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Research paper

Mechanical characterization of the softening behavior of human vaginal tissue

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ABSTRACT

The mechanical properties of vaginal tissue need to be characterized to perform accurate simulations of prolapse and other pelvic disorders that commonly affect women. This is also a fundamental step towards the improvement of therapeutic techniques such as surgery.

In this paper, the softening behavior or Mullins effect of vaginal tissue is studied by proposing an appropriate constitutive model. This effect is an important factor after the birth, since vaginal tissue has been supporting a high load distribution and therefore does not recover its original behavior. Due to the anisotropy of the tissue, the mechanical testing of vaginal tissue, consists in loading–unloading uniaxial tension tests performed along the longitudinal and transverse axes of the vagina. A directional pseudo-elastic model was used to reproduce the inelastic behavior of the tissue. The obtained results may be helpful in the design of surgical procedures with autologous tissue or smart prostheses. A good qualitative agreement has been found between the numerical and experimental results for the vaginal tissue examples, indicating that the constitutive softening model can capture the typical stress–strain behavior observed in this kind of fibrous soft tissue.

1. Introduction

Pelvic organ prolapse (POP), characterized by the loss of normal vaginal support, is widespread (43%–76%) among the female population (Barber, 2005). POP is a multifactorial problem, although obstetric complications related with vaginal birth have been pointed out as a major risk factor (Lukacz et al., 2006). There are several health problems associated with POP. Urinary incontinence (UI) and stress urinary incontinence (SUI) are counted among the most common (Jelovsek et al., 2007). Sometimes these problems lead to incapacitation, a common situation in third World countries. In

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developed countries, SUI represents a heavy toll on health care systems (Kenton and Mueller, 2006). The tendency of life expectancy to increase (especially in the developed world) (Christensen et al., 2009), will mean that in the near future, many more women will suffer from pelvic disorders. Projections from the United States Census Bureau, claim the number of American women aged 60 and over will almost double between 2000 and 2030. The pathophysiology is multifactorial and complex, with collagen levels, vaginal child birth, advancing age, and increasing body-mass index as the most consistent risk factors (Swift et al., 2005).

The medical community starts to acknowledge the importance of numerical simulation tools as an aid (Petros, 2007) to deepen the (classical) medical knowledge of the physiology and pathophysiology of tissues, organs and systems. In this sense, finite element modelling (FEM) techniques may be a valuable tool to understand the biomechanics of the pelvic cavity. There have been some significant efforts (Boukerrou et al., 2007; Parente et al., 2008; Chen et al., 2009) to produce FEM simulations capable of an accurate modelling of the female pelvic cavity. In this context, the current study addresses a major issue of the finite element simulation process, which is the link between theoretical modelling and biological material specificity, which is provided by experimental measurement and subsequent determination of material model parameters. Some urogynecology specialists (DeLancey, 2005; Epstein et al., 2008) consider the research in biomechanical properties as a way for possible improvement of both the assessment and treatment of pelvic floor dysfunctions.

The authors of this paper have been using uniaxial tension tests to investigate the mechanical properties of prolapsed vaginal tissue during the last few years. Our first approach used static loading conditions under the theoretical framework of nonlinear solid mechanics, and led to the proposal of a strain-energy function (SEF) adapted to the tissue structure (Martins et al., 2010). This work was followed by an investigation concerning the damage mechanisms in the tissue due to the application of stresses outside the physiological range (Calvo et al., 2009). The authors investigated the viscoelastic mechanical properties of vaginal tissue on their last paper on this subject (Peña et al., 2009a).

However, when a soft biological specimen in general, and vaginal tissue in particular, is loaded in simple tension from its original state, unloaded and then reloaded, the stress required on reloading is less than that reached in the initial loading for stretches up to the maximum stretch achieved in the previous loading step. This stress softening phenomenon is referred to as Mullins effect. This effect is an important factor after the birth, when the vaginal tissue supports high load distribution and the tissue do not recover its original behavior. There is evidence that the vagina undergoes significant changes during women's reproductive life. Events such as pregnancy and menopause play a major role, due to significant changes in hormonal status (mainly estrogen production). In fact, Alperin and Moalli (2006) concluded that the vagina and its supportive tissues actively remodel in response to different environmental stimuli (pregnancy, menopause, the administration of hormone therapy, and prolapse).

The aim of this paper is to provide a systematic study of the softening behavior or Mullins effect of vaginal tissue in the longitudinal and transverse directions of the vaginal axis. A directional pseudo-elastic model proposed by Peña and Doblaré (2009) for soft biological tissues is used to model this effect in the context of continuum mechanics. The predictions of the model are examined in detail and compared with those from experiments. To our knowledge, this study has not been applied to vaginal tissue.

2. Experimental data

For the present study, tissue samples from seven postmenopausal patients, with a mean age of 66.5 ± 11.7 years were used. Following a protocol approved by the ethics committee of *Hospital de S. João do Porto*, the prolapsed vaginal tissue was excised during surgery and frozen in a saline solution bath at -20 °C until the mechanical tests were performed. Both the cooling down and heating up processes were gradually carried out. Samples were conducted to an intermediate temperature (+4 °C), reaching a stationary state and after cooling to −20 °C or heating to room temperature, depending on the cooling or heating process. Rubod et al. (2007) demonstrated that the mechanical behavior of the vaginal tissue was unaffected by freezing. The whole vaginal wall, including mucosa, muscular layer and adventitia (Junqueira and Carneiro, 2007), was tested. The vaginal muscular layer is mostly composed of smooth muscle cells oriented in the longitudinal direction. *Adventitia* is formed by dense connective tissues with many elastic fibers and extensive nerve supply. The circular cell nucleus shape points out that the bundles run parallel to the test direction, constituting the anisotropy directions of the tissue.

The longitudinal and transverse strips (approximately 6 mm wide and 15 mm long) and a portion of the tissue for histological studies were cut from each patients, Fig. 1(a). Specimens with holes, cuts or apparent damage were not tested. Due to stroke limitations of the soft vaginal tissue, "dogbone" specimens could not be used in the experiments. Instead, parallel sided (prismatic) strip specimens were used. Two circular black spots were painted on the surface of the strip to measure the deformation. In all experiments, the tags were placed at least 5 mm away from the grips to ensure that a uniform uniaxial region exists between them, Fig. 1(b). Thickness was determined by placing the strips between two glass plates. A Mitutoyo Absolute Digimatic micrometer, which held the measurement when the contact force reached a value of 0.5 N, was used to measure the distance between the plates. Three measurements at different locations were taken for each sample in order to assess the sample thickness homogeneity $e = 2.34 \pm 0.76$ mm. Those samples in which noticeable thickness variations were observed (>10%) were also rejected. Finally, seven valid tests (longitudinal and transverse directions) were performed for the longitudinal and transverse directions, respectively.

Simple tension tests of the tissue strips were performed in a high precision drive Instron Microtester 5548 system adapted for biological specimens. Force was measured with a 50 N load cell with a minimal resolution of 0.01 N. Axial