Original Article

The Correlations between Three Methods of Pelvic Floor Muscle Strength Assessment in Nulliparous Women: 2D Transperineal Ultrasound, Modified Oxford Scale, and PFX2® Perineometer

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Abstract

Objective To study the correlation between three methods for pelvic floor muscle strength assessment in nulliparous women.

Methods: A cross-sectional study, 50 nulliparous were recruited. Modified oxford scale (MOS) was assessed by one author (OW) and highest maximum squeeze value was recorded. The vaginal pressure during maximum squeeze with PFX2® perineometer was recorded by one trained nurse. The midsagittal view of anteroposterior (AP) hiatal dimension using 2D transperineal ultrasound (TPUS) was done by the other author (PL) to measure the difference between the AP hiatal dimension in the resting stage compared to maximum squeeze.

Results: The mean MOS ± SD was 4.4 ± 0.7. The mean ± SD PFX2® perineometer was 10.4 ± 1.8 cmH2O. The mean ± SD difference of AP dimension using TPUS was 1.1 ± 0.6 cm (22.8 ± 10%). PFX2® perineometer was poorly correlated with the different AP dimension using TPUS (r = 0.19, *p-value* = 0.18) and weakly correlated with the percent of difference AP dimension using TPUS (r = 0.21, *p-value* = 0.15). MOS was moderately correlated with the difference and percent of difference AP dimension using TPUS (r = 0.35, *p-value* <0.05 and r = 0.34, *p-value* <0.05 respectively). MOS was strongly correlated to PFX2® perineometer (r = 0.73, *p-value* < 0.05).

Conclusions: In healthy nulliparous women, PFX2® perineometer and MOS could be used to assess the strength of the pelvic floor muscles, but two-dimension TPUS could not be used to assess it. Because the difference hiatal dimension is small due to nulliparous characterization.

Keywords: Transperineal ultrasound, Perineometer, Pelvic floor muscle strenth

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Introduction

Female pelvic floor muscles (PFM) consist of the levator ani (pubococcygeus muscle, iliococcygeus muscle, puborectalis muscle) and the coccygeus muscle. Their function is to support the pelvic structure including urethra, bladder, uterus and bowel. In case of PFM dysfunction, patients may present with pelvic organ prolapse, stress urinary incontinence, fecal incontinence, sexual dysfunction and chronic constipation among others.[1] The prevalence of pelvic organ prolapse is 3-50% (with a high prevalence in elderly woman). The prevalence of urinary incontinence is 25-45% (in Thailand, the prevalence is 36.5%).[2] These conditions may cause medical illness, distress and may affect the quality of life of women around the world.[2, 3]

Factors contributing to pelvic floor dysfunction include pregnancy, vaginal delivery, smoking, chronic cough, chronic constipation, and genetic factors.[4, 5] Vaginal childbirth may cause two types of levator ani muscle injury: macrotrauma (partial or complete tearing of muscle tissue) and microtrauma following the sudden distention of the levator ani muscle. Both injuries result in a decrease in the effectiveness of levator ani muscle contraction, a hiatal overdistention and a pelvic organ prolapse (especially uterine prolapse and cystocele).[6, 7]

The 6th International Consultation on Incontinence recommended that PFM training should be offered as a first line of treatment for urinary incontinence, fecal incontinence, and mild pelvic organ prolapse. PFM strength is the main focus for treatment in these patients. The success of PFM training depends on muscle strength, endurance and patients' diligence.[8, 9] There are several ways to assess PFM strength. Vaginal palpation by Modified Oxford Scale (MOS) can be used to assess PFM strength, but it could be qualitative and inaccurate. Because of this limitation, the perineometer (Peritron®, PFX2®) was invented to help assess PFM strength, but it is invasive and not widely available.[10] Transperineal ultrasound (TPUS) is the new method now used to assess PFM strength because it is non-invasive and easy to perform.[11]

In the past, studies comparing the three PFM strength assessment methods (MOS, perineometer, TPUS) in pelvic organ prolapse and urinary incontinence patients showed no statistically significant difference among different assessment methods.[12-14] In 2007, Nadia M, et al. reported a TPUS assessment of the PFM (morphological and dynamic function) in women with pelvic floor dysfunction symptoms. Their results showed that the mean percent of the difference in anteroposterior hiatal dimensions using TPUS (LHap) between rest and maximum squeeze decreased significantly with low MOS score for the women. A cut-off percent decrease in LHap between rest and maximum squeeze of less than 6.5% predicted a low MOS score.[15] At present, no comparative study among three PFM strength assessment methods (MOS, perineometer, and TPUS) in heathy nulliparous women has been undertaken.

The purpose of this study is to evaluate the correlation between the three methods of PFM strength assessment (TPUS, MOS, and PFX2® perineometer) in nulliparous women.

Materials and Methods

Study design

A cross-sectional study was conducted at Thammasat University Hospital (TUH), a tertiary referral center, in Thailand. The study obtained ethical approval from the TUH ethics committee. (MTU-EC-OB-0-240-63)

Study Population

Participants who were of the reproductive age (18-50 years old) from the general gynecology unit in Thammasat University Hospital were recruited. All participants signed an informed consent form.

Inclusion criteria were nulliparous, sexual active and able to contracted pelvic floor muscle correctly by visualization from TPUS examination. Exclusion criteria were women with pelvic organ prolapse, lower urinary tract symptoms (LUTs), history of gynecologic surgery, history of gynecologic cancer, prior pelvic reconstructive and anti-incontinence surgery, pregnancy, and inability to give informed consent.

Study Protocol

After signing the informed consent form, each participant answered a questionnaire concerning age, body weight, height, underlying disease, and family history of pelvic organ prolapse and a Urogenital Stress Inventory questionnaire (UDI questionnaires) by a research nurse. All participants were examined by three blinded examiners. The sequence of the three PFM strength assessment methods was randomized to minimize measurement and information bias.

The participants began by making sure that their bladders were empty. They were then examined in the lithotomy position. A digital exam was performed and assessed by the co-author (OW) to assess pelvic muscle strength using the MOS (patients were told to squeeze 3 times and the highest value was recorded). The co-author inserted her index and middle fingers approximately 4 cm into the vagina canal of each patient and the puborectalis muscle at each side of the vagina was palpated during contraction. The pelvic floor muscle strength (by MOS) was classified as a scale of 0-5 (0 = no contraction; 1 = minor muscle 'flicker'; 2 = weak muscle contraction without a circular contraction; 3 = moderate muscle contraction; 4 = good muscle contraction and 5 = strong muscle contraction).[16]

PFX2® perineometer is a conical sensor covered with a medical silicone rubber sheath used for taking the vaginal pressure measurement. It was covered with a sterile latex sleeve for each patient and the middle of the balloon was placed approximately 3.5 cm inside the introitus. Patients were told to squeeze 3 times and the highest value was recorded by a trained nurse.

Two dimension TPUS using the SAMSUNG UGEOH60 B-mode capable 2D ultrasound system with cineloop function, a 3.5-6 MHz array transducer using a gel was performed by author (PL). The midsagittal view of genital hiatus was examined to measure the difference between the anteroposterior hiatal (AP) dimension in the resting stage and the maximum squeeze (the patients were instructed to squeeze three times and the highest value was recorded).[17-19] (Picture 1)

Statistical Analysis

A statistical analysis was performed with the STATA version 15. General characteristic was determined as the mean ± SD. Spearman's rank correlation coefficient (r) was used to assess the correlation among the three methods. The correlation was classified as r = 0-0.20, poorly correlated; r = 0.21-0.40, weakly correlated; r = 0.41-0.60, moderately correlated; r = 0.61-0.80, strongly correlated; r = 0.81-1, very strongly correlated.[20] A *p-value* < 0.05 was considered statistically significant.

<u>Sample size</u>

The sample sized was calculated by this formula[21]

$$\mathbf{N = [\ (Z_\alpha + Z_\beta) / c]^2 + 3}$$

$$N = [\ (1.96)^2 + (1.282)^2 / c^2] + 3$$

$$N = [(3.842+1.644)/\ 0.116] + 3$$

$$N=47+3$$

$$N=50$$

N = The number of population

α = 5% significance level test = 0.05

β = probability of failing to reject the null hypothesis under the alternatiive hypothesis = 0.10

c = 0.5 x In [(1+r)/(1-r)] = 0.3416

r = the expected correlation coefficient from the pilot study = 0.329

Result

A total of 50 nulliparous women, all sexually active with no family history of pelvic organ prolapse, were included in study. The mean age ± SD of the participating women was 29 ± 7.9 years (minimal age was 20 years and maximum age was 40 years). They had a mean body weight ± SD of 53.7 ± 8.7 kg, A mean ± SD height was 161.5 ± 5.6 cm and a mean ± SD body mass index of 20.6 ± 3.1 kg/cm^2.

Their mean ± SD MOS was 4.4 ± 0.7 and their mean ± SD PFX2® perineometer was 10.4 ± 1.8. The mean ± SD of AP dimensions, using TPUS at rest and at maximum squeeze, were 4.9 ± 0.7 cm and 3.8 ± 0.6 cm respectively. The mean ± SD difference in their AP dimensions using TPUS was 1.1 ± 0.6 cm while the mean ± SD percent difference in their AP dimensions using TPUS was 22.8 ± 10 (Table 1)

According to the Spearman's rank correlation coefficient, the PFX2® perineometer was poorly correlated with the difference in AP dimensions using TPUS (r = 0.19, p-value = 0.18, as shown in Figure 1) and weakly correlated with the percent difference in AP dimensions using TPUS (r = 0.21, p-value = 0.15, as shown in Figure 2). Meanwhile, MOS correlated moderately with difference in AP dimensions using TPUS (r = 0.35, p-value < 0.05, as shown in Figure 3) and with the percent difference in AP dimensions using TPUS ($r = 0.34$, p-value < 0.05, as shown in Figure 4). MOS was strongly correlated the PFX2® perineometer ($r = 0.73$, p-value < 0.05, as shown in Figure 5)

Table 1 The average result of three methods for pelvic floor muscle strength assessment.

Measurement method	**Mean ± SD**	**Range**
Modified oxford scale	4.4 ± 0.7	3-5
PFX2® perineometer (cmH_2O)	10.4 ± 1.8	6-12
AP*dimension using TPUS* *at rest (cm)	4.9 ± 0.7	3.3-6.4
AP*dimension using TPUS* *at maximum squeeze (cm)	3.8 ± 0.6	2.1-5.2
Mean difference of AP*dimension using TPUS** between rest and maximum squeeze (cm)	1.1 ± 0.6	0.1-3.2
Mean percentage difference of AP*dimension using TPUS**between rest and maximum squeeze (%)	22.8 ±10	2.6-51.6

*AP: Anteroposterior hiatal, **TPUS : Transperineal ultrasound

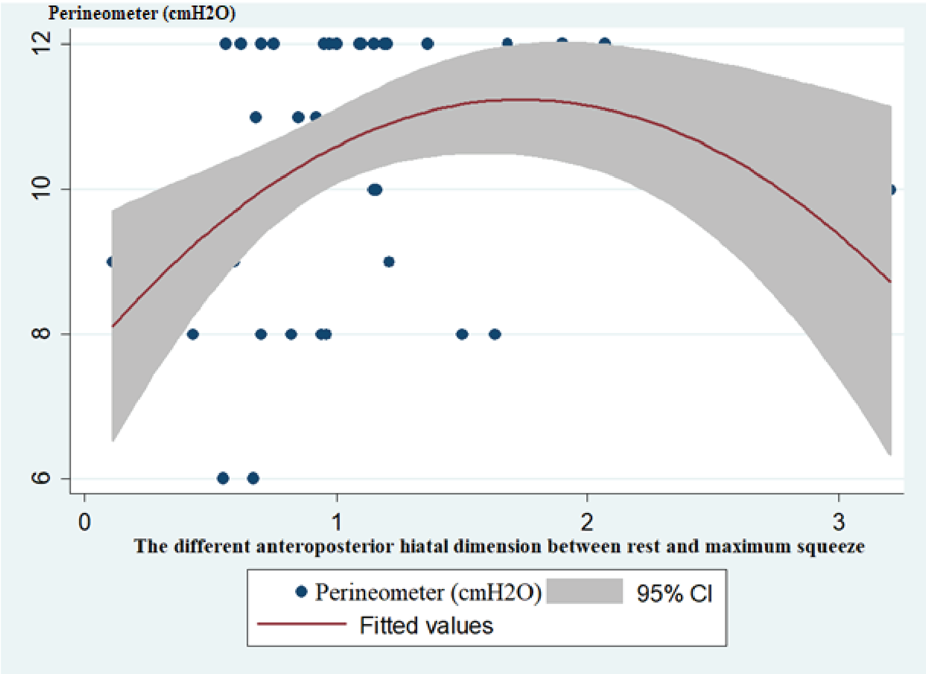

Figure 1 The Spearman's rank correlation coefficient between PFX2® perineometer and the difference anteroposterior hiatal dimension between rest and maximum squeeze ($r = 0.19$, p-value = 0.18)

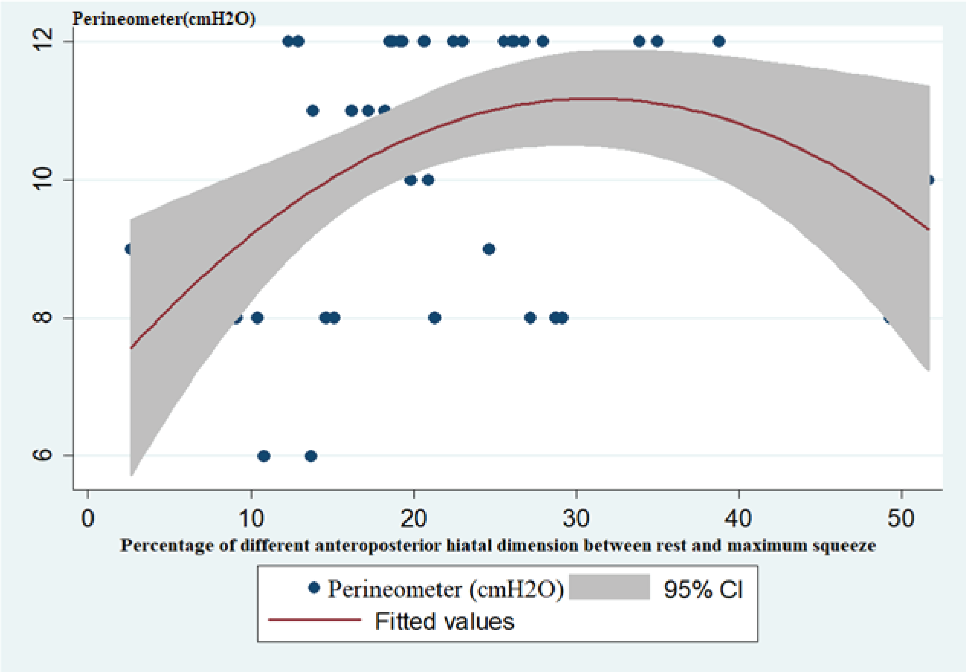

Figure 2 The Spearman's rank correlation coefficient between PFX2® perineometer and percent of difference anteroposterior hiatal dimension between rest and maximum squeeze (r = 0.21, p-value = 0.15)

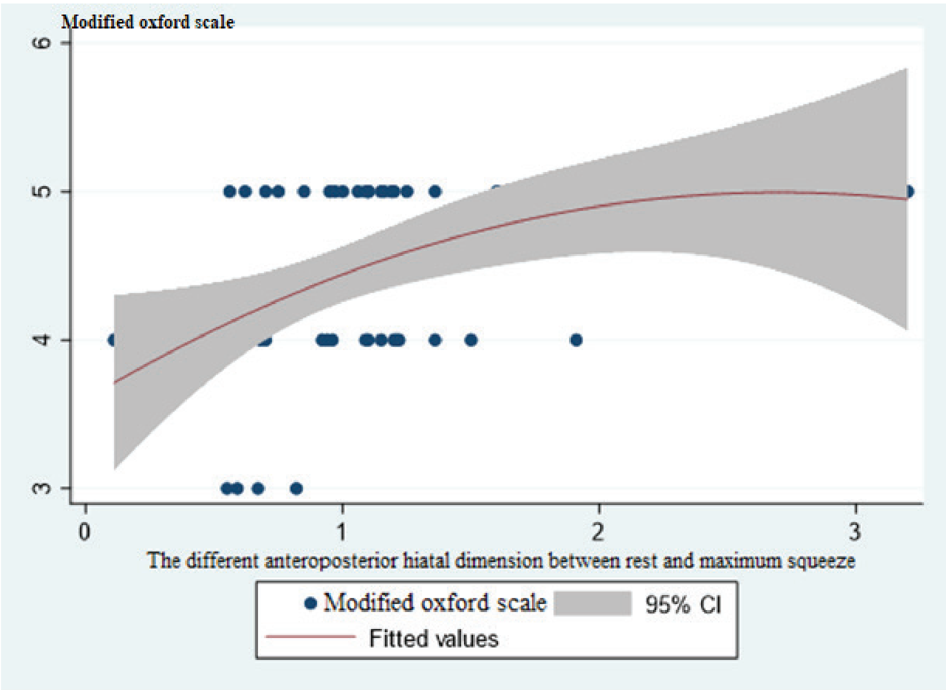

Figure 3 The Spearman's rank correlation coefficient between Modified Oxford scale and the difference anteroposterior hiatal dimension between rest and maximum squeeze (r = 0.35, p-value < 0.05)

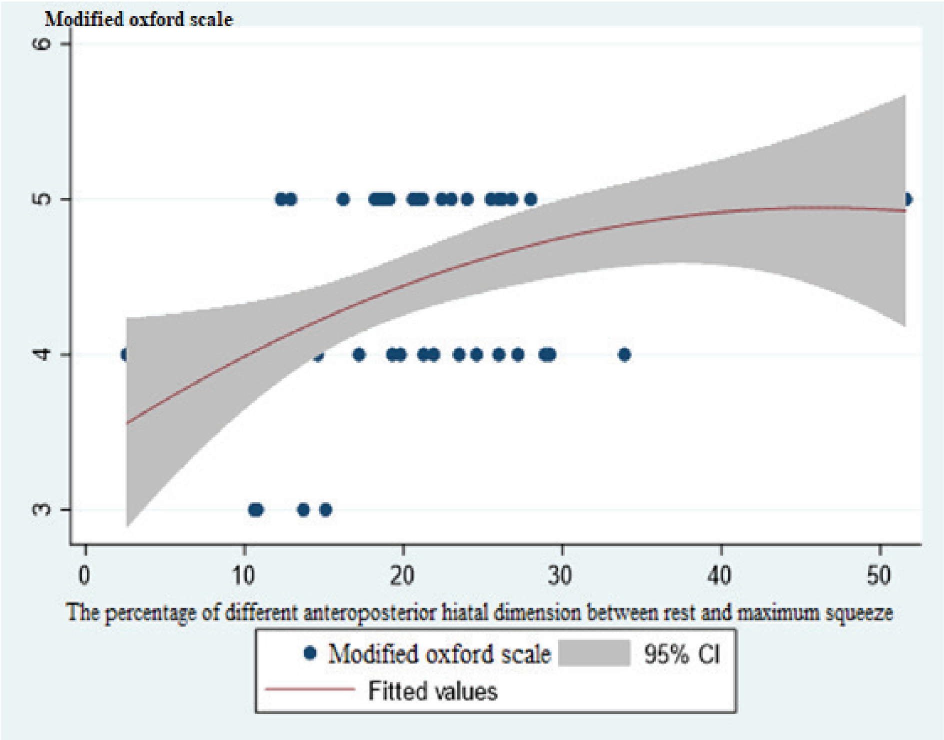

Figure 4 The Spearman's rank correlation coefficient between Modified Oxford scale (MOS) and percent of difference anteroposterior hiatal dimension between rest and maximum squeeze ($r = 0.34$, $p\text{-value} < 0.05$)

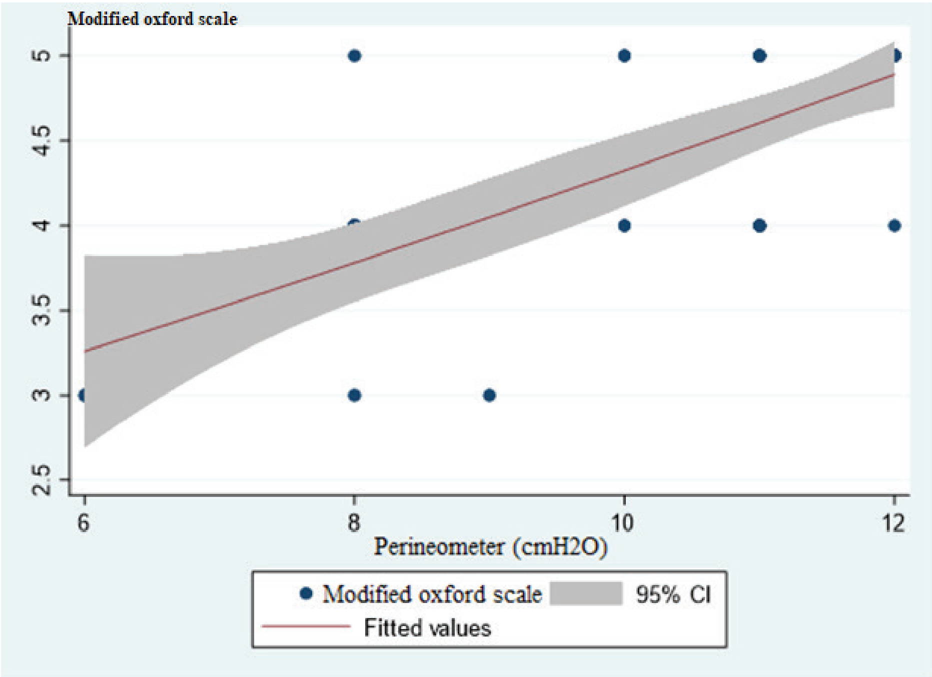

Figure 5 The Spearman's rank correlation coefficient between Modified Oxford scale (MOS) and PFX2® perineometer ($r = 0.73$, $p\text{-value} < 0.05$)

Discussion

The pelvic floor strength assessment is crucial for the diagnosis and treatment of patients with pelvic floor dysfunction, who show symptoms of pelvic organ prolapse, stress urinary incontinence, fecal incontinence, sexual dysfunction and chronic constipation. In most cases, pelvic floor dysfunction often follows vaginal birth and leads to injury of the PFM by causing tearing and stretching. In 2017, Nadia M, et al.[15] studied a TPUS assessment of the PFM (morphological and dynamic function) in women with pelvic floor dysfunction symptoms. The results showed that the mean percent difference in the AP dimensions using TPUS (LHap) between at rest and at maximum squeeze decreased significantly in low MOS women (r = 0.67). Thus, this study supports our hypothesis that widening the genital hiatus reduces PFM strength. There are various techniques to assess the strength of the pelvic floor, such as vaginal palpation using Modified Oxford scale (MOS), perineometer, 2D/3D/4D transperineal ultrasound, among others.

Our study showed that the difference in the AP dimensions using TPUS was poorly correlated with the PFX2® perineometer, which is the standard method of measurement (r = 0.19). The percent difference in the AP dimensions using TPUS weakly correlated with the PFX2® perineometer (r = 0.21), while both values of TPUS were moderately correlated with MOS (r = 0.35 and 0.34, respectively). Our results were different from the study conducted by VOLLØYHAUG, et al.[14] in 2015. They found that the correlation of change in hiatal AP diameter (at rest and maximum squeeze) with Camtech AS® perineometer was moderate (r = 0.58). However, our study has produced different results from that prior study, possibly because of the difference in demographics of the patients, especially multiparity, since multiparity is the most significant factor in incidences of pelvic floor dysfunction.

We noticed a small difference in AP dimension using TPUS at rest and maximum squeeze (the mean difference in the AP dimension using TPUS was 1.1 ± 0.6 cm and the mean percent difference in the AP dimensions using TPUS was 22.8 ± 10%) in the genital in our sample of nulliparous women. The nulliparous women experienced either minimal or no PFM trauma. They therefore had good muscular integrity.

The MOS measurement has weakness as a pelvic floor muscle strength measurement, because it is measured as a subjective value, it depends on the examiners experience for measuring vaginal pressure. This subjective measurement could be inaccurate. The perineometer (Peritron®, PFX2®) was developed to improve the level of accuracy by using quantitative measurements instead of qualitative assessments, as in the use of MOS, and is now the objective standard method. The disadvantage of the PFX2® perineometer is its invasiveness and the machine was designed for personal use. TPUS is a new objective method, which is noninvasive and easy-to-perform. It assesses PFM by measuring the difference in anteroposterior hiatal dimension, which is different from the two previously mentioned methods (MOS and perineometer), which measure the pressure of the vagina. Thus, this functional difference may be the reason that the correlation between the MOS and the perineometer was stronger, then when making comparisons by use of the TPUS.

TPUS measures the difference anteroposterior hiatal dimension, while the MOS and PFX2® perineometer measures the pelvic floor muscle power. We presumed that the difference in anteroposterior hiatal dimension was correlated to the pelvic floor muscle power. But from our study, we found poor correlation between TPUS and PFX2® perineometer. Using this parameter is not appropriate, because the difference anteroposterior hiatal dimension when resting and maximum squeezing is small due to nulliparous characterization.

The strength of this study was that it is the first prospective cross-sectional study to assess pelvic floor muscle strength by MOS, perineometer and different AP dimension using TPUS in healthy Asian nulliparous women of reproductive age. All participating women were clinically examined by three blinded examiners. Three PFM strength assessment methods were randomized to decrease measurement and informational bias. The examiners alone were blinded to the ultrasound-examination data, thus eliminating inter-observer variation, and data was randomized in each of the collection methods. The limitation of this study is that it is only a single center study and with one operator for its measurement. To confirm this negative result, the study should be repeated in other medical centers.

In healthy nulliparous women, PFX2® perineometer and MOS could be used to assess the strength of the pelvic floor muscles, but two dimensional TPUS should be avoided, because the difference in hiatal dimension is small in nulliparous women.

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Compliance with Ethics Requirements: none

Conflict of interest: none

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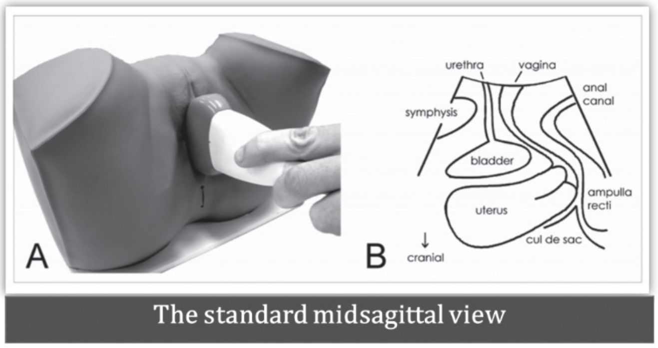
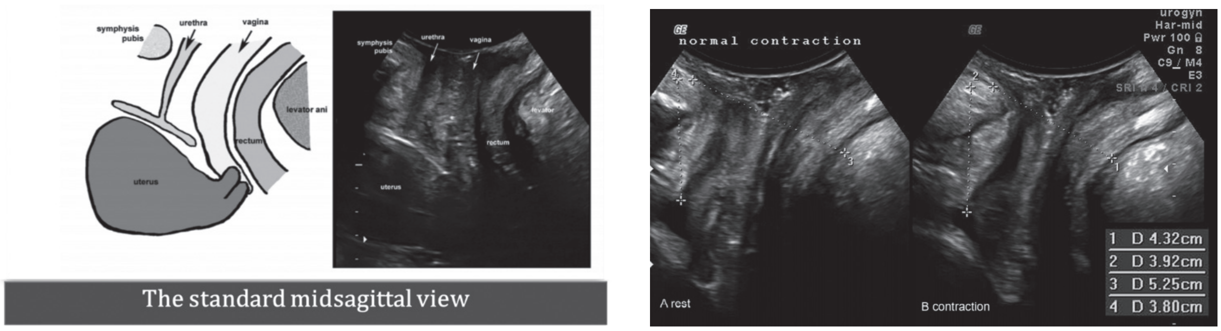


Picture 1 The midsagittal view measure the difference between the anteroposterior hiatal dimension in the resting stage compared to maximum squeeze using 2D transperineal ultrasound.[17-19]



Picture A at rest, **Picture B** during muscle contraction. Difference point: 3-1 = 0.93

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