

Penile Stretching as a Treatment for Peyronie's Disease: A Review

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ABSTRACT

Introduction: Peyronie's disease (PD) is a debilitating condition that affects a sizable number of men worldwide. Current treatment options consist of oral therapy, intralesional injections, and surgery. Penile stretching has been used as a treatment for PD, including penile traction therapy (PTT) and vacuum erection devices (VEDs), with numerous trials completed or underway.

Aim: To present and summarize the current literature on penile stretching for the treatment of PD.

Methods: Using PubMed, we performed a literature review of studies from January 1990 through July 2018 that focused on penile stretching for PD management. PTT and VED were included in the search criteria.

Main Outcome Methods: Penile curvature correction was effective, and stretched penile length was improved.

Results: PD therapies that use penile stretching as a mechanical intervention to alter tissue characteristics were studied. PTT has been successful in primary penile lengthening and curvature correction in the acute phase of PD. PTT also improved length retention in men undergoing plication and incision/grafting procedures. Combination of PTT and intralesional injection therapy for PD treatment requires further investigation. There are fewer studies investigating VEDs and their role in PD management, but initial small trials suggest a role in curvature correction and penile lengthening.

Conclusions: Penile stretching is an effective therapy for PD. Data from limited trials suggest a role for PTT and VEDs in the management of PD, although further research is needed. **Cowper MG, Burkett CB, Le TV et al. Penile Stretching as a Treatment for Peyronie's Disease: A Review. Sex Med Rev 2019;XX:XXX–XXX.**

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Key Words: Peyronie's Disease; Penile Stretching; Treatment; Traction Therapy; Vacuum Erection Device

INTRODUCTION

Peyronie's disease (PD) is characterized by scarring of the tunica albuginea, resulting in a plaque that can lead to penile shortening, curvature, indentation, and pain.¹ Treatment modalities include topical treatment, oral medications, penile stretching, intralesional injections (ILI), and surgical correction. PD was first described in 1743 by Francois Gigot de la Peyronie, the personal physician to King Louis XV of France.¹ Historically, PD was considered a rare and purely cosmetic condition. Various studies revealed that PD was, in most cases, a progressive condition, with 77% of patients experiencing negative psychological consequences and 63% of patients describing their condition as disabling.^{1–4} The prevalence of PD is estimated to be at 3% to

9%, with many men going undiagnosed due to failure to seek help because of embarrassment or a lack of knowledge by primary care physicians.⁵ Risk factors for the development of PD include genital injuries, transurethral procedures, diabetes mellitus, Dupuytren's contracture (DC), smoking, and excess alcohol consumption.⁶

PD shares many similarities with DC, which is a fibrotic disorder of the ligaments in the hand. Continuous mechanical traction has been used with durable success in the treatment of DC. Traction therapy results in collagen remodeling and tendon healing.⁷ Histologic staining after traction therapy confirmed reorganization and remodeling of collagen fibers into uniform densely packed fibrils that are parallel to the axis of mechanical strain.⁸ DC is not a perfect model for PD, because the plaques in DC are cordlike, whereas plaques in PD can take various forms. Nevertheless, the success of traction therapy in the treatment of DC has stimulated research and development in the treatment of PD.

The 2015 American Urological Association (AUA) guidelines recommend ILI therapy with clostridium collagenase histolyticum (CCH) for men with stable PD with penile curvature >30° and <90° with intact erectile function. They also

Received August 31, 2018. Accepted November 11, 2018.

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<https://doi.org/10.1016/j.sxmr.2018.11.002>



Figure 1. Penile harness with weight, advertised to extend penile length (Zenbala, Suzhou City, Jiangsu Province, China).

recommend tunical plication for men with intact rigidity for coitus and penile prosthesis for men with concomitant erectile dysfunction. The AUA does not currently recommend any oral agents. There are currently no recommendations regarding penile stretching, with the AUA stating that mechanical therapies require further study before being generally adopted.⁹ Penile traction therapy (PTT) is included in current International Consultation on Sexual Medicine and European Association of Urology guidelines and will be discussed in its respective section.

Penile stretching is not a new concept, and many “do-it-yourself” efforts have been developed by those looking to extend their penile length. One of the most common strategies is the use of penile weights (Figure 1). The concept is that attaching a small weight to the penis for a set amount of time every day will elongate the penis. A similar concept has been used with neck rings. Most authorities discourage the use of penile weights attached to the end of the penis to increase length or girth of the penis. This practice may cause severe swelling, sensory nerve injury, and erectile dysfunction.¹⁰

However, the evidence suggests that medically directed penile stretching does have a role in the treatment of PD.¹¹ What follows is a comprehensive review assessing different modalities that use penile stretching, including PTT and vacuum erection devices (VEDs). The main outcome measures are resolution of effective penile curvature (EPC) and improved stretched penile length (SPL).

PENILE TRACTION THERAPY

Initially described in 2001, PTT is a relatively new therapeutic option for men with PD, with most of the research done over the last 2 decades.¹¹ This technique uses mechanotransduction, which involves mechanical forces to lengthen or stretch the

Table 1. Commercially available penile traction devices

Device	Manufacturer
Andropenis	Andromedical, Madrid, Spain
Golden Erect extender device	Ronas Tajhiz Teb, Tehran, Iran
SizeGenetics	GRT Net Services Inc., Gresham, OR, USA
Andropeyronie	Andromedical America, New York, NY, USA
PhysioMed Penile Extender	Aliso Viejo, CA, USA
Vimax Extender	OA Internet Services, Montreal, Quebec, Canada
PeniMasterPro	MSP Concept, Berlin, Germany
Phallosan Forte	Swiss Sana Ansalt, Vaduz, Liechtenstein
ProExtender	Leading Edge Herbals, Greeley, CO, USA
X4 Labs Penis Extender	X4 Labs, Montreal, Quebec, Canada
RestoreX	PathRight Medical, Plymouth, MN USA

tunica albuginea, gradually expanding tissues and transmitting mechanical stimuli to cellular biochemical responses.¹² On a histologic level, PTT has been demonstrated to reorient collagen fibrils parallel to the axis of stress. Chung et al¹² observed that penile stretching reduced smooth muscle actin, leading to decreased myofibroblast activity and increased metalloproteinase activity in Peyronie plaques. A list of commonly used commercially available penile traction devices is included in Table 1.

In general, traction devices vary in shape and size depending on the company, but the underlying concept is ubiquitous. Most of these devices use parallel rods connected to 2 padded rings, 1 proximally at the base of the penis and a second distally proximal to the corona. The device works by holding the penis with a clamp in a small frame, subjecting it to gentle and progressive traction forces usually less than 1 lb. The Phallosan Forte (Swiss Sana Ansalt, Vaduz, Liechtenstein) and the PeniMasterPro (MSP Concept, Berlin, Germany) use a suction cup to keep the penis in place instead of a clamp. Additionally, the PeniMasterPro uses an elastic belt to generate traction. Restorex (PathRight Medical, Rochester, MN USA) uses a ratcheting body with springs and generates both longitudinal and oppositional angular force (Figure 2) to generate up to 7 lb of force.

A number of studies have reported on the effectiveness of PTT for men with PD. Most of them are descriptive in nature or cohort with a small sample size and without a control arm. PTT has been used as the primary treatment or in combination with ILI or surgery (Table 2).

PTT AS PRIMARY TREATMENT

One of the earliest reports on the use of PTT as a primary treatment in patients with PD was presented at the 4th Annual European Society for Sexual and Impotence Research meeting in



Figure 2. Demonstration of the oppositional angular force used with RestoreX (PathRight Medical, Rochester, MN USA).¹³

2001. Scropo et al¹¹ reported on a small study of 8 men with PD without erectile dysfunction. The subjects were instructed to use the penile traction device for at least 4 hours per day for a total treatment period of 3–6 months. The authors reported a 4.1-cm increase in SPL ($P < .05$) and a 14° decrease in EPC (from 34° to 20°; $P < .05$).¹¹

In another pilot study in 2008, Levine et al¹⁴ evaluated the efficacy of PTT as a nonsurgical treatment option in 10 men with PD. The patients were instructed to wear the device for a minimum of 2 hours per day and gradually increase their usage to a maximum of 8 hours per day. There were non-statistically significant improvements in EPC, ranging from 10° to 45° and an increase in SPL of 0.5 cm to 2.0 cm.¹⁴ The FastSize Penile Extender (FastSize, LLC, Aliso Viejo, CA, USA) used in this study has since been recalled and is no longer commercially available.

1 year later, Gontero et al¹⁵ reported the results of PTT use in 19 men with a minimum of 12 months of PD and pre-existing curvature of less than 50°. Notably, penile measurements were obtained using photographs taken by the researchers after a vasoactive agent induced an artificial erection. The subjects were instructed to use the PTT for a minimum of 5 hours per day, up to a maximum of 9 hours. For the 15 patients who completed the study, there was a significant improvement in the mean flaccid and SPL measurements of 1.3 and 0.8 cm, respectively, and a non-significant reduction in EPC from 31° to 27°.¹⁵

In the largest study of PTT to date, Martinez-Salamanca et al¹⁶ specifically assessed the efficacy of a penile traction device for the treatment of men in the acute phase of PD. The acute phase was defined as a clinical diagnosis of PD within the last 12 months. 55 men with PD underwent PTT for 6 months and were compared with 41 patients in the acute phase of PD without active therapy. After treatment, PTT users were significantly more likely to experience increases in SPL (1.5 vs −2.6 cm) and decreased EPC (−18° vs 23°). Furthermore, PTT was associated with the disappearance of sonographic penile plaques in 48% of patients with PD and decreased the need for surgery by 40% in patients who were initially good candidates for surgery.¹⁶

Recently, Ziegelmann et al¹⁷ reported the preliminary results of a cohort of patients with PD in an ongoing randomized controlled study (clinical trial number NCT03389854). The aforementioned novel PTT device, RestoreX, was developed specifically as a primary or adjunctive therapy for PD. In this study, 38 men with PD were randomized into 1 of 4 groups: no therapy (control) or treatment with RestoreX for 30 minutes 1, 2, or 3 times daily for 3 months. All men then entered the open-label phase for an additional 3 months. Inclusion criteria were no current or recent PD therapies and a $\geq 30^\circ$ curvature. The authors reported that PTT significantly improved SPL (absolute change: 2.4 vs 0.2 cm, $P < .001$; percentage change: 15.8% vs 1.5%, $P < .001$) and EPC (absolute change: −14.5° vs 3.2°, $P < .001$; percentage change: −43.2% vs 10.6%, $P < .001$), compared with control subjects. No significant adverse events were reported in any group, and no significant differences were noted between traction groupings (1, 2, or 3 times daily).¹⁷

COMBINATION OF PTT AND ILI

Several studies have also examined the concomitant use of PTT in conjunction with non-surgical treatments for PD, especially ILI. In 2012, Abern et al¹⁸ investigated the benefit of PTT when combined with intralesional verapamil injections and oral L-arginine and pentoxifylline in 74 men with PD. Patients who opted for PTT used the device for 2–8 hours daily. A total of 54% of patients reported improvement in EPC in the PTT group compared with 46% of patients who did not use PTT, but there were non-significant differences in EPC and SPL between the groups. Multivariate analysis confirmed that the duration of PTT use significantly predicted SPL gain (0.38 cm gain for every additional hour per day of PTT use, $P = .007$).¹⁸

In 2015, Yafi et al¹⁹ compared outcomes of men treated with ILI of interferon α -2b and PTT vs interferon alone. 112 patients underwent a median of 12 interferon α -2b injections; 31% of patients used PTT daily. The authors concluded that PTT did not change penile girth. However, men who used PTT 3 or more hours per day gained significantly greater SPL (0.4 vs 0.1) compared with those who did not undergo PTT.¹⁹

A more recent study by Ziegelmann et al²⁰ investigated 51 men with PD who were prospectively followed up during CCH injection therapy. This was the only study evaluating the effectiveness of combined PTT and CCH. Patients were instructed to use PTT for at least 3 hours daily. 35 men with combined therapy were compared with 16 men treated with CCH alone. No statistically significant differences were identified in mean EPC improvement (PTT = −19.60 vs no PTT −23.60) or SPL (0.4 vs −0.35 cm).²⁰

COMBINATION OF PTT AND SURGERY

PTT has been studied as an adjunctive therapy before placement of a penile prosthesis and after PD surgery. In 2007, Moncada-Iribarren et al²¹ reported on the use of a traction device

Table 2. Summary of studies evaluating efficacy of penile traction therapy (PTT) in men with PD

	Study design, no.	Population studied	Device and duration	Results
PPT				
Scroppo et al ¹¹	Prospective, 8	Acute phase, mean PD duration: >3 mo	4 h/d 3–6 mo	EPC: 20°–34° SPL: 4.1 cm
Levine et al ¹⁴	Prospective, 10	Chronic phase, mean PD duration: 29 mo	FastSize Penile Extender. 2–8 h/d 6 mo	EPC: 10°–45° SPL: 0.5–2 cm
Contero et al ¹⁵	Prospective, 15	Chronic phase, mean PD duration: 12 mo	Andropenis 5–9 h/d 6 mo	EPC: 4° SPL: 0.8 cm
Martinez-Salamanca et al ¹⁶	Prospective, open label, 96	Acute phase, mean PD duration: 7–8 mo	Andropeyronie 6–9 h/d 6 mo	EPC (PTT+): –18° EPC (PTT–): 23° SPL (PTT+): 1.5 cm SPL (PTT–): –2.6 cm
Ziegelmann et al ¹⁷	Randomized control trial, 38	Acute phase, mean PD duration: 16.7 mo	RestoreX 0.5–1.5 h/d 3 mo	EPC (PTT+): –14.5° EPC (PTT–): 3.2° SPL (PTT+): 2.4 cm SPL (PTT–): 0.2 cm
PTT and ILI				
Abern et al ¹⁸	Prospective, nonrandomized, 74	Chronic phase, mean PD duration: 1.1–1.8 y	Andropenis 2–8 h/d 6 mo	EPC (PTT+): –26.9° EPC (PTT–): –20.9° SPL (PTT+): 0.3 cm SPL (PTT–): –0.7 cm
Yafi et al ¹⁹	Retrospective, 112	Chronic phase, mean PD duration: 2.9 y	Andropenis ≥2 h/d	EPC (PTT+): –8° EPC (PTT–): –10° SPL (PTT+): 0.2 cm SPL (PTT–): 0.1 cm
Ziegelmann et al ²⁰	Retrospective, 51	Chronic phase, mean PD duration: 29 mo	Andropenis 3 h/d	EPC (PTT+): –19.6° EPC (PTT–): –23.6° SPL (PTT+): 0.4 cm SPL (PTT–): –0.35 cm
PTT and surgery				
Moncada-Iribarren et al ²¹	Prospective, open label, 40	Mean PD duration not provided	Andropenis 8–12 h/d 4 mos	SPL: 1–3 cm
Rybak et al ²²	Retrospective, 111	Mean PD duration not provided	PhysioMed 2–6 h/d 3 mo	Plication group: SPL (PTT+): 0.6 cm SPL (PTT–): –0.5 cm Grafting group: SPL (PTT+): –0.4 cm SPL (PTT–): –1.6 cm

EPC = effective penile curvature; ILI = intralesional therapy; PD = Peyronie's disease; PTT = penile traction therapy; SPL = stretched penile length.

to treat penile shortening after PD surgery. A total of 40 men who had PD surgery (12 men with penile grafting and 28 men with penile plication) were randomized to PTT vs observation. For both groups, penile shortening after surgery ranged from 0.5 to 4.0 cm. The authors concluded that SPL of the patients in the PTT group increased (ranging from 1 to 3 cm), and this increase was proportional to the number of hours per month using PTT.²¹

In 2012, Rybak et al²² investigated the SPL change and penile satisfaction after surgery (penile plication or partial plaque excision and grafting) with or without PTT after surgery. PTT was

initiated at 3–4 weeks after surgery for 2–6 hours daily for 3 months. Results demonstrated statistically significant improvements in penile length in the plication (0.6 vs –0.5 cm) and grafting (–0.4 vs –1.6 cm) cohorts with PTT.²² A summary of these PTT studies is included in Table 2.

RECOMMENDATION AND GUIDELINES

PTT is increasingly being studied and used in the treatment of PD. Devices are widely available, easy to use, and have minimal

Table 3. Recommendation of International Consultation on Sexual Medicine²⁴ and European Association of Urology guidelines²⁵ about PTT in PD

Recommendation	Level of evidence	Strength
PTT is a viable treatment option to modestly improve penile length. ²⁴	2	B
PTT can be used adjunctively before penile prosthesis placement in men with decreased penile length or after surgery for PD to optimize patient outcomes. ²⁴	3	C
PTT can correct curvature in men presenting during the acute phase of PD. ²⁴	2	C
The benefits of PTT in men with PD in the chronic phase of disease are unclear. ²⁴	3	C
Use penile traction devices and vacuum devices to reduce penile deformity and increase penile length. ²⁵	—	C

PD = Peyronie's disease; PTT = penile traction therapy.

side effects. However, several important issues need to be considered in PTT, such as the efficacy of these devices in the various subgroups of PD, patient-disease demographics, and effect on sexual and erectile functions, as well as patient safety, tolerability, and compliance. Some authors suggest that selected cases of PD may benefit from a conservative approach with PTT alone, resulting in increased penile length and reduction of penile deformity.^{16,23}

Thus far, 2 notable guidelines have been published on the role of PTT in the management of PD.^{24,25} The first specific guideline on PTT was published in 2016 and included statements from a consensus panel of sexual medicine experts who convened during the International Consultation on Sexual Medicine in 2015.²⁴ The second one was the 2018 update of Guideline on Male Sexual Dysfunction of European Association of Urology.²⁵ The level of evidence for these recommendations is not strong because of the lack of the randomized control trials using PTT for the treatment of PD (Table 3).

Further randomized controlled trials comparing various traction protocols would be the next logical step in investigating the efficacy of PTT. Specifically, the optimum time and duration of PTT application must be thoroughly investigated before it is accepted as a standard of care for men with PD.

VACUUM ERECTION DEVICES

VEDs were first described as a treatment for erectile dysfunction by the American physician John King in 1874. However, VEDs did not become popular for treating erectile dysfunction until the 1960s.²⁶ The role of VEDs as a treatment for PD is less well established. In the most basic sense, VEDs are conceived to work by boosting penile arterial blood flow while

simultaneously decreasing venous outflow.²⁷ The additional penile blood flow enhances tissue oxygenation, which is postulated to lead to better erectile function and sexual satisfaction for patients.²⁸ Furthermore, VEDs are hypothesized to work through a variety of different molecular mechanisms. Yuan and colleagues²⁹ investigated the molecular mechanisms of VEDs in rats. They found that rats exposed to VEDs had increased levels of endothelial nitric oxide synthase and α -smooth muscle actin, as well as decreased expression of hypoxia-inducible factor-1 α , transforming growth factor- β 1 (TGF- β 1), and collagenase.²⁹ These findings suggest that VEDs preserve erectile function through antihypoxic, antiapoptotic, and antifibrotic mechanisms. The observed down-regulation of TGF- β 1 was notable because it is linked to the pathogenesis of PD.²⁹ In 2017, in addition to confirming the immunohistochemical patterns reported in rats with PD, Lin et al³⁰ reported increased intracavernosal pressures after therapy with VED when compared with PTT and control.

VEDs have recently gained popularity in the management of PD. This recent interest can be linked to the low morbidity and non-invasive nature of this method.²⁶ However, the effects of VEDs on penile length in men with PD have not been well documented. A number of studies have evaluated the efficacy of VEDs on increasing penile length in men with erectile dysfunction. Canguven et al³¹ reported a 0.8-cm increase in penile length when a VED was used 10 to 15 minutes daily for the 30 days before the insertion of a penile prosthesis. In this study, 51 patients with ED scheduled for penile prosthesis implantation were randomized into either an intervention group (preoperative VED use) or control group (no intervention). The mean SPL change for the intervention group was greater by 0.6 cm compared with placebo.³¹

Furthermore, the effects of VEDs on increasing penile length have been studied in men undergoing penile rehabilitation after radical prostatectomy. Kohler et al³² noted that men undergoing early (1 month) treatment with a VED after prostatectomy had a slower rate of penile length loss than men undergoing late treatment (6 months). Similarly, Raina et al³³ studied the efficacy of VED after prostatectomy to determine where VEDs facilitate early sexual activity and return of earlier erectile function by subjecting 74 patients to VED therapy daily for 9 months. They concluded that early use of VEDs after nerve-sparing radical prostatectomy facilitates early sexual intercourse, patient/spousal sexual satisfaction, and earlier return of natural erections.³³

EVIDENCE FOR CURVATURE CORRECTION FROM VEDS

The effects of VED on penile curvature in men with PD has been examined in several studies. Raheem et al³⁴ observed that VED resulted in a 5–25% improvement of penile curvature in 21 men with PD. This study found a significant improvement in penile length, curvature, and pain after 12 weeks of using

VEDs.³⁴ Additionally, Lin et al³⁰ noted VEDs to significantly decrease penile curvature in rats with induced fibrous plaques. In this study, VEDs were also shown to reduce TGF- β 1, further supporting the notion that VEDs could have a potential anti-fibrogenic mechanism.³⁰

Overall, the effectiveness of VEDs in treating PD is still not well established. Limited data suggest that VED is effective in penile lengthening after radical prostatectomy and before penile prosthesis surgery. More studies are needed to further understand the benefits of VED in treating PD.

DISCUSSION

There is a range of treatments that use stretching of the penis to treat PD. We analyzed PTT and VEDs. These interventions each use mechanical force to produce both macroscopic and molecular change. Immunohistochemical staining of tissue exposed to PTT and VEDs demonstrate reduced levels of apoptotic markers and fibrosis inducing TGF- β .²⁹ Further research is needed to characterize the immunohistochemical profile of PD plaques in men who undergo penile prosthesis implantation. VED therapy has also revealed increased intra-cavernosal pressures in rats with PD.³⁰

PTT and VED have demonstrated promising results in treating men with PD in early trials. PTT has been shown to be effective as a primary therapy for penile lengthening and curvature correction.^{11,15–17} Additionally, PTT also aided in length retention and gain when used after plication or grafting surgery^{21,22} and before penile prosthesis placement.¹⁴ However, when used as a combination therapy in conjunction with ILI, trials have reported mixed results regarding penile lengthening^{18–20} and no solid evidence of increased curvature correction.²⁰ Additional research is required to further elucidate the role of combination therapy. Furthermore, larger randomized controlled trials are needed to better define the role of PTT as treatment for PD. Current trials use small sample sizes and devices that generally require patients to spend 2–3 hours using the PTT device—a burdensome amount of time that may lead to patient non-compliance and the varied results observed. Of note, RestoreX demonstrated improvement with 30 minutes of daily use.

Trials containing VED therapy for PD are limited in number and participants. VED therapy has been used to facilitate penile lengthening before IPP placement,³¹ and during penile rehabilitation after radical prostatectomy.^{32,33} VEDs have shown evidence for curvature correction in both men³⁴ and rat models.³⁰ Combining these modest early trials with our current understanding of the molecular and vascular changes associated with VED therapy predicts a role for its use in treatment for PD. VED therapy usually requires 30 minutes per day, which lends itself to higher compliance. As of this writing, only 1 uncontrolled trial had been performed for VED as

monotherapy. Larger randomized controlled trials are needed to reaffirm its role in treating PD.

Early data certainly suggest that patients with PD can benefit from therapies that use the concept of penile stretching. When deciding between the different modalities discussed, patients must consider the nature of their plaque, the time involved, and cost. The cost of VED and PTT devices are similar, but variables depend on device and country of purchase. These devices are both less expensive than more-invasive options and represent appropriate therapies for motivated patients.³⁵ PTT is the preferred modality because it has substantially more trials showing efficacy.

More-invasive options can also be considered. ICI is an often used as a first-line treatment for PD, but it is an expensive therapy. The mainstay of treatment for PD with refractory erectile dysfunction is penile prosthesis. The significant costs of therapy for PD must always be considered when advising patients.

The innovations of penile stretching for PD are encouraging. The RestoreX device's use of oppositional angular force is a unique strategy for altering the axis of force of the mechanical traction delivered to the PD plaques. This may make combination therapy with ILI and tractions superior to monotherapy.

PD is a disabling condition that affects a sizable number of men around the world. In the last 20 years more therapies have emerged to treat PD and improve a patient's quality of life. More basic and clinical research is required to clarify the role of penile stretching in PD, but with existing trials and research ongoing, the potential is encouraging.

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Conflicts of Interest: Dr Hellstrom is on a speakers bureau for Endo Pharmaceuticals. The other authors report no conflicts of interest.

Funding: None.

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