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RECONSTRUCTIVE UROLOGY

A novel approach to Peyronie's disease: Intralesional injection of lyophilized platelet-derived growth factors

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Introduction Platelets store numerous growth factors that are released upon activation at sites of tissue injury. These factors support the wound healing process by enhancing chemotaxis, angiogenesis, cellular proliferation, extracellular matrix synthesis, and tissue remodeling.
The aim of the study was to evaluate the therapeutic effect of intralesional lyophilized platelet-derived growth factors (PDGF) in men with Peyronie's disease (PD).

Material and methods This prospective study included 42 patients diagnosed with PD between June 2022 and October 2023; four were lost to follow-up. After providing informed consent, all participants underwent clinical evaluation, including medical history, physical examination, Sexual Health Inventory for Men (SHIM), Erection Hardness Score (EHS), Peyronie's Disease Questionnaire (PDQ), intracavernosal injection test, and penile duplex ultrasonography. Patients received six biweekly intralesional injections of lyophilized PDGF (one vial every two weeks over 12 weeks).

Results A significant reduction in penile curvature was observed, with the mean angle decreasing from 34.62 ±16.37° to 11.40 ±8.84° (mean reduction of 23.22°). Plaque size was also significantly reduced, from a mean of 2.70 ±0.87 cm to 1.43 ±0.44 cm. PDQ scores improved in all domains: Domain 1 by 9.18 points, Domain 2 by 14.74 points, and Domain 3 by 8.3 points. Additionally, erectile function improved, with no patients reporting an EHS grade of E1 or E2 after treatment.

Conclusions Intralesional injection of lyophilized PDGF appears to be a promising non-surgical option for improving curvature, plaque size, and sexual function in patients with Peyronie's disease. Further studies are recommended to validate these findings.

Key Words: intralesional injections ‹› lyophilization ‹› platelet-derived growth factors (PDGF) ‹› Peyronie's disease ‹› fibrosis ‹› penile curvature

INTRODUCTION

Peyronie's disease (PD), formerly known as *indu-ratio penis plastica*, is characterized by abnormal collagen deposition within the tunica albuginea of the corpora cavernosa, resulting in fibrous plaque formation. These plaques can cause penile curvature, shortening, and erectile dysfunction [1]. In the early phases of the disease, management is generally conservative and includes oral therapies (e.g., vitamin E, tamoxifen, colchicine, carnitine esters, pentoxifylline, para-aminobenzoate), intralesional injections (e.g., corticosteroids, verapamil, interferon, collagenase), and non-invasive approaches such as iontophoresis, extracorporeal shockwave therapy, traction, and vacuum devices [2, 3].
However, the European Association of Urology (EAU) no longer recommends oral treatments such as vitamin E, tamoxifen, pentoxifylline, para-ami-

nobenzoate, or carnitine esters due to lack of efficacy. While intralesional collagenase clostridium histolyticum remains a viable nonsurgical option for patients with stable PD and dorsal or lateral curvature, its outcomes remain limited, with few patients experiencing substantial correction [4]. In more advanced or refractory cases, surgical intervention remains the gold standard for restoring penile function and correcting deformity [5].

Beyond their role in hemostasis, platelets are critical to tissue repair, releasing growth factors such as platelet-derived growth factors (PDGF), transforming growth factor β (TGF-β), vascular-endothelial growth factor (VEGF), epidermal growth factor (EGF), insulin-like growth factor (IGF), and fibroblast growth factor (FGF) upon activation [6, 7]. Advances in biotechnology have enabled the lyophilization of trehalose-loaded platelets, allowing long-term storage of bioactive platelet-derived cytokines at room temperature [8, 9]. This process yields standardized, allogeneic, lyophilized PDGF, offering a more consistent and controlled alternative to conventional autologous platelet-rich plasma (PRP) [10].

Lyophilized PDGF has shown promise in various fields, including dermatology – for treating striae distensae and female pattern hair loss [11, 12], and orthopedics for managing subacromial impingement syndrome and knee osteoarthritis [13, 14].

This study aims to assess the therapeutic potential of intralesional lyophilized PDGF in patients with Peyronie's disease, selected over autologous PRP to ensure consistency, reproducibility, and standardized growth factor concentrations.

MATERIAL AND METHODS

This prospective, non-randomized clinical study enrolled married male patients presenting with either acquired penile curvature or non-calcified penile plaques. Participants were recruited from the Andrology Outpatient Clinic at Kasr Al-Ainy Hospitals, Cairo University. All patients were diagnosed with Peyronie's disease in its acute phase, defined by symptom duration of less than 18 months, the presence of penile pain, and absence of plaque calcification on penile ultrasonography [15, 16].

Due to the unavailability and the high cost of collagenase clostridium histolyticum in the country, patients were offered an alternative treatment involving intralesional injection of lyophilized PDGF directly into the penile plaque.

Exclusion criteria included a history of previous medical or surgical treatment for Peyronie's disease, prior exposure to extracorporeal shock wave therapy (ESWT), the presence of complex deformities such as hourglass or hinge-type curvature, and active infection at the intended injection site.

Sample size

The sample size was calculated using G*Power version 3.1.9.7, with an alpha error of 5%, a study power of 95%, and a confidence level of 95%. Based on these parameters, a minimum of 40 patients was required. To accommodate potential dropouts, 42 patients who met the inclusion criteria were enrolled in the study.

Methodology

Eligible patients were enrolled in the study and underwent thorough medical history taking and genital examination. They were then asked to complete the Sexual Health Inventory for Men (SHIM) questionnaire [17], the self-reported Erection Hardness Score (EHS) [18], and the Peyronie's Disease Questionnaire (PDQ) [19]. Following this, each patient underwent a pharmacologically induced color Doppler ultrasound (CDU) examination using 20 μg of prostaglandin E1 (PGE1). Erection response was evaluated alongside peak systolic velocity (PSV) and end-diastolic velocity (EDV), using a Mindray Z5 duplex ultrasound system [20].

Plaque size was measured according to its maximum linear dimension (in millimeters), and its anatomical location was classified as proximal, medial, distal, or septal. All CDU assessments were performed by the same clinician to ensure consistency. The angle of penile curvature was assessed using a stainless-steel goniometer protractor during full rigid erection, as directly observed and measured by the physician, rather than relying on patient-submitted photographs.

Preparation of platelet-derived growth factors

The PDGF used in this study were produced according to a patented method registered under a European patent number issued in November 2016 [21]. Platelet concentrates were collected at the Cairo Medical Centre Hospital blood bank. Prior to processing, all units were screened for infectious agents including hepatitis B surface antigen, hepatitis C virus antibodies, HIV I/II antibodies, and p24 antigen, and *Treponema pallidum* antibodies using enzyme-linked immunosorbent assay (ELISA; R&D Systems, Minneapolis, MN, USA) and polymerase chain reaction (PCR; Thermo Fisher Scientific, Boston, MA, USA). All samples tested non-reactive.

Subsequently, pathogen inactivation was performed using the Mirasol Pathogen Reduction Technology System (Terumo BCT, Ltd., Tokyo, Japan). Platelet activation was induced by incubating the concentrate with sterile human thrombin (500 units/mm^3; Sigma Chemical Co., Munich, Germany) at 37°C for 3 hours, triggering the release of growth factors, cytokines, and fibrinogen. The fibrinogen formed a clot that retracted, leaving a fluid phase-platelet releasate.

This releasate was centrifuged at 1,500 × g for 20 minutes, and the supernatant was collected and subjected to a secondary pathogen reduction step using a solvent/detergent treatment (0.3% tri-n-butyl phosphate and 1% Tween 20d) at 31°C for 1 hour. Residual solvents and detergents were eliminated by triple-phase extraction using sterile castor oil (7.5% of total volume), followed by separation via gravity and repeated centrifugation (1,500 × g, 4°C, 20 minutes). The purified platelet releasate was sterile-filtered and dispensed into glass vials at a standardized concentration equivalent to 2 million platelets/μl.

The final product was lyophilized into a stable pale-yellow powder, ensuring long-term storage at 4°C. Prior to intralesional injection, each vial was reconstituted in 2 ml of sterile normal saline.

Procedure

The injection site was sterilized using alcohol swabs, followed by intralesional administration of 2 ml of reconstituted PDGF while the penis was in a flaccid state. Manual compression was applied for 2 minutes after the injection (Figure 1). Each patient received a total of six PDGF vials, administered at two-week intervals over a 12-week period. Plaque size and penile curvature were evaluated at both 6 and 12 weeks following the initial injection using penile color Doppler-duplex ultrasound (CDDU) after pharmacological erection induction with 20 μg of prostaglandin E1 (PGE1). Erectile function was assessed concurrently using the Sexual Health Inventory for Men (SHIM) and the Erection Hardness Score (EHS). Upon study completion, patients were also asked to complete the Peyronie's Disease Questionnaire (PDQ).

Statistical methods

Data were coded and entered into IBM SPSS Statistics version 28 for analysis. Quantitative variables were summarized using means and standard deviations, while categorical variables were described with frequencies and percentages. Group comparisons for normally distributed quantitative data were performed using ANOVA followed by post hoc tests. For non-normally distributed quantitative data, the Kruskal-Wallis test and Mann-Whitney U test were applied. To analyze repeated measurements within groups, repeated measures ANOVA was used for normally distributed variables, whereas the Friedman test and Wilcoxon signed-rank test were employed for non-normally distributed variables. A p-value of less than 0.05 was considered statistically significant.

Bioethical standards

All participants provided written informed consent prior to enrollment. The study was conducted in accordance with the ethical principles outlined

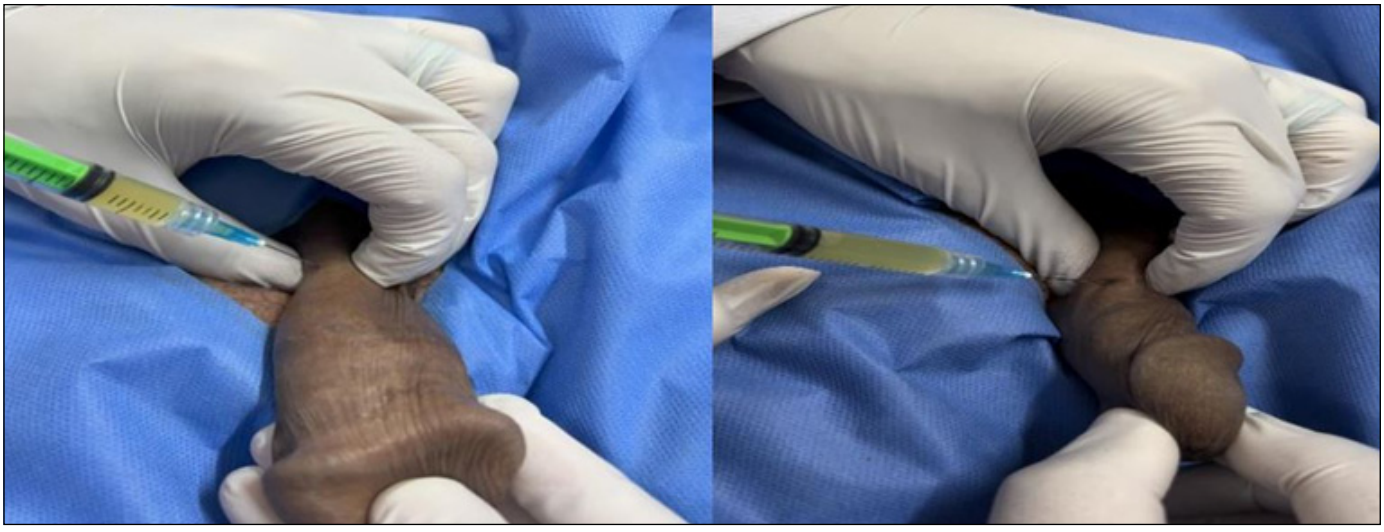

Figure 1. *Illustration of the platelet-derived growth factor (PDGF) injection technique.*

in the Declaration of Helsinki. Ethical approval was obtained from the Cairo University Faculty of Medicine Ethical Review Committee (approval No. MD–210–2022), which reviewed and approved both the study protocol and the informed consent form.

RESULTS

A total of 42 male participants meeting the inclusion criteria were enrolled in the study, with a mean age of 52.83 years (range: 23–78). Four patients were lost to follow-up: two due to residing in remote areas and refusing to return, one who traveled abroad for work, and one lost contact. No patients were excluded during the study, as no serious adverse effects or worsening of symptoms were observed throughout the treatment protocol.

Demographic analysis revealed a high prevalence of diabetes and smoking among participants, whereas hypertension and benign prostatic hyperplasia were less common (Table 1). The primary presenting symptom was penile curvature, reported by nearly half of the cohort, while erectile dysfunction and mixed symptoms were less frequent (Table 2).

Regarding curvature patterns, ventral deviation was the most common, though a significant portion (38.1%) had no detectable curvature. Plaque location assessment demonstrated notable differences between clinical examination and ultrasound findings; duplex ultrasound identified dorsal plaques more frequently than palpation alone (Table 3). Erectile rigidity was assessed using the Erection Hardness Score (EHS), which grades responses to intracavernosal injection (ICI) from E1 (penis larger but not hard) to E4 (fully rigid). After treatment, there was a marked improvement in erectile rigidity, with E4 responses increasing from 28.6% to 84.2%, and inadequate E2 responses completely eliminated (Table 4).

The mean plaque size significantly decreased from 2.7 ±0.9 cm before treatment to 1.4 ±0.4 cm after treatment ($p < 0.001$), with no patients exhibiting plaque enlargement after therapy (Table 5). Patients without curvature were excluded from curvature analysis. The average curvature angle decreased significantly from 34.6 ±16.4 degrees before treatment to 19.4 ±12.4 degrees after six weeks, with

Table 1. *Age of patients and descriptive analysis of risk factors*

Age (range) years		DM	HTN	BPH	Cardiac	Smoking
23–73	Count	14	6	2	4	13
Mean 52.8	%	33.3%	14.3%	4.8%	9.4%	31.0%

BPH – benign prostatic hyperplasia; DM – diabetes mellitus; HTN – hypertension

Table 2. *Descriptive analysis of patients' presenting symptoms*

	Curvature	Weak erection	Penile lump with penile pain	Mixed
Count	19	4	13	6
%	45.2%	9.5%	30%	14.3%

Table 3. *Plaque position at the main plane among cases according to clinical exam and penile duplex ultrasound*

	According to clinical exam			According to penile duplex ultrasound		
Plaque position	Proximal third	Middle third	Distal third	Ventral	Dorsal	Lateral
Count	17	19	6	5	27	10
%	40.5%	45.2%	14.3%	11.9%	64.3%	23.8%

Table 4. *Comparison between EH score before and after treatment*

	E1	E2	E3	E4
EH score baseline (n = 42)	0%	6 (14.3%)	24 (57.1%)	12 (28.6%)
EH score after 12 weeks (n = 38)	0%	0%	6 (15.8%)	32 (84.2%)

Wilcoxon signed-rank test
EH – erection hardening; E1 – penis is larger but not hard; E2 – penis is hard but not hard enough for penetration; E3 – penis is hard enough for penetration but not fully rigid; E4 – penis is fully hard and completely rigid

Table 5. *Comparison between plaque size before and after treatment by penile duplex ultrasound*

	Mean	SD	Minimum	Maximum	P-value compared to baseline
Plaque size in cm baseline	2.7	0.9	1.5	5.0	–
Plaque size in cm after 6 weeks	1.9	0.6	1.1	3.4	*<0.001
Plaque size in cm after 12 weeks	1.4	0.4	0.9	2.8	*<0.001
Plaque size cm after 24 weeks	1.4	0.4	0.9	2.8	*<0.001

Paired t-test
SD – standard deviation

further reduction noted at twelve weeks (Table 6). Sexual function, measured by the Sexual Health Inventory for Men (SHIM), showed significant improvement, increasing from 20.6 ±3.9 to 22.5 ±1.5 after twelve weeks (Table 7). Clinically, eight patients regained the ability to engage in intercourse, and 70% of those with baseline erectile dysfunction achieved normal function, with the most pronounced benefits seen in patients with moderate to severe ED.

The Peyronie's Disease Questionnaire (PDQ) scores also improved significantly across all domains: domain 1 (psychological and physical symptoms) decreased from 12.7 ±4.5 to 3.5 ±3.2, domain 2 (penile pain) from 17.7 ±4.2 to 3.0 ±3.7, and domain 3 (symptom bother) from 10.6 ±2.3 to 2.3 ±1.8 (Figure 2). Throughout the study period, no adverse effects such as pain, bruising, or infection were reported.

Table 6. *Comparison between penile curvature degrees before and after treatment*

	Mean	SD	Minimum	Maximum	P-value compared to baseline
Curvature degree baseline	34.6	16.4	15	80	–
Curvature degree after 6 weeks	19.4	12.4	5	60	*0.013
Curvature degree after 12 weeks	11.4	8.8	5	45	*<0.001
Curvature degree after 24 weeks	11.4	8.8	5	45	*<0.001

Paired t-test
SD – standard deviation

DISCUSSION

Currently, the most effective treatment for the acute phase of Peyronie's disease is collagenase clostridium histolyticum, the only therapy approved by the U.S. Food and Drug Administration (FDA) [22–25]. However, its high cost and limited availability, particularly in developing countries, make access challenging. Existing evidence has yet to identify an ideal intralesional agent with a clearly favorable benefit-risk profile, highlighting the urgent need for further research into new treatment options [26, 27]. To our knowledge, this study is the first to evaluate intralesional lyophilized PDGF as a treatment for Peyronie's disease.

Several studies have explored the efficacy of platelet-rich plasma (PRP) injections for Peyronie's disease, with mixed results. Culha et al. (2019) [28], using a TGF-β1-induced rat model, found no therapeutic benefit from intralesional PRP. In contrast, Matz et al. (2018) [29] treated 17 patients with an average of 2.1 PRP injections each, reporting a 4.14-point increase in International Index of Erectile Function (IIEF) scores and subjective improvement in curvature in 80% of patients. Our study, involving 38 patients with an average of six injections, demonstrated a 1.93-point increase in SHIM scores and a reduction in curvature from 34.62° to 11.40°. Additionally, the Erection Hardness Score (EHS) improved, with no patients remaining at the lower E1 or E2 level after treatment.

Virag et al. (2016) [30] combined PRP with hyaluronic acid in 90 patients, achieving an 18.08° reduction in curvature over two months, alongside improved erectile quality and sexual activity, with

Table 7. *Comparison between SHIM scores before and after treatment*

	Mean	SD	Minimum	Maximum	P-value compared to baseline
SHIM score baseline	20.6	3.9	6	24	–
SHIM after 12 weeks	22.5	1.5	17	24	*0.002
SHIM after 24 weeks	22.6	1.3	18	24	*0.002

Paired t-test
SHIM – sexual health inventory for men; SD – standard deviation

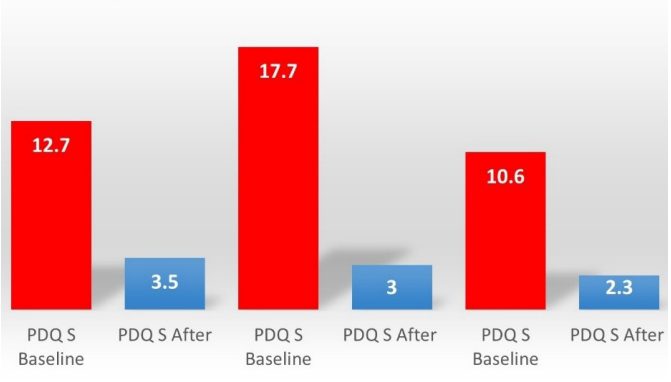

Figure 2. *PDQ response before and after treatment (paired samples t-test).*

Red columns represent before, and blue columns represent after treatment

PDQ S represents the Psychological and Physical Symptoms domain; PDQ P represents the Penile Pain domain; PDQ B represents the Symptom Bother domain

minimal side effects such as ecchymosis (16.7%) and hematoma (10%). In comparison, our study observed a greater mean curvature reduction of 23.22°, an increase in IIEF scores from 20.57 ±3.9 to 22.50 ±1.54, and no reported complications. Notsek and Boiko (2019) [31] compared intralesional PRP to saline in 59 patients, with 50% of the PRP group showing curvature improvement vs 22.2% in controls. Regarding erectile dysfunction, 56.3% of the PRP group had increased IIEF-5 scores compared to just 3.7% in the control group. Our findings revealed a 23.22° average curvature reduction and a 23.8% increase in IIEF-5 scores, slightly lower possibly due to smaller sample size and higher baseline erectile function. Pain improvement was 60%, compared to 84% reported by Notsek and Boiko.

Achraf et al. (2022) [32] reported a 17.07° mean curvature improvement and a 55.5% increase in IIEF-5 scores. In our study, the curvature reduction was greater (23.22°), but the IIEF-5 improvement was more modest (23.8%). Complications were minimal. Schirmann et al. (2022) [33] observed an 11.8° curvature reduction, significant improvements across three PDQ questionnaire domains, and a 5-point increase in IIEF-EF after 6 months. In comparison, our study demonstrated a larger curvature reduction (23.22°) and more pronounced improvements in PDQ domains (9.18, 14.74, and 8.3).

Moreover, plaque size significantly decreased from 2.70 ±0.87 cm to 1.43 ±0.44 cm, with no cases of plaque enlargement during follow-up. Collectively, these results suggest that intralesional PRP therapies may offer meaningful benefits in reducing penile curvature, improving erectile function, and decreasing plaque size in Peyronie's disease.

The penis's structural integrity largely depends on the bi-layered tunica albuginea, the fibrous outer casing that maintains the penile shape during erection [34, 35]. Future studies could incorporate 3D visualization techniques using the Visible Human datasets, which provide detailed models to better understand penile anatomy [36]. Demonstrating the ability of PDGF injections to permanently restore the tunica albuginea would mark a major breakthrough in the treatment of Peyronie's disease, offering a reliable therapeutic option in a field where consistent and effective solutions are still lacking. However, further studies using a sham-controlled design are necessary to evaluate its efficacy.

Limitations of the current study include the small sample size and the absence of clinical trial registration. Moreover, all assessments, including ultrasound evaluations, were conducted by a single researcher.

CONCLUSIONS

This study is the first to objectively evaluate the impact of lyophilized PDGF in treating early-stage Peyronie's disease. Initial results indicate that intralesional injections of lyophilized PDGF may offer a promising therapeutic option. However, further double-blind, randomized, placebo-controlled trials are essential to rigorously determine its efficacy under sham-controlled conditions.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

FUNDING

This research received no external funding.

ETHICS APPROVAL STATEMENT

The study was approved by the Cairo University Faculty of Medicine Ethical Review Committee (approval No. MD–210–2022), which reviewed and approved both the study protocol and the informed consent form.

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