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Dr. Rishabh Soni
3rd Year Resident, Department of Orthopaedics, Mahatma Gandhi Medical College and Hospital, Sitapura, Jaipur, Rajasthan, India

Dr. Rajendra Kumar Verma
Professor Department of Orthopaedics Mahatma Gandhi Medical College and Hospital Sitapura, Jaipur, Rajasthan, India

Dr. Rajat Jangir
Assistant Professor, Department of Orthopaedics Mahatma Gandhi Medical College and Hospital Sitapura, Jaipur, Rajasthan, India

Correspondence
Dr. Rajendra Kumar Verma
Professor Department of Orthopaedics Mahatma Gandhi Medical College and Hospital Sitapura, Jaipur, Rajasthan, India

Prospective randomized study of outcome of proximal femur nail (PFN) in proximal femur fractures

Dr. Rishabh Soni, Dr. Rajendra Kumar Verma and Dr. Rajat Jangir

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Abstract
Proximal Femur fractures are common injuries occurring predominantly as low-energy injuries in the elderly, mostly due to direct injury to hip (e.g. fall). These days intramedullary nails are becoming the implant of choice for unstable proximal femur fractures, as it offer certain distinct advantages in proximal femur fractures. This prospective randomized study was conducted at department of Orthopedics in Mahatma Gandhi Medical College and Hospital, Sitapura, Jaipur to compare outcomes of proximal femur nail. Surgery duration was less in PFN because most of the cases were reduced closed, less exposure was done and associated less closure time. Intra operative image intensifier use was significantly more in PFN group because of requirement of accurate placement of lag screw, distal locking and identification of nail length.
Post operatively sole aim of the treatment was to make the patient upright, mobilize as early as possible.
In follow up of cases at 16 and 24 weeks as per activity of daily living Patients had very little restriction in Activity of Daily Living.
On concluding the outcome as per Salvati-Wilson Score at 24 weeks excellent score was found in 50% cases of PFN while it was fair in 50% cases.

Keywords: Intramedullary nails, surgery duration, image intensifier, activity of daily living, Salvati-wilson score

1. Introduction
Proximal Femur fractures are common injuries occurring predominantly as low-energy injuries in the elderly, mostly due to direct injury to hip (e. g. fall). The financial burden to the society is tremendous [1, 2]. Gulberg *et al*. has predicted that the total number of hip fractures will reach 2.6 million by 2025 and 4.5 million by 2050 [3]. In 1990 26% of all hip fractures occurred in Asia whereas this figure could rise to 37% in 2025 and 45% in 2050 [4].
Cooper was the first one to classify hip fractures into extra capsular (intertrochanteric) and intra capsular (femoral neck).
Since the 1800s, a lot has changed in the way these fractures are managed. Starting from conservative treatment which includes hip spice and pin traction with bed rest, to the operative fixation with modern surgical techniques, implants and infrastructure, we have come a long way. Early attempts at surgical management were marred by poor asepsis, lack of intraoperative imaging, poor implant design and quality, and incomplete understanding of fracture mechanics.
Lange beck was the first to internally fix an intertrochanteric fracture with a nail [5]. The modern era of hip fracture fixation began in 1925 when Smith Peterson introduced a tri flanged nail [6]. The real benefit of fixation lies in improving functional outcome and mortality rates, which are attributed to the early mobilization and better nursing care possible only after surgery.
Various modalities of implants have been used for fixation such as Smith Peterson nail, jewett nail, trochanteric buttress plate, angled blade plate, got fried percutaneous compression plate enders nail, dynamic hip screw (DHS), med off plate, proximal femur locking compression plates and cephalo medullary nails.
Pugh and Massie first developed the DHS in 1950s by modifying the sliding hip screw systems [7, 8] and it quickly became the gold standard and most commonly used implant worldwide for

fixation of intertrochanteric fractures. The two important complications related to DHS are uncontrolled collapse and lag screw cut-out (with or without varus collapse) [9].

These days intramedullary nails are becoming the implant of choice for unstable proximal femur fractures, as it offer certain distinct advantages:

1. It does not allow lateral translation of proximal fragment by acting as a buttress.
2. The intramedullary implant is stronger at resisting the bending force.
3. The intramedullary nail reduces the distance between the weight bearing axis and the implant and thus provides a shorter lever arm.
4. The intramedullary device is a load sharing device thus making the patient to mobilize early.
5. The intramedullary nail is a more biological method of fixation as it is less invasive.

However, their use is also associated with many complications: screw cut-out/blade cut-out (including Z effect and reverse Z effect), varus deformity, lateral wall blowout during reaming, difficult insertion in curved femurs, peri-implant fracture (subtrochanteric fractures in short nails), and implant breakage [10-13].

Material and Methods

Study Design

This prospective randomized study was conducted at department of orthopedics in Mahatma Gandhi Medical College and Hospital, Sitapura, Jaipur.

Duration of study

November 2015 to September 2017.

Informed consent was taken from the patients who are included in this study for the selection criteria.

Method of collection

The ethical committee of Mahatma Gandhi Medical College, Jaipur was informed about the intended work and permission was obtained to conduct the work.

Number of cases

In this study 20 patients attending Orthopaedics OPD in Mahatma Gandhi Hospital during November 2015-September 2017 of proximal femur fractures and willing to undergo the study were taken. These will be selected based on inclusion and exclusion criteria.

Eligibility Criteria

Inclusion criteria

All adults and elderly patients of both genders with proximal femur fractures attending MGMC&H Casualty/OPD/IPD

Exclusion criteria

- Patient unfit for anesthesia/surgery
- Patient with severe co-morbid medical conditions
- Open contaminated fractures
- Patients were admitted in Orthopaedic ward on analgesics and temporary kin traction.
- Patients underwent full investigations pertaining to pre-anesthetic checkup. Following fitness for anesthesia, patients of this group will were taken up for elective surgery and the study was recorded in a pro forma.
- Following the treatment followed up at outpatient department at regular intervals for clinical and radiological evaluation. The patients were followed up till fracture union and functional recovery. If necessary, subsequent follow up was done.

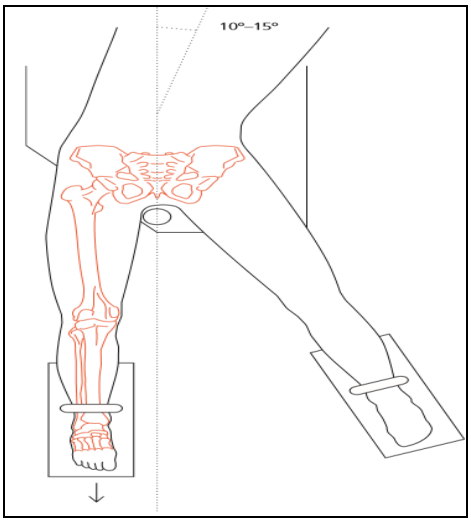
Patient positioning

Patient is postioned supine on an extension table or on a radiolucent operating table. C-Arm images are taken in such a way that it can visualize the proximal femur exactly in the lateral and AP planes.

For unimpeded access to the medullary cavity was abducted by about 10-15º to the contralateral side.

Reduce fracture

If possible, closed reduction of the fracture was tried under image intensifier. Exact reduction and secure fixation of the patient to the operating table are essential for easy handling and a good surgical result.

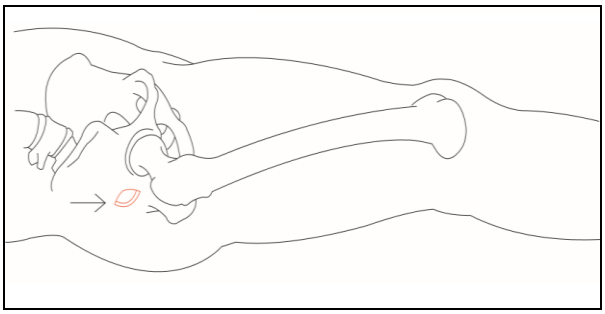


Determine nail diameter

Nail diameter was determined under image intensifier control, or by placing the Measuring Device on the femur and position the square marking over the isthmus. If the transition to the cortex was still visible to the left and right of the marking, the corresponding nail diameter was used.

Approach

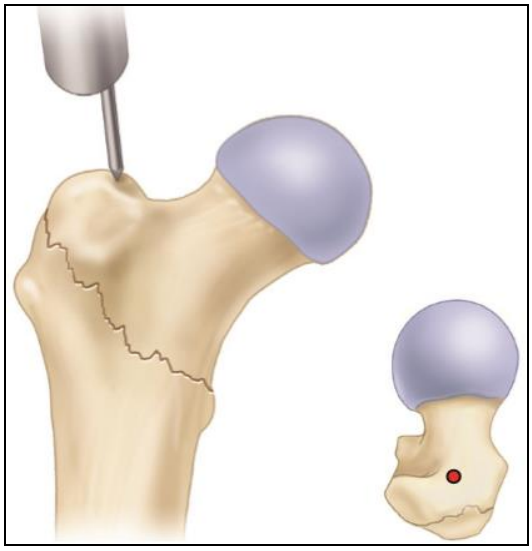
Palpate the greater trochanter. Make a 5cm incision approximately 5 to 8cm proximal from the tip of the greater trochanter. Make a parallel incision in the fasciae of the gluteus medius and split the gluteus medius in line with the fibres.



Entry Portal

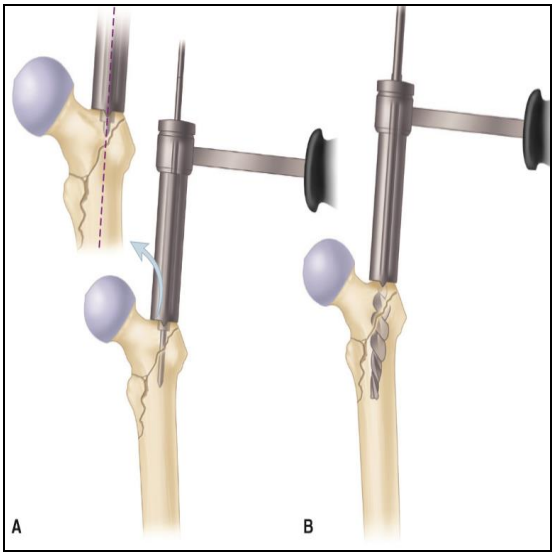
For fixation of proximal femur fractures, as well as many other fractures of the femur, we use a modified medial trochanteric portal. The medial trochanteric portal is located

on the medial aspect of the greater trochanter along the trochanteric ridge on the anteroposterior view and in line with the femoral shaft on the lateral view.

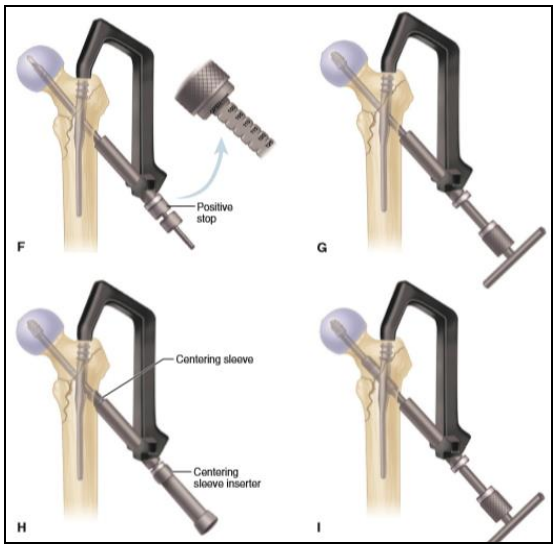


Technique

- Localize a guide pin on the medial aspect of the greater trochanter (modified medial trochanteric portal).
- Insert the guide pin 2 to 3 cm distally into the proximal fragment. At this point use fluoroscopy to assess the guide pin placement in both planes. Make any corrections of the guide pin with a two-pin technique and a honeycomb type guide.
- We believe that the use of a two-pin technique saves significant fluoroscopic time in the operating room.
- Use the proximal reamer to ream over the guide pin to a depth just below the level of the lesser trochanter. Correct any malreduction before reaming.



- Place the ball-tip guide pin down the shaft of the femur to the physeal scar, and measure the guide pin to determine the appropriate length of the intramedullary nail.
- We typically use a 10-mm diameter nail for intertrochanteric femoral fractures. We believe there is no significant benefit to placing a larger diameter nail in most situations and that placing a larger nail may increase the risk of anterior cortical perforation.
- Ream to a diameter 1.5 mm larger than the diameter of the intramedullary nail. Pay careful attention to the anterior bow of the femur and, if necessary, ream 2 mm larger than the nail diameter.
- After selecting the appropriate length and diameter of the nail, assemble the nail and drill guide.
- Insert the nail with the guide facing anteriorly to use the bow of the nail to make insertion easier. Rotate the guide laterally after the nail has been inserted approximately halfway down the intramedullary canal. During nail placement, evaluate its placement with lateral fluoroscopically to avoid anterior cortical perforation.
- Insert the nail to a depth that allows center-center positioning in the femoral head with the lag screw. Remove the ball-tipped guide pin.
- Evaluate version of the nail on the lateral fluoroscopic view; version is correct when the nail, guide, and femoral neck and head are all aligned.
- Make a small incision laterally through the skin and fascia, and place the appropriate drill sleeve into the lateral aspect of the femur.
- Advance a guide pin to within 5 mm of subchondral bone. Confirm appropriate center-center position in the femoral head.
- Measure for the length of the lag screw.
- Ream for lag screw
- Insert the lag screw
- After releasing traction, place the desired amount of compression using the compression screw
- Place distal interlocking screws as desired.



Armamentorium of Proximal Femur Nail

Results and Discussion

Table 1: Reduction on fracture table

	PFN	
Pre op Reduction	**No.**	**%**
closed	15	75
open	5	25
Total	20	100

IN 15 patients of PFN group it was possible to reduce the fracture close on fracture table, where as 5 patients required Open Reduction.

Table 2: Surgery Duration

Surgery Duration			
	N	**Mean**	**Std. Deviation**
PFN	20	94.65	30.981

Mean surgery duration was 94.65 minutes
In a study by ES De Land evoisin mean operating time of PFN is 47.

Table 3: Blood loss

Blood loss			
Group	**N**	**Mean**	**Std. Deviation**
PFN	20	131.50	17.925

Mean Blood loss was 131.50
LIU *et al*. mean Blood loss in PFN is 136

Table 4: x ray exposure shots

		X ray exposure shots
PFN	N	20
	Mean	85.90
	SD	12.47

In this study, Mean X ray exposure shots was significantly more in PFN i. e. 70.
It was because of most of the cases of PFN were done with closed reduction, requirement of accurate placement of lag screw and need of distal locking.

Post-Operative Findings

Table 5: Distribution of the cases according to mortality and morbidity status

	PFN	
	No.	%
Mortality	0	0
Morbidity		
Present	1	5
Absent	19	95

In this study No. mortality was observed during surgery.
In 1 patient of PFN morbidity was observed due to intra-operative rise in blood pressure.
In a study by Guilherme Ricci *et al*. the mortality rate after one year of follow-up of untreated proximal fracture was 28.7%.

Table 6: Post-operative Management

	PFN	
	No.	**%**
Post-operative day 1 Made to sit	20	100
Compression Bandaging	0	0
Post-operative day 2 Antibiotics Stopped	20	100
Quadriceps Strengthening	20	100
Post-Operative Day 3-5 First Dressing	20	100
Knee Bending	18	90
Post-Operative Day 6-14 Sutures Removed	20	100
Superficial Wound Infection	0	0

Table 7: Distribution of the cases according to Immediate and late complication

	PFN	
	No.	%
No. complications	19	95
varus deformity	1	5
No. n union	1	5
Screw cut out	0	0
wound infection	0	0
Reoperation	0	0
Implant Failure		0

According to Immediate and late complication, No. significant morbidity was observed.
In this study only one case in PFN group, show Non-union and Screw cut out.
In a study of 182 patients treated with PFN SEMMI *et al*. found varus deformity in 13 patients, 3 cases of infection and 5 cases of implant failure.
Shen *et al*. believed that basic difference in outcome is due to different level of experience in surgeons.

Table 8: Distribution of the cases according to Limb Length Discrepancy

LLD	**PFN**	
	No.	**%**
0	18	90
2	1	5
3	1	5
4	0	0
Total	20	100

In this study 10% patients treated with PFN had LLD
In a study by Platzer P *et al*. a cephalo medullary nail was more successful in preventing limb length discrepancy in unstable fracture

Follow Up Data at 16 Weeks

Table 9: Distribution of the cases according to pain at 16 weeks

	PFN	
Pain at 16weeks	**No.**	**%**
Constant but bearable	3	15
No. pain at rest	14	70
Little pain on activity	3	15
occasional slight pain	0	0
Total	20	100

Constant but bearable pain was observed in 15% cases.
Most of the cases were in No. pain at rest (70%)

Table 10: Distribution of the cases according to walking capacity at 16weeks

Walking capacity at 16weeks	PFN	
	No.	%
One stick distance <400 yards	12	60
One stick long distance	2	10
with walker	6	30
Total	20	100

Cases with One stick distance <400 yards were 60%

Table 11: Distribution of the cases according to ADL at 16weeks

	PFN	
ADL at 16weeks	No.	%
House bound	2	10
Limited house work	14	70
Shopping	4	20
Total	20	100

Follow Up Data at 24 Weeks

Table 12: Distribution of the cases according to pain at 24 weeks

	PFN	
Pain at 24weeks	**No.**	**%**
Constant but bearable	1	5
Little pain on activity	6	30
No. pain at rest	2	10
occasional slight pain	11	55
Total	20	100

Constant but bearable pain was observed in 7.5% cases.
Occasional slight pain was found in 55% cases.

Table 13: Distribution of the cases according to walking capacity at 24weeks

	PFN	
walking capacity at 24weeks	No.	%
one stick distance <400yards	4	20
one stick long distance	8	40
unaided, unrestricted	7	35
with walker	1	5

Cases with unaided, unrestricted were 35%.

Table 14: Distribution of the cases according to ADL at 24 weeks

	PFN	
ADL at 24 weeks	**No.**	**%**
House bound	1	5
limited house work	2	10
No. rmal activities	2	10
Shopping	7	35
very little restriction	8	40
Total	20	100

8 Patients (40%) in PFN group had very little restriction in Activity of Daily Living.

Observations as Per Scoring

Table 15: Salvati-Wilson Score at 16 Weeks

SWS 16 weeks	PFN	
	No.	**%**
Fair	17	85
Good	2	10
Poor	1	5
Mean ± SD	19.50	3.10

Fair score was found in up to 85 % cases in PFN.

Table 16: Salvati-Wilson Score at 24 Weeks

	PFN	
SWS 24 weeks	**No.**	**%**
Excellent	10	50
Fair	1	5
Good	8	40
Poor	1	5
Mean SD	30.00	6.19

Excellent SWS was found in 50% cases while fair were 50% of cases.

Discussion

- In this study trivial fall was the commonest most of injury (52.5%) indicating the effect of even a minor trauma on the osteoporotic bones.
- 60% cases were of right side, side does not makes any difference but this difference occurs due to fall on to the dominant side.
- In this study all of the patients had isolated injury.
- In this study most of the cases belong to (AO II and AOIII) because most of the fractures occurred in older age group in which such fractures are common.
- Surgery duration was less (Mean 94.65) because most of the cases were reduced closed, less exposure was done and associated less closure time.
- Intra operative image intensifier more (Mean 70.45) because of requirement of accurate placement of lag screw, distal locking and identification of nail length.
- Post operatively sole aim of the treatment was to make the patient upright, mobilize as early as possible.
- Patients were made to sit on Post-operative day 1 and Knee bending was started from 2nd post-operative day, and patients were mobilized as early as possible depending on the fracture pattern
- Regarding complication Only one case in PFN group, show Non-union and Screw cut out,
- One of the major concern in fixation of hip fracture is limb length discrepancy post operatively In this study 10% patients had LLD
- In Follow up of cases as per pain 16 and 24 weeks Occasional slight pain was found in 55% cases in PFN
- In follow up of cases at 16 and 24 weeks as per activity of daily living PFN group had very little restriction in Activity of Daily Living.
- On concluding the outcome as per Salvati-Wilson Score at 16 weeks significant difference was observed, Fair score was found in up to 85% cases in
- On concluding the outcome as per Salvati-Wilson Score at 24 weeks Excellent score was found in 50% while it was fair in 50% CASES.

Conclusion

As we have started our work on this controversial topic, initially it was assumed that DHS is the best implant for the inter trochanteric fractures but it was associated with several complication and limitations.

After the introduction of PFLCP which was more biological, biomechanical as well as authentic implant there was a lot of comparison between PFLCP and DHS which has also been proved in our study.

After the introduction of advanced intramedullary nail i. e Proximal Femur Nail surgeons started achieving very good results out of it, but, yes it has a long learning curve. Once the surgeon becomes accustomed to closed reduction it has a lot of advantage.

So, in this study on the basis of results we found that looking at the fracture pattern PFN is a better implant in most of cases of proximal femur fractures.

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