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# A Novel Penile Splint as Early Traction Therapy After Grafting Techniques for Peyronie's Disease

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## ABSTRACT

**Background:** Some studies showed encouraging results on the efficacy and safety of penile traction therapy after Peyronie's disease (PD) surgery. The early traction therapy (ETT) could be an effective and safe approach to minimize penile shortening in patients undergoing PD surgery.

**Aim:** To evaluate the feasibility, efficacy, and safety of a novel penile splint as ETT in patients with PD undergoing grafting techniques.

**Methods:** Patients with PD underwent plaque incision and grafting technique; at the end of the procedure, a novel penile splint (ETT) was applied to all patient. The device consisted of 2 10CH intubating stylets, self-adapted to each patient, that kept the penis stretched with the aid of non-absorbable sutures. The total expense for the materials needed to build each penile splint was less than 15 euros. This active traction was maintained for 1−3 weeks; then, we removed the stitches leaving the device on-site for a passive traction. Within 3−4 weeks from surgery, the penile splint was replaced by a standard penile traction device.

**Outcomes:** The main outcomes evaluated at 6 months included stretched penile length (SPL), penile curvature, International Index of Erectile Function-erectile function (IIEF-EF) domain, patient satisfaction, and time to first satisfactory sexual intercourse.

**Results:** A total of 46 patients were enrolled. The median preoperative IIEF-EF, penile curvature, and SPL were 27 points, 70°, and 13 cm, respectively. The median follow-up was 15 months. The median postoperative IIEF-EF was 25 points ($P < .001$). The median residual penile curvature was 10° ($P < .001$). The median postoperative SPL was 13 cm ($P = .269$). 8 patients (17.4%) lost 1 cm of SPL; no shortening greater than 1 cm was recorded. The median time to first satisfactory sexual intercourse and patient satisfaction score was 6 weeks and 9 points, respectively.

**Clinical Implications:** Our results could pave the way for a new line of research, which in turn could lead to an improvement in the postoperative management of the patient undergoing surgery for PD.

**Strength & Limitations:** This is the first study evaluating the ETT after PD surgery. The main limitation of this study is the lack of a randomized control group. Other weaknesses are the small sample size and the short follow-up time.

**Conclusion:** Our novel penile splint is inexpensive, easy to assemble, and adaptable to the patient. ETT using this novel device, followed by standard traction therapy, seems to be feasible, effective, and safe. **Fernández-Pascual E, Manfredi C, Cocci A, et al. A Novel Penile Splint as Early Traction Therapy After Grafting Techniques for Peyronie's Disease. J Sex Med 2020;XX:XXX−XXX.**

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**Key Words:** Early Traction Therapy; Penile Traction Therapy; Penile splint; Peyronie's disease; Penile shortening

## INTRODUCTION

Tunical lengthening procedures are the gold standard treatment for patients with Peyronie's disease (PD), in stable phase of disease, with severe curvature, short penis, or complex deformities, without erectile dysfunction.[1] These procedures are performed on the concave side of the penis and consist of making an incision or partial excision of the plaque and covering the defect with a graft.[2] The tunical lengthening techniques aim to minimize the penile shortening, nevertheless, a significant reduction in length of penis was described by several authors.[3,4]

The current European Association of Urology guidelines recommend the use of penile traction therapy (PTT), as conservative treatment of PD, alone or in combination with other procedures, although outcome data are limited.[1,5] The clinical goals of PTT are to reduce curvature, enhance circumference, and recover lost length, causing only limited adverse events (AEs). Several studies showed encouraging results on the efficacy and safety of PTT in both the acute and chronic phase of PD, as well as after PD surgery.[6–8]

The penile splint is a device, generally assembled by the surgeon and applied at the end of the penile surgery, which aims to improve the surgical outcomes.[9–13]

### Rationale and Aim

The early traction therapy (ETT), applied immediately at the end of the surgical procedure, could be an effective and safe approach to minimize penile shortening in patients undergoing PD surgery. The aim of the present study is to evaluate the feasibility, efficacy, and safety of a novel penile splint as ETT in patients with PD undergoing grafting techniques.

## INDICATIONS FOR PROCEDURE

Patients with stable PD for at least 3 months, normal erectile function with or without pharmacological treatment, any type of penile curvature >60° and/or no adequate penile length and/or complex deformities (hourglass, hinge), and undergoing grafting technique were included in the study. Active infectious diseases and suspect of penile tumor were the exclusion criteria. Calcified plaques were not an exclusion criterion. All patients in whom a reduction of the penile length of at least 2 cm with shortening procedures was expected were considered to have a no adequate penile length.

### Recruitment and Assessment of Patients

Patients of the present study were recruited from February 2017 to July 2019. All subjects were informed about the surgical procedure and provided written informed consent. Each patient enrolled underwent medical and sexual history as well as a physical examination. The short version of the International Index of Erectile Function for the evaluation of the erectile function (IIEF-EF)[14] and the Peyronie's Disease Questionnaire[15] were self-administrated to patients. The penile curvature was evaluated with the Kelami method.[16] The stretched penile length (SPL) was assessed by a urologist using a tape measure, from the base (pubo-penile junction) to the tip of the glans (meatus) on the dorsal aspect of the penis. The study of penile plaques was performed with ultrasonography by a radiologist.

### Statistics

We used the median as a measure of central tendency and the interquartile range (IQR) as a measure of statistical dispersion. The Wilcoxon signed-ranks test was used to analyze the data. All tests were 2-sided with a significance set at $P < .05$. IBM SPSS Statistics (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0.; IBM Corp., Armonk, NY) was used for the statistical analyses.

## PREOPERATIVE PREPARATION

Patients were placed in the supine position and washed with chlorhexidine gluconate soap. Intravenous sedation with local anesthesia, as well as preoperative single dose of cefazolin, were administered to all patients.

## INTRAOPERATIVE CONSIDERATION

A Gittes test[17] was performed with intracavernous saline injection to evaluate penile curvature degree and any other deformities. All patients underwent plaque incision and grafting (PIG) technique with TachoSil (Baxter, CA, USA). In all cases, the whole graft (9.5 × 4.8 cm) was used to cover the tunical defect. Each subject underwent circumcision, whereas none received the implantation of a penile prosthesis. All surgeries were performed by a single experienced surgeon in an ambulatory center. At the end of the procedures, the penile splint (ETT) was applied to all patient by the surgeon, adapting it based on penile size (length and girth).

### Penile Splint: Assembly and Cost

First of all, the penis was wrapped with a cotton wool roll to protect the skin from pressure ulcers. Then, 2 10CH intubating stylets (Shiley/Mallinckrodt, Medtronic, MN) (Figure 1) were positioned vertically and fixed to penile skin with 2 1-0 Polypropylene Sutures (at 3o'clock and 9o'clock) (Figure 2). Finally,

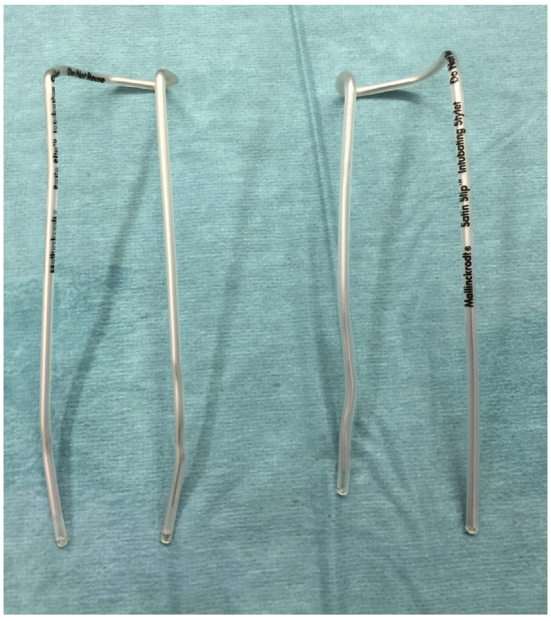

**Figure 1.** 10CH intubating stylets (Mallinckrodt, Medtronic, MN). Figure 1 is available in color online at www.jsm.jsexmed.org.

an elastic bandage was applied, and the distal parts of the stylets were bent (Figure 3) to improve patient comfort. The assembly time was always less than 5 minutes. The cost of each stylet was less than 5 euros, and the total expense for the materials needed to build each penile splint was less than 15 euros.

**Figure 2.** Assembly of the penile splint. Figure 2 is available in color online at www.jsm.jsexmed.org.

**Figure 3.** Aspect of the assembled penile splint. Figure 3 is available in color online at www.jsm.jsexmed.org.

## POSTOPERATIVE MANAGEMENT AND FOLLOW-UP

Patients were discharged with penile splint in 2–3 hours after the procedure, being instructed to maintain the device until the next revision. No antibiotic was prescribed, while common analgesics as needed was allowed.

Until January 2018, we maintained the active traction (device with stitches) for 2–3 weeks; subsequently, owing to observed discomfort and pain of the patients, we reduced this time to 7 days. Once these first days of active traction were over, we removed the stitches leaving the device on-site (passive traction) until 3–4 weeks after surgery. Wound cleaning and dressing changes were performed every 7 days. In all patients, after this period, when the circumcision was healed, the penile splint was replaced by a standard penile traction device (Andropeyronie/Andropenis, Andromedical SL, Madrid, Spain) for at least 4–6 months with intensive daily use (at least 3 hours a day).

After 6 months from surgery, changes in penile curvature, SPL, and IIEF-EF, as well as time to first satisfactory sexual intercourse and patient satisfaction on a scale of 0 to 10,[18] were assessed. All observed AE during the study period were recorded.

## OUTCOMES AND COMPLICATIONS

A total of 46 patients, with a median (IQR) age of 55 (45.5–61.3) years, were enrolled in the study. The median (IQR) preoperative IIEF-EF, penile curvature, and SPL were 27 (24–29) points, 70 (60–81.3) degrees, and 13 (12-15) cm, respectively. Only 3 patients (6.5%) took an intermediate dosage of phosphodiesterase type 5 inhibitors before the surgery. The baseline characteristics of patients are reported in Table 1.

**Table 1.** Baseline characteristics of patients

| | |
|---|---|
| Subjects, *n* | 46 |
| Age, *y* median (IQR) | 55 (45.5–61.3) |
| Time from onset of disease, *mo* median (IQR) | 18 (14–24) |
| Penile curvature | |
| Angle, *degrees* median (IQR) | 70 (60–81.3) |
| Direction | |
| Dorsal, n (%) | 31 (67.4) |
| Lateral, n (%) | 9 (19.6) |
| Dorsolateral, n (%) | 6 (13.0) |
| Ventral, n (%) | 0 (0) |
| Complex deformities | |
| Hourglass, n (%) | 7 (15.2) |
| Hinge, n (%) | 10 (21.7) |

IQR = interquartile range.

The median (IQR) operative time and follow-up were 80 (70–90) minutes and 15 (11.3–24) months, respectively. 28 patients (60.9%) used the early active traction for 7 days, whereas only 7 subjects (15.2%) for more than 2 weeks. The median (IQR) time of early active traction was 7 (7–14) days.

The median (IQR) postoperative IIEF-EF was 25 (22–27) points ($P < .001$), 13 patients (28.3%) worsened this score and reached the minimal clinically important difference (MCID) after the surgery.[19] The median (IQR) residual penile curvature was 10 (5-10) degrees, with a statistically significant difference from the baseline ($P < .001$). 10 patients (21.7%) at 6 months of follow-up used phosphodiesterase type 5 inhibitors; however, only 6 subjects really needed it as they were unable to have a satisfactory intercourse, and another 4 did not want to interrupt the treatment because they noticed an improvement in erectile function compared with their condition before surgery. 8 patients (17.4%) had a residual curvature of 15°, and no subject exceeded this value. The median (IQR) postoperative SPL was 13 (12.8–15) cm, without a significant difference from the baseline ($P = .269$). Only 8 patients (17.4%) lost 1 cm of SPL; no shortening greater than 1 cm was recorded in any subject, the median difference of postsurgical SPL and presurgical SPL was 0 cm. A statistically significant ($P < .001$) postoperative improvement of all Peyronie's Disease Questionnaire domains was reported. The median (IQR) time to first satisfactory sexual intercourse and patient satisfaction score was 6 (5-8) weeks and 9 (8–9) points, respectively. Patients did not report any changes between the 6-month visit and the end of the follow-up. The postoperative outcomes are reported in Table 2. No intraoperative complications occurred. 5 cases (10.9%) of postoperative hematoma and 2 cases (4.3%) of glans numbness at 6-month follow-up visit were recorded. No severe complications (Clavien-Dindo III–V)[20] were revealed, in particular, only grade I AEs occurred during the study. There was no fall or movement of the dressing that required its repositioning; this was favored in the first weeks by the presence of the sutures that fixed the entire device to the penile skin. Only 3 patients (6.5%) required removal of the bandage because of excessive compression; however, the penile splint was maintained by replacing only the dressing.

## Brief Literature Review and Discussion of Results

Currently, there are no studies investigating assessing the ETT after PD surgery, as well as there are no articles evaluating the use of a penile splint as traction therapy in PD setting.

Only 2 articles investigated the role of PTT after PD surgery;[21,22] however, in both studies, the traction was not applied immediately after the end of the surgery but several weeks later.

Moncada-Iribarren et al[21] reported the use of a traction device (Andropenis, Andromedical SL, Madrid, Spain) after penile grafting or plication. PTT was applied when the circumcision had healed (2 to 3 weeks after surgery), 8 to 12 hours daily during at least 4 months. A total of 40 men who had PD surgery (12 men with penile grafting and 28 men with penile plication) were randomized (20:20) to PTT vs observation. Globally, penile shortening after surgery ranged from 0.5 to 4.0 cm. SPL of

**Table 2.** Postoperative outcomes

| | Baseline | At 6 mo from surgery | *P* |
|---|---|---|---|
| Penile curvature, *degrees* median (IQR) | 70 (60–81.3) | 10 (5–10) | <.001 |
| SPL, *cm* median (IQR) | 13 (12–15) | 13 (12.8–15) | .269 |
| IIEF-EF, *points* median (IQR) | 27 (24–29) | 25 (22–27) | <.001 |
| PDQ | | | |
| PDQ-SB, *points* median (IQR) | 11 (9–13.3) | 2 (0–4.3) | <.001 |
| PDQ-PP, *points* median (IQR) | 3 (0.8–6) | 0 (0–0.8) | <.001 |
| PDQ-PS, *points* median (IQR) | 15 (10–18.5) | 3 (2–6) | <.001 |
| Patient satisfaction, *points* median (IQR) | NA | 9 (8–9) | NA |
| Time to first satisfactory sexual intercourse, *wk* median (IQR) | NA | 6 (5-8) | NA |

IIEF-EF = International Index of Erectile Function-erectile function; IQR = interquartile range; NA = not available; PDQ = Peyronie's Disease Questionnaire; PDQ-PP = PDQ-penile pain; PDQ-PS = PDQ-psychological and physical symptoms; PDQ-SB = PDQ-symptom bother; SPL = stretched penile length.

the patients in the PTT group increased ranging from 1 to 3 cm, and the increase was proportional to the number of hours per month of PTT use.

Rybak et al[22] reported in a non-randomized retrospective study the use of a traction device (USPhysioMED Penile Extender, USPhysioMED, Aliso Viejo, CA) after penile plication or partial plaque excision and grafting. PTT was recommended for 2−6 hours a day for 3 months, typically starting 3−4 weeks postoperatively. In total, 27 of 52 plication patients and 36 of 59 plaque excision and grafting patients performed PTT. Patients who performed PTT had a significantly greater mean increase in SPL (compared with preoperative measurements) than the patient without traction. This was true for both the plication group (+0.85 cm vs −0.53 cm; $P < .001$) and the graft group (+1.48 cm vs +0.24 cm; $P < .001$).

Several studies evaluated the use of penile splints in the last few decades.[9−13] These devices were built by the surgeon and applied at the end of the surgical procedure. They were generally real craft products assembled with easily available materials such as plastic bottles, thermocol glasses, plastic syringes, or gauzes.[10−13] The purpose of penile splints was to achieve a compressive effect or keep the penis in a specific position or stretched, to reduce edema or improve the wound healing after surgery.[9,11,13] Despite the abundance of studies on the topic present in the literature, the overall quality of them is low because of major methodological issues, including the lack of use of standardized outcome measures, with results reported in qualitative rather than quantitative form.

The penile shortening described in other PIG series reflects, in most cases, the occurrence of a graft contraction.[23−29] In a recent review of Rice et al[4] was reported that between 4.9% and 40.0% of patients experienced shortening of penis after PIG. The use of our novel penile splint seems to prevent the graft shrinkage during the initial healing phase, and subsequent standard traction therapy strengthens the graft stretching; this could favor the preservation of the penile length after surgery. On the other hand, the low incidence of hematomas in our study, probably owing to the maintenance of the bandage for a longer period of time, could promote the early recovery of sexual activity.

### Strength and Limitations of Our Results

Despite abundant literature on PTT in patients with PD, this is the first study evaluating the feasibility, efficacy, and safety of ETT after PD surgery. Our encouraging results could pave the way for a new line of research regarding this topic, which in turn could lead to an improvement in the postoperative management of the patient undergoing surgery for PD.

The main limitation of this study is the lack of a randomized control group. Other weaknesses are the small sample size and the short follow-up time.

## TAKE-HOME MESSAGE

ETT using our novel penile splint, followed by standard traction therapy, seems to be feasible, effective, and safe. The device is inexpensive, easy to assemble, and adaptable to the patient. No significant penile shortening, an early recovery of satisfactory sexual activity, as well as no severe AE, can be obtained with its use. However, randomized controlled trials, with large sample size and long follow-up, are needed to confirm these preliminary results and to define the most appropriate duration of early traction.

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