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Comparison of Tibial Intramedullary Nailing Guided by Digital Technology Versus Conventional Method: A Prospective Study

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Background: This prospective study aimed to compare clinical effects of intramedullary nailing guided by digital and conventional technologies in treatment of tibial fractures.

Material/Methods: Thirty-two patients (mean age 43 years, 18 males and 14 females) who were treated for tibial fractures from October 2010 to October 2012 were enrolled. They were sequentially randomized to receive intramedullary nailing guided by either digital technology (digital group, n=16) or conventional technology (conventional group, n=16). The operation time, fluoroscopy times, fracture healing time, distance between the actual and planned insertion point, postoperative lower limb alignment, and functional recovery were recorded for all patients.

Results: The mean operation time in the digital group was 43.1±6.2 min compared with 48.7±8.3 min for the conventional technology (P=0.039). The fluoroscopy times and distance between the actual and planned insertion point were significantly lower in the digital group than in the conventional group (both P<0.001). The accuracy rate of the insertion point was 99.12% by digital technology. No difference was found in fracture healing time and good postoperative lower limb alignment between the digital and conventional groups (P=0.083 and P=0.310), as well as the effective rate (100% *vs.* 87.50%, P=0.144).

Conclusions: Intramedullary nailing guided by digital technology has many advantages in treatment of tibial fractures compared to conventional technology, including shorter operation time, reduced fluoroscopy times, and decreased distance between the actual and planned insertion point of the intramedullary nail.

MeSH Keywords: **Fracture Fixation, Intramedullary • Recovery of Function • Tibial Fractures**

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Background

Tibial fractures are serious and clinically common long-bone fractures, due to the potential of malunion, nonunion, long-term dysfunction, and open injury [1,2]. It is usually caused by high-energy trauma, such as traffic accidents and falling from a height. Various therapeutic methods have been developed for tibial fractures, such as open reduction and external fixation, plate fixation, or intramedullary nail fixation [3]. Among those treatments, intramedullary nailing has often been considered as the standard treatment of choice for closed and open diaphyseal tibial fractures (such as displaced/unstable tibial shaft fractures) because of its high mechanical stability and minimal invasion, as well as superior outcomes in closed stable or unstable fractures [4–8].

With the wide application of intramedullary nailing, selection of the most appropriate nail entry point is a challenging task [9] because some postoperative complications may result from the inappropriate insertion point or length and diameter of the intramedullary nail [10,11], such as a valgus or varus deformity, together with the medial or lateral shift of distal fragment [12], and even iatrogenic fractures. A previous study showed that cone-beam computed tomography (CBCT) can accurately locate intramedullary nail holes, and can be applied to guide a surgeon in the management of tibia and femur fractures [13]. Three-dimensional analysis for the intramedullary canal axis of the tibia indicated that the appropriate insertion point for a tibial nail was the slightly medial aspect of the lateral tibial spine [14]. Therefore, digital technology has been used to guide intramedullary nailing in the clinical treatment of tibial fractures.

Furthermore, computed tomography (CT) with three-dimensional reconstruction is increasingly available; it can provide a better understanding of the fracture pattern if this is unclear with plain radiographs, and can be used to plan operative procedures [15]. The current study aimed to prospectively evaluate the efficacy of intramedullary nailing guided by digital technology (CT with three-dimensional reconstruction) versus the conventional method for tibial fractures with respect to operative procedure and functional recovery.

Table 1. The demographic and clinical data of patients with tibial fractures.

Parameter	Conventional group (n=16)	Digital group (n=16)	*P*-value
Age, years (range)	42±2.5 (19–65)	43±3.1 (22–69)	0.323
Gender			>0.999
Male, n (%)	9 (56.3)	9 (56.3)	
Female, n (%)	7 (43.7)	7 (43.7)	
Causes of fracture, n (%)			0.909
Road traffic accidents	11 (68.75)	10 (62.5)	
Falling down	3 (18.75)	4 (25)	
Other accidents	2 (12.5)	2 (12.5)	
AO classification, n (%)			0.997
A2	3 (18.75)	3 (18.75)	
A3	2 (12.5)	3 (18.75)	
B1	4 (25)	4 (25)	
B2	5 (31.25)	4 (25)	
C1	1 (6.25)	1 (6.25)	
C2	1 (6.25)	1 (6.25)	
Affected side, n (%)			0.723
Left	9 (56.3)	8 (50)	
Right	7 (43.7)	8 (50)	

$P<0.05$ was considered statistically significant.

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Figure 1. High-speed multislice computed tomography (CT) images of the affected and healthy tibias.

Material and Methods

Patient

All the procedures were approved by the Institutional Review Board and informed consent was obtained from each patient or candidate. This prospective randomized controlled trial enrolled a total of 32 patients (mean age 43 years, 18 males and 14 females) who were treated for unilateral tibial fractures in our department from October 2010 to October 2012. The inclusion criteria included: age range of 18–70 years; unilateral tibial fractures with no multiple injury; and closed reduction should be performed. Anyone who had open fractures or bilateral tibial fractures was excluded. Patients who meet the eligibility criteria were sequentially randomized to 2 groups to receive intramedullary nailing guided by either digital technology (digital group, n=16) or conventional technology (conventional group, n=16). The demographic and clinical data are shown in Table 1, including causes of fracture, the fracture types according to Association for Osteosynthesis/Orthopaedic Trauma Association (AO/OTA) classification [16], and affected side. Briefly, there were 21 cases of fractures caused by traffic accidents, 7 cases by falling, and 4 cases caused by other accidents. The fractures included: A2 (6 cases), A3 (5 cases), B1 (8 cases), B2 (9 cases), C1 (2 cases), and C2 (2 cases). Simple fractures were defined as types A2 and A3, wedge fractures were defined as type B1 and B2, and complex fractures were defined as type C1 and C2 [17].

Preoperative preparation

Emergency surgery was performed on 15 patients, including 7 patients in the digital group and 8 cases in the conventional group. The other 17 patients underwent surgery at 3 d to 7 d (average 4 d) after the accidents. For the digital group, the patients' bilateral tibias were firstly scanned *in situ* by high-speed multislice CT scanners (slice thickness: 1.0–1.5 mm; radiation dose: 3.72 mSv, Figure 1) preoperatively. Then, the original image data in Dicom format were analyzed by Mimics software (Materialise, Leuven, Belgium) and PACS system to establish three-dimensional images modeling (Figure 2). Thereafter, the length, diameter, and insertion point of the intramedullary nail were simulated at the imaging workstation for the guidance of the following surgery procedure. Thus, suitable intramedullary nail and appropriate insertion point were determined for individual patients in the digital group based on this digital technology, whereas conventional measurement of shank length was conducted for patients in conventional group.

Surgical procedures

All procedures were performed under lumbar or epidural anesthesia. Patients were placed in a supine position, and no tourniquet was used. The skin and subcutaneous tissue was incised at the inner margin of the patellar ligament between the inferior margin of the patella and tibial tubercle, and then the patellar

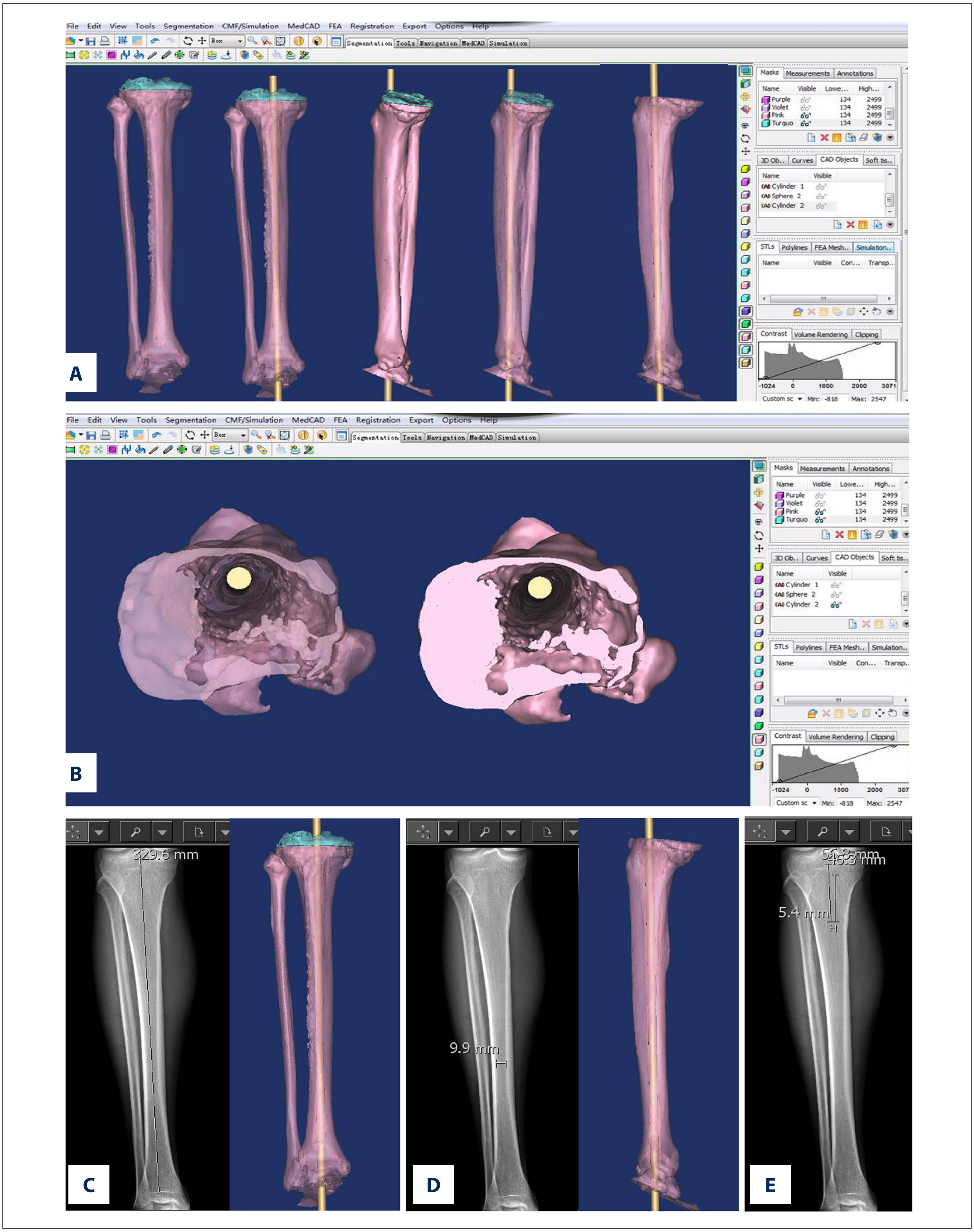

Figure 2. Preoperative simulation of intramedullary nailing at imaging workstation. (**A**) Simulated implantation of intramedullary nail; (**B**) Simulated insertion point of intramedullary nail; (**C**) Maximum length of intramedullary nail; (**D**) Maximum diameter of intramedullary nail; (**E**) The distance between the insertion point and the line from the tibial tubercle perpendicular to the tibial plateau.

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ligament was split and pulled outward. For the digital group, the insertion point was determined and exposed on the basis of the measured distance between the insertion point and the line from the tibial tubercle perpendicular to the tibial plateau at the imaging workstation. For the conventional group, the insertion point was determined at the anterior border of the tibial plateau along the juncture of the marrow cavity and the lateral tubercle of the intercondylar eminence (i.e., inward 0.5 cm along the line from the tibial tubercle vertical to the tibial plateau). Once the insertion point position had been accepted, a sharp cone was used to open a hole. Following closed reduction, an entry reamer was introduced to expand the medullary cavity, and the cancellous bone on the reamer was saved. Intramedullary nails were selected according to the simulation at the imaging workstation connected to the handle and connecting-rod devices in the digital group, whereas in the conventional group, intramedullary nails were chosen according to the preoperative measurement of shank length and the length of the guide pin entered into the medullary cavity. Thereafter, the Expert Tibial Nail (ETN; Synthes, Solothurn, Switzerland) was inserted into the medullary cavity, and the distal positioning rod and gunsight were installed. Intramedullary nail location and fracture reduction were reconfirmed using C-arm fluoroscopy. Two blocking screws were used to facilitate reduction and correct rotation displacement. If there was space between the ends of fractures, compression was applied by beating the intramedullary nail. If there was large separation among the bone block of fractures, limited open reduction was performed and the previously saved cancellous bone was implanted. Finally, 2 screws were implanted for the proximal fractures of the tibia.

Postoperative treatment and functional evaluation

Neither drainage nor external fixation was performed postoperatively. Patients were required to elevate the affected extremity higher than the heart and perform passive flexion and extension exercises of knee and ankle joints from the first day. All patients were followed up for fluoroscopy every month until fracture healing, and further rehabilitation training was instituted for individual patients according to their reduction and intraoperative fixation. The intraoperative and postoperative data of the conventional and digital group were recorded, including operation time (min), fluoroscopy times, fracture healing time (weeks), distance between the actual and planned insertion point (mm), and postoperative lower limb alignment. Functional recovery of all patients was categorized as excellent, good, fair, or poor based on Johner-Wruhs criteria [18,19] at 1 year after the operation, and both excellent and good were considered effective outcomes.

Statistical analyses

All the analyses were performed using SPSS 19.0 software (SPSS, Chicago, IL, USA). Quantitative data were presented as mean ± standard deviation (SD) and analyzed using the *t*-test. Qualitative data were presented as percentages and analyzed using the χ^2-test. A *P*-value <0.05 was considered statistically significant.

Results

As shown in Table 1, the age, sex, causes of fracture, AO/OTA classification, and affected side were all similar between both groups (*P*>0.05). The locked intramedullary nailing fixation was performed successfully in all patients, with a mean operation time of 47.1±8.3 min. The mean operation time in the digital group was 43.1±6.2 min compared with 48.7±8.3 min for the conventional technology (*P*=0.039). The fluoroscopy times and distance between the actual and planned insertion point were significantly lower in the digital group than the conventional group (5±0.4 times *vs.* 11±2.6 times and 1.4±0.2 mm *vs.* 4.3±0.7 mm, respectively, both *P*<0.001). The accuracy rate of the insertion point was 99.12% by digital technology.

During the mean follow-up period of 13 months (range, 8–15 months), all the patients attended clinical and radiographic return visits and obtained primary healing. The X-ray examinations showed that fracture healing appeared in all patients at an average of 16.1±1.2 weeks after surgery, with a range of 13–41 weeks. No difference was found in fracture healing time and good postoperative lower limb alignment between the 2 groups (*P*=0.083 and *P*=0.310, Table 2). According to the Johner-Wruhs score, 13 patients obtained excellent functional recovery and 3 cases obtained good recovery at 1 year after the operation in the digital group; whereas in the conventional group, the functional recovery was recognized as excellent in 9 cases, good in 5 cases, fair in 1 case, and poor in 1 case (Table 3). Accordingly, the effective (excellent and good) rate was 100% (16/16) in the digital group and 87.50% (14/16) in the conventional groups (*P*=0.144).

Discussion

The digital technology of three-dimensional reconstruction based on high-resolution spiral CT scan plays an important role in modern clinical application, especially in fracture diagnosis and characterization, and bone quality assessment [20–23]. This study was performed to evaluate the clinical significance of digital technology in guiding intramedullary nailing for the treatment of tibial fractures. The results showed shorter operation time, fewer fluoroscopy times, and shorter distance between the actual and planned nail insertion point in the digital group compared with the conventional group. Nevertheless, the effective rate of patient functional recovery was similar between the 2 groups.

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Table 2. The intraoperative and postoperative data of patients with tibial fractures.

Parameter	Conventional group (n=16)	Digital group (n=16)	*P*-value
Operation time, min	48.7±8.3	43.1±6.2	0.039
Fluoroscopy times	11±2.6	5±0.4	<0.001
Distance between the actual and planned insertion point, mm	4.3±0.7	1.4±0.2	<0.001
Fracture healing, weeks	16.7±2.4	15.5±1.1	0.083
Good postoperative lower limb alignment, n (%)	15 (93.8)	16 (100)	0.310

$P<0.05$ was considered statistically significant.

Table 3. The Johner-Wruh score of patients with tibial fractures at postoperative 1 year.

Data	Conventional group (n=16)				Digital group (n=16)			
	Excellent	Good	Fair	Poor	Excellent	Good	Fair	Poor
Non-union, osteomyelitis, amputation	16	0	0	0	16	0	0	0
Neurovascular injury	16	0	0	0	16	0	0	0
Deformity								
Varus/valgus	14	1	1	0	16	0	0	0
Anteversion/recurvation	14	2	0	0	16	0	0	0
Rotation	14	1	1	0	16	0	0	0
Shortening	16	0	0	0	16	0	0	0
Range of motion								
Knee joint	9	5	1	1	13	3	0	0
Ankle joint	11	4	1	0	14	2	0	0
Subtalar joint	11	4	1	0	14	2	0	0
Pain	10	4	1	1	13	3	0	0
Gait	10	4	1	1	14	2	0	0
Weight-bearing ability	10	4	1	1	14	2	0	0
Total	9	5	1	1	13	3	0	0

According to the Johner-Wruh scoring, the function recovery of patients was evaluated as excellent, good, fair or poor.

In recent years, flexible intramedullary nailing has become a preferred method for the treatment of tibial shaft fractures that require operative fixation [24–26]. The application and development of digital orthopedic technology might have great potential to facilitate intramedullary nailing in the treatment of tibial fractures [27–29]. Previously, CT with three-dimensional reconstruction was compared with knee radiographs and shown to be more sensitive for fractures (100% *vs.* 83% for radiographs), and to reflect the severity of tibial plateau fractures more accurately [30]. In this study, we preoperatively used high-speed multislice CT together with three-dimensional reconstruction to simulate and determine the size and insertion point of intramedullary nails, showing that the distance between the actual and planned insertion point were significantly lower using digital technology than conventional technology ($P<0.001$), with an accuracy rate of the insertion point of 99.12%. The higher accuracy rate achieved by digital technology might be also the reason for the reduced fluoroscopy times as well as the shorter operation time in the digital group. Despite no statically significant difference ($P=0.144$), patients in the digital group had improved functional recovery compared with the conventional cases, among whom 2

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patients had fair and poor outcome, respectively. Thus, the intramedullary nailing guided by digital technology appears to be efficient and convenient for clinical treatment of tibial fractures. However, considering the extra radiation dose and higher cost using digital technology, digital technology would be more beneficial for comminuted fractures for which proper intramedullary nail length cannot be calculated easily. In simple fractures, a contralateral side radiograph is usually sufficient to calculate the proper length of the nail and thickness.

Several limitations in our study must be addressed. First, the number of cases included in the study was small, which might be why we found no significant difference in the effective rate between the 2 groups. Second, the treatment effects of intramedullary nailing guided by digital technology in other different kinds of complex bone fractures, especially comminuted fractures, have not been evaluated. Thus, further prospective studies with larger numbers of patients and various kinds of complex bone fractures are required to compare the clinical outcomes of tibial fractures after locked intramedullary nailing guided by digital technology.

Conclusions

In conclusion, intramedullary nailing guided by digital technology showed many advantages in treatment of tibial fractures, including shorter operation time, reduced fluoroscopy times, and decreased distance between the actual and planned insertion point of the intramedullary nail. However, there was no difference in patient functional recovery between the digital and conventional groups.

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Conflict of interest

None declared.

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