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Enhanced cephalomedullary nail lag screw placement and intraoperative tip-apex distance measurement with a novel computer assisted surgery system

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ABSTRACT

Objective: The goal of this study was to evaluate the ability of a novel computer assisted surgery system to guide ideal placement of a lag screw during cephalomedullary nailing and then accurately measure the tip-apex distance (TAD) measurement intraoperatively.
Design: Retrospective case review.
Setting: Level II trauma hospital.
Patients: The initial 98 consecutive clinical cases treated with a cephalomedullary nail in conjunction with a novel computer assisted surgery system were retrospectively reviewed.
Intervention: A novel computer assisted surgery system was utilized to enhance lag screw placement during cephalomedullary nailing procedures. The computer assisted surgery system calculates the TAD intraoperatively after final lag screw placement.
Main outcome measures: The ideal TAD was considered to be within a range of 5 mm–20 mm. The ability of the computer assisted surgery system (CASS) to assist in placement of a lag screw within the ideal TAD was evaluated. Intraoperative TAD measurements provided by the computer assisted surgery system were then compared to standard postoperative TAD measurements on PACS (picture archiving and communication system) images to determine whether these measurements are equivalent.
Results: 79 cases (80.6%) were available with complete information for a retrospective review. All cases had CASS TAD and PACS TAD measurements >5 mm and < 20 mm. In addition, no significant difference could be detected between the intraoperative CASS TAD and the postoperative PACS TAD ($p = 0.374$, Wilcoxon Test; $p = 0.174$, paired T-Test). A cut-out rate of 0% was observed in all patients who were treated with CASS in this case series (95% CI: 0 – 3.01%).
Conclusions: The novel computer assisted surgery system tested here is an effective and reliable adjunct that can be utilized for optimal lag screw placement in cephalomedullary nailing procedures. The computer assisted surgery system provides an accurate intraoperative TAD measurement that is equivalent to the standard postoperative measurement utilizing PACS images.
Level of evidence: Therapeutic Level IV.

Introduction

Lag screw insertion in cephalomedullary nailing procedures typically relies upon external guides, surgeon experience, and/or, frankly, trial and error. These are all imprecise tools in a technically demanding procedure. The result may be multiple guide pin holes in the proximal femur, which may lead to further instability of the fracture and difficulty in obtaining an accurate placement of the lag screw. This technique may also lead to prolonged surgical time, increased radiation exposure, and poor patient outcomes postoperatively.

Ideal lag screw placement in cephalomedullary nailing procedures is typically defined by the tip-apex distance. The tip-apex distance (TAD) was first introduced by Baumgaertner et al. in 1995 [1]. It is measured postoperatively by adding together the distance, in millimetres, from the tip of the lag screw to the apex of the femoral head on the anterior-posterior (AP) and lateral views, while correcting for image magnification [1]. Multiple authors have shown that a tip-apex distance of 25 mm or less has been

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associated with fewer instances of fixation failure of the lag screw in the femoral head, also known as cut-out [1–10]. TAD measurements of less than 20 mm [3,7] and less than 15 mm [4] have been shown to be even better in preventing the cut-out complication. The original measurement was based on postoperative radiographic films, but now as technology has evolved, PACS (picture archiving and communication system) images have become standard and have been utilized in TAD measurement [11]. Unfortunately, the measurement is still a postoperative calculation. If an inappropriate TAD is measured at that time, there is not an opportunity to improve the placement of the lag screw without a return to the operating room.

Computer assisted surgery has been studied by other authors in an effort to improve lag screw placement and to decrease the risks associated with surgery. Mayman et al. presented their results utilizing a computer assisted surgery system (CASS) on a Sawbones® model [12]. The authors found that the computer assisted technique significantly reduced the number of guide pin passes required to achieve acceptable placement. The use of CASS also significantly reduced the number of fluoroscopic images required to achieve that acceptable guide pin placement. Herman et al. presented their results with a different computer assisted surgery system in a clinical trial comparing cases with and without the use of CASS [13]. Similar to Mayman et al. [12], there was a significant decrease in the number of attempts needed for appropriate guide pin insertion and a significant decrease in the use of fluoroscopy. No clinical outcome data was presented by Herman et al. [13].

In this paper, we present our initial results with a new computer assisted surgery system that is now available not only to provide assistance in optimal placement of the lag screw but also to calculate the TAD intraoperatively. The ADAPT System (sold and cleared (FDA approved and CE marked) under the name “FluoroMap System” (Manufacturer: Stryker Leibinger GmbH & Co. KG, Freiburg, Germany)) is a computer assisted stereotaxic device intended to assist a surgeon with the insertion of the lag screw within the femoral head during Gamma cephalomedullary nailing procedures. The system uses and manipulates 2D fluoroscopic C-arm images taken during the surgical procedure to create a 3D reconstruction of the femoral head. It then provides the information that the surgeon needs to place the lag screw in the ideal position. Once the lag screw is inserted to an appropriate depth, the system calculates the tip-apex distance based on the lag screw position, providing an objective evaluation of appropriate lag screw placement. A cadaver study utilizing this novel computer assisted surgery system has been published previously [14]. The ADAPT System was described in detail within that paper.

Patients and methods

This study is a retrospective review of the initial clinical cases which utilized the ADAPT System. It was designed as a pilot study to evaluate the accuracy of the computer assisted surgery system in guiding appropriate lag screw placement and measuring the tip-apex distance intraoperatively.

Institutional Review Board (IRB) approval was obtained for this study through the St. Cloud Hospital, St. Cloud, MN, a Level II Trauma Centre, where all of the cases were performed.

From September 1, 2011 to April 2, 2014, 98 consecutive cases were performed utilizing this novel CASS. During this time, the CASS was used in all possible procedures. A thorough review of the hospital electronic medical records was performed to describe the patient population, fracture types, and postoperative outcomes. The TAD was measured postoperatively on the PACS images taken after implant insertion and then corrected for magnification, as previously described [10]. The CASS TAD measurements were obtained from the case information saved on the CASS hard drive.

The focus of this study was twofold. First, we wanted to evaluate the ability of the CASS to assist in optimal lag screw placement, defined here as a TAD within a range of 5 mm–20 mm. Second, we wanted to evaluate the accuracy of the intraoperative CASS TAD measurements. The PACS TAD measurements were used both as the standard for evaluation of acceptable implant placement and as the control for comparison to the CASS TAD.

Surgical technique

All cases were performed on a fracture table. Closed reduction of the fracture was successful with manipulation of the extremity using the fracture table in a vast majority of the cases (75/79 or 94.9%). The remainder required an open reduction. Standard cephalomedullary nailing surgical technique was performed in all cases. The ADAPT System was utilized as a procedure enhancement for guidance of lag screw placement and intraoperative TAD measurement. All cases presented here were performed by a fellowship trained orthopaedic trauma surgeon (MK).

During the procedure, two items with multiple, embedded stereotactic beads are utilized for providing the necessary information, through C-arm images, back to the ADAPT System. The first item is the ADAPT clip, which is affixed to the insertion handle that connects to the intramedullary nail. The other is the FluoroDisc, which is attached to the C-arm receiver. No extra incisions or trackers are needed on the patient, and no extra cameras are required.

The ADAPT System utilizes the standard anteroposterior (AP) and lateral C-arm images obtained during the procedure to project the eventual trajectory of the guide pin and lag screw canal, based on the position of the intramedullary nail. The surgeon can then reposition the nail as needed until the appropriate trajectory is achieved. The ADAPT System defaults to a central or a slight inferior lag screw placement on the AP view and a central placement on the lateral view, but this setting may be altered based on surgeon preference.

Once the intramedullary nail is in the appropriate position, the guide pin is then inserted into the femoral head. With new c-arm images the ADAPT System then projects the lag screw placement with a ruler to assist in determination of appropriate lag screw length. The default lag screw position is set to put the tip of the screw 5 mm from the articular surface of the femoral head. It should be noted that this lag screw position is based on the system's 3D reconstruction of the femoral head, not the 2D C-arm images. Drilling for the lag screw is then performed using standard technique. Subsequently, as the actual lag screw is advanced over the guide pin and new c-arm images are obtained, the ADAPT System provides feedback regarding the insertion distance needed for placement of the lag screw 5 mm from the articular surface of the femoral head. The final position of the lag screw is, of course, at the discretion of the surgeon. Once this final position is reached, the TAD is calculated by the ADAPT System, providing an objective measurement of appropriate lag screw placement intraoperatively.

Postoperative TAD measurement

Tip-apex distance measurements were performed using the PACS images obtained at the end of each case. This technique has been previously described in the literature [11]. The measurements were performed down to a tenth of a millimetre on both the AP and lateral images, as this is the accuracy of measurement for our PACS images. Image magnification was then adjusted as previously described [1]. The data was placed into a spreadsheet, and the

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