considered to be a well-recognized therapy for shaft femur fractures with a union rate ranging from 85% to 100%, non-union is a frequent issue for orthopedic specialists. To accomplish union, it often takes numerous actions, which raises the costs and worsens recovery [7].
One of the best surgical techniques is intramedullary nail fixation by closed reduction because it may offer an effective internal fixation with a tiny incision and without affecting the local blood supply at the site of the fracture.

Many factors may affect stability of fracture and union. These factors include surgical, patient, and fracture factors. Surgical factors such as degree of reduction which may be (anatomic or insufficient reduction), the method used to place the nail (retrograde or antegrade), and the nail's size (reamed or un-reamed). Patient factors such as nutritional and metabolic status, general health, level of activity, and tobacco smoking. Fracture factors such as fracture site (proximal or distal), and shape of fracture (transverse, oblique and spiral) which considered important variables affecting the internal fixation stability.

The achievement of improved surgical results and the prevention of non-union may result from a comprehensive knowledge of the components and their impact on the process of bone healing [7].

The purpose of this work was to study and assess the variables that lead to nonunion fracture shaft femur in adults treated by IMN.

Patients and Methods

This prospective and retrospective randomised work was performed on 150 individuals aged 18 years old or older, both sexes, with clinical criteria of diaphyseal fractures shaft femur and closed fractures shaft femur.

The Orthopedics Department' Ethical Committee gave its clearance before the research was carried out, Tanta University Hospital, Egypt from April 2020 to April 2021 for 94 prospective cases and since 2019 for 56 retrospective cases informed written consent was obtained from full counseling of participants in this research.

Criteria of exclusion were individuals under the age of 18, femur intra-articular fractures, pathologic fractures, and open femoral shaft fractures.

Preoperative: First aid was done: patients were admitted at hospital for further investigations, medical history taking and planning for operations, radiographic imaging of patients showed femoral shaft fracture.

Operative: Decision made for patients to fix their fractures by IMN, after confirming of patient viability of operation, patient prepared for operation.

Ante grade nailing: Was employed as the patient is positioned on their back on supine position upon a fracture table. The non-injured leg was in the hemi lithotomy position, extensively flexed and abducted, and skin traction was being administered to the foot, which was put in a boot, scrabbing of injured limb by betadine, the site of skin incision was located by palpating the greater trochanter, An incision of 3 to 5 cm was performed on the anatomical femoral bow's proximal extension, scissors was used to cut the fascia, then the gluteus muscle was divided along its fibers. Dissection was performed into the bone, a finger was introduced to feel the greater trochanter, the point of entry of the greater trochanter was confirmed by AP and lateral views with an imaging intensifier, the path was initiated with an awl, a firm reamer was introduced for widening the medullary canal, and a guiding wire was introduced at a slightly oblique angle across the medullary canal.

Once the tissue protector had been implemented, the reaming shaft with the first reamer head was introduced over the wire used as a guide and progressed into the distal primary fragment till it was approximately 5 mm proximal to the intercondylar notch. This was done to avoid eccentric reaming and subsequently nail malposition that could cause valgus, varus, antecurvatum, and retrocurvatum malalignment.

With a 9mm medullary reamer as the starting point, reaming was carried out sequentially, rising by 0.5mm each. Adequate reaming must be carried out in order to accommodate for smooth nail implantation. A radiographic ruler was used to measure the length of the nail, with the tip placed in the middle of the femur distal end. The greater trochanter tip was not used to determine the length of the nail; instead, the insertion handle was attached to the nail with the matching connection screw. The nail was manually placed, turned around 90 degrees from its entrance site to its ultimate position, controlled by the image intensifier, forced down to the fracture zone, and then fully entered. To offer and preserve rotational length and stability, locking screws were added.

Retrograde nailing: The patient was lying on a fracture table with a roll beneath the thigh to maintain the knee flexed by 30 degrees. A 2 cm incision in the skin was performed longitudinally immediately distal to the inferior pole for sterilization across the iliac crest to the foot, To introduce a guide wire, the medial parapatellar soft tissues were stretched longitudinally along the patellar tendon using scissors, and the tendon was softly retracted laterally, The entrance site was selected using an image intensifier; the wire used for guidance should be positioned in the prolongation of Blumensaat's line on the lateral view and in the centre of the intercondylar notch on the AP view, The guide wire was introduced up to the region of the greater trochanter, and the entry site of the nail was located in alignment with the medullary canal axis, just beneath the intercondylar notch' crest, radiographic ruler and guide wires, with the ruler tip placed at the piriformis fossa, were used to measure nail length, the ceiling of the intercondylar notch at the femur distal end should be situated where the nail's length should be measured. A reaming shaft with the first reamer head was put over the guiding wire, starting with a 9mm medullary reamer, the reaming was carried out in successive stages, rising by 0.5mm each. In order to accommodate for a smooth nail insertion, the reaming must be carried out one or two increments exceeding the desired nail diameter, Following the best possible reduction of the fracture, the distal fragment was initially locked using the targeting device coupled to the insertion handle. After making sure the distal end of the nail is in the right place beneath the image intensifier, proximal locking is carried out.

Postoperative: Full weight bearing was done with a walker or crutches, mobilization began on postoperative day 1 even though there were further injuries or difficulties, Regular short-term evaluations of wound healing were conducted over the first 2 weeks. Following that, radiographic pictures were taken at 6, and 12 weeks to preserve reduction and track healing progress.

Statistical analysis

Stata® version 14.2 (Stata Corp LLC, College Station, TX, USA) was used to analyze the data. Utilizing the Shapiro-Wilk test, the normality of the distribution of numerical information was evaluated. The numerical information that were not normally distributed were given as medians and interquartiles, and the Wilcoxon rank sum test or the Kruskal-Wallis test were used to assess intergroup variation (for two-group comparisons or multiple group comparisons, respectively). Multiple ordered groups were compared using

the Jonckheere-Terpstra trend test. With the aid of the Bonferroni correction for multiple comparisons, the Conover post hoc test was employed for pair-wise comparisons after the Jonckheere-Terpstra test or the Kruskal-Wallis test, if required.

Results:

By clinical examination of all cases on arriving to emergency department and x ray demanded, we found various types of fracture patterns of all cases. Table 1

Table 1: Demographic and fracture data of all cases (n = 150)

Descriptive Statistics	BMI	35.433±9.579
	Age	29.562±4.121
Gender (N %)	Male	108 (72.00)
	Female	42 (28.00)
	Total	150 (100.00)
Nonunion (N %)	Yes	11(7.33)
	No	139 (92.67)
Diabetes (N %)	Yes	22 (14.67)
	No	128 (85.33)
Smoking (N %)	Ex-Smoker	13 (8.67)
	Smoker	59 (39.33)
	Non-smoker	78 (52.00)
	Total	150 (100.00)
NSAIDs	Yes	43 (28.67)
	No	107 (71.33)
Type of fracture	Transverse	102 (68.00)
	Oblique	16 (10.67)
	Bending wedge	11 (7.33)
	Spiral wedge	8 (5.33)
	Simple spiral	7 (4.67)
	Complex irregular	4 (2.67)
	Fragmented wedge	2 (1.33)
	Total	150 (100.00)
Multiple fractures	Yes	17 (11.33)
	No	133 (88.67)
Nail insertion	Antegrade	139 (92.67)
	Retrograde	11 (7.33)
	Total	150 (100.00)
Nail size	Reamed	132 (88.00)
	Unreamed	18 (12.00)
	Total	150 (100.00)
Delayed weight bearing	Yes	25 (16.67)
	No	125 (83.33)

No statistically substantial correlation was existed among nonunion and gender, age, smoking but a statistically substantial correlation was existed among nonunion and BMI, DM and using NSAIDs. Table 2.

Table 2: Relation between nonunion and gender, age, BMI, DM, smoking and NSAIDs

		Nonunion (n=11)		p-value
		Yes	No	
Gender N (%)	Male	7 (63.64)	101 (72.66)	0.521
	Female	4 (36.36)	38 (27.34)	
	Total	11 (100.00)	139 (100.00)	
Age (years)		32.182±10.008	35.691±9.534	0.243
BMI		32.955 ±4.520	29.294±3.983	0.004*
Diabetes N (%)		5 (45.45)	122 (87.77)	0.003*
Smoking N (%)	Ex-Smoker	0 (0.00)	13 (9.35)	0.402
	Smoker	6 (54.55)	53 (38.13)	
	Non-Smoker	5 (45.45)	73 (52.52)	
NSAIDs N (%)		7 (63.64)	4 (36.36)	0.008*

A statistically substantial correlation was existed among non-union and type of fracture, but no statistically substantial correlation was existed among non-union and multiplicity of fractures. Table 3

Table 3: Relation between nonunion, type of fracture and multiple fractures

Nonunion (n = 11)			p-value
Type of fracture	Transverse	2 (18.180	<0.001*
	Oblique	0 (0.00)	
	Bending wedge	4 (36.36)	
	Spiral wedge	3 (27.27)	
	Simple spiral	0 (0.00)	
	Complex irregular	1 (9.09)	
	Fragmented wedge	1 (9.09)	
Multiple fractures	Yes	2 (18.18)	0.457
	No	9 (81.82)	

There was no statistically significant relation between nonunion and nail insertion, but there is statistically significant relation between nonunion, nail size and delayed weight bearing Table 4.

Table 4: Relation between nonunion, nail insertion, nail size and delayed weight bearing

Nonunion N (%) (n = 11)			p-value
Nail insertion	Antegrade	9 (81.82)	0.152
	Retrograde	2 (18.18)	
Nail size	Reamed	6 (54.55)	<0.001*
	Undreamed	5 (45.45)	
Delayed weight bearing	Yes	6 (54.55)	<0.001*
	No	5 (45.45)	

Discussion

Femoral shaft fracture non-union is a complex procedure, and the impact of associated risk factors may change depending on the kind of therapy used and the patient's individual features, especially in the middle age group [8].

The study showed that 10 cases (62.5%) with fractures type 32A and 6 cases (37.5%) with fractures type 32B. No statistically substantial correlation was existed among the type of fracture and nonunion. Taitsman, *et al.* [9] showed 46 cases diagnosed with nonunions (4.1%) were seen among the 1,126 patients with fractures of the femoral shaft who underwent intra-medullary nailing (IMN). These cases were 32 male (70%) and 13 female (30%). Gender showed no statistical significance. Their mean age was 35.4 years, and their ages varied from 16 to 60. age was not a statistically significant factor. 27 cases (59%) were smokers and diagnosed nonunion. There was a statistically significant relation between nonunion and smoking. 18 cases (39%) with fractures type 32A according to AO/OTA classification, 17 cases (37%) with fractures type 32B and 11 cases (24%) with fractures type 32C. No statistically substantial correlation was existed among type of fracture and nonunion. 38 cases (83%) with antegrade insertion of the nail and 8 cases (17%) with retrograde insertion of the nail. No statistically substantial correlation was existed among antegrade or retrograde insertion of IMN and incidence of nonunion.

Ma YG, *et al.* [7] shown that closed fracture reduction and fixation with an interlocking IMN were used to treat 425 individuals who have closed fractures of the femoral shaft in skeletally mature individuals. They had a 37.6 average age and were made up of 254 men and 171 women. Antegrade insertion of nail was done in 334 patients, while 91 patients were treated by retrograde nail imsetion. Reaming of medulla

was done in 243 cases, while unreaming of medulla was done in 182 instances. Among them, 12 cases had been diagnosed with diaphyseal non-union, consisting of 9 men and 3 women. Kim JR, *et al*. [10] examined a sample of 35 individuals who had interlocking intramedullary nailing-related femoral shaft non-union. 26 men and 9 women were present. On 29 and 6 instances, respectively, IMN with and without reaming was carried out. No statistically substantial variation was existed in the bony union period with regard to gender, age, and reaming (or non-reaming). Regarding smoking, A statistically substantial variation was existed in the bony union among smokers and nonsmokers.

Wu, Kuan-Jou, *et al*. [8] demonstrated that 16 instances diagnosed nonunion, 10 men (62.5%) and 6 women (37.5%). While Taitsman LA, *et al*. [9] showed 32 male (70%) and 13 female (30%). Ma YG, *et al*. [7] showed 12 cases diagnosed nonunion, 9 were males and 3 were females. Kim JR, *et al*. [10] showed 35 patients diagnosed with nonunion 26 men and 9 women. Gender showed no statistical significance in all of them. In our study, 11 cases were diagnosed nonunion. 7 of them were males (63.6%) and 4 females (36.4%) that showed also not statistically significance. Wu, Kuan-Jou, *et al*. [8] reported that age was a statistically substantial parameter for nonunion, 3 cases (18.8%) below 50 years old and 13 cases (81.2%) above 50 years old. While Taitsman LA, *et al*. [9] and Kim *et al*. [10] showed that age was not a statistically substantial parameter as in the study of Taitsman LA, *et al*. [9], ages ranging from 16 – 60 years old with mean age 35.4 and in the study of Kim JR, *et al*. [10] the average age was 38.3 (ranged from 20 to 67). In our study, age was not a significant factor as the ages of cases diagnosed nonunion ranged from 19 – 47 years old with mean age 32.18. Studying of obesity factor in of Body mass index (BMI) of cases in our study showing that cases underwent nonunion were BMI range from 24.6 to 38.3 and mean was 32.955, which was a statistically significant factor. While Wu, Kuan-Jou, *et al*. [8] showed 5 cases (31.3%) with normal BMI and 11 cases (68.7%) were overweight and this was not a statistically significant for nonunion. Relation between nonunion and DM was showed by Wu, Kuan-Jou, *et al*. [8] as statistically significant as 10 cases (62.5%) had DM and diagnosed nonunion. Also, in our study DM showed a statistically significant relation with nonunion by 5 cases (45.45%) had DM.

Taitsman LA, *et al*. [9] and Kim JR, *et al*. [10] reported a statistically significant relation between nonunion and smoking by 27 cases (59%) smokers and diagnosed nonunion in the study of Taitsman LA, *et al*. [9] While in the study of Kim JR, *et al*. [10], there was 27 patients (77.1%) were smokers.

Wu, Kuan-Jou, *et al*. [8] showed no statistically significant relation by 5 cases (31.2%), and as 9 cases (56.2%) used Non-steroidal Anti-inflammatory Drugs (NSAIDs) for more than one month. In our study, we showed no statistically substantial relation among nonunion and smoking in 6 cases (54.55%) and showed statistically significant relation with nonunion by 7 cases (63.64%) used NSAIDs for long period. While Taitsman LA, *et al*. [9] showed 18 cases (39%) with fractures type 32A according to Arbeit gemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification, 17 cases (37%) with fractures type 32B and 11 cases (24%) with fractures type 32C. Wu, Kuan-Jou, *et al*. [8] showed that 10 cases (62.5%) with fractures type 32A and 6 cases (37.5%) with fractures type 32B. all of these studies showed no statistical significant relation between type of fracture and nonunion. In our study, we showed a statistically significant relation by presenting 2 cases (18.18%) with transverse fractures (type 32A), 8 cases (72.72%) with fractures type 32B and only one case (9.09%) with fracture type 32C.

Taitsman LA, *et al*. [9] and Ma YG, *et al*. [7] reported that there was not a statistical significant relation between antegrade or retrograde insertion of Intramedullary nailing (IMN) and incidence of nonunion by showing in the study of Taitsman LA, *et al*. [9] that 38 cases (83%) with antegrade insertion and 8 cases (17%) with retrograde insertion. While in the study of Ma YG, *et al*. [7], Only 2 cases were retrograde nail insertion and in 10 cases nails were inserted antegradely. In our study, we also showed that there was not a statistically significant relation between antegrade or retrograde insertion of IMN and incidence of nonunion by showing that 9 cases (81.82%) with antegrade insertion and 2 cases (18.18%) with retrograde insertion.

To achieve widening of medulla and insertion of a well fit bigger nail, reaming of medulla is done. Ma YG, *et al*. [7] showed that nonunion was correlated significantly with unreamed nails by 7 cases were done unreamed and 5 cases were reamed before nail insertion. While Kim JR, *et al*. [10] showed no statistically significant relation by 29 cases with reaming and 6 cases were unreamed. We showed in our study a statistically significant relation between size of nail and incidence of nonunion by 6 cases (54.55%) were reamed and inserted with a well fitted nail and 5 cases (45.45%) were unreamed.

Conclusions

The gold-standard procedure for treating femur shaft fractures is intramedullary nailing (IMN). Although high union rates of IMN for fractures of femoral shaft, nonunion is still a common problem that occurs. Nonunion is defined as failure of the fracture to heal or lack of signs of healing for six to nine months. A number of risk factors are thought to be necessary for the onset of fracture nonunion, which is a complex condition. These risk factors could be general factors and related to patient such as age, gender, DM, smoking, obesity and taking NSAIDs, and local risk factors that related to fracture type and surgical skills like type of fracture according to AO/OTA classification of femoral shaft fractures, nail size (reamed or unreamed), insertion of nail (antegrade or retrograde), multiplicity of fractures and delayed weight bearing. In our study that was done on 150 cases diagnosed with femoral shaft fractures and treated by IMN, 11 cases had not achieved full union and were diagnosed with nonunion. By studying the risk factors that could be contribute to nonunion, we found that overweight, DM, NSAIDs, type of fractures, nail insertion without reaming and delayed weight bearing had a statistically significant relation with nonunion of femoral shaft fractures that were treated by IMN.

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