Biomechanical Evaluation of Proximally Placed Femoral Less-Invasive Stabilization System Plates

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Abstract

Loss of fixation of the Synthes 13-hole femoral Less-Invasive Stabilization System (LISS) plate has been noted. The biomechanical stability of this plate may be affected by improper proximal placement.

We conducted a study to determine if there is any difference in fixation failure, deformation, or stiffness based on proximal placement. Using synthetic composite bones, we created a comminuted supracondylar distal femur fracture, AO/OTA (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association) 33-A3. Three groups of 9 femurs each were created: 1 correctly positioned group and 2 incorrectly positioned groups, 1 with the proximal aspect of the plate 1 cm anterior and 1 with the proximal aspect of the plate 1 cm posterior. The constructs were tested in axial, torsional, and cyclical axial modes to assess plastic and total deformation and stiffness.

Under axial loading, the posteriorly placed plate showed a 16.4% increase in stiffness. There was a significant increase of 12% in torsional stiffness in the anteriorly placed plate. Under cyclical axial loading, there was a significant increase of 14% in total deformation in the anteriorly placed plate. No fixation failure was observed.

One-centimeter variation in proximal placement of a 13-hole LISS plate in a synthetic composite fracture model had little effect on the overall construct.

Several surgical options are available for treatment of supracondylar and intercondylar distal femur fractures, AO/OTA (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association) type 33. Preserving the osseous blood supply via indirect reduction techniques has been shown to increase union rates without the need for bone grafting.[1,2] The Less-Invasive Stabilization System (LISS) made by Synthes (Paoli, Pennsylvania) melds minimally invasive internal fixation with multiple fixed-angle distal screws. It allows for submuscular placement, percutaneous unicortical screws in the diaphysis, and preservation of the metaphyseal fracture soft-tissue envelope.[3]

Proper lateral placement of the plate on the femur proximally can be difficult. Kregor and colleagues[3] noted that 6% of cases did not have ideal placement on the lateral shaft of the femur when the 13-hole LISS plate was used. They advocated making a small incision at the proximal end of the LISS plate to aid in proper lateral placement. Kolb and colleagues[4] noted that 2 of 31 patients had a "cutting out" of the proximal screws on LISS plates with anterior placement on the femur that eventually required repeat surgery in order to heal. This malpositioned plate was present at the end of the operation. These authors also recommended a proximal incision to avoid the issue. Schütz and colleagues[5] noted that there were 4 cases of implant loosening among 107 distal femur fractures treated with LISS plating and that the unicortical screws in the diaphysis had loosened. They suggested anterior placement of the plate as a possible reason for fixation failure.

Although several studies have noted proximal screw pullout, and proximal anterior malposition in the sagittal plane of the LISS plate has been suggested as a possible cause, we found no studies comparing incorrect proximal positioning on the femoral shaft with correct lateral placement of the LISS plate. Therefore, we used a previously established biomechanical model to compare LISS plates proximally placed either too anterior or too posterior to the direct lateral position on the femoral shaft. The constructs were tested in axial, torsional, and cyclical axial modes to assess plastic and total deformation, stiffness, and fixation failure.

Materials and Methods

Using fourth-generation femoral synthetic composite bones (Sawbones; Pacific Research Laboratories, Vashon, Washington) and a 13-hole Synthes femoral LISS plate, we made 3 groups of 9 specimens each, for a total of 27 femurs. The number of specimens was based on a power assessment in a study by Khalafi and colleagues.[8] Several studies have validated

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Figure 1. Fourth-generation femoral synthetic composite bones (Sawbones; Pacific Research Laboratories, Vashon, Washington) with 13-hole Less-Invasive Stabilization System (Synthes, Paoli, Pennsylvania) plate in (A) correct position, (B) anterior position, and (C) posterior position.

use of Sawbones instead of cadavers in biomechanical testing to prevent variability.[6-9] Proximal fixation was achieved with 5 unicortical screws (26 mm long) at screw holes 13, 11, 9, 7, and 4. All distal screw holes were filled for distal fixation with 75-mm-long screws to achieve bicortical fixation.

After application of the LISS plate, an AO/OTA 33-A3 fracture model was created in each specimen. A 1-cm gap was made 6 cm proximal to the intercondylar notch to create an unstable distal femur fracture pattern. In the method described by Zlowodzki and colleagues,[10] an additional 3-cm cut was made diagonally in the medial cortex to prevent contact of the bone during mechanical testing.

Three different plate positions were used. The correct group was placed directly laterally proximally (**Figure 1A**). One incorrect group was plated with the proximal aspect of the plate 1 cm anterior (anterior group) (**Figure 1B**), and another incorrect group was plated with the proximal aspect of the plate 1 cm posterior (posterior group) (**Figure 1C**). Anterior or posterior plate placement resulted in some of the proximal screws having a more tangential placement, with fewer screws engaged compared with the properly placed plate.

Figure 2. Setup for axial simulated loading.

The distal and proximal ends of each specimen were held to simulate the mechanical axis of the femur. This design was based on a model by Cordey and colleagues.[11] A materials testing system (MTS, Minneapolis, Minnesota) was used for mechanical testing of the model.

Based on the protocol of Khalafi and colleagues,[8] the models were tested in axial, torsional, and cyclical axial modes (**Figures 2, 3**). Axial loading consisted of a preload of 100 N followed by a compressive loading rate of 100 mm per minute in a displacement control mode. Testing was considered completed when 1 of 3 events occurred: 500 N was reached, the medial fracture gap closed, or fixation was lost. Torsional loading involved a preload of 5 Nm and subsequent torqueing at 20° per minute up to 20 Nm or loss of fixation or screw pullout.[8] Cyclical axial loading was based on protocols described by Marti and colleagues[2] and Zlowodzki and colleagues.[10] The initial load was 10 cycles of 300 N. Each subsequent load increment was increased by 100 N up to 1000 N, providing 10-second rest increments. This loading was conducted in a displacement control mode at 0.75 mm per second. Testing was aborted on fixation loss or complete closure of the medial fracture gap.

After testing was completed, statistically significant between-groups differences in plastic deformation and axial and torsional stiffness were determined by performing a Tukey-Kramer honestly significant difference test. Significance was set at $P \leq .05$.

Results

During axial loading, there was no visual loss of fixation or change in displacement of the fracture gap for any group, and there was no screw cut-out or pull-out from the cortex during testing. In 1 plate in the posterior group, the most proximal screw made only loose contact with the cortex at only the distal portion of the screw. There was no significant difference ($P = .9762$) in stiffness in axial loading between the anterior group and the correct group. There was a significant ($P = .0261$) 16.4% increase in stiffness in the posterior group compared with the correct group (**Table**).

There was no screw cut-out, fixation failure, or change in displacement of the fracture gap for any group during torsional loading. There was a statistically significant ($P = .0062$) 12% increase in mean torsional stiffness in the anterior group compared with the correct group. There was no statistically significant difference ($P = .1623$) between the posterior group and the correct group (**Table**).

For cyclical axial testing, total deformation and plastic de-

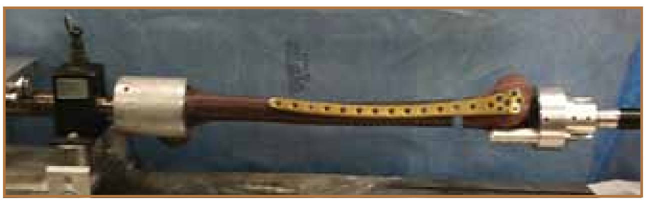

Figure 3. Setup for torsional simulated loading.

formation were obtained by determining displacement under the initial 100 N load in the static/resting state. That number was then subtracted from maximum displacement, the peak value on the time-versus-displacement graph, to obtain the value for total deformation. Plastic deformation was calculated by subtracting initial displacement from final displacement in the static/resting state. The static/resting state is represented by the dips in displacement after each cycle on the time-versus-displacement graph (**Figure 4**).

There was a statistically significant (P = .0207) 14% increase in total deformation of the anteriorly positioned plate compared with the correctly positioned plate. There was no statistically significant difference in total deformation between the posteriorly placed plates and the correctly placed plates (**Table**).

There was no significant difference in plastic deformation between any of the groups in this study. There was no screw cut-out or fixation loss in any group to suggest a clinically relevant difference based on proximal placement of the LISS plate.

Discussion

In evaluating the stability of various constructs for fixation of distal femur fractures, the literature is consistent in reporting stiffness as the key factor. Stiffness is determined most often in terms of motion at the fracture site, as measured by displacement under axial and torsional loads.[2,8,10,13] The LISS plate, which acts essentially as an "internal fixator" with proximal unicortical fixed-angle locking screws, has been shown to be comparable to other established methods of fixation.[10,12] Zlowodzki and colleagues[10] reported that the LISS plate had a higher load to failure when compared with angled blade plating and intramedullary nailing. Their study used fresh-frozen cadaver specimens from patients 70 years old or older. They concluded that, for distal femur fractures in osteoporotic bone, the LISS plate provided improved distal fixation.

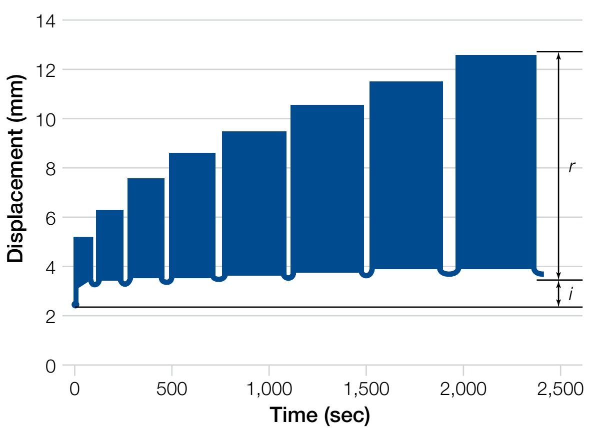

Figure 4. Typical time-versus-displacement curve. As demonstrated in previous studies, cyclical axial loading was performed with initial 300 N load being increased for 10 cycles in 8 increments. Each incremental increase was by 100 N up to maximum load of 1000 N.

In the present study, the posteriorly placed LISS plate outperformed the correctly placed plate in axial stiffness by 16.4%. However, there was no statistically significant difference in torsional stiffness and cyclical axial loading. This result is difficult to explain given that there was no screw cut-out or fixation loss for any of the constructs. Theoretically, with less proximal screw purchase in the posteriorly placed plate, the overall construct should be more susceptible to screw cut-out and fixation loss resulting in less axial stiffness overall.

Khalafi and colleagues[8] created a distal femur fracture model using Sawbones with a 1-cm fracture gap. Using the 9-hole LISS plate for fixation, they tested this construct under axial, torsional, and cyclical axial loads. They tested 2 groups of 9 femurs. For group 1, the LISS plate was placed in the correct position on the distal femur, with the proximal end in the correct position on the femoral shaft. In group 2, the LISS plate was rotated 1 cm anteriorly. They found that axial stiffness (N/mm) was 21.5% greater in the correctly positioned plate. The anteriorly positioned group demonstrated 55% more irreversible or plastic deformation. The authors concluded that correct positioning of the femoral LISS plate provided improved mechanical stability.

Table. **Axial and Torsional Stiffness and Total and Plastic Deformation of Femoral Less-Invasive Stabilization System Plate Constructs as a Function of Plate Position**

	Plate Position		
	Correct (n = 9)	Anterior (n = 9)	Posterior (n = 9)
Axial Stiffness, N/mm			
Mean	73.3	72.4	85.3
SD	5.7	7.0	12.9
Difference from correct placement	—	−0.9	12.0
P[a]	—	.9762	.0261
Torsional Stiffness, Nm/°			
Mean	1.7	1.9	1.6
SD	0.1	0.1	0.2
Difference	—	0.2	−0.1
P[a]	—	.0062	.1623
Total Deformation, mm			
Mean	10.6	12.1	10.1
Range	9.5-11.6	10.2-13.6	8.4-12.7
SD	0.8	1.1	1.3
Difference	—	1.5	−0.5
P[a]	—	.0207	.4222
Plastic Deformation, mm			
Mean	1.1	1.2	1.0
SD	0.1	0.3	0.1
Difference from correct placement	—	0.1	−0.1
P[a]	—	.7281	.3723

[a]Comparison of means using Tukey-Kramer honestly significant difference test; $P \leq .05$ is statistically significant.

Overall, our study results did not agree with those of Khalafi and colleagues[8] in terms of the mechanical stability of a malpositioned LISS plate. Our construct showed a significant increase in torsional stiffness in the anteriorly placed plate. However, our construct also showed a significant increase in total deformation in cyclical axial loading in the anteriorly placed plate. There was no increased plastic deformation in either of the incorrectly placed groups in our study. The difference in results between studies can best be explained by the difference in plate lengths. We used a 13-hole plate, and Khalafi and colleagues[8] used a 9-hole plate. Our theory is that the longer plate provided more resistance to relatively minor variations in plate position at the proximal end and thus resulted in less change in stiffness and stability around the fracture site.

Our model differed from that used in other biomechanical studies using Sawbones to simulate distal femur fractures in that it used the entire femur, including the proximal portion.[8,13] This setup theoretically resulted in a more anatomical weight distribution compared with other models, in which the proximal portion of the femur was potted in polymethylmethacrylate. This difference in weight distribution could explain the variation in our results compared with other biomechanical studies. In addition, with use of different boundary conditions, the distal femur had unconstrained distal motion similar to the native environment of the femur.

This study had several limitations. First is its relatively low power (9 femurs per group). Although groups of 9 specimens in 2 groups were used in the study by Khalafi and colleagues[8], testing a larger number of femurs could potentially identify more subtle differences between the 3 groups in our study. Second, given that femoral LISS plates come in different lengths, this study could be expanded to include the other plate sizes, as plate length could potentially play a role in stability at the fracture site. Third, though this Sawbones model has consistently reproduced the stability characteristics of human bone without variation between specimens, an osteoporotic model could be explored, as the femoral LISS plate is often used in osteoporotic fractures.[7,14]

Conclusion

Overall, our study results showed that 1-cm variations, anterior or posterior, had little effect on axial or torsional stiffness or plastic deformation under cyclical axial loading. Although these data can be promising for clinical application, the anterior placement of the LISS plate noted in failed fixation in other studies necessitates cautious interpretation of this study. Our use of a 13-hole (longer) plate, versus the 9-hole plate used in other studies, could explain the lack of variation between the 2 groups as well as the stability and tolerance of inappropriate placement. An osteoporotic model could help clinicians further discern the importance of accurate proximal placement of the femoral LISS plate.

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This paper will be judged for the Resident Writer's Award.