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Penile traction therapy with the new device 'Penimaster PRO' is effective and safe in the stable phase of Peyronie's disease: a controlled multicentre study

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Objectives

To evaluate the efficacy and safety of a new penile traction device (PTD), 'Penimaster PRO', in a group of patients with stable Peyronie's disease (PD) compared with a non-intervention group in a multicentre study.

Material and Methods

A total of 93 patients with chronic stable PD (without erectile dysfunction, with no significant pain, and with a unidirectional curvature of at least 45° being stable for > 3 months) were recruited and followed for a 12-week period. Of these patients, 47 were randomly assigned to the Penimaster PRO group (PG) and 46 to the non-intervention group (NIG). Patients were asked to apply the PTD 3–8 h a day for 12 consecutive weeks, with specific instructions regarding the progressive increase of traction force applied to the penis over time. The primary outcome of the study was the change in the degree of curvature measured in the fully erect state after intracavernosal injection of alprostadil at baseline, 1, 2 and 3 months. Other variables, such as the type of curvature, stretched penile length (SPL), Peyronie's Disease Questionnaire (PDQ) scores, erectile function domain of the International Index of Erectile function (IIEF-EF) score and adverse events (AEs) were also assessed in each visit.

Results

Forty-one patients in the PG and 39 in the NIG completed the study. There was an overall reduction in curvature of 31.2° ($P < 0.001$) at 12 weeks compared to baseline in the PG, representing a 41.1% improvement from baseline, which significantly correlated with the number of daily hours the device was applied in a dose-dependent manner. Those patients using the device < 4 h/day experienced a reduction of 15°–25° (mean 19.7°, 28.8% improvement; $P < 0.05$), while patients using the device > 6 h/day experienced greater curvature reduction, ranging from 20° to 50° (mean of 38.4°, 51.4% improvement; $P < 0.001$). In contrast, no significant changes in curvature were observed in the NIG. Furthermore, SPL increased significantly in the PG compared to baseline and compared with the NIG, ranging from 0.5 to 3.0 cm (mean 1.8 cm; $P < 0.05$). The IIEF-EF score also improved in patients in the PG (by a mean of 5 points). Mild AEs occurred in 43% of patients, such as local discomfort and glans numbness.

Conclusion

The use of the Penimaster PRO PTD, a non-invasive treatment, should be offered to patients with stable PD for 3 consecutive months before performing any corrective surgery, as this provided a significant reduction in the curvature, an increase in penile length and a significant improvement of the symptoms and bother induced by PD.

Keywords

#Andrology, #Peyronies, Conservative treatment, Penile Curvature, penile traction therapy, Penimaster PRO, Peyronie's disease

BJU International © 2018 BJU International | doi:10.1111/bju.14602
Published by John Wiley & Sons Ltd. www.bjui.org

Introduction

The 2018 European Association of Urology (EAU) guidelines [1] states that there is 'level 1b' evidence for the use of intralesional clostridium collagenase (CC) and intralesional verapamil as part of the non-surgical management of the stable phase of Peyronie's disease (PD), but include only a 'weak' recommendation for penile traction therapy (PTT) at present, in view of the lack of adequate studies. Similarly the 2015 American Urological Association AUA guidelines [2] for stable PD with penile curvature >30° and no erectile dysfunction (ED) include a 'conditional' recommendation for intralesional verapamil (evidence strength Grade C), and a 'moderate' recommendation for intralesional interferon α-2b (evidence strength Grade C) and intralesional CC (evidence strength Grade B).

Various studies [3,4] have assessed the natural history of PD and have noted spontaneous improvement of penile curvature (without surgical treatment) in up to only 13% of patients. This usually occurs in the acute phase and not when the plaque is stable.

The use of conservative measures has a role in the stable phase of PD in patients who prefer a less invasive treatment. In this context, the application of intralesional CC has been shown to be effective in restoring penetrative intercourse, preventing the need for surgical intervention, based on patient-reported outcomes in patients with stable PD [5]. Although the efficacy of CC is limited, the results are clearly better when penile manual modelling or other forms of PTT were applied together with the injection [6]. Thus, it would seem reasonable to think that the PTT alone could be beneficial in the management of PD.

The application of continuous traction increases the activity of degradative enzymes. In *in vitro* studies, PTT decreases α-smooth muscle actin and increases matrix metalloproteinase activity within the treated tissue. Ultimately mechano-transduction (a cellular process that translates mechanical stimuli into a chemical response that leads to activation of cell proliferation) via tissue traction leads to collagen degradation and scar remodelling, as evidenced by the re-orientation of collagen fibrils in line with the direction of applied force [7,8].

Indeed, the PTT has been previously suggested as a non-invasive treatment and has been shown to have some efficacy in several non-controlled studies [9]. The International Society of Sexual Medicine Guidelines published in 2010 regarding the management of PD suggested that PTT, according to early evidence (from non-controlled prospective trials), led to a reduction of deformity and increased penile length [10]. Existing PTDs are based on the use of a silicone band that grasps the glans penis in the coronal sulcus, exerting its traction and 'strangulating' the glans penis [11,12]. The use of these types of PTD was accompanied by 25% of patients complaining about pain and discomfort in the penis.

A new penile traction device (PTD), the 'Penimaster PRO' (MSP Concept, Berlin, Germany) is now available. This system was marketed in 2011, but has only recently become available for medical use. The system is based on a vacuum cup that grasps the glans, exerting traction force through the entire surface of the glans, presumably making the traction less painful and better tolerated.

The present study reports the results of a prospective multicentre controlled trial using the Penimaster PRO for the conservative treatment of patients with stable PD. The aim of the study was to evaluate the efficacy and safety of this new PTD in a group of patients with stable PD compared with a non-intervention group.

Materials and Methods

Design

Between March 2016 and June 2017, 93 patients with chronic stable PD were recruited at six university hospitals and followed up during a 12-week period. The Ethics Committees of the participating hospitals approved the study protocol. All patients were fully informed and signed written informed consent. Inclusion criteria were: patients diagnosed with PD for at least 1 year, without ED, no significant pain and with a unidirectional curvature of at least 45°, stable for at least 3 months prior to inclusion into the study. Patients with hourglass deformity, complex curvatures or areas of tunical indentation were excluded from the study. Patients submitted to previous collagenase or any other intralesional treatments were also excluded.

Forty-seven of the patients were randomly assigned to the Penimaster PRO traction device group (PG) and 46 to the non-intervention group (NIG). Patients assigned to the PG were asked to apply the PTD for 3–8 h/day, preventing its use during sleep, for 12 consecutive weeks and specific instructions were given regarding the progressive increase of traction force applied to the penis over time (Table 1). Patients were also taught to remove the device every 2 h for

Table 1 Penile traction therapy schedule (At 4, 8, 12 weeks).

Adaptation period		
First 5 days	Initial size, no stretching	3 h/day
Days 6–10	+ 0.5-cm rod	3–6 h/day
Days 11–15	+ 0.5-cm rod	6–8 h/day
Evolution period		
2 weeks	+ 0.5 every week	6–8 h/day
4–8 weeks	+ 0.5 every week	6–8 h/day
8–12 weeks	+ 0.5 every week	6–8 h/day

30 min, or when they felt discomfort/numb, and then to massage the glans.

The Penimaster PRO is a novel PTD that allows the penis to be stretched for a period of time based on principles of tissue expansion. The device uses a unique gentle vacuum-based self-adaptive physiological mechanism for comfortable fixation of the glans penis (Fig. 1). In connection with the glans fixation device, the rod expander system generates the pulling force that allows stretching of the penis in an axially symmetrical manner (Fig. 2).

The patients were taught the importance of patience and perseverance in order to remain adherent to the protocol. To assess adherence, each patient was given a diary to record the number of times he used the device, with the specific duration each time and the total time the PTD was used. The presence of adverse events (AEs) and a sexual encounter profile also had to be recorded in this diary. In addition, a study nurse contacted all the patients weekly by telephone to ensure compliance with the protocol. Patients failing to use the PTD for at least 21 h/week (a mean of 3 h/day) were withdrawn from the study. Patients could also abandon the study voluntarily at any time. Patients assigned to the NIG received general information about the natural history of the disease and the treatment options but did not receive any active treatment during the study period.

Main Outcome Measures and Follow-up Visits

The baseline patient assessment included a full medical and sexual history, and physical examination. The following variables were recorded: age at diagnosis; duration of disease from the onset of symptoms (months) and time in stable phase of the disease (no penile pain, no further progression of the curvature); nature and degree of curvature after in-office intracavernosal injection of 20 μg alprostadil using a goniometer (mean of three consecutive measurements); stretched penile length (SPL), measured using a metal ruler from the pubis to the tip of the glans (the mean of three consecutive measurements); flaccid penile girth at mid-shaft using a flexible tape (mean of three consecutive measurements; Table 2).

A validated Spanish version of the Peyronie's Disease Questionnaire (PDQ) was used at every visit. Patients completed the PDQ during the baseline visit and at each study visit. The PDQ quantitatively assesses the physical and psychological symptoms of PD by providing information from

Fig. 1 Vacuum based glans chamber.

Fig. 2 Rod expander system.

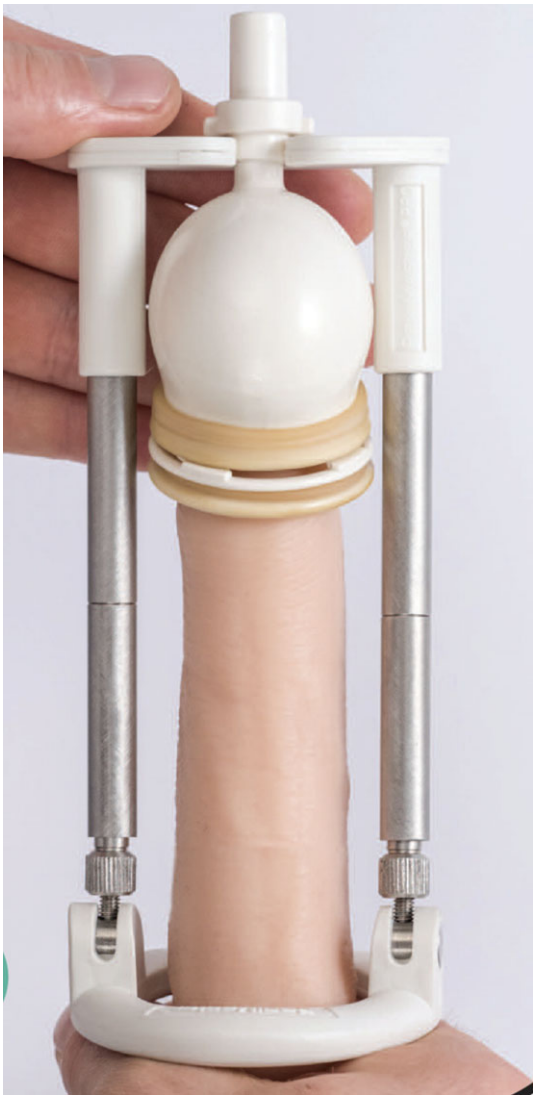


Table 2 Evaluation in all patients (at baseline, 4, 8, and 12 weeks).

Informed consent
Medical history
Sexual history
IIEF- EF questionnaire
PD history
Time from onset
Time stable
Examination of the flaccid penis
SPL
Penile circumference
Examination of the erect penis (after intracavernosal injection of alprostadil)
Curvature deformity measurement
PDQ
AEs

AE, adverse event; PD, Peyronie's disease; PDQ, Peyronie's Disease Questionnaire SPL, stretched penile length.

three subscale domains: PD symptom bother; PD psychological and physical symptoms; and penile pain. Erectile capability was assessed using the erectile function domain of the International Index of Erectile Function (IIEF-EF) questionnaire (cut-off score <21) and recorded for every visit.

We defined 'responders' to the PTT using the concept published by Levine *et al.* [13]: a 'composite responder' was a patient who experienced both a ≥20.0% improvement in penile curvature deformity and either an improvement in PDQ PD symptom bother domain score of ≥1 or a change from no sexual activity at screening to reporting sexual activity. Patients were assessed by an independent examiner in every centre who was blind to the assignment group of the patient. The change in the angle of penile curvature (at erection) was measured in degrees with the use of a goniometer and was considered the main outcome measure. This was measured after intracavernosal injection of 20 μg alprostadil, carried out in-office at baseline, 1, 2 and 3 months. Those patients who were unable to achieve a rigid erection in-office underwent maximum manual compression of the penile base to measure the exact angulation.

Statistical Analysis

The Wilcoxon signed-rank test was used to compare the first and second measurements of penile length and girth with baseline. Student's *t*-test was used for comparison of continuous variables and the chi-squared test for categorical data. A Cox proportional hazard univariable and multivariable analysis including relative risks and CIs was performed to identify predictive factors of treatment success. P values < 0.05 were taken to indicate statistical significance.

Results

Patient allocation is summarized in Fig. 3. A total of 80 patients completed the study protocol and were included in the efficacy analysis: 41 in the PG and 39 in the NIG.

Analysis of the baseline data is shown in Table 3 and all baseline variables (age, duration of symptoms from onset, duration of stable phase of PD, mean baseline curvature, SPL, penile girth and IIEF-EF score) were comparable in the two groups.

Effectiveness of Penile Traction Therapy

As shown in Fig. 4, there was a statistically significant reduction of the curvature in the PG compared with the NIG. There was an overall reduction in curvature of 31.2° (ranging from 15° to 50°), which represents a 41.1% improvement of the curvature compared with baseline. This reduction significantly correlated with the number of daily hours using the device in a dose-dependent manner.

Patients using the PTD < 4 h/day experienced a reduction of 15°–25°(mean 19.7°; $P < 0.05$), which was a 28.8% improvement in the curvature compared with baseline. Patients using the PTD > 6 h/day experienced a reduction of 20°–50° (mean of 38.4 degrees; $P < 0.05$), which was a 51.4% improvement with regard to baseline. The reduction in curvature was maximum at 3 months, although there were no statistical differences between 2 and 3 months (Figs 5 and 6).

Additionally, there was a significant increase in SPL in the PG compared with baseline, as well as when compared with the NIG, ranging from 0.5 to 3.0 cm (mean 1.8 cm; $P = 0.03$). Although there was an increase in the penile circumference from 11.3 (SD 2.2) to 11.9 cm (SD 2.9), this difference was not statistically significant compared with baseline or compared with the NIG ($P < 0.2$).

The mean (range) IIEF-EF score also improved from 23.6 (22–27) to 26.1 (22–29), but this difference was not statistically different compared with baseline and the NIG ($P < 0.23$).

Major changes were seen in the psychological and physical symptom domain of the PDQ (PS-PDQ) as well as the bother and distress domain (BD-PDQ), whereas there was no impact on the penile pain domain (PP-PDQ) score as patients were included in the stable phase of the disease with no pain. The PDQ-PS changed significantly ($P < 0.001$) from 12.3 to 7.8 (4–19) compared with baseline, and compared with the NIG in which there were no changes compared with baseline. In addition, the mean (range) PDQ-BD score improved significantly from 13.8 to 7.2 (5–16) Fig. 7.

Adverse Events

We observed AEs occurred in 43% of cases; they included mainly local discomfort and glans numbness. These AEs were mild in nature, short duration and were well tolerated. Only three patients (6.5%) discontinued the study because of an AE. There were two cases of glans oedema, which resolved

Fig. 3 Patient allocation.

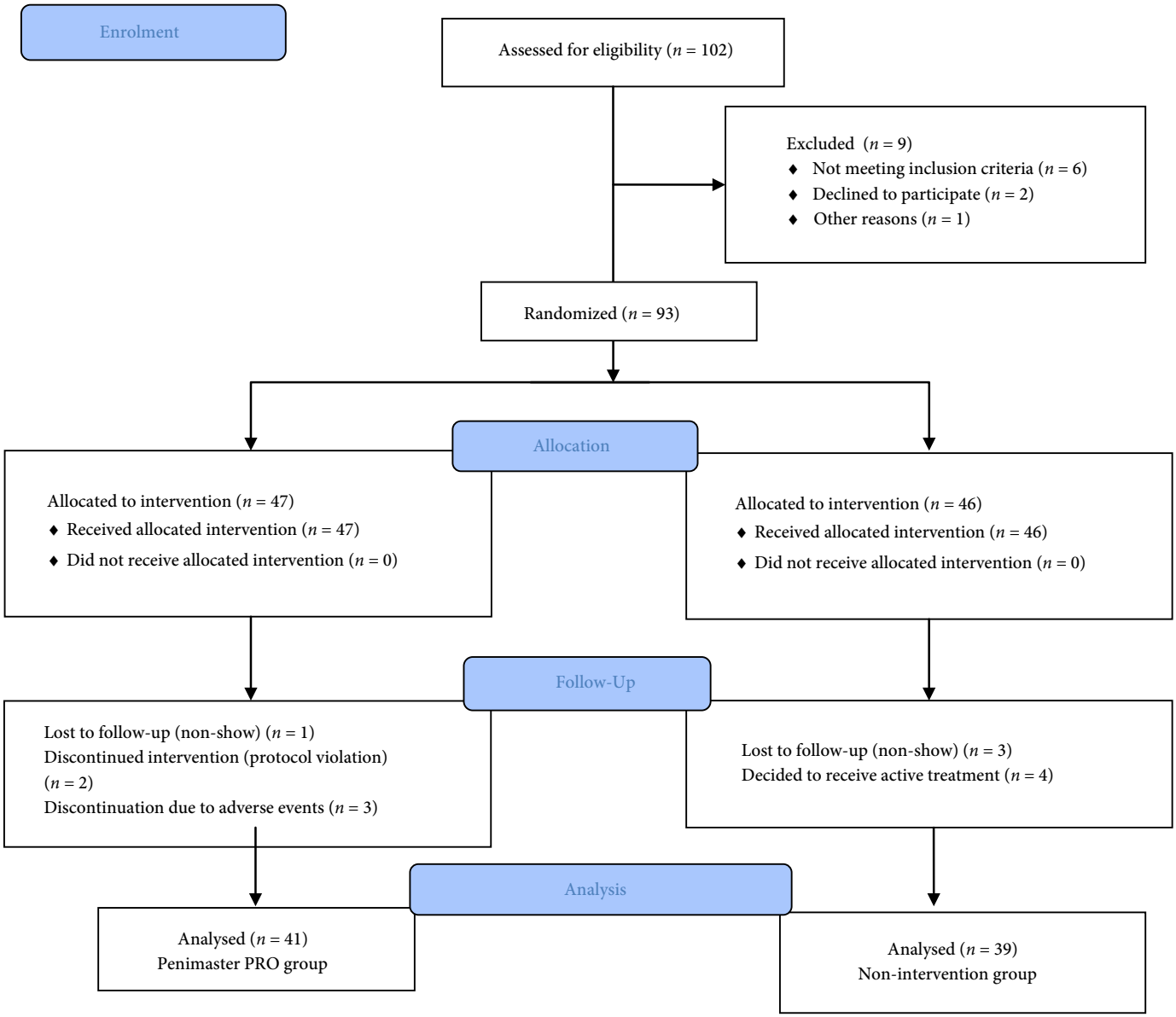


Table 3 Baseline demographics and clinical characteristics.

Variable	'Penimaster PRO' Group (PG) (*N* = 41)	Non-intervention Group (NIG) (*N* = 39)
Mean (SD) age, years	57.9 (11.69)	58.2 (11.57)
Median (SD) duration from onset of symptoms, months.	19 (6.3)	20 (4.7)
Median (SD) time in stable phase, months	8 (4.1)	9 (4.2)
Mean (range) degrees of curvature	72.3 (61–105)	68.7 (58–102)
Stretched penile length. Centimeters. Mean (SD)	11.9 (3.0)	11.2 (3.4)
Mean (SD) penile girth in flaccidity, cm	11.3 (2.2)	10.8 (3.1)
Mean (range) IIEF-EF domain score	23.6 (22–27)	22.9 (21–28)
Mean (range) PDQ-PS score	12.3 (6–26)	15.1 (8–28)
Mean (range) PDQ-PP score	0.4 (0–3)	0.5 (0–3)
Mean (range) PDQ-BD score	13.8 (7–23)	12.1 (7–21)

IIEF-EF, erectile function domain of the International Index of Erectile function; PDQ, Peyronie's Disease Questionnaire; PDQ-BD, Bother and Distress domain of the PDQ; PDQ-PP, Penile Pain domain of the PDQ; PDQ-PS, Psychological and Physical Symptom domain of the PDQ; PL, stretched penile length

Fig. 4 Efficacy data: changes in curvature.EOS, end-of-study; NIG, non-intervention group; PG, Penimaster PRO traction device group.

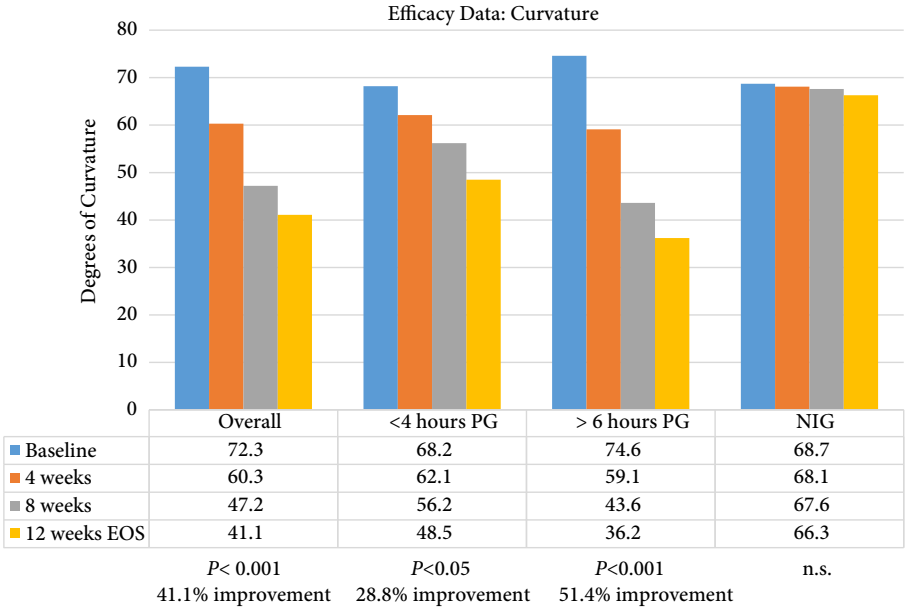
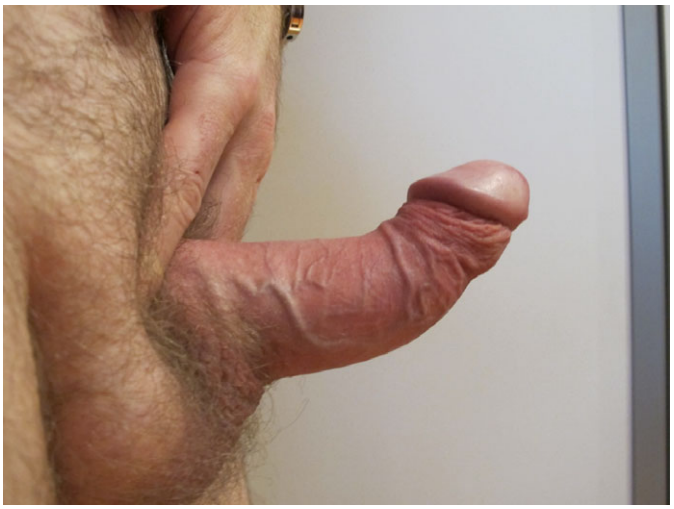


Fig. 5 Erection at baseline.

Fig. 6 Penile erection after 12 weeks.



with local conservative measures and after stopping PTT for 24–48 h, but both patients discontinued the study. One patient had significant penile shaft pain as a result of over-stretching the penis beyond the recommendation in the protocol and discontinued the study.

No cases of ED were reported.

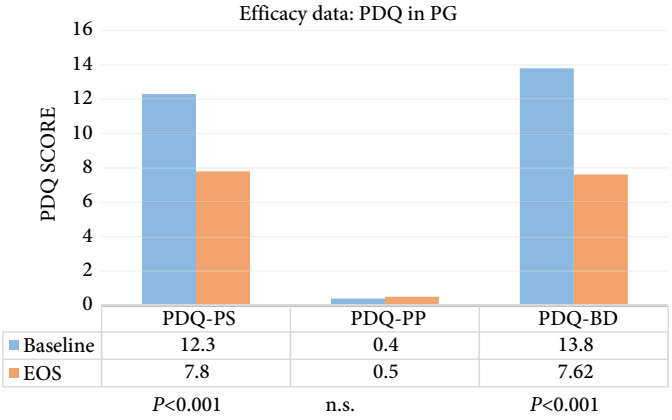
Discussion

The present study describes the role of PTT in the management of patients with PD in the stable phase, with the absence of ED. The results of the study showed that PTT using the novel device Penimaster PRO is both effective and safe. The use of this device for 12 weeks produced a significant correction of the curvature that was not only statistically significant but also clinically meaningful. A number of patients would be able to avoid surgery after the PTT or would require less invasive surgery.

Scroppo et al. [14] published one of the first reports of the use of PTT in patients with PD in 2001. They found significant improvement in SPL (+4.1 mm; $P < 0.001$) and a decrease in the angle of curvature (14°; $P < 0.001$) in patients who used the PTD for 4 h/day.

In 2007, Moncada-Iribarren et al. [15] published further evidence of the benefit of PTT in a randomized controlled trial

Fig. 7 Efficacy data: changes in Peyronie's Disease Questionnaire (PDQ) score in the Penimaster PRO traction device group (PG). PDQ-BD, Bother and Distress domain of the PDQ; PDQ-PP, Penile Pain domain of the PDQ; PDQ-PS, Psychological and Physical Symptom domain of the PDQ.



of daily PTT after definitive surgical management for PD. In a cohort of 40 patients, they noted that 8–12 h of daily stretching for at least 4 months resulted in a 1–3-cm increase in SPL. Also, Levine et al. [13] examined the role of PTT usage for 2–8 h/day for 6 months in 10 patients with chronic PD and found a 17° reduction in mean penile curvature and a 0.5–2-cm increase in SPL. Gontero et al. [16] published a study under similar circumstances and noted a 0.8-cm increase in SPL in patients who underwent PTT for 5–9 h/day.

Martínez-Salamanca et al. [17] published a paper in 2014 assessing the role of PTT in the acute phase of PD. In that study, PTT was safe and effective in the acute phase of PD in terms of pain reduction, penile curvature (reduction >10° in 36.4% of patients), overall satisfaction, sexual function improvement and avoidance of subsequent surgery in a substantial percentage of patients.

The design of the present study has several factors that need to be highlighted. Firstly, this was a 12-week follow-up study. We considered that if a patient was unable to see a positive effect (clinically significant correction) in 3 months of treatment then he would abandon the treatment anyway. The tissue expanders used in plastic surgery to harvest skin for grafting tend to be in place for a few weeks. Skin expansion is a common surgical procedure to gain extra skin surface through a controlled mechanical overstretch. When skin is stretched beyond its physiological limit, mechano-transduction pathways are activated. This leads to cell growth as well as to the formation of new cells. In some cases, this may be accomplished by the implantation of inflatable balloons under the skin and periodically, over weeks, injects a saline solution to slowly stretch the overlaying skin [18]. The time needed for stretching soft tissue with normal elastic properties is obviously significantly shorter than the time needed to stretch more rigid tissue. Fibrotic tissue present in PD plaques is probably more difficult to stretch, so we have suggested a 12-week period as a reasonable time limit; however, stretching a penis with PD will remodel the fibrotic tissue, which has less 'memory' than the normal elastic tissue. It is reasonable to assume that the penile lengthening effect would be lost some time after finishing the treatment, but this would not happen with the 'remodelling' of the penile fibrosis. Long-term clinical data on these patients are not yet available, but it would be interesting to know the percentage of patients who required surgical interventions later and the type of the surgical intervention.

The second important factor in the design of the present study was the use of a novel PTD, the Penimaster PRO. This PTD uses the same principles of traction to remodel the fibrosis of the penis in patients with PD, which is continuous and progressive traction; however, the difference is that it uses traction from the entire glans instead of the coronal sulcus alone. The system uses a vacuum cup in which the glans is grasped and a gentle vacuum that pulls the glans inside the chamber; a lubricating gel is used to maintain the surface tension. Then, the traction force is applied via a rod system (Figs 1 and 2).

There are no studies comparing the Penimaster PRO system with the classic coronal sulcus silicone band system to determine which one is better tolerated. The latter produces a blockade of blood circulation to the glans as a result of the strangulating band that holds the penis, making the system uncomfortable. The recommendation with these systems is to release the band for 30 min every 2 h and to massage the glans to avoid permanent numbness. The Penimaster PRO can be in place for several hours because there is no 'ischaemia' of the glans and patients very rarely complain about numbness or painful glans.

The magnitude of the curvature reduction correlated with the number of hours per day that the patient wore the device and with the number of visits. The curvature reduction was of 15°–25° (mean 19.7°) in patients with fewer hours (3–5 h) of device usage; therefore, as a mean, a patient with a curvature of 72° would end up with a curvature of 52° after 12 weeks of PTT. This reduction is statistically significant when compared with the NIG but barely clinically significant. Patients wearing the device for > 6 h/day, however, experienced a reduction ranging from 20° to 50°, with a mean of 38.4° compared with baseline. A patient with a 72° curvature would therefore end up with a 34° curvature (Figs 5 and 6), a 51.4% improvement that is statistically significant and clinically meaningful. Overall, 65.3% of patients showed a clinically meaningful improvement as they were considered 'composite responders'; 78.2% of those using the PTT for ≥6 h/day had this clinically meaningful improvement while 48% of patients using the PTT for ≤4 h 'responded'.

In 2012, Abern et al. [19] reiterated that the benefit of PTT seems to be related to treatment adherence and demonstrated that men using the PTT for > 3 h/day had significantly better results. We recommend that our patients use the PTT at least 6 h/day, but also encourage them to reach an 8-h/day programme if possible. As patients were highly motivated and the schedule was limited to 12 weeks, the mean treatment adherence rate was 5.2 h/day, better than in previous publications. In the present study, we did not recommend that patients wear the system for < 3 h/day because we suspected that treatment adherence rate would decrease dramatically, thus achieving worse results.

The results of the present study are consistent with previous studies in small series of patients, such as the pilot study by Levine et al. [13] of 10 patients with PD in which nearly all (90%) had failed prior medical therapy; PTT was applied for 2–8 h/day for 6 months. The PTT resulted in subjectively and objectively measured improvement in penile deformity, enhanced stretched flaccid length and erect girth, as well as improved sexual function, with no reported AEs.

Not all previous studies showed a positive effect of PTT. Ziegelmann et al. [20] recently published a paper in which the use of PTT with a different PTD (Andropenis®) showed no significant improvement in penile curvature or SPL, with a mean of 10 h of weekly concurrent PTT. PTT was used in combination with CC injection and only 69% of men reported any use during the combination therapy, and only 37% reported using the therapy for > 3 h/day. This is noteworthy, as the majority of studies have suggested that traction durations of 3–8 h/day are associated with better clinical outcomes.

In the present study, nearly half of the patients, 43%, reported some local discomfort with the use of the device. Although this seems a high proportion of patients, it should be understood that putting the penis in traction is bothersome. Levine rightly commented on Ziegelmann's article [20]: 'Yet, tolerating prolonged forces on the penis has proven to be difficult, particularly with most of traction devices on the market. These devices are uncomfortable to wear, limit activity, can readily dislodge with movement and must be removed every 2 h to reduce risk of injury to underlying tissues.' The PTD used in our study, the Penimaster PRO, was quite well tolerated and compliance was good. Only three patients abandoned the study as a result of AEs.

Limitations of the present study include the open-label design; to overcome observer bias, the examiner in each centre was blinded to the use of the device. The duration of the study could also be considered a limitation as all previous studies were of longer duration; however, to assess the efficacy and maximize treatment adherence, we decided that the study should be of short duration, and 3 months was considered ideal. Nevertheless, the durability of the improvement in terms of correction of curvature and length of the penis or the possible recurrence of the curvature after stopping the PTT was not assessed in this study. It is reasonable to expect that, because of the elastic nature of the penile tissues, some degree of recurrence of the curvature could occur.

In conclusion, the results of the present study support the use of PTT in the stable phase of PD as a non-invasive therapy with high short-term efficacy and very few AEs. The use of the Penimaster PRO, a new vacuum-based PTD, during 3 consecutive months in patients with stable PD provides a significant reduction of the curvature, an increase in penile length, and improvement of the symptoms and bother induced by PD. In our opinion the use of this non-invasive treatment should be offered to patients with stable PD before any correcting surgery.

Acknowledgement

We thank Prof. Arthur L. Burnett, from Johns Hopkins University, for reviewing the manuscript and providing valuable suggestions.

Conflict of Interest

Penimaster PRO was provided free of cost to all patients. None of the authors have any conflict of interests to declare.

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Abbreviations: PTD, penile traction device; PD, Peyronie's disease; ED, erectile dysfunction; SPL, stretched penile length; PDQ, Peyronie's Disease Questionnaire; CC, clostridium collagenase; PTT, penile traction therapy; PG, Penimaster PRO traction device group; NIG, non-intervention group; PS, psychological and physical symptom; BD, bother and distress; PP, penile pain; AE, adverse event.