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ORIGINAL RESEARCH

Plication for Severe Peyronie's Deformities Has Similar Long-Term Outcomes to Milder Cases

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ABSTRACT

Introduction: Penile plication (PP) for Peyronie's disease (PD) is an established treatment option for mild to moderate curvature, but scant data exist regarding its utility in severe deformities.

Aim: To evaluate long-term outcomes among men undergoing PP for PD, comparing severe to mild/moderate penile deformities.

Methods: We performed a retrospective review of patients who underwent PP for PD between 2009 and 2017. All patients underwent multiple parallel tunical plication without degloving. Severe PD was defined as either curvature ≥60 degrees or biplanar curvature ≥35 degrees. Patient demographics and surgical outcomes were analyzed. A modified PD Questionnaire and International Index of Erectile Function (IIEF)-5 were administered by telephone.

Main Outcome Measure: Long-term patient-reported outcomes were evaluated from a modified survey incorporating the PD Questionnaire and IIEF-5.

Results: Of 327 PP patients, 102 (31%) responded to the telephone survey at a median 59.5 months (interquartile range 28.3–84) since surgery. Patients were equally distributed into severe (n = 51) and mild/moderate (n = 51) groups. Despite a greater mean degree of curvature in severe compared to mild/moderate patients (71.6 degrees vs 37.7 degrees, respectively, $P < .001$), correction of penile curvature was achieved in 91% of patients, with a mean change of 60.7 degrees in severe cases compared to 31.4 degrees in mild/moderate cases ($P < .001$). Equal numbers of patients in severe and mild/moderate groups reported improvement of penile curvature (74.5% vs 74.5%, $P = 1.0$) and sexual function (51.0% vs 49.0%, $P = .84$). PD Questionnaire metrics were likewise similar between severe and mild/moderate patients ($P > .1$), as were rates of subjective penile shortening (62.7% vs 62.7%, $P = 1.0$) and IIEF-5, both pre-operatively (19.5 vs 19.7, $P = .9$) and post-operatively (19.4 vs 17.6, respectively, $P = .15$). On multivariate logistic regression, worsening sexual function was significantly associated with increased age (odds ratio 1.07, $P = .01$) and pre-operative IIEF (odds ratio 1.14, $P = .02$).

Clinical Implications: PP should be considered in PD patients with severe deformities, as outcomes are favorable and comparable to those with milder curvature.

Strength & Limitations: This is a novel study evaluating long-term patient-reported outcomes after PP, comparing patients with severe deformity to those with mild/moderate curvature. The study was limited by retrospective design, relatively low survey response rate (31%), and lack of validated post-operative PD questionnaire.

Conclusion: Long-term patient-reported outcomes of PP for severe PD deformities are comparable to mild/moderate cases, supporting broader application of PP beyond milder deformities. **Reddy RS, McKibben MJ, Fuchs JS, et al. Plication for Severe Peyronie's Deformities Has Similar Long-Term Outcomes to Milder Cases. J Sex Med 2018;15:1498–1505.**

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Key Words: Peyronie's Disease; Plication; Patient-reported Outcomes

INTRODUCTION

Peyronie's disease (PD) is an acquired penile deformity that impedes sexual intercourse and has detrimental effects on patient quality of life.[1] While a variety of non-operative treatments for PD have been described, few have been robustly tested and none have been approved for treatment of severe curvature. Only

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intralesional collagenase clostridium has been Food and Drug Administration—approved and endorsed by the American Urologic Association for patients with mild to moderate deformities.[2,3] Surgical correction remains the gold standard for patients with stable curvature due to high efficacy and low morbidity.[4]

Penile plication (PP) is traditionally recommended for patients with mild to moderate PD curvature,[5,6] whereas plaque incision with grafting is generally reserved for severe or complex deformities. In recent years, several centers have supported an expanded role for PP in patients with severe deformities, reporting good short-term safety and efficacy.[7–11] Though PP is now used in a wider breadth of PD deformities, scant data exist on long-term outcomes in more severe cases.[8] We sought to evaluate long-term patient-reported outcome measures (PROMs) after PP, comparing patients with severe curvature to those with mild/moderate PD deformities in our large single-surgeon experience. We hypothesized that patients with severe deformities would report outcomes comparable to those with milder disease.

METHODS

After obtaining institutional review board approval, we conducted a retrospective review of all patients who underwent PP for PD by a single surgeon at our tertiary center between 2009 and 2017. All men presented with persistent painless penile curvature for at least 6 months and were grouped for analysis by severity of deformity as determined by office history and/or intraoperatively after intracorporal alprostadil injection. The severe group included patients with either curvature $\geq$60 degrees or biplanar curvature $\geq$35 degrees, while the mild/moderate group included patients with uniplanar curvature $<$60 degrees or biplanar curvature $<$35 degrees. Patients with an hourglass deformity were excluded from this study. Patients with erectile dysfunction (ED) were liberally prescribed oral phosphodiesterase-5 inhibitors to confirm adequate rigidity for penetration before PP. Those with refractory ED were offered concomitant penile prosthesis with PP and were excluded from this study.

Surgical Technique

After induction of general anesthesia, an artificial erection is induced with intracorporal injection of 20 μg of alprostadil. If poor erectile response is noted, a second 20-μg dose is administered to achieve a sufficient erection for evaluation. Maximum degree of curvature is measured by consensus of the surgical team, and photographs of the erect penis are taken from the lateral and inferior perspectives. Before intracorporeal injection, stretched penile length (SPL) is determined by compressing the suprapubic fat pad and measuring the dorsal distance between the pubic symphysis and the penile tip while on maximal stretch.

Our minimally invasive surgical technique for multiple parallel PP without degloving has been described in previous studies.[7–10,12] PP is performed through a 2— to 3-cm longitudinal incision along the proximal or mid shaft opposite the direction of curvature. After the initial dissection is carried through the Dartos and Buck fascia, Senn retractors are used to further expose the tunica albuginea proximally, distally, and rotationally. Beginning proximally, the tunica albuginea is then repeatedly corrected with short inverting plication sutures of 2-0 Ethibond (Ethicon Inc, Somerville, NJ, USA) spanning a total of 15 to 20 mm, while retracting the incision over areas of greatest convexity. The patient is re-examined during proximal shaft compression after each suture and additional sutures are placed until adequate correction of the deformity is achieved.

The incision is closed in 3 layers; Buck and Dartos fascia are closed in 2 layers using 2-0 and 4-0 Monocryl (Ethicon Inc), and skin is closed in subcuticular fashion with 4-0 Monocryl and Dermabond (Ethicon Inc). Intraoperative photographs and SPL measurements are repeated (Figure 1), and a lightly compressive Coban (3M Company, Maplewood, MN, USA) dressing is applied. A penile ring block is performed using 0.25% bupivacaine. All patients are discharged on the same day and are asked to abstain from sexual activity until the day prior to their follow-up visit in 4 to 6 weeks for wound evaluation, SPL measurement, and assessment of deformity correction and sexual function.

Patient Questionnaire

All patients were contacted by telephone by a non-clinical research assistant who was not part of the surgical team. Willing participants were administered a 15-item questionnaire modified from the PD Questionnaire,[13] the International Index of Erectile Function (IIEF)-5,[14] and the Patient Global Impression of Improvement.[15–17] The questionnaire assessed patient perception of post-operative penile curvature, sexual function, erectile strength, pain with erection or intercourse, sensation, penile length, and presence of bumps or nodules. Level of bother associated with each of these outcomes was also assessed.

Statistical Methods

Perioperative and survey data were compared between the severe and mild/moderate PD groups using the χ^2, Mann-Whitney U, and independent sample t tests for categorical, ordinal, and continuous variables, respectively. Logistic regression analysis was used to identify any variables associated with post-operative sexual function. Parameters meeting a threshold $P < .15$ on univariate analysis were included in a multivariable logistic model of sexual function. Statistical significance was considered at $P < .05$ and reported P values were 2-sided. All analyses were performed with software (SPSS, Version 25.0; IBM Corp, Armonk, NY, USA). Figures 1 and 2 were created with software (GraphPad Prism, Version 7.03; GraphPad Software, La Jolla, CA, USA).

RESULTS

Perioperative Outcomes

Among 327 patients undergoing PP for PD during the study period, 102 (31%) responded to the telephone questionnaire a

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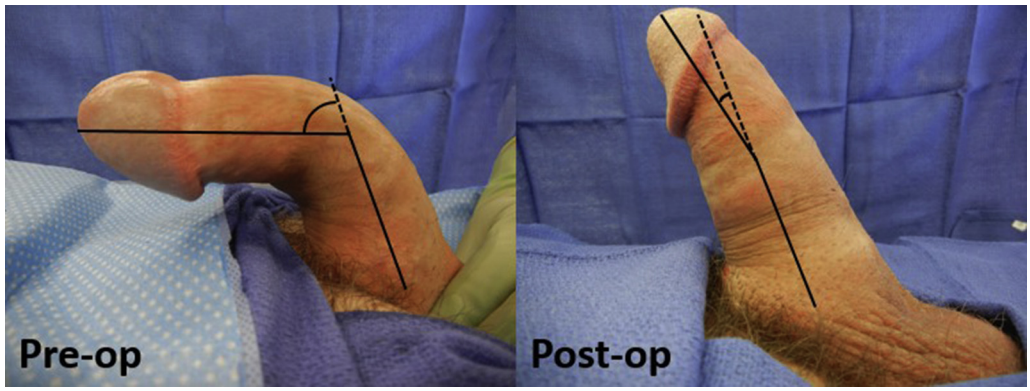

Figure 1. Penile plication for severe Peyronie's disease deformities. Pre-operative photograph demonstrating 70-degree dorsal curvature. Excellent straightening (8-degree residual dorsal curvature) was achieved via minimally invasive plication without degloving using 20 sutures. Stretched penile length was 14 cm both pre- and post-operatively in this case. Figure 1 is available in color online at www.jsm.jsexmed.org.

median 59.5 months after PP (interquartile range 28.25–84 months). Respondents were equally distributed between severe and mild/moderate groups (51 patients in each group) (Table 1). Mean pre-operative penile curvature was approximately twice as great in the severe group (71.6 degrees) compared to mild/moderate PD patients (37.7 degrees, $P < .001$). Patient characteristics were otherwise similar between severe and mild/moderate PD groups (Table 1). Pre-operative ED was reported by 15.7% of patients, with similar rates in the severe and mild/moderate groups (19.6% vs 11.8%, respectively, $P = .28$).

Number of plication sutures required for correction of penile curvature corresponded with severity of disease, with severe PD patients requiring a mean of 9.7 sutures (range 4–25 sutures), compared to 6.5 sutures (range 2–11 sutures) for mild/moderate patients ($P < .001$). Correction of penile curvature, defined as post-operative curvature less than 20 degrees, was achieved in 93 patients (91.2%) immediately post-operatively, with a mean change in angle of 60.7 degrees in severe cases compared to 31.4 degrees in mild/moderate cases ($P < .001$). SPL did not change significantly as a result of PP in either group (mean change −0.04 cm in severe and 0.002 cm in mild/moderate groups).

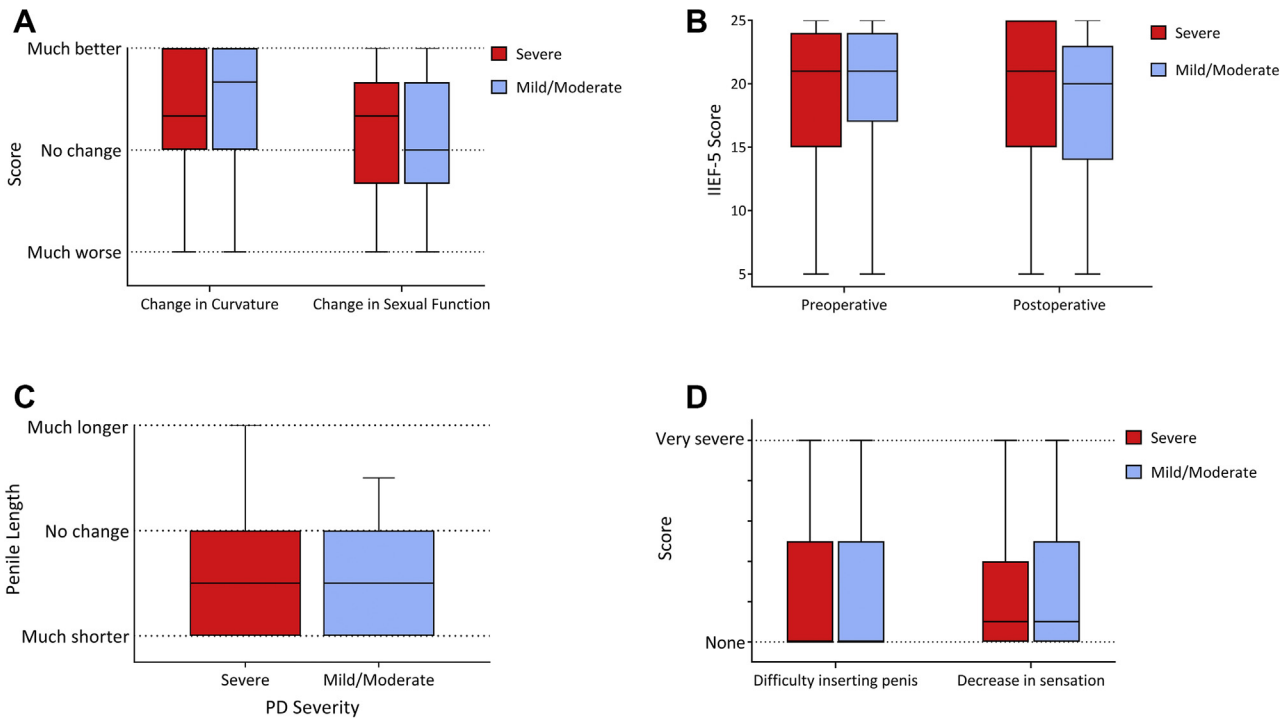

Figure 2. Patient-reported outcomes after penile plication surgery comparing severe and mild/moderate cases. A, Changes in curvature and sexual function. B, Pre-operative and post-operative International Index of Erectile Function (IIEF)-5 scores. C, Change in penile length. D, Difficulty inserting penis and decrease in sensation. PD = Peyronie's disease. Figure 2 is available in color online at www.jsm.jsexmed.org.

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Table 1. Surgical outcomes of penile plication by Peyronie's disease severity (n = 102)

	Severe PD, n = 51	Mild/moderate PD, n = 51	*P* value
Age, y, mean ± SD	57.1 ± 11.3	55.0 ± 10.1	.33
Direction of curvature, n			
Dorsal	29	31	
Ventral	5	5	
Lateral	17	15	.908
Angle, degree, mean ± SD			
Pre-operative	71.6 ± 24.8	37.7 ± 8.3	**<.001**
Post-operative	9.9 ± 7.6	6.7 ± 6.4	**.04**
Change in angle, degrees, mean ± SD	60.7 ± 18.9	31.4 ± 7.5	**<.001**
Sutures, n, mean ± SD	9.7 ± 4.1	6.5 ± 2.0	**<.001**
Correction/suture, degree, mean ± SD	7.8 ± 2.9	5.6 ± 2.8	**.002**
Change in SPL, cm, mean ± SD	−0.037 ± 0.19	0.0021 ± 0.22	.38
Decrease in SPL, n (%)	2 (3.9%)	5 (9.8%)	.24
Pain after 1 mo, n (%)	9 (17.6%)	3 (5.9%)	.065
Repeat procedures, n (%)	2 (3.9%)	3 (5.9%)	.65
Release of sutures, n (%)	1 (2.0%)	0 (0%)	1.0
ED, n (%)			
Pre-operative	10 (19.6%)	6 (11.8%)	.28
1 mo Post-operative	20 (39.2%)	14 (27.5%)	.21

Bold text indicates statistical significance.
PD = Peyronie disease; SPL = stretched penile length.

Proportionate decrease in SPL relative to baseline length was minimal and similar between groups following PP (3.9% in severe PD vs 9.8% in mild/moderate PD, $P = .24$).

Although patients in the severe PD group tended to report penile pain at their 1-month post-operative visit more frequently (17.6% in severe PD vs 5.9% in mild/moderate PD), this difference was not statistically significant ($P = .065$). The proportion of men who reported ED at their 1-month visit did not differ between the severe and mild/moderate groups (39.2% vs 27.5%, $P = .21$).

Long-Term PROMs

Men reported improvement in both curvature and sexual function at similar rates after PP regardless of severity of baseline curvature. Three quarters of men reported improvement of penile curvature (74.5% in both severe and mild/moderate PD, $P = 1.0$), while half reported improvement in sexual function (51.0% in severe group vs 49.0% in mild/moderate group, $P = .84$) (Figure 2 and Supplementary Table 1) at a median of 59.5 months (interquartile range 28.3−84 months) after PP. Preservation of erectile function was achieved in both the severe and mild/moderate PD groups, with minimal change in IIEF-5 at long-term follow-up (−0.14 vs −2.08, respectively, $P = .22$). Most patients reported erection strength adequate for intercourse, with no difference between the severe and mild/moderate groups (82.4% vs 82.4%, $P = 1.0$).

The severe and mild/moderate groups were comparable in other long-term PROMs after PP, including penile length, pain with erections or intercourse, difficulty with penile insertion, penile sensation, and knot palpability (Figure 2 and Supplementary Table 1). Subjective observation of penile shortening was common, but at a similar rate in severe and mild/moderate PD groups (62.7% vs 62.7%, $P = 1.0$). Pain following PP was infrequent with both erections (21.6% in severe PD vs 13.7% in mild/moderate PD, $P = .3$) and intercourse (25.5% in severe PD vs 13.7% in mild/moderate PD, $P = .16$). Similar proportions in the severe and mild/moderate groups had no difficulty inserting their penis into their partner's vagina (51.0% vs 58.8%, $P = .44$) and no decrease in sensation (47.1% vs 47.1%, $P = .98$). Although 70.6% of the severe group and 72.5% of the mild/moderate group felt bumps or nodules on the penis ($P = .83$), most were not bothered in either group (63.9% vs 56.8%, $P = .89$). In a multivariable model of post-operative sexual function, adjusting for pre-operative and post-operative degree of curvature, only increasing age and baseline IIEF remained significantly associated with worsening sexual function (Table 2).

DISCUSSION

The present study provides support for the expanded use of minimally invasive PP for severe PD. When comparing outcomes between patients with severe and mild/moderate PD, PP is equally effective irrespective of severity of curvature, with similar improvements in sexual function and penile curvature across the spectrum of cases. This study is the first to report long-term patient-reported outcomes using a uniform minimally invasive PP technique via longitudinal penile incision; the median follow-up of 59.5 months extends far beyond our previous

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Table 2. Univariate and multivariable analysis of factors associated with change in sexual function

	Univariate		Multivariable	
Parameter	OR	*P*	OR	*P*
Age at surgery, per y	1.08 (1.03–1.14)	.001	1.07 (1.01–1.14)	**.01**
Time since surgery, per mo	1.01 (0.99–1.03)	.06	1.02 (1.00–1.05)	.05
Pre-operative IIEF, per increment	1.16 (1.05–1.28)	.0008	1.14 (1.01–1.29)	**.02**
Pre-operative curvature, per degree	1.00 (0.98–1.01)	.8	0.98 (0.95–1.01)	.3
Post-operative curvature, per degree	1.07 (1.00–1.14)	.05	1.03 (0.94–1.13)	.5

IIEF = International Index of Erectile Function; OR = odds ratio.

studies using this technique, which ranged from 14 to 15.4 months.[8–11] These data suggest that the minimally invasive PP can effectively and safely correct severe penile deformities with durability extending nearly 5 years.

PP for Severe Deformity

Traditional surgical algorithms for PD suggest that PP be reserved for those with mild to moderate curvature.[5,6] In recent years, multiple studies have challenged this notion and have utilized PP for a wide spectrum of penile deformities with success.[7–11,18] 1 Recent PD review suggested increased use of PP for simple curvature up to 90 degrees.[19] Our mean correction of 60.7 degrees in the severe group without worsening of any measurable outcomes corroborates this more liberal approach.

Gholami and Lue[18] were the first to describe the 16-dot technique that involved both a circumscribing incision to correct lateral or ventral deformities and also a ventral longitudinal incision to correct dorsal deformities. Our experience suggests that a modified approach without circumcision is feasible for virtually all directions and degrees of deformities and can be safely combined with IPP placement.[7–11] The present study expands on these findings by evaluating the long-term efficacy of PP in our large cohort using PROMs across a wide spectrum of patients.

PROMs

Curvature

Most PP series have demonstrated adequate correction of penile deformity, defined by expert opinion as less than 20 degrees of residual curvature.[3] Successful results extend to patients with severe PD, as multiple studies have reported minimal revision rates for severe PD patients ranging from 2.1–3% with intermediate follow-up.[4,9,18] Our study reinforces these findings with a low revision rate of 5.4% over nearly 5 years of follow-up.

Severity of penile curvature did not affect surgeon ability to correct curvature effectively. We previously reported that 96% of patients with severe PD reported adequate straightening at an average 14 months after PP.[9] In the present study, with extended follow-up, 74.5% of patients report improvement in penile curvature, with no differences between the severe and mild/moderate groups. This lower improvement rate may be due to the long-term nature of the study, with attendant aging and possibly progression of the PD process.

Erectile and Sexual Function

Post-operative de novo ED is an important potential complication of surgical correction of penile deformities. In particular, plaque incision and grafting procedures carry a risk of ED due to trauma to the delicate erectile tissues and possibly the neurovascular bundle. A long-term study of 46 patients who underwent graft procedures noted worsening IIEF-5 scores in all patients at 5-year follow-up.[20] In contrast, PP has demonstrated more favorable outcomes with respect to preservation of erectile function. Gholami and Lue[18] noted a 3% incidence of ED 6 months after PP, increasing slightly to 6% at follow-up extending to 6 years. Similarly, Kadirov et al[21] demonstrated preservation in IIEF-5 scores 18 months post-operatively in 52 patients undergoing PP. The present study found no difference in IIEF-5 scores up to 5 years post-operatively in both severe and mild/moderate PD patients.

Although improvement in overall sexual function was noted in only 51% of our severe PD group, we found age and baseline IIEF to be independent predictors of worsening sexual function. Normal aging and underlying disease processes likely factor into patients' overall perception of sexual function long-term after PD correction. The risk of ED remains one of the most compelling arguments against grafting procedures, as trauma to deep penile structures can have significant erectile and sensory consequences, with perhaps marginal length gains. PP avoids dissection of these deep and delicate structures, minimizing the risk of attendant complications.

Penile Shortening

Patients with PD are often distressed by penile length loss caused by the contractile forces of the tunical plaque and/or concomitant ED. Although over half (32/51) of our severe PD patients reported subjective penile shortening, only 2 (3.9%) had an objective, intraoperative decrease in SPL of limited clinical significance (mean 0.4 cm). Perceived loss of penile length following PD surgery has been reported across multiple studies despite minimal objective length change.[22,23] In prior PP series, subjective decrease in penile length was reported by 75% of men,

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though only 16% of men had measurable changes pre-PP and post-PP.[9] Taylor and Levine[24] also reported striking differences between measured and perceived length loss both in patients undergoing PP (18% vs 69%) and those undergoing plaque incision and grafting (33% vs 59%).

The discrepancy between the subjective and objective measurements may be explained by a combination of both penile shortening related to contractile forces of the PD plaque, as well as the tendency for patients to inaccurately estimate both penile length and curvature for a wide variety of surgeries including anterior urethroplasty and radical prostatectomy.[25–27] The mean loss of length of 0.4 cm in our severe PD patients corroborates earlier studies reporting small decreases in length, ranging from 0.5–1.5 cm.[8–10,18,28] These results suggest that patients may misinterpret the loss of penile volume that occurs with PD as a loss of penile length, and concern over length loss should not preclude patients from undergoing PP. However, discussion of possible length or volume loss should factor into pre-operative counseling to help set realistic post-operative expectations. We advocate quantitative documentation of SPL at all visits, as demonstration of length preservation to the patient can help alleviate concerns.

Penile Sensation

Patients undergoing surgical correction of PD commonly report changes in penile sensation post-operatively, with rates varying greatly for both PP (6–75%) and plaque incision with grafting (7.1–60%).[18,29–31] The present study demonstrates a rate of decreased sensation (52.9%) within the range reported in previous literature, though most patients report minimal decrease (median 1 on 10-point scale). One study comparing PP to grafting procedures found that patients undergoing plaque incision with grafting were far more likely to experience a decrease in sensation than those undergoing PP (60% vs 19%).[31] This safety difference highlights a clear advantage of PP over grafting procedures, as the minimally invasive technique without degloving or dorsal neurovascular mobilization avoids delicate deep and distal structures.[32]

Suture Knot Palpability

Knot palpability is inherent to PP and discussing this with the patient during pre-operative counseling sets accurate expectations. Although knots formed by the permanent sutures in PP are frequently palpable, particularly within the first 3 months post-operatively, bother from knots is reliably low, ranging from 0–40%.[18,29,33,34] Our study supports these findings, with 70.6% of the severe PD group reporting palpable knots and only 36.1% of this subset bothered by them. Our surgical technique limits palpability by burying knots using the inverted vertical mattress configuration, along with closing the incision in 3 layers. We continue to use non-absorbable braided sutures since prior studies using absorbable sutures report failure rates as high as 28.9%.[35] Tension is reduced on each knot by placing multiple short sutures in parallel, rather than fewer longer sutures.

Limitations

Our study is retrospective in nature with the usual biases. Although we used elements of various validated questionnaires, our study as well as other PD studies are limited by the lack of a standardized survey. We elected to use relevant items adapted from the PD Questionnaire, as well as the Patient Global Impression of Improvement, a validated questionnaire that more adequately assesses post-operative outcomes and has been used to assess patient satisfaction after anti-incontinence, urogenital prolapse, and penile prosthesis procedures.[15–17] We also included the IIEF-5 in our questionnaire, which has been validated and used for the evaluation and post-treatment follow-up of patients with ED.[14] Although pre-operative IIEF-5 scores were obtained during the patients' post-operative telephone interviews, we found the scores correlated well with the documented history of erectile function during the pre-operative clinic assessment.

Our modest response rate of 31% to telephone questionnaire may be attributable to the long-term nature of the study; it is comparable to the 23% response rate to a recent long-term outcomes study of non-surgical PD patients,[36] and in the range of normal for telephone surveys.[37,38] Furthermore, response rate was similar between severe and mild/moderate PD groups, suggesting no confounding bias for responders in the comparison of patient-reported outcomes. Despite these limitations, this study provides further evidence that PP can effectively correct severe penile deformities secondary to PD, with PROMs comparable to mild/moderate cases. With a median follow-up of nearly 5 years, PP is durable.

CONCLUSION

PP for severe PD deformities results in long-term PROMs comparable to patients with milder disease. These findings support broader application of PP across the spectrum of PD severities, as the procedure is safe and demonstrates favorable outcomes.

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jsxm.2018.08.006.

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