

A Retrospective Comparative Study of Traction Therapy vs. No Traction Following Tunica Albuginea Plication or Partial Excision and Grafting for Peyronie's Disease: Measured Lengths and Patient Perceptions

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DOI: 10.1111/j.1743-6109.2012.02849.x

ABSTRACT

Introduction. Loss of penile length is a recognized and common consequence of Peyronie's disease (PD). Traction therapy (TT+) has been reported to decrease post-op length loss as well as increase stretched penile length (SPL) prior to surgery.

Aim. The aim of this study was to study patient outcomes with penile length change and patient satisfaction after surgery following tunica albuginea plication (TAP) and partial plaque excision and grafting (PEG) with or without postoperative TT.

Methods. Retrospective analysis was performed from our cohort of Peyronie's reconstructive surgery between 2007 and 2010. SPL was measured dorsally from pubis to corona and recorded at the initial office visit and then compared to most recent postoperative visit. Patients were then stratified by procedure and whether TT was used (TT+ and TT-; TAP N = 52 [27 TT+ and 25 TT-] and PEG N = 59 [36 TT+ and 23 TT-]). Traction therapy was initiated for >2 hours a day for 3 months typically starting 3–4 weeks postoperatively. A non-validated mailed questionnaire assessed patient perceptions.

Results. Mean length change seen in TAP (TT+) was 0.85 cm (0.25–1.75) vs. -0.53 cm (-1.75 to 0.5) in TAP (TT-) ($P < 0.001$). The mean length change seen in PEG (TT+) was 1.48 cm (0–6) vs. PEG (TT-) 0.24 cm (-1 to 2.5 cm) ($P < 0.001$). Sixty-one percent of surveys were returned; 85% lost length prior to the initial office evaluation, with an average of -2.5 cm lost. Importantly, in those who used traction, there was no perceived length loss, 58% reported a mean erect length gain of 1.1 cm. However, only 54% of all patients were satisfied with their current erect length.

Conclusions. Loss of length in men with PD remains a serious concern. It appears that postoperative TT can result in length preservation, and in many, a measured and perceived length gain following correction of the curvature.

Rybak J, Papagiannopoulos D, and Levine L. A retrospective comparative study of traction therapy vs. no traction following tunica albuginea plication or partial excision and grafting for Peyronie's disease: Measured lengths and patient perceptions. J Sex Med 2012;9:2396–2403.

Key Words. Peyronie's Disease; Penile Traction Therapy; Tunica Albuginea Plication; Partial Plaque Excision and Grafting; Penile Length; Traction Therapy

Institutional relationships:

Auxilium Pharmaceuticals Consultant/Advisor, Investigator, Meeting Participant/Lecturer

AMS Corp, Consultant/Advisor, Meeting Participant/Lecturer

Coloplast Corp, Consultant/Advisor, Meeting Participant/Lecturer

U.S. Physiomed Consultant/Advisor, Lilly, Meeting Participant/Lecturer

Introduction

Peyronie's disease (PD) is a fibrotic wound healing disorder of the tunica albuginea. It is both a physically and psychologically devastating disorder that causes penile deformity, curvature, hinging, narrowing, shortening, and painful erections [1]. Surgical correction of PD offers the patient correction of the deformity with several risks including more loss of length [2]. Penile shortening has been associated with negative patient perceptions and diminished patient satisfaction [3]. Multiple surgical techniques have been described for the surgical correction of PD, including plication and grafting procedures.

External penile traction therapy (TT) has been reported to result in recovery of up to 3 cm of stretched penile length (SPL) in men with PD as monotherapy [4,5]. Moncada et al. originally reported on the management of penile shortening after Peyronie's surgery and found a postoperative length increase of 1–3 cm in those using TT [6].

TT or the use of tension to elicit a biologic response has been examined in several other disease states and many disciplines. Mechanotransduction is the process of converting mechanical stimuli into cellular biochemical

responses. Although it has not been studied in the penis or Peyronie's model, this response to tension has been examined in skin, bone, skeletal muscle, and the Dupuytren's model [7–9]. Mechanotransduction is believed to activate both intracellular and extracellular pathways, leading to tissue remodeling of the cytoskeleton, extracellular matrix, ultimately leading to physiologic change. To assess penile length before and after treatment including surgery, a variety of methods have been presented. We have elected to use the SPL technique as presented by Wessells et al., which was shown to correlate well to erect penile length in men without PD [10].

We examined the effects of TT in the postoperative period after corrective surgery for PD in a population of men who underwent surgical correction with either tunica albuginea plication (TAP) or partial plaque excision and grafting (PEG) using Tutoplast processed human cadaveric pericardium (Coloplast, Minneapolis, MN, USA). Both objective and subjective outcomes were evaluated in order to determine measured and perceived penile length change following surgery (Table 1). In addition, an author-generated non-validated questionnaire was used to assess patient satisfaction (Table 2, Appendix S1).

Table 1 Patient demographics

	TAP TT+	TAP TT–	P value
Age	52.6 (34–68)	53 (32–72)	0.84
Degree of deformity	49.2 (35–80)	48.5 (35–70)	0.83
Mean length change (cm)	0.85 (0.25–1.75)	–0.53 (–1.75 to +0.5)	<0.001
95% CI	95% CI (0.57–1.13)	95% CI (–0.8 to –0.22)	
Length of follow-up (months)	10.4 (1–30)	8.3 (1–26)	0.39
Median time from surgery to onset of traction therapy	21 days (14–28)	NA	NA
Baseline stretched penile length	10.8 cm (7–13)	11.2 cm (7.5–16)	0.36
Baseline SPL postoperative prior to traction	11.0 cm (8–13)	11.2 cm (7.5–15)	0.76
Baseline SPL at last follow-up after traction if used	11.65 cm (8–14.5)	10.7 cm (7.5–15)	0.04
Mean duration of traction (hours/day)	2.6	NA	
Mean duration of traction (days/week)	4.7	NA	
Mean duration of traction (months)	2.9	NA	
	PEG TT+	PEG TT–	P value
Age	55.4 (49–80)	56.8 (38–71)	0.46
Degree of deformity (degrees)	80.8 (45–125)	76.9 (40–120)	0.54
Mean length change (cm)	1.48 (0 to 6)	0.24 (–1 to 2.5)	<0.001
95% CI	95% CI (1.11–1.85)	95% CI (–0.12 to 0.6)	
Length of follow-up (months)	7.1 (1–36)	6.1 (1–19)	0.6
Average graft size (cm ²)	26.2 (15–49)	26.1 (14–36)	0.94
Median time from surgery to onset of traction therapy	21 days (14–28)	NA	NA
Baseline stretched penile length	9.9 cm (7–12)	9.95 cm (7–12)	0.8
Baseline postoperative SPL prior to traction	11.75 cm (9–14)	11.8 cm (10–13.5)	0.82
Baseline SPL at last follow-up after traction if used	11.4 cm (9–14.5)	10.2 cm (8–12)	0.002
Mean duration of traction (hours/day)	2.4	NA	
Mean duration of traction (days/week)	5.4	NA	
Mean duration of traction (months)	4.1	NA	

TAP = tunica albuginea plication; PEG = partial plaque excision and grafting; TT+ = those who used traction therapy; TT– = those who did not use traction therapy

Table 2 Mailed questionnaire results

Question	TAP TT+	TAP TT-	P value	PEG TT+	PEG TT-	P value	Overall total
Capable of sex	90%	79%	0.37	84%	78%	0.66	84%
Currently engaging in sex	76%	71%	0.74	68%	71%	0.85	72%
Would you undergo surgery again	81%	65%	0.29	73%	85%	0.41	76%
Satisfied with surgical outcome	85%	57%	0.08	63%	64%	0.95	69%
Satisfied with correction of curvature	95%	93%	0.8	90%	100%	0.25	94%
Satisfied with current erect length	61%	50%	0.52	58%	43%	0.4	54%
Perceived erect length gain	68%	7%	0.001	47%	14%	0.05	58% (TT+)
Perceived erect length loss	0%	79%	0.0001	0%	57%	0.007	
Perceived erect length no change	32%	14%	0.24	53%	29%	0.17	
Average perceived length change (cm)	0.68	-1.45	<0.001	1.6	-2.6	<0.001	

Materials and Methods

Retrospective analysis was performed on our cohort of Peyronie's reconstructive surgery patients between 2007 and 2010. We identified 134 patients who had undergone corrective surgery with either TAP or PEG. Complete charts for review were available on 111 patients. Chart review allowed for assessment of recorded SPL; this was measured at the initial office visit before surgery as well as postoperatively before and after the completion of the traction protocol. Flaccid SPL was measured dorsally from pubis to corona by pressing down on the prepubic fat pad. All SPL measurements were completed by the same senior investigator (LAL) to minimize interobserver variability. This was done with the patient supine and the length was measured after placing the penis on stretch at a 90° angle to the body. Patients were consented for this protocol and were recommended to use TT following surgery. Patients were informed that the goals for the postoperative TT would be to prevent penile length loss, possibly encourage length gain, as well as encourage healing in the straightened condition (much like a splint). They were informed that the risks with this approach include failure to provide additional length, local penile tissue injury due to compression by the device, sensory changes, pain, and erectile dysfunction.

TT was recommended for 2–6 hours a day for 3 months typically starting 3–4 weeks postoperatively, once the patient could tolerate placement of the traction device, using the U.S. PhysioMed Penile Extender (Aliso Viejo, CA, USA) (Appendix S2). The choice of corrective surgery with TAP vs. PEG was based on degree of deformity and preoperative erectile function, as defined in previously published algorithms [11,12]. Patients were then stratified by procedure and whether TT was used (TT+) or not used (TT-). The distribution patient groups by the type of surgery and whether traction was used (TAP

TT+ N = 27, TAP TT- N = 25, PEG TT+ N = 36, PEG TT- N = 23). Prior to 2008, TT was not used routinely, and subsequently, those who were offered but declined TT were included in the TT- group. Data were then compiled into a database, and statistical analysis was performed using either a two-sided *t*-test or chi-square to determine *P* value of recorded measurements; in addition, measured length means were calculated using a 95% confidence interval. The mailed questionnaire assessed patient perception of penile length change and satisfaction before and after surgery. In addition, self-reported use of the traction device, in terms of duration, side effects, and erectile function were reported on the questionnaire (Table 2). Patients with congenital chordee, ventral curvature, and previous use of TT were not included in this study.

Results

All patients in the traction arms completed the protocol, however, with different use patterns. The mean postoperative follow-up period was 10.4 months (1–30), for TAP TT+ and TAP TT- 8.3 was months (range 1–26), for PEG TT+ 7.1 months (1–36) and PEG TT- was 6.1 months (1–19). The reported average daily use was 2.5 hours, for 4.5 days a week, for an average duration 3.8 months (1–13) (Table 1). Measured post-traction SPL increased in both traction groups (TAP and PEG) compared with baseline preoperative SPL. In the TAP TT+ group, the mean SPL increased 0.85 cm (0.25–1.75 cm), whereas in the TAP TT- group, there was an average length loss of 0.53 cm (-1.75 to 0.5) (*P* < 0.001) (Table 1 and Figure 3). There were no statistical differences in age, preoperative measured degree of deformity, or duration of follow-up between the TAP groups. In the PEG TT+ group, the average SPL increased 1.48 cm (0–6 cm) from preoperative baseline. In those who underwent PEG without TT, the average SPL

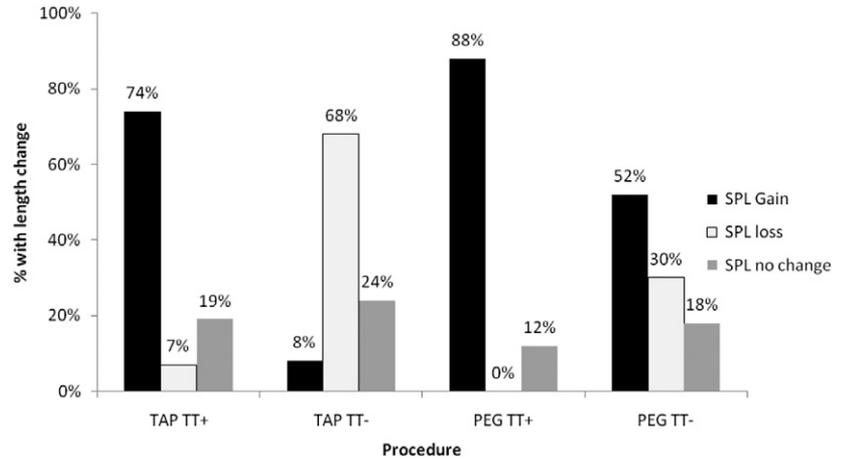


Figure 1 Measured postoperative SPL outcomes. SPL, stretched flaccid penile length

increased 0.24 cm (-1 to +2.5) ($P < 0.001$). There were no statistical differences in age, degree of preoperative measured deformity, or duration of postoperative follow-up between the PEG groups (Table 1).

Survey Results

Sixty-eight patients (~61%) returned the survey questionnaire. The breakdown of respondents was as follows: TAP TT+ N = 21, TAP TT- N = 14, PEG TT+ N = 19, and PEG TT- N = 14. Prior to corrective surgery, 85% of the entire cohort reported loss of an average of ~2.5 cm (-6 to 0 cm) of penile length. In those men who underwent TAP with traction, 68% perceived an average erect penile length gain of 0.68 cm (0-3.8 cm) (Figure 4). No patient (0%) in the TAP TT+ group perceived length loss after TT. In those who

underwent PEG with traction, 47% of patients perceived an erect penile length gain of on average of 1.6 cm (0-6 cm). No patient (0%) in the PEG TT+ group perceived length loss after TT. In those who underwent TAP without traction (TT-) 79% perceived erect length loss of an average of -1.45 cm (-3.8 to 0) (Figure 1). In those who underwent PEG without traction, 57% perceived erect length loss, on average of -2.6 cm (-5.0 to 0) (Figure 2).

Patient satisfaction (Table 2) in the TAP TT+ group was 95% for correction of curvature and 90% stated they had erections adequate for coitus. In the TAP TT- group, the patients reported 93% satisfaction with correction of curvature, 72% stated they had erections adequate for coitus. (Table 2). In the PEG TT+ group, patient satis-

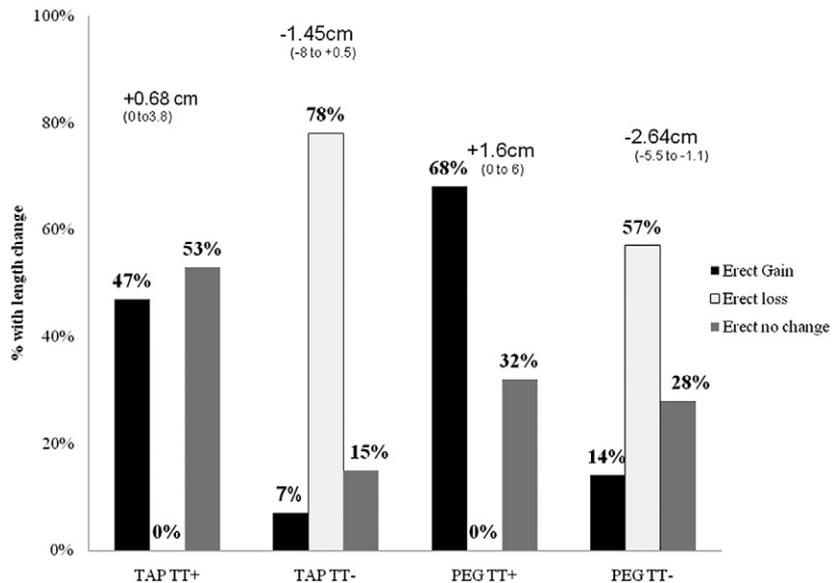


Figure 2 Patient estimated postoperative erect length change

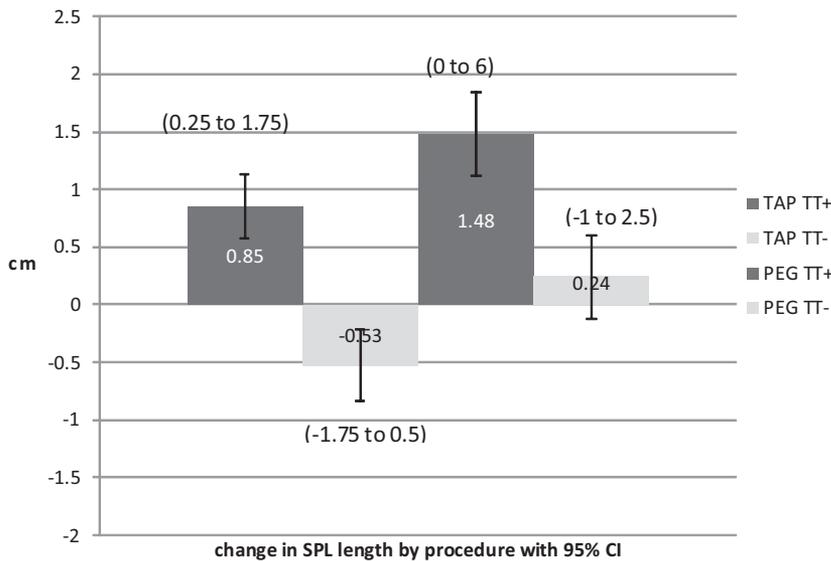


Figure 3 Change in measured SPL length by procedure

faction was 90% for correction of curvature, and 84% stated they had erections adequate for coitus. In the PEG TT- group, 100% were satisfied with correction of curvature, and 78% stated they had erections adequate for coitus.

Ultimately, those men who did not use TT (TT-) after either TAP or PEG had more perceived length loss compared with actual measured length change ($P < 0.001$) (Table 2 and Figure 4).

There is a high level of satisfaction with correction of curvature after surgery in all groups (94%).

Although not statistically significant, there was a trend of higher satisfaction in the TT+ groups for erect length 61% vs. 50% in the TAP TT- group ($P = 0.52$) and for the PEG TT+ group was 58% vs. 43% ($P = 0.40$) in the PEG TT-, respectively. (Table 2). The primary complaint by 47% of those who used the traction device was difficulty with application of the device and keeping it on for the desired amount of time. Importantly, there were no reported or visualized skin ulcerations, abrasions, changes in penile sensation, or device malfunction.

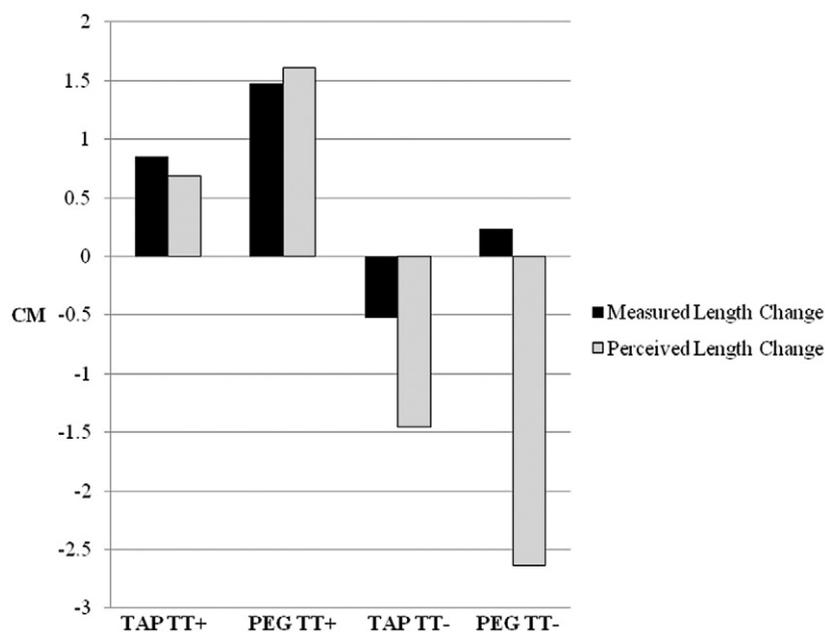


Figure 4 Objective and subjective length change

Discussion

Loss of penile length is a common presenting complaint in men with PD [13]. Reconstructive surgery has the potential to cause further loss of length regardless of the surgical approach, but typically more loss is reported with plication than grafting procedures. Penile shortening following reconstructive surgery for PD has been reported in 73–90% of patients [14–16]. The amount of shortening is variable but has been reported to be as much as 5 cm [14]. The goal of TT after surgery is to not only encourage straight healing but to prevent further length loss and possibly recover lost length as compared with preoperative length. This study indicates that in men undergoing corrective surgery for PD with either TAP or PEG benefit from postoperative TT with respect to preservation of penile length and may even gain some length that was lost as a result of the scarring process associated with PD. The causes of penile shortening due to PD and subsequent corrective surgery are thought to be multifactorial. There is a significant contribution to length loss due to the shortening of the convex aspect of the penis during plication procedures. Other mechanisms include postoperative tunica albuginea and/or cavernosal scarring. Erectile dysfunction may contribute to smooth muscle atrophy, and fibrosis due to increased collagen production may result in loss of tunica albuginea elasticity, as is seen in patients after radical prostatectomy [17].

Several postsurgical options have been considered in the past to try to lengthen the penis. Lue et al. examined the use of vacuum erection device (VED) therapy after circumferential tunica incision covered by a circular venous graft in four men. VED was used for 30 minutes daily for 4–6 months postoperatively starting at 1 month after surgery. Three of the four had gained 2 inches but had decreased erectile rigidity associated with hourglass deformity. The authors did not recommend this procedure without placement of a penile prosthesis [18]. Recent studies have examined the response of penile tissue to TT. Gontero et al. showed that an external penile traction device can provide penile length gain in a study of 15 patients with a short penis (defined as <4 cm flaccid and less than 7 cm erect). The subjects were asked to use a penile extender for at least 4 hours per day for 6 months. After 6 months, the mean length gain was 2.3 cm for flaccid length and 1.7 cm for SPL [19]. In 2008, Levine et al. performed the first prospective pilot study on patients with PD that utilized

traction alone without surgery [4]. Ten men entered the study and applied the device for 2–8 hours per day for 6 months. At the completion of the study, all men subjectively reported increased penile length and had a measured increase of 0.5–2.5 cm. In addition, all subjects had a mean measured curvature reduction ranging from 10 to 45°. In a small study, TT was examined in 10 men who complained of a shortened penis prior to penile prosthesis placement (PD, previous explanted prosthesis, radical prostatectomy) [20]. No men lost length in the study, and 70% gained erect length with the mean SPL gain of 1.6 cm (range 0.5–2.5 cm). In a separate study comparing intralesional verapamil injections with or without TT in two groups of men with PD, Abern and Levine determined that the minimum duration of TT needed to attain length gain was 3 hours daily, and found a dose response curve, with positive results occurring progressively with each additional hour per day [21]. Compliance and adherence to the traction protocol remains the most difficult factor, but it is necessary to achieve the desired results, as was suggested in the study by Moncada et al. [6].

The mechanism of action of penile TT has not been studied in the penis, but is presumed to be similar to what has been reported in other tissues. TT has been used in plastic, orthopedic, and maxillofacial surgical applications for many years. It has been reported to activate the extracellular matrix and cytochemical interaction by a process known as mechanotransduction. This has been shown to result in cellular proliferation by several mechanisms including upregulation of cyclin D1 by removing cell cycle checkpoints, increased platelet-derived growth factor with subsequent paracrine signaling and stimulation of adjacent cells, activation of the IP3/DAG pathway, thereby increasing intracellular calmodulin activity, and increase in bone morphogenic protein leading to Smad induced cellular proliferation through activation of the transforming growth factor beta superfamily of growth factors [22–24]. In the Dupuytren's contracture model, TT has been shown to induce histologic changes within the collagen fibers where the disordered collagen fibers demonstrated realignment of the collagen parallel to the traction forces [25]. Other studies using the Dupuytren's model with traction have demonstrated an increase in metalloproteinases, which are known to be involved in scar remodeling [26]. These cellular and extracellular changes appear to induce scar remodeling which likely results in the

change in penile length and deformity seen when traction is applied to the penis of men with PD.

The questionnaire allowed analysis of patient-reported perceived length change. Those in the traction arm (TAP TT+ and PEG TT+) had SPL changes that corresponded with perceived length change. However, those who did not use traction (TAP TT- and PEG TT-) had more perceived erect length loss compared with actual measured SPL change. This may be due to the actual length loss, but exacerbated by the negative psychologic effects known to accompany PD [27,28]. Those in the TT+ arm may have a more realistic view of perceived length change, as they are actively involved in a daily regimen to stretch the penis. Patients in the TT+ group did note a higher rate of rigidity than those who did not use the device, but we did not intend to suggest that this was a treatment to enhance rigidity. Although there is some difference in rigidity between the groups, it is not statistically significant, nor clinically meaningful. Diminished satisfaction with penile length is common in the Peyronie's population, as many patients desire to have their pre-PD penile length (or better) after surgery despite resolution of curvature. In this study, only 54% of the entire cohort was satisfied with their postoperative erect length, in spite of the measured and perceived length gains. Chung et al. reported their experience with different grafts without postoperative TT and reported that 87% of the patients in the Tutoplast human pericardial graft arm (Coloplast, Minneapolis, MN, USA) had resolution of curvature. Yet in the same study, the overall satisfaction on a five-point scale was 2.6, with more than 65% of patients dissatisfied with the outcomes of the Peyronie's graft surgery suggesting other factors have an impact on patient satisfaction other than curve correction [3]. Others have examined satisfaction rates after surgical correction of PD and found varying rates of up to 89% [29]. Moncada et al. were the first to examine the effects of TT on length loss after grafting and plication procedures and in the overall cohort found length loss of 0.5–4 cm after surgery, but in the traction group, there was a length gain of 1–3 cm, they also reported that length increase was proportional to hours per month of use [6].

One weakness of this report is that it is a non-randomized, retrospective study. TT was first offered to all postsurgical PD patients in 2008. Some declined to use it, primarily due to not having the time for device use and several stated out-of-pocket cost concerns. Another weakness is that the questionnaire was an author-generated non-

validated instrument. But, we do feel that the 61% response rate is clinically meaningful and is regarded as such in the epidemiologic literature for this type of study [30]. Another possible concern is that SPL measurements were taken by a single investigator, but the same approach was employed in all patients and is therefore in principle subject to the same intraobserver error. Lastly patients did not use the TT in a consistent fashion, with respect to daily application or duration of postoperative use, which may compromise outcomes.

Conclusions

Loss of penile length in men with PD is a serious concern, as it is a source of significant patient distress and postoperative dissatisfaction with treatment. It appears that postoperative TT can, at a minimum, result in perceived and measured SPL preservation. The traction protocol was safe and well tolerated, as there were no local complications and no change in penile sensation. The protocol is tedious and requires compliance to be effective. Men who used TT (TT+) after corrective surgery for PD experienced statistically significant gain in measured SPL ($P < 0.001$); in addition, none of the men who used traction had a perceived penile length loss in both the TAP and PEG groups. In this population, there was a high level of satisfaction with correction of curvature after surgery (94%) (Table 2). In spite of the length gain found with TT, only 60% of the TT+ group and 46% of the TT- group were satisfied with their current erect length. We feel that this likely reflects the overall psychologic distress associated with this disorder. Therefore, setting attainable expectations regarding curvature and length correction remains a critical preoperative process.

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Conflict of Interest: None declared.

Statement of Authorship

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Category 2**(a) Drafting the Article**

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Category 3**(a) Final Approval of the Completed Article**

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1 Peyronie's disease patient questionnaire, perceived length loss and satisfaction with Tx outcomes

Appendix S2 Instructions for external penile traction device

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