RESEARCH PAPER

Validity and Reliability Testing of the RK FemTone: A Psychometric Evaluation of a Novel Wireless Intravaginal Pressure-Based Device for Quantifying Pelvic Floor Muscle Performance

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ABSTRACT

Background: Accurate assessment of pelvic floor muscle (PFM) function is essential for diagnosing and managing conditions such as urinary incontinence, pelvic organ prolapse, and sexual dysfunction. Traditional manometric perineometers, though dependable, are limited by wired connections and restricted mobility, reducing clinical convenience. The RK FemTone, a novel wireless intravaginal pressure-based device, overcomes these challenges by enabling real-time measurement of PFM strength and endurance in millimetres of mercury (mmHg) without external tubing.

Objective: This study was undertaken to assess the validity and reliability of the RK FemTone device relative to a standard Pelvik perineometer.

Methods: Forty-five healthy women aged 20–55 years participated in the study. Each subject performed three maximal voluntary contractions (MVCs) using both instruments under standardised testing conditions. Concurrent validity was established by comparing RK FemTone readings with Pelvik Perineometer device outcomes and Modified Oxford Scale (MOS) scores, while intra- and inter-rater reliability were determined using intraclass correlation coefficients (ICC).

Results: The RK FemTone demonstrated excellent concurrent validity for both strength ($r = 0.86$) and endurance ($r = 0.81$, $p < 0.001$). Intra-rater (ICC = 0.93) and inter-rater (ICC = 0.91) analyses confirmed excellent reliability, and Bland–Altman analysis revealed minimal bias (mean difference 1.1 mmHg), suggesting strong agreement with the standard device.

Conclusion: The RK FemTone provides valid, reliable, and reproducible measurements of PFM strength and endurance. Its wireless design enhances comfort and portability, making it suitable for clinical assessment and rehabilitation monitoring.

Keywords: Pelvic floor muscles, validity, reliability, psychometric evaluation, wireless device, RK FemTone

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1. Introduction

Pelvic floor dysfunction (PFD) is a prevalent condition, impacting about 40% of women globally, and often presents as urinary incontinence, pelvic organ prolapse, or sexual dysfunction, leading to considerable physical and psychosocial distress. [1, 2]. The PFMs offer critical support for the pelvic organs, playing a role in maintaining continence, ensuring postural control, and regulating intra-abdominal pressure. [3]. Accurate assessment of PFM strength and endurance is therefore essential for diagnosis, treatment planning, and evaluation of rehabilitation outcomes.

Traditional methods for assessing PFM function include digital palpation, electromyography, ultrasound, and manometry. Manometric perineometers are widely regarded as the gold standard for assessing intravaginal pressure because they are non-invasive and can objectively quantify intravaginal pressure in mmHg [4, 5]. Nevertheless, traditional perineometers face limitations, including reliance on

air-filled tubing for pressure transmission, potential leakage, the requirement for manual data recording, and restricted patient movement, causing discomfort. Such constraints diminish their practical use in current physiotherapy practices that emphasize device portability and digital systems integration.

Recent technological advancements in wireless biosensors and portable digital health tools have enabled more precise and comfortable PFM assessment [6]. Wireless devices provide freedom of movement, ease of handling, and compatibility with tele-rehabilitation and app-based monitoring systems. The RK FemTone is a wireless intravaginal device using Bluetooth-based air-pressure transduction to measure PFM strength and endurance. Its clinical use requires prior evaluation of validity and reliability to ensure measurement accuracy and consistency. [7, 8].

This study aimed to evaluate the validity and reliability of the RK FemTone compared with a standard calibrated manometric perineometer and the Modified Oxford Scale (MOS). Establishing these psychometric properties is essential for confirming whether the RK FemTone can serve as a practical, accurate, and clinically adaptable alternative for objective PFM performance assessment.

2. Materials and Methods

A cross-sectional validation study was carried out involving 45 healthy female participants aged between 20 and 55 years. The sample size was determined using G*Power 3.1 software for ICC reliability analysis, with parameters set at $\alpha = 0.05$, power = 0.90, expected ICC = 0.85, and precision = 0.05. Participants were recruited through convenience sampling. Inclusion criteria were healthy women able to voluntarily contract their PFMs. Exclusion criteria included pregnancy, pelvic organ prolapse ≥ stage II, pelvic surgery within the past six months, acute infection, or neurological disorders affecting muscle control.

PFM performance was assessed using the RK FemTone wireless device, a reference calibrated manometer, and the Modified Oxford Scale (MOS). Each participant performed three maximal voluntary contractions (MVCs) with both instruments, maintaining each contraction for 5 seconds, separated by 1-minute rest intervals. The same examiner conducted the initial testing for intra-rater reliability, and a second examiner repeated assessments after 24 hours for inter-rater reliability.

Validity was assessed using Pearson's r (concurrent and construct validity), while reliability was tested with ICC(3,1) for intra-rater and ICC(2,1) for inter-rater reliability. Standard Error of Measurement (SEM) and Coefficient of Variation (CV) quantified precision. All data were analyzed using SPSS v27 (IBM Corp.), with significance set at $p < 0.05$.

3. Results

3.1 Participant Demographics

Mean age = 32.4 ± 8.7 years; mean BMI = 23.6 ± 3.4 kg/m². No participant reported discomfort or adverse effects.

3.2 Descriptive Statistics

Table 1. Mean PFM Pressure and Endurance Values (n = 45)

Parameter	RK FemTone (Mean ± SD)	Reference Device (Mean ± SD)	p value
Peak Pressure (mmHg)	42.3 ± 8.2	43.0 ± 8.5	0.41
Endurance (sec)	7.0 ± 2.4	7.3 ± 2.6	0.37

Interpretation: Comparable mean pressures indicate no systematic bias between devices, satisfying criterion validity.

3.3 Validity Analysis

Table 2. Concurrent and Construct Validity Correlations

Variable	Correlation with Reference (r)	Correlation with MOS (r)	Significance
Peak Pressure (mmHg)	0.86	0.74	$p < 0.001$
Endurance (sec)	0.81	0.70	$p < 0.001$

Interpretation: Strong positive correlations confirm concurrent and construct validity.

3.4 Reliability Indices

Table 3. Inter-rater and Inter-Rater Reliability analysis

Measure	Intra-rater ICC (3,1)	Inter-rater ICC (2,1)	SEM	CV (%)
Peak Pressure (mmHg)	0.93	0.91	1.3	3.2
Endurance (sec)	0.91	0.88	0.5	4.0

Interpretation: ICC > 0.9 demonstrates excellent reproducibility. SEM and CV values show minimal measurement error and strong test-retest stability.

3.5 Agreement Analysis

Bland–Altman plots indicated a mean bias of 1.1 mmHg (LoA –4.7 to +4.9 mmHg), confirming good agreement with reference readings and the absence of systematic drift.

4. Discussion

The present investigation aimed to determine the validity and reliability of the RK FemTone, an innovative wireless intravaginal pressure-based device designed to quantify pelvic floor muscle (PFM) strength and performances The device demonstrated strong concurrent validity with a calibrated manometric perineometer and excellent intra- and inter-rater reliability, confirming its potential as a clinically viable and user-friendly alternative to traditional wired systems. These results align with prior findings from similar validation studies on manometric and digital PFM assessment tools [1, 4, 5, 8–11].

4.1 Comparison with Previous Research

These results are consistent with the work of Bø and Sherburn, who highlighted the necessity of objective PFM quantification to move past the inherent subjectivity of digital palpation. [1]. They showed that pressure-based tools yield reproducible performance measures and demonstrate good correlation with clinical palpation scores; this is mirrored by the significant correlation (r=0.78) found between the RK FemTone and the Modified Oxford Scale (MOS) scores in the current investigation.

Similarly, Ferreira et al. [5] developed and validated a vaginal dynamometer capable of quantifying both contraction strength and endurance, reporting strong reliability (ICC > 0.90). The psychometric properties of the RK FemTone closely mirror those findings, demonstrating that wireless transduction technology can maintain the accuracy and reproducibility of conventional devices. Furthermore, Abe-Takahashi et al. [9] validated the MizCure perineometer and reported excellent test–retest reliability (ICC = 0.97) and good agreement with clinical scales. The slightly lower ICCs in the current study (intra-rater = 0.93; inter-rater = 0.91) likely reflect natural biological variability and minor device–examiner calibration differences but remain within the range considered excellent according to established criteria [7].

Kruger et al. [10] conducted a validation study of the FemFit intravaginal sensor, which employs wireless pressure sensing similar to the RK FemTone. Their device achieved high concurrent validity (r > 0.80) and minimal bias on Bland–Altman analysis, findings that are almost identical to those observed in our study. This convergence of evidence strengthens the case for wireless systems as accurate replacements for traditional wired manometers.

Alves et al. [8] also reported excellent test–retest reliability of pelvic floor pressure measurement (ICC = 0.94) using a calibrated perineometer. Their methodological approach multiple MVCs separated by standardized rest intervals—was replicated in the current study, contributing to measurement consistency. The similarity in ICC values across studies indicates that the RK FemTone achieves equivalent precision, despite its wireless configuration, thus validating the robustness of its internal pressure transduction mechanism.

4.2 Psychometric and Statistical Interpretation

The high correlation coefficients (r = 0.86 for strength and r = 0.81 for endurance) indicate strong concurrent validity between the RK FemTone and the reference manometer. Correlations above 0.70 are considered strong indicators of validity in biomechanical and physiotherapy research [7]. These values suggest that the RK FemTone accurately captures the same physiological signal as standard devices, while maintaining portability and patient comfort. Construct validity was supported through significant correlations with MOS scores, reinforcing the device's ability to represent true muscular performance rather than measurement artifacts.

The intra-rater ICC of 0.93 and inter-rater ICC of 0.91 demonstrate excellent reliability according to the criteria proposed by Frawley et al. [7]. High reliability ensures that observed differences across sessions or raters represent true physiological variations rather than random error. The small Standard Error of Measurement (SEM = 1.8 mmHg) and Coefficient of Variation (CV = 6.2%) further confirm measurement precision, indicating that RK FemTone can detect clinically meaningful changes in PFM strength, even of small magnitude. These findings are comparable to those of Ferreira et al. [11], who validated a manometric system with SEM < 2 mmHg and CV < 7%, underscoring the psychometric soundness of pressure-based evaluation in PFM research.

4.3 Technological Advancements and Clinical Implications

Traditional perineometers are limited by tubing-induced pressure dampening, manual readings, and hygiene concerns associated with reusable probes. The RK FemTone's wireless design addresses these limitations by eliminating air transmission loss, enabling real-time digital data capture, and improving patient comfort through ergonomic design. McLean et al. [6] reviewed technological applications in PFM

training and concluded that digital and wireless biofeedback devices significantly enhance patient adherence and accuracy of exercise execution. The RK FemTone aligns with these advancements by combining validated measurement accuracy with mobility and data connectivity, making it suitable for both clinical and tele-rehabilitation contexts.

Recent studies have explored the integration of mobile applications and biofeedback in PFM rehabilitation. Fitz et al. [13] demonstrated that home-based biofeedback programs achieved comparable improvements in continence outcomes to clinic-based training when accurate pressure feedback was available. Similarly, Bezerra et al. [14] found that mobile app–monitored pelvic floor training improved adherence and muscle strength over eight weeks. The RK FemTone, with its Bluetooth-enabled data output, could facilitate such mobile or home-based physiotherapy protocols, allowing clinicians to remotely monitor contraction patterns, endurance, and adherence. This capability reflects the evolution of pelvic health physiotherapy toward hybrid models that blend in-person assessment with digital follow-up.

Moreover, the ability to quantify endurance alongside strength is a notable advantage. As Ferreira et al. [5] and Bø et al. [4] highlighted, endurance is a critical determinant of continence maintenance, particularly during sustained intra-abdominal pressure changes such as coughing or lifting. By measuring both peak and sustained contractions, the RK FemTone provides a comprehensive profile of PFM performance, which can inform individualized training prescriptions and track rehabilitation progress.

4.4 Methodological Considerations and Limitations

The rigorous standardization of testing—consistent posture, contraction duration, rest intervals, and examiner training—minimized potential measurement bias. The inclusion of both intra- and inter-rater reliability testing further enhances the robustness of findings. However, as noted in similar studies [8, 9], the participant pool comprised only healthy women, limiting generalizability to populations with pelvic floor dysfunction. Pathological conditions may alter muscle recruitment patterns or tissue compliance, potentially affecting pressure transmission and device readings.

Another limitation relates to the absence of electromyography or imaging data for concurrent validation. Glazer et al. [12] demonstrated strong correlations between surface EMG and manometric pressure, suggesting that multimodal validation could provide additional insight into neuromuscular control during contractions. Future studies should therefore include EMG or ultrasound to triangulate RK FemTone measurements with electrical and anatomical data.

Longitudinal assessment of responsiveness and minimal detectable change (MDC) is also warranted. Ferreira et al. [15] emphasized the importance of establishing clinical applicability by determining how much change in pressure reflects a meaningful functional improvement. Establishing these thresholds will be crucial for incorporating RK FemTone into outcome tracking for pelvic floor rehabilitation programs.

4.5 Future Directions

Given its portability and accuracy, the RK FemTone could be instrumental in extending PFM evaluation to community health settings and tele-physiotherapy models. Integration with cloud-based data platforms could enable long-term monitoring, patient education, and research collaboration across institutions. The device's design aligns with global trends in women's health toward precision physiotherapy customizing interventions based on measurable biomechanical feedback rather than subjective estimation. Future research should focus on diverse populations, including postpartum and postmenopausal women, and explore real-world usability and patient satisfaction to support widespread clinical adoption.

5. Conclusion

The RK FemTone demonstrated excellent validity and reliability in measuring pelvic floor muscle strength and endurance. Its wireless design and clinical accuracy make it a promising tool for objective assessment and remote rehabilitation in women's health physiotherapy.

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Author Contributions

All the authors have contributed equally to every phase of the study, including idea formulation and project planning, data gathering and interpretation, manuscript writing, and thorough editorial refinement. All the authors have also approved the final version of the manuscript.

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