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Evaluation of an accelerometer-based digital health system for the treatment of female urinary incontinence: A pilot study

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Abstract

Aims: To assess the effectiveness and patient satisfaction of pelvic floor muscle training (PFMT) guided by an intravaginal accelerometer-based system for the treatment of female urinary incontinence (UI).

Methods: Premenopausal women with mild-to-moderate stress or mixed UI were recruited to participate in PFMT with an accelerometer-based system for 6 weeks with supervision. Objective outcomes included pelvic floor muscle (PFM) contraction duration, number of contractions in 15 seconds, and angular displacement of the accelerometer relative to earth during PFM contraction. Subjective outcomes and quality-of-life were assessed with validated, condition-specific questionnaires. Results are presented as means, standard error of the mean, and 95% confidence intervals unless otherwise indicated.

Results: Twenty-three women (age 42.0 ± 10.7 years, mean $\pm$ standard deviation) completed the study. Scores on the Urogenital Distress Inventory (UDI) decreased from 36.7 ± 4.7 at baseline to 1.45 ± 0.8 at 6 weeks ($P < .0001$). The Patient's Global Impression of Severity score decreased from 1.5 ± 0.1 to 0.2 ± 0.1 ($P < .0001$) at study endpoint. At 6 weeks, the PFM contraction duration increased from 13 ± 2.6 at baseline to 187 ± 9.6 seconds ($P < .0001$). Repeated contractions in 15 seconds increased from 5.9 ± 0.4 at enrollment to 9.6 ± 0.5 at 6 weeks ($P < .0001$). Maximum pelvic floor angle (a measure of lift) increased from $65.1 \pm 2.0°$ to $81.1 \pm 1.8°$ ($P < .0001$). Increasing PFM contraction duration and maximum pelvic floor angle correlated with decreasing UDI-6 scores, $r = -0.87$, $P = .01$; $r = -0.97$, $P = .0003$, respectively. No device-related adverse events occurred.

Conclusions: Pilot testing of this accelerometer-based system demonstrates improvements in objective PFM measures, patient-reported UI severity and condition-specific quality of life, with results evident after 1 week of use.

KEYWORDS
biofeedback, pelvic digital health system, pelvic floor muscle training, urinary incontinence

1 | INTRODUCTION

Urinary incontinence (UI) is experienced by an estimated 20% to 50% of women,[1] and pelvic floor muscle training (PFMT) is globally recognized as a front-line conservative treatment for women with UI.[2] Biofeedback has been used as an adjunct to enhance the effectiveness of PFMT by providing visual, tactile, or auditory cues related to pelvic floor muscle (PFM) performance in real-time.[3] Biofeedback devices for PFMT have primarily included surface electromyography (sEMG) and pressure perineometry, both of which have limitations. Crosstalk from surrounding musculature may influence sEMG data, thereby impacting its validity and effectiveness as a biofeedback tool.[4] Transvaginal pressure perineometry detects maximum squeeze pressure exerted on the device, a value which may also be influenced by activation of surrounding musculature and/or straining.[5]

The physiologic action of the PFM, important for continence, involves not only a squeezing motion, whereby the urethral and vaginal openings are compressed but also superior displacement that causes a cranioventral shift of the pelvic organs. This motion is equally important, as it lifts and stabilizes the bladder neck and provides urethral support.[6,7] In addition to the limitations listed above, sEMG and pressure perineometry do not assess this important function of PFM. Transvaginal and transperineal ultrasound confirm this motion, and visualization of this movement during PFMT may help to elicit a proper PFM contraction.[7] However, use of real-time ultrasound as a biofeedback tool is costly and requires expert training.

The leva Pelvic Digital Health System (leva), Food and Drug Administration (FDA)-cleared (510[k] K133990 and K180637) for use in the treatment of female UI, uses an intravaginal accelerometer-based system that detects and displays real-time and historic PFMT information (Figure 1). The device utilizes six accelerometers arranged in sequence on an intravaginal sensor that assess the precise movement of each section of the sensor relative to the earth and relative to one another during a PFM contraction. The angle of the intravaginal axis relative to the earth increases when a squeeze-and-lift contraction is performed and decreases with a Valsalva maneuver. Users receive real-time visual feedback on a smartphone application that reflects this change in angle. Data from the smartphone uploads to a storage cloud, allowing for adherence monitoring. The device differs from other forms of PFM assessment, as it relies on movement (lift or descent) of the PFM, in contrast to electrical activity or pressure, which do not measure PFM movement.

The aim of this pilot study is to evaluate the effectiveness and usability of this technology in improving PFM function and UI symptoms and related quality-of-life (QoL) measures. In addition, this study serves as the foundation for future RCTs comparing outcomes of PFM rehabilitation with and without this device.

2 | MATERIALS AND METHODS

2.1 | Study design

This prospective, single-center, open-label study assessed the effectiveness of PMFT facilitated by the accelerometer-

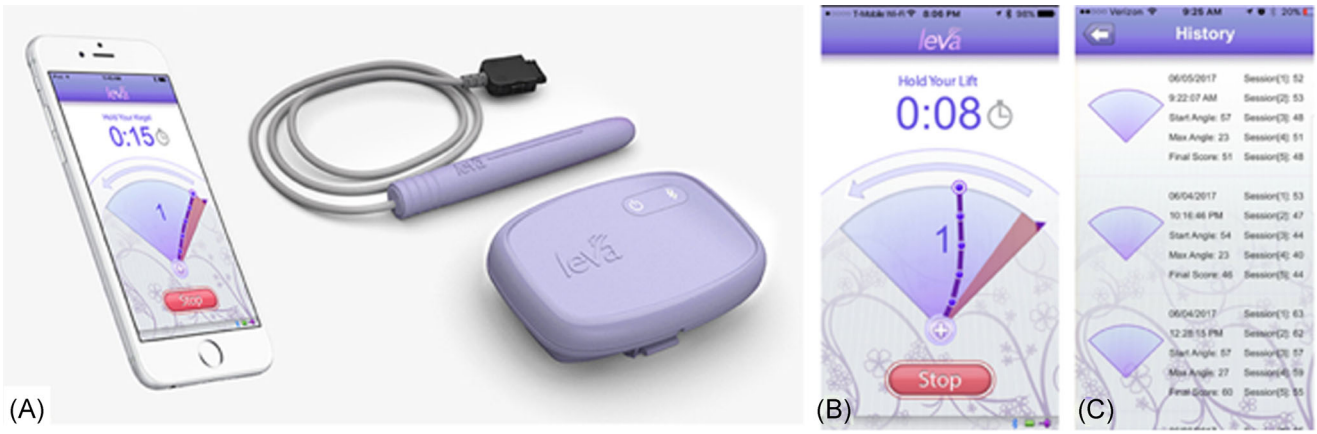

FIGURE 1 The leva Pelvic Digital Health System components and Visual Interface. A, The system consists of an intravaginal sensor and a battery-powered Bluetooth transmitter that sends visual output to the user's smartphone. B, The system provides real-time PFM training coaching to the participant using a graphic assessment of the pelvic floor angle achieved and duration of each contraction, and (C) stores these data in a training history file that is accessible by the user and, with permission, her health care provider. The system also provides pictorial examples of pelvic floor functional anatomy during properly and improperly performed muscle contractions to help the user visualize and reinforce correct pelvic muscle action during training (not shown). PFM, pelvic floor muscle

based system over 6 weeks of twice daily use. Participants were recruited via online advertisements, flyers, and word of mouth between April and August 2017. Subjects who satisfied all study criteria, as detailed below, provided written informed consent before enrollment. The study was approved by and performed with oversight of the Chesapeake Institutional Review Board (Columbia, MD). Participants were deidentified in all study documents. This investigation adhered to the tenets of the Declaration of Helsinki and was HIPAA-compliant.

2.2 | Inclusion/exclusion criteria

Subjects completed the Medical, Epidemiologic, and Social Aspects of Aging[8] questionnaire to evaluate UI type and severity. Subjects who indicated stress UI or stress-dominant mixed UI (stress percent score more than urge percent score) were eligible for inclusion. Additional enrollment criteria included: age ≥18-years old and premenopausal status. Exclusion criteria included: (a) history of lower back or pelvic surgery; (b) pregnancy or less than 12-month postpartum; (c) more than three vaginal deliveries or any prior operative delivery; (d) self-reported symptoms of pelvic organ prolapse; (e) history of supervised PFMT within 12 months; and (f) current medications for UI.

2.3 | PFMT program

Subjects performed PFM exercises guided by the accelerometer-based system twice daily for 6 weeks. The 6-week study period was deemed adequate to assess short-term results based on exercise physiology data demonstrating measurable neural and muscular adaptations within this timeframe.[9,10] After inserting the intravaginal probe, subjects completed the exercise regimen in standing. They were instructed to wear similar footwear for each training session to ensure consistent angle measurement and were provided verbal cues to "stand up tall." Each training session entailed five repetitions of 15-second PFM contraction followed by 15-second relaxation over a period of 2.5 minutes. This regimen was based on the protocol included in the device and used for FDA clearance. Weekday daytime training sessions (5/week) took place at an outpatient clinic and were supervised by the same research assistant trained in the use of the device. Subjects received similar instructions for use during supervised visits. Unsupervised weekend and evening sessions consisted of the same regimen.

2.4 | Objective outcomes

At baseline and weekly intervals through 6 weeks, the accelerometer-based system captured pelvic floor angle measurements at rest, with strain, and with PFM contraction, measured by cueing each participant to give maximal effort to lift and squeeze PFM. Additional objective measures, not included in the training regimen, comprised a maximum duration of a sustained pelvic floor contraction (seconds) and a maximum number of repeated contractions in 15 seconds. All measurements were recorded by the same research assistant before the supervised training session.

2.5 | Outcome measures

At baseline and weekly intervals thereafter, subjects completed the following validated questionnaires with a higher score on each indicating greater symptom severity: (a) the short form Urogenital Distress Inventory (UDI-6) that measures severity of urogenital complaints, including UI, bladder emptying, and pelvic discomfort; score ranges 0 to 100, but must be converted to the UDI long form (range 0-300) to evaluate minimum important difference (MID) = 11[11,12]; (b) Incontinence Impact Questionnaire (IIQ-7) that measures the impact of UI on daily activities; score ranges 0 to 100 with MID = 16[11,12]; (c) Patient's Global Impression of Severity (PGI-S), range 0 = no symptoms to 3 = maximum symptoms, MID = 1.[13] At 3 and 6 weeks, the subjects also completed the Patient's Global Impression of Improvement (PGI-I) questionnaire; score ranges from 1 = "very much better" to 7 = "very much worse." Scores of 1 or 2, "very much better" or "much better," indicated significant improvement.[13] At 6 weeks, the subjects also indicated user-friendliness on a 0 to 10 scale (easiest—impossible).

2.6 | Statistics

Continuous outcomes measured weekly, including UDI-6 and IIQ-7, were evaluated using repeated measures one-way analysis of variance, followed by post hoc pairwise comparisons using Dunnett's test with the baseline value used as "control". A linear trend test over weeks was also performed on continuous outcomes. Pearson's correlation coefficients were calculated to test the strength and direction of the association between changes in objective and subjective measures. UDI-6 scores were converted to long-form UDI scores,[14] as previously reported MID was determined for the UDI long form only. Survival analysis was performed to determine average time to achieve a MID of 11 points.[11] A $P < .05$ was considered statistically significant. Outcome data are presented as means, standard error of the mean, and 95% confidence intervals, unless otherwise indicated. Post hoc power analysis to detect MID from baseline to 6 weeks was performed

($\alpha = .05$). Data were analyzed using Prism v6.05 (GraphPad Software Inc, San Diego, CA).

3 | RESULTS

3.1 | Demographics and clinical characteristics

A total of 27 women were screened. Of these, 23 (85%) met the inclusion/exclusion criteria and constituted the study cohort. There were no losses to follow-up or discontinuations. Participant demographics are shown in Table 1. Ten women had previously sought medical attention for UI; of those, five had been prescribed treatment, which included either unsupervised PFM exercises or PFM rehabilitation guided by a pelvic floor physical therapist.

3.2 | Incontinence symptoms and quality of life

During the 6-week study period, participants reported a significant reduction in UI symptoms and decreased the negative impact of UI on performing daily activities (Table 2). A significant positive trend across time was evident for all subjective outcomes.

Figure 2 illustrates decreasing scores on UI-specific questionnaires from baseline through 6 weeks of training. Participants reported improvements in symptom severity and QoL, demonstrated by a significant decrease in scores on the UDI-6, IIQ-7, and PGI-S. The mean difference in scores (and associated 95% CI) from baseline to 6 weeks for each of these measures was: 35.3 (22.2, 48.4), 17.4 (4.9, 29.9), and 1.4 (1.0, 1.7), respectively. Significant improvement was noted after 1 week of training on all measures. Final UDI-6 scores indicated the resolution of stress UI symptoms in 87% (20/23) of participants, and all women with mixed UI reported resolution of the urgency UI component at the study endpoint. Impact of UI on daily life, as measured by IIQ-7, was also significantly improved after 1 week of training. At 6 weeks, one participant reported mild frustration regarding incontinence, with none of the women reporting any other negative impact in any IIQ-7 category.

On the PGI-I, 74% (17/23) of participants reported high levels of improvement in the general condition after 6 weeks of training. All subjects reported some measure of improvement; none rated their health status as unchanged or worsening. On a user-friendliness scale of 1 to 10 (easiest—impossible), participants rated the leva system as 2.0 (range 1.4–2.6).

TABLE 1 Participant demographics

Parameter		Value (N = 23)
Age, y	Mean ± SD	42.0 ± 10.7
	Median (range)	47 (20–53)
Race, n (%)	Asian	2 (8.7)
	Black	3 (13.0)
	White	17 (73.9)
	Other	1 (4.3)
BMI	Mean ± SD	26.0 ± 4.0
	Median (range)	26.0 (19.0–32.0)
Parity, n (%)	0	6 (26)
	1	5 (22)
	2	10 (44)
	3	2 (9)

Abbreviations: BMI, body mass index; SD, standard deviation.

3.3 | PFM performance

Figure 3 illustrates changes in objective parameters related to PFM function. The mean resting pelvic floor angle was 54.4° at baseline and was not significantly different after 6 weeks of PFMT ($P = .2$). The pelvic floor angle at maximal effort contraction increased by 16.0° (10.2, 21.8) from 65.1° at baseline to 81.1° at 6 weeks ($P < .0001$; Figure 3A). The pelvic floor angle upon bearing down was modestly but significantly reduced after PFMT, from 48.3° at baseline to 43.7° at the study conclusion ($P = .0043$). The mean maximum duration of continuous voluntary PFM contraction increased by 174.8 seconds (148.2, 201.5) from baseline to 6 weeks ($P < .0001$; Figure 3B). The maximum number of contractions performed within 15 seconds increased by 3.7 repetitions (2.5, 4.8) from enrollment to study endpoint ($P < .0001$; Figure 3C).

Pearson's correlation coefficients were calculated to determine associations between objective and subjective measures. A significant negative relationship was identified, such that an increase in muscle endurance (duration of contraction) was associated with a decline in UI symptoms and severity, as reported on UDI-6, $r = -0.87$, $P = .01$. Similarly, the increase in pelvic floor angle measured during maximal effort contraction was significantly correlated with a decrease in scores on UDI-6, $r = -0.97$, $P = .0003$ and IIQ-7, $r = -0.89$, $P = .0077$. A survival analysis examined time to achieve a clinically significant difference in UDI converted full score from baseline; more than 50% of participants achieved 11 points or greater decrease in UDI score by week 1 of training.

TABLE 2 Outcome mean scores baseline and weekly measurements for UI-related questionnaires and objective measures of PFM function are reported as means (SEMs) with 95% CIs.

	Mean scores (SEM)								
Outcome measures	**Baseline**	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Repeated measures ANOVA**	**Linear trend test**
UDI-6 score	36.71 (4.71)	15.46 (2.92)	10.14 (1.84)	5.07 (1.48)	3.62 (1.29)	1.69 (0.89)	1.45 (0.80)	<0.0001	<0.0001
95% CI	[26.95, 46.48]	[9.40, 21.52]	[6.34, 13.95]	[2.01, 8.14]	[0.95, 6.30]	[−0.15, 3.53]	[−0.21, 3.10]		
IIQ-7	17.60 (4.50)	0.11 (0.88)	0.83 (0.38)	0.62 (0.45)	0.41 (0.29)	0.41 (0.29)	0.21 (0.21)	0.0009	<0.0001
95% CI	[8.28, 26.92]	[1.28, 4.93]	[0.03, 1.63]	[−0.32, 1.56]	[−0.18, 1.01]	[−0.18, 1.01]	[−0.22, 0.64]		
PGI-S	1.52 (0.12)	0.85 (0.15)	0.30 (0.10)	0.35 (0.10)	0.26 (0.11)	0.22 (0.11)	0.17 (0.10)	<0.0001	<0.0001
95% CI	[1.27, 1.78]	[0.53, 1.16]	[0.10, 0.51]	[0.14, 0.56]	[0.03, 0.49]	[−0.01, 0.44]	[−0.04, 0.39]		
Maximum lift duration (s)	12.57 (2.59)	43.57 (3.52)	75.78 (5.17)	108.60 (7.59)	128.50 (6.67)	159.50 (6.67)	187.40 (9.62)	<0.0001	<0.0001
95% CI	[7.19, 17.94]	[36.27, 50.86]	[65.05, 86.51]	[92.83, 124.30]	[114.70, 142.40]	[145.60, 173.30]	[167.40, 207.30]		
# Repetitions in 15 s	5.91 (0.41)	7.87 (0.45)	8.04 (0.41)	8.96 (0.51)	9.30 (0.53)	9.44 (0.52)	9.57 (0.50)	<0.0001	<0.0001
95% CI	[5.06, 6.77]	[6.94, 8.80]	[7.18, 8.90]	[7.89, 10.02]	[8.21, 10.40]	[8.36, 10.51]	[8.53, 10.60]		
Maximum lift angle (degrees)	65.09 (1.97)	70.65 (1.66)	76.13 (1.60)	78.39 (1.38)	79.57 (2.16)	79.35 (2.00)	81.09 (1.81)	<0.0001	<0.0001
95% CI	[61.00, 69.17]	[67.21, 74.10]	[72.81, 79.45]	[75.53, 81.25]	[75.08, 84.05]	[75.21, 83.49]	[77.34, 84.83]		

Note: A significant change from the baseline mean was identified at each time point for each measure. One-way repeated measures ANOVA and linear trends tests were conducted, and significance levels are indicated accordingly.

Abbreviations: ANOVA, analysis of variance; CI, confidence interval; PFM, pelvic floor muscle; SEM, standard error of mean; UI, urinary incontinence.

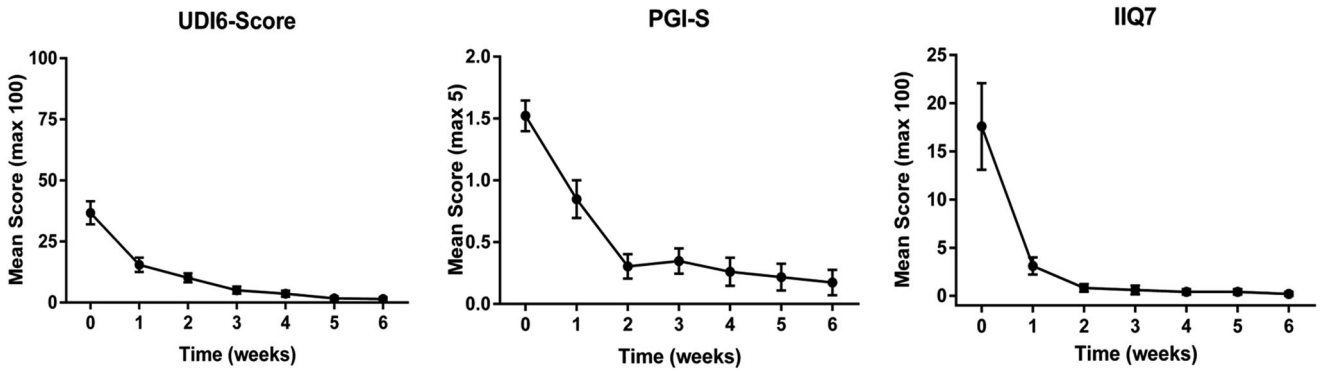

FIGURE 2 Incontinence symptoms and condition-specific quality-of-life measures. Mean values ± SEM for each UI-specific questionnaire are illustrated. A significant linear trend from baseline through 6 weeks was identified for each measure. SEM, standard error of the mean; UDI-6, urogenital distress inventory; UI, urinary incontinence

3.4 | Adverse events

No serious AEs occurred. Three women experienced minor adverse events (AEs), specifically upper respiratory infection, migraine headache, and suspected urinary tract infection (culture-negative, treated with trimethoprim/sulfamethoxazole). All resolved without sequelae and did not interfere with training.

4 | DISCUSSION

This pilot study demonstrates the feasibility of safely using an accelerometer-based system to guide PFMT in a small cohort of women with stress-dominant UI. Early results indicate a significant, positive impact on UI-specific subjective outcomes and objective measures of PFM function. Moreover, the technology was

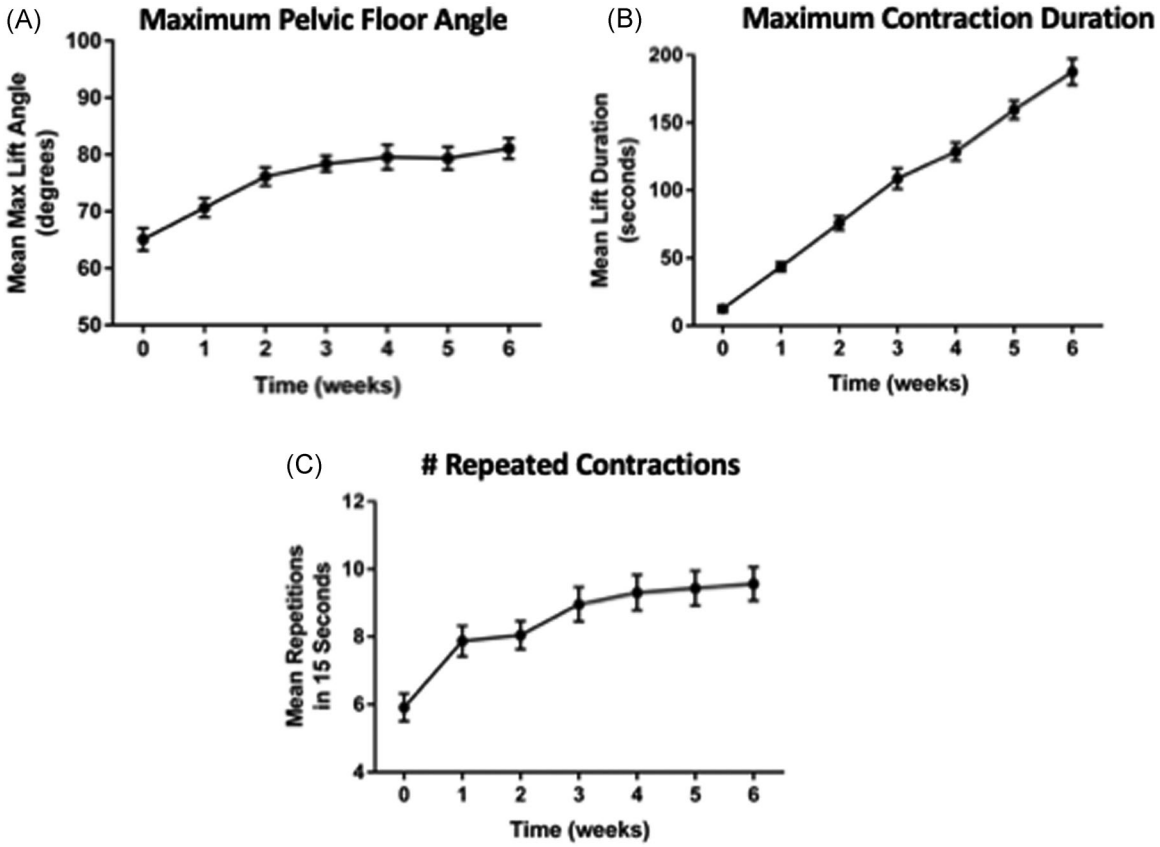

FIGURE 3 Objective measures of PFM function. Mean values for PFM objective measurements include (A) maximum contraction duration, (B) the maximum number of repeated contractions in 15 seconds, and (C) pelvic floor angle relative to the earth with maximal effort contraction. PFM, pelvic floor muscle

found to be easy-to-use and acceptable among study participants.

The magnitude of improvement experienced by study subjects after just 1 week of training with the device is compelling and warrants further investigation. The ability to visualize the direction of PFM movement in real-time and to report this information as a change in angle measurement is unique to this accelerometer-based system. It is plausible that the increase in angle measured in our study reflects improved PFM function, whereby subjects learned how to effectively recruit and use their PFM to maintain continence.[14] Validation studies are needed to confirm that this change in angle measurement correlates well with PFM action measured during a real-time ultrasound or functional MRI.

Adherence to PFMT is a known barrier to achieving and maintaining the resolution of or improvement in UI symptoms.[15] The current study regimen requires a commitment of 5 minutes/day for 10 maximal effort contractions (2½ min, 2×/day, five maximal effort contractions/session), performed in the standing position, with significant symptom improvement achieved within the first week of training. Other reported PFMT protocols require 3 to 10 training sessions daily, ranging from 30 to 100 contractions per day, most often performed while supine.[15] The minimal time requirement with this accelerometer-based system may facilitate greater adherence to PFMT. Reduction in UI symptoms within the first week of use may also serve as positive reinforcement to continue with the exercise regimen. In addition, improvements in muscle performance, strength, and power are specific to posture employed during training.[17] Given that participants in our study practiced PFM exercises while standing, it is possible that this position enhances PFM action during functional tasks, including those more likely to be associated with stress UI.

Objective evaluation of PFM performance, as measured by maximum contraction duration, the number of repeated contractions, and pelvic floor angle change indicated consistent improvement across the 6-week program and correlated with a reduction in incontinence symptoms as reported on the UDI-6. The strong negative correlation between both pelvic floor angle and maximum contraction duration (a measure of endurance) and symptom severity suggest this parameter may be useful in understanding which subjects have achieved a level of pelvic floor function associated with continence. Further evaluation will be required to determine the pelvic floor angle and contraction duration that is most associated with continence, and whether these parameters may serve to differentiate women who require additional intervention for UI, such as surgery, from those who may respond well to conservative treatment.

4.1 | Study limitations

This is a pilot study on a small sample of women with stress-dominant UI. The study utilized a sample of convenience (N = 23); however, post hoc analysis of power to detect MID from baseline to 6 weeks is as follows: 100% for converted UDI (effect size = 1.56); 96% for IIQ-7 (effect size = 0.80), and 100% for PGI-S (effect size = 2.08). The lack of a comparison group in our study does not allow for any definitive conclusions regarding improvements specifically associated with the accelerometer-based system; however, the post hoc power calculations suggest the study was adequately powered to detect the observed differences from baseline to postintervention. This research serves as a foundation for future RCTs comparing this technology to other accepted interventions for UI.

In this proof-of-concept study, subjects generally reported mild UI, and approximately 25% of women were nulliparous. This may limit the generalizability of results, although the mean baseline UDI-6 score (36.7 ± 4.7) was above the benchmark score of 25, which distinguishes care seekers from noncare seekers.[18]

Regular interaction with the research assistant in our study may have increased the level of subjective improvement that participants reported, in that these were ideal conditions for PFMT.[19] However, it is unlikely that such interaction affected objective measures of PFM function, all of which showed significant improvement through the 6-week study period.

5 | CONCLUSIONS

Results from this pilot study demonstrate preliminary outcomes suggesting that incontinence therapy guided by an accelerometer-based system significantly improves patient-reported UI symptom severity and condition-specific quality of life during 6 weeks of use and is easy and safe to use. These improvements are associated with gains in objective measures of PFM strength and function under ideal conditions. Further prospective research is required for validation and comparison of this intervention with other accepted UI treatments.

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AUTHOR CONTRIBUTIONS

All authors contributed to study design, recruitment, data acquisition, data interpretation, draft construction and/or critical review and approved this submission for publication.

DISCLOSURES

Peter Rosenblatt is a consultant for and has received an honorarium and research funding from Boston Scientific Corporation (Marlborough, MA) and Coloplast Incorporated (Minneapolis, MN), an honorarium from Medtronic (Minneapolis, MN), and is a consultant for and received stock options from Solace Therapeutics (Framingham, MA). RJI, JM, RCS, and SJP are employees of Renovia Inc.

PRÉCIS

PFMT guided by a new accelerometer-based system significantly improves symptoms and condition-specific QoL in women with mild-to-moderate stress/mixed UI.

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