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Clinical, functional and radiological outcomes of proximal femoral nail (PFN) with proximal femoral nail antirotation Asia (PFNA2) in the treatment of intertrochanteric and peritrochanteric femur fracture

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Abstract
Background: The incidence of unstable intertrochanteric fractures is increasing due to increased life span. These fractures require stable fixation and early mobilisation to reduce the morbidity and mortality. Extramedullary implants are biomechanically inferior in these cases. The Proximal Femoral Nail (PFN) and Proximal Femoral Nail Antirotation Asia (PFNA2) is an intra-medullary nail system designed for such fractures in the Asian population.
Materials and methods: 61 patients with unstable intertrochanteric fractures who presented to us between 1st May 2019 to 20th February 2020 were treated with PFN & PFNA-II. The clinical, functional & radiological outcomes of these patients were assessed. Out of 61 patients, 11 patients were not included in the study; 5 patients didn't gave consent for the inclusion in the study and remaining 6 patients were lost to follow up.
Results: Mean operative time for PFN was 56 minutes & for PFNA2 was 45 minutes. The mean amount of blood loss for PFN is 102 ml & for PFNA2 is 90 ml. Mean radiological union time was 14.05 weeks for PFN & 12.23 weeks for PFNA2. The functional status according to Harris hip score was excellent in 8, good in 9, fair in 7 cases and poor in 1 case in PFN & excellent in 10, good in 12, fair in 3 cases and poor in 0 case in PFN. Mean Harris hip score is 84 in PFN & 88 in PFNA2.
Conclusion: PFNA2 is an optimum implant for the internal fixation of intertrochanteric & peritrochanteric femur fractures in elderly patients with advantages of a simple operation, very few complications, and good clinical efficacy, less surgical operative time, stable fixation, early load sharing fixation, early weight bearing and ambulation, shortened hospital stay and improved rate of union with early resumption of independent life style, excellent functional outcome, less soft tissue dissection and less blood loss, less time interval between Injury and Surgery, less fluoroscopy images, less length of surgical incision & Improved Harris hip score.

Keywords: Intertrochanteric fractures, peritrochanteric femur fractures, proximal femoral nail (PFN), proximal femoral nail antirotation Asia (PFNA2 or PFNA II), intramedullary nail

Introduction

Intertrochanteric fracture is the fracture of the proximal femur, in which the fracture line extends from the greater trochanter to lesser trochanter.

Intertrochanteric fractures commonly occur in elderly patients with osteoporosis, usually following trivial trauma and its incidence will continue to rise due to the increasing life expectancy. In the younger age group of people, in whom it is uncommon, it occurs almost always due to high velocity trauma. Female to male ratio is 2:1 These fractures are usually classified as Stable and Unstable Fractures. The characteristics of unstable variety are posteromedial fragmentation, Basicervical patterns, reverse obliquity patterns, displaced greater trochanteric (lateral wall Communition) fractures. These fractures can be treated both conservatively and operatively, due to higher risk of mortality and morbidity associated with conservative management. There is a need for internal fixation for early mobilization to avoid complications further. The focus of surgical research regarding internal fixation in late 20th century was to minimize implant failure and cut out of the femoral head and neck fixation components, with the complicit acceptance of loss of reduction of the fracture.

Rigid internal fixation and early mobilization is the present standard method of treatment. The current practice of treatment of stable variety of intertrochanteric fracture with dynamic hip screw is widely accepted, however unstable variety of intertrochanteric fractures are better treated with cephalomedullary nails. Cephalomedullary device has many potential advantages like more efficient load transfer, provides resistance to varus collapse and provides better rotational stability of the head; the amount of sliding is limited by intramedullary location, therefore less chance of shortening and deformity with shorter operative time, less soft tissue dissection and less blood loss.

Since the introduction of PFNA and PFNA-II, the cephalomedullary nail with a single head-neck helical blade has commonly been used to treat osteoporotic geriatric patients with unstable per-trochanteric and inter-trochanteric fractures. Good results and functional outcomes have been reported globally by many authors.

The evolution of the implant has proceeded from extramedullary plates to intramedullary nails which provide stable fixation of peritrochanteric femur fractures.

The ideal internal fixation device should be such that the patient can be mobilized at the earliest without jeopardizing the reduction, stability and union of the fracture. 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.

The types of implant used in these fractures have been divided into extramedullary implants and intramedullary nails. The choice of implant is mainly determined by the fracture pattern (stable or unstable). 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.

Several clinical and biomechanical studies have analysed the results of different implants such as the dynamic hip screw (DHS), the Gamma nail (GN) and the proximal femoral nail (PFN). Those devices have suffered a variety of complications like cut-out, screw back out, implant breakage, femoral shaft fractures and subsequent loss of reduction.

PFN has some demerits like implant failure, screw cut out and screw migration which is also called Z effect. In this Z effect proximal screw (de-rotation screw) of PFN migrate medially and distal screws (lag screw) migrate backward, while in reverse Z effect proximal screw (de-rotation screw) migrate laterally and distal (lag screw) migrate medially.

Intramedullary nailing has advantage of short incision, less operative time, rapid rehabilitation, less duration of hospital stay, increased modified Harris hip score and decreased medical complications. The latest generation PFNA II, specially designed for Asian population, is newer intramedullary implant developed to obtain better fixation strength in osteoporotic bones. Biomechanical studies has demonstrated that PFNA II blade has a significance of higher cut out resistance than other commonly used screw systems

The PFNA is also preferred for its distinctive features like one single helical blade perforated into the femoral head, wrench-in, large axial contact area and squeeze cancellous bone, while PFNA II was modified to avoid lateral cortex impingement during the insertion of nail.

The PFNA-II design has three modifications to the PFNA to accommodate Asian anatomic characteristics:

1. The proximal nail diameter was reduced from 17 mm to 16.5 mm
2. The mediolateral angle was reduced from 6° to 5°
3. A flat proximal lateral surface was adapted to avoid impingement of the femoral lateral cortex. The PFNA-II is available in four lengths (170 mm, 200 mm, 240 mm, and long).

There are four distal diameters available (9 mm, 10 mm, 11 mm, and 12 mm), all measuring 105 mm in proximal segment length. The long types of PFNA-II are designed with an anterior curvature (radius, 1500mm) to meet the bow of the femur

The common indications of proximal femur nailing are Intertrochanteric fractures of the femur, Sub-trochanteric fracture femur, Neck of Femur Fracture and Proximal Femoral shaft fractures

Methods

Source of data

This study was conducted in the Department of Orthopaedics, MGM Medical College & Hospital, Navi Mumbai, India during the period 1st May 2019 to 20th February 2020 and were treated surgically using PFN and PFNA2 for patients who were diagnosed with unstable peritrochanteric and intertrochanteric fracture femur.

Inclusion criteria

Inclusion criteria were closed unstable intertrochanteric fracture (AO/OTA TYPE 31A2.2 to 31A3.3); subtrochanteric femur fracture, ability to walk independently prior to injury, Age between 18 - 90 years, Men and women both included in study, Patient undergoing Primary or Index surgery, Different mode of injuries i.e. fall from standing height, slippage, road traffic accident, fall from height are included, Patients who survives minimum 6 months after operation are included, Patients who are medically fit & willing for surgery and willing to participate in the study.

Exclusion criteria

Exclusion criteria were open fracture; intracapsular fracture neck of femur; pathological fracture; Poly trauma patients, medically unfit patients, Age less than 18 years, Previous surgery on proximal femur, Old non-unions and mal-unions, Patients unwilling to give consent for surgery, Refusal for inclusion in the study, Patients who are medically unfit for surgery.

Inpatients meeting the inclusion and exclusion criteria will be selected for the study after obtaining written and informed consent. Demographic data, history, clinical examination and details of investigations will be recorded in the study proforma. Routine pre-operative investigations will be done and radiographs to study the fracture anatomy will be taken. Written informed consent and pre anesthetic evaluation will be done for the surgery. Under anesthesia, closed reduction and internal fixation with Proximal femoral nail will be done using image intensifier

Preoperatively

Radiological confirmation of the diagnosis was carried out by taking anterior-posterior & lateral x-rays of hip and the fractures were classified according to AO/OTA Classification, UNSTABLE varieties include 31A2.2 to 31A3.3.

Intraoperatively

Intertrochanteric fractures were treated by closed reduction on a fracture table and internal fixation using a Proximal Femoral

Nail Antirotation Asia (PFN-A2) and Proximal Femoral Nail (PFN) inserted under radiographic control.

Post-operative regimen

Parenteral antibiotics, usually third generation cephalosporin were started immediately after the admission and postoperatively. Static quadriceps exercises were encouraged from the first day and the knee was mobilized from the same day. Check x-rays were taken on the same day as soon as patient was stabilized following the surgery. Simultaneously active hip and knee strengthening exercises are also started. The stitches are removed on 14th post-operative day. Post operatively, the patient will be made to sit on 2nd post op day

The patients are taken up for surgery under spinal or epidural anaesthesia, positioned supine on fracture table, uninjured leg held in wide abduction. C- Arm image intensifier is positioned between patient`s leg. Close reduction of fracture by manipulation is performed. 50 cases were studied. Patients were followed up for a minimum period of 3 months. With each follow up clinical and radiological evaluation was done.

Patients were first followed up usually at stitch removal if not already done or at one and a half months after discharge, if stitch removal is already done. Clinical assessment of fracture union, range of movement of hip and knee and radiological assessment of fracture union is done on subsequent follow up. If union is found satisfactory and radiological union is found to be in progress, partial weight bearing is started as tolerated.

At each follow up, consent will be obtained from the patients and a detailed clinical examination will be done followed by specific functional scores and measurement of radiographic parameters. Assessment at regular intervals will be made at 3rd, 6th, 12th, 24th post op week and reassessment, both clinical as well as radiological outcomes done and if union is found to be progressing satisfactorily full weight bearing is started as tolerated. Patients are next called at every 3 months and reassessment done; clinical, functional as well as radiological outcomes assessed. Functional outcome assessed using Modified Harris Hip Score

Ethical consent: Ethical clearance was taken from the institutional committee

Statistical analysis

Statistical analysis was done using SPSS Software (IBM Version-20). In the study, almost all the patients were above 45 years of age. The mean age of the patients was 70.83 years of age. Around 26 of the patients were female and around 24 of the patients were male. 28 patients had sustained low velocity injuries due to fall on floor or trivial trauma whereas around 22 sustained injuries due to RTA. In present study left side is more involved around (54%) than right side around (46%). All fractures were classified according to the A.O. classification. 32 patients have AO type AO31A2 and 18 patients have type AO31A3 fractures

Table 1: Age

Age	Average in PFN group	Average in PFNA2 group	Mean
Male	67	74	72
Female	66	73	70
Mean	66.5	73.5	70.83

Table 2: Sex

Sex	PFN	PFNA2	Total
Male	12	14	26
Female	13	11	24
Total	25	25	50

Table 3: Side involved

Side	Right	Left	Total
PFN	11	14	25
PFNA2	12	13	25
Total	23	27	50

Table 4: Mode of Injury

Mode of Injury	No. of patients
Low velocity injury (Fall on ground/Trivial trauma)	28
High velocity injury (RTA)	22
Total	50

Table 5: Classification

AO/OTA	No. of patients
AO31A2	32
AO31A3	18
Total	50

Table 6: ASA Classification

ASA Classification	PFN	PFNA2
1	9	7
2	11	12
3	5	6
Total	25	25

Table 7: Comorbidity

Comorbidity	PFN	PFNA2
Hypertension & CVS Diseases	11	12
Diabetes Mellitus	8	9
Sequelae of Cerebral Infarction	2	3

Table 8: Time interval between Injury and Surgery (In days)

Time interval between Injury and Surgery (In days)	Range	Mean
PFN	1 to 4	2.8
PFNA2	1 to 3	2.4

Table 9: Operative time (In minutes)

Operative time (In minutes)	Range	Mean
PFN	40 to 65	56
PFNA2	35 to 55	45

Table 10: Amount of blood loss (In ml)

Amount of blood loss (In ml)	Range	Mean
PFN	70 to 140	102
PFNA2	60 to 120	90

Table 11: Complications

General complications		
1.	Decubitus ulcer	0
2.	Urinary tract infection	0
3.	Chest infection	0
4.	Deep vein thrombosis	0
Local complications		
1.	Superficial Infection	1
2.	Implant break	0
3.	Cut out of the implant	0
4.	Pull out	0
5.	Shortening (>2)	0
6.	Thermal necrosis	0
7.	Loss of reduction	0
8.	AVN Hip	0

Table 12: Modified Harris Hip Score

Modified Harris Hip Score	PFN	PFNA2
Excellent (90 to 100)	8	10
Good (80 to 89)	9	12
Fair (70 to 79)	7	3
Poor (Less than 70)	1	0
Total	25	25

Table 13: Fluoroscopy Images

Fluoroscopy Images	Range	Mean
PFN	4 to 10	7.5
PFNA2	4 to 8	4.5

Table 14: Length of hospital stay (Post-operative)

Length of hospital stay (In days)	Range	Mean
PFN	1 to 4	2.6
PFNA2	1 to 3	2.2

Table 15: Length of Incision (In cm)

Length of Incision (In cm)	Range	Mean
PFN	5 to 9	7
PFNA2	4 to 8	6.5

Table 16: Fracture healing Time (In weeks)

Fracture healing Time (In weeks)	Range	Mean
PFN	11.5 to 14.5	14.05
PFNA2	10.5 to 13.5	12.23

Table 17: Post-Operative Complications

Post-Operative Complications	PFN	PFNA2
Screw/Blade Cutout	Nil	Nil
Screw back out	Nil	Nil
Z Effect	Nil	Nil
Reverse Z Effect	Nil	Nil
Medial Migration	Nil	Nil
Implant breakage	Nil	Nil

Table 18: Length of the Nail

Length of the Nail	PFN
170	12
250 (Standard)	13
340 to 420 (Long)	Nil
Total	25

Length of the Nail	PFNA2
170 (Extra Small)	Nil
200 (Standard / Small)	14
240 (Medium)	11
240 to 420 (Long)	Nil
Total	25

Table 19: Diameter of the Nail

Diameter of the Nail	PFN	PFNA2
9	Nil	4
10	8	6
11	10	9
12	7	6
Total	25	25

Table 20: Neck Shaft Angle (NSA) – In degrees

Neck Shaft Angle (NSA)	PFN	PFNA2
125	Nil	12
130	11	13
135	14	Nil

The mean time in surgery was 56 minutes (40 – 65 minutes) for PFN & 45 minutes (35 - 55 minutes) for PFNA2. The mean amount of blood loss in surgery was 102 ml (70-140 ml) for PFN & 90 ml (60 – 120 ml) for PFNA2.

Mean radiological union time was 14.05 weeks for PFN & 12.23 weeks for PFNA2. No patient had any of general complication. In our study, we had local infection in 01 patient.

The functional status according to Harris hip score was excellent in 8, good in 9, fair in 7 cases and poor in 1 case in PFN & excellent in 10, good in 12, fair in 3 cases and poor in 0 case in PFN. Mean Harris hip score is 84 in PFN & 88 in PFNA2.

So in this study, intertrochanteric fracture treated with PFN & PFNA2 gives modified Harris hip score Excellent to Good in 17 patients & 22 patients, respectively.

All cases are evaluated according to modified Harris hip score on residual effects on clinical grounds at routine examination. Pain and functional capacity are the two basic considerations for this scoring system. Points are given for pain, function, range of motion and absence of deformity.

Discussion

The management of unstable intertrochanteric fractures pose a significant challenge to the orthopaedic surgeon. These fractures represent a technical difficulty in reduction of fractures and implication of surgical implant may lead to failure of primary fixation of fracture. The medial and posteromedial fracture fragments are the most important elements in determining the severity of intertrochanteric fracture.

Cephalo-medullary femoral reconstruction nails with a trochanteric entry point are biomechanically stronger than extramedullary implants. In unstable intertrochanteric fractures, the control of axial telescoping and rotational stability is essential. The recent implant for management of unstable intertrochanteric fracture is Proximal Femoral Nail Antirotation Asia 2- PFNA2.

PFN-A2 has advantages over PFNA in following ways

a. The proximal nail diameter was reduced from 17mm to 16.5mm
b. The Medio-lateral angle was reduced from 6 degree to 5 degree
c. A flat proximal lateral surface was adapted to avoid impingement of femoral lateral cortex

Bhatti *et al*. concluded Proximal Femoral Nail was associated with reduced blood loss, shorter hospital stays, less morbidity compared with Dynamic Hip Screw.

Klinger *et al*. did a comparative study of unstable intertrochanteric fractures and concluded that Proximal Femoral Nail was associated with shorter operation time, shorter hospital stays, higher rate of patient with early full weight bearing, fewer complications compared with Dynamic Hip screw.

Tornetta *et al*. concluded that patients aged more than 65 years treated either with Gamma nail or a compression hip screw have no overall difference in functional outcomes. However, when patients with unstable fracture patterns were analysed, those with an intramedullary nail had better walking ability at 12 months than those treated with compression hip screw.

Simmermacher *et al*. concluded that PFNA currently is an optimal implant with regard to prevention of femoral head

penetrations for the treatment of unstable trochanteric fractures.

E. Soucanye de Landevoisin *et al*. concluded that PFNA has additional benefits in patients with osteoporotic trochanteric fractures, both by preventing rotation and by ensuring cancellous bone compaction. This design may diminish the rate of complications associated with the cervical implant, provided the implantation procedure is scrupulously followed and fracture reduction is optimal.

Macheras *et al*. concluded that PFNA II avoided lateral cortex impingement experienced with PFNA, providing fast and stable fixation of the unstable peritrochanteric fractures.

Manoj *et al*. concluded that both PFN and PFNA perform well, showing equally good functional outcomes following fixation of unstable trochanteric fractures. When compared to PFN, use of PFNA significantly reduces the duration of surgery, the amount of operative blood loss and fluoroscopic imaging.

Gururagavendra *et al*. concluded that both the implants (PFN and PFN-A2) have comparable radiological and functional outcome for unstable intertrochanteric fracture except for less surgical time and blood loss in PFN A2.

In our study, a new cephalo-medullary proximal femoral nail antirotation Asia (PFN-A2) for unstable intertrochanteric fractures were used. These nails prevent the rotation and collapse of the head neck fragment and smaller diameter of distal shaft of nail results in less stress concentration at the tip of the nail. The antirotation screw at the proximal aspect of nail increases the biomechanical stability of the fracture fixation.

PFN-A2 have the biological advantages in terms of restoration of abductor-lever-arm mechanism, decreased tensile strain on the implant and maintenance of controlled fracture impaction.

Stable fixation for trochanteric fractures is the goal of treatment. It allows early weight bearing and restoration of function. The PFNA2 device is a reliable intramedullary implant that can share a large axial load, its helical blade achieves an excellent fit through bone compaction with less bone removal. The inserted blade prevents rotation by locking with the nail and accordingly, it may be a more suitable implant for unstable trochanteric fractures especially in the presence of osteoporosis. Biomechanical studies have shown that the blade has a higher resistance to head collapse than commonly used screw design.

Mean time for doing PFN was 56 minutes & for PFNA2 was 45 minutes. The mean amount of blood loss for PFN is 102 ml & for PFNA2 is 90 ml. Mean radiological union time was 14.05 weeks for PFN & 12.23 weeks for PFNA2.

Zeng *et al*. found that PFNA use was associated with a significant reduction in duration of surgery, overall complication rate, post-operative fixation failure rate, and intraoperative blood loss as compared to PFN.

Takigami *et al*. also found that the surgical time and operative blood loss were lower with the use of PFNA as compared to PFN. Takigami *et al*. found cut out rates of 2%, Sahin *et al*. found it to be 4.7% in their study.

Mora *et al*. recommend PFNA2 for treatment of trochanteric fractures in the elderly as its blade demonstrated a lower incidence of cut out in their study.

Aguado - Maestro *et al*. in their study of 200 patients treated with PFNA found that helical blade device reduced the rate of cut out & accurate placement of helical blade was key factor to prevent mechanical failures.

Table 21: Functional outcomes of PFNA2 (as per Harris hip score system)

	Mean Harris hip score
Present study	88.00
Liu *et al*. [15]	84.00
Sahin *et al*. [12]	77.80
Kashid *et al*. [16]	88.48

The functional status according to Harris hip score was excellent in 8, good in 9, fair in 7 cases and poor in 1 case in PFN & excellent in 10, good in 12, fair in 3 cases and poor in 0 case in PFN. Mean Harris hip score is 84 in PFN & 88 in PFNA2.

Conclusion

Modified Harris Hip score is good score to evaluate functional outcome of the patients. In conclusion the PFN-A2, is an optimum implant for the internal fixation of intertrochanteric fractures in elderly patients with advantages of a simple operation, very few complications, and good clinical efficacy, less surgical operative time, stable fixation, early load sharing fixation, early weight bearing and ambulation, shortened hospital stay and improved rate of union with early resumption of independent life style, excellent functional outcome, less soft tissue dissection and less blood loss, less time interval between Injury and Surgery, less fluoroscopy images, less length of surgical incision & better functional outcomes as well as Harris hip score.

Proximal femoral nail antirotation Asia 2 (PFN-A2) is an ideal implant for unstable intertrochanteric fractures, leading to high rate of bone union restoring the lateral femoral wall, reducing the chances of implant failure and decreasing the post-operative morbidity by increasing the functional quality of life.

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Conflict of interest: None

Ethical approval: The study was approved by the Institutional Ethics Committee (IEC)

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