

REVIEW PAPER

**INNOVATIONS IN PELVIC FLOOR REHABILITATION: A REVIEW OF
WIRELESS INTRAVAGINAL BIOFEEDBACK DEVICES FOR WOMEN**

Krupa Tank^{1(A,B,C,D,E,F)}, **Priyanshu Rathod**^{1(A,B,C,D,E,F)}

¹School of Physiotherapy, RK University, Rajkot, Gujarat, India

Tank K, Rathod P. Innovations in pelvic floor rehabilitation: a review of wireless intravaginal biofeedback devices for women. Health Prob Civil. <https://doi.org/10.5114/hpc.2025.152430>

Tables: 2

Figures: 1

References: 36

Submitted: 2025 Jan 25

Accepted: 2025 Jun 27

Address for correspondence: Krupa Tank, School of Physiotherapy, RK University, Kasturba Dham, Tramba, Rajkot-360005, Gujarat, India, e-mail: dr.krupatank@gmail.com, phone: +91 099099 52030
ORCID: Krupa Tank <https://orcid.org/0000-0002-9720-7328>, Priyanshu Rathod <https://orcid.org/0000-0002-7663-2413>

Copyright: © John Paul II University in Białą Podlaska, Krupa Tank, Priyanshu Rathod. This is an Open Access journal, all articles are distributed under the terms of the Creative Commons AttributionNonCommercial-ShareAlike 4.0 International (CC BY-NC-SA 4.0) License (<https://creativecommons.org/licenses/by-nc-sa/4.0>), allowing third parties to copy and redistribute the material in any medium or format and to remix, transform, and build upon the material, provided the original work is properly cited and states its license.

Summary

Pelvic floor dysfunction (PFD) is a common yet underdiagnosed condition affecting women globally, often leading to urinary incontinence, pelvic organ prolapse, and reduced quality of life. Despite its high prevalence, awareness and access to effective treatment options, including physiotherapy-based interventions, remain limited, particularly in resource-constrained regions. Wireless invasive biofeedback devices have emerged as innovative rehabilitation tools, offering real-time feedback, gamified exercises, and smartphone integration to enhance user engagement and adherence to pelvic floor muscle training programs. This review systematically analyzed 18 studies, identifying 12 commercially available devices and 4 patented innovations, evaluating their technological advancements, clinical efficacy, and market accessibility. Devices such as Elvie Kegel Trainer, PeriCoach, and MAPLe utilize pressure sensors, accelerometers, and AI-driven interfaces to provide personalized biofeedback. However, challenges such as high costs, limited distribution, and the need for specialized training restrict their widespread adoption, particularly in developing regions like India. To overcome these barriers, cost-effective, user-friendly solutions tailored to diverse populations are needed. Enhancing accessibility requires local manufacturing, public healthcare integration, AI-driven coaching, ergonomic designs, multimodal feedback, and multilingual interfaces. Future innovations should bridge the gap between affordability and technological sophistication to maximize rehabilitation outcomes and empower women with self-managed pelvic health solutions.

Keywords: urogenital health, gamified health solutions, intravaginal biofeedback, women's health technology, digital health interventions

Introduction

Pelvic floor dysfunction (PFD) is a widespread yet underdiagnosed condition affecting millions of women worldwide, with prevalence rates ranging from 19.3% to 58% in India alone. Among its various manifestations, urinary incontinence (UI) remains the most common, significantly impacting women's quality of life [1,2]. Factors associated with increased PFD risk include advanced age, vaginal delivery, higher parity, and increased body mass index (BMI) [1,3]. Despite the high burden of PFD, awareness and accessibility to effective treatment options—particularly physiotherapy and biofeedback interventions—remain limited, especially in low-resource settings.

Biofeedback technology has emerged as a transformative approach in pelvic floor rehabilitation, offering real-time monitoring and guided exercises to enhance muscle control [4]. In recent years, wireless invasive biofeedback devices have gained prominence, integrating cutting-edge advancements such as gamification, smartphone connectivity, and AI-driven guidance to improve adherence and outcomes [5]. However, challenges persist in terms of affordability, accessibility, and user-centered design, particularly in developing regions.

Aim of the work

This review aims to critically analyze the evolution of wireless invasive biofeedback devices for PFD management, assessing their features, functionality, and clinical applications. By synthesizing current research, identifying gaps, and evaluating market trends, this paper provides a comprehensive overview of the state of knowledge in this field. Despite the high prevalence, awareness of treatment options, particularly physiotherapy interventions, remains low, especially in rural areas [2].

This review considers studies published between January 2009 and January 2025. While global databases were explored, particular emphasis was placed on the relevance and availability of these technologies in India, with broader applicability to other developing nations. The primary objective is to evaluate and analyze the features, functionalities, and limitations of wireless invasive biofeedback devices used to treat PFD in women. The review focuses on technological advancements in device design, usability, and clinical application, aiming to support more effective rehabilitation strategies. Additionally, it seeks to identify existing gaps related to affordability, accessibility, and user-centered design and provides recommendations for future innovations that can enhance the quality of life for women affected by PFD.

Methods

A comprehensive literature search was conducted between January 10th and January 27th, 2025, using established databases such as PubMed, Scopus, Web of Science, Cochrane Library, and Google Scholar. The search strategy employed Boolean operators and Medical Subject Headings (MeSH) terms, including combinations such as “wireless intravaginal biofeedback”, “pelvic floor muscle training”, “invasive biofeedback devices”, and “digital pelvic health interventions”. Grey literature sources—such as conference proceedings, clinical trial registries, theses, and white papers—were also explored to identify unpublished or non-indexed research.

Patent repositories, including Google Patents and the Intellectual Property India (IPR India) database, were reviewed for innovations relevant to wireless pelvic floor devices.

Additionally, official manufacturer websites were consulted to extract technical specifications, usability features, and device pricing details.

The selection criteria focused on human-based studies, published in peer-reviewed journals, in English language, and involving the use of wireless invasive biofeedback devices for pelvic floor rehabilitation in women. Studies involving animal models, non-invasive sensors, electrical stimulation-only protocols, or non-English publications were excluded. After screening 320 articles and 7 patents, 18 eligible studies and 4 patented innovations published between January 2009 and January 2025 were included for final analysis.

The literature search identified 320 research articles and 7 patented devices, of which 18 were eligible for detailed analysis. From these, 12 commercially available wireless invasive biofeedback devices and 4 patented devices were reviewed, with 272 articles excluded due to relevance and duplication issues. This is explained in detail below (Figure 1).

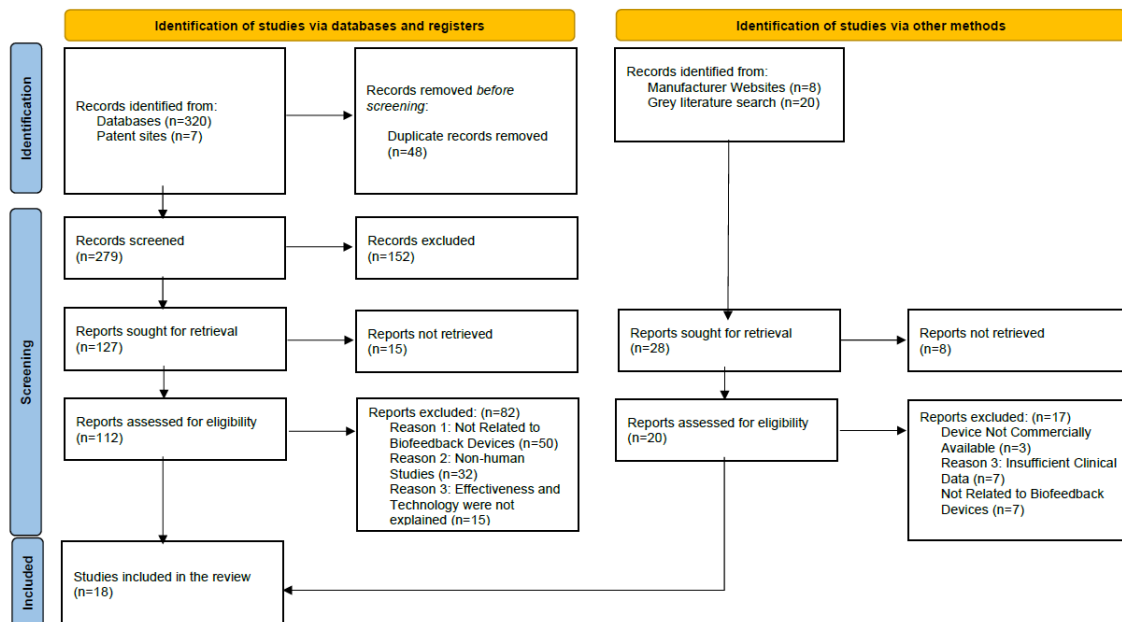


Figure 1. PRISMA flow diagram of literature review

Two reviewers independently evaluated the risk of bias in each study to minimize initial bias and personal judgment errors. Their assessments were then compared to identify

discrepancies, ensuring a consistent application of the criteria. Any differences were resolved through discussion, involving re-evaluating study data, revisiting criteria, and clarifying misunderstandings, ultimately achieving consensus through collaboration.

Literature review results

A growing body of evidence supports the integration of biofeedback devices and technology-assisted pelvic floor muscle training (PFMT) to improve the management of UI and other forms of PFD. These interventions have evolved from simple pressure-based tools to sophisticated sensor-integrated mobile platforms, enhancing user engagement, feedback accuracy, and clinical outcomes. To better understand the scope and effectiveness of such innovations, a comprehensive review of recent studies was conducted, encompassing randomized trials, validation studies, pilot clinical assessments, and product evaluations. Table 1 summarizes key findings from 18 relevant studies and innovations in pelvic floor biofeedback devices and training programs, highlighting their research design, methods, conclusions, and clinical significance.

Table 1. Summary of literature review

Study number	Title	Authors	Type of research design	Method	Conclusion	Year
1	Pressure-mediated biofeedback with pelvic floor muscle training for urinary incontinence: a randomized clinical trial	Wang et al. [6]	Multicenter randomized clinical trial	The authors compared PFMT alone vs. PFMT + home-based pressure-mediated biofeedback device among postpartum women.	Biofeedback significantly improved cure rates, muscle strength, and QoL outcomes.	2024
2	Intra-abdominal and perineal pressures during abdominal exercises: a cross sectional study in postpartum women	Djivoh et al. [7]	Cross-sectional study	IAP and PP were measured in 17 Beninese postpartum women at rest and during various abdominal exercises using Phenix USB 4, a dual-channel biofeedback device. Exercises included Cough, PFC, Curl-up, DA, Drawing-in, and combinations. ANOVA was used for comparison.	Diaphragmatic aspiration (DA) is the safest exercise for pelvic floor protection, while Curl-up presents moderate risk. Individual variations should be considered.	2022
3	Reliability and validity of intravaginal pressure measurements with a new intravaginal pressure device: the FemFit®	Cacciari et al. [8]	Prospective test-retest study	The authors tested FemFit® sensor reliability/validity during standardized PFM tasks in different positions.	FemFit® demonstrated excellent reliability and validity for clinical and research use.	2020
4	Assessing vaginal pressure profiles before and after prolapse surgery using an intravaginal pressure sensor (femfit®)	Marriott et al. [9]	Pilot clinical study	The authors used FemFit® to evaluate pelvic floor function pre- and post-pelvic organ prolapse surgery.	FemFit® effectively detected changes in PFM strength and intra-abdominal pressure.	2020
5	Using codesign to develop a mobile application for pelvic floor muscle training with an intravaginal device (femfit®)	Pedofsky et al. [10]	Usability and app design study	The authors developed FemFit® mobile app and assessed user feedback for biofeedback training.	FemFit® app received positive ratings for usability, motivation, and engagement.	2021
6	The feasibility of pelvic floor training to treat urinary incontinence in women with breast cancer: a telehealth intervention trial	Colombage et al. [11]	Prospective intervention study	The authors used FemFit® for PFMT in breast cancer survivors on aromatase inhibitors.	Significant improvements were observed in urinary symptoms and PFM strength.	2021
7	Randomized trial comparing efficacy of pelvic floor muscle training with a digital therapeutic motion-based device to standard pelvic	Weinstein et al. [12]	Randomized controlled trial	The authors used accelerometer-based pelvic floor monitoring for PFMT in women with urinary incontinence.	Leva system demonstrated superior outcomes compared to standard PFMT.	2021

	floor exercises for treatment of stress urinary incontinence (SUV trial): an all-virtual trial design					
8	The WOMEN-UP solution, a patient-centered innovative e-health tool for pelvic floor muscle training: qualitative and usability study during early-stage development	Anglès-Acedo et al. [13]	Research protocol	The study aimed at developing a combined serious gaming + sensor device platform for PFMT.	The early pilot suggests improved adherence and usability; final results pending.	2020
9	Cost comparison between home biofeedback using PeriCoach® and supervised pelvic floor muscle training	de Winter et al. [14]	Randomized controlled trial	The authors compared 54 women with SUI or MUI using the PeriCoach® system (without formal instruction) to supervised PFMT. Outcomes measured via ICIQ-SF, Incontinence Severity Index, Modified Oxford Score, and Female Sexual Function Index.	PeriCoach is non-inferior to supervised PFMT for treating urinary incontinence and is more cost-effective, improving pelvic floor strength, incontinence severity, and sexual function.	2020
10	Reliability and validity of a mobile home pelvic floor muscle trainer: the Elvie Trainer	Czyrnyj et al. [15]	Clinical validation report	The authors examined force and motion sensing accuracy of Elvie Trainer during contractions.	Elvie reliably detected pelvic floor muscle contractions; effective for user training.	2019
11	Prospective evaluation of the connected biofeedback EMY Kegel trainer in the management of stress urinary incontinence	Jochum et al. [16]	Prospective observational study	The authors studied gamified pelvic floor training using Emy with app feedback.	High compliance and quality-of-life improvement were observed in 12-week follow-up.	2018
12	Comparison of the efficacy of perineal and intravaginal biofeedback assisted pelvic floor muscle exercises in women with urodynamic stress urinary incontinence	Özlü et al. [17]	Randomized controlled trial	The authors compared intravaginal pressure biofeedback vs. perineal EMG biofeedback vs. PFMT alone in SUI women.	Both biofeedback methods were more effective than PFMT alone; similar efficacy was observed between devices.	2017
13	Device-assisted pelvic floor muscle postpartum exercise programme for the management of pelvic floor dysfunction after delivery	Artymuk et al. [18]	Product clinical review	The authors evaluated Bluetooth-guided pelvic floor rehabilitation postpartum using Magic Kegel Master device.	Improvement in pelvic floor function, sexual health, and UI symptoms were noted.	2017
14	Device and method for sensing, guiding, and/or tracking pelvic exercise	Siegel [19]	Patent application	The author designed device with sensors for monitoring pelvic muscle contraction, force, and exercise form.	The device was intended to improve compliance, diagnosis, feedback, and treatment adherence.	2015

15	Comparison of Kegel exercises and a combination of Kegel exercises with the use of the KegelSmart biofeedback device in the treatment of static urinary incontinence	Begić et al. [20]	Clinical study summary	The authors evaluated touch-sensitive adaptive PFMT device for improving UI symptoms.	The results showed positive symptom relief and user satisfaction.	2015
16	Using the Vibrance Kegel Device with pelvic floor muscle exercise for stress urinary incontinence: a randomized controlled pilot study	Ong et al. [21]	Clinical case series	Vibrational feedback device was used to guide correct contraction during PFMT sessions.	Early improvements were observed in continence symptoms with user-friendly design.	2014
17	Perineometer with wireless biofeedback	Hoffman et al. [22]	Patent design	The authors designed a wireless perineometer that provides tactile, visual, and auditory biofeedback.	The device facilitates convenient and effective pelvic floor training at home or clinic.	2010
18	A new pelvic muscle trainer for the treatment of urinary incontinence	Schmidt et al. [23]	Randomized controlled trial	The authors compared PFME alone vs. PFME+biofeedback vs. PFME+electrical stimulation using a novel device.	All groups showed improved UI control and quality of life; compliance was good across groups.	2009

Notes: PFMT – pelvic floor muscle training, PFD – pelvic floor dysfunction, UI – urinary incontinence, SUI – stress urinary incontinence, MUI – mixed urinary incontinence, QoL – quality of life, IAP – intra-abdominal pressure, PP – perineal pressure, PFC – pelvic floor contraction, DA – diaphragmatic aspiration, ICIQ-SF – International Consultation on Incontinence Questionnaire-Short Form, PFME – pelvic floor muscle exercise, EMG – electromyography.

The integration of wireless biofeedback technology into pelvic floor muscle (PFM) rehabilitation represents a significant advancement in the conservative management of PFD. This review highlights the clinical relevance, usability, and technological sophistication of various wireless devices, reinforcing their potential to improve patient compliance, comfort, and treatment outcomes. The shift from traditional wired systems to wireless platforms addresses barriers related to mobility, ease of use, and discreetness—factors critical for long-term adherence, especially among women managing conditions such as urinary incontinence, pelvic organ prolapse, or postnatal PFM weakness.

Table 2 highlights the key characteristics and clinical applicability of various wireless biofeedback devices currently utilized for PFD. This comparative overview provides a

foundation for deeper insight into their functional roles, technological specifications, and user considerations. Building upon this, the following section explores the scientific literature supporting the efficacy and limitations of these devices, offering a comprehensive understanding of their practical implications in physiotherapeutic interventions.

Table 2. Comparison of wireless invasive pelvic floor devices

No	Device	Technology used	User-friendliness	Effectiveness
1	Femfit® [8-10]	Flexible wireless vaginal sensor with 8 pressure points transmitting real-time data via Bluetooth	The intuitive, motivational app, that provides real-time visual biofeedback	Significant improvement seen in pelvic floor muscle (PFM) strength, continence, and post-POP surgery recovery
2	Vibrance Kegel Device (VKD) [21,24]	Pressure-sensitive device that vibrates to guide users during correct contractions	A small, mobile device that provides simple vibrational feedback to ensure correct Kegel exercise performance	Early improvements in muscle strength and reduced stress urinary incontinence (SUI) symptoms
3	Kegel Smart [20,25]	Touch-sensitive vaginal trainer that automatically adjusts exercise levels based on muscle performance	Very user-friendly, with vibration coaching that helps especially beginners do effective exercises	Significant improvement observed in urinary continence when combined with daily use
4	MAPLe [26,27]	Clinical probe with 24 electrodes for real-time EMG mapping and identification of specific muscle groups.	Requires professional handling and interpretation, limiting home usability	Proven reliable in detecting isolated pelvic floor muscle activities, crucial for tailored rehabilitation
5	iBall [28]	Bluetooth-enabled vaginal sensor measuring strength and endurance with gamified biofeedback	Offers gaming options for motivation, but technical and comfort issues were reported	Pilot results were mixed; limited additional benefit compared to standard PFMT
6	Magic Kegel Master [29]	Peanut-shaped Bluetooth vaginal trainer with inbuilt pressure sensors and app guidance	Simple insertion, playful app interface, and real-time feedback make it engaging	Significant improvement seen in sexual function and decreased urinary/fecal incontinence
7	PeriCoach [14,30]	Vaginal probe with tri-sensor pressure recording, app connectivity, and clinician web portal	App that sends reminders, progress reports, and provides an optional clinician monitoring mode	8-week structured program demonstrated strength improvements and reduced leakage episodes

8	Elvie Trainer [15,31]	Egg-shaped Bluetooth vaginal device with a force sensor and accelerometer for movement tracking	Sleek, waterproof, easy-to-insert device; app that assesses correct vs incorrect PFM contractions	Accurately detects correct contractions, though force measurement is less valid than standard dynamometers
9	EMY Kegel Trainer [16]	Connected biofeedback vaginal probe pairing with a smartphone app	App that gamifies exercises and tracks adherence, boosting compliance	Significant improvements in quality-of-life scores and decreased urinary symptoms over 3 months
10	Leva [12,32,33]	Digital intravaginal accelerometer array tracking pelvic floor motion, connected to smartphone	Easy setup, real-time feedback on correct muscle lifts, excellent for unsupervised use	Superior outcomes compared to home training alone, reducing UI symptoms significantly
11	WOMEN-UP Solution [13]	e-Health solution integrating a wireless vaginal device, serious games, and remote professional monitoring	Fun, game-based app that improves user engagement and motivation for PFMT	Early prototypes show promising engagement; final trials pending for efficacy confirmation
12	PHENIX Vivaltis [34]	Wireless biofeedback and electrostimulation and a touchscreen interface	High touchscreen, biofeedback, preset programs and patient-motivating interfaces	Proven improvement in urinary incontinence, PFM strength, and pelvic floor function through clinical trials

Notes: PFM – pelvic floor muscles, UI – urinary incontinence, SUI – stress urinary incontinence, POP – pelvic organ prolapse, PFMT – pelvic floor muscle training, EMG - electromyography.

Challenges and market analysis of wireless invasive biofeedback devices for PFD

User-centric device evolution

The evolution of wireless invasive biofeedback devices has been marked by a significant shift towards user-centered design, prioritizing comfort, adaptability, and accessibility. This approach has driven innovations in the size, shape, and functionality of these devices, aiming to enhance user experience and engagement during pelvic floor rehabilitation.

Devices such as the Elvie Trainer exemplify a compact and ergonomic design, with an egg-shaped form and a 35 mm diameter [15]. This waterproof and wireless device integrates piezoelectric sensors and accelerometers, ensuring accurate feedback while maintaining user

convenience [15]. Similarly, the Femfit introduces a unique thin and flexible probe design with eight pressure sensors, contoured to fit comfortably against the vaginal wall to minimize movement [9,10]. Despite these advancements, challenges remain in making such devices more user-friendly and universally accessible.

Addressing accessibility challenges, particularly in regions like India, remains a critical concern. High-cost devices such as the PeriCoach, EMY Kegel Trainer, and Elvie are seldom distributed widely, limiting their reach to urban or affluent populations. Moreover, advanced options like MAPLe and WOMEN-UP Solution are often unavailable in the Indian market, leaving a significant portion of the population without access to these innovative solutions [15,16,26,33]. To bridge this gap, there is a need to develop affordable, user-friendly biofeedback devices tailored to the economic and cultural contexts of developing regions.

The Phenix Vivaltis stands out among wireless intravaginal devices by combining biofeedback and electrostimulation capabilities within a touchscreen-guided platform, making it a comprehensive solution for both assessment and rehabilitation. Designed for clinical and home use, it features pre-set protocols tailored to various pelvic floor conditions, improving ease of use for practitioners and patients alike. Its intuitive interface delivers real-time visual feedback and customizable treatment options, which are particularly effective for patients with low muscle activation or neuromuscular dysfunction. Moreover, the inclusion of motivational games and patient-specific reporting enhances engagement, adherence, and long-term treatment outcomes. Despite its strong clinical utility, the device's higher cost and limited availability outside Europe remain key barriers to broader implementation in resource-limited settings [34].

This focus on user-centered innovation and greater accessibility is essential to ensuring pelvic floor rehabilitation technologies effectively reach and benefit the populations that need them most.

Technology-driven rehabilitation

Advancements in wireless invasive biofeedback devices have transformed pelvic floor rehabilitation by integrating cutting-edge technologies such as real-time biofeedback, gamification, and smartphone connectivity. These features have significantly enhanced user engagement, adherence to rehabilitation programs, and overall outcomes, empowering women to take charge of their health.

Real-time biofeedback is a cornerstone of these devices, providing instant visual or vibrational cues to guide users during pelvic floor muscle exercises. Devices like the PeriCoach and EMY Kegel Trainer use force sensors to detect muscle contractions and relay the data to smartphone apps, offering precise feedback on the strength and duration of contractions [15,16,30]. This lets users adjust their techniques immediately, ensuring proper execution and maximizing benefits. The Elvie Kegel Trainer, with its piezoelectric sensors and accelerometers, further enhances this experience by delivering accurate, real-time monitoring in a compact and user-friendly design [15].

Gamification has emerged as a powerful tool for improving motivation and adherence. The WOMEN-UP Solution employs gamified exercises through its mobile application, turning rehabilitation sessions into interactive and engaging experiences. This approach not only enhances concentration but also fosters a sense of accomplishment, encouraging consistent use of the device. Similarly, patented devices, such as those incorporating real-time feedback with gamified mobile apps, represent a growing trend in making rehabilitation enjoyable and sustainable [13].

Smartphone integration has redefined accessibility and convenience, enabling users to monitor their progress, customize exercise regimens, and receive feedback directly on their devices. Many devices, including the Magic Kegel Master and iBall, leverage Bluetooth

technology to sync with apps that provide detailed feedback, guidance, and data tracking [16,18,29,35]. These features empower users by allowing them to track their improvement over time while providing healthcare professionals with the ability to remotely monitor progress and make informed adjustments to treatment plans.

Together, these technological advancements have reshaped the landscape of pelvic floor rehabilitation. By combining innovation with user-centered design, these devices enable women to actively participate in their recovery, ultimately improving adherence, outcomes, and quality of life.

Barriers to adoption and proposed solutions

Wireless invasive biofeedback devices have significantly advanced pelvic floor rehabilitation, yet their widespread adoption remains limited due to high costs, device complexity, and restricted availability, particularly in developing regions like India. Addressing these challenges requires a focus on affordability, user-friendly designs, and technological improvements to ensure broader accessibility.

One major barrier is the high cost and limited availability of these devices. Products like PeriCoach, Elvie Kegel Trainer, and EMY Kegel Trainer remain expensive, making them inaccessible to many users. Additionally, advanced solutions such as MAPLe and WOMEN-UP Solution, which offer detailed neuromuscular assessments and gamified rehabilitation, are seldom available in India, further restricting access [13,16,26,30,31]. To enhance affordability, manufacturers should adopt cost-effective production methods, use locally sourced materials, and collaborate with public healthcare systems and insurance providers to subsidize costs. Introducing lower-cost alternatives with essential features can ensure biofeedback technology reaches a broader population while maintaining clinical effectiveness.

Another challenge is the complexity of use and the need for simplified interfaces. Devices like MAPLe require specialized training, limiting their use to professionals rather than individual users. Similarly, WOMEN-UP Solution, which integrates multiple biofeedback technologies, may overwhelm users unfamiliar with digital health interventions [13,26]. Moreover, the iBall device, despite its advanced features, lacks precise pressure measurement calibration, affecting biofeedback accuracy. To improve usability, manufacturers should develop intuitive mobile applications with AI-driven coaching, reducing the need for external training [20]. Additionally, training programs for healthcare providers can enhance adoption and ensure correct device usage in clinical settings.

User comfort and engagement remain critical concerns, as many devices struggle with design limitations and a lack of adaptive features. For example, the Vibrance Kegel and Kegel Smart lack audio-visual feedback, reducing user engagement during rehabilitation. Some devices may also not be adaptable to different anatomical variations, limiting their effectiveness. Future innovations should focus on ergonomic and flexible designs, incorporating adjustable probes, customizable resistance levels, and enhanced biofeedback mechanisms such as voice coaching, LED indicators, and vibration-based feedback to improve motivation and ensure correct exercise performance [25,26].

Biofeedback devices must be affordable, user-friendly, and adaptable to diverse populations to achieve wider adoption. Addressing cost, usability, and engagement barriers will ensure that these innovations reach those who need them most. By prioritizing user-centered improvements and accessibility initiatives, future developments in pelvic floor rehabilitation technology can significantly enhance the quality of care and treatment outcomes for women worldwide.

Global perspective with local implications

Wireless invasive biofeedback devices have gained popularity worldwide, particularly in countries like Australia, the USA, the UK, and the Netherlands. Devices such as PeriCoach, Elvie Kegel Trainer, MAPLe, and Femfit integrate advanced technology for pelvic floor rehabilitation [10,15,26,30]. These devices offer real-time biofeedback, gamification, and smartphone connectivity, enhancing user engagement. However, despite their effectiveness, their high cost and limited distribution make them inaccessible in many developing regions, including India.

In high-income countries, insurance coverage, regulatory approvals, and strong distribution networks support device adoption. The Leva Pelvic Health System, for example, is FDA-cleared and allows remote monitoring by healthcare providers [32,33]. Similarly, the WOMEN-UP Solution in Europe integrates gamified rehabilitation to improve adherence [13]. In contrast, India faces significant barriers, including high costs, limited local availability, and a lack of financial support for physiotherapy-based interventions.

Key challenges include limited distribution, as devices like PeriCoach, Elvie, and MAPLe are seldom available in the Indian market. Affordability remains a major concern, with most devices priced beyond the reach of the average consumer. Additionally, some devices require specialized training, making them less suitable for self-administered rehabilitation.

Cost considerations and market variability

In addition to differences in design and functionality, wireless invasive biofeedback devices also vary widely in cost, which significantly influences their accessibility and adoption. Entry-level devices like the Vibrance Kegel Device and KegelSmart are relatively affordable,

typically priced between \$50 and \$100, making them more accessible for individual users. In contrast, advanced systems such as the Elvie Trainer, PeriCoach, and MAPLe range from \$200 to over \$500, placing them out of reach for many in low-resource settings. High-end devices often justify their cost through features like real-time data transmission, clinician monitoring portals, and AI-driven feedback; however, the economic barrier they pose limits equitable access. This cost disparity highlights the need for scalable, affordable alternatives that retain core therapeutic functions while being economically viable for broader populations, particularly in developing countries like India.

To bridge this gap, local production of affordable biofeedback devices, expansion of distribution networks, and integration with government health programs are essential. Introducing multilingual, user-friendly interfaces, AI-powered coaching, and audio-visual guidance can further improve accessibility. Raising awareness through community health initiatives will also encourage more women to seek treatment for PFD.

While biofeedback technology has transformed pelvic floor rehabilitation globally, its adoption in India remains limited. Affordable, accessible, and user-friendly solutions are crucial to ensuring that these life-changing devices benefit a broader population [35].

Patented innovations: bridging the future

Patented biofeedback devices have the potential to address current limitations in pelvic floor rehabilitation by introducing new technologies and improved designs. While commercially available devices have advanced features such as real-time biofeedback, gamification, and smartphone integration, they still face challenges related to cost, user comfort, and accessibility. Emerging patented devices aim to overcome these barriers and redefine the future of pelvic floor muscle training.

The Perineometer with Wireless Biofeedback [US20060036188A1, 2006] introduces a wireless audio-visual display unit that enhances user engagement by providing real-time muscle contraction feedback. However, it lacks customized exercise programs that could improve adherence [22]. Similarly, the Device and Method for Sensing, Guiding, and Tracking Pelvic Exercise [US20150196802, 2015] integrates force sensors in a flexible polymeric structure, offering precise muscle tracking and gamification through a mobile app. Despite its technological advancements, user discomfort with the handle design remains a concern [19].

The Kegel Training System [China, CN215961035U, 2021] focuses on vibration-based biofeedback, ensuring an interactive and engaging experience. Its elliptical shape enhances user-friendliness, but the lack of audio-visual feedback limits its ability to provide comprehensive training guidance. These patents showcase promising technological advancements yet highlight the need for further refinements to enhance user comfort and engagement [36].

Future innovations should integrate AI-driven guidance, adjustable ergonomic designs, and multimodal feedback systems to create more personalized and effective rehabilitation experiences. By refining these patented technologies, the next generation of wireless invasive biofeedback devices can bridge the gap between current limitations and future advancements, making pelvic floor rehabilitation more accessible, efficient, and user-friendly.

Conclusions

Wireless invasive biofeedback devices have transformed pelvic floor rehabilitation by integrating real-time biofeedback, gamification, and smartphone connectivity. Despite these advancements, high costs, limited availability, and user adaptability, challenges continue to restrict their widespread adoption, particularly in developing regions like India. Addressing

these barriers requires a collaborative effort among technology developers, physiotherapists, and public health advocates to design solutions that are affordable, accessible, and user-friendly.

Innovations in patented biofeedback devices demonstrate promising advancements, such as wireless monitoring, AI-driven guidance, and ergonomic designs, but further refinements are necessary to enhance user comfort and engagement. Expanding local production, integrating devices into healthcare programs, and raising awareness will be key to bridging the accessibility gap.

Moving forward, interdisciplinary collaboration is essential to drive cost-effective innovations and improve pelvic health rehabilitation outcomes. By leveraging technological advancements, clinical expertise, and public health initiatives, the future of PFD management can be transformed, empowering women worldwide and significantly improving their quality of life.

Disclosures and acknowledgements

The authors declare no conflicts of interest with respect to the research, authorship, and/or publication of this article.

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

During the preparation of this work, the authors used ChatGPT-4 to improve writing quality. After using this tool/service, the authors reviewed and edited the content as needed and took full responsibility for the content of the publication.

References:

1. Gaddam R, Gangadharan K, Shivaraju P, Basappa PK. Prevalence of pelvic floor dysfunction in women attending obstetrics and gynaecology OPD at PES Institute of Medical Sciences and Research, Kuppam. *Int J Reprod Contracept Obstet Gynecol.* 2020; 9(12): 5087. <https://doi.org/10.18203/2320-1770.ijrcog20205251>
2. Rathod D, Suvarna D. Prevalence of pelvic floor dysfunction in women residing in rural areas – a cross-sectional study. *Int J Health Sci Res.* 2024; 14(4): 44-48. <https://doi.org/10.52403/ijhsr.20240407>
3. Krishna Rao B. Prevalence of pelvic floor dysfunction among married women of Udupi Taluk, Karnataka, India. *Journal of Womens Health Care.* 2015; 04. <https://doi.org/10.4172/2167-0420.1000236>
4. Aukee P, Immonen P, Laaksonen DE, Laippala P, Penttinen J, Airaksinen O. The effect of home biofeedback training on stress incontinence. *Acta Obstet Gynecol Scand.* 2004; 83(10): 973-977. <https://doi.org/10.1111/j.0001-6349.2004.00559.x>
5. Hou Y, Feng S, Tong B, Lu S, Jin Y. Effect of pelvic floor muscle training using mobile health applications for stress urinary incontinence in women: a systematic review. *BMC Women's Health.* 2022; 22(1): 400. <https://doi.org/10.1186/s12905-022-01985-7>
6. Wang X, Qiu J, Li D, Wang Z, Yang Y, Fan G, et al. Pressure-mediated biofeedback with pelvic floor muscle training for urinary incontinence: a randomized clinical trial. *JAMA Netw Open.* 2024; 7(11): e2442925. <https://doi.org/10.1001/jamanetworkopen.2024.42925>
7. Djivoh YS, De Jaeger D. Intra-abdominal and perineal pressures during abdominal exercises: a cross sectional study in postpartum women. *Neurourol Urodyn.* 2023; 42(1): 205-212. <https://doi.org/10.1002/nau.25069>

8. Cacciari LP, Kruger J, Goodman J, Budgett D, Dumoulin C. Reliability and validity of intravaginal pressure measurements with a new intravaginal pressure device: The FemFit®. *Neurourology and Urodynamics*. 2020; 39(1): 253-260. <https://doi.org/10.1002/nau.24179>
9. Marriott J, Pedofsky L, Smallldridge J, Hayward L, Budgett D, Nielsen PFM, et al. Assessing vaginal pressure profiles before and after prolapse surgery using an intravaginal pressure sensor (femfit®). *Int Urogynecol J*. 2021; 32(11): 3037-3044. <https://doi.org/10.1007/s00192-020-04576-y>
10. Pedofsky L, Nielsen PMF, Budgett D, Nemec K, Dumoulin C, Kruger J. Using codesign to develop a mobile application for pelvic floor muscle training with an intravaginal device (femfit®). *Neurourology and Urodynamics*. 2021; 40(8): 1900-1907. <https://doi.org/10.1002/nau.24775>
11. Colombage UN, Soh SE, Lin KY, Kruger J, Frawley HC. The feasibility of pelvic floor training to treat urinary incontinence in women with breast cancer: a telehealth intervention trial. *Breast Cancer*. 2023; 30(1): 121-130. <https://doi.org/10.1007/s12282-022-01405-6>
12. Weinstein MM, Pulliam SJ, Richter HE. Randomized trial comparing efficacy of pelvic floor muscle training with a digital therapeutic motion-based device to standard pelvic floor exercises for treatment of stress urinary incontinence (SUV trial): an all-virtual trial design. *Contemporary Clinical Trials*. 2021; 105: 106406. <https://doi.org/10.1016/j.cct.2021.106406>
13. Anglès-Acedo S, López-Frías L, Soler V, Alonso JF, Kastelein AW, de Graaf BC, et al. The WOMEN-UP solution, a patient-centered innovative e-health tool for pelvic floor muscle training: qualitative and usability study during early-stage development. *IJERPH*. 2021; 18(15): 7800. <https://doi.org/10.3390/ijerph18157800>

14. de Winter KL. Cost comparison between home biofeedback using PeriCoach® and supervised pelvic floor muscle training [Internet]. Brisbane: Pericoach; 2020 [access 2025 May 8]. Available from: <https://www.pericoach.com/wp-content/uploads/2021/05/2020-deWinter-PeriCoachCostComparison.pdf>
15. Czyrnyj CS, Bérubé M, Brooks K, Varette K, McLean L. Reliability and validity of a mobile home pelvic floor muscle trainer: the Elvie Trainer. *Neurourology and Urodynamics*. 2020; 39(6): 1717-1731. <https://doi.org/10.1002/nau.24439>
16. Jochum F, Garbin O, Godet J, Ragueneau M, Meyer C, Billecocq S, et al. Prospective evaluation of the connected biofeedback EMY Kegel trainer in the management of stress urinary incontinence. *Journal of Gynecology Obstetrics and Human Reproduction*. 2022; 51(2): 102280. <https://doi.org/10.1016/j.jogoh.2021.102280>
17. Özlü A, Yıldız N, Öztekin Ö. Comparison of the efficacy of perineal and intravaginal biofeedback assisted pelvic floor muscle exercises in women with urodynamic stress urinary incontinence. *Neurourology and Urodynamics*. 2017; 36(8): 2132-2141. <https://doi.org/10.1002/nau.23257>
18. Artymuk NV, Khapacheva SY. Device-assisted pelvic floor muscle postpartum exercise programme for the management of pelvic floor dysfunction after delivery. *The Journal of Maternal-Fetal & Neonatal Medicine*. 2022; 35(3): 481-485. <https://doi.org/10.1080/14767058.2020.1723541>
19. Siegel AC. Device and method for sensing, guiding, and/or tracking pelvic exercise. US20150196802A1 [Internet]. www.patents.google.com; 2015 Jul 16 [access 2024 Jul 24]. Available from: <https://patents.google.com/patent/US20150196802A1/en>
20. Begić M, Kapidžić-Bašić N, Hotić-Hadžiefendić A, Konjić A, Bojinović-Rodić D, Hudić I. Comparison of Kegel exercises and a combination of Kegel exercises with the use of the KegelSmart biofeedback device in the treatment of static urinary

incontinence. *Medicinski Glasnik*. 2023; 20(2): 276-281.
<https://doi.org/10.17392/1584-23>

21. Ong TA, Khong SY, Ng KL, Ting JRS, Kamal N, Yeoh WS, et al. Using the Vibrance Kegel Device with pelvic floor muscle exercise for stress urinary incontinence: a randomized controlled pilot study. *Urology*. 2015; 86(3): 487-491.
<https://doi.org/10.1016/j.urology.2015.06.022>
22. Hoffman C, Hoffman G, England M. Perineometer with wireless biofeedback. US20060036188A1 [Internet]. www.patents.google.com; 2006 Feb 16 [access 2024 Jul 24]. Available from: <https://patents.google.com/patent/US20060036188A1/en>
23. Schmidt AP, Sanches PRS, Silva DP, Ramos JGL, Nohama P. A new pelvic muscle trainer for the treatment of urinary incontinence. *International Journal of Gynecology & Obstetrics*. 2009; 105(3): 218-222. <https://doi.org/10.1016/j.ijgo.2009.01.013>
24. www.mddionline.com [Internet]. Vibrance Kegel Device [access 2024 Sep 16]. Available from: <https://www.mddionline.com/ivd/vibrance-kegel-device>
25. www.intimina.com [Internet]. KegelSmart™ – Intelligent Kegel Exerciser INTIMINA [access 2025 Feb 06]. Available from: <https://www.intimina.com/kegel-smart>
26. Voorham-van Der Zalm PJ, Voorham JC, van den Bos TWL, Ouwerkerk TJ, Putter H, Wasseret MNJM, et al. Reliability and differentiation of pelvic floor muscle electromyography measurements in healthy volunteers using a new device: the multiple array probe leiden (MAPLe). *Neurourology and Urodynamics*. 2013; 32(4): 341-348.
<https://doi.org/10.1002/nau.22311>
27. www.gillianmccabe.co.uk [Internet]. MAPLe [access 2025 Feb 5]. Available from: <https://www.gillianmccabe.co.uk/maple>
28. Dufour S, Fedorkow D, Kun J, Deng SX, Fang Q. Exploring the impact of a mobile health solution for postpartum pelvic floor muscle training: pilot randomized controlled

- feasibility study. JMIR Mhealth Uhealth. 2019; 7(7): e12587.
<https://doi.org/10.2196/12587>
29. www.magicsmotion.com [Internet]. Kegel Master Gen2 – MagicMotion [access 2024 Jul 24]. Available from: <https://www.magicsmotion.com/p-kegel-master-gen2.html>
30. Monsour M, Cornelius C, Noursalehi M. PeriCoach® structured programming and effect of clinical engagement [Internet]. Brisbane: Pericoach; 2019 [access 2024 Sep 16]. Available from: <https://www.pericoach.com/wp-content/uploads/2019/12/USANZ-2019-PeriCoach-RWD-Clinician-Impact-FIN-UPDATED-1April2019.pdf>
31. www.hatchery.com.sg [Internet]. Singapore: Hatchery Cribs Singapore. Elvie Trainer: award winning Kegel trainer for stronger pelvic floor [access 2025 Feb 3]. Available from: <https://www.hatchery.com.sg/products/elvie-trainer-award-winning-kegel-trainer-for-stronger-pelvic-floor>
32. www.advantiahealth.com [Internet]. Leva® Pelvic Health System [access 2025 Feb 3]. Available from: <https://www.advantiahealth.com/services/leva-pelvic-health-system/>
33. Weinstein MM, Dunivan G, Guaderrama NM, Richter HE. Digital therapeutic device for urinary incontinence: a randomized controlled trial. *Obstetrics & Gynecology*. 2022; 139(4): 606-615. <https://doi.org/10.1097/AOG.0000000000004725>
34. www.vivaltis.com [Internet]. [Home physiotherapist solution] [access 2025 May 8]. Available from: <https://www.vivaltis.com/phenix-nano> (in French).
35. Artymuk NV, Khapacheva SY. Pelvic floor muscle training after childbirth to prevent pelvic organ dysfunction: a prospective, single-center, open, randomized study. *Pharmateca*. 2019; 26(6): 6. <https://doi.org/10.18565/pharmateca.2019.6.47-52>
36. Yong Y, Wang Y. Kegel training system and Kegel trainer thereof. CN215961035U [Internet]. www.patents.google.com; 2022 Mar 8 [access 2025 Jul 2]. Available from:

[https://patents.google.com/patent/CN215961035U/en?q=The+Kegel+Training+System+\[China%2c+CN215961035U%2c+2021\]+](https://patents.google.com/patent/CN215961035U/en?q=The+Kegel+Training+System+[China%2c+CN215961035U%2c+2021]+)

ONLINE FIRST