PROSTHETICS/ORTHOTICS/DEVICES

Design and Evaluation of a New Bladder Volume Monitor

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ABSTRACT. Wang J, Hou C, Zheng X, Zhang W, Chen A, Xu Z. Design and evaluation of a new bladder volume monitor. Arch Phys Med Rehabil 2009;90:1944-7.

Objective: To introduce and evaluate a new implantable bladder volume monitor.

Design: Experimental study.

Setting: Animal laboratory.

Animals: Eight dogs.

Interventions: A coin-shaped permanent magnet was stitched onto the anterior bladder wall and a magnetic field sensor was fixed onto the lower abdominal external wall in 8 male dogs. The bladder was filled with sterile normal saline in consecutive steps of 25mL each from 0 to 200mL by a transurethral catheter.

Main Outcome Measure: Sensor readings were recorded after each step of bladder filling.

Results: The sensor baseline was set at 70° when the bladder was empty. After filling the bladders with 25, 50, 75, 100, 125, 150, 175, and 200mL saline water, the sensor readings were 74.6±0.9°, 79.6±1.2°, 84.5±0.9°, 90.1±0.8°, 95.5±1.1°, 101.8±2.1°, 110.5±2.9°, and 121.9±3.5°, respectively. Sensor readings were positively correlated with bladder volume (r=1; P<.01).

Conclusions: The design of a new bladder volume monitor that is made up of an external magnetic field sensor and an internal permanent magnet is reasonable and feasible. The new bladder volume monitor is simple in structure.

Key Words: Electromagnetic fields; Equipment and supplies; Rehabilitation; Spinal cord injuries; Urinary bladder; neurogenic.

INJURY TO THE SENSORY afferent conduction pathway from the bladder to the central nervous system arising from spinal cord injury, diabetes mellitus, and other diseases may result in a loss of bladder sensation.[1] Currently there is no effective way to recover bladder sensation, and therefore, patients have to rely on scheduled urination, which is, of course, disadvantageous in that it may lead to serious complications such as urinary tract infection, incontinence, and bladder high pressure.[2-5] Helping patients move toward optimal urination is therefore of great significance.

Devices that can continuously monitor urinary bladder volume and alert the patient to urinate at the right time ideally may become an alternative for the treatment of loss of bladder sensation. Several design protocols have been reported in the literature, but they have rather limited significance clinically because of some vital shortcomings.

The bladder volume sensor designed by Dreher et al[6] consisted of a transmitter reed switch and a magnet that were fixed onto the bladder surface wall. Local fibrosis and fibrotic encapsulation would inevitably change bladder wall compliance and therefore disable the sensor. This shortcoming also existed for the design reported by Woltjen et al,[7] which consisted of a Hall effect detector and magnet.

A third design measures the impedance between opposing electrodes sutured diametrically to the detrusor muscle in the external surfaces of the bladder wall.[8,9] Many disadvantages such as fibrotic encapsulation of the electrodes and electrode or lead-wire breakage may impede its clinical application.

A fourth design measures bladder pressure using a pressure sensor, but it can cause major problems such as bladder muscle perforation as a result of the sensors.[10-12]

The most common method uses ultrasound devices to measure bladder volume. Although traditional ultrasound devices have extensively been used to measure bladder volume at the hospital, they are not well suited for patients at home because they are usually large and complicated, require manipulation capabilities beyond those of the subject, and need professional manipulation. Portable ultrasound devices are more suitable and appealing than traditional ones in monitoring bladder volume in elderly and handicapped patients.[13,14] However, they are designed to detect bladder volume intermittently, not continuously. Miniaturized, wearable bladder monitors have been assumed to be able to monitor bladder volume automatically and continuously.[15-17] In practice, they are not well suited for continuous monitoring because of probe displacement. Currently, few studies involve long-term follow-up of ultrasonic bladder monitors although they have been developed over a number of years.

Here, we present and evaluate a new simple bladder volume monitor that consists of a permanent magnet and a magnetic field sensor.

METHODS

Basic Structure and Measuring Principle

This device consists of a coin-shaped permanent magnet embedded with a silicon membrane and a magnetic field sensor, which is in fact an alarm triggered by a special element called a compass switch because it functions similarly to a compass. This switch consists of a hand, a small magnetic bar, a central fulcrum, and a side fulcrum. The sensor is fixed onto the lower external abdominal wall with the magnetic bar lying in the median sagittal plane. The magnet is fixed onto the median anterior bladder wall with a pole at either face oriented parallel to the central fulcrum (fig 1). The magnet moves cranially with an increase in bladder volume, and caudally with a decrease. Any change in position of the magnet changes the direction of the

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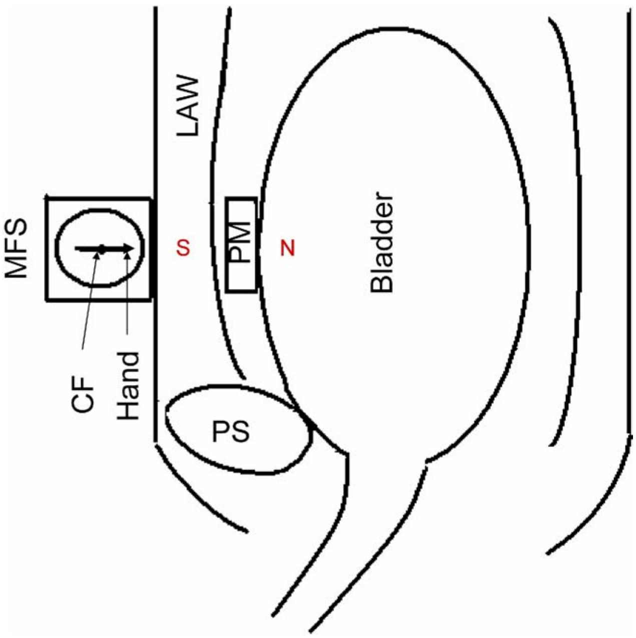

Fig 1. Schematic drawing of the measuring principle of the monitor. Abbreviations: CF, central fulcrum; LAW, lower abdominal wall; MFS, magnetic field sensor; N, north pole of the PM; PM, permanent magnet; PS, pubic symphysis; S, south pole of the PM.

magnetic field where the central fulcrum of the sensor is located, thus forcing the magnetic bar to cause the central fulcrum and hand to rotate. When the hand turns to connect with the side fulcrum, the sensor circuit closes and therefore sounds an alarm to remind the patient to urinate.

Experimental Model

To demonstrate design feasibility, we manufactured an experimental model according to this description. The sensor was $44\times44\times44mm^3$. The central fulcrum, side fulcrum, and hand were made from 1-mm-diameter Kirschner wire.[a] The central fulcrum was 22mm away from the side fulcrum. The hand was 25mm long and directly connected to the central fulcrum. The distance from the central fulcrum to the bottom surface of the sensor was 17mm. The N45 Brand NdFeB magnetic bar[b] was 21mm long and 3mm in diameter. The semicircular dial was divided into 180°, with 5° in each graduation. The coin-shaped NdFeB magnet was 10mm in diameter and 3mm in thickness with a magnetic induction intensity of about 0.3 tesla at the center of the pole face surface. The coin-shaped magnet was embedded with 1-mm-thick silicon membrane[c] for 1 pole face and 0.1-mm-thick silicon membrane for all other surfaces.

Animal Test

This study complied with the Declaration of Helsinki and conformed to the protocol and the ethical and humane principles of research. Eight adult male mongrel dogs[d] ranging from 12 to 14kg in weight were used in this study. After urination, anesthesia was induced by intravenous injection of 3% sodium pentobarbital (25mg/kg body weight) and maintained with further injections, if necessary. A dog was placed in the supine position. After an abdominal midline incision was made, the peritoneal cavity was opened to expose the bladder. An 8-F catheter was inserted into the bladder through the urethra, through which 50mL sterile normal saline was infused into the bladder at a 20mL/min rate. This conveniently allowed the suturing of the silicon membrane–embedded magnet onto the median ventral surface of the bladder proximal to the dome, at two thirds the distance between the base and the dome (fig 2). The abdomen was finally closed layer by layer.

Bladder fluid was drained through the catheter naturally until there was no more fluid outflow, which was regarded as the initial state before bladder filling. With the side fulcrum detached in advance to avoid stopping the hand, the sensor was positioned on the lower abdominal external wall with a sensor reading of 70°. Sterile normal saline was infused into the bladder at a 20mL/min rate, and sensor readings at volumes of 25, 50, 75, 100, 125, 150, 175, and 200mL were recorded.

Fifty milliliters of fluid was drained to reduce the filling volume to 150mL. The sensor was then attached to the side fulcrum and positioned on the lower abdominal wall with a sensor reading of 90° (as the hand connected with the side fulcrum, it closed the circuit and therefore sounded the sensor alarm). Bladder emptying was continued until the filling reached the initial state (the hand detached from the side fulcrum and the circuit was open). Bladder filling was repeated in the same way, and filling was recorded when the sensor sounded.

Data were analyzed with SPSS 10.0 software[e] and expressed as mean ± SD. Bivariate Pearson correlation was conducted between bladder fillings and sensor readings.

RESULTS

Results of the animal test are shown in table 1. With gradual filling of the bladder, the sensor hand rotated from 70° to the range of 117° to 127° from 0 to 200mL, respectively. On average, readings were 74.6±0.9°, 79.6 ±1.2°, 84.5±0.9°, 90.1±0.8°, 95.5±1.1°, 101.8±2.1°, 110.5±2.9°, and 121.9±3.5° at bladder filling of 25, 50, 75, 100, 125, 150, 175, and 200mL, respectively. Bladder filling correlated positively with sensor reading ($r=1$; $P<.01$). When bladder filling was preset at 150 mL, the mean filling volume that started the sensor to sound was 147.6 mL (range, 135–160 mL), deviation less than 15mL (10%).

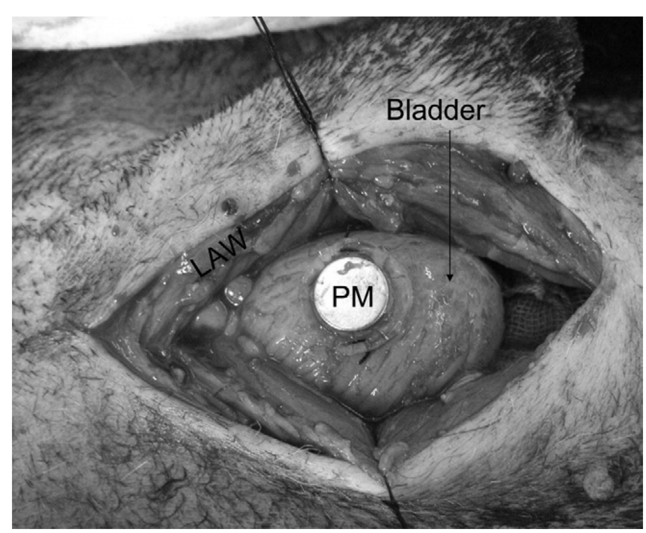

Fig 2. Photograph showing the silicon membrane–embedded magnet as it was stitched onto the median ventral surface of the bladder. Abbreviations: LAW, lower abdominal wall; PM, permanent magnet.