

RESEARCH ARTICLE

Comparison of the Dynamic Hip Screw with the Dynamic Hip External Fixator for Intertrochanteric Fractures: Report of a Randomized Controlled Trial

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Abstract

Background: Pelvic fracture is one of the most common fractures in the elderly, especially in the intertrochanteric region. Therefore, in the present study, an external fixator was designed specifically for intertrochanteric fractures. The present study aimed to compare the operating time, amount of bleeding, and mortality rate between the patients who received either dynamic hip external fixators (DHEF) or dynamic hip screw (DHS).

Methods: In 2018, 46 patients with intertrochanteric fracture due to trauma and high anesthesia risk were included in the study and randomly assigned to two groups of control (n=24, patients treated with DHS) and intervention group (n=22, patients treated with the DHEF). Treatment was carried out using the DHEF which was newly designed and placed outside the patient's body under short and light anesthesia. After 3 and 12 months of follow-up, the two groups were compared for some variables, including mortality rate, pain intensity, Harris hip score (HHS), cut-off rate of the device, femoral neck angles before and after the operation, hemoglobin changes, hematocrit levels before and after the operation, the number of injected blood units, and the number of hospitalization days.

Results: Mortality rate was higher in open surgery with DHS. The assessment of variables in both intervention and control groups demonstrated that duration of operation ($P<0.001$), hospitalization length, time to union ($P=0.001$), pain intensity five days after the operation, as well as changes in Hb and HCT, were significantly higher in the control group than the intervention group. The mean HHS scores of 83.5 ± 14.3 and 78.2 ± 11.5 were gained for the DHEF and DHS groups, respectively ($P=0.22$).

Conclusion Considering the superior results of treatment with the external fixator in comparison with the DHS, such as lower mortality rate and fewer complications, a dynamic hip external fixator can be prescribed in patients with intertrochanteric fractures and high anesthesia risk.

Level of evidence: I

Keywords: Dynamic hip screw, Dynamic hip external fixator, Intertrochanteric fracture

Introduction

Pelvic fracture is one of the most common fractures in the elderly, especially in the intertrochanteric region (1, 2). This fracture is

more likely to occur in the elderly who have chronic diseases (such as diabetes, pulmonary heart diseases, and hypertension) and poor tolerance for surgery (3).

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Moreover, open reduction and fixing the fractures with an internal device cause bleeding and stress, leading to a high number of postoperative deaths (4). Therefore, in many cases, surgeons are obliged to refuse to perform an operation on the patient, which in turn, leads to a pressure ulcer, deep vein thrombosis, brain and lung embolisms, and sometimes patient's death (5). Even in the cases where the patients are able to withstand such conditions, the limb shortens and malunion occurs (6).

The external fixators were not commonly used for intertrochanteric fractures in the past (7, 8). Primary uses of external fixators for pelvic fractures resulted in some complications, such as loosening of the pins, infections, and varus collapse of the femoral head (9). Nevertheless, today, with improvements in the therapeutic procedures, satisfactory results have been reported in the studies conducted in European countries with 95%-100% of improvement (7, 10-12). It is used for specific groups due to the considerable advantages of this device, such as shorter operation time, less bleeding, and the possibility of using this device without general anesthesia (13). The use of local anesthesia is a major advantage of external fixators, which is absent in other methods (14, 15). In this regard, several studies have recommended using them for American Society of Anesthesiologists (ASA) class III and IV patients (12, 16-18).

It is also suitable for patients with high anesthesia risk. This device consists of an external fixator with two or three of its pins at neck and femoral head regions extending to a 10 mm distance from subchondral bone (19). Therefore, considering its merits and demerits, the present study aimed to compare the use of the external fixator with the old dynamic hip screw (DHS). To this end, an external fixator was designed specifically for intertrochanteric fractures, placed outside the patient's body under short and light anesthesia and without bleeding, and was extracted after the union of the region. In this device, similar to the DHS, there is a section that dynamically compresses the trochanteric region and, in fact, it is a dynamic hip external fixator (DHEF).

Therefore, the present study was conducted to answer the following main question: Is the mortality rate reduced in patients treated with the DHEF, compared to those who received the DHS with intertrochanteric fracture and high risk of anesthesia? Do function and radiologic indexes differ in the two study groups? Do the complications differ in the group treated with the DHEF, compared to those who used the DHS? The working hypothesis was that the DHEF may result in superior outcomes for patients with high anesthesia risk and intertrochanteric fractures.

Materials and Methods

Study design

The present parallel randomized controlled trial was performed on 46 patients with intertrochanteric fractures referring to the Imam Reza Hospital in Mashhad, Khorasan Razavi province, Iran, in 2018. This study was started after obtaining an approval from the Ethics Committee of Mashhad University of Medical Sciences (IR.MUMS.REC.1396.331), registration in the Iranian registry of clinical trials (IRCT20181015041344N1).

Inclusion and exclusion criteria

Adult patients with type 1 and 2 intertrochanteric fractures according to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification were eligible to be included in the study (20). All the patients had high anesthesia risk according to the American Society of anesthesiologist (ASA) Classification (patients at risk of ASA anesthesia classes of III and IV). On the other hand, all the patients with previous hip fractures, fracture secondary to tumors, soft tissue or bone infections in the area of operation, history of chemotherapy, simultaneous fractures at other locations, previous hip deformity, and those who were unwilling to continue the study were excluded from the study.

Randomization

Patients were randomly assigned to two groups of A (treatment with DHS) and B (treatment with DHEF) by simple randomization [Figure-1] using a computer-generated sequence that was kept in the sealed envelopes. In the course of operation, the variables of operation time and the amount of transfusion of the packed cells were recorded.

Technical details regarding the Dynamic Hip External Fixator

The DHEF is a type of external fixator which is specifically designed for intertrochanteric fractures. It has a dynamic part that compresses the fracture site, similar to what happens in the DHS [Figure.2 number 1, 5, and 8, as well as Figure.3]. The Schanz pins are connected at the anterolateral femoral shaft in a triangular manner away from the anus.

The DHEF consists of a head, a semi-lunar part, a short rod, long rods, a sliding core, pulleys, a semi-lunar part-head connecting screw, a compression screw, an above-the-head screw, a nutting screw, and rod screws [Figure.2]. The dynamic part consists of a sliding core gliding in the head, allowing the surgeon to get double-stage compression at the end of the operation and two weeks later in the clinic. The innovators believe that the double-stage compression accelerates the union by compressing the femoral neck to the intertrochanteric region. The semi-lunar part in the DHEF places the Schanz pins in the anterolateral thigh, away from the anus region, providing more comfort at lying position. Three-dimensional placement of Schanz pins with the help of long and short rods provides additional stability for distal femoral shaft fixation [Figure.4]. It is noteworthy that this device has received national approval.

Surgical technique for Dynamic External Fixator insertion

After setting up the operation room (patients transport to the fracture table, controlling the C-arm for correct imaging during the surgery, and closed reduction maneuvers), preparation and draping will be performed. One 20-mm Steinmann pin will be inserted percutaneously just superior to the inferior calcar region with an angle between 120 and 150 degrees under fluoroscopic control. It is better to suit the pin in the center of the femoral neck under the lateral view of fluoroscopy. The pin should pass

through the pinhole in the inferior site of the jigs. Predrilling through the inferior Schanz hole should be performed by the 3.2mm drill bit. Thereafter, a 250*5 mm Schanz pin is inserted up to 5 mm of the articular surface of the femoral head. The surgeon can select a 17 or 20 mm sliding core depending on the femoral neck diameter.

The suitable jig helps the surgeon to predrill and insert the next Schanz pin. Nutting screws can tighten the sliding core over the Schanz pins 5-7 cm close to the skin. The head of the DHEF will be suited over the sliding core.

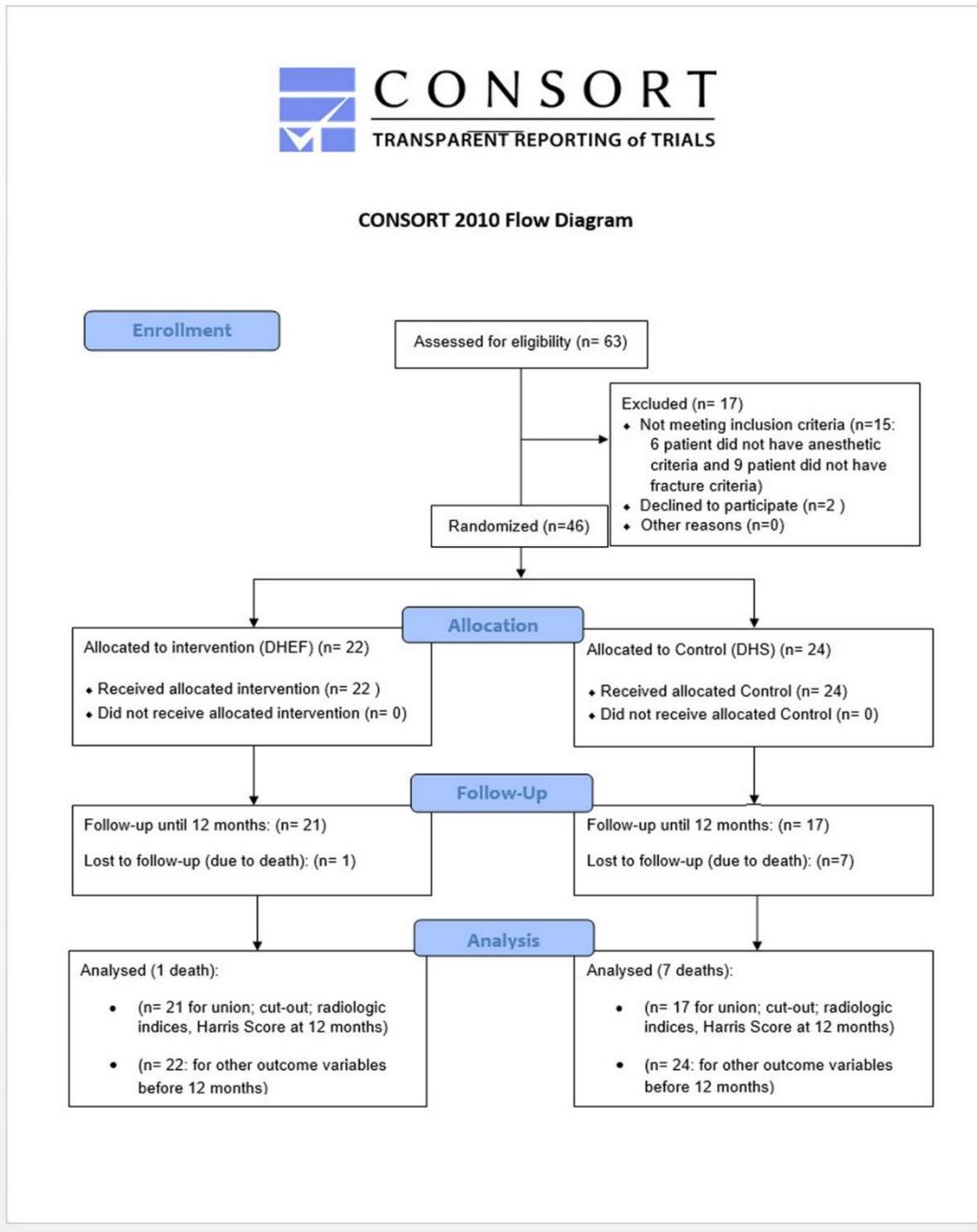


Figure 1. Study design at a glance

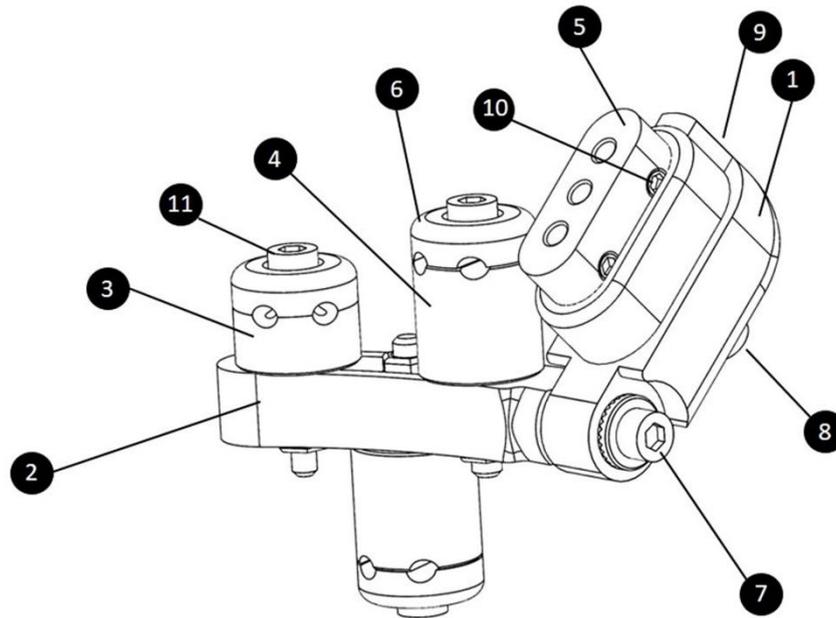


Figure 2. Dynamic External fixator components: 1: Head, 2: Semi-lunar part, 3: Short rod, 4: Long rod, 5: Sliding core, 6: Pulley, 7: Semi-lunar part-head connecting screw, 8: Compression screw, 9: Above the head screw, 10: Nutting screw, and 11: Rod screw

The above-the-head screw fixes the sliding core within the DHEF head with a maximally allowed distance to perform the maximal compression at the fracture line. The orientation of the semi-lunar part will be adjusted so that it is posteriorly fixed with the DHEF head. Thereafter, one short and one long rod will be fixed in the superior side of the semi-lunar part anteriorly and posteriorly, respectively. One long rod will be fixed inferiorly between two superior rods.

The 150*5 mm Schanz pin will be inserted in the proximal femoral shaft with a bicortical purchase by the guidance of the pulley above rods. The thinner sleeve is entered in the thicker one, and the sleeves are then placed in the related rod hole to place the shaft Schanz pins. Following that, an incision is made in the skin, and the sleeves are placed on the femoral shaft. Thereafter, both cortices should be drilled with a 3.2 mm drill bit. After the removal of the thinner sleeve and the drill bit, the 5*150 Schanz pin can be placed. A similar procedure is performed for other rods. Traction from the leg will be released to compress the fracture line. Subsequently, tightening the compression screw will pull the sliding core into the DHEF head and compress the femoral neck into trochanteric metaphyseal bone (stage one of fracture compression).

Tightening the nut screw will fix the position of the sliding core in the head, compression dressing around the pins will be applied, and finally, the patient is transferred to the recovery room. Gait training with a walker begins the day after the surgery. Compression dressing should

be changed daily. Nut screws can be released two weeks after the surgery to allow more dynamic compression in the patients who are able to walk. For non-ambulatory patients, the compression is applied with tightening of the compression screw at this time (stage two of fracture compression). The estimated time to achieve the radiologic union is about 2.5 and 3.5 months in the ambulatory and non-ambulatory patients, respectively. The external fixator will be removed after the union [Figures 5, 6].

Follow-up and Outcome Parameters

The demographic data were collected after the enrollment of the subjects. Before the operation, the degree of osteoporosis (assessed using the dual-energy x-ray absorptiometry (DEX) method in the opposite side hip and the spine), hemoglobin concentration, and hematocrit levels of the patients were checked. After the operation, the length of hospital stay and the patient's pain intensity (using the visual analog scale) were recorded five days after the operation. It is noteworthy that 12 months after the operation, mortality rate, radiographic reduction criteria (e.g., varus and valgus, as well as the displacement of parts in relation to each other), rate of complication (e.g., cutout, pin tract infection, and shortness of limb), and the final hip function status were investigated by an assessor blind to treatment based on the Harris hip score (HHS).

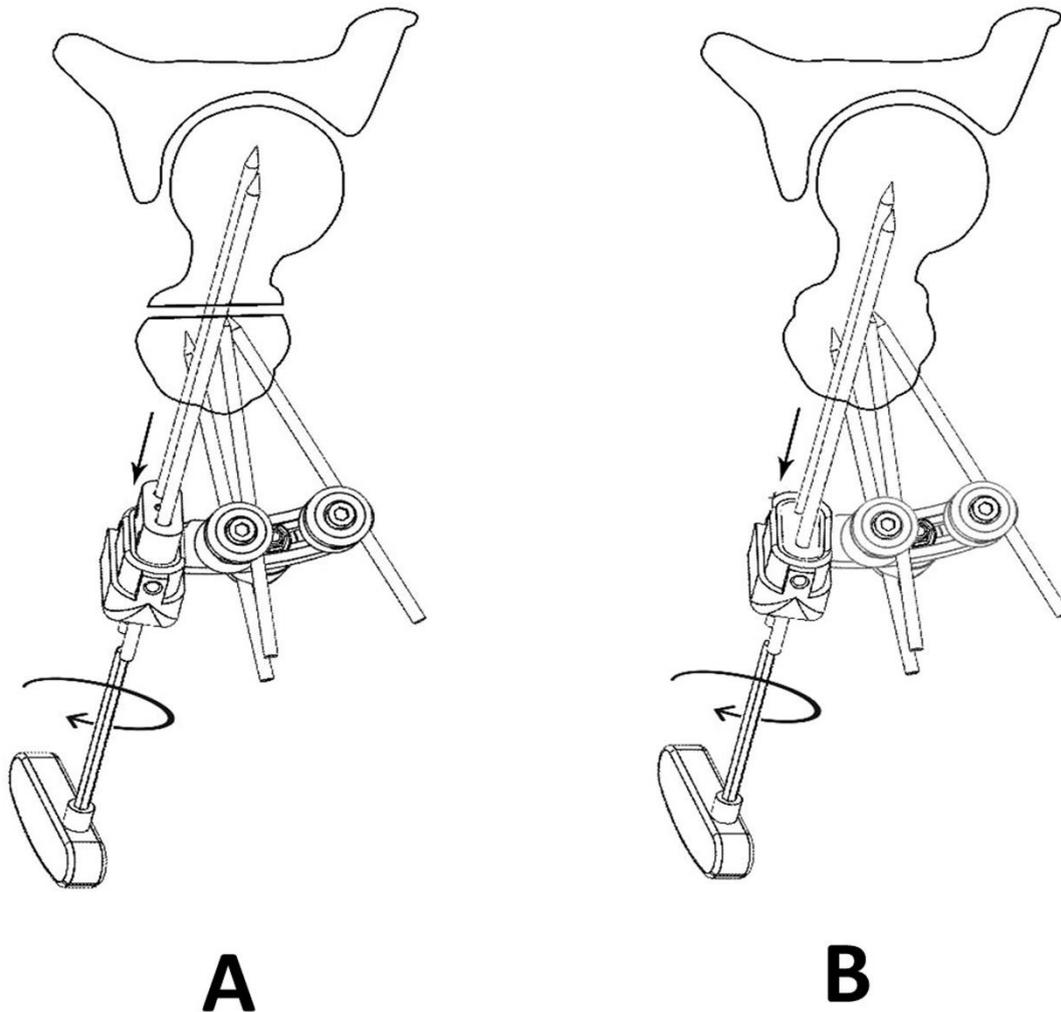


Figure 3. First stage fracture compression. A: Before core sliding in the head, B: After sliding

Time to union was measured in the DHEF-treated group at the time when the external fixator was removed, while in the DHS group, it was performed according to the serial radiography in the follow-up visits.

Statistics (Measurements)

American Society of Anesthesiologists (ASA) Scale

This questionnaire was used to assess the physical condition of patients before the surgery in five classes ranging from a normal healthy patient to a dying patient

who is not expected to survive (21).

Harris Hip Score (HHS): It is a validated tool to assess the pelvic surgery results and is intended to evaluate the disabilities and treatment methods. The original version was published in 1969. The HHS is a physician-based measure used by a health care professional, such as a physician or a physical therapist. The domains of the questionnaire included pain, performance, absence of abnormalities, and range of motion (22).

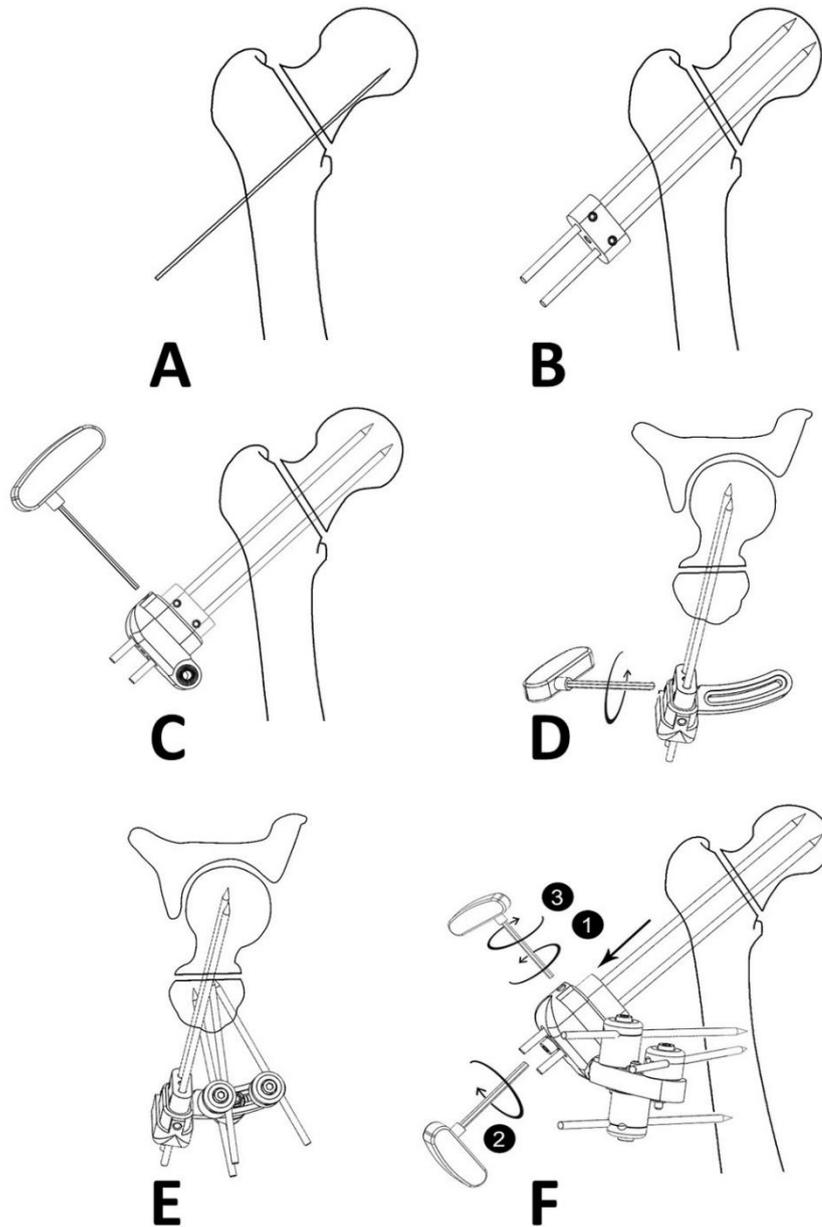


Figure 4. Technique of Dynamic Hip External Fixator Insertion: A: One 20mm Steinmann pin will be inserted percutaneously just superior to the inferior calcar region angled between 120 and 150 degrees under fluoroscopic control. B: Two 250*5mm Schanz pins are inserted up to 5 mm to the articular surface of the femoral head parallel to the pin using the specific jigs. Nutting screws can tighten the sliding core over Schanz pins 5-7 centimeters close to the skin. C: Head of the dynamic hip external fixators (DHEF) will be suited over the sliding core. The above the head screw fixes the sliding core within the DHEF head with maximally allowed distance to permit maximal compression at the fracture line. D: Orientation of the semi-lunar part will be adjusted so that it fixes with the DHEF head posteriorly. E: Femoral shaft Schanz pins insertion. F: First stage fracture compression

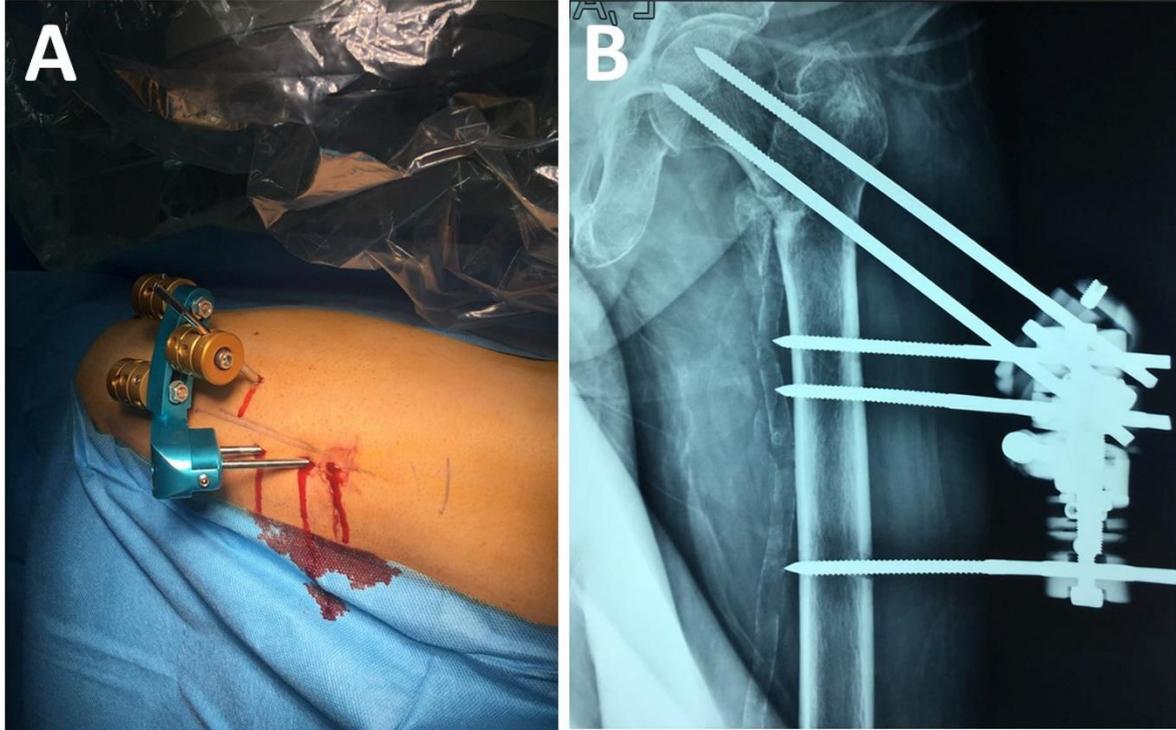


Figure 5. A: Dynamic Hip External Fixator after insertion in the operation room, B: post-operation anteroposterior radiograph of fixed and compressed intertrochanteric fracture

Statistical Methods

Data analysis was performed in SPSS software (version 16.0) (SPSS Inc., Chicago IL). Differences in categorical variables (e.g., gender, AO classification, and anesthetic risk) were tested by the Chi-Square or Fisher's exact tests. Based on data distribution, the mean of continuous variables was compared between two study groups using the Mann-Whitney U test or the Student's t-test. A p-value less than 0.05 was considered statistically significant.

Results

The mean age of the patients with femur intertrochanteric fracture was reported as 77 ± 7.8 years (23 males and 23 females). Table 1 displays other demographic indexes. The two study groups did not significantly differ in terms of age, gender, anesthesia class, osteoporosis, and fracture type [Table 1].

Mortality

The mortality rate was lower in the group treated with the DHEF, as compared to that in the DHS group (1 out of 22 patients in the DHEF-treated group and 7 out of 24 patients in the DHS group, $P=0.049$) [Table 2].

Function

There was no significant difference in the HHS between the two study groups in 3 and 12 months after the operation [Table 3]. The intensity of pain five days after the operation was significantly lower in the DHEF-treated group, as compared to that in the DHS group [Table 3].

Radiological outcomes

There was no significant difference in the radiological indices, such as femoral neck angles in both anterior-posterior (AP), lateral views, and shortness of limbs 12 months after the surgery, between the two groups [Table 3].

Complications

In terms of complications, union time was shorter in the DHEF-treated group, as compared to that in the DHS group; nonetheless, the final union rate did not differ between the two groups ($P>0.99$) [Table 2 and 3]. There was no significant difference in the cut-off rate between the two groups ($P=0.682$). No infection was observed in the DHS group; however, 15 (71.8%) patients had some degrees of pin tract in the DHEF-treated group [Table 2, 3, and 4].

Table-1. Baseline characteristics in two groups (Dynamic external fixator and DHS)

| Variables | Kind of operation | N | Mean | Std. Deviation | P value* |
|---------------------------------------|-------------------|--------|---------|----------------|----------|
| Age | External Fixator | 22 | 79 | 8.821 | 0.348 |
| | DHS | 24 | 76.54 | 8.758 | |
| L.T score | External Fixator | 21 | -2.3619 | 0.9917 | 0.936 |
| | DHS | 16 | -2.3894 | 1.04872 | |
| H.T score | External Fixator | 21 | -2.5952 | 1.06746 | 0.077 |
| | DHS | 16 | -2.0356 | 0.69707 | |
| Variables | Kind of operation | Values | | P value** | |
| Sex (Men, Women) | External Fixator | 10, 12 | | 0.768 | |
| | DHS | 13, 11 | | | |
| AO classification (Type 1, Type 2) | External Fixator | 9, 13 | | 0.138 | |
| | DHS | 16, 8 | | | |
| anesthetic risk (ASA3, ASA 4) | External Fixator | 16, 6 | | 0.484 | |
| | DHS | 20, 4 | | | |

*Mann-Whitney Test; ** Fisher's exact test
L=Lumbar, H= Hip, DHS=Dynamic Hip Screw

Table-2: Compression of treatment outcome in trochanteric fractures with DHS or DHEF (qualitative variables)

| Variable | DHEF | DHS | P value* | Relative Risk |
|---------------|------|-----|--------------|---------------|
| Union (n=39) | | | | |
| Yes | 20 | 18 | >0.99 | 0.52 |
| No | 1 | 0 | | |
| Cutout (n=39) | | | | |
| Yes | 3 | 4 | 0.682 | 0.71 |
| No | 18 | 16 | | |
| Death (n=46) | | | | |
| Yes | 1 | 7 | 0.049 | 0.15 |
| No | 21 | 17 | | |

*Fisher's exact test
DHEF=Dynamic Hip External Fixator, DHS=Dynamic Hip Screw

Table-3. Compression of treatment outcome in trochanteric fractures fixed with DHS or DHEF

| Variable | Number | DHEF | | DHS | | P value | |
|--------------------------|--------|--------|--------|--------|--------|---------|---------|
| | | Mean | SD | Number | Mean | | |
| Operation time (minutes) | 22 | 47.86 | 9.224 | 24 | 114.38 | 38.002 | <0.001* |
| PC transfusion (no) | 22 | 0 | 0 | 24 | 1.5 | 1.251 | <0.001* |
| Hb (before OP) | 22 | 11.791 | 1.7926 | 24 | 12.088 | 1.9922 | 0.599** |
| Hb(after OP) | 22 | 11.355 | 1.7366 | 24 | 10.367 | 1.6423 | 0.053** |
| HCT(before OP) | 22 | 35.132 | 4.7488 | 24 | 35.704 | 5.4926 | 0.708** |

| | | | | | | | |
|-----------------------------------------------|----|--------|---------|----|--------|---------|--------------------|
| HCT(after OP) | 22 | 34.023 | 4.9966 | 24 | 32.246 | 5.2473 | 0.246** |
| Post operation hospital stay (day) | 22 | 3.32 | 1.323 | 20 | 5.3 | 2.296 | 0.001* |
| Neck-Shaft Angle AP (After Operation)(degree) | 21 | 130.86 | 4.43 | 18 | 133.11 | 4.874 | 0.138** |
| Neck-Shaft Angle AP (After Union)(degree) | 21 | 129.29 | 5.396 | 18 | 131.33 | 6.212 | 0.277** |
| Neck-Shaft Angle Lat (After Union) (degree) | 21 | 10.71 | 2.741 | 21 | 10.71 | 2.741 | 0.118** |
| Displacement (mm) | 20 | 2.25 | 4.518 | 18 | 5.89 | 8.029 | 0.096* |
| Union duration (day) | 21 | 74.05 | 12.31 | 18 | 91.67 | 16.539 | <0.001* |
| limb shortening(Cm) | 21 | 0.48 | 0.75 | 18 | 0.44 | 0.705 | 0.946* |
| Harris score (Month 3) | 21 | 56.119 | 17.3881 | 17 | 49.588 | 12.3393 | 0.185** |
| Harris score (Month 12) | 21 | 83.57 | 14.316 | 17 | 78.29 | 11.542 | 0.226** |
| Pain after 5 day OP | 21 | 2.95 | 1.687 | 19 | 5.68 | 1.529 | <0.001** |
| HB change | 22 | 0.4364 | 0.28208 | 24 | 1.7208 | 0.97534 | <0.001* |
| HCT change | 22 | 1.1091 | 1.85804 | 24 | 3.4583 | 3.75892 | <0.001* |
| Neck-Shaft Angle (AP) change | 21 | 1.5714 | 4.03201 | 18 | 1.7778 | 4.23647 | 0.826* |

*Mann-Whitney Test

**Independent t-test

DHEF=Dynamic Hip External Fixator, DHS=Dynamic Hip Screw, OP=Operation

Discussion

The use of an external fixator for the treatment of intertrochanteric fractures was first suggested in 1957 (23). In primary subsequent studies, no favorable outcomes were obtained (15, 24); nonetheless, the recent studies have demonstrated different and better results (7, 11, 25). On the other hand, Dynamic Hip Screw is still a valuable device for the fixation of intertrochanteric fractures, and a recent meta-analysis has pointed to its superiority to gamma nail (26), as well as equivalent mortality rate and complication, compared to the percutaneous compression plate (27). The fast and simple use, low bleeding, low pain rates, and higher patient satisfaction are among the most reported advantages of external fixators (15, 24, 28).

In the present study, the two groups were similar in terms of demographic information, such as age, gender, as well as hemoglobin and hematocrit levels. The obtained results indicated that mortality rate, operation time, and duration of postoperative hospitalization were significantly reduced in the intervention group. Moreover, union time, postoperative

pain, as well as hemoglobin and hematocrit changes, were significantly lower in the intervention group than in the control group. Functional outcomes and radiological criteria were comparable in both groups. The pin tract infection was the main complication in the DHEF-treated group.

Mortality rate

Hip external fixators decrease the mortality rate. For instance, Subasi et al., in a study on 33 patients with intertrochanteric fracture treated with the external fixator demonstrated that none of the patients died within the first two years after the operation (28). In another two-armed clinical trial study with 30 patients in each group in 2014, the mortality rate was reported as 7 and 5 in the DHS and HEF groups, respectively (8). In the current study, the mortality rate was significantly higher in the DHS group. However, in a meta-analysis of randomized controlled trials in 2016, the pooled result displayed no significant difference in mortality rate between the patients treated with the external fixators and DHS (29). In the same context, in a study on 785 patients

Table 4. Pin tract Frequency in patients treated with Dynamic hip external fixator

| Grade | Frequency | Percent |
|-------|-----------|---------|
| 0 | 6 | 28.6 |
| 1 | | 33.3 |
| 2 | 3 | 14.3 |
| 3 | 2 | 9.5 |
| 4 | 2 | 9.5 |
| 5 | 0 | 0 |
| 6 | 1 | 4.8 |
| Total | 21 | 100 |

with hip fracture, Ercin reported that the number of comorbidities, transfusion requirement, and ASA anesthesia class IV were significant predictors of mortality among the elderly with hip fractures, while surgery types did not have any significant role in mortality rate (30).

Function and pain

In a clinical trial in 2006, Moroni et al. treated 20 patients with intertrochanteric fractures with external fixators and Schanz hydroxyapatite-coated pins and 20 other patients with the same profile with the DHS. The HHSs were similar in both groups (11). Kazemian et al. found no difference in the HHS between the two groups after 12 months as well (HHS: DHS=65 and HEF=66) (8). In a similar vein, in the present study, the HHS was compared 3 and 12 months later in both groups; nonetheless, no significant difference was observed.

In the current study, the intensity of pain was also evaluated five days after the operation. The results demonstrated that the amount of postoperative pain was significantly lower in the DHEF-treated group, as compared to that in the DHS group. In another study, Moroni et al. found that the pain was less severe in the external fixator group five days after the surgery (11). Kazemian et al. reported no difference in chronic pain in both groups (5.5 in the HEF and 5.3 in DHS groups) (8). The pooled result of four randomized controlled trials indicated that the external hip fixator may cause lower pain, compared to the DHS (29).

In early studies, femoral neck collapse was reported up to 12%, which can be reduced by readjusting the external fixator after the surgery (7). However, the results of the present study showed that the femoral neck-shaft angle in the anteroposterior and lateral views after the union and after the operation were not significantly different in the two groups.

Radiological indexes

Moroni et al. reported the neck-shaft angle of 134 ± 6 (immediately after the surgery) and 128 ± 10 (six months after the operation) degrees in the patients treated with the DHS. These values were reported as 132 ± 4 and 130 ± 4

degrees immediately after the surgery and six months after the surgery in the group treated with the HEF (11). Kazemian et al. illustrated that among 30 patients in each group, the reduction of DHS and HEF was acceptable in 28 and 26 patients, respectively (8). In another study on 33 patients with intertrochanteric fractures, only 3 patients had femoral varus mal-union with more than 20 degrees or shortness of more than 2 cm (28). After 12 months of follow-up, all patients had complete union within 12 weeks. In the present study, the duration of union was significantly lower in the patients treated with an external fixator, as compared to that in the DHS group. Nevertheless, limb shortness did not significantly differ in the two groups. Limb shortness was about 0.48 cm for the external fixator group.

Complications

Subasi et al. reported pin infections in 7% of all the applied pins (28). Vossinakos and Badras (31) indicated that out of 50 patients, 21 cases had grade 1 pin infection and 9 patients had grade 2 pin infection, which was resolved with oral antibiotics (32); however, Moroni et al. observed no infection in their study (11) since they had used hydroxyapatite-coated pins. The good results reported in their study were possibly due to better bone integration achieved by hydroxyapatite-coated pins (33). Although the rate of pin infection has been reported in 7%-60% of patients in different studies, rare progress has been made towards osteomyelitis and major complication (17, 28, 31, 32). In the present study, 14 (66%) patients had resolvable infections, and only one patient experienced a serious infection. Moroni et al. reported the cutout in 1 out of 20 patients in both DHS and HEF groups (11). There was no difference between the two groups in terms of the cutout.

Others

Duration of postoperative hospitalization and operation time was significantly higher in the DHS group, as compared to that in the DHEF-treated group (8, 11). In line with the results of the present study, Kazemian et al. reported 8.4 and 2.2 days of hospital stay in the DHS and HEF groups, respectively. It was found that operation time was much shorter using an external fixator than DHS insertion (8, 34, 35). Moroni et al. reported 34 min as operation time in the external fixator group, while it was obtained at 64 min in the DHS group, which is twice the case of an external fixator (11). During the HEF insertion, bleeding is at the minimum level and postoperative hemoglobin levels are similar to the preoperative ones, and no blood transfusion is required, in comparison with other surgical methods (34, 36, 37). When the external fixator is used, the amount of bleeding and the need for blood transfusion is less than the case of an internal fixator (7, 11). Even some studies have stated that no blood was injected in the group treated with the external fixator,

while blood transfusion was frequently needed in the DHS group (15, 24). Moroni et al. reported that the average pack cell unit was equal to 2.0 ± 0.1 for the DHS operation; however, none was needed in the HEF surgery (11). In another study, out of 30 patients, 27 cases needed a blood transfusion, while none of the patients in the HEF group did (8).

In the present study, although hemoglobin concentration was not significantly different between the two groups, it was higher in the DHEF-treated group. The investigation of hemoglobin changes in the current study indicated that these changes were significantly lower in the DHEF-treated group, confirming a low bleeding rate in patients. In fact, the need for blood transfusion was significantly higher in the DHS group, as compared to that in the group treated with the external fixator.

Among the notable limitation of the present study, we can refer to the fact that it was a monocentric randomized controlled trial with less than 50 patients; therefore, multicenter studies with more patients are required to confirm the obtained results. One of the DHEF claims is decreasing the union time with double compression at the fracture site. The confirmation of this hypothesis requires trials which compare the static hip external fixators with dynamic ones. Since pin infection was the major complication, it is suggested to use the hydroxyapatite or antibiotic-coated Schanz pins in future studies.

Conclusions

In conclusion, DHEF is a reasonable substitute for the DHS in the treatment of patients with type 1 and 2 intertrochanteric fractures and high anesthesia risk. Equal functional outcome, less mortality rate, and preservation of anatomical reduction are the main advantages of the DHEF. Prolonged union time and patients' discomfort during the application of the external fixator are among the concerns of using DHEFs. In the present study, serious attempts were

made to solve these problems with double compression at the fracture site and compact design of the DHEF at the end of the operation and two weeks later in the clinic. Pin tract infection is still the main problem in the universal use of hip external fixators.

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Disclosure of Interest

All the authors declare that they have no conflict of interest except the first author who has designed the DHEF and has the unique selling proposition (USP) on it (Application number: 15/328632).

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