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Interlocking nailing of femoral shaft fractures with an extremely narrow medullary canal is associated with iatrogenic fractures

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ABSTRACT

Introduction: Controversy exists regarding the use of reamed interlocking nailing in femoral shafts with extremely narrow medullary canals (diameter ≤ 9 mm). The aims of this study were to (1) investigate the association of age and sex on femoral canal diameter in patients with a simple femoral shaft fracture and (2) compare the outcomes and complications of interlocking nailing between wide and extremely narrow intramedullary canals.

Patients and methods: For the purposes of this retrospective cohort study, consecutive patients with simple femoral shaft fractures were recruited between January 2009 and December 2016. The patient demographic data were analyzed. Then, fractures treated with interlocking nailing were divided into the wide group (canal diameter > 9 mm) and narrow group. The primary outcome was union rate, and the secondary outcomes were complications such as thermal necrosis, fat embolism syndrome, iatrogenic fracture, and implant failure.

Results: This study included 340 femoral shaft fractures. The average canal diameter was 9.97 ± 1.79 mm, with significantly wider canals in men than in women. Overall, 289 of the patients had undergone interlocking nail fixation, and a similar union rate and complications were noted between the wide canal and narrow canal groups, with the exception of the incidence of iatrogenic fracture.

Conclusions: Femoral shaft fractures associated with extremely narrow medullary canals are more common in women than in men. There was a similar union rate found when using interlocking nailing in a femoral shaft fracture in cases with extremely narrow and wider canals. Iatrogenic fracture is the only significant risk when using interlocking nailing in femoral shafts with extremely narrow canals.

Introduction

Although reamed interlocking nailing has emerged as a preferred procedure for femoral shaft fractures and has a union rate of up to 85% [1,2], controversy remains regarding whether reamed interlocking nailing should be employed in femoral shafts with extremely narrow medullary canals (diameter ≤ 9 mm) [3]. The risk can be divided into biological risk and mechanical risk.

In terms of the biological aspect of the issue, intramedullary reaming has been proposed as a method to increase the stability of fixation by applying a larger nail. Relevant articles in the literature also support the belief that reamed interlocking nailing significantly reduces the incidence of nonunion, delayed union, and reoperation rates compared with unreamed interlocking nailing for shaft fracture of the femur [4, 5]. However, overaggressive reaming for an extremely narrow canal may increase cortical temperature [6, 7] and result in thermal necrosis, especially in humeral and tibia shaft fractures [3, 8-10]. Reaming is also associated with increased intramedullary pressure and bone marrow embolization [6]. Overzealousness in the reaming and nailing of the medullary cavity may increase the risk of developing fat embolism syndrome [11].

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Mechanically, inserting the interlocking nail into an extremely narrow canal requires a lot of effort, and forceful insertion is associated with iatrogenic fracture of the femoral neck [12]. Narrow canals are also associated with iatrogenic fracture comminution resulting from the nailing of humeral diaphyseal fractures [13]. Finally, only nails with a small diameter can be used if the medullary canal is extremely narrow, and such nails are associated with nonunion [14].

For these reasons, some surgeons regard the use of interlocking nails in extremely narrow canals as risky and instead recommend the application of plate osteosynthesis [15-18]. However, plate osteosynthesis for femoral shaft fractures is associated with higher rates of complications such as nonunion or infection [19, 20]. Furthermore, no evidence supports the benefits of using plating for fractures of femoral shafts with extremely narrow canals.

Therefore, we conducted a retrospective study to evaluate clinical outcomes following reamed interlocking nailing of femoral shafts with various canal diameters. The aims of this study were (1) to investigate the association of age and sex on the diameter of the femoral canal in patients with a simple femoral shaft fracture and (2) to evaluate the outcomes and complications associated with interlocking nailing of both wide and extremely narrow intramedullary canals. We hypothesis that use of interlocking nails in femoral shaft fractures with extremely narrow canal has inferior union rate and higher complication rate than that in femoral shaft fractures with wide canal.

Materials and methods

This retrospective cohort study was approved by the institutional review board. Patients who had undergone surgical fixation of a broken femur were recruited at two hospitals: National Cheng Kung University Hospital and its Douliu branch between January 1, 2009, and December 31, 2016. All fractures were identified using Taiwan's National Health Insurance coding system. The inclusion criteria were a simple femoral shaft fracture, namely Arbeitsgemeinschaft für Osteosynthesefragen and Orthopaedic Trauma Association (AO/OTA) classifications 32-A1, 32-A2,32-A3, 32-B1, or 32-B2. The femoral shaft was defined as being between 5 cm distal to the lesser tuberosity and 9 cm proximal to the joint line [21]; any fractures that extended beyond this range were excluded. The exclusion criteria were comminuted fractures (AO/OTA classification 32-B3, 32-C1, 32-C2, or 32-C3), fractures in skeletally immature patients, revision procedures, peri-implant fractures, combined fracture with a femoral neck or peri-trochanter fracture, open fractures classified as Gustilo III, fractures for which surgery was delayed because of an open fracture or multiple trauma sites, pathological fractures, and insufficient follow-up (less than 12 months).

Eligible fractures were categorized according to the narrowest diameter of the intramedullary canal. The pre-operative anterior-posterior view and lateral view were measured by two of our colleagues. Both measured the narrowest diameter in the isthmus of the femoral canal, and the final data was the average diameter. However, if the difference between both measurements was more than 1 mm, a third colleague also measured, and this data was averaged into the final data. Images of the patients included in this study were displayed and measured using digital imaging in medicine image-viewing software (πViewTM, INFINITT Co., Ltd., Seoul, Korea).

The "narrow" group was defined as the narrowest diameter being less than 9 mm [3]; the "wide" group was defined as the narrowest diameter being greater than or equal to 9 mm. This definition is based on AO Foundation [3] and our clinical experience mentioned below. After grouping, the medical records of each patient and the associated fracture were reviewed to obtain patient demographic characteristics, including age, sex, fracture classification, canal diameter, and treatment method. After excluding the cases with bilateral femur fractures or concomitant lower extremity involvement, the fractures that had undergone interlocking nail fixation were then divided into "narrow" and "wide" groups. The nail size, primary outcomes, and complications were recorded.

The primary outcomes included bony union and nonunion, where a "bony union" was defined as a bridging callus formation in both the anterior-posterior and lateral view within 12 months postoperatively. "Nonunion" was defined as there being no bridging callus, bridging callus formation only in the anterior-posterior or lateral view, or the fracture having received any revisional procedures, including nail exchange, plate augmentation, or bone grafting within 12 months.

Complications included thermal necrosis, fat embolism syndrome, iatrogenic fracture, fracture comminution, and implant failure. Thermal necrosis was defined as a cutaneous blister over the fracture site soon after the operation [9] and following osteocutaneous necrosis [10]. Fat embolism syndrome was diagnosed according to Gurd's criteria [22]. If a patient met at least one of Gurd's major criteria and at least 4 minor criteria, a diagnosis could be confidently made. Iatrogenic fracture was defined as a femoral neck or peri-trochanteric fracture present after interlocking nailing in which the fracture was not observed before surgery. Fracture comminution was defined as a newly developed fracture line extending from a previous fracture site. Implant failure was defined as the breaking of the nail for which revision surgery was necessary. Breaking of the locking screws of the interlocking nail was not included.

All fractures that underwent interlocking nail fixation were reduced through closed surgery or a mini-open incision. The reamer used in both hospitals was the Zimmer Pressure Sentinel reamer (Zimmer USA, Warsaw, IN, USA), the smallest size of which is 8 mm. Both hospitals used two types of interlocking nails: the Aesculap Targon nail (Aesculap, Tuttlingen, Germany) and the Stryker T2 femoral nailing system (Stryker, Mahwah, NJ, USA), for which the smallest diameter available is 10 mm. In order to insert the nail smoothly, the operators tended to over-ream the canal 1.5∼2.0 mm larger than the nail. This meant that the operators had to ream the diameter at least to 11.5 mm, or at least 2.5 mm larger than original size when the canal diameter is less than 9 mm. All nails were inserted antegradely through the piriformis fossa. One proximal locking screw was secured obliquely from the greater tuberosity to the lesser tuberosity, and two distal locking screws were secured vertically to the nail.

The postoperative rehabilitation programs were similar for all individuals. Partial weight bearing under crutch protection was allowed immediately after surgery except where an iatrogenic fracture was noted intra-operatively. The timing of full weight bearing depended on the formation of callus, which was usually 6 to 8 weeks after the surgery, when some callus formation was noted on the plain film.

Statistical analysis

The results were analyzed using SPSS statistical software (SPSS Inc., USA). A univariate analysis was conducted to evaluate the union rate and occurrence of each complication using a chi-square test. Continuous variables were evaluated with the unpaired Student's *t*-test. A p value of $<.05$ was considered statistically significant.

Results

Using Taiwan's National Health Insurance database coding system, 340 fractures were included in this study: 188 fractures in

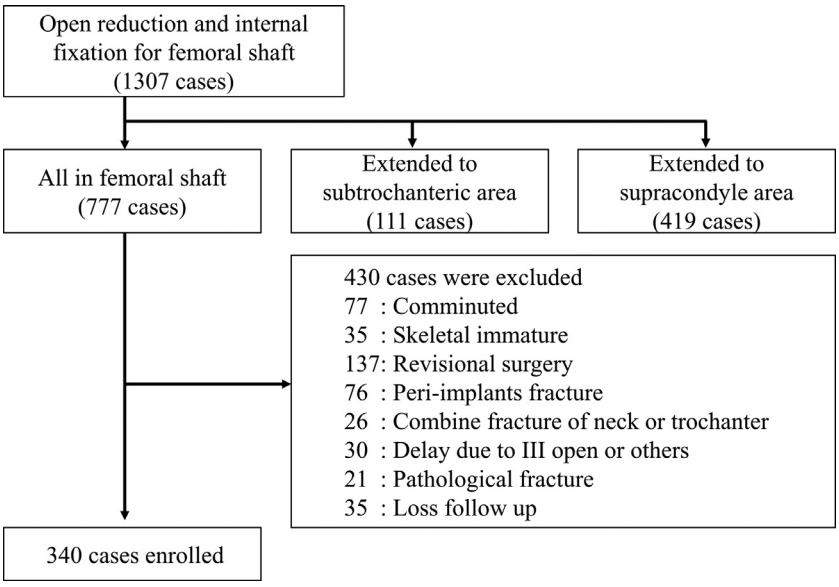

Fig. 1. Patient flow chart.

men (55.3%) and 152 in women (44.7%) (Fig. 1); the mean age of patients (±standard deviation) was 32.5 ± 18.6 years. The average width of the medullary canal in the eligible fractures was 9.97 ± 1.79 mm (10.39 ± 1.77 in men and 9.46 ± 1.68 in women). The medullary canal was significantly smaller in women.

Among the eligible fractures, 302 (88.9%) underwent interlocking nail fixation; 31 (9.1%) underwent plate fixation, and the other 7 (2%) received nonlocking Küntscher nail fixation. However, Küntscher nail fixation was not performed in either hospital after 2010. Thus, the fractures with Küntscher nail fixation were not included in the further analysis.

Comparison of the narrow group and wide group for all fractures

The narrow group consisted of 107 fractures (31.5%), and the wide group consisted of 233 (68.5%) fractures. The average age and fracture classification were similar for both groups, but a significant between-group difference was noted with respect to the sex distribution. There was also a significant between-group difference in treatment selection and nail size, where plating was more favored in the narrow group than in the wide group (Table 1).

Comparison of the narrow group and wide group for fractures with interlocking nail fixation

Although 302 femoral shaft fractures were fixed using an interlocking nail, 13 of them were excluded due to a bilateral femur or concomitant lower extremity involvement. Of the remaining 289 fractures, 78 had narrow canals, and the other 211 had wide canals. The nail diameter in the narrow group was significantly smaller than that in the wide group; by contrast, the nail to canal ratio was significantly larger in the narrow group as compared to the wide group. 246 (85.12%) fractures united smoothly within the following period, and the other 43 (14.88%) fractures did not unite or united after revision surgery. No significant between-group differences were observed in the union rate.

Regarding complications, 23 (7.96%) iatrogenic comminutions were noted on the original fracture sites. In addition, six (2.07%) iatrogenic fractures were noted around the insertion point after the interlocking nail insertion, of which 5 were femoral neck fractures, and one was an intertrochanteric fracture (Fig. 2). A significantly higher rate of iatrogenic fracture was noted in the extremely narrow group. Regarding other complications, eight (2.77%) cases

Table 1
Demographics of patients with fractures of femoral shafts with narrow (<9 mm) and wide (>9 mm) canals.

Characteristic	Narrow canal ($n = 107$)	Wide canal ($n = 233$)	*p*value
Age (year)	34.14	31.76	.275
Sex			<.001
Male	44	144	
Female	63	89	
AO Classification			.199
34A1	1	10	
34A2	43	74	
34A3	39	85	
34B1	1	8	
34B2	23	56	
Treatment			<.001
Intra-medullary nail	88	221	
Plate	19	12	

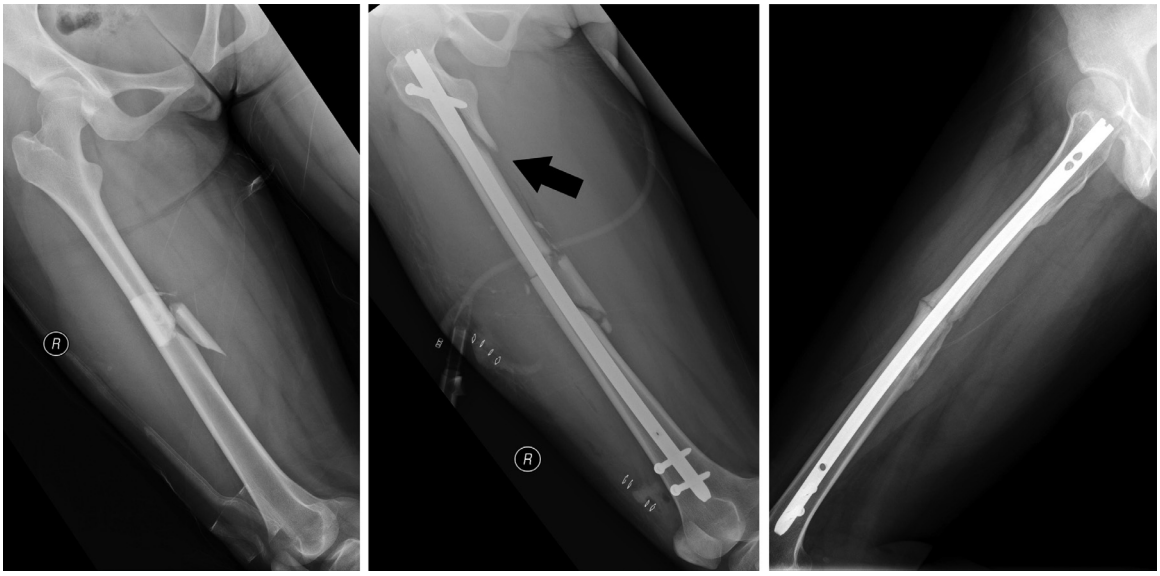

Fig. 2. Eighteen-Year-Old Woman With Extremely Narrow Canal Who Underwent Interlocking Nail Fixation for Her Right Femur (a) Preoperative, (b) immediately postoperative, and (c) 6 months postoperative. An iatrogenic intertrochanteric fracture was noted after surgery, and nonsurgical treatment was given. The iatrogenic fracture was healed six months after the fracture.

Table 2
Nail size, nail to canal ratio, primary results, and complications in patients undergoing interlocking nailing for fractures of femoral shafts with narrow (<9 mm) and wide (>9 mm) canals.

Characteristic	Narrow canal ($n=78$)	Normal canal ($n=211$)	*p*value
Nail size	10.43	11.25	**<.001**
Nail-canal ratio	1.30	1.05	**<.001**
Primary outcome			.102
Union	62	184	
Nonunion	16	27	
Complication			
Fracture site extend	9	14	.172
Iatrogenic fracture over proximal femur	4	2	**.027**
Implants failure	2	7	.743
Fat embolism	2	6	.898

presented with fat embolism syndrome, and nine (3.11%) fractures had implant failure, for which the average time from implantation to implant failure was 10.0 months. The incidences of fat embolism syndrome and implant failure were similar between the two groups. No thermal necrosis was noted in the eligible cases (Table 2).

Discussion

The diameter of the femoral intramedullary canal is critical for preoperative assessment. During surgical management of femoral shaft fractures, difficulties arise when treating patients with extremely narrow femoral diaphyseal canals [23]. This study investigated the association of age and sex on the diameter of the femoral canal in order to compare clinical outcomes between extremely narrow and wide canals in the interlocking nailing of femoral shaft fractures.

The first finding of this study was that the diameter of the medullary canal is significantly correlated with sex and is smaller in women. This result is not only similar to that published in a report by Milligan et al. [24] but also revealed a more significant between-sex difference. When analyzing the study populations, Milligan et al. examined patients with a mean age of 68.8 years who had undergone total hip arthroplasty, whereas the patients in our study had a mean age of 32.5 years. The differences between these two study populations may have contributed to the significant difference in the diameter of the medullary.

Our second finding was the similar union rate between the wide and extremely narrow canals after the interlocking nailing of femoral shaft fractures. The patient-independent risk factors associated with nonunion after intramedullary fixation included open fracture [25], fracture comminution [26], unreamed interlocking nailing [5,14], nonisthmal fracture [27], and small nail diameter [28,29]. In the presented results, the nail diameter was significantly smaller in the extremely narrow canal group, but no difference was noted in the union rate. This can be explained by the larger nail to canal ratio between these two groups. Although the nail diameter was smaller in the extremely narrow canal group, the same nail fit could be achieved in this group as in the wide group, thus resulting in the same union rate. Miller et al. [30] also reported that poor nail fit, rather than nail size itself, is an independent predictor of femoral shaft nonunion.

The aforementioned finding also revealed a similar between-group complication rate, with the exception of peri-operative iatrogenic fractures. Heat necrosis is one of the most severe complications after reaming in extremely narrow canals [3,8-10]. However, relevant studies have reported the occurrence of heat necrosis only in humeral and tibial shaft fractures. Thus, the incidence of heat necrosis may be rare and also difficult to diagnose in femoral shaft fractures because of the high rate of soft tissue coverage.

Fat embolism is thought to be another risk following reaming, but the results of the current study failed to show any significance in extremely narrow canals. Although an increase in intramedullary canal pressure can result in intravasation of bone

marrow and fat into the venous blood system, the symptom may be transient and subclinical [31]. Thus, previous literature on this topic has also failed to demonstrate the relationship between reaming and fat embolism [31,32]. In addition, the reaming procedure in this work was started using the smallest size, an 8 mm Pressure Sentinel reamer, which may also have decreased the risk of intravasation of bone marrow and fat.

Iatrogenic fracture, which is an uncommon but devastating complication, is the only significant complication that occurs during interlocking nailing in the case of extremely narrow femoral canals. Several factors, such as incorrect entry point [33,34], forceful use of a bone awl [34], associated greater trochanteric tip fracture [35], and other technical errors [36] have been reported to induce this complication. The relationship between an extremely narrow canal and iatrogenic fracture is not clear. It may be because an extremely narrow canal is unable to tolerate minimal technical error at the entry point or forceful insertion of the nail by the surgeon. Among the six iatrogenic fractures in this study, one was an intertrochanteric fracture and was treated nonoperatively. In the case of the other five femoral neck fractures, two were recognized intraoperatively and immediately fixed with cannulated screws. However, the other three fractures were noted after surgery, and the patients were sent back to the operating room. Because iatrogenic fractures are unexpected, repeated fluoroscopy should be performed intraoperatively to ensure that no other associated fracture exists before wound closing, especially in fractures of femoral shafts with extremely narrow canals.

This study has some limitations. First, the data were collected from 2 hospitals, where surgeries were performed by different surgeons. Individual surgeons may follow different indications for the use of interlocking nailing or plating, mini-open reduction or closed reduction, and lateral decubitus position or supine position on fractures when in the operating room. The postoperative rehabilitation programs at these hospitals are slightly different, which may have affected the study outcomes, particularly for fixation failure. We identified some possible confounding variables, such as fracture classification. However, some related factors that could not be controlled for, such as bone quality or patient compliance, may have had an influence. Second, the sample size was relatively small, and the study may have lacked sufficient power to detect meaningful differences between the union rate or the incidence of other complications between the extremely narrow and wide groups. Third, this study primarily focused on radiologic results and a simple review of medical records. Further investigation is required, and precise measures of functional results, such as range of motion, knee score, or an injury-specific questionnaire, should be utilized in future research.

Conclusion

Fractures of femoral shafts with extremely narrow canals are more commonly reported in women than in men. To treat simple femoral shaft fractures, interlocking nailing provides favorable outcomes, with a union rate of 85.12%. In addition, extremely narrow canals and wide canals exhibit similar union and complication rates, except for the incidence of iatrogenic fractures. Surgeons should be aware of this severe complication, especially when applying interlocking nailing to femurs with extremely narrow canals.

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