Validation of a Finite Element Model to Characterize the Strength of a Fracture Fixation Plate

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INTRODUCTION: The ASTM standard F382-17[1] provides a test method to characterize the bending strength of metallic bone plates used in the internal fixation of the skeletal system. The FDA guidance document *Orthopedic Fracture Fixation Plates-Performance Criteria for Safety and Performance Based Pathway* also recommends using this method. In this study, we utilized Finite Element Analysis (FEA) to characterize the bending strength of a fracture fixation plate. ASME V&V 40[2] guidelines were followed to validate the FEA model.

METHODS: A CAD model of a straight fracture fixation plate, replicating the shaft design of a distal radius plate, was utilized for FEA setup. The test apparatus geometry was simplified, and in accordance with ASTM F382-17 A1.6.1.3, the loading rollers were positioned such that two screw holes of the plate were situated between the loading rollers, which were located at one third of the total distance between the support rollers (Figure 1). No simplifications were made to the plate model. Loading roller and support roller models were simplified since rollers were not components of interest in this study. To approximate the behavior of the material after yielding, a bilinear material model was utilized for the plate. Second order components were used to model the plate. The loading rollers were free to displace along the Y-axis and confined along all other translational and rotational axes. This was done to imitate the physical test. For the FEA simulation, ANSYS® WORKBENCH 2022R1 was utilized. For each simulation iteration, a force vs. deflection diagram was plotted from FEA results. Bending strength and structural stiffness were identified as the Quantities of Interest (QOI) and calculated in accordance with ASTM F382-17. Model risk was considered high, and credibility factors were evaluated according to ASME V&V 40. For model verification, a sensitivity study was conducted to investigate two credibility factors: *discretization error* and *numerical solver error*. For validation, computational *model form* and *model input credibility factors* were considered. Based on model risk, a sensitivity study for model form was carried out. Critical model inputs, including the plate's width, height, and slot length, as well as friction coefficient were identified, and sensitivity analysis and uncertainty quantification[3] were performed for each parameter. Baseline FEA model QOIs were compared with QOIs from changed input parameters. For *comparator credibility factor*, two physical samples were fabricated based on the CAD model specifications and four-point bend testing was performed on an Instron 8874 servo-hydraulic test machine. The *assessment credibility factor* will be studied at a later date to validate the FEA model.

RESULTS: A mesh convergence study was performed for the credibility factor *discretization error*. For the consecutive iterations of mesh refinement, 1.9 % change was observed in bending strength and 0.72% change was observed in structural stiffness. Various solver parameters were changed and QOIs were observed for the credibility factor *numerical solver error*. A maximum 2.2% change was observed in bending strength and a maximum 0.4% change was observed in structural stiffness, indicating that there was no significant change in QOIs. Mesh size and solver parameters were therefore accepted. In the *model form credibility factor* sensitivity study, 2.8% change was observed in QOI, which indicates that there is no significant effect of the model form assumptions on the QOIs. For the *model input credibility factor*, both sensitivity and uncertainty were determined (Figure 2). The bending strength QOI showed the highest sensitivity for the width parameter. The structural stiffness QOI showed the highest sensitivity for the height parameter. Next, standard uncertainty was calculated for each parameter. The height parameter was associated with the highest uncertainty. A comparison of physical test and FEA simulation was carried out for the *comparator credibility factor*. A maximum 2% and 3% deviation was observed in bending strength and structural stiffness, respectively, when comparing QOIs between FEA and physical test. This indicates that FEA simulation results are aligned well with the physical test results.

DISCUSSION: The presented FEA simulation methodology follows ASME V&V 40 guidelines to characterize the mechanical properties of a fracture fixation plate. Test conditions of ASTM F382-17 were successfully replicated. By following ASME V&V 40, simulation iterations were carried out for verification and validation of the FEA model. Testing of additional physical samples is planned to further increase the credibility of the FEA model. However, the current comparison demonstrates the utility of ASME V&V 40 in achieving close replication of physical four-point bend testing of fracture fixation plates in an FEA simulation environment.

SIGNIFICANCE/CLINICAL RELEVANCE: Finite Element models verified and validated via ASME V&V40 can be utilized to reduce the burden of physical testing by replicating test setups in a simulation environment. As such, FEA simulation can help characterize the mechanical properties of orthopedic implants and reduce time and cost of implant development cycles and thereby contribute to timely availability of innovative and safe implants to the benefit of healthcare providers and patients alike.

REFERENCES: [1] ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws. 2017, ASTM International: West Conshohocken, PA. [2] Assessing Credibility of Computational Modeling Through Verification and Validation: Application to Medical Devices, ASME V&V 40, 2018 [3] EURACHEM/CITAC Guide Quantifying Uncertainty in Analytical Measurement, Third edition, Editors S L R Ellison (LGC, UK) A Williams (UK)

IMAGES AND TABLES:

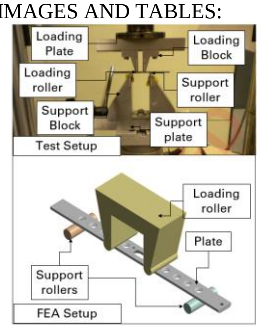

Figure 1: Test apparatus and FEA setup

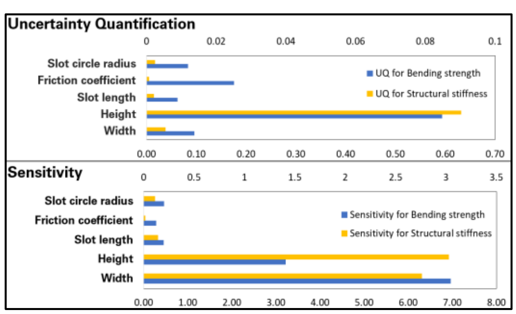

Figure 2: Sensitivity and uncertainity of each model input parameters

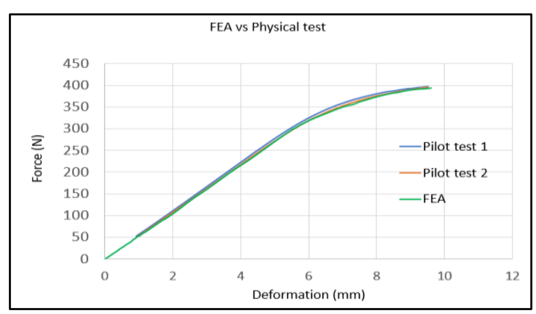

Figure 3: Physical test vs FEA simulation