Results of angular-stable locked intramedullary nails in the treatment of distal tibia fractures

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## A R T I C L E   I N F O

Article history:
Accepted 9 September 2014

Keywords:
Fracture
Leg
Tibia
Nailing
Locking

## A B S T R A C T

Introduction: Intramedullary nailing in distal tibial fracture is controversial because of a lack of stability. The present study sought to assess radiological and clinical results for a new “angular-stable” locking system in difficult indications for intramedullary nailing.

Material and method: A prospective study recruited 41 patients (41 tibias) with distal tibial fracture consecutively managed using angular-stable locked intramedullary nails. Radiologic assessment comprised AP and lateral lower-limb views, taken postoperatively and through to last follow-up. The mean distance was measured between fracture and joint line. Fusion, with or without malunion, primary reduction defect, non-union and secondary displacement were recorded, as were all complications.

Results: Mean follow-up was 18 ± 5 months; 3 patients were lost to follow-up. Mean fracture distance from the joint line was 63 ± 25 mm. Fusion was achieved within 3 months in 29 cases (76%); delayed fusion in 7 patients (18%) required secondary dynamization at a mean 3 months, with favorable evolution. Revision surgery was required in 2 cases: 1 for secondary displacement exceeding 10°, and 1 for non-union at 7 months. Other complications mainly comprised 4 malunions of less than 10° due to primary reduction defect.

Conclusion: Angular-stable locked lower-limb intramedullary nailing provided a very satisfactory fusion rate, with few complications. It is, however, a demanding procedure, especially as regards fracture reduction and nail positioning in the distal fragment.

Prospective cohort study: level IV.

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## 1. Introduction

Closed intramedullary nailing is the reference attitude in tibial shaft fracture, thanks to its high rates of fusion [1–4]. In distal third fracture, it is more controversial [5–7]. Diameter is greater than in the shaft and intramedullary filling by the nail is insufficient; this is an anatomic factor impairing mechanical stability [8,8]. The long lever arm and enlargement of the metaphysis also create problems for reduction and nailing [9]. Moreover, fusion instability is exacerbated by standard distal locking systems, which create a further area of mobility between nail and screw [1]. These factors of instability induce fusion defect, with or without secondary displacement, leading to malunion [7].

New locking systems have been developed to improve mechanical stability and thus fusion after intramedullary nailing of distal tibial fracture [10–14]. One such is the Angular-stable Locking System (ASLS, Depuy-Synthes). The principle involves distal locking screws introduced in a resorbable expansile sleeve to enable fixation in the two cortices and in the nail. Mechanical stability has been assessed on several biomechanical animal cadaver studies, with promising results [12,15]. There has, however, as yet been only one preliminary clinical and radiological study, including femoral, humeral and tibial indications [16].

The present study sought to assess radiological and clinical results and complications after intramedullary nailing of distal tibial fracture using this angular-stable distal locking system. The study hypothesis was that fusion rates would be very satisfactory, with few complications, in what is a difficult indication.

## 2. Materials and methods

A single-center prospective study recruited 41 patients (41 tibias) with distal tibial fracture, managed by intramedullary nailing...
in the orthopedic department of Bichat Hospital, Paris (France), between 2009 and 2012.

2.1. Inclusion and exclusion criteria

Inclusion criteria were: age > 18 years, any displaced distal tibial fracture managed by anodegrade intramedullary nailing with angular-stable distal locking (Expert tibial nail, Depuy-Synthes ASLS screw). Fractures were open or closed, Gustilo 1 or 2 with or without associated fibular fracture [17]. Minimum follow-up was 12 months.

All other forms of tibial fracture were excluded (except articular or medial malleolar fracture), as were fractures initially managed by external fixator, pathologic fractures and fatigue fractures.

2.2. Study population

Forty-one patients (41 fractures) (28 male, 13 female) were recruited. Mean age was 45 ± 13 years. Three patients were lost to follow-up before month 3; 38 patients had complete assessment.

2.3. Technique

Positioning was systematically supine. The contralateral limb was secured to a gynecological support allowing the fluoroscope to be positioned perpendicular to the operative side. The fractured limb was positioned hanging, with a support under the knee.

Primary fibular osteosynthesis, by screwed plate or intramedullary K-wire, was performed in 11 cases (29%) for syndesmosis lesion, or lateral malleolar fracture.

The nail was introduced in the standard way, with a drill-hole 1.5 mm wider than the nail diameter. Locking screw diameter ranged from 4 to 5 mm, depending on the nail diameter, which ranged from 9 to 12 mm. The Expert nail (Synthes) and screws were in titanium (TiA16N17). Instrumented proximal locking used 2 standard screws and distal locking was performed freehand under fluoroscopic control. The angle screws had 3 successive diameters (Fig. 1): the narrowest, most distal from the screw-head, held the non-expanded sleeve for insertion and anchoring in the far cortex; the second expanded the sleeve to chock it within the nail to ensure angular stability; the largest diameter section then anchored the screw in the near cortex.

Screwing began by reaming the two cortices aligned on the axis of the locking hole under fluoroscopic control. A manual drill then enlarged the hole through the near cortex and up to the nail. The resorbable poly (L-lactide-co-D, L-lactide) sleeve was then inserted onto the screw, with the lower lip toward the screw-head and the screw tip protruding (Fig. 1). The screw + sleeve assembly was then pushed into the prepared hole, tapping the screwdriver lightly if necessary to complete insertion. Screwing began once the sleeve was in the nail, and continued until the screw-head reached the first cortex.

Dynamization by ablation of the distal locking system was not systematic but only performed in case of non-fusion after 3 months.

2.4. Postoperative course

Postoperatively, no immobilization was imposed. Complete weight-bearing on the operated limb was authorized immediately, with 2 crutches for the first 6 weeks, to promote functional recovery and fusion by compression effects.

2.5. Radiologic assessment

Radiologic assessment was based on plain AP and lateral lower-limb views taken postoperatively and at each follow-up consultation (1½ months, 3 months then every 2 months until complete fusion, and then every 6 months). Assessment concerned: distance (mm) between distal part of fracture line and tibial talar joint line, primary reduction error, fusion, secondary displacement, non-union (at 6 months), malunion and malalignment.

Malalignment comprised varus/valgus and flexion/extension equal to or greater than 10. Rotational disorder was assessed clinically. Limb length discrepancy was counted if equal to or greater than 10 mm.

Any reaction around nail or locking screws (ossification, lysis, etc.) was recorded.

All complications were recorded: compartment syndrome, infection, complex regional pain syndrome (CRPS), skin lesion. Revision surgery, cause and technique were also recorded.

3. Results

Mean follow-up (38 patients) was 18 ± 5 months. The main fracture characteristics found in the study are presented in the Table 1. There were no associated joint fractures. There was 1 medial malleolar displacement fracture, requiring complementary screwing.

Mean surgery time was 80 ± 30 min. A mean 2 angular-stable distal locking screws were used per nail.

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**Table 1**

<table>
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<th>Characteristics of the distal tibia fractures included in the study.</th>
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<td><strong>Mean distance of lower part of fracture line to tibial talar joint line</strong></td>
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<td><strong>Associated fibula fracture</strong></td>
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<td><strong>Fibula osteosynthesis</strong></td>
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3.1. Radiologic assessment

On immediate postoperative X-ray, 4 patients showed $<10^\circ$ malalignment: 3 varus, 1 extension. There were no rotational disorders.

By D90, 29 fractures (76%) showed fusion (Fig. 2); 8 showed delayed fusion, managed by secondary dynamization at month 3, with 7 (18%) of the 8 cases achieving fusion by the end of month 6 (Fig. 3). The final case involved associated distal fibular fracture without osteosynthesis; a larger diameter nail was inserted after complete reaming, and immediate weight-bearing gave favorable evolution (Fig. 4).

One case of early secondary displacement in $>10^\circ$ valgus (3%) required surgical revision at 1 month: reaming, larger diameter nail and angular-stable locking.

On radiologic assessment at last follow-up, the 4 patients (10%) with initial reduction error showed no increase in displacement. No secondary displacements were found, other than the case managed by early revision.

3.2. Complications

There were no infections or severe skin lesions. One case of compartment syndrome required aponeurotomy. There was 1 case of CRPS.
4. Discussion

In the present series, all distal tibial fractures treated by intramedullary nailing with angular-stable locking showed favorable evolution, apart from 2 revision surgeries. These results can be attributed to the biomechanical properties of distal angular-stable locking. Recent cadaver studies [12,15] demonstrated that the system significantly enhanced resistance to compression and torsion stress and to mobility variation as compared to standard locking. This led us to authorize very early weight-bearing to promote fusion without increasing the risk of secondary displacement.

There has been a single report of clinical and radiological results in distal fracture nailing with angular-stable locking, in a preliminary study that combined femoral and distal and proximal nailing: surgeons were satisfied with the stability the system provided and with the low rate of complications; no further information was given [16].

In surgical management of distal tibia fracture, intramedullary nailing is in competition with open screwed plate osteosynthesis [18]. The main advantage of plate osteosynthesis lies in optimal reduction and satisfactory mechanical stability [7]. A recent systematic review including the only two randomized studies on the subject found that the two forms of treatment gave comparable fusion rates [7]: distal locking was of the standard type for nailing; lack of power, however, precluded concluding in favor of one or the other technique. An older review of the literature, including 1125 distal tibial fractures, reported 5.5% non-union and 16.4% surgical revision with intramedullary nailing and comparable rates with plate osteosynthesis [6]; several limitations of standard nailing were, however, highlighted, including risk of joint lesion and, above all, problems of alignment. Janssen reported 50% malalignment with nailing versus 17% with plate osteosynthesis [5], and considered this enough to prefer open reduction by screwed plate [5]. In Zelle’s systematic review, on the other hand, alignment issues were comparable between nailing and plating, with a rate of 16.2% for both [6]. Moreover, plating involves a risk of septic non-union and frequent skin lesions due to the large surgical approach [2,18].

Distal tibial fracture is often associated with fibular fracture, which is mainly distal [19]. There is controversy as to the interest of associated fibular osteosynthesis, which may facilitate tibial reduction and improve mechanical stability [20,21]. A recent study was contributive in this regard [19], comparing 146 distal metaphyseal fractures with reduction and osteosynthesis with versus without associated fibular osteosynthesis: tibial axis correction and tibial fusion were better after primary fibular osteosynthesis; however, fibular fixation could also worsen the persistence of abnormal tibial reduction. Fibular osteosynthesis should not be systematic, but is recommended in case of syndesmosis lesion or distal, medial or proximal fracture involving the distal third of the fibula [9,19].

The present study had certain methodological limitations. Although prospective, it was not comparative. The series was small. Five surgeons were involved, most of whom were in training, which may have led to treatment bias; however, such is the real-life situation, where surgery is always under the supervision of a senior surgeon, available in case of problems.

In conclusion, intramedullary nailing of distal tibial fracture with angular-stable locking provided very satisfactory fusion rates with few complications. The technique may be demanding, especially as regards reduction and nail positioning in the distal fragment. Fibular osteosynthesis should be considered, to improve stability and facilitate reduction. The present results bear out the study hypothesis and encourage us to continue with this surgical technique for distal tibial displacement fracture.
Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References