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Invited Review

Vacuum erectile devices for erectile dysfunction: recommendations from the 5th international consultation on sexual medicine

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Abstract

Introduction: Vacuum erectile device (VED) is 1 of the main approved therapies for erectile dysfunction (ED). The introduction of phosphodiesterase type 5 inhibitor (PDE5i) for ED significantly changed the roles of VED in contemporary sexual medicine.

Objective: To provide updated clinical evidence to inform health care providers on best practices with VED.

Methods: A consensus panel was held with leading sexual medicine experts during the 5th International Consultation on Sexual Medicine (ICSM). Relevant peer-reviewed literature was reviewed with focus on research from the last 10 years, but not limited to the last 10 years. The expert panel generated consensus statements based on the quality of evidence and criteria of Grading of Recommendations Assessment, Development and Evaluation.

Results: As a primary or combination therapy for ED, VED has been shown to be successful in all populations studied, including difficult to treat cohorts, such as diabetes mellitus, spinal cord injury, and post-radical prostatectomy (RP), but long-term attrition rates are high. Available evidence has shown that VED can preserve or restore penile size for patients after RP, after incision and grafting surgery for Peyronie's disease, before and after penile prosthesis, and after other post pelvic surgeries. However, it has not demonstrated a more rapid recovery of spontaneous erectile function after RP. VED does not increase penile length for subjective short penis. Studies with female specific VED for female sexual dysfunction are very limited.

Conclusions: Since the prior 4th ICSM, more evidence is available to support the new roles of VED in contemporary sexual medicine. Research into the penile pathophysiologic changes with VED therapy and clinical outcomes for various conditions are ongoing. We encourage sexual medicine clinicians to follow the 5th ICSM recommendations, but providers should also use their own judgement and adopt shared decision making with their patients/partners when considering VED for a specific disorder.

Keywords: vacuum erectile device; erectile dysfunction; radical prostatectomy; penile prosthesis; Peyronie's disease; female sexual dysfunction; short penis; radical proctectomy; posterior urethroplasty.

SUMMARY OF RECOMMENDATIONS

- 1—Clinicians should offer vacuum erectile device (VED) alone or combined with other therapies for erectile dysfunction (ED) for intercourse, even in difficult to treat populations, such as diabetes mellitus (DM), spinal cord injury, and post-radical prostatectomy (RP). The quality of evidence is moderate. Strength of recommendation: strong.
- 2—Clinicians should offer VED early in the post-operative setting to maintain penile size following RP. The quality of evidence is moderate. Strength of recommendation: strong.
- 3—Clinicians should not offer VED to restore spontaneous erectile function more rapidly or to a greater degree when used as a rehabilitation therapy after RP. The quality of evidence is high. Strength of recommendation: strong.

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- 4—Clinicians may offer VED before or after penile prosthesis implantation to improve surgical outcomes. The quality of evidence is low. Strength of recommendation: weak.
- 5—Clinicians may offer VED as a primary treatment or combined with other therapies for Peyronie's disease. The quality of evidence is low. Strength of recommendation: weak.
- 6—Clinicians should be aware of studies with VED use for female sexual dysfunction, subjective short penis, post proctectomy and after urethroplasty. The quality of evidence is very low. No recommendation can be given due to very limited publications.

Introduction

Vacuum erectile device (VED) is the oldest therapy used for male sexual function in modern medicine.[1] Historically, VED was also referred to as vacuum constriction device (VCD), vacuum tumescence device or external vacuum device. The 4th International Consultation on Sexual Medicine (ICSM) detailed the history and development of VED for erectile dysfunction (ED).[2] Briefly, VED was introduced for ED nearly 150 years ago, cleared by the US Food and Drug Administration in 1982 and adopted by the American Urological Association in 1996 as a standard of care.[1] Since introduction of phosphodiesterase type 5 inhibitor (PDE5i) for ED in 1998, the role of VED in sexual medicine has changed significantly. Even though it is still a recommended therapy for ED, its use as a primary therapy has declined.[3] However, this time-tested modality has found new indications in sexual medicine in the PDE5i era.

Methods

A consensus panel was held with leading sexual medicine experts during the 5th ICSM. There will be a summary to outline the detailed methodology for all 5th ICSM publications. For this report related to VED, a literature search was performed in PubMed via Medline using combination of key words: VED, ED, radical prostatectomy (RP), penile prosthesis, Peyronie's disease, female sexual dysfunction, short penis, radical proctectomy and posterior urethroplasty. Google Scholar and Cochrane Library search was also performed to identify any additional relevant publications. All relevant peer-reviewed literature was reviewed with focus on research from the last 10 years, but not limited to the last 10 years as necessary. The quality of each individual study was judged with Oxford levels of evidence (LOE) criteria, but overall LOE were not used as systematic review was not performed. The expert panel generated consensus statements based on the quality of evidence and the criteria of Grading of Recommendations Assessment, Development and Evaluation (GRADE). The final recommendations were presented in Madrid, Spain at the 5th ICSM on June 29, 2024, to all participants who were able to make comments and seek clarification. The present article is the final consensus based on feedback received.

Devices and usage

The VEDs include a wide variety of devices, which consist of a closed-end cylinder, vacuum pump, and constriction ring. The vacuum chamber creates an erection by generating negative pressure within the penis, increasing blood flow, and distending the corporeal sinusoids.[4] Patients first apply the water-soluble lubricants to the base of the penis to create a tight seal between the device and pelvis. Negative pressure (100–225 mmHg) is then generated, either through a manual or battery-controlled pump, and an artificial erection is created.[5] The time required to achieve an erection may take about 30 s to 7 min.[6,7] The device is prepared in advance by placing a constriction ring over the open end of the cylinder. If the user desires to maintain the erection, the constriction ring is displaced onto the base of the penis to limit drainage of blood and to sustain an erection for penetration. This may be maintained for up to 30 min, at which point it is recommended that the constriction ring be removed to reduce the likelihood of penile ischemia.[8] Since there are variety of devices availabe and many of them are widely promoted by direct-consumer marketing, physicians should guide our patients to use regulatory approved VED to avoid poor-quality devices.[9]

The VED may also be used without the constriction ring in certain clinical settings, such as penile rehabilitation after RP. Although an optimal rehabilitation protocol has not been established, the commonly recommended protocols include achieving an erection for 1–2 min, releasing for 1 min, and then repeating the cycle 5 to 8 times in 10–15 min daily.[10] Reported protocols for Peyronie's disease and other conditions will be discussed under each respected condition.

VED as primary treatment for ED

A significant amount of clinic evidence has proven the effectiveness of VED for ED since the early 1980s. Patients' satisfaction rates varies from 27% to 92%.[4] However, readers need to understand that most studies were published prior to the PDE5i era, and no validated erectile function questionnaire were used in majority of studies. The 4th ICSM provided detailed information regarding VED outcomes as well as, patients and partner satisfaction (Table 1).[2]

In reviewing published outcomes, VED consistently demonstrates high efficacy rates for achieving an erection in most populations, including 70%–82% in DM, 70%–93% in spinal cord injured men, 88% for arterial insufficiency and 69%–76% for venous leak.[6-8,13-38] Subset analyses of men with arterial insufficiency suggest potential improvements in spontaneous erections in select groups, with some data suggesting enhanced nocturnal and morning erections.[8,18,19] The presence or severity of veno-occlusive disorder (VOD) does not correlate with VED outcomes with even higher efficacy compared to DM or neurogenic ED.[18,23,26] VED may also have a role in improving psychosexual aspects of ED with improved self-esteem in 47% of participants in a study for men with difficult to treat ED (DM, pelvic surgery, radiation).[22] This observation was confirmed by other studies and showed effect augmentation for psychotherapy among men with psychogenic ED.[27,38] In a randomized controlled trial (RCT) of 45 men with psychogenic ED, men receiving psychotherapy alone experienced 60% improvements compared to 84% of those treated with combination psychotherapy and VED.[27]

Since the publication of the 4th ICSM, there are limited new publications evaluating VED as a primary treatment for ED. Pajovic et al.[11] investigated changes in penile hemodynamics

Table 1. Summary of VED as primary treatment for ED.

Author	Year	N	Follow-up	Study design	Therapy type	Level of evidence	Significant findings
Trost et al[2]	2016			ICSM 2015 review	VED as primary therapy for ED	2	VED is effective in creating an erection satisfactory for intercourse (69%–93%), even in difficult to treat populations such as DM, spinal cord injury, and post-RP.
Pajovic et al[11]	2017	50	6 months	Cohort	VED ≥ 4 times/month with in-person and audio–visual instruction	3	Significantly higher values of PSV were obtained in patients with Type II DM compared to patients with type I DM. Both groups of patients had significant improvements of IIEF scores.
Beaudreau et al[12]	2021	57	6 months	Cohort	VED with comprehensive education and training	3	96% of patients endorsed the ability to maintain an erection with the device and 100% indicated they would recommend the device to others. 83.8% partners rated sex as better with the device.

VED=vacuum erection device, ED = erectile dysfunction, N = number of participants, ICSM = international consultation on sexual medicine, PSV = peak systolic velocity, DM = diabetes mellitus, IIEF=International Index of Erectile Function

in patients with ED related to type I and II DM after 6-month VED use. They found that significantly higher values of peak systolic velocity (PSV) were obtained in patients with Type II DM compared to patients with type I DM. However, both groups of patients had significant improvements in the international index of erectile function (IIEF) scores with VED treatment for 6 months. A recent study published in 2021 evaluated satisfaction with VED as primary therapy for ED among middle-aged and older veterans.[12] Patients received comprehensive education and training and ongoing follow-up of device use, which included a semi-structured interview. Over 96% of patients endorsed the ability to maintain an erection with the device and 100% indicated they would recommend the device to others.

The effect of VED therapy for ED between patients and their partners were also studied.[15,16,20,29,36] When compared to their partners, men utilizing VEDs tended to report slightly higher rates of successful erections (93% men vs 83% partners) and overall satisfaction (98% men vs 85% partners).[20,29] Patients utilizing VED also reported improved sexual relationships (60% men, 42% women) and marital satisfaction.[15,29] The above mentioned most recent study showed that female partners can have high satisfaction as well (83.8%) when both patients and their female partners received comprehensive training for VED usage.[11]

Reduced efficacy of VED is reported in difficult to treat population with prior pelvic surgery/radiation, history of penile implants, penile fibrosis, history of venous surgery, or men unresponsive to injection therapies.[22,25] Difficulty obtaining erections with the device was more common with older age.[12]

VED as a combination therapy for ED

As VED use as the primary therapy for ED has declined, VED use has been explored as a combination modality to salvage monotherapy failures (Table 2). The ICSM 2015 provided detailed information regarding the regimens and the success of the VED as a combination therapy.[2] In reviewing published outcomes, VED combined with ICI significantly improved penile buckle pressures for patients failed VED or ICI as monotherapy. One study showed mean buckle pressures increased from 117 gm (ICI alone) and 125 gm (VED alone) to 565 gm following combination therapy (ICI + VED).[39] When patients failed PDE5i or VED monotherapy, combination of PDE5s and VED improved IIEF-5 scores significantly to 27.4 compared to 15.7 with PDE5 and 17.1 with VED monotherapies, respectively.[40] For patients who failed PDE5i monotherapy that originally answered "no" to the Sexual Encounter Profiled (SEP)-2 and SEP-3 questions, 79% and 70% had changed their responses to "yes," respectively after combined with VED.[41] VED is also used in progressive, stepwise algorithms for managing difficult to treat ED populations. In a study to evaluate ED treatment after RP, 85 men were prospectively treated with VED, PDE5s, ICI, or ICI + VED in a stepwise fashion depending on responsiveness and patient choice to continue with therapy. Among those who were unresponsive to VED, PDE5s, or ICIs alone, 44% achieved a satisfactory erection with combination ICI and VED.[42] Another study similarly performed stepwise therapy for 284 DM men.[16] Patients were treated with PDE5s initially, followed by VED, ICI, PDE5 + ICI, ICI + VED, and finally PP. A total of 70% of men trialing VEDs alone responded with an adequate erection; Of those who were poorly responsive to PDE5s, VED, ICI, or combination PDE5s and ICI, 69% responded to ICI + VED.

Again, limited new studies are available since the publication of ICSM 2015. In a short communication published in 2017, Mantovani used alprostadil plus VED in 12 patients with severe ED (IIEF-15 score between 15–20) to facilitate reproducible rigidity both in clinic and at home for penetration. However, no follow up or satisfaction data were reported.[43] A recent RCT looked at the efficacy of low

Table 2. Summary of VED as combination therapy for ED.

Author	Year	N	Follow-up	Study design	Therapy type	Level of Evidence	Significant findings
Trost et al[2]	2016			ICSM 2015 review	VED as combination therapy for ED	2	VED is effective to create an erection for PDE5i or ICI monotherapy failures in 69%–79% patients, including difficult to treat patients such as DM.
Mantovani F[43]	2017	12	N/A	Case series	Intra-urethral Alprostadil + VED	3	Patients obtained reproducible rigidity both in clinic and at home. No follow up or satisfaction data provided.
Tao et al[44]	2022	105	3 months	RCT	Li-ESWT + VED	1	VED plus Li-ESWT therapy achieved the MCID in most patients compared with either VED or Li-ESWT monotherapy (66.7% vs 17.6% vs 36.4%). Significant higher number of patients with answer "yes" to SEP2 and GAQ1 in combination group compared to either VED or Li-ESWT monotherapy groups (66.7% vs 29.4% vs 39.4% for SEP2 and 66.7% vs 35.3 vs 45.5%).

VED=vacuum erection device, ED = erectile dysfunction, N = number of participants, ICSM = international consultation on sexual medicine, DM = diabetes mellitus, RCT = randomized control trial, Li-ESWT = low intensity extracorporeal shock wave treatment, MCID = minimal clinical important difference, IIEF=International Index of Erectile Function, SEP = sexual encounter profile, GAQ = global assessment question

intensity extracorporeal shock wave (Li-ESWT) combined with VED in diabetic ED patients failed PDE5i. 105 eligible patients were randomly divided into 3 groups: group A (VED), group B (Li-ESWT) and group C (VED plus Li-ESWT). Follow-up was conducted at 4 weeks, 8 weeks, and 12 weeks after the end of treatment. VED treatment protocol was 15 min per day, 3 times a week during 9-week trial period with repeatedly creating penile erection without the use of constriction ring. All patients were not allowed to receive PDE5is 1 month before and during the study. After the last treatment, they were allowed to use PDE5is on demand. VED plus Li-ESWT therapy achieved the minimal clinical important difference (MCID) in most patients compared with either VED or Li-ESWT monotherapy (66.7% vs 17.6% vs 36.4% at 12 weeks follow ups). There were also significant higher number of patients with answer "yes" to SEP2 and GAQ1 in combination group compared to either VED or Li-ESWT monotherapy groups at the 12 weeks follow ups (66.7% vs 29.4% vs 39.4% for SEP2 and 66.7% vs 35.3 vs 45.5%).[44]

VED therapy after RP

Several roles for VED use in the post-RP population have been described with aims to: (1) Achieve a firm erection following RP, including during the post-operative recovery period with or without erectile aids, (2) Enhance extent or speed of recovery of erectile function, and (3) Minimize peri-operative morbidity of reduced penile size. The mechanism of VED therapy after RP was previously reviewed.[10] By periodically increasing in mix-oxygenated blood flow into corporal cavernosa, VED therapy activates anti-apoptotic and anti-fibrotic process and potentially preserves veno-occlusive mechanisms.[8,45-48] It was proposed that activating or mobilizing the endogenous stem cells in cavernous tissues may triggers the pro erection cascade reaction with VED. However, a most recent study did not show any effect of VED on endogenous stem cells.[49]

The efficacy of VED in achieving an erection sufficient for penetrative intercourse has been well established in men following RP (Table 3). As mentioned in the combination therapy section, a cohort of 85 men with ED after RP were prospective treated and evaluated with a tiered regimen, progressing based on response to VED, sildenafil, ICI, or ICI + VED.[42] Over the 12-month evaluation period, 92% of men successfully responded to VED. Among those not responding, only 20% (14/69) were able to be salvaged by sildenafil alone, followed by 85% (51/60) with ICI, and 44% (4/9) with ICI + VED. These results highlight the efficacy of VED in post-RP men. A similar study prospectively followed 76 men post non-nerve sparing RP over a 12-month period.[50] Patients were treated in a tiered manner with oral apomorphine, followed by PDE5i, VED, ICI single agent, ICI multiagent, and finally PP. Results demonstrated that among those failing to respond to apomorphine and PDE5i, 52% were successfully salvaged with a VED. These findings are further supported by Raina and colleagues who noted an 80% response to VED therapy in a mixed cohort of nerve-sparing and non-nerve sparing RP men.[51] Another 2 studies evaluated the role for VED as a combination therapy with PDE5i following RP.[52,53] Among a group of 31 men who were dissatisfied with VED alone, 77% reported improved rigidity with the combination of PDE5i and VED.[52] A subsequent randomized trial of 23 men undergoing nerve-sparing RP treated men with either tadalafil 20 mg 3 times weekly or combined tadalafil and VED beginning 1 month post-operatively.[53] Results demonstrated that 92% of men in the combination group were able to achieve erections satisfactory for penetrative intercourse compared to 57% in the tadalafil monotherapy arm. Using the more stringent criteria of ability to maintain the erection to orgasm, combination therapy was found to be successful in 92% of cases compared to 29% with monotherapy.

The concept of penile rehabilitation after RP was introduced to clinical practice more than 20 years ago. VED has been used as 1 of the leading modalities for penile

Table 3. Summary of VED after radical prostatectomy.

Author	Year	N	Follow-up	Study design	Therapy type	Level of evidence	Significant findings
Baniel et al[42]	2001	85	12 months	cohort	VED, PDE5s, ICI, or ICI + VED in a stepwise fashion	3	92% of men successfully responded to VED. Among those not responding, 44% were salvaged with ICI + VED.
Gontero et al[50]	2005	76	12 months	cohort	Tiered therapy with oral apomorphine, followed by PDE5s, VED, ICI single agent, ICI multiagent, and PP.	3	Among those failing to respond to apomorphine and PDE5s, 52% were successfully salvaged with a VED.
Raina et al[52]	2005	31	4.5 months	Case series	VED + sildenafil after failed VED monotherapy	3	77% with improved penile rigidity and sexual satisfaction.
Raina et al[51]	2006	109	9 months	RCT	VED daily vs. no VED (rehab)	1	80% response to VED therapy in a mixed cohort of NS and NNS RP men. No difference of EF recovery (32% vs 37%). VED users were less likely to report penile shrinkage (23% vs 63%, respectively).
Dalkin et al[54]	2007	39	3 months	Case series	VED daily (rehab)	3	Only 3% of men with good VED compliance (used device >50% of days) had a decrease in SPL of ≥1.0 cm, compared to a prior study of 48% of men after surgery without use of VED and 67% in men with less compliance with VED use.
Köhler et al[55]	2007	28	9.5 months	RCT	VED daily 1 month vs. 6 months after NSRP (rehab)	1	The IIEF scores were significantly higher with early VED users at 3 m (11.5 ± 9.4 vs 1.8 ± 1.4; $P = .008$) and 6 months (12.4 ± 8.7 vs 3.0 ± 1.9; $P = .012$. No EF difference at the final follow ups. 45% delayed vs. 12% early VED users experienced >2 cm loss of penile length ($P < .05$).
Engel JD[53]	2011	23	12 months	RCT	VED daily + tadalafil 1 month after NSRP vs. tadalafil only (rehab)	1	92% of combination patients responded yes to the vaginal penetration question vs 57% of the Tadalafil group. 92% vs 29% reported orgasm. Compliance to the VED was superior to that of Tadalafil.
Nason et al[56]	2016	65	3 months	cohort	VED use and education provided at dedicated clinic (rehab)	3	Significant differences noted between 3-month postoperative IIEF score and the post-VED use IIEF score (11.3 ± 3.08 vs 16.74 ± 2.62, $P = .0001$). All patients reported that the dedicated VED was helpful and would recommend it to other patients.
Zhang et al[57]	2022	100	12 months	RTC	VED vs tadalafil vs VED + tadalafil vs no treatment	1	VED + tadalafil not only improved IIEF-5 scores, it also resulted in higher rate of successful penetration (SEP 2) compared to other groups. No significant differences in the return to target EF among the groups. VED alone or combined with tadalafil maintained penile length compared to no treatment or tadalafil only groups.

VED=vacuum erection device, N = number of participants, RCT = randomized control trial, NSRP = nerve sparing radical prostatectomy, IIEF=International Index of Erectile Function, SEP = sexual encounter profile

rehabilitation by American urologists.[58] VED therapy can create multiple erections daily regardless of cavernosal nerve integrity.[1,10] Unfortunately, results of VED as a rehabilitation strategy to enhance or speed the recovery of erectile function are disappointing. It is possible that VED induced mix-oxygenation is suboptimal for erectile function recovery than fully oxygenated arterial blood in the cavernosa with spontaneous erection. In a study of 109 post-RP men randomized to either a VED for 9 months or observation beginning 4 weeks after surgery, no sustained benefits were noted among VED-treated men, including spontaneous erectile function (32% with VED, 37% on observation) and

erections sufficient for vaginal penetration (17% with VED, 11% on observation).[51] Similar outcomes were reported in a RCT of 28 men comparing early (1 month) to late (6 months) VED use (twice weekly) following RP.[55] The IIEF scores were significantly higher in early VED use group than late VED use group at 3 months and 6 months, but with 0% of either group reporting IIEF-5 scores of ≥12 at a mean follow up of 9.5 months. The previously mentioned RCT compared effects of a combination therapy of tadalafil + VED vs. tadalafil only 1 month following a nerve-sparing RP.[53] The IIEF-5 scores for the combination group were significantly higher than tadalafil only group at 6, 9, and 12-month follow-up, but no clear information was provided about recovery of unassisted erectile function. The efficacy of VED for penile rehabilitation after RP was also reported in a dedicated Irish VED clinic.[56] 40 out of 65 men (76.3%) purchased VEDs following detailed education to use devices. There were significant differences noted between the mean preoperative and the 3-month postoperative IIEF scores (22.08 ± 3.16 vs 11.3 ± 3.08, P = .0001) and between the 3-month postoperative IIEF score and the post-VED use IIEF score (11.3 ± 3.08 vs 16.74 ± 2.62, P = .0001). Despite VED use, there was a significant reduction in erectile function from pre-surgery status (22.08 ± 3.16 vs 16.74 ± 2.62, P = .0001). All patients reported that the dedicated VED was helpful and would recommend it to other patients. Obviously, no control group and short follow up with this study provide no meaningful information regarding spontaneous erectile function recovery. A most recent RCT compared rehabilitation effects of VED, tadalafil, VED combined with tadalafil to no treatment after nerve sparing RP in 100 patients.[57] The study showed that VED combined with tadalafil not only improved IIEF-5 scores at 6 and 12 months, it was also resulted in higher rate of successful penetration (SEP 2) at 12 months follow up compared to other groups. However, there were no significant differences in the return to target EF after 12 months among the groups.

Available clinical evidence supports the role of VED in tissue preservation. In the previously cited 2006 RCT by Raina and colleagues, 35% of men who were randomized to VED use reported decreases in penile length compared to 63% in the observation arm.[51] If the treatment group was further stratified into VED responders versus non-responders, only 23% of those who responded reported penile length loss compared to 85% of non-responders. Similar findings on reducing penile length loss were demonstrated in the previously cited RCT by Kohler and colleagues.[55] In comparing outcomes between men treated with a VED at 1 month (early) versus 6 months (late) post-RP, 45% of men in the late group experienced ≥2 cm of penile length loss compared to 12% in the early group (P = .04). The analysis of frequency of VED use in the post-RP period also demonstrated a > 1 cm penile length loss in 3% of men who utilized the device >50% of days compared to 67% (2/3) who have poor compliance with VED.[54] The most recent RCT further confirmed that VED alone or combined with tadalafil maintained penile length compared to no treatment and tadalafil only groups.[57]

Like other penile rehabilitation modalities, the major issue with VED use is compliance. A recent study showed that only 55.8% and 45% of men adhered with PDE5i and VED rehabilitation at 12 and 24 months, respectively due to cost, inconvenience, and perceived ineffectiveness.[59]

VED with penile prosthesis

Penile size is a constant concern for many patients and implant surgeons. VED has been used to improve penile rigidity and penile size with penile implants (Table 4). The earliest such study was a phone survey of 12 men who had been utilizing VED following penile implants and found that 11 of the 12 patients reported improved erectile rigidity and girth when using the VED concomitantly.[60] Since the publication of ICSM 2015, there are a few more studies that evaluated the use of VED to improve the penile size in men undergoing penile prosthesis placement. A study looked at the VED use preoperatively for at least 10–15 min/twice daily for a minimum of 3 months in 13 men with severe corporal fibrosis.[61] VED appeared to soften corporal fibrosis and facilitate placement of penile prosthesis. Patients also had a mean increase of SPL of 0.92 cm after penile implants compared to preoperative lengths. Another study randomized 51 patients to 10–15 min daily VED use preoperatively versus no pre-op interventions and found that daily VED for at least 1 month led to a statistically significant increase of SPL by a mean of 0.8 cm compared to the control group.[62] VED therapy was also used to improve IPP results for patients with PD.[63] A total of 145 patients underwent endocavernous disruption of PD plaques with the scratch technique followed by IPP insertion. Postoperatively patients were assigned to VED therapy for 3 min twice daily to continue penile curvature correction. Follow-up continued for 1 year after surgery. Patients with plaques in the proximal third, middle third and subcoronal areas of the penis had a mean ± SD postoperative residual curvature of 21.5 ± 4.5, 17.3 ± 4.8 and 14.1 ± 3.1 degrees, respectively. After 24 weeks of vacuum therapy the mean penile curvature deviation decreased to 8.7 ± 2.5, 9.1 ± 2.9 and 7.7 ± 0.9 degrees, respectively. The mean IIEF-5 score was 9.8 ± 2.3 preoperatively, 18.9 ± 3.1 at 6 months (P < .001) and 24.1 ± 3.6 at 1 year (P < .001). The mean Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) score at the end of follow-up was 64.6 ± 11.8. A most recent study reported postoperative rehabilitation with VED 5 min twice daily for 6 months in 74 patients underwent AMS™ LGX 700® IPP placement.[64] Baseline median preoperative stretched penile length and girth were 14 cm (range 10–17) and 9 cm (range 7–12), respectively. At the end of the study (1 year) penile median dimensional outcomes were 17 cm (range 13–23) for length and 11 cm (range 10–13) for girth. The IIEF-5 scores were increased to 20 (range 18–26) and 25 (range 20–27) at the 6 and 12 month follow ups compared to 9 (range 5–11) at the baseline (P < .0001). The EDITS score at the end of the follow-up was 74 (range 66–78). Unfortunately, there was no control group to compare VED user to VED none-user after AMS™ LGX 700® IPP so it was unclear whether the size increase was from girth and length expansion cylinders or VED use.

VED and Peyronie's disease

Although limited data exist, VED has been suggested as a potential therapy both to directly improve outcomes of men with PD and as an adjunctive therapy (Table 5). A case series of 31 men with PD used VED as their primary therapy for 3 months.[65] About 35% of men experienced more than 0.5 cm length increase and 68% of patients reported a reduction in curvature by 5–25 degrees. McDonald et al[66] retrospectively looked at 20 men with PD who used VED for at least 10 min

Table 4. Summary of VED with penile prosthesis.

Author	Year	N	Follow-up	Study design	Therapy type	Level of evidence	Significant findings
Soderdahl et al[60]	1997	12	Phone survey at various time	Case series	VED use after penile implants	3	11/12 patients reported improved rigidity and girth with VED concomitantly.
Tsambarlis et al[61]	2017	13	3 months	Case series	VED 10-15 min/twice daily	3	VED use before surgery resulted in softening of corporal fibrosis and facilitates placement of IPP. SPL increased 0.92 cm after penile implants compared baseline SPL.
Canguven et al[62]	2017	51	1 month	RCT	VED 10-15 min daily before penile implants	1	0.8 cm increase of SPL with VED therapy vs. 0.19 cm increase of SPL without VED use before the penile implantation ($P < .05$). Surgeons' subjective report of smoother corporal dilatation.
Antonini et al[63]	2018	145	1 year	Case series	VED 3 min twice daily for 6 months after IPP for PD	3	Patients with plaques in the proximal third, middle third and subcoronal areas of the penis had a post-IPP residual curvature of $21.5 \pm 4.5°$, $17.3 \pm 4.8°$ and $14.1 \pm 3.1°$, respectively. After 6 months of VED the penile curvature deviation decreased to $8.7 \pm 2.5°$, $9.1 \pm 2.9°$ and $7.7 \pm 0.9°$ at 1 year follow-ups, respectively.
Antonini et al[64]	2020	74	1 year	Case series	VED 5 min twice daily for 6 months after IPP	3	Preoperative median SPL and girth were 14 cm and 9 cm. 1 year after the IPP, the inflated median penile length and girth were 17 cm and 11 cm. No control group to compare VED user to VED none-user after the IPP.

VED=vacuum erection device, N = number of participants, RCT = randomized control trial, SPL = stretched penile length, IPP = inflatable penile prosthesis, PD=Peyronie's disease

twice daily and 33 men with PD who did not use VED. Patients were followed for 14 months. All 20 men with VED use had a significant improvement in penile curvature with a mean improvement of 23°; while only 9 of 33 untreated patients had an improvement in curvature, with a mean improvement of 3.6°. The VED use group had statistically insignificant improvement in SHIM scores. However, the untreated group had statistically significant reduction in SHIM score.

Regarding VED as an adjunctive therapy, an early case series looked at patients with severe PD and penile shortening who used VED following circumferential tunical incision and circular venous grafting.[67] Patients with 6-month postoperative VED usage experienced an increase in penile length of 5.1 cm compared to 2.5 cm in patients without VED use. These results were not statistically significant due to the small sample size. Another study used VED after plaque incision and saphenous vein grafting.[68] 22 patients with adequate follow-up for at least 3 months had an average mean length increase of 2.1 cm. VED was also used as a concurrent therapy with collagenase *Clostridium histolyticum* (CCH) injections. A study followed 53 men with PD who underwent twice daily use of VED along with CCH injections.[69] Patients had an average length gain of 0.4 cm which was statistically significant. They also had an improvement in penile curvature by a mean of 17.36°. It is important to emphasize that these studies did not have a control group. It is impossible to know whether these improvements were related to VED use or purely due to primary therapies. A recent randomized, single-blinded trial looked at effect of VED combined with ESWL for PD.[70] 32 patients with PD were randomized to for active ESWT ($n = 16$) or sham ESWT ($n = 16$) treatment once a week for 5 weeks. All patients used VED followed by manipulation exercises. After 6 months, there were no significant differences in changes of penile curvature, IIEF-5 score, and pain scales assessed with both VAS and PDQ between the groups.

VED therapy as a part of penile rehabilitation (PR) regimen may have a prevention effect for PD after RP. Kiannian et al[71] recently retrospectively reviewed the charts of 581 patients with RP who engaged in a PR program with daily tadalafil, L-citrulline, weekly VED and the optional intracavernosal injections. They found the incidence of PD to be 2.9% compared to historical data of 15.9% in post-RP general population.[71,72] They suggested that PR regimens programs may be associated with a reduced incidence of PD in post-RP patients. Obviously, it is not possible to confirm which modality contributed the most to reduce incidence of PD from this complex PR program, if any.

The mechanism of VED therapy for PD is unclear with very limited studies. In an animal model with TGF-β_1 plus sodium tetradecyl sulfate induced PD, VED therapy was found to preserve smooth muscle, decrease collagen and reduce fibrosis via decreased TGF-β_1 expression and remodeling the tunica albuginea.[73,74]

Table 5. Summary of VED for Peyronie's disease.

Author	Year	N	Follow-up	Study design	Therapy type	Level of evidence	Significant findings
Lue et al[67]	1999	4	18 months	Case series	VED 30 min daily for 6 months after circular venous grafts for PD with penile shortening	3	3 patients gained 2 In at 6 months. 2 patients gained 3 In at 18 months. 1 patient did not use VED had 1 In length gain.
Yurkanin et al[68]	2001	22	3 months	Case series	VED daily after plaque incision and saphenous vein grafting.	3	Average mean length increase was 2.1 cm.
Raheem et al[65]	2010	31	3 months	Case series	VED 2 10-min daily for PD.	3	35% of men experienced more than 0.5 cm length increase. 68% of patients reported a reduction in curvature by 5-25 degrees.
Abdel Raheem et al[67,69]	2017	53	3 months	Case series	VED twice-daily along with modified collagenase *clostridium histolyticum* injections.	3	An average length gain of 0.4 cm (statistically significant compared to baseline). Penile curvature improved by a mean of 17.36°
MacDonald et al[66]	2020	53	14 months	Retrospective	20 men with PD used VED for at least 10 min twice daily. 33 men with PD did not use VED.	3	VED users had a significant improvement in mean penile curvature (23°) compared to non-VED users (3.6°).
Mortensen et al[70]	2021	32	6 months	RCT	ESWT vs. sham ESWT once a week for 5 weeks followed by VED use and manipulation exercises.	1	No statistically significant changes in mean penile curvature (-12.8°) in the treatment group compared to control group (–6.6°). No differences in IIEF-5 score and Pain scales assessed with both VAS and PDQ between ESWT treatment group vs. sham group.
Kianian et al[71]	2023	581	2 years	Retrospective	PR with daily tadalafil, L-citrulline, weekly VED and the optional ICI.	3	Incidence of PD was 2.9% with combined PR with VED compared to historical data of 15.9% in post-RP general population.

VED for female sexual dysfunction

Billups et al[75] published a study looked at the changes of sensation, lubrication, orgasm, and sexual satisfaction in 12 normal volunteers and 20 women with female sexual dysfunction (FSD) after the use of a clitoral specific vacuum device (Table 6). The study showed that 90% of patients with FSD and 58% of normal volunteers reported that their sensation was greater with the use of the device than without using the device. Eighty percent of the FSD subjects and 33% of normal volunteers reported increased lubrication. Fifty-five percent of the FSD subjects and 42% of normal volunteers reported an increased ability to achieve orgasm. Finally, 80% of the FSD subjects and 25% of normal volunteers reported that device use resulted in increased sexual satisfaction. Another pilot study evaluated the efficacy of this device in alleviating sexual dysfunction in irradiated cervical cancer patients. Fifteen women were enrolled and 13 completed the study. At baseline, all patients reported symptoms of sexual arousal and/or orgasmic disorders, and some also had sexual desire and pain disorders. At 3 months, statistically significant improvements were seen in all domains tested, including sexual desire, arousal, lubrication, orgasm, sexual satisfaction, and reduced pain. The median Female Sexual Function Index total score increased significantly from 17 to 29.4.[76] These studies were published about years ago and there are no further studies to confirm the efficacy of this device for FSD.

VED for short penis

VED was evaluated to improve penile length in men with small penis (Table 6). A prospective study of 37 sexually active men with SPL < 10 cm were treated with VED for 20 min/day, 3 times/week, for 6 months.[77] Mean penile length increased was about 0.3 cm (from 7.6 cm to 7.9 cm) and was statistically insignificant. The patient satisfaction rate was 30%. It appears that VED is not an effective method for penile elongation with subjective short penis.

VED after radical proctectomy

Learned from RP rehabilitation, VED is used as a part of rehabilitation strategy after rectal cancer treatment with surgery (Table 6). Seventy-one patients after laparoscopic nerve-preserving radical proctectomy were assigned in a nonrandomized fashion to no-intervention, nightly use of sildenafil 25 mg, or combination of nightly sildenafil 25 mg/day and a VED 10 to 15 min/day for 3 months after surgeries.[78] All participants were followed prospectively for over 12 months. In the no-intervention group, the mean baseline IIEF-5 score of 21.9 decreased significantly to 5.0, 9.2, and 10.9 at 3, 6, and 12 months, respectively. In the sildenafil only therapy group, the mean baseline IIEF-5 score of 22.4 also decreased significantly to 9.0, 14.9, and 15.1 at 3, 6, and 12 months, respectively. In the combined therapy group, the mean baseline IIEF-5 score of 23.0

Table 6. Summary of VED for other conditions.

Author	Year	N	Follow-up	Study design	Therapy type	Level of evidence	Significant findings
Billups et al[75]	2001	32	3 months	Cohort	12 normal volunteers and 20 women with FSD used clitoral specific VED	2	80% of the FSD subjects and 25% of normal volunteers reported that device use resulted in increased sexual satisfaction
Schroder et al[76]	2005	13	3 months	Case series	13 women with FSD after radiation used clitoral specific VED	3	Significant improvements were seen in all FSFI domains tested, including sexual desire, arousal, lubrication, orgasm, sexual satisfaction, and reduced pain. The median FSFI total score increased significantly from 17 to 29.4.
Aghamir et al[77]	2006	37	6 months	Case series	VED for 20 min/day, 3 times/week for men with SPL < 10 cm	3	Mean penile length increased was about 0.3 cm from 7.6 cm to 7.9 cm, statistically insignificant. Patient satisfaction rate was 30%.
Deng et al[78]	2017	71	12 months	RCT	VED 10 to 15 min/day + nightly sildenafil 25 mg/day vs. nightly sildenafil 25 mg/day only vs. no-intervention for 3 months after radical proctectomy	1	Combination group had the best IIEF-5 scores (18.7) compared to sildenafil only and no treatment groups (15.1 and 10.9) at the 12 months follow-ups.
Zhang et al[79]	2019	78	6 months	Cohort	VED 10 min twice a day + tadalafil 10 mg once every other day vs. tadalafil only after urethroplasty	2	VED + tadalafil therapy significantly improved penile length compared to tadalafil only treatment (0.4 ± 0.9 vs -0.8 ± 0.7 cm). More patients in combination group than tadalafil only group were able to penetrate (58.3% vs 45.2%).

VED=vacuum erection device, N = number of participants, FSD = female sexual dysfunction, FSFI = female sexual function index, RCT = randomized control trial, SPL = stretched penile length

decreased slightly to 15.0 at 3 months, 18.0 at 6 months, and maintained at 18.7 at 12 months. Findings suggested the early use of PDE-5 combined with VED after LNRP provides best chance for patients with reasonable erectile function at 12 months.

VED after posterior urethroplasty

ED is common after pelvic fracture-related urethral injury (PFUI) and its surgical repair with urethroplasty (Table 6). Even with nerve protective surgical technique during urethroplasty, the incidence of postoperative ED in these patients ranges between 20% to 80%.[79] VED was used in 78 PFUI patients with ED after primary posterior urethroplasty.[79] The patients were treated with either VED plus tadalafil or tadalafil only. Patients in the combination group were instructed to undergo daily use of VED without a constriction ring for 10 min twice a day and tadalafil 10 mg once every other day for 6 months. The patients in monotherapy group were treated with tadalafil 10 mg once every other day for 6 months. The study showed that VED plus tadalafil therapy significantly improved penile length compared to tadalafil only treatment (0.4 ± 0.9 cm vs -0.8 ± 0.7 cm). IIEF-5 and Quality of Erection Questionnaire scores were significantly higher in the combination group compared to tadalafil only group. More patients in combination group than tadalafil only group were able to penetrate (58.3% vs 45.2%). The non-randomized nature with potential patient selection bias and no long term follow up are the limitations of the study.

Compliance and preference issues

The major problem with VED therapy is high dropout rate and long-term compliance, possibly related to its cumbersome usage. About 19%–30% patients declined to use VED when they were offered the therapy.[20,24,26] Immediate dropout rates were about 13%–31% after patients used the devices and long-term data suggested attrition occurring in up to 65% of initial study participants (mean follow-up 37 months).[8,16,19-21] A study showed that even though the successful erections were achieved in 70% of patients with VED and 69% of patients with ICI plus VED, only 12% agreed to continue its use.[17] At 24-month follow-up, only 3% were utilizing the VED alone, while 1% combined VED and ICI. Another study with 85 men after RP showed good erection with VED therapy in 92% of men initially, only 14% agreed to continue with therapy at home.[42] In a retrospective longest-term study with 141 motivated patients after RP, actual utilization of VED was 39% at 1-year post-RP and only 5% at 5 years follow ups.[52]

Another issue with VED is preference. A randomized study with 60 spinal cord injury men showed that 70% preferred PDE5s to ICI and 100% preferred PDE5s to VED.[32] In a direct comparison of 36 men who responded equally to VED or PDE5s, although overall improvements in IIEF-15 were higher for VEDs over PDE5s (67 vs 60), the majority of men (67%) preferred PDE5s to VED.[3]

Obviously, even though VED therapy has consistently demonstrated excellent effect to create erection, it is not

appealing to many patients. Poor compliance and high dropout are related to its cumbersome nature, but may also be associated with loss of interest, loss of partners, acute illness, function recovery or response to other therapies.[39,78,80] Providers' efforts to educate patients probably play a significant role in patients' compliance as well.

Adverse effects and contraindications

VEDs are very safe to use in general. In contrast to a natural erection, VEDs result in notable differences related to the use of constriction ring including hinging or unstableness, reduced penile temperature, and decreased penile sensation. Reported side effects are penile petechiae (7%–27%), discomfort caused by constriction bands (1.5%–23%), cyanosis (11%), hematoma (10%), ecchymoses (7%–10%), subcutaneous bleeding (6%), anesthesia (5%), ischemia (3%), skin injury (2%), and edema.[6,12,14,19,20,28,29,31,35,36,41] All adverse effects are generally mild and temporary in nature. There was a case report that VED use may cause the artificial urinary sphincter (AUS) rupture.[81] However, no rationale or postulated mechanism was given how VED caused AUS rupture. VED is not recommended for patients with bleeding disorders and with high risk of priapism.

Conclusion

Vacuum therapy is the oldest non-invasive mechanical therapy that remains in use in contemporary sexual medicine. As a primary therapy for ED, it has been shown to be successful in all populations studied, including difficult to treat cohorts such as DM, spinal cord injury, and post-RP. However, its role in the post-PDE5i era has changed significantly since a majority of patients prefer PDE5s to VED and long-term VED attrition rates are high. Research into the penile pathophysiologic changes with VED therapy and clinical outcomes for various conditions are ongoing. Clinical evidence related to the new role of VED in sexual medicine will continue to evolve. For now, the use of VEDs for penile rehabilitation after RP has not demonstrated more rapid recovery of spontaneous erectile function, but it is promising to preserve or restore penile size for patients with RP, incision and grafting surgery for PD, the neoadjuvant/adjuvant therapy in men undergoing PP placement. The emerging data has also showed potential benefits of VED for patients undergoing other pelvic surgeries. With no anatomic benefits, VED is not recommended for subjective short penis. This committee is also calling for more studies regarding female specific VED for FSD. We encourage physicians to follow ICSM recommendations, but providers should also use their own judgement and adopt shared decision making with their patients/partners when considering VED for a specific disorder.

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Conflicts of interest

None.

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