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Computer-assisted navigation for intramedullary nail fixation of intertrochanteric femur fractures: A randomized, controlled trial☆

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ABSTRACT

Introduction: Lag screw cutout is one of the most commonly reported complications following intramedullary nail fixation of intertrochanteric femur fractures. However, its occurrence can be minimized by a well-positioned implant, with a short Tip-to-Apex Distance (TAD). Computer-assisted navigation systems provide surgeons with the ability to track screw placement in real-time. This could allow for improved lag screw placement and potentially reduce radiation exposure to the patient and surgeon.

Methods: Between Oct 2014 and Jan 2016, patients with intertrochanteric femur fractures being treated with intramedullary nail fixation by one of three fellowship-trained orthopaedic traumatologists were enrolled. Inclusion criteria were low-energy mechanism of injury and fracture class 31-A1/A2. Open fractures and patients with multiple injuries to the lower extremity were excluded. Patients were randomly assigned to computer-assisted navigation or a conventional fluoroscopic technique for lag screw placement. The primary outcomes were TAD, measured by postoperative anteroposterior and lateral x-rays by an independent reviewer, and radiation exposure measured in seconds of fluoroscopy time. Surgical time was also recorded.

Results: 50 patients were randomized, 26 to the computer-assisted navigation group and 24 to the control group. The mean manually-measured TAD in the computer-assisted navigation group was 14.1 mm ± 3.2 and in the control group was 14.9 mm ± 3.0 ($p = 0.394$). There was no difference between groups in total radiation time (navigation: 58.8 s ± 23.6, control: 56.5 s ± 28.5, $p = 0.337$) or radiation time during lag screw placement (navigation: 19.4 s ± 8.8, control: 18.8 s ± 8.0, $p = 0.522$). The surgical time was significantly longer in the computer-assisted navigation group with a mean surgical time of 45.8 min ± 9.8 compared to 38.4 min ± 9.3 in the control group ($p = 0.009$).

Conclusions: Computer-assisted navigation consistently produced excellent TADs, however it was not significantly better than conventional methods when done by fellowship-trained orthopaedic traumatologists. Surgeons with a lower volume trauma practice could potentially benefit from computer-assisted navigation to obtain better TAD.

Introduction

Intertrochanteric (IT) femur fractures are considered a surgical injury with few cases that are appropriately treated non-operatively (medically unfit for surgery, non-ambulatory patient with minimal pain) [1]. The use of intramedullary nails for fixation of IT femur fractures has become a well-accepted and increasingly more common procedure among orthopaedic traumatologists [2]. Lag screw cutout is one of the most common postoperative mechanical complications with rates up to 15% being reported in the literature [3–6]. However, its occurrence can be minimized by a well-positioned implant, with a short tip-to-apex distance (TAD). The landmark study in 1995 by Baumgaertner et al. established guidelines for lag screw placement and TAD to minimize risk of lag screw cutout, determining that a TAD <25 mm provides the most optimal fixation [7].

☆ This study was conducted with IRB approval: Beaumont Health IRB# 2014-111.

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A recently-introduced computer-assisted navigation system, the ADAPT (Stryker, NJ), provides surgeons with the ability to track screw placement in real-time. This could allow for improved screw placement and potentially reduce radiation exposure to the patient and surgeon. To date, the potential advantages of computer-assisted navigation in lag screw placement for intramedullary nails has not been studied. The purpose of this prospective, randomized study was to evaluate TAD, radiation time, and surgical time in the management of IT femur fractures treated with an intramedullary nail using a computer-assisted navigation system for lag screw placement compared to the conventional fluoroscopy method.

Methods

Study design and patients

Patients undergoing intramedullary nail fixation by one of three fellowship-trained orthopaedic trauma surgeons at a level-1 trauma center were screened for eligibility. Patients included in this study are those that had a diagnosis of an intertrochanteric femur fracture (AO Classification 31-A1 or 31-A2) [8] with a low energy mechanism of injury (i.e. fall from standing, twist). Patients were excluded if they were minors (less than 18 years), had a high energy mechanism of injury (e.g. motor vehicle accident, fall from height), had an open fracture, presented with multiple injuries to the lower extremity, or refused to give written consent. Informed written consent was obtained before surgery. An institutional review board approved this study and it was registered in clinicaltrials.gov.

Introductory phase

Each of the surgeons did four introductory operations using computer-assisted navigation for lag screw placement on all four patients. This was to ensure that each surgeon had adequate experience using the system, to help eliminate the impact of a learning curve on the data.

Experimental phase

Following the introductory phase, newly enrolled patients were randomized in a 1:1 ratio to have their procedure performed either with the ADAPT system (computer-assisted navigation group) (Fig. 1) or with conventional fluoroscopy (control group) for lag screw placement. Patients were randomized from sequentially numbered, opaque envelopes, which were prepared by non-study personnel to ensure random selection. Inside each envelope a card described which procedure arm the patient was to be enrolled in.

Surgical protocol

All procedures were done by one of three fellowship-trained orthopaedic trauma surgeons. All procedures were performed under general anesthesia. The attending surgeon determined whether to use a short or long implant. All nails had a distal interlocking screw. Navigation was not used for insertion of the distal screw.

Study end points

The primary outcome of interest in this study was the distance between lag screw tip and femoral head surface (TAD). Radiographs (anteroposterior and lateral) taken immediately postoperatively were reviewed by an independent, fellowship-trained trauma surgeon with 21 years of post-fellowship experience, who was blinded to the patients' assigned group. This surgeon measured the TAD according to Baumgaertner et al. [7].

Additionally, radiation exposure was assessed by fluoroscopy time. An independent research coordinator in the operating room recorded fluoroscopy exposure times during the procedure, read directly off of the C-Arm. The fluoroscopy time for lag screw placement was recorded as the time from when the nail was fully in place as verified by radiograph until the time when the lag screw was fully inserted. Total fluoroscopy time for the case was also recorded. The total surgical time and estimated blood loss were also collected. Intraoperative complications were recorded, including device breakage, intraoperative fracture, and patient death. Additionally, sex, age, BMI, and ASA score was collected for each patient from medical records.

Statistical analysis

The *a priori* sample size determination was based on a review of the literature. Based on the study by Baumgaertner et al. the maximum TAD without screw cut-out is 25 mm, and the average TAD in patients that had screw-cutout was 38 mm, with an overall standard deviation of residuals of 9 mm [7]. With a power of 0.80, a standard deviation of 9 mm, and a sample size of 25 per group, we can find a minimum detectable difference of 7.3 mm in the mean TAD. This was determined to be adequate to examine the primary objective.

All analyses were performed in SPSS (Version 22; IBM Inc, Armonk, NY, USA). Continuous variables were assessed for

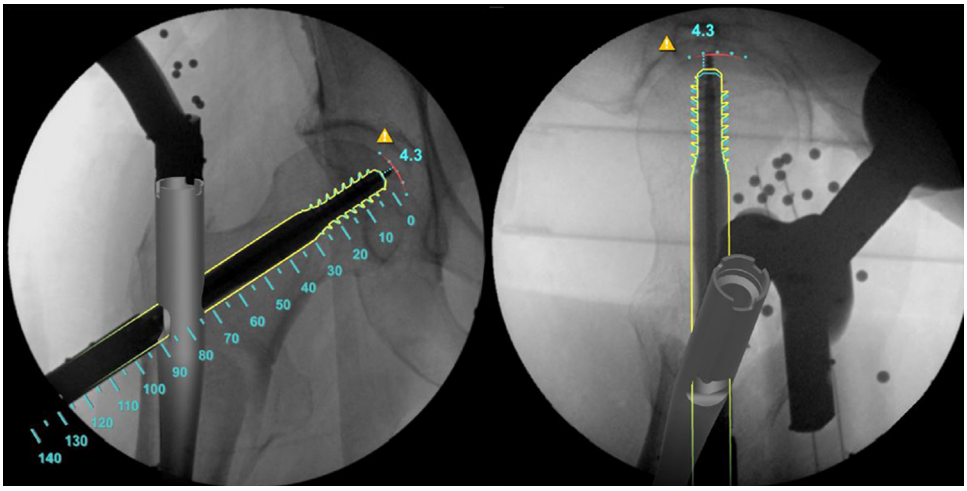

Fig. 1. Images from the ADAPT navigation system. The software superimposes the nail and screw on the live radiographs and is then able to calculate a tip-to-apex distance to help the surgeon with screw placement. The system allows for tracking of screw placement in real-time.

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