Finite Element Analysis of Tensile Fatigue Behavior of Coronary Stent

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Coronary stent has been popular method for the treat of coronary artery stenosis while stent fracture has been observed sometimes after implantation. Tensile fatigue behavior of stent plays an important role and the effective analysis method of stent properties is needed. In addition, from the data of patients we know that the stent always appears to have an elliptical shape in the vessels and it may affect the performance of stent. In this study, the tensile fatigue performance of one stent was analyzed by the finite element simulation method. An effective simulation process was performed to analyze the tensile fatigue behavior under different maximum strain and the effect of diameter of stent was considered. An equivalent stress (SEQA) was applied in evaluation and the results showed different results by comparing with Mises stress. A Goodman fatigue analysis was performed using the equivalent stress and fracture was predicted. Also, the effect of elliptical shape was analyzed and it showed no significant difference of SEQA between the circle and elliptical model on tensile fatigue performance.

Keywords: coronary stent, tensile fatigue behavior, finite element method, equivalent stress

1. Introduction

Coronary disease has been one of the leading causes of death all over the world. Coronary stent treatment is an effective vascular reconstructive procedure to the coronary artery stenosis. In the United States, approximately 1.5 million stents are used every year, and Japan has become the second largest market of stent, just following the United States.1) Despite the popularity of stenting, some problems such as stent fracture were observed after implantation and aroused the interest of researchers. Although the new generation of devices such as drug eluting stents has brought great advantages, the problem associated with stent fracture still remains. The mechanical properties play a crucial role in the restenosis. For this reason, the analysis of mechanical properties of stents calls for attention.

Finite element method (FEM) is a useful tool to investigate the stent mechanical performance. As many factors may influence the fracture of stent, various studies have focused on the interaction during expansion. Many studies used FEM to characterize the effect of balloon on the stent system.2) Stress distribution at the contacts between the stent and the artery has also been analyzed.3) However, the analysis of stent fatigue behavior after expansion is more important, while it has not been fully investigated because of the complicated conditions.

In fact, stent bears a cyclical displacement in the axial direction during the cardiac cycles after implantation. For this reason, tensile fatigue behavior of stent plays an important role and the effective analyzing method of stent properties is needed. At the same time, we know that the expanded diameter of stent is also an important factor in real treatment. In addition, the stent always appears an elliptical shape in the vessels. Recently only a few studies did FEM analysis about asymmetry.4) However, they do not analyze the mechanical properties systematically and just performed simple fatigue analysis.

The aim of this work is to investigate the fatigue performance of stent in axial direction. A series of simulation processes was made to analyze the stress condition during the whole process of tensile fatigue loading and the effect of diameter of stent was considered. A Goodman fatigue analysis was performed using the equivalent stress amplitude. At the same time, an elliptical shape model was simulated and the effect of ellipse on the tensile fatigue behavior was analyzed.

2. Materials and Methods

2.1 Model

As shown in Fig. 1(a), we developed a 3D model of coronary S-Stent™ (Biosensors International) by commercial software package Abaqus 6.10 (Simulia). The main stent dimensions were obtained from SEM graphs. Considering the symmetrical condition during tensile in both axial and circumferential directions, a 1/4 model was used for the analysis. A mesh of hex dominated type was generated with 48416 3D 8-node linear hexahedral solid elements and 1280 3D 6-node linear wedge solid elements. The model was meshed with an average size of 16 µm to ensure a reasonable approximation.

The stent was made of 316L stainless steel. The steel was modeled as a homogeneous, isotropic, elasto-plastic material with a Young modulus of 193 GPa, a Poisson ratio of 0.3 and a true strain–true stress relation in plastic region.5,6)
An ellipse was used to simulate the geometrical shape that stent performed after implantation (Fig. 1(c)). The model was first expanded to 2.33 mm and then a linear distributed displacement was applied on the internal surface to form the elliptical shape. During this process, the internal surface was fixed in the axial direction.

2.2 Boundary conditions and simulations

The initial diameter of the finite element model was 2.8 mm, and it experienced during crimping (manufacturing), expansion and tensile fatigue process. The crimping was simulated to introduce the proper residual stress caused during stent manufacturing.

2.2.1 Step 1 Crimping

The crimping of the stent from the initial diameter of 2.8 to 1.2 mm was made by displacement control of the external surface of the model.

2.2.2 Step 2 Expansion

The stent was expanded to different diameters (3.0, 4.0 and 5.0 mm) by the displacement control on the internal surface of the model. Also the following recoil was performed.

2.2.3 Step 3 Tensile fatigue

The tensile fatigue process was carried out by the displacement control on the distal surface of the model. At the same time, the proximal surface was totally fixed. Firstly, in order to simulate the maximum tensile strain of 0.2, 0.15 and 0.1, different displacement was applied and the model was stretched. Secondly, according to the fatigue condition the displacement returned to 10% of the maximum displacement, and this process was repeated for one more cycle.

During all these processes above, symmetrical boundary conditions were applied to the circumferential surfaces shown in Fig. 1(b). And the proximal surface was fixed in longitudinal direction to prevent rigid movement.

2.3 Fatigue analysis

In order to evaluate the stent long-term fatigue performance under the loading condition of tensile fatigue movement with stretching and compressing, the following equivalent stress amplitude (SEQA) was used:

\[ \text{SEQA} = \left[ \left( \Delta \sigma_{xx} - \Delta \sigma_{yy} \right)^2 + \left( \Delta \sigma_{yy} - \Delta \sigma_{zz} \right)^2 + \left( \Delta \sigma_{zz} - \Delta \sigma_{xx} \right)^2 + 6 \left( \Delta \tau_{xy} \right)^2 + \Delta \tau_{yz}^2 + \Delta \tau_{xz}^2 \right]^{1/2}/ \sqrt{2} \]  

(1)

The stress components at the largest strain position (\( \varepsilon_{\text{max}} \)) and the smallest strain position (\( \varepsilon_{\text{min}} \)) of the tensile step were used to calculate \( \sigma_{\text{max}} \) and \( \sigma_{\text{min}} \), where \( \varepsilon_{\text{min}}/\varepsilon_{\text{max}} = 0.1 \). And the change of each stress component in the model was calculated as \( \Delta \sigma_{xx} = \left| \sigma_{xx,\text{max}} - \sigma_{xx,\text{min}} \right|/2 \) and so on. Using the SEQA mentioned above, the stress distribution was analyzed by considering the effect of different maximum strain and stent diameters.

A Goodman fatigue analysis was performed using the SEQA in tensile fatigue process. The Goodman relation states that fatigue failure will occur if the stress satisfies the relation:

\[ \frac{\sigma_a}{\sigma_{\text{fat}}} + \frac{\sigma_m}{\sigma_{\text{ts}}} \geq 1 \]  

(2)

where \( \sigma_a \), \( \sigma_m \), \( \sigma_{\text{fat}} \) and \( \sigma_{\text{ts}} \) represent stress amplitude, mean stress, fatigue limit for completely reversed loading and ultimate tensile stress, respectively. The expression of SEQA was used to calculate \( \sigma_a \) and \( \sigma_{\text{fat}} \), where \( \Delta \sigma_a = |\sigma_{\text{max}} - \sigma_{\text{min}}|/2 \) and \( \Delta \sigma_{\text{fat}} = (\sigma_{\text{max}} + \sigma_{\text{min}})/2 \). The fatigue limit for completely reversed loading was 381 MPa, and ultimate tensile stress was 560 MPa.

The fatigue safety factor (FSF) was calculated.

\[ 1/\text{FSF} = \frac{\sigma_a}{\sigma_{\text{fat}}} + \frac{\sigma_m}{\sigma_{\text{ts}}} \]  

(3)

3. Results and Discussion

3.1 Stress and fatigue analysis

The stress path in the axial direction during the tensile fatigue process is shown in Fig. 2. The initial stress is 407 MPa and it is caused by the pretreatment process. After the initial startup step the stress moves between the maximum (608 MPa) and minimum (539 MPa) stress. We continue the tensile simulation process with stretching and compressing one more cycle, and the results show that stress condition repeats the path of the loop cycle between the maximum (608 MPa) and minimum (539 MPa) stress. This means our simulation method is acceptable to reflect the stress condition of the long-term tensile fatigue behavior.

The tensile fatigue process with maximum strain of 0.2 applied to the stent model resulted in the Goodman diagram of Fig. 3. On the Goodman diagram, points which are below and to the left of the Goodman line mean safe, while points that are above and to the right of the Goodman line mean unsafe. Considering the safety condition of one point on the diagram, the distance between this point and the Goodman line is a measure of the factor of safety. If locate in the safe area, points that are far away from the Goodman line mean very safe. While considering points which locate in the unsafe area, the distance from the Goodman line is larger, it means more dangerous design. Under the condition of maximum strain of 0.2 many points fall over the Goodman line, and some lie far away from the Goodman line, which means fracture would happen at many positions and some points are under very dangerous situation.

The distribution of \( 1/\text{FSF} \) was shown in Fig. 4. Fracture would happen at the places with the value of inverse FSF.
over unity. The maximum 1/FSF is 2.05 and locates at the circular-arc near the link part, which means this position has the highest probability of fracture.

### 3.2 Effect of diameter

Figure 5 shows the relation of SEQA and maximum strain of model with different expanded diameters. At larger diameter, the stent model shows a lower SEQA level. This indicates that the performance of stent in the axial direction increases when the stent is expanded to larger diameter. While the maximum SEQA of model shows a linear increase when the maximum tensile strain increases.

At the same time, result calculated by maximum Mises stress is shown in Fig. 6. It shows completely opposite with the result calculated by SEQA. At larger diameter, stent has worse tensile fatigue performance. Also the maximum Mises stress do not change under different strains when the stent is expanded to different diameter. As discussed in the section above, experiments proved that the evaluation by SEQA is more efficient.

### 3.3 Effect of shape

The results of maximum SEQA of both circle and elliptical stent model are plotted in Fig. 7. Evaluating by maximum SEQA, there is no significant difference between circle and elliptical model in the tensile process. The SEQA of elliptical model increases slightly while the Mises stress of stent increases almost 50%. In order to examine the results, we plan to do the tensile fatigue tests in the next research step. At the same time, the results show that the maximum SEQA and maximum strain are also in a positive linear relation in elliptical model.
The maximum Mises stress of both elliptical and circle model under different strains are depicted in Fig. 8. Comparing the two models, the maximum Mises Stress increases dramatically in elliptical model, and this is caused by the high stress induced during the formation of ellipse. While when the maximum strain increases, the maximum Mises stress almost do not change under both models. Mises stress just reflects the stress condition of stent at the maximum strain state. As shown in Fig. 2, between the maximum and minimum strains the stress path shows a loop and the SEQA reflects the stress condition of the tensile process that between the maximum and minimum strains. SEQA may be applied on the extension of static yield criteria to fatigue behavior. Considering the complicated condition of stress during the estimation of tensile fatigue performance, SEQA may be more efficient to evaluate the fatigue performance of stent. Also, the evaluation by SEQA has been reported to be more efficient, and experiments are needed to prove this point in the future research.

4. Conclusion

The whole simulation process successfully described the stress conditions during the tensile fatigue loading. About the fatigue performance, Goodman graph method predicted fracture at many points under the maximum strain of 0.2. The distribution of $1/FSF$ indicated that the place with the highest probability of fracture locates at the circular-arc near the link part. To consider the effect of diameter, the result of SEQA showed that the tensile performance of stent increased when it was expanded to larger diameter. The results of SEQA in both circle and elliptical model showed that ellipse did not affect the tensile performance greatly.

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