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Fecobionics: A novel bionics device for studying defecation

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Abstract

During defecation, solid, semisolid or liquid stools are eliminated via the anus in a complex physiological process. Up to 25% of the population are affected by anorectal disorders that are poorly recognized and treated. We developed a new bionics device, a simulated stool named Fecobionics, to replace several current tests of anorectal function. Fecobionics was developed to simulate the defecation process that depends on rectal forces, the anorectal size angle, and anorectal size and sensitivity. Fecobionics provided axial pressure signatures, measurement of bending (anorectal angle) and geometric mapping in a single examination. It had the consistency and shape of normal stool. The device had a soft core with embedded electronics and a bag for distension. The paper describes the device development and validation. Furthermore, data were obtained in preliminary experiments in pigs, healthy human subjects and patients with focus on four important features of the system, i.e. measurements of pressure signatures, bending characteristics, impedance measurements and data transmission. Accurate pressure and orientation data as well as geometric profiles were successfully obtained on the bench as well as in vivo in pigs and human subjects during defecation. Fecobionics is a novel technology imitating defecation. The clinical future ultimately depends on its ability to impact on daily treatment of anorectal disorders. A potential long-term clinical application is use of the device for biofeedback training for dyssynergic defecation.

Keywords

Anal sphincter relaxation; Anorectal physiology; Bionics; Defecation; Fecobionics

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Conflict of interest

Hans Gregersen has filed applications for patents on the technology.

INTRODUCTION

During defecation, solid, semisolid or liquid stools are eliminated via the anus in a complex physiological process.^{5,23} Up to 25% of the population are affected by anorectal disorders that are still poorly recognized and treated.^{3,9,19} Physiologically relevant and easy-to-use diagnostic tests for identifying underlying mechanisms are missing. Especially, the opening characteristics of the anal sphincter and the relaxation of the puborectalis muscle during defecation cannot be described in detail with any currently available technology. For example, defecography does not provide information about anorectal pressures, the balloon expulsion test (BET) does not assess geometry, and high-resolution anorectal manometry (HRAM) and the Functional Luminal imaging Probe (FLIP) distensibility test are not done during defecation. Considerable disagreement have been found between the results of various anorectal tests and they correlate poorly with symptoms and treatment outcomes.^{3,17,19} Therefore, a new anorectal function test is warranted. Previous attempts to make artificial stool for evaluation of defecation have been made, i.e. both BET⁴ and Fecom¹⁸ are devices to be defecated. BET is currently being used in some clinical laboratories. However, the only parameter assessed is the expulsion time. Fecom never found widespread use.

We aimed to fundamentally rethink the approach to anorectal functional testing based on the bionics concept. The biomechatronics device, named Fecobionics, was developed to simulate the defecation process. It provided geometric mapping and pressure signatures, as well as measure the bending of the device, i.e. a proxy of the anorectal angle during defecation. Fecobionics contained a soft core with embedded sensors and other electronics. Furthermore, it had a bag mounted for rectal distension. The goal was to provide a mechanistic understanding of defecation in health and defecatory disorders. We created the device with mechanical properties similar to stool. It provided physiologically relevant measurements of anorectal function during defecation. Recently, the first physiology data were published.⁷ The pressure signature could distinguish five distinct phases during defecation. The present paper describes the device development and validation experiments. Furthermore, pilot data obtained in pigs and human subjects with a tethered embodiment and the preliminary work to develop a wireless prototype are described. In addition, further thoughts on data analysis are provided.

MATERIALS AND METHODS

General concept, design and materials

Fecobionics is an electronic simulated feces that has the consistency and shape of normal stool. It was designed to have a consistency and deformability of Type 4 on the Bristol stool form scale.⁹ The range from types 3-5 in the Bristol stool form scale is seen in 70% of healthy subjects. Fecobionics integrates several other technologies for obtaining physiologically relevant measures during defecation.^{7,17,21} It records pressures, orientation, shape, and viscoelastic properties. Based on consideration of anorectal anatomy and current anorectal devices, Fecobionics was constructed as a 10cm-long and 12mm-wide bendable core with embedded electronics and a bag mounted (Figure 1).

Core.—The core was made of medical grade silicone resin that contained the electronics (Figure 2). Silicone was the ideal core material due to its softness, durability, non-degradability, electrical current insulation, and lack of phthalates and other chemicals suspected of having carcinogenic and mutagenic effects on the skin and mucous membranes. Several resins of different hardness were trialed after cure in a mechanical test machine. The silicone core ensured that electrical components were not in direct contact with tissue, which is important if batteries leak or the electronics short-circuits.

Bag.—A 30- μ m thick polyester-urethane (PU) bag spanned most of the length of the core. The bag was manufactured using a mold that heated two sheets of PU together. The bag was mounted on the core using medical grade glue (Figures 1 and 2). The distended spherical bag could contain up to 70 ml without being stretched. It had a maximum diameter of 6 cm.

Electronics.—Three pressure sensors were embedded in the core at the front, rear and inside the bag. Two Motion Processor Units (MPUs) for orientation, angle, and bending measurements were placed towards the front and rear. Some prototypes contained electrodes for impedance measurements (Figure 1). The pressure sensors, MPUs and impedance electronics are described separately below.

The wired prototype presented in this paper had the sensors and the Microprogrammed Control Unit (MCU) inside the device. Batteries and the data transmitter were external. Figure 3 shows an electronic circuit diagram. To avoid potential stimulation of the anal canal, the preferred future embodiment will be wireless with batteries and wireless transmitter embedded in the core (see later). The MCU and Wireless Transmitter Unit (WTU) was the IAP15L2K61S2 (STC4, China). The specifications are 61 Kbyte flash and 2 Kbyte RAM. The MCU needs 22 Kbytes of flash and 3 Kbytes of RAM to run the motion driver for the MPU chips. The selected MCU is sufficient for the current prototyping though the embedded software will surely expand when more functionalities are added. Most of the RAM usage can be moved to the flash to fulfill the 2 Kbyte RAM requirement. The MCU has two UART ports for communication with other parts of the system.

Pressure measurements

Miniature gel-filled pressure sensors (MS5837-30BA, TE connectivity, USA) were selected and placed at the front, inside the bag, and at the rear of the core. Many types of medical-grade pressure sensors are commercially available. The MS5837-30BA sensor was found suitable for the prototype development. The sensor size is 3.3 $\times$ 3.3 $\times$ 2.75mm with an operating pressure range of 0-6MPa with 0.054kPa resolution. The gel protection and antimagnetic stainless steel cap make the module water resistant. Since the sensor measures absolute pressure, zero pressure reference adjustment at atmospheric pressure was needed before measurements. Pressure data were stored and displayed in real-time on the user interface. One of the novelties of Fecobionics is that it measures axial pressures in the front and rear of the device. This is distinctly different from other anorectal pressure measurement devices such as high-resolution manometry and high-definition manometry that measure radial pressures.^{12,16}

Orientation, angle and bending measurements and calculations

A variety of commercially available gyroscopes and accelerometers were considered. The MPU6050 (InvenSense, USA) was chosen as the motion processor unit to measure orientation and acceleration. By combining signals from two MPUs we were able to compute the bending of the device (see below). This chip contains a triple axis accelerometer, a triple axis gyroscope and a Digital Motion Processor (DMP) in a 4×4×0.9mm package, which processes complex 6-axis motion algorithms.

The gyroscope outputs the angular velocity. The angle is the integration of the angular velocity. Since each gyroscope readout has a small error, such errors will accumulate as time goes by due to integration.

The accelerometer continuously measures the acceleration. When the accelerometer is tilted, the accelerometer angle relative to the field of gravity can be calculated. Gyroscopes provide good dynamic response but drifting is a problem. The accelerometer has gravity as permanent reference but the drawback is low signal-to-noise ratio compared to gyroscopes (the accelerometer has a SNR of around 65 dB while the gyroscope has a SNR of around 88 dB). Therefore, a complementary filter was designed to achieve a better dynamic response and to solve the drift problem. Mathematically, low-pass filtering of the accelerometer signal makes it smoother and the high-pass filtering of the gyroscope signal eliminates the drifting problem.¹⁰ It can be stated as:

$$\theta(n) = 0.9 \times (\theta(n-1) + \omega(n) \times \Delta t) + 0.1 \times \theta_a(n) \quad (\text{Eq. 1})$$

where θ is the angle, ω is the angular velocity read from the gyroscope, t is the time difference between two readouts, and θ_a is the angle measured by the accelerometer. The first part of the equation is equivalent to a high-pass filter and the second part is equivalent to a low-pass filter.

The time constant of the filters was 0.48s and the cutoff frequency of both filters was 0.33Hz.

Electrical impedance measurements

In some of the prototypes, electrodes were mounted on the surface of the core inside the fluid-filled bag. Two outer electrodes generate a constant alternating electrical field inside the saline-filled distension bag (70 microA RMS at 10kHz sine wave). Nine equidistant detection electrodes measure the impedance of the fluid between them (measurement from 8 pairs). Analysis of changes in the impedance signals during movement of device is used to calculate the velocity of the device since the distance between measurements are known. This will allow measurement of the expulsion velocity. In addition, using a simple extension of Ohm's law named impedance planimetry,^{6,8} the cross-sectional area of the bag can be measured between each pair of detection electrodes.¹ The device was connected to an impedance data acquisition system and the data were analyzed off-line. As expected the voltages as function of the diameter of the calibration tubes fitted a logarithmic function. The highest amplitudes were found for the measurements in the middle of the bag, i.e.

furthest away from the pair of excitation electrodes where the electrical field was most uniform. This is consistent with previous publications on impedance planimetry.^{6,8,21}

Data transmission of tethered prototype

Fecobionics was at first developed as a tethered device. Four wires connected the embedded MCU with the laptop for data transmission and power supply (Vcc, GND, TX and RX). The wires were exteriorized from the front of the core outside the bag, i.e. close to where the tube for infusion fluid into the bag was connected (Figures 1 and 2). In the tethered Fecobionics, the MCU sent 76 bytes raw data out (a bit rate of 115200 bit/s for 5.3ms). Further processing was done in MATLAB.

Wireless development.—Work was initiated on making the device wireless. Wireless transmission must be stable and provide reliable communications.²² Medical wireless communication technologies cover a large range including electromagnetic methods, acoustic links, optical links, and RF band.¹¹ Ultra-high-frequency (UHF) transmission was selected.¹⁵

In addition to considering transmission efficiency, another reason for choosing 433 MHz RF was that this technology has been well developed and applied in capsule endoscopy.^{2,14,15} The successful application in the capsule endoscope made it a suitable option for Fecobionics. We gave due consideration to power, size, signal-to-noise ratio, cost and safety. We selected for the wireless Fecobionics the LINX TXM-433-LR wireless transmission module (Linx Technologies, OR, USA). The receiver antenna was placed in the receiver outside the body. We removed the cover of the chip (12mm wide) and used the PCB directly (9mm wide) to make it fit into the Fecobionics core.

The transmission speed of the wireless Fecobionics will be lower (only one-byte data in 3ms) than in the tethered version. In order to achieve a higher frequency, some of the processing must be moved into the MCU. We reduced the 76 bytes from the MCU in the tethered version to 8 bytes in the wireless device. The MPU calculated the front, rear and bending angle and the front, middle and rear pressures before the wireless transmitter sent the data. These tasks were repeated until a stop command was received.

Like other wireless modules, RF 433 MHz has noise when operating and in general for RF wireless transmission, the transmitter and receiver do not pair with each other. Hence, the data stream may be interrupted by noise from the environment and it is important to calibrate before data transmission. Using the specifications from the manufacturer, we converted the collected sensor data into 8-bit numbers with one byte information in each package. Theoretically, this gave us a maximum frequency of 80.1 Hz.

To test wireless transmission performance, we programmed a fully functional probe to send the numbers 1-255 repeatedly at 80 Hz frequency through air, water or human tissue (placed inside the mouth, as well as doing a defecation experiment). The receiver antenna was placed 4 meters away from the transmitter. The data loss rate and data error rate were defined as:

$$\text{Data loss rate} = \frac{\text{total data sets number reciever(receiver end)}}{\text{total data sets number sent(transmitter end)}} \quad (\text{Eq. 2})$$

$$\text{Data error rate} = \frac{\text{incorrect data sets number}}{\text{total received data sets number}} \quad (\text{Eq. 3})$$

In all tests, each set of data contained 8-byte information. Transmission rate was set at 80Hz. In the air, water and “inside mouth” experiments (n=4 for each experiment with one minute recordings), the transmitted data set numbers were between 6423 and 6743. It was 3444 in the defecation experiment.

The remaining element to consider for making Fecobionics free of all tethering was the tubing for filling the bag. A variety of solutions were considered for detaching the tube. In the current prototype, we embedded a valve in the infusion line inside the core. When the tube was retracted after filling the bag, the valve would close. The tube was embraced by an overtube that aided the detachment of the tube without movement of the core inside the rectum during detachment.

Power supply

The driving voltage for the circuits and sensors was 3.3 volts. For the tethered Fecobionics we used an external power supply from the USB port. In the wireless embodiment, the key issue was the current drain. Small-sized batteries with high volumetric energy density were required for Fecobionics². Based on manufacturer data for the various components, the current drain for Fecobionics was estimated to be:

$$(0.6 \mu\text{A} * 3) + (3.9 \text{ mA} * 2) + (5.0 \text{ mA}) + (29 \text{ mA}) = 42\text{mA} \quad (\text{Eq. 4})$$

representing the current drain from pressure sensors, MPU, wireless transmitter and MCU, respectively.

Taking internal battery resistance and wire resistance into consideration, the battery capacity should exceed 50mAh to power Fecobionics to work for at least 20 minutes. The battery time must allow time for initialization, calibration, insertion into rectum and defecation of the device. We selected 1.55V Renata 380 silver oxide coin battery for the prototype. Three batteries were connected in series to power the wireless probe for testing battery duration. The batteries had a capacity of 82mAh. When the voltage of the battery dropped to below 3.3V, the MCU stopped working. Preliminary experiments demonstrated that the batteries powered Fecobionics between 17 and 24 minutes (n=3). This was considered satisfactory since initialization, calibration and insertion and bag distension would take less than 12 minutes and most persons will be able to defecate the device within two minutes (which is the cutoff limit between normal and chronic constipation during expulsion of BET).⁴ If a patient cannot defecate the device within 5-10 minutes, it should be retracted manually. This

is easily done with the tethered device. For the wireless prototype, a thread as used in tampons may be used for this purpose.

In vivo testing

Human and animal experiments were done according to national and institutional rules and the protocols were approved by the Institutional Review Board in the New Territories of Hong Kong and by the Institutional Animal Care and Use Committee at California Medical Innovations Institute. The preliminary human experiments adhered to the Helsinki Declaration as revised in 2000. Three healthy subjects (age range 28-54 years) were studied for testing the tethered prototype and the wireless approach was tested in one of the healthy subject on a separate occasion (male age 54 years). The subjects gave informed consent. None of the healthy subjects took any kind of medication. They reported that they never had abdominal surgery and that their defecation pattern was normal. Data are also presented from a patient suffering from fecal incontinence and from a patient suffering from obstructed defecation. In addition, the wireless prototype was tested in a 60kg pig for evaluation of transmission parameters. The probe was inserted into the rectum through the anus. The bag was filled inside rectum with 30ml saline and recordings were made until the pig expelled it.

RESULTS

Bench testing

Several resins were purchased and tested after hardening. The core must be readily bendable to allow unbiased measurement of anorectal angle changes during defecation. After experimenting with four different hardness types, silicone rubber PS6600 (Yipin Mould Material Ltd, China) with hardness shore A5 was selected for the prototype development. The resin cured in 20-30 minutes after mixing the components. Figure 4 (top) shows the bending test set up and results from one of the experiments.

Pressure measurements and analysis

It was confirmed experimentally that the pressure sensors gave accurate pressures within the specifications provided by the manufacturer. Three repeated tests were done by dipping the Fecobionics into water with an increment of 5 cm up to 40cm below the surface. The depth of the water was measured by a ruler. The pressure sensor was held for 5 seconds at each pressure level and the sampling rate was 30 samples per second, i.e. for the three tests a total of 450 samples were obtained at each pressure level. The average values deviated less than 1.1cmH₂O from the reference pressure value. Drift did not occur as long as the silicone cap on the sensor was not damaged and excessive stretch not imposed to the wires and connections.

Orientation and angle measurements

The Fecobionics probe was bent to 90 degrees with increments of 10 degrees controlled by a protractor. One end of Fecobionics was fixed. The probe was held for 3 seconds at each preselected angle and the test was repeated 3 times, i.e. 270 samples were collected at each angle. The angle was measured by the algorithm which combines the measurement of accelerometer and gyroscope. Average measured angles deviated less than 2.7 degrees from

the reference angle. The standard deviation (σ) was less than 2.8 degrees. Drift did not occur in the 1.5-minute bending tests. A capture from graphical user interface (GUI) during bending testing is shown in Figure 4 (lower panel). During the test, the rear MPU was bent from 10 degrees to 90 degrees with an increment of 10 degrees while the front MPU was fixed.

In vivo testing

Several expulsions were done in each of the three healthy subjects (n=2, 3, and 3). After instruction of the subjects, initialization and calibration, the Fecobionics device was inserted into the rectum through the anus with the subject placed in supine position lying on the left side. The subject moved to sit on a commode chair. The bag was inflated at a rate of 60ml/min until the subject felt urge-to-defecate. This sensation appeared when 20-60ml fluid was infused into the bag. The subjects were asked to defecate the device. The subjects were able to expel Fecobionics within 1 minute. The entire procedure time including initialization, calibration, insertion, distension and expulsion lasted 8-10 minutes. No adverse effects were reported. Defecation of Fecobionics were described as similar to defecation of intestinal contents.

Pressure signatures and anorectal angle measurements.—A schematic of a typical pressure signature as function of time is shown in Figure 5. Useful physiological and clinical information can be extracted from the rear and front pressure measurements and in the difference between these two measures. In two expulsions, Fecobionics was expelled during a single abdominal pressure increment. However, it seems to be a more common pattern that the healthy subject used 2-4 abdominal pressure increments to expel the device (figure 6).⁷ The rear and front pressure data can be converted to loop diagrams showing the rear pressure as function of the front pressure as shown in Figure 5 and 6. The analogy is the cardiac preload-afterload diagram.^{5,7} The driving force will be picked up by the rear pressure sensor whereas the front pressure sensor will record the afterload. Figure 6 shows data from a healthy subject who increased the abdominal pressure three times to evacuate the device (A and B). Figure 6C and D are data from a subject suffering from fecal incontinence who easily evacuated Fecobionics. Data obtained in a subject with obstructed defecation, who was not able to evacuate the device within 2 minutes, are shown in figure 6E and F.

The MPUs recorded changes in orientation during the passage from rectum through the anal canal to the outside environment. The orientation relative to the field of gravity changed when passing from the rectum into the anal canal. The device landed in horizontal position in the pot below the commode chair, which was confirmed by the orientation measurement. The bending angle changed during the expulsion. From being straight inside the rectum, the angle changed to 120-140 degrees when passing into the anal canal, which corresponds to data from the literature on defecography.¹³ Figure 6F shows MPU data from the subject with obstructed defecation. This subject was not able to evacuate the device within 2 minutes.

Impedance measurements and analysis.—The recorded pressure and diameters along the eight impedance electrode pairs during expulsions (n=3) were used for further

geometric and biomechanical analysis. During the expulsion, the device moved from the rectum with the front entering into the anal canal followed by the rest of the device sliding through the anal canal to the exterior (line AA' in Figure 7 top). The expulsion path of the bag $l(t)$, (line AA' in Figure 7 top) was used for calculating the device movement. The expulsion path showed an exponential relationship to the expulsion time and was expressed as:

$$l(t) = a(e^{(b * (t - t_0))} - 1) \quad (\text{Eq. 5})$$

where $l(t)$ is the expulsion path of the bag, i.e. the bag movement in the anal canal at time t , t_0 is the entry time of the front, i.e., the device starting to enter the anal canal. The constants a, b can be obtained by curve fitting Eq. 5 to line AA' in Figure 7 top.

The expulsion velocity v was calculated from Eq. 5 as:

$$v = dl(t) / dt \quad (\text{Eq. 6})$$

The expulsion path demonstrated the changes in shape during the passage through the anal canal (Figure 7 top). Recordings for the point that entered into the anal canal was more stable than the recordings for the point that left the anal canal, especially when the expulsion velocity increased dramatically at the end of the expulsion. It means the forefront data were optimal for expulsion path definition and velocity calculations. In this part of the study, the test was conducted on healthy volunteers ($n=3$, one expulsion in each) with normal function of the anal sphincter. The expulsion path showed an exponential relationship to the expulsion time. However, due to dysfunction in patients with anorectal disorders, the expulsion path may be quite different in patients and the analysis may be refined if required.

Using the computed expulsion velocity, the bag movement and the corresponding shape change can be reconstructed with realistic geometry. The final data visualization is animations of geometry and pressure changes of the bag during expulsion. Anatomical features of the anal canal and rectal wall were reconstructed from the calculated bag movement and the bag shape change. Figure 7 (bottom) shows four representative still pictures from an animated reconstruction from expulsion data. The anatomical data were reconstructed from the bag geometric data when the bag passes from the rectum through the anal canal to outside the body.

Wireless transmission parameters.—Table 1 shows data from the wireless transmission experiments. For transmission in air and with the transmitter in water or inside the mouth, no data loss and data error were encountered for the four-meter distance between the transmitter and receiver.

For the defecation test, we embedded the wireless transmitter in the core and mounted the bag. We calibrated a functional probe with wireless transmitter and activated the wireless data transmission function. The device was inserted into the rectum of a healthy subject and

the bag was filled like in other experiments until the urge-to-defecate level. The subject defecated the probe when asked to do so. During the whole process, data were collected from the transmitter and receiver. To optimize data quality we set the transmission frequency at 14Hz (Table 1). The data loss rate and data error rate were approximately 1%, which was considered acceptable.

We used 14Hz during the defecation test despite the transmitter was capable of 80Hz because the sensors require time to respond and the MPU is only capable of running one task at a time. To complete one cycle the total time is 53.5ms. The corresponding frequency is 18.6Hz

In the pig experiment, recordings were obtained for 6 minutes before the wireless device was defecated. The receiver antenna was 1-2 meters away from the pig. The data loss and data errors rates were less than 1:100. The pressure recording during the porcine defecation of Fecobionics is shown in Figure 8. In addition, the MPU recordings indicated that the pig does not have an anorectal angle like humans. In contrast to humans, the rectum seems to continue straight into the anal canal without significant bending.

DISCUSSION

We have demonstrated successful design, bench testing and application of Fecobionics in humans. Proof-of-concept was obtained. Nevertheless, the prototypes can be optimized in several ways spanning from reducing the energy consumption to increasing wireless transmission speed. Fecobionics may improve current diagnostic technologies. It provides several innovations including 1) Mechanical properties of the device that mimic normal stool, 2) Objective electronic measurement of the anorectal angle independently of direction/rotation or personal interpretation (Figure 2B), and 3) Integration of geometric data with multiple pressure measurements. Especially, the pressure signature with the phase-division of expulsion is novel. Since Fecobionics integrates several current tests, it potentially provides simple and inexpensive assessment of a range of defecation biomarkers that will be important in both research and clinical practice. Fecobionics has potential to shift the current paradigms by addressing pitfalls with current tests. It holds potential to differentiate patient groups and provide insight into causes and mechanisms of functional anorectal disorders. Technology-related issues yet to address are improving wireless transmission, position determination for identifying the trajectory and establishment of libraries based on physiological and clinical data.

Using Eq. 6, we found the frequency to be 18.6Hz. Lower frequency will be encountered if data are lost. The defecation process is quite fast with the evacuation as short as in a few seconds. To capture accurate angle change information, higher frequencies are required (at least 20Hz for each sensor). Another consequence of low frequency is idle state noise when the transmitter is waiting for data to refresh. This explains why the data error rate and data loss rate are higher in the real test compared to the maximum frequency test. The transmitter itself is capable of sending data with high enough frequency. When combined with other electronics both frequency and accuracy must be improved.

The clinical future of Fecobionics ultimately depends on its ability to impact on daily treatment of anorectal disorders. First healthy signatures and different patient groups suffering from fecal incontinence and chronic constipation, and their subtypes, must be characterized. The present studies merely provides illustrative examples of preliminary clinical data. A potential long-term clinical application is use of the device for biofeedback training for dyssynergic defecation.²⁰

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FIGURE 1:

Schematic of the system with a tethered embodiment (upper panel), an untethered embodiment with impedance electrodes on the core surface (middle panel) and wireless transmission (lower panel). The core was made from soft silicone resin. It contained three pressure sensors placed at the front, rear and inside the bag. Two Motion Processor Units (MPUs) were imbedded for determination of orientation and bending during defecation (measurement of the anorectal angle during passage from the rectum to the anal canal). In addition, the core contained the Microprogrammed Control Unit (MCU). A tube was

attached to the front for filling the bag. Middle panel: In the wireless prototype, a tube detachment system secures that the device disconnect the tube after the bag filling. In some prototypes, impedance electrodes were mounted on the surface of the core (middle). They provided measurement of geometric parameters as well as the velocity could be computed. Lower panel: The device inside the rectum transmitting data wireless to the received outside the body.

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FIGURE 2:

Mounting of electronic components in the lower part of the mold being filled with resin (upper panel). The cured core with three boards connected with 8pin JST connectors for the pressure sensors, MPUs and MCU lying by the side (middle panel), and the device with mounted bag (lower panel). The impedance electrodes were not mounted in the prototype shown in the photos.

FIGURE 3:

The signal processing circuit consists of five parts: 1) 10kHz band-pass filter; 2) Differential amplifier (MCP6N11T); 3) MCU (DSPIC33EP512); 4) Differential 4 to 1 multiplexer (ADG759); and 5) Two single 8-1 multiplexer (ADG58). The signal processing based on these circuits were: the MCU generates the AC with 10kHz frequency to the two outer electrodes to generate a constant alternating field inside the saline bag. The voltage differences between adjacent electrodes were sent to the differential amplifier to be amplified 100 times through the two single 8-1 multiplexer. The band-pass filter was used to extract the effective pure sine wave by filtering the harmonic wave. Finally the MCU collected the effective signal through A/D. Long time one-way movement of ions will cause systemic error due to electrolytic reaction. We used a differential 4 to 1 multiplexer to exchange signal input direction for the 10Hz to make the voltage difference more stable. Two gyroscopes and three pressure sensors communicated with the MCU through I2C bus to transfer the raw data. Then MCU communicated with the outside receiver by wired or wireless communication.

FIGURE 4:

Bending test of the core with embedded electronics. Left top panel) the test setup. Right top panel) Linear relationship between force and displacement. Lower panel) A capture from the user interface, which shows the angle measured from both MPUs during the bending test. Front angle means the angle measured by the front MPU. Rear angle means the angle measured by the rear MPU.

FIGURE 5:

Schematics of pressure data representations. The front and rear pressures and the difference between the two pressures are shown in the upper panel. The expulsion through the anal canal can be characterized by five different phases (human data in ref [7]: P_1 is characterized by similar pressure increase in both sensors. P_2 represents the beginning of anal muscle relaxation with the relative deviation between the two pressures, and P_3 the passage of the front through the anal canal. In P_4 , the front is outside the anal verge while the rear is entering the anal canal. In P_5 the rear passed the anal canal. It is highly likely that

the five phases will be different in patients with fecal incontinence, dyssynergic and slow transit constipation. The lower panel shows an idealized pressure loop diagram with analogy to the cardiac preload-afterload diagram. It can be derived from the upper figure that a normal healthy subject will follow path A. It is anticipated that patients with chronic constipation during to lack of anal sphincter relaxation will follow path B whereas patients suffering from fecal incontinence due to a weak anal sphincter will follow path C. The analysis can be further refined using the impedance planimetric cross-sectional area data which will allow for a better calculation of outflow resistance that represented with the front pressure alone. Anorectal angle measurement may add another layer to the afterload computations.

FIGURE 6:

Illustrations of pressure data obtained in a healthy subject (A and B), a patient suffering from fecal incontinence (C and D) and a subject with obstructed defecation (E). Panels A, C and E shows the front and rear pressures and the difference between them. Arrows indicate the start of defecation, when the front is outside the anus and when the rear is outside the anus. Panels B and D shows the front pressure as function of the rear pressure for the healthy subject and the patient with fecal incontinence. The healthy subject used several contraction cycles to evacuate the device whereas the patient with fecal incontinence could not hold Fecobionics inside rectum. Figure 6F shows the MPU data (bending angle and orientation) for the patient with obstructed defecation. Data were kindly borrowed from an ongoing clinical trial (see acknowledgements).

FIGURE 7:

Top: Spatio-temporal diameter map for showing the expulsion path during an expulsion. The colors from blue to red illustrate increasing diameter. The diameter was calculated from the recorded CSA as: $\text{Diameter} = 2 \times (\text{CSA} / \pi)$. Each column depicts the configuration of the bag at a specific time and each row depicts change in diameter over time at a particular position along the probe. The vertical axis on the left represents the location of each CSA sensor and the pressure (white line) changes over time. The line AA' represents the each point along the probe that enter into the anal canal and the line BB' represent that each point

along the probe that out of the anal canal, the blue area between AA' and BB' represent the anal canal area. At the same location of the probe, the distance between AA' and BB' shortened with the expulsion time, indicating increasing velocity during the expulsion.

Middle. the pressure change during an expulsion, the red dots indicate the time point when (t1) the distended bag before expulsion attempt, (t2) the bag entering the anal canal being compressed from above (t3), the bag inside the anal canal during the expulsion and (t4) the bag leaving the anal canal. **Bottom.** The reconstructed bag with realistic geometry at the corresponding red dots time point in the upper panel. The color bar on the right and the bag color represent pressure increase (from blue to red color).

FIGURE 8:

Front and rear pressure recordings from the wireless device in the pig experiment. It is clearly seen that the front passes the anal canal to the outside environment before the bag and rear.

Table 1.

Wireless test results

Tests (4 meter distance)	Transmission frequency (Hz)	Number of transmitted data sets	Received data sets number (error number)	Data loss rate	Data error rate
In air	80	6,423	6,423 (0)	0%	0%
In water	80	6,529	6,529 (0)	0%	0%
Inside mouth	80	6,743	6,743 (0)	0%	0%
Expulsion test (raw data)	14	3,444	3,402 (308)	1.2%	9%
Expulsion test (processed data)	14	3,444	3,402 (14)	1.2%	<1%