Prostatic Disease & Male Voiding Topics

Comparison of In-person Versus Online Comprehensive Pelvic Floor Rehabilitation Program Following Prostatectomy

Dylan Hutchison, Marieke K. Jones, Soutik Ghosal, Jack Lawton, Kirsten L. Greene, and David E. Rapp

OBJECTIVE To compare continence outcomes in post-prostatectomy patients undergoing supervised in-person versus online pelvic floor muscle training and pelvic floor education (iPMFT vs oPFMT/PFE). Despite the proven benefit of in-person PFMT for urinary incontinence (UI) following prostatectomy, numerous barriers impede access. We developed a comprehensive online program to deliver oPFMT/PFE.

METHODS We performed a retrospective review of patients receiving iPFMT versus oPFMT/PFE with minimum 12-month follow-up. Outcomes were assessed at 3 weeks, 3-, 6-, and 12 months following robotic-assisted laparoscopic prostatectomy using validated ICIQ-MLUTS and IIQ-7 questionnaires and additional items (daily pad use [PPD] and satisfaction). The primary study outcome was ICIQ-MLUTS SUI domain score (SDS). Secondary outcomes were PPD, PPD cure (0 PPD at 12 months), SUI cure (12-month SDS = baseline score), and QOL score (IIQ-7 Sum).

RESULTS Analysis included 41 men. Though men enrolled in oPFMT/PFE demonstrated lower SUI domain scores than iPFMT at most time points (3 wk $P < .01$, 3 mo $P = .04$, 6 mo $P = .15$, 12 mo $P = .04$), the rate of improvement from 3 weeks to other time points was similar between groups (P = NS at all time points). SDS Cure was no different for oPFMT/PFE (75%, 15/20) compared to iPFMT (60%, 12/20, $P = .3$). PPD and IIQ-7 were also similar at all time points and demonstrated a similar rate of decrease over time through 12 months.

CONCLUSION Significant and similar improvements in UI and QOL are seen both in men completing iPFMT or oPFMT/PFE programs. Our novel online program provides another option to improve PFMT/PFE access in men undergoing RALP. UROLOGY xx: xxx–xxx, xxxx.

Pelvic floor muscle training (PFMT) is an important component of comprehensive prostate cancer (CaP) care pathways and the optimization of functional outcomes following prostatectomy. PFMT has demonstrated significant benefit in the treatment of urinary incontinence (UI) and its use following prostatectomy is recommended by numerous professional societies including the American Urological Association (AUA), Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU), and European Association of Urology (EAU).[1-6]

Such care pathways are critical given the significant incidence and impact of UI following prostatectomy, in addition to the increasing number of CaP survivors. Numerous studies find that a majority of men undergoing radical prostatectomy will suffer from some degree of long-term urinary incontinence.[7,8] Resultant UI is associated with significant negative impacts on quality of life (QOL), psychological well-being, and is the most significant predictor of health-related QOL following prostatectomy.[1,9] At the same time, CaP survivorship is increasing and estimated to exceed 3.6 million men.[10,11] For these reasons, increased focus has been placed on optimizing continence following prostatectomy.

The authors declare that they have no relevant financial interests.

From the Department of Urology, University of Virginia Health System, Charlottesville, VA; the Department of Public Health Sciences, University of Virginia, Charlottesville, VA; and the University of Virginia School of Medicine, Charlottesville, VA

Address correspondence to: David E. Rapp, M.D., Department of Urology, UVA Medical Center, Fontaine Research Park, 500 Ray C. Hunt Drive, Charlottesville, VA 22908. E-mail: der4m@uvahealth.org

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Unfortunately, multiple barriers hinder access to critically important PFMT care. Barriers include limited access to specialized pelvic floor therapists, patients' desire 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. Such education often involves limited handouts or online resources detailing basic Kegel exercises and lacks the comprehensive approach characteristic of focused in-person pelvic floor rehabilitation. The negative impact of this more limited approach is seen in our previously published investigation demonstrating that in-person, long-term FMPRS-directed PFMT (iPFMT) is associated with greater improvements in validated UI scores following RALP as compared to men undergoing PFMT directed by the patient's RALP surgeon.[12]

These data support the importance of comprehensive pelvic rehabilitation and the need to develop alternative options to improve care access. As such, we then reported the development of an innovative comprehensive PFMT and pelvic floor education program (oPFMT/PFE) delivered online to improve patient access to comprehensive care for UI following prostatectomy.[13] Significant improvements in validated urinary incontinence (UI) and QOL measures were seen in men completing our novel oPFMT/PFE program, which also demonstrated ease of use, and had high patient satisfaction and compliance scores. The present study is the next step in this effort and sought to compare continence outcomes in post-prostatectomy patients receiving iPFMT versus oPFMT/PFE.

MATERIALS AND METHODS

We performed a retrospective comparison of 2 sequential study cohorts (iPMFT, enrollment dates: 3/2018-3/2021; oPFMT/PFE, enrollment dates: 6/2021-9/2022)) of adult men undergoing RALP who received iPFMT or oPFMT/PFE with minimum 12-month follow-up. Our initial iPMFT program and assessment were developed as an independent quality initiative to understand and optimize functional outcomes following RALP. We then developed and performed prospective feasibility testing of our comprehensive oPFMT/PFE as a sequential clinical experience, including 6-month continence outcomes. This study represents a retrospective comparison of these cohorts, including extended follow-up through 12 months.

In both cohorts, patients anticipating RALP by 1 of 3 participating urologic oncology providers were recruited. Following enrollment, all patients completed a pre-operative visit and received education about UI following prostatectomy and a detailed overview of their pelvic rehabilitation program (iPFMT or oPFMT/PFE). Patients enrolled in iPMFT received baseline education and training by a FPMRS specialist (DER) to facilitate proper pelvic floor musculature contractions. Patient undergoing oPFMT/PFE received a tutorial on the program website, calendar, and educational resources. Patients then underwent RALP using techniques including anterior approach, anterior approach with Hood technique reconstruction, and pelvic fascial sparing approach. Patients in both cohorts were instructed to begin the home program at 3 weeks following RALP.

Complete descriptions of both iPFMT and oPFMT/PFE home regimens have previously reported. Both programs comprise a robust pelvic floor workout and include a combination of exercises of varied contraction types, duration (quick flick vs sustained), and exercise positions (supine, seated, and standing), as well as additional physiotherapy techniques including counterbracing and knack skills. The oPFMT/PFE is a comprehensive program that also includes dietary modification, behavioral therapy, and pelvic floor anatomy and physiology education. The program is available at www.hfitness.com.

Validated questionnaires assessing lower urinary tract symptoms (ICIQ-MLUTS) and quality of life (IIQ-7) were completed at baseline and at 3 weeks and 3-, 6-, and 12 months post-operatively. [14,15]

Primary Outcomes

The primary outcome was the ICIQ-MLUTS stress urinary incontinence (SUI) Domain Score (SDS). SDS ranges from 0-4 (0 ='Never'; 1 ='Occasionally'; 2 ='Sometimes'; 3 ='Most of the time'; 4 ='All of the time'). Secondary outcomes included daily pad use (PPD), quality of life score (IIQ-7), and SDS and PPD Cure. Daily pad use was assessed using single questionnaire item. SDS Cure was defined as returning to baseline SDS by 12 months post-RALP while PPD Cure was defined as using 0 daily pads at 12 months post-RALP.

Statistical Analyses

Baseline balance was assessed using appropriate bivariate statistics tests: two-sample t-tests, Wilcoxon rank-sum tests, and Fisher's exact tests. Then, propensity score (PS) weights were calculated to account for possible confounders and reduce treatment selection bias. Using the overlap method in the PSweight R package[16], weights were calculated from a logistic regression model explaining treatment group with baseline measures of age, estimated blood loss, BMI, pre-operative PSA, Gleason group, lymph node dissection, adjuvant radiotherapy, smoking status, nerve sparing, any comorbidities, hypertension, positive surgical margins, pelvic fascial sparing, and pre-operative use of benign prostatic hyperplasia medication (alpha blocker or 5ARI), and primary surgeon.

Statistical analyses assessed improvement from 3 weeks within each cohort, differences at each time point between cohorts, and any difference in the rate of change from 3 weeks between cohorts. The 3-week assessment

was included to capture continence nadir as incontinence is commonly most severe in the several weeks following catheter removal. A linear generalized estimating equation model was used to estimate SDS over time adjusting for PS weights and clustering due to patient repeated measures. An interaction term between time and cohort was included in the model. A similar model with a Poisson distribution was built for PPD. For QOL scores, we fit a zero-inflated Poisson mixed effects model using baseline values as a covariate, with time, treatment group, and their interaction as predictors in both model portions. The model was also weighted using the PS weights. For all 3 longitudinal models, the emmeans R package[17] was used to test for differences in the marginal means between cohorts at each time point, differences within each cohort over time, plus differences in trends over time between cohorts. Logistic regression weighted by PS weights was used for SDS and PPD Cure at 12 months post RALP. All analyses were conducted using R version 4.3.2 and results were considered significant at $P < .05$.

RESULTS

The analytic sample consisted of 41 men with a minimum 12-month follow-up receiving iPFMT (n = 20) versus oPFMT/PFE (n = 21). Table 1 details patient demographics and clinical characteristics. The distribution of Gleason group differed by cohort with more patients in Gleason group 2 and fewer in Gleason group 4 for the oPFMT/PFE group ($P = .02$). Baseline differences were controlled in longitudinal models through PS weighting. SDS score at baseline (pre-surgery) was 0 for all patients in the oPFMT/PFE group and was 1 for 2/20 patients in the iPFMT group ($P = .20$). At baseline, no patients were using any pads. The QOL score at baseline was no different for oPFMT/PFE (1.5 ± 1.9) compared to iPFMT (1.1 ± 1.6, $P = .4$).

Table 2 shows cohort differences in outcomes over time. Table 3 details the rate of change from 3 weeks and the difference by cohort. Men enrolled in oPFMT/PFE showed lower SDS scores than men in iPFMT at each time point, though the 6-month time points did not statistically differ. Both groups improved significantly from their 3-week scores, with patients in iPFMT showing significant improvement by 3 months (2.2 ± 0.3 vs 1.3 ± 0.2, $P < .01$), which was sustained through 12 months. The oPFMT/PFE group showed significant improvement from the 3-week time point at 6- and 12 months (1.1 ± 0.2 vs 0.5 ± 0.2 $P < .01$ and vs 0.3 ± 0.1 $P < .01$). Importantly, the rate of improvement from the 3-week time point to other time points was not statistically different by cohort (Table 3, Fig. 1A). SDS Cure was no different for oPFMT/PFE (75%, 15/20) compared to iPFMT (60%, 12/20, $P = .6$).

Daily pad use was lower for oPFMT/PFE than for iPFMT at all time points, but not significantly (average decreases at each time point were 19%, 41%, 47%, and 54%, Table 2). While each cohort showed a significant decrease in PPD at all time points compared to 3 weeks ($P < .01$ for all comparisons), the rate of decrease did not statistically differ between groups (Table 3, Fig. 1B). PPD Cure was achieved for 80% (16/20) and 90% (18/20) of men enrolled in iPFMT and oPFMT/PFE, respectively ($P = .8$).

The QOL score did not differ by cohort at any time point (Table 1). Additionally, though both cohorts showed mild improvement from 3 weeks, neither reached significance (Table 3). The rate of decrease was similar for oPFMT/PFE compared to iPFMT at all follow-up time points (3 mo: 67% ± 35% vs 64% ± 23% $P = .9$, 6 mo: 63% ± 37 % vs 32% ± 38% $P = .6$, 12 mo: 73% ± 36% vs 37% ± 42% $P = .5$) (Fig. 1C).

Table 1. Patient characteristics stratified by cohort.

Characteristic	iPFMT, N = 20	oPFMT, N = 21	*P*-value
Age, mean (SD)	62 (8)	64 (6)	.2
BMI, mean (SD)	28.4 (3.0)	27.5 (4.5)	.4
Surgeon			.009
A	6 (30%)	15 (71%)	
B	6 (30%)	5 (24%)	
C	8 (40%)	1 (5%)	
EBL, median (IQR)	175 (100, 300)	100 (75, 200)	.07
Pre-op PSA, mean (SD)	8.0 (4.2)	8.3 (4.5)	.8
LND	18 (90%)	15 (71%)	.2
Gleason Grade Group*			.02
0	1 (5.0%)	0 (0%)	
1	3 (15%)	1 (4.8%)	
2	4 (20%)	13 (62%)	
3	7 (35%)	5 (24%)	
4	4 (20%)	0 (0%)	
5	1 (5.0%)	2 (9.5%)	
Prior AI Repair	0 (0%)	0 (0%)	
Pre-BPH Med	4 (20%)	7 (33%)	.5
Smoking	8 (40%)	7 (33%)	.8
Nerve Sparing			.8
none	3 (15%)	1 (4.8%)	
bilateral	15 (75%)	17 (81%)	
unilateral, R	1 (5.0%)	2 (9.5%)	
unilateral, L	1 (5.0%)	1 (4.8%)	
Positive Surgical Margins	6 (30%)	5 (24%)	.7

AI, Anti-incontinence; BMI, body mass index; BPH, benign prostatic hyperplasia; EBL, estimated blood loss; LND, lymph node dissection; PSA, prostate-specific antigen.
*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).
P-values calculated using t-tests (means), Mann-Whitney U-tests (medians) or Fisher's exact tests.

DISCUSSION

The present study is part of a dedicated multi-phased initiative to better elucidate continence outcomes and

Table 2. Differences between treatments based on estimates from longitudinal models.

	Predicted Mean ± SE			
	oPFMT/PFE	iPFMT	Difference	*P*-value
ICIQ SUI Domain Score (SDS)			oPFMT/PFE–iPFMT diff ± SE	
3 wk	1.1 ± 0.2	2.2 ± 0.3	-1.1 ± 0.4	< .01
3 mo	0.7 ± 0.2	1.3 ± 0.2	-0.6 ± 0.3	.04
6 mo	0.5 ± 0.2	1.0 ± 0.3	-0.5 ± 0.4	.15
12 mo	0.3 ± 0.1	0.9 ± 0.3	-0.7 ± 0.3	.04
Daily Pad Use (PPD)			Percent decrease for oPFMT/PFE compared to iPFMT	
3 wk	2.7 ± 0.5	3.3 ± 0.5	19 % ± 20%	.4
3 mo	0.7 ± 0.2	1.2 ± 0.2	41 % ± 18%	.09
6 mo	0.4 ± 0.2	0.7 ± 0.2	47 % ± 26%	.2
12 mo	0.2 ± 0.1	0.4 ± 0.2	54 % ± 38%	.3
IIQ-7 Sum Score			Percent decrease for oPFMT/PFE compared to iPFMT	
3 wk	8.7 ± 3.8	12.7 ± 4.0	32 % ± 37%	.5
3 mo	2.8 ± 2.8	4.6 ± 2.6	39 % ± 69%	.7
6 mo	3.3 ± 2.8	8.7 ± 4.0	62 % ± 37%	.3
12 mo	2.4 ± 2.9	8.4 ± 4.8	72 % ± 38%	.4

SDS and PPD were missing for 2 oPFMT/PFE patients group at 3 weeks and 1 oPFMT/PFE patient at 6- and 12 months. QOL score was missing 2 iPFMT and 2 oPFMT/PFE patients at 3 weeks, 1 iPFMT and 1 oPFMT/PFE patient at 3- and 6 months, and 2 iPFMT and 2 oPFMT/PFE patients at 12 months

ICIQ, International Continence Impact Questionnaire; IIQ-7, Incontinence Impact Questionnaire; SE, standard error of the mean; SUI, stress urinary incontinence

improve access to PFMT and conservative therapies in men undergoing RALP. Our earlier work sought to understand whether supervised in-person PFMT was associated with improved continence outcomes as compared to the more commonly provided standard postoperative rehabilitation pathway (unsupervised pelvic floor exercises directed by the primary oncologic surgeon).[12] We reported that in-person, long-term FMPRS-directed PFMT was associated with better-validated stress urinary incontinence scores at both 6- and 12 months following RALP as compared to the standard pathway. This long-term difference is important as some investigation suggests the benefit of PFMT is only short-term (ie, earlier return to continence) and that similar outcomes are ultimately seen over longer-term follow-up.[3-5] As continence status generally remains stable after 1 year postoperatively, the benefit of iPFMT observed at 12 months in our prior study is likely durable.

Despite this benefit over unsupervised pelvic floor exercises, iPFMT is often not possible as a result of both patient and provider barriers. For this reason, we developed an innovative, online alternative and performed

Table 3. Differences in trend based on estimates from longitudinal models.

	Change from 3 wk					
	oPFMT/PFE	*P*-value	iPFMT	*P*-value	Difference of Difference	*P*-value
ICIQ SUI Domain Score (SDS)	Time—3 wk				oPFMT/PFE - iPFMTdiff ± SE	
3 mo	-0.4 ± 0.2	.09	-0.9 ± 0.2	< .01	0.5 ± 0.3	.3
6 mo	-0.6 ± 0.2	< .01	-1.2 ± 0.4	< .01	0.6 ± 0.4	.4
12 mo	-0.8 ± 0.2	< .01	-1.3 ± 0.4	< .01	0.4 ± 0.5	.4
Daily Pad Use (PPD)	Percent Decrease from 3 weeks				Rate Change for oPFMT/PFE compared to iPFMT	
3 mo	73% ± 7.0%	< .01	62% ± 7.0%	< .01	-28% ± 23%	.3
6 mo	87% ± 5.3%	< .01	80% ± 5.1%	< .01	-35% ± 31%	.4
12 mo	94% ± 4.0%	< .01	89% ± 5.2%	< .01	-43% ± 47%	.5
IIQ-7 Sum Score	Percent Decrease from 3 weeks				Rate Change for oPFMT/PFE compared to iPFMT	
3 mo	67% ± 35%	.3	64% ± 23%	.11	-11% ± 112%	.9
6 mo	63% ± 37%	.3	32% ± 38%	.5	-45% ± 62%	.6
12 mo	73% ± 36%	.3	37% ± 42%	.5	-59% ± 60%	.5

SDS and PPD were missing for 2 oPFMT/PFE patients group at 3 weeks and 1 oPFMT/PFE patient at 6- and 12 months. QOL score was missing 2 iPFMT and 2 oPFMT/PFE patients at 3 weeks, 1 iPFMT and 1 oPFMT/PFE patient at 3- and 6 months, and 2 iPFMT and 2 oPFMT/PFE patients at 12 months

ICIQ, International Continence Impact Questionnaire; IIQ-7, Incontinence Impact Questionnaire; SE, standard error of the mean; SUI, stress urinary incontinence.

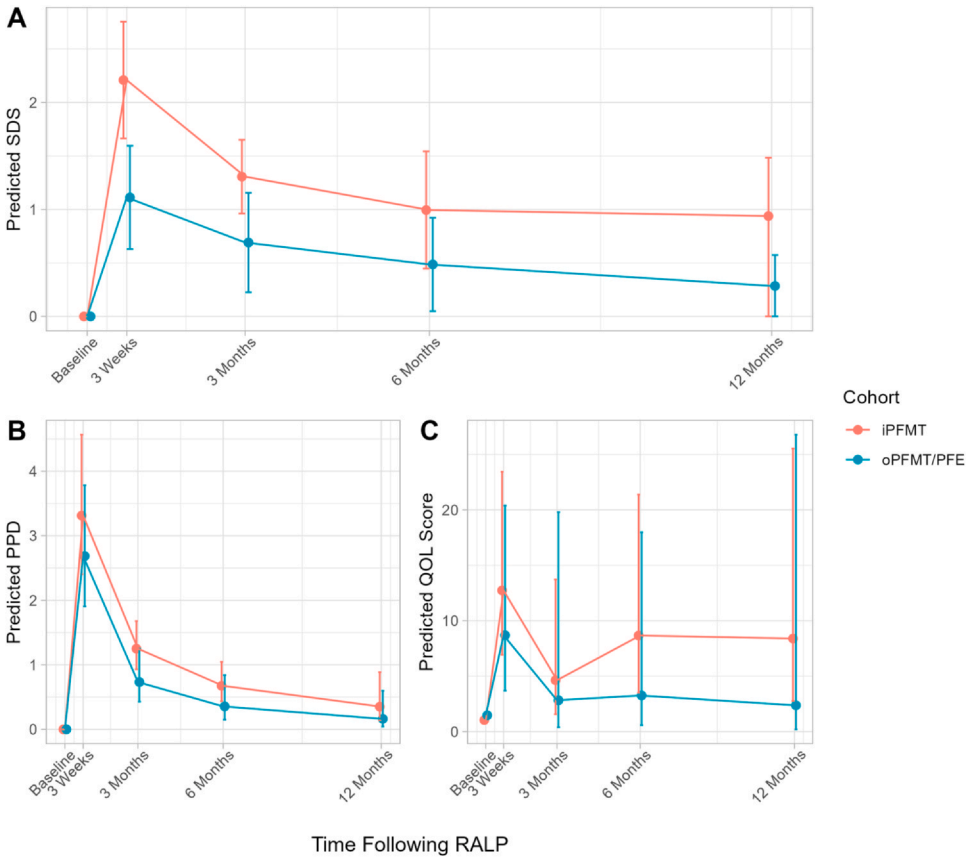

Figure 1. Longitudinal outcomes over time by cohort. Estimated marginal means ± standard error for **(A)** SUI Domain score, **(B)** Daily Pad Use, and **(C)** IIQ-7 Sum Score which measures quality of life. **A** was modeled with a propensity-score weighted linear generalized estimating equation model, while **B** used a similar Poisson GEE. **C** was modeled with a propensity-score weighted zero-inflated Poisson mixed effects model using baseline values as a covariate.

prospective feasibility testing. Significant improvements in validated UI and QOL measures were seen with our oPFMT/PFE program, in addition to ease of use, and high satisfaction and compliance scores.[13] The present comparative study is the important next step, designed to assess whether long-term outcomes in men undergoing oPFMT/PFE are similar to those receiving iPFMT. Accordingly, we demonstrate similar outcomes and rate of improvement at multiple time points through 12 months post-operatively. Combined, our results suggest that oPFMT/PFE may be a viable alternative to iPFMT for men lacking access to in-person options.

Our experience suggests a defined approach to providing better recovery care and optimizing continence outcomes following prostatectomy. Specifically, our combined investigations demonstrate that men should be provided with either in-person PFMT by a specialized provider or therapist, or a proven online alternative. Our online program is associated with long-term continence outcomes similar to those in men undergoing in-person PFMT by an FPMRS specialist and has demonstrated ease of use, high patient satisfaction, and good compliance scores. At the time of this publication, we are aware of no other comprehensive online pelvic floor rehabilitation program that has published comparative long-term continence outcomes similar to in-person rehabilitation.

Although we believe that this care pathway is effective and easy to implement, we also forward that additional progress is needed across the urologic community with respect to our assessment and prioritization of functional outcomes as part of CaP care. Foremost, it is critical that we are transparent about the true incidence of incontinence following prostatectomy. Incontinence following prostatectomy is common, not only during short-term recovery but as a long-term outcome. Stanford et al reported incontinence in 66% of patients at 6-month follow-up, with 18% still reporting no urinary control/frequent leakage at 15-year follow-up.[8,18] Contemporary studies demonstrate significant 12-month incontinence rates following RALP based on both questionnaire evaluation (63%) and pad use (40%).[19,20]

Despite this, other series commonly report UI rates following prostatectomy of less than 10%. This significant discrepancy is in part the result of using different definitions of continence that classify patients with incontinence as continent (eg, social continence). Further highlighting this issue is a study demonstrating a large

difference in continence rates when comparing post-prostatectomy patients' medical records and subsequent interview findings (30% vs 63%).[21] Continence is a critical outcome measure in studies assessing RALP and we argue that the term is only appropriate when achieving complete absence of incontinence episodes. In contrast, measures and terms commonly reported such as social continence (frequently defined as □ 1 pad daily) are misleading. Similar to continence literature at large, such measures are better described as improvement. Our own strict 12-month continence rates (SDS = 0 ['Never']) reported herein were 75% and 60% for oPFMT/PFE and iPFMT cohorts, respectively. Although we are encouraged by the significant improvement in these rates as compared to our own previously reported controls, these data highlight the need for continued efforts. Underscoring our strong belief that reporting strict continence rates is important, our oPFMT/PFE continence rates are significantly higher using alternate definitions (0 PPD = 90%).

Second, it is critical that we acknowledge the impact of UI, even more minor degrees, to men following RALP. In short, we must listen to our patients. Research demonstrates that worsening urinary function following prostatectomy causes significant and deleterious impacts on mental health and influences treatment regret.[22] Indeed, the use of any pads is associated with lower QOL.[23] Accordingly, it is important that we both accurately counsel patients on the true incidence and impact of UI following prostatectomy and place emphasis on improving and standardizing rehabilitation pathways, including concerted efforts to ensure men have access to intensive and proven PFMT programs.

Finally, it is important that we are honest about the quality of pelvic rehabilitation that we are delivering. Providing a 1-page handout or online reference to basic Kegel exercises is not same as undergoing a comprehensive in-person or online pelvic floor rehabilitation program directed by a specialist. Indeed, comprehensive programs deliver not only a great variety of tailored exercises, but also pelvic floor anatomy and physiology education, dietary modification, and behavioral therapy. Such comprehensive rehabilitation is important not only for successful treatment of SUI but also for treatment of urge urinary incontinence (UUI) that includes alternative PFMT exercises such as quick flick squeezes focused on fast-twitch musculature and urgency suppression techniques.[24,25] We have previously reported significant rates of de novo UUI following RALP (62%, 6-month follow-up), highlighting that UUI is another important functional outcome to follow in these patients.[26]

From the standpoint of urology providers, multiple barriers to providing quality, comprehensive pelvic floor care exist. First, the number of physiotherapists with pelvic floor specialization is limited, and patient demand far exceeds supply.[27] This limitation is particularly notable in rural areas. Alternatively, frequent in-person PFMT by appropriately trained urology providers is unrealistic given the limited number of surgeons with this training and limited time of a clinic visit. The average urology clinic visit duration in the contemporary healthcare environment averages 9-17 min.[28,29] Indeed, these barriers combined with the importance of providing comprehensive pelvic floor rehabilitation following RALP were the genesis of this project. We hope that our oPFMT/PFE program can help providers deliver effective pelvic floor rehabilitation in the setting of the many barriers that exist in the contemporary healthcare environment.

Study limitations include the lack of randomization and potential selection bias. Larger, multi-institutional, randomized studies are helpful. Despite this, we believe our reported investigations provide an actionable roadmap to increase access and improve pelvic rehabilitation following RALP. Our data are strengthened by the numerous time points and outcome measures assessed longitudinally as well as analysis of rate of change.

CONCLUSION

Significant improvements in UI and QOL outcomes are seen in men completing our novel oPFMT/PFE program following RALP. These outcomes are similar to those observed with in-person PFMT and may provide an option to significantly improve access to care for men undergoing RALP.

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. Study approval was provided by the University of Virginia Institutional Review Board and informed consent was obtained from all individual participants.

Declaration of Competing Interest

Dr. Rapp 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 Dr. Rapp present. All subjects were informed of Dr. Rapp's financial interest in HFITNESS, LLC and provided with ombudsperson contact information to approach if they believed that Dr. Rapp's financial interest interfered with the course of research. Dr. Rapp provided website and program tutorial at program initiation. All outcomes 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 to ensure data integrity.

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