CLINICAL ARTICLE

Reduced Surgical Time and Higher Accuracy of Distal Locking with the Electromagnetic Targeting System in Humeral Shaft Intramedullary Nailing

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Objective: To evaluate the efficacy of the electromagnetic distal targeting system in the treatment of humeral shaft fractures.

Methods: From January 2012 to December 2018, we retrospectively reviewed 60 patients with humeral shaft fractures treated by intramedullary nailing. Among 60 cases, 41 were men and 19 were women. The average age at surgery was 48.5 years (range, 21–81 years). We performed the same surgical procedure for all patients. According to the different distal locking technique used, all patients were divided into two groups. The standard fluoroscopic free-hand technique was used for Group FH, while the electromagnetic real-time targeting technique was used for Group EM. All procedures were performed by two senior surgeons. Overall surgical time, cases of complications, failure of distal locking, union time, and shoulder function assessment were recorded intraoperatively and during follow-up.

Results: Twenty-seven patients in Group FH and 33 patients in Group EM met the inclusion criteria. No significant difference was found in the demographic data of the two groups. The mean surgical time was 76.48 ± 10.73 min in Group FH and 65.61 ± 8.91 min in Group EM ($P < 0.05$), showing significant difference. Seven failures occurred in Group FH and two failures occurred in Group EM ($P < 0.05$). No relevant complications were noted. The average union time was 3.37 ± 0.49 months in Group FH and 3.39 ± 0.50 months in Group EM ($P = 0.855$). The mean follow-up was 14.30 ± 2.28 months in Group FH and 15.27 ± 2.83 months in Group EM ($P = 0.153$). The disabilities of the arm, shoulder and hand score (DASH) score, the range of motion (checked with the constant score), and the degree of functionality were, respectively, 21.52 ± 3.23, 27.04 ± 1.84, and 81.31% ± 3.88% in Group FH and 19.09 ± 2.40, 26.18 ± 1.70, and 77.97% ± 3.91% in Group EM ($P = 0.233$, 0.971, and 0.607).

Conclusion: The electromagnetic real-time targeting system reduced surgical time and improved accuracy, and there was no radiation exposure in the distal locking procedure for humeral shaft fractures.

Key words: Distal locking; Electromagnetic targeting system; Humeral shaft fracture; Intramedullary nail; Radiation exposure

Introduction

Humeral shaft fractures are commonly encountered by orthopaedic surgeons, accounting for 20% of humeral fractures and approximately 3% of all fractures[1,2]. These fractures commonly occur in low-energy ground-level falls in the elderly, but may also occur as a result of high-energy trauma, particularly in motor vehicle crashes. The therapeutic goal of humeral shaft fractures is to obtain a union with an admissible alignment and to regain the pre-injury function level. Both surgical and nonoperative treatment are widely used for humeral shaft fractures. In most cases, humeral shaft fractures can be treated with conservative

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methods such as functional bracing[3–7]. Operative management is recommended for open fractures, segmental fractures, high-energy fractures associated with neurovascular injuries, or cases of unacceptable alignment following functional bracing[8,9].

There is no concensus in the published literature on the optimal surgical treatment for humeral shaft fractures[10–13]. Clinically, intramedullary nailing and locking compression plates are used to achieve surgical stabilization of humeral shaft fractures. Open reduction and internal fixation with a plate and screws remains a standard method to surgically treat humeral shaft fractures[14–16]. Plate and screw fixation allows direct visualization, anatomic reduction, and interfragmentary compression of the fracture and facilitates identification, exploration, and protection of the radial nerve. In addition, neither the shoulder nor elbow joint is violated, thereby preserving function and motion. However, there are drawbacks associated with plate osteosynthesis, such as increased soft-tissue stripping, risk of radial nerve injury, risk of fracture at the end of the plate, and poor screw purchase in osteoporotic or comminuted bone[17].

Intramedullary nailing of long-bone fractures has been very effective in the lower extremities but historically has been limited in the upper extremity owing to concerns of shoulder and elbow dysfunction, nonunion, and reoperation. The theoretical benefits are significant and include smaller incisions, maintenance of fracture hematoma, and an implant that is load-sharing and can be used *ad libitum*[12]. Recent advances in techniques, implants, and surgeon skill, and improved study design have renewed interest in intramedullary nailing. Thus, the use of intramedullary nails has been introduced as an alternative to plate osteosynthesis.

However, distal locking remains a difficult and sometimes frustrating part of intramedullary nailing. Because this procedure is usually performed freehand (FH), guided under fluoroscopy, it can be time-consuming and expose the surgeon, the surgery personnel, and the patient to a considerable amount of radiation. In some cases, the radiation time needed for distal locking accounts for half of the total radiation time for intramedullary nailing. Fluoroscopy is of great importance for the whole operation and also facilitates the reduction of the fracture, the identification of the nail's entry point, and the insertion of distal locking screws. In addition, repeated drilling is likely to cause cortical deficit and even iatrogenic fractures in close proximity. Therefore, high accuracy is required for distal locking procedures. The risk of radiation exposure and the need to shorten the operation time in intramedullary nailing are concerns that have led to the development of various alternative distal locking methods.

Recently, a new distal targeting system (SURESHOT, Smith & Nephew, Memphis, TN, USA) was introduce that uses computerized electromagnetic field tracking technology (EM technology) to insert screws during the distal locking procedure. The system uses non-radiation technology to provide real-time 3D feedback of the drill bit position and orientation relative to the nail locking hole. Compared to the traditional "freehand" method, the advantages of this new technology are reduced surgery time and reduced radiation exposure[18–20]. Even though different authors have evaluated the application of this technique in femoral and tibial fractures, there is little data on its application in humeral shaft fractures. Therefore, it is not clear whether EM technology can effectively help surgeons when performing intramedullary nailing in humeral shaft fractures.

The purpose of this study is to evaluate the efficacy of the electromagnetic distal targeting system in the treatment of humeral shaft fractures. We hypothesize that: (i) compared with the standard fluoroscopy freehand techniques, the distal targeting system can reduce the overall surgical time; (ii) the distal targeting system has a higher accuracy in distal locking, with no radiation exposure; and (iii) the distal targeting system can reduce complications in the process of distal locking.

Patients and Methods

Inclusion and Exclusion Criteria

Inclusion Criteria

The inclusion criteria: (i) patients had been diagnosed with a humeral shaft fracture through medical history, symptoms, physical examination, and humeral anteroposterior and lateral radiography; (ii) patients were treated with intramedullary nailing; (iii) intraoperative and postoperative comparisons were made with items including overall surgical time, accuracy of distal locking, complications, and shoulder function; (iv) reduced surgical time and higher accuracy of distal locking should be expected; and (v) the study design was a retrospective study.

Exclusion Criteria

The exclusion criteria were as follows: (i) polytrauma; (ii) open fracture with severe soft tissue damage; (iii) pathological fractures; and (iv) neurovascular injury.

General information of participants

The study was approved by the institutional internal review board of the participating institution, and informed consent was obtained from all patients.

All patients who had humeral shaft fractures and were treated with intramedullary nails from January 2012 to December 2018 were screened. For each patient, demographic information was catalogued, including gender, age, cause of injury, side of the fracture, medical comorbidities, and associated complications.

Two independent reviewers inspected X-ray images and all fractures were classified on the basis of AO classification. A consensus was reached with discussion in cases of disagreement. The patients who met the inclusion criteria were divided into two groups according to the different methods of distal screw locking: Group FH and Group EM.

Surgical procedure

Incision and Exposure
We performed the same surgical procedure for all patients. Patients were placed in the supine position with the head rotated to the contralateral side. An incision of approximately 3 cm was made anterior to the acromion, the fibers of the deltoid were separated, and the tendon of the rotator cuff was exposed (Figs 1 and 2).

Reduction
Closed reduction was used to achieve the insertion of the guide pin (In some cases, a small 2-cm incision was done at the fracture site and a finger was used to reduce the fracture. This maneuver not only facilitated nail insertion into the distal part of the humerus but also ensured that no soft tissue and nerves were entrapped at the fracture site.

Reaming
We did not routinely ream, to avoid iatrogenic fracture or nerve entrapment, but when the intraoperative fluoroscopy measurement found an inadequate ratio between the nail and the humeral canal diameters (making nail insertion impossible), we reamed the humerus 1 mm more than the nail diameter. We inserted a suitably sized intramedullary nail. The nail was buried slightly in the humeral head to avoid subacromial friction.

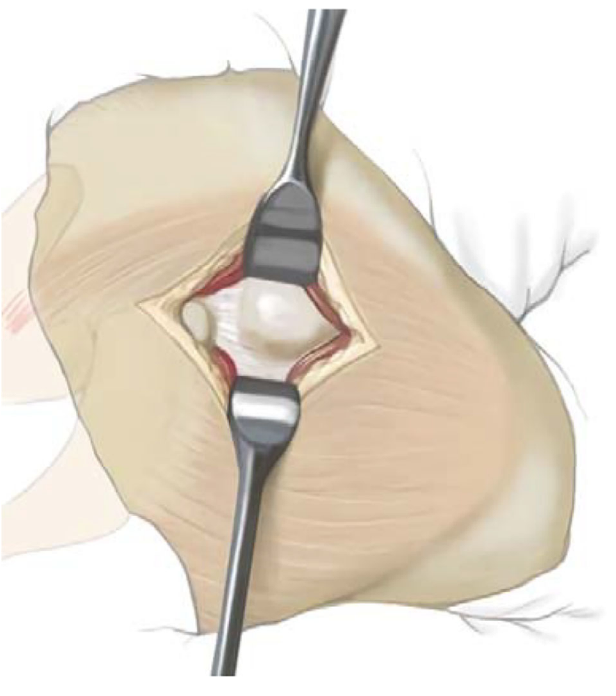

Fig. 1 Skin incision is performed at the anterior edge of the acromion and is directed towards the lateral and distal part. The deltoid muscle is subsequently released 1–2 cm from the anterior margin of the acromion.

Fig. 2 The correct entry portal is located posterior to the biceps tendon at the apex of the humeral head, which is situated 1–1.5 cm medial to the insertion of the supraspinatus tendon.

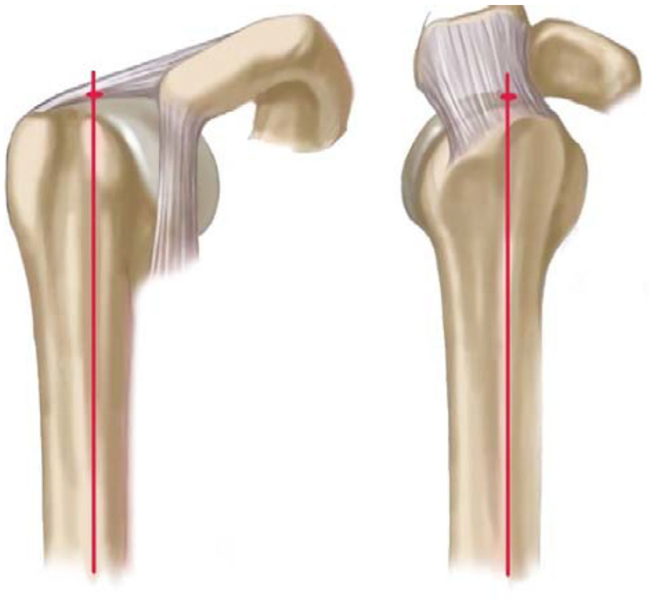

Fig. 3 The ideal entry point is in line with the anatomic axis of the humeral diaphysis in the anteroposterior and lateral views.

Fig. 4 The position and direction of the guide rod should be checked carefully in both planes and, if necessary, corrected by drilling machine.

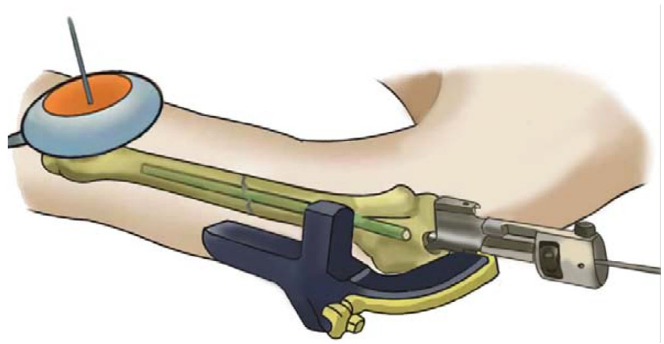

Fig. 5 The overall schematic diagram of the electromagnetic targeting system shows how it is used for the distal locking.

Fig. 6 The screen shows a trajectory line connecting the green and red circle indicating the direction for drilling and screw insertion.

Distal Locking

We preferred to use antero–posterior screws for distal interlocking, because they were safer, as shown by studies on cadavers[21]. An incision of 3 cm was needed to make the holes, exposing the bone under visual control to avoid radial nerve injury. Group FH had locking screws placed using the standard fluoroscopically assisted technique (perfect circles). Following the EM technique, the distal screw locking was made with the SURESHOT system (Fig. 5). The system created a virtual real-time image of the distal part of the nail. On the display unit, a trajectory line connecting the green and red circle appeared as the direction for drilling and screw insertion (Fig. 6). To verify the correct placement of the drill through the nail, the previously used guide pin was again passed through the nail up to the interlocking hole. If the drill was properly positioned, the guide pin could not pass distal to the interlocking hole and would generate a tactile sensation and an audible metallic tapping. Optimal screw insertion was eventually verified intraoperatively by means of anteroposterior and lateral X-ray views. For both groups, proximal locking screws were inserted with fixed mechanical guiding support.

Assessment of Surgical Outcome

We collected basic information for the patients, including overall surgical time, the accuracy of distal locking, complications, union time, and clinical assessment.

Overall Surgical Time

Overall surgical time refers to the time from skin incision to final suture. It was adopted to illustrate whether the electromagnetic targeting system could significantly reduce the overall surgical time.

Accuracy of Distal Locking

Any drill or screw misplacement was recorded. Failure of the technique was defined by the number of cases in which targeting the distal locking hole was impossible or the correct position of the screw was not obtained.

Complications
Intraoperative and postoperative complications were documented, including infection, iatrogenic extension of fractures, presence of fracture gap postoperatively, development of non-union and malunion, and iatrogenic nerve damage.

Union Time
Anteroposterior and lateral X-rays of the operated humerus were taken at each follow up to examine for evidence of healing. Radiographic healing was defined as the point at which callus bridged the former fracture site. Nonunion was defined as lack of radiographic healing progression over 3 consecutive months of radiographs along with patients' reported symptoms of pain or disability, or lack of cortical bridging at 6 months.

Clinical Assessment
Clinical assessment of the patient focused on shoulder functionality by means of the disabilities of the arm, shoulder and hand score (DASH) functional scoring system, modified by Beaton *et al.*[22] for subjective assessments. Scores between 0 and 20 were considered excellent, between 21 and 40 satisfactory, and between 41 and 100 poor. Range of motion was checked with the constant score[23] and the degree of functionality in the operated shoulder was compared with the score of the opposite side.

Statistical Analysis
All data were analyzed using the SPSS v. 22.0 software (Chicago, IL, USA). The collected data were presented as mean and standard deviation. The Student *t*-test was used to compare the data between the two groups. A *P*-value of <0.05 was considered statistically significant.

Results

Demographic Data
Twenty-seven patients in Group FH and 33 patients in Group EM met the inclusion criteria for this study. The mean age at time of injury was 48.30 ± 14.19 years in Group FH and 48.64 ± 15.66 years in Group EM ($P = 0.931$). There were 19 men and eight women in Group FH, and 22 men and 11 women in Group EM ($P = 0.759$). According to AO classification, 21 fractures were A, 32 were B, and seven were C. Patients in Group FH waited 2.56 ± 0.70 days for surgery, while patients in Group EM waited 2.58 ± 0.66 days ($P = 0.909$). The demographic data of the two groups showed no significant differences (Table 1).

Overall Surgical Time and Union Time
The average surgical time was 76.48 ± 10.73 min in Group FH and 65.61 ± 8.91 min in Group EM ($P < 0.05$). A significant reduction was noted between the two groups. The mean union time was 3.37 ± 0.49 months in Group FH and 3.39 ± 0.50 months in Group EM ($P = 0.855$) (Table 2).

Accuracy of Distal Locking
All the patients in both groups were treated with Trigen Nail (Smith & Nephew) with two distal locking screws inserted (Fig. 7). Distal locking was accomplished successfully in most procedures. Failure of distal locking was found in two patients in Group EM. Therefore, subsequent conversion to the standard freehand fluoroscopic technique was undertaken. Seven failures occurred in Group FH. In four cases, while aiming for the distal hole, the drill went out anterior to the nail because of secondary intradrilling malalignment. In three cases, the misguided locking screw engaged the nail, causing a fissure fracture on the contralateral cortex. After readjusting the direction of the drill bit, the secondary drilling became wider, thus avoiding the correct tightening of the screw. Therefore, a locking hole was formed. The accuracy of distal locking was higher in Group EM than in Group FH ($P < 0.05$) (Table 2).

Disabilities of the Arm, Shoulder and Hand Score
Shoulder functionality was observed, with a mean DASH score of 21.52 ± 3.23 in Group FH and 19.09 ± 2.40 in Group EM ($P = 0.233$). No significant difference was noted between the two groups (Table 2).

Table 1 Demographic data

Characteristics	Group FH	Group EM	*P*-values
Age (year)	48.30 ± 14.19	48.64 ± 15.66	0.931
Gender (M/F)	19/8	22/11	0.759
AO classification (A/B/C)	9/14/4	12/18/3	0.788
Wait for surgery (day)	2.56 ± 0.70	2.58 ± 0.66	0.909
Follow-up (month)	14.30 ± 2.28	15.27 ± 2.83	0.153

The average (±standard deviation) age, wait for surgery, follow up, proportion of gender, and fracture types showed no statistical difference between the two groups ($P > 0.05$)

Table 2 The clinical outcomes

Characteristics	Group FH	Group EM	*P*-values
Surgical time (min)	76.48 ± 10.73	65.61 ± 8.91	<0.05
Failure of locking	7/54	2/66	<0.05
Union time (month)	3.37 ± 0.49	3.39 ± 0.50	0.855
DASH score	21.52 ± 3.23	19.09 ± 2.40	0.233
Range of motion (0–40)	27.04 ± 1.84	26.18 ± 1.70	0.971
Degree of functionality (%)	81.31 ± 3.88	77.97 ± 3.91	0.607

DASH score, Disabilities of the Arm, Shoulder and Hand score.; Union time, DASH score, range of motion (constant score), and degree of functionality showed no statistical difference between the two groups ($P > 0.05$). The mean surgical time and failure of locking showed statistical differences between the two groups

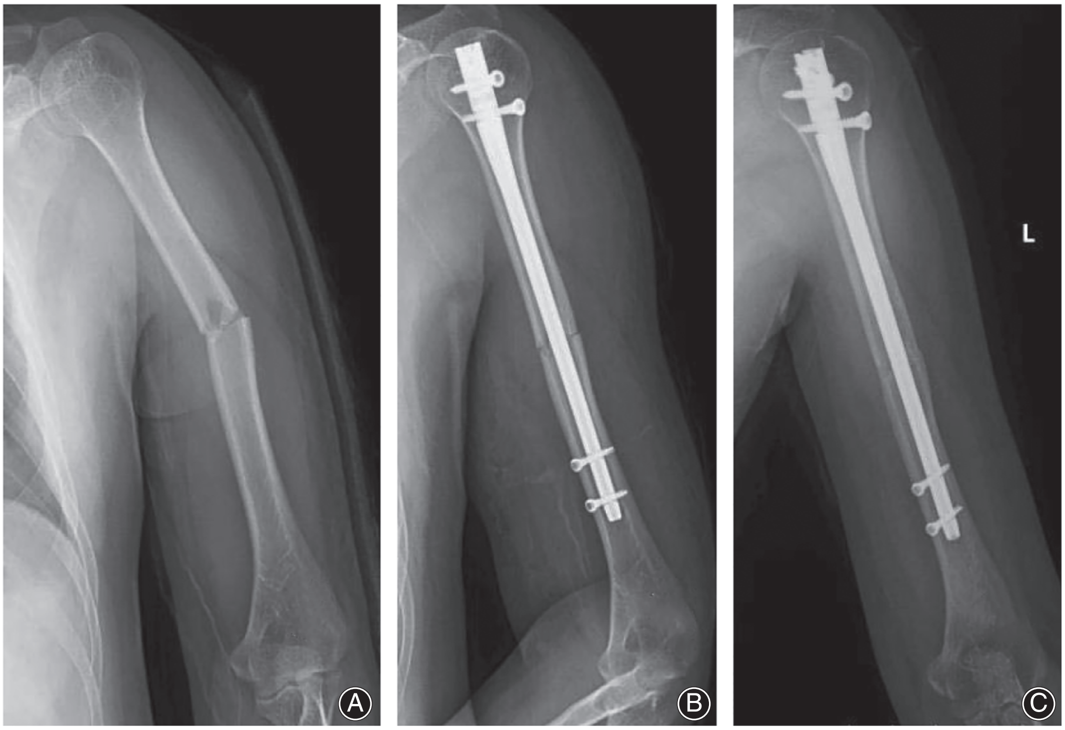

Fig. 7 A patient with a humeral shaft fracture fixed with intramedullary nails is presented. (A) Preoperative anteroposterior projection of the humerus. (B) Postoperative anteroposterior view. (C) Anteroposterior projection 3 months postoperatively.

Shoulder Range of Motion and the Degree of Functionality

The shoulder range of motion on the operated side reached a mean, assessed by the constant score of 27.04 ± 1.84 in Group FH and 26.18 ± 1.70 in Group EM ($P = 0.971$). The degree of functionality was 81.31% ± 3.88% in Group FH and 77.97% ± 3.91% in Group EM ($P = 0.607$) (Table 2).

Complications

No complications related to the intramedullary nailing, such as iatrogenic fractures, nail rupture, separating displacement, or poor alignment, were noted in either group.

Discussion

Our results showed that the EM distal targeting system could significantly reduce the overall surgical time of the intramedullary nailing procedure for humeral shaft fractures and it showed higher accuracy.

Indispensable High Accuracy in Distal Locking Procedure

Difficulties in distal locking of intramedullary nails are a common complaint among orthopaedic surgeons, especially at the beginning of their professional careers. This can be ascribed to the interlocking process itself and its technical details. Regardless of the targeting method chosen, distal interlocking in diaphyseal areas of long bones must be performed meticulously. Unnecessary holes in the cortex should be avoided to prevent late stress fractures. Blind percutaneous clamping of the lower extremity during distal screw insertion is not safe for the humerus. Even with radiolucent drill bits, it remains difficult to target a hidden hole inside the medullary cavity. Yet distal locking of the humerus is accompanied by some problems. The lateral view of the humerus is not easily obtained, the locking hole is narrow, the lateral surface of the humerus is "slippery," and the danger of injury to the radial nerve and other vulnerable structures lurks[24–26]. When the drill is aligned with the hole or pressure is applied during drilling, involuntary movements can cause deviation in the distal locking[27, 28]. In this critical time frame, when most complications occur[29, 30], continuous real-time fluoroscopy exposes both the patient and the surgeon to a certain dose of ionizing radiation.

One of the main advantages of the EM technique is the feature of ionizing radiation-free real-time monitoring, making incorrect position or drill slippage detection possible. Moreover, the possibility of drilling correction at any time reduces complications within this critical time frame.

Reduced Overall Surgical Time

Hoffmann *et al.*[31] reported a high reliability of the EM technique in a study on tibial fractures. In addition, compared to the FH technique, fewer complications and reduced surgical time were noted in the EM group with no radiation exposure. A meta-analysis by Zhu *et al.*[20] found that in distal locking for tibial or femoral shaft fractures, the EM technique could significantly reduce the distal locking time and the overall surgical time. Although many studies focus on the use of EM in lower extremity fractures, there are few studies that compare the distal locking technique with intramedullary humeral nailing[32–34]. Camarda *et al.*[35] reported that use of the EM technique was not able to significantly reduce the overall surgical time of the humeral shaft fixation. The finding was not in accordance with other studies on tibial or femoral fractures. According to Persiani *et al.*[36], a significant reduction in the surgical time for the correct positioning of the distal locking screw was noted in an EM group, which was consistent with our results.

No Radiation Exposure

Ionizing radiation has no safe threshold of exposure below, which it does not bring about adverse effects[37, 38]. Moreover, the long-term effects of radiation exposure are unknown[39]. Therefore, every effort must be taken to minimize radiation exposure[37, 39]. During intramedullary nailing surgeries, the distal locking is the phase with the higher percentage of exposure to radiation, reaching as much as 50%[39]. The EM technique has intrinsic radiation-free advantages over the FH technique. In our study, there was no radiation exposure during screw insertion. As no complications occurred using the EM technique for distal locking, no interim fluoroscopic controls were needed. The EM-navigated procedure in our study was accomplished without using X-ray radiation. Single or multiple fluoroscopy machines were not used over the 6-year period and the parameters were not consistent. As the radiation dose is closely related to machine performance and parameters, the same piece of equipment must be used for consistency, and regularly tested.

Limitations

The present study has many limitations. First, it was a retrospective study, which had a lower level of evidence than a randomized, prospective study would. Second, the sample size was relatively small, resulting in it having relatively less external validity. In addition, larger and high-quality studies are still needed to evaluate the effectiveness of the techniques.

Conclusion

The standard FH technique and the EM technique are effective procedures for distal locking in humeral shaft fractures. Compared to the FH technique, the EM technique demonstrates reduced surgical time and higher accuracy with no radiation exposure in the distal locking procedure.

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