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ORIGINAL ARTICLE

Home-based noninvasive pelvic floor muscle training device to assist women in performing Kegel exercise in the management of stress urinary incontinence

Huann-Cheng Horng[a,b,c], Wei-Ting Chao[b,c,d,e], Jui-Fa Chen[f], Chia-Pei Chang[b,c], Peng-Hui Wang[b,c,d,e], Po-Lun Chang[a,*]

[a]Institute of BioMedical Informatics, National Yang Ming Chiao Tung University, Taipei, Taiwan, ROC; [b]Department of Obstetrics and Gynecology, Taipei Veterans General Hospital, Taipei, Taiwan, ROC; [c]Faculty of Medicine, School of Medicine, National Yang Ming Chiao Tung University, Taipei, Taiwan, ROC; [d]Institute of Clinical Medicine, National Yang-Ming University, Taipei, Taiwan, ROC; [e]Institute of Clinical Medicine, National Yang Ming Chiao Tung University, Taipei, Taiwan, ROC; [f]Department of Information Engineering and Computer Science, Tamkang University, New Taipei City, Taiwan, ROC

Abstract

Background: Stress urinary incontinence (SUI) is a major health problem affecting approximately 50% of the female population over 45 years of age. We evaluated the therapeutic effects of a home-based non-invasive wireless sensor pelvic floor muscle training (PFMT) device with assisted Kegel exercise for SUI.

Methods: We included 60 women 40 to 60 years of age who were diagnosed with urodynamic SUI (mean pad test, 10.52 g). The PFMT device applicator was clamped on the upper inner thigh, and the patients could self-train at home. The signal was recorded and delivered to a 3G/4G smartphone via Bluetooth, which also allows guided feedback via the smartphone's voice. To evaluate the therapeutic effect, all patients completed the following questionnaires: a 3-day bladder diary, the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), the Urogenital Distress Inventory-Short Form, and the Incontinence Impact Questionnaire-7 (IIQ-7). One-hour pad test measurements were performed before the test (M0) and at 1 (M1), 2 months (M2), and 3 months (M3) after the PFMT device-assisted Kegel exercise.

Results: The 1-hour pad test and the scores of the ICIQ-SF, UDI-6, and IIQ-7 questionnaires were improved at M1, M2, and M3, compared with the M0 values. The mean value of the post-voiding residual urine (PVR) significantly decreased at M2 and M3. The subjective and objective improvement rates at M3 were 80% and 72%, respectively.

Conclusion: The data demonstrated that 3 months of Kegel exercise assisted with a home-based PFMT device improved the number and severity of episodes, PVR, and quality of life in patients with SUI, suggesting that this device might serve as an alternative non-invasive therapy for mild and moderate SUI.

Keywords: Home-based device; Kegel exercise; Pelvic floor muscle training; Stress urinary incontinence

1. INTRODUCTION

Stress urinary incontinence (SUI) is a major health problem affecting approximately 50% of the female population over 45 years of age.[1,2] Several movements can increase abdominal pressure on the bladder, thus leading to urine leakage in SUI, including sneezing, coughing, jumping, laughing, and exercising. Importantly, for this type of urinary incontinence, leakage is induced without bladder detrusor muscle contraction. SUI symptoms may affect a woman's physical and psychological status, and her personal and social activities.

Aging, vaginal delivery, obesity, heavy work, chronic pulmonary disease, and menopause are risk factors for SUI. The quality of life (QoL) of patients with SUI is severely impacted by restricted daily activities and unpleasant feelings and odors caused by contact with wet diapers, which easily cause discomfort and chronic infection of the urinary tract and pelvic genital organs.[3] SUI further affects sexual and personal behavior, thus causing shame, depression, reduced work efficiency, reduced employment, and the probability of entering a nursing home in old age.[4,5] Global healthcare expenditures for the treatment of urine incontinence are increasing. In the United States, the direct cost of treating patients with urinary incontinence is estimated to be as high as 20 billion US dollars per year.[6,7] There are currently many treatment methods, which are as follows: lifestyle changes and pelvic floor muscle training (PFMT) may be effective for mild symptoms; electrical stimulation and vaginal devices are minimally invasive methods for temporary symptom control; botulinum injections and fillers are less invasive and have short-term effects;

*Address correspondence. Dr. Po-Lun Chang, Institute of BioMedical Informatics, National Yang Ming Chiao Tung University, 155, Section 2, Linong Street, Taipei 112, Taiwan, ROC. E-mail address: polunchang@gmail.com (P.-L. Chang).

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and middle urethral sling correction has a long-term effect.[8] Each of these therapies has its strengths and limitations that should be considered according to individual needs, health status, and SUI severity, and to economic considerations.

Global health care spending for the treatment of this disease is increasing SUI. Dr. Arnold Kegel was the first to report successful improvement in women with SUI symptoms using pelvic floor muscle exercises in 1948. Later, different types of physiotherapy have been developed (such as biofeedback, electrostimulation, vaginal cones, and vaginal balls) for SUI therapy, with varying reported success rates. In a recent literature review, PFMT has been shown to improve SUI symptoms.[9] Most PFMT programs are performed under the regular control of physical therapists in physical therapy hospital centers, which may be time-consuming and not cost-effective.[10–12] Even the home-use Vibrance Kegel device is still inconvenient and not popular, because it needs to be inserted into the vagina in private rooms, and the long-term usage rate is not high.

A previous study[13] described a safe and effective first-generation non-invasive device for PFMT, which can help patients to perform rehabilitation at home, without medical assistance, and also assists doctors in collecting sensor data. In this study, we aimed to assess the effects of a second-generation home-based non-invasive PFMT device for assisted Kegel exercises in women with SUI. This PFMT device has several convenient features and can be used at any time without an isolated or private room. The entire rehabilitation device weighs only 160 g, including a 9-V battery weighing 42 g (Fig. 1A). It is clamped on the upper inner thigh as close as possible to the perineum. It can be operated while standing or sitting. The signal can be transmitted and recorded on a mobile smartphone through a Bluetooth interface, which also provides guided feedback via the smartphone's voice to encourage and help the patient in completing the training course.

The aim of this study was to evaluate the therapeutic effects of this second-generation device.

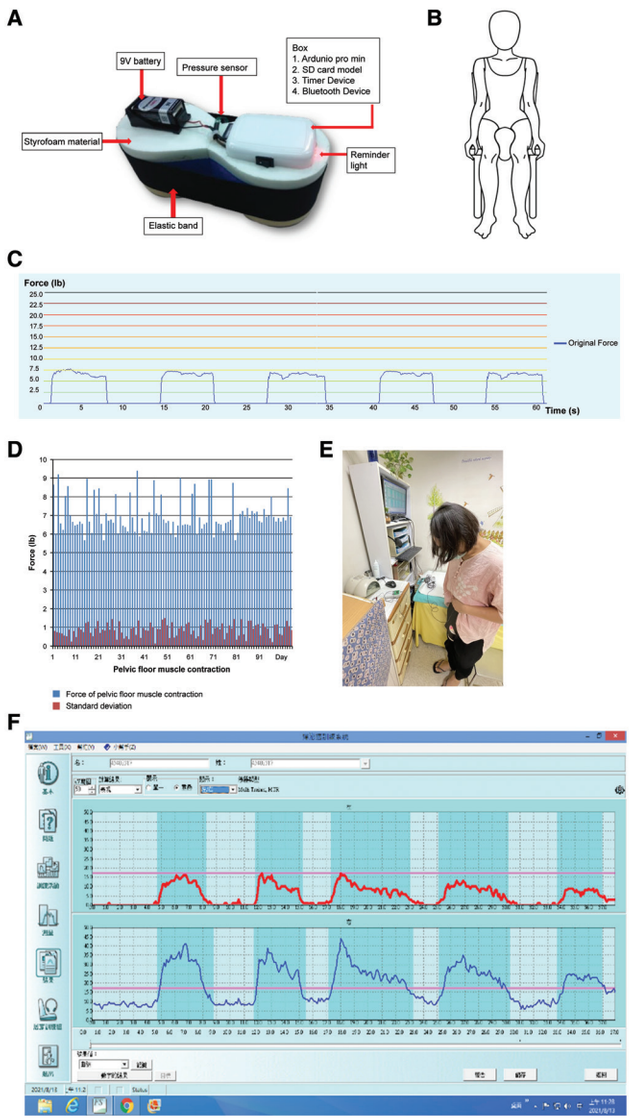

Fig. 1 Architecture of the pelvic floor muscle training (PFMT) transmission system. A, Architecture of the non-invasive wireless physical device (PMFT device). B, The physical device is clipped on the upper inner thigh close to the perineum. C, Daily signal of pelvic muscle contraction using the PFMT device, recorded by the smartphone. D, Summary of the quantized contraction force and its SDs captured by the PFMT device for 3 months. E, The double light on the PFMT device is a signal that the rehabilitation device is compressed by the upper thigh muscles. F, Signal of traditional biofeedback vaginal probe.

2. METHODS

This study was a prospective, single-arm clinical trial performed at a tertiary hospital center from January to May 2021. All patients provided informed consent before entering the study and had complete medical history record, physical examination, and blood tests at the hospital department. The study was approved by the Institutional Review Board of our institution (IRB approval date and number: TPEVGH IRB, 2021-06-012AC).

Female patients 40–60 years of age who were diagnosed with urodynamic stress incontinence at our gynecologic department were enrolled. Exclusion criteria were anti-incontinence or prolapse surgical history, pregnancy, active urinary tract infection or pelvic inflammatory disease, residual volume >100 mL, advanced pelvic organ prolapse (>POP-Q stage II), and comorbidities affecting the lower urinary tract, such as psychiatric disease, diabetes mellitus, neurological diseases, heart failure, or renal failure.

The physical and metabolic blood parameters associated with SUI symptoms were recorded.[14] The physical parameters assessed (Table 1) included age, parity, height, body weight, body mass index, and blood pressure. Blood parameters including glycated hemoglobin, fasting blood sugar, liver enzyme, renal function, and lipid profile were measured to investigate the baseline data of the participants.

We initially enrolled 76 patients, of which 15 were excluded due to failure to complete the study, and one due to refusal to proceed after signing the informed consent. Finally, 60 patients completed the study. They filled the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), the Urogenital Distress Inventory-Short Form (UDI-6-SF), and the Incontinence Impact Questionnaire-7 (IIQ-7); and completed a three-day bladder urinary diary. One-hour pad tests were performed before the study (M0), and at 1 (M1), 2 (M2), and 3 (M3) months after the study.

The home-based non-invasive wireless sensor PFMT device was designed under the instruction of two authors (J.F.C. & P.L.C.). The architecture of the PFMT transmission system features three layers (Fig. 1), the sensing layer, the network layer, and the application layer. Through wired or wireless transmission technology, the rehabilitation process and its results are transmitted to the patients' family members or caregivers; in addition to the rehabilitation results, the patient's actions and environment during rehabilitation are also transmitted to the hospital or rehabilitation center to provide reference data for physicians or rehabilitation practitioners. When doctors or rehabilitation practitioners receive the transmitted data, they can track and observe whether the patient is regularly performing the rehabilitation, and, at the same time, analyze whether the patient's actions are correct, enabling them to provide feedback based on the rehabilitation status of the patient and the rehabilitation plan.

The physical device is a non-invasive wireless sensor device, consisting a gourd-shaped Styrofoam piece, an elastic band, a 9-V battery, and a wireless signal transmission box. The device contains a pressure sensor connected to an Arduino control board to measure the contraction force of the pelvic floor muscle, as illustrated in Fig. 1A.

The three layers of the device architecture are as follows: (1) sensing layer: a pressure sensor is used to detect contraction power and duration. Using the physical device shown in Fig. 1B during pelvic floor muscle contraction using a clamped PFMT device (between the upper inner thighs, as close as possible to the perineum), the strength and duration of the muscle contraction force can be measured; (2) network layer: a Bluetooth device is used to transmit the sensor data to smartphones, laptops, or tablets for storage, real-time analysis, and feedback. The contraction data can be sent directly to the hospital server via a smartphone. In this way, we can track the patient's recovery in real-time and provide appropriate treatment. If the Bluetooth device fails to connect to a smartphone or tablet, the same data can be obtained from the secure digital card in the box of the device; and (3) application layer: This layer is divided into two systems, that is, server and client. The server is an intelligent medical treatment system located at the hospital, whereas the client is located in the home rehabilitation system.

All 60 patients learned to control the PFMT device and downloaded the application (APP) to a personal smartphone, then performed every day for 3 months the following standard Kegel exercise procedure:

(1) Make sure your bladder is empty, then stand or sit;
(2) Tighten your pelvic floor muscles after wearing the PFMT device;
(3) Hold tight and count 3–5 seconds. Relax the muscles and count again 3–5 seconds;
(4) Repeat 10 times, three times per day (morning, afternoon, and night).

The daily contraction signal (Fig. 1C) and the entire 3-month course of the signal were integrated and recorded (Fig. 1D).

Table 1

Characteristics of the study population (N = 60) at baseline (M0)

Parameter	Mean ± SE	Range
Age (years)	53 ± 5.53	40-60
Parity	2.3 ± 0.2	1-4
Height (cm)	157 ± 6.14	148-172
Weight (kg)	55.45 ± 7.51	43-71
BMI (kg/m^2)	26.4 ± 2.88	19.5-29
Systolic pressure (mmHg)	120.24 ± 18.85	100-122
Diastolic pressure (mmHg)	73.0 ± 11.5	60-80
MAP (mmHg)	90.51 ± 11.50	70-110
Serum parameter		
HbA1c (%)	5.60 ± 0.01	4-6
AC sugar (mg/dL)	99.4 ± 2.5	65-108
BUN (mg/dL)	12.05 ± 0.45	8-20
Creatinine (mg/dL)	0.71 ± 0.03	0.42-1.01
GOT (AST) (IU/L)	25.3 ± 1.2	10-41
GPT (ALT) (IU/L)	23.2 ± 1.3	10-40

Data are shown as mean ± standard error (SE) and range.
AC = ante cibum (before meals); BMI = body mass index; BUN = blood urea nitrogen; MAP = mean arterial pressure; HbA1c = glycated hemoglobin; GOT = glutamate oxaloacetate transaminase; GPT = glutamate pyruvate transaminase.

2.1. The mechanism of this PFMT device

This lady is wearing a PFMT device and traditional biofeedback vaginal probe. When the upper and inner thigh muscles clamp the PFMT device, the anal muscles contract at the same time, which drives the contraction of the pelvic levator anus muscles. This can be demonstrated from the demonstration (Fig. 1E). The double light on the PFMT device is a signal that the rehabilitation device is compressed by the upper thigh muscles. At the same time, the vaginal probe is also contracted by the levator anus muscle of the pelvis, which can be seen on the display signal of monitor (Fig. 1F).

3. RESULTS

Between January and June 2021, a total of 60 female patients diagnosed with pure SUI with 1 hour pad test >2 g were enrolled in this study. The baseline parameters of the patients before the study (M0) are summarized in Table 1, and were within normal limits. The mean age of the enrolled patients was 53.0 ± 5.53

Table 2

Measurement results of the study population (N = 60)

Parameter	SUI (mean ± SE)			
	M0	M1	M2	M3
1-hour pad test (g)	10.52 ± 3.04	6.12 ± 0.85[a]	5.30 ± 1.02[a]	4.20 ± 0.30[a]
3-day bladder diary				
Intake (mL)	1886.25 ± 88.21	1855 ± 95.21	1921 ± 90.21	1845 ± 11201
Output (mL)	1780 ± 91.45	1845 ± 89.89	1804 ± 92.45	1785 ± 98.21
Average voiding volume (mL)	221 ± 12.21	229 ± 20.10	228 ± 20.61	230 ± 30.1
Urinary frequent (times/24 hours)	7.54 ± 0.35	7.11 ± 0.56	6.15 ± 0.68[a]	6.39 ± 0.44[a]
Nocturia (times)	1.11 ± 0.11	1.05 ± 0.14	0.96 ± 0.20	0.80 ± 0.18[a]
Functional bladder capacity (mL)	365.82 ± 15.41	370 ± 18.21	370 ± 20.14	373 ± 30.12
Post-voiding residual urine (mL)	48.45 ± 5.1	43 ± 4.5	34.9 ± 3.8[a]	28.45 ± 3.3[a]

Values are expressed as mean ± SE.

[a]$p < 0.05$ vs baseline (M0); M, month; M0, baseline; M1, 1 month of PFMT; M2, 2 months of PFMT; M3, 3 months of PFMT; SE = standard error.

years. The values of all serum parameters at baseline are shown in Table 1. Serum data were also within the normal range.

The involuntary bladder leakage of urine during physical activity was calculated using a pad test. The average one-hour pad test was significantly reduced from 10.52 ± 3.04 g to 6.12 ± 0.85 g ($p < 0.05$), 5.30 ± 1.02 g ($p < 0.05$), and 4.20 ± 0.30 g ($p < 0.05$) at M1, M2, and M3, respectively (Table 2 and Fig. 2A). A significant improvement in urine leakage was thus observed at M1, M2, and M3.

The results of the analysis of 3-day urinary diaries at M0, M1, M2, and M3 are presented in Table 2. There was no significant difference in the mean average voiding volume or functional bladder capacity among the time points. However, the mean post-voiding residual urine (PVR) was noticeably decreased from 45.45 ± 5.1 mL (M0) to 34.9 ± 3.8 mL ($p < 0.05$) and 28.45 ± 3.3 mL ($p < 0.05$) at M2 and M3, respectively. Moreover, urinary frequency was significant decreased from 7.54 ± 0.35/day (M0) to 6.15 ± 0.68/day ($p < 0.05$) and 6.39 ± 0.44/day ($p < 0.05$) at M2 and M3. The frequency of nocturia also significantly decreased from 1.11 ± 0.11 times (M0) to 0.80 ± 0.18 times ($p < 0.05$) at M3. These findings indicated that subjects with SUI exhibited a trend of decreased PVR, urinary frequency, and nocturia, as reported in bladder diaries, after PFMT treatment.

We also investigated the relationship between PFMT device treatment and subjective evaluation using the ICIQ-SF, UDI-6-SF, and IIQ-7 scores, which revealed significant improvement at M1, M2, and M3 (Table 3 and Fig. 3A–C). The ICIQ-SF score was significantly decreased from 10.54 ± 0.56 to 6.44 ± 0.62 ($p < 0.05$), 6.50 ± 0.77 ($p < 0.05$), and 5.40 ± 0.68 ($p < 0.05$) at M1, M2, and M3, respectively. The UDI-6-SF score was decreased from 7.31 ± 0.54 at M0 to 4.42 ± 0.56 ($p < 0.05$), 3.51 ± 0.58 ($p < 0.05$), and 3.30 ± 0.73 ($p < 0.05$) at M1, M2 and M3, respectively. The IIQ-7 score was decreased from 7.54 ± 0.79 at M0 to 4.28 ± 0.70 ($p < 0.05$), 3.34 ± 0.87 ($p < 0.01$), and 3.12 ± 0.71 ($p < 0.05$) at M1, M2, and M3, respectively. When examining questionnaire data, we found that the bother-related questionnaire scores (ICIQ-SF, UDI-6-SF, and IIQ-7) were significantly improved at M1, M2, and M3, compared with the M0 values ($p < 0.05$).

3.1. Statistical analysis

The questionnaire scores (ICIQ-SF, UDI-6-SF, and IIQ-7), the 1 hour pad test, PVR, and 3-day urinary diaries were used to

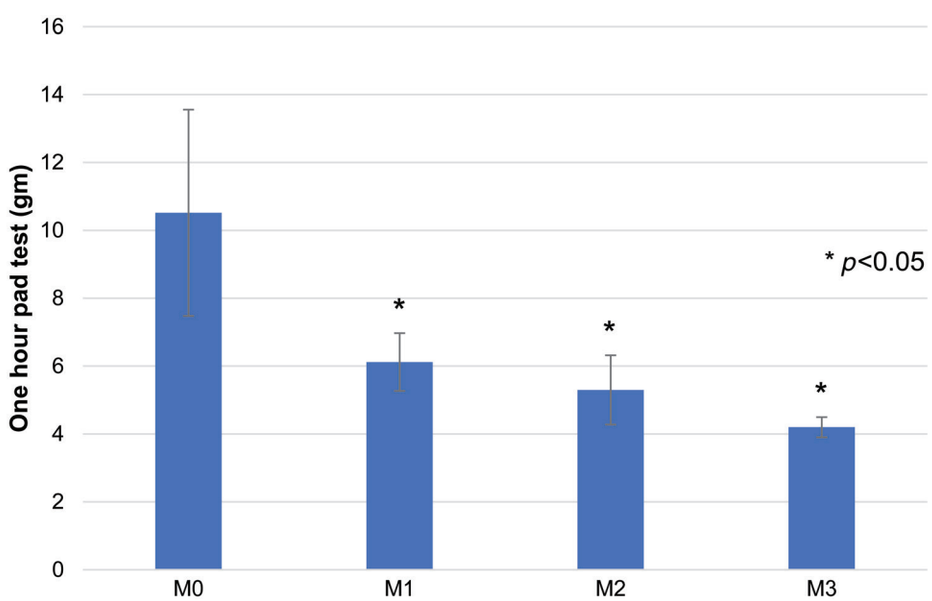

Fig. 2 One-hour pad test results of the study population (N = 60) after 1 month (M1), 2 months (M2), and 3 months (M3). Values are means ± SE. *$p < 0.05$ compared to the baseline (M0) by paired *t*-test. SE = standard error.

Table 3

International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) score, Urogenital Distress Inventory (UDI-6)-Short Form, and Incontinence Impact Questionnaire-7 (IIQ-7) score at 1 (M1), 2 (M2), and 3 months (M3) after treatment

	M0	M1	M2	M3	*p*
ICIQ-SF score	10.54 ± 0.56	6.44 ± 0.62[a]	6.50 ± 0.77[a]	5.40 ± 0.68[a]	<0.05
UDI-6 SF score	7.31 ± 0.54	4.42 ± 0.56[a]	3.51 ± 0.58[a]	3.30 ± 0.73[a]	<0.05
IIQ-7 score	7.54 ± 0.79	4.28 ± 0.70[a]	3.34 ± 0.87[a]	3.12 ± 0.71[a]	<0.05

Values are shown as means ± SE.

[a]$p < 0.05$; compared to the baseline score (M0) by paired *t*-test. N = 60.

evaluate the efficacy and safety of the treatment performed with the PFMT device in patients with SUI. To clarify the effect of PFMT device therapy on SUI, we compared the pretreatment and posttreatment scores (M1 and M0, M2 and M0, M3 and M0) as intra-group comparisons. Paired t-tests were used to analyze intragroup differences pretreatment and posttreatment and the related comparison *p*-values.[15,16] For all statistical analyses, statistical significance was set at $p < 0.05$. All statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC, USA).

4. DISCUSSION

No single effective treatment is widely recommended for patients with SUI. The management options include PFMT, biofeedback, electro-stimulation, vaginal laser therapy, bulking agent, and mid-urethral sling surgery. In 2017, the efficiency with acceptable morbidity of synthetic slings for SUI was acknowledged by the European Urology Association.[17] However, the treatment entails surgical risks and complications such as bladder perforation, hematoma, bowel injury, vaginal mesh extrusion, de novo urgency, urinary tract infections, and voiding dysfunction, with incidences ranging from 4.3% to 75.1%.[18]

The pelvic floor muscles, which include the levator ani and coccyx muscles, are essential for supporting the pelvic organs, but may become weak due to age, pregnancy, vaginal delivery, or surgery. As a result, patients may suffer from urinary incontinence and pelvic organ prolapse. Kegel exercises were first described by Arnold Kegel in 1948 and were used to strengthen the pelvic floor muscles. The results showed that these exercises help prevent uterine prolapse, cystocele, rectocele, and urinary

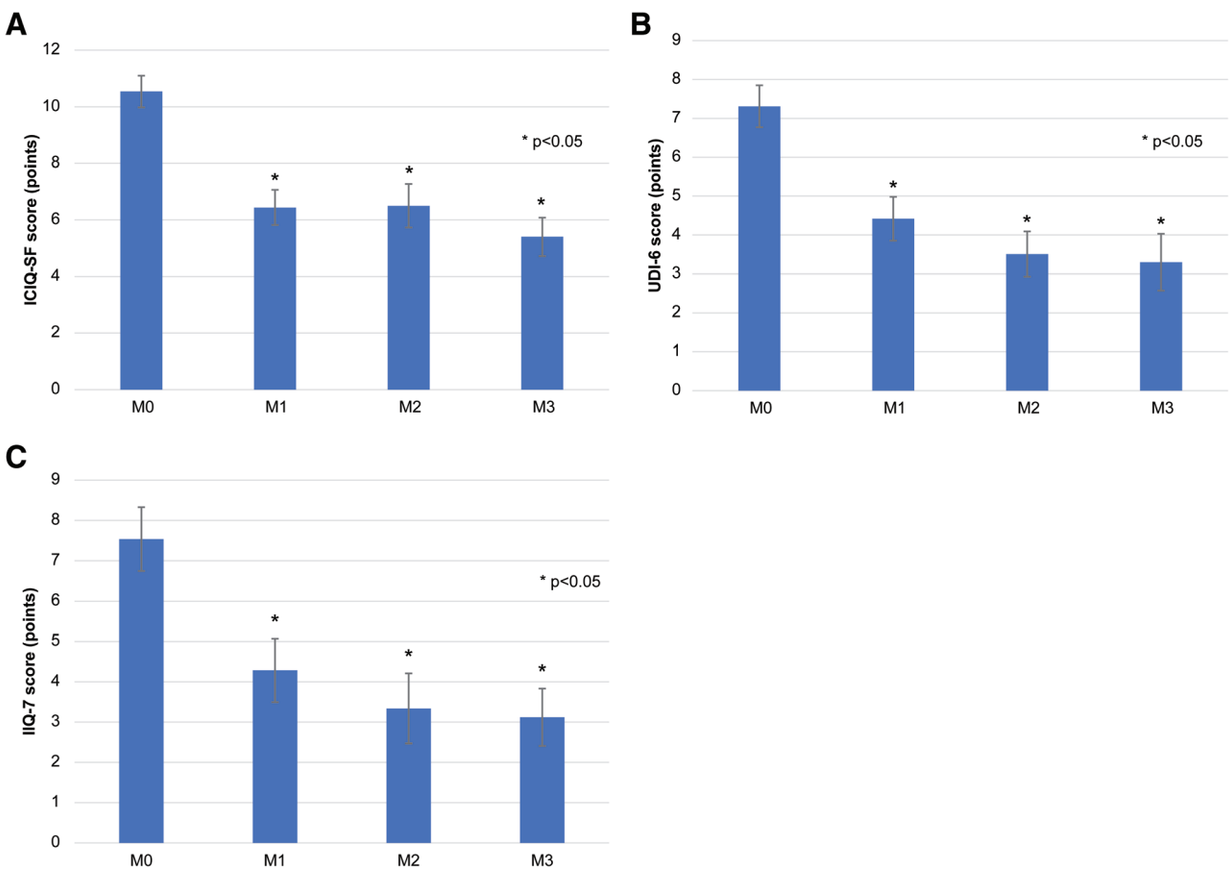

Fig. 3 A, International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) score at 1 (M1), 2 (M2), and 3 (M3) months after treatment. Values are shown as means ± SE. *$p < 0.05$ compared to baseline (M0) by paired *t*-test. N = 60. B, Urogenital Distress Inventory (UDI-6)-Short Form score at M1, M2, and M3. Values are shown as means ± SE. *$p < 0.05$ compared to the M0 values by paired *t*-test. N = 60. C, Incontinence Impact Questionnaire-7 (IIQ-7) score at M1, M2, and M3. Values are shown as means ± SE. *$p < 0.05$ compared to the M0 values by paired *t*-test. N = 60. SE = standard error.

Table 4

Subjective improvement as measured by the UDI-6 score at 1 (M1), 2 (M2), and 3 (M3) months after treatment and objective improvement as assessed by the 1-hour pad test at the same time points (N = 60)

	M1	M2	M3
Subjective improvement	68%	71%	80%
Objective improvement	65%	68%	72%

UDI-6 = Urogenital Distress Inventory.

incontinence.[19] Ashton-Miller et al[20] stated that these exercises can strengthen a woman's urethral sphincter and support system and prevent urinary incontinence and genital prolapse. The support system is composed of the pelvic floor muscles, vaginal wall, pelvic arch fascia, and pelvic fascia.[20] Although Kegel exercise was recommended by the International Continence Society, there are no standard exercise parameters regarding muscle contraction and relaxation, such as frequency, duration, repetitions, and positions. Without immediate clinical improvement and being unable to quantitatively check or record their own exercise power and frequency, patients tend to easily give up the Kegel exercises.[21] The right approach, continuous maintenance, and scientific recording systems are of paramount importance. Therefore, alternative therapies, such as shock wave[22] or adjuvant home-based device-assisted Kegel exercises, need to be developed, since a lifelong practice of Kegel exercises might be needed to help manage SUI without performing invasive surgery.

Kegel exercise is economical and effective for mild to moderate urinary incontinence.[23] Therefore, our SUI cases were in the range of 2-20 g (mean 10.52 g) of urine leakage as assessed by the 1-hour pad test. Women between 40 and 60 years of age are knowledgeable and can easily learn the PFMT procedure and control the smartphone APP by themselves. During the first month of the study period, our study nurse regularly asked about the status of home use by phone and instructed the patients on its correct use. If the problem could not be solved over the phone, the patient was asked to return to the hospital. In the second and third months, there were almost no problems with the use of this PFMT device. There are more than half of our cases of SUI ever learned the information of kegel exercise by medical professionals, Internet information or book introduction with more easy to learn our PFMT device training program and less of cases drop out.

The ICIQ-SF, UDI-6-SF, and IIQ-7 score systems are commonly used to evaluate the quality and impact on life of urinary incontinence. The results revealed that the objective improvement rate, as measured by the 1-hour pad test, after 1, 2, and 3 months of home-based PFMT device-assisted Kegel exercises were 65%, 68%, and 72%, respectively, and most patients were

Table 5

Summary of the studies of PMFT devices for SUI

Editor/year	Sugaya et al[24]/2003	Kashanian et al[12]/2011	Dufour et al[26]/2015	Ong et al[25]/2019	Present study/2021
Type of study	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial (from week 6 postpartum to week 13 postpartum)	Randomized controlled trial	Prospective cohort study
Patient grouping	Control group (PFMT) (n = 20) Device group (PFMT + device) (n = 21)	Control group (Kegel exercise) (n = 50) Device group (Kegelmaster) (n = 41)	Control group (PFMT) (n = 10) Device group (PFMT + iBall device) (n = 13)	Control group (PFMT) (n = 19) Device group (PFMT + Vibrance Kegel device) (n = 21)	Single arm (home-based non-invasive PFMT device) (n = 60)
Duration of intervention	8 weeks	12 weeks	16 weeks	16 weeks	12 weeks
PFMT device mode	Rapid mode (pelvic floor muscle contraction and relaxation every 2 seconds for 1 minute) Slow mode (pelvic floor muscle contraction every 10 seconds and relaxation every 10 seconds for 1 minute)	Six to 8 seconds of contraction with 6 seconds of rest for 15 minutes, twice daily	A number of activities that could strengthen the pelvic floor muscle were tracked and monitored.	Slow mode (pelvic floor muscle contraction for 10 seconds and relaxation for 10 seconds) Speed mode (pelvic floor muscle contraction and relaxation every 2 seconds) Three to five sets of each type of training	Pelvic floor muscle contraction and relaxation every 3-5 seconds for ten times Three times daily
Improvement of urinary incontinence score (e.g., UDI-6, IIQ-7)	Control group: Non-significant change Device group: $p = 0.004$	Control group: $p = 0.000$ Device group: $p = 0.000$	Control group: $p = 0.009$ Device group: $p = 0.004$	Control group: $p = 0.001$ Device group: $p < 0.001$	Improvement with significance
Improvement of pelvic floor muscle strength or pad test results	Control group: non-significant change Device group: $p = 0.001$	Control group: $p = 0.000$ Device group: $p = 0.000$	Control group: $p = 0.24$ Device group: $p = 0.27$	Control group: $p = 0.059$ Device group: $p = 0.001$	Improvement with significance
Summary	Device maybe useful for managing SUI	These two methods are effective for SUI improvement without significant differences between the two	Only the UDI-6 score significantly changed in both groups Device was not superior to basic PFMT Technical difficulties, cumbersome initiation process, and discomfort from device use are reasons preventing acceptability	Device showed early improvement of SUI score and pelvic muscle strength Device proved useful as an adjuvant for PFMT	Our device might serve as an alternative non-invasive therapy for mild and moderate SUI

willing to introduce family or friends to this treatment (Table 4). There were 10 cases of surgical sling plan, and 18 cases of vaginal laser plan, which were canceled.

The study indicated that the PFMT device could play an effective adjuvant role in improving the QoL and reducing bothersome urinary symptoms as demonstrated by the results of the questionnaire surveys, pad tests, bladder diaries and exhibited significant decrease in mean PVR by PFMT.

In Table 5, we summarized previous studies on non-invasive device-assisted PFMT for SUI. For each study, we report the type of study, patient grouping, duration of intervention, PFMT device mode, improvement of urinary incontinence score, improvement of pelvic floor muscle strength, or pad test. Sugaya et al[24] designed a device assisting the PFMT and randomly assigned patients to the device and control groups with a follow-up of 8 weeks. In the device group, the episodes of daily urinary incontinence, daily number of pads used, and pad weight improved significantly, with high satisfaction. Sugaya et al supported this device as an adjuvant therapy for SUI. Ong et al[25] also designed a Vibrance Kegel device showing significant early improvement in SUI score and pelvic muscle strength, proving such device to be useful as an adjuvant therapy for SUI.

However, Kashanian et al[12] designed a Kegelmaster device, which showed no significant difference from the traditional PFMT alone. PFMT with or without the Kegelmaster device was effective for the improvement of SUI. Dufour et al[26] designed an iBall device-assisted PFMT for women with SUI at 6 to 13 weeks postpartum. At 16 weeks, compared with baseline, only the UDI-6 score improved significantly in both groups. Technical difficulties, a troublesome initiation process, and discomfort from device use are common reasons preventing device acceptability. Our home-based, non-invasive device led to a significant improvement in SUI score, pad test results, and QoL. In contrast to previous studies, our patients showed high acceptance of the device and were satisfied with the outcome of PFMT.

The current study had some limitations. It was a single-arm study, without randomized controls and a small number of cases. The benefit of this PFMT device remains to be confirmed in larger prospective studies and needs validation. This study analyzed only short-term follow-up outcomes. Therefore, the durability of these effects and the long-term results are still unclear.

In conclusion, the current study demonstrated the efficacy of using a PFMT device for female SUI in a short follow-up period. It is a promising alternative to invasive surgical interventions with potentially curative properties to the weakened pelvic floor muscles in patients with mild and moderate SUI.

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