



Modeling the response of nonlinear viscoelastic biodegradable polymeric stents

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ARTICLE INFO

Article history:

Received 26 August 2011
Received in revised form 27 October 2011
Available online 10 January 2012

Keywords:

Biodegradable polymers
Nonlinear viscoelastic
Finite element
Stent
Degradation

ABSTRACT

We analyze the response of nonlinear viscoelastic biodegradable polymers when subject to mechanical loading coupled with the diffusion of a fluid (water) through the polymers and the degradation that occurs over a period of time. We consider the quasi-linear viscoelastic (QLV) model introduced by Fung (1981) that has been found to be reasonably good in modeling tissues undergoing moderate deformations for modeling the nonlinear viscoelastic response of the biodegradable polymer that is being studied, i.e., poly-lactic acid (PLLA). We modify the QLV model to incorporate changes in the material parameters that are a consequence of the degradation that the polymers undergo. We assume that the rate of degradation increases with an increase in the magnitude of strains and concentration of water. We also assume that the degradation softens the polymers and that the rate of stress relaxation (or the rate of creep) of the polymer increases with degradation. Our primary intention is to examine the effect of viscoelasticity on the degradation in virtue of the time-dependent response of such bodies, and also due to the effect of the diffusion of water that leads to degradation. The problem leads to three different time histories associated with the strong coupling between the mechanical loading, diffusion of a fluid (water), and the degradation. As the biodegradable stent is placed inside a nonlinear viscoelastic arterial wall, we further examine the effect of the coupling between the response of the polymeric stent and arterial wall on the degradation of the biodegradable polymeric stent.

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1. Introduction

Biodegradable polymers such as poly-glycolic acid (PGA) and poly-lactic acid (PLLA) are becoming the materials of choice in many biomedical applications such as sutures, stents, and tissue engineering. While some sutures and stents are intended to be permanent, others are to be kept in place temporarily so as to provide mechanical support for the wounded tissues until they heal. As the wounded tissues heal, the mechanical loads will be gradually transferred to the healed tissues and the implants are no longer needed to bear the load. In such cases, using biodegradable implants helps one to avoid the need for additional surgical interventions to remove the implants at the end of their functional life. Biodegradable polymers have appealing characteristics that can be gainfully exploited for drug delivery applications, such as in drug eluting stents, in order to carry medicine that enhances healing. Another advantage to using biodegradable polymers is that it is possible to control the degradation at the appropriate rate by altering the macromolecular structure of the polymers by adding catalysts or other additives. The degradation mechanism in these polymers is primarily due to hydrolysis (Piskin et al., 1994): water diffuses through the biodegradable implants, breaking the long

polymer chains, which causes reduction in the molecular weight and eventually leads to erosion (loss of mass) from the solid polymers into water soluble materials. These water soluble materials can diffuse out of the polymer implants. Degradation occurs when the rate at which the water diffuses through the polymer is slower than the rate of conversion of the polymer into water soluble materials (see Gopferich (1996) and Moore et al. (2010) for details).

PGA and PLLA and their implants show stress-relaxation (and creep) and undergo large deformation when subjected to mechanical loads, and behave in a nonlinear fashion. Miller and Williams (1984) performed uniaxial tensile tests on PGA sutures. The sutures were loaded under several constant strains: 25% and 50% of the ultimate static failure strain while immersed in saline liquid at 37 °C. They observed some stress relaxation in the specimens and they found that the rate of degradation due to hydrolysis increased with increasing magnitude of strain. Agrawal et al. (1992) evaluated the mechanical properties of PLLA filaments and stents at various draw ratios, 4–8, and temperatures, 0–200 °C. They found that the elastic modulus and tensile strength of the PLLA filaments increase with increasing draw ratio,¹ but the ultimate elongation decreases with increasing draw ratio. The PLLA polymers were also shown to be viscoelastic. Grabow et al. (2007)

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¹ This of course presupposes that the PLLA is modeled as a linearized viscoelastic body.

showed that significant creep in the radial displacements of the PLLA and PLLA/PCL/TEC² stents under a constant pressure of 100 mm Hg leads to collapse (or buckling) of the stents. Soares (2008) conducted uniaxial tensile tests on PLLA fibers and he confirmed the nonlinear viscoelastic characteristics of the PLLA fibers.

For sutures and stents that provide mechanical support for the wounded tissues, the implants should possess appropriate mechanical properties, i.e., strength, stiffness, and ductility (extensibility). An ideal implant would have the physical and mechanical properties close to those of the tissues. Grabow et al. (2005) and Moore et al. (2010) have discussed the challenging design process one faces in the development of biodegradable stents which is driven by the complexity of the viscoelastic material behavior, geometry of the stent, time-dependent loading, and the coupling between the response of the biodegradable stent and the arterial wall. Current designs of biodegradable polymeric stents are carried out by considering the elastic and/or inelastic behavior of the polymer, neglecting any changes in the properties of the stent with degradation (Moore et al., 2010). Recent development of constitutive models of biodegradable polymers takes into account the nonlinear elastic response which allows for strain assisted degradation, i.e., the rate of degradation depends on the deformation gradient (Soares, 2008; Soares et al., 2010a,b; Moore et al., 2010), focusing on PLLA polymers and stents. The deformation of the PLLA polymer is described by a neo-Hookean model and it is assumed to be incompressible and isotropic.

Constitutive models for viscoelastic polymers have been developed to incorporate the response of the body to external stimuli such as temperature and deformation, by defining material functions that depend on such physical entities. Another important aspect concerns the changes in the properties of polymers due to their microstructural changes, i.e., scission due to mechanical, thermal and other stimuli, which is essential in determining long-term stability and the time-dependent performance of polymers. Only limited studies on elastomers include the effect of microstructural changes in the polymer's macromolecules, cross-links, and entanglements, e.g. (Huntley et al., 1996; Rajagopal and Wineman, 1996; Wineman and Min, 2002; Shaw et al., 2005). In biodegradable polymers, in which the degradation is related to scission, it is then important to incorporate the effect of microstructural changes in the polymers during the degradation process for predicting the response. Based on a phenomenological approach Muliana et al. (2009) and Muliana and Rajagopal (2011) have considered changes in the properties of materials due to the diffusion of a fluid in analyzing the deformation of linearized elastic and viscoelastic bodies. They assumed that the properties of materials at a particular location depend on the concentration of fluid at that location, that the values of the elastic moduli decrease with increasing fluid content, and that the materials undergo faster stress relaxation with increasing fluid content. While the mechanical properties of the materials are assumed to depend on the fluid concentration, the diffusion process is assumed to be independent of the deformation of the materials and governed by Fick's law, thus it cannot take into account swelling in the solid body due to the diffusion of a fluid. It is noted that the diffusivity of polymers can also depend on the temperature, moisture content, strain, and stress and in most cases the diffusion process does not follow Fick's law (see Wright, 1981; Weitsman, 1987; La Saponara, 2011).

Given the fact that the degradation occurs when the macromolecular chains of the polymers break (scission occurs) due to the process of hydrolysis and when the polymers are being strained, the degradation takes place at a faster rate, accelerating the degra-

ation process; to the best knowledge of the authors, modeling the response of biodegradable polymers that takes into account the nonlinear viscoelasticity of the polymers, diffusion of water through the polymers, and strain/stress assisted degradation, is currently unavailable in the literature. In the present study, we analyze the response of nonlinear viscoelastic biodegradable polymers subject to coupled mechanical loading and diffusion of a fluid (water) through the polymers. We use the quasi-linear viscoelastic (QLV) model introduced by Fung (1981) that has been found to be reasonably good in modeling tissues undergoing moderate deformations. The non-degraded polymers are assumed to be isotropic and homogeneous, the material moduli changing with the extent of degradation that the body has suffered. We assume that the material moduli decrease with degradation, i.e. degradation softens the polymers, and the rate of relaxation (or the rate of creep) of the polymer increases with degradation. We adopt the strain-dependent rate of degradation model of Soares (2008) and Soares et al. (2010a,b) and modify it to include the effect of water concentration on the degradation. The diffusion of water is assumed to be governed by a generalization of Fick's law. We also formulate a numerical algorithm for the nonlinear QLV model undergoing degradation and integrate it with a finite element (FE) formulation in order to solve the time-dependent boundary value problem (BVP), coupling the response of the biodegradable polymeric stent and the arterial wall. We corroborate the non-degraded QLV model with experimental data on PLLA fibers reported by Soares (2008) and human arteries obtained from Mohan and Melvin (1982).

This manuscript is organized as follows. Section 2 presents the QLV model, which is used for describing the deformation of the viscoelastic biodegradable polymer and the arterial wall, followed by material characterization and parametric studies in Section 3. Section 4 deals with the analysis of the response of a viscoelastic cylindrical stent of finite length, due to degradation. We also consider the stent placed inside a viscoelastic arterial wall and examine the coupling in the response of the biodegradable stent and the arterial wall. Section 5 is dedicated to conclusions.

2. Nonlinear viscoelastic model for the biodegradable polymeric solid and arterial wall

2.1. Constitutive model

In this study, we adopt the QLV constitutive model (Fung, 1981) for predicting the time-dependent mechanical response of polymeric stents, which are comprised of PLLA, and also for the arterial wall. The QLV model was primarily derived for modeling biological tissues, which in a one-dimensional (1D) representation and in absence of degradation is written as:

$$P(t) = \int_0^t E(t-s) \frac{dF}{d\varepsilon} \frac{d\varepsilon}{ds} ds \quad (2.1)$$

where E is the relaxation modulus, F is the strain measure, and P is the Piola stress, which is defined as force divided by the undeformed cross-sectional area. The extensional strain is defined as $\varepsilon(t) = \frac{L(t)}{L(0)} - 1$; where $L(t)$ is the length at current time t . In this study, the following form of the strain measure is used (see Fung (1981) and Rajagopal et al. (2007) for a detailed discussion):

$$F(\varepsilon(t)) = A [e^{B\varepsilon(t)} - 1] \quad (2.2)$$

where A and B are the material constants which can be calibrated by fitting experimental data. Furthermore, based on experimental observations concerning many biological tissues, the response under a quasi-static loading is quite insensitive to the rate of loading; thus it is possible to separate the time-dependent function from the

² This is a PLLA with a triethylcitrate (TEC) plasticizer.

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