

Comparison of free-hand fluoroscopic guidance and electromagnetic navigation in distal locking of tibia intramedullary nails

Yinsheng Wang, MM, Bing Han, MM, Zhigang Shi, MM, Yu Fu, MM, Yong Ye, MD, Juehua Jing, MD, Jun Li, MD*

Abstract

Background It is challenges for surgeon to position the distal locking screw of a tibia intramedullary nail. The traditional free-hand (FH) technique is related to the proficiency of surgeons and has a long learning curve. Furthermore, the radiation dose and the accuracy of screw placement should be taken into account. The new technology, the electromagnetic navigation system (ET), which is a radiation-free way to locate the position of the drill bit. The purpose of our study is to evaluate the results of the ET for distal locking screw of a tibia intramedullary nail and to compare the effects with the FH technique.

Methods Eighty-nine cases of tibia diaphyseal fracture who needed to treat by intramedullary nails were analyzed retrospectively, and were divided into 2 groups. Patients in navigation group (n=54) were treated with intramedullary nail using the ET for distal locking, while other 35 patients using FH technique. Intraoperative fluoroscopy exposure times, screw insertion times, and healing times were recorded. The parameter was used for comparison in 2 groups.

Results The mean time of distal locking in the ET technique was significant less than that in the FH group (5.89 ± 2.02 minutes vs 12.26 ± 4.40 minutes) and the exposure time was reduced in ET group significantly (2.13 ± 0.73 seconds vs 19.09 ± 10.41 seconds). The healing time was proved to be coincident in FH group and ET group (15.34 ± 2.98w vs 16.06 ± 3.74w). The one-time success rate of distal locking nail operation was 100% in the navigation group, which was significantly higher than that in FH group ($P < .05$).

Conclusion Compared with the FH technique, the ET for distal locking of tibia intramedullary nail has the advantages of high efficiency and short locking time without radiation.

Abbreviations: ET = electromagnetic navigation system, FH = free-hand.

Keywords: electromagnetic navigation system, free-hand technique, intramedullary nailing, radiation exposure, tibia fracture

1. Introduction

Intramedullary nailing is one of the current standard treatment for diaphyseal long bone fractures of the lower limb, because it provides a dequate fracture stabilization and allows early mobile sation and return of function to the injured limb performing in a minimally invasive manner.^[1–6] However, this method also has disadvantages, including operational difficulty of the locking nail

and broken nails, especially, the distal locking still remains a challenging and sometimes frustrating part of intramedullary nailing. The free-hand (FH) under fluoroscopic guidance is usually performed in distal locking.^[7] Consequently, the patient and the surgeon must be suffered from a considerable amount of radiation in the whole surgical procedure.^[7–11] It is an undeniable fact that fluoroscopic guidance play a vital role in reduction of the fracture and the identification of the nail's entry point and its insertion.^[10]

In order to minimize the adverse effects of radiation on the patient and the staff and to insert the distal locking screws effectively, more and more novel technologies have been introduced, including hand-held targeting devices and radiolucent drill guides,^[12] laser-guided systems,^[13] computer-assisted systems,^[14] self-locking nailing systems.^[7,15] Each technique has its own advantages and disadvantages. Simple proximally mounted distal locking devices seem to fail because of lacking compensation for deformation of the nail caused by bending and rotational forces during insertion after its insertion to the tibia.^[10,16] Although computer-assisted method can achieve good results, the method is comparatively complicated and depends largely on the quality of the fluoroscopic image.^[7,10,17] For many surgeons, the FH technique which based on fluoroscopic remains the prevailing method for distal locking. However, the FH technique is related to the proficiency of surgeons and has a long learning curve. Furthermore, the radiation dose and the accuracy of screw placement should be taken into account. The new advanced technique should be developed to solve the problem.

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Department of Orthopaedics, The Second Affiliated hospital of Anhui Medical University, Hefei, Anhui, P.R. China.

* Correspondence: Jun Li, Department of Orthopaedics, The second affiliated Hospital of Anhui Medical University, 678 Furong, Hefei, 230601, P.R. China (e-mail: efylijunpaper@163.com).

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A new electromagnetic computer-assisted guidance system (Smith & Nephew, Inc., Memphis, TN) was designed to reduce radiation exposure and operation time during locking distal screws. There has, however, as yet been only a few preliminary clinical and radiological study comparing the difference between FH technique and electromagnetic computer-assisted guidance system for the distal locking of tibia nails. Therefore, the aim of this study was to compare the efficacy of the standard FH technique with a new electromagnetic navigation system (ET) for distal locking in terms of reliability, operation time, healing time, and radiation exposure.

2. Patients and methods

The patients with tibia fracture were enrolled into our study, who were subjected to intramedullary nails (Smith & Nephew, Inc., Memphis, TN) after receiving informed agreement at the Second Hospital of Anhui Medical University, from February 2010 to December 2015. The patients with an acute, displaced, extra-articular fracture of the distal tibia were eligible, while the patients with pathological or periprosthetic fractures and open fracture treated with external fixation were excluded (Fig. 1). The study has been approved by the ethics committee of our hospital. Patients were numbered and divided into 2 groups randomly,

based on the technique used for placing distal locking screws. Patients in group 1 have been performed 2 distal locking screws using the standard FH method, while group 2 using ET (SURESHOT). All distal locking procedures were performed by the same surgeon.

Both the electromagnetic navigation group and the FH group are definitely needed to place the main nail with intramedullary nail. Firstly, the position of guide needle of intramedullary nail is adjusted by the imaging system, so as to ensure the punching center is consistent with the medullary cavity. After that, move the guide needle through the near fracture section to fracture line, reset the proximal fracture block and distal end, and the guide needle should be inserted in alignment of direction of distal fracture block. Finally, through the front and back, and side position x-ray, it proves that the guide needle is inserted into the marrow cavity, and the main nail with intramedullary nail with appropriate length and diameter is inserted after reaming. For distal locking nail implantation, the operation method of 2 groups is as follows. For the group 1 performing the FH technique. The first step is to conform that the passage for each screw appears as a perfect circle in the center of the image when the image intensifier Compact was aligned with the 2 distal nail holes. Then, a skin incision was made through the soft tissue, down to the bone cortex. The guide pin is punched in the nail

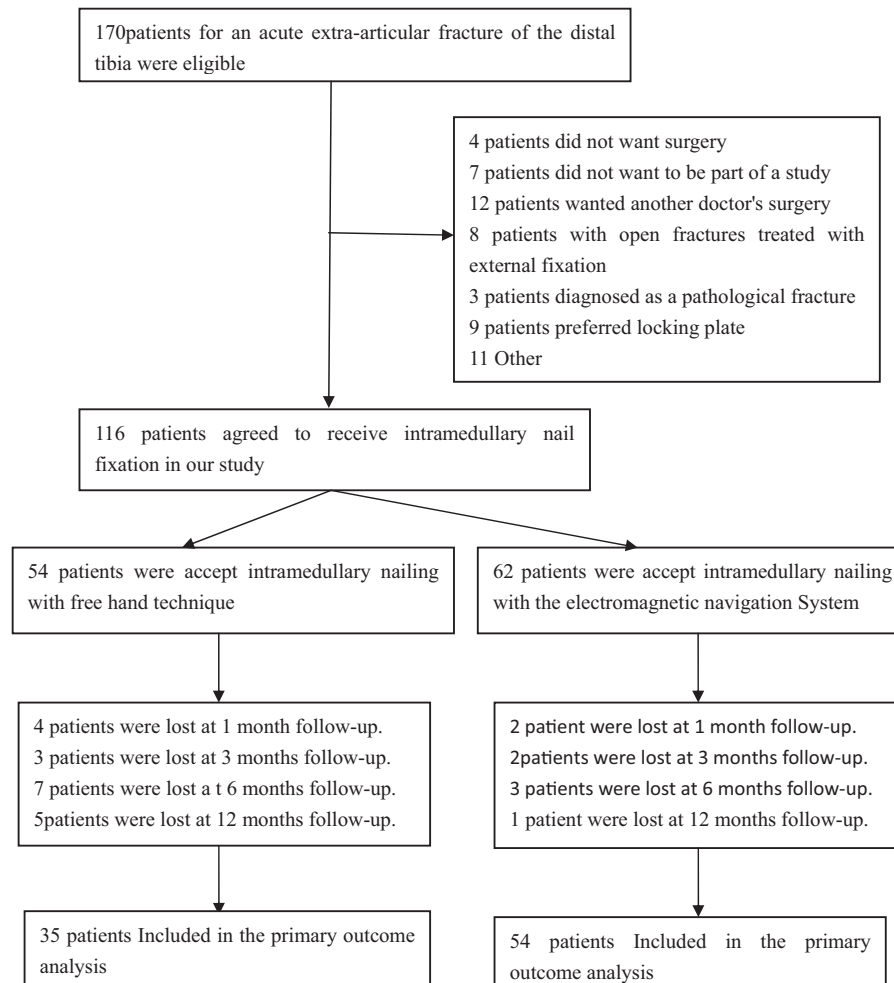


Figure 1. Flow of patients through the trial.

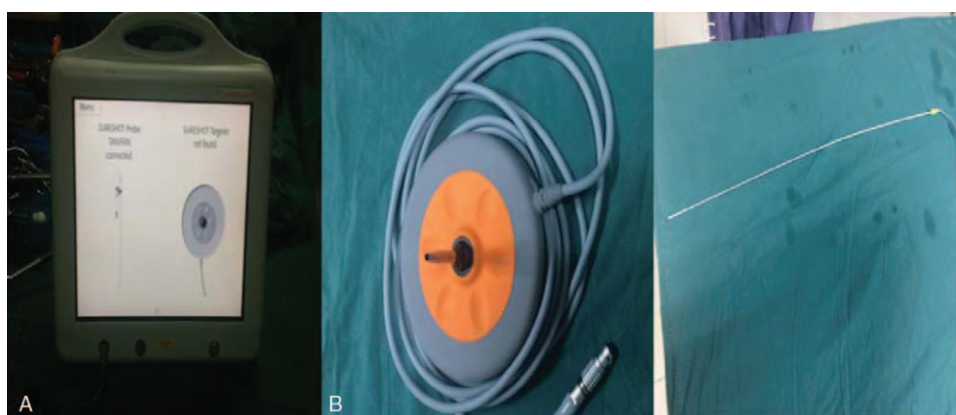


Figure 2. The electromagnetic navigation system. A: Computerized control unit. B: The electromagnetic field generator. C: The electromagnetic probe.

hole, ensure that the guide pin is at the center point of the lock hole by means of the imaging system. It means that the circle of drill and the distal locking hole were stayed on the same axis. Finally, the guide pin is pulled out and the appropriate locking screw is inserted to fix in the bone cortex. Another distal screw was performed in the same way. Once the operation is completed, it has to confirm the integrity and effectiveness of intramedullary nailing system through x-ray again. The total amount of exposure time should be recorded in the operation so as to facilitate the analysis of data in the next step.

The electromagnetic computer-assisted guidance system contains 3 main parts: a computerized control unit, a hand-held

“donut-shaped” targeter that produces a focused electromagnetic field, and a sensor probe (Fig. 2), inserted in the nail and mediating information to the control unit. A nail length adjusted probe was inserted into the proximal end of the nail according to the real-time information provided by electromagnetic tracking data. For the distal locking procedure, the surgeon performed a drill through a central slot in the electromagnetic field generator. The location of drill and locking holes was visualized on a computer monitor providing the real-time information for the surgeon during the locking procedure. The distal screws were inserted when the green and the red targeting circles were overlaps presented on the computer monitor (Fig. 3). Another

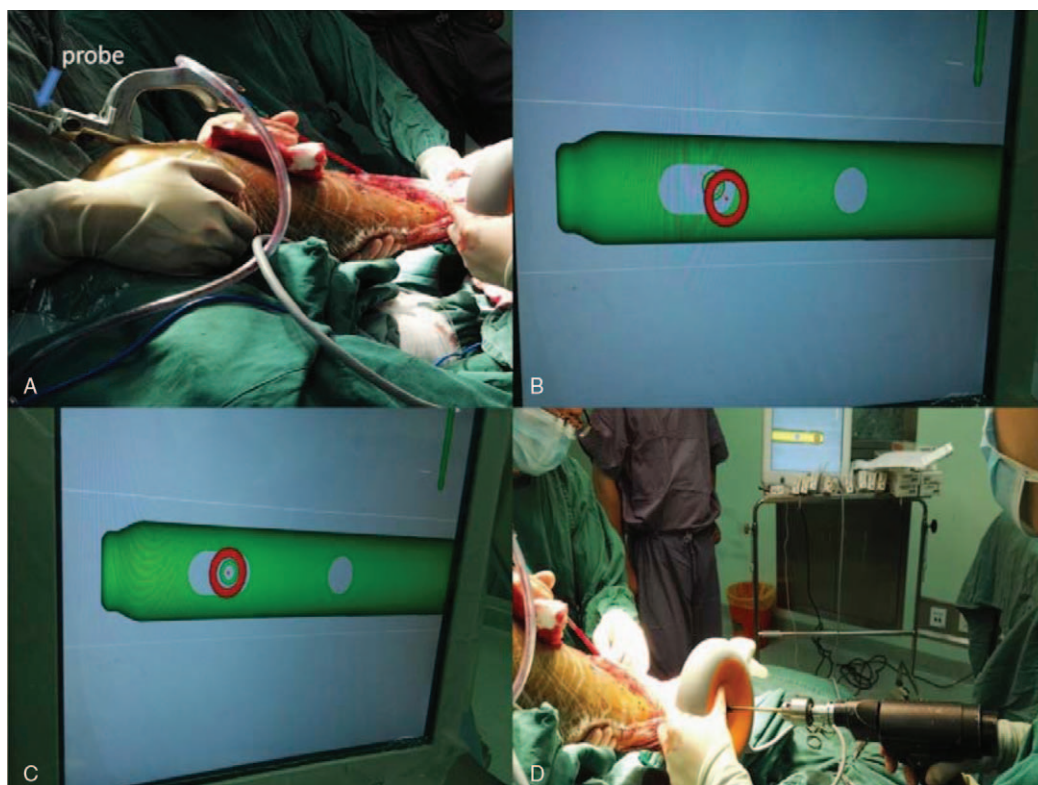


Figure 3. Distal locking using the electromagnetic navigation system (ET). (A) A nail length adjusted probe was inserted into the proximal end of the nail. (B) The location of drill and locking holes was visualized on the computer monitor (C) made the 2 circles overlap by adjusting the control unit (D). The distal screws were inserted when the green and the red targeting circles were overlaps presented on the computer monitor.

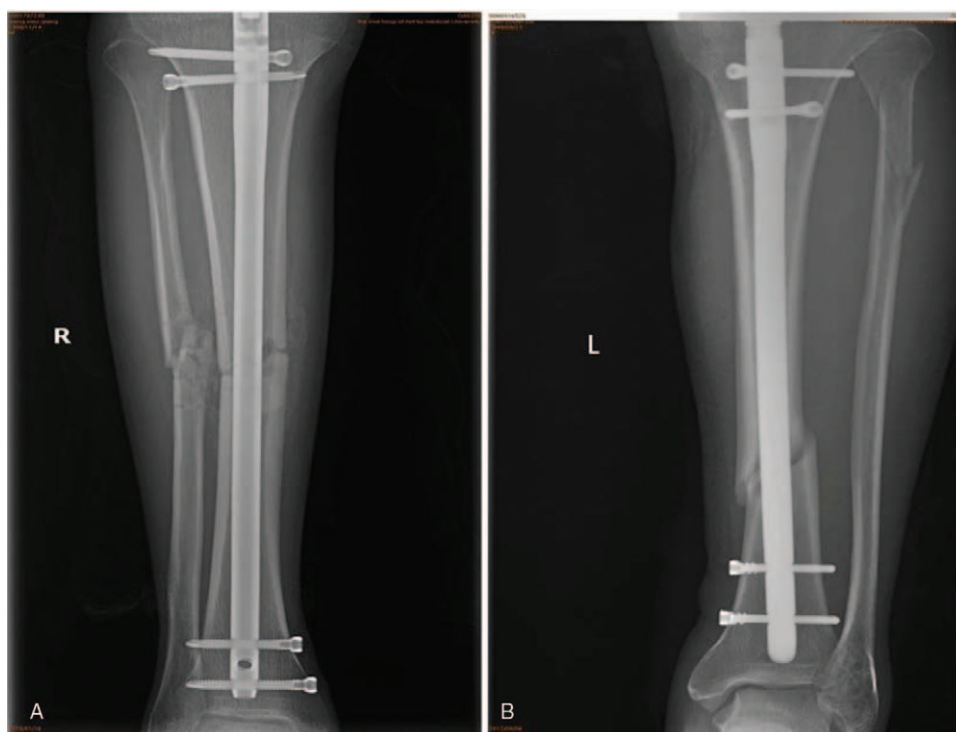


Figure 4. X-ray images of 2 patients with tibia fracture after treatment by 2 technology on the first day of postoperative. A: Treated with intramedullary nail using the ET for distal locking. B: Treated with intramedullary nail using FH technique. The internal fixation position both in 2 groups showed reliable. ET = electromagnetic navigation system, FH = free-hand.

distal screw was performed in the same way. Finally, the distal screw was confirmed whether or not the right positioning based on the fluoroscopy.

During the operation, the procedure time of locking the distal screw of the tibial nail (from the start of drilling to confirm the successful lock) and the number of successful one-time lock were recorded. The internal fixation position both in 2 groups showed reliable (Fig. 4). All patients were followed up at 1, 3, 6, and 12 months to evaluate the fracture healing (Fig. 5).

Statistical analysis was carried out using Statistical Package for Social Sciences (SPSS, Inc., Chicago, IL). Data including the number of successful one-time lock, distal locking time, and healing time were presented as mean \pm standard deviation for continuous variables. The *t* test or rank sum test were used for independent samples between groups. The number of successful one-time lock was expressed as percentage. Fisher exact test or chi-squared test was applied for the samples in each group. $P < .05$ was considered as significantly different.

3. Result

Eighty-nine patients who agreed to undergo intramedullary nails because of tibia diaphyseal fracture were enrolled the study. There were 35 case (26 men, 9 women) accept intramedullary nailing with FH technique, while 54 case (40 men, 14 women) undertaken intramedullary nailing with the ET. The mean age of the FH group was 39.40 (rSD, 16.50), and ET group was 41.52 (SD, 13.05), respectively. The mechanism of injury about these patients, 57.30% traffic accident (51/89), 23.60% traumatic injury (21/89), 6.74% falling from the height (6/89), and 12.36% any other accident (11/89). According to the AO classification,

our research objects were classified type 42-A (65), type 42-B (14), type 42-C (1c0). Of these, there were 32 open fractures and all were categorized into grade I on the basis of Gustilo Classification. There was no statistically significant difference in age, grade, injury mechanism, and open fractures. According to the results of AO classification, the fracture type of electromagnetic navigation group is more serious than that of the FH group, and therefore the difference is of significance in terms of statistics (Table 1).

The mean time of distal locking was 12.26 ± 4.40 minutes in the FH technique, whereas the time was 5.89 ± 2.02 minutes in ET group. The exposure time for the FH group was 19.09 ± 10.41 seconds, while 2.13 ± 0.73 seconds for ET group, ET group was obviously shorter than FH group. The fracture healing time in electromagnetic navigation group was slightly shorter than that in the FH group ($15.34 \pm 2.98w$ vs $16.06 \pm 3.74w$), the difference was not statistically significantly ($P = .34$). The mean time of distal locking for placing of the distal screws was statistically significantly shorter in ET group compared with FH group ($P < .05$) (Table 2).

The one-time success rate was 100% in the ET group and 34.3% in the FH group, with statistically significant difference ($P < .05$) (Table 2).

4. Discussion

The FH technique is still the most common application in distal locking of intramedullary nailing, although the technique is associated with high radiation exposure to the surgeon and the patient and requires a long learning curve. However, all orthopedic surgeons and patients must confront with the

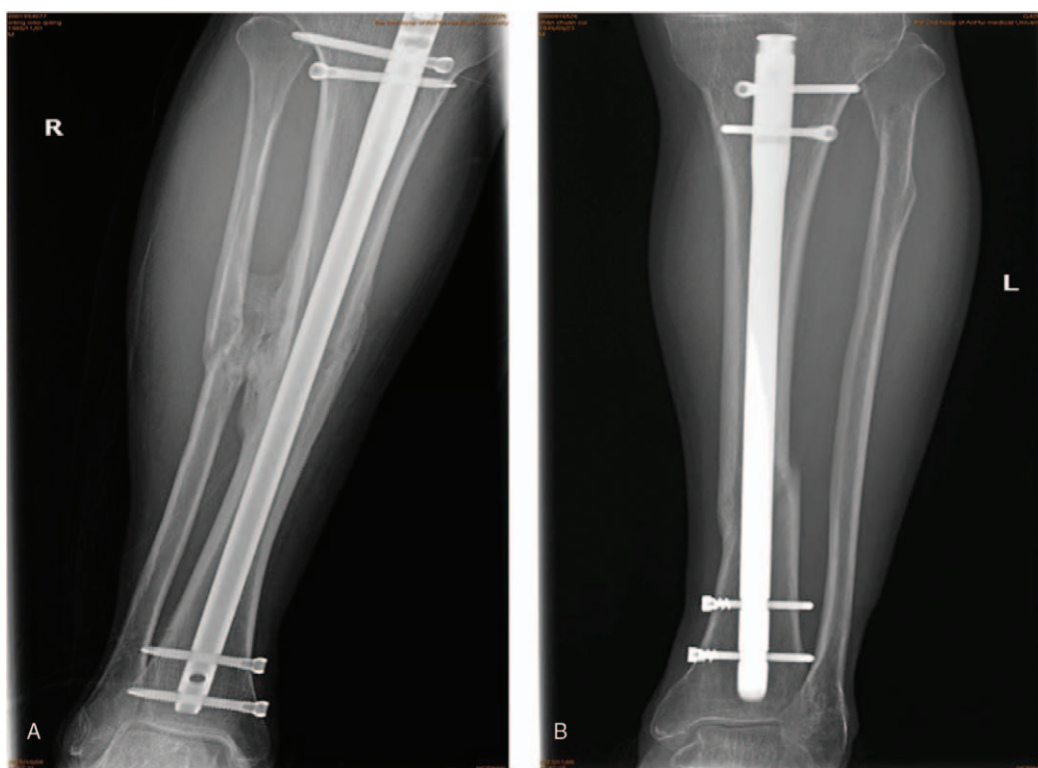


Figure 5. X-ray images of 2 patients with tibia fracture after treatment by 2 technologies on 6 months of postoperative. A: Treated with intramedullary nail using the ET for distal locking. B: Treated with intramedullary nail using FH technique. All patients were followed up at 1, 3, 6, and 12 months to evaluate the fracture healing. ET=electromagnetic navigation system, FH=free-hand.

radiation exposure in the procedure during operations. The critical values of the effective dose were 20, averaged over 5 years, with no more than 50mSv in any 1 year for occupational exposure based on the recommendations of the International Commission on Radiological Protection (ICRP).^[18] Mehlman reported that surgeons working within 24 in. of the fluoroscopy beam receive significant radiation exposure to their unprotected eyes, thyroid, and hands. Of course, the people in the operating room will be within this distance and are exposed to radiation. Kirousis et al^[19] have reported that the primary operator should not exceed the dose constraint of 10mSv per year when distal screws were inserted with FH technique under fluoroscopic

guidance. Although recent studies have shown that radiation exposure will do harm to people’s health, their results cannot be ignored. It is very necessary to minimize the risks of radiation exposure when locking screws.

In our study, we found that the ET achieve a positive result with less radiation dose compared with the FH technique. The exposure time for FH group was 26.8±13.3seconds and 2.2±1.1seconds for ET group. The fluoroscopy was used to identify the location of the distal screw and made sure the alignment between the drill and the nail holes in the procedure of intramedullary nailing. The outcome was supported by a cadaveric study comparing the free hand technique and the electromagnetic field real-time system (EFRTS) published by Michael et al.^[11] The current study^[10,20,21] suggests that the principal advantage of the distally based the ET is its decreased radiation exposure required for placement of intramedullary nailing. In addition, the time of distal locking was significantly shorter in 2 groups. Mean distal locking time was 19.1 seconds in group 1 and 2.1 seconds in group 2. According to data analysis of AO classification, the fracture type of electromagnetic navigation

Table 1
The characteristic of patients in 2 groups.

Characteristic	Freehand group n=35	Electromagnetic group n=54	P-value
Age	39.40±16.50	41.52±13.05	.50
Sex n (%)			
F	26 (74%)	40 (74%)	.98
M	9 (26%)	14 (26%)	
Fracture type			
Closed	22	35	.99
Open	13	19	
Right tibia	14	25	.56
left tibia	21	29	
AO classification			
42-A	31	34	.03
42-B	2	12	
42-C	2	8	

Table 2
The results of 2 groups.

	Freehand group	Electromagnetic group	P-value
Healing time, w	15.34±2.98	16.06±3.74	.34
Exposure time, s	19.09±10.41	2.13±0.73	<.05
Distal locking time, min	12.26±4.40	5.89±2.02	<.05
One-time success rate	34.3% (12/35)	100% (54/54)	<.05

group is more serious than that of the FH group, but it has no effect on our results. On the contrary, for the time of operation and the time of exposure, electromagnetic navigation are shorter than that of the FH group, and therefore it further proves the high efficiency and effectiveness of ET as well.

More recent literatures^[22,23] have shown the simultaneously expanded feedback offered by the newer technology is likely to be an useful tool to teach surgical techniques and doesn't do harm to learning. Basing on this presupposition, Leroux et al^[24] conduct a trial to make a comparison on what will the fluoroscopy or electromagnetic (EM) guidance bring to the surgical new hands' studying about the locking of inserting screw in tibial nails. In the techniques of distal locking of screw insertion, the EM guidance is of great importance to the training of surgical new hands. This technology can raise the efficiency of finishing the task, use the radiation less and doesn't compromise the skill acquisition. Compared with the EM guidance, the surgeon using free hand technique will be exposure to the radiation inevitably. Blatter et al^[25] found the fluoroscopy has great influence on the aggregated amount of radiation exposure to orthopedic surgeons in the intramedullary fracture fixation. Consequently, the surgeon should take a long time to acquire experience with the use of intraoperative fluoroscopic techniques. Through our study, results show that the fluoroscopy was used to confirm there is nearly 2.1 seconds for radiating screw placement the majority of procedures performed with EM. What it suggests is that the EM guidance is of great significance to train new hands although the fluoroscopy is only used after training, with the added interests which can shorten the radiation being used for learning techniques.

Distal locking failure is another major problem in the process of distal locking. The deformation of nails inserted into the medullary canal should be responsible for failure in distal locking. Anastopoulos et al^[26] reported 5 cases were unsuccessful in 127 patients being treated with the use of a proximally mounted aiming device. From our data, there was no failure in both groups. It is possible that both of target devices can compensate the deformation of nails. The shift in the nail or patient position, or misdirection of the drill, was realized in real time and was easily corrected using the EFRTS. In addition, all locking procedures were performed by an experienced surgeon and completed quickly. The surgeon must pay attention to the metal objects in close to the targeter, although the EM device is accurate and easy to use as described in this study. According to the recent study^[27] large objects such as a metal leg holder or hammer will register on the machine, and a warning tone move metal objects will be clearly displayed on the computer screen. Smaller objects within 6in. of the targeter will distort the EM tracking and affect the accuracy of the device.

Although this study presented an outcome based on the fact persuasively, it still has several limitations. First, we did not design a control group to compare the learning curve between the distal locking procedures. In addition, the evaluation for the dose of exposure to radiation was ignored.

5. Conclusion

Compared with the free-hand technique, the ET for distal locking of tibia intramedullary nail has the advantages of high efficiency and short locking time without radiation. This new technology makes it easier to position the distal locking screw of tibia intramedullary nail, it is worthy to be advocated in clinical practice.

Author contributions

Conceptualization: Zhigang Shi, Yong Ye, Juehua Jing.

Funding acquisition: Jun Li.

Investigation: Juehua Jing.

Methodology: Jun Li.

Resources: Zhigang Shi, Juehua Jing, Jun Li.

Software: Bing Han, Yong Ye.

Supervision: Jun Li.

Validation: Yu Fu.

Writing – review and editing: Yinsheng Wang.

References

- [1] Rand JA, An KN, Chao EY, et al. A comparison of the effect of open intramedullary nailing and compression-plate fixation on fracture-site blood flow and fracture union. *J Bone Joint Surg Am* 1981;63:427–42.
- [2] Bone LB, Johnson KD. Treatment of tibial fractures by reaming and intramedullary nailing. *J Bone Joint Surg Am* 1986;68:877–87.
- [3] Alho A, Ekeland A, Stromsoe K, et al. Locked intramedullary nailing for displaced tibial shaft fractures. *J Bone Joint Surg Br* 1990;72:805–9.
- [4] Tornetta P3rd, Tiburzi D. The treatment of femoral shaft fractures using intramedullary interlocked nails with and without intramedullary reaming: a preliminary report. *J Orthop Trauma* 1997;11:89–92.
- [5] Rose DM, Smith TO, Nielsen D, et al. Expandable intramedullary nails in lower limb trauma: a systematic review of clinical and radiological outcomes. *Strategies Trauma Limb Reconstr* 2013;8:1–2.
- [6] Riedel MD, Gonzalez T, Kwon JY. How much is too much? A guide to appropriately bending ball tip guide wires when using intramedullary nails for the treatment of lower extremity long bone fractures. *Injury* 2016;47:954–7.
- [7] Whatling GM, Nokes LD. Literature review of current techniques for the insertion of distal screws into intramedullary locking nails. *Injury* 2006;37:109–19.
- [8] Levin PE, Schoen RWJr, Browner BD. Radiation exposure to the surgeon during closed interlocking intramedullary nailing. *J Bone Joint Surg Am* 1987;69:761–6.
- [9] Sanders R, Koval KJ, DiPasquale T, et al. Exposure of the orthopaedic surgeon to radiation. *J Bone Joint Surg Am* 1993;75:326–30.
- [10] Stathopoulos I, Karampinas P, Evangelopoulos DS, et al. Radiation-free distal locking of intramedullary nails: evaluation of a new electromagnetic computer-assisted guidance system. *Injury* 2013;44:872–5.
- [11] Hoffmann M, Schroder M, Lehmann W, et al. Next generation distal locking for intramedullary nails using an electromagnetic X-ray-radiation-free real-time navigation system. *J Trauma Acute Care Surg* 2012;73:243–8.
- [12] Goodall JD. An image intensifier laser guidance system for the distal locking of an intramedullary nail. *Injury* 1991;22:339.
- [13] Stedfeldt HW, Jurowich B, Baumer F, et al. [Laser focusing device for the distal locking of intramedullary nails]. *Chirurg* 1990;61:469–72.
- [14] Malek S, Phillips R, Mohsen A, et al. Computer assisted orthopaedic surgical system for insertion of distal locking screws in intra-medullary nails: a valid and reliable navigation system. *Int J Med Robot* 2005;1:34–44.
- [15] Huang ZL, Yang HL, Xu JK, et al. Rotary self-locking intramedullary nail for long tubular bone fractures. *Chin Med J (Engl)* 2013;126:3874–8.
- [16] Krettek C, Konemann B, Miocla T, et al. In vitro and in vivo radiomorphometric analyses of distal screw hole position of the solid tibial nail following insertion. *Clin Biomech (Bristol, Avon)* 1997;12:198–200.
- [17] Suhm N, Messmer P, Zuna I, et al. Fluoroscopic guidance versus surgical navigation for distal locking of intramedullary implants. A prospective, controlled clinical study. *Injury* 2004;35:567–74.
- [18] Wrixon AD. New ICRP recommendations. *J Radiol Prot* 2008;28:161–8.
- [19] Kirousis G, Delis H, Megas P, et al. Dosimetry during intramedullary nailing of the tibia. *Acta Orthop* 2009;80:568–72.
- [20] Moreschini O, Petrucci V, Cannata R. Insertion of distal locking screws of tibial intramedullary nails: a comparison between the free-hand technique and the SURESHOT Distal Targeting System. *Injury* 2014;45:405–7.
- [21] Langfitt MK, Halvorson JJ, Scott AT, et al. Distal locking using an electromagnetic field-guided computer-based real-time system for orthopaedic trauma patients. *J Orthop Trauma* 2013;27:367–72.

- [22] Gofton W, Dubrowski A, Tabloie F, et al. The effect of computer navigation on trainee learning of surgical skills. *J Bone Joint Surg Am* 2007;89:2819–27.
- [23] Nousiainen MT, Omoto DM, Zingg PO, et al. Training femoral neck screw insertion skills to surgical trainees: computer-assisted surgery versus conventional fluoroscopic technique. *J Orthop Trauma* 2013;27:87–92.
- [24] Leroux T, Khoshbin A, Nousiainen MT. Training distal locking screw insertion skills to novice trainees: a comparison between fluoroscopic- and electromagnetic-guided techniques. *J Orthop Trauma* 2015;29:441–6.
- [25] Blattert TR, Fill UA, Kunz E, et al. Skill dependence of radiation exposure for the orthopaedic surgeon during interlocking nailing of long-bone shaft fractures: a clinical study. *Arch Orthop Trauma Surg* 2004;124:659–64.
- [26] Anastopoulos G, Ntagiopoulos PG, Chissas D, et al. Evaluation of the Stryker S2 IM nail distal targeting device for reduction of radiation exposure: a case series study. *Injury* 2008;39:1210–5.
- [27] Chan DS, Burris RB, Erdogan M, et al. The insertion of intramedullary nail locking screws without fluoroscopy: a faster and safer technique. *J Orthop Trauma* 2013;27:363–6.