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

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Summary

Locking plates provide improved fixation strength and support biological fixation. However, due to their considerable stiffness, locked plating constructs suppress interfragmentary motion to a level that may be insufficient to reliably promote callus formation and fracture healing (Figure 1). This concern has been substantiated by recent studies reporting non-union rates of up to 19% with periarticular locking plates.[2]

Furthermore, deficient healing may contribute to late hardware failure seen with locking plates[7] since in absence of bony union, constructs remain load bearing and eventually will fail by fatigue fracture of the plate or screws.

This exhibit first summarizes biomechanical and clinical studies performed to investigate the effect of construct stiffness on fracture healing with locking plates:

1. **CHALLENGE: Are locked plating constructs too stiff?**
2. **EVIDENCE: Locked plating leads to inconsistent and asymmetric callus formation**

Subsequently, the exhibit describes the function, benefits, and clinical application of a stiffness-reduced locked plating technique, termed **F**ar **C**ortical **L**ocking (FCL):

3. **SOLUTION: FCL reduces construct stiffness while maintaining construct strength**
4. **BENEFITS: FCL delivers stronger and more consistent fracture healing**
5. **APPLICATION: FCL for periarticular plating**

Results of this research are two-fold:

- **The high stiffness of locked plating constructs can suppress callus formation and fracture healing.**
- **By providing flexible fixation and parallel interfragmentary motion, FCL constructs provide significantly stronger and more consistent fracture healing.**

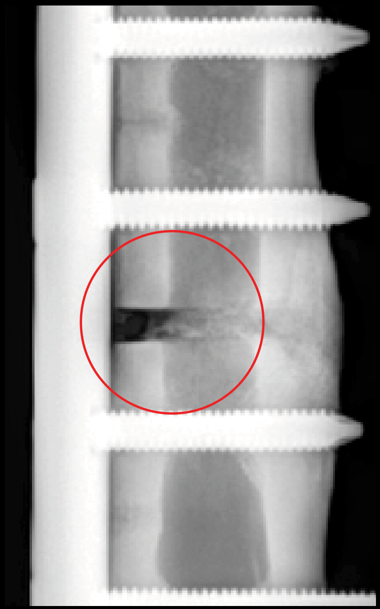


Fig 1: Incomplete union adjacent to stiff plate.

Challenge: Construct Stiffness

Are locked plating constructs too stiff to reliably promote fracture healing? [1]

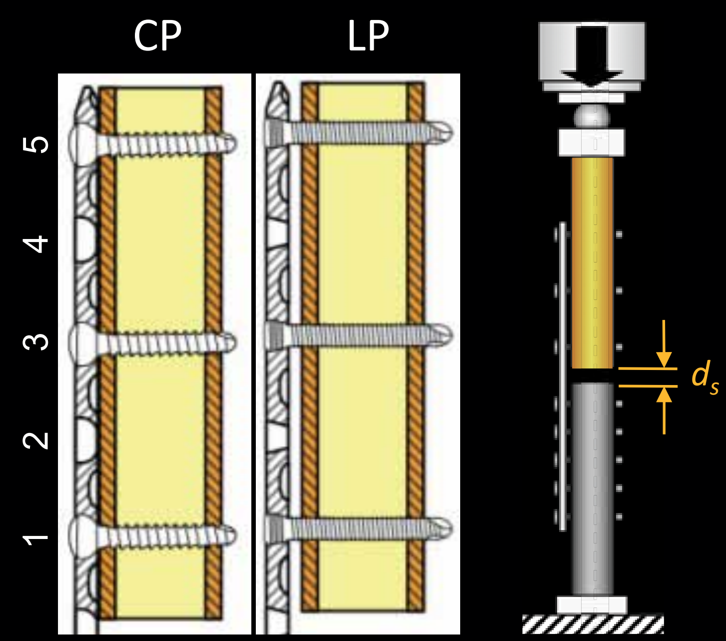
Locked plating (LP) osteosynthesis relies on secondary bone healing with callus formation by targeting biological fixation and functional reduction over absolute stabilization and anatomic reduction [8].

Callus formation is mediated by interfragmentary motion (IFM) in the millimeter range, which requires flexible fixation constructs such as external fixators [9]. Conversely, callus formation can be suppressed by rigid fixation with compression plates [10]. To assess if LP constructs are sufficiently flexible to target secondary bone healing, the stiffness of an LP construct was compared to that of a non-locked conventional plating (CP) construct in a biomechanical study [1].

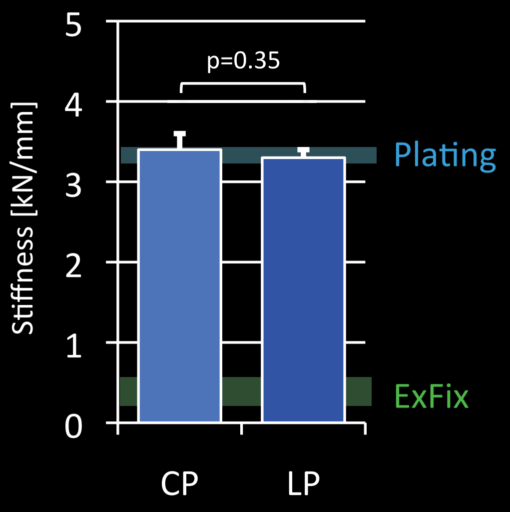
The axial stiffness of locked (LP) and non-locked (CP) bridge plating constructs was assessed. Generic 4.5 mm titanium plates and bi-cortical screws were used to bridge a fracture gap in a validated model of the femoral diaphysis. Proximal diaphyseal fixation was achieved with three locked screws (LP group) or non-locked screws (CP group), placed in the 1st, 3rd and 5th plate hole. Construct stiffness was measured in terms of the motion d_s at the fracture gap in response to axial loading.

The axial stiffness of the LP construct (3.3 ± 0.1 kN/mm) was not significantly lower than that of the conventional plating construct (3.4 ± 0.2 kN/mm) (p=0.35). In both constructs, axial loading induced asymmetric gap closure due to plate bending, with gap motion being attenuated toward the near cortex underlying the plate. Gap motion in response to 400 N "toe-touch" weight bearing was less than 0.1 mm at the near cortex.

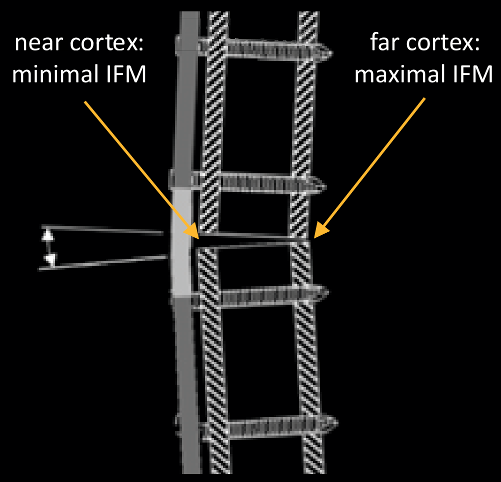
Diaphyseal Fixation   Axial Loading



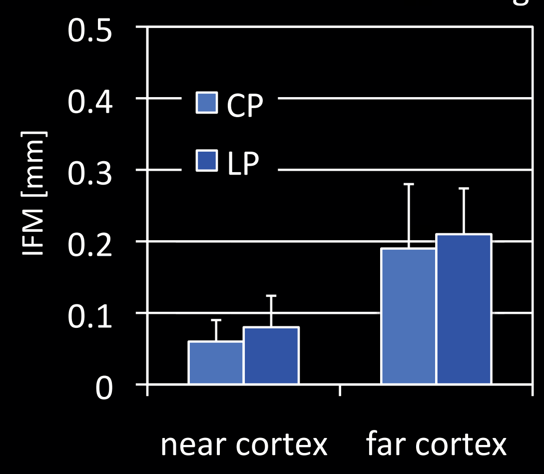
Construct Stiffness



Asymmetric Gap Closure



Interfragmentary Motion
at 400 N 'toe touch' loading



CONCLUSIONS

- **Locked plating constructs are as stiff as non-locked plating constructs in axial compression.**
- **Locked constructs are one order in magnitude stiffer than external fixators (0.05 – 0.4 kN).**
- **Interfragmentary motion is minimal at the near cortex underlying the plate.**
- **Post-operative IFM may be too small to promote callus formation, especially at the near cortex.**

[1] Fitzpatrick DC, et al. Relative stability of locked plate fixation in a model of the osteoporotic femoral diaphysis. Clin Biomech,24(2):203, 2009.

2 Clinical Evidence: Inconsistent Healing

Locked plating leads to inconsistent and asymmetric callus formation [2]

A retrospective cohort study [2] of supracondylar femur fractures stabilized with periarticular locking plates was conducted to measure periosteal callus formation, which is the principal hallmark of secondary bone healing.

Hypothesis 1: Locked plating constructs may be too stiff to reliably promote secondary bone healing.

Hypothesis 2: More callus will form on the medial cortex where plate bending induces more IFM than at the anterior and posterior cortices.

In a consecutive cohort of 66 distal femur fractures (AO 32A, 33A-C), the periosteal callus size was measured on lateral and antero-posterior radiographs obtained 6, 12, and 24 weeks post surgery. Custom software was developed to objectively extract callus size without manual tracing of callus boundaries [11]. Projections of the medial, anterior and posterior callus were evaluated separately to investigate the effect of plate proximity on callus formation.

Inconsistent callus: Periosteal callus ranged from 0 to 670 mm^2 (Figure 2).
At 24 weeks, 37% of all fractures had deficient callus formation ($\leq 20\ mm^2$).

Asymmetric callus: Medial cortices had 64% more callus than the anterior or posterior cortices ($p = 0.001$).

Non-unions: There were 14 non-unions (18.6%). Non-unions had 65% less callus than all remaining fractures ($p = 0.035$).

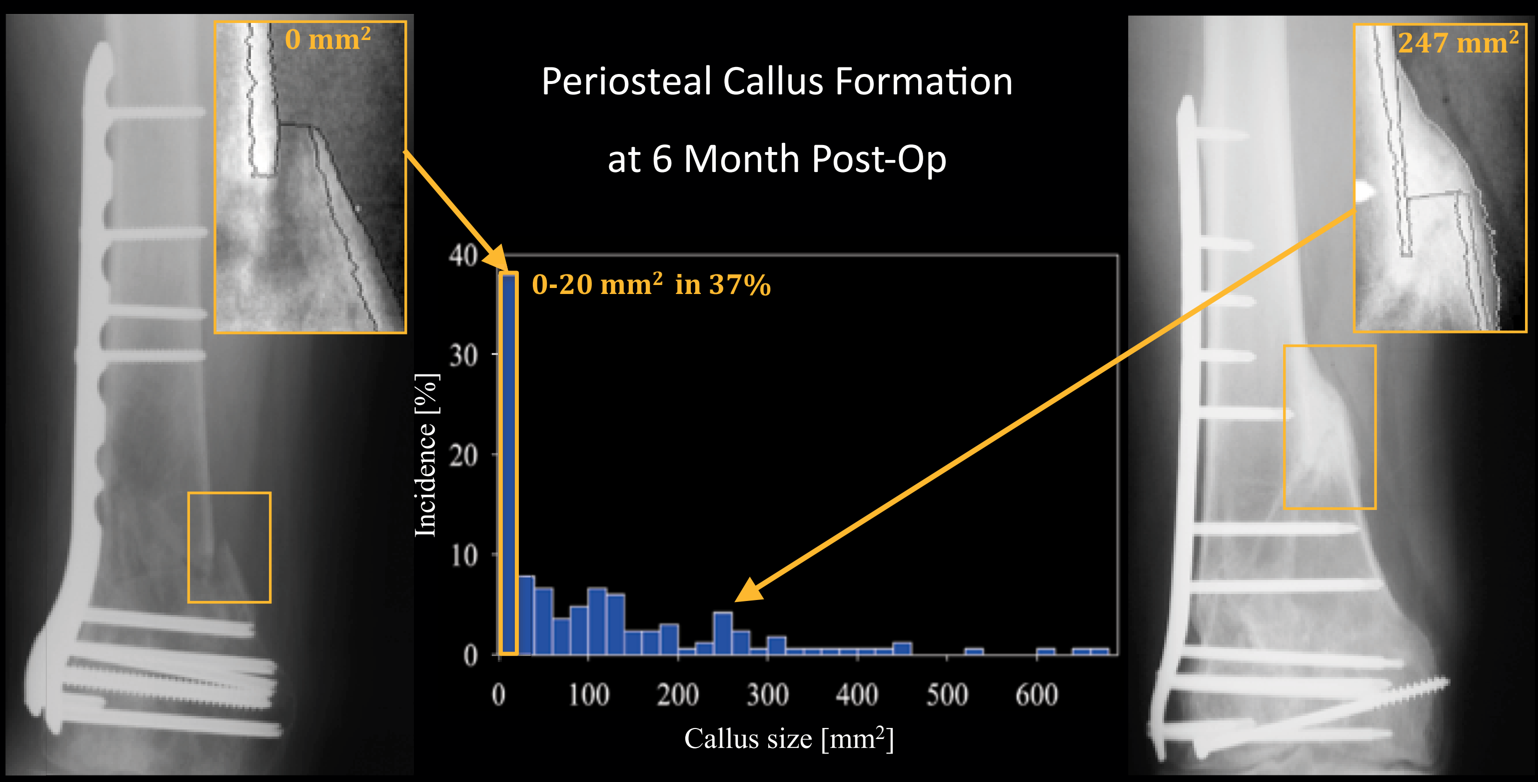


Figure 2: Periosteal callus distribution at 6 months post-op demonstrates that 37% of fractures had formed no or very little callus ($\leq 20\ mm^2$). Radiographs depict examples of callus projections in a non-union (0 mm^2) and a union (247 mm^2).

CONCLUSIONS

- **Locked plating can suppress callus formation: 37% of fractures formed no or very little callus ($\leq 20\ mm^2$).**
- **Locked plating leads to asymmetric callus formation: callus stimulation was attenuated in proximity to the plate, where fracture motion is minimal.**
- **Locked plating constructs may be too stiff to reliably promote healing: 18.6% of fractures failed to unite.**

[2] Lujan TJ, et al. Locked plating of distal femur fractures leads to inconsistent and asymmetric callus formation. J Orthop Trauma, 24:156, 2010.

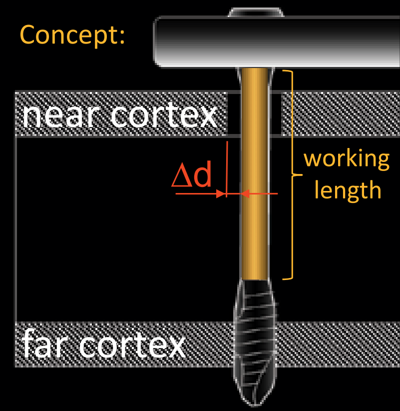
Solution: Far Cortical Locking (FCL)

FCL reduces construct stiffness while maintaining construct strength [4]

Far Cortical Locking (FCL) is a strategy to reduce the stiffness of a locked plating construct while retaining construct strength. In addition, FCL is capable of generating parallel motion at the fracture. By providing flexible fixation and parallel motion, FCL seeks to actively promote secondary bone healing across the entire fracture gap.

Concept: FCL screws lock into the plate and the far cortex of a diaphysis. FCL screws have a reduced diameter mid-shaft to bypass the near cortex. Therefore, FCL screws have an increased working length, allowing for elastic cantilever bending of the screw shaft within a controlled motion envelope Δd in the near cortex. Under elevated loading, contact of the FCL shaft at the near cortex provides added support and load sharing with the near cortex.

Concept:

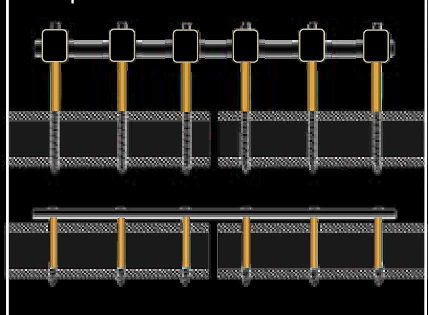


Low Stiffness: Analogous to external fixator pins, FCL screws provided flexible fixation by elastic bending of screw shafts. FCL screws reduced the initial axial stiffness of a locked plating construct by 88%.

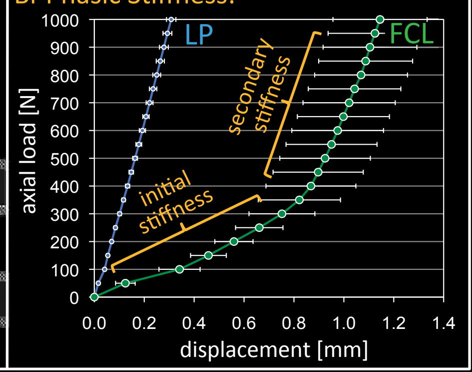
Bi-Phasic Stiffness: At elevated loading, near cortex support of FCL screws provided a 6-fold stiffness increase. This bi-phasic stiffness resembles progressive stiffening behavior characteristic for Ilizarov fixators.

Low Stiffness:

comparable to External Fixator

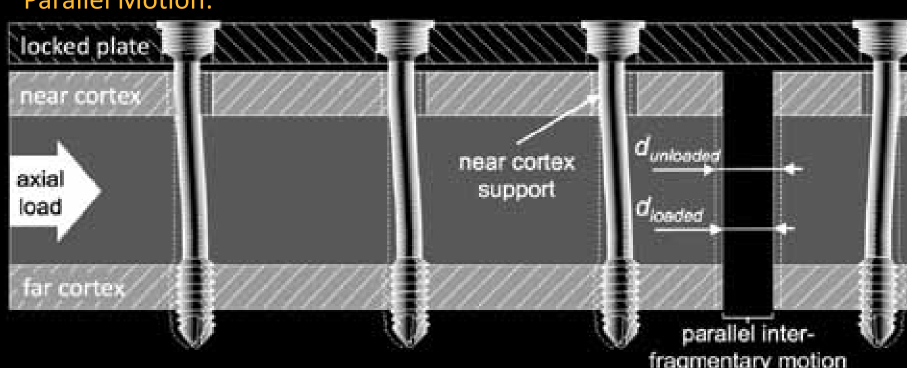


Bi-Phasic Stiffness:



Parallel Motion: At 200 N weight bearing, the FCL construct delivered gap motion of 0.51 mm (near cortex) and 0.59 mm (far cortex). A standard locked construct yielded gap motion of 0.02 mm (near cortex) and 0.05 mm (far cortex).

Parallel Motion:



Strength in osteoporotic diaphysis: Compared to standard locked constructs, FCL constructs had 7% less compressive strength, 54% more torsional strength, and 21% more bending strength.

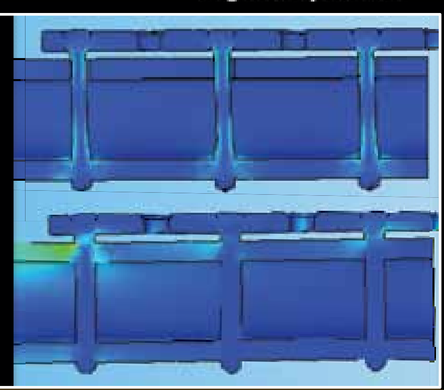
Strength in non-osteoporotic diaphysis: Compared to standard locked constructs, FCL constructs had 16% less compressive strength, 9% more torsional strength, and 20% more bending strength.

Load Distribution: FCL constructs provide evenly distributed load sharing among all FCL screws. In contrast, the end-screw of a standard locked construct induces a stress riser [12], which reduces construct strength in bending and torsion.

Load Distribution:

FCL

standard locked



CONCLUSIONS

- **FCL screws can reduce the stiffness of a locked construct to that of an external fixator.**
- **FCL constructs can deliver nearly parallel fracture site motion.**
- **Compared to a standard locked construct, FCL constructs retain at least 80% of axial strength and are up to 54% stronger in torsion and up to 21% stronger in bending.**

[4] Bottlang M, et al. Far Cortical Locking can reduce stiffness of locked plating constructs while retaining strength. J Bone Joint Surg 91(8), 2009.

Benefits: Improved Healing

FCL delivers stronger and more consistent fracture healing [5]

Healing of fractures stabilized with a standard locked plating (LP) construct and with a Far Cortical Locking (FCL) construct was evaluated in 12 sheep.

Hypothesis: By providing flexible fixation and parallel interfragmentary motion, FCL constructs improve fracture healing compared to a standard locked plating construct.

In an established ovine fracture healing model, tibial osteotomies with a 3 mm gap were induced in 12 sheep and were randomly stabilized with LP or FCL constructs. Each construct used the same locking plate that was applied either with six locking screws (LP group) or with six FCL screws (FCL group). Compared to the LP construct, FCL constructs had an 84% lower initial stiffness and provided parallel interfragmentary motion. Progression of fracture healing was monitored on weekly radiographs. After sacrifice at week 9, healed tibiae were analyzed by CT, histology, and mechanical testing in torsion to failure.

Callus Formation: The FCL group formed significantly more callus than the LP group from week 4 -9. At week 9, the FCL group had 36% more callus (p=0.03) and 49% more bone mineral content (BMC, p=0.01).

Callus Symmetry: The FCL group formed callus evenly around the entire cortex. Callus in the LP group formed asymmetrically and had 49% less BMC at the near cortex than at the far cortex (p=0.003).

Bridging: Three of six LP specimens failed to bridge at the near cortex under the plate, developing a 'partial non-union'. In the FCL group, bridging callus consistently formed at the near and far cortices in all specimens (Fig 3a).

Strength: FCL specimens healed to be 54% stronger (p = 0.023) and tolerated 157% more energy until failure (p < 0.001) than LP specimens (Fig 3b).

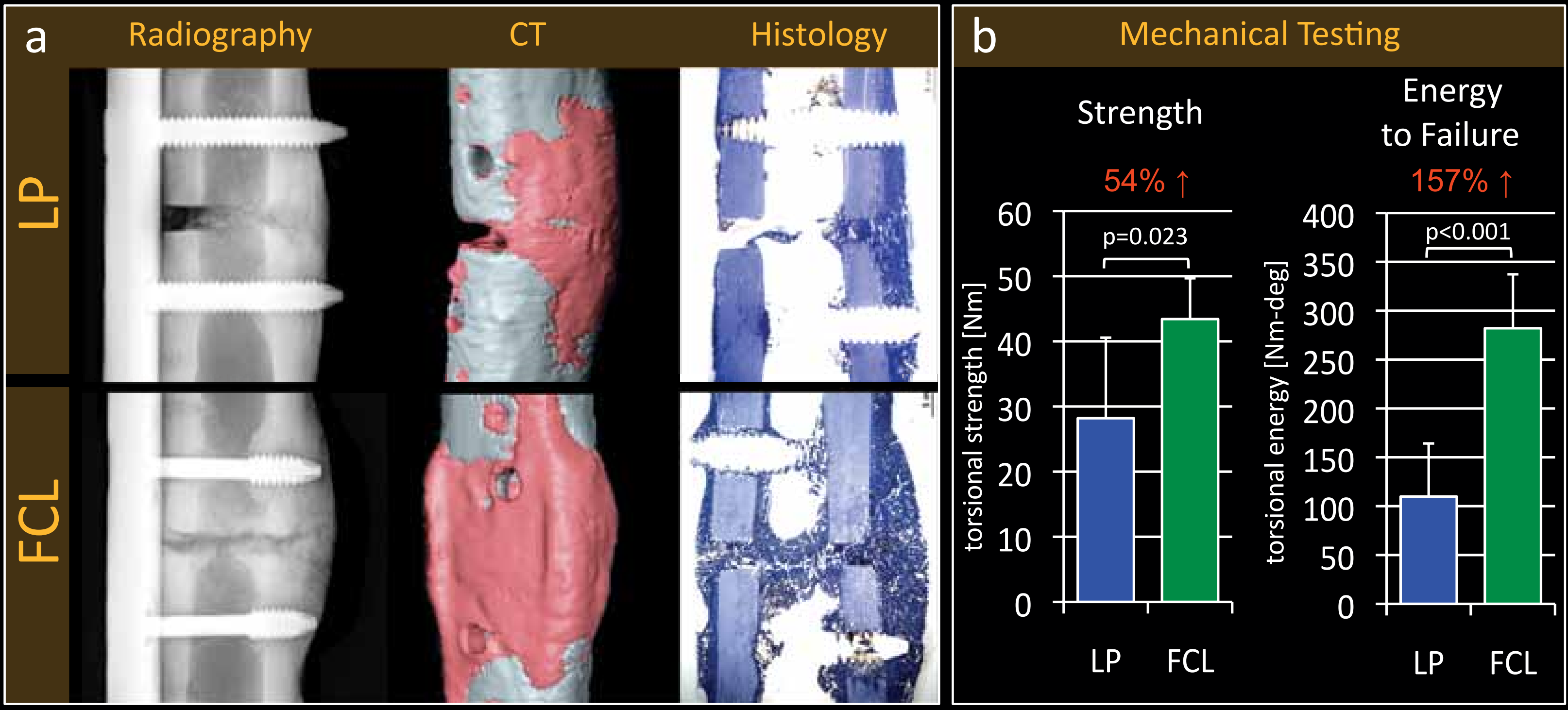


Figure 3: a) LP constructs suppressed callus formation at the near cortex where gap motion is minimal. FCL constructs induced more callus, symmetric callus, and reliable bridging. b) FCL specimens were 54% stronger and tolerated 157% more energy to failure.

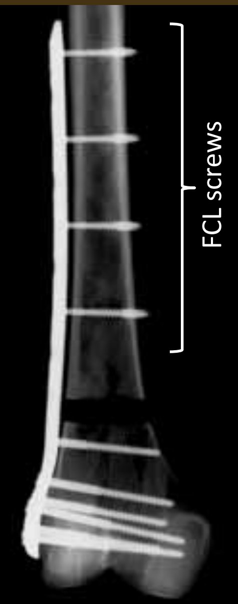
CONCLUSIONS

- **LP constructs: High construct stiffness and asymmetric gap closure caused inconsistent and asymmetric callus formation, with fracture healing being attenuated toward the plate side.**
- **FCL constructs: By providing flexible fixation and parallel interfragmentary motion, FCL constructs yielded significantly stronger and more consistent fracture healing.**

[5] Bottlang M, et al. Far cortical locking can improve healing of fractures stabilized with locking plates. J Bone Joint Surg (A), 92:7, 2010.

Clinical Application: Periarticular Plating

FCL fixation with periarticular distal femur plates [6]



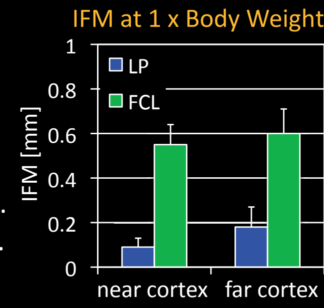
Diaphyseal fixation of periarticular femur plates using either FCL screws or standard locking screws was evaluated in paired human femurs.

Hypothesis: Diaphyseal fixation of a periarticular femur plate with FCL screws will reduce construct stiffness and will induce parallel interfragmentary motion (IFM) without decreasing construct strength compared to standard locked plating.

Distal femur fractures (AO/OTA A33-3) were simulated in 22 paired human femurs by a 1-cm gap osteotomy. DEXA T-scores of femurs ranged from -2.7 to 2.5, enabling construct evaluation in osteoporotic and strong bone. All femurs were stabilized with the same periarticular locking plate (NCB, Zimmer) applied distally with six 5.0 mm locking screws. For proximal fixation, either four FCL screws (FCL group) or four standard 5.0 locking screws (LP group) were used. Hip loading was induced through the femoral head center with a material test system for evaluation of construct stiffness, durability, strength and failure modes. Construct stiffness was determined by measuring interfragmentary motion (IFM) in response to femur loading. Construct durability was evaluated by dynamic loading representative of level walking (1,870 N amplitude) up to 100,000 cycles. If constructs survived, their residual strength was determined by static loading to failure.

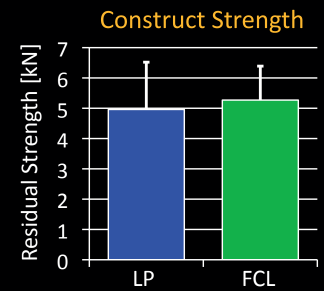
Stiffness: The initial stiffness of FCL constructs was 81% lower compared to LP constructs.

IFM: In FCL constructs, one bodyweight loading induced 0.6 mm IFM at the near and far cortex. In LP constructs, this loading yielded IFM of 0.1 mm (near cortex) and 0.2 mm (far cortex).



Durability: FCL constructs were as durable as LP constructs. Three of 11 specimen pairs failed during dynamic loading after an average of 12,700 cycles (FCL) and 8,150 cycles (LP, p= 0.24).

Strength: FCL constructs were as strong as LP constructs. Specimens that survived 100,000 loading cycles had a residual strength of 5,269 N (FCL) and 4,956 N (LP, p=0.3).



Failure Mode: Ten of 11 femur pairs sustained distal fixation failure by progressive loss of metaphyseal fixation. The remaining femur pair (T-score: 2.5) failed by diaphyseal fracture. Among all FCL constructs, loading to failure caused neither bending nor pull-out of FCL screws.

CONCLUSIONS

- **FCL fixation of distal femur plates reduced construct stiffness by 81% and induced parallel gap motion.**
- **FCL fixation was as durable and strong as standard locked plating in both osteoporotic and strong bone.**
- **FCL screws showed no failure (bending, pull-out).**

[6] Doornink J, et al. Far Cortical Locking enables flexible fixation while maintaining construct strength. 56th ORS Meeting, Abstract 1767, 2010.

References:

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