Evaluation of Rotational Malalignment after Intramedullary Nailing of the Femur
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ABSTRACT
Background: In many hospitals, closed interlocking intramedullary (IM) nailing is the recommended method of therapy for most femoral shaft fractures. Nails that are locked retain length and offer rotational stability in comminuted or segmental fractures. However, there are certain disadvantages to such a technique; any alignment issues that existed before the interlocking will continue. Even with expertise, rotational alignment mistakes can happen. The main objective of our study is to determine the incidence and degree of rotational malalignment. Also, we aimed to determine the patient’s complaints concerning pain, daily activities, and the ability to propose a technique to avoid rotational.

Patients and method: Thirty-three patients who had received intramedullary nailing for a unilateral femoral fracture were included in the study. Patients were divided into 2 groups: group A (16 patients) used the profile of the opposing lesser trochanter to measure rotation during intramedullary nailing, and group B (17 patients) used intraoperative clinical assessment to measure rotation during intramedullary nailing. Results: The findings showed that in group A, 7 patients (48.5%) had actual rotational deformity, 5 patients (31.3%) had potential rotational deformity, and 4 patients (25.0%) had no rotational deformity. In contrast, in group B, 3 patients had no rotational deformity (17.6%), 5 patients had potential rotational deformity (29.4%), and 9 patients had actual rotational deformity (52.9%).

Conclusion: After intramedullary repair of femur fractures, a radiographic technique that uses the profile of the contralateral lesser trochanter as a reference may be useful in decreasing rotational malalignment.

Keywords: Femur, fracture, malalignment, intramedullary nail, clinical trial, Assiut University.

INTRODUCTION
Adult femoral shaft fractures are now often treated with intramedullary (IM) nailing. Because of the little dissection, tiny incision, efficient fracture healing and quick patient recovery, intramedullary nailing is appealing. Rotational control is a drawback of IM nailing compared to plate fixation, which is one reason why plating still plays a significant role in the management of femoral non-unions (1).

Radiography can detect and evaluate a torsional difference between the damaged and unaffected side. The approach that is most frequently used to evaluate rotational malalignment clinically has been reported to have poor accuracy (2).

Because of the precise patient positioning requirements, the X-ray method is challenging to employ. The most reliable techniques are computed tomography (CT) and ultrasound (3).

The main objective of our study is to determine the incidence and degree of rotational malalignment. Also, we aimed to determine the patient’s complaints concerning pain, daily activities, and the ability to propose a technique to avoid rotational.

PATIENTS AND METHOD
This research is a prospective randomized controlled clinical trial; randomization using the concealed envelop technique. Thirty-three patients with unilateral femoral shaft fractures were reamed antegrade from January 2014 to July 2016. All participants received intramedullary nailing for a unilateral femoral fracture. Patients were divided into 2 groups: group A (16 patients) used the profile of the opposing lesser trochanter to measure rotation during intramedullary nailing, and group B (17 patients) used intraoperative clinical assessment to measure rotation during intramedullary nailing.

- **Inclusion criteria:** Adult patient with unilateral fracture shaft femur treated with antegrade intramedullary femoral nailing without fracture table.
- **Exclusion criteria:** Bilateral fracture femur, ipsilateral or contralateral fracture of lesser trochanter, ipsilateral or contralateral fracture neck of femur or lower end femur fracture, ipsilateral or contralateral fracture hip or knee arthroplasty. Patient is unfit for surgery, Ipsilateral patellar or ankle fractures, ipsilateral or contralateral fracture femoral deformity, ipsilateral or contralateral fracture femur surgery, ipsilateral or contralateral hip or knee disease. Also, patients who refused to participate in the study were excluded from our analysis.

Classification of femoral shaft fractures: Fractures were categorized based on fracture geometry (AO Classification 1991) (4) and fracture comminution (Winquist-Hansen Classifications, 1984) (4).

Methods:
The cases were checked into EL-EMAN general hospitals’ trauma center. A comprehensive general and local examination was conducted after obtaining the history. First, a general examination was conducted to evaluate vital signs and rule out any other skeletal and/or extra-skeletal injuries that may be present. To confirm the diagnosis of femoral fractures and determine the wounded limb's neurovascular condition, a local examination was required. The standard treatment for these injuries was open fractures. Plain X-ray examinations and other radiological modalities,
such as plain x-ray chest, stomach sonography, and/or brain Computerized Tomography (CT) in patients with multiple injuries, were carried out as necessary based on the patient's condition. The interval between a trauma and surgery was measured.

**Surgical technique:**

In our study, spinal anesthesia was administered to every patient. On a radiolucent surgical table, the patient was laid supine. To guarantee appropriate vision in both the antero-posterior and lateral views, the C-arm fluoroscopy equipment was used to evaluate the whole limb while it was positioned on the side opposite the surgeon. Make an incision about 3 cm above the GT, parallel to the femur (move incision superior if patient obese). Use a cautery to cut through subcutaneous tissue and a sharp dissection tool to cut through the fascia lata to reach the greater trochanter, and then palpate the tip of the greater trochanter.

Select and mark the starting location of the guide pin; the piriformis starting point is located on the piriformis fossa. Use fluoroscopy to verify the gazing point. Check biplanar pictures by inserting a guide pin into the lesser trochanter. Put the soft tissue protection in place, then press the entrance reamer until the reaming is parallel to the femur. Use traction on the affected extremity to reduce the fracture before nailing it. External manipulation can be used to lessen fracture. To reduce fracture, a reduction tool could be required. A head-up guide pin used a T-handle to manually advance a lengthy guide wire past the fracture location. Look into biplanar imaging utilize a ruler intraoperatively to gauge the optimum nail length.

Intramurcular canal reaming: Ream up between 0.5 and 1.0mm with each reamer after starting with a size 9mm reamer. About 1.5 mm above the final nail's size is reamed. Keep on drilling in the canal (avoids incarceration of reamer head). Build a nail, place it on the back of the table, and make sure the aiming guide corresponds to the nail's holes. Insert the nail over the guide wire and into the intramedullary canal, following the anterior bow of the femur. As soon as the nail is placed, spin the handle so that it is facing up and parallel to the femur. Hold the nail by the handle rather than the aiming aid. Inside the medullary canal, a forward nail. To prevent iatrogenic comminution or the potential formation of additional fracture lines while using the mallet, manually move the nail past the fracture site. Check the seating in the nail by fully inserting it and sitting in distal femur.

The ideal radiographic image to evaluate nail implantation is a lateral radiograph of the knee. Next, the guide rod was taken out. A centralizer was then put together after the distal targeting and aiming devices were joined. Using the suitable standard fixed aiming device, distal locking was accomplished. Both screws could be inserted through a single 2-cm incision that was made from bone to skin and through the iliotibial band. After inserting the proper drill sleeve, a 4.1 mm drill bit was used to drill both cortices.

The nail system we employed in our series comprises a proximal targeting tool for inserting proximal locking bolts, which were done so from the lateral to the medial, once the distal locking screws have been inserted. Both screws could be inserted through a single 2-cm incision that was made from bone to skin and through the iliotibial band. The correct drill sleeve was then installed, and a 4.0 mm drill bit was used to drill both cortices before a 5.0 mm proximal locking bolt was placed (s). When two proximal locks were inserted, we referred to it as static locking; when one proximal lock was inserted, it was termed dynamic locking.

Before closure under suction drainage, the joint was carefully irrigated. In an effort to prevent heterogeneous bone development, bony debris from the hip was washed away. An absorbable suture was used to seal the iliotibial band. Non-absorbable sutures were used to seal the skin, and then the incisions for the locking screws were closed. The limbs were covered in a thick layer after surgery.

Patients received postoperative care and were monitored until they had fully healed their fractures and had a functional range of motion in their knees. The Harris Hip Score, Tegner-Lysholm Knee Scoring Scale, and Neer's Score were used to evaluate the results.

**Ethical consent:**

The Academic and Ethical Committee of the National Heart Institute approved the study. Each patient completed a written informed consent form to accept the procedure and take part in the trial. The Declaration of Helsinki, the code of ethics of the World Medical Association, was followed when conducting this research on humans.

**Statistical Analysis**

First, the data were checked using the Anderson-Darling test for normality and for homogeneity variances. Number and percentage (N, %) were used to represent categorical variables, whereas the mean and standard deviation were used to express continuous variables (Mean, SD). When comparing categorical variables, the chi-square test and the fisher exact test are employed, whereas the student’s t-test is used to analyses continuous variables. Statistical significance was defined as a two-tailed p ≤0.05. The IBM SPSS version 20.0 program was used for all analyses.

**RESULTS**

As shown in table 1, participants were split into two groups for the purposes of the current study, with a significant difference between group A and group B in terms of age distribution (p=0.02) and an insignificant difference in terms of laterality (p=0.55).

According to the Winquist classification, which was used to rate the fracture's comminution, group A (which included 16 patients) had the preponderance of type I (50%) and type II (31.2%) fractures. The bulk of the fractures in group B (17 patients) correspond to type I (41.2%) and type II (23.5%) patients, with negligible
differences. The bulk of fractures in group A (16 patients) fall into types A3 (50%) and B2 of the AO classification (31.3%). While the bulk of the fractures in group B (17 patients) belonged to individuals with type B2 (29.4%) and type A2, B3 (17.6%) with negligible differences.

Regarding the mechanism of damage in group A (16 patients), all (100%) of the patients' injuries were caused by automobile accidents. While in group B (17 patients), the mechanism of injury was a road traffic accident in 52.9% of cases, a firearm injury in 17.6% of cases, a fall to the ground in 11.8% of cases, a fall from a height in 11.8% of cases, and a patient being kicked by an animal in 5.9% of cases. This difference between groups A and B was significant (p=0.04).

In group A (16 patients), all (100%) of the patients who had closed fracture reduction experienced success. Group B (17 patients) had closed reduction performed on 41.2% of patients, while open reduction was performed on 58.8%. Significant differences between group A and group B in terms of the reduction approach were found (p=0.000).

Distal targeting devices were effectively employed in 13 of the 16 patients in group A (81.2%), while the "Free Hand Technique" was used in 3 of the patients (18.8%). In contrast, group B (17 patients) saw the effective use of the distal targeting device in 12 patients (70.6%) and the "Free Hand Technique" in 5 patients (29.4%). Distal locking procedures had no statistically significant difference between group A and group B (p=0.47). There were 6 surgeries (37.5%) with dynamic locking in group A (16 patients), compared to 10 procedures (62.5%) with static locking. While there were 4 surgeries (23.5%) with dynamic locking in group B (17 patients), there were 13 procedures (76.5%) with static locking. As for the proximal locking technique, there is no statistically significant difference between groups A and B (p=0.91).

Following a follow-up period of 3 to 32 months, with an average of 8.440.94 months, time to partial weight-bearing (PWB) was measured to be on average 3.82.1 weeks (ranged from 0 to 6 weeks). Partial Weight-Bearing (PWB) averaged 2.8 2.2 weeks in group A whereas 4.8 1.6 weeks in group B, with a significant difference between the two groups with regard to PWB (p=0.004). While the combined fractures' average time to full weight-bearing (FWB) was 9.5 to 9.1 weeks (ranged from 6 to 40 weeks). There was a significant difference between group A and group B in terms of FWB (p=0.048), with full weight bearing (PWB) in group A averaging 6.30.7 weeks and in group B 12.512.1 weeks.

In our series, patients were classified as having true rotational deformity if their limp was rotated by less than 15 degrees, as having possible rotational deformity if their limp was rotated by between 10 and 15 degrees, and as not having any rotational deformity if their limp was rotated by more than 10 degrees. According to the findings, in group A, 7 patients (48.5%) had actual rotational deformity, 5 had potential rotational deformity (31.3%) and 4 had no rotational deformity (25%). In contrast, there was no statistically significant difference between group A and group B in terms of rotational deformity (p=0.83) in group B, where 9 patients (52.9%) in that group had true rotational deformity, 5 patients (29.4%) had possible rotational deformity, and 3 patients (17.6%) had none.
In patients without rotational deformity, the findings revealed that 4 (57.1%) patients had outstanding ratings, 3 (42.9%) patients had good scores, and none of the patients had fair or bad scores. Three (30%) individuals obtained good scores, 7 (70%) had outstanding scores and none had fair or poor ratings among patients who may have had rotational deformity. Also, among patients with real rotational deformity, 9 (57.1%) had outstanding scores, 3 (18.8%) had good scores, 1 (6.3%) had fair scores, and 3 (18.8%) had bad scores, with no statistically significant correlation between Rotational deformity and Tegner-Lysholm Knee Scoring Scale (p=0.452) (Table 3).

The findings of the NEER Score test indicated that in group A, 13 (81.2%) patients had outstanding scores, 3 (18.8%) patients had adequate scores, and none had unsatisfactory scores. While in group B, 5 (29.4%) patients received outstanding scores, 9 (52.9%) patients received adequate scores, and 3 (17.6%) patients received bad scores, there was a significant difference between group A and group B in terms of NEER score (p=0.009).

| Table 3. Relationship between Tegner Lysholm Knee Scoring Scale and rotational deformity |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Tegner Lysholm Knee Scoring Scale | Deformity | P-value |
|                                 | No | %   | Possible | No | %   | True rotation | No | %   |
| Poor                            | 0  | 0.0 | 0        | 0  | 0.0 | 3              | 18.8 |
| Fair                            | 0  | 0.0 | 0        | 0  | 0.0 | 1              | 6.3  |
| Good                            | 3  | 42.9| 3        | 30 | 30.0| 3              | 18.8 |
| Excellent                       | 4  | 57.1| 7        | 70 | 70.0| 9              | 56.3 |

Figure 1. Relationship between NEER score and rotational deformity

The findings revealed that among patients who did not have rotational deformity, 5 (71.4%) received outstanding scores, 1 (14.3%) patient received good scores, and 1 (14.3%) patient (poor scores) received unsatisfactory scores. When it came to patients who could have rotated, 7 (70%) patients received great scores, 3 (30%) patients received adequate scores, and none of the patients received subpar scores. Additionally, of the patients who had real rotational deformity, 6 (37.5%) patients had outstanding scores, 8 (50%) patients had good scores and 2 (12.5%) patients had unsatisfactory scores; the link between NEER score and Rotational deformity was negligible (p=0.31) (Figure 1).

In cases treated with open reduction and IMN, the association between deformity and manner of reduction of fracture revealed that 2 (20%) patients had no rotational deformity, 3 (30%) patients had potential rotational deformity, and 5 (50%) patients had actual rotational deformity. In cases treated with closed reduction and IMN, there was no significant correlation between reduction technique and rotational deformity (p=0.991); 5 (21.7%) patients had no rotational deformity, 7 (30.5%) patients had possible rotational deformity, and 11 (47.8%) patients had true rotational deformity.

Relationships between deformity and proximal locking revealed that there was no significant relationship between proximal locking technique and rotational deformity (p=0.69), and the relationship between deformity and distal locking revealed no significant relationship between those two (p = 0.259).
DISCUSSION

In the current study, we sought to ascertain the prevalence and severity of rotational malalignment as well as the patients’ complaints of discomfort and daily activities, with the hope of developing a method to prevent rotational malalignment.

After IM nailing of femoral shaft fractures, studies employing clinical evaluation found a very low frequency of rotational malalignment. Wiss et al. (15) discovered 7 percent more than 1, but Kempf et al. (11) and Johnson and Greenberg (12) found none. One patient out of 123 was identified by Alho et al. (14) to have a rotational malalignment of more than 20. This low incidence might be due to the inaccuracy of the clinically established femoral rotational deformity (13-17).

The prevalence of rotational malalignment was found to be greater in studies employing CT or ultrasonography. Sennerich et al. (18) (using CT) showed that in a group of 45 patients who were all given an intramedullary nail for a femoral fracture, there were 40% more than 10° and 16% more than 20% of fractures. With the use of ultrasonography, Braten et al. (19) evaluated a sample of 110 patients who had received a femoral nail and discovered rotational malalignment in 43 percent and 15 percent more patients, respectively, than expected. Patients in our series who had a rotational discrepancy of around 30 decline corrective surgery. Another drawback of the current study is that the functional scores were employed despite being intended and validated for conditions other than femoral malalignment since there were no other appropriate evaluation instruments available. This is still another drawback that has to be taken into account. Rotational variations between the two femora of up to 10 degrees are regarded as physiological. Theoretically, one patient may have a difference of just 5° from before the femoral fracture and be identified as having a rotational malalignment (15), whereas another patient may have a difference of 24° from before the femoral fracture and not be identified as having a rotational malalignment of the femur. This will continue to be a concern since CT measures of the patient’s femoral rotation taken prior to the femoral fracture are typically not accessible.

CONCLUSION

Radiographic techniques may be useful in decreasing rotational malalignment following intramedullary repair of femur fractures (using the profile of the contralateral lesser trochanter as a reference).

RECOMMENDATIONS

For patients with IMN of the femur, we urge regular early post-operative CT scanning to assess post-operative femoral rotation. However, further research is still needed.

Financial support and sponsorship: Nil.
Conflict of interest: Nil.

REFERENCES