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Are piriformis reconstruction implants ideal for prophylactic femoral neck fixation?

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ABSTRACT

Objectives: Prophylactic femoral neck fixation may be performed in the setting of geriatric diaphyseal femur fracture, pathologic or impending atypical femur fractures. Fixation constructs often utilize cephalomedullary implants with one or two proximal interlocking screws into the femoral head/neck. Variations in proximal femoral anatomy and implant design can interfere with the placement of two screws in the femoral head and neck. Our objective was to assess the strength of piriformis entry reconstruction implants with one versus two proximal interlock screws for prophylactic femoral neck fixation.

Methods: Thirty fourth generation synthetic femur models were separated into 5 groups. The control group was an intact femur, and the second group was an intact femur with an entry hole in the piriformis fossa. The remaining groups had an intramedullary nail placed with either 0, 1, or 2 screws placed into the femoral head and neck. Each femur was mechanically loaded along the mechanical axis through the femoral head. Load to failure and failure displacement were recorded.

Results: Mean load to failure was 5583 ± 543 N in the intact femur. Constructs with 2 screws had a significantly higher mean load to failure (3223 ± 474 N) compared to one screw constructs (2368 ± 280 N). All of the experimental groups remained significantly lower than the intact femur model ($p < 0.05$).

Conclusion: Our results demonstrate that piriformis entry reconstruction implants have a significantly lower load to failure compared to an intact femur irrespective of screw construct. Further studies are needed to investigate this potential iatrogenic weakening.

Introduction

Fixation constructs for diaphyseal fractures in the elderly typically include screw fixation into the femoral neck/head to theoretically prevent future fractures of the femoral neck (Fig. 1A). However, the amount and type of protective fixation remains unclear. Current intramedullary nail options include antegrade implants inserted either through the piriformis fossa or laterally in some part of the greater trochanter. Currently, there are no biomechanical studies comparing on versus off-axis start site implants. Our institutional preference has been to perform piriformis start nailing with an implant having two proximally directed interlocking screws into the femoral neck/head. Frequently, we have encountered a mismatch between the patient's proximal femoral anatomy and trajectory and position of the proximal interlocking screws. This mismatch can limit the location and/or the number of screws that can be safely inserted within the cortices of the femoral neck. Occasionally, if two screws are desired, the implant must be left prominent above the bony insertion site (Fig. 1B). Clinically, this can cause significant soft tissue irritation and symptoms for patients. Potential treatment alternatives include selecting an alternative piriformis nail design (with different positions and neck shaft angles for the proximal interlocks), deeper insertion of the same implant and placement of a single interlock screw in the neck, inserting independent screws outside of the nail, or changing to a trochanteric start site implant. The purpose of this study was to determine whether interlocking screw number affects the load to failure for prophylactic femoral neck fixation.

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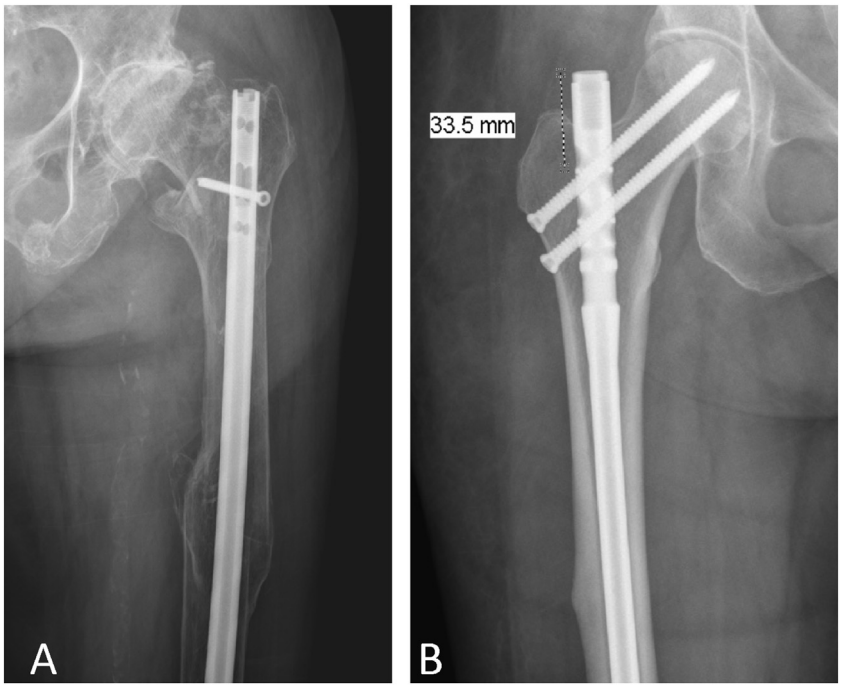

Fig. 1. A, Anteroposterior hip radiographic of a 98-year-old female who sustained a basicervical femoral neck fracture around an intramedullary nail previously placed for a femoral shaft fracture. B, Anteroposterior hip radiograph of a patient demonstrating a notably proud piriformis start reconstruction implant after initial treatment. Note how prominent the nail is above the greater trochanter and is nearly 3.5 cm outside of the piriformis fossa.

Methods and materials

Thirty 4th generation synthetic complete femur models (Sawbones, Vashon Island, WA) were separated into 5 groups with 6 specimens each. Group 1 consisted of unmodified intact femur models while Group 2 had a 14.5 mm entry hole in the piriformis fossa. The remaining groups represented femurs stabilized with a piriformis start site cephalomedullary implant (Natural Antegrade Femoral Nail; Zimmer Biomet, Warsaw, IN) using three different proximal interlocking configurations; Group 3 had two transverse proximal shaft screws and no screws into the femoral head/neck, Group 4 had 1 neck screw, and Group 5 had 2 neck screws.

Specimen preparation

Each bone model was prepared according to the surgical technique provided by the implant manufacturer. For groups 2–5, we created an entry point 3 mm anterior to the piriformis fossa in line with anatomic axis of the femur in the coronal plane with a 3.0 mm threaded guidewire followed by a 14.5 mm opening reamer. In groups 3–5, the medullary canal was reamed to 13.5 mm to accommodate a 12 mm implant. Group 3 had two transverse 5.0 mm screws placed into the proximal femoral shaft and none placed into the femoral neck. For the two different reconstruction screw constructs in groups 4 and 5, either one or two 6.0 mm screws were placed into the femoral neck/head. Lastly, the distal femur for all instrumented specimens was stabilized with two transverse 5 mm interlocking screws in standard technique.

Mechanical loading

All mechanical testing was performed using a materials testing machine (Instron, Norwood, MA) with continuous digital data collection. We fixed the specimens in a custom polymethylmethacrylate jig holding the femur in anatomic alignment and used a flat platen to apply a load through the femoral head at an 18° angle in the coronal plane simulating load along the mechanical axis (Fig. 2). [1] An axial preload of 100 N was applied to stabilize the testing construct followed by an axial compressive load applied at a rate of 1 cm/s until failure occurred. Load to failure was chosen as the mode of mechanical testing as it most closely simulated the clinical scenario of a ground level fall resulting in a femoral neck fracture. Each femur was tested individually with new implants for each specimen.

Statistical analysis

The mean ± standard deviation was reported for each of the specimen groups. Differences between implant types were compared using a Kruskal-Wallis Test. Where statistical differences were detected using the Kruskal-Wallis test, a post-hoc Steel-Dwass test was used to determine which groups were different from one another. Computations were performed using statistical software (JMP Pro, 13.0, http://www.jmp.com). Significance was set at $p < 0.05$.

Results

The mean load to failure for all specimens is listed in Table 1. The mean load to failure for the intact femurs, group 1, was 5583 ± 543 N. Each intact femur failed with a subcapital/transcervical femoral neck fracture pattern. All of the experimental groups were significantly weaker than the intact femur (Fig. 3). Comparing experimental groups, group 5 (2 screws, 3223 ± 474 N) had a significantly higher load to failure compared to group 4 (1 screw, 2368 ± 280 N). There was no statistical difference amongst the rest of the groups except for a difference between the 1 screw construct and the isolated entry hole. Lastly, each mechanical failure in groups 2–5 consisted of a basicervical/intertrochaneric fracture that included the entry hole near the piriformis fossa (Fig. 4).

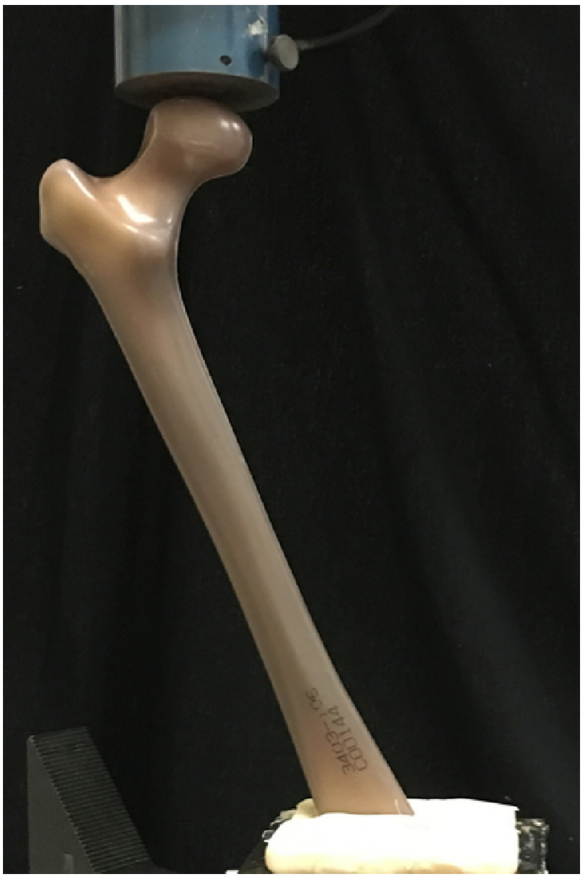

Fig. 2. Photograph depicting the experimental setup consisting of a synthetic femur model potted into the polymethylmethacrylate jig and contained within the materials testing machine with pending axial load.

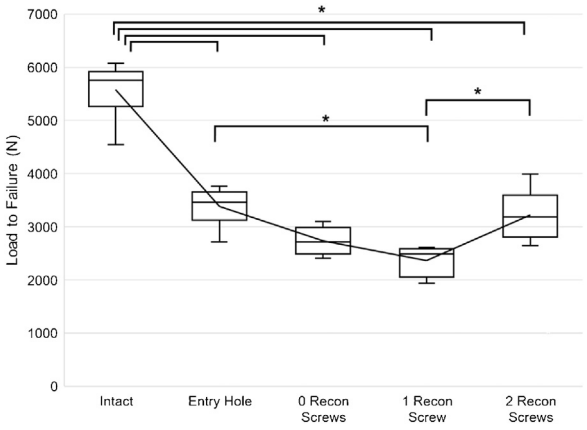

Fig. 3. Scatterplot demonstrating effect of entry hole placement and reconstruction screw constructs. Note that the intact femur is significantly stronger than the experimental groups. Asterisks indicate significant differences between groups, * $p < 0.05$.

Discussion

The Russell-Taylor reconstruction (Smith and Nephew, Memphis, TN) was a second generation intramedullary nail that allowed for the placement of two interlocking screws into the femoral head and neck for the treatment of ipsilateral femoral neck and shaft fractures [2]. Since then, indications have expanded to include various fractures and pathologies about the trochanteric region, and its concept has since been utilized in newer generations of intramedullary nails [3]. Reconstruction nails are now commonly used in complex proximal femur fractures, subtrochanteric femur fractures, atypical proximal femur fractures, pathologic femur fractures, and in the prophylaxis for impending pathologic femur fractures [4–9].

Patton et al reported on late femoral neck fractures following intramedullary nailing for femoral shaft fractures in the elderly [10]. In their series, 2.7% of their patients developed a proximal femur fracture adjacent to an intramedullary implant. Three fractures occurred within 2 weeks post-operatively while the remaining 11 fractures occurred months to years later. Most of these patients were over the age of 60, female gender, had low energy falls, and had intracapsular femoral neck fractures. The intracapsular femoral neck fractures were treated with arthroplasty procedures while the extracapsular fractures were treated with revision to a cephalomedullary implant or sliding hip screw. Furthermore, their analysis showed that patients with proximal third diaphyseal fractures, low energy mechanism, and severity of osteoporosis were associated with late hip fractures. Stemming from their data, they suggested that protecting the femoral neck during fixation of osteoporotic femoral shaft fractures with a reconstruction nail may be effective.

The decision to include prophylactic fixation in the femoral neck is ultimately at the surgeon's discretion. In the trauma setting, some authors have advocated for femoral neck prophylaxis in all femoral shaft fractures due to the concern for iatrogenic and/or missed femoral neck fractures [11,12]. Furthermore, it theoretically protects the patient against future fractures about the proximal tip of an intramedullary implant as the patient ages and risk increases for low-energy proximal femur or femoral neck fractures. In the orthopaedic oncology literature, many also advise for femoral neck prophylaxis in the setting of femoral metastases to protect the entire length of the femur. Van der Hulst was one of the first to suggest the routine use of reconstruction nails for all pathologic or impending diaphyseal lesions due to concern for missed metastatic lesions in the proximal femur [6]. Newer imaging and treatment modalities have helped practitioners better identify proximal femur lesions, and subsequent studies have found no increased risk of metastatic spread to the femoral neck following intramedullary nailing for diaphyseal metastases [13]. Nevertheless, the practice of protecting the entire femur including the femoral neck remains commonplace within the orthopaedic community.

This study has demonstrated biomechanically that piriformis entry reconstruction nailing for prophylactic femoral neck fixation does not restore the strength of an intact femoral neck. All experimental groups, regardless of the presence or configuration of instrumentation, demonstrated loads to failure that were statistically lower than that of the intact proximal femur. Our fracture patterns were similar to prior cadaveric studies in that all resultant fractures occurred through the piriformis start site entry hole and extended into the base of the femoral neck

Table 1
Mean Load to Failure.

	Group 1: Intact Femur	Group 2: Entry Hole Only	Group 3: 0 Recon Screws	Group 4: 1 Recon Screw	Group 5: 2 Recon Screws	P – Values*
Load to Failure (N/mm)	5583 ± 543	3383 ± 368	2734 ± 259	2368 ± 280	3223 ± 474	< 0.0001

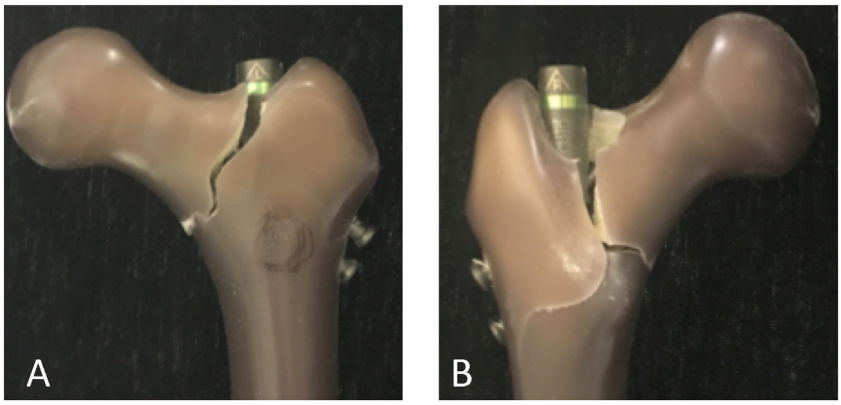

Fig. 4. Clinical photograph from an anterior (A) and posterior (B) view of a sawbones femur instrumented with a reconstruction intramedullary nail and two screws into the femoral neck and head. Note the involvement of the implant start site within the fracture.

whereas intact femurs sustained subcapital or transcervical fractures [14–17]. We postulate that this may be the result of the large entry hole through the piriformis fossa creating a significant structural defect at the base of the femoral neck. Prior biomechanical studies have shown that an entry hole located over 6 mm anterior to the ideal starting point increases the hoop stresses about the proximal femur and places the anterior cortex at risk of bursting during nail placement [18,9]. Anterior placement also places the base of the femoral neck at risk of iatrogenic injury [14]. In our specimens, we were careful to place the entry hole no more than 3–4 mm anterior to the piriformis fossa to protect the proximal femur from such iatrogenic insult and potential weakening as would be performed clinically. Nevertheless, the proximal femur was substantially weakened by the 14.5 mm piriformis fossa entry hole when subjected to axial loads despite the presence of intramedullary fixation.

Although two proximally directed screws were statistically stronger than a single screw, the load to failure of either remained significantly lower than that of the unfractured femur. Surprisingly, there was no significant difference between having two proximal screws and having an isolated entry hole in the piriformis fossa. Furthermore, a single reconstruction screw was actually biomechanically weaker than a femur with an isolated entry hole without an implant. This finding may be the result of creating a secondary stress riser with the entry hole as well as inadequate points of fixation in comparison to two reconstruction screws. When attempting to apply these results clinically, this raises concern for iatrogenic weakening of the femoral neck, especially in elderly patients. Further, we question whether an implant with a trochanteric or lateral start site should be considered in the above-mentioned patients as it would avoid creating a hole in the piriformis fossa and thereby decrease any potential weakening of the proximal femur in these at-risk patients. Strand et al showed in a cadaveric study that reaming through the piriformis fossa led to a 100% fracture rate through the entry hole when axial load was applied, whereas 30% of specimens fractured through a trochanteric entry hole [15]. Additional studies investigating the use of trochanteric implants are relevant and needed.

There are several limitations to our study. First, we note that this is a biomechanical study using synthetic femur models and may not accurately represent the mechanics of human bone, especially in the elderly. The sawbones were used in an attempt to limit the variability present with cadaveric specimens at this stage of our investigation. Even though this initial study utilized non-osteoporotic sawbones, we hypothesize the results would demonstrate different absolute values but a comparable trend if osteoporotic femur models were utilized instead. A valuable future study would include osteoporotic models or cadaveric femurs. Second, the axial load provided by the mechanical testing machine may not accurately mimic the physiologic load or vector experienced during a standard ground level fall. However, the testing model here has been validated and previously utilized in multiple biomechanical studies and was felt to be the most accurate and applicable method to isolate the strength of the proximal femur from the surrounding soft tissues and muscular forces [14–16,19]. Third, we tested sawbones with no capacity for healing or recovery. Although we are not aware of any data or timeframe regarding remodeling about the piriformis fossa, one can assume that the proximal femur undergoes some degree of osseous remodeling after initial instrumentation. This remodeling could potentially fill in the initial defect created by the opening reamer and could possibly negate the stress riser demonstrated in this model. We feel the model is still applicable as it serves as a worst-case scenario in a patient sustaining a fall before any remodeling has occurred. Fourth, we only tested load to failure rather than cyclic loading, as our goal was to investigate what protection the fixation construct provides against a catastrophic event such as a fall. The potential stress riser impact of the entry hole with normal weight bearing and ambulation was not investigated but could be clinically applicable. Next, the question of whether a fixed angled implant or a sliding implant could offer better prophylaxis remains unknown and could also be another issue for future study. Lastly, the sample sizes of the groups were limited in number, and additional samples may have provided a more accurate representation of the load to failure of the femur models.

Conclusion

Based on our results generated through biomechanical tests, we conclude that the prophylactic fixation of the femoral neck using a piriformis entry reconstruction implant with two proximally directed screws along the femoral neck did not restore the strength of the proximal femur to unfractured levels. Similarly, there was no significant difference with an implant with two reconstruction screws compared to an intramedullary nail with transverse proximal interlocking screws. Although an implant with two reconstruction screws was statistically stronger than a single screw, both constructs were unable to replicate the strength of a normal femoral neck. Further biomechanical studies investigating alternate intramedullary nail designs or starting points are indicated to determine the optimal construct to maximize prophylactic femoral neck fixation.

Conflicts ofInterest and source of funding

No authors have conflicts of interest for this study. The implants used in this study were provided by Zimmer Biomet, Warsaw, IN.

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