Outcome of intertrochanteric fractures treated by intramedullary nail with two integrated lag screws
A study in Asian population

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ABSTRACT
Background: The incidence of intertrochanteric fracture has increased during recent years as life expectancy has also increased. Currently, orthopedic surgeons use various fixation methods for intertrochanteric fractures like, intramedullary (IM) nailing or dynamic hip screws and plates. The intramedullary (IM) nail with two integrated lag screws has been used recently in intertrochanteric fractures to overcome Z-affect phenomenon. However, no study is available in an Asian population. This prospective study was undertaken to document the clinical and radiologic outcomes of the IM nail with two integrated lag screws and its limitations in Asian patients.

Materials and Methods: Osteosynthesis was performed using InterTAN nail in 100 patients with an intertrochanteric fractures followed up for at least 1 year after surgery. We evaluated the recovery rates to prefracture status, time to bony union and the incidence of complications.

Results: Seventy four patients were available for at least 1 year followup examinations. Forty-five patients (60.8%) recovered prefracture status. Mean time to bony union was 18.3 ± 8.6 weeks. Intraoperative technical problems related to an unavoidable superior positioning of the lag screw occurred in five cases. Postoperative complications requiring reoperation occurred in three patients; two cases of varus collapse with cut out and one case of periprosthetic fracture.

Conclusions: The IM nail with two integrated lag screws showed favorable outcomes in Asian patients with an intertrochanteric fracture even though several complications that were not previously reported with this nail were found. The proper selection of patients and careful insertion of two lag screws should be mandatory in Asian patients.

Key words: Hip, intertrochanteric fracture, intramedullary nail, proximal femur
MeSH terms: Hip fracture, intertrochanteric fracture, fracture fixation, intramedullary nailing, osteosynthesis fracture

INTRODUCTION
The incidence of intertrochanteric fracture has increased during recent years as life expectancy has also increased.¹,² Population based epidemiologic studies of hip fracture in Asia have reported relatively high incidence and confirmed that the number of hip fractures are likely to increase markedly in the near future.³,⁴ Various types of devices have been developed to reduce surgery time and to allow immediate mobilization because most patients with intertrochanteric fractures are elderly.⁵ Currently, orthopedic surgeons use various fixation methods for intertrochanteric fractures like, intramedullary (IM) nailing or dynamic hip screws and plates. Although no implant fully satisfies all fixation requirements for these fractures, IM nailing remains popular and has been reported to produce good results.⁶,⁷ In particular, an IM nail with two lag screws improves rotational stability and the bony purchase within the femoral head and thus, resists cut out and subsequent fixation failure.⁸ However, this design lost favor due to the Z-effect phenomenon first described by Werner-Tutschku et al.,⁹ and later described by several investigators.¹⁰,¹¹ Nevertheless, an IM nail with two lag screws (InterTAN nail, Smith-Nephew, Memphis, TN) was recently reintroduced. This nail was designed with two integrated lag screws to overcome Z-effect complications, and provides immediate intraoperative linear compression and rotational stability. Furthermore, several reports on this nail have presented
excellent results and no complication, including freedom from the Z-effect phenomenon.\textsuperscript{12,13}

However, to the best of our knowledge, there is no prospective study of this nail in Asian patients. Accordingly, we undertook this study to report our clinical and radiologic outcomes of this type of nail in Asian patients with an intertrochanteric fracture.

**Materials and Methods**

100 consecutively patients with an intertrochanteric fracture treated at four hospitals between December 2010 and November 2011 were enrolled in study. These hospitals treat more than 200 patients of hip fracture per year and four orthopedic surgeons representing these hospitals are specialized in the treatment of hip fractures and related diseases.

The inclusion criteria were an age of >60 years with a community ambulator with or without a cane before surgery. Patients with a pathologic fracture or severe medical comorbidities were excluded. The approval was given by the Institutional Review Board of our institution and informed consent was obtained from all patients who participated in this study. Prior to commencing the study, surgical procedure for the InterTAN nail (a caput-collum-diaphysis (CCD) angle of 130°) and rehabilitation protocols were standardized and discussed with patients.

The patients were placed supine on a fracture table, closed reduction was confirmed by fluoroscopy before draping. The acceptable reduction was when neck-shaft angle was reduced within <5° and fracture site displacement <4 mm as compared to normal side. A guide wire for the nail was placed to the tip of the greater trochanter and the position of the guide pin was checked fluoroscopically in both planes. A 16-mm-diameter double reamer was then inserted to cut a path for the nail and the InterTAN nail was inserted. The guide wire for the large lag screw was targeted to be centrally located in antero posterior (AP) view and centrally or posteriorly located in lateral view, as determined using a C-arm image intensifier. To avoid rotation of the head/neck fragment while drilling and inserting the lag screw, an antirotation blade was inserted into the lower screw hole.

The large lag screw was then advanced to locate its tip as close to the subchondral bone (to a tip-apex distance (TAD) of <20 mm). The distal lag screw (compression screw), which was 5 mm shorter than the proximal lag screw, was then inserted until anatomical alignment was achieved, and the fracture was under compression. Distal static locking screws were then inserted into the nail using the screw guide.

The intraoperative variables evaluated were duration of surgery, the estimated blood loss and number of blood units transfused. Adequacy of fracture reduction was evaluated using the criteria proposed by Fogagnolo et al.,\textsuperscript{14} the position of lag screws were evaluated using TAD\textsuperscript{15} and the cleveland index.\textsuperscript{16} Intraoperative complications including the technical problems were recorded.

All patients were given a single dose of prophylactic antibiotics immediately after surgery and low molecular weight heparin was administered postoperatively until the patients started to ambulate with assistance. After surgery, patients were instructed to stand with assistance with no weight bearing restriction and to use an assistive device (walker, crutches, or cane), as tolerated, on the 3\textsuperscript{rd} postoperative day. As walking ability improved, assistive devices were changed at the discretion of responsible physical therapists. Patients were followed for a minimum 1-year. Clinical and radiological examinations were performed at 6 weeks and 3, 6, 12 months after surgery.

Postoperative clinical outcome was evaluated using the recovery rates to prefraction status at 1-year after surgery. Radiologic outcomes were evaluated using time to bony union. Postoperative complications were recorded. Bony union was defined as evidence of bridging callus or cortical continuity involving at least two cortices in hip AP and lateral views.\textsuperscript{17} Radiological measurements were performed by two orthopedic surgeons who did not perform any operative procedure.

**Statistical analysis**

Reliabilities of agreement for determining radiological measures were assessed using Kappa coefficients for the two reviewers. Kappa coefficients were interpreted as follows: <0.00 = Poor agreement; 0.00–0.20 = Slight agreement; 0.20–0.40 = Fair agreement; 0.40–0.60 = Moderate agreement; 0.60–0.80 = Substantial agreement; and >0.80 = Almost perfect agreement.\textsuperscript{18} The Student’s t-test was used to analyze continuous data. Results were expressed as mean and standard deviation. Statistical significance was accepted for $P < 0.05$.

**Results**

All patients underwent closed reduction for intertrochanteric fracture. There were 35 men and 65 women and mean age at time of fracture was 77.8 years (range 63–92 years). Fracture classifications according to the AO classification were: 12 cases of 31A1, 73 cases in 31A2 and 15 cases in 31A3 fractures. Stable fractures were of 31A1.1 to 2.1, and unstable fractures were considered of 31A2.2 to 3.3.
All patients underwent operative treatment after obtaining medical clearance [Table 1]. Mean operative time (skin incision to wound closure) was 77.7 min (range 20–120 min). Mean operation times were significantly dependent on fracture types \((P = 0.009)\) (48.9 ± 29.0 min for stable fractures and 88.7 ± 30.4 min for unstable fractures). Postoperative radiographs taken after surgery showed that acceptable reduction was achieved in 91% cases [Table 2]. Superior positioning of the lag screws in the femoral head occurred in 11 cases including the unavoidable superior positioning of lag screws in 5 cases [Figure 1]. In these five cases, the lag screw could not be fixed in the desired position due to the narrow width of the femoral neck or varus neck geometry for two integrated lag screws [Figure 2]. The lag screws in the other six cases positioned at the superior area resulted from the technical error with the lack of time for their repositioning because of their comorbidities.

Mean hospital stay was 13.3 days (range 7–18 days) and postoperative complications during the hospitalization occurred in three cases; two hematoma formations and one pseudoaneurysm around the operative sites. Cases of hematoma resolved satisfactorily with conservative care, and the pseudoaneurysm resolved satisfactorily after angiographic intervention [Table 3].

Seventy four patients were available for 1 year followup examination; 10 patients died and 16 were lost to followup within a year after surgery. Forty five patients (60.8%) recovered prefracture status at 1 year followup. During followup, postoperative complications occurred in four patients; two cases of varus collapse with cut-out, one case of periprosthetic fracture and one case of compression lag screw back-out [Figure 3]. The patients with varus collapse and cut-out underwent replacement arthroplasty. The patient with a periprosthetic fracture underwent refixation with a longer IM nail.

Mean time to bony union in 72 patients (excluding the 26 cases of follow up loss and 2 cases of varus collapse with cut out) was 18.3 weeks (range 6–24 weeks). Intra and inter-observer reliabilities for the assessment of radiographic healing were 0.78 and 0.75, respectively, indicating substantial agreements.

**Discussion**

The IM nail with two integrated screws has been recently introduced and has several unique features as compared with other IM nails. The most important feature is that it

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**Table 1: Preoperative clinical details**

| Characteristic                  | Data       |
|--------------------------------|------------|
| Age (years)                    | 77.8±9.1   |
| Sex male (female)              | 35 (65)    |
| Type of fractures (cases)      |            |
| Stable                         | 38         |
| Unstable                       | 62         |
| BMD (t-score)                  |            |
| Hip                            | -2.7±1.0   |
| Spine                          | -2.9±1.4   |
| Admission to operation (days)  |            |
|                               | 2.9±1.3    |

BMD=Bone mineral density, ASA=American society of anesthesiologist

**Table 2: Perioperative data**

| Variable                             | Data       |
|--------------------------------------|------------|
| Duration of surgery (min)            | 77.7±30.9  |
| Estimated blood loss (ml)            | 183.6±98.2 |
| Transfusion (units)                  | 1.2±0.5    |
| Adequacy of fracture reduction (cases) |           |
| Good                                 | 75         |
| Acceptable                           | 16         |
| Poor                                 | 9          |
| TAD (mm)                             | 15.3±3.7   |
| Time to bony union (weeks)           | 18.3±8.6   |

TAD=Tip-apex distance

**Table 3: Complications related with surgery**

| Complication                                      | Cases |
|---------------------------------------------------|-------|
| Intraoperative                                    |       |
| Unavoidable superior position of the lag screw    | 5     |
| Lateral wall fracture                             | 3     |
| Postoperative                                     |       |
| Varus collapse with cut out                       | 2     |
| Periprosthetic fracture                           | 1     |
| Compression lag screw back out                    | 1     |
| Hematoma formation                                | 2     |
| Pseudoaneurysm                                    | 1     |

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**Figure 1:** This figure showing the number of lag screws positioned in each area of the femoral head. In eleven of our cases, lag screws were placed in the superior area.
has two integrated lag screws that also function as a ‘worm gear mechanism’. The two integrated lag screws not only provide rotational stability at fracture sites but also prevent Z-effect complications, which can occur when an IM nail with two separate lag screws is used.\textsuperscript{9-11} In the present study, we did not encounter a Z-effect in any patient; although one case of compression lag screw back out occurred at 2 months after surgery, no related complication was evident at final followup.

The worm gear mechanism of the two integrated lag screws 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.

This nail has a split distal tip that reduces overall cross sectional stiffness of the distal implant. 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.\textsuperscript{19-21} This is more important in Asian patients because they tend to have short statures and femur lengths. Leung \textit{et al}. reported that a short femur and excessive anterior bowing in older Chinese lead to the tip of standard gamma nails (even the shortest nails) passing beyond the most convex portion of the anterior bow.\textsuperscript{22} Ruecker \textit{et al}. encountered no nail impingement or thigh pain problems in patients treated for an intertrochanteric fracture using this nail.\textsuperscript{13} We also had no experience about nail impingement or thigh pain even though one periprosthetic fracture occurred at 1 month post surgery.
after fall from height.

We, however, experienced technical difficulties associated with this nail. In five cases, two integrated lag screws were unavoidably fixed in the superior position during surgery. Kim et al. reported that the cross-sectional area and width of the femoral neck is lower in Koreans than in Caucasian and African-Americans. For this reason, the two integrated lag screws were sometimes fixed in the superior portion of the femoral head in the Asian patients with narrow femoral neck width. Moreover, superior position of the lag screw could be common in Asian patients with varus neck geometry. Superior position of the lag screw in the femoral head is a well known risk factor of varus collapse with cut out requiring reoperation. In the present study, 2 of 11 patients with a superior position of the lag screw resulted in varus collapse with cut out and finally underwent reoperation. In this study, we only used the InterTAN nail with a 130° CCD angle for reasons of availability. Proper modifications of this nail such as a smaller diameter of two integrated lag screws and a <130° CCD angle of the lag screw are necessary for Asian patients with narrow femoral width or varus neck geometry.

Despite using this new type of implant, the efforts of accurate reduction and proper insertion of the lag screw are extremely important to avoid the complications such as lag screw back out and cut out which did not occur in patients with the unavoidable superior fixation of lag screws in this study.

In the present study, mean operation time (77 min) was longer than previously reported. Reucker et al. reported a mean operation time for the InterTAN nail of 41 min, which is similar to that reported by Utrilla et al., a mean operation time of 46 min for the trochanteric gamma nail and of 44 min for the compression hip screw. However, Qin and An reported a mean operation time for the InterTAN nail of 74.5 min and Yaozeng et al. reported a mean operation time for proximal femoral nail antitrotation of 66.6 min and third generation of gamma nail of 73.1 min. Although mean operation times are obviously dependent on fracture complexity, we believe that the technical difficulty associated with narrow width of femoral neck or varus neck geometry in several patients might account for longer operation times.

Nevertheless, we found that clinical and radiologic outcome of this nail in our patients were favorable and similar to those of other nails previously reported considering the recovery to prefracture status, time to bony union and the incidences of complications requiring reoperation [Table 4].

This study had some limitations that warrant consideration. First, the number of patients were too small to allow comprehensive evaluation of the usefulness or the incidences of complications, and thus, we suggest that a large prospective study be undertaken to compare this type of nail with other fixation devices in these respects. Second, this study was performed by several surgeons in different hospitals and thus, different surgical experiences and the different techniques are problematic. However, the four surgeons were trained at one hospital, and lag screw position was checked in all cases.

To conclude the IM nail with two integrated lag screws showed the favorable outcomes in Asian patients with an intertrochanteric fracture even though several complications that were not previously reported with this nail were found in the present study. The proper selection of patients and careful insertion of two integrated lag screws should be mandatory in Asian patients.

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Table 4: Recent reports of intramedullary nailing on the Asian patients with intertrochanteric fractures

| Study          | Fracture type | Implant used           | Recovery rates to prefracture status (%) | Complications requiring reoperation (cases) | Time to bony union (mean) |
|----------------|---------------|------------------------|------------------------------------------|---------------------------------------------|---------------------------|
| Pu et al.      | Unstable      | PFNA                   | 77 (67/87 patients)                       | Shaft fracture (1)                          | No data                   |
| Qin and An     | All type      | InterTAN               | 57 (20/35 patients)                       | None                                        | 2.8 months                |
| Yaozeng et al. | All type      | PFNA or TGN            | 56 (51/91 patients)                       | Shaft fracture (1), poor reduction (1)      | No data                   |
| Zhao et al.    | All type      | TAN                    | 70 (114/174 patients)                     | Shaft fracture (2), screw cut out (1)       | 4.2 months                |
| Our study      | All type      | InterTAN               | 61 (45/74 patients)                       | Shaft fracture (1), screw cut out (2)       | 4.3 months                |

PFNA=Proximal femoral nail antitrotation, TGN=Third generation of gamma nail, TAN=Trochanteric antegrade nail
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