

# Distal Axial Pin Lock without or with Nail Lock of Femoral Hybrid Intramedullary Nailing (FHIN) for Femoral Shaft and Distal Femoral Fractures - A Novel Technique of Distal Lock

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## Authorship and contribution Declaration:

Each author of this article fulfilled ALL 04 Criteria of Authorship:

1. Conception and design of or acquisition of data or analysis and interpretation of data.
2. Drafting the manuscript or revising it critically for important intellectual content.
3. Final approval of the version for publication.
4. All authors agree to be responsible for all aspects of their research work

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## ABSTRACT

**Objective:** A new technique of distal axial pin lock without or with nail lock for distal locking of femoral hybrid intramedullary nailing (FHIN) was devised for fixation of femoral shaft and distal femoral fractures. It could redress the difficulties of distal locking, hazards of extensive radiation exposure in lateral projection and the susceptibilities of screw/nail bend/break and mediolateral toggling of distal end of nail after conventional locking of femoral locked intramedullary nails (FLINS).

**Methods:** 63 femoral shaft and distal femur fractures, treated by FHIN were prospectively assessed in this study. All FHIN implantations were distally locked with axial pin without or with nail lock depending on level and comminution of fracture. Axially stable femoral shaft fractures (FSFs) were distal locked with axial pin only. Axially unstable FSFs were distal locked with axial pin and oval nail hole. While distal femoral fractures were locked with axial pin and both oval and round nail holes. Postoperative assessment was made for accuracy of distal axial pin locking procedure. Technical distal axial pin lock problems and inability to find the nail slot were also recorded. Patients were followed until the time of solid union of fractures. During follow up X-rays patients were evaluated for complications of distal screw/nail bend /break and toggling of nail.

**Results:** Of a total 63 distal axial pin lock procedures the accuracy of installation was 100% with single attempts and significantly shortened distal axial pin locking time. During follow up complications of distal axial pin/screw/nail bend/break, toggling of distal end of nail, distal migration of the nail, and loss of reduction were not noted. The number of radiation exposures, distal locking time and total operation time was significantly reduced as image intensifier use and its lateral adjustment was not required. The technique was quite easier and straightforward with shorter time period and learning curve.

**Conclusion:** Primary distal axial pin lock without or with nail hole(s)lock of FHIN for treatment of femoral fractures can reduce the incidence of distal screw/nail bend/break and toggling of distal end of nail to the negligible extent. It also looks to be a predictable solution to decrease radiation dosage and its vulnerability during FHIN fixation by avoidance of image intensifier exposure and its lateral adjustment. Thus, reducing the radiation exposure and total surgical time.

**Keywords:** Distal axial pin lock, femoral hybrid intramedullary nailing; femoral shaft and distal femoral fractures.

This article may be cited as:

M. Amin Cheema, Hammad Amin Cheema. "Distal Axial Pin Lock without or with Nail Lock of Femoral Hybrid Intramedullary Nailing (FHIN) for Femoral Shaft and Distal Femoral Fractures - A Novel Technique of Distal Lock." J. Pak. Orthop. Assoc. 2023; Vol 35 (03):152-158.

## INTRODUCTION

Approximately 70% of FSFs are axially stable<sup>1</sup>. Locked intramedullary nailing of femur with distal screw-nail lock (interlock) mode with variable styles alone, is a standard treatment for FSFs, requiring a skilled and difficult accomplishment of the procedure<sup>2</sup>. A lot of painful experience is needed for

both the surgeon and the radiographer to attain distal locking in interlock mode correctly, in the shortest possible time, and with the lowest possible image intensifier exposure to ionizing radiation.

Orthopedic surgeons are very careful and stressful in carrying out distal interlocking of conventional FLINs. Many surgeons have used

distinct targeting devices to bring about distal locking<sup>3</sup>. Novice orthopedic surgeons, at their white-collar stage, are commonly seen complaining of troubles in distal locking of intramedullary nails due to its technical details and interlocking process itself.

Without taking into account the method chosen for targeting, meticulous accomplishment of distal interlocking for FSFs is an essential requisite. The problem of multiple holes drilling with their sequelae of late stress fractures continues to exist because of hardships to target a hidden hole inside the medullary cavity. Involuntary movements during alignment of drill bit with the hole or application of pressure during drilling can cause deviation in the distal locking<sup>4</sup>. Additionally repeated attempts of drilling can cause cortical deficits and even iatrogenic fractures in close proximity. For that reason, to execute distal locking procedures higher correctness is needed. In this specific period of manifestation of obstacles<sup>5</sup>, continuous real-time fluoroscopic exposures expose both the surgeon and the patient to extensive ionizing radiation dosage. Even under fluoroscopic control accurate installation of the distal screws (85%), being not only is a deficiency of FLINs yet to be solved, but also is the most difficult task to accomplish with problems of incorrect positioning, low first favorable outcome rate and long tedious learning curve<sup>6,7</sup>.

The stress of the locking screws is extraordinarily high particularly around the proximal distal screw hole of the nail or at the proximal distal screw, resulting in frequent mechanical failure of screw/nail bend/break<sup>8,9</sup> and mediolateral toggling of distal end of nail. The C-arm dependent free hand technique is considered as the standard for distal locking; but, extensive dosage of ionizing radiation exposure to the surgeon and operating team is a major concern. Thus, making them undesirable and the reason why alternative searches for mode of locking or approaches of conventional interlock are welcome<sup>10,11</sup>.

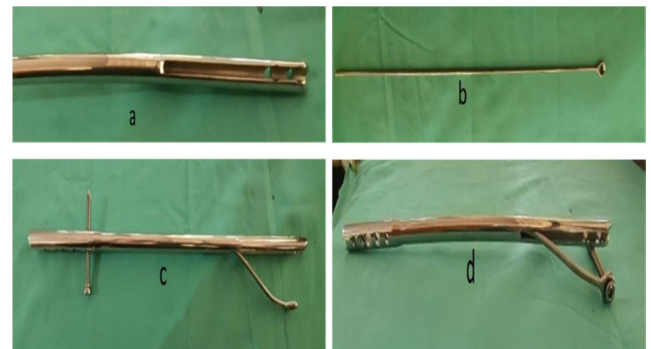
The challenges encountered led us to some innovations to overcome the difficulties and the susceptibilities of distal femoral interlocking of conventional FLINs. We have designed an alternative mode of distal lock using axial pin lock without or with nail interlock with advanced FHIN. The system of axial pin lock itself provides the drill bit position and orientation for locking relative to the nail locking hole.

The objective of this article is to assess the effectiveness and safety of the new technique of free hand distal axial pin lock without or with nail lock

with advanced FHIN in the treatment of femoral shaft and distal femur fractures. Our hypothesis was that distal axial pin lock without or with nail lock with advanced FHIN can reduce: i) per operative complications during the process of distal locking; ii) postoperative complications of distal locking; iii) radiation exposure in distal locking; and iv) overall surgical time.

### Design Features of Distal Axial Pin Lock Construct

The distal axial pin hole lock technique utilizes 1) the cannulation, distal 10cm laterally directed slotted portion of the Pak-made FHIN; 2) a pin with a hole at one end for locking screw insertion, and 3) proximal inlay engagement of pin round end with the slot and cannulation of the nail through a uni-cortical hole and distal on-lay placement of hole end of pin over lateral cortex of bone; 4) locking of axial pin hole with a screw behind and around the distal round nail hole preferably or at distal tip of nail (figure 1).



**Figure 1. shows: a)** slotted distal end of the FHIN with an oval and round nail hole; **b)** a 3.5mm diameter pin with a hole for 6.5 mm screw at one end and rounded other end; **c)** axial pin in nail slot and its cannulation; **d)** distal axial pin lock behind and around the distal round nail hole or at distal tip of nail.

## MATERIALS AND METHODS

Demographic and clinical data From January 2016 to December 2019, 62 patients of both genders with average age of 47.30 years (range, 18 -76 years) were enrolled for this prospective study. 55 femoral shaft and 8 distal femoral fractures, which were treated with the FHIN and distally locked with axial pin hole lock technique without or with one or two screw-nail hole(s) interlock, were screened. One patient was having bilateral femoral shaft fractures. The institutional review board of the Orthopedic and Trauma Surgery Hospital approved the study. All patients gave their informed consent before their inclusion in the study. Radiographic images in

anteroposterior and lateral views of whole femur bone including both hip and knee joints were obtained and inspected by senior author. During preoperative planning comminution of fractures was categorized comminution according to Winquist and Hansen (WH) classification. Patients with no or moderate comminution (WH types I and II) were considered as axially stable fractures and patients with severe comminution (WH types III and IV) were considered as axially unstable fractures.

Of 55 FSFs 39, and 16, were stable and unstable FSFs respectively. The axial pin lock technique of distal lock of the FHINs was performed in all patients. In axially stable or made stable with cerclage wire FSFs only distal axial pin lock technique was used. In unstable FSFs oval nail hole was additional interlocked. While in distal femoral fractures both distal nail holes were additional locked. Free hand distal axial pin without or with nail hole(s) locks were performed by a senior author.

The patients: i) diagnosed with femoral shaft and distal femoral fracture; ii) treated with Pak-made advanced FHIN; iii) evaluated intraoperatively accuracy of distal locking, overall surgical time, and complications; iv) expected higher trueness of distal locking and reduced surgical time; and v) designed prospective randomized, were included in this study. The patients having: i) poly-trauma requiring damage control; ii) accompanied severe soft tissue damage of open fracture; iii) neurovascular injury, were excluded. All patients were followed for at least 2-year.

### **Surgical technique**

Distal locking procedures of axial pin lock without or with nail lock were performed under identical operating conditions to maintain uniformity. Operations were performed closed/open in lateral/semi-lateral position with the fractured leg uppermost and flexed at hip and knee under regional/general anesthesia. We used an advanced Pak-made FHIN and the entry point and the insertion of the nail were same as used in standard intramedullary nailing procedure<sup>7</sup>. This new distal axial pin locking technique was accomplished by using the same nail application set and proximal jig guide and targeting device.

### **Distal Locking**

An appropriate selection of the FHIN length is made and axial pin length is measured between from the proximal interlocking hole of the FHIN to the concavity of the distal tip of the distal end of the nail

depending on type of distal lock. After installation of the FHIN, mounted on proximal jig guide device with target arm, into 1.0 to 1.5mm over-reamed medullary canal to the desired extent a 3 to 5cm longitudinal skin incision at distal end of nail corresponding to the nail holes was made and lateral cortex of bone exposed (fig.2a). A true lateral adjustment of proximal external jig guide device was made. Free hand distal axial pin without or with nail hole(s) locks are performed with target device without image intensifier exposure.

For axially stable FSFs a 4mm uni-cortical drill hole is made 1cm proximal to the distal oval nail hole in the mid of the lateral cortex through target device and is made oblique directed upward(fig.2b). A 2.5mm K-wire is inserted to find the hollow of the nail through its slot as a metallic feel with to and fro movements along the axis of the nail slot. If needed rotational adjustment to find the nail slot can be made through jig guide device. Insert round end of the axial pin of measured length into the nail slot and confirm its proper entry by inserting a guide wire through proximal end of nail with sounding technique. Direct the axial pin obliquely upward and push half of its length into the nail cannulation. Accomplish proximal interlocking of FHIN through 5<sup>th</sup> passageway with 5mm cortical screw. Now further push the axial pin till it hits the proximal interlocking screw or no more would go in. After slightly bending the pin posteriorly lock the axial pin hole with a screw behind and around the distal round nail hole preferably or at distal tip of FHIN. For axially unstable FSFs first interlock distal oval nail hole through target device then accomplishes axial pin lock behind and around the distal round nail hole as described above (fig. 2c).

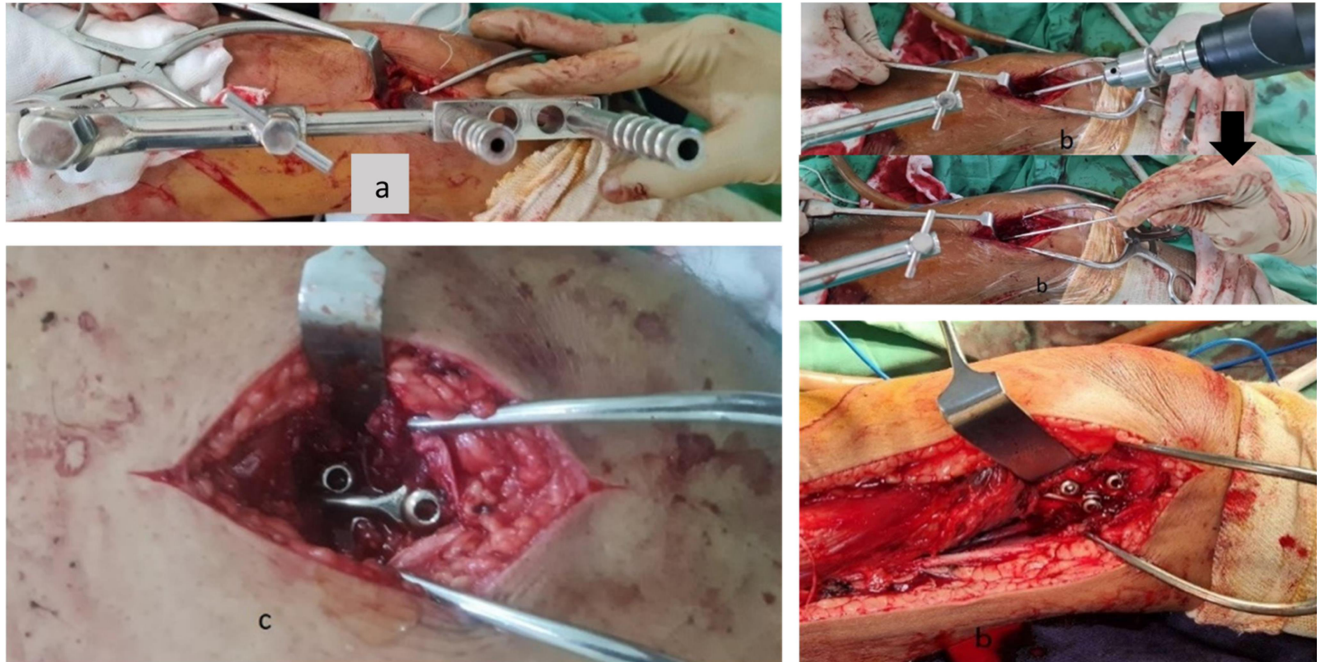
For distal femoral fractures with or without extension into the knee joint, after nail insertion and obtaining adequate limb alignment and if needed holding it with interfragmentary K wires/screws both distal nail holes are interlocked followed by axial pin lock behind and around the round nail hole (fig.2d).

Immediate postop evaluation was done under fluoroscopic exposure only for confirmation of accurate axial pin engagement in the nail slot and cannulation, axial pin hole and nail hole screw lengths depending on axial stability of fracture and screw-screw hole overlap. If head of the screw was covered the distal axial pin /nail hole(s), distal locking was considered as successful. The number of cases in which the correct position of the axial pin in the nail slot and screw placement was not obtained was considered as failure of the procedure. Technical

distal locking problems with the axial pin-nail lock were also recorded.

After operation, Patients were allowed full weight bearing only when there were no clinical signs of nonunion and radiographic union were evident. Patients were followed for about two years or at least until the time of solid union of fractures.

During follow up X-rays evaluation parameters recorded were postoperative complications of loss/loosening of distal fixation, distal screw/nail bend /break and toggling of nail (Wind-Shield Wiper effect), and clinical assessment.



**Figure 2:** shows intraoperative demonstration of: (a)exposed lateral cortex of bone corresponding to distal nail holes and a 4.0mm uni-cortical hole drilled through lateral cortex with target device 1cm proximal to the distal oval nail hole; (b) Uni-cortical hole was made obliquely directed upward and measured length axial pin was inserted until it hits the proximal interlocking screw; (c) construct of distal axial pin screw lock and an additional oval nail hole screw lock for axially unstable FSFs; and (d) constructs of either distal axial pin screw lock and an additional oval nail hole screw lock or distal axial pin screw lock and both oval and round nail holes screw locks for distal femoral fractures.

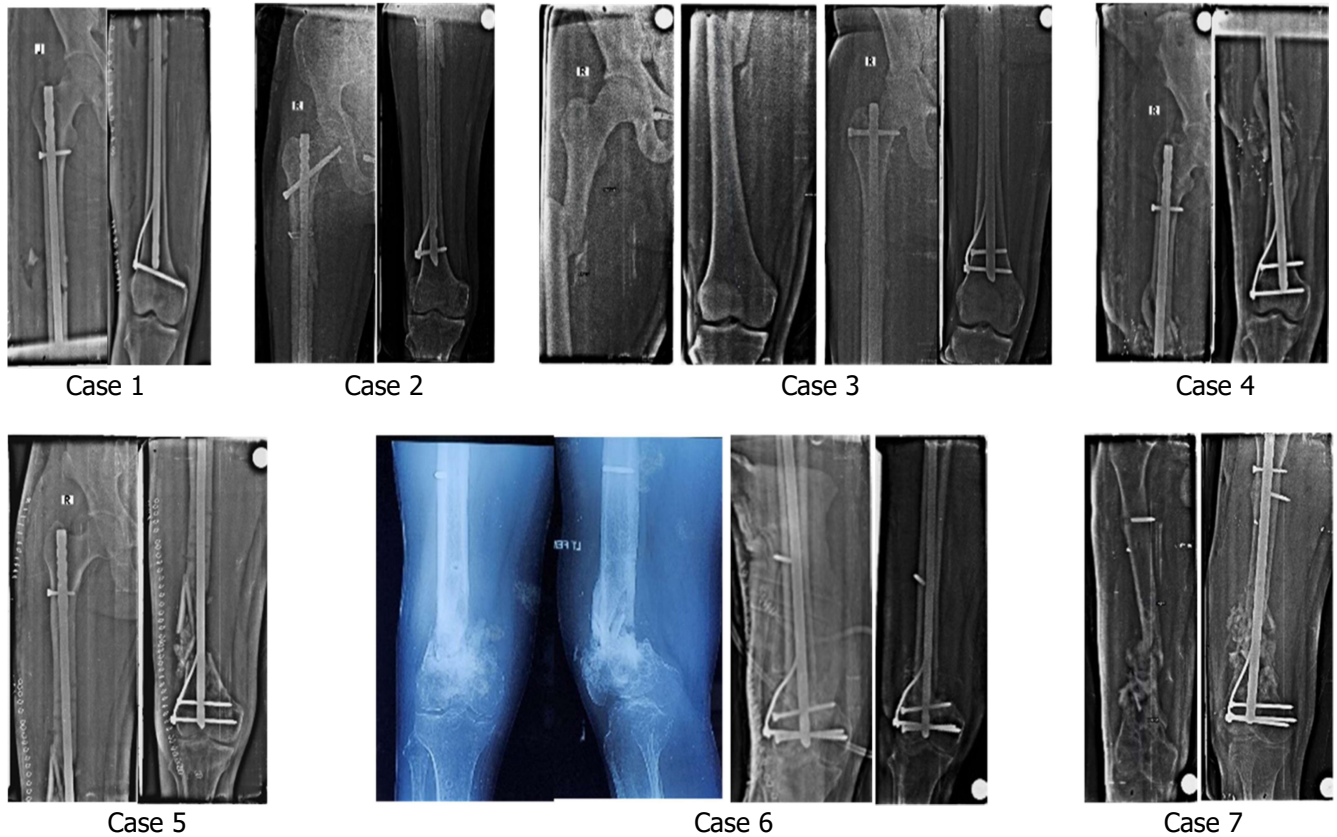
## RESULTS

There were 44 (71%) male patients and 18(29%) females with average age of 47.30 years (ranged, 18 to76 years) who underwent distal locking of FHIN by axial pin hole lock without or with one or two screw-nail hole lock. Of a total 63 femoral shaft and distal femoral fractures 37 axially stable FSFs underwent distal axial pin lock only and 18 axially unstable fractures were additionally screw-nail locked with another screw. 8 distal femoral fractures were additional two screw-nail interlocked. The accuracy of installation of distal axial pin lock without or with screw-nail lock was 100%. There was no case of failure of distal locking in any patient. In no case detecting the axis of distal holes was difficult. There was no new fracture or screw failure obtained during the distal locking in any patient. Distal locking time was significantly shorter with the new technique as in

the presence of distal nail slot finding of distal nail holes was easier. All locks were accomplished with single attempts because the proximal uni-cortical hole for axial pin insertion and inserted pin itself guided for screw alignment to lock screw holes so no widened hole entry was detected. Complications of iatrogenic fractures, distal screw/nail break/bend, toggling of distal end of nail, distal migration of the nail, poor alignment, or loss of fraction reduction, were noted. (fig. 3). Postoperative radiographies, both on first day and in the second year, revealed that all the screws were in the correct position and remained in the correct position. No revision surgery regarding distal lock was needed in any of the cases. The number of radiation exposures, distal locking time and total operation time was significantly reduced as image intensifier exposure and its lateral adjustment was not required and the new technique

of distal axial pin lock without or with nail lock in the presence of nail slot was quite easier and straightforward. Polar screws were not used for

unstable diaphysis and distal meta-diaphysis fractures that were rotational unstable.



**Figure 3:** shows radiographic configurations of clinical applications of distal axial pin lock without or with one or two screw-nail lock of FHIN with preop/immediate postop/healing X-rays: Case 1&2 are images of distal axial pin lock only for axially stable or axially made stable femoral shaft fractures; Case 3&4 shows images of distal axial pin hole lock plus a nail hole lock for axially unstable femoral shaft fractures; and case 5,6&7 demonstrates images of distal axial pin hole lock plus one or both nail hole(s) lock for distal femur fracture depending on instability/intraarticular involvement.

### DISCUSSION

Our results showed that the free hand distal locking by axial pin lock without or with screw-nail lock of advanced FHIN for FSFs and distal femur fractures was quite secure from liability to harm and uncomplicated with reduced duration of distal locking, avoiding C-arm exposures, higher accuracy and reducing the overall surgical time. Postoperatively this would have significantly reduced the incidence of distal screw/nail bend/break and mediolateral toggling of nail to the negligible extent. Moreover, we discovered that our technique avoided the drill misplacement and frequent drilling which is the leading cause of unwanted complications of bone and soft tissues. This clinical study was first of its kind that used the distal axial pin lock without or with nail lock to ease the distal locking of the FHINs.

The function of different intramedullary nails applicable to long bone fractures of the lower extremity is related to their locking mode and the most used locking is screw-nail interlock. The additional locking mode of FHIN we have developed and described in this paper is named the axial pin lock, where proximally the pin is engaged with nail through nail slot and cannulation for rotational and axial stability without or with nail interlock as per need.

Jinn L et al.<sup>12</sup> analyzed stress of angular and rotational deformation on the distal interlocking screw and concluded that the screw stress increased as the length of nail-cortical contact and the distance between the distal interlocking screw and the fracture site decreased. They also found that the stress of the first screw was more than 6 times that of the second screw. In another study Bucholz et

al.<sup>13-15</sup>, in the finite element model found that the stress around the screw hole increases drastically when the distance between the fracture site and the screw hole is shorter than 5 cm accounting for the reports of high incidence of implant failure around the proximal of the two distal locking screws. We eliminated or divided the stress load of proximal of the two distal locking nail holes by using axial pin lock by creating an inverted V-shaped construct to: 1) reduce/eliminate the stress load preventing screw-nail bend/break; and 2) provide better rotational stability and less spring back. Theoretically we can say that about  $\frac{1}{4}$  of the axial/vertical eccentric/concentric loading in coronal and sagittal plane is diffused out by inverted V shaped construct of distal end of nail and pin. The remaining  $\frac{3}{4}$  is equally distributed/shared between axial pin lock and distal locking nail holes. Therefore, with this new technique of locking stress load of screw-nail hole interface is decreased, as a result the incidence of screw/nail bend/break may be significantly decreased to the negligible extent.

Durall et al.<sup>16,17</sup> described that mediolateral instability of interlocked nailing with conventional distal screw-nail interlock alone may cause Wind Shield-wiper effect of toggling of distal end of nail accompanied by clinical signs such as lameness, pain on limb palpation and crackles on physical examination. The presence of axial pin lock and creating an inverted V-shaped construct of pin and nail in distal femur may completely eliminate mediolateral instability and increase the fixation stability eliminating the chance of Wind Shield-wiper effect. Proximally the pin lies in nail cannulation, exits at nail slot and bone cortical hole in oblique diverging manner and locked distally with a screw, this path of the pin has no sagittal toggle laxity decreasing the angular load on any screw-pin/nail hole interlock phase also.

Yong-qing et al.<sup>18</sup> reported that accurate installation of the distal screws is a deficiency of distal interlocking of intramedullary nails yet to be solved. We have not found any deficiency of FHIN distal locking yet to be solved as accurate installation of the distal screws was 100%. With the introduction of axial pin lock in the presence of nail slot and axial pin guidance distal locking may have become easy to accomplish with increased rate of accurate installation of the distal screws.

The free hand technique of distal interlocking under image intensifier lateral projection<sup>19</sup> has a well-known complication of creating multiple cortical holes. In our technique of axial pin lock with FHIN we

have fulfilled the distal locking process with single cortical entries.

The axial pin lock without or with nail lock technique of distal lock with FHIN does not require a learning curve but needs fine motor skills as we have used it and experienced in 63 procedures with successful results. This technique uses simple instruments and is without any need of extensive skill.

As described in the literature, insertion of distal locking screw with standard freehand method takes about 7–15 minutes<sup>20</sup>. This operative and radiation exposure time may be further increased for the novice surgeons. There may be increased incidence of lateral cortical defect leading to reduced stability of interlocking nail and cortex because of repeated positioning, resulting in nail withdrawal and affecting the surgical effect of internal fixation<sup>21</sup>. Compared with the standard image intensifier dependent freehand method, this new technique of free hand distal axial pin lock without or with nail lock with target device and without image intensifier could increase the first success rate, improve the efficiency of the operation and shorten the operative time.

The limitations of our study include: 1) we performed this procedure of distal locking only in 63 fractures, with relatively less external validity requiring larger and high-quality studies to establish the effectiveness of the this technique and to determine the rate of success; 2) A 3 to 5cm distal skin incision is essential with this technique of distal lock; 3) we did not confirm distal axial pin lock without or with nail lock radio graphically in two planes because we typically had a single view. But, based on the intraoperative check with sounding technique and the single postoperative radiograph, we trust that we accurately determined whether locking was achieved.

## CONCLUSION

The free hand axial pin lock without or with nail lock technique with FHIN use is an effective procedure for distal locking in femoral shaft and distal femoral fractures and can prove a novel technique with advantages of easy installation, accurate positioning, and faster. Postoperatively the incidence of screw/nail bend/break may be reduced to the negligible extent. Avoidance of image intensifier use during distal locking procedure may demonstrate reduced overall surgical time and reduced radiation exposure preventing cumulative side effects of radiation for the surgical team. The learning curve

was almost nil and our hypothesis is established. In other words, this method was undemanding to learn.

**Conflict of Interest:** None

**Grants/Funding:** None

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