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Original Article

Outcomes of surgical correction of Peyronie's disease with plaque excision and grafting: Comparison of testicular tunica vaginalis graft versus bovine pericardium graft

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KEYWORDS
Peyronie's disease;
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Abstract *Objective:* Peyronie's disease (PD) is an abnormal wound healing in the penile tunica albuginea. After fibrotic plaque excision, different graft materials have been used to repair the defects, but the optimal graft remains unknown. This study aimed to compare the functional outcomes of testicular tunica vaginalis grafts and bovine pericardium grafts in patients with severe PD.
Methods: A retrospective comparative study was conducted on 33 PD patients undergoing partial plaque excision and grafting from September 2015 to May 2021. The patients were divided into two groups depending on the type of graft used. For 15 patients in Group B, testicular tunica vaginalis grafts were used to repair the defect, while for 18 patients in Group A, bovine pericardium grafts were used. Data of the patient's age, comorbidities, sexual function, penile curvature, postoperative complications, need for further treatment, change in penile length, and satisfaction were gathered and compared between the groups. Sexual function was evaluated using the 5-item version of the International Index of Erectile Function (IIEF-5), and a

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functional less than 20-degree penile curvature after surgery was considered a successful intervention.
Results: There was no difference in age, comorbidities, degree of curvature, perioperative IIEF-5, operative time, plaque size, or complication rates. After surgery, a statistically significant improvement in curvature degree ($p<0.05$) and satisfactory penile appearance ($p<0.05$) were seen in both groups without any superiority between the two groups ($p=0.423$ and $p=0.840$, respectively). With a 30-month follow-up, the IIEF-5 was consistent in both groups, with no statistical significance between the groups ($p=0.492$). The main change in penile length during the operation was increased and still positive in the last follow-up in both groups without statistical significance ($p=0.255$ and $p=0.101$, respectively).
Conclusion: Partial plaque excision and corporoplasty with both testicular tunica vaginalis or bovine pericardium grafts are equally effective in treating males with clinically significant PD.
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1. Introduction

Peyronie's disease (PD) is an abnormal healing disorder of the penile tunica albuginea. Fibrous plaques cause painful erections and penile flexibility loss and deformity, ultimately leading to sexual dysfunction [1]. The incidence rate of PD ranges from 3.2% to 8.9%, but the actual number is presumably higher since many men are ashamed of reporting the disease and seeking treatment [1,2]. There are two inflammatory phases in PD: acute and chronic. Medical therapy is used in the acute phase or for those unable to undergo surgery. At the same time, surgical intervention is the gold standard for PD because it provides the most consistent and long-lasting correction of penile deformities [2]. Different surgical methods, including Nesbit, Yachia, plication, and grafting, are used for PD correction [3]. Tunical lengthening procedures are preferred for patients with a short penis, hourglass curvature, and more than 60-degree complex curvature. Recently, total plaque excision has been no longer suggested due to the high postoperative erectile dysfunction (ED) risk, leaving plaque incision or partial excision as the preferred technique [4,5]. This helps the surgeons avoid damaging the underlying veno-occlusive mechanism while making room for the graft by removing sufficient calcified plaque [6].

Occasionally used grafts include autologous, synthetic, and xenografts. The vein wall, rectus sheath, and buccal mucosa are different types of autologous grafts [7]. The testicular tunica vaginalis is one of the most recently introduced autologous grafts [8].

The use of the testicular tunica vaginalis grafts in penile repair was first introduced in 1980 by Das [9]. It is accessible and easy to obtain with an excellent arterial flow, lower rejection rate (histocompatible), lower rate of postoperative infections, and elasticity which guarantees satisfactory penile erection and a favorable cosmetic appeal [8,10,11]. Despite their benefits, autologous grafts, such as veins, buccal mucosa, testicular tunica vaginalis, or albuginea, require additional incisions for graft retrieval and have a related risk of complications [5]. As for xenografts, animal pericardium (bovine pericardium, tissue-engineered sheep pericardium, and porcine pericardium) and human cadaveric pericardium have been tested in urologic surgeries. Using bovine pericardium graft in cardiac surgery has already shown its merits, including flexibility, biocompatibility, resistance to dilatation and retraction, and absence of antigenic reaction [12]. Despite the potential feasibility, xenografts are more expensive than autografts and have not yet been widely implemented [13].

There is a lack of a standard questionnaire for following up on the clinical course of PD patients. This has caused some disparities in the literature reports on the penile length, straightness, and evaluation of postoperative sensation [4]. Since solid evidence is lacking, guidelines have yet to provide urologists with the golden graft option for PD patients. This study compares the testicular tunica vaginalis graft versus the bovine pericardium graft as a xenograft by assessing functional outcomes and patient satisfaction after surgery in our tertiary center.

2. Patients and methods

2.1. Study design

In this retrospective cross-sectional study, we evaluated 33 cases of severe PD from September 2015 to May 2021 who had undergone surgical repair. All patients had undergone corporoplasty with plaque excision (partial) and graft using two different graft materials. The patients were divided into two groups depending on the graft used: Group A and Group B. In Group A, we used a bovine pericardium graft (SJM Pericardial Patch with EnCap™ AC Technology, St. Jude Medical Saint Paul, MN, USA), while testicular tunica vaginalis grafts were used in Group B.

2.2. Ethical consideration

In compliance with the Helsinki Declaration, the ethics committees of Shiraz University of Medical Sciences approved this thesis (the ethical code number: IR.SUMS.-MED.REC.1400.485). We obtained informed consents from the patients in our project. Patients and their partners were informed in detail about different surgical procedures, and each approach's benefits and side effects were discussed with them.

2.3. Inclusion criteria

PD patients with a stable plaque for at least 12 months requiring intervention (curvature of more than 60-degree, penile shortening, and calcified plaque) were enrolled in this study. A single academic urologist (Eslahi A) performed the surgeries using standardized methods.

2.4. Exclusion criteria

Any patient with congenital curvatures or those requiring prostheses were rolled out. Patients with constriction bands, unilateral indentations, and hourglass deformities in the exam were also excluded from the study.

2.5. Data gathering

Patients were assessed with a general physical and urological examination, and detailed medical and sexual history was obtained from the patients. Data on the patients and their preoperative characteristics (such as age, comorbidities, degree of penile curvature and ED) and operative elements (such as surgical time, change in penile length, flap usage, success rate, complications, degree of ED after the operation, and patients' satisfaction after surgery) were collected, analyzed, and compared between the groups.

For grading the severity of ED, we used the 5-item version of the International Index of Erectile Function (IIEF-5). Using the standardized procedure, a single urologist (Eslahi A) measured penile curvature during and after the surgery. Necrosis, ischemia, edema, infection, and sensation loss were the main documented postoperative complications.

2.6. The surgical procedure of Group A (bovine pericardium grafts)

In a supine position after administration of prophylaxis antibiotic (Ceftriaxone 1 g intravenously, Exir Pharmaceutical Company, Borujerd, Iran), the patient was sedated under generalized anesthesia. A 16 Fr Foley catheter was inserted in the sterilized field, and the penis was degloved via a sub-coronal incision. Artificial erection was induced by injecting saline into the corpus cavernosum to evaluate the severity of the curvature [14]. To avoid damage, the neurovascular bundle was carefully separated and preserved using scissors and a cold scalpel. After the separation of the neurovascular bundle and plaque excision, the pericardial graft was inserted. For cleansing, the bovine graft was soaked in saline solution for at least 5 min and then cut to an appropriate size (2—3 mm larger than the defect). The graft was secured in the position using a synthetic absorbable suture at the corners and the intercavernous septum. Using a 4—0 monofilament synthetic absorbable suture, a continuous suture was performed with the penis maximally stretched. Curvature correction was rechecked. Additional minor plications were occasionally used to ensure the minimum curvature (Fig. 1). Following each grafting procedure, a artificial full erection was obtained with saline as needed to determine functional straightness (less than 20-degree) [15]. The overlying layers of penile fascia were repaired, and a light-pressure dressing was applied for 4 days, which was changed daily.

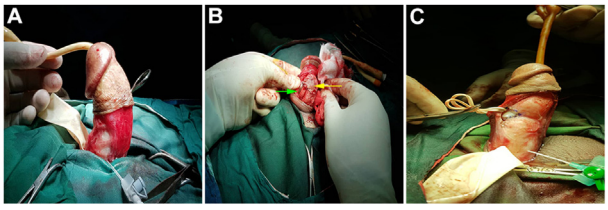

Figure 1 Intraoperative photos of pericardium bovina grafting. (A) Degloving the penis and degree of curvature; (B) Peyronie's plaque removal and grafting over the corpora cavernosa (yellow arrow), and dissection of the neurovascular bundle from the tunica albuginea (green arrow); (C) Penile appearance after curvature correction.

2.7. The surgical procedure of Group B (testicular tunica vaginalis grafts)

Under generalized anesthesia, after prepping and draping, a 2—3 cm longitudinal incision was made at the anterior wall of the scrotum. The parietal wall of the tunica vaginalis was exposed, and a trimmed flap was moved to cover the defect as a graft [8]. The graft was then sutured to the tunica albuginea with 5—0 absorbable sutures (Fig. 2). The rest of the procedure was similar to Group A.

2.8. Postoperative follow-up

During the follow-up visit by the urologist, the patient's recovery progress and determination to stick to the follow-up treatment schedule were monitored. After 2 weeks of operation, this follow-up treatment schedule includes 3 months of daily uptake of tadalafil 5 mg, producing erection three times a day via a vacuum device lasting 5 s, and frequent mechanical traction using a penile extender. Depending on postoperative IIEF-5 scores, phosphodiesterase-5 inhibitors (PDE5-Is) would be prescribed to the patients [16].

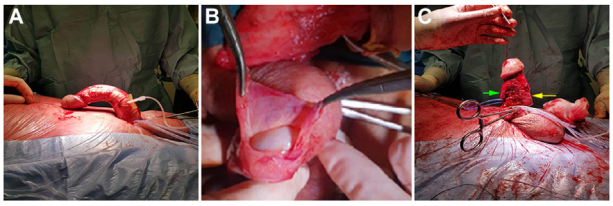

Figure 2 Intraoperative photos of testicular tunica vaginalis grafting. (A) Degloving the penis and degree of curvature; (B) Testicular tunica vaginalis dissection; (C) Penile appearance after curvature correction after Peyronie plaque removal, grafting over the corpora cavernosa and fixation (yellow arrow), and dissection of the neurovascular bundle from the tunica albuginea (green arrow).

2.9. Main outcome measures

The main outcomes were postoperative complications, the IIEF-5 score, satisfaction, need for additional treatments, change in penile length, and degree of curvature.

2.10. Statistical analysis

We used mean and standard deviation (SD), median and interquartile range (IQR) to describe quantitative variables, while we used frequency (proportion) for qualitative variables. We used Chi-square test and Fisher's exact test to compare the qualitative variables. The Student's *t*-test and Mann–Whitney test were used to compare quantitative variables. To compare the means before and after surgery in the groups, we used paired samples *t*-test; if the assumption of normality was not established, we used the Wilcoxon signed-rank test. A *p*-value of less than 0.05 was considered statistically significant. All statistical analyses were done using SPSS software (SPSS version 20, IBM Corp, Armonk, NY, USA).

3. Results

Bovine pericardium graft (Group A) was used in 18 (54.5%) out of 33 enrolled patients, and testicular tunica vaginalis graft (Group B) was used in 15 (45.5%) patients. The patients' characteristics and operative findings are shown in Table 1. The mean age of groups A and B was 56.00 (SD: 10.00) years and 56.00 (SD: 9.65) years, respectively, without statistically significant differences ($p=1.000$). The degree of curvature before surgery in groups A and B was 53.33 (SD: 6.18) and 54.33 (SD: 8.42), respectively, without statistically significant between groups ($p=0.697$) (Table 2).

The mean follow-up after surgery was 31.11 (SD: 10.93) months in Group A and 35.60 (SD: 8.32) months in Group B. Postoperative complications were hypoesthesia in three patients in each group, and infection occurred in one patient in Group A, which was treated with the proper antibiotic (Table 3).

Intraoperative measurement of stretched flaccid penile length demonstrated a mean net increase in penile length of 21.05 (SD: 5.57) mm for Group A and 23.46 (SD: 6.36) mm for Group B, and there was no statistically significant difference between the groups ($p=0.255$).

At the last follow-up, the mean increase in penile length remains slightly positive without statistically significant (mean±SD: 15.27±4.40 mm [Group A] *vs.* 18.20±5.54 mm [Group B], $p=0.101$) (Table 3). Although still being net positive, a reduction in stretched flaccid penile length is likely the result of general postoperative tissue contraction. We attempted to minimize the effect of graft contraction by strongly postoperative recommending producing erection three times a day via a vacuum device lasting 5 s and strict external traction therapy [15]. The degree of curvature was improved after surgery in both groups ($p<0.001$) without any superiority between the two groups ($p=0.423$) (Table 2).

As for patients and their partners' postoperative satisfaction, the satisfactory resolution was very satisfied and equally satisfied in 14 (77.8%) and 4 (22.2%) versus 13 (86.7%) and 2 (13.3%) in groups A and B, respectively, with no statistically significant difference between the groups ($p=0.840$) (Table 3). The IIEF-5 was consistent in the last follow-up in both groups without any superiority between the two groups ($p=0.492$) (Table 2). In the last follow-up, there were 11 (33.3%) patients (5 *vs.* 6 patients in groups A and B, respectively) that needed to use PDE5-Is to attempt penetrative sex. This may not reflect ED as a result of the grafting procedure but may also be related to age-related changes occurring over the mean follow-up period [15].

4. Discussion

Despite receiving medical treatment, PD is a devastating physical and psychological condition that shows an unreliable improvement in the deformity rate [5]. Meanwhile, surgery could be the definitive treatment in selected cases that meet all the criteria. Tunical lengthening surgeries are preferred for patients with a short penis, hourglass curvature, and complex curvature of more than 60-degree [17].

Incision or partial excision of penile plaque helps avoid damage to the underlying veno-occlusive mechanism while making room for the graft. Currently, there is no consensus on the "golden graft" choice for PD patients in evidence-based guidelines. Thus, most surgeons take time with their patients to discuss the procedure, understand their preferences, and carefully choose the right graft option after considering their experience with each grafting technique, availability, and cost [5]. Due to the known risk of postoperative ED development in PD patients, establishing a diagnosis before surgical treatment is crucial. The risk of ED

Table 1 Demographic characteristics and operative findings of the patients.

Variable	Group A ($n=18$)	Group B ($n=15$)	*p*-Value
Age[a], year	56.00±10.00	56.00±9.65	1.000
Comorbidity, *n* (%)			0.693
Diabetes mellitus	7 (38.9)	8 (53.3)	
Hypertension	2 (11.1)	1 (6.7)	
Using PDE5-Is, *n* (%)	3 (16.7)	2 (13.3)	1.000
Plaque size[a], mm	23.13±1.88	23.11±1.74	0.970
Change of penile length during operation[a], mm	21.05±5.57	23.46±6.36	0.255

PDE5-Is, phosphodiesterases-5 inhibitors.
[a] Values are presented as mean±standard deviation.

Table 2 Comparison of the international index of erectile function and degree of curvature between pericardium graft and tunica vaginalis graft.

Variable	Group A (n=18)	Group B (n=15)	MD (95% CI)	p-Value
IIEF-5				
Before surgery[a]	17.44±0.70	17.46±0.74	−0.02 (−0.53 to 0.49)	0.937
In the last follow-up[a]	17.11±0.75	16.93±0.73	0.18 (−0.34 to 0.70)	0.492
MD (95% CI)	0.33 (−0.18 to 0.84)	0.53 (−0.005 to 1.04)		
p-Value	0.189	0.058		
Degree of curvature				
Before surgery[a]	53.33±6.18	54.33±8.42	−1.00 (−6.19 to 4.19)	0.697
After surgery[a]	1.39±0.50	1.53±0.51	−0.14 (−0.50 to 0.21)	0.423
MD (95% CI)	51.94 (48.93–54.95)	52.80 (47.96–57.63)		
p-Value	<0.001	<0.001		

CI, confidence interval; IIEF-5, the 5-item version of International Index of Erectile Function; MD, mean difference.
[a] Values are presented as mean±standard deviation.

Table 3 Postoperative complications, follow-up duration, change in penile length, and satisfaction in both groups.

Variable	Group A (n=18)	Group B (n=15)	p-Value
Complication, n (%)			
Hypoesthesia	3 (16.7)	3 (20.0)	0.876
Infection	1 (5.6)	0	
Follow-up after surgery[a], month	31.11±10.93	35.60±8.32	0.202
Change of penile length in the last follow-up[a], mm	15.27±4.40	18.20±5.54	0.101
Using PDE5-Is in the last follow-up, n (%)	5 (27.8)	6 (40.0)	0.458
Satisfactory resolution, n (%)			
Very satisfied	14 (77.8)	13 (86.7)	0.840
Equally satisfied	4 (22.2)	2 (13.3)	

PDE5-Is, phosphodiesterases-5 inhibitors.
[a] Values are presented as mean±standard deviation.

development might be related to different surgical approaches or other medical co-morbidities [16]. In a small study to evaluate ED risk factors after penile straightening surgeries, no definitive preoperative risk factors or duplex ultrasound findings were reported [18].

This study is the first to compare the outcomes of testicular tunica vaginalis graft and bovine pericardium graft in PD patients. In literature, there are disparities in the definition of penile length and straightness. Following most studies, we defined a postoperative curvature as less than 20-degree as functionally straight, compatible with intercourse. Since no tissue is being excised during these procedures, the main advantage seems to be the absence of penile "shortening" [16]. Our surgical success rate was 100%, with all patients presenting a functional curvature of fewer than 20-degree, consistent with the previously published series [8,10,11].

For example, Silva-Garretón et al. [19] reported the achievement of penile straightening in 95.3% of patients using bovine pericardium graft. Ainayev et al. [20] also showed a penile straightening of 100% at 3 months and 90% at 24 months in patients using a testicular tunica vaginalis graft. As the first study to compare the testicular tunica vaginalis graft and the bovine pericardium graft, we found no superiority between groups in curvature improvement in the 30 months of follow-up (p=0.423). Gundogdu et al. [21], in an experimental study, suggested a possible downside to testicular tunica vaginalis flaps with reports of elevated levels of corporal fibrosis.

Harper and colleagues [22] also suggested that exposure of testicular tunica vaginalis grafts to the external environment and transposition into the urethra could lead to fibrosis and possible graft retraction. Similarly, in our study, the effect of graft retraction on penile length was observed. However, the penile length was still positive during the 30 months of follow-up without superiority between groups. Further studies with extended assessment periods are required to follow the outcome of different grafts.

The importance of informed consent before Peyronie's surgical interventions cannot be overstated. Surgery complications, especially postoperative ED development, must be discussed clearly with patients and their partners. Additionally, the patient should be informed that surgical treatment aims to restore sexual functionality and not necessarily the previous peak level of sexual function. Outcomes, such as perfect penile straightness and sensation, spontaneously normalized erectile function, and complete recovery of penile length, may not always be achievable [16].

As for complications using a tunica vaginalis graft, Helal et al. [23] reported that 8.3% of cases present scrotal hematoma and glandular hypoesthesia after surgery. In the study by Rico et al. [11], scrotal hematoma, glandular

hypoesthesia, orchialgia, and orchitis were reported in 17.3%, 56.5%, 8.3%, and 8.3%, respectively. The reported complication of bovine pericardium graft was cyst formation, graft contraction, infection, loss of sensation, and rarely urethral cutaneous fistula [12,19,24]. Conversely, in our study, the reported complications were hypoesthesia in three cases in each group, and infection, which was presented in one patient in the bovine pericardium group and managed with medical therapy. As expected, since all surgeries in our study were carried out by a single academic urologist with many years of experience in this field, we had lower rates of complications in comparison to other researchers.

In our study, the difference between IIEF-5 scores in the pericardial graft and testicular tunica vaginalis groups was statistically insignificant. In contrast, the mean baseline IIEF-5 scores in both groups were slightly decreased, which was statistically insignificant ($p=0.492$). Reviewing previous literature, we found disparities in the reported IIEF-5 scores after the surgery. For instance, Flores and his team [25] reported a 6-point reduction in IIEF-5 after the surgery. Similarly, Chung et al. [26] noted a decrease of 5 points in the IIEF-5 scores after PD graft surgery. On the contrary, Ainayev et al. [20] reported a 2-point improvement in the IIEF-5 score within 2 years after the surgery (mean 18.4 [SD 2.5] to 20.6 [SD 2.60]). Likewise, Liu et al. [8] reported improvement in the IIEF-5 score with the follow-up from 12 months to 43 months. Differences between the studies in factors like case selection, surgeon experience, patient orientation, and level of education could explain these disparities in the IIEF-5 scores.

Long-term studies highlight the risks of decreased erectile function in response to the progression of arteriogenic or veno-occlusive dysfunction. For example, Kalsi et al. [27] reported a 22% decreased erectile function within 5 years of follow-up. Taylor and Levine [28] reported a 21% postoperative ED in the follow-up. Additionally, a recent literature review regarding plaque incisions and grafting showed that 4.6%—67.4% of patients required medicine to have erections postoperatively, and 0%—11.8% were utterly unable to achieve erections [29]. On the other hand, current studies suggested penile prosthesis implantation with or without additional straightening maneuvers for severe PD and concomitant ED [6,30].

In our study and within the follow-up period, there were 11 (33.3%) patients (5 *vs.* 6 patients in groups A and B, respectively) who used PDE5-Is to attempt penetrative sex. The need for PDE5-Is may not reflect ED as a result of the grafting procedure but may also be related to age-related changes occurring over the mean follow-up period [15].

Regarding satisfaction with the results, most patients and their partners were satisfied in both groups without a statistically significant difference (77.8% in pericardium graft *vs.* 86.7% in tunica vaginalis graft). The overall satisfaction is in accordance with a recent review by Ragheb et al. [5], which reported an overall satisfaction rate of 91.2% in pericardium grafted and 100.0% in tunica vaginalis grafted patients. Another multicenter study also described long-term outcomes for grafting 157 patients with the bovine pericardium, with a 97% satisfaction rate among patients within 2 years after surgery [31]. Case selection might be the key to our research's highly successful outcomes and satisfaction rates. Only those patients who met our criteria underwent surgery. Less strict exclusion criteria might lead to poorer outcomes which should be investigated in future studies. Additionally, we had an extended follow-up period compared to the previous studies, and having a single academic urologist during the follow-up visits helped us monitor and assess our patient's progress carefully while keeping patients motivated and involved in their treatments.

Despite including all PD patients who required graft surgery for 6 years between 2015 and 2021, the small number of cases in this study was our main limitation. We suggest further studies with a more extensive study population and better randomization.

5. Conclusion

Our results indicate that partial plaque excision and corporoplasty with testicular tunica vaginalis graft or bovine pericardium graft are equally effective treatments for men with clinically significant PD.

Author contributions

Study concept and design: Ali Eslahi.
Data acquisition: Payam Ghasemi, Hanieh Alimardani, Bahareh Ebrahimi.
Data analysis: Hossein-Ali Nikbakht, Iman Shamohammadi.
Drafting of the manuscript: Ali Eslahi, Faisal Ahmed.
Critical revision of the manuscript: Faisal Ahmed, Mohammad Reza Askarpour.

Conflicts of interest

The authors declare no conflict of interest.

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