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Sensors Selection for Continuous Monitoring of Bowel State and Activity

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Abstract

New research and diagnosis tools are needed to continuously measure bowel state and activity. We investigated functionality of several sensors *in vivo* and *in vitro*. Five sensor types, including pressure, infrared, color, conductivity and capacitance, were tested to validate functionality inside the colon. Initial wired prototypes were tested and calibrated in benchtop testing and then inserted intraluminally into pig colon and rectum in three acute surgical procedures. The results from both benchtop and in-vivo testing correlate and indicate that pressure, conductivity, and capacitance measurements could provide information on the state of the bowel and its activity.

I. INTRODUCTION

Bowel function during storage and emptying is poorly understood, including the coordination between colon, rectum, and anal activity and the neural mechanisms underlying control of these structures. Mapping studies to understand the neural control of the bowel would significantly improve our knowledge of bowel function and identify potential targets for therapeutic interventions for different disease states. Thus, a tool to provide a biomarker of bowel function is needed.

Several methods have been developed to diagnose bowel dysfunction clinically and these methods are used for research studies to understand the neural control of bowel function. These methods include passing objects through the alimentary canal, such as fluoroscopic markers or the Smart Pill [1]; pressure manometry using fluid-filled balloons inserted into the rectum [2]; and anal electromyogram [3]. These approaches are informative but have

practical limitations. Swallowing markers does not provide continuous measurement of bowel function and can be costly and inconvenient. Pressure manometry may be physically uncomfortable and impractical for use during normal daily activities. Thus, they are insufficient for chronic, ambulatory sensing of bowel fullness and activity.

The neural control of the bowel can be determined using existing methods, such as implantable or percutaneous real-time neural recording devices [4]. However, without measurement of bowel function and activity, it is difficult to elucidate cause and effect from neural recordings. Hence, the neurophysiology of bowel motility is not fully understood. We propose that physical measures of bowel function could be combined with neural recordings to help map neuroanatomy and neurophysiology of the bowel. Logistically, this approach requires sensors that can remain in the same location within the bowel for several days to weeks, to provide reference recordings of bowel function at specific sites which can be correlated with neural recordings. To enable this function, we are developing a system for continuous, wireless measurement of bowel function to monitor bowel fullness and bowel activity. This system is designed to be used in conjunction with electrophysiology tools to understand the neural mechanisms underlying bowel function in health and disease.

Our proposed solution to multi-day bowel activity monitoring is a sensor platform inserted intraluminally into the colon or rectum and fixed to the colon wall using mucosal clips. These clips are typically used for closing mucosal defects, such as during polyp removal procedures, and remain in place typically for approximately 2–3 weeks when they are naturally evacuated [5]. These clips could anchor a small sensor in place for conscious monitoring of humans or research animals. After the measurement period, the sensor would be passed during normal defecation.

Here, we present the first steps in developing this device: understanding the criteria for measuring bowel activity and selecting appropriate sensors to monitor key physiologic parameters. A benchtop testing system was developed to validate the functionality of the initially selected sensors for our intended use. Based on the specifications of the sensors and the results taken from the benchtop tests, selected sensors were further evaluated qualitatively *in vivo*.

II. SENSOR SELECTION AND BENCHTOP VALIDATION

A. Sensor types and sensing modalities

The colon and rectum move stools by coordinated contractions of circular and longitudinal smooth muscles. Our goal was to measure the fullness, activity, and motility of a section of colon. We identified a set of promising sensor modalities (Table I) to measure colon fullness (volume), colon activity (contractions), and colon motility (movement of contents). The pressure sensor was designed to detect contraction of circular smooth muscle in the bowel. By monitoring multiple sensors at different locations, peristalsis can be detected. Infrared (IR) sensing was expected to measure the distance between the sensor and colon wall or stool, providing an estimate of bowel fullness.

The color sensor was expected to discern the empty pink colon from brown or green stools. Conductivity and capacitive sensors were expected to measure volume changes of the stool at the sensor location. Increasing or decreasing the volume of stool would be expected to change the resistivity or dielectric effect. Our benchtop and *in vivo* testing results confirmed the best practical choices to be later considered.

Two important factors in sensor selection for a wireless implanted device are size and power consumption. Since the final device is expected to be inserted and fixed inside the colon, it should be small enough to easily pass through the rectum and colon and not obstruct the colon during normal physiological function. Our measurements of pig colons revealed that the average colon diameter was approximately 3–5 cm. Since the final sensors will communicate wirelessly with an external portable transceiver for at least 48 hours, they should be capable of functioning at low power [6].

B. Sensor functional testing and selection

Sensors were mounted to small, wired test boards and encapsulated to be waterproof for benchtop and *in vivo* testing (Fig. 1). The first fabricated board was approximately 20 mm × 50 mm with pressure and IR sensors as well as 8 electrodes for conductivity measurements in two dimensions (Fig. 1, device 1). The board was modified with a smaller pressure sensor (P), a color sensor (Clr), and conductivity measurements along a single axis (Fig. 1, device 2). During initial *in vivo* testing, we found that as soon as Clr and IR sensors were coated by stool, they would not detect further changes in stool volume. A thick window of clear epoxy was incorporated above the color sensor and its nearby LED to attempt to resolve the issue (Fig. 1, device 3). However, in further *in vivo* testing, we found that this design did not provide significant improvements in sensor function.

The most recent design iteration comprised a miniaturized PCB (7 mm × 36 mm) with three sensor modalities, including pressure, conductivity, and capacitive sensors (Fig. 1, device 4). Overall, this design was based on two major concepts: (1) measurement of pressure, which can detect peristalsis and the level of pressure inside the colon or rectum and (2) conductivity and capacitive measurements, which provide information about the presence and volume of stools surrounding the sensor.

Conductive and capacitive sensors can differentiate between the state and type of the substances by recording changes in either resistivity or the dielectric effects of substances. Such changes could be because of the stool volume change or attachment of the colon wall to the sensor (empty colon). Therefore, the combination of pressure, conductivity, and capacitive sensors will provide useful information about the state and activity of the colon in addition to the type and volume of the substances. Importantly, these simple sensor modalities are easily implemented in low-power hardware and at small scales.

C. Fabrication of multi-mode sensor platform

A sensor board was designed to include only pressure, conductivity, and capacitive sensors (device 4). The pressure sensor was located at the head of the PCB and the metal mesh electrodes for conductivity and capacitive sensors were located at the tail of the device. The pressure sensor was protected from the aqueous environment by coating it in dielectric

silicone gel. Each prototype consisted of four electrodes (three cathodes (CA1, CA2, CA3) and one anode (A)) located at different distances from each other (Fig. 2). The electrodes were made of 316 alloy stainless steel mesh which has robust corrosion resistance properties. Coated stainless steel wires were soldered to the electrodes to enable measurement. These electrodes were also used to form the plates for capacitive measurements (Fig. 2). Capacitance is determined in this device through RC decay time measurement, which is easily measured by microcontrollers in a time-to-digital coding. Stool volume change could result in the dielectric change and therefore RC decay change. For conductivity, the three transmitting electrodes drive electrical current into the stool while the common anode (A) measures the voltage drop due to the stool. Therefore, the stool would either change the dielectric effect or resistivity.

The PCB and the solder joints of the electrodes were coated by epoxy for insertion into the pig colon for acute *in vivo* testing. The only exposed sections of the device were the pressure sensor head (protected with gel) and the electrodes. Finally, a U-shape handle was placed at the head of the PCB to be used for the attachment of the device to the colon wall using mucosal clips (Fig. 1, device 2).

D. Prototype Sensor Bench Test and Calibration

To test and calibrate the sensors prior to *in vivo* use, the prototype device responses to pressure, infrared (IR), color, conductivity and capacitive measurements were characterized through benchtop testing in a colon phantom (Fig. 3). To simulate the environment of a colon on the bench, the prototypes from Fig. 1 were inserted into a silicone phantom (3.5 cm diameter) while it was filled with liquid, gas, or solid materials (Fig. 3).

E. Animal Preparation

A total of 3 acute *in vivo* experiments were performed in male and female pigs. All animal care and experimental procedures were approved by the Institutional Animal Care and Use Committee (IACUC) of the Cleveland Clinic.

Animals were sedated with xylazine and anesthesia was induced and maintained with isoflurane. Animals were placed supine to access the abdomen and anus. Sensors were calibrated before insertion into the colon through a speculum to distances of 10 – 50 cm.

III EXPERIMENTAL RESULTS

A. Bench top test results

Color and IR sensors successfully detected the contraction of the phantom due to the proximity of the phantom wall to the sensors. They were able to distinguish between the gas and liquid materials. However, in solid material tests they were blocked and could not provide further data (Fig. 3).

The pressure sensor is capable of detecting pressure changes due to squeezing the phantom and increasing volume of the stools. Conductivity and capacitance correlated with stool volume.

B. In vivo test results

In the first experiment, color and IR sensors were blocked by stool and were not sensitive to colon contraction or stool volume changes. This effect was expected from bench top testing. Therefore, the sensors were disregarded for further consideration in the later experiments.

Conductivity and capacitive sensors were initially tested by putting stool on the closest electrodes (~1.65 V at Fig. 4). More stool was then added to cover the second electrode. The same trend was continued for covering the third electrode with stool (Fig. 4 & 5). As each electrode came in contact with stool, a monotonic increase in conductivity was seen. When all of the electrodes were covered with stool, adding more stool showed further shifts in the conductivity measurement (Fig. 4, 150s). Therefore, conductivity measurement is feasible for volume estimation of the stool inside the colon. Although capacitive sensing was able to detect the presence of stool over the sensor and some changes in volume, it was not sensitive to the volume changes after the gaps between the plates were totally filled with stool. (Fig. 5). Next, the sensor was inserted in the rectum through the anus and by squeezing the abdomen, the stool was moved across the device. Conductivity measurements showed these simulated contractions (Fig. 6). After this, the sensor was inserted into the rectum with different volumes of stool (Fig. 7). The conductivity sensor detected the volume change inside the rectum; however, the capacitive sensor was not as sensitive, although it was able to distinguish between a full and an empty rectum (Fig. 8).

A laparotomy was then performed to access and visualize the colon. A small incision was created to insert the sensor board inside the colon. To test functionality of the sensors to discern between the colon wall and the stool, the sensor was tested under three conditions, including (1) an empty colon with the electrodes facing into the colon wall; (2) an empty colon with the electrodes facing into the empty lumen; and (3) a colon filled with stool and the electrodes facing the stools (Fig. 9). The conductivity sensors were capable to discern between facing the colon wall and facing the stool.

The pressure sensor was tested by inserting the sensor board inside the colon and then muscle contractions were induced using electrical stimulation of the exterior colon surface (Fig. 10). Stimulation was administered every second in bursts of 20 pulses at 100 Hz at 40 mA and 0.5 ms pulse width.

IV CONCLUSION AND ONGOING WORK

Several sensor methods were considered based on their potentials to detect the activity and states of the bowel, their size, and power consumption. The functionality of each method was tested and validated in a benchtop test system. Based on the results of the bench tests, modified sensors were further evaluated in three in-vivo experiments. The final validated sensors, including (but not limited to) pressure, conductivity, and capacitive sensors, may provide enough information for monitoring bowel state and activity. These sensors will be used in developing a novel wireless device, which would be inserted intraluminally and affixed to the colon or rectal wall using mucosal clips. The device will communicate with an external portable transceiver for continuous data collection.

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Fig. 1:

Prototype bowel sensor designs based on results from benchtop and *in vivo* experiments. # 1 shows the initial fabricated prototype, and #2 shows a smaller design with a u-shaped handle to attach the mucosal clip to the colon wall. Boards 1, 2, and 3 tested four types of sensors: Pressure (P), infrared (IR), Color (Clr), and conductivity (Co), with Clr coated in clear epoxy in #3. #4 is the most updated sensor board, with P, one anode (A) and three cathodes (C₁, C₂, C₃) for both conductivity and capacitance measurements.

Fig. 2:

Three cathodes (CA1, CA2, and CA3) and one anode (A) are used as conductance and capacitive sensors (C1, C2, and C3). The differing electrode spacings enable detection of stool volume change.

Fig. 3:

Benchtop test phantom. Sensor boards were tested in three conditions: solid, liquid, and gas. The board was inserted in the phantom (#1) and the phantom was filled with liquid (#2) or gas (#3). For solids, sensors were tested by passing artificial stool through the phantom over the sensor board (# 4 & 5).

Fig. 4:

Conductivity sensor response to stool volume change. 1) Only CA1 and A (Fig. 3) are covered with stool. 2) CA2 also covered. 3) Adding more stool to cover CA1, CA2, CA3 and A. 4) Adding more stool to increase the total volume of the stool.

Fig. 5:

Capacitive sensor capability in stool appearance detection. 1) Only CA1 and A (Fig. 3) are covered with stool. 2) Adding more stool to cover CA1, CA2, and A. 3) Adding more stool to cover CA1, CA2, CA3 and A. 4) Adding more stool to increase the total volume.

Fig. 6:
Conductivity sensor capability in contraction detection. 1) No contraction. 2) Simulated contractions start.

Fig. 7:

Conductivity sensor differentiation between stool volume and gas. 1) Sensor inserted into the rectum while it is full with stool. 2) Sensor was taken out of the rectum. 3) Sensor was inserted back to the rectum with lower volume of stool.

Fig. 8:

In vivo capacitive sensor measurements. 1) Sensor inserted into the rectum, full of stool. 2) Sensor removed from rectum. 3) Sensor was reinserted into the rectum with lower volume of stool.

Fig. 9:

Conductivity measurement of the colon wall vs the stool-filled colon lumen. 1) Sensors facing the stool. 2) Sensor board rotated to face the colon wall. 3) Sensor board rotated and facing the stool.

Fig. 10:
Pressure sensor capability in detecting bowel fast waves.

TABLE I:

BOWEL SENSORS EVALUATED IN THIS STUDY.

Sensing Method	Fullness	Activity	Motility	Size (<i>mm</i>)
Pressure [7]		✓	✓	2×2×0.76
Infrared [8]	✓			2.7×3.4×1.6
Color [9]	✓			2×2.4×0.6
Conductivity	✓	✓	✓	~20–30 long
Capacitance	✓	✓	✓	~20–30 long