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Instrumented Urethral Catheter and Its Ex Vivo Validation in a Sheep Urethra

Mahdi Ahmadi, Rajesh Rajamani, Gerald Timm, and Serdar Sezen

Department of Mechanical Engineering, University of Minnesota – Twin Cities, 111 Church Street SE, Minneapolis, MN 55455, USA

Department of Urology, University of Minnesota, Twin Cities, Minneapolis, MN 55455, USA

St. Cloud State University, St. Cloud, MN 56301, USA

Abstract

This paper designs and fabricates an instrumented catheter for instantaneous measurement of distributed urethral pressure profiles. Since the catheter enables a new type of urological measurement, a process for accurate ex-vivo validation of the catheter is developed. A flexible sensor strip is first fabricated with nine pressure sensors and integrated electronic pads for an associated sensor IC chip. The flexible sensor strip and associated IC chip are assembled on a 7 Fr Foley catheter. A sheep bladder and urethra are extracted and used in an ex-vivo set up for verification of the developed instrumented catheter. The bladder-urethra are suspended in a test rig and pressure cuffs placed to apply known static and dynamic pressures around the urethra. A significant challenge in the performance of the sensor system is the presence of parasitics that introduce large bias and drift errors in the capacitive sensor signals. An algorithm based on use of reference parasitic transducers is used to compensate for the parasitics. Extensive experimental results verify that the developed compensation method works effectively. Results on pressure variation profiles circumferentially around the urethra and longitudinally along the urethra are presented. The developed instrumented catheter will be useful in improved urodynamics to more accurately diagnose the source of urinary incontinence in patients.

Keywords

Urethral pressure; urinary incontinence; micro-sensors; capacitive sensors; pressure sensors; parasitic capacitance

1. Introduction

The bladder and the urethra are the main parts of the lower urinary tract. If functioning well, they store incoming urine from the upper urinary tract without any leakage or urgency of voiding. In normal micturition, evacuation starts by voluntary controlling the external urethral sphincter and detrusor. This delicate function can be altered by neurogenic or mechanical failures which if present can lead to urinary incontinence (UI) in patients. UI is “the complaint of any involuntary leakage of urine” [1]. UI is believed to affect at least 13 million people in the United States, 80% of them women [2–9]. A standard approach used to diagnose and find the appropriate treatment for patients suffering from UI is urodynamics

[10]. Urodynamics normally consists of two main phases [11]. First, cystometry to investigate the storage function in the bladder during filling, including the ability to store without leakage during provocative maneuvers such as coughs and stationary jogging. The second phase is single point pressure-flow measurement in the bladder and then the urethra to examine urine voiding performance and urethral closure pressure. Further ambulatory urodynamic studies with natural filling have also been applied for patients to avoid the unnatural environment of the urodynamic tests [12]. Ambulatory studies have been found useful for confirming overactive detrusor muscle activity in patients for whom conventional urodynamic tests failed to reproduce symptoms [13]. Intravaginal or perianal electrode is used to additionally measure the electrical activity of the pelvic floor muscles [14].

The first clinical method to measure urethral pressure (P_{ura}) was introduced in 1960 by Lapides et al. [15]. They measured P_{ura} by measuring fluid pressure in direct contact with urethral walls. In this method a whistled-tip catheter was inserted into the urethra. At its distal end the catheter was connected to a manometer which was filled with enough water to ensure that water can discharge in the urethra (Figure 1a). Water height would go down in the manometer until pressure from the walls in the urethra was equal to water column pressure. That pressure was recorded as pressure at that specific point in urethra. To measure urethral pressure profile (UPP), the measurement had to be repeated at many points in the urethra. Not only was this laborious and time consuming, it was also not possible to get real time data for provocative actions. In 1967 Brown and Wickham went farther and proposed a new method by defining P_{ura} as the pressure needed for a liquid to slightly open the collapsed urethral walls [16]. In their method, a urethral catheter with side holes was used. A syringe connected to the catheter stands outside the urethra to pump the fluid into the bladder and a pressure transducer is connected to this hydrodynamic system to measure the pressure in the liquid. During the test the inserted catheter is manually drawn through the urethra to measure the pressure at different points and construct the UPP (Figure 1b). In this method it is important to remove all the bubbles from the tubes carefully. Otherwise the readings will be altered by air compressibility. Like the Lapides's method, the Brown-Wickham method needs tubing and external setups to do the measurement. Moreover the Brown-Wickham method cannot create a urethral pressure profile during fast maneuvers like coughing and Valsalva.

The modern solution to measuring urethral pressure is using a cylindrical balloon that is mounted on a catheter [17]. The fluid in the balloon (Figure 1c) that transmits pressure signal to the external pressure transducer could be either water or air [18]. The water filled balloon's bandwidth is larger than the air charged ones that makes them suitable for pressure measurements in provocative maneuvers [18]. The balloon should be partially charged otherwise the elastic force in the balloon's membrane makes the pressure change inside the balloon different than real pressure change inside the urethra. In this method the balloon averages out the pressure in both circumferential and longitudinal directions inside urethra. In case of using water as the medium, the external transducer outside body should be leveled by the catheter tip to avoid error in pressure measurement. The air charged catheters do not need the transducer to be leveled by the catheter tip but their response is slow [18]. Again, to measure the UPP, the catheter should be moved slowly through the urethra and pressure should be recorded by the external setup. There is no possibility to get real time distributed

data in the urethra, therefore the study of sudden changes in abdominal pressure like coughing is not possible.

Alternatively the pressure transducer can be placed on the tip of catheter itself, like fiber-optic catheters with a single pressure sensor at the tip [19]. Their bandwidth is high and good for measuring sudden changes in abdominal pressure. Also they are free of tubing complexities like levelling and bubble removal from the liquid. These sensors are expensive and not disposable and since the transducer is mounted at the tip of the catheter the pressure measurement is performed between rather than at the urethral walls. So the pressure is different than urethral pressure. Moreover the catheter still needs to be moved slowly through the urethra to construct the UPP [21].

The development of micro sensors for pressure and force measurement is in general a topic of strong interest and has been pursued recently for a variety of applications [20], [22], [23], [24]. To move beyond currently available techniques, we developed a new inexpensive disposable instrumented Foley catheter with a continuous array of flexible capacitive pressure sensors on it. This sensing strip is placed along 4 cm of the catheter to measure pressure in real time and send the data to a capacitance to digital signal converter chip that is mounted on the catheter. Placing the capacitance to digital converter chip on the sensing strip reduces the signal lines and hence the parasitic capacitance. A convenient plug-in interface cable eliminates the complexity of tubing and transmitting pressure to an external transducer and also in the case of using water filled catheters it avoids air bubble removal. In order to obtain adequate sensitivity for measurement of low urethral pressures, capacitive sensors with small micron-sized air-gaps on a flexible substrate are utilized. This sensor strip can be utilized with 7 Fr and larger catheters. The proposed technique provides instantaneous real-time measurement of the distribution of pressure and can be used for urethral measurement during provocative maneuvers, such as coughing, pressing the stomach, or in stationary jogging.

To verify the performance of the new instrumented urethral catheter, a new validation procedure is required due to two reasons:

- a. Other existing sensors can only measure average circumferential pressure at a single point in the urethra.
- b. No other existing sensors can measure dynamic changes in pressure and the urethral pressure profile along the length of the urethra during provocative maneuvers such as coughing and Valsalva.

This paper develops a validation procedure using an extracted sheep bladder and urethra as a platform for ex-vivo urodynamics.

2. Sensor design and fabrication

Pressure inside the urethra for a healthy adult varies from zero at the orifice opening to a typical maximum value of ~100 cmH₂O somewhere close to the middle and beneath the sphincter muscle (Figure 2a) [25]. The proposed pressure measurement resolution specification for our device is 5 cm H₂O. A capacitive pressure sensing mechanism was

selected to get tiny sensors with high sensitivity, high flexibility and robustness against temperature changes [20]. An array of 9 individual sensors was made with 5 mm spatial resolution along 4 cm which is the average length for an adult female human's urethra (Figure 2c). The width of the strip is 2 mm and it can be placed on 7 Fr (and above) Foley catheters. We placed our sensor on a 7 Fr Foley catheter (TDOC-7FSC) for testing purposes.

In the new version of the sensor, the electronics for the capacitance measurement chip are incorporated directly on the sensing strip. The chip is integrated on the strip and mounted on the catheter itself. Measurement of capacitance and digitization occurs on the catheter right next to the sensors, thus preventing addition of noise during signal transmission. Further, a custom test and validation process is developed to test the actual urethral measurement ability of the catheter using an ex-vivo sheep bladder and urethra. Finally, the ability of the system to compensate for tissue parasitics and accurately measure urethral pressures accurately is verified, by using a reference parasitics transducer and a compensation algorithm.

The top and bottom electrodes of the sensors on the strip were fabricated by photolithography patterning techniques on polyimide single sided electro deposited copper clad laminate (DuPont™ Pyralux® AC091200EV). The bottom and top electrodes are shown in Figures 2(e) and 2(f) respectively. Between top and bottom electrodes a spacer layer, as shown in Figure 2(b), made of PDMS (Sylgard 184, Dow Corning) is placed and patterned. The PDMS layer separates the top and bottom electrodes and contains the etched cavities into which the top electrode deforms due to pressure on each sensor. To measure and remove the parasitic capacitance, two separate single bare electrodes were built in the sensing strip to sense the parasitic noise due to neighboring tissues and moisture. Figure 2(d) shows the long bare reference electrode next to the bottom electrodes of the individual pressure sensors. To minimize the analog signal traces' lengths and hence decrease the parasitic capacitance the flexible sensing strip was extended to integrate the sensors with a 16 bit capacitance-to-digital converter chip AD7147 (Analog Devices CDC) on the catheter, as seen in Figure 2(e). This chip sends the digital data serially via I²C to a central microcontroller (pic16f1823) on a detachable data acquisition card. The sampling frequency is 10 Hz and every sample contains capacitance readings from 12 channels.

After the sensor was assembled (Figure 3a) it was cut out (Figure 3b) using a custom made laser cutting setup (2W 445nm LD module with 405-G-2 glass lens). A 4 Volt input was enough to cut the 24 micron polyimide plus ~10 micron of PDMS. For final installation of the sensor on the catheter a supporting block of PDMS was molded around the catheter (Figure 3c). This increases the real size of the catheter from 7 Fr to 8 Fr. The sensor strip was fixed on this supporting layer by curing a brushed layer of PDMS on it (Figure 3d). The setup was left in water for several hours to verify the sealing quality and ensure its imperviousness to liquid. Note that the CDC chip is located on the distal end of the catheter, as shown in Figures 3(c) and 3(d).

After the sensing strip was installed on a 7 Fr Foley catheter, it was first calibrated in an air pressure chamber. The sensitivity of sensors varies between 0.36 fF/cmH₂O to 0.64 fF/cmH₂O. The parasitic reference electrodes were not responding to applied pressure and

responded only to parasitic capacitance. This behavior enables us to estimate the parasitic capacitance in the sensors and compensate for these parasitics to get the absolute pressure values inside the urethra correctly.

3. Ex-Vivo Experimental setup

To verify the sensors' functionality before doing tests in real patients, the catheter was tested in a custom made ex-vivo setup (Figure 4). As described in the introduction, the validation of the instrumented catheter is a challenge due to lack of other gold standard sensors that can make distributed measurements in the urethra. The design of the custom designed test setup replicates the human lower urinary tract structure (Figure 4a–b). The setup consists of three major parts (Figure 4a): first, a rotating disk to set relative angle between cuff and the catheter. This enables us to get data at different angles and construct 3-dimensional pressure distribution circumferentially and longitudinally along the urethra. Second, a pneumatic circuit that consists of a 100 ml syringe (pump), a cuff (AMS 800 Urinary Control System Cuff) and sphygmomanometer is used. This cuff works as an artificial sphincter muscle and exerts pressure on outer part of the urethra. In addition a sphygmomanometer is connected to the line to measure pressure inside the cuff. And finally the third part of this test setup is a sheep's urethra that is extracted from lower urinary tract of a sacrificed sheep. This urethra transmits the cuff's pressure to the sensing catheter inside it (Figure 4b).

A Goby™ portable urodynamics system was also used that measures pressure inside the urethra using a single air charged balloon.

A sheep's bladder and urethra were chosen as the ex vivo model because

- a. The sheep urethra is 4 cm long, similar to the female human urethra
- b. The passage from the external body opening to the urethral opening is very short in a sheep, again similar to the female human anatomy.

4. Experimental Data: Measurement of Dynamic Pressure

The test procedure is performed as follows: the disk is fixed at angle zero, recording data starts when the catheter is in atmospheric pressure outside of the urethra. Then the sensing catheter is inserted into the sheep's urethra. The signal shifts at this point due to both parasitic capacitance created between sensing electrodes and the urethra plus some pressure exerted by urethral walls (Figure 5). Then the cuff is wrapped and locked around the urethra. Sensors 5 to 8 are under the cuff and respond to applied pressure while sensors 1 to 4 are not under the cuff and hence do not respond to cuff's pressure. At this point three different sequentially pressure values of 34 cmH₂O, 68 cmH₂O and 136 cmH₂O (each one for 3 times) are applied on the sensing area by the cuff. Then the cuff is opened and the disk is rotated by 30 deg and locked to repeat pressure test at the new angle. The sampling rate for recording real time data was 10 Hz. This is done until a complete data for every 30 deg around one revolution is obtained. Software in MATLAB is used to record and process the data.

The output signal from any single sensor is the summation of capacitance change due to applied pressure plus parasitics. This parasitics can be viewed as an additional capacitor working in parallel with the sensor (Equation 1):

$$S = \gamma P + N \quad (1)$$

where S is the measured output signal, γ is the calibration coefficient, P is the actual pressure that is unknown and N is the parasitic capacitance.

Two single electrodes are built in the sensor strip to obtain a real-time estimate of the parasitic capacitance. In the calibration of the sensing catheter in the pressure chamber we saw these electrodes do not respond to the applied pressure and are just sensitive to parasitics. So if the material around the sensors remains uniform and does not change then any change in the signal is related purely to change in cuff's pressure (Equation 2).

$$\Delta S = \gamma \Delta P \quad (2)$$

To verify and calibrate the performance of the sensors the same tests were performed on an air-charged balloon sensor on a T-DOC catheter using a Goby™ portable urodynamics system. A 7 Fr T-DOC catheter was connected to the external pressure transducer and the balloon was partially charged as is mentioned in the manual. Because of the shape of this sensor the contact area of the sensor and the urethral wall will be cylindrical and pressure will be averaged on that area.

To compare the results of the new sensor and the air-charged balloon sensor, we measured pressure at different angles with the new sensor and calculated the average circumferential pressure. It should be noted that no circumferential variation in pressure at any one longitudinal location in the urethra is expected in a live animal. The circumferential changes in these ex vivo tests occurred due to use of an artificial cuff to provide urethral pressure. In Figure 6 the response to pressure change in the cuff is plotted against different angles and then integrated and compared with the value read from T-DOC catheter. The cross section of the cuff after inflation creates three connected chambers that are folded (Figure 6a) and hence the applied pressure distribution around the urethra is not uniform and varies between local minimums at the folded edges to maximums at the middle of the chambers. Three minimums corresponding to the three folded edges of the cuff can be seen in Figure 6b. They occur at angles 60 deg, 150 deg and 300 deg. Also three maximums related to inflated chambers can be identified at angles 0 deg, 120 deg and 210 deg. The difference between the average value of sensor 6 over different angles and the single reading from the air-charged balloon sensor is 1.96 cmH₂O for 34 cmH₂O inside the cuff. As the pressure is increased to 68 cmH₂O (Figure 6c) and 136 cmH₂O (Figure 6d) the difference between minimums and maximums is reduced. It is because in higher pressures the folded edges are partially inflated, that makes the pressure distribution more uniform.

5. Experimental Data: Parasitic Signal Compensation for Measurement of Absolute Pressure

To find the absolute pressure in Equation 1 the parasitic capacitance N should be removed from the signal:

$$P = (S - N) / \gamma \quad (3)$$

The parasitic capacitance N is estimated in real-time by using the signal from one of the two bare reference electrodes. In this paper, the long reference electrode shown in Figure 2(d) was utilized. It is assumed that N is proportional to the signal on the reference electrode:

$$N = \theta R \quad (4)$$

where the coefficient θ is an unknown constant multiplier and R is the parasitic signal that is measured by the reference electrode. The parameter θ can be pre-calculated for each of the 9 capacitive pressure sensors, if we have additional calibration data at different points in the urethra from another pressure measurement transducer. Measuring S and R from the MEMS sensor strip and the pressure P for calibration from another reference pressure transducer, the parameter θ is obtained using

$$\theta = (S - \gamma P) / R \quad (5)$$

To find θ , pressure distribution inside the sheep's urethra was constructed point by point using a Goby™ portable urodynamics system. This θ value is then used for cancellation of parasitic capacitance in later tests. This data is shown in Figure 7a. The calculated θ is presented in Figure 7b.

Now that θ is found using equation 5, parasitic capacitance can be removed in real time from the signals and absolute pressure in the urethra can be calculated (Equation 6):

$$P = (S - \theta R) / \gamma \quad (6)$$

6. Data Analysis and Verification

After parasitic capacitance removal the absolute pressure can be calculated (Equation 6) for the 9 sensors on the strip and plotted against position along the urethra to construct the UPP in the ex-vivo test setup. Reference pressure magnitude at different locations inside the urethra is measured point by point by using an air-charged balloon (TDOC-7FSC) that is connected to Goby™ portable urodynamics. To compare the results from the capacitive sensing strip with an air-charged balloon sensor the average value of each sensor's reading at different angles are taken.

Pressure distribution inside the urethra against the angle is plotted for sensor 6 on the sensing strip (Figures 8a–c). The average value of these readings is taken and plotted with the reading from the balloon sensor. The difference between balloon sensor (reference) and the average value from our sensor was 0.96 cmH₂O, 2.33 cmH₂O and 5 cmH₂O for $P = 34$ cmH₂O, $P = 68$ cmH₂O and $P = 136$ cmH₂O inside the cuff respectively. This also shows that the balloon sensors take the average of the pressure at different angles. Placing the pressure-angle plots along the length of the urethra for the first time creates a 3 dimensional UPP that gives us pressure at different locations and angles inside the urethra (Figure 8d). The maximum of the pressure is measured by sensor 6 at $x = 2.5$ cm.

7. Conclusions

A solution to make an inexpensive, disposable sensing strip that can be installed on Foley catheters of various sizes was proposed. A flexible capacitive sensor strip was micro fabricated and calibrated first with high sensitivity using an air pressure chamber. It's robustness against water leakage into the sensor was verified. This instrumented catheter gives instantaneous real time pressure at 9 points in the urethra and constructs the UPP instantaneously. This solves the old problem of having to move the catheter slowly through the patient's urethra to construct the UPP and avoids otherwise common tubing complexities in the pressure measurement. Its sampling rate allows it to even obtain the UPP during fast maneuvers such as coughing. The performance of the sensing catheter was studied in an ex-vivo human-like urethral setup developed in the lab using an extracted sheep bladder and urethra. Two cuffs on the urethra and variable pressure in the cuffs were used to create distributed pressure profiles. Capacitive sensor parasitics due to tissue was removed using a compensation algorithm and reference transducers that responded only to parasitics. The results were quantitatively verified with repeated measurements using a Goby™ portable urodynamics system.

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Manometer

Infusion setup

Pressure transducer

Figure 1.

Urodynamics in a female patient: (a) Lapires's method for measuring pressure in urethra using a manometer, (b) Brown-Wickham method for constructing UPP by constant low volume rate of perfusion and an external transducer, (c) air/water-charged balloon sensor

Figure 2.

Sensor components: (a) Schematic of sensor strip being used in urodynamics test, (b) schematic of a single pressure sensing element (c) sensor strip layers and structure (polyimide is not shown), (d) zoomed-in view of bottom electrodes and long bare reference electrode, (e) sensing bottom electrodes and AD7147 chip at distal end, (f) top grounded electrodes.

Figure 3. Sensor assembly: (a) assembled sensing strip, (b) sensing strip cut out with laser, (c) PDMS ground molded around the catheter, (d) sensor strip fixed on a 7 Fr urethral catheter

(a)

(b)

Figure 4.

Ex-vivo test setup: (a) side view of an extracted sheep's bladder and urethra, (b) test setup

Figure 5. Sensors' responses to the cuff pressure: the two regions enclosed by dashed rectangles are responses of the sensors to the cuff pressure at angles of 0 and 30 deg

Figure 6.

(a) Cuff's cross section after inflation. The blue arrows show high pressure locations and the red ones point to the angle with low pressure, (b) sensor 6 response to $P=34 \text{ cmH}_2\text{O}$ at different angles and comparing the average value with air-charged balloon sensor, (c) sensor 6 response to $P=68 \text{ cmH}_2\text{O}$ at different angles, (d) sensor 6 response to $P=136 \text{ cmH}_2\text{O}$ at different angles

Figure 7.

- (a) Pressure distribution in sheep's urethra measured using a T-DOC single sensor catheter,
 (b) θ values for each sensor on the catheter for parasitic capacitance compensation

Figure 8.

(a) Pressure distribution in sheep's urethra using T-DOC single sensor catheter, cuff pressure 34 cm H₂O (b) Pressure distribution in sheep's urethra using T-DOC single sensor catheter, cuff pressure 68 cm H₂O (c) Pressure distribution in sheep's urethra using T-DOC single sensor catheter, cuff pressure 136 cm H₂O (d) 3-dimensional pressure distribution along the

urethra for a cuff pressure equal to 136 cm H₂O, (e) Pressure distribution along the longitudinal direction of the sheep urethra

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