RESEARCH ARTICLE

Clinical Outcomes of Intramedullary and Extramedullary Fixation in Unstable Intertrochanteric Fractures: A Randomized Clinical Trial

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Abstract

Background: The best method for repairing intertrochanteric fractures is still controversial. The fixation methods include extramedullary (EM) and intramedullary (IM). Studies that compare IM and EM fixations for unstable hip fractures are rare. In this study, our goal was to compare the efficacy of EM and IM fixation in treatment of unstable intertrochanteric fractures.

Methods: A total of 113 patients with unstable intertrochanteric were randomized in this cohort study between March 2016 and June 2018 in trauma center of Kashani and Alzahra Hospitals, Isfahan, Iran. The patients were followed for a period of 12 months with sequential clinical and imaging evaluations. Baseline data were recorded at the time of injury. Radiographs were evaluated immediately post-operatively and at the scheduled follow-up intervals.

Results: A total of 20 of patients were excluded during the study and finally 93 patients (43 males and 50 females) with mean age of 62.74±16.4 completed the follow-up sessions. Mann-Whitney test indicated a significant difference in tip-apex distance between the two groups. While the two groups were homogeneous in the baseline LEM score, it was not significantly different between two groups after 1 and 3 months of surgery as well. However, the LEM score was significantly higher in IM group after 6 and 12 months of surgery.

Conclusion: According to our findings, IM nails (such as the cephalomedullary nail) afforded more advantages over EM devices (such as the DHS and DCS) in the treatment of unstable intertrochanteric fractures. Our results indicated that the final LEM scores as well as the time to union were better in IM fixation group.

Level of evidence: I

Keywords: Extramedullary, Intertrochanteric fracture, Intramedullary

Introduction

Intertrochantric fracture is a severe and prevalent injury that occurs with high mortality rate mainly in the elderly (1). As the population age increases, the number of pelvic fractures increases. The mortality rate varies between 15% and 30% while the best way to repair the intertrochanteric fractures is still unclear (2). The surgical treatment options include extramedullary (EM) and intramedullary (IM) fixation. Intertrochanteric fractures with the following characteristics are all unstable: 1) multi-part posteromedial site fracture;

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2) reverse oblique fracture line; 3) extension of the fracture line to subtrochanteric region; and 4) type 2 intertrochanteric fracture (AO/31-A2) (3).

Surgery is the common therapy for intertrochanteric fractures as this fracture takes a long time to heal on its own. Open reduction and internal fixation (ORIF) is one of the surgical treatments for this fracture (4). Based on the location and type of the fracture different kinds of fixation devices are used (5). However, the best repairing method for intertrochanteric fractures is still controversial. EM fixation of unstable intertrochanteric fractures involves the application of a plate and screws to the lateral side of the proximal femur. In external fixators, the stabilizing component is held outside the thigh by pins or screws driven into the bone (4). IM fixation is used in segmental and compound fractures, unstable fractures, or with poor skin condition or osteopenic bones. It consists of a rod that is placed in the femur bone channel and hinged in the upper part through a screw.

The Dynamic Hip Screw (DHS) is used to fix the femoral head to the femur shaft and control the femoral head movements. Dynamic compression allows the bone to carry weight and places the bone under remodeling and repair of the fracture. Since the screw does not support the mainstay of the proximal part of the device, proximal segment can slide towards the lateral side when put under weight pressure. This can lead to detachment of the device and more importantly, malunion or non-union. Dynamic Condilar Screws (DCS) put perpendicular forces on the weight-bearing site and seem to be a better device from this point of view.

Studies that compare IM and EM fixations for unstable hip fractures are rare. Our goal in this study was to compare the efficacy of EM and IM fixation in treatment of unstable intertrochanteric fractures.

Materials and Methods

Study population and design

All patients with unstable intertrochanteric femoral fractures in trauma center of Kashani and Alzahra Hospitals, Isfahan, Iran, were randomized in this cohort study between March 2016 and June 2018. The surgeons were assigned, in turn, to perform all operations (EM or IM fixation). All orthopedic devices used in the present study were provided by Osveh Asia Medical Instrument Company, Mashhad, Iran. A written informed consent was obtained from all patients prior to the enrollment. The study was approved by the ethics committee of "Isfahan University of medical sciences, Isfahan, Iran" (IR.MUI.REC.1395.3.987).

The patients were assigned into one of the two groups for two different treatment methods (EM (DHS or DCS) or IM fixation). Surgical groups were categorized in accordance to the fixation method: 1) Dynamic Hip Screw (DHS group); 2) Dynamic Condylar Screw (DCS group); and 3) Cephalomedullary nail (IM group).

The inclusion criteria included: 1-unstable intertrochanteric fracture, 2- being candidate for EM (DHS or DCS) or IM surgery (using cephalomedullary nail), 3-ability to walk without any assistance before the fracture, and 4- signed the informed consent. Patients with uncontrolled diabetes mellitus, individuals using immunosuppressive drugs and patients with any kind of malignancies as well as those patients who refused to continue the trial were excluded from this study.

Randomization into the groups was performed using stratification and blocking methods. Each surgeon performed identical numbers of both types of operations in order to minimize the surgical bias. The patients' radiological and functional statuses during follow-up examinations were reordered.

Data collection and outcome measurements

Quantitative data, including age, weight, height, body mass index (BMI), shortening of lower limb, lower extremity measure (LEM) score (6) and tip-apex distance were expressed as mean or median and data such as gender, mal- or non-union (evaluated by x-ray graphy), postoperative infection, device failure, need for re-intervention and past medical history were expressed as percentile information. The LEM score and significant limb shortening considered as the primary outcomes while device failure and need for reoperation were considered as secondary outcomes.

The actual limb length was measured from the anterior superior iliac spine to the medial malleolus. Limb shortness more than 2 cm was considered as significant shortening and measured as the actual length of the limb in comparison with the healthy foot, three months after surgery. The tip-apex distance was estimated based on the total distance from the tip of lag screw to the center of the femoral head apex which is the sum of the measurements on the anteroposterior and lateral radiographs [Figure 1].

The LEM score included: getting out of bed, getting in/out of bathtub, getting on/off toilet, showering, putting the pants, stockings, and shoes on, raising from chair, standing upright, kneeling, getting up from kneeling, bending to pick something up off the floor, sitting, walking upstairs/downstairs, walking inside/out-side, walking up/down ramp, getting in/out of car, using public transportation, socializing with friends/family, performing and finishing usual daily activities, gardening/yard work, preparing own meals, spending usual amount of time doing daily activities, doing light/heavy house work, and food shopping. This rating is summarized in the appendix. Device failure criteria included: 1) cut out 2) migration of screw 3) breakage of implant. The diagnosis of postoperative infection was based on the clinical signs and laboratory findings.

We obtained radiographic plains from patients for the evaluation of fracture union. We also defined fixation success as the presence of fracture healing (union), maintenance of reduction, and in the absence of any major complication [Figure 2].

Follow up

Patients were followed for a period of 12 months with sequential clinical and imaging evaluations. Baseline data were registered at the time of injury. Radiographs were evaluated immediately post-operatively and at the scheduled follow-up intervals. The clinical evaluations

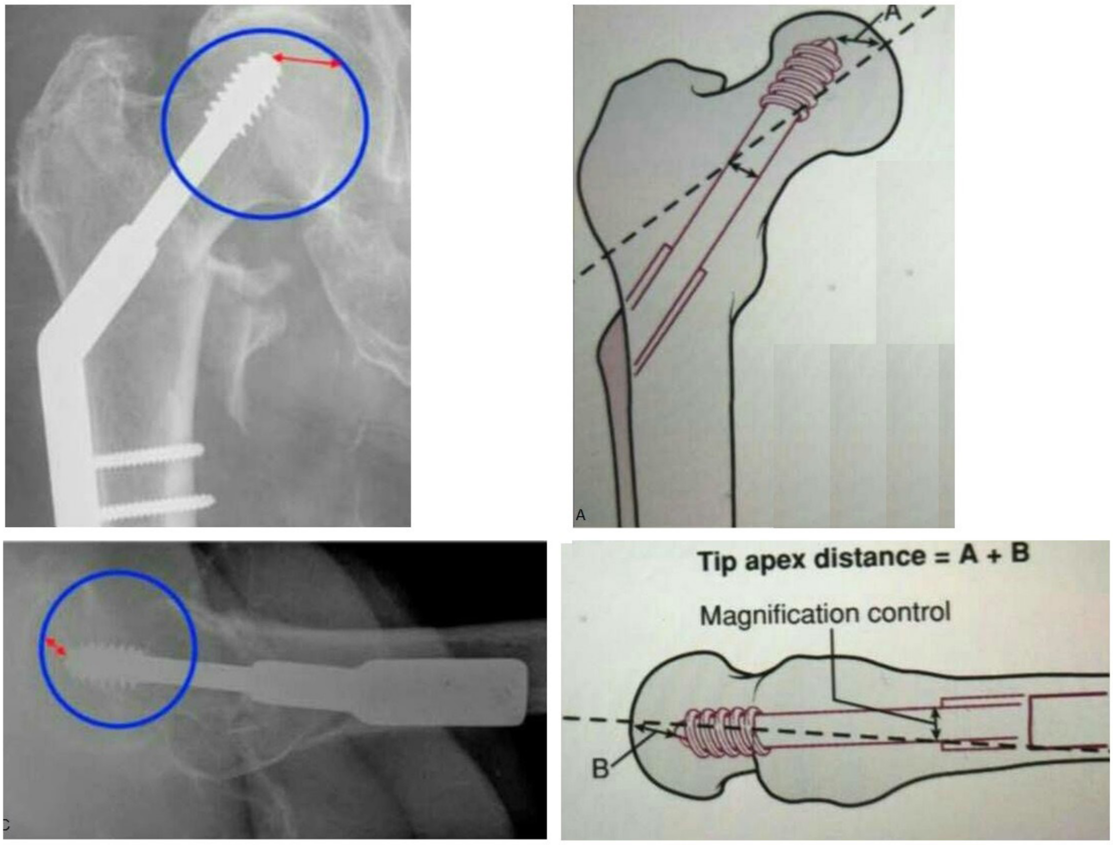

Figure 1. Measurement of the tip-apex index (A), which consists of the sum of the measurements of the anteroposterior and lateral radiographs. (B,C)

Appendix: LEM score	
1	impossible[completely unable to do]
2	extremely difficult
3	moderately difficult
4	a little bit difficult
5	not at all difficult
6	task not applicable

were performed at the 2nd and 6th week as well as the 3rd, 6th, and 12th months of study. It should be noted that the ability to perform daily activities was mentally investigated. Patients were asked whether they can perform the same preoperative activities after the surgery.

Statistical analysis

Descriptive statistics were used to compare the basic characteristics of patients in both groups. Data were analyzed using student's unpaired test and chi-squared test. Independent t-test was used for the analysis of quantitative data and chi-square and fisher's exact test were used for nominal data. A *P<0.05* was considered as statistically significant. Data are given as mean ± standard deviation (SD). Statistical analyses were performed using SPSS for Windows software (ver. 22; SPSS Inc., Chicago, IL, USA).

Results

Demographic characteristics

A total of 113 patients with unstable intertrochanteric fractures were assessed, however, 20 0f them excluded during the study [Figure 3]. Finally, 93 patients (43 males and 50 females) with mean age of 62.74±16.4 completed the follow-up sessions. The patients' baseline characteristics and demographic information are demonstrated in Table 1. Independent t-test showed no significant difference between the two groups of IM and EM regarding age, BMI, fracture mechanism, and sex distribution. Thirty-eight patients (41%) underwent fixation with cephalomedullary nail and 55 patients (59%) underwent fixation using EM screws, including 43% and 16% in DHS and DCS group, respectively.

Radiographic findings

Evaluating each patient's radiographic outcomes at

Figure 2. Radiographs of the IM devices applied in our study. Before operation (A) After six weeks (B) After 6 months, complete fusion (C).

different checkpoints of the follow up demonstrated that the mean TAD was 20.52±3.7 and 21.50±3.0 in EM and IM groups, respectively (*P=0.01*) Mann-Whitney test indicated a significant difference in tip-apex distance between the two groups (*P=0.01*).

Clinical features

LEM score was measured and analyzed at baseline, one, three, six, and 12 months after surgery [Table 2]. T-test revealed no significant difference in baseline LEM score between the two groups. Also, LEM score was not significantly different between the two groups after 1 and 3 months of surgery. However, it was significantly higher in IM group after 6 and 12 months of surgery.

Given the fact that we considered limb shortening of 20 millimeters or more as significant shortening of the lower limb, 20.4% of the patients have had developed shortening of the limb in 12th month of their follow-up. 20% of patients developed limb shortening; however, significant limb shortening (>20 millimeter) was significantly higher in EM group (*P<0.05*).

Return to previous (before fracture) level of activity was faster in IM group compared to the EM group (5 vs 8.2 months, *P<0.001*).

Surgery complications

Regardless of surgery technique, 68.8% % of the total number of patients did not encounter any type of post-operative complications. 10.7% developed post-surgical infection. Postoperative complications were not significantly different between the two study groups. Moreover, device failure and necessity for secondary fixation was non-significantly higher in EM group.

Eight patients in EM group experienced post-surgical infection (superficial infection in 6 patients and deep infection in 2 patients). Superficial infections were treated with wound care and antibiotic therapy. One patient with deep infection was treated with irrigation and debridement. Another case who suffered from implant failure underwent device removal and osteosynthesis after infection control [Figure 4]. Two patients in IM group were infected and treated with wound care and antibiotic therapy. Device failure took place in eight patients in EM group; three of whom were likely due to poor fracture reduction, three cases happened in spite of good fixation and reduction, and two cases failed due to high TAD and inappropriate implant position. Two patients in IM group experienced device failure, one of whom was likely due to high TAD and another one because of poor reduction. Need to reoperation found in 12 patients in EM group; two of whom was due to non-union and one patient underwent total hip arthroplasty and another one underwent osteotomy and osteosynthesis. Two of whom were due to infection. Five patients needed reoperation due to device failure. Total hip arthroplasty was performed for two of them [Figure 5]. Another three patients underwent osteosynthesis and retraction. Three patients were bed-ridden and this was the cause of device failure. They were unable for reoperation because of their inappropriate medical condition. Reoperation was performed in three patients in IM group; of whom, two patients underwent total hip arthroplasty and one patient underwent reduction and osteosynthesis.

Discussion

The best management of intertrochanteric fractures remains controversial. Cephalomedullary nail and DHS have been the most commonly used devices to fix these fractures over the past decade (7). For unstable intertrochanteric fractures, an interamedullary fixation is better in biomechanics, and many clinical benefits have been suggested for this method (8).

In our study, postoperative complications were not significantly different between the two study groups. Moreover, device failure and necessity for secondary fixation was non-significantly frequent in EM group. EM and IM fixation were comparable in terms of postoperative stiffness and survival during cyclic testing (9). A previous study has shown a high degree of nail failure in stable fractures, therefore, IM fixation was preferred during unstable intertrochanteric fractures (9). A review article in 2004 on treatment of unstable intertrochanteric fractures with EM devices showed that displacement and dislocation rates were high in this method of fixation (7, 10). Also wounds and infections are more common in this method. Treatment of unstable

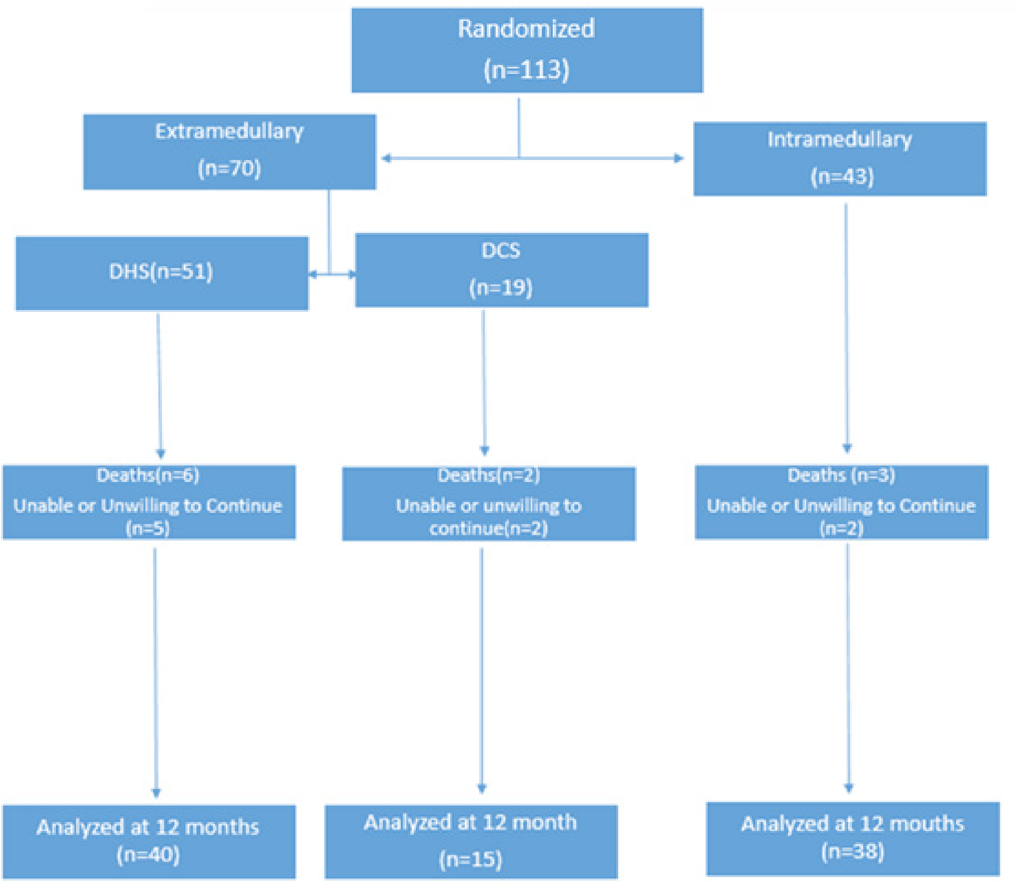

Figure 3. Patients' enrollment and follow-up algorithm.

Table 1. Baseline characteristics and demographic features of patients

Variable EM (55 patients)		**Group**		***P-value***
		IM (38 patients)		
Age		61.45±17.0	64.40±15.5	0.46
Gender	Male	26 (47.2%)	17 (44.7%)	0.83
	Female	29 (52.7%)	21 (56.2%)	
Fracture mechanism	Falling	35 (63.63%)	27 (71.0%)	0.50
	Motor to vehicle accident	20 (36.3%)	11 (28.9%)	
Body mass Index (BMI)		25.03±3.9	25.17±4.7	0.47
BMI status	Underweight	3 (5.4%)	5 (13.1%)	0.30
	Normal BMI	25 (45.4%)	11 (28.9%)	
	Overweight	21 (31.1%)	16 (42.1%)	
	Obese	6 (10.9%)	6 (15.7%)	

Table 2. Comparison of radiographic and clinical findings among two extra- and IM groups

Variable/Time Point	Mean (SD) or %		*P value*
	EM(55 patients)	IM (38 patients)	
Lower limb shortening (mm)	13.23±5.46	9.3±4.02	0.87
Significant lower limb shortening (N-%)			
No	40 (72.7%)	34 (89.4%)	<0.001
Yes	15 (27.2%)	4 (10.5%)	
LEM (points)			
Baseline	70.65±9.8	71.24±9.3	0.18
6 weeks	44.94±9.3	42.92±2.7	0.13
3 months	53.41±8.3	56.07±9.7	0.25
6 months	61.18±9.4	65.86±9.5	0.03
12 months	64.56±9.4	69.34±8.9	0.02
Post-operative complications			
Infection	8 (14.5%)	2(5%)	0.15
Non-union	2 (3%)	1 (2%)	0. 78
Return to previous activity (months)	8.25±1.7	5.05±1.3	<0.001
In less than 6 months	10 (18.1%)	30 (81.57%)	<0.001
In more than 6 months	45 (81.81%)	7 (18.4%)	
Device failure	8 (14.5%)	2 (5%)	0.15
Secondary Fixation	9 (16%)	3 (8%)	0.23
Tip-apex distance (mm)	20.52±3.7	21.50±3.0	0.01

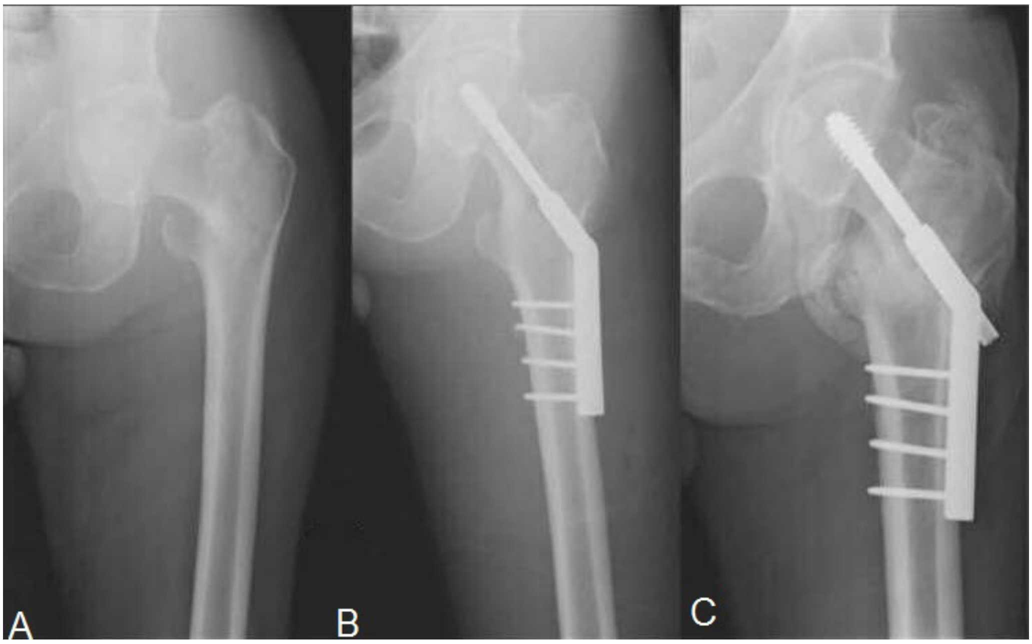

Figure 4. A: Unstable intertrochanteric fracture in a 65y/o man. B: The patient underwent fixation with DHS. C: 6 weeks after surgery. Reduction failure due to infection.

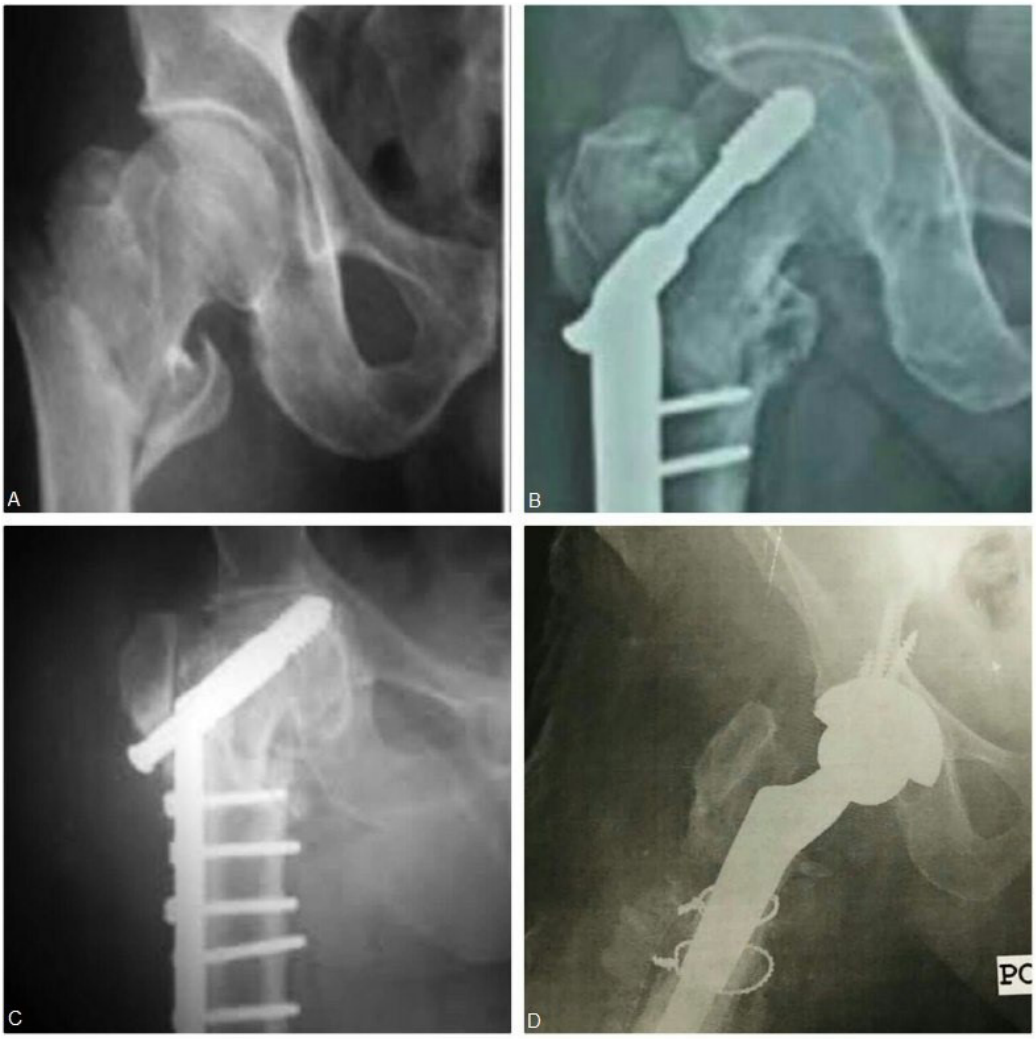

Figure 5. A: Unstable intertrochanteric fracture type 31-A2. B: Fixation with DHS. It seems that reduction is not done well and TAD is higher than normal. C: Penetration of femur head three months after surgery. D: Total hip arthroplasty 6 months after first reduction.

intertrochanteric fractures with IM devices showed less side effects and needed less reoperation (11). DHS placement is not safe and effective compared with novel IM techniques in already vulnerable patients with unstable intertrochanteric fractures. In patients with stable fractures, IM fixation did not afford any advantage (9). Verettas et al, in a prospective randomized study found no significant difference between the two methods of fracture stabilization in terms of perioperative systemic effects (12).

We found that cephalomedullary technique has a significantly lower rate of non-union in this follow-up. In the comparison between the two mentioned techniques made by Reindl et al., EM device had a higher prevalence of non- and mal-union due to its favorable biomechanical properties, allowing direct full weight-bearing (13). Proximal femoral shortening is associated with gait impairment and lower physical function. In the present study, LEM was considered as the main hip-specific functional outcome assessment tool. We found that patients were not significantly different regarding LEM score. This result of ours is inconsistent with the literature since Gilat et al. concluded that there is an association between higher amounts of proximal femoral shortening and fixation failure (14). However, Reindl et al. used LEM as their main hip-specific functional test and suggested that lower scores of LEM do not necessarily mean that the patient will have a lower physical function (13). In the study of Saudan et al, social function and mobility of patients were compared in two groups that were treated with cephalomedullary nail and DHS, 3, 6 and 12 months after surgery. According to the results of their study, there were no significant differences in 12 months follow-up of patients in terms of return to preoperative level of ability and independence between these two groups (15). Another study compared functional recovery in 12 months after IM or EM fixation of intertrochanteric fractures; final assessments revealed that there were no differences between the two groups in recovery score.

Our study had some limitations. First, our sample size was small; second, our study had short duration of follow-up. Further studies with larger samples and longer duration of follow-up are required to confirm our findings.

According to our findings IM nails (such as the cephalomedullary nail) afforded more advantages over EM devices (such as the DHS and DCS) in treatment of unstable intertrochanteric fractures. Our data indicated that the final LEM scores and the times to union were better in IM fixation group.

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