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• BASIC RESEARCH •

A non-invasive method for gastrointestinal parameter monitoring

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Abstract

AIM: To propose a new, non-invasive method for monitoring 24-h pressure, temperature and pH value in gastrointestinal tract.

METHODS: The authors developed a miniature, multi-functional gastrointestinal monitoring system, which comprises a set of indigestible biotelemetry capsules and a data recorder. The capsule, after ingested by patients, could measure pressure, temperature and pH value in the gastrointestinal tract and transmit the data to the data recorder outside the body through a 434 MHz radio frequency data link. After the capsule passed out from the body, the data saved in the recorder were downloaded to a workstation via a special software for further analysis and comparison.

RESULTS: Clinical experiments showed that the biotelemetry capsules could be swallowed by volunteers without any difficulties. The data recorder could receive the radio frequency signals transmitted by the biotelemetry in the body. The biotelemetry capsule could pass out from the body without difficulties. No discomfort was reported by any volunteer during the experiment. *In vivo* pressure and temperature data were acquired.

CONCLUSION: A non-invasive method for monitoring 24-h gastrointestinal parameters was proposed and tested by the authors. The feasibility and functionality of this method are verified by laboratory tests and clinical experiments.

Key words: Gastrointestinal monitoring system; pressure; Temperature; Hydrogen Ion Concentration

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INTRODUCTION

Measurement of physiological parameters such as pressure and pH value is important for gastrointestinal motility study and diagnosis of gastrointestinal motility disorders[1]. The conventional ways for internal monitoring and examining human digestive tract are the open-ended catheter method, bladder catheter method or by means of sensors embedded in flexible cannulae[2,3]. These approaches need pipes inserted into the alimentary tract of patients. As a result, these methods are invasive and can cause a great pain for the patients. In addition, patients must have an "empty stomach" when these conventional methods are performed. So the data acquired are limosis data and can not show the natural and real conditions of the alimentary tract. Furthermore, physicians can not collect the data from the whole gastrointestinal tract because catheters can not reach so far in the small intestine.

Gastrointestinal motility can also be studied through myoelectric activities of the intestine[4-7], small bowel sound recording[8-11], radio-opaque makers[12] or magnetic makers[13-17] and ultrasound methods[18-20]. These techniques have several disadvantages such as indirection, uncertainty, patient discomfort, and high cost.

To overcome these shortcomings, the authors developed a miniature, multi-functional gastrointestinal monitoring system employing micro-electro-mechanical system (MEMS), wireless communication and packaging techniques. This device makes it possible to monitor a 24-h pressure, temperature and pH value in gastrointestinal tract. This device was initially developed for measuring the intestinal motility of constipation patients, but it can be employed in the gastrointestinal motility study and other motility disorder diagnosis.

MATERIALS AND METHODS

Overview

The whole monitoring system comprises four blocks: a biotelemetry capsule, a data recorder, an ultrasonic electrode waistcoat and a workstation (Figure 1). Two types of capsules have been developed currently. One is for pressure and temperature monitoring, called PT capsule, and the other is for pH monitoring, called pH capsule. The biotelemetry capsule is orally ingested by patients, and then it is propelled by peristalsis through the gastrointestinal tract and does not require a pushing force to propel it through the stomach, small bowel or colon. When the capsule passes through the alimentary tract, it transmits pressure, temperature or pH data to the data recorder attached to the body at a preset time interval of 1.15 s using radio frequency at approximately 434 MHz. The data recorder receives the data and stores them into a flash memory card. The position of the capsule in the body is detected by ultrasonic electrodes mounted on the key points of the body surface. The position data are also stored by the data recorder. Patients do not need to stay in the hospital. They could swallow the biotelemetry capsule, attach the recorder to their belt and go out to take part in their daily activities. After the capsule passes out from the body with stools, the recorder is sent to the physician's office. The data stored in the recorder are downloaded to the workstation through a wired link, and then the physician analyses the data using a special software to pinpoint the problem area and assists in the diagnosis.

Device design

The biotelemetry capsule was made of the following functional blocks: batteries, a signal processor, a power manager, a radio frequency (RF) transmitter, micro sensors and an outer shell (Figure 2). The power source for the capsule was two commercially available high-density silver-oxide cell batteries. The nominal capacity of each cell battery was 40 mAh. To ensure durable and stable power supply for the capsule, a step-up direct-current to direct-current (DC-DC) converter with a regulated voltage output was implemented. Analog switches were implemented in the power manager to govern the power sequencing of the micro sensors under the control of the signal processor. In this way, the lifespan of the batteries was greatly prolonged.

Several miniature biochemical and physical sensors were employed. These sensors included a biomedical absolute pressure sensor, a medical grade temperature sensor and an ion-selective field effect transistor (ISFET) pH sensor. The range and precision of each sensor are shown in Table 1.

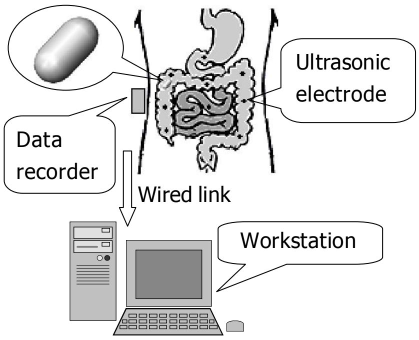

Figure 1 Components of the entire monitoring system.

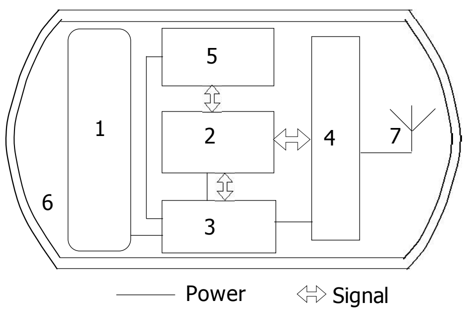

Figure 2 Components of the biotelemetry capsule. 1: batteries; 2: signal processor; 3: power manager; 4: RF transmitter; 5: micro sensors; 6: outer shell; 7: antenna.

Table 1 Range and precision of each sensor

Sensor	Range	Precision
Pressure	-60 to +200 mmHg	1% FS
Temperature	34 to 42 ℃	±0.2 ℃
pH	1 to 13	±0.2

To ensure a non-invasive measurement, an RF transmitter was constructed[21]. The RF carrier frequency was in the 434 MHz ISM (Industrial, Scientific and Medical) frequency band. This frequency was selected because the maximal radiation was found to occur in this band[22-24]. Amplitude-shift keying (ASK) modulation scheme was adopted to lower the power consumption. The RF transmitting power of the transmitter was 0 dBm.

The outer shell was made of medical-grade silicone to ensure biocompatibility of the capsule. The sensors were surface mounted at the ends of the outer shell. All other parts were sealed in the shell by silicone (Figure 3). The weight and dimension of each capsule are shown in Table 2.

The data recorder is a stand-alone unit that could communicate with the biotelemetry capsule to receive the collected data and then store them into its flash memory card (Figure 4). The data recorder could also store the capsule position information detected by the miniature ultrasonic electrodes embedded in the waistcoat. A universal synchronous asynchronous receiver transmitter (USART) port was designed to transmit the data to the workstation.

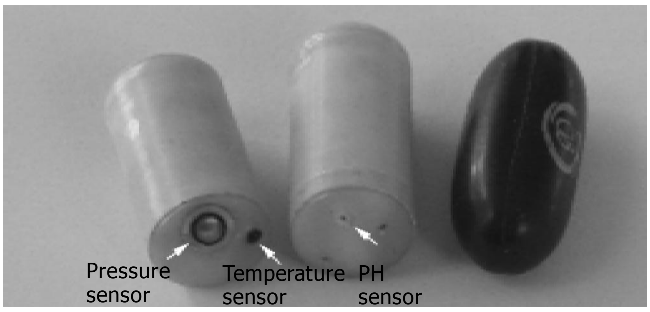

Figure 3 Different biotelemetry capsules. Left, a pressure capsule; middle, a pH capsule; right, a pharmaceutical capsule.

Figure 4 Data recorder and flash memory card. Left, data recorder; right, flash memory card.

Table 2 Weight and dimension of each capsule

Parameter	PT capsule	pH capsule
Diameter (mm)	10.0	10.0
Length (mm)	21.1	24.0
Weight (gram)	2.9	5.2

Laboratory test and clinical experi ment

The monitoring system was checked and tested by Shanghai Medical Device Monitor and Test Center under State Food and Drug Administration, National Center of Measurement and Test for East China. The test results were listed in the next section.

To test and verify the *in vivo* performance of the monitoring system, fasting healthy volunteers, including 6 males and 1 female, were adopted. Their age ranged from 34 to 55 years (Table 3). No gastrointestinal preparations, such as cleaning of all fecal materials in the intestine and fasting before the examination, which were required by the traditional methods, were done before the experiment. The PT capsule, after sterilized, was taken with warm boiled water. The data recorder was attached to the belt of volunteers. The foods for volunteers were rice, vegetable and meat. Sleeping time was 8 to 10 h per day. X-ray films were acquired to verify the position of the biotelemetry capsule in the body (Figure 5).

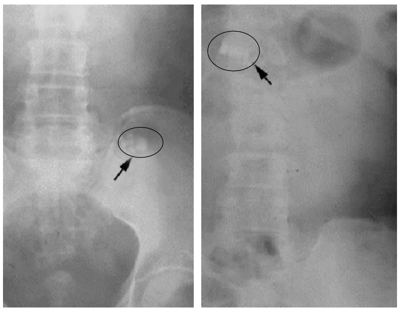

Figure 5 Biotelemetry capsule in the body shown on two X-ray films.

Table 3 Volunteers and CIB time

Volunteer no.	Sex	Age (yr)	CIB time (h)
1	M	42	25.78
2	M	52	33.83
3	M	34	28.22
4	F	50	11.72
5	M	55	19.07
6	M	54	33.12
7	M	49	18.77

M: male; F: female; CIB time: capsule in body time.

RESULTS

The laboratory testing data provided by the authorised institutes are shown in Tables 4-6. The gauge data in the tables were readings shown by the monitoring system.

In 7 clinical experiments, all biotelemetry capsules could be swallowed without any difficulties. The data recorder could receive the RF signals transmitted by the biotelemetry in the body throughout the experiment. All biotelemetry capsules could pass out from the body without difficulties (Table 3). No break was found in all biotelemetry capsules in the surface test after they passed out from the body. No discomfort was reported by any volunteer during the experiment. A sample of pressure and temperature plot of clinical experiments is shown in Figure 6.

Table 4 Pressure data

Pressure		Gauge data			
(kPa)	(mmHg)	Up	Down	Up	Down
-8.00	-60.0	-59.6	-60.0	-60.4	-60.7
-4.00	-30.0	-29.3	-28.9	-30.4	-30.6
0.00	0.0	0.0	1.2	-0.4	-0.4
5.33	40.0	38.0	40.4	38.0	39.3
10.67	80.0	79.0	80.7	79.0	79.8
16.00	120.0	121.2	121.8	120.8	121.2
21.33	160.0	161.7	162.5	159.9	160.9
26.00	200.0	200.8	199.8	199.8	199.8

1 mmHg = 0.133322 kPa.

Table 5 Temperature data

Temperature (℃)	Gauge data
34.00	34.02
36.00	35.91
38.00	38.03
40.00	40.06
42.00	42.11

Table 6 pH data

pH	Gauge data				
	1	2	3	4	5
4.00	4.4	4.3	4.3	4.3	4.4
6.86	6.7	6.7	6.8	6.7	6.7
9.18	9.2	9.3	9.3	9.2	9.3

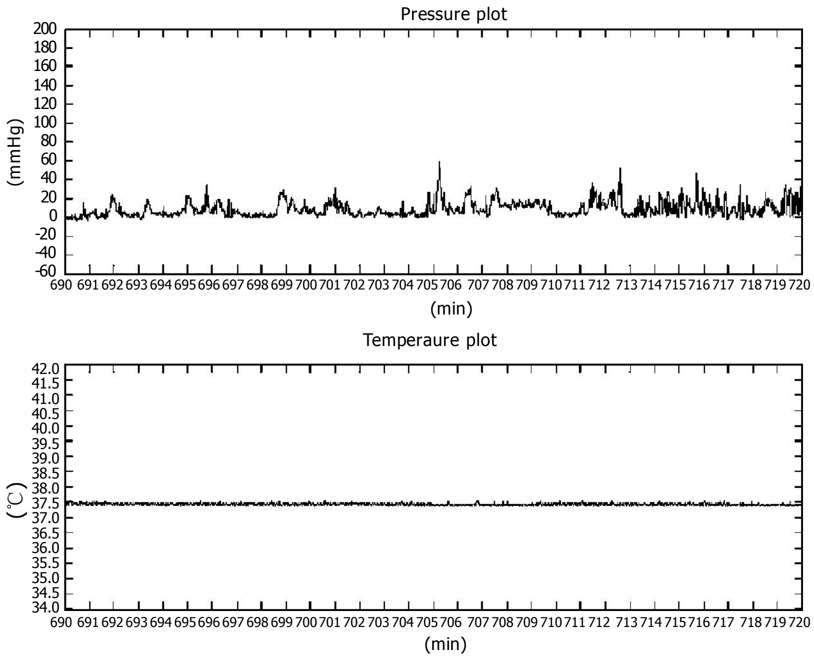

Figure 6 Pressure and Temperature plots.

DISCUSSION

In vitro and *in vivo* tests verified the feasibility and functionality of the monitoring system. By means of micro sensors and wireless communication, this system could provide a non-invasive and direct method to measure and monitor gastrointestinal parameters. Intralumen pressure is an important parameter of gastrointestinal motility. Exposure to extreme weather or physical work conditions could lead to dangerous core temperature changes and clinical syndromes accompanying them. Core temperature measurement is the main tool for diagnosing these syndromes[25]. Intragastric pH value has been verified to be a standard indicator of duodenogastric reflux[26,27]. There is a direct correlation between other diseases and gastrointestinal pH value[28,29]. This method could not only avoid discomforts and even great pains caused by conventional methods, but also give physicians the possibility to study multi-parameters of the entire gastrointestinal tract and to better diagnose gastrointestinal disorders. Although capsule endoscopy has been invented recently[30], it could not monitor a 24-h motility and other parameters which are quantitative indexes of gastrointestinal motility and other diseases.

The biotelemetry capsule system can be used to monitor a 24-h pH value for the diagnosis of gastroesophageal reflux disease with proper improvement, and to evaluate the recovery state of patients after gastrointestinal operation.

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