6-Month Outcomes with RestoreX Penile Traction System in Men with Peyronie’s Disease: a Randomized, Controlled Trial

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Abstract

Introduction and Objectives: Penile traction therapy (PTT) is an established treatment for Peyronie’s Disease (PD). Given limitations with existing devices, a novel PTT device, RestoreX (RxPTT), was developed as a primary or adjunctive therapy for PD. Data here is a randomized controlled trial of men with (PD) undergoing RxPTT for 90–100 daily minutes versus control (no therapy) to evaluate the impact of RxPTT on penile length, curvature, and erections.

Methods: A randomized, controlled, that included 101 men with PD with limitations with existing devices, a novel PTT device, RestoreX (RxPTT), was developed as a primary or adjunctive therapy for PD. Data here is a randomized controlled trial of men with PD undergoing RxPTT for 90–100 daily minutes versus control (no therapy) to evaluate the impact of RxPTT on penile length, curvature, and erections.

Results: Over 60% of patients achieved a meaningful difference in penile length. RxPTT increased penile length and improved all domains of the IIEF.

Conclusions: RxPTT resulted in significant improvements in penile length, curvature, and all domains of the IIEF and FGQ, except organic function. Adverse events were mild and transient. External validation is warranted.

Study Protocol

Cross-Over Phase (3-6 months)

As-Treated Analysis (0-6 months)

Subjective Outcomes (6-9 months)

Adverse Events

Erectile Function (IIEF)

Conclusions

- PTT with RestoreX for 30-90 minutes daily is safe, with only mild, transient adverse events
- After 6 months, compared to baseline, PTT with RestoreX significantly improved:
  - Penile length
  - Erectile curve
  - Erectile function in men with ED
- All subdomains of the IIEF
- All subdomains of the FGQ