RESEARCH LETTER

Anorectal Friction Force Is Reduced in Fecal Incontinence

Fecal incontinence (FI) and obstructed defecation syndrome (ODS) are important anorectal disorders that affect a large proportion of the population. They are underdiagnosed and represent a psychologically and socially debilitating problem that affects quality of life.[1] The pathophysiology is multifactorial. Due to limitations with current technology for anorectal function studies, an unmet need exists for new technology and metrics for diagnosis and mechanistic insight. Current technologies have added significantly to our understanding of functional anorectal disorders but have limitations in being relatively unphysiological, discrepancies exist for results obtained with different technologies, and correlation with symptoms is low.[2–4]

Fecobionics technology has the potential to change the field since it integrates elements from current technologies into one test that is bionic, ie, the device is a simulated stool with consistency and shape as natural feces.[5,6] Evacuation procedures are done in privacy. A less advanced wired Fecobionics device, primarily based on pressure recordings, showed significant potential in anorectal diagnostics being capable of subtyping ODS and FI patients with strong correlation with symptoms and treatment outcomes.[7–9] The new wireless Fecobionics system is an integrated test with multiple measures (pressures, diameters, acceleration, orientation, and bending) providing unprecedented possibility for development of new metrics. Here we present a novel friction force metric that integrates pressures, shape, size, and the anorectal angle for assessment of defecatory function. This study focuses on development of the model and testing friction force in a small group of normal subjects (NS) and FI patients. Studies were conducted at the California Medical Innovations Institute and at University of California San Diego after IRB approval and informed consent. Trial Registration. www.clinicaltrials.gov Identifier: NCT04765138.

The subjects were 18 years of age and older. Pregnant women and morbid obese subjects were excluded. Demographic data and FI severity index (FISI) scores were obtained from questionnaires. The wireless Fecobionics device was inserted in 15 NS (median age 49 years (quartiles 27–56) and 10 FI patients (age 47 years (39–62)). Sixty percent of the subjects were females. The bag on the device was distended inside rectum to urge-to-defecate volume and the device was evacuated in privacy. High-resolution anorectal manometry (HRAM, Manoscan, Medtronic) using the London Protocol and balloon expulsion test (BET, Mui Scientific) were used for reference and comparison. Friction force was computed using a force equilibrium model (Figure A and Supplementary Material). The model is purely physical, ie, not based on empirical parameters. It takes the rear (driving), bag, and front (resistive) pressures into account along with the gravitational force, and device bending, shape and size. Mann-Whitney test and Spearman correlation tests were used.

The FISI score in NS and FI patients was 0 (0–2) and 22 (14–34). Most patients were women with anal injuries caused by deliveries earlier in life. Several patients had comorbidities such as hypertension, hypothyroidism and depression and were on medications, eg, omeprazole. One patient had prior hysterectomy, another had prior rectal cancer surgery. All subjects evacuated Fecobionics within 2 minutes, most within 20 seconds. A few patients dropped the device before attempting to evacuate it. In comparison, 8 NS and 3 FI patients could not evacuate BET. The median urge-to-defecate volume was 75–85 ml without difference between groups ($P > .5$). The friction force was lowest in patients ($P < .05$, Figure B and C) and negatively correlated to the FISI score ($r = -0.46$, $P < .05$). Fecobionics data showed higher correlation with symptoms in patients than ARM-BET (see below). The friction force showed strong association with the Fecobionics rectoanal pressure difference (F-RAPG, $r = 0.68$, $P < .001$, Figure D) and the bag pressure ($r = 0.61$, $P < .01$), and moderate correlation with maximum rectal diameter ($r = 0.58$, $P < .01$) and rear pressure ($r = 0.56$, $P < .01$). The minimum anal diameter and device bending (a proxy of the anorectal angle) did not correlate with the friction force. Friction force showed moderate correlation with the HRAM resting anal pressure ($r = 0.55$, $P < .05$).

HRAM anal resting and squeeze pressures differed between groups ($P < .05$) and showed negative correlation with the FISI score ($P < .05$). The HRAM-RAPG during push maneuvers did not differ between the groups ($P > .05$) and did not correlate with the FISI score ($P > .3$). The HRAM resting anal pressure correlated with the friction force ($r = 0.46$, $P < .05$) whereas the anal squeeze pressure and the HRAM-RAPG showed no association.

An limitation is the small group sizes. Despite this, results were statistically conclusive. The next step is to conduct large-scale follow-up studies in well-defined groups of FI and ODS patients to obtain mechanistic insight into the pathophysiology. The comorbidities and medications of the FI patients are not believed to affect our conclusions, eg, removing the patient with prior rectal surgery would not have changed the conclusions. The patients were not subtyped into passive and urge incontinence since this classification has been questioned.[10] Some FI patients with low anal resting pressure drop the device.[8] These patients were included since the device recorded the event. A

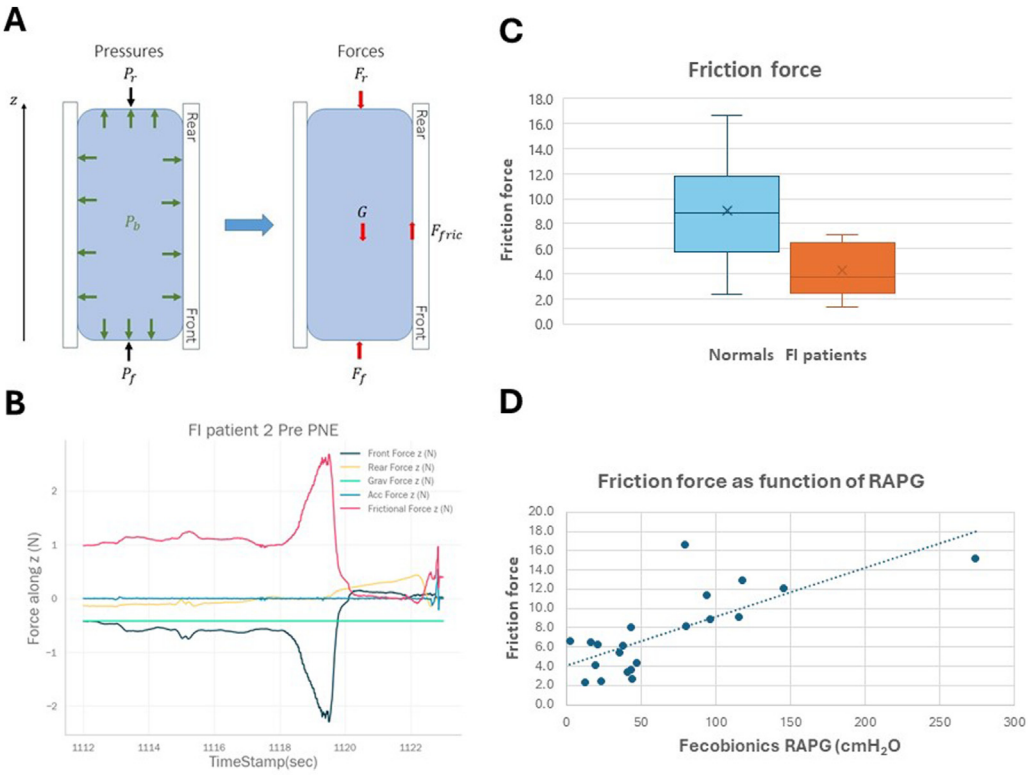

Figure. (A) Force balance model for anorectal expulsion of Fecobionics. *F, r, f, G* and *fric* denote force, rear, front, gravitational force and friction force, respectively. (B) Tracing showing forces as function of time during evacuation in a patient with FI. (C) Friction force was lower in patients with FI compared to NS. (D) Scatter plot with regression line for friction force versus the RAPG. A strong association was found ($r = 0.68$, $P < .001$).

high percentage of NS surprisingly could not expel BET but expelled Fecobionics.

The present data are the first with wireless Fecobionics in patients and the first to present advanced metrics, ie, friction force, a physics-based force balance metric, representing the mechanical coupling between anorectal muscle and feces. The metric is well-suited for Fecobionics since it measures all factors of importance. Low friction, ie low resistance to the passage of feces, is a promoter of anal leakage. Hence, the target for FI therapies is to increase the friction force. As expected, friction force was lowest in patients and correlated negatively with the FISI score. Decomposing the friction force showed that the F-RAPG and bag pressure were the most significant contributors. These mechanistic data from NS and FI patients do not exclude that other factors such as anal diameter are determinants of friction force in ODS patients. Future studies will investigate this. HRAM confirmed differences between the groups but only the resting pressure correlated with friction force. The HRAM-RAPG was not associated with any other measure.

The study shows the potential for integrated bionic technology and metrics in anorectal assessment. We seek to identify novel biomarkers that can help to predict success or failure of therapies such as biofeedback therapy and tune personalized therapies. Future studies will address our long-term goal of providing mechanistically based effective biomarkers for functional anorectal disorders.

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Supplementary Materials

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Abbreviations used in this paper: **BET, balloon expulsion test; F, force; f, front; FI, fecal incontinence; F-RAPG, fecobionics rectoanal pressure gradient; Fric, friction force; G, gravitational force; HRAM, high-resolution anorectal manometry; IRB, institutional review board; NS, normal subject; ODS, obstructed defecation syndrome; RAPG, rectoanal pressure gradient; R, rear**

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Conflicts of Interest:
These authors disclose the following: Hans Gregersen and Ghassan Kassab have filed patent applications. The remaining authors disclose no conflicts.

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Ethical Statement:
Studies were conducted at the California Medical Innovations Institute (IntegReview IRB reference no. CALM-CLIN-2019-01) and at University of California San Diego (UCSD IRB project no. 200496).

Data Transparency Statement:
Access to data can be granted upon reasonable request, which should be directed to the corresponding author.

Reporting Guidelines:
Helsinki Declaration.