DISTAL UNLOCKED PROXIMAL FEMORAL NAIL - A PROSPECTIVE STUDY AND REVIEW ABOUT ITS FUNCTIONAL OUTCOME AND COMPLICATIONS IN INTERTROCHANTERIC FRACTURES.

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Abstract
Background: Proximal femur nailing has become the treatment of choice in intertrochanteric femur fractures. There are different views regarding the use of distal locking in these fractures. It is said that the distal locking does not only provide rotational and axial stability but also improves the fracture healing; However, reports of implant failure, implant breakage, stress fracture at nail tip or at distal screw insertion site, thigh pain, cortical hypertrophy and difficulty in distal screw insertion are among the possible complications that can be encountered. In our study we investigated the outcome of omitting the distal screw in intertrochanteric fractures.

Materials and Methods: 19 patients with intertrochanteric femur fractures were treated with proximal femoral nail without distal locking. Distal locking was omitted when a tight fit of PFN was felt in the medullary canal by the operating surgeon. The results were evaluated with Modified Harris Hip Score.

Results: 19 patients were followed up clinically and radiologically for 2 years.

Conclusions: Distally unlocked proximal femoral Nail is an effective treatment modality with minimal complications in treatment of only STABLE intertrochanteric fractures.

Keywords: PFN, without distal lock, intertrochanteric fractures

Introduction:
The intertrochanteric fractures continue to pose a major challenge to the orthopaedic surgeons. The incidences of fractures in the trochanteric area is increasing with the increasing numbers of elderly persons with osteoporosis[1,2]. Given the magnitude of this problem, considerable resources have been expended in an attempt to determine the optimal treatment fixation.

One line of modern research is going along the lines of primary arthroplasty in proximal femur fractures.[3] However osteosynthesis is still the preferred option for most surgeons. There are two main types of implants available for the treatment of these fractures, namely extramedullary and intramedullary implants. The intramedullary implants have a huge variety of choices with the earliest being the short gamma nail followed by the trochanteric gamma nail and long gamma nails. The most common of them is proximal femoral nails with two lag screws in neck of femur. Common to all of these intramedullary implants is the distal fixation advised into the femoral shaft. In spite of several advances in nail technology and technique, no fool proof method of facilitating distal locking has been designed.[4,5]

Distal locking screws of the intramedullary nail were designed for preventing longitudinal or rotational instability as well as movement of the nail tip in broadened canal femurs.[6] Various complications have however, also been highlighted for distal locking of intramedullary nails, including loosening, breaking and subsequent peripheral injuries, and secondary femoral fractures. Increased operative time, X-ray exposure and potential stress during drilling should also be taken into account[6,7] if recommended techniques are not followed considerable damage to soft tissues can cause post operative pain[8]. Due to these factors, many researchers have reduced their indications for distal locking in trochanteric fractures or they do not use it at all. It has been postulated that in a distal unlocked fracture construct the stability to an intramedullary nail is provided by the friction of the nail against a tight fitting medullary canal wall, which in turn provides a controlled dynamic stability as against rigid fixation with an interlocking bolt. This in turn allows controlled vertical collapse.

Thus, in this prospective study, we tried to find out drawbacks of omitting distal lock in intertrochanteric fracture fixation and whether this any way influences operative time and post operative morbidity.

Method and Material

Our prospective study involved 19 patients with intertrochanteric fractures presenting to our hospital from May 2017 to May 2020. The average age of patients was 64.88 with 65 percent having unstable and rest having stable fracture configurations (as per Evans classification).
The intertrochanteric fractures considered for study were fresh fractures and included after due consent was taken. The pathological fractures, open fractures, bilateral hip fracture and fracture with neurological involvement are excluded in our study. After the approval of the institute's ethical committee they were treated with PFN done without distal locking. Patients were seen postoperatively at regular intervals of first month, third month, sixth month and then annually. All the patients were evaluated for peroperative parameters like screening time, operating time (in minutes), blood loss during surgery (in millilitres), ease of procedure; possible intraoperative complications like malreduction/failure of reduction, fracture displacement. Blood loss during surgery included blood loss due to fracture and operative losses. Here screening time meant the time during which a particular fracture was screened under image intensifier during surgery. Postoperatively they were assessed for pain, range of movement, rehabilitation malunion, delayed union, general and local complications and any additional revision surgery required. Overall outcome was assessed, categorizing the result as Excellent, Good, Fair and Poor as per Modified Harris Hip score.

Operative Procedure

After proper preanaesthetic evaluation, patient was taken on the traction table under spinal anesthesia. Reduction was achieved after traction and manual manoeuvre under c arm guidance. The tip of the greater trochanter was identified by palpation and a 5-cm incision extended proximally from it. Entry point was made at the medial aspect of tip of greater trochanter. Reaming was done only of the proximal part one size greater than the size of the nail to be inserted. Size of nail was measured under carm and nail is prepared for insertion and fixed with zig. The surgeon determines the feel of nail fitting in the medullary canal. If it was tight fitting enough to withstand moderate rotational stress it is deemed fit for our study and distal locking is omitted. Otherwise it fits the exclusion criteria and surgeon decides to perform distal locking after inserting proximal neck screws.

Quadriceps strengthening exercises were encouraged from the first postoperative day. Non-weight bearing ambulation touch toe using a walker was permitted in self confident patients by the 12th post-operative day. Patients were called for review after a month and assessed clinically for any limb length discrepancy and malalignment of the limb. Radiological assessment was done to verify the position of the implant as a check to compliance with the postoperative ambulation protocol. During the first followup at one month xray pelvis with both hips anteroposterior (AP) view and involved hip lateral was done. Partial weight bearing was initiated after the sixth week. It was gradually progressed to full weight bearing as per tolerance and absence of radiological evidence of collapse. Successive reviews were done at six-week intervals during which rotations in flexion/extension, limb length discrepancy and knee range of motion were assessed. In the event of patient complaining knee pain, X-ray distal femur with knee AP was done.

Results

The mean duration of surgery in our study was 46 minutes. In studies of rohan etal10, ozkan etal11 and xinglietal12 mean duration of surgery for distal unlocked nails were 53.48 and 39.2 minutes respectively. In study of Dousa et al10, rosenbulum et al11, Xing li etal12 mean duration of surgery using locked PFN were 61, 50 and 48.5 minutes respectively. The Average fluoroscopy time in our study was less than 3 minutes of total exposure.

This clearly indicate that the omission of distal lock significantly reduces the operative time and total carm exposure time. Our findings are also in compliance with the recent metaanalysis published comparing locked and unlocked cephalomedullary nail.\(^{(25,26,29,31)}\)

Patients stayed an average of 6 days post op with us when they were given knee physiotherapy and gait training of non weight bearing as and when allowed. After discharge patients were followed up initially at 1 month, 3 months and 6 months interval. 2 patients developed superficial infection at proximal stich site which was relieved by drainage and antibiotic course.

On an average radiological union occurred at 3.4 months but was delayed in patients having inadequate or varus fixation and unstable fractures. In studies of rohan etal, ozkan etal and rosenbulum et al mean duration of union was 3.6, 3.4, 3 months respectively.

2 out of 29 patient had collapse and subsequent pull out of lag screw. No patient had z effect, stress shielding, non union, malunion or implant breakage.

At final follow up, 20.6% patients had mild thigh pain. 6.8% had moderate pain and these were the patients with implant related complications like bursitis or prominent proximal end or malaligned fixation. No patient had significant limb length discrepancy or significantly restricted knee movements.

At final follow up 45.7% patients had slight pain which occurred after strenuous activity. 22.9% patients had mild pain demanding occasional use of analgesics. 17.1% had moderate pain and these were the patients with implant related complications like bursitis or prominent proximal end or malaligned fixation.

17 patients had excellent and good results, 10 patients had fair results and 2 patient had poor result according to harris hip score. Average harris hip score was 84.
The type and degree of instability of fractures were found to influence the outcome. Majority of fair and poor results were seen in unstable fractures. The adequacy of reduction and immediate post fixation alignment had a major bearing on the outcome. Varus fixation took longer to unite, the average being 5.9 months. They also had more implant related complications.

**Table 1:** comparative biomechanical study of distal locked and unlocked proximal femoral nail.

<table>
<thead>
<tr>
<th>No.</th>
<th>PROPERTY</th>
<th>LOCKED NAIL</th>
<th>UNLOCKED NAIL</th>
</tr>
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<tbody>
<tr>
<td>1.</td>
<td>axial compressibility</td>
<td>Rigid construct</td>
<td>Controlled dynamicity</td>
</tr>
<tr>
<td>2.</td>
<td>Proximal femoral strain</td>
<td>present</td>
<td>Equal to locked nail</td>
</tr>
<tr>
<td>3.</td>
<td>rotational stability</td>
<td>superior</td>
<td>inferior</td>
</tr>
<tr>
<td>4.</td>
<td>Stress riser</td>
<td>++</td>
<td>+</td>
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</tbody>
</table>

**Discussion**

Intramedullary nailing continues to be the treatment of choice for stabilisation of the majority of proximal femoral fractures. The results of our study indicate that stable intertrochanteric fractures can be treated successfully with intra-medullary nails without distal locking, reducing patient and clinical personnel radiation exposure and sanitary costs (surgery time and screws costs).

Few high-quality studies and metaanalyses are available to confirm our results. In our study we are also reviewing various biomechanical studies to compare the locked and unlocked nails. (table 1).

In a study, it was found that a locked nail behaves as a more rigid construct whereas in an unlocked nail, there is liberty of friction of nail against the tight fit construct; thereby providing controlled dynamicity at fracture and hence support fracture healing.

Rosenblum et al. used 12 ten cadaveric femurs to evaluate the effect of the gamma-nail on strain distribution in the proximal femur, with or without distal interlocking, before and after experimentally-created two-part and four-part fractures. The insertion of the distal interlocking screw was not associated with change of the proximal femoral strain pattern. This demonstrates that a distal locking screw might not be necessary for stable intertrochanteric fractures. However, Tobert et al. 13 hypothesized that a lack of distal fixation in a long Cephalomedullary nail would allow a longer working length and therefore more stress on the proximal fixation leading to a propensity for cut-out. They did not, however, found a confirmatory data to support their hypothesis.

In studies it was found that distal locking in an intramedullary nail augments the rotational stability of the construct, but Kane et al. found that unlocked distal constructs provide similar torsional stiffness compared with locked fixation in both fresh fracture and a healed, stable intertrochanteric fracture modality. In their study, they concluded that unlocked and dynamically-locked devices were equivalent with regard to catastrophic failure torque magnitude and may be superior in terms of plastic deformation. The authors suggested that locked distal constructs may fatigue and break earlier when subjected to torsional loading in the clinical setting both in stable and unstable fracture patterns, often leading to implant failure and revision surgery. This may imply that an unlocked construct can tolerate a greater degree of rotation before plastic deformity than in locked nails.

Physiological loading of a nail-bone device in an intertrochanteric fracture patient treated with a cephalomedullary nail comprises three forces: torsion, compression of the medial aspect of the nail and tension on the lateral aspect. Distribution of those forces between the bone and the nail is variable, and largely depends on the fracture pattern and the reduction achieved. When there is no cortical contact, as in unstable fracture-implant system both compressive and rotational loads are transmitted distally through the nail to the distal interlocking screw. Which will resist fracture collapse and length loss until their fatigue failure or fracture healing occurs. Hence aids in union. Here distal screw positioning avoids implant telescoping and promotes healing. Stable fractures-implant systems are associated with good cortical contact after adequate surgery, thereby allowing compressive loads to the bone cortex and not to the nail; in these cases, distal interlocking screws seem to be unnecessary. Hence the type of fracture and the precision of reduction are two important factors which decide the usage of distal screw or not. In our study too, the poor overall function is associated with unstable fractures and the fractures with varus reduction.

Besides these biomechanical analysis related to unlocked nail, there are certain other factors which gave rise to a legitimate question about the necessity of this technique.

In most cases the problems with distal locking were caused by incorrect surgical technique. No foolproof method has been devised. Incorrect incision of the fascia may force out the targeting device off the distal locking hole. Lacroix et al. pointed out the damage that may be caused to the lateral cortex byawl. Hesse et al. reported the fracture of the femur in repeated drilling for the distal locking, locking screw inserted outside the nail or excessive tightening of the distal locking screw. Increased stress at distal nail tip has also been reported in locked nails. These stresses may lead to local cortical hypertrophy, thigh pain and fracture around the distal locking screws.

Radford et al. came to the conclusion that distal locking was performed only when indicated for longitudinal or rotational instability. He considered that weakening of the
bone by the presence of locking screws should be avoided wherever possible because the distal part of the nail already provides a concentration of stress at that site. Bellabarba et al. \(^{20}\) did not use distal locking in any of their 90 patients with a fracture of the proximal femur. Shen \(^{21}\) recommended distal locking of cephalomedullary nail only in highly unstable fractures or in broad medullary canal. According to De Lucas et al. \(^{22}\), locking of stable pertrochanteric fractures is not necessary. Utilla et al. \(^{23}\) in their 104 trochanteric fractures treated with Gamma nail distal concluded that routine distal locking is unnecessary for stable trochanteric fractures.

Rosenbaum et al.\(^{11}\), Xing Li et al. \(^{24}\), Lanzetti et al. \(^{30}\) compared two groups of patients treated for pertrochanteric fractures with an intramedullary hip nail with distal locking and not distally locked. Comparison of the two groups of patients did not show any difference in terms of the period of fracture healing, radiological and functional results or frequency of complications but show subtle advantages in reducing blood loss, operative time and fluroscopy as well. Rohan et al.\(^{39}\) also in their study concluded that omission of distal lock does not affect the outcome of fracture. It significantly reduces duration of surgery and related complications.

As we know that the intertrochanteric fractures are common in elderly people with multiple comorbidities. The duration of surgery significantly matters in these cases as it may help to reduce anaesthesia and surgical complications perioperatively and postoperatively. Duration of radiation exposure of c arm has significant impact on health of surgeon and OT staff. Using unlocked nails reduces exposure time to an extent as insertion of distal screw often requires quite a many c arm shots. Our study clearly shows the reduced surgical time and radiation exposure in distally unlocked nail. Hence we advocate the use of distally unlocked nails in intertrochanteric fractures.

In recent metaanalysis \(^{25,26,29,31}\), it was clearly concluded that distal locked intramedullary nail should not be recommended as outline choice in stable intertrochanteric fractures. The use of locked or unlocked intramedullary nailing does not affect long term outcomes regarding complication and functions.

In our study as well the complication and fair to poor harris score was associated with unstable fractures. Hence we advocate the use of distally unlocked proximal femoral nail only in stable intertrochanteric fractures.

There are some researchers who questioned the unlocked nail in stable fractures as well. Rosenbulum et al.\(^{18}\) found that the patient without distal locking had 85.7% greater risk of perimplant fracture. Claudia et al.\(^{27}\) in their study concluded that unlocked femoral nail with the cortical impingement is a configuration to avoid in stable pertrochanteric femur fractures.

Conclusion
Our results suggested that the PFN can be successfully implanted without distal interlocking only in a stable intertrochanteric fracture.

References
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