THE JOURNAL OF
SEXUAL MEDICINE

EXPERT OPINION

Is There Still a Role for Vacuum Erection Devices in Contemporary Sexual Medicine?

Run Wang, MD, FACS

Key Words: Vacuum Erection Devices; Penile Rehabilitation; Peyronie's Disease; Penile Prosthesis; Urethroplasty; Penile Dysmorphic Disorder; Female Sexual Dysfunction

INTRODUCTION

The vacuum erection device (VED) is the oldest therapy used for male sexual function among all approved modalities. It was introduced for erectile dysfunction (ED) nearly 150 years ago, cleared by U.S. Food and Drug Administration in 1982 and adopted by American Urological Association (AUA) in 1996 as a standard of care.[1] 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%.[1] Since introduction of phosphodiesterase type 5 inhibitor (PDE5i) for ED after 1998, the role of VED in sexual medicine has changed significantly. Compared to PDE5i, only 33% of patients prefer VED for ED due to its inconvenience.[2] The effect of VED requires a constrictive ring to maintain erection for penetration[1]; which can be uncomfortable and possibly painful during ejaculation. Good dexterity is also required to use devices. However, this cumbersome, yet time-tested modality has persevered and has also found new indications in sexual medicine in the PDE5i era. This expert opinion is to summarize current use of VED in sexual medicine. Studies published in English from the Medline PubMed search are included.

VED for Penile Rehabilitation After Radical Prostatectomy

The concept of penile rehabilitation after radical prostatectomy (RP) was introduced to our clinic practice more than 20 years ago. Despite the controversial effect of current rehabilitation strategies in improving recovery of spontaneous erection, VED is one of the leading modalities adopted for penile rehabilitation.[3] VED therapy can create multiple erections daily without need for intact cavernosal nerves, a benefit versus PDEis. The mechanism of VED for penile rehabilitation was previously reviewed.[3] By periodically increasing in oxygenated blood flow into corporal cavernosa, VED therapy activates anti-apoptotic and anti-fibrotic process and potentially preserves veno-occlusive mechanisms.[3] A most recent study showed that activating or mobilizing endogenous stem cells in cavernous tissue plays a limited role, if any.[4] Further studies are warranted to explore what triggers the cascade reaction with VED to preserve cavernous tissues.

Available clinical evidences are reviewed recently and support the role of VED for penile rehabilitation.[5] To determine if VED has beneficial effects on preserving penile length after RP, a randomized controlled trial (RCT) demonstrated that daily VED use for 9 months resulted in a 28% decrease in self-reported subjective losses of penile girth and length compared to the control group (35% vs 63%). There was also an association between VED use and earlier ability to have intercourse. However, the recovery of natural erection was about the same with 32% in VED group compared to 37% in control group.[6] A small prospective study followed men treated with VED for 90 days following RP. Ninety two percent (36/39) of men had preservation of stretched penile length (SPL) with VED use.[7] Another RCT looked at the effect of early (1 month after RP) vs late intervention (6 months post-operative) with VED for 10 min/day. The early intervention group had preserved penile length (+0.6 cm) versus loss of penile length (-1.8 cm) in the late group. The International Index of Erectile Function (IIEF) scores were significantly higher in early VED use group than late VED use group at 3 months and 6 months.[8] However, long-term benefit for recovery of spontaneous erection was not established. Additionally, another RCT assigned 23 men to either a combination therapy of tadalafil 20mg, 3 time/week + VED for 10 min/day, 5 days/week or a control group receiving tadalafil only 1 month following a nerve-sparing RP. These patients were followed for 12 months. The IIEF-5 scores for the combination group was significantly higher than tadalafil only group at 6, 9, and 12-month follow-up. There was 92% successful vaginal penetration in combination group vs 57% in tadalafil only group and 92% successful orgasm in combination group vs 29% in tadalafil only group at 12 month follow-up.[9]

Due to small sample size and short-term follow up, the quality of these studies is questionable. The penile size preservation is

Received November 9, 2021. Accepted February 10, 2022.

Director of Sexual Medicine Fellowship Program, University of Texas McGovern Medical School and MD Anderson Cancer Center, Houston, TX

https://doi.org/10.1016/j.jsxm.2022.02.013

more assuring than recovering of nature erectile function with VED. Further RCTs with large sample sizes, multi-center nature and longer follow up may provide better evidence to guide our practice. For now, VED will continue to serve as one of the leading modalities for penile rehabilitation after RP for potential benefits mentioned above with minimal, if any, risks for our patients.

VED for Peyronie's Disease

For patients with Peyronie's disease, VED has been studied as both a primary treatment option and adjunctive therapies with intralesional injection or surgical treatment.[5] A case series of 31 men with PD used VED as their primary therapy for 3 months. 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.[10] A most recent study published in 2020, retrospectively looked at 20 men with PD who used VED for at least 10 minutes 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 scores of Sexual Health Inventory for Men (SHIM). However, the untreated group had statistically significant reduction in SHIM score.[11]

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. 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.[12] These results were not statistically significant due to the small sample size. Another study used VED after plaque incision and saphenous vein grafting. 22 patients with adequate follow-up for at least 3 months had an average mean length increase of 2.1 cm.[13] 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. 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°.[14]

Lacking controls and retrospective nature of VED studies for PD either as primary or adjunctive therapy make it impossible to know whether any improvements are related to VED use or purely due to nature course of the disease or the effect of primary therapies. The study related to the mechanism of VED therapy for PD is also limited. 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.[15] Further studies are necessary to provide in depth scientific evidence to understand the benefit, if any, of VED for patients with PD.

VED and Penile Prosthesis

Penile size has been a concern for many patients and implant surgeons. Few studies evaluated the use of VED to improve the penile size in men undergoing penile prosthesis placement. 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.[16] Another prospective study investigated VED use after penile implant for PD as part of post implant rehabilitation in 145 patients. There was significant reduction of residual curvature and improvement of IIEF-5 scores.[17] A third study looked at the VED use preoperatively for at least 10-15 minutes/twice daily for a minimum of 3 months in 13 men with severe corporal fibrosis. 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.[18] Lastly, a study randomized 51 patients to 10-15 minutes 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.[19]

Despite limited studies, VED use prior to penile prosthesis implantation has become a common practice by many implant surgeons, particularly for patients with known penile fibrosis. VED use after penile implantation are less likely to be offered, partly because many surgeons believe penile implants meet most patients' needs already. Regardless surgeons' preferences, scientific evidence is not robust either ways and further quality studies are necessary.

VED After Posterior Urethroplasty

Both pelvic fracture-related urethral injury (PFUI) and surgical repair with urethroplasty can cause ED. Even with nerve protective surgical technique during urethroplasty, the incidence of postoperative ED in these patients ranges between 20% to 80%.[20] An interesting study looked at 78 PFUI patients with ED after primary posterior urethroplasty who were treated with either VED plus tadalafil or tadalafil only. Patients in the combination group were instructed 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 vs -0.8 ± 0.7 cm). IIEF-5 and Quality of Erection Questionnaire scores were significantly higher in 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%). Another interesting finding was that patients in the combination therapy group had markedly improved testosterone levels.[20]

This is the first and currently only study using VED combined with tadalafil to treat ED after PFUI and urethroplasty.

Obviously, the non-randomized nature with potential patient selection bias and no long-term follow up are the limitations of the study. Nevertheless, this study will stimulate future interests for clinical trials to look at the role of VED after urethroplasty for patients with PFUI.

VED for Subjectively Short Penis

Most men with subjectively small penis have a normal phallus and are likely to have some form of body and/or penile dysmorphic disorder and should be reassured that their penises are normal. Invasive procedures should be avoided in these patients. In patients with subjectively short penis, VED was evaluated to improve penile length. A prospective study of 37 sexually active men with SPL < 10 cm were treated with VED for 20 minutes/-day, 3 times/week, for 6 months. Mean penile length increased was about 0.3 cm (from 7.6 cm to 7.9 cm), but was not statistically significant. Patient satisfaction rate was only 30%.[21]

Clearly, VED is not an effective method for penile elongation with subjective short penis. Physicians should inform patients with subjective short penis that VED may only provide psychological satisfaction for some men.

VED for Female Sexual Dysfunction

The concept of vacuum therapy was also tested to treat female sexual dysfunction (FSD). A clitoral vacuum device was FDA cleared more than 20 years ago.[22] The battery -powered device is placed over the clitoris and a gentle vacuum is created by activating the pump. This causes blood flow to increase with clitoral engorgement and ultimately improve arousal in women with FSD. The patient can adjust the vacuum level and the time during use. The only published study looked at the changes of sensation, lubrication, orgasm and sexual satisfaction in 12 normal volunteers and 20 women with FSD. 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. About 80% of the FSD subjects and 33% of normal volunteers reported increased lubrication. About 55% 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.[22] These results are very encouraging not only for patients with FSD, but also for women without complaints of FSD.

Paucity of effective treatment for disorders related to FSD is the key obstacle for physicians to provide best care. Even though VED is tested for arousal disorder with encouraging results, it is impossible to give recommendation based on 1 study published more than 20 years ago. Quality studies are necessary to confirm effectiveness of female specific VED for FSD.

CONCLUSIONS

Research into the penile pathophysiologic changes with VED therapy and clinical outcomes for various conditions are ongoing. Clinical evidence related to the new roles of VED in sexual medicine will continue to evolve. Readers should understand that there are many VED models on the market and no standard treatment protocols have been validated for any particular disorders with VED therapy. Therefore, high quality studies are lacking and accurate interpretation of available data are difficult. Since current clinical evidences have not met the scientific needs to guide our practice, for now, physicians will have to use their own judgement and adopt shared-decision making with their patients when considering VED for a specific condition. Nevertheless, VED therapy showed promising benefits in most studies for various disorders and has proven to be very safe. We believe it will continue to play an important role in contemporary sexual medicine.

Corresponding Author: Run Wang, MD, FACS, Director of Sexual Medicine Fellowship Program, University of Texas McGovern Medical School and MD Anderson Cancer Center, Houston, TX 77030.; E-mail: run.wang@uth.tmc.edu

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

Funding: None.

STATEMENT OF AUTHORSHIP

Conceptualization, Methodology, Investigation, Writing – Original Draft, Writing – Review & Editing, Funding Acquisition, Resources and Supervision: RW.

REFERENCES

1. Yuan J, Hoang AN, Romero CA, et al. Vacuum therapy in erectile dysfunction—science and clinical evidence. **Int J Impot Res 2010;22:211–219.**
2. Chen J, Mabjeesh NJ, Greenstein A. Sildenafil versus the vacuum erection device: patient preference. **J Urol 2001;166:1779–1781.**
3. Wang R. Vacuum erectile device for rehabilitation after radical prostatectomy. **J Sex Med 2017;14:184–186.**
4. Yang B, Luse D, Cao Y, et al. The role of long term label-retaining cells in the treatment of erectile dysfunction by vacuum erectile device. **Sex Med 2021;9:100442.**
5. Sultana A, Grice P, Vukina J, et al. Indications and characteristics of penile traction and vacuum erection devices. **Nat Rev Urol 2021 [Online ahead of print]. doi: 10.1038/s41585-021-00532-7.**
6. Raina R, Agarwal A, Ausmundson S, et al. Early use of vacuum constriction device following radical prostatectomy facilitates early sexual activity and potentially earlier return of erectile function. **Int J Impot Res 2006;18:77–81.**
7. Dalkin BL, Christopher BA. Preservation of penile length after radical prostatectomy: early intervention with a vacuum erection device. **Int J Impot Res 2007;19:501–504.**

8. Kohler TS, Pedro R, Hendlin K, et al. A pilot study on the early use of the vacuum erection device after radical retropubic prostatectomy. **BJU Int 2007;100:858–862.**
9. Engel JD. Effect on sexual function of a vacuum erection device post-prostatectomy. **Can J Urol 2011;18:5721–5725.**
10. Raheem AA, Garaffa G, Raheem TA, et al. The role of vacuum pump therapy to mechanically straighten the penis in Peyronie's disease. **BJU Int 2010;106:1178–1180.**
11. MacDonald LP, Armstrong ML, Lehmann KJ, et al. Outcome analysis of patients with Peyronie's disease who elect for vacuum erection device therapy. **Can Urol Assoc J 2020;14: E428–E431.**
12. Lue TF, El-Sakka AI. Lengthening shortened penis caused by Peyronie's disease using circular venous grafting and daily stretching with a vacuum erection device. **J Urol 1999;161:1141–1144.**
13. Yurkanin JP, Dean R, Wessells H. Effect of incision and saphenous vein grafting for Peyronie's disease on penile length and sexual satisfaction. **J Urol 2001;166:1769–1972.**
14. Abdel Raheem A, Capece M, Kalejaiye O, et al. Safety and effectiveness of collagenase clostridium histolyticum in the treatment of Peyronie's disease using a new modified shortened protocol. **BJU Int 2017;120:717–723.**
15. Lin H, Liu C, Wang R. Effect of penile traction and vacuum erectile device for Peyronie's disease in an animal model. **J Sex Med 2017;14:1270–1276.**
16. Soderdahl DW, Petroski RA, Mode D, et al. The use of an external vacuum device to augment a penile prosthesis. **Tech Urol 1997;3:100–102.**
17. Antonini G, De Berardinis E, Del Giudice F, et al. Inflatable penile prosthesis placement, scratch technique and postoperative vacuum therapy as a combined approach to definitive treatment of Peyronie's disease. **J Urol 2018;200: 642–647.**
18. Tsambarlis PN, Chaus F, Levine LA. Successful placement of penile prostheses in men with severe corporal fibrosis following vacuum therapy protocol. **J Sex Med 2017;14: 44–46.**
19. Canguven O, Talib RA, Campbell J, et al. Is the daily use of vacuum erection device for a month before penile prosthesis implantation beneficial? A randomized controlled trial. **Andrology 2017;5:103–106.**
20. Zhang DL, Chen Z, Wang FX, et al. Adding a vacuum erection device to regular use of Tadalafil improves penile rehabilitation after posterior urethroplasty. **Asian J Androl 2019;21:582–586.**
21. Aghamir MK, Hosseini R, Alizadeh F. A vacuum device for penile elongation: fact or fiction? **BJU Int 2006;97:777–778.**
22. Billups KL, Berman L, Berman J, et al. A new non-pharmacological vacuum therapy for female sexual dysfunction. **J Sex Marital Ther 2001;27:435–441.**