Mechanophysiological analysis of anorectal function using simulated feces in human subjects

Daming Sun [a,1], Donghua Liao [b,c,1], Ssu Chi Chen [d], Cherry Wong [d], Wing Wah Leung [d], Kaori Futaba [d], Tony Mak [d], Simon Ng [d], Hans Gregersen [d,e,∗]

[a] School of Microelectronics and Communication Engineering, Chongqing University, Shapingba, Chongqing, 400044, China
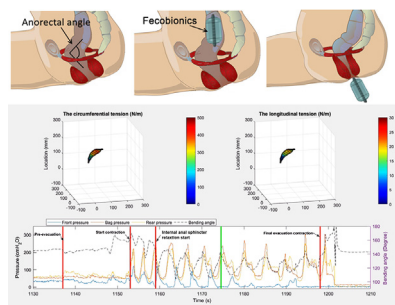[b] Mech-Sense, Department of Gastroenterology and Hepatology, Aalborg University Hospital, Denmark
[c] GIOME Academia, Department of Clinical Medicine, Aarhus University, DK-8200 Aarhus, Denmark
[d] Department of Surgery, Clinical Sciences Bldg., Prince of Wales Hospital, Shatin, Hong Kong
[e] California Medical Innovations Institute, USA

GRAPHICAL ABSTRACT

ARTICLE INFO

ABSTRACT

Introduction: Defecation is a complex process that is difficult to study and analyze.
Objectives: Here, we present new analytical tools to calculate frictional force and tension during expulsion of the Fecobionics simulated stool in human subjects.
Methods: The 12-cm-long Fecobionics device contained pressure sensors, motion processor units for measurement of orientation and bending, and impedance rings for measurement of cross-sectional areas. Eight normal subjects defecated Fecobionics. The bending angle of the device, frictional force between the device and the surrounding tissue, and the stretch tensions were calculated.
Results: The bending angle and pressures changed during expulsion with the maximum pressure recorded at the rear. The averaged circumferential tension, longitudinal tension and friction force in each subject were associated with the front-rear pressure difference ($r > 0.7$, $p < 0.005$). The peak circumferential tension, longitudinal tension, and friction force immediately before expulsion of the rear were significantly higher compared to when the front entered the anal canal ($F = 164.7$, $p < 0.005$; $F = 152.1$, $p < 0.005$; $F = 71.4$, $p < 0.005$; respectively.).
Conclusion: This study shows that Fecobionics obtained reliable data under physiological conditions. Mechanical features such as frictional force and stretch tensions were assessable during Fecobionics expulsion.

Introduction

The mechanisms of defecation and continence depend on several factors including colorectal motility, stool consistency, rectal capacity and compliance, anorectal sensitivity, and coordination of the pelvic floor muscles and anal sphincters [1,2]. Although technological advancements have been achieved such as high-resolution anorectal manometry (HRAM) [3] and anal functional luminal imaging probe (FLIP) technology [4,5], they have only had a modest impact on the field. There is considerable disagreement between the current anorectal tests for diagnosis and subtyping constipation [6]. Hence, a new gold standard is needed. For example, HRAM shows dyssynergic abnormality in 90% of healthy subjects [7]. Such complexities impact patient management and care and may lead to wrong diagnosis [8–12]. Since defecation is a mechanosensory event, detailed mechanosensory analysis is needed for proper assessment of defecation [1,13]. Improved devices for integrated anorectal function studies and advanced analysis are warranted to improve diagnostics and therapies such as biofeedback treatment [14].

To overcome technology pitfalls, we have developed a novel Fecobionics device [15–19] that integrates measurements from most current clinical tests and beyond for novel anorectal assessment. Fecobionics is an insertable device that provides high-resolution anorectal data on pressures, orientation, bending and shape during defecation of the device. It is simulated feces that electronically measures relevant parameters of defecation such as the propulsive force, anal sphincter relaxation, and the anorectal angle. The novelty is that the electronically measured bending angle of the Fecobionics device is a proxy of the anorectal angle (determined by the contractility of the puborectalis muscle) and that axial pressure measurements (front and rear) reflect the pushing force and anal sphincter tone and relaxation. Development studies, feasibility studies and human studies with various stages of functional prototypes have shown agreement with comparable parameters obtained with current technologies [16,19]. Additional clinically relevant data that cannot currently be obtained with current technology such as axial pressure signatures and preload-afterload data are obtained with Fecobionics and show distinctly different signatures between normal subjects, fecal incontinence and chronic constipation patients [19]. The studies demonstrated that defecations can be characterized mechanically in a consistent manner. However, previous Fecobionics prototypes were not fully integrated and functional with simultaneous acquisition of anorectal pressures, orientation, bending (anorectal angle) and anorectal geometry. Hence, in-depth analysis including assessment of tension and frictional force has until now not be possible.

The aim was to conduct the first-in-man studies with a fully integrated Fecobionics device, to generate functional plots, and to compute novel parameters including anal canal length, frictional force and tension distribution in human subjects. Expulsion characteristics are described with endpoints of potential physiological and clinical value. The analysis and data will be a reference for future clinical studies.

Materials and methods

Eight healthy subjects (4 female and 4 males) aged 46–67 years (mean 54.5 years) were studied with Fecobionics. None of the subjects had any history of pelvic disease or surgery. All reported normal bowel function and scored low on fecal incontinence and constipation questionnaires [20,21]. All subjects had participated in anorectal studies within the preceding 3 months of the Fecobioics experiment. All subjects had normal balloon expulsion test (BET), HRAM test and anal ultrasonography without defects in the internal anal sphincter (IAS) and the external anal sphincter (EAS). Human experiments were done according to internationally accepted principles and adhered to the Helsinki Declaration as revised in 2000. All subjects gave written informed consent. The protocol was approved by the Joint CUHK-NT East Cluster Clinical Research Ethics Committee, New Territories, Hong Kong (ref. no. 2017.122). The study was registered at www.clinicaltrials.gov. Identifier: NCT03317938.

Fecobionics

Fecobionics is a novel bionics device for studying defecation [15–19]. It integrates measurements from several technologies for obtaining physiologically relevant measures during defecation including pressure, orientation, bending and geometry of the distending bag.

The design of the Fecobionics prototype used in this study are illustrated in Fig. 1. Fecobionics was constructed as a 12 cm-long and 12.5 mm-wide bendable core (made of medical grade Silicone rubber (PS6600, Yipin Mould Material Ltd, China) with hardness shore A5). A 25-μm-thick polyurethane bag was mounted on the core for distension. The spherical bag could be distended with 120 ml saline without stretching the bag (maximum 70 mm diameter). The filling tube (2 mm ID) was connected to a syringe. The core contained pressure sensors (MS5837-30BA, TE connectivity, USA) at the front, rear and inside the bag, two 6-axis motion processor units (MPUs, combined gyroscopes and accelerometers, MPU6050, InvenSense, USA) and printed circuit boards including the Microprogrammed Control Unit (MCU) (IAP15L2K61S2, STC, China). Nine impedance electrodes were mounted on the surface of the core inside the bag with 10 mm center spacing to measure the cross-sectional area (CSA) at eight serial locations covering a total length of 8 cm. The CSA range that could be measured with the probe was approximately 100–1200 mm^2 corresponding to 12–40 mm in diameter. The power source was external to the body and connected with the core using thin wires. With the chosen device architecture, hardness shore and the bag, Fecobionics obtained consistency that corresponds to types 3–4 on the Bristol stool form scale [22,23]. Data were recorded at 30 Hz sampling rate for pressure and orientation, and 7 Hz for CSA. Data were transferred to a personal computer and displayed by a custom-made user interface programmed in Matlab R2015a (Mathworks, MA, USA).

Calibration and in vivo studies

Before each test, the pressure sensors, impedance and the MPUs were calibrated to ensure reliable data. The gyroscopes in the MPUs were calibrated by placing Fecobionics in horizontal, vertical upward, vertical downward and horizontal orientation again for 10 s in each orientation. The pressure sensors were pre-calibrated by the manufacturer and the baseline was determined. The impedance (diameter) was calibrated by inserting the probe and inflated the bag inside seven straight tubes with diameters ranging from 15 to 40 mm. Impedance was recorded for 10 s in each tube and the calibration curve was generated and applied for estimation of diameters.

During in vivo studies, the probe was gently inserted through the anal canal into rectum with the subjects placed in left lateral position. The subjects moved to the commode chair. Before distension of the bag, the subjects were asked to squeeze and cough twice. This was done to verify that the probe was placed correctly inside rectum with the front facing the anal canal. The bag was distended until the subject felt urge to defecate or to a maximum volume of 80 ml, whatever came first. The investigators left the room and the subjects defecated the device in privacy.
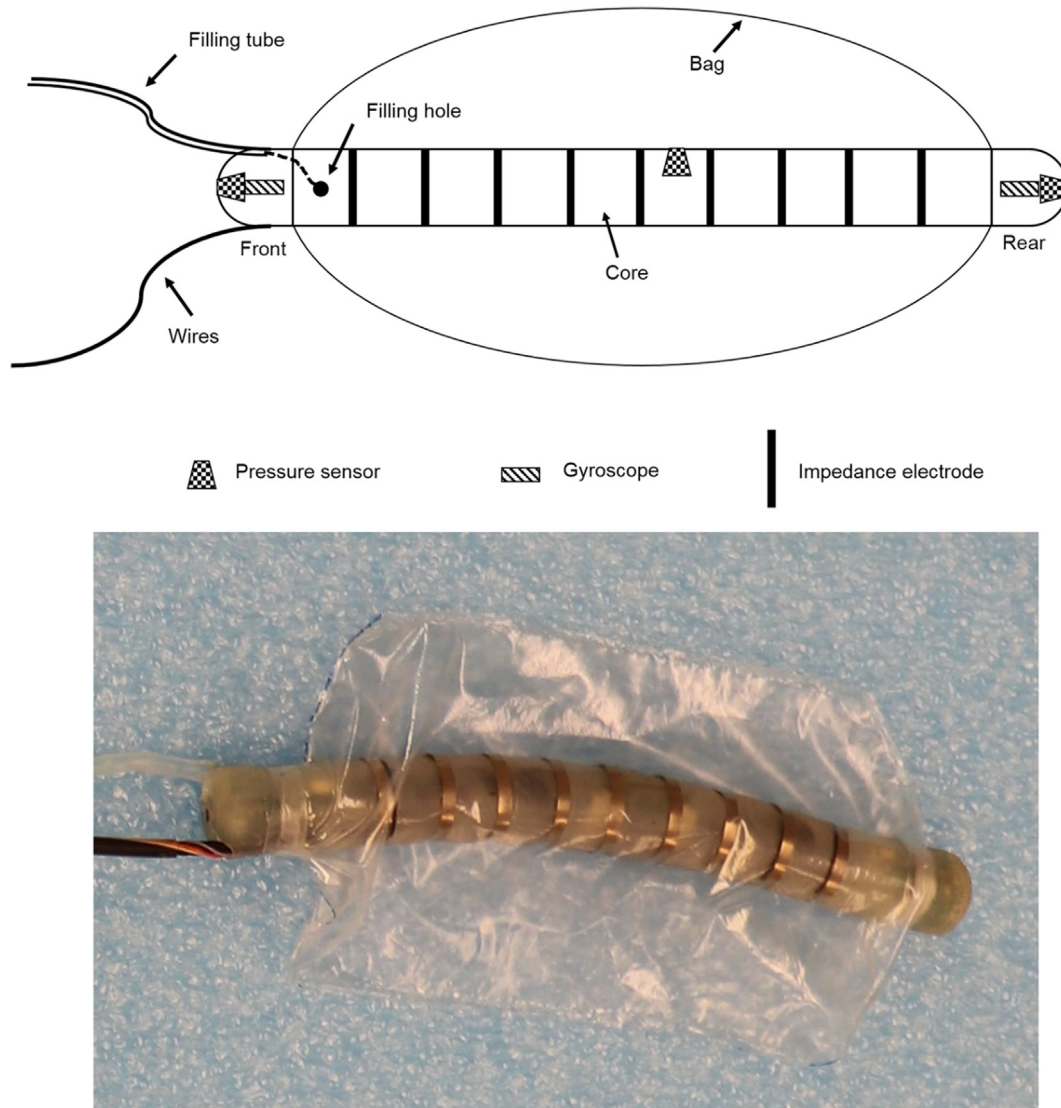
Fig. 1. Schematic and a photo of the tethered Fecobionics prototype used in this study. The core is made from soft silicone resin and contains three pressure sensors placed at the front, rear and inside the bag. Two 6-axis motion processor units (MPUs, i.e. gyroscopes and accelerometers) were imbedded for determination of orientation and bending during defecation (measurement of the anorectal angle during passage from the rectum to the anal canal). Nine impedance electrodes were mounted on the surface of the core to capture eight cross-sectional areas. A filling tube was attached to the front for filling the bag. A cable was attached for data transmission and power supply.

Data analysis

Custom-made analysis software was programmed in Matlab R2015a (Mathworks, MA, USA) for analysis and reconstruction of spatio-temporal diameter maps obtained by Fecobionics. The diameter maps were generated by interpolation the diameters obtained via each CSA channel with an accuracy of 0.1 mm. The calculated diameters served for further geometric and biomechanical modeling analysis. During the expulsion, the device moved from rectum with the front entering into and sliding through the anal canal (line AA' in Fig. 2a). Line BB' in Fig. 2a shows the passage of the rear through the anal canal. These lines were used for computation of expulsion duration, expulsion velocity and the anal canal length.

The anal canal length L was calculated as:

$$L = \frac{\int_{t_2}^{t_3}(l_{AA'}(t) - l_{BB'}(t))}{t_3 - t_2} = \frac{A}{t_3 - t_2} \tag{1}$$

where t_2 is the time point when the front leaves the anal canal (pressure drop to atmospheric pressure), and t_3 is the time point

when the rear enters the anal canal, A is the area made of lines AA' and BB' between t_2 and t_3 (Fig. 2a, the area inside the white lines). The anal canal length derived from Fecobionics data was compared to the length measured by endoanal ultrasonography (done on a separate day with the subject lying in left lateral position with bended knees and hips by an experienced ultrasound clinical expert using a 2202BK ultrasound scanner with a standard 18 mm anal scanner probe (BK Medical, Guangzhou, China).

The average expulsion velocity V of Fecobionics was determined as:

$$V = \frac{L - L_0 + 80}{t_4 - t_1} \tag{2}$$

where L_0 is the length of the Fecobionics bag located in the anal canal at t_1 (Fig. 2a). t_1 is the time point when the front started to be expelled, and t_4 is the time point when the rear was expelled (pressure drop to atmospheric pressure).

The delta pressure (P_{delta}) was computed as:

$$P_{delta} = P_r - P_f \tag{3}$$

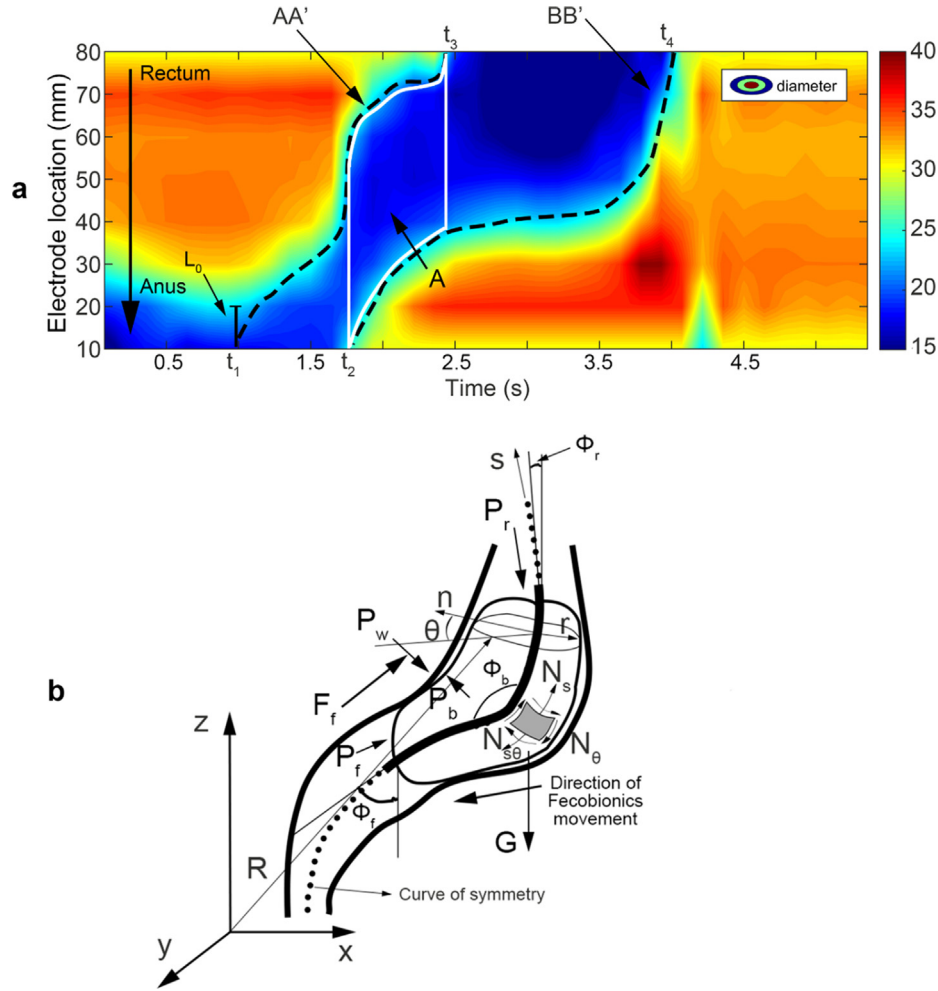where P_r and P_f are rear and front pressures.

Fig. 2. (**a**) Diameter distribution map for showing the expulsion path during an expulsion. The colors from blue to red illustrate increasing diameter. 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 Y-axis represents the location of each CSA sensor changes over time. The line AA' represents 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 time point, the distance between AA' and BB' shows the passage length of probe in anal canal. t_1, t_2, t_3 and t_4 represent the entry and expulsion time of front and rear of the probe, respectively. A is the area of Line AA' and BB' between t_2 and t_3. (**b**) Schematic diagram of an anorectal segment distended by Fecobionics. X, Y and Z are global coordinates. s, θ is the local coordinates with arc of length s along the curve of symmetry and θ the polar angle. s and θ form a set of curvilinear orthogonal coordinates. Membrane stress are N_θ, $N_{s\theta}$, N_s, the circumferential, shear and longitudinal membrane stress. n is the principal normal vectors of the curve, R is the position vector of a point on the reference surface, r is the radius at a cross section along s. Forces on Fecobionics acting on the normal and along the anorectal segment. The forces are the contractile forces from the segment (P_w), the pressure in the bag (P_b), the friction force between the device surface and the wall (F_f), pressure from the fluid within the segment at the inlet (rear pressure, P_r), the pressure from the segment and the atmosphere at the outlet (front pressure, P_f), and also the gravity (G) of Fecobionics. ϕ_r, ϕ_f is the the angle between the tangent lines of rear and front and gravity direction. ϕ_b is the bending angle of the probe.

The angle between the tangent lines of each end of the Fecobionics and the gravity direction was calculated as (Fig. 2b):

front MPU angle ϕ_r : $\phi_f(n) = 0.9 \times (\phi_f(n-1) + \omega(n) \times \Delta t)$
$$+ 0.1 \times \phi_a(n)$$
rear MPU angle ϕ_r : $\phi_r(n) = 0.9 \times (\phi_r(n-1) + \omega(n) \times \Delta t)$
$$+ 0.1 \times \phi_a(n) \qquad (4)$$

where ω is the angular velocity recorded from the gyroscope, $\Delta t = t_n - t_{n-1}$ is the time difference between two readouts n. ϕ_a is the angle measured by the accelerometer relative to gravity.

The bending angle was calculated from Eq. (4) as:

$$\phi_b = \begin{cases} 180^o - |\phi_r - \phi_f|, & |\phi_r - \phi_f| < 90° \\ |\phi_r - \phi_f|, & |\phi_r - \phi_f| \geqslant 90° \end{cases} \qquad (5)$$

where ϕ_b, ϕ_r, ϕ_f are the bending, rear, and front angle, respectively. 180° means that the device is straight.

Membrane tension analysis [18]

The Fecobionics bag and anorectal shape was assumed as a curved thin-wall shell of revolution during the device movement (Fig. 2b). The anorectal wall resists the pressure induced by the distension and the shear stress through the friction between the bag and tissue wall. Using an arbitrary surface coordinate system, the following equations of equilibrium on the anorectal surface were derived:

$$\alpha_s \frac{\partial(N_\theta)}{\partial\theta} + \frac{\partial(\alpha_\theta N_{s\theta})}{\partial s} + \frac{\partial\alpha_\theta}{\partial s} N_{s\theta} - \frac{d\alpha_s}{d\theta}(N_s - N_\theta) = -\alpha_s \cdot \alpha_\theta \cdot f_\theta$$

$$\alpha_s \frac{\partial(N_\theta)}{\partial\theta} + \frac{\partial(\alpha_\theta N_{s\theta})}{\partial s} + 2\frac{\partial\alpha_s}{\partial\theta} N_{s\theta} - \frac{d\alpha_\theta}{ds} N_\theta = -\alpha_s \cdot \alpha_\theta \cdot f_s$$

$$\frac{N_s}{R_s} + \frac{N_\theta}{R_\theta} = -f_w \qquad (6)$$

where f_w is the force across the tissue wall, f_s and f_θ are the distributed force (force per unit area) between Fecobionics and the wall along the s and θ directions. Membrane stress resultants were N_s, $N_{s\theta}$ and N_θ, the longitudinal, shear and circumferential membrane tensions, respectively. Details about the definitions of these coordinates and geometric features have been published [18].

The boundary condition for the bag in anorectum is $N_s = N_{s\theta} = 0$ when $s \to \infty$. During defecation, the distension, contractile force from the anorectal muscles, and forces from the probe will cause deformation and stretch of the wall. We assumed the forces across the wall were represented by the recorded bag pressure. Hence, the membrane tensions during Fecobionics expulsion can be determined from Eq. (6).

Friction analysis

Analysis of friction is gaining interest in gastroenterology [24,25]. For Fecobionics (simulating feces) to be expelled through the anorectum, a variety of forces acting on it must be overcome (Fig. 2b). According to Newton's second law, the friction force between the surface and the wall (F_f) during Fecobionics expulsion can be calculated with an estimated expulsion velocity along the anorectal segment as:

$$\sum F_s = \left[(-P_r + P_b) \cdot A_{rear} + (P_f - P_b) \cdot A_{front} \right] + F_f - G_s = m\dot{v}$$

$$F_f = m\dot{v} - \left\{ \left[(-P_r + P_b) \cdot A_{rear} + (P_f - P_b) . A_{front} \right] - G_s \right\} \qquad (7)$$

where P_b is the bag pressure. P_r and P_f are rear and front pressures. G_s is the gravity component in s direction, A_{rear} and A_{front} are the surface areas at both ends of the probe, m is the mass, $\sum F_s$ is the resultant force along the s direction. $\dot{v} = dv/dt$ is the acceleration of the movement, $v = dl_{AA'}/dt$ is the expulsion velocity of the probe. The expulsion velocity was assumed $v = 0$ before the front starts to slide into the anal canal (time t_1 in Fig. 2a). Hence, the force distribution (force per unit area, f_s) in the s direction between Fecobionics and the anorectal wall can be determined as:

$$f_s = \frac{\sum F_s}{A_{surface}} \qquad (8)$$

where $A_{surface}$ is the contact surface area between the probe and the anorectal wall. In this study, we assumed the distribution forces along and normal to the s direction were symmetrically loaded to the center line of the anorectal surface. Hence, the shear membrane tension $N_{s\theta}$ is eliminated.

Statistic

All results were expressed as mean ± SEM unless otherwise stated. Bland Altman analysis [26] and paired *t*-test method were used to compare the anal canal length obtained with Fecobionics movement analysis and endoluminal anal ultrasonography measurement. One-way ANOVA analysis was used to compare the tension and friction force calculated at different stages of Fecobionics transit. Spearman's correlation test was used to estimate the association between P_{delta}, tension and friction force. All analysis was done using IBM SPSS Statistics 22 (IBM Corp. USA). The results were considered significant when $p < 0.05$.

Results

Fecobionics expulsion recordings

Characteristics of the subjects and key data recorded during Fecobionics expulsions (duration, change in bending angle and pressures) are provided in Table 1. Four subjects felt urge at bag volumes 40–70 ml whereas the rest felt urge at the maximum bag volume of 80 ml. The average expulsion time was 28 ± 8 s. Two representative integrative examples of the pressures, bending angle and diameters during expulsion are displayed in Fig. 3. In addition, the data in Fig. 3b are presented as a video clip (upload). All pressures during abdominal contractions increased in a predictable manner after defecation was initiated. When the subject generated sufficient pushing force (increase in intra-rectal pressure), the front of Fecobionics moved into the anal canal with simultaneously relaxation of the anal sphincter (Fig. 3). Due to friction force between the bag and the tissue wall, the passage of Fecobionics through the anal canal started slowly. After overcoming the friction force, the entire device was expelled in very short time. The velocity of the final expulsion was 37.9 ± 6.8 mm/s.

Anal canal length

The anal canal length calculated from Fecobionics expulsion was 3.0 ± 0.2 cm. Comparative values measured by ultrasonography was 2.8 ± 0.2 cm. The measured anal canal length by using these two method were associated, i.e. correlated positively (r = 0.77, p < 0.05). A Bland Altman plot was generated (Fig. 4). The bias was small with the zero difference line within the confidence interval. The anal canal length recorded by the two methods did not differ (Bland Altman: p = 0.12; Paired *t*-test: t = 1.81, p = 0.12).

Table 1
Subject data and key data recorded during expulsions.

Subjects	Sex	Age	Weight (kg)	Filling Volume (ml)	Expulsion duration (s)	Change of bending angle (degrees)	Rest front pressure (cmH$_2$O)	Rest rear pressure (cmH$_2$O)	Maximum rear pressure (cmH$_2$O)	Relaxation ratio (during expulsion)
01	M	46	45.5	40	3.8	21.2	5	N/A	195.5	63%
02	M	63	68	60	12.4	16.1	18	41.3	140	100%
03	F	47	60	80	15.9	19.4	N/A	28	158.5	N/A
04	F	62	67.2	80	13.7	N/A	13	30	136	83%
05	F	55	61.6	80	57.4	7.8	64	47	203	76.5%
06	M	50	69.1	70	36.7	16.5	67	104	258.7	46%
07	M	66	66	80	64.9	15.1	33	61	235.5	100%
08	F	48	46.2	60	17.7	15.4	43	38	186	34.9%
Mean ± SEM		54.6 ± 2.8	60.5 ± 3.4	68.8 ± 5.2	27.8 ± 8	15.9 ± 1.6	34.7 ± 8.7	49.9 ± 9.3	189.2 ± 15.5	71.8 ± 9.6%

Explanatory notes. Change of bending angle: the average peak value vs rest value; Relaxation ratio: the average value of full relaxation of the front vs its rest value. Data are expressed as mean and SEM. N/A means no recording available.
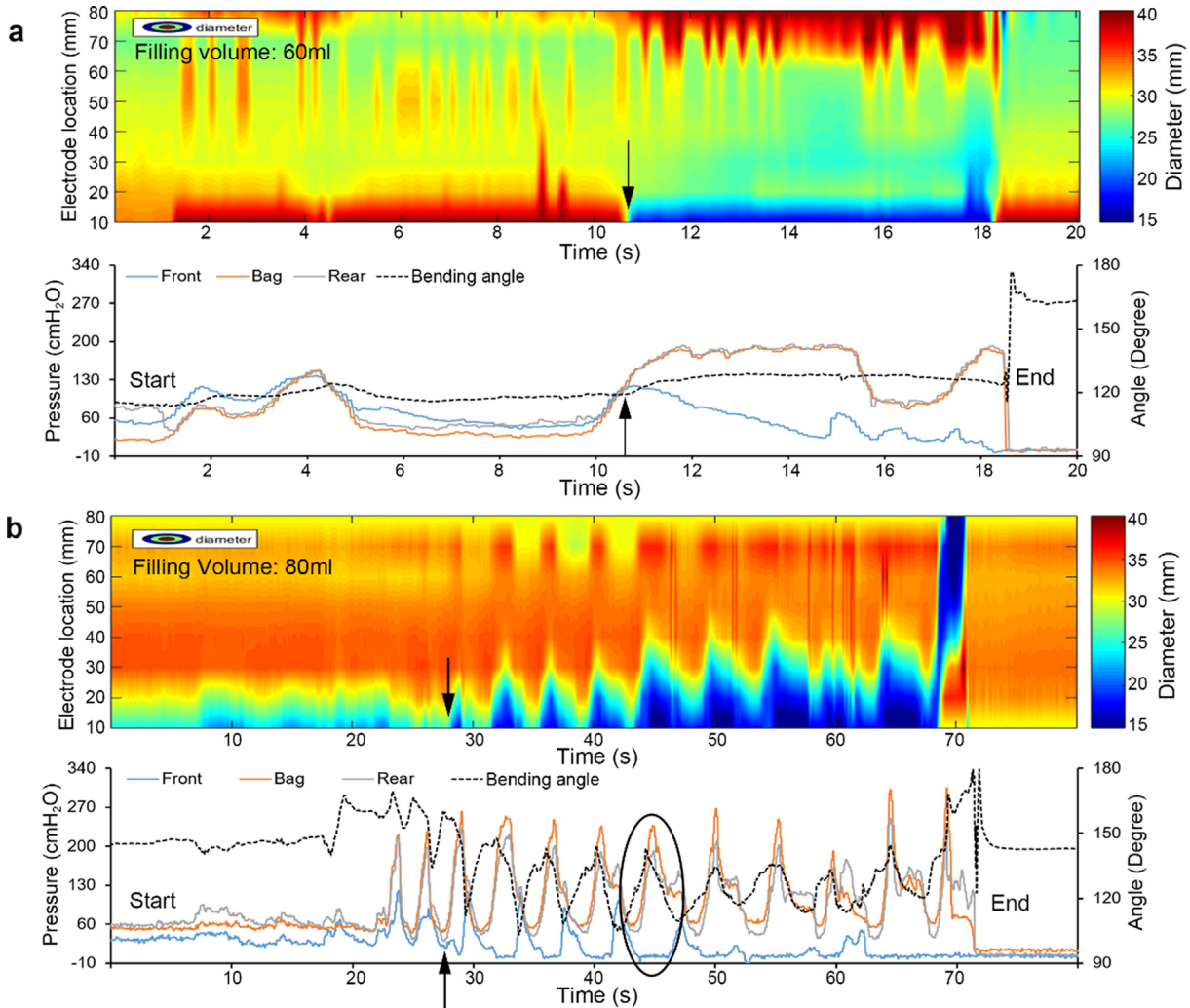
Fig. 3. Two representative recordings of Fecobionics expulsion. The subject in Fig. 3a quite easily expelled the device using few contractions, whereas the subject in Fig. 3b used more contractions and longer time. All pressures fluctuated with abdominal pressure increments after expulsion started. The front of Fecobionics moved to the anal canal (Arrows). Intra-rectal pressure increased and simultaneously the anal sphincter relaxed (ellipse). The device was fairly straight initially with bigger anorectal angle (bending angle, 180° means the device is straight). During the first contractions, the bending angle decreased, which will impede defecation. Towards the end of the contractions when the anal sphincter was relaxed, the angle increased again, facilitating defecation. Straightening of the device also occurred during the contractions. These coordinated actions resulted in expulsion through the anal canal.
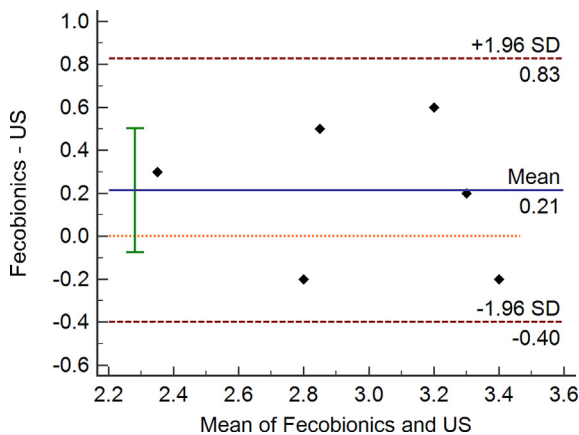

Fig. 4. Bland Altman plot of the anal canal length measured by Fecobionics and by Endoluminal anal ultrasonography (US). The green bar shows the confidence interval. The two methods did not differ (Bland Altman: p = 0.12; Paired *t*-test: t = 1.81, p = 0.12).

Computed membrane tension and friction force

Two representative examples of color graphs of circumferential tension, longitudinal tension, friction force and delta pressure–time relationships during Fecobionics expulsion are illustrated in Fig. 5. The averaged circumferential tension, longitudinal tension and friction force in each subject were all associated with the delta pressure (r = 0.79 ± 0.07, p < 0.005 for the circumferential tension; r = 0.78 ± 0.07, p < 0.005 for the longitudinal tension and r = 0.77 ± 0.07, p < 0.005 for the friction force). Before the device started to move through the anal canal, high tensions were recorded at the rear. The tensions decreased toward the front in both circumferential and longitudinal directions. However, as soon as the front had passed the anal canal, the main body of the probe went through the anal canal very quickly with increased tensions in both circumferential and longitudinal directions (Fig. 5ab). The friction force (positive means the direction along the movement) increased significantly when the main body of the device entered the anal canal. This contributed to quick expulsion of the device (Fig. 5ab).

The circumferential tension, longitudinal tension and friction force differed among six predefined states, Rest, Relax, Entry$_{front}$, Squeeze, Max and Exit$_{rear}$ (Figs. 5 and 6). Data at the Rest, Relax and Entry$_{front}$ states (lower value group) were significantly lower than at Exit$_{rear}$, Squeeze and Max states (higher value group) (circumferential tension, F = 164.7, p < 0.005; longitudinal tension, F = 152.1, p < 0.005; friction force, F = 71.4, p < 0.005). The friction force at Exit$_{rear}$ (2662.5 ± 256.5 N/m^2 were significantly higher than at the Squeeze state (968.3 ± 240.9 N/m^2, F = 23.2, p < 0.005). The circumferential, longitudinal tension and the friction force at Exit$_{rear}$ (291.5 ± 25.9 N/m, 14.9 ± 1.5 N/m, and 968.3 ± 240.9 N/m^2, respectively) were higher than at Entry$_{front}$ (96.6 ± 10.7 N/m, F = 48.5, p < 0.005; 4.6 ± 0.5 N/m, F = 41.0, p < 0.005; 431.6 ± 210.3, F = 117.4, p < 0.005; respectively). The maximum friction force (2662.5 ± 256.5 N/m^2) was found at the time point immediately before being expelled from the anal canal.
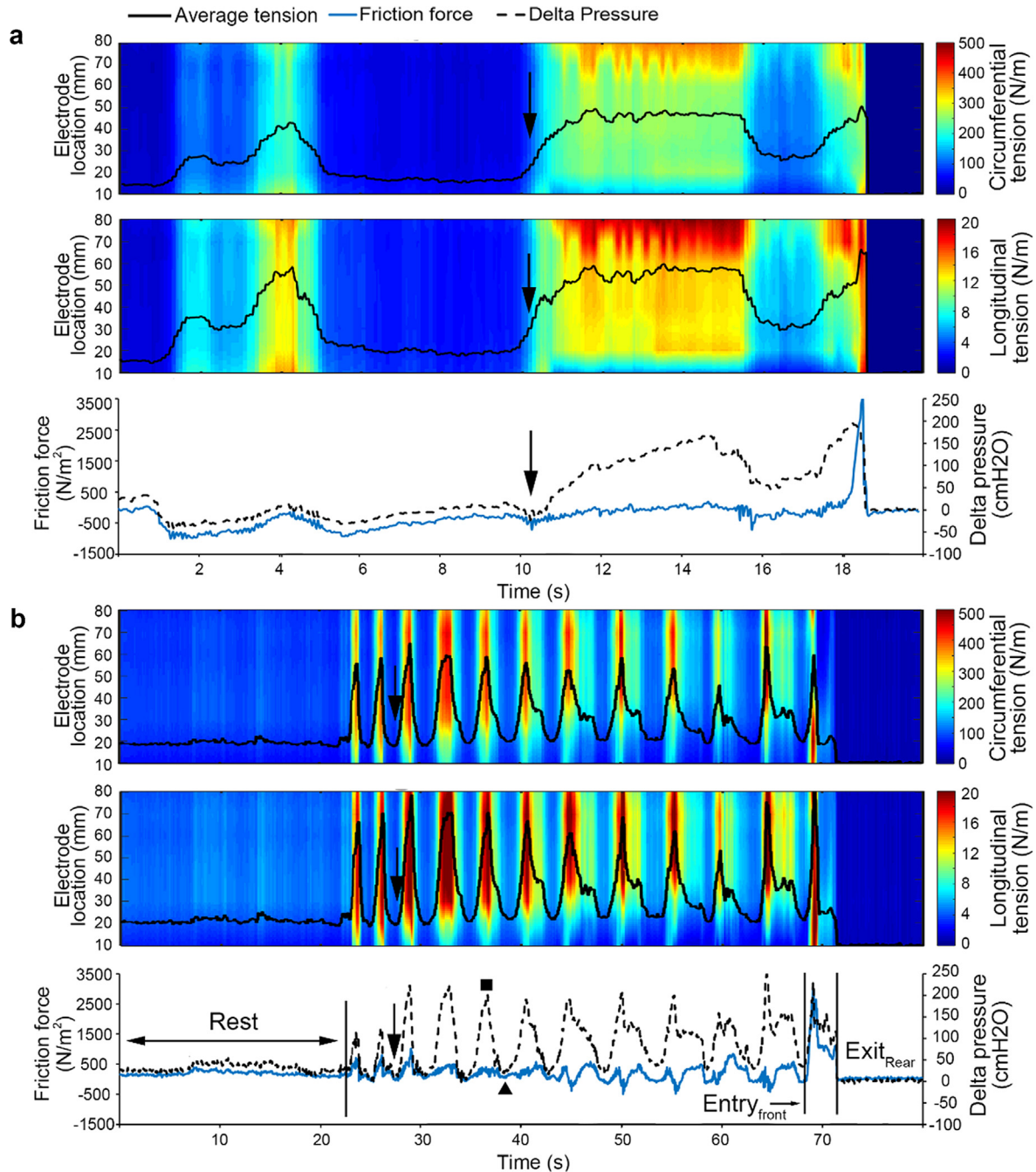

Fig. 5. Representative examples of the circumferential tension, longitudinal tension, friction force and delta pressure change during Fecobionics expulsion. Significant positive correlations were found between delta pressure and circumferential tension (subject **a**: r = 0.61, p < 0.005; subject **b**: r = 0.85, p < 0.005), delta pressure and longitudinal tension (subject **a**: r = 0.56, p < 0.005; subject **b**: r = 0.87, p < 0.005), delta pressure and friction force (subject **a**: r = 0.90, p < 0.005; subject **b**: r = 0.53, p < 0.005). During the short passage f the probe was expelled, the tensions were higher in rear and decreased toward the front in both circumferential and longitudinal directions. Square: time point at a squeezing; Triangle: time point at a relaxation; Rest: time during resting state; Entry$_{front}$: time point when the front entering the anal canal, Exit$_{rear}$: time point when the last peak value before the expulsion of the rear.
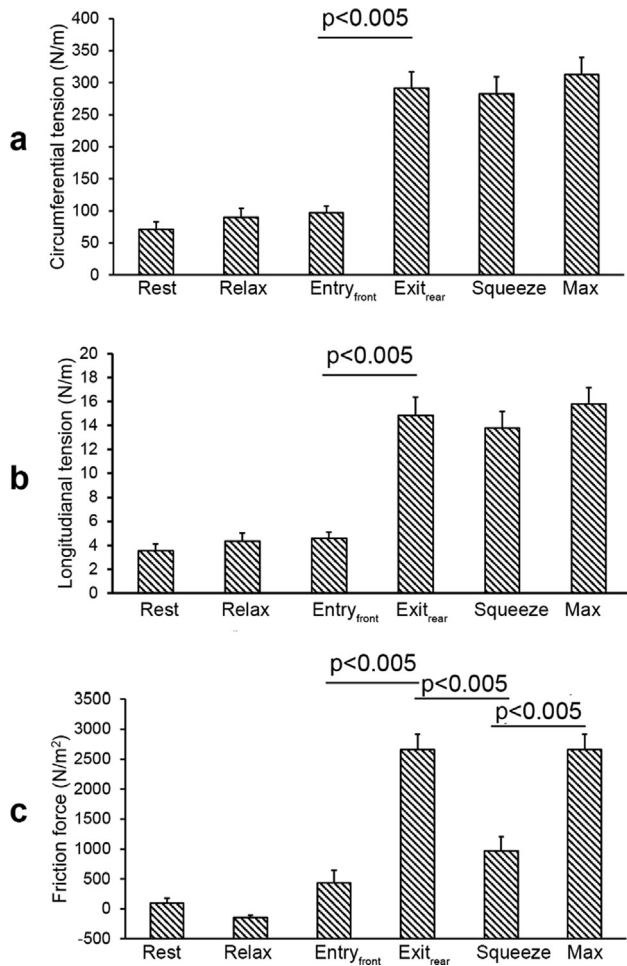
Fig. 6. The circumferential tension, longitudinal tension and friction force at different predefined states. Rest: Averaged value at resting state, Relax: averaged value of each relaxation, Entry$_{front}$: the front entering the anal canal, Exit$_{rear}$: the last peak value before the expulsion of the rear, Squeeze: average value of each squeezing peak, Max: the maximum value. See Fig. 5 for graphical explanation of the definition of each state. See the text for supporting statistical data.

Discussion

Summary of major findings

In this study, we aimed to explore the mechanophysiological functions of anorectum in human subjects with a novel simulated fecal device named Fecobionics. Pressures, orientation and CSAs were measured during defecation of Fecobionics. Furthermore, bending angle, shape, tensions and friction force were computed. All measurements and parameters fluctuated as expected during abdominal contractions, anal relaxation and expulsion of the device. Furthermore, we found that the averaged circumferential tension, longitudinal tension and friction force change were positively correlated with delta pressure. The peak tensions and friction force immediately before expulsion of the rear were higher compared to when the front entered the anal canal. The friction force increased significantly to promote expulsion when the main body of Fecobionics entered the anal canal. Finally, the anal canal length measured by Fecobionics was consistent with the length measured with *endo*-anal ultrasonography.

Anorectal function and significance of new parameters

Anorectal function is complex and may easily get disturbed causing symptoms such as chronic constipation and fecal incontinence [27,28]. Due to the significance of such symptoms, it is warranted to rethink the scientific and clinical approach in term of new bionics technology like Fecobionics, and novel modelling approaches. The present work is part of our ongoing work to better understand anorectal function and defecation. The strategy is first to build anatomically correct models, then mechanophysiological models, and finally mechanosensory models. Such models are important for our understanding of organ function and the wide variability encountered in biology. Fecobionics has several advantages to current technology, i.e. the simulated feces integrates a variety of measurements in a single test and demonstrates the fine coordination between the elements in the defecatory process This is clearly visualized in Fig. 3 where the color contour plot (CSA) topography visualizes the shape of the bag and how Fecobionics moves antegrade and retrograde before being finally expelled. The associated angle and pressure measurements are consistent with these movements, i.e. with straightening of the anorectal angle and increase in rear and bag pressure, whereas the front pressure decreases, reflecting anal relaxation.

Defecation is a mechanical event; it is achieved by several interacting mechanisms including the ability to create a high intra-abdominal pressure, colorectal motility, rectal distensibility, anorectal angle and coordination of pelvic floor muscles and anal sphincter. During the expulsion of Fecobionics, not only the surface interactions with the anorectal surface are complex. Fecobionics must also overcome a variety of forces, which will be acting to move Fecobionics along the anorectal canal. These forces include contractions and the friction between Fecobionics and the anorectal wall. The friction and distension of Fecobionics lead to anorectal tissue stretch in axial and circumferential direction. It is accompanied by changes in the surface geometry and mechanical behavior of the tissue. The anorectal segment is a soft-curved tube with anisotropic and hyperelastic mechanical properties. When the Fecobionics distends and moves, the anorectal segment stretches and resists distension and movement. The critical condition for movement of Fecobionics is the frictional resistance between the device and the anorectal wall. The frictional resistance equals the tension resulted from the stretch of the segment and the gravity of the Fecobionics. When the tension of the segment and the gravity are larger than the frictional resistance of Fecobionics, the friction converts from static friction to sliding friction, i.e. evacuation of Fecobionics starts. In this regard, it is of interest to notice in Fig. 5 that the tension in the rear of the bag is much higher than at the front during contractions. This facilitates movement of the device towards the relaxing anal canal. The computed tension, friction, and the recorded deformation of anorectum can be used to estimate the biomechanical properties of the anorectum (distensibility/elasticity). The rational of the study is to provide a method for determination of the dynamic distribution of the 3D tension and friction force on the anorectal wall during Fecobionics expulsion. The Fecobionics data obtained in the present study including pressures, CSA and tension are comparable to previous data with Fecobionics [15,16,19] as well as to other technologies [2,29–32]. Furthermore, the present study showed good agreement of anal canal length measurements between Fecobionics and ultrasonography.

For the analysis presented in Eq. (6), we can simplify the model as a straight thin-wall shell of revolution. Consequently Eq.6 can be derived from the Eqs. (5) and (6) in previous work by Gregersen and coauthors [18], indicating the effectiveness of the current model. Furthermore, the proposed analysis framework can be used to simulate mechanical behavior of anorectum in patients suffering from defecatory disorders by combining monomeric and movement properties measured by Fecobionics.

Limitations of the study

The gravity force component normal to the movement direction was neglected in this study. The total gravity force was less than 10% of the force produced by the pressure difference of the rear or front, even at the condition when the bag was inflated to volume 80 ml. Consequently, the shear deformation produced by gravity force can be neglected. As mentioned before, the anorectal segment is a soft-curved lumen with anisotropic and hyperelastic wall properties [29,33]. In this study, the tensions and friction force calculations were based on infinitesimal deformation theory instead of on large deformation theory [1,13]. This limitation can be overcome later with further developed numerical simulation models.

The current Fecobionics prototype was tethered (wires to the power supply and a thin filling tube). The subjects did not sense the tethers in the anal canal and we anticipate that the tethers do not affect measurements. However, a new prototype is currently being developed with internal power source and a detachable filling tube to overcome this potential problem.

Conclusions and perspectives

In this study, we utilized data from the newly developed Fecobionics device. For the first time, a fully functional prototype with simultaneous measurement of pressures, orientation, and CSAs was used to compute physiologically relevant parameters including bending angle, tension, and friction force. We demonstrated how the parameters change during expulsion of the simulated feces in normal subjects. The tension and friction force models are straightforward and take the rectal pressure, as well as the anal resistance (relaxation) into account. In the future, the model can be further developed to integrate the resistive effect of varying degrees of anorectal angle using equations for pressure, velocity and friction in bent tubes. For example, is anorectal angle really critical for the continence/ incontinence function has never been addressed. Our hope is that modelling will be able to determine if the above is correct, which can also be true for the other variables that we record. The model, which is based on the laws of mechanics, will serve to determine material parameters as well as develop modifications of the Fecobionics device.

Future use of a mathematical model of anorectal passage of Fecobionics will improve our understanding of the normal and abnormal defecatory patterns including the length-tension properties, pressures, anorectal angle, sphincter relaxation and friction. Since most patients with fecal incontinence and obstructed defecation have abnormal functional measures, we expect the parameters to be biomarkers of anorectal disorders. Future studies with the Fecobionics technology will focus on patients with various types of defecatory disorders, where the biomechanical model can be used for prediction of outcome and to inform clinical decision/making, i.e. a patient-specific mathematical model.

Compliance with Ethics Requirements

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). Informed consent was obtained from all patients for being included in the study.

Declaration of Competing Interest

Hans Gregersen has filed for patent rights on the Fecobionics technology. All other authors have declared no conflict of interest.

Acknowledgements

References

[1] Gregersen H, Christensen J. Clinical Gastrointestinal Mechanics. An Introduction: Bentham Publishers; 2016.

[2] Rao SS, Kavlock R, Rao S. Influence of body position and stool characteristics on defecation in humans. Am J Gastroenterol 2006;101(12):2790–6. doi: https://doi.org/10.1111/j.1572-0241.2006.00827.x.

[3] Heinrich H, Sauter M, Fox M, Weishaupt D, Halama M, Misselwitz B, et al. Assessment of Obstructive Defecation by High-Resolution Anorectal Manometry Compared With Magnetic Resonance Defecography. Clin Gastroenterol Hepatol 2015;13(7). doi: https://doi.org/10.1016/j.cgh.2015.01.017. pp. 1310–7 e1.

[4] McMahon BP, Frokjaer JB, Kunwald P, Liao D, Funch-Jensen P, Drewes AM, et al. The functional lumen imaging probe (FLIP) for evaluation of the esophagogastric junction. Am J Physiol 2007;292(1):G377–84. doi: https://doi.org/10.1152/ajpgi.00311.2006.

[5] Sorensen G, Liao D, Lundby L, Fynne L, Buntzen S, Gregersen H, et al. Distensibility of the anal canal in patients with idiopathic fecal incontinence: a study with the Functional Lumen Imaging Probe. Neurogastroenterol Motil 2014;26(2):255–63. doi: https://doi.org/10.1111/nmo.12258.

[6] Palit S, Thin NN, Knowles CH, Lunniss PJ, Bharucha AE, Scott SM. Diagnostic disagreement between tests of evacuatory function: a prospective study of 100 constipated patients. Neurogastroenterol Motil 2016;28(10):1589–98. doi: https://doi.org/10.1111/nmo.12859.

[7] Grossi U, Carrington EV, Bharucha AE, Horrocks EJ, Scott SM, Knowles CH. Diagnostic accuracy study of anorectal manometry for diagnosis of dyssynergic defecation. Gut 2016;65(3):447–55. doi: https://doi.org/10.1136/gutjnl-2014-308835.

[8] Selby W, Corte C. managing constipation in adults. Australian Prescriber 2010;33(4):116–9.

[9] Drossman DA. The functional gastrointestinal disorders and the Rome III process. Gastroenterology 2006;130(5):1377–90. doi: https://doi.org/10.1053/j.gastro.2006.03.008.

[10] Simren M, Palsson OS, Whitehead WE. Update on Rome IV Criteria for Colorectal Disorders: Implications for Clinical Practice. Curr Gastroenterol Rep 2017;19(4):15. doi: https://doi.org/10.1007/s11894-017-0554-0.

[11] Chang L, Toner BB, Fukudo S, Guthrie E, Locke GR, Norton NJ, et al. Gender, age, society, culture, and the patient's perspective in the functional gastrointestinal disorders. Gastroenterology 2006;130(5):1435–46. doi: https://doi.org/10.1053/j.gastro.2005.09.071.

[12] Locke 3rd GR, Pemberton JH, Phillips SF. American Gastroenterological Association Medical Position Statement: guidelines on constipation. Gastroenterology 2000;119(6):1761–6. doi: https://doi.org/10.1053/gast.2000.20390.

[13] Gregersen H. Biomechanics of the gastrointestinal tract. London: Springer-Verlag; 2002.

[14] Rao SS, Seaton K, Miller M, Brown K, Nygaard I, Stumbo P, et al. Randomized controlled trial of biofeedback, sham feedback, and standard therapy for dyssynergic defecation. Clin Gastroenterol Hepatol Off Clin Pract J American Gastroenterol Associat 2007;5(3):331–8. doi: https://doi.org/10.1016/j.cgh.2006.12.023.

[15] Gregersen H, Krogh K, Liao D. Fecobionics: Integrating Anorectal Function Measurements. Clin Gastroenterol Hepatol 2018;16(6):981–3. doi: https://doi.org/10.1016/j.cgh.2017.09.057.

[16] Sun D, Huang Z, Zhuang Z, Ma Z, Man LK, Liao D, et al. Fecobionics: A Novel Bionics Device for Studying Defecation. Ann Biomed Eng 2019;47(2):576–89. doi: https://doi.org/10.1007/s10439-018-02149-1.

[17] Gregersen H, Lo KM. What Is the Future of Impedance Planimetry in Gastroenterology. J Neurogastroenterol 2018;24(2):166–81. doi: https://doi.org/10.5056/jnm18013.

[18] Liao D, Chen AS, Lo KM, Zhao J, Futaba K, Gregersen H. Theoretical tools to analyze anorectal mechanophysiological data generated by the Fecobionics device. J Biomech Eng 2019. doi: https://doi.org/10.1115/1.4044134.

[19] Gregersen H, Chen SC, Leung WW, Wong C, Mak T, Ng S, et al. Novel Fecobionics Defecatory Function Testing. Clin Transl Gastroenterol 2019;10 (12):. doi: https://doi.org/10.14309/ctg.0000000000000108e00108.

[20] Andromanakos N, Skandalakis P, Troupis T, Filippou D. Constipation of anorectal outlet obstruction: pathophysiology, evaluation and management. J Gastroenterol Hepatol 2006;21(4):638–46. doi: https://doi.org/10.1111/j.1440-1746.2006.04333.x.

[21] Sonnenberg A, Koch TR. Epidemiology of constipation in the United States. Dis Colon Rectum 1989;32(1):1–8. doi: https://doi.org/10.1007/bf02554713.

[22] Avunduk Canna. Manual of Gastroenterology: Diagnosis and Therapy. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins; 2008.

[23] Bedine MS. Textbook of gastroenterology. Gastroenterology 2000;118 (5):984–5. doi: https://doi.org/10.1016/s0016-5085(00)70191-0.

[24] Lin CX, Li W, Deng HY, Li K, Zhou ZR. Friction Behavior of Esophageal Mucosa Under Axial and Circumferential Extension. Tribol Lett 2019;67(1):9. doi: https://doi.org/10.1007/s11249-018-1123-x.

[25] Zhang C, Liu H. Analytical Friction Model of the Capsule Robot in the Small Intestine. Tribol Lett 2016;64(3):39. doi: https://doi.org/10.1007/s11249-016-0774-8.

[26] Giavarina D. Understanding Bland Altman analysis. Biochem Med. 2015;25 (2):141–51. doi: https://doi.org/10.11613/BM.2015.015.

[27] Bharucha AE, Wald A, Enck P, Rao S. Functional anorectal disorders. Gastroenterology 2006;130(5):1510–8. doi: https://doi.org/10.1053/j.gastro.2005.11.064.

[28] Monson JRT. The ASCRS Textbook of Colon and Rectal Surgery. Diseases Colon Rectum 2008;51(6):979.

[29] Liao D, Frokjaer JB, Yang J, Zhao J, Drewes AM, Gilja OH, et al. Three-dimensional surface model analysis in the gastrointestinal tract. World J Gastroenterol 2006;12(18):2870–5. doi: https://doi.org/10.3748/wjg.v12.i18.2870.

[30] Petersen P, Gao C, Rössel P, Qvist P, Arendt-Nielsen L, Gregersen H, et al. Sensory and biomechanical responses to distension of the normal human rectum and sigmoid colon. Digestion 2001;64:191–9. doi: https://doi.org/10.1159/000048861.

[31] Petersen P, Gao C, Arendt-Nielsen L, Gregersen H, Drewes AM. Pain intensity and biomechanical responses during ramp-controlled distension of the human rectum. Dig Dis Sci 2003;48:1310–6. doi: https://doi.org/10.1023/A:1024107209436.

[32] Andersen IS, Gregersen H, Buntzen S, Djurhuus JC, Laurberg S. New probe for measurements of dynamic changes in the rectum. Neurogastroenterol Motility 2004;16(1):99–105. doi: https://doi.org/10.1046/j.1365-2982.2003.00465.x.

[33] Liao D, Zhao J, Gregersen H. Gastrointestinal tract modelling in health and disease. World J Gastroenterol 2009;15(2):169–76. doi: https://doi.org/10.3748/wjg.15.169.