Original Article

# Novel online comprehensive pelvic floor therapy program following prostatectomy

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**Background:** Although pelvic floor muscle training (PFMT) is widely shown to improve post-prostatectomy incontinence (PPI), numerous barriers impede access to formal PFMT and include the limited availability of specialized therapists and financial or scheduling barriers. To address these barriers, we developed a novel online program delivering comprehensive long-term PFMT, pelvic floor education (PFE), and dietary/behavioral modification education. This study is a prospective interim analysis of online PFMT/PFE (oPFMT/PFE), with focus on feasibility, satisfaction, and continence outcomes.

**Methods:** Patients anticipating robotic-assisted laparoscopic prostatectomy (RALP) were recruited (6/2021–9/2022) for oPFMT/PFE. oPFMT/PFE comprises a 12-month program of 3 phases, including multiple exercises with varied contraction types and duration, and comprehensive dietary and behavioral technique education. Incontinence and quality of life (QOL) outcomes are assessed at 3 weeks, 3, 6, and 12 months following RALP using validated International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms (ICIQ-MLUTS) and Incontinence Impact Questionnaire (IIQ-7) questionnaires and additional items assessing satisfaction, improvement, and daily pad use. Primary study outcomes included ICIQ-MLUTS stress urinary incontinence (SUI) domain score (SDS) and SUI cure [ICIQ SUI domain score (SDS) =0]. Interim 6-month analysis was performed using mixed effects linear regression and mixed effects Poisson regression.

**Results:** Analysis included 21 men (64±6 years). At 6-month follow-up, men undergoing oPFMT/PFE showed significant improvement in SDS compared to the 3-week time point [mean ± standard error (SE) =1.05±0.24 *vs.* 0.45±0.17, P=0.011], but still experienced higher scores than at baseline (P=0.017). Six-month patient-reported improvement averaged 7.42±0.74 (10-point Likert scale). All (100%) of 19 respondents (2 missing data) found the program easy to use, educational, and would recommend it to others, with 89% expressing satisfaction with the program. During patient interview at 6-month follow-up, no men reported inability to access the program online or any adverse events. Finally, IIQ-7 score improved significantly from the 3-week timepoint (4.47±1.10) at both time points (3-month 1.14±0.44, P<0.001 and 6-month 1.10±0.37, P<0.001), and neither 3- nor 6-month scores differed from baseline (P=0.808 and P=0.444, respectively).

**Conclusions:** Our novel oPFMT/PFE yields significant improvements to validated urinary incontinence (UI) and QOL measures, providing a valuable and accessible treatment option for PPI.

**Keywords:** Pelvic floor therapy; prostatectomy; stress urinary incontinence (SUI)

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## Introduction

Post-prostatectomy incontinence (PPI) is common, with multiple studies demonstrating that a majority of men will suffer from long-term incontinence to some degree following prostatectomy (1,2). PPI is associated with a significant and deleterious impact to quality of life (QOL) and well-being (3). This data is even more concerning given the significant number of men surviving prostate cancer (CaP), with data estimating that CaP survivors account for 4 in every 10 cancer survivors and comprise more than 3.6 million men (4,5). As such, CaP survivorship has received increasing attention and long-term assessment and treatment of physical (e.g., urinary, sexual, bowel) and psychosocial effects of CaP treatment is recommended in the American Cancer Society CaP survivorship guidelines (6).

Surgical therapies, including artificial urinary sphincter and male sling placement, are widely established and efficacious options for the treatment of PPI (7). However, whereas up to 70% of men experience some degree of long-term PPI, rates of anti-incontinence surgery following prostatectomy are only approximately 3% (1-2,8). The reasons underlying this discrepancy are complex and include access to specialized surgeons performing prosthetics placement as well as patient-related factors that influence treatment decision making (9). Importantly, despite experiencing bothersome or severe incontinence, many men are not interested in surgery and prosthetic placement (9).

For these reasons, conservative therapies to treat PPI are critical. Formal pelvic floor muscle training (PMFT) is widely demonstrated to be a beneficial treatment for PPI (10-13). As such, PFMT is a recommended treatment for PPI by numerous professional societies including the American Urological Association, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, and European Association of Urology (11,14).

Despite the proven effectiveness of PFMT and support for its use by expert societies, numerous barriers impede access to formal PFMT with a therapist. Such barriers include limited access to specialized pelvic floor therapists, the desire by patients to avoid associated co-pays, or scheduling barriers (lack of transport or work conflict). As a result, more limited PFMT education is often provided by a patient's robotic-assisted laparoscopic prostatectomy (RALP) surgeon, who may lack specialized training in incontinence and physiotherapy techniques.

Given the concern that this more limited pelvic floor education (PFE) and rehab may not be as efficacious as formal PFMT, we previously compared the efficacy of PFE directed by RALP surgeons with in-person, long-term (12 months) PFMT directed by a trained Female Pelvic Medicine and Reconstructive Surgery (FPMRS)-specialist (15). In-person PFMT by a FPMRS provider was associated with superior validated stress urinary incontinence (SUI) scores at 6- and 12-month post-operatively, underscoring the benefit to formal and comprehensive therapy by trained providers. Despite this, in-person therapy by a trained therapist or urologist is unrealistic given that the provider time required to deliver such intensive therapy is significant and difficult given the present fee-for-service reimbursement system and often times limited appointment durations.

The present study is the next step in our comprehensive effort to improve access to formal pelvic floor physical therapy (PFPT) given its demonstrated benefit as compared to more limited PFE. Accordingly, we developed and tested a comprehensive online program designed by physical therapy and urology providers to provide an alternative and innovative delivery solution for formal PFMT in the treatment of PPI. We report the interim results of our pilot study of online PFMT, with focus on describing our program and experience, as well as evaluate the feasibility and early outcomes following RALP. We present this

### Highlight box

**Key findings**

- We developed a novel online comprehensive program [online pelvic floor muscle training/pelvic floor education (oPFMT/PFE)] to deliver pelvic floor education, dietary and behavioral modification programming, and pelvic floor muscle training in men following prostatectomy.
- Men completing long-term oPFMT/PFE demonstrate significant improvements to validated urinary incontinence and quality of life measures and also report program ease of use and satisfaction.

**What is known and what is new?**

- Post-prostatectomy incontinence (PPI) is common, with multiple studies demonstrating that a majority of men will suffer from long-term incontinence to some degree following prostatectomy.
- Pelvic floor muscle training is widely shown to improve PPI, however, numerous barriers impede access to formal pelvic floor muscle training.
- Our online pelvic floor program provides a new, effective alternative to in-person care.

**What is the implication, and what should change now?**

- Our online program has the potential to significantly improve access to standard of care therapy for men undergoing prostatectomy.

 

article in accordance with the PROCESS reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-436/rc) (16).

## Methods

We performed a prospective single-arm pilot case series trial (6/2021–9/2022) in adult men undergoing RALP. Patients anticipating RALP were recruited in the urology clinic. Patients without access to a computer and internet were not eligible for study inclusion. Following enrollment, patients completed a pre-operative visit with the study personnel and received education about PPI and a detailed overview of the program, including a tutorial of the website, program calendar, and educational resources. Patients underwent RALP by one of three different fellowship-trained surgeons using techniques including anterior approach, anterior approach with Hood technique reconstruction, and pelvic fascial sparing approach. Patients were instructed to begin the oPFMT/PFE at 3 weeks following RALP. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Study approval was provided by the University of Virginia Institutional Review Board (No. 20830) and informed consent was obtained from all individual participants.

The oPFMT/PFE is a comprehensive program consisting of PFMT, dietary modification, behavioral therapy, pelvic floor anatomy and physiology education, and PMFT. The oPFMT/PFE was designed by both urology and physical therapy providers to simulate the comprehensive approach of formal, in-person PFMT that would be used in a pelvic floor center. The program is available at www.hfitness.com.

The online program resources include a variety of written and video tutorials. A program calendar is provided and available at www.hfitness.com. The first week consists of educational videos designed to provide patients with an understanding of pelvic floor anatomy and physiology of urinary incontinence (UI). Video tutorials also provide behavioral modification techniques including timed/double voiding and appropriate toileting posture. Patients are then taught a basic pelvic floor squeeze (i.e., Kegel). Over the first month, patients then complete a comprehensive PFMT workout that includes a combination of exercises including varied contraction types and duration (quick flick versus sustained) and exercise positions (supine, seated, and standing). Additional exercises focus on posture and stretching. Finally, additional physiotherapy techniques introduced include counterbracing and knack skills. The exercise sessions last approximately 20 minutes, performed every other day. Patients then transition to a second exercise workout in months 2 and 3 that includes similar components of a more advanced nature.

Concurrently, patients also perform dietary modification. Written online resources (www.hfitness.com) guide patients through a weekly dietary modification plan with the aim of helping patients identify and then avoid possible bladder stimulants/irritants.

During phase 2 (months 3–6) and phase 3 (months 6–12), men are transitioned to more focused exercises of shorter duration in an effort to promote daily muscle activity and patient compliance. Accordingly, in phase 2 patients complete 3 exercises daily, again including varied contraction types and positions. Combined, a total of 30 repetitions are performed daily (10 repetitions/exercise). Phase 3 maintains these exercises while adding counterbracing and progressive loading techniques.

Functional outcomes assessment and surveillance was longitudinally performed using robust validated questionnaires assessing lower urinary tract symptoms [International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms (ICIQ-MLUTS)] and QOL [Incontinence Impact Questionnaire (IIQ-7)] (17-19). Questionnaire assessment was performed at baseline and at 3-week, 3-, and 6-month timepoints following RALP. The 3-week assessment was included in an attempt to capture continence nadir as, in our experience, incontinence is commonly most severe in the several weeks following catheter removal. Additional original questionnaire items assessed patient satisfaction, self-reported improvement, and program characteristics (e.g., ease of use) (Figure S1).

### *Primary and secondary outcomes*

The primary study outcome was ICIQ-MLUTS SUI domain score (SDS). This domain score ranges from 0–4 (0= 'Never'; 1= 'Occasionally'; 2= 'sometimes'; 3= 'Most of the time'; 4= 'All of the time'). Secondary outcomes included pad use per day (PPD), SUI cure [SDS =0 ('Never')], and QOL score (IIQ-7). Given our prior study demonstrating significant rates of *de novo* urge urinary incontinence (UUI) following RALP, ICIQ-MLUTS UUI domain score (UDS) was also assessed given the potential efficacy of PFMT in the concurrent treatment of UUI.

 

**Table 1** Patient demographics and characteristics

| Factor | oPFMT (n=21) |
|---|---|
| Age (years), mean ± SD | 64±6 |
| BMI (kg/m$^2$), mean ± SD | 27.5±4.5 |
| EBL (mL), median [IQR] | 100 [75, 200] |
| Pre-op PSA, mean ± SD | 8.3±4.5 |
| LND, n [%] | |
| No | 6 [29] |
| Yes | 15 [71] |
| Grade group*, n [%] | |
| 0 | 0 |
| 1 | 1 [5] |
| 2 | 13 [62] |
| 3 | 5 [24] |
| 4 | 0 |
| 5 | 2 [10] |
| Prior AI repair, n [%] | |
| No | 21 [100] |
| BPH treatment, n [%] | |
| No | 14 [67] |
| Yes | 7 [33] |
| Smoking, n [%] | |
| Never | 14 [67] |
| Current | 1 [5] |
| Former | 6 [29] |
| Nerve sparing, n [%] | |
| None | 1 [5] |
| Bilat | 17 [81] |
| Unilat right | 2 [10] |
| Unilat left | 1 [5] |

*, Gleason Grade Group System: Grade group 0, no cancer; Grade group 1, Gleason 3+3; Grade group 2, Gleason 3+4; Grade group 3, Gleason 4+3; Grade group 4, Gleason 8 (4+4, 3+5, 5+3); Grade group 5, Gleason 9–10 (4+5, 5+4, 5+5). oPFMT, online pelvic floor muscle training; SD, standard deviation; IQR, interquartile range; BMI, body mass index; EBL, estimated blood loss; PSA, prostate specific antigen; LND, lymph node dissection; AI, anti-incontinence; BPH, benign prostatic hyperplasia; bilat, bilateral; unilat, unilateral.

### *Statistical analyses*

The present analysis is a 6-month interim analysis. The study population was summarized using standard descriptive statistics. Following enrollment and initial pre-RALP orientation, five patients withdrew prior to starting the program and left 21 for final analysis. Out of 21 patients, 1 was missing UDS values at baseline, 2 were missing all values at 3 weeks, 1 patient was missing IIQ-7 sum score at 3 months, and 1 patient was missing all values at 6 months. One patient was missing 1 question composing the 6-month IIQ-7 sum score so that item was imputed using the mean of the patient's other items at that time point.

A linear mixed-effects model was used to estimate SDS over time, which allows for missing data and accounts for repeated measurements on each patient (20). SUI cure was calculated as the proportion of patients experiencing SDS score of 0 at a given time. Proportions were compared using the chi square test. Poisson mixed-effects models were used for UDS, PPD and IIQ-7 sum outcomes. For all outcomes, the delta method with robust variance estimator was used to test for differences in the marginal means between the 3-week timepoint and the 3- and 6-month times (21). Then the unadjusted 3- and 6-month scores were compared with baseline scores using Wilcoxon Signed Rank test, using list-wise deletion for missing values. All analyses were conducted using R (version 4.2.3) and plots were created using tidyverse packages and cowplot (22,23). P values were considered significant at 0.05.

## Results

Analysis included a total of 21 men. *Table 1* details patient demographics and characteristics. Patients were an average of 64±6 years old, with median estimated blood loss (EBL) of 100 mL [interquartile range (IQR) =75–200 mL], with 2 of 21 patients undergoing adjuvant radiotherapy (9.5%), 15/21 with lymph node dissection (71.4%). Mean and 95% confidence interval for patient-reported outcomes across all time points are shown in *Table 2* and in *Figure 1*.

SDSs for men enrolled in oPFMT/PFE showed improvement from at the 3-week time point [mean ± standard error (SE) =1.05±0.24] to the 3-month (0.76±0.19, P=0.18) and the 6-month follow-up (0.45±0.17, P=0.011), though only the 6-month comparison met statistical significance criteria. Both 3- and 6-month follow-up scores

 

**Table 2** Patient-reported outcomes, differences from 3 weeks from the adjusted longitudinal models, and differences from baseline using non-missing, unadjusted values

| Time | oPFMT/PFE unadjusted mean ± SE, n | P value | |
|---|---|---|---|
| | | Comparison to 3-week[1] | Comparison to baseline[2] |
| ICIQ SUI domain score | | | |
| Baseline | 0.00±0.00, n=21 | | |
| 3-week | 1.05±0.24, n=19 | | |
| 3-month | 0.76±0.19, n=21 | 0.180 | <0.001 |
| 6-month | 0.45±0.17, n=20 | 0.011 | 0.017 |
| ICIQ UUI domain score | | | |
| Baseline | 0.30±0.11, n=20 | | |
| 3-week | 1.16±0.21, n=19 | | |
| 3-month | 0.71±0.16, n=21 | 0.281 | 0.033 |
| 6-month | 0.35±0.13, n=20 | 0.012 | 0.790 |
| Daily pad use | | | |
| Baseline | 0.00±0.00, n=21 | | |
| 3-week | 2.32±0.45, n=19 | | |
| 3-month | 0.71±0.16, n=21 | <0.001 | 0.001 |
| 6-month | 0.35±0.13, n=20 | <0.001 | 0.030 |
| IIQ-7 sum score | | | |
| Baseline | 1.48±0.41, n=21 | | |
| 3-week | 4.47±1.10, n=19 | | |
| 3-month | 1.40±0.44, n=20 | <0.001 | 0.808 |
| 6-month | 1.10±0.37, n=20 | <0.001 | 0.444 |

[1], based on differences between estimated marginal means calculated from longitudinal models; [2], based on non-missing pairs of unadjusted scores using Wilcoxon Signed Rank test. oPFMT, online pelvic floor muscle training; PFE, pelvic floor education; SE, standard error; ICIQ, International Consultation on Incontinence Questionnaire; SUI, stress urinary incontinence; UUI, urge urinary incontinence; IIQ-7, Incontinence Impact Questionnaire.

remained higher than at baseline (P<0.001 and P=0.017, respectively). At 3 months 10/21 (47.6%) of patients reported SUI cure and by 6 months, the proportion rose 14/20 (70.0%) of patients reported SUI cure. Both 3- and 6-month proportions were significantly lower than at baseline, when all patients (21/21) reported an SDS of 0 (P<0.001 and P=0.023, respectively).

UUI domain at 3 months (0.71±0.16, P=0.281) demonstrated non-significant improvements in comparison to 3-week scores (1.16±0.21), but by 6 months the improvement reached statistical significance (0.35±0.13, P=0.012). While 3-month scores did not improve to baseline (0.03±0.11, P=0.033), by 6 months the difference between 6-month and baseline scores was no longer significant (P=0.790).

Pads per day reached its peak at 3 weeks (2.32±0.45), falling significantly by 3 months (0.71±0.16, P<0.001) and 6 months (0.35±0.13, P<0.001). Daily pad use at both 3- and 6-month follow-up continued to differ from baseline when all patients reported using 0 pad per day (P=0.001 and P=0.030, respectively).

QOL (IIQ-7 sum) score improved significantly from the 3-week timepoint (4.47±1.10) to both follow-up visits (3-month 1.14±0.44, P<0.001 and 6-month 1.10±0.37, P<0.001), and neither 3- nor 6-month scores differed from baseline when QOL averaged 1.48±0.41 (P=0.808 and P=0.444, respectively)

 

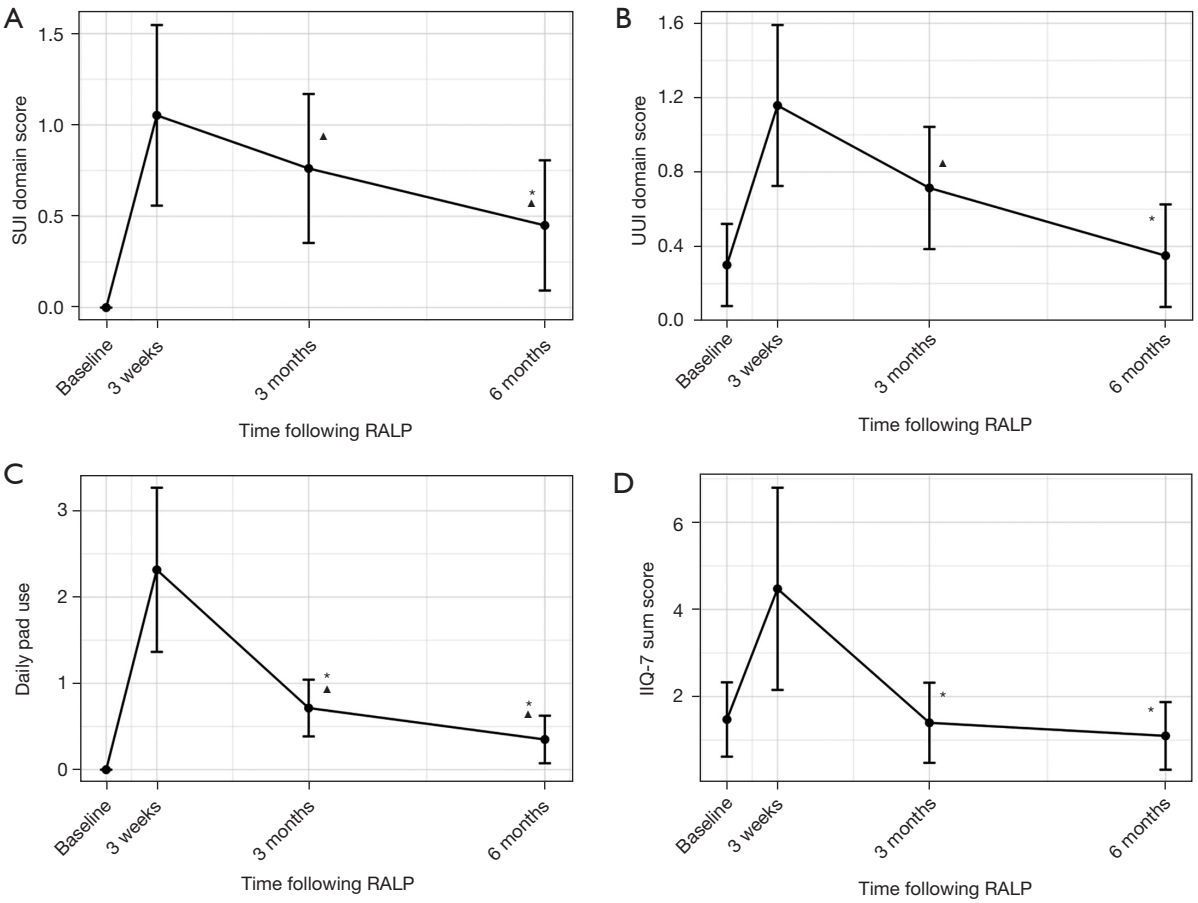


**Figure 1** Outcomes over time. Unadjusted mean and 95% CI for (A) SUI domain score, (B) UUI domain score, (C) daily pad use, and (D) IIQ-7 sum score. Asterisks represent statistically significant differences from the 3-week timepoint based on estimated marginal means calculated from linear mixed effects model (A) and Poisson mixed effects model (B-D). Triangles represent statistically significant differences between 3- or 6-month follow-up and baseline calculated using Wilcoxon Signed Rank test on the unadjusted scores. SUI, stress urinary incontinence; UUI, urge urinary incontinence; IIQ-7, Incontinence Impact Questionnaire; RALP, robotic-assisted laparoscopic prostatectomy; CI, confidence interval.

showing that patients returned to their previous QOL.

At 6 months, the patient-reported improvement averaged 7.42±0.74 (10-point Likert scale). Of 19 respondents (2 missing data), the majority (89%) reported symptom improvement, with 89% expressing satisfaction with the program. All respondents (100%) found the program easy to use, educational, and would recommend it to others. During patient interview at 6-month follow-up, no men reported inability to access the program online or any adverse events.

## Discussion

We demonstrate the successful development and use of a comprehensive online PFMT/PFE program in the treatment of PPI. Our analysis and experience included outcomes evaluating program feasibility. Our data showed that patients were able to access and use online program education and materials, with all respondents reporting ease of use. No patients reported inability to access online materials or adverse event related to PFMT.

Our study demonstrates significant longitudinal improvement to PPI using oPFMT/PFE using a variety of patient-reported outcomes. At 3- and 6-month follow-up, men enrolled in oPFMT/PFE showed significant improvement in SDSs compared to the 3-week time point. In addition, significant improvements in daily pad use were seen at 3- and 6-month follow-up. At 6-month follow-up

 

70% of men reported complete absence of SUI (SDS =0), a continence rate similar to that reported in other series (12,13). Notably, these other series utilized formal PFMT (versus more limited surgeon-directed PFE). We are thus encouraged by our data suggesting similar continence rates via online format and highlight the importance of comparative study between oPFMT/PFE and formal in-person PFMT as the next step in our larger effort.

Equally importantly, patients reported a very high rate of program compliance. Excluding five patients who withdrew from the study, all remaining patients reported program compliance and exercise completion through 6-month follow-up. This is a notable finding as the project genesis aimed to develop an online PFPT program to help improve access and compliance for more patients following prostatectomy. Although data regarding PFMT access and compliance specific to patients undergoing RALP is limited, literature focused on pelvic floor physiotherapy in women with UI commonly demonstrates poor compliance with treatment (24).

As outlined previously, multiple barriers impede patient access to formal PFPT that is necessary to optimize continence outcomes following RALP. Foremost, there is a limited number of physiotherapists with pelvic floor specialization and the patient demand far exceeds this provider pool (25). When available, insurance coverage barriers or required co-pays often create financial hardships that prevent access. Scheduling barriers are also significant, as formal PFPT often requires numerous visits that can conflict with work or create transportation barriers for specific patients.

As a result of these barriers, PFMT instruction is often provided by the patient's treating urologic surgeon. Unfortunately, this does not promote optimal outcomes as these providers generally lack formal training in pelvic floor physiotherapy. Patient training in these settings is also problematic as it is generally provided during more limited visits scheduled for prostate specific antigen (PSA) surveillance (e.g., every three months) rather than more frequent sessions that occur when undergoing physiotherapy (e.g., weekly). Finally, given the significant and increasing number of CaP survivors, it is also likely that the management of treatment effects including UI will be commonly managed by primary care providers (4).

Underscoring this problem are data demonstrating primary care for patients with UI often lacks sufficient adherence to care guidelines (26).

These deficiencies are further compounded by the decreasing time available for urology clinic visits in the contemporary health care environment, reported to average between 9–17 minutes (27,28). Indeed, the provider time required to deliver comprehensive PFE and exercise training is significant and unrealistic given the limited time available. Nonetheless, given the importance and impact of appropriately delivered conservative therapy for PPI, it is critical that innovative care solutions be developed. Our online program is one such potential option.

Our program was carefully developed to facilitate patient comprehension and success. The oPFMT/PFE was designed by both urology and physical therapy providers to mirror the comprehensive care that would be provided in person across both provider types. For this reason, our program included not only PFMT but also pelvic floor, dietary, and behavioral education. Numerous studies demonstrate the efficacy of these conservative educational and dietary approaches in the treatment of UI and underscore the importance of including these interventions along with PFMT to deliver a comprehensive pelvic floor program (29). The exercise modules were also comprehensive, including numerous varied isometric pelvic floor contraction types but also stretching and posture exercises to facilitate pelvic floor function. Finally, inclusion of general pelvic floor anatomy and physiology education was based on evidence showing that patients who are well educated about their health conditions engage more actively in their care and can yield improved health outcomes (30,31).

Another benefit to our oPFMT/PFE is the comprehensive exercise program offered, which incorporated variations used for both SUI and UUI. In contrast to PFMT training regimens for SUI that generally include focus on muscle endurance, regimens for UUI more commonly include quick flick squeezes focused on fast-twitch musculature and pelvic floor contractions to suppress urgency episodes (32,33). Our program includes exercises of all types which is important given the significant rate of UUI reported following prostatectomy (34). We have previously reported *de novo* UUI rates of 56% and 62% of RALP patients at 3- and 6-month timepoints, respectively (35).

Study limitations include lower patient number and the lack of a control arm. As detailed, this was a pilot study with focus not only on symptom outcomes but also designed to understand and assess user interface and ease, patient compliance, and other related data. This single-arm analysis was important to identify any prospective issues related to online interface or program comprehension. Having successfully demonstrated program feasibility, we are

 

performing comparative study between long-term (12-month) oPFMT/PFE and formal in-person PFMT. Additional study assessing the benefit of oPFMT/PFE in other cohorts [i.e., post-holmium laser enucleation of the prostate (HoLEP)] is also needed given prior study suggesting the benefit of PFMT in this population (36).

## Conclusions

Our novel oPFMT/PFE is easy to use and had high patient satisfaction and compliance scores. This program also yields significant improvements to validated UI and QOL measures, providing a valuable and accessible treatment option for all men with PPI regardless of geography and insurance status.

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## Footnote

*Reporting Checklist:* The authors have completed the PROCESS reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-23-436/rc

*Data Sharing Statement:* Available at https://tau.amegroups.com/article/view/10.21037/tau-23-436/dss

*Peer Review File:* Available at https://tau.amegroups.com/article/view/10.21037/tau-23-436/prf

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-23-436/coif). D.E.R. is the owner of HFITNESS, LLC and creator and owner of the website and copyright for educational materials of the reported oPFMT/PFE. Conflict of Interest exemption and related management plan was approved by the UVA COI Committee (2018-17). As part of this plan, enrollment was performed by study research coordinators without D.E.R. present. All subjects were informed of D.E.R.'s financial interest in HFITNESS, LLC and provided with ombudsperson contact information to approach if they believed that D.E.R.'s financial interest interfered with the course of research. D.E.R. provided website and program tutorial at program initiation. All outcome data collection and related database entry, including validated questionnaires, was performed independently by clinical research coordinators. All data and statistical analysis were performed independently by UVA Department of Public Health Sciences. An independent faculty member not participating as a study investigator was also appointed to review project results in order to ensure data integrity. The other authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Study approval was provided by the University of Virginia Institutional Review Board (No. 20830) and informed consent was obtained from all individual participants.



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