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To cite this version:

Mohamed Dieng, Alexandre Trezel, Armand Chevrot, Grégory Chagnon, Sandrine Voros. Development of a biomechanical model and design of a realistic phantom for the evaluation of an innovative medical vacuum hemostasis device for the treatment of benign prostatic hyperplasia. Surgetica 2017, Nov 2017, Strasbourg, France. hal-01872403v2

HAL Id: hal-01872403
https://hal.science/hal-01872403v2

Submitted on 31 Jan 2019

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Development of a biomechanical model and design of a realistic phantom for the evaluation of an innovative medical vacuum hemostasis device for the treatment of benign prostatic hyperplasia

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This work aims at designing a prototype of a prostate phantom and at creating a 3D geometric model of the organs of the pelvic region. This investigation is part of the preclinical study of a treatment of bleeding after transurethral resection of a prostate (TURP).

The prototype of this transparent prostate phantom was made with the combination of two materials: a RTV (Room Temperature Vulcanization) silicone and a two-component PDMS (polydimethylsiloxane). Bleeding in the area of prostate resection was represented.

The biomechanical model geometry is based on the geometry of the pelvic organs generated from MRI (magnetic resonance imaging) images. The shape of the pelvic organs and the kinematic boundary conditions have helped to establish the relevance of the geometric model.

1 Introduction

Researchers and clinicians from the university hospital of Grenoble have developed a new technique based on depressed hemostasis to prevent severe bleeding. This led to the emergence of a range of new clinical devices in clinical areas such as cardiac and thoracic surgery, ENT (ear, nose and throat) surgery and obstetrics [1].

In urological surgery, Transurethral Resection of Prostate (TURP) is the reference treatment for benign prostatic hyperplasia (BPH) with 70,000 interventions performed each year in France [2]. This minimally invasive procedure involves the trans-urethral removal of part of the adenoma in the prostate to reconstruct a canal and allow the urine to be evacuated more easily. The haemostasis performed during the operation is not sufficient to stop the bleeding permanently. This major complication can lead to consequences such as long-term blood transfusions, surgical re-interventions and lengthening of hospital stay. Until now, there is no medical device to effectively stop bleeding after a TURP.

To fill this gap, a new device based on vacuum hemostasis was developed [1]. In view of future clinical trials, pre-clinical evaluations are mandatory. However, there is no animal model sufficiently close to the human anatomy and the pathology targeted by the application. Similarly, human anatomical models will not allow to fully evaluate the device because of the absence of bleeding. There is therefore a strong need to develop a finite-element biomechanical model and to design and implement a scientific test bench for realistic preclinical evaluations to evaluate the performance of the new hemostasis device.

2 Materials and Methods

- ### Biomechanical model geometry

The 3D model of the prostate environment was obtained by segmenting a MRI undergone by a TURP patient the day after surgery, with the urinary catheter in place. The latter is left in place for 2 days depending on the progress and recommendations of the surgeon. This 70-year-old patient underwent the bipolar-TURP technique. These images were performed the day after the surgery. ITK-Snap (version 3.6.0) was used for segmentation. Semi-automated segmentation was performed. All structures in contact with the prostate were segmented.

- ### Test bench

The test bench was developed to mimic the male post TURP urogenital anatomy. Its design is based on the molding of elastomeric materials (Silicone RTV EC00 and Wacker SilGel 612), selected because their elasticity is similar to that of human tissue [3]. Mechanical tests on the elastomers composing the phantom were carried out in order to compare their mechanical properties to measurement of the prostate found in the literature. The moldings were made using 3D printed molds. In particular, the prostate was created from the segmentation of MRI images to obtain realistic shapes, and a "virtual" resection was performed on the model to represent the prostate post TURP. The Phantom was made transparent so as to be able to observe at best what is happening in the area of resection. In order to simulate bleeding, a capillary network was molded in the prostate. This network consists of a degradable ABS (Acrylonitrile butadiene styrene) wire introduced during molding and then disintegrated. A pump connected to tubing allows to inject a fluid directly into the network to create haemorrhages. The phantom is molded in a Plexiglas frame. A cable gland at the entrance of the urethra provides a seal after insertion of a urinary catheter.

3 Results and Discussion

- **Biomechanical model geometry**

This geometric model is volumetric and represents seven distinct bodies that are potentially in contact: prostate, bladder, rectum, pubis, levator ani muscle, pub- prostatic ligament and pelvic floor (cf. Figure 1).

This model can be judged satisfactory since it has confirmed the feasibility of creating 3D geometries of pelvic organs from MRI images. In addition, this model reflects the reality, in particular with regard to the geometry and dimensions of the resected prostate. According to the opinion of a urologist, the kinematic boundary conditions are respected. The contacts will be managed later for a better simulation of the interaction between this gland and the other organs.

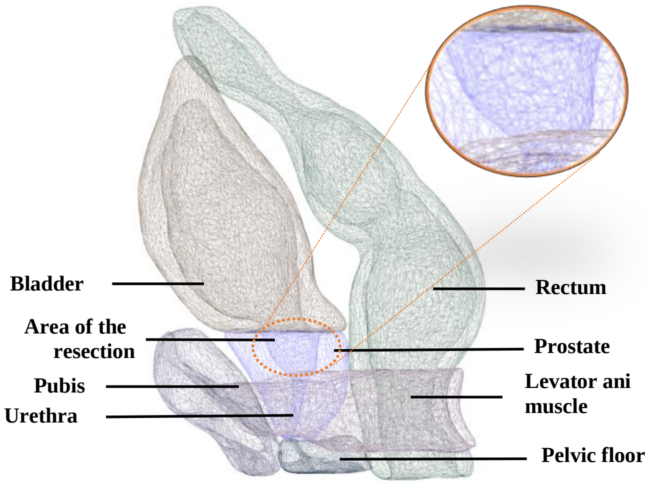

Figure 1: 3D model created

- **Test bench**

This first test bench consists of two parts: a prostate phantom with a capillary network and a surrounding environment including the urethra and the bladder (cf. Figure 2). The prostate phantom reproduces pearlescent (diffuse) hemorrhages in the resection lodge. The surrounding environment is more flexible than that used for the prostate, according to our clinical partner. The transparency of the phantom is sufficient to distinguish the prostate and its internal network. The bladder is open and can be filled with a liquid for testing.

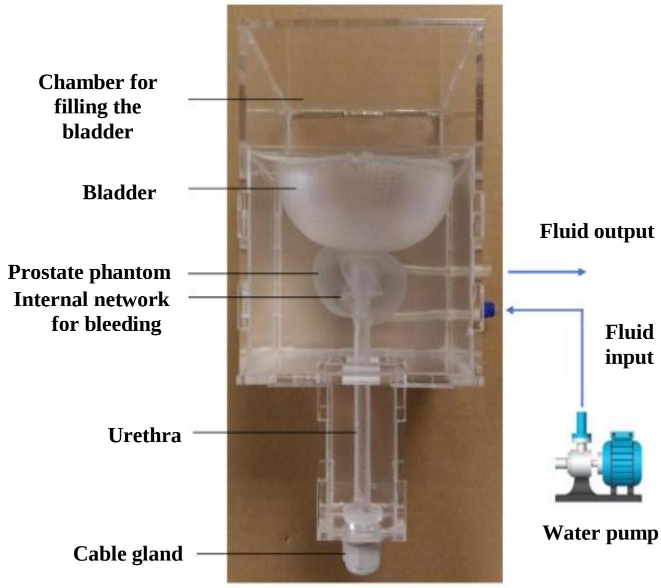

Figure 2: First prototype of the test bench

4 Conclusion

The purpose of this design and modeling work is to conduct a feasibility study. The first prototype of test bench developed in this study is quite satisfactory, but it needs to be improved by making it more complete, more realistic and instrumented. The objective of the biomechanical model, in the long term, is to implement a finite element simulation which will allow to estimate the pelvic configurations to follow the movements and deformations of the prostate. The mechanical behavior of each organ will be identified by appropriate mechanical tests. After validation of the simulations, evaluation and improvement of the new device of hemostasis by depression will be initiated.

Funding/Support and role of the sponsor:

This work was supported by French state funds managed by the ANR within the Investissements d'Avenir programme **Labex CEMAM** under reference ANR-10-LABX-44-01 and **Labex CAMI** under reference ANR-11-LABX-0004.

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