Novel Concept for a Mechanical Intraurethral Artificial Urinary Sphincter

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Abstract: Stress urinary incontinence is a common pathologic condition in society and an increasing socio-economic challenge. Current artificial urinary sphincters for severe cases have high failure rates, cannot be applied sex-independent and their handling is not intuitive. To address these issues, a novel intraurethral closure system was developed. It works without an external energy supply and consists of an inflatable balloon that presses against the inner contour of a surrounding cylindrical structure implanted in the urethra. Regulation of the closure system is achieved by the interaction of the three main components: the closure balloon, the throttle and the compensating reservoir. The developed closing mechanism seals the bladder at rest and during short peak loads and opens only when the bladder pressure is increased by pressing with the abdominals for a longer period of time for micturition.

1 INTRODUCTION

1.1 Urinary Incontinence

Urinary incontinence is a common pathologic condition in society, which is defined as the "involuntary leakage of urine" (Schmelz et al. 2014). It is estimated that five to eight million people in Germany and 50 to 200 million people worldwide suffer from some form of urinary incontinence. An exact number of those affected cannot be determined since the tabooing of the subject is leading to an avoidance of consultation, and thus a lack of acquired data. (Sebsthilfeverband Inkontinenz e.V. 2013; Niederstadt et al. 2007) Along with the physical pathology, those affected experience a high level of psychosocial stress and the costs for the national health care systems are high (Milsom and Gyhagen 2019). This leads to socio-economic challenges in addition to the medical ones (Yoo et al. 2020). Urinary incontinence can be divided into stress, mixed and urge incontinence. This publication's focus is on stress incontinence, which can be distinguished from the other forms of urinary incontinence both in its occurrence and in its causes and treatment. It is defined by the involuntary leakage of urine during load and without bladder contraction, caused by an insufficient closure system. (Sebsthilfeverband Inkontinenz e.V. 2013; Niederstadt et al. 2007).

The main risk factor for the development of stress incontinence is age. The connective tissue loses tension in the later years of life and thus favors a change in position of the bladder and urethra, so that its closure is no longer guaranteed. In men, there is an age-related increase in the size of the prostate, which often necessitates surgery and can lead to the postoperative occurrence of stress incontinence. In the context of demographic change, an increase in the number of people with stress incontinence is to be expected, since the older part of the population is growing steadily. Other causes are stresses on the pelvic floor, such as those occurring during

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pregnancy and childbirth, but also as a result of obesity. Due to the increasing number of obese people in the population, a higher number of people suffering from stress incontinence is also to be expected. (Niederstadt et al. 2007; Bundeszentrale für politische Bildung 2020; Radtke 2017; Gasser 2019)

1.2 State of the Art of Surgical Therapy

The therapy of stress incontinence depends on the severity. For mild forms, conservative and drug therapy methods are used, while for more severe degrees, surgical procedures are standard. The goal of these procedures is mostly to reposition the urethra and support the sphincter muscle. (Hamann et al. 2014; Manski 2020) Depending on the method, these have very high efficacy rates, but at the same time entail a risk of complications during the procedure and during use. In women, the former standard is colposuspension according to Burch, where the success rate is around 90% after one year and 70% after 10 years. Perioperative complications such as bladder injury, hematoma, and wound healing problems occur in 5-10% of treatments. Colposuspension has mostly been replaced by tension-free suburethral band surgery, for example tension-free vaginal tape (TVT) surgery, which has a 90% success rate even 11 years after surgery. Complications with this method are much less frequent, mainly basal perforations (2-5%) and retropubic bleeding and hematoma (0.5-1%) occur. Implantation of the sling via the transobturator access route (TOT), has slightly lower success rates (84%) and muscular discomfort is more common, but there are less complications regarding bladder voiding dysfunction or bleeding. Sphincteric prostheses are used only in cases of complete loss of sphincteric function with subjective recovery rates of 59-88%. However, this contrasts with revision surgery in 42% of cases within 10 years and the risks of perioperative complications such as injury to the urethra, bladder, and rectum. (Hamann et al. 2014; Reisenauer et al. 2013)

In contrast to the surgical therapeutic methods for women, the use of artificial sphincters is the gold standard for male patients with a success rate of 80-85%. However, a prerequisite is sufficient manual dexterity of the patient. Revision rates of 30% occur due to mechanical problems and complications such as arrosion, infection, or urethral atrophy are present in 7-17% of patients. Male sling systems have success rates as high as 70% with complications including local wound infections, urinary tract infections,

perineal discomfort, and bladder voiding dysfunction (up to 21%). Success rates are not higher with adjustable slings, but readjustment is necessary in one-third of patients. Complications with adjustable systems include perineal pain, wound infection, and bladder injury. (Hamann et al. 2014; Bauer et al. 2014)

1.3 Advantages of a Mechanical Intraurethral AUS

The development of a purely mechanical, intraurethral closing mechanism is intended to circumvent the first-mentioned disadvantages. The closing mechanism can be controlled by bladder pressure alone and thus be self-sufficient from external energy sources. A rechargeable battery mechanism, as well as a charging mechanism, which draws energy internally or externally, occupies a certain amount of space, which, however, is anatomically limited. In addition, a mechanical implant is expected to be less expensive than a mechatronic variant, due to its lower complexity. The intraurethral placement of the artificial sphincter also results in a number of other advantages. For example, the complex multi-cavity surgical procedure of the current gold standard can be avoided and a simple ambulatory implantation can be performed, resulting in a reduced cost, time and risk of complications and infection. In addition, the significantly smaller installation space required allows a sex-independent use, and control by bladder pressure enables the intuitive and unobtrusive usage of the system.

2 MATERIALS AND METHODS

The relevant parameters include the pressures at the various sites in the lower urinary tract and the different phases of the micturition process. According to the definition of the International Continence Society (ICS), these are given in the unit cmH_2O. Measurement ranges of the pressures present are mostly between 0-250 cmH_2O. It should be noted that the pressure is always measured against a zero value, which corresponds to the ambient pressure, and that the measurement height has a direct influence on the measured value. Measured values such as filling volume, bladder pressure and urethral pressure can be recorded directly. Other values, such as the pressure introduced from detrusor contraction, are determined indirectly. (Schmelz et al. 2014; Schultz-Lampel et al. 2012) Thus, the detrusor pressure (p_det) is calculated from the measured values of the abdominal

pressure (p_abd) and the bladder pressure (p_ves) as follows:

$$p_{det} = p_{ves} - p_{abd} \qquad (1)$$

As the main function of an artificial urinary sphincter is the sealing of the urethra at a certain bladder pressure and for certain times, the following criteria for the implant can be derived from the urodynamic conditions:

- The flow of urine has to be interrupted at a sustained p_{ves} below 50 cmH$_2$O.
- If a p_{ves} above 50 cmH$_2$O is lasting longer than 5 seconds, urine flow should be allowed.
- If a p_{ves} above 100 cmH$_2$O occurs, urine flow should be blocked for at least 1-2 seconds.

This means, that the implant should be continuously closed up to a certain pressure and also should stay closed for pressure peaks with a short duration, which are for example caused by physical events like coughing.

2.1 Design of the AUS

The novel concept (figure 1) presented in this paper is based on a balloon sealing the urethra. Therefore, a cylindrical, tubular casing is inserted into the urethra, which does not allow urine to flow past it laterally. Prior to implantation, the balloon located in the tube body is filled with liquid and a suitable internal pressure is set so that the balloon is pressed against the wall of the tube. The balloon is connected via a throttle to an elastic compensating reservoir, which ensures that the closing pressure is maintained.
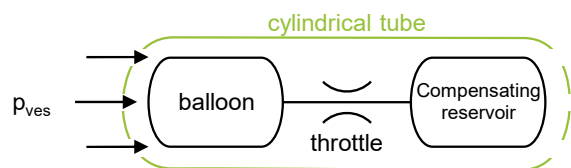

Figure 1: The concept for the artificial urinary sphincter uses a pressurized balloon to block of urine flow.

If the bladder pressure increases, it presses against the balloon and increases the pressure inside, so that the liquid flows out of the balloon through the throttle and into the compensating reservoir. This reduces the volume of the balloon and allows urine to flow past it. The throttle is used here to ensure that the sealing effect only diminishes at longer pressures and that short-term pressure peaks are not causing any involuntary leakage.

2.2 Experimental Analysis

Following components and machines were used for the experimental analysis of the concept:

- Balloons "Endo-Breezer" from servoprax GmbH (Germany), as the main obstructive mechanism.
- Pressure sensors "MPX-4250DP" from NXP Semiconductors (Netherlands), to measure the bladder and balloon pressures.
- Inflator "Everest" from Medtronic (Ireland), to control the fill volume of the balloons in the submillilitre range.
- Material jetting printer "Agilista 3200W" from Keyence (Japan), to manufacture the cylindrical tube and auxiliary parts.

In a first experiment, the balloon properties are recorded (figure 2 A). The expansion of the balloon at a certain filling volume plays an important role, since, depending on the filling volume, the balloon material expands elastically, resulting in an additional internal pressure. The aim of the experiment is to determine the internal pressure of the balloon at free expansion as a function of the filling volume. For this purpose, the prepared balloon is connected to a pressure sensor and to the inflator.
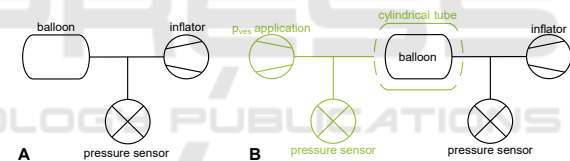

Figure 2: To analyze balloon behavior, two experimental setups where used to test balloon pressure depending on fill volume (A) and balloon pressure correlated to bladder pressure and the systems leakage point (B).

As the bladder pressure increases, the balloons internal pressure also increases. Since this phenomenon is relevant for the closure system, it is examined in more detail by the following experiment. As an experimental setup, the balloon is placed in the associated cylindrical tube. The balloon is connected to a pressure sensor and the inflator. The proximal end of the tube is connected to a second pressure sensor and a device for applying the bladder pressure. In the experimental procedure, the balloon pressure is set to 100, 150, and 200 cmH$_2$O, respectively. Now the bladder pressure is increased in 10 cmH$_2$O steps up to a maximum pressure of 200 cmH$_2$O. Each step is held for 15 seconds to reduce measurement deviations.

Next, for a given bladder pressure, it is determined at which fill volume leakage of the

closure system occurs. The previous used setup is also adopted for this experiment (figure 2 B). The balloon is connected to the inflator and a pressure sensor. The cylindrical tube containing the balloon is connected to the device for applying the bladder pressure and the second pressure sensor. The balloon is brought to a pressure of 100, 150 and 200 cmH_2O respectively and a constant bladder pressure of 200 cmH_2O is applied. Now the balloons volume is decreased by removing 0.055 ml of fluid from the balloon step by step. Each step is again paused for 15 seconds to reduce the measurement error. The volume removal is continued until water flows out through the closure system.

Lastly, the numerical simulation software ANSYS Fluent is used to suitably design the throttle. Here the influences of diameter and length of the throttle, as well as the influence of the applied pressure difference were analyzed.

3 EXPERIMENTAL RESULTS

Figure 3 shows the balloons internal pressure in relation to the filling volume. It can be seen that the balloons show a very strong increase in pressure when they are filled for the first time, in contrast to the subsequent filling processes. At the maximum filled volume, the pressure values no longer deviate so much. In reference tests after a 24 h waiting period, this strong pressure increase is not observed. For all filling processes except the first, the values fluctuate within a certain tolerance range, with a standard deviation of max. ± 38 cmH_2O. The strong pressure increase during the first filling can possibly be explained by sticking and very strong relaxation of the material during the first use after production. As a result, it can be stated that the balloons used exhibit a relatively constant expansion behavior.
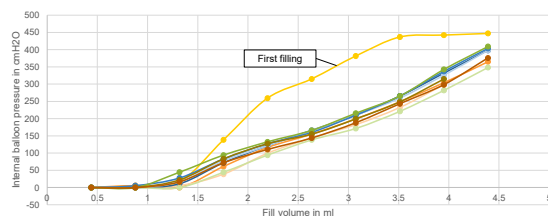

Figure 3: The balloons internal pressure increases with fill volume.

Figure 4 shows the influence of the bladder pressure on the internal balloon pressure. It can be seen that the balloon pressure increases differently dependent on the initial pressure, which leads to a decrease of pressure difference at higher bladder

pressures. From this experiment, it is evident that the valve system is partially a self-amplifying system as the bladder pressure is passed on to the balloons internal pressure and thus pressing it against the outer contour. However, the bladder pressure is not completely transferred to the balloons internal pressure. This is because the pressure distribution on the proximal and distal sides is different and the bladder pressure on the proximal side displaces volume from the balloon to the distal side, where there is no additional ambient pressure.
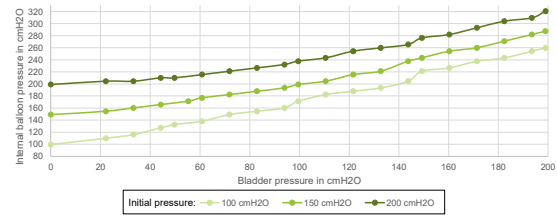

Figure 4: The balloons internal pressure increases with bladder pressure.

The relation of balloon pressure and urine leakage is shown in Figure 5. Here the removal volume in ml is shown on the X-axis and the balloons internal pressure in cmH_2O on the Y-axis. The lowest value in each test series represents the last internal balloon pressure at which the system is still sealed at the applied bladder pressure of 200 cmH_2O. It can be seen that a higher initial balloon pressure, which also means a higher initial fill volume, leads to a larger volume being able to be removed before the system is not any longer sealed.
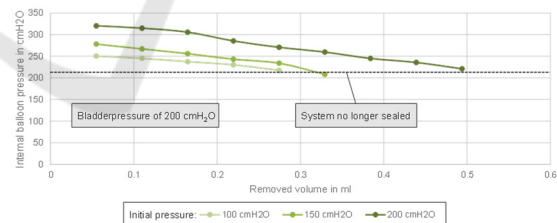

Figure 5: The removed volume needed to cause the leakage of urine increases with initial internal balloon pressure.

The influence of the flow rate through the throttle can be seen in Figure 6. As can be seen, the flow rate increases with increasing throttle diameter and pressure difference and decreases with increasing throttle length. The simulation also shows, that the throttle diameter is the most influential factor, regarding this simple throttle, especially considering the limited building space available.
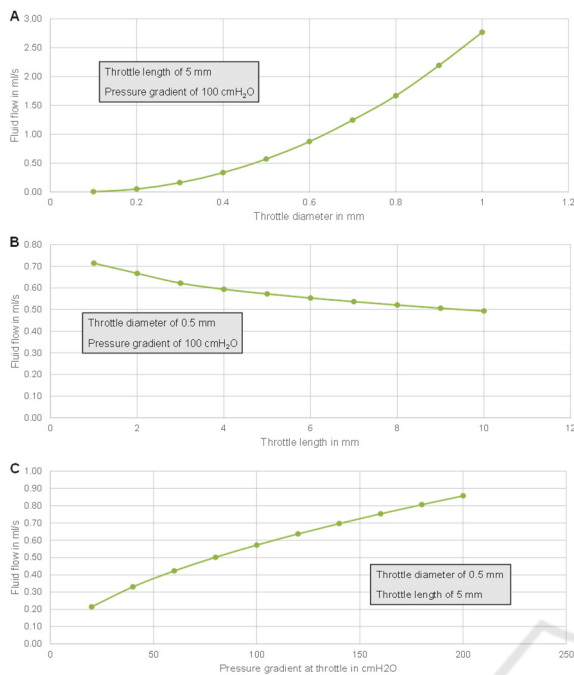
Figure 6: Fluid flow through the throttle increases with diameter (A) and differential pressure (C) and decreases with increasing throttle length (B).

4 DERIVATION OF THE SYSTEM BEHAVIOR

Based on the previously conducted experiments, the behavior of the overall system under three scenarios relevant to the implants function is derived. The basic state is the filling of the bladder over a longer period of two hours up to a bladder pressure of 50 cmH$_2$O. The sudden load is defined as the occurrence of a peak in bladder pressure with a maximum value of 200 cmH$_2$O over a period of two seconds. The final scenario examined is the voluntary micturition, in which bladder pressure increases to 100 cmH$_2$O with the patient pressing and is maintained until the bladder is completely emptied. Figures 7 to 9 show the pressure curves for these three scenarios. In each case, the curve of bladder pressure, internal balloon pressure, and internal pressure of the compensating reservoir are plotted over the appropriate time axis for the corresponding scenario. Based on bladder pressure, the dashed line indicates the leakage point at which the balloons internal pressure is low enough to cause the closure system to leak. This leakage point is calculated using the formula:

$$p_{tipping\ point} = 0,849 * p_{ves} + 62,85 \qquad (2)$$

The experiments showed, that the internal balloon pressure is influenced by the bladder pressure. An internal pressure of 100 cmH$_2$O in the balloon is set as the starting pressure to close the closure system in the basic state. The direct influence of the bladder pressure on the balloons internal pressure is calculated using the formula:

$$p_{balloon} = 0,774 * p_{ves} + 98,567 \qquad (3)$$

For the basic state, a bladder pressure of 0 cmH$_2$O at the beginning is assumed, which increases to 50 cmH$_2$O over the duration of two hours. Accordingly, the balloons internal pressure is set to 100 cmH$_2$O at the beginning and increases to 137 cmH$_2$O. The calculated leakage point is not undershot at any time, which means that the sealing of the system can be assumed. The pressure increase in the balloon causes a pressure difference between the balloon and the equalizing body, which is balanced by the flow of fluid out of the balloon and into the compensating reservoir. Due to the throttle, the pressure in the equalizing body rises with a slight delay in relation to the pressure inside the balloon.
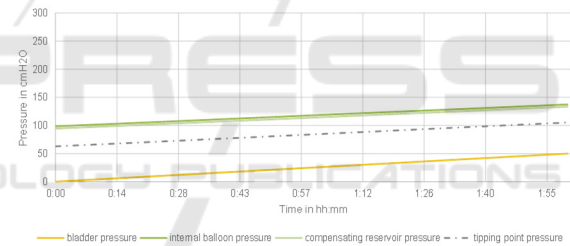

Figure 7: The model shows, that the closure system stays sealed during the filling phase of the bladder.

During the sudden load, the bladder pressure increases abruptly from 20 to 200 cmH$_2$O for the duration of two seconds and then drops again to 20 cmH$_2$O. Both, internal balloon pressure and leakage point can be calculated using the formulas 2 and 3 presented before. When the bladder pressure increases to 200 cmH$_2$O, the balloons internal pressure also increases from 114 to 253 cmH$_2$O. Due to the throttle, the system is quasi blocked at first, so that there is a pressure difference of 253 cmH$_2$O in the balloon to 114 cmH$_2$O in the compensating reservoir occurring, which leads to a fluid flow from the balloon into it. Derived from the previous experiments, in order to reach the leakage point, of 233 cmH$_2$O, a volume of 0.22 ml has to flow into the compensating reservoir. The simulation shows that a throttle with a diameter of 0.3 mm and a length of 5 mm is sufficient to prevent the balloons internal

pressure from dropping below the leakage point for about two seconds, thus ensuring the sealing of the closure system. Following the load, the system returns to its initial state.
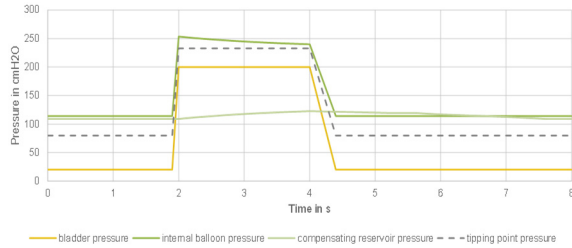

Figure 8: It is shown, that the closure system stays sealed for at least two seconds, when high sudden loads occur.

During micturition, the bladder pressure is increased from 50 to 100 cmH_2O by active abdominal pressing of the patient. The balloons internal pressure thus increases to 175 cmH_2O, which, with a leakage point of 148 cmH_2O, results in a volume of about 0.4 ml needed to flow into the compensating reservoir. At a flow rate of 0.06 ml/s through the throttle described above, this corresponds to a duration of about 7 seconds. After a sufficient drop in internal balloon pressure, micturition occurs, at the end of which the bladder pressure drops again to 0 cmH_2O. The pressure gradient between the balloon and the compensating body is reversed, so that fluid flows back into the balloon and the initial state with an internal balloon pressure of 100 cmH_2O is re-established.
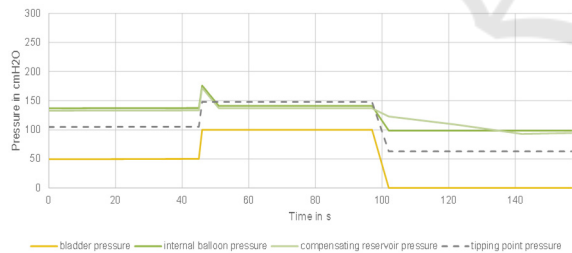

Figure 9: Through active pressing for at least seven seconds, the closure system can be opened and the micturition can be conducted.

5 SUMMARY AND OUTLOOK

The aim of this work was to develop a concept for a closing mechanism that functions autonomously without external energy generation or supply. For this purpose, the relevant requirements for the mechanical closing mechanism were analyzed. Based on the conducted experiments and derived models an advanced functional concept for the closing mechanism was developed, shown in Figure 10. The closure system consists of an inflatable balloon that presses against the inner contour of an outer cylinder. Regulation is achieved by the interaction of the three main components, the closure balloon, the throttle and the compensating reservoir. The presented closing mechanism fulfills the requirements placed on the implant, sealing the bladder at rest and during short peak loads and opening only when the bladder pressure is increased by pressing with the abdominals for a longer period of time for micturition. Particularly advantageous for this mechanism is the simple design and the low number of components, which means that a high reliability can be expected due to the limited interfaces between the different components. In addition, the low number of components has an advantageous effect on the expected manufacturing costs.
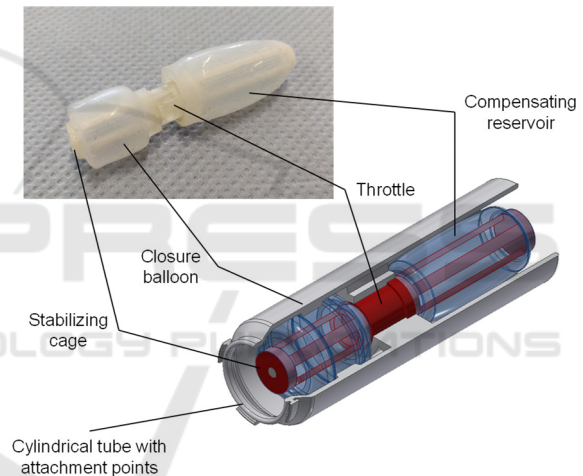

Figure 10: Resulting prototype of the artificial urinary sphincter based on the data acquired and models derived from the presented experiments.

In the case of the individual functional elements, there is potential for optimization and a number of properties that require further investigation. For the balloons, a better sealing effect can be produced by changing the basic geometry. The shape and material thickness can be used to control the behavior of the balloon more precisely. Here especially the investigation of different fabrication strategies for the balloons should be conducted, since the currently applied method does not provide consistent results. In addition, it is necessary to investigate how the balloons behave over a longer period of time. In the case of the outer cylinder, which is also part of the closing system, different geometries need to be investigated. Additionally, the installation space for

the throttle can be reduced by using different throttle shapes, e.g. with inserted flow obstacles or by introducing a low-viscosity fluid instead of water, thus changing the flow properties. For the compensating reservoir, the pressure-volume characteristic needs to be optimized to allow a better control of the system behavior. In addition, further investigations into the behavior of the overall system are necessary, as the long-term stability of the implant in contact with urine has not yet been investigated and the question of whether complete voiding of the bladder is possible with this concept has not yet been clarified.

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