Critical analysis of tibial fracture healing following unreamed nailing

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Abstract

Purpose Unreamed nails have revolutionised the treatment of tibial shaft fractures. Many authors, however, have reported increasing bone healing complications with these implants. Unfortunately, few studies have addressed the factors affecting bone healing after unreamed tibial nailing.

Methods One-hundred and sixty tibial fractures in 158 patients (mean age 39.5 years) fixed using unreamed nails were reviewed. There were 78 AO type-A, 65 type-B and 17 type-C fractures (115 closed and 45 open fractures). Twelve patient, injury and surgery variables were analysed for their influence on fracture healing.

Results Union occurred in all fractures after a mean time of 24.3 weeks. Additional surgery to achieve union, apart from dynamisation, was done in nine (6%) cases. The most important variables affecting healing were the mechanism of trauma ($p=0.005$), fracture site gap ($p=0.01$), degree of comminution ($p=0.0003$), associated soft tissue injuries ($p=0.02$) and the time to dynamisation ($p=0.0001$).

Conclusions High-energy trauma and fracture comminution have a negative impact on bone union and require close follow-up. It is essential to avoid distraction over three millimetres with unreamed nailing. Dynamisation is advised within ten weeks in axially stable fractures to encourage bone healing and avoid failure of the locking screws.

Introduction

Significant advances have been made in the last century in fracture management through a better understanding of fixation biomechanics and a greater respect given to the biological role of the soft tissues. The introduction of unreamed nails in treating open tibial fractures has reduced several complications that accompanied medullary reaming with good clinical results [1, 2]. A reduced trauma of nail insertion with less blood loss and shorter operative time are discussed as advantages [3]. The absence of reaming preserves the endosteal blood supply, which may allow early bone healing with less risk of infection [4, 5], and avoids serious complications, both locally as compartment syndrome and systemically as fat embolism and adult respiratory distress syndrome [6].

Expanding the indications for unreamed tibial nailing and the widespread use of these implants in closed fractures, however, have been associated with a longer time to union and a higher complication rate as several randomised prospective trials have shown [7–9]. Some studies revealed that up to 48% of tibial fractures treated with small-diameter nails inserted without reaming require a secondary procedure to achieve union [10–13]. Other problems, such as early fatigue failure of nails and locking screws, were reportedly increased [9–15]. Unfortunately, most papers reporting the use of unreamed nailing included a small number of cases with different classification and treatment protocols making statistical evaluation difficult [15]. The aim of this study was to evaluate fracture healing using unreamed nails in diaphyseal tibial fractures and to determine the variables that influence bone union following such procedures.

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Materials and methods

Between April 1991 and December 2002, 160 diaphyseal tibial fractures in 158 skeletally mature patients were treated using the AO Unreamed Tibial Nail (UTN®, Synthes GmbH, Umkirch, Germany) by experienced trauma specialists in a Level I trauma centre. The study included 105 men and 53 women (ratio 2:1), who ranged in age between 16 and 89 (mean 39.5) years. Eighty-two patients were treated for a right-sided fracture, 74 for a left tibial fracture, and two male patients had bilateral UTN-fixed fractures. The indications for fixation were displaced or unstable fractures, polytrauma, multiple injuries, open fractures, high-energy closed soft tissue injury as well as segmental fractures. Pure articular or subchondral fractures without diaphyseal extension and paediatric fractures were excluded.

Fractures were classified anatomically as involving the proximal ($n = 9$), middle ($n = 37$) or the distal third of the tibia ($n = 101$), or as segmental fractures ($n = 13$). Half of the fractures (78 cases) were simple AO type A fractures (41 type-A1, 16 type-A2 and 21 type-A3), 65 were wedge type B fractures (15 type-B1, 30 type-B2 and 20 type-B3), and 17 were complex type C fractures (2 type C1, 13 type-C2 and 2 type-C3). Fracture comminution was judged using Winquist et al. criteria [16]. There were 41 fractures (25%) without comminution, 47 (30%) type-I (minimal comminution), 32 (20%) type-II (with at least 50% contact), 23 (14.5%) type-III (>50% comminution), four (2.5%) type-IV (no cortical contact) and 13 (8%) segmental fractures.

One-hundred and fifteen cases were closed (72%) and 45 were open (28%) fractures. There were 25 fractures without soft tissue injury. Closed soft tissue injury was classified according to Tscherny and Gotzen [17] into 52 G-I, 28 G-II, and ten G-III injuries. Open fractures were classified into Gustilo et al. [18] type I ($n = 21$), type II ($n = 13$) and type III ($n = 11$) fractures. The causative injury was a high-energy trauma (traffic accidents, work injuries and falls from a height) in 100 patients (64%). Fifty percent of cases ($n = 79$ patients) had additional injuries and 35 patients (22%) were victims of polytrauma. The most common associated injury was head trauma ($n = 18$ patients). Most fractures ($n = 119$) were fixed immediately after injury; for the remainder, the mean delay was 18.7 days.

All procedures were done in a standard operating room without laminar flow. The surgical technique involved positioning the patient supine under general or regional anaesthesia on a radiolucent operating table with biplanar fluoroscopic control. Traction was not required. A second generation cephalosporin was given intravenously as a pre-operative single-shot antibiotic prophylaxis with the induction of anaesthesia in all cases. Fracture reduction was done in all but one case using closed manipulation and manual longitudinal traction. This was sometimes helped by the

percutaneous use of a reduction forceps, a large distractor, or a previously applied external fixator. The nail most commonly used was the 9-mm UTN, in 78 fractures (49%). The 8-mm UTN was used in 63 fractures (39%) while 10-mm nails were used in 19 cases (12%). Nail length varied between 255 and 420 mm. Seventeen fractures were associated with an intact fibula. Fibular plating was done in 12 of the remaining 143 cases. In distal tibial fractures, an effort was made to insert the nail tip centrally close to the ankle joint line. Static locking was done in 143 nails (89%) and primary dynamic locking in 17 cases (11%). The most common mode for static locking was using four coronally-oriented locking screws (two in each end) in 100 nails (62.5%) followed by five screws (two proximal and three distal) in 29 nails (18%). Primary dynamic locking uses the proximal dynamic slot as the only site for proximal locking. Distal locking was then done using two coronal screws in 11 nails, one coronal and one AP screw in one nail, all three distal screw holes in three nails, and only one coronal screw in two nails.

All patients received non-steroidal anti-inflammatory drugs postoperatively. All postoperative X-rays were examined for fracture site gap and described as none, minimal (less than one millimetre), mild (one to three mm), moderate (three to five mm), severe (over five mm), cases with defects due to displaced fragments or comminution and cases with both distraction and comminution. The quality of reduction was also assessed. Serial follow-up radiographs were made every three to four weeks to detect secondary displacement, mechanical axis deviation, implant failure or loosening and progress of fracture union. Early knee and ankle joint motion was allowed immediately postoperatively. Patients with stable fractures were allowed 20-kg partial weight-bearing for four to six weeks. Weight-bearing was then increased as tolerated. Patients with fracture comminution were kept non-weight bearing for at least six weeks.

Sixty-one static nails were not dynamised. Operative dynamisation was done in 40 nails. Autodynamisation through fatigue failure of the locking screws occurred in 32 fractures, and there was no information about dynamisation in ten patients. Nails were removed after a mean of 20 months ranging between 16 days (suspicion of infection) and ten years. An alcoholic polytrauma patient died of multiple organ failure. Six cases were lost to follow-up and eight had incomplete records or radiographs. Finally, 145 cases were reviewed after a mean follow-up of 35.5 (range 12–148) months.

Statistical analysis was done using SAS software (SAS Institute, Cary, NC). The major outcome measure was the time to union in relation to 12 variables. These variables were patient's age and sex, mechanism of injury, associated injuries, fracture site, pattern and comminution, soft tissue injury, surgical delay, nail diameter, fracture site gap and the

time to dynamisation. One-way ANOVA was first conducted for each factor. Variables that showed substantial influence were included in multifactorial ANOVA and the p -value was calculated. Tukey test detected differences in union time among levels of a factor. For delayed-/non-union a dichotomous dependent variable was used. A chi-square test was done followed by multiple logistic regression. A backward selection was applied and the odds ratios were estimated.

Results

Union was defined as the ability to bear full weight without support on the injured leg, if other injuries allowed, with no fracture site pain or tenderness, together with the presence of mature bridging callus in at least three of four cortices seen in anteroposterior and lateral radiographs. Delayed union (DU) was defined as lack of union at 26 weeks, whereas non-union (NU) was defined as failure of a fracture to heal within 39 weeks.

The mean time to union for all fractures was 24.3 (range, 11–134) weeks (Fig. 1). Thirty-six fractures had a delayed ($n = 20$) or non-union ($n = 16$). Additional surgery to achieve union, apart from dynamisation, was done in only nine cases. An alcoholic non-compliant patient broke his nail. Ilizarov fixation ended in infection requiring amputation.

No significant differences existed in the mean time to union for patients younger (24 weeks) or older (25.3 weeks) than 40 years. The time to union in female patients averaged 20 weeks. Males required a mean of 26.5 weeks. The difference was not statistically significant.

Collectively, low-energy mechanisms had a mean time to union of 20 weeks with a combined DU/NU rate of 15% (six DU and two NU). On the other hand, high-energy injuries had a mean time to union of 27 weeks with a combined DU/

NU rate of about 30% (14 cases each). The difference was statistically significant ($p=0.005$).

Fractures in patients without associated injuries united after an average of 21.5 (range 11–58) weeks. There were 13 delayed unions and three non-unions. Patients with associated injuries united after an average time of 29.8 (range 12–134) weeks with 13 non-unions, seven delayed unions, one death and one above-knee amputation. Patients with polytrauma had a mean time to union of 26.3 weeks.

Fractures of the proximal third united after a mean of 24.7 weeks. The time to union for midshaft fractures averaged 23.5 weeks. Distal third tibial fractures had a mean time to union of 20.7 weeks. Segmental fractures united after a mean time of 27.6 weeks. Except for segmental fractures, the differences were not statistically significant.

The fracture pattern was an influential parameter affecting bone healing (Fig. 2). AO Type A fractures united after a mean of 21 weeks. Five DU (7.5%) and three NU (4.5%) were seen in this group. Type B and C fractures had a mean time to union of 27 weeks. DU/NU occurred in 30% of patients (ten cases each) in the former and 43.5% in the latter. Winquist type 0 fractures had a mean time to union of 20 weeks whereas type IV and segmental fractures had a mean time to union of nearly 28 weeks. Type III fractures had the longest time to union (32 weeks). The odds for having a DU/NU were 6.5 times more with comminution more than half of the cortical circumference than when more than 50% bony contact was present. The difference was statistically significant ($p=0.0003$).

The degree of soft tissue injury clearly affected the healing process (Fig. 3). Grade III open fractures had a longer time to union (mean, 44 weeks) than grade I and II open and closed fractures. Fractures with closed soft tissue injury were associated with 22% rate of DU/NU. This rate was doubled in open fractures (40% DU/NU).

Fractures treated within hours of the injury united after a mean time of 24 weeks. Cases operated upon after 24 hours

Fig. 1 Type A distal tibial fracture fixed by unreamed tibial nail (UTN) with percutaneous screw fixation of the Volkmann's triangle. Full union occurred after dynamisation

Fig. 2 Time to union according to the fracture pattern (maximum value 134 weeks)

had a mean union time of 25 weeks. Fractures nailed after a delay of less than one week, however, had a longer time to union (mean 28.5 weeks). This may be due to the lack of preliminary stabilisation in most of these cases. The difference, however, was not statistically significant.

With an 8-mm UTN®, union occurred after a mean of 23 weeks. The average time to union with the 9-mm UTN® was 26 weeks. As for 10-mm nails, one patient broke his nail and was later amputated for an infected NU, three patients had delayed union (16.6%) and the mean time to union was 20 weeks.

Statistical analysis showed that gaps at the fracture sites significantly affected the time to union ($p=0.01$). The odds for having a DU/NU were 1.6 times with distraction of one to three mm, six times with gaps more than three mm and nine times with gaps from comminution, respectively. Patients with fracture site compression united after a mean of 17 weeks whereas with fracture site gap over five mm, the mean time to union was 29.5 weeks (Fig. 4). Comminuted fractures with distraction had the longest time to union (mean 34 weeks).

There was no significant difference between cases with and cases without fibular plating. Both groups united after a mean of 25 weeks, which is 5.5 weeks longer than the mean time to union in isolated tibial fractures. Fibular plating,

however, was associated with a higher rate of delayed union (36%) than in uniplated fractures (10%).

Delay in nail dynamisation was the most significant parameter in the development of DU/NU ($p=0.0001$). The odds for having a DU/NU rise from two to four times when dynamisation was performed between ten and 20 weeks of nailing. Nails dynamised after 20 weeks are 52.5 times at risk of having a DU/NU. As for the time to union, dynamically locked nails united after a mean of 21.5 weeks. There were four cases of DU. Dynamisation within ten weeks resulted in union after a mean of 23 weeks with four NU. Dynamisation at ten to 20 weeks resulted in union after 24.3 weeks with five cases of DU and three NU. Fractures dynamised after 20 weeks united after 42 weeks with 75% DU/NU rate (Figs. 5 and 6).

As for other complications, two patients with C3 fractures developed deep venous thrombosis while in external fixation before nailing. A third patient with bilateral fractures developed pulmonary embolism. Compartment syndrome occurred after nailing in two patients. Early wound complications were observed in seven patients (4%). Superficial infection occurred in four cases, all of which responded to local wound care and antibiotic treatment. Deep infection occurred in three cases after UTN. Malunion was seen in 16 fractures: six cases

Fig. 3 Time to union according to the associated soft tissue injury (C closed, O open)

Fig. 4 Fracture distraction and union time (*None* no distraction, *Min* minimal distraction [<1 mm], *Mild* 1–3 mm distraction, *Mod* moderate distraction [3–5 mm], *Sev* severe distraction [>5 mm], *C* comminution, *D&C* distraction with comminution)

with valgus malunion ($6\text{--}12^\circ$), of them one had 1.5-cm tibial shortening as well, three varus malunion ($6\text{--}9^\circ$) and seven with external tibial torsion ($15\text{--}24^\circ$).

Fig. 5 Fracture union according to nail dynamisation (*Dyn* dynamisation, *w* weeks)

Discussion

This study is one of the largest series reported from one centre on unreamed tibial nails. Although the literature is rich in articles related to tibial nailing, few studies have been dedicated to analysing fracture union. The mean time to union for all fractures was 24.3 weeks. This agrees with other reports by Haddad et al. [10] (22 weeks), Angliss et al. [19] (21 weeks excluding four non-unions), and Krettek et al. [20] (23 weeks in severe closed fractures). Although this time is longer than that reported by Greitbauer et al. [21] using Howmedica's solid tibial nail (15 weeks) and Boenisch et al. [14] using Russel Taylor and AO unreamed nails (18.5 weeks), this time was clearly shorter than that reported by Wiss and Stetson [22] using reamed nailing (28 weeks in closed and 39 weeks in open fractures) and by Singer and Kellam [11] where 42 of 43 unreamed nailings united after a mean of 6.1 months.

The definition of non-union is still controversial. Court-Brown regarded any tibial fracture that unites without grafting or exchange nailing as healed uneventfully [23]. Others report non-union if healing does not occur after three [9], six [21], nine [3, 22] or 12 [24] months. Because of the different protocols regarding dynamisation, grafting or exchange nailing, non-union was here defined on time basis whether or not an intervention took place. Additional surgery to promote union, apart from dynamisation, was done in 6% of cases. These results are better than in other series of unreamed nailing [11–13].

It has been well known since ancient Egyptian times that tibial fractures are not all alike, and that prognosis varies with the severity of injury. The importance of open wounds extending to the fracture was recorded in Edwin Smith papyrus. Nicoll [25] studied 705 tibial shaft fractures and recognised displacement, comminution, soft-tissue damage and infection as predictors for a poor outcome. Trafton [26] described severe soft-tissue injury, articular involvement, complete displacement, comminution and transverse fractures as indicators for instability that preclude non-operative treatment. Gaebler et al. observed a significant increase in complications in grade III open fractures, type C fractures and to a lesser extent in distal fractures [15].

Several authors noted that the type of trauma (direct or high-energy versus indirect or low-energy) had a significant effect on the outcome and related this to the associated soft tissue damage [14, 19, 21]. Gaebler et al. had the highest rate of delayed union in grade III open fractures [15]. Similar findings were shown in this study. Some authors, however, consider closed fractures as less than optimal indications for unreamed nailing. Court-Brown et al. found that reamed nails in type I closed tibial fractures result in rapid union and less additional surgery than unreamed nails [7]. Blachut et al. reported a trend toward improved union with reamed nailing for closed tibial fractures with significantly more screws failed

Fig. 6 A segmental tibial fracture went on to non-union. Healing occurred after failure of all three static locking screws

in unreamed (16%) than in reamed (2.7%) nailing [9]. The SPRINT study recently showed a possible benefit of reamed nailing in closed tibial fractures with no difference between both approaches in open fractures [8].

The mechanism of injury was influential in fracture union. High-energy trauma occurred in 78% of cases with delayed or nonunion. Oni et al. noted that the only major clinical factor associated with delayed union was a high-energy injury [27]. The time to union was 20 weeks in stable low-energy fractures and more than 30 weeks in unstable high-energy fractures. The time to union in this series was also directly proportional to the energy transfer during injury. In contrast to spiral fractures, transverse fractures produce circumferential periosteal laceration and complete marrow transection [28]. Boenisch et al. noted that type A and B fractures took 17 weeks to unite whereas type C fractures united after 33.6 weeks [14]. Gaebler et al. [15] found a high delayed union rate in type C fractures (16%), compared with type A (7%) and B (6%). Angliss et al. had all type A fractures united at 17.7 weeks. Nonunion occurred in three type B and one type C fractures with a mean union time for the rest of cases of 26.3 and 19.7 weeks, respectively [19]. The union time in Greitbauer et al. study was 12, 13 and 22 weeks for type A, B and C fractures, respectively [21].

According to Winquist, comminution ranges from none to circumferential involvement [16]. In the present study, comminution significantly affected the union time. Bone et al. also noted a relationship between fracture comminution and the need for secondary procedures [1]. All seven non-comminuted fractures healed uneventfully whereas 13 of 22 comminuted fractures needed an additional procedure to achieve union.

It is important not to ignore the fibula, as it may help to reconstruct a severely traumatised leg. An intact fibula, however, may compromise union of an isolated tibial fracture [29]. Oni et al. denied this concern [27]. In the present study, an intact fibula mostly signified a low-energy stable fracture with a better outcome as isolated tibial fractures

needed a shorter time to union. On the other hand, fibular plating was associated with a higher risk of delayed union than in un plated fractures.

Several reports have shown that delayed union is more common with fracture site gaps [15, 24]. Gaebler et al. found that fracture distraction of over three mm increases the odds for a delayed union by 12 times and a nonunion by four times [15]. In the present study, fractures with distraction over five mm needed double the union time of those without gaps. Combined distraction and comminution had the longest time to union and the highest rate of delayed and non-union. These results are supported by biomechanical studies [30].

While locking is advisable with reamed nails, it is virtually mandatory in unreamed nailing since nails are thinner and the nail-bone construction is less stable [31]. Dynamisation converts a load-bearing nail into a load-sharing device. This avoids delayed union and hardware failure [1]. Stegemann et al. recommended that locked small-diameter nails should either be dynamised or bone-grafted after six to eight weeks [2]. Other authors also advocated early dynamisation in axially stable fractures [24]. Riemer et al. found that tibias treated with dynamic nails united in a mean of 20 weeks with three reoperations, whereas tibias with static locking united after 30 weeks with 21 reoperations [12]. In the present study, delay in dynamisation was the most influential parameter affecting union. This was proved biomechanically [30]. It has also been shown that minimal interfragmentary movement stimulates callus formation and bone healing [32].

Based on this study, the following recommendations are offered:

- It is important to differentiate between low- and high-energy transfer and not to underestimate the associated soft tissue injury.
- Fracture site compression and careful reposition of displaced vascular fragments should be done to eliminate large interfragmentary gaps.

- Early bone grafting or exchange nailing should be considered with high comminution (>50%) to decrease the risk of non-union.
- Nail dynamisation should be done within ten weeks to improve fracture healing and avoid breakage of the locking screws.

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