Journal of Orthopaedics and Clinical Research
Saket R, et al., 2023- J Orth Clin Res
Research Article

Mechanical Aiming Device For Distal Locking in Femur Nail-An Undeveloped Part of Femur Nail System

Rahul Saket[1*], Arun Kumar Naik[1], Pragnya Pramita Mishra[2], Rituraj Pratap[3] and Malay Sahoo[3]

[1]Assistant Professor, Department of Orthopaedic, Hi-Tech Medical College, Rourkela, Orissa, India

[2]Department of Pathology, Hi-Tech Medical College, Rourkela, India

[3]Junior Resident, Department of Orthopaedic, Hi-Tech Medical College, Rourkela, Orissa, India

[*]**Corresponding Author:** Saket R, Assistant Professor, Department of Orthopaedic, Hi-Tech Medical College, Rourkela, Orissa, India.

Received Date: 04-10-2023

Accepted Date: 04-20-2023

Published Date: 04-29-2023

Abstract

Introduction: The success of interlocking nail is due to proximal and distal locking, giving stability to nail. For proximal locking authors have inbuilt aiming system in jig, but distal locking is done free hand. Free hand method is associated with radiation exposure and time taking. In this study authors emphasized the importance of mechanical aiming system for distal locking.

Objective: The study is a comparative study between, distal locking by free hand method and distal locking by proximally mounted mechanical distal aiming device (DAD) with respect to radiation exposure and time taken.

Methods: It was a prospective study conducted over a period of one and a half years. Cases under study were patient with mid-shaft femur fracture (type32a simple). Comparison was done for c-arm shots and time required for distal locking.

Results: A total of 140 patients were assessed. There were 70 patients in free hand group and 52 patients in DAD group. There was dramatic decrease in radiation exposure (free hand group-13.5 c-arm shots, DAD group-2 c-arm shots) and time required (free hand group-22.4 min(mean), DAD group-7.8 min (mean)) for distal locking. There was also decrease in drill bit/nail graze in DAD group.

Conclusion: Distal locking by free hand method is time taking and associated with radiation exposure. There is a learning curve for distal locking in free hand technique. But distal locking by DAD is user friendly just like proximal locking with decrease in locking time and radiation exposure.

Keywords: Distal locking; Femur fracture; Radiation exposure.

Citation: Saket R, Naik AK, Mishra PP, Pratap R, Sahoo M. Mechanical aiming device for Distal Locking in femur nail-an undeveloped part of femur nail system. J Orth Clin Res. 2023;1(2):78-86.
DOI: https://doi.org/10.37191/Mapsci-JOCR-1(2)-010

Abbreviation: DAD-Distal Aiming Device.

Introduction

A major breakthrough in operative orthopedics, has been the introduction of intra-medullary nail for fracture shaft femur. With the first design as K-nail, now a days interlocking nail is in vogue. Interlocking nail has advantage of proximal and distal locking. Distal locking is most commonly done free hand, under c arm guidance. To achieve accurate distal locking in the shortest amount of time and radiation exposure, both the surgeon and the radiographer must have prior experience. Numerous techniques and devices have been proposed in this regard. These include hand-held guides [1-3] image intensifier-based devices [4] and nail-based guides [5,6].

Computer-assisted methods are under research [7,8]. Each technique has its own advantages and disadvantages, but free hand technique is most common used for distal locking [5,9]. However, anyone within range of six feet of the fluoroscopy beam gets exposed to substantial radiation, particularly to thyroid, bones of hands, and other exposed body parts [10]. So, radiation exposure should be minimized [11].

Recently for distal locking, proximally mounted distal aiming devices (DAD) have received greater interest. These devices failed initially, because a simple aiming arm couldn't compensate for the implant deformation, due to insertion-related bending and rotational forces [12].

Recently, DAD with improved design has been developed. It is based on an aiming devise that is readjusted to the deformed nail. It works through a distal working channel [13]. However, the benefits of such a system have not been established. The purpose of this study was to compare prospectively the time required and amount of radiation exposure in distal locking by a radiation-independent distal aiming device (DAD) with those using the free-hand technique.

Material and method

A prospective study was conducted from January 2021 to April 2022 at Hi-tech medical college and hospital after approval of ethical committee. Total 140 patients were under study between age group 20-60 years, having isolated fracture mid shaft femur according to AO classification 32A simple. All patients were first stabilized using trauma protocol and were posted for surgery after PAC clearance.

All patients were randomly assigned into 2 groups of 70 patients each. In group A, distal locking was done using free hand technique. In group B distal locking was done using DAD. Operations were performed under image intensifier, with patient in lateral decubitus with the fractured leg uppermost. Nailing was performed as per the standard procedure [14] except the distal interlocking.

Distal locking in group B: Standard method of nailing [14] was used except for the distal locking. Medullary canal was over reamed by 1.5 mm, to avoid nail deformation during insertion. On OT table the nail system was assembled with DAD (Figure 1a,b) before insertion of nail into femoral canal. With

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trocar and canula authors checked whether the drill bit was transversing the channel for distal screws in femur nail (Figure 1c). Then the DAD was removed from the nailing system. After nail insertion, at time of distal locking, DAD was attached. Authors first performed the lower distal locking then the upper distal locking. Using trocar and canula, entry point was marked (Figure 2). After incision, using trocar and canula, drilling was done. To check whether the drill bit was inside the nail, authors used two methods.

1. Length of guide wire (same guide wire which authors use during reaming and nail insertion) inside the nail before and after entry of drill bit (Figure1b, 1c). If drill bit transverses the channel of distal lock, the effective length of guide wire inside the femur nail decreased.
2. A metallic sound was felt when the guide wire hit the drill bit.

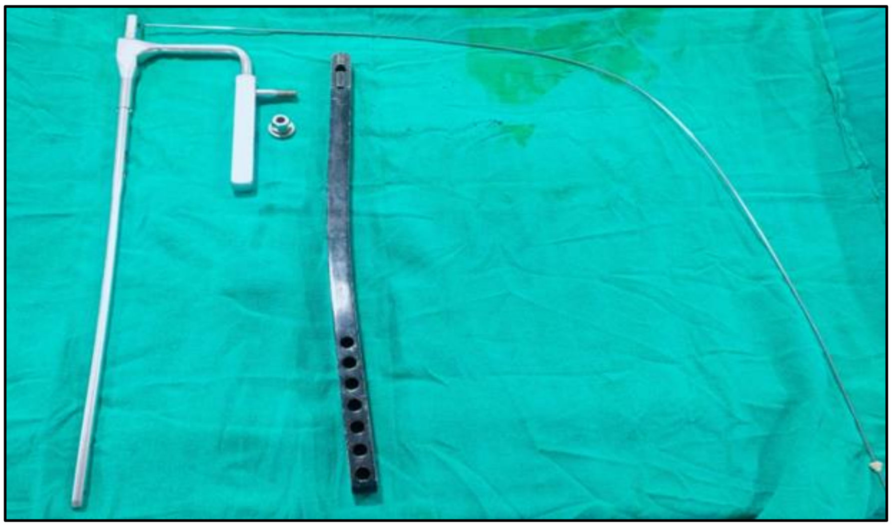

Figure 1a: It shows instrument required for distal locking by DAD.

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Figure 1b: It shows length of guide wire inside the nail when drill bit not in used. Artery clamp is used as marker for length of guide wire inside/outside the nail.

Figure 1c: It shows with drill bit inside the nail the effective length of guide wire inside nail decreased. It is reflected by distant position of artery clamp from nail zig.

Figure 2: DAD in use intra-operative.

Many times, the drill bit used to hit the nail with no more forward movement or was outside the nail. Then authors used to manipulate trocar axially and rationally and check the status.

Even after 3-4 manipulation, if the drill bit was outside the nail or continued to hit the nail, authors abandoned distal locking by DAD and carried out distal locking by free hand method. These patients were excluded from the DAD group during tabulation of data. Proximal locking is performed using a proximal interlocking guide.

Both groups were compared, with regards to distal locking on following parameters:

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1. Total time taken for insertion of distal screw.
2. Number of c-arm shoots required during distal locking.
3. The precision of passing of drill bit through the distal interlocking channel in the nail i.e., drill bit- nail contact. It was felt by surgeon.

Authors categorized it into 2 groups:

1. None or mild graze
2. Significant graze

Statistical analysis

Data were analyzed by chi-square test with Yates' correction and Student's t test. For all tests, the probability of less than 0.05 was considered significant.

Result

There was a total of 140 patients having midshaft fracture (AO/OTA Classification-32A-Simple). Patients were randomly divided into 2 equal groups based on method of distal locking. In group A (free hand technique) there were total 70 patients, 40 male and 30 female with average age 36.5 years. In group B (DAD) there were a total of 52 patients (because of exclusion of 18 failed cases) (Table 1). There were 34 males and 18 female patients, with average age 34.5 years. With regards to age, sex and fracture pattern, there was no statistically significant difference between two groups.

Distal Locking by DAD	Successful cases	Failed cases	Total cases
Lower transverse screw	52(74%)	18(26%)	70
Upper transverse screw	53(75.7%)	17(24.3%)	70

Table-1: It shows success rate of DAD for distal locking both upper and lower distal screw.

There was statistically significant difference, between two groups, in regard to number of c-arm shots taken, for distal locking ($p<0.05$) (Table 2). In DAD group, position of drill bit and screw, inside the nail was confirmed by guide wire. Length of the distal screw was assessed by depth gauge.

So, authors required only 2 c-arm shots (one AP and one lateral view) just to confirm the position and length of the distal screw radiologically. But in free hand method, except for screw length assessment, all steps have to be confirmed under c-arm, thereby increasing c-arm shots required. The average number of images taken to achieve distal locking with the free hand technique in study was in the range (11.5-43.7) as reported in the literature [3,5,15]. There was statistically significant difference in total time required for distal locking ($p<0.05$) (Table 2). In DAD group, in those cases where there was no drill bit -nail graze, average total time for distal locking was 6-8 minutes (average 6.8 minutes). But in those patients where there was drill bit nail graze (Table 3), to minimize

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screw thread wear, authors manipulated the drill bit, thereby increasing the time required. Generally, the extra time required was 2-5 minutes (mean value 3.5 minutes). So, the average time for distal locking was 7.8min.

The average total time required for the free hand method was 20-24 minutes. It was comparable to the total time taken for distal locking, by free hand method, as shown in other studies [16].

Distal locking	Dad	Free hand
Number of c-arm shots (KV-52, MA-02.0)	2	Mean-13.5 SD-12.84
Time taken (min)	Mean=7.8 SD=2.01	Mean=22.48 SD=7.62

Table 2: It shows number of c-arm shots and time required for distal locking in both groups.

Distal locking	No or mild drill bit-nail graze	Appreciable drill bit-nail graze	Total cases
Free hand method	42(60%)	28(40%)	70
DAD	36(69.2%)	16(30.8%)	52

Table 3: It shows drill bit-nail graze in both groups.

There was more drill bit-nail graze in free hand method as compared to DAD (Table 3). Though it was an experience, but authors were not able to quantify this. Till date authors have not carried out implant removal in the study group, so authors are not able to document screw wear.

In the DAD group technique failure was more with lower transverse screw. Authors attributed it, due to design problem of DAD (Table 1). There was clinical union in all case. There was no post operative infection, or implant failure. There was no mortality.

Discussion

Radiation exposure has no threshold value, below which it has no harmful effects [7,17]. Long-term effects of radiation exposure are unknown [18]. So, authors should try to minimize radiation exposure [17]. Authors choose free hand technique for comparison because it is radiation dependent and most commonly used by surgeons for distal locking [9].

As with other radiation independent aiming systems, the device used in this study is newer version of distal interlocking devices. Previously, proximally mounted aiming arms have failed [19] because, insertion-related nail deformation [12] was not considered during devise design. The device used in this study, is designed with nail deformation in consideration.

The data of nail deformation was based on the results of an experimental study which showed that the insertion-related nail

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translations was seen in both medio-lateral and antero-posterior directions, which required the aiming arm to compensate by at least 1.5 cm [20]. To accomplish this necessary fine tuning, the system uses a distal working channel [21].

The average number of images taken to achieve distal locking with the free hand technique in series was within the range (11.5-43.7) as reported in the literature [3,5,15]. But while using DAD only 2 images where required, just to confirm the position of screw in AP and Lateral view. DAD is radio-opaque, so c-arm use was not possible, while using it. To confirm position of drill bit and distal screw, authors used guide wire, which was radiation independent and easy to use. Decrease in radiation exposure during locking is statistically significant ($P<0.05$). Though radiation exposure has been discussed time and again, but main academic books and sites like master's technique [22] and AO method [23] all use radiation dependent method. It is surprising, that though research is being done on improving nail design, with first generation of k-nail, then came piriformis fossa entry interlocking nail and now there is SFN. But no research is being conducted for improvement in DAD design or other radiation free distal locking method.

Time required for distal locking by DAD was less compared to free hand technique($p<0.05$), reason being that DAD was very easy to assemble proximally, for confirming position of drill bit and screw, guide wire was used, so time was saved. In free hand method first additional time and radiation is required to achieve perfect circular image of locking channel in C-arm. Position of k-wire, drill bit and locking screw in locking channel, is confirmed by C-arm. After positioning of k-wire/drill bit or screw into locking channel c-arm has to be taken out of operative field so as to use drill bit and screwdriver. Every time authors require C-arm exposure, during different steps of distal locking, it takes additional time, to bring and position C-arm into operative field.

Learning curve of distal locking by DAD is very easy as compared to free hand technique. In this technique there are basically two steps. To assemble DAD proximally and to use guide wire to confirm position of drill bit and distal screw. Since drilling is done using trocar and canula, the initial steps of free hand technique like skin marking under C-arm and using k-wire/steinman pin for making bony channel is not required. So, this technique is same as proximal locking, except for accuracy. In free hand technique, there is learning curve in achieving correct picture of distal locking hole radiologically and manipulation of k-wire/steinman pin through distal locking hole. DAD used in the procedure can be reused after autoclaving. So, this is a very cost-effective procedure. Cost effectiveness has huge significance in authors country. One of the barriers for use of recent method like image intensifier mounted device has been cost considerations. New instrument was required for every procedure, increasing cost of surgery.

But there are few lacunas in the study. It was not multi-centric. Multi-centric study will give better feedback about surgeon experience, regarding ease of doing distal locking with DAD, learning curve, amount of

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over reaming done and also the success rate of distal locking by this method. This will help in getting more data and improving DAD design. Since this technique has failure rate (27%), so the surgeon should be well versed in free hand technique also. If authors compare with other studies like kretek, et al., [6] The failure rate was more. But their study was cadaveric study. Through the study authors want to emphasize the decrease in distal locking time and radiation required for it, through use of DAD. Author have previously also emphasized that though AO has brought changes in nail design and bolt design, but method of distal locking has remained the same i.e., under C-arm guidance [23]. In view of failure associated with DAD, authors advocate that first DAD should be used, if failed then free hand method should be used. The canal has to be reamed 1.5 mm more than the diameter of the nail, to prevent deformation of the nail. Over-reaming is the key to success of this technique.

Conclusion

From the study authors can conclude that DAD significantly decreases time and radiation exposure. But the design of DAD in present time, is not foolproof. So, the surgeon should also know free hand technique. In authors opinion, distal locking should first be tried by DAD, if not successful then by free hand technique. This study should also be a message for AO and other research body regarding necessity for research into method of easy distal locking. Though nail design has evolved, but even with more understanding of nail bending inside the nail, authors are not able to reap benefit.

Acknowledgement

First, I would like to thank my senior colleague and co-author Dr. AK Naik for his pain staking effort in completion of study. I am highly greatful to Dr Rakesh Panigrahi, trustee Hi-Tech hospital and Mr. Sushant Acharya, CEO Hi –Tech medical college, for giving administrative support. I am also thankful to Mrs. Archana Thakur for proof reading.

Declaration

Conflict of Interest

No.

Funding

Not received.

Ethical approval

Taken from college ethical committee.

Informed consent

Taken from patient.

Competing interest

All authors have declared that no competing interests exist.

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