Rethinking the 10% Rule: Virtual Mechanical Testing Detects High Strains in Physiologically Loaded Ovine Tibial Osteotomies

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INTRODUCTION: The 2-10% strain rule was introduced by Prof. Stephan Perren in 1979 and has been widely discussed as a rule of thumb for the strain limits tolerated in secondary bone healing, with strain greater than 10% believed to predispose a fracture to nonunion. Mechanical strain is well-understood to be a primary driver of the fracture healing response, but it is impossible to directly measure *in vivo*. Recently, we developed techniques for using subject-specific finite element modeling to visualize and quantify the perifragmentary strain environment virtually. For this technique to yield insights, it is critical to appropriately model the bone, implant, and loading conditions using methods that represent a physiologically relevant scenario. The technical objective of this study was to identify a simplified superposition loading state representing active weight-bearing that generates physiologic strains in intact ovine tibial diaphysis models and can be translated readily to osteotomy models for characterization of interfragmentary strains. The study hypothesis was that under physiologic loads, gap strains exceed 10% in plated fractures that heal successfully.

METHODS: Samples for virtual modeling were chosen at random from our library of microCT scans of excised tibiae from Swiss Alpine sheep (average body weight 68 kg, age 2-3 years). These animals were all part of previously completed research studies (1); no new animal experiments were performed. There were five operated limbs with 3 mm osteotomies stabilized by 12-hole stainless steel plates and 3.5 mm screws, and there were six intact control contralateral tibiae. Image-based finite element models were created using Materialise Mimics. To generate models representing the immediate post-operative scenario, no callus was included in the models and Solidworks CAD models of the plate and screws were virtually installed, matching visible screw holes in the scans. Intact tibia models were constructed using intact scans. All models consisted of the diaphyseal segment and no joint surfaces, based on the segments that had been previously scanned (Fig. 1). To identify a loading condition for the diaphyseal segment models that represents weight bearing, an optimization was performed on the intact models to select a combination of bodyweight-scaled axial load and bending moments needed to achieve midshaft bone strains comparable to those previously reported for midstance loading from *in vivo* strain gauge measurements (2). Finite element meshes were generated using 3-Matic with quadratic tetrahedral elements. All simulations were performed in ANSYS Workbench Mechanical. A root-mean-squared (RMSE) minimization was performed and a superposition loading state was selected based on midshaft normal strains. This combination axial loading and bending moments was then applied to the plated osteotomy models. A 3D strain visualization region was added to the osteotomy models using submodeling in ANSYS to calculate strains within and around the fracture gaps.

RESULTS: Optimization successfully identified a combination of axial loads and bending moments that achieved the expected physiologic strain state associated with anterior tension and posterior compression during walking (Fig. 2). The RMSE minimization showed that combining an average bodyweight-scaled midstance axial load of -1418 N with an anteroposterior bending moment of 20,000 N-mm and mediolateral bending moment of -15,000 N-mm achieved the overall best match with the reported *in vivo* strain gauge data. Applying these loads to the operated limbs produced high strains (&gt&gt 10% von-Mises strain) in and around the fracture gaps in all models tested (Fig. 3). The volume of elements with von-Misses strain greater than 10% in body weight variation 100% was 9.88 $\pm$ 3.68 cm^3.

DISCUSSION: The results of this study showed that strain in and around the fracture gap of plated ovine osteotomies was likely substantially higher than 10% in a surgical model that reliably produced union. Notably, the gap regions where strain was highest were also delayed in mineralization compared to the pericortical callus (Fig. 3). This suggests that secondary fracture healing is robust to high gap strain because healing is initiated from more strain-favorable regions outside the gap, where callus appeared on X-ray very early in the healing period. Progressive mineralization of the callus ultimately reduced gap strains to a favorable level for bone formation, but the local delay within the gap was clearly evident in the postmortem microCT scans.

SIGNIFICANCE/CLINICAL RELEVANCE: Under physiologically relevant loading, plated ovine osteotomies spontaneously unite in the presence of gap strains much higher than 10%, suggesting that this value is likely not a limiting threshold associated with nonunion.

REFERENCES: (1) Schwarzenberg et. al, J. Orthop. Res. 39, 727-738 (2021). (2) Lieberman et. al, AJPA. Res. 123, 156–171 (2004).

Fig. 1: Representative models for intact control limbs and operated limbs with constraints. (A) Simplified loading conditions were defined using a pinned support on distal end and roller support on the proximal end. (B) A 12-hole stainless-steel plate and screws were virtually implanted in the operated limb models.

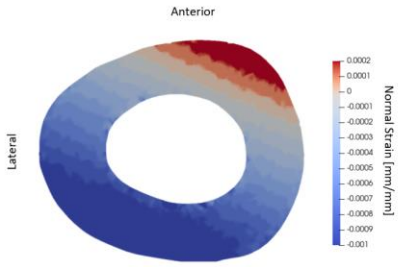

Fig. 2: Optimizing the superposition of loads applied to the diaphyseal segment models produced midshaft normal strains with the expected isoclines at midstance: a slightly medialized anterior tension and lateralized posterior compression state.

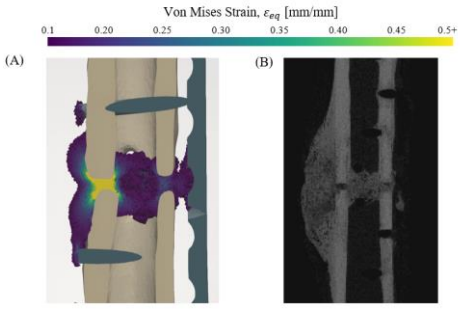

Fig. 3: A) Section view showing the region with >10% von Mises strains under weightbearing load immediately post-op. B) The corresponding CT slice taken at 9 weeks shows delayed mineralization in the fracture gap where strain was initially high, but this fracture successfully united.