

Design and implementation of an automated artificial urinary sphincter

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Abstract—Severe urinary incontinence is defined as an involuntary urine loss in great quantity. Implantation of an artificial urinary sphincter can overcome this handicap and make the patient recover a normal social life. Today, the prosthesis (AMS 800™) implanted is manufactured by the American Medical System company. It provides good results on human incontinence and has demonstrated its reliability on about 80% of implanted patients. However, surgical revision rate linked to mechanical breakdowns or urethral atrophy, secondary to continuous high pressures exerted on the urethra, remains high. Moreover, the use of this prosthesis is difficult and, then, not adapted to all patients. The purpose of this study is an improvement upon the AMS 800™ system by dynamically regulating the pressure within the cuff in order to maintain an optimum pressure applied on the urethra. Ergonomics is aimed to be improved as well.

I. INTRODUCTION

About 10% of patients who underwent radical prostatectomy suffer from urinary incontinence. These patients can recover partial or total continence by means of an artificial urinary sphincter (AUS). The AMS 800™, commercialized by the American Medical System company, is the only AUS commercially available for about thirty years. This prosthesis is a hydraulic system made up of three parts (see fig. 1): an occlusive cuff placed around the urethra (1), a regulating pressure balloon (2) exerting hydraulic pressure on the cuff and a pump (3), placed in the scrotum, allowing micturition by transferring liquid from the cuff to the balloon. After a few minutes, thanks to a delay-fill resistor within the pump, the liquid automatically flows to the cuff and the urethra becomes closed.

This urinary prosthesis is reliable and provides good results on human incontinence. Indeed, a study on 2600 AMS 800™ implanted [1] has shown that continence improved in 88% of patients and total continence was achieved in 73%. However,

global revision rate is estimated at about 32%, mainly caused by either mechanical breakdowns (pump or pressure balloon) or urethral atrophies. In fact, the AMS 800™ mechanical system can only provide a continuous pressure on the urethra to avoid urine leakage. The pressure has to be sufficiently high to prevent urine loss in the worst case (full bladder and high intra-abdominal pressure) but, on the other hand, most of the time little pressure values could be applied on the urethra while maintaining continence in the patient. This means that pressure on the urethra is often too high and, thus, blood flow around this area is highly reduced which it may involve urethral atrophy.

Furthermore, some patients may have difficulty manipulating the pump because of its small size and its location. Due to this problem, the AMS 800™ could not be adapted to patients who suffer from other handicaps.

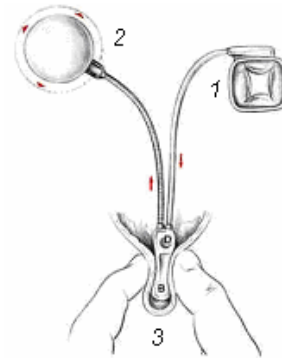


Fig. 1: The AMS 800™ artificial urinary sphincter

We present in this paper preliminary work of a new urinary prosthesis. The aim of this study is to replace the mechanical regulating pressure system (balloon and pump) by an electronic device which dynamically controls the pressure in the cuff according to real-time physiological and postural

measures of the patient. The pressure applied on the urethra would then be optimized, avoiding atrophies and an ergonomic control of the prosthesis would also be possible by using the electronic system to trigger the bladder voiding when it is desired.

II. METHODOLOGY

The whole system will be embedded in a single device comprising the AMS 800™ cuff, the sensors, the pressure actuator, the telemetry system, the battery and the microcontroller commanding the prosthesis behaviour. Each part of the automated artificial urinary sphincter (AAUS) is described in this paper.

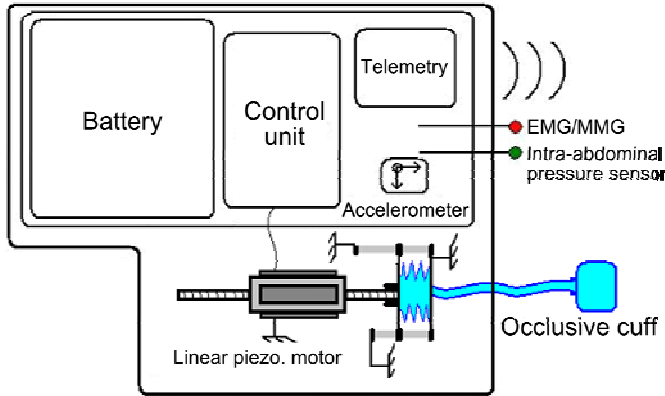


Fig. 2: The automated artificial urinary sphincter

A. Sensors

3 sensors are embedded in the prosthesis to monitor 4 different signals. These measures are processed by the control unit in order to provide to the hydraulic system a pressure value high enough to prevent bladder leakage without damaging the urethra.

1) *Abdominal muscle activity*: Rectus abdominis electromyography and mecanomyography experiments are currently ongoing. The purpose of these experiments is to compare several of these parameters such as time response, noise immunity and power consumption to know which technology would be the most suitable to monitor the rectus abdominis contraction when the AAUS will be implanted. The activity of this muscle is closely linked to the intra-abdominal pressure. Furthermore, thanks to this measure, it would be possible to anticipate quick intra-abdominal pressure raises during coughing. Indeed, surface electromyographic signal of the rectus abdominis shows that muscle contraction begins approximately 100ms before cough [2]. Coughing involves high intra-vesical pressures and, consequently, is one of the major causes of urine loss in incontinent patients.

2) *Intra-abdominal pressure*: A study of a pressure transducer placed against the bladder wall of live dogs [3] has shown a good correlation between the intravesical pressure and the sensing signal. The AAUS includes a sensor placed in the same way giving intra-vesical pressure estimation. Our sensor is a balloon filled of water connected to a hydraulic

pressure transducer. This measure will be correlated with the muscle activity signal by the control unit. This will allow getting a good estimation of the intra-abdominal pressure.

3) *Patient posture and activity*: they are both measured by a 3-axis accelerometer. Patient posture is estimated from the earth gravity force after low-pass filtering of the accelerometer signal. This measure will be used to decrease the occlusive pressure when, for instance, the patient lies down. Activity of the patient will be an additional data which will enable modulating the pressure applied on the urethra according to the other sensing signals.

4) *Time between micturitions*: After micturition, it is not necessary to apply high pressure on the urethra to avoid bladder leakage. Therefore, the prosthesis takes into account time between each micturition. This data is, like the activity of the patient, used to modulate the occlusive pressure by increasing gradually the pressure after a micturition.

B. Signals Analysis

The occlusive cuff pressure variation is bound by power consumption constraints. As a matter of fact, occlusive pressure varies according to a finite number of values instead of varying continuously. Therefore, several occlusive pressure values will be saved; each of them would correspond to a pressure applied on the urethra by the cuff for a specific patient posture and activity. Figure 3 shows an example of 4 different mean pressures P_i . More than 4 values could be also considered.

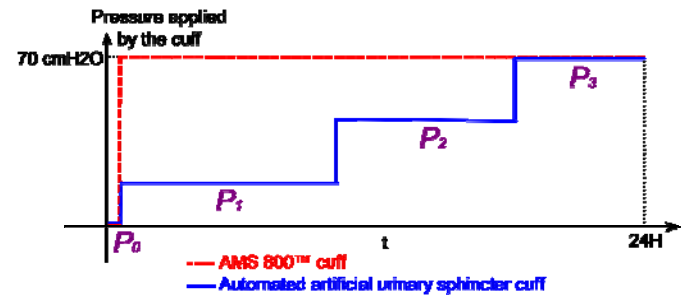


Fig. 3: 24H mean pressures comparison

In this example, we have considered 2 steady pressures P_0 and P_1 and 2 variable pressures P_2 and P_3 . P_2 and P_3 evolve gradually throughout the time until reach their maximum value according to the last time micturition parameter.

- P_0 is very low (less than 10cmH₂O); it corresponds to the pressure exerted by the occlusive cuff on the urethra during micturition. P_0 is similar to the pressure in the AMS 800™ cuff during micturition.
- Occlusive cuff pressure is set at P_1 when the patient lies down. P_1 is settled in order to avoid urine loss when the patient is lied down. It is considered low and could be near P_0 in certain cases.
- P_2 is set during a “normal” activity of the patient, when the intra-vesical pressure does not require exerting on the urethra high pressures to avoid urine leakage.

- P_3 is the maximum pressure which can be applied. The occlusive cuff pressure is set to this value when the intra-abdominal pressure estimated from the monitoring sensors is high.

Some time after AAUS implantation, P_1 , P_2 and P_3 values are settled via telemetry by healthcare staff following a procedure consisting in monitoring the multimodal signals during patient exercises. In the same procedure, different thresholds are saved to determine situations corresponding to each pressure values. This enables identification of the pressure applied on the urethra by the occlusive cuff for a specific patient posture and activity. After this initialisation phase, when similar situations are detected by the control unit, the piezoelectric actuator (see fig. 2) will adapt the pressure in the cuff to the adequate value.

Assuming that the occlusive cuff pressure would be in 24h at P_0 during a few minutes, at P_1 during 8h, at P_2 during about 13h and at P_3 during 3h, pressure applied on the urethra would be reduced of approximately 30%-50% (depending on P_i values) comparing to the AMS 800™.

To trigger micturition, we propose to monitor pelvic muscles activity, which would enable detection of a specifically coded sequence of muscles contractions that the patient would be able to activate without any help of an external device.

C. Pressure actuator

Pressure applied by the AMS 800™ regulating balloon in the cuff goes from 41cmH₂O (4.02kPa) to 90cmH₂O (8.83kPa) depending on patient characteristics. Difference in volume within the cuff between 0cmH₂O pressure and maximum pressure represents about 0.5mL depending on the cuff size.

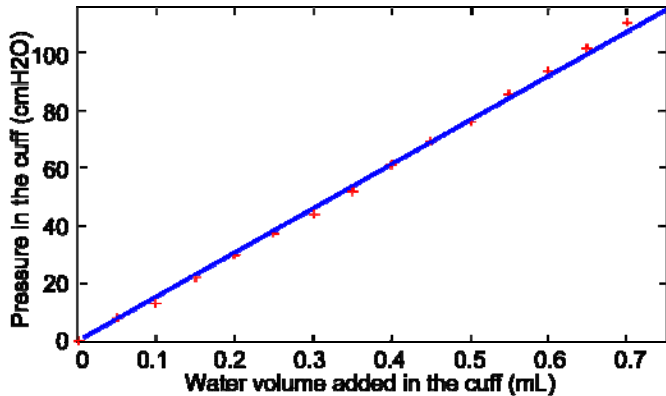


Fig. 4: Cuff pressure vs. water added in the cuff

As shown in figure 4, pressure increases linearly when water is added in the occlusive cuff. Consequently, control of the cuff pressure by our system will be simple. The pressure system (see fig. 5) consists of a bellows filled with 0.7mL of water and connected to the cuff tube. The linear piezoelectric motor provides a nominal push force on the bellows of 1N at 6mm/sec with a power consumption of approximately 500mW. According to the hydraulic design, this corresponds to a pressure rise time up to 70cmH₂O/s which is sufficient to

prevent urine loss during a pressure transition in the occlusive cuff. In fact, a compromise has to be made between power consumption and system performances. A powerful actuator would provide fast pressure transition while consuming a lot of energy. On the other hand, a tiny actuator, according to its low power consumption and its size, could fit to a urinary prosthesis in which pressure applied on the urethra would vary slowly; such a system could be an AUS taking only into account time from the last micturition and making the pressure in the cuff increase gradually. However, our control unit system assesses temporal constraints on the hydraulic system; in our case, the linear piezoelectric motor used is a good compromise. Moreover, this actuator has MRI compatibility and does not need external mechanical system such as reducer or motion transformation mechanism.

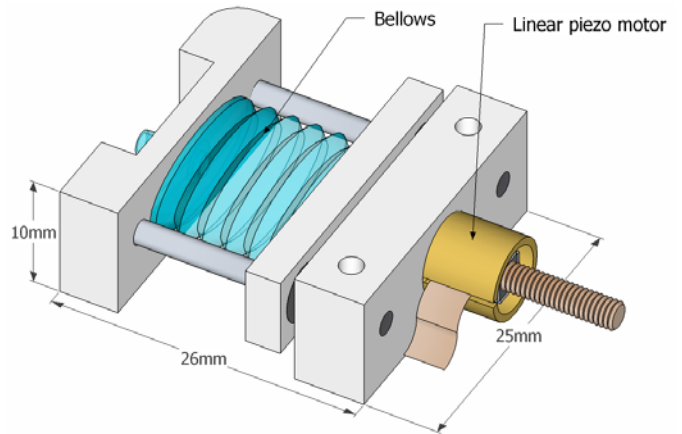


Fig. 5: The pressure system

D. Power supply

The first prototype is currently under development for animal experiments. Its size will be approximately 40×60×10mm and it will run on battery. The components embedded in the first AAUS are all commercially available. They have been chosen for their performances but also for their low power consumption characteristics. The actuator and the sensors are in idle mode most of the time and woken up by the microcontroller only during short periods.

A theoretical study of power consumption of the whole system according to both electrical consumption of electronic components and power losses of the device (battery and components) has shown that our prototype consumes about 10J per day. That means that if the prosthesis carries a battery of 2000mAh with a voltage of 3.6V, we can estimate that it could run during about one year without changing or recharging battery. This operation time will be large enough to evaluate the system efficiency and its real power consumption throughout animal experiments.

Because of the pressure actuator electrical power consumption, the prosthesis could not be powered only by a primary battery in the case of a human implantation. Consequently, another power source would be needed in order to get a reasonable autonomy of the prosthesis. We propose to use an energy scavenger which could be either a mechanical

or a glucose-based fuel cell power source. Both of these technologies are elaborated in our laboratories and could be well adapted for the AAUS.

III. CONCLUSIONS

A dynamic control system of the pressure applied on the urethra could improve considerably the AUS efficiency and the comfort of the patient. Urethral atrophy rate would become lower and most of the patients could achieve total continence thanks to the telemetry parameterization of the pressure values, in each case, after implantation. This would also be a real improvement comparing to the AMS 800™ on which the regulating pressure balloon is chosen before the surgical intervention and cannot be modified afterwards.

Comparing to some other implantable systems, the AAUS has greater electrical power consumption, however, an alternative to this problem could be the use of an autonomous power scavenger and an optimised control algorithm of the piezoelectric actuator. An integration of the different sensors and the control unit just as an advanced power control of each electronic component could also reduce dramatically the electrical consumption.

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