SOMAerect: The Clinical Experience

1. Introduction

Erectile Dysfunction is a major healthcare issue that affects every one in 10 men, and up to 20% of men between the ages of 40-70. ED is defined as 'the persistent inability to attain or maintain a penile erection sufficient to permit satisfactory sexual performance'.⁽¹⁾

The prevalence of ED increases with age and is especially high among men with chronic conditions such as diabetes, hypertension, and cardiovascular disease. ED is a serious condition that should be treated, as it can cause considerable distress and reduced quality of life. (2)

SOMAerect Vacuum Therapy devices offer patients a safe, non-invasive, non-pharmacological means of treating their erectile dysfunction problem. Clinical Studies have consistently shown that Vacuum Therapy is more effective than any other treatment option for ED being effective in over 90% of cases. (3,4,5,6,7)

"The outcomes balance sheet shows that about 75% of those who obtain a Vacuum Therapy Device (VTD) continue to use it regularly". (8,9) The majority of men report satisfaction with penile rigidity, length and circumference; frequency of intercourse; and partner satisfaction. (10) They also report improvement in self-esteem and sense of well-being.

In one study, Patient and Partner satisfaction were 84% and 89% respectively in a group of 115 men followed from 11 months to 63 months (mean follow-up 29 months). (11)

2. Safety

The Medical Grade erection maintenance rings supplied with all SOMAerect devices carry a CE mark and are designed so that they DO NOT stop the flow of blood into or out of the penis. They merely maintain an equilibrium in blood flow when the penis is fully rigid. Two studies used plethysmography to verify continuing blood flow during use of an erection maintenance ring to maintain a vacuum induced erection. (12,13)

Thirty minutes is a very safe time limit for wearing the erection maintenance ring. Users are encouraged to stay within this recommended time limit. In a number of published clinical studies, patients who had worn a medical grade erection maintenance ring carrying a CE mark for longer than 30 minutes did not damage their penile tissues.

3. Contraindications

Vacuum Therapy systems are contra-indicated for patients with sickle cell disease, multiple myeloma, hodgkinsons lymphoma or any blood dyscrasia that carries a risk of clotting or priapism.

4. Eligibility for NHS Prescription

SOMAerect Vacuum therapy devices and accessories are available under Schedule 11 restriction of the NHS (General Medical Services) Regulations 1992 (Part IXA Drug Tariff: Appliances).

Patients who suffer from one of the following medical conditions qualify for NHS prescriptions:

5. Schedule 11 Criteria

Diabetes – prostate cancer - prostatectomy -Multiple Sclerosis – Parkinson's Disease – poliomyelitis — radical pelvic surgery – severe pelvic injury – renal failure treated by dialysis or transplant – single gene neurological disease – spinal cord injury – spina bifida.

6. Patient Selection

Contraindicated for drug treatment
Drug therapy ineffective
Patient unable to afford drug therapy
In combination with drug therapy
Chronic E.D.
Peyronies disease
Reverse penile tissue shrinkage and circulation reduction (non-use atrophy).

7. Writing an NHS Prescription

Prescriptions must be written on an FP10 and marked 'SLS' (Selected List Scheme), including the name of the device, order code, and if applicable, PIP code.

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CLINICAL STUDIES AND DATA

1. Penile Revascularization, Penile Health & Prevention of Erectile <u>Dysfunction</u>

Revascularization is defined as "the restoration of an adequate blood supply to a part, as by means of a vascular graft or prosthesis". (9)

Vacuum Therapy use produces "a significant increase (in the penile-brachial pressure index) following six months' use". (10)

"The patients who underwent Vacuum Therapy daily showed, at the end of the treatment (6 months), a significant improvement in spontaneous erectile ability" (11)

"Of 1,517 patients prescribed Vacuum Therapy and participating in a follow up survey, 92.35% Recommend the therapy to other men with Impotence; 91.82% Report that the therapy provides a 'hard' or 'firm' erection; 57.54% credit the therapy as being "The Most Positive Thing In Years" in affecting their Self-Image; 25.04% Credit the therapy as allowing them to perform Occasionally without use of an aid; and 17.86% Credit the therapy with the restoration of natural potency." (12)

Vacuum Therapy use resulted in "statistically significant improvement in the spontaneous capacity for erection after use of the device for six months. No relationship was found between quality of spontaneous erection and etiology of erectile difficulty: subjects in the organic, mixed and psychogenic erectile failure groups all reported equivalent improvements in spontaneous erectile capacity. Interestingly, similar improvements in spontaneous capacity for erections have not been reported in any studies of Intracavernous injection therapy." (13)

SOMA-Therapy-ED® technology serves as an "external prostheses" to "restore adequate blood supply causing revascularization of penile vascular tissues and "restoration of an adequate blood flow to (the penis)". This allows spontaneous erections to reoccur, serves as an aid to create functional erection for sexual intercourse, and as a therapy to overcome problems of penile atrophy associated with the absence of nocturnal penile tumescence.

2. Nocturnal Tumescence Therapy

"The duration and extent of nocturnal penile tumescence and rigidity at the start and the end of the study (using vacuum therapy) improved. Patients reporting spontaneous morning erections showed significant improvements in total erection-time, erection-phase and plateau-phase duration, effective rigidity and tumescence increase." (14)

"SOMATherapy-ED® helps to keep the penile vascular system healthy by drawing in oxygen rich blood. There can be a case made that any man who has long-term plans to remain sexually active will benefit from the therapeutic application of SOMA-Therapy-ED®. This ensures improved oxygenation of the vascular tissues."—J Osbon

3. A Safe, Effective, Spontaneous & Immediate Therapy

"...the safety profile of the properly used vacuum constriction device is unblemished; for these reasons, vacuum constriction devices should be offered initially to patients who have no discernible correctable cause of impotence."

"Because of its safety record and low expense, I recommend a vacuum constriction device to all of my patients (except those with coagulation disorders and sickle cell trait) as an initial treatment option." (2)

"Vacuum tumescence therapy is an effective and simple treatment which requires little investigation." (3)

- "... (with)...penile plethysmography to estimate penile blood flow on ... before, during, and after the use of the constrictor ring. ... continuous blood flow was maintained in each case. Within sixty seconds after removal of the ring, the amplitude returned to baseline values for all men. These findings suggest normal penile blood flow, and indicate that the use of constrictor rings may be safe." (4)
- "... 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. A recently reported survey of 5,847 vacuum users showed that 83.5% of patients continue to use the device for intercourse as desired. 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" (27)

"This study was conducted in 272 patients with ED of various etiologies, with favorable results in 93.3%. 94% presented no complications, which were otherwise minimal (pain, haematoma) in the rest, 94% were in favor to using vacuum as therapy. This study demonstrates that vacuum is an effective methodology free from complications which allows application in most ED patients, its inclusion as a routine study of signs and symptoms of ED appearing to be very useful." (29)

"The effectiveness of vacuum-assisted erection devices was evaluated in a prospective trial involving 18 men with erectile dysfunction. The patients were reviewed at 1, 3 and 6 monthly intervals by the same interviewer using a standard questionnaire. Sixteen patients (88.9%) were able to attain satisfactory erections. The overall satisfaction rate was 83.3%. Sixteen patients (88.9%) found the device easy to use. Thirteen patients (72.2%) were able to master using the device in less than one week, and 11 patients (61.1%) were able to get it working at the first attempt." (30)

4. Vacuum Therapy Improves the Effectiveness of Viagra®

".... Ongoing multi-institutional study to assess the enhancement effect of addition of vacuum erection devices (VED) without the use of constriction rings for patients on the maximum dosage of Sildenafil (Viagra). Sixty-one "patients who had a previous partial response to the 100 mg of Viagra were qualified for the study ... Each patient in the study received individual training in the use of the vacuum device. Of the 55 patients completing the study, 54% reported enhancement of penile rigidity for satisfactory intercourse with addition of VED." The results.... showed that the addition of the vacuum device enhanced penile rigidity and sexual satisfaction in a statistically significant number of participates. Satisfaction rates increased for both the patient and his partner, as did rigidity ratings. Patient satisfaction ratings increased approximately 25% (from 3.5 to 4.2 on a scale of 1-5) while rigidity ratings increased over 40% (58.9% to 84.6% on a scale of 1-100) ".... most of the patients studied continued to use the (vacuum system therapeutically) along with their Viagraa, However, a subset of men chose to use the vacuum with the tension ring alone, probably because of the expense of Viagra tablets.".... (conclusion) "This study provided substantial evidence that the combination of Viagra and VED without use of constriction rings can improve penile rigidity and increase patient's satisfaction for intercourse." (22)

"SOMA-Therapy-ED® creates erection immediately and is more spontaneous than any drug treatment. Spontaneity is a topic that gets a lot of rhetoric and little substance from the drug people. What they avoid discussing is the pre-medication and post-medication routine required for all drug therapies. When these

time restraints are factored into the "window of opportunity" for intimacy, and consideration is given to the unknown extent and duration of the drug, planning becomes an important part of the equation. Planning is just the opposite of spontaneity." - J Osbon

5. Patient Preference: Viagra vs. Vacuum Therapy

"We evaluated the preference of patients with erectile dysfunction who had been effectively treated with a vacuum erection device and then switched to Sildenafil ... 36 (of 52) participants in whom the efficacy of Sildenafil was similar to that of a vacuum erection device 12 (33.3%) decided to resume use of a vacuum erection device while 24 (66.6%) preferred to continue Sildenafil.... The adverse side effects of Sildenafil were the main reason for preferring a vacuum erection device. Even in an era of effective oral medication, the vacuum erection device remains a preferred treatment option for a substantial number of patients with erectile dysfunction." (23)

6. Patient Preference: Vacuum Therapy vs. Intracavernous Injection

"... study conducted on 200 patients with ED of different etiologies, included the vacuum test and the Intracavernous injection of vasoactive drugs. The assessment included the response to each methodology; which of the two systems offered better response; and initial usage readiness to each system. Positive response was 93% in the vacuum test, and 40% in the Intracavernous injection. Improved erection was reported by 73% with vacuum and only 13% with the Intracavernous injection. With regard to usage readiness 60.5% favored vacuum and only 14.5% the Intracavernous injection." (28)

7. Vacuum Therapy Success Following a Failed or Rejected Penile Implant

Of particular interest is the use of Vacuum Therapy with the most difficult patient possible, the "explant" patient. Following the insertion and removable of one or more penile implants due to infection, rejection, device malfunction or for other reasons and penile vascular tissue was destroyed; Vacuum Therapy was documented in the Walter Reed Army Medical Center Explant Study to successfully provide functional erection 91% of the time. (21)

8. Vacuum Therapy Success with a Penile Implant in Place

"After using the vacuum device to augment the erection, all reported increased rigidity and patient/partner satisfaction, and 11 of 12 described improved length and girth. Minimal complications were noted. Concomitant use of an external vacuum device and penile prosthesis was safe in this select population. The combination may be indicated in patients with penile prostheses who are dissatisfied with size and/or rigidity, and in those who refuse or who are poor candidates for prosthesis revision." (20)

"A challenging problem for a surgeon preparing for penile implantation is the optimum prosthesis size to insert into a penis that has been reduced in length and girth due to non-use atrophy. If the patient has experienced organic erectile dysfunction for an extended period of time he also has not experienced nocturnal erection. Nocturnal erection is nature's way of keeping the penis functional for reproduction and sexual needs. The loss of erectile function in most cases has diminished the flaccid size of the penis. This is sometimes referred to as the "senile-penile" syndrome." J Osbon

9. Injection Therapy vs. Vacuum Therapy

"Of particular interest was that over half of the patients who had successfully been treated with pharmacologic injections switched to the vacuum constriction device at the end of the study. The data indicate high levels of patient satisfaction with the vacuum constriction devices, even among subjects in whom prior alternative impotence therapy had been successful." (24)

"While the primary focus of any therapy developed for treating any disorder is safety and effectiveness, the patient using drug therapy for ED (oral, urethral, injectable, topical) is also very interested in predictability and control. Predictability & control are difficult if not impossible for any drug therapy." - J Osbon

10. Prostatectomy Recovery Therapy

"During the period of nerve recovery after radical prostatectomy, the penis is inactive and not stimulated, as it is not being engorged with blood during nocturnal erections. By inducing penile engorgement with the vacuum constriction device (VCD), corporeal fibrosis might be prevented, providing a quicker return to normal function."

(15)

"The natural recovery of erection function (after radical retro pubic prostatectomy) takes as long as 24 months and can be expedited by early treatment..... Sildenafil does not seem to be effective early in the recovery phase but increases in efficacy as the nerves recover from intraoperative injury..... Other modalities in the early recovery phase in the order of increasing effectiveness are intraurethral prostaglandin, the vacuum erection device, and intracorporal injection therapy. After 2 years from surgery, the recovery of natural function and improved Sildenafil responsiveness are unlikely....." (16)

"... Of the 85 patients, 78 (92%) responded to the vacuum erection device (with an erection sufficient for vaginal penetration) following radical retro pubic prostatectomy (RRP) for prostate cancer..." (17)

"Vacuum erection devices may be successful in restoring erections (after radical Prostatectomy)." (18)

11. Peyronie's Correction Therapy

- "... we studied the effect of vacuum therapy on penile curvatures and their associated fibrotic plaques ... more than half of the patients stated that their curvatures disappeared and their plaques softened....In patients with penile curvatures, who chose for a non-invasive treatment, the daily application of a vacuum device might be an alternative of choice." (5)
- "... 24... men underwent plaque incision and saphenous vein grafting with postoperative daily use of a vacuum erection device. ... Of the 22 patients in whom adequate follow-up data were available mean penile length was increased 2.1 cm. ..." (6)
- "... In my practice we have had equally satisfactory results with our combined injection (10 pg. prostaglandin El) and stimulation (vacuum Therapy) test." (7)

"We evaluated the results of chronic intermittent stretching with a vacuum erection device after circumferential tunical incision and circular venous grafting in 4 patients with penile shortening from severe Peyronie's disease... We advised patients to use a vacuum device on a daily basis for 6 months starting 1 month after surgery. Our technique offers a reasonable solution for correction of penile shortening in patients with Peyronie's disease." (8)

12. The SOMACorrect® Peyronie's Correction System

"The SOMACorrect® Technique for the treatment of Peyronie's involves a staging of multi-circumferential vacuum cylinders. Used therapeutically, the negative pressure stretches the Peyronie's scar tissue while the cylinders keep the penis from bending. The technique improves or eliminates penile curve and plaque buildup that is synonymous of Peyronie's. SOMACorrect® is an excellent therapeutic system to concomitantly use as part of any protocol for the treatment of Peyronie's." - J Osbon

13. Concomitant Therapy

"The adverse effects of vacuum therapy and Intracavernous self-injection in patients on warfarin do not exceed the rate in the general urological population. These therapies appear to be safe in patients receiving warfarin." (25)

"The vacuum tumescence device can be effective in the treatment of impotence after penile prosthesis explantation, in enhancement of inadequate girth with prosthesis in place, and after surgical or radiation therapy for prostate or colon carcinoma." (19)

"The therapeutic benefit of SOMA-Therapy-ED® improves the health of the penile vascular system and enhances the effects of oral, urethral, topical or injectable drugs. SOMA-Therapy-ED® can also be used when the patient is on drugs that might have negative interactions with ED drugs." - J Osbon

14. The Lowest Cost Therapy

Oral therapy for **one patient** @ £6 per tablet over a 5 year period (4 administrations per month for 60 months) = approximately £1440.

ICI alprostadil @ £12 per alprostadil 20microgram powder and solvent for solution for injection vials for **one patient** over a 5 year period (4 administrations per month for 60 months) = approximately £2880.

£1440 will treat almost **9 patients** on vacuum therapy in the same time -5 years.

£2880 will treat almost 18 patients on vacuum therapy in the same time -5 years.

"A treatment plan algorithm was developed from a MC perspective to model the initial treatment selection of various patient groups [vacuum erection device, intracavernosal injection (ICI) therapy, transurethral alprostadil suppository, Sildenafil, testosterone replacement therapy, penile prosthesis] and their therapy outcomes during a 3-year period. Overall cost was based on 1998 US dollars. Vacuum Therapy was projected to cost 3% of the cost of Sildenafil, 23% of the cost of transurethral Alprostadil Suppository, 61% of the cost of ICI Therapy and 63% of Testosterone Transdermal Patch." (26)

The Projected 3-Year Cost Of Treating 100,000 Patients

\$1,728,142 Viagra \$226,483 Muse \$84,624 ICI Therapy \$81,866 Transdermal Patch \$51,930 Vacuum Erection Device

That's why SOMA-Therapy-ED[®] is not only the safest & most effective treatment for ED; it is also the lowest cost. Many patients are able to obtain SOMA-Therapy-ED[®] at no cost to themselves (NHS Schedule 11 patients). iMEDicare provides comprehensive technical support & warranty.

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