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Pinch Valve Approach for a Biofilm Resistant Mechatronic Intraurethral Artificial Urinary Sphincter*

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***Abstract*— Stress urinary incontinence is the involuntary leakage of urine during increased abdominal pressure, such as coughing, sneezing, laughing, or exercising. It can have a significant negative impact on a person's quality of life and can result in decreased physical activity and social isolation. The presented closure mechanism for a mechatronic intraurethral artificial urinary sphincter is designed to be inserted minimally invasive into the urethra. The device consists of a solid shell, which serves as a housing for the electronics and is designed to enable fixation in the urethra. During micturition, the urine flows through the system, where it is guided through an elastic silicone-tube that, on the one hand, enables closure by a squeezing mechanism and, on the other hand, prevents biofilm growth by oscillation at a frequency of 22.5 Hz. The squeezing mechanism consists of a pinch valve system actuated by a piezo motor. The system has been tested under urodynamic conditions and the results show that it is able to close the urethra effectively to restore continence. The device is able to withstand sudden loads and shows good performance in terms of biofilm prevention during first experiments with artificial urine. The results show that the mechatronic intraurethral artificial urinary sphincter has the potential to be an effective and minimally invasive alternative to current treatment options for stress urinary incontinence.**

***Clinical Relevance*— This novel concept of a mechatronic intraurethral artificial urinary sphincter presents a promising alternative treatment option for patients suffering from stress urinary incontinence. As it is designed to be inserted minimally invasive, it reduces the impact and complications associated with current treatment options. The future development and testing of the device could lead to a safe and effective option for clinicians to offer their patients with stress urinary incontinence, which can improve their quality of life, and decrease costs for society and healthcare systems.**

I. Introduction

Stress urinary incontinence causes high costs for society and negatively affects the lives of those affected. The condition is defined as the "the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction" [1]. Increased abdominal pressure can occur for example during physical activities like coughing, sneezing, laughing, or exercising and is able to surpass the low closure pressure of an insufficient urethral closure. This insufficiency may be caused by a malfunction of one or more of the three components of continence: urethral tone, passive pressure transmission to the bladder neck, and contraction of the sphincter and pelvic floor muscles. [2] It can be supported by different risk factors, namely family history, sex, ethnicity, age, obesity, low physical activity, smoking and alcohol consumption, parity, trauma to the closure mechanism e.g. during radical prostatectomy, or infections of the urinary tract [3], [4]. Stress urinary incontinence can have a significant negative impact on a person's quality of life, as it can cause embarrassment and lead to decreased physical activity and social isolation. The direct and indirect costs of stress urinary incontinence, including lost productivity and decreased quality of life, are significant and can be a burden on individuals, families, and the healthcare system. [5]

Prostheses for the urinary sphincter are used in severe cases of stress urinary incontinence, but are currently not reliable, uncomfortable and need high impact surgery. These hydraulic devices like the AMS 800 by Boston consist of a cuff placed around the urethra, a reservoir for pressure regulation placed in the pelvic area and a control mechanism, usually a pumping mechanism placed in the scrotum for males or the labia majora for females. To open the cuff, the fluid is pumped manually into the reservoir. After a few minutes, it flows back into the cuff and applies the needed closure pressure to the urethra to restore continence. [6], [7] Especially for the elderly population these systems can be hard to use, as they require some dexterity. They can also be uncomfortable and may require frequent adjustments or replacements. In addition, the surgery to insert the device is highly invasive, resulting in up to six weeks of recovery needed before use of the device and carrying a risk of complications, such as bleeding, infection, and damage to surrounding tissue. As a result, prostheses are typically considered a last resort for the treatment of stress urinary incontinence and are only used in severe cases where other treatments have been unsuccessful. [8], [9]

This paper presents a novel valve for a biofilm resistant mechatronic intraurethral artificial urinary sphincter for the therapy of stress urinary incontinence, which is usable for both male and female patients. The system is designed as a small tube that can be inserted minimally invasive into the urethra and fixed to a urinary stent. Internally, a pinch valve-like system is used, actuated by a piezo motor to close a biofilm-resistant silicone-tube. The communication with the implant can be implemented either via MICS radio band or by utilizing bio-signals detected directly in the patient's body as shown in

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[10] and [11]. Different possible solutions for energy supply were also already investigated and are currently not integrated in the test setup. Mainly super capacitors combined with a miniature energy harvesting system show promising results. Further details on this topic are shown in [10] and [12].

II. Methods

The closing mechanism was designed and simulated using Autodesk Inventor and ANSYS. Autodesk Inventor was used to create the design files for the closure mechanism itself as well as different molds or devices for manufacturing of individual components. ANSYS Mechanical and ANSYS Fluent were used to simulate different geometries, flow rates and fluid structure interactions.

The components were manufactured using low force stereolithography and dip coating. The housing of the system was manufactured with the low force stereolithography printer Form 3+ by Formlabs using Clear Resin and a layer height of 25 µm. The silicone-tube was manufactured by dip coating 4 mm diameter aluminum rods using Elastosil P7670 A/B by Wacker Chemie with a Shore A hardness of seven. Before coating, the silicone components were stirred under vacuum to eliminate bubbles. Only the necessary 17.2 mm center parts of the 60 mm long silicone-tubes were used by cutting them from the manufactured piece after crosslinking. This approach led to silicone-tubes with a consistent wall thickness around 400 µm. As actuator the linear SQL-RV-1.8 piezo motor from NewScale Technologies was used, which was attached to a sling made out of generic PA6.6 yarn with a diameter of 200 µm. The final closing mechanism is shown in Fig. 1.

To test the silicone-tube on its biofilm formation properties, cyclic flow experiments where conducted using artificial urine according to ISO 20696. The experimental setup used consists of sterilized disposable components. At the very top is a cylindrical reservoir with a filling volume of 500 ml, which acts as an artificial urinary bladder and stores the urine. The filling level is measured by the pressure at the bottom of the reservoir, which is connected to an SP844 pressure sensor from HJK. Thus, the pressure change inside the reservoir, during the emptying and filling phase can be recorded. From the reservoir, the artificial urine flows with a gravitationally induced pressure between 70 and 50 cmH_2O through the silicone-tube attached underneath. Overall, two configurations were investigated here: First, the oscillating silicone-tube and second, a silicone-tube which was clamped in such a way that no oscillation occurs. The silicone-tube is closed in each case by the SQL-RV-1.8 piezo motor already mentioned. During micturition, the artificial urine is collected by a collection container and then pumped back into the reservoir using a G928 peristaltic pump from Grothen. This cycle was run a total of 31000 times over a period of 22 days in each case during the course of the work. The analysis of the oscillation was carried out using a high frame rate camera and analyzing the resulting video. The subsequent comparison of the silicone-tubes was carried out by means of observation under an OBE 114 light microscope by Kern.

To test the system's capability to grant continence, an urodynamic test bench was utilized, which can replicate physiological pressure curves of the lower urinary tract, in this work intravesical pressures. The experimental setup

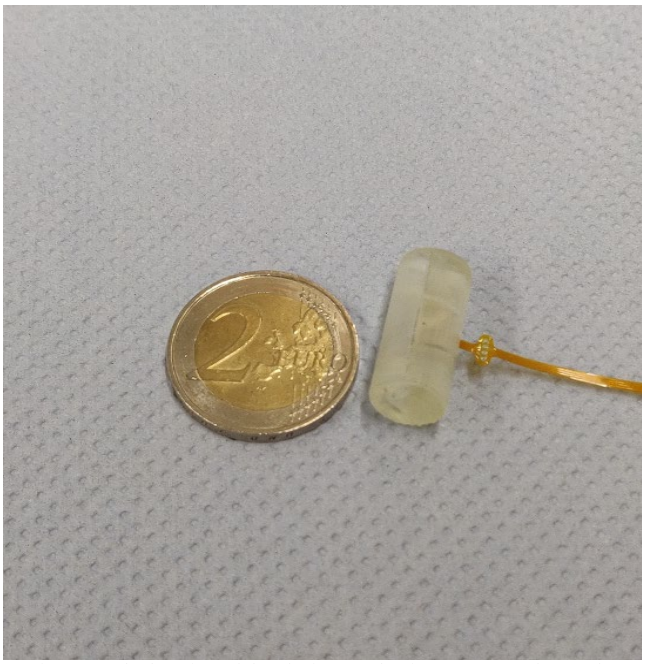

Figure 1: The housing of the closing mechanism was manufactured by low force stereolithography using Clear Resin by Formlabs and the silicone-tube by dip coating using Elastosil P7670 A/B by Wacker Chemie.

consists of a WPDC-05.0L-5.4M-12VDC mini centrifugal pump from Rotek, whose pump speed or the resulting pressure in the system is controlled with a Metro M4 microcontroller from Adafruit. The current pressure is measured using an SP844 pressure sensor from HJK, as in the previous experimental setup. The output tube is then connected to the evaluated system. The fluid is sucked in via the thicker input tube, with a surge tank attached between the pump and the fluid input to also enable cyclic tests. It is therefore possible to form a closed system. To verify the ability of the closure system to maintain continence, tests were performed at 25, 40, 50, 60, 70 and 120 cmH_2O.

TABLE I. Table 1: Composition of artificial urine (ISO 20696)

CH_4N_2O	25.0 g
NaCl	9.0 g
Na_2HPO_4	2.5 g
KH_2PO_4	2.5 g
NH_4Cl	3.0 g
$C_4H_7N_3O$	2.0 g
Na_2SO_3 (hydrated)	3.0 g
H_2O	1.0 l

III. Results

The concept of the mechatronic intraurethral artificial urinary sphincter (Fig. 2) is based on classical pinch valve approaches and is, contrary to state-of-the-art solutions, placed inside the urethra. The implant consists of a solid shell, which serves as a housing for the electronics and enables fixation in the urethra. During micturition, the urine flows through the openings at the top and bottom of the system, where it passes

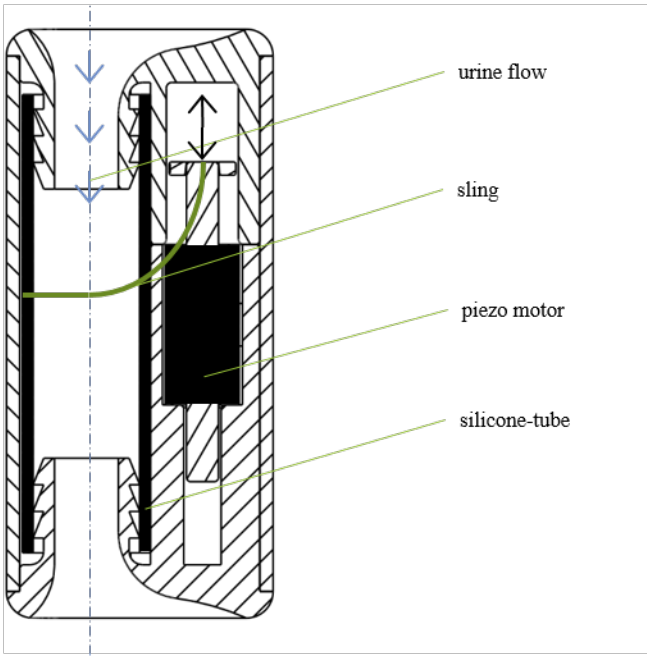

Figure 3: The closure mechanism uses a pinch valve approach, where the elastic silicone-tube is squeezed against a wall by tightening a sling around it, actuated by a piezo motor.

through an elastic silicone-tube that enables closure by a squeezing mechanism and serves to prevent biofilm growth. The squeezing mechanism consists of a sling that is placed around the tube and presses it against a wall to close the system. This squeezes the tube shut, preventing the flow of urine. During micturition, the sling is loosened and the silicone-tube's elastic properties together with the pressure of the urine open the system. A self-locking piezo motor actuates the system so that energy is only consumed to open and close it, keeping the overall energy consumption of the system as low as possible. Interaction with the patient is enabled via an integrated radio module or direct control by biosignals such as special patterns of sound or pressure. This allows easy control of the implant by the user. The concept presented in this paper focusses on the closing mechanism.

The silicone-tube that transports the urine is oscillating during micturition, which leads to less biofilm adhesion and urine stone formation as shown in Fig. 3. Silicone is biocompatible, has a very smooth surface and is elastic. Unlike PVC and latex, silicone is therefore more comfortable for the patient and the risk of incrustation is lower. [13] A soft silicone of Shore A hardness of seven with a diameter of 4 mm was used for the cast inner lumen of the implant. Several studies have shown that changing the shape of the surface can detach biofilm with great success. In methods described in literature, the change of the surface is actively initiated by mechanical actions, such as pressure, ultrasound or the application of stress fields. [14]–[19] In contrast, a passive approach was chosen for the present concept, in which the silicone-tube is oscillating, caused by the resulting turbulence when assembled with slight torsion. This approach reduces the required installation space and energy consumption, since no actuators, energy storage devices or other additional electric components are needed. In endurance tests with artificial urine according to ISO 20696, it was shown that the formation of biofilm is significantly reduced by oscillation at 22.5 Hz.

Initial experiments to investigate the operation of the system at realistic pressures were conducted with a low-cost DC gear motor. For the final prototype, it was replaced by a self-locking, linear SQL-RV-1.8 piezo motor from NewScale Technologies, which, with dimensions of 2.8 x 2.8 x 6 mm, requires significantly less installation space and can nevertheless apply a sufficient force of five Newton. To change the state of the system, the loop attached to the linear axis is tightened or loosened with the help of a deflection tube.

A housing within physiological acceptable dimensions for both sexes was created, using low force stereolithography. In the final concept, the outer housing has a length of 22.1 mm, a diameter of 10.0 mm and still has sufficient installation space for integrating the communication module and energy storage. The connection point between the housing and the silicone-tube is the narrowest flow point with a diameter of 2.4 mm. Flow simulation with ANSYS Fluent shows that thus, under normal urodynamic conditions with an intravesical pressure between 50 and 80 cmH_2O, this leads to a micturition flow rate of 6 to 7 ml/s. This is significantly slower than the normal 10 to 20 ml/s present without obstruction. [2]

The fluid tests using typical urodynamic pressure conditions show that the implant stays sealed during all relevant situations. To test the sealing system for leak tightness, six different pressure courses were tested. These were 25, 40, 50, 60, and 70 cmH_2O applied for 40 s each, and 120 cmH_2O for one second to simulate coughing or similar

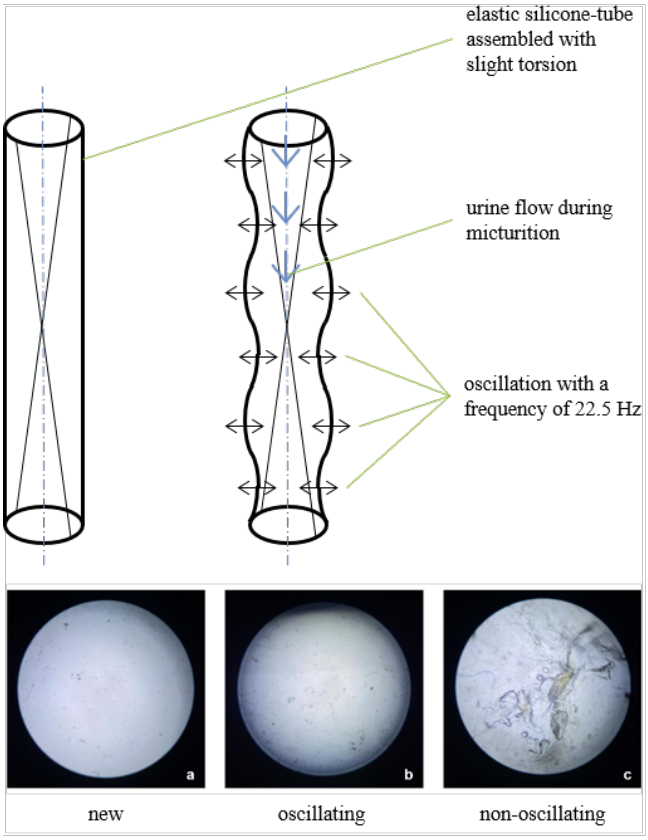

Figure 2: The silicone-tubes assembly with slight torsion is causing oscillation at 22.5 Hz during micturition, which leads to less biofilm adhesion and urine stone formation during a period of 22 days with 31000 micturition cycles.

pressure peaks. The system was able to maintain continence in all test cases.

IV. Discussion

The results show, that a silicone-tube-based intraurethral artificial sphincter can be built in the small space available and is able to allow patients to willingly control their own micturition. With dimensions of 22.1 x 10.0 mm, the demonstrator shown is sufficiently small to be placed in the urethra regardless of sex. The tests carried out showed that the system can ensure continence in the relevant urodynamic pressure range. By using a silicone-tube oscillating at 22.5 Hz during micturition, the formation of biofilms inside the implant could be significantly reduced. A limitation of the approach shown is the reduction of the micturition flow rate to about 6 to 7 ml/s, which is caused by the small diameter of 2.4 mm at the junction of the housing and the tubing. This junction is also an area where the formation of a biofilm is favored. In order to circumvent these points, a modified tube geometry is already being considered, which would eliminate the need for connecting elements and thus achieve an inner diameter of 4 mm with a micturition flow rate of 18 to 19 ml/s and oscillation along the entire length of the implant.

The developed concept is less invasive, more comfortable to control and could allow even outpatient implantation. Due to the intraurethral approach, a minimally invasive implantation by attaching the system to a urinary stent is possible. Since the shown concept is an artificial urinary sphincter, it allows the patient to eliminate additional continence devices such as a pad or catheter, to collect urine that may be required when other procedures are used. Because the closure mechanism is a mechatronic system, it can be controlled willingly, for example remotely via a handheld device, which greatly increases comfort. However, it is important to note that this is just a first concept that needs to be further designed, tested, and evaluated to determine its safety and effectiveness for the treatment of stress urinary incontinence.

In future research, the integration of all the above-mentioned single components as well as the design for biocompatibility will be conducted. The shown concept mainly describes the approach for a mechatronic intraurethral closure mechanism. Other components like the controller, power supply and communication module still have to be integrated. Currently extensive research on the ethical implications of a mechatronic implant controlled directly by the patient is conducted and a user-centered approach is used to create a control system with a high usability. Additionally, the aspects of biocompatibility are researched, which includes geometry optimizations and further development and characterization of the oscillating silicone-tube as well as the investigation of different surface coatings for example utilizing spider silk or doped biopolymer microgels [20].

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