Ther Adv Urol
2019, Vol. 11: 1–11
DOI: 10.1177/1756287219838139

The use of penile traction therapy in the management of Peyronie's disease: current evidence and future prospects

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Abstract: Peyronie's disease is a disorder of abnormal and dysregulated wound healing leading to scar formation in the tunica albuginea of the penis. Penile traction therapy has emerged as an attractive therapeutic option for men with Peyronie's disease in both the acute and chronic phases. Currently, clinical studies are limited by lack of randomization, small cohorts, and lack of patient compliance with therapy. Despite these shortcomings, studies have shown a potential benefit with minimal morbidity. Specifically, penile traction may help to preserve or increase penile length and reduce penile curvature when used as monotherapy or as adjuvant therapy for surgical and intralesional treatments. Further study is necessary to define patient characteristics that are predictive of improved outcomes, determine the duration of treatment needed for clinical effect, and improve patient compliance.

Keywords: curvature, erectile dysfunction, penile length, penile traction therapy, Peyronie's disease

Received: 13 September 2018; revised manuscript accepted: 18 February 2019.

Introduction

Peyronie's disease (PD) is a debilitating syndrome consisting of pain, erectile dysfunction, penile curvature, shortening, and sexual dysfunction. The disease was first described over 250 years ago, by its namesake Fracois Gigot de la Peyronie, but mechanisms underlying the pathophysiology remain relatively unelucidated.[1,2] The hypothetical mechanism of PD relates to trauma to the erect penis during sexual activity leading to abnormal and dysregulated wound healing. Not all trauma leads to PD and unrecognized minor trauma is also though to result in PD. Other risk factors include diabetes, hypertension, prostatectomy, smoking and transurethral urological procedures, which may cause or increase the risk of microtrauma leading to PD.[3,4] There appears to be a complex genetic and environmental interplay, with some studies suggesting a familial genetic link.[3,5,6] The prevalence of PD is reported between 3.2–8.9%.[2,7] The true incidence is likely higher due to underreporting from men not seeking treatment.

The pathophysiology of PD centers on trauma to the tunica albuginea causing an inflammatory cytokine release. The release of transforming growth factor-beta (TGF-β) and the inactivity of matrix metalloproteases (MMP) leads to fibroblast and myofibroblast proliferation that causes persistent collagen and fibrin deposition (plaque).[8] This plaque often results in an angulation of the penis in the direction of the plaque or other deformities such as narrowing and indentation. The patient's psychologic stress also contributes to the morbidity associated with the disease. PD is not a life threatening disease, but the combination of penile deformity, impotence, and pain have been shown to cause severe mental distress and depression.[9] A study by Nelson and colleagues found that 48% of PD patients undergoing evaluation were classified as depressed on a validated scale including 26% meeting criteria for moderate depression and 21% severe.[10] Also, upwards of 80% report distress related to PD, and over 50% of men report that PD has negatively impacted their relationships.[11]

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The disease itself is divided into an active phase and a chronic phase. The active or acute phase, which can last up to 18 months, is characterized by active plaque formation, penile or glanular pain with or without erections, and progressive penile deformity (curvature and, indentation/narrowing) and length loss.[2,5] In contrast, the chronic phase, which has been defined as symptom stability and lack of progression for ⩾3 months, is characterized by deformity stabilization and pain improvement or resolution in most cases.[5] Also, the palpable penile plaque, if present, may harden and flatten out. Commonly the plaque is located in the mid-dorsal shaft or distally retro-coronal and is anchored to the septum. PD patients can have a dorsal, dorsolateral, or ventral penile deformity. Concurrent erectile dysfunction (ED) is also common and occurs in up to one-third or more patients with chronic PD.[5] The underlying etiology for ED varies and can be physiologic secondary to painful erections, vasculogenic from arterial insufficiency or veno-occlusive dysfunction, or psychogenic.[12]

PD is similar to another disease of collagen remodeling, Dupuytren's contracture, which has been shown to respond favorably to traction therapy.[13] Dupuytren's contracture is caused by fibrosis of the palmar fascia leading to chronic flexion of one or more digits. Much like PD, it is caused by dysregulated fibroblast function.[14] Multiple studies have shown an epidemiological link between the two diseases. Bjekic and colleagues showed that in 82 patients with PD, 39% had a history of Dupuytren's contracture.[3] Another similar study showed that 21% of patients with PD had a history of Dupuytren's contracture.[6] Additionally studies have shown a protentional familial inheritance of both diseases.[15,16] Histological staining of diseased tissue after mechanical traction from Dupuytren's contracture patients demonstrates reorganization and remodeling of collagen fibers in the direction of the mechanical strain and resultant deformity correction.[13,17] Given the genetic and histologic similarities, it is not a far stretch to hypothesize that PD patients would similarly respond to traction therapy. In an elegant study from Chung and colleagues, tunica cells from PD patients and controls were subjected to mechanical stress and studied.[8] The PD tissue cells responded to the applied forces with alterations in the connective tissue structure and collagen remodeling including upregulation of smooth muscle α-actin, β-catenin, and Hsp-47 proteins relative to the controls. Importantly they also found increases in MMPs (MMP-8) in the strained samples, an enzyme with anti-fibrotic activity that is reduced in PD plaques. These findings are similar to those seen in Dupuytren's contracture cells when exposed to traction therapy.[13,17] There are two animal studies that also investigated these changes. Lin and colleagues found significant improvements in penile curvature in a sample of adult male rat PD models exposed to vacuum erection therapy (VED) or penile traction over control. The VED group also showed preservation of smooth muscle α-actin and less TGF-B1.[18] Li and colleagues also found smaller PD plaque sizes and improved erectile function in a group of PD model rats exposed to VED over control.[19]

These studies support an underlying cellular mechanism for penile traction therapy (PTT) as a nonsurgical option for PD. Several clinical studies evaluating PTT as monotherapy or in combination with oral, intralesional, or surgical treatments have been published suggesting varying levels of efficacy. Historically, the standard traction device has consisted of a plastic support ring (lying on the base of penis), distal ring below the corona and two parallel stabilizing rods. The rods are extended *via* a spring device with the penis held in between. The patient can add on extenders after removing the device to exert progressive traction (Figure 1). Because PTT is relatively non-invasive and can be marketed direct to consumers, it is a desirable treatment option for many patients. This, along with the aggregation of clinical data, has led to an increase in its use. Although VED has been studied for PD in a limited number of studies, the current article will instead focus on the evidence for PTT, its optimal use, and associated morbidity.

Methods

A literature search was performed on the *PubMed* database (www.pubmed.gov) for articles and studies relating to PTT for PD. Keywords utilized were 'penile traction,' 'vacuum erection device,' and 'Peyronie's disease'. These results were narrowed down based on relevance. Where available, outcomes reviewed included changes in penile length, curvature and the International Index of Erectile Function (IIEF) score. Articles were divided by treatment categorizations including their use as monotherapy, adjuvant therapy, or as a pre- or post-treatment adjunctive therapy.

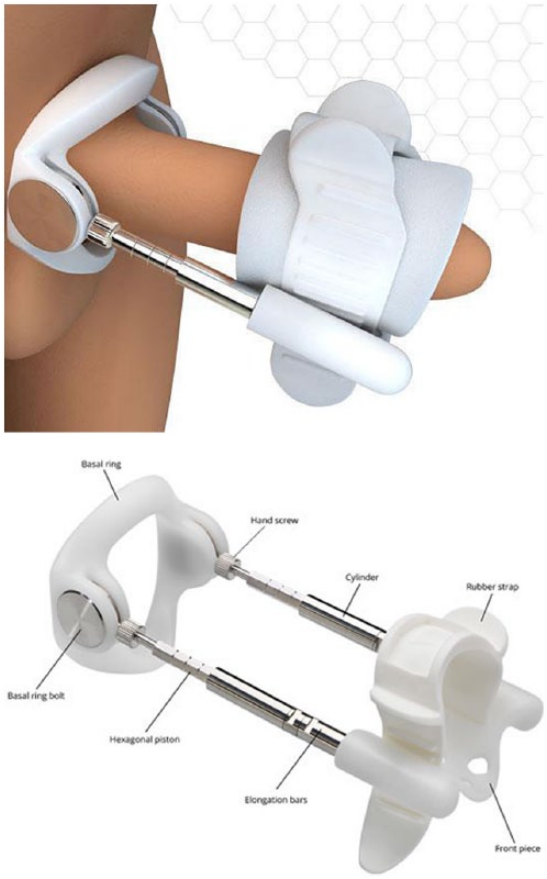

Figure 1. Penile traction device.

Articles also were distinguished based on the underlying population, being in the acute phase (defined as <12 months unless otherwise stated) or chronic phase (⩾12 months). Only articles from peer-reviewed journals and abstracts from conferences were included. A summary of the relevant articles is summarized in Tables 1 and 2.

Penile traction monotherapy for PD

Scroppo and colleagues gave what is considered to be the first report of PTT for patients with PD at the 4th annual meeting of the European Society for Sexual and Impotence Research in 2001. A total of eight men with at least a 3 months history of PD and without ED underwent PTT. No controls were included in the study. They were instructed to perform PTT for 4 h per day for a total of 3–6 months. There was a reported decrease in erect penile curvature (EPC) of 14° (from 34° to 20°; $p < 0.05$). There was also 4.1 mm increase in mean penile length ($p < 0.05$).[20]

The first published study on PTT was published by Levine and colleagues in 2008.[21] A pilot study was performed on 11 men with long standing PD (mean 29 months) utilizing the FastSize penile extender (Fastsize Medical, Allso Viejo, CA, USA). The patients were instructed to use traction for 2 h a day increasing the duration to 8 h a day, with the extender rods lengthened 0.5 cm every 2 weeks for 6 months. Reported outcomes included changes in EPC, stretched penile length (SPL), and penile girth. Additionally, erectile and sexual function were assessed using the IIEF-5 questionnaire. A total of 10 men completed the study. All 10 men reported subjective improvements in penile curvature. Objective EPC decreased by a mean 33% (range 10–45°), increased penile length (0.5–2.5 cm), and increased erect penile girth (0.5–1 cm). Hinge effect resolved in 4/4 men as well. IIEF increased at least 4 points in 50% of patients (mean IIEF-5 score increased from 18 to 23.6). Importantly no adverse events were reported such as decreased penile sensation, worsening ED or skin injury.

In 2009 a small study was published on the use of PTT by Gontero and colleagues[22] This study reported on PTT in 15 men with PD for a minimum of 12 months, and pre-existing curvature of less than 50°. Patients were instructed to wear the device for a minimum of 5 hours/day, up to a maximum of 9 h. Penile measurements were then determined by photography taken by the investigators after a pharmacologically induced erection in the office or at home. There was a nonsignificant decrease in mean penile curvature from 31° to 27° ($p = 0.056$). However, there was significant improvement in the mean flaccid and stretched penile measurements of 1.3 cm and 0.8 cm respectively. Critically, the decrease in penile curvature and increase in penile length was preserved in the following 6 months after the device was no longer used.

Another important study was performed by Martinez-Salamanca and colleagues in 2014.[23] This was study was a nonrandomized, prospective study in 55 patients. This study, unlike those from Levine and Gontero, focused on patients in the acute phase of PD. The 55 men underwent PTT for 6–9 h a day × 6 months. Importantly the average actual use was 4.6 h a day. These patients were compared with a control group of 41 patients with acute phase PD who were observed without traction. The patients in the PTT group had a reduction of curvature from 33° to 15° at 6 months

Table 1. PTT monotherapy for PD.

Author	Number of patients	Patient group	PTT duration (hours)	PTT duration (months)	Actual PTT use (hours)	SPL	Curvature (°)	IIEF
Scroppo and colleagues[20]	8	PD mixed acute and chronic	4	3–6	-	4.1 cm	34–20 mean 14	N/A
Levine and colleagues[21]	10	PD chronic	2–8	6	4.5	1–2.5 cm	10–45 mean 33%	18–23.6
Gontero and colleagues[22]	15	PD chronic minimum 50° curvature	5–9	6	5.5	0.8 cm	31–27	No change
Martinez-Salamanca and colleagues[23]	55	PD acute phase	6–9	6	4.6	1.5 cm	33–13 mean 20	+6
Moncada and colleagues[24]	80	PD chronic phase	3–8	3	N/A	1.8 cm	15–50 mean 31	+2.5

IIEF, International Index of Erectile Function; N/A, not available; PD, Peyronie's disease; PTT, penile traction therapy; SPL, stretched penile length.

Table 2. PTT combination therapy for PD.

Study	Type[a]	*N*	PTT patients (%)	Intervention	Mean duration of disease (PTT, control)	Mean duration of PTT use (h/d)	Change in SPL (cm) *p* value	Change in curvature (pre-post mean)
Abern and colleagues[25]	P	74	39 (52%)	Pentoxifyllin, L-arginine, and ILI verapamil	13 ± 0.05 1.8 ± 0.23 (years)	3.3 ± 1.3	+0.3 ± 0.9 −0.7 ± 1.1 p = N/A	25 ± 37° 41 ± 45° $p = 0.22$
Rybak and colleagues[26] (1)[b]	R	52	27 (52)	Plication	Stable[c]	2.6 ± N/A	+0.9 ± 0.4 −0.53 ± 0.5 $p < 0.01$	-
Rybak and colleagues[26] (2)[b]	R	59	36 (61)	PEG	Stable[c]	2.4 ± n/a	1.5 ± 0.6 0.2 ± 0.4 $p < 0.01$	-
Yafi and colleagues[27]	R	112	34 (30%)	ILI interferon α-2b	33.6 ± 26.4 36 ±48 (months)	n/a	2.4 ± 0.9 1.3 ± 0.8 $p = 0.56$	19 ± 15° 23 ± 21° $p = 0.49$
Ziegelman and colleagues[28]	P	51	35 (69)	CCH	23.6 ± 27.6 18.5 ± 15.3 (months)	1.7 ± 0.9	0.4 ± 1.5 −0.35 ± 1.5 $p = 0.21$	33 ± 27° 28 ± 30° $p = 0.3$
Metanalysis		348	171 (49)				+1.02 95% CI: 0.64–1.40; $p < 0.01$	

[a]None were randomized.
[b]Rybak and colleagues' study was divided since two interventions were used.
[c]Although no length of PD was given, the fact they had a surgical intervention implies stable disease.
CCH, *Clostridium histolyticum;* CI, confidence interval; ILI, intralesional injection; N/A, not available; P, prospective; PD, Peyronie's disease; PTT, penile traction therapy; R, retrospective; SPL, stretched penile length.

and 13° at 9 months, with an overall mean decrease of 20° ($p < 0.05$). The nontreatment group had an increase in degree of curvature from 29° to 52° at 9 months (increase of 23°). Additionally, in the PTT cohort, SPL and IIEF scores significantly increased over controls (+1.5 *versus* −2.6 cm, +6 *versus* −6, respectively; $p < 0.05$) and penile pain significantly decreased. In 48% of men sonographic evidence of PD disappeared and 40% of patients were able to avoid surgical intervention. Importantly, multivariate analysis showed that predictive factors of success included age <45 years [hazard ratio (HR) 1.19, $p = 0.023$], initiation of therapy <3 months from PD onset (HR 2.26, $p < 0.001$), penile curvature <45° (HR 2.26, $p < 0.001$), penile pain >5 (HR 1.69, $p < 0.001$), and absence of discernable plaque on ultrasound (HR 2.45, $p < 0.001$). This study suggested the benefit of PTT in the acute phase of the disease, with a decrease in pain, curvature, and increase in IIEF and SPL.

The most recent published report on PTT monotherapy came from Moncada and colleagues who reported on 93 patients with chronic phase PD.[24] Patients were randomly assigned to PTT with the PeniMaster Pro (MSP Concept, Berlin, Germany) PTT device or a non-intervention group. The PeniMaster Pro utilizes a novel glans vacuum cup to apply the force over the entire glans in order to decrease patient discomfort and improve tolerability. Patients assigned to the PTT group were instructed to use the device for 3–8 h daily with a stepwise weekly increase in the amount of traction force applied to penis. Exclusion criteria included curvature <45°, PD duration <12 months, PD symptom stability <3 months, multi-planar curvature, and indentation/hourglass deformities. Also, those failing to utilize PTT for 3 or more hours daily were ultimately excluded. In total 80 patients completed the protocol and were included in the final analysis included 41 in the PTT group and 39 in the non-intervention group. Mean curvature improvement in the PTT group was 31° (41%; range 15–50°) and a dose-dependent response was identified wherein those who used the therapy for <4 h daily realized a mean improvement of 20° compared with a mean improvement of 38° when the device was used for >6 h daily ($p < 0.05$). SPL increased by a mean 1.8 cm (range 0.5–3 cm; $p = 0.03$) and penile girth increased as well. Adverse events, most commonly glans sensation changes and penile discomfort, were reported in 43% of patients but only 6% discontinued therapy as a result. In contrast there was no significant change in outcomes for those patients in the non-intervention group. An impressive 87% of patients assigned to the PTT arm completed the protocol, a compliance rate which is far greater than that seen with the majority of PTT studies discussed in the current review.

It is worth noting that in all of the aforementioned studies, average traction duration in excess of 3–6 h per day was utilized to achieve the results. A more recent study presented at the 2018 American Urological Association (AUA) annual meeting in San Francisco, CA, USA evaluated the use of a new traction device known as RestoreX© (PathRight Medical, Inc, Plymouth, MN, USA) designed to minimize the discomfort associated with traditional traction devices.[29] The authors hypothesized that the novel device mechanisms, including a new clamp design, ability to dynamically alter the traction forces applied to the penis with the device in place, and ability to apply force in the direction opposite the direction of curvature would result in significant improvements in PD outcomes with a shorter duration. The authors reported preliminary results of their randomized controlled study of men assigned to one of four groups: no therapy (control), or treatment with RestoreX© for 30 min 1×, 2× or 3× daily for 12 weeks. They reported on their preliminary data of 38 patients (controls $n = 11$, PTT $n = 27$), although the goal for the study based on the power analysis was 120 patients. The patients had a mean duration of PD of 34 (16.4) months. The PTT cohort had improved penile length (absolute change: +2.4 *versus* +0.2 cm, $p < 0.001$; percentage change: +15.8% *versus* +1.5%, $p < 0.001$) and penile curvature (absolute change: –14.5 *versus* +3.2°, $p < 0.001$; percentage change: –43.2% *versus* +10.6%, $p < 0.001$). Notably, while no patients were undergoing other concurrent therapies, 75% of both groups had prior Xiaflex therapy. It is important to emphasize that these are early results from an ongoing randomized trial. Finalized trial data are eagerly awaited in order to determine whether this will serve as an effective alternative to traditional PTT devices.

PTT combination nonsurgical interventions

Given the morbidity of surgical intervention for PD, there have been multiple oral and intralesional therapies utilized to change the course of PD and avoid surgical intervention. Oral therapies such as pentoxifylline, vitamin E, and colchicine were historically used.[2,5,21] However, none of

those treatments have been shown to have a significant clinical benefit and therefore are not recommended as monotherapy by the AUA guidelines.[5] Intralesional treatments including intralesional injections (ILIs) such as interferon 2α and calcium channel blockers have been shown to have some benefit by reducing fibroblast proliferation and increasing collagenase activity in vitro, but clinical data has been mixed.[2,5,30] Notably, early results from PTT monotherapy prompted an interest in the use of PTT as an adjuvant therapy either with surgery or injectable therapy. Interest in this multimodal approach has been increased with the introduction of *Clostridium histolyticum* (CCH), which is the only United States Food and Drug Administration (US FDA) approved nonsurgical intervention for PD.[5,9] CCH, is a collagenase that breaks up collagen, thereby weakening the plaque. Theoretically, once the plaque is weakened combining it with PTT and modeling could have a synergistic effect in reducing curvature and increasing penile length.

The first study to explore multimodal treatment with PTT and nonsurgical intervention was a retrospective study by Abern and colleagues in 2012.[25] This study reported on 74 men with chronic PD (duration 1.1–1.8 years). The patients were given pentoxifylline (400 mg TID), L-arginine (1 g BID), and ILIs with verapamil (10 mg q2 weeks for 12 injections). Patients were encouraged to perform PTT for 2–8 hours/day × 6 months as well. The 39 patients (53%) who elected to perform PTT averaged 3.3 hours/daily for 6 months. Both groups had a significant decrease in EPC, although there was no significant difference between those who did and did not use PTT (26.9° versus 20.9°; $p = 0.22$). SPL increased nonsignificantly by 0.3 cm in patients utilizing any PTT compared with a loss of 0.7 cm in those who did not use PTT. Notably, while not statistically significant, there was a trend towards greater improvement with PTT > 3 h per day (0.6 cm *versus* 0.07 cm; $p = 0.09$). On multivariable analysis, the duration of PTT predicted penile length gain (0.38 cm gain per hour of use, $p = 0.007$).

Yafi and colleagues examined PTT combined with interferon α-2b injections.[27] A total of 112 patients with chronic PD (mean 2.9 years) had a median of 12 interferon α-2b injections, with 34 patients using daily PTT for 2 h. Age and length of PD were similar between the two groups. The mean age in the PTT group and control were 52.6 ± 8.5 and 54.2 ± 9.6 years respectively. The duration of PD was 33.6 ± 26.4 in the PTT group and 36 ± 48 months in the control group. There was no difference between the groups in SPL (+2.4 *versus* +1.3 mm, $p = 0.56$) or reduction in EPC (−8.1° *versus* −9.9°, $p = 0.49$). Notably, in subgroup analysis of the 10 patients who reported >3 h of PTT the authors did find a significant increase in SPL (+4.4 *versus* +1.3 mm, $p = 0.04$).

Ziegelmann and colleagues in 2017 published the first study evaluating outcomes in patients using CCH and PT.[28] A total of 51 completed CCH treatment (two injections per series, 1–3 days apart for a total of four series and were included in the analysis). All patients were advised to do PTT with the Andropenis device (Andromedical America-Asia, New York, NY, USA) for a minimum of 3 h along with home modeling. A total of 35 patients performed PTT and were compared with the 16 patients who deferred PTT. Patients did not differ in age (PTT 58.6 ± 9.1 *versus* 55.8 ± 6.6 $p = 0.27$), PD duration (PTT 23.6 ± 4.7 *versus* 18.5 ± 15.3 $p = 0.53$), baseline SPL (PTT 13.5 ± 1.9 *versus* 13.8 ± 2.2 $p = 0.77$), or EPC (67.4 ± 25.1 *versus* 62.1 ± 24.9 $p = .41$). There was no significant difference in mean penile curvature improvement between the PTT *versus* non-PTT group (19.6° *versus* 23.6°, $p = 0.3$). Also, while not statistically significant, there was a trend towards improvement in SPL in those patients who utilized PTT compared with those who did not (+0.4 *versus* −0.35 cm, respectively; $p = 0.21$). Patient compliance with PTT was poor, averaging 1.7 h daily (9.6 h per week). Only 69% of patients used PTT at any point during the study, and only 37% averaged 3 or more hours daily as recommended by the authors. The percentage of patients utilizing PTT continued to decline with each injection cycle as well, from 60% with the first two series to 40% by the last series. A subgroup analysis did not reveal any significant different in EPC or SPL outcomes based on duration of PTT. However, the authors and an accompanying guest editorial comment on potential limitations including the small cohort size, reliance on patient reporting with respect to PTT utilization (9% compliance), and poor overall compliance.[31] As such, further study is necessary to determine the true impact of concurrent PTT with CCH.

In summary, the aforementioned studies suggest that adjuvant PTT with intralesional therapy may improve SPL, although the clinical significance of

this improvement is unclear. In contrast, there is no strong evidence to support a significant difference in penile curvature improvement with PTT. It is important to emphasize that the currently available studies are limited by poor compliance with PTT. Therefore, further studies are needed to truly examine the benefit of adjunct PTT in this setting.

PTT preoperatively

Surgery for PD remains the gold standard for the correction of penile curvature whether plication, plaque excision and grafting (PEG) or insertion of an inflatable penile prosthesis (IPP). Importantly, a significant patient concern is the risk of associated penile shortening. This results from the underlying pathophysiology of PD but can also be exacerbated by surgical reconstruction. Therefore, there is an interest in using PTT to preserve or decrease penile length loss preoperatively or postoperatively.

One of the first reports of utilizing preoperative PTT to enhance penile length with subsequent surgical intervention was actually a case report by Moskovich and colleagues.[32] They reported on a patient who received an IPP 6 years prior for post prostatectomy ED who requested a revision secondary to inability to maintain penetration. Prior to surgery, the patient performed VED twice daily for 10 min for 1 year and PTT 8 h daily for 6 months prior to surgery. Ultimately, erect penile length and SPL increased 4.4 cm and 2.3 cm respectively. This allowed for a 20% longer IPP cylinder to be placed (increased from 15 to 18 cm). However, as the authors note, the presence of a working IPP prior to revision likely contributed to the corporal expansion experienced by this patient as well.

In 2011 Levine and Rybak reported on 10 men with ED requiring IPP placement and shortened penile length included 2 from PD, 4 with a history of prostatectomy, and 4 with a history of prior IPP.[33] They were counseled to use PTT for 2–4 h for 2–4 months prior to IPP placement. After 4 months, in 70% of the men there was a gain in SPL, mean 1.5 cm. However, 60% of men had difficulty applying the device and 40% of men reported decreased use secondary to discomfort.

As is shown, the evidence for PTT use preoperatively to increased penile length is limited. However, given that many patients in the acute phase of PD or those undergoing intralesional therapies ultimately progress to surgery, data for PTT from the previously studies for PTT as monotherapy or in combination may conceivably be applied to the preoperative patient population as well. Overall, PTT is a viable option in patients concerned with their penile length, given its low morbidity, minimally invasive intervention that may have benefit. For those patients with preoperative ED and concurrent PD undergoing penile prosthesis placement, experienced implanters can also use multiple length restoration techniques including modified sliding technique, multiple slice technique, or Egydio techniques to optimize postoperative length as well.[34–36] However, these procedures carry a higher risk for postoperative morbidity and many surgeons are uncomfortable with length restoration techniques.

PTT postoperatively

There is more evidence for postoperative PTT after surgical intervention for PD. The first report of postoperative PTT was at the 2007 AUA annual meeting. There, Moncada and colleagues reported on the use of PTT after PD surgery for length shortening.[37] A total of 40 men who underwent PD surgery (12 PEG and 28 plication) were randomized to have PTT *versus* observation. Patients were instructed to use PTT daily postoperatively for 8–12 h for a total of 4 months. Immediate postoperative penile shortening was reported in both groups ranging from 0.5 to 4 cm. In those who complied with the recommended PTT protocol (37/40; 93%), penile length increases ranging from 1 to 3 cm were observed. This was proportional to the number of hours per month patients were compliant with the regimen.

In their 2012 study, Rybak and colleagues evaluated PTT in 111 patients after surgical management of PD with either plication or PEG. Patients were instructed to initiate PTT starting at 3–4 weeks postoperatively, for 3 h daily, at least 5 days out of every week, for at least 3–4 months. In total 27/49 plication patients (55%) and 36/59 PEG patients (61%) performed PTT. In the plication cohort, SPL increased by 0.85 cm compared with a loss of 0.53 cm in the non-PTT group ($p < 0.01$). In the PEG cohort there was also a significant increase in SPL of +1.48 cm when PTT was performed, compared with a +0.24 cm increase in those who did not perform PTT ($p < 0.01$). Overall patients who used PTT had no perceived length loss and 58% of patients reported a mean erect length gain of 1.1 cm. This

study supports postoperative PTT for penile length preservation or even improvement after plication and PEG procedures. As the authors note, in those patients who are at risk for postoperative ED with PEG but are also concerned about penile shortening, plication may be combined with pre- and postoperative PTT to preserve penile length.

Meta-analyses

Recently a meta-analysis was published by Haney and colleagues examining the role of PTT as adjuvant therapy after primary treatment for PD.[38] Overall four studies were included, Albern and colleagues, Rybak and colleagues (subdivided between plication and PEG cohorts, i.e. Rybak 1 and Rybak 2), Yafi and colleagues and Ziegelman and colleagues for a total of 348 patients, with 171 patients in the treatment group and 177 controls (no PTT).[25–28,38] The outcome of interest was SPL as the largest study involved surgical therapy thereby eliminating EPC. There was no difference between the groups in age (PTT 56.1 years *versus* control 55.3 years), baseline SPL after primary treatment (PTT 11.7 ± 1.6 cm *versus* control 12.1 ± 1.6 cm, $p > 0.05$), and EPC (PTT 41 ± 7.2° *versus* control 36.9 ± 7.1° $p > 0.05$). The authors identified a 1.02 cm greater improvement in SPL for those patients utilizing PTT compared with those who did not [95% confidence interval (CI): 0.64–1.40; $p = 0.009$]. In a subgroup analysis there was no difference seen in SPL if patients underwent primary surgical intervention *versus* ILI (1.01 *versus* 1.29 cm, $p = 0.84$). A summary of the studies can be seen in Table 2. As the authors note, this meta-analysis, although comprehensive, is limited by the quality of the studies included in the analysis. Limitations include the heterogenous patient population, variation in the applied concurrent PD treatment, selection bias (patients were not randomized in most studies), poor overall compliance rates, and overall improvements in SPL of questionable clinical significance (although statistically significant).

Adverse events

Adverse events are not extensively reported in the literature. They are usually mild and self-limiting; however, it may partly account for lack of patient compliance with PTT. The most commonly reported symptoms with PTT include transient pain (0–25%), erythema (0–2%), ecchymoses (0–13%) and pruritis (0–7%).[23,28,39,40] There has also been a case report of pubic bone edema associated with vigorous usage.[41] In general, all of these adverse events are self-limited and resolve with discontinuation of the therapy.

Discussion

Evidence for PTT to treat PD continues to mount. Martinez-Salmanca and colleagues provided data to support PTT monotherapy for acute phase PD, wherein 40% of patients were reported to have avoided surgical intervention.[23] From a mechanism standpoint, this makes sense as previous work on a cellular level has shown that PTT can alter the active remodeling process that underlies PD.[8,16–19] In chronic PD the data are more obtuse. Until recently, the available literature appeared to support the premise that SPL may be the best symptom target for PTT in patients in the chronic phase. There are reports of penile length gain in excess of 4 cm in some patients, but other studies have not identified a significant change relative to non-PTT patients.[20,22,42] However, the recent report from Moncada and colleagues where the PeniMaster Pro device was used in patients with chronic phase PD also suggests that improvements in penile curvature may also be realized.[24] There appears to be a clear link between PTT duration and response, suggesting that patient compliance is mandatory to optimize outcomes. Yafi and colleagues showed there was a marked difference in the patients who used PTT > 3 h 4.4 cm *versus* 2.4 cm and Abern and colleagues found a significant increase in SPL for every 1 h increase in daily PTT.[20,25,27] Moncada found that patients utilizing PTT for >6 h daily had a significantly greater improvement in penile curvature relative to those who used the device <4 h daily. However, in contrast with their high compliance rate with the recommended 3–8 h of daily PTT (85%), others have reported significantly lower rates. For instance, Ziegelmann and colleagues reported a compliance rate with the recommended PTT duration (⩾3 h daily) was <40%.[25,28] This may in part explain why the studies on multimodal therapy showed poorer response than in monotherapy, quite simply utilization appeared greater in many of the monotherapy series.

In the postoperative and preoperative settings there does appear to be evidence for PTT to preserve SPL, but as stated above the most important factor is patient compliance which remains difficult. Additionally, historical PTT devices were

considered to be bulky, uncomfortable, and overall difficult to wear for prolonged periods. Several newer PTT devices have been introduced to address shortcomings. For instance, as discussed above the PeniMaster Pro (MSP Concept) has a form-fitting glans adapter and, in addition to a more classic rod system, there is also a belt system that can be worn more discretely under clothing which may improve patient compliance.[24] Also, as previously mentioned, another new device, known as the RestoreX©, was designed to improve patient comfort.[29] Multiple clamp designs were evaluated to identify the mechanism that would allow for patient comfort with increased traction force. This and other novel mechanisms, such as the ability to bend the penis in the direction opposite the curve deformity while the traction force is applied, are hypothesized to improve patient outcomes due to greater tolerability, thus improving overall patient compliance rates. However, caution must be emphasized as definitive data regarding all devices is relatively lacking and comparisons amongst currently available PTT devices are not yet available.

Conclusion

To date, the evidence for PTT is limited. However, several studies have shown a potential benefit when PTT is used as monotherapy or in combination with oral medications, intralesional injections, or surgery for PD. Given the low risk for side effects, PTT should be considered for the motivated patient. This is especially true with patients in the acute phase PD and those concerned with penile length (and possibly girth) preservation. Current data support that devices should be used in excess of 3–6 h daily to optimize outcomes. Future studies will identify crucial points that are critical to optimizing outcomes with PD including issues of patient compliance and duration of use.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest statement

The authors declare that there is no conflict of interest.

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