Mechanically Compliant Fracture Fixation Plates for Increasing the Magnitude and Symmetry of Interfragmentary Strain in Diaphyseal Shaft Fractures

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INTRODUCTION: Experimental and clinical literature from the last half-century has consistently demonstrated that controlled interfragmentary strain (IFS) between 10-40% in the axial direction can improve the strength and rate of bone healing by stimulating callus formation[1-3]. Current rigid locking plates generally do not allow for this micromotion. These plates tend to deliver suppressed, asymmetrical interfragmentary motion (IFM) since they are stiff in compression[4]. Many efforts have been made to "de-rigidize" plates, including low-modulus material plates, sliding mechanism motion plates, and elastic insert-based plates. For many of these efforts, potential challenges involve long-term biocompatibility questions, friction and wear, and detailed assembly of many parts. The objective of this work is to introduce and evaluate a novel axially flexible (Axi-FLEX™) bone plate design which leverages mechanical compliance (flexibility) to elastically compress and expand under physiological loads. By leveraging compliant beam-like elements (flexures), the plates can be made of as little as one piece of stainless steel, a surgeon-preferred material that traditionally may be too stiff for reliably promoting callus formation.

METHODS: Two sets of biomechanical simulations were performed to compare rigid plates to mechanically compliant plates consisting of two types of flexures under axial or bending loads. In both analyses, ABAQUS 3-dimensional (3D) finite element analysis (FEA) was used with tetrahedral quadratic elements, following a mesh convergence protocol[5] and a coupled reference point (RP) based approach[6] **(Fig. 1).** This approach describes screws and bone as rigid bodies with non-deformable properties and can enable greater computational efficiency and similar force and displacement results compared to fully-meshed construct models[6]. Loads and boundary conditions were applied to proximal and distal RPs which are kinematically coupled to the proximal and distal screw holes, respectively. RPs are also present proximally and distally at near and far cortices. The location of the RPs is based on the geometry of an average adult humeral shaft **(Fig. 1)**. All plates were simulated with stainless steel material properties (modulus of 200 GPa), and four proximal and distal screw holes occupied. The mechanically compliant plates are designed to be manufactured using wire electrical discharge machining (EDM) of high strength 316LVM stainless steel. **Analysis 1:** In the first set of simulations, offset axial loading up to 350N was simulated for both a 9-hole commercially available rigid locking plate (LP) and compliant plate design 1 (CP1), consisting of straight flexures with an axial range of motion of 0.3mm **(Fig. 2).** IFM at the near and far cortices were recorded. **Analysis 2:** Our previous analytical modeling[7] has shown that when larger IFM is desired, compliant plates require longer flexures (serpentine flexures) to deliver this motion while possessing an acceptable maximum stress. Thus, a second set of simulations was conducted to explore how the bending stiffness of compliant plates changes when their axial range of motion is increased. These compliant plates (CP2, CP3, and CP4) involved identical serpentine flexures designed to withstand 0.6mm of axial motion with a maximum stress less than 500MPa. CP2 was a planar single-piece serpentine flexure plate; CP3 incorporated a top cover plate connected to the outer frame; and CP4 incorporated four transverse pins through oblong slots in the plate **(Fig. 2).** The cover plate and transverse pin features in CP3 and CP4 were designed to prevent out of plane rotation of the flexible plate regions. The LP was compared to CP1, CP2, CP3, and CP4 in bending with a 5Nm moment applied about the proximal RP and pinned boundary conditions at the distal RP.

RESULTS: Analysis 1 **(Fig. 3A)** shows that compliant plate 1 (CP1) increased the magnitude and symmetry of simulated interfragmentary motion. At 100N, the compliant plate delivers more than 0.2mm of IFM at both cortices, the reported minimum threshold required for callus formation[3,8], while the LP does not reach this threshold at 350N. The IFS was more than three times more symmetric with the compliant plate, with a mean symmetry ratio ($IFS_{\text{far cortex}}/IFS_{\text{near cortex}}$) of 1.88 and 5.85, for the CP1 and LP, respectively. Plate angular rotation under 350N was 1.08˚ and 0.25˚ for the CP1 and LP, respectively. Analysis 2 **(Fig. 3B)** shows that for 0.6mm IFM compliant plates, the addition of bending resistance features (included in CP3 and CP4) can increase the bending stiffness from 2.6Nm/˚ (CP2) to 8.4 and 7.3Nm/˚ (CP3 and CP4), compared to 5.6Nm/˚ and 34Nm/˚ for CP1 and LP, respectively.

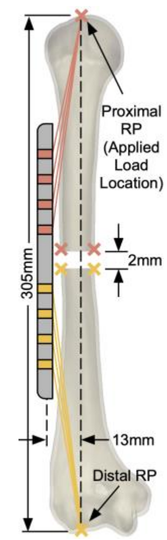

Fig. 1: Simulation Setup

DISCUSSION: This biomechanical simulation study demonstrates the preliminary feasibility of mechanically compliant flexure-based bone plates to deliver greater and more symmetric interfragmentary strain than traditional locking plates. Potential advantages of the proposed compliant plates compared to other alternatives include the use of a single material and, in some embodiments, a single-piece, reduced friction and wear, and bi-phasic stiffness to prevent over-strain. While bending reinforcement features were shown to be effective, the bending stiffness is less than rigid plates. However, the compliant plates offer a considerably improved off-axis-to-axial stiffness ratio, favoring the callus-stimulating direction of motion. Selecting an optimal compliant plate design involves a tradeoff between the simplicity of single piece designs and the improved bending stiffness of reinforced designs. A limitation of this study is the modeling of bone and screws as rigid bodies, as described in [6]. This approach provides comparative results between plate designs, however, the absolute values for IFM require experimental validation. Future work involving biomechanical testing of novel compliant plates is underway.

SIGNIFICANCE: The proposed plating technology has the potential to ultimately reduce the non-union rate in long bone shaft fractures by delivering the amount of interfragmentary strain known to facilitate faster and stronger secondary bone healing.

REFERENCES: [1] Goodship et al., 1985 [2] Madey et al., 2017 [3] Claes et al., 2020 [4] Lujan et al., 2010 [5] Oefner et al., 2021 [6] Mühling et al., 2021 [7] Huxman et al., 2023 [8] Claes et al., 2011

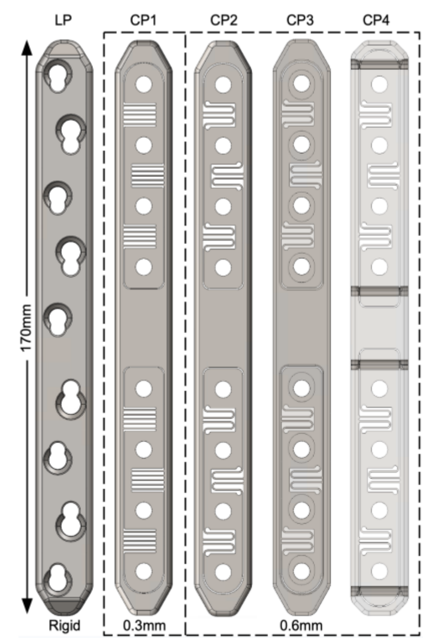

Fig. 2: Locking plate (LP) and proposed mechanically compliant plates (CP1-4)

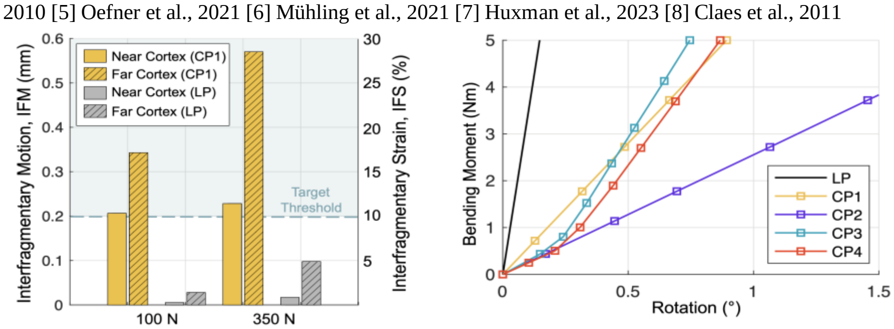

Fig. 3: Left) Interfragmentary motion and strain for compliant plate (CP1) and rigid locking plate (LP) under axial loading; Right) Bending stiffness of compliant plates with larger 0.6mm motion range