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Optimization of the artificial urinary sphincter: modelling and experimental validation

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Abstract

The artificial urinary sphincter should be long enough to prevent strangulation effects of the urethral tissue and short enough to avoid the improper dissection of the surrounding tissue. To optimize the sphincter length, the empirical three-parameter urethra compression model is proposed based on the mechanical properties of the urethra: wall pressure, tissue response rim force and sphincter periphery length. *In vitro* studies using explanted animal or human urethras and different artificial sphincters demonstrate its applicability. The pressure of the sphincter to close the urethra is shown to be a linear function of the bladder pressure. The force to close the urethra depends on the sphincter length linearly. Human urethras display the same dependences as the urethras of pig, dog, sheep and calf. Quantitatively, however, sow urethras resemble best the human ones. For the human urethras, the mean wall pressure corresponds to (-12.6 ± 0.9) cmH_2O and (-8.7 ± 1.1) cmH_2O, the rim length to (3.0 ± 0.3) mm and (5.1 ± 0.3) mm and the rim force to (60 ± 20) mN and (100 ± 20) mN for urethra opening and closing, respectively. Assuming an intravesical pressure of 40 cmH_2O, and an external pressure on the urethra of 60 cmH_2O, the model leads to the optimized sphincter length of (17.3 ± 3.8) mm.

1. Introduction

The urinary sphincter muscle ensures continence during the filling phase of the bladder. Sphincter abnormalities lead to stress urinary incontinence (SUI), which is defined as involuntary loss of urine during coughing, sneezing or any other kind of related physical exertion. In severe cases, it presents as continuous loss of urine (Blaivas *et al* 1997). In men, sphincter abnormalities are most commonly caused by anatomic disruption after radical prostatectomy for prostate cancer in 5 to 30% (Peyromaure *et al* 2002) or, occasionally, by trauma or neurological disorders.

Currently used treatment options for severe urinary incontinence are injections of bulking agents into the urethra (Elsergany *et al* 1998, Tiguert *et al* 1999), implantable pressure devices like different sling procedures (Nilsson 1998, John 2004) and artificial urinary sphincters (Litwiller *et al* 1996, Elliott *et al* 1998), which have achieved the most frequent use in the treatment of post-prostatectomy SUI. The currently used artificial urinary sphincter model is the urinary control system AMS 800^{TM} (American Medical Systems, Minnetonka, Minnesota, USA). The AMS 800^{TM} consists of cuff, pump, reservoir and flexible connecting tubes. The device is designed to be placed around the bulbar urethra or bladder neck and to provide an increase in outlet resistance via compression of the urethral or bladder neck cuff by transferring fluid from the reservoir into the inflatable cuff. Activating the pump by deflating the cuff enables voiding, and the cuff inflates again automatically to restore continence (Barrett and Licht 1998). In a significant number of cases, however, the mechanically driven device has led to mechanical and non-mechanical failures. Especially urethral atrophy and erosion remain crucial so that the techniques are constantly improved and revised (Mourtzinos *et al* 2005). The system has further disadvantages. First, the geometry of the AMS 800^{TM}, i.e. the length and the diameter, is given by the producer and cannot be adapted after implantation. Second, the cuff pressure has to be determined during implantation and is, therefore, fixed. In severe SUI, the surgeon can implant a second cuff next to the first one, which is only connected by an additional tube. This double cuff is said to ensure continence, because a longer part of the urethra is compressed (Brito *et al* 1993, Kowalczyk *et al* 1996, O'Connor *et al* 2003). A recent *in vitro* study (Marti 2004) demonstrates that if there is a gap between the two cuffs, such a procedure has no benefit. Consequently, it is highly desirable to find alternatives with optimized sphincter geometry.

From the engineering point of view, the urinary sphincter acts as the valve. It is usually closed and opens for an appropriate period of time to pass water. In order to close the urethra against the bladder pressure, a well-defined pressure on the urethra along a certain length has to be applied. Lower pressures lead to incontinence. The pressure on the urethra, produced by the artificial urinary sphincter device, and the length of the pressure device determine the risk of erosion and atrophy, because the compressed tissue can become insufficiently supplied. The pressure to close the urethra depends on the sphincter geometry. Longer sphincter devices reduce the pressure. Therefore, we conclude that an optimized length for the sphincter exists.

In this paper, 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, i.e. ignoring the continuous changes in the bladder pressure. The applicability of the model is demonstrated by performing *in vitro* experiments with explanted human and animal urethras.

2. Experimental details

2.1. Definitions of urethral and intravesical pressures

The urinary bladder produces the pressure acting to open the urethra, which is usually termed *intravesical pressure*. To reach continence, the sphincter has to generate a sufficiently high force, which is related to the *external pressure*. This pressure is acting externally on the urethra. For the AMS 800^{TM}, the pressure of the liquid within the cuff causes this external pressure. In the present study, we are interested in the leak-point. In most cases, the *intravesical leak-point pressure* (ivLPP) is defined as the lowest intravesical pressure required for leakage with Valsalva manoeuvre or cough (Weber 2001). For the *ex vivo* experiments, as an alternative to increase the intravesical pressure, one can keep the intravesical pressure constant and reduce the external pressure. The value for the external pressure, when the sphincter opens, is termed the *external urethral leak-point pressure* (euLPP). This value is significantly lower than the pressure to close the open urethra increasing the external pressure. Consequently, we distinguish between the *closing* and the *opening* euLPP.

2.2. Simulation of the intravesical pressure

The intravesical pressure was simulated using the fluid reservoir. The vertical tube, 10 cm in diameter, can be filled with the fluid up to the level of 100 cm. The transparent hosepipe was applied to control the level in the tube between 10 and 100 cm. The pump continuously compensated the loss of fluid during the experiment. Consequently, the fluid generated a constant, hydrostatic pressure simulating the intravesical pressure. The fluid used for the experiments shown was water with different salt concentrations. It should be noted that for the *in vitro* experiments, pure water could be used instead of water with salt concentrations up to 12% or even human urine, since the friction increase as a result of the viscosity change is smaller than the related error bars.

As an alternative, we used a conventional infusion bottle positioned at the height chosen to generate the hydrostatic pressure applied during the experiment. The infusion tube connected the bottle with the urethra.

2.3. Urethras used

Since the production of artificial urethras, which represent the mechanical properties and variances of the *in vivo* situation, is difficult (e.g. Allaire and Reynolds 1991), the experiments are based on explanted animal and human urethras. Explantation and handling of the different urethras were performed according to the local regulations and the ethical guidelines. The behaviour of the human urethras explanted a few hours after the death of male patients (age 35 to 70 years, $n = 3$) is compared with the ones explanted from domestic feeding pigs (sows: $n = 9$ and boars: $n = 6$), dog ($n = 1$), calf ($n = 1$) and sheep ($n = 1$). The relatively high number of sow urethras was chosen because of their anatomical and functional similarities to the urinary tract of humans (Melick *et al* 1961, Mokhless *et al* 1988). Especially the voiding behaviour and the mechanisms underlying continence appear to be very similar for female pigs and humans, although the urethral anatomy is somewhat different (Dass *et al* 2001). The urethras from sow and boar are easily distinguished as a result of their different geometries, mechanical behaviour and appearance. While the sow urethras with a length of about 80 mm and a diameter of about 12 mm exhibit a white appearance, the stiffer and more heterogeneous boar urethras have diameters of about 16 mm and lengths of about 150 mm, and are red due to the higher amount of muscle. Therefore, the sow urethras qualitatively resemble the human ones best. The pigs with an age of 6 months weighed between 80 and 100 kg.

To keep the experiments rather simple, the urethras were tested in air at room temperature. We are aware that the behaviour of the explanted urethras can significantly differ from the *in vivo* situation, since blood flow and pressure are absent. In addition, the compression cycles by the sphincter can further alter the mechanical properties of the urethra. Finally, the experiments are performed at room temperature in ambient air and not at the human body temperature of 37 °C in physiological environment. To determine the potential changes of the mechanical properties of the urethras as a result of repeated cycles of loading and storage, we repeated the experiments several times.

The urethras were connected to the fluid reservoir by the use of a conventional tube and clamped with a wire. The specially designed aluminium holders kept the urethras exactly in a horizontal position.

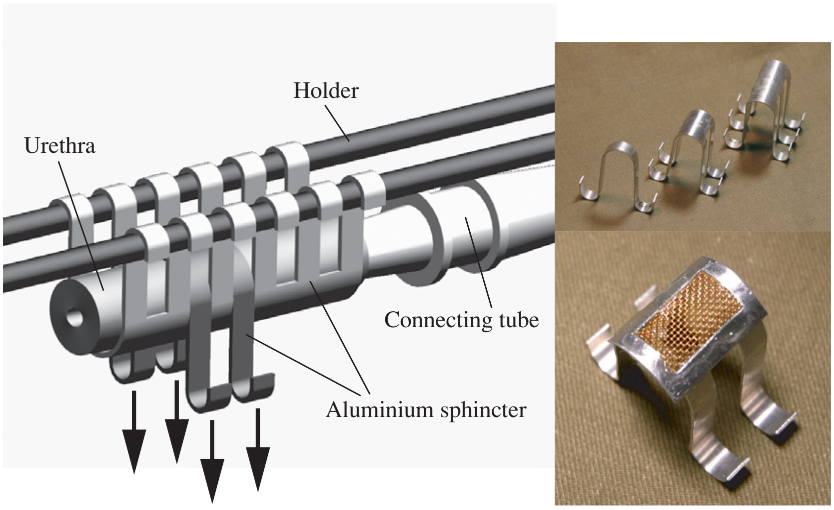

Figure 1. 3D scheme of the urethra embedded between the two halves of the aluminium sphincter in a horizontal position for the *in vitro* experiments. The bottle to be connected with the upper half of the sphincter can be filled with water to generate the well-defined euLPP indicated by the arrows. The set of aluminium sphincters is designed for the *in vitro* experiments to determine the optimized sphincter length. The photographs show a selection of the aluminium parts for the artificial sphincters with and without a mesh as used for the *in vitro* measurements.

(This figure is in colour only in the electronic version)

2.4. *Artificial sphincter*

The sphincter muscle surrounds the urethra. In general, the urethra is closed. Moderate expansions of the sphincter muscle open the urethra. The cuff (cp. AMS 800$^{\mathrm{TM}}$) can simulate this valve-like behaviour. Such a cuff, however, has several disadvantages, especially in performing well-defined experiments to determine an optimized sphincter length. The pressure along the interface of cuff and urethra is non-uniform, e.g., due to wiggles (Hajivassiliou and Finlay 1999) formed. The change of the external pressure within the cuff further alters the forces along the interface. Consequently, an alternative has to be developed, which shows the almost identical behaviour to the AMS 800$^{\mathrm{TM}}$ cuff within the clinically relevant range of pressures, but provides a well-defined, uniform pressure along the interface sphincter-urethra. Such a sphincter for *in vitro* experiments may consist of two identical halves of the pipe made of a rigid material such as aluminium with the diameter where the urethra could be placed in-between (see figure 1). As shown in figure 1, the aluminium part with a length of 95 mm is attached to the holder and carries the explanted urethra in a horizontal position. The counterpart has the same cross section, but is shorter and, therefore, determines the length of the aluminium sphincter. For the *in vitro* experiments, sets of these aluminium-sphincters, 0.5 mm thick, are manufactured with lengths between 2 and 29 mm (2.0, 4.5, 6.5, 9.0, 11.5, 14.5, 17.5, 20.0, 22.5, 25.5 and 29.0 mm) and radii of 5.5, 7.0 and 8.5 mm. The radii at the ends of the aluminium parts correspond to 3 mm. The length between the two curved zones is about 18 mm. These ‘legs’ are 4.5 mm wide with a distance of 5.5 mm to avoid tilt and friction. The pressure to close the urethra is applied to the shorter aluminium part using the gravity of water in a suitable bottle. Water was removed or added with the help of a 60 ml syringe. Thus, the vertically exerted pressure is constant along the urethra and perpendicular to the sphincter

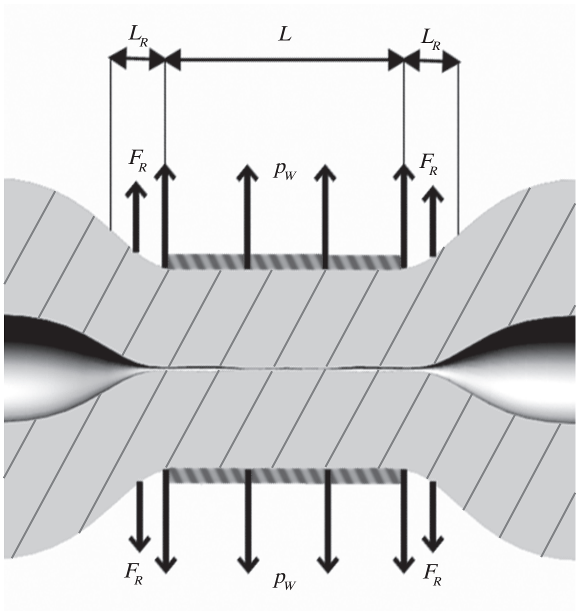

Figure 2. The sphincter of length L compresses circularly the urethra as illustrated by the schematic cross section. The external pressure acts against the urethral wall formally divided into the force along the sphincter ($p_W \cdot A$) and the rim force F_R, and can close the urethra on the length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

wall if the urethra behaves liquid-like, a reasonable assumption as shown by Griffiths (1985). Therefore, the urethra is compressed circularly as in the *in vivo* situation.

For the *in vitro* experiments, two 50 mm cuffs of the AMS 800^{TM} were used, which have a sphincter length of about 17.5 mm and give rise to a radius of less than 7 mm. The pressure within the cuff was realized by the hydrostatic pressure, which was generated using a reservoir positioned at the related height. Tubes connected the reservoir with the cuff.

2.5. Urethra compression model

The human urethra consists of anisotropic, visco-elastic tissue exhibiting an inner diameter of about 5 mm and an outer one of about 12 mm. As a rough approximation, one can assume that the leakage starts when the external sphincter pressure equals the intravesical 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 equally present on both sides of the aluminium sphincter (see figure 2). This empirical model, termed *urethra compression model*, contains three parameters, which can be positive and negative, respectively, to be determined on the basis of well-defined experiments. In our approximation, we assume that the three parameters are independent of each other, constant within the relevant *in vivo*-like situations for all sphincter lengths and intravesical pressures, and equally present at both ends (distal and proximal).

The external (or sphincter) force F_{ex} corresponds to the external pressure p_{ex} times the sphincter surface perpendicular to the force vector $A_{ex} = 2RL$. The urethra becomes closed if the external force is at least equal to the sum of the forces as a result of the intravesical pressure p_{ves}, the wall pressure p_{W} and the rim forces F_{R}.

$$F_{\mathrm{ex}} = (p_{\mathrm{ves}} + p_{\mathrm{W}}) \cdot A_{\mathrm{in}} + 2F_{\mathrm{R}}. \tag{1}$$

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

$$p_{\mathrm{ex}} = (p_{\mathrm{ves}} + p_{\mathrm{W}}) \cdot (1 + 2L_{\mathrm{R}}/L) + F_{\mathrm{R}}/RL. \tag{2}$$

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

$$\mathrm{euLPP} = (\mathrm{ivLPP} + p_{\mathrm{W}}) \cdot (1 + 2L_{\mathrm{R}}/L) + F_{\mathrm{R}}/RL. \tag{3}$$

The equation combines euLPP, ivLPP and L. The radius R is held constant. The three parameters p_{W}, L_{R} and F_{R} are to be determined on the basis of the *in vitro* experiments. It should be noted that equation (3) yields for the optimization of the three parameters one unique solution. Equation (3) can be rewritten as

$$\mathrm{euLPP} - \mathrm{ivLPP} = \alpha + \beta \cdot \mathrm{ivLPP}/L + \gamma/L \tag{4}$$

with $\alpha = p_{\mathrm{W}}$, $\beta = 2L_{\mathrm{R}}$ and $\gamma = 2L_{\mathrm{R}}\,p_{\mathrm{W}} + F_{\mathrm{R}}/R$. Because of the simple linear combination, only one triplet (α, β and γ) exists, where the minimum square deviation is minimal. Consequently, also the parameters p_{W}, L_{R} and F_{R} are well defined. To measure euLPP for a given bladder pressure and sphincter length, the external pressure can be reduced by taking out water from the bottle directly acting on the artificial sphincter until the onset of leakage. Hence, euLPP can be quantified pointwise as the function of L and ivLPP. These two series of measurements are applied to fit the three parameters by the use of the Levenberg–Marquardt algorithm (Marquardt 1969) of the pro Fit code (pro Fit 5.6.4, Quantumsoft, Zurich, Switzerland).

The measurements are performed in the following way: to measure the euLPP as a function of L, we usually started with the shortest sphincter length L and increased L stepwise. To measure the euLPP as the function of ivLPP, the experiments usually started with the largest value. To rule out any influence of the sequence, selected experiments were carried out in opposite sequence. The combined fit of the two dependences to uncover the three parameters and their mean standard deviations was carried out by a rather simple program incorporated into the pro Fit code.

3. Results

3.1. Linear dependence of ivLPP and euLPP for different sphincters

According to the urethra compression model, equation (3), euLPP should be a linear function of ivLPP for a given sphincter length L, a hypothesis, which has to be proven experimentally. Figure 3 shows this linear behaviour for porcine urethras within the physiological range of pressures. In the upper part of figure 3, the cuff of the AMS 800$^{\mathrm{TM}}$ and the aluminium sphincter are compared using sow urethras. Although the slope of the fits may slightly differ, the experimental data are equivalent (cp. error bars, which are represented as the standard deviation of repeated measurements). In the lower part, the aluminium sphincter is compared with the modified one (see figure 1) using boar urethras. Here, a mesh is introduced, which could allow the diffusion of oxygen and other nutrients into the urethra tissue through the sphincter, if a similar mesh is used *in vivo*. Applying the typical external pressure of about 60 $\mathrm{cmH_2O}$ (Weber 2001), the in-growth of blood vessels is not expected although desirable. The data demonstrate that such a modification does not significantly alter the linear dependency.

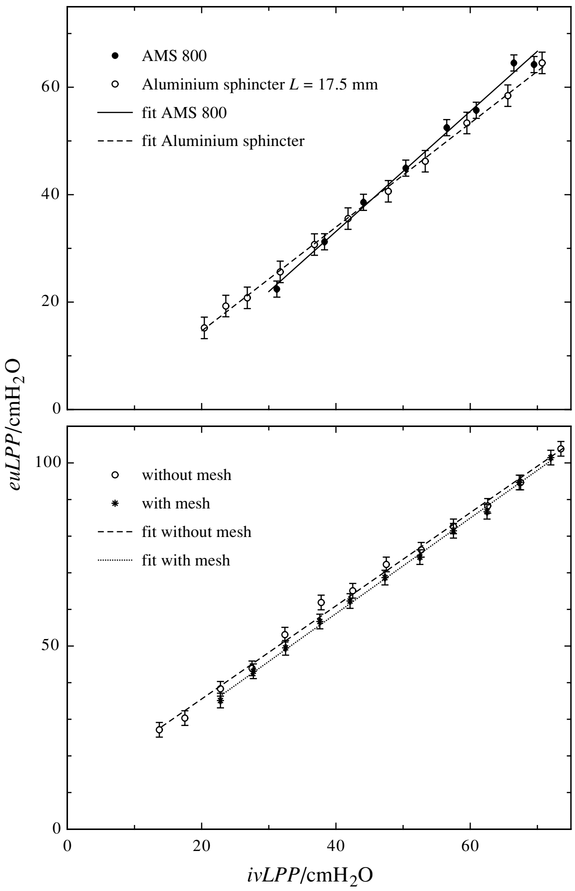

Figure 3. The euLPP as the function of ivLPP for the pressure range investigated exhibits a perfectly linear behaviour for the cuff (AMS 800^{TM}) and the 17.5 mm long aluminium sphincter (upper part) as well as for the 17.5 mm long aluminium sphincter with and without a mesh (lower part). The dependence is studied for different animal urethras (3 sows, 4 boars, 1 ram, 1 calf) and three human urethras at two different positions (distal and proximal). In the upper part, the results of a sow urethra measured at the position 6 cm to the bladder junction and, in the lower part, the ones of a boar urethra at about 10 cm to the bladder junction are exemplarily represented. The measurements were repeated for 8 and 11 times, respectively.

The data presented are obtained from different porcine urethras. The upper part of figure 3 shows experiments with one sow urethra, stored for 5 days in 2.5% saline at a temperature of 6 °C. For the experiments represented in the lower part, one boar urethra, stored for 12 days under the conditions mentioned, was used. It should be noted that due to the different mechanical properties of sow and boar urethras, the slope of the curves differs significantly.

In conclusion, for the different kinds of sphincters and urethras investigated, the euLPP is always a linear function of ivLPP, an observation, which proves the first basic assumption of the urethra compression model.

3.2. *Linear dependence of external force and sphincter length*

The urethra compression model predicts the linear dependence of the external force $F_{\mathrm{euLPP}} = \mathrm{euLPP} \cdot 2LR$ on the sphincter length L for the selected ivLPP.

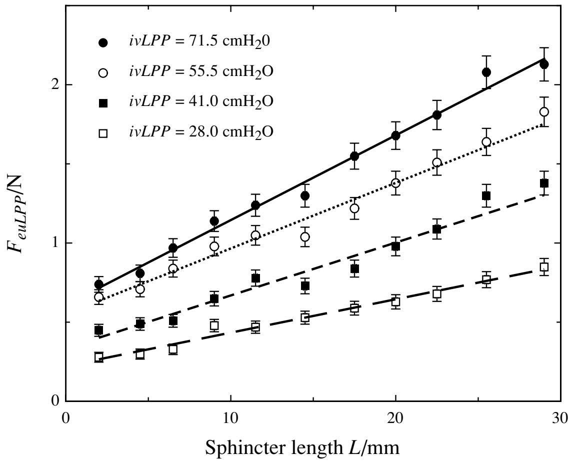

Figure 4. The F_{euLPP} as the function of the sphincter length L exhibits the predicted linear behaviour as measured for different animal urethras (4 sows, 1 boar, 1 sheep, 1 dog) and three human urethras, but only the data of human no. 1 (cp. table 1) are shown for the four selected ivLPP. A set of 11 aluminium sphincters with lengths between 2 and 29 mm was used.

$$F_{\mathrm{euLPP}} = 2R(\mathrm{ivLPP} + p_{\mathrm{W}}) \cdot (L + 2L_{\mathrm{R}}) + 2F_{\mathrm{R}}. \tag{5}$$

Using the set of 11 aluminium sphincters with lengths L between 2 and 29 mm, this linear behaviour is shown for four different ivLPP in the physiological range of bladder pressures in figure 4. The data are obtained from the freshly explanted human urethra. This linear behaviour is found for the very different human and animal (pig, dog, sheep) urethras without exception.

3.3. Fitting the parameters p_W, F_R and L_R

From the anatomical point of view, the ivLPP has to be determined by increasing the bladder pressure. For the given configuration, one can alternatively reduce the external force to find the ivLPP. Both protocols lead to the opening leak-point pressure. If the sphincter simply acts as the valve, one can also determine the ivLPP closing the urethra by increasing the external pressure. The result for closing, however, yields a larger euLPP with respect to the opening euLPP, as shown in figures 5 and 6. The linearity is still given. Therefore, the urethra compression model should be equally applicable for the closing, but gives rise to a different set of parameters (p_{W}, F_{R}, L_{R}). These parameters are extracted by the combined fitting of both dependences euLPP = f (L, ivLPP). The data and the related fits for opening and closing, respectively, are represented in figures 5 and 6 for the freshly explanted human urethra (Human 1 cp. table 1) using the set of aluminium sphincters. Thus, the three parameters of the urethra compression model reasonably describe the experimental data for both opening and closing situations. Note that the data for the closing euLPP show less scattering than for the opening euLPP, an observation valid for the entire comprehensive study.

The fitted parameters for the different urethras (pig, sheep and human) are summarized in table 1. For three human urethras, where both dependences are thoroughly measured, the following mean values for urethra opening are extracted: $p_{\mathrm{W}} = (-12.6 \pm 0.9)$ cmH_2O, $L_{\mathrm{R}} = (3.0 \pm 0.3)$ mm and $F_{\mathrm{R}} = (0.06 \pm 0.02)$ N. For the urethra closing, we found

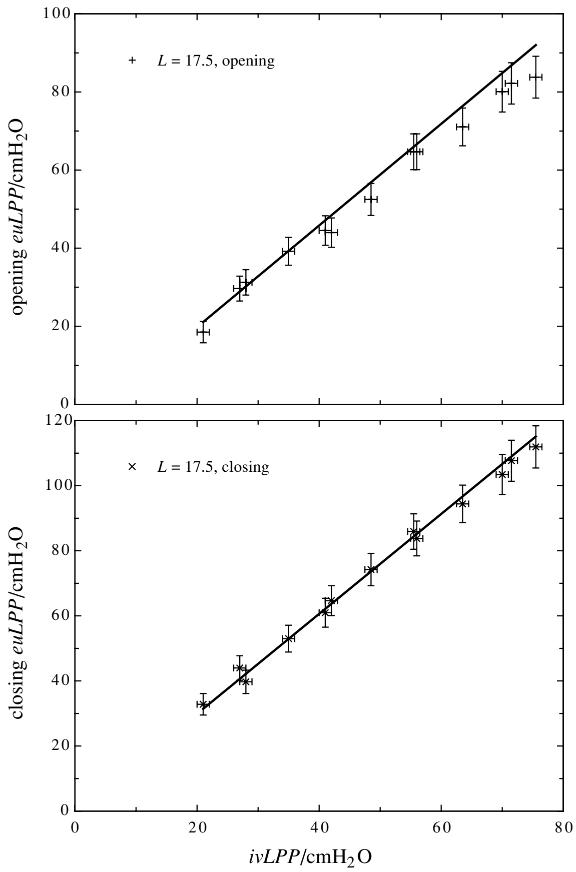

Figure 5. Opening and closing euLPP as the function of ivLPP for the 17.5 mm long aluminium sphincters exhibit the predicted dependence as shown for the urethra human 1 (cp. table 1). The closing euLPP, however, is significantly larger than the opening euLPP. Note that the scattering of the values is smaller for the closing euLPP than for the opening one. Although the slope is different for the measured animal urethras (3 sows, 4 boars, 1 ram, 1 calf) and the three human urethras, the linearity is always given.

$p_W = (-8.7 \pm 1.1)$ cmH$_2$O, $L_R = (5.1 \pm 0.3)$ mm and $F_R = (0.10 \pm 0.02)$ N. For the closing procedure, the fitted parameters p_W, F_R and L_R are always larger.

3.4. Influence of the variation of the sphincter diameter on the euLPP

One might expect that the diameter of the aluminium sphincter, $2R$, has to be precisely adapted to the urethra geometry. The nature of the urethra, which exhibits liquid-like behaviour (Griffiths 1985), however, could lead to identical results, if the diameter is slightly different. In order to identify the potential influence of the sphincter diameter to the euLPP, we have performed the experiments with a boar urethra using the sets of aluminium sphincters with $R = 7.0$ mm and $R = 8.5$ mm. Figure 7 shows the experiments after 1 day storage. Experiments with the same urethra, but after 12 days storage time, are already shown in figure 3, lower part. From these experiments, the fits shown in figure 7 are extracted. The perfect correspondence of the data with the fit is a strong indication that the mechanical behaviour of the urethra does

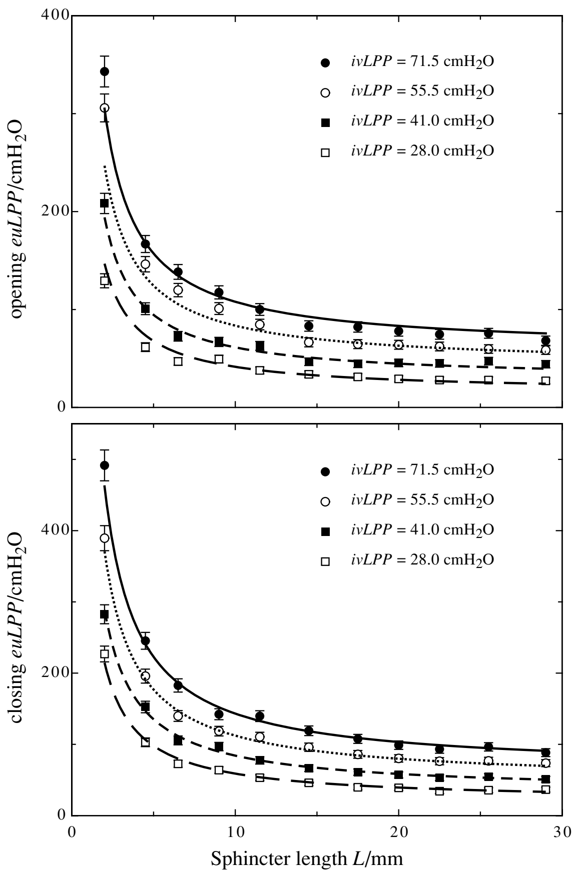

Figure 6. The opening and closing euLPP as the function of L for physiologically relevant bladder pressures show the behaviour predicted by the urethra compression model. As a typical example, the data of human 1 are shown. It should be noted that the same set of parameters (p_W, F_R and L_R) is applied for the fits in figures 5 and 6, indicating the validity of the proposed model. The results are confirmed by *in vitro* experiments using different animal urethras (4 sows, 1 boar, 1 sheep, 1 dog) and two additional human urethras.

not significantly change during storage times of up to 2 weeks. Differences in the *in vitro* experiments are only seen for quite short lengths of the artificial sphincter, which are clinically irrelevant. Even more important, the experiments demonstrate that there is no difference in euLPP, if the sphincter diameter is varied by a value as high as 20%, valid for both opening and closing situations, respectively.

4. Discussion

On the one hand, the artificial sphincter has to be as long as possible to reduce the external pressure of the bulbo-urethral device, which guarantees an acceptable degree of continence, and thereby to minimize the risk of urethral erosion and atrophy. On the other hand, the length must be kept as small as possible to avoid large surgery, which interferes, e.g., with the blood supply of the urethra. Furthermore, the implant that is too large might cause

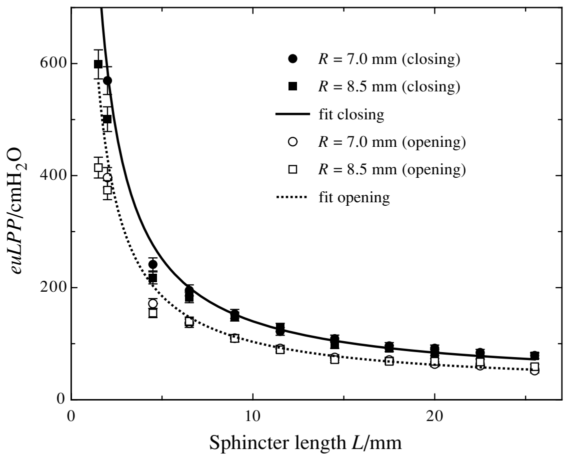

Figure 7. The opening and closing euLPP as the function of L for ivLPP = 42.9 $\mathrm{cmH_2O}$ for two different sphincter diameters at the same boar urethra show that the choice of the diameter of the sphincter is not critical and that the mechanical properties of the urethra are almost constant during the storage in 2.5% saline solution for many days.

Table 1. The parameters of the urethra compression model for different urethras including an optimized sphincter length L_{opt}. The grey-shaded boxes describe the closing ivLPP, whereas the blank boxes are related to the opening ivLPP. 'd3a' and 'd3b' are two subsequent measurements of the same urethra at a distal position (about 11.5 cm from the bladder junction) after 3 days storage time. 'p9' and 'p13' are also measurements of this urethra at proximal position (about 2.5 cm from the bladder junction) after 9 and 13 days storage time, respectively. The other numbers of the urethras mark different animals and humans.

	$-p_{\mathrm{W}}$ ($\mathrm{cmH_2O}$)	F_{R} (N)	L_{R} (mm)	R (mm)	L_{opt} (mm)
Boar d3a	16.2 ± 1.8	0.28 ± 0.03	1.4 ± 0.3	7.0	13 ± 3
	15.9 ± 2.2	0.45 ± 0.04	2.3 ± 0.3	7.0	21 ± 4
Boar d3b	13.4 ± 1.3	0.25 ± 0.02	1.6 ± 0.2	7.0	13 ± 3
	13.1 ± 1.6	0.41 ± 0.03	2.3 ± 0.3	7.0	22 ± 5
Boar p9	24.3 ± 1.2	0.44 ± 0.02	4.2 ± 0.3	7.0	17 ± 3
	16.8 ± 1.4	0.50 ± 0.03	6.1 ± 0.3	7.0	27 ± 5
Boar p13	19.5 ± 2.1	0.38 ± 0.04	2.8 ± 0.4	7.0	16 ± 3
	12.8 ± 2.6	0.44 ± 0.06	5.3 ± 0.5	7.0	28 ± 6
Sow 1	15.0 ± 0.6	0.23 ± 0.01	-2.2 ± 0.3	5.5	9 ± 2
	6.1 ± 0.8	0.13 ± 0.02	2.2 ± 0.3	5.5	15 ± 2
Sow 2				7.0	17 ± 6
Sheep	15.6 ± 1.1	0.08 ± 0.02	-1.0 ± 0.4	5.5	2.2 ± 0.5
	8.4 ± 1.3	0.12 ± 0.03	-0.1 ± 0.5	5.5	6.6 ± 1.6
Dog				7.0	5 ± 1
Human 1	12.9 ± 0.9	0.10 ± 0.02	2.6 ± 0.3	5.5	10 ± 2
	8.1 ± 1.1	0.11 ± 0.02	4.7 ± 0.3	5.5	18 ± 4
Human 2	13.4 ± 0.9	0.03 ± 0.02	3.3 ± 0.3	5.5	7 ± 2
	9.5 ± 1.0	0.09 ± 0.02	4.6 ± 0.3	5.5	15 ± 4
Human 3	11.7 ± 0.9	0.05 ± 0.02	3.1 ± 0.3	5.5	8 ± 2
	8.4 ± 1.1	0.09 ± 0.02	5.9 ± 0.4	5.5	19 ± 5
Ø Human	12.6 ± 0.9	0.06 ± 0.02	3.0 ± 0.3		8.2 ± 1.6
	8.7 ± 1.1	0.10 ± 0.02	5.1 ± 0.3		17.3 ± 3.8

discomfort in sitting position and during activities, or pain and urge to pass water. Therefore, the optimization of the sphincter length is of utmost importance.

The urethra compression model predicts and the experimental results confirm the linear dependence of ivLPP and euLPP for differently designed sphincters, as previously demonstrated for the inflatable cuff hydraulic urinary sphincter (Elliott *et al* 1998) and in a rather preliminary *in vitro* study with the AMS 800^{TM} (Hajivassiliou and Finlay 1999). This means for the *in vivo* situations, to maintain continence, the pressure of the device has to be adapted in a linear manner to the bladder pressure. The other important result is the linear dependence between the external force acting on the urethra and the sphincter length L. The substitution of the force by the pressure p_{ex} leads to equation (2), a function monotonously descending with L. For very long sphincters, p_{ex} asymptotically approaches the sum of bladder and wall pressure (cp. curves in figures 6 and 7). Thus, for longer sphincters the benefit is getting smaller and smaller. Hence, a range of lengths can be defined where, at constant p_{ves} and an increasing length, only an insignificant decrease of euLPP is noted. This fact permits the optimization of euLPP and the length of the pressure device L for given bladder pressures.

The urethra compression model describes the condition of constant intravesical pressure. Changes of the intravesical pressure in time, as present during coughing or physical activity, are not directly included. Preliminary experiments, however, show that the pressure rise is of minor importance (Blunschi 2005). For the dynamic situation, i.e. stress urinary incontinence, the maximal amplitude of the intravesical pressure seems to be dominant parameter (Blunschi 2005). Therefore, the maximal intravesical pressure can be used in equation (3) to determine the pressure within the cuff of the AMS 800^{TM} necessary for continence. For this, the only task remaining is to extract reasonable values for the three parameters p_W, F_R and L, because the manufacturer defines the geometry of the artificial sphincter. Since extended *in vivo* measurements are complex and expensive, realistic estimates are obliging. For these estimates, one needs the dependence of euLPP on the sphincter length L. The variation of L for the cuff of the AMS 800^{TM} requires huge efforts. Hence, the proposed design of the aluminium sphincter belongs to the solutions, which help to determine the parameters of the urethra compression model as shown in the previous section and summarized in table 1 for human and animal urethras.

The parameter p_W is found to be negative. This means it acts against the intravesical pressure and closes the urethra, if no intravesical pressure is applied. The pig bladder–urethra combinations are watertight even after their removal from the pig, an observation, which explains the relative high absolute values for p_W. The significant difference between opening and closing, often termed (mechanical) hysteresis, is attributed to the visco-elastic behaviour of the urethral tissue. Considering the mean values of the human urethra, the intravesical pressure has to reach at least 12.6 cmH_2O to open the closed urethra without using any sphincter. If the intravesical pressure is smaller than 8.7 cmH_2O, the open urethra closes without applying any external force. The rim force reaches reasonable values with the order of magnitude, which corresponds to 10 g on both ends. The range, where this force is active, relates to the rim length L_R, which is, in general, positive. The rim lengths seem to be rather large. Taking into account the inner and outer diameters of the urethras, however, the values sound realistic. Again, the rim length is significantly larger for the closing than for the opening. Here, we speculate that the actual shape of the 'liquid-like' urethra (Griffiths 1985) during the opening and closing determines the rim length. It is expected that the rim force and length are different at the distal and the proximal end of the artificial sphincter. Our model, however, cannot predict such a difference, which is an important limitation. Therefore, both parameters are mean values of both ends.

Incorporating these three parameters into the urethra compression model, one can determine an optimized sphincter length L_{opt}. It is, however, unclear, which values for the maximal bladder pressure and the pressure of the artificial urinary sphincter should be selected to extract the optimal length. Therefore, the choice is somehow arbitrary. Our discussion is based on the clinical experience with the urinary control system AMS 800™. The surgeon can choose a reservoir providing pressure from 51 to 90 $\mathrm{cmH_2O}$ outflow resistance depending on his judgment whether the urethra of the patient has higher or lower risk factors for atrophy. Usually, a reservoir providing a pressure of 51 to 70 $\mathrm{cmH_2O}$ is implanted (Barrett and Licht 1998). In order to reduce the risk of atrophy, the pressure within the cuff should not exceed 60 $\mathrm{cmH_2O}$ (Weber 2001). So far, individual urodynamic results of the patient did not determine the choice of the external pressure. In clinical practice, the detrusor pressure corresponds to the pressure caused by the bladder muscle. Hence, for example, the intravesical pressure is the combination of the abdominal and the detrusor pressure. If urine storage occurs at a detrusor pressure greater than 40 $\mathrm{cmH_2O}$, upper tract decompensation is more likely (McGuire *et al* 1981). Because the abdominal pressure is absent in the *in vitro* model, this aspect leads to the intravesical pressure of 40 $\mathrm{cmH_2O}$ that should be chosen to determine the optimized length using the urethra compression model. *In vivo*, such a choice, however, implies the loss of urine for intravesical pressures higher than 40 $\mathrm{cmH_2O}$ usually present during stress situations such as coughing. Consequently, the closing of the urethra is the more critical phenomenon and the optimized sphincter length should rather be chosen according to the closing than to the opening procedure. The implementation of these data into the urethra compression model using the fitted parameters p_{W}, F_{R}, L_{R} and 1 $\mathrm{cmH_2O} = 100$ Pa leads to the optimized lengths

$$L_{\mathrm{opt}} = (2L_{\mathrm{R}}(4000\,\mathrm{Pa} + p_{\mathrm{W}}) + F_{\mathrm{R}}/R)/(2000\,\mathrm{Pa} - p_{\mathrm{W}}), \qquad (6)$$

shown in the last column of table 1. For the determination of the optimized length L_{opt}, only the dependence euLPP $=$ f(L) is necessary and not the entire parameter set of the model. In this way, the data for dog and sow 2 are included.

The last column of table 1 first shows that the urethras of a dog and sheep do not resemble human urethras. Second, the data for boar give rise to longer optimized sphincter lengths. Thus, these urethras are not really comparable with human ones. The sow urethras, however, closely resemble the human ones and can, therefore, be likewise used for *in vitro* studies.

Allaire and Reynolds (1991) described their difficulties with the limited use of canine urethras to only one or two experiments before the urethras are damaged, an experience we were not faced with. They further claim that porcine urethras lasted for 2 weeks and after thermal treatment even longer. We can quantitatively support their observation. The optimized lengths for the boar urethra, measured after different periods of time, are identical and show much less variances than comparing urethras of different pigs. Hence, for detailed comparative *in vitro* studies, it is recommended to concentrate on the use of one individual urethra and store it in saline at a temperature of about 6 °C between the experiments.

The liquid-like tissue of the urethra (Griffiths 1985) allows adapting different geometries and rather isotropic pressure generation. Our experiments confirm this phenomenon. No detectable difference in euLPP is found, if the sphincter diameter varies by a value as high as 20%, with the exception of clinically irrelevant short lengths of the artificial sphincter. Therefore, to a certain extent, the urethra can adapt the elliptical shape without a noticeable change of euLPP. Consequently, a certain range of tolerance exists for the adjustment of the diameter of the artificial sphincter in clinical practice. The surgeon is not compelled, pre- or intra-operatively, to proceed to the meticulously accurate adaptation or selection of pre-fabricated sphincters of corresponding diameter.

In severe stress urinary incontinence, the AMS 800^{TM} with two cuffs is implanted to improve the result of continence (Brito *et al* 1993, Kowalczyk *et al* 1996, O'Connor *et al* 2003). The urethra compression model quantitatively describes this benefit. If the second cuff is implanted close to the first one, the sphincter length simply corresponds to the sum of the individual cuff lengths. Consequently, the surgeon should avoid any significant gap between the implanted cuffs.

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