

## Original Article

# Comparison of the Expandable Nail with Locked Nail in the Treatment of Closed Diaphyseal Fractures of Femur

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ABSTRACT

**Background:** Expandable nails achieve stability only by hydraulic expansion; therefore suggest less radiation exposure and operation time. In this study, we aimed to compare the results of expandable femoral nails with locked intramedullary nails in the treatment of diaphyseal fractures of femur. **Materials and Methods:** Isolated closed AO = Arbeitsgemeinschaft für Osteosynthesefragen type 32.A or 32.B unilateral femoral shaft fractures operated with expandable or locked nail were evaluated retrospectively. We match patients who undergone expandable nail fixation with patients of the same-sex, age, and fracture type who undergone locked nailing. A match was done for 31 expandable nail. At follow up, healing was assessed radiologically and clinically. Outcome measures included duration of hospital stay, time taken to achieve bony union, and participation in full activities. **Results:** The average duration of surgery in the expandable group was 60.9 min and in the locked group was 82.4 min. In the expandable group, the average clinical healing time was 15.5 weeks and radiographic healing time was 21.7 weeks. In the locked IMN group, the average clinical healing time was 18.4 weeks and the average radiographic healing time was 24.1 weeks. We observed seven (22.6%) non-union in expandable group and four (12.9%) non-union in locked group. In the expandable group, type of the fracture was AO 32.B in all of the non-union patients. We achieved union in all of non-unions of the locked group only with dynamization. In the expandable IMN group, five (16.1%) patients required major surgery, in the locked group none of the patients required major surgery. **Conclusion:** Non-union rate of the expandable nail is higher than that of the locked nail for femoral diaphyseal fractures. It may be a treatment option in simple fractures like AO 32.A and in patients where rapid fixation is demanded. It has advantages of reduced operative time and less radiation exposure in comparison with reported series of conventional nails.

**KEYWORDS:** Expandable nail, femur fracture, intramedullary nailing, self-locking

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## INTRODUCTION

Femoral diaphyseal fractures are seen frequently in young adults after a high-energy trauma. Despite various internal or external fixation methods used in adult femoral diaphyseal fractures, intramedullary nailing is the gold standard method. Main advantages of the nailing are rapid fracture stabilization using a minimal invasive approach and allowing early mobilization and return of function to the injured limb.<sup>[1-4]</sup> Medullary reaming should be done for insertion of thicker nail with a tight fit

throughout a longer segment of the shaft for improving stability.<sup>[5]</sup> Proximal and distal interlocking was added to the initial unlocked design so that stability is improved and indications are expanded including comminuted fractures.<sup>[5-7]</sup> The axial and rotational stability of locked nails depends primarily on locking screws. The technique

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is now well established in the management of fractures of long bones of the lower limb.<sup>[1,3,4,6,8]</sup>

The Fixion (Disc-O-Tech, Tel Aviv, Israel) nail is an expandable, stainless steel cylindrical nail folded longitudinally in a specially designed process.<sup>[9-11]</sup> These are IM = intramedullary nails that are implanted without the need for a guide wire or reaming, and are inflated with saline to conform anatomically to the diaphyseal cortex.<sup>[12]</sup> The nail can be 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 which is theoretically stable enough to maintain fracture reduction, and avoid the need for locking screws; therefore suggest less radiation exposure and operation time.<sup>[11,13]</sup>

In this study, we have reported the results of intramedullary nailing using the Fixion system (Disc-O-Tech, Tel Aviv, Israel) in the lower limb. We present the results of the 62 femur diaphyseal fractures comparing the use of the Fixion system versus classical interlocked intramedullary nailing.

## MATERIALS AND METHODS

Patients operated for femoral fracture with expandable or locked intramedullary nail were evaluated retrospectively. Inclusion criteria were: isolated closed traumatic unilateral fractures of the femoral shaft, AO type 32.A or 32.B, and skeletally mature patient aged 18 or above. We tried to match each of the patients who had undergone intramedullary fixation with an expandable nail system with a patient of the same-sex and approximately same age that had undergone statically locked intramedullary fixation with slotted nail. Patients were also matched with the type of fracture. A match was done for 31 patients treated with expandable nail from 235 statically locked intramedullary fixation patients performed at our institution. We report 21 male and 10 female patients in each group. The AO classification was used. Each group was formed by 20 AO 32. A type (spiral, short, oblique, and transverse) and 11 AO 32.B type (wedge) fractures.

All nailing were done by anterograde and closed method with the patient in supine position using image intensifier control. General anesthesia was used in all of the patients. Same protocols of antibiotic prophylaxis and low molecular weight heparin prophylaxis were given to the entire patients. First dose of the antibiotic was begun with the induction of anesthesia and continued for 3 days postoperatively.

Expandable Intramedullary nail (Fixion) is composed of a central folded space where inflated by ringer's

solution for expansion and four external longitudinal bars that are forced against cancellous and cortical bone to match the medullary canal, thereby giving the nail self-lock capability. The nail has a blunt and solid distal end, and proximally it has a unidirectional valve mechanism. After inflation, the nail acquires the shape of the medulla as it expands less at the isthmus. Pressure is distributed over the entire length of the nail contrary to localized pressure at the locking screws of interlocking nails. In our patient group, we performed expandable nails without reaming and intramedullary wire guidance. Only in patients with a narrow isthmus, we enlarged the canal 2 mm greater than the planned nail size. Nail entrance point detection, fracture reduction, and nail inflation controls were done under fluoroscopy control. Nails were inflated to 70 mmHg as the manufacturer advises.

Locked intramedullary nails were performed under fluoroscopy control. Femoral canal were reamed 2 mm larger than the nail size in all the patients, and reduction were done under intramedullary wire guidance. All of the nails were locked proximally and distally by free hand technique. We report 31 patients who were matched with the patients treated with an expandable nail according to the criteria stated above.

Patients were routinely followed up until fracture healing was seen and more frequent outpatient appointments were given if clinically necessary. We reviewed follow up, radiographies, and clinical recordings retrospectively for assessing fracture healing. We recorded patient details, the type of nails used, duration of surgery, screening times with image intensifier. Outcome measures included duration of hospital stay, time taken to achieve bony union, and participation in full activities. 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 radiography demonstrated bridging callus on three cortices on anteroposterior and lateral radiographs. Non-union was considered present if signs of the union were not established after 6 months.

Data were analyzed using the Statistical Package for Social Sciences 10.0 for Windows (SPSS Inc., Chicago, IL). The Chi-square test, or Fischer exact test, and independent samples *t* test were used to compare the variables. The results for all items were expressed as mean  $\pm$  standard deviation, assessed within a 95% confidence interval and at a level of  $P < 0.05$  significance. All subjects gave informed consent to participate in the study and the protocol was approved by the research ethics boards of the institution.

## RESULTS

In the expandable intramedullary nail group, traffic accident was the cause of fracture in 24 patients, five others fall from a height, and two sustained their accident at work. In the locked intramedullary nail group, traffic accident was the cause of fracture in 22 patients, eight fall from height, and one sustained occupational accident. All of the patients were operated in the first 24 h of the injury; only, five from the expandable IMN group and three from locked IMN group because of being multi-trauma patients were operated 72 h after the injury. Twenty five patients (12 in the expandable IMN group, 13 in locked IMN group) were transfused intra or perioperatively with an average of 1.1 blood units (range: 1–3). In the expandable IMN: intramedullary nail group, the average duration of surgery was  $60.9 \pm 13.5$  min (range: 40–88 min). In the locked IMN group, the average duration of surgery was  $82.4 \pm 20.9$  min (range: 45–120 min), ( $P < 0.01$ ). We had not seen any infection or other postoperative complications in the patients of the two groups. Also, fluoroscopy screening time was lower in the expandable nail group [Table 1].

In the expandable IMN group, seven patients went into non-union, as radiologically we had not seen cortical bridging on three cortices at the sixth month of surgery [Figure 1a–b]. We also saw and confirm non-union site by computed tomography. All of the non-unions were hypertrophic type. We performed autologous bone grafting to this seven patients as it is less invasive than exchange nailing. After grafting, in two of the non-unions we achieved union and, in five patients,

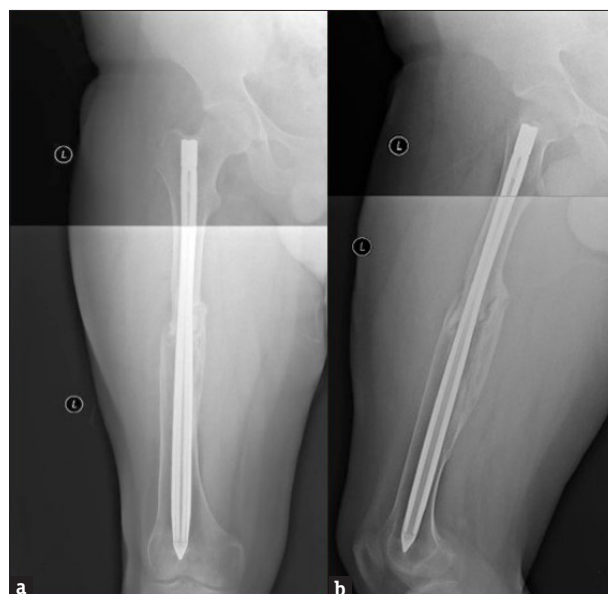
we exchanged the nails with locked IMN. In the locked IMN group, four patients went into non-union, as we had not seen cortical bridging on three cortices at the sixth month. We did dynamization for these patients as the first line of treatment and achieved union only with this intervention.

In the expandable IMN group, excluding seven patients who required additional interventions, the average time for clinical healing was  $15.5 \pm 4.5$  weeks (range: 9–24 weeks) and the average time for radiographic healing was  $21.7 \pm 4.5$  weeks (range: 13–30 weeks). In the locked IMN group, excluding four patients whom dynamization was done, the average time for clinical healing was  $18.4 \pm 4.4$  weeks (range: 10–26 weeks) and the average time for radiographic healing was  $24.1 \pm 4.4$  weeks (range: 17–32 weeks). The difference in clinical healing was statistically significant ( $P = 0.02$ ), [Table 1].

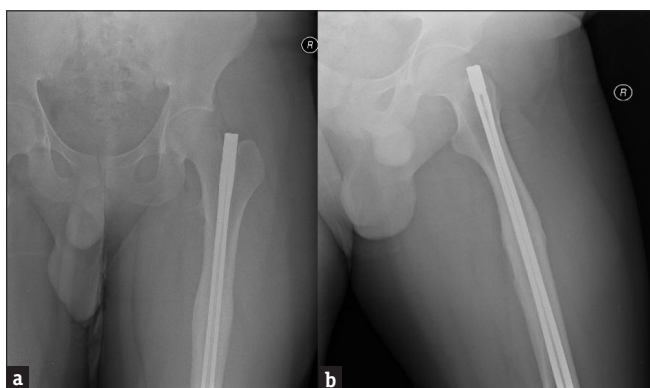
In the expandable IMN group, all of the seven non-union patients' fracture type was AO 32.B. Three of five patients in the expandable IMN group, whom exchanged locked IMN was performed, achieved union with shortening. No rotational, varus, or valgus malalignment was seen in the rest of the expandable IMN group [Figure 2a–b]. In the expandable IMN group, we observed seven (22.6%) non-union. However, in locked IMN group four patients were accepted as non-union (12.9%) and dynamization was done to them for treatment. Non-union rate between two groups was not statistically significant. In the expandable IMN group, five (16.1%) patients required major surgery as exchange nailing was done; however in the locked nailing group, none of

**Table 1: Comparison of expandable and intramedullary nails**

	Expandable Nail Group	Locked Intramedullary Nail Group	P
Patients age (years) ( $n=31$ ; 10 females in each group)	$28 \pm 18$	$29 \pm 19$	NS
Duration of surgery (minutes)	$60.9 \pm 13.5$	$82.4 \pm 20.9$	$P < 0.01$
Blood transfusion	11	13	NS
Screening time (seconds)	$31 \pm 18$	$93 \pm 39$	$P = 0.02$
Clinical healing	$15.5 \pm 4.5$	$18.4 \pm 4.4$	$P = 0.02$
radiographic healing	$21.7 \pm 4.5$	$24.1 \pm 4.4$	$P = 0.02$
Non-union	7 (22.5%)	4 (12.9%)	NS
Major surgery (Nail exchange)	5 (16.1%)	-	$P < 0.05$
Full activity (months) (return to work)	$5.1 \pm 2.3$	$6.2 \pm 2.4$	NS



**Figure 1 (a-b):** A non-union patient from expandable group



**Figure 2 (a-b):** Healed fracture from expandable group

the patients required major surgery ( $P < 0.05$ ). In IMN group, all of the non-unions were healed by dynamization.

## DISCUSSION

Femoral diaphyseal fractures commonly occur after high-energy trauma, affecting relatively young, active individuals. Historical evidence suggests that the best treatment for diaphyseal fractures of the lower limb is locked IM nailing.<sup>[1-4]</sup> As it is on the weight-bearing axis, an intramedullary nail has mechanical advantages over other fracture stabilization devices. This fixation is successful for simple fractures in the diaphyseal region; however in multi-fragmented fractures or fractures in the proximal or distal metaphysis of the femur it is unsatisfactory. As with the advent of locked nails, these problematic fractures have been able to be treated adequately without femoral shortening and malrotation. But, with locking the contact between nail and bone is becoming unnecessary, therefore the contact between bone and screw and screw and nail is becoming the first line, therefore load sharing role of the nail is changed to load bearing. In delayed union or non-union dynamization of the nail may be needed to achieve fracture union. By this way, nail returns to load sharing form. The other problem in the application of the locked nail is the difficulty in the placement of distal locking screws. Proximal screws can be easily placed by its guide but distal screws are usually placed by using a radiographic technique. Guides to target the distal screws have not been as successful owing to slight bending and deformation of the implant and guide. General application is usually accomplishing distal locking by free hand technique which depends on fluoroscopic imaging; however this results in exposure of the patients and surgical team to high dose radiologic beams and increases surgery time. The other problem in distal locking screw is screw

breakage. As reported in biomechanical studies, for supplying security of distal fixation, at least two screws are needed.<sup>[14]</sup> This also increases locking duration and as a result fluoroscopy duration. The use of devices that reduce and minimize exposure to ionizing radiation is beneficial to both surgeons and patients.<sup>[15]</sup> In this respect, the Fixion nail performs significantly better than traditional intramedullary nails, as it does not require imaging for transverse locking. Also, it appears to be significantly quicker to implant than a standard locked IM nail.<sup>[12,16,17]</sup> The other reason for this is presumably that the nail does not always require reaming before insertion. Also in our study, operation duration was significantly shorter in expandable nail group. In the multiply injured patient, where surgical procedures should be done rapidly and minimal systemic insult may be beneficial, the expandable nail is a potentially useful device.

Reaming allows us to insert a nail of a larger diameter that provides better stability. However, reaming can be a significant factor in delaying fracture union because it damages the intramedullary blood supply, with the degree of damage proportional to the amount of endosteal reaming.<sup>[18,19]</sup> Cardiopulmonary complications can be anticipated while reaming because it causes passage of the lipid and medullary elements into the circulation as it increases intramedullary pressure.<sup>[20]</sup> Reaming deteriorate lung functions and, especially in thoracic contusion patients increases incidence of ARDS: acute respiratory distress syndrome as Pape reported in their study.<sup>[21]</sup> Chapman, in his study, showed medullary ingredients passage into the circulation and 30-80% decrease in the cortical blood circulation on the other hand, in unreamed technique endosteal blood supply is preserved. But he suggested that reaming allows more stable fixation.<sup>[22]</sup> Proponents of unreamed nailing also believe that the risk of infection increases with reaming, especially with open fractures.<sup>[23]</sup> On the other hand, reaming produces internal bone graft, which may well stimulate fracture union and reduce the need for bone grafting.<sup>[3]</sup>

Reamed intramedullary nailing of femoral diaphyseal fractures demonstrate none or delayed union rate of 5%.<sup>[24,25]</sup> This rises to 24% should nails be inserted unreamed.<sup>[24,26]</sup> However, lower rates of non-union or delayed union are informed for expandable nails. Kapoor *et al.*,<sup>[27]</sup> in his study, said that he saw two delays and one malunion in 22 femoral fracture operated with expandable nail. Also, Smith *et al.*<sup>[28]</sup> informed one non-union in the 22 femoral fracture implanted with expandable nail. Rose *et al.*<sup>[29]</sup> said in their study that non-union or delayed union resulted from 5 of 212

(2.4%) femoral expandable nailing procedures. In our study, non-union rates were 22% and 12% in the reamed and expandable group. There are complications specific to expandable nail in the literature. Ozturk *et al.*<sup>[30]</sup> reported an intraoperative extension of the fracture during inflation of the femoral nail and converted to conventional locked nail. Smith *et al.*<sup>[28]</sup> reported post-operative fracture shortening of greater than 1 cm in six cases with a mean shortening of 2.2 cm (range: 1.1–3 cm). Each case was revised to a conventional interlocking nail. Zoccali *et al.*<sup>[17]</sup> also reported two cases of shortening of greater than 2 cm in their cohort. Inflator breakage during inflation, nail leakage precluding inflation are other reported complications.<sup>[11]</sup> Zoccali *et al.*<sup>[17]</sup> reported a total of five cases where the expandable nail either bent or failed in some way during the insertion process, also requiring exchange nailing. Rose *et al.*<sup>[31]</sup> reported that the overall complication rate for expandable nailing was 13% for femoral nails while the rate of reoperation was 10% and 11%, respectively. In our study, 16% of the expandable nails required major surgery. The most important complications associated with the expandable nail are postoperative shortening and fracture propagation on inflation of the nail. Smith postulated that this was due to fracture propagation during inflation of the nail, indicating that some length-stable fractures had become unstable after implantation. As a consequence, their prospective cohort study was terminated early due to the unacceptably high complication rate.<sup>[28]</sup>

One of the main purported advantages of the expandable nail is that it does not require reaming of the intramedullary canal during insertion. Reaming allows insertion of larger nails, thereby improving construct stability, reducing time to fracture union and the rate of hardware failure.<sup>[22]</sup> However, reaming increases intramedullary pressure, intravasation of intramedullary debris have been shown to be associated with both reamed and unreamed nail insertions, this effect appears to be particularly severe with reaming.<sup>[32,33]</sup> Rose *et al.*<sup>[29]</sup> reported whether reaming had been performed during expandable nail implantation, 35% of femora had been reamed, suggesting that the theoretical advantage of avoidance of reaming with the expandable nail is not always borne out in practice.

Studies reported time to radiological union after femoral fracture fixation with an expandable nail ranging from 9.5 to 16 weeks.<sup>[13,27]</sup> Lepore *et al.*<sup>[34]</sup> reported the mean time for clinical (3.8 vs. 6.8 months) and radiographic (3.5 vs. 7.5 months) union to be significantly shorter in the Fixion nail versus the reamed intramedullary nail fixation groups. In our study, radiographic healing was

seen in expandable group at 21 weeks and in reamed group at 24 weeks. Also, patients return to work times were not statistically different when we compared two groups.

The duration of surgery is expected to be shorter for patients who underwent expandable nailing compared to conventional nails as no need for reaming and distal locking. Zoccali *et al.*<sup>[17]</sup> reported significantly shorter operative time (55 vs. 74 min,  $P<0.01$ ) with 21 acute femoral fractures treated with an expandable nail, when compared to a matched control group treated with a locked IM nail. Kapoor *et al.*<sup>[27]</sup> also informed 90 min operation time for expandable group as significantly lower than the locked nail group. We also found lower operation time for expandable group. In addition, fluoroscopy duration is shorter in expandable group than the locked nail group in our study as expected. Kapoor *et al.*<sup>[27]</sup> and Panidis *et al.*<sup>[35]</sup> also found shorter fluoroscopy durations in the expandable group compared to conventional nails.

Expandable nails may be more useful for specific fracture patterns as informed in a biomechanical study. Maher *et al.*<sup>[36]</sup> compared the expandable nail with a standard locked nail in fracture model, finding that spiral fracture patterns, rather than transverse fractures, were more suitable for expandable nail fixation. However, in this study bending and torsional stiffness were tested. As shortening is a potential complication for expandable nails, resistance to axial shortening and, therefore potential for fracture shortening should be studied with further studies.<sup>[28]</sup> Cases of nails bending with further fracture were reported in the literature specific to expandable nails. In Kapoor *et al.*'s series, a bent femoral Fixion nail was left *in situ*, the femur eventually uniting in a shortened and angulated position.<sup>[27]</sup> Pascarella *et al.*<sup>[11]</sup> and Ozturk *et al.*<sup>[30]</sup> observed bending of the Fixion nail in the femur and tibia, respectively, both carrying out revision to a conventional locked nail after removal of the damaged device. We have not seen any nail bending in our series. Last complication specific to expandable nails is the potential dangers of exploding expandable nails during the cremation process as presented by case report in the literature.<sup>[37]</sup>

## CONCLUSION

Non-union rate of the expandable nail is higher than the locked nail in the treatment of the diaphyseal femur fractures. It may be a treatment option in simple fractures like AO 32.A and in patients where rapid fixation is demanded such as in the poly-trauma patient. It has definite advantages of reduced operative

time and less radiation exposure in comparison with conventional interlocking nail. However, you should be aware of the complications such as non-union, device failure, and limb shortening when you use this nail.

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### Conflicts of interest

There are no conflicts of interest

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