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Study on functional outcome and mechanical failure in intertrochanteric femur fracture treated with proximal femoral nail antirotation-II

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Abstract
As the life expectancy has increased in recent years, the incidence of proximal femoral fractures is on rise. Common techniques for fixation of these fractures are sliding hip screw and plate or intramedullary nailing. Intramedullary nailing has advantage of short incision, less operative time, rapid rehabilitation & thus decreased medical complications. PFNA-II is newer intramedullary implant developed to obtain better fixation strength in osteoporotic bones.
Prospective observational study was conducted on 49 patients. All fractures were classified by AO/OTA classification system. Patients were followed up at 4, 8, 12 and 16-weeks. Functional outcomes were assessed according to pain assessment by numeric rating scale, Parker Palmer mobility score, Harris hip score. Fracture union and mechanical failure were assessed radiologically. Mean age of the entire group was 71.84years. Male to female sex ratio was 0.81:1.00. 32.7% had A1 type, 61.2% had A2 type and 6.1% had A3 type fracture. Mean OT time was 49.29mins and mean blood loss was 117.14ml. Mean pain score at 16-weeks was significantly lower compared to that at 4, 8 and 12-weeks post-op follow-up. Distribution of mean Palmer Parker mobility score and Harris hip score at 16-weeks post-op follow-up was significantly higher compared to that at 4, 8 and 12-weeks post-op follow-up. 38.8% had excellent, 40.8% had good, 12.2% had fair and 8.2% had poor functional outcome. Helical blade back out, cut-out and medial migration was seen in one patient each. 95.9% cases had maintenance of reduction and fracture union. Mean time for fracture union was 14.26 weeks.
Use of the PFNA-II to treat intertrochanteric fractures has the following advantages: quick procedure with small incision, less operative time, minimal blood loss, few complications, early weight bearing, less union time, good clinical efficacy and very few cases of complications. Good functional outcomes can be achieved, when the radiological parameters are restored. We conclude that PFNA-II is an effective treatment modality for intertrochanteric fractures, with excellent functional outcome and regaining back the pre-fall ambulatory status with minimal mechanical complications.

Keywords: intertrochanteric fractures, intramedullary nailing, proximal femoral nail antirotation-II, Palmer Parker mobility score, harris hip score

Introduction
Proximal femoral fractures are usually complicated with pre-existing medical co- morbidities like osteoporosis, diabetes, hypertension, renal failure. Today operative treatment has largely replaced conservative measures and choice of implant is mainly determined by the fracture pattern namely stable and unstable fractures. For fixation of unstable fractures, over the time, various designs of nails like PFN, have become popular. Although PFN proved to be superior to extramedullary devices, screw cut-out, back out, varus collapse and rotational instability continued to be significant complications, with up to 31% complication rates being reported in literature [1].
PFNA was introduced in 2003 and it utilizes a helical blade which is said to increase the bone-implant interface and result in compaction of cancellous bone, thereby providing excellent stability of fixation2. Biomechanical studies have proven that the helical blade, by compaction of cancellous bone around it, has superior resistance to rotation and varus Collapse [3].

Studies on fixation with the helical blade have shown that blade can also be associated with cut-through into the hip joint, cut-out and back-out just like other implant designs [4]. However, complications like lateral wall impingement, prominence of the proximal end of the nail and abutment of the distal nail tip to the anterior femur cortex were reported during its clinical use in Asian patients [5]**.** To overcome these problems, the PFNA-II was introduced in 20086. The PFNA-II is more appropriately designed for the Asian population by having a proximal diameter of 16.5mm, 0.5mm smaller in diameter, and a medial lateral angle of 5°, decreased by 1° compared to original PFNA. The PFNA-II has a single helical blade with locking mechanism and is better in achieving anti-rotation and adequate stability compared to other devices [7]. A single helical blade PFNA-II is technically better for small size femur in Asian population. Biomechanically, helical blade in PFNA-II has better cut-out resistance levels than screws8. Limited studies are available on the newer design PFNA-II in Indian population [9].

This prospective clinical study was performed to assess the functional outcomes and complications with the use of proximal femoral nail antirotation-II (PFNA-II) in treatment of intertrochanteric fractures.

Materials and Methods

1. **Study Site:** Jehangir Hospital, Pune, Maharashtra.
2. **Study Design:** Prospective Observational Study.
3. **Study Duration:** The study was carried out from August, 2019 to July, 2020.
4. **Sample Design:** Convenience Sampling Method.
5. **Sample Size:** 49 IPD patients with intertrochanteric femur fractures of Jehangir hospital who satisfied the eligibility criteria were included in the study. 56 patients were taken into consideration during study period. 7 patients were lost to follow up after surgical intervention.
6. **Sample Size Calculation:** Sample size was determined by using the effect size from the previously published study, Khairnar A. *et al.* 10 and with the help of following formula -n = z2 pq/(me)2 p = 0.755(75.5%) (Published estimate of incidence of excellent or good functional outcome post PFN), q = 0.245(24.5%) (Complement of 'p'), Z = 1.96 (score at 95% confidence interval), me = 0.12 (margin of error). n = 1.96^2 *0.755* 0.245/(0.12^2) = 49.34.
7. **Statistical Data Analysis:** The statistical significance of difference of distribution of categorical variables was tested using Chi-Square test or Fisher's exact probability test. P- values less than 0.05 were considered to be statistically significant. The entire data was statistically analyzed using Statistical Package for Social Sciences (SPSS ver 21.0, IBM Corporation; NY, USA) for MS Windows.
8. **Inclusion Criteria:** Patients diagnosed with intertrochanteric femur fractures of age>18 years and those who were willing for treatment, giving informed and written consent with fracture age <02 weeks in medically fit patient.
9. **Exclusion Criteria:** Patients less than 18 years of age, those with poly trauma, compound fractures, pathological fractures, fracture age more than 2 weeks, associated neurovascular injury, patients medically unfit for surgery, immunocompromised status, previous implant failure cases and patients who have not given consent for surgery.
10. **Ethical Consideration:** Informed consent was taken from the patients who were included in the study and approval was taken from the institutional ethical committee.

Methodology

Initial Treatment

- Affected hip was radiographed in standard AP view of pelvis and cross table true lateral view of proximal femur. Fractures were classified according to AO/OTA classification for proximal femur fractures (31A). Radiographs were used for estimation of the size of the canal, determination of the nail diameter and length, and also to get idea about anatomical femur bowing. The degree of osteoporosis was evaluated by Singh's index.
- Initial treatment was given in the form of non-adhesive skin traction with appropriate amount of weight for affected lower limb, in addition to analgesics, rest, intravenous fluids, air bed, and necessary medical and symptomatic management.

Pre Operative Evaluation:

- Routine standardized protocols for investigation were followed.
- Physician opinions were taken as to the fitness of patient before surgery. All the co-existing medical co-morbidities were optimized.
- Pre anesthesia checkup was done a day prior to surgery. According to the ASA scoring system fitness was given.

Operative Protocol

- All the fractures were treated with initial closed reduction. When close reduction was not satisfactory, open reduction was performed by minimal opening of the fracture site.
- Operations were performed by one of three experienced Orthopaedics trauma surgeons holding an experience more than 15 years. All surgeons were familiar with the technique of intramedullary nailing of the proximal femur. A standard operative technique recommended by the manufacturer, as described in detail in instruction manuals, was used.

Post Operative Protocol

Post-operative management

- Clinical and local assessment: All patients were assessed clinically and locally in immediate post-operative period for need for blood transfusion, post-op shortening of affected limb and other local and systemic complications like infection at surgical site, ICU admission, decubitus ulcer, urinary tract infection, chest infection and DVT.
- Radiological assessment: Post-operatively, quality of reduction was assessed by comparing neck shaft angle of operated hip to that of normal hip from the radiographs. The difference of less than 5° was considered excellent, 5°–10° as good and more than 10° as poor reduction11. Quality of fixation was assessed using tip apex distance12. The Cleveland index13 was used to note the position of the tip of helical blade. The measurements were done using computed radiographic system of our hospital.

Post-operative rehabilitation

- The rehabilitation protocol was uniform in all patients regardless of the fracture pattern and the type of fixation. Non weight bearing walking with walker support was initiated from day two. Partial weight bearing walking with walker support was initiated at the first radiological sign of fracture

healing, usually at 6 to 8 weeks. Full weight bearing walking was allowed after assessing for radiological union.

Follow UP Period

- After the completion of the hospital treatment, patients were discharged and called for follow up at outpatient level, at regular intervals at 4 weeks, 8 weeks, 12 weeks and 16 weeks for clinical and radiological evaluation. Patients at each visit were evaluated using pain assessment by numeric rating scale, Parker Palmer mobility score and Harris hip score [14].
- Anteroposterior and lateral plain radiographs were obtained at each visit and reviewed for the progression and time of fracture union, tip apex distance, fracture alignment, cut-out or medial migration of helical blade and other implant related complications. Fracture union was determined by radiological union score of hip (RUSH)15 Data collected at the end of the study was statistically compared and analyzed with the similar studies done before.

Implant Details and Design

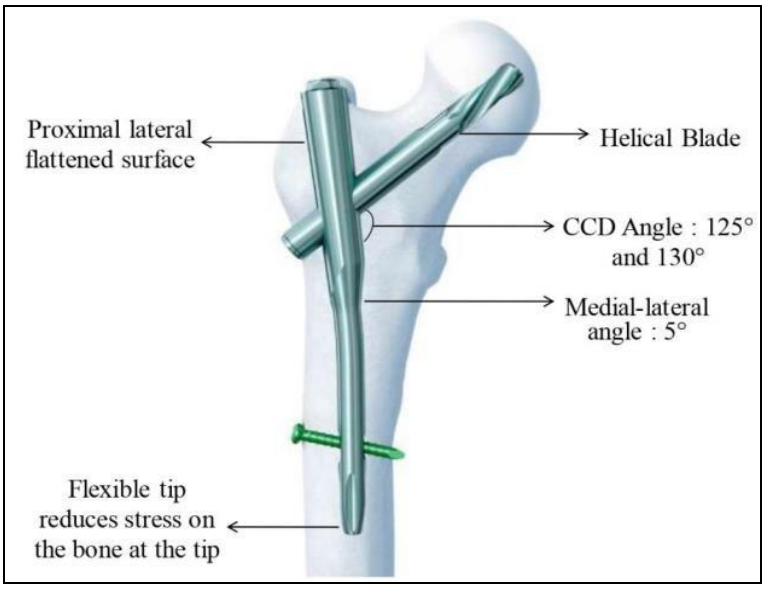
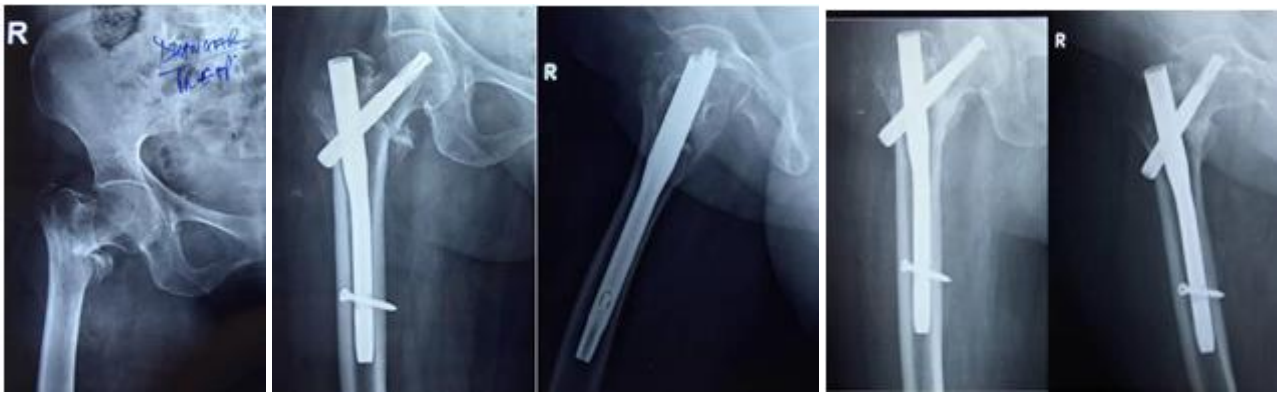


Fig 1: PFNA-II Implant Design

Follow Up Cases:

CASE 1: 63 years male patient had right side intertrochanteric fracture, following domestic fall and was treated with PFNA-II. Functional outcome at 16 weeks. Pre-op, post-op and 16 weeks
post-op X-rays.

Fig 2: Functional outcome of case no. 1.



Pre-op X-ray Post-op X-ray 16 weeks post-op X-rays

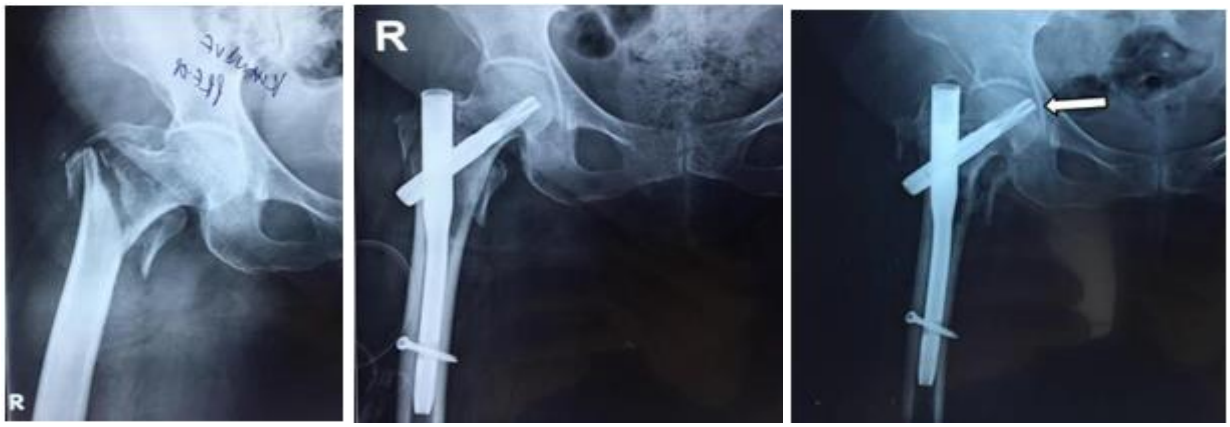
Fig 3: X-rays of case no. 1.

Case 2: 74 years female patient sustained right side intertrochanteric fracture following fall in bathroom, which was treated with PFNA-II. Pre-op, post-op and 16weeks post-op X-rays.

Pre-op X-ray Post-op X-ray 16 weeks post-op X-ray

Fig 4: X-rays of case no. 2.

Case 3: 69 years male patient treated with PFNA-II for right side intertrochanteric fracture. Pre- op, post-op, and 12 weeks post-op Xrays. He had medial migration of helical blade at 12 weeks.



Pre-op X-ray Post-op X-rays 12 weeks post-op X-ray

Fig 5: X-rays of case no. 3.

Results

The present observational prospective study was done on 49 cases at our tertiary care
hospital to assess the functional outcomes and mechanical failure of intertrochanteric fracture when treated with proximal femoral nail antirotation-II. The mean age of the entire group of cases studied was 71.84 years. Maximum patients were in the age group of 71-80 years (30.6%), immediately followed by 61-70(26.5%). The incidence of intertrochanteric fracture was found to be more in females with a sex ratio of 0.81:1.0. Maximum number (73.5%) of patients sustained intertrochanteric femur fracture due to simple domestic fall. Road traffic accident was major cause of fracture in younger age group. Maximum number (53.1%) of patients had left side involved than right side. Maximum number (42.9%) of patients had grade III Singh's index of osteoporosis. Majority (61.2%) of cases has A.O. A2 type fracture, type A3 was seen in (6.1%) least cases.

The mean interval between injury and the surgery in the study group was 3.91 days, with majority 44.9% had 4-5days of interval, followed by 42.9% cases had 2-3 days of interval. The mean of duration of OT time in the study group was 49.29 mins, with majority (83.7%) of cases had OT time between 30-60mins.

Table 1: Distribution of grade of fracture

AO Classification	No. of cases	% of cases
A1	16	32.7
A2	30	61.2
A3	03	6.1
Total	49	100

Table 2: Distribution of OT time.

OT time (Mins)	No. of cases	% of cases
30-60	41	83.7
60-120	08	16.3

study group was 1.06cm and the minimum–maximum range 0.0–2.5cm. Majority (61.2%) cases had post op neck-shaft angle difference less than 5 degrees, 77.6% cases had tip apex distance less than 25mm and 75.5% cases had helical blade position between 4-5, as per Cleveland index.

Distribution of mean pain score at 16-weeks post-op follow-up is significantly lower compared to mean pain score at 4, 8 and 12-weeks post-op follow-up. The mean Parker Palmer score at pre-injury and 16-weeks post-op follow-up was 8.51

and 8.02 respectively, which is statistically comparable. Distribution of mean Harris hip score at 16-weeks post-op follow-up is significantly higher compared to mean Harris hip score at 4, 8 and 12-weeks post-op follow-up.

Of 49 cases studied, 40.8% had good outcome, 38.8% had excellent functional outcome. Mean age of time for fracture union among the cases studied was 14.26 weeks. Maximum (95.9%) cases had maintenance of reduction and fracture union. Total 03 patients had implant related complications, 1 patient (2.0%) had helical blade back out, 1 case (2.0%) had medial migration of helical blade and 1 patient (2.0%) had helical blade cutout. Of 49 cases studied, none had re-fracture or implant breakage. We did not encounter any deep surgical site infection in any of our patients.

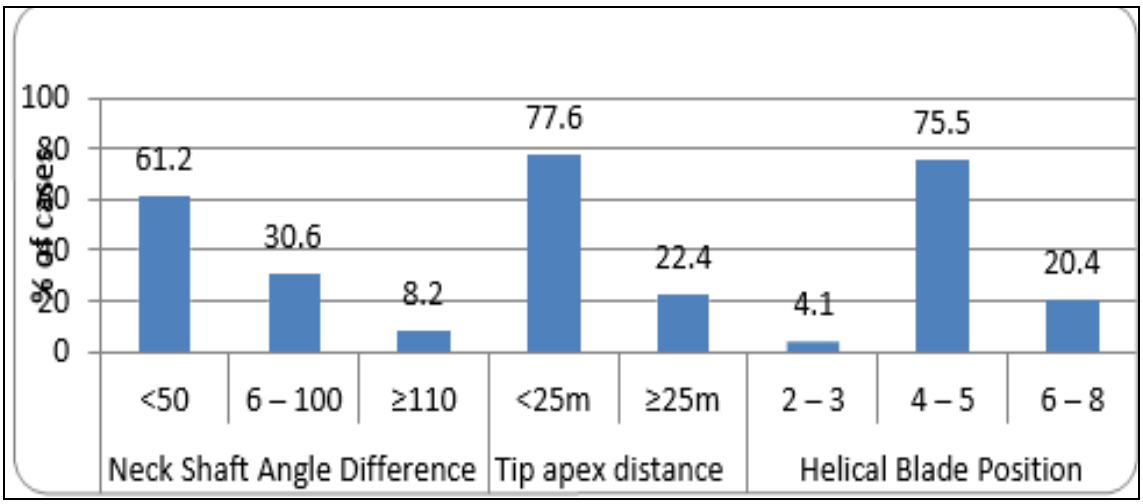


Fig 6: Distribution of immediate post-op radiological assessment.

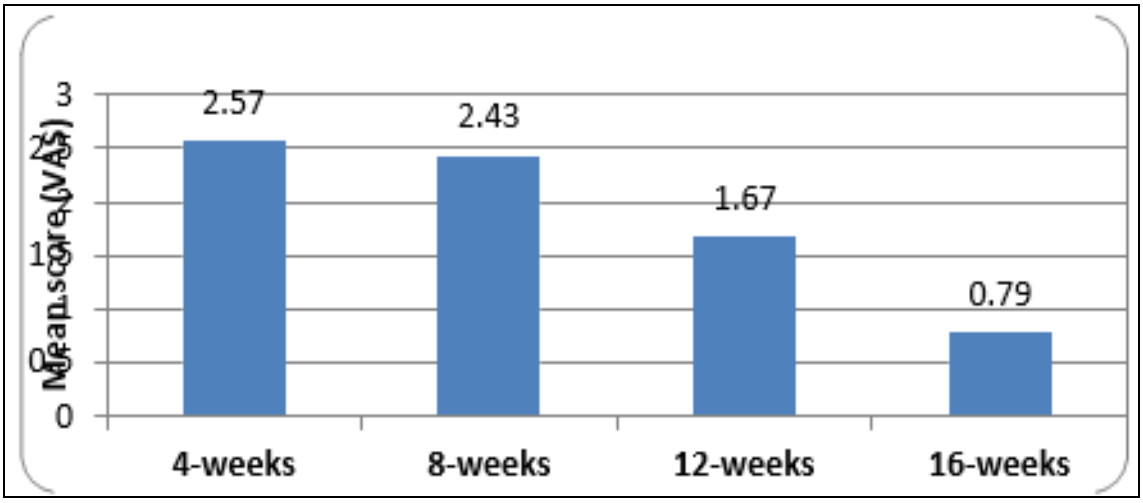


Fig 7: Distribution of mean pain score at all post-op follow-ups.

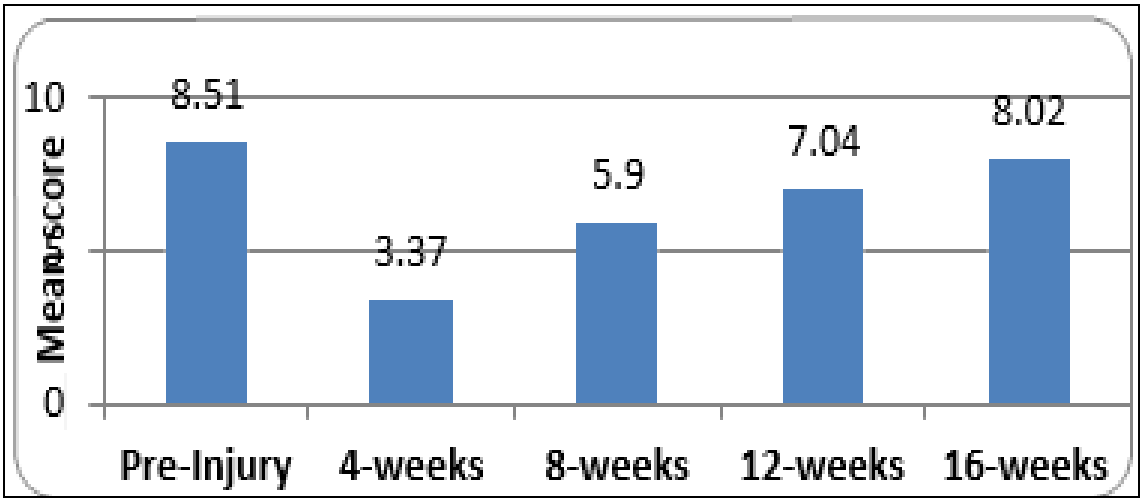


Fig 8: Distribution of mean Parker Palmer score at all post-op follow-ups.

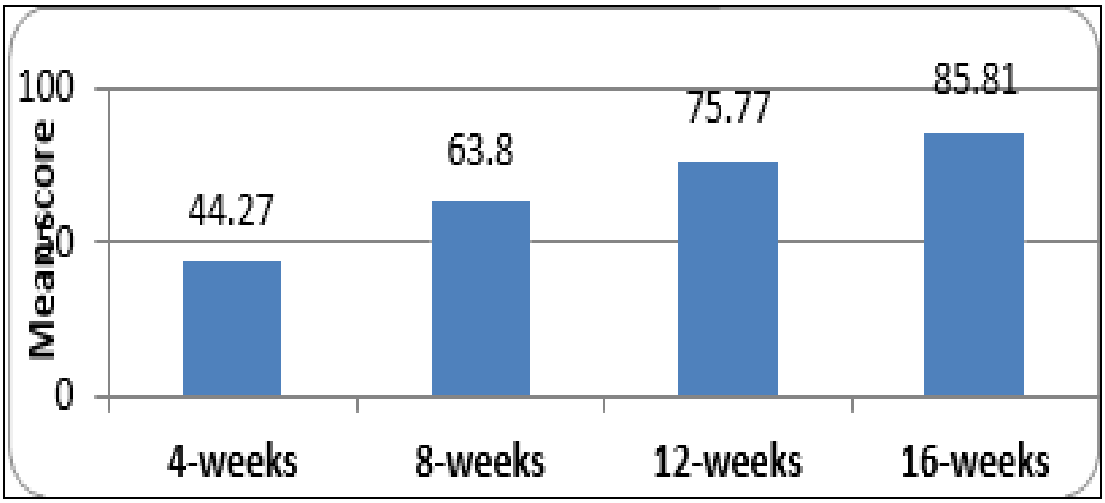


Fig 9: Distribution of mean Harris hip score at all post-op follow-ups.

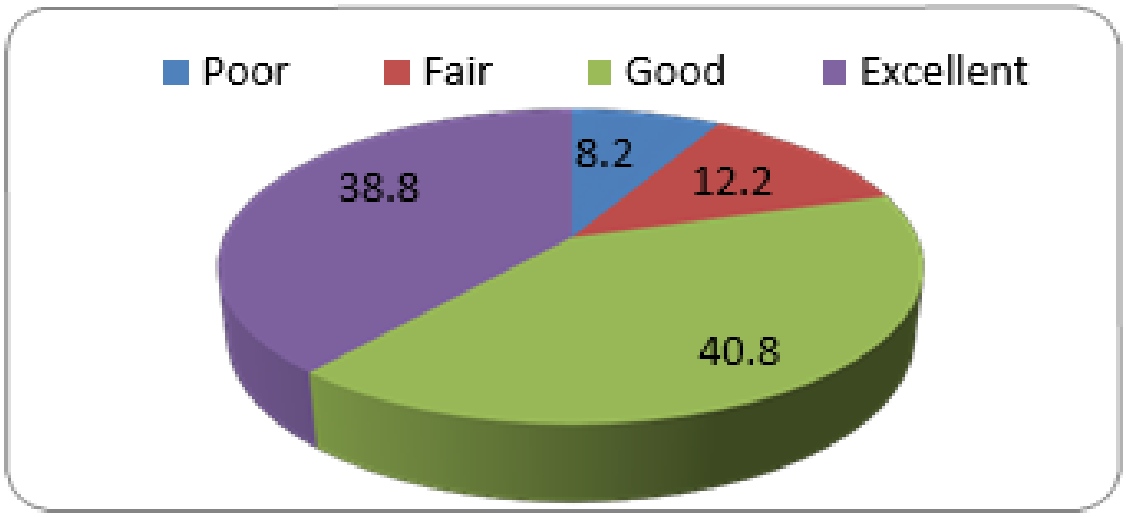


Fig 10: Distribution of Harris hip score at 16-weeks follow-up.

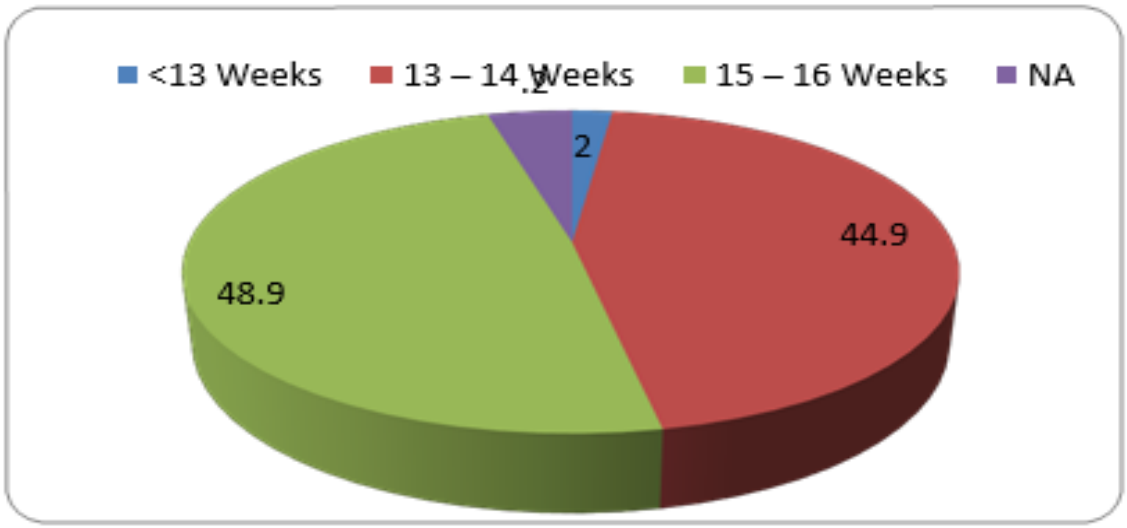


Fig 11: Distribution of fracture union time among.

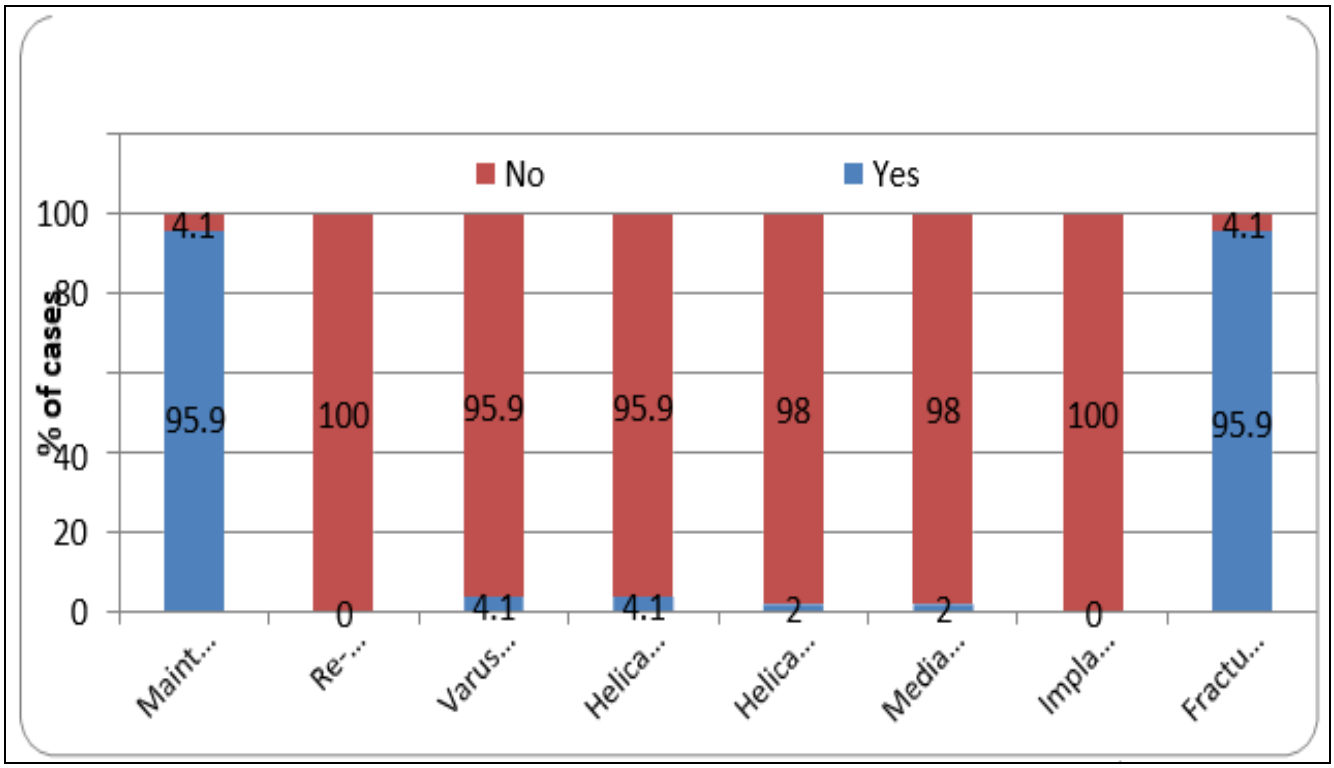


Fig 12: Distribution of radiological assessment at 16-week follow-up.

Discussion

The incidence of hip fractures in the elderly continues to increase dramatically. Studies have shown that surgical treatment of intertrochanteric fractures is associated with a significantly lower mortality rate and higher quality of life [16]. The mechanical axis of the intra-medullary system is close to the centre of the body, decreasing the lever arm of the implant and hence offering better mechanical properties [17]. The implant also acts as a buttress against medialisation of the shaft. PFNA-II 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 trochanteric fractures especially in the presence of osteoporosis.

In the present study, 41(83.7%) had closed type of reduction and 8(16.3%) had limited open reduction. This finding was comparable with the studies of Li M *et al.* [18], they observed of 163 patients, 131 underwent closed reduction and 32 underwent open reduction. The mean±SD of incision length in the study group was 6.91cm (range 5-14cm). This is in concordance to the study of Li M *et al.* 36, they found the average total incision length of 6.5cm (range 5.5–13.0cm). The average number of fluoroscopic images taken intra-operatively was 34.24 in our study. Similar observations were noted in the studies of Mallya S *et al.* [19] where they observed mean value of fluoroscopic images of [27].

In the present study, the mean of blood loss was 117.14ml (range 70-210ml). This is comparable to the studies of Li M *et al.* [36], in which they observed intraoperative blood loss of 115.2ml (range, 65-430ml). Of 49 cases studied, 2(4.1%) had ICU admission immediately from recovery area, for overnight monitoring of general medical condition, Raj P *et al.* 20 noted similar observations in his study which showed requirement for ICU admission in 3 patients of PFNA-II group. 1(2.0%) patient in our study had superficial surgical site infection which was completely treated with appropriate intravenous and oral antibiotics (depending on culture reports) for 3weeks. This is comparable with study from Santharam B *et al.* [21], they noted in PFNA-II group, 2 cases had infection. 1(2.0%) patient in our study developed decubitus ulcer which was successfully managed with regular dressings, which is comparable with study from Harshwardhan H *et al.* [22], in which they reported 1 case of decubitus ulcer. 1(2.0%) patient in our study had UTI, which was medically managed with antibiotics as per culture report; none of the patients had chest infection and DVT.

In our study, Mean±SD of pain score at 4-weeks, 8-weeks, 12-weeks and 16-weeks post- op follow-up was 2.57±0.61, 2.43±0.71, 1.67±0.93 and 0.79±0.81 respectively. Distribution of mean pain score at 16-weeks post-op follow-up is significantly lower compared to mean pain score at 4-weeks, 8-weeks and 12-weeks post-op follow-up (P-value<0.05 for all), which signifies that the pain is significantly reduced over the time.

It was observed in the present study that Mean±SD of Parker Palmer mobility score at pre-injury, 4-weeks, 8-weeks, 12-weeks and 16-weeks post-op follow-up was 8.51±0.71, 3.37±0.49, 5.90±0.96, 7.04±1.20 and 8.02±1.05 respectively. Distribution of mean 16-week Parker Palmer mobility score is significantly higher compared to the mean at 4-weeks, 8-weeks and 12-weeks post-op follow-up (P-value<0.05 for all). This is in concordance to the study of Loo WL *et al* [13], in which they reported that 83.9% of patients were able to gain preoperative mobility status by 6 months following surgery.

It was observed in our study that, the mean±SD of Harris hip score at 16-weeks post-op follow-up was 85.81±7.67. Distribution of mean Harris hip score at 16-weeks post-op follow-up is significantly higher compared to mean Harris hip score at 4-weeks, 8-weeks and 12-weeks post-op follow-up (P-value<0.05 for all). This is comparable to the study of Santharam B *et al.* [21], Li M *et al.* [18], and Harshwardhan H *et al.* [22]. Santharam B *et al.* [21] study reported the mean Harris hip score at 6 months in PFNA-II of 86.80. Li M *et al.* [18] study reported the mean Harris hip score of 85.6±17.5 (range,

65-100). Harshwardhan H *et al*. [22] study observed, the mean Harris hip score of 82.86. Of 49 cases studied, 19(38.8%) had excellent functional outcome, 20(40.8%) had good outcome, 6(12.2%) had fair outcome and 4(8.2%) had poor functional outcome as per Harris hip score. The poor outcomes were due to helical blade back out, helical blade cutout and medial migration. This is concordant to the studies of Santharam B *et al*21 and Li M *et al*. [18]. Santharam B *et al*. [21] study observed in PFNA-II, 60% had had excellent, 20% had good, 5% had fair and 15% had poor outcome. Li M *et al*. [18] study observed Harris hip score was excellent in 41(25.15%) cases, good in 92(56.44%) cases, moderate in 26(15.95%) cases, and poor in 4(2.45%) cases.

It was observed in the present study that of 49 cases studied, 30(61.2%) had neck-shaft angle difference less than 5 degrees, 15(30.6%) had neck-shaft angle difference between 6-10 degrees and 4(8.2%) had neck-shaft angle difference more than 11 degrees in the study group, patient of helical blade cutout had neck-shaft angle difference of 7 degrees. 38(77.6%) patient of our study had <25 mm tip apex distance (TAD) and 11(22.4%) had TAD more than 25 mm in the study group. Only one patient with implant complication (helical blade cutout), had TAD more than 25 mm. Out of 11 patients with TAD >25mm, 3 patients had fair results. 2 (4.1%) cases of our study had helical blade position between 2-3, 37(75.5%) had helical blade position between 4-5 and 10(20.4%) had helical blade position between 6-8, as per the Cleveland index. Zone 5 was the most common zone of placement of the helical blade tip on post-op X-rays. Two of three complications had sub-optimal position of blade. This is consistent with the study of Mallya S *et al*. [19], in which they observed that, 22/37 in PFNA-II group had excellent reduction (difference in NSA between operated to normal hip 10°) 11/37 in PFNA-II group had good reduction (5°-10°). Four patients in PFNA-II group had poor reduction. All four patients with poor reduction in PFNA-II group had poor functional results. Two out of four complications seen in PFNA-II group had poor reduction (>10°). They observed 1/2 patients, with implant failure, in PFNA-II group had TAD more than 25 mm. Out of nine patients, with TAD>25 mm in PFNA-II group, five patients had poor functional outcome, two had fair, and two had good results. They noted, in PFNA-II group, 25/37 (67.56%) had optimal position of implant in the head of femur as per Cleveland index (centre-centre, inferior-centre). Out of 12 patients with sub-optimal position in PFNA-II group, two had implant failure.

Of 49 cases studied, 2(4.1%) did not have maintenance of reduction, of these two cases, one had cutout and other had helical blade back out which was united in malposition with varus angulation and 47(95.9%) had maintenance of reduction. None had re-fracture. 1(2.0%) patient had helical blade back out, which was united in malposition with varus angulation, implant removal is planned for this patient in near future. 1(2.0%) of our case had helical blade cutout, for which implant removal and bipolar hemiarthroplasty was done. Medial migration of helical blade was seen in 1(2.0%) patient, for which implant removal and total hip replacement was done and 48(98.0%) did not have medial migration of helical blade. None had implant breakage. 47(95.9%) patients had fracture union. 2(4.1%) cases did not have fracture union (one case of helical blade cutout and other of helical blade medial migration). These findings were consistent with the studies of Mallya S *et al*. [19] and Li M *et al*. [18]. Mallya S *et al*. [19] observed, PFNA-II group had overall four complications, 1 had screw back out, 1 had screw cut out, 1 had subtrochanteric fracture and 1 had screw in the joint. Two out of four complications seen in PFNA-II group had poor reduction (>10°). Li M *et al*. [18] reported that, one patient developed reamer cutout into the acetabulum, and three developed reamer exit.

In the present study, the mean±SD of time for fracture union was 14.26±2.32 weeks (range, 13-16weeks). Similar observations were noted in the studies of Li M *et al*. [18] and Harshwardhan H *et al.* [22]. Li M *et al*. [18] study reported the fracture healing time of 14.0±2.5 weeks (range, 11-19weeks). Harshwardhan H *et al.* [22] study reported, the mean union time for intertrochanteric fractures of 13.5weeks.

Conclusion

- Intertrochanteric fractures pose a great challenge for Orthopaedic surgeons to manage surgically. Due to the evolution of load sharing devices, it is possible to manage the fractures with internal splinting.
- This study shows that use of the PFNA-II to treat intertrochanteric fractures in elderly patients has the following advantages: quick procedure with small incision, less operative time, minimal blood loss, few complications, early weight bearing, less union time, good clinical efficacy and very few cases of back out, medial penetration and cut-out of helical blade were seen.
- PFNA-II has a superior performance over other intramedullary devices in the setting of osteoporosis, which is attributed to compaction of cancellous bone by the helical blade. The PFNA-II implant provided significantly lower rates of implant failure and delayed healing.
- Nevertheless, it must be remembered that no implant design can compensate for poor reduction or poor implant placement. Good functional outcomes can be achieved, when the radiological parameters are restored i.e. Cleveland index in centre-centre position and neck-shaft angle difference less than 5 degrees.
- We conclude that, the PFNA-II is an effective treatment modality for all intertrochanteric fractures, especially in the elderly with osteoporosis, with excellent functional outcome and regaining back the maximum pre-fall ambulatory status with minimal mechanical complications.

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