A commentary by Erika Jasmin Mitchell, MD, is linked to the online version of this article at jbjs.org.

Dynamic Stabilization with Active Locking Plates Delivers Faster, Stronger, and More Symmetric Fracture-Healing

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Background: Axial dynamization of fractures can promote healing, and overly stiff fixation can suppress healing. A novel technology, termed active plating, provides controlled axial dynamization by the elastic suspension of locking holes within the plate. This prospective, controlled animal study evaluated the effect of active plates on fracture-healing in an established ovine osteotomy model. We hypothesized that symmetric axial dynamization with active plates stimulates circumferential callus and delivers faster and stronger healing relative to standard locking plates.

Methods: Twelve sheep were randomly assigned to receive a standard locking plate or an active locking plate for stabilization of a 3-mm tibial osteotomy gap. The only difference between plates was that locking holes of active plates were elastically suspended, allowing up to 1.5 mm of axial motion at the fracture. Fracture-healing was analyzed weekly on radiographs. After sacrifice at nine weeks postoperatively, callus volume and distribution were assessed by computed tomography. Finally, to determine their strength, healed tibiae and contralateral tibiae were tested in torsion until failure.

Results: At each follow-up, the active locking plate group had more callus ($p < 0.001$) than the standard locking plate group. At postoperative week 6, all active locking plate group specimens had bridging callus at the three visible cortices. In standard locking plate group specimens, only 50% of these cortices had bridged. Computed tomography demonstrated that all active locking plate group specimens and one of the six standard locking plate group specimens had developed circumferential callus. Torsion tests after plate removal demonstrated that active locking plate group specimens recovered 81% of their native strength and were 399% stronger than standard locking plate group specimens ($p < 0.001$), which had recovered only 17% of their native strength. All active locking plate group specimens failed by spiral fracture outside the callus zone, but standard locking plate group specimens fractured through the osteotomy gap.

Conclusions: Symmetric axial dynamization with active locking plates stimulates circumferential callus and yields faster and stronger healing than standard locking plates.

Clinical Relevance: The stimulatory effect of controlled motion on fracture-healing by active locking plates has the potential to reduce healing complications and to shorten the time to return to function.

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Research over the past fifty years has consistently shown that controlled axial dynamization promotes callus formation and improves the speed and strength of fracture-healing¹⁻⁸. For example, Goodship and Kenwright demonstrated that 1-mm axial dynamization delivered more than three times stronger healing and two times faster healing compared with rigid fixation⁴. Conversely, deficient fracture motion caused by overly stiff fixation constructs can suppress secondary fracture-healing, contributing to delayed union, nonunion, osteolysis, and fixation failure⁹⁻¹³. Consequently, there have been persistent efforts to develop plating technologies for controlled axial dynamization^{1,3,4,8,14,15}.

Before the advent of locked plating, these efforts did not yield clinically viable solutions, as plates needed to be firmly compressed onto the bone surface to obtain stable fixation. For example, Longfellow¹⁵ was granted a patent in 1949 for a sliding plate “to permit axial movement for growth of callous [sic],” reasoning that “holding fragments in fixed positions forestalls natural movement between fragments necessary for growth of callous [sic].” A subsequent study demonstrated that sliding plates led to faster healing by allowing axial loading at the

fracture site⁶. However, concerns about implant wear and fracture stability detracted from the clinical feasibility of the sliding plate concept. Foux et al. explored an axially flexible plating concept using elastic sleeves between screw heads and plate holes³. They demonstrated superior healing compared with rigid plating in a canine model. Their strategy relied on plate sliding on the bone surface to achieve fracture motion, which precluded screws from being fully tightened. Hence, their concept enabled motion at the cost of construct stability. To overcome this lack of stability, Uthoff et al. replaced elastic sleeves with resorbable sleeves, allowing for delayed motion after sleeve resorption⁸. However, delayed motion is less effective than early motion to stimulate callus formation¹⁶.

The advent of locked plating enabled novel strategies for dynamization, because locked constructs with fixed-angle locking screws do not require plate compression onto the bone surface. For example, far cortical locking enables controlled axial dynamization through flexion of screws that lock into the plate and the far cortex, but retain a motion envelope at the near cortex. Far cortical locking enables dynamization without sacrificing construct stability¹⁷. It delivered symmetric callus

TABLE I Comparison of Outcome Parameters Between the Standard Locking Plate Group and the Active Locking Plate Group

Parameters	Standard Locking Plate Group*	Active Locking Plate Group*	Difference	P Value
Sheep characteristics				
Weight (kg)	71 ± 9	65 ± 5	-8%	0.21
Age (mo)	24 ± 1	25 ± 2	1%	0.58
Construct stiffness (N/mm)				
In compression ≤700 N	6239 ± 740	667 ± 161	-89%	<0.001
In compression >700 N	5023 ± 420	1805 ± 116	-64%	<0.001
Callus volume from tomography scans (cm ³)				
Total	6.0 ± 1.8	13.0 ± 2.7	117%	<0.001
Anterior	1.3 ± 0.9	4.5 ± 2.0	252%	0.006
Posterior	1.0 ± 0.6	2.5 ± 0.8	147%	0.004
Lateral	3.0 ± 0.5	4.4 ± 0.5	46%	<0.001
Mechanical properties, absolute				
Peak torsion (Nm)	28 ± 25	72 ± 9	157%	0.006
Rotation to failure (deg)	7 ± 2	16 ± 1	131%	<0.001
Energy to failure† (Nm × deg)	134 ± 152	669 ± 105	399%	<0.001
Mechanical properties, normalized‡				
Peak torsion (Nm)	34 ± 30	87 ± 11	156%	0.003
Rotation to failure (deg)	42 ± 12	92 ± 8	119%	<0.001
Energy to failure† (Nm × deg)	17 ± 17	81 ± 9	371%	<0.001
Mechanical properties, contralateral§				
Peak torsion (Nm)	80 ± 12	83 ± 11	4%	0.62
Rotation to failure (deg)	16 ± 2	17 ± 1	8%	0.21
Energy to failure† (Nm × deg)	738 ± 156	825 ± 108	12%	0.30

*The values are given as the mean and the standard deviation. †These results represent the area under the torsion-rotation curve. ‡These values were the percentage of the contralateral tibiae. §These values were for the contralateral tibiae of the standard locking plate and active locking plate groups, provided for reference only.

bridging and yielded 157% stronger healing compared with standard locked plating in an ovine study¹. Clinically, distal femoral fractures stabilized with far cortical locking constructs healed at a mean time of sixteen weeks with a 3% nonunion rate¹⁸. Far cortical locking has been implemented in commercial implants^{7,19-22} and has been simulated using standard locking screws by means of overdrilling¹⁴ or slotting²³ of the near cortex.

The present study investigated an alternative strategy for axial dynamization of locking plates, termed active plating. Active plates utilize standard locking screws that lock into the threaded hole of elastically suspended sliding elements embedded inside the plate. A biomechanical study demonstrated that active plates provide axial dynamization without decreasing construct strength²⁴. This prospective, controlled animal study evaluated healing of fractures stabilized with active plates in comparison with standard locking plates in an ovine osteotomy model. We hypothesized that symmetric axial dynamization with active plates will yield circumferential callus formation and will provide faster and stronger healing compared with standard locking plates.

Materials and Methods

Using an established, large-animal, fracture-healing model²⁵, twelve sheep were randomly assigned to receive a standard locking plate or an active locking plate for stabilization of a 3-mm transverse osteotomy gap. This gap model correlates clinically with bridge plating of a comminuted fracture, in which all load is initially transmitted through the plate. Fracture-healing was monitored weekly on radiographs. After sacrifice at nine weeks postoperatively, the callus volume and distribution were assessed by quantitative computed tomography (QCT). Finally, to determine their strength, healed tibiae and contralateral tibiae were tested in torsion until failure.

Locking Plate Constructs

Standard locking plates and active locking plates had an identical cross-sectional geometry, representative of typical 4.5-mm large-fragment plates. Plates had six holes; were 127 mm long, 16 mm wide, and 5.6 mm thick; and were made of Ti6Al4V ELI (extra low interstitial) titanium alloy. Plates only differed in that locking holes of active locking plates were integrated in individual sliding elements that were elastically suspended in a silicone envelope inside lateral plate pockets (Fig. 1). The silicone suspension consisted of long-term implantable medical-grade silicone elastomer (HCRA 4750; Applied Silicone) that was molded onto the sliding elements. Lateral pockets were arranged in an alternating pattern from both plate sides, resulting in a staggered locking hole configuration. The pocket geometry combined with the silicone suspension allowed controlled axial translation, which enabled up to 1.5 mm of axial motion across the fracture gap while providing stable fixation in response to bending and torsional loading²⁴.

The stiffness of standard locking plate and active locking plate constructs was characterized by bench testing of three plates per group, applied to bridge 3-mm gap osteotomies in cadaveric ovine tibiae. Axial compression was applied through a sphere proximally to permit physiological bending under axial loading^{17,24,26}. Constructs were stepwise loaded in 50-N increments up to 1000 N. The resulting motion at the medial and lateral aspects of the osteotomy was measured with calipers for calculation of construct stiffness.

Animal Model

The ovine tibia osteotomy model was employed as it represents the most prevalent large-animal model for evaluation of fracture-healing^{25,27}. The study protocol and sample size were approved by the pertinent animal care committee and were consistent with a prior study on locking plate dynamization to facilitate result comparability¹. Twelve skeletally mature female Swiss Alpine sheep, with a mean value (and standard deviation) of 2.0 ± 0.1 years for age and 68 ± 7 kg for weight, were randomized into the standard locking plate group or the active locking plate group. Under general anesthesia, an approximately 8-cm-long medial incision was made over the tibia of one hind leg, with the surgical procedure being randomized between the right and left hind legs. All six screw holes were drilled from medial to lateral in the intact tibia with a

Fig. 1
Figs. 1-A through 1-D Standard and active locking plates. **Fig. 1-A** The standard locking plate (LP) and active locking plate (ACTIVE) were identical, with the exception of elastic suspension of locking holes in ACTIVE plates. **Figs. 1-B and 1-C** Cross-section and semitransparent illustration of an ACTIVE plate. **Fig. 1-D** Sliding element with locking hole, embedded in silicone envelope.

custom template. A transverse osteotomy was performed with a 0.6-mm-thick saw blade under constant irrigation. Osteotomies were stabilized with plates applied to the medial tibial shaft in a periosteum-sparing biological fixation technique to preserve periosteal perfusion²⁸, using six 4.5-mm bicortical locking screws. The resulting osteotomy gap had a controlled width of 3 mm, formed by the distance between the central screw holes in plates, which was 2.4 mm greater than that in the drill template, and by the osteotomy cut of 0.6 mm. For medication, the standard protocol of the ovine fracture model was followed^{7,27}. Antibiotic prophylaxis with benzylpenicillin and gentamicin and analgesia with carprofen (4 mg/kg of body weight) and buprenorphine were initiated preoperatively and were continued for four days postoperatively.

Postoperatively, a cylindrical cast was applied over a soft padding layer proximal to the hoof and extending to the stifle joint. In the ovine osteotomy model, this routine prophylactic measure is essential to prevent tibial fracture caused by bending loads while allowing axial load-bearing and walking immediately postoperatively^{1,7}. Each sheep was housed in a single 2.5-m² pen and walked on the first postoperative day. After two weeks, sheep were housed in pairs in 5-m² pens until sacrifice at postoperative week 9.

Radiography

Radiographs were made immediately postoperatively and at weekly intervals, starting at postoperative week 3. To make radiographs without cast interference, casts were removed and were reapplied weekly through postoperative week 9. At each time point, an anteroposterior radiograph and two lateral oblique radiographs (+10° and -10° from straight lateral) were made to visualize the anterior, posterior, and lateral cortices without obstruction by the medially applied plate. Projected callus areas were measured using validated custom software developed to objectively quantify periosteal callus size²⁹.

For volumetric callus assessment at postoperative week 9, QCT scans of the excised tibiae were obtained in accordance with an established protocol³⁰ after implant removal to prevent metal interference. Callus volume was rendered (Amira, FEI) in an automated, non-blinded approach, using consistent Hounsfield unit (HU) thresholds of 600 HU to differentiate callus from soft tissue and 1600 HU to differentiate callus from cortical bone. To quantify callus distribution, the total callus volume was divided into four quadrants, and the volumes of the anterior, posterior, and lateral callus were extracted.

Mechanical Testing

The proximal and distal ends of the tibiae were cemented in mounting fixtures that were separated by 170 mm and were aligned with the tibial shaft axis. To ensure unconstrained torsion of the tibial shaft in a materials testing system (Instron 8874), the distal fixture was mounted on an x-y table that enabled

translation but prevented rotation of the distal fixture around the diaphyseal axis. After implant removal, rotation was applied proximally at 10° per minute until specimen failure in torsion. Failure was defined as the instant at which rotational displacement caused a decrease in torsional moment due to specimen fracture or shear movement at the osteotomy. The failure mode was identified on QCT reconstructions obtained after the torsion test. The strength of healed tibiae was quantified by their energy to failure, calculated by integrating the area under the torsion versus rotation curve up to the peak torque at which failure occurred¹.

Statistical Analysis

All data are reported as the mean and the standard deviation. Statistical differences between groups were tested using two-tailed, unpaired Student t tests at a level of significance of $\alpha = 0.05$. Paired tests were performed for comparison of medial and lateral cortex motion within the same groups.

Results

Eleven of twelve sheep had an uneventful experimental procedure and recovery. One sheep developed a painful hoof infection of a foreleg, unrelated to the experimental procedure. This infection prevented weight-bearing and required intensive treatment with nonsteroidal anti-inflammatory drugs known to suppress fracture-healing³¹. This sheep was replaced to retain the original sample size.

Construct Stiffness

Bench-top tests demonstrated that the initial axial stiffness of active locking plate constructs (667 ± 161 N/mm) was 89.3% lower ($p < 0.001$) compared with standard locking plate constructs (6239 ± 740 N/mm) (Fig. 2-A). The axial stiffness of active locking plate constructs increased for loads of >700 N to 1805 ± 116 N/mm because of progressive compression of the silicone suspension, but remained 64% lower compared with standard locking plate constructs ($p < 0.001$). In active locking plate constructs, 700-N loading induced motion of 1.2 ± 0.3 mm at the lateral cortex and 1.0 ± 0.3 mm at the medial cortex (Fig. 2-B). In standard locking plate constructs, motion in response to 700-N loading remained below the 0.2-mm threshold required for stimulation of callus formation^{2,4,32}, and

Fig. 2
Figs. 2-A and 2-B Construct stiffness and interfragmentary motion at 700 N for both locking plate constructs. **Fig. 2-A** Active locking plate (ACTIVE) constructs were up to 89% less stiff than the standard locking plate (LP) constructs. **Fig. 2-B** ACTIVE constructs induced symmetric motion of 1.0 to 1.2 mm at 700-N compression, and LP constructs induced asymmetric motion of <0.2 mm. The error bars indicate the standard deviation.

Fig. 3

Figs. 3-A and 3-B Periosteal callus formation and callus at postoperative week 6 for both groups. **Fig. 3-A** Progression of periosteal callus formation. The active locking plate (ACTIVE) group developed significantly more callus ($p < 0.001$), indicated by asterisks, than the standard locking plate (LP) group at each time point from postoperative weeks 3 through 9. The error bars indicate the standard deviation. **Fig. 3-B** By week 6, all visible cortices had bridged in the ACTIVE group, but only 50% of these cortices had bridged in the LP group, as shown in two representative specimens.

the medial cortex motion (0.07 ± 0.02 mm) adjacent to the plate was significantly lower ($p = 0.01$) than lateral cortex motion (0.16 ± 0.03 mm).

Radiographic Assessment

At each time point, the active locking plate group had significantly more callus ($p < 0.001$) than the standard locking plate group (Fig. 3-A). At the earliest time point (postoperative week 3), callus in the active locking plate group (296 ± 84 mm²) was more than six times greater ($p < 0.001$) than it was in the

standard locking plate group (47 ± 55 mm²). At postoperative week 6, all tibiae of the active locking plate group had bridging callus at the lateral, anterior, and posterior cortices visible on radiographs (Fig. 3-B). In the standard locking plate group, only 50% of these cortices had bridging callus.

The total callus volume assessed from QCT at postoperative week 9 was 117% greater in the active locking plate group compared with the standard locking plate group ($p < 0.001$) (Table I). Transverse QCT slices extracted adjacent to the osteotomy gap demonstrated that each active locking plate group specimen

Fig. 4

Transverse cross-sections adjacent to the osteotomy and volumetric renderings depict circumferential and abundant callus in the active locking plate (ACTIVE) group, but not the standard locking plate (LP) group. Images depict the medial (plated) cortex to the right.

Fig. 5

Figs. 5-A and 5-B Photograph of the active locking plate (ACTIVE) specimen and scatterplot showing the strength of the healed tibiae in the ACTIVE group and the standard locking plate (LP) group. **Fig. 5-A** Torsion test setup with ACTIVE specimen. **Fig. 5-B** Strength of healing in terms of energy to failure in torsion, normalized to the native strength of contralateral tibiae (100%).

developed circumferential callus that circumscribed the lateral, anterior, and posterior cortices up to the medial plate (Fig. 4). In contrast, only one of the six standard locking plate constructs developed circumferential callus. In standard locking plate constructs, the mean callus volume in the anterior quadrant ($1.3 \pm 0.9 \text{ cm}^3$) and posterior quadrant ($1.0 \pm 0.6 \text{ cm}^3$) was more than two times smaller than that in the lateral quadrant opposite the plate ($3.0 \pm 0.5 \text{ cm}^3$).

Mechanical Testing

After implant removal, active locking plate group specimens sustained a 157% greater torque until failure ($p = 0.006$) than standard locking plate group specimens. The strength of active locking plate group specimens, expressed in terms of the energy to induce failure, was 399% greater than in standard locking plate group specimens ($p < 0.001$). Compared with contralateral intact tibiae, active locking plate group specimens

Fig. 6

Failure mode: all active locking plate (ACTIVE) specimens failed by spiral fracture proximal or distal to the osteotomy gap, but standard locking plate (LP) specimens fractured through either completely or partially through the osteotomy gap. The arrows indicate the ends of the fracture.

had recovered 81% (range, 70% to 96%) of their native strength (Fig. 5). Standard locking plate group specimens had recovered 17% (range, 3% to 43%) of their native strength. All active locking plate group specimens failed by spiral fracture through a screw hole outside the callus zone (Fig. 6). In contrast, all standard locking plate group specimens fractured through either completely or partially through the osteotomy gap.

Discussion

Results of this investigation validated the hypothesis that axial dynamization with active locking plates yields circumferential callus formation and provides faster and stronger healing compared with standard locking plates in a controlled ovine fracture-healing model.

Circumferential callus formation was likely a consequence of the symmetric axial motion provided by active plating constructs. In contrast, deficient and asymmetric motion in standard locking plate group constructs prevented circumferential callus formation and suppressed cortical bridging at the plate side where motion is minimal^{9,33}. This healing suppression adjacent to the plate can persist for a prolonged time. A recent study documented that, twenty-one months after locked plating of high tibial osteotomies, 65% of patients displayed incomplete consolidation of the osteotomy underneath the locking plate¹¹. Asymmetric motion can also be exacerbated by two alternative strategies for stiffness reduction of locked plating constructs: the use of flexible titanium plates⁹, and increasing the bridge span over the fracture^{26,34}. Both of these strategies enhance plate flexion, which increases motion at the cortex opposite the plate, but not adjacent to the plate³³. In contrast, active plates deliver symmetric motion without requiring a long bridge span, as demonstrated in the present study by locking screws placed in proximity to the osteotomy gap.

Faster healing with active locking plate constructs compared with that with standard locking plate constructs is supported by the findings that active locking plate specimens had more than six times more periosteal callus by postoperative week 3 and had bridging callus at all visible cortices by postoperative week 6. Clinical benefits of faster healing include an earlier return to function and a lower risk of fixation failure due to a reduced load-sharing duration of the fixation construct.

Stronger healing with active locking plate constructs compared with that with standard locking plate constructs is supported by the findings that active locking plate group specimens survived a 131% greater torsional displacement and a 157% higher torsional load and required 399% more energy to induce failure. Energy to failure is a clinically relevant strength measure, as it provides a summary index accounting for the load and the torsional displacement to failure. Active locking plate group specimens consistently recovered between 70% and 96% of the strength of the non-involved contralateral tibiae. Moreover, the callus strength in active locking plate group specimens was likely greater than the reported strength results, as failure occurred by spiral fracture through screw holes outside the callus zone. Extrapolating from a cadaveric study on the effects of screw holes on diaphyseal strength³⁵, a 4.5-mm screw hole will

reduce the strength of the ovine tibia by 15% to 30%, which would fully account for the observed strength loss in active locking plate group specimens compared with contralateral tibiae. In contrast, the finding that half of all standard locking plate group specimens recovered <10% of their native strength, and none recovered more than 43% of their native strength, provides further evidence that excessively stiff fixation suppresses healing.

Silicone elastomer has been used for more than forty years for finger joint replacements³⁶ and continues to serve in a range of dental³⁷, spinal³⁸, and arthroplasty^{36,39} implants to provide elastic fixation, motion, and impact damping⁴⁰. Its use for osteosynthesis implants is novel and active plates have only recently been cleared by the United States Food and Drug Administration. Long-term implantable silicone elastomer is highly biocompatible and complications are rare and are limited to arthroplasty implants embedded inside a joint capsule⁴¹. For active plating, no sign of adverse reactions was found during dissection of soft tissues adjacent to the plate. Given its long clinical history, the use of silicone elastomer constitutes a novel yet conservative strategy to integrate controlled dynamization in modern locking plates.

Results of the present study can be directly correlated with those of two studies that employed the ovine osteotomy model to investigate locking plate dynamization with far cortical locking screws¹ and Dynamic Locking Screws (DLS) (DePuy Synthes)⁷. Standard locked constructs in all three studies caused deficient, asymmetric callus formation, whereby healed tibiae of the locked control groups failed at torsional loads of $28 \pm 12 \text{ Nm}^1$, $27 \pm 15 \text{ Nm}^7$, and $28 \pm 25 \text{ Nm}$ in the present study. Dynamic stabilization increased the mean torsional load to failure by 54% with far cortical locking screws, 106% with DLS, and 156% with active locking plates. This comparison suggests that active plates provide a highly effective alternative for axial dynamization of locking plates.

The present study had several limitations. Results were specific to the ovine 3-mm gap osteotomy model and therefore require careful interpretation before extrapolation to clinical practice. The ovine model was selected as it represents the most established fracture-healing model in large animals^{25,27}. Load transmission in the ovine tibia corresponds in magnitude to lower-extremity loading in humans⁴². Also, fracture-healing in sheep is similar to that in humans²⁵. Nevertheless, further studies are required to establish the clinical efficacy of active plates and to explore their effects on the healing of simple, well-reduced fractures. As a further limitation, strength assessment was limited to torsion because of the destructive nature of strength tests. Torsion was chosen over bending because bending strength is highly affected by rotational orientation of the tibia and torsional strength is not.

Furthermore, findings are specific to fracture fixation in strong, non-osteoporotic bone, whereby early and controlled dynamization consistently improved the speed and strength of fracture-healing compared with that of standard locked plating. Additionally, given that locked and nonlocked plating constructs have a comparable stiffness in strong bone⁴³, it seems unlikely that nonlocked constructs will provide sufficient dynamization to

stimulate fracture-healing comparable with that for active locking plates. For fracture fixation in osteoporotic bone, active locking plates combine the strength benefits of fixed angle locking screws with accelerated fracture healing to attain fracture-healing prior to fatigue of the osteosynthesis.

In conclusion, the results of this study confirmed that overly rigid locked plating constructs suppress callus formation and healing. By providing symmetric axial dynamization, active locking plates delivered faster callus formation, consistent and circumferential bridging, and stronger healing compared with standard locking plates. Although caution is advised in applying these results to clinical practice, it would seem wise to use standard locking plates in diaphyseal fracture locations only with careful consideration of the risk of excessive stiffness of these implants. ■

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