

## **A PROSPECTIVE STUDY- COMPARSION OF DISTAL UNLOCKED VERSUS LOCKED PROXIMAL FEMORAL NAILS IN STABLE INTERTROCHANTERIC FRACTURES**

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### **ABSTRACT**

#### **INTRODUCTION:**

Intertrochanteric fractures are commonly seen in patients over 70yrs of age. In younger population, intertrochanteric fracture occurs due to high velocity trauma, whereas in elderly population, it is most often due to trivial trauma. Cephalomedullary device is used for management of intertrochanteric fracture

#### **OBJECTIVES :**

To compare the surgical results in patients with inter-trochanteric femur fractures Treated by PFN with and without distal locking .

**METHODOLOGY:** In a prospective study 40 patients were enrolled with mean age 59.05 years with proximal femur fracture which included 25females and 15 males who underwent Long proximal femoral nail with distally locked and distally unlocked. AO system of classification was used. 31 A1 was the commonest type. Operative time, overall fluoroscopy shots, intra-operative blood loss, the duration of hospitalization, and the surgical complications were noted. Patients were followed up at 6weeks, 3months, 6 months. Functional outcome assessed according to the Harris hip scoring system.

#### **RESULTS:**

Mean age of 59.05 years in PFN without distal locking and 54.75 years in PFN with distal locking. Mean duration of surgery in PFN without and with distal locking was 40.45 & 54.75 mints respectively. Mean amount of blood loss in PFN without and with distal locking 154.7 ml and 206.3 ml respectively .Mean length of incision in PFN without and with distal locking was 10.95 & 12.65 cm respectively. Mean fluoroscopic time in PFN without and with distal locking was 61.3 & 71.3 shots respectively. Mean duration of hospital stay in Group A & B is 15.3 & 15.2 days respectively . Out of 40 cases no case was lost in follow up. we had good to excellent results in 90%, fair in 10%, we had no case with poor results.

## **CONCLUSION:**

From this study, we consider that long proximal femoral nailing without distal locking shows subtle advantages for duration of surgery, amount of blood loss, incision length, fluoroscopy exposure time, post-op stiffness in stable intertrochanteric fracture.

**Key words:** Intertrochanteric Fracture; Proximal femoral nail; Harris Hip Score.

## **INTRODUCTION**

According to recent estimates the number of hip fractures worldwide will drastically increase in the next few decades, with an anticipated incidence of 500,000 fractures per year by 2040<sup>(1)</sup>

Intertrochanteric fractures are common in old age group, but it is not uncommon in younger age group. These fractures unite readily with conservative line of treatment and there is no fear of complications like, avascular necrosis of head and its sequel of osteoarthritis. In trochanteric fractures treated without surgical interventions, malunion with coxa vara deformity resulting in shortening of limb and limp are commonly seen<sup>(2)</sup>.

Various operative procedures with different implants have been described for the treatment of intertrochanteric fractures. Earlier active treatment was usually delayed for as long as 3 to 4 weeks which lead to secondary complications. The primary goal of the treatment has to be early mobilization to avoid secondary complications, which can be achieved by open reduction and internal fixation.

Intramedullary device-Proximal Femoral Nail was designed in 1996 which gives an advantage of minimally invasive surgery<sup>(3)</sup>. Here is an effort to study the results of Proximal Femoral Nail in the management of intertrochanteric fractures by analyzing the factors which influence the post operative mobility.

In recent years, intramedullary nails have gained widespread popularity with the advantages of earlier weight-bearing activities, less post-operative complications and providing a more biomechanically stable construct than extramedullary implants<sup>(4)</sup>. Usually, intramedullary nails are designed with various distal fixation options to improve axial and rotational stability, which can also restrain the movement of distal tip of nail when a broad femoral medullary canal was encountered.<sup>(5)</sup>

The application of distal locking (DL) screws leads to some new problems including an additional incision, secondary femoral fractures and increased surgery-related costs. Moreover, longer operation time and more X-ray exposure, as well as potential stress concentration should also be taken into account<sup>(6)</sup>. Besides, fascia lata irritation and lag screw cut-out were also reported in patients treated with distal locked intramedullary nails<sup>(7)</sup>. Therefore, whether the distal locked intramedullary nailing is essential for intertrochanteric fractures is still in dispute.

The incidence of fractures in the trochanteric area has risen with the increasing numbers of elderly persons with osteoporosis.

Although the PFN system developed by the AO/ASIF overcame many of the previously mentioned limitations of the Gamma nail, it still has some disadvantages. Distal locking screws can act as stress risers that cause subsequent implant breakage and can also induce fascia lata irritation. Thus, in this prospective study, we tried to find out whether two lag screws can be applied to the PFN without distal proximal locking screws in 31-A1 and 31-A2 fractures.

Biomechanical studies revealed that distal locking of stable intertrochanteric fractures may not be required<sup>[8]</sup>. Rosenblum et al. found that the use of distal locking screw does not change femoral stress load for stable intertrochanteric fractures, and the tension of the proximal femoral bone does not change<sup>[8]</sup>.

Various complications have been highlighted in the use of distal locking of intramedullary nails, including fascia lata irritation, additional operative time, intraoperative bleeding, radiation exposure, superficial femoral artery tear, implant loosening, and secondary femoral fractures [9,10].

In particular, our main purpose was to demonstrate that unlocked nails are equivalent to static and distal locked nails regarding clinical and radiological outcomes, providing the advantage of intraoperative variables' reduction. Hence the need for the study is to assess the effectiveness of unlocked distally versus locked proximal femoral nail in proximal femoral fractures.

**METHODS:**

This was a prospective study and the main source of data were from the subjects who have sustained a intertrochanteric fracture and who are admitted to Raja rajeshwari Medical College and Hospital , Bangalore Satisfying the inclusion criteria are taken for this study period of November 2019 to May 2021 will be included.

Cases selected from the patients with intertrochanteric fracture who require Cephalomedullary nail , after taking consent , will be analyzed clinically and radiological. All the patient selected for the study to be examined according to protocol, clinical and laboratory investigations will be carried out in order to get fitness for surgery. Patient will be subjected into two groups by purposive sampling technique. Group A will be operated using proximal femoral nail without distal locking and Group B will be operated using proximal femoral nail with distally locked. The Sample Size is 40 and is Calculated based on previous studies and Number of cases in the above mentioned duration Satisfying inclusion and exclusion criteria. The post operative functional outcome was determined by Harris Hip Score (HHS).

**Table: 1. INCLUSION CRITERIA & EXCLUSION CRITERIA**

<b>INCLUSION CRITERIA</b>	<b>EXCLUSION CRITERIA</b>
A) Age $\geq$ 18 years (skeletal mature )	A) Patient who sustained polytrauma
B) Patient who have sustained Intertrochanteric fracture of femur undergoing Fixation within 3 weeks	B) Patient who had pathological fracture other than osteoporosis.
C) Patients with closed fractures according to AO classification) .	C) Injury of more than 3 weeks duration.
	D) Patient who were not ambulatory , Prior to fractures .
	E) Active malignancy/Active infection

**Statistical tests:**

The collected data will be analyzed using descriptive and inferential statistics. Software used for analysis are MS.Excel and SPSS (v 2.0). The Student's unpaired t-test will be used for the study. The Pearson's chi-square or Fisher's exact test will be used to compare the difference between categorical variables. P value  $\leq 0.05$  will be considered statistically significant.

**RESULTS:**

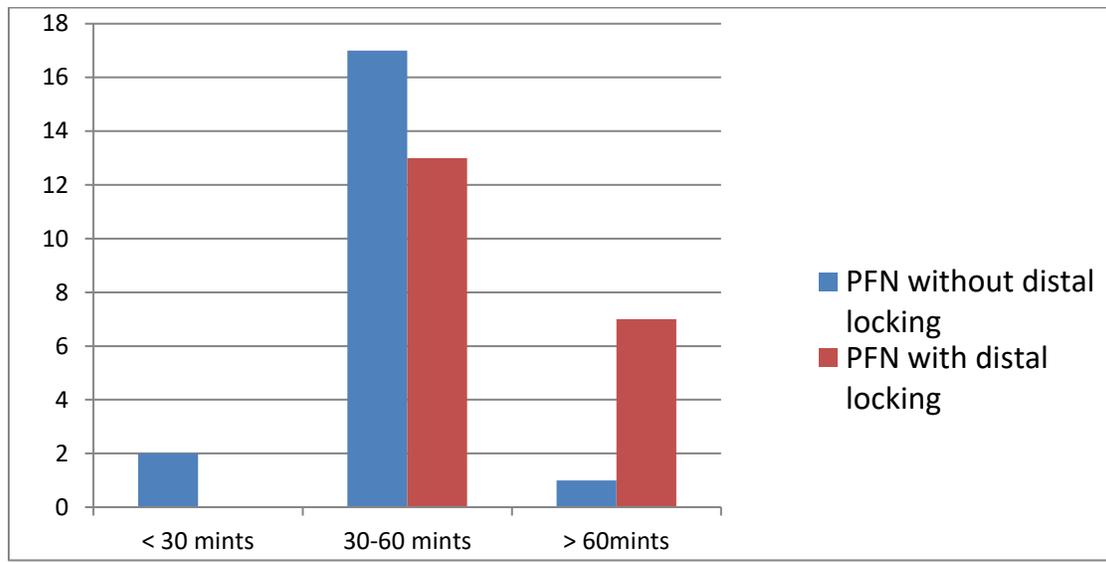
In our series of 40 cases there were 25 males and 15 females, maximum age of 82 and minimum age of 38 years most of the patients were between 40-60 years. 67.5% cases were admitted due to fall. Mean age of 59.05 years in PFN without distal locking and 54.75 years in PFN with distal locking. Mean duration of surgery in PFN without and with distal locking was 40.45 & 54.75 mins respectively. Mean amount of blood loss in PFN without and with distal locking 154.7 ml and 206.3 ml respectively. Mean length of incision in PFN without and with distal locking was 10.95 & 12.65 cm respectively. Mean fluoroscopic time in PFN without and with distal locking was 61.3 & 71.3 shots respectively. Mean duration of hospital stay in Group A & B is 15.3 & 15.2 days respectively. Out of 40 cases no case was lost in follow up. We had good to excellent results in 90%, fair in 10%, we had no case with poor results. One patient had lag screw cut-outs in distally locked group, No patient had complications like non-union or malunion. The fractures healed in all patients; the average consolidation time was 14 weeks (range: 9-28). No intraoperative complications occurred.

**TABLE 2 : COMPARISON OF THE MEAN AGE BETWEEN THE GROUPS USING INDEPENDENT SAMPLE T TEST**

METHODS	N	Minimum	Maximum	Mean	S.D	Mean diff	T value	P-Value.
PFN Distally unlocked	20	42	80	59.05	15.8	1.32	0.89843	.374615
PFN with distal locking	20	38	82	54.75	14.48			

**TABLE 3 : COMPARISON OF BOTH GROUPS ACCORDING TO DURATION OF SURGERY**

Duration of surgery	PFN without distal locking		PFN with distal locking	
	No	%	No	%
< 30 mints	2	10%	0	0%
30-60 mints	17	85%	13	65%
> 60mints	1	5%	7	35%



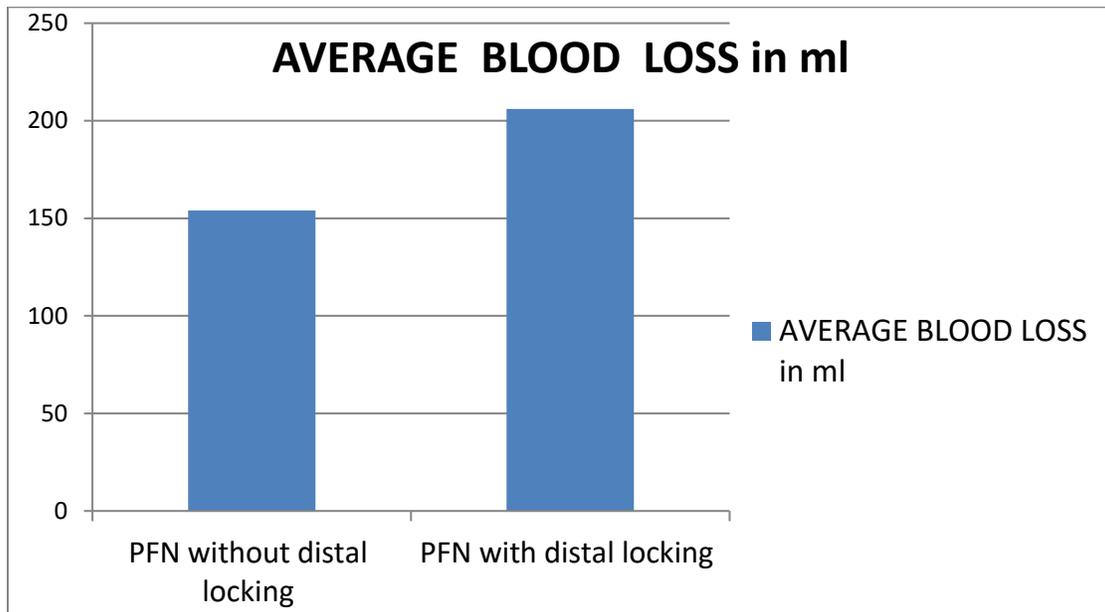
PARAMETER	GROUP 1 PFN unlocked distally		GROUP 2 PFN with distal locking		95% C.I	T-statistic	p-Value
	MEAN	SD	MEAN	SD			
Duration of Surgery(min)	40.45	11.18	54.75	10.15	7.46 to 21.14	4.23	0.001

**TABLE 4 : COMPARISON OF BOTH GROUPS ACCORDING TO AMOUNT OF BLOOD LOSS**

PARAMETER	GROUP 1 PFN distally unlocked		GROUP 2 PFN with distal locking		95% C.I	T- statistic	p- Value
	MEAN	SD	MEAN	SD			
Amount of blood loss(ml)	154.7	42.24	206.3	54.0303	20.55 to 82.64	3.365	0.0018

**TABLE 5 : COMPARISON OF BOTH GROUPS ACCORDING TO AMOUNT OF BLOOD LOSS**

PARAMETER	GROUP 1 PFN without distal locking		GROUP 2 PFN with distal locking		95% C.I	T- statistic	p-Value
	MEAN	SD	MEAN	SD			
Length of incision	10.95	1.27	12.65	1.22	0.89 to 2.49	4.31	0.0001



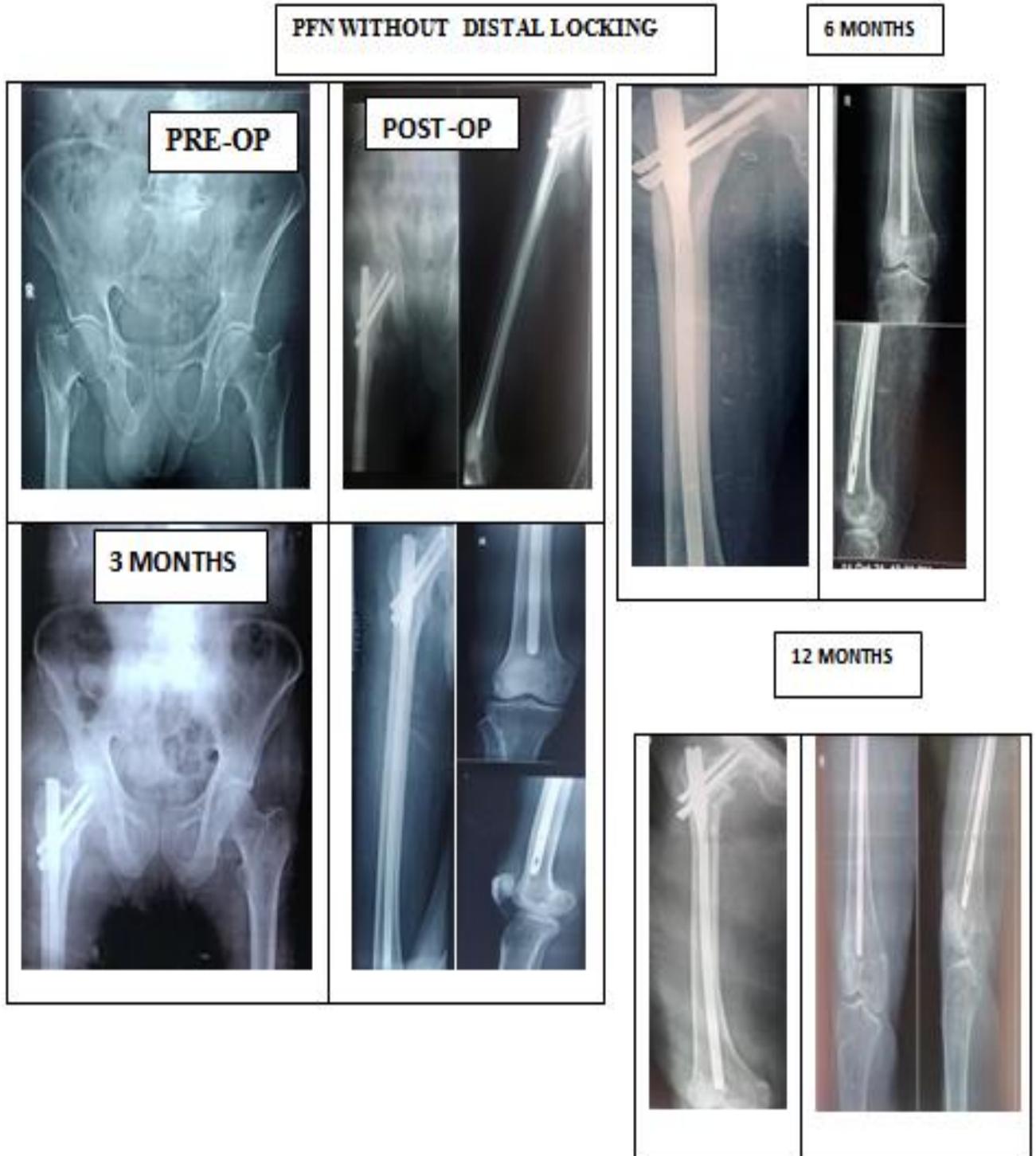
**TABLE 6 : COMPARISON OF BOTH GROUPS ACCORDING TO FLUOROSCOPY EXPOSURE TIME**

PARAMETER	GROUP 1 PFN without distal locking		GROUP 2 PFN with distal locking		95% C.I	p-Value
	MEAN	SD	MEAN	SD		
Fluoroscopy exposure time	61.3	9.68	75.2	12.48	6.75 to 21.05	0.0003

**TABLE 7 :COMPARISON OF THE MEAN HARRIS HIP SCORE BETWEEN THE GROUPS USING INDEPENDENT SAMPLE T TEST**

Time interval	Groups	Minimum	Maximum	Mean	S.D	Mean diff	T-Value	P-Value
6weeks	PFN without distal locking	45.0%	60.0%	64.6 %	6.916	2.143	1.942	.0595
	PFN with distal locking	55.0%	65.0%	60.95 %	4.773			
3 months	PFN without distal locking	75.0%	90.0%	80.75 %	5.68	0.88	1.075	0.2889
	PFN with distal locking	75.0%	90.0%	78.9 %	4.87			
6 months	PFN without distal locking	75.0%	90.0%	84.05 %	4.740	0.274	0.721	0.4753
	PFN with distal locking	75.0%	90.0%	83.45 %	4.466			

**FIGURE 1: RADIOLOGICAL IMAGES**



**FIGURE 2: RADIOLOGICAL IMAGES**



**DISCUSSION:**

Nowadays, various designed intramedullary devices have already gained widespread application to treatment of intertrochanteric fractures<sup>(11)</sup>.

However, the popularity of intramedullary devices has led to an increase in distal screw-related complications. There is still insufficient evidence to verify the necessity of distally locked screws for intertrochanteric fractures. In this study, distal unlocked intramedullary nails showed better intra operative outcomes than the distal locked. Besides, both post-operative functional parameters and local complications indicated no difference between the two groups.

The exception was thigh pain, which developed more in Distally locked group.

The increased operation duration and fluoroscopy exposure time in distally locked group cannot be considered negligible. Longer operation time usually means longer anesthesia exposure and more blood loss. They can further lead to pulmonary infections, anemia and hypoalbuminaemia.

Anatomical fracture reduction and the insertion of the inferior lag screw as close as possible to the inferior cortex of the femoral neck is strongly recommended because the compression trabeculae and tensile trabeculae of the proximal femur intersect at the inferior part of the femoral neck, constituting the strongest architecture. Further, the lag screws should be inserted 10 mm into the subchondral bone to enhance stability. Increased stresses at the distal nail tip have also been reported. These stresses may lead to local cortical hypertrophy, mid-thigh pain and fractures around the distal locking screws. Distal cortical hypertrophy is a radiological sign of proximal stress shielding with load concentrations at the tip of the nail<sup>[12]</sup>.

Hardy et al. stated that using two static locking screws during intramedullary fixation of intertrochanteric fractures is correlated with a high rate of cortical hypertrophy, while the use of a dynamically locked nail significantly reduces the rate of this complication<sup>[12]</sup>. By avoiding the use of distal locking screws, we had the added advantage of decreased operation and fluoroscopy exposure time, increased patient mobility due to less tissue dissection and a low probability of iliotibial tract irritation due to the omission of a distal screw.

**CONCLUSION:**

In summary, no significant differences in the complication rate and the fracture healing were found between the distally unlocked and distally locked groups in our study. From this study, we consider that long proximal femoral nailing without distal locking shows subtle advantages for duration of surgery, amount of blood loss, incision length, fluoroscopy exposure time, post-op stiffness in stable intertrochanteric fracture. The terms of successful outcome include a good understanding of fracture biomechanics, proper patient selection, good preoperative planning, accurate instrumentation, good image intensifier.

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