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Computer navigation in the reduction and fixation of femoral shaft fractures: A randomized control study☆

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ABSTRACT

Objectives: We investigated the accuracy of reduction of intramedullary nailed femoral shaft fractures in human cadavers, comparing conventional and computer navigation techniques.
Methods: Twenty femoral shaft fractures were created in human cadavers, with segmental defects ranging from 9 to 53 mm in length (Winquist 3–4, AO 32C2). All fractures were fixed with antegrade 9 mm diameter femoral nails on a radiolucent operating table. Five fractures ("Fluoro" group) were fixed with conventional techniques and fifteen fractures ("Nav 1" and "Nav 2" groups) with computer navigation, using fluoroscopic images of the normal femur to correct for length and rotation. Postoperative CT scans compared femoral length and rotation with the normal leg.
Results: Mean leg length discrepancy in the computer navigation groups was smaller, namely, 3.6 mm for Nav 1 (95% CI: 1.072 to 6.128) and 4.2 mm for Nav 2 (95% CI: 0.63 to 7.75) vs. 9.8 mm for Fluoro (95% CI: 6.225 to 13.37) ($p < 0.023$). Mean rotational discrepancies were 8.7° for Nav 1 (95% CI: 4.282 to 13.12) and 5.6° for Nav 2 (95% CI: −0.65 to 11.85) vs. 9.0° for Fluoro (95% CI: 2.752 to 15.25) ($p = 0.650$).
Conclusions: Computer navigation significantly improves the accuracy of femoral shaft fracture fixation with regard to leg length, but not rotational deformity.

Introduction

Femoral shaft fractures are frequently encountered in orthopaedic surgery. The epidemiology of femoral shaft fractures has been studied in various countries. One study reported 37.1 incidences per 100 000 person years for the period 1965–1984.[1] Another investigation tracked 9.9 fractures per 100 000 person years between 1985 and 1994, with peak incidences seen in males between 15 and 24 years of age and in females over the age of 75 years, occurring as a result of high-energy trauma and osteoporosis, respectively.[2]

The 'gold standard' treatment for treating these fractures is fixation with intramedullary nails. The original technique of unlocked nailing has a high rate of union with a low incidence of complications.[3] By using locking screws proximally and distally, improved control of length and rotation is achieved, extending the indications of femoral nailing to proximal and distal fractures and to fractures with unstable fracture patterns.[4]

Malunion is a possible complication following any fracture fixation. In femoral shaft fractures, length, angulation and rotation must be accurately corrected during the intramedullary nailing procedure. Reported incidence of postoperative shortening and malrotation varies. In a series of 520 femoral fractures,[4] shortening of >1 cm occurred in 9% of cases, and malrotation of >10° occurred in 10% of cases. In a recent prospective randomised study, the incidence of shortening >1 cm or malrotation >10° were 7% and 34%, respectively, in the fracture table treatment group.[5]

Computer navigation has evolved as a tool in orthopaedic surgery. With the use of a camera and trackers on patients, the computer is able to monitor the position and orientation of surgical

☆ *Devices and materials:* The focus of this investigation was assessment of rotational and leg length deformity following reduction and antegrade nailing of femoral shaft fractures using computer navigation and conventional techniques.

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instruments and bones. Image-free systems use predetermined anatomical models and combine these with intra-operative information to customise the model to the specific patient. Image-based systems combine intra-operative information with radiological images. These images can be acquired either preoperatively, usually in the form of computed tomography (CT) or magnetic resonance (MR) scans, or intra-operatively, with the use of a modified fluoroscopic C-arm. However, no studies to date have investigated the use of this technology specifically for improved reduction of femoral shaft injury.

The aim of this study was to investigate whether a novel computer-assisted technique for reducing femoral shaft fractures would improve the accuracy of fracture fixation in a human cadaveric model of femoral shaft fractures compared with conventional reduction techniques.

Methods

General approach

Eighteen matched-pair cadaveric femurs were used, two of which were used twice (Table 1). Right femurs underwent fracture and repair using one of three methods. A 'Fluoro' control group ($n = 5$) was repaired using traditional fluoroscopic techniques. A 'Nav 1' ($n = 10$) and a modified 'Nav 2' ($n = 5$) study group were repaired employing computer navigation. All left femurs remained intact. Mean leg length discrepancy and rotational deformity from the three repair groups were finally compared with contralateral intact femurs. The same experienced fellow performed all surgeries with the assistance of co-workers.

Specimen preparation

Twenty full body human cadavers embalmed with introfiant were obtained with permission of our institution's ethics board. The cadavers were examined visually and fluoroscopically to confirm they had undergone no previous surgery involving either femur. Two cadavers were identified as having had such surgery and were excluded. Therefore, two of the remaining cadavers were used twice; the difficulty in obtaining two new cadavers and the financial costs involved made this decision necessary.

Fractures in the diaphysis were created to model an unstable fracture (Winquist 3/4, Arbeitsgemeinschaft für Osteosynthesefragen (AO) 32-C2 classification). Using an anterior approach with splitting of the quadriceps muscle, sections of bone ranging from 5 to 50 mm in length were excised from the femoral diaphysis and removed from the thigh. The fracture area was completely stripped of soft tissue for a distance of 10 cm proximally and 10 cm distally, simulating the soft-tissue injury that occurs in a femoral diaphyseal fracture. Prior to completion of the osteotomies, the defect length was measured with a Vernier calliper, having a precision of 0.1 mm. The measured defect included the length of resected bone and the bone removed by the thickness of the saw blade for each of the two cuts made. The wound was then closed, making the fracture representative of a closed femoral shaft fracture. All left femurs remained intact.

Surgical repair technique

All fractures were fixed using 9 mm diameter antegrade femoral nails on a radiolucent operating table. The proximal femur was reamed to a 12-mm diameter to accommodate the chosen design of femoral nail, and the diaphysis was reamed to a 10.5-mm diameter prior to nail insertion. The nail was locked with proximal and distal locking bolts. It should be noted that the real advantage of locking bolts was that they helped maintain whatever rotational reduction was achieved surgically with the femoral nails (whether excellent or poor), rather than expecting the bolts to alleviate rotational abnormalities, as such.

Fractures in the Fluoro control group ($n = 5$) were fixed with conventional reduction techniques. Fluoroscopic images of the fracture and control limb were compared to optimise length and rotation, prior to locking of the nail. A radio-opaque ruler was used to measure the length of normal and fractured femurs to guide correction of length. Radiographs of both femurs were compared, examining profiles of the proximal femur, particularly the lesser trochanter and the knee, ensuring rotation was similar in both femurs.[6]

Fractures in the Nav 1 ($n = 10$) and Nav 2 ($n = 5$) study groups were fixed with computer navigation, using fluoroscopic images of the normal femur to correct for length and rotation (Figs. 1 and 2). The navigation system used active infrared trackers. The C-arm had a tracker ring attached to the camera, which corrected image distortion and relayed information regarding the position of the C-arm to the computer. Trackers were fixed to the proximal and distal femur of the fractured limb and to the midshaft of the control limb with unicortical pins. Antero-posterior and lateral images were obtained of the hip and knee of both femurs and of the fracture site.

The normal left limb in each cadaver was used as the 'template' to guide reduction of the fractured right limb in both the computer navigation (i.e., Nav 1 and Nav 2) and control (i.e., Fluoro) groups. Consequently, accurate reduction was intended to give equal limb length and alignment in both groups.

Computer navigation for Nav 1 and Nav 2 groups

The iNstride System (Stryker, Mahwah, NJ, USA) was used in this study. Using the images of the hips, the centre of the femoral head, the piriform fossa and the proximal medullary canal (at the level of the lesser trochanter) were identified on both antero-posterior and lateral views. Using the images of the knees, the distal joint line was recorded on the antero-posterior view, and the centre of the epicondyles (defined as the centre of a sphere, placed on the distal femoral joint line) was recorded on the lateral view (Fig. 3). The computer created intersecting planes from these landmarks, allowing calculation of the femoral neck anteversion, the trans-epicondylar axis and the femoral length, in relation to the control femur.

By digitising the edges of the proximal and distal fracture fragments, fracture reduction and passage of the guide wire were performed with virtual fluoroscopy. This allowed real-time movement of the fracture fragments in relation to each other to be seen without using fluoroscopy. Manual traction was applied and, once reduction was reasonable, the distal locking screw was inserted. Fine adjustments to length and rotation were then made using the navigated measurements displayed on the computer prior to proximal locking.

Two cadavers (cases 12/16 and cases 11/17) were used twice with the two navigation software protocols to compensate for exclusion of two previously operated specimens. To prevent bias, the second case with each cadaver used a different length nail locked distally with antero-posterior bolts, as opposed to lateral bolts in the first nailing procedure.

The first 10 navigated fractures used the initial landmark protocol described above (Nav 1). The remaining five navigated fractures were fixed using a modified landmark protocol with an adjusted software program (Nav 2). This adjusted protocol was used to more reproducibly identify the piriform fossa using antero-posterior lateral images and anteromedial/anterolateral oblique images. Specifically, instead of using the piriform fossa as a proximal landmark, the centre of the medullary canal at the level of