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Analysis of clinical, radiological and functional outcome of proximal femoral nail antirotation II in the treatment of unstable inter-trochanteric fracture

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Abstract
Purpose: To study the clinical, radiological and functional outcome of patients with IT fractures treated with pfn AII methods-An Hospital based Observational study was done at A J Institute of Medical Sciences and Research Centre, Mangalore. During the period June 2019 to April 2021, on 36 patients who underwent PFN AII fixation for Intertrochanteric fracture. Patient had regular follow ups at 1, 3, 6 and 9 month. Clinico-radiological outcome was assessed at the end of 9 months. Functional outcome was assessed using Harris Hip Score.
Results: Among 36 patients with Intertrochanteric fracture meeting Inclusion criteria, patients studied, the mean time of union is 10.88 weeks. 2 patients presented with minor complications such as superficial skin infection treated conservatively. All fractures United uneventfully, no patients underwent re-surgery.
Conclusion: PFN A-II is a significant advancement in the treatment of trochanteric fractures which has the unique advantage of closed reduction, preservation of fracture hematoma, minimal soft tissue damage during surgery, early rehabilitation and early return to work.

Keywords: Inter-trochanteric fracture, proximal femoral nail antirotation

Introduction
Intertrochanteric fracture is a common fracture in elderly people [1, 2]. Their incidence has increased due to the increased life expectancy and osteoporosis [1, 2]. Earlier, these fractures continued to be a problem, especially with the unstable type of fractures.

Osteoporosis and instability are the most important factors leading to unsatisfactory results [1, 2]. In internal fixation for unstable fractures, a period of restricted mobilization is suggested, which may lead to complications such as atelectasis, bed sores, pneumonia and deep vein thrombosis [3, 4].

The management of intertrochanteric fractures is very challenging as they most often take place in the elderly patients having severe osteoporosis of the bone along with other comorbidities that increase the risk associated with anesthesia and surgery.

Therefore, it is a challenge to choose the optimal method of fixation that has the best possible postoperative effect. The other important role of surgery in intertrochanteric fractures is to be able to mobilize the patient as early as possible because they are at increased risk of disorders related to immobilization like decubitus ulcers and venous thromboembolic episodes.

Hence, it is also important to choose an implant that not only allows weight bearing but also has as low rates of complications as possible. Often whenever an implant is chosen by the orthopaedician it is determined by the type of fracture pattern whether it is stable or unstable.

There are various studies that have analyzed the results of different implants that have been used in intertrochanteric fracture management like the dynamic hip screw, the proximal femoral nail, the gamma nail, and hip replacement. Each type of implant has its own advantages, complications and setbacks in terms of clinical results. Despite advances in internal fixation techniques, the failure rate of the dynamic hip screw is 6.8% to 9.8%, while failure rate of the proximal femoral nail is between 7.1% and 12.5% in unstable fractures [3, 4]. There have been various reports of successful outcomes after the use of hemiarthroplasty and total hip arthroplasty (THA) [8-15].

Endoprosthetic replacements have also been shown to achieve early rehabilitation of the patient and good long term results. Many authors have reported that primary cemented endoprosthesis brought better results than compression hip screw in unstable intertrochanteric fractures in elderly osteoporotic patients who were eligible for early mobilization [10-18].

The Proximal Femoral Nail (PFN) system was put into clinical use by the Association for Osteosynthesis/Association for the Study of Internal Fixation (AO/ASIF) in 1996. PFNA II is a newer Intramedullary implant developed to obtain better fixation strength in osteoporotic bones and advantage of short incision, less operative time, rapid rehabilitation and thus decreased medical complications. Biomechanical studies have demonstrated that the PFNA II blade has a significance of higher cut-out resistance than other commonly used screw systems. Intramedullary nailing is a more technically demanding procedure.

Proximal femoral nail antirotation II is an effective intramedullary load-sharing Device. It incorporates the principles and theoretical advantages of the Dynamic hip screw and locked intramedullary nail. Hence in this study we aim to evaluate the functional outcome of PFN A II in treatment of unstable intertrochanteric fractures.

Materials and Methods

Data for the study was collected from the inpatients and out-patients of the orthopaedics Department in A J Institute of Medical Sciences and Research Centre, Mangalore. during the period June 2019 to April 2021 who were treated surgically using proximal femoral nail anti-rotation II for patients diagnosed with unstable intertrochanteric fracture femur.

A) Study Design: Hospital based Observational study.
B) Study period : 22 months, June 2019 to April 2021
C) Place of study: A.J. Institute of Medical Sciences, Mangalore.
D) Sample size: 36 patients.
E) Sampling method: Purposive sampling was adopted to select the cases who met the inclusion criteria.
F) Inclusion criteria

1. Unstable inter-trochanteric fracture Boyd and griffin type 2, 3 and 4
2. Patients of the age group more than 20 years.
3. Comminuted inter-trochanteric fracture.
4. Ability to walk independently (walking aids are allowed) prior to injury.

G) Exclusion criteria

1. Neck of femur fracture
2. Pathological fracture.
3. Compound injury
4. Medically unfit patients.
5. Patients below 20 years of age.

Data collection: This study was conducted as a cross-sectional observational study, wherein written informed consent was taken prior to the investigation after detailed information was given to the participant/patient party regarding the study.

Statistical analysis: The data obtained was coded and entered into a Microsoft excel spreadsheet and a statistical package was used for data analysis.

- Baseline data was represented by a table and a diagram.
- Quantitative data was represented by mean range standard deviation.
- Paired T test was used to test significant differences in clinical radiological and functional outcome of proximal femoral nail anti-rotation II for the treatment of intertrochanteric fracture.
- Chi square test was used to test the significant difference in pain, operative time, at the follow up.

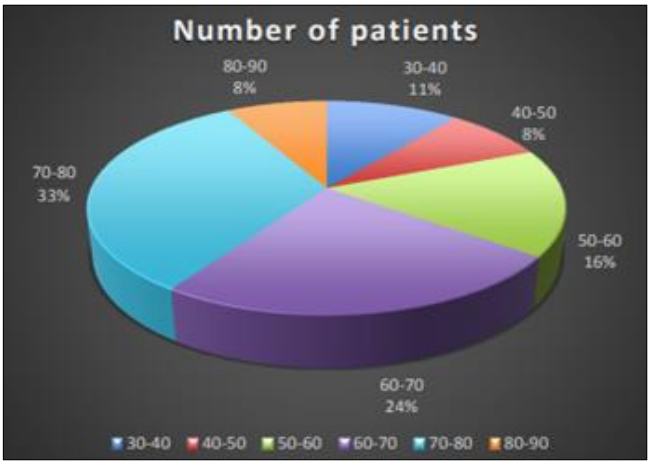
Observation and Results

Demographic Data

Age distribution

Table 1: Age distribution

AGE	NUMBER OF PATIENTS
30-40	4
40-50	3
50-60	6
60-70	9
70-80	12
80-90	3

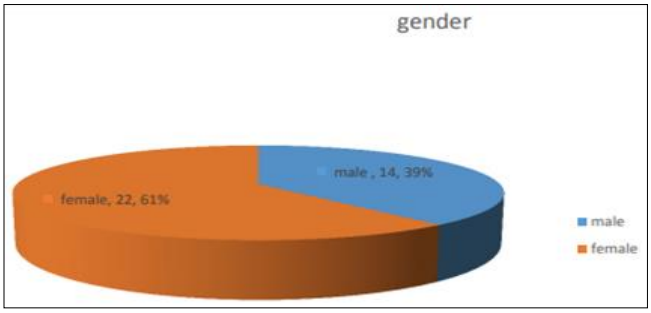


Graph 1: Age distribution

Gender distribution

Table 2: Gender distribution

GENDER	CASE NO	FREQUENCY
MALE	14	38.89%
FEMALE	22	61.11%

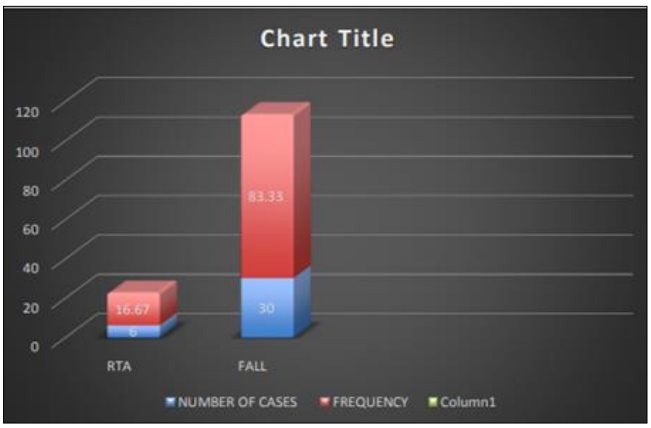


Graph 2: Gender distribution

Mechanism of Injury

Table 3: Mechanism of Injury

CAUSE OF ACCIDENT	CASE NO	FREQUENCY
RTA	6	16.67%
FALL	30	83.33%

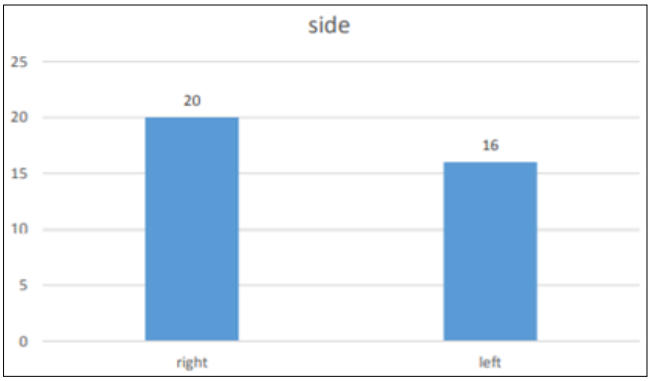


Graph 3: Mechanism of Injury

Fracture details

Table 4: Side of Fracture

SIDE OF FRACTURE	CASE NO	FREQUENCY
RIGHT	20	55.56%
LEFT	16	44.44%

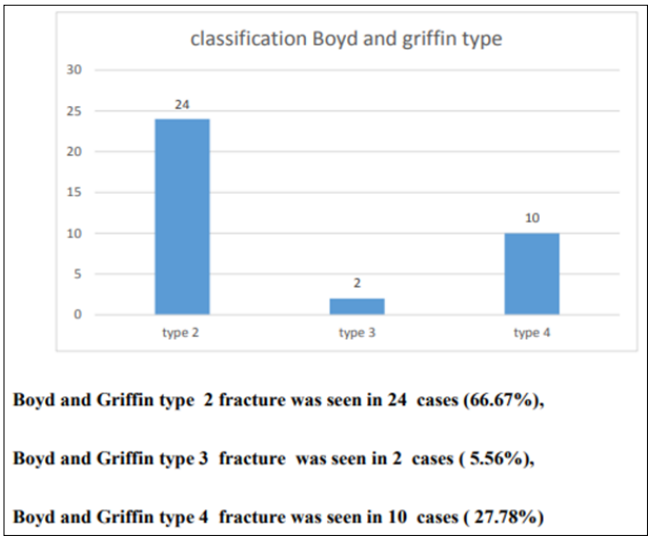


Graph 4: Side of Fracture

Type of Fracture

Table 5: Classification Boyd and Griffin type

CLASSIFICATION BOYD AND GRIFFIN TYPE	CASE NO	FREQUENCY
Type 2	24	66.67%
Type 3	2	5.56%
Type 4	10	27.78%

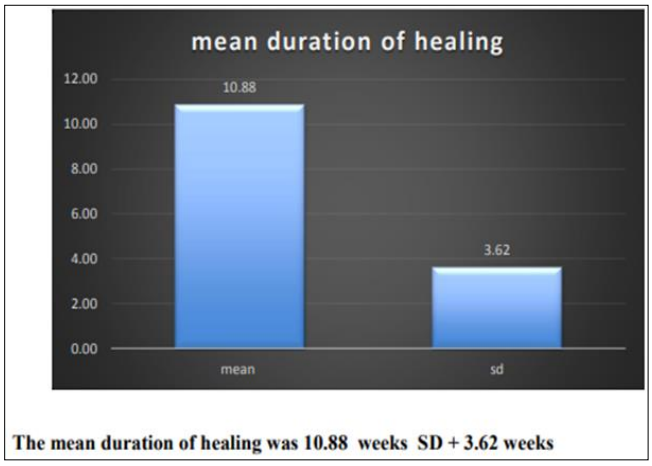


Graph 5: Classification Boyd and Griffin type

Mean duration of Healing

Table 6: Mean duration of Healing

MEAN DURATION OF HEALING	In weeks
MEAN	10.88
SD	3.62

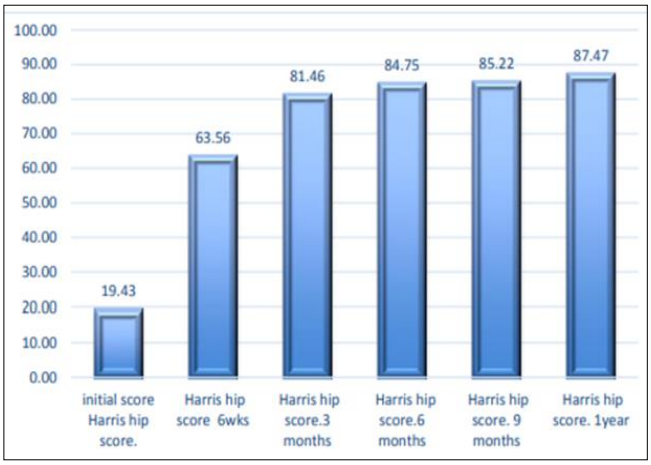


Graph 6: Mean duration of Healing

Outcome

Table 7: Harris Hip Score

	Initial Harris hip score.	Harris hip score 6wks	Harris hip score. 3 months	Harris hip score. 6 months	Harris hip score. 9 months
MEAN	19.43	63.56	81.46	84.75	85.22
SD	5.78	5.94	7.36	7.49	6.91



Graph 7: Harris Hip Score

Complications

Table 8: Complications

COMPLICATIONS	case no	Frequency
Superficial skin infection	2	5.56%

Mortality

TOTAL PATIENTS	MORTALITY
36	2

Discussion

1. Intertrochanteric fractures commonly occur in elderly patients with osteoporosis and its incidence will continue to rise due to the increasing life expectancy. Many methods have been recommended for the treatment of intertrochanteric fractures. The main aim of surgery is to mobilize the patient early. It is crucial to use an implant that is minimally invasive, allows early weight bearing and has low complication rates.
2. Unstable intertrochanteric fractures are those with major disruption of the posteromedial cortex because of comminution or are fractures with reverse oblique patterns or fractures with subtrochanteric extension. Fractures without posteromedial cortex disruption or subtrochanteric extension are considered stable.
3. Common techniques for fixation of intertrochanteric fractures are sliding hip screw and plate or intramedullary nailing. Intramedullary nailing has the advantage of short incision, less operative time and rapid rehabilitation.
4. The PFN A-II is an effectively designed intramedullary load - sharing device. It incorporates the principles and theoretical advantages of the Zicker Nail, Dynamic hip screw locked intramedullary nail, with modifications for Asian population.
5. Biomechanically PFN A-II, just like the conventional PFN, is more stiff, it has shorter moment arm i.e. from the tip of helical blade to the center of femoral canal whereas the DHS has a longer moment arm undergoes Discussion Page 49 significant stress on weight bearing and hence higher incidence of Lag screw cut-out and varus malunion.
6. The larger proximal diameter (17 mm) of the PFN A-II compared with PFN (15 mm) gives additional stiffness to the nail. Minimal blood loss, shorter operative time, early weight bearing, less chances of implant failure, minimal fluoroscopy time, easier helical blade insertion (compared with cumbersome lag screw and derotation screw), lesser chances of post op hip pain, better performance than any other implant in elderly osteoporotic patients are all advantage of PFN A-II.
7. In the current study the union rate was 100%. There were no cases of preoperative and postoperative femoral fractures. There were no cases of varus malunion.
8. The average blood loss in patients treated with the PFN A-II nail was 130 ml, ranging from 50 to 275 ml.
9. The results were comparable with the Levent Karapinar *et al*. study. 76 Average blood loss Levent Karapinar *et al*. 127 ml Yu. W. Zhang *et al*. 180 ml J Zou, Y Xu *et al*. 180 ml Li J *et al*. 131.86 ml. Our series 130 ml
10. Average operating time in our series was 62.6 minutes. In our initial cases operating time was in the higher range (Range 43 – 82 min). With experience the operating time is reduced. The operating time was more in. type 3 and 4 of Boyd and Griffin types compared with other types
11. Results were comparable to the series of Yu. W. Zhang *et al*. [44] and J Zou et.al. [45]. Average operating time Levent Kayapinar *et al*. [46] -44.7min Yu. W. Zhang *et al*. [44] - 55.6min J Zou, Y Xu *et al*. [45] - 68 min Li J *et al*. [47] – 66.25 min Our series 62.6min
12. The use of the image intensifier was 13 shots in patients treated with the PFN, which was comparable with the above-mentioned studies. In our study it ranged from 8 – 20 shots. Fluoroscopy was more needed in type 3 & 4 Boyd and griffin classification.
13. The time to union was 13.09 weeks in our study, ranging from 12 to 16 weeks. This was comparable to Levent Karapinar *et al*. [46] 77 Average union time Levent Kayapinar *et al*. [46] 14weeks Yu. W. Zhang *et al*. [44] 15.7 weeks J Zou, Y Xu *et al*. [45] Li J *et al*. [47] 12.5 weeks Our series 13.09 weeks
14. The average Harris Hip Score [43] in our patients was 79.8 (at the end of three months) and 82.3 (at the end of six months). Most of them were graded as “good” as per HARRIS HIP SCORING. Fair scores were seen with higher age groups and higher Boyd and Griffin types. Average HARRIS HIP SCORE Levent Kayapinar *et al*. [46] 80.75 Yu. W. Zhang *et al*. [44] 81.90 Li J *et al*. [47] 86.19 Our series 82.3
15. The length of hospital stay in our study was 11 days (5 - 24 days) and it was comparable to Li J *et al*. [47] (10.8 days) and other studies. Even other studies mentioned above in comparison have higher exposure to fluoroscopy and greater blood loss in types 3 and 4 of Boyd and Griffin. The complications in our study included superficial skin infections (which settled subsequently with Intravenous antibiotics) post-op Hip pain. These were also present in other studies of PFN A-II with comparable rates.
16. A major complication of screw cut out was reported in other studies in few cases Two cases of helical blade cut

out (out of 42 patients) were reported by Levent 78 karapinar *et al*. Our study didn't have any complications of screw cut out or revision surgeries as in our study all helical blades were placed as per the tip apex distance as mentioned by Baumgartener *et al*. Yet, our sample size is inadequate to report this complication

17. There were no cases of non-union reported in our study comparable to Levent Karapinar *et al*. [46] wherein there were no reported cases of non-union. Studies which reported non-union were highlighting that higher types (type 3 and 4) showed a tendency towards non-union. Preoperative and postoperative Femoral fractures have been documented in patients treated with the PFN and PFN A-II. Multiple factors have been implicated like implant design and. operative technique. Decreases in implant curvature, diameter, over reaming of femoral canal by 1.5 to 2mm, insertion of the implant by hand and meticulous placement of the distal locking. Screws without creating additional stress risers decreases the complication rate of femoral shaft fracture (I.B. Schipper *et al*. 2004) [48]. Patients with narrow femoral canal and abnormal curvature of the proximal femur are relative contra-indications to intramedullary implants (Halder *et al*. 1992) [29].
18. We have followed these recommendations in our series. Hence in our series we don't have encountered any preoperative and postoperative femoral shaft fractures. A larger cohort of patients is necessary to document the incidence of preoperative and postoperative femoral shaft fractures, which is a limitation of our study.
19. In short the PFN A-II is a better implant with specific design superior to conventional PFN and with distinct advantages over other implants to treat intertrochanteric fractures. With adequate surgical technique, the advantages of the PFN A-II increases and the complication rate decreases.

Conclusion

Intramedullary nailing with the PFN A-II has distinct advantages over Conventional PFN or DHS like shorter operating time and lesser blood loss for elderly, osteoporotic unstable trochanteric fractures. Early mobilization and weight bearing is allowed in patients treated with PFN A-II thereby decreasing the incidence of bedsores, uraemia and hypostatic pneumonia.

The operative time is much lower compared with other procedures which also contributes with lesser blood loss. The incidence of postoperative femoral shaft fractures, Non-union rates in PFN A-II can be reduced by good preoperative planning and correct surgical technique, adequate reaming of the femoral canal, insertion of implant and meticulous placement of distal locking screws.

PFN A-II is a significant advancement in the treatment of trochanteric fractures which has the unique advantage of closed reduction, preservation of fracture hematoma, minimal soft tissue damage during surgery, early rehabilitation and early return to work. Several clinical and biomechanical studies have analyzed the results of different implants such as the Dynamic hip screw (DHS), the Gamma nail (GN) and the Proximal femoral nail (PFN) and Proximal femoral nail A. Those devices have suffered a variety of complications like cut-out, screw back out, implant breakage, screw migration, femoral shaft fractures and subsequent loss of reduction.

Comparison of complications in both the groups

	DHS(n = 30)	PFNA-II(n = 30)	p values
Orthopaedic complications			
Varus Collapse	1	0	p > 0.05
Lateral migration of blade/screw	1	1	
Cut out	0	0	
Non union	1	0	
Implant failure	0	0	
Infection	0	1	
Fracture shaft of femur	0	1	
Reoperation	1	2	
General complication			
Symptomatic DVT	0	0	P > 0.05
Decubitus ulcer	0	1	
Hyponatremia	0	1	
Atrial fibrillation	0	1	
Pneumonia	0	1	
Total	4	9	

Functional outcome at one year follow up

Functional outcome variables	PFNA II (mean ± SE) (n = 24)	DHS (mean ± SE) (n = 25)	P-value
Modified Harris Hip Score(MHHS)	79.73 ± 1.20	85.46 ± 1.60	0.14
SF-12 PCS	43.56 ± 11.25	47 ± 10.89	0.18
MCS	51.89 ± 12.56	53.46 ± 11.54	0.21

SF-12:Short form-12; PCS-phyical component summary; MCS-mental component summary.

Baseline characteristics.

Parameters		PFNA II(n = 30)	DHS(n = 30)	Total(n = 60)	P-value
Age(mean ± SD) in years		72.76 ± 9.5	69.33 ± 5.7		>0.05
Sex	Male	9	16	25	
	Female	21	14	35	
Mode of injury	Fall	23	25	48	
	RTA	7	5	12	
Fracture Classification(AO)	31 A1.1-A1.3	22	20	42	

	31 A2.1	8	10	18
ASA grade	I	20	23	43
	II	8	6	14
	III	2	1	3

PFNA II – Proximal femoral nail antirotation-Asia; DHS-Dynamic Hip Screw.

ASA- American Society of Anaesthesiologists.

Comparison of Intraoperative variables in both the groups.

Intraoperative variables	PFNA II	DHS	P-value
Blood loss(ml)	116 ± 48.6	207.24 ± 81.3	0.001
Fluoroscopy time(Sec)	43.75 ± 2.263	39.34 ± 2.96	0.379
Duration of surgery(min)	54.66 ± 19.20	71.1 ± 24.81	0.005

PFNA II– Proximal femoral nail antirotation-Asia.

Comparison of Neck shaft angle in both the groups.

Implant	NSA 1	NSA 2	P-value
PFNA II	129.96 ± 0.53	127.56 ± 0.53	0.001
DHS	130.76 ± 0.56	128.2 ± 0.65	0.001
P-value	0.274	0.605	

NSA 1-Neck Shaft angle at immediate post surgery.

NSA 2-Neck Shaft angle at one year follow up.

Comparison of TAD in both the groups.

Implant	TAD 1(Mean ± SE)	TAD 2(Mean ± SE)	P-value
PFNA II	25.13 ± 1.37	26.36 ± 1.27	0.001
DHS	19.33 ± 1.18	20.16 ± 1.15	0.007
P-value	0.001	0.001	

TAD 1-Tip Apex distance at immediate post surgery.

TAD 2-Tip Apex distance at final follow-up of one year.

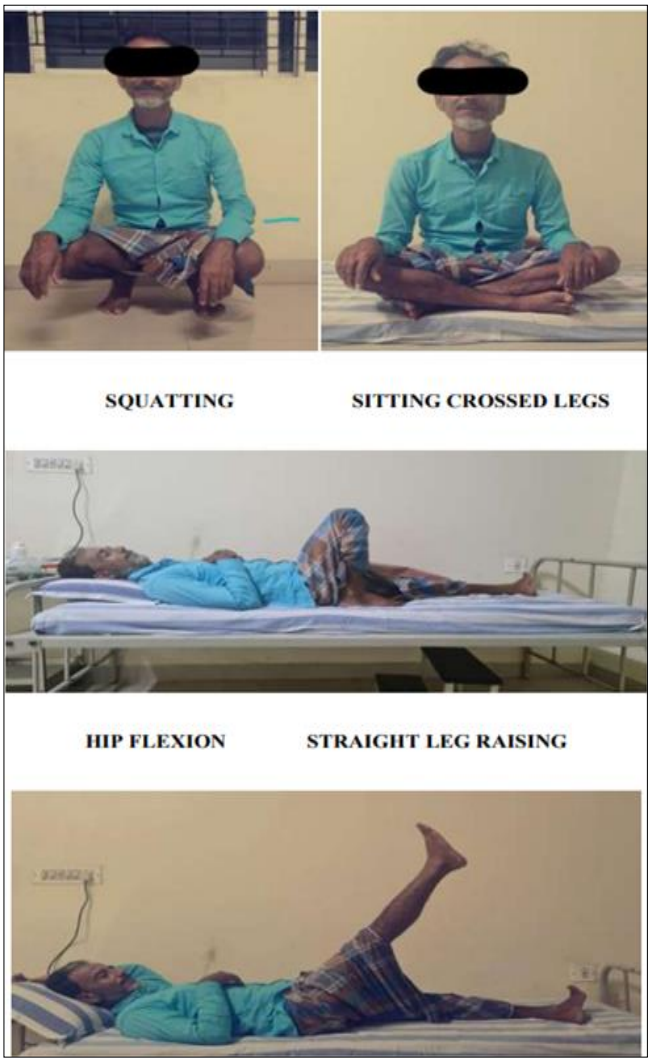
IMMEDIATE POSTOPERATIVE X-RAY

3 MONTHS POSTOPERATIVE X-RAY

Case: Mr Manja 58/Male

PREOPERATIVE X-RAY

WEIGHT BEARING



Summary
Study Was Conducted With 36 Patients Who Underwent Proximal Femoral Nailing Antirotaion II For The Treatment Of Unstable Intertrochanteric Fracture.
The Age Group of The Study Subjects Ranged Between 30-90 Years With The Mean Age Being 59 Years. The Most Common Age Group Was Between 70-80 Years In Which We Had 12 Patients.
38.89% Were Male Patients And 61.11% Were Female Patients. 16.67% Of Patients Came With History of Rta And 83.33% Of Patients Came With History Of Trivial Fall.
Diagonsed Radiologically With Inter-Trochanteric Fracture of Femur. Right Sided Fracture Was Noted In 55.56% Patients And Left Sided In 44.44% Patients With Maximum Patients Having Type 2 Classification of Boyd And Griffin Classification.
All 36 Patients Underwent Proximal Femoral Nailing Antirotation Ii Under Spinal Anaesthesia With Average Operating Being 62.6 Minutes. Blood Loss During Surgery Was Between 50-275ml.
Average Union Time Was 10.88 Weeks. With Harris Hip Score Being 79.8 At The End Of 3 Months And 82.3 At The End of 6 Months.
No cases of non-union noted in our study.

Conflict of Interest
Not available

Financial Support
Not available

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