Distal Locking of Femoral Nails: Evaluation of a New Radiation-Independent Targeting System

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Objectives: The purpose of this study was to assess the effectiveness of a novel radiation-independent aiming device for distal locking of intramedullary nails in a human cadaver model.

Methods: A new targeting system was used in 25 intact human cadaver femora for the distal locking procedure after insertion of an intramedullary nail. The number of successful screw placements and the time needed for this locking procedure were recorded. The accuracy of the aiming process was evaluated by computed tomography.

Results: The duration of the distal locking process was 8.0 ± 1.8 minutes (mean ± SD; range, 4–11 minutes). None of the screw placements required fluoroscopic guidance. Computed tomography revealed high accuracy of the locking process. The incidence angle (α) of the locking screws through the distal locking holes of the nail was 86.8° ± 5.0° (mean ± SD; range, 80°–96°). Targeting failed in 1 static locking screw because of a material defect in the drilling sleeve.

Conclusions: This cadaver study indicated that an aiming arm–based targeting device is highly reliable and accurate. The promising results suggest that it will help to decrease radiation exposure compared with the traditional “free-hand technique.”

Key Words: femur, intramedullary nailing, locking screws, targeting device, nail deformation

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INTRODUCTION

Reamed intramedullary nailing has become the standard treatment of diaphyseal fractures of long bones.1,2 Proximal and distal interlocking is recommended to prevent secondary skeletal shortening or malrotation.3 The former is readily undertaken by means of a proximally mounted targeting device, but this technique fails for distal locking because the guiding arm cannot counterbalance insertion-induced nail deformation.4,5

Numerous innovative techniques and devices have been proposed to simplify distal locking.6–17 Each has its own limitations, and as a result, the fluoroscopy-dependent “free-hand technique” remains the most popular method.11,12,18,19 However, radiation exposure to the patient and operating room staff remains of concern.20–22

We developed a radiation-independent targeting device based on a mathematical model and a biomechanical analysis. This system consists of a proximally mounted aiming arm that compensates insertion-induced nail deformation by means of a magnetic sighting mechanism.

Our intent in undertaking the present study was to evaluate the efficacy and accuracy of this novel radiation-free targeting device for distal locking of femoral nails in a human cadaver model. Furthermore, the duration of this interlocking process was determined.

MATERIALS AND METHODS

All investigations were carried out on 25 intact lower extremities of 12 female and 12 male fresh human cadavers according to ethical guidelines and recommendations for working with cadaver material.23 In one cadaver, the procedure was undertaken bilaterally. The mean age at the time of death was 81 years (range, 69–94 years). Information such as identity and medical history was not disclosed.

The implants used were commercially available 12-mm cannulated, closed-section femoral nails (Sirus intramedullary nail; Zimmer, Warsaw, IN). Long nails were chosen (length, 400 mm) to produce large implant deformations. The interlocking screws measured 5.5 mm in thread diameter; the size of the drill bit was 5.0 mm. All interventions were undertaken by the same surgeon (Y.A.), who was familiar with the targeting device mentioned below. To assess the accuracy of the locking procedure, computed tomography scans on a CT LightSpeed 8 unit (GE Healthcare, Milwaukee, WI) with the following parameters were carried out: collimation, 1.25 mm; slice width, 1.25 mm; and reconstruction increment, 1.0 mm. Review of primary 2-dimensional images and 3-dimensional reconstructions were performed on an Advantage Workstation 4.3 (GE Healthcare). Descriptive analyses were carried out.
with a commercial statistical package (Analyse It for Microsoft Excel; Microsoft, Redmond, WA).

Description of the New Targeting Device

The targeting system consisted of 3 major components (Fig. 1). The first component was a guide wire (the so-called “magic stick”) equipped with a magnetic emitter on its distal part. Before nail insertion, the magnetic emitter was calibrated to the distal dynamic locking hole of the nail. The second component was a length-adjustable, stable aiming arm, which can be applied to any commercial nail system. This aiming arm defined the rotation and level of the static and dynamic distal locking hole. However, accurate adjustment to insertion-induced nail deformation in the sagittal and coronal plane was achieved by means of the third component of the targeting system: a magnetic sighting mechanism (Fig. 2). This consisted of a targeting sleeve for the dynamic locking hole and a coordinated drilling sleeve for the static locking hole. The targeting sleeve housed a needle with a magnetic emitter on its distal part, which aligned in a nearly frictionless manner, to the magnetic field produced by the magic stick (Fig. 2). An articulation between the sighting mechanism and the aiming arm allowed accurate adjustment to the locking holes of the nail, which was indicated by a perfect alignment of magnetized needle to the center of the cross lines (Fig. 3).

Surgical Procedure

The entire cadaver was placed on a radiolucent table. Nail introduction was done according to the manufacturer’s guidelines (Sirius Intramedullary Femur Nail System, Surgical Technique). The correct entry point at the greater trochanter was determined with the assistance of an image intensifier. After opening of the medullary canal, a guide wire was introduced and all femurs were progressively reamed up to 14 mm. Before nail insertion, the aiming device and magic stick were adjusted to the length of the selected nail. The targeting and drilling sleeves were positioned so that the drill bit passed smoothly through the distal locking holes (Fig. 4). A 12-mm closed-section femoral nail was then manually introduced over the guide wire and advanced to the most distal position allowed by the anatomy of the femur. After verification of the position of the nail in 2 planes using the image intensifier, distal locking was carried out according to the following steps: (1) removal of the guide wire; (2) introduction of the magic stick adjusted to the dynamic locking hole; (3) assembly of the calibrated aiming arm to the nail handle and insertion of the targeting sleeve; (4) preliminary targeting of the locking holes (this step was performed to choose the correct location for the skin incision and consisted in the same procedure as for the definitive targeting, with the only difference that the sighting sleeve was not in bone contact) (Figs. 2, 3, and 5); (5) small incision in the skin at the tip of the targeting and drilling sleeves and cross-incision of the fascia lata; (6) advancement of the targeting and

FIGURE 1. Overview of the targeting device mounted on a nail handle. (1) Special guide wire (“magic stick”) distally equipped with a magnetic emitter (arrow) and proximally with a plug (asterisk), which allowed length adjustment until the magnetic emitter precisely fitted to the dynamic locking hole. (2) Length-adjustable aiming arm; (3) magnetic sighting mechanism, which allowed the fine-tuning for the targeting process.

FIGURE 2. Close-up view of the sighting mechanism: (1) drilling sleeve for the static locking hole, (2) targeting sleeve, in which a magnetized needle (3) freely aligns to the magnet field, produced by the magic stick. In this particular case, insertion-induced nail deformation mainly occurred in the sagittal plane. The articulation between the sighting mechanism and the aiming arm is now adjusted (4) till the magnetized needle (3) perfectly aligns to the center of the targeting sleeve’s cross lines.

FIGURE 3. The magnetized needle (1) is now perfectly centered in the cross lines of the targeting sleeve. The articulation is locked (2), which transforms the sighting mechanism and the aiming arm to a stable unit for drilling.
drilling sleeves until good contact with bone was achieved; (7) definitive targeting, which was done by fine adaptation of the articulation between the aiming arm and the sighting mechanism until the magnetized needle of the targeting sleeve was perfectly aligned to the center of the cross lines, and after this fine adaptation, the articulation was locked, which transformed the targeting device to a stable unit for drilling (Fig. 5); (8) drilling of the static locking hole, and the drill bit was left in place after passage of the second femoral cortex, transforming the guiding arm and the intramedullary nail to a stable targeting frame (Fig. 6); (9) removal of the magic stick and the targeting sleeve and introduction of the drilling sleeve for dynamic locking; (10) drilling, measuring, and dynamic looking; (11) removal of the drill bit from the static locking hole followed by the introduction of an appropriate static locking screw; and (12) radiologic verification of the correct position of the static and dynamic distal interlocking screw.

Documentation

The following parameters were documented: (1) distal interlocking time, counted from the introduction of the magic stick to the static locking (steps 2 to 11 of the surgical procedure described above), (2) number of successfully placed static and dynamic interlocking screws, and (3) the accuracy of the aiming process. The latter was evaluated by means of a computed tomography scan on which the incidence angle \( \alpha \) of the locking screws through the locking holes of the nail was measured in 2 planes (Fig. 7). High accuracy was defined with an incidence angle of 90° ± 10°.
RESULTS

The duration of the distal locking process was 8.0 ± 1.8 minutes (mean ± SD; range, 4–11 minutes). All procedures were carried out without an image intensifier. Radiation exposure was used only after the locking process to confirm correct placement of the screws. Analyses of the computed tomography scans revealed a high accuracy of the locking process with an incidence angle α of the locking screws through the distal locking holes of the nail of 86.8° ± 5.0° (mean ± SD; range, 80°–96°). Apart from 1 failure (2.0%) with the placement of a static locking screw, there were no complications observed.

DISCUSSION

During the last decades, intramedullary nailing has become the standard treatment of diaphyseal fractures of long bones.1,2,24 The techniques of distal and proximal interlocked nailing widely expanded its indication, making comminuted fractures and fractures of the metaphyseal zone also amenable to this kind of treatment.25–31 Despite improvements in instrumentation, surgical techniques, and nail design, radiation exposure to patients and operating room staff remains a concern. In a prospective study of 65 orthopedic procedures undertaken with fluoroscopic assistance, Sanders et al21 showed that intramedullary nailing significantly involved more fluoroscopic time than did other types of procedures. The greatest level of radiation was recorded during intramedullary femoral nailing that involved distal interlocking. In an attempt to reduce this radiation burden, several innovative targeting devices have been proposed. Of these, the readily applicable nail-mounted aiming arms (already successfully used for proximal locking) garnered the greatest interest.12,33 Unfortunately, most of them failed because these simple targeting arms do not compensate for insertion-induced nail deformation.4,5

Using a mathematical model and a biomechanical analysis, we previously demonstrated a quite large targeting range for the passage of a drill bit through the distal locking hole of a given nail. Based on a proximally mounted guiding arm, only relatively small adjustments are needed to allow successful distal interlocking. Krettek et al24 described an aiming arm–based system using an asymmetric anterior spacer to implement this “fine-tuning.” However, this spacer was introduced through an additional anterior 6-mm drill hole, making the procedure more invasive. Furthermore, such a drill hole could act as a stress raiser and potentially function as future source of fracture. The novel radiation-independent targeting device evaluated in the present study aligns the targeting sleeves to the distal locking holes by means of a magnetic emitter. The system showed high efficacy. Of 50 locking procedures undertaken, the percentage of successful procedures was 98%. Only 1 static locking screw was misplaced right at the beginning of the study because of a material defect in the prototype of the guiding device. After this event, the material was changed and the drilling sleeve for static locking was more rigidly linked to the targeting sleeve for the dynamic locking hole. After these adjustments, no further failure of locking occurred.

The accuracy of the aiming process was excellent, with an almost perpendicular incidence angle α of the locking screws (86.8° ± 5.0°) (Figs. 7, 8). Other authors have demonstrated high levels of radiation during distal interlocking with fluoroscopic guidance,21,35,36 but our system is radiation free. With a mean time of 8 minutes, the locking process was quickly completed, and was in the range of 7 minutes that Krettek et al24 used for distal interlocking in a similar cadaver study applying their radiation-free mechanical aiming device. The targeting device can be linked to any unslotted, cannulated nail system and does not need an external power supply. It could thus be used by any surgeon in any hospital. However, in the presented version, it is only designed for standard locking procedures and does not allow oblique interlocks.

The present study had several limitations. First, all locking procedures were undertaken by an experienced surgeon (Y.A.) already familiar with the aiming device. Less experienced surgeons may need a learning curve before achieving the same promising results. Furthermore, even if we feel that the procedure is relatively simple, we do not know if the device is sufficiently easy to handle for other surgeons. Second, the investigation was carried out on cadavers using intact human femora. Currently, we cannot predict how the system will work under in vivo conditions, in which electronic instruments (for instance those of the anesthesiologist) could interfere with the magnetic aiming process. These questions will be addressed with a prospective clinical investigation.
CONCLUSIONS

This cadaver study indicated that our aiming arm–based targeting system is highly reliable and accurate. The magnetic sighting mechanism allows adjustments to insertion-induced nail deformation without the use of an image intensifier. Its application requires a certain level of familiarity with the targeting device and a structured surgical technique. Once mastered, we strongly believe that it will not only help to decrease radiation exposure but also simplify the distal locking process compared with the traditional free-hand technique.

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REFERENCES