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Research Article

Comparison of the Surgical Outcome of Intertrochanteric Fracture with Gamma Nail Insertion Through Inferior-Center and Center-Center Blade Entry Point; A Randomized Control Study

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Abstract

Introduction: Cephalomedullary nails (CMNs) are preferred over sliding hip screws (SHS) for treating intertrochanteric fractures (ITF) due to less intraoperative blood loss, operating time, varus collapse, and femoral shortening. However, the optimal blade position in the femoral head remains controversial despite its critical role in preventing complications. This study aims to determine the best blade position to enhance outcomes and reduce implant failure in ITF patients treated with CMNs. The purpose of this study was to determine the optimum helical blade position in intertrochanteric fractures fixed via cephalo-medullary nail. The results of this study will help orthopedic surgeons choose the best blade position in patients with ITF treated with CMN to reduce implant failure.

Methods: 167 patients with intertrochanteric fractures were randomly assigned to two study groups. The helical blade was applied inferior-center (I-C) in the first group, and the second group applied center-center (C-C). Tip-apex distance (TAD), neck shaft angle (NSA), and femoral neck axis length (FNAL) were measured in early postoperative and six months postoperative.

Results: In the C-C group, the immediate and six-month postoperative NSA was 132.9 ± 5.72 and 131.1 ± 5.78, TAD was 18.7 ± 5.39 and 18.8 ± 5.8, and FNAL was 114.7 ± 13.6 and 110.7 ± 11.1, respectively. In the I-C group, the immediate and six-month postoperative NSA was 134.7 ± 5.19 and 131.6 ± 5.76, TAD was 20.4 ± 6.4 and 20.5 ± 8.24, and FNAL was 112.1 ± 10.5 and 108.5 ± 12.6, respectively.

Conclusion: Regarding radiologic parameters, the I-C helical blade position achieved the same results as the C-C blade position.

Keywords: Hip Fracture; Intertrochanteric Fractures; Cephalomedullary Nail; Neck Shaft Angle.

Introduction

Since various treatment options are presented for intertrochanteric fractures(ITF), fixed-angle devices such as sliding hip screws (SHS) and cephalo-medullary nails (CMNs) remain the preferred option [1, 2, 3, 4, 5]. It is demonstrated that CMN is superior to SHS in treating ITF due to less intraoperative blood loss, operating time, varus collapse, and femoral shortening, even in stable fractures [6, 7]. Consequently, CMN become the popular device for treating ITF, especially in elderly and unstable fractures [8]. Despite good outcomes, some failures and complications may happen [9].

It is presumed that the blade position in the femoral head is a determinant factor in these complications. Although many studies have been done, the optimal position of the blade remains controversial [10]. Kuzik et al. demonstrated that the inferior lag screw position on anteroposterior (AP) radiographs and central on lateral (Lat) radiographs will produce the highest stiffness among synthetic femurs [11]. However, some studies recommended the central position of the lag screw on AP radiographs [12].

Although there is a paucity of qualified studies focusing on blade position, this randomized controlled study was designed to determine the optimum helical blade position. The results of this study help orthopedic surgeons choose the best blade position in patients with ITF treated with CMN to reduce implant failure.

Methods

Study design

A prospective, randomized controlled trial, with institutional review board approval, was conducted at our institution between March 2020 and March 2021 to assess the outcome of ITF fixation via CMN. The trial protocol was registered on the Iranian Registry of Clinical Trials website (IRCT20180404039188N4). Written informed consent was obtained from all the participants prior to recruitment.

Participants, randomization, and blinding

This study was conducted at one of the university hospitals, which is a Level I trauma center. The inclusion criteria were 1) patients who presented to the emergency department and were diagnosed with ITF and 2) they could walk independently before the fracture. Exclusion criteria included 1) patients who had pathologic fractures and 2) patients who had any previous fracture at the hip.

Patients were randomized to intervention group one, "I-C group," and intervention group two, "C-C group." The first researcher checked the computer-generated random number list, divided the patients into their corresponding groups, and informed the other researchers. The other researchers were blinded to the patient's allocation before receiving information from the first. Also, the first one was blinded to all the clinical information about the patients postoperatively. So, using a convenient sampling technique, a total of 148 patients, 77 were in the C-C group, and 71 were in the I-C group, enrolled within the defined study period.

All patients undergo surgery by a senior hip surgeon. Patients and care providers were also blinded to the details since they became aware of fixation via CMN. Two orthopedic dic surgeons blinded to the outcome of the patient's surge studies numbered immediate postoperative X-rays. They studied chemical fixation to determine the neck-shaft angle (NSA), calcar gap, blade positions, tip apex distance (TAD), and FNAL. Prior training of these two surgeons was conducted to minimize interobserver variability.

Procedure and Interventions

After spinal or general anesthesia, the patient was transferred to a fracture table in the supine position. All the study patients underwent close reduction confirmed with fluoroscopy and internal fixation using PFNA (XRBestâ) by a senior hip surgeon. Following the surgery, blade position was confirmed in all patients using plain radiography in the AP and lateral (Lat) views. In the AP radiographs, the blade was supposed to have central or inferior locations in the patients of the C-C and I-C groups, respectively (Figure 1).

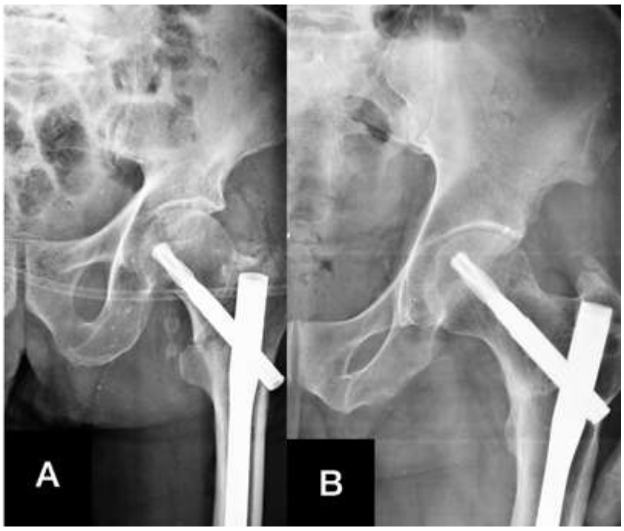

Figure 1: Inferior-Center helical blade position in (A), Center-Center helical blade position in (B).

However, they must be central in the Lateral radiographs taken from all patients. Finally, the wound was gently rinsed with normal saline and was closed in anatomic layers.

After surgery, patients are monitored in the recovery room for vital signs such as blood pressure, heart rate, blood oxygen saturation, and respiratory rate.

The day after surgery, patients were allowed to weight bear as tolerated, with no limitation in joint mobilization as they were discharged. The antibiotic regimens based on Ciprofloxacin (500 mg every 12 hours) and Cephalexin (500 mg every 6 hours) were used for 3-5 days after surgery, and low-molecular-weight heparin (4000 IU subcutaneously once daily) was received for four weeks after surgery for deep vein thromboembolism prophylaxis. Supplements such as calcium (1000-1500 mg daily) and vitamin D (400 IU daily) were given to all patients during the research period.

Outcomes

Data collected included patient age, gender, smoking, ASA score [4], fracture classification according to the OTA/AO classification, Dorr classification [13], body mass index (BMI), neck-shaft angle (NSA), femoral neck axis length (FNAL), and tip-apex distance (TAD) (Figure 2).

Figure 2: How to measure the TAD: sum of the distance, in millimeters, from the tip of the helical blade to the apex of the femoral head measured on an anteroposterior and lateral radiograph after correction has been made for magnification

All radiologic parameters were measured on early post-op and 6-month post-op radiographs with a picture archiving and communication system (PACS), and patients were followed for one year to detect any complications.

The calcar gap is defined as the displacement of the medial calcar on the immediate postoperative postoperative AP and lateral XR. The tip apex distance is the sum of the distance, in millimeters, from the tip of the helical blade to the apex of the femoral head measured on an anteroposterior and lateral radiograph after correction has been made for magnification [6]. Neck shaft angles (NSA), the angle between the neck and femoral shaft axes, were also assessed using radiographs taken immediately after the surgery and six months later (Figure 3). The loss of the NSA after the operation indicates medial fragments collapse and varus deformity formation during the bone healing. Moreover, the femoral neck axis length (FNAL) was assessed immediately and six months after the operation. FNAL is the distance between the lateral cortex and the head apex [14] (Figure 4). Proximal femur shortening (PFS) in this study is defined as the difference of FNAL between postoperative postoperative immediate and after 1-year measurements. PFS severity is defined as mild (less than 5 mm), moderate (5 to 10 mm), and severe (more than 10 mm).

Figure 3: The angle between the neck axis and femoral shaft axis (NSA).

Figure 4: FNAL is the distance between the lateral cortex and to head apex.

Statistical methods

The collected data were entered into the statistical software SPSS version 26.0 and analyzed. Normality of data approved by kolmogorov smirnov test. Descriptive statistics were presented in mean and standard deviation (for quantitative variables) and frequency and percentage (for categorical variables). Data were analyzed using the Chi-square test to compare qualitative variables, the ANCOVA test to compare one or more categorical independent variables, and the paired T-test to compare intergroup variables before and after intervention. Independent t-test for quantitative variables with normal distribution. This study's statistical significance level was considered as P-value less than 0.05.

Results

Finally, Among the 167 patients, 19 subjects were excluded from the study due to the long distance and difficulty of commuting or lack of consent to continue cooperation, and 148 patients were included in the analysis, of which 77 were in the C-C group, and 71 were in the I-C group. Recruitment started in March 2020 to March 2021. All patients were followed for one year, and the trial was completed in March 2022.

The study participants included 82 males (55.03%) and 67 (44.96%) female patients, with the I-C group including 36 women and 35 men and the C-C group including 47 men and 30 women. Therefore, there was no significant intergroup difference in gender (P=0.151). Also, the participant's mean age was 57.1±21.2 years and 61.2±20.3 years in the C-C and I-C groups, respectively, showing no significant intergroup differences in age (P=0.232). In the I-C group, the mean BMI was 25.04±4.87, 25.44±4.36 for the C-C group (p=0.77). Regarding the fracture type, A2 was the most common fracture type observed in 94 (66.66%) patients. Moreover, 30 (21.27%) and 17 (12.05%) patients had A1 and A3 fractures, respectively. The prevalence of A1 fracture was 25% (n=18) in the C-C group, while A2 and A3 fractures were observed in 47 (65.3%) and 7 (9.7%) patients in this group, respectively. Also, 12 (17.4%), 47 (68.1%), and 10 (14.5%) patients in the I-C group suffered from the A1, A2, and A3 fracture types, respectively. There was no significant difference between the groups in fracture type (P=0.435). In terms of ASA score, in the I-C group, there were 21 patients (29.57%) with type 1, 31 patients (43.66%) with type 2, 14 patients (19.71%) with type 3, and 5 patients (7.04%) with type 4. In the C-C group, there were 23 patients (30.66%) with type 1, 38 patients (50.66%) with type 2, 11 patients (14.66%) with type 3, and 3 patients (4%) with type 4. The two groups had no significant difference regarding ASA score (P=0.37). Regarding Dorr classification, in the I-C group, there were 20 patients (28.57%) with type A, 45 patients (64.28%) with type B, and five patients (7.14%) with type C. In the C-C group, there were 34 patients (48.57%) with type A, 31 patients (44.28%) with type B, and five patients (7.14%) with type C. There was no significant difference between the two groups regarding Dorr classification (P= 0.48).

Post-operative gap was measured in both groups. The mean gap was 2.90±1.62 in the C-C group and 3.48±1.63 in the I-C group with no intergroup significant difference (P=0.11). The intergroup comparisons in age, gender, BMI, fracture type, ASA score, and Dorr classification of the study participants are presented in (Table 1) in detail.

Table 1: Patient characteristics

Variables		C-C (n = 77)	I-C (n = 71)	P value
Age (year)		57.1 ± 21.2	61.2 ± 20.3	0.232
Gender	Male	47 (61)	35 (53.9)	0.151
	Female	30 (39)	36 (50.7)	
Smoker	No	60 (77.9)	59 (83.1)	0.535
	Yes	17 (22.1)	12 (16.9)	
Type of Fracture	A1	18 (25)	12 (17.4)	0.435
	A2	47 (65.3)	47 (68.1)	
	A3	7 (9.7)	10 (14.5)	
BMI		25.44±4.36	25.04±4.87	0.77
ASA score	1	23 (30.66)	21 (29.57)	0.37
	2	38 (50.66)	31 (43.66)	
	3	11 (14.66)	14 (19.71)	
	4	3 (4)	5 (7.04)	
Dorr classification	A	34(48.57)	20 (28.57)	0.48
	B	31 (44.28)	45 (64.28)	
	C	5 (7.14)	5 (7.14)	

According to our findings, the mean TAD was 20.4 ± 6.4 mm in the I-C group and 18.7 ± 5.39 mm in the C-C group immediately after the surgery, showing no significant intergroup difference (P=0.114). However, it decreased in both groups six months later, reaching 18.8 ± 5.8mm in the C-C group and 20.5 ± 8.24 mm in the I-C group with no significant intergroup differences (P=0.094). There was also no significant difference between the two groups regarding TAD decrease (P=0.23). In terms of the NSA, the mean NSA of the fixed femurs was 132.9 ± 5.72° and 134.7 ± 5.19° in the C-C and I-C groups immediately after the surgery, respectively, with no significant difference (P=0.459). The mean NSA six months later was 131.1 ± 5.78° and 131.6 ± 5.76° in C-C and I-C groups, respectively, with no significant difference (P=0.689). Regarding FNAL, the mean post-operative FNAL of the C-C group was 114.7 ± 13.6 mm and 112.1 ± 10.5 mm in the I-C group (P=0.135). After six months, it decreased to 110.7 ± 11.1 mm in the C-C group and 108.5 ± 12.6 mm in the I-C group (P=0.142). The I-C group's mean proximal femur shortening (PFS) was 3.41±7.70 mm, and 4.78±6.85 mm in the C-C group (P=0.25). Regarding the PFS severity, there were 45 mild shortenings (63.4%) in the I-C group and 42 milds (54%) in the C-C group. Moderate shortening happened in 17 (23.9%) and 18 (23.4%) of the I-C and C-C groups. Severe shortening happened in 9 (12.6%) and 16 (20.7%) of the I-C and C-C groups, respectively. The two groups had no significant difference regarding PFS severity (P=0.18). Radiologic results are summarized in (Table 2).

Table 2: The results of the parameters, months 1^{st} and 6^{th} operatively in two groups.

		1^{st} M-Op	6^{th} M Post-Op	P-value**	P-value***
FNAL	C-C	114.7 ± 13.6	110.7 ± 11.1	<0.001	0.778
	I-C	112.1 ± 10.5	108.5 ± 12.6	<0.001	
	P-value*	0.135	0.142		
TAD	C-C	18.7 ± 5.39	18.8 ± 5.8	0.842	0.834
	I-C	20.4 ± 6.4	20.5 ± 8.24	0.876	
	P-value	0.114	0.094		
NSA	C-C	132.9 ± 5.72	131.1 ± 5.78	0.009	0.679
	I-C	134.7 ± 5.19	131.6 ± 5.76	<0.001	
	P-value	0.459	0.689		

*Independent T Test, **Paired T Test ***ANCOVA

Discussion

We reviewed the effect of helical blade position on the surgical outcome of ITF fixed with CMN. Our results demonstrated that the I-C helical blade position achieved the same results as the C-C blade position regarding radiologic parameters. However, higher failure rates are the cardinal drawbacks of the I-C position.

Femoral ITF, due to its high incidence and disability, is one of the leading fractures, especially in fragile and elderly patients [15]. Kligman and Roffman [16] demonstrate that the results of conversion of a failed internal fixation to total hip arthroplasty are unsatisfactory among these patients compared to primary total hip arthroplasty. Consequently, efforts have decreased the CMN failure as the treatment of choice. Previous articles demonstrated the risk factors for failure of ITF fixation and include the base of neck fractures [17], varus displacement, TAD more than 20 to 27, helical blade position not in a C-C or I-C position in the femoral head according to Cleveland zones [18, 19, 20, 21, 22, 23]. However, more studies are still needed to focus on risk factors for failure, especially optimum helical blade position. Thus, we focus on the blade position among patients undergone internal fixation with CMN and assess TAD, FNAL, and NSA, post-operative and 6 months later, in two different conventional positions. Besides radiologic parameters, we followed our cases for at least one year for any complications.

Chang et al. introduced anteromedial cortical support, which results in more stability and decreased implant-related complications [24]. As one of the risk factors of anteromedial cortical support failure, the calcar fracture gap plays a crucial role in predicting fixation failure [25]. As measured in both groups, there was no significant difference in the post-op gap; we did not measure these parameters six months later because the continued gap after six months was presumed to be nonunion. According to the findings, there is no significant relationship between helical blade position and calcar fracture gapping.

Tip-apex distance (TAD), the summation of blade to femoral head distance on AP and Lat radiographs, is shown as a method for evaluating screw position and an important predictor of fixation failure [21, 26]. Of course, many studies have shown the importance of TAD during ITF internal fixation [27]. Based on this study, we use this element to follow our patients and measure the TAD alteration among these two groups. There was no significant difference regarding immediate TAD between the two groups (P=0.114). Also, after six months of follow-up, both groups had no significant difference in TAD (P=0.094). Interestingly, there was no significant alteration difference among C-C and I-C groups (P=0.834). Thus, according to TAD, the C-C helical blade position has no advantage over I-C.

In terms of NSA, it decreased in both groups post-operative. After NSA reevaluation after six months, it was determined that post-op NSA had decreased. These findings showed that varus collapse happened in both groups. Changing the helical blade position could not maintain the immediate post-op NSA, and varus collapse was inevitable. Thus, to reduce varus collapse, inferior positioning of the helical blade took no advantage over center positioning (P=0.679).

As proved by former studies, proximal femur shortening (PFS) is a common complication after CMN of ITF. In practice, PFS is often caused by compression of fracture ends, which intensifies fracture healing [28]. Moreover, PFS is correlated with fixation failure [29]. This crucial element is proven to threaten gait velocity, ambulatory capacity, and hip abductors [29, 30, 31]. PFS ≥ 5 mm reduces the abductor's arm, increases the use of walking aids, and reduces hip discomfort [32]. More than 20 mm of shortening causes claudication and limb dysfunction [33]. According to our data, PFS happened in both groups. There was no difference in the amount of PSF between the two groups. Hence, it was 3.41±7.70 mm in the I-C group and 4.78±6.85 mm in the C-C group (P=0.25). However, the PFS severity between the two groups was not significantly different (P=0.18).

In terms of TAD, NSA, and FNAL, there was no significant difference between the two groups. Hrubina et al. [34] considered that the optimum position of the screw in DHS is in the middle third of the femoral neck to decrease implant failure, and that was confirmed by other studies [35]. Despite Hrubina et al. and Lui et al. results, Kuzyk et al. [11] Considering that lowering the blade's location results in lower failure; moreover, this has been confirmed by other studies [36]. In a retrospective study, Sadic et al. [10] concluded that the optimum blade position remains unknown, as Zeng et al. [35] mentioned that they confirmed our results. Zhang et al. [37] demonstrated that the blade should be the center of the head in a lateral view.

Few studies elaborated on helical blade position in cephalo-medullary nailing in ITF among patients, and most studies were finite element analyses. Despite the scarcity of qualified studies addressing blade position, this randomized controlled trial was designed to identify the optimal helical blade position. The findings from this study help orthopedic surgeons, enabling them to select the best blade position in patients with ITF-treated CMN to minimize the risk of implant failure. Thus, we tried to evaluate two acceptable helical blade positions using radiologic parameters in a randomized controlled study.

Limitation

This current study may be criticized for needing more functional evaluation before and after surgery, excluding the complicated cases during the study, evaluating just good reduction (under the supervision of a hip surgeon), not all types of reductions, and short-term follow-up.

Conclusion

The I-C helical blade position plays a crucial role in ITF fixation. Regarding radiologic parameters, the I-C helical blade position achieved the same results as the

C-C blade position.

Limitation

This current study may be criticized for needing more functional evaluation before and after surgery, excluding the complicated cases during the study, evaluating just good reduction (under the supervision of a hip surgeon), not all types of reductions, and short-term follow-up.

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Conflict of Interest Disclosures

The authors declare no competing interest.

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Authors' Contributions

Reza Zandi: the main surgeon, supervised the project and article writing, Nima Keyhaninejad: gathered data, Ahmadreza Ahmadi Abdashti, Ehsan Akbari, and Nasim Nouri revised the first draft, Mohammad Ali Okhovatpour: article preparation and data analysis.

Ethical Statement

Ethical committee confirmation code: IR.SBMU.RETECH.REC.1399.1369.

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