

# A Prospective Randomized Study of Patients with Unstable Intertrochanteric Fracture Femur Treated with InterTan Nailing

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## ABSTRACT

**Introduction:** Unstable intertrochanteric fractures are one of the challenging fractures to deal with. Intramedullary implants have biomechanical advantages over extramedullary ones thus avoiding adverse complications. The aim of this study was to assess the functional outcome of InterTan nailing using Kyle's criteria.

**Material and Methods:** 38 patients with unstable intertrochanteric fractures, were operated between December 2014 and December 2015 using the Intertan nail. The inclusion criteria were patients with >60 years of age who were pre fractured community ambulatory with unstable intertrochanteric fractures as per Evans classification system. Patients with severe medical co-morbidities and pathological fractures were excluded from the study.

**Results:** The mean age of the patient was 77±04 years. Domestic fall was found to be the commonest mechanism of injury involving 33 (86.84%) of patients. Average duration of surgery was 58±17.4 minutes. 6 cases had post-operative abductor lurch which improved gradually. There was no case of infection encountered in the present study. There was 1 (2.6%) case with varus collapse and 1 (2.6%) case with cut out of the screw. The average time for radiological union was 16±04 weeks in majority of the cases. 32 cases had good to excellent results using the Kyle's criteria (statistically significant P<0.002).

**Conclusion:** InterTan provides intra-operative linear compression which improves resistance to femoral head rotation and cut outs thus converting the construct to a fixed angle device. Minimal dissection, less operative time and preservation of biomechanics are few advantages with good long term promising outcome.

**Keywords:** Femur fractures, InterTan, Intramedullary nail.

mechanism, thus allowing linear intra operative compression and rotational stability of head/neck fragment.

## MATERIAL AND METHODS

38 patients with unstable intertrochanteric fractures, presenting between December 2014 and December 2015 were randomly selected and operated using the Intertan nail (Smith and Nephew, Memphis, TN, USA) at a tertiary care hospital in Mumbai city. Randomization was done using the closed envelope technique. The envelope was opened by the patient just prior to the surgery. The inclusion criteria were patients with >60 years of age who were pre fractured community ambulatory with unstable intertrochanteric fractures as per Evans classification system. Patients with severe medical co-morbidities and pathological fractures were excluded from the study. Well written informed consent was taken from all the patients enrolled in the study. Ethical committee approval was obtained prior to the commencement of the study.

## Operative Technique

Spinal combined with epidural anesthesia was used in majority of the cases. Three doses Second generation cephalosporin injection were given (one just after the induction of anesthesia another two in 12 hourly interval). Fracture reduction was achieved in all the cases prior to the commencement of the surgery on traction table and was confirmed in both the orthogonal planes. The reduction was taken as acceptable when neck-shaft angle was reduced within <5° and fracture site displacement <4 mm as compared to normal side. Standard surgical steps were followed in all the cases. 5 cm incision level was made at the point of intersection of a perpendicular line drawn from ASIS and the line extending proximally from the greater trochanter. Tensor fascia lata Followed by the fibers of Gluteus medius was incised. Palpation of the greater trochanter was done manually followed by insertion of 3.2mm guide wire through the medial aspect of the greater trochanter followed by 12.5mm proximal reamer through the 16mm channel reamer. The position of guide wire was checked at every step in both the orthogonal views. Fracture was reduced with the

## INTRODUCTION

Intertrochanteric fracture is one of the most common fractures of the hip especially in the elderly. The incidence of the same has been on a rise since past few decades owing to the presence of increased number of elderly population superadded with osteoporosis. By 2040, the incidence is estimated to be doubled. In India the figures may be much more.<sup>1</sup> Early intervention in the form of surgery often helps to hasten the recovery and return to activities of daily living, thus avoiding serious consequences related to the non-operative management. Dissatisfaction with the use of the extramedullary devices like the Dynamic Hip Screw (DHS) in unstable intertrochanteric fracture patterns led to the evolution of intramedullary devices like Proximal Femoral Nail (PFN).<sup>2</sup> Even the second generation intramedullary nails like PFN, may lead to collapse in the fracture area and reverse displacement of the proximal locking screw or the "Z" effect.<sup>3,4</sup> The purpose of the present study was to study the effectiveness and drawbacks of one such newer third generation intramedullary device, the Intertan nail for the management of intertrochanteric fractures that uses two cephalo cervical screws in an integrated

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**How to cite this article:** Waybase Hanumant Ashok, Naik Lokesh Gudda, Rajiv Mario Colaco, Sharma Gaurav Mahesh. A prospective randomized study of patients with unstable intertrochanteric fracture femur treated with intertan nailing. International Journal of Contemporary Medical Research 2017;4(1):45-48.

help of reducer. Intertan nail with 16.25mm trapezoidal shape proximally was mounted over zig and inserted over the guide wire. Guide wire was inserted through the proximal sleeve for the compression screw insertion from the lateral cortex directing towards the femoral head in the subchondral bone. Adequate Tip apex distance was maintained to less than 25mm. 11mm integrated interlocking lag screw was inserted over the guide wire in the proximal slot. 7mm compression screw was inserted in a similar manner in the second slot which was 10mm smaller than the drilling depth. The compression screw was finally tightened over the lag screw in figure of eight manner thus achieving the intra-operative compression. Distal locking was done in a dynamic manner. Final reduction was checked under fluoroscopy in both the orthogonal views. Intra-operative complications including technical problems were recorded. Wound was closed over layers followed by compression dressing. Similar pain management protocols were followed in all the cases. Toe touch weight bearing was started immediately with the help of support. Clinical and radiological assessment was done at 1,3,6 and 12 months post-operatively.

### STATISTICAL ANALYSIS

Sample size calculation was done using the Post-hoc Analysis. 12 patients were required to be enrolled to achieve 80% power and 95% confidence interval. The above analysis was determined on the basis of similar studies by Gadegone et al.<sup>5</sup> and Sharma Vipin et al.<sup>6</sup> The final results were calculated using Chi-square and Paired t test respectively.

### RESULTS

The mean age of the patient was 77±04 years with the youngest patient of 65 and the eldest patient of 91 years respectively. There was a female predominance, accounting for 28 (73.69%) patients. Diabetes mellitus and Hypertension were the commonest co-morbidities encountered in the present study comprising of 8 (21.06%) patients. 34 (89.48 %) patients used some form of support in the pre fractured period like a single stick. Domestic fall was found to be the commonest mechanism of injury involving 33 (86.84%) of patients. Left side involvement was seen more commonly affecting 28 (73.69%) patients.

27 (71.05%) patients had Type 3 fracture as per the Evan classification system, thus making it the most common type

of fracture. All the fractures were reduced by closed method. 130 degree nail was used in majority of the cases. The average duration of surgery was 58±17.4 minutes. Good intra-operative reduction was achieved in 28 (73.69%) cases as checked on fluoroscopy. 6 (15.7%) cases had post-operative abductor lurch which improved gradually at 6 months of follow-up. There was

#### KYLES criteria

All the patients after union of fracture or after 16 weeks will be grouped and the anatomical and functional results will be evaluated as follows.

1. **Excellent**
  - a. Fracture united.
  - b. No pain.
  - c. No infection.
  - d. Full range of motion at hip.
  - e. No shortening.
  - f. Patient able to sit crossed legged and squat.
  - g. Independent gait.
2. **Good**
  - a. Fracture united.
  - b. Occasional pain.
  - c. No infection.
  - d. Terminal restriction of hip movements.
  - e. Shortening by half an inch.
  - f. Patient able to sit crossed legged and squat.
  - g. Use of cane back to full normal activity.
3. **Fair**
  - a. Fracture united.
  - b. Moderate hip pain.
  - c. No infection.
  - d. Flexion restricted beyond eighty degrees.
  - e. Noticeable limb shortening up to one inch.
  - f. Patient not able to sit crossed legged.
  - g. Patient walks with support of walker.
  - h. Back to normal activities with minimal adjustments.
4. **Poor**
  - a. Fractures not united.
  - b. Pain even with slightest movement at hip or rest.
  - c. Infection
  - d. Range of movements at hip restricted, flexion restricted beyond sixty degrees.
  - e. Shortening more than one inch.
  - f. Patient not able to sit crossed legged or squat.
  - g. Patient cannot walk without walking aid.
  - h. Normal activities not resumed.



Figure-1: Pre-operative x ray; Figure-2: Post-op AP view

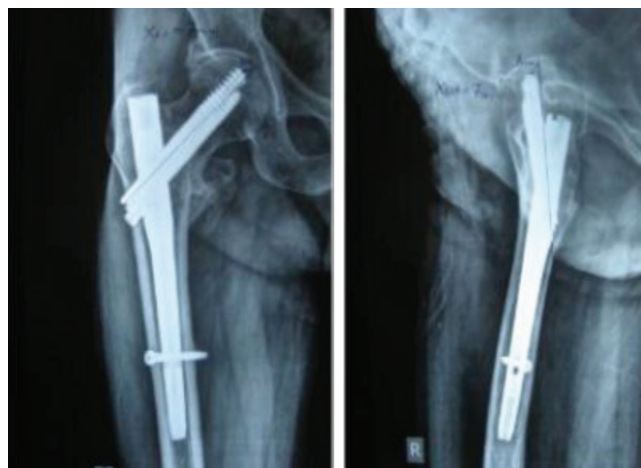


Figure-3: 2 Months AP view; Figure-4: 12 Months Lat view

no case of infection encountered in the present study. There was 1 (2.6%) case with varus collapse and 1 (2.6%) case with cut out of the screw observed in the present study. The average time for radiological union was  $16 \pm 04$  weeks in 21 (55.26%) cases,  $18 \pm 06$  weeks in 13 (34.22) and  $20 \pm 07$  weeks in 4 (10.52%) cases respectively. Regular Follow-up was done at 1,3,6 and 12 months.

Final results were calculated using the Kyle's criteria<sup>7</sup> and 32 (84.21%) cases had good to excellent results, 5 (13.15%) had fair and (2.63%) case had poor result respectively which was statistically significant ( $P < 0.002$ ).

## DISCUSSION

Unstable intertrochanteric fractures are associated with comminution of posteromedial buttress which often poses a challenge for the treating surgeon. Successful treatment of intertrochanteric fractures depends on surgeon independent variables like bone quality (osteoporosis), fracture pattern and fracture stability. Surgeon dependent variables are quality of fracture reduction, choice and placement of implant.<sup>8</sup> Dynamic Hip Screw has been accepted as the gold standard for stable intertrochanteric fractures but cutting out of the screw, excessive medialization of the distal fragment, and collapse upon weight bearing are major concerns associated with it.<sup>9,10</sup> In addition, this open technique entailing the sliding hip screw may result in deterioration of pre-existing co-morbidities in elderly patients owing to increased blood loss, soft-tissue damage, and longer rehabilitation.<sup>11</sup>

The management of unstable Intertrochanteric fractures with intramedullary nail has recently gain much attention.<sup>12,13</sup> Apart from being Load sharing device, nail incorporates the benefit of controlled collapse due to the presence of sliding screw. They also avoid medialization of the femur shaft by acting as a buttress. Moreover, this technique requires less blood loss and less soft tissue dissection finally decreasing the overall morbidity.<sup>14</sup> The original design of the Gamma nail was rigid and associated with anterior thigh pain, fixation failure, and fracture of the femoral shaft distal to the tip of the nail.<sup>15,16</sup> The newer Gamma nail is a less invasive technique, but is associated with higher rate of screw cut out and less foresaid complications.<sup>17,18</sup> It has a technical and mechanical failure rate of about 10%.<sup>18</sup>

Several studies have reported incidences of secondary femoral shaft fractures (up to 17%) due to anterior cortical impingement of the nail tip and distal locking bolt problems when a short IM device is used. This is more important in Asian patients because they tend to have short statures and femur lengths.<sup>19</sup>

Egol KA et al<sup>13</sup> did a study on the mismatch of current intramedullary nails with the anterior bow of the femur. They inferred that Intra-operative complications such as splintering and fractures are due to oversized implants that are manufactured according to western population parameters. In another recent study using InterTan nails, a 6% rate of postoperative femoral fractures was reported<sup>20</sup>. No case of femur shaft fracture was reported in the present study.

Zhang S et al<sup>21</sup>, in their study concluded that the rate of thigh pain was lower in the InterTan group than PFNA group. Albeit, the present study did not compare InterTan nail with some other intramedullary nail, there was no case of anterior thigh pain reported.

There was 1 (2.6%) case with varus collapse and 1 (2.6%) case with cut out of the screw observed in the present study. Implant cut out was comparable to a study by Ruecker et al<sup>22</sup>, who had a rate of 4.16% in one year follow-up.

The newer third generation InterTan nail comprises of two lag screws and works on worm gear mechanism which converts rotational forces into linear compression. The smaller compression lag screw (the worm screw) position is fixed within the nail, and acts as a pinion whereas the large lag screw functions as a rack. After the head of the compression lag screw contacts the lateral side of the nail, further turns of the compression lag screw causes the large lag screw to move axially, which results in compression between the proximal and the distal fragment<sup>19</sup>. This nail has a split distal tip that reduces overall cross sectional stiffness of the distal implant.

Nuchtern et al<sup>23</sup> found that the Tip Apex Distance (TAD) has a major effect on the final outcome of the procedure, irrespective of the number of screws used. In the present study, the TAD was 14.76 mm (SD 2.44) in accordance to the study by Kim JW et al<sup>19</sup> who had a TAD of 15.30 mm (SD 3.70). The higher rate of screw cut out in the present study can be explained due to the increased TAD in the two cases.

Good pre-operative reduction was obtained in 28 (73%) cases in the present study which was comparable to the study by Kim JW et al<sup>19</sup> who had 75% of the cases with good reduction.

As per the Kyle's criteria, 32 (84.21%) cases had good to excellent results which are comparable with the studies by Gadegone et al<sup>5</sup> and Sharma Vipin et al<sup>6</sup> with 90% and 82.92% cases respectively.

The present study had few limitations like small number of sample size, less duration of follow-up. Also, large multicentric and more randomized studies are need for a promising conclusion.

## CONCLUSION

The Unstable Intertrochanteric fracture in elderly patient treated with InterTan nail provides intra-operative linear compression which improves resistance to femoral head rotation and cut outs while tightening of preloaded lag screw converts construct to a fixed angle device thus showing favorable outcome. The proper selection of patients, good pre-operative planning and careful insertion of nail is are the pre-requisites.

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compression. *J Orthop Trauma*. 2009;23:22-30.

**Source of Support:** Nil; **Conflict of Interest:** None

**Submitted:** 10-12-2016; **Published online:** 24-01-2017