# A pilot study on the early use of the vacuum erection device after radical retropubic prostatectomy

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## OBJECTIVE

To evaluate the effect of the early use of the vacuum erection device (VED) on erectile dysfunction (ED) and penile shortening after radical retropubic prostatectomy (RP), as these are important concerns for men choosing among treatment alternatives for localized prostate cancer.

## PATIENTS AND METHODS

Twenty-eight men undergoing RP were randomized to early intervention (1 month after RP, group 1) or a control group (6 months after RP, group 2) using a traditional VED protocol. An International Index of Erectile Function (IIEF) score of >11 (no, mild or mild to moderate ED) was required as a baseline criterion for inclusion in the study. Only patients in whom unilateral or bilateral nerves were spared were subsequently randomized. Patients in group 1 followed a daily rehabilitation protocol consisting of 10 min/day using the VED with no constriction ring, for 5 months. Patients were evaluated with the IIEF-5 questionnaire and measurements of penile flaccid length, stretched length, prepubic fat pad, and midshaft circumference before and at 1, 3, 6, 9 and 12 months after RP; the mean (range) last follow-up visit was 9.5 (6–12) months after RP.

## RESULTS

The mean (SD) baseline IIEF scores were similar in groups 1 and 2, at 21.1 (4.6) and 22.3 (3.3), respectively ($P = 0.54$). The IIEF scores were significantly higher in group 1 than group 2 at 3 months, at 11.5 (9.4) vs 1.8 (1.4) ($P = 0.008$) and at 6 months, at 12.4 (8.7) vs 3.0 (1.9) ($P = 0.012$) after RP. There were no significant changes in penile flaccid length, prepubic fat pad, or mid-shaft circumference in either group. Stretched penile length was significantly decreased at both 3 and 6 months, by ≈2 cm ($P = 0.013$) in group 2. By contrast, stretched penile length was preserved in group 1 at all sample times. At the last follow-up, the proportion of men with a mean loss of penile length of ≥2 cm was significantly lower in group 1 than group 2 (two/17, 12%, vs five/11, $P = 0.044$).

## CONCLUSIONS

Initiating the use of a VED protocol at 1 month after RP improves early sexual function and helps to preserve penile length.

## KEYWORDS

vacuum erection device, erectile dysfunction, penile rehabilitation, penile length, radical prostatectomy

## INTRODUCTION

Erectile dysfunction (ED) after radical prostatectomy (RP) for prostate cancer has decreased as a result of improvements in surgical technique. The most important predictor of ED after RP is pre-existing erectile function and preservation of the neurovascular bundles. Despite these improvements in technique, erectile function returns in only 9–40% of patients [1–3]. The practice of early penile rehabilitation after RP seeks to improve on these rates, but the optimal rehabilitation regimen is yet to be established.

Options currently available for patients with ED include oral pharmacotherapy, intraurethral prostaglandin E1, injection therapy, vacuum erection devices (VEDs), penile implants and vascular reconstruction. In a study of 30 patients, Montorsi *et al.* [4] assessed early prophylactic vasoactive intracavernosal injection therapy with alprostadil after RP, and reported a 67% incidence of return to spontaneous erectile function, compared with 20% with no treatment. This success rate has not been reproduced in more contemporary series, and the use of injectable agents is considered invasive and cumbersome by many patients. Phosphodiesterase-5 inhibitors (PDE-5i) offer a less invasive and more manageable alternative for penile rehabilitation after RP, but the utility of PDE-5i might be limited by the severity of cavernosal nerve injury after RP, which in turn inhibits initiation of the required erectile cascade for PDE-5i to be effective [5].

Another potential sequelae of RP is penile shortening. Apoptosis has been detected in rats after penile denervation [6], and the resulting fibrotic changes in the corporeal bodies after RP were recently evaluated and described, both of which could contribute to shortening [7]. Many authors have reported decreases in both penile length and circumference after RP. Fraiman *et al.* [8] reported a progressive loss in the mean values of flaccid length, erect length and circumference after RP, most of which occurred within the first 3–4 months. Munding *et al.* [9] showed that the stretched penile length decreased at 3 months after RP in 71% of their patients. Savoie *et al.* [10], in a prospective study evaluating penile length 3 months after RP, found a significant decrease in the flaccid, stretched and circumferential measurements of the penis.

| Variable | Group 1 | Group 2 | P* |
|---|---|---|---|
| No. of patients | 17 | 11 | |
| Mean: | | | |
| Age, years | 58.2 | 60.5 | 0.332 |
| Sexual activity coitus/month | 9.2 | 4.9 | 0.12 |
| Penile length, cm | 12.7 | 13.2 | 0.75 |
| IIEF score | 21.1 | 22.3 | 0.54 |
| PSA level | 7.0 | 5.5 | 0.22 |
| Gleason score | 6.5 | 6.7 | 0.54 |
| Percentage of cores +ve | 22.5 | 25 | 0.85 |
| Currently married | 9 | 7 | 0.58 |
| Hypertension | 6 | 7 | 0.14 |
| Diabetes | 1 | 2 | 0.54 |
| Back surgery | 2 | 3 | 0.35 |
| Depression | 1 | 3 | 0.27 |
| Tobacco use | 6 | 4 | 0.95 |
| Both nerves spared | 16 | 10 | 0.75 |
| Penile curvature | 0 | 0 | – |

*TABLE 1*
*The patients characteristics before RP*

**t-test or chi-square*

Overall, 68% of patients had a decrease in stretched penile dimensions.

Zippe *et al.* [11] reported a study in which patients successfully used a VED after RP and confirmed its safety and tolerability. Numerous published studies report successful erections being attainable with the VED in 84–95% of patients [12–15]. Most patients report an improved sex life [13], seen by an increase in both the quality and frequency of intercourse and orgasm. There was an improvement in marital relationships and self-esteem as a result [13,16–18]. Columbo *et al.* [19] reported a series of 52 patients in whom daily use of the VED with no constriction ring, unrelated to intercourse, led to an improvement in spontaneous erections in 31 of the men (60%).

Raina *et al.* [20] showed that the use of a VED after RP (with and with no nerve preservation) improved the International Index of Erectile Function (IIEF) scores, patient reported preservation of penile length, and aided in the early return of spontaneous erections. In a separate small series of patients, use of a VED had some benefit in correcting penile shortening in men with Peyronie's disease after tunical incisions and grafting [21].

Thus the objective of the present study was to assess, in the first randomized prospective clinical trial addressing this issue, the effectiveness of the VED in assisting with sexual functioning and preservation of measured penile length afetr RP.

## PATIENTS AND METHODS

The study was initiated after consent was obtained from the institutional review boards of the participating institutions. Twenty-eight patients having a unilateral or bilateral nerve-sparing retropubic RP gave consent and were randomized to early intervention (1 month after RP, group 1) and a control group (6 months after RP, group 2). Baseline information was obtained from all patients, including age, sexual activity, penile characteristics, IIEF scores, PSA level before RP, Gleason score, percentage of biopsy cores positive, marital status, hypertension, diabetes, history of back surgery, depression, tobacco use, number of nerves spared, and penile curvature; the patients' baseline characteristics are summarized in Table 1.

To be deemed eligible for the study patients had to be able to attain a partial or full erection before RP and have only mild to moderate ED (IIEF score of $\geq 12$). Excluded were patients on anticoagulation therapy or those with bleeding diatheses, insufficient manual dexterity of the patient or spouse to use the VED, an IIEF score at baseline of $<12$, or those who did not have a nerve-sparing RP.

Men in the group 1 were instructed to use the VED daily starting 1 month after RP; all used the Osbon ErecAid (Timm Medical, Eden Prairie, MN). The men were instructed to inflate the device for two consecutive 5-min periods after a brief release of suction in between inflations. The use of a tension band for intercourse was forbidden for the first study month (second month after RP). Thereafter, the men were allowed to use the constriction band for intercourse if desired. By contrast, the group 2 were given instructions to use the VED after 6 months and to do so whenever they wished to attempt intercourse. The use of PDE-5i was not allowed in the first 6 months in either group, but after the first 6 months both groups were allowed to use PDE-5i if they so desired.

The men were evaluated with the IIEF-5 questionnaire, and with questions on spontaneous erections and adequacy of erections for intercourse. Stretched penile length (an accepted surrogate for erect penile length [22]), penile flaccid length, prepubic fat pad, and mid-shaft circumference were also measured. Data were acquired before and at 1, 3, 6, 9 and 12 months after RP. The primary endpoint of the study was the proportion of patients with moderate to severe ED (IIEF $\leq 11$) after randomizing to groups 1 and 2. Secondary endpoints included penile size, including significant penile shortening, for which 2-cm was used as the threshold, progression of IIEF scores over time, and occurrence of spontaneous erections in the early period after RP. Questionnaires were completed before contact with physician visits and given to the study co-ordinator. After completing the paperwork, the penile measurements were obtained by six physicians who were unaware of the patient responses and patient study status.

All results were analysed statistically using Student's *t*-tests and paired sample *t*-tests, with significance indicated at $P < 0.05$.

## RESULTS

Compliance with the protocol was excellent, with no patients in either group reporting difficulties with the rehabilitation protocol. There was no early cessation of therapy due to VED-related side-effects in either group; no patients withdrew in the first 6 months of the study. The mean (range) follow-up was 9.5 (6–12) months; after 6 months, four patients in group 1 and one in group 2 withdrew because they lived too far from the study centre or started radiation therapy for increasing PSA levels. Only one patient in each group had a unilateral nerve-sparing RP. Before RP, both groups had similar mean (SD) IIEF scores; in group 1 it was 21.1 (4.6), and of these men,

53% had no ED (score 22–25), 29% had mild ED (17–21) and 18% had mild to moderate ED (12–16). Group 2 had a mean IIEF score of 22.3 (3.3) and of these 11 men, five had no ED, five had mild ED, and one had mild to moderate ED.

There were significant differences between the groups in the primary endpoint of the proportion of men classified with no, mild or mild to moderate ED (IIEF ≥ 12) after RP at both 3 and 6 months. Both groups had similar values before RP and after 1 month, with all men having an IIEF of ≥12 before RP, and 39% and 43% with mild to moderate ED or better, respectively, at 1 month. The proportion with mild to moderate ED or better (IIEF ≥ 12) in group 1 remained relatively constant, with values of 31%, 38% and 38% at 3 and 6 months and the last follow-up, respectively. However, all men in group 2 classified themselves as having worse than mild to moderate ED at 3 or 6 months. After 6 months group 2 was allowed to use a VED and thereafter the prevalence of mild to moderate ED, at three of 11, approached that of group 1 at the last follow-up (Fig. 1a). The proportion of mild to moderate ED was significantly different at 3 ($P = 0.005$) and 6 months ($P = 0.033$). At the last follow-up there was no significant difference between the groups ($P = 0.75$). The mean IIEF scores at the various sample times are shown Fig. 1b. No spontaneous erections adequate for intercourse were reported at the last follow-up for any patient in either group. Partial erections were reported for two patients in the group 1 vs none in group 2. PDE-5i use was similar in both groups, with 47% (eight/17) of group 1 beginning use at a mean date of 10 months after RP, vs six of 11 of group 2 beginning use at a mean of 6 months after RP.

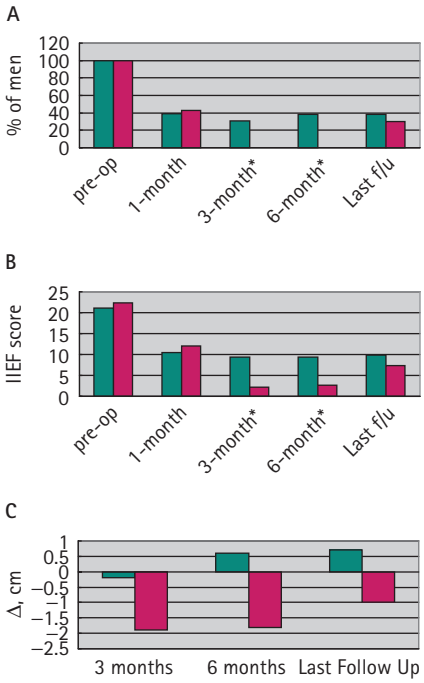
Analysis of secondary endpoints showed a significant loss of stretched penile length in group 1 than in group 2 (Fig. 1c). In group 2, the mean (95% CI) loss in penile length was 1.87 (–3.26 to 0.48) cm at 3 months ($P = 0.013$) and 1.82 (–3.2 to 0.47) at 6 months ($P = 0.013$). At the last follow up (up to 1 year in half the sample), the mean loss in penile length was 1 (–2.8 to 0.8) cm but was not statistically significant ($P = 0.242$). By contrast to group 2, group 1 had no significant decrease in stretched penile length at any time; the mean change in penile length at 3 and 6 months was –0.24 (–1.04 to 1.05; $P = 0.7$) and 0.6 (–2.53 to 1.29; $P = 0.5$). There were no significant differences in penile girth, flaccid penile length, or suprapubic fat pad dimensions. When using a threshold of 2 cm for penile shortening at the last follow-up, five of 11 patients in group 2 had penile shortening, vs two of 17, 12%, in group 1 ($P = 0.044$).

## DISCUSSION

As shown in previous studies, the present study showed a statistically significant benefit with the early use of a VED after RP, and established the safety of early initiation of VED use. IIEF scores were significantly improved at 3 and 6 months for group 1. After group 2 was allowed to use the VED when they desired, after 6 months, the IIEF scores increased to approach those in group 1. Indeed, at the last follow-up (mean 9.5 months) there was no statistical difference between the groups. Importantly, in the period after group 2 were allowed to use the VED, the mean IIEF score increased by >4 points (indicating a noticeable increase in function to the patient, as in previous studies). The most plausible explanation for this is that group 2 started using their VEDs and this affected the IIEF scores, but this increase might also represent the expected return of erectile function at 6–12 months after RP. If this were the case, a parallel increase in the scores in group 1 might be expected, but this did not occur. Also importantly, many men in group 1 commented on how they felt empowered and were pleased to be taking an active role in their penile rehabilitation. PDE-5i use is another factor that could influence IIEF scores; as the percentage of PDE-5i use was similar in both groups (eight/17, 47%, in group 1; and six of 11 in group 2) it probably had similar effects on both groups. However, of those who use PDE-5i, men in group 2 tended to initiate its use 4 months earlier (6 months in group 2 vs 10 months in group 1) which might confound the IIEF scores after 6 months.

Despite the long-standing experience of ED induced by RP, penile shortening after RP has become clinically recognized only recently [8–10]. There is an overlap between the causes of ED after RP and penile shortening. Current theories to explain this include cavernosal nerve injury and its associated structural alterations in the penis, cavernosal hypoxia and its induction of structural changes in the penis, and sympathetic hyper-innervation

*FIG. 1. The change with time in:* ***a,*** *percentage of men with an IIEF score of >11;* ***b,*** *the IIEF scores; and* ***c,*** *the change in stretched penile length.*




[23]. Physiologically, VED tumescence occurs from passive engorgement, with constriction rings preventing venous return of blood [24]. A study by Bosshardt *et al.* [25] confirmed that there is a passive congestion of mixed arterial and venous blood, with extra-tunical tissue making up a large component of the increased diameter. Some authors speculated that the use of the VED helps to inhibit abnormal collagen or scar formation in the hypoxic penile conditions after RP, perhaps prompting a faster return of nocturnal tumescence, which would improve penile oxygenation [20]. This, in turn, could promote the earlier return of erectile function and/or prevent penile shortening. Given the incomplete understanding of ED after RP a causal or corollary pathway between the success of penile rehabilitation and the use of a VED is speculative.

The present study showed preserved penile length in group 1, vs a statistically significant loss in group 2 at 3 and 6 months. At the last follow-up *t*-tests showed no significant difference in length in group 2, even though the mean loss was 1 cm. The lack of significance at the last follow-up is probably multifactorial. Penile shortening might have

been attenuated by using the VED after 6 months in group 2, as well as differences in the time of starting PDE-5i. Alternatively, 6 months might not be the optimum duration of penile rehabilitation; it is possible that an extended period of up to 1 year might have further benefit. Finally, patient withdrawal after 6 months meant that there were too few patients to maintain sufficient statistical power to detect significant differences.

The overall incidence of any penile shortening in group 2 was similar to that reported previously, at six of 11 vs ≈70%. Previous studies reported that a mean 1–2 cm of shortening (10–15% loss of erect penile length) can be anticipated in those men who report penile shortening after RP [9,10]. Thus we used a threshold of ≥2 cm (which translates to an ≈11% decrease in penile size in our sample) to compare the two groups; using this value, 12% of patients met the criterion in group 1, vs five of 11 in group 2 ($P = 0.046$).

The present sample size limits the inferences that can be drawn from statistical analyses. With increased patient awareness of the potential benefits of penile rehabilitation, in particular related to studies using PDE-5i, patient recruitment with a possibility of being randomized to no penile rehabilitation for 6 months became increasingly difficult. A second weakness of the study is the potential for interobserver variability in measuring penile length. Although only physicians measured the penile length while unaware of treatment group, six physicians took the measurements at different times.

Patients were well matched after randomization; all the preoperative characteristics were not statistically different ($P > 0.05$). All patients entering the study were strongly motivated to retain their erectile function, and indeed complied with the rehabilitation protocol as documented in their treatment diaries. The present study is the first to assess the change in erectile length and function in a randomized study. As further understanding of penile rehabilitation advances, it might become increasingly difficult to conduct studies with no active intervention control, e.g. the use of PDE-5I; as such, the present study offers unique data.

In conclusion, this pilot study showed that initiating an early VED protocol at 1 month after RP improved early sexual function and helped to preserve penile length. Urologists should consider adding a VED to the penile rehabilitation regimen after RP. By contrast with other alternatives for penile rehabilitation, the VED might be more cost-effective, with low risks of systemic side-effects, and present the added benefit of empowerment through active involvement of the patient and his partner in rehabilitation and recuperation.

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## CONFLICT OF INTEREST

None declared.

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Abbreviations: **ED**, erectile dysfunction; **RP**, radical prostatectomy; **VED**, vacuum erection device; **PDE-5i**, phosphodiesterase-5 inhibitors; **IIEF**, International Index of Erectile Function.