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## A prospective study to evaluate the clinical and functional outcomes in the management of unstable extracapsular proximal femoral fractures using proximal femoral nail with a helical blade construct (PFNA-II) at a tertiary care hospital

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### Abstract

**Background:** Extracapsular proximal femoral fractures are one of the most common fractures of the hip especially in the elderly with osteoporotic bones, usually due to trivial trauma. Presently, unstable extracapsular proximal femoral fractures are treated commonly with intramedullary nailing devices. Various designs of intramedullary nail are introduced. The conventional design has given diverse outcome and complications have also been noted with this implant. Newer designs like Proximal Femoral Nail Antirotation-II have been introduced for Asian population. There is paucity of the prospective studies on the effectiveness of PFNA-II system. Most have been retrospective studies and there are not much evidences regarding the postoperative complications in a long term. So a prospective study is needed to evaluate the effectiveness and long term problems if any with PFNA-II system and to modify the design further if required.

**Aim and Objectives:** To evaluate the clinical and functional outcomes in the management of unstable extracapsular proximal femoral fractures using proximal femoral nail with a helical blade construct (PFNA-II) at a tertiary care hospital.

**Materials and Methods:** A prospective study was undertaken in a Tertiary Hospital from April 2018 to April 2019, 30 patients (age >18 yrs) with extracapsular proximal femoral fracture i.e. AO type 31-A2 and type 31-A3 operated with PFNA-II. The patients were followed up at 6<sup>th</sup> week, 12<sup>th</sup> week and 6 months from the date of surgery. Clinical and Functional assessment was done using Harris Hip Score during follow up. X-ray was done at 12 weeks to assess the fracture healing, position of the implant and any complication. Data collected of these 30 patients were statistically analysed using SPSS (Statistical Package for the Social Sciences) version 16.0, IBM Corporation; NY, USA for MS Windows.

**Results:** The mean post-op (3 Months and 6 Months) Harris Hip score is significantly higher compared to the mean post-op (6 Weeks) Harris Hip Score (P-value<0.001 for all). The mean post-op (6 Months) Harris Hip score is significantly higher compared to the mean post-op (3 Month) Harris Hip Score (P-value<0.001). The mean% improvement in Harris Hip score from 6 Weeks to 3 Months, from 6 Weeks to 6 Months and from 3 Months to 6 Months is 66.91%, 111.09% and 26.54% respectively. Of 30 cases studied, 3 (10.0%) had reasonable functional outcome, 8 (26.7%) had good functional outcome and 19 (63.3%) had excellent post-op functional outcome at 6 months.

**Conclusion:** Unstable extracapsular proximal femoral fractures treated with PFNA-II with a helical blade construct has satisfactory clinical and functional outcomes with minimal complications and thus it is an excellent modality to treat unstable extracapsular proximal femoral fractures.

**Keywords:** Unstable Extracapsular Proximal Femoral Fracture, Harris Hip Score, Proximal Femoral Nail Antirotation-II (PFNA-II) system

### Introduction

Globally, proximal femoral fractures have been on the rise with the increase in life expectancy and osteoporosis in the elderly population and road traffic accidents among the younger counterparts<sup>[1, 2]</sup>. A study revealed that 50% women and 36% men over the age of 50 have low bone mass in India<sup>[3]</sup>.

Hip fractures are common in this group of population and 50% of hip fractures in elderly patients are extracapsular of which more than 50% are of unstable type [4]. Hip fractures are associated with the risk of urinary tract infections, pneumonia, bedsores, and thromboembolic complications. They cause physical impairment, reduce the quality of life, and cause significant mortality. Management of such fractures aims to achieve early union and mobilization of the patient where some form of internal fixation is the method of choice [5]. The compression hip screw is the standard implant in the management of stable inter-trochanteric fractures [6, 7], but in unstable intertrochanteric fractures (AO Type 31A2 and Type 31A3) it has a higher incidence of cut-out failure (6% to 19%) [8, 9]. However, an intramedullary device with a shorter lever is likely to improve the biomechanics providing more load sharing and limiting collapse at the fracture site [10]. Biomechanical cadaveric studies demonstrated that PFNA fixation using a helical blade was better compared to the sliding hip screw. PFNA, characterized by rotational along with angular stability has biomechanically improved purchase in the osteoporotic bone due to the bony impaction it achieves in the femoral head and neck [11, 12]. PFNA was designed for femoral geometric proportions of the Caucasian population but differences exist between Asian and Caucasian femoral geometry [13]. Serious complications occurred when PFNA was used for Asians [14] which led AO/ASIF to design a new proximal femoral nail anti-rotation Asia (PFNA 2) for Asian femoral geometry [15]. This study was undertaken to analyse the results of unstable extracapsular fracture of femur fixed with PFNA 2, its functional and radiological outcomes in the tertiary care hospital.

#### Aim and Objectives

1. To treat unstable extracapsular proximal femoral fractures using proximal femoral nail with a helical blade construct (PFNA-II) system.
2. To evaluate the clinical and functional outcome in patients at 6 weeks, 12 weeks and thereafter at 6 months postoperatively using Harris Hip Score.
3. To arrive at a consensus about the status of using PFNA-II in treating unstable extracapsular proximal femoral fractures.

#### Materials and Methods

A prospective interventional study was done in the Department of Orthopaedics in Inlaks and Budhrani Hospital, Pune, Maharashtra between 19/04/2018 to 18/04/2019, 30 cases of extracapsular proximal femoral fractures classified as AO types 31A2 and 31A3 and treated with proximal femoral nail anti-rotation Asia (PFNA-II) and were included in the study after obtaining informed, written consent. Clearance from the institutional ethics committee was obtained before starting of the study.

#### Inclusion criteria

1. Patient with fracture type 31 - A2 and 31 - A3 according to AO classification of Proximal Femoral Fractures.
2. Patient of age >18 years
3. Both sexes; Males and Females
4. Patient willing for surgery and giving informed and written consent.

#### Exclusion criteria

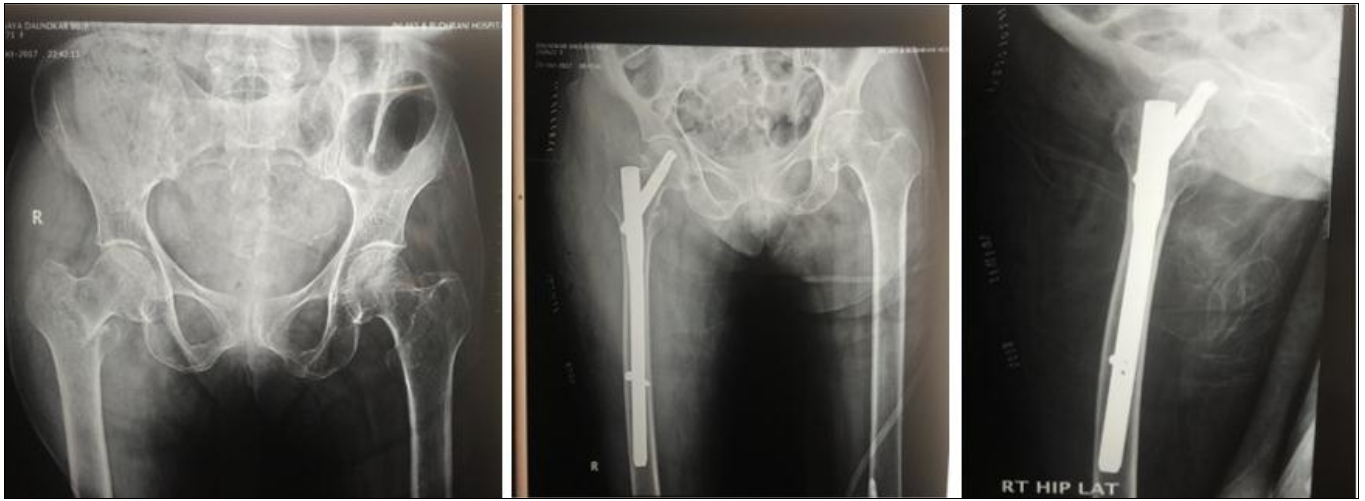
1. Patient of age < 18 years
2. Patient with stable Extracapsular fracture
3. Patient with Intracapsular fracture
4. Patient with pathological fracture
5. Patient unfit for surgery

#### Methodology

On admission Patient's demographic data, mode of trauma, the onset and duration of symptoms were sought and recorded. Any history of associated co-morbidities and treatment received was noted. Anteroposterior and lateral radiographs of the affected hip were taken. Patient was stabilized haemodynamically. The patient was then put on skin traction over a Bohler –Braun frame. The fractures were classified as per AO-OTA classification. Type 31-A2 and Type 31-A3 were considered as unstable fractures. A pre-anaesthetic examination was also done prior to surgery. Informed consent was obtained from the patient after explaining to him / her the nature of the procedure to be performed, its possible complications, and the need to follow a rehabilitation protocol post operatively. Fracture reduction was achieved on the fracture table and surgical fixation of the fracture done with PFNA II (Proximal Femoral Nail Anti-rotation Asia, Synthes, Switzerland). The accepted position of the blade intraoperatively was central or inferior in the anteroposterior (AP) view and central in the lateral view. Immediate postoperative radiographs were evaluated for grading of the fracture reduction and measurement of Tip Apex Distance (TAD) as developed by Baumgaertner *et al.* The Helical blade position by dividing the femoral head into superior, central, and inferior thirds on the AP radiograph and anterior, central, and posterior thirds on the lateral radiograph as per Cleveland's zones.

Patients were allowed to weight-bear to pain tolerance with a walker subject to the general condition of the patient, intra-operative reduction, and bone quality. In patients with poor bone quality, comminution, or frail general condition weight-bearing was delayed.

Patient was called for suture removal on the 12th post op day. The next follow up was done at 6 weeks, 12 weeks and 6 months from the date of surgery. Clinical and Functional assessment was done using Harris Hip Score during follow up.



**Fig 1: Pre-Op Xray**

**Immediate**

**Post-Op Xray**

**Three months post-op**



**Full weight bearing**



**Flexion and active Straight Leg Raising**



**Abduction**

**Fig 2: Functional Outcome**

Data analysis was done by using SPSS (Statistical Package for the Social Sciences) version 16.0, IBM Corporation; NY, USA for MS Windows. Exploration of associations of different outcomes and subgroups by gender, age, co-morbidity, etc was done by Chi Square test and ODDS ratio with 95% confidence intervals for categorical data. Wilcoxon’s signed rank sum test was used to test the significance of difference in the categorical variables before and after the surgical intervention. The underlying assumption of normality was tested before subjecting the study variables to t test. T-tests were used for the significance of difference and the level of significance was assessed with P value (significant when  $P < 0.05$ ).

**Result**

The total number of patients in our study were 30 which included 16 females (53.3%) and 14 males (46.7%). The mean age was 71.9 years (SD = 11.0 years) and the minimum -maximum age range was 48-96 years. 13 (43.3%) had right limb involved and 17 (56.7%) had left limb involved. 22 (73.3%) had trivial fall, 6 (20.0%) had fall from height and 2 (6.7%) had road traffic accident. 10 (33.3%) had 31-A2.1 type of fracture, 11 (36.7%) had 31-A2.2 type of fracture, 4 (13.3%) had 31-A2.3 type of fracture, 1 (3.3%) had 31-A3.1

type of fracture and 4 (13.3%) had 31-A3.2 type of fracture. 8 (26.7%) had no co-morbidity, 5 (16.7%) had diabetes, 11 (36.6%) had hypertension, 5 (16.7%) had both diabetes and hypertension and 1 (3.3%) had asthma. 25 (83.3%) had Grade I pre-injury walking ability and 5 (16.7%) had Grade II pre-injury walking ability. 28 (93.4%) did not have any post-op complications, 1 (3.3%) had anterior thigh pain and 1 (3.3%) had deep venous thrombosis. The mean post-op (3 Months and 6 Months) Harris Hip score was significantly higher compared to the mean post-op (6 Weeks) Harris Hip Score ( $P$ -value<0.001 for all). The mean post-op (6 Months) Harris Hip score was significantly higher compared to the mean post-op (3 Month) Harris Hip Score ( $P$ -value<0.001). The mean% improvement in Harris Hip score from 6 Weeks to 3 Months, from 6 Weeks to 6 Months and from 3 Months to 6 Months was 66.91%, 111.09% and 26.54% respectively (Table 1). The mean post-op (6 Months) Range of motion was significantly higher compared to the mean post-op (3 Month) Range of motion ( $P$ -value<0.001). The mean% improvement in Range of motion from 3 Months to 6 Months was 103.05% (Table 2). 3 (10.0%) had reasonable functional outcome, 8 (26.7%) had good functional outcome and 19 (63.3%) had excellent post-op functional outcome at 6 months (Table 3).

**Table 1:** Pair-wise comparison of post-op Mean Harris Hip Score (n=30).

Follow-up	Harris Hip Score	
	Mean	SD
Post-op (6 Weeks)	42.77	3.51
Post-op (3 Months)	71.67	2.76
Post-op (6 Months)	90.33	5.49
Mean% Change (from 6 Weeks to 3 Months)	68.29%	
Mean% Change (from 6 Weeks to 6 Months)	111.73%	
Mean% Change (from 3 Month to 6 Months)	25.97%	
P-value (Intra-Group)		
Post-op (6 Weeks) v Post-op (3 Months)	0.001***	
Post-op (6 Weeks) v Post-op (6 Months)	0.001***	
Post-op (3 Months) v Post-op (6 Months)	0.001***	

P-values by Repeated Measures analysis of variance (RMANOVA). P-value<0.05 is considered to be statistically significant. \*\*\*P-value<0.001 (Highly Significant).

**Table 2:** Pair-wise comparison of post-op Mean Range of Motion (n=30).

Follow-up	Range of Motion (Deg)	
	Mean	SD
Post-op (3 Months)	102.00	9.96
Post-op (6 Months)	205.83	9.29
Mean% Change (from 3 Month to 6 Months)	103.05%	
P-value (Intra-Group)		
Post-op (3 Months) v Post-op (6 Months)	0.001***	

P-values by paired t test. P-value<0.05 is considered to be statistically significant. \*\*\*P-value<0.001 (Highly Significant).

**Table 3:** Distribution of functional outcome at 6 Months (n=30).

Outcome at 6-months	No. of cases	% of cases
Reasonable	3	10.0
Good	8	26.7
Excellent	19	63.3
<b>Total</b>	<b>30</b>	<b>100.0</b>

**Discussion**

The goal of the study was to evaluate the clinical and functional outcomes in the management of unstable extracapsular proximal femoral fractures using proximal

femoral nail with a helical blade construct (PFNA-II). Our study consisted of 30 patients with unstable extracapsular proximal femoral fractures who were treated with PFNA-II. The age of the patient ranged from 48 to 96 years. The majority of the patients were between 60 to 80 years of age with the average age of 71.86 years. All the fractures that occurred in patients older than 60 years were due to Trivial fall. This supports the view that bone stock plays an important role in the causation of fractures in the elderly, which occurred after a trivial fall. No attempt was made to measure the degree of osteoporosis by the Singh index, as it involves a great inter-observer variability and depends on good quality x-rays. In a study by Li M *et al* [16] average age of patients with hip fractures was 74.7 years; where study by Kumar GK *et al* [17] has reported an average age of 61 years and study by HU SJ *et al* [18] has reported the average age of 78.6 yrs which is correlated with our study. In our study there were 14 males and 16 females showing female preponderance with the gender ratio of male to female was 0.87:1. The higher ratio of females can be explained by the fact that females are more prone for the osteoporosis after menopause. Sex distribution in our study correlates with that of other studies. of 30 cases, 13 (43.3%) had right limb involved and 17 (56.7%) had left limb involved. 22 patients (73.33%) had associated co-morbidities. 5 (16.7%) had Diabetes, 11 (36.6%) had

Hypertension, 5 (16.7%) had both Diabetes and Hypertension and 1 (3.3%) had Asthma. So Hypertension was the most commonly encountered co-morbidity in our study. Commonest mode of injury was trivial fall which was noted in 22 patients (73.3%). All the fractures that occurred in younger patients were either due to a fall from height or a road traffic accident. This supports the view that bone stock plays an important role in the causation of fractures in the elderly, which occur after a trivial fall. Similar results were obtained in a study published by Sadic S *et al* [19] which showed that low energy trauma was the cause of fracture in 90.5% cases. Our series consisted of 30 unstable intertrochanteric fractures which were classified according to AO/OTA [20] classification. Out of 30 patients, 25 were of 31A2 type with 31A2.2 being the most frequent type. In a study published by Ye PH *et al* [21] most of the fractures were 31A2 type. Another study published by HU SJ *et al* [22] also had the same observation with type 31A2 type being the most frequent type. We did not encounter any intraoperative complication in this study. In all the 30 cases, obliteration of fracture line was seen at 12 weeks follow up with helical blade in Postero-inferior position and there was no migration of the blade. The complications we encountered in our series were Deep Venous Thrombosis (DVT) in 1 patient (3.3%). This is in concordance with a similar study published by Sadic S *et al* [19] in which 3 patients (4.76%) developed DVT. Another complication was anterior thigh pain in 1 patient (3.3%). Similar complication of the thigh pain was observed in some other studies such as Kumar GK *et al* [17], Li M *et al* [16], etc.

The mean postoperative range of movements was 102 at 3 months follow up and it was 205 at 6 months follow up. The mean post-op (6 Months) Range of motion was significantly higher compared to the mean post-op (3 Month) Range of motion (P-value<0.001). The mean% improvement in Range of motion from 3 Months to 6 Months was 103.05%. Harris hip score [22] was selected for the evaluation of Functional outcome of extracapsular proximal femoral fractures as it was found more reliable and validated as compare to Oxford Hip score, WOMAC score (Western Ontario and McMaster University Osteoarthritis Index) and HOOS (Hip disability and osteoarthritis outcome).

In our study, 3 patients (10.0%) had reasonable functional outcome, 8 patients (26.7%) had good functional outcome and 19 (63.3%) had excellent post-op functional outcome at 6-months. The average Harris Hip Score was 42.77±3.51 SD at 6 weeks follow up, 71.67±2.76 SD at 12 weeks follow up and 90.33±5.49 SD at 6 months follow up. There was statistically significant improvement in the functional outcome measured by Harris hip score at 6 months follow up as compared to 6 weeks and 12 weeks follow up. The mean% improvement in Harris Hip score from 6 Weeks to 12 Weeks, from 6 Weeks to 6 Months and from 12 Weeks to 6 Months was 66.91%, 111.09% and 26.54% respectively. This result was in concordance with similar studies such as Li M *et al* [16] in which the average Harris Hip Score was 85.6 with the use of PFNA-II. Kumar GK *et al* [17] published a study which concluded that excellent to good results were accounted in 78% cases by using Harris Hip Score. In a study published by Lv C *et al* [23] 78% patients had excellent to good results according to Harris Hip Score. In our study, excellent to good results were accounted in 90% cases according to Harris Hip Score. The clinical and functional outcome at the end of 6 months follow up using Harris Hip Score was statistically significant with the p value of <0.001.

## Conclusion

In our short term study, we arrived at the following conclusions: At 6 months follow up, The mean Harris Hip Score was 90.33 with the use of PFNA-II. Excellent functional outcomes were obtained in 63.3% patients while good outcomes were obtained in 26.7% patients. No case related to mechanical failure of the implant was noted. Complications were not significant and were encountered in only 6.6% patients. Hence, in our opinion, Proximal Femoral Nail with a Helical Blade construct (PFNA-II) is a very effective implant in the management of unstable extracapsular proximal femoral fractures with very good clinical and functional outcomes. However, a prospective randomized controlled trial and long term follow up is needed to further validate our findings.

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**Conflicts of Interest:** Nil

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