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# Intramedullary nailing of the femur with an inflatable self-locking nail: comparison with locked nailing

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**Abstract** We report a comparative study between an inflatable expandable nail and a traditional locked intramedullary implant in closed fractures of the femoral shaft. We matched each of 43 patients who had undergone intramedullary fixation with an inflatable expandable nail with a patient of the same sex, age (within 2 years), and fracture who had undergone statically locked intramedullary fixation with traditional nails. The mean duration of surgery was significantly shorter in the patients who were treated with the inflatable expandable nail. There were no differences in average blood loss, transfusion requirements, or hospitalization. Five of the patients who underwent traditional nailing required dynamization to achieve union. The inflatable expandable nail allows effective management of diaphyseal fractures of the femur. Interlocking is not necessary, operative times are reduced, and exposure to ionizing radiation is minimized. At present, however, the inflatable expandable nail used in the this investigation is markedly more expensive than traditional devices.

**Key words** Intramedullary nailing · Expandable · Self-locking · Unreamed

## Introduction

Intramedullary nailing was originally performed using thin, flexible rods.[25] Reamed nailing allows insertion of larger nails with a tighter fit throughout a longer segment of the shaft, with improved stability and increased nail strength.[19] The initial unlocked design was modified to allow proximal and distal interlocking.[3,14,16,18] This further improved stability and expanded the indications for nailing to include comminuted fractures.[18,19,25] The technique is now well established in the management of fractures of long bones of the lower limb.[1,5,6,14,28]

The Fixion nail[10,11,20,23] is an expandable, stainless steel cylindrical nail folded longitudinally in a specially designed press. The nail is designed to be inserted without reaming and then expanded up to approximately 175% with highly pressurized normal saline. As the nail, after expansion, abuts the inner surface of the medullary canal along its entire length, interlocking is not necessary with this system.

We have reported the results of our first 50 intramedullary nailings using the Fixion system in both the lower and upper limb,[20] and there have been recent encouraging reports on the use of this expandable nail in the humerus[10,11] and lower limb.[23] In this article, we report the results of a study comparing the use of the Fixion system versus classical interlocked intramedullary nailing in the lower limb. The patients reported in our original study[20] were excluded from the present one.

## Patients and methods

All procedures were performed after local Ethics Committee approval had been granted. All patients taking part in this study gave written informed consent. Only skeletally mature patients aged 18 years and above with isolated closed traumatic unilateral fractures of the shaft of the femur, AO type 32.A or 32.B, were included in the study.

The Fixion nailing system (Fixion; Disc-O-Tech, Tel Aviv, Israel) is hydraulically inflated and "self-locks" inside the medullary canal. After it is positioned in the medullary canal, the system is inflated with Ringer's solution through a unidirectional valve, expanding the nail's original diameter by up to 50%. A small manual pump generates the required pressure of up to 70 bar. In cross section, the nail has four external longitudinal bars that are forced against the cancellous and cortical bone

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to match the medullary canal, thereby giving the nail self-lock capability. The large frictional contact area prevents localized pressure peaks, and the ridges of the bar control rotation. Pressure is distributed over the entire length of the nail, avoiding the highly localized forces that are typically seen with the screws that secure standard interlocking nails. Hydraulic inflation provides the type of stability that one would experience when unsuccessfully attempting to deform a full, sealed metal can manually. Inflation of the nail makes the diaphysis of the bone stable over most of the length of the nail. In addition, the lack of locking screws reduces X-ray exposure for both operating room personnel and patients, and it shortens the operating time.

The inflation device is a single-use manual plastic pump. A pressure gauge enables continuous monitoring of the pressure in the system. An outlet tube at the distal end of the pump has a quick-connect couple to the insertion handle. The plastic insertion handle, a cylinder connected to the proximal end of the nail, is used for nail insertion, precise positioning, and adjustment in the medullary canal. After inserting the nail, a clinical torsional test under image intensifier verifies the stability of the reduction.

We tried to match each of the patients who had undergone intramedullary fixation with the Fixion (Disc-O-Tech Medical Technologies, Unimedical BIO. Tech, Torino, Italy) system with a patient of the same sex who was within 2 years of age at the time of operation and who had undergone statically locked intramedullary fixation with slotted nails (Stratec Medical, Welwyn Garden City, UK). Patients were also matched for the type of fracture. A match was possible for 43 of the 50 patients treated with the Fixion nail, and we therefore report on 32 males and 11 females in each group (Table 1). The AO classification was used.[22] In each group, there were 35 of the 32.A fractures (spiral, short oblique, and transverse) and 15 of the 32.B (wedge) fractures.

All nailings were performed using a closed method on a fracture table with the patient supine using image intensifier control. Routine anesthesia, antibiotic prophylaxis, and deep vein thrombosis (DVT) prevention were used. All patients received a prophylactic intravenous antibiotic at the induction of anesthesia and two doses postoperatively. A drain was inserted at the site of the main incision at the discretion of the surgeon (28 drains in the Fixion group, 31 in the Stratec group).

### *Intramedullary fixation with Fixion nails*

During August 2000 to April 2001 we implanted 50 Fixion intramedullary nails in the femur for the fractures described above (Figs. 1–3).

### *Intramedullary fixation with Stratec nails*

During July 1989 to February 1998 a total of 412 primary reamed femoral intramedullary nailings were performed at Aberdeen Royal Infirmary.[24] In this study,

**Fig. 1.** Lateral view of a femoral fracture in and 18-year-old male motorcyclist

**Table 1.** Comparison of Fixion and Stratec nails

| Parameter | Fixion | Stratec | Significance |
|---|---|---|---|
| Patients age (years) ($n$ = 43: 11 females in each group) | 33 ± 18 (18–78) | 32 ± 18 (18–79) | NS |
| Duration of surgery (hours) | 2.4 ± 0.6 (1–3) | 3.1 ± 0.5 (1–4) | 0.05 |
| Blood loss (ml) | 800 ± 190 (450–1200) | 850 ± 180 (450–1100) | NS |
| Hospital stay (days) | 17 ± 9 (11–35) | 13 ± 6 (7–29) | 0.05 |
| Screening time (seconds) | 28.6 ± 19.2 (20–71) | 79.3 ± 48.1 (55–124) | 0.01 |
| Return to previous occupation on a full-time basis (months) | 6.9 ± 4.1 (4–15) ($n$ = 32) | 4.9 ± 3.3 (4–11) ($n$ = 38) | 0.03 |

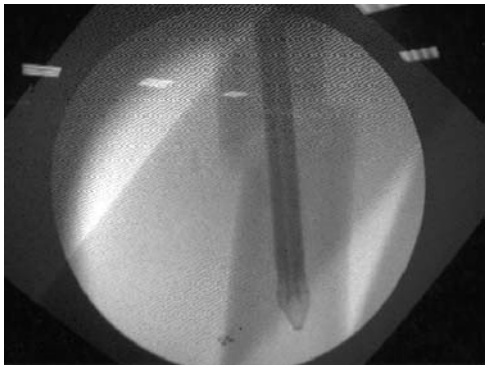

**Fig. 2.** Unreamed insertion of the Fixion nail. The nail here has just gone past the fracture site

**Fig. 3.** At the end of the procedure

we report on 43 patients who were matched with patients treated with a Fixion nail according to the criteria stated above.

*Follow-up*

Patients were followed up prospectively until the fracture healed. After the operation, patients were normally reviewed at 2 and 6 weeks and then at 2-month intervals until healing occurred. More frequent outpatient appointments were given if clinically necessary. At each follow-up, healing was assessed radiographically and clinically.

*Data collection*

We recorded patient details (e.g., age, sex), the mechanism of injury, the type of nails used, duration of surgery, screening times with the image intensifier, the time between the accident and fracture fixation, locking of the nails, blood loss, and blood transfusion.

*Outcome measures*

Outcome measures included duration of hospital stay, time to full weight-bearing, time taken to achieve bony union, return to work, and participation in full activities. Further surgery or significant complications following nailing were also recorded. Clinically, full weight-bearing was defined as no or minimal pain at the fracture site and being able to walk unaided. Radiographic fracture union was considered present if radiographs demonstrated bridging callus on three cortices on anteroposterior and lateral radiographs. Nonunion was considered present if signs of union were not firmly established after 6 months.

*Statistics*

The data were entered in a commercially available database. Means, standard deviations, and ranges were calculated; and contingency tables were built. Differences in the variables examined were analyzed using the chi-square test. The SPSS (release 9.0.1. standard version; SPSS, Chicago, IL, USA) statistical package was used to analyze the results. A probability level of $P < 0.05$ was considered significant.

## Results

*Patients*

In the Fixion group, a road traffic accident was the cause of injury in 28 patients; 4 others fell from a height, 5 sustained their accident at work, and 6 fell at home. Seven patients had chest injuries, six had head injuries, one had abdominal injuries, and three had miscellaneous minor injuries. In 19 patients, we reamed the medullary canal to 1 mm more than the diameter of the nail, as the isthmus of the femur was too narrow to allow insertion of the nail.

In the Stratec group, a road traffic accident was the cause of injury in 31 patients, 5 fell from a height, 5 sustained their accident at work, and 2 fell at home. Nine patients had chest injuries, four had head injuries, one had abdominal injuries, and three had miscellaneous minor injuries. In all patients, we reamed the medullary canal to 1 mm more than the diameter of the nail to enable insertion.

*Surgery*

Patients underwent surgery an average of 14.6 h after admission to hospital, with no significant differences between the two cohorts. Altogether, 25 patients (12 in the Fixion group, 13 in the Stratec groups; NS) were transfused intra- or perioperatively with an average of

1.3 blood units (range 1–4; NS). Eight patients (four in each group) were admitted to the intensive therapy unit for an average 24 h of ventilation. In the Stratec group, five patients required dynamization to achieve union an average of 4.6 months (range 3–7 months) after the index operation. In the Fixion group, the average time for clinical healing (full weight-bearing) was 3.8 months (range 3–9 months), and the average time for radiographic healing was 3.2 months (range 3–9 months) (Figs. 3–6). In the Stratec group, excluding five patients who required dynamization and one patient in whom the nail broke, the average time for clinical healing (full weight-bearing) was 4 months (range 3–9 months) (NS), and the average time for radiographic healing was 3.5 months (range 3–9 months) (NS). When these six patients were included in the analysis, the average time for clinical healing (full weight-bearing) was 6.8 months (range 3–11 months) ($P = 0.02$), and the average time for radiographic healing was 7.5 months (range 3–12 months) ($P = 0.01$).

**Fig. 4.** At the sixth postoperative week

All patients in both groups proceeded to union. In the Fixion group, 32 patients returned to work and full activities; 25 of the 32 returned to the same job. In the Stratec group, 38 patients returned to work and full activities ($P = 0.05$), with 30 returning to the same job.

No patient developed a deep-seated infection. In the group treated with Stratec implants, two patients developed irritation and reddening over one of the distal locking screws. The screws were removed at 7 and 9 weeks, respectively, after the index operation with no sequelae.

Five patients, all in the Stratec group, had not progressed to union 6 months after injury. They required dynamization of the implant.

In the Stratec group, a male motorcyclist who had been hit by a lorry and sustained a femoral fracture with a chest injury had a fat embolism from which he recovered completely. None of the other patients with chest injuries developed a fat embolism.

In one of the patients treated with Stratec implants, the nail was broken and required an exchange nailing. The fracture healed uneventfully thereafter. In four patients in whom a solid nail had been used, one of the two distal screws broke at an average of 7.8 weeks (range 6–12 weeks) after the operation. In two of them, the broken screw was removed.

There have been no deaths in either group of patients.

## Discussion

Femoral shaft fractures commonly occur after high-energy trauma, affecting relatively young, active individuals. Intramedullary interlocking nailing has become the standard management for closed diaphyseal fractures of long bones.[4] Being closer to the weight-bearing axis, an intramedullary nail has mechanical advantages over other fracture stabilization devices such as plates, external fixators, and casts. Excellent results have been

**Fig. 5.** Clinical result 5 months after the operation

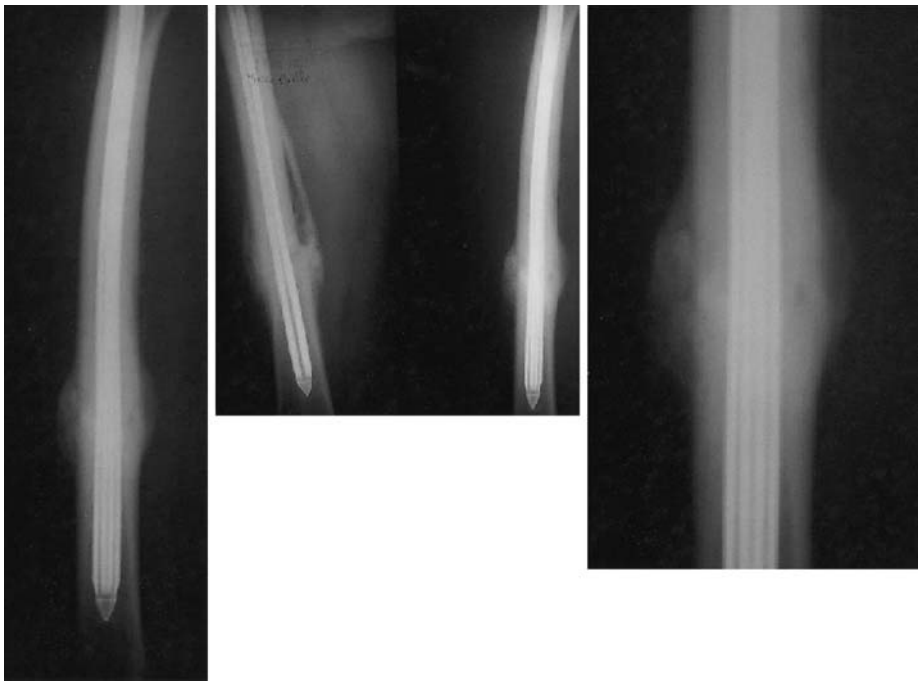

**Fig. 6** Radiographic result 5 months after the operation. Note the full bridging of the fracture site by mature callus

reported for intramedullary nails in lower limb fractures.[4,24] The introduction of interlocking for more proximal and distal and open shaft fractures has further extended the indication for nailing.[6]

Reaming allows us to insert a nail of a larger diameter that provides better stability. However, some consider reaming a significant factor in delaying fracture union because it damages the intramedullary blood supply,[26] with the degree of damage proportional to the amount of endosteal reaming.[12] Reaming also increases the intramedullary pressure, introducing fat and medullary debris into the circulation, which can lead to pulmonary and cardiac complications.[13] Proponents of unreamed nailing also believe that the risk of infection increases with reaming, especially with open fractures.[8] On the other hand, reaming produces internal bone graft, which may well stimulate fracture union and reduce the need for bone grafting.[5] Anglen and Blue[2] have also reported faster healing times in fractures treated with reamed nails. Finkemeier et al.,[9] Court Brown et al.,[7] and Wiss and Stetson[29] have found that reaming promotes fracture healing in nonunions compared with the insertion of unreamed nails.

Orthopedic surgeons are exposed to X-rays.[15,21] The use of devices that reduce and minimize exposure to ionizing radiation is beneficial to both surgeons and patients.[27] In this respect, the Fixion nail performs significantly better than traditional intramedullary nails, as it does not require imaging for transverse locking.

Conventional nails rely on interlocking screws for axial and rotational stability. The Fixion nail anchors with its longitudinal bars along the endosteal wall of the femur. In this way, weight-bearing forces are homogeneously shared on the entire diaphysis, unlike classical interlocking nails, which have three-point fixation.

In the present study, the time to return to work was significantly shorter for the patients treated with Stratec implants. However, it should be kept in mind that the welfare arrangements are different in the two countries in which the study was carried out. This does not imply that one implant is superior to the other in this particular aspect. Comparisons with other studies should be made with caution, as our study populations may differ from those in other investigations.

## Limitations of the current study

Although this report investigates two cohorts of patients broadly comparable, and the patients were followed prospectively as part of their clinical evaluation, this study is not a randomized controlled trial. All our patients undergoing traditional nailing underwent reamed nailing. This reflects current clinical practice and cannot necessarily be considered a hindrance to the interpretation of the results of the present investigation.[24]

Despite their limitations, these studies marry the realities of clinical practice with the rigors of scientific investigation and may invite hypotheses for future prospective randomized trials. Also, although patients were discharged when their healing was satisfactory clini-

cally, functionally, and radiographically, we could not be absolutely certain that no problems arose subsequently and were addressed by other centers. However, given the "open door" policy implemented in our settings, it is unlikely that these patients had problems after discharge.

## Conclusions

The Fixion intramedullary nail allows effective management of diaphyseal fractures of the femur. Its main advantage is that interlocking is not necessary, so operating times are reduced and exposure to ionizing radiation is minimized. Although the device was conceived to be inserted unreamed, surgeons should be aware of the need to perform at least some intramedullary reaming in selected patients. As with any new device, use of the Fixion intramedullary nail requires initial training, but in the hands of trauma surgeons experienced in traditional nailing techniques this has proved not to be a problem. The role of the Fixion intramedullary nails remains to be established for other indications such as nonunion, prophylactic nailing of impending pathological fractures, and exchange nailing during procedures where other devices have failed. Although we have not performed a cost-effectiveness analysis, it should be acknowledged that, at present, a Fixion intramedullary nail is markedly more expensive than traditional devices: Its initial cost is approximately five times that of traditional reamed intramedullary nails.

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