ORIGINAL RESEARCH

A randomized trial comparing the outcome of proximal femoral nailing and proximal femoral nailing antirotation-II for unstable intertrochanteric femur fracture

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ABSTRACT

Background: Proximal Femoral Nailing (PFN) and Proximal Femoral Nailing Anti-rotation (PFNA II) are both intramedullary implants having 6 degrees of proximal valgus angulation. The helical blade compacts the cancellous bone in femoral head when it is driven inside. **Aim:** The aim of our study is to compare radiological and functional outcome and superiorityover other in management of unstable intertrochanteric fracture by PFN and PFNA II. **Methods:** The study was conducted from october 2021 to september 2022 which included 76 patients of unstable Intertrochanteric fractures of femur. **Results:** In PFN group, Harris hip score was Excellent in 23 cases (60.52%), Good in 12 cases (31.57%), Fair in 2 case (5.26%) and poor in 1 case (2.63%). In PFNA II group, Harris hip score was excellent in 24 cases (63.15%), Good in 13 cases (34.21 %), Fair in 1 case (2.63%) and Poor in none of the cases. **Conclusions:** PFNA II significantly reduces the operative time and blood loss compared to PFN. However Both PFN and PFNA II implants offers no significant advantages over each other in terms of fracture unions, functional and radiological outcomes, post-operative complications and recovery outcomes.

INTRODUCTION

Intertrochanteric fracture of femur is an extracapsular fracture occurring between the greater and lesser trochanters. It occurs mostly in elderly population with osteoporosis, and also among the young individuals involved in high velocity trauma [1].

The aim for treating this fracture is to reduce displacement and stabilize with implants to allow early mobilization and weight bearing, thereby reducing complications caused by long-term bed rest, reducing disability and mortality, and improving the patients' quality of life.[2] Various studies have been done on extramedullary implant Vs intramedullary implant. Intramedullary implant provides better biomechanical properties and more resistant to implant failure.[3]

Proximal Femoral Nailing (PFN) and Proximal Femoral Nailing Anti-rotation (PFNA II) are both intramedullary implants having 6 degrees of proximal valgus angulation. The helical blade compacts the cancellous bone in femoral head when it is driven inside. This compaction enhances femoral head strength and increases the pull-out strength. A single helical blade PFNA II is technically better for smaller femoral head in Asian population. Biomechanically, helical blade in PFNAII has better cut-out resistance levels than screws.[4]

PFNA II uses a single helical blade for fracture stabilization as compared to two screws in PFN. The PFNA II involves gentle tapping of the helical blade over a guide pin, thereby avoiding the steps involved in reaming of canals for lag screw and de-rotation screw as required in a PFN.

Some advocates PFNA II in osteoporotic bone due to better Anchorage but other advocates PFN due to its theoretical benefits as it gives better rotational stability. Very few studies have been done on comparative study on both PFN and PFNA II. However, no study supports superior outcome of any one procedure over other.

The aim of our study is to compare radiological and functional outcome and superiority over other in management of unstable intertrochanteric fracture by PFN and PFNA II.

METHODOLOGY

This study was carried out in Rajendra Institute of Medical Sciences, Ranchi. This is a prospective study, period from November 2021 to October 2022. The patients were examined intraoperatively and postoperatively. Follow up of the patients were done at 1 month, 3months and 6 months.

- Group I (n=38)**:** patients who were operated with Closed reduction and internal fixation with PFN.
- Group II (n= 38)**:** patients who were operated with Closed reduction and internal fixation with PFNA II.

INCLUSION CRITERIA

1. All patients undergoing PFN and PFNA II surgery for unstable intertrochanteric femur fracture. (AO/OTA31.A2 to 31.A3).
2. age more than 18 (eighteen) years of both sexes.

EXCLUSION CRITERIA

1. All patients unfit for anaesthesia.
2. Patients who don't give consent to be a part of the study.
3. Open fractures
4. Fractures with bone loss
5. Presence of coexisting systemic disease or Co-morbid conditions which might affect boneunion.
6. Patients with neurovascular injury.
7. Patients with pathological fractures.

The study was analysed on the basis of the following variables:

- Operation time, blood loss, complications, weight bearing, rate of union, time to union, radiological assessment, functional assessment and recovery outcome of the patients.
- Radiological assessment of the patients were analysed by using RUSH score.
- Functional assessment of the patients were analysed by using Harris Hip score
- Recovery status of the patients were analysed on the basis of following variables: Walking ability up to pre-injury status, walking with aid, wheelchair bound.

OPERATIVE TECHNIQUE

ANAESTHESIA

Spinal or Epidural Anaesthesia was given to all patients according to the surgeon's and anaesthesiologist's preferences.

1. Patient positioning (same for PFN and PFNA II)

The patient was placed in supine position on a fracture table with the unaffected leg, flexed and abducted as far as possible in order to accommodate the image intensifier. Operative leg was put on traction. Upper body tilted to unaffected side, for easy insertion of the nail. The image intensifier was positioned so that AP & lateral views of the hip and proximal femur could be taken.

Closed reduction was achieved by traction and internal rotation primarily, and adduction or abduction as required. In cases where reduction becomes very difficult, Steinmann pins were used as joysticks to reduce the fracture percutaneously. Reduction was checked in a C-arm with anterior- posterior and lateral view.

2. APPROACH (same for PFN and PFNA II)

The tip of the greater trochanter was located, by palpation in thin patients and inhefty patients, we used the image intensifier, and a 5 cm longitudinal incision was madeproximal to the tip of the greater trochanter. An incision was made in the fascia lata and gluteus medius was split in line with the fibres. Tip of the greater trochanter was exposed.

3. Determination of the entry point and insertion of guide wire

In AP view on C-arm, the entry point was on the tip of the greater trochanter. In lateral view, guide wire position was confirmed in line with the medullary cavity. Entry was made with a bone awl. A 2.8 mm long guide wire was inserted into the femoral medullary cavity, across the fracture site under C-arm guidance.

4. Reaming of the proximal femur

Over the guide wire, a 15 mm cannulated reamer was inserted through the protection sleeve and manual reaming was done till the stopper on the protection sleeve. Protection sleeve was now removed. In osteoporotic bone, extensive reaming may not be required.

5. Reaming of medullary canal

The femoral canal was reamed serially from size 8 till the reamer was considered tight fit at the level of isthmus. One size smaller nail compared to the size of the reamer was applied.

6. Insertion of the PFN or PFNA II nail

After satisfactory fracture reduction, an appropriate size nail as determined preoperatively and cross checked intraoperatively under C-arm was assembled to theinsertion handle/ Jig. Before insertion of the nail, the drill sleeves for the proximal screws and distal bolts were inserted into the jig and confirmed if they matched with theholes on the nail. Now the nail was inserted manually into the femoral opening with limb in adduction. This step was done by twisting movements of the hand under C-armguidance until the hole for helical blade is at the level of inferior margin of neck. Light blows with the hammer may be carefully applied if needed. If the nail is inserted to the correct depth, proximal tip of nail usually corresponds to tip of greater trochanter.

7. Insertion of the guide wires for Helical blade (for PFNA II): (insertion of guide wire for derotation screw and femoral neck screw for PFN)

After making a stab incision and blunt dissection the drill sleeve along with the aiming arm for the helical blade was first inserted appropriately into the jig and pushed up to the lateral femoral cortex, . 2mm Guide

wires provided for the cannulatedproximal screws are not meant to drill hole in the lateral cortex. Hole was made in the lat cortex with trocar first, to avoid bending of guide wire. This step prevents a lot of guide wire related complications. It is important that the sleeves rest against bone and not the vastus lateralis muscle. The guide wire was then inserted through the sleeves into the femoral neck and head using image intensification and advanced deeper into the head up till the subchondral bone. The final position of this guide wire was in the lower half of the neck in AP view and in the centre in lateral view. The size of helical blade was measured. The lateral cortex was drilled uptil the tip of guide wire.

8. Insertion of the Helical blade (for PFNA II): (insertion of derotation screw and femoral neck screw for PFN)

The PFNA helical blade was attached to the inserter. The inserter was then turned anticlockwise to the attach marking to lock the blade. The PFNA blade was then inserted into the jig and passed into the nail with the help of guide wire. The inserter was gently hammered till the PFNA blade reaches the desired position in the subchondral bone. The inserter was turned clockwise to lock the blade and to provide the desired compression. The jig and inserter is then removed from the nail.

9. Distal locking

Before doing the distal locking, traction was released. Under C- arm guidance, the hole for the distal screw was visualized in lateral view. A stab incision was applied and blunt dissection was done upto the bone with artery forceps. Adrill hole was made with 4 mm drill bit through both cortices through the distal hole. Confirmation of drill bit entry through the distal hole is confirmed under C-Arm guidance. Length was measured directly from the drill bit or with a depth gauge.

4.9 mm locking bolt was inserted with the help of screwdriver. Position and size of the screw was confirmed with C-arm.

10. Closure

Stability of the construct was then assessed. Wash was given using normal saline. Incision was closed in layers with vicryl absorbable sutures, over a negative suction drain (if required). The skin was closed using skin staplers. Sterile dressing was applied over the wounds and compression bandage was given.

The statistical analysis of data was performed using the computer program, statistical package for social sciences (SPSS for windows, version 20.0 Chicago, SPSS Inc.) And Microsoft Excel 2010.

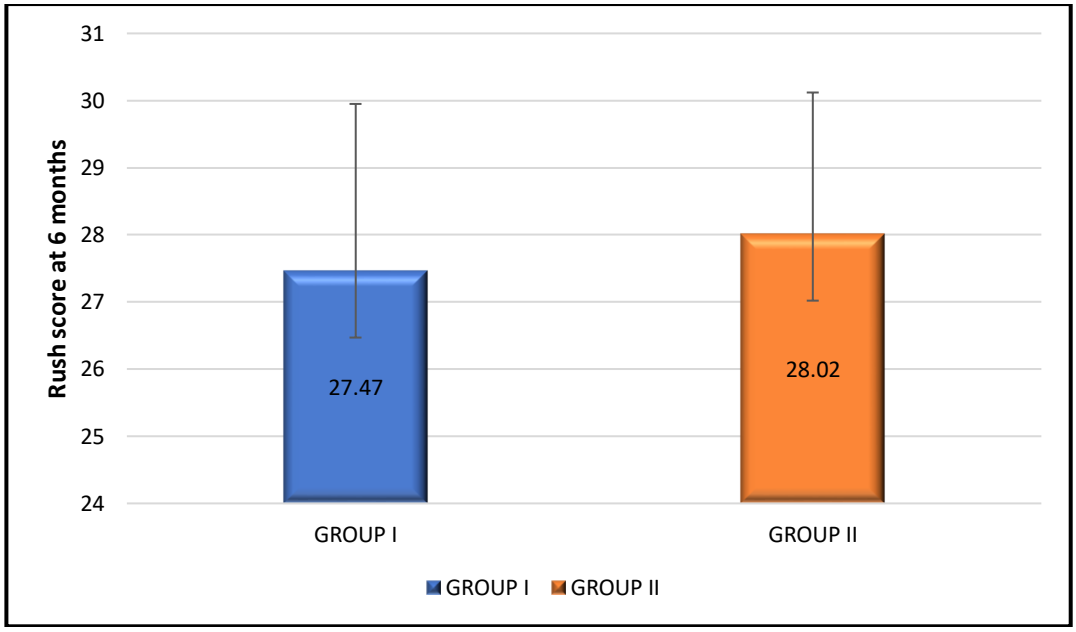
The mean age of the PFN group was found to be 65.31±9.63 years where as the mean age of PFNA II group was 65.52±9.42 years. This shows that there was no significant age bias. Group I (PFN) has 17 males and 21 females and group II (PFNA II) has 18 males and 20 female patients. In Group I (PFN), out of 38 patients, 8 (21.1%) patients sustained injury due to RTA, 27 (71.1%) due to self-fall and 3 (7.9%) due to fall from height. In group II (PFNA II), out of 38 patients, 10 (26.3%) sustained injury due to RTA, 24 (63.2%) due to self-fall and 4 (10.5%) due to fall from height. The mean time interval between trauma to surgery in PFN group was 11.37 ± 3.74 whereas in PFNA-II group, it was 11.08 ±4.10 which is not statistically significant between the two groups. The average duration of surgery was **63.05 ± 4.47** mins for the **PFN** group and **44.58± 5.01** minutes for **PFNA II** group. This shows that duration of surgery is lesser in PFNAII group compared to PFNA group, which is statistically significant ($p< 0.0001$). The mean intraoperative blood loss was **201.84± 7.11ml** in **PFN** group and **169.89±10.83 ml** in **PFNA II** group. This shows that there is lesser blood loss in PFNAII group compared to PFN group which is statistically significant ($p<0.0001$).

After 6 months of follow up, uniting fractures were seen in all the patients. Out of 38 patients treated with PFN, 32 patients (84.21%) shows full union of fractures and 6 patients (15.79%) shows partial union. Out of 38 patients treated with PFNA II, 35 patients (92.11%) show full union of fractures and 3 patients (7.89%) shows partial union. There is no statistically significant deference in rate of union of fractures between the groups. (p value is 0.28278). The time required for union was observed to be 19.28 ± 1.82 weeks in PFN group and 18.91± 1.32 weeks in PFNA II group. After 6 months of follow up, out of 38 patients treated with PFN, 34 of the patients can bear their full body weight without any assistance while 4 of the patients were able to do partial weight bearing. And out of 38 patients treated with PFNA II, 35 of the patients were able to tolerate their full body weight without any assistance while 3 of the patients were able to do partial weight bearing. The statistical difference between the groups comes out to be insignificant (p-value is 0.6892)

RESULTS

Table- 1: RUSH Score

RUSH score at 6 months	MEAN	SD	p-value
GROUP I (PFN)	27.47	1.33	**0.091**
GROUP II (PFNA II)	28.02	1.47	



The mean RUSH score at 6 months for PFN group is 27.47 and the mean RUSH score for PFNA II group is 28.02. In our study, the mean RUSH score for both the groups are more than 18. This indicates that there is less chance of going into nonunion.

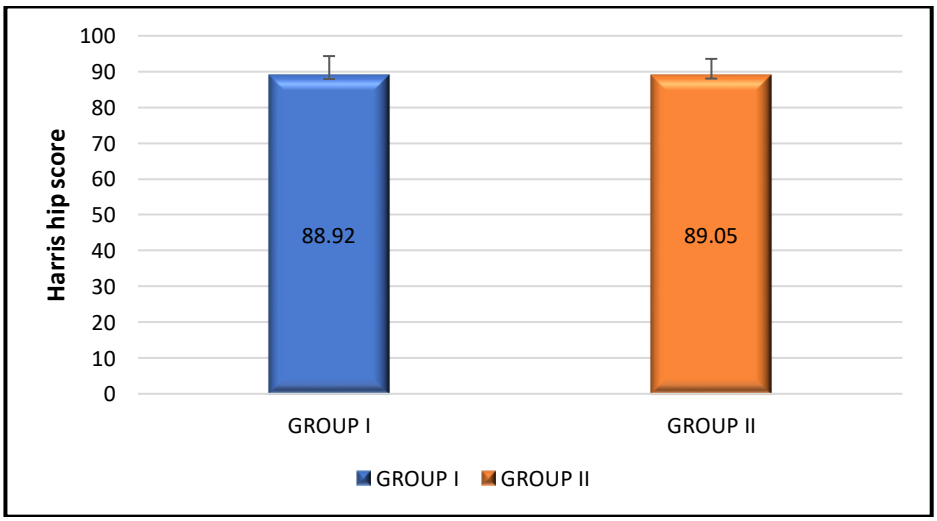
The statistical difference between the groups comes out to be insignificant for RUSH score (p-value is 0.091).

HARRIS HIP SCORE

The mean Harris hip score (HHS) was 88.92 ± 5.41 in PFN group and 89.05 ± 4.55 in PFNA II group. There is no significant difference in Harris hipscore between the two groups (p= 0.9090).

Table -2

Harris hip score	MEAN	SD	p-value
GROUP I (PFN)	88.92	5.41	0.9090
GROUP II (PFNA II)	89.05	4.55	



In PFN group, Harris hip score was Excellent in 23 cases (60.52%), Good in 12 cases (31.57%), Fair in 2 case (5.26%) and poor in 1 case (2.63%). In PFNA II group, Harris hip score was excellent in 24 cases (63.15%), Good in 13 cases (34.21 %), Fair in 1 case (2.63%) and Poor in none of the cases.

Among the various post-operative complications, SSI was seen in 3 out of the total 38 patients (7.89%) in group I and in group II, SSI was seen in 2 out of 38 patients (5.26 %). 2 cases (5.26%) of shortening were seen in patients treated with PFN and 1 case (2.63%) in PFNA-II group. It was also observed that 5 patients (13.16%) complain of hip pain with regard to PFN treatment and with PFNA-II treatment, 3 patients (7.89%) complain of hip pain. There was 1 (one) case each of hip joint stiffness in both the group. In all the cases there was no significant difference in both the groups.

Regarding PFN treatment,3 out of 38 patients (7.89%) were walking with aid, 34 out of 38 patients (89.47%)

were walking to preinjury status and 1 patient (2.63%) was wheel chair bound. None of the cases were bed ridden.

On the other hand, with regard to PFNA-II treatment, 2 out of 38 patients (5.26%) were walking with aid, 36 patients (94.74%) were walking to pre injury status and there was no case of patients bound to wheelchair neither was a case of bed ridden. It was not statistically significant in both the cases.

DISCUSSION

Proximal Femoral Nailing (PFN) and Proximal Femoral Nailing Anti-rotation (PFNA II) are both intramedullary implants having 6 degrees of proximal valgus angulation. The helical blade of PFNA II has better Anchorage and high pull-out strength as cancellous bone get compacted during procedure. However theoretically in PFN, two screw inside femur head and neck gives better rotational stability but in PFN, no such compaction of cancellous bone occurs. Both implants have their own advantages and disadvantages over each other.

The mean age of this study was found to be 65.42years (range 40 to 79 years), which suggests that intertrochanteric fracture is commonly seen in elderly population. In the study of **Pearce et al**.[5] the mean age was found to be 68 years. The reason why intertrochanteric fractures is common in elderly is probably due to tensile osteoporosis. Out of the 76 cases selected for our study, 25 were males and 41 were females. PFN group had 17 males and 21 females and PFN-II group had 18 males and 20 females.

Boone et al.[6] in their study include 54 male and 140 females, which correlates with our study. In many studies, higher incidence of intertrochanteric fractures was seen in females which is probably due to higher incidence of osteoporosis in females.

The findings in our study were similar with the study done by Pajarinen *et al*.[7]. They reported that 89.8% of the injuries were due to trivial fall.

According to Harshwardhan et al[8], Helical blade PFNA-II implant shows short operative time[21] and minimal blood loss and Dr Manjit Singh et al[9] also did a comparative study in elderly patients with intertrochanteric fracture femur treated with PFN and PFNA II. They concluded that, PFNA II gives better result than PFN in intertrochanteric fractures treatment in terms of amount of duration of surgery and blood loss. These findings are correlated with our study.

Dr Manjit Singh et al.[9] did a comparative study in elderly patients with intertrochanteric fracture femur treated with PFN and PFNA II. The mean Harris Hips score of the PFN group and PFNA II were found to be 86.40 and 89.87 respectively. They reported that non-significant results were obtained while comparing the mean time of full weight bearing status between PFN and PFNA II groups. This result correlates with our study.

In our study, the mean RUSH score for both the groups are more than 18. This indicates that there is less chance of going into nonunion using both the implants. Frank T et al reported that, RUSH score of < 18 have 10 times more chances of going into nonunion of fracture[10].

CONCLUSION

Thus, based on the findings from our study, we came to a conclusion that, both PFN and PFNA II implants offers no significant advantages over each other in terms of fracture unions, functional and radiological outcomes, post-operative complications and recovery outcomes. However, PFNAII is better option for treatment of unstable intertrochanteric fracture femur, as the duration of surgery and intraoperative blood loss were significantly lesser in PFNA II group when compared to PFN group.

The short duration of our study and smaller sample size, were the biggest limitation of our study. As the study was time bound, the patients were followed up for a period of 6 months only and the long-term effects of these interventions like the difficulty level of removing the implants when required have to be assessed in future. Larger sample size and long duration of study is recommended to strongly exert our conclusion.

CASE ILLUSTRATIONS

ARMAMENTARIUM

Figure 1: Pre-Operative

Figure 2: Intraoperative image showing patient's position in supine position on traction table also showing guide wire insertion after making entry point with awl.

Figure 3: Procedure of Closed reduction and internal fixation with Long PFNA. (i) Incision (ii) Guide wire insertion (iii) Nail insertion (iv) Reaming for PFNA blade (v) Insertion of PFNA blade (vi) Closure

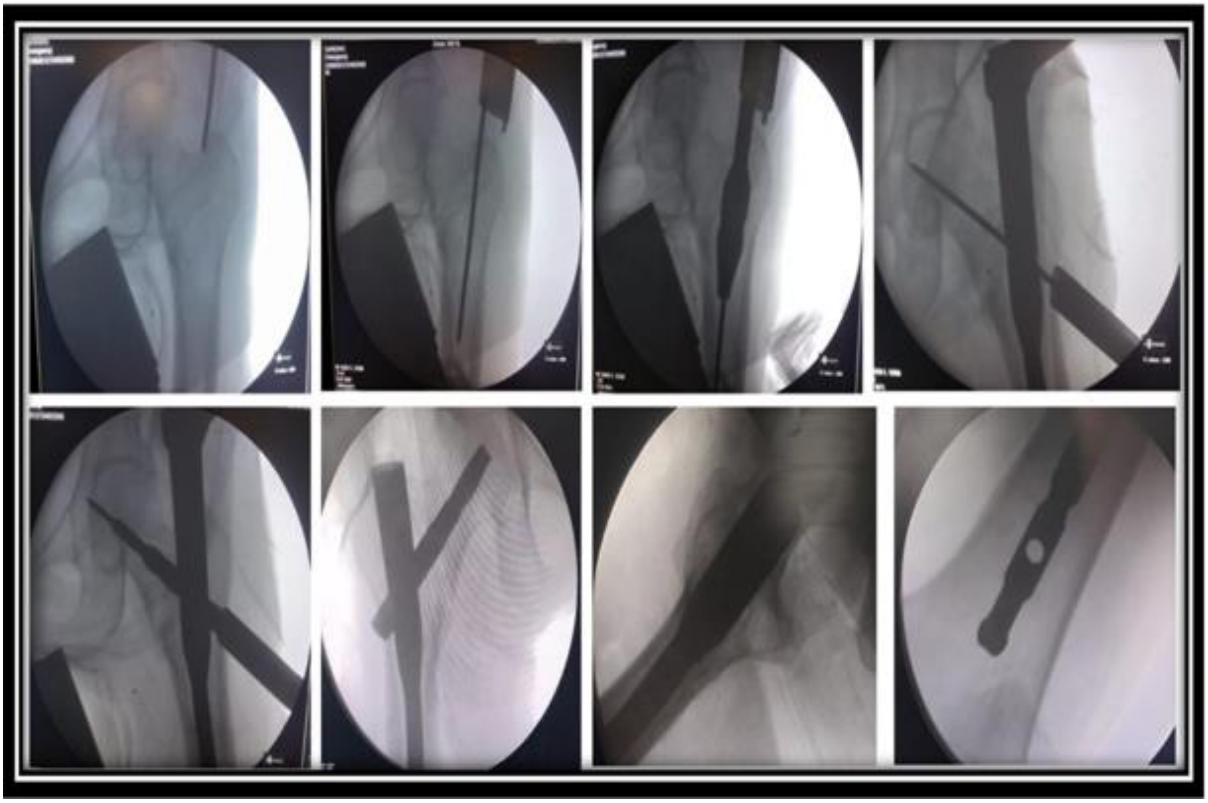


Figure 4: C-arm images of the procedure. (i) Entry point selection. (ii) Entry withguide wire (iii) Proximal reaming (iv) Guide wire for PFNA blade (v) Reaming for PFNAblade(vi) Intra-operative nail assessment –AP view (vii) Intra-operative nail assessment-Lateral view

Figure 5: Intraoperative images showing the procedures close reduction internal fixation with PFN.

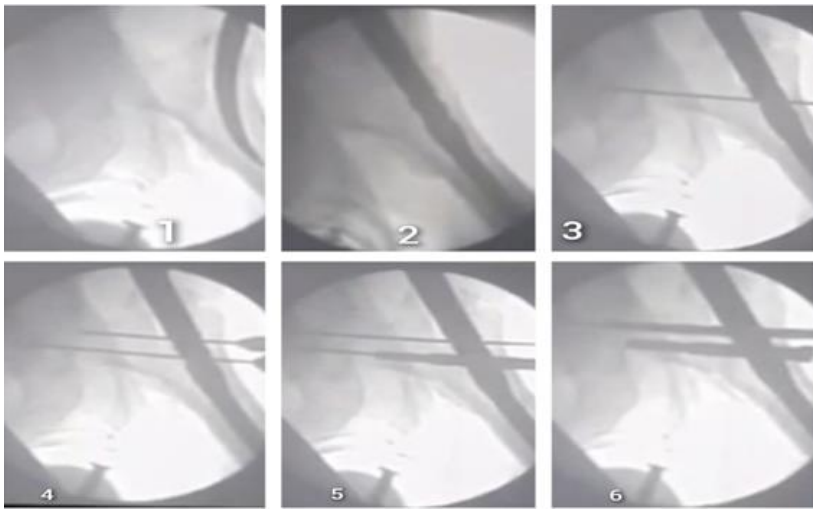


Figure 6: C arm images of PFN procedure

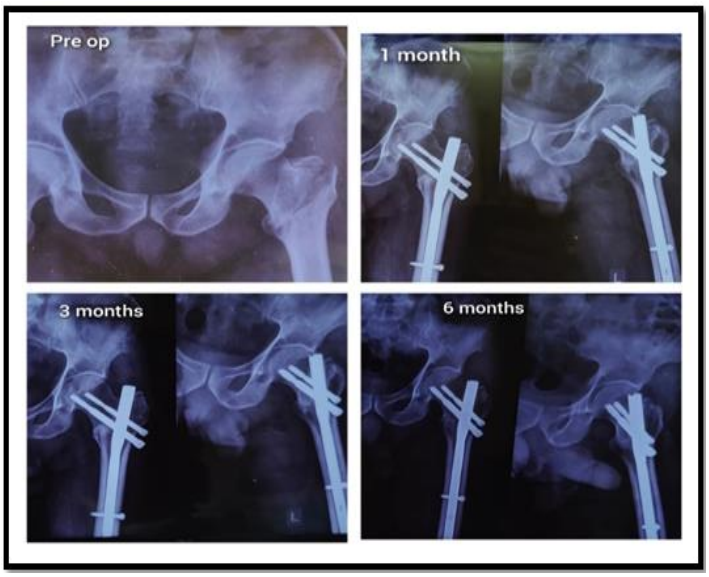


Figure 7: pre-op X-rays and follow up X-rays of PFN group at 1 month, 3 month and 6 months.

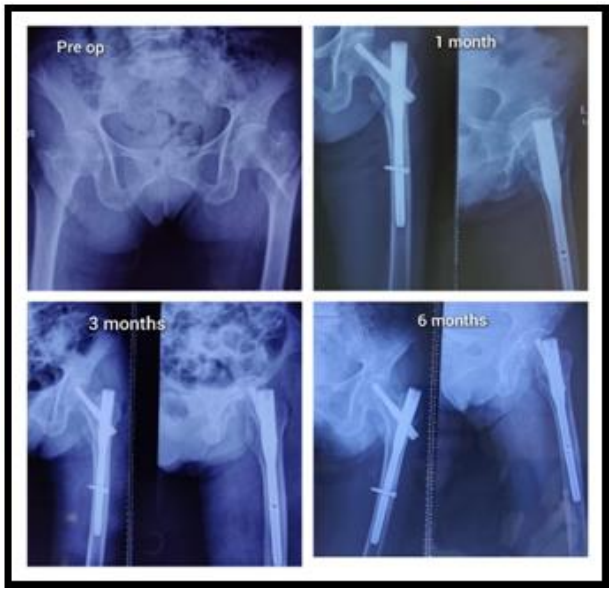


Figure 8: Pre-op Xray and follow up X-rays at 1 month, 3 months and 6 months of a patients treated with PFNA II

Figure 9: clinical photos showing range of motion of hip in PFN group during follow up.

Figure 10: Follow up patients of PFNA II group showing squatting and walking without support

REFERENCES

1. Korkmaz MF. Outcomes of trochanteric femoral fractures treated with proximal femoral nail: an analysis of 100 consecutive cases. Clinical Interventions in Aging 569, 2014. doi:10.2147/cia.s59835
2. Sheehan SE, Shyu JY, Weaver MJ, Sodickson AD, Khurana B. Proximal Femoral Fractures: What the Orthopaedic Surgeon Wants to Know. Radiographic. 2015; 35:1563-1584.
3. Parker MJ, Handoll HHG Gamma and other cephalocondylic intramedullary nails versus extra medullary implants for extra capsular hip fractures in adults. Cochrane Database Syst. Rev, CD000093, 2005.
4. Kashid MR. Comparative study between proximal femoral nail and proximal femoral nail antirotation in management of unstable trochanteric fractures. International Journal of Research in Orthopaedics. 2016; 2:354
5. Pearce McCarty L II. Wixted J, Vrahas M. Smith M. Use of the Long Trochanteric Fixation Nail for Unstable Intertrochanteric and Subtrochanteric Fractures: http://www.orthojournalhms.org/volume9/manuscripts/ms18.pd
6. Boone C, Carlberg KN, Koueiter DM, Baker KC, Sadowski J, Wiater PJ, et al. Short versus long

intramedullary nails for treatment of intertrochanteric femur fractures (OTA 31-A1 and A2). Journal of orthopaedic trauma. 2014;28(5): e96-e100.
7. Pajarinen J, Lindahl J, Michelsson O, Savolainen V, Hirvensalo E. Pertrochanteric femoral fractures treated with a dynamic hip screw or a proximal femoral nail. A randomised study comparing post-operative rehabilitation. J Bone Joint Surg Br 2005; 87:76-81.
8. Harshwarden H, Jain S, Sharma M. an outcome analysis of intertrochanteric femur managed with PFNA-II. International Journal of research in Orthopaedics. 2019; 5:699.
9. Dr. Manjit Singh, Dr. Dilmahon Singh Karday, Dr. Dharminder Singh. A comparativestudy of 30 cases of intertrochanteric fracture femur in elderly patients treated with PFNA-II and PFN. European Journal of Molecular and Clinical medicine 2021: ISSN 2515-8260 Volume 08, Issue 03.
10. Frank T, Osterhoff G, Sprague S, Garibaldi A, Bhandari M, Slobogean GP, et al. The Radiographic Union Score for Hip (RUSH) identifies radiographic nonunion of femoral neck fractures. Clin Orthop Relat Res 2016; 474:1396-404.