

SIMULATION OF IMPLANTABLE NITINOL STENTS

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Abstract

Finite element methods continue to play an ever expanding role in the design and validation of medical devices. The ability of the finite element technique in dealing with both complex geometries and materials is key to the success of this method in the medical field. This synergism is clearly evident in the analysis of devices based on Nitinol, a nickel-titanium alloy, and a complex superelastic material. The particular device explored here is a stent, which is a mesh tube that is inserted into blood vessels to counteract the effects of vascular diseases. Both the manufacturing process and deployment are considered.

Introduction

Medical technology continues to advance rapidly as physicians and engineers move closer to and understand better each other's needs. Nowhere is this better evidenced than in the development of advanced medical implants. Traditionally, new products were developed by prototyping and evaluating. However, this process is very time consuming and often does not fully reveal potential failures. Finite element modeling and analysis greatly reduce testing and time to market by allowing the designer to simulate product performance in advance of any prototyping (Haridas, 1999). Algorithms have been developed which allow for the accurate predictive finite element analysis of nickel-titanium alloys which have extremely complex but highly attractive mechanical behavior for medical applications.

Since its discovery and first fabrication, Nitinol alloys have come to be used in a myriad of unique ways. The superelastic and shape memory properties of the alloy along with its biocompatibility and fatigue properties have given the material a wide range of applications from thermal switches and electrical connectors to cardiovascular stents. However, the many benefits of the material come at a cost. The complexity of its properties makes it difficult to process. Trial and error techniques have been commonly employed in the past; it is, however, very time consuming; and in today's market place, time is among the most valuable commodities. FEA can be employed to hasten time to market of Nitinol products by greatly reducing the number of design iterations required, hence expediting the design process. This article describes material models capable of simulating the superelastic behavior of alloys such as Nitinol, and shows how they can be used to simulate the fabrication and deployment of cardiovascular stents.

The purpose of FEA is to possibly expose and solve design flaws before a product is produced. It does not normally preclude the manufacture of prototypes, but it should greatly reduce the number of prototype iterations required, and in the best case, will reduce the number of prototypes to one. In fact, in areas of high confidence of the materials and the model set-up, it is possible that prototyping can be eliminated altogether.

Superelastic Alloy Material Behavior

While highly attractive for medical applications, Nitinol's behavior is complex, as can be seen in the mechanical characterization provided in Figure 1. At rest, the material presents itself in an austenite phase, which behaves linear elastically. Upon loading, this austenite phase transforms into a martensite phase, which is also linear elastic; however, the elasticity of each phase has different constants. The transformation produces a substantial amount of strain and is triggered by stress, over a relatively narrow range. Upon unloading, the transformation is reversible. However, the stress levels at which such reversible transformation occurs are smaller than the

stresses which were required to produce the original transformation. Because the material, upon unloading, completely recovers its original shape, it is described as elastic. In addition, because the transformation strains are so large (of the order of 6%) compared to the typical elastic strains in a metal, the material is said to be superelastic.

If a reverse loading is applied (for instance in compression instead of tension), a similar behavior is observed, with the exception that the stress levels required to produce the transformations are higher, while the transformation strain is lower. The net result is that Nitinol is an extremely flexible metal alloy that can undergo very large deformations without losing the ability to recover its original shape upon unloading.

The constitutive laws used in simulations should embed the characteristics just described. It is relatively straightforward to generate a material model that reproduces the desired behavior if the deformation being simulated is uniaxial. Unfortunately, it rarely is in practice.

Until very recently, there were no generally accepted material models, which were capable of reproducing all of the characteristics of the material just described. A popular close approximation, capable of modeling the loading part of the model, is hyperelasticity, which is commonly used to represent rubber behavior (Pelton, 1994). Several other models have recently been proposed to address Nitinol's behavior (Auricchio, 1997; Auricchio, 1996; Qidwai, 2000). However, a thorough verification of these models has been difficult. This is because the manufacturing requirements of the material are complex. As a result, Nitinol is typically available as relatively thin wires and tubes, from which most of the testing data available is uniaxial. While it is relatively straightforward to produce a uniaxial model, it is much more difficult to produce a model that represents Nitinol's three-dimensional stress-strain behavior. At Hibbitt, Karlsson & Sorensen (West), a user material routine (UMAT/Nitinol) was written following the model

proposed by Auricchio and Taylor (Auricchio, 1997; Auricchio, 1996). This theory is based on the concept of generalized plasticity (Lubliner, 1996). The theory is deemed acceptable because it is based on physical principles. The theory decomposes strain into two parts — a purely linear elastic component and a transformation component:

$$\Delta \boldsymbol{\varepsilon} = \Delta \boldsymbol{\varepsilon}^{el} + \Delta \boldsymbol{\varepsilon}^{tr}$$

The austenite to twinned martensite transformation is driven by the resolution of shear forces, and it takes place within a range of stress levels that are characteristic of the material.

$$\Delta \boldsymbol{\varepsilon}^{tr} = a \Delta \mathbf{z} \frac{\partial F}{\partial \boldsymbol{\sigma}}$$

$$F^S \leq F \leq F^F$$

where \mathbf{z} is the fraction of martensite, and F is a transformation potential. The same is true for the reverse transformation, but at different stress levels. The intensity of the transformation follows a stress potential law:

$$\Delta \mathbf{z} = f(\mathbf{s}, \mathbf{z}) \Delta F$$

Any change in stress direction produces a reorientation of the martensite with negligible additional effort. Changes in temperature produce a shift in the stress levels at which the transformations take place. This shift is linear in temperature. Because there is a volume increase associated with the transformation, it requires less stress to produce the transformation in tension, and more in compression. This is modeled with a linear Drucker-Prager approach for the transformation potential:

$$F = \bar{\mathbf{s}} - p \tan \mathbf{b} + CT$$

with \bar{S} being the Mises equivalent stress, p the pressure stress, and T the temperature.

Although the original model does not take it into account, a rule of mixtures was used to implement the change in linear elasticity from the austenite phase into the martensite phase; the implementation is, at present, approximate.

In addition to the usual stresses and strains, the UMAT routine tracks variables specific to the model. These variables include distribution of fraction of martensite, transformation strains, and equivalent stresses and strains. These are points in the uniaxial tensile curve into which material points that have a three-dimensional state, specific fractions of martensite, and a specific loading/unloading history are mapped. The material data required by the model are obtained from straightforward observations of uniaxial tests in terms of loading, unloading, reverse loading, and temperature effects. The calibration consists of 13 values (Figure 2). In addition, the user may anneal the material in the middle of an analysis.

Figure 3 displays a comparison of a set of experimental stress-strain curves, in which successively larger strains were imposed, with the same curves obtained by a simulation of the uniaxial test. Figure 4 shows the behavior of the model upon repeated loading and unloading. Figures 5 and 6 show the behavior of the model subjected to an 18°C temperature range while strains are applied.

Stent Analysis

Stents are cylindrical metal mesh tubes made of materials such as Nitinol and inserted into blood vessels to counter act the effects associated with vascular diseases, such as narrowing of blood vessels due to the build up of plaque.

In this section, we present an example of a stent analysis in which both the manufacturing process and deployment are considered, courtesy of Nitinol Devices & Components, Cordis Corporation, a Johnson & Johnson company. One of the key issues in medical implants is device lifetime or, in

engineering terms, fatigue life. Fatigue testing normally takes such a long time that it is incompatible with old-fashioned build-test design cycles. Finite element analysis provides quantitative measures of stress and strain without the need to build the devices. This process not only allows the optimization of designs, but also provides an opportunity to predict the device's life.

The large elastic strains possible in Nitinol reduce the risk of damage to the stent both during delivery into the body, and due to accidents while in operation. The large elastic strains also permit the deployed configuration to be close to the unloaded configuration.

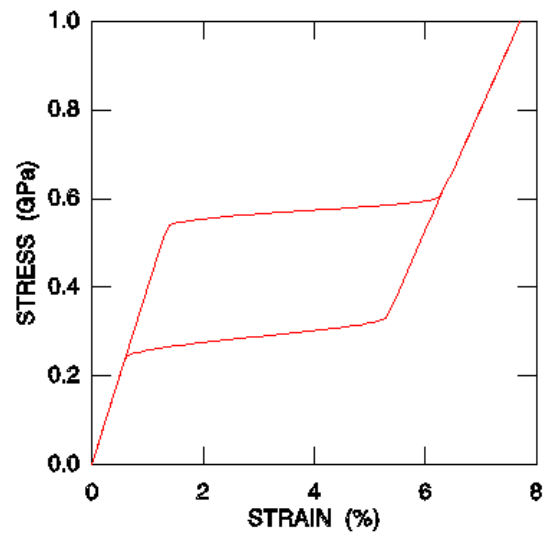
A possible manufacturing process of Nitinol stents starts from a thin tube in which a pattern is electromachined. The FEA model is built from this machined tube. Since the pattern repeats itself, only a part of the stent with appropriate symmetry boundary conditions is considered in order to simplify the complexity of the models (Figure 7). The stent is expanded to its nominal dimensions, typically at a diameter many times larger than the original tube diameter (Figure 8). While loaded, the stent is annealed to provide its new unloaded configuration. The stent is crimped from the outside, and inserted into the delivery system (usually a system of catheter tubes), as shown in Figure 9. Once inside a patient's body, the delivery system pushes the stent out of its containment (Figure 10). Once delivered, the response to blood pressure pulsing loads may be used to determine the fatigue life of the stent. The calculation reveals stress or strain concentrations during all three aspects of manufacturing, deployment, and service loading (Figure 11). Auxiliary information is also available from the calculation; such as how much martensitic transformation has occurred, and therefore, how close the design is to the limits of the material flexibility (Figure 12).

Conclusion

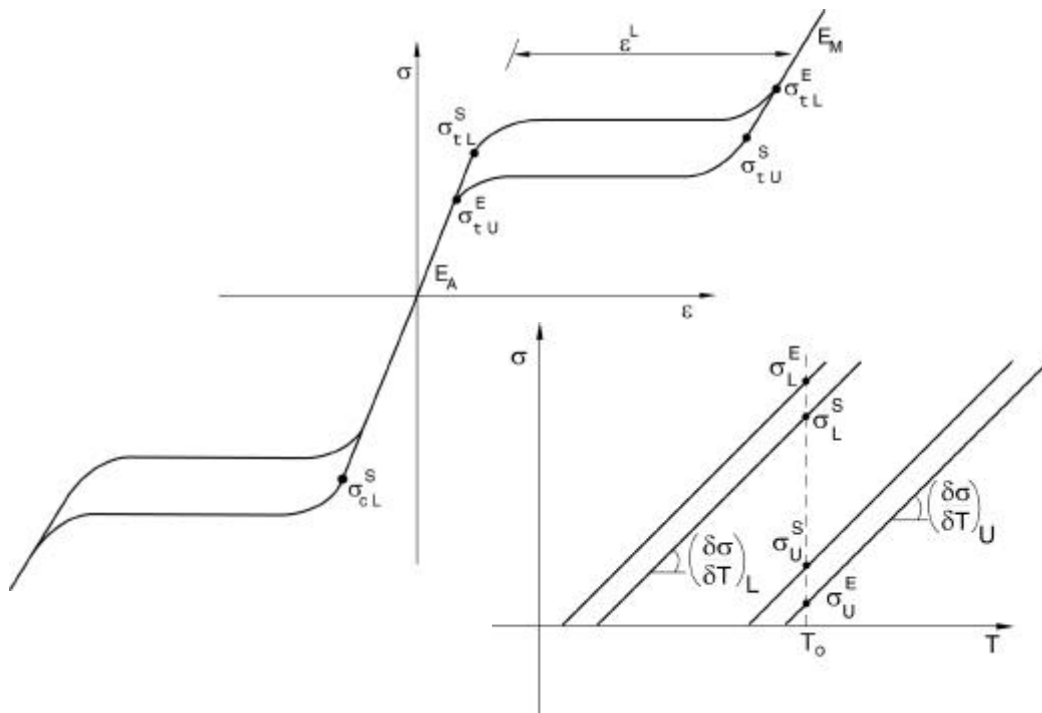
Finite element analysis is a method well suited to the needs of the product designer. The method allows the designer to quickly assess his or her design and to iterate the design on a computer before a single piece of metal is ever touched. The finite element method's ability to quickly and accurately solve complex material problems, such as those of Nitinol alloys, makes it an ideal candidate for such situations. Complexity of stent designs and of the actions taken to deploy them requires sophistication in the finite element tool used. Proper material behavior is just one requirement. Quite often, advanced capabilities are required in terms of contact with both rigid tools and other flexible bodies, large deformations, localized buckling, material removal, complex loading sequences and synchronization. These basic robust capabilities in ABAQUS make the software particularly suitable for stent design.

References

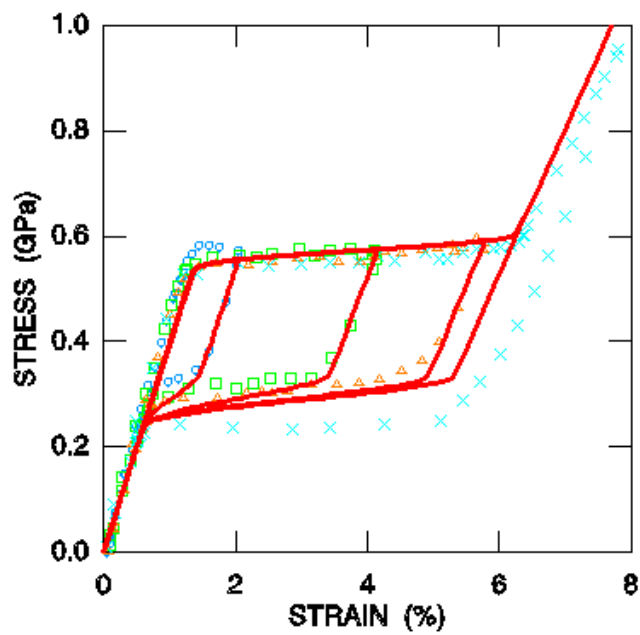
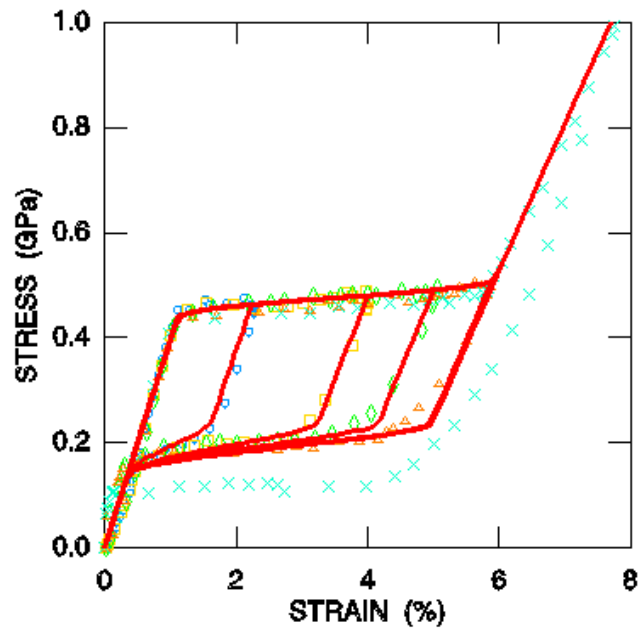
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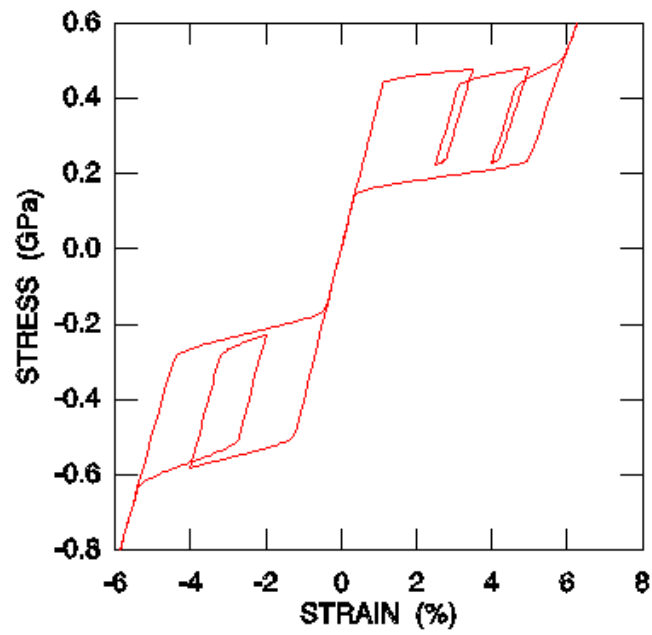
1. Mechanical behavior of Nitinol.



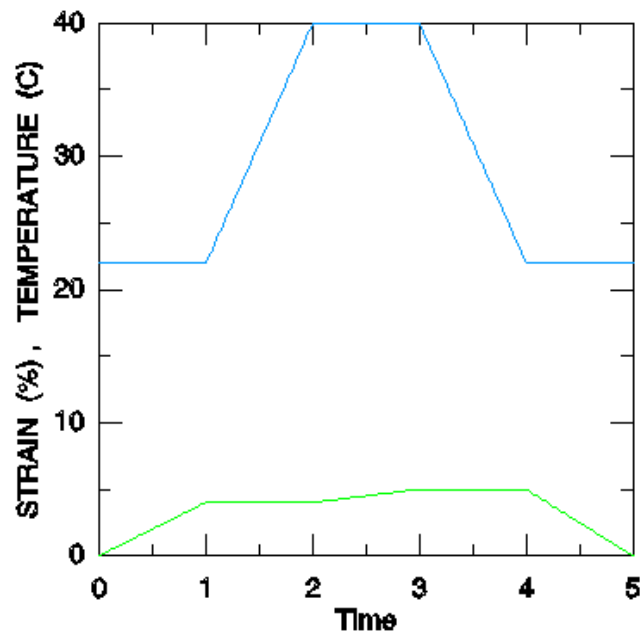
2. Data required to define superelastic behavior in the ABAQUS model.



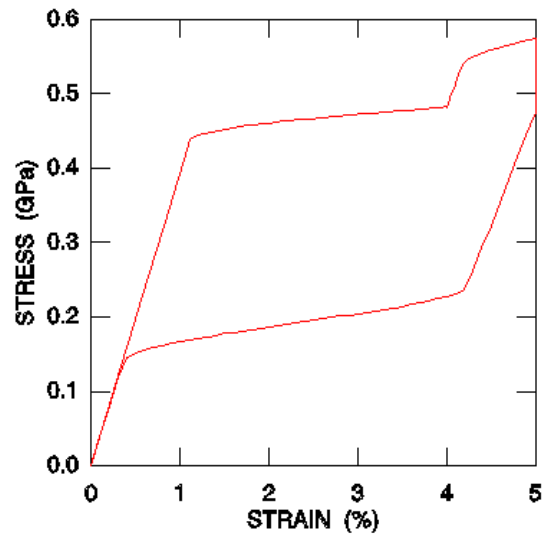
3. The ABAQUS algorithm for NiTi alloy modeling closely matches experimental measurements where successively larger strain loads are applied to the alloy at different temperatures, 22°C (top) and 37°C (bottom).



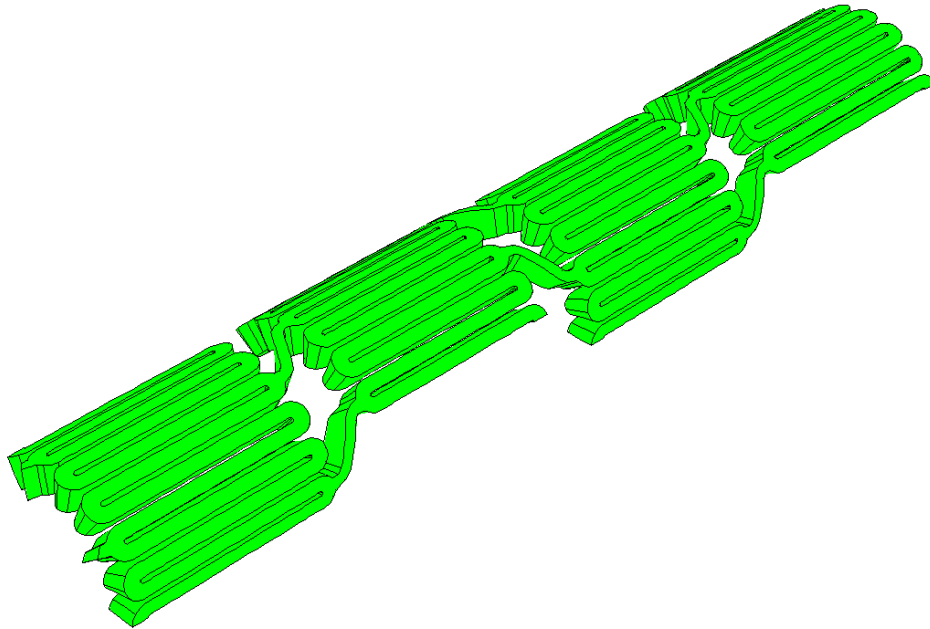
4. Model showing the effects of repeated loading and unloading of Nitinol.



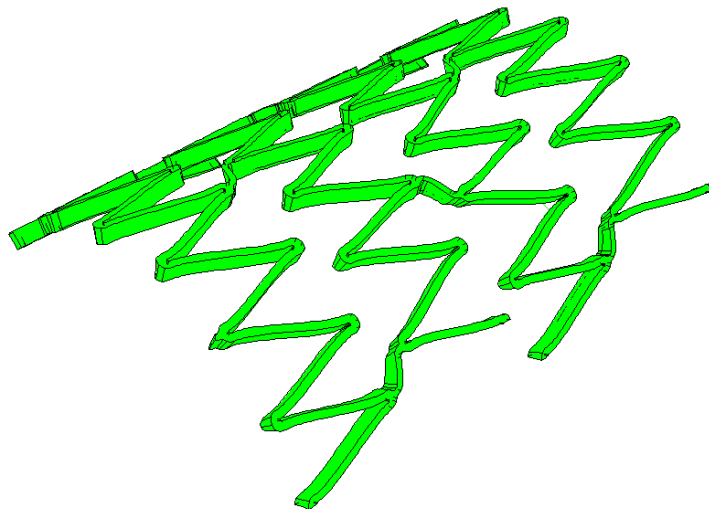
5. Model showing loading in terms of temperature and strain.



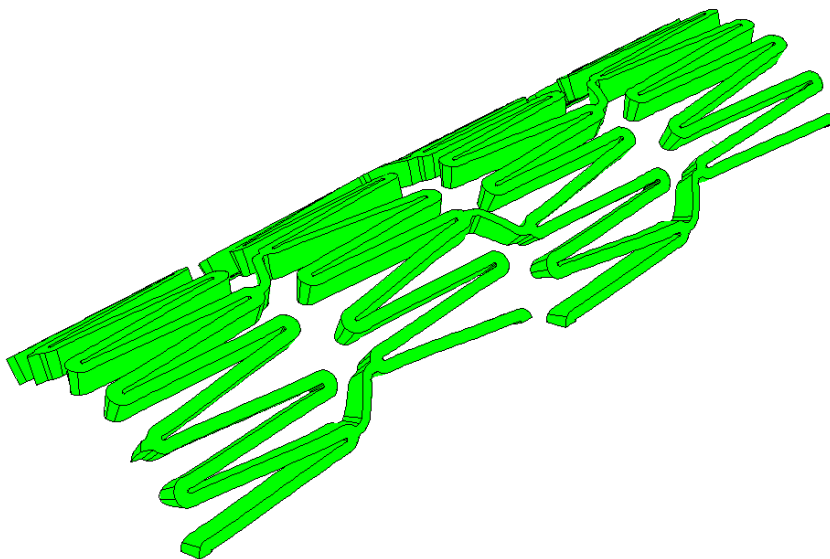
6. Stress-strain curve results for Nitinol based on loading shown in Figure 5.



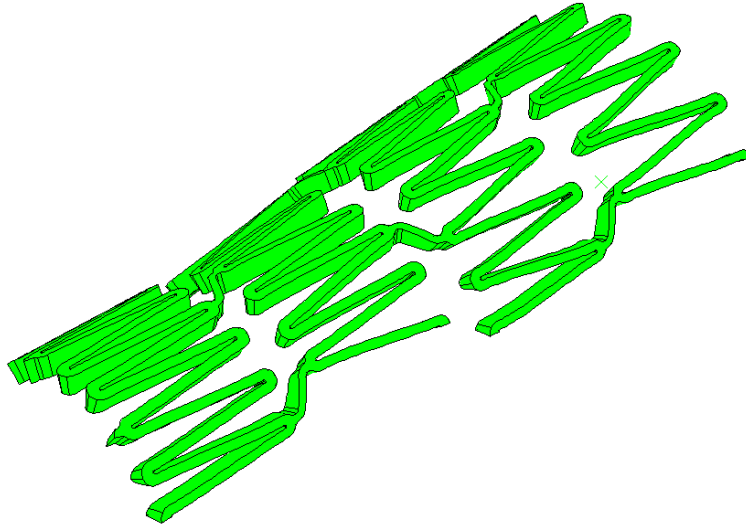
7. Stent model in its initial configuration.



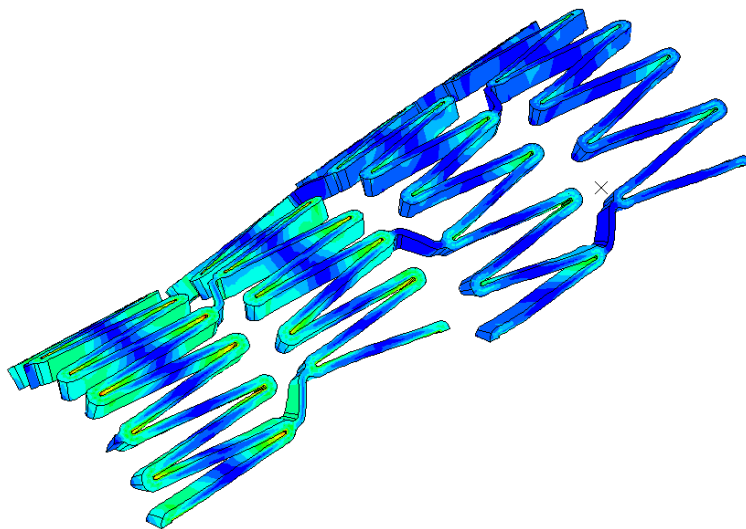
8. Expanded stent.



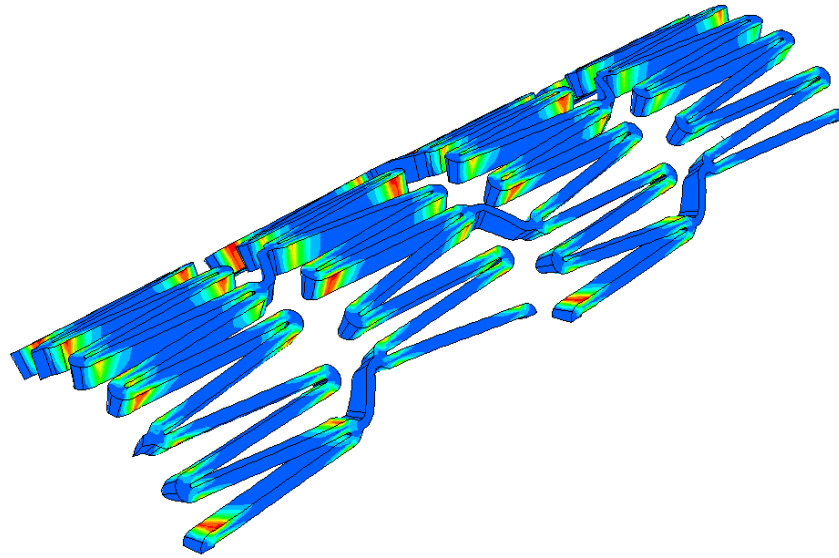
9. Retracted stent.



10. Partially deployed stent.



11. Von Mises stress intensity during deployment.



12. Martensitic transformation level in retracted stent.