'Endoscopy assisted distal locking of intramedullary nail’, a new experimental technique to reduce the radiation exposure during the distal locking of the intramedullary nails.

Serkan Davut (serkandavul@gmail.com)
Mustafa Kemal University Faculty of Medicine: Mustafa Kemal Universitesi Tayfur Ata Sokmen Tip Fakultesi
https://orcid.org/0000-0003-3871-786X

Yunus Doğramacı
Mustafa Kemal University Faculty of Medicine: Mustafa Kemal Universitesi Tayfur Ata Sokmen Tip Fakultesi

Research Article

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Abstract

Introduction: The gold standard for treating a lower extremity long bone shaft fracture is closed reduction and internal fixation using the locking intramedullary nailing. The fracture is stable if the nail is locked distally and proximally. Usually all the aiming devices are successful to lock the proximal but not with the distal screws. Distal locking step is the main source for radiation exposure during this type of surgery. In this study we tried to reduce the radiation exposure using an intra-nail endoscopic visualisation and illumination method for distal locking.

Methods: 20 fresh bovine tibia bone were included in this study. Two groups each with 10 samples were prepared. We applied a standard nailing process in both groups, the study group (10 sample) locked by the new technique "Intranail endoscopic illumination and visualisation locking method" and the control group (10 sample) were locked by the free hand fluoroscopic guidance technique. We measured the surgical period time and the radiation exposure time required for distal locking procedure in both groups.

Results: The radiation exposure time was statistically significantly lower in the study group comparing to the control group. Also the time period required for distal locking in the study group were statistically significantly lower than the control group.

With the use of the intranail endoscopic illumination guidance and visualisation assistance technique, the mean period time required for distal locking procedure reduced from 477.5 to 223.5 seconds (p < 0.001). The radiation exposure dramatically reduced from 13.5 to 2 seconds (p < 0.001). The attempt number reduced from 6.5 to 2 times (p < 0.001).

Conclusions: This study showed that using a simple intranail endoscopic visualisation and illumination guidance will make the distal locking step safer by reducing the radiation exposure time and also reduce the surgical period.

Introduction

For the last 50 years the standard treatment for lower extremity long bone shaft fracture is the intramedullar nailing; a stable fixation is achieved by locking the intramedullar nail proximally and distally with screws. When a targeting device is used, the distal locking usually fail due to the deforming forces in the nails [1, 2, 3].

The most common problems are improper insertion of distal locking screws, greater exposure to radiation, long surgery time. On the other hand, all unsuccessful attempts for the distal locking step lead to implantation failure due to increased radiation exposure, soft tissue trauma and bone weakening due to cortical bone injury after redrilling attempts and repeated drill-nail contact problems[4, 5]. So distal locking step becomes the main problem for the intramedullary nailing procedure. Surgeons try to find a safe solution because the free hand distal locking technique has became the most commonly preferred
technic for distal locking using a C arm Xray device. Some modifications or tricks or tools used with the C arm but no one make the team and patient safe from the radiation[6, 7].

To our knowledge, the malignancy risk of the orthopedic surgery team is raised by the ionised radiation. And this risk is thought to be related to the total ionizing radiation received in fluoroscopy used in all surgeries. Barry reported that cancer risk of Orthopedic surgeons is raised 5 times compared with the general population[8]. Singer [9] declare the malignancies as solid organ, skin and hematopoietic cancers and and Chou et al [10] reported that breast cancer prevalence ratio as 2,88 and for all cancer types as 1,9.

Although there are so many methods and devices using worldwide for distal locking to avoid the ionised radiation exposure, only the free hand technic remains the commonly used technique [3, 11, 12, 13, 14, 15, 16, 17].

The aim of the current study was to introduce a new technic which makes the distal locking easier and safer for orthopaedic trauma surgeons who are dealing with long bone fractures.

**Material And Method:**

20 fresh bovine hindlimbs were dissected to obtain tibial bones. The bovine (average age 12–14 months) were all healthy adults and had been killed for selling purposes. All bone specimens has approximately similar dimensions regarding the bone length and canal diameter. The tibial bones were removed from fresh limbs and kept moist in saline solutions during preparations, and testings were performed on the same day. The specimens were randomly placed into two equal groups for intramedullary nailing. We applied a standard tibial intramedullary nail (Manyetix®, İMD Medical Products Ltd., Istanbul, Turkey) and standard intramedullary nailing process in both groups, the study group (n:10) locked by the new technic ‘Intranail endoscopic illumination guidance and intranail visualisation assistance locking technic’ and the control group (n:10 ) were locked by the classical free hand fluoroscopic guidance technic. We applied a standard intramedullary nailing procedure regarding the entry point and the insertion of the nail. However, we modified the distal locking technic in the study groups using the same nail implementation set and the endoscopic illumination guidance and also intranail visualisation assistance. An endoscopic camera for visualisation and a bright, intense light source for illumination made by using a flexible endoscope (ENTity SDXL, Optim LLC, Sturbridge, USA)(Fig. 1).

After intramedullary nail insertion, the endoscope inserted inside the nail and the room light brightness decreased 30 % (Not was necessary but for optimal illumination) to visualize the hole reflection site of the distal locking by the light applied through the tunnel (Fig. 2). The distal locking hole targeted through the illumination which was visible through the cortices (Fig. 3). This inside out illumination technique guidance was fairly enough for exactly targeting the locking point (Fig. 4). The center of the visualized light was our drilling point (Fig. 5). The passing drill visualised endoscopically through the distal hole which make the distal locking more precise (Fig. 6). In addition, the correlation made by observing the
clear light seen outer the bone through the drilling hole (Fig. 7) (Also demostrated in implementation video).

In the study group, the locking step made by the light guidance and confirmed by intranail visualisation. The fluoroscopy is only used at the end of the procedure to authenticate the screw position with the anterior-posterior (Fig. 8) and lateral fluoroscopic views (Fig. 9).

In the control group, fluoroscopic guidance were used throughout the distal locking process.

In both groups we measured the time period required for distal locking (seconds), the radiation exposure time used for the distal locking (seconds) and the attempt number for a succesful locking.

The variable data values analysed with Statistical Package for the Social Sciences (SPSS 13). Mann-Whitney Test used for variable analyze.

**Results**

The application data for each sample is noted in the Table 1.

| Sample | Study Group | | Control Group | |
|--------|-------------|-----------------|-----------------|-----------------|
|        | Distal locking time (sec) | Floroscopy time (sec) | Attempt number | Distal locking time (sec) | Floroscopy time (sec) | Attempt number |
| 1      | 233         | 2               | 2              | 410             | 12              | 6              |
| 2      | 252         | 2               | 2              | 523             | 9               | 5              |
| 3      | 267         | 2               | 2              | 395             | 16              | 8              |
| 4      | 264         | 2               | 2              | 612             | 19              | 9              |
| 5      | 243         | 2               | 2              | 356             | 11              | 6              |
| 6      | 214         | 2               | 2              | 466             | 15              | 7              |
| 7      | 186         | 2               | 2              | 532             | 16              | 8              |
| 8      | 211         | 2               | 2              | 489             | 12              | 6              |
| 9      | 199         | 2               | 2              | 421             | 8               | 4              |
| 10     | 156         | 2               | 2              | 495             | 15              | 7              |
In study group, the mean time for distal interlocking was 222.5 seconds, ranging from 156 to 267 seconds. The mean fluoroscopy time during distal interlocking was 2 seconds to document the locking step by two x-ray images. All samples were targeted and drilled at the first attempt.

In control group, the mean time for distal interlocking was 469.9 seconds, ranging from 356 to 612 seconds. The mean fluoroscopy time during distal interlocking was 13.3 seconds ranging from 8 to 19 seconds. The mean attempt number of distal interlocking (for both holes) was 6.6 ranging from 4 to 9 attempts.

Distal locking period time, fluoroscopy time, and attempt number were statistically significantly reduced in study group compared to control group (P < 0.001) (Table 2).

| Grup            | N   | Distal locking duration (sec) (Mean-Max-Min) | Radiation Duration (sec) (Mean-Max-Min) | Attempt number (Mean-Max мин) | P value |
|-----------------|-----|---------------------------------------------|----------------------------------------|------------------------------|---------|
| Study Group     | 10  | 222.5 (156–267)                              | 2 (2–2)                                | 2 (2–2)                      | < 0.001*|
| Control group   | 10  | 469.9 (356–612)                              | 13.3 (8–19)                            | 6.6 (4–9)                    | < 0.001*|

* Statistically significant

**Discussion**

This study showed that using endoscopic visualisation and illumination will make the distal locking safer and easier via reducing the distal locking period time and the fluoroscopy time required to insert distal interlocking screws. Furthermore, we found that our technique reduces the drill misplacement rate and frequent drilling rates which is the main cause of unnecessary bone and soft tissue complications.

To our knowledge this is the first experimental study which use the endoscopy to facilitate the distal locking of the nails. It has been proven that the free hand technique decreased the distal locking time and the radiation exposure time, as compared with the aiming devices which may end with multiple misdrilling attempts. Kirousis et al [18] reported 25 cases results treated with free hand technique and they declared that the mean fluoroscopy time was 71 s (19 to 141 s) and the mean operation time was 101 min (48–240 min) and they declare that the primary surgeon is at higher risk and the operation team must take care for radiation dose optimisation. Veen et al [19] reported 30 cases treated with a distal aiming device in which 16 of the cases needed fluoroscopy. And they declare that the use of an aiming device for distal locking of a tibia nail lengthens operation time rather than reducing. Differently Gugala et al [20] reported in their study that a distally based distal targeting device can significantly decrease (60% of reduction by using device) the mean fluoroscopy time necessary to complete distal interlocking versus free-hand technique but the surgery time and distal locking time were same.
In our study we found that the intramedullary illumination and intranail visualisation technic has both reduced the distal locking time and the fluoroscopy time into 53.2% and 85.2% subsequently compared with free hand technic.

In different studies reports, the personal experience of the surgeon with the free-hand technique would affect the radiation exposure dose and the surgery time [14, 20, 21, 22, 23, 24]. In the current study, we found that a short learning curve was required to successfully locking the holes using the new technique.

In light assisted illumination guidance and intranail visualisation assistance method, the bone cortex can be protected from unnecessary misdrilling complications by reducing the number of drilling attempts. Anastopoulos et al [25] reported 63 patients treated with a distal targeting device with failure in two cases and also medial cortex penetration in other three cases. Our study had shown that the distal locking procedure with illumination and visualisation technic reduced misplacement screw rates and make the distal locking step easier. We had no failure of distal locking attempt with the illumination device.

A limitation of this study is the use of bovine tibial bones instead of human bones or cadeveric specimens. But we had no choice because our university is newly established and in the development stage. We don’t have enough cadaver at our laboratory. Also the bovine bone may differ in structural quality from those of the human; they are more thick and they have thicker bone cortex than human’s. This was an advantage and we thought that the light guidance seen out of the bone will be much more accurate if used with the human specimens or invivo tests. Over all, bovine bones are cheap and available, also they used in previous experimental studies and in the reports the authors declared that bovine bones had the same structural quality with the human bones [26, 27]. Another limitation is that we designed an experimentel process without creating a fracture so the effect of fracture was not taken into consideration. Furthermore, these tests should be supported by in vivo studies. Currently, a recent study is going on in our clinic regarding the invivo application of the illumination assisted and visualisation assistance distal locking.

In conclusion, this experimental study showed that the endoscopic illumination and intranail visualisation technic can reduce the radiation exposure time and the period requied for distal locking compared with free hand fluoroscopic guidance.

**Declarations**

**COMPLIANCE WITH ETHICAL STANDARDS**

**Conflict of Interest:**

The authors declare that they have no conflict of interest.

**Ethical approval:**
This article does not contain any studies with human participants or animals performed by any of the authors.

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**Competing Interests:**

The authors have no relevant financial or non-financial interests to disclose.

**Authors Contributions:**

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by all authors. The first draft of the manuscript was written by all authors, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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