Novel Fecobionics Defecatory Function Testing

Hans Gregersen, MD, PhD, AGAF[1], Ssu-Chi Chen, MD[1], Wing Wa Leung[1], Cherry Wong[1], Tony Mak, MD[1], Simon Ng, MD, PhD[1] and Kaori Futaba, MD, PhD[1]

INTRODUCTION: **Defecation is a complex process that can be easily disturbed. Defecatory disorders may be diagnosed using specialized investigation, including anorectal manometry (ARM) and the balloon expulsion test (BET). Recently, we developed a simulated stool named Fecobionics that integrates several tests and assesses pressures, orientation, and bending during evacuation. The aim was to evaluate the feasibility and performance of Fecobionics for assessing defecatory physiology in normal subjects.**

METHODS: **Physiological expulsion parameters were assessed in an interventional study design. The 10-cm-long Fecobionics probe contained pressure sensors at the front and rear and inside a bag and 2 motion processor units. The bag was distended in the rectum of 20 presumed normal subjects (15 female/5 male) until urge to defecate. ARM-BET was also performed. Three subjects used +2 minutes to evacuate BET, and 1 subject had a high fecal incontinence score. Therefore, the normal group consisted of 16 subjects (13 female/3 male aged 25–78 years).**

RESULTS: **All subjects reported that Fecobionics evacuation was similar to normal defecation. Fecobionics expulsion pressure signatures demonstrated 5 phases, reflecting rectal pressure, anal relaxation, and anal passage. Preload-afterload loop diagrams demonstrated clockwise contraction cycles. The expulsion duration for BET and Fecobionics was 16 ± 2 and 23 ± 5 seconds ($P > 0.2$), respectively. The duration of the Fecobionics and BET expulsions was associated ($P < 0.001$). The change in bending of Fecobionics during defecation was 40 ± 3°.**

DISCUSSION: **Fecobionics obtained reliable data under physiological conditions. Agreement was found for comparable variables between ARM-BET and Fecobionics but not for other variables. The study suggests that Fecobionics is safe and effective in evaluation of key defecatory parameters.**

SUPPLEMENTARY MATERIAL accompanies this paper at http://links.lww.com/CTG/A133

Clinical and Translational Gastroenterology 2019;10:e00108. https://doi.org/10.14309/ctg.0000000000000108

INTRODUCTION

Defecation is a complex physiological process through which stools are eliminated via the anus (1–3). Defecation is initiated by an urge to defecate predominantly resulting from filling of stool in the rectum. During evacuation, the abdominal pressure increases, the anal sphincter relaxes, and the anorectal angle straightens. The evacuation process may easily get disturbed, resulting in symptoms such as pain, fecal incontinence (FI), and constipation (4). Defecatory disorders affect 25% of the population with rising incidence (1,4). The disorders pose a major health care burden but are poorly recognized and treated (4). Constipation, a symptom of underlying disease, affects 12%–19% of Americans (1). The need for physiologically relevant and easy-to-use diagnostic tests for identifying underlying mechanisms is substantial.

Anorectal physiology and defecatory disorders can be assessed using specialized investigation including anorectal manometry (ARM), balloon expulsion test (BET), and defecography (4–7). BET is a test where a bag is distended with 50 mL followed by attempts to expel the bag (8,9). Physiological evacuation phenomena such as the opening characteristics of the anal sphincter during defecation cannot be described in detail with current technology. For example, defecography does not measure anorectal pressures, BET does not assess geometry, and ARM is not performed during defecation. Considerable disagreement exists between the results of various anorectal tests, and they correlate poorly with symptoms and treatment outcomes (4,10). Therefore, new anorectal function tests for diagnostic assessment of evacuation are warranted.

We aimed to change the approach to anorectal functional testing with the overall goal to provide mechanistic understanding of defecation. Fecobionics simulates stool and integrates BET and other technologies (5–10). Pressures and

[1]Department of Surgery, the Chinese University of Hong Kong, Shatin, Hong Kong. **Correspondence:** Hans Gregersen, MD, PhD, AGAF. E-mail: hag@giome.org.
Received June 7, 2019; accepted October 21, 2019; published online November 27, 2019

the anorectal angle are measured during defecation in a single examination. Fecobionics makes it possible to describe the opening characteristics during entry into the relaxing anal canal without disturbing the defecation process. Recently, preliminary data (11) and technological validation (12) were published. It was indicated in preliminary experiments on a small number of subjects that the axial pressure signature distinguished 5 distinct phases during defecation (11) and that preload-afterload analysis may provide useful end points (12).

The aim was to evaluate the feasibility and performance of Fecobionics for assessment of defecation parameters in a group of presumed normal subjects. We provide detailed descriptions of novel pressure signatures, as the article will serve as a reference for future clinical studies. Expulsion characteristics are described with end points of physiological and potential clinical value. Furthermore, key Fecobionics data are compared with ARM-BET data.

METHODS

Subjects

Twenty subjects were invited to participate in this exploratory study through advertisement at Prince of Wales Hospital and The Chinese University of Hong Kong. The lower age limit was 18 years. No upper limit was imposed. If deemed "normal" during a phone interview, where we asked about stool diaries and medications (use of gastrointestinal medications were not allowed), subjects were asked to visit the anorectal function laboratory for further interview and testing. Data were obtained on age, sex, health status, symptoms, diseases, and previous treatments. FI and chronic constipation questionnaire data were obtained (13,14). All subjects had endoanal ultrasonography performed to exclude anal sphincter defects that could affect the results.

Before the experiments, the subjects were asked to empty their rectum if they were able to. Enema was not used to make the test as natural as possible. Anorectal examination was performed before insertion of the Fecobionics to assess anal tone and verify that the lower rectum was empty. Experiments using Fecobionics and ARM-BET were performed randomized on the same day with appropriate time between the tests. All subjects had the tests completed. They were considered normal if FI and chronic constipation questionnaire scores <5 (13) and <8 (14) and if ARM-BET was expelled in <2 minutes (8). The protocol was approved by the Joint CUHK-NT East Cluster Clinical Research Ethics Committee (ref. no. 2017.122).

Testing techniques

Reference testing consisted of ARM with BET (see Supplementary Material, Supplementary Digital Content 1, http://links.lww.com/CTG/A133).

The basic design of Fecobionics has been described (11,12), is sketched in Figure 1a and Figure 2, and detailed in the Supplementary Material, Supplementary Digital Content 1, http://links.lww.com/CTG/A133. In the present study, we used a slightly upgraded Fecobionics version to that reported previously (11). Fecobionics was 12-mm-outer diameter, 10-cm-long, and contained pressure, motion sensors, and other electronics embedded in the silicone (15). With the architecture, hardness shore, and the bag, Fecobionics obtained consistency that corresponds approximately to type 4 (range 3–4) on the Bristol Stool Form Scale (16). The range from types 3–4 is found in +60% of healthy subjects (16). The bag was connected through tubes extending from the front of Fecobionics to a syringe containing saline and to the USB port of a computer for power supply and real-time data transmission.

The settings were made private using curtain to shield the patient and the investigators left the room during the defecation. Fecobionics was manually inserted in the rectum. The subject changed from the horizontal to sitting position and moved from the bed to the commode chair. After approximately 5 minutes of resting, the subjects were asked to squeeze the anal muscle twice and to cough twice to validate correct placement, i.e., that the front sensor recorded pressure change on squeezing and coughing. Anal squeezes confirmed that the subjects were able to contract the anal sphincter. Afterward, the bag was distended until urge to defecate. The urge volume was noted, and the subjects were allowed to evacuate Fecobionics.

The urge volume for Fecobionics would likely not be the same as the 50 mL volume used in ARM-BET. Therefore, we conducted an additional study in 7 subjects. In random order, these subjects did 2 more defecations of Fecobionics at bag volumes 20 and 50 mL to evaluate the effect on expulsion duration.

Data analysis

Multiple parameters were calculated including the questionnaire score, duration of the whole experiment, expulsion duration, and pressure amplitudes. Advanced parameters and analyses comprised expulsion velocity, defecatory phases (11) (Figure 1b), preload-afterload (2,15) (Figure 1c), orientation, and bending angle (definitions in the Supplementary Material, Supplementary Digital Content 1, http://links.lww.com/CTG/A133). The preload-afterload diagram is a new way to express Fecobionics data. Preload-afterload diagrams have significant functional value in cardiology (2,15) but were suggested as useful in modified forms for the gastrointestinal tract (2). In cardiac physiology, preload is the end diastolic volume that stretches the ventricles to their greatest dimensions under variable physiologic demand. Afterload is the pressure against which the heart must work to eject blood during systole. The analogy for defecation is that rectum or abdominal muscle contractions generate the preload, whereas the afterload is due to anal resistance. Fecobionics measures the preload and afterload with the rear and front sensors.

Because ARM shows a high proportion of abnormal pressure profiles in healthy volunteers (17), it was analyzed how many subjects would show similar patterns in this study with ARM and Fecobionics. For the first contraction, pressure increase in the front sensor to the same or lesser extent as in the rear sensor (which is due to the rectal positioning of Fecobionics) was considered "normal," whereas more increase in the front sensor than in the rear sensor was considered "abnormal."

Statistics

The experimental data were considered normally distributed, and consequently, mean ± SEM was computed. Data for the 2 anal squeezes and 2 coughs were averaged, respectively. T-test and one-way analysis of variance were used for studying differences. Median and quartiles were described for the volume test ($n = 7$) and for the number of cycles. Pearson correlation was used for analysis of association of data obtained with the technologies used. The chi-squared mcNemar test was used to analyze to what extent Fecobionics testing replicated the ARM-BET results on the 2-minute cutoff limit. Results were considered statistically significant when $P < 0.05$ (2 tailed).

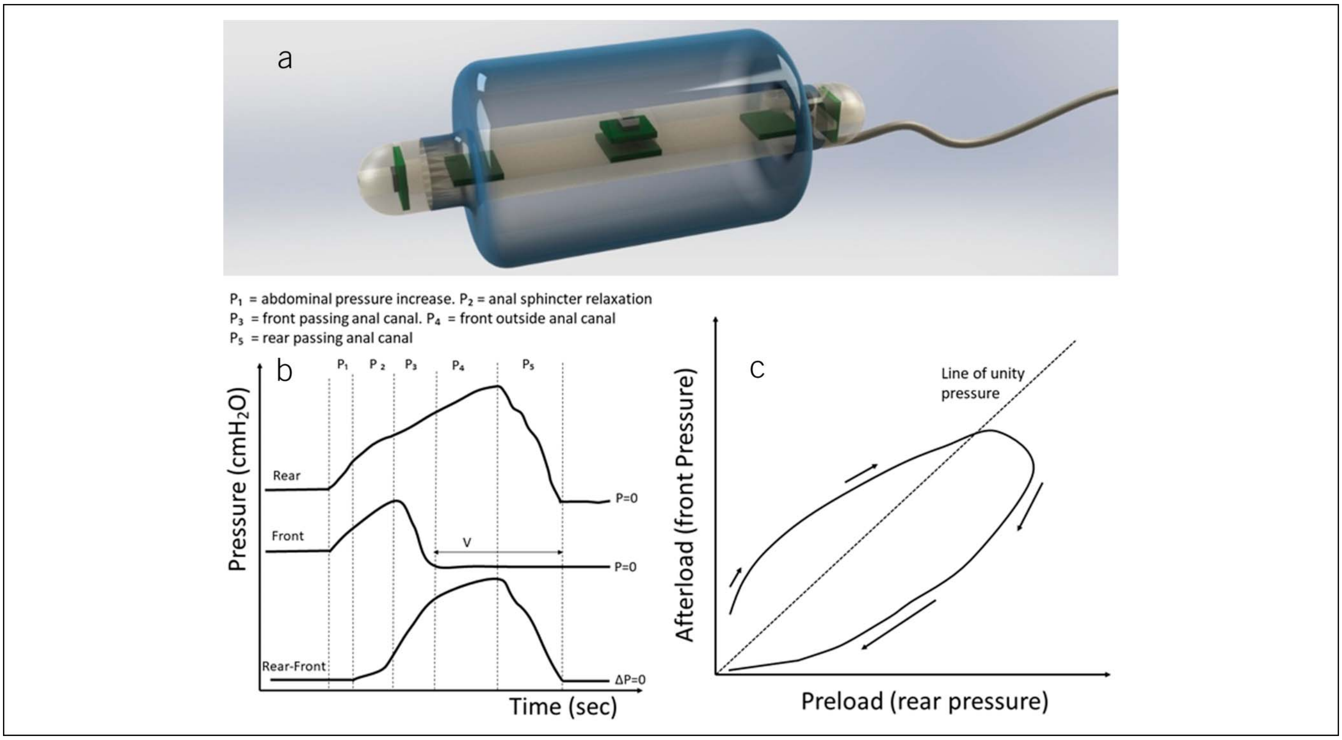

Figure 1. Fecobionics and analysis approach. (**a**) Sketch of the tethered Fecobionics device with pressure sensors placed at the front, rear, and inside the bag. Two motion processor units (gyroscope-accelerometer) were imbedded for determination of bending. The bag was distended through the connecting tube that contained wires for power supply and data transmission. (Courtesy: Seegert and Sun, modified from previous publications). (**b** and **c**) Idealized sketches of defecatory function analysis. (**b**) The front and rear pressures and the delta pressure. An idealized expulsion is characterized by 5 phases. P1: abdominal pressure increase recorded equally by both sensors; P2: beginning of anal relaxation; P3: passage of the front end through the anal canal; P4: the front end is outside the anal verge; P5: last phase of defecation. (**c**) An idealized front-rear pressure loop diagram. The dotted line is the line of pressure unity.

RESULTS

Exclusion of subjects from the normal subject group

Twenty Asians living in Hong Kong were studied (15 female/5 male). One female had a FI score of 12, and 3 subjects (1 female/2 male) exceeded the 2-minute limit on ARM-BET (134 seconds, 408 seconds, and 1 subject who could not expel the balloon). These subjects were excluded from the normal group that subsequently consisted of 16 subjects (13 female/3 male, age 25–78 years, weight 40.8–69.1 kg, height 146–175 cm, and body mass index [BMI] 17.2–29.2 kg/m^2). Because abnormal phenotypes have clinical interest, we report the Fecobionics study of the 4 excluded subjects in the Supplementary Material, Supplementary Digital Content 1, http://links.lww.com/CTG/A133. All subjects except the person with the high FI score had normal questionnaire scores. Technical problems with one of the pressure sensors were experienced in 3 cases. Unless otherwise specified, all values are from 16 subjects.

Fecobionics data

During a typical Fecobionics study, insertion required 10–30 seconds, movement to the commode chair and assessment of resting pressure took 1–3 minutes, anal squeeze maneuvers took 1–2 minutes, distension of the bag took 1 minute, and evacuation required 1–5 minutes. Because all subjects in the normal group evacuated Fecobionics in <1 minute, the total study time was 5–8 minutes.

Device insertion and predistension maneuvers

Shortly after the manual insertion, the subjects were asked to sit up in the bed. Figure 3 shows representative pressure and angle recordings from a subject during the insertion and when changing from the horizontal to sitting position.

The squeezes after insertion confirmed that the subjects were able to contract the anal sphincter in a controlled manner, i.e., the front pressure increased instantly (Figure 3). The anal squeeze pressure during both squeezes was 144 ± 10 cmH_2O and reproducible. The anal squeeze pressure measured by Fecobionics was lower than the squeeze pressure measured by ARM ($P < 0.05$, see below). Anal squeezes changed the bending angle 14.2 ± 2.4°. This was primarily due to change in the orientation of the rear motion sensor (rear 13.4 ± 2.4°, front 5.2 ± 1.6°). Coughing induced simultaneous pressure increase in all channels (typically 100–150 cmH_2O) but minimal change in the bending angle (7 ± 1°, Figure 3d).

Bag distension

The bag was distended until the subjects felt urge to defecate. The distension resulted in variable bag pressure increase and often in concomitant internal anal sphincter relaxation. All subjects felt urge to defecate before the maximum volume of 80 mL was reached. The urge volume was 39 ± 6 mL. It was not associated with the weight, BMI, or age of the subjects ($P > 0.2$). The volume at urge using Fecobionics was significantly lower than the ARM-BET urge volume ($t = -5.7, P < 0.001$, see below and Figure 5 bottom). The urge volume by the 2 methods was not associated ($r = 0.28, P > 0.2$).

Evacuation of Fecobionics

After the urge-to-defecate level was reached, the subjects were asked to evacuate Fecobionics. The subjects (normal and abnormal) did

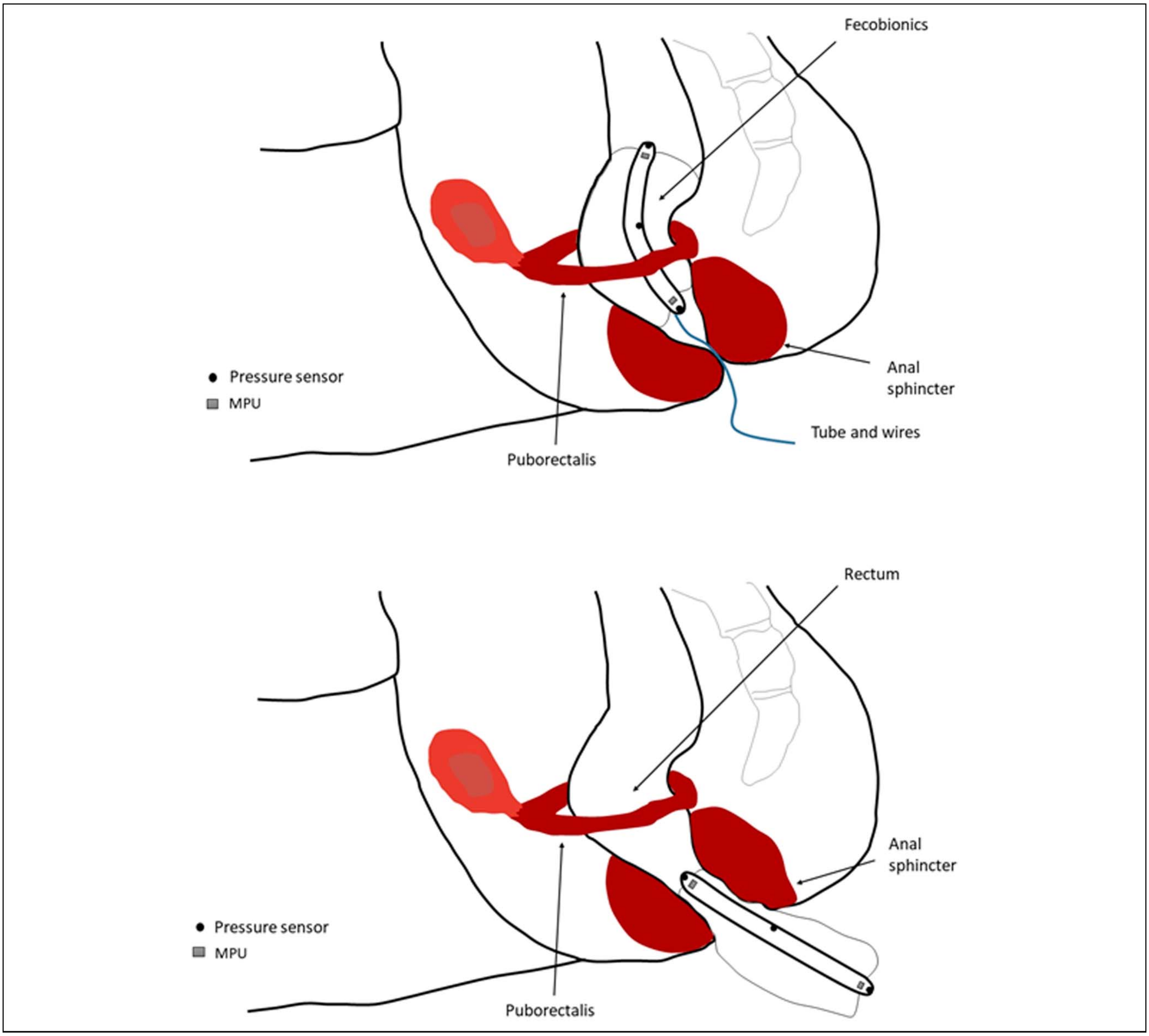

Figure 2. Sketches of the Fecobionics device located in the rectum during the start of the procedure (top) and during evacuation (bottom).

not report pain, other symptoms, or bleeding from the anus. Several subjects said spontaneously that defecating Fecobionics was no different from defecations at home. Figure 4a,b shows representative patterns of evacuations from normal subjects. The defecation was initiated by a pressure increase recorded by all pressure sensors (start of phase 1). Usually, the abdominal pressure increased and decreased for several cycles. At some point, the front pressure leveled off, i.e., deviated from the rear pressure, suggestive of anal sphincter relaxation and movement of Fecobionics into the anal canal (start of phase 2, see below). The subsequent rear pressure local maximum represents the start of phase 3. The front pressure eventually reached zero (atmospheric pressure, start of phase 4), indicating that the front was outside the anus. After reaching its maximum value (start of phase 5), the rear pressure dropped and reached zero, indicating termination of the evacuation. The evacuations were somewhat different in terms of number of cycles to expel the device (median 2.5, quartiles 1.5–5.5, range 1–12), but otherwise many similarities were demonstrated between subjects. The maximum pressure levels during the evacuation were 139.0 ± 11.3 and 99.5 ± 11.1 cmH_2O for the rear and front pressure sensors. Because the front often reached outside the anus before the maximum rear pressure was measured, the maximum difference between the rear and the front pressures was 137.9 ± 11.0 cmH_2O. Defecations were subdivided into 5 phases based on the pressure signature (11). It was easiest to distinguish the phases when evacuation happened with only few cycles. The duration of the phases differed, with phase 3 being the longest (phases 1, 2, 3, 4, and 5 lasted 3.5 ± 1.2, 2.9 ± 1.3, 8.1 ± 1.6, 5.1 ± 1.9, and 2.4 ± 0.6 seconds, respectively, $F = 2.82$, $P < 0.05$). Based on our definition of normal or abnormal first contraction, we found that 12 of the 16 subjects showed normal pressure profile, 2 subjects were abnormal, and another 2 could not be determined, i.e., 75% or more showed normal pressure profiles.

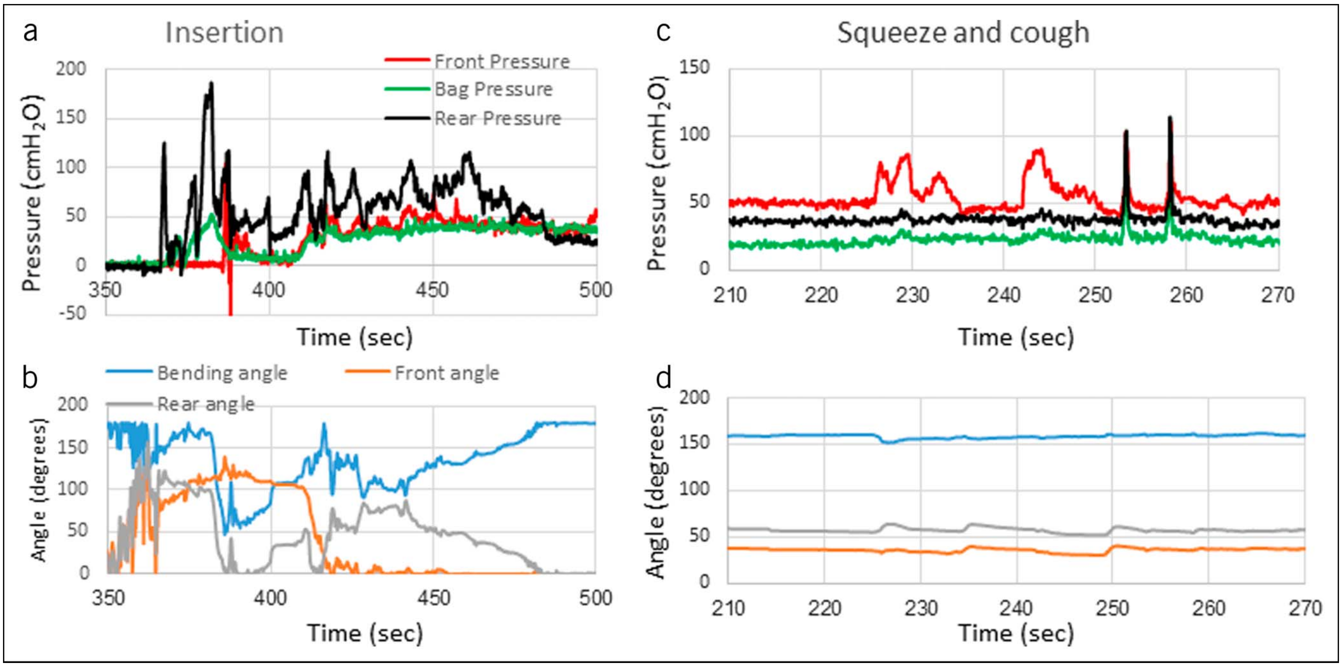

Figure 3. Pressure and angle data during insertion and movement from lying to sitting position (**a** and **b**) and during anal squeeze and cough (**c** and **d**). High rear pressure is observed during the insertion that lasted about 10 seconds. The front angle changes during the position shift. The device straightens again after a while (180° = straight device). The anal squeeze induced pressure increase in the front but not in the other pressure sensors. See text for group data. Coughs increased pressures simultaneously in all sensors but only had little effect on the angles.

Front-rear pressure diagrams express clockwise contraction cycles (Figure 4c,d). Repeated contractions translated the tracings downward, and at some point, a cutoff was reached where the anal pressure dropped quickly followed by complete expulsion of the device.

The expulsion duration for Fecobionics was 23 ± 5 seconds. None of the 16 subjects used more than 60 seconds to evacuate Fecobionics. The expulsion duration was not associated with age, BMI, or weight ($P > 0.2$). Furthermore, the expulsion duration was not dependent on the urge volume (Figure 5 top). The Fecobionics expulsion duration did not differ from the expulsion duration for ARM-BET (t = 1.6, $P > 0.2$). Association was not found for the expulsion duration between the 2 technologies in the normal group ($r = 0.28$, $P > 0.3$). However, linear association was found for the whole group of subjects (n = 20, $r = 0.92$, $P < 0.001$, Figure 5 middle).

The expulsion velocity (Fecobionics length divided by the time difference between the rear and front pressure sensors reached the outside) was 4.2 ± 1.7 cm/s. Variability spanned from 0.4 cm/s in a subject with several attempts to expel Fecobionics to 20.0 cm/s (54-year-old woman who showed no specific characteristics). The expulsion velocity correlated positively with the maximum pressure difference ($r = 0.61$, $P < 0.05$). The urge volume did not correlate with the expulsion velocity or with the expulsion duration. No difference in the expulsion duration was found for the 3 volumes (at 20 mL, 50 mL, and at urge [average 39 mL as reported above]). The duration was 14 (11–14), 13 (3–17), and 13 (6–17) seconds, respectively.

Before defecation, the front and rear sensors had an average orientation of 20 and 50°, respectively, relative to the field of gravity. The orientation approached vertical when passing from the rectum into the anal canal. The device landed in the horizontal position in the pot below the commode chair, which was confirmed by the orientation measurement. The change in the bending angle during defecation was 40 ± 3°. The corresponding changes in the orientation of the rear and front motion processor units were 43 ± 7 and 29 ± 4°, respectively. Characteristics for the subjects excluded from the normal group are provided in the Supplementary Material, Supplementary Digital Content 1, http://links.lww.com/CTG/A133.

Reference recordings

ARM showed the presence of rectoanal inhibitory reflex in all subjects. The resting pressure and maximum squeeze pressure were 66.1 ± 6.4 and 233.7 ± 15.9 mm Hg, respectively. Eighty-eight percent (14 of 16 normal subjects) showed abnormal anal pressure patterns on push maneuvers. For ARM-BET, the urge volume and the maximum tolerable volume were 92 ± 9 and 154 ± 11 mL, respectively. The expulsion duration for the 50 mL balloon was 15.7 ± 2.2 seconds.

DISCUSSION

Fecobionics provides a new bionics concept to studies of anorectal physiology and diagnostics by integrating several current tests. Preliminary data (11) and technological validation data (12) were reported previously. Compared with the descriptive data presented previously, the present study is the first quantitative study conducted in a group of presumed normal subjects. The aim was to describe defecatory physiology and performance to serve as a reference for future clinical studies. We demonstrated successful access in all subjects with no device-related adverse events or device malfunctions. Fecobionics was able to record anorectal pressures, orientation, and bending, as well as providing data for novel analysis of "preload-afterload loops." Agreement

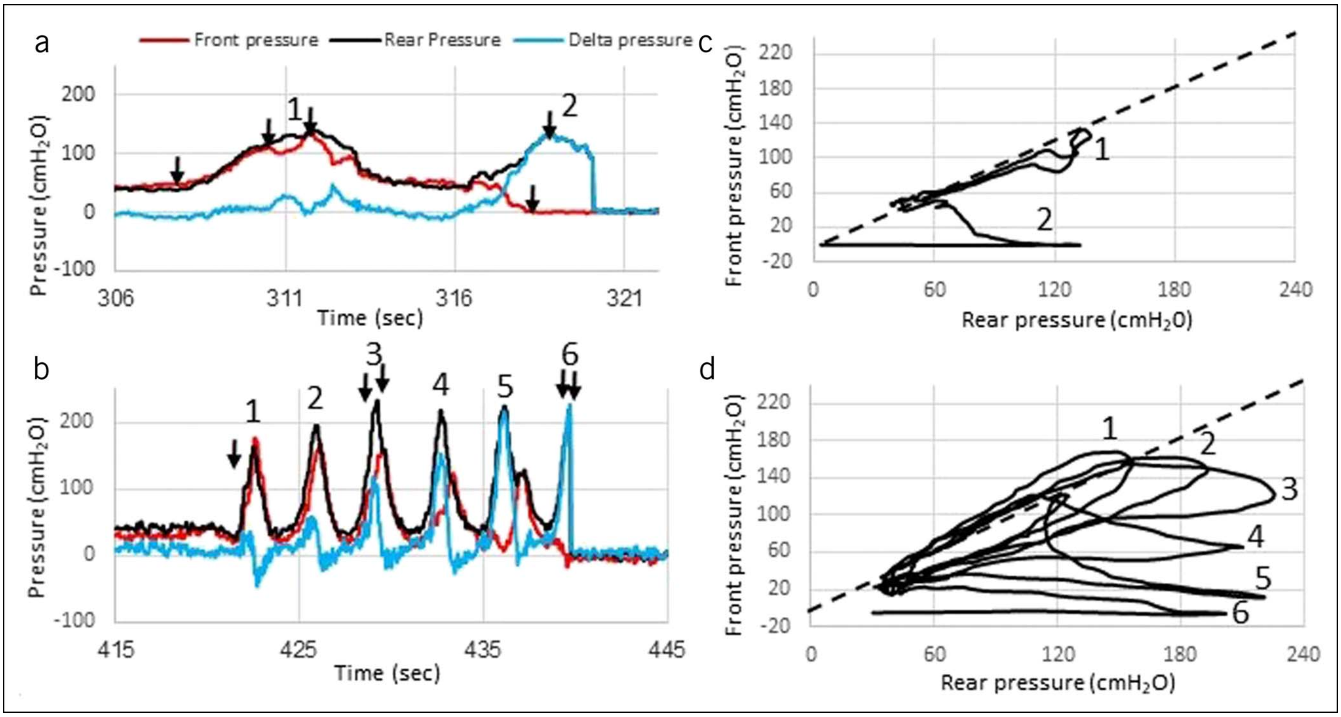

Figure 4. Representative examples of defecations from 2 normal subjects. The left diagrams illustrate the front and rear pressures and the delta pressure as function of time (**a** and **b**). The right diagrams show the front pressure as function of the rear pressure (**c** and **d**). The stippled line is the line of unity. The defecations were somewhat different, dependent on the number of abdominal contractions required to defecate the device. However, most subjects used 1–6 abdominal contractions. The subject shown in **a** and **c** used 2 contractions to evacuate Fecobionics, whereas the other subject (**b** and **d**) used 6 contractions. The clockwise contraction loops are labeled with numbers to ease interpretation. Repeated contractions shifted the loops to the right and downward. The arrows show the beginning of the 5 phases (left).

between Fecobionics and ARM-BET was found for comparable variables such expulsion duration, whereas other differed.

Methodological aspects and limitations

Technological aspects and further methodological aspects are described in the Supplementary Material, Supplementary Digital Content 1, http://links.lww.com/CTG/A133. The pressure sensors at the 2 ends pointed in the axial direction, i.e., in the direction of the trajectory, which is important for acquiring data for the preload-afterload diagram. This is a key design feature distinctly different from high-resolution and high-definition ARM that measure radial pressures (7). ARM and Fecobionics record the circumferential force induced by anal sphincter contraction. The anal squeeze pressure measured by Fecobionics was lower than the pressure measured by ARM. The likely explanation is that ARM provides a stationary measure along the entire anal canal length, whereas Fecobionics measures in the proximal part of the sphincter and may be pushed in the rectal direction during the squeeze. Furthermore, there was difference in posture during between the 2 tests.

We aimed to compare key variables between ARM-BET and Fecobionics. Agreement was found between BET and Fecobionics for comparable variables such as expulsion duration. The 3 subjects who did not evacuate BET before the 2-minute cutoff limit also did not evacuate Fecobionics within 2 minutes. Furthermore, the expulsion duration for Fecobionics and ARM-BET was similar, and association was found for the expulsion duration between the 2 technologies for the whole group of subjects (Figure 5). This is encouraging because BET has been shown to be predictive of response to biofeedback therapy (18). However, differences between technologies were also noted, e.g., the urge volume differed somewhat. BET uses an air-filled balloon that is stretchable and tends to stretch most where least resistance is encountered (2) (the standard in our unit) and may stimulate more proximally in the rectum than Fecobionics. This may contribute to the observed differences. Future studies should look into these aspects including if a redesign of the Fecobionics bag is needed to capture hyposensitive constipation patients. Differences in volumes during defecation of the 2 devices is another issue. However, the Fecobionics bag volume seems not to have significant importance, at least in the range from 20 to 50 mL volume. Furthermore, it is generally known that anorectal physiology is characterized by wide variability, as also evidenced by our data on volume at urge (Figure 5). Therefore, we do not believe that type 2 errors would explain the lack of significance. Our study largely confirmed previous data (17) that a high proportion of normal subjects show abnormal (dyssynergic) ARM pressure profiles. In this study, 88% were abnormal using ARM. Interestingly, using our defined criteria for analysis of Fecobionics data, we found that maximum 25% showed an abnormal pattern. This topic needs further study.

Physiological aspects

Fecobionics defecation consists of 5 phases (11). The shift between phases is defined by identifiable pressure landmarks. We present normal subject phenotypes (Figure 4). Fecobionics was expelled during a single abdominal pressure increment in some evacuations (25%). However, it was more common that subjects used 2–6 cycles to expel Fecobionics. It is easiest to define the phases in subjects with few contraction cycles. The classification

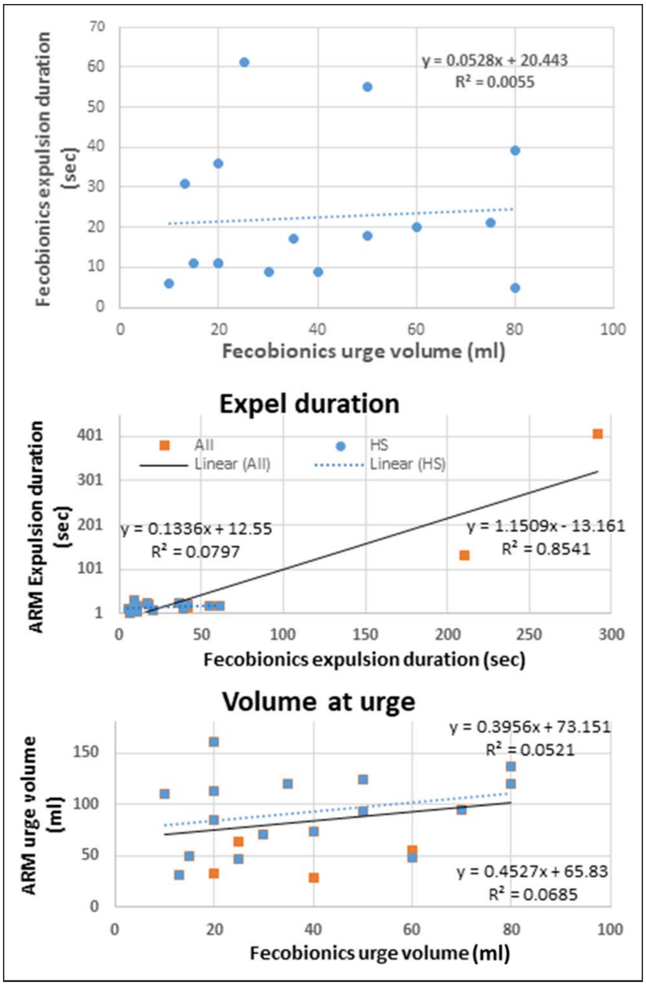

Figure 5. Top: The Fecobionics expulsion duration as function of Fecobionics urge volume. Middle: correlations between duration for expulsion of the ARM-BET balloon and duration for expulsion of the Fecobionics bag. Significant correlation was found for the total group (the normal group and the 4 abnormal subjects, n = 20). Bottom: correlations between the volume at urge using ARM-BET and volume at urge for Fecobionics. The association was nonsignificant and indicates the large variation encountered in normal subjects. Linear regression statistics are provided in the diagrams.

seems useful for defining physiological end points that potentially may serve as clinical biomarkers. However, at this stage, the clinical value is yet to be determined because only 4 abnormal subjects were studied.

Fecobionics data were also analyzed as preload-afterload data (Figure 4b,d and see Figure S1, Supplementary Digital Content 1, http://links.lww.com/CTG/A132). It allows evaluation of pressures cycles without the time element where rectum or abdominal muscle contractions generate the preload and the afterload reflects anal resistance. The preload must exceed the afterload before evacuation can take place because feces movement cannot occur against an anorectal pressure gradient. Fecobionics (and feces) will be expelled when the rectoanal pressure gradient is large enough to overcome the frictional force between the surface and mucosa. Measurement of axial pressures at front, rear, and inside the bag is essential in this regard. The usefulness of the loop diagram it convincingly illustrated in Figure 1, Supplementary Digital Content 1, http://links.lww.com/CTG/A132, where the subject with a high FI score at all time had higher preload than afterload (low anal resistance), whereas most subjects "prepare" for expulsion by running several cycles with gradual changes toward evacuation (Figure 4).

We reported changes in orientation and angles during defecation of Fecobionics. The bending of Fecobionics, which is indicative of the anorectal angle, changed 40° during expulsion, which is roughly consistent with data from the literature on defecography (5,19). Because of ethical reasons, we could not expose the subjects to radiation. Defecography is performed primarily in patients with severe constipation in our unit. Hence, we plan to obtain comparative data with defecography in future clinical trials. The novelty of Fecobionics is that the angle is measured electronically (objectively).

Pathophysiological aspects

The present study focused on presumed normal subjects. Data on abnormal subjects are provided in the Supplementary Material, Supplementary Digital Content 1, http://links.lww.com/CTG/A133. The definition of "normal" is not straightforward, and some subjects may not be normal as first claimed. Anorectal disorders are frequent with FI and constipation as common symptoms. Effective treatment requires determination of the cause. Dyssynergic defecation is believed to be the result of pelvic floor dysfunction. Dyssynergic defecation is a diagnostic challenge (4,17). Improved integrated diagnostics may aid individualized treatment of subtyped patients and define those who may benefit from biofeedback training (4).

Despite our best efforts to enroll normal subjects, 20% of the study group turned out to be abnormal. It was not a big surprise considering the wide variability in anorectal physiology and previous literature showing abnormal BET in healthy subjects with no constipation symptoms (20). Other studies have shown that 90% of healthy subjects have a pattern that is regarded as abnormal by ARM (17). This was confirmed in the present study (88%). One subject had a high FI score, and 3 exceeded the 2-minute limit for BET. Fecobionics picked up the same 3 subjects and no others, i.e., full agreement exists between BET and Fecobionics despite difference in technology and procedure. The subject with a high FI score defecated Fecobionics immediately with the pressure loop below the line of unity at all time. Hence, it did not require much force to overcome the flow resistance. Needless to say, well-designed clinical studies are required to evaluate the clinical potential of Fecobionics, especially for patients with constipation, which likely is the primary indication for Fecobionics. Our study demonstrates indications of future clinical outcomes.

Future aspects and conclusions

We demonstrated successful design, bench testing (11,12), and application of Fecobionics in human subjects. Fecobionics provides several improvements to current anorectal functional assessment technologies, including mechanical properties that mimic stool, objective electronic measurement of the anorectal angle, and pressure measurements in the direction of the trajectory. Fecobionics has significant potential to shift the current paradigm because it is a simulated stool that provides novel end points not simultaneously assessed with current technologies. This study suggests that the device is safe, novel for assessment of anorectal physiology and evacuatory efficacy, and that disease phenotypes may express different signatures. Future larger scaled studies are needed to shed more light on repeatability and defecatory mechanisms in health and disease.

CONFLICTS OF INTEREST

Guarantor of the article: Hans Gregersen, MD, PhD, AGAF.
Specific author contributions: H.G., K.F., T.M., and S.N. designed the study and advised the experimental work during the study period. S.-C.C., K.F., W.W.L., and H.G. participated in the experiments. Data analysis was conducted by S.-C.C. and H.G. and interpreted by all authors. All authors had access to the data, revised the manuscript, and approved the final version for submission.
Financial support: The Chinese University of Hong Kong (strategic recruitment funding) and RCG grant 14106717.
Potential competing interests: H.G. has filed patent applications. No other conflicts of interest noted.
Trial registration: www.clinicaltrials.gov identifier: NCT03317938.

Study Highlights

WHAT IS KNOWN

- ✓ The physiology of defecation and the pathophysiology of defecation disorders have been described in numerous studies.
- ✓ Disagreement exists between results of anorectal tests, and they correlate poorly with symptoms.

WHAT IS NEW HERE

- ✓ We tested a novel Fecobionics device, a simulated integrated stool in normal subjects.
- ✓ New pressure signatures during defecation and electronic measurement of anorectal angle are presented.

TRANSLATIONAL IMPACT

- ✓ Agreement was found between Fecobionics and current technology for comparable variables but not for other variables.
- ✓ Novel parameters were generated, which may be important for subtyping of patients with anorectal disorders.

REFERENCES

1. Suares NC, Ford AC. Prevalence of, and risk factors for, chronic idiopathic constipation in the community: Systematic review and meta-analysis. Am J Gastroenterol 2011;106:1582–91.
2. Gregersen H, Christensen J. Clinical Biomechanics in the Gut. An Introduction. Bentham Science Publishers: Sharjah, United Arab Emirates, 2016.
3. Gibbons CP. The mechanics of the anal sphincter complex. J Biomech 1988;21:601–4.
4. Rao SS, Bharucha AE, Chiarioni G, et al. Functional anorectal disorders. Gastroenterology 2016;150:1430–42.
5. Tirumanisett P, Prichard D, Fletcher JG, et al. Normal values of assessment of anal sphincter morphology, anorectal motion, and pelvic organ prolapse with MRI in healthy women. Neurogastroenterol Motil 2018;30:e13314.
6. Bharucha AE. Update on tests of colon and rectal structure and function. J Clin Gastroenterol 2006;40:96–103.
7. Van Koughnett JAM, da Silva G. Anorectal physiology and testing. Gastroenterol Clin North Am 2013;42:713–28.
8. Chiarioni G, Kim SM, Vantini I, et al. Validation of the balloon evacuation test: Reproducibility and agreement with findings from anorectal manometry and electromyography. Clin Gastroenterol Hepatol 2014;12:2049–54.
9. Carrington EV, Heinrich H, Knowles CH, et al. The international anorectal physiology working group (IAPWG) recommendations: Standardized testing protocol and the London classification for disorders of anorectal function. Neurogastroenterol Motil 2019:e13679. doi: 10.1111/nmo.13679. [Epub ahead of print].
10. Palit S, Thin N, Knowles CH, et al. Diagnostic disagreement between tests of evacuatory function: A prospective study of 100 constipated patients. Neurogastroenterol Motil 2016;28:1589–98.
11. Gregersen H, Krogh K, Liao D. Fecobionics: Integrating anorectal function measurements. Clin Gastroenterol Hepatol 2018;16:981–3.
12. Sun D, Huang Z, Zhuang Z, et al. Fecobionics: A novel bionics device for studying defecation. Ann Biomed Eng 2019;47:576–89.
13. Agachan F, Chen T, Pfeifer J, et al. A constipation scoring system to simplify evaluation and management of constipated patients. Dis Colon Rectum 1996;39:681–5.
14. Rockwood TH. Incontinence severity and QOL scales for fecal incontinence. Gastroenterology 2004;126:S106–S113.
15. Takeuchi M, Odake M, Takeoka H, et al. Comparison between preload recruitable stroke work and he end-systolic pressure volume relationship in man. Eur Heart J 2003;13:80–4.
16. Heaton KW, Radvan J, Cripps H, et al. Defecation frequency and timing, and stool form in the general population: A prospective study. Gut 1992;33:818–24.
17. Grossi U, Carrington EV, Bharucha AE, et al. Diagnostic accuracy study of anorectal manometry for diagnosis of dysynergic defecation. Gut 2016;65:447–55.
18. Rao SS, Welcher KD, Leistikow JS. Obstructive defecation: A failure of rectoanal coordination. Am J Gastroenterol 1998;93:1042–50.
19. Mahieu P, Pringot J, Bodart P. Defecography: I. Description of a new procedure and results in normal patients. Gastrointest Radiol 1984;9:247–51.
20. Coss-Adame E, Rao SSC, Valestin J, et al. Accuracy and reproducibility of high-definition anorectal manometry and pressure topography analyses in healthy subjects. Clin Gastroenterol Hepatol 2015;13:1143–50.