Fecobionics Evaluation of Biofeedback Therapy in Patients With Fecal Incontinence

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INTRODUCTION: **Biofeedback therapy (BFT) is a well-known treatment for functional anorectal disorders. The effect of BFT was monitored in fecal incontinence (FI) patients with the Fecobionics test and with the conventional technologies, anorectal manometry (ARM) and balloon expulsion test (BET).**

METHODS: **Studies were performed in 12 patients before and after 8 weeks of biofeedback training. The Fecal Incontinence Severity Index (FISI) score was obtained. Anal resting and squeeze pressures were measured before the bag was distended in the rectum until urge to defecate. Pressure recordings were made during Fecobionics evacuation.**

RESULTS: **BFT resulted in 24% reduction in FISI scores ($P < 0.01$). Seven patients were characterized as responders. Anal pressures, the urge-to-defecate volume, and defecatory parameters did not change significantly during BFT. For ARM-BET, the maximum anal squeeze pressure, the urge-to-defecate volume, and the expulsion time were lower after BFT compared with those before BFT ($P < 0.05$). For Fecobionics, the change in urge volume ($r = 0.74$, $P < 0.05$) and the change in defecation index ($r = 0.79$, $P < 0.01$) were associated with the change in FISI score. None of the ARM-BET parameters were associated with the change in FISI score. It was studied whether any pre-BFT data could predict treatment success. The Fecobionics expulsion duration and the defecation index predicted the outcome ($P < 0.05$). The defecation index had a sensitivity of 100% and a specificity of 72%. None of the ARM-BET parameters predicted the outcome (all $P > 0.2$).**

DISCUSSION: **Fecobionics was used as a tool to monitor the effect of BFT and proved better than conventional technologies for monitoring and predicting the outcome in the FISI score.**

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INTRODUCTION

Fecal incontinence (FI) is characterized by involuntary loss of rectal content through the anal canal. It is a psychologically and socially debilitating problem that can dramatically affect quality of life and is underdiagnosed. Overall, 15.3% of the population in the United States older than 70 years and up to 9.5% younger than 70 years suffer from FI (1). The pathophysiology of this condition can have many causes and, hence, may not be adequately treated. Management options for these patients are complicated in part because of the multifactorial control of defecation and continence and also because of difficulties in identifying the exact cause of FI with the range of diagnostics available at present. Furthermore, disagreement has been found between the results of various anorectal tests, and they do not correlate well with symptoms and treatment outcomes (2–7).

Biofeedback therapy (BFT) is a treatment option for FI and obstructed defecation used in clinical laboratories worldwide (8–10). It is used in patients who have not responded to conservative medical treatment. It retrains bowel and muscle to normalize patterns of bowel function and lessen gastrointestinal symptoms caused by functional bowel disorders such as FI. The treatment seeks to correct the impairment, that is, to strengthen the anal sphincter muscle, reduce hypersensitivity, or improve coordination of pelvic floor muscles.

We are seeking to change the approach to anorectal functional testing with the overall goal to provide a mechanistic understanding of defecation using a simulated tool named Fecobionics. It integrates the balloon expulsion test (BET) and anorectal manometry (ARM). Fecobionics is a defecatory test measuring multiple physiological variables during evacuation of the device. Technological validation (11) and studies on normal subjects and patients with FI, obstructed defecation, and low anterior resection syndrome have been published (12–17). In

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agreement with other technologies, simple measures obtained by Fecobionics did not show differences between FI patients and normal subjects (15). However, axial pressure signatures (12), preload-afterload analysis, and distensibility indices (DIs) by Fecobionics provided useful end points for FI and constipation (11–17).

This exploratory study aims to describe the pathophysiological characteristics and patterns of anorectal function using Fecobionics to monitor FI patients before and after biofeedback training. Expulsion characteristics are described with end points of physiological and potential clinical values. It was tested on an exploratory basis whether the change in FISI score was associated with change in Fecobionics parameters and whether Fecobionics end points could predict the outcome in the FISI score. Reference data were obtained with ARM-BET, although the main purpose of this study was not comparative. Previous studies have shown marked differences between Fecobionics and ARM-BET data (13–16).

METHODS

Twelve patients attending the functional colorectal surgery clinic at Prince of Wales Hospital in Shatin, Hong Kong with FI and eligible for treatment with BFT were invited to participate in this exploratory study. The BFT was performed as clinical care, whereas the Fecobionics and ARM-BET monitoring before and after BFT was part of the research protocol. The BFT was conducted by coauthor Leung, who was not aware of the outcome of the Fecobionics study before the entire data set had been analyzed offline. The patients fulfilled the Rome IV criteria for FI (18) and were motivated for BFT training. Contraindications included spinal cord injury or other neurological disorders, inability to participate in a sound way, pregnancy, and severe internal anal sphincter damage associated with low or absent resting anal canal pressure. The patients had not responded to conservative medical treatment including dietary and lifestyle modifications and medicine (typically loperamide).

The lower age limit was 18 years. Because most of the patients referred to our clinic are women, to avoid variation due to sex, only female patients were included. Data were obtained on age, health status, body mass index, symptoms, other diseases, and previous treatments. FI Severity Index (FISI) scores and FI quality of life (QOL) scores were obtained (19–21). FISI scores <5 were considered normal (21). The patients were studied before and after 8-week BFT.

Before functional testing, the patients were asked to empty their rectum if they were able to. Enema was not used to make the test as natural as possible. Digital rectal examination was performed before insertion of Fecobionics to assess anal tone and verify that the lower rectum was empty. Experiments using Fecobionics and ARM-BET were performed in a randomized order on the same day with appropriate time between the tests. At least 20 minutes separated the tests. All patients underwent endoanal ultrasonography. This study was IRB-approved (Protocol No. 2017.122). Trial Registration: www.clinicaltrials.gov identifier: NCT03317938.

The basic design of Fecobionics has been described (11,12). Fecobionics was 12 mm in outer diameter and 10-cm long and contained pressure sensors embedded at the front, inside the bag, and at the rear of the silicone rubber core (Figure 1). A 30-μm thick and 8-cm long polyester-urethane bag spanned most of the core length. The bag was connected through a thin tube extending

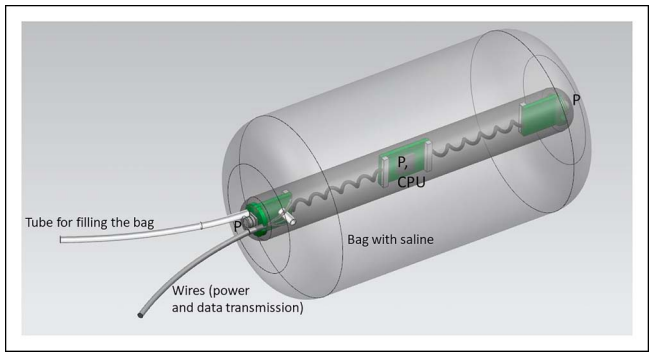

Figure 1. Schematic diagram of the 10-cm long Fecobionics device. Fecobionics contains 3 pressure sensors placed at the front, rear, and inside the bag and the central processing unit. A filling tube system and wires are attached at the front. P, pressure sensor.

from the front of Fecobionics to a syringe containing saline. With the architecture, silicone hardness shore, and the bag, Fecobionics obtained consistency that corresponds approximately to type 4 (range 3–4) on the Bristol Stool Form Scale (22). Wires were threaded inside a thin tube extending from the front to a laptops universal serial bus port for power supply and real-time data transmission and display.

The Fecobionics protocol reported previously was followed (13,15). In brief, Fecobionics was manually inserted into the rectum, the patients moved to the commode, the device placement was confirmed manometrically, and the bag distended to the urge-to-defecate level, where the patients attempted to evacuate Fecobionics in privacy. ARM-BET was conducted with a standard single-use 8ch anorectal catheter (G-90150; MMS, Enschede, Netherlands). Standard procedures and the manufacturer's instructions for use were followed. The experiments adhered to the London protocol (3) with stabilization, rest anal squeezes, cough, push, rectal sensory testing, and the rectoanal inhibitory reflex (RAIR) before balloon expulsion. Resting anal pressure, maximum anal squeeze pressure, RAIR, urge volume, maximum tolerable volume, and expulsion duration for the 50-mL balloon were evaluated. BET was performed on the commode chair in privacy.

Multiple Fecobionics parameters were calculated including the duration of the whole experiment, expulsion duration, pressure amplitudes from the rear, bag and front sensors, and difference between the rear and front pressure sensors (delta pressure). The rear-front (preload-afterload) diagrams were plotted (11,13,23,24). These diagrams constitute a useful way to display data (14–17). The preload that must exceed the afterload before evacuation can take place because feces movement cannot occur against an anorectal pressure gradient. The DI for the pressure difference between the rear and front pressures was computed during evacuation (named DI_{delta}). DI_{delta} normalized with respect to the duration of the evacuation was also computed and named $DI_{delta/s}$. These parameters represent the pressure load during evacuation.

Biofeedback training was performed using NeuroTrac Myo-Plus Pro (Verity Medical, Hampshire, UK) 2 times per week for a total of 16 sessions. An 11-cm long rectal probe (TensCare, Surrey, UK) was used by each patient. Before the start of the training, the therapist performed digital rectal examination to assess the length and strength of the anal sphincter. Afterward the

probe was inserted. Baseline resting electromyography (EMG) was assessed before the treatment started for the evaluation of the progress and to set the treatment goals. The BFT was divided into 2 parts: sphincter muscle strengthening and sensory training. Each part lasted 20 minutes. For the sphincter muscle strength training, the patients were provided with the NeuroTrac MyoPlus Pro machine with visual feedback of their resting EMG signal. Patients squeezed with maximal strength for 5 seconds, and the peak of the EMG signal was monitored in a 30-second interval. Once the peak was identified, the program was changed to a "work/rest" session in which the patients squeezed their sphincter muscles to at least 80% of the peak value. The "work/rest" program used a setting of a 5-second working period and 5-second resting phase. The period could be adjusted according to the performance of the patient. For the sensory training, an ETS (EMG Triggered Stimulation) program was used. When the patient achieved maximum squeeze EMG signal, electrical stimulation was given from the biofeedback machine to facilitate more muscle fibers to contract. The initial electrical stimulation period was 5 seconds. It could be adjusted according to the progress of improvement for the patients.

The sample size was largely decided on an exploratory basis and based on previous data on data variation in FI patients and normal subjects (12,15). If the data passed the normality test, they were considered normally distributed, and consequently, mean ± standard error of the mean (SEM) were computed. The paired *t* test was used for studying differences. Median and quartiles and nonparametric statistics including the Mann-Whitney *U* test and Wilcoxon signed-rank test were used where appropriate. Treatment success may be defined in different ways such as 50% reductions in FI episodes or 20% or 50% reduction in FISI scores (9,25–28). We did not define treatment success a priori but instead used a natural cutoff point to distinguish responders from nonresponders (see Results). The χ^2 test was used to analyze associations between responders/nonresponders and other subgroups. Linear regression analysis was performed to test whether the change in FISI score during treatment was associated with the change in other parameters. The Fisher exact test was used to test whether any parameter obtained before treatment could predict the outcome in the FISI score, that is, responder vs nonresponder. Optimal cutoff values were determined for the 2 × 2 contingency table analysis. Results were considered statistically significant when $P < 0.05$ (2-tailed). SPSS (v20.0; IBM, New York, NY) and Excel were used for statistical testing.

RESULTS

All patients were female Asians living in Hong Kong. The age was 61 ± 3 years. Their symptom duration spanned between 1 and 20 years (median 5 years), and the median number of vaginal deliveries was 1 (range 0–4). One patient had anal sphincter defects visible on anal ultrasonography (1-cm long defect at 12–4 o'clock, involving internal anal sphincter and external anal sphincter), and 3 patients had apparent thin walls anterior, posterior, or lateral. Four patients suffered from lower back pain. Ten FI patients had low anal sphincter tone on digital rectal examination. Seven of the 12 patients had urge incontinence, 4 patients had passive incontinence, and one patient had mixed type FI. All 12 patients completed the BFT program as well as the Fecobionics and ARM-BET studies before and after treatment.

The FISI score was 33.9 ± 3.1 before treatment. Biofeedback resulted in average 24% reduction in symptoms (FISI score post 26.2 ± 2.9 [t = 3.62, $P < 0.01$]). Table 1 lists the FISI and QQL scores. All patients had improvement in symptoms except 2 who did not change. Most improvement was due to less incontinence for solid stool and to some extent also for liquid stool. No improvement was observed for gas and mucus. Five patients were characterized as nonresponders because they improved less than 7% in the FISI score. The other patients improved between 19% and 50%. The nonresponder patients had similar FISI and QOL scores before the treatment as the responders (all $P > 0.2$). No association was found between responders/nonresponders and urge/passive FI subtype ($P > 0.5$).

None of the Fecobionics studies lasted more than 10 minutes, and no adverse effects (pain, bleeding, or other symptoms) were reported during insertion, rectal distension, or device evacuation. Basic Fecobionics and BET data are listed in Table 2. The Fecobionics anal resting pressure, maximum anal squeeze pressure, and urge volume did not change significantly during BFT (all $P > 0.5$). For ARM-BET, the anal resting pressure and the maximum tolerable volume did not change during BFT, whereas the maximum anal squeeze pressure, the urge volume, and the expulsion time were all lower after BFT compared with those

Table 1. Symptom and QOL scores

Parameters	Pre-BFT	Post-BFT	*P* values
FISI score (gas)	11.8 ± 0.1	11.8 ± 0.1	>0.5
FISI score (mucus)	1.8 ± 0.8	1.7 ± 0.9	>0.5
FISI score (liquid stool)	11.8 ± 1.4	8.8 ± 1.6	<0.05
FISI score (solid stool)	8.5 ± 1.6	3.5 ± 1.6	<0.05
FISI score (total)	33.9 ± 3.1	26.2 ± 2.9	<0.01
QOL score (life style)	2.8 ± 0.2	3.1 ± 0.2	>0.2
QOL score (coping/behavior)	2.1 ± 0.2	2.3 ± 0.3	>0.5
QOL score (depression/self-perception)	3.0 ± 0.2	3.2 ± 0.2	>0.5
QOL score (embarrassment)	2.3 ± 0.1	2.3 ± 0.2	>0.5

Data are mean and SEM. The statistics are for comparison of pre-BFT versus post-BFT values. The Wilcoxon signed-rank test was used.
BFT, biofeedback therapy; FISI, fecal incontinence severity index.

Table 2. Basic Fecobionics and ARM-BET data

Parameters	Pre-BFT	Post-BFT	*P* values
Fecobionics			
Anal resting pressure (cmH_2O)	17.6 (6.0–24.8)	13.2 (6.2–31.9)	>0.5
Maximum anal squeeze pressure (cmH_2O)	54.7 (48.3–71.4)	54.7 (42.4–69.0)	>0.5
Urge volume (mL)	35.0 (20.0–56.3)	42.5 (21.3–50.0)	>0.5
Evacuation duration	11.0 (4.5–14.0)	5.0 (3.5–8.5)	>0.1
Maximum delta pressure during evacuation (cmH_2O)	99.6 (54.9–141.5)	92.0 (78.0–92.8)	>0.5
Maximum rear pressure during evacuation (cmH_2O)	91 (51.4–139.1)	92.1 (78.0–101.2)	>0.5
DI_{delta} (cmH_2O)	275.6 (185.6–806.7)	236.9 (169.6–386.8)	>0.1
$DI_{delta/s}$ ($cmH_2O\ sec^{-1}$)	34.2 (28.3–58.5)	49.6 (36.1–56.2)	>0.5
ARM-BET			
Anal resting pressure (mm Hg)	41 (34.25–59)	41.5 (29.75–55.75)	>0.5
Maximum anal squeeze pressure (mm Hg)	131.5 (118.75–178.25)	111.5 (79.5–147.25)	<0.01
RAIR absent	0/12	3/12	>0.2
Urge volume (mL)	81 (72.75–92.25)	62 (58.25–86)	<0.05
Maximum tolerable volume (mL)	106.5 (90.25–129)	100 (91.5–118.3)	>0.5
Evacuation duration (seconds)	28 (12.5–37.75)	17 (13.25–21.25)	<0.05

Values are median and quartiles. The statistics are for comparison of pre-BFT versus post-BFT values. The Wilcoxon signed-rank test was used except for the Fisher exact test that was used for RAIR.
ARM-BET, anorectal manometry and balloon expulsion test; BFT, biofeedback therapy; RAIR, rectoanal inhibitory reflex.

before BFT (Table 2). In agreement with previous comparative studies, the Fecobionics data were lower than those obtained with ARM-BET data for these parameters ($P < 0.05$). All patients had RAIR in the ARM study before treatment, but 3 of them had the absence of RAIR after BFT. Two of these 3 patients were nonresponders.

Three patients spontaneously evacuated Fecobionics before and after BFT during the initial procedures or bag filling. The data from these patients were included in the analysis because data were available for the anal pressures and during the spontaneous evacuations. All 12 patients evacuated Fecobionics within 30 seconds without change during BFT ($P > 0.1$, Table 2). BET showed longer expulsion duration than Fecobionics ($P < 0.05$), and the BET duration decreased during BFT ($P < 0.05$, Table 2). One patient used more than 1 minute to evacuate BET before treatment. The Fecobionics maximum rear pressure and the maximum pressure difference between the rear and front sensors (delta pressure) did not change during treatment ($P > 0.5$). The same was the case for the 2 defecation indices DI_{delta} and $DI_{delta/s}$ (Table 2). The Fecobionics front pressure was zero or very low in 7 patients before and during evacuations, indicating a weak closure function of the anal sphincters and possibly the existence of air passageways between rectum and the outside. Five of the 7 patients had urge FI, 1 had passive FI, and 1 was of the mixed type.

The pressures during evacuation of Fecobionics were plotted as a function of time. Figure 2 shows typical patterns before and after BFT in a patient who did not show improvement in pressures (a, b) and in a patient with a good response (c, d). The patient illustrated in Figure 2a,b had very low anal pressure both before and after treatment. Both evacuations lasted approximately 4 seconds, which is below the average for the FI group. The patient in figures c, d clearly used longer time to expel Fecobionics after the treatment and contracted the anal sphincter during the initial part of the evacuation. Figure 2e–h shows the preload-afterload diagrams for the same patients before and after treatment. These diagrams provide a good visual expression of the data. The pressures from the first patient are basically a flat line, whereas the second patient shows clockwise preload-afterload curves with normalization of the front pressure pattern as a function of the rear pressure. Before the treatment, tracings from most patients were below the line of unity. Three patients showed clear normalization of the curves, that is, they contracted along the line of unity before anal relaxation (Figure 2d).

Predictions and associations between changes in physiological end points and FISI scores

We analyzed whether the change in any of the Fecobionics and ARM-BET parameters was associated with the change in FISI score. For Fecobionics, the change in urge volume ($r = 0.74$, $P < 0.05$) and the change in DI_{delta} ($r = 0.79$, $P < 0.01$) were positively associated with the change in FISI score. The change in expulsion duration was borderline significant ($r = 0.54$, $0.05 < P < 0.1$). For ARM-BET, none of the parameters were associated with the change in FISI score, although the urge volume was borderline ($r = 0.55$, $0.05 < P < 0.1$).

It was studied whether any pre-BFT data could predict the outcome for an improved FISI score and which cutoff values to

use. For Fecobionics, the expulsion duration (cutoff value 10 seconds, $P < 0.05$) and DI_{delta} (cutoff value 280 cmH_2O, $P < 0.05$) predicted the outcome. DI_{delta} had a sensitivity of 100% and a specificity of 72%. The urge volume was borderline significant (cutoff value 40 mL, $0.05 < P < 0.1$). None of the ARM-BET parameters predicted the outcome (all $P > 0.2$).

DISCUSSION

In this study, we used the novel Fecobionics technology to test pathophysiological parameters in FI patients who received BFT. The commercially available standard technologies ARM and BET were also used, and the patients had ultrasonography for visualization of anal sphincter damage. BFT resulted in 24% reduction in FISI scores. Basic Fecobionics parameters did not change significantly during the therapy. Exploratory analyses were performed on potential predictors of successful outcome. The change in Fecobionics urge volume and DI_{delta} was associated with the change in FISI score, whereas none of the ARM-BET parameters were associated with the change in FISI score. Furthermore, the Fecobionics expulsion duration and DI_{delta} predicted the FISI outcome, whereas none of the ARM-BET parameters predicted the outcome.

Defecation is a complex physiological process (23,29). Fecobionics provides a new bionics concept to study anorectal physiology. Technological validation and data on normal subjects

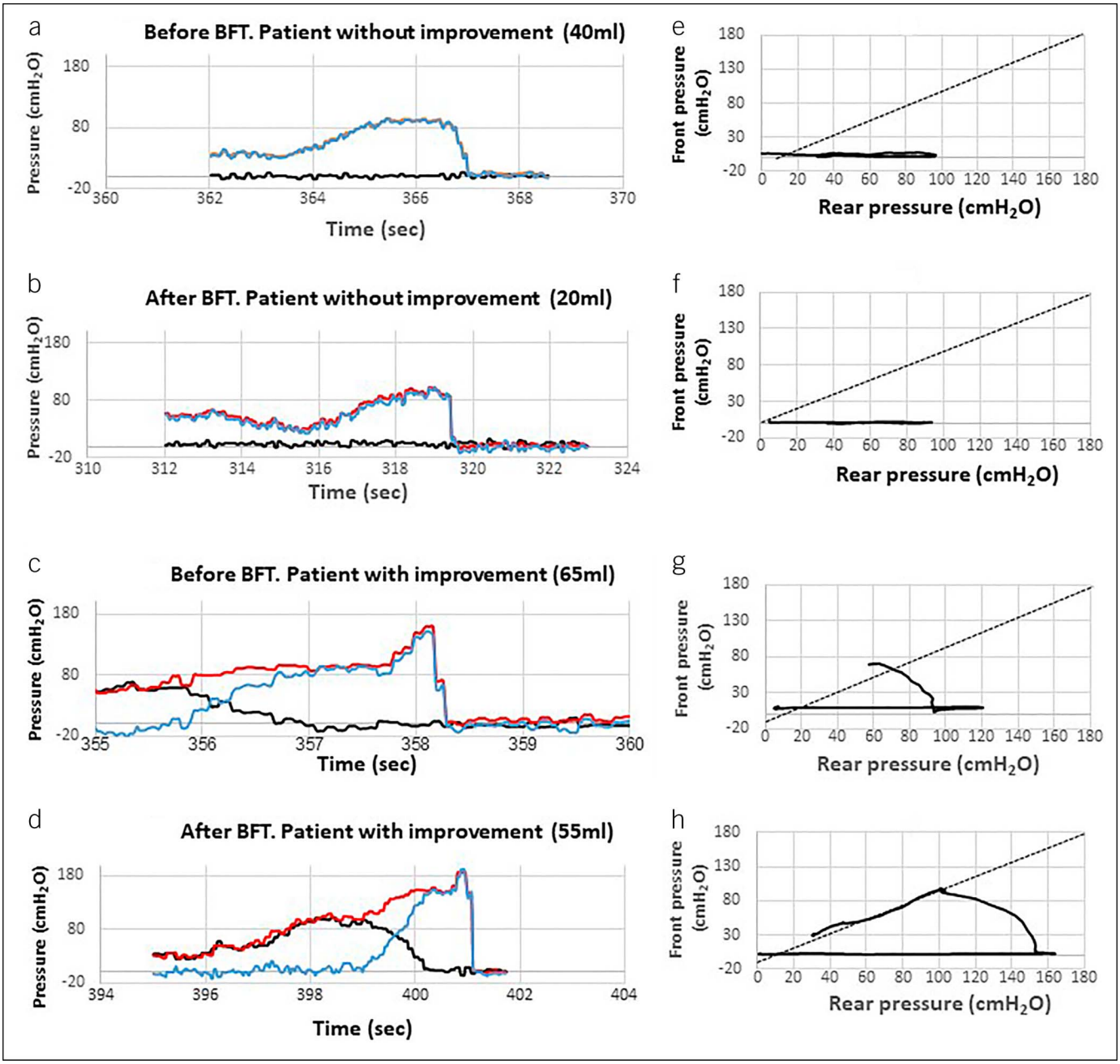

Figure 2. Representative examples of pressure as a function of time during defecations from a patient who showed no improvement in pressure response during biofeedback therapy (**a**, **b**) and from a patient with a good response to therapy (**c**, **d**). The front pressure, rear pressure, and delta pressure are shown in black, red, and blue, respectively. The right diagrams show the front pressure as a function of rear pressure (**e**–**h**) from the same patients. The stippled line is the line of unity. The second patient clearly shows better defecation dynamics and longer defecation time.

have been reported previously (11–13,30,31). Small-scale clinical studies have been performed in patients with FI, constipation, and low anterior resection syndrome (14–17). This study is the first exploratory study for monitoring the effect of BFT in FI patients and will serve as a reference for future larger scale clinical studies with further optimized technologies. Current anorectal functional tests including ARM and BET have provided valuable insight into anorectal physiology and pathophysiology with useful metrics, especially for obstructed defecation (32). However, ARM-BET may not cover all facets of anorectal function or identify the underlying mechanisms. Defecography is the only technology that reflects the dynamics of defecation, but unfortunately, it does not provide information about anorectal pressures and is often not used in FI patients. Furthermore, BET assesses the time it takes to evacuate the balloon but assesses no other defecatory parameters such as pressure (32,33). ARM is not performed during defecation, although defecation is simulated by the push procedure, and there exists a huge overlap between health and disease (34). Considerable disagreement has been found between the results of various anorectal tests (2). Furthermore, poor correlation has been found between various tests and between test results and symptoms (2–7,35). Hence, current paradigms for defecatory disorders may benefit from new approaches with new technology that can provide real time, quantitative, and mechanistic insights by simulating defecation through multidimensional measurements. We demonstrated successful access in all patients with Fecobionics and no device-related adverse events.

The main limitation of this study is the size of the study (n = 12). Therefore, it is considered an exploratory study. Larger clinical studies must be designed for detailed statistical analysis including FI subgroups based on strict inclusion criteria for each subgroup. Despite the small size, the data clearly demonstrate useful end points and parameters of predictive use (see below). Another limitation is that the ARM system used does not allow computation of the rectoanal pressure gradient (RAPG or delta pressure). This parameter may have performed better in the analysis of ARM-BET data. On the other hand, the RAPG parameter has largely been found useful in analysis of patients with constipation. Furthermore, symptoms may be categorized in different ways such as urge versus passive incontinence. Larger scale studies must be conducted in the future to address FI subtypes.

Although not a primary aim of this study to compare ARM-BET with Fecobionics, we found profound differences for several parameters. The main conclusions from this study and previous comparative studies (12,13) are that data differ between technologies and that Fecobionics provides quantitative measures that cannot be obtained with ARM-BET. Differences exist in device designs, dimension, location in the rectum, and procedures. A very significant difference to ARM is that Fecobionics measures pressures in the axial direction at the front and rear, that is, in the direction of the trajectory during expulsion. This is important because pressures are direction-dependent (36). It may explain why Fecobionics can detect air passageways through the anal canal (see below).

Pathophysiological aspects

The goal of BFT is to improve the underlying physiological dysfunctions that cause FI (8). The program we used aimed at increasing the strength of the anal sphincter and rectal sensitivity, that is, to improve the ability to detect weak signals during rectal sensations. It is anticipated that patients need a different kind of BFT, for example, a patient may benefit from strengthening of the anal muscles, whereas others may benefit from BFT that focuses on coordination of the pelvic floor muscles or sensitivity training. The severity of disease in this study was approximately the same as in other studies, for example, a FISI score of 35 (37). The effect of BFT has been disputed, although most studies point to the beneficial effects in the short term and long term (8). We found 24% reduction in symptoms, and 7 patients (58%) were considered responders. This is close to what have been reported by others, such as 53% (38) and 63% (39). It is better than that in another study (37) that by the way also showed no improvement in the QOL score. However, great variability exists, which may be due to differences in the patient population, BFT protocols, home versus in-clinic treatment, etc.

Often studies fail to show end points that change significantly from pre-BFT treatment to post-BFT treatment. The same was largely the case in this study, except for 3 ARM end points (lower values for maximum anal squeeze pressure, urge volume, and evacuation duration after BFT compared with those before BFT). It is difficult to explain why ARM recorded a lower anal squeeze pressure post-BFT considering the improvement in the FISI score. Other changes such as the shorter evacuation duration may be due to improved pelvic floor function.

We went a step further than merely comparing standard parameters before and after BFT. We analyzed (i) preload-afterload plots, (ii) computed DIs, (iii) whether change in parameters was associated with change in clinical outcome, that is, in FISI score, and (iv) whether any pre-BFT parameter could predict responders and nonresponders. As shown in other studies, the Fecobionics preload-afterload diagrams are a useful way to display data and computation of defecation indices provide novel metrics that need to be explored further (14–17). The preload must exceed the afterload before evacuation can take place. Fecobionics (and feces) will be expelled when the rectoanal pressure gradient is large enough to overcome the frictional force between the surface and the mucosa. Most FI patients were below the line of unity at all times, which leads to leakage of rectal contents. The goal is normalization of the tracings in the preload-afterload diagram and some patients reached that. For the association and prediction analyses, the data were clear. Despite the lack of differences between data obtained before and after BFT, Fecobionics had several parameters, including DI_{delta}, that were significant predictors and others were borderline, whereas ARM had no significant parameters. The reason that there was no overall difference but the data predicted the FISI score is that the responders improved parameters whereas nonresponders did not. Thus, Fecobionics can generate data that correlate better with symptoms than ARM-BET does and provide better predictions.

In several patients, Fecobionics measured zero pressure or a very low pressure before evacuation. Although we cannot entirely exclude that the front may have stuck out slightly from the anus in a few cases, it points to that air passageways spanning the entire anal canal are present in some FI patients. An air passageway would be a channel with air passage from the rectum to the outside atmosphere because of the complex geometry of the folds and valves of the anal mucosa. Fecobionics seems capable of detecting such passageways. This may be because Fecobionics measures axial pressures and the front is located just proximal to the anal sphincter. ARM may not measure such passageways because of the size of the catheter and because it may be trapped within the folds and valves of the anal canal. The number of patients with potential passageways did not change during therapy. This is consistent with

the fact that the improvement in the FISI score was due to less incontinence for solid stool and to some extent also for liquid stool. No improvement was observed for gas.

We demonstrated successful Fecobionics application in FI patients in BFT. Fecobionics provides several improvements to current anorectal functional assessment technologies including mechanical properties that mimic stool and pressure measurements in the direction of the trajectory. This study demonstrated better association with FISI scores than current technologies and provided positive predictors of outcome. Hence, we believe that Fecobionics is a reliable quantitative tool for diagnostics and for the assessment of the efficacy of therapy in defecation disorders including FI. However, large-scale studies are required to further assess subtype phenotypes and treatment effects. Future studies may take advantage of improved wireless devices that in addition can measure the anorectal angle and the bag shape (38–42). Future studies may also examine the efficacy of Fecobionics as a therapeutic tool for performing biofeedback treatment in FI patients. In this regard, Fecobionics with improved visual display can enhance the learning process and serve as a more effective feedback device than current pressure-based manometric feedback. These results will address our long-term goal of developing and providing mechanistically based effective FI treatments.

CONFLICTS OF INTEREST

Guarantor of the article: Hans Gregersen, MD, PhD, MPM.

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., K.F., W.L., and H.G.: participated in the experiments. Data analysis was conducted by S.C. and H.G. and interpreted by all authors. All authors revised the manuscript and approved the final version for submission.

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Potential competing interests: H.G. has filed patent applications. No other conflicts of interest noted for other authors.

Study Highlights

WHAT IS KNOWN

- ✓ Fecobionics is a novel integrated simulated feces technology that can assess defecatory physiology.
- ✓ Patients suffering from fecal incontinence are often studied with anorectal manometry and the balloon expulsion test and may be treated with biofeedback therapy.

WHAT IS NEW HERE

- ✓ Several Fecobionics parameters were associated with the change in FI severity index (FISI) score, whereas none of the parameters based on anorectal manometry and the balloon expulsion test were associated with the change in FISI score. The Fecobionics expulsion duration and the defecation index predicted the FISI score outcome, whereas none of the anorectal manometry and balloon expulsion test parameters predicted the outcome.
- ✓ Fecobionics was used as a tool to monitor the effect of biofeedback therapy and proved to be better than conventional technologies for monitoring and predicting the outcome in the FISI score.

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