

Role of lingual mucosa as a graft material in the surgical treatment of Peyronie's disease

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Abstract

Background: Peyronie's disease (PD) is a localized fibrosis of tunica albuginea, which causes the anatomical and functional changes to the penis. Corporoplasty with grafting is indicated in severe ($>60^\circ$) and complex curvature. Buccal mucosa is the most favored autologous graft material nowadays. The ventrolateral aspect of lingual mucosa has similar histological features to the rest of the oral cavity.

Methods: This study aimed to test the efficacy, safety, durability, and reproducibility of corporoplasty with lingual mucosal graft (LMG) in the surgical treatment of PD in terms of surgical outcome, sexual function, and donor site complications. This prospective study included 19 patients of PD with severe and complex curvature, who underwent corporoplasty with LMG. Surgical and functional outcomes were assessed at follow-up planned at 2 weeks, 3 months, 6 months, 1 year, and 2 years.

Results: The mean operative time was 126.31 ± 21.45 min. Additional Nesbit's plication to correct the residual deformity was required in 26% (5 / 19) of patients. Straightening of the penis (curvature $<10^\circ$) was achieved in 89% (17 / 19) of patients. Increase in the penile length (>1 cm) postoperatively was achieved in 63% (12 / 19) of patients and a shortening of penis occurred in 5% (1 / 19) of patients. Newer onset erectile dysfunction developed in 11% (2 / 19) of patients, and patient and partner satisfaction rates were 89% (17 / 19) and 84% (16 / 19), respectively, in a mean follow-up of 20.66 ± 5.37 months. Donor site complications were minimal and no patient had any salivary changes or speech disturbances.

Conclusion: LMG provided excellent short-term results in terms of deformity correction, improved sexual function, and minimal donor site morbidity. The method is simple and reproducible, and multicenter studies with larger number of cases with longer follow-up are required to confirm these favorable results.

Keywords: Autologous graft, corporoplasty, erectile dysfunction, lingual mucosal graft, penile straightening

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INTRODUCTION

Peyronie's disease (PD) is a benign fibroproliferative disorder which causes a localized fibrosis of tunica albuginea with

resultant anatomical and functional changes in the penis. The most commonly affected age group is 50–55 years and the overall prevalence of PD varies from 3.2% to 13%.^[1]

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There is no global consensus regarding the standard therapy for PD.^[2] Surgical intervention in well selected subjects, aims for the correction of penile deformity, symptomatic relief, and recovery of the ability to perform intercourse.^[3,4] Corporoplasty with grafting is indicated in severe ($>60^\circ$) and complex curvature.^[3,4]

A wide variety of graft materials have been used in literature for PD procedures. Buccal mucosa is the most favored autologous graft material nowadays.^[5,6] In India, especially in our region, the widespread oral tobacco abuse renders the buccal mucosa unhealthy and unsuitable for use as a graft. However, the lingual mucosa is relatively spared in oral tobacco abusers and provides a viable alternative to buccal mucosa for graft harvesting. There is a single published series of lingual mucosal graft (LMG) in surgical treatment of PD till now.^[7] Considering the properties of LMGs and the encouraging results we achieved using these in anterior urethral reconstruction, we decided to use LMG in the surgical reconstruction of PD.^[8,9]

The present study aims to test the efficacy, safety, and reproducibility of corporoplasty with LMG in the surgical reconstruction of penile curvatures secondary to PD in terms of surgical outcome, sexual function, and donor site complications.

METHODS

This prospective, descriptive study was carried out in the department of urology of our institute from September 2015 to August 2019. Ethical approval from the institutional committee was obtained before the commencement of the study.

We selected 102 patients, who presented with complaints of penile pain, penile induration, and penile deformity in the urology outpatient department. A comprehensive medical and sexual history was taken. Erectile function was assessed using the International Index of Erectile Function (IIEF-5). History of prior therapy for PD with response was noted. The physical examination of the penis included the appearance of the penis in a flaccid state, the location and size of the plaque, and measurement of stretched penile length (SPL). Autophotography of erect penis in two projections was used for initial evaluation of penile curvature. Conventional B-mode and color Doppler sonography after combined intra-cavernosal injection and stimulation bimix test was performed to objectively assess penile curvature, plaque characteristics, and erectile function. Ultrasonographic plaque patterns were defined according to Bekos classification.^[10] Erectile response was

graded according to the Erection Hardness Scale (EHS) by the physician on eyeball evaluation. Girth-related changes were recorded as described by the patient.

Inclusion criteria were stable disease for at least 6 months with penile curvature $\geq 60^\circ$ interfering with intercourse, patients with complex deformity, e.g., hourglass or hinge deformities, failure of conservative therapy and patients willing for surgical correction, in stable phase of the disease. Exclusion criteria were disease duration <1 year and moderate-to-severe erectile dysfunction (ED). After scrutinizing with the above criteria, 19 cases were selected for the study. All patients were counseled about the nature of their disease, various surgical treatment options, expected results, donor site morbidity, and possible side effects. Consent for using their lingual mucosa to replace the fibrotic PD plaque was obtained. Corporoplasty with partial excision of plaque with LMG was performed in all patients.

Surgical technique [Figure 1]

The procedure was performed under general anesthesia. The dorsal SPL was measured, and a 14-Fr Foley catheter was placed. An artificial erection was induced by placing a needle through the glans and injecting saline solution inside corpus cavernosum for the assessment of deformity. Circumcoronal incision was used and the penis was degloved down to the Buck's fascia. Area of maximum

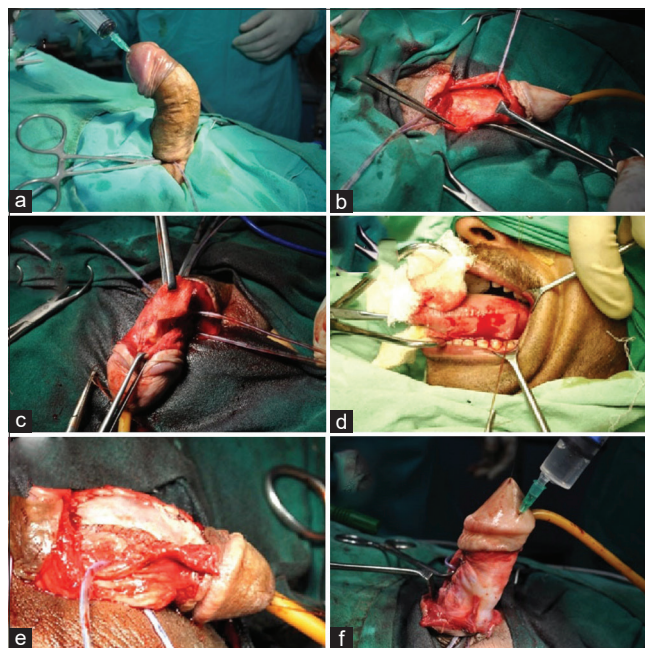


Figure 1: Surgical steps: (a) Penile curvature on artificial erection, (b) the neurovascular bundle was carefully dissected and elevated away, (c) excision of plaque from underlying cavernosal tissue, (d) harvesting full thickness mucosal graft from ventrolateral aspect of tongue, (e) lingual mucosal graft (LMG) secured to the defect, (f) penile straightening confirmed by artificial erection after LMG

deformity was marked for partial plaque excision. Partial excision of plaque was done with taking care of the neurovascular bundle. The ventrolateral aspect of the tongue was marked according to the required length and width of the graft. Full-thickness LMG harvested and the donor site was closed with a 4-0 polyglactin suture in a continuous running fashion. The graft was secured in the tunical defect with 4-0 polyglactin sutures placed in a running fashion. An artificial erection was re-established to confirm the correction of the curvature; significant residual curvature was further corrected with tunical plication. Once satisfactory deformity correction had been accomplished, the incision was closed in layers. Bio-occlusive mild compressing dressing was applied to limit edema.

Postoperatively, all patients were allowed cold oral fluids on the same day and soft diet on the first postoperative day. Foley's catheter was removed on the postoperative day 1 and the dressing was removed on day 3. Nocturnal phosphodiesterase-5 (PDE5) inhibitors (tadalafil 5 mg once daily) were started after 1 week to enhance postoperative vasodilation, which supports graft take, reduces cicatrix contraction, and decreases the chances of postoperative ED.^[11] Penile rehabilitation point massage and stretch therapy were initiated 2 weeks after surgery. All patients were advised to resume intercourse after 1 month.

Follow-up visits were scheduled at 2 weeks and 3, 6, 12, and 24 months postoperatively. Examination of recipient and donor site was done in all visits to exclude any complications. Patients were enquired about erection resumption and voiding symptoms at 2 weeks. The IIEF-5 questionnaire and the patient global impression of improvement (PGI-I) questionnaire were used for the assessment of erectile function and satisfaction, respectively, at all follow-ups from 3 months onward. At the 6-month visit, all patients underwent a combined intracavernosal injection and stimulation bimix test to evaluate penile rigidity (EHS), straightness, and length. Bimix test was done in further follow-up if patients complained of worsening of curvature or *de novo* ED.

The paired sample *t*-test was used to compare patient's data. The significance level was set at *P* < 0.05. All calculations were carried out with IBM-SPSS, version 22.0. Chikago, IL, USA.

RESULTS

The characteristics of patients selected for LMG are given in Table 1. All patients had difficulty in intercourse due to penile deformity. According to IIEF 5 Score, 84% (16/19)

of patients had normal erectile function and 89% (17/19) of patients had rigidity enough for penetration according to EHS. USG findings are mentioned in Table 2. All patients had a history of failed oral treatment (Vitamin E/anti-inflammatory/antibiotics/PDE 5 inhibitors), and additional intralesional therapy (verapamil/triamcinolone) was used in 47% (9/19) of patients.

The mean operative time for the procedure was 126.31 ± 21.45 min. Nesbit's plication to correct the residual deformity after excision of plaque and LMG was required in five patients. The straightening of the penis

Table 1: Characteristics of the patients

Patient's characteristics	Number (%)
Preoperative parameters and intraoperative findings	
Age (years)	Mean 52.59±6.01 (range 44–65)
Duration (months)	Mean 19.63±5.14 (range 15–36)
Angle of deformity	Mean 65.55°±13.75° (range 45°–95°)
Shortening (>1 cm), n (%)	16 (84.21)
Angle >60°, n (%)	15 (78.94)
Location of deformity, n (%)	Dorsal: 13 (68.42) Dorsolateral: 4 (21.05) Ventral: 2 (10.52)
Hourglass deformity, n (%)	3 (10.52)
Hinge deformity, n (%)	1 (5.26)
Mean IIEF-5 score	21.89±1.8 (range 17–24)
Operative time (min)	Mean 122.4±23.5 (range 80–160)
Additional procedure, n (%)	5 (26.31) Nesbit's Plication
Outcomes after surgery	
Postoperative penile deformity (at 2 years of follow-up), n (%)	
<10°	10 (89.47)
>10°	2 (10.52)
Change in penile length, n (%)	
Increase (>1 cm)	12 (63.15)
No change/increase (<1 cm)	6 (31.57)
Shortening	1 (5.26)
Change in IIEF-5 score at 1-year follow-up, n (%)	
Increase	10 (52.63)
Same	8 (42.1)
Decrease	1 (5.26)

IIEF: International Index of Erectile Function-5

Table 2: Plaque characteristics according to ultrasonography findings (B mode)

Characteristic	Dimensions		
	Mean	Median	Range
Length (mm)	18.84±6.72	20	8–38
Volume (mL)*	192.77±119.55	166.4	37.44–521.66
Beko's plaque type			
Characteristics of plaque			Number (%)
A	Solitary hyperechoic lesion without acoustic shadow		1 (5.26)
B	Multiple moderate hyperechoic lesions with acoustic shadows		7 (36.84)
C	Dense calcified hyperechoic plaques with acoustic shadows		11 (57.89)

* Ellipsoid volume formula (volume is reported in mL)

(curvature $<10^\circ$) was achieved in 89% (17/19) of patients. The two patients in whom deformity of $>10^\circ$ persisted after surgery had a preoperative curvature of $>80^\circ$. All patients had resumption of spontaneous erection within 5 days (2–5 days).

Postoperative IIEF 5 values showed a significant improvement in comparison with the preoperative values ($P = 0.001$). EHS increased in 26% (5/19) of patients, remained similar in 63% (12/19) of patients (11 patients had maximum EHS of 4), and decreased in 11% (2/19) of patients (*de novo* ED). According to the PGI-I questionnaire, 63% (12/19) and 26% (5/19) of patients reported that they were “very much better” and “much better,” respectively. Partners of 84% (16/19) of patients were satisfied (42% “very satisfied”) with the treatment. Further worsening of erectile function and penile curvature was noted in one patient at 6 months of follow-up. Fourteen patients reported at the last follow-up at 2 years and reported stable results. The mean follow-up was 20.66 ± 5.37 months [Table 1].

Mild edema and ecchymosis of the penis developed in four patients which healed within a week. Three (16%) patients reported glans hypoesthesia postoperatively on the first follow-up at 2 weeks, which resolved by the follow-up at 6 months.

Ninety-five percent (18/19) of patients experienced pain at the donor site on the first postoperative day. Pain was severe (75–100 mm) in only 11% (2/19) of patients according to visual analog score on the first postoperative day. By the end of the 1st week, no patient reported the pain at donor site. One patient had mild swelling at the donor site, likely a hematoma, which resolved within 1 week. There was complete healing of the donor site in 5–7 days in all patients. Numbness of the anterior half of the tongue was noted in 11% (2/19) of patients, and it completely subsided at the 3-month follow-up. No patient had any problem with salivation or speech disturbances.

DISCUSSION

PD is a physically devastating disorder that has negative psychological effects on patients due to performance anxiety, partner's sexual dissatisfaction, deformed physical appearance, and loss of sexual confidence.^[12]

Corporoplasty with grafting is recommended for severe ($>60^\circ$) and complex curvature. Partial excision or incision of plaque is advised to minimize trauma to the corpora cavernosa, maintaining the veno-occlusive mechanism.^[6] A wide range of graft materials has been utilized in numerous studies, but no single graft material has shown clear superiority over others and an ideal graft material is yet to be determined. The ideal graft for PD reconstructive surgery should be easy to harvest, resistant to infection, should not contract, promote hemostasis, preserve erectile capacity, and be cost-effective.^[4,13,14]

Buccal mucosa was first used as a free autograft in the surgical reconstruction of PD in 2005 by Shiohvili and Kakonashvili.^[5] They reported that the buccal mucosa supported by the submucosal layer has better revascularization capacity and adaptability, which ensures rapid uptake of graft. These results were further confirmed by different authors with the use of buccal and LMGs.^[6,7,15-19] Table 3 summarizes the results of different series, which used buccal mucosal grafts and the single series utilizing LMG in PD. The reported rates of penile straightening ranged from 88.2% to 100%, while rates of penile shortening ranged from 0% to 15.4% (except for one series reporting 80%). The rate of new-onset erectile dysfunction (ED) ranged between 0% and 18% of patients, and patient satisfaction rates ranged from 85% to 100%. Our results are comparable with the previous studies which utilized oral mucosa (buccal and lingual) as graft material.

Simonato *et al.* first described the use of a LMG in urethroplasty in 2006.^[20] There is a single published series

Table 3: Outcomes for plaque excision or incision and oral mucosa grafting

Authors	Year	Number of cases	Mean follow-up (months)	Straightening of penis (%)	Penile shortening	ED	Satisfaction rate (%)
Buccal Mucosa							
Shiohvili TJ <i>et al.</i> ^[5]	2005	26	38.4	93.6	15.4	7.7	NA
Liu B. <i>et al.</i> ^[15]	2009	24	6.84	87.5	12.5	12.5	100
Cormio L. <i>et al.</i> ^[6]	2009	15	12.1	100	0	0	93.3
Zucchi A. <i>et al.</i> ^[16]	2015	28	43	96.5	0	3.5	85
Fabiani A. <i>et al.</i> ^[17]	2016	17	22.5	100	0	5.9	94
Molina-Escudero <i>et al.</i> ^[18]	2016	10	22.7	100	80	10	NA
Cormio <i>et al.</i> ^[19]	2018	68	62	100	0	0	86.7
Lingual Mucosa							
Salem <i>et al.</i> ^[7]	2014	17	15	88.2	0	5.88	94
Present series	2019	19	20.66	89.47	5.26	10.52	89.47

NA: Not available, ED: Erectile dysfunction

of 17 patients by Salem *et al.* with the use of LMG in PD before our study. In their series, the mean age of the patients was 52 (± 4.7) years and the mean angle of deformity was 60 (± 5.1). They achieved complete penile straightening in 15 patients with mild curvature recurrence ($<20^\circ$) in two patients at the 3rd month. *De novo* mild ED was reported by one patient. Patients' and partners' satisfaction were reported in 16 patients. These results remained stable until the end of the follow-up period.^[7]

The mean operative time in our study was 122.4 ± 23.5 min. Fabiani *et al.*, using buccal mucosal grafts, reported a mean operative time of 115.3 min (80–165), while Salem *et al.* (2014) reported a mean operative time of 130 ± 11 min with the use of LMGs.^[7,17] These mean operative times are longer than studies using allografts: 94.2 min (65–165) with the use of collagen fleece by Hatzichristodoulou *et al.*;^[21] 66 (55–81) min with use of acellular porcine pericardium; and 130.5 (107–167) min using venous patch by Kayigil *et al.*^[22] Although the operative times with the use of “off the shelf” allografts are significantly shorter, this advantage has to be weighed against the risk of problems associated with the use of allografts, namely, the cost, longer integration times, more scarring in comparison to autologous tissues, and the risks of disease transmission.^[14] The donor site morbidity and the need for general anesthesia in harvesting oral mucosal grafts are an important consideration, but experience and expertise in these techniques have largely mitigated these concerns.^[3]

Five patients in our study required additional tunical plication for significant residual curvature after the primary procedure. Most of these cases had a large plaque volume and relatively complex curvature. Cormio *et al.*, in a series of 72 patients, described the need for additional tunical plication in 43 (57.9%) patients and suggested that additional small tunical plications help in penile straightening and better stretching of graft with significantly less postoperative penile shortening in comparison to the BMG alone group.^[19]

In our study, two patients developed *de novo* ED. Both these patients were >60 years, had a preoperative curvature $>70^\circ$, and a preoperative IIEF-5 score <20 . One of these patients also had a history of long-standing diabetes mellitus. The available literature suggests that the risk factors for postoperative ED include previous ED, age >55 years, evidence of corporal veno-occlusive dysfunction on duplex ultrasound analysis, a resistance index of <0.80 , predominantly ventral curvature, and possibly the severity of the curvature.^[3,23]

In a comprehensive review, Garcia-Gomez *et al.* (2018) analyzed 69 articles reporting the use of a wide variety of graft materials and found that buccal mucosa, pericardium, SIS, and TachoSil patches were being used more extensively with good results. The researchers could not reach a definite conclusion about the ideal graft material due to significant variability in the published studies, including differences in the number of patients, selection criteria, follow-up duration, and outcome analysis. The review concluded that the final decision depends on the surgeon's expertise, the patient's preferences, economic considerations, and the nature of the plaque.^[13]

Hatzichristodoulou *et al.*, in a review of 42 contemporary articles related to grafting techniques used in the surgical treatment of PD from 2011 to 2016, emphasized the need for careful patient selection, thorough preoperative counseling, and a fully documented and signed informed consent regarding possible adverse outcomes, such as ED, glans hypoesthesia, and penile shortening. Along with these key issues, we recommend that any unrealistic expectations of the patient should be addressed and cleared preoperatively.^[14]

It is evident from recent literature that buccal mucosa is the most favored autologous graft material today because it is inert, biocompatible, and the donor site heals rapidly.^[3,13,19] All these factors lead to an early resumption of spontaneous erection and sexual activity and reduce the risks of recurrence of curvature and postoperative ED. Another advantage of the oral mucosa graft is its low cost. LMG has similar or superior to buccal mucosa in several studies of urethroplasty in terms of donor site complication and as a graft material.^[22,24] The procedure of graft harvesting is simple with acceptable donor site morbidity. It also proved safety, reliability, feasibility, and a satisfactory outcome for the treatment of PD. Studies with a larger number of cases with longer follow-up are required to confirm these favorable results.

The limitations of the present study included limited number of cases, owing to the rarity of the disease and limited indications for intervention, relatively short follow-up, and lack of head-to-head comparison with other graft materials.

CONCLUSION

Early revascularization, rapid adaptability, and less integration time with minimal tissue reaction make lingual mucosa a promising graft material in the treatment of PD. LMG provided excellent short-term results in terms

of deformity correction, improved sexual function, and minimal donor site morbidity. The method is simple and reproducible and can be recommended for wider use in clinical practice for surgical treatment of PD. Multicenter studies with larger number of cases with longer follow-up are required to confirm these favorable results.

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Conflicts of interest

There are no conflicts of interest.

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