

# Penile traction therapy and Peyronie's disease: a state of art review of the current literature

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**Abstract:** In recent years, penile traction therapy (PTT) has gained considerable interest as a novel nonsurgical treatment option for men with Peyronie's disease (PD) and short penises. The current published literature suggests that selected cases of PD may benefit from a conservative approach with PTT, resulting in increased penile length and reduction of penile deformity. It appears to be safe and well tolerated but requires a great deal of patient compliance and determination. This article reviews the current literature pertaining to the use of PTT in men with PD, short penises and in the setting of pre- and postprosthesis corporal fibrosis.

**Keywords:** Erectile function, penile length and curvature, penile traction therapy, Peyronie's disease

## Introduction

Peyronie's disease (PD) is an acquired disease of the tunica albuginea. The fundamental mechanism of injury relates to the repetitive buckling forces (trauma or microtrauma) to the erect penis during sexual activity. However, not every penile trauma leads to development of PD; this aberrant wound healing appears to be more common in certain men with genetic predispositions [Ralph *et al.* 2010]. PD is associated with various penile deformities and sexual dysfunction, including penile plaque, curvature, shortening, narrowing, pain and erectile dysfunction (ED). Although PD was first described more than 250 years ago, much of our understanding of this condition was realized over the past 25 years.

From the extravasation of fibrin and initial perivascular inflammatory infiltrate following the disruption of the penile tunica albuginea, there is activation and proliferation of fibroblasts into myofibroblasts, resulting in persistent fibrin and collagen deposition, as well as disorganization of extracellular matrix and elastic fibres [Ralph *et al.* 2010; Chung *et al.* 2011a]. Published literature highlights the role of various cytokines and growth factors, such as transforming growth factor  $\beta$ -1 in the pathogenesis of this condition [Chung *et al.* 2011a; El-Sakka *et al.* 1998; Gonzalez-Cadavid

*et al.* 2005]. Nonetheless there remains a lack of clear understanding of the exact pathogenesis in this sexually debilitating condition [Gonzalez-Cadavid *et al.* 2005]. Presently, none of the available therapeutic options is curative. The current conservative or nonsurgical treatment for PD has limited evidence of benefit and most of the published studies were not well controlled, with a small number of participants in various stages of PD, and with limited outcome measures of PD such as reduction in penile pain, plaque size, and deformity [Ralph *et al.* 2010].

Several studies have demonstrated that PD shares many similarities with Dupuytren's contracture [Bjekic *et al.* 2006], including many genes involved in collagen degradation such as matrix metalloproteinases and those involved in myofibroblast differentiation [Qian *et al.* 2004]. It is possible, therefore, that the two conditions may share a common underlying pathophysiology, and therefore potentially respond to similar treatment modalities. It is well documented that the use of mechanical traction and tissue expansion therapy results in alteration of connective tissue by cellular proliferation and expansion of the extracellular matrix [Alenghat and Ingber, 2002]. This mechano-transduction process was first described in use to stimulate bone remodelling in the late

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1960s [Illizarov and Soibeman, 1966], and since then, the concept has spread to other tissue models including the muscle and Dupuytren's scar [Brighton *et al.* 1996; Alman *et al.* 1996]. In Dupuytren's contractures, continuous and prolonged mechanical tension on the diseased tissue resulted in collagen remodelling and tendon healing [Bailey *et al.* 1994]. Histological staining following traction therapy confirmed reorganization and remodelling of collagen fibres into uniform densely packed fibrils that are parallel to the axis of mechanical strain [Brandes *et al.* 1994]. Experimental study from our unit using primary Peyronie's cell cultures in an *in vitro* strained cell-culture system demonstrated significant alterations in the ultrastructure of connective tissue with decreased collagen and elastin staining as well as increased collagenase activity [Chung, 2012].

Therefore it seems logical that penile traction therapy (PTT) should offer a similar effective treatment solution for PD. The idea of a nonsurgical method that generates progressive mechanical traction to the deformed penis by lengthening and correcting any abnormal penile curvature is very attractive. In recent years, a great deal of attention has been given to the use of a penile traction device, with many websites and advertisements proclaiming that these noninvasive methods increase the penile size and correct penile curvature. These devices usually consist of a plastic support ring, a silicone band, and two dynamic rods. The PTT works by holding the penis in a cradle and subjecting it to gentle and progressive traction forces that can be achieved by the addition of small metal extensions to the dynamic rods and cradle frame every few weeks. There are several commercially available penile stretching or traction devices such as Andropenis (Andromedical, S.L., Madrid, Spain), Golden Erect extender device (Ronas Tajhiz Teb, Tehran, Iran), SizeGenetics (GRT Net Services Inc, Gresham, OR, USA), Vimax Extender (OA Internet Services, Montreal, Canada) and ProExtender (Leading Edge Herbals, Greeley, CO, USA) just to name a few. The following article reviews the current literature pertaining to the use of PTT in PD and evaluates the efficacy and safety profiles of these devices.

### Materials and methods

Articles from peer-reviewed journals, abstracts from scientific meetings, and literature searches by hand and electronically formed the basis of

this review. Electronic search involved unrestricted, fully exploded medical subject headings using the terms related to PTT and PD to thoroughly search the PubMed database (<http://www.ncbi.nlm.nih.gov/sites/entrez>) of the US National Library of Medicine and the National Institutes of Health. While the penile vacuum erectile device (VED) is a form of physical therapy to increase the length of a man's penis, the predominant use of VED is to achieve an erection. Therefore this article will focus predominantly on (non-VED) penile traction devices.

### What is the evidence for penile traction therapy?

One of the earliest reports into the use of PTT in patients with PD was presented at the 4th Annual European Society for Sexual and Impotence Research (ESSIR) meeting in 2001 on a small study of eight men [Scroppo *et al.* 2001]. The inclusion criteria for the study involved all men with minimum 3 months of PD without concomitant ED and the men were instructed to use the traction device for at least 4 h a day for a total of 3–6 months. The authors reported an increase in the mean penile length of 4.1 mm (100.5 mm before and 104.6 mm after PTT) ( $p > 0.05$ ) and decrease in mean erect penile curvature (EPC) of 14° (from 34° to 20°) ( $p < 0.05$ ) in this small case series. The same group also presented their later findings on the use of PTT at the ESSIR meeting in the following year. Daily use of a penile traction device for 6 h a day in men with PD and severe penile retraction was associated with a longer stretched penile length (SPL) (average 0.8 cm gain) [Colpi *et al.* 2002a].

In the same meeting, the authors also reported the efficacy of PTT in 'small penis' treatment [Colpi *et al.* 2002b]. In a small series of nine men with 'small penis' and an initial mean SPL of 12 cm, PTT of at least 6 h per day for a minimum of 4 months resulted in the mean SPL gain of 1.8 cm (range 0–3.1 cm). The majority of patients did not report significant adverse events despite the long duration of PTT. These findings were confirmed by another prospective study conducted in 23 men who complained of short penis [Nikoobakht *et al.* 2011]. Following PTT for 4–6 h per day during the first 2 weeks and then 9 h per day until the end of the third month with increasing traction forces during determined intervals, there was a statistically significant increase in penile length both for the flaccid

(mean  $8.8 \pm 1.2$  cm to  $10.5 \pm 1.2$  cm) and for the stretched state ( $11.5 \pm 1$  cm to  $13.2 \pm 1.4$  cm), after 3 months of use. Despite the significant increase in the circumference of the glans penis following PTT use, this study did not demonstrate any significant change in the proximal penile girth and the increase in distal penile girth was likely attributed to glans enhancement. In contrast, negligible changes in penile girth after 6 months of PTT were reported in a pilot prospective study in men with short penis [Gontero *et al.* 2008].

Moncada-Iribarren and colleagues presented the first noncontrolled randomized study on the use of PTT in men who underwent PD surgery [Moncada-Iribarren *et al.* 2007]. A total of 40 men who had PD surgery (12 men with graft and 28 men with penile plication only) were randomized to penile traction *versus* observation. The penile extender was instituted once the surgical incision had healed (approximately 2–3 weeks), for 8–12 h daily for a total treatment period of at least 4 months. For both groups, penile shortening after surgery ranged from 0.5 to 4.0 cm. The use of a penile extender device was associated with increased penile length ranging from 1 to 3 cm and appeared to be proportional to the number of hours per month that the patient was wearing the traction device. Furthermore, sustained treatment with PTD for 4 months provided an increase in penile length from 1 to 4 cm. The use of the device was well tolerated and only three patients had to decrease the number of hours of traction device use due to mild penile pain.

Levine conducted a pilot study of 11 men with longstanding PD (mean 29 months) who were trialled on PTT and instructed to wear the device for a minimum of 2 h per day, increased to a maximum of 8 h per day with the extender rods lengthened by 0.5 cm every 2 weeks for 6 months [Levine *et al.* 2008]. Of the 10 men who completed the study, there was a 33% measured improvement in EPC, ranging from  $10^\circ$  to  $45^\circ$ , and a reduction in mean EPC from  $51^\circ$  to  $34^\circ$ . The SPL increased by 0.5 cm to 2.0 cm. They reported for the first time that PTT increased the erect penile girth by 0.5 to 1.0 cm with an improvement in hinge effect in four out of four men with advanced narrowing or indentation. No patient reported significant adverse events such as changes to penile sensation, worsening erectile function or skin injury. Overall the patients reported high satisfaction rates and the

(International Index of Erectile Function) IIEF scores increased by at least four points in 50% of subjects (from 18.3 to 23.6) after 6 months of PTT.

Another important study in the use of PTT for men with PD was published a year later. Gontero and colleagues reported the results of PTT use in 19 men with minimum of 12 months of PD and pre-existing curvature of less than  $50^\circ$  [Gontero *et al.* 2009]. In contrast to the study by Levine and colleagues [Levine *et al.* 2008], the penile measurements were determined by photography taken by the investigators after a pharmacologically induced erection in the office or at home. The patients were required to wear the device for a minimum of 5 h per day, up to a maximum of 9 h. For the 15 patients who completed the study, the penile curvature decreased from a mean of  $31^\circ$  to  $27^\circ$  and there was significant improvement in the mean flaccid and SPL measurements of 1.3 and 0.8 cm respectively. Importantly, the authors showed no further change in penile curvature or length in the following 6 months after the device was not used. In addition, there was no significant change to the IIEF score.

The role of PTT as part of a multimodal treatment strategy for men with PD was also explored by Abern and Levine in 2008 [Abern and Levine, 2008]. In a noncontrolled pilot study, there was a trend toward improvement with intralesional injections plus PTT compared with injections alone. The study was formally published in 2011 [Abern, 2012] and involved a 24-week study with the combined use of PTD in addition to intralesional verapamil and oral L-arginine and pentoxifylline in men with PD with symptoms for over a year. This is a patient self-driven PTT group and those electing to wear a traction device were advised to wear the device for 2–8 h daily, but for intervals no longer than 2 h, and to add progressive device traction every 2–3 weeks. A total of 54% of patients reported improvement in EPC in the PTT group compared with 46% of patients who did not use PTT. In patients who responded to PTT, the mean reduction in EPC was  $26.9^\circ$  *versus*  $20.9^\circ$  in men without PTT ( $p = 0.22$ ). With regards to SPL, patients on PTT gained a mean of 0.3 cm (SD 0.9 cm;  $p = 0.06$ ), while the men without PTT lost an average of 0.7 cm of length (SD 1.1 cm;  $p = 0.46$ ). Subgroup analysis of men on PTT showed a trend toward SPL benefit, with 56% of men with PTT use greater than 3 h per day having measured SPL gain *versus* 43% of men

using it up to 3 h per day ( $p = 0.18$ ). Multivariate analysis confirmed that the duration of PTT use significantly predicts SPL gain (0.38 cm gain for every additional hour per day of PTT use,  $p = 0.007$ ).

Most men with advanced ED sometimes also report shortening of penile length and require penile prosthesis implantation. The potential benefit of PTT to preserve and maintain penile length following the removal of penile prosthesis implantation was highly desired given that significant corporal fibrosis occurred following penile prosthesis explantation. Levine reported a noncontrolled pilot study in 10 men with drug refractory ED and a complaint of a shorter penis, who were subjected to PTT use to maintain the penile length before inflatable penile prosthesis implantation [Levine and Rybak, 2011]. At the end of the 4-month study period of 2–4 h daily use of PTT, 70% of men had measured erect length gain compared with baseline pretraction SPL up to 1.5 cm. No man had measured or perceived penile length loss after inflatable penile prosthesis implantation. However 60% of men complained of difficulty applying the device, with occasional pain that diminished with use in 40% of men.

#### **The use of a vacuum erectile device for penile length preservation**

VED functions through the creation of a vacuum around the penis, which leads to an erection by engorgement of penile tissue. The devices are easy to use, widely available, have few contraindications and require no testing prior to use. While its main role is in penile erection, the role of VED use for penile rehabilitation is questionable because theoretically it can potentially cause corporal fibrosis, ischemia, acidosis, and lack of smooth muscle relaxation leading to penile fibrosis [McCullogh, 2008]. Aghamir and colleagues reported that 6 months after VED use, there was a nonstatistically significant increase in mean penile length from 7.6 to 7.9 cm [Aghamir *et al.* 2006]. While the efficacy of VED treatment was approximately 10%, there was a 30% patient satisfaction rate. Among men with PD, Raheem and colleagues found a clinically and statistically significant improvement in penile length (35% of men had a mean increased SPL of 0.5 cm), angle of curvature (67% of patients with reduction of 5–25°) and pain after 12 weeks of VED

use [Raheem *et al.* 2010]. However there was no significant change in the sexual and erectile functions.

In the penile rehabilitation post-prostatectomy group, several reports showed that VED use is associated with preservation or increased penile length. A pilot study of 28 men randomized to either early daily VED use for 10 min/day starting at 1 month postoperatively for 5 months or on-demand VED use after 6 months showed the SPL was maintained with daily VED use but significantly decreased (by approximately 2 cm) in the late on-demand use [Kohler *et al.* 2007]. Raina and colleagues found that 23% of men who were compliant with VED use complained of decreased penile length and girth compared with 85% who were noncompliant [Raina *et al.* 2006]. This finding was also echoed by Dalbin and Christopher, who reported good preservation of penile length with early and daily use of VED [Dalbin and Christopher, 2007].

Soderdahl and colleagues reported that VED use in a cohort of men who underwent penile prosthesis implantation for ED described improved length and girth and that concomitant use of VED and a penile prosthesis may be indicated in men with penile prostheses who are dissatisfied with size or rigidity [Soderdahl *et al.* 1997]. A recent case report by Moskovic and colleagues showed that following the application of VED twice daily for 10 min per session for 1 year as well as 8 h of PTT for 8 months, there was a 20% longer revision penile prosthesis length (15–18 cm) and 4.4 cm increase in erect penile length despite having penile prosthesis implantation 6 years ago [Moskovic *et al.* 2011].

#### **Expert opinion**

For a relatively new medical device to gain commercial success, several important factors need to be achieved [Cooper and Kleinschmidt, 1987]. The current medical therapies for PD have been far from ideal and there is no doubt that men are eager to preserve or increase the length and correct existing deformity of their penises with minimal invasive treatment. These penile traction devices can be easily purchased anonymously on the internet and patient education is often minimal for these devices. Enthusiastic support from several international experts and strong commercial marketing on these traction devices have



**Table 1.** Ideal patient characteristics for PTT.

1. Men with acute phase of PD or short penises
2. Greater EPC
3. Absence of calcified Peyronie's plaque
4. Acceptable penile girth or absence of hour-glass penile deformity
5. Normal erectile function
6. Highly motivated and compliant use (minimum 4-6 hours of use per day, for 3-6 months)
7. Addition of multimodal treatment strategy (such as oral PDE5 inhibitors and intra-lesional injections)

further assisted in the product launch and mass appeal. Furthermore, in the last few years there have been an increased number of published articles and international scientific sessions advocating the use of PTT in various penile deformities. However, several important issues should be considered in PTT, such as the efficacy of these devices in the various subgroups of PD, patient-disease demographics, impact on sexual and erectile functions, as well as patient safety, tolerability, and compliance.

The published outcomes from these PTT trials have several shortcomings. Many criticisms to current published trials include the nonrandomized nature of patient selection when there is a potential for selection bias and the impact of patient self-motivation and compliance could affect the study outcome. The assignment of patients to the treatment group was based predominantly on patient preference and willingness to comply with the study protocol of PTT. Furthermore, it is difficult to control the amount of traction placed on the penis with the spacing segments on the traction device, therefore it may be possible that some patients underutilized the device, thus compromising any potential benefit. In addition, investigators of the trial were not blinded and blinding of the patients was not technically feasible with this protocol. Last but not least, the use of PTT in different stages of PD, minor differences in device properties, and various treatment schedules described in the published literature place considerable limitations on the generalization of PTT benefits in men.

The PTT is a novel modality that requires a great deal of patient compliance and determination (Table 1). Early evidence suggests that selected cases of PD may benefit from a conservative approach with PTT, resulting in increased penile length and reduction of penile deformity. The

greater improvements in penile length and curvature in the Levine study (0.5–2 cm gain in penile length and 33% mean reduction in EPC) [Levine *et al.* 2008] compared with the Gontero study (1.3 cm gain in penile length and 13% mean reduction in EPC) [Gontero *et al.* 2009] may be in part because some patients have more acute disease or greater EPC (Gontero study excluded patients with curvature greater than 50°) and the absence of calcified Peyronie's plaque may respond better to PTT. It has been claimed that PTT can increase the penile girth [Levine *et al.* 2008] through soft tissue cellular proliferation and growth in a multiplanar fashion from chronic traction. However, two studies found no significant changes to the penile circumference following PTT [Gontero *et al.* 2009; Nikoobakht *et al.* 2011]. It is interesting, however, that no girth decrease was reported with PTT, as one would have instinctively thought. At present, there is no strong evidence that PTT or any medical treatment may have beneficial effects on the sexual function of patients with PD [Ralph *et al.* 2010]. Post-PTT improvement in IIEF domain scores in the Levine study was marginal and nonsignificant compared with baseline erectile score [Levine *et al.* 2008]. The changes in IIEF domain scores are likely dependent on baseline sexual dysfunction score, as shown in the Gontero study [Gontero *et al.* 2009].

In comparison to PTT in treating dysmorphic and postsurgical short penises, the elongating effect in PD was lower in magnitude. The reduction in penile elasticity as a consequence of the reduced content in elastin within the fibrous plaque could explain why PD patients are less susceptible to the elongating effects of the penile extender [Pryor and Ralph, 2002]. The restoration of penile lengthening would involve a complete reversal of the underlying fibrotic process, a finding that has never been proved to occur with

any specific treatment modality in PD. Surgical intervention in PD is associated with a high dissatisfaction rate irrespective of which surgical procedure is used [Kendirci, 2004; Kadioglu, 2011]. However, the role of antifibrotic agents such as phosphodiesterase inhibitors [Valente *et al.* 2003; Safarinejad *et al.* 2010; Chung *et al.* 2011b] in reversing or altering PD progression could play a synergistic role in the use of PTT as part of a multimodal treatment strategy.

The lack of precise understanding of the pathogenesis of PD is probably a key element that explains the absence of truly effective treatment strategies for this condition. The current literature on the role of medical therapies in PD remains controversial. Furthermore, the reduction of penile pain that appears to resolve with time untreated, and reduction of plaque size, which has never been found to correlate with curvature improvement [Ralph *et al.* 2010], has never been shown in PTT. PTT certainly meets the need of a well defined patient population, namely men with a more acute phase of PD and greater penile curvature.

The penile traction device is tolerable, has minimal adverse outcome, and men are generally satisfied with the device. However, further investigation is needed to determine the optimum time of device application (6 or 8 h or longer), duration of PTT (such as longer than 6 months of use), the efficacy of various PTT devices, and patient demographics (young *versus* old; short penises *versus* postprostatectomy *versus* penile prosthesis implantation) before PTT is accepted as a standard of care for men with penile fibrosis and curvature. A study of the role of PTT in combination with other pharmacological agents in PD remodelling and the impact of PTT on pre- and postsurgical candidates for penile implants and penile reconstruction following radical prostatectomy in large-scale multicentre trials with long-term results may reveal that PTT could play an essential role in a multimodal treatment strategy.

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### Conflict of interest statement

The authors declare no conflicts of interest in preparing this article.

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