LOCKED INTRAMEDULLARY FLEXIBLE OSTEOSYNTHESIS

A MECHANICAL AND CLINICAL STUDY OF A NEW PIN FIXATION DEVICE

JEAN-YVES DE LA CAFFINIÈRE, FRANÇOIS PELISSE, MARC DE LA CAFFINIÈRE

From Saint-Denis Hospital, Île-de-France, France

We report the use of a new method of locked intramedullary flexible osteosynthesis (LIFO) in the treatment of 118 unstable fractures of the femur and tibia. The implant utilises a set of flexible pins with a separate locking device for their proximal ends.

The LIFO system proved capable of stabilising unstable fractures, and most of the complications occurred during the early testing. At follow-up, 19 of 21 femoral fractures had healed; one became infected and one showed defective callus. Of the 78 tibial shaft fractures, five failed to consolidate and five had inadequate callus. Reaming of the tibial medullary canal was never necessary. Of 28 open fractures only one became infected. The system was most difficult to use in comminuted distal fractures of the tibia, with five failures of healing in 19 cases; these cases require considerable technical proficiency.

The flexibility of the system appears to promote earlier consolidation of open fractures, and normal consolidation times for fractures with interfragmentary gaps of up to 10 to 12 mm. A comparative study of callus density in tibial fractures showed a mean improvement of 50 days in cases treated by the LIFO system compared with similar cases treated by rigid nailing.


The use of thin flexible intramedullary nails to promote osteogenesis in fractures of the shafts of long bones has been studied for many years (Hackethal 1961; Firica et al 1977). Pankovich, Tarabishy and Yelda (1981) reported encouraging results in tibial fractures treated with Ender nails, and others have employed them for open tibial fractures because flexible pins can be inserted without preparatory reaming (Cabanac, Butel and Escoulès 1964; Hasenhuittl 1981; Mayer et al 1985; Wiss 1986; Holbrook, Swiontkowski and Sanders 1989; Levy et al 1990; Whitelaw et al 1990; Jahnke et al 1992).

The mechanical limitations of this method are, however, well recognised: since there is no effective locking device it is suitable only for stable fractures. For unstable fractures, locked nailing is more attractive, preventing secondary angulation and shortening. Locked nails, however, have the disadvantages of rigidity, difficulty with insertion, a prolonged operating time and the risk of infection associated with medullary canal reaming (Maurer, Merkow and Gustilo 1989; Tornqvist 1990; Koval et al 1991; Matsoukis et al 1991). Delayed healing and nonunion have been reported, particularly when there were gaps between the bone ends. After locked nailing a second operation may be needed to unlock the fixation and establish contact between bone ends (Kempf, Grosse and Lafforgue 1978; Klemm and Börner 1986; Russell et al 1991).

In view of these concerns, we have developed a new system which combines narrow flexible nails and a locking device to manage unstable fractures of the tibia and femur.

OUTLINE OF TECHNIQUE

The technique for locked intramedullary osteosynthesis (LIFO) utilises a set of flexible pins 4 or 5 mm in diameter and a new device allowing proximal interlocking and fixation of the first two pins (Fig. 1), which have curved distal tips. These pins are bent by the surgeon before insertion so that distal locking can be achieved when they spread out and obtain a hold in the distal part of the bone. The combination of two pins and the locking device is the basic requirement, but is insufficient if used alone. One or two additional flexible pins are also inserted into the medullary canal through drill holes in the lateral
aspects of the proximal epiphysis. Preparatory reaming is usually unnecessary for tibial fractures, but most femoral fractures do require reaming. The procedure is monitored at intervals by the image intensifier.

**PART 1: MECHANICAL EVALUATION**

For mechanical studies of the device 24 tibiae and 21 femora were collected from fresh cadavers. The bones were cleaned of soft tissues, and immediately frozen at \(-20^\circ\)C until testing. Before each test they were rehydrated for a few hours in Ringer lactate solution. Radiography was used to exclude any bone abnormality, to assess Femoral curvature and the diameter of the medullary canal, and to detect any gross osteoporosis.

The first investigation was on matched pairs of femora and tibiae obtained from the same cadaver. In each of eight pairs of tibiae and seven pairs of femora with standard simulated fractures, one side was fixed with LIFO flexible pins and the other with Kuntscher (K) nails or Grosse and Kempf (GK) nails. The decision on side was made at random, but for each single simulated fracture, comparisons were made only between the data obtained for bones of the same cadaver.

A second investigation used eight tibiae and seven femora to study the LIFO device alone and confirm the precision and reproducibility of the measurements recorded during the first investigation.

Fractures were simulated by osteotomy cuts: horizontal for midshaft fractures; oblique for upper and lower shaft fractures (Fig. 2); double transverse for segmental fractures; and a 2 to 3 cm shaft resection for complete fractures (Fig. 3).

**Experimental fixation.** Each implantation followed the usual surgical techniques. For femora, we performed osteotomy before nail insertion to avoid damage to specimens with marked anatomical curvatures. This was not necessary for the LIFO pins, and osteotomy was therefore performed after insertion. The tibial nails ranged from 8 to 12 mm in diameter and femoral nails from 13 to 14 mm. For the latter reaming was necessary to enlarge the canal to 1 mm wider than the nail. The LIFO device was always placed without reaming, using two 5 mm pins with angled tips and two 4 mm straight pins for each femur. Tibial LIFO used either 5 or 4 mm pins in two-pin combinations or 4 mm pins in three- or four-pin combinations.

The two precurved pins with angled distal ends were introduced through a hole drilled in the centre of the anterior aspect of the proximal epiphysis. Under image-intensifier control the distal beaks were driven to the distal end of the bone and directed to splay from the midline into the lateral cortex as seen in the frontal plane, to ensure effective distal locking. Proximal locking of those nails was achieved with the specially designed locking block.

In femora, the basic module was always supplemented by straight pins inserted through the anterior and posterior aspects of the greater trochanter. These two pins were driven to the distal end and left in place between the first pins.

In tibiae, transverse midshaft osteotomies were fixed by the basic pair of 5 mm pins with angled tips, but the other simulated fractures were fixed by three or four pins, depending on the diameter of the medullary canal.

For the comparative nailings, we followed the recommended methods of osteosynthesis: proximal and distal locking was used after fragment resection or double osteotomies. Upper oblique cuts were fixed by nailing with a proximal locking screw, and lower oblique cuts with a distal locking screw. Midshaft fractures received a plain K nail.

**Mechanical testing.** We used a standard machine for testing the strength of materials (Fig. 4; Giet and Géminard
1972). The distal end of each specimen was secured to the headstock and load stresses were applied by the tailstock. The bone ends were secured by a four-needle revolving wheel which allowed axial loads to be modified at will. Torsion stresses were applied to the distal end of the specimen by a transverse bar capable of transmitting increasing loads.

The loads applied were consistent with those reported to be sustained by different fracture sites in the leg (Perren and Cordey 1980; Uthhoff and Finnegar 1983; Swiontkowski et al 1987) but did not exceed 50 kg (approximately half the weight of the body) since our aim was not to determine the strength of the implant under stress, but its behaviour in a broken femur or tibia. The axial loads ranged from 0 to 5.0 N rising by 1 N increments. Torsional forces applied ranged from 0 to 0.05 N, rising by 0.01 N increments. Stress was applied to the flexible area of the specimen where deformation was proportional to the strain and recovery of initial position was obtained when the load was removed according to Hooke’s law. The cumulative effect of loading and unloading was determined by measurement of the displacement between two rings surrounding the bone on either side of the osteotomy. Torsional deviations were evaluated by angular measurement, and the relative elasticities were assessed by the degree of recovery to initial position when the load was removed.

Each experiment started with flexion tests, followed by torsion tests. The second series of tests, using only the LIFO system, was reversed in order to reduce error caused by bone deterioration during testing and torsion tests were followed by flexion tests.

Statistical analysis. The quantitative data were obtained from a relatively small number of samples for each type of fracture (n = 4). We therefore used a non-parametric method, comparing measurements by the Mann-Whitney U test.

RESULTS

Femur. For each type of simulated fracture, there was a statistically significant difference between LIFO and locked GK nailing (p = 0.0442) but only for loads of 2.0 N or more. Differences between LIFO and K nailing were not statistically different because of the small number of samples. Shortening at an osteotomy site under increasing axial load was significantly greater with LIFO than with locked nailing (p = 0.06; Fig. 5), but the statistical analysis of distribution of means for all types of axial stresses showed that the differences were very

Figure 2 – Experimental tibial fixation after osteotomy of the lower shaft: the LIFO system versus GK nailing.
Figure 3 – Experimental femoral fixation: the LIFO system versus GK nailing (right and left bones from same cadaver) after midshaft resection.
was confirmed by the recovery of initial position recorded on load removal. This flexibility was observed in all specimens for both axial and torsional stresses.

**Tibia.** Tibial osteotomy sites were less distorted under axial loads than femoral sites. Statistical analysis of means showed that, for all osteotomies and all directions of axial stress, deviations did not exceed 0.1 mm for four-pin LIFO, locked nailing or plain K nailing. We found no difference between LIFO four-pin and LIFO three-pin mountings, but the basic two-pin combination after midshaft osteotomy showed fourfold greater deviations than the K nail which is commonly used for stable fractures. In all cases, deformation disappeared when loads were removed.

Torsional torque increasing from 0.01 to 0.05 N, produced no large distortion, with no statistically significant difference of means between locked nailing and LIFO \( (p=0.6742) \), but even the basic two-pin LIFO was three times more resistant to torsional stresses than K nailing.

The second series of tests used only the LIFO implant. We aimed to assess the quality of distal locking, and the curved tips of the two basic pins were therefore placed as laterally as possible against the internal cortex of the metaphyseal region. Each series started with torsion tests followed by axial load tests. These tests showed greater rigidity to both torsion and axial compression, with better elasticity after loading.

## PART 2: CLINICAL STUDY

We assessed the results in 118 cases, 21 fractures of the femoral shaft and 97 fractures of the tibia.

Follow-up was at monthly intervals: successful healing was recorded when weight-bearing caused no pain, forced rotation of the limb segment caused no local pain and radiographs showed some bone continuity, however partial.

Residual angulation was evaluated as minimal \( (0^\circ \text{ to } 5^\circ) \), moderate \( (5^\circ \text{ to } 8^\circ) \), or severe \( (> 8^\circ) \). Rotation by over \( 10^\circ \), detected clinically, was recorded as a major defect. Leg length was measured and compared with that of the normal side.

Radiographic gaps between the main fragments were
assessed by width in the ranges of 1 to 5 mm, 6 to 10 mm, and > 10 mm.

The development of callus was rated by evaluating its density on a simple five-grade scale. The density of tibial callus was compared with that of the adjacent fibula and femoral callus density with that of the lower end of the fractured femur. Absence of callus was rated as grade 0; density matching cortical bone as grade IV. That which matched the medullary canal was grade II; grades I and III were intermediate ratings. This scale avoids uncertainties related to variations in radiographic images. The callus of unstable fractures treated by LIFO was compared with that in a series of similarly unstable fractures treated from January 1988 to June 1989 by plain tibial nailing (112), locked tibial nailing (27), plain femoral nailing (30) and locked femoral nailing (27). A total of 676 consolidation sites were examined.

**Femoral fractures.** From March 1990 to September 1993, we treated 21 unstable fractures of the femur by LIFO (Fig. 6). This was one-third of all unstable femoral fractures seen during the period. Three fractures had been unsatisfactorily treated a few days before LIFO, one by external fixation and two by plain nailing.

There were 14 men and 7 women (13 right and 8 left legs). Eighteen were under 55 years of age and had been injured in road accidents. Five of these also had a second fracture; in two of them the other femur was treated by another method. There were six open fractures, five grade I and one grade II. The other three patients were older, and had had accidents in the home. All 21 fractures involved cortical bone and the AO classification (Müller, Nazarian and Koch 1987) is shown in Figure 7.

All primary cases were nailed on the day of the accident or the next day.

**Technique.** A traction wire is passed through the distal femur. Fractures of the lower femur are treated with the patient supine, midshaft or upper femoral fractures with the patient on his side. Except in elderly patients, pin insertion is preceded by medullary canal reaming not exceeding 13 mm. The first pin with its curved tip is inserted before removing the reaming guide. The number of pins used for each fracture changed during the series; the first three fractures had only two pins, the next five had three pins and the last 13 four pins. We now usually use a four-pin system. The first two pins were 5 mm in
diameter; additional pins were either 4 or 5 mm in diameter. Surgery at the fracture site was required in three cases, in one to complete fracture reduction and in two to wire a long spiral fracture.

Knee bending and weight-bearing with the help of walking aids were allowed within a week of the operation. In the absence of associated lesions, patients were discharged within an average period of 15 days (10 to 18).

**Tibial fractures.** From July 1989 to July 1993, we treated 97 tibial fractures by LIFO (Fig. 8), nearly 50% of all unstable fractures. Two patients had bilateral fractures; there were 52 of the right leg and 45 of the left leg in 61 men and 34 women with a mean age of 39 years (17 to 88).

Among the recorded causes of fracture, road accidents accounted for 70 cases and domestic accidents for 19, usually in older patients. Only nine patients had associated fractures. Seventy-four of the patients were in good health, but in seven the general condition was poor.

Of the 97 fractures, 28 were open: 22 grade I, five grade II, and one grade III. The LIFO system was used for two distinct types of fracture: 78 were shaft fractures at least 8 cm below the knee, and 19 were distal metaphyseal fractures at least 3 cm above the ankle (Fig. 9).

The AO classification of the fractures is shown in Figure 10. All the supramalleolar fractures were unstable and 11 were comminuted. There was severe osteoporosis in 11, six of which were supramalleolar fractures. All had fixation within 24 hours after the accident, the open fractures within six hours followed by a six-day course of antibiotics. All were operated in a supine position with the leg dependent. No traction was used for midshaft fractures; transcalcaneal pin traction was used for segmental or lower tibial fractures.

**Technique.** Operation was through a vertical incision in the medial part of the patellar tendon. Two angle-tipped intramedullary pins were inserted through a hole drilled in front and on the medial side of the tibial spinous process. The fracture was reduced during the introduction of these two pins; it was necessary to ream the medullary canal in only four cases. Additional circumferential wiring was required for eight open fractures with large intermediate bone fragments, and in two cases in which the fracture required open reduction.

Twenty-three patients treated early in the series had only the two angle-tipped pins, but it became evident that at least one additional pin was necessary; 34 three-pin and 21 four-pin systems were then used. After operation, the leg was held in a below-knee cast to maintain the foot in the correct position. For all cases of fracture of the distal metaphysis and in the four patients with an open fracture and bone loss exceeding 1 cm, a thigh-to-foot plaster was worn until union took place within 3 to 4 months, after which weight-bearing was allowed. Except for these eight cases, casts were removed after three weeks and the patients allowed to walk with crutches or sticks as soon as possible.

**RESULTS**

**Unstable fractures of the femoral shaft.** In the 21 unstable fractures, 17 implants were entirely satisfactory, three had slight problems which had no adverse effect on the final anatomical result and one failed. Alignment was normal in 13 cases and there was valgus of less than 8° in six and over 8° in two. In ten cases contact between the bone ends was restored. In four there was a 1 to 5 mm gap, in four a 6 to 8 mm gap and in three a 9 to 12 mm gap. All these gaps were considered to be iatrogenic in origin.

Two elderly patients died early from unrelated causes, leaving 19, all of whom had satisfactory healing of their fractures. This was at 2 months in 8 patients, 3 months in 5, and at 4 to 5 months in 6. Complications were infection in one implant, secondary external rotation after two-pin fixation in one, and osteitis after open compared these 74 cases (17 + 57) with a similar series...
treated by LIFO implants was 101 days on average, a gain of 60 days over rigid nails. This difference did not reach statistical significance.

Interfragmentary gaps. There were interfragmentary gaps after 32 femoral nailing and 51 tibial nailing.

In femora treated by LIFO, all gaps of more than 8 mm were filled by primary osteogenesis within normal healing times. By contrast, two cases with 8 to 10 mm gaps treated with rigid nails failed to heal.

In tibiae, except for four cases with massive bone loss, the gaps in the five cases of pseudarthrosis were 1 to 5 mm; all gaps of 10 to 12 mm healed in less than four months. By contrast, 8 of the 27 cases with 5 to 8 mm gaps treated with rigid locked nails failed to heal.

Callus density. In femora, callus maturation was similar after all types of implant.

In tibiae, callus matured an average 50 days earlier after LIFO treatment than after treatment with locked nails (Fig. 12). This difference was even greater for grade-III open fractures with a single fracture line (Fig. 13).

DISCUSSION

Four years of clinical experience have shown that the LIFO device can provide reliable fixation for unstable femoral and tibial fractures. Secondary angulation and pin migration were always related to technical error, to comminution and osteoporosis of the distal metaphysis of the tibia.

We had no cases of unexpected implant loosening or of leg shortening. The failures occurred mostly during the early trials and were usually due to insufficient spread of the curved pin ends and to the use of the two-pin construct on its own. The basic two-pin fixation should always be complemented with at least one additional pin, using 4 mm pins for the tibia and 5 mm pins for the femur.

The LIFO device appears to be particularly safe for treating open tibial fractures, because no reaming is required. We now use it instead of external fixators except for the rare Gustilo III-B and III-C types.

In distal fractures of the metaphysis of the tibia, we had many complications mainly due to operating difficulties, caused by the dependent leg and peroperative traction. Imperfect reduction requires open surgery, and it is necessary to insert four pins so that their tips fork out to the four corners of the distal end of the bone (see Fig. 9). This requires considerable training and experience, especially when the cancellous bone is very demineralised.

An important aspect is the promotion of osteogenesis in compact bone (Goodship and Kenwright 1985). Our biomechanical tests showed the flexibility of the pin has the same rigidity as a locked nail. In both the femur and the tibia, the rigidity and torsional strength of the LIFO system is greatest when the distal ends of the pins are set widely apart and contact cortical bone.

Although our clinical study allows no definite conclusions to be drawn about the role of flexibility in osteogenesis, it is notable that all femoral shaft fractures showed primary consolidation at about three months, despite comminution, instability and interfragmentary gaps of up to 8 to 10 mm. In the tibia, the mean consolidation time was more than a month less than after locked nailing. The consolidation time for open fractures treated by LIFO was nearly the same as that for closed fractures: flexibility appeared to compensate for the
pseudarthroses were in the proximal tibia, close to the locking system, tending to confirm that prediction (Fig. 14).

We are encouraged by our preliminary investigation to believe that the relatively simple implant can hold unstable fractures until they consolidate. The pins can be cut to length by the operating surgeon, reducing the need for expensive stocks of implants. Compared with locked nailing, LIFO is more convenient and requires less exposure to radiation. The use of a pin system with a separate locking device allows the surgeon to place the pins securely before they are permanently locked. A disadvantage is the need for considerable proficiency in intramedullary techniques. There are technical problems, especially in very unstable comminuted fractures of the lower end of the tibia and many questions remain unanswered which will only be solved with increasing clinical experience.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

REFERENCES


