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Smart Artificial Urinary Sphincter: Preserving Organs and Patient's Quality of Life

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Abstract

Implantation of an Artificial Urinary Sphincter (AUS) is considered the gold standard treatment for severe stress urinary incontinence. The operation of this hydromechanical device consists in pressing around the urethra in order to keep it closed. Common reasons for device revision are urethral atrophy and the resurgence of the incontinence caused by constant pressure. In addition, the operation of this implant requires dexterity, which limits its implantation in some patients. In this manuscript, a new smart AUS is presented. The proposed device is remotely controllable and does not require manual pumping, which diminishes surgery incisions and facilitates implantation. Its pressure can be fine-tuned post-operation thus reducing atrophy risks. It is fitted with an adaptive control algorithm. It is compatible with existing AUS and can be utilized for treating other sphincter deficiencies**.** The device has been tested on pig bladders ex-vivo. Design challenges and results are presented and discussed here**.**

Key words: Artificial Urinary Sphincter, implantable medical devices, AMS 800, urinary incontinence, remote control

1. Introduction

Jean-Jacques Rousseau was one of the most pre-eminent philosophers of the Enlightenment age and a spiritual father thereof. However, in spite of all the compliments, the deference and the admiration that his presence would stir up, seldom did Rousseau leave his house for long and would avoid any invitation to a social event. After one of his artistic performances, Rousseau had an invitation to King Louis XV's palace. Sensing that such an honour could hardly be so bluntly turned down, Rousseau fled the city under doubtful pretences, which made the King feel greatly offended. Is there anything more frightful for a person than the wrath of a king feeling hurt? Well, Rousseau was dreading his urinary incontinence much more than the fury of a king. Having to endure urinary incontinence means that the person is unable to control himself or herself; it causes discomfort and results in noticeable psychological and social repercussions. Physical activities are thus considerably reduced and social and sexual life are perturbed [1]. Moreover, since urinary incontinence develops dampness, it increases the chances of infection and can produce red skin rashes and ulcers. In his days, Rousseau used to treat his incontinence with candle wax and warm cloths. Nowadays modern medicine treats urinary incontinence through medication, re-educating the pelvic muscles, and other minimally invasive means. When these prove insufficient, the urologist then makes use of such implantable devices as the AUS AMS 800™, which is regarded as the most advanced treatment for severe urinary incontinence. It is a hydromechanical implant, which exerts a regular pressure on the patient's urethra to keep it closed. When in need of urinating, the patient presses on a manual pump located in their scrotum or Labia Majora to activate the opening of the urethra. Throughout the last three decades, the AMS800 has shown satisfactory continence rates ranging from 59 - 97% among men to 60 - 92% in women [2] .Yet, within the first 5 to 10 post-implantation years, 37 to 50% of the implants require a revision surgery due to mechanical problems, urethral atrophy, infection and erosion [3, 4]. A high and regular pressure upon the urethra usually causes such erosion and atrophy. The pressure exerted by a natural urinary sphincter does undoubtedly vary according to the patient's activity. Unfortunately, the AMS800 can only generate one pressure level that is unalterable after implanting, which may compromise the vascularisation of the urethral tissues. Besides, the use of the device requires some dexterity, the patient has to both locate and press on a pump. Such a task may prove difficult with aging, obesity, Parkinson disease, stroke or paralysis [5-7]. Finding it hard to use his implant the patient feels compelled to require the help of an intimate person,

becoming thus dependent and handicapped, with a limited range of activities. Research seeking to solve such issues is not of a recent date, but they remain inconclusive and need further elaboration [8-12]. Thus, urinary incontinence appears today as one of the largest biomedical companies markets to be still underdeveloped [13]. This represents a major motivation for developing such an increasingly tempting sector. In an effort to produce an AUS capable of preserving the patient's continence and quality of life, we have attempted in this manuscript to spell out our concept of an electronic AUS (eAUS). Through its smart pressure varying device, which can be remotely readjusted and controlled it allows :1) An easy and accessible mictions by simply pressing a remote control button; 2) A postoperative sphincterian pressure readjustment, improving thus continence and minimizing urethral damage; 3) A smart pressure-regulation algorithm capable of self-adaptation to the urethral morphology free of calibration; 4) A much easier implantation, wholly internal and away from Labia Majora and the scrotum while securing a retro-compatibility with pre-implanted sphincters. In the first part of this manuscript, our hydraulic circuit together with its operating principle are presented. Next, in the second part, is given an overview of the control unit, its design and its pressure control algorithm. The third part provides an account of our *ex-vivo* experiments with fresh bladders together with presentation and discussions of the results and design related hardships.

2. Material and methods

The timid development of the AUSs can undoubtedly be justified by the numerous challenges and trade-offs confronting the designers of such devices. In theory the human urethra begins to show leaks when the sphincter pressure somewhat equals the pressure in the bladder. Yet in real life, things are much more complex than this rather simplistic rule. Urethra's tissue is anisotropic and viscoelastic which act with or against the external pressure. Therefore, a complete closing of the urethra may requires a high or a low pressure. The pressure along the interface between the urethra and the compressive device is not evenly distributed; if it is too high the urethral tissue can be damaged, but if it is too low continence is compromised. Besides, there is a difference in urethral morphology between men and women. Furthermore, urethral morphology is patient specific, which requires compressive means of different sizes. The size of the artificial sphincter is also important. It has to be the longest possible to reduce the effect of external pressures and minimize the hazards of urethral lesions. It must also be reduced to the maximum to avoid, large incisions during implantation that could jeopardize urethral vascularization [14, 15]. In view of such numerous constraints, we have adopted for our system the hydromechanic mechanism already used in the current AUSs. This concept, based on an inflatable occlusive cuff

placed around the urethra is simple and effective. It has been investigated in many research publications and its complications and the effects of utilizing it have been well highlighted. The AMS 800 occlusive cuff is biocompatible and its size is appropriate; its integration into our system guaranties its viability and retro-compatibility; thus leaving us to focus on fixing the previously mentioned weak points of actual AUSs. Our device is then principally bi-module. It integrates an electromechanical hydraulic mechanism capable of varying the occlusive pressure, and a control unit responsible for controlling the hydraulic-circuit microactuators and interacting with the remote control as well as supervising the implant physical parameters.

2.1 The hydraulic design

The complexity of the mechanism that produces the pressure required for closing the urethra has a direct impact on the control electronics complexity. Such a mechanism should be simple, reactive and have low power consumption. It also needs to be capable of preserving the urethral vascularization while ensuring continence. Sensitively considering these criteria, we suggested the hydraulic circuit shown in Fig.1.

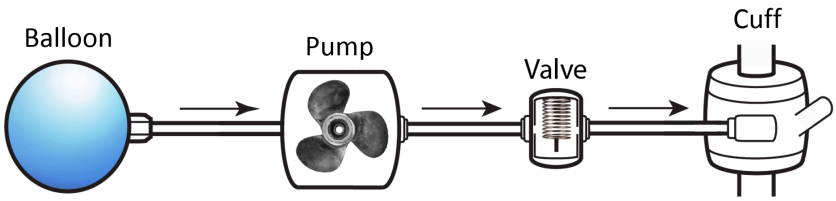


Fig.1. Proposed hydraulic circuit

It is a non-complex hydraulic circuit involving no more than two hydraulic microactuators: a centrifugal micro-pump immediately followed by a bi-stable microvalve both located between the balloon and the cuff. The balloon pressure is equals the atmospheric pressure. It serves as a fluid dispenser feeding the pump. The centrifugal micro-pump has a high flow that is stable and pulse-free, therefore ideal for regulating pressure in a rapid and precise way. The bi-stable valve requires energy only when its state is changed and presents no leaking. Located around the urethra, the occlusive cuff applies a pressure that is function of its hydraulic pressure. The system operates as follows: First, the valve is opened and the pump is powered on. Once activated the pump then fills the cuff with fluid, thus increasing its hydraulic pressure. When the desired pressure is reached it is maintained steady for a given time span; the valve is then closed and the pump deactivated. Sealed with the valve, the cuff is kept pressurized and presses on the urethra to keep it closed. As for reducing pressure or relaxing the urethra, simply opening the valve causes

the cuff to empty its fluid into the balloon; since, centrifugal pumps allow the fluid to freely flow both ways when inactivated.

2.2 The control unit

Besides the ability to perfectly mimic the behaviour of a healthy natural sphincter, without impairing the patient's organs, an ideal smart AUS must have a low power consumption, a high reliability and a minimal size, same as any electronic implants [16]. Likewise, being accessible and offering a great autonomy are equally important, particularly for the patients. Such criteria are essential for an easy use and helps reduce the frequency of recharging. Depending on their life style, people in good health perform an average of five to seven mictions daily; throughout these acts all the AUS components are powered on in order to open then close the urethra. For the remaining part of the day, the hydraulic circuit will be closed and the embedded control unit will be waiting for connexion requests. Therefore, it is important to devise an energy management system that would keep unpowered any non-required module while maintaining the system available for any external connexion request. In order to meet the above-mentioned criteria we suggested the control unit shown in Fig.2. It is a non-complex system that involves a minimal number of components while combining reliability, small size and low power consumption. It is composed of a micro-controller, a pressure sensor with its amplifier, a Bluetooth 4.0 modem, a dual H-bridge and analog switches. (Fig.3).

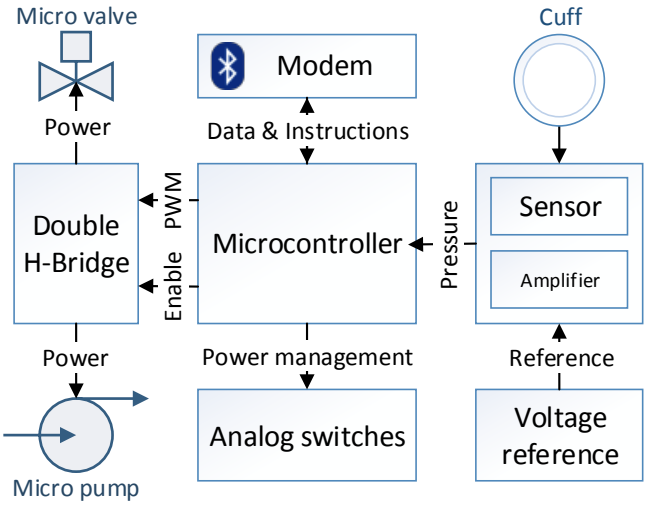


Fig.2. Proposed control circuit

The microcontroller combines powerful computing and low power consumption. With its PWM signal generator, it controls the microactuators through the H-bridges. It acquires

analogical values through its analog to digital converters (ADC). It manages the control unit power supply lines through the analog switches and uses the Bluetooth transceiver for communication with external devices. The Bluetooth protocol has been adopted for its low power consumption and its compatibility with most mobile devices. Such an approach does not limit the patient to a particular control system and does expand the ways of supervising and controlling the implant. A temperature compensated sensor, adapted to the hydraulic circuit tubing, measures the occlusive cuff pressure (OCP). A voltage reference circuit generates a stable and accurate voltage for the ADCs and the pressure sensor, which allows to adequately acquire the OCP independently from voltage variations in the control unit. When offline, the microcontroller goes into a deep sleep mode and the other circuits of the control unit are switched off. Only the Bluetooth module is kept functional and saves energy by periodically activating its radio to verify if there is any call for connexion. As soon as a connexion is established, the Bluetooth module wakes-up the microcontroller, which then powers-up the whole control unit and interacts with the external control system by executing its instructions and answering its requests; thus it offers the connected system a full access to the various features of the implant. The user can then activate the microactuators; perform a pressure regulation, configure the pressure setpoint and obtain the different system parameters such as the battery power level or the actual OCP. Once the external control device is disconnected, the microcontroller saves its parameters, powers down the different control unit components and goes back into deep sleep mode. The Bluetooth module again starts checking periodically for external connexion requests. This optimized operating mode significally expands the autonomy of the system. The small energy contained in two common button-cells is enough to supply the control unit and allows it to remain on standby for connexion during two years without interruption.

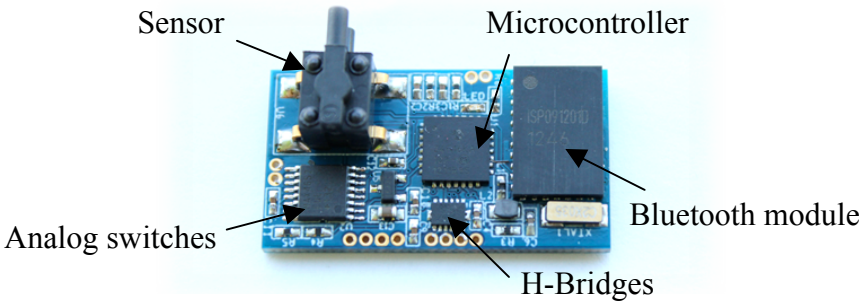


Fig.3. Proposed hydraulic circuit

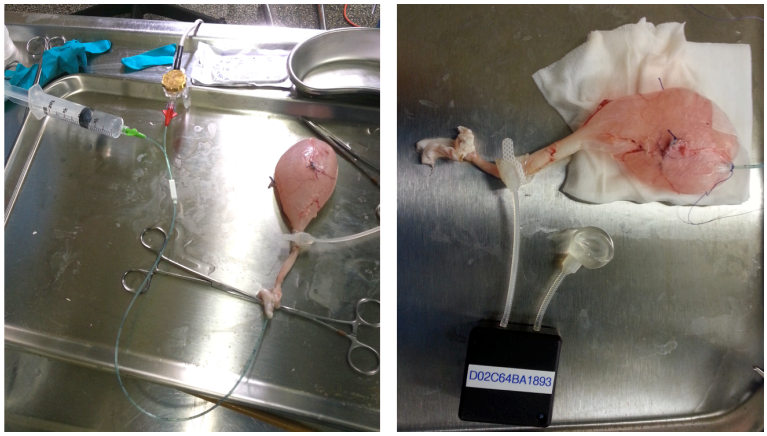
2.3 Pressure control

AUSs are excellent radial pressure generating systems. Such a pressure value must be carefully chosen in order to keep the urethra closed without interfering with its blood circulation. The accuracy of the established pressure value is also important. The more accurate the pressure control system is, the more the urologist has chances to identify the optimal pressure value adapted to the patient. The classical control algorithms such as PID are adequate for most control processes and have the advantage of employing a reduced number of parameters; yet in our case, applying them would entail certain limitations. The urethral morphology varies with patients, which requires control parameters adjustment at each implantation. Such parameters cannot be anticipated since the morphological properties of the urethra cannot be identified in preoperative conditions. It may be easy for an engineer to tune a controller but this task may prove complicated for an urologist. Besides, erosion and atrophy may, as time goes by, alter the urethra morphology; which would require a re-adjustment of the regulation parameters. Employing adaptive pressure control algorithms may seem a good alternative. Yet, the limited resources of the control unit may affect their implementation and their performance. However, the centrifugal pump offers a possibility of obtaining a simple and effective adaptive pressure regulation. The functioning of centrifugal pumps is based on the principle of centrifugal forces. Those forces are transferred onto the liquid being pumped. As in any turbo machine, such a transfer rests on invariable hydrodynamic processes [17]. Thus, in a closed system like our hydraulic circuit, pressure within the system can be controlled by varying the electric power supplied to the pump. The generated pressure is invariable no matter what volume is being shifted. Such an approach greatly simplifies the pressure control algorithm, which in our case is a simple mathematical function that can be written on a single code line.

2.4 Ex-vivo experiments

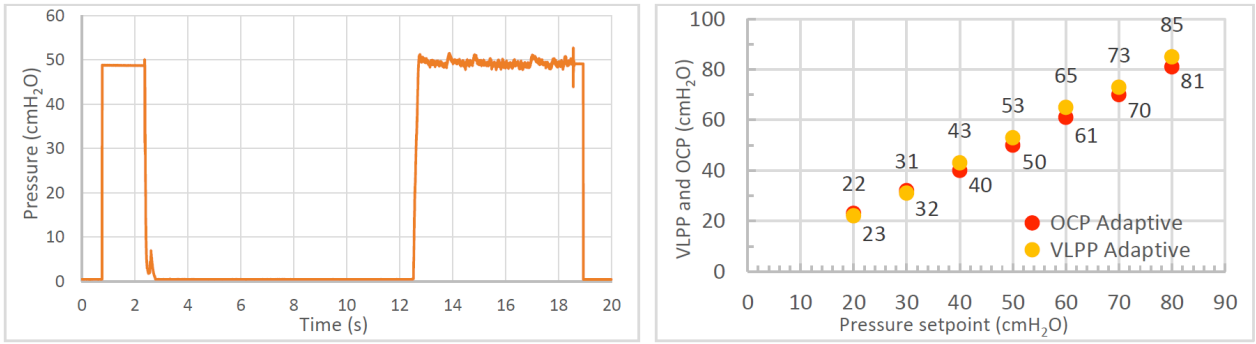
A prototype has been assembled in a standard 50mm × 50mm × 20mm case and a configuration and control computer interface has been developed. It allows to remotely communicate with the implant and to display its activity in real time (state of the connexion, tasks performed, packets sent and received, etc.). A smartphone has also been configured to interact with the implant. The implant has been equipped with an AMS 4-cm cuff and an AMS balloon partly filled with fluid used as a simple reservoir. The mounting and utilisation of the proposed eAUS, the relationship between intravesical pressure and OCP, together with efficiency of the control algorithm with the urethral tissues have all been evaluated on a fresh pig bladder. The bladder was filled with 200 ml of normal saline and its intravesical pressure was measured through an urodynamic system designed for humans (Fig.4a). The prototype was mounted on the

bladder and was remotely controlled in order to exert different pressure levels on the urethra (Fig.4b). At each sphincterian pressure the intravesical pressure was manually raised until a leak occurred thus identifying the Valsalva Leak Point Pressure (VLPP).



(a) (b)

Fig.4. (a) Bladder filling with normal saline; (b) Installation of the implant on the fresh bladder



(a) (b)

Fig.5. (a) OCP measurements; (b) LPP and achieved OCP versus OCP setpoint.

3. Results

Proposed eAUS power management and the impact of proposed hydraulic circuit on the OCP are depicted in Fig.5 which is a record of the pressure sensor's signal when the implant is commanded to open the initially closed urethra, then re-close it through a 50 cmH_2O sphincterian pressure: A) the control unit is powered up. The sensor starts measuring the OCP and generating a signal. B) Following the request for opening the urethra, the micro-valve opens up and the cuff passively deflates itself into the balloon. The sensor detects an impulse due to the mechanical triggering of the micro-valve. C) Immediately on receiving the request for closing the urethra, the pressure control process initiates. The pumping system increases the OCP to the setpoint value and keeps it steady during a pre-selected duration (6 seconds for this test). Past this span the

micro-valve is closed, which once again produces a pulse detected by the sensor. D) Sealed with the micro-valve, the cuff tightly holds its pressure. Following a disconnection; the control unit is powered down and the transceiver goes back into stand-by mode, waiting for connexion requests. The same behaviour was observed for the different tested pressure levels. During experimentation, the adaptive control algorithm proved efficient (Fig.5b). It gave a ± 2 cmH_2O precision. The recorded VLPP was very close of the OCP. Which confirms that in fact the implant respects the pressure setpoint (Fig.5b). During the experimentations, the eAUS was easily configured and used. The connexion with the external controller was established in few seconds. The control of the opening of the urethra was achieved by simply pressing a button. Changing the pressure setpoint could be made easily and at any time.

4. Discussion

We presented in this study a novel smart artificial sphincter using actual AUS elements. It is capable of varying the pressure on the urethra accurately and efficiently thus improving continence and reducing damages suffered by the patient's organs. Proposed eAUS is retro compatible with already implanted AUSs. It is controlled remotely, which facilitates its use by persons suffering from a lack of dexterity and allows them to maintain their independence. Since it does not require manual pumping the system becomes eligible for deep and discreet implantation. With its variable occlusive pressure and precise control algorithm which is not affected by the morphology of the compressed organ, it could be used with some modifications for the treatment of other sphincter dysfunction (esophageal, anal, etc.) or even for erectile dysfunctions. With its Bluetooth 4.0 transceiver proposed AUS combines energy saving and interoperability. Connected to a PC, the implant can be configured through internet. This opens up opportunities for practicing telemedicine and would save the patients the difficult task of moving to the hospital for routine checks. Exploiting the effectors of the AMS 800, proposed eAUS still depends on the lifetime of these elements that degrade and lose their elasticity over time. However, the possibility of connection with smart phones allows the use of mobile applications that can check the status of the implant periodically in order to detect anomalies, the aging of the elements, and correct the pressure if it drops. Although the cuff significantly loses its elasticity, the system would be able to continuously correct the pressure and preserve patient continence until revision surgery takes place. If Bluetooth becomes an obstacle to implantation, it is possible to change the current transceiver with another module operating using the medical implant communication service (MICS) frequency band dedicated to medical implants. By using MICS/Bluetooth patch-modem interfaces [18], it is possible to take advantage of both

technologies: Bluetooth interoperability and reliability of the MICS band. Although the reported system is a prototype, its weight and the actual dimensions do not affect its potential for implantation. However, the presence of an electromechanical mechanism and a flowing fluid complicates the study of heat dissipation into the implant and requires simulations to which we will proceed after placement and final choice of the micro-actuators. Demographic change and the continuous rise of the elderly population, further increases the need for new nature analogue implants more developed than the 31 years old AMS 800. Although it is in prototyping phase, the proposed system showed acceptable performance and opened new possibilities. Further developments of the device will be made in order to increase its efficiency and enhance its design.

Conclusion

In this paper, we have presented a new remotely controlled AUS capable of varying the pressure exerted on the urethra in an adaptive way. The proposed AUS eliminates the manual pump, which eases implantation. It ameliorates continence and limits urethral damage. It is compact and can be as a good option for a deep implantation and the treatment of others health issues such as fecal incontinence and erectile dysfunction. The results yielded with tests on a fresh bladder are promising: the implant ensures continence, regulates pressure rapidly and accurately and offers various control options. Further investigations will be conducted in order to improve its performances and prove its efficacy in vivo.

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