Comparison of the clinical results of closed intramedullary nailing in femoral shaft fractures between 1997-1999 and 2015-2019

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Abstract
Aim: In this study, we aimed to show the changes in treatment principles and factors affecting healing by comparing the previous clinical results of the antegrade closed intramedullary nail (ACIMN) application with the current clinical results in the treatment of Femoral Shaft Fractures (FSF).

Material and Methods: Patients who underwent ACIMN due to FSF were named Group A (years 1997-1999) and Group B (years 2015-2019). Group A consisted of 25 patients, with a mean age of 41 years, and a mean follow-up of 29.1 months. Group B consisted of 17 patients, with a mean age of 51 years, and a mean follow-up of 22.3 months. Patients with pathological fractures, polio sequelae, cerebral palsy and pelvic fractures were excluded from the study. The clinical length of stay and operation processes of the groups were followed. Evaluations were made according to Thoresen criteria.

Results: In Group A, it was observed that union was sufficient in the clinical and radiological examinations of 17 patients who came for control. In Group B, of the 15 patients, 13 had complete union and 2 patients had delayed union. The mean between operation and trauma (days) in Group A was found to be significantly higher than in Group B (p = 0.0001). The mean operation time (min) in Group A was found to be significantly lower than Group B (p = 0.0001). No significant difference was observed between the Thoresen criteria distributions of both groups (p = 0.52).

Discussion: The ACIMN technique continues to be the preferred method in FSF. While there were no significant changes in etiology, frequency and treatment principles, improvements were observed in the structure, design and locking methods of implant materials. Significant improvements were observed in the preoperative waiting periods and operation times of the patients. We can attribute these developments to improved clinical conditions and increased surgical experience. Despite all the developments, there was no significant difference in the basic principles of the surgical technique and clinical results. We think that more comprehensive studies using different treatment modalities and more patient numbers are needed in the future.

Keywords
Femoral Fractures; Nailing; Intramedullary Nailing; Osteosynthesis

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Closed intramedullary nailing in femur fractures

Introduction

FSF, which constitutes 8% of all fractures, occurs with high-energy trauma (traffic accident, falling from height) [1,3,6,7,12,15]. It is a cause of high mortality and morbidity as it causes fat embolism and Acute Respiratory Distress syndrome [10].

The first IMN application started with Küntcher in 1940 and in the following years different researchers developed their own nails (Klemm –Shellman 1972, Grosse –Kemps 1978, Hucksetp 1979) [2,5,9,14]. It has been reported that a force of 280 newton meters is required to fracture the femur, and forces above this value spread to soft tissues [8,11].

The currently accepted classification of femoral fractures is the AO classification, and a coding system is used to describe the type of fracture that results in 27 different models [24]. (3 = femur, 2 = diaphysis). In our study, the fracture types of the patients were 3.2.A and 3.2.B.

These fractures have a high potential for union and a low rate of pseudoarthrosis [3,7,11,4,22,25]. The aim of treatment is to achieve union by providing anatomic length and axis with early mobilization [7,12]. Rapid union after closed intramedullary nailing is due to excessive collateral circulation around the femoral shaft. High rates of union and low infection rates have been reported with the use of closed nailing techniques [4,7,11].

Static locking should be used in segmental fractures to prevent shortening and rotation. Since static locking will delay fracture union, it should be dynamized 8 to 12 weeks after the operation [2,5,8,13,17,21].

Reamerization increases the stability of the fracture line by providing a larger contact surface between the bone and nail, so a larger diameter stronger nail can be placed. Additionally, endosteaal blood flow is stimulated, which activates factors that accelerate union at the fracture site [1,6,13]. Although those who support reamerization of the medulla are in the majority, some researchers consider reamerization unnecessary [4,9,23].

Material and Methods

In Group A, ACIMN technique was applied to 25 patients between 1997-1999 in Istanbul Training and Research Hospital. Seventeen patients came for control. In Group A, the mean age was 41 years, 16 patients were male, 9 were female; 14 left, 11 right, 14 static and 11 dynamic locking nails of different brands (Orthofix-italy, Russel Tailor -USA, Ünku type 1-Turkey) were applied (Figure 1).

The average follow-up time was 29.1 months. In addition to FSF, 7 patients had different types of fractures (wrist fracture, Humerus fracture, forearm fracture, tibia fracture, clavicle fracture, etc.). In our study, the fracture types of the patients were 3.2.A and 3.2.B, according to AO classification (Table 1).

Etiological reasons were as follows: 13 patients had a traffic accident; 11 patients had fallen from height and 1 patient had fractures as a result of a fall of a heavy object. In Group A, according to the AO classification, 18 patients had 32-A and 7 patients had 32-B type fractures. The average nail thickness was 10.7 mm, and the average nail length was 36.9 cm. Nails of the thickest possible diameter were used, taking as the beginning the piriform fossa entrance and reamerizing the medulla. Locking was done with proximal and distal locking screws placed externally, but difficulties caused by the instrument set during locking caused both prolongation of time and excessive damage to the tissues. The patients who were mobilized on a postoperative day 2 were invited to the control visits at 1, 3, 6 and 12 months and followed up clinically and radiologically.

In Group B, ACIMN technique was applied to 17 patients with nails of different brands (Titan-USA, TST-Turkey Tımped-Turkey, Discotech, Polmed-Turkey) between 2015-2019 in Sakarya Yenikent State Hospital. Fifteen patients came for control visits. The mean age was 51 years, 10 patients were men, 7 were women, in 12 patients on the right, in 5 patients on the left, static locking was applied to 11 patients and dynamic locking was applied to 6 patients, the average follow-up period was 22.3 months. In addition to FSF, 4 patients had different fracture types (tibia fracture, wrist fracture, patella fracture, etc.). The etiological reasons were a fall from a height in 7 patients and a road traffic accident in 10 patients. According to the AO classification, 13 patients had 32-A and 4 patients had 32-B type fractures. The patients were operated with ACIMN technique with scopi on the traction table. In 2 patients who had difficulty in reduction, the fracture was reduced by opening the fracture site with a 5 cm minimal incision. The locking mechanisms of the nails contain mechanisms, which are different from each other.

Instead of the classical locking screw from the outside, the Discotech nail is inflated with a solution to lock the nail, while rigid fixation is provided by using internal locking nails in TST and Polmed nails. In practice, the medulla was reamerized with reference to the entrance to the piriform fossa. The patients were regularly called for follow-up visits at the postoperative 1, 3, 6, and 12th months, and their radiological and clinical examinations were performed. The nail thickness used is on average 10.8 mm and the nail length is on average 36.9 cm. The patients were mobilized on the post-op 2nd day and quadriceps and hamstring exercises were started.

Statistical Analysis

Statistical analyzes in this study were performed using the NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) package program. In the evaluation of the data, in addition to descriptive statistical methods (mean, standard deviation), the distribution of variables was examined with the Shapiro-Wilk normality test, the independent t-test was used for the comparison of the normally distributed variables in binary groups, and the chi-square test was used for the comparison of qualitative data. The results were evaluated at the significance level of p <0.05.

Results

Thoresen’s classification was used to evaluate the results. According to this table, the results were divided into 4 categories according to the fracture axis, ipsilateral knee motion arc, pain, and the presence of edema and classified as excellent, good, moderate and poor [16]. In Group A, union was observed in all of our 17 patients. Limited range of motion was found in 2 patients. As the callus formation was sufficient in the radiological controls of 14 patients who underwent static locking, it was dynamized at the end of 12-14 weeks. According to the Thoresen criteria, 14 patients were...
Closed intramedullary nailing in femur fractures

evaluated as excellent, 1 patient was evaluated as good due to tuberositas pain, 1 patient as moderate due to 5-degree valgus deformity developed post-op, and 1 patient as bad due to post-op infection. In one of our patients, purulent discharge occurred from the incision site after the operation.

The infection in the patient was treated by applying specific antibiotherapy. One patient was revised due to a near-distal fracture and a 20-degree valgus deformity due to the fact that the distal fragment could not be controlled during the operation.

In the 2-year follow-up of this patient, it was observed that the fracture was fully welded, the hip and knee movements were complete, and a 5-degree valgus deformity sequela remained in the radiological examination.

Group B had complete union in 13 patients and delayed union in 2 patients. On clinical examination, hip and knee range of motion was found to be complete, except for 2 patients. Static locking patients were dynamized on average at 13 weeks. Complete union was observed in the 6th week after dynamization. Two patients, who were hospitalized in the intensive care for a long time due to multiple trauma, developed limitation of movements in the hip and knee joints. There were no signs of infection in the patients. Edema developed due to deep vein thrombosis in 2

<table>
<thead>
<tr>
<th>Table 1. OTA Classification</th>
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<tr>
<td><strong>Femoral Fracture 3=Femur 2=Shaft</strong></td>
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<tr>
<td><strong>Simple</strong></td>
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<tr>
<td>A1 - Spiral</td>
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<td>A2 - Oblique, angle &gt; 30 degrees</td>
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<td><strong>Wedge</strong></td>
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<td>B1 - Spiral wedge</td>
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<td>B2 - Bending wedge</td>
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<tr>
<td><strong>Complex</strong></td>
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<tr>
<td>C1 - Spiral</td>
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<td>C2 - Segmental</td>
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<th>Table 2. Statistical Table</th>
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<tr>
<td><strong>Group A n:25</strong></td>
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<tr>
<td><strong>Age</strong></td>
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<td><strong>Gender</strong></td>
</tr>
<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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<td><strong>Side</strong></td>
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<tr>
<td>Left</td>
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<tr>
<td><strong>Trauma Type</strong></td>
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<tr>
<td>Traffic accident</td>
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<td>Crush Injury</td>
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<td>Falling from high</td>
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<td><strong>AO Classification</strong></td>
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<tr>
<td>32-A</td>
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<tr>
<td>32-B</td>
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<tr>
<td><strong>Time between Operation and Trauma (Days)</strong></td>
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<td><strong>Operation Time (Minutes)</strong></td>
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<td><strong>Nail Diameter (mm)</strong></td>
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**Figure 1.** Femoral shaft fracture ( Pre-op- and Post-op)

**Figure 2.** Operation Time (minutes)

**Figure 3.** Statistical Clinical Results

* Independent t-test + Chi-square test
patients and necrosis due to compression in the wound area in 1 patient. Circulation problem was treated with DVT treatment and wound problem by debriding necrotic tissues and applying wet dressing. According to Thoresen criteria, 13 patients in Group B were evaluated as excellent, 1 patient as good, and 1 patient as fair. In Group A, the period between hospitalization and surgery was quite long, such as 10-15 days, in the past, due to the inadequacy of health facilities and the problems in the supply of hospitals. Skeletal traction was applied to the patients during this period. The long waiting time before the operation created some difficulties due to the contraction of the muscles and tissues during the operation. In group B, all patients were operated on the traction table. The time between hospitalization and operation was approximately 3-4 days (Table 2). The increase in the number of health institutions and the diversity of the supply of materials in recent years has enabled patients to be operated in a short time.

The mean time between operation and trauma (days) in Group A was found to be statistically significantly higher than in Group B (p = 0.0001). The average operation time (minutes) in Group A was found to be statistically significantly lower than in Group B (p = 0.0001) (Figure 2). The mean follow-up time (months) in Group A was found to be statistically significantly higher than in Group B (p = 0.006). Statistical clinical results of the groups are shown in Figure 3.

Discussion

The AKIMN technique has an advantage over other techniques in FSF’s union and clinical recovery [2,3,6,9,13,16,22]. In this technique, since the fracture line is not opened and the fracture hematoma is not evacuated, fracture healing and union time are much more advantageous than the open IMN technique [1,4,11]. At the entrance, the piriform fossa or trochanter type is referenced [1,2,6,7,9,13,15,17]. FSF is usually seen in young people aged 20-40. Hans Decker in a series of 1003 cases, found an average age of 31.3 years; Goran Denckward and Lilliestron found an average age of 32.4 years in 45 cases, and Kalenderer, in 71 cases, determined the average age of 35 years [6,9,20]. In this study, the average age in Group A was 41.5 years, and the average age in Group B was 51.3 years. Among the etiological reasons, Brumback stated that traffic accidents accounted for 84% and 16% were other causes in etiology. Kalenderer explained the etiological reasons with 66.1% of traffic accidents, 33.9% other factors and Enson explained the etiological reasons with 68.6% traffic accidents [14,15,20]. In this study, the main etiological cause in Group A was traffic accidents because it prevents shortening and rotation in FSF’s union and clinical recovery [2,3,6,9,13,16,22]. In this study, the main etiological cause in Group A was traffic accidents because it prevents shortening and rotation in FSF's union and clinical recovery [2,3,6,9,13,16,22].

In FSF, reamerization techniques of the medullary canal provide both mechanical and biological support for intramedullary nailing. Local formations accumulated at the fracture site by reamerization support union by functioning like a bone graft containing osteoprogenitor cells and inductive molecules. Reamerization increases the joining rate 4 times. While the union is 98.5% in reamerized intramedullar nails (RIN), this rate is 84% in unreamerized nails (URIN) [1,4,9,16,23]. A-Bing Li et al showed in their study that RIN improved the rate of union of fractures, shortened the time to union, and decreased the incidence of nonunion or delayed union [1]. Reamerization can damage the blood flow of the internal cortical bone, but as a reaction, the periosteal blood flow may increase 6-fold, which can stimulate fracture healing, and it has been stated that RIN can provide greater stability and reduce the risk of implant replacement [3,5,7,11,17,23]. Clowesworthy et al concluded that fracture stability is an important determinant of rapid union [25]. A wider nail can be inserted into the medullary canal after reamertization to improve cortical contact and provide greater stability. Grundnes et al reported that a tight-fitting nail increases the periosteal reaction [17]. Tornetta in a series of 81 patients, applied reamerized IMN to 42 patients and unreamerized IMN to 39 patients [12]. The bone healing rate is much higher in the RIN group. The blood loss may be greater, but it will never be at the level that requires a blood transfusion [4]. Thorosen et al. applied RIN to 48 patients and reported very good results [16]. In our study, we applied RIN to all patients in both groups. As a result, complete union was achieved in all our patients. It is clearly seen that the RIN technique in IMN application has significant advantages over the URIN technique in terms of both stability and joining time. Nader Helmy et al evaluated the functional results of FSF treated with anterograde IMN by performing 2 different objective measurements (KinCom muscle test and Gait analysis) [11]. Isokinetic muscle testing was performed on hip abductors, hip extensors, and knee extensors using a KinCom muscle testing machine. In addition, walking laboratory analysis was performed on the patients. As a result, they stated that in IMN techniques with anterograde entry, it caused a slight lack of muscle strength in the hip abductors and extensors, which returned to normal in the later periods, and that it did not cause any change in the gait model in gait analysis [11]. Brumback and Vurkus explained that IMN techniques may cause embolization by causing a slight decrease in endosteal blood flow and an increase in intramedullary pressure, but this effect is temporary; however, this complication is slightly more pronounced in URIN compared to RIN [14].

In the AKIMN method, there are different opinions about whether the locking should be static or dynamic. Those who argue that static locking should be made to prevent shortening and rotation are in the majority. Thorosen et al. applied 35 dynamic and 13 static locking to 48 patients. As a result, they stated that static locking is appropriate in cases where there is doubt about the stability of the fracture [16]. Enson et al. performed static locking in 8 of 12 patients and dynamic locking in 4 and achieved union in a mean of 17.1 weeks [15]. Abas performed 9 unlocking, 39 dynamic and 16 static locking [7]. In our study, in Group A, static locking was performed in 14 patients and dynamic locking in 11 patients. In Group B, static locking was applied to 11 patients and dynamic locking was applied to 6 patients. In conclusion, static locking should be preferred in the treatment of comminuted and unstable femoral fractures because it prevents shortening and rotation deformities. 25 Static IMN carries weight, controls shortening and rotation, but osteoporosis develops in the bone when
stress is reduced. Dynamic locked system, on the other hand, is a system that shares the load, so it allows easy load delivery, and there is no screw breakage problem. However, it has less control over shortening and rotation. Dabezies et al. stated that while maintaining the length and rotation in the fracture line with static locking, micro movement is limited [19]. In the literature, it has been reported in many studies that delayed union or nonunion is more common in static locking than dynamic locking. There have been many studies in the literature regarding when dynamization will occur after static locking. In order to accelerate the healing of the fracture in patients, dynamization should be started as of 12-16 weeks when sufficient callus formation is seen. Tornetta started to dynamize on average in 10-12 weeks, Akbaş in 12 weeks, Brumbach in 14-16 weeks and Kalender in 9 weeks [7,12,14,20]. After dynamization, the load placed on the implant before will cause stress on the bone, this stimulates the formation of callus and increases the hardness of the existing callus [1,2,5,8,11,16,22]. In our study, we applied dynamization as of the 12th week in cases where we performed locking statically. As a result, dynamization is a method that accelerates fracture healing and increases the hardness of the callus. Since a long time ago, closed anterograde IMN technique has been the first method preferred by orthopedists in FSF. While there were no significant changes in the etiological causes, and treatment principles over time in both groups, improvements were observed in the structure, design and locking methods of the implant materials applied. In both groups, past and current treatment principles are not different, and success in such fractures is high with appropriate indication and correct application technique. Static locking should be used to prevent shortening and rotation in fractures with segmental fragments. The medulla must always be reamed. When mobilizing patients on the first day after surgery, hip and knee rehabilitation should be started earlier. Although we investigated the effectiveness of current treatments in our study, we think that studies using new techniques and new treatment modalities with larger numbers of patients are needed in the future.

Scientific Responsibility Statement
The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement
All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflicts of interest
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References