



Computational Assessment of Orthopedic Implant Durability Using Finite Element Analysis

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Abstract. Finite Element Analysis (FEA) provides a rapid and cost-effective method to evaluate orthopedic implants. This research investigates the mechanical performance and long-term durability of a seven-hole SS 316L Basic Fragment Set (BFS) reconstruction plate designed for pelvic fractures. Adhering to ASTM standards, material properties were defined via tensile testing (ASTM E8), while static and fatigue analyses were performed using a displacement control method in a four-point bending test setup in SOLIDWORKS 2024 (ASTM F382). The static analysis predicted failure from plastic deformation at a force of 367 N, with a maximum stress of 621.92 MPa. The fatigue simulation predicted a lifespan of 483,754 cycles. To validate the simulation, these computational results were compared to experimental data, demonstrating high accuracy with deviations of only 3.34% for maximum force and 1.19% for fatigue life. These findings confirm that FEA is a highly reliable tool for predicting mechanical performance, enabling the orthopedic industry to optimize implant designs, enhance patient safety, and improve production efficiency.

Keywords: biomechanics, fatigue, finite element analysis, orthopedic biomechanics, implant validation

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1. Introduction

Pelvic fractures are among the most challenging orthopedic injuries to treat due to the complex structure of the pelvic anatomy and its critical role in supporting body weight [1]. Surgical treatment for these fractures often requires the use of reconstruction plates that are specifically tailored to the unique anatomical shape of each patient [2]. The Basic Fragment Set (BFS) Reconstruction plate is a popular choice for this purpose, valued for its high adaptability and flexibility to conform to intricate pelvic structures [3]. The use of BFS Reconstruction plates has shown positive outcomes, particularly in accelerating recovery and reducing postoperative complications [4].

Despite its advantages, the process of shaping these plates during surgery remains a significant clinical challenge [5]. Anatomical differences between patients and the risk of damaging adjacent soft tissues complicate the procedure [5]. Therefore, a deeper understanding of plate design optimization and proper surgical techniques is necessary to improve clinical outcomes for patients with pelvic fractures [6].

While significant progress has been made, various biomechanical complications continue to pose clinical challenges. Stress shielding, in particular, occurs when the implant's mechanical properties differ significantly from natural bone, which can hinder bone remodeling and increase the risk of refracture [7]. To mitigate this, recent studies have explored advanced solutions like variable stiffness plates [8]. In addition to these static load challenges, another critical factor is the cyclic loading from daily activities. Research indicates that such repetitive loading significantly influences the fatigue life of orthopedic implants [9]. Evaluating the biomechanical response under these dynamic conditions is therefore crucial for ensuring long-term reliability and durability [10].

One area that has received less attention is the use of computational analysis with the Finite Element Method (FEM) to evaluate both static performance and fatigue resistance in reconstruction plates [11]. Recent advancements in computational modeling have made it possible to simulate complex loading conditions that better reflect real-world scenarios. Some studies have used patient-specific finite element models to assess how different plate designs respond under physiological stresses [12].

However, the accuracy of FEM simulations is critically dependent on experimental validation to confirm the clinical outcomes of computational models [13]. This is underscored by previous research employing a force control method in 4-point bending tests, which reported a validation accuracy of only 77.8% [14]. To enhance predictive capabilities, the integration of *in vitro* fatigue testing with *in silico* models is a key strategy for assessing long-term implant performance [15]. Concurrently, advances in additive manufacturing are enabling the development of patient-specific plates customized for optimal biomechanical compatibility, further improving treatment outcomes [16].

Furthermore, the adoption of computational biomechanics is highly relevant to developing sustainable medical technology. Aligning with the principles of a circular economy, such as those applied in industrial recycling to reduce waste [17], the use of FEA minimizes material consumption from physical prototypes and fosters more efficient design cycles. This highlights the need for robust and validated computational approaches, a common theme in materials science where strategies are developed to bridge the gap between theoretical predictions and experimental reality [18].

The central novelty of this study is the application and validation of the displacement control method, which is hypothesized to provide significantly higher fidelity in predicting the mechanical behavior of orthopedic plates. Therefore, the objective of this research is to investigate the static and fatigue performance of a seven-hole reconstruction plate using a validated Finite Element Method simulation to ensure its long-term durability in clinical applications for pelvic fractures.

2. Methods

2.1. Tensile Test for FEA Material Properties

The tensile testing procedure in this study adhered to ASTM E8 standards, which outline general requirements for equipment setup and testing procedures for metallic materials [19]. This standard is widely utilized to assess the mechanical properties of metals, particularly in determining parameters

such as tensile strength, strain, and elastic modulus. The tensile test involves applying a uniaxial load to a specimen until it undergoes plastic deformation and ultimately fractures, providing insights into the material's behavior under tensile stress. In this study, the test plate was positioned within the fixture according to the configuration illustrated in Figure 1a.

The material tested was a stainless steel SS 316L plate with a thickness of 2 mm, as depicted in Figure 1b. This material was chosen due to its excellent mechanical characteristics, including high corrosion resistance and good workability, making it suitable for various industrial applications. SS 316L is particularly known for its durability in chloride-rich environments, making it a preferred option for applications demanding both strength and resistance to chemical degradation. The detailed dimensions of the test specimen are presented in Table 1 and Figure 1c. The experiment was conducted in the Materials Laboratory at the Mechanical Engineering Department of Universitas Diponegoro to ensure compliance with testing protocols and generate reliable data for further analysis.

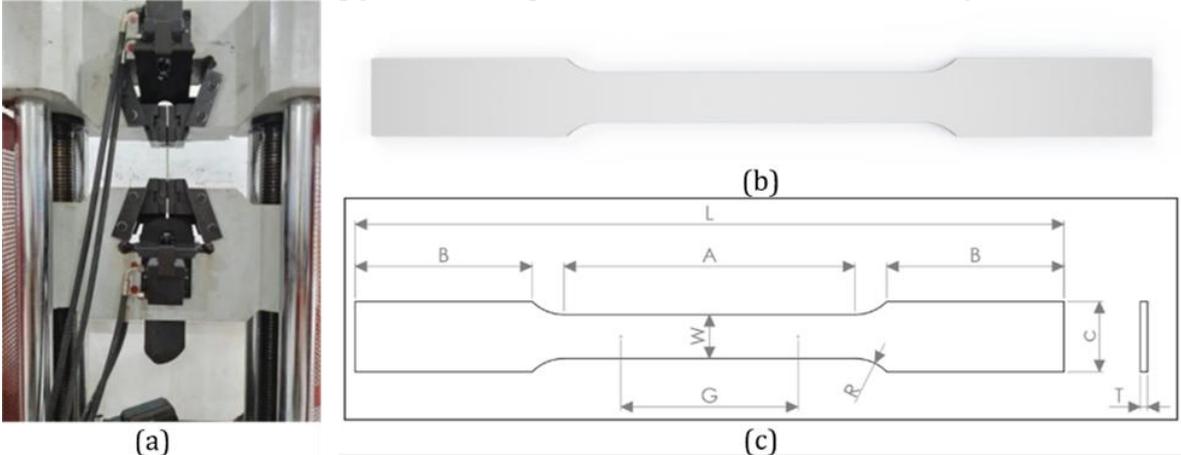


Figure 1. (a) Tensile test configuration (b) 316L plate 2 mm (c) specimen dimensions.

Table 1. Specimen plate dimensions for testing

Information	Dimensions (mm)
G-Gage length	50
W-Width	12.5
T-Thickness	2
R-Radius of fillet	12.5
L-Overall length	200
A-Length of reduced section	57
B-Length of grip section	50
C-Width of grip section	20

The material used in this study refers to ASTM F745 standards, which outline the specifications for austenitic stainless steel in both engineering and medical applications. This standard ensures that the material meets essential mechanical and chemical criteria, making it suitable for environments that demand high corrosion resistance and structural durability. SS 316L is particularly noted for its low carbon content, which enhances its resistance to intergranular corrosion, thereby minimizing the risk of material degradation when exposed to harsh conditions [20].

Furthermore, SS 316L offers an excellent combination of mechanical strength, ductility, and biocompatibility, making it a widely used material across structural and biomedical applications. Its strong resistance to pitting and crevice corrosion, especially in chloride-rich environments, makes it ideal for marine and chemical processing industries. In medical applications, its biocompatibility and resistance to bodily fluids ensure its widespread use in orthopedic implants, surgical instruments, and other medical devices that require long-term implantation or frequent sterilization.

To determine the yield strength, the 0.2% offset yield method was employed, which is standard in stress analysis [21]. The data used for analysis in the FEA software included true stress and true strain [22]. These true stress values were calculated using the following equations:

$$\sigma_u = \sigma(1 + \epsilon) \quad (1)$$

These true strain values were calculated using the following equations:

$$\epsilon_u = \ln(1 + \epsilon) \quad (2)$$

Where σ_u is the true stress (MPa), σ is the ultimate strength (MPa), ϵ is the elongation (%), and ϵ_u is true strain depends σ_u .

These equations allow for the conversion of engineering stress-strain data into true stress-strain data, which is more representative for use in FEA analysis as it accounts for changes in cross-sectional area and length during the testing process [23].

2.2. Plate

This study utilized a seven-hole SS Stryker plate provided by Stryker Trauma AG, Selzach, Switzerland [24]. The plate is part of the Stryker Plating System (SPS) Basic Fragment Set (BFS) Reconstruction Plate (REF 432207) and is made of annealed SS 316L stainless steel. It measures 110 mm in length and 3.1 mm in thickness, with hole configurations designed to accommodate 4.5 mm diameter screws (see Figure 2b). The span dimensions are defined as $L_o = 80$ mm and $L_i = 32$ mm. A comprehensive overview of the plate's specifications, dimensions, and the testing procedure is provided in Figure 2, which details both the testing configuration and the plate's measurements.

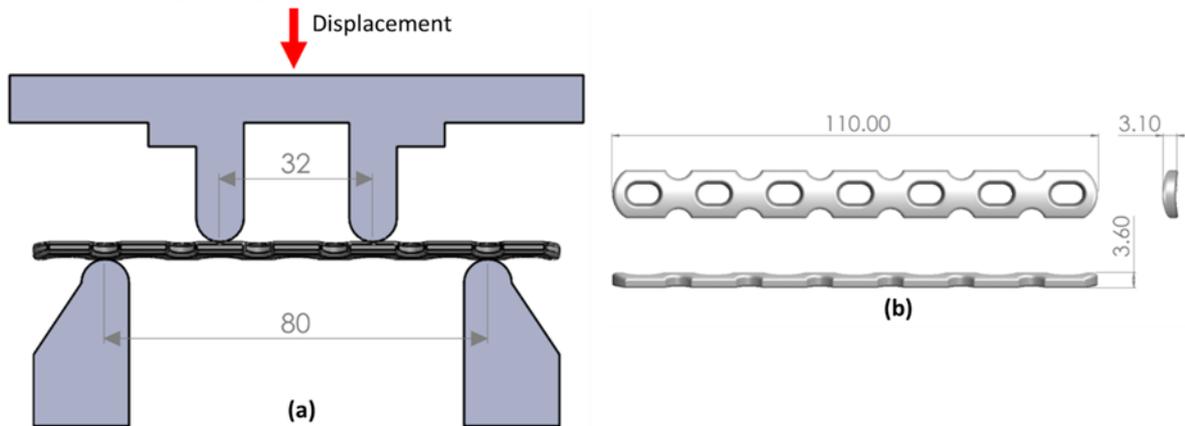


Figure 2. (a) Testing configuration (b) BFS reconstruction plate dimensions.

2.3. Finite Element Modeling and Simulation

2.3.1. Determination of the Optimal Mesh Size

A mesh convergence study was conducted to identify an optimal mesh size that balances result accuracy with computational efficiency. In this test, a load of 230 N was applied to the model, while the mesh element size was systematically varied to analyze its impact on the stress results. The objective of this process was to find the point at which further mesh refinement no longer produced significant changes in the results, a condition that indicates numerical stability. As shown in the convergence results in Figure 3 and Table 2, a tetrahedral mesh with a maximum element size of 7 mm and a minimum of 1.4 mm was determined to be the optimal configuration. This mesh setup was selected because it yielded a minimal deviation of only 0.21% compared to a finer mesh. With a deviation percentage well below 5%, which is commonly considered the threshold for convergence, this mesh configuration was confirmed to have reached a reliable convergence for the subsequent analyses [25].

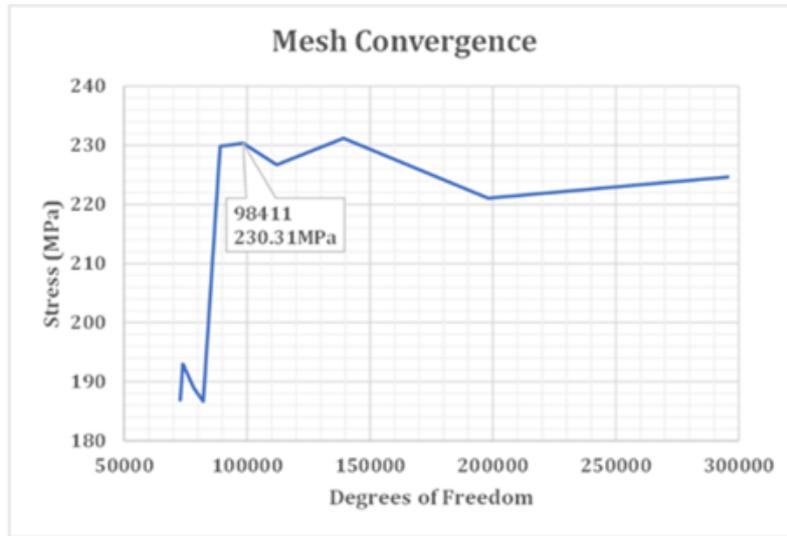


Figure 3. Mesh convergence.

Table 2. Mesh testing results data

No	Mesh (mm)		Degrees of Freedom	Stress (MPa)	Deviation (%)
	max	min			
1	12	2.40	72 857	186.88	-
2	11	2.20	73 878	193.00	3.27
3	10	2.00	78 379	188.90	2.12
4	9	1.80	82 216	186.68	1.18
5	8	1.60	89 105	229.83	23.11
6	7	1.40	98 411	230.31	0.21
7	6	1.20	112 055	226.68	1.58
8	5	1.00	139 253	231.17	1.98
9	4	0.80	198 065	221.06	4.37
10	3	0.60	295 582	224.65	1.62

2.3.2. Mesh Classification and Density

Based on the convergence study, the mesh sizes used in this research were classified into two categories. A mesh with element sizes ranging from 12 mm to 8 mm is defined as a coarse mesh density. Conversely, element sizes between 7 mm and 3 mm are categorized as a fine mesh density. The use of a fine mesh is intended to achieve more detailed and accurate simulation results. The visual difference between these two mesh densities is illustrated in Figure 4.

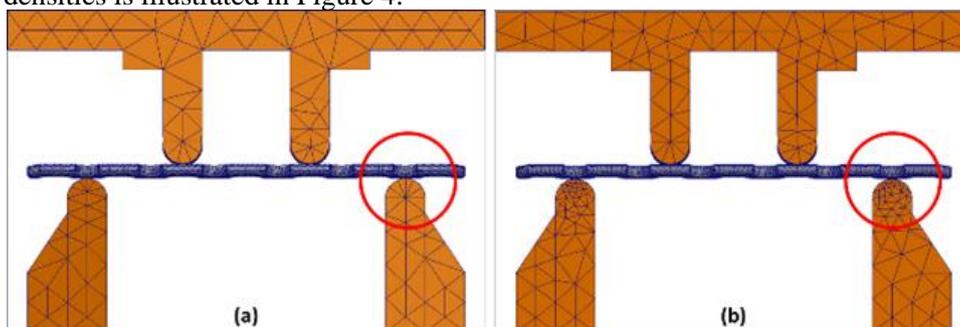


Figure 4. Mesh density (a) coarse and (b) fine.

2.3.3. Static Analysis Setup

A static analysis was conducted using SOLIDWORKS 2024 software to evaluate the plate's mechanical performance, adhering to ASTM F382 standards [26]. A nonlinear static analysis was performed to accurately capture the material's behavior, including the effects of plastic deformation. The simulation utilized a displacement-controlled loading of 25 mm. This method was chosen for its ability to provide a more reliable prediction of the failure load compared to the force control method, which has shown lower accuracy in previous studies [14].

For the simulation setup, the testing fixtures were modeled as rigid bodies to optimize computational time. A "No Penetration" contact set was defined between the fixture and plate surfaces to ensure a realistic physical interaction. The material's behavior was defined in the model using the true stress-strain curve obtained from the tensile tests.

2.3.4. Fatigue Analysis Setup

The fatigue analysis was performed using the FEA method, adhering to the guidelines of ASTM F382 [26]. A stress-life (S-N) fatigue analysis was conducted to evaluate the long-term durability of the plate. The modeling parameters for this analysis were distinct from the static setup. The applied loading condition was a zero-based cyclic load with a maximum magnitude of 236 N. This load value was derived from the 0.2% offset yield point determined in the static analysis. The simulation was run for a target of 1,000,000 cycles to predict the fatigue life of the orthopedic plate.

3. Results and Discussion

3.1. Tensile Test

A tensile test was conducted on a 316L stainless steel specimen with a thickness of 2 mm and a cross-sectional area of 25 mm². During the test, the specimen was subjected to a maximum load of 15 kN. The results of this test are illustrated in Figure 5, which presents the load-displacement curve recorded during the tensile test. This graph demonstrates how the specimen deforms under applied tensile force until failure occurs. From this data, key mechanical properties such as yield strength, ultimate tensile strength, and plastic deformation behavior can be further evaluated by converting it into a stress-strain curve.



Figure 5. Force-displacement curve

The analysis of the tensile test results reveals two primary curves: the engineering stress-strain curve and the true stress-strain curve. The engineering stress-strain curve illustrates the relationship between engineering stress and strain, calculated based on the applied force, the initial cross-sectional area, and the change in length relative to the original length. The yield point was determined using the 0.2% offset method, yielding a strength of 408 MPa with a corresponding strain of 0.054.

In contrast, the true stress-strain curve provides a more precise representation of the material's behavior under loading, as it accounts for the continuous changes in cross-sectional area during deformation. Figure 6 highlights the differences between these two curves, showing that the true stress-strain curve offers a more accurate depiction of the material's response compared to the engineering stress-strain curve. From this curve, the ultimate tensile strength (UTS) of the material is observed at 740 MPa with a strain of 0.22, demonstrating its ability to undergo plastic deformation before failure.

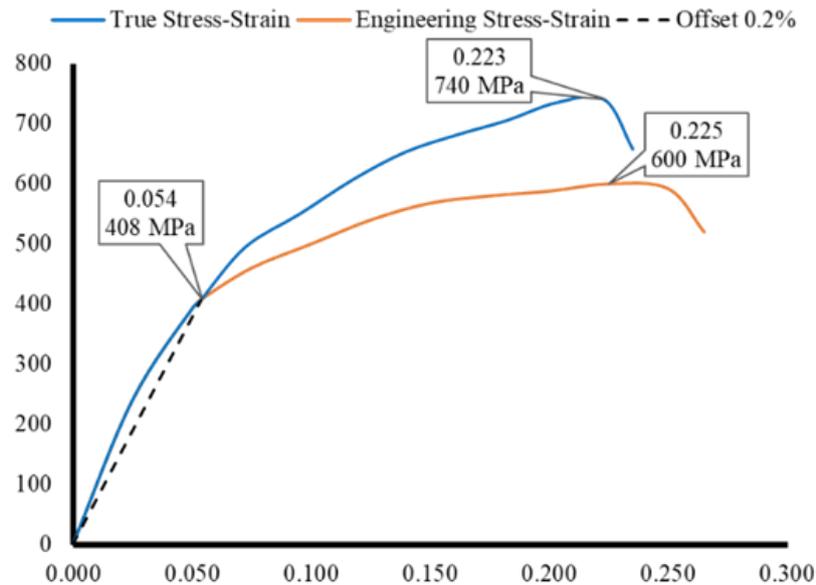


Figure 6. Stress-strain curve

Engineering stress-strain is a method for calculating stress and strain based on the initial dimensions of the test specimen, where stress is determined by dividing the applied force by the original cross-sectional area, and strain is calculated as the change in length relative to the initial length. This approach is widely used in material characterization due to its simplicity; however, its accuracy diminishes under large deformation conditions, as it does not account for the geometric changes of the specimen during loading.

In finite element analysis (FEA), the true stress-strain curve will be incorporated as the material property to ensure that the numerical model accurately represents the actual material behavior under loading conditions. By considering the real-time cross-sectional area dimensional changes of the material throughout deformation, this approach is expected to enhance the reliability of the simulation results in predicting the material's mechanical response to applied forces.

3.2. Static Analysis

The results of the bending test indicate that the finite element method (FEM) encountered failure during the plastic deformation phase, marking a significant shift in the material's mechanical response. This failure occurred at a peak force of 367 N, with a displacement of 13.22 mm. Additionally, the strain value reached 0.17, while the stress level rose to 621.92 MPa, as depicted in Figure 7. These findings are crucial in identifying the critical threshold where the material transitions from elastic to plastic behavior under bending loads. The data obtained from this analysis provide valuable insights into the structural performance of the metal bone plate, particularly in its ability to withstand mechanical stress and deformation. Understanding these parameters is essential for optimizing the design and ensuring the long-term reliability of the implant in clinical applications.

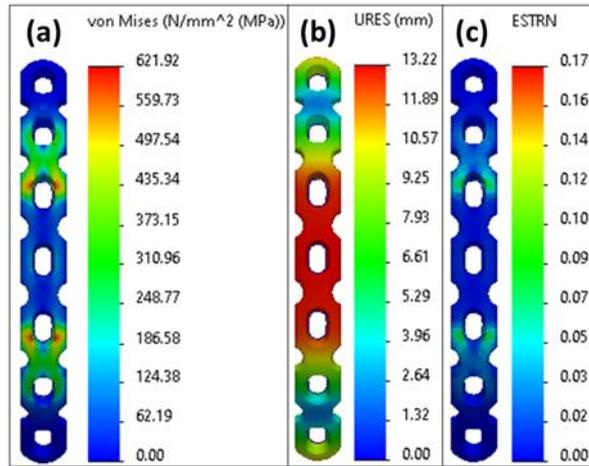


Figure 7. FEA results (a) maximum stress (b) maximum displacement (c) maximum strain.

3.3. Fatigue

The results of the fatigue testing conducted on the implant indicate that failure occurred when the material had already entered the plastic deformation phase, during which the implant structure underwent irreversible changes before ultimately experiencing complete structural breakdown and losing its intended functionality. This failure was specifically observed at cycle 483754, as illustrated in Figure 8. These findings strongly suggest that the implant exceeded its fatigue life due to the cyclic loading conditions that were continuously applied over a certain period of time. Consequently, a more in-depth evaluation of the material's characteristics and overall performance is essential to ensure that the implant possesses sufficient durability to withstand dynamic loading during long-term clinical applications. This aspect is particularly critical in determining the reliability of the implant, especially in medical applications that require structural stability and the ability to endure mechanical forces that are repeatedly exerted throughout its functional lifespan.

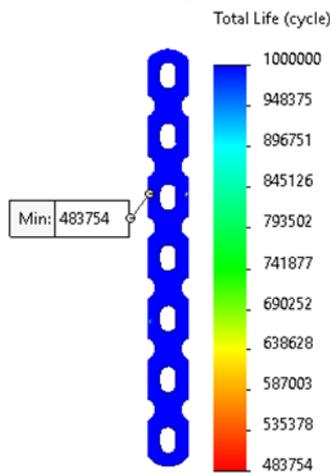


Figure 8. Total live (cycle) based on FEA simulation

3.4. Discussion

According to ASTM F382 standards, the 0.2% offset method is employed to determine the material's yield point [26]. Based on the simulation result curves, this yield point is identified at a displacement of 6.01 mm, where the force reaches a value of 236.38 N (Figure 9). Determining this yield point is crucial as this value forms the basis for setting the load in the subsequent fatigue testing. The ultimate yield point is identified at the moment the reaction force reaches 367.27 N (Figure 9). At this point, the material achieves its maximum strength before it begins to fail. Once this point is surpassed, the reaction

force starts to decrease, signifying that the material's strength limit has been exceeded and structural failure will occur.

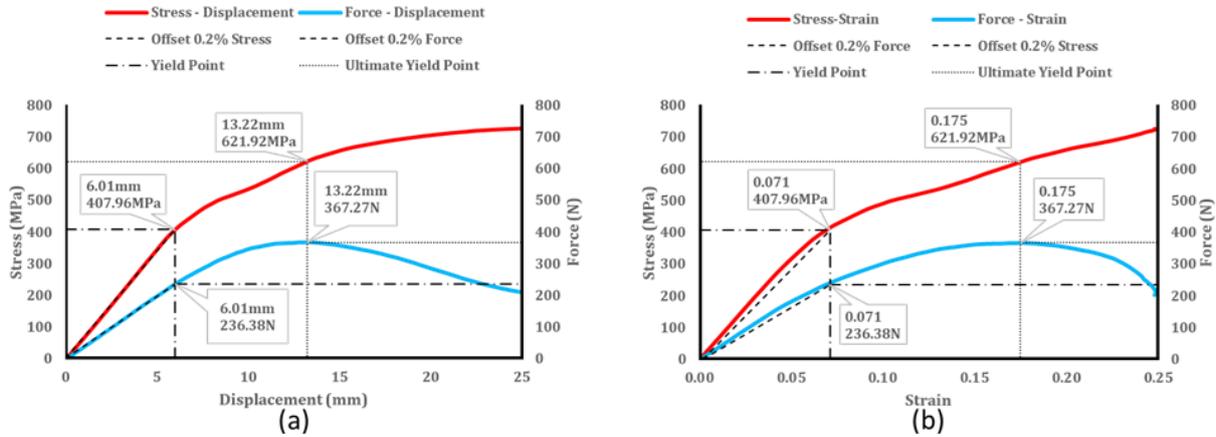


Figure 9. Curve (a) stress-force-displacement (b) stress-force-strain

The foundation of this study's predictive accuracy also lies in the material model. Utilizing the true stress-strain curve is critical, as it provides a more realistic representation of material behavior under large deformations by accounting for changes in the cross-sectional area, which is essential for nonlinear analysis [22, 23]. The high fidelity of this FEA approach is subsequently confirmed through direct comparison with existing experimental data [24]. The simulation's prediction of a 367.27 N maximum force and a 483,754-cycle fatigue life corresponds to accuracies of 96.66% and 98.81% for the static and fatigue tests, respectively (Table 3). This level of accuracy marks a significant improvement over the force control method, which has previously reported accuracies as low as 77.8% in similar bending test simulations [14]. This strong correlation therefore validates the displacement control method as a more reliable and superior tool for predicting the mechanical performance of orthopedic plates.

Table 3. Comparison of experimental and FEA results

Parameter	FEA Results	Experimental Results [24]	Deviation (%)	Accuracy (%)
Maximum Force (N)	367.27	355 ± 3.1	3.34	96.66
Fatigue Life (Cycles)	483754	478000 ± 24160	1.19	98.81

These validated findings have significant practical implications for both implant design and clinical decision-making. For implant designers, the stress distribution map (Figure 7a) provides a clear visual guide to high-stress concentrations, particularly around the central screw holes where bending moments are highest. This information allows for targeted design optimization, such as adding fillets or marginally increasing plate thickness in these critical areas, to enhance fatigue resistance without significantly altering the overall implant profile. For clinicians, a tangible fatigue life of approximately 480,000 cycles provides a crucial data point for patient management. This allows surgeons to provide more specific advice on postoperative activity levels and helps in selecting the appropriate implant for patients with different functional demands and healing timelines.

The scope of this study should be noted. The analysis focused on the plate's intrinsic mechanical performance under a standardized testing configuration, rather than its interaction within a patient-specific anatomical model. This approach is essential for establishing a reproducible baseline for design evaluation. A valuable direction for future research is to apply this validated computational model to patient-specific simulations, incorporating variables such as unique pelvic geometries. Furthermore, the SS 316L material was modeled as isotropic, which is a common and valid assumption for this type of engineering analysis. While the manufacturing process can induce some material anisotropy, exploring its effects was beyond the current scope but remains another valuable area for future investigation.

The successful validation in this study is consistent with findings across the broader field of computational biomechanics. Previous investigations have been published related to computer analysis using finite element simulation on several cases: bionic foot prototypes [27], ESAR foot [28], bionic hand prototypes [29]-[30], and artificial hip joint models [31]-[32]. All of these computer investigations in the previous research reported that the simulation fits well during validation steps. This body of work underscores that finite element simulation is an important and efficient tool for predicting the stress, strain, and safety factor of medical devices.

Today, FEA is widely used as a substitute for costly experimental testing, allowing for faster and more affordable innovation without the need for physical prototypes. However, as this and other studies demonstrate, experimental testing remains essential to validate FEA results [12, 33, 34]. Ultimately, this study reinforces the value of validated FEA as a cornerstone of modern orthopedic engineering. The ability to accurately predict the point of static failure and long-term fatigue life provides a significant advantage over purely experimental approaches, contributing to the development of safer, more reliable medical devices and promoting a more efficient and sustainable pathway for innovation.

4. Conclusion

This study successfully demonstrates that the displacement control method in Finite Element Analysis is a highly accurate and reliable tool for predicting both the static strength and long-term fatigue life of orthopedic reconstruction plates, achieving 96.66% and 98.81% accuracy, respectively, compared to experimental data. This validated method is pivotal for the orthopedic industry as it enables extensive virtual prototyping to optimize implant designs while significantly reducing reliance on costly physical prototypes. In the clinical realm, this approach unlocks future potential for pre-surgical planning. Therefore, the next research direction is to apply this model in patient-specific simulations to tailor implant performance to unique individual anatomies, ultimately improving patient outcomes.

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