Development of a pelvic floor muscle strength evaluation device

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Introduction

Stress urinary incontinence (SUI) is defined as involuntary loss of urine on effort or physical exertion, or on sneezing or coughing. SUI is a common and distressing condition among women and can have a considerable impact on their quality of life (QOL). In a previous systematic review, pelvic floor muscle training (PFMT) was recommended as the first option for treatment of SUI. Biofeedback has been developed with the purpose of making the patients more aware of muscle function, and to enhance and motivate patient's effort during training. In our previous study, we had developed and validated a pelvic floor muscle strength evaluation device and found that the vaginal pressure level highly correlated with muscle strength assessed by two experienced examiners using the modified Oxford grading system. However, squeeze pressure measurement can be invalid due to abdominal pressure from abdominal wall muscle contraction effect. Therefore, we would like to develop a device that can measure vaginal pressure and abdominal wall muscle activity simultaneously and test this device in clinical setting.

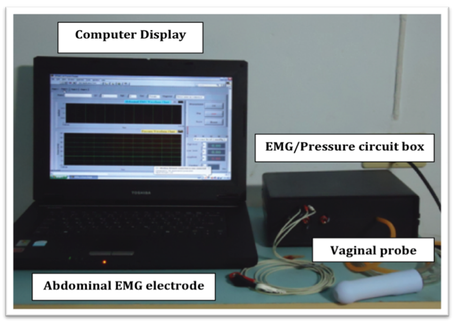
Objectives

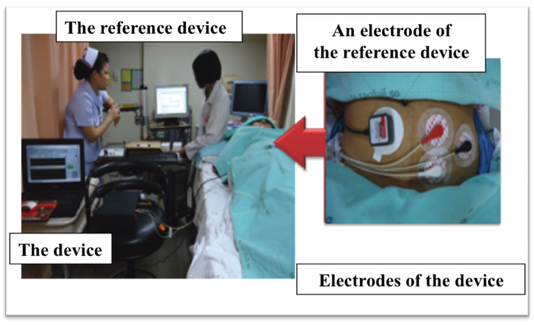
(1) To validate the pelvic floor muscle strength evaluation device and
(2) To investigate the effect of using this device in aiding pelvic floor muscle training on symptoms, quality of life and pelvic floor muscle strength in women with stress urinary incontinence.

Materials and Methods

In this study, our device was designed to measure pressure changes in vagina in response to pelvic floor muscle contractions using air-pressure balloon and abdominal wall muscle activities using surface electromyography (EMG). The pressure and EMG were detected, analyzed and display as real-time waveforms simultaneously on a screen.

To test the accuracy of the device, for vaginal pressure measurement, a Mercury sphygmomanometer was used as a gold standard and for abdominal wall muscle activity, a standard biofeedback machine was used as a reference device.

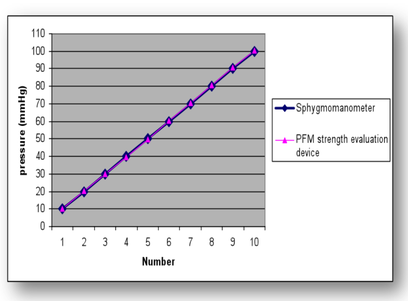


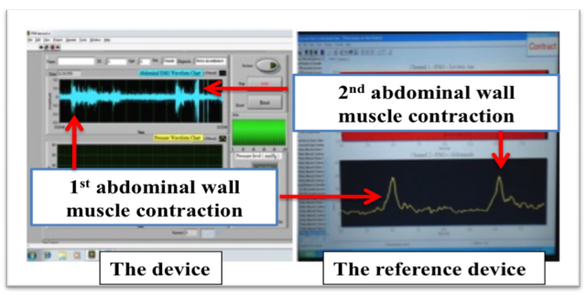


A randomized, controlled trial was conducted. Sixty-one women with stress urinary incontinence symptoms were recruited. All women were individually given verbal information and written instructions about pelvic floor muscle home exercise, and were asked to exercise three times every day for 16 weeks. Then, they were randomly divided into two groups undergoing PFMT with a single 15-minute biofeedback session (PMFT + biofeedback group) or without biofeedback (PFMT group). They were asked to rate their symptoms severity and complete the Thai version of incontinence-specific quality of life questionnaire (I-QOL) at first visit and after 16 weeks of the study. Pelvic floor muscle strength and abdominal wall muscle activity measurements were taken with the device at baseline and at 8 weeks and 16 weeks after treatment.

Results

Firstly, the device was tested in 10 subjects for its' accuracy. The accuracy of vaginal probe pressure perineometry was 98% compared to a standard sphygmomanometer at pressure range 0-100 mmHg. Our device could detect abdominal wall muscles activities at 10 ms (100 Hz), 20 ms (50 Hz) and 50 ms (20 Hz). The sensitivity was lower than the reference biofeedback machine.





Then we proceeded to the clinical setting. At baseline, there were no significant differences in age, body mass index, parity and all outcome parameters between the two groups. The mean age was 47.77 ± 7.08 years. One participant from each group dropped out, one withdrew because the protocol was found to be too demanding and the other one lost to follow-up after first visit. After 8 and 16 weeks of treatment, there were statistically significant intra-group differences in the maximum vaginal squeeze pressure in both groups. However, the inter-group differences were not demonstrated at week 8 and week 16 ($P > 0.05$). The proportion of women who performed pelvic floor muscle exercise correctly was significantly higher in the PFMT + biofeedback group (72.41%) compared to the PMFT group (21.88%) at week 16 ($P < 0.05$).

Table 1 Vaginal squeeze pressure at baseline, week 8 and week 16

Pressure (mmHg)	PFMT + Biofeedback		PFMT	
	Mean	SD	Mean	SD
At baseline	23.02	9.61	22.69	8.83
Week 8	27.04	15.57	26.21	10.76
Week 16	30.85	12.49	28.83	12.68

$P > 0.05$ between the two groups

Women in both groups reported improvement of incontinence symptoms and I-QOL scores after 16 weeks of treatment.

Table 2 Incontinence-specific quality of life questionnaire (I-QOL) score at baseline and week 16

Subscale Scores	PFMT + Biofeedback		PFMT	
	At baseline	Week 16	At baseline	Week 16
Avoidance and limiting behaviors	28.14 ± 7.18	36.79 ± 3.99	27.44 ± 6.44	35.38 ± 6.92
Psychological impacts	36.41 ± 8.51	42.55 ± 5.09	34.88 ± 7.35	42.13 ± 6.34
Social embarrassment	16.76 ± 5.55	22.31 ± 3.42	15.88 ± 5.25	22.16 ± 4.19
Overall	53.92 ± 18.26	72.57 ± 10.81	51.08 ± 15.93	70.60 ± 15.49

$P > 0.05$ between the two groups

Interpretation of results

The pelvic floor muscle strength evaluation device has been developed and tested in the clinical setting. It provided accurate vaginal pressure and adequate abdominal wall muscle activity measurements.
Pelvic floor muscle training with or without biofeedback showed positive effects on reducing severity of stress urinary incontinence, improving quality of life and increasing pelvic floor muscle strength. In our study, no significant difference was found between groups with regards to symptoms severity, quality of life and pelvic floor muscle strength in women with stress urinary incontinence after 16 weeks of treatment. It might be explained by the non-intensive biofeedback used in this study compared to previous reports. Nevertheless, nearly three fourths of women in the biofeedback group did not contract their abdominal muscles during pelvic floor exercises.

Concluding message

The simple pelvic floor muscle strength evaluation device might be helpful in pelvic floor muscle training in low resource setting. Pelvic floor muscle training with or without biofeedback can be an effective and safe conservative treatment option for stress urinary incontinence. The only benefit of using non-intensive biofeedback is that women could control their pelvic floor and abdominal wall muscle during pelvic floor exercises.