Noninvasive Fracture Healing Monitoring with Direct Electromagnetic Coupling

***Kirk C. McGilvray, PhD**; Kevin Labus, PhD; Jakob Wolynski, PhD; Jeremiah Easley, DVM; Branislav Notaros, PhD; Milan Ilic, PhD; Christian Puttlitz, PhD*

Purpose: Temporal monitoring of mechanical changes of stabilized fractures is an excellent indicator of the acute bony healing cascade. Our group has developed a noninvasive, direct electromagnetic coupling (DEC) technology in which a radio frequency-based measurement of in vivo implant deflection resulting from an applied external load allows for the straightforward calculation of fracture site compliance as a predictor of acute healing. The hypothesis is that DEC will allow for the early (≤4 weeks) prediction of nonunions, ultimately becoming a clinical tool to inform on the administration of osteogenic therapies.

Methods: Ewes received a metatarsus osteotomy with nail fixation with a 3-mm defect (union model) or a 10-mm defect (delayed healing model) and were euthanized at 4 (N = 4) or 8 weeks (N = 4). A multi-antenna DEC array was used to calculate fracture site compliance (degrees/kN-m) under 4-point bending twice a week for 4 weeks, then once a week until sacrifice. Biweekly radiographic union scores for tibial fractures (RUST) data, ranging from 4 (no visible callus) to 12 (fully bridged), were also calculated. Following sacrifice, the nails were removed; the metatarsi fracture underwent micro-CT analysis of bone mineral density (BMD), followed by 4-point bending to failure.

Results: The DEC measured mean (± standard deviation) change in compliance per day during the healing period (first 4 weeks) was significantly different (P = 0.02, t-test) between the union (–6.9 ± 4.9°/kN-m/day) and delayed (2.3 ± 2.5°/kN-m/day) models (Fig. 1). In contrast, the radiographic RUST assessments showed a relatively delayed response and were not predictive in the acute time frame (Fig. 1). DEC bending stiffness measured at the sacrifices showed strong correlations with the ultimate bending strength (r2≥0.72) and BMD (r2≥0.82).

Conclusion: The DEC approach detected significant differences between the proper and delayed healing groups before radiographic scores, providing an earlier diagnostic indication of healing compared to the current standard of care. The DEC data also give insight into the BMD and bending strength of the callus. This ability to identify a potential nonunion/malunion with the initial 4-week healing cascade represents a paradigm shift in a clinician's ability to treat these afflictions early—which has been shown to reduce the socioeconomic burden associated with nonunions significantly.

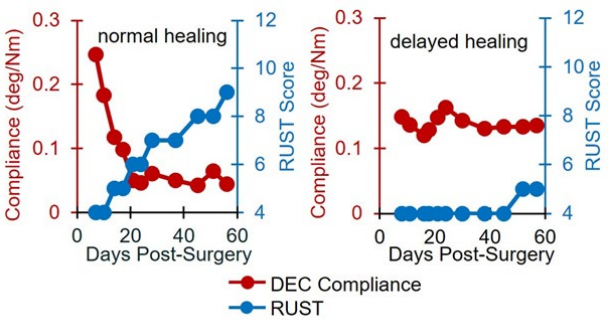

Fig 1: Temporal DEC compliance measurements are shown overlayed with radiographic union score for tibia (RUST) scores for representative animals in the (left) 3 mm osteotomy (proper healing) group and (right) 10 mm osteotomy (delayed healing) group. During proper healing (B), rapid changes in compliance are seen while RUST scores are less than 6, indicating that the callus is just becoming radiographically visible

See the meeting website for complete listing of authors' disclosure information. Schedule and presenters subject to change.