DOI: *10.4081/aiua.2026.14737*

REVIEW

Extracorporeal shock wave therapy in the treatment of Peyronie's disease: Our initial experience

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Summary ***Background: Peyronie's Disease (PD) is a connective tissue disorder of the penis that causes pain, curvature, and erectile dysfunction.***
Methods: A prospective study was conducted on 112 patients treated with ESWT. Each received three sessions of 3,000 shockwaves at 0.11-0.17 mJ/mm [2]. Pain, curvature, and erectile function were assessed.
Results: Pain relief occurred in 90% of patients (mean VAS reduction: 3, p < 0.00001); 57.1% had curvature improvement (mean 30°, p < 0.001); 26.2% of ED patients improved ≥ 4 points in IIEF.
Conclusions: ESWT appears safe and effective in improving pain and curvature in PD patients.

KEY WORDS: *Peyronie's disease; Erectile dysfunction; Extracorporeal shock wave therapy; Low intensity; International index of erectile function.*

Submitted 15 December 2025; Accepted 5 January 2026

INTRODUCTION

Peyronie's disease (PD) is a connective tissue disorder of the penis characterized by the formation of fibrotic plaques within the tunica albuginea. Although many patients do not recall a specific injury, the condition is often linked to microtraumas, particularly those associated with sexual activity. These minor injuries initiate a pathological healing process in susceptible individuals, leading to the formation of the characteristic fibrotic lesions (1, 2). The hallmark of PD is an aberrant wound-healing response. Microvascular trauma to the tunica albuginea triggers excessive deposition of fibrotic material, driven by an imbalance in the activity of myofibroblasts and regulatory proteins, such as tissue inhibitors of metalloproteinases. Transforming growth factor-beta, a protein released during the wound healing process, promotes fibroblast and myofibroblast proliferation and encourages collagen production (3). The resulting plaques, which may or may not be palpable, impair the mechanical properties of the tunica, causing uneven expansion during erection. This dysfunction leads to a variety of penile deformities, including curvature, narrowing, or indentation, and in some cases, an hourglass-like appearance. Such deformities frequently interfere with sexual function and may be accompanied by varying degrees of pain or discomfort. PD evolves through two distinct stages. The active phase is defined by progressive symptoms, including worsening curvature and pain, as the plaques actively remodel and mature. This phase can last over a year before stabilizing. The stable phase is characterized by the cessation of symptom progression. While pain typically diminishes or resolves, the structural deformities and functional impairments often persist, leaving a lasting impact on the patient's quality of life. Stability is generally recognized after at least three to six months without further changes in symptoms or deformity (4, 5).

The diagnostic process involves obtaining a detailed patient history, focusing on the onset, progression, and duration of penile deformity, as well as any associated symptoms such as pain, discomfort, or psychological distress. A comprehensive medical and family history is crucial to uncover potential risk factors or related conditions, including penile trauma or Dupuytren's contracture. During the physical examination, the genital region should be evaluated to identify anatomical abnormalities, palpable plaques, or areas of tenderness. Assessment in both flaccid and erect states is essential, with baseline curvature measured using visual inspection, home photography, or precise instruments like a protractor or goniometer. Although a thorough history and clinical examination are often adequate for diagnosing PD and guiding initial treatment, distinguishing between the active (inflammatory) and stable phases of the disease is vital, as it significantly impacts management decisions (6).

The treatment of PD is highly individualized and depends on the phase of the disease and the severity of symptoms. In the active phase, characterized by evolving penile deformity and discomfort, conservative therapies are typically recommended. These include oral and topical medications, intralesional injections, and external energy therapies, such as *low-intensity extracorporeal shockwave therapy* (LI-ESWT). While conservative treatments do not cure PD, they may help alleviate symptoms and improve the patient's quality of life, especially prior to more definitive surgical interventions. Surgical treatment remains the gold standard for correcting significant penile curvature, but it is reserved for patients in the stable phase, where the disease has remained unchanged for at least three months. Common surgical options include tunica plication, plaque incision or excision with or without

grafting, and penile prosthesis implantation. However, surgery carries risks such as penile shortening, *erectile dysfunction* (ED), and reduced penile sensation, making it an option primarily for severe cases. LI-ESWT has gained attention as a minimally invasive therapy for symptomatic PD plaques.

This technique employs acoustic wave energy to induce tissue remodeling and has demonstrated potential benefits, including the resolution of penile pain, improvement of local circulation, and stimulation of angiogenesis through the activation of pathways like VEGF and endothelial nitric oxide synthase. The therapy may also promote macrophage activity, leading to plaque lysis. However, its effectiveness on penile curvature and plaque size remains inconsistent, and standardized protocols for its use in PD are lacking. Reported side effects are generally mild and self-limiting, such as local pain, hematomas, or petechiae (7). Although conservative therapies like LI-ESWT offer a noninvasive alternative for pain relief and symptomatic management, their overall success is limited due to the complex and poorly understood mechanisms of PD. Surgical correction continues to be the definitive treatment for severe cases, but it is often avoided when less invasive methods can manage symptoms effectively (7, 8).

Materials and methods

A prospective study was conducted on 112 patients from January 2022 to January 2023 at the *Istituto Clinico Città Studi* (ICCS) in Milan, Italy. Each participant underwent a minimum of three sessions of *low-intensity extracorporeal shockwave therapy* (ESWT), with 3,000 shockwaves delivered per session at an energy density of 0.11-0.17 mJ/mm², administered at three-week intervals. ESWT was applied in both patients presenting with acute-phase (active) Peyronie's disease plaques and stabilized (chronic-phase) plaques. Penile curvature was evaluated using auto-photography, with a mean pre-treatment angulation of 48 degrees (range: 10-100 degrees). Pain during erection was assessed using a *visual analog scale* (VAS, 0-5), where all patients reported symptoms, and 60 of them scored the maximum value of 5. Erectile function was measured through the *International Index of Erectile Function* (IIEF) questionnaire, revealing erectile dysfunction (IIEF < 18) in 42 patients (37.5%). Moreover, these patients were using tadalafil 20 mg soft gels, as needed, before/during/after ESWT treatment. The plaque was localized through palpation. The mean duration of the disease prior to treatment was 18 months (range: 4-60 months). Treatment indications were based on both the time elapsed since the initial diagnosis and the severity of symptoms. Patients with significant pain, particularly those scoring 5 on the VAS, were considered to be in the active (acute) phase of PD, while others with longer disease duration and stable deformity were considered in the chronic (stable) phase. Accordingly, 70 patients (62.5%) received ESWT during the active (acute) phase, while 42 patients (37.5%) were treated during the chronic (stable) phase. Patients were followed for an average of 9 months (range: 4-24 months).

Table 1.
Clinical outcomes and safety of ESWT treatment in patients with Peyronie's Disease.

Outcome	Result
Treatment completion	All patients completed the protocol with excellent tolerance
Pain relief during erection	54/60 (90%) patients; mean reduction 3 on VAS ($p < 0.00001$)
Improvement in penile curvature	64 patients (57.1%) improved > 10°; mean reduction: 30° ($p < 0.001$)
Erectile dysfunction improvement	11 patients (26.2%) had > 4-point increase in IIEF
Perceived plaque smoothness	62 patients (55.4%) reported improvement
Adverse effects	2 patients (1.8%) had minor bruising
Major complications	None observed

Results

All patients successfully completed the treatment protocol, demonstrating excellent tolerance and safety. Outcomes were statistically analysed using the Wilcoxon signed-rank test. Among the 60 patients reporting maximum pain during erection (VAS 5), who were all in the acute phase, 54 (90%) experienced immediate pain relief following ESWT, with a mean reduction of 3 points on the visual analog scale ($p < 0.00001$). In the chronic phase patients, where baseline pain was lower, minor reductions in discomfort were observed. Improvement in penile curvature, defined as a reduction of more than 10 degrees, was observed in 64 patients (57.1%) overall, with an average reduction of 30 degrees ($p < 0.001$). When analyzed by disease phase, curvature improvement was noted in both acute and chronic phase patients, indicating benefits in both stages. Additionally, 11 patients with erectile dysfunction (26.2%) reported an increase of more than 4 points in their IIEF scores, with improvements seen in both acute and chronic phase groups. Perceived plaque smoothness was noted by 62 patients (55.4%), again occurring in patients across both phases. Minimal adverse effects were reported, with only two patients (1.8%) experiencing minor bruising at the treatment site, which resolved the following day. No major complications were observed (Table 1).

Discussion

The aim of this study is to prospectively evaluate the clinical efficacy and safety of ESWT as a conservative and non-invasive treatment option for managing Peyronie's Disease. This condition is a connective tissue disorder affecting the tunica albuginea and adjacent erectile tissue, characterized by the formation of localized plaques. In its early stages, the disease manifests as thickening of the tunica, progressing to fibrosis that may calcify over time. First described by François de la Peyronie in 1743, the condition often results in penile deformity, shortening, pain, and, in more advanced cases, erectile dysfunction or distal flaccidity (9, 10). Peyronie's disease evolves through an acute phase, marked by penile pain, followed by a chronic phase during which stable deformities, including penile shortening, develop. The disease significantly impacts patients' quality of life, causing psychological distress, sexual dysfunction, anxiety, depression, and relationship challenges. Its prevalence is notably higher in

specific groups, such as diabetic patients and individuals who have undergone radical prostatectomy. The underlying pathophysiology likely involves repetitive microvascular trauma that induces fibroblast proliferation and excessive collagen deposition, resulting in dense plaques that cause penile curvature. Although various medical therapies have attempted to target this pathway, their effectiveness remains uncertain. Surgical correction, the standard treatment during the chronic phase, carries risks such as penile shortening and post-surgical erectile dysfunction (10, 11). ESWT has been introduced as a non-invasive alternative, aiming to mechanically disrupt and remodel plaques, enhance local vascularity, and promote tissue regeneration. While the precise mechanism of action remains unclear, LI-ESWT has shown potential in facilitating plaque resorption, reducing calcifications, and softening plaques, with the possibility of improving penile curvature. Despite this promise, the efficacy of LI-ESWT varies, and additional studies are necessary to establish its role, particularly in preventing disease progression during the acute phase (12, 13). In this context, several clinical studies and meta-analyses have investigated the role of extracorporeal shock wave therapy in Peyronie's disease, reporting heterogeneous and sometimes conflicting results. Although the use of shock wave therapy for PD was described in early clinical experiences, research remains controversial and outcomes variable. For example, some observational studies have suggested that ESWT may reduce pain and improve functional scores in PD patients, with reports of decreased plaque size and improved curvature following treatment protocols involving weekly sessions of ESWT in larger patient cohorts (e.g., 325 patients showing reductions in plaque size and curvature with significant improvements in pain and IIEF scores) (14). However, randomized controlled trials have produced mixed results. In a prospective, placebo-controlled, randomized study involving PD patients treated with ESWT, a reduction in pain with shock wave therapy was observed in patients reporting baseline discomfort, but no significant improvement in penile deviation or plaque size was shown compared to placebo, and some outcomes such as deviation angle did not improve significantly (15).

Systematic reviews and meta-analyses of randomized controlled trials have provided a more comprehensive evaluation of ESWT in PD. One meta-analysis concluded that ESWT may reduce plaque size, but it failed to significantly improve penile curvature or pain when compared with control groups, and the clinical significance of plaque reduction remains uncertain (16). An updated meta-analysis further indicated that although ESWT can safely reduce plaque size and may alleviate pain, it does not significantly improve penile curvature or sexual function, and long-term efficacy remains unproven (17). More recently, a systematic review and meta-analysis including seven controlled studies and 475 patients evaluated the efficacy of LI-ESWT in Peyronie's disease. The analysis demonstrated that LI-ESWT was associated with a significantly higher proportion of patients experiencing plaque size reduction, improvement in penile curvature, pain relief, and complete remission compared with placebo or control treatments. However, no significant improvement in sexual function, as assessed by the IIEF, was observed. The main outcomes and characteristics of the studies included in this meta-analysis are summarized in Table 2 (18). The findings of our study support ESWT as a safe and effective conservative treatment for Peyronie's disease. All patients adhered to the treatment protocol, demonstrating excellent tolerance and safety. Statistically significant improvements were observed: among 60 patients reporting pain during erection, 54 (90%) experienced immediate relief, with an average pain reduction of 3 points on the visual analog scale ($p < 0.00001$). Penile curvature improved in 64 patients (57.1%), with an average reduction of 30 degrees ($p < 0.001$). Additionally, erectile function, measured through IIEF scores, improved by more than four points in 11 patients (26.2%). Perceived plaque smoothness was reported by 62 patients (55.4%). Adverse effects were minimal, with only two cases (1.8%) of minor bruising at the treatment site, which resolved spontaneously. No major complications were noted. Despite these promising outcomes, certain limitations must be acknowledged. The study lacked a control group, and the follow-up period was relatively short, limiting conclusions about long-term efficacy and safety. Future research should prioritize understanding the biological mechanisms underpinning ESWT's effects on plaque remodeling and fibrosis and explore its potential for mitigating disease progression during the acute phase. Extended follow-up studies are essential to confirm whether the observed improvements in pain, penile curvature, and erectile function are sustained over time.

Table 2.
Outcomes from the meta-analysis by Li et al. (2024) on LI-ESWT for PD (475 patients, 7 studies, 1999-2023).

Outcome	Result
Reduction in penile plaques	Significant *vs* placebo (p = 0.02)
Improvement in curvature	Moderate improvement (p = 0.05)
Pain alleviation	Significant reduction *vs* placebo (p = 0.04)
Complete remission	Highly significant (p < 0.00001)
Sexual function improvement	No significant difference *vs* placebo (p = 0.53)

Declarations

Ethical approval and consent for participate: *Not applicable.*

Consent for publication: *Not applicable.*

Availability of data and material: *Data available upon reasonable request to the corresponding author.*

Competing interests: *The authors declare that they have no competing interest.*

Funding: *This research received no external funding.*

Authors' contributions: *GS and MS designed the study. GS, RT, and MS wrote the manuscript. GDP, ASC, FAM, and ALM collected data. All authors approved the final version.*

Acknowledgments: *Not applicable.*

While this study adds valuable evidence to the field, further investigation is crucial to optimize treatment protocols and improve outcomes for patients with Peyronie's disease.

Conclusions

ESWT appears to be an effective, feasible, and safe conservative treatment option for Peyronie's disease. The therapy demonstrates significant potential in alleviating pain during erection and, in certain cases, improving penile curvature. Nevertheless, further research and extended follow-up are essential to confirm these outcomes and better understand the long-term efficacy of this approach.

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