Femoral Midshaft Fractures: Expandable Versus Locked Nailing

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Femoral midshaft fracture is one of the most common clinical injuries and is often caused by high-energy traffic accidents. Intramedullary nailings, plates, and external fixators are all used as treatment alternatives for a variety of patients depending on fracture location, displacement, comminution, soft tissue condition, and local tradition. Locked intramedullary nailing is currently the preferred treatment method for most diaphyseal fractures and has good clinical results. The goal of this study was to compare expandable and locked intramedullary nailing for the treatment of AO type 32A and 32B1 femoral midshaft fractures. The authors performed a retrospective analysis of 46 patients (33 men and 13 women; mean age, 32.3 years; range, 22-52 years) with femoral midshaft fractures who were divided into 2 groups—one treated with an expandable intramedullary nailing method and the other with a conventional locked intramedullary nailing. The 2 groups were compared with respect to operation time, fluoroscopic time, amount of estimated blood loss, hospitalization time, healing time, and complications. Patients were followed for at least 1 year. The results of this study showed that all of the patients achieved bone union within 12 to 24 months. Expandable nailing performed better than locked nailing in operation time, fluoroscopic time, amount of estimated blood loss, and healing time (P<.001). There was no difference in hospitalization time and no visible shortening or severe complications were observed in either group. Based on the results of this study, the expandable intramedullary nailing is an easy and effective treatment for AO type 32A and 32B1 diaphyseal femoral fractures. [Orthopedics. 2015; 38(4):e314-e318.]
Femoral midshaft fractures, usually caused by high-energy trauma, affect relatively young, active individuals. Locked intramedullary nailing is currently the preferred treatment method for most diaphyseal fractures and has good clinical results.1,3

In the 1940s, German surgeon Gerhard Küntscher developed the intramedullary nail system. Modification of the original Küntscher nail with locked screws in the 1970s improved both the axial and torsional control of the nail and expanded the indications for intramedullary nailings.4

Subsequently, an expandable intramedullary nail system (Fixion; Disc-O-Tech, Israel) was developed in 1999 to capitalize on the benefits of intramedullary nailing while eliminating the disadvantages associated with locking screws. This device does not require locking because of its unique ability to inflate the nail while gripping the intramedullary sides. Pressure distributed over the entire length of the nail avoids the use of highly localized forces associated with the locking screws. Clinical studies have documented high success rates using the Fixion nail in treating various long-bone fracture patterns, nonunions, and pathologic fractures and even in joint hemiarthroplasty.5-10 However, some reports questioned the use of the expandable nail in lower limb fractures, mainly due to the complications encountered, such as shortening, rotational malalignment, and the high reoperation rate, and the potential for fracture propagation during inflation.11,12

The authors present their experience with using both the self-locking expandable nail and the conventional locked intramedullary nail in the treatment of 46 AO type 32A and 32B1 femoral fractures. The time of operation, irradiation exposure, amount of estimated blood loss, hospitalization, healing, and complications were compared.

**Materials and Methods**

In this retrospective study, 46 consecutive patients with AO type 32A and 32B1 femoral fractures were treated with either the Fixion nailing (expandable group) or the conventional locked intramedullary nailing (Kanghui, Changzhou, China) (locked nailing group) from June 2006 to March 2012 at the authors’ institution. All patients were skeletally mature, older than 18 years, and had isolated closed traumatic unilateral fractures of the femoral shaft. All procedures were performed after written informed consent was signed. The Ethics Committee of the Second Affiliated Hospital of Soochow University approved both the study and the consent procedure.

All nailings were performed with a closed method under fluoroscopy on a fracture table with the patient supine. In the expandable group, the fracture was reduced and the nailing commenced through the tip of the greater trochanter in the usual fashion. Reaming was done in all cases over a guidewire, which was passed across the fracture site after obtaining a satisfactory reduction. To ensure a smooth nail insertion, the medullary canal was usually reamed 1 mm more than the diameter of the nail. The nail width was selected preoperatively on the basis of the minimum and maximum width of the intramedullary canal. The nail length was determined intraoperatively by using a metal ruler and fluoroscopy. After reaming, the guidewire was removed gently with caution to maintain the reduction. Once the nail was satisfactorily placed in the medullary canal, it was inflated by pumping in normal saline up to a maximum pressure of 70 bar under fluoroscopic guidance. Satisfactory expansion of the nail and reduction were confirmed under fluoroscopy.11,12 After removal of the insertion device, the nail cap was tightened in the proximal end of the nail.

In the locked nailing group, reaming was performed routinely to a diameter of 1 mm more than the preselected nail diameter in all cases. Nails with proper lengths and diameters, assessed by preoperative radiographs, were then inserted. The nail length was also determined intraoperatively using a metal ruler and fluoroscopy. After fixing the gunsight, both the distal and proximal ends of the locking pin were screwed. Proper positioning was confirmed with intraoperative radiographs.

Antibiotic prophylaxis and deep vein thrombosis prevention were used. All patients received a dose of prophylactic intravenous antibiotic at the induction of anesthesia, which was continued for 24 hours postoperatively. A drain was inserted at the site of the main incision.

Physical therapy was started the second day postoperatively. Only touchdown weight bearing was allowed until clinical and radiographic evidence of progress of union, after which load bearing was gradually increased. Patients were followed up at routine intervals of 2 and 6 weeks and then at 4-week intervals until fully healed. Additional outpatient appointments were scheduled whenever necessary.

Healing was considered complete when both clinical and radiological criteria for union were met. Clinical criteria for union were the absence of localized tenderness at the fracture site and the absence of pain on walking. Radiographic criteria of union were based on continuity in at least 3 cortices in both anteroposterior and lateral views.14 Specific note was taken for evidence of complications, such as infection, malunion, delayed union, nonunion, and shortening. According to the criteria used by Smith et al,11 malunion was defined as more than 5° of angulation in any plane; nonunion was defined as the absence of healing at 9 months or no sign of progression of healing at 3 months; and delayed union was defined as lack of evidence of radiographic healing or progression at 6 months.

Statistical analysis was performed with SPSS version 19.0 software (IBM SPSS Statistics, Armonk, New York). Means and standard deviations were calculated. Differences in the variables examined were analyzed using the Student’s t test. The level of significance was set at a P value of .05.
The study cohort comprised 33 (71.7%) men and 13 (28.3%) women, with a mean age of 32.3 years (range, 22-52 years). The modes of trauma were road traffic accidents (n=43) and falls from a height (n=3). Median time of surgery since injury was 9 days (range, 1-14 days). In comparison of the 2 groups, the authors’ data showed no difference in age, sex, mechanism of trauma, and time to surgery.

Mean operative time was 71.7 minutes (range, 45-105 minutes) in the expandable group vs 108.9 minutes in the locked nailing group (P<.001). Mean fluoroscopic time was 30.2 seconds (range, 18-45 seconds) in the expandable group and 61.4 seconds (range, 45-80 seconds) in the locked nailing group (P<.001). Mean blood loss was 217 mL in the expandable group vs 574 mL in the locked nailing group (P<.001). Hospitalization time was 13 days in the expandable group and 15 days in the locked nailing group (P=.057). Healing time was 22.0 weeks (range, 18-26 weeks) in the expandable group vs 26.7 weeks (range, 22-42 weeks) in the locked nailing group (P<.001).

No obvious shortening or severe complications were observed in either group. In the locked nailing group, 2 patients had irritation and reddening over 1 of the distal locking screws. The screws were removed at 10 and 14 weeks, respectively, with no sequelae. A third patient had early surgical site infection. It was successfully managed 4 weeks later with debridement, intravenous antibiotics, and dressing. This particular fracture went into delayed union where healing was achieved at 10 months. In addition, 3 patients also required dynamization to achieve union at an average of 4.0 months (range, 3-6 months) after the index operation. One distal locking screw was bent in 1 patient and 2 distal screws were broken in another patient. These screws were all removed. The fracture healed uneventfully thereafter.

All patients achieved bony union, with a healing time of 22.0 weeks in the expandable group and 26.7 weeks in the locked nailing group (P<.001). Postoperative checks showed good alignment in all cases with a good rotational control. No angle greater than 5° or clinically evident rotatory deformity was observed, nor was any obvious shortening observed (Figures 1-2).

Patients were followed for an average of 16 months (range, 12-24 months). No patient was lost to follow-up.

### DISCUSSION

Femoral diaphyseal fractures are usually high-energy injuries that most commonly affect young individuals. Intramedullary nailings, plates, and external fixators are used as treatment alternatives for a variety of patients. By taking each patient’s individual status into consideration, surgeons choose the most appropriate treatment method for a given fracture. In this study, the operation time, estimated blood loss, radiographic exposure, and healing time were decreased when using expandable nails compared with locked nails for the treatment of AO type 32A and B1 femoral fractures. Mean operative time was 71.7 minutes in the expandable group vs 108.9 minutes in the locked nailing group, and estimated blood loss was 217 mL in the expandable group vs 574 mL in the locked nailing group. Radiograph exposure of the expandable group was also reduced significantly.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean±SD (Range)</th>
<th>P</th>
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<tbody>
<tr>
<td>Operative time, min</td>
<td>71.7±16.7 (45-105)</td>
<td>108.9±24.6 (73-180) &lt;.001</td>
</tr>
<tr>
<td>Fluoroscopic time, sec</td>
<td>30.2±8.9 (18-45)</td>
<td>61.4±10.0 (45-80) &lt;.001</td>
</tr>
<tr>
<td>Estimated blood loss, mL</td>
<td>217±41 (150-300)</td>
<td>574±166 (300-900) &lt;.001</td>
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<tr>
<td>Hospitalization time, d</td>
<td>13±3 (6-21)</td>
<td>15±3 (10-21) .057</td>
</tr>
<tr>
<td>Healing time, wk</td>
<td>22.0±3.2 (18-26)</td>
<td>26.7±4.5 (22-42) &lt;.001</td>
</tr>
<tr>
<td>Obvious shortening</td>
<td>None</td>
<td>None</td>
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<td>Severe complications</td>
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Locked intramedullary nailing is widely accepted as a standard management for closed femoral shaft fractures. It shows mechanical advantages over other stabilization devices and can be used for various fractures with satisfactory results.

Although the advantages of locked intramedullary nailing have been proven, it is not without its drawbacks. The procedure relies on interlocking screws for axial and rotational stability, has a longer operative time, and has increased intraoperative blood loss. Locking screws have also been associated with a 2% to 30% risk of neurologic or vascular damage, although mainly for the treatment of tibia fractures.

The distal locking procedure itself is technically demanding and time consuming. Experience is required of both the surgeon and radiographer to reach precise locking. Repeated radiation also results in concern about exposure. In addition, locking screws increase the transmission of force through the nail, reduce bone load sharing, and might contribute to delayed union or even nonunion. Placement of a locking screw is also associated with late symptoms related to additional hardware and patient discomfort, possibly necessitating a second surgery. The results of the current authors’ locked nailing group coincided with these reports that there was longer operation and irradiation time, as well as more blood loss. Fortunately, no neurologic or vascular damage was encountered during distal end locking.

The expandable intramedullary nailing system is a relatively new device in the treatment of diaphyseal fractures. It retains the mechanical characteristics of a large diameter locked nail while avoiding the necessity to lock. The method uses a stainless tube with 4 longitudinal bars that are forced against the cancellous and cortical bone to match the medullary canal. On correct positioning, it can be expanded hydraulically with saline by up to 160% of its original diameter using a manually operated pump. With its longitudinal bars along the endosteal wall of the femur and weight homogeneously shared on the entire diaphysis, it allows for fast, minimally invasive, and stable internal fixation. The large frictional contact area prevents both localized pressure from peaks and the ridges of bars from rotation. In this way, surgeons are able to avoid the procedure of locking, save operative time, reduce blood loss, and minimize radiation exposure. Nevertheless, Lepore et al compared the 2 nailing earlier on femoral fractures and concluded that there were no differences in average blood loss, transfusion requirements, or hospitalization with the exception that the inflatable expandable nail used in their investigation was markedly more expensive than traditional devices. Smith et al noted a high rate of shortening and a tendency for some stable fractures to become less stable during nail expansion. An unplanned return to the operating room occurred in 16.5% of their patients because of postoperative shortening. However, reports were also found that advocated the use of expandable nailing on those stable fractures because of its obvious advantage in decreasing operative time and eliminating the complications and reoperations associated with the use of locking screws and its probable high union rate.

Previous studies have suggested that expandable intramedullary nailing had poor stability (especially in rotation) compared with locked intramedullary nailing. However, in the current study, the authors observed neither malrotation (5° or more) nor shortening of more than 2 cm. This might be attributed to their relatively young cohort of nonosteoporotic patients and their mid-shaft fractures, in which the expandable nail could anchor tightly along the intramedullary canal. In addition, reaming might also play an important role. Although the expandable intramedullary nailing system was designed to avoid reaming because it may damage the intramedullary blood supply, causing possible thermal necrosis and increased risk of pulmonary and cardiac complications, the current authors performed appropriate reaming on all the patients, allowing for the insertion of a larger diameter nail with a tighter fit throughout a longer segment of the shaft, with improved stability and increased nail strength but without any complications related to reaming.

The current authors found that the fractures in the expandable group often achieved ideal reduction postoperatively and that most of them reached anatomic reduction. This might be attributable to the application of reaming, strict preoperative indications, and surgeon experience. Good reduction decreased the possibility of malrotation and promoted fracture healing.
Nail dynamization is usually the first treatment option in cases of femoral shaft nonunion, with the initial treatment of intramedullary nailing in a static locking mode. The method converts the fixation from static to dynamic and promotes callus remodeling, stimulates osteogenesis, and induces fracture union by allowing the weight-bearing forces to transfer through the site of nonunion. Although this intervention is undertaken to boost an impaired bone healing process, nonunion rates up to 42% have been reported after application of dynamization. Furthermore, complication rates of 0% to 21% for excessive shortening and 0% to 10% for malrotation have also been reported.\(^3\) In the current authors’ series, 3 patients in the locked nail group who had not progressed to union 3 to 6 months after the index operation accepted dynamization and achieved bony union with no sequelae. The healing time in the authors’ expandable group (22.0 weeks) was significantly shorter than that of the locked nailing group (26.7 weeks), most likely due to the fact that all patients in the expandable group were born dynamized (due to no locking screws).

Although 2 cohorts of retrospective patients were broadly comparable, this study was not a randomized controlled trial and the sample size was limited, as such it was amenable to biased and invalid results. Further studies in the form of prospective, randomized controlled trials will be needed for more systematic evaluation of the Fixion system.

**CONCLUSION**

For stable OA type 32A and 32B1 diaphyseal femoral fractures, the Fixion intramedullary nail allows for an easier and more effective management with few complications compared with locked intramedullary nail. Nevertheless, treating femoral fractures of other AO types using the Fixion intramedullary nail should be done cautiously to prevent complications due to shortening and rotational malalignment. Locked nailing is still the preferred method of treating difficult fractures.

**REFERENCES**