Buccal mucosa is a promising graft in Peyronie's disease surgery. Our experience and a brief literature review on autologous grafting materials

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Aim: Peyronie's Disease (PD) is an under reported acquired benign condition that, at the moment, is not curable with medical therapy.

Surgery represent the gold standard of treatment. Surgical approaches are several and they consist in "plication techniques" or plaque incision/excision with grafting of resulting albuginea defect. Among grafting procedures, albuginea defect substitution with autologous materials demonstrated over the years not inferior results respect to heterologous grafts. Buccal mucosa graft (BMG) is not usually emphasized in many review articles and clinical series are yet limited.

Methods: We present our experience with seventeen plaque incision procedures and BMG in surgical correction of complex penile curvatures due to PD performed in a period of 30 months. Our analyses was focused on buccal mucosa graft characteristics as major determinant of the surgical success. We also conducted a brief literature review on autologous grafting materials used in reconstructive penile surgery for PD.

Results: Our cosmetics and functional results consists in a 100% of functional penile straightening with no relapses and 5,8% of de novo erectile dysfunction. Mean age was 56.4 years, mean follow-up of 22.5 (6-36) months. No complications graft related were observed. Operative time was 115.3 minutes in mean. Over 94% of patients referred they were "really much better" and "much better" satisfied based on PGI-I questionnaire administrated at the last follow-up visit.

Conclusion: BMG is revealing as an optimal choice for reconstructive surgery in PD. Anatomical characteristics consisting in the great elasticity, the quick integration time and the easy harvesting technique lead to high cosmetics and functional success rate, without omitting economical and invasiveness aspects.

KEY WORDS: Buccal mucosa; Graft; Peyronie disease; Autologous materials; Surgery.

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Introduction

Peyronie's Disease (PD) is an acquired benign condition that presents with a palpable induration and curvature or indentation of the erect penis (1). The average age of men affected by this disease is approximately 50-55 years and prevalence varies between 3,2% and 13 % (2). However, the disease is under reported as a consequence of embarassement felt by affected men (3). More cases are being identified with the advent of PDE5 inhibitors (PDE5-i) requests for erectile dysfunction treatment (1). Moreover, there is an increasing number of cases diagnosed in the younger population (< 40 years) due to the modification of demographic and social contexts determining a better understanding and information on PD (4). At the present, there is no cure for PD. The medical best approach seems to be "multimodal therapy" that is able to achieve greater results than any single drug alone tested in scientific literature (5-6). Surgery represent yet the gold standard of treatment. Surgical approaches are several, consisting in "plication techniques" or plaque incision/excision with grafting of determined albuginea defect. Indications for surgery are well established and the goal is to reliably and rapidly restore a coital function with a satisfactory and comfortable erection for both patient and partner (7). In our surgical practice, we had focused the attention on grafting techniques with buccal mucosa. As in case of medical therapy, because of data variability obtained from the wide range of autologous and heterologous grafts, we are inable to define which is the real "gold standard" for albuginea substitution. From literature, it is possible to note that biocompatible materials do not provide better outcomes in terms of satisfaction or postoperative erectile dysfunction (ED) than autologous grafts (8-9). Moreover, many studies did not include complete information about the outcome of surgery such as satisfaction rate or globally post operative ED. When published, the outcomes are comparable, especially between pericardial graft (10-11) and buccal

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mucosa graft series (12-13). In the present paper we explain how the characteristics of an ideal graft were achieved with this surgical procedure and outcomes data obtained from our series of 17 patients who underwent a complex corporoplasty using a buccal mucosa graft, compared with literature results. We had also conducted a literature review on autologous graft materials focusing on the buccal mucosa patch characteristics respect the main autologous graft employed in reconstructive penile surgery for PD.

MATERIAL AND METHODS

We have evaluated the clinical, pathological, intraoperative and post surgical data of a series of 17 consecutive cases treated with a plaque incision/partial excision and buccal mucosa grafting in the correction of severe secondary penile curvatures due to a stabilized PD and not responders to other medical treatment or previous surgical procedures. In a period of 30 months, in our Urologic Center we performed 17 plaque incision and grafting procedures after a training of 3 cases (not included in this report) carried out under the supervision of the Author (AZ) skilled in the technique. All surgical procedures were performed by the same equipe (AF, LS, FF) and each member was employed alternatively in buccal mucosa harvesting time or in penile corporoplasty and grafting. The pre-operative work-up included a clinical examination, a detailed clinical history, the IIEF (IIEF-5) questionnaire and penile ultrasound scans in tumescence and PGE1-induced erection (10 mcg) to determine plaque dimensions, curvature, erection hardness score (EHS) (14) and vascular penile status. Ultrasonographic plaque patterns was defined according on Bekos classification (15). The grafts needed were harvested as described by Eppley et al. (16). The corporoplasty procedures were done essentially the same way as for all others grafting techniques (17). Circumcisions were made by a "sleeve technique" or a "forceps-guided method". Dorsal neurovascular bundle was ever elevated in a centripetal manner. In case of ventral curvature, urethra was carefully isolated from corpora cavernosa. The relaxing incision was made as a double Y or H shaped at the point of maximum curvature. The margins of the incision are carefully prepared on all sides, preserving the underlying erectile tissue. After "defatting", buccal mucosa patch was apposite to cover the albuginea defect with the submucosa surface in contact with the cavernous tissue in order to obtain a quick blood supply and sutured with a 3/0 adsorbable sutures in each of four sides of the graft. Artificial erection was repeated in order to evaluate the curvature and deformity correction, defining the need of complementary tunica albuginea plications. Buck's fascia was closed with interrupted adsorbable suture or urethra was fixed to corpora cavernosa with tension free stitches. A drainage was placed between the Buck's fascia and the dartos in order to facilitate secretion discharge. Circumcisional incision was closed and a "mummy wrap" with a non sticky dressing was performed around the base to the circumcision site (18). Penis was located in a ventralized position. Patients were discharged at third post operative day after catheter, drainage and dressing removal. The time of spontaneous erection resumption was recorded for each patient. To improve blood supply to the graft a low-dose PDE5-i was prescribed for all patients for a period of two months, starting immediately after discharge. Check-ups were scheduled every 3 months. After 6 and 12 months patients underwent to a penile echo- color- Doppler ultrasound dynamic scan (EHS determination) and compiled the IIEF-5 and the PGI-I (Patient's Global Impressions of Improvement questionnaires), a 1-item questionnaire designed to assess the patient's impression of changes in his own condition (19). Finally partner satisfaction was assessed (very satisfied, satisfied, fairly satisfied, dissatisfied) at each control. After 1 year, check-ups were scheduled at 12 month intervals. Literature review on autologous graft materials employed in reconstructive penile surgery for PD was conducted using key words "graft", "corporoplasty", "buccal mucosa", "autologous materials".

RESULTS

During a 30 months period, seventeen patients underwent complex corporoplasty with buccal mucosa graft. Pre-operative data, operative times, complications, and post operative findings are summarized in Table 1 and Table 2. The mean age was 56.4 years (range 45-71) and the mean follow-up was 22.5 months (range 6 - 36). All patients had sexual activity with valid erections with or without PDE5-I assumption. PDE5-I use was declared in medical history by 10 patients before surgery (58,8%). After curvature correction, PDE5-I frequency use was confirmed and introduced in one more patient because of de novo erectile dysfunction. In all the cases the procedure was indicated because of great difficult during sexual intercourse caused by penile curvature. All patients previously received a peri-plaque medical treatment with verapamil (70.5%) or pentoxiphilline (29.5%). An immediate post operative complication developed in one patient at the cheek (donor site). Resolution was obtained by an haemostatic suture performed 3 hours after the ending of corporoplasty. Penile haematoma with spontaneous resolution was observed in one case. At last follow-up no relapses were recorded. One patient refers a worsening of erectile function (IIEF score 15) nevertless the EHS assessed was the same than in preoperative evaluation. All other patients had complete spontaneous erections 4-5 days after surgery without use of any device. Mean operative time was 115.3 minutes (range 80-165). Mean plaque volume was 151.45 ml. About PGI-I questionnaire, at last follow-up, over 94% of patients referred they were "really much better" and "much better" (Table 3) and 76,5% of partners were satisfied (64,7% "very satisfied"). Only one partner reported no change in sexual satisfaction after surgical curvature correction.

DISCUSSION

Reconstructive surgery represents the gold standard of therapy in PD in cases of failure of conservative approach in restoring penetrative and coital capacity. When PD is a stabilized disease, the three basic surgical approaches are

Table 1.Pre-operative patient's characteristics and surgical informations.

Pts	Age	Medical history/ treatment for PD	Site of curvature	Degree of curvature	IIIEF-5 score	EHS*	Operative time (minutes)	Duration of disease (months)	Bekos plaque type	Plaque dimensions (mm)**	Complications
1	48	-	Dorsal	60	24	4	140	16	А	18 x 15 x 3.5 (491.4 ml)	Haemorrage at the donor site
2	54	Dupuytren disease	Dorsal	75	22	4	145	19	А	12 x 4 x 2 (49.92 ml)	-
3	71	-	Dorsal	50	18	2	140	18	С	12 x 6 x 3 (112.32 ml)	De novo erectile dysfunction
4	48	PDE5i use/ radical prostatectomy	Dorsal	60	20	3	150	14	В	8 x 5 x 2 (41.6 ml)	-
5	62	PDE5i use/ traumatic event	Ventral	45	23	4	165	12	А	10 x 5 x 3 (78 ml)	-
6	52	-	Dorsal	50	23	4	120	17	С	14 x 6 x 3 (131 ml)	-
7	55	PDE5i use/ diabetes mellitus	Dorsal	50	22	4	95	13	С	9 x 4 x 3 (56.16 ml)	-
8	50	-	Dorsal	60	22	4	100	14	С	16 x 6 x 3 (149.76 ml)	Penile shaft haematoma
9	68	PDE5i use/ diabetes mellitus	Dorsal	45	24	4	80	18	В	20 x 5 x 2 (104 ml)	-
10	58	Previous plication procedure/PDE5i use	Dorsal	45	24	4	80	12	В	6 x4 x 2 (24.96 ml)	Glandular erection pain
11	52	PDE5i use	Dorsal-HG	75	24	4	125	13	С	18 x 7 x 2 (131 ml)	-
12	63	Phymosis/preputial lichen sclerosus/ PDE5i use	Dorsal-lateral	85	18	2	135	16	С	25 x 10 x 3 (390 ml)	-
13	53	HIV disease	Dorsal-HGD	90	24	4	145	17	С	25 x 9 x 3 (351 ml)	-
14	57	PDE5i use	Dorsal	45	22	4	90	12	А	10 x 5 x 2 (52 ml)	-
15	68	PDE5i use/ radical prostatectomy	Dorsal	45	21	3	85	24	A	11 x 4 x 2 (45.76 ml)	-
16	55	PDE5i use	Dorsal	60	23	3	85	48	В	6 x 4 x 2 (24. 96 ml)	-
17	45	-	Dorsal	90	24	3	80	10	С	23 x 10 x 3 (358.8 ml)	-
Mean	56.4			57.4			115.3	17.2		151.45 ml	-

^{*} Erection hardness score.

represented by excisional or incisional corporoplasty (i. e. Nesbit or Yachia procedures), plication techniques and plaque surgery procedures with or without graft materials employement (7). At the moment, no one surgical technique demonstrates superiority. Is it clear that when penis have a severe curvature (> 60°) or deformity or it is affected by marked shortening or narrowing, plaque incision/partial excision and the graft of the resulting albuginea defect is the preferred surgical approach (20). Complete excision of the plaque should never be offered to patients, as it would then require a larger graft and therefore it is associated with an unacceptably high rate of post operative erectile dysfunction (21). Various graft materials have been used by many investigators. They may be Synthetic Inert Substances, allografts or

xenografts, or tissues harvested from the patient (autologous materials) at the time of surgery with a presumed additional morbidity and an highest operative time. The ideal graft should be easy to harvest, be taken reliably, heal without contracture, resistant to infection and preserving erectile capacity (22). Despite a large amount of data obtained from numerous studies, ideal graft material has yet to be established. The most common Syntethic Inert Substances used are Goretex and Dacron while the most common autologous materials used are saphenous vein, dermis, buccal mucosa, rectus fascia and fascia lata. Bovine and cadaveric pericardium, porcine small intestine submucosa and cadaveric fascia lata represent the allo/xenograft more frequently employed (23). Each grafting material has its own advantages and drawbacks in

^{**} Plaque dimensions were recorded during pre operative ultrasound evaluation and calculated considering the ellipsoid volume formula (volume is reported in ml). HGD: Hourglass deformity.

Table 2.Post operative erectile function and couple satisfaction.

Pts	Time of spontaneous erections resumption (days)	IIEF-5 pre operative score	IIEF-5 post operative score at last follow-up	Patient satisfaction (PGI-I score) at 3 months	Patient satisfaction (PGI-I score) at 6 months	Patient satisfaction (PGI-I score) at 24 months	Global follow-up (months)	Partners satisfaction at last follow-up	EHS score at last follow-up
1	4	24	24	1	1	1	36	1	4
2	3	22	22	1	1	1	36	1	4
3	2	18	15	4	3	4	29	4	3
4	3	20	24	1	1	2	29	2	4
5	4	23	24	2	2	2	29	2	4
6	4	23	24	2	2	2	25	3	4
7	7	22	24	3	3	1	25	1	4
8	5	22	23	2	2	1	25	1	4
9	5	24	24	2	2	-	22	3	4
10	3	24	24	2	2	-	18	1	4
11	2	24	24	1	1	-	18	1	4
12	2	18	24	1	1	-	18	3	3
13	3	24	24	2	2	-	18	1	4
14	3	22	24	1	1	-	12	1	4
15	4	21	24	1	1	-	12	1	4
16	4	23	24	1	1	-	7	1	4
17	1	24	24	1	1	-	6	1	3

Table 3.Results of buccal mucosa (BM) grafting vs saphenous vein (SV) graft as reported in recent scientific literature.

Authors (reference)	Graft	Patients	Mean follow-up (mo)	Straighteningof penis (%)	Postop erectile dysfunction (%)	Shortening of penis (%)	Patient satisfaction (%)
Porena M. et al. (31)	SV	12	NA	83%	0	0	NA
Kadioglu A. et al. (36)	SV	22	>60	72.8	13.6	NA	81.8
Kalsi J. et al. (37)	SV	113	12	86	15	25	96
Montorsi F. et al. (38)	SV	50	>60	72	22	100	60
El Sakka al. et al. (39)	SV	112	18	96	12	17	92
Akman T. et al. (40)	SV	56	37.1	73	8	NA	NA
Adeniyi AA. et al. (41)	SV	51	16	82	8	35	92
Akkus E. et al. (42)	SV	50	32	80	6	40	88
De Stefani S. et al. (43)	SV	8	13	87.5	0	0	100
Yourkanin JP. et al. (44)	SV	22	13.4	66.6	46	0	NA
Shioshvili TJ et al. (28)	BM	26	38.4	93.6	7.7	15.4	NA
Liu B. et al. (29)	BM	24	6- 84	87.5	12.5	12.5	100
Cormio L. et al. (12)	BM	15	12.1	100	0	0	93.3
Zucchi A. et al. (13)	BM	28	43	96.5	3,5	0	85
Present series	BM	17	22.5	100	5,9	0	94
Gvasalia B. et al. (45)	BM	33	42	100	18	15	85

terms of availability, antigenicity and cost effectiveness. Buccal mucosa is used for reconstructing oral and maxillofacial defects, repairing the conjuctival mucosa of the eye, oral pharyngeal reconstructive surgery and reconstructing vaginal defects (24-25-26-27). In 2005, buccal mucosa was introduced as free autograft in the surgical treatment of PD (28) and then, during the years, evaluated in several others series (12-13-29). Results were very interesting since from data reported by Shioshvili and collegues (28). After the surgical treatment, with a mean follow-up of more than 3 years, they observed the complete straightening of the penis in 92.3% of 26 patients treated

with a residual curvature (< 10°) in two cases (7.7%), the shortening of penis in four patients (15.4%) and in two patients a partial reduction of erectile power (7.7%). They concluded that their plaque excision and graft with buccal mucosa technique, showing high properties of adaptation and revascularization, good anatomical and functional clinical results, and demonstrating a stable elasticity without shrinkage, is simple and can be recommended for wide use in clinics for surgical treatment of PD. Similarly, *Liu et al.* (29) performed the surgical replacement of the plaque by free autograft of buccal mucosa on 27 patients with Peyronie's disease, ranging in age from

24 to 72 years (mean 53), varying in disease course between 1 and 13 years, with a penile curvature angle of 30°-80° in erection. Satisfactory results were achieved in all the cases, with no such complications as hematoma, infection, oral numbness, and tightness of the mouth. Of the 24 cases evaluated, with a follow-up ranging from 6 months to 7 years, complete straightening of the penis was achieved in 21, slight residual curvature (< 15 degrees) was noted in 3 (12,5%), a little shortening of the penis (< 1 cm) in 2 (8,3%), and erectile pain in 3 cases (12,5%). The Authors underlined in they conclusions the stable elasticity and no shrinkage of buccal mucosa graft. Modifying the procedure from a plaque excision with substitution to an incision with insertion of a buccal mucosa patch, Cormio and co-workers (12) reported in 15 patients, operated without complications (56.3 years of mean age and 72° of mean penile curvature degree), a 100% of penile straightening, 1.8-cm mean increase in length of affected side, no curvature recurrence or de novo erectile dysfunction, 1.6 mean increase in IIEF-5 score, and patient and partner satisfaction of 93.3% and 100%, respectively. These results were recently confirmed by Zucchi et al. (13) in 32 patients treated with this procedure between 2006 and 2013. In their evaluable 28 cases, they reported no complications and a curvature relapse, after 1 year, in 3.5%. IIEF scores improved significantly after 1 year confirming stability in 50% of cases after 2 years. Patients satisfaction was 85% on PGI-I questionnaire. They concluded that corporoplasty with buccal mucosa represent a good treatment choice for most forms of PD. Gvasalia et al. (45) confirmed the previous good results. In a population study of 33 patients with a 43 months of mean follow-up, they reported a satisfaction rate of 85%. Complete penis straightening was achieved in 73%, with a residual curvature (< 20°) in 27%. And post operative erectile dysfunction was observed in 18% with a good response to PDE 5 inhibitors. Authors underline that erectile dysfunction was common in elderly patients. Also in our present work we are able to confirm these favorable results even if our series includes a non selected population. In fact, surgical procedures were performed in patients who required surgical correction of a curvature causing a great difficult during sexual intercourse or psychological impairment. Patients are variably aging, with a medical general history characterized from different comorbidities as diabetes mellitus, cardiovascular disease, HIV or previous pelvic surgical procedure for prostate cancer. One patient underwent a previous failed plication procedure. Pre-operative use of PDE5 inhibitors was referred by 10 patients (58.8%). Thus, considering that recognized risk factor of post operative erectile dysfunction are pre operative sexual function, patients age and operative technique (larger and ventral graft) (21), the probability of de novo erectile dysfunction was high in several patients of our study. In contrast, results obtained were very comfortable. Rate of functional penis straightening was 100%. De novo erectile dysfunction was registered only in one case (5.9%) in which EHS recorded at follow-up was the same than pre operatively anyway. Satisfaction for both patient and partner was achieved. Globally, in terms of overall success rate, BMG series reported results between 87.5% and 100%

(Table 3). Patient satisfaction rate ranged from 85-100% when investigated (12-13) and no decrease is observed over the years. The rate of "de novo" erectile dysfunction ranged between 0% to 18%. No patch bulging are yet reported. Only a case of "seroma" was cited but not reported (13). Loss of glans sensitivity or recurrent erection penile pain were common symptoms reported by the patients, especially in the first three or six months from the intervention. As observed in our experience, they are related to surgical procedure "per se" (eg. plaque location near to glans or attached to dorsal neurovascular bundle, requiring difficult dissection) and not directly to the patch. These symptoms are safely managed with the common analgesic/anti-inflammatory drugs. At the least, the need of a multiple harvesting from cheek is very rare and the elasticity of buccal mucosa permits to avoid any patch oversizing respect to plaque dimensions (13). Prior of these evidences, the venous graft was advocated as the more physiologic than others autologous tissue (30-31). The advantages presented to support this use were several (32-35). As reported in Table 3, overall success rates for straightening of the penis with the use of saphenous vein grafting ranged between 66.6% and 96% (36-45). Despite promising theoretical properties, saphenous vein grafting clinical results are not so satisfactory. In fact, penile shortening occurs in 17-100% of cases and de novo erectile dysfunction in up to 46% of cases. In addition, the patient satisfaction rate in the short term ranged from 88% to 100% but it tends to decrease to 60-86% in the few series with a follow-up longer than 5 years (38). The major drawback of venous graft was the need for a second incision to harvest the vein, then the bulging of the graft, indentations or hourglass deformities, sensory loss and persistent pain (36). Compared with the others graft material, characteristics of buccal mucosa are more favorable, also considering the functional and cosmetic results as reported in our experience and in literature (Table 4 and related references in Supplementary Materials posted in www.aiua.it). Similarly to venous graft, the buccal mucosa is a living tissue with an elevated binding capacity and revascularization which is immediately supplied with blood from the cavernous tissue. As vital tissue, buccal mucosa tends to heal rapidly, immediately integrating with the surrounding albuginea tissue. This translates into a more rapid resumption of spontaneous erections (mean of 3.5 days in our experience) and sexual activity and into a reduced risk of curvature relapse and ED after surgery (13). The thickness of the buccal mucosa is nearly the same of the tunica albuginea favoring easy adaptation to all sides of albuginea's incision ensuring a perfect seal. These characteristics reduce the risk of curvature relapse and erectile dysfunction after surgery. Another advantage of the BMG is its low cost (47). Biocompatible materials are expensive and the rehabilitation to prevent scarring related retraction (48) implies the adjunctive cost of buying or hiring a vacuum device. Despite these evidences, BMG is not usually emphasized in many review articles and clinical series are vet limited. Many authors not understand the anatomic logic for use of buccal mucosa as a tunica albuginea substitutes (49) but it must take into account that, as noted by Cormio et al. (12), clinical experience with BMG was begun after having examined the "ideal" substitute of penile tunica albuginea in experimental animal models (50). In this experience, buccal mucosa obtained the best results in terms of elasticity, coefficient of lengthening, and morphological structure. Plaque excision and BMG was then applied in humans obtaining the reported very interesting cosmetic and functional results. In particular, as previously mentioned, we would like underlines the great elasticity of BMG that permits to harvest a patch with no need of oversizing respect plaque dimensions and the integration time allows a rapid resumption of spontaneous erections. Moreover, the absence of accessory wounds and severe complications at the side of patch harvest, lead us to consider BMG as a preferable option for PD surgery. In addition, operative time are no longer than these registered in others penile grafting procedures. We had observed a mean operative time of 115 minutes that we consider very acceptable for a complex surgical procedure that allows to restore a functional penile shaft for sexual intercourse. If in clinical setting also the surgeons expectations, so the reproducibility of surgical technique and the availability of the graft may be considered important, the first outcomes to be achieved in reconstructive surgery for PD are the patient perspectives in terms of patient's and partner satisfaction that, over the time, BMG seems able to assure.

CONCLUSION

Buccal mucosa graft is revealing as an optimal choice for reconstructive surgery in PD, determining a high satisfaction rate over the time for both the patients and the partner. Anatomical characteristics consisting in the great elasticity, the quick integration time and the easy and reproducible harvesting technique lead to high cosmetic and functional success rate, without omitting economical and invasiveness aspects. Considering the not satisfactory results observed at the long term in cases of venous grafting procedures, we need an higher follow-up period and an higher number of cases treated with a BMG to define buccal mucosa a first choice in the surgical management of PD.

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