Annals of COLOPROCTOLOGY

Brief Communication

Ann Coloproctol 2025;41(3):248-252
pISSN: 2287-9714 • eISSN: 2287-9722
https://doi.org/10.3393/ac.2025.00066.0009

Anorectal manometric data depend on the direction of pressure measurements in healthy individuals and in patients with functional constipation

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Anorectal function serves to temporarily store feces, maintain continence, and allow defecation at appropriate times. This function relies on complex mechanisms that can become disturbed. During evacuation, feces move in the axial (longitudinal) direction of the anorectum. High-resolution anorectal manometry (ARM) is the state-of-the-art technology for functional anorectal assessment and for diagnosing fecal incontinence (FI) and functional constipation (dyssynergia) [1]. ARM is not a defecatory test; rather, it is a catheter-based procedure that simulates defecation by having subjects perform a push maneuver, during which they increase abdominal pressure and relax the anal sphincter [1–5]. A major issue with the ARM push procedure is that the rectoanal pressure gradient (RAPG) during the push phase is often negative in both control subjects and patients [1–3]. The RAPG, however, is expected to be positive given the increased abdominal pressure and intended sphincter relaxation. This discrepancy may be attributed to the stiffness of the ARM catheter and the fact that pressures are measured radially rather than along the axial direction of the fecal trajectory.

In recent years, a rectally insertable device known as Fecobionics has been developed for use in evacuation tests [6–11]. This bionic device is equipped with multiple sensors and exhibits properties corresponding to type 3 to 4 shapes and consistency on the Bristol Stool Form Scale (BSFS) [12, 13]. Fecobionics measures pressures at the front and rear of the device along the axial direction, i.e., along the defecatory trajectory. As expected, the Fecobionics RAPG is positive during both the push phase and evacuation [7, 10]. Compared to ARM, Fecobionics data correlate more strongly with symptom scores in FI and functional constipation patients [6, 7, 10] and can predict responders to biofeedback therapy in FI patients [9]. Additionally, so-called air passageways—recordings of atmospheric pressure in the distal rectum—have been demonstrated in FI patients [10]. These passageways result from open channels through the anal sphincter and are frequently observed in patients with severe FI [10]. Because ARM does not detect air passageways, axial pressure recordings appear to offer a significant advantage.

The aim of this study was to determine whether radial and axial

Received: January 27, 2025; Revised: March 24, 2025; Accepted: March 31, 2025
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pressures differ during the evacuation of the Fecobionics device.

A specially designed Fecobionics device, 10 cm long and 10 mm wide, was developed to measure both radial and axial pressures at the front (aboral) and rear (oral) of the device, as well as the pressure inside the distension bag (Fig. 1). "Radial pressure" refers to measurements taken by a sensor oriented radially, where the pressure force acts perpendicular to the contacting surface. Similarly, an axial-oriented pressure sensor records force perpendicular to the axial surface. Measurements were conducted at Daping Hospital (Chongqing, China), following ethical committee approval (No. 2023238), in 9 control subjects and 11 functional constipation patients. Written informed consent for publication of the research details was obtained from the patients. The trial was registered at chictr.org.cn (identifier: ChiCTR2300078807; https://www.chictr.org.cn/showproj.html?proj=206583). Control subjects did not exhibit symptoms of defecatory disorders or other diseases affecting anorectal function, and their Wexner constipation scores were below the threshold for constipation. The functional constipation diagnosis for patients was made according to the Rome IV criteria. Two trained investigators performed the procedures. After rectal insertion of the Fecobionics device while the subject was lying on the bed, the subject moved to a sitting position on a commode. The device was evacuated in privacy after the bag was filled either to the urge-to-defecate level or to a maximum volume of 80 mL. If subjects could not evacuate the device within 2 minutes, it was retracted manually. Fecobionics procedures, data accuracy, and test results in patient populations have been described in detail [6, 7, 9, 10]. Data were visualized and collected in real time on a computer and subsequently analyzed offline using MATLAB (MathWorks) and Microsoft Excel (Microsoft Corp). Outcomes included maximum pressure, the duration to reach atmospheric pressure, the area under the front pressure curve, mean pressure, and defecation time. The durations from the start of evacuation until the pressure reached zero (atmospheric) temporarily (axial, t1; radial, t2) and permanently (axial, t3; radial, t4) were measured (Fig. 2). Results are reported as medians with interquartile ranges (IQRs), and nonparametric statistical tests (Wilcoxon signed rank and Mann-Whitney tests) were used.

The sex distribution, age, and body mass index were 9 female and 11 male patients, median 58 years (IQR, 41.62 years), and median 21.3 kg/m^2 (IQR, 19.7.22.8 kg/m^2), respectively, with no significant differences between control subjects and patients. Patients had moderate Wexner constipation scores of median 14 (IQR, 12–15) and exhibited typical patterns of dyssynergia, including signs of rectal hyposensitivity, paradoxical contractions, and prolonged defecation times. Volumes at first sensation, moderate sensation, and urge were 50 mL (IQR, 18–80 mL), 70 mL (IQR, 47–80 mL), and 80 mL (IQR, 77–80 mL), respectively, in functional constipation patients, compared to 30 mL (IQR, 13–41 mL), 48 mL (IQR, 38–72 mL), and 80 mL (IQR, 70–80 mL), respectively, in control subjects ($P<0.05$ for first and moderate sensations). Most patients and control subjects reached the maximum allowed volume of 80 mL before the urge was felt. Evacuation time was significantly longer in patients compared to control subjects (93 seconds [IQR, 49–120 seconds] vs. 19 seconds [IQR, 14–35 seconds], $P<0.01$). Four patients were unable to evacuate the device within the 2-minute period, necessitating manual retraction, whereas all control subjects successfully evacuated the device. Moreover, patients used more abdominal contractions, exhibited lower rectal contractile pressure, and demonstrated more paradoxical anal sphincter contractions during the evacuation attempt than control subjects.

Fig. 2 illustrates representative examples of radial, axial, and bag pressures during device evacuation in a control subject and a patient. The rear and bag pressures exhibited similar contraction

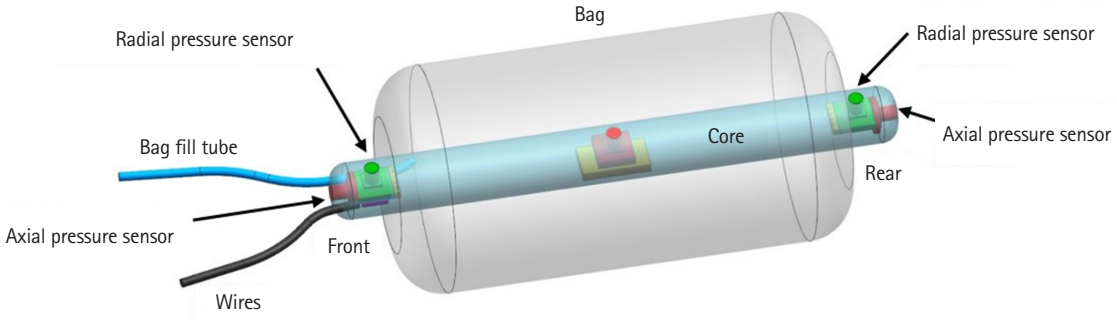

Fig. 1. Schematic of the Fecobionics device. The device is 10 cm long and 10 mm in diameter and has a mounted bag. Wires for power, data communication, and a fill tube for the bag are exteriorized at the front. Both the front and rear contain axial (at the tips) and radial (on the side) pressure sensors, with a 5-mm distance between them.

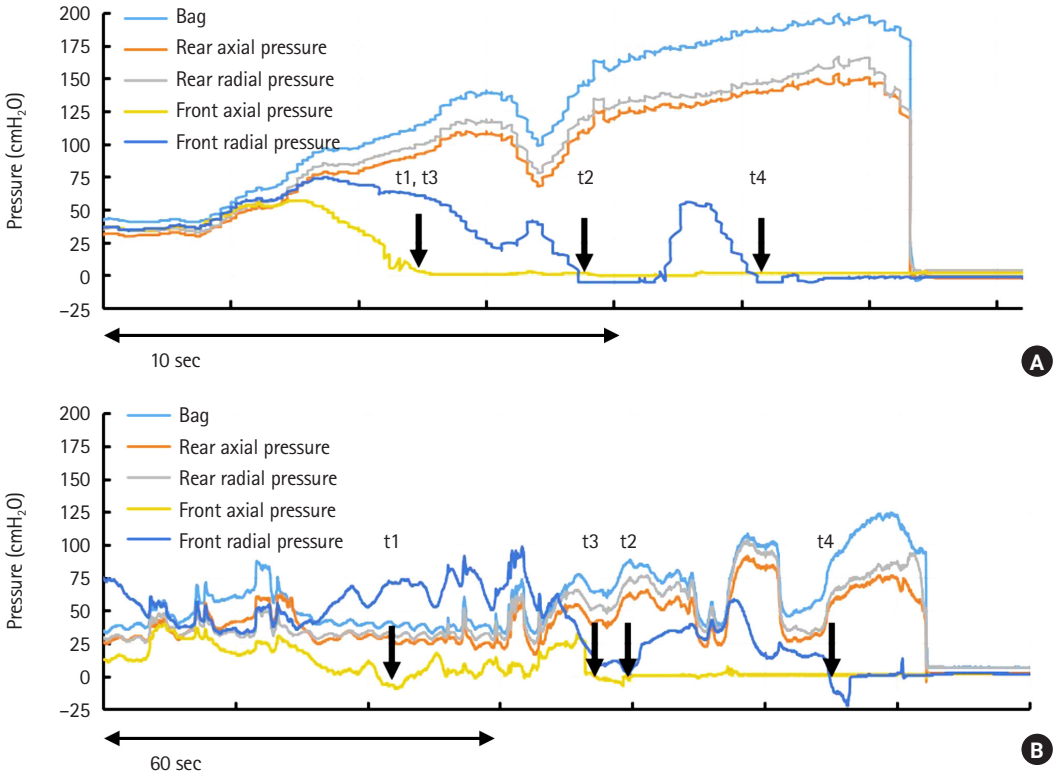

Fig. 2. Fecobionics pressure recordings during device evacuation in (A) a control subject and (B) a patient with functional constipation. The control subject evacuated the device in 14 seconds, whereas the patient took 120 seconds. t1, axial pressure reached 0 cmH_2O temporarily; t2, radial pressure reached 0 cmH_2O temporarily; t3, axial pressure reached 0 cmH_2O permanently; t4, radial pressure reached 0 cmH_2O permanently.

Table 1. Duration for time point metrics

Group	t1 (sec)	t2 (sec)	t3 (sec)	t4 (sec)	P-value (axial vs. radial)
All subjects (n = 20)	23.6 (8.3–32.9)	28.2 (13.7–49.4)	28.9 (15.0–82.6)	35.7 (17.0–102.5)	< 0.05
Control subjects (n = 9)	4.5 (3.0–10.4)	12.8 (7.5–17.9)	15.3 (4.5–16.6)	17.7 (11.0–19.1)	< 0.05
Functional constipation patients (n = 11)	31.4 (23.6–33.0)	41.8 (28.2–57.1)	51.7 (28.9–120.0)	90.2 (35.7–120.0)	< 0.05
P-value (control vs. patients)	< 0.05	< 0.05	< 0.05	< 0.05	-

Values are presented as median (interquartile range).
t1, axial pressure reached 0 cmH_2O temporarily; t2, radial pressure reached 0 cmH_2O temporarily; t3, axial pressure reached 0 cmH_2O permanently; t4, radial pressure reached 0 cmH_2O permanently.

patterns. These pressures were higher in control subjects compared to functional constipation patients; for example, the maximum radial expulsion pressure was 157 cmH_2O (IQR, 108–182 cmH_2O) in control subjects versus 98 cmH_2O (IQR, 85–106 cmH_2O) in patients ($P < 0.05$). The axial and radial front pressures differed substantially. The overall pressure profiles in the radial and axial channels were distinct, with axial pressure deviating more rapidly from the other recordings than radial pressure. The time required for the front pressure to reach 0 cmH_2O at t1 to t4 was significantly longer in the radial direction than in the axial direction and was longest in patients ($P < 0.05$) (Table 1). Although the maximum front pressure and RAPG did not differ significantly between the 2 directions ($P > 0.05$), the RAPG during Fecobionics evacuation was higher in control subjects than in patients (axial: 150 cmH_2O [IQR, 111–181 cmH_2O] vs. 69 cmH_2O [IQR, 55–95 cmH_2O]; radial: 109 cmH_2O [IQR, 89–152 cmH_2O] vs. 80 cmH_2O [IQR, 57–94 cmH_2O]; $P < 0.05$). When both groups were combined, the area under the front pressure curve differed significantly between the axial (598 cm/sec [IQR, 231–1,279 cm/sec]) and radial directions (766 cm/sec [IQR, 421–1,673 cm/sec],

https://doi.org/10.3393/ac.2025.00066.0009

P < 0.05). A similar difference was observed for the mean pressure (P < 0.05). Overall, patients had a significantly larger area under the front pressure curve and a higher mean pressure than control subjects (P < 0.001).

Pressure recordings must take the direction of measurement into account. Ideally, measurements should be made along the direction of intestinal content movement—that is, in the axial direction—using an evacuating device, as this approach is more physiological than using stationary catheters. In these experiments, such axial measurements were directly compared with radial measurements, and profound differences were observed. This finding may have several implications. Although the RAPG is an important ARM metric, it has been criticized because ARM–RAPG values are often negative or near zero, despite expectations that they should be positive during the push procedure (simulated defecation) when abdominal pressure is raised and the sphincter relaxes [1, 4, 5]. In contrast, the Fecobionics RAPG was positive in this study, as previously demonstrated [6, 7, 10], although only a borderline difference was observed between axial and radial directions. The differences between technologies may stem from different experimental conditions (simulated versus actual defecation) and device properties such as measurement direction and stiffness [11, 13–15]. Previous studies in FI patients have demonstrated the presence of air passageways with axial measurements using Fecobionics but not with ARM radial pressure measurements [10]. This supports the notion that anorectal pressures are direction-dependent, as predicted by biomechanical analyses [14, 15]. The area under the curve (integrated front pressure), the mean pressure, and the durations to reach atmospheric pressure (both temporary and permanent) differed significantly between the 2 measurement directions. Axial pressure recordings reached atmospheric pressure much faster than radial recordings, an observation that is important for interpreting anorectal pressures and anal sphincter relaxation. Given the expulsion speed, the 5-mm difference in the axial location of the sensors cannot explain the observed differences.

This study has several limitations. First, the small number of subjects sometimes necessitated combining groups to avoid type II errors, although most measures still differed significantly. Although sex differences in anorectal pathophysiology are well-known, it was not feasible to analyze these differences due to the limited sample size. Future large-scale studies are needed. A second limitation is that the device's diameter was larger than that of the ARM catheter. However, the data obtained in this study are consistent with published ARM data [1–5], suggesting that the Fecobionics radial pressure recordings are representative of ARM. Another limitation is that correlation analyses with constipation scores could not be performed due to the narrow variation in scores within the patient group. Future studies should include a larger and more diverse patient population.

In conclusion, significant differences were observed between radial and axial pressures during evacuation, as well as between patients and control subjects. Because propulsive and resistive forces should be measured along the fecal trajectory [14, 15], these data call into question the validity of radial measurements using ARM. The clinical implication is that failing to consider the direction of pressure measurement may lead to erroneous diagnoses, ultimately resulting in suboptimal treatments.

ARTICLE INFORMATION

Conflict of interest

Hans Gregersen and Daming Sun hold IP rights to the Fecobionics technology. No other potential conflict of interest relevant to this article was reported.

Funding

This study was supported by the National Natural Science Foundation of China grant (No. 11902057), Natural Science Foundation of Chongqing, China grant (No. CSTB2022NSCQ-MSX0767 and No. CSTB2022NSCQ-MSX1508), and Project to Enhance the Scientific and Technological Innovation Capabilities of the AMMU (No. 2022XLC07).

Author contributions

Conceptualization: all authors; Data curation: ZH, MY, HG; Formal analysis: all authors; Funding acquisition: ZH, MY, DS; Investigation: all authors; Methodology: all authors; Writing–original draft: all authors; Writing–review & editing: all authors. All authors read and approved the final manuscript.

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https://doi.org/10.3393/ac.2025.00066.0009