Δ Smart Fracture Plate Monitors Callus Stiffness

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Purpose: Nonunion of fractures treated with plate osteosynthesis results in substantial morbidity and return to the operating room. The diagnosis of nonunion is based on qualitative clinical examination and radiographic assessment of callus. These are subjective and often ambiguous. Measurement of callus stiffness provides a quantitative assessment of fracture healing. Biomechanically, a plate is loaded in parallel with the bone. Initially, all loads (ie, during weight bearing) are transmitted through the plate, but as callus stiffness increases, forces through the plate decrease. In this way, a "smart" fracture plate that measures force can serve as an objective indicator of fracture healing. Previously, transducer technology has required bulky electronics and modification to the plates. We have developed a novel wireless sensor technology and technique to measure forces with no modification to the plate. The purpose of this study was to demonstrate the ability to distinguish different phases of fracture healing using a wireless force-sensing smart osteosynthesis plate.

Methods: A 6-mm osteotomy was created in the distal third of three Sawbones biomechanical femurs to simulate an OTA 33A-3 fracture. A novel wireless, batteryless, disk-shaped force sensor of 9-mm diameter and 350-μm thickness was placed on the outside surface of a distal femoral locking bridge plate over an open hole near the fracture. A small "force concentrator" was then placed over the sensor and affixed to the plate by placing screws through it and the plate. In this way, no modifications of the plate are required. Because fracture plates are inherently loaded in eccentric axial compression, the load causes them to bend slightly. During this slight deformation, the force concentrator acts as a mechanical amplifier and loads the sensor transversely. Constructs were placed into a mechanical testing machine with a 6° valgus anatomic axis. Loads were applied in 50-N increments to 700 N. Loading was repeated with the osteotomy defect empty (to simulate the acute postoperative period) and then filled with silicone (early callus formation) then polymethylmethacrylate (hard callus). Data were compared between treatment conditions using an analysis of variance and Games Howell test to determine if the smart plate could detect differences in callus stiffness.

Results: For applied axial force greater than 100 N, there was a statistically significant difference in force measured by the sensor for the acute postoperative phase (empty osteotomy) and the other two stages of healing. For all values of applied axial force greater than 150 N, there were statistically significant differences in measured force between all three stages of healing.

Conclusion: Results from this preliminary study demonstrate that the smart plate is effective at discerning between stages of healing. The technology is promising as an objective assessment of fracture healing.

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