An Original Study

Biomechanical Evaluation of Locking Plate Fixation With Hybrid Screw Constructs in Analogue Humeri

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Abstract

Locking plates are well suited to complex fracture patterns and weak bone. In the study reported here, we compared the structural stability of 3 different locking compression plate (LCP) constructs using composite analogue humeri.

Eighteen analogue composite humeri were used as bone models. A 6.5-mm osteotomy gap was stabilized with a 9-hole 3.5-mm narrow LCP using four 3.5-mm self-tapping locking screws on each side of the fracture with the middle hole empty. Three construct configurations were studied: B (all screws bicortical), BU (bicortical screw on each side of fracture gap and remaining screws unicortical), and U (all screws unicortical). Each bone model was fixed in a customized jig and subjected to mediolateral and anteroposterior 4-point bending and external rotational torque to assess rigidity, stiffness, and failure.

There were significant (*P*<.05) differences in torsional stiffness but no significant differences in terms of flexural rigidity between each of the constructs. The results also indicated that construct BU provided as much stability as the other constructs. Therefore, consideration should be given to type of fixation construct, especially when torsional stability is required.

Replacing a single set of unicortical locking screws with bicortical locking screws closer to the fracture site improved construct stability compared with any unicortical screw construct. A hybrid fixation construct that provides bicortical screws at any location may provide equivalent construct stability in this model. Hybrid fixation constructs may provide adequate fracture stabilization for a fracture pattern that would typically be considered unstable.

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Locking plates—fixed-angle devices that provide internal fixation with minimal periosteal stripping—are well suited to complex fracture patterns and weak (osteopenic) bone. Use of locking plate systems obviates the need for extensive bony exposure because direct compression of the plate against the bone is not necessary for fracture stabilization. This system reduces damage to the already tenuous vascular supply associated with comminuted fractures or osteoporotic bone.[1] Few investigators have published data specifically addressing the stability of various locking plate constructs with different screw configurations for comminuted diaphyseal fractures. Unicortical locking screws are used clinically, but the precise indications for their use are unclear. The pertinent question is which locking-plate-and-screw configuration provides the most appropriate stability for fracture fixation. Evaluating 4 different types of locking plate configurations with 3 screws placed on either side of the osteotomy, Roberts and colleagues[2] found that hybrid fixations that replace the end screws of locking unicortical fixation with bicortical screws improved torsional stability significantly. However, it remains undetermined as to whether a hybrid fixation construct, that replaces the screws closer to the fracture gap with bicortical screws, will result in similar flexural and torsional stabilities to the constructs in which all screws are bicortical.

Commercially available mechanical analogue bone models are widely used for fracture fixation construct

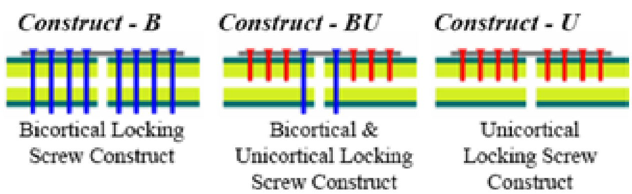


Figure 1. Three plate fixation constructs.

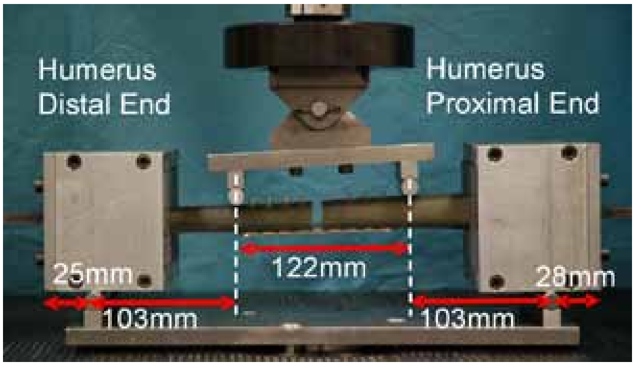


Figure 2. Experimental setup for anteroposterior 4-point bending.

evaluation. These analogue model bones, which are made from short-glass-fiber composite materials and have nearly isotropic cortical properties and consistent geometry and properties, provide a realistic model for surgical cutting and broaching, and allow for biomechanical analyses that otherwise could not be performed using human cadaveric fresh or formalin-fixed bones.[3] These analogue bone models also have the advantages of less interspecimen variability, easy availability, simple and safe handling, nondegradable properties, and consistency for standardization in biomechanical analyses.[3-5] We previously evaluated the Fourth-Generation (Pacific Research Laboratories, Vashon, Washington) analogue composite humerus for its diaphyseal structural properties and found that it performed within the physical properties of real bone with respect to failure strength, flexural rigidity, and torsional stiffness.[6]

The objective of the present study was to compare the flexural and torsional stabilities of 3 different locking plate constructs used for fixation of comminuted humeral diaphyseal fractures by using analogue humeri. Testing was performed in anteroposterior (AP) 4-point bending, mediolateral (ML) 4-point bending, and external rotation (torsion) with a materials testing system (MTS). For a given test mode, the null hypothesis for the present study was that a 3.5-mm narrow locking compression plate (LCP), with a bicortical locking screw placed closer to the fracture gap, and the remaining screws unicortical, would be at least as stiff as the same plate fixation with all bicortical locking screws but would also provide more stability than the constructs fixed with all unicortical screws alone.

Materials and Methods

Eighteen Fourth-Generation composite analogue humeri (model 3404) were used for each screw configuration, which was mechanically tested in vitro. Six specimens were tested for each category: unicortical locking, hybrid locking (bicortical locking screw placed closer to fracture gap and remaining screws unicortical), and bicortical locking. Six specimens for each category were chosen on the basis of previous study

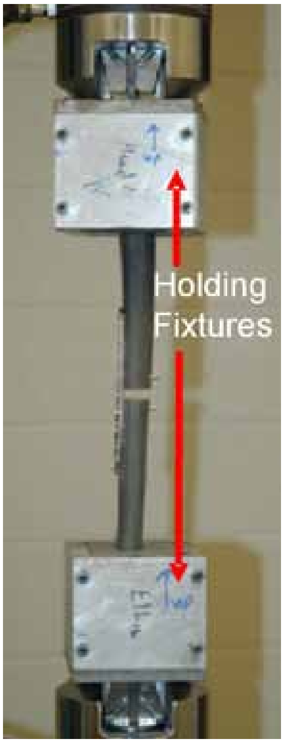


Figure 3. Experimental setup for external rotation torsion.

results[6,7] showing that these specimens have low variability between specimens for all loading regimens. The bone models were prepared for implantation by placing each composite humerus in a customized cutting jig and generating a standardized 6.5-mm osteotomy gap at the midshaft level. The gap was used to represent the worst-case scenario of a severely comminuted diaphyseal fracture, such that there were no contact points at either end of the fracture site and the fracture ends were not allowed to limit the deflection. Standard AO (Arbeitsgemeinschaft für Osteosynthesefragen) technique was used to fix with a 9-hole 3.5-mm narrow LCP (Synthes model 223.591; West Chester, Pennsylvania) to each fractured analogue humerus.

The customized cutting jig was also used to standardize the implantation location for all specimens by anchoring the locking plate with a nonlocking screw through the central hole of the locking plate, which was left empty, into the predetermined center of the cutting jig. Three different plate fixation constructs (Figure 1) were investigated. Construct B specimens were fixed posteriorly with an LCP with four 3.5-mm bicortical self-tapping locking screws (Synthes Recess 30 mm, model 212.111) on each side of the gap with the central hole left empty; construct BU specimens were fixed posteriorly with an LCP with a 3.5-mm self-tapping bicortical locking screw on each side of the gap with the central hole left empty and three 3.5-mm self-tapping unicortical locking screws (Synthes Recess 14 mm, model 212.103) at both sides of the bicortical locking screws; and construct U specimens were fixed posteriorly with an LCP with four 3.5-mm self-tapping unicortical locking screws on each side of the gap with the central hole left empty. The same surgeon placed each specimen for all the constructs in the same manner using the standard surgical instrumentation designed for the LCP system.

Each plate fixation construct was tested under bending and torsional loading in a servohydraulic MTS (Bionix model 858; MTS Systems Corporation, Eden Prairie, Minnesota). Load and deflection or torque and rotation angle data were measured and collected by the MTS. The load/deflection or torque/rotation slope was calculated by linear regression. Means and standard

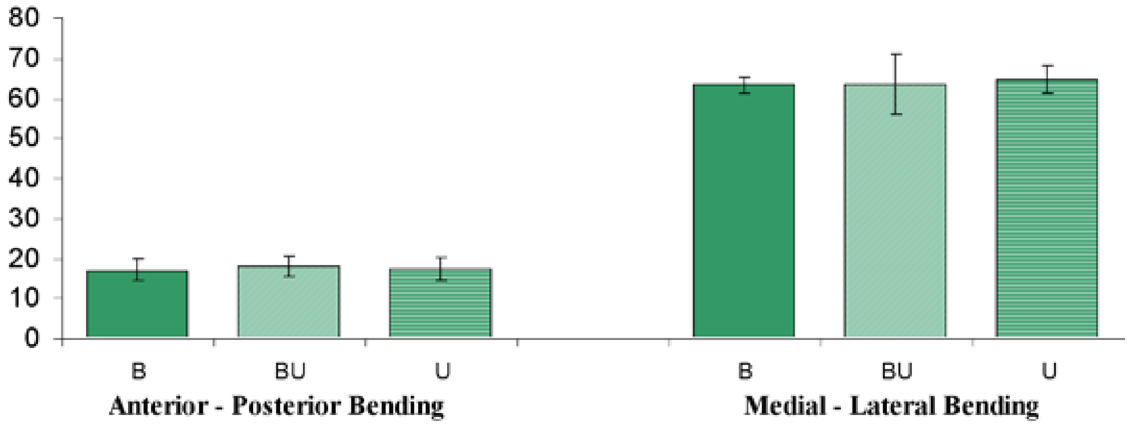


Figure 4. Construct flexural stability results for construct with all screws bicortical (B), construct with bicortical screw on each side of fracture gap and rest of screws unicortical (BU), and construct with all screws unicortical (U).

deviations of the series were calculated for each type of construct in the corresponding test, and each specimen was tested in random order for AP bending, ML bending, and external rotation torque.

Flexural Rigidity Test

A 4-point bend test, with 328 mm between outer loading points and 122 mm between the inner loading points, was used to determine the flexural rigidity in the AP and ML tests. A customized holding fixture, in which both ends of the analogue humeri were locked in aluminum-filled epoxy (Ren Epoxy model RP 200 R/H; Freeman Mfg & Supply Co, Avon, Ohio) casted blocks, was used to standardize the testing position (Figure 2). The mid-diaphysis of each humerus was measured along its longitudinal axis and marked for alignment with the bending jig. Each specimen was aligned at the center of the 4-point bending fixture, and either the posterior surface or the lateral surface was positioned in tension. The ML plane was defined as the plane between the medial and lateral humeral epicondyles, and the AP plane was tangent to the ML plane. The central loading piston was coupled to a hinge joint to allow for self-alignment of the inner loading points during the test, and the customized holding fixture was not constrained at the bottom outer loading points to allow for rotation and translation motion.

Each specimen was loaded in 4-point bending from 15 N to 150 N at a loading rate of 50 N/s, corresponding to bending moments of 1.5 Nm to 15.5 Nm. Testing was initiated with 2 preconditioning loading cycles and then followed by 4 data collection loading cycles while force and displacement data were collected every 0.1 second. This procedure was repeated 6 times for each specimen for each surface, removing and repositioning the specimen every 2 times.

The load-deflection slope was converted to apparent flexural rigidity (EI) with the equation $EI = (4.59/12) \times SC^3$, where E (N/m^2) is the elastic modulus, I (m^4) is the moment of inertia, S (N/m) is the slope of the load-deflection curve, and C is the distance between inner and outer support (0.103 m).

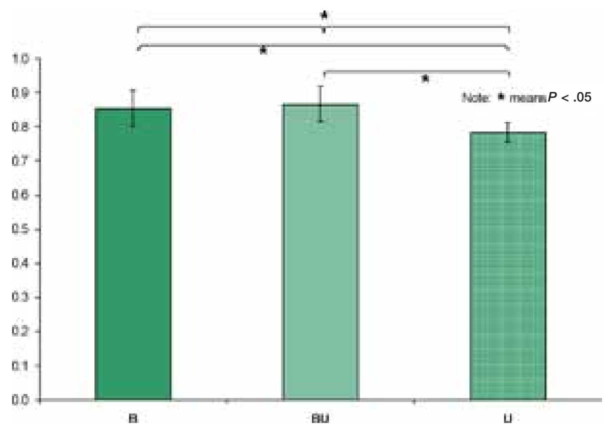


Figure 5. Construct torsional stability results for construct with all screws bicortical (B), construct with bicortical screw on each side of fracture gap and rest of screws unicortical (BU), and construct with all screws unicortical (U).

Torsional Stiffness Test

Torsional stiffness was determined by proximally and distally locking the specimens in the customized holding fixtures used in the flexural rigidity test, with an exposed length of 23.3 cm in the middle (Figure 3). The holding fixtures were positioned on and secured to the actuator of the MTS with hydraulic grips, and the axis of the alignment was checked carefully with the longitudinal axis of the diaphysis.

Each specimen was axially loaded to –15 N (under load control), and then torque was applied from –10 Nm to +10 Nm at a loading rate of 0.25 Nm/s. Testing was initiated with 2 preconditioning torque cycles, and then torque and rotation angle were recorded every 0.1 second for the next 4 cycles. This procedure was repeated 6 times for each specimen while removing and repositioning the specimen every 2 times. Mean torsional stiffness was calculated as torque-rotation slope (Nm/°) multiplied by specimen exposed length (0.23 m).

Table. Differences Between Flexural and Torsional Stability of the 3 Constructs

Stability Parameter	Construct Comparison	*P* Value	Overall *P* Value
Anteroposterior	B vs BU	.302	.548
	B vs U	.806	
	BU vs U	.425	
Mediolateral	B vs BU	.995	.873
	B vs U		.655
	BU vs U	.659	
Torsion	B vs BU	.633	.018
	B vs U		.022
	BU vs U	.008	

Abbreviations: B, construct with all screws bicortical; BU, construct with bicortical screw on each side of fracture gap and rest of screws unicortical; U, construct with all screws unicortical.

Failure Test of Plate-Fixed Specimens

After flexural rigidity and torsional stiffness testing was completed for all plate fixation constructs, 2 samples of each construct were tested and analyzed for ultimate strength in AP 4-point bending, ML 4-point bending, and torsion. The protocol for the AP and ML 4-point bending failure tests was similar to that for the flexural rigidity test. Each specimen was loaded from 15 N to complete structural failure at a rate of 50 N/s. Testing was initiated with 2 preconditioning loading cycles from 15 N to 150 N at a rate of 50 N/s, and then the load was applied continuously until failure while force and displacement data were collected every 0.1 second.

The protocol for the torsional failure test was similar to that for the torsional stiffness test. Each specimen was axially loaded to –15 N (under load control), and then external rotational torque was applied from 0 Nm to complete structural failure at a loading rate of 0.25 °/s. Two preconditioning loading cycles were initiated from 0 Nm to 15 Nm at a rate of 0.25 Nm/s, followed by continuous data collection of rotational angle and torque every 0.1 second until failure. We defined specimen breakage, screw pull-out, plate failure, or fixation loss as "clinical failure."

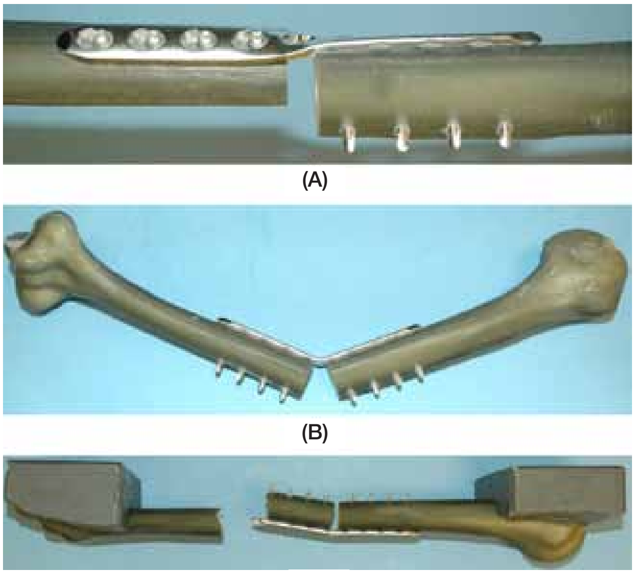
Statistical Analysis

General linear modeling with SPSS version 16.0 (SPSS, Chicago, Illinois) was used to compare the flexural and torsional stability of the 3 different plate fixation constructs, and post hoc analysis was performed with the least significant difference (LSD) test for multiple comparisons. Level of significant difference was defined as $P<.05$. Sample power analysis was performed with SPSS SamplePower version 2.0 for comparison of the construct stiffness/rigidity from the 3 plate fixation constructs.

Results

Overall, all 3 constructs exhibited significant (P=.018) differences in torsional stiffness but comparable stability in terms of flexural rigidity. Figures 4 and 5 show the flexural rigidity and torsional stiffness of the 3 different plate fixation constructs, respectively. The Table summarizes the differences between the flexural and torsional stability of the 3 constructs.

Comparison of the flexural rigidity of the 3 different plate fixation constructs revealed no significant differences with respect to AP or ML flexural rigidity (Table). Mean flexural rigidity of AP and ML bending was 17.4 Nm^2 (range, 16.3-21.1 Nm^2) and 63.8 Nm^2 (range, 53.8-72.9 Nm^2), respectively. Retrospective analysis showed that the statistical power for the AP and ML flexural rigidity test was more than 89% (AP, 89%; ML, 100%). There was a significant (P=.018) difference between the torsional stiffness of the 3 different plate fixation constructs. Post hoc comparisons revealed that only construct U torsional stiffness exhibited a significant (B vs U, P=.013; BU vs U, P=.008) difference compared with the other 2 constructs. Retrospective analysis showed that the statistical power for the torsional stiffness test was 100%. According to statistical analysis, construct BU provided as much stability, both flexural



(A) (B) (C)

Figure 6. Modes of locking plate failure for torsional and 3-point bending tests: (A) external rotation torque failure, (B) mediolateral bending failure, (C) anteroposterior bending failure.

rigidity and torsional stiffness, as construct B in the analogue humerus, and construct U provided as much stability as constructs B and BU with respect to flexural rigidity but not torsional stiffness where a significant (P<.05) difference was observed. Therefore, the results indicate that consideration should be given to which type of fixation construct should be selected, particularly when torsional stability is required.

In all the completed construct failure tests, the locking plate failed before the analogue humerus did (plate bent in 4-point bending test, plate twisted in torsional test; Figure 6), and screw pull-out or specimen breakage was observed in none of the specimens. The results indicated that the plate yielded at about 200 N in AP bending, at about 600 N in ML bending, and at about 11 Nm in torsion.

Discussion

The advantage of a locking plate system over a conventional plate system is reduced periosteal vascular disruption (stable fracture fixation no longer relies on plate contact with bone).[1,8] The locking plate system acts as an internal fixator, providing both angular and axial stability, whereas conventional plate systems depend on plate–bone contact and screw purchase.[9] An LCP construct may be particularly advantageous in certain situations in which operative fixation of the fracture is required—such as comminuted fractures in which the blood supply is compromised, fractures in weaker (osteopenic) bone, and polytrauma cases.[10-12]

In the current standard of humeral plating for fixation of comminuted humeral diaphyseal fractures, based on Stannard and colleagues,[13] a 4.5-mm dynamic compression plate with appropriate length is typically used, and 6 to 8 cortices above and below the fracture site are recommended. Healy and colleagues[14] recommended at least 6 cortices above and below, whereas Micic and colleagues[15] used 8 cortices above and below to fix failed 6-cortice treatment. The model in our study assumed humeral diaphyseal fractures for a smaller person; therefore, we used a 9-hole 3.5-mm narrow LCP with 8 cortices above and below the fracture site. Sheerin and colleagues[16] reported that 3.5-mm plates have been used with either nonlocking or locking screws with encouraging results. When composite, homogeneous bone models were used, the variation in results remained low; however, our testing model was designed to examine the worst-case scenario and help understand the stability of fracture fixation with a bicortical locking screw placed closer to the fracture gap and the remaining screws unicortical.

Several studies similar to ours were reported as comparing locking and nonlocking screws, screw hybrids (1 standard screw in hole nearest osteotomy site plus 2 screws locked distally in each fragment), or hybrids that replace the end screws of a locking unicortical fixation with bicortical fixation in the humeral shaft.[2,9,17,18] Roberts and colleagues[2] found that replacing a single set of unicortical locking screws with locking or nonlocking bicortical screws distant from the fracture site improved torsional construct stability more than 50%, providing stability equal to that of standard nonlocking plates; they also found a mean (SD) of 0.43 (0.02) Nm/° for their hybrid constructs. Gardner and colleagues[17] found that the hybrid of 1 standard screw in the hole nearest the osteotomy site and 2 screws locked distally in each fragment is mechanically similar to locking constructs, and both are significantly more stable than nonlocking constructs under torsional cyclic loading; they also found a mean (SD) of 0.46 (0.07) Nm/° for their hybrid constructs. However, both Roberts and colleagues[2] and Gardner and colleagues[17] used only 6 cortices above and below the fracture site; therefore, the results of their studies are not directly comparable to ours because we used 8 cortices above and below the fracture site. Nevertheless, we found significantly improved (>50%) torsional stability in constructs with 8 cortices above and below the fracture site compared with 6 cortices above and below the fracture site for both all-unicortical and all-bicortical screw fixation.

O'Toole and colleagues[18] also used 8 cortices above and below the fracture site with either locking or nonlocking screws in both synthetic and cadaveric bone. Their resulting mean torsional stiffness for bicortical locking screws in cadaveric bone was 0.85 Nm/°; the mean for our construct B, using a synthetic bone model, was also found to be 0.85 Nm/°.

Fulkerson and colleagues[9] compared conventional plate fixation with locking plate fixation of a comminuted diaphyseal fracture of synthetic osteoporotic ulnae. Their biomechanical study compared various constructs after cyclic axial loading and 3-point bending. Their results showed that bicortical locking screws with minimal displacement from the bone provided the most stable construct—the result of the increased working length of the locking screws, as demonstrated by Stoffel and colleagues.[19] Our findings closely agree with those of Fulkerson and colleagues[9] and Stoffel and colleagues[19] in that the bicortical locking screw constructs proved more stable than the unicortical locking screw construct. Roberts and colleagues[2] conducted a biomechanical study comparing unicortical locking fixation with mixed bicortical–unicortical fixation in a sawbone radius model, and their results indicated that hybrid fixations that replaced the end screws of unicortical locking fixation with bicortical screws improved torsional stability. Our results, however, also demonstrated that the hybrid fixation construct that replaced the screws closest to the fracture gap with bicortical screws (construct BU) provided as much stability as exclusive bicortical locking screw constructs in analogue humeri. Therefore, we are confident that any hybrid fixation construct that replaces the screws of unicortical locking fixation at any location with bicortical screws will provide equivalent or superior construct stability.

In this study, we have demonstrated that a unicortical locking construct provides as much stability as bicortical and mixed bicortical–unicortical locking constructs in the analogue humerus only in terms of flexural rigidity, not torsional stiffness. Cadaveric humeri were not used in this study because the variation in bone quality would have added a confounding effect; furthermore, analogue humeri have uniform interspecimen mechanical properties, which enabled us to more accurately compare stability based on fixation constructs. Results of laboratory studies, however, cannot readily be extrapolated to clinical situations, and follow-up in vivo study is needed to confirm the clinical relevance of our findings. Furthermore, specific studies on screw constructs in osteoporotic bone would likely yield important information regarding fracture fixation stability in patients who may benefit most from LCPs.

The humerus is not a weight-bearing long bone in the same sense as the femur and the tibia; it is mainly subject to bending and torsional forces. However, the humerus is subject to more rotation forces and minor axial loading. Henley and colleagues[20] found that the human humerus has a mean (SD) torsional stiffness of 0.26 (0.11) Nm/°. Even though a significant (B vs U, $P = .013$; BU vs U, $P = .008$) difference in torsional stiffness was detected between construct U and the other 2 constructs, the magnitude of the difference in stiffness is much higher than the mean human torsional stiffness. Therefore, this observed small change in torsional stiffness is in fact not that meaningful clinically. Further clinical research is needed to confirm our results.

This study has some limitations. Our model assumed an unstable fracture pattern in a worst-case scenario of cortical bone loss or extensive comminution in which angular deflection would be limited only by plate fixation construct and position. We recognize that, in some fracture patterns, cortical contact of the humeri would add to the stability of the bone–implant construct, but we were examining the worst-case scenario. Another obvious limitation is that synthetic bone models were used. Studies of this nature do not account for the biological factors that contribute to fracture healing and the soft-tissue attachment effects on structural properties. In addition, synthetic bone models simulate adult healthy bone. Although construct BU provided satisfactory stable fixation in this test model, this construct may perform more dramatically in osteoporotic bone. One other limitation was absence of cyclic loading tests. We recognize that, during cyclic loading tests, the construct is likely to decrease the life of the implant. Therefore, testing by cycling loading for the 3 different locking plate constructs used for fixation of comminuted humeral diaphyseal fractures would be the next step in assessing fracture fixation stability.

In summary, findings from this study showed that, when a locking device is used, the hybrid fixation construct that replaces the screws closer to the fracture gap with bicortical screws may provide the necessary biomechanical stability for satisfactory fixation and clinical benefit.

Authors' Disclosure Statement and Acknowledgments

The authors report no actual or potential conflict of interest in relation to this article.

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