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ORIGINAL CLINICAL ARTICLE

Reliability and validity of intravaginal pressure measurements with a new intravaginal pressure device: The FemFit®

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Abstract

Aims: To test the reliability and validity of intravaginal pressure measurements acquired during pelvic floor muscle (PFM) tasks in different body positions using the FemFit®, a new intravaginal pressure device.

Methods: Twenty healthy adult women participated in this study. Two assessment sessions were conducted. Intravaginal pressure measurements using the FemFit® were repeated during PFM contraction and straining maneuvers while lying and standing. Maximal intravaginal pressures were collated and compared within and between sessions. They were also correlated to maximal force measurements obtained by dynamometry and vaginal digital palpation. Test-retest reliability was assessed using intraclass correlation coefficient, standard error of measurement and Bland-Altman plots. The validity of the pressure measurements was assessed using Pearson's correlation (dynamometry) and Spearman's rho (palpation).

Results: This test-retest study indicate excellent reliability for PFM contraction and straining maneuver both in lying and standing, within and between sessions. For the straining maneuver while standing, increased variability was suggested by a wider limit of agreement on Bland-Altman plots (spanning 31.3 to 43.3mm Hg). A significant moderate to strong correlation was found when comparing measurements of PFM contraction using the FemFit® and the dynamometer or the palpation (Pearson's coefficient = 0.72, $P = .006$; Spearman's rho = 0.68, $P = .005$, respectively).

Conclusion: Our research findings suggest that intravaginal pressures can be reliably measured during PFM contraction and straining manoeuver while lying and standing, using the FemFit® device, both within and between sessions. A moderate to strong correlation between the FemFit® pressure and the force measurements obtained by dynamometry or palpation reinforce the validity of measurements.

KEYWORDS
female, intra-abdominal pressure, intravaginal pressure, pelvic floor, physiotherapy

1 | INTRODUCTION

The normal function of the pelvic floor muscles (PFMs) is defined as a level of constant resting tone (except during straining for voiding or defecation), with the ability to voluntarily and involuntarily contract and relax.[1] This constant resting tone keeps the urogenital hiatus closed by compressing the vagina, urethra, and rectum against the pubic bone, pulling the pelvic floor structures in a ventro-cephalic direction.[2]

Voluntary or reflex contraction of the PFM results in further constriction and inward/lifting (ventro-cephalic) movement of the pelvic openings,[1] increasing this compression force to balance downward forces from increases in intra-abdominal pressure, maintaining continence, and supporting the pelvic floor structures during effort activities such as coughing or jumping.[2]

An objective evaluation of the PFM is necessary to identify this balance to properly treat, give feedback, and document changes in PFM function throughout a rehabilitation process. However, there is no gold standard and measuring tools are still a topic of debate.

Different measurement technics have been applied in the objective assessment of PFM function, with manometry being the most commonly used assessment tool, both in research and clinic settings.[3] Intravaginal manometers were first introduced as an objective measure of PFM function in 1950.[4] Since then, smaller multiarray devices have been used in research settings to better characterize the pressure profile of a PFM contraction, defined as asymmetric, with a high-pressure zone occurring 3 to 4 cm from the vaginal opening, mainly in the anteroposterior direction.[5-7]

In clinical settings, up to now, the most used intravaginal manometers are still air pressure balloon-type devices. These are inflated (altering the normal anatomy of the pelvic floor), usually hand-held dependent (limiting the assessment to the lithotomy position) and, most importantly, meant to measure only the resultant pressure inside a large area of the vaginal canal, lacking the ability to differentiate pressures related to PFM contractions from the ones resulting from increases in intra-abdominal pressure.[8-10]

The possibility to acquire reliable intravaginal pressures at different depths along the length of the vaginal canal under a more "ecologically valid" condition (ie, meant to conform and sit within the rugae of the vaginal wall without altering its anatomy), is likely to be useful both for understanding the role of intra-abdominal pressure on the pelvic floor normal function and later on, for decision making when choosing PFM safe exercises (ie, favoring those producing less intra-abdominal pressure) for women with a dysfunctional pelvic floor (ie, stress urinary incontinence or pelvic organs prolapse).[11]

The aim of this study is to test the reliability and validity of maximal intravaginal pressure measurements, during PFM contraction and during straining maneuvers while lying and standing using the FemFit®, a new thin, flexible, wireless, and multiarray intravaginal pressure device.

2 | MATERIALS AND METHODS

2.1 | Design and participants

This was a prospective test-retest cohort study. A convenience sample of healthy adult women was recruited using community advertisements. Women were included if they were aged 18 years and older, continent and not actively participating in a PFM training program during the study period. The exclusion criteria included pregnancy, presence of urinary incontinence or any genital prolapse, pelvic pain, use of any medication (for urinary incontinence or affecting skeletal muscles), or history of any condition likely to interfere with the PFM assessment.

The institutional Ethics Committee approved the study (CER VN 17-18-22) and each volunteer gave her written consent before participation.

The reliability of the intravaginal pressure measurements using the FemFit® device was tested within and between sessions, in two body positions (lying and standing) and during two tasks (maximal PFM contraction and straining maneuvers). The validity of the proposed protocol was tested by comparing the FemFit® pressure measurements with two commonly used approaches to assess PFM function: intravaginal digital palpation and dynamometry.

2.2 | Measurement devices

The FemFit® (Version 0.7) is a pressure sensor array still in prototype phase, designed to measure the pressure profile along the length of the vagina (Figure 1A). It contains eight pressure sensors (MS5803-02BA; Measurement Specialties), which are mounted onto a flexible printed circuit board (PCB).[11,12] The PCB is encapsulated in soft biocompatible silicone (MED-4901; NuSil). The FemFit® has a total length of 80 mm, a maximal width of 24 mm and is only 4 mm thick. These dimensions, and the soft compliance of the device, allow absolute pressure measurements without distending or deforming the vaginal walls. The contoured edges of the device cover a distance of 55 mm and are designed to sit within the rugae of the vaginal wall to reduce device movement. Pressure data from the FemFit® are transmitted via Bluetooth, to an

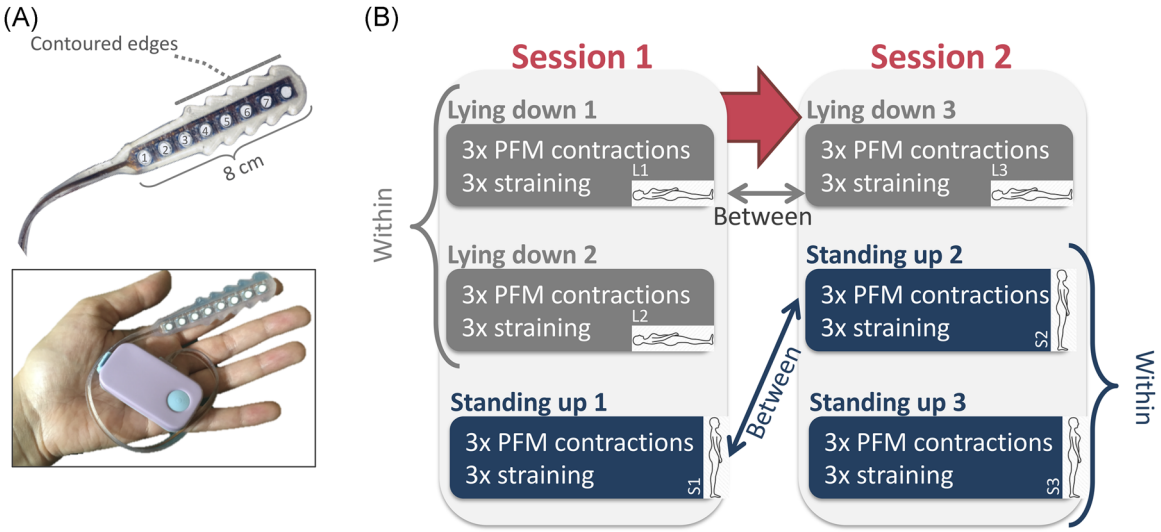

FIGURE 1 A, FemFit® V0.7 device: eight pressure sensors arranged in a flat soft flexible linear array. Pressure data transmitted to tablet using Bluetooth. B, Study protocol including two sessions of data acquisition (30 days apart). Each session including three repetitions of a set of tasks including pelvic floor muscle (PFM) contractions and straining maneuvers

Android tablet for data logging, real-time display, and user feedback. Each pressure sensor is sampled at a rate of 100 Hz.

Other measurement devices or approaches used in the study are the Montreal dynamometer and the vaginal digital palpation using the modified Oxford grading scheme, both already shown to have good reliability and internal validity.[13-16]

The Montreal dynamometer is an instrumented speculum that can measure the force inside the vaginal cavity at different vaginal apertures. Details about this instrument have been presented previously.[13-15] Briefly, it consists of two aluminum branches (the speculum) equipped with strain gauges mounted in a differential arrangement. This allows the PFM resultant force to be measured independently of where it is applied to the lower branch. For the purpose of this validity study, PFM dynamometric force measurements were taken at minimum aperture (corresponding to an anterior-posterior diameter of 19 mm) to better correspond to the FemFit® measurement device (4-mm thick).

Vaginal digital palpation remains the first choice of assessment among clinicians, mainly because it is fast, requires no equipment, and selectively depicts PFM activity.[9] For the purpose of this validity study and again to better correspond to the FemFit® measurement device, we used single-digit palpation with the modified Oxford grading scheme to quantify PFM strength. This is a 6-point scale, 0 being absence of PFM contraction, and 5 being a strong contraction with elevation of the posterior vaginal wall.[16]

2.3 | Trial procedures

One pelvic floor physiotherapist (FR) was responsible for all study assessments. Data were acquired using the FemFit® during a set of tasks, including PFM contractions followed by straining maneuvers. These tasks were repeated in the same order within and between sessions in two body positions (lying and standing). A schematic of the study protocol is presented in Figure 1B.

2.3.1 | First session

At the beginning of the first session, the participants were in the supine position with hips and knees flexed, and feet flat on the table. They were then taught, using one digit vaginal palpation, how to perform a maximal PFM contraction, defined as a maximal constriction, and inward (ventro-cephalic) movement of the pelvic openings[1] without compensation (gluteal, adductor, and abdominal muscle contraction). The PFM contraction was then graded from 0 to 5 according to the modified Oxford grading system, which was used for the validity study.[16] Participants were also instructed how to perform a maximal straining maneuver, by pushing as much as possible against a closed glottis, as if defecating.[17]

Before data acquisition with the FemFit®, the device was covered with a condom, lubricated with hypoallergenic gel, and inserted into the participant's vaginal cavity, in an anterior-posterior axis by the assessor. Further, to ensure comfort and familiarization with the device and procedure, participants were asked to

perform three unrecorded PFM contractions. Once comfortable, they were asked to perform a set of tasks including three PFM contractions (held for 5 seconds each) and three straining maneuvers (also held for 5 seconds each). Each trial (each contraction or straining maneuver) was followed by a 1-minute rest period to avoid fatigue. For both PFM contraction and straining, maximal performance was encouraged by the physiotherapist by standardized verbal command (squeeze and lift as much as possible, as if holding urine or gas without contracting gluteals, hip adductors, or rectus abdominis; push as much as possible against a closed glottis, as if defecating).

The set of tasks was repeated twice in the lying position (L1 and L2) with a 15-minutes rest period, between sets. After another 15-minutes rest period, the participants stood up, and repeated the same set of tasks (S1), accounting for a total of three sets of tasks.

In the lying position we were able to ensure that only correct trials were recorded, with PFM contractions considered valid only when accompanied by a constriction of the pelvic openings and discrete inward movement of the FemFit® device, as observed by the assessor; straining maneuvers were considered valid only when accompanied by a discrete vaginal opening and outward movement of the FemFit® while the device was kept in place, as observed by the assessor. In both lying and standing, the FemFit® device placement in the vagina was visually verified by the physiotherapist after every task and repositioned when needed. For both tasks, participants were verbally encouraged to perform to their maximal ability. Further, the participants were asked to report and rate on a visual analog scale ranging from 0 to 10 any discomfort/pain with the device during the measurement protocol.

At the end of the first session, measurements from the Montreal dynamometer were obtained to complete the validity component of the study by comparing measurements obtained to those of the FemFit® device. Before data acquisition, the dynamometer speculum branches were covered with a condom, lubricated with hypoallergenic gel and inserted by the physiotherapist, into the participant's vaginal cavity to a depth of 5 cm, as per protocol.[13-15] To ensure comfort and familiarization with the procedure, women were asked to perform three unrecorded PFM contractions. The participants were then asked to perform a final set of three recorded maximal PFM contractions (held for 5 seconds each and separated by 1-minute rest).

Finally, to avoid potential changes in the task performance between assessments, participants were asked not to perform PFM contractions until after the second assessment session.

2.3.2 | Second session

The second session was scheduled 1 month apart at the same time of the day (±2 hours) and at the same phase of the women's menstrual cycle, to control for potential effects of circadian and hormonal rhythm on the PFM function.[18] Following the FemFit® preparation and insertion, the participants completed one set of tasks while lying (L3) and two set of tasks while standing (S2 and S3), also with 15-minutes rest periods between them, accounting for a total of three set of tasks as in the first session.

2.4 | Outcomes and statistical analysis

The FemFit® data consists of eight sensors, each one sampled 100 times per second. To support comparison against the other two measurement protocols, we opted in this phase to analyze only the maximal pressure observed during the time interval of each task, regardless of its location. The mean maximal pressure (kPa) of the three trials (across sensors 1 to 8) of each task (maximal PFM contraction and straining maneuvers) in each body position (lying and standing) was used for the analysis. For the Montreal dynamometer data, the mean maximal force (N) of the three PFM contractions was considered for the analysis. For the vaginal digital palpation the maximal PFM contraction, graded from 0 to 5, was used for the analysis.

Test-retest reliability of the intravaginal pressure measurements using the FemFit® device was assessed within and between sessions for each task, in the lying and the standing position, using intraclass correlation coefficient (ICC) and standard error of measurement (SEM). ICC values lower than 0.4 were considered poor, 0.40 to 0.75 fair to good, and 0.75 to 1.00 excellent.[19] In addition, Bland-Altman plot analyses were used to determine the limits of agreement of each outcome (within and between sessions, for each task and body position).

Validity of the FemFit® pressure measurements was assessed using Pearson's correlation for normally distributed data (FemFit® and dynamometry) and Spearman's rho for non-normally distributed data (FemFit® and modified Oxford scale obtained on digital palpation) to determine the association between the new measurements and the two most commonly used assessments of PFM strength: dynamometry and the vaginal digital palpation. Correlation coefficients between 0.4 and 0.69 were considered moderate, and higher than 0.7 were considered as strong.[20]

TABLE 1 Subject demographics

n = 20	Data
Age, y—means ± SD	51.6 ± 19.7
BMI, kg/m^2—means ± SD	24.5 ± 4.0
Parity—no. (%)	
Nulliparas	9 (45)
Primiparas	1 (5)
Multiparas	10 (50)
Menopausal status—no. (%)	
Premenopausal	11 (55)
Postmenopausal	9 (45)

Abbreviations: BMI body-mass index, IQR interquartile range.

3 | RESULTS

Twenty healthy adult women participated in this study. Mean age of the participants was 51.5 years (SD ± 19.7) range 26 to 87 years. Mean BMI was 24.5 kg/m^2 (SD ± 4 kg/m^2). Eleven participants were parous, with a median parity of 1.50. More details on the demographics of the participants are summarized in Table 1. One participant was excluded for not being able to follow the physiotherapist instructions. Three participants were lost to follow up and did not complete the second assessment session (one disliked vaginal evaluation and two reported lack of time).

Mean pressure increase during PFM contractions was 12.2 mm Hg (SD ± 6.7; range = 2.59-36.15 mm Hg). During the straining maneuvers the mean pressure increase was 18.9 mm Hg (SD ± 11.3; range = 3.9-56.7 mm Hg).

The FemFit® did not fall out, but had to be repositioned on two occasions between the straining maneuver trials in the lying position and on four occasions between the straining maneuver trials in the standing position. None of the participants reported any discomfort during the assessments. Among the data sets, 4 of the 192 (16 participants × 6 set of tasks × 2 tasks) pressure profiles obtained were inadequate for analysis (ie, interference noise that prevented signal processing in two cases, momentary loss of connection with the data logging in two cases).

3.1 | Reliability results

In both positions (lying and standing) intra and intersession reliability of measurements were excellent for the mean maximal pressure obtained during PFM contraction and the straining maneuver, with SEM varying from 1 to 6 mm Hg (ICC and SEM results are presented in Table 2). For both tasks, ICC confidence intervals and Bland-Altman limits of agreement (Bland-Altman plots are presented in Figure 2) were generally wider for between sessions compared with within sessions, and wider for standing compared with lying position. Further, ICC confidence intervals and Bland-Altman limits of agreement were also generally wider for the straining task compared with the PFM contraction task.

3.2 | Validity results

A significant strong correlation was found when comparing measurements of maximal PFM contraction using the FemFit® and using the Montreal dynamometer (Pearson's correlation coefficient of 0.72, $P = .006$). Likewise, a significant moderate correlation was found when comparing measurements of maximal PFM contraction using the FemFit® and the vaginal digital palpation (Spearman's rho of 0.68, $P = .005$). More details about these results are presented in Table 3.

TABLE 2 Reliability of pressure profile measurements within and between visits, while lying and standing

			ICC		
	Session 1	Session 2/3[a]	ICC (95% CI)	*P*	SEM
Lying position					
PFMC within	12.6 ± 8.8	12.1 ± 7.4	0.98 (0.93 to 0.99)	<.001	1.12
PFMC between	12.6 ± 8.8	14.1 ± 8. 7	0.78 (0.30 to 0.93)	.006	3.60
Straining within	16.5 ± 10.8	13.5 ± 9.3	0.86 (0.57 to 0.95)	<.001	3.74
Straining between	16.5 ± 10.8	17.6 ± 10.4	0.83 (0.52 to 0.94)	.001	4.29
Standing position					
PFMC within	11.5 ± 4.5	14.2 ± 7.0	0.78 (0.35 to 0.93)	.001	2.80
PFMC between	11.5 ± 4.5	10.3 ± 5.8	0.82 (0.50 to 0.94)	.001	2.18
Straining within	23.1 ± 13.8	22.6 ± 9.9	0.88 (0.65 to 0.96)	<.001	4.10
Straining between	23.1 ± 13.8	20.1 ± 12.1	0.79 (0.38 to 0.93)	.003	5.87

Note: Values are presented as mean ± SD.

Abbreviations: CI, confidence interval; ICC, intraclass correlation coefficient (two-way mixed-effects model, absolute agreement, average measures); PFMC, pelvic floor muscle maximal contraction; SEM standard error of measurements.

[a]Session 2 for within comparisons and session 3 for between comparisons.

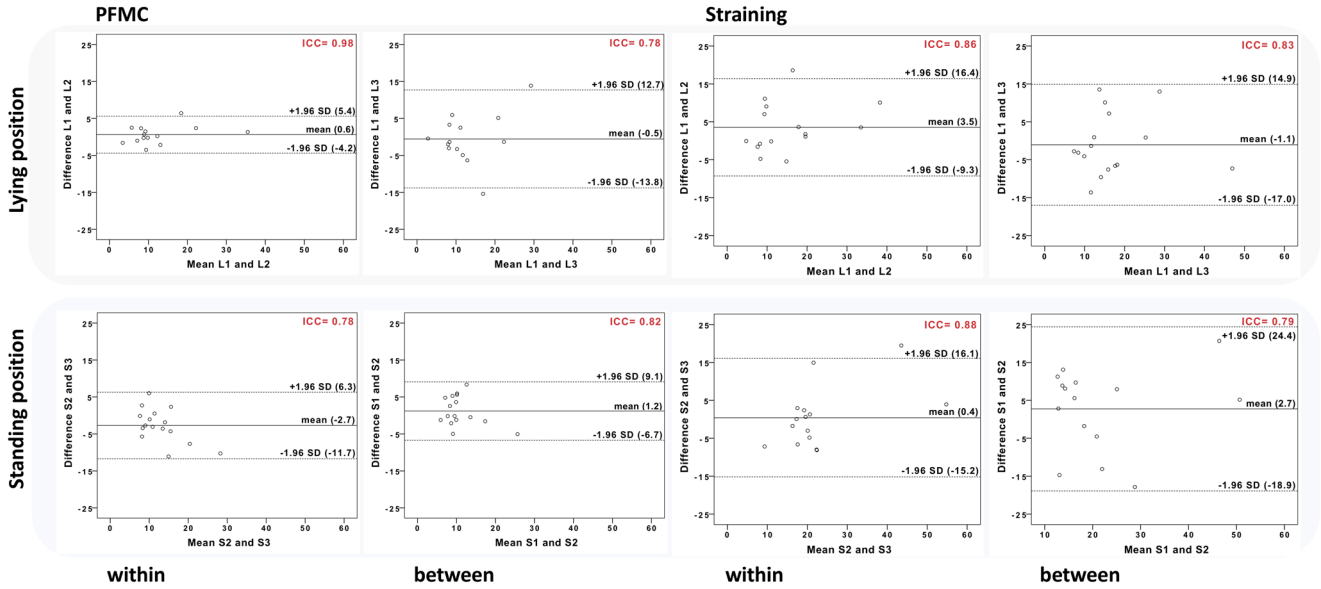

FIGURE 2 Bland-Altman plots of pressure profile measurements within and between visits, while lying (L) and standing (S). ICC intraclass correlation coefficient (two-way mixed effects model, absolute agreement, average measures); PFMC pelvic floor muscle maximal contraction

4 | DISCUSSION

Results from this test-retest study indicate excellent reliability for maximal PFM contraction and straining maneuver both in lying and standing position, within and between sessions. For all comparisons of the maximal PFM contraction task the reliability results were reinforced by the Bland-Altman plot analysis, which showed narrow limits of agreement. Similar results were observed for the straining maneuver in lying position within and between sessions. However, for the straining maneuver task while standing even though excellent ICC results were observed within and between sessions, a higher difficulty level in measuring this condition was suggested by a wider ICC confidence interval and limit of agreement on Bland-Altman plots (spanning 31.3 to 43.3 mm Hg).

These results could be explained by the larger number of displacements of the FemFit® observed while performing the straining maneuver. Although the device never completely fell out of the vaginal cavity during any of the assessments, the need for repositioning the device was noted by the physiotherapist in a 6 of 96 (16 participants × 6 set of tasks) occasions after the straining task, mainly in the standing position.

Compared to many of the existing manometers[7,10,21] designed to measure intravaginal pressure during PFM tasks, the FemFit® has similar test-retest reliability results in the lying and standing position[10] and has the advantage of being thin and flexible to conform to the natural shape of the vagina. The participants experienced no particular discomfort during the insertion/exertion of the device, and reported they were able to perform the proposed tasks very comfortably either while lying or standing. Another advantage of the FemFit® is the possibility of performing measurements in different body positions, since it has a wireless connection to the data acquisition (and analysis software) and does not have to be held in place. It should be acknowledged, however, that SEM can be higher and limits of agreement can be wider for measurements taken in the standing compared to the lying position, particularly for the straining task.

The higher variability found for the straining task could also be reduced by involving the participant

TABLE 3 Validity of pressure profile measurements while lying

	FemFit® (mm Hg)	Dynamometry (N)	mOxford (0-5)	Pearson's correlation	Spearman's correlation
PFMC	12.6 ± 8.8	3.2 ± 3.6	3.8 ± 0.9	0.72[a]	0.68[b]

Note: Values are presented as mean ± SD.

Abbreviation: PFMC pelvic floor muscle maximal contraction.

[a]Pearson's correlation for FemFit® vs dynamometry, $P = .006$.

[b]Spearman's rho for FemFit® vs the modified Oxford (mOxford), scale with higher values indicating increased strength, $P = .005$.

perception of device displacement, as a complement to the visual inspection of the physiotherapist. Another feasible solution to improve this protocol would be to standardize the straining task with the use of a mouth manometer for example.

Further, the FemFit® device is designed to be used by a single user. This would allow the device to be used without a cover, which would optimize the function of its contoured edges meant to reduce device displacement. However, in this prototype phase, there were insufficient units to enable each participant to have her own. In this case, for sanitary reasons the research center ethics board required the devices to be protected with a condom, possibly disabling the function of its scalloped edges.

Another possible advantage of the FemFit® is its ability to measure the intravaginal pressure in different locations along the vaginal length. With eight sensors distributed in its 8 cm length we can be confident that one of the sensors is placed in the high-pressure zone of the vaginal cavity (known to be located 2 to 4 cm from the vaginal introitus).[7] At the same time, the most proximal sensor is placed above the PFM region, possibly representing the intra-abdominal pressure variation related to the intra-abdominal cavity.

In this study, we observed the cross-talk of pressure between some of the adjacent sensors. Our analysis used only the maximal pressure value of the entire device and this would not be influenced by sensor cross-talk. With the results from this study, adjustments have been made to the device and further psychometric evaluations are being conducted.

Limitations also include the population of this study, which accounted for a wide age range (26 to 87 years) but did not include women with known pelvic floor dysfunctions, urinary incontinence, and pelvic organ prolapse. For example, it is possible that these measurements would not be suitable for women with severe pelvic organ prolapse in which the unit could possibly be pushed out.

To our knowledge, this is the first study to report the reliability of maximal intravaginal pressure measurements during straining maneuver task, which were excellent either while lying or standing. Further studies are needed to differentiate pressure patterns along the vaginal cavity between tasks and patient conditions or to test the sensitivity of these measurements to detect changes pre vs post PFM training.

5 | CONCLUSION

Our research findings are original as they suggest that maximal intravaginal pressures can be reliably measured in asymptomatic women during PFM voluntary contraction and straining manoeuver, while lying and standing, using the FemFit® device, both within and between sessions. No discomfort was experienced during measurements, and the device remained in position most of the time. Only the straining task in standing position showed high variability within and between sessions. More research is needed to assess the FemFit® device's sensibility to distinguish patterns of pressure distribution corresponding to different tasks and patient conditions.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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