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2018

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BACKGROUND

Stent implantation is widely used to treat blocked lumen. Stents were meshed structure made of polymers and metal alloys, including stainless steel, cobalt chrome and nitinol [1]. Clinical studies had demonstrated that stents helped to scaffold the diseased lesion up to one year when tissue adapted to the stented environment [2]. However, the permanently implanted stents inside artery were associated with complications such as stent fracture, tissue inflammation, in-stent restenosis and thrombosis [3]. Currently, biodegradable stents are attracting more attention due to its potential long-term efficacy in treating blocked lumens. The detailed characterizations of biodegradable stents are essential for the desired clinical outcomes.

In this work, the mechanical performance of Absorb GTI™ Bioresorbable stent made of PLLA (Poly-L-Lactide Acid) was studied using finite element method (FEM). Both the stent crimping and deployment were quantified towards the optimization of its scaffolding capacity in a limited time.

METHODS

A three-dimensional model of the stent was constructed in ABAQUS with the total length as 9.9 mm, outer diameter as 4.08 mm, strut thickness as 0.15 mm, and the link between stent rings as 0.8 mm (Figure 1).

The PLLA stent was assumed as isotropic homogeneous materials with an ideal elastic-plastic constitutive model. The Young's modulus was set as 3.3 GPa, Poisson ratio as 0.3, and density as 1.25 g/cm^3. The yield strength of PLLA was 51.5 MPa at body temperature 37 °C [3].

The stent was discretized with hexahedral reduced integrated elements (C3D8R). The element size of 0.03 mm was adopted following the mesh convergence study.

Both stent crimping and expansion process were simulated as the quasi-static process by using ABAQUS Explicit solver. Six rigid shells, formed into one seamless cylinder at the nominal dimension of the stent (Figure 1), were used to crimp the stent into a catheter. During crimping process, a linear ramped radial displacement of −1.25 mm was applied to all rigid shells and then unloaded. Next, reverse radial displacement of 1.3 mm was utilized to expand the stent to sustain the plaque burden. The unloading led to the final dimension of the stent. General contact between crimping shells and stent were used with a friction coefficient 0.2 [4].

RESULTS

The load required for stent deployment were depicted in Figure 2. The force was defined as the contact force divided by the initial stent length.

During stent crimping process, i.e., from point A to point C, the stent outer diameter reduced from the original 4.08 mm to 1.93 mm. The required crimping force was up to 2.5 N (point B) where plastic deformation initiated at the tips of stent rings (Figure 3). The plastic deformation zone kept expanding with relatively less crimping load until fit into the catheter with an inner diameter of 2.20 mm (point C). During the crimping process from point B to C, the required crimping load slightly reduced. As the stent was confined into the catheter, the crimping load was released, and the stent recoiled back to the size of the catheter (points C to D). The elastic radial recoil, defined as the relative change in stent diameters during the unloading following crimping, was 13.9%.

During the stent expansion (points D to F), the balloon pressure expanded the stent up to an outer diameter of 4.19 mm (point F). The elastic recoil led to a final stenting diameter of 4 mm (point G). The elastic recoil, during the unloading following expansion, was 4.53%.

During the expansion, the length of stent reduced from 10.75 mm to 10.17 mm. The longitudinal foreshortening, defined as the relative change of stent length, was 5.35%. As expected, the required force from balloon increased during expansion. The slope reduced around point E due to the decrease of the growth rate of plastic deformation area (Figure 4).

INTERPRETATION

Mechanical behaviors of Absorb GTI™ Bioresorbable PLLA stent was characterized using FEM. Both the crimping and expansion procedures were captured regarding the required external force, longitudinal shortening and elastic recoil. All these parameters were desired to be as small as possible.

A large elastic recoil demand over-expansion to accommodate the targeted lumen size. This will, in turn, induce larger stress and strain in the arterial walls, leading to a greater risk of mechanical injury and tissue inflammation [5]. Our results have shown that the elastic recoil for crimping was 13.9% and the one for expansion was 4.53%. This aligns with the observations by Wang et al. [5], who reported a radial recoil for PLLA stent crimping and expansion as 10.87% and 4.19%, respectively.

For metallic stents, the radial recoil of expansion process was reported as 6.7% and 8.6% for cobalt chromium (L605) stent and magnesium alloy (WE43) one, respectively [6]. It is clear that the PLLA stent has less recoil, indicating less risk of complications. It is also interesting to observe that the yield strength of PLLA (51.5 MPa) is much smaller than either L605 (629 MPa) and WE43 (216 MPa) materials. The lower yield strength of PLLA accelerates its progress into plastic deformation along with larger percentage area of plastic deformation. These, in turn, resulted in less radial recoil of PLLA, which could lead to a less over-expansion compared to metallic ones.

A larger longitudinal foreshortening was also correlated with higher risk of longitudinal shear stress and strain in the arterial walls, and the corresponding tissue damage. The longitudinal foreshortening for our PLLA stent was estimated as 5.35%, which was found to be sensitive to the deformation of stent rings. It was much larger than the 1% shortening of stainless steel stent [7]. Again, this was attributed to the design of stent rings.

The plastic energy was under investigation for justifying the relation between the stent loading and diameter. Along the same line, we are going to deploy the PLLA stent inside the stenosed artery to address clinical questions such as how the deployment of PLLA stent differs with a metallic stent.

Acknowledgments

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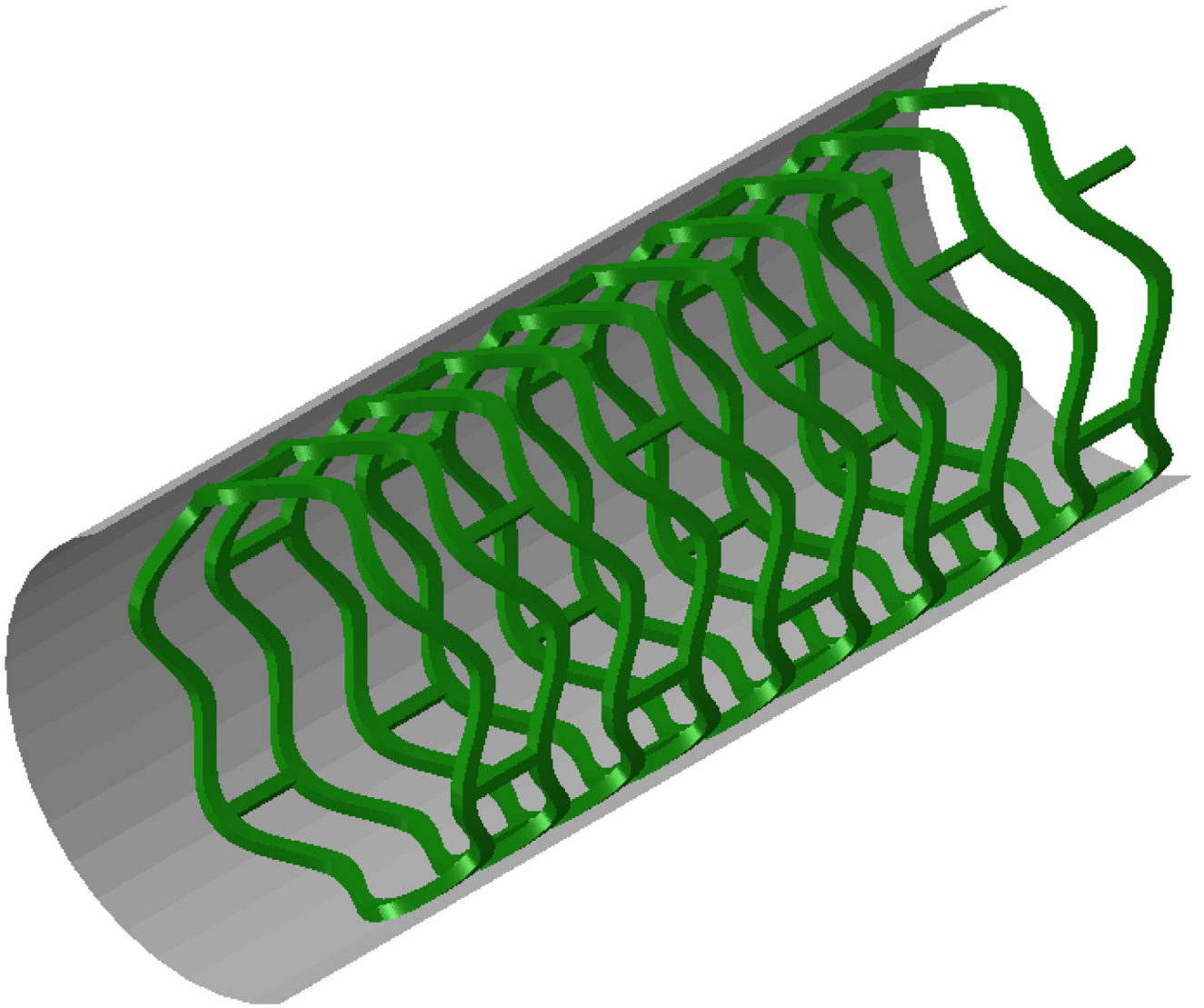
Figure 1.
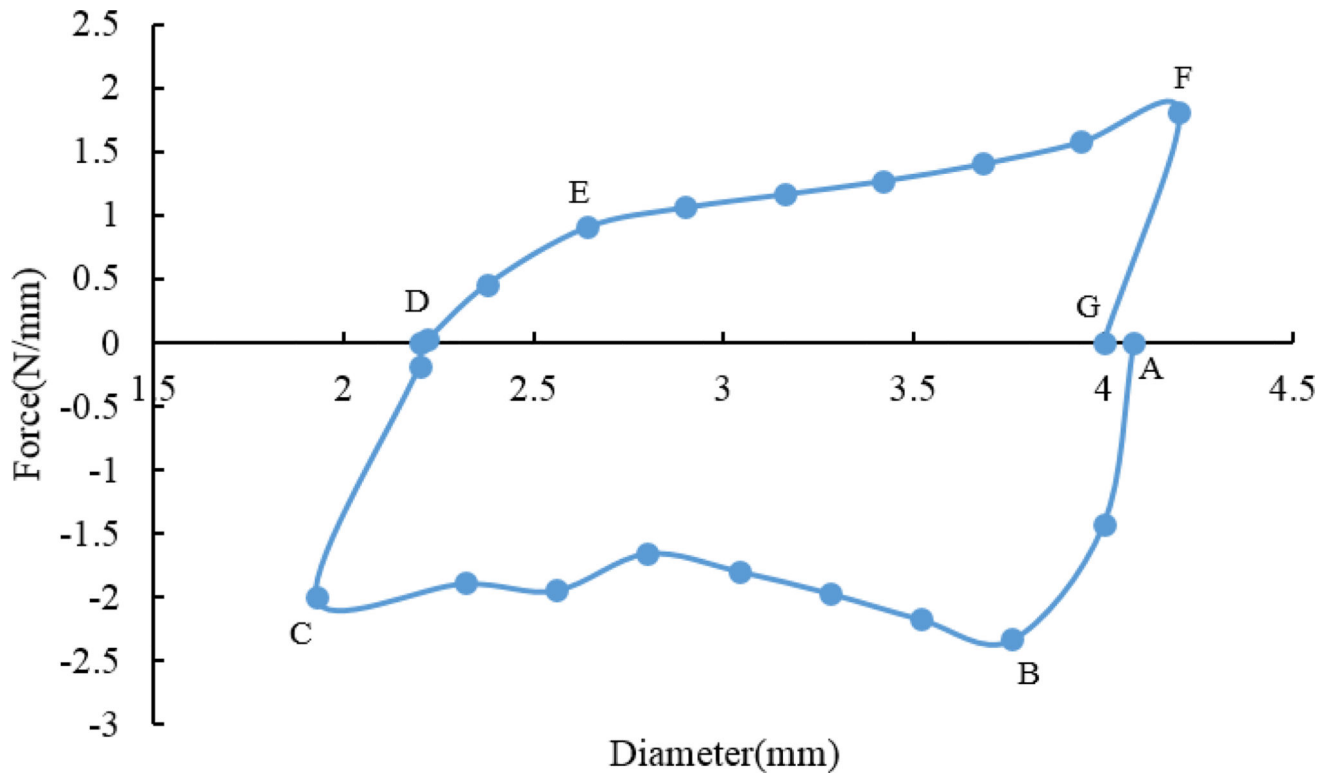Stent model with the rigid crimper

Figure 2.
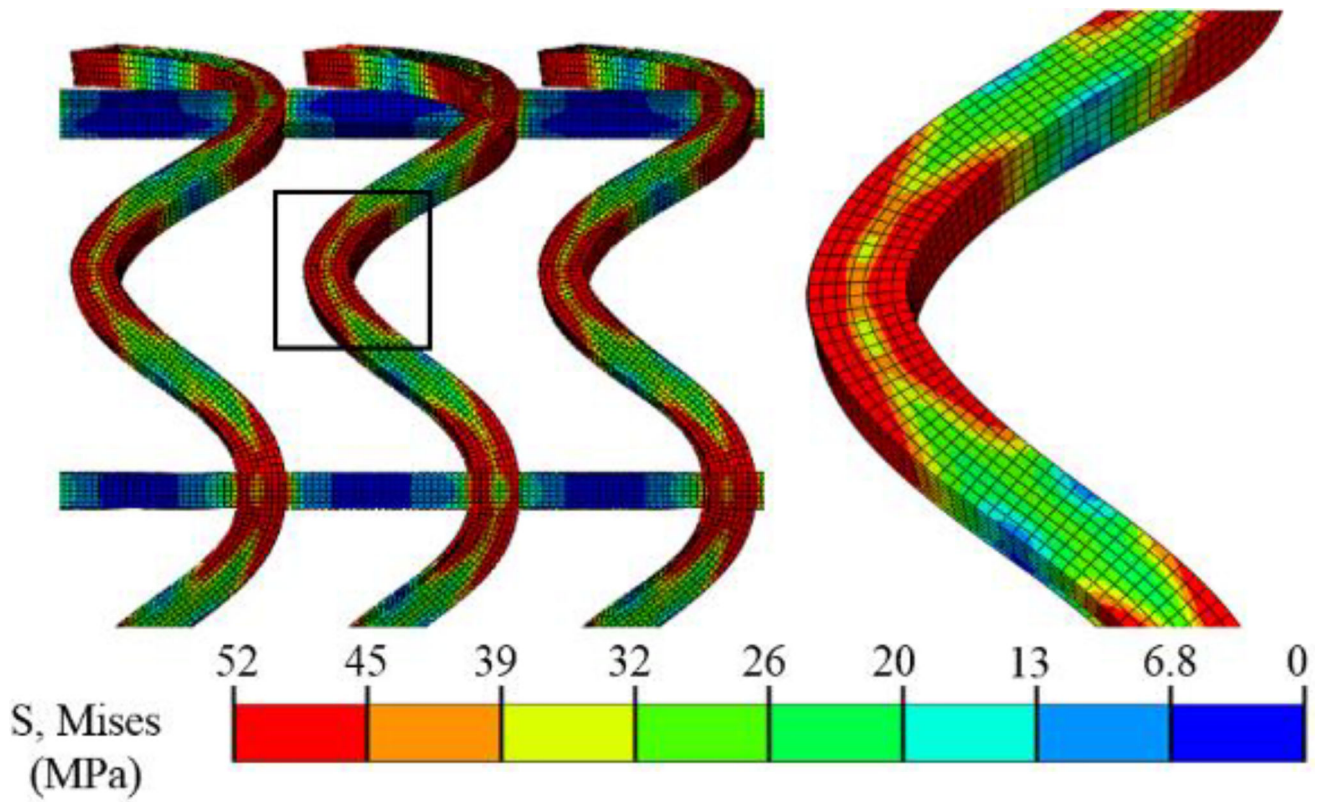Load required for stent crimping and expansion

Figure 3.
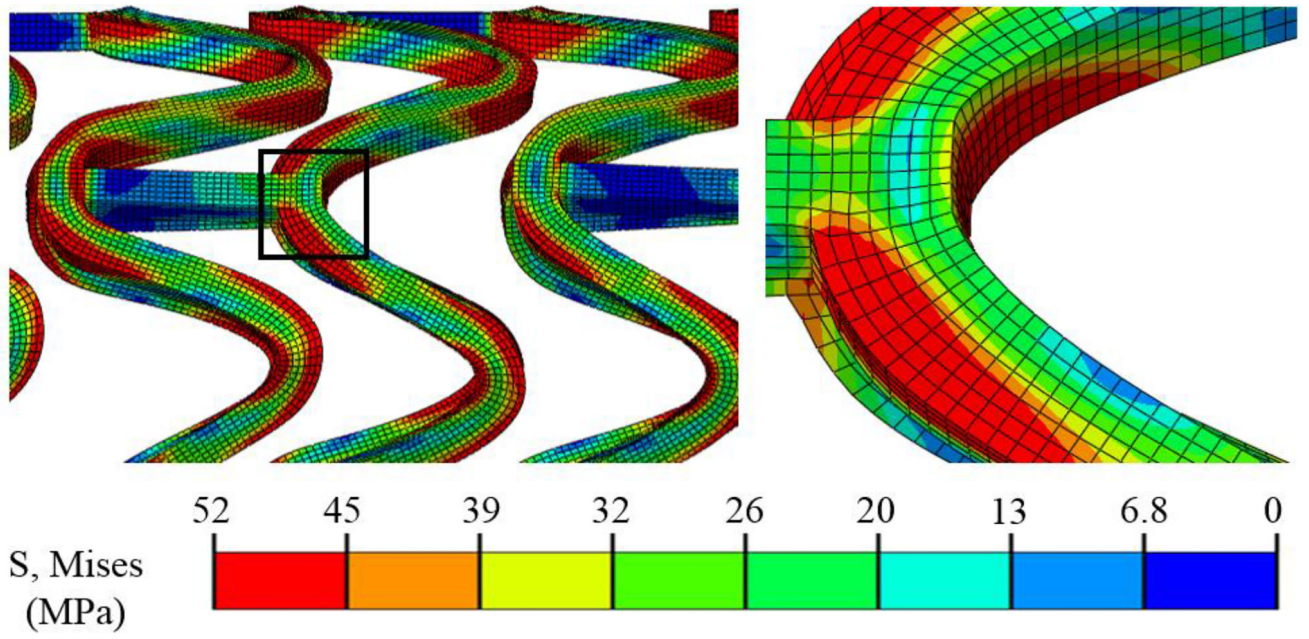Stress distribution during stent crimping (Point B)

Figure 4.
Stress distribution during stent expansion (Point E)