Inflatable Penile Prosthesis Placement, Scratch Technique and Postoperative Vacuum Therapy as a Combined Approach to Definitive Treatment of Peyronie's Disease

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Abbreviations and Acronyms

ED = erectile dysfunction

EDITS = Erectile Dysfunction Inventory of Treatment Satisfaction

IIEF-5 = International Index of Erectile Function

IPP = inflatable penile prosthesis

MRI = magnetic resonance imaging

PD = Peyronie's disease

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Purpose: Peyronie's disease is a devastating condition resulting in penile malformation, erectile dysfunction, pain and emotional distress. In this prospective, 2 institution study we evaluated a multimodal surgical and mechanical combined approach to the definitive treatment of Peyronie's disease and concomitant erectile dysfunction.

Materials and Methods: A total of 145 select patients underwent endocavernous disruption of Peyronie's disease plaques via the scratch technique, followed by inflatable penile prosthesis insertion. Postoperatively patients were assigned to vacuum device therapy for 3 minutes twice daily to continue penile curvature correction. Followup continued for 1 year after surgery. Anatomical and functional results were assessed.

Results: Patients with plaques in the proximal third, middle third and subcoronal areas of the penis had a mean ± SD postoperative residual curvature of 21.5 ± 4.5, 17.3 ± 4.8 and 14.1 ± 3.1 degrees, respectively. After 24 weeks of vacuum therapy the mean penile curvature deviation decreased to 8.7 ± 2.5, 9.1 ± 2.9 and 7.7 ± 0.9 degrees, respectively. The mean IIEF-5 (International Index of Erectile Function) score was 9.8 ± 2.3 preoperatively, 18.9 ± 3.1 at 6 months ($p < 0.001$) and 24.1 ± 3.6 at 1 year ($p < 0.001$). The mean EDITS (Erectile Dysfunction Inventory of Treatment Satisfaction) score at the end of followup was 64.6 ± 11.8. Operative and postoperative complications were minimal.

Conclusions: Our novel combination of intraoperative and postoperative therapies in the treatment of patients with Peyronie's disease and an inflatable penile prosthesis was safe and efficacious with excellent functional outcomes. Penile curvature corrections were statistically significant and complications were negligible.

Key Words: penile prosthesis; penile induration; urologic surgical procedures, male; tissue expansion devices; patient reported outcome measures

Peyronie's disease is an acquired condition of the penis characterized by fibrosis of the tunica albuginea accompanied by pain, malformation, ED and emotional distress.[1] Prevalence rates are variable and range from 0.5% to 20.3% worldwide.[2–4] The accepted pathophysiology is

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microvascular trauma secondary to sexual activity and the consequent inflammatory response in the tunica albuginea. These events slowly lead to plaque formation and penile malformation. Erectile tissue can also be affected and ED coexists in 31.5% to 60.1% of PD cases.[5,6] PD is also characterized by narrowing and shortening of the penis, painful erection, difficult penetration and emotional distress.[7,8]

Treatments include a large variety of oral, topical, mechanical and surgical options. Despite these options and even with the AUA (American Urological Association) and the EAU (European Association of Urology) guidelines there is wide variation in treatment algorithms in the andrology community.[9,10] Guidelines indicate that IPP placement should be recommended for PD in patients with ED.[11] Other surgical management options, including plication and grafting procedures, are appropriate only in patients without ED.[12,13]

Complete resolution of curvature with IPP placement is often seen in patients with mild to moderate penile curvature (ie less than 30 degrees). More severe curvature requires additional maneuvers such as Wilson penile modeling.[14] In 2013 Perito and Wilson described the scratch technique as an adjunct to modeling performed intraoperatively before device placement to globally disrupt the plaques in 3-dimensional fashion.[15] The principles of this technique were derived from the 2-dimensional approach using an endoscopic carpal tunnel scalpel described in 2006 by Bella et al.[16] Given the high likelihood of recurrent curvature postoperatively and the possibility of inadequate correction intraoperatively, we incorporated a vacuum device as adjuvant therapy in the early postoperative period to stretch the tunica albuginea and prevent the pseudocapsule coffin effect responsible for penile retraction.[17]

The aim of the study was to report methodology, safety and efficacy results in our prospective cohort of patients with severe penile curvature and/or complex PD plaque as well as ED who were treated with our novel multimodal surgical and mechanical combined approach.

MATERIALS AND METHODS

A total of 256 patients with stable penile curvature greater than 30 degrees with or without ED were identified and enrolled in this 2 institution study between June 2013 and May 2016. The study was performed under institutional review board protocols from the Andrology Clinic, Department of Gynecological-Obstetric Sciences and Urological Sciences, Sapienza Rome University, Rome, Italy, and the Urology Division, Coral Gables Hospital, Coral Gables, Florida. The study was performed in line with European urology and GCP (Good Clinical Practice) guidelines, and the ethical principles of the latest version of the Declaration of Helsinki. Informed consent was obtained from every patient to participate in the study.

Penile curvature was preoperatively examined using 2 methods, including photography at home and intracavernous injection within 3 months of surgery. Patients were asked to obtain penile photographs from 3 angles if natural erection was possible. The cohort was assessed preoperatively by a detailed sexual and medical history, focused physical examination and imaging studies. All patients underwent preoperative duplex Doppler ultrasonography and/or penile MRI to identify ED, characterize the plaques and identify penile malformation. Penile Doppler studies were performed with a 7.5 to 13 MHz high frequency ultrasound probe. The corpora cavernosa were studied at baseline and following intracorporeal injection of 5 to 20 μg alprostadil. Preoperative MRI studies were performed with a 3 Tesla Discovery™ MR750 MRI scanner.

Study exclusion criteria were absent penile curvature, or ventral penile curvature 30 degrees or less, previous penile surgery, neurological disease precluding successful IPP operation such as Parkinson's disease, Alzheimer disease, amyotrophic lateral sclerosis, etc, major psychiatric disorders and patients who refused to participate in the study. As a result 48 patients were excluded and 208 were selected for further study. The supplementary table (http://jurology.com/) summarizes the characteristics of these patients. A total of 63 patients with erectile function responsive to medical management were also excluded.

The 145 patients with moderate to severe ED refractory to conservative management with phosphodiesterase-5 inhibitors and intracavernous injection underwent minimally invasive infrapubic IPP placement with endocavernous rupture of PD plaques using the scratch technique.[15,18] All procedures were performed by 2 experienced implant surgeons using an identical surgical technique. Patients were administered cefuroxime twice daily for 2 days preoperatively and then received vancomycin and gentamicin dosed at the ideal body weight in the immediate preoperative period. No postoperative antibiotics were administered.

At the beginning of the procedure a saline artificial erection was induced to identify all known and unknown penile pathology prior to any cylinder placement. The pathology zone was marked externally with a pen. Any penile curvature greater than 30 degrees, penile indentation or hourglass malformation was addressed by the scratch technique. An 80 mm nasal speculum was passed across the plaque and opened transversely to fracture the plaque along the x-axis. A 12-blade scalpel was used to scratch the plaque internally along the z-axis (longitudinally). The depth of the scratch further disrupted the plaque along the y-axis, completing the internal 3-dimensional disruption of the plaque. After the implant was placed any additionally needed Wilson modeling was performed.

Starting 2 weeks after discharge home the patients were asked to purchase and use a Medis® or Osbon ErecAid® vacuum device for a 12-week period without the constriction ring for 3 minutes twice daily. Patients

completed the IIEF-5 questionnaire before surgery and at the end of followup. Questions 1 to 5 regarding erectile function and question 15 on personal confidence were used to preoperatively and postoperatively determine ED grade. Satisfaction after implantation was defined using the EDITS scale, which evaluates satisfaction with ED treatment modalities on a 0 to 100 scale.

Followup with evaluation of curvature at 12, 24 and 48 weeks was performed in the whole cohort. During followup penile angulation in each patient was measured with a goniometer after maximal IPP inflation in clinic.

RESULTS

A total of 145 patients with a mean ± SD age of 51.6 ± 10.6 years completed the study, and 102 Coloplast® (70.3%) and 43 AMS™ (29.6%) IPP devices were placed. Mean operative time from incision to closure was 58.1 ± 18.4 minutes and no intraoperative complications were reported. All patients were discharged home at a mean of 1.31 ± 0.58 days.

PD plaques were mainly located in 3 areas, including the proximal third, the middle third and the subcoronal zone of the penis. In patients with plaques localized to the middle third, the proximal third and the subcoronal zone the mean preoperative penile curvature was 65.6 ± 10, 71.8 ± 4.5 and 49.2 ± 7.4 degrees, respectively. Six patients (5.3%) had a concomitant hourglass malformation.

Table 1 summarizes intraoperative and postoperative complications. In the early postoperative period infectious criteria complications developed in 6 patients (4.1%), including fever 38C or greater, neutrophilic leukocytosis and rising C-reactive protein, respectively, within 3 weeks after surgery. Strict daily evaluation was initiated along with intramuscular injection of antibiotics for 14 days. All symptoms resolved and no patient required device explantation or salvage. No further complications were reported. Impending lateral extrusion of the IPP cylinders developed in 3 patients (2%). They underwent surgical repair of the defect according to the distal corporeal anchoring stitch technique.[19]

Table 1. *Intraoperative and postoperative complications*

No. pts (%)	145 (100)
Mean ± SD operative time (mins)	57.1 ± 18.8
No. device type implanted (%):	
Coloplast	102 (70.3)
AMS	43 (29.6)
Mean ± SD hospital stay (days)	1.31 ± 0.58
No. early postop complications (%):	33 (22.7)
Infectious manifestations	6 (4.1)
Urethral erosion	0
Prosthesis extrusion	3 (2)
Mild scrotal hematoma swelling	18 (75)
Severe scrotal hematoma	6 (25)
No. long-term 12-mo followup complications (%):	14 (9.6)
Mechanical failure	3 (2)
Significant relapse, greater than 15-degree curvature	9 (6.2)
Worsened erectile dysfunction secondary to psychological disorder	2 (1.3)

There were no intraoperative complications and no neurological impairment, long-term penile shortening or palpable subcutaneous induration.

Regarding long-term complications 3 (2%) patients experienced prosthesis mechanical failure 0.7, 1 and 1.2 years postoperatively and all proceeded to revision surgery. Two patients (1.3%) complained of worsening ED after surgery. Each of them underwent physical examination and MRI to exclude any equipment malfunction. After we confirmed normal device function these patients were referred for psychosexual counseling, which revealed mental illness.

Immediately postoperatively patients who presented with plaques at the proximal third, middle third and subcoronal zones of the penis had a mean residual curvature of 21.5 ± 4.5, 17.3 ± 4.8 and 14.1 ± 3.1 degrees, respectively. After 12 weeks of vacuum pump therapy the results showed increased penile remodeling, achieving mean curvature deviations of 9.2 ± 2.9, 9.5 ± 3.1 and 8.5 ± 1.3 degrees, respectively. At 24 weeks the data revealed mean residual curvature of 8.7 ± 2.5, 9.1 ± 2.9 and 7.7 ± 0.9 degrees, respectively. At the end of 1 year of followup the data showed mean penile curvature angles of 10 ± 2.9, 10.2 ± 3.5 and 9.1 ± 1.7 degrees, respectively.

At the end of the protocol we observed absent penile curvature, defined as an angle deviation of 15 degrees or less, in 93.7% of the study group. Only 9 patients (6.2%) reported significant relapse or persistence of greater than 15-degree penile deviation 1 year postoperatively. In these men mean curvature was 23.2 ± 3.7 degrees. None of these patients underwent any further treatments except continued use of the vacuum device. When comparing residual curvatures at any time during followup, penile deviation was statistically significantly decreased ($p < 0.0001$). Table 2 lists the locations and morphological preoperative characteristics of the plaques detected by MRI and Doppler investigations. Table 3 shows a comparison between preoperative and postoperative penile curvature outcomes.

The mean preoperative IIEF-5 score was 9.8 ± 2.3, at 6 months it was 18.9 ± 3.1 ($p < 0.001$) and at 1-year followup it was 24.1 ± 3.6 ($p < 0.001$). The mean EDITS score at the end of followup was 64.6 ± 11.8.

DISCUSSION

The presence of unifocal or multifocal PD plaques and a concomitant hourglass defect can lead to various penile malformations ranging from minor

Table 2. *Morphological characteristics and anatomical localization of PD plaques*

Localization	No. Pts (%)	No. Main Penile Curvature Orientation (%)	Mean ± SD Length (cm)	Mean ± SD Thickness (cm)
Middle third:	137 (65.8)		2.2 ± 0.5	0.88 ± 0.34
Dorsal		67 (48.9)		
Lateral		22 (16)		
Mixed		48 (35)		
Proximal third:	52 (25)		1.83 ± 0.45	0.89 ± 0.33
Dorsal		22 (42.3)		
Lateral		5 (9.6)		
Mixed		25 (48)		
Subcoronal:	19 (9.1)		1.27 ± 0.28	0.61 ± 0.16
Dorsal		9 (47.3)		
Lateral		3 (15.8)		
Mixed		7 (36.8)		
Totals:	208 (100)		2.21 ± 0.60	0.86 ± 0.34
Dorsal		98 (47.1)		
Lateral		30 (14.4)		
Mixed		80 (38.5)		

angulation (15 degrees) to extreme angulation (150 to 170 degrees).[20] In this wide variation of anatomical presentations it is necessary to distinguish between patients with acute vs stable disease before initiating treatment.[21] The decision to proceed with surgical correction of PD should be offered to men with severe penile malformations which preclude penetration after considering important aspects such as age, the degree of curvature, erectile function and at least 3 months of stable disease.[22,23]

In addition to our primary outcome, we underscore the importance of a second level imaging study during preoperative planning, such as penile MRI. As noted in the EAU guidelines, ultrasound measurement of plaque size is inaccurate during diagnostic evaluation since palpable plaques can only be localized accurately in 39% to 65% of cases using ultrasonography.[24] In our experience MRI offers a better anatomical correlation between plaques and other penile structures, thus avoiding blind dissection during the scratch technique. Gadolinium enables better differentiation between plaques with inflammatory changes and those that are purely fibroblastic, aiding in the detection of patients with active disease who should not undergo surgery.[25] Intraoperative artificial erection can also aid in technical planning.

The aim of all repair techniques is to correct penile curvature and enable satisfactory erection. One of the first described options was the Nesbit procedure, which along with its variations involves shortening the tunica albuginea on the normal convex side of the penis. This leads to penile shortening without the ability to correct indentation or an hourglass malformation.[26] Other lengthening procedures involve plaque incision or excision with graft placement but they have variable results. To our knowledge the ideal graft material to cover tunica albuginea defects is not established. This approach may be associated with a high rate of postoperative ED due to the subsequent venous leak.

The choice of prosthesis placement for PD represents a valuable alternative resulting in good curvature correction from cylinder placement alone. The development of the intraoperative modeling maneuver described by Wilson and Delk,[14] as expanded by the scratch technique,[15] enabled the correction of significant PD curvatures without performing invasive and time-consuming grafting procedures. We believe that the internal 3-dimensional disruption of penile plaque accomplished by endocavernous dissection (or scratch) releases the fibrotic adherences and traction forces responsible for PD curvature which could not be

Table 3. *Preoperative and postoperative penile degree curvature outcomes*

Localization	No. Pts (%)	No. Main Penile Curvature Orientation (%)	Mean ± SD Curvature (degrees)*				
			Preop	Discharge	12-Wk Followup	24-Wk Followup	48-Wk Followup
Middle third:	96 (66.2)		65.6 ± 10	21.5 ± 4.5	9.2 ± 2.9	8.7 ± 2.5	10 ± 2.9
Dorsal		47 (48.9)					
Lateral		15 (15.6)					
Mixed		34 (35.4)					
Proximal third:	37 (25.5)		71.8 ± 4.5	17.3 ± 4.8	9.5 ± 3.1	9.1 ± 2.9	10.2 ± 3.5
Dorsal		18 (48.6)					
Lateral		2 (5.4)					
Mixed		17 (45.9)					
Subcoronal:	12 (8.2)		49.2 ± 7.4	14.1 ± 3.1	8.5 ± 1.3	7.7± 0.9	9.1 ± 1.7
Dorsal		6 (50)					
Lateral		1 (8.3)					
Mixed		5 (41.6)					
Totals:	145 (100)		65.8 ± 10.4	19.8 ± 5.1	9.2 ± 2.9	8.8 ± 2.5	10 ± 3
Dorsal		71 (48.9)					
Lateral		18 (12.4)					
Mixed		56 (38.6)					

*Each preoperative to 48-week followup curvature $p < 0.001$.

otherwise eliminated entirely by Wilson modeling and/or device inflation alone.

At discharge home our cohort had a mean residual curvature of 19.8 ± 5.1 degrees. Further improvement in curvature reduction and IIEF-5 scores were obtained after vacuum pump therapy and at the end of followup. There was slight worsening of curvature at the last checkup during the study period. The exact reasons for this are unknown but they could be related to PD progression or postoperative changes after IPP placement.

The role of mechanical therapies as the primary treatment choice in select PD cases has been described in a few articles. Evidence for these therapies is lacking due to the absence of large randomized controlled trials.[27,28] A notable contribution came from Raheem et al, who reported on a cohort of 31 patients who underwent vacuum therapy for PD and described how this approach could improve or stabilize penile curvature.[29] More recently Lin et al explored the possible cellular and molecular mechanisms associated with penile traction and vacuum therapy in a rat model of PD.[30] They noted that the beneficial anatomical and functional results observed in the rat cohort may have been related to the induction of anti-apoptosis, antifibrosis pathways and smooth muscle preservation factors. They also found that mechanical traction therapies reduced the expression of transforming growth factor-β1.

In our cohort vacuum pump therapy was introduced as an adjuvant therapy after IPP placement. To our knowledge this represents an essential part of our therapeutic management algorithm for several reasons. The previously described surgical adjustments may not achieve complete resolution of PD curvature intraoperatively. Adjuvant vacuum pump therapy may have an important role in improving microscopic compliance of the areolar cavernous tissue and achieving better collateral oxygenation of the residual cavernous tissue surrounding the cylinders and the glans. This last aspect, which is supported by the mentioned recent molecular study,[30] could be reflected in the high mean level of erectile function and treatment satisfaction delineated by the IIEF-5 and EDITS scores at the end of followup in our cohort.

Several limitations of our study should be noted. This was not a randomized, double-blind, placebo controlled study. Our results are prospective but no control arm was created for comparison. All surgical procedures and PD correction maneuvers were performed by high volume, experienced surgeons and results may not be similar for less experienced implanters. Ventral curvature was not evaluated, given the rarity of presentation and the need for more complex repair maneuvers to treat this condition. We do not advise using the scratch technique for ventral curvature unless it is performed by someone experienced with the technique. Finally, device choice was determined by the surgeon and no analysis was performed to evaluate differences in clinical efficacy.

CONCLUSIONS

Our multimodal surgical approach is a safe and effective definitive treatment in patients with PD and ED. Patient satisfaction was high, and intraoperative and postoperative complications were rare. We believe that this is a feasible technique for experienced surgeons which can be applied in select patients with severe penile curvature who are candidates for definitive surgical correction.

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