



Comparison of intraoperative radiation exposure with and without use of distal targeting device: a randomized control study

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Abstract

Introduction When locking intramedullary nails, inserting the distal interlocking screw accurately and quickly with less radiation exposure is very important. The purpose of this randomized control study was to compare radiation exposure and accuracy of distal locking screws between free-hand fluoroscopic guidance and the use of a distal targeting system (DTS).

Materials and methods Inclusion criteria of this study were patients older than 60 years who need an intramedullary nailing due to unstable intertrochanteric and subtrochanteric fracture. The primary outcome was the attempt numbers of image intensifier during the insertion of distal locking screws. Secondary outcomes were operative time and angles between distal locking screws and nail.

Results A total of 36 patients participated in the study. Eighteen patients using free-hand fluoroscopic guidance were assigned to Group I while 18 patients using DTS were assigned to Group II. The number of attempts of image intensifier during distal screw insertion (57.3 ± 31.42 vs. 11.5 ± 7.41 , $p < 0.001$), ratio of attempt number for distal screws to the total attempts (0.33 ± 0.21 vs. 0.12 ± 0.08 , $p = 0.001$), the number of hand exposure to image intensifier directly (75.0 ± 29.55 vs. 13.5 ± 19.07 , $p < 0.001$), and the time of radiation exposure during distal screws insertion (42.57 ± 2.42 s vs. 12.72 ± 8.10 s, $p < 0.001$) were significantly lower in Group II compared to those in Group I. And, operation time ($96.3 \text{ min} \pm 18.94$ vs. $76.1 \text{ min} \pm 14.10$, $p < 0.001$) was also statistically significantly lower in Group II. Both distal locking screws were significantly closer to perpendicular direction to the nail in Group II.

Conclusion The attempt number of image intensifier during the insertion of two distal locking screws was significantly reduced with DTS compared with that with free hand fluoroscopic guidance. Angle between distal locking screws and nail was also more accurate using DTS.

Keywords Distal target device · Radiation · Intramedullary nail · Hip fracture

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Introduction

The prevalence of osteoporosis in the elderly population has increased by an annual average of 8.37% for men and 5.68% for women in Korea [1–3]. The incidence of elderly fragility fractures is also continuously increasing [4, 5]. For example, the incidence of hip fractures was increased 24.1% from 2008 to 2012 [6]. Hip fracture is known to increase the mortality rate of elderly patients [7–9].

Internal fixation using intramedullary (IM) in elderly patients with intertrochanteric and subtrochanteric fracture is the best treatment option in terms of biomechanical property [10, 11]. The use of X-ray image intensifier devices, such as C-arm, is essential for reduction of treatment-related fractures and for accurate guidance of IM nail insertion [12].

However, radiation exposure can cause harm, whether small or large, to both patient and the surgeon [13–15]. Therefore, any practical method to reduce the radiation exposure to both patients and surgeons must be addressed. For surgeons, it has been strongly advised to use shielding cloths and shielding tools in order to avoid the direct radiation exposure during operation. However, this method is not only inconvenient, but also technically difficult to use in all surgeries, especially the use of shielding gloves to protect operators' hands.

More importantly, this does not give any help to reduce the patient's exposure. The only way to reduce the radiation exposure to patients, and also an effective way to reduce that to surgeons, is to reduce the use of radiation itself during procedure.

Several methods have been devised to reduce radiation exposure in a reasonably achievable level, one of which is a distal targeting device examined in the study [16]. During operation using long IM nail, distal screw fixation should be performed continuously through the x-ray image intensifier to inspect the direction of screw insertion. However, the distal targeting device has the advantage of reducing radiation dose and operation time by fixing the screw insertion.

Therefore, the purpose of this randomized control study was to compare radiation exposure and accuracy of distal screw insertion between freehand method and distal targeting device groups.

Materials and methods

Trial design

The protocol of this trial was approved by the Medical Ethics Committee of the Affiliated Hospital of Gyeongsang Medical University (GNUH-2017–06-008–003). The trial was registered at CRIS (KCT0002560). Data were collected, analyzed, and reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement.

Participants

Patients with hip fractures including unstable intertrochanteric fracture and sub-trochanteric fracture who underwent surgery from March 2017 to June 2018 were eligible to participate in this study.

The inclusion criteria of the study were patients older than 60 years who need an intramedullary nailing due to unstable intertrochanteric and subtrochanteric fracture. Pathological fractures due to tumors and patients with reoperation due to nonunion were excluded from this study.

Interventions

Operations were performed with free-hand method for Group I and with distal target device for Group II. All patients were treated with long Gamma-3 nail (Stryker, Mahwah, NJ, USA) using two distal locking screws.

Surgical technique

Usual indications and customary nailing techniques were used for this study. A fracture table was always used with the contralateral limb in a gynecological stirrup. The first step to use distal targeting device was to confirm the device on the nail. The drill guide was positioned according to the length of the nail. It was then adjusted using the drill guide sleeve and passing for drill bit through the locking screw hole. Drill bit had to be exactly in the center of the nail hole (Fig. 1).

Once the nail was in place and the cervicocephalic lag screw was posed, the targeting device was mounted on the traditional nail-guide instrumentation. With a fluoroscope, a perfectly aligned image of the sleeve on the distal hole and the image of round holes were unnecessary. A view at a 30° angle of the nail was possible. This angle gave the surgeon working space, facilitating the procedure and limiting the risk of infection. The nail and drill sleeves were brought together under fluoroscopic control. This was facilitated by using a targeting guide so that the drill bit could be adapted vertically.

There are two steps in this procedure. First, the nail and reference lines of the targeting guide were lined up by fluoroscopy until they were parallel to each other. Second, the nail and the drill sleeve were lined up (Fig. 2). Coronal plane deformity and torsion have very little influence on the distal locking screw and the use of the targeting device while sagittal plane deformity affects the targeting angle. Correction was therefore necessary. With the drill guide wrench, it was possible to correct 14 mm downwards and upwards. Performing the distal locking screw procedure in two steps by leaving a drill bit in the distal hole provided additional stability to the system by creating a frame.

Outcomes

The number of radiation exposure by C-arm was compared between the two groups. Total radiation exposure, the number of radiation exposures during distal locking screw insertion, the number of radiation exposures during distal locking screw insertion versus total radiation exposure, and the number of exposed radiation fields were measured (Fig. 3). To evaluate the insertion accuracy of the two distal locking screws, the screw angle to the nail axis was measured (Fig. 4).

Fig. 1 Adjustment of position of drill guide by passing for drill bit through the locking hole before nail insertion. **a** Before adjustment, drill bit is passed beside screw holes. **b** After adjustment, drill bit is passed through screw holes exactly

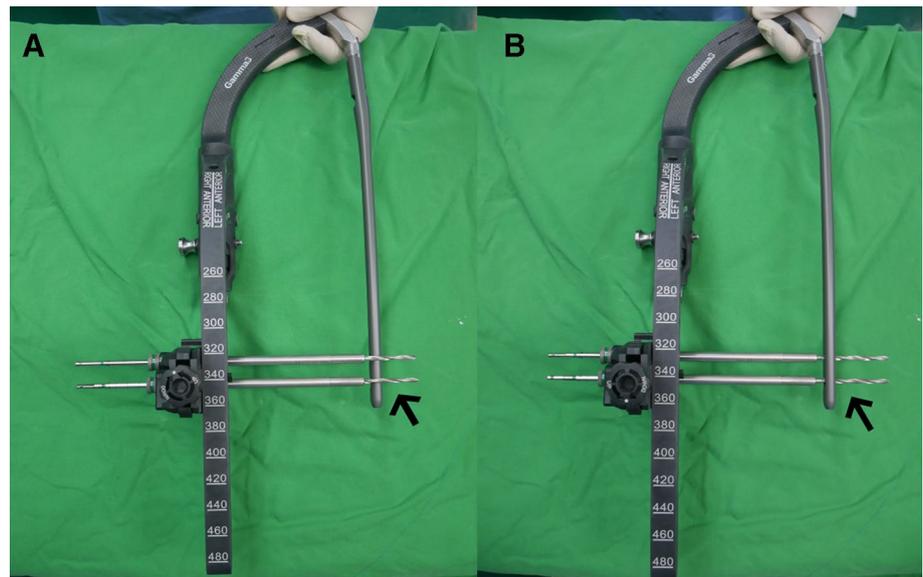
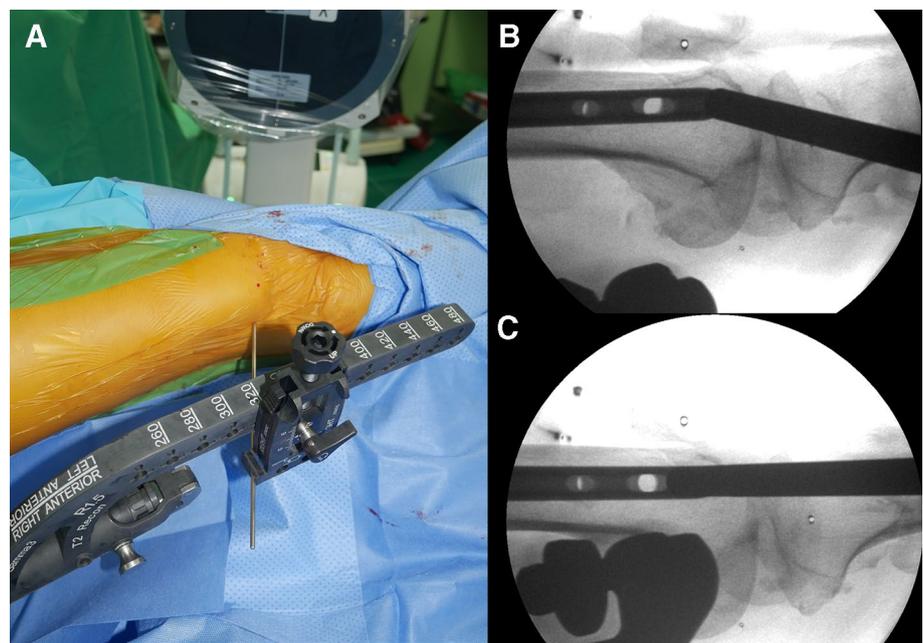


Fig. 2 **a** Mount of the distal targeting device and placement of image intensifier along the guide pin. **b** Incorrect C-arm positioning; the nail and the sleeve are not in parallel. **c** After adjustment, correct C-arm positioning; the nail and the sleeve are in parallel



Estimated blood loss (EBL) was calculated based on the drop in Hb between the preoperative measurements and the measurements 24–48 h postoperatively according to a formula developed by Brecher et al. [17]

Sample size calculation

Based on previous research results [18], the number of subjects was calculated using G power 3.1.9 (Franz Faul, University Kiel, Germany). The sample size was calculated by setting α error (two-sided) to 5% and statistical power of 80% (β error = 0.20). The sample size was 15 patients per group and a total of 30 patients were required. Considering

a drop-out rate of 20%, the sample size was determined to be 18 per group.

Randomization

Enrolled patients were randomized (1:1) to two groups. Sequentially numbered opaque envelopes in which the allocation was sealed were generated by a person who was not clinically involved in this study. When a patient consented to the trial, he or she was selected by a research nurse.

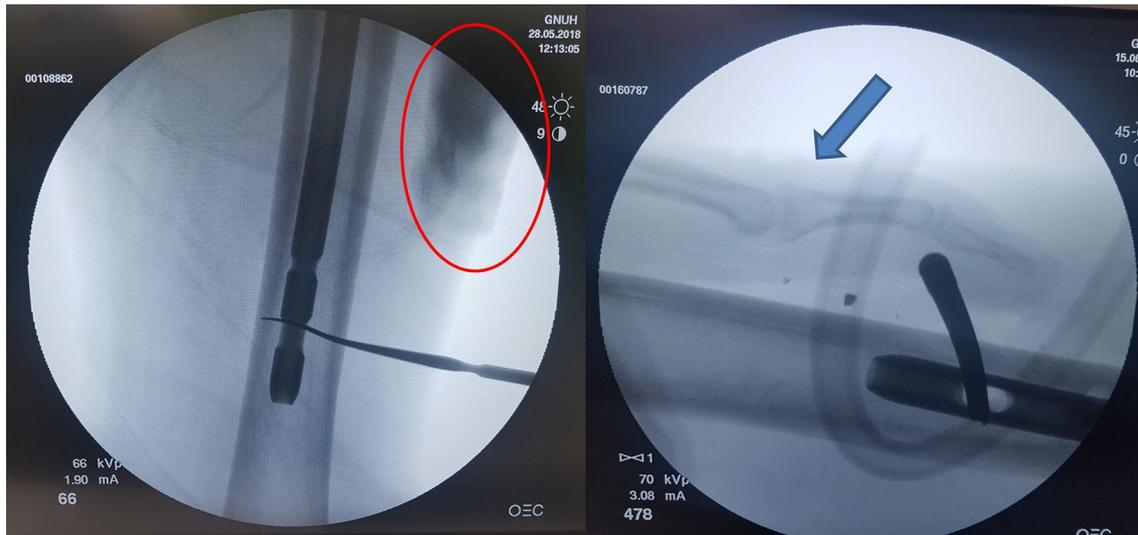


Fig. 3 Intraoperative radiographs of hands exposed to radiation field directly



Fig. 4 Measuring the angle between the screws (dot line) and the perpendicular axis of nail (black line)

Statistical methods

Chi-square test and independent *T* test were used to compare proportions and continuous variables between groups, respectively. All *p* values were compared at significance level of 0.05. All statistical analyses were conducted using

SPSS v 22.0 (SPSS Inc., Chicago, IL, USA) and $p < 0.05$ was considered statistically significant.

Results

A total of 36 patients participated in this study. Eighteen patients who underwent free hand technique were assigned to Group I and 18 patients who underwent surgery with distal targeting system were assigned to Group II. We used different length of nails; 280 mm in 10 hips, 300 mm in 6 hips, 320 mm in 7 hips, 340 mm in 7 hips, 360 mm in 6 hips. Age (82.67 ± 1.75 vs. 76.89 ± 11.01 , $p = 0.04$), operation time (96.33 ± 18.94 vs. 76.11 ± 14.10 , $p < 0.001$), blood loss (747.50 ± 830.89 vs. 530.0 ± 465.03 , $p = 0.02$) were significantly lower in Group II compared to those in Group I. However, sex, type of fracture, BMI, transfusion amount, or comorbidities were not statistically different between the two groups (Table 1).

In the result of radiation exposure between two groups, the number of attempt of image intensifier during distal screws insertion (57.33 ± 31.42 vs. 11.50 ± 7.41 , $p < 0.001$), ratio of attempt number for distal screws to the total attempts (0.33 ± 0.21 vs. 0.12 ± 0.08 , $p = 0.001$), the number of hand exposure to image intensifier directly (75.0 ± 29.55 vs. 13.56 ± 19.07 , $p < 0.001$), and the time of radiation exposure during distal screws insertion (42.57 ± 2.42 s vs. 12.72 ± 8.10 s, $p < 0.001$) were statistically significant lower in Group II compared to those in Group I (Table 2). As a result of comparing the accuracy of the insertion of distal locking screw between the two groups, both distal locking screws were significantly closer to perpendicular direction

Table 1 Demographic characteristics of patients

Variable	Group I (FH) (n = 18)	Group II (DTS) (n = 18)	p value
Age (years)	82.67 ± 1.75	76.89 ± 11.01	0.04
Sex (female)	66.7%	77.8%	0.71
Type of fracture (ITN/STN)	7/11	12/6	0.18
Operation time (min)	96.33 ± 18.94	76.11 ± 14.10	<0.001
BMI (kg/m ²)	23.01 ± 3.20	22.06 ± 4.67	0.67
Blood loss (mL)	747.50 ± 830.89	530.00 ± 465.03	0.02
Transfusion amount (mL)	690.00 ± 798.61	798.61 ± 528.09	0.1
DM	19.4%	14 (32.6%)	0.44
Liver disease	12.9%	7%	0.45
CKD	6.4%	11.6%	0.62
CHF	16.1%	27.9%	0.48
COPD	6.4%	25.6%	0.06

FH free handle technique, DTS distal targeting system, BMI body mass index, DM diabetes mellitus, CKD chronic kidney disease, CHF congestive heart failure, COPD chronic obstructive pulmonary disease

Table 2 Comparison of radiation exposure by C-Arm

Variable	Group I (free) (n = 18)	Group II (DTS) (n = 18)	p value
Total radiation exposure (n)	184.67 ± 42.46	99.50 ± 50.02	<0.001
Radiation exposure during distal screw insertion (n)	57.33 ± 31.42	11.50 ± 7.41	<0.001
Ratio of radiation exposure during distal screw insertion	0.33 ± 0.21	0.12 ± 0.08	0.001
Radiation exposure of hand (n)	75.0 ± 29.55	13.56 ± 19.07	<0.001
Time of radiation exposure during distal screw insertion (s)	42.57 ± 2.42	12.72 ± 8.10	<0.001

n number

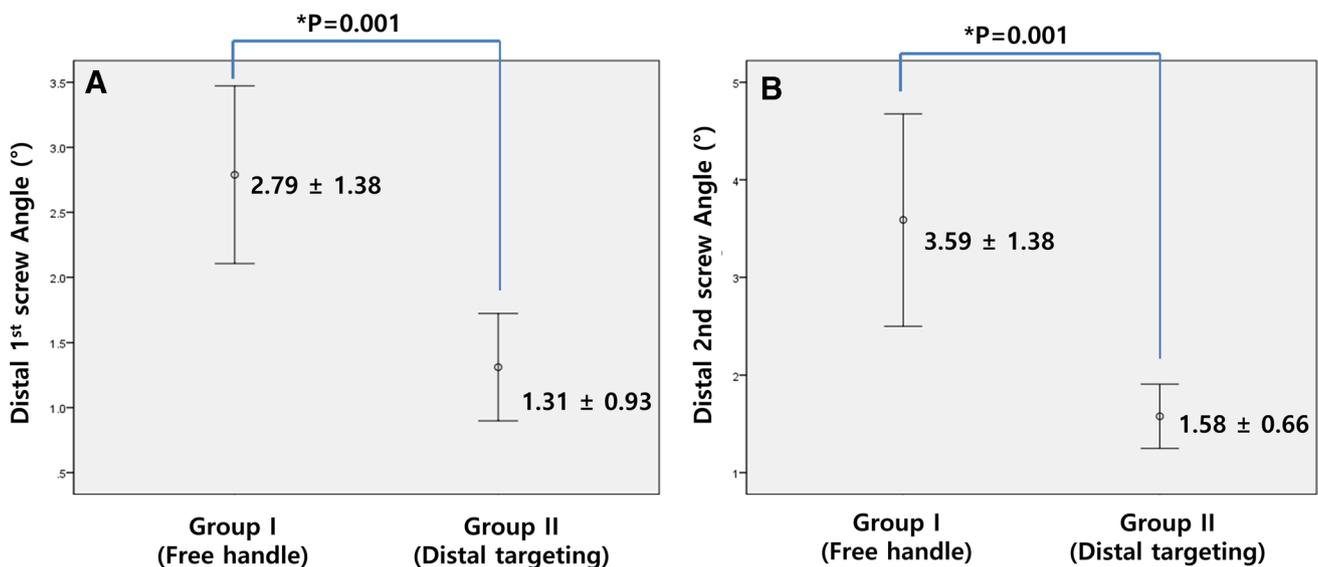
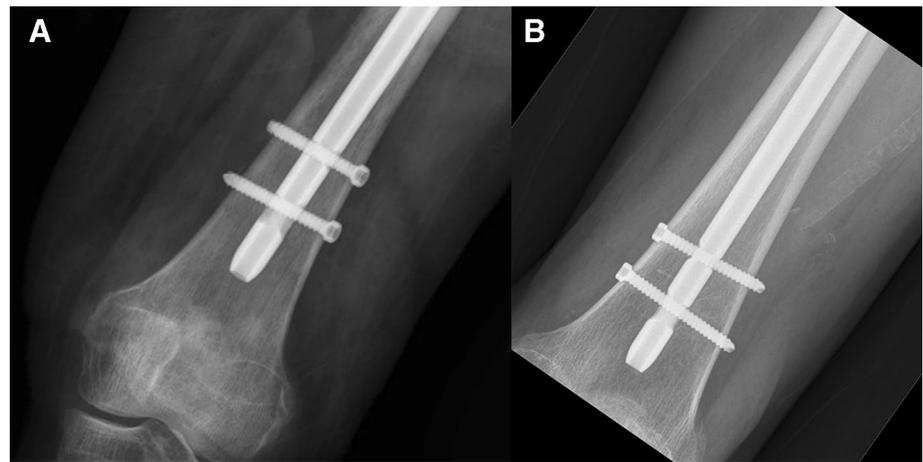
**Fig. 5** Comparing the accuracy of the insertion of distal locking screw between the two groups: **a** distal 1st screw angle, **b** distal 2nd screw angle

Fig. 6 **a** Distal locking screw placement with distal target system, **b** distal locking screw placement with free handle technique



to the nail in Group II compared to those in Group I (Figs. 5 and 6).

Discussion

The main finding of this study was that radiation exposure during distal screw insertion was significantly lower in Group II (using distal targeting device) compared to that in Group I (using free hand technique) (57.33 ± 31.42 vs. 11.50 ± 7.41 , $p < 0.001$). Especially, the frequency of hand exposure to radiation directly (75.0 ± 29.55 vs. 13.56 ± 19.07 , $p < 0.001$) and operation time (96.33 ± 18.94 vs. 76.11 ± 14.10 , $p < 0.001$) were significantly lower in Group II compared to those in Group I. As a result of comparing the accuracy of the insertion of distal locking screw between the two groups, a pair of the distal locking screws was placed more perpendicular to the vertical axis of nail in Group II compared to that in Group I. The mean difference of between screw and perpendicular axis of nail was bigger in second screw, which is supposed to pass through dynamic hole of nail.

In 1998, Krettek et al. reported a new mechanical aiming device for the placement of distal interlocking screws in femoral nails. They found for the first time that the primary advantage of the target device was reduced precision exposure to radiation and precise screw placement with little insertion-related hardware damage [19]. Recently, a new system has been introduced, TRIGEN SURESHOT®, designed by Smith & Nephew, in which distal lockage of intramedullary nail (IMN) no longer requires fluoroscopy. Bogdan et al. performed that 102 patients with closed diaphyseal fractures (34 femoral shaft and 68 tibial shaft fractures) were treated by IMN using the SURESHOT® for distal interlocking. They concluded that new method avoids exposure to ionizing radiation, while showing an accuracy of 96–100% and a low learning curve [20].

Orthopaedic surgeons are routinely exposed to intraoperative radiation. Although direct evidence linking adverse health effects to orthopaedic occupational radiation exposure is limited, there are indirect evidence from historical and proceduralist literature indicating that orthopaedic surgeons should continue to follow the principle of “as low as reasonably achievable” to minimize occupational radiation exposure. Gausden EB et al. [21] performed a prospective study to assess the amount of cumulative radiation exposure received by 16 orthopaedic surgeons and 24 residents in various subspecialties. They reported that residents and attending surgeons performing trauma or deformity surgical procedures were exposed to significantly higher doses of radiation compared to those with other subspecialties within orthopaedic surgery, although their doses did not exceed the recommended tolerance.

As the frequency of radiation exposure by fluoroscopy continues to increase in orthopaedic fields, the level of hazard for the orthopaedic surgeon is also increasing. The exposure of a clinician’s hand is the highest during surgery or procedures within actual clinics. There have been studies reporting the radiation exposures, such as to thyroid, eye, and whole body, the effects of radiation treatment for cancer or dermal lesions occurring from therapeutic intervention on the body such as heart and liver, and the radioactive damage to hands derived from radioactive material handlers. Recently, Shim et al. [22] have reported a case of chronic radiation dermatitis and necrosis of an orthopaedic surgeon’s hand as well as its soft tissue defect. In the present study, we found that the use of distal targeting device could be helpful to reduce the overall radiation exposure by C-arm, and thereby to reduce the unnecessary exposure to clinician’s hands.

Distal locking failure is another major problem in the process of distal locking. Deformation of nails inserted into the medullary canal is responsible for failure in distal locking. Anastopoulos et al. [23] reported that five cases are

unsuccessful in 127 patients treated with the use of a proximally mounted aiming device. In addition, attempting to insert the distal locking screw several times to have correct angle in patients with osteoporotic fractures may cause problems such as torsional instability. Bryan et al. [24] performed a biomechanical study to evaluate torsional biomechanical properties of three-part intertrochanteric femur fractures in a cadaveric bone model using two different distal fixation strategies, an unlocked long cephalomedullary nail versus a dynamically locked nail. They hypothesized that a long cephalomedullary nail did not require distal locking fixation when it was used to treat a three-part intertrochanteric fracture. However, they found that the distal locking of a long cephalomedullary nail increased the stiffness of the nail-femur construct in a three-part biomechanical fracture model. In our results using distal targeting system (DTS), distal locking screws were inserted at correct angle. There was no failure at all. A follow-up study should be done to observe mechanical failure. However, the stability of the group using DTS is likely to be higher.

Although this study presented an outcome based on the fact persuasively, it had several limitations. First, we did not design a control group to compare the learning curve between distal locking procedures. The difference of surgical time which is about 20 min seems too long to experts. However, surgeons performed the procedure in this study are the junior surgeons who had less than 1 year of clinical experience. Nevertheless, we can reduce the surgical time and the number of radiation exposure using DTS. Second, the size of the patient group was small compared to other studies. Third, the amount of radiation dose exposed during procedure was not quantified due to technical difficulties. Because this was a prospective study for patients who needed surgical treatment, direct dose measurement method that did not give any interference to the surgical procedure was inherently limited. Moreover, direct hand exposure was not performed using hand dosimeter. Because of the risk of contamination, it was difficult to attach the hand dosimeter with gloves in the operating field. In addition, phantom studies are being planned to measure the amount of radiation exposed to the hand of the surgeon. Although the amount of dose was not quantified in the study, it is very commonly accepted that the risk of radiation exposure is proportionally increased with the radiation dose accumulated over a lifetime. Therefore, it would be very important to make an attempt to reduce unnecessary radiation exposure while not compromising the surgical accuracy, using advanced tools, such as DTS examined here.

In conclusion, the amount of X-ray irradiation required to correctly guide the distal locking screws is significantly reduced when using the DTS compared to using free-hand fluoroscopic guidance. Operative time and the appropriateness of placement for the distal locking screw are also

significantly reduced and improved, respectively, with the DTS.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors. The design and protocol of this study were approved by the institutional review board of Gyeongsang Medical University (GNUH-2017-06-008-003).

Informed consent Informed consent was obtained from all individual participants included in the study.

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