

TREATMENT OF GRADE-IIIB OPEN TIBIAL FRACTURES

A PROSPECTIVE RANDOMISED COMPARISON OF EXTERNAL FIXATION AND NON-REAMED LOCKED NAILING

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Severe open fractures of the tibia have a high incidence of complications and a poor outcome. The most usual method of stabilisation is by external fixation, but the advent of small diameter locking intramedullary nails has introduced a new option.

We report the early results of a randomised, prospective study comparing external fixation with non-reamed locked nails in grade-IIIB open tibial fractures. Of 29 patients, 15 were treated by nails and 14 by external fixation. Both groups had the same initial management, soft-tissue procedures, and early bone grafting. All 29 fractures healed within nine months, but the nailed group had slightly better motion and less final angulation. Complications included one deep infection and two pin-track infections in the external fixator group and one deep infection and one vascular problem in the nailed group.

Although the differences in healing and range of motion were not statistically significant, we found that the nailed fractures were consistently easier to manage, especially in terms of soft-tissue procedures and bone grafting. It is the treatment preferred by patients and does not require the same high level of patient compliance as external fixation. The only factors against nailing are the longer operating time and the greater need for fluoroscopy.

We consider that locked non-reamed nailing is the treatment of choice for grade-IIIB open tibial fractures.

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Open fractures of the tibia are among the most difficult to treat, because of the poor soft-tissue cover and blood supply of the tibial shaft. Both the extent of the soft-tissue injury and the amount of comminution are directly related to the level of energy which caused the fracture. Gustilo, Mendoza and Williams (1984) first quantified the importance of soft-tissue damage as an important predictor of infection and poor outcome and this has since been confirmed (Rosenthal, MacPhail and Ortiz 1977; Waddell and Reardon 1983; Burgess et al 1987; Caudle and Stern 1987; Edwards et al 1988; Fischer, Gustilo and Varecka 1991). In particular, grade-IIIB open tibial fractures are associated with high rates of infection, nonunion, malunion, and amputation (Gustilo, Gruniger and Davis 1987).

Infection rates in these fractures are reported to be much higher than those for grade-I and grade-II fractures: Gustilo, Merkow and Templeman (1990) had infection rates for grades I, II and III of 0% to 2%, 2% to 7%, and 10% to 50% respectively. The same authors also found a large difference between grade-IIIA and grade-IIIB fractures, with infection rates of 4% and 52% respectively, but these cases were not treated by early flap coverage (Gustilo et al 1987).

The increasing use of immediate antibiotics, aggressive and repeated debridement, fracture stabilisation, early bony coverage, and prophylactic bone grafting has greatly reduced the rates of infection and nonunion (Edwards 1983; Patzakis, Wilkins and Moore 1983a; Burgess et al 1987; Blick et al 1989; Fischer et al 1991). In most large series of grade-IIIB fractures treated in this way, external fixation has been used to stabilise the fracture, partly to avoid the further damage to the blood supply of the bone which would be caused by reaming. Most of these severe injuries are too comminuted to allow the use of unlocked intramedullary nails such as the Lottes or Enders patterns. The advent, however, of small diameter interlocking intramedullary tibial nails which can be placed without reaming, has provided a new method for stabilisation of these fractures.

We report a randomised, prospective study which compares external fixation with non-reamed interlocked intramedullary nails for grade-IIIB open tibial fractures. We compared the rates of infection, malunion and

nonunion, and also the ease of care with these two methods of stabilisation, using an otherwise identical protocol.

PATIENTS AND METHODS

All 35 patients who presented to Kings County Hospital Centre with a grade-IIIb open tibial fracture between January 1989 and January 1991 were considered for the trial. Fractures were graded IIIb if there was significant soft-tissue injury or contamination, and periosteal stripping (Gustilo et al 1987). For the study group, we excluded fractures associated with a known arterial injury (whether repaired or not), those within 4 cm of the ankle or proximal to the tibial tubercle, and those with an undisplaced intra-articular extension. We also excluded patients with bilateral fractures, and those who presented more than eight hours after injury.

After these exclusions, 20 men and nine women were randomised on the basis of odd or even medical record number. Fifteen patients were treated by statically locked non-reamed intramedullary nails (11 Gross-Kempf, 3 Alta and 1 AO) and 14 by external fixators (7 Hoffman anterior and 7 Ace multiplane). The patient groups were comparable in terms of age, mechanism of injury, and associated injuries (Table I). The intramedullary nails were placed through a portal medial to the patellar tendon with the leg draped free and without using a guide wire (Tornetta and Barbera 1992). Because of their fracture pattern, seven of the patients in the external fixation group had multiplane fixation.

Other than the method of stabilisation, we followed a standard treatment protocol for both groups; examples are shown in Figures 1 and 2. Irrigation and antibiotic cover with a cephalosporin and an aminoglycoside began in the emergency room and operation was performed with continued irrigation, debridement and stabilisation as soon as the patient's general condition was satisfactory. Antibiotics were continued for 72 hours after the initial procedure and for 48 hours after each additional procedure. Debridement was repeated at 48-hour intervals until the wound was clean and all necrotic tissue had been removed.

Soft-tissue cover was obtained in each case with a muscle flap or skin graft at from 3 to 10 days after the injury. The 29 patients required 22 rotation flaps (19 soleus, 3 gastrocnemius), one fasciocutaneous flap, one free latissimus flap, and 25 split-thickness skin grafts (Table II). After muscle-flap procedures, cephalosporin treatment was continued until the deep drain had been removed (mean 13 days). In only four patients was it necessary to allow some portion of the wound to heal by secondary intention.

Early prophylactic bone grafting at 4 to 10 weeks (mean 6) was performed for patients with severely comminuted and segmental fractures. It was not used when there was over 75% of bony apposition or definite callus formation by 8 to 10 weeks. Nine patients in the

external fixation group and ten in the intramedullary nail group had bone grafts, all of which were placed via a posterolateral approach. No patient had a revision of reamed nailing.

Postoperatively, patients in the intramedullary nail group used an ankle-foot orthosis at night, and nine of the 14 patients in the external fixation group had a temporary metatarsal pin to stabilise the ankle in a neutral position, as recommended by Edwards (1983). Range of motion exercises with a physiotherapist were started before three weeks, but patients remained non-weight-bearing, until toe-touching at about 30 lb (14 kg) was allowed at three weeks and continued until callus appeared at the fracture site. Partial weight-bearing then started provided that the fracture site was painless on examination or weight-bearing. Full weight-bearing was allowed when bridging callus was visible on radiographs. The external fixators remained in place unless a pin-track infection developed. This was seen in three patients; their fixators were removed in the clinic and replaced by patellar-tendon-

Table I. Details of the patients, the mechanism of injury and associated injuries in the two groups of patients with grade-IIIb open tibial fractures

	External fixator (n = 14)	Intramedullary nail (n = 15)
Male:female	9:5	11:4
Mean age (years; range)	37 (19 to 86)	41 (21 to 73)
Mechanism		
Motor-vehicle accident	1	2
Motor-vehicle v pedestrian	11	10
Fall from height	2	3
Type of fracture		
Unstable	9	10
Stable	5	5
Associated injury		
Other fracture	9	9
Head injury	2	1
Abdominal injury	1	2

bearing casts. Bone grafting was repeated if no bridging callus had appeared by 20 weeks; it was needed in three patients.

RESULTS

The patients were followed for 19 to 36 months (mean 21). All the fractures healed in an average time of 23 weeks (12 to 30) for the intramedullary nail group and 28.3 weeks (14 to 38) for the external fixation group. Healing was defined as bridging callus on anteroposterior and lateral radiographs, with no pain on palpation or weight-bearing. In cases that had bone grafting, a complete synostosis was considered as evidence of healing. The time to partial weight-bearing was 10.4 weeks (4 to 22) for the former group and 11.3 (6 to 20) for the latter group. At healing the range of motion for the intramedul-

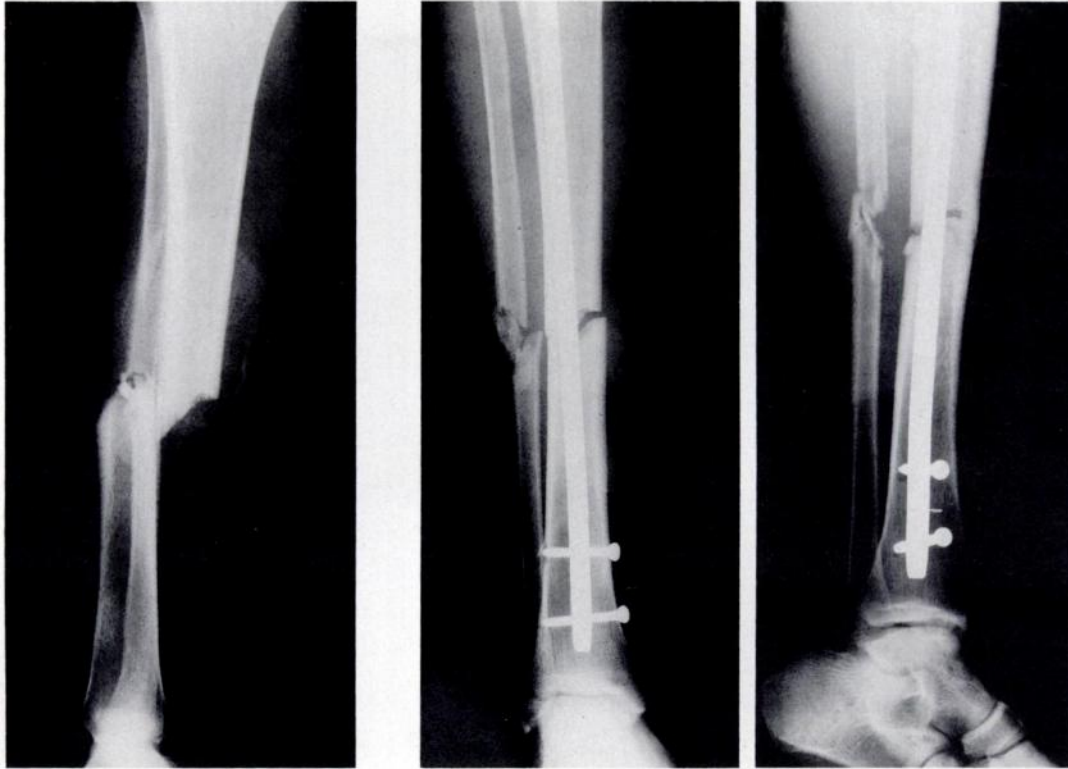


Fig. 1a

Fig. 1b

Fig. 1c



Fig. 1d

Fig. 1e

Fig. 1f

Fig. 1g

Figure 1a – Radiograph of a grade-IIIb open tibial fracture sustained by a 32-year-old man who was struck by a car. The leg was rotated 90° but there was no serious neurovascular damage. Figures 1b and 1c – After non-reamed locked intramedullary nailing. Figures 1d and 1e – After a soleus rotational flap performed four days after injury. Figures 1f and 1g – At 16 weeks the fracture shows bridging callus and tibiofibular synostosis, ten weeks after posterolateral bone grafting. The patient was fully weight-bearing and had no pain.

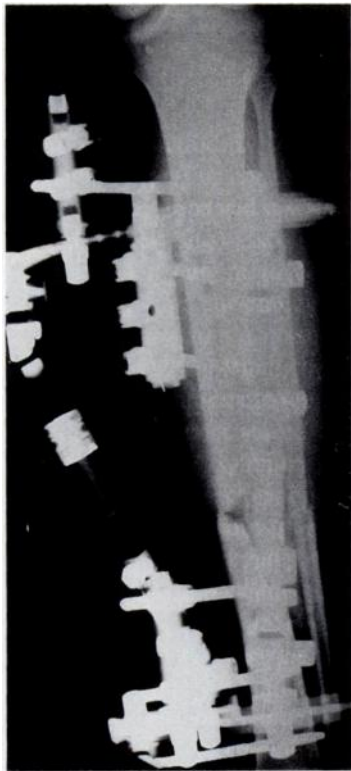


Fig. 2a



Fig. 2b



Fig. 2c



Fig. 2d

Figures 2a and 2b – Radiograph of a grade-IIIb open tibial fracture in a 26-year-old man, at 18 weeks. The patient had been treated by an external fixator, with a soleus flap at five days, and posterolateral bone grafting at eight weeks. The lateral view shows mild anterior angulation and the beginning of infection around the most proximal pin, which needed removal. There is a bony deficit at the original site of a devitalised butterfly fragment. The bone graft has not yet consolidated. Figures 2c and 2d – Healing at 30 weeks, ten weeks after a second bone graft. The lateral view shows that the anterior angulation has been corrected at the time of the second bone graft.

Table II. Secondary procedures in both groups

	External fixator (n = 14)	Intramedullary nail (n = 15)
Muscle flaps		
Days to flap (range)	5.8 (4 to 10)	4.9 (3 to 7)
Soleus	9	10
Gastrocnemius	1	2
Free latissimus	1	0
Fasciocutaneous graft	0	1
Skin graft	12	13
Bone graft		
Early	9	10
Secondary	2	1

lary nail group was 2° to 115° at the knee and 0° to 30° at the ankle. The external fixation group had ranges of 0° to 95° at the knee and 0° to 20° at the ankle.

At latest follow-up the mean range of motion at the knee was 0° to 130° in the nailed group and 0° to 120° in the external fixation group. Mean ankle motion was 0° to 35° in the nailed group and 0° to 30° in the external fixation group. The time to healing, time to partial weight-bearing, ankle and knee range of motion, and number of procedures were not statistically different between the two groups (Table III).

In the external fixation group there were three pin-

track infections which required unplanned removal of the fixator. One of these patients developed local osteomyelitis requiring sequestrectomy and intravenous antibiotics. Two other patients had superficial infection which cleared after a short course of intravenous antibiotics and wound care. One patient has recently presented with radiographic signs of chronic osteomyelitis despite having a well-healed fracture and no history of drainage. Two fractures have healed with mild varus malunion, one 6° and the other 7°. Two patients required second bone grafts at 20 and 22 weeks, but had healed by 32 and 38 weeks respectively. There were no late amputations.

In the IM nail group, there were two superficial infections, one at the insertion site and one at the site of a soleus flap. One other patient developed an infection at the donor site of his iliac-crest bone graft. One case of deep infection at the fracture site required local debridement and subsequent bone graft to obtain union. One patient needed a second bone-graft procedure and healed at 30 weeks. There were no cases of malunion. One patient had temporary occlusion of the anterior tibial artery from a distal locking screw that was too long, but the pulse returned after the screw had been withdrawn a little in the angiography suite.

Procedures to provide soft-tissue cover were thought

Table III. Results in both groups

	External fixator (n=14)	Intramedullary nail (n=15)
Follow-up (weeks)	22	20
Weeks to partial weight-bearing (range)	11.3 (6 to 20)	10.4 (4 to 22)
Weeks to union (range)	28.3 (14 to 38)	23 (12 to 30)
Motion at union		
Knee	0° to 95°	2° to 115°
Ankle	0° to 20°	0° to 30°
Final motion		
Knee	0° to 120°	0° to 130°
Ankle	0° to 30°	0° to 35°
Infection		
Pin-track	3	0
Superficial	2	2
Deep (localised)	1	1
Arterial injury	0	1
Malunion	2	0
Delayed union	2	2
Nonunion	0	0

to be much easier in the nailed group than in the external fixation group, because of easier access for preparation and positioning, and the lack of pins in the operative field. In six of the seven patients with multiplane fixators, the removal of one stabilising bar was necessary before a secondary procedure. Two other patients required pin exchange to allow access for a soft-tissue procedure. Changes of dressings in the wards were distinctly easier in the nailed group. The physiotherapists who treated both groups considered that the patients in the external fixation group were more timid in regard to the use of their legs and were less easily trained to use crutches.

DISCUSSION

Before discussing the problems and treatment of open tibial fractures it is important to note that there is some controversy about the grading of IIIb injuries. Where muscle cover procedures are required there can be little question that IIIb is the correct grade. However, several of our cases had fasciocutaneous flaps, skin grafts or were allowed to heal by granulation. All these fractures had extensive contamination as well as periosteal stripping and soft-tissue damage. Grade-IIIb open tibial fractures are associated with many complications and occasional amputation. Infection rates have been reported to be as high as 50%, with amputation rates as high as 30% (Lawyer and Lubbers 1980). The paramount principle of treatment is the creation of a suitable environment for healing. During the last 20 years, the use of standardised protocols has reduced the complication and amputation rates (Edwards 1983; Burgess et al 1987; Edwards et al 1988; Blick et al 1989).

We believe that reconstruction of the soft-tissue envelope and stabilisation of the fracture are crucial.

An important factor is the timing of soft-tissue coverage. Fischer et al (1991) reported that only two of 11 patients became infected after early cover (≤ 2 weeks) as against nine of 13 patients who had subacute or late cover. Early cover not only reduces infection, but also improves the blood supply to the healing bone.

Adequate stabilisation is also important in preventing infection and encouraging healing. Many methods have been used, including casts, pins and plaster, flexible non-reamed nails, reamed nails, external fixation, and more recently, non-reamed locking nails. It is not yet clear from published reports which is best, but external fixation seems to be generally preferred. This is partly because high infection and poor union rates have been reported after the use of intramedullary nails (Table IV), but these figures are difficult to interpret. Most series group all cases of open fracture together, and very few published reports separate grade-IIIb from grade-IIIa fractures, although these require very different management.

In reported series of external fixation by intramedullary nails the infection rates are remarkably similar (Table V). Edwards et al (1988) treated 202 grade-III open tibial fractures using a standard protocol, and had a 15% infection rate and a 7% amputation rate. They found that more aggressive debridement lowered their infection rate to 9% in the second half of their study. They used bone grafts in 49 of the 176 patients reported. This landmark study defined the protocol used by most trauma centres including aggressive debridement, early soft-tissue cover and bone grafting, but they did not differentiate between grade-IIIa and grade-IIIb fractures. Karlström and Olerud (1975), Behrens et al (1983b) and Etter et al (1983) have shown that open tibial fractures stabilised by external fixators have a better union rate when bone grafting is used. Heiser and Jacobs (1983) reported 50% nonunion

Table IV. Results reported for intramedullary nailing in tibial fractures

Author	Grade III/Total	Reamed	Union	Infection (per cent)	Amputation (per cent)
Hamza et al (1971)	6/22	Yes	4 mths	13.6	0
Velazco et al (1983)	32/50	No	98%	6	2
Wiss (1986)	6/56	No	5 mths	67	0
Bone and Johnson (1986)	1/26	Yes	13 mths	100 (1/1)	
Kellam et al (1989)	12/22	Yes	4.1 mths	8.3	0
MacKenzie et al (1990)	36/99	Yes	100	22	0
Whittle et al (1991)	30/50	No	96%	10	0
Court-Brown, Christie and McQueen (1992)	16 (IIIa) 16 (IIIb)	Yes Yes	6.5 mths 12 mths	0 16	0 0
Contreras et al (1992)	39/39	No	90% < 6 mths	0	0

Table V. Results reported for external fixation of tibial fractures

Author	Grade III/Total	Bone graft	Union	Infection (per cent)	Amputation (per cent)
Karlstrom and Olerud (1975)	18/28	18/28	7.9 mths	5.5	0
Lawyer and Lubbers (1980)	10/26	4/10	8.8 mths	14	30
Velazco and Fleming (1983)	28/40	4/40	92% ≤ 18	12	12
Etter et al (1983)	41/56	22/56	6 to 7 mths	9.7	7.3
Heiser (1983)	16/20	0/16	50	19	0
Behrens et al (1983b)	3/31	19/31	6.1 mths	13	0
Edwards et al (1988)	202/202	49/176	9.0 mths	15	7

in 20 open tibial fractures of which 16 grade-III injuries were treated by external fixation and no bone grafting. External fixation can be effective for these cases, but union and infection rates seem to depend on adequate soft-tissue cover and the addition of bone grafting.

Hamza, Dunkerley and Murray (1971) reported a 13.6% infection rate in 22 open tibial fractures treated by a reamed nail and Lottes (1974) found an infection rate of 6.3% in 251 open tibial fractures (47 grade III) treated by a non-reamed, unlocked nail.

Velazco and Fleming (1983) and Velazco, Whitesides and Fleming (1983) reported much better results for union, infection and amputation after using non-reamed unlocked nails than after external fixation. Without locking, however, only stable fractures could be stabilised by intramedullary nailing, and the more severe injuries were treated by external fixation.

Kellam, McMahon and Dust (1989) and MacKenzie et al (1990) treated open tibial fractures by delayed reamed locked nailing, with infection rates of 8.3% and 22% respectively, but neither distinguished grade-IIIb fractures.

Santoro et al (1990) reported a prospective randomised study which directly compared stabilisation with

external fixation by non-reamed locked nailing. They found a higher union rate, a shorter time to union, and fewer malunions in their nailed group, but of 65 patients, only 12 had grade-IIIb fractures, which are not reported separately. Although the general principles of aggressive debridement, stabilisation, antibiotics, early soft-tissue cover, and early prophylactic bone grafting are accepted, it is not clear which is the best method of stabilising grade-IIIb fractures. Theoretical arguments based on blood supply to the fracture favour external fixation, but Rhinelander (1974) found that intramedullary nails interrupted the blood supply only temporarily and then only when there was direct contact with the cortex. Small-diameter *non-reamed* locking nails do not require a tight interference fit, and need very little cortical contact for stability. It is also probable that early flap coverage will improve the blood supply to the fracture site regardless of the type of fixation. Other factors in the choice of method of stabilisation include ease of application, alignment, local complications, ease of secondary procedures, and available salvage procedures. Patient acceptance and ease of nursing care also matter.

The use of non-reamed nails is easily learned and requires fluoroscopic control only for distal locking. In

our series nailing seemed better than external fixation in providing excellent, lasting alignment, making soft-tissue procedures and secondary reamed nailing easier, and improving patient compliance. We saw few local complications. External fixation is bulky, requires meticulous pin care and has been reported to have an incidence of pin-track infections as high as 80% (Velazco and Fleming 1983). It also has an unacceptably high rate of infection with secondary intramedullary nailing (McGraw and Lim 1988). On the basis of our study, we recommend the use of non-reamed locked intramedullary nails for the stabilisation of grade-IIIb open tibial fractures. For the more severe fractures, we performed prophylactic posterolateral bone grafting at 4 to 10 weeks on patients in both groups to keep the groups identical in all respects except the method of stabilisation. Patients treated by a non-reamed nail after high-energy injuries without segmental bone loss may alternatively be treated prophylactically by exchange reamed nailing instead of open bone grafting.

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