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External vacuum therapy for erectile dysfunction: use and results

Summary This review assesses the continuing role of noninvasive vacuum therapy as treatment for erectile dysfunction and discusses the action of negative pressure in producing assisted erection. Though recent research in this area has centered on the development of pharmaceutical therapies, vacuum-therapy programs appear to be a consistent long-term option for patients experiencing either chronic or occasional impotence of any etiology. Very little testing is required before the initiation of vacuum treatment, and the overall clinical success rate is approximately 90%. Significant success has been reported in more difficult patient populations, including those with veno-occlusive disorders and explanted penile prostheses. Vacuum therapy may also be used in conjunction with other therapies to enhance results. Contraindications to the use of vacuum therapy are few and primarily include patients with unexplained intermittent priapism and bleeding disorders. Side effects such as occasional numbness, pain, penile bruising, or petechiae have a low incidence. A recently reported survey of 5,847 vacuum users showed that 83.5% of patients continue to use the device for intercourse as desired. Patients should receive individual instruction in the use of these devices and should expect a learning or practice period to achieve optimal results. As newer treatments for erectile dysfunction gain increasing attention, it should be kept in mind that nearly every patient showing impotence of any degree or duration as well as patients who have failed other therapeutic choices are candidates for vacuum therapy.

The modern treatment of erectile difficulties with vacuum pump and tension rings was developed in the 1960s by Geddings D. Osbon, Sr., an Augusta, Georgia businessman, who found that there was no medical treatment option at that time to meet his personal need for erectile assistance. By 1974 he had formed a company to market his device, and in 1982 the federal Food and Drug Administration granted to Osbon the first permission to market and distribute a noninvasive treatment for impotence.

Though the method met with early skepticism within the medical community, two urologists, Drs. Perry Nadig and Roy Witherington, were instrumental in the medical acceptance of external vacuum therapy, which today is prescribed for approximately 150 000 patients annually. Nadig et al. [16] and Witherington [22] made the first scientific presentations and later published the first two articles evaluating this type of therapy for erectile dysfunction in 1986 and 1989, respectively.

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Eligible patients

Almost all patients suffering from erectile dysfunction are eligible candidates for vacuum therapy, as this treatment has an average effectiveness rate of about 90%, regardless of the etiology of the impotence [22]. In goal-directed therapy the vacuum-therapy option may be chosen by the patient, preferably along with his sexual partner, after the evaluating history and physical examination have been accomplished. After serious or life-threatening etiologies such as severe vascular disease have been ruled out, there is little need for further testing to determine the etiology of the erectile dysfunction if external vacuum therapy is the desired treatment. Also, for patients who desire further testing and for those who have failed other therapeutic choices, vacuum treatment is always an option for continued therapy.

Even patients who have experienced failure or removal of a penile prosthesis have been successful in subsequent use of the vacuum device [8, 14]. Moul and McLeod [14] reported that 71% (or 10 of 14) of explanted patients engaged in regular successful intercourse using a vacuum device, including 5 of 6 men who

had the penile prosthesis removed due to infection. In all, 6 of 11 (55%) patients in this study who tried home use stated that the vacuum device was much better or better than the previous penile implant. Korenman and Viosca [8] reported good success with the vacuum device in four of five patients who had a penile prosthesis explanted and enhancement of sexual activity in four patients with an indwelling semirigid implant. Other investigators have reported similar enhancement [18]. Many anecdotal reports confirm penile enhancement in patients who use vacuum therapy concurrently with penile implants (both positionable and inflatable). The vacuum device has also been recommended for patients with a veno-occlusive disorder, with 20 of 29 patients (69%) reporting success, and as enhancement to intracavernous pharmacotherapy [2, 3, 11].

Patients who have severe penile scarring of the corpora cavernosa (due to priapism or a severe intracavernosal infection associated with a penile prosthesis) may not obtain full penile engorgement with the vacuum device [13]. Some patients with Peyronie's disease who have a severe curvature with penile erection cannot use the vacuum device because of the lack of freedom of movement of the penis within the vacuum cylinder. Relative contraindications to the use of vacuum therapy for erectile dysfunction are few and include patients with a history of unexplained intermittent priapism or diseases rendering them prone to priapism and those with bleeding disorders, particularly those with enhanced capillary fragility. However, patients on well-controlled anticoagulant therapy have been shown to be at no added risk using vacuum therapy [10]. If the patient has severe phimosis, a circumcision may be necessary before he can successfully use the vacuum device.

Vacuum therapy – types and use

The different manufacturers and brand names of vacuum devices offered in the United States market are listed in Table 1. One paper compares the responses to various devices among novice and regular users [17]. Differences among the individual devices are presented herein as each of the components is described in the following discussion. Although the cost may vary according to quality and geographical region, one of the larger companies cites a complete program of patient support as justification for the higher cost of its units. The program includes availability of a 24-h telephone line for consultation by a trained professional staff as well as prepurchase, in-office education and training sessions for individual patients. Proprietary data show that education, training, and continuing patient assistance greatly aid in long-term patient satisfaction with this type of therapy [23], and other studies have noted the relationship of patient education and support to success [9, 21]. The soon-to-be-released American Urological Association (AUA) guidelines for treatment of impotence recommend individual instruction for each patient, starting with external vacuum therapy. Several of the companies listed provide some degree of telephone support, and most of these devices come with a video tape to demonstrate proper assembly, care, and use of the device.

The components of the vacuum system are essentially three: the cylinder, the pump, and the tension or occlusion rings (see Fig. 1). The cylinders are generally constructed of clear plastic, some of them tapering out distally, with a nipple-like extension for the attachment of plastic tubing to a hand-held vacuum pump. Some cylinders are open-ended at the distal end to allow for direct attachment of the pump, comprising a one-piece unit with a pump handle or with an outer pumping cylinder over an inner cylinder. Several companies also produce a battery-driven pump particularly designed for patients who lack the mechanical facility or strength to produce hand-motion pumping. Some companies provide different cylinder choices with each unit to allow for variance in penile size, whereas others use various optional inserts to modify the internal diameter of the cylinder. Some companies have larger cylinders available for the rare patient who obtains significantly greater penile circumference with application of the vacuum

Table 1 External vacuum devices

E/P System (NuMedTec, Inc., Encino, Calif.)
ErecAid System Classic (Osbon Medical Systems, Ltd., Augusta, Ga.)
ErecAid System Esteem (Osbon Medical Systems, Ltd., Augusta, Ga.)
Pos-T-Vac vacuum therapy (Post-T-Vac, Dodge City, Kan.)
Response/Touch vacuum constriction (Mentor, Goleta, Calif.)
VED vacuum erection device (Mission Pharmacal, San Antonio, Tex.)
VET vacuum erection technologies (Vetco, Birmingham, Ala.)
VTU system (Encore, Louisville, Ky.)

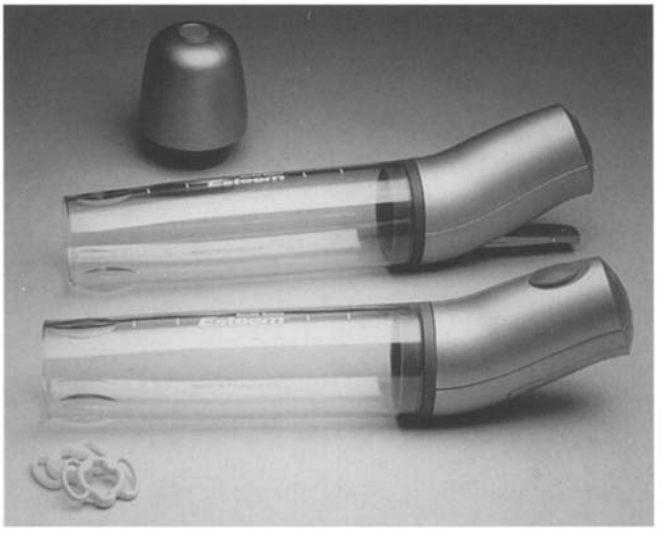

Fig. 1 Examples of two vacuum-therapy devices with (*top*) a tension ring loader to aid in the placement of tension rings on the cylinder and (*bottom*) tension rings (Osbon Medical Systems)

device. Larger cylinders may also be necessary for patients with severe penile angulation secondary to Peyronie's disease who have difficulty removing the cylinder once engorgement has been obtained.

As a safety feature built into the pump, most devices have a vacuum valve that activates after a certain negative pressure has been reached (300–350 mmHg). To produce adequate rigidity of the penis, the vacuum pressure must exceed 90 mmHg. All devices have a release mechanism built into the pump for release of the negative pressure when adequate penile engorgement has occurred and tension rings have been placed around the base of the penis. After use, all parts of the vacuum devices, except for the pump itself, can be submerged in soapy water for cleaning. Tension prostheses can be wide-width rubber bands, rings of varying size and tension, or plastic discs with a central opening. Some companies produce round tension bands of varying width, whereas another company produces rings molded to include a urethrasparing notch on the inside curve of the ventral position of the ring. Tension rings must have tabs or strings to ease their removal after use.

Several companies market constriction rings alone for patients who can achieve an initially good erection but cannot maintain rigidity. Examples are the Osbon StayErec System,[1] which comes with an applicator cone and plastic ring to facilitate placement of the tension ring around the base of the penis, and Pro-Long rings[2]

The patient assembles the device by placing the tension apparatus (sometimes using more than one tension ring) on the proximal end of the cylinder and connecting the pump to the cylinder on the distal end. He then lubricates the proximal open end of the cylinder with a water-soluble lubricant so as to obtain a better seal to the skin surrounding the base of the penis. If excessive public hair prevents a tight seal at the abdomen, the patient may have to shave or cut some of this hair. With one hand around the cylinder, the patient presses the device against the skin surrounding the base of the penis and begins to pump by hand or by activating the pump switch on the battery-powered model. If the cylinder design allows it, some users press the distal end of the cylinder against a table or counter to free one hand. Once adequate penile rigidity has been obtained, the preloaded tension rings are eased off of the proximal end of the cylinder and onto the base of the penis. The vacuum is released by a valve or button on the pump, the cylinder is removed, and the patient is ready for intercourse. It is recommended that the tension rings be left in place for no longer than 30 min.

The number of strokes necessary with manual pumping devices and the time needed to produce an adequate erection vary. Witherington [22] reported that the average time required to obtain a usable penile erection was 2.5 min (range 30 s to 7 min). Sidi and associates [18] reported that 88% of 100 patients obtained optimal tumescence and rigidity within a period ranging from 30s to 2 min. Intermittent pumping may result in a more engorged penis, producing more satisfactory rigidity for vaginal penetration. Many manufacturers advise the patient to pump for 1–2 min, release the pressure, and then pump again for 3–4 min.

The assisted erection obtained with a vacuum device is slightly different from an erection obtained normally in that there is no initial relaxation of the sinus smooth muscle within the corpora cavernosa. Instead, all tissue of the penis becomes engorged with trapped blood, which has been drawn into the penis by the action of negative pressure. In some cases the actual penile size (especially the glans) achieved by vacuum-assisted erection is larger than that obtained with a natural erection. Because the buried portion of the corpora cavernosa may not become tumescent proximal to the tension ring, there is some lack of fixation of the penis as compared with a normal erection. The penis may become slightly cool or numb and may become slightly bluish in color due to cyanosis. Some partners are unhappy with the coldness of the penis and the need to use lubricating jelly.

Pain with penile engorgement and application of the vacuum device is rare, mostly of a mild nature, and usually not a concern for the patient. Pain with ejaculation related to trapping of the ejaculatory fluid is extremely rare. With orgasm and ejaculation there may not be expulsion of fluid from the penis because of the tension apparatus around the shaft of the penis. This is not always the case (30–40%) but is commonplace and does not present a problem, especially if the patient has been forewarned. When the rings have been removed after intercourse and ejaculation, the seminal fluid will usually run or drip from the penile meatus. Recorded data from one manufacturer's patient assistance line shows the relative frequency of some of these user concerns (see Fig. 2).

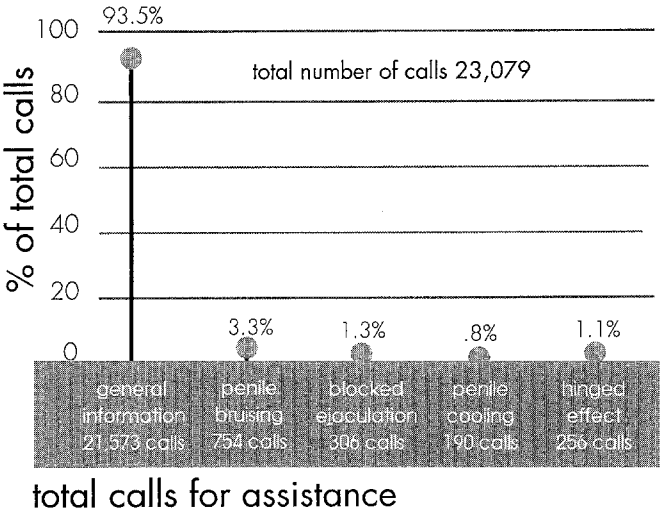

Fig. 2 Data from one manufacturer's patient assistance line, showing the relative frequency of some user concerns

[1]Osbon Medical Systems, Augusta, Ga., USA

[2]NuMedTec Inc., Encino, Calif., USA

It is recommended to the patient and his partner that the device be used in practice sessions before attempts are made to have intercourse, since some practice is needed for facility of use. The videos supplied with the devices are quite helpful in answering problem questions and, as mentioned above, some companies maintain health-care professionals available by telephone for help during use of the device. The treating physician should recommend that the patient use these services when they are available.

Results obtained using the vacuum device

As mentioned above, Dr. Perry Nadig published one of the first scientific reports regarding vacuum therapy for impotence, originally working with Geddings Osbon and the Osbon device before developing his own variation of the Osbon device. He has continued to update his patients' results [15, 16]. His most recent review, published in the *Journal of Urology* in 1993, compared the results obtained in two groups: group 1, responding to a short-term evaluation (with an average follow-up of 3 months), and group 2, responding to long-term evaluation (with an average 29-month follow-up) [4]. Regular use was reported in 69% of group 1 and 70% of group 2. Rates of patient and partner satisfaction were 82% and 87% for group 1 and 84% and 89% for group 2, respectively. The overall quality of erection was greater than 90% in both groups for the following three parameters: hardness of erection, length of penis, and circumference of penis. The median number of occurrences per month of successful intercourse were one, four, and four for the year before, during, and after acquisition of the vacuum device in group 2. It was felt by the authors that this study substantiated data shown by previous reports that regular use of the vacuum device is continued by the majority of patients who use the device successfully for 3 months.

Nadig stated that the following side effects were reported in groups 1 and 2, respectively: (1) occasional numbness, 48% and 49%, and numbness as a major problem, 6% and 5%; (2) increased climax or orgasm, 38% and 50%; (3) decreased climax or orgasm, 23% in both groups; (4) pivoting of the base of the penis, 35% and 29%; (5) bruising of the penis, 32% in both groups; (6) penile petechiae, 32% and 38%; (7) pain or swelling after device use, 16% and 28%; and (8) pain with orgasm related to the tension device, 19% in both groups. The last five side effects were often-occurring, or major, events in less than 6% of the patients in both groups. Nadig has stated that the most frequent complaint by men using vacuum therapy is the unnatural interruption of the act of love-making.

In 1990, Sidi et al. [18] reported a 68% success rate in 100 patients who used the Osbon ErecAid device and were followed for 2–14 months (average 7.9 months). In all, 11 patients continued to use the device but were neutral regarding satisfaction; 21% discontinued use of the device. Reasons for discontinuation included the following: inability to achieve and maintain a full erection (12); pain and discomfort (4); inconvenience and awkwardness of the device (4); and reasons not related to the device, such as poor health or marital problems (5).

In 1991, Turner and associates [19] reported the results of a year-long prospective study in which patients used the external device for treatment of erectile dysfunction. The results showed that 87% of 36 men achieved erections sufficient for intercourse. There was a 20% dropout rate [19].

Other investigators have not reported such good results. One study from the Netherlands found that only 22 of 72 patients considered vacuum-device therapy successful; however, as all of these patients had failed previous therapy, patient selection may have been a significant factor. None of the nine psychogenically impotent patients in this series liked the device as a treatment, although all acknowledged function. Of four patients in this series who felt that their Jonas prosthesis was too short, three were satisfied with the enhancement afforded by the vacuum [13]. In an earlier report, Gilbert and Gingell [5] noted only a 26.7% rate of satisfactory intercourse in 12 of 45 patients.

Recently, the Impotence Resource Center of the Geddings Osbon Foundation conducted a questionnaire survey of 34,777 registered owners of Osbon vacuum products. The survey was a stratified, disproportionate sample of owners (100% of owners acquiring the device between 1974 and 1988; 50%, in 1989; 35%, in 1990; 30%, in 1991; and 25%, in 1992). In all, 7,075 (20.3%) owners returned the questionnaire; 5,847 of the completed forms were considered valid, and results were compiled from those responses. When training and support were used, they were supplied by the prescribing physician for 24.9% of respondents, by Osbon's certified technicians for 19.8%, and by Osbon's telephone help line for 26.6%. Over 75% (76.8%) of the respondents remain continuous users, with 83.5% having sex as often as desired, 65.4% reporting an improved self-image, and 69.6% reporting an improved relationship with their partners.

Of 1,357 respondents who had ceased using the device, 42.9% reported a reason for cessation not related to the device (no partner, 17%; natural erections returned, 10.8%; health problems, 9.3%; no desire for sex, 5.8%). A total of 1,377 respondents ceased using the device due to dissatisfaction with the apparatus. The reasons given (more than one reason in some cases) were the following: inability to achieve an adequate erection, 42.7%; pain or discomfort, 40.9%; too much trouble, 35.9%; partner nonacceptance, 20.6%; and a switch to other treatments, 15.8%. In summary, if early use of the device is positive, it is sustained with training and support, which contribute significantly to patient satisfaction and continued use.

Witherington [22] published the first results of a retrospective survey of Osbon vacuum devices in 1989. In all, 92% of the 1,517 patients who used the device from 1974 to 1987 and mailed in a questionnaire reported

satisfactory erection, and 77% stated that they used it at least every 2 weeks. Patients reported that an average period of 1 week, with an average of four practice sessions, was required to gain facility for device use.

Gould et al. [6] presented a study comparing use of the external vacuum device with pharmacologic erection therapy. The following groups were studied: 21 men who had failed pharmacologic stimulation, 12 men who had successfully used pharmacologic treatment for at least 6 months at home, and 13 men who had never used pharmacologic treatment. In all, 71% of the first group chose continued vacuum-device treatment after 3 months of a successful trial at home; 58% of the 12 patients who had successfully used injection therapy elected to continue therapy with the vacuum device alone; and 62% of the 13 patients in the last group chose continued vacuum therapy [6].

Turner and associates [20] compared a group of 42 patients using self-injection with papaverine and phentolamine with a group of 36 patients using the Osbon ErecAid, following both groups for 12 months. Both treatments were used with equal frequency and rates of success, yet there was a 60% dropout rate for the injection therapy as compared with 20% for the vacuum device in this report [20]. In another publication by the same group the sexual, martial, and psychological responses of women to their partner's use of two different treatments, pharmacologic injection and vacuum tumescence therapy, were reported. Statistical analysis indicated that the women responded equally well to both treatments [1].

Complications from use of the vacuum devices are minor and rare. Some patients develop minimal bruising or petechiae of the superficial shaft of the penis. Some patients complain that scrotal tissue is drawn into the cylinder when the vacuum is applied. If the rings are left on for prolonged periods, there can be potential severe ischemic damage to the penis, though no such report exists in the literature. However, manufacturers nonetheless advise a time limit of 30 min for use of the tension rings. Skin necrosis was reported in a paraplegic man who used a vacuum device three times daily on 3 successive days [12]. Kim and Carson [7] reported development of Peyronie's disease in a patient who had used a vacuum device for 4 years on a weekly basis as a treatment for his impotence. However, no cause-and-effect relationship between vacuum therapy and Peyronie's disease has been established.

This review of the use and results of vacuum therapy suggests that this noninvasive treatment for impotence has become increasingly well recognized and widely accepted in both the medical community and various patient populations. As new therapies for erectile dysfunction are developed, external vacuum therapy will continue to play a significant role in the impotence treatment protocol.

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