Effects of Tensile Stress on Degradation of Poly Lactic Stents

Meng Guo [a], Li Wang [b], Wentao Feng [c]

School of Biological Science and Medical Engineering, Beihang University, Beijing 100191, China

[a]madfrog88@qq.com, [b]459038090@qq.com, [c]fengwnt@qq.com

Abstract

Poly lactic acid (PLA) is widely used for the manufacture of biodegradable stents (BDSs). It was observed and investigated that tensile loads can significantly affect the degradation rate of PLA in our previous study. Additionally, non-uniform degradation can arise from complicated stress distributions in implanted stents under long-term and pulsatile tensile loading. The objective of this work is to develop a model of PLA degradation that is able to predict the degradation rate, thus providing a valuable tool for the design of biodegradable stents. In this study, an innovative method for simulating BDS degradation was developed. The degradation was assumed to be a linear function of the tensile load, based on previous experiments. The model was developed in an FE framework using ABAQUS/Explicit. The evolution law affects the updated stress state in the explicit time integration scheme. The damage evolution is calculated by means of a user subroutine (VUMAT). The developed model can reproduce the behavior of BDSs subjected to long-term tensile loading; stent fracture occurs more rapidly in a high-stress field. This simulation gives new insights into in vivo BDS performance and how stent geometry may affect long-term performance. It was indicated that strengthening the high-stress parts of a BDS is important for achieving uniform degradation over time and for decreasing the risk of fracture.

Keywords

PLA; Biodegradable stent; FEA.

1. Introduction

The poly lactic acid is commonly used in the application of biodegradable stent. The BDS could release the sustained drug while degrading into nontoxic compounds [1]. It offered the potential to improve long-term patency rates by providing support just long enough for the artery to heal [2]. However, the stress distribution of BDS after implantation has been shown to be quite non-uniform, which may cause the undesirable degradation and compromise the long-term function of the stent [3]. Thus, investigating the degradation behavior of the BDS after implantation is necessary for the improvement of the stent performance.

Considering the very tiny structure of the BDS and the high cost of prototype manufacture, finite element analysis (FEA) has been taken as an efficient tool to analyze the degradation behavior of the BDS [4]. The performance of BDSs will be greatly enhanced if one can predict how a given structure stent degrades over time in response to the cyclic loading [5]. As demonstrated previously, the external environment where the polymer degradation occur influence the degradation process greatly [6]. Consequently, establishing a constitutive model to describe the degradation mechanism of PLA is extremely complicated. Experiments were carried out to develop an available constitutive model. It was initially developed within the scope of the linearized theory of elasticity [7] and then extend to nonlinear properties [8]. Thereafter, These models were used to simulate the degradation of the PLA polymer stents by finite element methods and experiments [9].

These models considered the effects of degradation on the mechanical properties of the polymers and also promoted the application of FEA in the degradation behavior of BDS. However, the degradation rate and stress were interactive. The effects of different kinds of stress on the polymer degradation rate were different [10]. Tensile stress could accelerate the degradation of poly (glycolide-co-L-lactide) (PDLLA) [11] and dynamic load lead to a more quick loss of mechanical properties [12]. Moreover, the mechanical environment of the implanted stent was quite complicated, which make it difficult to control the degradation rate and predict the mechanical behavior of the stent. Thus, the interaction of stress and degradation after implantation is crucial and necessary to be considered in the polymer degradation model.

Therefore, the aim of this research is to reproduce the degradation process of a PLA stent of a given structure under the effects of tensile stress, by which we can also predict the fracture caused by the non-uniform degradation. An efficient stress-degradation FE model based on our previous study was established. The degradation of BDS under a simplification way of load caused by the coronary artery vessel was simulated numerically.

2. Materials and Methods

2.1 Degradation model

In order to characterize the degradation behavior of an implanted BDS, a birth-death element method was applied into the FEA model. According to the previous study [13], a higher tensile stress resulted in more quickly degrade of PLA polymer. The relationship between tensile stress and degradation rate was assumed linear. The degradation rule was given by (1). For element k, when $D_k \geq D_{kc}$, the element will degrade from the stent model. Where the D_k is a status varible to describe the mass loss and D_{kc} is related to the volume fraction. $f(\sigma, t)$ is the mass loss rate which related to the tensile stress and degradation time. The larger the volume element, the longer time will be required for the element to be degraded.

$$f(\sigma, t) = (\sigma + 1) \times \frac{t}{8} \tag{1}$$

$$\begin{cases} D_k < D_{kc}, & \text{element active} \\ D_k \geq D_{kc}, & \text{element degraded} \end{cases} \tag{2}$$

$$D_k = \int_0^T \frac{\partial f(\sigma, t)}{\partial t} \cdot dt \tag{3}$$

$$D_{kc} = \frac{V_k}{V_{max}} \times 100\% \tag{4}$$

Where

T is the degradation time,

σ is the tensile stress of element k,

V_k is the element volume of element k,

V_{max} is the volume of the largest element,

2.2 Geometry & Finite element model

The size and strcture of the stent model is shown in Figure 1. The rings are conected by a “S” type link. The model is meshed with 28912 C3D8R elements. A radial displacement load is applied to the stent, the amplitude is 0.1mm.The degradation time was 8 weeks. Based on the in vitro experiment, a PLA was chosen as the stent material in the present study. The FE model was established with an experimentally determined Young’s modulus of E=830 MPa and a Poisson’s ratio of v=0.22. The density of the polymer is 1.2×103 kg/m3.

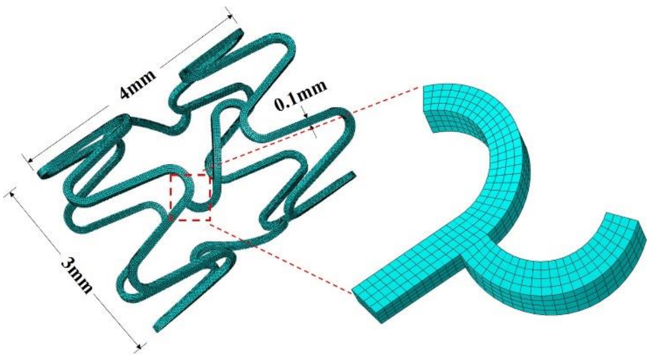

Fig. 1 The geometry and mesh details of the PLA stent

3. Result and Discussion

The degradation of biodegradable polymers is very sensitive to the stress environment. Once the polymer is implanted into the human body, the distribution of stress has shown to exhibit local differences, which may change the degradation rate, leading to non-uniform degradation, thus stent fracture. In this study, the degradation behavior of a PLA stent was reproduced numerically. The effect of tensile stress on the degradation rate was first considered. The degradation process, stress distribution, mass loss and breakage of the PLA stent were analyzed

As a preliminary simulation of the stent degradation, the results showed that the tensile stress can lead to non-uniform degradation and the failure of the stent structure. Figure 2 shows the distribution of equivalent stress and damage evolution of the stent. The links area of the stent degrades first since the beginning of the fourth week due to the high tensile stress level. In the next four weeks, the links degrades rapidly and the fracture was first occurred at 8th week in the middle part of the links. These fracture regions were coincide with the study by Soares et al. showing that the material at the links between the stent rings had a more quickly decay of the mechanical properties[14]. The results indicated that the links area should be strengthened in the optimization of the PLA stent or the structure should be changed in the next design.

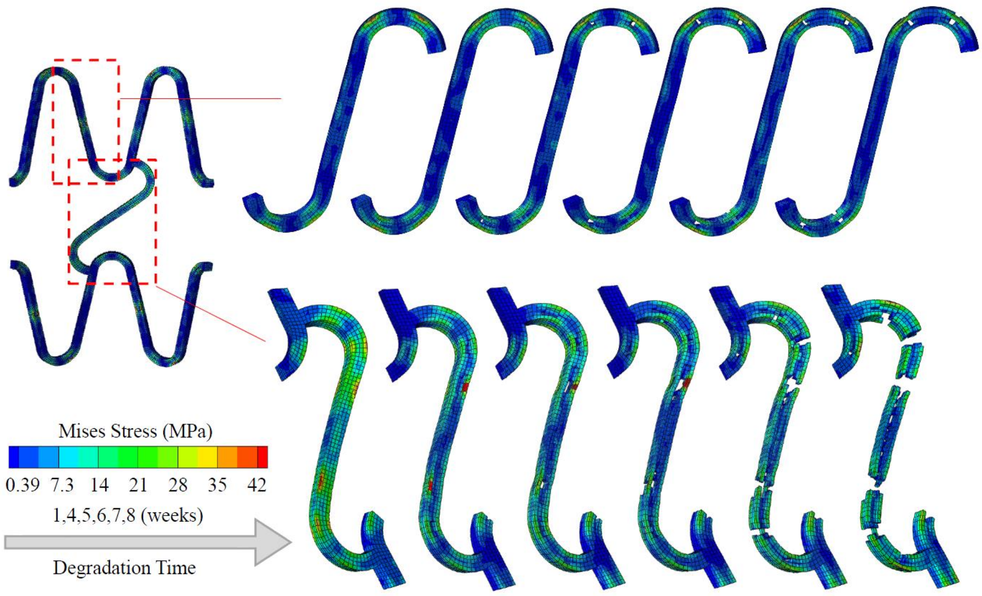

Fig. 2 The stress distribution and damage during degradation

It should be noted that this study has simulated the degradation process under only one boundary condition. Since the mechanical behavior and degradation mechanism of the stent after implantation is much more complicate, more complex boundary conditions and degradation models should be considered in the further simulation. The relationship between the tensile stress and degradation was assumed as liner. This is not consistent with the actual situation and more accurate model should be developed. Notwithstanding its limitation, this study is helpful for understanding the degradation behavior of biodegradable stent after implantation, and also provides a theoretical foundation for the optimization of the biodegradable polymer stent.

4. Conclusion

The simple model presented here provided a new point of view for the pre-clinical evaluation of the functional compatibility and the optimization of BDS. The effects of tensile stress on the degradation of PLA stent should be taken into consideration during the analysis of the stent degradation behavior. In further research, BDS designers can optimize the material formulation and geometry of the stent that will satisfy the immediate needs of percutaneous coronary intervention (PCI).

References

[1] Muramatsu T, Onuma Y, Zhang Y J et al. Progress in treatment by percutaneous coronary intervention: the stent of the future. Revista Española De Cardiología, vol. 66(2013), 483–496.
[2] J. E. Moore, J. S. Soares, and K. R. Rajagopal, "Biodegradable Stents: Biomechanical Modeling Challenges and Opportunities," Cardiovasc. Eng. Technol., vol. 1 (2010), 52–65,.
[3] J. S. Soares and J. E. Moore, "Biomechanical Challenges to Polymeric Biodegradable Stents," Ann. Biomed. Eng., vol. 44(2016), 560–579.
[4] D. Gastaldi, V. Sassi, L. Petrini, et al. "Continuum damage model for bioresorbable magnesium alloy devices - Application to coronary stents," J. Mech. Behav. Biomed. Mater., vol. 4 (2011), 352–365.
[5] W. Wu, S. Chen, D. Gastaldi, et al. "Experimental data confirm numerical modeling of the degradation process of magnesium alloys stents," Acta Biomater., vol. 9 (2013), 8730–8739.
[6] H. Juuti, A. Kotsar, J. Mikkonen, et al. "The effect of pH on the degradation of biodegradable poly(L-lactide-co-glycolide) 80/20 urethral stent material in vitro.," J. Endourol., vol. 26(2012), 701–5.
[7] W. Wu, D. Gastaldi, K. Yang, et al. "Finite element analyses for design evaluation of biodegradable magnesium alloy stents in arterial vessels," Mater. Sci. Eng. B Solid-State Mater. Adv. Technol., vol. 176 (2011), 1733–1740.
[8] A. C. Vieira, R. M. Guedes, and V. Tita, "Constitutive modeling of biodegradable polymers: Hydrolytic degradation and time-dependent behavior," Int. J. Solids Struct., vol. 51(2014), 1164–1174.
[9] J. A. Grogan, S. B. Leen, and P. E. McHugh, "Optimizing the design of a bioabsorbable metal stent using computer simulation methods," Biomaterials, vol. 34(2013), 8049–8060.
[10] Y. B. Fan, P. Li, L. Zeng, et al. "Effects of mechanical load on the degradation of poly(d,l-lactic acid) foam," Polym. Degrad. Stab., vol. 93 (2008), 677–683.
[11] Q. Luo, X. Liu, Z. Li, et al. "Degradation model of bioabsorbable cardiovascular stents," PLoS One, vol. 9(2014), 1–9.
[12] Y. Yang, Y. Zhao, G. Tang, et al. "In vitro degradation of porous poly (l-lactide-co-glycolide) /β-tricalcium phosphate (PLGA/β-TCP) scaffolds under dynamic and static conditions," Polym. Degrad. Stab., vol. 93(2008), 1838–1845.
[13] P. Li, X. Feng, X. Jia, et al. "Influences of tensile load on in vitro degradation of an electrospun poly(L-lactide-co-glycolide) scaffold," Acta Biomater., vol. 6(2010), 2991–2996.
[14] J. S. Soares, J. E. Moore, and K. R. Rajagopal, "Modeling of Deformation-Accelerated Breakdown of Polylactic Acid Biodegradable Stents," J. Med. Device., vol. 4 (2010), 041007.