

The Resurgence of the Vacuum Erection Device (VED) for Treatment of Erectile Dysfunction

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ABSTRACT

Introduction. Vacuum erection devices (VEDs) have been approved in the United States since 1982 and offer a viable alternative to oral phosphodiesterase type 5 inhibitors (PDE5i), injections and transurethral suppositories. Studies have demonstrated efficacy in erectile dysfunction (ED) associated with a variety of conditions. More recently, this modality has been evaluated in initial phosphodiesterase inhibitor nonresponders as well as for post-prostatectomy penile rehabilitation.

Aim. This article provides a detailed overview of the history of VEDs, a review of the literature, and a concise description of their new applications in modern urological practice.

Methods. A retrospective review of publications relevant to the field of VEDs.

Main Outcome Measures. Review of the historical milestones, evolution, and modern utilization of VEDs in modern urological protocols.

Results. Studies have demonstrated efficacy in ED associated with a variety of conditions. Early penile rehabilitation after surgery for prostate cancer with the VED appears to improve erectile function and penile length. Adverse events are transient and not serious.

Conclusions. The VED has continued to show efficacy for treatment of ED due to various etiologies and should be considered an attractive second-line therapy. In select cases such post-prostatectomy penile rehabilitation, as well as in men who cannot use a PDE5i, the vacuum device should be considered first-line treatment. **Brison D, Seftel A, Sadeghi-Nejad H. The resurgence of the vacuum erection device (VED) for treatment of erectile dysfunction. J Sex Med 2013;10:1124–1135.**

Key Words. Erectile Dysfunction; Vacuum Erection Device; Penile Rehabilitation; Prostate Cancer; Radical Prostatectomy

Introduction

Erectile dysfunction (ED) is defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual activity [1]. It is associated with a number of diseases and conditions including psychosocial (psychological distress); neurogenic (spinal cord injury, stroke); systemic diabetes mellitus, kidney disease; and cavernosal (Peyronie's disease) [2]. A number of commonly prescribed drugs can also cause ED, including specific serotonin reuptake inhibitors [2].

The basic mechanism of ED is failure of smooth muscle relaxation in the corpus cavernosum. Penile erection occurs when blood flow to

the penis is increased, cavernous blood outflow is decreased, and cavernous smooth muscle is relaxed [3]. During sexual excitement nitric oxide (NO) release from cavernous nerves is increased; as a result guanylate cyclase in the smooth muscle cell is activated, resulting in an increase in cyclic guanosine monophosphate (cGMP). The increased cGMP decreases cytosolic calcium, resulting in relaxation of cavernous smooth muscle.

The enzyme phosphodiesterase type 5 (PDE5) curtails the action of cGMP, thereby causing detumescence. The mechanism of the oral agents used to treat ED is based on their ability to inhibit the PDE5 enzymes, thereby allowing for accumulation of cGMP.

There are a variety of treatments for ED, with patient preference depending on factors such as efficacy, side effects, concurrent morbidities, and cost. These include intracavernosal injections (ICI), transurethral suppositories, vacuum erection devices (VEDs) and, most recently, oral PDE5 inhibitors (PDE5i). The latter are the most widely used because of convenience, but they are not effective in all men and the patient is usually responsible for at least some of the cost. Many patients are also unable to use this class of medications because of adverse events or contraindications such as concomitant use of nitrates. As a result, other treatment modalities are frequently used.

The current review summarizes the resurgence of VED in the treatment of ED and its potential for penile rehabilitation after radical prostatectomy (RP) for prostate cancer. The term VED will be used for all vacuum devices, whether used in conjunction with a constriction band or by itself.

VEDs for the Treatment of ED

In 1874, the American physician John King noted that a “glass exhaustor” applied to the male organ could increase the size of that organ. The glass exhaustor was simply a vacuum device that produced an artificial erection. Once the exhaustor was removed from the penis the erection disappeared. Over the ensuing years a number of different devices were developed and used to produce erections, but Geddings D. Osbon Sr. is regarded as the person that popularized the VED in the 1960s [4]. In 1974, his son marketed the first commercial vacuum constriction therapy for erections and was later awarded a U.S. patent for this device, which he had originally intended for his personal use. The U.S. Food and Drug Administration cleared the first marketed VED, the ErecAid, in 1982. The VED has been accepted by the American Urological Association for treatment of ED in general, including that which commonly occurs after RP.

Studies by Nadig et al. and by Witherington in the 1980s were instrumental in demonstrating the efficacy of the VED. Nadig et al. [5] reported on a study of 35 men with organic impotence that used the VED along with rubber bands to constrict the penis during erection (Table 1). The authors reported that 32 of the participants achieved penile rigidity sufficient for vaginal penetration. During a follow-up period lasting 8–22 months, 24 of 30 participants used the device regularly and reported

Table 1 Erectile dysfunction of organic, psychogenic, or mixed etiology

First author	Publication year	Population studied	N	Modality	VED efficacy findings
Nadig	Urology 1986	Organic impotence	35	VED + tension bands	32/35 (91%) of subjects reported penile rigidity sufficient for vaginal penetration 24/30 (80%) subjects used the VED regularly and reported satisfactory results - Average of 2.5 minutes to create an erection adequate for intercourse
Witherington	J Urol 1989	VED users	1,517	VED	92% of subjects reported an erection or erection-like state that was sufficient for intercourse 77% of subjects reported successful intercourse every 2 weeks 92% of users would recommend the system to others 68% overall user satisfaction
Sidi	J Urol 1990	Erectile dysfunction	100	VED	70% of subjects used the VED regularly
Cookson	J Urol 1993	Erectile dysfunction with long-term VED use	216	VED	- Patient and partner satisfaction 84% and 89%, respectively, in long-term users - Erection quality rated at >90%
Bosshardt	Br J Urol 1995	Erectile dysfunction and VED users	30	VED	After 6 months, average rigidity at base and tip of penis was >80%
Lewis	World J Urol 1997	Erectile dysfunction	6,000	VED	75% of subjects remained continuous users 83.5% reported sex as often as desired 65% of subjects reported improved self-image 70% reported improved relationship with partners - In long-term users (primarily patients who did not respond to ICI) 98% of patients and 85% of partners were satisfied with the vacuum therapy 84% of users showed some improvement
Derouet	Andrologia 1999	Erectile dysfunction	110	VED	
Wylie	J Sex Marital Ther 2003	Psychogenic erectile dysfunction	25	VED + psychotherapy	

ICI = intracavernous injections; ED = erectile dysfunction; VED = vacuum erection device

satisfactory results. Penile ecchymoses developed in three patients while petechiae were reported in eight subjects on one or more occasions; these side effects were painless and transient.

Witherington [6] reviewed questionnaires completed by 1,517 men who had used a VED between 1974 and 1987. Of these, 92% achieved an erection or an erection-like state that was sufficient for intercourse; a majority of the respondents reported successful intercourse every 2 weeks. No significant or serious adverse events were reported.

Since the original marketing clearance, many other brands of VED have become available in the United States. The majority of the devices consist of a pump (either manual or battery powered) and a cylinder. A constriction ring is usually included with the device. The ring is initially placed on the proximal end of the cylinder, and the pump is connected to the distal end of the cylinder. A water-soluble lubricant is spread around the proximal end to attain a better seal to the skin surrounding the base of the penis. Once the cylinder is correctly placed around the penis the patient starts to pump, thus creating a vacuum. Newer versions of the vacuum devices are equipped with battery-powered pumps, allowing easier use in men with dexterity problems.

After adequate penile rigidity has been obtained, the constriction ring is slid down the cylinder onto the base of the penis. The vacuum is released, the cylinder is removed and the patient is ready for intercourse. The constriction ring should not be left on the penis for more than 30 minutes to prevent ischemia.

The mechanism of the vacuum-induced penile rigidity is thought to be increased cavernous arterial blood flow [7,8]. Application of the constriction ring reduces venous outflow of blood, thereby preventing early detumescence. An intriguing hypothesis postulates that, in addition to the effects on blood flow, VEDs increase NO release [9], which, along with cGMP, mediates corporal smooth muscle relaxation and penile erection. Whether this ancillary action is involved in the effects of VEDs is not known. Another possible mechanism of the erectile response to the vacuum device is reduction of hypoxia inducible factor-1 α and transforming growth factor beta-1 and increased smooth muscle/collagen ratio [10], all of which could improve penile blood flow especially after RP.

VEDs have few side effects. Adverse events include penile numbness and/or pain, a feeling of penile coldness, and bruising. Contraindications

are bleeding disorders and priapism. The VEDs are generally considered safe and well accepted for ED associated with a variety of conditions.

ED of Organic, Psychogenic, or Mixed Etiology

Many studies have demonstrated long-term effectiveness and acceptance by both the patient and his partner. Sidi et al. [11] retrospectively analyzed 100 men with ED for patient acceptance, who used an external negative pressure device. Overall, 68% of the users were satisfied. Patients who were not satisfied, or who discontinued use of the device, cited premature loss of tumescence and rigidity, pain or discomfort as reasons.

Cookson and Nadig studied 216 men with ED, who reported long-term use of a VED [12]. Patients completed a questionnaire after 3 and 29 months of use. The device was used regularly by approximately 70% of the subjects. Patient and partner satisfaction were 82% and 87%, respectively, in the short-term users, and 84% and 89%, respectively, in the long-term users. The quality of the erections (hardness, penile length, and circumference) was rated greater than 90% in both groups. Long-term users reported an increase in the frequency of intercourse, which was sustained beyond the first year.

Bosshardt et al. [13] studied 30 men who used a vacuum device for 6 months. The average rigidity at the base and tip of the penis after 6 months was greater than 80%. In addition, there was an increase in nocturnal penile tumescence and rigidity. The duration and extent of nocturnal penile tumescence and rigidity at the start and the end of the study improved, especially in men who experienced spontaneous nocturnal erections. Those men showed significant improvements in total erection-time, erection-phase and plateau-phase duration, effective rigidity, and tumescence increase. The authors reported a decrease in penile blood gases 30 minutes after application of the constriction ring. This is in concert with the manufacturer's instructions to remove tension rings after 30 minutes.

Lewis and Witherington [4] reviewed vacuum therapy as a treatment for ED and noted a success rate of around 90%. In a survey of almost 6,000 vacuum users they reported that over 75% remained continuous users, and 83.5% of patients reported having sex as often as desired, 65% reported an improved self-image, and 70% reported improved relationship with their partners. Of the respondents who ceased using vacuum therapy, 43% stated that it was due to a reason that

Table 2 Diabetes mellitus

First author	Publication year	Population studied	N	Modality	VED efficacy findings
Bodansky	Diabet Med 1994	Diabetic men with ED	19	Battery-powered vacuum assist device	• After 6 months patient's and partner's sexual satisfaction and self-esteem increased significantly • Used 4 times per month
Arauz-Pacheco	Am J Med Sci 1992	Men with erectile impotence related to diabetic neuropathy	12	Vacuum device	• After 3 months, 75% reported improved erectile function
Price	Diabet Med 1991	Diabetic men with impotence	44	Vacuum tumescence therapy	• 75% were able to have satisfactory intercourse after 2 months • Median frequency of use was 5.5 times per month
Kaplan	S Afr Med J 1995	Diabetic organic impotence	8	VED	• 75% reported successful intercourse at 6 months
Israilov	Int J Impot Res 2005	Diabetic men with ED most of whom had failed sildenafil citrate	162	Progressive treatments including VED	• 70% responded well • 12% continued its use

ED = erectile dysfunction; VED = vacuum erection device

was unrelated to the device. The authors also concluded that training and support contribute significantly to patient satisfaction and continued use.

Derouet et al. [14] reported that, among long-term users, 98% of patients and 85% of their partners were satisfied with the vacuum therapy. Side effects were minor and consisted of hematoma (9.8%) and skin injury (2.2%).

Wylie et al. [15] reported on the successful use of a vacuum device in men with psychogenic ED. A group of 25 couples had psychotherapy in addition to a device, while 20 couples had therapy but no device. In the first group 84% of the couples reported some improvement compared with 60% of those who did not use the device. This suggests that combining the VED with psychotherapy may benefit men with psychogenic ED.

Diabetes Mellitus

ED is a significant problem in diabetic men. Studies indicate that more than 8 million men with diabetes in the United States have ED [16], with the condition occurring in 32% of men with type 1 and 46% of those with type 2 diabetes [17]. Results from the Massachusetts Male Aging Study suggest that men with diabetes have a threefold increase in the incidence of ED compared with those with no diabetes [18]. Prevalence estimates of ED in diabetic populations range from 20% to 71% [19]. The high levels of blood sugar causes blood vessel and nerve damage that affect many processes in the body including the release of NO and the subsequent reduction of blood flow to the penis. A number of factors appear to be involved in vasculogenic changes that result in ED in this population, including increased glycation end products,

reduced NO synthesis, elevated endothelin B receptor binding sites, and elevated levels of oxygen free radicals [20].

While PDE5i are the mainstay of treatment of ED in men with diabetes, VEDs provide a rational alternative noninvasive treatment option [21,22]. Bodansky [23] evaluated the use of a VED in diabetic men with ED over a 6-month period (Table 2). Of the 19 patients in the study 11 used the device for the duration of the trial. Patient's and partner's sexual satisfaction and self-esteem increased significantly over the duration of the study. The device was used an average of four times per month and was well tolerated.

Arauz-Pacheco and colleagues reported on the use of a VED in 12 men with ED associated with diabetic neuropathy [24]; after 3 months, 75% of the patients reported improved erectile function. Price et al. [25] studied 44 diabetic men who were treated with a VED; 75% were able to have satisfactory intercourse after 2 months. In a 6-month study involving eight men with diabetes, six reported successful intercourse after use of a VED [26].

Israilov et al. evaluated a progressive treatment program for ED in diabetic patients [27]. A total of 284 patients entered a phased program, starting therapy with sildenafil citrate, then progressing to a VED and subsequently other treatments. Of the initial 284 patients, 276 were eligible for sildenafil and 53% had a positive response. Of 162 patients treated with a VED 70% responded well.

These authors have demonstrated improved erectile function, increased sexual satisfaction of the man and his partner, and improved self-esteem when treating diabetes-associated ED with a VED.

Spinal Cord Injury

Spinal cord injuries (SCI) are frequently associated with ED. Men with upper motor neuron lesions can have reflex erections, but these are often transient and not adequate for intercourse, while most men with lower motor neuron lesions are unable to have erections [28].

A limited number of studies have investigated the effects of VEDs in SCI patients. Zasler and Katz [29] reported on a silicone sheath vacuum device that was used in 20 patients with neurogenic impotence caused by a SCI (Table 3). Patients and partners reported good to excellent efficacy of the device as well as increased satisfaction with their sex life. The device was well tolerated.

In 1992 Heller et al. reported on the use of a VED in 17 men with chronic neurologic impotence [30]. After a mean follow-up of 21 months over 50% of the patients were still using the device, with an average frequency of coitus of 1.5 times per week. There were no significant side effects reported.

Denil et al. described results of VED use in 20 SCI male patients with ED [31]. After 3 months 93% of the men reported rigidity sufficient for vaginal penetration; the corresponding satisfaction figure for their female partners was 83%. At 6 months the satisfaction rate was 41% for the men and 45% for the women. The most common complaint was premature loss of penile rigidity during intercourse. Side effects were minor and consisted of petechiae and penile skin edema.

In a study that included 85 men with SCI, 28 used a VED while 26 used penile injections [32]. The latter group of patients reported that they had intercourse a mean of three times per month, while those using VED reported a mean intercourse rate of five times per month. Two patients using the VED reported subcutaneous bleeding and one developed penile ischemia.

Moemen et al. [33] describes a comparative study in which men with SCI and ED used sildenafil or ICI or a VED with subsequent treatment with sildenafil. Men in all groups reported statistically significant improvements in International Index of Erectile Function (IIEF) and IIEF-erectile function domain (IIEF-EF). Seventy percent of men using the VED reported normal (26–30) IIEF-EF scores after treatment, compared with 0% before treatment. Men utilizing sildenafil or injections comparatively reported 90% normal IIEF scores after treatment.

These and other studies [34,35] have demonstrated that VEDs are a viable alternative for treatment of ED in the SCI population. They are well tolerated and improve erectile function and sexual satisfaction.

VEDs as an Alternative to Medical Management

It is fortunate that a number of different treatments for ED are available, since not all therapies are efficacious or tolerable by every patient and many cannot be used at all due to specific contraindications. The latter is especially relevant

Table 3 Spinal cord injury

First author	Publication year	Population studied	N	Modality	VED efficacy findings
Zasler	Arch Phys Med Rehabil 1989	Neurogenic ED caused by SCI	20	Synergist silicone sheath vacuum device	• Good to excellent efficacy • Increased satisfaction with sex life reported by patients and partners
Heller	Paraplegia 1992	Chronic neurological impotence	17	Vacuum tumescence constriction therapy	• After mean of 21 months over 50% of patients were using the device with an average frequency of coitus of 1.5 times per week
Denil	Arch Phys Med Rehabil 1996	Spinal cord injured men with ED and their heterosexual partners	20	VED	• After 3 month 93% reported rigidity sufficient for vaginal penetration with 83% satisfaction for partner • At 6 months satisfaction rate was 41% for men and 45% for women • 60% of men and 42% of women indicated an improvement of the sexual relationship
Watanabe	J Spinal Cord Med 1996	SCI and ED	28	VED	• Reported mean intercourse of 5 times per month
Moemen	Int J Impot Res 2008	SCI and ED	60	Consecutive use of variety of ED treatments, including VED then sildenafil	• 70% reported normal IIEF-EF scores (26–30) after VED treatment

to the PDE5i class of medications that, despite excellent overall efficacy, do not always provide an optimum response [36,37]. Furthermore, PDE5i are contraindicated in men taking organic nitrates for conditions such as angina due to a potential interaction between the drugs that can cause a potentially fatal drop in blood pressure.

Canguven et al. [38] studied 69 men who failed PDE5i therapy that were treated with both a PDE5i and a VED for 4 weeks (Table 4). At the end of the study there was a significant increase in the IIEF, Sexual Encounter Profiles (SEP 2 and 3), and the Global Patient Assessment Scale (GPAS). The conclusion of the study was that combination therapy with a PDE5i and a VED may restore erectile function in those men who do not fully respond to oral therapy.

Sadeghi-Nejad et al. [39] conducted a similar study of 77 men with ED who did not respond to PDE5i treatment. The subjects used a VED alone or in combination with the PDE5i. The authors reported that the use of the VED alone provided a significant improvement in erectile function as assessed by the mean IIEF-EF, SEP, Erection Hardness Score, and GPAS. They concluded that in men who have failed PDE5i the use of a VED alone or in conjunction to standard PDE5i therapy appears to offer advantages compared with the PDE5i alone.

Chen et al. [40] reported on 52 patients with ED who were initially treated with a VED and were then switched to sildenafil. In 36 patients in whom the efficacy of the PDE5i was similar to the VED, 12 resumed use of the device while the remaining 24 continued using sildenafil. Thus, while more patients preferred sildenafil, a significant number (33%) of the patients opted to use the VED.

Marmar et al. studied 22 men with ED who had a partial tumescence to ICI [41]. They reported that the use of a VED immediately after partial tumescence was attained produced a rigid erection in 21 of the subjects. Chen et al. [42] studied combination therapy with ICI and an external vacuum in men with ED who had failed monotherapy. He found that combination therapy produced increased rigidity.

The VED is a valid alternative therapy for those patients who do not respond to PDE5i or who, for whatever reason, cannot take such medications.

VEDs after RP

Prostate cancer is one of the most common solid cancers in males in the United States [43].

Table 4 Alternative to medical management

First author	Publication year	Population studied	N	Modality	VED efficacy findings
Canguven	J Sex Med 2009	Men with ED who failed maximum dose PDE5i therapy	69	Combination PDE5i + VED	• Mean IIEF-5 increased from 9.0 to 17.6 ($P < 0.001$) • 79% of men who responded "No" to SEP-2 at baseline responded yes after 4 weeks ($P < 0.001$) • 70% of men who responded "No" to SEP-3 at baseline responded yes after 4 weeks ($P < 0.001$) • In men who responded "not at all" or "slightly" at baseline 74% responded "moderately" or "greatly improved" after 4 weeks in the GPAS • VED alone provided a significant improvement in IIEF-EF, SEP, EHS, GPAS • No statistically significant difference between groups in any of the assessments • 69% were able to achieve similar efficacy with sildenafil, of whom 33% elected to continue VED use rather than sildenafil • The increase in IIEF score was higher in those using VED. Mean increase was 66.8 vs. 60.4 for VED and sildenafil users, respectively ($P = 0.002$) • After a partial ICI-induced tumescence, 95% produced a rigid erection in 30–60 seconds • No patient achieved adequate rigidity with a single therapy as measured by buckle pressure • 100% of subjects responded to combination therapy with adequate rigidity
Sadeghi-Nejad	J Sex Med 2012	Men with ED who failed PDE5i therapy	77	PDE5i + VED or VED alone	
Chen	J Urol 2001	Men with ED who achieved satisfactory erections with VED then switched to sildenafil	52	VED or sildenafil	
Marmar	J Urol 1998	Men with ED who had a partial tumescence to ICI	22	ICI + VED	
Chen	J Urol 1995	Men who had previously failed attempts with either ICI or VED	10	ICI + VED	

ED = erectile dysfunction; EHS = Erection Hardness Score; GPAS = Global Patient Assessment Scale; ICI = intracavernous injections; IIEF-5 = International Index of Erectile Function—5 Questionnaire (SHIM); PDE5i = phosphodiesterase type 5 inhibitor; SEP-2 = Sexual Encounter Profile question 2; SEP-3 = Sexual Encounter Profile question 3; VED = vacuum erection device

Improved detection methods allow for earlier diagnosis and more successful treatment. RP is a widely used treatment for prostate cancer [44]. While generally recognized as a safe and effective treatment for RP, the procedure is associated with short- and long-term sexual dysfunction. Following open or robot-assisted laparoscopic RP for prostate cancer, there may be inadvertent damage to the penile vascular supply and nerves despite meticulous nerve-sparing surgery. Rabbani et al. report that recovery from RP-induced ED may continue up to 5 years after surgery [45].

Penile Rehabilitation

Penile rehabilitation is “the use of any drug or device at or after RP to maximize erectile function recovery” [46]. It is suggested that early penile rehabilitation (initiated within 2–4 weeks of RP) limits ED after surgery by decreasing or preventing the tissue changes that can occur during neural recovery [47]. Immediately after RP most men experience a period of neuropraxia as a result of tissue manipulation and nerve exposure. Since this initial cause of ED may be transient, early erectile stimulation could minimize cavernous tissue fibrosis, thus decreasing irreversible injury.

A potential benefit of penile rehabilitation is that of increased oxygen saturation in cavernosal tissue. Oxygenation is critical for regulation of the local mechanisms of erection. Arterialized blood flow, e.g., during nocturnal erections, may provide the oxygen necessary for the formation of NO. Men with ED are reported to have diminished corporal penile oxygen saturation [48]. Transurethral (ICI) prostaglandin E1 has been shown to increase corporal oxygen saturation in men with ED [49], which may be responsible, in part, for the erectogenic effect of the agent.

At this time there is no standard protocol or guideline for penile rehabilitation, primarily due to a lack of studies that provide definitive data as to the best treatment(s), timing for initiation of therapy, and optimal frequency of treatment. However, penile rehabilitation subsequent to RP has been reported with most types of ED therapies, including PDE5i [50,51], ICI [52], intraurethral alprostadil [53], and VEDs [54–56].

Kohler and colleagues investigated the effects of early vs. late intervention with a VED in RP patients [57] (Table 5). Subjects were randomized to begin VED treatment either 1 month or 3 months after surgery. The IIEF score in the early intervention group was 11.5 at 3 months and 12.4 at 6 months, compared with 1.8 and 3.0 at

the same time points in the late intervention group. This data demonstrated the importance of starting use of the VED as soon as possible after surgery.

Raina et al. reported on the efficacy of VEDs in 109 RP patients who subsequently developed ED; subjects had either a nerve-sparing or a non-nerve-sparing procedure [54]. The participants were randomized to VED use daily for 9 months (74 subjects) or observation alone without any erectogenic aids (35 patients). VED use began an average of 3.9 weeks after RP. Eighty percent of the patients used their VEDs for vaginal intercourse at a frequency of twice per week with a spousal satisfaction rating of 55%. The authors concluded that early use of the VED following RP facilitates early sexual intercourse, early patient/spousal sexual satisfaction, and potentially an earlier return of natural erections. They suggest that sexual activity that occurs early after surgery helps maintain the sexual interest and comfort that existed preoperatively.

These results, along with conclusions from other authors [58–60], suggest that the VED may become a first-line treatment for penile rehabilitation after surgery for prostate cancer.

Another distressing side effect of RP is penile shortening. Munding et al. evaluated stretched penile length (SPL) in 31 men 3 months after RP [61]. Of these, 22 (71%) had a decrease in SPL of 0.5–4.0 cm; 15 of these had decreases of 1.0 or more cm. In a study in which RP was performed using robotics, there was a decrease of SPL of 0.64 cm after 1 month, with a trend toward recovery out to 11 months [62]. Gontero and colleagues reported a mean decrease in SPL of 0.84 cm at the time of catheter removal after RP; the effect was still present, although less so, at 1 year [63].

Studies have demonstrated the benefit of using a VED after RP in terms of decreasing the effect of surgery on SPL. Raina et al. showed that early VED use by patients after nerve-sparing surgery preserves penile length and girth [54]. Patients used a VED for 5 minutes every other day for at least 9 months after surgery; another group did not use VEDs. In the former group 14 (23%) reported a decrease in length and girth, compared with 63% of the subjects in the non-VED user group.

Dalkin and Christopher studied 42 men who had RP and used a VED every day from the day of catheter removal through 90 days [64]. In men who used the device more than 50% of the time, only one (out of 36) had a decrease in SPL of

Table 5 Post radical prostatectomy

First author	Year	Population studied	N	Modality	VED efficacy findings
Köhler	BJU Int 2007	1 month after RP (Group 1) or 6 months after RP (Group 2)	28	VED	- In men who started VED at 1 month after RP IIEF-EF was 11.5 after 3 months and 12.4 at 6 months - In men who started VED at 6 months after RP IIEF-EF was 1.8 and 3.0 after 3 and 6 months, respectively - Stretched penile length was preserved in Group 1 and significantly decreased by approximately 2 cm in Group 2
Raina	Int J Impot Res 2006	RP patients who subsequently developed ED	109	VED or observation alone	80% used their VED at a frequency of 2 times per week with a spousal satisfaction rating of 55%
Zippe	Curr Urol Rep 2008	Patients after NSRP	60	VED vs. no VED	- In compliant men, 23% reported decrease in length and girth vs. 63% in the non-VED user group after 9 months of use 80% of compliant men reported a quicker return to sexual activity
Dalkin	Int J Impot Res 2007	Men with good preoperative function after NSRP	42	VED	In those who used the device 50% or more of the time, only 1/36 (3%) had a decrease of less than or equal to 1.0 cm
Gontero	BJU Int 2005	Potent men after NNSRP	76	Consecutive treatment of sildenafil then VED and other ED treatments	52% were considered responders to VED - At 1 year 20% were still using erectile aids
Engel	Can J Urol 2011	Men with prostate cancer after bilateral nerve-sparing robotic prostatectomy	23	Tadalafil or tadalafil + daily unbanded VED	- IIEF-5 was significantly higher for combination group at 6, 9, and 12 months - Penile hardness scores were significantly greater at 6 and 9 months - At 12 months 92% of combination patients responded yes to the vaginal penetration question (SEP2) compared with 57% who used tadalafil only - At 12 months 92% of combination patients responded yes to the intercourse to organism question (SEP3) compared with 29% who used tadalafil only
Baniel	BJU Int 2001	Men undergoing RRP	85	Progressive ED treatments, starting with VED	92% responded to the VED with an erection sufficient for vaginal penetration 14% agreed to continue it at home

ED = erectile dysfunction; IIEF-EF = International Index of Erectile Function-erectile function domain; IIEF-5 = International Index of Erectile Function—5 Questionnaire (SHIM); NNSRP = non-nerve-sparing radical prostatectomy; NSRP = nerve-sparing radical prostatectomy; RP = radical prostatectomy; RRP = retropubic radical prostatectomy; SEP-2 = Sexual Encounter Profile question 2; SEP-3 = Sexual Encounter Profile question 3; VED = vacuum erection device

greater than or equal to 1.0 cm. Of three men with poor compliance to the device, two had a decrease of greater than or equal to 1.0 cm.

Long-Term ED Following RP

Penson et al. [65] reported that 24 months after RP, 22% of a sample of 1,288 men had erections firm enough for intercourse; this increased to 28% at 60 months. Even with the advent of nerve-sparing RP in the 1980s, there is great variability in the incidence of ED, with reports ranging between 16% and 82% [66]. The extent of nerve damage during surgery is one of the primary determinants of whether sexual dysfunction will occur; damage to the nerves decreases the amount of NO that is released during sexual activity, and, as a result, sexual function is adversely affected [67]. Studies have demonstrated that erectile function is better preserved in men who have a bilateral vs. a unilateral nerve-sparing procedure, as is also the case with a unilateral vs. a non-nerve-sparing procedure [68,69], early post-RP presentation, young age, and absence of vascular comorbidities [50,51,70].

Long-term ED after RP is often treated with a variety of oral and non-oral therapies, including VEDs [45,66,71]. Gontero et al. [72] evaluated the use of a VED for ED in patients who had a non-nerve-sparing RP. A total of 52% were considered responders when the response was defined as complete tumescence sufficient for vaginal penetration. However, by combining treatments with different mechanisms of action for restoring erectile function, there is a better chance for obtaining a more optimal response than using monotherapy. Thus, the PDE5i, which require nerve involvement, may work suboptimally in a patient who has some residual nerve function. Combining this with a vacuum device that is not dependent on nerve function but acts mechanically to increase blood flow should provide a better response than the PDE5i alone.

Engel [73] studied men who had a nerve-sparing RP and were treated either with the PDE5i tadalafil or a combination of tadalafil and a

VED. After 12 months 92% of combination patients vs. 57% of tadalafil patients answered yes as to whether the erection was sufficient for vaginal penetration, while another 92% of combination patients compared with 29% of tadalafil patients answered yes as to whether they had intercourse to orgasm.

Baniel et al. [74] treated patients who developed ED after RP with a number of accepted therapies; treatment was initiated with a VED, which was followed by a PDE5i, ICI, and finally ICI plus VED; patients progressed to the next treatment only if they failed the previous one. Of 85 patients, 78 (92%) had an erection sufficient for vaginal penetration after VED.

As mentioned earlier, oxygenated arterial blood flow is important in the generation of NO and therefore the ability to have an erection. Vacuum devices act by increasing arterial blood flow and thereby the delivery of oxygen to the cavernosal tissue. By providing more oxygen a VED may have both an acute effect, i.e., erectogenic, and also a more chronic, healing effect on tissues and nerves that have been damaged by the surgical procedure. The VED has the potential to be a first-line therapy in the treatment of ED after RP and should be considered for early penile rehabilitation [75,76].

Other Uses

Sexual dysfunction is not infrequent in the male dialysis patient. Testosterone was administered to hypogonadal dialysis patients, with varied success [77] (Table 6). Vacuum devices were used by 26 of the patients with ED; 19 (73%) had full correction of their dysfunction. Penile discomfort was reported by five of the patients.

One issue that could affect use of the VED, especially in the elderly population, is the manual dexterity that is required to use the device. This has not appeared to be a major factor in whether a patient would accept a VED, and, as stated earlier, battery-powered pumps allow for more facile use in those with dexterity problems.

Table 6 Other uses

First author	Year	Population studied	N	Modality	VED efficacy findings
Lawrence	Am J Kidney Dis 1998	Dialysis patient who failed testosterone replacement	32	VED	• 26 elected to use the device and 73% reported full correction of erectile dysfunction with 6 patients (23%) continuing depot testosterone to maintain their libido

VED = vacuum erection device

Conclusions

ED can be successfully treated using a number of different oral and non-oral therapies. VEDs have been approved in the United States since 1982 and offer a viable alternative to oral PDE5i, injections and transurethral suppositories. The VED is non-invasive, relatively easy to use and, because most insurance companies cover the device it is economical. Studies have demonstrated efficacy in ED associated with a variety of conditions. Early penile rehabilitation after surgery for prostate cancer with the VED improves erectile function and penile length. Adverse events are transient and not serious. **The VED should be considered an attractive second-line therapy and, in some cases such as men who cannot use a PDE5i or in penile rehabilitation the vacuum device should be considered first-line treatment.**

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