PEYRONIE'S DISEASE

Combined Plague Incision, Buccal Mucosa Grafting, and Additional Tunica Albuginea Plication for Peyronie's Disease



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ABSTRACT

Introduction: Surgery remains the gold standard for treatment in stable patients with penile deformity associated to Peyronie's disease (PD).

Aim: To evaluate the long-term results of plaque incision and buccal mucosa grafting (BMG), with or without additional tunica albuginea plication (TAP), in the correction of severe penile curvatures secondary to PD.

Methods: 72 patients with severe curvature caused by PD, normal erections, and stable disease entered this prospective study. Preoperatively, they underwent penile duplex ultrasounds with measurement of curvature and length of affected side. All procedures were carried out by 1 surgeon. Patients were seen at 1, 3, 6, and 12 months postoperatively, then yearly. Subjective outcome was assessed by the Sexual Encounter Profile (SEP) questionnaire, and objective outcome was assessed by an intracavernous injection (ICI) test performed within the first year for evaluating penile rigidity, straightness, and length.

Main Outcome Measure: Long-term outcomes include penile straightening, penile shortening, and sexual satisfaction.

Results: Mean curvature was $71.32 \pm 17.6^{\circ}$ (range 40–110); 33 (45.8%) patients had a 2-sided curvature with a mean second curvature of $33.79 \pm 12.2^{\circ}$ (range 10–60). Additional TAP was needed in 60% of patients for complete straightening or graft stretching. All patients resumed unassisted intercourse 1 month after surgery; 4 (5.5%) refused follow-up, claiming excessive penile shortening. In the remaining 68, the ICI test showed no recurvature, shortening, or de novo erectile dysfunction. At mean follow-up of 62.01 ± 34.3 months (range 12-135), all were able to obtain an erection (SEP-1), 97.1% to penetrate (SEP-2), and 89.7% to successfully complete intercourse (SEP-3); 80.9% of them were satisfied with erection hardness (SEP-4) and 86.8% were overall satisfied (SEP-5), with the main reason for dissatisfaction being expectation of better length and rigidity.

Conclusion: BMG, with or without TAP, provides excellent long-term results and is safe and reproducible, representing a valuable treatment option for PD, but great care should be taken in patient counseling to avoid unrealistic expectations. Cormio L, Mancini V, Massenio P. Combined Plaque Incision, Buccal Mucosa Grafting, and Additional Tunica Albuginea Plication for Peyronie's Disease. Sex Med 2019;7:48-53.

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Key Words: Peyronie's Disease; Penile Curvature; Tunica Albuginea Plication; Buccal Mucosa; Graft; Penis; Surgical Therapy

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INTRODUCTION

Peyronie's disease (PD) affects 0.4-9% of men during their life, most commonly during the sixth decade.^{1,2} Despite the availability of several "conservative" treatments,³ only a small percentage of men will experience a significant straightening of the penis by this approach. Therefore, surgery remains the gold standard for definitive treatment in stable patients with penile deformity hampering intercourse.⁴

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Ta	ble	1.	Preo	perative	and	operative	data
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Data	Overall	BMG	BMG + TAP	P value
No. of patients (%)	72	29 (40.3)	43 (59.7)	_
Age, y	59.80 ± 5.31 (40-69)	61.18 ± 4.03 (55–68)	59.45 <u>+</u> 5.9 (40—69)	.19
Duration of disease, mo	15.83 ± 6.39 (12-36)	15.29 <u>+</u> 4.93 (12—24)	16.1 ± 6.9 (12—36)	.68
Primary penile curvature, $^{\circ}$	71.32 ± 17.6 (40—110)	66.37 ± 18.18 (40-90)	74.65 ± 17.43 (40—110)	.059
Site of primary curvature				
Dorsal	52/72 (72.2%)	20/29 (68.9%)	32/43 (74.41%)	.61
Lateral	12/72 (16.6%)	6/29 (20.68%)	6/43 (13.95%)	.45
Ventral	8/72 (11.1%)	3/29 (10.34%)	5/43 (11.62%)	.86
No. of patients with second penile curvature (%)	33 (45.8%)	10 (34.5%)	23 (53.5%)	.11
Secondary penile curvature, $^{\circ}$	33.79 <u>+</u> 12.2 (10-60)	31.66 ± 9.71 (20-45)	32.95 ± 11.64 (10-60)	.77
Site of secondary curvature				
Dorsal	6/33 (18.1%)	2/10 (20%)	4/23 (17.4%)	.86
Lateral	27/33 (81.8%)	8/10 (80%)	19/23 (82.6%)	.85
Ventral	0	0	0	/
Preoperative length of affected side, cm	10.81 ± 1.27 cm (8—14)	10.8 ± 1.51 cm (8—14)	10.83 ± 1.1 cm (9–13)	.92
Preoperative IIEF-5 score	21.3 ± 1.92 (18—24)	21.53 ± 1.89 (18—24)	20.86 ± 1.82 (18–23)	.35
Duration of surgery, min	130.51 ± 26.52 (90-200)	121.5 ± 23.03 (90-190)	135.46 ± 26.08 (90-200)	.06
Postoperative length of affected side, cm	13.2 ± 1.54 cm (10.20–18)	13.16 ± 1.47 cm (11–16)	13.22 ± 1.58 cm (10.2–18)	.92
Penile elongation, cm	2.43 ± 0.89 (1–3.1)	2.55 ± 0.97 cm (1.7–3.1)	2.37 ± 0.86 cm (1.1–2.9)	.503

Continuous values are expressed as mean \pm SD (range).

BMG = buccal mucosa grafting; IIEF = International Index of Erectile Function; TAP = tunica albuginea plication.

Patients with normal erectile function (EF) can be treated by shortening of the unaffected side or lengthening of the affected one based on penile length and severity of penile deformity.⁵ Lengthening procedures, which are preferred in men with severe deformities and short penis given their lower risk of penile shortening,⁶ involve plaque incision and grafting, but there is no consensus on the ideal graft. Tissue-engineered grafts have been developed with the aim of avoiding the additional time and morbidity associated with harvesting autologous ones, but they cause additional costs and may pose biocompatibility risks in terms of infection⁷ or immunologic response.⁸ Moreover, they do not perform better than saphenous vein grafting, the most commonly used autologous graft, in terms of preventing postoperative scarring and de novo erectile dysfunction (ED).⁴

An experimental study in dogs demonstrated that buccal mucosa had better elasticity, coefficient of lengthening, and ability to take than conventional autologous grafts (vein, derma, aponeurosis, and peritoneum).⁹ Plaque incision with buccal mucosa grafting (BMG) was subsequently shown to be a safe and reproducible technique associated with fast return of spontaneous erections, thus providing excellent short- and mid-term results.^{10,11} The present study aimed to determine the long-term results of plaque incision and BMG, with or without additional tunica albuginea plication, in the correction of severe penile curvatures secondary to PD.

MATERIALS AND METHODS

The study was carried out on 72 patients with PD who underwent plaque incision and BMG at our institution from March 2006 to June 2016, thus having a minimum follow-up >1 year. All patients reported normal erections with a severe, stable, and painless penile curvature of \geq 12 months' duration, making intercourse difficult or impossible. All had undergone our preoperative evaluation including detailed medical and sexual history, physical examination, International Index of Erectile Function (IIEF-5) questionnaire, and penile duplex ultrasounds (PDUs) after intracavernous injection (ICI) of prostaglandin E1 (PGE1) with measurement, in full erection replicating that achieved at home, of angle and direction of curvature (goniometer over 2 rigid rulers), as well as of length of the affected side measured from the penile base to the urethral meatus (by means of a flexible ruler). Indications for plaque incision and BMG were (i) full erection with normal PDU findings

Table 2. Patient data according to site of curvature

	Dorsal/Lateral (64 patients)	Ventral (8 patients)	P value
Age, y	60.13 ± 5.5 (40-69)	60.29 ± 3.57 (55–66)	.99
Primary penile curvature, $^\circ$	71.9 ± 17.7 (40—110)	68.75 ± 18.15 (40-90)	.67
No. of patients with second penile curvature (%)	29 (45.31)	4 (50)	.80
Secondary penile curvature, $^\circ$	32.59 ± 11.49 (10–60)	32.5 ± 8.29 (20-30)	.98
Site of secondary curvature			NA
Dorsal	NA	0	
Lateral	NA	4	
Ventral	0	NA	
Preoperative length of affected side, cm	10.63 ± 1.16 (8-13)	12.18 ± 0.95 (11–14)	.00083
Preoperative IIEF-5 score	21.2 ± 1.93 (18-24)	21.46 ± 1.7 (18–24)	.70
Duration of surgery, min	128.64 ± 23.64 (90–190)	148.75 ± 39.9 (105-200)	.14
No. of patients requiring additional TP (%)	35 (54.7)	4 (50)	.80
No. of additional TP stitches	2.17 ± 0.87 (1–4)	2.75 ± 0.83 (2-4)	.22
Postoperative length of affected side, cm	13.058 ± 1.53 (10.2–18)	14.41 ± 1.01 (13–16)	.046

Continuous values are expressed as mean \pm SD (range). Values in italics are significant.

IIEF = International Index of Erectile Function; TP = tunica plication.

(peak systolic velocity >35 cm/s; resistance index >0.9), (ii) curvature entity and length of the affected side exposing risk of excessive penile shortening; and (iii) the patient's wish to reduce the risk of penile shortening. Specifically, patients were informed that after plication, the expected length of the penis would be approximately that of the affected side, whereas BMG would provide a mean elongation of the affected side in the range of 2 cm, which would definitely not restore the size of the penis before the disease. They also were informed that plication is an easier procedure and that mean penile length for healthy Italians is 12.5 cm, thus making it unnecessary to obtain further than this length. Based on such information, they were allowed to choose between the 2 procedures.¹²

The study protocol had been approved by the local ethical committee and conformed to the provisions of the Declaration of Helsinki. All patients were informed that they were undergoing a new surgical technique with no long-term data; accordingly, they all had to sign a detailed informed consent to be enrolled.

The surgical procedure has already been described.¹⁰ All procedures were carried out under general anesthesia by a single surgeon (L.C.). After circumcision and penile degloving, Buck's fascia was entered and the neurovascular bundle and urethra mobilized to obtain adequate exposure of the affected area. Following artificial erection, the length of the affected side was measured and the site of maximal curvature incised; over the years, we progressively moved from an H-shape to a horizontal double-Y (>-<) incision. BMG was harvested from the left cheek as large as possible, making no effort to match the size of the graft with that of the tunical gap, and the defect closed with a continuous 2-0 Vicryl rapid suture (Ethicon, LLC, Somerville, NJ, USA). The graft was cleaned of superfluous muscular tissue and sutured to the tunica albuginea gap with its submucosal surface placed onto the cavernous tissue. Penile straightening and length were then tested by artificial erection; in case of incomplete straightening, plication stitches were used to correct the residual curvature.¹³ Buck's fascia and circumcision were carefully closed. The Foley catheter and penile dressing were removed on postoperative day 1, and the patient was discharged on postoperative day 2. Because all patients reported spontaneous erections within 1 week after surgery, they were not given phosphodiesterase type 5 inhibitors (PDE5is) and were allowed to resume intercourse 30 days after surgery.

Follow-up visits were scheduled at 1, 3, 6, and 12 months postoperatively, then yearly, and carried out by a third party (P.M. or N.D.). All patients were scheduled to have, at the 12-month follow-up, objective evaluation of penile rigidity, straightness, and length by means of ICI of PGE1 10 mcg; this test was anticipated at the 3-month follow-up in patients reporting surgery not leading to fully successful intercourse. Penile straightening was defined as absence of curvatures reaching $\geq 15^{\circ}$; penile shortening, measured by a flexible ruler, was defined as a reduction in penile length of ≥ 0.5 cm as compared with that measured at the end of surgery. Subjective outcome was evaluated using the Sexual Encounter Profile (SEP) questionnaire, which is considered to be more effective and detailed than IIEF-5 in assessing the entire sexual function subjectively (including curvature effect on intercourse). All clinical data were prospectively collected.

RESULTS

The clinical data of the enrolled patients are summarized in Table 1. Mean duration of surgery was 130.51 ± 26.52 minutes

(range 90–200). We always used a single graft, the largest being 2.7 \times 5.0 cm. Additional small tunical plication stitches were needed to obtain complete penile straightening or to better stretch the graft in 43 of 72 (57.9%) patients; as expected, they were more common in patients with a 2-sided curvature than in those with a single-sided curvature (69.7% vs 51.3%, respectively; P = .1495). Mean number of plication stitches was 2.23 \pm 0.89 (range 1–4); there was no difference in the number of stitches needed by patients with a single-sided curvature (2.22 \pm 0.91, range 1–4) and those with a 2-sided curvature (2.23 \pm 0.86, range 1–4). Mean length of affected side after straightening was 13.21 \pm 1.54 cm (range 10.2–18), with a mean elongation of 2.43 \pm 0.89 cm. Table 2 compares patient data according to the site of curvature.

There were neither intraoperative complications nor deviations in the postoperative course. Glans numbness was reported by 6 (8.3%) patients; however, it lasted <6 months in all cases and was not particularly annoying owing to the fact that patients had fully been informed about such possibility.

As in our initial experience,¹⁰ all patients reported rigid spontaneous erections within 1 week after surgery, and all were able to resume intercourse 1 month after surgery even though they were not given any pharmacologic support. At the 3-month follow-up, 4 (5.5%) patients refused being evaluated again because they claimed excessive penile shortening, so they were lost to follow-up. Of the remaining 68 patients, 9 (13.2%) were not fully satisfied at the 3-month follow-up; 6 expected greater penile rigidity, whereas 3 expected greater penile elongation. The ICI test showed full penile rigidity and straightening in all cases, as well as a length of the affected side overlapping the one recorded by the end of the surgical procedure. Although reassured by the results of the ICI test, they all were given tadalafil 5 mg daily to promote more successful intercourse. At the 6-month follow-up, all patients reported successful unassisted intercourse, but 1 claimed development of premature ejaculation; he was successfully treated with the combination of dapoxetine and behavioral treatment.¹⁴

The 12-month ICI test showed, in all cases, full penile rigidity, absence of recurvature, and length of the affected side overlapping the one recorded by the end of the surgical procedure. To date, mean follow-up is 62.01 ± 34.30 months (range 12-135). 1 patient presented a granuloma at the site of circumcision requiring surgical excision 8 months after surgery; 2 presented 13 and 16 months after surgery with a seroma at the patch site that was successfully treated by aspiration in both cases. 1 patient died 38 months after surgery owing to myocardial infarction, another lost his partner 27 months after surgery and ceased sexual activity, and a third patient developed ED following retropubic radical prostatectomy performed 18 months after BMG but successfully responded to PGE1 ICI. 10 (14.7%) patients needed PDE5i treatment owing to progressive inability to obtain and maintain a rigid erection; 8 were successful, 1 was not, and another feared PDE5i use because of cardiac problems.

These last 2 patients refused any other treatment (ICI, penile prosthesis implantation), claiming to be satisfied with non-penetrative intercourse. At the last follow-up, all patients reported being able to obtain an erection (SEP-1), 97.1% being able to penetrate (SEP-2), and 89.7% being able to successfully complete intercourse (SEP-3); 80.9% were satisfied with erection hardness (SEP-4) and 86.8% were satisfied with overall sexual experience (SEP-5), with the main reasons for dissatisfaction being expectation of better length and rigidity.

Results were similar in patients with ventral curvatures. 1 (12.5%) patient refused being followed, claiming excessive shortening; at a mean follow-up of 52.14 ± 30 months (range 12–114), however, 100% answered "yes" to all 5 questions on the SEP questionnaire.

DISCUSSION

The present study confirms short- and mid-term findings of BMG efficacy and safety in the correction of severe penile curvatures secondary to PD.^{10,11} Long-term results can be summarized as follows: 100% penile straightening, 100% ability to obtain an erection, 97.1% ability to penetrate without (85.3%) or with (11.8%) PDE5is, 89.7% ability to successfully complete intercourse, and 86.8% satisfaction with intercourse.

Despite such a high success rate in terms of penile morphology and function, the most relevant problem with this kind of surgery remains patient expectations. 4 (5.5%) of our 72 patients refused being followed up, claiming subjective excessive penile shortening. In the remaining 68 patients, the rate of satisfaction with erection hardness (SEP-4) and the overall intercourse experience (SEP-5) were 80.9% and 86.8%, respectively. It is worth mentioning that 9 (13%) patients, who reported being dissatisfied with intercourse (SEP-5), were the same who expected better penile length and rigidity at the 3-month followup. The ICI test demonstrating full penile rigidity and a penile length comparable to that reported in the literature for normal Italian men¹² proved to be effective in reassuring them; nevertheless, although keeping their ability to penetrate (SEP-2), they reported being dissatisfied with their overall sexual experience (SEP-5). Such discrepancy between successful penile morphology/function and satisfactory intercourse speaks for the key role of careful patient counseling before this type of surgery. Specifically, it is of major importance to make clear the impossibility to restore a normal penis (ie, the state before disease occurrence) to avoid unrealistic expectations.

In the 68 patients who underwent the postoperative ICI test, there was no case of surgery-related de novo vasculogenic ED, no case of penile recurvature, and no case of penile shortening (as compared with penile length at the end of the surgical procedure). These findings, together with the occurrence of rigid spontaneous erections within 1 week after surgery and the capability of patients to successfully resume intercourse 1 month after surgery without any pharmacologic support, speak for the

 Table 3. Long-term results with various graft materials

Authors	Graft	No. of patients	Mean follow-up (months)	Penile straightening (%)	Penile shortening (%)	De novo ED (%)	Patient satisfaction (%)
Montorsi et al ¹⁵	Vein	50	>60	72	100	22	60
Kalsi et al ¹⁶	Vein	51	≥60	80	35	22.5	86
Kadioglu et al ¹⁷	Vein	22	>60	72.8	NA	13.6	81.8
Taylor & Levine ¹⁸	Pericardium	81	58	79	–1.5 to 2 cm	21	78
Zucchi et al ¹¹	Buccal mucosa	28	43	100	0	3.5	>85
Chow et al ¹⁹	Pericardium	240	61	88	0	20	80
Current study	Buccal mucosa	68	62	100*	0*	0*	86.7

ED = erectile dysfunction.

*Surgery related, as assessed by the intracavernous injection test performed within 1 year after surgery or as needed.

very fast graft take demonstrated by Kakonashvili and Shioshvili.⁹ They postulated that the peculiar source of blood supply of cheek mucosa (large, middle, and small capillary vessels located in the submucosa layer) promoted immediate graft nourishment when placed in direct contact with a well-vascularized tissue such as the corporeal one. Such prompt graft revascularization or, in other words, such a short duration of temporary ischemia may prevent the well-known process of hypoxia-induced and transforming growth factor β 1-mediated fibrosis,¹⁰ thus reducing the risk of scarring responsible for penile shortening/recurvature and de novo ED.

Our long-term results compare favorably with those obtained by other grafts at a similar time span despite the known limitations of this kind of comparison. Specifically, 3 studies (Table 3) addressed the long-term results (≥ 60 months) of saphenous vein grafting, showing penile straightening in 72–80% of patients, penile shortening in 35–100% of patients, ED development in 13.6–22.5% of patients, with patient satisfaction ranging from 60% to 86%.^{15–17} Reasons the theoretical advantage of endothelial-endothelial contact provided by a vein graft did not turn into successful long-term results are not fully understood. However, shortening, recurvature, and vasculogenic ED have all been attributed to graft contracture/scarring.

1 study (Table 3) addressed the long-term results (58 months) of Tutoplast (processed human and bovine pericardium; Coloplast US, Minneapolis, MN, USA) showing the rates of penile straightening, ED development, and patient satisfaction being 79%, 21%, and 78%, respectively.¹⁸ Again, penile recurvature and shortening, as well as vasculogenic ED, were all attributed to graft contracture/scarring. A very recent study from the same working team (Table 3) demonstrated, in line with our findings, that the addition of plication stitches to plaque excision and Tutoplast grafting in men with severe compound curvature provided similar results to plaque excision and grafting alone.¹⁹

Differently from the previously mentioned grafts (vein and pericardium), in our study there was no case of recurvature following BMG. This finding, together with prompt return of spontaneous erections, would speak for no or very limited graft contracture/scarring. It is worth mentioning that additional small tunical plication stitches were used not only to complete penile straightening but also to obtain better extension/stretching of the graft, without causing significant penile length loss compared with the BMG group. Whether such measures contributed to avoiding graft contracture/scarring remains speculative.

Differently from previous studies, we attempted to understand the cause of patients' reported postoperative ED. Specifically, all patients underwent an ICI test within 1 year after surgery as a means of obtaining objective evaluation of penile morphology and vascular function. By doing so, it was possible to determine absence of shortening, recurvature, or de novo vasculogenic ED that could be clearly attributed to the surgical procedure. Moreover, the ICI test was a relevant source of reassurance for those patients (13.2%) who were not fully satisfied with the initial results of the procedure. Although there was no case of surgically related postoperative ED, almost 15% of our patients reported progressive reduction of their penile rigidity over time, probably owing to the negative impact of factors such as hypercholesterolemia, diabetes mellitus, and blood hypertension on their penile vascular function. Despite this, all patients were able to obtain an erection (SEP-1), 97.1% to penetrate (SEP-2), and 89.7% to successfully complete intercourse (SEP-3). Again, we used the SEP questionnaire to better understand which domain of EF had been compromised.

Finally, there were no intraoperative complications and postoperative complications were minor, because they consisted of 1 skin granuloma treated by excision and 2 seromas successfully treated by aspiration. Most importantly, there was no "donor site" complication. Buccal mucosa harvesting certainly requires additional surgical time or a second surgical team, but such costs do not exceed those of tissue-engineered grafts; moreover, buccal mucosa does not involve biocompatibility risks in terms of infection/immunologic response.^{7,8}

Strong points of our study include (i) a single surgeon (L.C.) performing all procedures and a third party performing evaluation of results at all stages, and (ii) objective evaluation of penile straightening, length, and rigidity by means of the ICI test. Potential study limitations include its descriptive nature, because there is no direct comparison with another graft material, not having used a specific PD questionnaire or any traction device.

CONCLUSION

Plaque incision and BMG, with or without additional plication stitches, demonstrated standing the test of time, because it proved to be safe and effective in the long term. Specifically, the graft kept the promises of having an extremely low risk of undergoing contracture and scarring, which are responsible for recurrence of deformity and de novo ED seen in the long term with both saphenous vein and pericardium grafting. The main limitation of this, like any other kind of lengthening procedure for PD, remains patient expectations, thus making counseling a crucial issue.

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