



## Expandable intramedullary nails for fixation of tibial shaft fractures

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**Interlocking intramedullary nailing is currently the preferred treatment for most tibial fractures requiring operative treatment, with good results and a relatively low complication rate as reported in large clinical series. However, vascular and neurological complications caused by interlocking screws have been reported. In addition, insertion of distal interlocking screws can be technically demanding and may entail substantial exposure.**

**We present the results with an expandable self-locking nail in the management of 52 AO type A and B tibial shaft fractures. The mean time to union was 15.8 weeks and the rate of union was 98%. The average surgical time was 60 minutes. Complications were those usually seen in diaphysis nailing and no complication was noted during nail expansion. Interlocking screws are not necessary, which reduces the risk of iatrogenic lesions. The expandable nail allows effective management of AO type A and B diaphyseal fractures of the tibia, a lower radiation exposure and shorter operative time.**

**Keywords :** tibia ; diaphyseal fracture ; intramedullary nailing ; expandable nail ; Fixion nail.

### INTRODUCTION

Locked intramedullary nailing is a standard procedure in many countries to manage tibial shaft fractures. Proximal and distal interlocking improve rotational stability (6,15), allow the treatment of polyfragmental fractures and the prevention of shortening or lengthening. Disadvantages of inter-

locking screws include the risk of neurovascular injuries (11,19,20,21), soft tissue damage and difficulties in insertion of distal interlocking screws increasing radiation exposure.

The Fixion nail (Fixion, Biomet, Belgium) is an expandable, stainless steel nail especially designed to expand up to 160% of its original diameter by inflating via a pressure hydraulic system using saline. By doing so, the nail will fit the isthmus of the bone and establish a direct contact with the endosteum which allows stability of the fracture. Interlocking is not necessary with this system.

The purpose of this study is to answer the following questions : Is the Fixion nail an effective implant for the fixation of the pre-selected fractures ? Does the implant allow to reduce operative time and radiation exposure ? What are the complications inherent to this implant ? Two trauma centres participated in this retrospective study.

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## MATERIALS AND METHODS

This retrospective study was conducted in two level 1 university trauma centres. From 2002 to 2006, 79 patients were treated with the Fixion nail for tibial and femoral shaft fractures, non unions and pathological fractures. To decrease heterogeneity of the group, femoral fractures ( $n = 9$ ) pathological fractures ( $n = 3$ ) and non unions ( $n = 8$ ) were excluded from the series. Seven patients were lost to follow-up. Fifty-two fractures in 52 patients were available for follow-up until union at a mean of 20 months (6 to 36). Based on the radiographic assessment, AO type C fractures were not treated by this technique. There were 42 men and 10 women. The mean age was 37 years (range 15 to 75). We treated 32 polytrauma and/or polyfractured patients. There were 9 open fractures (7 Gustilo 1, 1 Gustilo 2 and 1 Gustilo 3A). Road traffic accident was the mechanism of injury in 30 patients (57.7%), fall from a height in 12 patients (23%), sports injury in 8 patients (15.4%) and assault in 2 patients (3.8%). AP and lateral views of the tibia were available in all patients. Fractures were classified according to the AO classification. AO C type fractures were not treated by this technique. There were 12 A1 (simple spiral), 9 A2 (simple oblique), 11 A3 (simple transverse), 10 B1 (spiral wedge), 9 B2 (bending wedge) and 1 B3 fractures (fragmented wedge). Thirty fractures were in the middle third (zone 2) and 22 fractures in the distal third (zone 3) of the tibial diaphysis.

### Surgical technique

Surgeons involved in this study included 3 senior orthopaedic trauma surgeons and 4 registrars from both trauma centres. Nailing was carried out with the patient lying supine, with the knee on the affected side hanging at 90° flexion. No traction was used. The nail was inserted from a medial approach along the patellar tendon. A guide wire was passed across the fracture site and reaming was carried out in 50 cases. The canal was overreamed to one and a half millimetre more than the diameter of the nail to ensure smooth nail insertion. In 2 cases of open fractures (Gustilo 2 and Gustilo 3A) reaming was not performed and the nail diameter was chosen 2 millimetres less than the measured intramedullary canal diameter on the preoperative radiographs. After reaming, the guide wire was removed and the nail was inserted as it is not canulated. The expandable nail diameter was chosen 1.5 millimetres smaller than the diameter of the last reamer. The initial tibial nail diameter was 8 millimetres in 6 cases, 8.5 millimetres in

26 cases and 10 millimetres in 20 cases. The 8 mm nail can be expanded up to a maximum of 12.7 mm diameter, the 8.5 mm nail up to 13.7 mm diameter and the 10 mm nail up to 16 mm diameter. The length of the nail was 320 mm in 2 cases, 340 mm in 14 cases, 360 mm in 34 cases and 380 mm in 2 cases. Distal positioning of the nail is similar to the classic interlocking nails. For the fractures of the distal third of the diaphysis, a minimum distance of 7 cm between the fracture line and the tip of the nail is necessary to provide stability. After insertion, the nail was inflated gradually by pumping in normal saline to a pressure of 50 to 80 bars (the target pressure was 70 bars) under fluoroscopy guidance.

Postoperative care and follow-up: Knee and ankle motion was started in day one post-operatively when feasible. Weight bearing was allowed as tolerated in A2 and A3 fractures (fractures with no risk of shortening) and touchdown weight bearing during 6 weeks in other cases. Clinical records and radiographs were reviewed retrospectively by a senior orthopaedic surgeon from each centre. Postoperative information, based on the medical records, were collected retrospectively. Complications and time to healing were recorded. Radiographs in AP and lateral view of the tibia were performed the day after surgery and during follow-up at 6 to 8 weeks intervals thereafter until clinical and radiological union of the fracture had occurred.

Evaluation: Union was defined as complete bridging of at least 3 cortices in AP and lateral views. Based on the anaesthetic charts the time of incision and closure were used to calculate the duration of surgery. The use of fluoroscopy was calculated in one trauma centre in 10 unselected cases. Duration of hospital stay and complications were recorded. Postoperative shortening was evaluated on digital radiographs by measuring the outcome over time of the gap or the overlapping between the proximal and distal fragments. The measures were performed based on first postoperative radiographs and after weight bearing. Non-union was defined as absence of consolidation at 9 months (12). Malunion defined as an angular deformity  $> 5^\circ$  was evaluated in both sagittal and frontal planes.

Influence of fracture characteristics on union was tested by the log rank test in Kaplan-Meier analysis for the time to union. Values for  $p < 0.05$  were regarded as significant.

## RESULTS

Union was achieved in 51/52 patients (98%) without additional surgery. The mean time to healing

Table I. — Influence of fracture characteristics on union

Fracture type	Number of patients (n = 52)	Mean time to union (weeks)	p value*
Closed	43	12.6	0.447
Open	9	14.2	
<b>Stability</b>			
Stable (AO A2-3)	22	12	0.02
Unstable (AO A1 - B1-2-3)	30	14.2	
<b>Fracture level (third of diaphysis)</b>			
Middle (zone 2)	30	12.28	0.39
Distal (zone 3)	22	13	

\* Log rank test.

was 15.8 weeks (range 8 to 20). The results of the analysis of the time to union according to fracture characteristics are shown in Table I. The time to union was not significantly longer for open fractures than for closed fractures. Similarly the time to union was not significantly longer at different locations of the tibial diaphysis (zone 3 versus zone 2). Time to union was significantly longer in unstable than in stable fractures. The average surgical time was 60 minutes (range : 25 to 130 minutes). The average time of fluoroscopy use was 96 seconds. The average duration of hospital stay was 3.2 days for the isolated fractures (28 patients). In 17 cases the nail was removed after fracture healing, upon patient's request, without any difficulties.

### Complications

Intraoperatively, fracture propagation occurred within the distal fragment in 2 cases : during reaming in one and during nail insertion, before inflating, in the other.

Early postoperative complications : there were 3 compartment syndromes which needed fasciotomies, 1 transitory common peroneal nerve palsy and 1 superficial wound infection treated with antibiotics, which did not require device removal.

Late postoperative complications : postoperative shortening calculated on the digital radiographs occurred in 4 cases (range : 3 to 7 mm). We did not note radiographic angulation exceeding 5 degrees in both frontal and sagittal views of the tibia on the final follow-up radiograph. Malrotation could not

be evaluated because of lack of data in the clinical notes. We had one non-union in a patient with multiple fractures who had a closed B1 fracture of the distal third of the tibia. He developed a compartment syndrome which was treated by fasciotomy. After 8 months without signs of union, the nail was exchanged for a classic interlocking nail and bone grafting.

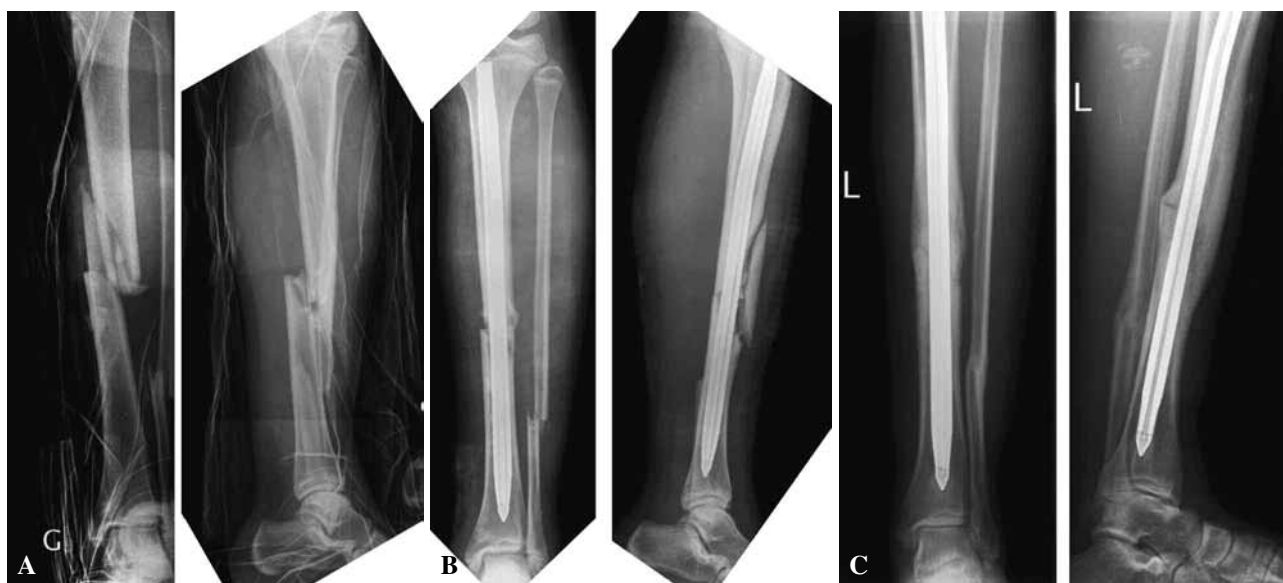
### DISCUSSION

In this series, the variety in fracture patterns, the inclusion of closed as well as open fractures and the use of the nail in isolated fractures as well as in polytrauma patients make it difficult to delineate the indications and contraindications for the technique. However our results show that the implant can be used efficiently in various indications.

We found that the mean time to union was not significantly longer in open fractures than in closed fractures.

The location of the fracture along the tibial diaphysis appeared in previous reports (8,9) to affect the time to union. In our study, the time to union was not significantly longer in zone 3 compared with zone 2.

We found a significant difference in the mean time to union between unstable and stable fractures. A similar observation has been made in one previous study (9), whereas the results of other studies of tibial intramedullary nailing failed to show significant differences (1).



**Fig. 1.** — (A) : Pre-operative radiograph of a 15-year-old boy who sustained a closed, isolated AO B1 unstable mid shaft (zone II) fracture after a road traffic accident. (B) : Post-operative radiograph. (C) : Radiograph 9 months after intramedullary nailing.

Our results have shown an overall union rate of 98% which is comparable to the union rate with the expandable nail and classic interlocking nails in previous reports. However, direct comparisons are difficult because of variations in the classifications of the fractures and the outcome criteria used. The mean time to healing was shorter compared with the classic interlocking nails (4,7,8,14) and similar to other series using the expandable nail (3,13,16,17). Early dynamisation of the fracture site, as the expandable nail avoids the need for interlocking screw insertion could encourage early bone union. In this series, A2 and A3 fractures (20 cases) were considered as stable with low risk of secondary shortening and were allowed post-operative weight bearing as tolerated. In all other cases, full weight bearing was allowed after 6 weeks (Fig. 1 & 2).

In our series the average surgical time was 60 minutes. Ben-Galim *et al* (3) compared in a prospective, randomized clinical trial the expandable nail with an interlocking nail in tibial shaft fractures. The authors did not specify how many screws were inserted in the interlocking group. The operation time was significantly shorter in the expandable group (52.9 minutes) compared with

the interlocking group (104 minutes). A similar observation was made by Lepore *et al* (13).

Several minutes of live fluoroscopy are required during stabilisation of long bone fractures with interlocking intramedullary nailing in order to determine the appropriate location of the starting hole and alignment for the distal locking screws (10,18). There is no need for interlocking screws with the expandable nail, which reduces radiation exposure. Another disadvantage of interlocking screw insertion is the associated risk of neuro-vascular injuries (8,11,21). Such complications are avoided with the expandable nail.

Fracture propagation was recorded in 2 cases, before inflating. In one case the crack occurred during reaming and in the other case during nail insertion (Fig. 3). None of these iatrogenic fractures were related to the expansion concept of the nail. Despite this complication, the expandable nail was used in both cases without further complications because there was enough intact bone between the fracture and the distal end of the nail. One potential complication with the expandable nail is fracture propagation during inflation (3,4). In a few cases we noted a sudden drop in the pressure during nail



**Fig. 2.** — (A) : Pre-operative radiograph of a 32-year old polytrauma patient after a road traffic accident with a closed AO A1 distal third (zone III) fracture of the tibial diaphysis, head injury and contralateral hip fracture. (B) : Post-operative radiograph. (C) : Radiograph 12 months after intramedullary nailing.

expansion. This phenomenon occurred while approaching or passing beyond the aimed pressure of 70 bars. We could not establish a relationship between the drop in pressure and fracture propagation, as we did not demonstrate either pre-operatively, using the image intensifier, or post-operatively, any fracture propagation. The exact cause for this drop in pressure in a few cases is still unclear.

Digital radiographic measurement demonstrated secondary impaction of the fracture site in 4 cases. The amount of shortening, ranging from 3 to 7 mm, was not significant and was without clinical consequences (Fig. 3). Shortening during the healing process is a potential complication with the expandable nail. Smith *et al* (16) reported in a prospective study of 49 long bone fractures treated by expandable nailing a rate of 14.3% of post-operative shortening and mentioned that a potential cause for this complication could be an occult crack during nail expansion. In our study, we did not demonstrate any fracture progression during inflating, and secondary shortening was not significant. We think that the choice of the correct diameter of nail, which was selected on the basis of the diameter of the last

reamer used, is an important factor to have a good fit within the intramedullary canal. Another important factor to avoid secondary shortening is the time to weight bearing with respect to the fracture type. In our study, only patients with AO A2 and A3 fractures were allowed full weight bearing post-operatively. In all other cases full weight bearing was allowed only after 6 weeks.

The overall rate of non-union was 1/52 (1.92%) in our study. A review of the literature demonstrates rates of reoperation required to achieve union ranging from 14 to 57% for tibial shaft fractures. The most commonly performed procedures were dynamisation of a statically locked nail and removal of broken locking screws, procedures not required with the expandable nail (4,7,8,9).

Another potential complication is unacceptable malrotation after nail expansion, in which case the nail should be removed. Proper examination of the intact contralateral leg is mandatory preoperatively in order to evaluate rotation. For tibial fractures, we check the position of the foot with respect to the patella on the intact side and we replicate the same position on the fractured side after nail insertion



**Fig. 3.** — (A) : Pre-operative radiograph of a 36-year-old man who sustained a closed, isolated AO type B1 mid shaft (zone II) fracture after an assault. (B) : Post-operative radiograph shows a distal extension of the fracture (thick arrow) which occurred during nail insertion. (C) : Radiograph 6 weeks after nailing showing secondary impaction (thin arrow) of 7 mm. (D) : Radiograph 6 months after nailing showing fracture union.

and before inflation. This simple check can avoid significant malrotation exceeding  $10^\circ$ .

Publications examining the use of the Fixion system in acute tibial shaft fractures were identified from MEDLINE and the Cochrane databases by Beazley *et al* (2). Among 41 citations generated by the search, two randomised trials and 8 case series satisfied their selection criteria and were reviewed. The average reoperation rate was 10.2%. Analysis of reoperation rates revealed a wide variation between cohorts. Shortening occurred in 3% of

cases and may be a problem in longitudinally unstable fractures (AO C type); however most cases of shortening were confined to one study. Fracture propagation on expansion of the nail was also a concern when using the Fixion system. Five cases (2%) of fracture propagation were reported amongst the studies. Three of these cases were reported by Smith *et al* (16).

Our results show that the implant can be used efficiently in different indications. The surgical technique is easy and reproducible as several

surgeons with different levels of experience were involved in the study. AO A and B type fractures are in our experience good indications for the expandable nail. The use of the Fixion system appears to save theatre time and decreases radiation exposure. It also appears that there may be an advantage in terms of union rate. More prospective studies are necessary to define more accurately the advantages and disadvantages of the expandable nail.

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