Controlled Axial Dynamization with a Novel Active Locking Plate Can Deliver Faster and Stronger Healing

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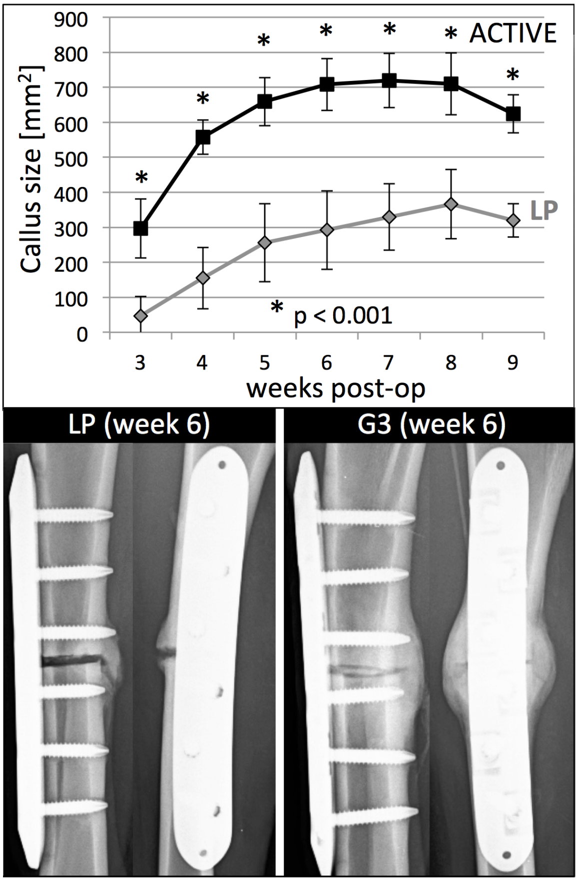
Background/Purpose: Controlled axial dynamization of a fracture promotes healing by callus formation, while overly stiff fixation constructs can suppress healing. A novel plating technology, termed active plating, has been developed that provides symmetric axial dynamization by elastic suspension of locking holes within the plate. This in vivo study evaluated the effect of dynamization with active plating technology on fracture healing in direct comparison to standard locking plates. We hypothesized that active plating delivers faster, stronger and more consistent fracture healing than standard locked plating.

Methods: Fracture healing was quantified in an established large animal model by stabilizing a 3-mm gap of the sheep tibia with bridge plating constructs. In 12 sheep, gaps were bridged with standard locking plates (LP group, n = 6) or active locking plates (ACTIVE group, n = 6). Both groups used titanium 4.5-mm locking plates and 5.0-mm locking screws. The only difference between groups was that locking holes of active plates were elastically suspended within the plate by means of a silicone envelope to provide controlled axial motion. Fracture healing was assessed weekly, starting at postoperative week 3, on anteroposterior and lateral radiographs to measure callus size and to detect bridging callus. Tibiae were harvested at week 9 postsurgery. Soft tissue in contact with active plates was evaluated for potential reaction to silicone. After implant removal, tibiae were biomechanically tested to failure to assess the strength of healing.

Results: At each time point from postoperative weeks 3 through 9, the ACTIVE group had significantly more callus (P <0.001) than the LP group (Fig. 1). Already at the earliest time point (week 3), the average callus size in the ACTIVE group (296 ± 84 mm2) was over six times greater than in the LP group (47 ± 55 mm2). Six weeks postsurgery, all six sheep of the ACTIVE group had bridging callus at the lateral, anterior, and posterior cortices that are visible on planar radiographs. In the LP group, only 50% of these cortices had bridging callus. After sacrifice at week 9, no soft-tissue reaction to the silicone envelopes of active plates was detectable. Torsion testing demonstrated that tibiae of the ACTIVE group had healed to be 158% stronger and required 398% more energy to induce failure compared to the LP group (P <0.001).

Conclusion: Due to their high stiffness, locked bridge plating constructs can suppress interfragmentary motion required for secondary fracture healing by callus formation. Conversely, by providing controlled axial dynamization, active locking plates delivered earlier callus formation, consistent bridging callus, and stronger healing than standard locking plates.

See pages 47 - 108 for financial disclosure information.



PAPER ABSTRACTS

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.