

**Oscillating pole treatment -
An improved approach for
Post-prostatectomy urinary incontinence.
A prospective randomised controlled trial**

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Abstract

Introduction

There is evidence that specialized “continence exercise” has a major effect on the recovery of continence after radical prostatectomy. Aim of this prospective randomized controlled trial was the search for an improved therapeutic approach treating post-prostatectomy incontinence.

Methods

200 patients (Ø 64.1 years) with post-prostatectomy urinary incontinence were evaluated. All patients passed a standard treatment program (continence exercise, general endurance and moderate strength training) for three weeks. Additionally the intervention group (IG) participated in a guided coordination training using an oscillating pole (daily, for 30 minutes). Urinary incontinence was evaluated using 1-h (ICS) and 24-hour pad-test. Quality of life was screened using FACT-P questionnaire.

Results

The data of 184 participants could be evaluated. Continence was significantly improved in both study groups [1-h-pad-test: 22,8 g to 8,6 g (IG) vs. 22,7 g to 17,9 g (control group - CG)/ 24-h-pad-test: 245,3 g to 127,7 g (IG) vs. 235,3 g to 179,3 g (CG)]. However, there was a significant difference between the IG and CG. Urine loss amounts were significantly lower in the study group using oscillation pole treatment ($p < 0,001$).

Conclusion

Early continence rates after prostate cancer surgery were significantly improved by a complex approach combining standard pelvic floor muscle exercise and the new oscillating pole therapy. Besides standard pelvic floor muscle reeducation and training - muscle coordination seems to play a key role in early continence recovery.

Introduction

Surgical treatment of prostate cancer has considerably advanced over the last years. However, stress urinary incontinence is a frequent, yet in most cases temporary functional problem after prostate surgery. Early overcoming of incontinence is an important objective in order to regain quality of life, patient satisfaction and early return to daily activities and work.

Pelvic floor muscle exercise and re-education (“continence training”), biofeedback, electrical stimulation, external magnetic innervation (Anderson CA, 2015, Baumann 2012) are some therapeutic options used for conservative treatment of postprostatectomy incontinence.

Based on the known success of daily guided and controlled continence training (otto, eigene 2008, van Kampen 2000) we were looking for an additional treatment option in order to support the patient and fast-track recovery of urinary continence. Due to physiological considerations and experiences from trunk muscle activation therapy we decided to study the effects of a device supported coordination and endurance training using an oscillation pole on continence recovery [Anderson 2008, Zermann 2000].

Patients and methods

We initiated a prospective randomized controlled trial. The intervention group performed daily controlled continence training (CCT) and additional device supported pelvic floor muscle training (DS PFMT) using an oscillating pole. The control group performed a daily controlled continence training only.

The standard continence training for both study arms includes pelvic floor reeducation and pelvic floor muscle training under guidance and control by a specialized physiotherapist. The training protocol was standardized and performed daily for 30 minutes over three weeks.

The intervention group performed an additional DS PFMT. As training device an oscillation pole (manufactured by Haider Bioswing Co., Pullenreuth, Germany) was used (fig. 1).

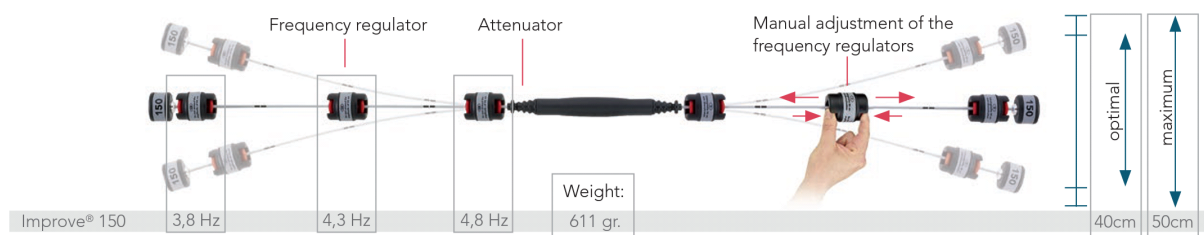


Figure 1: Oscillating pole BIOSWING Improve® 150 (with permission S. Brünner, C. Otte, Haider Bioswing GmbH, D-95704 Pullenreuth, 2014; www.bioswing.de)

The device model “Bioswing Improve 150” is a 150 cm long flexible rod consisting of spring steel with two adjustable weights at each side (total weight: 611 g). This allows oscillations in all possible directions. The oscillation frequency is dependent on the position of the weights on the device (ranging from 3,8 Hz in an outside to 4,8 Hz in an inside position).

The training device was presented and demonstrated in an introduction session followed by daily training sessions. Three basic exercises in different starting positions were performed by all study participants (see fig. 2) The oscillating pole was held in both hands, horizontally and vertically in front of the body. The stimulation of “Bioswing Improve” results in a forward and backward movement of the hands in extension of the forearms. Starting position and stable posture remain unchanged throughout the single exercise.



Figure 2: Exercises with the oscillating pole “Bioswing Improve 150”

The exercises were performed one time per day for 30 minutes under guidance of a physiotherapist. For intensity and duration with the oscillating pole see tab. 1.

| exercise time | exercise repetitions | overall exercise time | exercise cycles | break time |
|---------------|----------------------|------------------------------|-----------------|------------|
| 15 seconds | 6 | 30 minutes/ 1time per day | 1 | 10 seconds |

Table 1: Overview intensity and duration of the oscillating pole therapy

The functional results of the treatment process were evaluated by 1-hour- (ICS) and 24-hour-pad-test. In order to evaluate the impact of incontinence and their improvement on quality of life the FACT-P questionnaire was used [1,2].

The study design was approved by University ethical committee (#).

After informed consent patients were randomized to the intervention or control group. 200 consecutive patients with post-prostatectomy incontinence were evaluated. For inclusion and exclusion criteria see table 2.

Inclusion criteria

localized prostate cancer, no adjuvant cancer therapy
postprostatectomy urinary incontinence (> 1 g urine loss / 1-hour pad-test (ICS)
normal operative and postoperative course
time interval to surgery less than 6 weeks

Exclusion criteria

incontinence after prostatectomy
reduced physical capacity due to relevant comorbidities
no study consent
incomplete data

Table 2: Study inclusion and exclusion criteria

For data analysis the statistical software package SPSS Statistics Version 17 was used. Mann-Whitney-Test was used to test the changes of 1h and 24h pad-test between intervention- and control group. To evaluate urine loss (1h/ 24h pad-test) before and after 21 days of treatment Wilcoxon test was used. FACT-P-data were analysed by using ANCOVA. Correlation between incontinence and quality of life was assessed by Spearman-Rho-correlation. The effect size was evaluated using Cohen d.

Results

184 patients (medium 64,1 [46 – 78] years old) fulfilled all study inclusion criteria, completed the study successfully and their data were appropriate for statistical evaluation (see figure 3).

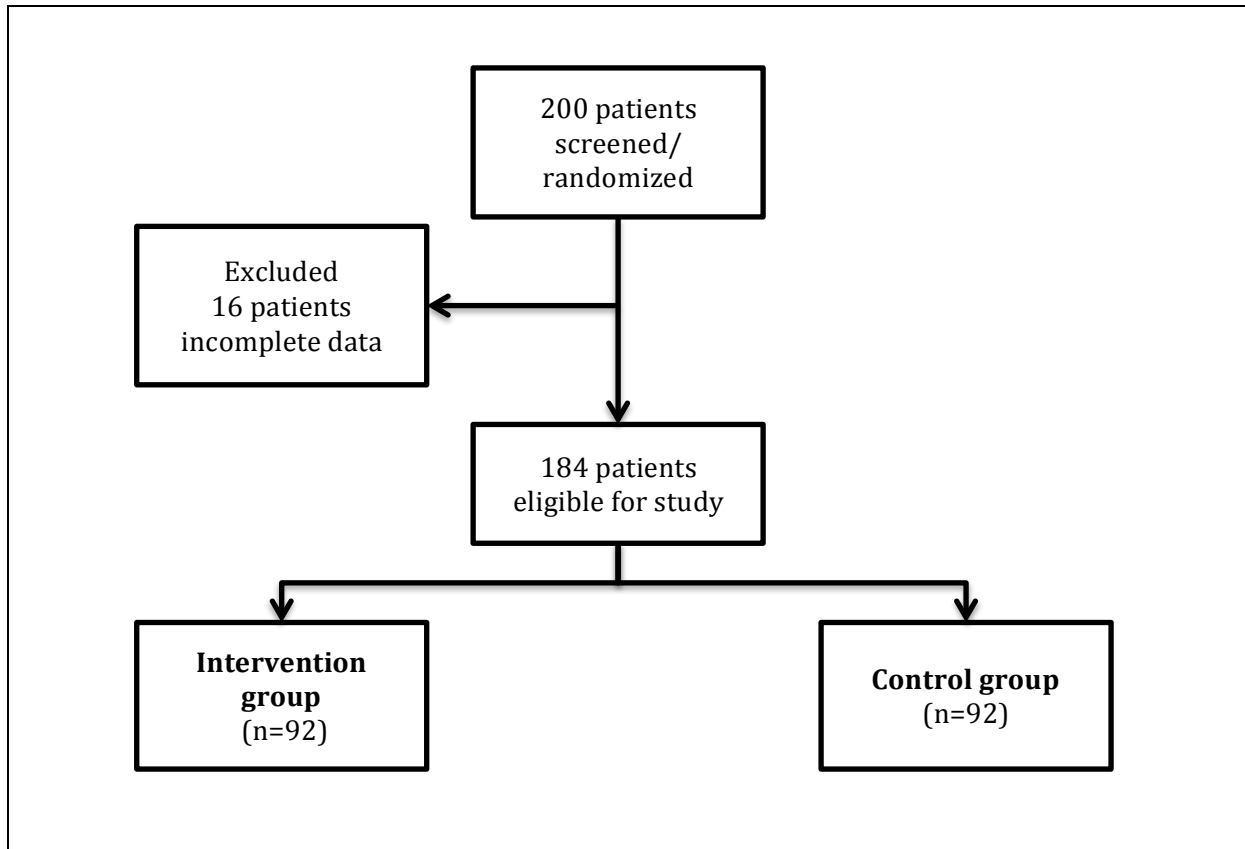


Figure 3: study flow chart

Urinary incontinence

1h pad-test (ICS)

There were significant improvements of urinary incontinence in both study groups. However, the decrease of urine loss in the intervention group was significantly better (from 22,8g to 8,6g ($p < 0,001$)) then in the control group (from 22,7g to 17,9g ($p < 0,01$)) (see fig4). The difference between the intervention and control group at study end was highly significant (1h pad-test $p < 0,001$). The effect size between the groups was 0.4.

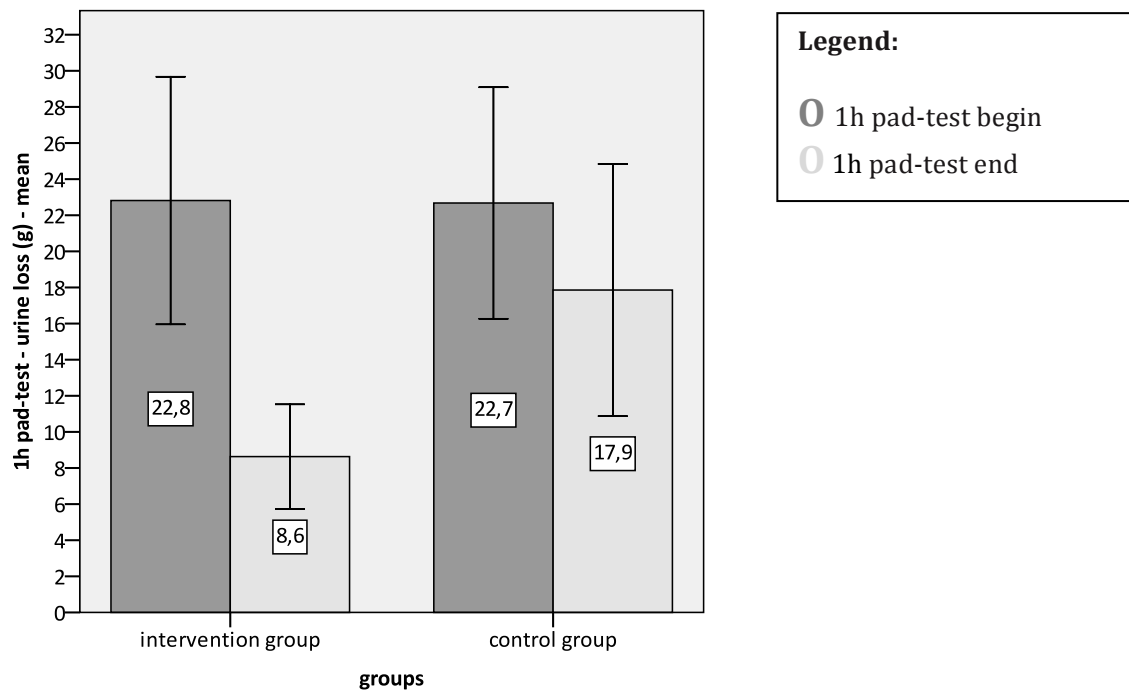


Figure 4: 1h pad-test outcomes

24h pad-test

The 24-h-Pad-test confirmed the results of the 1-h-pad-test. There was a significant improvement in the intervention from 245,3g to 127,7g ($p < 0,001$) and also in the control group from 235,3g to 179,3g ($p < 0,001$). There was also a significant difference between the intervention and control group after three weeks of treatment ($p < 0,001$). The effect size between the groups was 0.4.

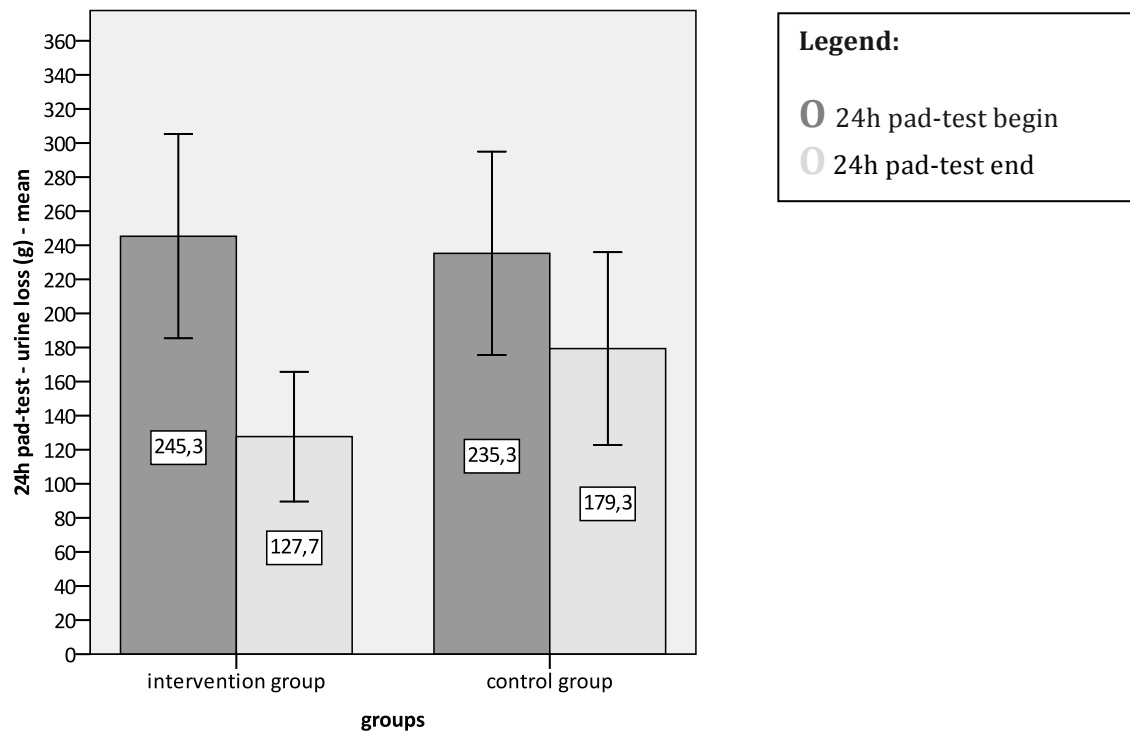


Figure 5 24h pad-test outcomes

Quality of life – FACT-P questionnaire

Based on excellent functional results regarding improvement of urinary incontinence in both study groups quality of life improved too. There were significant improvements in the intervention (from 31,18 to 34,25 ($p < 0,001$)) and control group (from 29,74 to 31,99 ($p < 0,001$)) (see fig. 6). The difference between the intervention and control group at study end was significant as well (FACT-P $p = 0,014$). The effect size between the groups was 0.2, showing a small effect only.

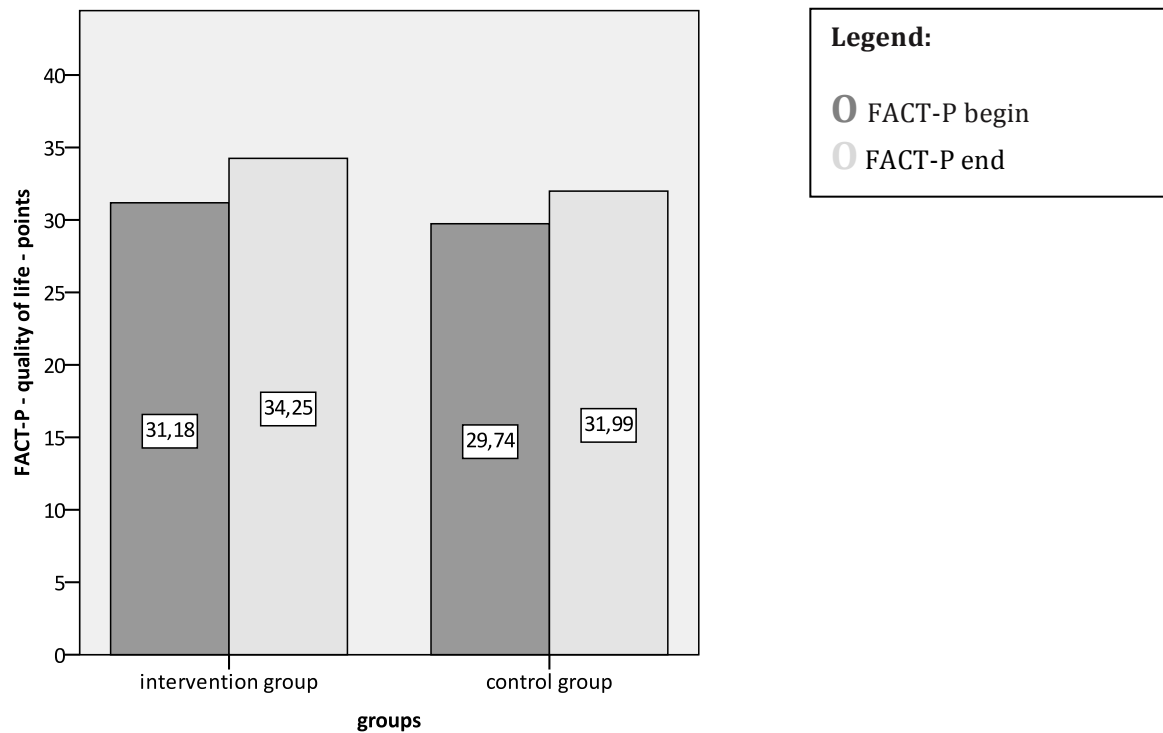


Figure 6: Quality of life questionnaire FACT-P outcomes

Correlation between 1h pad-test and quality of life

Figure 7 shows the regression between 1h pad-test and FACT-P at the end of the controlled study. Patients had a better quality of life measured by FACT-P questionnaire with decreasing incontinence values. There was a significant correlation between 1h pad-test and FACT-P at study end (Spearman coefficient = -0,324, $p < 0,001$).

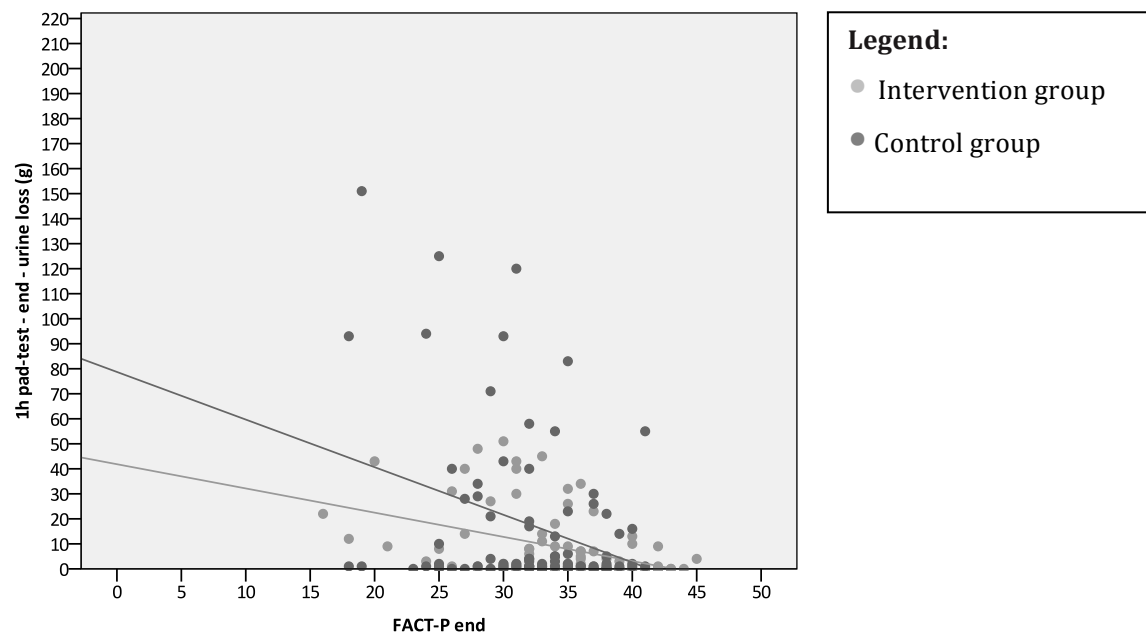


Figure 7 Regression between 1h pad-test and FACT-P after three weeks of treatment

Discussion

Post-prostatectomy urinary incontinence is still a challenge to urology. Conservative treatment options are the first choice of treatment. Guided and controlled pelvic floor muscle reeducation and training are sufficient options for timely continence recovery.

In this prospective, controlled and randomized trial we could show that classical continence training combined with an active pelvic floor coordination training, using an oscillating pole, shortens the recovery period and increases the success rate. Consequently the quality of life and patient satisfaction was positively affected.

Previous studies using a passive approach like electrical and magnetic stimulation are not that successful (Lit.)

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The key in timely overcoming urinary incontinence in patients without surgical complications is obviously a combination of reeducation, endurance and coordination training of the pelvic floor muscle and continence system. Rest and relaxing of the pelvic floor is as important as the training itself. Therefore the patient, suffering on post-prostatectomy urinary incontinence needs guidance, control and psychological support.

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Acknowledgements

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