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PENILE SENSORY CHANGES AFTER PLAQUE INCISION AND GRAFTING SURGERY FOR PEYRONIE'S DISEASE

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Abstract

Introduction—Plaque incision and Grafting (PIG) for Peyronie's disease (PD) is not devoid of complications such as erectile dysfunction and penile sensory changes.

Aims—The aim of this study was to define the rate and chronology of penile sensation loss after PIG surgery and to define predictors of such.

Methods—The study population consisted of patients with PD associated penile curvature who underwent PIG surgery and with at least 6 months of follow-up. Demographics and PD factors were recorded. Patient had preoperative assessment of penile sensation and deformity. Postoperative follow-up occurred at 1 week, 1 month, 6 months and 1 year after surgery. Neurovascular bundle elevation was conducted with loupe magnification.

Main outcomes measures—Penile sensation was evaluated with a biothesiometer and graded on a patient reported visual analog scale (0-10) where 0 defined a completely numb area and 10 perfect sensation. The degree of sensation loss was defined as extensive (any single area >5cm), major (2–5 cm) and minor (2cm). The penile sensation loss distribution was defined as focal (single site) or diffuse (>1 site).

Results—63 patients were analyzed. Mean age was 56±10 years. Mean duration of PD at the time of PIG was 15±7 (12–38) months. 75% had curvature alone, 25% had hourglass/Indentation deformities. Mean primary curvature was 64±28°. The mean operation duration was 3.5±1.8 hours. 21% had some degree of sensation loss at one week, 21% at one month, 8% at 6 months, 3% at 12 months. Only a single patient (1.5%) at 2 years continued to have extensive sensation loss on the glans and distal shaft with a very elevated sensitivity threshold. Using multivariable analysis the only predictor of penile sensation loss 6 months was duration of operation >4 hours, OR 2.1, 95% CI 1.2–3.0 (p<0.01).

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Conclusions—Sensation loss is not uncommon after PIG surgery. It decreases in frequency and severity with time with only rare cases occurring beyond 12 months. Longer operations appeared to be more likely associated with sensation loss.

Keywords

Peyronie's disease; plaque Incision; Grafting; Penile Induration; Surgical Treatment; Complications; Sensory

Introduction

Peyronie's disease (PD) is a fibrotic condition of the tunica albuginea that is associated with penile pain, deformity and erectile dysfunction (ED)¹.

The prevalence of PD in the general population ranges from 0.3–9% with an incidence of ^{2–5} up to 20% in diabetics patients⁶. The primary etiologic factor is not clear, numerous etiologic theories exist including: Genital Trauma, genetic predisposition, autoimmune disorder, collagen alterations, over expression of pro inflammatory cytokines⁷.

Surgical procedures remain the gold standard for definitive deformity correction. ⁸ The primary goal of surgery is to ensure the patient has a functional erection. Plaque incision and grafting has been used since 1950⁹ and represents a surgical option, typically reserved for men with severe curvature, complex deformities and those who have an hour glass deformity.

However, Plaque incision and Grafting (PIG) is not devoid of complications as postoperative ED rates range from $0-67\%^{1,\ 10-13}$. The issue of rates of postoperative penile sensory had been cited from $0-20\%^{1,\ 14-16}$. To date, there is little detailed information on the nature or chronology of this sensation loss.

The aim of this study was to define the rate and chronology of penile sensation loss after PIG and furthermore to define predictors of such sensory loss.

Methods

Patient Population:

Patients who had underwent PIG surgery for dorsal or lateral deformity and at least 6 months of follow-up were included in this analysis. Demographics and PD factors were recorded. Patient had a preoperative assessment which included penile sensation and curvature assessment. They had postoperative follow-up at 1 week, 1 month, 6 months and 1 year after surgery.

Curvature Assessment:

All curvature assessments were done after an intracavernosal injection (ICI). The injection agent used was trimix (papaverine/phentolamine/prostaglandin E1) with redosing of vasoactive agent used to induce a rigid erection. The degree of curvature was measured with

a goniometer¹⁷. The center of the goniometer was positioned over the point of maximum curvature. Stretched flaccid penile length was also measured.

Penile Sensation Assessment:

A biothesiometer (Biomedical Instruments, Newsbury, OH, USA) was used for vibratory sensation assessment (Set at 120Hz). This instrument is designed to measure simply and accurately the threshold of appreciation of vibration in human subjects. It is used in many neurological diseases such as, neuropathy in diabetes mellitus¹⁸. Previous studies have reported biothesiometry, as a reliable method to measure penile sensory loss ^{19–21}. During testing, participants were asked to lie on a bed in a relaxed position. Two cycles were performed in an "ascending-descending" order. The ascending phase began with the lowest level of stimulation increased until perceived; the descending phase began two levels above the previously detected threshold, and decreased until no longer perceived. The average of the 2 phases was recorded as the detection threshold for each point of stimulation. In each case, the stimulus was applied for 1.5 seconds followed by a 5-second delay to eliminate possible carry-over effects between stimuli. Values for vibration were expressed in volts (V) The procedure consisted of measuring the detection thresholds vibration of 6 body locations illustrated in figure 1 which includes; the penile dorsal base, the middle of dorsal penile shaft, the corona of the glans, the middle of the glans, the frenulum, the penile ventral base. Studies have defined a Score 7V as normal sensitivity²⁰, ²². A nomogram is available to define normalcy of vibration thresholds that has been shown to be superior to the use of a tuning fork in accuracy²⁰.

We also used a patient reported penile sensation visual analog scale (0–10) where 0 defined a completely numb area and 10 a perfect sensation. The grade of loss sensation was defined as extensive (any single area >5cm), major (2–5 cm) and minor (2cm). The penile sensation loss distribution was focal (single site) or diffuse (>1 site).

Surgical Procedure:

A single experienced surgeon did all of the procedures over a 6 years period 2004–2010. Under general anesthesia, the penis was degloved. The neurovascular bundle NVB was elevated under loupe assistance (3.5×). Prior to 2006 the procedure used an H-type incision, after this date the Egydio geometric incision has been used²³. Grafting was performed predominantly with cadaveric pericardium (Tutoplast, Coloplast, Mineapolis, MN, USA), although a small number of procedures were conducted using intestinal submucosa (SIS® surgisis, Cook Urological Incorporated) or dorsal/saphenous vein. Following incision of the tunica and straightening of the deformity, the graft was measured and sutured in place using 4/0 PDS suture. We never used a tourniquet during neurovascular bundle dissection or during plaque incision.

We always prescribe "penile rehabilitation" following surgery including PDE5i's and traction therapy commencing one week after surgery for a 3 month period after the PIG surgery.

Statistical Analysis:

Means (± standard deviations) and percentages are used to describe the study sample. Percentages are reported to outline the incidence of penile sensation loss, and correlation coefficients are used to determine the relationship between the visual analog score and the penile vibrotactile sensitivity thresholds. Logistic regression was used in multivariable analysis to define predictors of sensory loss. Factors entered into the model were patient age, presence of diabetes mellitus, Peyronie's disease duration, and operation duration. All statistical analysis were performed in SPSS (SPSS, Inc, Chicago, IL, USA)

Results

Patient Population:

63 patients were included in this analysis. Mean patient age was 56 ± 10 years. Mean duration of PD at the time of PIG was 15 ± 7 (12-38) months, the mean follow-up was 14 ± 12 months and self reported duration of stability was eight months. 10% had diabetes preoperatively with a mean HB_{A1C} =7.2 $\pm1.8\%$. 75% had a curvature alone, 25% had associated hourglass/ Indentation deformities. Mean primary curvature was $64\pm28^{\circ}$. 53 patients had grafting with human cadaveric pericardium, 6 with vein and 4 with intestinal submucosa. 38% (24/63) of the PIG used a H-incision and 62% (39/63) used the Egydio geometric incision. The mean operation duration was 3.5 ± 1.8 (2.5-5.5) hours. 80% had a preoperative and postoperative biothesiometry. Subject characteristics are presented in Table 1.

Penile Sensation:

21% had any sensation loss at one week, 21% at one month, 8% at 6 month, 3% at 12 months and only a single patient (1.5%) at 2 years continued to have extensive sensation loss on the glans and distal shaft (Figure 2). The severity and the distribution of the penile sensation loss are presented in Table 2. For the entire study group, the median biothesiometry score stayed 7 during all of the follow-up. The median biothesiometry scores were higher than 7 for all patients with loss of sensation. (Table 3). The single patient who continued to have a sensation loss after 12 months had persistently very elevated biothesiometry thresholds at 25. There was no difference in rates of nerve injury with the surgical technique (H-type incision or the Egydio geometric incision) or among graft type used.

Of the 63 patients, 20 had a significant decrease in their erectile rigidity after PIG surgery, 11 using PDE5i to aid in generating a penetration rigidity erection, 9 needing intracavernosal injections.

Using the multivariable analysis, only the duration of operation was a predictor of loss sensation at 6 months postoperatively, duration >4 hours being predictive, OR 2.1, 95% CI 1.2–3.0 (p<0.01).

Discussion

Surgical management is the gold standard for the definitive treatment in patients with stable PD. Many techniques have been described for the surgical correction of PD such as tunical

plication or the placement of an inflatable prosthesis. PIG is recommended for patients with complex penile curvature deformities $>60^{\circ}$, and/or short penile length, with no preoperative Erectile dysfunction and normal penile hemodynamic evaluation⁸.

This study was designed to evaluate the chronology, severity and the long-term resolution of penile sensory changes after PIG. 21% had some sensory loss at one week, 21% at one month, 8% at 6 months and 3% at 12 months. Only a single patient (1.5%) at 2 years continued to have sensation loss. In the literature, penile sensation loss after PIG has been cited as $0-20\%^{1, 14-16}$. However, in most series sensation loss has been evaluated solely by patient self-report 12, 14-16, 24-34 The major limitation of the aforementioned studies is the absence of a preoperative sensation assessment and the failure to use a objective assessment such as, biothesiometry.

Overall, complete penile loss sensation has not been mentioned in the literature and in most cases penile sensation was reported as recovering within a few months ^{12, 14–16, 24–34} Taylor et al evaluated sensation changes in patients who underwent PIG (n=81) or plication (n=61) surgery with a mean follow-up of 58 months in the PIG group²⁴. Sensation was assessed only by patient report. The authors found that 31% of patients had diminished sensation in both PIG and plication groups, but 90% of patients were capable to achieve an orgasm in the PIG group versus 98% in the plication group. Conversely 26% of plication group reported new onset "delayed orgasm" versus 23% of PIG patients²⁴. There was no analysis of the chronology of sensation recovery but the authors mentioned a recovery ranging from immediately to 9 months postoperatively²⁴.

More recently, Wimpissinger in a small series (n=30) reported the influence of comorbidities on outcomes and satisfaction after PIG¹⁶ with follow-up of more than 10 years. 20% of patients reported penile sensation loss on the glans after the operation. Many studies have reported a significant correlation between penile sensory thresholds and age, penile sensation diminishing with age^{35–39}. Another hypothesis for the high rate in this latter series might be the higher rate of diabetes mellitus, 43% in Wimpissinger versus 10% in our study, but only a single man with diabetes experienced sensation loss in Wimpissinger study¹⁶.

Knoll et al reported 17% (27/162) of their patients reported temporary penile sensation loss after PIG with small intestinal submucosa³³ (SIS® surgisis, Cook Urological Incorporated). These data are consistent with ours; the mean time of the penile sensation loss was 3 (2–12) months. Knoll et al were the only authors who used a validated instrument to measure penile sensation pre and post surgery. Once penile changes sensation resolved, they mentioned that the post-operative sensory thresholds, obtained with the biothesiometer, were the same from baseline assessment, but no detailed biothesiometry data were presented in the paper.

The biothesiometer has several advantages which include simplicity of usage, cost effectiveness and non-invasiveness. Bemelmans et al reported its excellent intra-individual repeatability³⁹, a fixed frequency is set and then the operator tests variable amplitude, expressed in volts^{20, 39}. However the reproducibility of biothesiometer had been discussed in the literature^{40, 41}, it might be explained by the variability of the loading that is applied by hand to the penis, by the variability of the bodily location and the attentiveness of the

patients during assessment. Breda et al reported an age dependency of penile sensory thresholds and developed a nomogram to define normalcy of penile sensory thresholds²⁰.

On multivariable analysis, the single predictor of penile sensory loss at 6 months post-PIG surgery was an operation duration >4 hours OR 2.1, 95% CI 1.2–3.0 (p<0.01). The mean operative time was 3.5 ± 1.8 (2.5–5.5) hours, consistent with previous PIG studies $^{14, 15}$. Although this is at odds some more recent literature 42, 43, intra-operatively we devote long periods of time to maximizing the health of the NVB in its separation from the plaque dorsally, as well as ensuring a watertight closure of the graft requiring a long period of time suturing. This finding is not surprising, as neurovascular bundle (NVB) dissection and elevation is laborious and time consuming. Furthermore, prolonged periods of NVB traction can lead to an increased risk of neuropraxia. We failed to show a positive correlation with others factors: patient age, presence of diabetes mellitus, Peyronie's disease duration. These findings are not consistent with previous studies where age and diabetes were associated with higher penile sensation thresholds than in population control^{35–39}, however the diabetic patient numbers in our study were probably too small to demonstrate a significant correlation. The duration of disease was not correlated with penile sensation loss, this is consistent with our experience, as we have not observed more difficult NVB dissection based on PD duration.

This study has some important clinical implications and contributes to our basic understanding of how PIG affects penile sensation. We believe the study highlights the need during patient consent to discuss penile sensation loss. Patients should be informed that rates of penile sensation loss ranges from 2–30% and most patients will have complete resolution of any sensation loss within one year of follow-up.

Furthermore, our study demonstrates the utility of biothesiometry in measuring penile sensation before and after PIG.

There is a paucity of well-designed studies and limited data concerning penile sensitivity following PIG. To our knowledge a single study reported on sensation evaluation with a validated instrument³³ and no other studies have described the chronology and severity of penile sensation following PIG. Currently no gold standard assessment exists for penile sensation; however, the biothesiometer is the most widely used quantitative somatosensory test when evaluating penile sensation ^{21, 37–39}. ^{44–54}.

However this study is not devoid of complications. First, quantifying the severity of sensation loss is a clinical challenge, and with vibration threshold assessment (biothesiometry) we can only evaluate the integrity of Pacini's and Meissner's corpuscle⁵⁵. A complete sensation assessment would also need to include light touch using the validated Semmens-Weinstein monofilaments (Meissner corpuscle), pressure using the vulvalgesiometer (Merkel Disc), and temperature and pain for free nerve (pain receptors)⁵⁵. Assessing all the sensation modalities would take an estimated 30–60 minutes and is not practical in routine clinical practice. For this reason we chose to limit our assessment to biothesiometry because of its simplicity of use and low cost. Second, we considered a cutoff for normalcy of 7 Volts, as reported in literature^{20, 22}. This cutoff may misclassify old or

diabetic patients and might not be capable of detecting early reductions in vibration perception thresholds. Third, number of patients and absence of control group represent a limitation, but to our knowledge this is the biggest series specifically focused on penile sensation assessment following PD surgery with biothesiometry published data. Finally, 20% of our patients did not have the biothesiometry conducted prior to their PIG surgery although 100% had postoperative evaluation.

Conclusions

Sensation loss is not uncommon after PIG surgery. It decreases in frequency and severity with time with only rare cases occurring beyond 12 months. Longer operations appear to be more likely associated with sensation loss.

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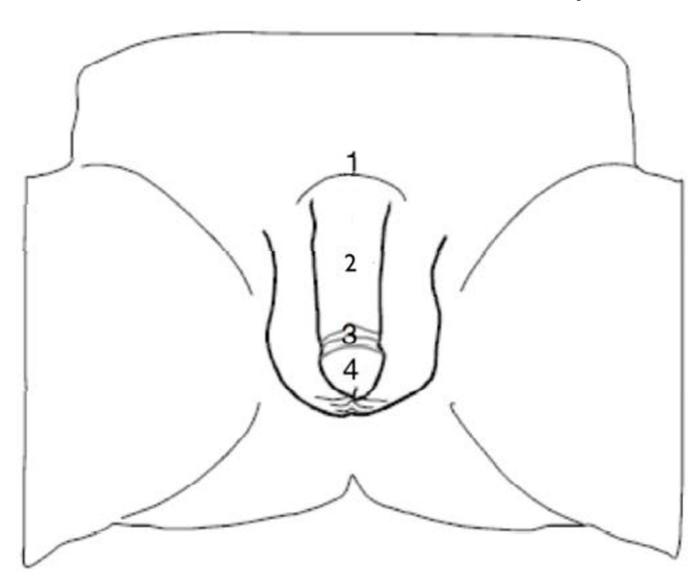


Figure 1. Location of biothesiometry assessment (dorsum). 1 = base of penis, dorsal shaft, foreskin retracted; 2 = mid-shaft dorsum; 3 = coronal sulcus, dorsum of the glans; 4 = mid-glans, dorsum.

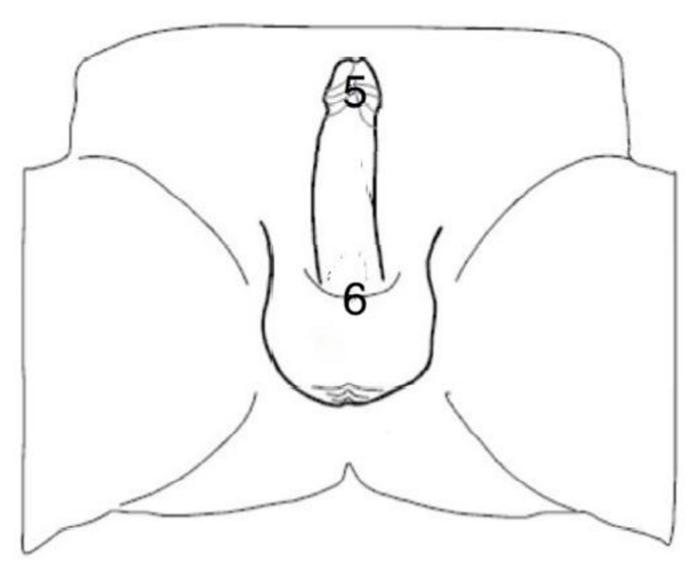


Figure 2.Location of biothesiometry assessment (ventrum). 5 = Frenulum, foreskin retracted; 6 = base, ventrum.



Figure 3. Chronology of Sensation loss

Table 1

Subject Characteristics

Variable	Result (±SD)
N	63 patients
Mean Age (Years)	56±10
Diabetes	10%
Mean Follow-up (Months)	14±12
Mean PD duration (Months)	15±7 (12–38)
Mean duration of self-reported stable PD (Months)	8
Curvature alone (%)	75%
Indentations/HGD (%)	25%
Mean primary curvature (Degrees)	64±28

Table 2

Sensation Loss Parameters

Parameter	1 Month (n=13)	6 Months (n=5)	12 Months (n=1)	
Mean VAS* score	3±2	5±3	7±3	
Grade				
Extensive (>5cm)	N=1 (8%)	N=1 (20%)	N=1 (100%)	
Major (2–5cm)	N=4 (31%)	N=2 (40%)	0	
Minor (<2 cm)	N=8 (61%)	N=2 (40%)	0	
Distribution				
Focal (1 site)	N=3 (23%)	N=6 (60%)	N=1 (100%)	
Multi-focal (>1 site)	N=10 (77%)	N=4 (40%)	0	

^{*} visual analog scale

 Table 3

 Median Biothesiometry Score (Inter Quartile range). Score 7 defined as normal sensitivity

Parameter	Baseline	1 Month	6Months	12 Months
All patients (frenulum)	3 (2,4)	5 (2,22)	5(2,17)	4(2,6)
Patient with loss (site of worst loss)	3 (2,4)	11 (8,27)*	10 (8,11) **	25 ***

^{*} n=13,

^{**} n=5,

^{***} n=1