EXTRALUMINAL AND INTRALUMINAL ARTIFICAL URINARY SPHINCTERS: A COMPARISON OF BIOMECHANICAL FUNCTIONALITY

Emanuele Luigi Carniel (1), Francesco Chitarin (2), Paola Pirini (2), Maria Vittoria Mascolini (1), Joseph Vannel Fotso Fogang (2), Chiara Giulia Fontanella (1), Alice Berardo (2,3), Tommaso Mazzocchi (4), Leonardo Marziale (4), Leonardo Ricotti (4), Gioa Lucarini (4), Nicolò Spiezia (5), Gianluca Mazzucco (2)

1. Department of Industrial Engineering, University of Padova, Italy
2. Department of Civil Environmental and Architectural Engineering, University of Padova, Italy
3. Department of Biomedical Sciences, University of Padova, Italy
4. The BioRobotics Institute, Scuola Superiore Sant'Anna, Pisa, Italy
5. M3E Srl, Padova, Italy

Introduction

Artificial sphincters are implantable prosthetic devices that interact with tissues in order to replace the function of natural sphincters. Different mechanisms are employed to perform the occluding action, such as hydraulic, magnetic, shape memory. The optimal artificial sphincter should mimic the action of the natural one, avoiding degenerative phenomena of the surrounding tissues. Artificial Urinary Sphincters (AUSs) aim to resolve urinary incontinence, whose spread is extremely wide and socio-economical costs are enormous. Many different AUSs have been proposed, considering both extraluminal and intraluminal devices. Extraluminal AUSs are placed by invasive surgery. They frequently require revision, and further surgery is necessary. On the other side, the invasiveness of placing intraluminal device is minor, but its dimension and shape can determine patient bother. A further topic pertains to the mechanical stimulation of urethral tissues because of permanent occluding or positioning action. The mechanical stimulation may induce degenerative phenomena, as vasoconstriction, infection, atrophy and/or erosion, with consequent failure of the intervention. Despite the relevance of the phenomena, the design and validation of AUSs are performed by experimentations on cadavers and animal models, and clinical trials only. Such methodology is ethically and economically expensive, and does not provide quantitative information about tissues mechanical stimulation. This work aims to highlight the potentiality of computational biomechanics for investigating the reliability of the two principal extraluminal and intraluminal devices: AMS 800 and Relief, respectively.

Materials and Methods

A computational model of the urethra was developed, consisting of a 50 mm length and 5 mm radius cylinder with an elliptical lumen (8 and 1.6 mm major and minor axes). With regard to the investigation of Relief, the model also included the bladder. Hyperelastic formulations characterised the tissues mechanical behaviour.

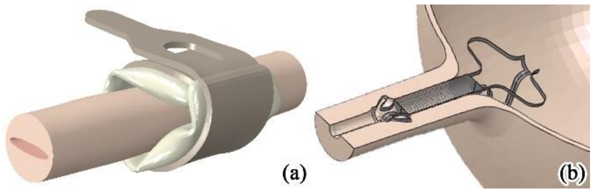

Figure 1: Coupled computational models of AUS-urethra systems: wrapped AMS 800 (a) and Relief (b).

Concerning AMS 800, the model included the polymeric cuff and the fibre reinforced band (Fig. 1a). AUS and urethra devices were coupled. Contact strategies specified the interaction between model surfaces. The computational analysis included a preliminary step to simulate AUS wrapping around the urethra. During the next step, cuff pressure was progressively increased up to clinically applied values, such as 6 or 8 kPa [1].

The Relief model (Fig. 1b) accounted for all the external components interacting with urethral tissues. In detail, the structure for device positioning is manufactured with SME alloy [2]. A superelastic model characterised the mechanical behaviour of such components, while linear elastic models were adopted elsewhere. Contact strategies specified interactions between the different surfaces. The computational analysis accounted for two principal steps: positioning of the device at the bladder neck and opening of the positioning structure.

Results

The computational analyses made it possible to evaluate the mechanical stimulation of urethral tissues, such as stress and strain fields, with particular regard to the mostly loaded urethral sections (Fig. 2).

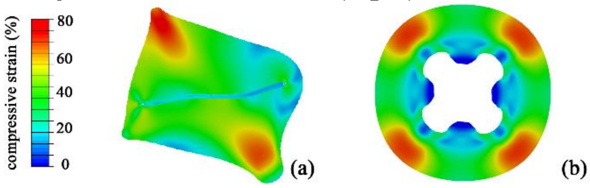

Figure 2: Contours of compressive strain in the case of urethra interaction with AMS 800 (a) and Relief (b).

Conclusions

An in silico methodology has been proposed to investigate the mechanical functionality of different AUSs. The data provided are mandatory for the actual reliability assessment of AUS devices.

References

1. Natali et al, Int J Numer Method Biomed Eng, 36:e3308, 2020.
2. www.reliefsrl.com

Acknowledgements

This work was supported by European Community, Project FF4EuroHPC, Experiment HERO, and by University of Padova, Project FONT_BIRD2020_01 AUS-DEV.