Computer-Assisted Surgery for Internal Fixation of Peritrochanteric Femur Fractures: A Randomized Controlled Study

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BACKGROUND

Peritrochanteric femur fractures are the most common type of fracture requiring orthopaedic surgical intervention. Successful surgery with cephalomedullary nail fixation can restore patients' baseline ambulatory function and prevent complications resulting from prolonged bedrest and immobilization. However, failure of fixation due to lag screw cut-out has an incidence rate of nearly 8% following open reduction internal fixation with an cephalomedullary nail. Given this high rate of failure, prior investigations have identified the strongest predictor of screw cut-out following cephalomedullary nail fixation, tip-apex distance (TAD) of the lag screw. TAD is defined as the sum of the distance from the tip of the lag screw to the apex of the femoral head on the anteroposterior and lateral radiographs. A TAD distance of greater than 25mm has been shown to be a strong predictor of screw cut-out and fixation failure. Although use of intraoperative two-dimensional (2D) fluoroscopy helps guide the operator on optimal lag screw placement, the femoral head is a three-dimensional (3D) spherical anatomic structure that is difficult to visualize using fluoroscopy alone. Computer navigation platforms have been developed to help reliably obtain a TAD of less than 25 mm, potentially reducing the risk of lag screw cut-out and failure. To date, however, only one clinical study has compared computer navigation to traditional fluoroscopy in achieving a TAD of less than 25 mm (Herzog et al. 2019). While this study demonstrated significantly improved accuracy of lag screw placement in the computer navigation cohort with no significant effect on average operating time, the study did not assess several other important variables nor did it report rates of lag screw cut-out. Despite the potential benefits of computer navigation, fluoroscopy remains the current standard of care for inserting cephalomedullary nails in the treatment of intertrochanteric femur fractures.

The purpose of this study is to evaluate the ADAPT (Adaptive Positioning Technology, Stryker©, USA) computer navigation platform in a controlled, randomized fashion to determine its effect on TAD, lag screw cut-out, operative time, fluoroscopy time and number of Kirschner wire (K wire) passes prior to insertion of the final implanted device. Additionally, 1 year follow-up will compare postoperative complications, mobility, range of motion, social dependency and pain level between procedures that utilized the ADAPT platform and those that did not.

Study Design: This will be a prospective, randomized, double-blind, controlled trial with two treatment cohorts. Cohort 1 will consist of 30 patients with closed peritrochanteric femur fractures who undergo open reduction internal fixation with a Stryker© Gamma intramedullary nail using traditional fluoroscopy for insertion of the lag screw (control group). Cohort 2 will consist of 30 patients with closed peritrochanteric femur fractures who undergo open reduction internal fixation with a Stryker© Gamma intramedullary nail using the Stryker© ADAPT platform to assist with insertion of the lag screw (treatment group). Patients will be blinded to treatment group allocation as will clinicians/researchers during data processing/analysis. The primary outcome will be TAD, as measured on AP and lateral hip radiographs. Secondary outcomes will be position of the lag screw as described by Cleveland et al, operative time, fluoroscopy time, and number of K wire passes prior to final placement of the lag screw. Additionally, evidence of lag screw cut-out on hip radiographs, hip range of motion relative to the contralateral hip, mobility and social dependency as defined by the Harris Hip Score, and pain level (visual analog scale) will be assessed at 3 month, 6 month, 1 year, and 2 year follow up visits.

Statistical Procedures: Descriptive statistics will be calculated to compare patient demographics between the two cohorts. The Student t-test and the Fisher's exact test will be used to compare outcomes between the two cohorts. Based on a previous study by Herzog et al (2019), we expect the ADAPT platform to lead to an average reduction in TAD of 8 mm (24.9 mm +/- 6.68 mm without ADAPT vs. 16.9 mm +/- 6.30 mm with ADAPT). Accordingly, in order to achieve a power of 0.8 with an alpha of 0.05 and a beta of 0.2, we will need to accrue 11 patients per cohort. Our plan is to enroll 30 patients per cohort.

RESEARCH AIMS & ABSTRACTS

Research Question(s)/Hypothesis(es): We hypothesize that use of the ADAPTTM platform will lead to a lower mean TAD and a greater proportion of patients with a TAD of 25 mm or less. We do not expect a difference in the proportion of patients with optimal lag-screw position within the femoral head as defined by Cleveland et al. Use of the ADAPT platform will lead to no difference in operative time or blood loss, decreased fluoroscopy use, and fewer K wire passes. In terms of radiographic evidence of screw cut-out, we expect no difference at any

of the follow up visit time points. Additionally, we expect no difference in hip range of motion, mobility and social dependency as defined by the Harris Hip Score, or pain level at any of the follow up visit time points.

Scientific Abstract: Peritrochanteric femur fractures are the most common type of fracture requiring orthopaedic surgical intervention. Successful treatment with cephalomedullary nail fixation can restore patients' baseline ambulatory function and prevent complications associated with prolonged bedrest and immobilization. However, failure of fixation due to lag screw cut-out has an incidence rate of nearly 8% following open reduction internal fixation with a cephalomedullary nail. Previous research has identified the tip-apex distance (TAD) of the lag screw as the strongest predictor of lag screw cutout. Accordingly, computer navigation platforms have been developed to reliably achieve a TAD of less than 25 mm. To date, however, only one clinical study has compared computer navigation to traditional fluoroscopy in achieving a TAD of less than 25 mm. While this study demonstrated significantly improved accuracy of lag screw placement in the computer navigation cohort with no significant effect on average operating time, the study did not assess other important intraoperative variables nor postoperative outcomes. The purpose of this study is to determine if computer navigated lag screw placement during cephalomedullary nail fixation utilizing the novel ADAPT platform will lead to a lower mean TAD and a greater proportion of patients with a TAD of 25 mm or less. This will be a prospective, randomized, single-blinded, controlled trial with two treatment cohorts. Cohort 1 will consist of patients with closed peritrochanteric femur fractures who undergo open reduction internal fixation with a Stryker© Gamma cephalomedullary nail using traditional fluoroscopy for insertion of the lag screw. Cohort 2 will consist of patients with closed peritrochanteric femur fractures who undergo open reduction internal fixation with a Stryker© Gamma cephalomedullary nail using the Stryker© ADAPT platform to assist with insertion of the lag screw. Patients will be blinded to treatment group allocation but clinicians/researchers will not. The primary outcome will be TAD as measured on postoperative AP and lateral hip radiographs. Secondary outcomes will be position of the lag screw as described by Cleveland et al, operative time, fluoroscopy time, and number of K wire passes prior to final placement of the lag screw. Additionally, evidence of lag screw cut-out on postoperative hip radiographs, hip range of motion relative to the contralateral hip, mobility and social dependency as defined by the Harris Hip Score, and pain level will be assessed at 3 month, 6 month, 1 year, and 2 year follow up

visits. Student t-test and Fisher's exact test will be used to compare outcomes between the two cohorts.

Hip fractures are common injuries in which the top part of the femur bone breaks. These fractures often require surgery and are frequently treated with a metal rod that goes inside the femur, known as a cephalomedullary nail. Successful treatment of hip fractures with a cephalomedullary nail can allow patients to start walking soon after surgery. However, the cephalomedullary nail must be inserted into the correct position in the femur, otherwise it may not work properly. Traditionally, surgeons use x-rays in the operating room to determine if a cephalomedullary nail is in the correct position within the femur. Recently, however, computer navigation technology has been developed to help surgeons correctly position cephalomedullary nail devices. To date, only one study has compared x-rays to computer navigation technology in the treatment of hip fractures. While this study demonstrated more accurate placement of the cephalomedullary nail with computer navigation, the study did not consider other important outcomes such as radiation exposure, hip function and pain after surgery. The purpose of this study is to further compare x-rays and computer navigation (the ADAPT platform) for the placement of a cephalomedullary nail when treating hip fractures. This study will have two groups: group 1 will consist of patients with hip fractures who undergo surgery with a cephalomedullary nail using only x-rays, and group 2 will consist of patients with hip fractures who also undergo surgery with a cephalomedullary nail but using computer navigation (the ADAPT platform) as well as x-rays. X-rays taken after surgery will be used to compare the average position of the cephalomedullary nail in the femur between the two groups. Other variables will also be compared between the two groups including the average time required to perform the surgery, the average number of x-rays taken during the surgery, the average number of attempts required to position the cephalomedullary nail, as well as the occurrence of signs on x-ray that suggest the cephalomedullary nail is not functioning properly, average hip range of motion, mobility, independence, and pain at 3 months, 6 months, 1 year and 2 years after surgery.

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