

Research Article

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Comparison of the Radiological and Functional Outcome of Proximal Femoral Nail with Helical Blade versus Lag Screw in Intertrochanteric Fractures

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Abstract

Introduction: Intertrochanteric fractures are defined as extracapsular fractures of the proximal femur that occur between the greater and lesser trochanter. These fractures occur both in the elderly and the young, but they are more common in the elderly population with osteoporosis due to a low energy mechanism. The female to male ration is between 2:1 and 8:1. Operative management of these fractures is considered urgent, not emergent. This allows the many comorbidities with which patients often present to be optimized preoperatively, to reduce morbidity and mortality.

Aim and objectives: Aim of the study is to compare the radiological and functional outcome of proximal femoral nail with helical blade vs. proximal femoral nail with lag screw in intertrochanteric fractures.

Materials and methods: Patients fulfilling the inclusion criteria were included in the study and randomly allocated in two groups. Group patients with intertrochanteric fracture were operated with proximal femoral nail using lag screw and group B patients were operated with proximal femoral nail using helical blade.

Keywords: Intertrochanteric fractures; Femoral nail; Osteoporoti

Introduction

Intertrochanteric fractures are defined as extracapsular fractures of the proximal femur that occur between the greater and lesser trochanter and are extremely common fractures occurring in elderly osteoporotic individuals [1]. Recumbence following a hip fracture is known to be associated with increased mortality in this group of patients. The female to male ratio is between 2:1 and 8:1 [2].

These fractures are usually a result of a ground-level fall in the elderly population and are classified as either stable or unstable. Determination of stability is important as it helps determine the type of fixation required for stability. Stable fractures have an intact posteromedial cortex and will resist compressive loads once reduced. Examples of unstable fractures include: comminution of the posteromedial cortex, fractures extending up to lateral wall, displaced lesser trochanter fracture, subtrochanteric extension and reverse obliquity pattern [3].

Intertrochanteric fractures are extra capsular and have a much more robust osseous blood supply, and therefore are much less likely to result in chronic complications such as AVN or nonunion. Thus, the primary concerns of inadequate treatment of trochanteric fractures are related to the risks of acute

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instability and possible nonunion/malunion with post injury deformity. Nonoperative treatment is rarely indicated and should only be considered for non-ambulatory patients and patients with a high risk of perioperative mortality [4].

Although there are multiple studies comparing PFN with other intra-medullary devices like Gamma nail, PFNA, limited studies are available which compares treatment outcomes of proximal femoral nail with lag screw and proximal femoral nail with helical blade. In view of the extremely limited literature available, we conducted this study to compare the clinical, radiological and functional outcomes of PFN with lag screw and helical blade PFN in management of intertrochanteric fracture.

Aim and Objectives

Aim of the present study is to compare the radiological and functional outcome of proximal femoral nail with helical blade vs. proximal femoral nail with lag screw in intertrochanteric fractures. Objective of the study Radiological outcome were compared between two groups with respect to Femoral Neck shaft angle, Horizontal Femoral offset, Total femoral length, Tip apex distance and Union at 3 months. Functional outcome was compared between of the two groups using Harris Hip Scoring system (HHS).

Material and Methods

The Randomized comparative interventional study was conducted in department of orthopedics SGRDIMSAR Sri Amritsar from 1st April 2021 to 31st July 2022, in which patients fulfilling the inclusion criteria were be randomly divided in two groups.

Helical blade group: Patients with intertrochanteric fracture operated using proximal femoral nail with helical blade.

Lag screw group: Patients with intertrochanteric fracture operated using proximal femoral nail with lag screw.

Randomization: All Patients having age 30 years and above with fracture intertrochanteric femur (AO/OTA classification).were included in the study after obtaining informed written consent for both the treatments i.e. proximal femoral nail with helical blade and lag screw. To avoid the selection bias computer generated random numbers were obtained and sealed in an envelope. The slip was then taken out by office clerk not involved in the study and whether to put helical blade or lag screw was then decided according to the coded slip. The patients and the operating surgeon were blinded in the present study till the insertion of column screw. Patients were followed up at 3 months after discharge.

Exclusion criteria:

- 1. Patients with previous ipsilateral hip or femur surgery.
- 2. Patients with pathological fractures.

3. Fractures extension into subtrochanteric region.

As per new AO/ OTA classification and fracture pattern, cases from both the groups were classified further into stable and unstable and various radiological and functional parameters were assessed accordingly.

Operative protocol:

All patients with trochanteric fractures which were operated by two surgeons of our unit were taken on radiolucent table with traction applied on injured limb. In all patient attempt of closed reduction was given on traction table and in fractures where closed reduction was not achieved then fractures were reduced with mini open or percutaneous methods. All cases were provisionally fixed with K wires out of the path of the nail and these k wires were maintained until the nail insertion.

After Palpating the greater trochanter, around 5 cm incision was given proximal to the tip of greater trochanter. Entry was made just medial to the tip of the greater trochanter and was confirmed on image intensifier in both AP and roll over lateral view, in lateral view the entry point was in line with the axis of the intramedullary canal of shaft and femoral neck.

Then guide wire was inserted, femur canal was opened with solid cannulated reamer of appropriate size. Medullary canal was not reamed during the surgery. In our study, after estimating the nail size and diameter preoperatively using image meter pro and confirming it on image intensifier intraoperative, guide wire for both cervical screws was inserted in dead center of femoral head and neck on roll over lateral view and slightly inferior or in center on AP view on image intensifier.

Proximal locking with helical blade: Select the appropriate length helical blade as measured. Align the back end of the helical blade with the impactor. Thread the connecting screw into the helical blade and finger-tighten the assembly. Hold the handle of the inserter and advance the blade as far as possible by hand. Use light hammer blows on the back of the connecting screw to seat the helical blade. Insert to the stop. The blade is fully inserted when the helical blade impactor comes to a stop at the back of the blade guide sleeve.

Proximal locking with lag screw: After selecting appropriate length lag screw, pass the screw insertion assembly over the guide wire, through the blade guide sleeve and through the nail. Advance the screw by turning the inserter clock- wise until the mark on the inserter meets the flange surface of the blade guide sleeve.

Both the type of column screws were locked in static mode using a set screw.

The result of this surgical procedure was analyzed on



the basis of various radiological and functional parameters. Follow up was done at third month. At each visit clinical, various radiological parameters and along with this function outcome was assessed using Harris hip score [5].

Analysis of Data

The data from the present study was systematically collected, compiled and statistically analyzed to draw relevant conclusions using SPSS Statistics-26 version. The observations were tabulated in the form of mean Standard Deviation (SD) and Number with percentage. In parametric data, unpaired student t test was used. Quantitative variables were correlated using chi square test. The data was analyzed and level of significance was determined as its 'p' value with p<0.05 as significant and p<0.001 as highly significant.

Results

The comparative interventional randomized study comprising of 29 patients of trochanteric femur fractures treated either with Proximal femoral nail with helical blade (n = 17) and proximal femoral nail with lag screw (n = 12). Patients were admitted in Department of Orthopaedics at Sri Guru Ram Das Institute of medical Sciences and Research, Amritsar between April 2021 to July 2022. This study was performed under the approval of our institution's ethical review board (Document number: Ant/85/2021). Informed consent was obtained from each participant. Out of 29 patients, 2 patients were lost to follow up. A single case of helical blade cut through was observed at 3rd week follow up due to unprotected weight bearing. The final outcome of 26 cases on the basis of radiological and functional parameters were assessed and is hereunder:

Baseline characteristics

Majority of patients belonged to age group of more than 65 years contributing 72 percent to the present study with minimum age of 25 years and maximum age of 89 years and the mean age of 68.76 ± 13.51 in *helical group* and mean age of 65.08 ± 14.40 in *lag screw group*. Out of 29 patients, 14 were male and 15 were female (Table 1).

As per AO/OTA guidelines, out of 29 intertrochanteric fractures, 19 were of stable fracture pattern and 10 were of

Table 1: Demographic data related to the present study.

Age Group	Number	Percentage
<65 Years	8	27.59
≥65 Years	21	72.41
Gender		
Female	15	51.72
Male	14	48.28
Stability		
Stable	17	58.62
Unstable	12	41.38

unstable fracture pattern. Further, it was observed that in helical blade group, 9 cases (53%) were of stable fracture pattern (AO31A1) and 8 cases (47%) were of unstable fracture pattern (AO31A2 and AO31A3). In lag screw group, 8 cases (67%) belonged to stable fracture pattern (AO31A1) and 4 cases (33%) belonged to unstable fracture pattern (AO31A2 and AO31A3). There was no statistically significant difference (P=0.174) in the proportion of fractures that were unstable or stable between the helical blade and lag screw group. The baseline characteristics demonstrated no statistically significant differences between the groups.

Radiological Analysis

Femoral Neck shaft angle:

Helical blade group: There was an overall average increase in femoral neck shaft angle at $3^{\rm rd}$ month from 129.13 ± 3.42 degrees (uninjured side) to 130.27 ± 3.84 degrees (operated side) (p = 0.059) irrespective of fracture pattern. We tried to achieve positive cortical reduction intraoperatively which led to valgus alignment of the neck shaft angle. On subgroup analysis on basis of fracture pattern: Among the *unstable fracture pattern* (n = 7), there was an average increase in neck shaft angle at $3^{\rm rd}$ month from 127.57 ± 2.64 degrees (uninjured side) to 128.71 ± 1.98 degrees (operated side) (p = 0.231). In stable fracture pattern (n = 8), there was an average increase in neck shaft angle at 3rd month from 130.5 ± 3.59 degrees (uninjured side) to 131.63 ± 4.66 degrees (operated side) (p = 0.185).

Lag screw group: There was an overall average increase in femoral neck shaft angle at 3^{rd} month from (127.63 ± 3.80) degrees (uninjured side) to (128.36 ± 4.76) degrees (operated side) (p = 0.363) irrespective of fracture pattern. On subgroup analysis on the basis of fracture pattern: Among the unstable fracture pattern (n = 3) there was an average increase in neck shaft angle in at 3^{rd} month from 127.57 ± 2.63 degrees (uninjured side) to 128.71 ± 1.96 degrees (operated side) (p = 0.321). On further analysis, amongst the stable fracture pattern (n = 8) fixed with lag screw, we observed an insignificant average decrease of neck shaft angle from (128.00 ± 3.891) degrees (uninjured side) to (127.78 ± 4.44) degrees (operated side) (p = 0.785) as one case was erroneously fixed in slight varus neck shaft angle intra-operatively which led to relative decrease in neck shaft angle degrees and affecting the outcome of this specific group but there was no further varus collapse i.e. the neck shaft angle was maintained at 3rd month follow up in this case. The patient achieved radiological union at 3 months and functional outcome was good. If we tend to exclude this case from our analysis, the results will be same as in other groups irrespective of fracture pattern or type of implant used. The average change in neck shaft angle of both the groups irrespective of fracture pattern was statistically insignificant (p = 0.270) (Figure 1).



Horizontal femoral offset (Neck length):

Helical blade group: There was an overall average decrease in horizontal femoral offset at $3^{\rm rd}$ month from 39.73 ± 4.35 mm (uninjured side) to 38.60 ± 4.56 mm (operated side) (p = 0.055) irrespective of fracture pattern. On subgroup analysis on basis of fracture pattern: Among the *unstable fracture pattern* (n =7), there was an average decrease in horizontal femoral offset at $3^{\rm rd}$ month from 42.14 ± 3.62 mm (uninjured side) to 41.43 ± 3.45 mm (operated side) (p = 0.441). Among the *stable fracture pattern* (n = 8) fixed with helical blade, there was an average decrease in horizontal femoral offset at 3rd month from 37.63 mm ± 3.96 mm (uninjured side) to 36.13 ± 4.05 mm (operated side) (p = 0.072).

Lag screw group: There was an overall average decrease in horizontal femoral offset at 3^{rd} month from 42.09 ± 5.394 mm (uninjured side) to 41.63 ± 5.163 (operated side) (p = 0.578) irrespective of fracture pattern. On subgroup analysis, among the unstable fracture pattern (n = 3), there was an average decrease in horizontal femoral offset at 3^{rd} month from 48.00 ± 5.292 mm (uninjured side) to 45.67 ± 6.65 mm (operated side) (p = 0.369). In stable fracture pattern (n = 8), there was an insignificant average increase in horizontal femoral offset at 3^{rd} month from 39.875 ± 3.60 mm (uninjured side) to 40.12 ± 3.98 mm (operated side) (p = 0.741). The variability in this group can be attributed to the case discussed above which led to an average increase in this subgroup. Both the outcomes in comparison were statistically insignificant (p = 0.126). Both the types of collum screws were statically locked with

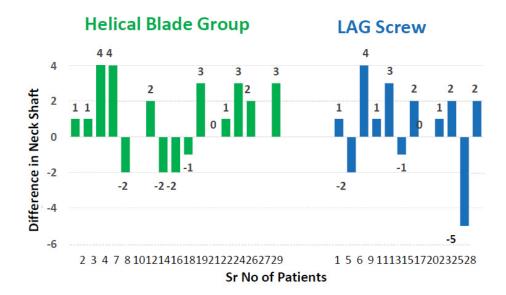


Figure 1: Difference of neck shaft angle at 3rd month with uninjured side in both groups.

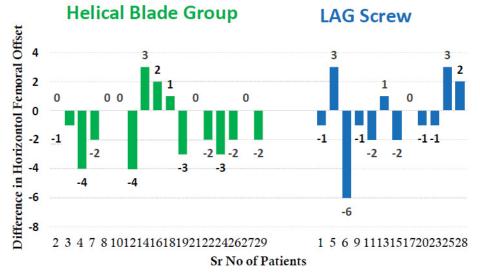


Figure 2: Difference of horizontal offset (mm) change at 3rd month with uninjured side in both groups.

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set screw to prevent any significant collapse irrespective of fracture pattern and type of implant used. (Figure 2).

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Total femoral length:

Helical blade group: There was an overall average increase in total femoral length at 3rd month from 391.67 \pm 40.039 mm (uninjured side) to $394.27 \pm 40.704 \text{ mm}$ (operated side) (p = 0.238) irrespective of fracture pattern. On sub group analysis, among the unstable fracture pattern, there was an average increase in total femoral length at 3rd month from 388.57 ± 37.79 mm to 392 ± 38.82 mm (p = 0.268) and an average increase in total femoral length at 3rd month from 394.38 ± 44.32 mm to 396.25 ± 44.86 mm (p = 0.583) in the stable fracture pattern.

Lag screw group: There was an overall average increase in total femoral length (Figure 3) at 3rd month from 391.364 \pm 16.170 mm (uninjured side) to 392.091 \pm 12.888 mm

(operated side) (p = 0.744). On further analysis, among the unstable fracture pattern, there was an average increase in total femoral length at 3^{rd} month from 391.67 ± 22.59 mm (uninjured side) to 393.67 ± 18.82 mm (operated side) (p = 0.713). In stable fracture pattern, there was average increase of total femoral length at 3^{rd} month from 391.250 ± 15.08 mm (uninjured side) to 391.500 ± 11.60 mm (operated side). Both the outcomes in comparison were statistically insignificant (p = 0.866).

Tip apex distance:

Helical blade group: The mean tip apex distance post operatively in this group was 21.67 ± 2.13 .

Lag screw group: The mean tip apex distance post operatively in this group was 21.27 ± 1.74

Union: Radiological Union at 3 months was achieved in

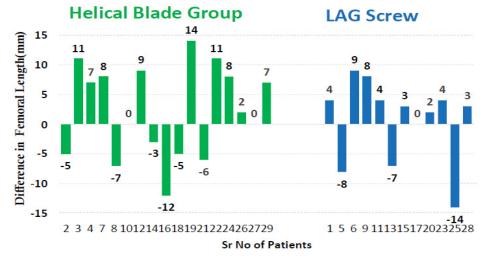


Figure 3: Difference of femoral length (mm) change at 3rd month with uninjured side in both groups.

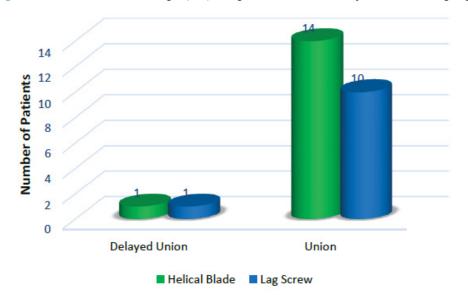


Figure 4: comparison of patients as per the union of fracture in both the groups.

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24 cases in total. Two cases had delayed radiological union each belonging to either group (unstable fracture pattern in helical group and stable fracture pattern in lag screw group) (Figure 4).

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Functional Outcome:

Functional outcome at 3^{rd} month which was assessed using Harris hip score showed statistically insignificant difference between the two comparison groups irrespective of fracture pattern and type of implant used (p = 0.967) (Figure 5).

Harris Hip Score

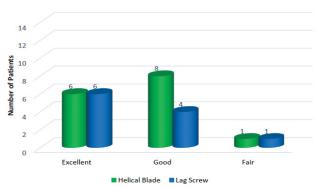
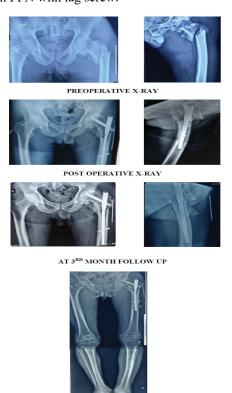


Figure 5: Harris hip score in both groups at three months.

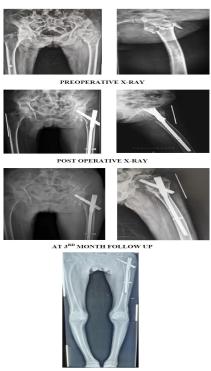
Case scenario 1:

A 75 year old male with unstable intertrochanteric fracture fixed with PFN with lag screw.



BILATERAL LOWER LIMB SCANOGRAM AT 3RD MONTH

Case scenario 2:



Discussion

With the increase in elderly population, the incidence of intertrochanteric fractures has increased year by year. Patients suffering from intertrochanteric fractures have a high incidence of morbidity and mortality. An early surgical procedure is now considered as preferred option for the treatment of intertrochanteric fractures providing an opportunity for early and full weight bearing mobilization. Surgical delay is associated with a significant increase in the risk of death and pressure sores [6].

Surgical implants employed to fix intertrochanteric fractures are dichotomized into being either intramedullary (cephalo-medullary nails) or extra-medullary (sliding hip screws). There is an increasing trend towards the use of intramedullary devices for the fixation of intertrochanteric fractures due to superior biomechanics and minimally invasive surgery particularly in unstable fracture patterns which enables immediate rehabilitation of the patient after surgery [7]. These devices allow controlled collapse at the fracture site.

Currently two different types of collum implants are available for proximal fixation, a traditional lag screw and a helical blade. Several randomized controlled trials and studies comparing helical blade with the lag screw in intramedullary fixations have demonstrated greatly different outcomes compared with published data and theoretical concepts. The optimal choice between the helical blade and lag screw is still controversial.



We conducted this randomized comparative study of 29 patients with intertrochanteric fracture, majority of patients belonging to age group of more than 65 years, which were randomized in two groups i.e. helical blade group (n=17) and lag screw group (n=12). All the patients were followed up for a time period of 3 months. Out of these, two patients were lost to follow up.

The aim of our randomized study was to assess if there were any differences in various radiological parameters and functional outcomes of patients with intertrochanteric fracture fixed with proximal femoral nail with helical blade and a proximal femoral nail with lag screw.

To avoid further bias in study, both the helical blade and lag screw were statically locked proximally to prevent undue collapse at fracture site.

Among the radiological parameters, an overall average increase of neck shaft angle at $3^{\rm rd}$ month was achieved irrespective of the fracture pattern and type of implant used. This average increase of neck shaft angle at 3rd month was statistically insignificant in comparison of both the groups (p = 0.270). We tried to maintain positive cortical reduction intra-operatively which led to valgus alignment of the neck shaft angle except in one case as discussed below. The average increase in neck shaft angle led to an overall average increase in total femoral length at $3^{\rm rd}$ month irrespective of fracture pattern and type of implant used. This average increase of total femoral length at 3rd month was statistically insignificant in comparison of both the groups (p = 0.866).

There was an insignificant average decrease in horizontal femoral offset irrespective of fracture pattern and type of implant used. This average decrease in horizontal femoral offset at 3rd month was statistically insignificant in comparison as well (p=0.126). On subgroup analysis, the variability i.e. an insignificant increase in horizontal femoral offset among stable fracture pattern group fixed with lag screw was observed due to a single case as discussed below.

We calculated the Tip apex distance on immediate postoperative x-ray. Average Tip apex distance (TAD) was within 10-25 mm in both the comparison groups. Radiological union at 3 months was achieved in 24 cases in total. 2 cases had delayed radiological union each belonging to either group. There was no statistical significant difference between the functional outcome of two comparison groups as measured by Harris Hip Score (HHS) at 3^{rd} month follow up (p = 0.967)

One case was erroneously fixed in slight varus neck shaft angle intra-operatively (Figure 6), which led to insignificant relative decrease in neck shaft angle degrees and insignificant relative increase in horizontal femoral offset among the stable fracture pattern group fixed with lag screw. But there was no further varus collapse i.e the neck shaft angle was maintained at 3rd month follow up in this case. The patient achieved

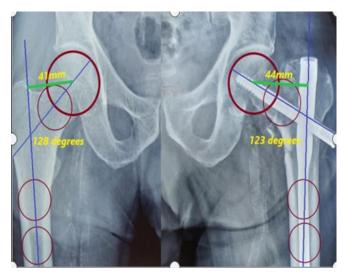


Figure 6: X-Ray radiograph of Pelvis (AP view) showing varus fixation of fracture.

radiological union at 3 months and functional outcome was good. If we tend to exclude this case from our analysis, the results will be same as in other groups irrespective of fracture pattern or type of implant used.

We also observed a single case of cut-through which was fixed with helical blade PFN at 3rd week follow up. Reason for which can be attributed to unprotected weight bearing.

A comparative study done by Talia chapman et al. [8] in 2018 on 126 patients treated with Trochanteric Fixation Nail (TFN; Synthes) with either a helical blade (71 [56.3%]) or screw (55 [43.7%]) concluded in their study that 7 failures of fixation (5.6%) occurred, all of which used a helical blade. 5 failures resulted from medial migration of the helical blade through the femoral head, while 2 resulted from typical supero-lateral cutout and varus collapse. There was no difference in average Tip Apex Distance (TAD) between the cases using blade versus screw fixation or between failures and the remainder of the cohort. This study showed a higher failure rate with use of the blade and supports the use of screw fixation in such fractures.

A Systematic Review and Meta-Analysis conducted by Kim et al. [9] in 2021 compared fixation failure between helical blade-type and lag screw-type CMNs with cut-out and cut-through rates as primary outcomes and degree of sliding length, time to union, and non-union rate as secondary outcomes. They concluded in their study that fixation failure (OR = 1.88, 95% CI: 1.09-3.23, P = 0.02), especially cut-through (OR = 5.33; 95% CI, 2.09-13.56; P < 0.01), was more common with helical blades than with lag screws, although the cut-out rate was not significantly different between both the comparison groups (OR = 0.87, 95% CI: 0.38-1.96, P = 0.73). In our study, we have observed a single case of cut through of helical blade as discussed earlier.



Following are the results of a biomechanical study conducted by Sommers et al. [10] and Al-Munajjed et al. [11] comparing helical blade and lag screw showing improved resistance of helical blade fixation to varus collapse and rotational control of the medial fracture segment compared to screw fixation (i.e., lag screw). These studies concluded that the improved resistance of the helical blade to cut-out has been attributed to radial compaction of cancellous bone as the blade is inserted. Major drawback of this study is that it is an in vitro study, so these results are hard to extrapolate on real life patients.

A recent study conducted by B J Punt [12] in 2019, on 631 patients which were surgically treated for an intertrochanteric femur fracture. Of this group, 239 patients (37.9%) were treated with Trochanteric femoral nail with helical blade and 392 patients (62.1%) with a Trochanteric femoral nail with femoral neck screw. This study demonstrated no statistically significant differences in primary and secondary outcomes between the use of a TFN with helical blade and a TFN with femoral neck screw (lag screw) for the surgical treatment of intertrochanteric femur fractures. A major drawback of our study was less number of patients taken into account and limited time duration for follow up. Although they have not mentioned about the distribution of the patients, an advantage of our study is that it is a randomized comparative study so that any bias is prevented.

Although we were able to achieve satisfactory results in both the comparison groups, as per surgeon's experience the operative technique for lag screw insertion was more technically complex as compared to helical blade insertion as the surgeon have to keep a check on rotation of femoral head segment while tightening the lag screw which may lead to loss of reduction intra-operatively. We have also used set screw to statically lock both helical blade and lag screw and have observed no case of non- union in any of our cases.

We acknowledge the limitations of the present study. Firstly our study group was small in number and we were unable to relate the age related osteoporosis with type of collum implant to be used as lack of availability of DEXA-CT scan at our institute.

Summary and Conclusion

So from current study comprising 26 patients of intertrochanteric fractures fixed with either Helical blade PFN or Lag screw PFN, we can conclude that Mean change in neck shaft angle and horizontal femoral offset at 3rd month was statistically insignificant irrespective of type of fracture pattern and type of implant used. Similarly mean change in total femoral length at 3rd month was statistically insignificant irrespective of type of fracture pattern and type of implant used. All the patients achieved radiological union. There was no case of non-union in any of the two comparison groups.

At the end we can conclude that good functional and radiological outcome in intertrochanteric fractures fixed with proximal femoral nail can be achieved with either of the collum implants as it depends upon the adequate reduction preferably positive in both the antero-posterior and lateral planes, proper placement of head neck implant with respect to Tip Apex Distance (TAD), statically locking both devices with set screw and quality of the bone and not on the type of implant used.

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