

Comparison between ender and unreamed interlocking nails in tibial shaft fractures

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ABSTRACT

الأهداف: للمقارنة بين مسامير الشبك المصمتة وغير المقورة في دراسة سريرية عشوائية.

الطريقة: خلال الفترة ما بين مارس 2001م وحتى مارس 2003م، تم إدخال عدد 131 مريضاً يعانون من كسور في منتصف الثلث الثاني من عظمة الضنبوب إلى قسم الطوارئ بمستشفى الشهداء - مدينة تابرز - بإيران، واستخدمت لهم إما مسامير الشبك المصمتة أو غير المقورة بشكل عشوائي كمعالجة أولية. تم تسجيل العمر، الجنس، نوع الكسر، والنتائج الجراحية في وقت العملية الجراحية، أثناء فترة البقاء في المستشفى، وخلال فترة المتابعة البالغة تسعة أشهر.

النتائج: خضع 67 مريضاً للعملية الجراحية باستعمال مسامير الشبك غير المقورة، و64 مريضاً بمسامير الشبك المقورة. لم يتبين وجود فرق إحصائي ملحوظ بين المجموعتين فيما يتعلق بالتحام الكسر وتأخر الالتئام وفشل الآلية. كانت فترة البقاء في المستشفى والوقت المطلوب لتحقيق الالتئام أعلى في مجموعة المسامير غير المقورة. كان عدم الالتئام ومعدل الالتهاب أعلى لدى مجموعة المسامير المصمتة ($p < 0.05$).

خاتمة: تدعم نتيجة دراستنا تلك الدراسات التي تشير إلى أن الخيار بين الطريقتين بالمسامير غير المقورة مثيرة للجدل بشكل رئيسي، معتمداً في ذلك على أولوية المريض والطبيب الجراح.

Objectives: To compare ender nails and unreamed interlocking nails in a randomized clinical trial study.

Methods: From March 2001 to March 2003, 131 patients with tibial fractures of the central two thirds of the tibia were admitted to the emergency ward of Shohada Hospital, Tabriz, Iran and were randomized to either an ender tibial nail or an unreamed interlocking tibial nail as their primary treatment. Age, gender, types of fracture, and surgical outcomes were recorded at the time of surgery, during hospital stay, and during the course of 9 months follow-up.

Results: Sixty-seven patients underwent surgery with interlocking nails and 64 with ender nails. No statistically significant difference was found between the 2 groups concerning mal-union, delayed union, and device failure. Durations of hospital stay, and time needed to achieve union was significantly higher in the unreamed interlocking group. Non-union and infection rate were higher in the ender group ($p < 0.05$).

Conclusion: The results of our study support those of other studies that indicate the choice between the 2 methods of unreamed nailing is mainly controversial, depending on the priorities of the patient and surgeon.

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The tibia is the most commonly fractured long bone in the body. Tibial shaft fractures are often the result of high-speed trauma, but can also be insidious in onset, such as stress fractures in active individuals. Most patients are often young and active and early return to daily activities is necessary. In tibial shaft fractures with massive bone and soft tissue injury; the treatment can be difficult. In fact, except for the fractures due to low energy and with minimal displacement, surgical treatment is usually indicated for the rest.^{1,2} Until

recently, non-operative management of tibial fractures was commonly accepted by the orthopedic surgeons. This method was accompanied by a high rate of non-union (32% versus 9%) and mal-union (80% versus 6%).^{2,3} Nowadays, surgical treatment of tibial fractures is widely accepted. External fixation, fixations with screws and plates and intramedullary nailing are the main methods used for unstable tibial fractures. Intramedullary nailing with interlocking screws has become the treatment of choice for most tibial shaft fractures. The prevalence of nonunion and mal-union is greatly decreased compared with the other methods of fixation. Patients are also able to return to low-impact activities much sooner than with the other treatments.⁴ While intramedullary nailing is generally accepted as the standard of care for treating many types of tibial shaft fractures, specific surgical techniques are prone for being controversial: the choice between the use of reamed or unreamed nails or the choice between different types of undreamed nails. Most orthopedic surgeons are of the opinion that the use of unreamed nailing can be recommended in tibial fractures, especially for open fractures, and fractures with severe soft tissue damage.^{5,6} Laboratory studies indicate that unreamed nailing leads to more rapid revascularization of the bone, which may result in earlier union compared with reamed nailing. This method is easier and quicker to perform by the surgeons. As a result of the disruption of intramedullary blood flow, reamed nailing may be associated with pulmonary emboli, which are important in patients with associated pulmonary injuries.⁷ Ender nails and unreamed interlocking nails are both used in intramedullary nailing without reaming. Ender nailing is of value both for the acute management of complicated high-energy fractures of the tibial shaft with extensive soft-tissue damage (type III fractures according to Gustilo and Anderson) and as a salvage procedure to maintain reduction of a fracture when other techniques. It maintains adequate elasticity at the fracture sites where much callus is formed, leading to a good union.⁸ Up to the present time, no study has been performed in Iran to compare the 2 methods of intramedullary nailing without reaming of endosteal canal. The aim of the present study was to compare the results of using the ender nails and undreamed interlocking nails in tibial shaft fractures. The authors also wished to conclude whether one method is more appropriate to use in Iranian population.

Methods. From March 2001 to March 2003, 154 patients with tibial fractures of the central two thirds of the tibia were admitted to the emergency ward of Shohada Hospital, Tabriz, Iran and were evaluated for

inclusion in the study. Twenty-three patients did not consent the study or did not meet the inclusion criteria. This left 131 patients who were randomized to either an ender tibial nail or an undreamed interlocking tibial nail as their primary treatment.

Randomization was carried out by surgeons by drawing pre-filled and pre-numbered nontransparent envelopes. The patients were randomized to receive either immediate unreamed interlocking, or ender nails based on the case number. Some patients were operated on with unreamed interlocking nails, and some patients underwent surgery with ender nails. All patients participating in the study were informed on the study conditions, objectives, advantages and risks, and on the possible treatment options if participation were not chosen. The study was approved by the Ethical Committee of Tabriz University of Medical Sciences. All study patients or those legally responsible for them signed a consent agreement. All attending surgeons were blinded. Closed and open fractures of the central two thirds of tibia in skeletally mature patients were included after giving written informed consent. Patients with severe osteoporosis, patients with neuromuscular disorders, patients who had other sites of fracture and non-cooperative patients unable to attend the 9 months follow-up program were excluded in the study. All fractures were operated on within 48 hours after the injury. The soft tissues were debrided and irrigated in the operating room immediately and at 2- to 3-day intervals.

Demographic data, types of fracture (classified according to Gustilo and Anderson) and surgical outcomes were recorded by the authors at the time of surgery, during hospital stay and during the course of 9 months follow-up. The classification for open fractures was described by Gustilo et al⁸ as follows: Type I: The wound is clean and is shorter than 1 cm. Type II: The wound is longer than 1 cm and does not have extensive soft tissue damage. Type IIIa: This fracture type is a wound associated with extensive soft tissue damage usually larger than 10 cm with periosteal coverage. This fracture type also includes less traumatic fractures with increased chances of complications, such as gunshot wounds, farmyard injuries, and fractures requiring vascular repair. Type IIIb: This type is defined as bone with periosteal stripping that must be covered; these fractures nearly always require flap coverage. Type IIIc: This type of injury requires vascular repair.

In general, patients were seen every 2 weeks for a minimum of 4 weeks after the injury and monthly intervals thereafter. Patients were assessed for showing any sign of surgical site infection, delayed union,

nonunion, and mal-union. The postoperative follow-up regimen included clinical and radiographic controls every 4 weeks until fracture union. The radiographs were read by the operating and attending surgeons and reviewed by the authors. There was no particular protocol for dynamization. The decision to dynamize was made by the attending orthopaedic surgeons based on the clinical and radiographic examinations. Partial weight bearing was recommended after callus formation and complete weight bearing was performed after complete healing. Superficial infection was defined as local erythema or swelling, which resolved with antibiotic therapy. Deep infection was defined as continuing wound drainage of pus or a positive bacteriological culture. Infection was also categorized according to time of occurrence: early surgical site infection during the first month after surgery and late surgical site infection thereafter. Delayed union was defined as lack of significant union within 6 months postoperatively and nonunion as having no signs of union after 9 months. Radiographic evidence of union was defined by the presence of bridging callus. Mal-union was defined as a rotational deformity of more than 10 degrees, an angulation deformity of more than 10 degrees or shortening by more than 10 mm.² Broken interlocking screws or nails was regarded as implant failures. None of the randomized patients were lost during follow-up. There were 64 patients in the ender group and 67 in the interlocking nail group available at final follow-up.

Statistical analysis was carried out with SPSS software, version 14. The comparison between the 2 groups regarding the defined variables were performed using t test and chi-square test. In all cases, a significance level of 5% ($p < 0.05$) was adopted.

Results. One hundred thirty-one patients (77.9% male and 22.1% female, mean age 33.3 ± 13.2 years) with tibial fracture were randomly assigned to surgery with either ender or undreamed interlocking nails from March 2001 to March 2003 in the orthopedic ward of Shohada Hospital, Tabriz, Iran. Open fractures, which accounted for 57.3% of fractures, were classified according to Gustilo and Anderson. Table 1 shows the details of fractures' classification. There were 45 cases of open fracture in the interlocking nail group and 30 in the ender group. Motor bike accidents were the most common cause of injury, followed by car accidents. These 2 accounted for all cases of open tibial fractures. The study groups were comparable with regard to age and gender, but not in the occurrence of open fracture types (Table 1). The skewed distribution of fractures within the groups was coincidental and could not be explained by randomization error. On average, the

patients were discharged from the hospital after 4.9 ± 2.5 days. Postoperative hospital stay, no surgical complication such as early surgical site infection, sepsis, compartment syndrome or neurological deficits were reported. During the follow up course, infection on the surgical site was noticed in 5 cases (3.8%). During the course of 9 months follow-up, 85.5% of patients showed radiological signs of callus formation at the end of 6 months. Non-union was diagnosed in only 5 cases

Table 1 - Classification of fractures.

Type of fracture	Interlocking nail	Ender nail n (%)	Total
Closed	22 (32.8)	34 (53.1)	66 (42.7)
Type 1	14 (20.9)	14 (21.9)	28 (21.4)
Type 2	10 (14.9)	8 (12.5)	18 (13.7)
Type 3A	16 (23.9)	8 (12.5)	24 (18.3)
Type 3B	5 (7.5)	0 (0)	5 (3.8)
Total	67 (100)	64 (100)	131 (100)

Table 2 - Characteristics of ender and undreamed interlocking nail groups.

Compared variables	Undreamed group (n=67)	Ender group (n=64)	P-value
	(%)		
Age	38.4±14.1	37.5±12.1	0.907
Gender			
Male (%)	82.1	73.4	0.331
Female (%)	17.9	26.6	
Length of hospitalization (mean±SD) (days)	5.6±2.6	4.3±2.2	0.001
Time needed for union (mean±SD) (months)	4.7±1.1	4.2±1.4	0.001
Delayed union			
Yes	4.5	25	0.44
No	95.5	75	
Non-union			
Yes	-	7.8	0.001
No	100	92.2	
Mal-union			
Yes	-	9.4	0.8
No	100	90.6	
Infection (late surgical site infection)			
Yes	-	7.8	0.001
No	100	92.2	
Device failure			
Yes	3	-	0.78
No	97	100	
Compartment syndrome	-	-	-
Neurological deficit	-	-	-

at the end of 9 months follow up. Duration of hospital stay was significantly higher in unreamed interlocking group ($p=0.001$). The time to union ranged from 3-9 months for unreamed interlocking nails and from 2-8 months for ender nails. Average time to fracture union was significantly lower in the ender group ($p=0.001$). Non-union was reported in 5 of 64 patients who underwent surgery with ender nails (2 of them had type III tibial fracture): the obtained result was statistically significant in comparison with unreamed interlocking nail group ($p=0.001$). All cases of surgical site infection were observed in ender nailing group and they all belonged to type III fracture. The comparison with unreamed intramedullary nailing group showed significant difference. The infection observed was of deep type and resolved by removing ender nails and antibiotic therapy. Device failure which was defined as broken interlocking screws or nails was observed in 3% of unreamed intramedullary nailing group. Since callus formation was complete long before the mentioned failures, there was no need for the patients to undergo re-operation. None of the patients with device failure had to undergo re-operation because of in-time callus formation. The authors found no statistically significant difference between the 2 groups concerning mal-union, delayed union, and device failure. Other details are mentioned in Table 2.

Discussion. In both groups, the majority of patients were in 30-40 years age group (average age 33.3 years), males (77.9%), and traffic accident victims (84.1%). These findings are in accordance with most studies related to tibial fractures.^{1,4,9} Although we have reported statistically significant difference between the groups regarding length of hospitalization and time needed for union, other results seem to be higher than ours. According to the authors, the length of hospital stay was 5.6 ± 2.6 days in the unreamed interlocking group and 4.3 ± 2.2 days in the ender group. In a randomized prospective trial in China, Chiu et al¹⁰ compared unreamed intramedullary nailing with ender nailing for tibial fractures. In the group with interlocking nails, hospital days were 10.4, and union time was 15.1 weeks for closed fractures and in the ender group hospital days were 8.3 days, and union time was 11.6 weeks for closed fractures. T-test showed statistically significant difference between the groups in all of the data.¹⁰ The so-called conflict may be due to different surgical methods (which we have not emphasized on in our study) and the different study population. However, Hussain et al¹¹ have obtained similar results as ours on time needed for union. The overall rate of device failure was 3%: much lower than other studies that report up

to 52% of device failure.^{11,12} Although all cases of device failure belonged to unreamed interlocking group, the 2 groups were not statistically different. Mal-union was detected in 6 cases (9.6%); all of them belonging to ender group. Our mal-union rate is more than 5.8% reported by Cozma¹³ and 5.4% reported by Zehtab¹⁴ but similar to the result obtained by Hussain et al.¹¹ According to the present study, the union rate at the end of 6 months was 95.5% for unreamed interlocking group and 75% for ender group. During the next 3 months, only 5 (7.8%) of ender group was diagnosed by the authors as non-union. That is more than 4.3% reported by Sakaki et al.¹⁵ According to authors, the rate of infection was significantly higher in the ender group (7.8%) and no infection was reported in the unreamed interlocking group. Wall et al reported a 40% and Cozma a 9.1% infection rate in patients treated with ender nails.^{13,16} The difference may be due to different surgical methods and antibiotic prophylaxis which is not reported by the authors. With regards to the above data, the results of our study support those of other studies that indicate the choice between the 2 methods of unreamed nailing is mainly controversial, depending on the priorities of the patient and surgeon and none of the methods can be stated as the treatment of choice for tibial fractures. As the present study was performed on the 131 patients attending only one orthopedic center, the authors suggest that other studies, preferably multi center, with larger sample size and more variables such as surgical method and antibiotic regimen are carried out to get certain results.

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