Ambulatory Device for Urinary Incontinence Detection in Females

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Abstract— This paper describes the design and use of an ambulatory monitoring device for recording urological response to intense physical activities of women. The system integrates a tri-axial accelerometer, a 360 degree biaxial inclinometer and a specially designed urine leakage detector(ULD) for sensing body motion and urine discharge. The device is small, lightweight and battery powered, and can be worn comfortably. All recordings are taken non-invasively and transmitted wirelessly to a receiver for real-time data logging. The experimental results show that the proposed system can record acceleration, inclination efficiently and detect urine leakage of amounts from 0.5ml to 10ml accurately. The unique design of the ULD sensor exempts it from sweating interference during vigorous activities.

I. INTRODUCTION

Urinary incontinence (UI) historically has been a more common concern for multi-parous and post-menopausal women than young healthy females. However a recent study [1] has shown a high prevalence of UI in young, physically fit female population. Although, UI is not a life-threatening or dangerous condition, it often results in social embarrassment and may cause withdrawal from social situations, thereby reducing quality of life.

To understand the relation between UI and physical activities, a variety of devices for detecting urinary leakage have been designed and applied to clinical populations. Broadly speaking, those systems fall into the following three categories according to different principles.

The first type makes use of the conductivity characteristic of urine. Back in 1970s, a measurement system consisting of a Urilos monitor and a disposable electronic nappy was proposed to detect and measure the volume of urine lost by patients [2]. Change of conductivity in the nappy was detected by the Urilos monitor and displayed on a moving-coil meter. This measurement system, however, is not convenient to use and no longer available. In later studies, Kelly and Krass [3] described a portable device for detecting when undergarments are wet with urine by sensing changes in conductivity. The ULD designed in [3] features special sensor fabrication and materials used therein.

The second category is based on the principle that freshly expelled urine is at approximately body core temperature, which will normally be somewhat higher than the ambient temperature within the incontinence pad. In [4], a sensor consisting of eight negative temperature coefficient surface mount thermistors is embedded in the incontinence pad to monitor temperature change due to urine leakage. However, there are two major limitations of such a system:

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(1) long time delay (about 3 minutes) before detecting successive incontinence event and (2) high manufacturing cost for bonding chip thermistors on to a flexible substrate. To improve performance, a telemetry system was proposed for monitoring urinary incontinence by measuring changes both in temperature and in impedance [5]. Thermistors and conductive electrodes were applied to monitor temperature and impedance response respectively. Yet, this system is not designed for an ambulatory application.

The last type of ULD is based on sensing humidity changes when urine leakage occurs. Many commercially available bedwetting alarms are designed by incorporating moisture sensitive sensors which are placed on the underwear. The Wet-Stop2 Bedwetting Alarm [6] and DRI Sleeper Eclipse bedwetting alarm [7] are two typical systems while differ in terms of communication method. The former is wired and the latter is wireless. The disadvantage of these products is that they are designed specifically for the alarm unit. The sensor alone is not available commercially.

The above three urine leakage detection systems are applicable to relatively stationary utilization of subjects. To the best of our knowledge, none of these systems address the situations when subjects are performing vigorous physical activities. In general, motion related noise and sweating interference will cause substantial disturbance such that erroneous detection probability is increased. Besides, the limitation of high cost of the current ambulatory devices hinders their popularization among patients.

By realizing the various shortcomings of the currently available urinary leakage sensors, we custom-designed a low cost ambulatory urine leakage detection system for recording urological response to intense physical activity of females. This system consists of a triaxial accelerometer, a 360 degree biaxial inclinometer, a urinary leakage detector (ULD), and a wireless transceiver module for real-time data logging. The device is small, lightweight and battery powered, and can be worn comfortably by women without preventing them from normal activity.

II. DESIGN

The ambulatory UI detection device incorporates three functional layers as shown in Fig. 1 of system architecture.

- The top sensor board layer hosts three sensors including a +/-25g tri-axial accelerometer, a 360 degree biaxial inclinometer and a resistor sensitive ULD.
- The data acquisition module in the middle provides power to the sensor board and samples analog signals from sensors.

• The bottom controlling layer manages all resources and the communication process. The ambulatory device worn on the body wirelessly transmits signal to the remote receiver for online data logging.

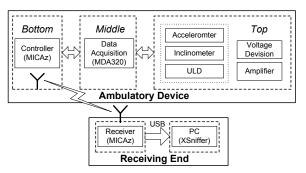


Fig. 1. System Architecture of the UID Device





The battery powered device is small $(5 \times 6 \times 4 \text{cm})$ and lightweight (less than 125g) as shown in Fig. 2, and can be worn comfortably by women without interfering with their activity. The design is specified in the following subsections.

A. Accelerometer

An accelerometer in this ambulatory device is intended to be used for keeping track of the intensity of physical activities. The three key parameters for choosing a proper accelerometer model are: (1) ability of measuring three axis (X, Y and Z) acceleration; (2) wide dynamic range that covers possible maximum acceleration; (3) high sampling frequency enough to capture the instant motion.

According to previous literature [9][10], the accelerometer should be able to measure the range of [-12g 12g] at a sampling frequency of at least 20 Hz to work properly in a free natural motion. In order to evaluate a more accurate acceleration range, we carried out an experiment at the baseline tennis center. A female subject wore the acceleration device (MotionMaster Recorder, model EDR-6DOF) in a pouch on a belt around her waist and jumped a few times from a table of heights between one and three feet [8]. This result showed that a range of [-14g 14g] with 30 Hz sampling rate is enough for normal physical activities.

Considering the above requirements (measurable range $> \pm 14$ g, frequency range ≥ 30 Hz and measurements in all 3 axis), as well as cost factor, we chose the 3D accelerometer

model CXL25LP3 from Crossbow for our system. It features small size, low power consumption, high response speed and high sensitivity with moderate noise level.

B. Inclinometer

Inclinometer is used to measure angles of slope (or tilt) of the body. The desired features of the inclinometer to be used in our system include small size, 360 full degree at least on two axis, fast response speed and low cost. By evaluating those design factors, a 360 degree dual-axis inclinometer (SQ-SI2X-360DA) from $SignalQuest^{TM}$ is applied in the system. This integrated-circuit based inclinometer with compact package supports both analogy and digital outputs, which enables a flexible implementation for data acquisition module. In addition, the linearity between the output and the inclination angles eases system validation.

C. Urine leakage detector

The ULD designed in this paper falls into the first category as described in Section I, which makes use of the conductive feature of urine. However, the proposed ULD design features unique advantages - its applicability under various motional conditions in the presence of sweat. The sketch of the sensor design is shown in Fig. 6.

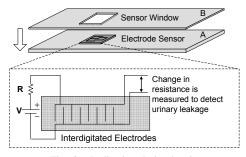
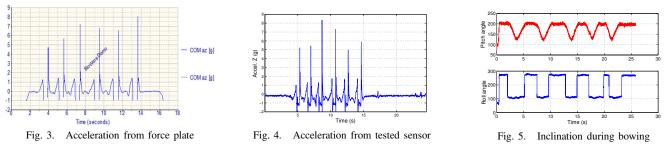


Fig. 6. Inclination during bowing

The center of the ULD is a $3cm \times 3cm$ resistor sensor which includes interdigitated double-side-conductive copper electrodes (IEs) glued on to a highly absorbent pad. This small sensor is then embedded to - but insulated from a regular pantiliner A of size $15cm \times 8cm$, such that the small sensor does not slip away even during intense activities. On the top of pantiliner A, another same sized pantiliner B carved with a window corresponding to the position where electrode sensor is placed, is used to cover the bottom layer. In such a design, the electrodes are located in a reservoir and thus are prevented from contacting the skin, which is essential to reduce the motion noise.

The ULD works in the following way. While the sensor is dry, the mounted electrodes form an open circuit. If large amount of sweat is generated, it can be quickly absorbed by the surface pantiliner B without affecting the center sensor. When leakage occurs, urine acts as a conductor that connects the IEs forming a closed circuit and thus causes a change in the resistance of the IEs. The resistance change is then detected in the form of voltage change as an indicator of urine leakage. Since the urine can be quickly absorbed by the pad, the resistor of the sensor recovers after seconds, which prepares the sensor to detect the next leakage event.



The sensor is comfortable to use due to the softness of copper electrodes and thin pantelinear. For safety, there is no energization of any of its part until getting wet, and even under wet condition there is less than 3V in contact with the human body.

D. Data Acquisition and Wireless Transceiver System

In order to sample the analog output of the three sensors efficiently and accurately, a data acquisition module MDA320 (Crossbow) is integrated in the system. It features 16bit ADC, 8 analog input channels and 25mA output capacity, which can perfectly interface and drive the three sensors. MICAz (Crossbow) wireless transceiver system acts as the central controller for both sensor management and wireless communication.

III. DEVICE EVALUATION

To validate the design of our ambulatory device, this section discusses the evaluation of the performance of each sensor and the system as a whole.

A. Sensor Validation

The three sensors are first validated separately before the system level tests. The accelerometer and inclinometer are attached to certain body position during different activities. The validation of ULD is then conducted in a laboratory using standard measuring devices.

1) Accelerometer Unit: In order to evaluate the performance of the accelerometer, two steps of validation are involved: the first step is to test the applicability of the accelerometer under various conditions; the second step is the accuracy calibration which is achieved via comparing the sensor's result with the acceleration measurements from a standard force plate.

In the first procedure, the subject wearing the ambulatory device (only accelerometer sensor was attached) performed different activities including running, jumping and walking stairs. The accelerometer was placed on low back or ankle in those exercises. Following table illustrates the detailed testing setup and results and also lists the corresponding results in the literature [9][10] for comparison.

Sports	Reference in literature [9][10]	Test results
Treadmill	Ankle:3-12g; Back: 0.9-5g	Back: 1-5.5g
Jumping	Ankle: 3-7G; Back: 3.9-6g	Ankle: $\leq 20g$
	(On trampoline)	(On hard floor)
Walking stairs	Ankle: ≤ 8.1 g	Back: $\leq 4g$
Daily walking	Up body: -0.3-0.8g	Back: ≤ 0.9 g

In general, the testing results from the accelerometer in this system are consistent with that in literature during treadmill and walking tests. Difference only exists in the jumping test. This is because our experiments were carried out on a hard floor with bare feet while the accelerometer was bound to the ankle. However the reference data was obtained on a trampoline which can absorb more force of the footstrike than a normal hard floor. Therefore, the deceleration in our test is reasonably larger than that from a soft trampoline.

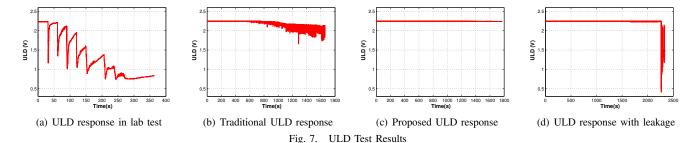
The second step of validation for the accelerometer is achieved by letting the subject jump six times on a force plate with sensor attached to the ankle. The real-time acceleration data from the force plate can be retrieved from the accompanied data recording software Bioware (Kistler). Fig.3 and Fig.4 compare the body acceleration measured by the force plate and that of the tested accelerometer in the vertical direction for illustration. The six peaks correspond to the landing deceleration. The mean of the six maximum values from the accelerometer is 6.2g corresponding to 6.4g measured from the force plate. The consistency between the two results verifies the accuracy of the applied accelerometer.

2) Inclinometer Unit: The inclinometer is a factory validated sensor, so only simple validation is performed. The subject wore the inclinometer on the low back and bowed five times toward the pitch axis. In Fig.5, the change pattern on pitch direction follows the expected linearity, while the transitions in the roll direction are due to the instant angle change during bow movement on that axis.

3) Urine Leakage Detector: The performance of the ULD is validated under controlled conditions in the lab. Urine was dropped from the burette in a controlled manner onto the sensor. The tests are designed to evaluate the sensitivity and absorption of the sensor.

For the sensitivity test, the amount of urine added to the sensor was varied from 0.3ml to 2ml. The results indicate that the rate of miss detection is decreased as the amount of drop increases. Particularly, 0.5ml is the critical point at which the sensor can always pick up the event.

The second aim is to evaluate how much the sensor can absorb before being saturated. The experimental results suggest that the saturation rate depends on both the amount of urine in each drop and the time break between two successive events. However, if the intermediate break is at least 30 seconds, the sensor can absorb as much as 10ml before getting irresponsive to further drops. Fig.7(a) illustrates the response of the sensor for successive 8 drops with 4 different amounts (twice for each): 0.5ml, 1ml, 2ml and 3ml. The graph shows that the sensor caught the first 7 drops but missed the last one when it was saturated.

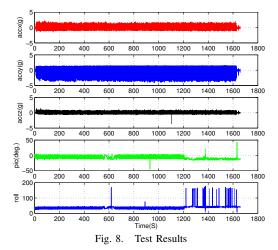


B. System Evaluation

This section evaluates the overall system performance during athletic activities. The accelerometer and inclinometer are attached to an elastic belt which has a pouch hosting the ambulatory device as shown in Fig. 2. The ULD sensor is attached on the undergarment. The weight difference before and after test is used to estimate the amount of leaked urine.

The first experiment is to test the ability of the prototype in the presence of sweat. For comparison, a conventional electrode sensor with IEs glued in the center $5cm \times 8cm$ area of a regular pantiliner is tested as well. The routine for each testing session is standardized as followings: (1) subjects are instructed to drink 700ml of water one hour before the test to generate enough sweat during test; (2) subjects apply an antiperspirant (Secret Clinical Strength Sport) to the groin area before test and then put on the device; (3) each experiment on the treadmill starts with a two minutes warm up period jogging at a speed level of 4.7 mph, followed by 25 minutes of jogging at a speed of 6.5 mph and ends with three minutes of cool down period; (4) the weight difference of the ULD sensor is recorded.

Fig 8 is the experiment results of the accelerometer and inclinometer. Fig 7(b) and Fig 7(c) are the results from conventional ULD and the proposed ULD respectively. Those graphes demonstrated that the whole system can function properly during data buffering, transmission and recording. Power supplies for all sensors and the ambulatory device were adequate as designed. Further, the difference between Fig 7(b) and Fig 7(c) suggested that the ULD proposed in this paper outperforms the regular electrode sensor in terms of resistance to sweat disturbance. It can be observed that, in the test using regular ULD, the superformer exceeded



substantial noise as the experiment proceeded, leading to false detection. However, the proposed ULD has very stable output in the same testing condition. The weight increasing of the regular pad was 1.8g compared to 0.2g(excluding the top pad B) of the new sensor due to sweat, which further confirmed the advantage of the improved sensor design.

The second experiment is to test the ULD's sensing ability of urine leakage; the same routine as above was applied except that a controlled urine discharge was performed at the end of the routine. The result is shown in Fig 7(d). We can conclude that the improved ULD maintains high sensitivity to urine leakage while staying free from sweat disturbance.

IV. CONCLUSION

This paper introduces an ambulatory monitoring device to record urological response to intense physical activities of women. The device weights only 125g with size of $5 \times 6 \times 4$ cm, and can be worn comfortably by women performing various physical activities. All recordings are taken non-invasively and transmitted wirelessly to a receiver for off-line data processing. Experimental results show that the proposed system can detect urine leakage from 0.5ml to 10ml accurately and is exempted from sweating interference. The output of this ambulatory device has already been applied in a finite element model of female pelvic floor to study the relation between UI and intense physical activities. It can also be used in medical treatments by which a proper physical activity plan needs to be designed for a female subject suffering from UI.

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