With the widely recognised concept of biological fixation in orthopedics, intramedullary nailing (IN) had become the preferred method in treating long diaphyseal fracture (LDF) with interlocking intramedullary nailing (IIN). Interlocking IN (IIN) fixation is a type of mid-axis fixation. It can distribute the stress evenly on the fractured segments, with small shielding effects, and strong anti-torsion and anti-bending stress abilities. Additionally, the surgical trauma produced is small, the reduction is satisfactory, and the fixation is stable; to some extent it can prevent limb shortening, rotation, and varus-valgus deformity. However, intraoperative distal locking is still a relatively more difficult part of the operation. Although a variety of tools and methods are available for distal locking, the success rate is variable. Learning curve and operating time is long. Since the fixation needs to be done under fluoroscopy, and the damage due to radiation accumulation cannot be ignored, especially in the distal femur, in which unsatisfactory postoperative knee function recovery has been reported to commonly occur in patients operated.

Targeting the various limitations in existing IIN-distal locking technologies, an electromagnetic navigation (EN)-guided distal targeting system was developed that can control the entire process of nail locking under EN guidance in real time, instead of radiography; and the success rate is high.

The aim of this study was to elaborate on the applications and effects of electromagnetic navigation technology in distal locking for the treatment of long diaphyseal fracture (LDF) with interlocking intramedullary nailing (IIN). The study was conducted with approval from the Ethics Committee of the University. Written informed consent was obtained from all participants.

This is a retrospective, comparative study of patients who underwent IIN for the treatment of long femoral and tibial diaphyseal fractures at The Second Affiliated Hospital of Soochow University, China, from March 2013 to July 2014, were selected. Half of them were operated under EN guidance (group A) and the other half under conventional targeting guidance (group B). The distal locking time and X-ray irradiation time of the two groups were compared.

Results: Each group included 16 (33.3%) cases of femoral fracture and 8 (16.7%) cases of tibial fracture. The success rate of distal locking in group A was higher than that in group B (95.8% vs. 83.3%, p=0.045). There were statistically significant differences in the distal locking time and X-ray irradiation time of femoral intramedullary nailing between the two groups (p=0.027 and p=0.001, respectively). There were no statistically significant differences in the distal locking time and X-ray irradiation time of tibial intramedullary nailing between the two groups (p=0.347 and p=0.056, respectively).

Conclusion: EN-IN was advantageous as it enabled easy targeting, significantly reduced intraoperative fluoroscopy and operation time and small trauma and had other advantages when used for treating LDFs, especially femoral diaphyseal fractures.

Key Words: Intramedullary nailing, Distal locking, Femoral/tibial fractures, Electromagnetic navigation.
EN-guided distal targeting system and applications.

Distal targeting system, including computer software-assisted real-time monitoring, sensor-contained probe and disc-shaped hand control gun sights that could generate electromagnetic filed; (B) The probe was inserted into the intramedullary nail centre intra-operatively, and at the distal locking site, placed the electromagnetic field-generating disc-shaped hand control gun sights near the bone surface, and constantly adjusted the direction of gun sights under real-time monitoring; (C) When the gun sights did not reach the specified location, the red circle and the green circle did not overlap in the screen; (D) When the gun sights was adjusted to the specified location, the red circle and the green circle overlapped and aimed at the locking hole, the hole could be drilled at this time to complete the locking.

Figure 1: EN-guided distal targeting system and applications. (A) Distal targeting system, including computer software-assisted real-time monitoring, sensor-contained probe and disc-shaped hand control gun sights that could generate electromagnetic field; (B) The probe was inserted into the intramedullary nail centre intra-operatively, and at the distal locking site, placed the electromagnetic field-generating disc-shaped hand control gun sights near the bone surface, and constantly adjusted the direction of gun sights under real-time monitoring; (C) When the gun sights did not reach the specified location, the red circle and the green circle did not overlap in the screen; (D) When the gun sights was adjusted to the specified location, the red circle and the green circle overlapped and aimed at the locking hole, the hole could be drilled at this time to complete the locking.

expansion size and the extent (length) of the penetration of the guiding pin into the medullary cavity. During surgery, epidural anesthesia was used. For the femoral fractures, an orthopedic traction table was used for the closed reduction of the fractured limb, with C-arm radiography, to confirm the position and alignment of the fracture; on the other hand, tibial fractures were treated with direct manual reduction. The greater femoral trochanter was set on top and 0.5 cm below the front edge of tibial plateau, respectively, as the nailing entry point; the cortex was drilled with an opening instrument; the guiding pin was inserted through the proximal and distal fractured segments in turn; the guiding pin was retained to expand the marrow until the diameter was 1.0 - 1.5 mm; then, the selected nail (INN) with the appropriate length and diameter table was inserted (Figure 1A). For group A, the Distal Targeting System V3.0 (Smith & Nephew Inc, 2013) was used. The probe was inserted into the intramedullary nail centre intra-operatively; and at the distal locking site, the electromagnetic field-generating disc-shaped hand control gun sights was placed near the bone surface, with the casing tube located at the centre of disk (Figure 1B). The whole procedure was assisted by the use of computer software, and monitored in real time on a screen. When the red circle and the green circle did not overlap on the screen (Figure 1C), the directions of the gun sights were adjusted until the red circle and the green circle overlapped and were aimed at the locking hole (Figure 1D). The skin was incised, and positioning, drilling, depth measurement were done; then, the first locking nail with the appropriate length was placed into the distal end, followed by the second locking nail.

For group B, the distal targeting method was used to implant the main nails. The aiming device was installed, under the guidance of which holes were drilled on the distal anterior side of the femur or tibia. The positioning rod was placed, letting it fall onto the positioning platform of the distal nail end; then, under the guidance of the positioning casing tube, drilling from the lateral femoral or medial tibial cortical bone until the contralateral cortex was done, and the two nails were inserted for locking.

The two groups were examined with a guiding pin inserted after the locking nails were implanted and confirmed by fluoroscopy. The proximal locking nail could be implanted under the guidance of a aiming device. All patients were treated with phase I static locking. Finally, the proximal ends of intramedullary nails were closed with nut caps, and the incisions were sutured. The time to the successful fixation of the two distal locking nails was recorded intraoperatively (including the whole procedure from the gun sights installation after the intramedullary nail was inserted, targeting, incision of the skin, drilling, and placement of the locking nail), as well as the X-ray irradiation time and one-time successful locking rate.

SPSS version 19.0 statistical software (IBM SPSS statistics version 19.0; IBM, Armonk, NY, USA) was used, and the measurement data were expressed as mean ± SD (χ ± s), median (IQR) values and frequency with percentages. Normality of data was checked using the Kolmogorov-Smirnov test. Once normal distribution of data was confirmed, data were compared across both groups, using the student's t-test. Otherwise, Mann Whitney U-test was applied. Relationships between nominal variables were calculated using the Chi-squared test. P < 0.05 was considered as significant for all statistical data.

RESULTS

Each group included 16 (33.3%) cases of femoral fracture and 8 (16.7%) cases of tibial fracture; there were 33 (68.75%) male and 15 (31.25%) female patients, aged 16 - 67 years (mean, 45.8 years). The fractures were fresh and closed, with 29 (60.4%) cases having an AO classification of type A, and 19 (39.6%) cases of type B. The time interval from injury to operation was 3 - 19 days, with an average of 10 days. There were 32 (66.7%) cases of traffic injury, 5 (10.4%) cases of fall causing injury, 5 (10.4%) cases of weight drop injury, 1 (2.1%) case of blast injury, and 5 (10.4%) cases of injury due to being hit with a heavy object.

All patients underwent successful closed reduction and nailing. For group A, the distal locking time of femoral IN was 738.75 ±108.927 (range, 540 - 960) seconds, and the X-ray irradiation time was 3 (2) (Median IQR, range,
Comparison of distal locking time and X-ray irradiation time of the 2 groups.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group A (n=24)</th>
<th>Group B (n=24)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral distal locking time (seconds) (mean ±SD)</td>
<td>738.75±108.927</td>
<td>945±324.59</td>
<td>-2.410</td>
<td>0.027</td>
</tr>
<tr>
<td>Femoral X-ray irradiation time (seconds) (median IQR)</td>
<td>3 (2)</td>
<td>5 (6)</td>
<td>-3.245</td>
<td>0.001</td>
</tr>
<tr>
<td>Tibial distal locking time (seconds) (mean ±SD)</td>
<td>637.50±101.1</td>
<td>720±217.518</td>
<td>-0.973</td>
<td>0.347</td>
</tr>
<tr>
<td>Tibial X-ray irradiation time (seconds) (mean ±SD)</td>
<td>2.3±1.0</td>
<td>4.5±2.8</td>
<td>-2.194</td>
<td>0.056</td>
</tr>
<tr>
<td>One-time success rate of distal locking (frequency %)</td>
<td>95.8% (n=23)</td>
<td>83.3% (n=20)</td>
<td>4.019</td>
<td>0.045</td>
</tr>
</tbody>
</table>

* Student's t-test; † Mann-Whitney U-test; ‡ Chi-square test.

1 - 5) seconds; for group B, the distal locking time of femoral IN was 945±324.59 (range, 600 - 1800) seconds, and the X-ray irradiation time was 5 (6) (Median IQR, range, 2 - 12) seconds. The differences between the two groups were statistically significant (p=0.027 and p=0.001, respectively). For group A, the distal locking time of tibial IN was 637.50±101.1 (range, 480 - 780) seconds, and the X-ray irradiation time was 2.3±1.0 (range, 1 - 4) seconds; for group B, the distal locking time of tibial IN was 720±217.518 (range, 480 - 1200) seconds, and the X-ray irradiation time was 4.5±2.8 (range, 2 - 10) seconds (Table I). The differences between the two groups were not statistically significant (p=0.347 and p=0.056, respectively).

The one-time success rate of distal locking was significantly higher in group A (95.8%, n=23) than in group B (83.3%, n=20, p=0.045, Table I); the postoperative radiographs revealed that group A included one case in which both the two distal femoral locking nails slipped outside the locking holes, and this patient was reoperated to relock the nails. On the other hand, group B included 4 cases of inaccurate distal locking, which then required gunsight removal and the manual completion of locking under X-ray irradiation. The failure of distal locking would cause repeated drilling; thus, the operation and wound exposure times would be prolonged. In addition, distal locking requires increasing the incision and drilling to place the positioning rod. The domestic IIN system used a positioning rod with increasing coarse diameter to ensure that it would not easily slip from the positioning platform of the distal nail end, which could worsen the injury and prevent wound healing. Some surgeons choose to complete the distal locking manually (by hand) under fluoroscopic guidance. This could reduce the incision and shorten the operative time; however, the time that the surgeon is exposed to radiation would also be increased, and it was reported that the radiation exposure time that the surgeon is exposed to could account for half of the entire radiation exposure time. For orthopedic surgeons, accumulated radiation damage would greatly increase their cancer risk. Thus, improving the distal locking technique, avoiding the persistent use of fluoroscopy, and reducing intraoperative radiation exposure are some of the aims in orthopedic surgery. Electromagnetic gravity is used in EN-INN distal targeting. When the distal end of the IN is aligned to the nail keyhole, it can be converted to an image and displayed on a screen monitor, thus facilitating the interlocking. This method does not require stopper-rod configurations (front); moreover, mild deformation of the intramedullary nail is allowed and the fixation devices are adjustable, making the operation simple, with less invasion, and with accurate positioning. Compared with

**DISCUSSION**

As the preferred method in treating LDF, the efficacies and advantages of IIN have been widely recognised. Many trauma centres in China and abroad had used the static IIN as a routine method in treating fresh LDF, and distal locking was the main difficulty in a successful static fixation.

The distal targeting system was widely used in China. However, because of its much more complex ancillary equipment, or the incompatibility between the intramedullary nail and the femoral curvature, the expansion of the medullary cavity is insufficient, so when the main nail is inserted into the medullary cavity, slight distortion and deformation of the nail body might occur, thus causing the corresponding displacement of the locking nail hole or the minor shifting of the nailing point forwards or backwards. These situations may cause the main nail to be inserted close to the cortical bone, which then may result in the forward or backward displacement of the main nail inside the medullary cavity. Distal locking of femoral nails is traditionally done without aiming devices in femoral nails; however, tibial nails have been distally locked using jigs which can lead to erroneous passage of screws outside nail holes. The direct consequence of these events is that the positioning rod could not be accurately located on top of the main nail, leading to the inaccuracy of distal locking. In addition to the requirements for the high precision of the surgical instruments, the manipulation techniques of the surgeons are also important, as well as any factor that could cause the failure of distal locking. It has been reported that the conventional positioning, rod-based three-dimensional positioning technology, had a failure rate of 8 - 29.1% in IIN distal locking.

In this study, group B included 4 cases of inaccurate distal locking, which then required gunsight removal and the manual completion of locking under X-ray irradiation. The failure of distal locking would cause repeated drilling; thus, the operation and wound exposure times would be prolonged. In addition, distal locking requires increasing the incision and drilling to place the positioning rod. The domestic IIN system used a positioning rod with increasing coarse diameter to ensure that it would not easily slip from the positioning platform of the distal nail end, which could worsen the injury and prevent wound healing. Some surgeons choose to complete the distal locking manually (by hand) under fluoroscopic guidance. This could reduce the incision and shorten the operative time; however, the time that the surgeon is exposed to radiation would also be increased, and it was reported that the radiation exposure time in distal locking could account for half of the entire radiation exposure time. For orthopedic surgeons, accumulated radiation damage would greatly increase their cancer risk. Thus, improving the distal locking technique, avoiding the persistent use of fluoroscopy, and reducing intraoperative radiation exposure are some of the aims in orthopedic surgery. Electromagnetic gravity is used in EN-INN distal targeting. When the distal end of the IN is aligned to the nail keyhole, it can be converted to an image and displayed on a screen monitor, thus facilitating the interlocking. This method does not require stopper-rod configurations (front); moreover, mild deformation of the intramedullary nail is allowed and the fixation devices are adjustable, making the operation simple, with less invasion, and with accurate positioning. Compared with
the standard free-hand fluoroscopic technique, the use of electromagnetic guidance system, showed high reliability and was associated with less complication, took significantly less time, and used no radiation exposure for distal locking procedures. Furthermore, there were reports about its applications in non-LDF cadaver cases. In clinical application, Moreschini et al. compared EN-INN-LDF distal locking and manual manipulations in 50 patients with tibial fractures who underwent INN. These patients were divided into two groups: group 1 underwent distal locking by hand, whereas group 2 were operated under EN guidance. The distal locking times were 20.98 and 10.06 minutes for the manual operation group and the EN group, respectively, whereas the average X-ray irradiation times were 19.4 and 4.6 seconds, respectively.

Langfitt et al. did the same comparison and found that the distal locking time of EN-INN-LDF distal locking was significantly shorter than that of the traditional manual operation, and the success rate was high. In this study, the EN group exhibited a distal interlocking accuracy of 95.8%, which was significantly higher than that of the traditional group (83.3%) (p=0.045). There was one case in which the postoperative radiograph revealed that both the two distal locking nails slipped outside the nail keyhole; this patient underwent surgery again for re-locking. The average time of femoral distal locking was 12.31 minutes, and that of tibial distal locking was 10.63 minutes (slightly higher than the literature reports), which might probably be related to the surgeon’s proficiency. It is worth mentioning that when performing femoral INN, EN significantly reduced the distal locking time and X-ray irradiation time compared with the traditional method, and the difference was statistically significant (p=0.027 and p=0.001, respectively). However, the difference in tibial INN was not significant (p=0.347 and p=0.056); considering that the nail in the distal femur is deeper than the distal tibia, distal locking is more difficult and the use of the traditional distal gunsight would much more easily result in deviation. Thus, compared with the traditional method, EN would be more effective, and with faster and more accurate locking, which could significantly shorten the operation time and reduce the intraoperative X-ray irradiation time. There was one case of unsuccessful locking, and it was considered to be because the drill slid when locating the drill, which deviated off the track, so both the two locking nails slipped outside the keyhole. Therefore, although this system is very reliable, the guiding pin should still be applied for the examination, and fluoroscopy should be performed for the confirmation to prevent the locking errors caused by various factors.

Although EN-INN could improve the accuracy of distal locking, reduce surgical trauma, shorten the operative time, reduce blood loss and surgical complications, and reduce the X-ray radiation exposure of patients and medical staff, it is still relatively expensive, currently; and still needs time to be more widely used. During surgery, the incision should completely separate the fascia and muscles, so that targeting could be close to the bone surface; after inserting the casing tube, the crenate surface should closely adhere to the bone surface, and reduce sliding. The drill should be sharp, and force could be applied along the casing tube when drilling, namely milling into the bone skin instead of pushing into the skin, and the drill should not slip on the bone surface. After drilling, the guiding pin could be inserted for the examination, and fluoroscopic confirmation could be performed to avoid locking errors. In this study, the limited case numbers in each group might have a certain influence on the results; thus, further clinical data are still needed to confirm our results.

**CONCLUSION**

Compared with the ordinary IN, EN-INN exhibited significant advantages in distal locking time and one-step locking success rate, especially for femoral diaphyseal fractures. Therefore, EN-INN is an effective method for solving the difficulties of distal locking. It could also reduce the operation time, reduce the X-ray radiation exposure of surgeons, is easy to learn, and should be widely applied.

**REFERENCES**


