นิพนธ์ต้นฉบับ

การศึกษาโคฮอร์ทแบบไปข้างหน้าเปรียบเทียบระยะเวลาในการใส่สกรูล๊อกที่ส่วนปลายของแกนโลหะระหว่างการใช้อุปกรณ์ช่วยใส่สกรูกับการใช้รังสีช่วยในการผ่าตัดใส่แกนโลหะดามกระดูกต้นขา

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บทคัดย่อ

บทนำ: การใส่สกรูล๊อกที่ส่วนปลายของแกนโลหะนั้นเป็นขั้นตอนที่ท้าทายสำหรับการผ่าตัดดามกระดูกที่หักบริเวณต้นขา การใช้อุปกรณ์ช่วยใส่สกรูจึงอาจช่วยลดเวลาการผ่าตัด และลดเวลาการรับรังสีระหว่างการผ่าตัดได้เมื่อเทียบกับการใช้รังสีช่วยในการผ่าตัด (free hand technique)

วัตถุประสงค์: เพื่อเปรียบเทียบเวลาที่ใช้ในการผ่าตัดใส่สกรูตัวปลายของโลหะดามกระดูกบริเวณต้นขา เวลา และจำนวนครั้งที่ใช้เครื่องเอกซเรย์ฟลูโอโรสโคปีในการใส่สกรูตัวปลายของแกนโลหะดามกระดูก ระหว่างการใช้อุปกรณ์ช่วยใส่สกรูกับการใช้รังสีช่วยในการใส่สกรูตัวปลายของแกนโลหะดามกระดูก

วิธีการวิจัย: การศึกษาโคฮอร์ทแบบไปข้างหน้า ในผู้ป่วยกระดูกต้นขาหัก ระหว่างการใช้อุปกรณ์ช่วยใส่สกรูกับการใช้รังสีช่วยในการผ่าตัดใส่แกนโลหะดามกระดูกต้นขา ระหว่างวันที่ 1 กรกฎาคม 2563 ถึง 1 เมษายน 2565 ที่โรงพยาบาลนครพิงค์ จังหวัดเชียงใหม่ ผลลัพธ์หลัก ได้แก่ เวลาที่ใช้ในการผ่าตัดใส่สกรูตัวปลายของโลหะดามกระดูกบริเวณต้นขาผลลัพธ์รอง ได้แก่ เวลา และจำนวนครั้งที่ใช้เครื่องเอกซเรย์ฟลูโอโรสโคปีในการใส่สกรูตัวปลายของแกนโลหะดามกระดูก วิเคราะห์ข้อมูลด้วยสถิติ T-tests, the rank-sum test, และ Fisher's exact ด้วยข้อมูลแบบ intention-to-treat

ผลการวิจัย: ผู้ป่วยกลุ่มที่ใช้อุปกรณ์ช่วยใส่สกรู 30 ราย และกลุ่มที่ใช้รังสีช่วย 28 ราย โดยทั้งสองกลุ่มใช้เวลาในการใส่สกรูตัวปลายไม่แตกต่างกัน กลุ่มที่ใช้อุปกรณ์ช่วยใส่สกรูมีเวลารวมที่ใช้เครื่องเอกซเรย์ฟลูโอโรสโคปีที่น้อยกว่าอย่างมีนัยสำคัญทางสถิติเมื่อเทียบกับกลุ่มที่ใช้รังสีช่วยในการผ่าตัด ที่ค่ามัธยฐานเวลา 19 วินาที (พิสัยควอไทล์ 24, ค่าต่ำสุด - ค่าสูงสุด 3-224 วินาที) และ 52.5 วินาที (พิสัยควอไทล์ 35.5, ค่ำต่ำสุด - ค่าสูงสุด 15-103 วินาที) ตามลำดับ (p-value < 0.001) กลุ่มที่ใช้อุปกรณ์ช่วยใส่สกรูเปลี่ยนไปใช้รังสีช่วยในการผ่าตัดจำนวน 8 ราย (ร้อยละ 26.67) พบว่ากลุ่มที่ต้องเปลี่ยนแผนการรักษามีตำแหน่งการหักใต้รอยคอดของกระดูกต้นขา (ร้อยละ 62.5)

สรุป: เวลาในการใส่สกรูระหว่างกลุ่มใช้อุปกรณ์ช่วยใส่สกรูกับกลุ่มที่ใช้รังสีช่วยในการผ่าตัดไม่ต่างกัน อย่างไรก็ตามแม้พบว่ากลุ่มที่ใช้อุปกรณ์ช่วยใส่สกรูใช้รังสีในการช่วยผ่าตัดน้อยกว่าแต่โอกาสเปลี่ยนแผนการรักษาไปใช้รังสีช่วยในการผ่าตัดมากขึ้น โดยเฉพาะในกลุ่มที่ตำแหน่งการหักใต้รอยคอดของกระดูกต้นขา

Thai Clinical Trial Registry: TCTR20230221005

คำสำคัญ: กระดูกต้นขาหัก, diaphysis ต้นขา, แกนโลหะ, สกรูตัวปลาย, อุปกรณ์ช่วย

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Original Article

Distal aiming device versus free hand technique for distal locking screw insertion time in femoral nail: a prospective cohort study

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ABSTRACT

Background: Distal locking screw placement is a challenging procedure for intramedullary nail of femoral shaft fracture. Assisting by aiming device may decrease operative time and reduce radiation exposure time compared to free hand technique.

Objectives: To compare the operative time for locking distal screw, fluoroscopic time and numbers of fluoroscopic shot for locking distal screw in two different techniques which were aiming device and free hand techniques.

Research Methodology: A prospective cohort study conducted in patients with femoral shaft fractures were treated using intramedullary nails, with two different techniques for distal locking screw insertion: the freehand technique and the aiming device technique. This study was conducted between July 1, 2020, and April 1, 2022, at Nakornping Hospital in Chiang Mai, Thailand. The primary outcome measured was the distal screw insertion time. Secondary outcomes included fluoroscopic time and the number of fluoroscopic shots during distal screw insertion. According to data analyses, intention-to-treat strategies were applied. T-tests, the rank-sum test, and Fisher's exact probability test were performed to compare the differences.

Results: Thirty patients underwent the aiming device technique, while 28 patients received the freehand technique. Although there was no significant difference in distal screw insertion time between the two methods, the aiming device technique significantly reduced fluoroscopic time, with median values of 19 seconds (range: 24.3-224 seconds) compared to 52.5 seconds (range: 35.5-103 seconds), p-value < 0.001. In the aiming device group, eight patients (26.67%) were switched to the freehand technique, primarily due to infra-isthmal femoral fractures, with a conversion rate of 62.5% in these cases (p-value < 0.05).

Conclusions: The study found no statistically significant difference in screw insertion time between the group using an aiming device and the group using freehand technique. However, the group using the aiming device required significantly less fluoroscopic assistance during surgery. Nonetheless, there was a higher likelihood of switching to the freehand technique, particularly in cases of infra-isthmal femoral fractures.

Thai Clinical Trial Registry: TCTR20230221005

Keywords: fracture femoral, femoral diaphysis, nailing, distal locking screw, aiming device

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Introduction

Femoral fractures are common injuries resulting from both high and low-energy trauma, affecting pediatric, adult, and elderly populations.[1-5] These fractures are often associated with other injuries, especially in cases of high-energy trauma[6], with a prevalence ranging from 21 to 37 per 100,000 people [1,3].

The treatment of femoral fractures offers various options, including conservative treatments such as skin traction,[7-8] cast braces, and external fixation[9-11], as well as surgical treatments involving plates and screws fixation or intramedullary nails. Both choices have their own advantages and disadvantages. Plate and screw fixation can result in non-union in 2-7% of cases[4] and infection rate of 1-7%[6,12-15], intramedullary nails have lower rates of non-union 2-6%[4] and infection rate 1%[6,16-18] Consequently, intramedullary nails are commonly used in the treatment of femoral fractures.

The intramedullary nail is the preferred method for treating femoral shaft fractures, and the distal locking screw insertion is a critical step in this procedure that requires a high level of technical skill. Usually, this step is performed with the assistance of a fluoroscope using the free-hand technique, which can take a long time to find the correct insertion position and result in excessive radiation exposure. The experience level of fluoroscopists and surgeons can also affect the accuracy and speed of this technique.[19-29].

While previous studies have not shown a direct correlation between surgical time and infection rates in intramedullary nail procedures, research in other medical fields suggests that longer surgeries may increase the risk of infection[30-32] For example, a study by Wang Q[32] indicated a significant difference in operative time between infection and non-infection groups in total hip arthroplasty, with the infection group having a longer operative time by seven minutes. This suggests that prolonged operations may elevate the risk of infection.

Radiation exposure poses risks of both short and long-term damage, including skin burns, cataracts, and DNA damage that can lead to cancer.[33-36]. The FDA recommended in 1996 that radiation exposure should not exceed 1 Gray per year.[36] Additionally, scatter radiation can range from 1-4 milli gray per hour if the operator is positioned 30-90 cm away from the fluoroscope.[35]

Recent studies have presented various techniques for distal locking screw insertion. Some studies have proposed alternative methods, though these do not provide a comparison with the standard technique.[24,37] While certain techniques aim to reduce radiation exposure, they have no effect on surgical time.[19,27-28] According to Krettek C.'s cadaver study[27] using an aiming device can significantly reduce radiation exposure in distal locking screw insertion by 37.3 and 0 seconds. However, it significantly increases surgical time by 4.8 and 6.6 seconds compared to using a radiolucent drill.[27] Surgical time and radiation exposure in live patients may differ from those in cadaveric studies due to the challenges in locating the correct position for screw insertion and the need for additional staff during the procedure. An aiming device, however, does not require a specific position for screw insertion like the free-hand technique. Therefore, this device may decrease the operation time, radiation exposure, and can be used by surgeons of any skill level.

Objectives

We aimed to compare the operative time for locking distal screw and fluoroscopic time and numbers of fluoroscopic shot for locking distal screw in two different techniques which were aiming device and free hand techniques.

Research Methodology

Study design and setting

This single-center, prospective cohort study was conducted at Nakornping Hospital in Chiang Mai, Thailand, involving patients with femoral shaft fractures from July 1, 2020, to April 1, 2022. Participants received treatment using either the aiming device technique or the free-hand technique. Both groups were treated with antegrade intramedullary nails by staff (16 individuals) or senior residents (5 individuals), following the same operative procedures from patient positioning to proximal locking screw insertion.

The Ethics Committee of Nakornping Hospital approved this research (approval number 152/63), and the study is registered with the Thai Clinical Trial Registry (TCTR20230221005). All patients provided written informed consent before enrollment in the study.

Samples and inception cohort

We included patients with femoral shaft fractures who were at least 18 years old and provided informed consent. Exclusion criteria included open fractures, bilateral femoral fractures, previous implantations, prior femoral deformities, or contraindications for nailing, such as a narrow canal that would not accommodate a nail, open growth plates, previous malunion that prevented nail placement, a history of intramedullary infection, associated ipsilateral femoral neck or acetabular fractures, or polytrauma with associated thoracic injuries.

After obtaining informed consent, all enrolled patients were divided into two groups based on the surgeon's preference after the completion of the proximal locking screw: the distal aiming device group and the free-hand technique group. There were 30 patients in the distal aiming device group and 28 patients in the free-hand technique group

Sample size estimation

The sample size was estimated using the formula for continuous data based on the research of Krettek C.[27] and Wang Q.[32] The distal screw insertion time was 6.6 ± 2.4 minutes for the aiming device technique group and 4.8 ± 1.5 minutes for the freehand technique.

To achieve 80% statistical power at a 5% significance level for detecting the input effect size, 20 patients were needed in each group. To account for potential dropouts, 20% of the sample size was added, and an additional 10 patients were included to compensate for confounding factors, resulting in a requirement of 58 patients

Data collection

Data collected included demographic information such as age, sex, BMI, site of injury, Winquist classification, surgeon, baseline pain score, waiting time for surgery, and the diameter and length of the nail.

Outcome Measurement

The primary outcome was the time (in minutes) required to insert the distal screw, measured from the completion of the proximal screw insertion to the completion of the distal screw insertion. Secondary outcomes included fluoroscopy time (in seconds) and the number of fluoroscopy shots taken during distal screw insertion, with data recorded from the completion of proximal screw insertion to the completion of distal screw insertion. Complications monitored included knee pain on the third day after surgery by visual analog scale, a decrease in hematocrit post-surgery, range of motion (ROM) of the knee one month after surgery by goniometer, and wound status one-month post-surgery to check for surgical site infection (SSI). The outcome assessors were blinded to the group assignments during outcome measurement.

Surgery Technique

All patients underwent the same anesthesia procedure, either a spinal block or general anesthesia if the spinal block failed. The surgeries were performed by either staff or senior residents. The patients were positioned supine on a fracture table, with the contralateral limb placed in a hemi-lithotomy position. An incision, approximately 5 cm above the greater trochanter and measuring 2-5 cm in length, was made. The recording of the operative time started when the surgeon made the incision. An awl was placed at the entry point, followed by the insertion of a guide, reduction, and guide insertion through the fracture site. The canal was reamed, starting at 8.5 mm. and increasing by 0.5 mm. increments until it reached the desired nail diameter plus 1.5 mm. The nail was then inserted, and rotation was checked, followed by proximal screw insertion. The distal screw insertion time was recorded when the surgeon finished the proximal screw insertion. The surgeon then chose either the free-hand technique or the aiming device technique to insert the distal screw, and the distal screw insertion time was stopped after the completion of the distal locking screw insertion. After the distal screw was inserted, an end cap was placed, and the soft tissue was sutured layer by layer. The operative time was stopped after the skin was closed.

Surgical Technique in distal locking screw

The initial time was recorded once the surgeon confirmed the completion of the proximal locking screw insertion. The time was stopped after the distal locking screw insertion was finished, and the surgeon declared the completion. The total time taken, as well as the fluoroscopy time and the number of fluoroscopy shots, were recorded.

Free hand technique group

After the surgeon declares that the proximal screw is finished, the patient's position is adjusted to hip abduction at the operative site, and the fluoroscope is repositioned perpendicular to the leg. The fracture table is then tilted to achieve a perfect circular image of the distal nail hole in the lateral view. An initial incision is made at the site of the screw hole, starting with the more proximal hole. The screw hole is then drilled, and the first screw is inserted. Using the same technique, the second screw is inserted. Once both screws are in place, their positions are checked with the fluoroscope. Finally, the surgeon announces the completion of the distal locking screw.

Aiming device technique group

After the surgeon declares that the proximal screw is finished, the distal aiming device is attached (Fig.1). An anterior hole is drilled to insert the jig of the aiming device. The jig is then positioned in contact with the anterior nail and confirmed through a lateral fluoroscope (Fig.2).

Figure 1. Aiming device

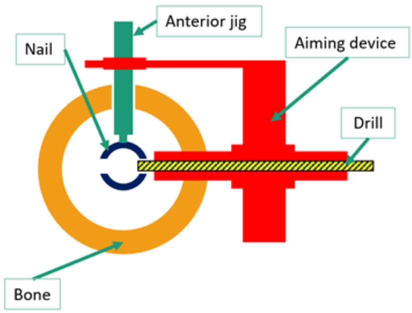

Figure 2. Cross-sectional diagram of the aiming device

Using the aiming device, the drill and screw are inserted at the lateral site, beginning with the more proximal hole. Afterward, the aiming device is removed. The positions of the screws are verified using the fluoroscope once both screws are in place. Finally, the surgeon announces the completion of the distal locking screw.

Converting group

In some cases, within the aiming device group, the anterior jig may not properly contact the nail or may be positioned on the medial or lateral side of the nail. Additionally, screws may miss the intended hole. When these issues occur, we switch from using the aiming device to the free-hand technique (Fig. 3).

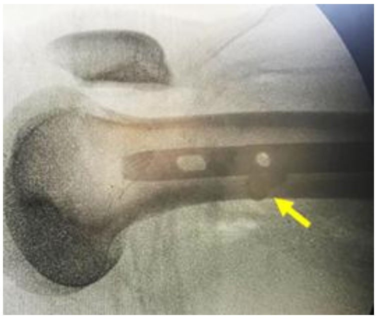

Figure 3. The arrow illustrated a missing screw.

Postoperative care

A standardized postoperative care protocol was implemented for all patients, encompassing monitoring of respiratory and hemodynamic functions from the recovery room until their return to the ward. To identify postoperative complications, patients underwent serial physical examinations until discharge and laboratory investigations, including a complete blood count, performed one day after surgery, along with daily pain score evaluations. Patients were instructed to perform range-of-motion exercises for their knee, from 0° to 90°, starting the day after surgery and were required to achieve a range of motion of at least 0° to 90° before being discharged.

Statistical Analysis

According to data analyses, intention-to-treat strategies were applied. Continuous variables were presented with mean and standard deviation, and t-tests were used for normally distributed data. For non-normally distributed data, the median, interquartile range, maximum, and minimum values were used, and the rank-sum test was performed. Fisher's exact probability test was used to analyze categorical variables. All analyses were conducted using Stata Statistical Software 16 (StataCorp, LP, College Station, Texas, USA), with a Type I error rate set at 0.05.

Results

A total of 279 patients with femoral shaft fractures were admitted to the hospital, out of which 69 received definite fixation using interlocking nails. 11 patients were excluded from the study due to deformities (2 patients) and open fractures (9 patients). Therefore, 58 patients were enrolled in the study, with 30 receiving treatments using the aiming device technique and 28 receiving treatments using the free-hand technique (Fig.4).

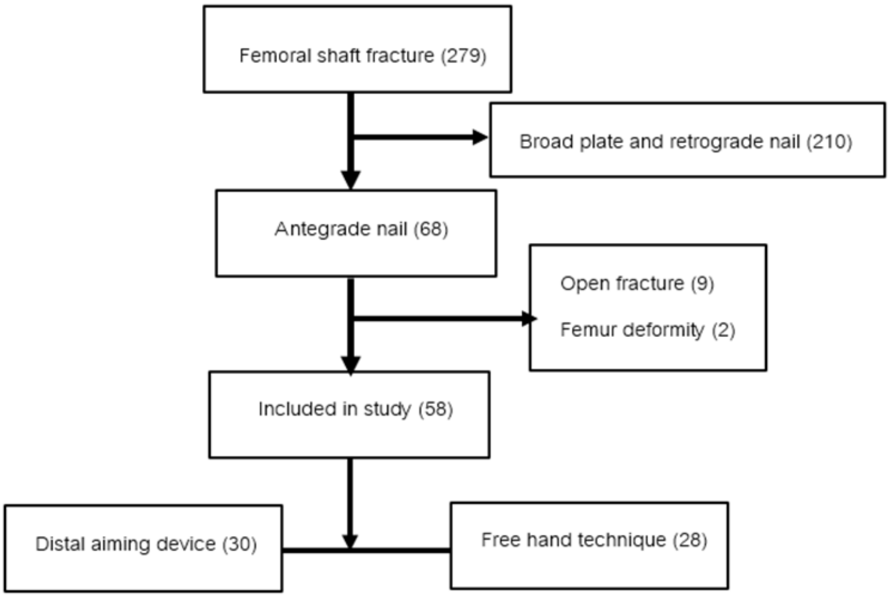

Figure 4. study flow

There were no significant differences in demographic data between the aiming device technique group and the freehand technique group. Variables such as age, BMI, baseline pain score, days from injury to surgery, sex, fracture site, fracture classification, operating surgeon, nail diameter, and nail length were comparable between the two groups (Table 1).

Table 1 Baseline characteristics between distal aiming device technique (n=30) and fluoroscope assist technique (n=28)

Characteristics		Distal Aiming Device technique (n=30) n (%)	Fluoroscope assist technique (n=28) n (%)	p-value
Sex				0.089
	Male	24(80.0)	16(57.1)	
	Female	6(20.0)	12(42.9)	
Site				0.599
	Right	17(56.7)	13(46.4)	
	Left	13(43.3)	15(53.6)	
Winquist Classification				0.502
	I	17 (56.7)	15(53.6)	
	II	3 (10.0)	5(17.9)	
	III	8 (26.7)	4(14.3)	
	IV	2 (6.67)	4(14.3)	
surgeon				1.000
	Resident	23(76.7)	21(75.0)	
	staff	7(23.3)	7(25.0)	

Table 1 Baseline characteristics between distal aiming device technique (n=30) and fluoroscope assist technique (n=28) (Cont.)

Characteristics	Distal Aiming Device technique (n=30) n (%)	Fluoroscope assist technique (n=28) n (%)	p-value
diameter			0.551
9	18(60.0)	14(50.0)	
10	10(33.3)	10(35.7)	
11	2(6.67)	4(14.29)	
length			0.350
320	1(3.3)	1(3.6)	
340	2(6.7)	5(17.9)	
360	13(43.3)	7(25.0)	
380	11(36.7)	14(50.0)	
400	3(10.0)	1(3.57)	
Age, mean±S.D.	31.4±15.98	31.71±18.05	0.520
BMI, mean±S.D.	23.43±7.26	23.88±5.57	0.794
Base line pain score, median (IQR, min-max)	7(5,0-10)	5.5(4,0-10)	0.087
Day of surgery (post injury), median (IQR, min-max)	5(4,1-13)	6.5(3,1-14)	0.117

There was no significant difference in distal screw insertion time between the freehand and aiming device techniques, with times of 18.5 (8.11-46) minutes and 20.5 (14.9-65) minutes, respectively (p-value=0.528). However, the amount of radiation exposure was significantly lower in the aiming device technique, with fluoroscopic time of 19 (24.3-224) seconds compared to 52.5 (35.5-103) seconds in the freehand technique (p-value<0.001) and fluoroscopic shots of 25 (34.4-210) compared to 71.5 (33.22-186) (p-value<0.001), as shown in Table 2.

Table 2 Outcomes between distal aiming device and fluoroscopic assisted techniques presented in median (IQR, minimum-maximum)

	Distal aiming device technique (n=30)	Fluoroscope assist technique (n=28)	p-value
Primary outcome			
Distal screw insertion time (minutes)	20.5(14,9-65)	18.5(8,11-46)	0.528
Operative time (minutes)			
Total operative time	96.4±31.88	90.8±31.95	0.501
Proximal screw time	56.46±26.74	53.11±19.25	0.587
First screw insertion time	15.5(11,6-55)	13(7.5,7-41)	0.218
Second screw insertion time	4.5(4,2-38)	6(2.5,3-14)	0.056
Close skin time	15.5(16,2-30)	13(13,1-60)	0.508

Table 2 Outcomes between distal aiming device and fluoroscopic assisted techniques presented in median (IQR, minimum-maximum) (Cont.)

	Distal aiming device technique (n=30)	Fluoroscope assist technique (n=28)	p-value
Fluoroscope time (seconds)			
Distal screw fluoroscope time	19(24,3-224)	52.5(35.5,15-103)	<0.001
Total fluoroscope time	120.5(93,48-359)	137.5(72.5,58-277)	0.396
Proximal fluoroscope time	99(71,31-227)	83(48.5,38-186)	0.858
Fluoroscope time in first screw insertion	14.5(14,2-171)	29(27.5,11-78)	<0.001
Fluoroscope time in second screw insertion	4(6,1-53)	10(12.5,2-81)	<0.001
Close skin fluoroscope time	4.5(7,1-85)	4(5,1-33)	0.489
Fluoroscope shot (numbers)			
Distal screw fluoroscope shot	25(34,4-210)	71.5(33,22-186)	<0.001
Total fluoroscope shot	179.5(101,82-677)	194(78,120-514)	0.371
Proximal fluoroscope shot	138.5(93,54-459)	129.5(60,56-326)	0.570
Fluoroscope time in first screw insertion shot	20.5(24,2-185)	50(33.5,17-165)	<0.001
Fluoroscope time in second screw insertion shot	5.5(9,1-78)	22(14.5,5-45)	<0.001
Close skin fluoroscope shot	5(8,1-30)	4(7.5,1-40)	0.419
Attempt (numbers)			
Attempt of first screw	1(1,1-5)	1(0,1-3)	0.158
Attempt of second screw	1(0,1-11)	1(0,1-3)	0.296
Convert (n)	8(26.67)	0(0.0)	0.005

In the aiming device technique group, 8 patients (26.67%) were converted to the freehand technique. However, there were no differences in knee pain, infection rate, decrease in hematocrit, and ROM of the knee at 1 month between the two groups, as shown in Table 3.

Table 3 Complications comparing between distal aiming device and fluoroscopic assisted techniques

	Distal aiming device technique (n=30)	Fluoroscope assist technique (n=28)	p-value
Attempt (attempt), median (IQR, min-max)	2(1,2-15)	2(0.5,2-5)	0.234
Converted to free hand technique, n (%)	8(26.67)	0(0.0)	0.005
Pain score, median (IQR, min-max)	3.5(3,0-10)	3(4.5,0-8)	0.077
Infection at 1 mount, n (%)	1(3.85)	1(3.85)	1.000
Decreases hematocrit (%), median (IQR, min-max)	3.95(9.6, 0-19.7)	5.55(6.4, -1.6-17.4)	0.876
ROM knee at 1 month (°), mean±S.D.	107.33±44.56	111.25±38.04	0.720

A subgroup analysis was performed only in the aiming device technique group to evaluate factors between the converted and non-converted to free hand technique groups. The data showed a statistically significant higher rate of conversion in infra-isthmal femoral fractures (p=0.048). Other variables, including the site of injury, comminution of fracture, nail length or diameter, and BMI, were not significant, as presented in Table 4.

Table 4 Baseline demographic data comparing between non-converted and converted groups in the aiming device technique group

Characteristics	Non-converted group (n=22)	Converted group (n=8)	p-value
Sex			1.000
Male	17(77.27)	7(87.50)	
Female	5(22.73)	1(12.50)	
Age, mean±S.D.	28.68±13.55	38.87±20.50	0.124
BMI, mean±S.D.	24.72±6.74	19.88±7.92	0.107
Baseline pain score, median (IQR, min-max)	7(5,0-10)	5.5(4,0-10)	0.096
Day of surgery (post injury), median (IQR, min-max)	4.5(4,1-13)	5.5(2,3-9)	0.381
Site			0.242
Right	8(36.36)	5(62.50)	
Left	14(63.64)	3(37.50)	
Winquist Classification			0.450
I	14(63.64)	3(37.50)	
II	2(9.09)	1(12.50)	
III	5(22.73)	3(37.50)	
IV	1(4.55)	1(12.50)	
Surgeon			0.143
resident	15(68.18)	8(100)	
staff	7(31.82)	0(0.00)	
Diameter (mm)			0.550
9	14(63.64)	4(50.00)	
10	7(31.82)	3(37.50)	
11	1(4.55)	1(12.50)	
Length (mm)			0.940
320	1(4.55)	0(0.00)	
340	2(9.09)	0(0.00)	
360	10(45.45)	3(37.50)	
380	7(31.82)	4(50.00)	
400	2(9.09)	1(12.50)	
Level of fracture			0.048
Supra isthmus	10(45.45)	1(12.50)	
Isthmus	9(40.91)	2(25.00)	
Infra isthmus	3(13.64)	5(62.50)	

Discussion

This prospective study compared operative time and radiation exposure between the aiming device and the standard freehand technique for inserting distal locking screws in intramedullary nail surgery for femoral shaft fractures. The results demonstrated that the use of the aiming device did not significantly increase operative time compared to the freehand technique (20.5 minutes [14,9–65] vs. 18.5 minutes [8,11–46], P = 0.528). However, the aiming device significantly reduced radiation exposure compared to the freehand technique (19 seconds [24,3–224] vs. 52.5 seconds [35.5,15–103], P < 0.001). These findings contrast with previous cadaveric studies, which reported a significantly shorter operative time with the aiming device (4.8 ± 1.5 vs. 6.6 ± 2.4 minutes, P = 0.002),[27] but were consistent in showing reduced radiation exposure (37.3 ± 15.5 seconds vs. 0 seconds, P < 0.0001)[27].

One potential explanation for the comparable operative times between the two techniques in our study is the relatively high conversion rate from the aiming device to the freehand technique (26.67%). Cases that required conversion had significantly prolonged operative times, which likely contributed to the lack of difference between the two groups. If conversion cases were excluded, the operative time in the aiming device group would have been shorter. Additionally, the aiming device technique requires less precision in fluoroscopic positioning than the freehand method, which depends on obtaining a perfect "circular" image. This likely contributed to the reduced radiation exposure observed in the aiming device group.

A subgroup analysis revealed that the failure rate of the aiming device was particularly high in infra-isthmal femoral fractures, with 62.50% of cases requiring conversion. This suggests that the aiming device may be less suitable for these types of fractures. Further analysis indicated that fracture topography was the only significant factor associated with failure, while other factors such as injury site, fracture comminution, nail length or diameter, and patient BMI were not statistically significant. However, the study may have lacked sufficient power to detect associations with these variables.

One of the key strengths of this study is its prospective design, making it the first study to directly compare these two surgical techniques in a clinical setting. Although this was an observational study, it applied an intention-to-treat approach, and the baseline characteristics of the study groups were comparable. Additionally, the inclusion of multiple surgeons with varying levels of experience improves the generalizability of the findings. Despite these strengths, a randomized controlled trial (RCT) would provide stronger evidence by minimizing potential confounding factors.

This study has several limitations. First, its observational design means that potential confounders cannot be fully controlled. Future research should involve an RCT to strengthen the validity of the findings. Second, the study did not exclusively involve expert surgeons, which may have contributed to the high conversion rate in the aiming device group. If only experienced surgeons had performed the procedures, the conversion rate may have been lower (all converted case in resident group 34.8%), potentially leading to different results. Lastly, given the high conversion rate and its association with fracture topography, further studies are warranted to identify patient characteristics that may predict successful use of the aiming device. This would allow for better patient selection and improved clinical outcomes.

Conclusion

This study demonstrated that while the use of an aiming device for distal screw insertion in intramedullary nail surgery does not significantly reduce operative time compared to the freehand technique, it does significantly decrease radiation exposure. However, the high conversion rate to the freehand technique, particularly in infra-isthmal femoral fractures, suggests that the aiming device may not be suitable for all fracture types. Given these findings, careful patient selection is essential when considering the use of an aiming device. Further randomized controlled trials are needed to validate these results and identify factors that may predict successful application of this technique in clinical practice.

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