Optimization of the Aritificial Urinary Sphincter: Modelling and Experimental Validation

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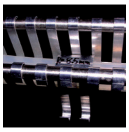
INTRODUCTION



Stress urinary incontinence (SUI) is defined as the uncontrolled loss of urine due to stress manoeuvres such as coughing or sport activities. It is a relevant social and clinical problem of senior people or patients after prostate resection. Severe SUI may be treated with an artifitial urinary sphincter. Often the AMS 800™ (American Medical Systems, Mennetonka, Minnesota, USA) is used. In a significant number of cases, however, the mechanically driven device has led to mechanical and non-mechanical failures. Therefore, it is highly desirable to find alternatives with optimized sphincter geometry. In this study, an empirical three-parameter model is presented for the description of the response of the urethra to the pressure of artificial sphincters and for the determination of the optimized sphincter geometry in the steady state conditions. The model is verified with in vitro experiments.

COMPRESSION MODEL

The urethra consists of anisotropic, visco-elastic tissue exhibiting an inner diameter of about 5 mm and an outer one of about 15 mm. As a rough approximation one can assume that the leakage starts, when the external sphincter pressure equals the vesical pressure. The tissue of the urethra, however, can act against or with the external pressure. This means that a higher or lower external pressure is necessary to close the urethra. This difference arises from the wall pressure p_W along the sphincter length L and from the stress of the urethra at both ends characterized by the rim force F_R. Since the inner part of the urethra can be closed on the length, which is smaller or larger than the sphincter length L, we introduce the rim length L_R present on both sides of the aluminium sphincter.

The urethra becomes closed if the external force is at least equal to the sum of the forces as the result of the vesical pressure p_{ves}, the wall pressure p_W, and the rim forces F_R:

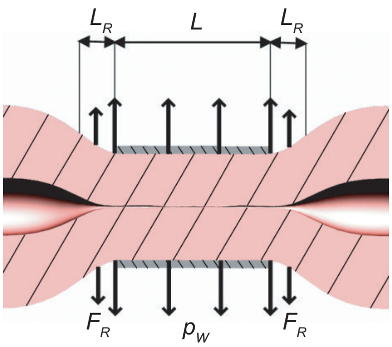
$$F_{ex} = (p_{ves} + p_W)\, A_{in} + 2F_R$$

A_{in} is the effective surface of the sphincter along the urethra $A_{in} = 2R*(L+2LR)$, whereby L is the length of the aluminium sphincter and R its radius. Therefore, one obtains for the external pressure p_{ex}:

$$p_{ex} = (p_{ves} + p_W)\left(1 + 2\frac{L_R}{L}\right) + \frac{F_R}{RL}$$

For the balance at the leak point, p_{ex} corresponds to *euLPP* and p_{ves} to *vLPP* and, consequently, the urethra compression model gives rise to:

$$euLPP = (vLPP + p_W)\left(1 + 2\frac{L_R}{L}\right) + \frac{F_R}{RL}$$

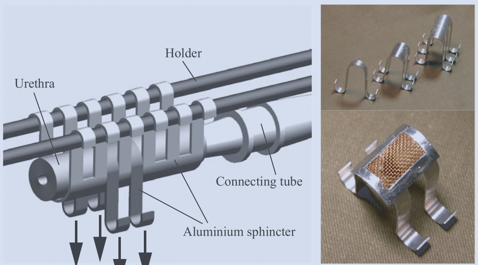


The sphincter of length L compresses circularly the urethra as illustrated by the schematic cross section. The external pressure acts against the urethral wall formally divided into the force along the sphincter ($p_W A$) and the rim force F_R and can close the urethra on the length $L+2L_R$.

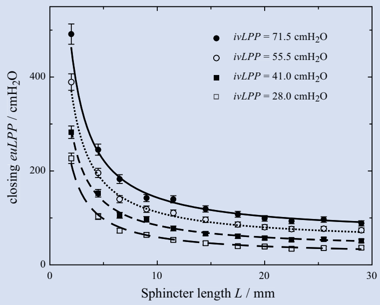
ALU SPHINCTER

To verify the urethra compression model, sphincters of different length are made. They consist of two identical halves of the pipe made of aluminium with the diameter that the urethra can be placed in between. The pressure to close the urethra is applied to the upper half of the pipe using the gravity of water in a suitable bottle. Thus, the vertically exerted pressure is constant along the urethra and perpendicular to the sphincter wall, if the urethra behaves liquid-like. Then, the urethra is compressed circularly as in the in vivo situation.

The urethra compression model combines *euLPP*, *vLPP*, and *L*. The 3 parameters p_W, L_R and F_R are to be determined performing experiments. To measure *euLPP* for given *vLPP* and *L*, the external pressure can be reduced taking out water from the bottle until the onset of leakage. Hence, *euLPP* can be quantified point-wise as the function of *L* and *vLPP*. These two series of measurements are applied to fit the parameters.



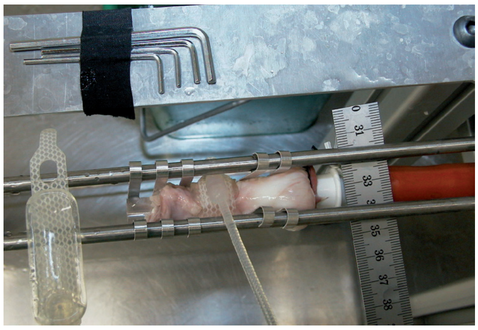
The aluminium sphincter is designed for the experiments to determine the optimised sphincter length. (a) 3D scheme of the urethra embedded between the two halves of the aluminium sphincter. (b) Picture of elements of the aluminium sphincter.



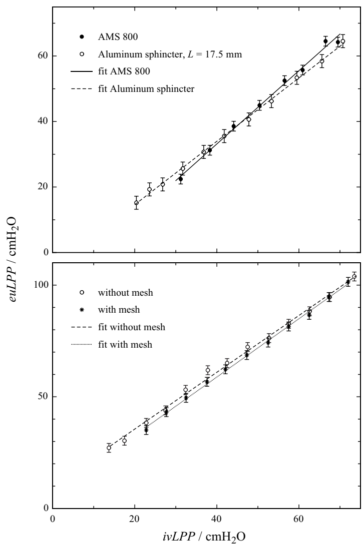
euLPP as the function of *L* for 4 physiologically relevant bladder pressures show the behaviour predicted by the urethra compression model.

AMS 800 EXPERIMENTS

The muscles of the sphincter and the M. detrusor surround the urethra. In general, the urethra is closed. Moderate expansions of the muscles open the urethra. The cuff (cp. AMS 800) can simulate this valve-like behaviour. In these experiments, the closure pressure of the cuff was generated with a water reservoir hold on a certain level, leading to a hydrostatic pressure.



The sow urethra is closed with a cuff. The urethra-sphincter system is fixed in a holder.



The *euLPP* as a function of *LPP* for the pressure range investigated exhibits a perfectly linear behaviour for the cuff (AMS 800) and the 17.5 mm-long aluminium sphincter (upper part).

CONCLUSION AND ACKNOWLEDGEMENT

The three-parameter model is adequate to describe the mechanical properties of the urethral tissue: The longer the artificial sphincter is, the higher is the force and the lower is the pressure needed to guarantee continence. However, long sphincters should be avoided to spare the urethral tissue. The optimized sphincter length of human urethras is (17.3 +/- 4) mm.

The urethra compression model was experimentally validated with both the specially designed aluminium sphincter and the AMS 800™.

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