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# A First Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Trial Evaluating Extracorporeal Shock Wave Therapy for the Treatment of Peyronie's Disease

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### Abstract

**Background:** Extracorporeal shock wave therapy (ESWT) is a conservative therapy for patients with Peyronie's disease (PD).

**Objective:** To investigate the effects of ESWT in patients with PD.

**Design, setting, and participants:** One hundred patients with a history of PD not >12 mo who had not had previous PD-related treatments were enrolled in a prospective, randomized, double-blind, placebo-controlled study. Patients were randomly allocated to either ESWT ( $n = 50$ ) or placebo ( $n = 50$ ). Erectile function (EF), pain during erection, plaque size, penile curvature, and quality of life (QoL) were assessed at baseline, at 12 wk, and at 24 wk follow-up.

**Intervention:** Four weekly treatment sessions were administered. Each ESWT session consisted of 2000 focused shock waves. For the placebo group, a non-functioning transducer was employed.

**Measurements:** EF was evaluated with the shortened version of the International Index of Erectile Function (IIEF-5), pain was evaluated with a visual analog scale (VAS; 0–10), plaque size was measured in  $\text{cm}^2$ , and penile curvature was measured in degrees.

**Results and limitations:** After 12 wk, mean VAS score, mean IIEF-5 score, and mean QoL score ameliorated significantly in patients receiving ESWT. Mean plaque size and mean curvature degree were unchanged in the ESWT group, while a slight increase was reported in the placebo group ( $p$ -value not significant vs baseline). After 24 wk, mean IIEF-5 score and mean QoL score were stable in the ESWT group, while mean VAS score was significantly lower when compared with baseline in both groups. Interestingly, after 24 wk, mean plaque size and mean curvature degree were significantly higher in the placebo group when compared with both baseline and ESWT values. The main limitations were that the QoL questionnaire was not validated, ED was not etiologically characterized, and inclusion criteria were restricted.

**Conclusions:** In patients with PD, ESWT leads to pain resolution and ameliorates both EF and QoL.

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