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Use of a motion-based digital therapeutic in women with fecal incontinence: A pilot study

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Abstract

Aims: There is limited data addressing the value of vaginal biofeedback (VBF) on fecal incontinence (FI) symptoms. The objective of this pilot study was to evaluate whether use of a motion-based VBF device and app was effective for at-home treatment of women with FI. We hypothesized that VBF would result in improvement in FI symptoms.

Methods: A single-arm 10-week prospective pilot trial in women with FI was conducted using the VBF device. The primary outcome was change in St. Mark's score from baseline to week 10. Secondary outcomes included change in 2-week bowel diary and FI quality of life (FIQoL). Statistical analysis included paired *t* test and Wilcoxon's signed-rank test.

Results: Of 29 enrolled women, 27 had data available for analysis. Mean (±SD) age was 60.9 (±14.4). 63% (17) subjects were White, 33% (9) were Black. Mean St. Mark's score was 14.6 (±4.4) at baseline and 11.6 (±5.1) at 10-weeks ($p = 0.005$). Changes in the total FIQol, and three of four subsets of the FIQoL scores were also significantly improved ($p < 0.001$). Bowel diary showed decrease in FI episodes, baseline 8.4 (±8.73) to 10 weeks 4.8 (±3.79), ($p = 0.052$).

Conclusions: In this pilot study, there was significant improvement in FI symptom-specific severity and quality of life using a vaginal, motion-based device for biofeedback. A larger study is needed to better understand the value of this device, which may be useful for women who prefer a vaginal device, which can be utilized at home compared with standard anal biofeedback for treatment of FI in the clinical setting.

KEYWORDS
biofeedback, digital health, fecal incontinence, female, pelvic floor

1 | INTRODUCTION

Fecal incontinence (FI) is defined by the involuntary loss of solid or liquid stool.[1] Prevalence estimates of FI among community-dwelling women are approximately 9% and increase with age.[2] A majority of patients with FI do not report symptoms to a health care provider and so, prevalence estimates are likely underrepresented.[3] FI has a significant impact on quality of life and psychosocial well-being, and is associated with depression, anxiety, and social isolation.[1,4]

Causes of FI are multifactorial and may be attributed to bowel disorders (i.e., constipation, diarrhea) and/or anorectal dysfunction, including pelvic floor muscle weakness, impaired rectal sensation, and poor rectal compliance.[5] Treatment options include conservative management and surgical interventions. Conservative treatment is considered first-line and consists of dietary and behavioral modifications, medications, physical supports/devices, and pelvic floor muscle training (PFMT) with or without a biofeedback component.[4]

Considering the barriers to treatment and social stigma associated with FI, there is an urgent need to investigate novel conservative therapeutic modalities with remote or at-home treatment capabilities. Digital therapeutics represent a new category of therapeutic interventions that are regulated, prescription-based, and incorporate digital systems (i.e., smartphone applications) to prevent, manage, or treat a particular health condition.[6] The primary objective of this study was to assess the effectiveness of a motion-based digital therapeutic system that guides PFMT for the treatment of FI. The secondary objective was to examine use of the technology and its impact on FI-related quality of life (QoL).

2 | MATERIALS AND METHODS

This prospective, single-arm, open label study examined the clinical effectiveness of PFMT assisted by a motion-based digital therapeutic system on FI symptoms and QoL over a 10-week period. Subjects were recruited from a hospital-based urogynecology department between August 2019 and October 2020. Before enrollment, all eligible participants provided written informed consent. This study was approved by the Western Institutional Review Board and the IRB at the University of Alabama at Birmingham (IRB 300002110). It was registered at Clinicaltrials.gov (NCT04027335).

The leva® Pelvic Digital Health System™ (Renovia, Inc.) is a digital therapeutic device cleared for the treatment of female urinary incontinence and pelvic floor muscle weakness (Food and Drug Administration [FDA]-cleared 510[k] K133990 and K180637). In this system an intra-vaginal biofeedback device that utilizes accelerometers to detect pelvic floor motion during muscle contraction is paired with a smartphone application that provides performance-specific feedback and records PFMT sessions. Data are cloud-captured and transmitted to the prescribing health care provider, so that adherence (based on passively collected data resulting from use of the device) and symptoms (via validated questionnaires) may be monitored. Efficacious use of this system in the treatment of stress and mixed urinary incontinence have been published previously.[7,8]

Subject eligibility included ambulatory women 18 years of age and older with FI symptoms, defined as any uncontrolled loss of liquid or solid fecal material that occurs at least monthly during the previous 3 months and that is bothersome enough to desire treatment. Exclusion criteria comprised the following: severe diarrhea or constipation (1 or 7 on the Bristol Stool Form Scale[9]), stool impaction; inflammatory bowel disease; current or history of colorectal or anal malignancy, rectovaginal fistula or cloacal defect, prior pelvic or abdominal radiation; prior removal or diversion of colon or rectum; Stage 3 or 4 pelvic organ prolapse; supervised PFMT and/or biofeedback training within the past 6 months; childbirth within the past 3 months; neurological disorders known to affect continence; presence of an active sacral neuromodulator.

At baseline, subjects provided demographic and medical history data and underwent a physical examination, including a digital rectal examination to evaluate for stool impaction and anal sphincter tone, a POP-Q examination to determine presence of pelvic organ prolapse, and an assessment of PFM strength. Assessment of strength was performed using the Brink scale, a three-item measure assessing pressure, vertical displacement, and duration, each on a 4-point scale. Eligible subjects were provided their own device and an iPod Touch preloaded with the associated application. They received training on the motion-based system, including instruction on placement, removal and care of the intra-vaginal component, and coaching on PFMT performance. Each PFMT session with the device lasted 2.5 min and entailed five 15-s contractions, followed by a 15-s rest period. During the baseline visit, subjects completed one 2.5-min training session under the supervision of a research assistant. Subjects were then instructed to complete twice daily training sessions at home with the accelerometer-based system for 10 weeks.

During the study period subjects participated in 15-min phone calls on Weeks 2, 4, 6, and 8 of the study period, during which a research assistant reviewed

adherence to the study protocol, addressed device-related questions, and documented adverse events. All subjects received a standardized handout regarding additional behavioral therapy and dietary modifications.

Outcome measures included a series of validated patient surveys assessing changes in FI symptoms and QoL from baseline to 10 weeks, with a mid-point assessment at 5 weeks. Surveys were completed at each time-point during an in-clinic visit or administered by phone. The primary outcome measure was assessed by change in St. Marks score, which measures the severity of FI symptoms during the previous 4 weeks using a 5-point scale (never, rarely, sometimes, weekly, daily).[10] It also includes questions regarding pad usage, constipating medications, and the ability to delay defecation for 15 min. The St. Mark's score ranges from 0 to 24 points, completely continent to completely incontinent, respectively. Secondary outcome measures included the change in the Patient Global Impression of Severity (PGI-S)[11] from baseline to Weeks 5 and 10, Patient Global Impression of Improvement (PGI-I) at 5 and 10 weeks posttreatment initiation where success was defined by a score of very much better, much better, or a little better, and the number of FI episodes reported on a 2-week bowel diary at baseline and at 10 weeks.

A symptom-specific related QoL survey included the Fecal incontinence Quality of Life (FIQoL)[12] score and a general QOL survey included the Short-Form-12 (SF-12)[13] were captured during in-person assessments at baseline and weeks 5 and 10. The FIQoL questionnaire evaluates the impact of FI symptoms on lifestyle, coping, depression, and embarrassment. Items are scored on a 1-4 point scale, where 1 indicates "very affected" and 4 indicates "not affected." Pelvic floor muscle strength and function was evaluated at baseline and 10-weeks by pelvic examination using the Brink score. Presence of other pelvic floor disorder symptoms was evaluated at baseline and weeks 5 and 10 using the Pelvic Floor Distress Inventory (PFDI-20).[14]

All subjects who logged at least one training session and measurement of any of the efficacy assessments were included in the modified Intention-to Treat (mITT) analysis (any subjects with Week 5 data but missing Week 10 were included using the 5-week data). Subject demographic and baseline characteristics, safety, and clinical activity data were summarized; categorical data by frequency distributions (number and percentage of subjects) and continuous data by descriptive statistics (number of subjects [n], mean, standard deviation [SD], median, range). Normality of the data was tested, and the Wilcoxon signed-rank test was chosen for the primary endpoint analysis and secondary efficacy and quality of life analysis.

3 | RESULTS

Thirty-one subjects were enrolled, and of those, 27 completed the 10-week study. Flow through the study is noted in Figure 1. The mean age of study participants was 60.8 (±14.57) years. The majority were categorized as overweight or obese based on body mass index, and presented with a history of at least one pregnancy and delivery. Of the 55 vaginal deliveries reported, forceps were used in 20. Other clinical demographic data are shown in Table 1.

Table 2 provides baseline and 10-week mean scores for the St. Mark's, FIQoL and PFDI-20 questionnaires (and associated subscores) and mean number of FI episodes on a two-week diary before and after the intervention. Mean St. Mark's scores decreased significantly from baseline to 10 weeks, 14.6 ± 4.37 to 11.6 ± 5.12 ($p = 0.008$), indicating a reduction in FI symptom severity. A significant improvement was also detected on three of the four FIQoL subscales, including lifestyle, coping, and depression categories ($p < 0.001$) and the CRADI-8 and POPDI-6 subscales of the PFDI-20 ($p < 0.01$). There were no differences in SF-12 mental and physical component summary between baseline and 10 weeks.

There were 21 complete bowel diaries available for this analysis. The number of incontinent episodes reported on a 2-week bowel diary decreased by approximately half, though this reduction did not achieve significance ($p = 0.0521$). Figure 2 illustrates pre- and postintervention FI episodes for these subjects. Ten of 21 (47.6%) subjects indicated $\geq 50\%$ reduction in the number of incontinent episodes at the end of the intervention period.

The proportion of subjects who were successful as measured by the PGI-I, increased from 9.7% at 5 weeks to 24.1% at 10 weeks. Similarly, the proportion of subjects with normal or mild symptom severity on the PGI-S increased from approximately one quarter in Week 5 to more than half at Week 10. Those with moderate severity symptoms decreased from 29.0% to 10.3% during this time-frame, and the proportion with severe symptoms remained relatively unchanged (16.1% and 17.2%). Adverse events included UTI ($N = 2$) and yeast infection ($N = 1$).

4 | DISCUSSION

PFMT using this motion-based vaginal biofeedback shows promising results in reducing FI symptom severity and improving quality of life for this small cohort of women. Significant improvements in St. Mark's and FIQoL scores were achieved with twice daily home use

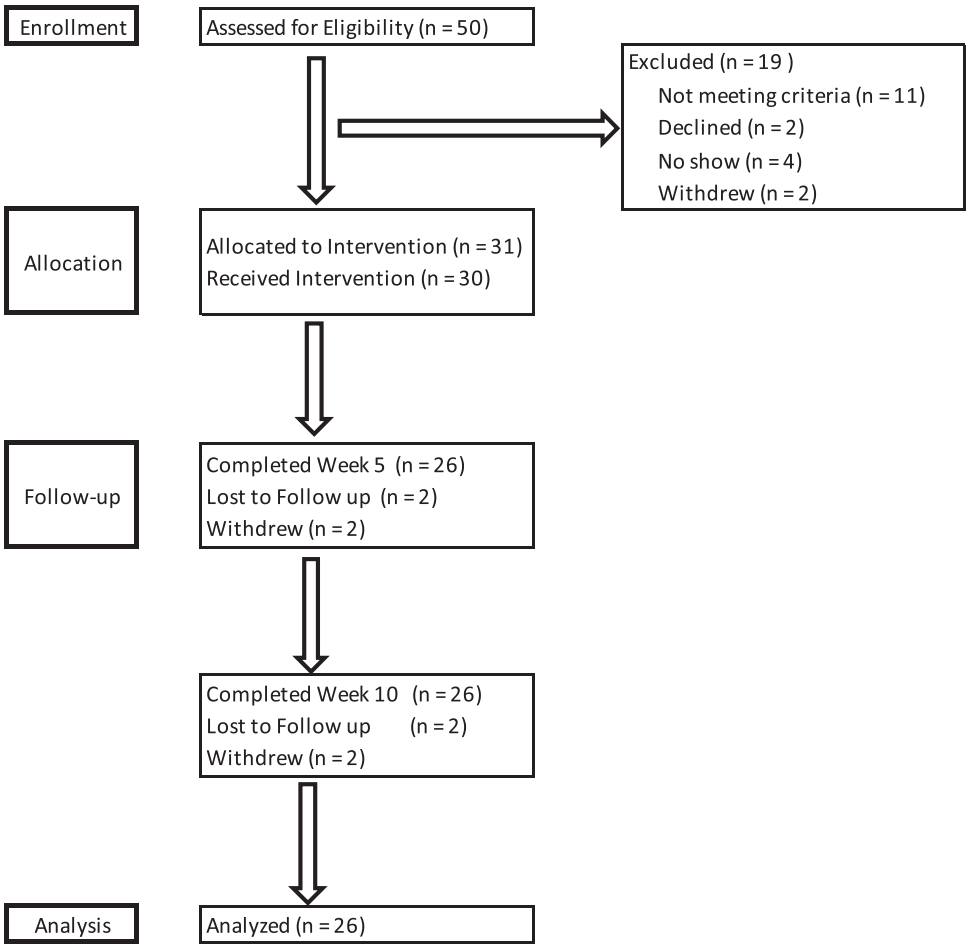

FIGURE 1 Flow diagram

over a 10-week period, and approximately half of subjects reported 50% or greater reduction in FI episodes. Prior research on PFMT with biofeedback for FI symptoms demonstrates 20%–54% remission rates with variation due to subject characteristics and treatment parameters.[15] Murad-Regadas et al.[16] report similar success rates; in their study, 56% of subjects indicated >50% reduction in symptoms following 6–10 sessions of biofeedback with anorectal manometry.

The minimum important difference (MID) for the St. Mark's score has been variously reported as −3 to −5 points, and for the FIQoL, it is 1.1–1.2 points.[17,18] The present study achieved a mean difference of −3 points on the St. Mark's score and 1.1 points on the FIQoL, demonstrating clinically meaningful improvement in FI symptoms. This aligns with results of a recent RCT of anorectal manometry-assisted biofeedback, in which the authors conclude effectiveness of the 6-session, 16-week intervention in improving symptoms in 75% of participants with a mean difference in St. Mark's score of 2.57 points (compared with 0.67 in the control group).[19] Another RCT with a factorial design reported on effectiveness of conservative treatments for FI, including biofeedback, education, and/or medications, noting a 5-point difference on St. Mark's scores at 24 weeks and 89% of participants achieving a 50% reduction in incontinent episodes.[20]

TABLE 1 Subject demographics

Subject characteristics	Mean (range), $n = 31$
Age	60.8 (28–86)
BMI	29.0 ± 6.73 (19.2–56.8)
Parity	2 (0-4)
Race/ethnicity	**Frequency**
White/Caucasian	20
Black/African American	10
Asian	0
Hispanic/Latino	0
Native Hawaiian/Pacific Islander	1

Abbreviation: BMI, body mass index.

TABLE 2 Baseline and 10-week scores for key outcome measures

Characteristics	*N*	Baseline, mean ± SD	Week 10, mean ± SD	*p* value[a]
St. Mark's score (Vaizey)	26	14.6 ± 4.37	11.6 ± 5.12	**0.008**
FI episodes (2-week bowel diary)	21	8.4 ± 8.73	4.8 ± 3.79	0.052
FIQoL—Total score	26	9.9 ± 2.74	11.1 ± 2.73	**0.001**
Lifestyle	26	2.7 ± 0.85	3.1 ± 0.84	**<0.001**
Coping/behavior	26	2.2 ± 0.73	2.5 ± 0.81	**<0.001**
Depression/ self-perception	26	3.0 ± 0.68	3.2 ± 0.70	**<0.001**
Embarrassment	26	2.1 ± 0.84	2.3 ± 0.88	0.060
PFDI-20	26	87.0 ± 48.16	67.3 ± 44.69	**0.005**
UDI-6	26	28.4 ± 24.59	24.5 ± 22.40	0.238
CRAD-8	26	41.7 ± 18.48	31.3 ± 19.53	**0.009**
POPDI-6	26	16.8 ± 16.53	11.5 ± 14.26	**0.002**

Note: Bold values are statistically significant $p < 0.05$.

Abbreviations: FI, fecal incontinence; FIQoL, Fecal incontinence Quality of Life.

[a]Wilcoxon signed-rank test.

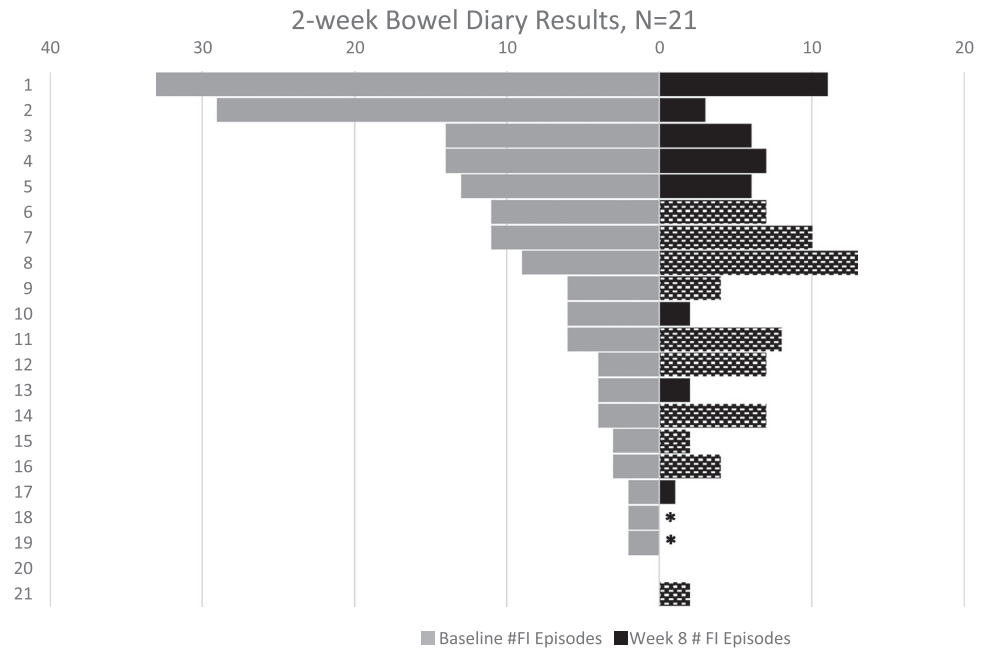

FIGURE 2 Results of 2-week bowel diaries, pre- and postintervention. *Subjects who reported no FI episodes on a two-week diary Hashed black bars are subjects who did not reach ≥ 50% reduction in FI episodes. FI, fecal incontinence

The mechanism by which PFMT ammeliorates FI symptoms is through improved muscle performance, coordination, and sensory awareness. It is widely recommended to patients with FI, although no consensus exists with regard to exercise parameters. Similarly, biofeedback protocols differ across studies, lending to variability in reported success rates.[21] Current biofeedback devices used in the treatment of FI include intra-anal electromyography (EMG) and anorectal manometry (pressure-based). In the current study, a vaginally-placed, motion-based biofeedback system was utilized. The levator ani muscle contraction produced during PFMT elevates the pelvic organs and compresses the anal and urethral openings, which has benefits for

both urinary incontinence and FI.[22] Thus, it is plausible that a vaginally placed device may benefit women with FI symptoms by optimizing PFMT performance. Prior research has demonstrated that levator ani contraction strength is strongly associated with FI severity.[22] Moreover, when compared with other physiologic parameters (i.e., squeeze pressure, rectal compliance, reflexes), significant improvements in levator ani muscle strength following biofeedback therapy correlate to clinically meaningful symptom improvement.[22]

Most research on PFMT and/or biofeedback describes clinic-based interventions. These require a commitment of time and effort by the patient, who must attend regular appointments and maintain a home program for a period of weeks or months. One study notes that, of patients with FI referred for biofeedback therapy, only 44% complete treatment.[23] Specialized training for health care providers is also required, which may not be available at all facilities and presents additional financial and time costs. The motion-based system utilized in the current study represents an at-home digital therapeutic treatment that provides movement-based visual biofeedback for PFMT. In contrast to other biofeedback protocols, the device requires minimal training to achieve proficiency on the part of the patient and the provider.[24] In addition, PFMT adherence and results may be monitored remotely, through regularly-scheduled phone calls as in the current study, thus, reducing the need for lengthy or frequent office visits. It is also possible that female patients with FI may find an intra-vaginal device more tolerable and acceptable than biofeedback that utilizes an intra-anal probe or balloon. At-home therapy that combines ease-of-use, comfort, and privacy may address several barriers to treatment and improve adherence.

This study has several limitations. First, this was a pilot study of a single cohort of women. The small sample size and absence of a control group limit our conclusions about the effectiveness of this intervention. Second, the Covid-19 pandemic contributed to delays in subject recruitment and affected some data collection. Bowel diaries were incomplete for a number of subjects, and missing data may have limited the ability to detect an optimal treatment effect for this parameter. Third, while in the current study we excluded those with prior anorectal/colon surgical history, a range of patient characteristics, including symptom severity and duration was included. Research suggests that variability in PFMT and/or biofeedback outcomes may be reduced by improving selection criteria, citing factors, such as vaginal and/or colorectal surgical history, FI symptom severity, and baseline anal sphincter squeeze pressure, as potential predictors of biofeedback success.[16] It is possible that the current outcomes were influenced by the prevalence and variability of certain subject characteristics, though this also contributes to the robustness and generalizability of our data, given that our study yielded significant results.

This study demonstrates feasibility of a new treatment option for women with FI and informs to future studies. The accelerometer-based system was acceptable to patients with no significant device-related adverse events reported. Results demonstrated limited efficacy with significant symptom improvements achieved over a 10-week period. Further research to determine intervention effectiveness will include a larger sample size and reliable comparator group.

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CONFLICT OF INTERESTS

Milena M. Weinstein, Royalties from UptoDate, Samantha J. Pulliam, employee of Renovia Inc.; Laura Keyser, employee of Renovia, Inc. The remaining author declares no conflict of interests.

ETHICS STATEMENT

This study was approved by the Western Institutional Review Board and the IRB at the University of Alabama at Birmingham (IRB 300002110). Informed consent was obtained from all individual participants included in the study.

AUTHOR CONTRIBUTIONS

Writing and editing: Milena M. Weinstein and Laura Keyser. *Writing, editing, and trial design*: Samantha J. Pulliam. *Trial design and execution, editing*: Holly E. Richter.

DATA AVAILABILITY STATEMENT

The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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