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ORIGINAL ARTICLE

Functional and radiological outcomes of dynamic hip screw with trochanteric stabilizing plate versus short proximal femoral nail in management of unstable trochanteric fractures: A randomized-controlled trial

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ABSTRACT

Objectives: This study aims to compare dynamic hip screw (DHS) with trochanteric stabilizing plate (TSP) versus short proximal femoral nail (PFN) in unstable trochanteric fractures in terms of the functional and radiological outcomes.

Patients and methods: Between June 2019 and March 2020, a total of 68 patients (32 males, 36 females; mean age: 69.7±8.2 years; range, 60 to 88 years) with unstable trochanteric fractures were included in this randomized-controlled trial. Eligible patients were randomized to undergo DHS with TSP (n=34) or short PFN (n=34) and followed for 12 months. The outcome measures including Harris Hip Score (HHS), operating room time, the amount of blood loss and need for intraoperative transfusion, return to activity, time to union, postoperative complications, failure rate, and mortality rate were analyzed.

Results: The mean operative time in the DHS+TSP group was 105±10 min, while in the PFN group it was 94±8 min (p=0.001). The mean time until union in the DHS+TSP group was 10.1±1.9 weeks, while in the PFN group, it was 8.8±1.8 weeks (p=0.008). The mean time to return to the pre-fracture activity level in the DHS+TSP group was 12.6±2.6 weeks, while in the PFN group, it was 10.8±2.1 weeks (p=0.005). The mean HHS for the DHS+TPS group was 77.9±8.4, while for the PFN group, it was 80.4±8.7 (p=0.26). There was no significant difference in the walking capability between the two groups. One-year mortality rate was 29.4% in the PFN group and 17.6% in the DHS+TSP group (p=0.284), indicating no significant difference. Mechanical failure was recorded in three cases (8.8%) in the DHS+TSP group compared to two cases (5.8%) in the PFN group with no statistically significant difference. These five cases needed later revisions with total hip replacement.

Conclusion: The use of PFN in unstable trochanteric fractures was associated with a shorter time until union and a faster return to the pre-fracture level of activity than the DHS+TSP group. Postoperative hip function, walking independence, as well as complication and one-year mortality rates were comparable.

Keywords: Dynamic hip screw, short proximal femoral nail, trochanteric fractures, trochanteric stabilizing plate.

Intertrochanteric femoral fractures are common in the elderly.[1] These fractures provide a remarkable problem for all orthopedic surgeons due to the high mortality and morbidity rates.[2,3] There are many ways to classify these fractures. The Evan's classification is the most well-known, which classifies fractures into stable and unstable based on their fracture pattern.[4] Dynamic hip screws (DHS) have been shown to be a valid option for treating stable trochanteric femoral fractures.[5,6] Trochanteric fractures with unstable fracture patterns are more likely to fail with standard therapy than stable fractures.[7-9]

Several factors contribute to the inherent instability of these fractures, including subtrochanteric extension, posteromedial calcar fracture, and lateral femoral

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wall insufficiency.[10,11] Lateral wall repair is a critical procedure to keep these fractures stable and improve function.[12] A variety of devices have been developed to replace DHS in unstable fractures, including different designs of cephalomedullary nails, proximal femoral locked plates, fixed angle blade plates, and trochanteric stabilizing plates (TSP).[13] According to the AO classification, the literature recommends the fixation of 31-A1 fractures with a DHS and all others with an intramedullary device.[14] Previous studies have demonstrated that with intramedullary nail insertion, postoperative weight-bearing and mobility are achievable, particularly in elderly patients.[15,16]

Stabilizing the greater trochanter and lateral wall with TSP is similar to using a DHS with a modular extension, resulting in a lower incidence of femoral medialization and a significant improvement in functional outcomes.[17] In the present study, we aimed to compare DHS with TSP and short proximal femoral nails (PFNs) in unstable trochanteric fractures in terms of the functional and radiological outcomes.

PATIENTS AND METHODS

This single-center, randomized-controlled trial (RCT) was conducted at Cairo University Kasr Al-Ainy Faculty of Medicine, Department of Orthopaedic and Traumatology between June 2019 and March 2020. We included patients above the age of 60 years with isolated unstable trochanteric fractures (AO/OTA 31-A2). Polytrauma patients and those with pathological fractures or incomplete follow-up records were excluded. Eligible patients were randomized to undergo DHS and TSP or short PFN and followed for one year. Randomization was conducted through a sealed envelope system. A total of 137 patients with intertrochanteric fractures were admitted from the accident and emergency (A&E) department during the study period. Seventy-two patients met the inclusion criteria: 36 were recruited in the DHS+TSP group (Group A) and 36 in the PFN group (Group B). Four patients dropped out during follow-up (n=2 in each group) and were excluded. Finally, a total of 68 patients (32 males, 36 females; mean age: 69.7±8.2 years; range, 60 to 88 years) were included in the study.

Operative techniques

All patients were assessed clinically and radiologically. Third-generation cephalosporins were given 30 to 60 min before surgery. All procedures were performed under spinal anesthesia, except in two patients. The patients underwent closed reduction and were positioned on the fracture table by slight internal rotation and abduction of the affected limb. Special attention was given to the medial calcar fragment, as it should be anatomically reduced (indicating good reduction under the image intensifier).

In the DHS+TSP group, we utilized a lateral approach, in which the skin incision extended from the greater trochanter tip to 5 to 7 cm below. The vastus lateralis was elevated to insert two Hohmann retractors and, then, a guidewire was inserted and centered to measure the length of the screw. The DHS plate was inserted and fixed by only the second plate screw to the shaft. Subsequently, the TSP was introduced over the DHS place; screws were inserted through the plates to the shaft. An anti-rotational screw was inserted through the TSP plate, followed by 3.5 cancellous screws added from the TSP to the greater trochanter, if required.

For the PFN group, a 3 to 5-cm skin incision was done parallel to the longitudinal axis of the femur, proximal to the greater trochanter. The nail entry point was optimized over the inner one-third point of the greater trochanter. Following guide wire introduction and reaming of the proximal canal, a nail of appropriate diameter was inserted. A lag screw was inserted, and a compression device was used to close the fracture surfaces. An anti-rotational screw was, then, added proximally, together with distal screws inserted through the targeting device.

In both groups, the tip of the lag screw was advanced to less than 25 mm on both anteroposterior (AP) and lateral views. All implants (PFN [3rd generation], DHS and TSP) were provided by a local manufacturer.

Postoperative follow-up

Postoperative care included broad-spectrum antibiotics for five days, low-molecular-weight heparin for four weeks, intravenous (IV) analgesics, and a suction drain. All patients were followed for one year postoperatively. Follow-up X-rays are done at Weeks 2, 4, and 6 and at 3, 6, and 12 months thereafter. Partial weight bearing was allowed starting at Week 6.

The hip function was assessed using the Harris Hip Score (HHS) starting from the six-month visit. In addition, we graded patients regarding their postoperative walking capabilities whether independent, assisted with one crutch, or two crutches, and compared it to their pre-fracture capabilities. Besides, we compared patients regarding their activity whether restricted to home or society.

The outcome measures including operating room time, the amount of blood loss and need for

TABLE I
Preoperative patients' characteristics

	DHS+TSP (n=34)			PFN (n=34)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			68.7±8.7			70.8±7.7	0.292
Right side	12	35		20	59		0.053
Mode of trauma							1
Low energy trauma	29			30			
High energy trauma	5			4			
Walking ability (pre-fracture)							1
Independent	14			14			
One crutch	20			20			
Level of activity (pre-fracture)							0.143
Home	12			18			
Society	22			16			
ASA score							0.659
ASA 1	12			16			
ASA 2	18			14			
ASA 3	4			4			

DHS: Dynamic hip screw; TSP: Trochanteric stabilizing plate, PFN: Proximal femoral nail; SD: Standard deviation; ASA: American society of anesthesiologists.

intraoperative transfusion, return to activity, time to union, postoperative complications, failure rate, and mortality rate were analyzed.

Statistical analysis

Using a clinical sample size calculator for RCT non-inferiority studies, with an alpha error of 0.05, power of the study of 0.8, 95% confidence interval (CI), enrolment ratio=1, and expected anticipated postoperative complication rate of about 10%; the minimal sample size calculated to detect the difference is 34 patients (17 in each group).

Statistical analysis was performed using the IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (interquartile range [IQR]) or number and frequency, where applicable. The hypothesis of a significant difference between both techniques in terms of postoperative radiological and functional was tested using the t-test or chi-square test. A p value of <0.05 was considered statistically significant.

RESULTS

Both patient groups had comparable demographics with most of the patients having low-energy trauma in the form of minor falls (Table I).

TABLE II
Intraoperative data

	DHS+TSP (n=34)			PFN (n=34)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Operative time (min)			105±10			94±8	0.001*
Blood loss (mL)			438±152			509±313	0.409
Intraoperative lateral cortex fracture	0	0		4	11.8		0.114
Reduction							0.040*
Closed	32	94.1		26	76.5		
Open	2	5.9		8	23.5		

DHS: Dynamic hip screw; TSP: Trochanteric stabilizing plate, PFN: Proximal femoral nail; SD: Standard deviation; * Statistically significant.

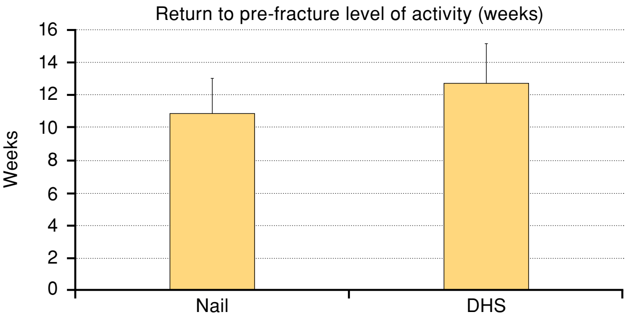

FIGURE 1. A graph showing the comparison between the two groups regarding return to pre-fracture level of activity in weeks.
DHS: Dynamic hip screw.

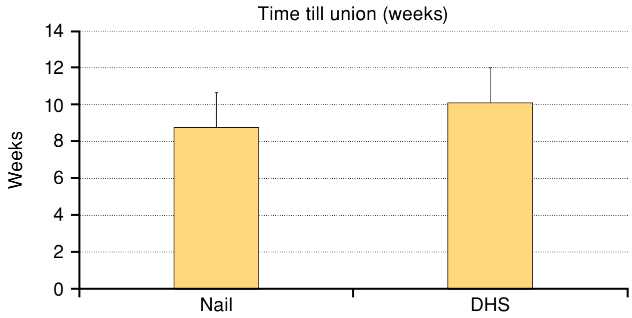

FIGURE 2. A graph showing the comparison between the two groups regarding time until union in weeks.
DHS: Dynamic hip screw.

Although more patients required open reduction for their fracture in the PFN group, the operating room time was significantly shorter than in the DHS+TSP group (p=0.001). However, the amount of blood loss and need for intraoperative transfusion were similar (Table II).

Union was assessed both clinically (absence of pain) and radiologically (bridging callus on X-rays). Time to union was significantly shorter and the patients' return to their pre-fracture level of activity was faster in the PFN group (Figures 1 and 2). On the other hand, the final patient function as assessed by HHS, ambulation, and walking aid dependence showed no difference between the groups (Table III).

From another perspective, we noted a direct impact of the mode of trauma on HHS both at 6 and 12 months (Table IV).

The rate of postoperative complications was comparable between the two patient groups. Five cases (7.3%) had a mechanical failure of the fixation construct and needed later revisions with total hip replacement. Moreover, four (11.8%) patients in the DHS+TSP group had deep wound infections. Infection was controlled with surgical debridement and IV antibiotic therapy. Similarly, two (5.8%) patients in the PFN group had deep wound infections, but unfortunately, these patients died before any intervention could be done.

TABLE III
Postoperative data

	DHS+TSP (n=34)			PFN (n=34)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Time to union (weeks)			10.1±1.9			8.8±1.8	0.008*
Return to pre-fracture activity (weeks)		12.6			10.8		0.005*
Complications							
Mechanical failure	3			2			0.114
Infection	4			2			0.099
HHS							
6 months			67.7±8.5			68.3±9.07	0.8
12 months			77.9±8.4			80.4±8.7	0.26
Walking ability (postoperative)							0.145
Independent	6			10			
One crutch	14			6			
Two crutches	14			6			
One-year mortality	6			10			0.284

DHS: Dynamic hip screw; TSP: Trochanteric stabilizing plate, PFN: Proximal femoral nail; SD: Standard deviation; HHS: Harris Hip Score; * Statistically significant.

TABLE IV
Relation between the type of trauma and Harris hip score at Months 6 and 12 after surgery

	Low energy		High energy		
	Mean±SD	Range	Mean±SD	Range	*p*
HHS at 6 months (post)	68.5±9	50-81	64.3±4.4	60-71	0.047*
HHS at 1 year (post)	80.1±8.6	62-93	72±4	68-78	0.011*

SD: Standard deviation; HHS: Harris Hip Score; * Statistically significant.

The one-year mortality rate was 23.5% for the whole patient cohort, indicating no statistically significant difference between the study groups (p=0.284).

DISCUSSION

Intertrochanteric fractures of the femur are quite prevalent in the elderly. Returning the patient to his/her pre-fracture level of activity is the ultimate goal of intertrochanteric fracture surgery. In this study, the mean operative time in the PFN group was significantly shorter than in the DHS+TSP group. Time until union was also significantly shorter, as well as return to the pre-fracture level of activity faster in the PFN group. The HHS at 6 and 12 months were similarly higher in the PFN group than the DHS+TSP group; however, it did not reach statistical significance. The complication and one-year mortality rates were also comparable between the two groups.

Patients in the Madsen et al.'s[19] study were treated with PFN and DHS. Surgical therapy for unstable trochanteric fractures had a significant failure rate, as this study indicated. The TSP, on the other hand, prevented severe femoral shaft fractures associated with the PFN design and decreased the concern of femoral shaft medialization and excessive fracture impaction found with traditional sliding hip screw systems. Another RCT was conducted by Klinger et al.[20] in 173 patients with trochanteric fractures: 51 were treated by DHS+TSP and 122 were treated by PFN. There was no significant difference between both groups in terms of functional scores. Revisions were needed in 16% of the PFN group and 21% in the DHS+TSP group. The authors recommended the use of PFN in unstable trochanteric fractures. Similarly, a prospective study conducted by Shetty et al.[17] in 32 patients with unstable trochanteric fractures who were treated with DHS and TSP showed that HHS after six months was excellent in nine patients, good in 10, fair in nine, and poor in four patients. No postoperative complications such as infection, scar dehiscence, implant failure, re-fracture, malunion, non-union, or requirement of re-surgery were noted in this series. Likewise, in another study, 20 patients with unstable trochanteric fractures and lateral wall fractures were treated with PFN.[21] The patients started partial weight-bearing one week after surgery. Zhang et al.[22] reported that using intramedullary fixation to treat unstable intertrochanteric femoral fractures was encouraging. The duration of the operation was relatively short, and the volume of blood loss during the operation was relatively small. They also found the patients restored ability to perform their activities as much as possible, while promoting fracture healing became the key for treating hip fractures. The authors believed that intramedullary fixation provided this possibility.

In the current study, the mean operational time in the DHS+TSP group was 105±10 min compared to 94±8 min in the PFN group. Although it was statistically significant, there was only an 11-min difference. Despite more patients requiring open reduction for their fracture in the PFN group, additional TSP, larger trochanter fixation by 3.5-mm cancellous screws, and restoration of posteromedial corner all contributed to longer operating duration in the DHS+TSP group. A similar operative time was found in the study by Shetty et al.,[17] but Klinger et al.[20] and Madsen et al.[19] reported a shorter operative time.

Furthermore, anesthetist-assessed intraoperative blood loss was 438 mL in the DHS+TSP compared to 509 mL in the PFN group. Although the difference was not significant, higher blood loss in the PFN group could be attributed to the more frequently required open reduction with wider incision and opening fracture hematoma which led to more blood loss. Intraoperative blood loss for our PFN group was comparable to that of Han et al.,[21] but considerably less in the Zhang et al.'s[22] study. According to Madsen et al.,[19] the DHS group lost more blood than the TSP group.

In the present study, the mean time until union in the DHS group was 10.1 weeks, while in the PFN group, it was 8.8 weeks. The nails are biomechanically more stable than DHS and TSP and preserve the fracture hematoma. Their follow-up X-rays usually revealed earlier callus. The findings from Klinger et al.[20] were similar to ours, 11 weeks for PFN and 12.5 weeks for DHS and TSP; however, it did not reach statistical significance. The time to union in the studies by Han et al.[21] and Zhang et al.[22] was 18.8 and 16 weeks, respectively.

Similarly, the mean time for the return to the pre-fracture level of activity was significantly shorter in the PFN compared to the DHS+TSP group. This could be explained by the union of the fracture which was faster with that group. After six months, the HHS outcomes of Han et al.[21] and Zhang et al.[22] were equivalent to our PFN group. In Shetty et al.'s[17] study, the results were inferior to our DHS and TSP group, while Madsen et al.[19] reported better functional outcomes with the DHS and TSP group.

Mortality rate is high for such frail patients and seems not to be affected by the type of fracture treatment. The one-year mortality rate in our DHS and PFN groups was 17.6% and 29.4%, respectively. As the patients were selected in a random fashion, there was no significant difference in the mortality rates between the two groups. Similarly, there was no significant difference in the mortality rates between the two groups in the Klinger et al.'s[20] study.

The results of the present study benefits from the prospective nature of data collection, as well as the RCT design. Nevertheless, we acknowledge that this study has several limitations including the small number of cases included compared to previous studies and the relatively short follow-up period. Further randomized studies with larger sample sizes and longer follow-up periods are, thus, needed.

In conclusion, the use of PFN in unstable trochanteric fractures is associated with a shorter time until union and a faster return to the pre-fracture level of activity than the DHS+TSP. However, postoperative hip function, walking independence, as well as complication and one-year mortality rates seem to be comparable. Based on these findings we suggest that PFN should be the first choice implant for the unstable (AO/OTA 31-A2) intertrochanteric fractures.

Ethics Committee Approval: The study protocol was approved by the Faculty of Medicine, Cairo University, Egypt Ethics Committee (date: 12.10.2019, no: 20191811). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, control/supervision, critical review: E.K., M.A.E.; Design, references and fundings: E.K., R.Y., M.A.E.; Data collection and/or processing: E.K., M.A., M.A.E.; Analysis and/or interpretation: E.K., R.Y., M.A. M.A.E.; Literature review, writing the article: R.Y., M.A.; Materials: E.K., R.Y., M.A.

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