

# The role of vacuum pump therapy to mechanically straighten the penis in Peyronie's disease

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Accepted for publication 27 November 2009

Study Type – Therapy (case series)  
Level of Evidence 4

## OBJECTIVE

To assess the efficacy of vacuum therapy in mechanically straightening the penile curvature of Peyronie's disease (PD).

## PATIENTS AND METHODS

Modelling of the tunica albuginea has been shown to be possible during penile implant surgery and this principle has been applied as an alternative conservative therapy. In all, 31 patients with PD (mean duration 9.9 months; mean age 51 years, range 24–71) completed the study. Over a 12-week

period, the patients used a vacuum device (Osbon ErecAid®, MediPlus, High Wycombe, UK) for 10 min twice daily. The assessment at study entry and at completion after 12 weeks included the International Index of Erectile Function questionnaire, a perceived pain intensity score, stretched penile length measurement and the angle of penile deformity after an intracavernous injection with prostaglandin E1.

## RESULTS

There was a clinically and statistically significant improvement in penile length, angle of curvature and pain after 12 weeks of using the vacuum pump. Of the 31 patients, 21 had a reduction in the angle of curvature by 5–25°, three had worsening of

the curvature and there was no change in the remaining seven. The curvature was corrected surgically in 15 patients while the remaining 16 (51%) were satisfied with the outcome.

## CONCLUSION

Vacuum therapy can improve or stabilize the curvature of PD, is safe to use in all stages of the disease, and might reduce the number of patients going on to surgery.

## KEYWORDS

Peyronie's disease, penile curvature, vacuum pump therapy

## INTRODUCTION

Peyronie's disease (PD) is an inflammatory condition of the penis characterized by the formation of fibrous plaques within the tunica albuginea. Typical features of the condition include penile curvature, shortening, pain and a variable degree of erectile dysfunction. The cause is unknown, although abnormal wound healing due to minor sexual trauma in the presence of an underlying genetic predisposition would seem to be the most likely cause [1,2].

The prevalence of PD is 3.2–8.9% and is age-related (mean 53 years, range 19–83) [3,4]. The natural history of the disease shows that spontaneous resolution of the disease is a rare event. This can occur in 13% of patients but usually disease progression (40%) or stabilization (48%) is the rule [5,6].

Surgery is indicated when the disease has been present for  $\geq 12$  months, stable for  $\geq 3$ –6 months, and there is a deformity that makes intercourse difficult. The quality of erection determines whether a reconstructive procedure or a penile prosthesis implantation should be offered. Conservative treatment should therefore be offered with the aim of reducing the penile curvature and pain, and thereby preventing the need for surgery [7,8].

However, the conservative treatment of PD remains controversial. Several therapies have been tried, including oral, topical and intralesional agents, iontophoresis, and extracorporeal shockwave therapy. However, their efficacy remains questionable, as well-designed, placebo-controlled trials have failed to confirm favourable results [8–14].

Residual curvature after inserting a penile prosthesis for PD is adequately managed by the moulding technique [15]. This involves mechanical stretching of the tunica to lengthen it, thereby straightening the penis. This concept has now been applied to the conservative management of the disease by trying to mechanically straighten the penis with the use of a vacuum device.

## PATIENTS AND METHODS

In all, 41 patients were enrolled into the study (mean age 51 years, range 24–71); their mean (range) duration of PD was 9.9 (2–23) months. Exclusion criteria included severe erectile dysfunction not responding to phosphodiesterase-5 inhibitors or intracavernous therapy, the absence of a penile curvature, previous penile surgery and

FIG. 1. The Osbon ErecAid vacuum pump.

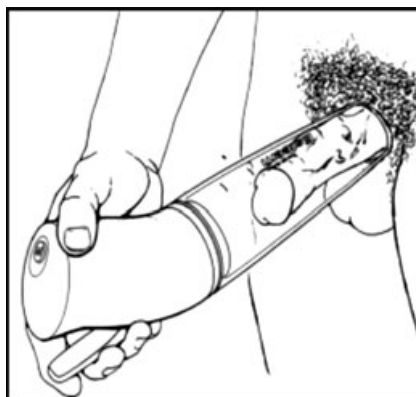


poor manual dexterity preventing the use of the vacuum pump.

After completing informed consent, all men had a full history taken and a detailed physical examination, to include a clinical assessment of the site, size and consistency of the plaque. The assessment at study entry and at completion after 12 weeks included: (i) A measurement of the flaccid stretched penile length dorsally from pubis to corona, and penile girth. (ii) The International Index of Erectile Function (IIEF) questionnaire was completed to assess erectile and overall sexual function. (iii) The perceived pain intensity was scored using a standard linear numerical scale rating (from 0, no pain, to 10, worst possible pain) with the patient marking the point along the line which corresponded to their current pain intensity. (iv) An intracavernous injection with prostaglandin-E1 (PGE1) to measure the direction and angle of curvature, using a protractor, after an adequate erectile response was achieved. The presence of a waist deformity or indentation was also noted.

Over a 12-week period, the patients used a vacuum device (Osbon ErecAid®, MediPlus, High Wycombe, UK; Figs 1,2) without the constriction ring, for 10 min twice daily to stretch the penis. The cylinder was applied to the penis and slowly inflated until the penis was erect and maintained in this position for 3 min. The vacuum was then released to allow the erection to subside and the process repeated over a 10-min period. Patients were encouraged to remain compliant with the protocol by 2-weekly telephone calls from the study nurse practitioner. The patients also completed a daily diary to monitor their pump

FIG. 2. The technique of application.



use and assess their compliance. This study had ethical approval from the local ethics committee.

The Wilcoxon matched pairs signed rank sum test was used to compare two groups of paired data [16]. The relationships between variables were investigated using Spearman's rank order correlation.

## RESULTS

Of the 41 patients screened, 31 completed the study; the reasons for excluding the other 10 were failure to attend the follow-up (four), failure to operate the pump (three), painful venous engorgement when using the pump (two) and a poor response to PGE1 (one).

The mean (range) penile curvature at presentation was 47.6 (10–95)°, with a waist deformity in nine patients. The mean (range) stretched penile length was 13 (10.4–16) cm. The plaque was hard in 20 patients and soft/fleshy in 11.

Analysis of the results showed there was a statistically significant improvement in the angle of curvature after 12 weeks of using the vacuum pump ( $P < 0.001$ ). Of the 31 patients who completed the study, 21 (67%) had a reduction in the angle of curvature by 5–25°, three (10%) had a worsening of the curvature and in seven (23%) there was no change in curvature (Fig. 3). The change in the angle of curvature after vacuum pump therapy was not significantly associated with patient age, the duration of the disease at presentation, the presenting angle of curvature or the presence of pain. However, nine of 11 of the patients with soft/fleshy plaques at

FIG. 3. Improvement in the angle of penile curvature.

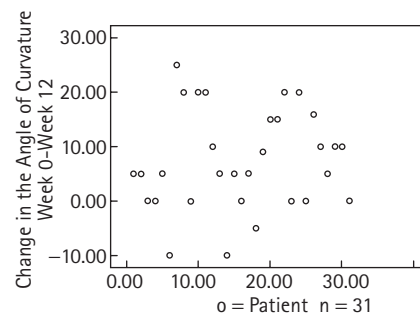
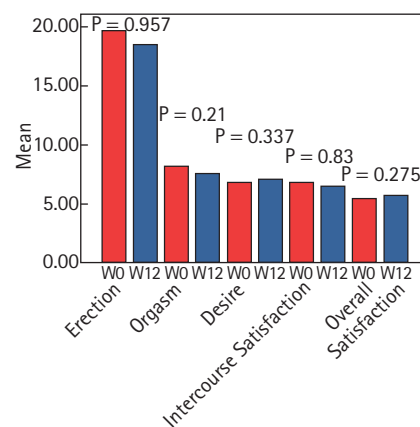


FIG. 4. Changes in the IIEF domain scores.



presentation had a reduction in the angle of curvature, compared to 12 of 20 for those with hard plaques.

Penile pain significantly improved from a mean pain score of 2.2 at presentation to 1 at the end of the study ( $P = 0.012$ ). There was an increase in stretched penile length in 11 patients, with a mean (range) of 0.5 (0.5–1.5) cm ( $P = 0.029$ ), although there was no change in penile girth or improvement in the waist deformity in the nine patients who presented with a waist deformity.

Erectile and sexual function did not significantly change, as identified in the IIEF domains (Fig. 4). At the end of the study period, 16 patients (51%) were satisfied with the outcome and wanted no further treatment, whereas 15 (49%) went on to have a surgical correction of the deformity.

Overall, the patients found the use of the pump acceptable and without complications. Minor bruising that settled spontaneously occurred in two patients who were aggressive

with pump inflation, and one patient occasionally found the pump painful.

## DISCUSSION

Several conservative treatment options have been used in PD, with no confirmed benefit in clinical trials [8–14]. In the present study we evaluated the role of vacuum pump therapy to mechanically straighten the penis in patients with PD. The rationale is that the regular application of this therapy would mechanically stretch the penis and cause remodelling of the fibrous plaque leading to straightening. Similar studies applying the principle of traction using the penile extender device have shown promising results [17].

The regular use of the vacuum pump stabilized or improved the curvature in 90% of the patients. This information would help patients, who are often worried about disease progression that can occur in up to half of patients [18]. Regular use also allows patients to become directly involved in their disease management, and this might be why the satisfaction rate with the outcome was 51%, as they avoided surgery.

The statistical analysis of the results identified no particular predictors of a successful outcome, and thus all patients should be allowed to try this form of therapy, even if waiting for surgery. Patients with a soft fleshy plaque had a higher success rate than if the plaque was hard. Although ultrasonography of the plaque was not used, it is possible that calcified plaques would be less likely to respond to this form of therapy. It therefore might be advisable to assess all prospective patients with ultrasonography before purchase of the device.

Penile pain resolves in most patients with time, even without treatment, so pain resolution in the present study might not be of significant relevance. Erectile function did not change over the 12-week period, although it was encouraging that all the patients attempted to have sexual intercourse. This therapy might therefore improve sexual motivation in an otherwise depressing condition.

The improvement in penile length is an encouraging feature and would fit with the improvement in the curvature that was achieved. This is the first study to describe the use of vacuum pump therapy in PD. Studies with more patients and with a more prolonged use of vacuum therapy are therefore needed in the future.

In conclusion, vacuum pump therapy might improve or stabilize the curvature of PD. Patients will become directly involved in their management, which might in turn improve sexual motivation. With longer term use, more patients might avoid surgery.

## CONFLICT OF INTEREST

None declared. Source of funding: Timm Medical.

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**Abbreviations:** PD, Peyronie's disease; IIEF, International Index of Erectile Function; PGE1, prostaglandin-E1.