



Original Article

## Assessment of the effect of pelvic floor exercises on pelvic floor muscle strength using ultrasonography in patients with urinary incontinence: a prospective randomized controlled trial

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**Abstract.** [Purpose] The aim of this study was to evaluate whether the effect of pelvic floor exercises on pelvic floor muscle strength could be detected via ultrasonography in patients with urinary incontinence. [Subjects and Methods] Of 282 incontinent patients, 116 participated in the study and were randomly divided into a pelvic floor muscle training (n=65) group or control group (n=51). The pelvic floor muscle training group was given pelvic floor exercise training for 12 weeks. Both groups were evaluated at the beginning of the study and after 12 weeks. Abdominal ultrasonography measurements in transverse and longitudinal planes, the PERFECT scheme, perineometric evaluation, the stop test, the stress test, and the pad test were used to assess pelvic floor muscle strength in all cases. [Results] After training, the PERFECT, perineometry and transabdominal ultrasonography measurements were found to be significantly improved, and the stop test and pad test results were significantly decreased in the pelvic floor muscle training group, whereas no difference was observed in the control group. There was a positive correlation between the PERFECT force measurement scale and ultrasonography force measurement scale before and after the intervention in the control and pelvic floor muscle training groups ( $r=0.632$  and  $r=0.642$ , respectively). [Conclusion] Ultrasonography can be used as a noninvasive method to identify the change in pelvic floor muscle strength with exercise training.

**Key words:** Pelvic floor muscle, Transabdominal ultrasonography, Urinary incontinence

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## INTRODUCTION

Urinary incontinence (UI) has been defined as the complaint of any involuntary loss of urine. The published prevalence rates of UI in adult women vary from 5 to 69%<sup>1)</sup>. The physiopathology of UI is multifactorial, and it is known that weak pelvic floor muscles (PFMs) represent a problem encountered in patients with UI<sup>2)</sup>. The PFMs play an important role in the maintenance of continence. Therefore, the purpose of PFM training is to increase strength and endurance as well as to provide neuromuscular facilitation<sup>3)</sup>. PFM training is generally recommended as the first choice of treatment for stress and mixed UI in women<sup>4)</sup>.

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Several subjective and objective methods have been used to assess PFM function in women attending physical therapy and exercise programs. The most commonly used tool in physical therapy seems to be digital palpation (modified Oxford Grading Scale)<sup>5</sup>). The PERFECT scheme (Power, Endurance, Repetition, Fast contractions, Every Contraction Timed) was developed to assess the primary components of PFM contractility via digital palpation<sup>2</sup>).

Real-time ultrasound imaging is a rapidly developing technique that is used by physical therapists to assess muscle structure, function, and activation patterns<sup>6-8</sup>). Unlike other methods that require intravaginal application, transabdominal ultrasonography (TAUS) has the advantages of noninvasiveness, comfort, and appropriateness in a specific population in which vaginal assessment may not be favorable (children, adolescents, victims of sexual abuse, men, and certain ethnic groups) with quick and easy applications<sup>9</sup>). TAUS has been found to be a valid and reliable method to measure the movement of the bladder base as an indicator of PFM activity during muscle contraction<sup>10</sup>). However, only patients with a score of 3 and above in muscle strength according to digital palpation were included in these studies<sup>10-13</sup>). In addition, to our knowledge, no study has investigated the correlation between TAUS measurement and the parameters of the PERFECT scheme.

Therefore, our aim was to measure the PFM strength objectively by TAUS before and after PFM training in patients with all levels of PFM strength (0-5) and to compare the findings of TAUS with digital palpation.

## SUBJECTS AND METHODS

This was a prospective randomized controlled clinical trial with testing performed before and after training. Approval was obtained from the Dokuz Eylul University Human Ethics Committee (Number: A 38 GOA 385 1.12.11) prior to this study, and written informed consent was obtained from subjects.

The patients of this study included 282 incontinent women selected from the individuals observed at a urogynecology unit. The exclusion criteria were pregnancy, pelvic organ prolapses, low back pain, spinal or pelvic fracture, urinary tract infection, vaginal infection, known neurologic disorders, respiratory diseases, menstruation at the time of assessment, history of spinal surgery, or history of PFM training (PFMT) during physiotherapy within the last two years. One hundred forty-two patients were excluded from the study. The remaining 140 patients who agreed to participate in the study were randomized to the PFMT group (n=70) or the control group (n=70) and were evaluated before and after the intervention. Randomization was carried out by the study coordinator using a computer-generated random number table by the pre-labeled sealed envelope method. Based on random number table, patients were assigned to the two interventions.

Data with regard to age, body mass index, waist/hip ratio, duration of urinary incontinence, number of pregnancies, and heaviest birth weight were collected from the medical records at the initial visit. All patients underwent a vaginal examination in the lithotomy position with an empty bladder. A preliminary assessment of PFM function was performed by an experienced pelvic floor physiotherapist using the palpation method<sup>2</sup>). The PERFECT, perineometric, and ultrasonographic measurements were performed three times, and the average of the three measurements was calculated. After these measurements, the stop test, pad test, and stress test were performed. A 30-minute rest period was given after each muscle strength test.

The strength of the PFM was measured via palpation with one to two fingers, and PFM function was evaluated according to the PERFECT scheme, which includes assessments of power, endurance, number of repetitions, and number of fast (1 s) contractions. Additionally, every contraction was timed. Power was graded from 0 to 5, according to the Oxford grading system. The PERFECT scheme of PFM evaluation was recorded and used as an exercise program for the PFMT group<sup>2</sup>). A Peritron 9300V perineometer (Cardio Design, Victoria, Australia) was used to measure the strength of PFM contractions.

A diagnostic ultrasound imaging unit set in B mode (Ultrasonix ES500, Ultrasonix Medical Corporation, Richmond, BC, Canada) with a 3.5-MHz curved array transducer was used for TAUS measurement. Two investigators with at least two years of experience in using TAUS examined all of the patients. A marker (X) was placed on the image of the central portion of the bladder base at the junction of the hyper- and hypochoic structures. The patients were asked to perform three PFM contractions with a 10-s rest between each contraction, and each image was captured at the point of maximal displacement and again marked with an X. The displacement was measured as the distance between the two points marked with X (mm). A physiotherapist confirmed the correctness of PFM contraction by examining any undesirable movement or contraction of other muscles<sup>12</sup>). Only contractions with cephalic movement of the bladder base were accepted as correct.

The stop test was performed by slowing or stopping urine flow after initiation of voiding with a full bladder. The one-hour pad test was performed by measuring the weight differences of pads after completion of recommended types of exercises. The stress test was performed by having the individual relax and then cough vigorously while the examiner observed them for urine loss from the urethra<sup>14</sup>).

The patients in the PFMT group participated in a 12-week exercise program. PFM exercises were practiced two days per week for the first three weeks with intravaginal digital palpation in different positions and monitoring by a physiotherapist. The patients performed the exercise program at home for the remaining 9 weeks. The exercises were individualized according to the degree of pelvic floor weakness, loss of proprioception, and the patient's tolerance. The exercise program included the positions in which the exercise would be done, the number of repetitions of slow and fast contractions, the duration of rest between the contractions, and the number of repetitions in a day and in a week. After isometric exercises, concentric and eccentric exercises were then respectively performed with a frequency of 2-7 sets per day with maximal voluntary contraction.

The data analysis was performed using a statistical analysis software (SPSS, v15.0, SPSS Inc, Chicago, IL, USA). The

variables were investigated with the Kolmogorov-Smirnov test to determine whether they were normally distributed. Descriptive analyses are presented using the means and standard deviations for normally distributed PERFECT, ultrasonography, perineometry, and demographic variables. The independent samples t-test and chi-square test were used for continuous and categorical variables, respectively, to test the difference between the pre- and posttreatment values in the study and control groups. The association among TAUS measurements, perineometry results, and three components of the PERFECT scheme (endurance, repetitions and fast) was assessed using Pearson's coefficient of correlation, while Spearman's rho was used to determine the association between TAUS measurement and digital palpation testing. A priori analysis for power indicated that 51 patients in each group were needed to produce 80% power for detecting a large-size effect (assuming a correlation  $\rho$  of 0.50 and population correlation  $\rho$  of 0.72) based on a one-tailed alpha value of 0.05. A post hoc statistical power analysis showed that with the effect size ( $r$ ) of 0.47, this study has 85% power to detect a significant correlation between the TAUS measurements and perineometry with an overall 5% type-I error level. The G\*Power 3 computer program was used for the power analysis<sup>15</sup>. An overall p-value of less than 0.05 was considered a statistically significant result.

## RESULTS

Among the 282 incontinent women, 91 were excluded from the study due to the exclusion criteria, and 51 did not agree to participate in the study. The remaining 140 patients were randomly divided into 2 groups. Each group initially had 70 patients, but 24 women did not complete the study, resulting in a drop-out rate of 17.14%. Five patients in the exercise group were excluded from the study because they did not participate in at least 75% of the treatment sessions. Nineteen patients in the control group who did not attend their secondary assessments due to personal reasons were also not included in the study (one woman had a change in her work situation, two women had other health problems, 16 women did not accept a second vaginal evaluation). Ultimately, the study was completed with 65 patients (27 with stress UI, 23 with urge UI, and 15 with mixed type UI) in the exercise group and 51 patients (21 with stress UI, 17 with urge UI, and 13 with mixed type UI) in the control group.

Table 1 shows the baseline demographic and clinical characteristics of the patients. Comparison of the groups showed no significant differences at baseline for age, body mass index, waist/hip ratio, duration of UI symptoms, number of pregnancies, and heaviest birth weight. There were statistically significant differences between the stress test measurements before and after exercise in the treatment group (15.4% vs. 3.1% positive stress test respectively,  $p < 0.001$ ) (Table 2).

There were no significant differences among groups in terms of the baseline stop test, one-hour pad test, strength measurements of the PERFECT scheme, perineometry, or TAUS (Table 3). When we compared the results for PFM strength, there was significant improvement in PFM strength in the PFMT group after treatment compared with before treatment. In the control group, no statistically significant difference was found after 12 weeks compared with baseline values. Improvements in all PFM strength parameters were significantly higher in the PFMT group than the control group after the 12 weeks of treatment ( $p < 0.05$ ) (Table 3). The percentages of PMF strength increases were 120.3% as measured by the power, 107.1% as measured by perineometry, 160.6% as measured by TAUS in the transverse plane, 169.4% as measured by TAUS in the longitudinal plane, 92.9% as measured by the pad test, and 93.2% as measured by the stop test.

There was a moderate positive correlation between all the parameters of the PERFECT scheme and TAUS results in both

**Table 1.** Baseline values of the PFMT and control groups\*

Variables	PFMT group (n = 65)	Control group (n = 51)
	Mean (SD)	Mean (SD)
Age (years)	51.7 (9.7)	49.6 (7.6)
BMI (kg/m <sup>2</sup> )	32.6 (14.2)	33.4 (22.7)
Waist/hip (cm)	0.9 (0.1)	0.9 (0.1)
Duration of symptoms (months)	64.3 (53.3)	56.5(47.8)
Number of pregnancy	3.3 (2.4)	2.7 (1.4)
Heaviest birth weight (gr)	3,608 (550)	3,342 (288)

\* $p > 0.05$ . BMI: body mass index; PFMT: pelvic floor muscle training; SD: standard deviation

**Table 2.** Stress test values of the PFMT group

Stress test	PFMT group (n = 65)	
Positive	20 (15.4%)	4 (3.1%)
Negative	45 (34.6%)	61 (46.9%)

$p = 0.001$ ,  $\chi^2 = 14.55$ ,  $SD = 2$ , chi-square test

transverse and longitudinal planes (TAUS-T and TAUS-L) (Table 4) ( $p < 0.05$ ). A moderate positive correlation was observed between perineometry and TAUS-T measurements ( $p < 0.05$ ), whereas no correlation was found between perineometry and TAUS-L measurements ( $p > 0.05$ ) (Table 3). We found strong positive correlation between transverse and longitudinal TAUS measurements ( $p < 0.05$ ). All the results of correlation analysis for the measurement methods were identical before and after training (Table 4).

To identify whether the strength increase in the PFMT group could be detected using ultrasound, the difference between the pre- and posttreatment values for power and the forces measured via TAUS were calculated. To determine the relationship between these two measurements, a correlation analysis was conducted. An increase of strength in the PFMT group was detected by measurement of power (average difference between pre- and post-exercise power values:  $1.73 \pm 0.76$ ) as well as by TAUS (average difference between pre- and post-exercise TAUS measurements:  $5.06 \pm 2.64$  mm). A statistically significant relationship was found between the two measurement systems regarding strength increase ( $p = 0.014$ ,  $r = 0.303$ ). There was no difference between power and TAUS with regard to pre- and posttreatment strength values. When the strength values measured by power increased, the values measured using TAUS also increased in the two groups ( $p < 0.01$ ,  $r = 0.632$ ;  $p < 0.01$ ,  $r = 0.642$ ).

## DISCUSSION

Our study demonstrated a statistically significant increase in the strength of the PFM after training in patients with all levels of PFM strength. This increase was detected by using the PERFECT and perineometric measurement methods and by

**Table 3 .** Strength measurements of the pelvic floor muscle (PERFECT testing, perineometry, stop test, pad test, and TAUS-T/L) before and after exercise training between and within groups.

Variables	PFMT group (n = 65)		Control group (n = 51)	
	Baseline	After exercise training	Baseline	12 w later
One hour pad test (gr)	3.1 (2.3)*	0.2 (0.5)**	3.4 (6.3)	3.6 (6.9)
Stop test (s)	12.6 (2.3)*	0.9 (1.9)**	8 (16.9)	8.3 (17.8)
TAUS-T (mm)	3.1 (2.8)*	8.2 (4.8)**	4.8 (2.8)	3.3 (11.4)
TAUS-L (mm)	4.2 (3.7)*	11.4 (5.9)**	5.2 (3.7)	6.5 (17.7)
Perineometry (cm H <sub>2</sub> O)	9.8 (2.8)*	20.3 (15.5)	18.5 (13.7)	16.2 (11.6)
PERFECT				
Power	2.3 (1.2)*	5 (1.2)**	3.1 (1.3)	3.3 (1.3)
Endurance	25.9 (18.3)*	57.6 (17.6)**	46.1 (33.3)	46.2 (31.7)
Repetition	13.4 (5)*	21.3 (5.6)**	13.3 (8.5)	12.6 (7.6)
Fast	12.9 (4.8)*	20 (5)**	14.4 (9.8)	14.3 (10.2)

Results are presented as the mean (SD)

\* $p < 0.05$  between baseline and post-training values of each group

\*\* $p < 0.05$  between values of the PFMT and control groups after 12 weeks

L: longitudinal; PFMT: pelvic floor muscle training; SD: standard deviation; T: transverse; TAUS: transabdominal ultrasonography

**Table 4.** Correlation between the PERFECT scheme, perineometry, and TAUS (n = PFMT group + Control group)

Variables	TAUS-L	TAUS-T	TAUS-L	TAUS-T
	measurement (mm)	measurement (mm)	measurement (mm)	measurement (mm)
	before training n = 140	before training n = 140	after training n = 116	after training n = 116
	r/rho	r/rho	r/rho	r/rho
PERFECT Power	0.4*	0.4*	0.5*	0.4*
PERFECT Endurance (s)	0.4*	0.4*	0.5*	0.4*
PERFECT Repetition (number)	0.4*	0.6*	0.5*	0.5*
PERFECT Fast (number)	0.4*	0.5*	0.4*	0.5*
Perineometry (cmH <sub>2</sub> O)	0.2	0.4*	0.2	0.5*
TAUS-T measurement (mm)	0.7*	1	0.7*	1

\* $p < 0.05$ . L: longitudinal; T: transverse; TAUS: transabdominal ultrasound

Data are shown as median values (range), and Spearman's Rho was calculated for power analysis.

TAUS, which is a noninvasive method. In addition, it was found that TAUS could detect the difference in strength even in PFM strengths of 0–2.

Regular PFM reassessment is suggested so that new exercise programs can be established and for monitoring progress<sup>2</sup>. Correct assessment of PFM strength is crucial when prescribing an exercise program according to patient needs, when determining the correct exercise load, and when demonstrating the effectiveness of the exercise. For suitable progression, frequent assessments must be performed due to changes in strength related to exercise training. Understanding how to correctly perform PFM contraction and giving biofeedback to the patient via TAUS during an exercise session could be helpful for women who are reluctant to receive an internal examination as well as for a continence physiotherapist.

The effects of pelvic floor rehabilitation on PFMs have been evaluated in previous reports that measured PFM strength directly by TAUS. However, there have been few studies with two-dimensional ultrasonography that have assessed changes in PFM strength after exercise training. Ariail et al.<sup>16</sup>) reported a case in which TAUS was used for PFM rehabilitation, muscle reeducation, strength assessment, and setting of the parameters of exercise prescriptions. However, unlike our study, not only the strength of the muscles but also the duration of contractions was detected using TAUS. Therefore, it seems that a patient's exercise prescription could be formed with the parameters obtained from TAUS. Braekken et al.<sup>17</sup>) assessed the differences in PFMs after PFM training with transperineal three-dimensional ultrasonography. The PFM thickness, levator hiatus dimensions, and pubovisceral muscle length were measured using three-dimensional ultrasonography at rest, during contraction, and during the Valsalva maneuver. At the end of the study, it was determined that the effects of the training program could be easily evaluated with three-dimensional ultrasonography<sup>18</sup>). The PFMT method, patient motivation method, and results of treatment in our study were the same as those in the study by Braekken et al.<sup>17</sup>). A significantly more detailed assessment can be performed with three-dimensional ultrasonography; however, two-dimensional ultrasound that we used in our study is a cheaper and more common method that could be used in all obstetrics and gynecology clinics.

Our results are consistent with some studies that have demonstrated a significant correlation between TAUS and digital palpation<sup>11, 18</sup>). However, in the study by Sherburne et al.<sup>10</sup>), no significant correlation between these two methods was identified. We propose that the result of that study was due to the use of different US measuring techniques. In addition, our results for the mean bladder base movement do not appear to be fully comparable with those of other reports because we had a mixed population and we accepted a contraction as correct if the pelvic floor was elevated.

Supervised, individually prepared PFMT programs are the most effective methods to relieve the symptoms of urinary incontinence. PFM rehabilitation is applied in 12- to 14-week and 6-month programs. A significant increase in PFM strength has been observed after 12-week programs<sup>15, 17</sup>). When home program applications were compared with long-term pelvic floor rehabilitation applications in a physiotherapy clinic, no difference was found between the results of the two applications in terms of a pad test or strength measurements<sup>19</sup>). Therefore, we prescribed an individual 12-week home exercise program coordinated by an experienced physiotherapist. Tsai and Liu<sup>19</sup>) taught a group pelvic floor exercises via intravaginal digital palpation, while their other group learned them via a brochure. They compared the efficacy of the two methods by examining the change in the 1-hour pad test results between before and after a 12-week intervention period. The pad test results were significantly better in the group that received one-on-one training by intravaginal digital palpation. Confirming the findings of the study of Tsai et al., we observed a statistically significant decrease in the pad and stop test results of the PFMT group, which was taught PFM exercises intravaginally.

Previous studies have found that TAUS can be used reliably in women with some degree of PFM activity on PFM grading with digital palpation (PFM grade >0)<sup>20, 21</sup>). In this study, we determined an upward bladder base displacement by TAUS in some women with a PFM strength grade of 0 according to the modified Oxford scale. The mean displacement was approximately 1.2 mm to 1.3 mm and was higher than the previously reported standard error of measurement (0.13–0.57 mm) or minimal detectable change (0.36 mm) of the TAUS technique in both planes<sup>10, 11, 20</sup>). To the best of our knowledge, this study is the first to note women with a PFM strength grade of 0 in a study population. We assert that TAUS can be a valuable tool in determining minimal or no PFM contraction and could replace or augment digital palpation. TAUS can be a reliable tool in planning an exercise program and in determining even slight progress in muscle contraction strength, especially in women with weaker PFMs.

There are several limitations of the current study. Firstly, the movement of the transducer in both planes during TAUS measurement can cause measurement errors. However, the examiner held the US transducer firmly against the abdominal wall to control and restrict excessive movement. Secondly, the lack of a fixed bony reference point can make TAUS less reliable than transperineal ultrasonography because the measurement of the bladder base elevation with TAUS is expressed relative to a movable starting point. Finally, although the group assignment was randomized, another limitation of the study was that the therapist that carried out the evaluation and treatment was not blinded; this could have influenced the results.

In conclusion, increments in force that occur with PFM training can be effectively demonstrated via noninvasive methods such as TAUS as well as by invasive methods. TAUS imaging without internal examination can be an alternative objective method for PFM assessment in UI populations in which internal or transperineal methods are not appropriate, in women who are reluctant to undergo an internal examination, and in women with low levels of (0–2) PFM strength. Therefore, measuring PFM contraction with TAUS may be clinically useful when planning an exercise program, during an exercise session, and to examine the patient's current status objectively to observe and plan the progress of continence therapy.



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