Fluoroscopy-Based Surgical Navigation versus Fluoroscopic Guidance to Control Guide Wire Insertion for Osteosynthesis of Femoral Neck Fractures

An Experimental Study

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Abstract

Background and Purpose: Long fluoroscopic times and related radiation exposure are a universal concern when C-arm fluoroscopy is used to guide percutaneous procedures. Fluoroscopy-based surgical navigation has been proposed as an alternative guidance method requiring limited fluoroscopic times to achieve precision. The purpose of this experimental study was to compare fluoroscopy-based surgical navigation with C-arm fluoroscopy for guidance with respect to the precision achieved, the fluoroscopic time, and the resources needed.

Material and Methods: 114 guide wires were placed in 38 synthetic bone models using either C-arm fluoroscopy (group A) or fluoroscopy-based surgical navigation (group B) for guidance. Precision of guide wire placement was rated on the basis of an individual CT scan on all fracture models of both groups. The fluoroscopic time, the procedure time, and the number of attempts required to place the guide wires were documented as well.

Results: An average fluoroscopic time of 26 s was needed with C-arm fluoroscopy to place three guide wires compared with an average fluoroscopic time of 2 s that was needed when fluoroscopy-based surgical navigation was used for guidance ($p < 0.0001$). Precision of guide wire placement and procedure times required to place the guide wires did not differ significantly between both groups. The number of attempts required for correct placement was found significantly reduced with fluoroscopy-based surgical navigation when compared with fluoroscopic guidance ($p = 0.04$).

Conclusion: Fluoroscopic times to achieve precision are reduced with fluoroscopy-based surgical navigation compared with C-arm fluoroscopy. The impact of this new technique on minimally invasive, percutaneous procedures has to be evaluated in controlled prospective clinical studies.

Key Words
Fluoroscopy · Surgery, computer-assisted · Fracture fixation · Femoral neck fracture · Fluoroscopy-based surgical navigation

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Introduction

Percutaneous screw fixation is increasingly discussed as a less invasive therapeutic option to treat femoral neck fractures [1, 2]. Correct screw position seems to be essential in order to address biomechanical issues [3–5]. This includes correct alignment of the screws with the femoral neck axis as well as parallel alignment of the screws [6].

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C-arm fluoroscopy is the standard technique used to guide percutaneous procedures [7–9]. C-arm fluoroscopy provides two-dimensional projections. Depending on the surgeon's experience, minutes of life fluoroscopy are needed to enable exact implant positioning. Long fluoroscopic times are responsible for significant radiation exposure to both the surgeon and the patient. It is the commonly held opinion that radiation exposure should be kept as low as reasonably achievable, because the long-term effects of exposure to low-level radiation are still largely unknown [8–12].

Furthermore, the need to rotate the fluoroscope in order to visualize different planes makes C-arm fluoroscopy a burdensome tool that prolongs operation times.

In an effort to resolve problems related to intraoperative fluoroscopic guidance, fluoroscopy-based surgical navigation has been proposed as an alternative method for intraoperative guidance [13]. Fluoroscopy-based surgical navigation provides continuous, multiplanar image guidance based on stored intraoperative fluoroscopic images. Use of stored intraoperative fluoroscopic views for visualization saves fluoroscopic time and therefore limits radiation exposure to the patient and to the surgical team. When fluoroscopy-based surgical navigation is used for guidance, the C-arm fluoroscope can be removed from the patient after successful image acquisition. This means the C-arm fluoroscope does no longer hinder the surgeon's free access to the patient.

The purpose of this experimental study was to compare fluoroscopy-based surgical navigation with C-arm fluoroscopy for control of guide wire placement with respect to the precision achieved, the fluoroscopic time, and the resources needed.

Material and Methods

Experimental Setup

The experimental setup (Figure 1) simulated a situation described for percutaneous screw fixation of femoral neck fractures [14]. The plastic femur models were held with clamps and rigidly fixed to a radiolucent operating table. The femur was covered with a sheet to obscure the anatomy for the surgeon and to prevent the surgeon from using macroscopic anatomic landmarks for orientation. Three guide wires were placed in each bone model using one of the two guidance methods alternatively.

The guide wires were placed within the synthetic bone models according to a defined pattern (Figures 2a to 2f) [14]: the femoral neck was imagined as being divided into four equal sectors, with the aim being to place one guide wire in the lower anterior sector of the femoral neck's cross section, and the second guide wire in the lower posterior sector. The third guide wire was placed in the center of the upper two sectors of the femoral neck's cross section. The guide wires were placed parallel to each other and parallel to the femoral neck's central axis. There should be a distance of at least 5 mm between the guide wire and the bone model's surface in order to prevent the femoral neck's surface from perforation if a cannulated screw, 7.3 mm in diameter, were inserted. There should be a distance of at least 10 mm between two guide wires in order to prevent two screws from direct contact.

Cannulated screws were not inserted into the bone models in order to reduce the metallic artifacts within the CT scans of the models that were acquired to evaluate precision of guide wire placement.

Three surgeons performed 38 experiments. Each of these 38 experiments included placement of three guide wires within a femoral bone model. In 19 experiments all guide wires were placed with fluoroscopic guidance (group A), and in another 19 experiments three guide wires were placed with surgical navigation for guidance (group B).

Surgeon 1 performed one experiment with fluoroscopic guidance and immediately afterwards a second experiment with surgical navigation for guidance. Subsequently, this procedure was repeated by surgeon 2, then by surgeon 3, and then again by surgeon 1. This design was chosen in order to have the same increase in skill with both methods and with all three surgeons.

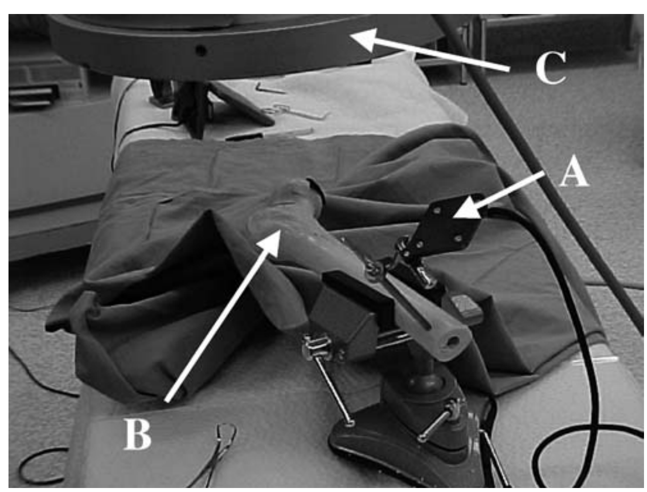
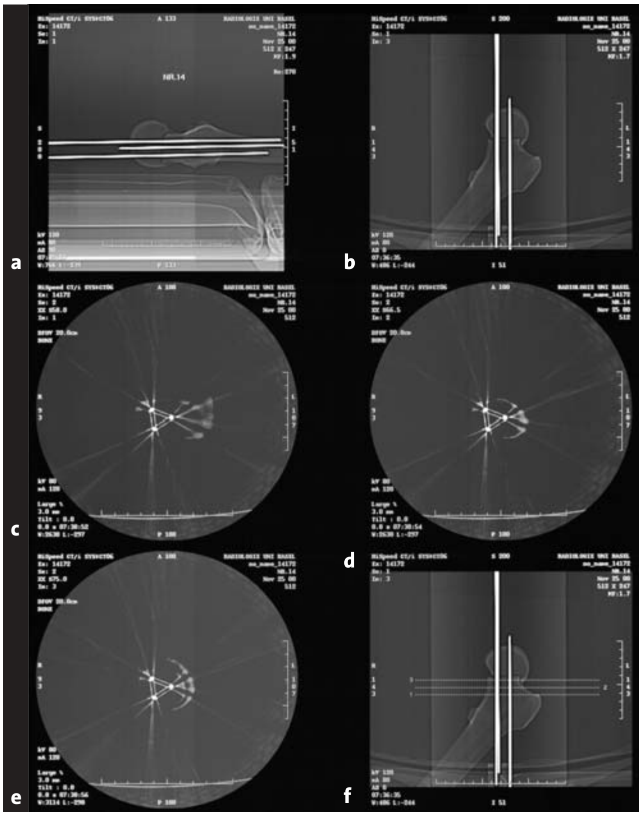


Figure 1. Experimental setup for navigated guide wire insertion. The position reference unit (A) is fixed to the synthetic bone model (B). The C-arm fluoroscope (C) is positioned for anterior-posterior projection.



Figures 2a to 2f. Accuracy evaluation of guide wire placement by means of a CT scan. Guide wire alignment is evaluated by an axial (a) and anterior-posterior (b) scout view of the specimen. Guide wire position is evaluated with cross sections through the femoral neck (c to e) at positions indicated in the anterior-posterior scout view by numbers 1–3 (f). Distances to each guide wire and to the bone model's surface are measured.

Surgical Technique

Intraoperative Guidance with the C-Arm Fluoroscope. A standard C-arm fluoroscope (Philips BV 29™, Philips Medical Systems, Best, The Netherlands) was used for fluoroscopic guidance. The entry point of the guide wire into the bone model and correct alignment of the guide wire during insertion were controlled with fluoroscopy, using alternating anterior-posterior or axial views of the bone model.

Multiplanar Image Guidance Using Fluoroscopy-based Surgical Navigation. Fluoroscopy-based surgical navigation describes a technique for surgical navigation that is based on intraoperative fluoroscopic images [13]. Stored fluoroscopic images are used for continuous visualization of the spatial relationship between the fractured bones and surgical tools.

A system for fluoroscopy-based surgical navigation consists of computation equipment, a C-arm fluoroscope adapted for use with a surgical navigation system, and equipment for optoelectronic position detection called tracking. We used the SurgiGATE™ surgical navigation system (Medivision, Oberdorf, Switzerland) for intraoperative guidance. All computation processes ran on a SUN ULTRA 1™ workstation (Sun Microsystems, Inc., Santa Clara, CA, USA). A standard Philips BV 29™ C-arm fluoroscope (Philips Medical Systems) was prepared for use with the navigation system by attaching a position reference unit to the image intensifier component of the C-arm fluoroscope. Position reference units are equipped with infrared light-emitting diodes (LEDs). The SurgiGATE™ system employs an infrared camera (Optotrack 3020™, Northern Digital, Waterloo, Ontario, Canada) to track the position of these LEDs. In the setup for navigated guide wire insertion, the compact air drive, the C-arm fluoroscope, and the fractured bone are equipped with position reference units to enable spatial position definition by the system's tracking unit.

Navigated insertion of guide wires into the femoral neck fracture model was performed in two steps.

- Step 1: image acquisition. The image data are acquired after fixation of the position reference unit to the synthetic bone model (Figure 1). Standard anterior-posterior and axial fluoroscopic shots of the proximal femoral bone are taken with the calibrated C-arm fluoroscope and downloaded to the workstation. The positions of the referenced C-arm fluoroscope and of the position reference unit attached to the bone model are tracked. The image and position data are transferred to the navigation system. The C-arm fluoroscope is removed from the model, and the computer screen of the navigation system is brought into sight.
- Step 2: insertion of the guide wires with continuous guidance by fluoroscopy-based surgical navigation. The positions of the referenced compact air drive and of the position reference unit that is attached to the bone model are tracked. A graphic display of the guide wire is then overlaid on the stored image of the synthetic bone model in real time. The guide wire is moved along the surface of the bone model until its projection on the computer screen is correct in the anterior-posterior and the axial view. When the guide wire's axis has been aligned with the axis of the femoral neck and with the axis of the other guide wires that had been previously inserted, the guide wire is driven into the bone model.

114 guide wires (Kirschner wire, diameter 2.0 mm, length 150 mm, stainless steel, STRATEC, Oberdorf,

Switzerland) were placed in 38 synthetic femur models (femur proximal, fracture type AO B3.1, SYNBONE AG, Malans, Switzerland). 57 guide wires were placed in 19 bone models using fluoroscopic guidance (group A), and 57 guide wires were placed in 19 bone models with fluoroscopy-based surgical navigation for guidance (group B).

Measurements

Fluoroscopic Times and Procedure Times. Fluoroscopic time and procedure time in group A involved all steps beginning with positioning of the C-arm fluoroscope ending with fluoroscopic verification of correct guide wire position. Procedure time and fluoroscopic time in group B involved all steps beginning with fixation of the position reference unit to the bone model ending with fluoroscopic verification of correct guide wire position.

Precision. After the experimental series had been completed, each fracture model was inspected visually for guide wire perforation. Precision evaluation also included acquisition of a CT scan of each fracture model. Axial cross sections, anterior-posterior scout views, and axial scout views allowed estimation of the guide wire position and of guide wire alignment within the femoral neck (Figures 2a to 2f).

Quantitative evaluation of guide wire position was performed by a radiologist who was blinded with respect to the method used for guidance. A maximum of twelve rating points could be achieved per bone model when three guide wires had been correctly placed. Precision of guide wire placement was assessed within four categories with a maximum of three rating points per category.

Evaluation of the guide wire's position within a femoral neck's cross section was performed by means of axial CT cross sections. There were three rating points when all distances were found correct, and three rating points when the position of all guide wires within the femoral neck's sectors was found correct. Each misplacement detected reduced the rating within the category by one point. No rating point was achieved in a category when more than three errors were detected.

Evaluation of the guide wire's alignment with the femoral neck's central axis and alignment with the other guide wires was assessed by means of anterior-posterior and axial scout views. There were three rating points when the alignment of all guide wires within the anterior-posterior scout view was found correct and another three rating points when the alignment of all guide wires within the axial scout view was found to be correct. A nonparallel situation was considered if two guide wires or a guide wire and the femoral neck's longitudinal axis formed an angle $> 3°$.

Power Analysis

The sample size required was calculated by means of a power analysis. The parameter the study was aiming at is the fluoroscopic time. In order to detect a treatment difference at a two-sided 5% significance level with a power of 80%, a total of 18 experiments were required in each treatment group. For this calculation, the true difference between the fluoroscopic times in group A and group B was estimated to be 1.5 times the standard deviation in group A. We decided to include 19 bone models in each treatment group in case we would have been forced to exclude one experiment from statistical evaluation.

Statistical Analysis

Paired t-test procedures for unequal variances were applied to exclude differences for the parameters "fluoroscopy time" and "procedure time" amongst the three surgeons obtained with the same guidance method. Paired t-test procedures were then used to assess differences between the two guidance methods with respect to fluoroscopic time and to procedure time. Mantel-Haenszel χ^2-tests were used to assess differences between the two guidance methods with respect to precision measurements. Statistical analysis was performed with the Statistical Analysis Software (SAS® version 8.E for Windows, The SAS Institute, Heidelberg, Germany). For all tests, $p < 0.05$ was considered significant.

Results

Differences in the parameters "fluoroscopy time" and "procedure time" amongst the surgeons obtained with the same guidance method were found not significant. Thus, application of a nonstratified analysis for these parameters is justified.

Fluoroscopic Time

The fluoroscopic time needed to place three guide wires was significantly reduced with fluoroscopy-based surgical navigation (26 ± 9.8 s with fluoroscopic guidance vs. 2 ± 3.5 s with fluoroscopy-based surgical navigation; $p < 0.0001$). The 95% confidence interval for the fluoroscopic time was 21.2–30.6 s in group A and 0.2–3.6 s in group B.

Precision

Visual inspection of the synthetic bone models did not show perforation of the model's surface by the guide wire in any synthetic bone model.

Precision of guide wire placement with fluoroscopic guidance did not differ significantly from the navigated group (Table 1).

With fluoroscopic guidance, 39 and 16 guide wires were correctly placed in the first and second attempt, respectively. Two guide wires could finally be correctly placed with the third attempt. With fluoroscopy-based surgical navigation, 54 guide wires were correctly placed in the first attempt, and a second attempt was needed with three guide wires. The difference between group A and group B in the number of attempts needed to achieve correct guide wire placement was significant (two-sided, continuity-adjusted χ^2-test; $p = 0.04$).

Procedure Time

The time needed to insert three guide wires with fluoroscopic guidance (14.3 ± 4.9 min) did not differ significantly from the navigated group (15.4 ± 3.7 min; $p = 0.249$). The 95% confidence interval for the procedure time was 11.9–16.6 min in group A and 13.6–17.1 min in group B.

Problems with the technical equipment were encountered with four fracture models. Intraoperative fluoroscopic images could not be transferred to the navigation system due to a user error in two experiments. Dislocation of the position reference unit after image acquisition had been performed was observed by the authors in two experiments.

Table 1. Results of precision evaluation of guide wire placement. The precision categories evaluated were guide wire position within the femoral neck's cross section, the guide wire's distance to the bone surface and to the other guide wires, the alignment of the guide wires with respect to other guide wires and with respect to the femoral neck's axis in the anteroposterior and the axial view.

Precision category	Guidance method	Rating points	Statistical significance level (p)
Position	Fluoroscopic	43	0.4240
	Navigated	40	
Distance	Fluoroscopic	50	0.0879
	Navigated	41	
Alignment anterior-posterior	Fluoroscopic	41	0.1879
	Navigated	47	
Alignment axial	Fluoroscopic	46	0.4521
	Navigated	49	

Discussion

Radiation exposure to the surgical team as well as to the patient during orthopedic procedures is a universal concern when C-arm fluoroscopy is used for guidance. The radiation risks to surgical personnel and measures that can be taken to prevent excessive exposures have been explored [7, 10]. Several studies have evaluated the radiation exposure to orthopedic surgeons [8, 9, 11], operating room staff [7], and patients [10].

Fluoroscopic times required to achieve precision were significantly reduced when using fluoroscopy-based surgical navigation for guidance. The reduction of fluoroscopic times documented in this experimental study might have essential impact on the radiation dose to the patient if the technique were applied in clinical routine, as the proximal femoral region is close to radiosensitive organs [10].

Fluoroscopy-based surgical navigation was evaluated for the guidance of distal locking of intramedullary implants. A significant reduction of the fluoroscopic times was also reported when fluoroscopy-based surgical navigation was compared with fluoroscopic guidance for this application [15]. However, the impact of this reduction on the patient's radiation dose might be limited, as the distal locking procedure is performed at large distance from the patient's radiosensitive organs.

The surgeon's radiation dose is reduced in both situations, as fluoroscopy-based surgical navigation allows him to keep any distance from the fluoroscope during image acquisition [7].

Hinsche et al. [16] reported inaccuracies when using the 2.8-mm guide wires for sacroiliac screw placement in an experimental setup. Bending of the guide wire was held responsible for the inaccuracies observed. Simulation of the guide wire's position and axis within stored fluoroscopic shots was based on the referenced compact air drive's central axis instead of the guide wire's longitudinal axis. This problem has been addressed in the meantime by the manufacturer: for percutaneous applications of surgical navigation with guide wires, a drill guide may now be equipped with a position reference unit instead of the compact air drive. The guide wire's actual longitudinal axis is then simulated within the stored fluoroscopic images.

The decrease in attempts needed for correct guide wire placement due to fluoroscopy-based surgical navigation speaks in favor of the new technique. The impact of this finding results from the difficulty to define a new pathway in osteoporotic bone when a guide wire had been previously inserted and was found displaced.

Increased procedure times were reported when fluoroscopy-based surgical navigation was applied to guide distal locking of intramedullary implants [15]. The system's capability to provide multiplanar on-line guidance could not be used with this clinical model.

Instead, this feature was found useful when the authors applied the technique for guide wire placement in the femoral neck, because position and alignment of the guide wire need to be checked in two projections.

The procedure times reported from the experimental study will not resemble the procedure times of a future clinical trial, as the experimental and the clinical setup are very different. However, the numbers reported allow a rough comparison of the procedure times needed when one of these techniques is applied for guidance.

Limitations of our study: there was a potential for user bias, as the surgeon could not be blinded with respect to the method used for intraoperative guidance.

As the authors did not place screws over the guide wires, the risk for perforation of the cortical bone surface of the fracture model might have been underestimated.

Conclusion

The major advantage of fluoroscopy-based surgical navigation for guidance is a significant reduction of the fluoroscopic time needed to achieve precision. Furthermore, the new technique makes intraoperative guidance easier, as it provides multiplanar guidance without the need to rotate the fluoroscope. The impact of this new technique on minimally invasive, percutaneous procedures has to be evaluated in controlled prospective clinical studies.

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