FEA of In-Vitro Test Methods for Radial Force Characterization

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Abstract

An overview of the typical in-vitro test methods used to characterize the performance of Nitinol stents is presented. Characterization requires a consistent definition and understanding of radial force as well as a consideration of the sensitivity of the various methods to friction, fixture compliance, material uncertainty and other experimental factors. These sensitivities are demonstrated using finite element analysis and in vitro experimentation. The results help guide the development of better experimental methodologies and interpretation of performance parameters such as radial force. Finally, we conclude with discussions on establishing a rigorous, self-consistent approach to Nitinol component design and testing.

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 difficult 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.

Idealized Radial Loading

Figure 1 shows contour plots of the typical stent geometry for a two strut model during idealized compression and the corresponding force per strut versus change in radius for various material models used in the analysis. The typical stent structure chosen consists of one row of struts arranged in a circumferential fashion and there are ten strut pairs in the stent. 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.

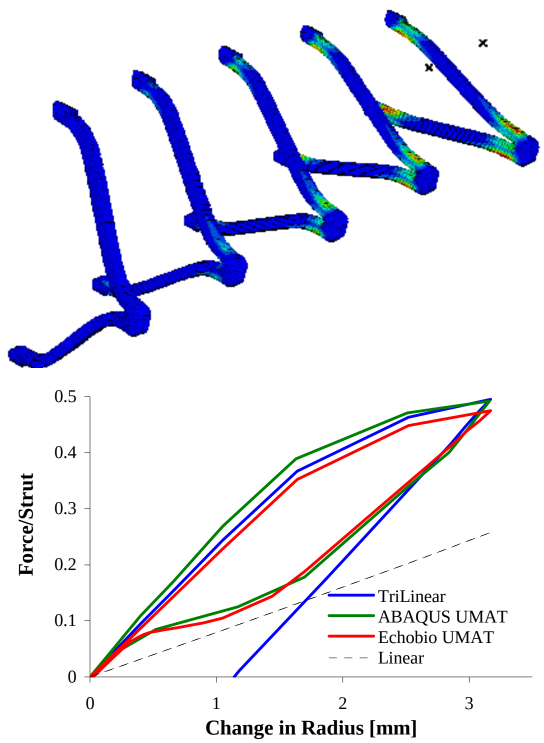

Figure 1 Contour plots of maximum principal strains for a typical two strut model during radial compression and representative radial force per strut response for various material model choices with FEA.

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 squish, pressurized cylinder and mechanical iris. For brevity, in this study, we focus our attention on the first three tests. Figure 2 shows the FEA model for these tests and we have taken advantage of symmetry by only modeling one half of the device and loading.

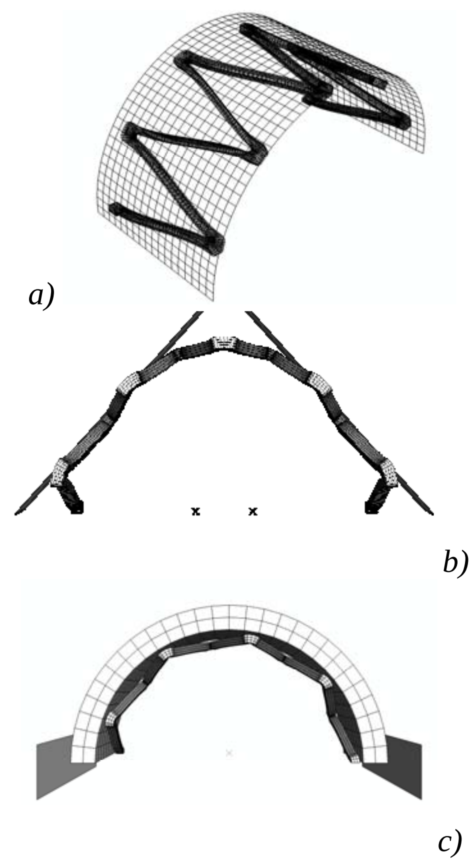

Figure 2. FEA models of the a) loop strap; b) clam shell; and c) flat plate crush tests.

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. The results are shown in Figure 4 which plots the load versus displacement for various stents tested. The plot on the left 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 plot on the right compares two strap materials, one made from mylar film and the other from a Teflon coated cloth. The results clearly show that there is significant scatter in the measurements from stent to stent and that this scatter is significantly larger than any clear discernible difference between the results shown here for the two strap materials. The sharp increase in the load displacement behavior as the displacement reaches past 4mm is due to the stent pinching between the roller supports in the fixture. Testing was reversed when this event was observed. During one of the tests, the stent and loop where pulled directly through to the other side of the rollers. Surprisingly, there was no noticeable damage to the stent after having experiencing such tortuous loading, and subsequently, this stent was relieved of further duties.

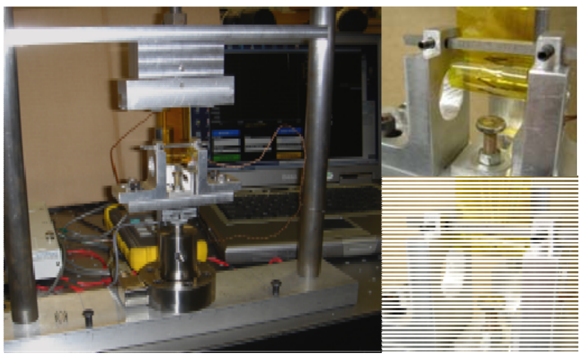

Figure 3 Photograph of the loop strap test set-up showing close-up views during testing.

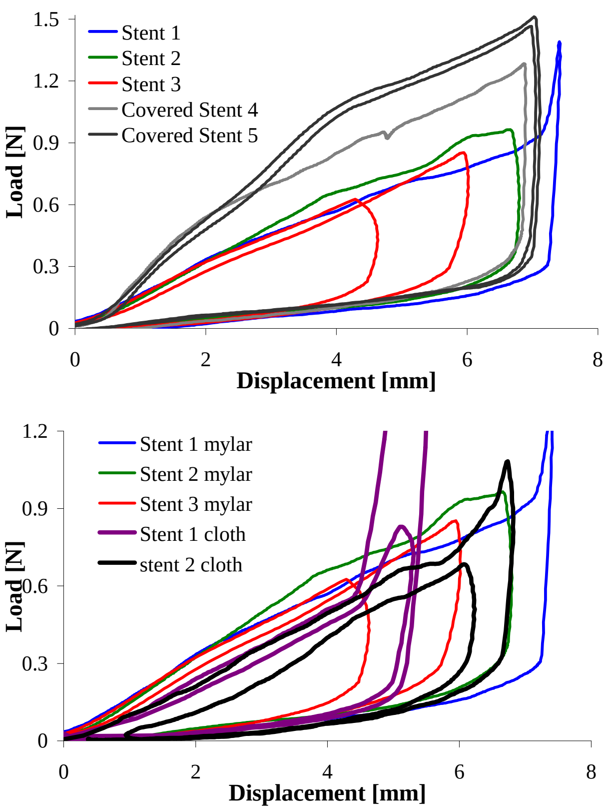

Figure 4 Results showing the load versus displacement showing the influence of stent covering and comparison between two strap materials

In-Silico Loop Strap Tests

FEA allows further investigation into the influence of test specific sensitivity parameters on the results of in vitro tests. The parameters that we varied in this study were friction, loop strap stiffness and loop strap thickness. Figure 5 shows contour plots of the loop strap test for two scenarios with different values of friction between the stent and the loop strap. 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 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 6 left and right show plots of the linear force versus displacement for three different values of the loop strap stiffness and thickness, respectively. It can be seen that over the range of values considered, the loop strap stiffness and thickness have little influence on the results.

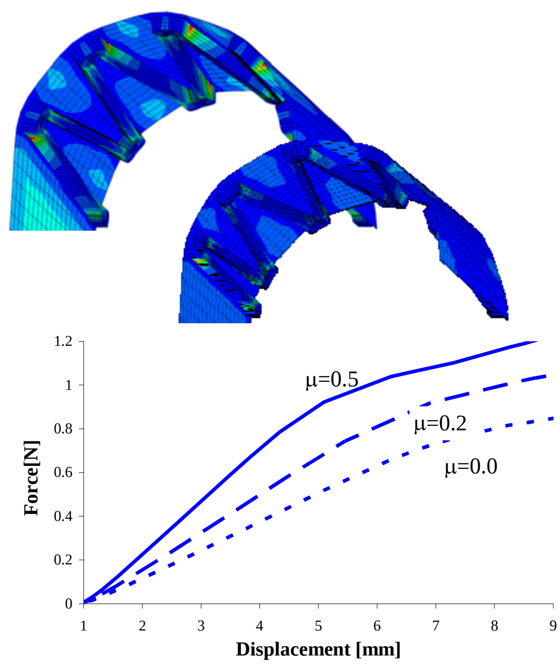

Figure 5 Sequence of contour plots during the in-silico loop strap test and plot of force versus displacement showing the influence of friction on the simulation results.

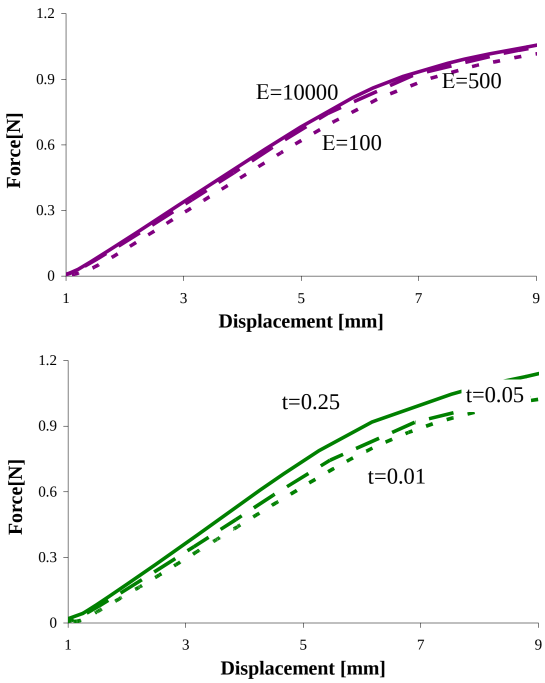

Figure 6 Plots of force versus displacement showing the influence of strap stiffness and thickness on the loop strap simulation results.

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 7 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 7 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.

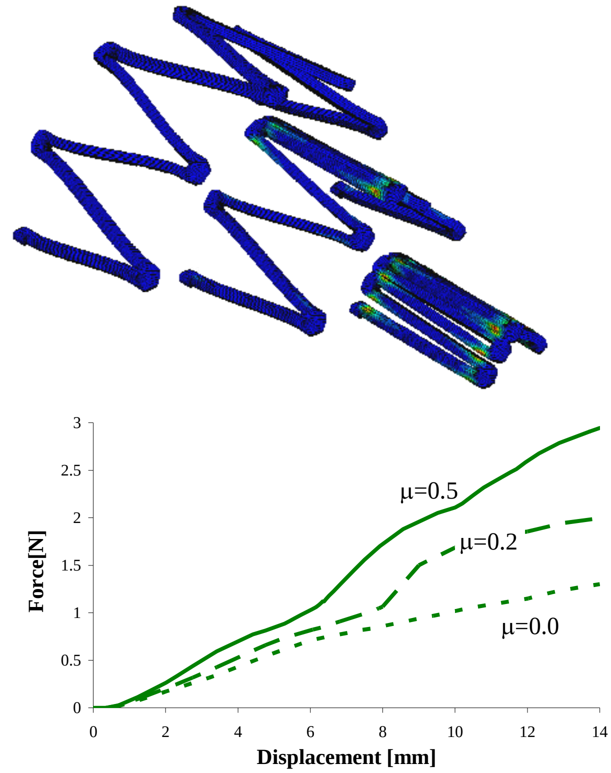

Figure 7 Sequence of contour plots during the in-silico clam shell test and plot of force versus displacement showing the influence of friction on the simulation results.

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 8 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 9 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. The plot on the bottom shows that this test does yield fairly consistent results. This may be attributed almost to having used the exact same piece of tubing for all of the tests. Furthermore, unlike the in-vitro loop strap test, the results of this test do not appear to be influenced by the presence of a graft material on the outside of the stent.

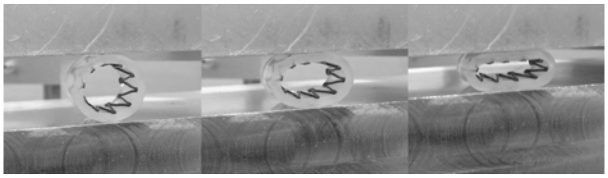

Figure 8 Sequence of photographs of a in-vitro flat plate crush test in progress.

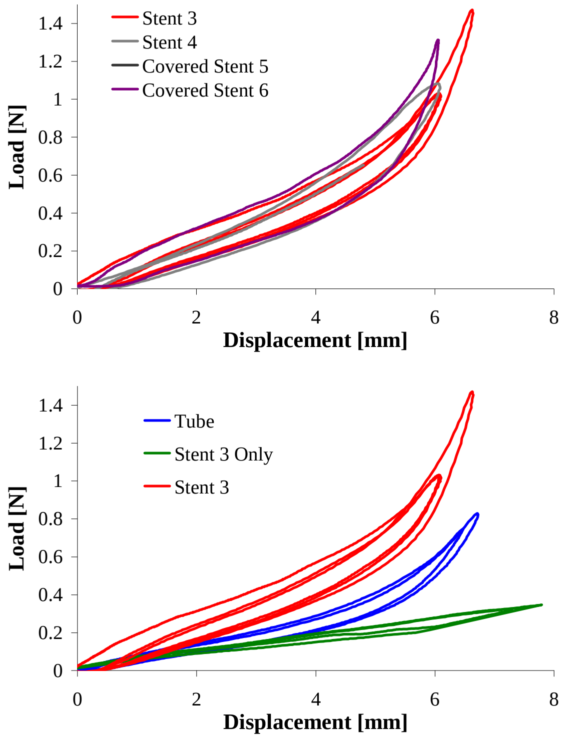

Figure 9 Plots of load versus displacement from the in-vitro flat plate crush test.

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 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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