Comparative Analysis of the Results of Trochanteric Femoral Nail and Dynamic Hip Screw in Treatment of Comminuted Unstable Trochanteric Fractures – a Prospective Randomised Controlled Trial on Indian Population

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ABSTRACT

Background and Purpose*: This study aimed to compare the results regarding functional outcome and rate of complications of the Trochanteric Femoral Nail device (TFN) with the Dynamic Hip Screw (DHS), in patients with comminuted unstable trochanteric fractures (AO 2.2 to AO 3.3).*

Method*: In this prospective, randomized study, total of 160 patients were randomized to the TFN group [Group A (n = 80)] and the DHS group [Group B (n = 80)]. All relevant perioperative information and complications were recorded, and assessments of functional outcome were made.*

Results*: The mean ± SD operative time was significantly longer in the group B (87.05 ± 17.36 min) than in the group A (68.55 ± 14 min) (P < 0.05). The mean ± SD fluoroscopy time was significantly longer in the group A (5.60 ± 1.32 min) compared with the group B (3.35 ± 0.75 min) (P < 0.05). The mean ± SD external blood loss during surgery was significantly lower in the group A (124 ± 18.2 ml) compared with the group B (240 ± 57.17 ml) (P < 0.05). In the present study group average hospital stay for the patients treated with DHS (Group B) was 15.5 days (range 8 to 33 days) and in case of TFN (Group A) average hospital stay was 12.5 days (range 7 to 28 days), not statistically significant at all. Union both clinically and radio logically had been achieved in all cases. Statistically significant differences were found in the complication rate between the two treatment groups regarding the rate of reoperation. Regarding functional outcome assessment by Harris Hip Score, there were no statistically significant differences between the two groups at the end of 6 months.*

Conclusion: *The present study showed that the TFN device can be used effectively to treat trochanteric fractures and may be the best choice particularly in unstable trochanteric fractures because of its low re-operation rate.*

Keywords: *Trochanteric Femoral Nail, Dynamic Hip Screw, Comminuted Unstable Trochanteric Fractures, Cut – out of screws, Rate of re – operation.*

INTRODUCTION

The incidence of the hip fracture has been rising with an aging population in many parts of the world, and the number of hip fractures is expected to reach 512,000 in the year 2040[1]. It has always been a controversial point of discussion regarding the management of comminuted unstable trochanteric fractures. Several implant designs have been developed in an attempt to aid fracture fixation, facilitate early ambulation, reduce the risk of complications and improve functional outcomes[2-4]. The screw-plate (extramedullary) and nailing systems (intramedullary) are the two basic osteosynthesis methods used in the management of trochanteric fractures.

Dynamic hip screw (DHS) has been the standard implant in treating trochanteric fractures[5–10]. However, when compared with the intramedullary implants, it has a biomechanical disadvantage because of a wider distance between the weight bearing axis and the implant[11]. It has performed less well in unstable trochanteric fractures, with high rates of failure [6,12,13]. The Trochanteric femoral nail (TFN) has been in use in treating trochanteric fractures in very recent years[14–16]. TFN being an intramedullary implant enjoys the theoretical advantage as more biomechanically stable construct. There are several reports showing benefits of proximal femoral nails[14-16], but it is still associated with technical failures[17,18].

The purpose of this study was to compare functional outcome and complications of the TFN device with the dynamic hip screw (DHS), in patients with comminuted unstable trochanteric fractures.

MATERIAL AND METHODS

Ethical Committee of the concerned Institution had granted Ethical approval for this study and it has been performed in accordance with the Ethical standards of the 1964 Declaration of Helsinki as revised in 2000.

In this prospective study, all consecutive patients with trochanteric femoral fractures having a comminuted unstable pattern (AO 2.2 to AO 3.3), of either sex between 20 to 60 years of age were randomized to undergo fixation with the DHS or the TFN device between June 2009 and May 2015. Patients with pathological fracture, inability to walk before the fracture, associated neurological disorders, poly trauma patients, and dropped out patients during the study period were excluded. Written informed consent in three languages (Local, National and English) were obtained from every patient, prior to include them in the study.

The hypothesis was that the TFN would have better functional outcome and fewer complication rates than the DHS. The primary comparative parameter was clinical and radiological union of the fracture. Secondary comparative parameters were intra-operative

complications, revision operations (related to the failure of primary treatment) and mortality. Baseline characteristics were documented pre-operatively; outcome measures were subdivided into intra-operative, post-operative and follow-up data at six weeks, three months, six months and one year.

Surgical Procedure

The TFN used in the study was a solid SS (316 LVM) nail of 180 mm in length and 10, 11, and 12 mm in diameter, which was inserted into the medullary canal. Two cervical screws were inserted in the femoral head-neck fragment. These screws provide rotational stability. The TFN can be distally locked either dynamically or statically. Surgery was performed with the patient in the supine position on a fracture table, with the injured extremity slightly adducted to facilitate insertion of the implant. Fracture fixation with the DHS was performed according to the surgical technique described by Campbell's Operative Orthopaedics 11th edition[19]. After surgery, the patients were mobilized and given standard rehabilitation instructions by a physiotherapist.

Patient Assessment and Follow Up

Intra-operatively, blood loss was measured from the swabs and the suction unit. The time required for closed reduction of the fracture, the operating time and the fluoroscopy time were recorded. The demographic data (age and sex), perioperative information and length of hospital stay were recorded for each patient.

Follow-up evaluations consisting of clinical examination, assessment of functional outcome and radiographs, were performed at 6 weeks, 3 months, 6 months and then annually. Patients were followed up for a minimum of 2 years. Functional outcomes were assessed using the Harris Hip scoring system. Patient outcome scores were categorized as excellent (≥ 90), good (89 – 80), fair (79 – 70) or poor (≤ 70). Radiographic evaluation was done for fracture union, extent of fracture collapse, medial displacement, neck-shaft angle alteration, implant failure and change in implant position. Radiographic fracture union was defined as the presence of bridging callus on antero-posterior and lateral radiographs.

Statistical Analysis

Data was compiled using MS office Excel 2007 and statistically analysed using SPSS version 16. For non-parametric distribution, Mann-Whitney U Test, Chi - square tests were used and parametric data was compared using Independent samples t test. A P-value of < 0.05 was considered to be statistically significant.

RESULTS

There were a total 160 patients in the study. Of these, 80 were randomised to intramedullary fixation by TFN (Group A) and 80 to extramedullary fixation by DHS (Group B).

Mean age was 42 years in group A (range 24 – 60 years) and 45 years in group B (range 22 – 60 years). The gender distribution was 70% men and 30% women in the group A, and 55% men and 45% women in the group B. The mean ± SD operative time was significantly longer in the group B (87.05 ± 17.36 min) than in the group A (68.55 ± 14 min) ($P < 0.05$). The mean ± SD fluoroscopy time was significantly longer in the group A (5.60 ± 1.32 min) compared with the group B (3.35 ± 0.75 min) ($P < 0.05$). The mean ± SD external blood loss during surgery was significantly lower in the group A (124 ± 18.2 ml) compared with the group B (240 ± 57.17 ml) ($P < 0.05$). In the present study group average hospital stay for the patients treated with DHS (Group B) was 15.5 days (range 8 to 33 days) and in case of TFN (Group A) average hospital stay was 12.5 days (range 7 to 28 days), not statistically significant at all. Union both clinically and radio logically had been achieved in all cases (Fig. 1).

Statistically significant differences were found in the complication rate between the two treatment groups (Table 1) regarding the rate of reoperation. In Group A (TFN), three patients had a superficial wound infection that responded nicely to antibiotics, one case had an incidence of guide wire breakage in the femoral head-neck fragment (Fig. 2) and one case had a Z-effect phenomenon (Fig. 3). No incidence of implant failure and proximal or distal femoral fractures were noted in the group A patients. In Group B (DHS), five cases of superficial wound infection occurred that responded well to antibiotics, but two cases had deep infection that required repeated debridement. Two cases had incidence of screw cut out for which reoperation was done. Gradual varus collapse happened in ten cases of DHS, among them three cases needed reoperation. Incidence of limb length shortening in most of the cases (Both TFN and DHS group) was below 2 cm and they were managed successfully with shoe raise. No incidence of non-union, few cases of delayed union which eventually united within 9 months. Penetration of the Richard's screw into the joint happened in a single case noticed at 3 months post op (Fig. 4), it required reoperation later on. Re-operations were done in cases of debridement, progressive varus collapse with neck-shaft angle less than 100 degrees, in cases of screw cut-out and in the case of penetration of screw into the joint. In Group B (DHS), re-operation was performed in eight patients (8/80), whereas no single patient needed the same in Group A (TFN).

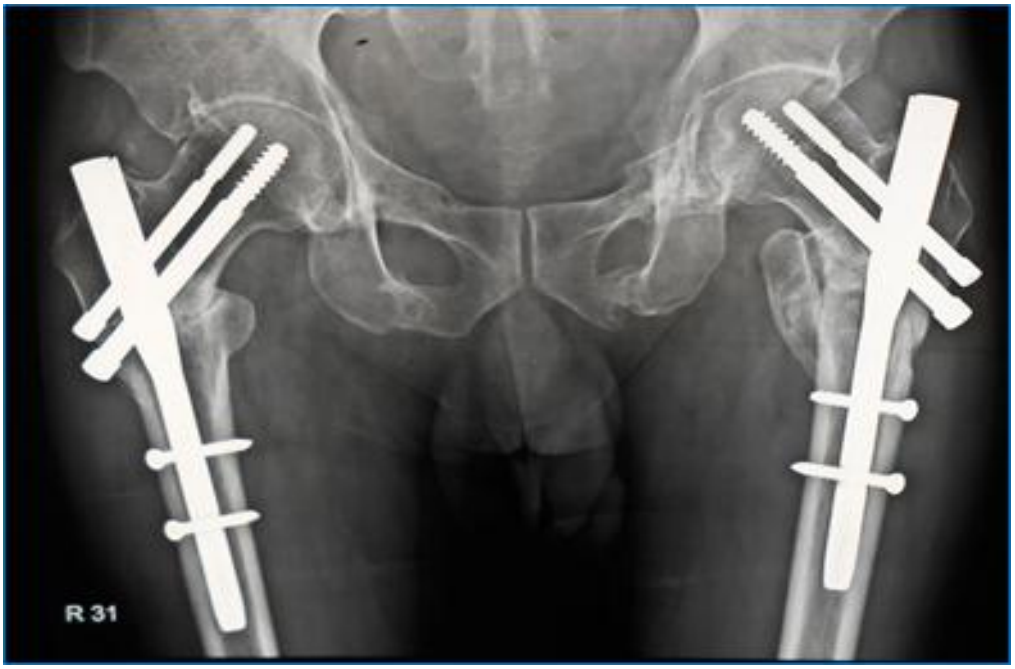

Fig.1: A case of post-traumatic bilateral unstable intertrochanteric fracture femur, treated with Trochanteric Femoral Nail (TFN): Follow – up radiograph at the end of one year

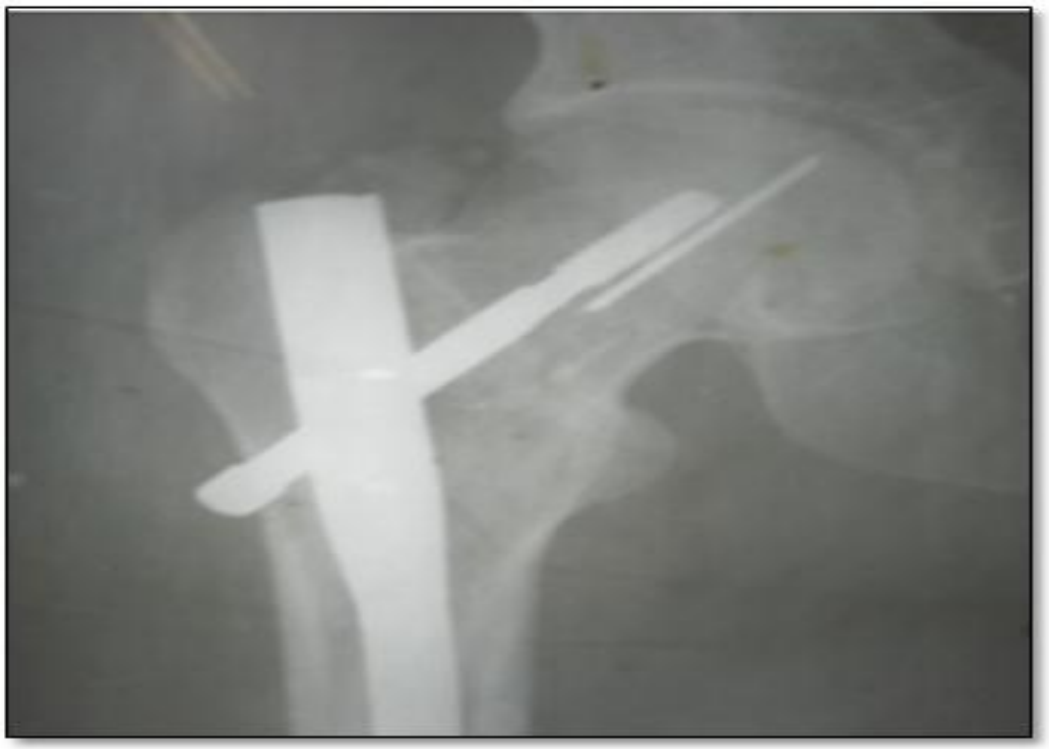

Fig. 2: Implant Breakage (guide wire) in the femoral head. No incidence of migration of the implant was noted at the end of 3 years

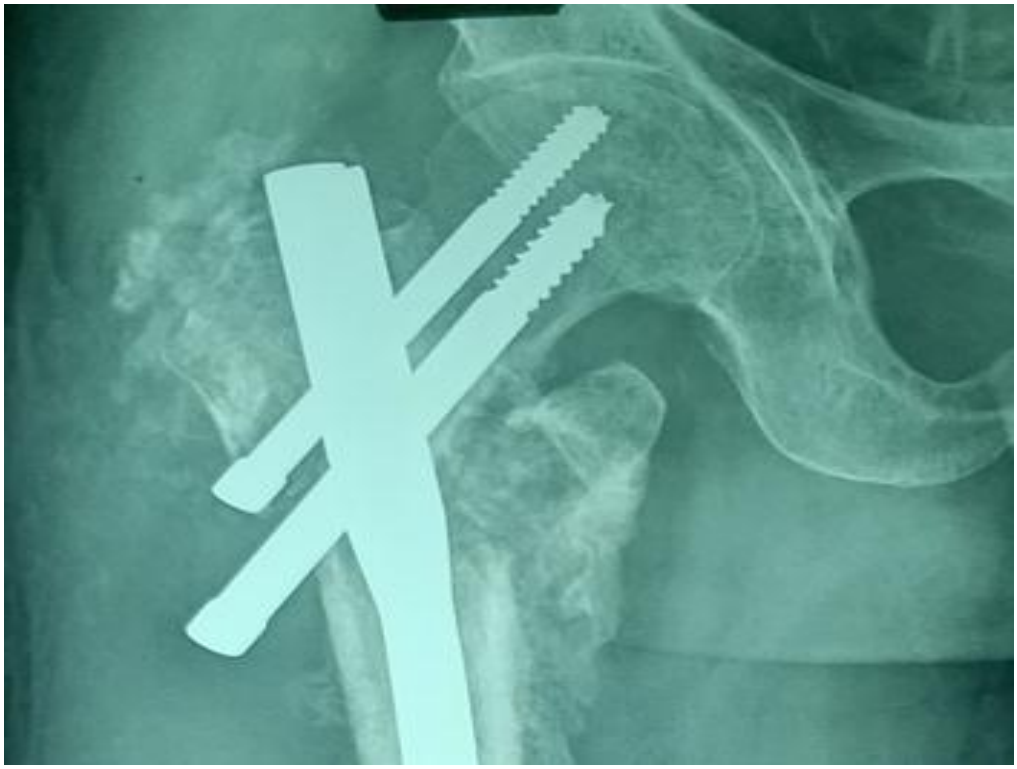

Fig.3: Migration of screw = 'Z – effect' phenomenon (medial migration of the superior screw and lateral migration of the inferior screw)

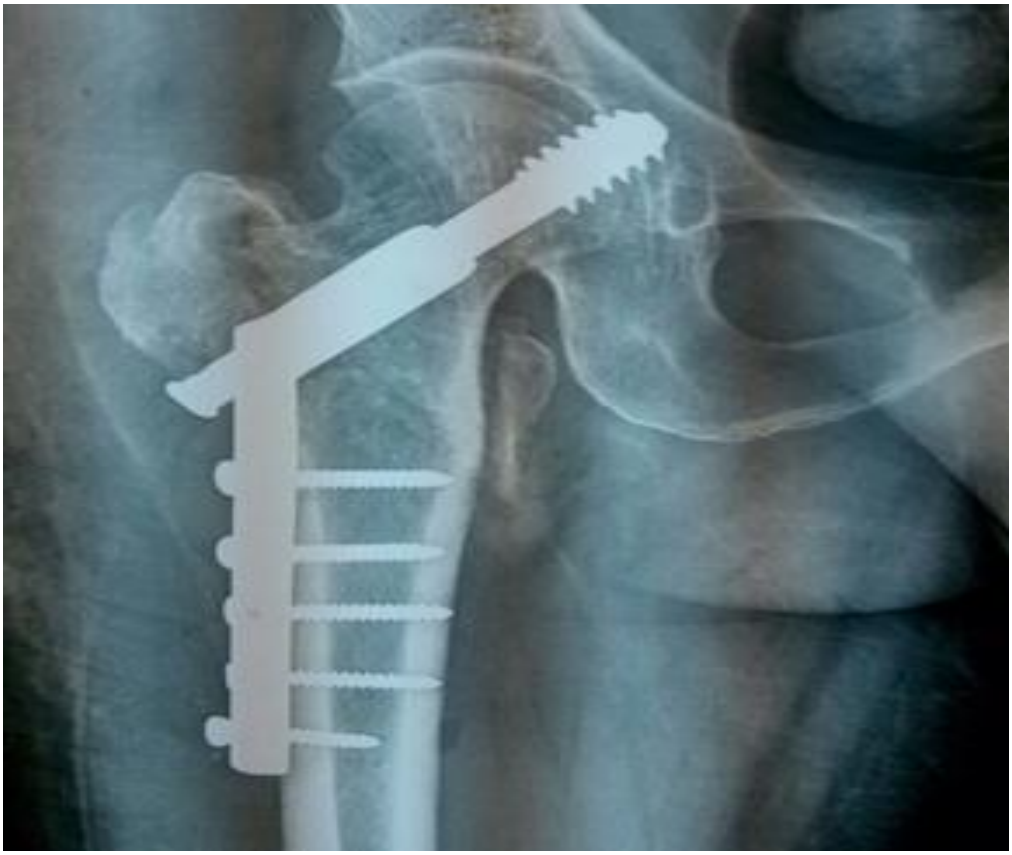

Fig.4: Penetration of the Richards Screw in the Hip joint detected at 3 months post-operative period

Table 1: Complications in Patients with Comminuted Unstable Trochanteric Fractures Treated with TFN or DHS

Complication	TFN (n = 80)	DHS (n = 80)
Superficial wound infection	3 cases (3.75%)	5 cases (6.25%)
Deep wound infection	nil	2 cases (2.5%)
Thromboembolic phenomenon	nil	nil
Coxa vara	1 case (1.25%)	10 cases (12.5%)
Shortening	7 cases (8.75%)	10 cases (12.5%)
Delayed union	2 cases (2.5%)	3 cases (3.75%)
Non union	nil	nil
Breakage of implant	1 case (1.25%)	nil
Migration of screw	1 case (1.25%)	nil
Cut-out	nil	2 cases (2.5%)
Femoral shaft fractures	nil	nil
Penetration of screw in Hip joint	nil	1 case (1.25%)
Re - operation	nil	8 cases (10%)

Functional outcome assessment using the HARRIS HIP SCORE in the two treatment groups is shown in Table 2. There were no statistically significant differences between the two groups at the end of 6 months.

Table 2 : Evaluation of the functional outcome by Harris Hip Score done at 24 weeks (6 months) follow up.

Treatment	HARRIS HIP SCORE			
	Excellent (≥90)	Good (89 – 80)	Fair (79 – 70)	Poor (≤70)
Group A (TFN) (n = 80)	18	52	9	1
Group B (DHS) (n = 80)	15	40	19	6

Data in the table shows the number of patients present in each group.

No statistically significant difference has been observed between the two treatment groups at the end of 6 months.

DISCUSSION

While a wide range of intertrochanteric fracture fixation devices have been employed over the years, the choice for optimal fixation device is still controversial at present. The successful treatment of trochanteric fractures depends on many factors, including the patients factor (age, general health, time from fracture to treatment, comminution, bone quality, concurrent medical treatment), surgeon factor (competency, stability of fixation) and the implant factor[5]. Sufficient knowledge regarding the biological and biomechanical principle of these devices should be obtained, as both of these intramedullary and extramedullary devices have advantages and disadvantages.

Sliding compression hip screws have been directly compared with intramedullary fixation in many studies. Early reports on intramedullary implants suggested some substantial advantages in association with this type of fixation, including a minimally invasive surgical technique, shortened operating times, decreased blood loss, improved biomechanics, greater stability of fixation, earlier patient mobilization, and shorter lengths of stay [20-22]. Jones et al.[23] compared the intramedullary nail (IMN), which involved gamma nail, intramedullary hip screw (IMHS), and PFN, with sliding hip screw for treatment of extracapsular proximal femoral fractures. Parker and Handoll [10] also compared gamma and other cephalocondylic intramedullary nails with extramedullary implants for extracapsular hip fractures in adults.

Trochanteric Femoral Nail (TFN) is one of the latest members in this intramedullary group. Very few biomechanical and clinical studies have been published over its efficacy [24]. No such published data have been acquired regarding the comparative study about the efficacy and functional outcome in the use of TFN and DHS in comminuted unstable trochanteric fractures.

In this series mean operative time was significantly longer in DHS group that is comparable with the study of P. Bienkowski et al[25] and H.M. Klinger et al[26]. This difference was probably related to the longer time required to dissect the subcutaneous tissue, iliotibial tract and vastus lateralis muscle and to repair them in the DHS group. In contrary, in case of TFN, intramedullary reaming is often not required as the nail usually ends before the femoral isthmus. Mean blood loss during surgery was significantly lower in the TFN group. This observation was comparable with the study of J. Pajarinen et al[27] and Hu W et al[28]. Greater amount of blood loss can be directly correlated with the longer operative time and the necessity of soft tissue dissection in the DHS group. The fluoroscopy time was significantly longer in the TFN group; this is probably due to the fact that, lateral view of the fractured hip has to be visualised more number of times in cases of TFN. No significant difference in the average hospital stay has been found between the TFN and DHS in our study. This observation was comparable with the study of H.M. Klinger et a [26] and Di Monaco et al[29]. Factors which has prolonged hospital stay in both of these groups were coexisting medical illness and the incidence of post-operative complications specially infection.

Regarding complications, in case of incidences of infection our study was statistically similar with the study of S.H.Bridle et al[13]. Deep infection which required repeated debridement delayed post-operative rehabilitation to some extent. Progressive varus collapse was significantly higher in the DHS group. This complication was typically encountered in fractures with posteromedial comminution, associated fractures of lateral femoral wall, and in fractures of reverse obliquity pattern. This observation was supported by a number of studies [30,31,32]. We had experienced cut-out of the DHS screw in two cases. Cut-out of the screw most commonly seen in osteoporotic bones [27,33] possibly as the result of varus deviation and rotation. It mostly occurs in the superomedial quadrant of the femoral head which in many anatomical and biomechanical studies have shown to be the weakest part [34]. These patterns of fixation failure are most often seen in DHS, which is mostly due to insufficient purchase of the implant in the femoral neck and lack of rotational stability. Surgical fault responsible for this failure is not following the tip apex distance concept. Both progressive fracture displacement and screw cut-out had led to reoperation.

The ideal implant for the treatment of unstable trochanteric fractures is an easily inserted, intramedullary device that allows for controlled impaction across the fracture zone while preventing fracture site rotation[35, 36]. Neck screws of the device must achieve sufficient purchase in the femoral head in order to resist cut-out. The intramedullary nail appears to be superior by maintaining the integrity of the lateral femoral wall. The reason could be that the nail-screw angle is fixed through the guide system, and if the lateral wall is fractured, the nail itself could have a lateral buttress effect by direct contact of the proximal part of the nail with the neck-head fragment [37]. Intramedullary fixation device (TFN) might, therefore, might be a better method of treatment in these types of fractures.

A consensus from recently published literature has been emerged that intramedullary nail fixation is associated with a higher complication rate (both intraoperative and postoperative fracture shaft), a higher rate of reoperation and no better outcomes[10, 23, 38]. On contrary, Saudan et al. 2002[39], Stern et al 2007[40], Anglen and Weinstein et al 2008[41], and Parker and Handoll et al 2010[10] have shown no such difference in reoperation rate between the two types of implants. In our study, patients treated with DHS had a reoperation rate of 8.75% (7/80); whereas no such patients operated with TFN needed a reoperation so far. We confer this observation as the stability of construct achieved by Trochanteric Femoral Nail. One meta-analysis of eleven studies that specifically focused on unstable fractures (Orthopaedic Trauma Association classification 31-A3) suggested that the failure rate associated with trochanteric nails was significantly lower than that associated with plate and screw fixation [42] can be corroborated with our study.

It is indicated in some studies that intramedullary devices helps in facilitating early postoperative rehabilitation[4, 43]. Differences in the postoperative recovery and functional outcome between Group A (TFN) and Group B (DHS) can be attributed to postoperative bone stability and invasiveness of each procedure to the hip muscles. In terms of bone stability, patients undergoing nail fixation had better HHS scores than those undergoing plate fixation as the mechanical axis of the intramedullary nail lies closer to the axis of the femur. Therefore, nail could decrease mechanical bending stress to the implant[44]. The TFN device is implanted through a small incision above the greater trochanter. This entry point causes less damage to the superior gluteal nerve and gluteus medius muscle. In our study, though there was a significant difference in HHS scores with better functional outcome in the Group A (TFN) in early post-operative phase (6 wks and 12 wks); at the end of 6 months, there was no statistically significant difference between the two groups. Patients who had reoperations later on had performed less well as per the scoring system.

Limitations of our study are, it would be better if we analysis the outcome of the two implant in a more specific fracture type (e.g. reverse oblique fracture). Furthermore, we have not analysed rate of Refracture after implant removal.

In conclusion, TFN and DHS are equally effective in the treatment of comminuted unstable trochanteric fractures. The TFN is a load-bearing device, reduces iatrogenic tissue trauma, allows for earlier postoperative weight bearing, and reduced re-operation rate, although it was associated with higher radiation exposure compared with the DHS. The present study showed that the TFN device can be used effectively to treat trochanteric fractures and

may be the best choice particularly in unstable trochanteric fractures because of its low re-operation rate.

CONFLICT OF INTEREST STATEMENT

The authors are hereby to declare that they have no conflict of interest related to the publication of this manuscript.

ETHICAL STANDARD STATEMENT

Ethical Committee of the concerned Institution had granted Ethical approval for this study and it has been performed in accordance with the Ethical standards of the 1964 Declaration of Helsinki as revised in 2000.The need for informed consent was waived by the ethical committee since rights and interests of the patients would not be violated and their privacy and anonymity would be assured by this study design.

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