Additive Manufacturing Variability on Medical Device Performance; Predicting Static Device Performance with FEA

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Abstract

Background: The growing need for personalized medical devices presents a considerable challenge to conventional manufacturing techniques. The emergence of Additive Manufacturing (AM) technologies has provided a solution to this problem. However, this process also poses its own risks, such as higher degree of variability in the final products impacting device reliability.

Purpose: This ongoing research aims to use *in silico* modeling to predict static device performance variability in AM using Finite Element Analysis (FEA).

Methodology: Mock bone plates were fabricated with Nylon and titanium alloy (Ti64). FEA is used to simulate the static four point bending tests. Data from both the literature and previous preliminary tensile tests were used as input for the material models. Static four point bending tests were performed using an Electropuls E3000 testing instrument according to ASTM F382 standard. Bending stiffness, bending structural stiffness, proof load, and proof displacement of the bone plates were assessed. An optical displacement measurement method was used to compare the results from FEA and experimental tests.

Results and Conclusion: Both Nylon and machined Ti64 bone plates exhibited plastic deformation failures. The FEA simulations showed similar failures. The load-displacement curves from the simulation of the Nylon bone plates matched the bench testing load displacement curves. The deformation of nylon bone plates measured with DIC during the experiment was similar to the predicted deformation in FEA.

Introduction

Additive Manufacturing (AM), also known as 3D printing, is increasingly being employed in industry to fabricate medical devices. This technology offers advantages over traditional manufacturing process like the ability to create intricate structures and rapid fabrication of personalized devices to match patients' unique anatomies which may significantly improve clinical outcomes due to high adaptability. There are various AM technologies used today which may have many build parameters controlling the fusing of material when compared to traditional manufacturing approaches. This increased number of build parameters along with the current inherent nature of the technology may result in significant material performance variability, and thus significant medical device performance variability. While manufacturers use consensus standards to provide evidence of device reliability, addressing the variability from a manufacturing process remains a challenge. This is **ongoing research** which aims to develop methods for estimating static device performance variability in AM and other manufacturing processes using Finite Element Analysis (FEA). One of the mock devices chosen to be investigated is the bone plate. Bone plates may have different structural stiffnesses depending on geometry and material which may influence bone healing and affect the long term performance of the device. Four point bending tests have been determined to provide a comprehensive mechanical strength reference for bone plates used in surgical interventions.

Materials and Methods

Mock Device: Bone plate mock devices were designed with 8 and 10 screw holes using SolidWorks. Nylon bone plates were additively manufactured with a EOS P396 Selective Laser Sintering (SLS) 3D printer from Nylon 12 (PA 2200) powder. Wrought titanium alloy (Ti-6Al-4V/Ti64) bone plates were machined with 8 and 10 screw holes as well.

Finite Element Simulation: The Computer Aided Design (CAD) model of the bone plates were imported from SolidWorks to Ansys Workbench. The static structural module was used to simulate four point bending tests of both the Nylon bone plate and Ti64 bone plate with 8 screw holes. Linear elastic material properties were attained from preliminary tensile tests of 3d-printed Nylon and wrought Ti64 respectively and from literature. Multi-linear isotropic (MISO) hardening was incorporated into the static FEA model to simulate plastic yielding, plastic deformation, and isotropic homogenous material properties. Load and boundary conditions were based on observations from experimental tests of static uniaxial loading conditions.

Bench Testing: Static four point bending tests were performed according to ASTM F382 (Standard Specification and Test Method for Metallic Bone Plates) using an Instron Electropuls E3000 load frame. The experiment was displacement-controlled at 0.2 mm/s at a maximum displacement of 20 mm for the nylon and 10 mm for the Ti64 bone plates. Load-displacement data were used to obtain bending strength (N-m), bending stiffness (N/mm), bending structural stiffness (N-m²), proof load (N), and proof displacement (mm), as defined by the standard and compared to results from computational models. Strain measurement: At least one specimen was tested in conjunction with an optical displacement measurement method; Digital Image Correlation (DIC) for comparison to the FEA deformation result (***Figure 3 and 5***).

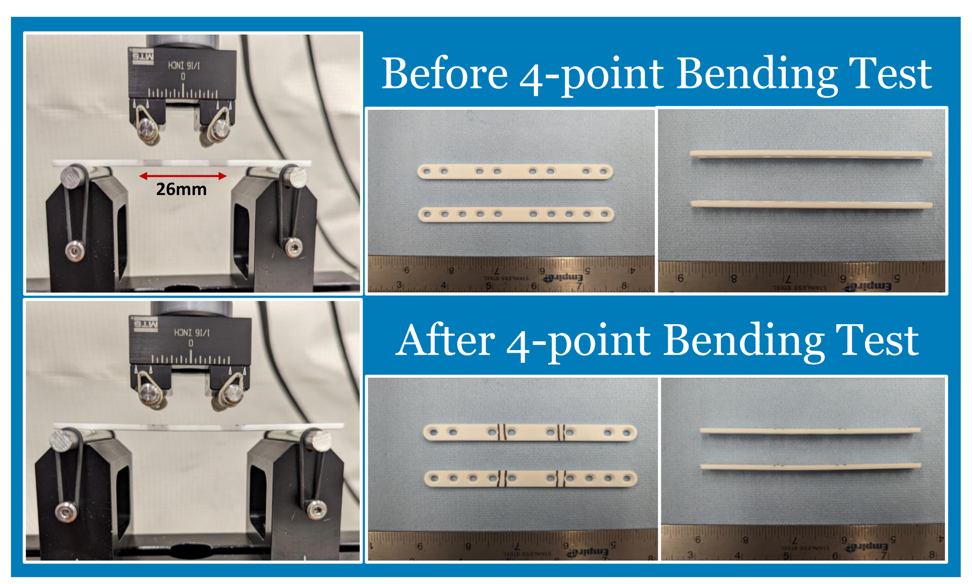

Figure 1: 4-point bending experimental setup for Nylon bone plates; test was performed with equal load and center span of 26 mm. All bone plates failed by plastically deforming.

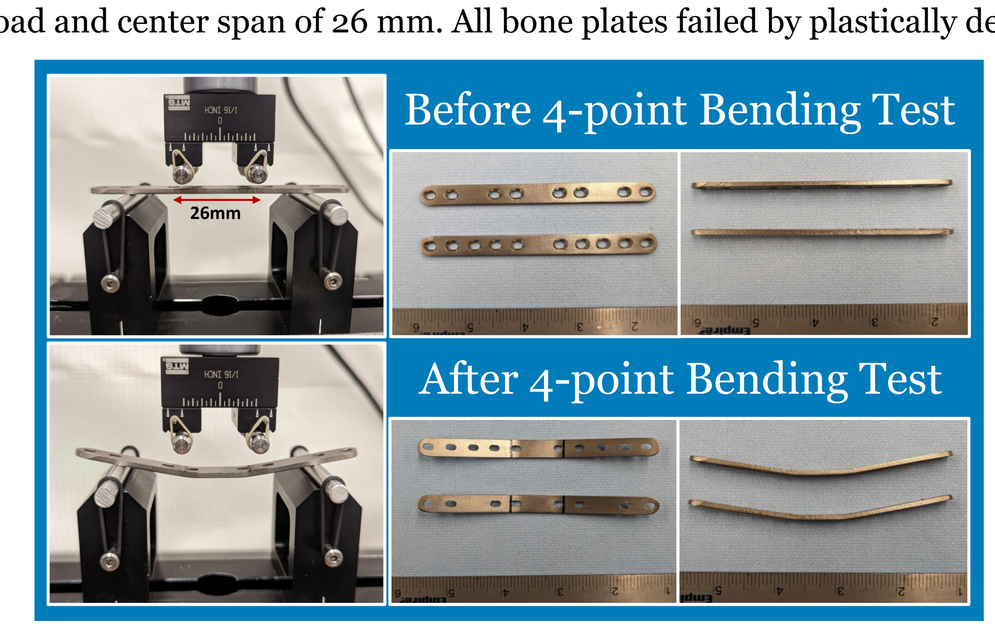

Figure 2: 4-point bending experimental setup for Ti64 bone plates; test was performed with equal load and center span of 26 mm. All bone plates failed by plastically deforming.

Results and Discussion

- Both the printed Nylon and machined Ti64 bone plates displayed plastic deformation failures (***Figure 1 and 2***).
- The static test results showed that the measured parameters were similar for nylon bone plates with 8 and 10 screw holes with the highest coefficient of variation (CV) of 2% for the bending stiffness of the plates (***Table 1***). This variation was higher for Ti64 bone plates with 8 and 10 screw holes with the highest CV being 5% for bending stiffness and bending structural stiffness (***Table 2***).
- The FEA load-displacement curves obtained for the Nylon bone plates matched the bench testing load displacement curves (***Figure 4B***).
- While the predicted maximum displacement was similar for both FEA and DIC, minimum displacement differed with CV of 9% (***Table 3***).
- The load displacement curves of the Ti64 bone plates were similar for both 8 and 10 screw holes bone plates (***Figure 6***).

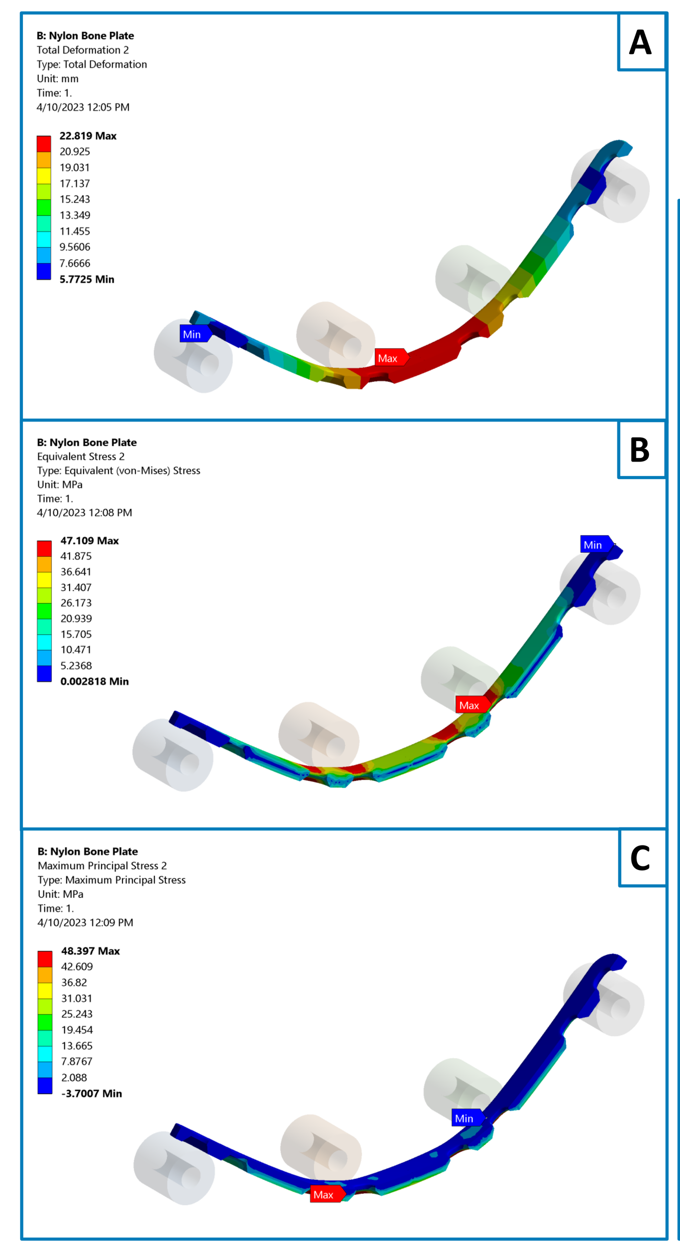

Figure 3: FEA contour images of Nylon bone plate bending simulation showing locations of maximum and minimum stresses and deformations; (A) Total deformation, (B) Equivalent Stress, (C) Maximum Principal Stress of the bone plate

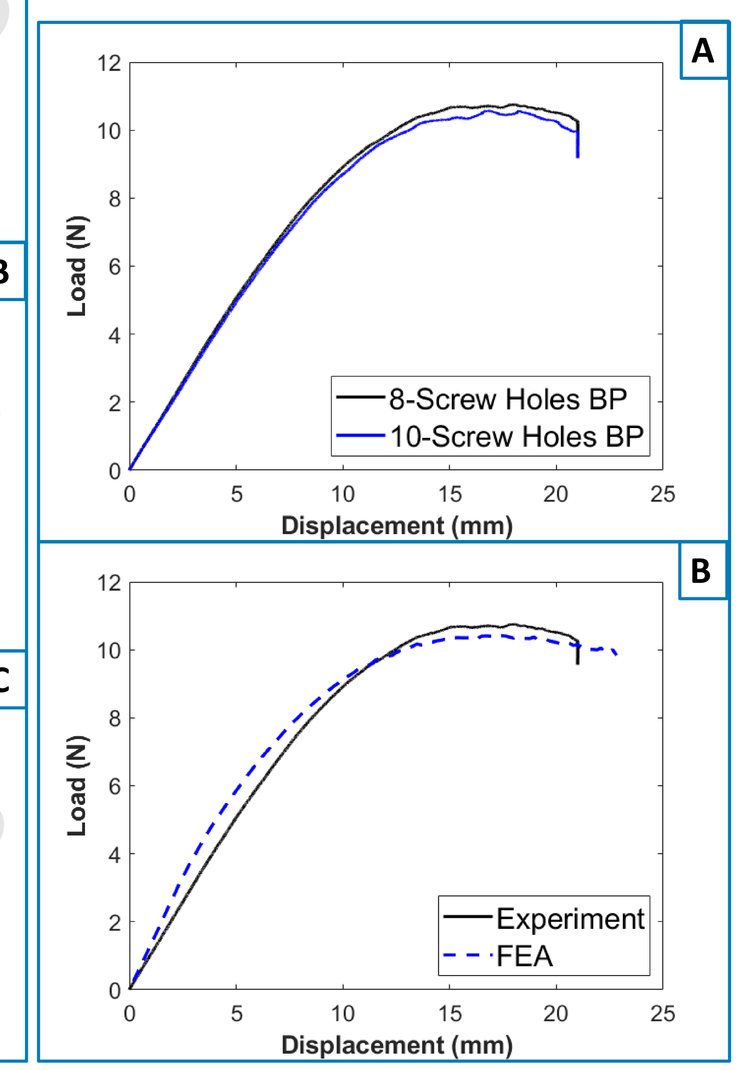

Figure 4: Load-displacement curves of (A) Nylon bone plate with 8 and 10 screw holes from experiment (B) Average of the Nylon bone plate with 8 screw holes from experiment and from FEA.

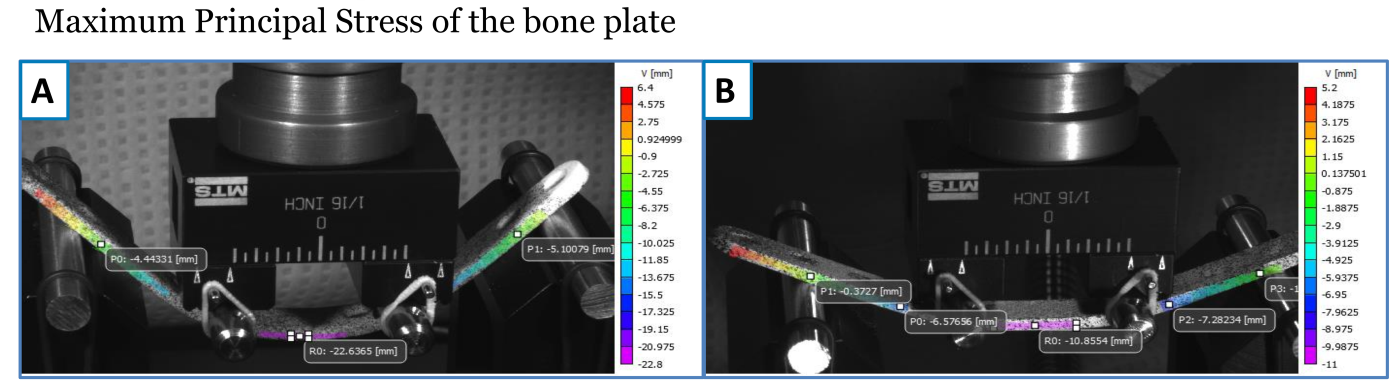

Figure 5: DIC test results showing maximum displacement of (A) Nylon bone plate and (B) Ti64 bone plate at localized regions and points.

NYLON BONE PLATE	8-Screw Holes BP	10-Screw Holes BP	Coefficient of Variation
Bending Stiffness (N/mm)	0.97	0.95	2%
Bending Strength (N-m)	0.10	0.10	1%
Bending Structural Stiffness (N-m²)	0.01	0.01	0%
Proof Load (N)	6.54	6.54	0%
Proof Displacement (mm)	6.68	6.75	1%

Table 1: Static test results for Nylon bone plates after 4-point bending test

TITANIUM BONE PLATE	8-Screw Holes BP	10-Screw Holes BP	Coefficient of Variation
Bending Stiffness (N/mm)	133.9	124.2	5%
Bending Strength (N-m)	7.04	6.80	3%
Bending Structural Stiffness (N-m²)	0.98	0.91	5%
Proof Load (N)	541.8	522.6	3%
Proof Displacement (mm)	4.06	4.25	3%

Table 2: Static test results for Ti-6Al-4V bone plates after 4-point bending test

Displacement Measurement	DIC	FEA	Coefficient of Variation
Maximum Displacement (mm)	22.64	22.82	1%
Minimum Displacement (mm)	5.10	5.77	9%

Table 3: Comparison of displacement results from FEA and experiment captured with DIC.

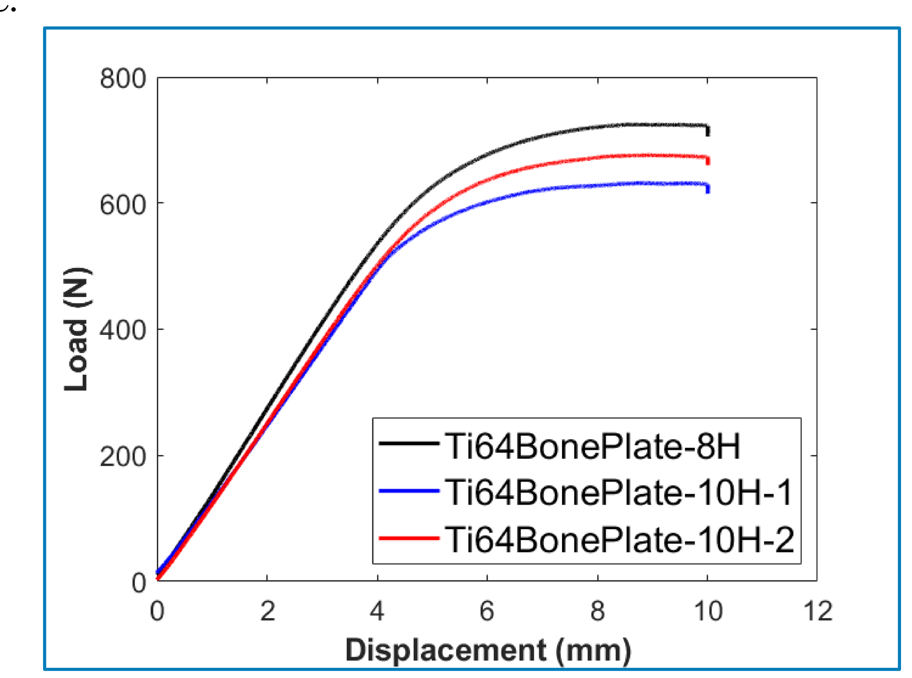

Figure 6: Load-displacement curves of Ti64 bone plate with 8 and 10 screw holes from experiment

Conclusion

- In this study, FEA was utilized to predict mechanical characteristics of printed nylon bone plates.
- In addition, DIC was employed to measure the deformation in specific regions during the experiment, which facilitated a more precise comparison with the FEA simulation of the test.
- The FEA simulation identified areas on the bone plate that underwent maximum stresses and strains. These findings corresponded with the observed deformation of the bone plates during experimental tests.