A COUPLED EXPERIMENTAL-COMPUTATIONAL METHOD TO STUDY THE PERFORMANCE AND RELIABILITY OF ARTIFICIAL SPHINCTERS

Maria Vittoria Mascolini (1), Ilaria Toniolo (1), Fabrizio Vittadello (2), Giacomo Sarzo (2), Chiara Giulia Fontanella (1,3), Emanuele Luigi Carniel (1,3)

1. Department of Industrial Engineering, University of Padova, Italy; 2. Padova University Hospital, Padova, Italy; 3. Centre for Mechanics of Biological Materials, University of Padova, Italy

Introduction

Artificial sphincters (ASs) are devices designed to restore the control of opening/closing bodily passages for the flow of biological substances, addressing issues like gastroesophageal reflux disease, urinary and fecal incontinence [1]. Despite their widespread clinical use, suboptimal outcomes are reported concerning the response of the biological tissues to the AS's permanent and non-physiological mechanical action, leading to degenerative phenomena like atrophy and erosion [1,2,3]. Traditional AS approval procedures involve experimental tests on cadavers or animals and clinical trials to collect clinically meaningful information related to the AS effectiveness. Investigative methods to assess the actual performance and reliability of the AS are not at disposal. This work proposes a coupled experimental-computational procedure to develop tools for evaluating AS functionality focusing on the mechanical interaction between the device and biological tissues, aiming to increase the application field of the ASs and minimize the surgical revisions after their implantation.

Methods

The procedure is designed by assuming the AS's performance and reliability as key functional characteristics. It applies to a specific category of ASs, with the same application and similar conformation but different geometric dimensions and constituent materials. Performance, defined as the AS's ability to guarantee adequate organ lumen occlusion, is evaluated through both experimental and computational methods. A custom-built *in vitro* test bench allows to apply the action of an effective AS to a tissue-mimicking phantom, monitoring intraluminal pressure levels and lumen occlusion in fluid-dynamic conditions. Measurements entail the relationship between AS action and the intraluminal pressure that leads to lumen opening.

Additionally, 3D finite element models of the AS and the tissue region, described by mechanical hyperelastic formulations from experimental investigations, are developed and assembled with specific contact strategies. Computational analyses (Abaqus Explicit 2022-2023) simulate the lumen occlusion under different AS actions and then, keeping constant the occlusive load, an intraluminal pressure is progressively increased up to the lumen opening. These simulations allow to evaluate not only the performance of the AS, but also its reliability by quantifying the tissue mechanical stimulation induced by the device.

Results

By experimental tests, the performance of a real AS is evaluable based on the pressure and flow measurements, considering the effective geometry and constituent materials. Computational analyses broaden the AS category by changing material constitutive parameters and geometrical features and quantifying their influence on functionality. The evaluation involves determining the lumen opening pressure corresponding to AS occlusive action and identifying the area under the lumen opening pressure-occlusive pressure curve as the performance parameter. Meanwhile, AS reliability is evaluated by the intensity and distribution of mechanical fields potentially responsible for vasoconstriction and tissue damage (such as, compressive strain and stress). A comprehensive assessment visualizes reliability parameters plotted against performance parameters, highlighting material and geometrical properties that maximize device functionality (Figure 1).

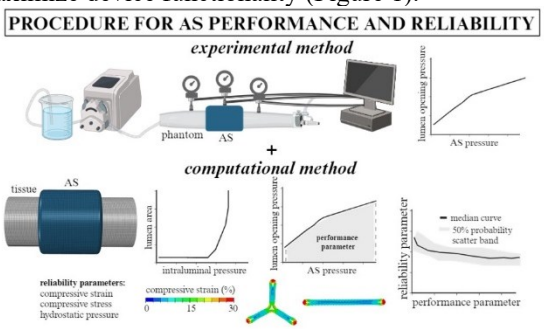

Figure 1: Scheme of the developed procedure for the evaluation of AS reliability and performance.

Discussion

The method is endowed with great flexibility for different categories of ASs, widening analyzable device configurations and minimizing the experimental and ethical efforts. In the context of clinical-surgical practice and biomedical industries, it provides novel support tools for the optimization of AS functionality.

References

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