

External Devices for Treatment of Erectile Dysfunction

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Treatment of erectile dysfunction may now be approached in a variety of ways. The hope is to provide a treatment that is reliable, safe, and effective as well as acceptable to the patient. Many men are not candidates for surgery and may fail or have contraindications to medical therapy. This article addresses the oldest available form of noninvasive device therapy for the restoration of erectile function.

Key Words: Erectile dysfunction; external devices; vacuum constriction devices.

Introduction

Although the success of surgical and medical therapy for erectile dysfunction (ED) has been documented, especially since the introduction of sildenafil citrate, patient demand for effective, noninvasive, drug-free management of ED has remained. As the world male population continues to age, acquiring the comorbidities commonly associated with ED, such as hypertension, diabetes mellitus, and atherosclerotic vascular disease, the demand for such treatment should persist. This chapter examines the development, mechanism of action, efficacy, and patient satisfaction regarding vacuum constriction and external erection devices.

The technique of applying negative vacuum pressure into the penis for ED was first prescribed by Dr. John King in 1874 (1). Over the years, multiple developments have ensued with improvements in design. Vacuum devices did not become commercially available until 1974, with the device known as NuPotent (2). Vacuum constriction devices (VCDs) are now recognized as one of the first-line therapies for the treatment of ED in the same class with oral treatments, hormonal therapy, and psychosocial counseling when indicated (3). Multiple devices have been developed and marketed, but as a result of a recent ruling by the Food and Drug Administration, VCDs can now be purchased over the counter, thereby reducing cost but, unfortunately, reducing the available services provided by the

manufacturers in the past. Regardless of the manufacturer, all VCDs consist of three basic components: (1) a vacuum chamber or cylinder, (2) a pump to produce the required negative pressure, and (3) constriction rings. The pump may be battery or hand powered. The constriction elastic rings are of various designs, and most manufacturers have produced shaped rings with a notch to be placed over the urethra to help reduce ejaculatory obstruction while keeping pressure on the corpora cavernosa.

Water-soluble lubricant is used to coat the penis and constriction rings. The rings are loaded onto the base of the cylinder. The cylinder is placed over the penis with the base held firmly against the patient's body to maintain an adequate seal (Fig. 1). Next, the pump is activated to slowly create negative pressure inside the cylinder, resulting in penile tumescence. Once the penis is adequately engorged, one or more of the constriction bands are pulled from the cylinder onto the base of the penis. The vacuum is then released through a valve and the cylinder removed. Constriction bands may be left in place for only 30 min to avoid the risk of injury owing to ischemia. The average time to obtain an erection through this process is 2–2.5 min.

The mechanism by which VCDs work has been evaluated. It appears that the tumescence within the penis occurs from passive flow of mixed venous blood, with the constriction rings preventing venous backflow of blood. The change in volume of the penis following VCD application is owing in part to intracorporal expansion, but at least 50% is owing to extracorporal engorgement (4–6).

Patient Satisfaction with VCDs, Adverse Events, and Contraindications

There have been numerous studies examining the efficacy as well as patient/partner satisfaction with VCDs. The great majority of these studies demonstrate that the erections obtained are satisfactory for vaginal penetration. Overall satisfaction with VCDs has been reported to range from 70 to 94%. However, most of these studies are the result of industry-supported trials based on return of questionnaires provided by the manufacturer.

Studies of VCD use have reported overall improvement in the sexual relationships of the participants, and the majority of partner surveys have also demonstrated satisfaction with this treatment for their partner's ED (7–9). Although high satisfaction rates have been documented, this is not

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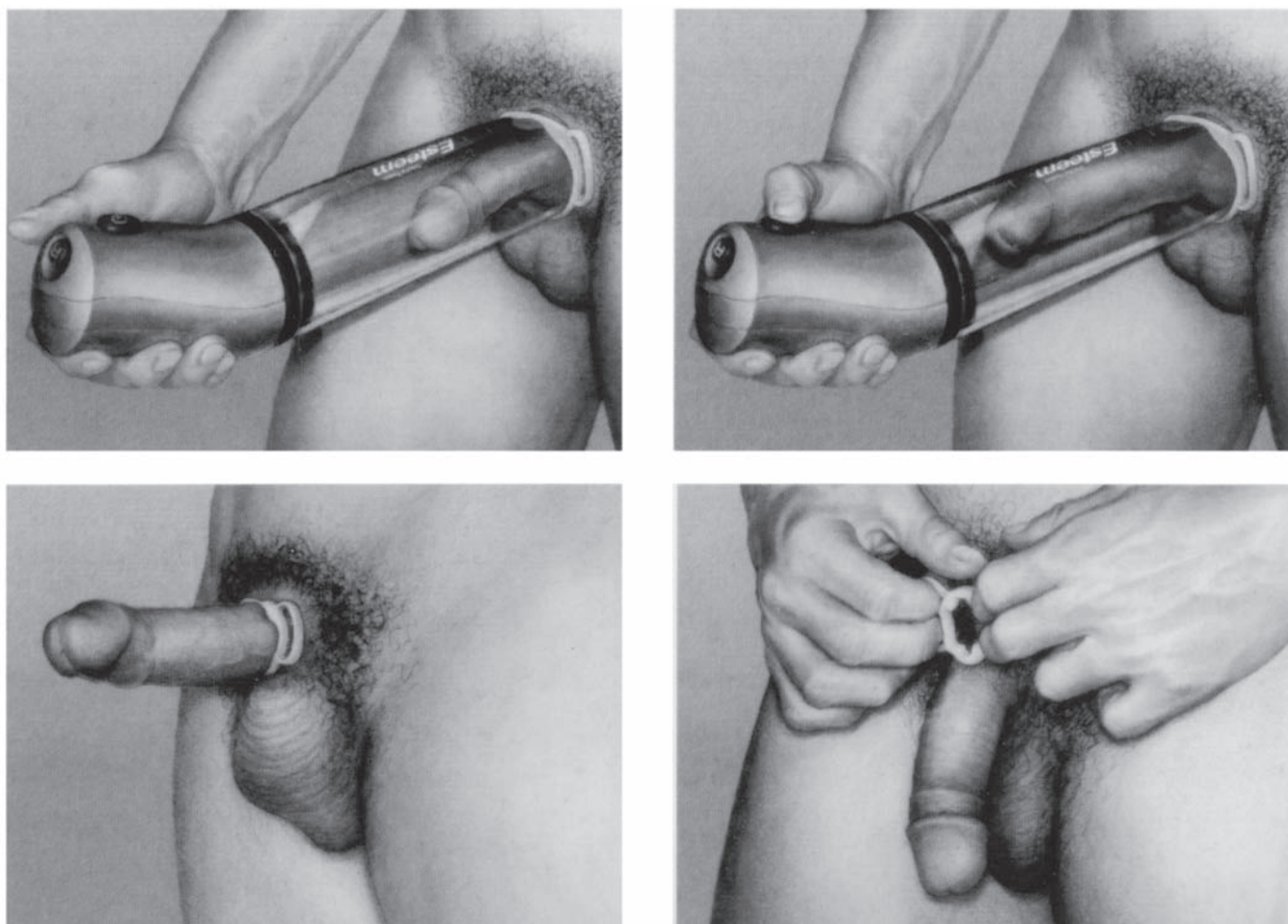


Fig. 1. Use of a battery-powered vacuum constriction device. Applying device, obtaining erection, applying constriction ring, and subsequent rapid detumescence when constriction ring removed. (Courtesy of Endocare.)

uniformly the case—there have been several published studies demonstrating satisfaction rates or ability to achieve a rigid penis in as little as 10–30% of subjects (10). In our center's experience, although 90% of men will obtain satisfactory rigidity and tumescence from their VCD, only 20–30% will be satisfied with the erections obtained using these devices (personal data).

The most common adverse events associated with the use of a VCD are those that ultimately result in decreased satisfaction with this approach. These include a change in skin color and temperature; pivoting of the penis at the base; pain during creation of the vacuum or with application of the constriction ring; inability to ejaculate; petechiae and/or bruising of the penis; numbness; and, most commonly, a sense that this approach lacks spontaneity and naturalness (11).

In addition to these complaints, a few serious adverse events have been reported in the literature, including only two instances of penile skin necrosis; development of Peyronie disease in three men; and rare reports of Fournier's gangrene, urethral bleeding, and herniation of scrotal tissue into the penile shaft (11,12).

Contraindications to VCD use are rare. Caution should be exercised in men receiving anticoagulation therapy and in those with bleeding diatheses. Men with impaired manual dexterity may have difficulty operating the devices, but a cooperative partner or a battery-operated device can certainly allow successful application of a VCD. Overall, it appears that men in stable relationships with a motivated, interested, and understanding partner seem to report the highest success rates with their devices.

Novel Uses of VCDs

VCDs have also been used to rehabilitate the penis in various circumstances. This includes after removal of an infected or defective penile prosthesis. The application of a VCD shortly after adequate healing time may prevent scar contraction resulting in loss of length and girth of the penis when used on a daily basis before fibrosis sets in. In fact, the use of a VCD in this circumstance may be all that is necessary to be able to engage in sexual activity again and may allow for increased ease of placement of a penile prosthesis at a later time (13). VCDs have also been anecdotally

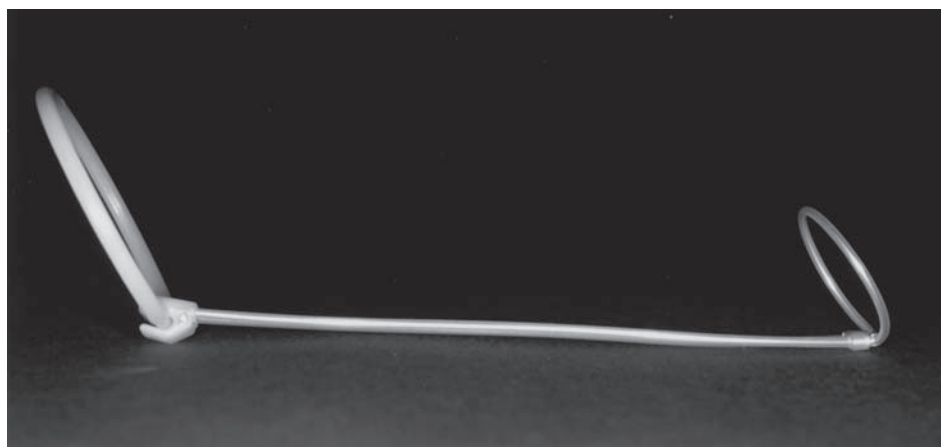


Fig. 2.



Fig. 3.

reported to straighten the penis when used on a daily basis in men with deformities associated with Peyronie disease. Only one unpublished study demonstrated such benefit in a small series of men with minimal deformity. In my own experience, the apparent straightening of the penis associated with a VCD may be owing to masking of the deformity of the tunica albuginea because of extracorporal engorgement.

Finally, it has been recommended that VCDs be employed shortly after radical prostatectomy as a form of rehabilitation to enhance return of erectile function (14). Although there is theoretical support for the use of VCDs as a form of rehabilitation following radical prostatectomy, evidence to this effect is very limited at this time.

External Penile Splints

There exists a subpopulation of men with ED who find that all of the available treatment options are unacceptable because of pain, inadequate erectile response, and/or their inherent unnatural approach. Further, some of these men may not be surgical candidates owing to medical contraindication or may simply refuse penile prosthesis placement as an option when all nonsurgical therapies fail. External penile splints have been available since the early 1900s, but their use and acceptance has been hampered by unnatural design. Devices have not been medically tested and have been historically quite unsightly and unnatural in their appearance. As a result of multiple components that may separate during coitus, the device can make intercourse uncomfortable and possibly painful. An external penile support device (EPSD) was developed and patented in an effort to provide an improved option to this group of difficult-to-treat patients (Figs. 2 and 3). In one trial presented in 1998 of 17 men with ED, adequate actual rigidity was reported in all men measured with a rigidometer (15). Improved ability for vaginal penetration was noted in 88%, and overall satisfaction with the device was reported in 82% of the patients and 71% of partners. There were no reported injuries to the patient or the partner. However, the devices become dislodged during coitus in 35% of men, a problem stemming from difficulties in establishing a design that would offer accurate sizing, which has led to the EPSD concept falling out of favor. In addition, lack of industry support prevented larger-scale trials. Therefore, although the EPSD is an intriguing and potentially effective treatment option, the need to precisely size this device for each individual has made mass production in its current form a difficult hurdle to overcome.

Conclusion

Vacuum constriction devices provide a satisfactory erect-like state in virtually all men who use this method. Unfortunately, it appears that many men do not continue this treatment for a variety of reasons. The risks of permanent penile injury or serious side effects are very low and there is growing evidence that vacuum therapy may be used following penile surgery or injury as a form of rehabilitation.

External penile devices such as those assisted by vacuum remain an important alternative approach for the motivated man with ED who would like to resume sexual relations without the use of drugs or a surgically placed device.

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