

Dynamization of Simple Fractures with Active Locking Plates Delivers Faster and Stronger Healing Relative to Conventional Compression Plating

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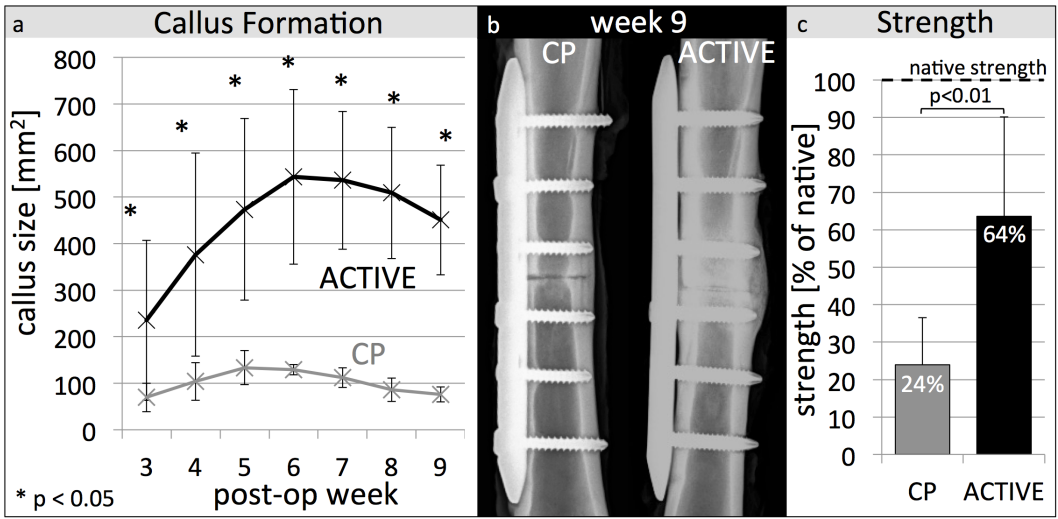
Background/Purpose: Controlled axial dynamization of fractures promotes healing by callus formation, while overly stiff fixation constructs can suppress healing. Novel active locking plates provide axial dynamization of a fracture by elastic suspension of locking holes within the plate. For bridge plating, active locking plates delivered stronger and faster healing of a 3-mm fracture gap compared to rigid fixation with standard locking plates. This in vivo study evaluated the effect of active plating on healing of a simple, anatomically reduced fracture. We hypothesized that dynamic fixation with an active locking plate delivers faster and stronger healing of an anatomically reduced fracture compared to standard compression plating.

Methods: Fracture healing was quantified using the established ovine tibia osteotomy model. 12 sheep were randomized to receive either a standard compression plate (CP group, n = 6) or an active locking plate (ACTIVE group, n = 6) for stabilization of an anatomically reduced tibial osteotomy. Both groups used titanium large fragment plates. In the CP group, absolute stability was achieved with six 4.5-mm cortical screws, applied in accordance with dynamic compression principles, including eccentric screw placement and mild overbending of the plate to ensure interfragmentary compression at the far cortex. In contrast, in the ACTIVE group, relative stability was achieved with six 5.0-mm locking screws, inserted in the active locking plate after anatomic fracture reduction. Locking holes were elastically suspended within the active locking plates by means of elastomer envelopes, permitting up to 0.5 mm of axial motion to retain controlled axial flexibility. Beginning at postoperative week 3, fracture healing was assessed on AP and lateral radiographs to measure callus size each week. Tibiae were harvested at week 9 postsurgery. CT scans were obtained to extract callus volume and distribution. Soft tissue in contact with active plates was evaluated for potential reaction to the elastomer. After implant removal, tibiae were biomechanically tested in torsion to failure to assess the strength of healing. For normalization to the native strength of tibiae, contralateral intact tibiae were tested to failure.

Results: At each time point from postoperative weeks 3 through 9, the ACTIVE group had significantly more callus ($P < 0.05$) than the CP group (Fig. 1a). At the earliest time point (week 3), the average callus size in the ACTIVE group ($235 \pm 172 \text{ mm}^2$) was already over 3 times greater than in the CP group ($70 \pm 31 \text{ mm}^2$). At week 9, the average callus volume in the ACTIVE group ($451 \pm 118 \text{ cm}^2$) was over 4 times greater than in the CP group ($76 \pm 16 \text{ cm}^2$) (Fig. 1b). After sacrifice at week 9, no soft-tissue reaction to the elastomer envelopes of active plates was detectable. Torsion testing after plate removal demonstrated that ACTIVE specimens required 2.5 times more energy to induce failure than CP specimens ($P < 0.05$).

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.

Normalized to contralateral intact tibiae, ACTIVE specimens had regained 64% of their native strength, while CP specimens had regained 24% of their native strength ($P < 0.01$) (Fig. 1c).



Conclusion: It is known that active plating of gap fractures results in more reliable and robust fracture healing. This study confirms that in the setting of a simple fracture, significantly improved fracture healing can be expected using active locking plates relative to conventional compression plating. This finding furthermore challenges the currently accepted axiom of compression plating for simple fracture patterns.