

# WHAT INFLUENCE DOES THE GEOMETRY OF THE ARTIFICIAL URINARY SPHINCTER HAVE ON THE RISK OF URETHRAL DAMAGE?

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## Introduction

Artificial Urinary Sphincters (AUSs) are prosthetic devices for the treatment of urinary incontinence secondary to sphincteric deficiency. The operating principle can be based on several mechanisms [1] and allows to occlude the urethral lumen ensuring the continence condition. A pressure loading is generally applied around the bulbar urethra through an inflatable cuff and no standardized methods of choice are clinically used for defining the appropriate cuff pressure and size. The long-term efficacy of an AUS has emerged related to the compatibility of the occlusive action, in terms of intensity and distribution, with the urethral tissue health. Tissue erosion and atrophy due to the cuff appear among the most critical complications after AUS implantation, requiring surgical revision [2].

For the identification of the propriety design for device durability, this work aims to evaluate the influence of geometric parameters of the AUS cuff on the stimulation of the urethral tissues through computational mechanics analyses. Models of a novel patented AUS [3] and of the bulbar urethra were developed and different cuff sizes were considered in terms of thickness and length.

## Methods

The 3D CAD model of the AUS cuff was designed as an inflatable cylindrical chamber combined with an external support band. Three different thicknesses (1, 2 and 4 mm) and two different lengths (8.5 and 17 mm) were considered for the chamber to evaluate the impact of the geometry on the performance of the device. An elastomer was assumed composing the AUS and defined through an hyperelastic formulation. On the other hand, the urethral model was developed with a simplified elliptical lumen and mechanically described through a previously identified hyperelastic formulation [4].

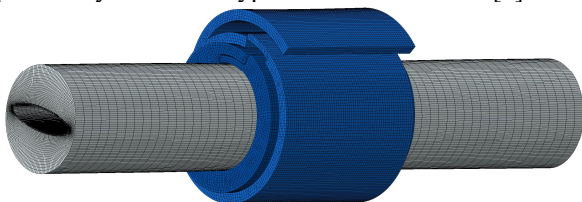


Figure 1: Cuff model (in blue), designed by thickness of 2 mm and length of 17 mm, in interaction with the urethral model (in grey).

Models were FE discretized and assembled (Figure 1) by defining the interaction through hard contact in the normal direction and through penalty approach in the tangential one. Computational mechanics analyses

simulated the lumen occlusion through the inflation of the AUS chamber up to 80 cmH<sub>2</sub>O pressure, by means of Abaqus/Explicit 6.14 non-linear dynamic solver.

## Results

Cuffs of different thicknesses involved a different distribution of the occlusive action on the urethra. In reference to the greater length, compressive strain results within the maximum stimulated urethral section are reported in Figure 2. Thicker cuffs exhibited a higher prevalence of strain values in the range 70-80 %, which may induce tissue degenerative phenomena. Similarly, the length of the cuff showed to influence the mechanical stimulation of urethral tissues.

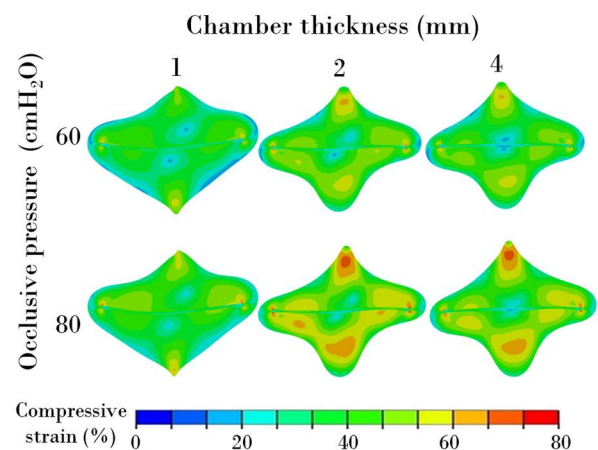


Figure 2: Contours of compressive strain by varying the chamber thickness and the occlusive pressure.

## Discussion

Computational techniques provide valuable tools for designing AUS by enabling the evaluation of the interaction between the device and the biological tissues based on the biomechanical compatibility.

## References

1. Toniolo et al, Artificial Organs,00: 1-23, 2022.
2. Ortiz et al, J Biomech Eng, 204:1027-1032, 2020.
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4. Natali et al, Exp Physiol, 101:641-656, 2016.

## Acknowledgements

This work was supported by MIUR, FISIR 2019, Project n° FISIR2019\_03221 (CECOMES: CEntro di studi sperimentali e COmputazionali per la ModEllistica applicata alla chirurgia) and by University of Padova, Project FONT\_BIRD2020\_01 "Characterization of Artificial Urinary Sphincters for the identification of new DEvices (AUS-DEV)".

