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Urethral lumen occlusion by artificial sphincteric device: Evaluation of degraded tissues effects

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ABSTRACT

Urinary incontinence can be surgically treated by means of artificial sphincters, based on a cuff that provides a pressure around the urethra to occlude the lumen. Considering the frequent access of elderly patients to this surgical practice, tissue degradation phenomena must be investigated, since they could affect treatment reliability and durability. The potential degradation can be interpreted considering a variation within soft tissue constitutive formulation, by means of a correlation between mechanical properties and tissues ageing. The overall compressibility varies, as characteristics aspect of soft tissue mechanical response with age, as well as the stiffness. The investigation is performed by means of a three dimensional numerical model of the urethral duct. The effects of the interaction phenomenon with a cuff is interpreted considering the changes, within the constitutive models, of the basic parameters that define the potential degradation process. The deformation related to compressibility is recalled, ranging between ten and fifty percent in dependence on the degradation level considered. This parameter, reported mostly as representative of the aging effect, shows a large variation that confirms the relevance of the investigation performed toward a sensitivity of the mechanical response of the urethral duct referred to the lumen occlusion.

1. Introduction

Male stress urinary incontinence is a widespread health and social problem with adverse effects on life quality and high costs for the sanitary system (Cornu et al., 2013). About 10–20% of men develop severe stress urinary incontinence (SUI) after radical prostatectomy (RP) for prostate cancer treatment (Kim et al., 2013) and nearly 6% of men who had a RP undergo surgical treatment for SUI (Kim et al., 2013). The Artificial Urinary Sphincter (AUS) has been utilized for over 30 years, with an estimate of thousand implants worldwide (Ratan et al., 2006; Myers et al., 2017). It is currently considered the most reliable surgical solution for male SUI (Lucas et al., 2012), despite some related complications, including tissue atrophy and erosion (Cordon et al., 2016) and a high long-term reoperation rates (Alwaal et al., 2016; Van Der Aa et al., 2013).

AUS often comprises an inflatable cuff placed around the bulbar urethra or the bladder neck, a reservoir located in the retropubic space and a control pump bulb positioned in the scrotum to control deflation and to enable micturition. The cuff, which is in direct contact with urethral tissues and applies pressure to the duct, is the component that mostly affects prosthesis efficacy and reliability.

Experimental testing on human urethras is complex and must take into account urethral tissues from different subjects with comparable body conformation and health conditions. Ex vivo tests on animal models are feasible (Fry et al., 2010), even though a comparative anatomy study should support the selection of suitable species, presenting similarities to human urethra in terms of histology and conformation. In previous works (Natali et al., 2016, 2017a) the horse urethra is investigated and considered comparable with the human one in terms of hysto-morphometric conformation and mechanical properties.

Particular attention is paid to the cuff action in relation with the biomechanical characteristics of biological tissues. While healthy condition represents a reference term for investigation, degradation due to ageing, pathology and trauma should be considered. Particular attention is paid to ageing in consideration of the typology of patients that undergo surgical treatment.

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The acquisition of experimental data on patients of different age and pathology is complex, because of the difficulties in obtaining samples and defining the experimental setup (Natali et al., 2016, 2017a) that defines the action of the sphincteric device during micturition (Idzenga et al., 2015).

Recalling the unavoidable aspect of ageing, experience in biological tissue mechanics highlights that the degradation of the tissues is correlated with a decrease in compressibility characteristics depending on reduced capability to keep functionally the liquid content (Diridollou et al., 2001; Natali et al., 2008; Willard et al., 2002). Moreover, the elastic properties of the biological tissues show a decrease in relation with elastin content, while the percentage increase of collagen determines a growing stiffness in the urethral duct (Macoska et al., 2014; Ma et al., 2012). Ma et al. (2012) reported that periurethral prostate tissues were stiffer in men with moderate-severe UI symptoms and exhibited significantly higher collagen content compared to men with limited UI symptoms. This study clearly demonstrated a direct correlation between patient ageing, increasing tissue stiffness related to increased collagen content and the uprising of SUI. Lepor et al. (1992) investigated the morphometry of human bladder, showing a reduction of smooth muscle percentage respect to connective tissue, due to ageing. Levy and Wight (1990) observed a significant increase of collagen percentage in the lamina propria of human bladders. Ewalt et al. (1992) also noticed a decrease of elastin fibers with increment of collagen surrounded by muscular fibers. Strasser et al. (2000) found an age-dependent decrease of striated muscle cells of the urethral sphincter, associated to a decrease in urethral pressure.

Under the condition of having very accurate three dimensional model of the overall duct and a refined constitutive modelling of the specific tissues that compose the duct itself (Natali et al., 2016, 2017a, 2017b, 2017c), numerical modelling offers the possibility to investigate the problem by means of a sensitivity analysis, adopting a variation of fundamental parameters that regulate material response with regard to degradation.

This approach represents a useful source of basic information about the biomechanical response under different degraded conditions and can be assumed to address the heavy experimental activity toward the most significant aspect during testing.

2. Materials and methods

2.1. Characterization of urethral tissue with ageing

As previously mentioned, particular attention is paid to the degradation process associated with ageing. The constitutive formulation must take into account the deceased capability to act as almost incompressible material, in relation with the liquid content that is a peculiar characteristic of healthy soft tissue (Fontanella et al., 2016; Natali et al., 2015; Pachera et al., 2016). Moreover, the conformation of different components varies because of a decrease in percentage of elastin with a growing value of collagen. These aspects are investigated and properly identified in different studies (Choi and Zheng, 2005; Da-Silva et al., 2002; Hayes et al., 1972; Willard et al., 2002) and in particular, with regard to urethral duct in (Macoska et al., 2014; Ma et al., 2012).

Experimental tests show that the tangent elastic modulus varies significantly in dependence on the age of the subject and the opportunity to investigate these conditions by a corresponding variation of the parameter that characterizes the mechanical response. In particular, results by Ma et al. (2012) provide a quantitative estimate of the stiffness variation of periurethral prostate tissues with ageing. The investigation often pertains to periurethral tissues in the prosthetic region, in consideration of the possibility to access to human samples in case of prostatectomy. The data on tensile modulus of post-prostatectomy in periurethral tissues showed a large range of variation with patients age increasing from 50 to 70 years (Macoska et al., 2014; Ma et al., 2012). These values are taken as reference for evaluating aged tissue stiffness. The histological and morphometric conformations of the tissue, as reported in (Ma et al., 2012), attest this trend. The median collagen percentage of periurethral prostate tissues was about 32% (Ma et al., 2012) considering that the increment with ageing suggests that average tissue stiffness improves as directly correlates with collagen percentage.

Also, the variation in terms of compressibility must be considered by means of the corresponding biomechanical parameters, recalling a characteristic behavior of soft tissue because of ageing. As reported in the following, this combination of events determines a significant variation in the overall mechanical response of the duct.

2.2. Constitutive modelling

The definition of a numerical model to interpret duct mechanical response under cuff loading is part of a research activity developed by the authors and reported in different works (Natali et al., 2016, 2017a, 2017b, 2017c). The virtual geometrical model of urethral duct is achieved starting from the histological images of transversal sections of the urethra (Natali et al., 2016) that identify the different tissues conformation, as a pseudostratified columnar epithelium around the lumen, a thin layer of dense connective tissue and a thick stratum of loose tissue. The geometrical model is imported into the finite element pre-processing software Abaqus/CAE 6.14 (Dassault Systèmes Simulia Corp., Providence, RI) (Abaqus Documentation, 2014) and the dimension of the geometrical model is enlarged in scale to correct shrinkage phenomena that occurred during histological analysis, according to data in literature (Dobrin, 1996). Subsequently, the 3D virtual solid (Fig. 1a-b-c) is provided up to a length of 20 mm. Eight nodes hexahedral elements with reduced integration are adopted to mesh the dense connective tissue layer and the loose tissue stratum. Different element sizes are adopted for different regions, to correspond to an adequate accuracy in the representation and reliability in the subsequent computations, with distinction for dense connective tissue layer and loose tissue stratum. Within the dense connective tissue layer, the mean element size in the transversal plane is 0.05 mm, while it shows a large range of variation between 0.05 and 0.5 mm in the loose tissue stratum. Element size along longitudinal direction is set at 0.3 mm. The model is composed of about nine hundred thousand nodes and elements. The mechanical contribution of the epithelial layer can be neglected, due to its low stiffness, while it must be taken into account under compressive loads, for correct application of a self-contact condition (Natali et al., 2017a). The model was tested by the usual procedures for convergence and efficacy evaluations, also in consideration of the non-linear aspects that characterize the analysis.

The mechanical behavior of dense connective and loose tissues is described by an hyperelastic constitutive formulation, which considers the volumetric and iso-volumetric terms, adopted to interpret the typical features of soft tissue mechanics investigated as reported in previous works (Carniel et al., 2014; Natali et al., 2010). While reference is given to the cited papers, a specific short note on the formulation developed is reported to have a direct reference to the parameters that govern the mechanical responses and that are associated with the variations of tissue properties in degraded conditions.

$$W(J, \tilde{I}_1) = U(J) + \tilde{W}(\tilde{I}_1) \quad (1)$$

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