

Treatment of penile curvature with aldehyde free bovine pericardium graft: an original and prospective evaluation of a cohort of patients with Peyronie's disease

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Abstract

Introduction: Peyronie's disease (PD) is a common condition that can cause penile curvature and/or deformities, thereby affecting the male sexual function. The most effective treatment for clinically significant and stable penile curvature due to PD is reconstructive surgery that involves techniques that do not shorten penile length. Among the techniques for the correction of curvature and restoration of penile length, the incision and/or excision of the plaque, followed by reconstruction of the defect with a graft, remains the gold standard. Although several materials have been used as a graft in the treatment of penile curvature due to PD, none have shown results good enough to be considered as the first choice. Herein, we aimed to evaluate the results of the surgical treatment of patients with penile curvature due to PD using a new biograft. **Methodology:** We performed the surgical management with graft technique in twelve men suffering from penile curvature due to PD. Penile curvature was measured before and one year after the reconstructive procedure. The graft of choice was bovine pericardium graft segment treated with L-Hydro aldehyde-free technology. Erectile function was evaluated by the IIEF questionnaire and penis length was measured by a rigid ruler during a pharmacologically induced erection test. **Results:** The overall success rate of correction of the penile curvature was 90.9% and the patients' satisfaction rate was 91.7%. No

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serious adverse events were found and the erectile function was impaired in 18.2% of cases. There was an increase in penile length, ranging from 0.7 to 3.0cm in 91.7% of cases. **Conclusion:** Correction of penile curvature due to Peyronie's disease using the technique of incision and/or excision of the plaque with an aldehyde-free bovine pericardium graft presents high success rates, both in terms of penile shaft rectification and patient satisfaction. L-hydro bovine pericardium graft is easy to handle surgically, allows a tight anastomosis and does not present serious postoperative complications. Furthermore, it can be used simultaneously with penile implants and appears to play a role in restoring penile length.

Keywords: Penis; Penile induration; Penile diseases; Surgery; Regenerative medicine.

Introduction

Peyronie's disease (PD) is a common condition affecting the male sexual function, whose prevalence can be as high as 20%.¹ PD is a fibrotic alteration of the penile tunica albuginea due to

an inflammatory process.² These tunica albuginea changes impair its elasticity and can, therefore, cause deformity during erection. Deformities can manifest themselves in different ways, including penile shortening, hourglass penis, and penile curvatures.

Clinically significant penile curvature impairs penetrative sex and also tends to cause psychological distress in patients.³ Difficulties during intercourse and social stigmas caused by the deformity and/or loss of length can affect these patients emotionally, leading them to withdraw from sexual activity and greatly impairing their quality of life.

The most indicated and effective treatment for clinically significant and stable penile curvature due to PD is reconstructive surgery.^{4,5} Currently, surgical techniques that do not shorten penile length are preferred, because these potentially avoid great dissatisfaction on the part of patients regarding penis size. Among the techniques that correct curvature while restoring the length and even lengthening the penis, the incision and/or excision of the plaque, followed by reconstruction of the defect with a graft, remains the gold standard.^{4,5}

Although several materials have been used as a graft in the treatment of penile curvature due to PD, none have shown results that are good enough to be considered a gold standard.⁶

The aim of this study is to prospectively evaluate the results of surgical treatment using a new biograft in patients with penile curvature due to PD.

Methodology

Thirteen men suffering from penile curvature due to PD who were routinely diagnosed in a urology clinic and referred for surgical treatment were enrolled in this study. All of them signed the informed consent form. The age of the patients ranged from 42 to 72 years. Diabetes Mellitus and Arterial Hypertension were comorbidities reported by two patients. Twelve men completed the 12-month postoperative follow-up period and were reassessed with regard to satisfaction with surgery, curvature correction, presence of surgical complications, erectile function, and penile length.

Penile curvature was assessed during a drug-induced erection test with 20 micrograms of intracavernous prostaglandin E1 before surgery and during the one-year follow-up consultation. Digital images were taken, and the angle of the curvature was measured using Kelami's five line protocol⁷. A free on-line software for measuring the angle was used. A Likert scale, ranging from 1 to 5, was used to assess the subjective satisfaction of penile curvature correction. The International Index of Erectile Function (IIEF-5) was used to assess erectile function.⁸ One patient was lost to follow-up. All patients underwent the technique of partial excision of the plaque + geometric relaxation incisions and implantation of a bovine pericardium graft segment treated with L-Hydro aldehyde-free technology (Vivendi UR®, Labcor, Contagem - Brazil). Three patients underwent a simultaneous semi-rigid penile implant due to associated severe erectile dysfunction.

Results

The overall success rate of the penile curvature correction was 90.9%. Eleven (91.7%) patients reported being satisfied (n=5; 41.7%) or very satisfied (n=6; 50%) with the surgical outcome of their penile curvature (Table 1). Only one patient showed dissatisfaction, the presumed reason for which was a decrease in penile size in the postoperative period. This fact was not confirmed

by objective measurements and the patient is still being followed up in a psychology clinic due to difficulties in self-perception of genital body image.

No serious adverse (grade II to V) events were found according to the Clavien Dindo scale.⁹ One patient had drainage of serous fluid through the surgical wound for 19 days, without inflammatory signs, which ceased after conservative treatment. A culture of the serous fluid was performed and no growth of bacteria or fungi was found.

Table 1. Comparative results from the baseline to 12 months follow-up of patients with penile curvature due to Peyronie's disease managed with non-aldehyde bovine pericardium matrix

Patient	IIEF-6 baseline	IIEF-6 12 months	Penis Length baseline	Penis Length 12 months	Penile Curvature baseline	Penile Curvature 12 months
1	6	29*	12.3	13	90° dorsal	Non-significant
2	24	21	12	11.5	70° lateral	Non-significant
3	20	10	11.1	12.1	70° lateral 70° dorsal	Non-significant
4	21	23	13.5	14.3	45° dorsal 25° right	Non-significant
5	15	13	13	13.9	32° dorsal 40° lateral	Non-significant
6	28	24	13.8	15.3	90° dorsal 45° lateral	60° lateral
7	17	29*	13	16	80° dorsal 30° lateral	Non-significant
8	6	6*#	12.5	14	40° ventral 60° lateral	#
9	22	25	13.8	15.5	25° ventral 55° lateral	Non-significant
10	27	24	12.5	14.5	95° dorsal 40° lateral	Non-significant
11	16	12	14	14.7	70° dorsal	Non-significant
12	15	7	11.8	12.5	60° dorsal 25° lateral	Non-significant

Legend: * Penile implant; # The penile prosthesis was removed at the request of the patient

Source: The authors (2023).

Erectile function was assessed in 11 patients (Table 1). One individual could not assess the result of erectile function at the end of the study because he had been submitted to the implantation of a penile prosthesis concomitant with correction of the penile curvature with a graft and voluntarily requested the removal of the prosthesis 3 months after the operation due to personal problems, even with the perfect and recognized straightening of the penile shaft. Two (18.2%) individuals showed significant worsening of erectile function, progressing to severe erectile dysfunction (IIEF-5 score 1-10).

There was an increase in penile length in 11 of the 12 subjects (91.7%) and this ranged from 0.7 to 3.0cm (Table 1). One patient (8.3%) presented a reduction of 0.5cm in penile length, although this was not the subject of any complaint.

Discussion

The use of aldehyde-free bovine pericardium as a graft has been widely known in cardiovascular surgery for more than two decades.^{10,11} Several clinical studies show that it has excellent biomechanical and long-term histocompatibility characteristics, confirming the safety of its use in humans. There is also evidence that the biointegration of the grafts occurs and promotes guided regeneration, a typical strategy of regenerative medicine based on scaffolds. The use of pericardium as a biograft for penile albuginea reconstruction has been widely described and shows a wide variation in success rates.^{12,13} However, despite the fact that bovine pericardium is excellent as a raw material for the production of matrices for grafting, to our knowledge no graft processed without aldehydes throughout the entire process has been previously used in clinical studies of penile reconstruction. The use of aldehyde solutions during processing or even in the final preservation of graft matrices induces an intense inflammatory reaction that can eventually evolve into the formation of calcium deposits.¹⁴ These alterations are very undesirable and can cause functional damage to the regenerated target organ.

Another important advantage of using aldehyde-free bovine pericardium graft is its pleasant surgical handling, allowing for easy apposition and tight suturing. Only the thickest part of the bovine pericardium was used to manufacture the final biograft and its thickness is similar to the human adult tunica albuginea. It has sufficient tear strength properties to ensure organ function until complete biointegration occurs and has a visceral and adventitial surface. The smoother and brighter visceral surface was used by us to maintain contact with the corpora cavernosa, since it induces less clot formation. Regarding this point, antithrombotic and anti-inflammatory agents were incorporated in the graft during the processing, making the microenvironment less hostile for tissue repair.^{15,16} We report no complications regarding to the graft and, therefore, considered that full biointegration of the graft was achieved. Although this finding would be better evaluated with new samples obtained from biopsies, this was not the purpose of this study. Other limitations of the study were the small number of patients and the fact that it was carried out in a single center. Finally, the excellent result of this initial study provides a basis for carrying out multicenter studies with a larger sample.

Conclusion

Correction of penile curvature due to Peyronie's disease using the technique of incision and/or excision of the plaque with an aldehyde-free bovine pericardium graft has high success rates in terms of both penile shaft rectification and patient satisfaction. L-hydro bovine pericardium graft is easy to handle surgically, allows a tight anastomosis and does not present serious postoperative complications. Furthermore, it can be used simultaneously with penile implants and appears to play a role in restoring penile length.

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