Effect of Adding Biofeedback to Pelvic Floor Muscle Training to Treat Urodynamic Stress Incontinence

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OBJECTIVE: To compare the effect of individual pelvic floor muscle training with and without biofeedback in women with urodynamic stress incontinence

METHODS: The study was a single, blind, randomized trial. All women completed 6 months of pelvic floor muscle training comprising three sets of ten contractions three times per day, supervised by a physical therapist. One group trained with a biofeedback apparatus at home, the other without biofeedback. The primary outcome measures were pad test with standardized bladder volume and self-report of severity.

RESULTS: A total of 103 women were randomized, and data from 94 women were analyzed. Mean age (range) was 46.6 (30–70) years, and mean (range) duration of symptoms was 9.7 (1–25) years. Seventy women had urodynamic stress incontinence alone, and 24 women reported additional urge symptoms. Women training with and without biofeedback showed a statistically significant reduction in leakage on pad test ($P < .01$) after 6 months of pelvic floor muscle training. Objective cure (2 g or less of leakage) in the total group was 58% in women training with and 46% in women training without biofeedback, and in the subgroup of women with urodynamic stress incontinence alone, 69% in women training with and 50% in women training without biofeedback. There was no statistically significant difference between the groups posttreatment in any outcome measure.

CONCLUSION: Cure rate was high, and the reduction in urinary leakage after treatment was statistically significant in both groups. However, there was no statistically significant difference in the effect of individual pelvic floor muscle training with and without biofeedback. (Obstet Gynecol 2002;100:730–9. © 2002 by The American College of Obstetricians and Gynecologists.)

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In addition to the authors, the research group comprised Unni Aspmo, Runa Heimstad, Bengt Johansson, Ove Mjølnerød, Kjell Åsmund Salvesen, Olaug Gimse Storrø, and Anita Vanvik. Jean Hay-Smith has given valuable help with the English revision of the manuscript.

Financial support was given by The Norwegian Industrial and Regional Development Fund, Norwegian National Insurance Administration, and by Trondheim Regional Hospital 2000, SINTEF Unimed, Trondheim and Vitacon, Trondheim, Norway.

Some 50 years have elapsed since Kegel first introduced pelvic floor muscle training to treat female urinary incontinence.[1] In his first uncontrolled studies, he claimed to have a greater than 84% cure rate in women with urinary incontinence.[1] The training protocol included vaginal palpation and clinical observation of a voluntary pelvic floor muscle contraction and the use of vaginal squeeze pressure measurement as biofeedback during exercise. Today, a wide variety of biofeedback apparatus is commonly used in clinical practice to assist with pelvic floor muscle training.

Biofeedback has been defined as "a group of experimental procedures where an external sensor is used to give an indication on bodily processes, usually in purpose of changing the measured quality."[2] Biofeedback equipment has been developed within the area of psychology, mainly for measurement of sweating, heart rate, and blood pressure during different forms of stress. In the area of pelvic floor muscle training, both vaginal and anal surface electromyograms and urethral and vaginal squeeze pressure measurements have been used with the purpose of making the patients more aware of muscle function, and to enhance and motivate patients' effort during training.[3] The term biofeedback is often used as something different from pelvic floor muscle training. However, biofeedback is not a treatment on its own. It is an adjunct to training, measuring the response while the patient is contracting.

Since Kegel[1] first presented his results, several randomized, controlled trials have shown that pelvic floor muscle training without biofeedback is more effective than no treatment[4–7] for female stress and urodynamic stress incontinence.

Several randomized, controlled trials have aimed to compare the effect of pelvic floor muscle training with additional biofeedback versus pelvic floor muscle training with no biofeedback on stress and urodynamic stress incontinence or mixed incontinence.[8–14] All but one of

0029-7844/02/$22.00
PII S0029-7844(02)02160-9

these trials failed to show any additional effect of adding biofeedback to the training protocol. In the trial by Glavind et al,[14] a positive effect was demonstrated. However, the result might have been confounded by different frequency of training between the two groups.

In most of the published trials on biofeedback and stress and urodynamic stress incontinence, the sample sizes are small, and type II error may have been the reason for negative findings.[13,15–17] Because pelvic floor muscle training is effective for stress and urodynamic stress incontinence without biofeedback,[4–7] a large sample size may be needed to show any beneficial effect of adding biofeedback to the training protocol. In addition, there are other methodologic problems with previous studies, such as poor randomization procedures, lack of masking of outcome assessors, and inadequate training protocols.[17]

The rationale for applying pelvic floor muscle training is theoretically better founded for stress and urodynamic stress incontinence than for urge and mixed incontinence.[18] All but one of the above-mentioned studies included women with stress and urodynamic stress incontinence. However, the largest study included women with mixed incontinence.[12] According to Burns et al,[12] the support of the exercise therapy with the aid of biofeedback may increase pelvic muscle coordination and control versus exercise therapy by itself. Berghmans et al[13] claim that adding biofeedback to pelvic floor muscle training as a support to pelvic floor exercises is most important in the beginning of the treatment period.

The aim of the present study was to compare the effect of 6 months of individual pelvic floor muscle training with and without biofeedback in women with urodynamic stress incontinence. The study was restricted to women with urodynamic stress incontinence because the rationale for applying pelvic floor muscle training is better founded theoretically for stress and urodynamic stress incontinence than for urge and mixed incontinence,[18] and the largest biofeedback study to date was in women with mixed incontinence.[12] A second aim was to rule out if there was a possible early effect of using biofeedback on pelvic floor muscle strength.

MATERIALS AND METHODS

The study was a single, blind, randomized, controlled trial with stratified design. Participants were women with symptoms of stress incontinence recruited by advertisements in local newspapers. A nurse conducted a standardized assessment at enrollment, which included history, uroflowmetry, cystometry, and pad test with standardized bladder volume. An urologist evaluated assessment findings, and if the patient was judged suitable for inclusion, a gynecologist performed a gynecologic examination to ensure that the patient was suitable for the planned treatment. The local ethics committee approved the study, and all women gave written consent to participate. The patients were recruited and followed in a period from May 1999 to November 2000.

Inclusion criteria were history of stress incontinence and more than 2 g of leakage measured by a pad test with standardized bladder volume. Exclusion criteria were involuntary detrusor contractions on cystometry, abnormal bladder function (residual urine more than 50 mL), previous surgery for stress incontinence, neurologic or psychiatric disease, urinary tract infection, other diseases that could interfere with participation, pregnancy, use of concomitant treatments during the trial period, and inability to understand instructions given in Norwegian.

We aimed to recruit 96 women with urodynamic stress incontinence, giving 80% power ($\alpha = 5\%$) to detect a 25% difference in the number of women with objective cure between the two groups, assuming that 60% would be cured with pelvic floor muscle training without biofeedback. These figures were conservatively based on findings in previous studies.[13,19] Taking possible withdrawals into account, 103 women were enrolled.

The randomization procedure was as follows. After the standard assessment at enrollment, the gynecologist referred the potential participants to the physical therapist. The participants were stratified into two groups according to results of a pad test with standardized bladder volume (20 g or less and more than 20 g of leakage). They were then randomized to one of two groups (pelvic floor muscle training with or without biofeedback) by using opaque sealed envelopes. The randomization procedure was centralized but not computerized. All the envelopes were mixed thoroughly before they were stored in a bigger envelope. From here, each participant drew one envelope herself. The envelopes were prepared, stored, and opened by the participants with no access for the professional staff doing the outcome assessments. The participants were asked to say nothing that could disclose group allocation to the staff doing the outcome assessments. The nurses and urologist doing the outcome assessments were masked to group allocation. The main investigator (SM) was not involved in any interventions or outcome assessments.

The following interventions were performed. All participants were individually instructed in pelvic floor anatomy and how to contract the pelvic floor muscles correctly. Correct contraction was assessed by vaginal palpation and observation of inward movement of the perineum during contraction.[20,21] Feedback, knowledge of results, and performance were provided by the physical therapist.

Participants in the two treatment groups were told that the treatments were expected to be equally effective and were discouraged from using other treatments during the 6-month trial period. The participants were not compensated financially.

The protocol for the pelvic floor muscle training has been described previously.[19] However, in the present study, the participants were all treated individually and not in groups. All patients in both groups met the physical therapist for individual training sessions, motivation, and monitoring of pelvic floor muscle strength, once per week during the first 2 months, and every second week during the next 4 months.

At each clinic visit, a total of three sets of ten contractions were completed. Participants aimed at holding each muscle contraction for 6–8 seconds, then to add three or four fast contractions on top of each sustained contraction. The participants in the biofeedback group trained with the biofeedback apparatus, and the participants in the other group were trained without. During the training sessions with the physical therapist, instructions concerning adjustments of the training, progression, and motivation were given.

In addition, at home, the participants in both groups were encouraged to conduct three sets of ten high-intensity (close to maximum) contractions per day, one group with and the other group without use of the biofeedback apparatus.

The biofeedback group used a biofeedback apparatus specially designed for home training of the pelvic floor muscles (BF-106 Biofeedback, Vitacon, Norway). A vaginal pressure probe was placed inside the vagina, measuring vaginal squeeze pressure. Under the physical therapist's supervision and encouragement, the participant conducted three sets of ten high-intensity (close to maximum) pelvic floor muscle contractions when using the biofeedback apparatus. The contractions were measured and stored in the apparatus, and used by the physical therapist to program individual templates for the patient to follow at home. New templates were programmed by the physical therapist when the measurement showed that the pelvic floor muscle strength had increased.

As part of the primary outcome measures, a pad test with standardized bladder volume was performed. After the bladder was emptied by catheter, it was refilled with 300 mL of saline. Women wore preweighed pads and jumped with legs in subsequent adduction and abduction (jumping jacks/star jumps: 20 repetitions) and coughed three times. After the test, the pad was reweighted. Objective cure was defined as 2 g or less of leakage.

A subjective assessment of severity followed. Women recorded how they perceived the condition before and after treatment on a 5-point scale (unproblematic, minor problem, moderate problem, problematic, very problematic).[6] Subjective cure was defined as reporting the leakage to be unproblematic after treatment.

As part of secondary outcome measures, a 48-hour pad test was performed. The patients conducted 48-hour pad weighs at home before trial entry and after the last clinic visit. Women were asked to choose two following days mirroring their average level of activity.[13]

The leakage index and social activity index, two instruments designed to measure how women perceive stress incontinence, tested for reproducibility,[22] were used before and after treatment. The leakage index is a 5-point scale (1 = never, 5 = always) containing 13 types of physical activities known to trigger urinary leakage. The social activity index contains nine social settings in which women may have problems with participation. For each characteristic, a 10-cm visual analogue scale (0 = impossible to participate, 10 = no problem to participate) was used.

The pelvic floor muscle function and strength were assessed. The physical therapist used vaginal palpation and observation to assess the women's ability to perform pelvic floor muscle contraction.[20,21] The women were in a supine position with straight legs. One finger was used for palpation. No observable synergistic contractions of hip adductors and gluteal muscles, or pelvic tilt, were accepted.

Muscle strength was measured by a vaginal balloon catheter (balloon size 6.7 × 1.7 cm) connected to a pressure transducer (Camtech Ltd., Sandvika, Norway), measuring vaginal squeeze pressure during pelvic floor muscle contractions.

Positioning was with the middle of the balloon 3.5 cm inside the introits vagina.[21] Only contractions with observed inward movement of the balloon catheter were accepted. The method has been found to be reliable and valid.[21]

Statistical methods were conducted as follows. The primary analysis was carried on data from treated participants by diagnostic group, with exclusion of data from those without final evaluation on efficacy variables. Additional intention-to-treat analysis was also done for all randomized patients including those who dropped out. The missing last values were considered as equal to baseline values.[23] Results are given as mean values with 95% confidence intervals. As several variables were not normally distributed, pair-wise comparisons were made with the Mann-Whitney U test to compare between groups (the group training with biofeedback with the group training without biofeedback), and Wilcoxon signed rank test to compare changes within each group. χ^2 tests were used if data were nominal or categoric. P

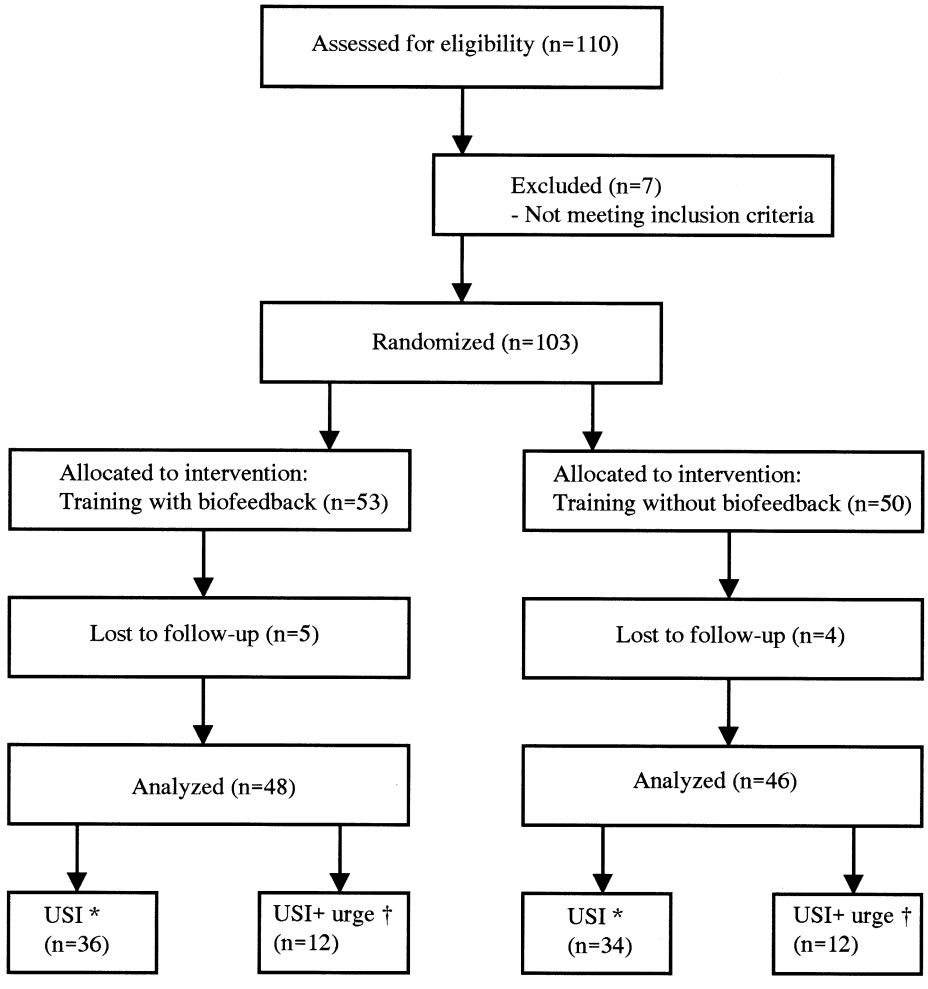

Figure 1. Flow diagram of subject progress through the phases of the randomized trial comparing pelvic floor muscle training with and without biofeedback. USI = urodynamic stress incontinence. *Women with urodynamic stress urinary incontinence without additional symptoms of urge incontinence. †Women with urodynamic stress urinary incontinence with additional symptoms of urge incontinence.

Mørkved. Pelvic Floor Muscle Training With Biofeedback. Obstet Gynecol 2002.

values $< .05$ were considered significant. The statistical software program used was SPSS 10-7 (SPSS Inc., Chicago, IL).

RESULTS

A total of 103 patients were randomized (Figure 1). Nine women did not complete the study (dropout rate 8.7%). There were four dropouts from each group because of changes in work situation, family causes, death, or disease in the family, or because they moved to other parts of the country. One woman dropped out from the biofeedback group because she disliked the biofeedback equipment. Seventy women had urodynamic stress incontinence alone (36 in the group training with biofeedback and 34 in the group training without biofeedback), and 24 women (12 in the group training with biofeedback and 12 in the group training without biofeedback) reported symptoms of urge incontinence in addition to urodynamic stress incontinence. Cystometry showed no urge in any women. Results are reported both in the total group and in the subgroup with urodynamic stress incontinence alone.

All the women were training their pelvic floor muscles regularly during the 6-month treatment period. In total, 88.9% of the women in the group training with biofeedback and 85.3% in the group training without biofeedback were training their pelvic floor muscles more than three times per week (not significant).

Table 1. Background and Outcome Variables at Baseline

	With biofeedback (n = 48)	Without biofeedback (n = 46)	P
Age (y)	47.8 (8.2)	45.4 (8.1)	.17
Body mass index (kg/m^2)	25.3 (3.7)	26.2 (4.3)	.33
Parity	2.3 (1.0)	2.5 (1.0)	.35
Duration of symptoms (y)	8.8 (6.2)	10.5 (6.6)	.23
Pelvic floor muscle strength (cmH_2O)	13.6 (9.8)	14.4 (7.8)	.66
n (%) with urodynamic stress incontinence alone	36 (75)	34 (74)	.90
n (%) with urodynamic stress incontinence with additional urge incontinence symptoms	12 (25)	12 (26)	.90
n (%) postmenopausal	13 (27)	10 (22)	.74
n (%) using estrogen	14 (29)	10 (22)	.41
n (%) undertaking regular exercise	29 (60)	29 (67)	.49
Stress pad test	25.7 (24.2)	29.0 (34.5)	.84
48-h pad test	39.8 (36.6)	44.6 (33.9)	.25
Leakage index	2.8 (0.7)	2.8 (0.5)	.83
Social activity index	9.1 (0.9)	9.2 (0.6)	.95

Values are means (standard deviation) unless stated otherwise (N = 94).

There were no significant differences between the groups training with and without biofeedback at baseline (Table 1).

Objective cure (2 g or less of leakage on the pad test with standardized bladder volume) after treatment is shown in Table 2. There was no statistical significant difference between women training with or without biofeedback.

Subjective cure (incontinence no longer problematic) is shown in Table 3. There was no statistically significant (total group: P = .353, subgroup: P = .193) difference in the number of women reporting that their incontinence was unproblematic/problematic between groups training with and without biofeedback.

Table 2. Objective Cure (≤2 g of Leakage on the Pad Test With Standardized Bladder Volume) in Women Training With (+) and Without (−) Biofeedback

	+ Biofeedback	− Biofeedback	P*
Total group	(n = 48)	(n = 46)	
n (%) women with objective cure	28 (58)	21 (46)	.219
USI	(n = 36)	(n = 34)	
n (%) women with objective cure	25 (69)	17 (50)	.097

USI = urodynamic stress incontinence.

Total group (N = 94) and subgroup of women with USI alone (N = 70).

* Pearson χ^2 test.

The results of the 48-hour home pad test in the total group showed cure after treatment in 31 (65%) women training with and in 26 (57%) women training without biofeedback. In women with urodynamic stress incontinence alone, 24 women (67%) in the group training with biofeedback and 22 (65%) in the group training without biofeedback were cured after the treatment period. The differences between groups were not statistically significant.

Outcome variables at baseline and after 6-month treatment are shown in Table 4. Comparison within groups training with and without biofeedback concerning change in outcome variables from baseline to after 6-month training showed statistically significant ($P <$ .05) reduction in gram leakage on the pad test with standardized bladder volume and the 48-hour home pad test, and improvement at the leakage index and the social activity index (Table 4).

Comparison between the groups training with and without biofeedback showed no statistically significant differences on changes in outcome measures or pelvic floor muscle strength (Table 5).

Details of the pelvic floor muscle strength increment within the groups training with and without biofeedback are shown in Table 6. Comparison within groups showed statistically significant ($P <$ .01) changes in pelvic floor muscle strength from baseline registration to 3- and 6-month treatments in both groups. However, in women with urodynamic stress incontinence alone, the change in pelvic floor muscle strength between 3- and 6-month measurements was statistically significant ($P <$ .05) only in the biofeedback group.

Additional subjective reports showed that ten of the 94 participants found the treatment unpleasant; seven in the biofeedback group found the use of the apparatus unpleasant, and three in the group training without biofeedback found the pelvic floor muscle training itself unpleasant. However, they followed the training protocol in spite of this. All women in the group training with and the group training without biofeedback reported that they would recommend the treatment to others. Eighty percent of the participants in the biofeedback group and 71% in the group training without biofeedback reported that they were satisfied/very satisfied with the treatment. None were unsatisfied with the treatment. Ninety-seven percent in the biofeedback group and 93% in the other group reported improvement after treatment. The remaining participants reported that their leakage problem was unchanged. Two women in the biofeedback group and three in the group training without biofeedback

Table 3. Subjective Cure: Experienced Problems With Urinary Incontinence Before and After 6-Month Pelvic Floor Muscle Training in the Groups Training With (+) and Without (−) Biofeedback

	Total group *n* (%)				USI *n* (%)			
	+ Biofeedback (*n* = 48)		− Biofeedback (*n* = 46)		+ Biofeedback (*n* = 36)		− Biofeedback (*n* = 34)	
	Baseline	6 mo	Baseline	6 mo	Baseline	6 mo	Baseline	6 mo
Unproblematic	0	19 (40)	0	14 (30)	0	16 (44)	0	10 (29)
Minor problem	13 (27)	17 (35)	12 (26)	18 (39)	10 (28)	12 (33)	11 (32)	17 (50)
Moderate problem	14 (29)	8 (17)	10 (22)	5 (11)	8 (22)	5 (14)	7 (21)	4 (12)
Problematic	16 (33)	3 (6)	16 (35)	6 (13)	14 (39)	2 (6)	13 (38)	2 (6)
Very problematic	5 (10)	1 (2)	8 (17)	3 (7)	4 (11)	1 (3)	3 (9)	1 (3)

USI = urodynamic stress incontinence.
Total group ($N = 94$) and subgroup of women with USI alone ($n = 70$).

wanted another kind of treatment (surgery) after they had finished the training period.

There was a significant reduction in pad use both in women training with and women training without biofeedback, but no significant difference between groups. Before treatment, 60% of all participants reported that they used pads often/always, compared with 39% after treatment.

The results according to the intention-to-treat analysis showed the same results as the treatment analysis.

DISCUSSION

The results of the present study correspond with the conclusion of randomized, controlled trials and meta-analysis comparing the effect of pelvic floor muscle training with and without biofeedback.[15–17] No statistically significant difference between the two groups was shown in any of the outcome variables or in muscle strength.

The strengths of the present study are the blinding of investigators, low dropout, high adherence, use of valid and reproducible outcome measures, and that the participants in both groups had the same training protocol and same amount of visits to, and attention from, the physical therapist. In addition, to date, this is one of the largest studies comparing pelvic floor muscle training with and without biofeedback. Except for the study of Burns et al[12] who had 40 in each group, the other published studies have sample sizes varying between ten and 20 in each group, a possible explanation for nonsignificant results.[8–13] Burns et al[12] included women with stress, urge, and mixed incontinence. However, our study confirms their findings with no difference between groups.

In a nonrandomized and nonblinded study, Burgio et al[24] showed that use of electromyograms was significantly more effective than verbal feedback both to improve pelvic floor muscle function and urinary incontinence. However, randomized, controlled trials have not been able to confirm their results.

Table 4. Outcome Variables at Baseline and After 6-Month Treatment in Groups Training With and Without Biofeedback: Reduction in Gram Leakage on Pad Test With Standardized Bladder Volume, and on 48-Hour Home Pad Test, Reduction on Leakage Index, and Improvement on Social Activity Index

	With biofeedback			Without biofeedback		
	Baseline	6 mo	*P**	Baseline	6 mo	*P**
Total group	(*n* = 48)			(*n* = 46)		
Standardized pad test	25.7 (18.7, 32.7)	6.1 (3.1, 9.1)	<.01	29.0 (18.8, 39.3)	10.6 (4.7, 16.4)	<.01
48-h home pad test	40.6 (30.2, 51.1)	6.5 (2.4, 10.6)	<.01	44.6 (34.5, 54.6)	6.0 (3.3, 8.8)	<.01
Leakage index	2.8 (2.6, 3.0)	1.9 (1.7, 2.1)	<.01	2.8 (2.7, 3.0)	1.9 (1.7, 2.1)	<.01
Social activity index	9.1 (8.9, 9.4)	9.5 (9.3, 9.7)	.01	9.2 (9.0, 9.4)	9.4 (9.2, 9.7)	.04
USI	(*n* = 36)			(*n* = 34)		
Standardized pad test	25.9 (17.1, 34.8)	5.5 (2.1, 9.0)	<.01	27.6 (15.0, 40.2)	9.9 (2.8, 17.0)	<.01
48-h home pad test	41.2 (28.2, 54.1)	7.0 (1.7, 12.4)	<.01	46.3 (33.6, 59.0)	3.8 (1.4, 6.2)	<.01
Leakage index	2.7 (2.5, 3.0)	1.8 (1.6, 2.0)	<.01	2.7 (2.5, 2.8)	1.8 (1.6, 2.0)	<.01
Social activity index	9.2 (8.9, 9.5)	9.6 (9.4, 9.8)	<.01	9.3 (9.1, 9.5)	9.5 (9.3, 9.8)	.01

USI = urodynamic stress incontinence.
Total group ($N = 94$) and subgroup of women with USI alone ($n = 70$). Mean and 95% confidence interval. P values are given for changes within groups.
* Wilcoxon signed rank test.

Table 5. Comparison of Changes in Outcome Variables and Pelvic Floor Muscle Strength From Baseline to After Treatment in Groups Training With and Without Biofeedback: Reduction in Gram Leakage on Pad Test With Standardized Bladder Volume and on 48-Hour Home Pad Test, Reduction on Leakage Index, and Improvement on Social Activity Index and in Pelvic Floor Muscle Strength

	With biofeedback	Without biofeedback	P*
Total group	($n = 48$)	($n = 46$)	
Standardized pad test	19.6 (14.4, 24.8)	18.5 (12.2, 24.7)	.73
48-h home pad test	34.1 (25.5, 42.8)	38.6 (29.1, 48.0)	.35
Leakage index	0.9 (0.7, 1.0)	0.9 (0.7, 1.1)	.61
Social activity index	0.4 (−0.1, 0.6)	0.3 (0.0, 0.5)	.79
Pelvic floor muscle strength	12.3 (9.5, 15.1)	11.1 (8.1, 14.1)	.57
USI	($n = 36$)	($n = 34$)	
Standardized pad test	20.4 (13.9, 26.9)	17.7 (10.1, 25.3)	.61
48-h home pad test	33.0 (22.5, 43.5)	42.5 (30.3, 54.7)	.14
Leakage index	1.0 (0.7, 1.2)	0.9 (0.6, 1.1)	.76
Social activity index	0.4 (0.1, 0.6)	0.4 (0.2, 0.7)	.61
Pelvic floor muscle strength	12.6 (9.4, 15.9)	11.2 (7.6, 14.8)	.54

USI = urodynamic stress incontinence.

Total group ($N = 94$) and subgroup of women with USI alone ($n = 70$). Mean and 95% confidence interval. P values are given for changes between groups.

* Mann-Whitney U test.

To date, there is no agreement about the most appropriate outcome measures for urinary incontinence. However, The Urodynamic Society and the standardization committee of the International Continence Society have recommended both use of measures of urinary leakage and self-report to evaluate treatment effect.[25] We, therefore, chose both a pad test and subjective report as primary outcome measures. Pad tests with standardized bladder volume have shown to be more reliable than tests without standardized volume.[26] However, the short pad test may be very provocative, and reflects activities that most women do not need to perform during daily life, eg, jumping jacks. The 48-hour pad test may reflect daily activities in a better way, but it is less reproducible.[26] In addition, it is difficult for women to remember what activities they were doing during a 2-day period 6 months ago and amount of physical activity, and hence exposure to provocation for leakage may vary considerably. In the present study, there was significant improvement in both pad tests for both groups after 6 months of training, and the cure rate was high in both groups. However, there was no statistically significant difference between the groups in any of the tests.

Wilson et al[16] concluded that improvement was more commonly reported than cure in pelvic floor muscle training studies. However, in some previous studies, cure has been reported. Bø et al[19] found that 60% had converted a negative closure pressure during cough to positive after 6 months of training, and 60% reported to be continent/almost continent. In a later, multicenter,

Table 6. Change in Pelvic Floor Muscle Strength Measured by Vaginal Squeeze Pressure (cm H_2O) at Different Times in the Groups Training With and Without Biofeedback

	With biofeedback		P*	Without biofeedback		P*
Total group	($n = 48$)			($n = 46$)		
0–3 mo	13.6 (10.7, 16.4)	22.5 (19.0, 26.0)	<.01	14.4 (12.0, 16.7)	22.0 (18.8, 25.3)	<.01
3–6 mo	22.5 (19.0, 26.0)	25.9 (21.8, 29.9)	<.01	22.0 (18.8, 25.3)	25.4 (21.2, 29.6)	.01
0–6 mo	13.6 (10.7, 16.4)	25.9 (21.8, 29.9)	<.01	14.4 (12.0, 16.7)	25.4 (21.2, 29.6)	<.01
USI	($n = 36$)			($n = 34$)		
0–3 mo	14.0 (10.3, 17.6)	23.3 (19.1, 27.6)	<.01	14.5 (11.7, 17.2)	23.2 (19.2, 27.2)	<.01
3–6 mo	23.3 (19.1, 27.6)	26.6 (21.6, 31.6)	<.01	23.2 (19.2, 27.2)	25.9 (20.5, 30.9)	.06
0–6 mo	14.0 (10.3, 17.6)	26.6 (21.6, 31.6)	<.01	14.5 (11.7, 17.2)	25.9 (20.5, 30.9)	<.01

USI = urodynamic stress incontinence.

Pelvic floor muscle strength increment from baseline to 3-month treatment, 3-month treatment to 6-month treatment, and from baseline to 6-month treatment. Total group ($N = 94$) and subgroup of women with USI alone ($n = 70$). Mean and 95% confidence interval. P values are given for changes within groups.

* Wilcoxon signed rank test.

randomized, controlled trial comparing pelvic floor muscle training with electrical stimulation, vaginal weighted cones, and control, 44% in the pelvic floor muscle training group had 2 g or less of leakage on the pad test with standardized bladder volume.[6] Fifty-six percent considered their incontinence to be unproblematic after 6 months of training.[6] These results were achieved after group training in women with urodynamically proven stress urinary incontinence, without additional urge incontinence symptoms. The present results showed equally or higher cure rates after individual training in a similar patient population, where 69% of the women in the biofeedback group and 50% in the group training without biofeedback had no leakage (2 g or less of leakage on the pad test with standardized bladder volume) after treatment. Interestingly, the cure rate in the present study was higher measured by the pad test than reported by the women.

Currently, a wide range of biofeedback equipment is used clinically. Among the randomized, controlled trials that have compared training with and without biofeedback, half of them have used different forms of surface electromyograms and the other half different measures of squeeze pressure.[17] Electromyograms and squeeze pressure measurements measure different qualities. Surface electromyograms aim to measure recruitment of activated motor units, the problems with this method being artifacts and overflow from other muscles contracting instead of or in addition to the pelvic floor muscles. Squeeze pressure aims to measure muscle strength including both activated motor units and the effect of muscle volume. Vaginal squeeze pressure was used in the present study. Vaginal squeeze pressure measurement has several problems, the most serious one being straining giving equal pressure rises as a correct contraction.[21] Hence, only contractions with simultaneous inward movement of the perineum were considered valid measurements in the present study.[21,27]

It has been suggested that use of biofeedback can teach the patient to contract correctly and that the patient may learn faster how to contract by use of either electromyograms or pressure measurements. To date, there are no studies investigating the effect of biofeedback in a population who are not able to contract the pelvic floor muscles.[16] Kegel,[20] however, did not use the "perineometer" to teach the contraction. For teaching purposes, he used vaginal palpation and observation of inward movement of the perineum with verbal feedback to the patient. It is difficult to understand how the biofeedback machine could teach the patient how to contract without verbal instruction and manual techniques by the therapist. In addition, both electromyograms and pressure measurements might measure the contraction of other muscles and straining. In the present study, biofeedback was used according to Kegel as an attempt to improve motivation and encourage greater effort during each contraction,[20] both in the clinic and during home exercises.

In only a few of the studies comparing training with and without biofeedback, pelvic floor muscle function or strength has been measured before and after the training period. Burns et al[12] found significant improvement in electromyogram signal during quick and sustained pelvic floor muscle contraction in favor of the biofeedback group. However, there was no difference in incontinence between the two groups. Berghmans et al[13] analyzed their results after 6 weeks to see whether the biofeedback group had better results at an early stage, but did not detect a statistical significant difference. Although studying pelvic floor muscle increment within the two groups, we found a significant change in pelvic floor muscle strength between 3- and 6-month measurements only in the biofeedback group.

So far, only short-term effects have been evaluated in this study. However, as for all other skeletal muscles, the pelvic floor muscles will be weaker and atrophy without use or training. After cessation of training, a 5–10% loss of muscle strength per week has been observed.[28] However, two sessions of strength training per week seem to be enough to maintain muscle strength, with intensity of each contraction being more important than frequency of training.[29] Hence, it is much easier to maintain than to build up muscle strength. In a 5-year follow-up study by Bø and Talseth[30] using the same program and length of training as in the present study, 70% were still training the pelvic floor muscles more than once a week, and 70% were satisfied with the condition and had no visible leakage during cough. However, their amount of leakage measured by the pad test had increased during the 5-year period without any intervention.

In our study, adding biofeedback to pelvic floor muscle training for female urodynamic stress incontinence showed no statistically significant additional effect. This corresponds with the results of several other randomized, controlled trials in this area, and with conclusions from randomized, controlled trials[15] and meta-analysis.[17] Previous studies have shown that pelvic floor muscle training is significantly better than no treatment.[4–6] The short-term cure rate in the present study was 50–69.4% for training without and with biofeedback, respectively. All women in the present study had thorough individual instruction, palpation and observation during contraction, and regular measurement of muscle strength by a skilled physical therapist to achieve this effect. To add biofeedback to the training in addition to this individual instruction and measurement does not

seem to increase the effect significantly. However, using an apparatus during training may motivate many women, and this should therefore be an option in clinical practice.

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Received November 15, 2001. Received in revised form March 5, 2002. Accepted April 11, 2002.