ndc

We are Nitinol.™

Finite Element Analysis on Nitinol Medical Applications

Gong, Pelton

Proceedings of IMECE-2002
Vol. 53
pp.1-2

2002

www.nitinol.com

47533 Westinghouse Drive   Fremont, California 94539   t 510.683.2000   f 510.683.2001

FINITE ELEMENT ANALYSIS ON NITINOL MEDICAL APPLICATIONS

Xiao-Yan Gong and Alan R. Pelton

Nitinol Devices & Components, 47533 Westinghouse Drive, Fremont, CA 94539 USA

ABSTRACT

This article presents two applications of the nonlinear finite element analysis (FEA) using ABAQUS/Standard with a user developed material subroutine Nitinol UMAT from Abaqus West. The analyses are found to agree well with the theoretical prediction and/or experimental measurement. In that first example, FEA predicts the stress-strain response of a superelastic Nitinol device at different A_f temperatures when tested at 37°C. The second example confirms the FEA prediction of the force-displacement relationship of a diamond-shaped fatigue specimen. The focus of this presentation is on the use of FEA as a predictive design tool for fast prototyping of Nitinol medical devices.

KEYWORDS

NiTi, finite element analysis, medical application, stent, minimally invasive surgery.

INTRODUCTION

Nitinol's biocompatibility has made it a great material for many medical applications such as dentures, orthodontic arch wires, needles, guide wires, heart valve instruments, self-expanding stents, vena cava filters, minimally invasive surgery instruments, and septal defect occlusion system, to name a few [1-4]. Many of these devices are implanted into the human body via minimally invasive surgical procedures taking advantage of the unique superelastic behavior of Nitinol. With increasing market demand and competition, a predictive method that can shorten the time and resources from design to production becomes the key in new product development. Traditional beam theory provides reasonable estimation in some application, but success is limited to small strain [5]. Nonlinear FEA, which is capable of not only dealing with the complicated geometry, but also modeling the nonlinear material response, becomes more and more important in product design.

The superelastic material behavior generates analysis difficulties due to its path-dependence and high non-linearity. This calls for efficient constitutive modeling because it is inevitable that numerical iteration is necessary during the analysis. Phenomenological approaches are the most suitable solution for the simulation efficiency. Theories based on either the generalized plasticity theory, which focuses on the material response at a given temperature, or a free energy framework, which focuses on the temperature dependencies of the material, or even the micromechnics models have been developed independently in the past decade [6-13]. Based on several of these approaches, Abaqus West commercialized a user-defined material subroutine UMAT specific to Nitinol based on the generalized plasticity theory [7-9]. Many applications demonstrated that the Abaqus West's UMAT is capable of predicting the uniaxial material response at different temperatures, a Nitinol stent's deformation, and Austenite or Martensite composition at any material point in addition to the stress and strain fields [14-15]. Recently, comparison of the Abaqus West UMAT and another UMAT by EchoBio has shown that both approaches agree to each other very well and they both predict the experiment results well [16].

This article focuses on analyzing Nitinol's medical applications in minimally invasive surgery. The analyses are divided into two categories. We choose a representative device from each category and discuss the analysis in detail. The first device analyzed is a Nitinol needle/wire locator. The second device is a self-expanding stent. They are chosen with general indications on many other applications as listed in the section below. In both cases, experimental data are used to compare with the analysis results. Theoretical estimations are also provided to further confirm the analysis results.

FEA ANALYSES ON MINIMALLY INVASIVE MEDICAL APPLICATIONS

In the needle/wire locator application, we show that the UMAT is able to predict the uniaxial material response at different A_f by comparing with the experimental data. This opens doors for the optimization of the A_f to achieve the most suitable design. It also indicates that the material properties at different Af or application temperatures are predictive. The stress analysis on the device is straightforward as the hook wire is constrained very tightly inside the needle. Furthermore, the peak stress and strain values can be estimated from pure geometry change. Comparison shows that FEA agrees well with the theoretical prediction.

In the stent application, we review the role of FEA in predicting the stent's fatigue life. Our focus is aimed on the FEA results on a fatigue specimen simulating the deformation of stent-like devices, *i.e.*, a diamond shaped specimen. Fatigue tests on this test specimen are used to set up the strain-life curve that dictates the baseline for fatigue prediction. FEA results on diamond shaped specimen are compared with the load-displacement results collected from the experiment. A theoretical solution based on a piece-wise linear approximation in combination with the fundamental beam theory is generated on the loading portion of the specimen for comparison. Results show good agreement between FEA, theoretical prediction and the experimental data.

NEEDLE/WIRE LOCATOR

Figure 1 shows the Homer Mammalok needle/wire locator. It is a two-piece device that consists of a Nitinol wire with a half circular shaped hook at one end, and a hollowed needle that the wire goes into. The locator is originally withdrawn inside the needle cannula [17]. During the application, the needle is inserted into the breast and adjusted until its tip is verified to be at the site of the tumor. The locator is then advanced and reforms back to the hook configuration. The position of the hook marks the correct location for the surgeon. If necessary, the locator can be withdrawn into the needle until the correct location is identified.

Figure 1. Homer Mammalok needle/wire locator

The design challenge is to have a strong hook so that it can be placed in position tightly, yet it is not too hard to withdraw the hook into the needle. One of the possible design options, from a material application point, is to choose the right A_f temperature. Pelton et al provided details on how to obtain the desired A_f [18]. Pelton et al later also pointed out that the best way to optimize both A_f and the geometry is to perform a FEA without actually making and testing the device [19]. This type of FEA normally involves a curved shaped wire being withdrawn into a straight tube. The analysis is very straightforward. One can mesh the wire with solid elements and simplify the needle as a rigid cylinder. Use of symmetry can reduce the model to a half of its actual size. Prescribed displacement condition can be used to pull the wire through the rigid cylinder. The outputs from FEA are the stress and strain fields and the contact pressure between the wire and the needle (rigid surface). The wire diameter is 0.38mm and the hook radius is 4.8mm in this study. The maximum tensile and compressive strains are theoretically estimated from the curved beam theory to be approximately 4.1% and –3.8% respectively.

A uniaxial tensile test is necessary to calibrate the UMAT for analysis. For comparison purposes, the tests were performed at 37°C for wires that are processed to have three different A_f temperatures, *i.e.*, -10°C, 14°C and 27°C. We used the highest A_f, *i.e.*, A_f = 27°C, to calibrate the UMAT. We then run a single element test to predict the stress-strain relations for the other two A_f wires. Figure 2 shows the comparison of the FEA prediction and the experimental results of the highest A_f wire. As one can tell, the calibrated material response reproduces the experimental results very well. Figure 3 and 4 show the comparison of the FEA prediction and the experimental results on the lower A_f wires. Again, the results agree, especially well in the range of application interests, *i.e.*, up to 6%.

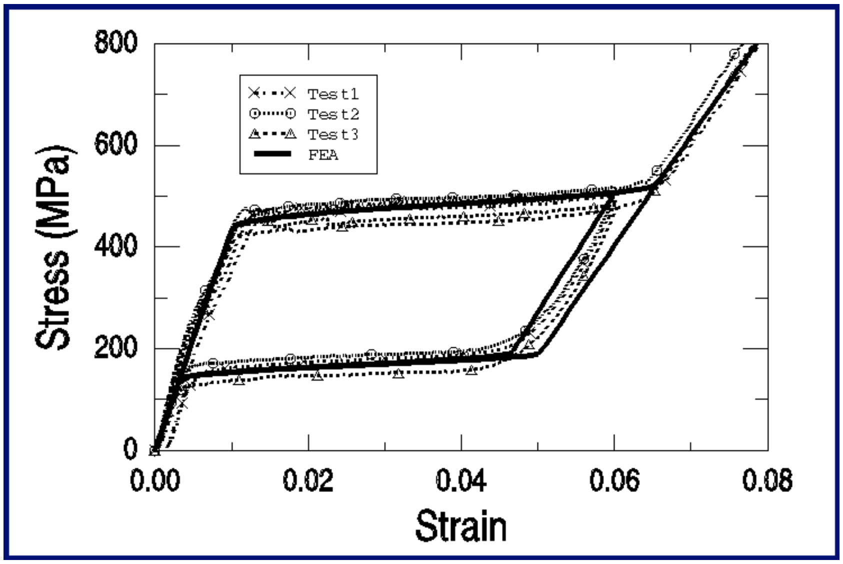

Figure 2. FEA material model calibrated using A_f = 27 °C

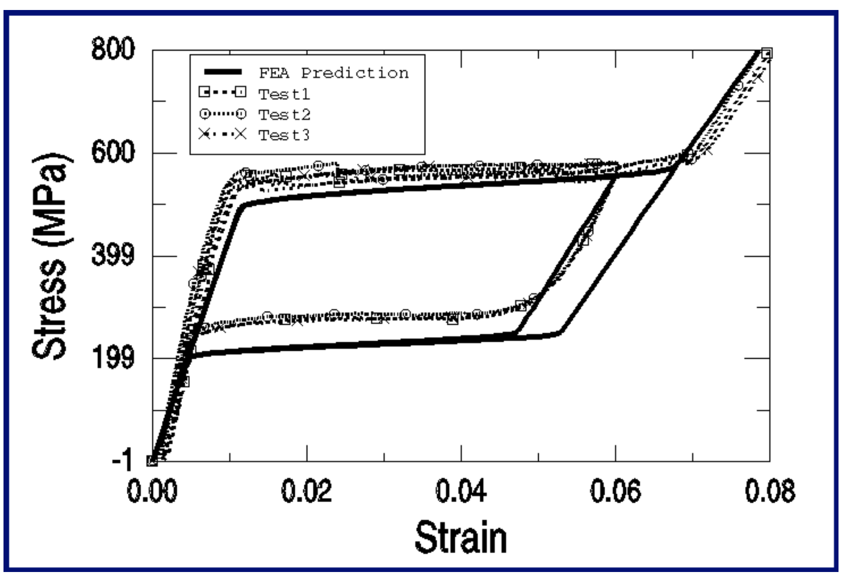

Figure 3. Comparison of the uniaxial tensile tests on Af = 14 °C wires with FEA prediction from A_f = 27 °C

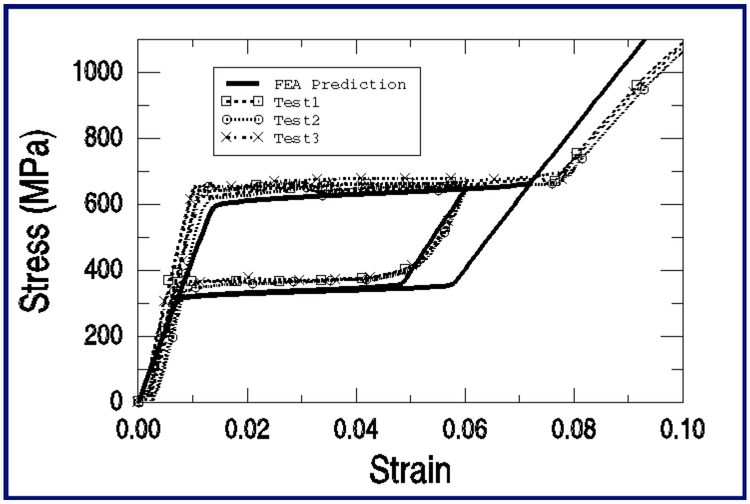

Figure 4. Comparison of the uniaxial tensile tests on A_f = -10 ^{o}C wires with FEA prediction from A_f = 27 ^{o}C

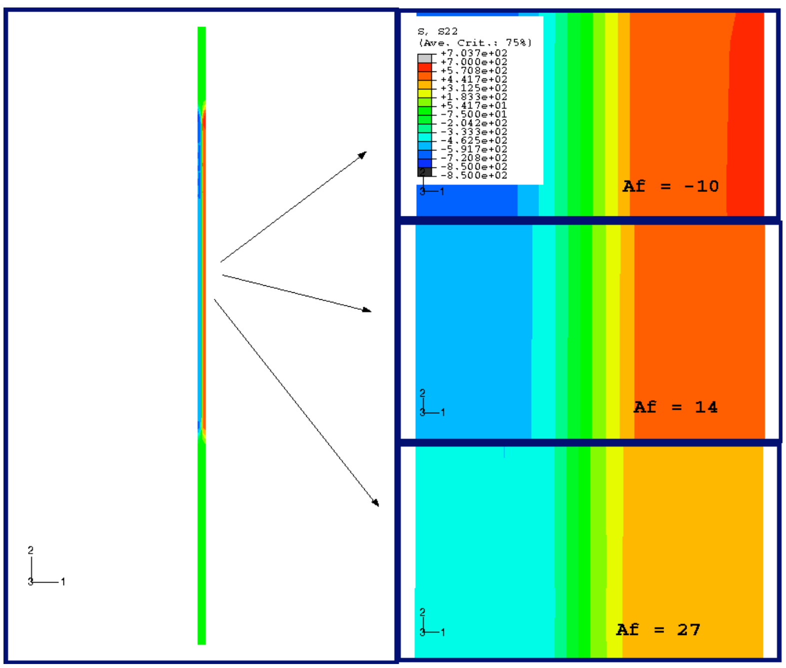

Figure 5. Longitudinal stress contours in the same scale when different A_f Nitinol locator has been withdrawn inside the needle indicates stress increases as A_f decreases

Figure 5 shows stress contour on the deformed shape for different A_f wires when they are withdrawn into the needle. Clearly the different A_f wire produces different magnitudes of stress field. The lower the A_f, the higher the stress it produces. Therefore, the lower the A_f, the harder to withdraw the wire into the needle. When the strain contours are plotted, there is less difference between the different A_f wires. This is because the deformation is bending dominant and the wire is so confined in the needle that despite the material responses differ for different A_f, the strain field, as in a same highly constrained environment, is less dependent of the material responses. Figure 6 plots the comparison of strain distributions for different A_f wires and the theoretical prediction. The results are almost identical. Notice these are the strain distributions in the body portion of the arc of the wire, at the locations where the wire changes from straight to arc the strain is slightly higher. This phenomenon, normally refers to as end effect, can only be predicted from the FEA. Figure 7 shows the strain distribution at this location with comparison to theoretical prediction. As one can tell, the strain is higher than the body portion of the curved wire. Therefore, even theory and FEA agree extremely well to predict the strain in the body portion of the curved wire. FEA can also capture the end effect nicely and predict the strain more accurately.

This analysis technique also applies to other wire-shaped devices such as a duct-occlusion device, a radio frequency interstitial tissue ablation device, and a hingeless grasper [1-2] and withdrawing of a vena cava filter.

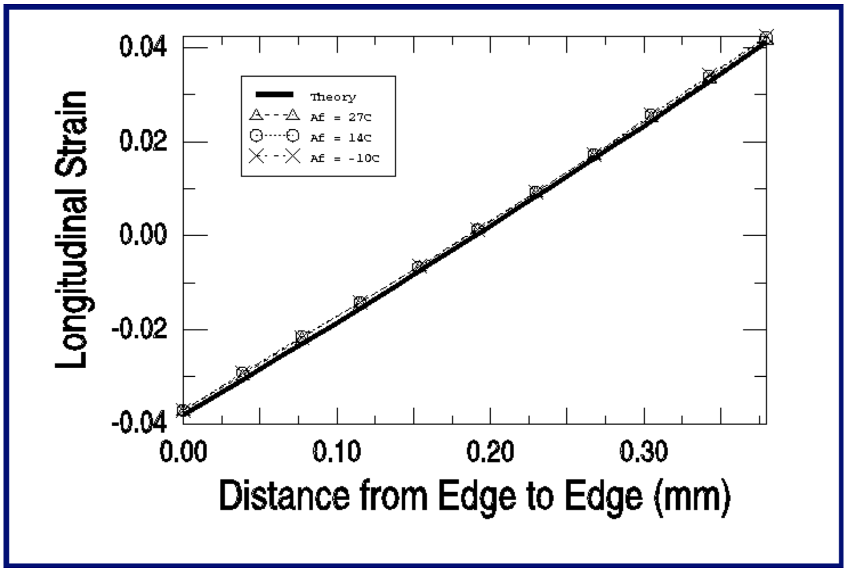

Figure 7. Edge to edge longitudinal strain distribution when Nitinol locator is withdrawn inside the needle

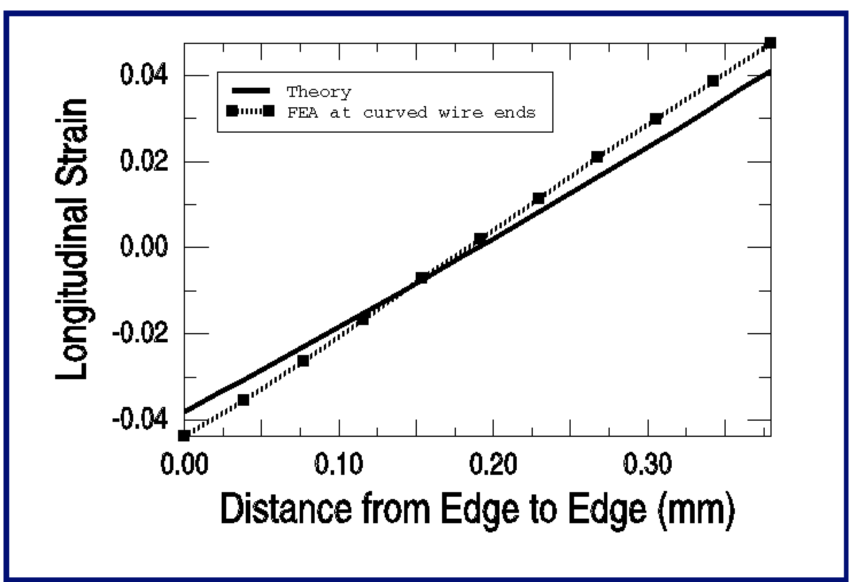

Figure 7. Edge to edge longitudinal strain distribution comparison at the end of curved wire when it is withdrawn inside the needle

STENT

A stent is a metal mesh made either from fine wires or from laser cutting the tubes into desired patterns set in place to hold a vessel open. The superelastic behavior of Nitinol eases the design due to its large strain capability. Duerig *et al* discussed the key differences between a balloon expandable stent normally made of stainless steel and a self-expanding stent made of Nitinol in addition to the key design issues [20-21]. Regardless of their differences, the key design issues for a successful stent remain to be the fatigue life and stiffness of the stent. Testing of a Nitinol stent's stiffness and corresponding prediction from nonlinear FEA are straightforward. Gong *et al* has recently demonstrated that FEA prediction of a Nitinol's stiffness agree well with experiment [22].

However, prediction of a Nitinol stent's fatigue performance is not an easy task. Based on the fundamental strain-life approach, prediction of a stent's fatigue performance requires a precise analysis of the fatigue strains of a stent *in vivo* and a profound understanding of Nitinol's fatigue behavior under the similar deformation patterns. Nonlinear FEA has been shown to be very effective in computing the fatigue stresses of a balloon expandable stent made of stainless steel [23]. A similar approach applies to Nitinol with cautions on the differences in material properties that are unique to Nitinol. An example of a FEA model for computing the fatigue strain of a Nitinol stent *in vivo* is shown in Figure 8 to summarize the computation steps below. The model contains a Nitinol stent and a "mock artery" to simulate the interaction of a stent and the artery *in vivo*. The flexible contact between "mock artery" and the stent is turned off until the final stage of the analysis. To ensure that the fatigue strains are evaluated at the loading path of the Nitinol, The first step of analysis is to expand the "mock artery" to a diameter that is slightly larger than the stent OD. This is done by applying an internal pressure on the "mock artery". Then, at second step, the contact between "mock artery" and stent is turned on and the pressure applied on the "mock artery" is now ramped down to zero. This final portion of analysis provides strain on the stent as function of the pressure on the "mock artery". Fatigue strains can then be determined by locating the strains at different pressures. In addition to fatigue strains, one can also obtain the stent diameters at different pressures. In our studies on several Cordis Nitinol self-expanding stent product lines, FEA predictions of the stent diameters have agreed extremely well with the actual lab measurement of the stent diameters. These build the confidence on the fatigue strain predictions [24].

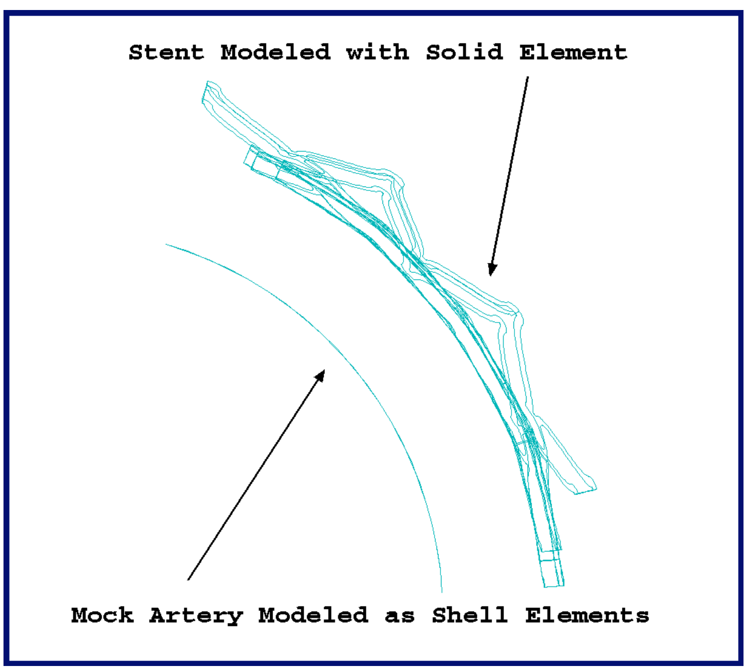

Figure 8. FEA model for stent fatigue strain analysis includes multiple rows of struts to cover the end effects and a mock artery to simulate the stent-artery interaction

To establish a fatigue baseline (a strain-life curve) for stent application, the test specimen must have a similar deformation patterns to the deformation of a stent *in vivo*. A direct and efficient way to establish the strain-life curve for a stent is to perform fatigue test on its individual struts. However, the unzipped stent is not easy to handle experimentally. We therefore built a unit cell of a stent, *i.e*., a diamond shaped specimen, to overcome the handling difficulties (Figure 9). It is designed to be similar to the strut geometry from a Cordis SMART stent. The small holes in the ends of the sample are for ease of crimping. The samples are processed in the same manner as a stent so that it has the same A_f and an electropolished surface finish. They are stretched and compressed before the actual fatigue test and the load and displacement are recorded to ensure the processing consistence in sample preparation.

Figure 9. Diamond-shaped specimen for fatigue study

FEA is used to calculate the strain field in the specimen so that the test can be planned at the most relevant *in vivo* conditions for stent application and the results can be interpreted as strain-life curve [22]. Notice that when only the loading portion of the curve is concerned, one can simplify the stress-strain curve as piece-wise linear. Under this simplification the beam theory can be used to estimate the maximum strain inside the specimen and predict the load-displacement relation on the loading path to confirm the FEA. Figure 10 shows that the theoretical prediction, FEA and the experimental data agree well.

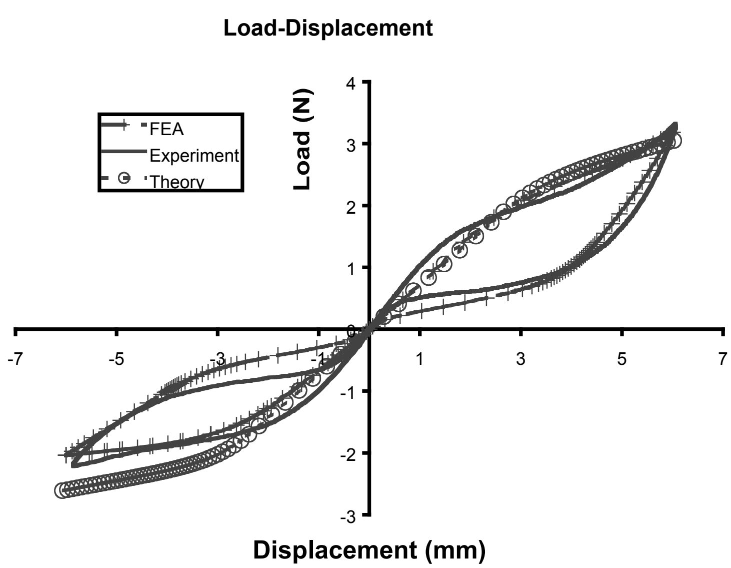

Figure 10. Comparison of FEA, theoretical prediction, and experimental data of load-displacement relation on diamond-shaped specimen

NDC has performed the fatigue test in the past two years and the test results are presented in reference [23]. By using the same analysis code, controlling the same process procedures, we are comfortable to ensure a fatigue safe stent. Our accelerated device tests performed on several Cordis stent production lines have confirmed our predictions.

CONCLUSION

We show from two typical minimally invasive medical device applications that ABAQUS, with user-defined material subroutine specific for Nitinol developed by Abaqus West, has opened the door for Nitinol engineering evaluations. This indicates that they can be used as a predictive tool prior to prototyping the designs to optimize the device functionality not only by varying the geometry of the design, but also tuning the material properties. In addition, FEA can identify the fatigue strains at given *in vivo* conditions. This address the fatigue life, which is essential for most implantable devices, provided a strain-life curve is established from the same FEA to ensure consistency. To summarize, the use of FEA helps to understand the device functionality and the fatigue properties of Nitinol. Experiments coupled with FEA can guide the device design to improve its service life and optimize the device functionality.

REFERENCES

1. D. Stoeckel, Nitinol Medical Devices and Implants, Min, Invas. Ther. & Allied Technol., Vol. 9, No. 2, 2000, p. 81.
2. D. Stoeckel and A. Melzer, The use of NiTi Alloys for Surgical Instruments, Materials in Clinical Applications, edited by Vincenzini, P., Techna Srl, 1995, p. 791.
3. S. Miyazaki, Medical and Dental Applications of Shape Memory Alloys, Shape Memory Materials, edited by Otsuka K. and Wayman C.M., Cambridge University Press, 1999, p. 267.
4. NDC web site, www.nitinol.com.
5. D. Tolomeo, T. Slater, and P. Wu, Predictive Modeling of Radial Force for Superelastic Stents, in SMST-2000: Proceedings of the International Conference on Shape Memory and Superelastic Technologies (S. M. Russell and A. R. Pelton eds.), Pacific Grove, California, USA, 2000, p. 517.
6. L. Anand and M. Kothari, A Computational Procedure for Rate-Independent Crystal Plasticity, J. Mech. Phys. Solids, 1996, 44, p. 525.
7. F. Auricchio and R. L Taylor, Shape-Memory Alloys: Modeling and Numerical Simulations of the Finite-Strain Superelastic Behavior, Comput. Methods Appl. Mech. Engrg., 1996, **143,** p.175-194.
8. F. Auricchio, R. L. Taylor, and J. Lubliner, Shape-Memory Alloys: Macromodeling and Numerical Simulations of the Superelastic Behavior, Comput. Methods Appl. Mech. Engrg., 1997, **146**, p. 281.
9. M. A. Qidwai and D. C. Lagoudas, Numerical Implementation of A Shape Memory Alloy Thermomechanical Constitutive Model Using Return Mapping Algorithms, Int. J. Numer. Meth. Engng. 46, 2000, p1123.
10. J. Knowles, Stress-Induced Phase Transitions in Elastic Solids, Comput. Mech. 1999, **22**, p. 429.
11. E. Patoor, A. Eberhardt, and M. Berveiller, Micromechanical Modeling of Superelasticity in Shape Memory Alloy, J. Phys. 1996, IV 6, p.277.
12. Q. Sun and K. Hwang, Micromechanics Modeling for the ConstitutiveBehavior of Polycrystalline Shape Memory Alloys – i. Derivation of General Relations, J. Mech. Phys. Solids, 1993, **41**, p. 1.
13. Q. Sun and K. Hwang, Micromechanics Modeling for the ConstitutiveBehavior of Polycrystalline Shape Memory Alloys – ii. Study of the Individual Phenomena, J. Mech. Phys. Solids, 1993, **41**, p.
14. N. Rebelo and M. Perry, Finite Element Analysis for the Design of Nitinol Medical Devices, Min. Invas. Ther. & Allied. Technol., 9 (2) 2000, p. 75..
15. N. Rebelo, M. Hsu and Foadian, H., Simulation of Superelastic Alloys Behavior with ABAQUS, in SMST-2000: Proceedings of the International Conference on Shape Memory and Superelastic Technologies (S.M. Russell and A.R. Pelton eds.), Pacific Grove, California, USA, 2000, p. 495.
16. X.-Y. Gong, A. R. Pelton, T. W. Duerig, N. Rebelo, and K. E. Perry, Finite Element Analysis and Experimental Evaluation on Superelastic Nitinol Stent, to appear in SMST 2003.

17. J. P. O'Leary, J.E., Nicholson, and R. F. Gatturna, The Use of Ni-Ti in The Homer Mammalok, in Engineering Aspects of Shape Memory Alloys, (T. W. Duerig, K. N. Melton, D. Stockel, and C. M. Wayman eds.), 1990, p.477.
18. A. R. Pelton, J. Dicello and S. Miyazaki, Optimisation of Processing and Properties of Medical Grade Nitinol Wire, Min. Invas. Ther. & Allied. Technol., 9 (2) 2000, p. 107.
19. A. R. Pelton, T.W. Duerig, and D. Stoeckel, Design with Nitinol, Presented at SMST 2001, in Kunming, China, Sept. 2001.
20. T. W. Duerig and M. Wholey, A Comparison of Balloon- and Self-Expanding Stents, Min. Invas. Ther. & Allied. Technol., 11 (4) 2002, p. 173.
21. T. Duerig, D. E. Tolomeo, and M. Wholey, An Overview of Superelastic Stent Design, Min. Invas. Ther. & Allied. Technol., 9 (3/4) 2000, p. 235.
22. X.-Y. Gong, J. Sheriff, A. R. Pelton, and T. W. Duerig, Fatigue Testing of NiTi on Diamond-Shaped Specimens, to appear in SMST 2003.
23. S. Oh, Finite Element Analysis of Endovascular Graft Stent Interacting with Human Aorta, ABAQUS Users' Conference, Newport, Rhode Island, June 2000, p. 535.
24. X.-Y. Gong, L. Zhu and A. R. Pelton, unpublished work.