A PROCEDURE FOR THE IN SILICO DESIGN OF ARTIFICIAL URINARY SPHINCTERS

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Introduction

Urinary incontinence represents a relevant healthcare problem worldwide, causing enormous socio-economical costs. With particular regard to male subjects, Artificial Urinary Sphincter (AUS) is the gold standard treatment. The principal component of the AUS is a cuff, which is wrapped around the bulbar urethra. The cuff is inflated with saline to occlude the urethral lumen. Cuff pressure is defined on the basis of clinical experience to ensure continence, up to high bladder pressure. Despite the continence efficacy, the physio-mechanical reliability of current AUSs is an open issue. AUS constantly applies occlusive actions that elicit non-physiological mechanical stimulations on tissues, leading to vasoconstriction, tissue infection, atrophy and/or erosion. Device revision is frequent, with relevant costs and patient bother. AUSs have been mostly designed on the basis of clinical experience, experimentations on cadavers or animal models and clinical trials. Such approach is extremely expensive and only a few configurations of the device can be analysed. Mostly, mechanical effects on urethral tissues are not investigated. In silico methods are expanding for the design of surgical devices. Biomechanical models allow to spread the investigation to many different configurations, providing also stress and strain fields within biological tissues, whose knowledge allows evaluating the physio-mechanical reliability [1]. The here proposed activities pertain to the definition of a procedure for the in silico design of AUS devices.

Materials and Methods

The procedure assumes a typical conformation of the AUS, as an inflatable cuff surrounded by a supporting band. The first step pertains to geometrical design, which investigates AUS wrapping uniformly around the urethra when the cuff is inflated. Parametric 3D CAD models and FEM computations allow evaluating different conformations. The design accounts for both overall geometry and details, such as the joint region.

Figure 1: Different 3D CAD models of the AUS defined within the procedure.

A specific hyperelastic formulation is defined for the mechanical behaviour of the device rubber material. The assumption of different constitutive parameters allows analysing devices with different characteristics. The further step of the in silico procedure pertains to the analysis of interactions between AUS and urethra, which is defined as a cylinder with lumen. Tissues mechanical behaviour is defined by means of hyperelastic formulations, whose identification accounted for extensive experimental data [2]. The next step of the procedure couples AUS 3D CAD model and urethra. Contact strategies specify the interaction between the different surfaces. After FE discretization, the models are exploited to simulate lumen occlusion at different cuff pressures.

Results

A specific procedure, which couples 3D CAD and FEM tools, has been defined to design artificial sphincters accounting for the wrapping capability of the urethra (Figure 2) and the mechanical stimulation of urethral tissues. The approach provides information about stress and strain, which are responsible for tissue damage, and hydrostatic pressure, which entails vaso-constriction phenomena, as novel parameters for AUS optimization.

Figure 2: Wrapping capability of a specific AUS configuration - conformations at different cuff pressures.

Conclusions

The investigations highlight the potentialities of in silico approach for design of AUS devices. The novelty of the proposed procedure is the evaluation of device reliability depending on mechanical stimulation of urethral tissues. The methodology further allows to specifically design the AUS depending on degenerative phenomena. In conclusion, the novel approach provides a design tool that amplifies the plethora of device configurations investigated, and minimizes the experimental and ethical efforts.

References

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2. Natali et al, Exp Physiol, 101:641-656, 2016.

Acknowledgements

This work was supported by University of Padova, Project FONT_BIRD2020_01 AUS-DEV.