Original Article

The effect of penile traction device in men with Peyronie's disease on penile curvature, penile length, and erectile dysfunction: a systematic review and meta-analysis

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Background: Peyronie's disease (PD) results in curvature, pain, and erectile dysfunction (ED). Penile traction devices (PTDs) are a non-invasive treatment option for PD by applying mechanical forces to elicit biochemical responses that reduce curvature and improve penile function. In the present study, we systematically reviewed and analyzed the literature investigating the use of PTD to treat PD.

Methods: We have conducted electronic and manual search strategies within the databases and included articles to find relevant studies. A total of Five studies met all the predefined inclusion criteria and were selected for inclusion in the review. Outcomes assessed are penile length, penile curvature, and erectile function (EF). The study population consisted of patients with PD, the intervention was penile traction therapy (PTT), the comparison was matched placebo or follow-up, and the study design was randomized controlled trials (RCTs) or cohort studies. The Cochrane risk of bias assessed the studies' quality for randomized studies and the Newcastle-Ottawa scale (NOS) for non-randomized observational studies. All statistical analyses were performed using R software. Results were considered statistically significant for $P<0.05$.

Results: Only five studies met inclusion and exclusion criteria and were published between 2014 and 2021. The sample sizes range [51–110], totaling 419, with a mean of 83.8 patients—the follow-up with a mean of 6.75 months. This meta-analysis evaluated the efficacy of PTD on curvature degree, penile length, and EF in patients. There is a significant positive effect on the curvature degree ($P=0.0373$), while there is no significant effect on penile length and EF ($P=0.5315$ and 0.1010), respectively. They are Indicating low heterogeneity with an estimated total heterogeneity of 0. Overall, the available evidence does not support the efficacy of the intervention for penile length or EF.

Conclusions: The current evidence suggests that PTDs can be a safe and effective treatment option for men with PD to reduce penile curvature. However, further research, including more RCTs with extended follow-up periods, is needed to fully understand their efficacy and determine the ideal timing and patient subtypes that would benefit from PTD.

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Keywords: Peyronie's disease (PD); erectile dysfunction (ED); penile traction therapy (PTT); penile length; curvature

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Introduction

Peyronie's disease (PD) is a connective tissue disorder that affects the penis and is characterized by the formation of fibrous plaques or scar tissue within the tunica albuginea, the tissue layer surrounding the corpora cavernosa. This can result in penile curvature, pain during erection, erectile dysfunction (ED), and significantly impact a man's sexual and psychological well-being (1). PD typically occurs during the fifth to sixth decade of life but can occur at any age (2). Studies have suggested that PD prevalence might be as high as 9% in the general population and higher in patients with diabetes or after radical prostatectomy (3-6). The prevalence of patients under 40 presenting with PD was 1.5% (7). While the exact cause of PD is not fully understood, it is believed to be related to trauma or injury to the penis, genetics, or a combination of both (8).

The management of PD is challenging, and its treatment options constantly evolve. Non-surgical interventions such as oral medications, topical creams, injection of medication into the plaques, extracorporeal shockwave therapy, and penile traction therapy (PTT) have been proposed as potential treatment options (9). However, in severe cases, surgical intervention may be necessary, but it carries the risk of further complications and a prolonged recovery period (10).

Recently, PTT using a penile traction device (PTD) has emerged as a non-invasive and potentially effective treatment option for men with PD (11). PTT involves applying a gentle, continuous force to the penis to stretch the tunica albuginea, which may reduce the curvature and other symptoms associated with PD. The hypothesized mechanism of action behind PTT is that it induces tissue remodeling through mechanotransduction. It is a process by which cells sense and respond to mechanical forces, leading to cellular behavior and tissue architecture changes. In the case of PTT, the mechanical force applied to the penis by the PTD is hypothesized to induce cellular remodeling in PD (12).

PTT using a PTD has several advantages as a non-invasive, safe, and self-administered treatment option for men with PD. The need for using traditional PTT devices for a significant amount of time each day, typically ranging from 2 to 9 hours, has been a major obstacle in their widespread acceptance and usage (13). It is associated with minimal discomfort and has a low risk of adverse effects, making it appealing to men who are reluctant to seek medical treatment due to the sensitive nature of the condition. Investigations have shown that PTT may have a promising role in various aspects of PD treatment. These include its potential as a primary lengthening therapy with modest improvements, its use for curvature correction before surgery or to attempt to avoid surgery and its use as part of post-operative rehabilitation after surgical correction of PD. Moreover, according to one study's findings, after a 10-year follow-up, PTT was determined to be the most cost-effective option. The average costs per patient were significantly lower for PTT at $883, compared to $11,419

Highlight box

Key findings

- There is a meaningful effect of penile traction devices (PTDs) on reducing penile curvature (P=0.0373) without significantly affecting penile length and erectile function.

What is known and what is new?

- Several studies have investigated the utility and effectiveness of PTDs, suggesting that PTDs can be effective with a mean follow-up of 6.75 months. Moreover, the most reported adverse events include temporary penile erythema or discoloration, which the patients tolerated.
- We systematically reviewed and analyzed the literature investigating the use of PTD in Peyronie's disease (PD). PTDs are a safe and effective treatment option for men with PD and can reduce penile curvature.

What is the implication, and what should change now?

- The future direction of PTDs, in combination with other treatments, design advancements, and market demand, can provide information on current trends and advancements. Nevertheless, further research is needed, including more randomized controlled trials with extended follow-up periods.

for surgery and $33,628 for collagenase clostridium histolyticum (CCH). Therefore, the study suggests that PTT may be a more economical choice for patients seeking the evaluated treatment (14). Additionally, pre-operative and post-operative PTT may effectively preserve length after surgery for PD (15). However, due to the limited number of randomized controlled trials (RCTs) and small sample sizes, the effectiveness and safety of PTT in men with PD still need to be determined.

Therefore, this systematic review and meta-analysis aimed to evaluate the current evidence regarding the efficacy and safety of PTT using a PTD in men with PD. This meta-analysis and systematic review aimed to provide a comprehensive and up-to-date summary of PTT's effectiveness and safety in treating PD by analyzing the available literature. The findings of this study may guide clinicians in making informed decisions when considering PTT as a treatment option for their patients with PD. The Prospero registration number was given to the protocol of this systematic review (CRD42023424605). We present this article in accordance with the PRISMA reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-310/rc).

Methods

Search strategy and study selection

Two investigators independently searched PubMed, Google Scholar, ScienceDirect, Clinicaltrial.gov, and Cochrane Library databases by title/abstract from inception to April 2023 to identify studies evaluating PTD as a primary or secondary intervention or before surgery for PD. In the study under consideration, we evaluated the impact of PTT in diverse treatment scenarios for PD. They included studies that investigated PTT as both a primary intervention and a secondary therapy. In some cases, PTT served as the main treatment for PD, constituting the initial therapeutic approach. In other instances, PTT was used as an additional treatment following a primary intervention such as injections. Furthermore, we examined the potential benefits of using PTT as a preparatory measure before performing surgery for PD. By encompassing these various treatment contexts, the study sought to provide a comprehensive understanding of PTT's efficacy and its role in managing PD.

The electronic search strategy used the keywords "curvature", "erectile dysfunction", "penile length", "penile traction therapy", and "Peyronie's disease". The full search strategy is provided in Appendix 1, section 1. The study based on the primary PICOS elements: P: Population/participants—patients with PD, I: Intervention—PTT, C: Comparison—matched placebo or no treatment, O: Outcome—pre- and post-study outcomes, S: Study design—RCTs or cohort studies.

The reference lists of screened full-text studies were also checked for other potentially eligible trials. To determine eligible studies, inclusive selection criteria were applied. These criteria required that the study population consisted of patients with PD, the intervention was PTD, the comparison was matched placebo or no treatment, and the study design was RCTs or cohort studies. In addition, studies were included if they met the following criteria: either all included men who received special primary treatment for PD (injection or surgical treatment) or a group of men who underwent adjunct penile traction after primary treatment or PTT as primary treatment.

Studies were excluded if they did not assess pre- and post-study outcomes or were observational studies without follow-up, case series, or case reports. The most comprehensive publication was used if several studies involved the same study population. Any discrepancies were resolved through discussion and adjudication by a senior reviewer.

Screening and data extraction

In the first phase of study selection, articles with irrelevant titles were excluded. Subsequently, in the second phase, abstracts and full texts of articles were reviewed to include those matching the inclusion criteria. Endnote X8 was utilized to organize and assess titles and abstracts and identify duplicate entries. A double screening technique was employed to ensure high-quality results, with one evaluation for titles and abstracts and the other for full texts. A piloted data-extraction sheet was used to gather information regarding the study period, study design, sample size, study region, age distribution, and follow-up. The study's pre-established primary outcome is the penile length before and after the intervention, while secondary outcomes include the degrees of curvature and various parameters related to erectile function (EF). EF was evaluated using Erectile Function domain of the International Index of Erectile Function (EF-IIEF) scores. Two investigators performed data extraction independently, and any discrepancies were resolved by consensus without any simplifications

or assumptions. The primary outcomes of this study were penile length, degrees of curvature, and ED.

Quality assessment of individual studies

To evaluate the methodological quality of RCTs included in this meta-analysis, we used the Cochrane risk of bias tool, which is a systematic approach used to assess the methodological quality and potential bias in RCTs and other types of studies. It provides a structured framework to evaluate seven key domains: Random Sequence Generation, Allocation Concealment, Blinding of Participants and Personnel, Blinding of Outcome Assessment, Incomplete Outcome Data, Selective Reporting, and Other Sources of Bias (16).

We used the modified Newcastle-Ottawa scale (NOS) Field (14,15) for non-randomized observational studies. The scale consists of three domains: the quality of methods, compatibility, and assessment and reporting of the results. Each category can be awarded a maximum of five, two, and three stars. The selection was evaluated based on power estimates, sequential participant selection, and recruiting bias. Studies were classified as poor [0–4], satisfactory [5–6], good [7–8], or very good [9–10]. Studies with minimal bias were given a maximum of five stars, and the total score ranged from 0 to 10 (17).

Statistical analysis

A random-effects model was used regardless of heterogeneity, and the I^2 statistic was used to report heterogeneity. I^2>50% indicates significant heterogeneity (18). We used R packages 'metafor' and 'mice' to perform statistical analysis on the effect sizes and variances of studies via R software version 4.2.2. The 'mice' package is used to impute missing data, and the imputed data is then used to compute the effect sizes and standard errors. The 'metafor' package is used to perform a random-effects meta-analysis on the effect sizes, which combines the results of multiple studies into a single estimate of the overall effect. The resulting summary and forest plot display the estimated effect size and its confidence interval (CI), as well as a measure of heterogeneity among the studies. Results were considered statistically significant for P<0.05.

Results

Search results

We conducted a comprehensive review of published literature up until April 2023 using databases such as PubMed, Google Scholar, ScienceDirect, Clinicaltrial.gov, and Cochrane Library. Following our search strategy, we examined a total of 638 publications. After removing duplicated records and irrelevant studies through abstract and title screening, we identified 24 abstracts that warranted further evaluation. These relevant abstracts were then subjected to a detailed review of their full texts. Among the 24 articles assessed, we found that 5 studies fully satisfied the predetermined inclusion criteria and were consequently chosen for inclusion in our review. A detailed flowchart of the search and selection results is shown in *Figure 1*.

Results of quality assessment

The risk of bias assessments for Joseph *et al.* [2020] (19), Moncada *et al.* [2019] (11), and Toussi *et al.* [2021] (13) indicate several common areas of concern. Random sequence generation and allocation concealment lack clear reporting across all studies. Blinding of participants and personnel raises a high risk in Moncada *et al.* [2019] and Toussi *et al.* [2021], contrasting with Joseph *et al.* [2020] which shows a lower risk. Blinding of outcome assessment varies, with Moncada *et al.* [2019] achieving low risk, while Joseph *et al.* [2020] and Toussi *et al.* [2021] have a high risk. All studies share a high risk of handling incomplete outcome data. Selective reporting and other bias are evident in Moncada *et al.* [2019] and Toussi *et al.* [2021], whereas Joseph *et al.* [2020] demonstrate a more comprehensive approach. In conclusion, these studies exhibit mixed risk profiles across different bias domains, emphasizing the importance of cautious interpretation and consideration of their methodological limitations (16) (*Table 1*). Regarding bias, the assessment of the included non-randomized studies using the NOS showed that three were satisfactory. None of the included studies showed unsatisfactory results, as presented in *Table 2* (20,21).

Characteristics and outcomes of the included studies

The main characteristics of the five included studies are presented in (*Table 3*) (11,13,19-21). The five studies were published between 2014 and 2021, and sample sizes range from 51 to 110, totaling 419. Among these studies, three were RCTs, one non-RCT, and one non-randomized prospective study. Follow-up of the patients ranged from 3 to 9 months with a mean =6.75 months (*Table 3*). Among the five studies, all studies reported penile length; four studies

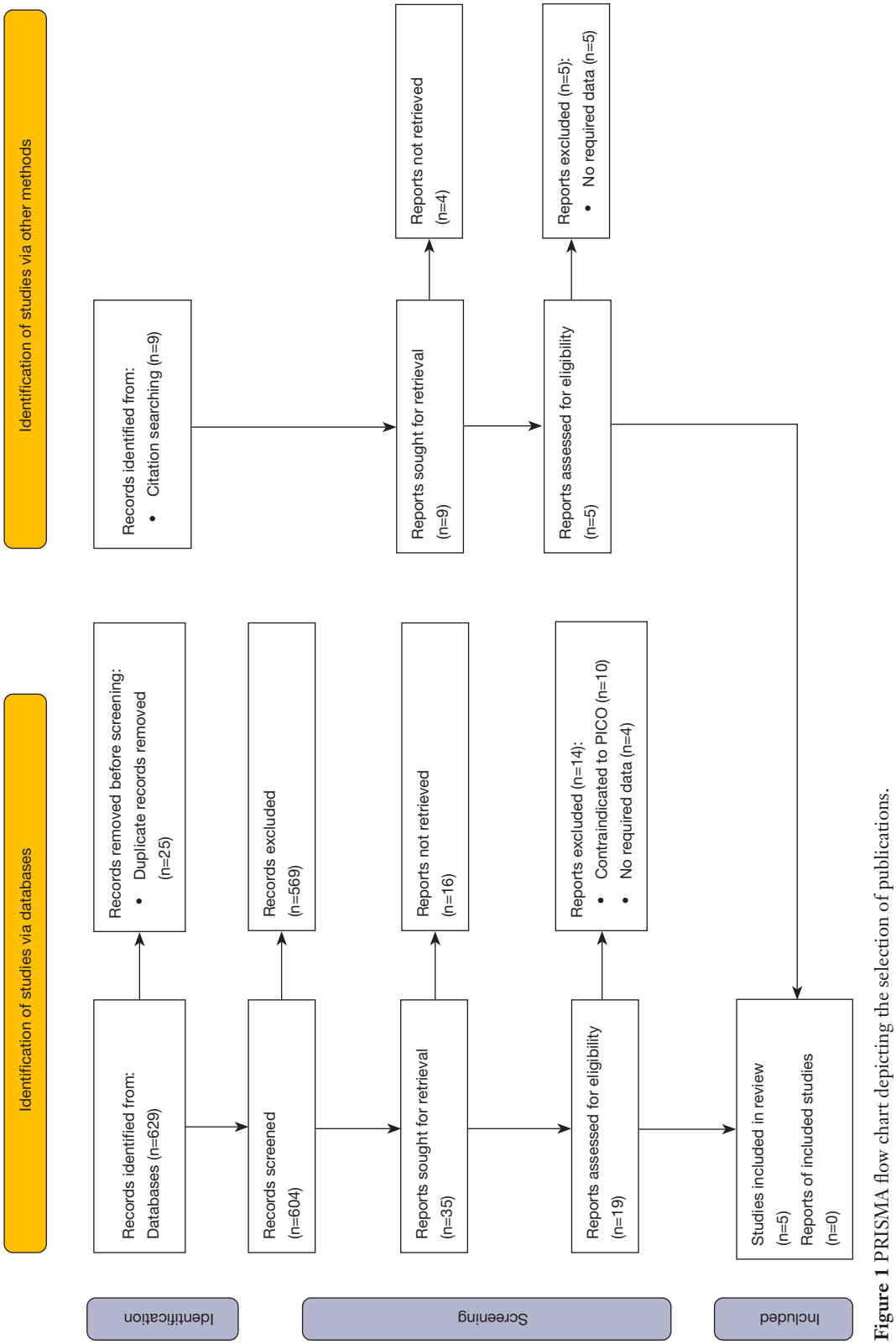

Figure 1 PRISMA flow chart depicting the selection of publications.

Table 1 Quality assessment of included RCTs using the Cochrane risk of bias assessment

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Joseph *et al.*, 2020, (19)	Unclear	Unclear	Low	High	High	Low	High
Moncada *et al.*, 2019, (11)	Unclear	Unclear	High	Low	Low	Low	High
Toussi *et al.*, 2021, (13)	Unclear	Unclear	High	High	High	Low	High

RCTs, randomized controlled trials.

Table 2 Quality assessment of included non-RCTs using the NOS scale

Domains	Selection	Comparability	Outcome	Total score
Ziegelmann *et al.*, 2017, (20)	***	–	**	5
Martínez-Salamanca *et al.*, 2014, (21)	***	*	**	6

*, one point; **, two points; ***, three points. RCTs, randomized controlled trials; NOS, Newcastle-Ottawa scale.

Table 3 Patient demographic information from included studies

Studies	Country	Study design	Data collection period	Number of participants (cases/controls)	Mean age ± SD (cases/control), years	Follow-up (months)
Joseph *et al.*, 2020, (19)	USA	A randomized, single-blinded, controlled study	October 2017–May 2019	82/28	Not reported	9
Martínez-Salamanca *et al.*, 2014, (21)	Madrid, Spain	Non-randomized prospective controlled trial	January 2009–October 2011	55/41	50.2±12/47.5±10	9
Moncada *et al.*, 2019, (11)	Multicentre	Randomized controlled trial	March 2016–June 2017	41/39	57.9±11.69/58.2±11.57	3
Toussi *et al.*, 2021, (13)	USA	Randomized controlled trial	April 2018–February 2020	55/27	58.7±6.8/58.2±4.5	6
Ziegelmann *et al.*, 2017, (20)	USA	A non-randomized, prospective cohort study	March 2014–July 2016	35/16	58.6±9.1/55.8±6.6	NR

SD, standard deviation; NR, not reported.

reported degrees of curvature, and four included studies reported EF (*Table 4*) (11,13,19-21).

Outcome measures

Our study aims to investigate the effects of certain factors on male sexual health. Specifically, we analyze three key characteristics: penile length, curvature, and EF. In this paper, we present the results of our analysis using a random effects model and discuss the implications of our findings.

To assess the impact of these factors on male sexual health, we utilized a random effects model. Before delving into the details of the statistical analysis, it is important to explicitly mention the characteristics we focused on: penile length, curvature, and EF. By examining these aspects, we aim to gain insights into the relationship between these variables and overall sexual health outcomes.

Based on the random-effects model analysis, there is no significant heterogeneity among the effect sizes for the whole study's data (P=0.9993). The estimated effect

Table 4 Outcome measure information from included studies

Studies	Safety/adverse events	Penile length (cm)			Degree of curvature (degrees)			Erectile function (scores)		
		Control	Pre-treatment	Post-treatment	Control	Pre-treatment	Post-treatment	Control	Pre-treatment	Post-treatment
Joseph *et al.*, 2020, (19)	Erythema, mild penile discomfort	11.8	11.3	13.3	68.7	69.6	54.7	28.5	13.4	21.1
Martínez-Salamanca *et al.*, 2014, (21)	Erythema, mild discomfort	14.5	12.4	13.9	29	33	13	16	18	28
Moncada *et al.*, 2019, (11)	Local discomfort and glans numbness, glans edema, penile shaft pain (due to over-stretching)	11.2	11.9	13	68.7	72.3	41.1	22.9	23.6	26.1
Toussi *et al.*, 2021, (13)	Erythema, mild discomfort, and sensation changes	8.6	11.2	12.8	NR	NR	NR	28	26.5	26.5
Ziegelmann *et al.*, 2017, (20)	NR	13.8	13.5	13.9	24.9	25.1	28.5	NR	NR	NR

NR, not reported.

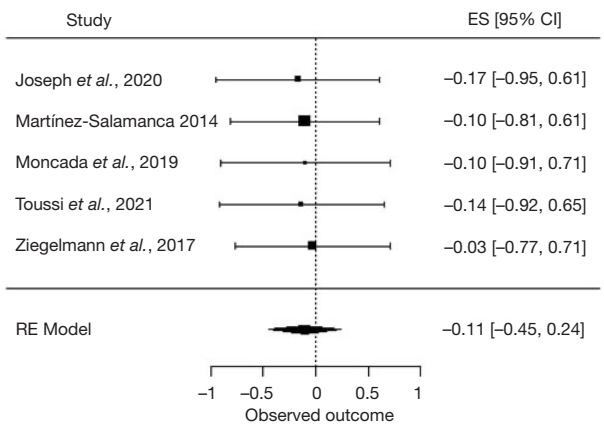

Figure 2 Forest plot showing the total difference in the outcomes of patients after PTT, with a P value =0.5436. ES, effect size; CI, confidence interval; RE, random effect; PTT, penile traction therapy.

size of −0.11 suggests a negative association but is not statistically significant (P=0.5436). The 95% CI for the effect size (−0.45 to 0.24) includes zero, indicating the lack of statistical significance. Therefore, based on this analysis, we do not have sufficient evidence to conclude a significant effect of the studied factor (*Figure 2*); for more details, see Appendix 1, section 2.

Evaluation of the influence of PTT on penile length

Based on the random-effects model analysis, there is no significant heterogeneity among the effect sizes for the penile length data (P=0.9989). The estimated effect size of −0.11 suggests a negative association between the studied factor and penile length, but it is not statistically significant (P=0.5315). The 95% CI for the effect size (−0.46 to 0.24) includes zero, indicating the lack of statistical significance. Therefore, based on this analysis, we do not have sufficient evidence to conclude a significant effect of the studied factor on penile length (*Figure 3*). For more details, see Appendix 1, section 3.

Evaluation of the influence of PTT on the degree of curvature

Based on the random-effects model analysis, we find a statistically significant effect on the degree of curvature (P=0.0373) with mean improvement =15.675 degrees. The estimated effect size of 0.28 indicates that an increase in the degree of curvature is associated with a positive change in the outcome. However, it's important to note that the 95% CI for the effect size ranges from 0.02 to 0.53, suggesting some uncertainty around the estimate. Additionally, the analysis does not provide strong evidence of heterogeneity

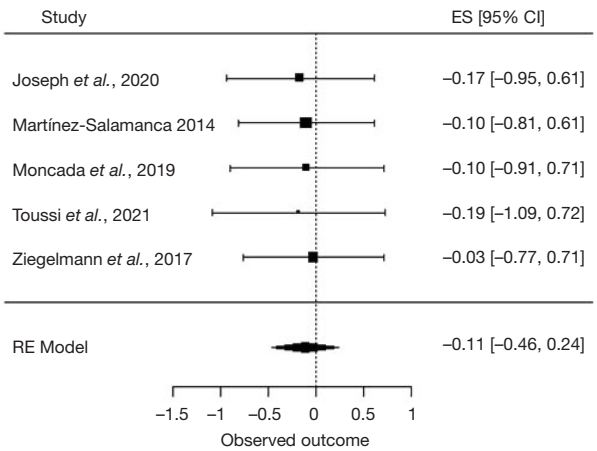

Figure 3 Forest plot showing the difference in the penile length of patients after PTT, with a P value =0.5315. ES, effect size; CI, confidence interval; RE, random effect; PTT, penile traction therapy.

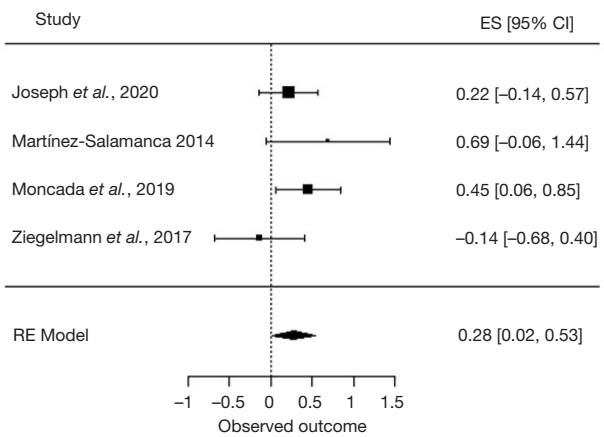

Figure 4 Forest plot showing the difference in the degree of curvature of patients after PTT, with P value =0.0373. ES, effect size; CI, confidence interval; RE, random effect; PTT, penile traction therapy.

among the effect sizes (P=0.2304). These findings indicate that the degree of curvature significantly influences the outcome (*Figure 4*). For more details, see Appendix 1, section 4.

Evaluation of the influence of PTT on EF

Based on the random-effects model analysis, no significant heterogeneity exists among the effect sizes for the EF data

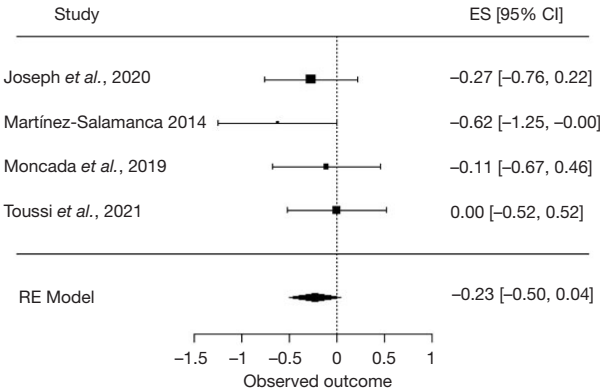

Figure 5 Forest plot showing the difference in the erectile function of patients after PTT, with, P value =0.1010. ES, effect size; CI, confidence interval; RE, random effect; PTT, penile traction therapy.

(P=0.4776). The estimated effect size of −0.23 suggests a negative association but is not statistically significant (P=0.1010). The 95% CI for the effect size (−0.50 to 0.04) includes zero, indicating the lack of statistical significance. Therefore, based on this analysis, we do not have sufficient evidence to conclude a significant effect of the studied factor on EF. Further research with more data may be needed to draw more definitive conclusions (*Figure 5*); for more details, see Appendix 1, section 5. Four studies assessed EF by EF-IIEF for the control group and patients before and after treatment (11,13,19,21).

Study objectives and protocols are summarized in *Table 5* (11,13,19-21).

The detailed adverse events following the treatment are explained in *Table 6* (11,13,19,21).

Combining the treatments

Ziegelmann *et al.* mentions that the study evaluated the efficacy of combining PTT with CCH injection therapy as a primary treatment option for men with PD. The study found that concurrent PTT with CCH did not significantly impact the extent of curvature improvement or stretched penile length with CCH therapy for PD. Additionally, there was no significant difference in the percentage of patients who found the therapy clinically meaningful, felt that the therapy prevented the need for therapy, or restored the ability for penetrative intercourse. Therefore, the study did not find evidence that coupling primary and secondary therapies improves efficacy (20).

Table 5 Study objectives and protocols summarized

Studies	Device	Objective	Protocol
Joseph *et al.*, 2020, (19)	RestoreX	Evaluation of the safety and efficacy of a penile traction therapy device (RestoreX) for the treatment of Peyronie's disease	The device is designed to be used for 30 minutes twice daily, and it is intended to be used for 3 months
Martínez-Salamanca *et al.*, 2014, (21)	Andropeyronie®	Assessment of the effectiveness and safety of a PED for the treatment of patients with acute phase PD	The PED was used for 6 hours per day for 6 months, and patients were followed up for 6 months after the end of treatment
Moncada *et al.*, 2019, (11)	Penimaster PRO	Evaluation the efficacy and safety of the Penimaster PRO device in a group of patients with stable Peyronie's disease	Patients were instructed to use the device for at least 4 hours per day, for a period of 12 weeks
Toussi *et al.*, 2021, (13)	RestoreX	Evaluation the efficacy of a novel penile traction device post-prostatectomy	The PTT group was instructed to use the device for a minimum of 4 hours per day for 6 months
Ziegelmann *et al.*, 2017, (20)	Andropenis® device	aimed to evaluate the efficacy and safety of PTT in men with PD who were undergoing CCH injection therapy	Patients were instructed to use it for at least 1 hour per day, 5 days per week, for the duration of the treatment

PED, penile extender device; PD, Peyronie's disease; PTT, penile traction therapy; CCH, collagenase clostridium histolyticum.

Table 6 Summary of the adverse events reported following the treatment

Studies	Penile erythema or discoloration	Penile discomfort	Sensation changes	Penile curvature	Follow up (months)
Joseph *et al.*, 2020, (19)	4 (48.78%)	4 (48.78%)	0	0	9
Martínez-Salamanca *et al.*, 2014, (21)	2 (3.63%)	14 (25.4%)	0	NA	9
Moncada *et al.*, 2019, (11)	NA	43%*	NA	NA	3
Toussi *et al.*, 2021, (13)	6 (20%)	11 (36.7%)	3 (10.1%)	1 (3.3%)	6

*, local discomfort and glans numbness. NA, not applicable.

On the other hand, Moncada *et al.* mention that the efficacy of CCH is limited, but the results are better when penile manual modeling or other forms of PTT are applied together with the injection. This suggests combining primary and secondary therapies may improve efficacy in managing PD (11).

In addition, Joseph *et al.* do mention that other therapies used in the study include CCH, oral treatments, vacuum devices, and surgery. Combining these therapies with PTT may improve efficacy, but this can only be confirmed with further information or a direct comparison study (19).

Discussion

In the present study, we systematically reviewed the literature investigating the use of traction therapy to treat PD. PD is characterized by developing fibrous scar tissue inside the penis, resulting in curvature, pain, and sometimes ED (22). PTDs are a non-invasive treatment option for PD that involves using an external device to apply mechanical forces to the penis to elicit biochemical responses that reduce curvature and improve penile function. Campbell and Alzubaidi. were the first to study the concept of urological applications (23).

Our analysis suggests a therapeutically meaningful effect of PTDs on decreasing penile curvature. A major advantage offered by the RestoreX device (Orem, USA), which was used by Joseph *et al.* and Toussi *et al.* in the included studies, is the short application duration (range, 30–90 minutes) in comparison to other PTDs (range, 2–9 hours) (13,19). Joseph *et al.* studied long-term outcomes with the RestoreX device and found statistically significant improvements in curvature (15%), length (10%), curvature plus length (63%), and EF (78%) when the PTD use extended from six to

nine months (19). Toussi *et al.* studied the efficacy of PTT using RestoreX device in post-prostatectomy patients using two PTT protocols consisting of low- and high-dose traction, and at six months, reported significant improvement/preservation of penile length (1.6 *vs.* 0.3 cm, P<0.01) and EF (IIEF-EF: 0 *vs.* –6.5, P=0.03), in addition to other parameters not included in our analysis such as intercourse satisfaction (IIEF-Intercourse Satisfaction: 1 *vs.* –3.5, P<0.01) and overall sexual satisfaction (IIEF-Overall Sexual Satisfaction: 0 *vs.* –3, P<0.01) (13).

Ziegelmann *et al.* used the Andropenis device (New York, USA) to study PTT efficacy as an adjunctive therapy to CCH treatment (20). The recommended duration of a minimum of 3 hours of PTT daily was only completed by 3 of 35 (8.6%) patients. No significant improvement in mean penile curvature was found when patients were stratified by PTT (PTT+ *vs.* PTT–: 19.6° *vs.* 23.6°, P=0.30). Further, no significant differences were noted in the proportion of participants who underwent >15° correction, including 24 (68.6%) PTT+ patients and 11 (68.8%) PTT patients (P=0.99). Stretched penile length increased by a mean of 0.4 cm in the PTT+ group compared to a decrease of 0.35 cm in the PTT group (P=0.21). The authors concluded that the use of PTT via the Andropenis device fell short of the recommended durations and waned over time, indicating issues with patient compliance (20). Gontero *et al.* also used the Andropenis device to study PTT's efficacy in patients with stable PD, penile curvature ≤50°, and without severe ED (24). They found an average reduction of borderline significance in penile curvature (31° *vs.* 27°, P=0.056) at six months. However, this magnitude of correction fell short of the expected effect size essential to declaring the therapy effective. The mean increase in stretched and flaccid penile length was 1.3 and 0.83 cm, respectively. Overall, PTT results were subjectively graded as acceptable despite curvature outcomes that ranged from "no change" to "mild improvement". The authors concluded that PTT using the Andropenis device only minimally corrected penile curvature. However, it provided a reasonably high patient satisfaction, which they attributed to penile lengthening (24).

Martínez-Salamanca *et al.* studied the efficacy of PTT using the Androperonie device (Madrid, Spain) in patients with active PD characterized by progressive penile curvature >15° and/or pain at rest or during the erection in the past year (21). They noted a mean curvature correction of 20° (P<0.05) in the PTT group at nine months. The visual analog scale pain score showed a mean decrease from 5.5 to 2.5 (P<0.05) at six months. The EF also showed significant improvement, with the IIEF-EF score being 28 in the intervention group and 10 in the non-intervention group (P<0.05). Further, the proportion of men unable to achieve penetration reduced from 62% to 20% (P<0.03). PTT also reduced the appearance of plaques on ultrasound in 48% of the individuals. The requirement for surgical intervention fell to 40% of the patient population. In one-third of the surgical recipients, PTT facilitated using more straightforward techniques like plication instead of grafting. The authors concluded that PTT via the Androperonie device showed clinical efficacy for managing acute phase PD for pain perception, penile curvature, and sexual function (21).

Moncada *et al.* evaluated the efficacy and safety of the PTD Penimaster PRO (Berlin, Germany) in patients with stable PD and noted an overall curvature correction of 31.2° (41.1%, P<0.001) at 12 weeks (11). Curvature reduction showed a dose-dependent relationship with the duration of device use. In patients where the device was used less than 4 hours per day, reduction ranged from 15° to 25° (28.8%; mean =19.7°, P<0.05), whereas in patients where the duration of device use extended to six hours per day or more, a higher correction was achieved spanning from 20° to 50° (51.4%; mean =38.4°, P<0.0001). Concerning penile length, a significant increase in length occurred in the intervention group, which ranged between 0.5 and 3.0 cm (mean =1.8 cm, P<0.05). The IIEF-EF score also showed improvement in the intervention group (mean =5 points) (11).

Several studies have investigated the utility and effectiveness of PTDs in PD. Overall, the results hold potential, suggesting that PTDs can be an effective treatment option for men with this condition. For example, a meta-analysis published in 2018 looked at four studies involving 348 men with PD who used a PTD following a primary intervention (25). The review found that adjunctive PTT in PD cases primarily treated with surgery or injection therapy led to an average 1 cm increase in penile length compared to men who did not undergo adjunctive PTT. The authors noticed a dose-dependent relationship between the duration of device use per day and penile length preservation. They concluded that PTT is a promising modality for PD management (25). However, our meta-analysis findings showed no significant effect on penile length or EF, while the degree of curvature showed a significant positive effect. The analysis indicated low heterogeneity among the included studies, and the estimated total heterogeneity was 0. Overall, the available

evidence does not support the efficacy of the intervention for penile length or EF.

Another study, a systematic review, and meta-analysis published in 2022 looked at the effect of CCH as an adjunct to mechanical therapies, including PTT, compared with CCH therapy alone (26). The study found that with adjunctive therapy, there was an additional average reduction of 0.3° in curvature (95% CI: −3.97 to 4.49, I^2=0%) and an additional average increase of 0.5 cm in length (95% CI: −0.32 to 1.4, I^2=70%). However, these insignificant results led the authors to conclude that adjunctive mechanical therapies, including PTT, were ineffective for active or stable PD management (26).

In this systematic review and meta-analysis, the most reported adverse events include temporary penile erythema or discoloration, mild, temporary penile discomfort, and loss of or abnormal penile sensation. These AEs were sometimes transient, meaning they resolved independently over time. In other cases, local measures or the temporary discontinuation of PTT were necessary to address the AEs. The studies suggest that while AEs are relatively common with PTT, they are generally mild and well tolerated by patients. Discontinuation of therapy due to AEs is rare.

Limitation

The findings of the present systematic review and meta-analysis should be interpreted with caution. Meta-analyses depend on the results of the original research, with no patient-level data available. The unblinded study design, lack of placebo group, lack of dividing the studies into acute and chronic phases of treatment, relatively low participant numbers, small duration of follow-up and use of clinically heterogenous protocol and treatment modalities, and a need for more research utilizing recommended treatment prevent us from extrapolating the results and coming to a definite conclusion. Also, the low-to-intermediate quality of the included studies in this review had different follow-up periods, and different or no primary therapies, providing a source of variability.

The analysis conducted revealed that no significant changes were observed concerning EF or length. However, promising trends suggesting potential beneficial effects were identified in both areas. As mentioned, wide CIs presented a challenge in drawing definitive conclusions from the data. The question is whether the lack of statistical support can be attributed to the underpowered meta-analysis. This proposition implies that the sample size or the number of studies included in the meta-analysis might have been inadequate for detecting statistically significant effects, resulting in inconclusive findings. Addressing this concern necessitates careful consideration of the potential impact of limited sample size on the ability to detect meaningful effects and draw robust conclusions from the meta-analysis.

Future direction and recommendation

PTDs, also known as penis extenders, are typically used to treat conditions like PD and to assist with penile enlargement. While we cannot predict the future direction of these devices with certainty, we provide some information on current trends and advancements.

(I) Advancements in design: manufacturers are continually working on enhancing the comfort and functionality of PTDs. This includes improvements in materials used, adjustable tension settings, and ergonomics to ensure optimal user experience.

(II) Research and clinical studies: ongoing research and clinical studies are being conducted to evaluate the effectiveness and safety of PTDs. These studies aim to gather evidence of their long-term outcomes and potential benefits.

(III) Combination approaches: PTDs may be combined with other treatments, such as medication or penile exercises, to improve outcomes. Future directions may explore the potential synergistic effects of combining different treatment modalities.

(IV) Telemedicine and App integration: with the increasing popularity of telemedicine and smartphone apps, it is possible that PTDs may incorporate digital health features. This could include remote monitoring, tracking progress, and providing personalized guidance through mobile applications.

(V) Customization and precision: as technology advances, there may be a shift towards more customizable and precise PTDs. This could involve 3D scanning and printing techniques to create personalized devices tailored to individual needs.

It's important to note that the future direction of PTDs will depend on ongoing research, regulatory approvals, market demand, and advancements in related fields. It is recommended to consult with healthcare professionals or experts in the field for the most up-to-date information.

Conclusions

Overall, while more research is needed to understand the efficacy of PTDs in PD fully, the available evidence suggests that they can be a safe and effective treatment option for men with this condition. This systematic review and meta-analysis demonstrate that PTDs can reduce penile curvature.

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Footnote

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