

Fatigue Life Estimation of Nitinol Medical Devices

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Abstract: Stents have been used in the treatment of coronary artery disease for decades, and their use in the peripheral arterial vasculature is growing rapidly. Mechanical loads imposed on peripheral stents may include loads due to arterial pulsation, axial compression, bending and torsion. These stents are most often manufactured using nitinol, a nickel-titanium alloy that exhibits unique shape memory and superelastic characteristics. Finite element analysis can be a powerful tool in designing medical devices to withstand such a rigorous loading environment. This paper will focus on the use of Abaqus/Standard for fatigue life characterization of nitinol stents and comparison of performance predicted by FEA to experimental data. Abaqus is used to simulate stent expansion and fatigue loading under expected physiologically relevant loading conditions. A strain based fatigue criterion is used to determine the fatigue characteristics of the stents, and bench top fatigue testing is used to verify the numerical results. The study is extended to a competitive benchmarking of different stent designs. Results show a close correlation between analytical and experimental results, indicating that finite element analysis is a powerful tool in the design and fatigue life estimation of nitinol medical devices subjected to complex loading conditions.

Keywords: Medical Devices, Stents, nitinol, Fatigue.

1. Introduction

Stents are tubular metal structures used in the treatment of occlusive arterial disease, delivered to the site of placement using minimally-invasive surgical techniques. Stents fall into two broad categories: balloon-expandable devices, which are mounted on and expanded to their operational diameter using an inflatable balloon, and self-expanding stents which expand to their operational diameter upon withdrawal of a constraining sheath. Most self-expanding stents are cut from drawn, seamless nitinol tubing and exhibit unique shape memory and superelastic attributes. These attributes make a self-expanding stent generally more flexible and conformable than its balloon-expandable counterpart.

It is well known that certain peripheral arteries, especially the superficial femoral artery, are subjected to radial as well as non-radial deformations (Smouse, 2004). Stents placed in these locations must be designed to withstand a complex fatigue loading environment, including radial pulsation, compression, bending and torsion (United States Food and Drug Administration guidance, 2005). The purpose of this study was to use finite element analysis (FEA) as a tool in

fatigue life characterization of a self-expanding nitinol peripheral arterial stent. Analytical predictions of device performance were validated through bench top fatigue testing under axial, bending and torsional loads.

2. Methods

2.1 Finite Element Analysis

2.1.1 Geometry and Finite Element Mesh

Nitinol stents are laser cut from drawn, seamless tubing and electropolished to eliminate imperfections and achieve the desired final dimensions. In this study, finite element models were created based on engineering drawings of the stent design. All meshes were generated in Abaqus/CAE and represented final, electropolished, nominal dimensions of the device. The models represented the complete cylindrical stent geometry at the cannula diameter (Figure 1).

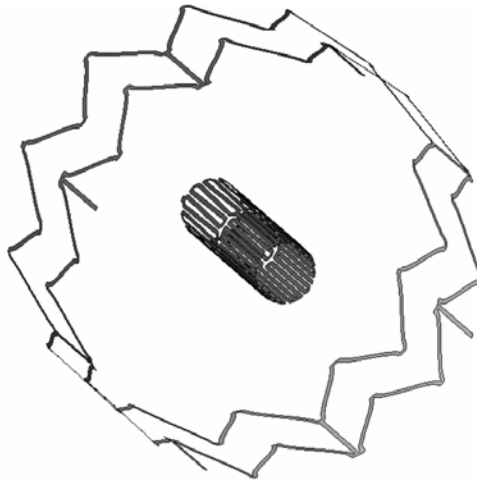


Figure 1. Stent in its as-cut and expanded configuration (partial model is displayed).

2.1.2 Material Properties

Nitinol is an alloy of nickel and titanium and possesses unique shape memory and superelastic characteristics. Superelastic behavior is caused by mechanical loading and manifests in the form of large recoverable strains (approximately 6-8%). The shape

memory effect is thermally induced, allowing a device to have different shapes at different temperatures. Both these phenomena are reversible and associated with a change in crystal structure between austenitic and martensitic phases.

A typical nitinol stress-strain plot is shown in Figure 2 and consists of three major regions:

- a) An initial elastic region corresponding to loading in an austenitic phase. The material begins to transform from austenite to martensite upon loading beyond a strain of approximately 0.8%.
- b) A superelastic region, characterized by large strain change and a minimal stress change. This transformation is reversible upon unloading and strains in this region are fully recoverable. Between 0.8% and approximately 6% strain, the material remains in a mixed austenite/ martensite phase.
- c) An elastic-plastic region beyond 6-8% strain, characterized by complete transformation into martensite and the development of additional elastic (recoverable) and nonrecoverable strains.

A user-defined material model was developed to capture the classical shape memory and superelastic characteristics of nitinol. Material constants used in the model are based on tensile testing performed on the nitinol tube used to manufacture the stents. Typical nitinol material properties (Mihalcz, 2001; Gong 2003) used with this model are shown in Table 1.

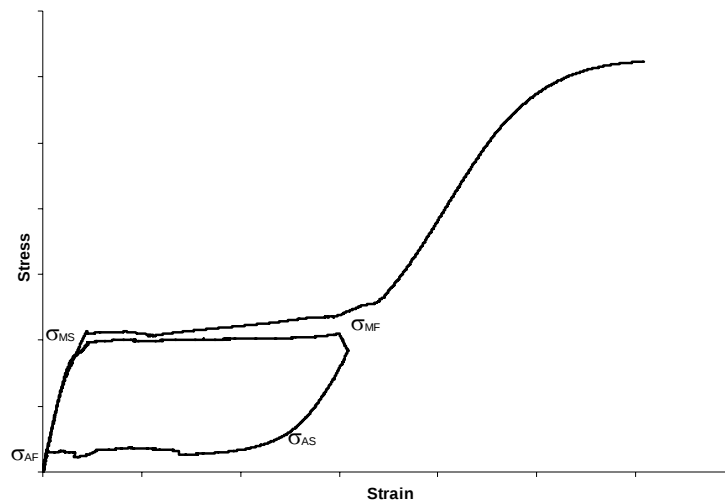


Figure 2. Typical nitinol stress-strain diagram from uniaxial tensile testing of nitinol tube.

Table 1. Typical nitinol material properties.

Property	Value
Austenitic elastic modulus	70,000-110,000 MPa
Martensitic elastic modulus	21,000-69,000 MPa
Loading plateau at 37°C	400-500 MPa
Unloading plateau at 37°C	150-250 MPa
Strain range for complete phase change	6-8%

2.1.3 Loads and Boundary Conditions

Abaqus/ Standard version 6.5-4 was used for all analyses. A minimal set of boundary conditions was applied to all models to suppress undesirable rigid body motions. Generally, these consisted of θ - and z - constraints in a cylindrical coordinate system, applied at a few nodes on planes of symmetry. Additional displacement boundary conditions were applied during axial, bending and torsional loading to achieve desired stent deformations. A temperature field set to body temperature (37 °C) was applied for all fatigue evaluations, whereas stent expansion was performed with the model at room temperature (23 °C). The analyses were performed as follows:

1. Stent Expansion

The stent was expanded from its as-cut configuration to its nominal diameter using a radially expanding rigid cylindrical surface. All stresses were removed from the model following expansion in order to simulate the heat setting process. The finite element model in this expanded, stress-free condition (Figure 1) was utilized for fatigue evaluation.

2. Axial, Bending and Torsional Loading

Axial bending and torsional loads were applied with the stent at its nominal diameter. Two reference nodes were placed along the stent axis and coupled to several nodes on the stent surface. Prescribed displacements were applied to these reference nodes to achieve the desired stent deformation.

For axial loading, one reference node was fixed and the other reference node was translated along the axis of the stent until a desired percent change in stent length was obtained. In the bending analysis, the stent was radially compressed (to simulate placement in a tube) and bent to the desired radius of curvature. For torsional analysis, one end of the stent was held fixed while a specified rotation about the longitudinal axis was applied to the other end.

2.1.4 Post-Processing

Analysis results were post-processed using a strain based fatigue criterion. The fatigue criterion consists of a horizontal line drawn through point A (Figure 3), corresponding to an alternating strain limit. Data in literature (Pelton, 2003; Pelton 2000) suggests an alternating strain limit between 0.4% and 0.6%. Point B represents the strain range for transformation from austenite to martensite. Point C is computed as the total strain at the completion of the phase transformation from austenite to martensite. Region B-C is a conservative estimate since the elongation at break of nitinol is much greater than the transformation strain (Figure 2).

For each loading mechanism, Mean and alternating strain pairs were generated from the final loading cycle using a python script. This strain data was then plotted against the fatigue boundary; as in any classical fatigue diagram, points lying above the boundary represented an unsafe level of strain, and corresponded to failure. A safety factor was also calculated based on the shortest distance between the mean and alternating strain pairs and the fatigue boundary. In addition, FEA was used to predict the load magnitude at which the strain data intersects the fatigue boundary for axial, bending and torsional loading; this was considered the limit load.

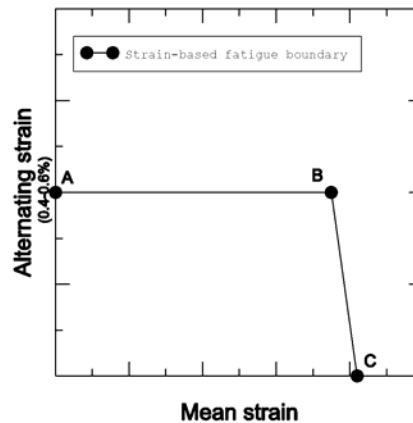


Figure 3. Strain based fatigue criterion used for post-processing analysis results.

2.2 Experimental Verification

Analytical prediction of limit loads under the axial, bending and torsional loading magnitudes was verified by bench top fatigue testing to establish the stent endurance limit. Devices were tested using a “fatigue to fracture” test methodology. This method requires testing at multiple load levels until a certain number of devices achieve run-out at one load level. Run-out was chosen to be 10 million cycles, a physiologically relevant number that corresponded to ten years’ lifetime *in vivo*. Testing was performed under

physiologic conditions (temperature of 37 °C in a solution of artificial plasma) at accelerated frequencies using EnduraTEC longitudinal and torsional fatigue testers.

3. Results and Discussion

Deformed shapes for axial, bending and torsional loads are shown in Figures 4, 5 and 6. A typical fatigue diagram illustrating the limiting case for an axial analysis is shown in Figure 7. Analytical predictions and experimentally obtained endurance limits are listed in Table 2, and are normalized to the predicted actual deformation magnitudes.

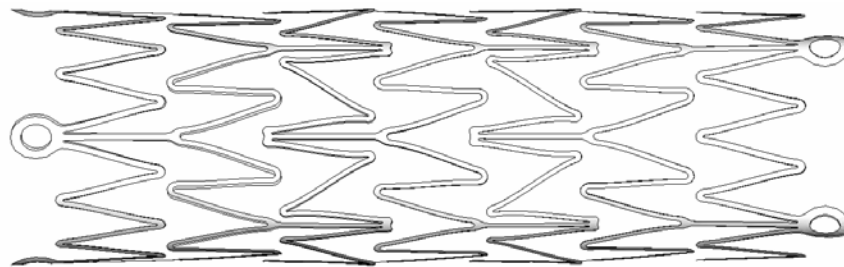


Figure 4. Deformed shape under axial load.

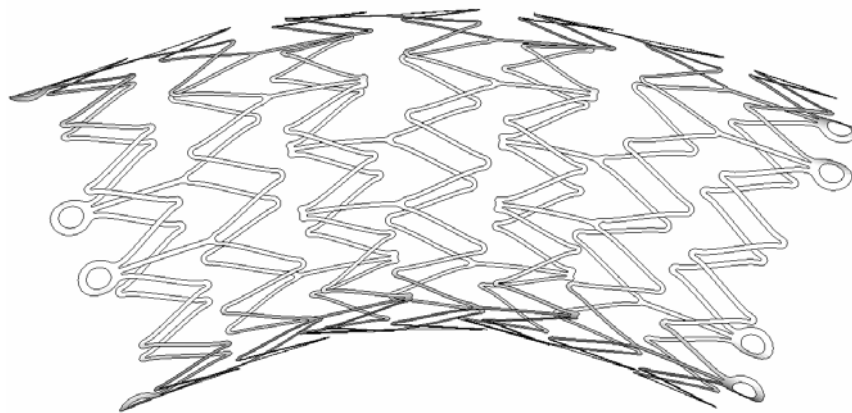


Figure 5. Deformed shape under bending load.

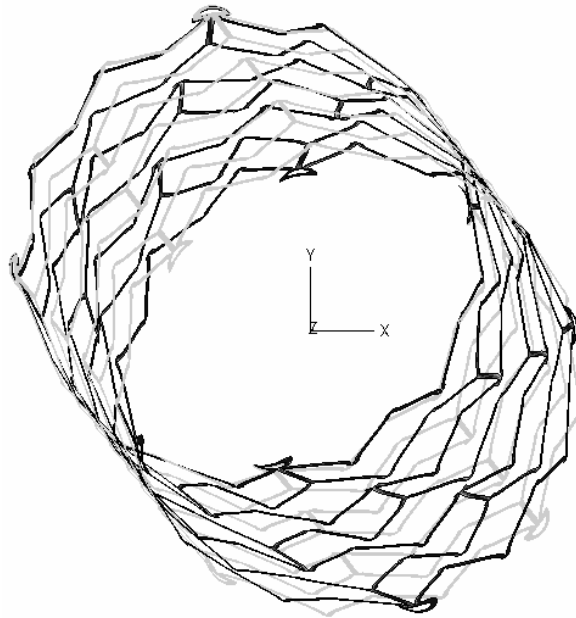


Figure 6. Deformed shape under torsional load.

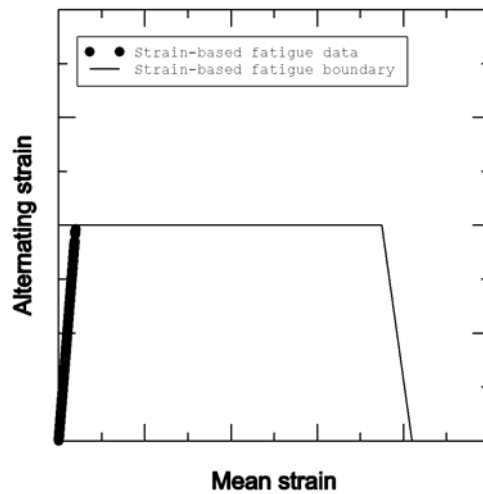


Figure 7. Typical fatigue diagram illustrating limiting case for compressive axial loading.

The results indicate that the experimental endurance limit for axial loading was obtained at a load fraction corresponding to 0.82 of the analysis prediction. The root causes for this difference may include test setup, geometric (dimensional), loading and material variability. The experimental endurance limits for bending and torsional loading were load fractions of 0.92 and 1.07 respectively. Both these results were within the resolution of the test method.

Table 2. Comparison of analytical and experimental results.

Loading Mechanism	Normalized FEA Predicted Limit Load	Experimentally obtained Endurance Limit
Axial	1.0	0.82
Torsion		1.07
Bending		0.92

The study was extended to an analytical and experimental benchmarking against a competitor stent design (“Design A”) with a history of clinical usage. Benchmark analyses were run at a fully reversed (zero mean) axial displacement that corresponded to a desired percent change in stent length. The results are presented in Table 3; Figure 8 shows a fatigue diagram for the competitor device. Analysis of the “Design A” stent predicted failure at a load fraction corresponding to 0.6 of the current design; experimental results showed fracture at a load fraction of 0.71. The experimental results were within 9% of the analysis prediction.

Table 3. Summary of benchmarking of stents subjected to axial fatigue loading.

Stent	FEA Predicted Safety Factor	Experimental Result
Current Design	1.0	Pass
Design A*	0.6	Fail at normalized load level of 0.71

*Design A represents a competitor stent with a history of clinical usage.

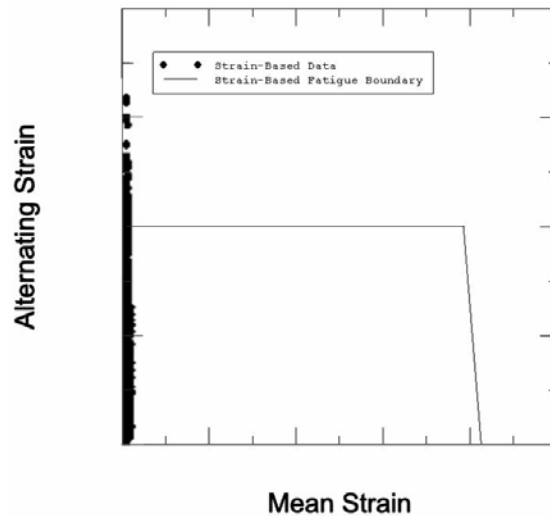


Figure 8. Fatigue diagram for “Design A” stent subjected to fully reversed axial fatigue loading.

4. Conclusions

Finite element analysis has been shown to be a powerful tool in the fatigue life characterization of self-expanding nitinol stents subjected to a complex loading environment. Analysis predictions of fatigue life were verified experimentally. Close correlation was obtained between analytical predictions and experimental results for axial and torsional load magnitudes. The difference in bending is likely due to differences between test and analysis methodology.

5. References

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