Deployment of a Self-expanding Stent in an Artery

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Abstract

Simulations of both the manufacturing process and the deployment of self-expanding stents using finite element analysis are becoming increasingly common. Such analyses are used to determine the structural integrity of the stents and to study the nature of the interaction between the stent and the vascular tissue. The loading conditions experienced by the stent during the manufacturing process and its subsequent deployment often employ the simplification of rigid surfaces. The rigid surfaces take on the role of the vascular tissue but reduce the complex nature of the models, which already take into account both the complex material behavior of the self-expanding stent and the large configuration changes that it undergoes during the deployment process. This paper demonstrates that, in addition to the stent, it is also possible to model the artery as a deformable body, with appropriate material behavior and geometry. Both the manufacturing process, which includes expansion, annealing and crimping of the self-expanding stent, and the subsequent deployment of the stent into vascular tissue were modeled using a
combination of ABAQUS/Standard and ABAQUS/Explicit. The results obtained provide insight into the stresses that the vascular tissue places on the stent during the deployment process.

1. Introduction

Self-expanding stents are being used extensively to treat occlusions in endovascular arterial lumens. These stents have proven to reduce the extent of arterial recoil and restenosis as compared to balloon angioplasty procedures and provide a less invasive alternative in the treatment of endovascular disease. However, poor performance of the intravascular device can result in undesirable clinical events such as thrombosis and intimal hyperplasia. In order to minimize these adverse events, it is important to obtain a thorough understanding of the factors that contribute to a adverse outcome during the stent deployment process. Such device-related factors could include the stent geometry (i.e. design, length, diameter, strut dimensions), the stent material and stent deployment procedure. Although extensive work has been done to evaluate the structural behavior of self-expanding stents [1-6], little attention has been focused on characterizing the structural interaction of these stents with the arterial wall.

Some of the studies evaluating the structural performance of self-expanding Nitinol stents reported in literature have utilized ABAQUS. Rebelo et al. (2001) have developed a user-defined material subroutine UMAT for Nitinol. They have used the routine to determine the Austenite/Martensite composition and the deformation fields developed in the stent upon deployment. Gong and Pelton (2002) have used ABAQUS and the UMAT for Nitinol developed by ABAQUS West Inc. to evaluate the strains generated in a unit cell of a stent and to determine the fatigue performance of the stent.

In this paper ABAQUS has been used to simulate the deployment of a self-expanding Nitinol stent inside an artery. The results of the analysis have been used to assess the impact of a stent on the artery and to assess the influence of the artery on the deformation field within the stent. Such analyses will provide valuable information about
the stent parameters (i.e. the stent design and strut dimensions) that can be optimized in order to maximize the effectiveness of the stent during the deployment process.

2. Methodology

2.1 Overview
Expansion, annealing, and crimping of the stent is performed using ABAQUS/Standard. During these stages, the diameter of the stent is controlled by means of contact with a rigid cylinder. The rigid cylinder has a varying diameter that corresponds to the various deformation stages of the stent. The user subroutine RSURFU is used to define this rigid cylinder.

Expansion of the deformed stent inside the artery is performed using ABAQUS/Explicit. The model of the artery is defined in the Explicit step, while the model of the deformed stent is imported from its state at the end of the last forming step in the earlier ABAQUS/Standard analysis followed by the definition of boundary conditions and contact interactions.

2.2 Rigid surface RSURFU
The rigid surface geometry, location, tangents, and normal directions are determined by a user subroutine, RSURFU (see Analysis User’s Manual, Section 25.2.15 “RSURFU: User subroutine to define a rigid surface”). The subroutine uses the current step time to vary the diameter of the rigid surface linearly between the diameter at the beginning of the step and the diameter at the end of the step.

2.3 Release of stent in artery
After import into ABAQUS/Explicit, the stent is allowed to expand by its own stored strain energy inside the artery. Typically, the external diameter of the stent at the end of the crimping step is smaller than the internal diameter of the artery. To save computation time and dynamic effects, an additional step is added to the implicit run to
expand the stent until its external diameter matches the initial internal diameter of the artery.

2.4 Estimation of Explicit computation time

The explicit computation time is proportional to the analysis time needed for the stent to fully expand in the artery. To approximate the analysis time needed by the stent to expand, we perform a frequency analysis on the stent. The first vibration mode of the stent is a major contributor to the stent expansion time. By ignoring the effect of the artery on the stent expansion, the stent expansion time is in the order of one half the first vibration mode period. This approximation must also take into account the mass scaling that will be used during the explicit analysis. The expansion time obtained from the frequency analysis must be multiplied by the root square of the stent mass scaling in the explicit analysis. To obtain the mass scaling of the stent, one can run a dummy explicit analysis with the stent model alone using the same mass scaling setup (*variable mass scaling). The stent mass scaling is printed in the status file.

2.5 Damping of explicit expansion

Surface viscous pressure damping is used to prevent oscillations after the stent is fully expanded. A general recommendation is to use a viscous pressure damping corresponding to 1% of the damping necessary to prevent the reflection of dilatational waves (see Analysis User's Manual, Section 19.4.2 “Specifying viscous pressure load in ABAQUS/Explicit”). In our analysis this damping was not significant. We gradually increase this damping until damping is effective in damping oscillations.

3. Model

First order reduced integration brick elements (C3D8R), which are compatible with both ABAQUS/Standard and ABAQUS/Explicit, were used in the creating the models for the stent and artery (see Fig. 1). Element based surfaces were defined on the inner and outer surfaces of the stent. During ABAQUS/Standard portion of the analysis, these
surfaces are in contact with the rigid surface specified by the RSURFU routine. Softened contact was used for this portion of the analysis. In order to capture the contact stresses and stress gradients generated on and near inner surface of the artery, the model for the artery had a finer mesh in the inner region as shown in Fig. 1. Also, it made the analysis computationally more efficient since the outer region of the artery does not experience high stress and stress gradients. In the ABAQUS/Explicit portion of the analysis, in order to specify the contact between the outer surface of the stent and inner surface of the artery, a node-based surface was defined on the inner surface of the artery. Instead of kinematic contact, penalty contact was used to specify the contact between the stent and the artery. This prevented chattering behavior that might occur due to the differences in mass densities between the stent and the artery materials during contact stent-artery contact. To simulate the worst-case scenario for maximum stress and strain, longitudinal constraints were applied at the axial boundaries for both the stent and the artery. The superelastic material properties used for Nitinol and the hyperelastic material properties used for the artery were measured in-house at Guidant.

4. Results

As described above, the stent was expanded, annealed and collapsed prior to being deployed in the artery. Figure 2 shows (a) the original geometry of the stent, (b) its expanded configuration, (c) the annealed shape, and (d) the final collapsed configuration.

It has been noted by other researchers that superelastic materials exhibiting strains reaching up to 8% can be recovered under superelastic conditions [1]. The maximum strain produced in the current stent design is on the order of 6% after the collapsing process. It was also noted that more strain is recovered after the expansion of the stent within an endovascular tissue model compared to an expansion into a rigid artery with an equivalent lumen diameter. Hence, inclusion of a tissue model provides a more realistic estimation of strain recovery.
A second parameter of interest in the design of an endovascular stent is the amount of lumen expansion that is achieved with a given stent design. This is a capability that is lost when the stent is expanded against a rigid surface. The current self-expanding stent design has a predicted lumenal expansion of approximately 7.5%.

Figure 3 shows contours of the Von Mises stress generated in the arterial wall upon stent deployment. While there is a base level of stress generated by the bulk expansion of the artery, the stresses that arise near the contact interface dominate the interaction. Within the contact regions, local stress concentrations arise where the stent exhibits the largest radial deformations.

5. Conclusion

A finite element methodology has been developed to study the nature of the stent-artery interaction. This methodology can be used to determine the impact of various stent design attributes on the vessel wall, as well as the impact that the tissue has on the behavior of the stent. This new predictive data provides an additional mechanism by which the performance of an endovascular stent is maximized.

6. References


Figure 1  Finite element mesh for the (a) stent and (b) artery
Figure 2  Stent configuration in the (a) original, (b) expanded, (c) annealed and (d) crimped states.
Figure 3  Stresses generated in the arterial wall upon stent deployment.