# Morphological Changes After Pelvic Floor Muscle Training Measured by 3-Dimensional Ultrasonography

A Randomized Controlled Trial

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**OBJECTIVE:** To investigate morphological and functional changes after pelvic floor muscle training in women with pelvic organ prolapse.

METHODS: This randomized controlled trial was conducted at a university hospital and a physical therapy clinic. One hundred nine women with pelvic organ prolapse stages I, II, and III were randomly allocated by a computer-generated random number system to pelvic floor muscle training (n=59) or control (n=50). Both groups received lifestyle advice and learned to contract the pelvic floor muscles before and during increases in intraabdominal pressure. In addition the pelvic floor muscle training group did individual strength training with a physical therapist and daily home exercise for 6 months. Primary outcome measures were pelvic floor muscle (pubovisceral muscle) thickness, levator hiatus

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area, pubovisceral muscle length at rest and Valsalva, and resting position of bladder and rectum, measured by three-dimensional ultrasonography.

RESULTS: Seventy-nine percent of women in the pelvic floor muscle training group adhered to at least 80% of the training protocol. Compared with women in the control group, women in the pelvic floor muscle training group increased muscle thickness (difference between groups: 1.9 mm, 95% confidence interval [CI] 1.1-2.7, P<.001), decreased hiatal area ( $1.8 \text{ cm}^2$ , 95% CI 0.4-3.1, P=.026), shortened muscle length (6.1 mm, 95% CI 1.5-10.7, P=.007), and elevated the position of the bladder (4.3 mm, 95% CI 2.1-6.5, P<.000) and rectum (6.7 mm, 95% CI 2.2-11.8, P=.007). Additionally, they reduced the hiatal area and muscle length at maximum Valsalva indicating increased pelvic floor muscle stiffness.

CONCLUSION: Supervised pelvic floor muscle training can increase muscle volume, close the levator hiatus, shorten muscle length, and elevate the resting position of the bladder and rectum.

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LEVEL OF EVIDENCE: I

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Dysfunction of the pelvic floor muscles may lead to urinary and fecal incontinence, pelvic organ prolapse (POP), problems with urination and defecation, sexual problems, and chronic pain. Several randomized controlled trials (RCTs) and systematic reviews have demonstrated that pelvic floor muscle training is effective in treating stress urinary incontinence in women, with cure rates of 44–80% in the adult female population. Scant data suggest that it is also effective in reducing severity and symptoms of POP (vaginal bulging/pelvic heaviness). However, there is little knowledge about how pelvic floor mus-



cle training works and there is wide variation in the training protocols applied.5

There are two main hypotheses regarding the mechanism of action of pelvic floor muscle training in treating or preventing stress urinary incontinence and POP.<sup>5</sup> According to the first hypothesis, behavior modification, simply teaching a woman to perform a conscious contraction of the pelvic floor muscles before and during increases in abdominal pressure, helps to prevent cough-related stress urinary incontinence.<sup>6</sup> While this may have an immediate effect, it is unlikely to change pelvic floor anatomy or provide long-lasting changes.<sup>6</sup> The second hypothesis is that strength training of the pelvic floor muscles builds up muscle volume, elevates the location of the pelvic floor muscles and pelvic organs, and closes the levator hiatus thus providing improved structural support for the pelvic floor as well as more optimal automatic function.<sup>3</sup> Previous research has demonstrated that women with pelvic floor muscle disorders may have reduced pelvic floor muscle thickness,<sup>7,8</sup> enlarged hiatal area,<sup>9-11</sup> and avulsions of the pelvic floor muscles.<sup>12</sup> If pelvic floor muscle training proves capable of changing these factors, then it may correct at least part of the underlying pathophysiology of pelvic floor disorders. The aim of this assessor blinded RCT was to evaluate in women with pelvic organ prolapse whether morphological and functional changes occur after 6 months of pelvic floor muscle training compared with a control group receiving lifestyle advice, including learning to contract their pelvic floor muscles before and during increases in abdominal pressure.

# MATERIALS AND METHODS

This is a planned secondary analysis of a RCT designed to assess whether pelvic floor muscle training is effective in preventing and treating women with POP. Results of the primary analyses showed improvement both in anatomic severity of POP and symptom relief and will be published elsewhere. The focus of the present study was to use three- and four-dimensional ultrasonography to assess possible changes in 1) morphology, such as pubovisceral muscle thickness, size of levator hiatus, and pubovisceral muscle length, and 2) function measured as position of the bladder and rectum and size of hiatus and muscle length during maximum Valsalva.

Women with POP, regardless of symptoms, were enrolled by community gynecologists working in the counties of Oslo and Akershus. Given paucity of data about pelvic floor muscle training and POP, we used an effect size of 0.6 for pelvic floor muscle training on stress urinary incontinence<sup>13</sup> to calculate the sample size. With a two-sided alpha of 0.05 and a power of 80%, a sample

size of 45 per group was required.<sup>14</sup> Due to possible drop-outs we chose to include at least 50 women in each group. The study was approved by the Regional Medical Ethics Committee (S-05146) and the Norwegian social science data services (200501371 SMRH). All women gave written, informed consent to participate.

Participants were at least 1 year postpartum and had stages I, II, or III POP determined by the Pelvic Organ Prolapse Quantification System (POP-Q).<sup>15</sup> Exclusion criteria were POP stages 0 or IV, inability to contract the pelvic floor muscles, breastfeeding, previous POP surgery, radiating back pain, pelvic cancer, neurological disorders, psychiatric disorders, untreated urinary tract infection, planning pregnancy, or planning to be away for more than 4 weeks of the intervention period.

After filling in questionnaires covering demographic variables, pelvic floor muscle function (ability to contract, strength, endurance, and vaginal resting pressure) was assessed by the physical therapist (I.H.B.) using a responsive, reliable, and valid vaginal squeeze pressure transducer (Camtech AS, Sandvika, Norway) previously described.<sup>13</sup> The POP-Q examination was performed by a study gynecologist at a university hospital in lithothomy position with a 30-degree table angle. Thereafter a 3- and 4-dimensional ultrasound examination was performed (described below).

Women were stratified into two groups by severity of prolapse: 1) maximal vaginal descent at or above the hymen, and 2) maximal vaginal descent below the hymen. Within each strata a computer-generated random number system with concealed envelopes, generated by a statistician, randomly assigned the women to either the pelvic floor muscle training or control group. The participants opened the allocation envelopes. The gynecologist (M.M.) performing all the POP-Q and ultrasound examinations was blinded to group allocation and clinical and background data. The ultrasound images were stored by anonymous code numbers and analyzed offline (4D View v 5.0 and 6.3; GE Healthcare, Oslo, Norway) by one investigator (I.H.B.) blinded to group allocation and clinical and background data.

Women in both the pelvic floor muscle training group and control group were advised to avoid straining, and the physical therapist observed and taught all the women how to contract their pelvic floor muscles before and during increases in abdominal pressure. Women in the control group were asked to not change frequency of (or not start) pelvic floor muscle training during the intervention period. The pelvic floor muscle training protocol for women in the pelvic floor muscle training group consisted of individual strength training

supervised by a physical therapist once a week during the first 3 months and then once every 2 weeks for the next 3 months in addition to daily home exercise for 6 months. The session included three sets of 8-12 maximal contractions in lying, sitting, and standing positions. The first set was in supine position and the pelvic floor muscle contractions were monitored with the same vaginal squeeze pressure transducer as previously described.<sup>13</sup> The protocol for daily home exercise included three sets of 8-12 close to maximal contractions per day. Women recorded their home training adherence using an exercise diary,13 and the physical therapist recorded the office visits. We defined adequate adherence as completing at least 80% of exercise sessions (144) days or more home exercise and 14 or more physical therapist sessions). This program has been successfully used in a RCT on women with stress urinary incontinence.<sup>13</sup> All women in the pelvic floor muscle training group also received a booklet and a DVD showing the exercise program.

The participants emptied their bladder before the POP-Q and ultrasound examination, and a bladder volume of less than 50 mL was confirmed on ultrasound. A GE Voluson 730 expert and E8 ultrasound system (GE Healthcare, Oslo, Norway) with a 3-/4dimensional ultrasound transducer (4-8 MHz, RAB 4-8 L/obstetric) was placed on the perineum in the sagittal plane. The field of view angle was set to its maximum (70×85°). Three three-dimensional static volumes were recorded in the lithotomy position while resting. Subsequently the participants were asked to stand upright with their legs slightly abducted and to perform three pelvic floor muscles contractions. They then did three Valsalva maneuvers in lithotomy position. The contractions and Valsalva maneuvers were recorded using four-dimensional real-time ultrasonography and took 10-15 seconds each to perform (3 volumes per second). All ultrasound images were previewed and excluded from analysis unless the complete inner border of the pubovisceral muscle was visible in the axial plane and more than 50% of the symphysis pubis was visible in the sagittal plane. All analyses in the axial plane were conducted in the plane of minimal hiatal dimensions, identified as the minimal distance between the hyperechogenic posterior aspect of the symphysis pubis and the hyperechogenic back sling of the pubovisceral muscle.<sup>16</sup> The pelvic floor muscle contraction with the most narrowing and the Valsalva with the most widening of the anterior-posterior hiatal distance were used in further analyses.

Thickness of the pubovisceral muscle was measured from the three-dimensional static volumes captured in lithotomy position and analyzed in the axial plane of

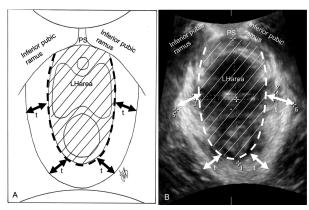


Fig. 1. Measurements in the axial plane of minimal hiatal dimensions illustrated on a drawing (A) and a corresponding ultrasound image (B). Levator hiatus area (LH area) is marked with lines. The pubovisceral muscle length is drawn as a dotted line. t, pubovisceral muscle thickness; SP, symphysis pubis. Reprinted from Brækken et al Neurourol Urodyn 2009; 28:68-7319 and Bo et al Int Urogynecol J 2009; 20:27-32.30 Reprinted with permission of Wiley-Liss, Inc Springer Science and Business Media; and John Wiley & Sons, Inc.

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minimal hiatal dimensions, at four different sites (Fig. 1), with the mean used in the analyses. Our research group has previously demonstrated moderate to very good test characteristics of pubovisceral muscle thickness measured by ultrasounography with intraclass correlation coefficients of 0.75 to 0.82 for interobserver repeatability<sup>17</sup> and intraclass correlation coefficients of 0.56 to 0.61 for intraobserver repeatability.<sup>18</sup> This is in agreement with other research groups. 16 Additionally, we have compared muscle thickness between ultrasonography and magnetic resonance imaging and found a correlation coefficient of 0.8 (Majida M, Braekken IH, Umek W, Bo K, Ellstrom-Engh M. Comparative study of the pubovisceral muscle at rest using three dimensional perineal ultrasound and magnetic resonance imaging [abstract]. Neurourol Urodyn 2008;27[7 suppl]:640-1).

Levator hiatus area was measured in the axial plane and defined as the area bordered by the pubovisceral muscle, symphysis pubis and inferior pubic ramus in the axial plane (Fig. 1). The area of levator hiatus was analyzed from 1) three-dimensional static volumes captured in lithotomy position at rest and 2) four-dimensional real-time volumes during maximum Valsalva in standing position. Based on our previous work, the intraclass correlation coefficients for interobserver<sup>17</sup> and intraobserver repeatability<sup>18,19</sup> was 0.92 and 0.56, respectively, for the three-dimensional static volumes and 0.92 for four-dimensional intertest observer reliability. The correlation between ultrasonography and magnetic res-

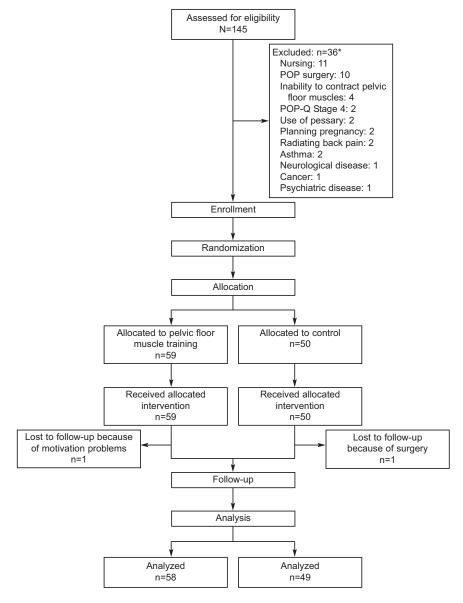


onance imaging for hiatal area measurement was 0.9 (Majida M, et al. Neurourol Urodyn 2008;27[7 suppl]: 640–1).

Pubovisceral muscle length was measured from the same volumes as the levator hiatus area and defined as the inner border of the muscle sling, calculated as the circumference of the levator hiatus minus the length of the right and left inferior pubic ramus (Fig. 1). This measurement has demonstrated good repeatability (intraclass correlation coefficients 0.76).<sup>19</sup>

The positions of the bladder and rectum at rest in the standing position were quantified in the midsagittal plane by locating the urethrovesical junction (bladder neck) and rectal ampulla (rectum), respectively.<sup>19</sup> The position of the organs was measured on a rectangular coordinate system, as described by Schaer et al.<sup>20</sup> Elevation of the pelvic organs was calculated as described by Pechers et al.<sup>21</sup> Results of our previous test retest study<sup>18</sup> correspond with those of Schaer et al,<sup>20</sup> finding good intraobserver agreement (intraclass correlation coefficients 0.73) of bladder neck position at rest.

Statistical analyses were carried out in SPSS v15 (SPSS Inc., Chicago, IL). The results are given as means with standard deviation (standard deviation) or 95% confidence intervals (CIs). Data were checked for normality by Kolmogorov-Smirnov and Shapiro-Wilk tests. Within- and between-groups comparisons were tested with Student t test (normally distributed) and Wilcoxon signed rank test/Mann-Whitney U Test (not normally



**Fig. 2.** Flowchart of participants through each stage of the randomized controlled trial. \*Two women were excluded for more than one reason. POP, pelvic organ prolapse; POP-Q, Pelvic Organ Prolapse Quantification System.

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distributed). Differences between groups in baseline categorical data were analyzed by  $\chi^2$ . Effect size was calculated using the formula (mean of pelvic floor muscle training group-mean of control group)/standard deviation. The relationship between increase in pelvic floor muscle strength and morphological changes was analyzed with Pearson product-moment correlation (r) for normally distributed data and Spearman rho for not normally distributed data. Interim analyses were not done, and because of low drop-out we did not perform per protocol analyses. Given that the purpose of this study was to assess morphological and functional changes of pelvic floor muscle training, rather than clinical effectiveness, results presented in the tables are analyzed without intention-to-treat analyses. However, intentions-to treat analyses were additionally used, and baseline values for women who dropped out were carried forward. P<.05 were considered significant.

## **RESULTS**

One hundred forty-five women with POP were recruited to the trial from November 2005 to April 2008. The flow chart (Fig. 2) presents the numbers and reasons for exclusion and dropout. One hundred nine participants were randomly allocated to pelvic floor muscle training (n=59) or control (n=50). Forty-seven (79%) of the women in the pelvic floor muscle training group reached an adherence level of 80%. On the 6-month postal questionnaire five of the 49 women in the control group stated that they had been doing pelvic floor muscle training more frequently after beginning the trial compared with the time period before the project. No adverse effects were reported. Table 1 shows background variables for both groups. Groups were similar in background variables and stage of POP (P=.54), except that women in the pelvic floor muscle training group were more likely to report the symptom of vaginal bulging/pelvic heaviness than were women in the control group. No statistical significant differences between groups were found for ultrasound measurements at baseline (muscle thickness P=.543, hiatal area at rest P=.167, hiatal area at Valsalva P=.678, muscle length at rest P=.093, muscle length at Valsalva P=.424, position of bladder P=.934, and position of rectum P=.091). During a single voluntary pelvic floor muscle contraction at baseline the hiatal area narrowed 4.8 cm<sup>2</sup> (95% CI 4.2–5.4, n=103) from 22.6 to 17.6 cm<sup>2</sup>, the bladder moved 8.3 mm (95% CI 7.1-9.5, n=89), and the rectum moved 13.4 mm (95% CI 11.6-15.1, n=82) in a cranial-anterior direction.

Baseline values, postintervention values, and within-group comparisons are presented in Table 2. Table 3 shows differences between groups in changes of all

Table 1. Background and Baseline Data for Women in the Pelvic Floor Muscle Training Group and Control Group

	Pelvic Floor Muscle Training Group (n=59)	Control Group (n=50)	
Age (y)	49.4±12.2	48.3±11.4	
Body mass index (kg/m²)	$25.8 \pm 3.8$	26.1±5.33	
Parity	$2.4\pm0.8$	$2.4\pm0.7$	
Stage of POP (POP-Q)			
(n=58)			
No. with stage I POP	8 (13.8)	11 (22.0)	
No. with stage II POP	36 (63.8)	29 (58.0)	
No. with stage III POP	14 (22.4)	10 (20.0)	
Position of the pelvic			
organs measured by ultrasound			
Bladder distance from	$8.3 \pm 5.3$	8.4±6.1	
SP (mm)			
Rectum distance from SP (mm)	$46.5 \pm 8.7$	43.0±9.8	
Number of women with			
Stress urinary	39 (66.1)	27 (54.0)	
incontinence			
Defecation problems	25 (42.4)	15 (30.0)	
Incontinence of flatus	34 (57.6)	23 (46.0)	
Fecal incontinence	14 (23.7)	10 (20.0)	
Symptoms			
No. with POP	43 (72.9)	26 (52.0)	
symptoms			
No. with bladder	51 (86.4)	36 (72.0)	
symptoms			
No. with bowel	38 (64.4)	27 (54.0)	
symptoms			

POP, pelvic organ prolapse; POP-Q, Pelvic Organ Prolapse Quantification System; SP, symphysis pubis. Data are mean±standard deviation or n (%).

ultrasound variables. Relative to baseline (Table 2) women in the pelvic floor muscle training group increased muscle thickness by 15.6%, narrowed the resting area of levator hiatus by 6.3%, reduced pubovisceral muscle length by 4.2% (Table 3), and elevated the resting position of the bladder by 4.2 mm and the rectal ampulla by 3.6 mm. A subgroup analyses of increase in pubovisceral muscle thickness in women with symptomatic POP stage II and III (n=59) demonstrated a difference of 1.6 mm (95% CI 0.6–2.9, P=.013) in favor of the pelvic floor muscle training group compared with 1.4 mm for all included women (Table 3). Intention-to-treat analyses did not significantly alter the results presented in Tables 2 and 3.

Women in the pelvic floor muscle training group increased their pelvic floor muscle strength by 13.1 cm  $H_2O$  (95% CI 10.6–15.5) compared with 1.1 cm  $H_2O$  (95% CI 0.4–2.7) in the control group (P<.01). There



**Table 2.** Three-Dimensional Ultrasound Measurements Before and After the Intervention Period for the Pelvic Floor Muscle Training Group and Control Group

	Pelvic Floor Muscle Training Group (n=59)		
	Pretest	Posttest	Р
Morphology			
Muscle thickness (mm)	9.0 (8.5–9.6) [58]	10.5 (9.8–11.1) [56]	<.001 [56]
Levator hiatus area at rest (cm <sup>2</sup> )	23.7 (22.4–25.1) [59]	22.2 (20.9–23.4) [58]	.002 [58]
Muscle length at rest (mm)	121.2 (117.0–125.5) [55]	117.2 (112.7–121.7) [56]	.001 [54]
Function			
Levator hiatus area maximum Valsalva (cm²)	29.5 (26.5–32.4) [37]	28.9 (26.3–31.4) [50]	.004 [36]
Muscle length at Valsalva (mm)	142.3 (132.8–151.9) [37]	140.0 (132.8–147.2) [50]	.001 [36]

Data are mean (95% confidence interval) [n].

were positive correlations between increased pelvic floor muscles strength and the following variables: increased muscle thickness (r=0.35, n=104, P<.001), decreased hiatal area at maximum Valsalva (rho=0.25, n=76, P=.028), shortened muscle length at Valsalva (rho=0.28, n=75, P=.013), elevated bladder (rho=0.25, n=92, P=.017), and elevated rectum (rho=0.38, n=74, P=.001). There were no significant correlations between increases in pelvic floor muscles strength and changes in size of levator hiatus and muscle length at rest.

### **DISCUSSION**

The present RCT supports the findings of uncontrolled studies that showed an increase in muscle thickness, <sup>22</sup> reduction of the levator ani muscle surface, <sup>23</sup> and elevated resting position of the bladder <sup>24</sup> and give further new insight into the effect of pelvic floor muscle training. While contracting their pelvic floor muscles during increases in abdominal pressure, a pelvic floor muscle precontraction at the moment of expected leakage, has been shown to decrease stress urinary incontinence, <sup>6</sup> our study shows that instruction to contract their pelvic floor muscles during increases in abdom-

inal pressure does not improve pelvic floor muscle strength or attribute to morphological adaptations. This is in agreement with the theoretical rationale for doing this maneuver.

The increase in strength after chronic exposure to high-resistance strength training is attributed to both neurological and morphological adaptations, and the primary morphological adaptation to general strength training is hypertrophy (whole-muscle growth.<sup>25</sup> We found a 44% increase in muscle strength, a 15% increase in muscle thickness, and a correlation between muscle thickness and muscle strength. This corresponds with results for strength training of the upper and lower limb, 25 and the increase in muscle thickness is higher than what was found for the pelvic floor muscles in a previously published uncontrolled study (8%).<sup>22</sup> This discrepancy in measured hypertrophy can be explained by the different ultrasound assessment methods, measurements sites, length of the training period, different pelvic floor muscle training dosages, and study populations. In addition to morphological changes, the present study demonstrated functional changes. The resting positions of the bladder and rectum were elevated, and

**Table 3.** Three-Dimensional Ultrasound-Measured Changes of Pubovisceral Muscle Morphology and Functional Changes After Pelvic Floor Muscle Training

	Pelvic Floor Muscle Training Group	Control Group	Difference Between Groups	P	Effect Size
Morphological changes					
Muscle thickness at rest (mm)	1.4 (0.8 to 2.0) [56]	-0.5 (-1.0  to  0.0) [47]	1.9 (1.1 to 2.7)	<.001	.85
Levator hiatus area at rest (cm2)*	-1.5 ( $-2.4$ to $-0.6$ ) [58]	0.3 (-0.7 to 1.2) [45]	1.8 (0.4 to 3.1)	.026	.51
Muscle length at rest (mm)*	-5.1 (-8.0  to  -2.3) [54]	1.0 (-2.7 to 4.7) [46]	6.1 (1.5 to 10.7)	.007	.52
Functional changes					
Bladder position at rest (mm)	4.2 (2.8 to 5.6) [45]	-0.1 ( $-1.9$ to $1.6$ ) [45]	4.3 (2.1 to 6.5)	<.001	.75
Rectum position at rest (mm)*	3.6 (-0.3 to 7.4) [35]	-3.4 (-6.4  to  -0.3) [37]	6.7 (2.2 to 11.8)	.007	.65
Levator hiatus area at Valsalva (cm2)*	-2.3 (-4.0  to  -0.5) [36]	0.1 (-1.7 to 1.8) [38]	2.3 (-0.1 to 4.8)	.021	.43
Muscle length at Valsalva (mm)*	-7.8 (-13.3 to -2.3) [36]	3.2 (-2.2 to 8.5) [37]	11.0 (3.4 to 18.5)	.001	.65

Data are mean (95% confidence interval) [n].



<sup>\*</sup> Data are not normally distributed.

Control Group (n=50)			
Pretest	Posttest	Р	
9.4 (8.6–10.1) [47]	9.0 (8.3–9.6) [48]	.065 [47]	
22.6 (21.0–24.2) [50]	22.6 (20.9–24.3) [45]	.870 [43]	
113.9 (108.3–119.9) [47]	115.6 (110.4–120.7) [47]	.441 [46]	
30.3 (27.6–33.0) [43]	30.6 (28.0–33.2) [42]	.512 [38]	
137.9 (129.5–146.3) [42]	141.1 (132.9–149.5) [42]	.106 [37]	

the pubovisceral muscle length and hiatus size at maximum Valsalva were reduced. These findings may be explained by increased "stiffness" in the muscle-connective tissue complex. Increases in the amount of collagen and muscle tissue, changes in muscle architecture, and altered structure of connective tissue have been described as other possible morphological adaptations after general strength training.<sup>25</sup>

It is unlikely that the changes in morphology at rest after 6 months of strength training of the pelvic floor muscles can exceed the displacements that happen during a single voluntary pelvic floor muscle contraction. Based on the results of the present study it can be expected that, after training, the resting position of the bladder will elevate with a distance equivalent to half of the lift during a voluntary contraction, the rectum with one fourth of the distance and the resting size of levator hiatus can constrict half of a voluntary pelvic floor muscle squeeze. Because of the lack of large crosssectional studies there is scant knowledge about biometric values of the pelvic floor muscles for women with normal and pathological pelvic floor support. In one study the urogenital hiatus was measured with a ruler and calculated to be 1 cm<sup>2</sup> larger for stage II compared with stage I prolapse, 10 and in another study, a difference of 4.3 cm<sup>2</sup> between women with and without prolapse was measured using ultrasonography.<sup>11</sup> We demonstrated a decrease in the levator hiatus area by 1.5 cm<sup>2</sup> after pelvic floor muscle training. In women with unilateral defects the cross-sectional area of the levator ani muscle has shown to be 13.7% lower on the affected side. 19 The present study found a 15% increase in mean muscle thickness after strength training.

Strengths of the present study include the use of a training protocol based on strength training recommendations,<sup>26</sup> a 6-month training period as recommended for achieving maximal hypertrophy,<sup>25</sup> high adherence to the training protocol (79%), low dropout rate (n=2), a randomized design, blinding of the assessors, and use of ultrasound imaging. Due to the fact that a higher proportion of women with POP may have muscular de-

fects,12 reduced pelvic floor muscles thickness,7,8 and increased size of the levator hiatus compared with women with stress urinary incontinence9 and healthy control group members, 9-11 we believe that the same, or even better effects, may occur in women with stress urinary incontinence alone and in asymptomatic women. However, the majority of the women in the present study had POP stage II, and the results may therefore not be generalizible to women with more severe POP. Research in the area of POP has suffered from the lack of a standardized definition of POP, and POP can be defined as stage I or more or stage II or more.<sup>27,28</sup> In addition, some research groups suggest including both physical findings and bothersome symptoms in the definition of POP.<sup>29</sup> We included women with stage I POP and asymptomatic women both to adhere to the definition of POP and because we wished to assess the effect of pelvic floor muscle training as a prevention strategy (that is, in women with early and asymptomatic prolapse) as well as a treatment strategy. The present study demonstrated that pelvic floor muscle training led to increased muscle thickness both in women with stage I POP and in symptomatic women with stage II or greater POP.

The intervention of this exploratory study is relatively rigorous. While this intervention can be replicated by others, it may be difficult depending on reimbursement patterns and patients' expectations and motivations. It would be clinically important to conduct future trials to determine whether similar results are achievable with a less-rigorous intervention, eg, teaching the same pelvic floor muscle training in groups<sup>13</sup> or with fewer visits. However, if future results indicate that a less-rigorous protocol is less effective, it would not be good practice to implement it.

The present study showed that pelvic floor muscle training has the possibility to "tighten up" the pelvic floor. The morphological changes found after pelvic floor muscle training can directly affect possible underlying anatomical and pathophysiological mechanisms such as decreased muscle strength, widening of the



hiatus, and descended pelvic organs. Hence, the results of this RCT demonstrate that it is possible to restore some of the pelvic floor dysfunction by pelvic floor muscle training. Longer follow-up studies are needed to determine if these changes are sustainable.

#### **REFERENCES**

- Bump RC, Norton PA. Epidemiology and natural history of pelvic floor dysfunction. Obstet Gynecol Clin North Am 1998;25:723-46.
- Hay-Smith E, Bo K, Berghmans L, Hendriks H, de Bie R, van Waalwijk van, Doorn E. Pelvic floor muscle training for urinary incontinence in women. Cochrane Database of Systematic Reviews 2007, Issue 1. Art. No.:CD001407.
- 3. Bo K. Pelvic floor muscle training for stress urinary incontinence. In: Bo K, Berghmans B, Morkved S, Kampen MV, editors. Evidence-based physical therapy for the pelvic floor. Philadelphia (PA): Elsevier; 2007. p. 171–87.
- Hagen S, Stark D, Maher C, Adams E. Conservative management of pelvic organ prolapse in women. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.:CD003882.
- Bo K. Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work? Int Urogynecol J Pelvic Floor Dysfunct 2004;15:76–84.
- Miller JM, Sampselle C, Ashton-Miller J, Hong GR, DeLancey JO. Clarification and confirmation of the Knack maneuver: the effect of volitional pelvic floor muscle contraction to preempt expected stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:773–82.
- Hoyte L, Jakab M, Warfield SK, Shott S, Flesh G, Fielding JR. Levator ani thickness variations in symptomatic and asymptomatic women using magnetic resonance-based 3-dimensional color mapping. Am J Obstet Gynecol 2004;191:856–61.
- Chen L, Hsu Y, Ashton-Miller JA, DeLancey JO. Measurement of the pubic portion of the levator ani muscle in women with unilateral defects in 3-D models from MR images. Int J Gynaecol Obstet 2006;92:234–41.
- Hoyte L, Schierlitz L, Zou K, Flesh G, Fielding JR. Two- and 3-dimensional MRI comparison of levator ani structure, volume, and integrity in women with stress incontinence and prolapse. Am J Obstet Gynecol 2001;185:11–9.
- Delancey JO, Hurd WW. Size of the urogenital hiatus in the levator ani muscles in normal women and women with pelvic organ prolapse. Obstet Gynecol 1998;91:364-8.
- Athanasiou S, Chaliha C, Toozs-Hobson P, Salvatore S, Khullar V, Cardozo L. Direct imaging of the pelvic floor muscles using two-dimensional ultrasound: a comparison of women with urogenital prolapse versus controls. BJOG 2007; 114:882-8.
- 12. Dietz HP, Simpson JM. Levator trauma is associated with pelvic organ prolapse. BJOG 2008;115:979–84.
- Bo K, Talseth T, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. BMJ 1999;318:487–93.
- Altman DG. Practical statistics for medical research. London (UK): Chapman & Hall/CRC; 1999.
- Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, Shull BL, Smith AR. The standardization of

- terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996;175:10–7.
- Dietz HP, Shek C, Clarke B. Biometry of the pubovisceral muscle and levator hiatus by three-dimensional pelvic floor ultrasound. Ultrasound Obstet Gynecol 2005;25:580-5.
- Majida M, Braekken IH, Umek W, Bo K, Saltyte, Benth J, Ellstrom Engh M. Interobserver repeatability of three- and four-dimensional transperineal ultrasound assessment of pelvic floor muscle anatomy and function. Ultrasound Obstet Gynecol 2009;33:567–73.
- Braekken IH, Majida M, Ellstrom-Engh M, Dietz HP, Umek W, Bo K. Test-retest and intra-observer repeatability of two-, three- and four-dimensional perineal ultrasound of pelvic floor muscle anatomy and function. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:227–35.
- Braekken IH, Majida M, Engh ME, Bo K. Test-retest reliability of pelvic floor muscle contraction measured by 4D ultrasound. Neurourol Urodyn 2009;28:68–73.
- 20. Schaer GN, Koechli OR, Schuessler B, Haller U. Perineal ultrasound for evaluating the bladder neck in urinary stress incontinence. Obstet Gynecol 1995;85:220-4.
- Peschers U, Schaer G, Anthuber C, Delancey JO, Schuessler B. Changes in vesical neck mobility following vaginal delivery. Obstet Gynecol 1996;88:1001–6.
- Bernstein IT. The pelvic floor muscles: muscle thickness in healthy and urinary-incontinent women measured by perineal ultrasonography with reference to the effect of pelvic floor training. Estrogen receptor studies. Neurourol Urodyn 1997; 16:237–75.
- 23. Dumoulin C, Peng Q, Stodkilde-Jorgensen H, Shishido K, Constantinou C. Changes in levator ani anatomical configuration following physiotherapy in women with stress urinary incontinence. J Urol 2007;178:970–7; quiz 1129.
- Balmforth JR, Mantle J, Bidmead J, Cardozo L. A prospective observational trial of pelvic floor muscle training for female stress urinary incontinence. BJU Int 2006;98:811–7.
- Folland JP, Williams AG. The adaptations to strength training: morphological and neurological contributions to increased strength. Sports Med 2007;37:145–68.
- Haskell WL, Lee IM, Pate RR, Powell KE, Blair SN, Franklin BA, et al. Physical activity and public health. Updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. Circulation 2007;116:1081–93.
- Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, et al. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn 2002;21:167–78.
- Weber AM, Abrams P, Brubaker L, Cundiff G, Davis G, Dmochowski RR, et al. The standardization of terminology for researchers in female pelvic floor disorders. Int Urogynecol J Pelvic Floor Dysfunct 2001;12:178–86.
- Swift S. Pelvic organ prolapse: is it time to define it? Int Urogynecol J Pelvic Floor Dysfunct 2005;16:425–7.
- 30. Bo K, Braekken IH, Majida M, Engh ME. Constriction of the levator hiatus during instruction of pelvic floor or transversus abdominis contraction: a 4D ultrasound study. Int Urogynecol J Pelvic Floor Dysfunct 2009;20:27–32.

