# Long-Term Effect of Early Postoperative Pelvic Floor Biofeedback on Continence in Men Undergoing Radical Prostatectomy: A Prospective, Randomized, Controlled Trial

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**Abbreviations and Acronyms**

BFB = biofeedback
ES = electrical stimulation
HE = home exercise
ICSI = incontinence symptoms of the International Continence Society male Short Form questionnaire
ICST = total score of the International Continence Society male Short Form questionnaire
IIQ-7 = Incontinence Impact Questionnaire
PFME = pelvic floor muscle exercise
PFMS = pelvic floor muscle strength
PFMT = pelvic floor muscle training
QOL = quality of life
RP = radical prostatectomy
UI = urinary incontinence

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**Purpose:** The impact of pelvic floor muscle training on the recovery of urinary continence after radical prostatectomy is still controversial. We tested the effectiveness of biofeedback-pelvic floor muscle training in improving urinary incontinence in the 12 months following radical prostatectomy.

**Materials and Methods:** A total of 73 patients who underwent radical prostatectomy were randomized to a treatment group (36) receiving biofeedback-pelvic floor muscle training once a week for 3 months as well as home exercises or a control group (37). Patients were evaluated 1, 3, 6 and 12 months postoperatively. Continence was defined as the use of 1 pad or less daily and incontinence severity was measured by the 24-hour pad test. Incontinence symptoms and quality of life were assessed with the International Continence Society male Short Form questionnaire and the Incontinence Impact Questionnaire. Pelvic floor muscle strength was evaluated with the Oxford score.

**Results:** A total of 54 patients (26 pelvic floor muscle training and 28 controls) completed the trial. Duration of incontinence was shorter in the treatment group. At postoperative month 12, 25 (96.15%) patients in the treatment group and 21 (75.0%) in the control group were continent ($p = 0.028$). The absolute risk reduction was 21.2% (95% CI 3.45–38.81) and the relative risk of recovering continence was 1.28 (95% CI 1.02–1.69). The number needed to treat was 5 (95% CI 2.6–28.6). Overall there were significant changes in both groups in terms of incontinence symptoms, lower urinary tract symptoms, quality of life and pelvic floor muscle strength ($p < 0.0001$).

**Conclusions:** Early biofeedback-pelvic floor muscle training not only hastens the recovery of urinary continence after radical prostatectomy but allows for significant improvements in the severity of incontinence, voiding symptoms and pelvic floor muscle strength 12 months postoperatively.

**Key Words:** urinary incontinence; biofeedback, psychology; prostatectomy; prostatic neoplasms, quality of life

RADICAL prostatectomy is a commonly performed surgery and the preferred therapeutic option for many patients with localized prostate cancer.[1] It is associated with high levels of cancer control and/or cure but may be associated with significant complications including UI and erectile dysfunction.[2] UI is a devastating complication after RP with a negative impact on patient QOL.[3] Despite advances in surgical technique the incidence of UI remains significant. UI develops in the majority of patients during the



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early postoperative days. However, spontaneous improvement in continence status may occur up to 1 year after RP.[4]

Because most patients regain urinary control within a few months to 1 year after RP, invasive treatments are not indicated during this period.[2,4,5] Various conservative therapeutic approaches such as pharmacological treatment and PFMT have been used with different protocols. However, often studies are not randomized or controlled.[6] Of the studies that followed patients up to 12 months postoperatively some showed better continence for the PFMT group[7–10] while other did not show improvement with treatment in the long term.[11,12] We tested the effectiveness of BFB-PFMT in decreasing the duration and severity of UI as well as in improving QOL in the 12 months following radical retropubic prostatectomy.

## MATERIALS AND METHODS

### Population

Between July 2006 and September 2007, 122 consecutive patients who underwent standard radical retropubic prostatectomy at our institution for clinically localized prostate cancer were screened for this study. Patients were included if they could regularly attend an ambulatory schedule. Exclusion criteria were prior urethral, bladder or prostate surgery, pelvic radiotherapy, neurological disease with a possible impact on continence or any medical condition that could limit participation in the training program.

### Treatment

After institutional review board approval we performed a prospective, randomized, controlled trial comparing early postoperative BFB-PFMT to usual care. Patients were randomized into a control group and a treatment group according to a randomization list. All patients signed an informed consent before randomization. After catheter removal on postoperative day 15 patients in the treatment group received BFB-PFMT once a week for as long as they were incontinent for a maximum of 12 weeks.

Each session lasted 30 minutes and was performed by the same physiotherapist. For BFB-PFMT sessions an electromyographic apparatus (Miotec®, Porto Alegre, Rio Grande do Sul, Brazil) was used. A surface electrode (ConSys™) was inserted into the anus and the reference electrode was placed on the left lateral malleolus. In the right lateral decubitus position patients practiced 3 series of 10 rapid contractions while viewing a computer monitor to improve the phasic musculature component. Then patients practiced 3 sustained contractions of 5, 7 or 10 seconds depending on ability to maintain the contraction of the pelvic floor muscle tonic component. Subjects were then placed in the supine position, with hips flexed to approximately 60 degrees, to practice 10 contractions during prolonged expiration, avoiding the Valsalva maneuver. Verbal and written instructions were used to conduct daily HE while lying, sitting and standing.

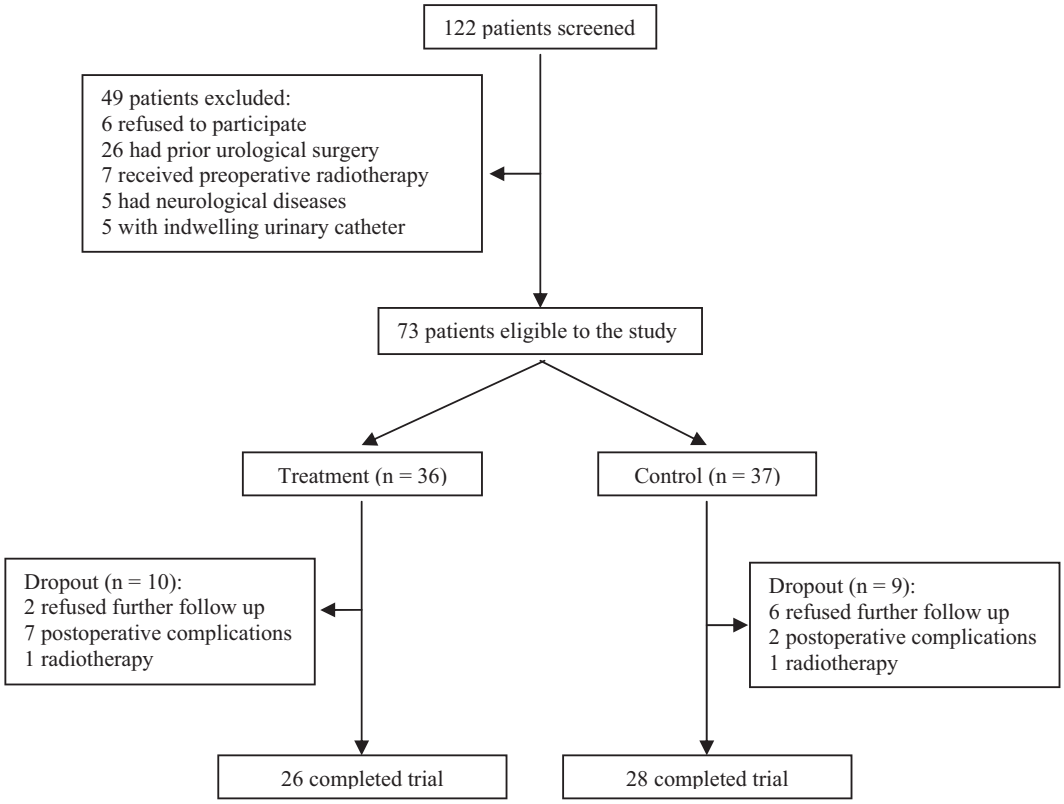


**Figure 1.** Study flow chart

**Table 1.** *Baseline characteristics*

| | Treatment Group | Control Group | p Value |
|---|---|---|---|
| Mean ± SD age | 62.2 ± 6.3 | 65.6 ± 8.0 | 0.079 |
| No. diabetes (%) | 6 (16.66) | 7 (18.92) | 1 |
| Mean ± SD body mass index | 26.0 ± 3.4 | 27.3 ± 4.0 | 0.228 |
| Mean ± SD gm prostate wt | 43.8 ± 25.6 | 45.0 ± 23.7 | 0.851 |
| Median PFMS (IQR) | 3 (3–4) | 3 (3–4) | 0.858 |
| Mean ± SD ICST | 11.5 ± 11.4 | 13.6 ± 8.2 | 0.421 |

Patients in the control group were not given formal education on PFME. They received brief verbal instructions from the urologist to contract the pelvic floor muscle. No specific exercise schedule was recommended.

### Outcome Assessments

The assessment of both groups was identical at all times including the baseline evaluation, as well as those performed 1, 3, 6 and 12 months after catheter removal. The primary outcome measure was the number of pads used daily. Continence was defined as the use of 1 pad or less daily.[9,12–16] Incontinence was graduated by the 24-hour pad test as mild (leakage less than 20 gm), moderate (between 21 and 74 gm) or severe (more than 75 gm).[17] Secondary outcome measures were incontinence symptoms measured by the ICSI,[18] lower urinary tract symptoms measured by ICST, the impact of incontinence on QOL measured by the IIQ-7[19] and PFMS measured by digital test graduated according to the Oxford scale.[20,21]

### Statistical Analysis

Data were expressed as means ± SD, medians and interquartile ranges, or absolute values and fractions. The Student t or Mann-Whitney U test was used to compare continuous variables while categorical variables were compared using the chi-square or Fisher's exact test. Comparison of continuous variables between groups was performed using 1-way ANOVA with the Bonferroni post hoc test to compare individual pairings of groups. Estimates of survival curves were calculated using the Kaplan-Meier method and compared using the log rank test. All tests were 2-sided with $p < 0.05$ considered statistically significant and were performed using GraphPad Prism® version 5.02 for Windows. Our initial estimate for the study was to include 40 patients in each group to have a power of 80% to detect a 20% increase in the treatment group.

## RESULTS

Of the 122 patients screened for this study 73 fulfilled the eligibility criteria of the trial, and were randomized into a control group (37) and a treatment group (36). There were 19 patients (26%) who did not complete the trial because they could not attend the ambulatory schedule for various reasons. All study dropouts occurred before the first month evaluations and the patients had not started PFMT. A total of 54 patients (74%) completed the trial including 28 in the control group and 26 in the treatment group (fig. 1). They were available for evaluation at all evaluated times and the postoperative results presented refer to these patients. Baseline characteristics were similar in the treatment and control groups (table 1).

Figure 2 shows the cumulative percentage of continent patients. Duration of incontinence was shorter in the treatment group than in the control group with a median of 1 and 6 months, respectively. At 12 months postoperatively 25 (96.15%) patients in the treatment group and 21 (75.0%) in the control group were continent ($p = 0.028$). The absolute risk reduction was 21.2% (95% CI 3.45–38.81) and the relative risk of continence recovery was 1.28 (95% CI 1.02–1.69) in the treatment group. The number needed to treat to obtain 1 additional continent patient was 5 (95% CI 2.6–28.6).

Table 2 shows median pad weight and percentage of patients with severe incontinence according to the 24-hour pad test. The rates of severe incontinence decreased with time in both groups and were higher in the control group ($p = 0.017$). Likewise median pad weights decreased with time in both groups and were higher at each followup evaluation for patients in the control group ($p < 0.001$).

Overall significant changes were demonstrated in both groups in terms of incontinence symptoms (ICSI), lower urinary tract symptoms (ICST), quality of life and PFMS ($p < 0.001$ for all parameters). Post hoc comparisons of these parameters in both groups at different times are also detailed in table 3.

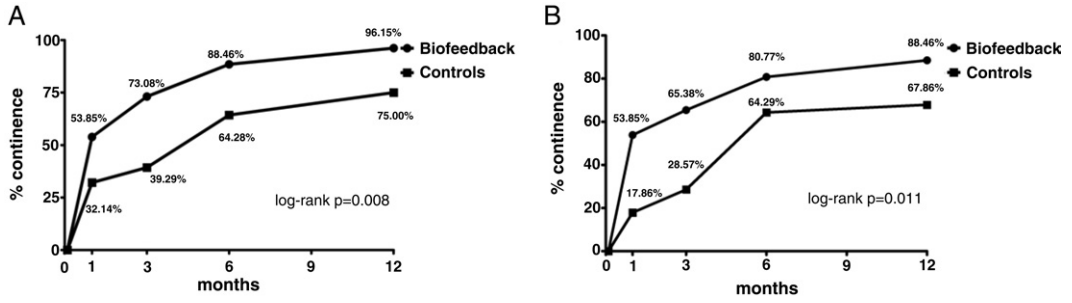


**Figure 2.** Cumulative percentage of continent patients, with continence defined as 1 pad or less daily (*A*), or no pads daily (*B*)

**Table 2.** *Pad weight and patients with severe incontinence*

| | Treatment Group | Control Group |
|---|---|---|
| Median gm pad wt (IQR): | | |
| 1 Mo | 28 (8–82) | 249 (15–605) |
| 3 Mos | 6 (0–24) | 58 (18–210) |
| 6 Mos | 2 (0–12.5) | 8 (0–164) |
| 12 Mos | 0 (0–3) | 4 (0–70) |
| % Severe incontinence: | | |
| 1 Mo | 27 | 69 |
| 3 Mos | 15 | 43 |
| 6 Mos | 4 | 32 |
| 12 Mos | 0 | 18 |

The average number of BFB-PFMT sessions in the treatment group was 8.8 ± 3.8 (range 3 to 12). Patients did not complain about any treatment side effect or discomfort during followup. Age, diabetes, body mass index, prostate size and preoperative PFMS were not predictors of continence recovery.

## DISCUSSION

In this study we tested the effectiveness of BFB-PFMT in decreasing the duration and severity of urinary incontinence, and improving quality of life in the 12 months following radical retropubic prostatectomy. We showed that patients in the treatment group had superior results in terms of incontinence duration and severity as well as urinary incontinence symptoms and PFMS.

The short and long-term effects of pelvic floor muscle rehabilitation after RP are still controversial. A recent Cochrane review stated that conservative treatment for UI after RP, including PFMT, remains uncertain because of the low to moderate quality of most studies, and the considerable variation in the interventions, populations and outcome measures.[6]

Since that review 5 studies with good methodology have been published, bringing the total to 18 randomized controlled trials on the subject.[7,8,13,22,23] Of these studies 9 show the beneficial effects of PFMT after RP[7–10,15,22,24–26] while 9 failed to do so.[11–14,16,23,27–29] There were several methodological differences among these studies including the delivery of PFMT (with or without BFB and/or ES), frequency of PFMT sessions (1 or more weekly sessions), duration of treatment, timing of PFMT (preoperative vs postoperative vs both) and intensity of PFMT performed by patients in the control group. We believe this is the main confounding factor leading to failure to show the ability of PFMT to hasten the recovery of UI in many studies.

Of the 9 studies that failed to show PFMT was beneficial 7 offered significant patient training and/or HE schedules that seem to have contaminated the nonPFMT group (table 4).[11–14,16,23,27–29] Of the 2 studies that did not offer a significant educational or training program 1 had a limited patient population (a total of 25 patients completed the study) and encouraged a timed voiding schedule as well as the use of techniques to decrease urgency and urge incontinence.[27] The other study did not define management of controls.[13]

Based on personal experience as well as on the medical literature we believe that the PFMT technique is not the most important issue and may even be unimportant provided that one can assure that training exercises are being properly performed. A qualified therapist can teach PFME without the use of BFB equipment. The use of BFB equipment for PFMT is an attractive option for patients and may be instrumental for the therapist in a particular patient, but may offer no advantage in terms of efficiency compared to PFMT delivered by an expe-

**Table 3.** *Changes in lower urinary tract symptoms, QOL and PFMS*

| | 1 Mo | 3 Mos | 6 Mos | 12 Mos |
|---|---|---|---|---|
| ICSI: | | | | |
| Treatment | 5.8 | 2.7 | 1.9 | 1.4 |
| Control | 10.9 | 6.7 | 4.3 | 4.2 |
| p Value | <0.01 | <0.05 | Not significant* | Not significant* |
| ICST: | | | | |
| Treatment | 15.2 | 10.4 | 5.5 | 5.3 |
| Control | 19.7 | 13.3 | 8.8 | 11.3 |
| p Value | Not significant* | Not significant* | Not significant* | Not significant* |
| IIQ-7: | | | | |
| Treatment | 3.0 | 2.4 | 0.5 | 0.7 |
| Control | 7.2 | 4.0 | 2.8 | 1.6 |
| p Value | <0.05 | Not significant* | Not significant* | Not significant* |
| PFMS: | | | | |
| Treatment | 3.9 | 4.5 | 4.2 | 4.5 |
| Control | 3.1 | 3.3 | 3.4 | 3.8 |
| p Value | <0.01 | <0.001 | <0.05 | Not significant* |

ANOVA $p < 0.0001$.
*$p > 0.05$.

**Table 4.** *Randomized controlled trials without beneficial effects of PFMT after RP*

| References | No. | Control Group Interventions | No. | Treatment Group Interventions |
|---|---|---|---|---|
| Mathewson-Chapman[28] | 24 | Significant instruction with nurse | 27 | BFB + HE |
| Franke et al.[27] | 15 | None | 15 | BFB + HE |
| Bales et al.[16] | 50 | Significant instruction with nurse | 50 | BFB + HE |
| Sueppel et al.[29] | 8 | Significant training with nurse | 8 | BFB + PFME post |
| Floratos et al.[14] | 14 | Significant instruction with nurse | 28 | BFB + HE |
| Wille et al.[12] | 47 | Significant training with physiotherapist | Group 1, 46 | PFME + ES |
| | | | Group 2, 46 | BFB + PFME + ES |
| Lilli et al.[23] | 45 | Significant instruction with therapist | 45 | BFB + PFME |
| Moore et al.[11] | 99 | Significant instruction with nurse | 106 | PFME + HE |
| Tobia et al.[13] | 19 | None | 19 | PFME + ES + HE |

rienced therapist. The fact that in most of those negative studies the patients in the control group received too much training and/or orientation to perform HE reinforces this hypothesis. In this scenario it may be argued that these studies were not really testing the usefulness of PFMT but rather comparing different ways to deliver it, ie with and without the enhancements of BFB or ES.

As was our belief when we conceived this study and because patients in our practice and probably in most clinical settings worldwide receive only verbal instructions from the urologist on how to perform pelvic exercises, we decided not to offer any additional instruction or exercise schedule other than the usual patient care. In addition, we chose a simple treatment schedule of only 1 weekly BFB-PFMT session and a maximum duration of 12 weeks. It is possible that a more intense and/or longer exercise regimen could afford better results, but it might not be practical and we would expect more patients to drop out of the training program. Based on our results and those of most investigators who used a similar control group we can affirm that BFB-PFMT is beneficial in decreasing the duration and severity of UI in the 12 months after radical retropubic prostatectomy.

In our series we defined UI by the number of pads used daily and not by pad weight because many continent patients in the treatment group did not complete the 24-hour pad test at 6 and 12 months. As reported by Moore et al we observed that patients resisted completing the 24-hour pad test when they were emphatic that they were continent.[30] We also found that continence rates among patients in both groups did not vary significantly when we changed the definition of continence from the use of 1 pad or less daily to the use of no pads daily.

An interesting aspect of our study was the fact that QOL, measured by the IIQ-7, was better in the treatment group only in the first month assessment despite the improvement in continence throughout the 12 months after surgery. The IIQ-7 was initially developed for women but was subsequently validated for men.[19] In 3 randomized controlled trials PFMT after RP was evaluated using the IIQ-7 to assess patient quality of life.[11,24,25] In none of the studies was QOL improved in the treatment group, even in the 1 that revealed better continence in the treatment group. The authors suggested the possibility that men found ways to circumvent the impact of incontinence on well-being or confounded differences in incontinence with other QOL issues such as recovery from surgery, anxiety about cancer or sexual dysfunction.[25] In our study despite the lack of a statistical difference QOL was always numerically superior in the treatment group, indicating a trend for improved QOL that might be demonstrable had we included more patients in the study.

## CONCLUSIONS

Our results demonstrate that early BFB-PFMT not only hastens the recovery of urinary continence after radical retropubic prostatectomy but allows for significant improvements in the severity of incontinence, voiding symptoms and pelvic floor muscle strength 12 months postoperatively.

## REFERENCES


1. Yossepowitch O, Eggener SE, Bianco FJ Jr et al: Radical prostatectomy for clinically localized, high risk prostate cancer: critical analysis of risk assessment methods. J Urol 2007; **178:** 493.
2. Slova D and Lepor H: The short-term and long-term effects of radical prostatectomy on lower urinary tract symptoms. J Urol 2007; **178:** 2397.
3. Trigo RF, Gomes CM, Mitre AI et al: A prospective study evaluating the efficacy of the artificial sphincter AMS 800 for the treatment of postradical prostatectomy urinary incontinence and the correlation between preoperative urodynamic and surgical outcomes. Urology 2008; **71:** 85.
4. Sacco E, Prayer-Galetti T, Pinto F et al: Urinary incontinence after radical prostatectomy: incidence by definition, risk factors and temporal trend in a large series with a long-term follow-up. BJU Int 2006; **97:** 1234.
5. Gomes CM, Broderick GA, Sanchez-Ortiz RF et al: Artificial urinary sphincter for post-prostatectomy incontinence: impact of prior collagen injection on cost and clinical outcome. J Urol 2000; **163:** 87.

6. Hunter KF, Glazener CM and Moore KN: Conservative management for postprostatectomy urinary incontinence. Cochrane Database Syst Rev 2007; **2:** CD001843.
7. Overgard M, Angelsen A, Lydersen S et al: Does physiotherapist-guided pelvic floor muscle training reduce urinary incontinence after radical prostatectomy? A randomised controlled trial. Eur Urol 2008; **54:** 438.
8. Manassero F, Traversi C, Ales V et al: Contribution of early intensive prolonged pelvic floor exercises on urinary continence recovery after bladder neck-sparing radical prostatectomy: results of a prospective controlled randomized trial. Neurourol Urodyn 2007; **26:** 985.
9. Filocamo MT, Li Marzi V, Del Popolo G et al: Effectiveness of early pelvic floor rehabilitation treatment for post-prostatectomy incontinence. Eur Urol 2005; **48:** 734.
10. Van Kampen M, De Weerdt W, Van Poppel H et al: Effect of pelvic-floor re-education on duration and degree of incontinence after radical prostatectomy: a randomised controlled trial. Lancet 2000; **355:** 98.
11. Moore KN, Valiquette L, Chetner MP et al: Return to continence after radical retropubic prostatectomy: a randomized trial of verbal and written instructions versus therapist-directed pelvic floor muscle therapy. Urology 2008; **72:** 1280.
12. Wille S, Sobottka A, Heidenreich A et al: Pelvic floor exercises, electrical stimulation and biofeedback after radical prostatectomy: results of a prospective randomized trial. J Urol 2003; **170:** 490.
13. Tobia I, Gonzalez MS, Martinez P et al: Randomized study on urinary continence after radical prostatectomy with previous kinesic perineal physiotherapy. Arch Esp Urol 2008; **61:** 793.
14. Floratos DL, Sonke GS, Rapidou CA et al: Biofeedback vs verbal feedback as learning tools for pelvic muscle exercises in the early management of urinary incontinence after radical prostatectomy. BJU Int 2002; **89:** 714.
15. Parekh AR, Feng MI, Kirages D et al: The role of pelvic floor exercises on post-prostatectomy incontinence. J Urol 2003; **170:** 130.
16. Bales GT, Gerber GS, Minor TX et al: Effect of preoperative biofeedback/pelvic floor training on continence in men undergoing radical prostatectomy. Urology 2000; **56:** 627.
17. O'Sullivan R, Karantanis E, Stevermuer TL et al: Definition of mild, moderate and severe incontinence on the 24-hour pad test. BJOG 2004; **111:** 859.
18. Donovan JL, Abrams P, Peters TJ et al: The ICS-'BPH' Study: the psychometric validity and reliability of the ICSmale questionnaire. Br J Urol 1996; **77:** 554.
19. Moore KN and Jensen L: Testing of the Incontinence Impact Questionnaire (IIQ-7) with men after radical prostatectomy. J Wound Ostomy Continence Nurs 2000; **27:** 304.
20. Wyndaele JJ and Van Eetvelde B: Reproducibility of digital testing of the pelvic floor muscles in men. Arch Phys Med Rehabil 1996; **77:** 1179.
21. Abrams P, Artibani W, Cardozo L et al: Reviewing the ICS 2002 terminology report: the ongoing debate. Neurourol Urodyn 2009; **28:** 287.
22. Mariotti G, Sciarra A, Gentilucci A et al: Early recovery of urinary continence after radical prostatectomy using early pelvic floor electrical stimulation and biofeedback associated treatment. J Urol 2009; **181:** 1788.
23. Lilli P, Mercuriali M, Fiori M et al: Impact of preoperative biofeedback on incontinence in cancer patients undergoing radical prostatectomy. Arch Ital Urol Androl 2006; **78:** 92.
24. Moore KN, Griffiths D and Hughton A: Urinary incontinence after radical prostatectomy: a randomized controlled trial comparing pelvic muscle exercises with or without electrical stimulation. BJU Int 1999; **83:** 57.
25. Burgio KL, Goode PS, Urban DA et al: Preoperative biofeedback assisted behavioral training to decrease post-prostatectomy incontinence: a randomized, controlled trial. J Urol 2006; **175:** 196.
26. Yokoyama T, Nishiguchi J, Watanabe T et al: Comparative study of effects of extracorporeal magnetic innervation versus electrical stimulation for urinary incontinence after radical prostatectomy. Urology 2004; **63:** 264.
27. Franke JJ, Gilbert WB, Grier J et al: Early post-prostatectomy pelvic floor biofeedback. J Urol 2000; **163:** 191.
28. Mathewson-Chapman M: Pelvic muscle exercise/biofeedback for urinary incontinence after prostatectomy: an education program. J Cancer Educ 1997; **12:** 218.
29. Sueppel C, Kreder K and See W: Improved continence outcomes with preoperative pelvic floor muscle strengthening exercises. Urol Nurs 2001; **21:** 201.
30. Moore K, Allen M and Voaklander DC: Pad tests and self-reports of continence in men awaiting radical prostatectomy: establishing baseline norms for males. Neurourol Urodyn 2004; **23:** 623.