

Development of a Pelvic Floor Muscle Strength Evaluation Device

Jittima Manonai MD*, Sakuntala Kamthaworn MSc**,
Kuson Petsarb MSc**, Rujira Wattanayingcharoenchai MD*

*Department of Obstetrics & Gynaecology, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

** Biomedical Instrumentation Research and Development Center, Institute of Molecular Biosciences,
Mahidol University, Bangkok, Thailand

Objective: To validate the device and investigate the effect of this device on symptoms, quality of life, and pelvic floor muscle strength.

Material and Method: The device was designed to measure vaginal pressure changes using air-pressure balloon and abdominal wall muscle activities using surface electromyography. 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 in sixty-one women with stress urinary incontinence. They were randomly divided into two groups undergoing PFMT with a single 15-minute biofeedback session (BF + PFMT group) or without biofeedback (PFMT group). The pelvic floor muscle strength, abdominal wall muscle activity and incontinence-specific quality of life questionnaire (I-QOL), measurements were evaluated at baseline and at 8- and 16-week after treatment.

Results: The accuracy of vaginal probe pressure perineometry was 98% compared to a standard sphygmomanometer. The device could detect abdominal wall muscles activities at 10 milliseconds (100 Hz), 20 milliseconds (50 Hz), and 50 milliseconds (20 Hz). 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. The proportion of women who performed pelvic floor muscle exercise correctly was significantly higher in the BF + PFMT group (72.41%) compared to the PFMT group (21.88%) at week 16 ($p < 0.05$).

Conclusion: The simple pelvic floor muscle strength evaluation device might be helpful in pelvic floor muscle training in a low resource setting.

Keywords: Device, Pelvic floor muscle, Quality of life, Stress urinary incontinence, Biofeedback

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Stress urinary incontinence (SUI) is defined as involuntary loss of urine on effort or physical exertion, or on sneezing or coughing⁽¹⁾. SUI is a highly prevalent and distressing condition among women and can have a considerable impact on their quality of life (QOL)^(2,3). In a previous systematic review, pelvic floor muscle training (PFMT) was recommended as the first-line conservative treatment of SUI⁽⁴⁾. In addition, women receiving regular supervision are more likely to report improvement than women doing pelvic floor muscle exercise with little or no supervision⁽⁵⁾. Biofeedback (BF) 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. As a result, biofeedback may provide benefit in addition to pelvic floor muscle training⁽⁶⁾. Nonetheless, pelvic floor training experts and biofeedback machines may not always be available in low resource settings. From our previous study, the authors 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⁽⁷⁾. 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 a clinical setting.

The objectives of the present study were
1) to validate the pelvic floor muscle strength

Correspondence to:

Manonai J, Department of Obstetrics & Gynaecology, Faculty of Medicine, Ramathibodi Hospital, Rama VI Road, Ratchathewi, Bangkok 10400, Thailand.

Phone: +66-2-2012167, Fax: +66-2-2012579

E-mail: rajmo@mahidol.ac.th

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.

Material and Method

Device

In the present 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), respectively. Surface EMG data were recorded from the abdominal muscles using bipolar pairs of silver-silver chloride electrodes. The pressure and EMG were detected, analyzed, and displayed as real-time waveforms simultaneously on a screen (Fig. 1). To test the accuracy of the device, for vaginal pressure measurement, a mercury sphygmomanometer was used as a gold standard. The standard for comparison of the abdominal wall activities was the measurement of rectus abdominis and transversalis muscle activities using a standard biofeedback machine. The measurements were performed in the supine position. Abdominal wall muscle activity measurements were recorded in triplicate using both devices at the same time. Then the sensitivity was calculated.

Subjects

A randomized, controlled trial was conducted. The present study was approved by the Ethical Clearance Committee on Human Rights Related to Researches Involving Human Subjects of Faculty of Medicine Ramathibodi Hospital, Mahidol University. Participants were recruited from the urogynecology

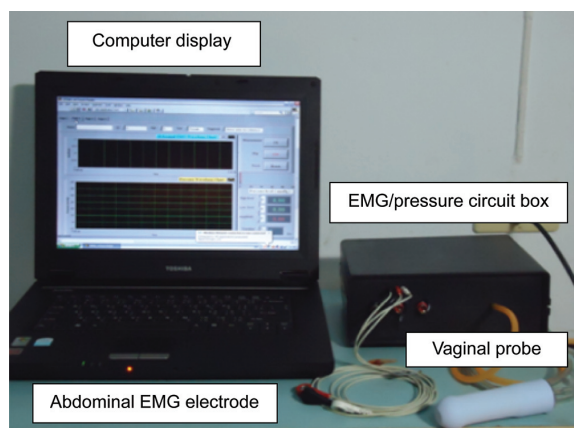


Fig. 1 Pelvic floor strength evaluation device.

clinic as well as in response to public advertising. Inclusion criteria were SUI diagnosed according to the International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction⁽¹⁾ and a leakage episode occurring more than once a week. Exclusion criteria were pregnancy, previous pelvic surgery for urology or gynecology in the past year, concomitant treatment for SUI during the trial period, neurological or psychiatric disease, urinary tract infection, any severe disease such as malignancy, and inability to understand the instructions. They were recruited and followed during a period between August 2012 and March 2013. All eligible women gave written consent before entering the study.

Randomization was performed by a person not involved in the study using a random numbers table, in blocks of four. The computer randomization sequence was generated independently of the investigators. In this type of intervention, the participants and the primary investigator (JM) involved in the intervention were aware of the group allocation. While questionnaire interviewers and outcome assessors were blinded in the present study.

Intervention

Women with stress urinary incontinence symptoms were recruited. All participants visited at least three times (at 0, 8, and 16 weeks). At the first visit, they were individually given verbal information and written instructions about pelvic floor muscle home exercise and a training diary. They were asked to exercise three times every day for 16 weeks. Each time consisted of sustained maximal contractions with at least 5-second hold and 10-second relaxation for 5-10 minutes, followed by 3-5 rapid maximal contractions with 2-second hold and 4-second relaxation as strength and endurance training. All participants were required to keep a diary to maintain their motivation during treatment and for adherence evaluation. Then, they were randomly divided into two groups undergoing PFMT with a single 15-minute biofeedback session (BF + PFMT group) or without biofeedback (PFMT group).

Each participant in the BF + PFMT group received individual verbal information about pelvic floor anatomy, muscle localization, and function, with the use of illustrations from the primary investigator (JM). Additionally, they learnt how to contract the pelvic floor muscle with the assistance of the pelvic floor muscle strength evaluation device. Using the

device, the vaginal squeeze pressure and abdominal muscle activity signals were visible on the computer screen. They confirmed correct contraction and relaxation by looking at the vaginal pressure and muscle activity signals themselves. This was considered as a non-intensive biofeedback since the whole process took 15 minutes.

Outcomes

As primary outcome measures, pelvic floor muscle strength using maximum vaginal squeeze pressure and abdominal wall muscle activity measurements were taken with the device at baseline and at 8 weeks and 16 weeks after treatment. Secondary outcomes of interest were the quality of life and symptoms severity. Participants were asked to complete the validated Thai version of incontinence-specific quality of life questionnaire (I-QOL)^(8,9) at first visit and after 16 weeks of the study. The participants were then asked to grade the severity of their urinary loss using a patient-based 3-point symptom severity scale of 1 (mild), 2 (moderate), or 3 (severe), and the Stamey grading system⁽¹⁰⁾. Changes in the secondary outcome measures were assessed before and after 16 weeks' exercise treatment.

Sample size

The sample size was calculated on the basis of a previous randomized controlled trial on the effect of adding BF to PFMT. The mean difference of pelvic floor muscle strength between the biofeedback and the control groups was 29.6 cmH₂O⁽¹¹⁾. Using the same outcome variable (vaginal squeeze pressure), the sample size was set at 26 subjects per group to provide a power of 80% and a significance level of 5% for detecting the difference between groups. A final sample size was set at 30, taking into consideration dropouts.

Data analysis

Statistical analysis was carried out in SPSS version 15. Demographic data from two groups were analyzed by using t-test and Chi-square test. Repeated measures ANOVA was used to compare the initial, week 8 and week 16 values for maximum vaginal squeeze pressure within group. Mann-Whitney U test and t-test were used for comparison between groups. Paired t-test and unpaired t-test were used to compare the initial and week 16 results for quality of life scores within and between groups, respectively. For all the comparisons made in the present study, $p < 0.05$ was the value regarded as statistically significant.

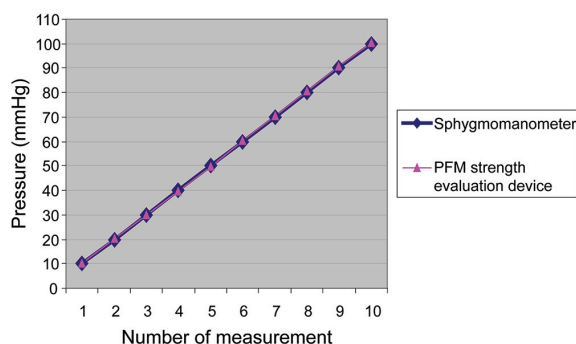


Fig. 2 The accuracy of vaginal probe pressure perineometry compared to a standard sphygmomanometer at pressure range 0-100 mmHg.

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 to 100 mmHg (Fig. 2). Our device could detect abdominal wall muscles activities at 10 milliseconds (100 Hz), 20 milliseconds (50 Hz) and 50 milliseconds (20 Hz). The sensitivity was lower than the referenced biofeedback machine (Fig. 3a, b).

Then we proceeded to the clinical setting. Sixty-one women were recruited. At baseline, there were no significant differences in age, body mass index, parity, and all outcome parameters between the two groups (Table 1). 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 was lost to follow-up after first visit (Fig. 4). Intention-to-treat analysis was used and baseline values were carried forward for the two participants who dropped out in each group.

Table 1. Characteristics of the participants at baseline

	BF + PFMT group (n = 29)	PFMT group (n = 32)
Age (years), mean ± SD	46.96±7.22	48.50±6.98
BMI (kg/m ²), mean ± SD	25.87±4.93	25.74±4.38
Parity, median (range)	2 (0-3)	2 (0-3)
Urinary loss severity, median (range)		
Patient-based 3-point scale	2 (1-3)	2 (1-3)
Stamey grading system	2 (1-3)	2 (1-3)

BF = biofeedback; PFMT = pelvic floor muscle training; BMI = body mass index
 $p > 0.05$

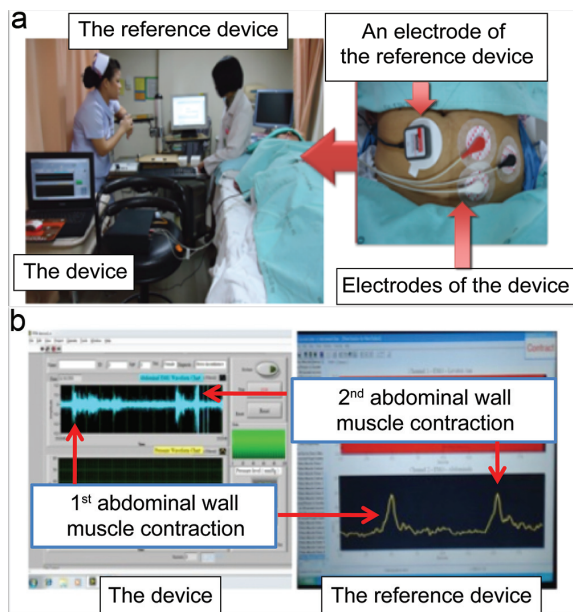


Fig. 3 (a) The method of comparing abdominal wall activity detection between the device and a standard biofeedback machine. (b) The real-time waveforms of abdominal wall muscle activity from the device and a standard biofeedback machine.

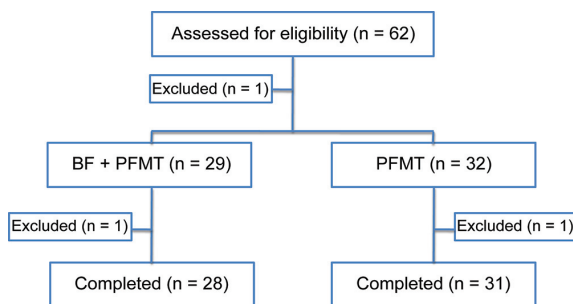


Fig. 4 Flow diagram of the randomized trial comparing pelvic floor muscle training with (BF + PFMT) and without biofeedback (PFMT) groups.

The results of changes in vaginal squeeze pressure were given in Table 2. At baseline, mean vaginal squeeze pressure were 23.16 ± 9.98 mmHg and 22.48 ± 8.43 mmHg in the BF + PFMT group and PFMT group, respectively. After 8 and 16 weeks of treatment, there were statistically significant within-group differences in the maximum vaginal squeeze pressure in both groups. However, the between-group differences were not demonstrated.

At baseline 16 women (55.17%) in the BF + PFMT group and 21 women (65.22%) in the PFMT group could not contract their pelvic floor

muscles correctly (they contracted their abdominal wall muscle simultaneously). At follow-up, 1 (3.45%) in the BF + PFMT group and 13 (40.62%) in the PFMT group were still not able to contract their pelvic muscles correctly. The proportion of women who performed pelvic floor muscle exercise correctly without abdominal muscle contraction was significantly higher in the BF + PFMT group (72.41%) compared to the PFMT group (21.88%) at week 16 ($p = 0.0436$).

With regard to women's perceptions of the change in severity of their urine loss, 69.6% of the women in the BF + PFMT group and 78.2% of the women in the PFMT group reported an improvement in their symptom. There was no statistically significant difference between both groups. The median values of patient-based 3-point symptom severity scale decreased from 2 (range, 1-3) to 1 (range, 0-3) in the BF + PFMT group and the PFMT group. The mean values of Stamey grading system also decreased from 2 (range, 1-3) to 1 (range, 0-2) in both groups.

Women in both groups reported improvement of I-QOL scores after 16 weeks of treatment (Table 3). The subscale scores of avoidance and limiting behaviors, psychological impacts, and social embarrassment including the overall scores increased significantly. There was no statistically significant difference was found between the two groups.

Adherence based on the training diary (at least one time a day) was lower in the PFMT group (56.2%) than in the BF + PFMT group (68.9%) at week 16. All women exercised at least two to three times a week.

Discussion

Pelvic floor muscle training (PFMT) is defined as 'any program of repeated voluntary pelvic floor muscle contractions taught by a healthcare professional' for urinary incontinence and pelvic organ prolapse treatment. It is the most commonly used and effective conservative treatment for women with stress urinary incontinence^(4,12) and recommended as the first-line

Table 2. Vaginal squeeze pressure at baseline, week 8 and week 16

Vaginal squeeze pressure	BF + PFMT group mean \pm SD	PFMT group mean \pm SD
At baseline	23.16 \pm 9.98	22.48 \pm 8.43
Week 8	26.32 \pm 10.45*	27.79 \pm 10.97*
Week 16	29.30 \pm 13.59*	30.00 \pm 11.60*

* $p < 0.05$ compared to baseline within groups
 $p > 0.05$ between the two groups

Table 3. Incontinence-specific quality of life questionnaire (I-QOL) score at baseline and week 16

Subscale Scores	BF + PFMT group		PFMT group	
	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

conservative treatment for women with urinary stress incontinence⁽¹³⁾. The treatment effect seems greater in women who participate in a supervised PFMT program for at least three months⁽¹²⁾. However, supervision and content of PFMT program is highly variable and the most effective approach to training is not known. With the ongoing search for low-cost treatments, the present study contributed to the development of a simple pelvic floor muscle strength evaluation device and an efficient treatment protocol with less expense for the public health system.

In the present study, the pelvic floor muscle strength evaluation device had been developed and tested in a clinical setting. It provided accurate vaginal pressure and adequate abdominal wall muscle activity measurements. There was strong evidence that PFMT for the treatment of urinary incontinence should be performed with the focus on strengthening the pelvic floor muscle. Therefore, teaching women to avoid straining or co-contraction of abdominal muscle during pelvic floor exercises would be appropriate. Abdominal muscle contraction in particular transverse abdominis may increase intra-abdominal pressure and hence, negatively affect the pelvic floor. However, if maximum or close to maximum PFM contraction is only possible with abdominal co-contraction, such co-contraction must be allowed during training, as close to maximum contraction is important in building pelvic muscle volume and strength. This device was designed to demonstrate to the women that they should consider whether they are contracting the correct muscles. In addition, it is simple to operate and comprises of a follow-up program. Not only pelvic floor training experts, but also primary health care providers are able to use it to supervise pelvic floor muscle exercises and follow their patients effectively.

In the present study, pelvic floor muscle training with or without biofeedback for 16 weeks showed positive effects on reducing severity of stress urinary incontinence, improving quality of life, and

increasing pelvic floor muscle strength. No significant difference was found between groups with regard to symptoms severity, quality of life and pelvic floor muscle strength after 16 weeks of treatment. Our results are in line with previous studies although both the study and the control groups improved^(14,15). It might be explained by the non-intensive biofeedback used in the present study compared to a previous report, which indicated that attending PFMT for more than two sessions per month was more effective than one or two sessions per month⁽¹⁶⁾. The improvement in the control group could be related to both an individual teaching session and a training diary with written instruction. Nevertheless, nearly three fourths of women in the biofeedback group did not contract their abdominal muscles during pelvic floor exercises while one fourth in the control group did. Additionally, the group receiving pelvic floor muscle training with biofeedback showed greater adherence to unsupervised exercise as in a previous study using vaginal cone⁽¹⁷⁾. Some women reported that the device helped with confidence that the correct muscles were being contracted, and helped motivation to sustain PFMT.

The strengths of the present study are the assessors blinded of the outcome, low dropout, use of validated outcome measures, and randomized, controlled trial. The vaginal squeeze pressure measured with the developed device in the present study was an objective assessment method and not influenced by the assessor. A limitation of the present study was that no objective assessment of severity of urinary incontinence e.g. pad test was used. The absence of long term monitoring was also a limitation; therefore, it was not possible to verify whether gains were maintained through the time and if any of the groups had a better long-term outcome. Future studies should perform follow-up for periods exceeding 16 weeks to verify the maintenance of long-term gains. Besides, cost-effectiveness outcome tools should be considered to evaluate the appropriate treatment and tool for women

with stress urinary incontinence in low resource settings.

Conclusion

The simple pelvic floor muscle strength evaluation device might be helpful in pelvic floor muscle training in a low resource setting. Pelvic floor muscle exercise 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.

What is already known on this topic?

Pelvic floor muscle training is effective, and should be included in first-line conservative management programs for women with stress and any type of urinary incontinence. The treatment effect seems to be greater in women with stress urinary incontinence, who participate in a supervised PFMT program for at least three months.

What this study adds?

The simple pelvic floor muscle strength evaluation device might be helpful in pelvic floor muscle training in a low resource setting. A single 15-minute biofeedback session using the simple device effectively aided women to control their pelvic floor and abdominal wall muscle during pelvic floor exercises.

Acknowledgements

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Potential conflicts of interest

None.

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การพัฒนาเครื่องมือประเมินความแข็งแรงของกล้ามเนื้ออุ้งเชิงกราน

จิตติมา มโนชัย, สกุนตลา คำถาวร, กุศล เพ็ชรทรัพย์, รุจิรา วัฒนายิ่งเจริญชัย

วัตถุประสงค์: เพื่อประเมินความถูกต้องแม่นยำของเครื่องมือ และศึกษาผลของการฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานโดยใช้เครื่องมือช่วยต่ออาการกลั้นปัสสาวะไม่อยู่ คุณภาพชีวิต และความแข็งแรงของกล้ามเนื้ออุ้งเชิงกราน

วัสดุและวิธีการ: ในการศึกษานี้ได้ออกแบบเครื่องมือที่สามารถใช้วัดแรงดันในช่องคลอดขณะเกร็งกล้ามเนื้ออุ้งเชิงกรานโดยใช้ลูกโป่งบรรจุอากาศ และวัดการทำงานของกล้ามเนื้อหน้าท้องโดยใช้เครื่องวัดสัญญาณไฟฟ้าที่เกิดจากกล้ามเนื้อ สำหรับขั้นตอนของการประเมินความแม่นยำของเครื่องมือในการวัดแรงดันในช่องคลอด ผู้นิพนธ์ใช้เครื่องวัดความดันชนิดปรอทเป็นมาตรฐานเปรียบเทียบ ส่วนการวัดการทำงานของกล้ามเนื้อหน้าท้อง คณะผู้นิพนธ์ใช้เครื่องมือ biofeedback เป็นมาตรฐานในการเปรียบเทียบ

มีสตรีที่มีอาการไอหรือจามปัสสาวะเล็ดจำนวน 61 ราย เข้าร่วมการศึกษา ทุกคนได้รับคำแนะนำเกี่ยวกับการบริหารกล้ามเนื้ออุ้งเชิงกรานด้วยวาจาเป็นรายบุคคล และคู่มือการบริหารเพื่อฝึกที่บ้าน หลังจากนั้นสุ่มแบ่งสตรียออกเป็น 2 กลุ่ม กลุ่มที่ 1 ฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานร่วมกับการใช้เครื่องมือที่พัฒนาขึ้นเป็นเวลานาน 15 นาที 1 ครั้ง และกลุ่มที่ 2 ฝึกบริหารด้วยตนเอง สตรีทุกรายจะประเมินความรุนแรงของอาการกลั้นปัสสาวะไม่อยู่ของตนเอง ตามแบบสอบถาม *incontinence-specific quality of life questionnaire (I-QOL)* ฉบับภาษาไทย เมื่อเข้าสู่การศึกษาและสิ้นสุดระยะเวลา 16 สัปดาห์ ของการรักษา ส่วนการวัดแรงดันในช่องคลอดขณะเกร็งกล้ามเนื้ออุ้งเชิงกรานและวัดการทำงานของกล้ามเนื้อหน้าท้องจะกระทำเมื่อเริ่มต้นการศึกษา และที่ระยะเวลา 8 และ 16 สัปดาห์ หลังการรักษา

ผลการศึกษา: เครื่องมือที่สามารถใช้วัดแรงดันในช่องคลอดขณะเกร็งกล้ามเนื้ออุ้งเชิงกรานโดยใช้ลูกโป่งบรรจุอากาศมีความแม่นยำร้อยละ 98 เมื่อเปรียบเทียบกับเครื่องวัดความดันโลหิต อุปกรณ์ดังกล่าวยังสามารถตรวจจับการเคลื่อนไหวของกล้ามเนื้อหน้าท้องได้ที่ระดับความถี่ 10 มิลลิวินาที (100 เฮิรตซ์) 20 มิลลิวินาที (50 เฮิรตซ์) และ 50 มิลลิวินาที (20 เฮิรตซ์) ผลการรักษาทางคลินิกในระยะเวลา 8 และ 16 สัปดาห์ ของการรักษา พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของแรงดันสูงสุดในช่องคลอดขณะเกร็งกล้ามเนื้อในทั้งสองกลุ่มเมื่อเปรียบเทียบกับก่อนรักษา แต่ไม่พบความแตกต่างระหว่างกลุ่ม สัดส่วนของสตรีที่บริหารกล้ามเนื้ออุ้งเชิงกรานอย่างถูกวิธีในกลุ่มศึกษาเท่ากับร้อยละ 72.41 ซึ่งสูงกว่ากลุ่มควบคุม (ร้อยละ 21.88) อย่างมีนัยสำคัญทางสถิติที่สัปดาห์ที่ 16

สรุป: เครื่องมือประเมินความแข็งแรงของกล้ามเนื้ออุ้งเชิงกรานที่พัฒนาขึ้น อาจมีประโยชน์ในการฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานในสถานที่ที่มีทรัพยากรจำกัด
