Pelvic Floor Muscle Training and Erectile Dysfunction in Radical Prostatectomy: A Randomized Controlled Trial Investigating a Non-Invasive Addition to Penile Rehabilitation

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ABSTRACT

Introduction: Pelvic floor muscle (PFM) training for postprostatectomy incontinence is considered a first line approach to rehabilitation, but PFM training for erectile dysfunction (ED) after surgery is less well known. With more than 1.4 million new cases diagnosed globally per year, there is a need for non-invasive options to assist sexual dysfunction recovery.

Aim: Commencing preoperatively and using both fast and slow twitch fibre training performed in standing postures, new protocols were developed to address clinical presentations with aims to reduce ED and impact on quality of life (QoL). Comparisons with “usual care” PFM training, prerehabilitation and postrehabilitation were then assessed.

Methods: A randomised controlled trial of 97 men undergoing radical prostatectomy (RP) were allocated to either a control group (n = 47) performing “usual care” of 3 sets/d PFMT or an intervention group (n = 50), performing 6 sets/d in standing, commencing 5 weeks before RP.

Outcome measures: Participants were assessed preoperatively and at 2, 6, and 12 weeks after RP using the Expanded Prostate Cancer Index Composite for Clinical Practice, International Index of Erectile Function-5, and real time ultrasound measurements of PFM function.

Results: At all time points, there was a significant difference (P < 0.05) between groups; however, the only time point where this difference was clinically relevant was at 2 weeks after RP, with the intervention group reporting less distress in the Expanded Prostate Cancer Index Composite for Clinical Practice QoL outcome. Secondary measures of EPIC-EF and real time ultrasound PFM function tests demonstrated improvement over all time points in both groups with lower bothersome scores in the intervention group.

Conclusions: Early PFM training reduces early QoL impact for postprostatectomy ED, with faster return to continence enabling earlier commencement of penile rehabilitation. While our 12-week protocol and sample size was not powerful enough to demonstrate conclusive benefits of early PFM training for ED, PFM intervention after RP over longer times has been supported by others.

Key Words: Erectile Dysfunction; Prostate Cancer; Pelvic Floor Muscle Training; Physiotherapy, Men’s Health; Real Time Ultrasound

INTRODUCTION

Prostate cancer (PCa) is the most commonly diagnosed cancer in men with more than 1.4 million new cases diagnosed globally. Radical prostatectomy (RP) is the gold standard approach to cure and approximately 97% of men can expect to survive at least 5 years following surgery. Side effects from treatment can, however, greatly impact on the quality of life (QoL) of a man and also his partner. These side effects include urinary incontinence (UI), erectile dysfunction (ED), and climpacturia (loss of urine with
orgasm). More than 70% of men report adverse effects following the diagnosis and treatment of PCa and ED is known to have a greater negative impact on QoL than UI, affecting 26–100% of men, with only 16–22% regaining pre-surgery levels of erectile function (EF)\(^7\). This large range reported by various authors is indicative of the challenges of research in this field, with many differing methods of assessment potentially adding to uncertainty and post-RP distress. Depression, anxiety, and post-traumatic stress occur 4 times more often in men with PCa, compared to their healthy counterparts,\(^8\) and the link with ED is well-established.\(^9\) Strategies to minimize the impact of ED following RP are an important consideration and education from the time of diagnosis should include conservative, evidence-based measures such as pelvic floor muscle (PFM) training\(^10\) and penile rehabilitation (PR)\(^11,12\) to enhance recovery.

Many studies have demonstrated the benefits of PFM training for treating UI in men following RP.\(^3,13-16\) Our recently published study utilizing high intensity PFM training, pre- and post-RP, to reduce the severity and duration of UI confirmed that the combination of fast- and slow-twitch muscle contractions performed in functional positions at a high frequency resulted in significantly less leakage and improved QoL outcomes associated with continence when compared to “usual care” patient controls.\(^15\) Previous literature regarding the role of PFM training in addressing sexual dysfunction in men following RP is limited to just 3 randomized controlled trials; however, 3 reviews outlining the link between ED and PFM training in normal populations have been published.\(^16-18\) This evidence has confirmed a direct link between PFM strength and increased rigidity in the erect penis, and as a result, PFM training is recommended as a first line approach for men seeking resolution of ED.

During RP, the cavernosal nerves that are responsible for EF may be damaged or even removed, compromising function.\(^19\) Nerve conductivity problems can ensue, which diminish nitric oxide synthesis required for mediating smooth muscle relaxation and vasodilation in normal penile erection.\(^20,21\) Nerve sparing techniques\(^22\) and PR utilizing medication, vacuum compression pumps, and intracavernosal injections are now considered best practice to minimize side effects, given that erectile tissue takes 3–4 months from surgery to recover, and potentially 3–4 years for resolution.\(^11,12,20\) Most of these strategies are invasive, however, and patient compliance to treatment can be poor, with 50–80% discontinuing within 1 year.\(^23,24\) Since EF is an important survivorship issue among PCa patients, opportunities to pursue and maintain ED treatments may be enhanced by the incorporation of non-invasive methods such as PFM training.

PFM training following RP is a relatively understudied topic, with only 3 randomized controlled trials\(^25-27\) and 1 case study\(^28\) found using multiple online search engines. Furthermore, there have been no published studies regarding the potential impact of preoperative PFM training (ie, performed prior to RP) on subsequent ED. Prehabilitation has been recommended for post-RP UI and several recent reviews have confirmed its benefit, with leakage and incontinence lasting for shorter durations.\(^29,30\) In this study, we aimed to assess the impact of PFM training on ED and QoL in a prospective study that compared “usual care” PFM training with an intervention of greater exercise intensity and volume, both beginning approximately 5 weeks prior to RP and continuing for 3 months thereafter.

### MATERIALS AND METHODS

This study was approved by the University of Western Australia Human Research Ethics Committee (ref: RA/4/1/6327) and all participants provided written informed consent. The trial was registered in the Australia New Zealand Clinical Trials Registry and allocated a unique registration number ACTRN12617001400358. Participants were enlisted from a cohort referred sequentially by their urologist for pre-prostatectomy PFM training to a single physiotherapy clinic, in line with standard procedure; no patient had surgery delayed as a result of enrollment in this study. We used a minimization approach to randomization, with each participant randomly allocated to one of 2 groups, “usual care” or “high intensity,” upon presentation to a high-volume physiotherapy clinic following a diagnosis of PCa. If randomly allocated to usual care, for example, the very next patient was allocated to the high intensity intervention group and this sequence continued until the desired sample was achieved. No a priori consideration was given to other factors such as age, surgical approach, surgeon, etiology, or BMI. Once consent was provided, enrolment in the study and interventions commenced without delay. Relevant notes were recorded in participant medical files, which were collated over the trial duration, with results subsequently analyzed by a blinded, independent statistician. Patients with pre-existing ED, type 1 diabetes, prior prostate surgery, or a history of receiving radiation or androgen deprivation therapy were excluded. Both open RP and robotic-assisted laparoscopic prostatectomy surgical types, performed by experienced surgeons operating at 2 high volume institutions, were included and similar numbers were assigned to each group (Table 1).

Furthermore, as contemporary management for post-prostatectomy patients favors the use of phosphodiesterase type

| Table 1. Inclusion and exclusion criteria |
|----------------------------------------|
| **Inclusion criteria** | **Exclusion criteria** |
| Preoperative radical prostatectomy | Acute illness |
| Open or robotic-assisted approaches | Prior urinary incontinence |
| Age >18 y | Current smokers |
| Diagnosed with prostate cancer and referred for pelvic floor muscle training | Diabetes: type 1 or 2 |
| Fully continent | Alcohol consumption ≥21 units/ wk |
| Impaired mental status | Prior prostate surgery |
| Undergoing or had prior radiation therapies | Undergoing or had prior androgen deprivation therapy |
5 inhibitor therapy, all participants were prescribed this medication.

Pre-Surgery PFM Training

Participants in both groups received physiotherapy-directed PFM training over 2 sessions of 30 minutes duration, approximately 5 weeks prior to RP surgery, with both groups then prescribed a daily PFM training program that differed in mode and intensity. All pre- and post-trial sessions were conducted in a private clinical setting in Western Australia. During the PFM training sessions, each participant was given written and verbal instructions on correct PFM exercise technique, to ensure a full contraction and relaxation cycle was implemented with the cue to “stop the flow of urine and shorten the penis while continuing to breathe.” Cues to relax abdominal muscles and avoid breath-holding were also communicated and confirmation of the correct technique was provided with real time ultrasound (RTUS) assessment as a biofeedback tool. Participants completed a PFM training diary to record the number, type, and position of exercises undertaken daily.

In the 5 weeks prior to surgery, members of the control group were directed to perform 3 sets of PFM exercises per day, with 10 contractions per set, aiming to hold for a duration of 10 seconds, with equal rest time, providing a total of 30 contractions per day. Each daily exercise set was to be performed once in supine, sitting, and then standing positions, in accordance with previously reported interventions. Members of the intervention group were required to perform 6 sets of PFM exercises per day, with each set comprising 10 fast (1 second duration) and 10 slow (10 seconds duration) contractions with an equal rest time, providing a total of 120 contractions per day. All sets were performed in standing position for this group. Adherence to PFM training programs for members of both groups was assessed via individual diary entries during fortnightly physiotherapy appointments.

Post-Surgery PFM Training

Post-surgery PFM training was recommenced following removal of the catheter. Members of the control group performed 3 sets per day of the same exercises performed pre-surgery, while members of the intervention group continued their exercise regime with 6 sets per day. Both groups exercised in the postures as described earlier for the pre-surgery period and these protocols were maintained throughout the 12-week assessment period.

Outcome Measures

EF was assessed preoperatively and at 2, 6, and 12 weeks post-RP using the validated International Index of Erectile Function (IIEF)-5 and Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) questionnaires. Participants completed the questionnaires in a private room at the completion of a scheduled physiotherapy appointment. Secondary measures of PFM function were assessed via RTUS and included the Rapid Response Test (RRT) and Sustained Endurance Test (SET), performed by a single operator for each measurement using a point-of-care ultrasound machine (3.5 MHz sector probe, Mindray DP-30 Ultrasound, 6U-42000440, China), and were recorded at each post-surgery time point.

Statistical Analysis

Outcome data were entered into SPSS (v22.0, SPSS Inc, Chicago, IL, USA) for subsequent analysis. A series of 2-factor, repeated measures ANOVA (Group × Time) were performed and significance was accepted for all analyses at $P < .05$. Where necessary, post-hoc t-tests for independent samples were performed to determine the time points at which group scores differed.

Our sample size included 101 participants, 97 after dropout, who were randomized to 2 groups (n = 50 and 47). Our power

| Table 2. Participant characteristics |
|-------------------------------------|
| **Characteristics** | **Control group (n = 47)** | **Intervention group (n = 50)** |
| Age (y) | 63.5 ± 6.8 | 62.2 ± 6.8 |
| BMI (kg/m²) | 25.4 ± 2.7 | 25.3 ± 2.7 |
| Pre-surgery training (wk) | 5.1 ± 3.2 | 5.2 ± 2.8 |
| Gleason score | 7 | 7 |
| Prostate size (g) | 49.5 ± 15.5 | 50.8 ± 18.6 |
| Operation type | 8 Open | 5 Open |
| Nerve sparing procedure | 39 Robotic-assisted | 45 Robotic-assisted |
| Catheter in situ (d) | 8.6 ± 3.0 | 8.1 ± 2.7 |
| Preoperative activity levels | | |
| Low (40–50% MHR) | 25 | 27 |
| Medium (50–70% MHR) | 20 | 20 |
| High (70–85% MHR) | 2 | 3 |

BMI = body mass index; MHR = maximum heart rate.
calculations were based on the study of Geraerts et al., as the closest exemplar. They studied 33 patients after RP who were randomized into a PFM training treatment group (n = 16) or control group (n = 17). The outcome measures were IIEF domain scores, similar to the current study (Table 2). Geraerts et al indicated a change of 4.1 units (+5.6) in the intervention group, with change of −0.2 (±2.4) in the controls. This difference was statistically significant (P = .025). Given highly conservative a priori assumptions of α = 0.01, a 2-tailed test, and a sample size of 40 per group, our study possessed >98% power to detect a similar effect size observed by Geraerts et al.

RESULTS

Of the 101 participants recruited to the study, 97 (n = 63 ± 7 years, BMI = 25.4 kg/m², Gleason 7, stage T2c) completed the trial, with 3 participants from the control group (n = 47) and 1 participant from the intervention group (n = 50) unable to finish the study due to medical complications. The study was completed over 2 years (2016–2018) and when the required recruitment and participation number was achieved. These complications included the need for radiation therapy (n = 2) and corrective surgery (n = 2). There were no significant group differences (P > .01) between participant characteristics (age, BMI, prostate size, pre-surgery training, or nerve tissue resection), with only a few in each group having open RP vs robotic-assisted laparoscopic prostatectomy surgery (see Table 1). Prostate size, Gleason score, and days of catheterization were also similar between both patient groups, as was the rate and type of cavernosal nerve sparing with an average 0.27 g nerve resection achieved in the control group compared with 0.32 g in the intervention group. Missing data were treated using a mean substitution method. Mean data for 6 participants were substituted at various assessment time points (less than 0.7% of data for analysis), due to several participants reporting “not applicable” for responses to sexual function. In these cases, participants were experiencing significant urinary leakage or had not yet reached a stage of recovery sufficient to attempt sexual activity with confidence.

EPIC-CP QoL Outcome Scores

The data are presented in Figure 1 for intervention and control patient groups from baseline (pre-surgery) to 12 weeks post-surgery on the EPIC-CP QoL score. The anova results show a significant main effect for Group (F = 4.607; P = .034) and Time (F = 143.364; P < .001), but not the Group × Time interaction (F = 1.002; P = .392). When assessing the effectiveness of the prehabilitation intervention, we note a statistical difference (P < .05) and clinically relevant difference between both groups at the 2-week time point, with the intervention group performing better. The group differences at baseline, and at weeks 6 and 12 post-surgery were only in the order of 2 units and this is not considered clinically relevant.37

Figure 1. Changes in the EPIC-CP QoL scores for patients following radical prostatectomy within the intervention and control groups at baseline, and then at 2, 6, and 12 weeks post-surgery, with lower scores indicating better outcomes. EPIC-CP = Expanded Prostate Cancer Index Composite for Clinical Practice; QoL = quality of life.

EPIC-CP EF Domain

Pre-surgery EF scores were similar between groups, and there were no other group differences at each of the post-surgery time points (Figure 2). The ANOVA results show a significant main effect for Time (F = 129.529; P < .001), but not for Group (F = 2.006; P = .160) or the Group × Time interaction (F = 1.217, P = .304).

IIEF EF

Pre-surgery scores were similar between groups, and there were no other group differences at each of the post-surgery time points (Figure 3). The ANOVA results show a significant main effect for Time (F = 159.656; P < .001), but not for Group (F = 0.575; P = .450) or the Group × Time interaction (F = 1.306, P = .273).

PFM Function Tests

Results for the RRT are shown in Figure 4. Pre-surgery RTUS assessments were not performed so as to avoid any possible training effect for the control group participants. However, at all time points post-RP, the intervention group recorded quicker (ie, enhanced) RRT scores compared to the control group (P < .05). The ANOVA results show significant main effects for Group (F = 16.132; P < .001) and Time (F = 69.790; P < .001), but not for the Group × Time interaction (F = 2.12; P = .123).

Finally, Figure 5 provides results for the SET assessment. At all post-surgery time points, the intervention group recorded more sustained (ie, enhanced) SET scores compared to the control group (P < .05). The ANOVA results show significant main effects for Group (F = 12.605; P = .001) and Time (F = 137.671; P < .001), but not for the Group × Time interaction (F = 0.679; P = .508).
DISCUSSION

In our trial, participants were randomized, 5 weeks prior to surgery, to either a high intensity or “usual care” PFM training program for the pre-rehabilitation of RP-related ED. Assessments were undertaken at baseline preoperatively (5 weeks) and at 2, 6, and 12 weeks post-RP surgery, to ascertain the effect on QoL and sexual dysfunction by utilizing the EPIC-CP and IIEF-5 questionnaires. Following RP there was a drastic and immediate reduction in EF in both groups. At all time points there was a significant difference ($P < .05$) between groups; however, the only time point when this difference was clinically relevant was at 2 weeks post-RP, with the intervention group reporting less distress in the EPIC-CP QoL outcome. This instrument includes an analysis of urinary bother, urinary leakage, and mood domains as well as ED. When assessing the ED domain scores only, there were no group differences across the time points and IIEF-5 scores were also similar.

Rates of improvement, supported by reductions in EPIC-CP and EPIC-EF scores and increases in IIEF-5 scores, occurred for patients in both groups, at a similar rate across all time points, with no appreciable differences between the 2 groups. Thus, we were able to confirm that there were no early benefits for EF as a result of pre- and early post-RP PFM training, and no apparent differences between the control and intervention protocols within the first 3 months following RP. Previous studies, however, have demonstrated improvements in EF scores when utilizing PFM training for 12 weeks post-RP when tracked over a longer follow-up period, with significant outcomes noted at 6 and 12 months post-RP for experimental vs
control groups. Prota et al for example assessed men who received PFM training with biofeedback, once per week for 12 weeks, and compared them to a control group. The authors reported that 47% of the intervention group were considered potent compared to only 12.5% of the controls. Of the 10 participants who regained potency, 90% regained full continence. Lin et al assessed the impact of PFM training on sexual dysfunction in a control group that commenced PFM training at 3 months post-RP compared to an intervention group that commenced training soon after catheter removal. Participants were assessed at 1, 3, 6, 9, and 12 months, with rates of sexual function reported as being poorer among the control group participants across all time points. The 12-month data showed the greatest difference, with 92.6% of the control group, vs 65.7% of the intervention group, displaying impotence. A 3-month PFM training intervention for men with long-term ED greater than 12 months post-RP was undertaken by Geraerts et al to ascertain benefits on both sexual dysfunction and climacturia, following the opportunity for spontaneous recovery. Their results revealed significant improvement in the recovery of EF and climacturia within the intervention group compared to the control participants. These results concur with evidence reporting a significant neuropraxic effect in the immediate postoperative time frame, after which erectile tissue begins to recover. In this context, it is notable that the most commonly utilized first-line treatment, phosphodiesterase type 5 inhibitor medications, provides only 12–17% of men with a response within 6 months of RP. Thus, although our 12-week exercise protocol and sample size were not powerful enough to demonstrate conclusive benefits of ED in this study, PFM training may prove effective with a 6–12 month follow-up, as has been reported by others. Since it was unethical to withhold treatment, our study enabled the control group to commence the high intensity PFM training protocol from 12 weeks post-surgery to enhance their continence recovery. Thus, comparisons between the 2 study arms could only be undertaken for the 5-week pre-habilitation plus 12-week post-surgery rehabilitation time frame.

In our study, a significant difference in urinary continence rates was observed, with 74% of the intervention group achieving full continence at 3 months, but only 43% of the control group dry at the same time point. Hence, extending the control group protocol beyond this time was not considered ethical, and at 3 months both groups continued with high intensity PFM training. Prota et al found a strong association between recovery of continence and potency, with continent patients having a 5.4-fold greater chance of being potent at 12 months post-RP. Similar findings by Kao et al and Burkhard et al further support the relationship between UI and potency following RP, with indications that nerve sparing and neurovascular bundle preservation may also assist the recovery of both functions. At 2 weeks post-RP, there was a significant difference (P < .05) in EPIC-CP scores between our intervention and control groups when UI questions were included in the analysis, indicating that QoL at the early stages of RP rehabilitation is most impacted by continence outcomes. As seen clinically, men report distress and embarrassment with loss of urine associated with EF. As both climacturia and sexual arousal incontinence occur in 20–40% of men following RP, many men choose to defer sexual activity until continence resolution.

Our secondary measures assessed PFM function utilizing functional tests, developed and validated for men and those that have been previously reported. Using RTUS tests that directly visualized and quantified the function of the PFM during standardized tests, we were able to demonstrate lower RRT scores across all time points for the intervention vs control group, corresponding to the finding of significantly less leakage at 2 weeks post-surgery and a quicker return to continence for men who undertook the intervention training protocol. Similarly, higher SET scores for the intervention group across post-surgery time points were also reflected in reduced leakage and time to continence for the intervention group. By providing men with an improved PFM training protocol for faster continence resolution, the opportunity to engage in sexual activity earlier is likely to have a positive impact on QoL, as evidenced by EPIC-CP at 2 weeks post-RP in the current study.

Following RP, QoL outcomes are a significant consideration, given the likelihood of long-term survival rates. Evidence from a recent study showed that only 16–22% of men return to preoperative erectile functional capacity at 2 years post-surgery, and just 28% report erections strong enough for intercourse at 5 years. In a qualitative analysis of 27 PCa survivors and their partners by Albaugh et al in 2017, issues of frustration due to changes in sexual function led to feelings of loss and grief and, in several cases, suicidal ideation. Men reported the psychologically devastating effects of feeling abnormal, unnatural, and less of a man due to their sexual dysfunction and, in both men and their partners, a sense that this change had a great impact on every aspect of their lives. The importance of education and comprehensive information before and following PCa treatment was considered a significant contributor to reducing distress, and for those men who had been well prepared for the sexual side effects of treatment, acceptance to the changes was far less devastating.

The opportunity to hasten recovery of EF is the goal of PR, and PFM training potentially offers an adjuvantive strategy. Whilst we were not able to demonstrate a significant impact of high intensity vs “usual care” PFM training on ED in the immediate post-RP period, longer term analysis may have mirrored the results of some previous investigations. However, given the importance of EF in survivorship following treatment for PCa and the expected time frame for spontaneous recovery, the addition of PFM training provides an opportunity for patient driven, positive rehabilitation strategies from the point of diagnosis. It is important to note, however, that pelvic floor exercises should not delay other treatments to recover erections and our...
investigations aim to only further enhance understanding of the many options available to assist this population. Faster uptake of traditional penile rehabilitation was observed within the intervention group, with a faster return to sexual activity reported by participants, an association most likely related to earlier continence recovery.

A further potential limitation of our study was the lack of a true control group (ie, with no PFM training) for comparison with the intervention study arm. However, given the exposure to varied medical, urological, community, and Internet recommendations regarding pelvic floor training in this population, it was deemed unethical to withhold treatment to a control group. We do not feel this was detrimental to the outcomes of our investigation, as no participant was compromised by enrolment, which was an important biopsychosocial consideration in this population.

CONCLUSIONS

In conclusion, PFM training has an important role in managing ED in normal populations and, as demonstrated in the literature, leads to a faster return to continence following surgery for PCa. Previous authors have established the benefits of PFM training and biofeedback in the long-term recovery of EF following RP. The opportunity to enhance QoL outcomes following diagnosis and treatment of PCa, through early interventions and education, is well supported in the literature. PFM training, whilst not immediately impacting on improved sexual function, causes no harm and has potential benefits that align with the normal progression of erectile tissue recovery following RP, and may be utilized as an additional, non-invasive component of PR.

ACKNOWLEDGMENTS

We would sincerely like to thank our patients who have taught us so much and acknowledge the inspiration provided by Prof Patrick Walsh who was the pioneer of nerve sparing radical prostatectomy, enabling generations of men to have hope with erectile function recovery following treatment.

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Conflict of Interest: The authors report no conflicts of interest.

Funding: None.

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