

ORIGINAL ARTICLE

Corporoplasty with small soft axial prostheses (VIRILIS I®) and bovine pericardial graft (HYDRIX®) in Peyronie's disease

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The surgical techniques used by Austoni and Egydio in the treatment of Peyronie's disease are based on geometric principles. The aim of this paper is to report our multicentric experience and technical changes to Austoni's original technique, focusing on several tips and tricks to make this technique easy to perform, even by less experienced practitioners. We performed operations in three different Italian institutions. We implanted a small soft Virilis I® axial prostheses (Ø 7 Fr.), using a bovine pericardium collagen matrix patch (Hydrix®) to cover the defect in the tunica albuginea. Sixty patients with a mean age of 58 years (range 44–76 years) underwent surgery between September 2005 and January 2010. After surgery, mean lengthening of the shaft was 2 cm (range 1.2–2.3 cm) with complete correction of penile recurvatum. Thirty-nine patients resumed sexual activity 60 days later, 14 after 90 days and 7 after 120 days. The international index of erectile function (IIEF) score was 15.5 before surgery and it improved to 23 at 12 and 24 months after surgery. Furthermore, the visual analogue scale (VAS) showed good results in terms of the recovery of natural sexual intercourse (over 80% of couples) and of the original length and girth of the penis. The soft implant we used takes advantage of erection that occurs spontaneously, using the residual erection of the spared cavernous tissue. The method is easy to learn and reproducible, and the use of pericardium speeds up the operation, while also covering large defects of the tunica albuginea that result from complex recurvatum. *Asian Journal of Andrology* (2013) 15, 275–279; doi:10.1038/aja.2012.156; published online 28 January 2013

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INTRODUCTION

Peyronie's disease is characterized by scarring of the tunica albuginea with loss of elasticity, resulting in different penile deformities. The disease is always associated with penile shortening, and it has a major influence on quality of life and serious psychological consequences. The incidence is 3%–10% among the male population and can be commonly found in men between 40 and 70 years of age, but it also affects the younger population under 30 years.^{1–3} Furthermore, Peyronie's disease is commonly associated with erectile dysfunction, ranging from 20% to 54% according to Usta *et al.*⁴

The indication for surgery begins with the disease being stable. The concept of stable disease has not been clearly defined, but is generally accepted as at least 1 year of disease and at least 6 months in which there has been no change in the deformity, and pain with erection or during plaque palpation has resolved. Progression of disease is uncertain, and there is no parameter to predict it. Furthermore, the surgical candidate must describe compromised ability or total inability to engage in coitus secondary to deformity or inadequate rigidity. In addition, a patient who has medical treatment failure and extensive plaque calcification is also a candidate for surgery.^{5,6}

Surgical treatment must be individualized, aiming not only at restoring penile function, but also restoring the patient's previous state as

much as possible. Different techniques have been proposed in the past and various graft materials were suggested to cover the tunica albuginea defect, but none of them currently represent the gold standard.

Following the evolution of techniques, the focus turned not only to improving penile recurvatum, but also length and girth in order to attain the best possible aesthetic and functional results. The techniques used recently by Austoni *et al.*⁷ and Egydio *et al.*⁸ are thus based on geometric principles, and Austoni's technique, in particular, entails positioning silicone penile prostheses in the corpora cavernosa, permitting penile extension towards the outside, and thereby making it easier to identify curvature and the point of traction. The soft implant is not actually a prosthesis, in the strict sense of the word, as erection occurs spontaneously, using the residual erection of the spared cavernous tissue; in fact, there is no need to manipulate the prosthesis to obtain an erection, unlike semirigid devices and inflatable prostheses. Furthermore, this prosthesis prevents cicatricial retraction after the grafting of a patch or the subsequent onset of recurrent fibrotic plaque.

Here we report our personal experience and the technical changes we made to Austoni's original technique, focusing on certain tips and tricks to make this technique easy to perform, even by less experienced practitioners.

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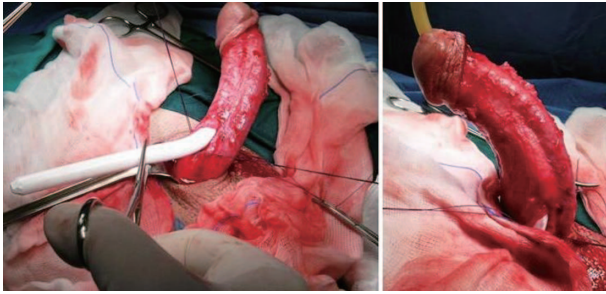


Figure 1 Prostheses (Virilis I®) implant showing penile dorsal recurvatum.

MATERIALS AND METHODS

We performed the operations at three different institutions (a multicentric study) in Italy, but using the same standardized modified procedure.

Original surgical technique (Austoni's procedure)

The original technique⁷ requires complete degloving of the penis through subcoronal incisions. Two ventral corporotomies are performed at the root of the corpora cavernosa for the implant. The implant of the soft Virilis I® (Giant medical, Cremona, Italy) axial implant (Ø 10 Fr.) is performed, shaping it 2 cm longer than the corpora cavernosa in order to stretch the penis and enhance the recurvatum (**Figure 1**). The Virilis I® implants from Italy are made of completely soft medical-grade silicone. These implants are 25 cm in length and are supplied in 7, 10 and 12 mm diameters.

A single calibration of the corpora cavernosa with Hegar number 10 is performed in order to preserve as much cavernosal tissue as possible. Insertion of the implant into the corpus cavernosum demonstrates penile recurvatum, and facilitates isolation of the dorsal neurovascular bundle. A relaxing plaque incision is made at the point of maximum curvature, sparing as much as possible of the underlying erectile tissue. This albuginea defect is then covered with a saphenous graft; to fix the graft to the tunica albuginea, a 3/0 absorbable single-thread running suture is performed. The operation is completed with circumcision and placement of a drain in the subdartos space; the area is dressed with a light compressive bandage in order to permit nocturnal erections and drain secretions of blood and serum.

Technical considerations and modifications proposed by the authors

We used a small soft Virilis I® axial prostheses (Ø 7 Fr.) that is approximately only 1 cm longer than the effective length of the corpora cavernosa: the aim is to avoid excessive traction on the isolated neu-

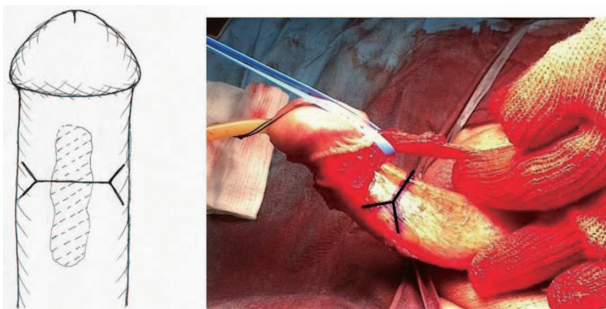


Figure 2 Plaque incision is performed after prostheses implant and the apexes are 'dovetailed' in order to permit fuller relaxation of the plaque.

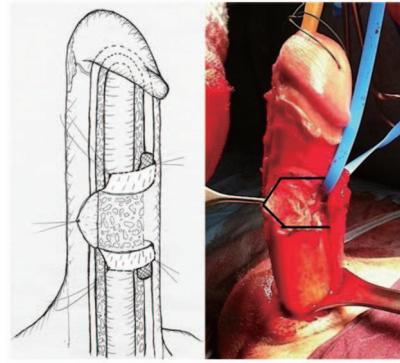


Figure 3 We proceed, by blunt dissection, along all the margins of the incision, to release the underlying cavernous tissue and remove traction at the same time in every side.

rovascular bundle and to spare as much as possible of the healthy cavernosal tissue, because this is essential to maintain a residual erection. To calibrate the corpora cavernosa and avoid cavernous tissue damage, we used only Hegar number 6. In this way, 30%–40% of erectile tissue is spared during implant surgery in order to preserve residual erection; the cavernous artery is preserved because we performed only single dilation with a small dilator.

The plaque was incised with a cold scalpel using an optical magnifying system (loops $\times 2.5$ – 3) in order to optimize the amount of underlying erectile tissue that was spared. The apexes of this incision are 'dovetailed' in order to permit fuller relaxation of the plaque (**Figure 2**). Once the incision was made, we proceeded, by blunt dissection, along all the margins of the incision to release the underlying cavernous tissue, removing traction at the same time on each side (**Figure 3**).

This surgical approach creates a large albuginea defect, larger than the one produced with the original technique, and a larger graft is thus required. In cases of penile recurvatum exceeding 50° – 60° , instead of the saphenous vein, we used a bovine pericardium collagen matrix patch, because the greater the degree of penile recurvatum, the greater the tunica albuginea defect and, consequently, the larger the area to be covered. The type of pericardial patch we used (Hydrix® (Assut Europe)) is particularly soft and easy to handle (**Figure 4**): just 72 h after grafting, the patch was inoscultated with the host tissue, and after 3 months, it could no longer be distinguished from the tunica albuginea tissue. The technical modifications described here were applicable to all types of penile recurvatum.

All patients in our case study underwent the following preoperative clinical diagnostic examinations: blood chemistry and hormone tests, nocturnal penile rigidity monitoring, dynamic penile color Doppler

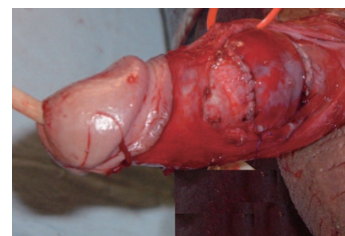


Figure 4 The graft of bovine pericardium (Hydrix®) is then apposed to cover the albuginea's defect.

ultrasound, self-shot photos of the erect penis (from each side), and international index of erectile function (IIEF) questionnaire. We waited at least 12–18 months following onset of the disease; all the patients had stable recurvatum and no local symptoms. Before surgery, all the patients underwent oral therapy with vitamin E and antioxidant agents; the patients had vitamin E treatment for a period of at least 6 months.

Furthermore, 40% had local infiltration with verapamil and 10% had Extracorporeal Shock Wave Treatment (ESWT). There were no differences, during surgery, between patients who underwent local injection or those who did not; however, some small problems were sometimes encountered at the site of the plaque during isolation of the neurovascular bundles.

Fifteen days after surgery, all patients underwent penile rehabilitation using phosphodiesterase type 5 (PDE-5) inhibitors twice a week for 45 days, in order to obtain trophic action on the residual erectile tissue near the prosthesis. Postoperative assessment of all patients was done at 15, 30, 60 and 90 days, and then at 6, 12 and 24 months using the IIEF questionnaire, administered to the individual patient, and a visual analogue scale (VAS) score applied during a couples' interview.

RESULTS

Using these technical modifications, 60 patients, with stabilized disease and a mean age of 58 years (range 44–76 years), underwent surgery between September 2005 and January 2010. The mean follow-up was 40 months (range 36–84 months). Erection was completely preserved in 24 patients, although they presented several predictive risk factors for erectile dysfunction, such as hypertension and severe dyslipidemia; six of them were heavy smokers. The remaining 36 patients had mild to moderate erectile dysfunction; six of them were diabetics taking oral hypoglycemic drugs and showing good glyco-metabolic compensation. The size of the plaque—there was only one in all cases—varied in length from 1.2 to 2.6 cm, and in width from 0.8 to 1.9 cm. The different types of penile recurvatum are summarized in **Table 1**.

In all but six of the patients, the operation was performed with subcoronal degloving; in six patients, a double coronal and scrotal incision was made to ensure greater penile mobility. The implanted prostheses ranged between 16.5 and 20 cm in length (from the crura to the apex of the corpora cavernosa). Mean lengthening of the shaft, measured before (PGE1 erection) and after surgery, was 2 cm (range 1.2–2.3 cm) with complete correction of penile recurvatum in all patients operated on.

Among the patients, 39 (65%) resumed sexual activity after 60 days, 14 after 90 days and 7 after 120 days. All patients reported a loss of sensitivity on the glans and 48 (80%) of them regained sensitivity after 8 months. We evaluated the penis at a baseline state and during erection at 3, 6, 12, 18, 24 and 36 months; we did not consider residual recurvatum of 12–15° as failure or a real problem because these patients reported normal, satisfying sexual intercourse.

The mean IIEF score was 15.5 before surgery, improving after surgery to 19 at 3 months, 21 at 6 months and 23 at 12 and 24 months. Furthermore, an evaluation of patients and couples using the VAS scale showed good results in terms of recovery of natural sexual intercourse (over 80% of couples) and of original length and girth of the penis. Unfortunately, several patients (17%) reported discomfort due to the persistent sensation of a cold gland and low sensitivity of the penis after 1 year. Eight patients used PDE-5 inhibitors for better erectile performance only occasionally (3–5 times per month), 15 (25%) of the patients reported regular sexual intercourse with more

Table 1 Type of penile recurvatum in operated patients

Recurvatum	Angle	Patients
Dorsal	50°	8
	60°	9
	75°	8
	45°	4
	70°	9
	90°	3
Left dorso-lateral	80°	6
	45°	3
Ventral	45°	2
	70°	2
Left lateral	45°	1
	60°	2
Right dorso-lateral	45°	1
Ring		1

than one partner and, 2 years after the operation, 15% reported that they had a stable relationship with a new partner. None of the patients developed lower urinary tract symptom.

As far as perioperative complications are concerned, we had to reoperate on two patients for hematoma of the dartos; long-term complications were represented by one case of prosthesis extrusion 6 months after implantation and one case of erosion of the tip of the corpora cavernosa after 7 months, resolved surgically by penile disassembly and a bovine pericardium patch to resurface the area of erosion.

DISCUSSION

There are various surgical techniques for the treatment of Peyronie's disease and they range from less invasive ones, which tend to correct penile recurvatum without acting on the fibrotic plaque, to more complex ones like corporoplasty, following specific geometric criteria and using various autologous or heterologous grafts.⁹ Less invasive techniques, such as that of Nesbit¹⁰ and Yachia,¹¹ mainly tend to act on the convex side of the curvature, contrasting the lines of force of the fibrotic plaque, but also shortening the tunica albuginea and the penis. One of the advantages of these techniques is the fact that shortening the shaft reduces the volume of the corpora cavernosa, thus making it possible to correct some of the forms of veno-occlusive erectile dysfunction that are present in many patients with inflatable penile prosthesis (IPP). At the same time, however, aesthetic results are often unsatisfactory because a reduction in the length of the shaft, which is always proportional to the degree of curvature, often creates significant psychological problems for the patient. Therefore, these techniques are mainly reserved for patients with good shaft length and lateral or ventral curvature of no more than 35°–40°, elderly patients and patients with considerable risk factors.

By contrast, plaque surgery provides a relaxing incision of the plaque in order to remove traction of the fibrotic tissue. The application of 'geometric' principles represents the evolution of this method, as simple incision eliminates traction but often it doesn't restore a good penile length and girth.^{7,8,12} This has led to a growing demand for larger grafts instead of autologous ones^{13,14} to cover large albuginea defects. They consist of biocompatible materials that are extremely resistant and elastic; these materials can mimic the tunica albuginea, avoiding as much as possible the fibroblastic reaction that often results in scar retraction and surgical failure.

Among the different 'geometric' techniques, one of the most noteworthy is the technique described by Egydio *et al.*,⁸ which uses a bovine pericardium collagen matrix patch. It is a very complex

procedure that requires a series of measurements, mainly to prepare the graft and to reestablish actual penile length and girth.

Plaque surgery using a Virilis 1[®] axial prostheses is unquestionably simpler. This technique, proposed several years ago by Austoni *et al.*,⁷ is easy to perform, promotes axial extension of the penis and facilitates observation of curvature and identification of the point of major curvature to make it possible to perform a correct relaxing incision. Nevertheless, the original technique involves the use of prostheses with a 10 Fr. diameter that fill almost the entire corpus cavernosum, sparing only a small part of erectile tissue. Furthermore, the excessive length of the prosthesis often leads to non-physiological traction of the neurovascular bundle, which, in some cases, can lead to serious dystrophic consequences on the glans or onto the tip of corpora cavernosa.

In turn, inflatable prostheses, with or without plaque surgery, are used only on patients with IPP and severe erectile dysfunction. In this case, we must recall that, aside from the high costs involved, the patient is not always psychologically open to a solution that makes an erection a completely artificial act. In a recent paper by Ralph and colleagues,¹⁵ the authors underlined the problem of penile shortening in patients with Peyronie's disease. In fact, due to loss of length, patients who had penile prosthetic implants for Peyronie's disease showed a statistically significant reduction in their levels of satisfaction when compared with other patients who underwent prosthetic implants for other reasons. The authors proposed the circular incision of the penis to obtain penile lengthening and implantation of hydraulic prostheses; furthermore, they used a patch to cover the defect of the tunica albuginea. In this series of 20 patients, there was an average length gain of 2.8 cm with normal sexual intercourse after surgery. Also in this case, patients had several complications, including diminished glans sensitivity in four (20%) and persistent dorsal curvature of less than 15° in three (15%) patients. Overall, 18 patients (90%) were satisfied with the cosmetic and functional results of the surgery.

However, a recent paper¹⁶ retrospectively reviewed patients undergoing IPP surgery to compare the durability and complication rates between patients with and without Peyronie's disease. The authors showed that Peyronie's disease was a significant predictor for component malfunction of the device in both univariate ($P=0.001$) and multivariate analyses ($P=0.002$), concluding that patients with Peyronie's disease implanted with an IPP had significantly higher component malfunction rates.

In this context, two differences must be emphasized regarding the use of soft axial prostheses. First of all, our prostheses help the patient to restore a natural spontaneous erection, which does not occur with hydraulic prostheses. Secondly, a hydraulic implant is more expensive than a soft axial implant (about 7000 Euros more).

In our experience, by implanting small prostheses (Ø 7 Fr.), we can preserve more of the cavernous tissue, resulting in good rigidity for penetration during erection and making the presence of the prosthesis easy to conceal, with a completely natural position of the flaccid penis. Furthermore, the pseudo-capsule that surrounds the small prosthesis, present as early as 2 months after surgery, has fewer consequences for the erectile tissue around it. In any case, the administration of PDE-5 inhibitors for the first 2 months after surgery is extremely useful for rehabilitating the cavernous tissue during this period.

As to the length of the prosthesis, it is better to use a size that is not much longer than the corpora cavernosa, because just 1 cm in prosthesis length is enough to show penile recurvatum. It is im-

portant to underline that an excessively long prosthesis does not lengthen the penis but merely produces greater traction and pressure on the penile tissues and neurovascular bundles, often causing problems of trophism.

Furthermore, from an aesthetic standpoint, excessive prosthesis length means that the penis is constantly erect or partially erect, contrary to the objective of the original technique, which is to only obtain a penis in extension and positioned at an acute angle towards the pubis during erection in order to facilitate penetration.

We believe that in the case of severe penile recurvatum ($>50^\circ$), a saphenous graft, as described in the original technique, should not be employed because the harvested tissue is often inadequate to cover any large albuginea defect. Therefore, covering large surfaces with the saphenous vein is not only technically difficult but is also not feasible; moreover, the preparation of saphenous patchwork grafts exposes the patient to postoperative complications and substantially lengthens the surgical time. Inversely, the pericardial patch (Hydrix[®]) we propose offers guarantees of elasticity and biocompatibility: inosculation of the albuginea tissue is complete and rapid, and there are no reports of cicatricial fibromatosis following its use. Furthermore, the use of this graft shortens the surgical time and reduces any complications associated with harvesting.

Lastly, it is important to note that there are no further papers about this technique in the current literature after the original one published by the authors of the technique in 2005.⁷ Unfortunately, we used the IIEF questionnaire and VAS scale instead of erectile dysfunction inventory of treatment satisfaction or SEP2/3, which are more useful for this kind of study, and this could result in a bias. However, IIEF is the only validated questionnaire that has been translated into Italian.

CONCLUSION

The method is easy to learn and readily reproducible, and the axial prosthesis guarantees shaft extension over time, preventing relapses. The surgical alternatives to this option are currently represented by geometric corporoplasty according to Egidio and/or inflatable prosthetic implants (with or without plaque surgery). Further, Egidio's solution is difficult to learn and can be mastered only by expert surgeons; moreover, it is used only on young patients with well-preserved erectile function. The use of soft axial prostheses is unquestionably a good compromise because it incorporates surgical speed and simplicity with good aesthetic and functional results. Above all, however, it involves the patient, who feels that he is an active party, maintaining his own residual erectile function and regaining a satisfactory penile image.

AUTHOR CONTRIBUTIONS

Protocol/project development: Alessandro Zucchi, Stefano Pecoraro, Mauro Silvani; Data collection or management: Mauro Silvani, Stefano Pecoraro; Data analysis: Alessandro Zucchi; Manuscript writing/editing: Alessandro Zucchi, Mauro Silvani.

COMPETING FINANCIAL INTERESTS

The authors declare that they have no competing financial interests.

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