Remote Detection of Gastroesophageal Reflux Using an Impedance and pH Sensing Transponder

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Abstract — In this work, we developed a dual-sensor system to monitor the symptoms in gastroesophageal reflux disease (GERD). The system consists of an implantable transponder and an external reader. The passive telemetry for signal transduction is based on an inductive link between two coil antennas. The reader supplies radio frequency power, obtains and stores the backscattered sensory data. The dual-sensor transponder detects both impedance and pH changes associated with the gastroesophageal reflux episodes and sends load-modulated signals back. Bench-top experiments were conducted to examine the robustness of the wireless transponding system. Preliminary in vivo experiments were conducted with a live pig. Our dual-sensor transponder system has successfully demonstrated its capability for effective GERD symptom monitoring.

Index Terms — Dual-sensor, GERD, impedance sensor, pH sensor, passive telemetry, wireless sensor system.

I. INTRODUCTION

Gastroesophageal Reflux Disease (GERD) is the condition wherein tissue damage is caused by the reflux of stomach contents, acidic or non-acidic, into the esophagus and pharynx. It affects nearly one-third of the adult population in the US of which about 10% experience symptoms of GERD on a daily or weekly basis [1]. GERD occurs when the lower esophageal sphincter fails to close completely or when timing is out of synchronization with stomach motility causing the stomach contents to rush into the esophagus, which results in rupturing and inflammation of esophageal tissues [2]. The reasons for GERD may be complicated and patient dependent so it requires careful evaluation for treatment options. While heartburn and acid regurgitation are common symptoms, chronic reflux could result in lung damage and Barrett’s syndrome, which is a major risk factor for incurable esophageal cancers [3]. Thus an accurate, reliable and comfortable system to monitor GERD symptoms over a long term to provide high-throughput screening, assessment for treatment options and track drug efficacy in vivo is required.

Changes in impedance and pH in the esophagus are considered to be indicative of reflux episodes. Monitoring systems based on detecting these changes have been developed [4]. The Bravo™ pH capsule which is attached on the wall of the esophagus has been clinically approved to detect acidic refluxes but has inherent limitations such as inability to detect non-acid refluxes, limited sampling rate, and limited battery life [5]. The multichannel intraluminal impedance probe (MII) uses several impedance and pH sensing electrodes for detecting variations at multiple points along the esophagus [6]. MII detects non-acid refluxes by detecting changes in ion concentration of the reflux contents. Despite the improvement in accuracy, the tethered and bulky probes of MII require a transnasal insertion connecting the internal electrodes on the lead to an external electronic unit. The patients are required to wear the transnasal wire and recorder for up to 96 hours causing discomfort and altering patients’ regular activities, which may result in erroneous readings.

In this work, we proposed and implemented a batteryless and wireless telemetry system using both pH and impedance sensors for monitoring of acidic and non-acidic reflux episodes. The system consists of an external reader embedded in a wearable belt and an implantable transponder designed to be attached on the esophageal wall. The power harvesting and wireless communication were accomplished by magnetic coupling between the two units. The transponder was encapsulated in biocompatible polymer with openings in the sensing electrode areas. The wireless link was tested to verify the robustness in transponding signals. In vivo experiments with a live pig were carried out. The conceptual design and the sensor are shown in Fig. 1.

Fig. 1 Passive wireless system using dual sensors in a single capsule to monitor GERD symptoms. The belt is moved down in order to show the implant. The sizes were also magnified for illustration purpose. The inset shows the actual implant compared with a US quarter.
II. SYSTEM OVERVIEW

The block diagram of the system is illustrated in Fig. 2. The coil antennas (L) and the tuning capacitors (C) formed resonant circuits tuned to operate at optimum efficiency at a frequency of 1.3 MHz. A class-E power amplifier amplified RF energy before transmission by the reader coil antenna. On the transponder side, a 4-stage voltage multiplier circuit and a voltage regulator were used to harvest the energy and maintain a constant DC voltage level to operate the circuits. Impedance and pH sensors were connected to respective frequency generators and the load-modulated frequencies were time-multiplexed before being transmitted back to the reader. In the reader, an envelope detector and a bandpass filter extracted the sensory data. A microcontroller and a memory card were used to record the sensory signals in ASCII format.

An interdigitated multi-finger electrode was used for impedance sensing. The variations in impedance occurred due to ion concentration changes in liquids passing through the electrode surface. Liquids having low impedance, such as strong acids or highly-concentrated salt solutions, gave high modulated frequency outputs while materials of high impedance, such as air, generated low frequencies.

Iridium oxide (IrO₃) sensing electrode along with a Ag/AgCl reference electrode fabricated on a polyimide flexible substrate were used as a pH sensor in the same package. The electrochemical potential varied 0.55 V corresponding to the pH levels between 1.9 and 12. For acidic solutions, the pH sensor produced a higher potential resulting in a high output frequency while alkaline ones gave low output frequencies.

III. EXPERIMENTS AND RESULTS

The 7-turn coil reader antenna has a size of 12×12 cm² while the 24-turn coil antenna in the transponder has a cross section of 1×2 cm². The size of the transponder was limited per clinical practicality. The capacitors were tuned so that both LC circuits resonated at 1.3 MHz. The DC power supply in the class-E amplifier was 9 V while the carrier signal was a square wave with 10 Vpp at 1.3 MHz.

A. Bench-top Wireless Experiments

The system was tested by positioning the reader and transponder to mimic different practical scenarios in patients. A known liquid was added on electrodes to obtain a load-modulated frequency at 13.56 kHz. When the transponder received sufficient energy to operate, the frequency recorded in the memory card at the reader was 13.56 kHz. The received frequency varied when the inductive coupling energy fluctuated due to distance or antenna orientation changes. When the signal was completely lost, the frequency jumped to the upper limit of 18 kHz.

The reader was fixed and the transponder was placed at different locations with the two coil antennas facing each other to investigate the effect of antenna misalignment due to body motion. The output frequencies were continuously recorded into the memory card while transponder moved. Four sets of data showing the modulated frequency maps were obtained with distances of 5, 7, 9 and 11 cm between the coils. Figure 3 shows the frequency deviation map at 11 cm, which was the worst scenario of the four cases because the inductive power was the lowest. The colors indicate the variation in percentages of the received frequency from the desired one (13.56 kHz). The x- and y-axes show the relative
positions of the transponder antenna from the center axis of the reader antenna. When the transponder was around the center within ±6 cm, it received sufficient power to operate the transponder and retransmitted back the sensor signals with less than 10% frequency shifts as errors. The errors were acceptable since the frequency shifts caused by reflux episodes were larger than 10% in general. The signals became noisy at the boundaries of reader antenna, and disappeared outside the reader coil area.

The effect of antenna orientation misalignment was examined. The transponder was placed at the center of the reader antenna with distances of 5, 7 and 9 cm between them. The transponder was rotated at angles of 10, 30, 50, 70 and 90° along x-, y- and z-axis. Figure 4 shows the results for y-axis rotation. The result was similar in the x-axis and no change was found with z-axis since the coils were facing each other in parallel when rotating in the z-axis. The system could tolerate up to ±55° angular misalignment.

These aforementioned results indicated that the system could work properly at a reasonable distance with some degrees of misalignment in position and angle between the reader and transponder.

B. Animal Experiments

Live animal experiments were conducted to examine the interference factors such as heart beat, blood circulation and body motion likely to occur in practical scenarios. The animal study was conducted in the animal lab at the Southwestern Center for Minimally Invasive Surgery, University of Texas Southwestern. The experiment was performed on a female pig weighing 47 kg with a chest perimeter of 78.5 cm measured at the level of mid-sternum. The dual-sensor transponder was attached inside the esophagus wall, several centimeters above the gastroesophageal junction. The coil distance through the tissues was estimated to be 5–6 cm. The RF energy from the external reader was able to penetrate through the tissues powering the internal transponder circuit and transponding the signals from both the impedance and pH sensors to the reader. The tests were carried out by passing solutions of different pH values at 2, 5, 7 and 11. Figure 5 shows the results. Each episode was clearly distinguishable by the impedance sensor with sufficient frequency margins between the solutions and air. The quick response time of impedance sensor was short enough to detect the episodes correctly. The pH sensor, with a longer transit time to return to the air condition, simultaneously provided output frequency corresponding to the solution pH values in each episode.

IV. CONCLUSION

An implantable batteryless wireless GERD sensing system has been designed and tested. Impedance and pH sensors have been implemented in a single transponder to detect the occurrence of reflux episode and its nature. Bench-top experiments have examined the implementation issues of the system. Dual-sensor performances have been investigated with solutions at different pH levels in an in vivo animal experiment proving the fidelity of the system.

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