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A preliminary material model to predict stress softening and permanent set effects of human vaginal tissue

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Abstract

In this paper the authors modified an available material model to account the stress softening and permanent set effects exhibit by human vaginal tissue during simple uniaxial tests. The preliminary model is based on four material parameter values i.e., the stress-like material constants, the stress softening and the permanent set effect material parameter constants. To assess the accuracy of the proposed model, the authors compared theoretical predictions with available simple uniaxial experimental data. It is shown that the proposed modifications describe well experimental data with 99% of accuracy.

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Keywords: Pelvic Floor Disorders; Vaginal Soft Tissue; Constitutive Modeling; Mullins Effect; Softening.

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1. Introduction

Pelvic floor is a set of muscles formed by the levator ani, coccygeus muscles and associate connective tissue, in charge of support the lower abdominal portion, bladder, uterus and a portion of the bowel. It is essential the maintenance of the correct functioning of this structure, since a reduction in the force exerted by one of these muscles, causes the dysfunction of any structure or muscle that integrate it, also called pelvic floor dysfunction (PFD).

A percentage greater than 50% of women of 55 years and older, suffers one or more problems related to PFD, disorders which one of each nine women will resort to surgery as a way to correct them. Although, men can suffer this kind of conditions, large differences in the anatomy and function of pelvic floor organs as the support of them, lead to a higher incidence of PFD in women than in men at a ratio of 8 to 1, respectively [1].

Pelvic floor disorders include urinary incontinence (UI), pelvic organ prolapse (POP), fecal incontinence (FI) and sexual dysfunction. Urinary incontinence defined as an involuntary loss of urine through the urethra, is the PFD with highest incidence, since between 15 to 50% of female population suffers from it, while the incidence of fecal incontinence caused by the loss in the control of the movements exerted by the bowel, ranges between 1.5 and 2.3% in general population [2].

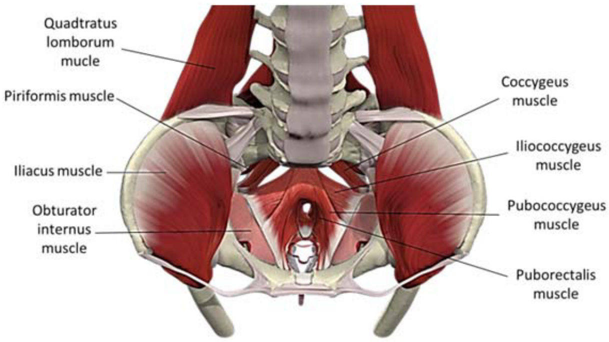

Fig. 1. Pelvic floor structure.

Pelvic organ prolapse defined as the slip of an organ out from its original position, inside or outside the human, mainly can be classified in three kinds: Rectocele, where the rectum slip through the posterior vaginal wall; Cystocele, bladder slip out from the human body through the anterior vaginal wall and enterocele, named to the prolapse of the bowel. According to a study realized by Women's Health Initiative, it is highlighted that 41% of women between 50 and 79 years old, suffers of some type of pelvic organ prolapse: Cystocele 34%, rectocele 19% and uterine prolapse 18.3% [3].

Although the highlighted prevalence of PFD in worldwide population, the underlying mechanism is poorly understood, vaginal reconstructive efforts are limited by incomplete understanding of the biomechanical and biochemical properties of pelvic tissues in healthy and affected individuals.

The vagina is a supporting hammock for the pelvic viscera, acting as the interface where forces are transmitted among pelvic organs. Thus, it is thought to be involved in the prolapse process and changes in vaginal wall properties can affect the developments of POP.

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

In order to do this, it is necessary the identification of a proper constitutive law able to describe well the peculiar mechanical behaviour of vaginal tissue. The model would combine simplicity and applicability in order to be implemented in a code for commercial FEM software. Moreover since biological tissue characteristics highly varies from patient to patient, this will be important not only for FEM codes, but even to numerically investigate the causes of their variability (such as: hormones, age and, in general, gender) through an experimental campaign.

2. Experimental data

The data that will be used during this study in order to validate the developed material model was provided by Estefanía Peña from the Group of Structural Mechanics and Materials Modeling and Aragón Institute of Engineering Research (University of Zaragoza, Spain), who performed experimental mechanical characterization on human vaginal tissues. The data provided is the same used to publish the works Peña et al [4-6].

The experimental data was obtained from successful mechanical tests realized over vaginal tissue from seven postmenopausal patients with a mean age of 66.5±11.7 years. Following a protocol approved by the ethics committee of Hospital de S. João de Porto, the prolapsed vaginal tissue was excised during surgery and frozen in a saline solution bath at -20 °C until mechanical tests were performed, before which samples were gradually carried out to room temperature and then to an intermediate temperature 4 °C, reaching stationary state.

Longitudinal and transverse strips of 6 mm wide and 15 mm long from whole vaginal wall including mucosa, muscular layer and adventitia were tested. Thickness was determined by placing strips between two glass plates, measuring the distance between them by a Mitutoyo Absolute Digimatic micrometer, three measurements at different locations were taken in each sample, in order to assess the sample thickness homogeneity: e=2.34 ±0.76 mm.

Uniaxial tensile tests were performed in an Instron Microtester 5548, force was measured with a 50 N load cell with a minimal resolution of 0.01 N, while axial strain was measured by using a non-contact Instron 2663-281 video-extensometer, equipped with a high performance digital camera with a megapixel sensor. All tests were performed in a 100% humid atmosphere to prevent the specimen from drying up. Different loading and unloading cycles were applied: 2, 4, 6 and 8 N (values chosen in order to avoid tissue damage during the loading test), a displacement rate of 2 mm/min was used [6].

As this work consists of a preliminary study, the data that will be employed during this, will consist of one valid test, with longitudinal and transversal directions.

3. Preliminaries

Some essential relations for finite deformations of an incompressible elastic material will be given briefly. Considering a material particle at the place $\boldsymbol{X}=X_k\boldsymbol{e}_k$ in an initially undeformed reference configuration of a body. When subjected to a prescribed deformation, the particle at X moves to the place $\boldsymbol{x}=x_k\boldsymbol{e}_k$ in the current configuration of the body in a common rectangular Cartesian frame $\phi=\{O;\boldsymbol{e}_k\}$ with origin O and orthonormal basis $\boldsymbol{e}_k$. A pure homogenous deformation is described by:

$$x_1 = \lambda_1 X_1, x_2 = \lambda_2 X_2, x_3 = \lambda_3 X_3 \tag{1}$$

In which λ_k are the principal stretches and x_k and X_k are the respective coordinates of x and X in ϕ. The incompressibility condition requires that the value of the stretch tensor **F** for all deformations be:

$$\det F = \lambda_1 \lambda_2 \lambda_3 = 1 \tag{2}$$

For the case of simple extension and under the hypothesis of incompressibility (equation (1)), the principal stretches satisfy the equation:

$$\lambda_1 = \lambda, \lambda_2 = \lambda_3 = \lambda^{-1/2} \tag{3}$$

A homogeneous deformation in simple extension and compression is produced by uniaxial stress $T_1 = T$ and the lateral traction-boundary condition is being specified with $T_2 = T_3 = 0$. The engineering stress σ is related to the Cauchy stress T by:

$$\sigma = TF^{-1} \tag{4}$$

Hence, the uniaxial engineering stress-stretch relation is given by:

$$\sigma_1 = \left(\frac{1}{\lambda_1} \right) T_1 \tag{5}$$

Finally, the principal Cauchy stresses T_i may be determinate from the strain-energy function as:

$$T_i = (\lambda_i) \frac{\partial w}{\partial \lambda_i} \tag{6}$$

The engineering stress σ could be determinated from equations (5) and (6) as:

$$\sigma_i = \frac{\partial w}{\partial \lambda_i} \tag{7}$$

where w is the strain-energy function of the material model chosen.

4. Review of Holzapfel material model

In literature several constitutive models are able to describe the phenomenological behaviour of different type of materials, especially elastomers. Enormous progress has been made during the last years in the modeling of soft tissues. In this work several models were studied and tested, in particular Arruda-Boyce 8-chain [7], Horgan and Saccomandi [8], Fung [9], and Holzapfel et al [10], in order to obtain a model with good accuracy to fit the experimental data provided. While models like Arruda-Boyce [7] and Horgan-Saccomandi [8], originally developed for elastomeric materials, proved to be incapable to describe the behaviour of vaginal tissue, Fung [9] and Holzapfel et al [10] models developed in order to predict the behaviour of different soft tissues, have been found able to describe the behaviour of vaginal tissue.

The Holzapfel material model [10] was chosen as the model that better predicts the nonlinear behaviour of vaginal tissue, since the results that gave were accurate and the independent terms that are involved in the model are the fewest so far. This material model, takes into account the anisotropic behavior of tissues, capturing the isotropy of the ground and the transverse isotropy associated to the collagen fibers, based on a strain-energy function of the form:

$$\Psi(I_{1,}I_4) = \Psi_g(I_1) + \Psi_f(I_{1,}I_4) \tag{8}$$

The "ρ model" proposed by Holzapfel, which modification was taken for the development of this work, is based on a weighting factor between full isotropy and full alignment as a measure of dispersion in the fiber orientation, using the strain-energy function presented in equation (8), with the term Ψ_f defined as:

$$\Psi_f(I_{1,}I_4) = \frac{k_1}{k_2}\left[e^{\{k_2\left[(1-\rho)(I_1-3)^2+\rho(I_4-1)^2\right]\}} - 1 \right] \tag{9}$$

where $k_1 > 0$ and $k_2 > 0$ are stress-like and dimensionless parameters, respectively, to be determined from mechanical tissue tests.

As mentioned before, the parameter ρ[0, 1] is a measure of dispersion in the fiber orientation, where an upper value limit of $\rho = 1$ corresponds to ideal alignment of collagen fibers (transverse isotropy) while in the lower limit $\rho = 0$ an isotropic distribution is obtained.

The formulation of the Holzapfel modified model used to describe the loading curve of virgin soft material is derived from the strain-energy function presented in equations (8) and (9):

$$\Psi(I_1) = \frac{k_1}{k_2}\left[e^{\left\{k_2\left[(I_1-3)^2\right]\right\}} - 1\right] \tag{10}$$

As can be seen, equation (10), is a particular condition of equations (8) and (9), obtained by replacing on equation (8) $\Psi_g(I_1) = 0$, taking into account only the energy component of the material that considers the collagen fibers and considering isotropic distribution, using $\rho = 0$ on equation (9). Please note that this is not a simplification, in fact the model was also tested with the term $\Psi_g(I_1)$ and it was found that despite having to introduce one more independent parameter, this term did not give any benefit to the accuracy of the model. Moreover the independent parameter obtained for each test was close to zero, emphasizing the fact that the model, for the materials analyzed, is more effective neglecting this term. The term $\rho = 0$ is an approximation and through the use of this value an isotropic distribution of fibers in the material is considered.

5. A preliminary constitutive model

To characterize the virgin material response of an incompressible and isotropic elastic material, the preliminary equation (7) was used into the Holzapfel modified material model shown in equation (10), obtaining the stress flow of the model.

In simple tension and under the hypothesis of incompressibility for I_1, the constitutive law that will be utilized to describe the loading curve of vaginal soft tissue is given by equation (11):

$$\sigma(\lambda_1) = 4k_1\left(\lambda^2 + \frac{2}{\lambda} - 3\right)\left(\lambda - \left(\frac{1}{\lambda^2}\right)\right)\exp\left(k_2\left(\lambda^2 + \frac{2}{\lambda} - 3\right)^2\right) \tag{11}$$

For modeling the unloading path of the vaginal tissue, it can be see that is certainly more complicated than the loading virgin curve. Two basic aspects have to be considered and taken into account in the model: 1) Softening phenomena, called Mullins effect, which causes that the unloading curve does not follow the virgin loading one and 2) these materials at the end of each unloading cycle exhibit a permanent residual deformation.

In order to describe the peculiar unloading behaviour of these materials, a new model has been developed. In the equation (12) the constitutive law in the form of engineering stress-stretch is shown:

$$\sigma_{unloading}(\lambda_1) = (\sigma_{virgin}(k_1, k_2) + f_{res}) \cdot F(m, M) \tag{12}$$

where $\sigma_{unloading}$ is the stress flow of the unloading curves, σ_{virgin} is the stress flow given by the model provided for the loading virgin curve, equation (11), $F(m, M)$ is the softening function and $f(\lambda_{res})$ is the term that takes into account the residual deformation.

The softening function is determined by a constitutive equation that describes the evolution of microstructural damage that begins immediately upon deformation from the natural, undistorted state of the virgin material; this function is in the form proposed by Elías-Zúñiga [11]:

$$F\left(m,M\right)=e^{\delta\left[\left(M-m\right)\left(\frac{m}{M}\right)^{\gamma}\right]^{\alpha}} \qquad (13)$$

where δ is a positive parameter related to the softening of the material that has to be determined, and γ and α are constants that are used to improve the fitting of experimental data. The terms m and M, are defined as the current elongation intensity and the maximum elongation intensity, respectively.

$$f_{res}=\frac{k_1}{C}\left(-n\lambda^{n-1}\left(\lambda_{max}^{2}-\lambda^{n}\right)+n\lambda^{-\left(1+\frac{n}{2}\right)}\left(\lambda_{max}^{-\frac{n}{2}}-\lambda^{-\frac{n}{2}}\right)\right) \qquad (14)$$

where C is a parameter related to residual deformation and n is a smoothing parameter.

The model proposed is able to perfectly describe the behaviour of the loading and unloading curves of the materials analyzed, solving the problem of softening and residual strain in a very simple way and with the use of only two independent parameters, the softening parameter δ and the residual strain parameter C. In fact, as a result of several tests, it was found that for these materials the best results are obtained by attributing to the constants γ and α the values of 1 and 0.9, respectively.

6. Results

In Figure 2 the stress-stretch response of the model proposed is shown. Equation (11), is compared to experimental data, recalling that all the curves presented in the figure, are in terms of engineering stress-stretch. The values of the independent parameters k_1 and k_2 have been found during the fitting process.

From the curves presented on Figure 2, it is possible to observe how the model chosen, perfectly describes the experimental data. It is important to remind that in cyclic tension tests, the material may be subject to a relaxation phenomenon.

In Table 1 the values obtained for the material parameters k_1 and k_2 are shown.

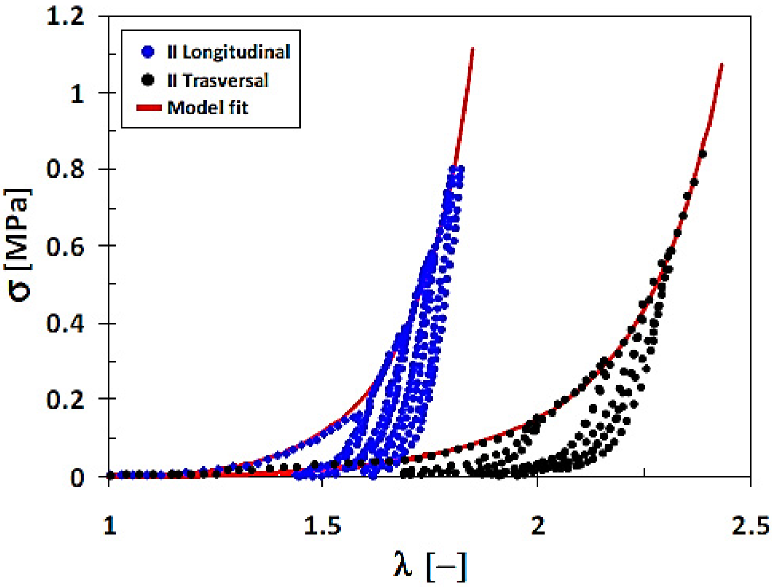

Fig. 2. Experimental loading engineering stress-stretch curves and numerical fitting.

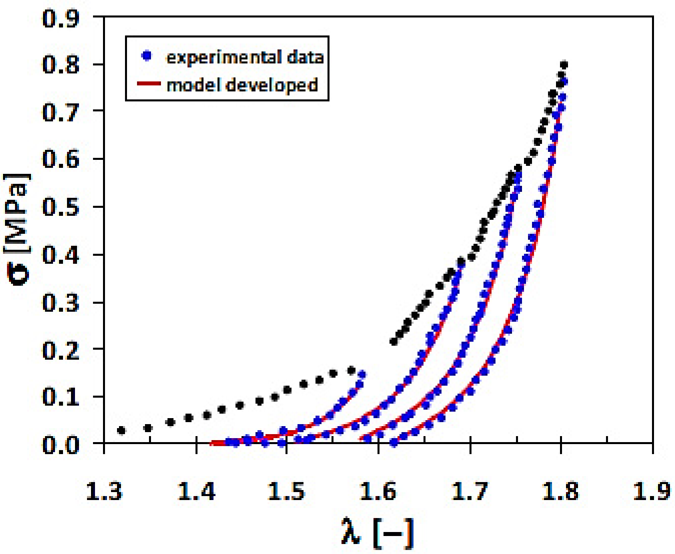

Fig. 3. Experimental unloading engineering stress-stretch curves and numerical fitting in longitudinal direction.

Table 1. Material parameters for loading experimental curves.

Specimen	*Longitudinal Direction Sample*			*Transversal Direction Sample*		
	k_1	k_2	R^2	k_1	k_2	R^2
II	0.0397	0.485	0.998	0.0069	0.110	0.999

The adjusted results shown in Table 1, demonstrate that the proposed model, equation (11), is in a preliminary way able to perfectly describe the behaviour of the human vaginal tissue, as regards the loading curves, for the entire specimen, in both directions: longitudinal and transversal.

In Figure 3, the stress-stretch response of the model represented by the equation (12) is shown. The figure compares the model results with experimental data in a longitudinal direction. In this figure, it is possible to observe the accuracy of the model developed, since it is able to describe perfectly the behaviour of the unloading experimental curves of the test performed, including stress softening phenomenon and permanent set effect. The fitting of the experimental data is virtually perfect, even better than the loading one.

In Table 2, the values obtained for the material parameters δ and C are shown. The level of accuracy of the fitting, given by the R-square value is not shown in the table because the value for any fitting result is greater than or equal to 0.996.

Table 2. Material parameters for unloading experimental curves, longitudinal direction.

Specimen	Cycle	λ_{max}	δ	C
II	1	1.585	14.12	1.768
	2	1.691	8.83	2.334
	3	1.754	8.23	2.428
	4	1.804	8.24	2.282

The results of Figures 2 and 3, show a very good correspondence between experimental data and numerical prediction. The behaviour of almost all the curves is predicted very well by the proposed model for each case. In general, the numerical prediction in the transversal direction is more accurate than in the longitudinal one, given that the function used to calculate the approximated value of δ in the transversal direction is more accurate than for the longitudinal one.

7. Conclusion

The aim of this paper was to analyze experimental data of tensile tests performed on vaginal tissue samples in order to identify a constitutive material law able to describe the mechanical behaviour of these soft tissues.

A comprehensive model which describes the mechanical behaviour of the analyzed tissues was developed and proposed. The model has been developed for the case of simple tension, starting from the strain-energy equation proposed by Holzapfel et al [10]. The model developed is able to predict the mechanical behaviour of the tissue for both situations, loading curves of the virgin material and unloading curves, taking into account complex aspects such as softening and the residual strain presented by the material.

The model developed requires only 4 independent materials parameters to be found from mechanical tensile tests. This represents an excellent result in terms of both: accuracy and simplicity of the model, further for loading and unloading curves; the fitting of the experimental data with the proposed models is 99%.

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