Evaluation of Fixation Constructs for Femoral Neck Fracture: a Sawbones Biomechanical Model

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INTRODUCTION: High complication rates continue to be reported for femoral neck fractures where over 30% of femoral neck fractures resulted in moderate to severe shortening. As femoral neck shortening increases, hip function declines. Therefore, it is imperative that a device construct resists femoral neck shortening, femoral head rotation and screw displacement. The purpose of this study was to investigate the use of a femoral neck fracture fixation device (SimpliFix Hip System) by evaluating its biomechanical performance to that of a clinically relevant construct using commercially available cannulated screws (CS) in a Sawbones femur model. It was hypothesized that the SimpliFix constructs would perform similar to CS constructs in terms of maintaining fracture gap area, resistance to rotation of the femoral head, screw displacement, and number of cycles to failure.

METHODS: A total of 12 Sawbones femurs (#3403, medium size) were divided into the following study groups: Group A (control; triangle screw configuration, n=6) was instrumented with three partially threaded cannulated screws in a clinically relevant configuration, and Group B (experimental; SimpliFix, n=6) was instrumented with the new fixation system that consisted of two partially threaded cannulated screws and a cross-screw. All constructs were prepared using a customized jig. The fracture pattern developed was modeled from a Garden Type II fracture with superior fracture comminution with a 3° wedge (Figure 1). Each sample was prepped and potted distally using high strength resin in a positioning ball joint allowing the sample to be locked in the sagittal plane in 10° of flexion and 10° of adduction to mimic heel strike.[5] Samples were mounted to a servohydraulic test frame (MTS Bionix) with 5-kN load cell. A series of non-destructive, preconditioning testing (torsional, bending and compression) was performed prior to dynamic testing on all constructs (Figure 2). The torsional preconditioning was at a rate of 1°/s applied to femoral head until +/- 5° rotation around the longitudinal axis of the femoral neck. The cantilever bending (anteroposterior loading) was performed where the samples were placed horizontally with a support beam under the minor trochanter, and load was applied anteriorly. Lastly, for axial compression, samples were mounted vertically in 10° adduction and 10° flexion. Following preconditioning loading, while still oriented in axial compression, baseline loading was performed for 10 cycles between 50 and 100 N at a frequency of 0.5 Hz. Thereafter, a step-wise increasing cyclic loading protocol based on reported body weight (BW) for the Sawbones model was followed. Each load step was at frequency of 1 Hz in increments of 1,000 cycles until 85% BW (658N) was achieved, whereafter each construct ran 4,000 cycles at 85% BW. Next, constructs continued in a step-wise loading fashion until 2X BW (1,646N), whereafter each construct ran 3,124 cycles at 2X BW for a total of 10,000 cycles. An additional fatigue protocol was performed that continuously loaded the constructs at 2X BW to a maximum of 30,000 cycles or until failure. Any construct completing 30,000 cycles would then be ramped to failure at a rate of 1 mm/s. Failure mode and cycles to failure were recorded. Metrics of interest were resistance to fracture gap area collapse (measurement for femoral neck shortening), resistance to rotation of the femoral head, screw displacement, and number of cycles to failure. Averages expressed as arithmetic means and variation as standard deviations. To determine sample equivalence, all comparisons were evaluated using the F-test (alpha=0.05) before applying the appropriate paired T-test with level of significance set to $p < 0.05$. The Pearson Correlation Coefficient was used to determine the relationship between outcomes, where appropriate.

RESULTS SECTION: At the conclusion of 10,000 cycles, Group B had significantly larger fracture gap area when compared to Group A (.12 ± .066 cm^2 vs. .03 ± .013 cm^2; p=.020). The fracture gap was also assessed after the additional fatigue protocol, and Group B continued to demonstrate the enhanced ability to resist femoral neck shortening compared to Group A (.09 ± .028 cm^2 vs. .029 ± .013 cm^2; p=.001). For femoral head rotation, Group B constructs demonstrated an average of 0.19° less rotation of the femoral head about the neck after 10,000 loading cycles (Group B: 3.96 ± 1.51°, Group A: 4.15 ± 2.43°). This decrease was not statistically significant (p=.88). From the zero position (0N) to pre-load (50N), Group B screws demonstrated .0911 mm less backout when compared to Group A. This decrease in backout was not statistically significant (p=.47). However, with each subsequent loading step, Group B screws demonstrated significantly less displacement ($p< .05$) than Group A screws when compared to the initial zero position measurement (Table 1). The reduction in fracture gap area demonstrated a strong negative correlation with screw displacement for both Group A (R= -.86) and Group B (R= -.96). During the fatigue testing up to 30,000 cycles, samples in Group B failed at 20,286 cycles and Group A failed at 14,001 on average, however, this was not statistically significant (p=.19). All constructs failed during the additional fatigue cycle testing except for one construct in Group B which was ramped to failure at 3,421 N. The failure modes were predominantly fracture of the Sawbone or severe collapse defined as excessive head rotation and loss of fracture gap area where the inferior surface of the neck was embedded into the femoral head.

DISCUSSION: Constructs in Group B outperformed constructs in Group A by demonstrating a statistically significant ability to retain an increased fracture gap area during cyclical testing. Although Group B demonstrated increased resistance to femoral head rotation, this finding was equivalent with Group A constructs. The ability to withstand screw displacement under repeat loading was significantly improved in Group B compared to Group A. Moreover, a strong inverse correlation between loss of fracture gap area and screw backout was determined. On average, Group B constructs demonstrated enhanced survival under repeat loading compared to Group A. Although Group A outperformed Group B by 6,286, on average, this was found to be equivalent. No implants broke during fatigue or load to failure.

SIGNIFICANCE/CLINICAL RELEVANCE: Clinically, the enhanced ability of Group B to resist femoral neck shortening may prevent poor alignment, hardware prominence, postoperative pain, gait disturbance and lower the risk for avascular necrosis of the femoral head. Maintaining femoral head rotation can reduce the risk of femoral neck shortening, gait disturbance and avascular necrosis of the femoral head.

IMAGES AND TABLES:

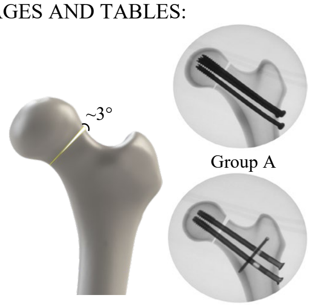

Figure 1. Illustrations of fracture model and test groups

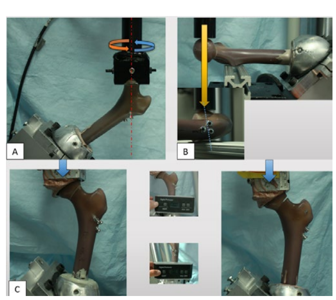

Figure 2. Biomechanical Testing Setup

Table 1. Screw displacement at each subsequent loading step