

Magnetic Equipped Wire Device-for Closed Interlocking Intramedullary Femoral Nailing: A Method That Avoids Exposure to Ionizing Radiations

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Background: Intramedullary nailing is probably the best procedure for treating the long bone fractures in the lower limb. Such operation is guided by fluoroscopy for the guide-wire insertion like fracture reduction and distal locking. Radiation exposure during interlocked nailing continues a matter of challenge.

Objectives: The aim of this experimental study was to design and test the new aiming device for closed intramedullary nailing and to reduce the radiation exposure and the operation time during the procedure.

Materials and Methods: A stainless steel femoral intramedullary guide wire equipped with a small magnet on its end was designed; and also an exchange tube that would enter into the bone canal upon the guide wire to maintain the alignment. Besides these mentioned parts, we applied the standard classic interamedullary nailing set. Pin guide was inserted in the femoral intramedullary canal from periformis fossa. Another equipped magnetic guide wire was inserted from distal portal which was created in the lateral epicondyle. Two opposite magnetic poles supposed to find each other in the fracture site. After replacing the guide-wire with guide wire; the alignment would be checked by a C-arm. The study has been designed in 4 phases including moulage phase, animal phase on young cows, and a human cadaveric phase. The last step of the study is under design and it consists of a randomized controlled clinical trial on the elective patients.

Results: Outcomes of applying the new system on 15 fiberglass artificial femurs and 20 bovine femurs as well as 10 human cadaveric femurs were successful.

Conclusions: We found the magnetic field assistant device to be an accurate, radiation-independent jig for close passing of guide wire after close reduction of femoral fracture. It can reduce the need for radiation during placement of guide wire for closed intramedullary nailing of the long bones. More studies are required to improve and evaluate the technique and equipment.

Keywords: Intramedullary Nailing; Bone Fracture; Radiation; Magnet; Magnetic

1. Background

Fractures involving the shaft of long bones are common worldwide. Femur is the largest, longest and the strongest bone in the human skeleton. Fractures of the shaft of the femur could be the result of high energy or low energy trauma; about one of three patients' fractures is caused by multiple injuries (1). The methods used to achieve skeletal stabilization could be various considerably, depending on the configuration of the fracture line and the geographical location of the surgeons' practices (2). Interests for minimally invasive surgery have led to increased number of procedures being done percutaneously (3, 4). Closed intramedullary nailing is guided by fluoroscopy for guide-wire insertion, closed reduction, and distal locking. Radiation exposure during closed intramedullary nailing is a challenging concern for surgeon and operating room personnel (5-8). Mehlman and Dipasquale (9) proved that operating room personnel within 24 inches from the fluoroscopy beam (like free-

hand technique for interlocking screw insertion by a radiolucent drill) received significant amounts of radiation exposure, especially to the insecure eyes, neck, and hands (10). Muller et al. (10) measured the radiation exposure to the hands of the surgeon during 41 procedures of intramedullary nailing of femoral and tibial fractures. Surgeons and their assistant wore ring dosimeters on their dominant index fingers. The average fluoroscopy exposure time was 4.6 min per procedure. Besides the average dose of radiation to the dominant hand of the primary surgeon was 1.27 and 1.19 mSv to the first assistant (10). The maximum permissible dose (MPD) for the whole body, head, neck, trunk, eyes, bone marrow and gonads, that was recommended by the International Commission on Radiological Protection (ICRP) is 50 mSv per year. Besides the MPD for the extremities, hands and feet is 500 mSv per year. A lead apron provides adequate protection for the trunk and gonads of the surgeon, while the hands

are exposed to scatter radiation (11, 12). The hypothesis for the current study was that this magnet equipped guide wire can reduce the need for x-ray exposure for closed intramedullary nailing. This device allows simple and accurate insertion of reduction guide-wire with minimum radiation exposure to the patients and the surgeons. It also decreased the operation time.

2. Objectives

The aim of this experiment was to design and evaluate the new tool to eliminate the radiation exposure and reduce the operation time during the procedure.

3. Materials and Methods

The present descriptive study was approved by the research committee of our institute. We have designed a magnetic-assistant device that included the following set;

1) A stainless style guide-wire with 3 mm diameter, and 1.5 mm length. It could be equipped at the end with different magnets in size and type, which was selected according to the patients' bone canal size.

2) A plastic or metal exchange tube that would enter into the bone canal upon the guide wire to maintain the alignment. By inserting a guide pin into the bone canal, reaming of the distal and proximal parts would be continued as a standard classic procedure.

3) Besides these mentioned parts, we applied the standard classic interamedullary nailing set.

3.1. Study Design

This study was designed in four phases. First, a moulage phase on 15 fiberglass synthetic bones. At the second step, we used 20 young cows' femoral bone, which were fractured in the mid-shaft. For the next part of this study, 10 human cadavers were considered with femoral bones mid-shaft fracture. A pin guide which was equipped with a 3*3mm powerful magnet at the tip was inserted in the femoral intramedullary canal from periformis fossa. Another portal was created in the lateral epicondyle of femur and the second equipped magnetic guide wire was inserted from this distal portal. Two opposite magnetic poles supposed to find each other in the fracture site with a small range of manipulation (Figure 1 a and b).

A standard exchange tube is used to magnetic guide wire, and the guide-wire replaced with guide pine for its reaming and then a magnetic equipped wire is removed. The alignment would be checked by a C-arm traditional method. This surgical set was registered in Iranian patent registry. The human phase of this study is under review and it consists of a randomized controlled clinical trial on the patients with mid-shaft femoral fractures after approval of Ethic Committee in Human Researches of our institution, Mashhad University of Medical Sciences.

4. Results

The results of applying the new system on 15 fiberglass



Figure 1. Two Opposite Magnetic Poles Are Finding Each Other on the Moulage Bone

artificial femurs and 20 bovine femurs as well as 10 human cadaveric femurs were presented successfully. The first phase was in moulage. It really helped as a theory to practice for the next steps. In the second phase, we administered the device in 20 cows with closed femoral bone fractures and we had little problem to find both ends of magnet equipped wire device. But the most difficult phase was in bovine bones in which reaming the big bones was really hard. Finding the alignment was a little difficult in cadaveric bones, because tissue stiffness manipulation required for magnets to fine each other was not as simple as live tissues. In this step, we operated 10 fractured cadaveric femoral bones with our magnetic set successfully. Instillation of C-arm was limited to final check in this group. On the other hand, operation of the 10 cadavers under the guide of fluoroscopy led to just 10 shots of C-Arm. No deviation from expected results was seen. We could create and maintain the alignment of fractured bones without applying the ionizing radiation.

5. Discussion

The exclusion of an image intensifier eliminates automatically the harmful effect of an increased dose of radiation for both the surgery team and the patient (2, 4-20).

It does not cost the patient a lot, and also it ensures high-quality fracture care comparable to any developed countries (2). Intramedullary nail insertion can be performed with minimal fluoroscopic control for fracture reduction and intramedullary reaming. Proximal interlocking screw placement can also be reliably performed by using a proximal targeting device and minimal fluoroscopy (13, 14, 21). However, one of the most difficult chores in intramedullary nailing insertion is closed passing of the guide wire for reduction at the fracture ends, especially when some days have left from the fracture, in the shortest time, and the least possible exposure to radiation. A variety of aiming tools that would limit the need of fluoroscopy for the correct insertion of the distal interlocking screws have been proposed. Anastopoulos and colleagues expressed that radiation exposure during distal locking was 36 seconds (19.08 minutes of surgical time for distal locking and 81 seconds of total fluoroscopy time) for the freehand technique contrast of 15 seconds (17.06 minutes of surgical time during distal locking and 69 seconds of total fluoroscopy time) for the Orthofix® targeting device (three distal screws) (20). Levin et al. (17) reported 2.7 minutes of fluoroscopy time that was ranged between 0.6-6.6 minutes with 12 mrem mean of radiation exposure for distal locking of tibial nails. Recent studies have reported that the mean fluoroscopy time was 3.44 minutes in Sanders et al. (19), and 137 ± 111 mGy and 5.7 ± 3.5 minutes of radiation exposure for tibial fracture nailing in Tsalafoutas et al. (22). Anastopoulos et al. required two exposures of 0.85 seconds that was ranged from 0.4 to 1.2 seconds and 1.4 mGy was ranged from 0.8 to 1.9 mGy for all cases (20). Orthofix® has developed a distal targeting device which compensates for the inevitable deformation of the nail in the sagittal plane during insertion for restriction the usage of fluoroscopy during distal interlocking screw placement. Babis et al. (23) has reported the usage of Orthofix® distal targeting device on 230 distal locking during 8 years study. They were not succeeded in inserting the distal locking screws at the first attempt without using the image intensifier 12 (5.2%) cases. They concluded that failure might be attributed to two reasons; first they are not adequate experienced in the initial learning curve period (24) and second there was not proper handling for the distal targeting device (23). Radiation exposure for classic intramedullary nailing of the femur and tibia is decreased due to the innovation of different targeting device for distal locking and continues experience of new orthopedic trauma surgeons. Our novel magnet equipped wire device system during reduction and guide wire passage is planned to make closed intramedullary reduction and nailing without exposure to X-ray. Regarding the different difficulties, our novel designed device could successfully perform all the nailing steps independent of an image intensifier in addition to reducing the expenses for the patients. We found the Magnet Equipped Wire Devices an accurate, radiation-

independent jig. With this new method of interlocking intramedullary nail, passing the wire and reduction of the fracture by the magnetic wire device, the need for radiation could be eliminated or decreased. These primary results should stimulate the further clinical application of this device.

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Authors' Contributions

Study concept and design: Farzadfar, Ebrahimzadeh, Birjandinejad and Ashraf; analysis and interpretation of data: Farzadfar, Taraz Jamshidi, and Ebrahimzadeh; drafting of the manuscript: Birjandinejad, Farzadfar, and Ebrahimzadeh; critical revision of the manuscript for important intellectual content: Ebrahimzadeh, Ashraf, Birjandinejad and Taraz Jamshidi. The authors declare that they have no conflict of interest. All the authors have checked and approved the last version of the manuscript.

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