Fatigue-to-Fracture Testing to Accelerate the Development of Nitinol Implants

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Abstract

Nitinol is a shape memory alloy that is composed of roughly equiatomic amounts of nickel and titanium. Unlike other metals, this material can withstand significant deformation and return to its original shape, through a mechanism known as psuedoelasticity, and the alloy has been adopted for use in medical implants like vascular stents, heart valves, and vena cava filters. Given the use of nitinol implants in critical anatomical locations, fractures from these implants can lead to complications for patients. Therefore, due to the need to withstand dynamic motions and mechanical stresses inside the human body for long periods of time, nitinol implants need to have high resistance to fatigue fractures. Multiple manufacturing and long-term durability testing standards are in place for nitinol medical devices to ensure that marketed products are safe; however, some of these tests require months-long experiments that can be a bottleneck to product development.

The newly developed ASTM F3211-17 "Standard Guide for Fatigue-to-Fracture (FtF) Methodology for Cardiovascular Medical Devices" aims to reduce testing time as it calls for applying higher loads than expected clinically, in contrast to the traditional test-to-success testing which uses physiologic loading and longer test times. Despite its potential to shorten pre-clinical testing, the standard is still new and knowledge about its reliability to predict long-term device performance is limited. Thus, the primary objective of this work is to critically assess 'Fatigue-to-Fracture' techniques as outlined in ASTM F3211-17. In this study, nitinol wires were subjected to rotary bend fatigue at alternating strains ranging from 0.28 to 2.66% out to 10^9 cycles (approximately equivalent to 25 years of heart beats). To assess the ability of FtF to evaluate a design geometry change and to utilize a specimen geometry similar to that of a stent, z-shaped wire specimens ("Z-specimens") were created from the same nitinol material and tested in fatigue. The combined data will be used as an input into statistical modeling to evaluate the ability of FtF to credibly predict Z-specimen fatigue life per ASTM F3211-17. These results will help manufacturers reduce the burden of high cycle fatigue tests and develop safer implants more quickly.

Introduction

Repeated mechanical loading of an implant can lead to fractures over time if elevated cyclic stresses cause cracks to grow through the structure. Some fatigue fractures (like the multiple fractures in the peripheral stent shown in Figure 1) can lead to patient complications like restenosis of the treated vessel. Thus, pre-clinical fatigue testing is an important part of the implant development process to prevent in vivo fractures. By evaluating different nitinol specimen geometries, this project seeks to improve high cycle fatigue predictions for a wide range of nitinol implants.

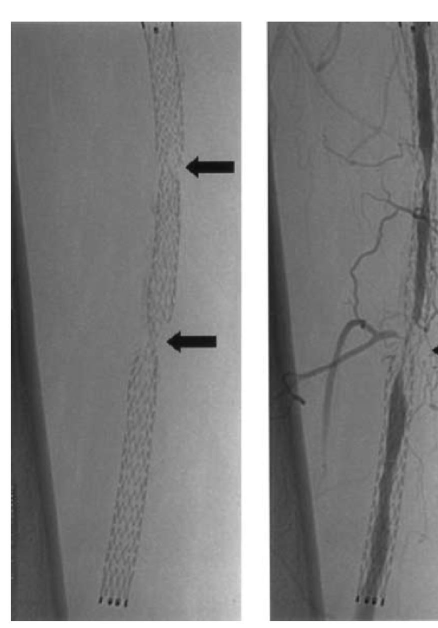
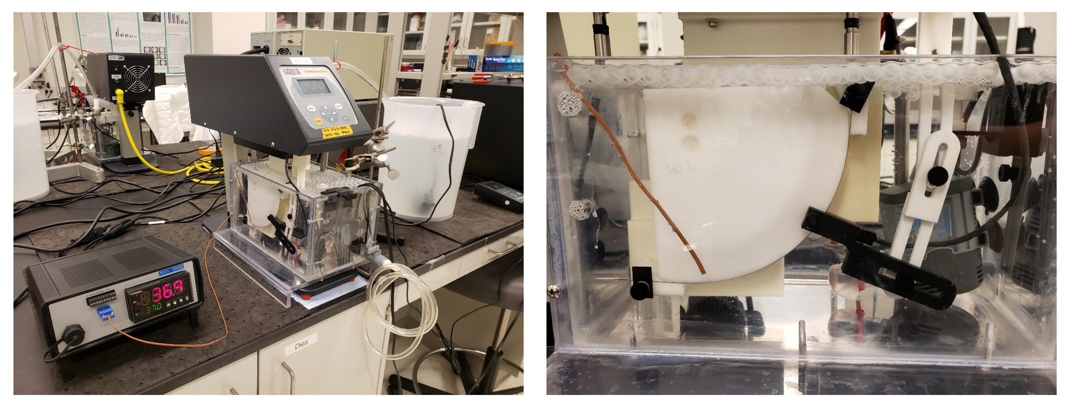


Figure 1. Scheinert, D, et al. "Prevalence and clinical impact of stent fractures after femoropopliteal stenting." *JACC* 45.2 (2005): 312-315.

Materials and Methods

Rotary Bend Fatigue Test

Straight nitinol wires were subjected to rotary bend fatigue per ASTM E2948-16a by rotating the specimens while they were held against disc guides. The specimens were submerged in phosphate buffered saline (PBS) at 37 °C and tested to 10^9 cycles or until fracture (Figure 2a) at a rate of 400 Hz. Disc guides of varying radii (Figure 2b) allowed for alternating strain amplitudes to range from 0.28% to 2.66%.

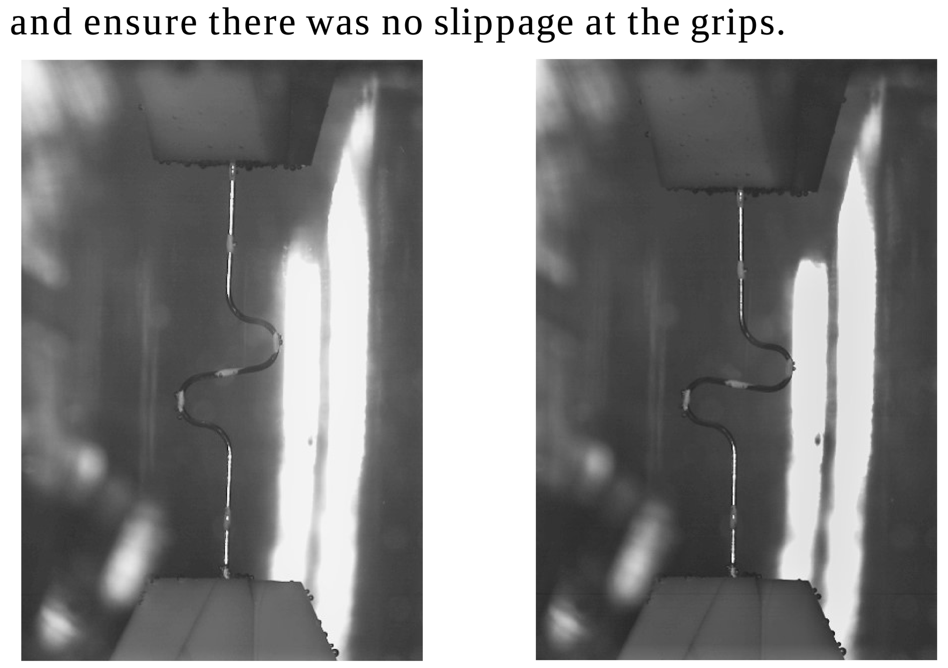


a. b.

Figure 2. (a) Test set up for rotary bend fatigue with (b) the disc guide.

Z-Specimen Fatigue Test

Nitinol Z-specimens were subjected to fatigue in PBS at 37 °C. Polymeric grips tightly held the Z-specimens at both ends (Figure 3) with the bottom grip stationary and the top grip driven. Tests were run at 40 Hz to multiple target displacements with comparative strains to the rotary bend fatigue test. During testing, high-speed videos were taken to observe the specimen motion and ensure there was no slippage at the grips.



a. b.

Figure 3. Z-specimen fatigue test setup showing grips tightly holding the Z-specimens during (a) tension and (b) compression taken with a high-speed camera.

Z-Specimen Finite Element Analysis (FEA)

FEA simulations of nitinol Z-specimens were performed in ABAQUS R2016x. Material properties were taken from tensile tests of straight nitinol wires per ASTM F2516-18. Mesh refinement studies were performed to estimate the discretization error and ensure it was sufficiently low. FEA simulations mirrored the Z-specimen fatigue test described above with one end of the Z-specimen held fixed and the other end driven to target displacements. Peak alternating strains were calculated for each target displacement condition.

Results and Discussion

Results from the rotary bend fatigue tests showed an increase in the number of cycles to failure as the alternating strain decreased (Figure 4). At alternating strain levels of 0.28% and 0.42%, none of the samples fractured before reaching 'run-out' at 10^9 cycles.

SEM images (Figure 5) revealed clear areas of fatigue crack growth and final overload. The crack growth area tended to be larger as the alternating strain decreased. The SEM images also demonstrated that the majority of the fatigue cracks had non-metallic inclusions at the site of crack initiation.

Preliminary results from the Z-specimen fatigue show the FEA simulations can qualitatively predict the location of fatigue fracture (Figure 6). Specifically, the FEA predicted the maximum strain would occur at the intrados of the Z-specimen curve, and this was indeed observed to be the site of fatigue crack initiation in the SEM images (Figure 7).

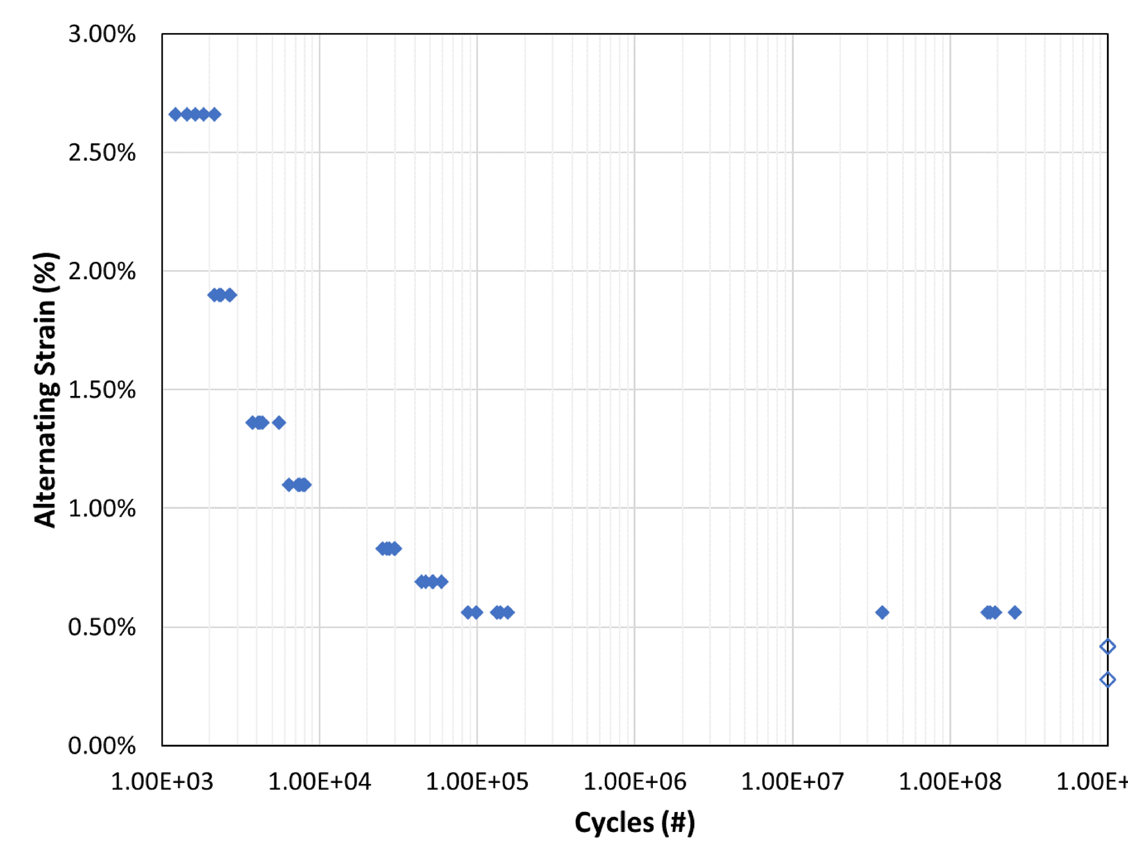


Figure 4. S-N curve of the rotary bend fatigue tests. Open diamonds represent 'run-out,' i.e. the sample reached 10^9 cycles without fracturing.

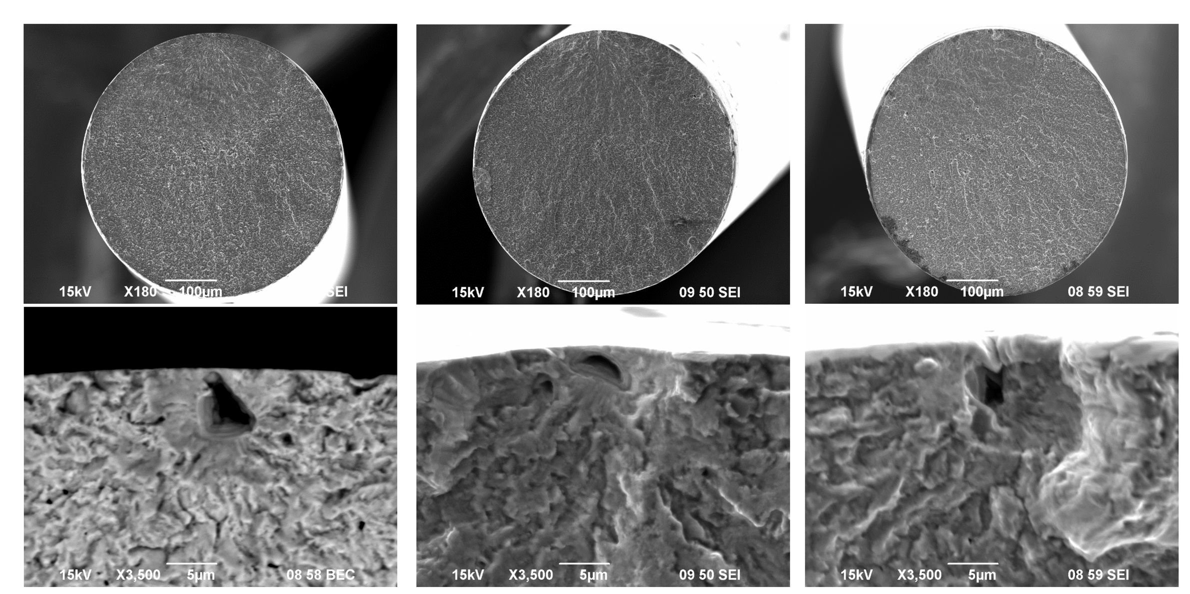
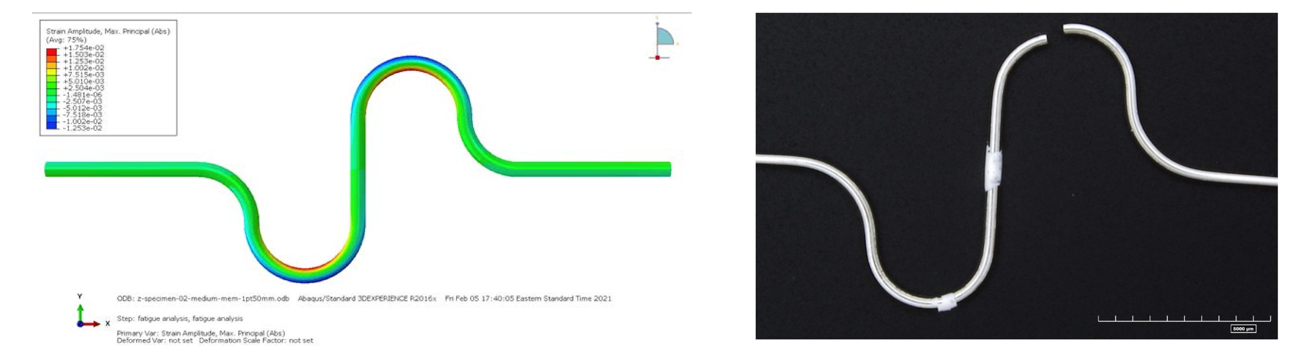


Figure 5. SEM images of 1.36%, 1.90% and 2.66% strain showing the overall fatigue fracture surface and the corresponding crack initiation site.



a. b.

Figure 6. (a) FEA simulation of the Z-specimen which shows that the maximum strain amplitude occurs at the intrados of the sample (red area). (b) Optical microscopy image showing a fractured Z-specimen. Note the location of fracture observed experimentally corresponds to the location predicted by FEA simulation.

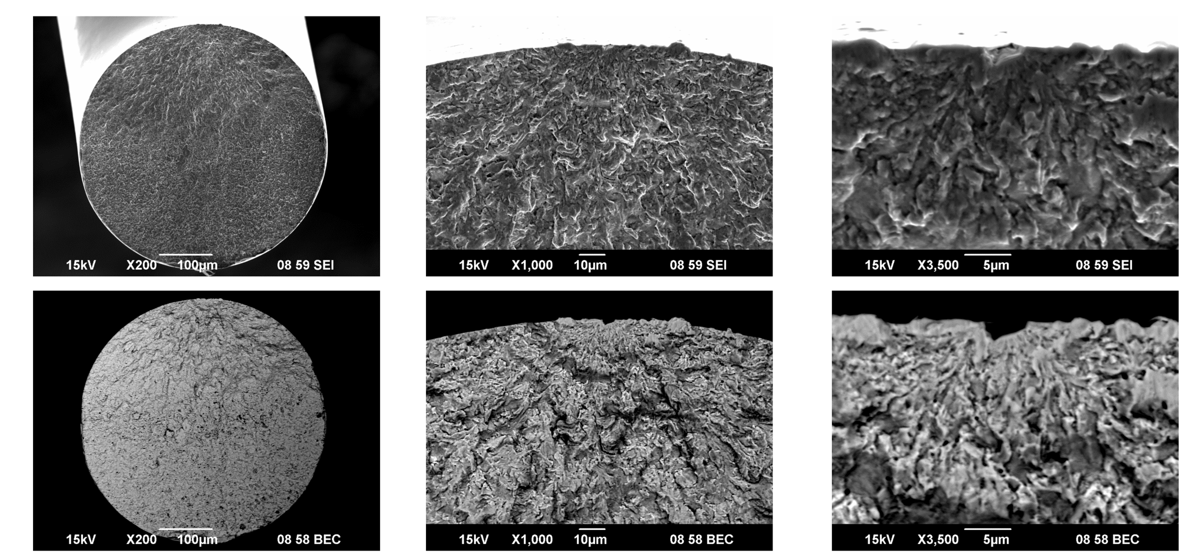


Figure 7. SEM images of the fatigue fracture surface of a Z-specimen with higher magnification of the crack initiation site.

Conclusion

This ongoing project seeks to improve the development of nitinol implants by characterizing nitinol fatigue for very long implantation times and by exploring the use of the FtF methodology. Statistical modeling to assess the ability of ASTM F3211-17 to predict Z-specimen fatigue life is ongoing. To date, the project team has:

- Conducted the first known nitinol fatigue tests to one billion cycles that will be published in the scientific literature.
- Utilized SEM to characterize fatigue fracture surfaces from both loading modes.
- Created a computational model of the Z-specimen capable of accurately predicting fatigue fracture location.

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