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Effects of Construct Stiffness on Healing of Fractures Stabilized with Locking Plates

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Introduction

The benefits of locked-plate fixation, which include improved fixation strength in osteoporotic bone and the ability to provide a more biologically friendly fixation construct, have led to the rapid adoption of this technology. Biological fixation of comminuted fractures with locking plates relies on secondary fracture-healing by callus formation, which is stimulated by interfragmentary motion in the millimeter range. Secondary bone-healing can be enhanced by active or passive dynamization. Conversely, bone-healing can be suppressed by rigid fracture fixation aimed at preventing interfragmentary motion.

Biomechanical studies have suggested that locked-plate constructs are stiff and suppress interfragmentary motion to a level that may be insufficient to reliably promote secondary fracture-healing. Recent clinical studies substantiate the concern that the inherently high stiffness of locked-plate constructs suppresses callus formation, contributing to a nonunion rate of up to 19% seen with periarticular locking plates. Deficient healing may also contribute to late hardware failures seen with locking plates since, in the absence of osseous union, constructs remain load-bearing and eventually fail by hardware fatigue or loss of fixation.

This paper summarizes a line of research that addresses two questions of critical importance when using locked-plate constructs:

1. Does the high stiffness of locked-plate constructs suppress callus formation and fracture-healing?
2. Can a stiffness-reduced locked-plate technique, termed far cortical locking, improve fracture-healing, compared with standard locked plating, by providing flexible fixation and parallel interfragmentary motion?

First, we will present the findings of biomechanical and clinical studies of the effect of construct stiffness on interfragmentary motion and fracture-healing with locking plates. Subsequently, studies that describe the function, benefits, and clinical application of far cortical locking are summarized.

Numerical results are presented as the mean and one standard deviation. Unless otherwise noted, statistical differences were tested with use of a two-tailed, unpaired Student t test at a level of significance of \( \alpha = 0.05 \).

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The Challenge: Construct Stiffness

Are Locked-Plate Constructs Too Stiff to Reliably Promote Fracture-Healing?

The stiffness of a fixation construct is a principal determinant of fracture-site motion and thereby affects the mechanism and progression of fracture-healing. Stiffness describes the flexibility of a fixation construct and is used to estimate interfragmentary motion in the early healing phase. Stiffness is simply calculated by dividing an applied load by the resulting displacement. However, reported stiffness values for the same implant can vary by more than one order of magnitude since they are highly influenced by the test setup, especially when stiffness is calculated from the displacement of the loading actuator. Actuator displacement represents deformation along the entire test specimen and can grossly overestimate the actual motion at the fracture site. On the basis of actuator displacement, construct stiffness of femoral locking plates has been reported to range from 63 N/mm² to 159 N/mm². This stiffness is comparable with that of external fixators (50 to 400 N/mm²), which are known to promote fracture-healing by callus formation. However, investigators who have measured the actual fracture-site motion at the far cortex (opposite the plate) have reported a more than tenfold higher stiffness (833 N/mm² to 2100 N/mm²) for locked femoral bridge-plate constructs. Furthermore, flexion of a bridging plate causes asymmetric gap closure, whereby interfragmentary motion...

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decreases with a decrease in the distance to the plate. Hence, the effective motion at the near cortex (adjacent to the plate) is considerably smaller than it is at the far cortex.

To assess if locked-plate constructs are too stiff to promote secondary bone-healing by callus formation, interfragmentary motion of bridge-plate constructs was measured at the near and far cortices in a biomechanical study.

**Methods**

Five locked-plate constructs were applied to bridge a 10-mm-gap osteotomy site in femoral diaphysis surrogates to characterize their stiffness and the resulting interfragmentary motion. Additionally, five nonlocked conventional-plate constructs were tested for baseline comparison. All constructs consisted of a generic 4.5-mm titanium eleven-hole plate and bicortical screws (Fig. 1, a). Proximal diaphyseal fixation was achieved with three locked screws (locked-plate group) or nonlocked screws (conventional-plate group), placed in the first, third, and fifth plate-holes (Fig. 1, b). The locking plates were applied at a 1-mm elevation to simulate biological fixation with preservation of periosteal perfusion. Compressive loading was applied through a ball bearing proximally, while the distal part of the diaphysis was rigidly fixed to the base of a materials testing system (Instron 8874; Instron, Canton, Massachusetts) (Fig. 1, c). Construct stiffness was assessed in terms of the amount of osteotomy gap closure in response to a 400-N load representative of postoperative toe-touch weight-bearing. Gap closure was measured at the near and far cortices with use of two miniature digital calipers (KSLR4610; Blitz, Jeffersonville, Indiana) with 0.01-mm accuracy to assess the magnitude and symmetry of interfragmentary motion.

**Results**

The axial stiffness of the locked-plate constructs (3.3 ± 0.1 kN/mm) was not significantly lower than that of the conventional-plate constructs (3.4 ± 0.2 kN/mm, p = 0.35) (Fig. 2, a). In both constructs, axial loading induced asymmetric gap closure as a result of plate-bending, with gap motion being attenuated toward the near cortex underlying the plate (Fig. 2, b). Gap motion in response to 400-N simulated toe-touch weight-bearing was <0.1 mm at the near cortex and remained below the motion window of 0.2 to 1 mm known to promote callus formation (Fig. 2, c).

**Conclusions**

Locked-plate constructs are as stiff as nonlocked-plate constructs in compression testing, and they are one order of magnitude stiffer than external fixators are in compression. Interfragmentary motion of locked-bridge-plate constructs is asymmetric, and is minimal at the near cortex underlying the plate. Postoperative interfragmentary motion provided by locked plates may therefore be too small to promote callus formation, especially at the near cortex.

**Clinical Evidence: Inconsistent Healing**

Locked Plates Lead to Inconsistent and Asymmetric Callus Formation

Fractures of the distal part of the femur are commonly treated with locked-plate constructs. Initial reports of
locked-plate constructs in the distal part of the femur showed high union rates with relatively few complications. Later studies, evaluating both unicortical and bicortical diaphyseal fixation constructs, demonstrated mixed results. Some showed excellent outcomes, while others demonstrated nonunion rates of 2% to 17%. The authors of some of these studies reported late failures of diaphyseal fixation and implants but did not include them in the nonunion rates. However, 52% of the implant failures in eight studies in which the authors reported the timing of these failures occurred more than six months after the index procedure, indicating that the failure was the result of implant fatigue in the presence of an established nonunion. Proper identification of late implant failures as nonunions in studies of locked plates should further raise the concern that locked-plate constructs may be too stiff to promote reliable healing.

Methods
Seventy-two adult patients with a total of seventy-five distal femoral fractures (AO 32A or 33A, B, or C) were treated with a titanium or stainless-steel locking plate between 2003 and 2008 at two institutions. Lateral and anteroposterior radiographs, along with patient charts, were reviewed at six weeks, three months, and six months postoperatively. Nonunion was defined as painful weight-bearing and the absence of progressive fracture-healing or bridging callus at the medial cortex on serial radiographs. Periosteal callus was measured on the medial, anterior, and posterior cortices with use of custom software to objectively extract callus size from radiographs without manual tracing of callus boundaries. This software was rigorously validated and was found to measure callus area in surrogate models with an error of <5%

Results
There were complications following treatment in twenty-nine (39%) of the seventy-five fractures, and fourteen (19%) of the seventy-five fractures failed to heal. Comparison of the fracture-healing and fracture-nonunion groups revealed no significant differences in terms of the rates of smoking, diabetes, open or closed fractures, or infections or in the injury severity scores. Nonunions had 65% less callus than all remaining fractures (p = 0.035).

At six months, the size of the periosteal callus ranged from 0 to 670 mm² (Fig. 3), and 37% of all fractures had little or no callus (<20 mm²). Over all time points, the medial cortices had 64% more callus than the anterior or posterior cortices (p = 0.001); fractures treated with a titanium plate had 68% more callus than those treated with a stainless-steel plate (p < 0.001); and there was no correlation between a longer bridging span and a greater callus size (r = 0.04, p = 0.4).

Conclusions
This study provided clinical evidence that locked-plate constructs may be too stiff to reliably promote fracture-healing. The 19% of the femoral fractures that became nonunions exhibited less callus formation, while stable implant alignment was maintained. This suggests that callus inhibition, rather
than implant failure, is the primary cause of these nonunions. Callus inhibition was readily apparent six months after surgery, as 37% of all fractures had no or very little callus. Callus formation was most inhibited closer to the plate, where the asymmetric gap closure characteristic of bridge-plate constructs causes the least interfragmentary motion.

It has been suggested that the stiffness of locked-plate constructs can be reduced by using longer bridging spans\textsuperscript{42}. However, this study\textsuperscript{17} showed that longer bridging spans correlated poorly with increased callus formation. Titanium plates, which are twice as flexible as stainless-steel plates, were associated with 68% more callus formation. Nevertheless, 26% of the fracture sites stabilized with a titanium plate had deficient callus formation at six months. This finding suggests that a further reduction in plate stiffness is required to decrease the incidence of deficient callus formation leading to fracture nonunion.

**Solution: Far Cortical Locking**

Far Cortical Locking Reduces Construct Stiffness While Maintaining Construct Strength

Several strategies to reduce the stiffness of locked-plate constructs have been proposed, including the use of thinner plates, increasing the plate elevation from the bone surface, using slotted holes in the near cortex, and increasing the plate span\textsuperscript{44}. However, either a reduction in stiffness is gained at the cost of construct strength or stiffness remains insufficient to promote bone-healing by callus formation. Far cortical locking was introduced as an alternative strategy to reduce the stiffness of a locked-plate construct without reducing its strength\textsuperscript{13}. Far-cortical-locking screws lock into the plate and the far cortex of a diaphysis and have a reduced midshaft diameter to bypass the near cortex (Fig. 4, \(a\)). Therefore, far-cortical-locking screws have an increased working length, allowing for elastic cantilever bending of the screw shaft within a controlled motion envelope (\(\Delta d\)) in the near cortex. Analogous to external fixators, far-cortical-locking constructs derive flexible fixation and parallel interfragmentary motion from elastic flexion of screw shafts (Fig. 4, \(b\) and \(c\)). Under elevated loading, contact of the far-cortical-locking screw shaft at the near cortex provides additional support and load-sharing with the near cortex. The ability of far-cortical-locking screws to reduce the stiffness of a locked-plate construct while retaining its strength was formally evaluated in a bench-top study of surrogates of normal and osteoporotic bone\textsuperscript{13}.

**Methods**

Locked-plate constructs and far-cortical-locking constructs were tested in a diaphyseal bridge-plate configuration under axial compression, torsion, and bending. Generic 4.5-mm locking plates and screws made of titanium alloy were used in all constructs. The far cortical locking was done with locking screws that had a smooth shaft with a 3.2-mm diameter to bypass the near cortex. Plates were applied at a 1-mm elevation from the bone with three screws placed proximally in the first, third, and fifth screw holes from the fracture site and with one hole left empty over the 10-mm osteotomy gap. First, the stiffness of the locked-plate and far-cortical-locking constructs were measured.
was determined in each principal loading mode in surrogates of a non-osteoporotic femoral diaphysis. Subsequently, the constructs were tested to failure in each loading mode under progressive dynamic loading to determine their strength. Finally, failure tests were repeated in a validated model of an osteoporotic femoral diaphysis to determine construct strength in a worst-case scenario of bridge-plate fixation in osteoporotic bone. Each loading mode and construct was tested in five specimens.

Results
The stiffness of the far-cortical-locking constructs was 88% lower than that of the standard locked-plate constructs under axial compression up to 400 N. At elevated loading, near-cortex support of the far-cortical-locking screws provided a sixfold increase in stiffness. The resulting biphasic stiffness of the far-cortical-locking constructs (Fig. 5, a) resembled the progressive-stiffening behavior characteristic of Ilizarov external fixators. In torsion and bending, the far-cortical-locking constructs provided a 58% and 29% reduction in stiffness, respectively, compared with that of the locked-plate constructs.

Interfragmentary motion of the far-cortical-locking constructs in response to 200 N of loading was nearly parallel (0.51 mm and 0.59 mm at the near and far cortices, respectively). Under the same loading, locked-plate constructs yielded less motion, and motion was significantly smaller at the near cortex (0.02 mm) than at the far cortex (0.05 mm, p < 0.01).

In the non-osteoporotic diaphysis, the strength of the far-cortical-locking constructs was 7% lower in compression, 54% higher in torsion, and 21% higher in bending compared with that of the locked-plate constructs. In the osteoporotic diaphysis, the strength of the far-cortical-locking constructs was 16% lower in compression, 9% higher in torsion, and 20% higher in bending compared with that in the locked-plate constructs.

Conclusions
The results of this study demonstrate that far-cortical-locking constructs combine three key factors aimed at promoting secondary bone-healing with locking plates: stiffness reduction, parallel interfragmentary motion, and progressive stiffening. Far-cortical-locking screws reduce the initial stiffness of a locked-plate construct to that of an external fixator. Far-cortical-locking constructs deliver nearly parallel interfragmentary motion within the 0.2 to 1-mm range, which is known to promote callus formation. Progressive stiffening of far-cortical-locking constructs provides a low initial stiffness, enabling interfragmentary motion under reduced postoperative weight-bearing, while increased secondary stiffness.
provides progressive stabilization at elevated loads. The far-cortical-locking constructs retained at least 84% of the axial strength of the locked-plate constructs and were up to 54% stronger in torsion and up to 21% stronger in bending than the locked-plate constructs. The considerable strength increase in torsion and bending may be attributed to evenly distributed load-sharing among all of the far-cortical-locking screws (Fig. 5, b). In contrast, the end-screw of a standard locked construct induces a stress riser, which reduces the construct strength in bending and torsion. In summary, far-cortical-locking constructs resemble “internal fixators” that combine the benefits of fixed-angle stabilization with flexible fixation for promotion of fracture-healing by callus formation.

**Benefits: Improved Healing**

*Far Cortical Locking Leads to Stronger and More Consistent Fracture-Healing*

Determining the effects of construct stiffness on fracture-healing is of central importance to improve clinical outcomes associated with locking plates. Analyzing fracture-healing in clinical studies is complicated by the inherent variability in fracture patterns, quality of fracture reduction and fixation, associated soft-tissue injuries, and patient comorbidities. For over three decades, an ovine tibial osteotomy model has been successfully employed to investigate fracture-healing in a controlled environment, but the model had not been used to study locking plates. In a recent study, the ovine fracture-healing model was employed to evaluate healing of fractures stabilized with a locked-plate construct and a far-cortical-locking construct to test the hypothesis that a stiffness-reduced far-cortical-locking construct can improve fracture-healing compared with that associated with a standard locked-plate construct.

**Methods**

In an established ovine fracture-healing model, tibial osteotomies with a 3-mm gap were performed in twelve sheep and were randomly stabilized with a locked-plate or far-cortical-locking construct (Fig. 6, a). Each construct used the same 4.5-mm titanium locking plate, which was applied either with six locking screws (the locked-plate group) or with six far-cortical-locking screws (the far-cortical-locking group). Compared with the locked-plate constructs, the far-cortical-locking constructs had an 84% lower initial stiffness and provided parallel interfragmentary motion. Progression of fracture-healing was monitored on weekly radiographs. After the animals were killed at week 9, the implants were removed and the callus volume and density were measured with quantitative computed tomography. The mechanical strength of the healed tibiae was assessed with torsion testing to failure in a materials testing system.
Finally, callus formation and bridging were analyzed on histological cross sections, harvested from the midsagittal plane of each callus specimen.

Results
The callus seen on the weekly radiographs was significantly greater in the far-cortical-locking group than it was in the locked-plate group from weeks 4 to 9 ($p = 0.004$). At week 9, the far-cortical-locking group had 36% more callus ($p = 0.03$) and 44% more bone mineral content ($p = 0.01$) than did the locked-plate group. Callus formed symmetrically in the far-cortical-locking group, and there was comparable bone mineral content at the near and far cortices in that group ($p = 0.91$). In the locked-plate group, callus formed asymmetrically, with 49% less bone mineral content at the near cortex than at the far cortex ($p = 0.003$). Loading the healed tibiae to failure demonstrated that, compared with the locked-plate specimens, the far-cortical-locking specimens were 54% stronger ($p = 0.023$) and tolerated 156% more energy until failure ($p < 0.001$) (Fig. 6, b). Histological sections depicted “partial nonunions,” whereby bridging callus did not form at the near cortex, at the sites of three of the six locked-plate constructs (Fig. 7). In the far-cortical-locking group, bridging callus formed at the near and far cortices in all specimens.

Conclusions
This study confirms that standard locked-plate constructs can lead to inconsistent and asymmetric callus formation, whereby fracture-healing is attenuated toward the near cortex adjacent to the plate. Deficient healing is likely caused by the high stiffness and asymmetric gap closure of locked-plate constructs. This study further confirmed that far-cortical-locking constructs actively promote fracture-healing by providing flexible fixation and parallel interfragmentary motion. Compared with locked-plate constructs, far-cortical-locking constructs were associated with more callus formation as well as healing with a stronger osseous union, and they effectively prevented the partial nonunions seen with the locked-plate constructs. Therefore, it was concluded that far-cortical-locking fixation may be advisable for reduction of the stiffness of locked-plate constructs to improve fracture-healing.

Clinical Application: Periarticular Plates
Far-Cortical-Locking Fixation with Periarticular Distal Femoral Plates

When used for periarticular distal femoral plate fixation, far-cortical-locking screws can readily be applied to the diaphyseal side of the fracture but not to metaphyseal fragments, where fixation in the far cortex cannot be obtained. Therefore, a cadaveric study was conducted to evaluate the efficacy of a hybrid far-cortical-locking construct for periarticular plate fixation whereby far-cortical-locking screws are used for diaphyseal fixation and conventional locking screws are used for metaphyseal fixation with a standard technique. We hypothesized that, compared with a standard locked plate, diaphyseal fixation of a periarticular femoral plate with far-
cortical-locking screws would reduce construct stiffness and induce parallel interfragmentary motion without decreasing construct strength.

Methods
Distal femoral fractures (AO/OTA A33-3) were simulated with use of a 1-cm-gap osteotomy in twenty-two paired human femora. The dual x-ray absorptiometry (DXA) T-scores of the femora ranged from –3.4 to 2.5, enabling evaluation of the constructs in osteoporotic and strong bone. All femora were stabilized with the same periarticular locking plate (NCB; Zimmer, Warsaw, Indiana). Six 5.0-mm locking screws were used distally. For proximal fixation, one femur of each pair was stabilized with a standard locked-plate approach with four 5.0-mm locking screws (the locked-plate group); in the contralateral femur, four far-cortical-locking screws (5.0 MotionLoc; Zimmer) were used for proximal fixation (the far-cortical-locking group) (Fig. 8, a). Quasi-physiologic loading was induced along the mechanical axis intersecting the femoral head center and intercondylar notch with a materials testing system (Fig. 8, b). First, specimens were loaded stepwise to 1200 N to assess construct stiffness, which was calculated by dividing the applied load by the resulting interfragmentary motion. Subsequently, 100,000 loading cycles of 1870-N amplitude were applied to assess construct durability during simulated level walking. Finally, the specimens that survived the level-walking test were loaded to failure to assess their residual strength and failure mode. Failure was defined as osteosynthesis gap collapse of 5 mm or catastrophic fracture, whichever occurred first.

Results
The initial stiffness of the far-cortical-locking constructs (1.2 ± 0.3 kN/mm) was 81% lower than the stiffness of the locked-plate constructs (6.1 ± 2.4 kN/mm, p < 0.001). Under elevated loading, the stiffness of the far-cortical-locking constructs increased to 3.7 ± 1.2 kN/mm as a result of the additional support of the far-cortical-locking screw shaft at the near cortex. The far-cortical-locking constructs exhibited substantially parallel interfragmentary motion, whereby loading at one times body weight (800 N) induced similar motion at the near cortex (0.57 ± 0.09 mm) and the far cortex (0.63 ± 0.11 mm, p = 0.68) (Fig. 9, a). The locked-plate constructs exhibited on average more than four times less motion (p < 0.001) in response to 800 N, and near-cortex motion (0.10 ± 0.04 mm) was 48% smaller than far-cortex motion (0.19 ± 0.09 mm, p = 0.002).

The far-cortical-locking constructs were as durable as the locked-plate constructs: during dynamic loading, four locked-plate constructs and three far-cortical-locking constructs failed. Furthermore, the far-cortical-locking constructs were as strong as the locked-plate constructs: the six surviving locked-plate constructs retained a strength of 4.9 ± 1.6 kN, and the seven surviving far-cortical-locking constructs retained a strength of 5.3 ± 1.1 kN (p = 0.7) (Fig. 9, b).

Radiographs confirmed the same failure modes in the locked-plate and far-cortical-locking groups. Ten of the eleven
femur pairs sustained metaphyseal fixation failure by gradual migration of distal screws. The remaining femur pair failed by diaphyseal fracture adjacent to the plate tip. None of the constructs sustained diaphyseal fixation failure, and none of the far-cortical-locking screws exhibited bending or fixation failure.
Effects of Construct Stiffness on Healing of Fractures Stabilized with Locking Plates

Conclusions
The results of this study confirm that a far-cortical-locking construct can be used effectively for periarticular plate fixation with the far-cortical-locking screws used only in the diaphyseal segment. When used for periarticular femoral plates, far-cortical-locking screws can reduce construct stiffness by 81% and enable parallel interfragmentary motion of sufficient magnitude to stimulate callus formation. Moreover, far-cortical-locking constructs are as strong and durable as standard-locking constructs in both normal and osteoporotic bone. Therefore, far-cortical-locking fixation may be advisable for periarticular plate fixation to stimulate fracture-healing by controlled interfragmentary motion.

Discussion
While locked-plate constructs are frequently referred to as “internal fixators,” they are much stiffer than external fixators in biomechanical testing and may not provide adequate fracture-surface motion to reliably stimulate secondary bone-healing in bridge-plate constructs, especially at the near cortex, where motion is most attenuated. Clinically, attenuated fracture motion resulted in deficient callus formation and a 19% nonunion rate in a retrospective series of supracondylar femoral fractures treated with locking plates. An ovine fracture-healing model furthermore demonstrated that locked-plate constructs cause asymmetric callus formation and suppress fracture union at the near cortex, where fracture motion is minimal. The resulting “partial nonunions” may contribute to late implant failures and may be underappreciated clinically, since the plate obscures the visibility of the near cortex on radiographs.

Far-cortical-locking screws reduce the stiffness of a locked-plate construct to that of an external fixator and provide parallel interfragmentary motion while retaining construct strength. Hence, far-cortical-locking constructs resemble a true “internal fixator” by combining fixed-angle stabilization and flexible fixation. The performance of far-cortical-locking constructs relies on a particular far-cortical-locking screw design that supports screw flexion while providing a controlled motion envelope in the near cortex to prevent flexion of screw shafts beyond their elastic limit. The ovine fracture model demonstrated that far-cortical-locking constructs outperformed locked-plate constructs by providing symmetric callus formation and reliable bridging and yielded a greater ultimate strength and a higher energy to failure. A study of cadaveric femora demonstrated that periarticular locking plates applied with far-cortical-locking screws in the diaphyseal segment effectively reduce construct stiffness and yield parallel interfragmentary motion in biomechanical testing. These periarticular far-cortical-locking constructs were as strong and durable as standard locked-plate constructs in both normal and osteoporotic bone.

In summary, this research presents further evidence that locked-plate constructs can be too stiff to promote fracture-healing by callus formation. Far-cortical-locking fixation significantly improves fracture-healing by reducing construct stiffness without sacrificing fixation strength or durability.

References


