Simulation of the Insertion of an Endostaple™ into a Vascular Stent and an Artery

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Abstract
In order to obtain FDA approval for the Endostaple™, a device to hold a vascular stent to the blood vessel wall, it was necessary to perform a non-linear finite element analysis of the insertion of the Endostaple into the stent and vessel wall. The insertion consists of feeding a bifilar nitinol wire that is initially in a double helix shape onto an optical cable. The optical cable ablates a hole in the graft and tissue and then the cable with the staple is placed through the hole in the stent and the vessel wall. Finally the optical cable is removed while the staple remains and attempts to return to its double helix shape. Initial modeling efforts, designed to characterize the response of the staple during initial stretch were centered on standard non-linear implicit static analysis procedures using ANSYS5.7. Due to the extremely large deflections and the significant number of complex interacting contact surfaces, it was decided that it would be more computationally efficient to perform the complete stretch/unloading analysis of the staple using ANSYS/LS-DYNA explicit dynamics analysis software to perform the quasi-static analysis. Initial explicit dynamics models implemented in this study made the assumption of no friction or damping, and were designed to reduce, or limit, the number of contact surfaces. These assumptions were incorporated in the spirit of minimizing the level of complexity of the resulting non-linear analysis; a tenet borrowed from implicit analysis. During post-analysis, these solutions gave obviously incorrect deformed shapes. It was only when the simplifying assumptions were removed and the fidelity of the explicit model improved to include as much of the correct physics as possible, that realistic solutions were obtained. The explicit dynamic analyses carried out in this study showed that the Endostaple™ experienced its most extreme strains once it is straightened onto the optical cable. They also showed that the strain ranges were not excessively large for the superelastic nitinol.

Introduction
A vascular Endostaple™ is an attachment device that is delivered via the lumen (i.e. inner passage) of a blood vessel; it is used to penetrate the entirety of the luminal structure of the blood vessel so as to strengthen the integrity of the structure or to secure an intraluminal prosthetic device (e.g. a vascular stent) to the full thickness wall of the luminal structure. Examples of possible application of Endostaples™ include the following: 1) sealing leaks "endoleaks"of arterial blood flow between the aortic neck wall and the endograft in patients with abdominal aortic aneurysms being treated with endoluminal devices to exclude the aneurysms; 2) preventing subsequent migration of endografts that do not have full thickness attachment at the proximal aortic neck attachment site; 3) attaching unsupported prosthetic bifurcation grafts to the proximal necks of abdominal aortic aneurysms.

The desirable attributes of an aortic Endostapling system include: 1) the insertion catheter should be small and flexible; 2) the delivery catheter head should be easily maneuverable; 3) there should be reliable penetration of the aorta, regardless of the degree of aortic wall calcification; 4) the Endostaple™ should
resist dislodgment both immediately after insertion as well as during the ensuing entire life of the recipient; and 5) the intraluminal portion of Endostaple™ should have a small profile.

The Endostapling system, which was subject to analysis in this study, and which was developed by EVA Corporation, is a device, which on preliminary testing, was found to meet all these criteria. The analyses that were undertaken in the study described below were pursued in order to satisfy FDA requirements for licensing of this device.

**Objectives**

The primary objective of this study was the execution of a non-linear finite element analysis of the insertion of an Endostaple into a stent and vessel wall, with the purpose of characterizing the deformation of the staple during the multi-phase process used in implementing the Endostaple to anchor the stent to the vessel wall. Particularly sought from this simulation was the location of the point at which maximum stress and strain values occur during the load history, as well as the magnitude of these values themselves. An important goal of the simulation was, therefore, a determination of the structural behavior of the Endostaple, consistent with the imposed load history and assumptions implemented in the development of the simulation.

**Description of Problem**

**Geometry and Loading**

The analysis described below is a simulation of the insertion of the Endostaple™ onto, or through, the stent and the blood vessel wall. The Endostaple™ consists of two nitinol wires. During the formation of the staple the wires are first twisted into a bifilar helix. The residual stresses are then annealed out so that the stress free state is the bifilar helix itself. Next, this single helix is bent into a larger helix and then the wire annealed again. The final stress free state of the uninstalled staple is thus a bifilar double helix as shown in Figure 1.

![Figure 1 - Stress-free Shape of Endostaple](image)

The installation process consists of 4 phases. The first phase consists of the insertion of the staple into a hole in a disk with a diameter slightly larger than the diameter of the initial single helix. This process bends the staple so that one of the helices has been straightened out. Phase 2 consists of the pushing of a optical cable through the hole in such a manner that the staple wraps around it (see Figure 2). The next phase involves the removal of the optical cable from the tool with the staple still attached (i.e. wrapped around it) and the subsequent insertion of these entwined optical cable/staple components through a hole in the stent and the vessel wall (see Figure 3) that was ablated by the optical cable. The last phase is characterized by the removal of the cable, leaving the staple straddling both sides of the hole. During this phase then, the
staple attempts to resume its stress free bifilar double helix state, which results in its coiling around both sides of the hole (see Figure 4). The beneficial result of this process is thus the development of a clamping force firmly attaching the stent to the vessel wall.

Figure 2 - Endostaple Installed on Optical Cable

Figure 3 - Endostaple and Optical Inserted into Hole in Stent and Vessel Wall
True Material Characteristics

The Nitinol used for the staple is a superelastic material. This means that the material behaves similarly to a metal except that it has an elastic stress-strain curve that is highly non-linear in nature, and it can tolerate a large amount of strain. The elastic stress-strain function for this material contains essentially 3 distinct regions of behavior. Initially, on loading, the behavior of nitinol is characterized by simple linear stress-strain response. The behavior in the first region is characterized by a typical linear stress-strain relationship. Once the stress reaches an initial limiting value, the stress-strain curve exhibits a plateau where large increases of strain result from relatively small increases of stress. Finally, a second limiting stress value signals the end of the plateau region, where the stress-strain curve exhibits another significant increase in slope to a value which is much larger than the slope in the plateau region, but less than the initial slope of the curve. A typical stress-strain curve for Nitinol is shown in Figure 5.
Initial modeling efforts, designed to characterize the response of the staple during initial stretch, were centered on standard non-linear implicit static analysis procedures using ANSYS5.7. During the implicit finite element modeling effort, the straightening of the double helix was approached via the insertion of the staple onto the optical cable. The implicit models that were implemented did not include self-contact of the filaments, or friction. Though attempts at modeling the initial portion of the straightening process using the implicit models were reasonably successful, it quickly became apparent that the complicated contact and large displacement behavior of the staple-cable system during the completion of the insertion process, and the subsequent releasing of the staple onto the stent wall, would result in unreasonably long run times at best, and severe, or even fatal, convergence problems at worst.

A more efficient way of carrying out the simulation was required. Due to the extremely large deflections and the significant number of complex interacting contact surfaces, it was decided that it would be more computationally efficient to perform the complete stretch/unloading analysis of the staple using ANSYS/LS-DYNA explicit dynamics analysis software to perform the quasi-static analysis. The interim results from the implicit model could then be used to compare and verify the initial stages of the explicit dynamics results.

The simulation of the insertion of the Endostaple™ into the hole in the vascular stent and the blood vessel wall was completed using the ANSYS/LS-DYNA-3D explicit dynamics finite element software package. Explicit dynamics finite element formulations are usually used to simulate high-speed situations such as automotive crash simulations, terminal ballistics analyses and metal forming analyses. However, by careful manipulation of the values of the part densities and damping coefficients of the dynamic model, dynamic relaxation techniques can be implemented to damp out dynamic effects in the solution, and the explicit dynamics method can be used in quasi-static applications. The types of problems where this approach is very useful usually involve very challenging contact problems or very large displacement or strain applications. The simulation of the insertion of the Endostaple™ involves, of course, all three of these classes of complications.

The concern with modifying the part densities in an explicit dynamic solution is that it can produce excessive kinetic energy compared with the internal (strain energy) for a quasi-static problem. This issue
was addressed in this study by (i) the use of appropriate values of coefficient of friction, (ii) the implementation of an adequate amount of global damping and (iii) the careful monitoring of the ratio of kinetic energy relative to internal energy. Except during the stretching of the coil, the kinetic energy in the entire model was less than 10% of the internal energy of the coil. Therefore the kinetic energy observed in the solutions was assumed to be small compared to the amount of internal energy in the system. Another feature of the explicit models implemented in the study were the addition of quiescent periods during the solution process (i.e. periods when no loads were changed in the system) in order to allow any remaining dynamic behavior to damp out.

During the initial attempt at defining the explicit model, many of the same assumptions that were implemented in the implicit analysis were also adopted for the explicit model as well. No friction or damping was applied. The initial analysis simulated stretching one end of the staple (with fixed displacement) and trying then to feed the optical cable through the center of the staple. The initial explicit model was a solid model (i.e. it used solid elements) representing only one of the fibers, and the only contact simulated was that between the staple and the optical cable. No self contact of the staple was included. Post analysis of the final solutions indicated that the solid model suffered from many problems. In all analyses in which this model was implemented, the cable passed through gaps in the staple. In addition, the deformation pattern generated by the solid elements was characterized by a large degree of hourglassing. Also, stress waves and other dynamic effects including an excess of kinetic energy for a quasi-static process dominated the solution. All these issues plaguing the solid model versions of the staple were exacerbated by the extremely large number of degrees of freedom (DOF) characterizing the model. The large number of DOF of course pointed to excessively long run times for a solution. All these issues, therefore, led the authors to turn to modeling the staple geometry with beam elements.

The bifilar nitinol coil analyzed in this study was based upon geometry provided by MedSource Technologies. Since, during the manufacturing process, the coil is annealed after being formed in the double helix shape; it was assumed that there are initially no residual stresses in the coil in the double helix shape. The geometry of the coil for analytical purposes was assumed to be an ideal double helix, and was generated mathematically, directly in ANSYS using the program's APDL programming capability. The coil geometry itself represented the full bifilar coil of 2 1/2 revolutions of the larger helix. The coil was modeled with 848 ANSYS/LS-DYNA-3D BEAM 161 elements using 1698 nodes. The beam element formulation used was the Belytschko-Schwer circular beam with 2x2 cross-section integration. Plots of the model are shown in Figure 6 and 7. Note that these figures show the element thicknesses or cross-sections.

![Figure 6 - Final Undeformed Finite Element Model](image)
The Belytschko-Schwer beam element employs a "co-rotational" technique in its mathematical formulation which makes the element suitable for implementation in analyses, such as that of the Endostaple, characterized by large displacement and large rotation; e.g. the element does not generate strains as a consequence of rigid body rotation.

The Belytschko-Schwer element is formulated as a straight beam element while the component under analysis, the Endostaple, possesses a highly curved geometry (i.e. a bifilar double helix) in its stress free state. The curved geometry of the staple in this analysis was, therefore, approximated by a series of piecewise linear segments. This is an acceptable procedure for characterizing a curved geometry provided that the degree of mesh refinement implemented is sufficient to accurately approximate the stiffness of the deforming curved component under load.

The mesh refinement implemented in this study was verified via an independent analysis of the out-of-plane bending of a curved bar. The curved bar in this case was a prismatic semi-circular beam, of solid circular cross-section, which was fully restrained against motion at the fixed end, and loaded perpendicular to the plane of the beam at the free end. This configuration was utilized because exact solutions for this problem are widely available in the open literature.

The material properties (e.g. modulus, Poisson's ratio, density, etc), primary geometry variables (e.g. radius of the curved beam, beam cross-section radius, etc.), finite element (i.e. The Belytschko-Schwer beam element), and mesh refinement implemented in constructing the curved bar model were the same as those implemented in the construction of the bifilar double helix Endostaple model described below. The applied out-of-plane loading at the free end of the curved beam was applied slowly enough to generate quasi-static behavior in the resulting ANSYS/LS-DYNA explicit transient dynamic solution. A comparison of predicted tip displacement between the ANSYS/LS-DYNA and the exact solutions showed the values to be in agreement to within an error of .02%; a result supporting the adequacy of the refinement used in implementing the straight beam elements in modeling the curved geometry of the Endostaple in this study.

In construction of the final explicit beam model, both the manufacturing device and the wall used to represent the combination of the stent and the blood vessel wall were assumed to be rigid. In both cases, this was a conservative assumption that significantly reduced the computational requirements for the
model. That this is a conservative assumption derives from the fact that a perfectly rigid blood vessel wall will stretch the Endostaple™ the most, and provide the largest strains in the Endostaple™ during deformation. In the final model, the contact models were broadened in order to allow all surfaces to contact with each other, including contact between the two filaments and self contact along each filament. The coefficient of friction assumed for all surfaces was 0.1.

There is an additional cone added on to the end of the manufacturing device. This simply directs the Endostaple™ into the device quicker than if the device had a flat end, reducing the run time of the simulation.

The Nitinol was modeled as a linear elastic material. In reality it is a super-elastic material with a stress strain curve as showed in Figure 4. The second curve shows the final linear elastic stress-strain function used here. Short of implementing a user material formulation, the other options for candidate material models would have been some sort of elastic-plastic or hyperelastic models. Since this simulation includes both loading and unloading, an elastic-plastic model would have left residual stress and permanent deformation during the unloading process from the plasticity incurred during the loading process. In addition even the loading process involves sections that periodically load and unload during the straightening process. One limitation of the implementation of beam elements for modeling the staple geometry is that hyperelastic material models, which are frequently used to represent the behavior of Nitinol, are not admissible constitutive relations for beam elements. Therefore, it was felt that a linear elastic material model would be the most appropriate of those available. The material constants used to model Nitinol are shown in Table 1. The Young's Modulus was chosen so that it would fit a line from the origin of the stress-strain function to a strain value on the strain plateau higher than the largest strain in the model. This would insure that the model would never be stiffer than the real Nitinol filaments. Thus, the strain level predicted should be conservative. During post-analysis it was intended that this strain level would be compared to the actual stress-strain curve to determine the corresponding conservative stress value. A study of the effect of Young's Modulus on the peak strain was performed. The results are discussed below.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Secant Modulus (E)</td>
<td>1.877 x 10⁶ psi</td>
</tr>
<tr>
<td>Poisson Ratio</td>
<td>0.33</td>
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<tr>
<td>Density</td>
<td>0.233 lb/in³</td>
</tr>
<tr>
<td>Tangent Modulus</td>
<td>216,453 psi</td>
</tr>
</tbody>
</table>

Table 1 – Material Properties for Nitinol

The load history applied to the explicit model of the staple tries to follow the process of inserting the Endostaple™ in a realistic manner. The first step was to straighten out the staple by stretching out one of the ends. However, since the Endostaple™ contains 2 ½ revolutions, the two ends are 180 degrees in angle out of phase (see Figure 1). Therefore, to prevent the introduction of a kink into the stretched helical shape, the staple was gripped and stretched by means of a displacement load of 0.6 inches at a point on each filament 2 full revolutions from the start of the staple. This load was ramped on over the first 0.05 seconds of the load history. The opposite end of the staple (referred hereafter as the back end) had all of its degrees of freedom constrained to zero displacement.

The second portion of the load history was designed to pull the staple into the manufacturing device. Since the relative velocity and displacement of the staple and the device are the same regardless of which part is moved, the authors opted to move the load device over the staple. This phase of the load history takes place over the period from 0.05 seconds to 0.1 seconds. It should be noted that the cone shaped structure appended to the front end of the device was designed to provide some measure of stability to the solution during this phase of the load program. At the end of this phase, the coil is deformed essentially into a single helix, as if it were inserted on to the optical cable. Since installing the optical cable into the device
would not change the results, the optical cable is not included in the analysis undertaken here. This load cycle also has a force applied to the extremity opposite to the back end (hereafter referred to as the front end). This is essentially similar to a person adjusting the staple as it goes into the tool; a procedure which happens during the actual process. The forces applied at the front end are 0.1 lb in the axial direction, and 0.1 lb in the direction from the front end to the eventual straight axis. The loads applied during this second phase are applied over the period 0.06-0.08 seconds of the load history.

During the third phase loading, the point 2 revolutions from the back end is released, and the vibrations are allowed to damp out through the global damping effects, and through friction mechanism interaction with the manufacturing device. Also during this phase, the rigid body component representing the stent and the blood vessel wall is moved into place. Relatively, this is the equivalent process of moving the staple into the wall on the optical cable. The third phase loading takes place from 0.10-0.13 seconds in the time history.

During the fourth load phase, the device (representing the optical cable) is pulled off the coil and the front end of the coil is allowed to begin to twist back up into a deformed double helix against the outside of the blood vessel wall. This phase extends from 0.13-0.18 seconds in the load history time scale.

The last phase consists of releasing the rear constraints on the staple. This represents releasing the end of the optical cable from the rear end of the staple. During this phase, the staple completes its attempt to return to a double helix shape around the hole in the stent wall/blood vessel wall.

**Analysis Results & Discussion**

As this analysis is a transient dynamic solution, it is necessary to look at the solution over time. A plot of the peak tensile strain in the staple over time is shown as Figure 8. A plot of the corresponding stress is shown in Figure 9. These figures show that the peak stress and strain occur during the process of inserting the staple on the optical cable. The stress reduces once it is released onto the stent/blood vessel wall. The strains are obtained at the integration points of the beam element, which are located at positions that are 0.707 of the distance from the center-line of the filament to the outer fiber of the filament.

![Figure 8 - Peak Tensile Strain Over Time](image-url)
Figure 9 - Peak Tensile Stress Over Time

Individual plots of the displaced shape of the system over time are provided in Figures 10 through 16. These displaced shapes are very similar to the shape of actual Endostaples™ observed during testing. It should be noted that all of these views have a side of the model of the manufacturing device removed for viewing purposes. The simulation undertaken in this study included a fully round manufacturing device. Also included below are strain plots of the filaments shown in Figures 17-24. The filament elements are shown as lines in these plots.
Figure 10 - Endostaple Displaced Shape - End of Phase 1

Figure 11 - Endostaple Displaced Shape - End of Phase 2
Figure 12 - Endostaple Displaced Shape - End of Phase 3

Figure 13 - Endostaple Displaced Shape - End of Phase 4
Figure 14 - Endostaple Displaced Shape - End of Phase 5

Figure 15 - Endostaple Displaced Shape - End of Phase 5
Figure 16 - Endostaple Displaced Shape - End of Phase 5

Figure 17 - Axial Strain at 0.95s at Integration Point 1
Figure 18 - Axial Strain at 0.95s at Integration Point 2

Figure 19 - Axial Strain at 0.95s at Integration Point 3
Figure 22 - Axial Strain at 2.3s at Integration Point 2

Figure 23 - Axial Strain at 2.3s at Integration Point 3
Finally the results of the sensitivity study of the effect of Young’s Modulus on the peak strain in the staple are shown in Figure 25.
Conclusion

There are two types of conclusions that can be drawn from this study. The first set of conclusions deal with the structural sufficiency of the Endstaple itself. The second set deal with lessons learned in performing quasi-static analysis utilizing explicit dynamics finite element software such as ANSYS/LS-DYNA.

The results of the simulation show displaced shapes that match tested prototypes fairly well. The strain results of the simulation predict that the maximum axial stress and strain occur during installation of the Endostaple™ onto the manufacturing tool and the optical cable and reduce dramatically once the Endostaple™ is in place on the stent/blood vessel wall. The peak strain during installation on the optical cable shown in the simulation lies on the plateau in Nitinol’s superelastic stress-strain function. The stress-strain state of the Endostaple™ at the end of installation is in the material’s initial linear portion of the stress-strain function.

Without material fatigue properties for Nitinol, it is impossible to predict fatigue life. However, with the dramatic difference in strain levels between the condition on the optical cable and once installed, it seems that the greatest risk of material failure would occur during the process of installing the staple onto the optical cable. It should be recalled that the staple remains after the optical cable has been removed and, as a consequence, stress states associated with removal of a staple do not have to be considered when seeking a maximum stress condition for design purposes.

The major lesson learned about performing quasi-static simulations using explicit dynamics software is that the kind of simplifying assumptions that are made while making a conventional non-linear simulation including large displacement and contact are not only unnecessary while using explicit dynamics but actually counter productive in result. The addition of damping and friction effects into the model adds little additional computational effort, but seemed to provide a stabilizing effect on the dynamic solutions obtained for the Endostaple™ load program. It was only when these sort of assumptions were no longer made, that the simulation undertaken began to reflect the proper behavior observed in the real system.

Acknowledgements

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