# Predicting Performance and Reliability of Nitinol Medical Implants

P.E. Labossiere and K.E. Perry
ECHOBIO LLC, Bainbridge Island WA

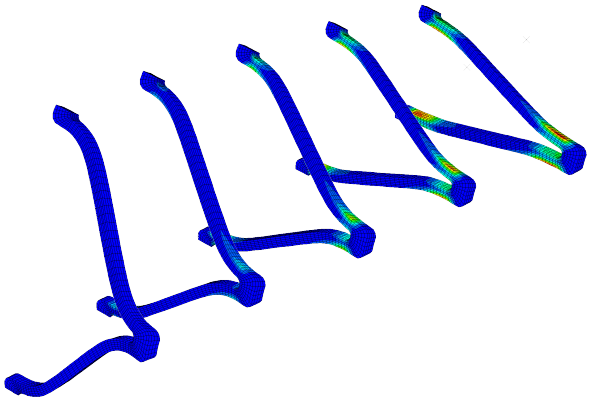
**ABSTRACT**
Radial force behavior is one of many engineering design criteria important to the design of implantable medical devices such as stents. Interpretation and extrapolation of bench-top data to predict in-vivo performance necessitates a thorough understanding of influence parameters such as boundary conditions and material uncertainty. An integrated modeling and test validation approach is needed to fully understand interactions of the influence parameters. This understanding helps establish reliable fatigue prediction methodologies that combines the load and displacement type boundary conditions. The approach is more broadly applicable to the unusual and complicated superelastic transformation behavior observed in Nitinol.

## Introduction

Superelastic properties of Nitinol make self-expanding stents an attractive alternative. Radial force is a critical performance parameter for many implantable medical devices. This force must be adequate to limit the mobility of the implant and provide support for the intended lumen but not so large as to cause damage to the body or cause device fracture. Modeling devices made from Nitinol is challenging because the material is more complex than traditional materials. The stress-strain behavior is highly nonlinear with a significant hysteresis loop during loading and unloading. This is due to the two-phase nature of the material. Furthermore, the material exhibits significant sensitivity to processing history and temperature and appropriate boundary conditions can be difficult to determine. The devices themselves are relatively small and may contain extremely fine features which may act as stress raisers and they are subjected to large displacements during deployment and have relatively high strains. All of these factors lead to highly nonlinear FEA models which in turn may lead to significant convergence and stabilization issues when modeling these devices. We begin with a description of idealized radial loading and evaluate four typical radial force characterization tests using various representative in-vitro and in-silico test results. The stent geometry used in the analysis and testing consists of a typical generic stent pattern made up of ten strut pairs forming one complete cycle around the circumference. For the in-vitro test program, several devices were fabricated and inspected for uniformity and consistency and graft materials were attached to several of the devices to explore its effect. For the in-silico analysis, the commercially available finite element analysis program Abaqus version 6.5-1 was used with additional user subroutines and coding included as necessary.

## Idealized Radial Loading

Figure 1 shows contour plots of the typical stent geometry considered herein. The model takes partial advantage of symmetry and consists of a two strut model subject to idealized compression. Figure 1 also shows the corresponding force per strut versus change in radius for various material models used in the analysis. The idealized loading consists of defining an analytical contracting cylinder which contacts the outer node set of the model. Contact parameters can be tailored to represent soft to hard contact. The contact force is determined from the sum of the contact forces between the rigid and deformable bodies. Modeling using the idealized approach during the component design phase is advantageous because the results are highly sensitive to small changes in the geometry and pre-expansion diameter. These small changes are often critical in the chronic outward radial force and overall performance of implantable medical devices. Furthermore, there can be very little run-time expense associated with the model.



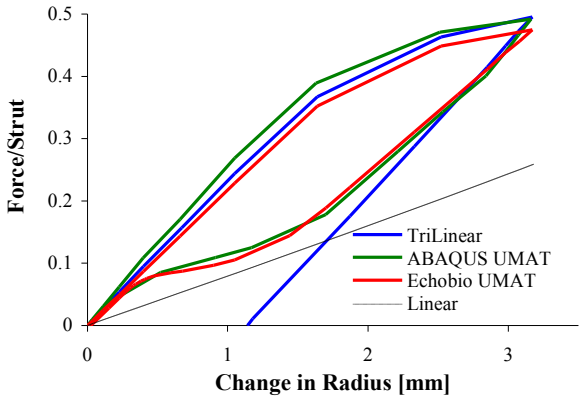



*Figure 1 Contour plots of maximum principal strains for a typical two strut model during radial compression and representative radial force per strut response for various material model choices with FEA.*

**In-Vitro Radial Force Test Methods**

There are several in-vitro test methods used for determining the radial force characteristics of implantable medical devices. These are the loop strap, the clam shell, flat plate crush, pressurized cylinder and segmental compression. Figure 2 shows the FEA models for the test methods considered herein and we have taken partial advantage of symmetry for each by only modeling one half of the device and loading.

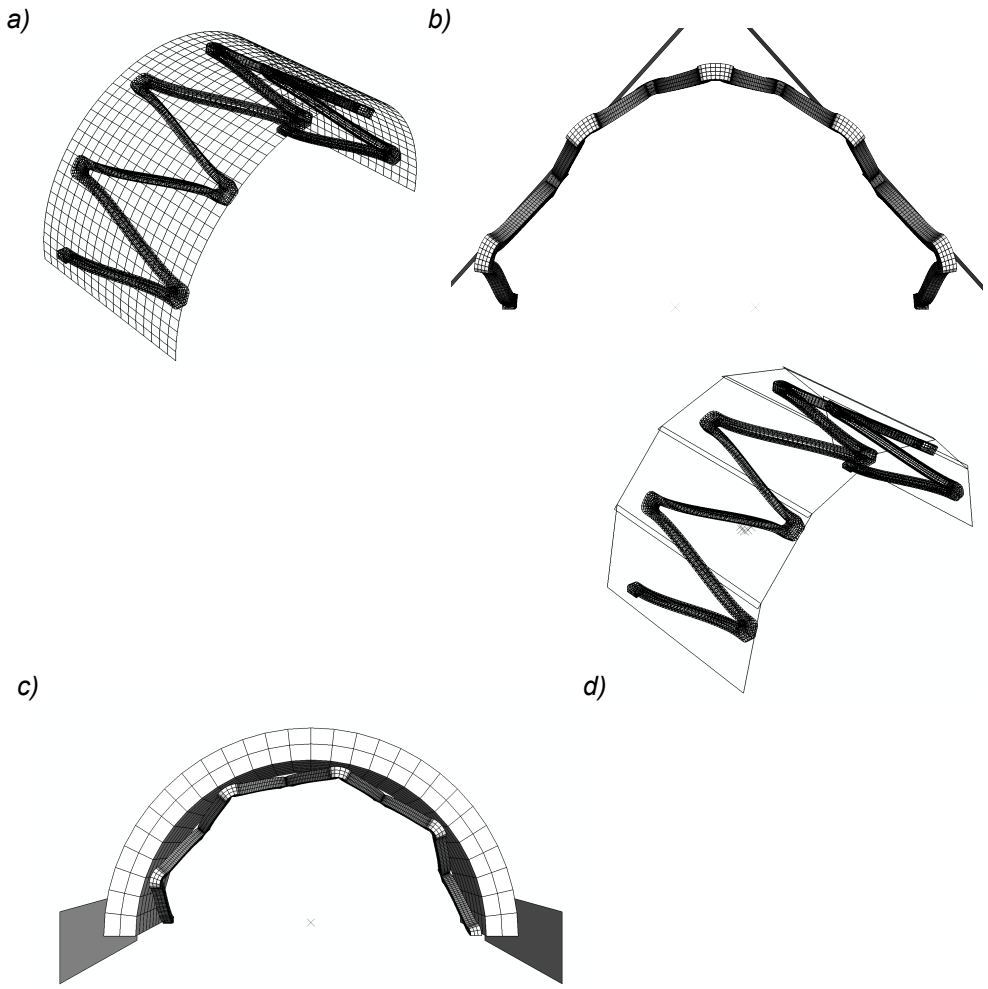



*Figure 2. FEA models of the a) loop strap; b) clam shell; c) flat plate crush ; and d) segmental compression tests*

**In-Vitro Loop Strap Tests**

In order to demonstrate the sensitivity of the in-vitro test methods, we begin by considering the loop strap test method. Figure 3 shows a photograph of the loop strap test fixture and close-ups of a typical test in progress. Representative results are also shown in Figure 3 which plots the load versus displacement for some of the various stents tested having the same stent geometry. The plot compares stents with and without attached covering material which indicates that the covering results in a significant increase in the radial stiffness of the stent. This result is counterintuitive because a thin membrane should have little or no compressive stiffness. The results show that there is significant scatter in the measurements from stent to stent and. Furthermore this scatter can be significantly larger than any clear discernible difference between the effect of strap materials and strap stiffnesses.

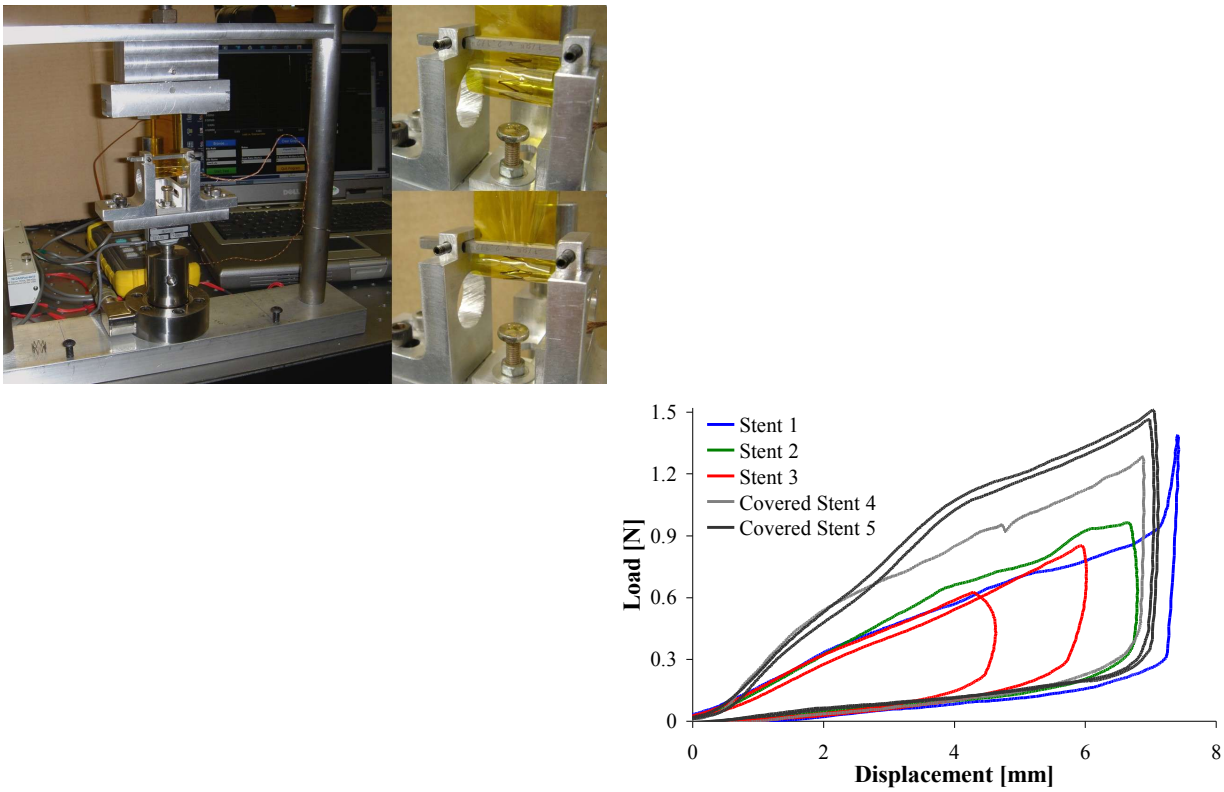



*Figure 3 Photograph of the loop strap test set-up showing close-up views during testing and results showing the load versus displacement showing the influence of stent covering.*

**In-Silico Loop Strap Tests**

FEA allows a detailed investigation into the influence of test specific sensitivity parameters on the results of in vitro tests. Among the parameters that we varied in this study were friction, loop strap stiffness and loop strap thickness. For brevity, only a few results are presented herein. Figure 4 shows contour plots of maximum principal strain during the loop strap test for two cases with different values of friction between the stent and the loop strap illustrating the nonuniformity of stent compression due to friction. Also shown in Figure 4 is the linear force versus displacement for three different values for the friction coefficient. It is apparent that friction plays a significant role in the apparent radial force of the stent. This is because friction influences the apparent portion of the stent being tested. For a large coefficient of friction, the stent struts closest to the retracting section of the loop undergo compression before the remainder of the stent struts. In the absence of friction, something which is impossible to achieve in the laboratory, the compression between adjacent struts is uniform throughout the stent.

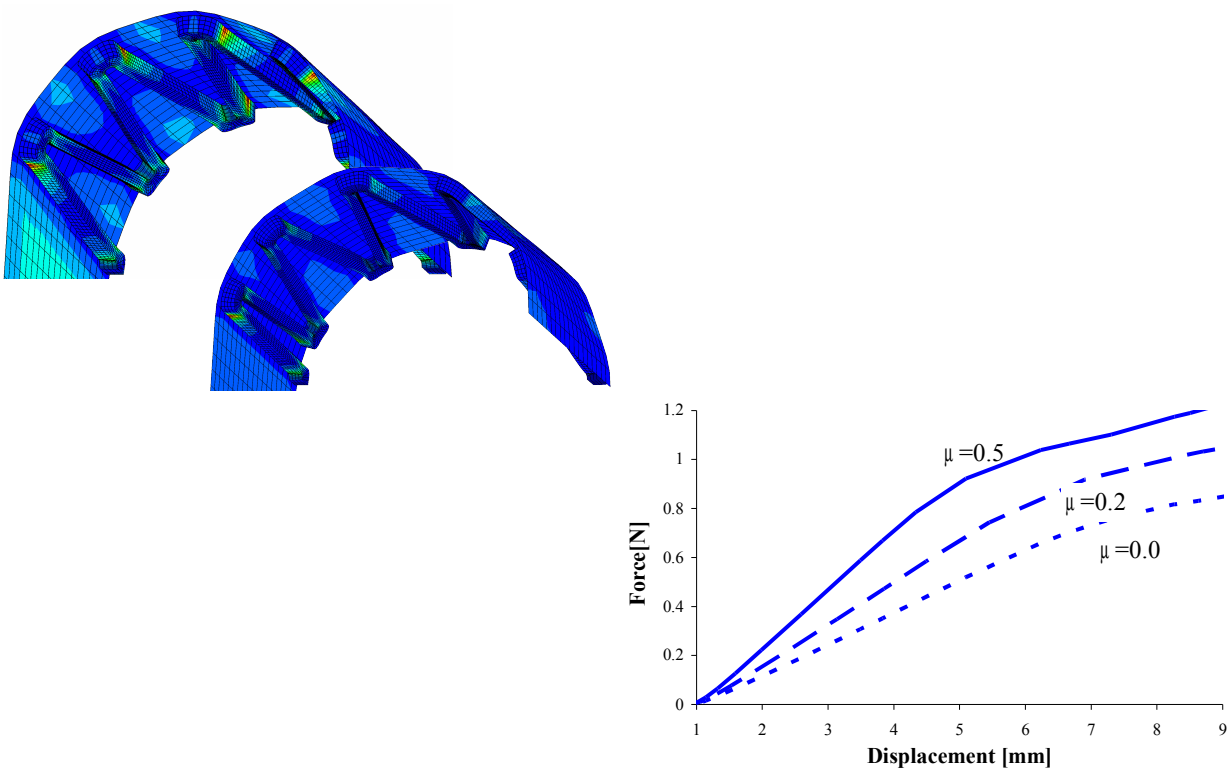
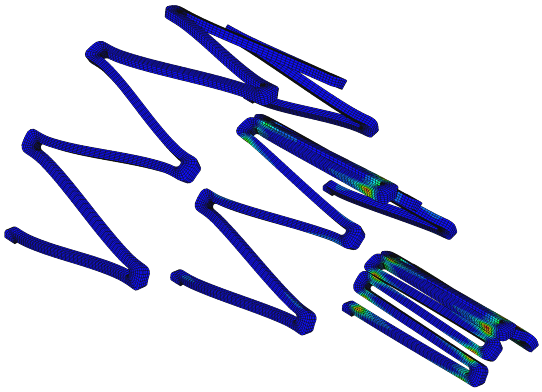



*Figure 4 Sequence of contour plots during the in-silico loop strap test and plot of force versus displacement showing the influence of friction on the simulation results.*

**In-Silico Clam Shell Tests**

The typical clam shell test consists of two right angled notched fixtures which clamp onto the outer surface of the stent. Figure 5 shows a sequence of contour plots during the in-silico clam shell test with nonzero friction between the stent and the clam shell. The two halves of the simulated fixture are oriented horizontally and move inwards compressing the stent. Also shown in Figure 5 is the linear force versus displacement for three different values for the friction coefficient. It is apparent that friction plays an even more significant role here than the loop strap test. Due to the highly faceted nature of the test there can be significant piling up of struts.



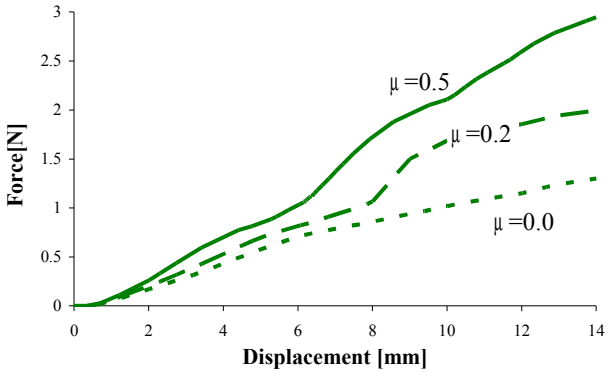
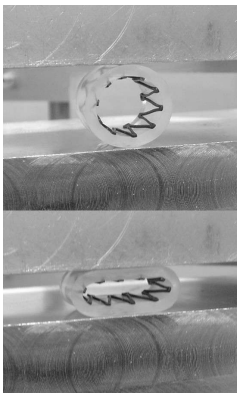
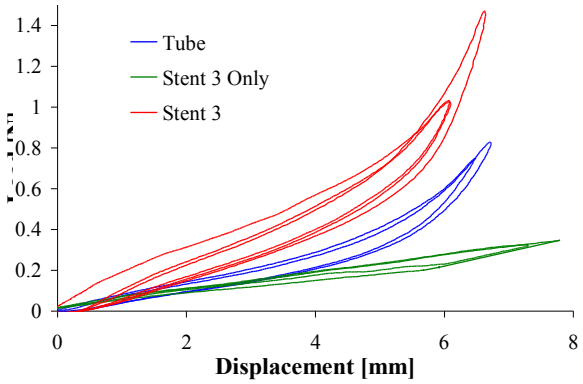



*Figure 5 Sequence of contour plots during the in-silico clam shell test and plot of force versus displacement showing the influence of friction on the simulation results.*

**In-Vitro Flat Plate Crush Tests**

The flat plate crush test consists of squishing a stent between flat parallel surfaces. Often the stent is deployed inside a silicon tube before performing the test. Figure 6 shows a sequence of photographs of an in-vitro flat plate squish test in progress with a stent inside a tube. The tube was made of silicon and was slightly smaller in diameter than the free standing stent. The diameter and thickness of the tube were consistent of what is typically used in flat plate crush testing. The top plot of Figure 6 also shows three curves, the lower one is the linear load - linear displacement response of the stent alone, the middle one of the tube alone and the upper one of the combined stent and tube. It is apparent that the overall behavior is greatly influenced by the choice of the tube material. Unlike the in-vitro loop strap test, the results of this test are not influenced by the presence of a graft material on the outside of the stent.





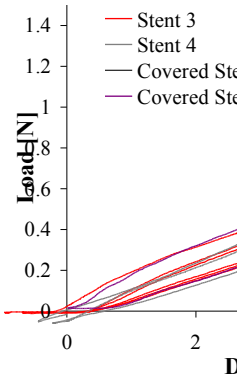
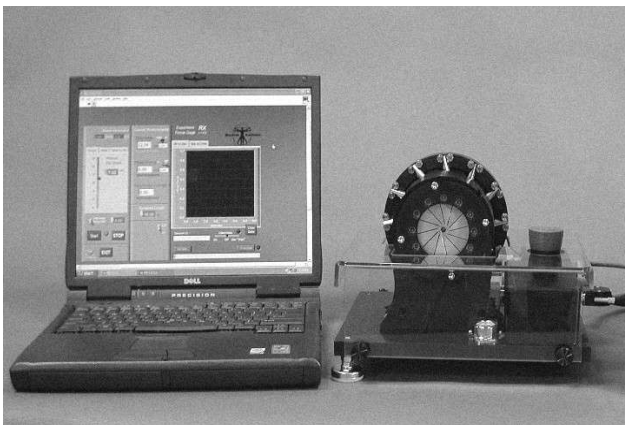




*Figure 8 Sequence of photographs of a in-vitro flat plate crush test in progress and plots of load versus displacement from the in-vitro flat plate crush test.*

**Segmental compression Tests**

The segmental compression test consists of using a highly specialized mechanical test device which collects data from twelve points of product contact providing a uniform radial measurement. The device consists of a series of wedge shaped elements which when individually actuated, pass through an arc such that the effective diameter of the opening in the middle changes. A device operating on this principle is available commercially by Machine Solutions Inc. Flagstaff, AZ , USA (MSI) and is sold specifically for the purpose of characterizing radial force of devices such as stents, stent graft products, collagen plugs, embolic filters, vena cava filters and other radially expanding intravascular products. Figure 9 shows a photograph of the segmental compression test device and set-up manufactured by MSI Radial Force Gauge RX500.

Careful design and calibration of this device allows for a high level of precision and repeatability. Friction, load frame compliance and system nonlinearities can be accounted for through calibration, but a known standard is required with accuracy that exceeds the intended application. Also shown in Figure 9 is a comparison of the segmental compression in-vitro and in-silico test results. The in-silico model consisted of defining the inner surfaces of the segmental compression and prescribing displacement to those surfaces consistent with the motion of the actual device. Two values for the coefficient of friction between the stent and the simulated device were evaluated showing that there is little influence on the results for the device and stent geometry considered. Also shown are the results for the idealized radial loading denoted by the dashed line. Interestingly, the idealized loading simulation does correspond reasonable well with the segmental compression test system used and stent design considered.



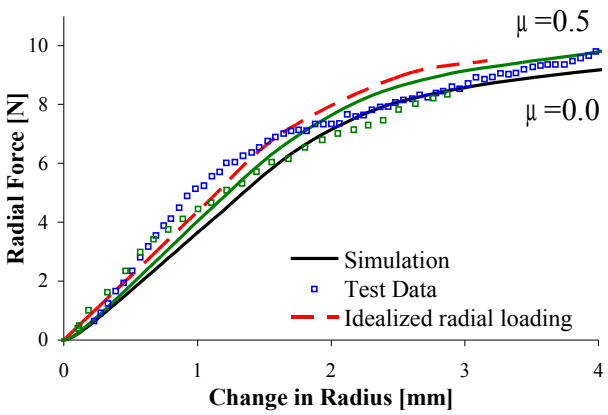



*Figure 9 Photograph of the segmental compression test using device manufactured by Machine Solutions Inc. (MSI) Radial Force Gauge RX500 and comparison of segmental compression in-vitro and in-silico test results. Also shown are the results for the idealized radial loading.*

## Discussion

The collaborative effort needed to develop a standardized approach to defining and measuring radial force is immense and this work is ongoing. The results presented herein are intended as a sampling of in-vitro tests, in-silico tests or both. Each highlight the many parameters that may influence results.

Based on the sampling of results presented herein, it is apparent that the various tests sampled are sensitive to different test and component specific influence parameters such as friction or tube material and graft covering material. At this time, we recommend a rigorous self-consistent engineering approach be used rather than any one specific test. Finite element analysis is an invaluable tool in the engineering design process and should be incorporated early and throughout any self-consistent engineering approach.

## Acknowledgement

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